Safety and Risk in Society Series

Victor E. Argosyan
Editor

Protective Devices

Types, Uses and Safety

NOVA

SAFETY AND RISK IN SOCIETY SERIES

PROTECTIVE DEVICES

TYPES, USES AND SAFETY

SAFETY AND RISK IN SOCIETY SERIES

Chemical Safety Board
Robert W. Talford (Editor)
2009. ISBN 978-1-60692-586-7

Consumer Product Safety Issues
Peter A. Varga and Mate D. Pinter
2009. ISMN 978-1-60456-826-4

Fire Safety
Ingmar Søgaard and Hans Krogh (Editors)
2009. ISBN: 978-1-60741-490-2

Fire In The United States: A Reference Work on the Nation's Fire Problem
Ciro Bouchard and Marco Fortin (Editors)
2009. ISBN: 978-1-60741-746-0

Accidents: Causes, Analysis and Prevention
Henri Bédard and Geraud Delashmit (Editors)
2009. ISBN 978-1-60741-712-5

Accidents: Causes, Analysis and Prevention
Henri Bédard and Geraud Delashmit (Editors)
2009. ISBN 978-1-61668-510-2 (Online book)

Protective Devices: Types, Uses and Safety
Victor E. Argosyan (Editor)
2010. ISBN: 978-1-60876-223-1

Risk Management
Benigno Jordão and Emilio Sousa (Editors)
2010. ISBN: 978-1-60876-011-4

Consumer Product Safety Commission Issues
Isaac E. Bowman (Editor)
2010. ISBN:978-1-60876-766-3

SAFETY AND RISK IN SOCIETY SERIES

PROTECTIVE DEVICES

TYPES, USES AND SAFETY

VICTOR E. ARGOSYAN
EDITOR

Nova Science Publishers, Inc.
New York

LIBRARY OF CONGRESS CATALOGING-IN-PUBLICATION DATA

Protective devices : types, uses and safety / editor, Victor E. Argosyan.
p. cm.
Includes index.
ISBN 978-1-61122-438-2 (eBook)
1. Safety appliances. I. Argosyan, Victor E.
T55.P785 2009
620.8'6--dc22
2009042896

Published by Nova Science Publishers, Inc. ✦ New York

CONTENTS

PREFACE

This book explores various protective devices utilized in the fields of medicine, automobile and motorcycle safety, and sports. This new and important work gathers the latest research from around the globe in the study of this field and highlights such topics as: head restraints and whiplash, mouthguards, particulate respiratory protection, distal protection filters for cartoid artery stenting, motorcycle helmet use in Argentina, hip protector devices, and others.

Chapter 1 - While fatalities due to rear impacts are lower than in other collision types, injuries represent a much larger percentage (approx. 26% of all injuries) and typically occur as neck strain (e.g. whiplash). Whiplash injuries occur when the sudden movement between the head and torso results in injuries to the soft tissues of the neck. This mainly occurs in rear-end collisions. The effectiveness of vehicle seats has been tested over the last 35 years and previous research shows that head restraints could reduce injuries by 14 to 18%. Vehicle seats have seen an evolution in terms of their characteristics and design since the 1970s from bucket seats to yielding seats to high retention seats, and more recently, energy absorbing anti-whiplash seats. Anti-whiplash seats were developed to absorb as much energy as possible while reducing the occupant acceleration and minimizing the movements of the neck. Other restraints that have been tested to be effective are active head restraints and restraints with better geometry. Research shows that serious neck injuries arising primarily from low impact rear-end motor vehicle collisions can be effectively prevented by the use and proper adjustment of head restraints with better static geometry. The major issue is that the public is not properly adjusting their head restraint. In 2008, the World Congress on Neck Pain highlighted that PREVENTION IS POSSIBLE, concluding that it was possible to reduce the risk of serious neck injuries arising from motor vehicle collisions by 35% if people purchased vehicles with good head restraints and adjusted them appropriately. This chapter provides: 1) a review the history, evolution, and scientific literature surrounding head restraints and whiplash-related injury; 2) the risk factors, and prevalence of inappropriate use of head restraints 3) the need to educate drivers, occupants, fleet owners, and policy-makers concerning the importance of head restraints that have obtained a rating of “good” or higher and the efficacy of the proper adjustment of head restraints for prevention of serious neck injuries; 4) new strategies addressing the three E’s of injury prevention including education, engineering, and enforcement, with a particular focus on social marketing and occupational health strategies that increase proper head restraint adjustment for preventing whiplash-related injuries and associated impairments and disability. Gaps in the literature and future directions surrounding the prevention of neck injury and whiplash are also provided.

Chapter 2 - A basic athletic mouthguard (or a mouthpiece, a gum shield) is a resilient device placed on the upper jaw to reduce orofacial injuries particularly to the teeth and surrounding structures. Several types of mouthguards are available (Figure I-1, 2). Like other protective devices, a mouthguard is essential to protect the body from sports-related dental injuries, which are not rare and are costly, disfiguring, and emotionally distressing (Figure I-3 to 7). Recently, mouthguard usage has been spreading gradually. Nevertheless, many sports-related dental and oro-facial injuries can still occur regardless of whether a mouthguard is worn or not. This is because, not only the level of comfort [1], but also the safety and so on of mouthguards is strongly influenced by the types available and the quality of manufacturing (Figure I-7 to 9). So it is dangerous to assume that all types of mouthguards offer the same level of protection. But most athletes have not recognized these problems. Thus, in order to solve them, we have conducted a series of studies.

Chapter 3 - This chapter is a brief review of respiratory protective devices for harmful airborne particulates. Particles in the breathing air present serious health hazards to civilians and workers in occupational settings. To reduce the inhalation of particles, respiratory protection is required when other control measures are not feasible or not yet implemented. For many years respiratory protection devices were used in industrial workplaces to minimize particulate exposures, then extended to other workplaces including healthcare. Respirators are required to reduce the exposure to airborne infectious diseases, including severe acute respiratory syndrome (SARS), pandemic influenza and multi-drug resistant diseases because implementation of administrative and engineering controls is not always feasible. Similarly, bioterrorism incidents involving viruses, bacteria and spores require respiratory protection. Another emerging area of concern is the recent technological developments in the nanotechnology industry for producing engineered nanomaterials. Nano-sized particles may potentially be more toxic than equal quantities of larger-sized particles.

The exposure to harmful nonbiological and biological aerosols can be addressed by proper selection of air-purifying respirators (APRs) recommended by regulatory agencies and other organizations. The National Institute for Occupational Safety and Health (NIOSH) and other standards organizations have developed performance standards for APRs. The NIOSH-certified APRs will provide expected protection levels when properly used. However, these devices do not fit all wearers equally well and impose varying levels of discomfort when fitted to the face. Poor fit of a respirator causes face seal leakage and compromises the respiratory protection levels. To address this issue, NIOSH has recently characterized face sizes and shapes characteristic of the current U.S. work force and developed new respirator fit test panels. Advanced respirator design for different facial features could improve respirator fit leading towards consistent protection.

Also, the physiological impact of some forms of respiratory protective equipment upon wearers has not been adequately examined. Re-use of disposable equipment is also an issue of recent importance given that supplies of disposable respirators may be insufficient in a pandemic-like setting. Recent technological developments have produced nanofibers which can be employed for producing efficient filters. Similarly, antimicrobial components can be incorporated into the filter media used for respirators to kill/ inactivate the microorganisms, as they pass through or are captured in the filter. The need for further research and developments in the different areas of respiratory protection are discussed.

Chapter 4 - Background: Cerebral palsy (CP) describes a group of movement and posture developmental disorders causing activity limitation, caused by nonprogressive disturbances occurring in the developing fetal or infant brain. Complex limitations in self-care functions, such as feeding, dressing, bathing, mobility and the ability to coordinate muscle action to maintain normal posture and to perform normal movements, may also occur. The goal in providing treatment for disabled individuals is to treat the patient in the safest and most efficient manner possible. For some disabled people, comprehensive dental services would be impossible without the more restrictive management techniques. The classic neurodevelopmental treatment (NDT), focus on sensorimotor components of muscle tone, reflexes and abnormal movement patterns, postural control, sensation, perception and memory.

Objective: Describe some methods opening facilitates access to internal surfaces of the maxillary molars, important for dental treatment as well as for preventive care procedures in disabled patients, such as cryotherapy and botulinum toxin A injection. And evaluate the electromyographic (EMG) activity of right and left anterior temporalis and masseter muscles during mandibular resting position in individuals with CP on dental chair, before and after assistive stabilization (NDT).

Method and Materials: A group of 32 spastic CP individuals of both genders, aged 8 to 14 years old (10.1 ± 3.6), were evaluated. The EMG signals of electric activity were obtained using a 8-channel module (EMG System do Brasil Ltda ®, Sao Jose dos Campos, SP, Brazil) from the bilateral anterior temporalis and masseter muscles in two stages (S1 and S2), stored and analyzed as root-mean-square with values expressed in microvolts. The individuals were firstly positioned on dental chair in their usual seating position with no assistive stabilization or head control (S1). After one week the same individuals were evaluated and positioned according to the NDT (S2). The nonparametric Wilcoxon t test, with significance level of 95%, was used to compare the EMG activity of the muscles on two stages.

Results: The right and left anterior temporalis muscles showed a statistically significant reduction in EMG activity ($p<0.001$ and $p<0.001$) after postural stabilization (S2), and the same pattern was observed for the right and left masseter ($p<0.001$ and $p<0.001$) (S2).

Conclusion: The assistive stabilization decreases the electromyographic activity of right and left anterior temporalis and masseter muscles during mandibular resting position due to the inhibition of the pathological postural reflexes in individuals with cerebral palsy, facilitating dental care and preventive measures.

Chapter 5 - Minimally invasive treatment of cardiovascular disease is becoming an increasingly popular alternative to surgery. In particular, carotid artery stenting (CAS) has gained attention and is also the subject of controversy for the treatment of cerebrovascular disease. Distal protection filters are used during CAS to capture peri-procedural emboli and early clinical trials have shown that they reduce the number of peri-procedural neurological events. The incidence of stroke and death following CAS is similar to that of the gold standard, carotid endarterectomy (CEA). This review focuses on performance and technical assessments of several distal protection filters used today by means of *in vitro* and *ex vivo* experiments, and clinical trials conducted in our laboratory and others. We will also discuss the limitations of these devices and suggest design considerations for future generations of distal protection filters. Parameters such as the ideal pore size, wall apposition and capture efficiency are discussed. In the future, it is likely that CAS and CEA will coexist for the treatment of cerebrovascular disease.

Chapter 6 - Introduction: The use of seat belts was made compulsory for all the occupants of a motor vehicle in Nigeria from January 1, 2003.

Objective: To determine the self-reported use of seat belts by mini-bus drivers in Osogbo, Nigeria and explore the various factors that influence seat belt use, such as the attributes of the drivers and possession of motor vehicle insurance.

Methods: A cross-sectional study of 525 mini-bus drivers in the city of Osogbo, Nigeria using a questionnaire designed for this study. It contained questions on the demographic characteristics of the respondents, the use of seat belt and factors influencing seat belt use such as the driver's normal route (intra-state, inter-state or both intra-state and inter-state) and the possession of motor vehicle insurance.

Results: A very high proportion (49%) of the respondents has been driving a mini-bus for less than 10 years. Most of the drivers (91%) had seat belts in their vehicles. The drivers aged between 25 and 34 years were the majority (46%) of the drivers with seat belts in their vehicles. The presence of a seat belt in the mini-bus was significantly associated with the normal route of travel (X^2=7.959, $p<0.05$).

It was in only 84% of the respondents that the seat belts in the mini-buses were functional. There was a statistically significant association between the presence of a functional seat belt in the mini-bus and the level of education of the driver (X^2=8.795, $p<0.05$) and the normal route of travel (X^2=9.965, $p<0.05$).

Most (85%) of the drivers knew about the regulation that required that they use seat belts while driving. The knowledge of seat belt regulation by the drivers was significantly associated with the number of years of driving a mini-bus (X^2=36.360, $p<0.05$), normal route of travel (X^2=11.8460, $p<0.05$) and possession of motor vehicle insurance (X^2=6.051, $p<0.05$).

Almost all the drivers (95%) were aware of the imposition of a fine when they do not use their seat belts while driving. Drivers aged 25 to 34 years had the highest level of awareness (47%) of the fine for non-use of seat belt when driving and those drivers aged 17 to 24 years had the lowest level of awareness (7%) of the fine. There was a statistically significant association between the age of the driver and the awareness of the imposition of a fine for the non-use of a seat belt when driving (X^2=14.926, $p<0.05$).

Majority of the drivers always (47%) or sometimes (44%) use a seat belt while driving. Only 9% of the drivers never use a seat belt while driving. The frequency of seat belt use by the drivers was associated with the normal route of travel (X^2=31.718, $p<0.05$) and possession of motor vehicle insurance (X^2=19.780, $p<0.05$).

The two main reasons given for the non-use of seat belt by mini-bus drivers were lack of safety consciousness (36%) and inconvenience (32%). Most of the drivers believe that enforcement of the seat belt regulation by the Police and Federal Road Safety Commission (96%), more education (92%) and more reminders (91%) will improve seat belt use by drivers.

Chapter 7 - Considerable empirical evidence indicates that helmet wearing effectively reduces motorcycle-related injuries. Nevertheless, in many developing countries the use of this safety device is still low. The aim of this research was to assess the prevalence and possible factors associated with helmet use among motorcycle riders in Mar del Plata city, Argentina. A non-participative, semi-structured observation method was used to assess the prevalence of helmet wearing and to detect factors associated with it. The sample included 1,106 observations of motorcyclists in this city. Data were analyzed through descriptive and inferential statistical methods. A multiple logistic regression model was applied to identify human and environmental predictors of helmet wearing. The general prevalence of helmet use amounted to 36%. Motorcycle passengers were helmeted less frequently than motorcycle drivers were (39.3% vs. only 23.7% passengers). Results of multiple logistic regressions revealed a greater use among women and variations in use depending on weather conditions, type of vehicle ridden, time of day, part of the week (weekday or weekend), and presence of a license plate. Results contributed to a better understanding of the factors involved in helmet use and evidenced the need to make greater efforts to enforce helmet wearing regulations and to intensify motorcycle riders' education.

Chapter 8 - Prevention of elderly people's fractures consists of prevention and treatment of osteoporosis, prevention of falling, and prevention of fractures using injury-site protection. Since great majority of hip fractures are caused by a sideways fall with direct impact on the greater trochanter of the proximal femur, one alternative to prevent the fracture is a padded, firm-shield external hip protector. With this type of two-part design the impacting force and energy are, at the time of the fall-impact, first weakened by the padding part of the protector and then shunted away from the greater trochanter by the shield part of the same.

Following this line, a series of consecutive studies by the Injury and Osteoporosis Research Center at the UKK Institute, Tampere, Finland, have shown that a padded, strong-shield KPH Hip Protector is effective in preventing hip fractures. The results have been encouraging to recommend the protector for high-risk frail elderly people, especially those who have fallen before, had fractures, poor balance and impaired mobility.

The most usual general problem with hip protectors is related to user compliance. Not all elderly people with a high risk of hip fracture will start to use hip protectors. Also, long-term adherence to use the protector can decrease. Therefore, in maintaining the compliance, caregivers' motivation and interest on fracture prevention is of great importance.

Chapter 9 - Traffic is a daily activity in all cities around the world, and traffic accidents are considered to be a leading cause of death. Safety apparatus is promoted to help lessen the severity of injuries from traffic accidents. In some countries, car and motorcycle accidents are the main cause of death. Motorcycle accidents often cause head injuries especially when the cycle falls to the ground. The helmet is a specific device developed to protect the head. A research overview of traffic accidents and helmets is the focus of this article.

Chapter 10 - A major drawback to routine general anesthesia in rabbits is the difficult task of securing airway patency. Intubation of the trachea is technically demanding and time-consuming, sometimes even in the experienced hands. As a result, administration of volatile agents often proves to be difficult, especially when controlled ventilation must be applied. Although laryngeal anatomy of the rabbit differs from that of humans, the LMA designed for use in humans fits well on the rabbit's larynx and provides a good seal around the laryngeal opening.

Chapter 11 - Medical protective devices are useful for prevention of contact with infectious diseases. There are several kinds of protective devices that are necessary as universal precautions. In a setting with a high prevalence of infectious disease, the focus on these protective devices is of interest. In this chapter, the author will detail and summarize the research and reports on medical protective devices in Thailand, a tropical country.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 1-60
ISBN: 978-1-60876-223-1

Chapter 1

HEAD RESTRAINTS AND WHIPLASH: THE PAST, PRESENT AND FUTURE

Ediriweera Desapriya [a, b], Marc White [c], Giulia Scime [b], Khairun Jivani [b], Shelina Babul [a, b], John Holland [d] and Ian Pike [a, b]

[a]Developmental Neurosciences and Child Health,Centre for Community Child Health Research, Child and Family Research Institute, Department of Pediatrics, University of British Columbia, L408-4480 Oak St., Vancouver, BC, V6H 3V4, Canada.

[b]British Columbia Injury Research and Prevention Unit, L408-4480 Oak St., Vancouver, BC, V6H 3V4, Canada.

[c]Canadian Institute for the Relief of Pain and Disability, 204-916 West Broadway Avenue, Vancouver, BC, V5Z 1K7, Canada; Department of Family Practice, University of British Columbia, Canada;
Harvard Medical School &Brigham &Women's Hospital, MA, USA.

[d]Department of Environmental and Occupational Health Sciences, University of Washington, WA, USA.

ABSTRACT

While fatalities due to rear impacts are lower than in other collision types, injuries represent a much larger percentage (approx. 26% of all injuries) and typically occur as neck strain (e.g. whiplash). Whiplash injuries occur when the sudden movement between the head and torso results in injuries to the soft tissues of the neck. This mainly occurs in rear-end collisions. The effectiveness of vehicle seats has been tested over the last 35 years and previous research shows that head restraints could reduce injuries by 14 to 18%. Vehicle seats have seen an evolution in terms of their characteristics and design since the 1970s from bucket seats to yielding seats to high retention seats, and more recently, energy absorbing anti-whiplash seats. Anti-whiplash seats were developed to absorb as much energy as possible while reducing the occupant acceleration and minimizing the movements of the neck. Other restraints that have been tested to be effective are active head restraints and restraints with better geometry. Research shows that serious neck injuries arising primarily from low impact rear-end motor vehicle collisions can be effectively prevented by the use and proper adjustment of head restraints with better static geometry. The major issue is that the public is not properly adjusting their head restraint. In 2008, the World Congress on Neck Pain highlighted that PREVENTION IS POSSIBLE, concluding that it was possible to reduce the risk of serious neck injuries arising from motor vehicle collisions by 35% if people purchased vehicles with good head restraints and adjusted them appropriately. This chapter provides: 1) a review the history, evolution, and scientific literature surrounding head restraints and whiplash-related injury; 2) the risk factors, and prevalence of inappropriate use of head restraints 3) the need to educate drivers, occupants, fleet owners, and policy-makers concerning the importance of head restraints that have obtained a rating of "good" or higher and the efficacy of the proper adjustment of head restraints for prevention of serious neck injuries; 4) new strategies addressing the three E's of injury prevention including education, engineering, and enforcement, with a particular focus on social marketing and occupational health strategies that increase proper head restraint adjustment for preventing whiplash-related injuries and associated impairments and disability. Gaps in the literature and future directions surrounding the prevention of neck injury and whiplash are also provided.

INTRODUCTION

Unintentional injuries, particularly road traffic injuries, are a key component of the burden of non-communicable diseases. Traffic-related injuries account for a substantial share of the disease burden in many countries worldwide. It is predicted that traffic crashes will become the 3rd major cause of mortality by 2020 (Murray, 2006). Reducing the severity of injuries from traffic crashes is one of the most effective means of improving traffic safety. In order to reduce the number of people killed and/or injured in traffic crashes, many research studies have identified the risk factors that can significantly influence traffic-related injuries and fatalities. Researchers have demonstrated the efficacy of interventions that could significantly reduce traffic-related crashes (Subzwari et al., 2008). Rear-end collisions are the most common type of traffic collision and whiplash is the most common complaint of those claiming bodily injury (Cassidy et al., 2000; Spitzer et al., 1995).

The Issue

In recent years, many countries have seen a significant increase in neck injuries arising from motor vehicles collisions, commonly known as 'whiplash-related injuries'. Previous research shows that serious neck injuries arising primarily from low impact rear-end motor vehicle collisions can be effectively prevented by the use and proper adjustment of highly-rated head restraints in motor vehicles (Farmer et al., 2003). Given that rear-end collisions will occur, the severity of whiplash-related injuries are dependent on three predominate factors: 1) the crashworthiness performance offered by the vehicle and its seating/safety system, 2) the ability of the seating/safety system to properly adjust to the occupant's characteristics (i.e. size, weight, age, gender, etc.), and 3) whether the occupant and seating/safety system are properly positioned or activated at the time of the collision. At present, improved seat and head restraint design technology in some vehicles offer greater protection to mitigate whiplash-related injuries, however due to a lack of knowledge resulting in a poor selection of vehicle features, and/or a lack of proper adjustment by the occupant, the effectiveness of these design improvements to reduce the overall societal cost of whiplash-related injuries has been severely limited.

A major issue in whiplash prevention is the lack of proper adjustment of the seating safety system by the occupant (or responsible driver) for proper protection. In manual systems (e.g. seat belts, child safety seats, head restraints, etc.), proper use requires sufficient knowledge and participation by the responsible occupant and remains a significant challenge to overcome, and one that may never be fully achieved. This factor alone contributes heavily to the lack of effectiveness of head restraints where manual adjustment is required for proper performance. To allow significant advancement in reducing whiplash-related injuries and associated impairments: 1) a larger proportion of vehicles with enhanced seating system performance in preventing whiplash are required in a changing vehicle fleet, and 2) the seating system in each vehicle must be properly adjusted and operated to suit the seated occupant in order to optimize the whiplash prevention capabilities of that system. These issues are not new, but rather are a continuing barrier to achieving improved success in reducing whiplash-related injuries and associated impairments and disability.

The major aims of this chapter are to: 1) review the history, evolution, and scientific literature surrounding head restraints and whiplash-related injury; 2) educate the drivers, occupants, fleet owners, and policy-makers concerning the need to purchase vehicles with head restraints that have obtained a rating of "good" or higher and the efficacy of the proper adjustment of head restraints for prevention of serious neck injuries; and 3) propose new strategies based on injury prevention theory and methods. The three E's of injury prevention including education, engineering, and enforcement, will be addressed, with a particular focus on social marketing and occupational health strategies to increase awareness and change behaviors surrounding proper adjustment of head restraints for preventing whiplash-related injuries and associated impairments and disability. A discussion of future directions surrounding the prevention of neck injury and whiplash will be provided.

A Brief History of Whiplash Injury

With the development and use of railways in the 19th century, whiplash-like injuries were first noted following train collisions. Formerly called "railroad spine", patients most often reported severe emotional disturbance leading them to be categorized as psychoneurotic (Scaer, 2007). With the invention of the motor vehicle, the first reports of persisting neck pain following motor vehicle collisions were found as early as 1919 (Scaer, 2007). American surgeon Harold Crowe coined the term "whiplash" in 1928 in the medical literature. He highlighted the issues related to neck movement to describe the sudden jolting of the head and neck in vehicle crashes (Croft et al., 2002; Farmer et al., 1999; Kullgren et al., 2000; Richter et al., 2000). In 1953, Gay and Abbott reviewed the cases of 50 patients who suffered whiplash injury over a 4 year period. The symptoms they described included pain, limitation of neck movement, spasm and tenderness in the cervical spinal musculature, with associated symptoms in the upper thoracic spine and shoulder girdle. Following Harold Crowe's work (1928), Gay and Abbott were among the first to suggest the concept of whiplash in the early 1950s. The word "whiplash" was in the title of Gay and Abbott's article (1953) and they later described the related symptoms that followed after rear-end collision impacts, introducing the medical term "whiplash injury".

Following a survey of 100 patients who had been referred for neurosurgical consultation on cervical whiplash injury, Gotten (1956) reported that after settlement of claims, approximately 30% of all traffic collisions resulted in whiplash-type neck distortions. This was the second article published in the Journal of the American Medical Association (JAMA) in a 3 year period that discussed the topic of whiplash injuries. Gotten (1956) noted "a wide divergence among specialists as to the severity of the injury" (p 866) and commented that "psychoneurotic symptoms were so prevalent and seemed to be such a dominant factor" (p 866) in these patients (Galasko et al., 1993; Richter et al., 2000).

In 1995, the Québec Task Force (QTF) on Whiplash-Associated Disorders (WAD) published the first best-evidence synthesis and consensus report on whiplash as a supplement to the journal, SPINE. The scientific committee found 10,382 published articles on whiplash (1980-April 1994) and only 1,204 met the preliminary screening criteria. Following a more rigorous review, there were only a core group of 294 studies with sufficient relevance and scientific merit for in-depth review and only 62 of the 294 (21%) considered high enough quality to inform best practices. Although there was insufficient research to make strong evidence-based guidelines, the QTF laid the groundwork for future research and recommended a classification system relevant to clinicians and researchers.

Early Definitions of Whiplash

Whiplash is commonly defined by the lay person to denote any injury to the neck sustained in a road traffic collision. Further, it implies that the neck behaves as a ‘whip’, that is, a low-velocity, high-energy input at the base producing a high-velocity excursion at the tip. The use of slow-motion video-recording of volunteers and dummies has shown the biomechanical forces at play in rear-end collisions. In 1964, McNab defined whiplash as 'acceleration extension injury'. However, as Morris (1989) noted 'acceleration hyperextension injury' would be a more appropriate term.

The terms "whiplash" and "whiplash associated disorders" (WAD) are used to describe neck disorders related to sudden movement of the neck. Whiplash is considered an injury to the soft tissue of the cervical spine, caused by the sudden acceleration of the head relative to the torso. This typically occurs during a rear-end collision, mostly at low impact velocities, typically less than 20 km/h (Deng, 1999; Deng et al., 2000a; Howard et al., 1998), and includes an acceleration-deceleration mechanism of energy transfer (Spitzer et al., 1995). Characteristic symptoms of WAD include neck pain, headache, and arm tingling. Whiplash injuries sustained in motor vehicle crashes have become an issue of growing concern. It is important to note that these types of injuries occur due to other mechanisms as well, not simply motor vehicle crashes (Jakobsson et al., 2004a; Kullgren et al., 2000; Minton et al., 2000). This chapter focuses on whiplash injuries and WAD that are related to motor vehicle collisions, primarily rear-end collisions.

Transition of the Term Whiplash Injury to "Whiplash Associated Disorders" (WAD)

Over time, the concept and definition of whiplash has evolved from "whiplash injury" to WAD recognizing the complex biopsychosocial factors that impact the clinical manifestation of symptoms following a motor vehicle collision. WAD partly replaced the older term "whiplash injuries" following the QTF's report published in 1995 (Spitzer et al., 1995). The new term 'WAD' encompasses a group of complaints characterized by a variety of symptoms such as pain and stiffness in the neck that often lacks any external or radiological evidence (Spitzer et al., 1995). The pathology accounting for whiplash symptoms has been and continues to be, the subject of considerable medical interest, investigation and debate.

More recently, many researchers have dropped the term "whiplash" and replaced it with the phrase "neck pain and associated disorders, arising from motor vehicle collisions", for several reasons. Firstly, "whiplash" incorrectly describes the real biomechanical process of changes in the occupant's head and torso motion during a rear-end collision. Secondly, the high prevalence of neck pain in the general population, in workers and after motor vehicle collisions - twelve month prevalence estimates of neck pain are 30-50%, (Hogg-Johnson et al., 2008), a broader conceptual framework is needed to consider a more extensive range of biopsychosocial factors that influence the natural course of history of neck pain in these populations. However, for the purpose of this chapter when we refer to "whiplash-related injuries" we are referring to neck injuries and the associated disorders as well as the "perceived" and real impairments, and disability.

A major and obvious outcome of whiplash or WAD is neck pain. In a best-evidence synthesis (1980-2006), to better understand the burden and determinants of neck pain due to WAD after traffic collisions, researchers found that the incidence of WAD has increased in western countries over the past 30 years and is likely to be at 300 per 100,000 inhabitants in North America and western Europe (Holm et al., 2008). Personal, societal, and environmental factors are of importance, although the evidence of determinants for WAD is quite meager. Attendance at the emergency department for WAD after a traffic collision has also increased over time, although this may reflect an increase in public awareness for seeking care. In terms of seeking care or filing an insurance claim, it appears that younger people, those with prior neck pain and females were at higher risk (Holm et al., 2008). There is preliminary evidence for the efficacy of whiplash protection devices such as properly positioned head restraints that limit head extension in rear-end collisions (Holm et al., 2008). Insurance claim data has indicated that active head restraints and adjustable head restraints rated as "good", were associated with a reduction in insurance claims for WAD, and had a greater effect among female drivers. Interestingly, researchers found no evidence to support the notion that crash severity was related to WAD (Holm et al., 2008).

Mechanism of Whiplash Injury Occurrence

Whiplash injuries and the mechanism that results from rear-end collisions are not fully understood. Biomechanical research has shown that the neck experiences compression, tension, shear force, flexion, and extension at different stages and at varying levels of the neck (Deng et al., 2000a). Compression of the neck occurs when the thoracic spine straightens and results in an upward ramping of the torso on the seat (Deng et al., 2000a). The upward motion of the torso combined with the static head, results in a compressed neck, followed by tension. Extension occurs in the lower end of the neck, while the upper neck is in flexion, causing an s-shape (Deng et al., 2000a). The different biomechanical processes that the neck undergoes contribute to stretching of the facet capsular ligaments, causing pain (Deng et al., 2000a).

However, over the last few decades, effective countermeasures for whiplash injuries have been recognized (Buitenhuis et al., 2009; Schmitt et al., 2003). Numerous vehicle crash studies and occupant injury studies indicate that low-speed rear impacts can lead to neck and back injuries causing long-term disability and discomfort. Although these injuries are usually classified as having a low threat to life, they are often associated with large societal costs (Gibson & McIntosh, 1997; Kahane, 1982; Spitzer et al., 1995; Viano & Olsen, 2001). It is evident that design changes to seat systems and/or head restraints to improve their use and the occupant protection they offer could make a positive impact in mitigating injuries from rear-end impacts.

Whiplash - Minor Injury and Low Priority?

Most whiplash injuries are regarded as minor (1) using the Abbreviated Injury Scale (AIS), and as such, are treated as low priority by most road safety organizations and vehicle manufacturers (Ardoino, 1996; Maher, 2000). However, contrary to these findings, research conducted in many countries (Baddick & Love, 1990; Kahane, 1982; Livingston, 1992; 1993; Maher, 2000; Nygren, 1984; O'Neill et al., 1972; O'Neill, 2000; Spitzer et al., 1995; Verhagen et al., 2007; Viano & Olsen, 2001; Young et al., 2005) reported that insurance claim frequency was highest in rear impact crashes and whiplash injuries. The cost of long-term whiplash injuries to front-seated occupants in the United Kingdom (UK) was estimated to be approximately £3 billion annually (Hynd et al., 2008). Hopkin and Simpson (1995) demonstrated that whiplash is by far the most costly injury, involving 31% of the total cost though it accounted for only a little over 15% of all injuries in the UK. Whiplash injuries appeared in 36% of all claims to the New South Wales Motor Collisions Scheme (Gibson & McIntosh, 1997). In Quebec, the 5,000 whiplash cases each year account for 20% of all traffic injury insurance claims (Spitzer et al., 1995). On average, whiplash injury costs Quebec $18 million annually (Spitzer et al., 1995). Sixty-eight percent of motor vehicle collision claims in British Columbia, and 85% in Saskatchewan, were related to whiplash injuries (Spitzer et al., 1995). In the US, the estimated annual cost of whiplash injury is $8.2 billion (Edwards et al., 2005) and $1.2 billion in the UK (Avery et al., 2007). It is important to note that whiplash injuries resulting from rear impacts have one of the highest rates of long-term injury-related consequences (Hell & Langwieder, 1998).

Relationship of Head Restraints and Whiplash Injuries

For the last 40 years, vehicle safety researchers have been acquiring information on the ability of head restraints to mitigate injuries resulting from rear-end collisions. Severy and colleagues (1968) produced a clear description of the ability of good seat design and head restraint positioning to prevent potentially injurious head-neck kinematics in rear-end collisions. They concluded that well designed safety seats would protect most passengers against sustaining any rear-end collision injuries (Severy et al., 1968).They showed that head restraints in rear-end crashes were as important as seat belts in frontal crashes.

The head restraint is a cushion attached to the top of the back of a vehicle seat and its main purpose is to prevent whiplash injuries by limiting the movement of the head and providing support in the case of a motor vehicle collision (Howard et al., 1998). The primary method of preventing whiplash-induced injury in motor vehicles is the correct adjustment and proper use of a head restraint. A properly adjusted head restraint will help to protect against whiplash, and the potential for long-term injury (Deng et al., 2000b).

Padded head restraints have been used since the mid 1950s. They were also proposed as countermeasures to the hyperextension phase of whiplash (Ruedemann, 1957). In the 1960s, head restraint and whiplash injury research informed federal mandates for vehicle head restraints (Severy et al., 1968). As a result of the research, Federal Motor Vehicle Safety Standard (FMVSS) 202 required that all passenger cars manufactured for sale in the US after December 31, 1968 included head restraints in the front outboard seating positions. The installation of head restraints in the front seats of Australian vehicles has also been compulsory since 1972 under Australian Design Rule (ADR) 22. The early research recommended that making head restraints compulsory in rear seats was not justified because of the small number of neck injuries that occurred in rear seated occupants (Maher, 2000). This is not the case today.

Definitions for Head Restraints

The US Insurance Institute for Highway Safety (IIHS) has created definitions for various types of head restraints. The definitions are presented in Table 1.

Table 1. Definitions for various types of head restraints.

Head restraint "Head restraint means a device designed to limit the rearward displacement of an adult occupant's head in relation to the torso in order to reduce the risk of injury to the cervical vertebrae in the event of a rear impact" (p. 1).
Integrated head restraint "Integrated head restraint or fixed head restraint means a head restraint formed by the upper part of the seat back, or a head restraint that is not height adjustable and cannot be detached from the seat or the vehicle structure except by the use of tools or following the partial or total removal of the seat furnishings" (p. 1).
Adjustable head restraint "Adjustable head restraint means a head restraint that is capable of being positioned to fit the morphology of the seated occupant. The device may permit horizontal displacement, known as tilt adjustment, and/or vertical displacement, known as height adjustment" (p. 1).
Active head restraint "Active head restraint means a device designed to automatically improve head restraint geometry during an impact" (p. 1).
Automatically adjusting head restraint "Automatically adjusting head restraint means a head restraint that automatically adjusts the position of the head restraint when the seat position is adjusted" (p. 1).

Source: The Insurance Institute for Highway Safety (IIHS, 2008, p.1).

Why Head Restraints are Required

In a rear-end crash the differential movement of the head and torso can be limited by either a high seat back or a separate head restraint positioned behind and close to an occupant's head (States et al., 1972). As part of recognition of this intervention in mitigating injuries, front-seat head restraints have been required in all new cars sold in many countries, including Canada, since 1969. Ruedemann (1969) reported on the introduction of a new device in motor vehicle design - the head restraint, introduced to prevent whiplash injury in rear-end collisions. However, it is unfortunate to note that nearly 40 years after introducing head restraints, whiplash injury from rear-end collisions remains an important public health problem with a significant economic and health burden (O'Neill, 2000; Welcher & Szabo, 2001), and despite the continuing innovation in head restraint design, whiplash injury claims in rear-end crashes have continued to increase worldwide (Viano & Olson, 2001).

Rear-End Collisions and Cost of Whiplash Injuries

Quinlan and colleagues (2004) noted that rear-end collisions continue to be a major cause of long-lasting neck and back injuries (i.e. whiplash) and a significant cause for pain and suffering (Quinlan et al., 2004). These injuries also constitute an enormous societal cost due to the following key components:

1. High and extended medical expenses
2. Time away from the workplace
3. Numerous liability and insurance claims

According to NHTSA (2001), an average of 805,581 whiplash injuries occur annually, that cost the US $5.2 billion (NHTSA, 2001). Whiplash injury claims are documented to have increased over the past two decades in Canada, with the societal costs exceeding $464 million per year in the province of British Columbia alone (Kumar et al., 2000). Whiplash injuries represent 68% of vehicle injury claims in British Columbia (Kumar et al., 2000). However, the main limitations of these cost estimates were that they never attempted to incorporate the costs associated with the reduction in the quality of life of the whiplash sufferers; which may in part be due to methodological difficulties in quantifying changes in quality of life following this type of injury. Estimates in the UK indicated that the cost of long-term whiplash injuries to front-seated occupants was approximately £3 billion annually. The same report highlighted that a static geometric head restraint requirement is the first step in mitigating low-speed rear impact injuries (Hynd et al., 2008).

Effectiveness of Head Restraints in Reducing Rear Impact Whiplash Injuries

As previously stated, the primary function of head restraints is to minimize the relative rearward movement of the head and neck in rear impacts (Maher, 2000). Frontal impact rebound protection has been highlighted as the secondary function of head restraints (Maher, 2000). Effectiveness of head restraints subsequent to FMVSS 202 has ranged from 13% to

18% reduction in injuries (Maher, 2000). It is reported that the neck injury incidence rate was 29% in vehicles without head restraints as compared to 24% in head restraint-equipped vehicles (O'Neill et al., 1972).

States and colleagues (1973) interviewed 439 Rochester, New York drivers and right-front passengers of rear-struck vehicles during the first three months of 1972. Results indicated that a total of 43% of occupants in vehicles without head restraints reported neck injuries, compared to 37% in vehicles with head restraints. Texas crash data analyzed in 1972, 1974 and 1977, compared rear-impact driver injury rates for cars of model year 1968 with those of model year 1969 (Kahane, 1982). After analyzing more than 20,000 drivers in each group, researchers found that 7.6% of those in the 1968 model were injured compared with 7% in the 1969 models (Kahane, 1982). After adjusting for the fact that 12% of 1968 models had head restraints and 12% of 1969 models did not, the effectiveness of head restraints was estimated to result in a 13% reduction in injuries, including 17% for fixed head restraints and 10% for adjustable head restraints (Kahane, 1982).

Incorrect Adjustment of Head Restraints and Risk of Whiplash Injury

Previous research has indicated an increased risk for neck injury in rear-end impacts if the head restraints are incorrectly positioned. There is an increased risk for neck injury in rear-end impacts if the backset is large, and/or the head restraint is low (Baddick & Love, 1990; Chapline et al., 2000; Farmer et al., 1999; Jakobsson, 2005; Kahane, 1982; Livingston, 1993; Nygren, 1984; O'Neill, 2000; O'Neill et al., 1972; Olsson et al., 1990; Young et al., 2005). This information was vital in setting the background for the geometric tests of seats and head restraints conducted by car manufacturers and safety organizations such as the Insurance Institute of Highway Safety (IIHS). The purpose of correctly adjusted head restraint positioning is to ensure proximity between the head and the head restraint. The ideal head restraint position occurs when there is zero backset and the top of the head is level with the top of the head restraint (Chapline et al., 2000, Nygren, 1984; O'Neill, 2000).

Following implementation of the US head restraint requirements, research has shown a decrease in neck injury rates for rear-end collisions (Kahane, 1982; O'Neill et al., 1972; States & Balcerak, 1973). O'Neill and colleagues (1972) reported that the incidence of neck injury (sample of 5663 rear-end crashes) was 5% less in head restraint-equipped vehicles compared to those without. Similarly, States and Balcerak (1973) noted a 14% reduction of whiplash injuries in vehicles equipped with head restraints.

After reviewing a random sample of 5,000 rear-end collision claims, Farmer and colleagues (1999) noted that head restraints must have good geometric design to prevent whiplash injuries (Farmer et al., 1999). Additional research indicated that properly positioned head restraints (i.e. no lower than the head's center of gravity and no farther behind the head than 11 cm) were more effective in preventing neck pain following rear impact (Chapline et al., 2000). In exploring sex differences, results were statistically significant for women, yet the effectiveness of the head restraint in reducing neck pain was similar for both sexes (42% and 44% reduction in risk of pain, respectively) (Chapline et al., 2000). Researchers reported that there were too few male participants with correctly positioned head restraints to allow adequate statistical power; therefore results for men were not significant (Chapline et al., 2000).

Definition for Correct Adjustment of Head Restraints

To prevent soft-tissue neck injuries through the correct adjustment and use of head restraints, specific recommendations were provided. The height of a restraint and the gap between the head and the restraint are critical in influencing injury risk. Head restraints in all sitting positions and minimum restraint height should correspond to the top of the head of at least, the 50th percentile of seated adult males. Ideally, restraint height should correspond to the top of the head of the 95th percentile of seated adult males. The smallest distance possible should be left between the back of the head and the point where it would first meet the restraint (Farmer et al., 1999; Fockler et al., 1998; Viano & Gargan, 1995).

Adjustable head restraints were defined as correctly adjusted if the top of the head restraint was approximately level with the top of the driver's ears or higher. Therefore, in Fockler’s study (1998) all head restraints observed to be positioned so that the top was lower than the driver's ears were defined as incorrectly adjusted (Fockler et al., 1998). Head restraints were rated as poor if, in the lowest position, they were more than 10 cm below the top of the head or 12 cm or more behind the head and, in the highest position, were more than 8 cm below the top of the head or 10 cm or more behind the head (Cullen et al., 1996).

Chapline and colleagues (2000) noted that US regulations mandated a minimum height of 27.5 inches above the seating reference point for head restraints in the highest position, however, there are no regulations governing a minimum height in the lowest position. In addition, a majority of the current US vehicle fleet has adjustable head restraints yet most individuals do not correctly adjust them (Chapline et al., 2000). They also suggested that the use of European head restraint standards would greatly benefit North American women and certainly men, however, until then, proper adjustment of head restraints should be encouraged (Chapline et al., 2000).

Research indicates that during normal driving, if all adjustable head restraints were adjusted to the correct vertical height, then a reduction of 28.3% in whiplash injuries and a significant reduction in the incidence of soft tissue injuries, from rear-end collisions can be expected (Chapline et al., 2000; Viano & Gargan, 1995).

Scientific Literature: The Relationship between Head Restraints and Whiplash

This section will provide a review of the scientific literature surrounding the relationship among vehicle stiffness, head restraints and whiplash. The literature includes research that utilizes dummies, computer simulations, cadavers and human volunteers, as well as comparison studies.

Over time, investigations were conducted using Hybrid II dummies, Hybrid III dummies, the Rear Impact Dummy (RID/RID2) necks, Biofidelic Rear Impact Dummies (BioRID), de Jager MADYMO necks, Whiplash Artificial Cervical Spine (WACSY) necks, Post-Mortem Human Subjects (PMHS; cadavers), volunteers, and car occupants in real rear-end impacts.

Human volunteers have been used in staged, slow speed, rear-end impacts for over 50 years, to test the kinematics of the motion of the volunteer, head and seat acceleration (DeRosia & Yoganandan, 2000). This research began in the 1950s (Severy et al., 1955), initiating additional research and awareness concerning seatback stiffness, head restraints, torso ramping, preparedness of the volunteer, the effects of pre-activated muscles on head motion and the potential for injuries (DeRosia & Yoganandan, 2000). Severy and colleagues (1955; 1968) were the first to assess the effects of head restraints through the use of dummies who were subjected to rear impacts. This early work lead to the establishment of head restraint standards in the US (FMVSS 202) and the recognition of head restraints as a safety device. In the 1960s Mertz and Patrick (1967) began utilizing sled simulators and testing car-to-car impacts with humans, dummies, and human cadavers. They examined muscle activation, effects of head restraints and seatback stiffness using electronic and photographic sensors. In the early 1970s researchers began investigating forward impacts and the effects on humans (DeRosia & Yoganandan, 2000). From the 1970s to the early 1990s, very little scientific research was conducted concerning human volunteers and slow speed, rear-end impacts. Research re-emerged in the 1990s and was pursued assertively from that point forward (DeRosia & Yoganandan, 2000).

Head-to-Neck Kinematics

Cervical hyper-extension was the most popular hypothesized mechanism for injury in the early research. Flexion of the cervical spine, shear load, localized cervical compression and tension, spinal canal pressure gradients, and muscle strain were all additional mechanisms for injury that were tested extensively (Szabo, 2000).

Darok and colleagues (2000a) applied computer simulations using the occupant simulation software MADYMO to investigate the Neck Injury Criterion (NIC) (Darok et al., 2000a). Additional research testing the shear force hypothesis of whiplash injury was conducted using computer simulations in combination with a high-speed x-ray system (Deng et al., 2000a). The research demonstrated the complex kinematics of the neck during rear-end impact showing that the neck experiences compression, tension, shear force, flexion, and extension at different stages and at varying levels of the neck (Deng et al., 2000a). When the thoracic spine straightens and an upward ramping of the torso on the seat occurs, compression of the neck ensues (Deng et al., 2000a). The upward motion of the torso combined with the stationary nature of the head, results in compression of the neck, followed by tension. The ‘head lag’ phenomenon also contributes to the tension in the neck (Deng et al., 2000a). This occurs when the torso moves faster than the head in the horizontal direction. The concept of shear force occurs in the neck when the torso moves forward due to an impact from behind. A flexion moment on the whole neck is a result of the shear force impact at the junction of the thoracic and cervical spine (Deng et al., 2000a). The lower end of the neck is then subjected to extension, while the upper neck is in flexion, causing an s-shape to occur (Deng et al., 2000a). The combination of compression, tension, shear force, flexion, and extension contribute to stretching of the facet capsular ligaments (Deng et al., 2000a).

Based on the numerous rear-end motor vehicle collisions that resulted in whiplash injuries and neck pain, research efforts increased and there was a major boost in the development of anthropometric test devices (ATD) and their components (Kim & Prasad, 2000). In the US, researchers from Chalmers University of Technology introduced the rear impact (RID) dummy neck in the early 1990s, which later developed into the BioRID P3.

TNO developed the TRID (TNO Rear Impact Dummy) neck and proceeded to develop an ATD specific to rear impact collisions (RID) (Kim & Prasad, 2000).

Dummies such as the Hybrid III with MADYMO with sophisticated cervical spine models were used to test head restraint properties (Kleinberger et al., 1999). Testing of the Hybrid III dummy indicated that it had adequate biofidelity for determining head-neck kinematics in rear impacts at various test severities (Kim & Prasad, 2000). Interestingly, the Hybrid III and the TRID necks were closer in stiffness to cadavers rather than human volunteers. Research indicated that the Hybrid III could be used to estimate the risk of high severity neck injuries in more severe rear impacts (Kim & Prasad, 2000).

The experience of pain has been investigated over time. McConnell and colleagues (1995) found that middle-aged healthy male subjects exposed to rear impacts of 4-8 kph experienced mild cervical strain without affecting range of motion. The facet capsules have been isolated as the point where whiplash-associated pain is centralized (Bogduk & Marsland, 1988). Upper cervical flexion and lower cervical extension are thought to cause headaches and neck pain (Yoganandan et al., 1998; 1999). Ono and colleagues (1997) showed that compressive loading on the cervical spine results from upward motion of the upper torso, which in turn causes the lower vertebral segments to extend beyond their normal range.

Head Restraint Height

Head-to-neck kinematics is influenced by the seat height, and there are definite benefits to increasing head restraint height (Jakobsson et al., 1993; Kleinberger et al., 1999; Szabo, 2000). Research that specifically investigated the effects of head restraint height on occupant kinematics and WAD is extensive and seems to have progressed from 1985 onwards including the work of: Nygren et al., 1985; Jakobssen et al., 1993; Ono & Kanno, 1993; Viano & Gargan, 1995; Eichberger et al., 1996; Minton et al., 1997; Hell & Langwieder, 1998; Kleinberger et al., 1999; Welcher & Szabo, 1999; Farmer et al., 1999.

Research conducted in the 1990s revealed that while it was better than no head restraint at all, the standard head restraint design was in the incorrect position to prevent injury (McConnell et al., 1993; McConnell et al., 1995). These results motivated future research that sought to update and improve the head restraint. In the mid to late 1990s, researchers investigated slow-speed collisions involving energy absorbing bumper systems (Szabo et al., 1994; Szabo & Welcher, 1996; West et al., 1993) and barrier impacts. West and colleagues (1993) calculated that a barrier impact speed of 11kph was the torque threshold past which injuries would occur. Szabo and colleagues (1994; 1996; Welcher & Szabo, 1999) investigated the effects of adding a layer of padding to the head restraints. They found that the muscle did not develop tension until the flexion phase of the impact, whereas with unpadded head restraints the muscles tensed earlier increasing the risk of neck pain (Szabo et al., 1994; Szabo & Welcher, 1996; Welcher & Szabo, 1999). Viano and Gargan (1996) reported that if adjustable head restraints were placed in the up position, the relative risk of whiplash injury would be decreased by 28.3% (Viano & Gargan, 1996).

In 1992, Gane and Pedder developed a head restraint measuring device (HRMD) to help provide an accurate and consistent means of measuring the position of head restraints (Gane & Pedder, 1996). The HRMD measured the vertical height and the setback of the head restraints in the front seats (Gane & Pedder, 1996). Although various factors affect the ‘best’ position for the head restraint, the HRMD provides a tool to identify those head restraints that are most effective in reducing neck injuries (Gane & Pedder, 1996).

Several studies showed that there was a reduced risk of whiplash injury in rear crashes due to the improvements that were made in head restraint geometry (Chapline et al., 2000; Farmer et al., 1999; 2003). Although, researchers also realized that improvements in geometry alone would not provide adequate protection for neck injuries (Zuby & Lund, 2007). This resulted in improvements to seatback design such as strong seatbacks with cushion systems that allowed an occupant's body to sink (Saab & General Motors), and some manufacturers also included active head restraints (Viano, 2002; Wiklund & Larsson, 1998). These improvements in seat design allowed for better support of the head and less stress on the neck (O'Neill, 2000).

Neck Injury Criterion (NIC)

The Neck Injury Criterion (NIC) is a tool that was commonly used to help explain dangerous impact conditions on the soft tissue injuries of the neck (Bostrom et al., 2000; Darok et al., 2000). Hybrid III dummies were used to investigate the efficacy of the NIC tool. Results indicated that the NIC seemed to represent the amount of kinetic energy loaded to the occupant, such that the correlation between Delta-V and the NIC was striking (Darok et al., 2000). In terms of the crash duration, there was an inverse relationship such that a decrease in NIC occurred with an increase in collision duration (Darok et al., 2000). There were low NIC and neck loads whenever the head restraint was close to the head (horizontal distance), and there was an increase in NIC when the head restraint was lowered (vertical distance). When the head restraint was removed, the neck torque increased dramatically, indicating that the NIC was designed for assessing the retraction motion of the neck and not for predicting hyperextension injuries (Darok et al., 2000). In testing seatback stiffness, results showed a possible reduction of the NIC and neck loads by using a stiff recliner joint. Researchers deduced that contact of the head with the head restraint occurs early and limits the amount of retraction and extension motion (Darok et al., 2000). Overall, the results showed a correlation between the NIC and velocity change, crash pulse, and head restraint position. The NIC was also correlated with the neck extension angle, head angular acceleration and neck torque (Darok et al., 2000). With respect to validation of the NIC, during the human volunteer tests, subjects did not complain about injuries in the cervical spine region after the test, and no neck pain was reported days later (Darok et al., 2000). Results showed that the NIC increases with the horizontal distance between the head and head restraint. In addition, an approximate correlation between the NIC and the maximum relative angle of the head and torso was also observed (Darok et al., 2000).

Delta-V

Reports indicate that injuries and fatalities in motor vehicle crashes are increasing in tandem with vehicle velocity. Delta-V or the 'change in velocity' is an important factor in the majority of motor vehicle-related injuries and outcomes. However literature shows that unlike other motor vehicle crash-related injuries, whiplash injuries occur even at a Delta-V of 10-15 kph. Therefore, Delta-V has limited value in the prognosis of whiplash injuries.

Seatback Stiffness

Seatback stiffness is a factor that contributes to the reduction of injury (Szabo, 2000). Mertz and Patrick (1967) were among the first to investigate the effects of seatback stiffness using dummies. They demonstrated decreased neck bending moments for the seat with reduced stiffness (Mertz & Patrick, 1967). Additional researchers replicated the findings indicating that there was decreased acceleration and velocity at the base of the neck, and a reduction in head rotation relative to the torso (Haland et al., 1996; Koch et al., 1995; Svensson et al., 1993; Watanabe et al., 1999).

Seatback Energy Absorption

An additional variable is the influence of seatback energy absorption (Szabo, 2000). Seatbacks with strong structural cross-members do not allow the occupant to sink into the seat, hindering energy absorption and reducing the space between the head and head restraint (Himmetoglu et al., 2008). Researchers found decreased adoption of the cervical s-curvature with an energy absorbing seat (Dippel et al., 1997), and the overall beneficial effects of increased seat energy absorption (Bostrom et al., 1997; Geigl et al., 1994; Gupta et al., 1996; Kihlberg, 1969; Martinez & Garcia, 1968; Olsson et al., 1990; Parkin et al., 1995; Welcher & Szabo, 1999). Volvo's WHIPS (Whiplash Protection System) seat also incorporates an energy absorbing feature and tests were conducted using BioRID dummies and Hybrid IIIs to examine acceleration and torso acceleration (Jakobssen et al., 1999; Lundell et al., 1998). Toyota's seat (Whiplash Injury Lessening; WIL) system was also successful in reducing several injury-related parameters using the Hybrid III dummy with a TRID II neck, testing rear impacts (Sekizuka, 1998).

Recent research investigating energy-absorbing seat designs included the following "essential design criteria for seats equipped with anti-whiplash features (Himmetoglu et al., 2008, p. 585):

1. Good head restraint geometry in terms of head restraint height and backset
2. Effective crash energy-absorbing characteristics
3. Minimum neck internal motion (OC relative to T1 motion), reduced S-shape (or retraction)
4. Low neck forces (compression, tensile, shear) and moments
5. Reduced ramping
6. Minimum rearward displacement of the seat
7. Limited seatback rebound
8. No activation of anti-whiplash devices during normal use
9. Improved performance at all impact severities"

In addition, results showed that WMS, DWMS, RFWMS, and DRFWMS anti-whiplash seat design concepts all performed well in reducing whiplash, and there was not much contrast among the results (Himmetoglu et al., 2008). However, it was found that the seat design concepts with inner seatback frames were advantageous compared to those without frames (Himmetoglu et al., 2008). Inner seatback frames provide earlier head restraint contact and reduce seatback angle, especially in higher severity impacts (Himmetoglu et al., 2008). In effect, the anti-whiplash seat performs best when it effectively absorbs the crash energy while simultaneously providing early head support (Himmetoglu et al., 2008).

The Entire Seat Plays a Role

Since the head restraint on its own, was not as effective as it could be, researchers deduced that the performance of the entire seat plays a role in reducing the risk of neck injuries. The WHIPS was introduced in Volvo vehicles in 1998 (Jakobsson et al., 2008). The BioRID dummy was used in the WHIPS testing procedures. The three guidelines underpinning the WHIPS were: a) reduce occupant acceleration; b) minimize relative spine movements; and c) minimize the forward rebound into the seat belt (Jakobsson et al., 2000). The innovation of the WHIPS seat consisted of a recliner mechanism, modified backrest characteristics and head restraint geometry (Jakobsson et al., 2008). The seat has been on the market for over 10 years and has proven effective in reducing injury, based on real-world data (Farmer et al., 2003; Kullgren et al., 2007; Jakobsson et al., 2008; Jakobsson & Norin, 2004). Results of the WHIPS showed that for occupants over 14 years of age without prior neck problems and at a moderate impact severity, neck injury reducing effects were 33% for initial neck injuries and 53% for symptoms lasting greater than one year (Jakobsson & Norin, 2004). The effects were more pronounced in women than in men, indicating that the WHIPS may be more effective in reducing the risk of neck injury in women (Jakobsson & Norin, 2004). Testing performed on the WHIPS demonstrated factors such as the importance of occupant characteristics, sitting posture, turned head and increased head to head restraint distance, all increased the risk of neck injury (Jakobsson et al., 2008).

When they examined the effects of seat design, the most comfortable seat was the WHIPS design and relative to the torso, it also exhibited the lowest head centre of gravity in rearward translation and the lowest head acceleration in extension and flexion (Welcher & Szabo, 1999). This new generation of yielding seats has proven effective in reducing whiplash (Viano, 2008). The seats feature: perimeter frame seatback; strong frame structure; strong recliners; open seatback; EA pelvic strap; pocketing into seatback; pelvic drop on rear loading; and, high, forward head restraint (Viano, 2008). This seat has evolved over time beginning with a yielding seat in the 1970s, to a stiff seat in the 1990s, and now the use of the current high retention seat. The high retention seat allows for minimal neck displacement when there is an increase in speed. The addition of the active head restraint has made it superior to earlier seat designs.

Active Head Restraints

Active head restraints were introduced because the population was typically not positioning their head restraints appropriately. Active head restraints were designed to actively decrease the distance between the head and head restraint immediately following rear impact acceleration. Active head restraints function by moving the head restraint forward (closer to the head) and upward when the lower unit is loaded by the pelvis, when a rear impact occurs. In the late 1990s, the active head restraint became popular, and tests were conducted using human subjects. Saab created a head restraint that moved forward when pressure was exerted by the upper torso during rear impact (SAHR; Wiklund & Larsson, 1998). This was based on the earlier SAHR (Self Aligning Head Restraint). As summarized above, Volvo's new seat modified the stiffness of the head restraint, upper seatback, lower seatback, and incorporated energy absorption of the seatback (WHIPS; Lundell et al., 1998). Toyota also tested a seat named the Toyota Whiplash Injury Lessening (WIL) system using human subjects (Sekizuka, 1998). The seat had an adjustable head restraint, and a seatback with reduced upper torso stiffness. General Motors also improved their seat designs including improved stiffness and geometry, adjustable head restraints or self-aligning head restraints (Insurance Institute for Highway Safety; IIHS, 1999). Mercedes Benz developed an active head restraint known as the NECK-PRO System. It was introduced in the E- and C-class models beginning in 2005. The active head restraint moves towards the occupant's head to shorten/close the gap between the head restraint and the head in the event of a rear-end collision (Hartlieb et al., 2007). The advantages of the NECK-PRO System include: reduced whiplash by minimizing head to torso motion; whiplash protection yet a comfortable head restraint position; activation at low Delta-V; non-aggressive deployment of the head restraint; activation is independent of occupant mass; easily reversible by the driver (Hartlieb et al., 2007). Mercedes Benz' active head restraint uses an on-board crash sensor that activates a linkage in the head restraint (Motor Insurance Repair Research Centre Thatcham, 2006).

New technology was developed in the UK - the Smart Head Restraint System (Acar et al., 2007). The Smart Head Restraint System proposes to move the head restraint into an optimum position and continuously monitor the changes in the position of the head and make adjustments to ensure that the head restraint is constantly ready for an impact to occur (Acar et al., 2007). This system consists of mechanical horizontal and vertical adjustment mechanisms with sensors to detect and monitor the person's head, and control software that continuously adjusts the head restraint position (Acar et al., 2007). Researchers expect that this system will increase the likelihood of the proper head restraint positioning and correct adjustment to ensure that at the point of impact there will be maximized whiplash protection and a decrease in future economic cost (Acar et al., 2007).

Testing of the active head restraints were conducted on sled tests utilizing the BioRID II dummy, while different pulses (shape and Delta-V) were applied. The tests became part of the consumer ratings and are performed according to the test protocols for IIWPG-Rating (IIHS & Thatcham), EuroNCAP, and FMVSS202a. As an overall summary, the neck shear force (Fx) was reduced by 50% and neck tension force (Fz) by 35%, compared to a passive head restraint. The test results were confirmed in vehicle to vehicle tests. In 2008, researchers investigated the reduction in neck injuries with an active head restraint (Kitagawa et al., 2008). They compared rear-impact simulations using a fixed head restraint and an active head restraint. Tests on the SAHR reduced whiplash injury risks by 75 +/- 11% from an 18 +/- 5% incidence in 85 occupants with standard head restraints to 4 +/- 3% in 92 occupants with SAHR (Viano & Olsen, 2001). Results for the active head restraint indicated a decrease in NIC and joint capsule strain due to the forward and upward motion of the head restraint, following a reduction in the magnitude of shear deformation in the facet joint (Kitagawa et al., 2008). The authors concluded that neck injury could be reduced by supporting the head earlier and through the trajectory stopping joint deformation (Kitagawa et al., 2008).

Overall Seat Design Principles

Viano (2008) provided an overview of design principles and seat characteristics that lower the risk of whiplash. The summary revealed that seat stiffness, frame strength, and a high forward head restraint are important factors in controlling neck displacement (Viano, 2008). The addition of an active head restraint had a greater impact on reducing neck displacement and load (Viano, 2008).

Recent research delved more deeply into the biomechanics, kinematics and mechanisms for whiplash-related injuries such as the rate of change of acceleration (Hynes & Dickey, 2008). This work investigated whether the head acceleration response to whiplash-like perturbation profiles was affected by a change in the rate of applied acceleration (termed "jerk") (Hynes & Dickey, 2008). The main findings suggest that when trying to predict injury from whiplash-like perturbations, Delta-V, mean acceleration or peak acceleration should not be the sole factors to consider (Hynes & Dickey, 2008). Jerk should be evaluated independently of acceleration level (Hynes & Dickey, 2008).

Vehicle Seat Ratings

The International Insurance Whiplash Prevention Group (IIWPG) was formed to assist with designing and implementing a low speed rear impact sub-system test to simulate the typical scenario in which whiplash injuries occur (Avery, 2008). The role of the published test results was to contribute pressure on the vehicle manufacturers to improve the seat and head restraint designs. The IIWPG includes international research centers that have testing sites at Thatcham (UK) and the Insurance Institute for Highway Safety (IIHS) (US). Over the past 3 years, test results using 250 new vehicle seats, have been published internationally (Avery, 2008). The first step in the testing is to statistically rate the geometry of the seat. The test consists of a simulated rear crash on a rear acceleration sled device using a BioRID II dummy that represents a 50^{th} percentile male occupant (Avery, 2008). The test simulates a 16 km/hr rear impact to determine a dynamic rating of how well the seat supports the torso, neck and head (Avery, 2008). The main outcome is to limit the retraction of the head relative to the neck, therefore the encouraged design philosophy is of energy absorption at T1 (1^{st} thoracic vertebrae) and early support of the OC (occipital condyle) (Avery, 2008). Through a combination of geometric and dynamic test ratings, the seat is rated as "good", "acceptable", "marginal" or "poor". When researchers compared vehicle model years 2005 to 2007, using European and US seat ratings, results indicated an 81% increase in seats that achieved a "good" rating and a corresponding 44% reduction in those that achieved a "poor" rating (Avery, 2008). These results are encouraging as they show that whiplash injuries can be reduced through independent benchmarking (Avery, 2008).

Over time, the design changes to seatbacks and the role of active head restraints reduced the rates of neck injury claims following rear crashes (Farmer et al., 2003; Jakobsson & Norin, 2004; Viano & Olsen, 2001). Recent research suggests that higher rated seats resulted in fewer neck injuries to the occupants that required 4 or more weeks of medical attention compared with lower rated seats (Kullgren et al., 2007). In addition, more recently, Farmer and colleagues (2008) investigated the relationship of dynamic seat ratings to real-world neck injury rates (Farmer et al., 2008). Results indicated that neck injuries tended to increase as seat ratings decreased, and driver neck injury rates were higher for vehicles with poorly rated seats (Farmer et al., 2008). However, driver neck injury rates for vehicles with acceptable or marginal seats did not demonstrate expected results (Farmer et al., 2008). The risk factor of being female was again apparent as female drivers were much more likely to claim neck injuries than male drivers (21.7% vs 13.9%) (Farmer et al., 2008). In terms of long term injuries, neck injury rates lasting 3 months or more, were 35% lower for seats rated good in comparison to poorly rated seats (Farmer et al., 2008).

In 2006, Thatcham investigated the proposed EuroNCAP test procedure on 93 seats. A modified SAE J826 H-point manikin, combined with a head restraint measuring device (Gane & Pedder, 1996; 1999), and the BioRID II dummy were used to test the parameters (Avery et al., 2007). Results showed that a seat that achieved a high score from the proposed EuroNCAP system was likely to achieve a good rating with the IIWPG criteria. The compatibility of the rating systems was recognized and reinforced the quality of the seats.

Comparing Dummies to Humans

More recent research has compared dummies to human subjects on several parameters (Jonsson et al., 2008). Researchers compared stature, weight and backset of the BioRID II (Biofidelic Rear Impact Dummy; Schneider, 1983) to the same variables on seated volunteers in a car (Jonsson et al., 2008). Results showed that the BioRID II corresponded to a 35th-45th percentile male in stature, a 35th percentile male in weight; a 96th percentile female in stature and 69th percentile female in weight (Jonsson et al., 2008). The average backsets were 26 mm for females and 63 mm for males in the front seat positions, however smaller differences appeared for the rear passenger position between the BioRID II and the humans (Jonsson et al., 2008). The most significant finding was the difference in backset between a driver with hands on the steering wheel and a front seat passsenger with hands resting in the lap. Differences in backset showed that the standardized seating procedure of the BioRID II more closely resembles the driver position than the front passenger position (Jonsson et al., 2008). The results of this study demonstrated the occupant size coverage of the BioRID II and interesting facts regarding backset for various seating positions in the car, for humans in relation to the BioRID II (Jonsson et al., 2008).

Most of the testing was conducted in the US (vehicle-to-vehicle impacts), Canada, Japan and Europe (sled tests). A decreased gap between the head and the head restraint and the central alignment of the head with the head restraint, has been integral to reducing the risk of whiplash and neck injuries (DeRosia & Yoganandan, 2000). The scientific literature surrounding whiplash and head restraints is extensive. Future work in this area is exciting as technology is constantly improving and several risk factors are being addressed.

RISK FACTORS FOR WHIPLASH INJURY AND ASSOCIATED DISORDERS

The aim of this section is to provide the reader with the fundamentals and role of epidemiological research in identifying the risk factors for whiplash. Although whiplash injuries are a common outcome of road traffic crashes, there have been very few epidemiological studies that have investigated the risk factors associated with the occurrence of such injuries (Caddy, 1998; Holm et al., 2008; Spitzer et al., 1995). Therefore, existing literature provides limited scientific evidence concerning the factors associated with the risk of whiplash injury (Spitzer et al., 1995).

A rear impact collision is a predominant risk factor for whiplash injury. Head restraint positioning and geometry are also key determinants of incurring whiplash injury. The mechanism surrounding a rear-end collision and the resultant whiplash injury is scientifically well established. There are several epidemiological factors and biomechanical theories that can help to explain the mechanism of how a rear-end collision can result in a whiplash injury. The risk factors for whiplash injury from epidemiological studies can be divided into three categories: 1. Individual-related risk factors; 2. Vehicle-related risk factors; 3. Social policy-related risk factors.

1. Individual-Related Risk Factors

a) History of neck pain or injury

Prior research has shown that preconditions of disease are a risk factor for whiplash and WAD (Kivioja, 2004). Specifically, the available research highlights that past history of neck pain (Parmar & Raymakers, 1993; Radanov et al., 1994) and headaches (Kivioja, 2004; Lee, 1999) are risk factors. Additional research also indicates that previous neck pain and headache impact the recovery process (Kivioja, 2004). A study examining the relationships between vehicle and occupant risk factors and the incidence of whiplash in rear-end impact crashes in Adelaide, Australia, identified a history of neck injury as an independent risk factor for whiplash injury (Adjusted odds ratio = 4.50, 95% CI 1.97-10.28) (Caddy 1998; Dolinis, 1997).

The hypothesis underlying this assumption is that any previous injury indicates that the existing tissue has already been weakened by the previous condition (Dolinis, 1997; Jakobsson et al., 2000b). Another possible explanation was that previous injuries weaken the tissues and they do not respond as well as strong tissues (Khan et al., 2000). Some authors have associated degenerative changes in the cervical spine with an increase in the risk of whiplash (Bogduk & Yoganandan, 2001). Although younger age groups are more likely to seek health care or file a claim for whiplash, Holm argues against that association, since degenerative changes are highly associated with increasing age (Holm 2008).

b) Lower Body Mass Index (BMI)

One study showed that weighing less than 130 pounds was a risk factor for whiplash injury (Banks et al., 2000). The explanation of lower body mass index (BMI) as a risk factor for whiplash injury occurrence is that less weight indicates that occupant doesn’t load the seat back as much or as long and is thrown forward much more quickly and faster creating higher “G” forces (Banks et al., 2000). An additional study found an increased risk for those with a BMI lower than 25, as they lack fat which could provide a cushion effect and absorb some of the energy of the traffic crash (Zhu et al., 2006).

In addition, related research concerning BMI/head neck index (i.e., decreased risk with increasing mass and neck size) has also been reported in the literature. Fewer neck injuries among people who reported having higher BMI could be due to their small head/torso mass ratio (Boulanger & Rodriguez, 1992; Ryb & Dischinger, 2008; van den Kroonenberg et al., 1998), and the cushion effect, without a significant increase in mass and momentum (Arbabi et al., 2003). Furthermore, research shows that obesity imparts anatomical and physiological changes that may either protect or interfere with the body's response to traffic crash-related injury (Zhu et al., 2006).

c) Tall drivers/occupants and head restraint geometry

Head restraints were developed for the 50th percentile of males; therefore drivers/occupants who are significantly taller than the average (e.g., 80th percentile male) are vulnerable to whiplash injuries, since the head restraint geometry is incorrect for their height. The hypothesis underlying this assumption is that tall occupants' head restraints are set too low and this acts as a fulcrum, thereby causing an increased chance of whiplash injury (Lundell et al., 1998; Ono & Kanno, 1996; Viano & Gargan, 1996). Human body characteristics such as height and weight tend to play an important role in traffic crash outcome (Arbabi et al., 2003).

d) Old age

Research has indicated that old age is a risk factor for whiplash injuries (Brison et al., 2000; Hijioka et al., 2001; Parmer & Raymakers, 1993; Radanov et al., 1993a; 1993b; Ritcher et al., 1999). A prospective Japanese study underlies the fact that older age delays the recovery process (Hijioka et al., 2001). Elderly people suffer from osteoarthritis, spondylosis, and other degenerative diseases. These pre-existing conditions are a risk factor for whiplash injuries as the conditions create an additional factor that exposes the elderly to greater risk (Bogduk & Yoganandan, 2001).

Age also plays an important role because as the body ages, ligaments become less pliable, muscles become weaker and less flexible, and a decrease in range of motion occurs (Lövsund et al., 1988; Ommaya et al., 1982; Otte & Rether, 1985; Radanov et al., 1991; Satoh, 1997).

That older occupants are at increased risk of whiplash injury is consistent with other research demonstrating a positive association between age and other types of motor vehicle collision-related injuries. Older drivers are unique in that they are subject to unpredictable health and cognitive changes that may affect their safe driving practices. Previous literature asserts that due to their greater frailty, the elderly are more likely to suffer significant injuries and have an increased recovery period (Subzwari et al., 2008).

e) Women

Knowledge of individual differences is important when analyzing motor vehicle collision data as well as designing protection systems. Previous literature has consistently found that demographics are a risk factor for whiplash. Several research studies have shown that women are more likely to sustain a neck injury in the event of a rear-end impact (Krafft et al., 2000; Lovsund et al., 1988; Lundell et al., 1998; Minton et al., 1997; Morris & Thomas, 1996; Otte et al., 1997; Spitzer et al., 1995).

The fundamental physiological differences between male and female bodies have been identified as the key reason why women are more vulnerable to whiplash injuries than men. The most prominent findings highlight the vulnerability of women to neck injury as compared to men (Berglund et al., 2003; Chapline et al., 2000; Dolinis, 1997; Huelke & Marsh, 1973; Jakobsson, 2005; Kihlberg, 1969; Krafft et al., 2003; O'Neill et al., 1972).

International research has indicated that females have a somewhat higher relative risk of whiplash injury than males (Berglund et al., 2003; Siegmund et al., 1999). The study by Siegmund and colleagues attempted to control for age, seating position and type of motor vehicle collision. Researchers asserted that anatomical diversities, such as neck strength, smaller muscle mass, and body height account for this sex difference (Berglund et al., 2003; Caddy, 1998; Dolinis, 1997; Siegmund et al., 1999). Australian research also successfully identified female sex as a risk factor for whiplash (Adjusted odds ratio = 2.08, 95% CI 1.13-3.82) (Caddy, 1998; Dolinis, 1997).

These findings are in contrast to population based studies of all-cause motor vehicle collision-related injuries that report a higher incidence of injury among men. The issue of gender and whiplash injury has been debated extensively. This literature demonstrates that women tend to have an increased incidence of both neck pain and whiplash injuries as compared to men (Vasavada et al., 2008). However, there is not a valid model of the female neck that allows for an exploration of sex differences, since researchers have hypothesized that it is not simply a smaller version of the male neck (Vasavada et al., 2008). Earlier work (Langweider et al., 2000) recognized this issue; however the research did not progress until the mid 2000s.

A study that explored this issue demonstrated that sex differences in several neck anthropometry parameters were larger than the differences in head anthropometry parameters (Vasavada et al., 2008). In addition, there were differences in vertebrae size in the anterior-posterior dimension but not in the medial-lateral dimension, and women's necks were found to be significantly weaker than men's. The overall conclusion of the study was that a female-specific model is required to develop and test head restraints since male and female necks are not geometrically similar (Vasavada et al., 2008). In earlier research, Viano and Gargan (1996) also noted that 1 in 5 women sit less than 12" away from the steering wheel, which has implications for vehicle seat and head restraint design. Other studies observed that females may be sitting too close to the steering wheel, foot pedal, airbag and/or have improperly fitted shoulder harnesses (Parkin et al., 1995). Knowledge of the demographic differences in vulnerability to whiplash injuries is important when designing effective protection systems. Since females tend to sit higher and closer to the steering wheel, and their back rest angle is more upright, this seating posture results in a slightly higher horizontal shear stress component to the spine in rear-end impacts compared to males (Cullen et al., 1996; McFadden et al., 2000; Parkin et al., 1995). A combination of these factors explains why females are highly vulnerable to whiplash injuries compared to their male counterparts.

In contrast, a systematic review by Scholten-Peeters and colleagues (2003) has counter-claimed the other studies which often mentioned factors like age, sex and compensation as a risk factor for whiplash injuries. This study also claims that these demographic and social policies do not seem to be of any prognostic value (Scholten-Peeters et al., 2003).

However, much of the research on this topic highlights that the differing anatomy is a factor in the higher risk faced by women for whiplash injuries. Studies have found that males have strong neck muscles to counteract the risk of whiplash injury (Vasvada et al., 2008), yet females have longer necks and smaller heads contributing to their higher vulnerability to whiplash injuries in rear-end crashes (Temming & Zobel, 1998). In summary, the majority of the research evidence supports the theory that women are at higher risk for whiplash injury.

2. Vehicle-Related Risk Factors

a) Wearing a seatbelt

There is a body of literature to suggest that the use of seatbelts prevents all other severe injuries, yet it actually increases the likelihood of injuries to the cervical spine. Several studies have concluded that wearing a seatbelt is a risk factor for whiplash injury (Allen et al., 1985; Borchgrevink et al., 1996; Deans et al., 1987; Dunn & Blazer, 1987; Evans, 1996; Hayes et al., 1991; Kallieris et al., 1991; Lange & Voas, 1998; Morris & Thomas, 1996; Mulhall et al., 2003; NASS, 1991; Nygren, 1984; Ommaya et al., 1982; Richter et al., 2000; Roh & Fazzalaro, 1993; Satoh et al., 1997; Teifke et al., 1993; Versteegen et al., 1998).

Conversely, there is also research that indicates that wearing a seatbelt is not a risk factor for whiplash injury. A recent case control study that utilized data from France and Spain contradicts many previous risk-related epidemiological studies by showing that wearing a seatbelt, being in a heavier car, and being older than 65 years of age were protective factors for whiplash injury and were associated with a lower risk of whiplash injury (Martin et al., 2008).

Regardless of the uncertainty of seatbelt use and whiplash injury, all occupants of motor vehicles should heed the ubiquitous message that proper seatbelt use is a highly effective means of reducing the risk of injury in general, and specifically reduces the risk of fatal injury.

b) Drivers and front-seated occupants

Whiplash injury is predominantly an injury issue for drivers and front seated occupants, while literature on the risk for rear-seated passengers is sparse. Consistent with other findings, Berglund and colleagues (2003) found that drivers had a higher risk of incurring a whiplash injury compared to rear-seated passengers (1.78; 95% CI 1.60-1.97) (Berglund et al., 2003). Similarly, additional studies have confirmed these findings indicating that the risk of whiplash injury is lowest for the rear-seated passengers and highest for drivers and front-seated occupants (Carlsson et al., 1995; Jakobsson et al., 2000b; Krafft et al., 2003; Lövsund et al., 1988; Otremski et al., 1989; Pamar & Raymakers, 1993; States et al., 1972). An explanation for the increased risk could be due to a more rigid, uniform and less elastic design of the rear seats than the front seats (Pamar & Raymakers, 1993). Additional proposed hypotheses for the increased risk of whiplash for drivers and front-seated occupants include the differences in seat back resistance and the potential to strike something (Carlsson et al., 1995; Kihlberg, 1969; Lövsund et al., 1988; Otremski, 1989; Otte et al., 1985; Pamar & Raymakers, 1993; States et al., 1972).

Volvo collision statistics reported a significantly higher risk of the driver sustaining a neck injury than the passengers (Lundell et al., 1998). Researchers hypothesized that the differences between the driver and front seated passenger could be due to different seating postures (Lundell et al., 1998). Drivers are more prone to bend forward and away from the seat backrest and head restraint than passengers, who are more relaxed and probably more likely to rest their head against the head restraint.

However, in contradiction, Krafft and colleagues (2003) found that when crash pulse and occupant seating positioning were controlled for, whiplash injury risk was higher for rear passengers in rear-end crashes (Krafft et al., 2003).

c) Mass of the striking vehicle

There is literature that demonstrates that impact by a striking vehicle of greater mass (i.e., 25% greater mass) (Force = Mass x Acceleration) is a risk factor for whiplash injuries (Caddy, 1998; Chapline et al., 2000; Dolinis, 1997; Kornhauser, 1996; Wood, 1997). Studies that examined side impact crashes also confirmed that the mass of the striking vehicle is a risk factor for severe injuries and fatalities (Desapriya et al., 2006; Evans & Frick, 1992; 1993).

d) Speed of the striking vehicle

In a series of human volunteer crash tests of low speed rear impact collisions, it was reported that the threshold for cervical spine soft tissue injury was 5 mph, and most injuries occur at speeds below 12 mph (Morris & Thomas, 1996; Olsson et al., 1990; Siegmund et al., 1999). Interestingly, epidemiological studies have shown that most rear impact crashes causing injury occur at crash speeds of 6 to 12 mph, which is below the threshold for property damage to the vehicle (Scholten-Peeters et al., 2003).

Often in other traffic crash-related injuries, speed is highlighted as a risk factor for crash outcome, and the risk of injury severity and fatality are increased in high velocity crashes compared to low velocity crashes. In contrast, a crash speed under 10 mph (low speed crashes) increased the risk of whiplash injuries. In slow speed crashes, the car does not crush or crumple therefore the energy is transferred to the occupant and is not absorbed by the car (Foret-Bruno et al., 1991).

Muscular strain may also occur as the muscles tighten during the early part of the collision as the head extends backward (Gross et al., 1996; Hurwitz et al., 1996). During low speed crashes rapid pressure changes in the spinal canal can create a great deal of strain on the spinal nerve roots which in turn can result in pain symptoms after a low speed collision (Aker et al., 1996).

e) Impact direction of the vehicle

According to a best evidence synthesis by Holm and colleagues (2008), few factors related to the collision itself (for example, direction of the collision, headrest type) were predictive of whiplash injury.

Whiplash injuries occur most commonly due to rear impact crashes. However, a contradictory finding surfaced showing that the absolute number of whiplash cases was greater in front and side impact crashes than rear-end crashes in France and Spain (Martin et al., 2008). Additional evidence was found to support this finding indicating that whiplash injuries occurred not only in rear-end collisions but also in other types of traffic collisions (Björnstig et al., 1990; Bogduk & Yoganandan, 2001; Cassidy et al., 2000; Deans et al., 1986; Hildingsson & Toolanen, 1990; Jakobsson et al., 2000b). However, confirming most international studies, research in Sweden showed that rear-end collisions were associated with the highest relative risk of whiplash injury when compared with side impacts (1.82; 95% CI 1.68-1.96) (Berglund et al., 2003).

f) Extent of vehicle deformation

There is a common belief that occupant injury correlates to the amount of damage to the vehicle in all types of crashes. However, the literature on this issue is quite clear and states that there is absolutely no correlation between the amount of damage to the car and the risk of injury (Hurwitz et al., 1996). Contrary to existing literature, one study found that vehicle damage severity is a risk factor for whiplash injuries and a crucial factor in whiplash injury recovery (Hijioka et al., 2001).

However, most of the literature determined that a vehicle with less damage may result in higher forces experienced by the driver and occupants compared with a vehicle with extensive damage (Berglund et al., 2003). According to research evidence, severity measures based on deformation depth has not been identified as a good predictor of whiplash injury risk (Jakobsson, 2000b). This is related to the literature on speed that indicates that the risk of whiplash injury is higher in low velocity crashes at speeds of 6 to 12 mph (Scholten-Peeters et al., 2003).

g) Stiff vehicle structure

There are some epidemiological studies to support the assumption that stiffer vehicles are a risk factor for whiplash. The injury mechanism occurs because the stiffer vehicle bounces in response to a crash rather than absorbing the energy of the impact (Gross et al., 1996; Hurwitz et al., 1996; Olsson et al., 1990). Vehicles with stiff rear-end structures and/or seatbacks produce greater torso accelerations, making it harder to keep the driver's head and torso moving together. It is the rapid acceleration of the head in relation to the torso that results in whiplash (Gross et al., 1996; Hurwitz et al., 1996).

Compatibility is important in order to secure mutual protection in collisions between large and small vehicles. To enhance compatibility, good structural interaction and stiffness matching are important elements (Hasegawa & Kudoh, 2009). In recent years, light truck vehicles (LTVs) have been infiltrating the traditional vehicle fleet that had previously been dominated by smaller cars. This new trend has created vehicle compatibility issues in motor vehicle collisions. When smaller cars are hit by LTVs, these crashes result in a disproportionate number of injuries and fatalities to the occupants of the smaller vehicles (Desapriya et al., 2006). In order to reduce the effects of incompatibility, car manufacturers have increased the structural stiffness of vehicles as a crash mitigating factor (Linder & Avery, 2004). Comparisons of vehicle accelerations and additional parameters have identified an increase in vehicle structural stiffness in vehicles manufactured between 1980 and 2001 (Linder & Avery, 2004). Vehicle stiffness is a risk factor for whiplash and related injuries, and therefore becomes problematic in attempts to mitigate these types of injuries (Linder & Avery, 2004; Richter et al., 2004; Sendur et al., 2005).

Researchers reported that vehicle structures have been getting stiffer since the mid 1990s and this trend is continuing (Richter et al., 2004; Sendur et al., 2005). Stiff vehicles that do not absorb sufficient crash forces in low-speed impacts may reduce vehicular damages, but they transmit increased crash forces to occupants, increasing the risk of injuries, particularly whiplash. A study was conducted that was limited to an impact magnitude of 10 kph as total energy was held constant, indicating that Delta-V was 10 kph. Results showed that vehicle stiffness had a strong influence on the retraction (70%), rebound (43%), and protraction (47%) phases of motion (Sendur et al., 2005). Head restraint backset demonstrated a strong influence on the extension (49%) and rebound (39%) phases. This study emphasized that a vehicle should be viewed as a system in which there are complex interactions among the vehicle, seat, and occupant, which are all risk factors for whiplash injuries (Sendur et al., 2005). This calls into question past policies that limited compensation primarily based on the extent of vehicular damage sometimes referred to as, "no crash no cash" rather than consider the crash and safety characteristics of specific vehicles (make, model and year).

h) Poor quality seats

Farmer and colleagues (2008) noted that the seats rated as "poor" by the Insurance Institute for Highway Safety's (IIHS) seat evaluation tended to increase the risk of whiplash injuries and longer term disability (Farmer et al., 2008). The stiffness of the seat and head restraint is also highlighted as a risk factor (Viano, 2003a, 2003b). However, a study by Szabo and colleagues (2003) contended that seat and head restraints were not factors in increasing the risk for whiplash injuries (Szabo et al., 2003). Although the majority of the research contends that the quality of the seat is an important risk factor for mitigating the occurrence of whiplash injury, studies do appear with contradictory findings.

3. Social Policy-Related Risk Factors

a) The existing insurance compensation system

There is sparse literature in the area of insurance compensation systems and the effect on whiplash injury. A review by Spitzer and colleagues (1995) reported varying annual incidence rates for whiplash injury ranging from 70 to 700 per 100,000 population in Canadian provinces. They indicated that these provincial (as well as international) prevalence rates are likely influenced by the legal/administrative provisions in operation in each jurisdiction (Spitzer et al., 1995). The study revealed that in jurisdictions with a 'no-fault' insurance provision (particularly those jurisdictions that could limit tort actions), there were lower claim rates for whiplash injuries (Spitzer et al., 1995).

A study conducted in the Canadian province of Saskatchewan demonstrated a 28% reduction in the incidence of WAD after insurance payments for pain and suffering were eliminated (Cassidy et al., 2000). This included claims, as well as all those requiring treatment for their neck injury. In addition, there was a 54% decrease in the time-to-claim closure after this policy change (Cassidy et al., 2000). Importantly, removal of compensation payments for pain and suffering for whiplash injury resulted in a substantial decline in the number of persons seeking care and a substantial improvement in recovery times (Cassidy et al., 2000). It is important that public health policies promote prevention and recovery from conditions such as whiplash or WAD and not create incentives for illness-promoting behavior, or inappropriate and excessive individual care (Cassidy et al., 2000; Holm et al., 2008).

There is a lack of extensive population-level research on whiplash and WAD and insurance policy changes; however, the available limited research shows a positive relationship among whiplash compensation availability and injury prevalence.

Gap in the Literature

A best evidence synthesis by Holm and colleagues (2008) highlighted the important gaps in the literature including risk factors for whiplash injuries and also showed that evidence regarding risk factors is inadequate and insufficient (Holm et al., 2008). Accordingly, investigators urged that more research using population-based whiplash risk data should be conducted and designed to strictly control for possible confounding factors using accurate denominators (Holm et al., 2008).

An additional best evidence synthesis by Guzman and colleagues (2008) also reported gaps in the literature concerning the frequency of risk factors, assessment, intervention course and prognostic factors for neck pain and its associated disorders, including whiplash injuries and that only 46% of the scientific literature on neck pain/whiplash was judged to be scientifically valid (Guzman et al., 2008).

A thorough examination of research databases, various papers, and the grey literature, revealed that compared to developed countries, there has been no epidemiological research available concerning whiplash and related risk factors common to populations living in developing countries. Most of the available literature focused on the epidemiological issues related to North American and European populations. There were a limited number of studies available that explored populations in Japan, Australia and New Zealand. The global burden of disease studies have repeatedly projected that traffic-related injuries will become the third largest contributor to global death and disability by the year 2020 (Murray, 2006; Murray & Lopez, 1996). The studies logically argue that much of the burden of traffic crashes in the future will remain in developing countries due to rapid motorization, lack of infrastructure development, and lack of prevention and treatment strategies. Therefore, future whiplash injury prevention efforts should be extended to explore the current status and epidemiology of these types of injuries in developing countries.

The development of strategies for future whiplash injury prevention in developing countries, as well as all of the above challenges should be addressed. Simultaneously, it is important for the field of whiplash injury epidemiology to move away from the largely descriptive studies with considerably small sample sizes that have been predominant in the literature, to the application of more rigorous analytical methods to identify demographic, vehicle and environmental risk factors for whiplash injuries. New advances in the prevention of whiplash injuries will continue to require a more analytical approach in order to understand the complex array of factors that influence the mechanism, severity, and outcomes of injury.

KNOWLEDGE AND AWARENESS OF CORRECT HEAD RESTRAINT POSITIONING

Knowledge and Awareness Studies

Many drivers do not correctly adjust their head restraints due to a lack of awareness of the consequences of incorrect adjustment. Surveys conducted on the general population demonstrated that they were unaware of the protective value of head restraints and believed that their current head restraint adjustment was adequate (Brown & Nepomuceno, 1999). Observational research in Canada, the UK and Europe show that there is low awareness about the protective value of head restraints and that most drivers and occupants in vehicles with adjustable head restraints have not adjusted them appropriately according to scientific guidelines (Braddick & Love, 1990; Garret & Morris 1972; Hong, 2004; Johnson, 1996; Lubin & Sehmer 1993; Mahaffey et al., 2002; Nygren et al., 1985; O'Neill et al., 1972; Parkin et al., 1995; Saab et al., 2000; Taylor et al., 2005; Viano & Gargan, 1996; Young et al., 2005). Current research suggests that serious neck injuries and associated disability can be reduced by 35% if the gap between what is known by high quality research and what is actually carried out in policy and practice can be reduced (Farmer et al., 2008; Zuby & Lund, 2007).

Research from the early 1970s to late 1990s investigated people's awareness and practices concerning head restraint adjustment while driving. O'Neill and colleagues (1972) demonstrated that 78% of drivers had incorrectly positioned their head restraint, while Garrett and Morris (1972) found that 73% of adjustable head restraints were left in the down position. This was consistent into the mid 1980s as Nygren and colleagues (1985) showed that 83% of adjustable head restraints were in the down position during driving. In the early 1990s the percentage of drivers with head restraints in the down position, decreased to 62% (Lubin & Sehmer, 1993). The percentage increased once again into the mid 1990s as Viano and Gargan reported that 83% of adjustable head restraints could have been raised for better protection of the driver (Viano & Gargan, 1996).

A survey revealed that less than half of drivers in British Columbia, Canada believed that incorrectly adjusted head restraints have an impact on insurance and health care costs (Fockler et al., 1998). Furthermore, over one-third of the respondents were not confident in their knowledge of the consequences of incorrectly adjusted head restraints. In the same survey, drivers were also asked to provide reasons for adjusting their head restraints. The most frequently reported reasons involved comfort, not safety. These results further underscore the need for increased recognition by the driving public, of the consequences of incorrectly adjusted head restraints (Fockler et al., 1998).

A number of studies have reported that adjustable head restraints are often improperly positioned by drivers (Cullen et al., 1996; Nygren et al., 1985; Viano & Gargan, 1995). Therefore, a comparison of adjustable head restraint designs must take into account the positioning of the head restraint relative to the driver's head both in the adjusted and unadjusted situations. In one study, greater than 70% (117) of the vehicles received poor evaluations of head restraint positioning (Viano & Gargan, 1995). Braddick and Love (1990) found that only 33% of head rests were correctly adjusted in the UK (Braddick & Love, 1990).

In the fall of 1995, the National Highway Traffic Safety Administration (NHTSA) conducted a survey of the positions of the occupant's head relative to the head restraint in 282 vehicles. Of these vehicles, 23% had fixed head restraints, with 77% of these restraints positioned at or above the occupants' ears. A lower percentage (59%) of the 77% of adjustable head restraints was positioned at or above the occupants' ears. About half of the adjustable head restraints were left in the lowest position (NHTSA, 1996).

O'Neill et al. (1972) observed drivers in 4,983 moving domestic passenger cars in the metropolitan areas of Los Angeles, CA, and Washington, DC. In Los Angeles, 57% of the women and 74% of the men had adjustable head restraints that were positioned incorrectly. Results indicated that more than half of the adjustable head restraints were incorrectly positioned (O'Neill et al., 1972).

Observation of 992 motor vehicles revealed that most drivers do not have their head restraints effectively positioned (Lubin & Sehmer, 1993). Improper positioning was more common with adjustable restraints, in commercial vehicles, and among male drivers. They found that only 40.3% of adjustable head restraints were positioned properly. This research also demonstrated that 30.2% of male drivers had correctly positioned the head restraints compared to 67.6% of females (Lubin & Sehmer, 1993).

A survey of drivers by Parkin and colleagues (1995) (involving 1,000 drivers and 19 different car models) in the UK found that 50% of the driving population had the head restraint positioned greater than 15 cm (6 in.) from the backs of their heads, horizontally. Drivers were filmed using a video camera equipped with a high speed shutter as they passed a white screen. Three separate locations were used, in which the camera could not be viewed by the drivers. This study found that only 5% of drivers had their head restraint correctly positioned vertically, with the great majority having it positioned too low. Fifty percent of the population had the head restraint positioned 10 cm (4 in.) or more below the center of the head. Currently, only a small proportion of drivers (7%) meet these standards in Portland, Oregon. Fixed head restraints were three times more likely to be optimally positioned than adjustable head restraints (Young et al., 2005).

The Insurance Corporation of British Columbia (ICBC) conducted a survey in 1996, in the Lower Mainland of British Columbia,Canada to evaluate the positioning of head restraints. The results showed that 57% of drivers with adjustable head restraints had them positioned incorrectly (Geddes et al., 1997).

The Insurance Bureau of Canada (IBC) conducted a study that rated the head restraint position of 7,571 drivers and 1,090 passengers from seven Canadian provinces as 'good', 'marginal', 'poor' or 'very poor'. Results showed that only 14% of drivers and 19% of front seat passengers had their head restraint in a position rated as 'good', and that for 53% of the drivers, the adjustment was so inadequate that it would have offered no protection in a rear-end collision (Mahaffey et al., 2002). Evidence shows that the typical driver and many professionals have poor knowledge of the correct use of head restraints. A cross-sectional study showed that even chiropractic interns' knowledge and application of correct head restraint positioning is lacking (Taylor et al., 2005). The study by IBC noted that drivers of large cars and light trucks were significantly below the average for properly adjusted head restraints (6% and 4% respectively compared to the 14% average) illustrating a large variation due to vehicle type (Mahaffey et al., 2002). This poses a safety concern as these vehicle types typically constitute a major component of the fleet driven by those in businesses, utilities and public service agencies (such as police, fire, government).

Table 2 provides a summary of the international observational and knowledge and awareness studies regarding the incorrect use of head restaints.

Table 2. International observational and knowledge and awareness studies – Incorrect use of head restraints.

Study	Methods	Participants	Results	Quality of the study
O'Neill et al., 1972 (USA)	Observational survey (convenience sample)	3345 males and 1638 female drivers	84% of male drivers and 71% of female drivers incorrectly positioned their head restraints	Moderate
Garret and Morris, 1972 (USA)	Observational survey (convenience sample)	237 vehicles	73% of drivers incorrectly positioned their head restraints	Moderate
Nygren et al., 1985 (Sweden)	Traffic crash data analysis	187 vehicles	83% of drivers incorrectly positioned their head restraints	Moderate
Braddick and Love, 1990 (UK)	Observational survey/ questionnaire (convenience sample)	150 male drivers	136 drivers knew that head restraints were a safety feature; only 24% identified correct position of the head restraint; 33% correctly adjusted the head restraint	Moderate
Lubin and Sehmer, 1993 (Canada)	Parking lot survey/ Roadside observational survey	708 vehicles in a parking lot/ 879 vehicles in motion (61.9% males and 38.1% women)	In a parking lot survey- 62% of the adjustable headrests were in the down position; in a roadside observational survey 46.3% of drivers' head restraints were adjusted correctly. Female drivers are more than twice as likely as males to have their head restraints positioned correctly.	Moderate
Parkin et al., 1995 (UK)	Roadside observational study	1000 drivers (75.8% male and 24.2% females) Random sample of vehicles	50% of the driver population had correctly adjusted their head restraints horizontally. Only 5% had correctly adjusted them vertically	Moderate
NHTSA, 1996 (USA)	Parking lot survey	Convenience sample of drivers (282)	47% of adjustable restraints were left in their lowest position. 26% of these were sufficiently high to have the top of the restraint above or at the top of the ear. 51% were not in their lowest position. 30% were below the top of the ear. 2% of all adjustable restraint cases could not be assessed.	Good

Table 2. (Continued)

Study	Methods	Participants	Results	Quality of the study
			Drivers had not perceived the head restraint as a protective device, but simply as a head rest or pillow.	
Viano and Gargan, 1996 (USA)	Observational survey (convenience sample)	Convenience sample of vehicles (1915)	10% of drivers had adjusted their head restraints correctly. 14.8% of women and 6.1% of men had a favourable, yet not absolutely correct head rest position.	Good
Johnson, 1996 (Canada)	Awareness survey (convenience sample)	338 Canadian medical students, 183 family doctors, and 45 trauma team members were asked about health promotion items. None included the topic of head rest adjustment as a health promotion to improve traffic safety in youth.	Only 18% of family practice instructors in a University of Toronto network agreed that they would counsel youth about proper adjustment of head restraints. Shocking results were found in this survey and the trauma team members did not expect primary care physicians to include head restraint position as an important item in health promotion.	Good
Saab et al., 2000 (Lebanon)	Observational survey (convenience sample)	Convenience sample of drivers (2105)	32.2% had their head restraints adequately adjusted.	Moderate
Mahaffey et al., 2002 (Canada)	Observational survey (convenience sample)	7571 drivers and 1090 passengers	46 % had their head restraints adequately adjusted. Females had correctly adjusted their head restraint at twice the rate of males. 60% of passengers had their head restraints adequately adjusted.	Good
Hong, 2004 (Korea)	Interview and observational survey	1100 vehicles/ drivers	19% had their head restraints adequately adjusted.	Moderate
Young et al., 2005 (USA)	Observational and awareness survey	4287 drivers/ 51 survey respondents	7% had their head restraints adequately adjusted. The questionnaire results indicated that: the head restraint is a safety device to prevent neck injuries (75%). However 55% of respondents had never adjusted the head restraints.	Good
Taylor et al., 2005 (Canada)	Awareness survey	30 chiropractic interns	Only 13.3% of chiropractic interns knew the recommen-ded vertical distance and only 20% knew the recommended horizontal distance for head restraints.	Good

Based on the review of the literature presented in this section, there is a significant lack of public awareness surrounding the proper use and correct adjustment of head restraints. It is not only the general public who are unaware of correct positioning, but also those in the medical profession (Johnson, 1996; Taylor et al., 2005). This may be due to lack of, or ineffective education, engineering, enforcement, media, and social marketing preventative efforts.

EVOLUTION OF CHANGES IN REGULATIONS, STANDARDS, AND POLICY FOR HEAD RESTRAINTS

This section focuses primarily on the US, Canada, and Europe, and describes how the standards from different countries were harmonized to develop a global technical regulation on head restraints. A summary of the various vehicle rating systems for head restraints is also provided.

Table 3. Summary of Standards, Regulations, Ratings, and Milestones.

Standard/Regulation	Year implemented
US Federal Motor Vehicle Safety Standard 202 (US FMVSS 202) (Minimum height of 700 mm)	1969
Canadian Standards (Same as above)	1978
European Standards (Minimum height of 750 mm, adjustable to 800 mm)	1978
IIWPG formed IIWPG/RCAR ratings created	2000
NHTSA issued notice of proposed rulemaking -US FMVSS 202a	2001-2004
Folksam Insurance & Swedish Road Authority (SRA) published seat/head restraint rating systems	2003
Ad Hoc Group on Head Restraints created (directed by UNECE)	2004
EuroNCAP ratings – amalgamation of RCAR/IIWPG & Swedish rating (SRA) systems	2008
All new US vehicles required to meet updated guidelines (FMVSS 202a) (Minimum height of 750 mm, adjustable to 800 mm, minimum backset of 55 mm)	2009 (September)
International Global Technical Regulation for Head Restraints	No implementation date yet

Table 3 provides a brief summary of the standards, regulations, ratings, and milestones surrounding head restraints.

Standards and Regulations

Vehicle manufacturers have been required to equip vehicles with head restraints since 1969 in the US, and since 1978 in Canada and in Europe. The European regulations include a minimum height of 750 mm (29.5 in) and restraints must be adjustable to 800 mm (31.5 in) above the seating reference point.

The US Motor Vehicle Safety Standard 202, in effect from 1969 to September 2009, required that head restraints be adjustable to a height of 700 mm (27.6 in) above the position of the center of rotation of the hip joint when a person is seated in the vehicle (seating reference point) (Kahane, 1982). This was problematic because the head restraints were not as high as the center of gravity of an average male's head.

In Canada, the safety standard enacted in 1978 was aligned with the US requirements for head restraints. The final rule modifying the requirements of safety standard 202 of the US was published in December 2004, and amended in May 2007. The new requirements increased the minimum height of the outboard head restraints from 700 to 750 mm, and introduced a maximum backset requirement, maximum gap requirement between the head restraint and seat and required testing for height retention and energy absorption (Department of Transport, 2008). There were also more stringent testing requirements for strength testing and backset retention and a new dynamic testing protocol with updated male test dummies (Department of Transport, 2008).

The amendment that is proposed for 2009 in both the US and in Canada, is a stepping stone toward international harmonization of head restraint requirements (Department of Transport, 2008), that will be developed as a global technical regulation.

An ad hoc informal working group on head restraints has been meeting since 2004 to discuss and evaluate issues surrounding the requirement of head restraints in vehicles, with the main goal of making recommendations concerning the development of a global technical regulation for head restraints. At a meeting in June 2006, the group began developing a proposal for a draft global technical regulation that was based on the requirements of the United Nations Economic Commission for Europe's (UNECE) Regulation 17, Regulation 25, and the upgraded FMVSS 202 (FMVSS 202a).

The group made several recommendations for the development of a global technical regulation, which are summarized below (Ad hoc Group on Head Restraints, Meeting Minutes June 23, 2006).

Head restraint height

For front outboard head restraint height, the recommendation was to increase to 850 mm above the reference point to accomodate taller populations. However, based on the evidence, it was determined that the current 800 mm was sufficient to protect the 95th percentile Netherlands male (tallest in the world). For rear outboard head restraint height, a 750 mm minimum height and static requirements, excluding backset was recommended. For front center, it was recommended that the head restraint conform to the same regulations as the rear outboard head restraints (optional, no backset requirement, 750 mm height). For the rear center, the requirements were the same as front center, although no height requirement was necessary (Ad hoc Group on Head Restraints, Meeting Minutes June 23, 2006).

Backset

In 2004, discussions continued on this parameter. There was concensus that a recommendation for backset was important, yet the 55 mm requirement may be too stringent. Issues arose regarding measurement methods and occupant comfort levels (Ad hoc Group on Head Restraints, Meeting Minutes June 23, 2006).

Dynamic test

An optional dynamic test was proposed as an option to the static requirements. Concerns arose surrounding which type of dummy to use. The Hybrid III dummy spine is not humanlike, nor is its motion during a dynamic test; however, the BioRID dummy, although preferred, is not ready to be made part of a regulation. It was decided that the dynamic test could be phased into the proposal at a later time (Ad hoc Group on Head Restraints, Meeting Minutes June 23, 2006).

At the group's seventh meeting, Canadian representatives presented their findings on the use of the Head Restraint Measuring Device (HRMD), created by the Insurance Corporation of British Columbia (ICBC), which was used for measuring backset. The testing confirmed that the HRMD provides repeatable and reproducible results, and that increasing the number of measurements reduces the backset variability (Gane & Pedder, 1996). The global technical regulation will include the use of the HRMD (Department of Transport, 2008).

The work of this group has now led to agreement regarding the parameters of a global technical regulation for head restraints, which was approved in March 2008. Due to a non-consensus regarding dynamic testing, only quasi-static testing requirements will be included in the global technical regulation. Work is underway to develop an internationally accepted dynamic testing protocol (Department of Transport, 2008).

In the US, 2009 will be a pivotal year for head restraints and and the prevention of whiplash. All 2009 vehicle models must include the mandated requirements of head restraints to all front seats as well as back seats. These include: a minimum of 29.5 inches (750 mm) from an occupant's hip to the top of the head restraint and the backset must be 2 inches (50.8 mm) between the head and the head restraint (IIHS, 2005).

Benefits of Harmonization

The approved harmonization of standards and regulations into a global technical regulation combined elements from the UNECE Regulations No.17, No. 25, and the newly upgraded US FMVSS 202a. International motor vehicle manufacturers, along with the entire industry benefit from harmonization and new technology-based improvements to the head restraint regulations. The benefits to industry include the improved safety of the head restraints, leveraging of resources, and the harmonization of requirements. Industry also benefits from a reduction in the cost of development, testing and the fabrication process of new vehicle models. Consumers worldwide benefit by having a choice of vehicles built to higher, globally recognized standards, providing an improved level of safety at a lower cost.

Safety Ratings

The regulations for head restraints were not completely effective in rear crashes, which lead to enormous costs for insurance companies; therefore, whiplash received considerable attention. It was a significant issue for insurance companies, vehicle manufacturers had to design improved head restraints that were appropriate for the majority of the driving and occupant population, and there was consumer pressure. This requirement has resulted in numerous rating systems for seats and head restraints (Avery et al., 2007). The current ratings include: the International Insurance Whiplash Prevention Group (IIWPG) ratings, the Swedish Road Administration (SRA) ratings, Federal Motor Vehicle Safety Standard (FMVSS) ratings and more recently, the European New Car Assessment Programme (Euro NCAP) ratings, which are a combination of the IIWPG and SRA systems.

IIWPG Rating System

The IIWPG utilizes a two-stage process for evaluating and rating the ability of seats and head restraints to prevent neck injury in moderate and low-speed rear-end impacts (IIWPG, 2004). First, the static geometry of the head restraint is measured and rated; second, a dynamic evaluation in a simulated rear-end collision is conducted and rated. The static geometry measurements include height and horizontal distance to the back of the head. Head restraints with geometric ratings of ‘acceptable’ or ‘good’, then go on to dynamic testing in a simulated 16 km/h rear impact to obtain a rating for how well the torso, neck and head are supported (IIWPG, 2004). The results of the geometric measurements and the dynamic testing are combined to produce an overall rating of the seat and head restraint as a whole (IIWPG, 2004).

The dynamic testing involves seat design parameters (time-to-head restraint contact; energy-absorbing characteristics) and test dummy response parameters (neck shear force; neck tension force). The simulated rear crash is tested using a sled device and a BioRID II crash dummy (IIWPG, 2004).

The detailed instructions for testing static geometry are available in the *Procedure for Evaluating Motor Vehicle Head Restraints* (RCAR, 2001), while the procedure for conducting dynamic testing is described in *IIWPG Protocol for the Dynamic Testing of Motor Vehicle Seats for Neck Injury Prevention* (RCAR, 2004).

Figure 1 provides the IIWPG’s matrix of criteria for how vehicle seats and head restraints are rated as ‘good’, ‘acceptable’, ‘marginal’, or ‘poor’.

Swedish Road Administration (SRA) Ratings

The Swedish Road Administration (SRA) partnered with Folksam Insurance and Autoliv in 2003 to publish vehicle seat ratings based on dynamic testing. Three tests are conducted using varying speed/acceleration levels, and three BioRID dummy response parameters (NIC, Nkm, head-rebound velocity) to create a rating score (Krafft et al., 2004). Five points are assigned to each of the three tests to create a maximum combined rating of 15 points. The points are assigned based on the magnitude of the measured value. Once all points are combined, the vehicle seats are rated using a color system of Green+ (0-2.5 points), Green (2.6-5.0 points), Yellow (5.1-10.0 points), or Red (10.1-15.0 points). Based on the points system, Red is the worst rating and Green+ is the best.

European New Car Assessment Programme (Euro NCAP) Ratings

The Euro NCAP ratings were developed in 2008 using a combination of parameters from the IIWPG and SRA ratings. The testing uses a dummy to assess the head restraint geometry and dynamic testing of the seat, using three impact severities of high, medium, or low (Euro NCAP, 2008). The rating also includes parameters such as ease of use (adjustment), locking of the head restraint, and overall seat reliability. The overall whiplash score calculated as a combination of head restraint/seat geometry and outcome of the dynamic tests, results in a rating of ‘good’, ‘marginal’, or ‘poor’ (Euro NCAP, 2008).

Initial Geometry	Dynamic Test Results					FINAL RATING
	HR Contact Time T_{HRC}	Torso Acceleration T1g	Neck Shear Fx	Neck Tension Fz	Summary Dynamic Performance	
Good Height ≥ -6 cm Backset ≤ 7 cm	≤ 70 ms	any value	≤ 130 N	≤ 600 N	Pass	GOOD
	any value	≤ 9 g				
	> 70 ms	> 9 g	any value	any value	3.1.1.1 Fail	ACCEPTABLE
	any value	any value	> 130 N	any value		
	any value	any value	any value	> 600 N		
Acceptable Height ≥ -8 cm Backset ≤ 9 cm	≤ 70 ms	Any T1g	≤ 130 N	≤ 600 N	Pass	
	Any T_{HRC}	≤ 9 g				
	> 70 ms	> 9 g	any value	any value	Fail	MARGINAL
	any value	any value	> 130 N	any value		
	any value	any value	Any value	> 600 N		
Marginal Height ≥ -10 cm Backset ≤ 11 cm	No Dynamic Test					
Poor Height ≤ -10 cm Backset > 11 cm						POOR

Source: European Enhanced Vehicle-safety Committee (EEVC), WG 20, March 2005, pp. 21

Figure 1. IIWPG Rating Matrix

Throughout the US, Canada and Europe, rating systems have evolved over time in an attempt to be as comprehensive as possible to ensure driver and passenger safety. Driven by a need to reduce insurance claims and the motivation of consumer awareness, the set of ratings that are currently in use are based on high calibre research and testing. The evolution of standards, regulations and rating systems has combined to develop safer vehicles in an effort to reduce the occurrence of neck pain and whiplash injury.

STRATEGIES TO REDUCE WHIPLASH INJURIES AND FUTURE DIRECTIONS

An international team of experts who completed a Cochrane systematic review in 2007 found little scientifically rigorous evidence to justify the effectiveness of most existing therapies for whiplash injuries (Verhagen et al., 2007). A previous comprehensive study also confirmed the ineffectiveness of existing whiplash injury treatments (Spitzer et al., 1995). Standard therapies were often ineffective, and sometimes even harmful (Spitzer et al., 1995). Even the few therapies that have been tested in a scientific manner, such as soft collars, muscle relaxants and other drugs, seemed ineffective in preventing neck pain due to whiplash injuries (Spitzer et al., 1995).

Motor vehicle crash prevention is dependent on evidence-based interventions such as engineering to build road infrastructure, traffic law enforcement, driver licensing renewal policies, availability of driver education and training, increased awareness via evidence-based approaches to increase the proper use of vehicle safety equipment such as head restraints, seat belts and child safety seats. These are all strategies that support driver safety and reduce the burden of traffic-related injury in society; however, these strategies vary by country and jurisdiction. There are several promising strategies that would extensively benefit drivers, including: developing a safe road system through evidence-based engineering, enhancing crashworthiness of vehicles and increasing awareness of safety values of appropriate adjustment of seat belts, head restraints and child safety seats (Desapriya et al., 2006).

It is acknowledged that traffic law enforcement is one of the chief strategies in which many countries make heavy investments to reduce motor vehicle collisions. However, driver education to enhance the understanding of safety values of existing safety equipment such as head restraints, safety belts and child safety seats is poor. This is evident by the higher incorrect adjustment of head restraints, lower use rates of seat belts and higher rates of misuse of child safety seats worldwide (Desapriya et al., 2008). In addition, occupational health strategies will be useful in mitigating neck pain and whiplash injuries. The evidence (Spitzer et al., 1995; Verhagen et al., 2007) further provides a rationale for drastically increasing our efforts to prevent the occurrence of whiplash injuries.

Future Research – Filling the Gaps

Surveillance

Thatcham in the UK conducts research targeted at containing or reducing the cost of motor vehicle insurance claims, while maintaining standards of quality and safety. In the UK, the insurance industry handles a large volume of personal injury claims, but has poor understanding of the issues across industries and over time (Avery & Weekes, 2008). Under-reporting of minor injuries tends to occur because most crash databases require a police report or a tow–away, in order to be included in the database. A new approach was undertaken in gathering insurance personal injury claims data - Real World Injury Claims (RWIC) database. The objective of the database was to provide an improved understanding of the differing injuries seen in motor vehicle collisions and how vehicle design could be an influential factor (Avery & Weekes, 2008). The dataset provided a complete set of whiplash claims, without limiting inclusion, to allow a better understanding of these claims. Capturing the data in this way allowed for AIS coding of injuries and classification of whiplash injury according to the WAD scale (Avery & Weekes, 2008). The dataset includes assessment by an independent company of medical doctors, details of the crash impact and vehicles involved using a form completed by the patient, the emergency services, health services, and medical treatment provided, and an AIS and WAD score.

After analysing 4,000 claims, results showed that over 80% of injury claims were due to whiplash. Average recovery time was approximately 9 months, and 8% of whiplash injuries were deemed to be permanent injuries (Avery & Weekes, 2008). Ninety-one percent of the claims were classified as WAD level 1 and the remaining 9% were level 2. Results were also positive with respect to changes in seat and head restraint design, such that whiplash injury claims were reduced in models that had incorporated anti-whiplash design (Avery & Weekes, 2008).

This novel database provides real-world evidence that there is a relationship between the vehicle model and the number of injury cases and encourages vehicle manufacturers to implement anti-whiplash design changes. This database could be a model for other countries to follow for their insurance databases.

Occupational Medicine

Physician specialists in occupational and environmental medicine are interested in neck pain from a broad perspective that ranges from primary prevention, to clinical care and the management of pain and disability. Occupational and environmental medicine (OEM), is both a clinical and preventive health specialty devoted to the prevention and management of occupational and environmental injury, illness and disability, and the promotion of the health and productivity of workers. Reflecting this dual preventive and clinical role, specialty training in occupational and environmental medicine includes epidemiology, biostatistics and ergonomics, as well as a focus on clinical care for and disability management, especially for musculoskeletal disorders (McCunney et al., 2003).

This broad scope of activities gives occupation and environmental medicine a more comprehensive focus than many other disciplines when addressing challenging public health issues, such as the prevention of neck pain and associated disability. In workplace settings, occupational medicine physicians work in collaboration with occupational health nurses, kinesiologists, ergonomists, industrial hygienists, safety specialists and human resource professionals in the identification, assessment and control of physical hazards in the workplace and general environment, and in helping to maintain the health and productivity of the workers.

Occupational and environmental medicine as a specialty has also assumed a leadership role in the use of evidence-based medicine (EBM) and effective disability management in workers' compensation settings. The American College of Occupational and Environmental Medicine (ACOEM), the primary professional organization for occupational and environmental medicine physicians, is in the development of evidence-based clinical practice guidelines for musculoskeletal disorders in working age adults. Such guidelines provide a reliable basis for clinical assessment and treatment of neck pain, using best scientific evidence, and incorporate a general approach based on rapid return to function and prevention of disability. In the US, the ACOEM guidelines have been adopted in whole or in part by several large health care systems, insurers, and state workers' compensation agencies (including those in California and New York) as the required (or "presumptively correct") guidelines for clinical care of musculoskeletal disorders. Health economics analysis suggests that when clinicians are required to follow comprehensive clinical practice guidelines are used in workers' compensation settings, both medical costs and disability can be reduced.

Burden of Neck Pain in Occupational Settings

Historically, workers' compensation boards (WCB) and occupational health professionals in North America appear to have viewed neck pain as a relatively low priority, with WCBs reporting that neck pain accounts for less than 5% of lost-time claims. From both a research and clinical care perspective, literature on neck pain in workers has typically looked at neck pain associated with either back pain or upper limb disorders, or in relation to postural issues at work or related to ergonomic design of office furniture. In addition, in the past, there was a lack of easily identifiable evidence-based systematic literature reviews and clinical practice guidelines focused on neck pain prevention, diagnosis and treatment. This may have contributed to lack of awareness, interest and action.

Recent research has found that neck pain may account for a much larger burden of illness in working populations than originally thought. Cote and colleagues (2008), in a large cohort study investigating the prevalence and incidence of work absenteeism involving neck pain in workers in the province of Ontario, Canada, concluded that the WCB estimates of neck pain based on claims data grossly underestimates the burden of neck pain due to errors or limitations in administrative coding processes. Using codes specific for neck pain, the estimated percentage of lost-time claimants with neck pain in 1998 was 2.8% (95% CI 2.5–3.3), when they accounted for neck pain in workers coded with other injuries, the annual prevalence of neck pain increased to 11.3% (95% CI 9.5–13.1). Specifically they found that the number of lost-time claimants with soft-tissue disorders to the neck varied from 88% in those coded with a disorder of the neck region, to 69% for claimants coded with disorders of the back and 55% for claimants with a brain injury (concussion). This 403% difference suggests that a significant amount of neck pain is hidden within the classification system used to code claims. There was no data reported on number of lost-time claims attributed to motor vehicle collisions alone.

Studies that are focused on specific industries have noted a substantial rate of injury claims for neck pain related to motor vehicle crashes in the course of work activities. For instance, Fordyce in a study of neck injuries among electric utility workers over a 12-year period (from 1995-2007) found meter readers had the highest rate of neck injuries from motor vehicle crashes (22.8 per 10,000 employee-years), which was much higher than the rate of line workers (6.47 per 10,000 employee years) which was the job class with the next highest rate of neck injury from vehicular accidents (Fordyce et al., 2008).

A search of the literature has determined that there is a lack of research in the area of whiplash in occupational drivers, such as bus drivers, delivery persons, taxi drivers, etc. It is suggested that research be conducted to improve our understanding of whiplash and WAD in the occupational driver population, and to explore the differences from the general population.

From a societal perspective, whether a motor vehicle collision occurred at work, travelling to and from work, or at leisure, the total physical and socioeconomic burden of neck pain and disability to employers, employees, communities and families is substantial. From an employer perspective, the prevention of neck pain and disability through the appropriate use of head restraints and other crash avoidance systems could make a major contribution to enhancing workplace health and productivity. There is an extensive body of research demonstrating that the direct cost to an employer due to an employee with a functionally limiting health problem, such as neck pain, includes not only direct cost of medical care and salary replacement, but also indirect costs from productivity loss for that employee. While the direct costs (for medical care and salary replacement) can in themselves be substantial, the indirect costs in terms of lost productivity to the business are often 3 to 4 times higher than the direct costs. This underscores the importance for both employers and society in preventing neck pain episodes, and a rapid return to function for those who do develop neck problems (Loeppke et al., 2007; 2009).

Growing Corporate Responsibility to Ensure Employee Safety

From a regulatory perspective all employers have a responsibility to protect workers in the workplace including employees who use vehicles for work. Fleet owners and operators have the difficult task of addressing competing pressures from government and corporate demands including reducing pollution, cost of purchase or lease, and repair, among others (Fleet News, 2008). Until recently, purchasing vehicles with head restraints rated "good" were limited to higher end vehicles; however, this is no longer the case. The larger issue is the lack of awareness of fleet managers and employers to include head restraint ratings in their purchase or lease criteria.

Need for Knowledge Mobilization

There is typically a 15 – 20 year gap between research and its utilization to inform training, policy renewal and practice. The organizers[1] for the 2008 World Congress on Neck Pain strategically invited government agencies, research funding organizations, professional and licensing bodies to become congress sponsors and, if appropriate, to recommend scientific representatives to participate as members of the Scientific Review Committee with the goal of cultivating interest in a dissemination meeting hosted by the National Institute for Occupational Safety and Health to begin discussions on future activities and stimulate a "Call for Action".

Current Initiatives

The Canadian Institute for the Relief of Pain and Disability (CIRPD)[2] as the lead organizer for the 2008 World Congress on Neck Pain is continuing its role in post-congress dissemination. To this end, it has partnered with the Canadian Institutes for Health Research (CIHR) and the CIHR Institute for Musculoskeletal Health and Arthritis under its Small Health Organization Partnership Program and The AUTO21 Network of Centres of Excellence[3] to fund Master and Doctoral Awards focused on preventing and mitigating injuries arising from motor vehicle collisions. In addition, it is working with licensing,

---

[1] The World Congress on Neck Pain was organized by the Canadian Institute for the Relief of Pain and Disability in collaboration with the American College of Occupational and Environmental Medicine

[2] CIRPD is a registered charity headquartered in Vancouver Canada. Its mission is to reduce pain, pain suffering and disability by reducing the gap between research and practice.

[3] AUTO21 is Canada's national automotive research and development program supporting more than 300 Canadian researchers at 43 universities. More information can be found at www.auto21.ca.

professional and government bodies in the US and Canada to collaborate on translating research to practice initiatives.

The American College of Occupational and Environmental Medicine is updating clinical practice guidelines on neck pain which will incorporate new evidence based knowledge on clinical care and prevention.

AUTO21, one of the congress sponsors, recently funded a research project entitled, *Reducing Occupant Injury from Rear End Collisions* (Principal Investigator - Douglas Romilly, University of British Columbia) to: 1) develop new strategies to better implement existing knowledge about head restraints into practice, 2) develop new knowledge and technology to a) remove the role of the operator from the safety system and b) to enhance occupant protection through the design of future vehicle/occupant integrated active whiplash mitigation systems.

Future Directions from an Occupational Health Perspective

There is a need to create persuasive educational resources to educate all stakeholders responsible for occupational health and safety to:

1. Understand the scope of the problem
   (a) prevalence of vehicle collisions and injuries,
   (b) health, social and economic impact
   (c) potential for prevention - on reducing injuries and related disability
   (d) potential for prevention - economic modeling of injury prevention efforts

2. Prevention strategies – role of vehicle design in collision and injury prevention
   (a) safety ratings from the Insurance Institute for Highway Safety (IIHS), including performance of head restraints, and collision safety features
   (b) seat assessment tools from Insurance Corporation of British Columbia (ICBC),
   (c) vehicle design elements that contribute to passenger safety
   (d) tool kits for vehicle purchase selection focused on safety

3. Prevention strategies – shaping driving
   (a) promotion of safe driving behaviors
   (b) tool kits for the family – creating safer drivers and occupants
   (c) tool kits for the community and schools – creating safer drivers and occupants
   (d) tool kits for the employers – creating safer drivers and occupants

4. Prevention strategies – promoting optimal recovery and reducing disability
   (a) optimal evidence-based health care for injuries from vehicular collisions
   (b) proactive management of disability to promote return to function

These future directions combined with a multi-faceted social marketing campaign would greatly benefit the population.

Using the 3 E's of Injury Prevention

Many existing motor vehicles have adjustable head restraints, yet the literature reports high rates of misuse of this type of head restraint. A possibility exists to educate the public to achieve the safety benefits that the correct adjustment of head restraints would provide. Simultaneously, there is a clear need for advocating change and disseminating information to drivers, occupants, the health care community and policy makers. There are efforts to install active head restraints in new vehicles; however vehicles with fixed and adjustable head restraints will continue to be part of the existing vehicle fleet for considerable time in the future. We require a global effective education campaign that would enhance drivers' and occupants' knowledge about the traffic safety benefits of the correct adjustment of head restraints. An international organization that manages and advocates for injury prevention such as the World Health Organization (WHO), is a platform that could be utilized to convey the safety message to a broader audience of drivers and occupants worldwide. We therefore urge policy makers to promote this strategy by mobilizing resources, use the services of health personnel and transport policy makers around the world to convey the message that the correct adjustment of head restraints can prevent whiplash injuries.

An approach that incorporates education, engineering and enforcement to increase driver awareness around motor vehicle collision risk factors has been widely utilized to prevent collisions in many countries. Interventions such as media campaigns to increase driver awareness and education to reduce alcohol impaired driving and increase the use of seat belts and proper use of child restraint seats, were shown to be effective. It is recommended that effective principles and tools should be utilized to prevent future whiplash injuries. Lack of education or knowledge about the effectiveness of this intervention may hinder drivers' and occupants' motivation to properly adjust their head restraint, which will mitigate or prevent whiplash injuries in our communities.

The Social Marketing Approach

To increase awareness and enhance safety behavior to prevent whiplash injuries and associated disorders, behavior change at the population level is required. There are various tools that can be used to influence and change behavior, such as i) education, ii) enforcement or iii) social marketing. Education involves conveying messages to an audience informing them how we would like them to behave – *"don't drink and drive"*. Enforcement is forceful and at times necessary. It demonstrates consequences of actions - *"if you drink and drive and we catch you, we will fine you"*. Social marketing attempts to understand why an individual behaves in a certain way and appeals to personal benefits and alternate choices - *"don't drive and we will give you a ride home."*

To address behavioral issues related to the use of head restraints using social marketing, there is a need to adopt an innovative and engaging strategy. However, it is important to note that social marketing is just one of the three foundational pillars of prevention, and success in reducing whiplash injuries will be garnered by the use of the three Es of prevention: *Education, Enforcement and Engineering.*

The following section discusses social marketing as one of the pillars – *Education*. Public health professionals can consider using this strategic approach to educate the public about prevention of whiplash injuries whether it relates to awareness of the causes and severity of the issue, the recommended best practices for head restraint use, or driver and passenger awareness, attitudes and behaviors related to head restraint use.

Social marketing has been defined as a systematic application of marketing alongside other concepts and techniques to achieve specific behavioral goals for a social or public good (French & Blair-Stevens, 2006). The term social marketing was introduced in 1971 by Philip Kotler, a professor of management at Northwestern University. Earlier, in the 1960s it was described as commercial marketing in the public sector. Over time, social marketing has evolved and continues to progress. It is an evidence-based, dynamic and strategic approach for achieving and sustaining beneficial behavior change.

Social marketing is also considered a powerful knowledge translation tool that draws from a wide variety of theory and practice and uses best practices to raise awareness and eventually influence attitudes and behaviors.

How is social marketing different from health education?

Social marketing uses a combination of marketing and health communication techniques to achieve social good or targeted behavior goals. Social marketing focuses on a target population and is developed to provide messages that are intended to motivate a desired behavior through revealing various choices and their risks and benefits. It takes into consideration the broader determinants of health and develops campaign concepts based on an understanding of the context in which the target audience exists (e.g. SES, education, age, sex).

Social Marketing is…	Social Marketing is not…
About social or behavior change	Just advertising
Targeting a given population at risk	Reaching everyone through a media blitz
Strategic & efficient use of resources	An image campaign, done in a vacuum
Integrated with a long-term plan	A magic bullet

Why Use Social Marketing in Public Health?

Social marketing campaigns have shown success in improving health-related knowledge, awareness and behaviors (Banspach, 2008; Grier & Bryant, 2005). They provide a relatively new perspective to health and safety promotion, and challenge health professionals to think and plan strategies using target audience and market research. Studies have shown that a well-tested and strategically planned social marketing campaign that is based on well-supported behavioral theories (e.g. Stages of Change Model – Prochaska & DiClemente, 1983) can work to bring about behavior change. However, it is crucial to realize that behavior change is a complex process and may take years to achieve. This approach, however, demands that health professionals develop or include expertise about understanding their target audiences current behaviors and readiness to change, prior to developing a campaign. Table 4 illustrates stages of readiness that help to understand the target audience's readiness to change.

Table 4. Stages of Change Model.

Pre-contemplation	Not even thinking about it – not aware of whiplash injuries
Contemplation	Thinking about it - have heard about whiplash injuries but are not quite motivated to take preventative measures
Preparation	Planning to act – Are aware of the risks and consequences of whiplash injuries. They are aware that by adjusting head restraints, these injuries can be prevented
Action	Make a move but not yet a habit – Adjust head restraints before driving to minimize risk for whiplash injuries
Maintenance	Example- Adjust head restraint before they start driving

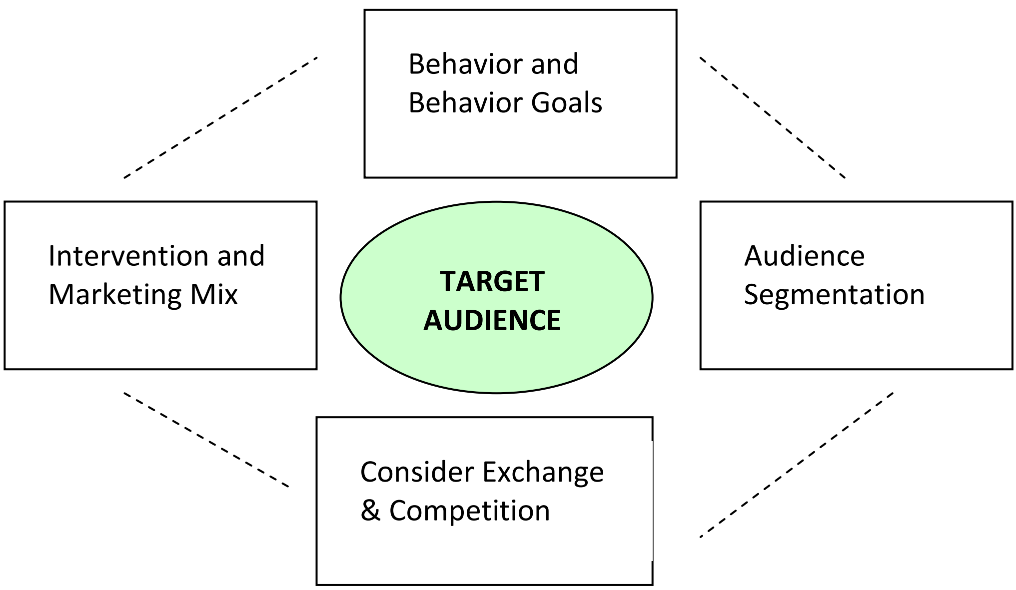


Figure 2. The Principles of Social Marketing.

Principles of Social Marketing

Figure 2 demonstrates the principles of social marketing indicating that it revolves around the target audience (also referred to as the consumer, customer or public). It emphasizes the importance of consumer and market research. It encourages social marketers to consider a theoretical framework (e.g. behavior change model) to understand the target audience's current behaviors and gain insight to consumers' thoughts, beliefs, fears, and motivations around the desired behavior. This insight may be garnered through the use of surveys, interviews, focus groups or observational studies.

Social marketing puts a strong emphasis on understanding the context in which the target audience exists, and in which the desired behavior is to be performed. It requires understanding of the competing interests, factors and barriers facing the target audience in attempting to implement the desired behavior. And, it recommends that program planners consider the value, and incentives, necessary for the target audience to adopt the desired behavior.

Social marketing uses the concepts of competition to examine the factors that compete for people's attention and willingness or ability to adopt a desired behavior. Furthermore, social marketing puts a strong emphasis on understanding what is to be offered to the target audience, based upon what they value and consider important (National Social Marketing Centre; NSMC-UK).

Target audience segmentation is a fundamental part of social marketing. It is a process of examining the target audience and seeking to identify distinct sub-groups (segments) that may have similar needs, attitudes or behaviors. This approach helps in understanding the current level of knowledge, stage of behavior and readiness for change for a given target audience and ensures a straightforward measure of success for the campaign outcomes.

The social marketing approach is dynamic and uses multiple channels and interventions to convey messages. This diverse approach is referred to as 'marketing mix'. This approach helps to engage the target audience, empowers them with choices and can lead toward initiating a social movement. Social marketing has been effective in bringing about changes in health-related behaviors and creating significant social change. An example of this is the national tobacco control campaign in England (National Tobacco Control Campaign, UK). The previous success of social marketing to improve health behaviors provides impetus to consider its utility to influence the correct use of head restraints among drivers and passengers.

A social marketing campaign to reduce whiplash injuries through increased correct use of head restraints while driving would need to:

1) Determine the target audience – e.g. whiplash injury statistics to determine the audience or audience segment to target
2) Understand the context in which the target audience exists – e.g. demographic data, vehicle use information
3) Understand the target audience's awareness, current attitude and knowledge of the whiplash injury issue
4) Understand the competing factors – e.g. convenience, time consumption, speed
5) Understand what is important and motivates the target audience – what positive benefits could be considered that would resonate with the target population and that would motivate and lead to a change in behavior to correct head restraint use
6) Understand the value and incentives that would cause and maintain correct use of head restraints
7) Develop, test and refine marketing campaign messages and communication vehicles
8) Launch and monitor the campaign

Examples of Successful Social Marketing Campaigns related to Driving

Click it or ticket (North Carolina, US)

This campaign began in 1993 and is ongoing. The target audience included drivers and passengers with the goal of increasing seatbelt use. The outcomes included an increase in seatbelt use from 63% to 80% in North Carolina. There was also a 14% reduction in fatal and serious highway injuries. The campaign concepts and activities were developed based on social marketing principles including marketing mix, community outreach and enforcement, audience segmentation, and redefined benefits based on consumer analysis. The details of this campaign are available at: http://www.social-marketing.org/success/cs-clickit.html.

Copy cat (UK)

This campaign ran for 1 year from 2007-2008 and targeted parents of 4-11 year old children. The goal of the campaign was to increase seatbelt use in parents so that children would copy this behavior. The outcomes demonstrated that 40% of the sample was aware of the Copy Cat campaign in the first year and 75% realized that the advertising conveyed the concept that children copy parents' behavior. The campaign concepts and strategies were developed based on consumer insight and audience segmentation. The details of the campaign are available at: http://www.larsoa.org.uk/news.php?article_id=386.

Zero tolerance means zero chances (US)

The results of this campaign demonstrated that awareness of the no tolerance law rose from 61% to 63% over six months. The details of the campaign are available at: http://www.nhtsa.dot.gov/people/injury/alcohol/zeropr/index.html.

Friends don't let friends drive drunk (US)

The outcomes of this campaign were positive showing that 80% of the sample reported that they took action to stop a friend from driving. Twenty-five percent of the sample actually did stop a friend from driving while intoxicated. The details of the campaign are available at: http://www.adcouncil.org/default.aspx?id=137.

Back Pain: Don't Take it Lying Down

From 1997 to 1999, a campaign ran in Victoria, Australia for workers. It was named 'Back Pain: Don't Take it Lying Down'. This mass media campaign was successful in enhancing Victorian workers' self-management abilities, thus and changing attitudes and behaviour concerning back pain (Buchbinder, 2008).

The Australian study (Buchbinder & Jolley, 2004; Buchbinder, Jolley & Wyatt, 2001) used prime-time television advertisements that featured health professionals, sports and local television celebrities, at the cost of 10.1 million dollars over three years, had the largest impact showing dramatic changes in beliefs about back pain as a consequence of advertising in the general population and general practitioners. The advertisements contributed to a 15% reduction in back pain claims during the intervention period and a 20% reduction in medical costs. Variations of the Australian study were attempted in Norway, Scotland and Alberta with much lower investment. The Alberta study invested less approximately 1 million dollars over three years, Norway less than $500,000 (Scottish figures not available). These interventions delivered fewer messages and did not use prime time television resulting in much lower market penetration. There were modest though significant changes in beliefs and attitudes in Norway and Scotland, and no impact on work absences, or back pain claims.

Neck Pain Beliefs and Head Restraint Social Marketing Campaigns

Bostick and colleagues (2007) conducted a population-based cross-sectional study surveying beliefs about neck pain from whiplash injury, work-related neck pain, and work-related upper extremity pain in two Canadian provinces to capture baseline data as well as explore whether the use of a social marketing campaign might be warranted. He found that the majority of respondents agreed that staying active was more important than rest which is congruent with evidence-based guidelines, however they found a much higher level of pessimism regarding likelihood of recovery of neck pain arising from motor vehicle collisions within the population. This higher level of pessimism concerning whiplash recovery might be an important consideration in developing and testing social marketing messages, for instance, “Worried about Whiplash?–Did you know Prevention is Possible?”

The Swiss Insurance Association in collaboration with the Council for Accident Prevention and the Swiss Road Safety Fund commenced a prevention campaign to increase awareness of the correct headrestraint position for safety (Soltermann, 2007). The campaign motto is ‘Drive safely – Avoid accidents – Prevent consequences of accidents’. Results of this campaign have not yet been published. A series of short commercials and posters can be found at http://www.kopfstuetzen.ch/

Social marketing campaigns can be effective means of influencing attitudes and behaviours, however they require sufficient investment in planning, implementation and evaluation. We believe such investment is warranted. We suggest the application of a social marketing strategy in order to bring about a behavior change regarding the proper positioning of head restraints for the prevention of whiplash and WAD.

CONCLUSION

This chapter has provided a summary of the past, present and future of the relationship between head restraints and whiplash injuries. We have examined the evolution of head restraints, the scientific evidence, the technological advances and the legislation and ratings surrounding their efficacy. With respect to preventing whiplash injury, it is evident that the engineering (technology) has advanced with the addition of active head restraints. The legislative side of enforcement has also advanced with the future implementation of a global technical regulation surrounding head restraints. We are aware that police enforcement of the proper position of an adjustable head restraint is not feasible. Educational efforts have been limited and untargeted. We recognize the complexity of the issue, yet changing the population’s behavior is the final required step. A social marketing campaign to address the issue would be beneficial for the prevention of whiplash and related injuries.

We end reiterating the closing remarks of Professor Matthew H. Liang, the Scientific Chair at the 2008 World Congress on Neck Pain.

> From a public health perspective the best way to reduce individual suffering and the socio-economic burden of neck pain arising from motor vehicle collisions is for the public to

use vehicles with good head restraints and to make sure that head restraints be adjusted appropriately.

ACKNOWLEDGMENTS

We would like to acknowledge Dr. Sayed Subzwari, (International Medical Graduate-Centre for Community Child Health Research, BC Injury Research and Prevention Unit) for his involvement in the initial planning of the book chapter. We would like to thank Doug Romilly for his assistance and expert advice, as well as David Zuby (Insurance Institute for Highway Safety), Jocelyn Pedder (RONA Kinetics), and Matthew Avery (THATCHAM, UK) for historical notes.

REFERENCES

Acar, M; Clark, SJ; Crouch, R. Smart head restraint system. *International Journal of Crashworthiness*, 2007, 12, 429-435.

Ad Hoc Group on Head Restraints. European Commision. Meeting Minutes, *Brussels*, 23 June 2006.

Aker, PD; Gross, AR; Goldsmith, CH; Peloso, P. Conservative management of mechanical neck pain: systematic overview and meta-analysis. *British Medical Journal*, 1996, 313, 1291–1296.

Allen, MJ; Barnes, MR; Bodivala, GG. The effect of seatbelt legislation on injuries sustained by car occupants. *Injury*, 1985, 16, 471.

Arbabi, S; Wahl, WL; Hemmila, MR; Kohoyda-Inglis, C; Taheri, PA; Wang, SC. The cushion effect. *Journal of Trauma*, 2003, 54(6), 1090-1093.

Ardoino, PL. Kinematics and dynamics of the vehicle/seat/occupant/system regarding whiplash injuries. In: A. Cesarani, D. Alpini, R. Bonvier, et al. (Eds.), *Whiplash Injuries: Diagnosis and Treatment.* Berlin: Springer; 1996.

Avery, M. An International insurance protocol for dynamic testing of vehicle seats to reduce whiplash injury risk. *Proceedings of the World Congress on Neck Pain*, January 20-22, 2008, Los Angeles, CA, 83.

Avery, M; Giblen, E; Weekes, A; Zuby, D. Developments in dynamic whiplash assessment procedures. *Proceedings International Conference on Neck Injuries in Road Traffic and Prevention Strategies.* Munich, Germany, 2007, Paper No. 5, 14.

Avery, M; Weekes, A. Real world injury claims database: a new approach in gathering insurance personal injury claims data. *Proceedings of the World Congress on Neck Pain*, January 20-22, 2008, Los Angeles, CA, 84-85.

Banks, R; Martini, J; Smith, H; Bowels, A; Mcnish, T; Howard, R. Alignment of the lumbar vertebrae in a driving posture. *Journal of Crash Prevention and Injury Control*, 2000, 2(2),123-130.

Banspach, SW. The VERB™ Campaign. *American Journal of Preventive Medicine*, 2008, 34(6), S275.

Berglund, A; Alfredsson, L; Jensen, I; Bodin, L; Nygren, A. Occupant- and crash-related factors associated with the risk of whiplash injury. *Annals of Epidemiology*, 2003, 13(1), 66-72.

Björnstig, U; Hildingsson, C; Toolanen, G. Soft-tissue injury of the neck in a hospital based material. *Scandinavian Journal of Social Medicine*, 1990, 18(4), 263-267.

Bogduk, N; Marsland, A. The cervical zygapophyseal joints as a source of neck pain. *Spine*, 1988, 13, 610-617.

Bogduk, N; Yoganandan, N. Biomechanics of the cervical spine. Part 3: minor injuries. *Clinical Biomechanics*, 2001, 16, 267-275.

Borchgrevink, GE; Lereim, I; Royneland, L; Bjorndal, A; Haraldseth, O. National health insurance consumption and chronic symptoms following mild neck sprain injuries in car accidents. *Scand J Soc Med*, 1996, 24(4), 264-271.

Bostick, GP; Ferrari, R; Carroll, LJ; et al. A population-based survey of beliefs about neck pain from whiplash injury, work-related neck pain, and work-related upper extremity pain. *European Journal of Pain,* 2009,13 (3), 300-303.

Bostrom, O; Haland, Y; Lovsund, P; Svensson, MY. Neck injury criterion (NIC) and its relevance to various possible neck injury mechanisms. In: Yoganandan N, Pintar FA (eds). *Frontiers in Whiplash Trauma: Clinical and Biomechanical.* The Netherlands: IOS Press; 2000; 455-466.

Bostrom, O; Krafft, M; Aldman, B; et al. Prediction of neck injuries in rear impacts based on accident data and simulations. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 24-26, 1997, Hannover, Germany, 251-264.

Boulanger, BR; Rodriguez, A. Body habitus as a predictor of injury pattern after blunt trauma. *J Trauma*, 1992, 33(2), 228-232.

Braddick, MR; Love, G. Car head restraints. *BMJ*, 1990, 301, 440.

Brison, RJ; Hartling, L; Pickett, W. A prospective study of acceleration-extension injuries following rear-end motor vehicle collisions. *Journal of Musculoskeletal Pain*, 2000, 8, 97-113.

Brown, B; Nepomuceno, J. A review of educational strategies to mitigate soft-tissue neck injuries. *Proceedings Whiplash Associated Disorders World Congress* (Traffic Safety and Auto Engineering Session), February 1999, Vancouver, BC, 489-499.

Buchbinder, R. Optimizing care for people with chronic disease. Self-management education en masse: effectiveness of the Back Pain: Don't take it lying down mass media campaign.*Medical Journal of Australia*, 2008, 189 (10 suppl.), S29-S32.

Buchbinder, R; Jolley, D. Population based intervention to change back pain beliefs: three year follow up population survey. *BMJ,* 2004, 328 (7435), 321.

Buchbinder, R; Jolley, D; Wyatt, M. Population based intervention to change back pain beliefs and disability: three part evaluation. *BMJ,* 2001, 322, 1516-1520.

Buitenhuis, J; de Jong, PJ; Jaspers, JP; Groothoff, JW. Work disability after whiplash: a prospective cohort study. *Spine*, 2009, 1, 34(3), 262-267.

Caddy, J. Risk factors for 'whiplash' in drivers: a cohort study of rear-end traffic crashes. *Injury*, 1998, 29(2), 147.

Carlsson, G; Nilsson, S; Nilsson-Ehle, A; et al. Neck injuries in rear-end car collisions: Biomechanical considerations to improve head restraints. *Proceedings of the International IRCOBI/AAAM Conference on the Biomechanics of Impacts*, Göteborg, Sweden, 1995, 277-289.

Cassidy, JD; Carroll, LJ; Côté, P; Lemstra, M; Berglund, A; Nygren, A. Effect of eliminating compensation for pain and suffering on the outcome of insurance claims for whiplash injury. *New England Journal of Medicine*, 2000, 20, 342(16), 1179-1186.

Chapline, J ; Ferguson, SA ; Lillis, RP ; Lund, AK; Williams, AF. Neck pain and head restraint position relative to the driver's head in rear-end collisions. *Accident Analysis and Prevention*, 2000, 32, 287-297.

Cote, P; van der Velde, G; Cassidy, JD; et al. The burden and determinants of neck pain in workers. Results of The Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Spine*, 2008, 33(4S), S60-S74.

Croft, AC; Haneline, MT; Freeman, MD. Low speed frontal crashes and low speed rear crashes: Is there a differential risk for injury? *Annual Proceedings – Association for the Advancement of Automotive Medicine*, 2002, 46, 79-91.

Cullen, E; Stabler, KM; Mackay, GM; Parkin, S. Head restraint positioning and occupant safety in rear impacts: the case for smart restraints. *Proceedings of the 1996 International Conference on the Biomechanics of Impacts*, *IRCOBI*, Lyon, France, 137-152.

Darok, M; Leinzinger, EP; Eichberger, A; Steffan, H. Neck injury criterion validation using human subjects and dummies. In: Yoganandan N, Pintar FA (eds). *Frontiers in Whiplash Trauma: Clinical and Biomechanical.* The Netherlands: IOS Press, 2000, 409-434.

Deans, GT; McGalliard, JN; Kerr, M; Rutherford, WH. Neck sprain-a major cause of disability following car accidents. *Injury*, 1987, 18, 10-12.

Deans, GT; McGalliard, JN; Rutherford, WH. Incidence and duration of neck pain among patients injured in car accidents. *BMJ (Clinical Research Edition)*, 1986, 11, 292(6513), 94-95.

Deng, B. *Biomechanics of the human cadaver cervical spine during low speed read-end impacts.* Ph.D. Dissertation, Wayne State University, 1999.

Deng, B; Begeman, PC; Yang, KY; King, AI; Tashman, S. Kinematics of human cadaver cervical spine during low-speed rear-end impacts. *Stapp Car Crash Journal*, 2000b, 44, 171-188.

Deng, B; Luan, F; Begeman, PC; Yang, KH; King, AI; Tashman, S. Testing shear hypothesis of whiplash injury using experimental and analytical approaches. In: Yoganandan N, Pintar FA (eds). *Frontiers in Whiplash Trauma: Clinical and Biomechanical.* The Netherlands: IOS Press; 2000a; 491-509.

Department of Transport, Government of Canada. Regulations amending the motor vehicle safety regulations (head restraints). *Canada Gazette*, September 13, 2008,142(37).

DeRosia, J; Yoganandan, N. Lessons from stages rear-end collisions using human volunteers. In: N. Yoganandan, & F. A. Pintar (Eds). *Frontiers in Whiplash Trauma: Clinical and Biomechanical.* The Netherlands: IOS Press; 2000, 265-294.

Desapriya, E; Fujiwara, T; Scime, G; Babul, S; Pike, I. Compulsory child restraint seat law and motor vehicle child occupant deaths and injuries in Japan 1994-2005. *International Journal of Injury Control and Safety Promotion*, 2008, 15(2), 93-97.

Desapriya, E; Pike, I; Subzwari ,S. Traffic safety and sports utility vehicles. *Lancet*, 2006, 15, 368(9531), 201-202.

Dippel, C; Muser, MH; Walz, F; Niederer, P; Kaeser, R. Neck injury prevention in rear impact crashes. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 24-26, 1997, Hannover, Germany, 239-250.

Dolinis, I. Risk factors for 'whiplash' in drivers: a cohort study of rear-end traffic crashes. *Injury*, 1997, 28(3), 173-179.

Dunn, EJ; Blazar, S. Soft-Tissue injuries of the lower cervical spine. *Instructional Course Lectures*, *American Academy Orthopaedic Surgeons*, Vol XXXVI, 499-512, 1987.

Edwards, M; Smith, S; Zuby, DS; Lund, AK. Improved seat and head restraint evaluations. *Proceedings 19th Enhanced Safety of Vehicles Conference*, 2005, Paper 05-0374-0.

Eichberger, A; Geigle, BC; Fachbach, B; Steffan, H; Hell, W; Langweider, K. Comparison of different car seats regarding head-neck kinematics of volunteers during rear end impact. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 11-13, 1996, Dublin, Ireland, 153-164.

European Enhanced Vehicle-safety Committee (EEVC), WG 20 Report. *Updated state-of-the-art review on whiplash injury prevention.* March 2005, 21.

European New Car Assessment Programme (Euro NCAP). (2008). Available from: http://www.euroncap.com/whiplash.aspx

Evans, L. Safety-belt effectiveness: the influence of crash severity and selective recruitment. *Accid Anal Prev*, 1996, 28(4), 423-433.

Evans, L; Frick, MC. Car size or car mass: which has greater influence on fatality risk? *American Journal of Public Health*, 1992, 82, 1105-1112.

Evans, L; Frick, MC. Mass ratio and relative driver fatality risk in two-vehicle crashes. *Accid Anal Prev*, 1993, 25, 213-224.

Farmer, CM; Wells, JK; Lund, AK. Effects of head restraint and seat redesign on neck injury risk in rear-end crashes. *Traffic Injury Prevention*, 2003, 4, 83-90.

Farmer, CM; Wells, JK; Werner, JV. Relationship of head restraint positioning to driver neck injury in rear-end crashes. *Accid Anal Prev*, 1999, 31, 719-728.

Farmer, CM; Zuby, DS; Wells, JK; Hellinga, LA. Relationship of dynamic seat ratings to real-world neck injury rates. *Traf Inj Prev*, 2008, 9, 561-567.

Federal Motor Vehicle Safety Standard 202a (FMVSS 202a), Head Restraints; Federal Register; US National Highway Traffic Safety Administration.

Fleet News. Safety dilemma for fleet operators. Friday May 2, 2008. Available from: http://www.fleetnews.co.uk/news/story/?nID=47136.

Fockler, SK; Vavrik, J; Kristiansen, L. Motivating drivers to correctly adjust head restraints: assessing effectiveness of three different interventions. *Accid Anal Prev*, 1998, 30(6), 773-780.

Fordyce, T; Kelsh, M; Mezei, G. Neck injuries among electric utility workers: 1995-2005. *Proceedings World Congress on Neck Pain*, January 20-22, 2008, Los Angeles, CA, 95.

Foret-Bruno, JY; Dauvilliers, F; Tarriere, C. Influence of the seat and head rest stiffness on the risk of cervical injuries. *13th International Technical Conference on Experimental Safety Vehicles*, S-8-W-19, 968-974, 1991.

French, J; Blair-Stevens, C. *Social Marketing Pocket Guide* (1st Edition). National Social Marketing Centre for Excellence. Available from: http://www.nsms.org.uk.

Galasko, CS; Murray, PM; Pitcher, M. Neck sprains after road traffic accidents: a modern epidemic. *Injury*, 1993, 24, 155-157.

Gane, J. Measurement of vehicle head restraint geometry. SAE No. 1999-01-0639. In: *Occupant Protection* (SP-1432), 45-50, 1999.

Gane, J; Pedder, J. Head restraint measuring device. *Paper No. 96-S10-W-27*. 1996.

Garrett, JW; Morris, DF. Performance evaluation of automobile head restraints. SAE Warrendale, PA. *Technical Paper* #720034, 1972.

Gay, JR; Abbott, KH. Common whiplash injuries of the neck. *Journal of the American Medical Association*, 1953, 29, 152(18), 1698-1704.

Geddes, E; Fockler, S; Felipe, E. Observational study of driver and passenger head restraint positions. *Proceedings of the CMRSC-X*, Toronto, Ontario, June 1997, 442-453.

Geigl, BC; Leinzinger, P; Roll; Muhlbauer, M; Bauer, G. The movement of the head and cervical spine during rear-end impact. *Proceedings 1994 International IROCOI Conference on the Biomechanics of Impacts*, September 21-23, 1994, Lyon, France, 127-137.

Gibson, T; McIntosh, A. Rear end impact associated neck injuries. *Proceedings of the 1997 Australian MADYMO Users Meeting*, Melbourne, April 1997.

Gotten, N. Survey of one hundred cases of whiplash injury after settlement of litigation. *JAMA*, 1956, 27, 162(9), 865-867.

Grier, S; Bryant, CA. Social marketing in public health. *Annual Review of Public Health*, 2005, 26, 319-339. Available from: http://www.toniyancey.com/is19/110706a.pdf

Gross, AR; Aker, PD; Goldsmith, CH; Peloso, P. Conservative management of mechanical neck disorders. A systematic overview and meta-analysis. *Journal of Current Clinical Trials*, 1996, 30, 200-201.

Gupta, V; Menon, R; Gupta, S; Mani, A; Shanmugavelu, I; Kossar, J. Improved occupant protection through advanced seat design. *Proceedings 15th International Technical Conference on Enhanced Safety of Vehicles*, May 13-16, 1996, Melbourne, Australia, 181-191.

Guzman, J; Haldeman, S; Carroll, LJ; et al. Clinical practice implications of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders: From concepts and findings to recommendations. *Spine*, 2008, 15, 33(4S), S199-213.

Haland, Y; Lindh, F; Fredriksson, R; Svensson, M. The influence of the car body and the seat on the loading of the front seat occupant's neck in low speed rear impacts. *Proceedings 29th ISATA Conference*, June, 1996, Italy, 21-30.

Hartlieb, M; Bihler, E; Bretner, R; et al. NECK-PRO – Mercedes Benz Active Head Restraint. *Proceedings of the International Conference for Neck Injuries in Road Traffic and Prevention Strategies*, November 5-6, 2007, Munich, Germany.

Hasegawa, T; Kudoh, T. Development of a test method to evaluate both stiffness and interaction of compatibility performance. *SAE International Journal of Passenger Cars-Mechanical Systems*, 2009, 1(1), 679-688.

Hayes, CW; Conway, WF; Walsh, JW; Coppage, L; Gerwin, AS. Seat belt injuries: radiological and clinical correlation. *RadioGraphics*, 1991, 11, 23-36.

Hell, W; Langwieder, K. Reported soft-tissue injuries after reat-end car collisions. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 16-18, 1998, Goteborg, Sweden, 261-274.

Hijioka, A; Narusawa, K; Nakamura, T. Risk factors for long-term treatment of whiplash injury in Japan: analysis of 400 cases. *Archives of Orthopaedic and Trauma Surgery*, 2001, 121(9), 490-493.

Hildingsson, C; Toolanen, G. Outcome after soft-tissue injury of the cervical spine. A prospective study of 93 car-accident victims. *Acta Orthopaedica Scandinavica*, 1990, 61(4), 357-359.

Himmetoglu, S; Acar, M; Bouazza-Marouf, K; Taylor, AJ. Energy-absorbing car seat designs for reducing whiplash. *Traf Inj Prev*, 2008, 9, 583-591.

Hogg-Johnson, S; van der Velde, G; Carroll, LJ; et al. The burden and determinants of neck pain the general population. Results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Spine*, 2008, 33(4S), S39-S51.

Holm, LW; Carroll, LJ; Cassidy, D; et al. The burden and determinants of neck pain in whiplash-associated disorders after traffic collisions. Results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Spine*, 2008, 33(4S), S52-S59.

Hong, SJ. Investigation of whiplash injury in Korea: Use of head restraint and its statistical analysis. *Proceedings of the JSAE Congress*, Japan, 2004, 21-24.

Hopkin, JM; Simpson, HF. Valuation of Road Accidents. *Transport Research Laboratory (TRL)* Report Number 163, Transport Research Laboratory UK, 1995.

Howard, RP; Bowles, AP; Guzman, HM; Krenrich, SW. Head, neck, and mandible dynamics generated by 'whiplash'. *Accid Anal Prev*, 1998, 30(4), 525-534.

Huelke, DF; Marsh, JC; DiMento, L; Sherman, HW; Ballard, WJ. Injury causation in rollover accidents. *Proceedings 17th American Association for Automotive Medicine Conference*, Morton Grove, IL, AAAM, 1973, 87-115.

Hurwitz, EL; Aker, PD; Adams, AH; Meeker, WC; Shekelle, PG. Manipulation and mobilization of the cervical spine: a systematic review of the literature. *Spine*, 1996, 21, 1746-1760.

Hynd, D; Carroll, JA; Bartlett, RS. UK cost-benefit analysis: enhanced geometric requirements for vehicle head restraints. Transport Research Laboratory (TRL) Transport Research Laboratory UK, 2008.

Hynes, LM; Dickey, JP. The rate of change of acceleration: implications to head kinematics during rear-end impact. *Accid Anal Prev*, 2008, 40, 1063-1068.

IIHS. *Head restraints will be higher and closer to the back of the head.* Status Report, 2005, 40(2).

IIHS. *Save our necks.* Insurance Institute for Highway Safety Status Report, 1999, 34(5).

Insurance Institute of Highway Safety (IIHS). Procedure for evaluating motor vehicle head restraints. March 2008; 3: pp 1. Available from: http://www.iihs.org/ratings/protocols/pdf/head_restraint_procedure.pdf

International Insurance Whiplash Prevention Group (IIWPG). *Rationale for IIWPG ratings of seats and head restraints for neck injury prevention.* December, 2004.

Jakobssen, L; Lundell, B; Norin, H; Isaksson-Hellman, I. WHIPS – Volvo's whiplash protection study. *Proceedings Whiplash Associated Disorders World Congress (Traffic Safety and Auto Engineering Session)*, February 1999, Vancouver, BC, 521-536.

Jakobsson, L. Field analysis of AIS 1 neck injuries in rear-end car impacts -injury reducing effect of the WHIPS seat. *Journal of Whiplash Related Disorders*, 2005, 3(2), 37-53.

Jakobsson, L; Isaksson-Hellman, I; Lindman, M. WHIPS (Volvo cars' whiplash protection system) - The development and real world performance of WHIPS. *Traf Inj Prev*, 2008, 9, 600-605.

Jakobsson, L; Lundell, H; Norin, H; Isaksson-Hellman, I. WHIPS-Volvo's whiplash protection study. *Accid Anal Prev*, 2000a, 32, 307-319.

Jakobsson, L; Norin, H. AIS1 neck injury reducing effect of WHIPS (Whiplash Protection System). *Proceedings of International IRCOBI Conference on the Biomechanics of Impacts*, 2004, Graz, Austria, 297-305.

Jakobsson, L; Norin, H; Isaksson-Hellman, I. Parameters influencing the risk of AIS1 neck injuries in frontal and side impacts. *Proceedings of the International Research Council on the Biomechanics of Impact (IRCOBI)*, Montpellier, France, September 20-22, 2000b.

Jakobsson, L; Norin, H; Jernstrom, C; Svensson, SE; Iasksson-Hellman, I; Svensson, MY. Analysis of different head and neck responses in rear-end car collisions using a new human-like mathematical model. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 8-10, 1993, Einhoven, The Netherlands, 109-125.

Jakobsson, L; Norin, H; Svensson, MY. Parameters influencing AIS 1 neck injury outcome in frontal impacts. *Traf Inj Prev*, 2004, 5, 156-163.

Johnson, D. Counseling to reduce road injuries and deaths. *Canadian Family Physician*, 1996, 42, 2154-2158.

Jonsson, B; Svensson, MY; Linder, A; Bjornstig, U. BioRID II manikin and human seating position in relation to car head restraint. *International Journal of Crashworthiness*, 2008, 13, 479-485.

Kahane, CJ. An evaluation of head restraints, Federal Motor Vehicle Safety Standard 202. Report no. DOT-HS-806-108. Washington DC: US Department of Transportation; 1982.

Kallieris, D; Mattern, R; Miltner, E; et al. Considerations for a neck injury criterion. SAE 912916. *Proceedings of the 35th Stapp Car Crash Conference*, Detroit, MI, Society of Automotive Engineers, 1991, 401-415.

Khan, S; Bannister, G; Gargan, M; Asopa, V; Edward, A. Prognosis following a second whiplash injury. *Injury*, 2000, 31, 249-251.

Kihlberg, JK. Flexion-torsion neck injury in rear impacts. *Proceedings of the 13th Annual Conference of the American Association for Automotive Medicine*, Ann Arbor, Michigan, 1969, 1-16.

Kim, A; Prasad, P. Hybrid III and Hybrid III with a TRID neck in low-speed rear impacts. In: Yoganandan N, Pintar FA (eds). *Frontiers in Whiplash Trauma: Clinical and Biomechanical.* The Netherlands: IOS Press; 2000, 435-454.

Kitagawa, Y; Yasuki, T; Hasegawa, J. Research study on neck injury lessening with active head restraint using human body FE model. *Traf Inj Prev*, 2008, 9, 574-582.

Kivioja, J. *Patient related aspects on WAD*. Stockholm, Sweden: Karolinska University Press; 2004.

Kleinberger, M; Sun, E; Saunders, J; Zhou, Z. Effects of head restraint position on neck injury in rear impact. *Proceedings Whiplash Associated Disorders World Congress (Traffic Safety and Auto Engineering Session)*, February 1999, Vancouver, BC, 361-390.

Koch, M; Kullgren, A; Lie, A; Nygren, A; Tingvall, C. Soft tissue injury of the cervical spine in rear-end and frontal car collisions. *Proceedings of the IRCOBI Conference on Biomechanics of Impacts*, Brunnen, Switzerland, 1995.

Kornhauser, M. Delta-v thresholds for cervical spine injury. SAE Technical Paper Series, 960093, 1-13, 1996.

Krafft, M; Kullgren, A; Lie, A; Tingvall, C. *Assessment of whiplash protection in rear impacts – crash tests and real-life crashes.* Folksam Research, 10660. Stockholm, Sweden, 2004.

Krafft, M; Kullgren, A; Lie, A; Tingvall, C. The risk of whiplash injury in the rear seat compared to the front seat in rear impacts. *Traf Inj Prev*, 2003, 4, 136-140.

Krafft, M; Kullgren, A; Tingvall, C. How crash severity in rear impacts influences short-and long -term consequences to the neck. *Accid Anal Prev*, 2000, 32, 187-195.

Kullgren, A; Krafft, M; Lie, A; Tingvall, C. The effect of whiplash protection systems in real-life crashes and their correlation to consumer crash test programmes. *ESV Paper No. 07-0468*, 2007.

Kullgren, A; Krafft, M; Nygren, A. Neck injuries in frontal impacts: influence of crash pulse characteristics on injury risk. *Accid Anal Prev*, 2000, 32, 197-205.

Kumar, S; Narayan, Y; Amell, T. Role of awareness in head-neck acceleration in low velocity rear-end impacts. *Accid Anal Prev*, 2000, 32, 233-241.

Lange, JE; Voas, RB. Nightime observations of safety belt use: an evaluation of California's primary law. *AJPH*, 1998, 88(11),1718.

Langweider, K; Schick, S; Hell, W. Rear-end impact characteristics leading to a dynamic seat test standard proposal. In: N. Yoganandan, & F. A. Pintar (Eds.), *Frontiers in Whiplash Trauma: Clinical and Biomechanical.* The Netherlands: IOS Press; 2000, 467-476.

Lee, WE. Biomechanical analysis and injury causation: an individual-specific and incident-specific approach. *43rd Annual proceedings of the Association for the Advancement of Automotive Medicine.* September 20-21,1999, Barcelona, Spain, 438-439.

Linder, A; Avery, M. *Change of Velocity and Pulse Characteristics in Rear Impacts: Real World and Vehicle Tests Data*. The Motor Insurance Repair and Research Centre. Thatcham, United Kingdom. Available from: http://www-nrd.nhtsa.dot.gov/pdf/nrd-01/esv/esv18/cd/files/18ESV-000285.pdf

Livingston, M. Whiplash injury and peer copying. *Journal of the Royal Society of Medicine*, 1993, 86, 535-536.

Livingston, M. Whiplash injury: misconceptions and remedies. *Australian Family Physician*, 1992, 21(11), 1642-3-1646-7.

Loeppke, R. The value of health and the power of prevention. *International Journal of Workplace Health Management*, 2009, 1(2), 95-108.

Loeppke, R; Taitel, M; Richling, D; et al. Health and Productivity as a business strategy. *Journal of Occupational and Environmental Medicine*, 2007, 49, 712-721.

Lövsund, P; Nygren, A; Salen, B; Tingvall, C. Neck injuries in rear end collisions among front and rear seat occupants. *International IRCOBI Conference on the Biomechanics of Impacts*, 1988, Bergisch-Gladbach, Germany, 319-325.

Lubin, S; Sehmer, J. Are automobile head restraints used effectively? *Can Fam Physician*, 1993, 39, 1584-1588.

Lundell, B; Jakobsson, L; Alfredsson, B; Jernstrom, C; Isaksson-Hellman, I. *Guidelines for and the Design of a Car Seat Concept for Improved Protection Against Neck Injuries in Rear End Car Impacts*. SAE Paper No. 980301, SAE International Congress and Exposition, Detroit, February 1998.

Mahaffey, T; MacAuley, K; Wright, BA. A study of head restraint use: preliminary findings and implications for a public awareness campaign. *Proceedings of the 32nd Annual Atlantic Schools of Business Conference*, Antigonish, NS, November, 2002.

Maher, J. Report investigating the importance of head restraint positioning in reducing neck injury in rear impact. *Accid Anal Prev*, 2000, 32, 299-305.

Martin, JL; Pérez, K; Marí-Dell'olmo, M; Chiron, M. Whiplash risk estimation based on linked hospital-police road crash data from France and Spain. *Inj Prev*, 2008, 14(3), 185-190.

Martinez, JL; Garcia, DJ. A model for whiplash. *J Biomech*, 1968, 1, 23-32.

McConnell, WE; Howard, RP; Guzman, HM; Bomar, JB. Analysis of human test subject kinematic responses to low velocity rear end impacts. In: *Vehicle and Occupant Kinematics*. SAE: Warrendale PA, 1993, 21-30.

McConnell, WE; Howard, RP; Poppel, JV; Krause, R; Guzman, H; Bomar, JB. Human head and neck kinematics after low velocity rear-end impacts – understanding “whiplash”. *Proceedings 39th Stapp Car Crash Conference*, November 8-10, 1995.

McCunney, RJ; Rountree, PP; Barbanel, CS; Borak, JB; Bunn, WB. *A Practical Approach to Occupational and Environmental Medicine*. (3rd Edition). Philadelphia, PA: Lippincott Williams & Wilkins; 2003.

McFadden, M; Powers, J; Brown, W; Walker, M. Vehicle and driver attributes affecting distance from the steering wheel in motor vehicles. *Human Factors*, 2000, 42(4), 676-682.

McNab, I. Acceleration injuries of the cervical spine. *Journal of Bone and Joint Surgery*, 1964, 46, 1797-1799.

Mertz, HJ; Patrick, LM. Investigation of the kinematics and kinetics of whiplash. *Proceedings 11th Stapp Car Crash Conference*, October 10-11, 1967.

Minton, R; Murray, P; Pitcher, M; Galasko, CSB. Causative factors in whiplash injury: implications for current seat and head restraint design. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 24-6, 1997, Hanover, Germany, 207-222.

Minton, R; Murray, P; Stephenson, W. Whiplash injury: Are current head restraints doing their job? *Accid Anal Prev*, 2000, 32, 177-185.

Morris, AP; Thomas, P. Neck injuries in the UK co-operative crash study. SAE 962433, 1996, 476, 317-329.

Morris, F. Do head-restraints protect the neck from whiplash injuries? *Archives of Emergency Medicine*, 1989, 6(1), 17-21.

Motor Insurance Repair Research Centre (Thatcham). 2006. Available from: http://www.thatcham.org/

Mulhall, KJ; Moloney, M; Burke, TE; Masterson, E. Chronic neck pain following road traffic accidents in an Irish setting and it’s relationship to seat belt use and low back pain. *Irish Medical Journal*, 2003, 96(2), 53-54.

Murray, CJ; Lopez, AD, editors. *The global burden of disease: a comprehensive assessment of mortality and disability from diseases, injuries and risk factors in 1990 and projected to 2020.* Cambridge (MA): Harvard University Press; 1996.

Murray, S. Global injury and violence. *Canadian Medical Association Journal*, 2006, 174(5), 620-621.

National Accident Sampling System/Crashworthiness Data System (NASS) 1988-1990. U.S. Dept. of Transportation, National Highway Traffic Safety Administration, 1991.

National Highway Traffic Safety Administration (NHTSA). *Head Restraints - Identification of issues relevant to regulation, design, and effectiveness*. National Highway Traffic Safety Administration. 1996. Available from: http://www.nhtsa.gov/cars/rules/CrashWorthy/HeadRest/status9/status9.html

National Social Marketing Centre (NSMC). United Kingdom. Available from: http://www.nsmcentre.org.uk.

National Tobacco Control Campaign. England, UK. Available from: www.givingupsmoking.co.uk.

NHTSA. Improving the head restraint requirements of Federal Motor Vehicle Safety Standard 202 (Docket No. NHTSA 2000-8570), March 5, 2001.

Nygren, A. Injuries to car occupants: some aspects of interior safety of cars. A study of five-year material from an insurance company. *Acta Otolaryngologica*, 1984, 395, 1-164.

Nygren, A; Gustafsson, H; Tingvall, C. Effects of different types of headrests in rear-end collisions. *Proceedings 10th International Technical Conference on Experimental Safety Vehicles*, July 1-4, 1985, Oxford, England, 85-90.

O'Neill, B. Head restraints – the neglected countermeasure. *Accid Anal Prev*, 2000, 32, 143-150.

O'Neill, B; Haddon, W; Kelley, AB; Sorenson, WW. Automobile head restraints-frequency of neck injury claims in relation to the presence of head restraints. *AJ PH*, 1972, 62, 309-406.

Olsson, I; Bunketorp, O; Carlsson, G; Planath, I; Norin, H; Ysander, L. An in-depth study of neck injuries in rear end collisions. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 12-14, 1990, Bron, Lyon, 269-280.

Ommaya, A; Backaitis, S; Fan, W; Partyka, S. Automotive neck injuries. *Ninth International Technical Conference on Experimental Safety Vehicles*, US Department of Transportation, National Highway Traffic Safety Administration, Kyoto Japan, Nov 1-4, 1982, 274-278.

Ono, K; Kaneoka, K; Wittek, A; Kajzer, J. Cervical injury mechanism based on the analysis of human cervical vertebral motion and head-neck-torso kinematics during low speed rear impacts. *Proceedings 41st Stapp Car Crash Conference*, November 13-14, 1997, 339-356.

Ono, K; Kanno, M. Influences of the physical parameters on the risk to neck injuries in low impact speed rear-end collisions. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 8-10, 1993, Einhoven, The Netherlands, 201-212.

Ono, K; Kanno, M. Influences of the physical parameters on the risk to neck injuries in low impact speed rear end collisions. *Accid Anal Prev*, 1996, 28(4), 493-499.

Otremski, I; Marsh, JL; Wilde, BR; McLardy Smith, PD; Newman, RJ. Soft tissue cervical spinal injuries in motor vehicle accidents. *Injury*, 1989, 20(6), 349-351.

Otte, A; Ettlin, TM; Nitzsche, EU. PET and SPECT in whiplash syndrome: a new approach to a forgotten brain? *Journal of Neurology*, *Neurosurgery and Psychiatry*, 1997, 63, 368-372.

Otte, D; Rether, JR. Risks and mechanisms of injuries to the cervical spine in traffic accidents. *Proceedings International IRCOBI/AAAM Conference on the Biomechanics of Impacts*, 1985, Goetborg, Sweden, 17-31.

Parkin, S; MacKay, GM; Cooper, A. How drivers sit in cars. *Accid Anal Prev*, 1995, 27(6), 777-783.

Parmar, HV; Raymakers, R. Neck injuries from rear impact road traffic accidents: prognosis in persons seeking compensation. *Injury*, 1993, 24(2), 75-78.

Prochaska, JO; DiClemente, CC. Stages and processes of self-change of smoking: Toward an integrative model of change. *Journal of Consulting and Clinical Psychology*, 1983, 51, 390-395.

Quinlan, KP; Annest, JL; Myers, B; Ryan, G; Hill, H. Neck strains and sprains among motor vehicle occupants-United States, 2000. *Accid Anal Prev*, 2004, 36(1), 21-27.

Radanov, BP; Di Stefano, G; Schnidrig, A; Sturzenegger, M. Psychosocial stress, cognitive performance and disability after common whiplash. *Journal of Psychosomatic Research*, 1993b, 37(1), 1-10.

Radanov, BP; Di Stefano, GD; Schnidrig, A. Cognitive functioning after common whiplash: a controlled follow-up study. *Archives of Neurology*, 1993a, 50, 87-91.

Radanov, BP; Di Stefano, GD; Schnidrig, A; Ballinari, P. Role of psychological stress in recovery from common whiplash. *Lancet*, 1991, 338, 712-715.

Radanov, BP; Sturzenegger, M; Di Stefano, G; Schnidrig, A. Relationship between early somatic, radiological, cognitive and psychosocial findings and outcome during a one-year follow-up in 117 patients suffering from common whiplash. *British Journal of Rheumatology*, 1994, 33, 442-448.

RCAR. A Procedure for Evaluating Motor Vehicle Head Restraints. Issue 2, February, 2001.

RCAR. IIWPG Protocol for the Dynamic Testing of Motor Vehicle Seats for Neck Injury Prevention. 2004.

Research Council for Automotive Repairs (RCAR)/ IIWPG Seat-Head Restraint Evaluation Protocol, Version 2.5, 2006.

Richter, M; Ferrari, R; Otte, D; Kuensebeck, HW; Blauth, M; Krettek, C. Correlation of clinical findings, collision parameters, and psychological factors in the outcome of whiplash associated disorders. *J Neurol Neurosurg Psychiatry*, 2004, 75(5), 758-764.

Richter, M; Otte, D; Blauth, M. Acceleration related injury of the cervical spine in restrained car drivers. Investigations on the trauma mechanism and severity of injury. *Orthopaedics*, 1999, 28, 414-423.

Richter, M; Otte, D; Pohlemann, T; Kretteck, C; Blauth, M. Whiplash-type neck distortion in restrained cart drivers: frequency, causes and long term results. *European Spine Journal*, 2000, 9, 109-117.

Roh, LS; Fazzalaro, W. Transection of the trachea due to improper application of automatic seatbelt (submarine effect). *Journal of Forensic Science*, 1993, 38(4), 972-977.

Ruedemann, AD. Automobile safety device-headrest to prevent whiplash injury. *JAMA*, 1957, 24, 164(17), 1889.

Ruedemann, AD. The electroretinogram in degenerative diseases. *International Ophthalmology Clinics*, 1969, 9(4), 1005-1023.

Ryb, GE; Dischinger, PC. Injury severity and outcomes of overweight and obese patients after vehicular trauma: A crash injury research and engineering network (CIREN) study. *The Journal of Trauma: Injury, Infection, and Critical Care*, 2008, 64, 406-411.

Saab, B-R; Usta, J; Hamadeh, G. Head restraint and seat belt use by car drivers in Lebanon. *International Journal of Risk and Safety in Medicine*, 2000, 13, 9-13.

Satoh, S; Naito, S; Konishi, T; et al. An examination of reasons for prolonged treatment in Japanese patients with whiplash injuries. *Journal of Musculoskeletal Pain*, 1997, 5(2), 71-84.

Scaer, RC. *The Body Bears The Burden: Trauma, Dissociation and Disease.* Binghamton, NY: Haworth Medical Press; 2007.

Schmitt, KU; Walz, F; Vetter, D; Muser, M. Whiplash injury: cases with a long period of sick leave need biomechanical assessment. *Eur Spine J*, 2003, 12(3), 247-254.

Schneider, LW. *Anthropometry of motor vehicle occupants*. Vol 1-3, University of Michigan Transportation Research Institute UMTRI-83-53/1/2/3, Ann Arbor, MI, 1983.

Scholten-Peeters, GG; Verhagen, AP; Bekkering, GE; et al. Prognostic factors of whiplash-associated disorders: a systematic review of prospective cohort studies. *Pain*, 2003, 104(1-2), 303-322.

Sekizuka, M. Seat designs for whiplash injury lessening. *Proceedings 16th International Technical Conference on the Enhanced Safety of Vehicles*, May 31-June 4, 1998, Windsor, Canada, 1570-1578.

Sendur, P; Thibodeau, R; Burge, J; Tencer, A. Parametric analysis of vehicle design influence on the four phases of whiplash motion. *Traf Inj Prev*, 2005, 6(3), 258-266.

Severy, DM; Brink, HM; Baird, JD. Backrest and head restraint design for rear-end collision protection. SAE No. 680079, 1968.

Severy, DM; Mathewson, JH; Bechtol, CO. Controlled automobile rear-end collisions. An investigation of related engineering and medical phenomena. *Canadian Services Medical Journal*, 1955, 727-759.

Siegmund, GP; Heinrichs, BE; Wheeler, JB. The influence of head restraint and occupant factors on peak head/neck kinematics in low-speed rear-end collisions. *Accid Anal Prev*, 1999, 31(4), 393-407.

Soltermann, B. Cranio-cervical acceleration/deceleration trauma in Switzerland: Documentation on initial consultation – incapacity to work – prevention. *Proceedings Cervical Spine Injuries in Road Traffic Accidents Conference,* November 5-6, 2007, Munich,Germany

Spitzer, W; Skovron, ML; Salmi, LR; Cassidy, JD; Suissa, S; Zeiss, E. Scientific monograph of the Quebec task force on whiplash-associated disorder; Redefining ”Whiplash” and its management. *Spine Supplement*, 1995, 20(8), S1-S73.

States, JD; Balcerak, JC. The effectiveness of head restraints in rear end impacts. Report no. DOT-HS-800-877. 1973. Washington DC: US Department of Transportation.

States, JD; Balcerak, JC; Williams, JS; et al. Injury frequency and head restraint effectiveness in rear end impact accidents. *Proceedings of the 16th Stapp Car Crash Conference*, 1972, Detroit, MI, 228-257.

States, JD; Balcerak, JC; Williams, JS; et al. Injury frequency and head restraint effectiveness in rear-end impact accidents. *Proceedings of the 16th Stapp Car Crash Conference. Society of Automotive Engineers*, 1973, New York, NY, 228-257.

Subzwari, S; Desapriya, E; Scime, G; Babul, S; Jivani, K; Pike, I. Effectiveness of cataract surgery in reducing driving-related difficulties: a systematic review and meta-analysis. *Inj Prev*, 2008, 14(5), 324-328.

Svensson, MY; Aldman, B; Hansson, HA; et al. Pressure effects in the spinal canal during whiplash extension motion: a possible cause of injury to the cervical spinal ganglia. *Proceedings International IRCOBI Conference on the Biomechanics of Impacts*, September 8-10, 1993, Einhoven, The Netherlands, 189-200.

Szabo, TJ. Influence of seat properties on occupant kinematics and injury potential in low-speed rear impacts. In: Yoganandan N, Pintar FA (eds). *Frontiers in Whiplash Trauma: Clinical and Biomechanical.* The Netherlands: IOS Press; 2000, 348-405.

Szabo, TJ; Voss, DP; Welcher, JB. Influence of seat foam and geometrical properties on biorid p3 kinematic response to rear impacts. *Traf Inj Prev*, 2003, 4(4), 315-323.

Szabo, TJ; Welcher, JB. Human subject kinematics and electromyographic activity during low speed rear impacts. *Proceedings 40th Stapp Car Crash Conference*, 1996, Albuquerque, NM.

Szabo, TJ; Welcher, JB; Anderson, RD; et al. Human occupant kinematic response to low speed rear impacts. *Proceedings 38th Stapp Car Crash Conference*, October 31 – November 4, 1994, Paper 921573.

Taylor, JA; Burke, J; Gavencak, J; Panwar, P. Knowledge and application of correct car seat head restraint usage among chiropractic college interns: a cross-sectional study. *Journal of the Canadian Chiropractic Association*, 2005, 45, 32-39.

Teifke, A; Degreif, J; Geist, M; Schild, H; Strunk, H; Schunk, K. Der Sicherheitsgurt: Auswirkungen auf das Verletzungsmuster von Autoinsassin. *Rof Fortschr Geb Rontgenstr Neuren Bildgeb Verfahr*, 1993, 159, 278-283.

Temming, J; Zobel, R. Frequency and risk of cervical spine distortion injuries in passenger car accidents; significance of human factors data. *Proceedings of the 1998 International IRCOBI Conference on the Biomechanics of Impacts*, 1998, Bron, France, 219-233.

van den Kroonenberg, A; Philippens, H; Cappon, J; Wismans, J; Hell, W; Langweider, K. Human head-neck response during low-speed rear end impacts. *Proceedings of the 42nd Stapp Car Crash Conference*, 1998, SAE 983157, 207-221.

Vasavada, AN; Danaraj, J; Siegmund, GP. Head and neck anthropometry, vertebral geometry and neck strength in height-matched men and women. *J Biomechanics*, 2008, 41, 114-121.

Verhagen, AP; Karels, C; Bierma-Zeinstra, SMA; et al. Ergonomic and physiotherapeutic interventions for treating work-related complaints of the arm, neck or shoulder in adults. A Cochrane systematic review. *Europa Medicophysica*, 2007, 43(3), 391-405.

Versteegen, GJ; Kingma, J; Meijler, WJ; ten Duis, HJ. Neck sprain in patients injured in car accidents: a retrospective study covering the period 1970-1994. *Eur Spine J*, 1998, 7, 195-200.

Viano, DC. *Role of the Seat in Rear Crash Safety.* Warrendale, PA: Society of Automotive Engineers. (2002).

Viano, DC. Seat design principles to reduce neck injuries in rear impacts. *Traf Inj Prev*, 2008, 9, 552-560.

Viano, DC. Seat influences on female neck responses in rear crashes: A reason why women have higher whiplash rates. *Traf Inj Prev*, 2003b, 4(3), 228-239.

Viano, DC. Seat properties affecting neck responses in rear crashes: A reason why whiplash has increased. *Traf Inj Prev*, 2003a, 4(3), 214-227.

Viano, DC; Gargan, MF. Headrest position during normal driving: implications to neck injury risks in rear crashes. *39th Annual Proceedings of AAAM Conference.* October 1995, Chicago, IL.

Viano, DC; Gargan, MF. Headrest position during normal driving: implication to neck injury risk in rear crashes. *Accid Anal Prev*, 1996, 28(6), 665-674.

Viano, DC; Olsen, S. The effectiveness of active head restraint in preventing whiplash. *J Trauma*, 2001, 51(5), 959-969.

Watanabe, Y; Ichikawa, H; Kayama, O; Ono, K; Kaneoka, K; Inami, S. Relationship between occupant motion and seat characteristics in low-speed rear impacts. SAE No. 1999-01-0635, *Occupant Protection* (SP-1432), 13-22.

Welcher, JB; Szabo, TJ. Relationship between seat properties and human subject kinematics in rear impact tests. *Proceedings WAD Compendium/Auto Safety and Auto Engineering*, Vancouver, BC, 1999, 243-274.

Welcher, JB; Szabo, TJ. Relationships between seat properties and human subject kinematics in rear impact tests. *Accid Anal Prev*, 2001, 33(3), 289-304.

West, D; Gough, J; Harper, G. Low speed rear-end collision testing using human subjects. *Accident Reconstruction Journal*, 1993, 5(3), 22-26.

White, MI; Davis, D; Holland, JH; Green, LW; Liang, MH. Using conferences as strategic events to support knowledge mobilization. *Proceedings of the World Congress on Neck Pain*, January 20-22, 2008, Los Angeles, California, 134.

Wiklund, K; Larsson, H. Saab active head restraint (SAHR) – seat design to reduce the risk of neck injuries in rear impacts. SAE Technical Paper Series 980297. Warrendale, PA: Society of Automotive Engineers, 1998, 1-7.

Wood, DP. Safety and the car size effect: a fundamental explanation. *Accid Anal Prev*, 1997, 29(2), 139-151.

Yoganandan, N; Pintar, FA; Kleinberger, M. Cervical spine vertebral and facet joint kinematics under whiplash. *Journal of Biomechanical Engineering*, 1998, 120, 305-307.

Yoganandan, N; Pintar, FA; Kleinberger, M. Whiplash injury biomechanical experimentation. *Spine*, 1999, 24, 83-85.

Young, AL; Ragel, BT; Su, E; Mann, CN; Frank, EH. Assessing automobile head restraint positioning in Portland, Oregon. *Inj Prev*, 2005, 11(2), 97-101.

Zhu, S; Layde, PM; Guse, CE; et al. Obesity and risk for death due to motor vehicle crashes. *AJPH*, 2006, 96(4), 734-739.

Zuby, DS; Lund, AK. Minor neck injuries in rear crashes – international problem and progress. *Proceedings of the Neck Injuries in Road Traffic and Prevention Strategies*. 2007, Germany.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 61-130
ISBN: 978-1-60876-223-1

Chapter 2

MOUTHGUARDS: THE EFFECTS AND THE SOLUTIONS FOR UNDERLYING PROBLEMS

Tomotaka Takeda, Keiichi Ishigami, Kazunori Nakajima and Katsuhide Kurokawa
Department of Sports Dentistry, Tokyo Dental College, Japan

INTRODUCTION

A basic athletic mouthguard (or a mouthpiece, a gum shield) is a resilient device placed on the upper jaw to reduce orofacial injuries particularly to the teeth and surrounding structures. Several types of mouthguards are available (Figure I-1, 2). Like other protective devices, a mouthguard is essential to protect the body from sports-related dental injuries, which are not rare and are costly, disfiguring, and emotionally distressing (Figure I-3 to 7). Recently, mouthguard usage has been spreading gradually. Nevertheless, many sports-related dental and oro-facial injuries can still occur regardless of whether a mouthguard is worn or not. This is because, not only the level of comfort [1], but also the safety and so on of mouthguards is strongly influenced by the types available and the quality of manufacturing (Figure I-7 to 9). So it is dangerous to assume that all types of mouthguards offer the same level of protection. But most athletes have not recognized these problems. Thus, in order to solve them, we have conducted a series of studies.

Needless to say, it is important for all age groups to live a physically active life. Reasons to participate in sports and physical activity are many, such as for pleasure, relaxation, competition, socialization, and maintenance and improvement of fitness and health [2]. On the contrary, a negative aspect of participation in sports and recreational activities is an increasing number of sports-related injuries. And sports-related dental injuries are not rare injuries; in addition, many of them are accompanied by disfigurement, and emotional distress.

Furthermore, unlike some other injuries, a single traumatic injury to the dentition may never heal completely, and it can require a lifetime of expensive, long-term problems for the affected athlete. [3],[4],[5],[6]. The total cost of tooth avulsions that are not properly preserved or replanted has been estimated to be $10,000–$15,000 per tooth over a lifetime.[5]. So, oral injuries sustained in athletic and recreational activities are a significant problem [7],[8],[9],[10] and should be avoided. This is why, just as other protective devices such as a helmet, a face guard, a neck guard, an eye guard and so on are essential to protect the body from an injury, a mouthguard is indispensable to protect teeth and the maxillofacial area from trauma.

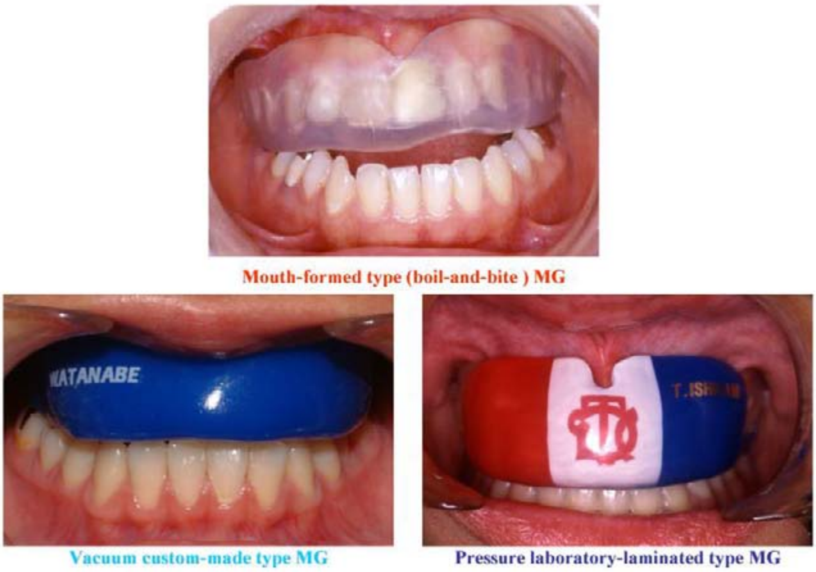


Figure I-1. Main types of mouthguards recently used.

1. Prevention of a player's orofacial tissue itself from an injury

- A tooth from the direct impact
- A tooth from an indirect impact (during destructive contact of upper and lower jaw which often occurs by vertical blow to a lower jaw)
- Soft tissues: a lip, a tongue, a gingiva, a cheek.
- Upper and lower jaw from a fracture (mouthguard is believed to be effective when player notices a danger and clenches at the time of an impact).
- A temporomandibular joint from an indirect impact applied to lower jaw .

2. Prevention of concussions

3. Prevention of injury caused when one player's face or head contacts the teeth of another player.

4. Prevention of transmission through blood

5. Maintenance and improvement of sports performance

Figure I-2. The purpose of the mouthguard.

Figure I-3. Typical oro-facial injuries related to sports (tooth fracture and tooth complete dislocation).

Figure I-4. Typical oro-facial injuries related to sports (mandibular fracture).

The positive effects of wearing a mouthguard to protect against tooth and maxillofacial trauma are indicated in various epidemiological and experimental studies. Firstly, as epidemiological surveys show, in a study of NCAA basketball teams, athletes wearing custom mouthguards incurred significantly fewer oral injuries (1.16 injuries per 1,000 athletic exposures) than players who did not (3.00 injuries per 1,000 athletic exposures)(Labella, Smith et al. 2002). A long-term study of Hawaiian student-athletes reported no intraoral injuries to athletes who wore mouthguards during play [11]. The significant protection provided by custom mouthguards also has been supported by one randomized controlled trial [12], and many other studies [13], [14], [15], [16], [17],[5], [18], [19], [20]. Secondly, many experimental studies [21],[22],[23],[24],[25],[26],[27],[28],[29],[30],[31],[32],[33],[34],[35] have been conducted. Most of these studies revealed that various mouthguards have, to some degree, an injury-preventing effect in dentition. Thus, there is an expectation that mouthguards can help prevent orofacial sports-related injuries.

Figure I-5. Typical oro-facial injuries related to sports (tooth concussion and discoloration).

Figure I-6. Typical oro-facial injuries related to sports (lip laceration).

Moreover, by providing cushioning between the maxilla and mandible, mouthguards also may lessen the incidence or severity of condoyle-displacement injuries and thereby reduce the potential for concussion. [36],[37],[38], [39],[40]. That is to say, mouthguards have been suggested to be effective in mTBI prevention—although, this claim is controversial[41], [42],[43-45].

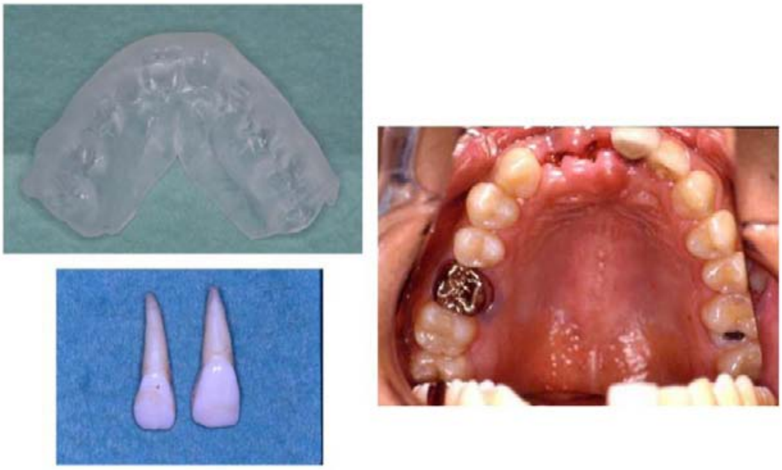


Figure I-7. Typical oro-facial injuries related to sports (during boil-and-bite type MG).

Figure I-8. Lack of maintenance in boil-and-bite type MG

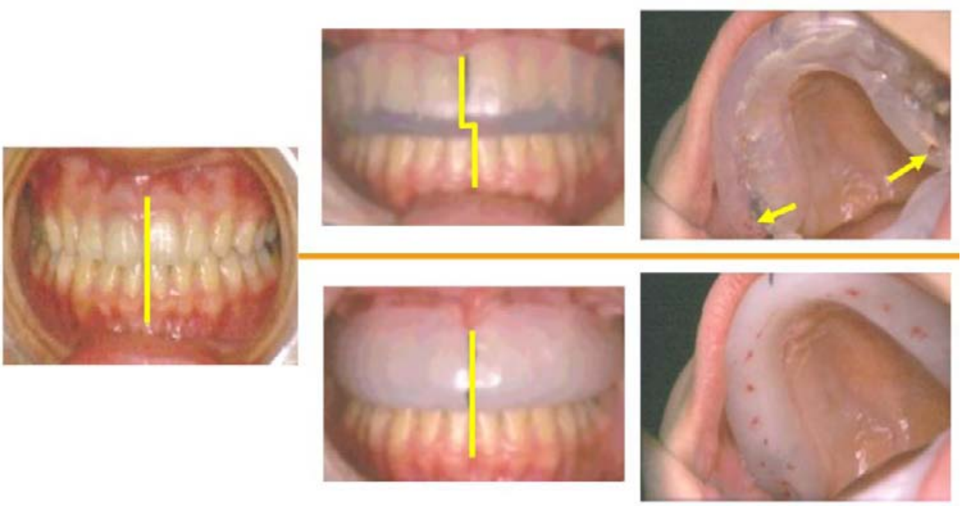


Figure I-9. Three dimensional malposition in boil-and-bite type MG

What is a mouthguard? The American Society for Testing and Materials [46] has defined a mouth protector, such as an athletic mouthguard, as a *resilient* device or appliance placed *inside the mouth (or inside and outside)* to reduce mouth injuries *particularly* to the teeth and surrounding structures. It also says a mouthguard is generally worn on upper dentition and covers the teeth and the surrounded teeth. (Figure I-1) Also, the Society [46] designated three categories for athletic mouthguards: 1. the ready-made, or stock, mouthguard; 2. the mouth-formed, “boil-and-bite” protector; 3. the custom-made model (also called custom-fitted), either vacuum-formed or pressure-laminated by a dentist or a dental laboratory (based on the dentist’s instructions). But we authors think it is necessary to divide a vacuum-formed and a pressure-laminated type into different categories.

When we discuss the mouthguard, the “Academy for Sports Dentistry” cannot be omitted. This Academy plays a leading role in Sports Dentistry literally. You can easily get information through its home page. (http://www.sportsdentistry-asd.org/what_is_sports_dentistry.asp). "Sports Dentistry" involves the prevention and treatment of orofacial athletic injuries and related oral diseases, as well as the collection and dissemination of information on dental athletic injuries and the encouragement of research in the prevention of such injuries. The Academy has released some important comments about mouthguards [47]. For example, **Who should wear a mouthguard?:** Anyone participating in a sport that contains a chance of injury to the teeth, jaws, or oral soft tissues or which presents a potential risk of concussion could benefit from the use of a mouthguard. In general, anyone participating in a contact or collision sport could benefit from a properly fitted and properly worn mouthguard. Participants in an individual sport, such as rollerblading, which puts the athlete at risk, should use a mouthguard. A properly fitted and properly worn mouthguard shouldn't interfere with an athlete performing any sport at the highest level. There is more very important information on the Web page.

History of mouthguards: Boxing is one of the oldest known sports, and it is deeply related to mouthguards. The rules changed over the years, for example, in the late 1800s with the adoption of gloves to cushion punches. The boxer’s mouthpiece was introduced in the early 1930s as “a rubber guard that helped prevent chipped teeth and cut lips resulting from blows to the head.” Thus boxing is the first sport to introduce some form of mouth protection for the athlete.

American football is another important sport in the discussion of mouthguards. To protect the head, neck and orofacial area from injuries, a large number of studies have been conducted. Plastic replaced leather for helmets and a lightweight plastic provided a bar or facemask to prevent facial injuries in the early 1950s. Cathcart [48] reported that 50% of all injuries to high school football players were in or around the oral cavity even after a plastic helmet with a bar or facemask was used. He concluded that a face mask alone was not sufficient to prevent all mouth injuries. After important mouthguard studies [49] in American football proving the efficacy of mouthguards for mouth injury protection, the National Alliance Football Rules Committee adopted a rule of wearing a mouthguard in 1962. This rule mandated for high school football that a mouthguard be a standard piece of equipment, just as important as a helmet, shoulder pads, or hip pads. After 1962 there was a marked reduction of dental injuries in high school football. However NCAA Football Rules Committee was reluctant to adopt the rule saying that the ability to speak could be affected. In 1974 it was demonstrated that a properly fitted mouthguard would allow the player to speak clearly, and the rule was finally passed. College football made it mandatory for players to wear mouthguards. Hockey followed suit in 1976. Thus, pioneers have left a lot of distinguished services in sports dentistry and mouthguards.

Nevertheless, many sports-related dental and oro-facial injuries can still occur regardless of whether a mouthguard is worn or not. The obvious cause of injury in mouthguard-wearing cases is when the impact force far exceeds the protective capability of a mouthguard. However, the ordinal impact power in sports is estimated to be smaller than that found in traffic accidents, etc.[50]. Because of this, many sports-related oro-facial injuries are assumed to be preventable by the use of an appropriate mouthguard. Namely, all athletes should use a mouthguard that has sufficient shock absorption ability in the buccal surface of upper anterior teeth where injuries are most frequent (about over 90%) and in the occlusal surface to maintain full balance occlusion and shock absorption ability against upper and lower dentition collisions. However, most players seem to wear inefficient mouthguards, such as the low safety boil-and-bite type or the too thin one-layer vacuum type.

Custom mouthguards can be the most expensive option, but the literature suggests that they generally provide better retention and comfort, less interference with speech and breathing, and more adaptability to orthodontic appliances [5],[51],[1]. Custom-made mouthguards are thought to be more protective than the stock ‘‘over the counter’’ or boil and bite models. [5], [52], [53], [54]. **What are the best mouthguards?** The position of the Academy for Sports Dentistry is that to be adequate, a mouthguard must be properly fitted and properly worn. In order to ensure a proper fit, a mouthguard is best fitted by a dental professional. It is generally accepted that a custom-fitted mouthguard fabricated over a dental cast of the athlete's teeth will give the best fit. Also, a dental professional can tailor the mouthguard to the demands of the athlete and the sport. Speech requirements, individual occlusal differences and relative dental and concussion injury risks of each sport can only be customized by fabricating an individual mouthguard. It is difficult to see how an over-the-counter mouthguard can fill all of an athlete's requirements without being checked and adjusted by an informed dental professional. Many research studies support the idea that the custom-made type is the best and is the only method to secure enough protection. Not only the level of comfort [1] but also the safety, and so on, of mouthguards is strongly influenced by the types available and the quality of manufacturing. So it is dangerous to assume that all types of mouthguards have the same level of protection. But, information and recommendations that athletes should wear an appropriate mouthguard is not enough. In addition, there is a need to spread adequate information, to dentists and dental technicians, which could allow them to manufacture appropriate mouthguards.

So, in order to accumulate sufficient data to compensate for the lack of information and recommendations, we authors conducted a series of studies which we introduce in this chapter.

No.1: The impact materials or causes of sports-related trauma would consist of various types of sports balls, pucks, wooden bats and the like. But, the impact absorption ability of the mouthguard is different depending on the materials impacted and not yet measured with these impact objects. So, to investigate the damping effect of various types of mouthguard materials based on the impact of actual sports equipment is measured [55].

No.2: To date, the minimum thickness required for a mouthguard has been assumed to be around 2 mm to 4 mm in conventional EVA materials. However, this figure is based mostly on experience and is yet to be standardized. So, the minimum thickness required to obtain sufficient energy absorption is investigated.

No.3: Problems associated with the occlusion of the mouthguard have not been considered deeply enough until now. With the market type currently available, it is difficult to give the mouthguard the appropriate occlusion needed. Moreover, some vacuum type custom-made ones seemed to have the same issue [25]. Meanwhile, it is thought to be essential to prevent injuries against the direct impact force applied to the maxillary anterior teeth, the most commonly injured area, with sufficient anterior occlusion achieved by full balanced occlusion. But this relationship has not yet been investigated. So, this study addresses that issue.

No.4: A full-balanced occlusion is essential for mouthguards mentioned in the No.3 study. However, some vacuum type mouthguards may not achieve a full-balanced occlusion, for example, when a player has an open bite, a large over jet, a malocclusion, an elongated molar or premolar tooth, or a maxillary protrusion. An improved vacuum fabrication method is presented in this study.

No.5**:** The laminated type is to be recommended as the best option. However, it is difficult to prevent all the injuries with conventional EVA Materials. So, we introduce a special method with high shock absorption ability. A three-layer type with an acrylic resin inner layer (hard-insertion), but with space that does not come into contact with tooth surfaces mouthguard showed quite high ability in the tooth distortion against direct impact to the tooth in this paper.

No.6: Some sports' accidents are responsible for inflicting traumatic brain injuries and mandibular bone fractures when impacts occur to the chin. It is often thought that mouthguards can prevent these injuries. However, such assertions may be insufficient without adequate research. So, to establish a systematic method of investigation to solve this problem and investigate the efficacy of mouthguards, a study was conducted.

No.7: The safety benefits of mouthguards have been demonstrated in many studies, with many authors and sports dentists strongly recommending the wearing of mouthguards. However, wearing a mouthguard with incorrect occlusion might cause a variety of problems. It comes as no surprise that a traumatic blow to the chin, while wearing an insufficient mouthguard lacking enough contact, could result in severe distortions to the mandibular bone, and bone fractures. The aim of this study was to clarify how ineffective insufficient occlusal supporting mouthguards are and how dangerous they can be to use.

STUDY NO.1: THE INFLUENCE OF IMPACT OBJECT CHARACTERISTICS ON IMPACT FORCE AND FORCE ABSORPTION BY MOUTHGUARD MATERIAL

The original article [55]

ABSTRACT

Most impact force and impact energy absorption tests for mouthguards have used a steel ball in a drop-ball or the pendulum device. However, in reality most sports-related trauma is caused by objects other than the steel ball, e.g., various sized balls, hockey puck, or bat or stick. Also, the elasticity, the velocity and the mass of the object could change the degree and the extent of injuries. In this study, we attempted to measure the impact force from actual sports equipment in order to clarify the exact mechanism of dental-related sports injuries and the protective effects of mouthguards. The present study was conducted using the pendulum impact device and load cell. Impact objects were removable. Seven mobile impact objects were selected for testing: a steel ball, baseball, softball, field hockey ball, ice hockey puck, cricket ball, and wooden baseball bat. The mouthguard material used in this study was a 3-mm-thick Drufosoft (Dreve-Dentamid GmbH, Unna, Germany), and test samples were made of the one-layer type. The peak transmitted forces without mouthguard ranged from the smallest (ice hockey stick, 46.9 kgf) to the biggest (steel ball, 481.6 kgf). The peak transmitted forces were smaller when the mouthguard was attached for all impact materials but the effect was significantly influenced by the object type. The steel ball showed the biggest (62.1%) absorption ability while the wooden bat showed the second biggest (38.3%). The other balls or the puck showed from 0.6 to 6.0% absorbency. These results show that it is important to test the effectiveness of mouthguards on specific types of sports equipment. In the future, we may select different materials and mouthguard designs suitable for specific sports.

INTRODUCTION

Factors such as specific elasticity, velocities, and varying amounts of mass that impact objects possess determine the extent and the types of injuries that can be sustained in real-life trauma[56]. It is commonly noted that the cause of dental-related sports injuries are one of three groups. These groups can be easily categorized in relation to the impact of different objects or surface areas: (i) another player, (ii) the ground or floor, (iii) the playing instrument being used for sports (e.g. balls, bats, rackets, and so on).

In sports injuries, it is said that there is a common pattern of causes which is particular to each sport and that the object or equipment used, the playing surface and the amount of the impact power. Therefore, to some degree, the type of sport will determine the type of injuries sustained, following a consistent pattern for each sport. Therefore, by understanding these patterns, it is possible to prevent many sports trauma using appropriate protection.

Many recent experimental studies [23],[21, 23-27, 31, 57-72] have provided the necessary data to show that there is an effective way to prevent tooth or maxillofacial trauma using a mouthguard (Tables 1 and 2). However, there are various types of mouthguards including the boil & bite, mass-produced and marketed to precision-manufactured, custom-made types. Thus, the attributes of mouthguards are not easy to identify, especially, the effectiveness of preventing trauma, which is influenced not only by the impact absorption ability of the material but also by the occlusal relationship. Appropriate control of these factors could ultimately make the manufacturing of mouthguards that suits each possible sport. According to Cummins, the shock absorbency of mouthguards was affected by the stiffness of the object with which it collided .[58]

Table 1-1. Previous studies for shock reduction ability with mouthguard materials itself

FirstAuthor	Target	Method	Impactor	Result
Going RE..	Material	Pendulum	Sttell head	45.0-57.4% ↓
Bishop BM.	Material	Drop ball	Steel ball	28.9-31.6% ↓
Yamamoto T.	Material	Drop ball	Steel ball	90% ↓
Ishijima T.	Material	Drop ball	Steel ball	3.33-33.3% ↓
Maeda M.	Material	Drop ball	Steel ball	2-11% ↓
PARK JB.	Material	Drop ball.	Steel ball	50.4% ↓
Auroy P.	Material	Pendulum	Steel stud	7.7-19.7% ↓ 13.5-16.6% ↓
Jagger R.	Material	Tensile machine	-	○
Westerman B.	Material	Pendulum	Steel straiker	Hard Insert ↓
Bulsara YR.	Material	Free-falling	Steel ram	30% ↓ Sorbothane
Westerman B.	Material	Pendulum	Steel straiker	Thinning results in reduction
Westerman B.	Material	Pendulum	Steel straiker	32% ↓ air inclusions.
Westerman B.	Material	Pendulum	Steel straiker	Optimal thickness =4mm
Craig RG.	Material	Pendulum	Sttell head	80.6-90.6% ↓
Low D.	Material	Ultra micro-indentation system	-	10 - 24% ↓

○:MG is protective. Without numerical data.
△:MG is protective only for hard-object collisions

Table 1-2. Previous studies for shock reduction ability with mouthguards

First Author	Target	Impact Method	Impactor	Result
Godwin WC	Acrylic casts	Pendulum	Steel ball	50%-92% ↓
Watermeyer GJJ	Plaster cast	Pendulum	-	○
Johnston T	Sheep mand. segments	Servohydraulic machine	-	○
Morii H	Bovine Tooth	Pendulum	Steel ball	8.1-30% ↓
de Wet FA	Artificial skull	Pendulum	Impact hammer	23%-55% ↓
Hoffmann J	Model Jaw	Pendulum	Steel head	7.5-58% ↓
Bemelmanns P	Simulated maxilla	Pendulum	Steel ram	25.7-33.3% ↓
Cummins NK	-	Finite element .	-	△
Hickey JC	Cadaver	Impact machine	Plastic strike	○
Oikarinen KS	Plaster model	Dropping object	Simulate ice hocky pack.	○
Wamet L	Simulated maxilla	Drop weight impact testor chanber	Hardwood impactor	○

○:MG is protective.Without numerical data.
△:MG is protective only for hard-object collisions

Therefore, to develop and evaluate new optimal mouthguard materials and manufacture mouthguards suited for each sport (i) the impact power of mobile sports object, (ii) the surfaces used at various sports events and (iii) the impact absorption ability of mouthguards in relation to them [73] must be fully understood.

To this point and with few exceptions [26],[60, 65, 70], mouthguards have been tested for impact energy absorption using drop-ball and/or pendulum devices with steel spheres as the common material of choice [21-23, 25, 27, 31, 57-59, 61-64, 66-69, 74]. A better choice of impact materials would consist of the actual material used in different sports. However, the impact materials would consist of various types of sports balls, pucks, wooden bats and the like, which normally account for actual trauma incidents. The purpose of this study was to investigate the damping effect of mouthguard materials based on the impact of various actual sports equipment.

MATERIALS AND METHODS

A pendulum device apparatus was constructed similar to that of a Charpy or Izod impact machine with the impact object being interchangeable (Figure 1-1). Seven types of mobile impact objects were selected for testing: a steel ball, baseball, softball, field hockey ball, ice hockey puck, cricket ball, and wooden baseball bat (Figure 1-2). Weight and Durometer hardness (except for steel ball) of the impact object are shown also in (Figure 1-2). The axis length of the pendulum was about 50 cm and the apparatus was adjusted to hit the center of a surface of the acrylic resin (attached two layer of plate) fixed onto a load cell (LUR-A-KNSAI: Kyowa Electronic Instruments Co. Ltd, Tokyo, Japan) and was hung perpendicularly. Forces transmitted through the acrylic resin plate itself or when protected by EVA mouthguards were measured with the load cell.

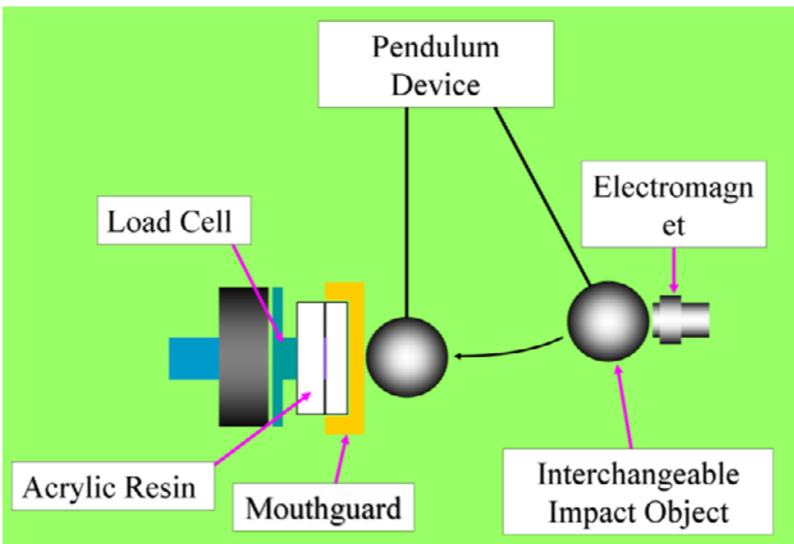


Figure 1-1. A pendulum device apparatus was constructed similar to that of a Charpy or Izod machine and the impact object can be interchangeable.

The mouthguard blanks used were Drufosoft (Dreve-Dentamid GmbH, Unna, Germany) with a 3-mm thickness. Three one-layer test samples of the same type were made by means of a Dreve Drufomat (Type SO, Dreve-Dentamid, Unna, Germany) air pressure machine on a flat-topped, round acrylic plate of 50 mm diameter and 30 mm height as a mould (it is of the same size as that of the resin plate attached to the load cell). To get a uniform thickness of around 2.7 mm, the same operating steps followed by adjustment of detailed thickness were conducted. For each sample, the impact test was repeated thrice. The electromagnet was used to control the release of the impact ram in order to concentrate the force over a smaller area and ensure a correct distance (50 cm) with the target (Figure 1-1). All tests were conducted in an air-conditioned room at 25°C.

	Weight (g)	Hardness
Steel ball	172.5	*
Baseball	147.3	82.5
Softball	197.4	79.5
G. hockey	176.6	91.5
Ice hockey	164.9	83.5
Cricket	160.9	91.9
Wooden bat	199.8	98.5

Figure 1-2. Impact Object. Seven types of mobile impact objects were selected for testing: (a) steel ball, (b) baseball, (c) softball, (d) field hockey ball, (e) ice hockcy puck, (f) cricket ball, and (g) wooden bat.

Measured mechanical forces were amplified with a Strain Amplifier (Kyowa DPM-712B) and then converted into an electric output voltage and stored as data in an Oscillographic Recorder (Kyowa RDM-200 A, Kyowa Electronic Instruments Co. Ltd, Tokyo, Japan), and analyzed with a personal computer (PC-SJ145V: Sharp Co. Ltd, Tokyo, Japan). The data were processed with Tooth Piece (Amisystem Co. Ltd, Tokyo, Japan). Figure 1-3 illustrates the measured heights of an impact response of the first wave as a peak transmitted force (or a maximum impact power). Means and standard deviations were calculated for each variable evaluated. Statistical comparisons were made using Student's t-test and a one-way analysis of variance (ANOVA) test followed by Tukey multiple comparison tests for further comparisons between sensors and impact objects using SPSSR (SPSS Japan Inc., Tokyo).

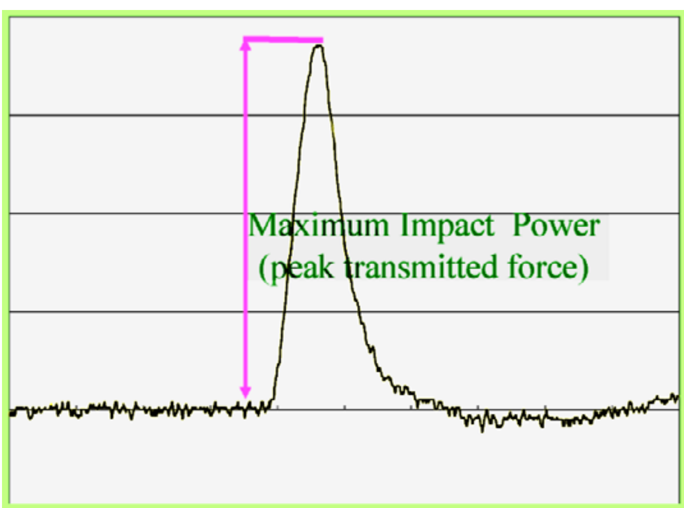


Figure 1-3. It measured that a height of an impact response of the first wave as a peak transmitted force (or a maximum impact power.)

RESULTS

Impact Object Differences and Peak Transmitted Force without Mouthguard

The waveform

The waveforms of the forces transmitted from various objects are illustrated in Figure 1-4(A-G). The waveforms for the steel ball and wooden bat were sharp and strong compared with those of the other tested objects.

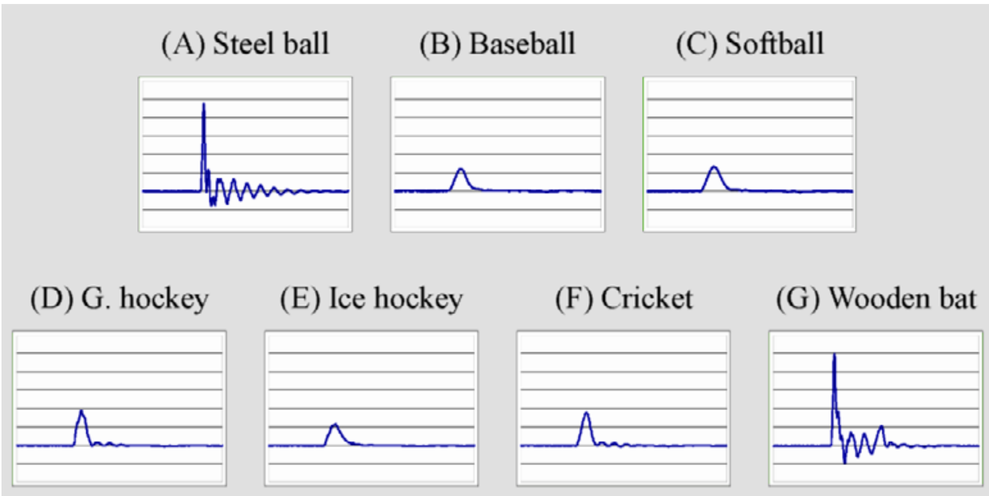


Figure 1-4. As for the steel ball and wooden bat, the waveforms without mouthguards were sharp and strong compared with that of the other impact objects.

Peak transmitted force

Peak transmitted forces of the seven different impact objects without mouthguard protection are shown in Figure 1-5 (the left white column). The peak transmitted forces ranged from the smallest ice hockey (46.9 kgf) to the biggest steel ball (481.6 kgf). The maximum energy transmitted from the steel ball and wooden bat were similar and were very different from all the other objects tested. Statistical analysis (ANOVA) showed significant differences between the seven impact objects ($P < 0.01$). A significant difference was found with all the combinations. (Tukey test, $P < 0.05$). Thus, the difference of impact object influenced the peak transmitted force.

The Effect of the Impact Object on Mouthguard Shock Absorption

The waveforms

The waveforms of the transmitted force of each impact object with mouthguards are illustrated in Figure 1-6(A-G). The waveform for a steel ball and wooden bat with a mouthguard was sharper and stronger with a longer duration and lower value compared to testing without a mouthguard (Figure 1-4). On the other hand, the tendencies seen for the steel ball and wooden bat were not as clear for the other balls and puck. Thus, the type of impact object used influenced shock absorption ability of the mouthguard.

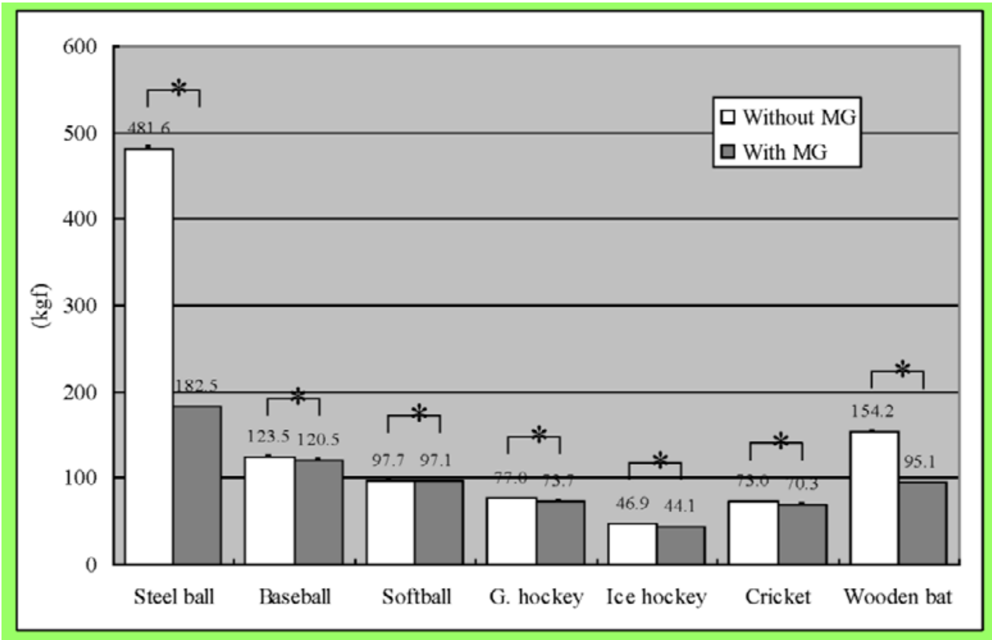


Figure 1-5. The peak transmitted forces were ranged from smallest ice hockey (46.9kgf) to the biggest steel ball (481-6 kgf) impact objects. The peak transmitted forces were smaller when the mouthguard was attached then when it was removed for all impact materials. But the tendency was strong at the steel ball and at the wooden bat. Thus, the mouthguard showed the shock absorption capacity regardless of impact object, and the impact equipment influenced the shock absorption ability strongly.

The peak transmitted forces

The peak transmitted forces of seven different impact objects with mouthguard are shown in Figure 1-5 (gray column) with the results for the t-test indicated by asterisks. The peak transmitted force was significantly smaller when a mouthguard was attached than when it was removed for all impact materials. However, the tendency was stronger when the steel ball and the wooden bat were tested.

The impact absorption rate (%)

The impact absorption ability by wearing the mouthguard is shown in Figure 1-7. The steel ball showed 61.3% and the wooden bat 38.3% of absorption compared to 0.7-6.0% with the other balls or puck (Figure 1-7). Statistical analysis (ANOVA) showed significant differences between the seven impact objects ($P < 0.01$). No significant difference was found between field hockey and cricket (Tukey test, $P < 0.05$). Thus, the absorption ability appeared to be the highest with the steel ball and wooden bat compared to the others.

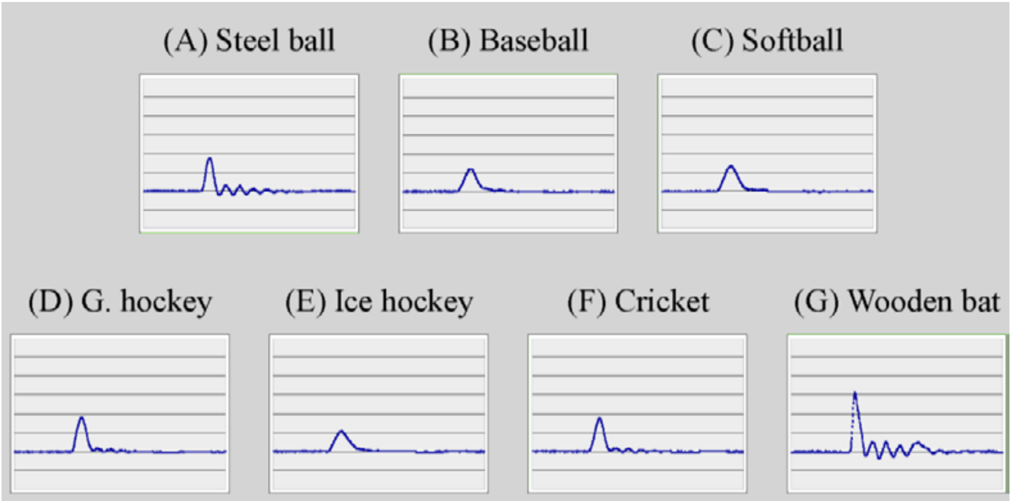


Figure 1-6. When looking at the effect of the mouthguard, the waveform of the steel ball with the mouthguard was flatter, weaker, and duration is longer compared to that without mouthguard (Fig. 4); and the wooden bat showed the approximate same tendency as the steel ball, even though the mouthguard's effect was small. On the other hand the effects were not so clear as the steel ball and wooden bat for the other objects.

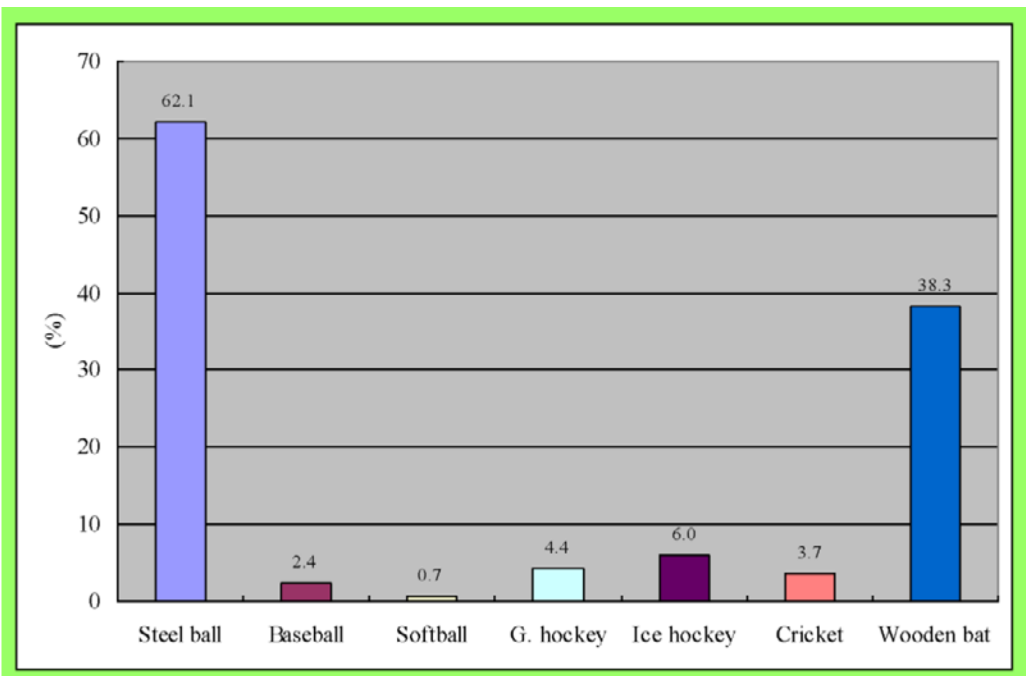


Figure 1-7. The steel ball showed the biggest (62.1%) absorption ability. The wooden bat showed the second biggest (38.3%); on the other hand, the absorption ability for the other balls went from 0.7 to 6.0%.

DISCUSSION

When an impact force is applied to a human body, there are two possible results. If the energy (momentum) is not big enough to damage the body, it is consumed as heat energy by the body. However, if the energy is large, it changes to a destructive energy which causes damage to the soft tissue, dislocations and the fracture of teeth, bone, etc. In sports, trauma occurs when the impact power exceeds the physical resistance of the player. Impact power is provided by collision with other players, the object used to play the sport, a fall on the floor, ground, or road, etc.

The most effective way of reducing orofacial injuries is to minimize the impact power on the athlete. Thus, in order to fabricate mouthguards suitable to each sport, the mouthguard must be designed to have enough impact absorption ability to limit the impact force unique to each sport. Though most research into the damping effect of mouthguard material and mouthguards have used the drop-ball or the pendulum-testing methods with steel ball as the impact. Exceptions include piston devices with plastic strikers attached at the end[60] to simulate an ice hockey puck[70], or hardwood impact objects[65], or simulated boot studs used in field sports [26]. However, mobile objects such as balls, pucks, and bats are more frequently associated with sports injuries than those stationary equipment made of steel. Therefore, the purpose of this study was to simulate the effect of different impact objects, as would be found in real sports situations involving real impact forces and to clarify the damping effect of mouthguards for each.

After reviewing the results, we see the influence of different impact objects on the impact energy. The waveforms recorded at the time of impact were sharp, high, and short in duration after the tests with a steel ball and wooden bat in contrast with various balls or pucks, where the waveform was not sharp and was rather low.

When viewing the waveform in relation to the effect of the mouthguards, it was noted that the height decreased when the steel ball and the wooden bat were tested. Moreover, the duration was extended and a flattening was observed and the height decreased with the steel ball and the wooden bat. Changes were not as dramatic as other types of balls or hockey puck.

Overall, mouthguards were effective in reducing the impact force of all impact objects; however, the effect depended enormously on the differences of each impact object. The impact absorption percentage of the steel ball (61.3%) and bat (38.3%) was vastly different compared to the other object tested (2.4-6.0%). Even though the method we used for the steel ball was slightly different, our results were comparable to those of Going et al. [22] (45.0-57.4%) and Park et al. [25] (50.4%) who used steel impact objects.

Thus, impact responses (impact power and impact absorption ability) are greatly influenced by the differences of the impact object used.

Weight appeared to play a minor role in impact energy, as we used and comparatively light steel ball of 168 kg and the wooden bat was not heavy. It appears that the impact energy and impact absorption ability is influenced by the hardness of the impact object explaining the high values resulting from the steel ball and wooden bat.

Our results are similar to Cummins & Spears [58], although our explanation of the results are different. Cummins & Spears[58] argued that low-stiffness guards (9 MPa) were representative of the common choices for materials used in mouthguard fabrication to absorb shock during hard object collisions (e.g. baseball), and may not protect the teeth or bones during soft object collisions (e.g. using boxing gloves)[75]. However, a few problems exist in making the assumption that the baseball is representative of all types of sports equipment stiffness. A substantial impact absorption ability was shown compared to other tests performed using the steel ball and wooden bat. It is easily understood in this report that 'When the material in both the object and the target are hard and difficult to transform, the mouthguard or damping material is very effective [75].

When the response of the impact is different from these results, the action (mechanism) to the body is also different. Therefore, mouthguards should be designed to control such forces[50]. Satoh reported [50] that when a sharp impact force is being exerted, the power acts near the point of the impact. Destruction will then take place in the very region the impact has occurred. On the other hand, when the impact is slow acting (a blunt impact); the likely destruction will happen to weaker regions such as the angle of the mandible, the neck of the ramus or around the impacted third molar. When a slow acting, blunt impact is applied to a body the force is distributed over the surrounding impact area (such as the mandibular complex). As this occurs, destruction takes place at the weakest point unable to endure the pressure.

The research of others [58] [73] has suggested that hard object collisions are more likely to cause fractures in impact zones. In contrast, collisions with soft objects are more likely to cause fractures away from the impact zone. In short, the process of fracture initiation is likely to differ depending on the type collision. That is, it is expected that in collisions with stiff objects, tooth fractures and direct bone fractures might occur at the point of impact. On the other hand, in sports dislocation of a tooth, an indirect bone fracture and or cerebral concussions often seem to occur, where there is a possibility of colliding with a comparatively soft ball or the ground when a player falls (from horseback or bike) or tumbles or makes contact with another player.

The results of the present study suggest that in collisions with stiff objects, the effectiveness of present-day mouthguards is remarkable. In sports that use goalposts or pointed spikes with almost the same hardness of a steel ball such as in soccer or the use of sticks or rackets such as in ice/field hockey, tennis or lacrosse, all with the approximate hardness of a strong wooden bat, it is necessary to use a mouthguard with high impact absorption ability as in contact sports.

CONCLUSION

It was found that mouthguards could reduce impact stress regardless of the impact object used. However, the mouthguards' shock absorption abilities varied depending on different impact materials. The impact absorption ability was the greatest in the steel ball and the wooden bat tests in the hard object collision category.

The results of this study indicate the need to select various impact objects for evaluation in conjunction with the shock absorption abilities of mouthguards in order to select appropriate materials for making mouthguards that are suitable for each sport. These results support the idea of establishing a set of standards for the manner in which one needs to evaluate the impact absorption ability of mouthguard material.

STUDY NO.2: IN SEARCH OF NECESSARY MOUTHGUARD THICKNESS. PART 1: FROM THE VIEWPOINT OF SHOCK ABSORPTION ABILITY.

The original article [35]

ABSTRACT

To date, the minimum thickness required for a mouthguard has been assumed to be around 2 mm to 4 mm. However, this figure is based mostly on experience and is yet to be standardized. The purpose of this study is to determine the minimum thickness required to obtain sufficient energy absorption. The thicknesses of the tested ethylene vinyl acetate) samples were 1, 2, 3, 4, 5, and 6 mm. The pendulum-type testing equipment used in the present study was also used in a series of earlier studies. Three types of sensors (strain gauge, accelerator, and load cell) and two different impact objects (a steel ball and baseball) were used. The results showed that all the abovementioned mouthguard thicknesses reduced shocks for all the three types of sensors and both types of impact objects; little difference was observed between sensors and clear results were obtained for the steel ball. An improvement in the energy absorption was observed with an initial increase in the thickness. However, a further increase in the thickness from 4 mm to 5 mm and 6 mm tended to yield a smaller improvement in energy absorption. Within the limitations of this study, from the view point of energy absorption ability, the minimum thickness required for a mouthguard is 4 mm, which is generally too large from the viewpoint of player comfort

INTRODUCTION

The most important function of a mouthguard is to absorb and spread the impact energy during sporting activities to reduce orofacial damage such as injuries to soft tissues and the temporomandibular joint, tooth fracture, tooth displacement, bone fracture, and concussion.[22, 23, 25-27, 29, 55, 57, 62, 64, 67-69, 74] These injuries occur in not only high-risk contact or collision sports such as rugby, ice hockey, and American football, but also in noncontact sports such as soccer, basketball, and baseball.[15-17, 76-78] Therefore, sports dentists believe that athletes should wear a mouthguard. Indeed, the use of mouthguards appears to be gradually spreading. However, sports injuries such as those mentioned above are still common.

The quality of the mouthguard, especially the thickness of the labial and occlusal surfaces, appears to be closely related to these issues. The impact absorption ability of a mouthguard is believed to be proportional to its thickness. Therefore, it is necessary to make the mouthguard sufficiently thick to prevent an injury, taking into consideration the impact absorption ability of the material used, the type and level of sports, age of player, wearer comfort and acceptance, free space, and economic issues. To date, the minimum thickness required has been assumed to be around 2 mm to 4 mm. However, this figure is based mostly on experience and is yet to be standardized. It is important to note that the relationship between thickness and impact absorption ability remains to be clarified.[69]

The purpose of this study was to determine the minimum mouthguard thickness required for obtaining sufficient energy absorption by using three types of sensors16 (strain gauge, accelerator, and load cell) and two different impact objects15 (a steel ball and baseball). The pendulum-type testing equipment used in the present study was also used in a series of earlier studies.[29, 55, 79, 80]

METHODS

The method is almost the same, excluding test samples' condition, as the research of the impact object [55] previously described. The mouthguard blanks and the air pressure machine used were same. The test samples thickness were finally adjusted to 1, 2, 3, 4, 5, and 6 mm (hereafter referred to as 1 mmMG, 2 mmMG, 3 mmMG, 4 mmMG, 5 mmMG, and 6 mmMG). Three samples were prepared for each thickness as well.

RESULTS

1. Comparison of Waveforms with and without Mouthguard

The waveforms obtained for 3 mmMG and NO MG (without mouthguard as control) with the steel ball are shown as representative examples in Figure 2-1.

With a mouthguard, the waveforms became smooth, regardless of the sensor or impact object. However, absorbency with the steel ball was clearer than that with the baseball.

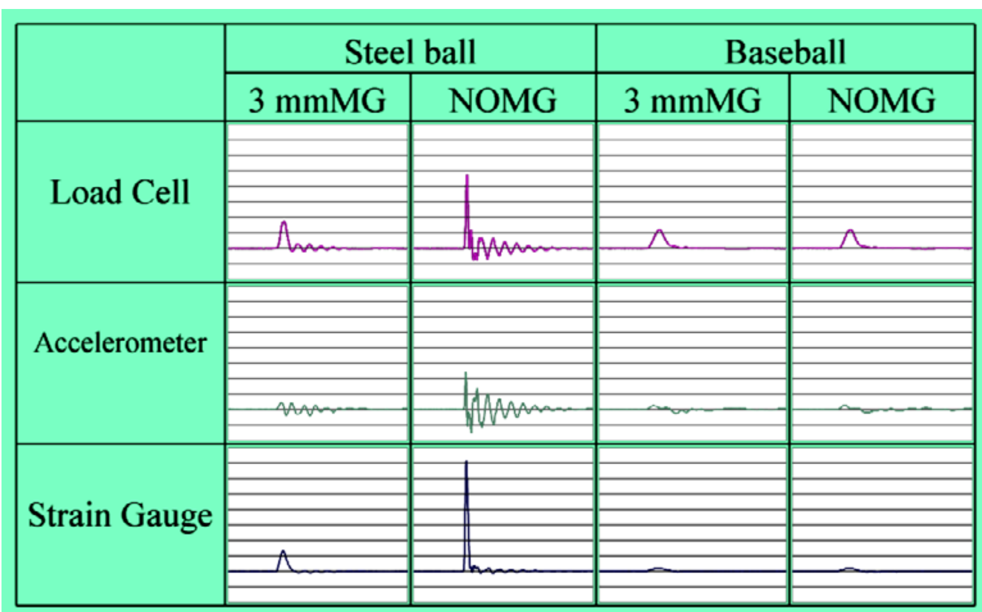


Figure 2-1. Comparision of waveforms with and without mouthguard. With mouthguard, waveforms became smooth, regardless of sensor or impact object. However, absorbency of a steel ball was clearer than that of a baseball.

2. Impact Forces for Three Different Sensors with or without Mouthguard (1–6 mm)

The impact forces and absorption abilities (%) registered by the three different sensors with and without a mouthguard are shown in Figure 2-2 to7.

With the steel ball, the mouthguard decreased the impact force, regardless of its thickness or the type of sensor. This effect appeared to be enhanced as the thickness increased: 2 mmMG showed an energy-absorbing ability of 50% or more in all the sensors and 3 mmMG showed an approximately 70% absorbency in load and strain and an approximately 85% absorbency in acceleration. However, a further increase in the mouthguard thickness from 4 mm to 5 mm and 6 mm showed a smaller improvement in the energy absorption (load: from 73% to 75%; acceleration: from approximately 88% to 90%), except for the strain. Statistical analysis (ANOVA) revealed significant differences between NO MG and the six different mouthguards ($p < 0.01$). Significant differences were found for all the combinations, except for combinations between 4 mmMG and 5 mmMG (load) and between 4 mmMG, 5 mmMG, and 6 mmMG (acceleration) (Tukey test).

With the baseball also, all the mouthguards decreased the impact force, regardless of their thickness or the type of sensor. However, the decrease was small and unclear compared with that for the steel ball. 2 mmMG showed an approximately 4% absorbency in load and strain and an approximately 22% absorbency in acceleration; 3 mmMG showed approximately 11% absorbency in load, approximately 23% absorbency in acceleration, and approximately 5% absorbency in strain. A further increase in the mouthguard material thick-ness from 4 mm to 5 mm and 6 mm showed a smaller improvement in the energy absorption (load: from approximately 12% to 14%; acceleration: from approximately 23% to 26%, except for the strain. Statistical analysis (ANOVA) revealed significant differences between NO MG and the six different mouthguards ($p < 0.01$). Significant differences were found between NO MG and many mouthguard thicknesses, except for 1 mmMG (load) and 1 and 2 mmMG (strain). Significant differences were also found among 4 mmMG, 5 mmMG, and 6 mmMG with regard to the strain, whereas no significant differences were found among 4 mmMG, 5 mmMG, and 6 mmMG with regard to the load and acceleration (Tukey test).

DISCUSSION

The results showed that all the thicknesses mouthguards reduced shocks according to the type of sensor and for both types of impact objects, with little difference between sensors and clearer results for the steel ball. An improvement in the energy absorption was initially observed with an increase in the thickness. However, a further increase in the thickness from 4 mm to 5 mm and 6 mm tended to yield a smaller improvement in the energy absorption, except for strain measurements. This indicates that from the viewpoint of the energy absorption ability only, the necessary thickness is 4 mm.

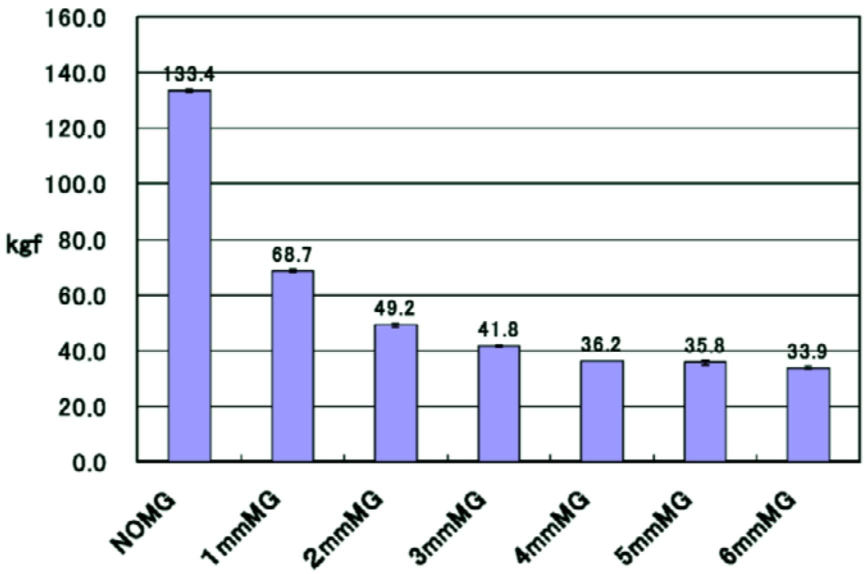


Figure 2-2. Impact forces and absorption abilities for steel ball (load). Mouthguard decresed the impact force, regardless of thickness. This effect appeared to be enhanced as the thickness increased. However, futher increase in mouthguard thickness fom 4 mm to 5 mm and 6 mm showed small improvement in energy absorption.

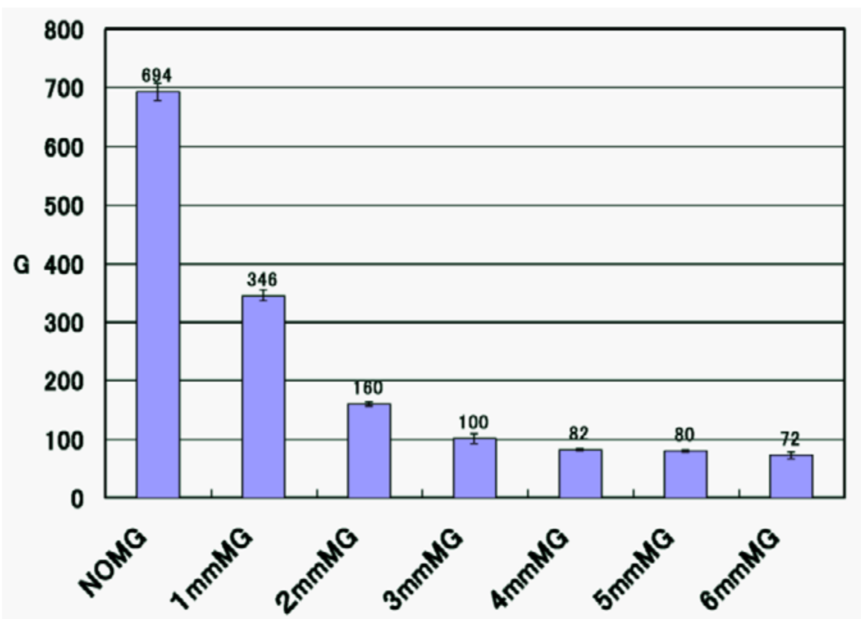


Figure 2-3. Impact forces and absorption abilities for steel ball (acceleration). Acceleration of steel ball showed almost the same tendency as its load result.

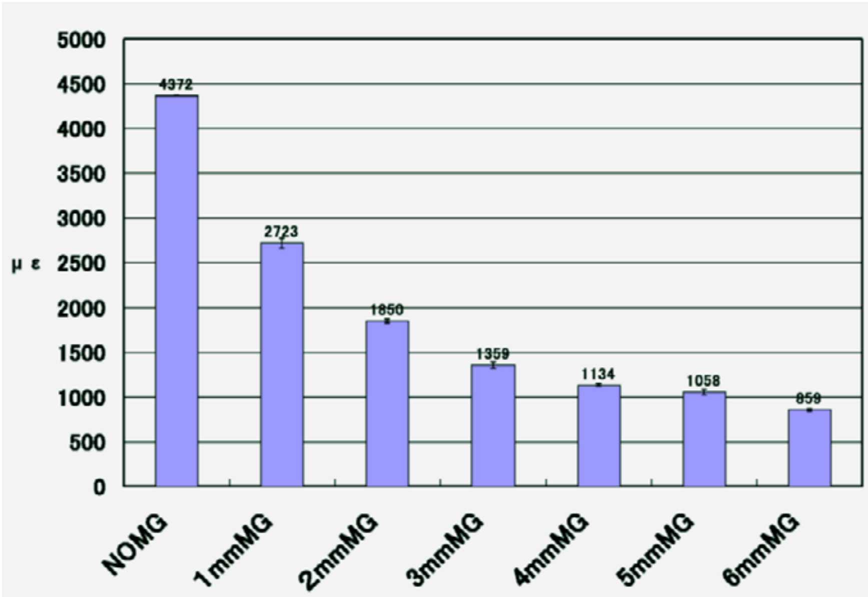


Figure 2-4. Impact forces and absorption abilities for steel ball (strain). Strain of steel ball showed almost the same tendency as load and acceleration until 3 mm thickness.

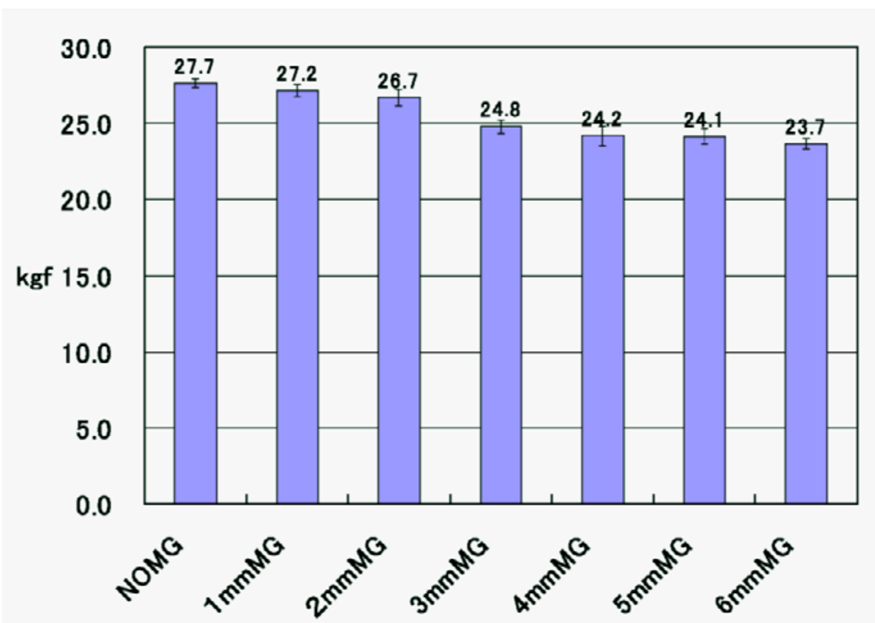


Figure 2-5. Impact forces and absorption abilities for baseball (load). All the mouthguards decresed the impact force, regardless of thickness. However, the effect for the baseball was smaller and unclear as compared with that for the steel ball. Futher increase in mouthguard thickness fom 4 mm to 5 mm and 6 mm showed smaller improvement in energy absorption.

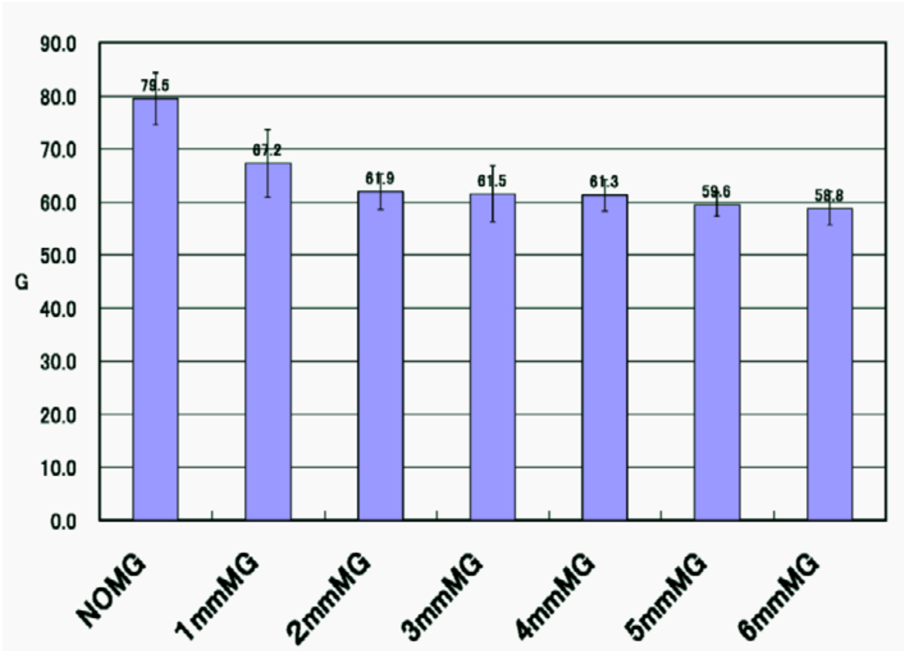


Figure 2-6. Impact forces and absorption abilities for baseball (acceleration). Acceleration of baseball showed almost the same tendency as its load result.

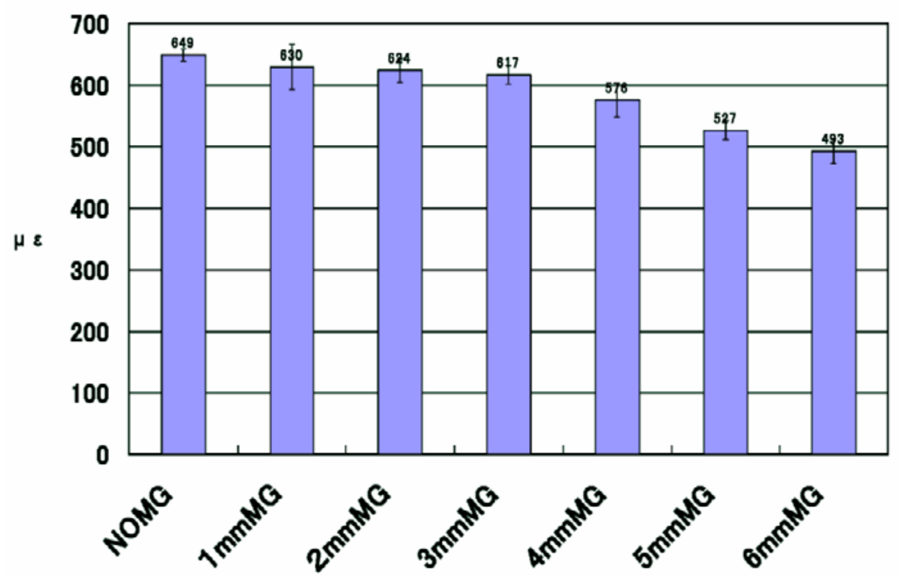


Figure 2-7. Impact forces and absorption abilities for baseball (strain). Strain of baseball showed almost the same tendency as load and acceleration until 3 mm thickness.

These results support those of previous studies.[57, 68, 69, 72, 74] The result for 2 mm, in particular, was the same as that obtained by Yamamoto et al, although the value was larger than that obtained by Maeda et al.5 Such differences may have originated from differences in the magnitude of the impact force used and the experimental method. The lack of major changes for the thickness of 4 mm or more was in accordance with the report of Westerman et al.[69] Clearer results were observed with the steel ball. This was easily explained by the results of an earlier report showing that when both the object and target are hard, making deformation difficult, a mouthguard or damping material is very effective.[75] One report indicated that although low-stiffness (9 MPa) guards (the type most commonly used) absorb shocks during hard-object collisions (e.g., baseballs), they might not protect the tooth bone during soft-object collisions (e.g., boxing gloves).[79] Mouthguards offer greater protection against a hard-object impact as compared to a soft-object impact.[55] In this study, no significant difference was found among 4 mmMG, 5 mmMG, and 6 mmMG with regard to the strain. This result may be explained by a study [29] that showed that a strain gauge was suitable and highly sensitive for measuring the absorbency at the impact point.

An impact is believed to be the force applied to a target, and the speed of the impact changes rapidly within a short interval of time. Generally, the force is strong and the duration of impact is short. The momentum is invariable, both before and after the impact. Therefore, when an impact force is applied to a human body, there are two different results. If the energy (momentum) is not sufficiently large to damage the body, it is consumed as heat energy by the viscosity of the joints or other soft tissues. On the other hand, if the energy is sufficiently large to cause damage, it becomes destructive, damaging soft tissues and dislocating and fracturing teeth and bones.[50]

It is believed that sports traumas occur when the impact power exceeds the physical resistance of a player to a collision with another player, floor, road, or event facilities. Therefore, to reduce orofacial injuries, it is best to minimize the impact power reaching the athlete.

The results of this study showing that the impact absorption increased with the mouthguard thickness agree with those of a study that suggested the minimum required thickness to be 4 mm.[69] However, it is difficult to provide a thickness of 4 mm to the labial aspect and occlusal surface of a mouthguard as the thickness is often a compromise between the shock absorption ability and wearer comfort. Thick mouthguards are often met with player resistance due to discomfort, speech interference, and respiratory restrictions.[81] Therefore, a thickness of 4 mm might not be user friendly.

The lips and cheeks protect the teeth from direct impact forces. Therefore, a mouthguard that is so thick that the lips cannot close the mouth is dangerous. Moreover, a thick mouthguard considerably increases the tension between the lips and the cheeks. Therefore, there is a danger of increasing the chances of an injury. The interocclusal space in the mandibular rest position ranges from 2 to 3 mm in general. Therefore, 4 mm is too large and would also be unsuitable neurophysiologically.

This suggests that it is necessary to improve the impact absorption ability through improvements in the design of the mouthguard. Many studies [27, 57, 59, 66, 67, 80] have investigated the improvement in the impact absorption ability resulting from the use of intermediate layers or an improvement in the mouthguard material itself. All these studies have insisted that the impact absorption ability of the mouthguard was improved by these methods.

These methods included the use of a modified 4-mm-thick EVA mouthguard incorporating air cells, which reduced the transmission of forces by 32% as compared with the traditional EVA mouthguards of the same thickness;[68] an intermediate layer of Sorbothane, which reduced the peak force significantly;[57] a half-round arch wire embedded in a double-layer EVA mouthguard, which was the most efficient;[66] a bilaminated mouthguard with a piece of sponge as an intermediate layer, which showed the highest shock absorption (49%);[59] the insertion of hard layers of EVA, which reduced energy absorption when compared with a control sheet of EVA without a hard insert;[82] and a specially designed three-layer custom-formed protector comprising a rigid outer layer of polycarbonate and an inner layer of EVA with an approximately 1-mm-wide space between the protector and the anterior teeth, which absorbed a large part of the impact energy. [80] showed that a three-layer-type mouthguard with an acrylic resin inner layer offered a large buffer capacity and furthermore that a similar type of mouthguard but with a space preventing contact with the tooth surface had a significantly greater buffer capacity than a conventional mouthguard.

Moreover, it is necessary to improve impact absorption by developing new materials. EVA materials are the most commonly used in the manufacture of both mouth-formed and custom-made mouthguards. Being nontoxic and easy to use, it has become widely accepted as a mouthguard material. However, there appears to be scope for further improvement. Materials believed to improve energy absorption by using polyolefin and polystyrene and by foaming of EVA have been marketed in Japan (sales discontinued at present) and the USA, respectively. Although these new materials are believed to result in improvement in energy absorption a detailed study remains to be performed.

Many players use too thin mouthguards, which are inadequate from the point of view of safety. Mouthguards are divided into two categories according to the method of manufacture. One type is mouth formed and the other is custom-made. Users manufacture the mouth-formed type by themselves. On the other hand, dentists or dental technicians fashion the custom-made type from plaster models obtained from the athlete. The differences between the two types, not only in terms of wearer comfort and adaptability, but also in terms of protective capacity, are apparent. The thickness of the mouthguard decreases during manufacture for the boil-and-bite type, from 70% at the labial surface to 99% at the occlusal surface.[25] This type often lacks a sufficient thickness. Therefore, sports dentists should do their best to discourage players from using the mouth-formed type. In addition, the thickness of finished custom-made mouthguards is also influenced by the fabrication method and heating and stretching on pull-down. The thickness of a vacuum-type mouthguard decreases from 25% to 50% during fabrication.[25] With this type, 3-mm or 4-mm blanks are commonly used, and the finished mouthguards are usually planed, resulting in insufficient protection. Therefore, candidates for this type should be selected with care. However, the pressure-laminated type allows the adjustment of the thickness since it possesses extra lamination.[82] [83] [84]These issues along with related issues should be taken into account when fabricating and recommending mouthguards.

Therefore, it is necessary to consider player comfort in addition to the energy absorption ability when determining the thickness required for a mouthguard. Thicker mouthguards are often criticized for lip and cheek displacements, speech interference, and respiratory restriction. At the same time, thin mouthguards are well accepted by players, but are less efficient. The results of the present study show that 2 mm and 3 mmMG had considerable energy absorption ability, especially against the steel ball. Currently, a thickness of 2 mm or 3 mm is recommended for conventional type custom-made mouthguards when using EVA material. However, it is necessary to improve the impact absorption ability by improving designs and developing new materials.

CONCLUSION

Within the limitations of this study, the following results were obtained:

1. The tested EVA mouthguards with different thicknesses (1–6 mm) showed shock absorption ability according to the type of sensor and for both types of impact objects, with few differences between sensors and clearer results for the steel ball.
2. An improvement in the energy absorption was observed with an initial increase in the thickness. However, a further increase in the thickness to over 4 mm yielded a smaller improvement in the energy absorption.
3. These results suggest that from the viewpoint of the energy absorption ability, the minimum thickness required to obtain sufficient energy absorption is 4 mm, but which is generally too thick from the viewpoint of player comfort. This finding indicates the necessity of improving the impact absorption ability of mouthguards by considering the design and developing new materials.

STUDY NO.3: ARE ALL MOUTHGUARDS THE SAME AND SAFE TO USE? PART 2. THE INFLUENCE OF ANTERIOR OCCLUSION AGAINST A DIRECT IMPACT ON MAXILLARY INCISORS.

The original article [79]

ABSTRACT

The purpose of this study was to clarify the influence anterior occlusion, of mouthguards, has on protecting against a direct collision to the maxillary anterior teeth. In other words, the support mandibular dentition has when wearing a mouthguard. Two types of mouthguards were used for this study, one with an appropriate anterior occlusion or a mouthguard with positive anterior occlusion (MGAO+) and another which was a single-layer mouthguard lacking the same occlusion or a mouthguard with negative anterior occlusion (MGAO-) but with the same thickness on the buccal side. The instruments used for testing were a pendulum-type impact device with two interchangeable impact objects (a steel ball and a baseball), with a plastic jaw model having artificial teeth. Four testing conditions were observed: one with the jaw open without a mouthguard (Open NoMG), the second with the jaw clenching (loaded with 30 kg weight) without a mouthguard (Clench. NoMG), the third with the jaw clenching with MGAO-) (Clench. MGAO-)) and the last with the jaw clenching with MGAO+ (Clench. MGAO+). The results are as follows: both types of mouthguards showed the effects in reducing the distortion of the teeth. However, the effect was significantly obvious (steel ball = about 57% shock absorption ability, baseball = about 26%) in the mouthguard with anterior occlusion or support by lower dentition through mouthguard (Clench. MGAO+)

than Clench. MGAO-). Thus, the influence of anterior occlusion of mouthguards or the support of mandibular dentition through the mouthguard (MGAO+) is indispensable in reducing the impact force and tooth distortion. The results of this research should further contribute to the establishment of guidelines for safer mouthguards.

INTRODUCTION

It is well known that approximately 90% or more of orofacial injuries involve the incisors of the maxilla [13, 15-17, 76]. The injury prevention characteristics of mouthguards against frequent injures, which are often caused by a direct blow to the teeth, have three factors that are thought to be effective: first, the impact absorption or dissipation effects through the mouthguard material itself, which covers the maxillary incisors' buccal surface (mandibular incisors when a mouthguard is used in mandibular for severe mandibular protrusion cases); secondly, the reinforcement effect of the mouthguard material covering the lingual surface of the maxillary incisors; and thirdly, the support of the maxillary teeth, dentitions and the alveolar bones by the mandibular dentition through the mouthguard. This third effect can be achieved only when mouthguards have a fully balanced occlusion and used while clenching as one of the action of a risk hedge. Thus, there might be a problem in the injury prevention effects of commonly used mouthguards, as many of them being used now are the boil and bite types made by the players themselves, so a maximum degree of safety cannot be achieved using such a method. In other words, a custom-fit type or vacuum-type mouthguards do not necessarily provide appropriate occlusion, especially, when players have malocclusion such as an elongated molar or premolar tooth, an open bite, a large overjet or maxillary protrusion, etc. Therefore, in these cases, only mouthguard material added onto the lingual side will provide a third preventive effect, achieved by having an appropriate full balanced occlusion.

However, former studies, concerning the mouthguards' impact absorption ability, have not placed importance on how effective it is. Thus, the purpose of the present study is to clarify the influence of anterior occlusion (a fully balanced occlusion) of mouthguards, or the support of mandibular dentition through mouthguards, on safety against a direct impact force applied to the maxillary anterior teeth's buccal surface. In this study, two types of mouthguards were used, one with the appropriate anterior occlusion and the other with a commonly used one-layer-type mouthguard without appropriate occlusion but with the same thickness against the buccal sides. The testing equipment used in this study consisted of a pendulum impact testing device used in a series of studies [29, 55] and the plastic jaw model with artificial teeth. Because various impact objects influence the shock power and shock absorption ability differently, two impact objects, a steel ball with sharp impact power and a higher energy-absorbing baseball with dull impact power and a lower energy-absorbing rate [29, 55], were used. It is hoped that the results of this research will further contribute to the establishment of guidelines for the design of safer mouthguards.

MATERIAL AND METHODS

The pendulum device apparatus [29, 55] was used to make an applied impact force equal in each impact object (Figure 3-1). Two mobile impact objects were selected for tests: a steel ball and a baseball. The apparatus was adjusted to hit the central surface of the right central incisor of an artificial jaw model (D18D-500H; Nisshin, Co., Ltd, Tokyo, Japan) at a bottom point. Consequently, impact forces were transmitted to acrylic resin teeth themselves or reduced by ethylene vinyl acetate (EVA) mouthguards, which were measured with a strain gage fixed on the buccal cervical aspect of the impacted tooth (Figure 3-1). Measured mechanical forces, by means of the strain gage, were amplified, converted and analyzed with the same methods of previously mentioned two tests[55] [35].

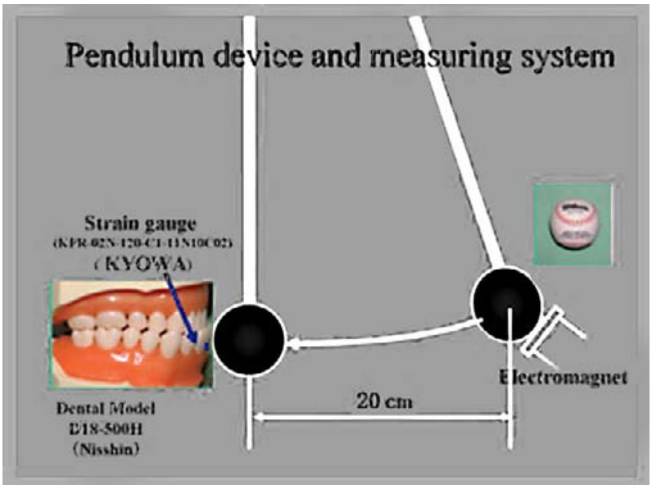


Figure 3-1. Specially designed device to mesuer the shock absorption ability of mouthguards.

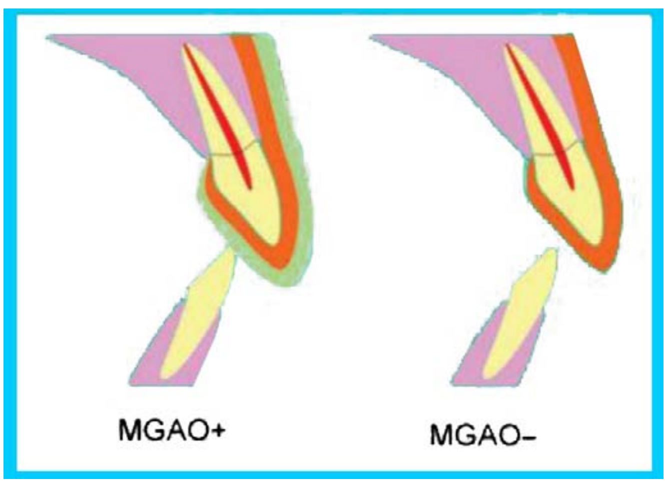


Figure 3-2. Left; Mouthguards with proper anterior occlusion (or the occlusion with support by the mandibular front teeth through the mouthguard = MGAO+). Right: mouthguard without those of occlusion or support MGAO -)).

Mouthguard blanks used were Drufosoft (Dreve-Dentamid GMBH, Unna, Germany) with 3-mm thickness. Two types of mouthguards were used as test samples: one was a two-layer type with proper anterior occlusion or with occlusal support of the mandibular front teeth through the use of a mouthguard, hereafter referred to as MGAO+ (Figure 3-2, left), and another was a one-layer type without occlusion or support [MGAO- (Figure 3-2, right)]. Both mouthguards were fabricated by means of a Dreve Drufomat (Type SO; Dreve-Dentamid) air pressure machine on a stone model impressed with an alginate material. Actual thicknesses of the buccal side at the impacted point for both the MGAO+ and MGAO- after adjustment were approximately 1.5 mm. Three mouthguards were made, and impact tests were carried out three times on each mouthguard.

Testing conditions were with the jaw open and without a mouthguard, as a control test (Open NoMG), with the jaw clenching (loaded by 30 kg weight) without a mouthguard (Clench. NoMG), with the jaw clenching with an MGAO- (Clench. MGAO-) and the jaw clenching with MGAO+ (Clench. MGAO+). To apply the weight, the model was mounted upside down (Figure 3-1).

The height of the first impact was analyzed as the transmitted force (or the maximum impact). Means and SDs were calculated for each variable evaluated. Statistical comparisons were made using a one-way analysis of variance (ANOVA) test followed by a Tukey multiple comparison tests for further comparisons between sensors and impact objects [$P < 0.05$, using spssR (SPSS Japan Inc., Tokyo, Japan)].

RESULTS

The maximum impact force of four different tests using a steel ball and a baseball records the distortion, as shown in Figures 3-3 and 3-4. The results of the distortion diminishing rate calculated against an Open NoMG as the control are also shown.

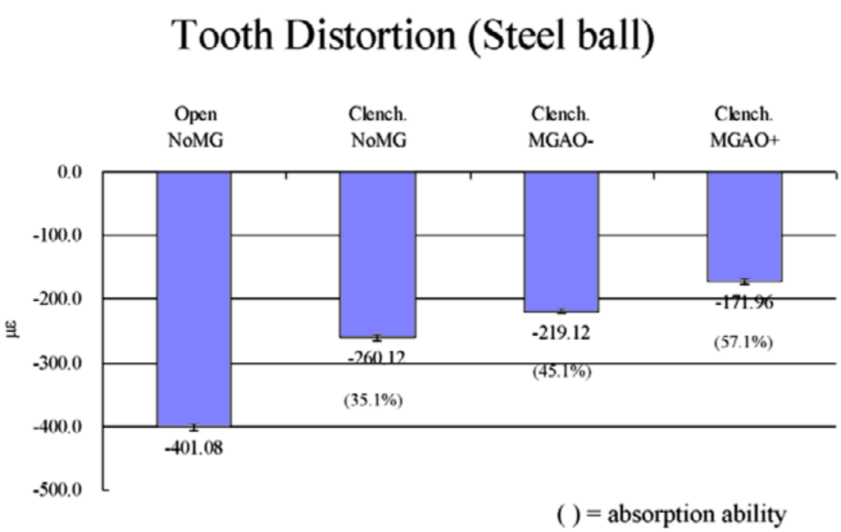


Figure 3-3. Tooth distortion occurred by the impact force of a steel ball: the effects of the mouthguard and clenching were admitted. The effect was obvious in the mouthguard with Clench. MGAO+.

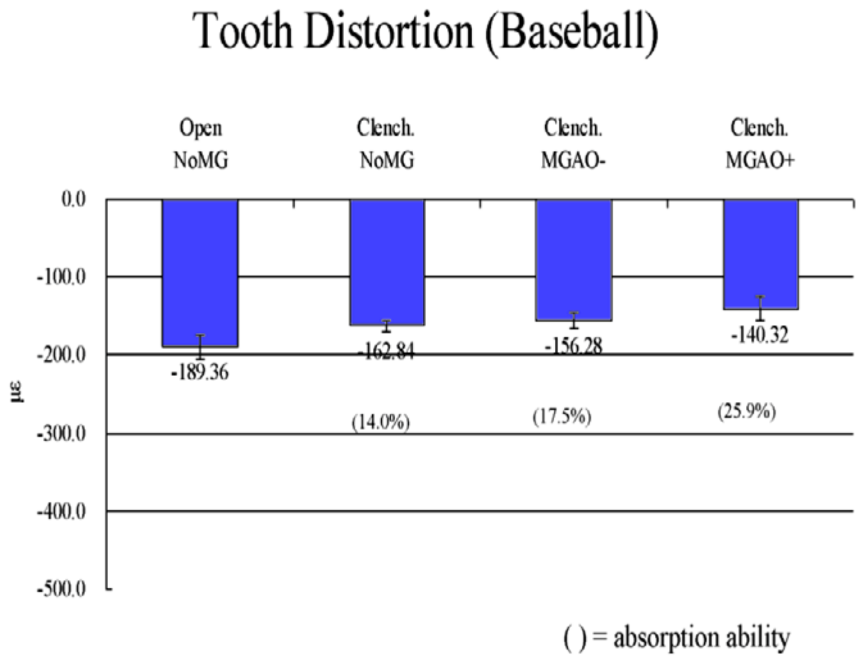


Figure 3-4. Tooth distortion occurred by the baseball impact: the effect was a little smaller compared with the steel ball, the tendency was almost the same.

In the steel ball, maximum 401.08 με was obtained with Open NoMG, and Clench. NoMG was 260.12 με (distortion diminishing rate is = 35.1%). The effect of the mouthguard was admitted even with Clench. MGAO- was 219.12 με (45.4%) and Clench. MGAO+ was 171.96 με (57.1%). In the baseball, maximum 189.36 με was obtained with Open NoMG, and Clench. NoMG was 164.32 με (14.0%). And Clench. MGAO- was 156.28 με (17.5%) and Clench. MGAO+ was 140.32 με (25.9%). Statistical analysis (ANOVA) showed differences in four tested conditions in both impact objects ($P < 0.05$). Furthermore, there were significant differences between all conditions except for between Clench. NoMG and Clench. MGAO- (Tukey multiple comparison test).

DISCUSSION

Most of the tests confirmed that the shock absorption ability of a mouthguard is proportional to its thickness. Therefore, it is the thickness, energy-absorption ability and how effective it is against a direct impact to the anterior teeth that determine its beneficial qualities.

On the other hand, it is thought that the insufficient occlusion of a mouthguard might cause mandibular bone fractures, which also reduces safety [79]. Problems associated with the occlusion of the mouthguard have not been considered deeply enough until now, especially based on the fact that many inexperienced players make their own mouthguards by themselves. With the market type currently available, to do this, it is difficult to give the mouthguard the appropriate occlusion needed. Moreover, even if the vacuum custom-made type with approximately 3-mm thickness was used, the material becomes thin by the heat and stretches during fabrication [25] So, an appropriate occlusion with enough anterior tooth contact cannot be established in all cases, especially, in the case where dentitions have severe open-bite or elongated teeth, etc. In addition, the lingual-side mouthguard material protecting the front teeth are often made extremely thin or removed intentionally so as not to restrict comfort, easiness to speak or breathe lately. In such a mouthguard, enough protective efficacies cannot be expected as mentioned above. However, up to now, this has not been examined, and as a result sufficient proof on how accurate and important anterior occlusion or the support of the mandibular dentition is through the mouthguard has not been explored. For this reason, such effects were examined in this study.

As for the distortion of the teeth, the effects of the mouthguard, with and without anterior occlusion (a fully balanced occlusion) of mouthguards, or the supports of mandibular dentition through mouthguards were investigated with both a steel ball and a baseball. The effect was most obvious (steel ball = about 57% shock absorption ability, baseball = about 26%) in clenching MGAO+ (the mouthguard with anterior occlusion or support by lower dentition through a mouthguard). Thus, the protective ability of the mouthguard showed an improvement with the support of the mandibular tooth through the mouthguard, irrespective of the hardness of the impact object.

Impact forces in sports should have enough power to cause injuries. A hockey puck, a 6-ounce piece of inch-thick rubber that can reach 120 mph and hit with an impact force of 1.250 lb (about 566 kgf) [85]. A baseball pitcher's fastball that can travel at more than 90 mph with a similar impact force. So it seems that a free-standing tooth or teeth in present alveolar bone fractures or other severe injuries occur easily. Also mouthguard material on the buccal surface could not always protect the teeth against injuries. Thus, to prevent the injury, it is important that the upper and lower dentitions are integrated with likewise condition of clench MGAO+ in the present study to distribute and absorb the impact power. In addition, it should be taken into consideration that the wearing a mouthguard could strengthen the occlusion force [86]. Namely, when players perceive danger, they should immediately clench with enough strength and with appropriate mouthguards to prevent injuries.

Moreover, the impact absorption ability of the mouthguard is thought to be affected by the differences in the impact objects' hardness, which is high in a hard impact object such as a steel ball, etc., although it is low in comparative terms to many soft balls, etc., commonly used in sports [29, 55]. Although few would disagree that low-stiffness guards absorb shock during hard-object collisions (e.g. baseballs), they may not protect the tooth and bone during soft-object collisions (e.g. using boxing gloves) [27]. So the effect against a soft object has been doubted. However, from the present results dealing with tooth distortion, the support of the mandibular tooth through the mouthguard (MGAO+) improved the effect of the mouthguard in a collision with a soft impact object, although the effect of the mouthguard with a softer baseball was smaller than that of a harder steel ball. In other words, an appropriate mouthguard with full balance occlusion had an injury prevention effect regardless of the impact object's hardness.

Therefore, to achieve enough protection, the mouthguard, in any dentition, must secure enough thickness for the maxillary front teeth lingual sides to establish sufficient occlusion (Figure 3-5). Additionally, considering previous reports [87, 88] that described the frequency, the range and the level of injuries became appalling as the overjet strengthened. An appropriate occlusal mouthguard as well as orthodontic treatment are strongly recommended for many cases with malalignment. In any case, it is important not to use the low safety market-type or the too thin one-layer vacuum-type mouthguard, which cannot secure anterior tooth occlusion if used (Figure 3-6).

Figure 3-5. To achieve enough protection, the mouthguard, in any dentition, must secure enough thickness for the maxiliary front teeth lingual sides to establish sufficient occlusion.

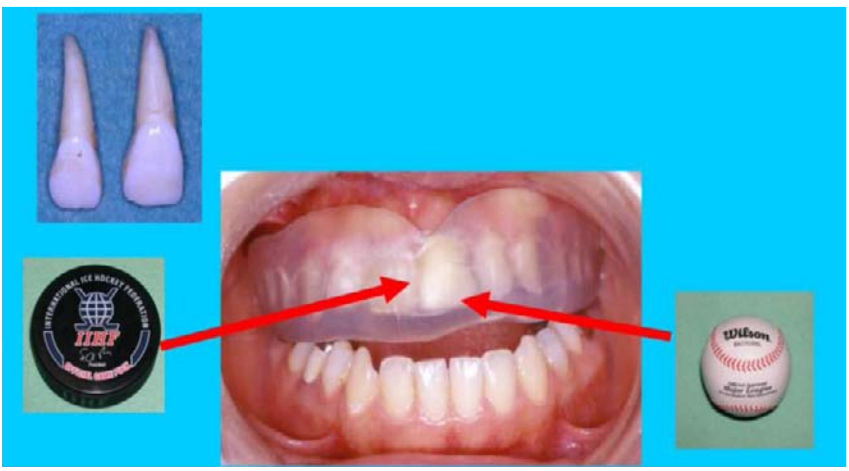


Figure 3-5. It is important not to use the low safety market type.

Although impractical for many sports, these kinds of injuries are preventable with a full-face guard such as in American football, boy's lacrosse, etc. If this is the case, then injuries from a direct blow can be prevented by using a face guard. Not surprisingly, the support of the mandibular teeth through the mouthguard is not necessarily essential for only these games. However, when teeth fractures happen by traumatic jaw closures, the mouthguard is still necessary to provide balanced occlusion for the posterior teeth [38].

CONCLUSION

To clarify the influence of anterior occlusion (achieved by full balanced occlusion) of the mouthguard or the support by mandibular dentition through mouthguard on safety against the direct impact force applied to the maxillary anterior teeth, two types of mouthguards were used in this study. One is with the appropriate anterior occlusion and the other was a single-layer type lacking the same degree of occlusion but with the same thickness on the buccal side. A pendulum-type impact testing device with two interchangeable impact objects and a plastic jaw model with artificial teeth were used.

As results, both types of mouthguards showed the effects in reducing the distortion of the teeth. However, the effect was significantly obvious in the mouthguard with anterior occlusion or support by lower dentition through mouthguard. Thus, the influence of anterior occlusion of mouthguards or the support of mandibular dentition through the mouthguard is indispensable in reducing the impact force and tooth distortion. The results of this research should further contribute to the establishment of guidelines for safer mouthguards.

STUDY NO.4 : A VACUUM TECHNIQUE TO INCREASE ANTERIOR THICKNESS OF ATHLETIC MOUTHGUARDS TO ACHIEVE A FULL-BALANCED OCCLUSION.

The original article [89]

ABSTRACT

A full-balanced occlusion is essential for mouthguards. It has been reported that a balanced occlusion for upper and lower anterior teeth is essential for prevention of injuries occurring to the maxillary anterior teeth and alveolar bone caused by horizontal direct impact. The support of the mandibular teeth through the mouthguard is critical to prevent maxillary front tooth injury from a direct impact force. However, some vacuum mouthguard designs may not achieve a full-balanced occlusion. For example: when a player has a malocclusion, an elongated molar or premolar tooth, an open bite, a large over jet or a maxillary protrusion. An improved vacuum fabrication method is necessary to obtain full balanced occlusion in these cases as opposed to conventional vacuum type single-layer mouthguard technique.

OUTLINE

The area where a balanced occlusion (especially in an anterior area) cannot be achieved by the conventional one-layer vacuum type mouthguard should be confirmed by examining the mounted casts. The first (additional) piece of EVA material is applied by using Erkostic (Erkodent, Pfalzgrafenweiler, Germany) and Gluefix 3002 (Steinel, Herzebrock-Clarhols Germany) etc. to the designated area. As in alternative methods, the cut sheet material is heated with the torch and pressed onto the cast. Next, the contour is straightened using silicon seating material and occluded with the opposite teeth. The vacuum formation is completed by the usual method of thermoforming an EVA sheet. The appropriate adhesive (Dreve: Drufosoft primer etc.) should be applied before vacuum sheet formation. This method will achieve a high safety full-balanced occlusal mouthguard easily using the conventional vacuum type machine. This technique is also useful to add materials to thicken the buccal surfaces as well as achieving correct mouthguard contours where teeth are missing.

Full-laminated mouthguards have the advantages of better adaptation, are more comfortable and longer wearing. This newly designed mouthguard is recommended for young adults and children, for athletes undergoing orthodontic treatment, and urgent cases when player has lost a mouthguard.

Full-balanced occlusion is necessary for mouthguards. It is reported [90] that the occlusion of the anterior teeth are essential for prevention against most common injuries occurred in the maxillary front teeth and alveolar bone caused by horizontal direct impact. In other words, the support by the mandibular teeth through the mouthguard is critical to prevent maxillary front teeth injuries from the direct impact force.

Recently, vacuum type and a laminated type mouthguards are increasingly used. The vacuum type has an advantage that the mouthguard can be fabricated easily and inexpensively. However, the vacuum type cannot necessarily achieve the full-balanced occlusion. Examples are when a player has a malocclusion, such as an elongated molar or premolar tooth, an open bite and a large over jet or maxillary protrusion. Conventional vacuum techniques cannot compensate for the decrease of the thickness during the fabrication [25]. However, the laminated type can secure necessary thickness and enough occlusion [25, 84] [82], and thus have many advantages so as to recommend it as the best option. However, it is difficult to convince all players to use the laminated type mouthguard for reasons such as cost, time or time spent to deliver the mouthguard. We introduce an improved vacuum fabricated method for those cases where a full balanced occlusion is difficult to obtain by the conventional vacuum type single-layer method.

It is conceded that laminate mouthguards can be better adapted and are usually more comfortable for the patient (3–6). However, the mouthguard described here is useful for children and young patients when they will have to be replaced many times or in emergency cases when an athlete has lost his/her mouthguard. In addition, modified this partial laminated technique should be useful to achieve full balanced occlusion in a fabricating mouthguard using pressure machine [34]

PROCEDURE

This method can provide a full-balanced occlusal mouthguard easily and reasonably even with the conventional vacuum type machine, which are inexpensive and in widespread use. This technique can also be used to increase the thickness of the mouthguard on the buccal surface (Figures 4-1 to 8).

Figure 4-1. Prefabrication examination: the area where it appears that enough occlusion (especially in an anterior area) by the conventional one-layer vacuum type Mouthguard cannot be achieved should be confirmed. Anterior space is examined using upper and lower mounted cast.

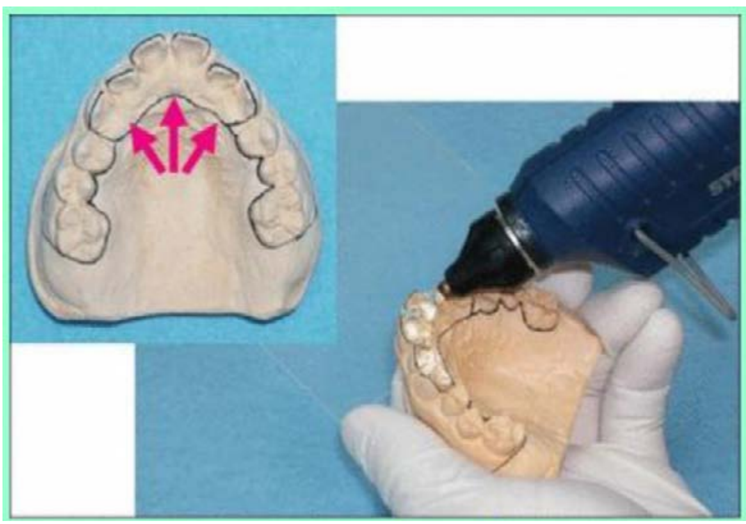


Figure 4-2. Out-line of the Mouthguard and the area where first EVA material is to be applied is drawn on the upper cast. Before fabricating the mouthguard, prepare the cast by blocking out undercut caused by deciduous, partially erupted teeth, and spaces of separated with an appropriate material such as a silicone and different colored dental stone if necessary.

Figure 4-3. Silicon sheet (Super-sheet, Dental Aid, Tokyo, Japan) is used to mould the EVA material while it is warm.

Figure 4-4. The form of the EVA material is corrected while confirming the occlusion.

Figure 4-5. Drufosoft Primer (Dreve-Dentamid GMBH, Unna, Germany) is applied and the surface is heated (until becomes it sticky. These surface treatments will improve the bond between the two EVA materials and prevent separation.

Figure 4-6. Vacuum moulding of the second EVA material layer.

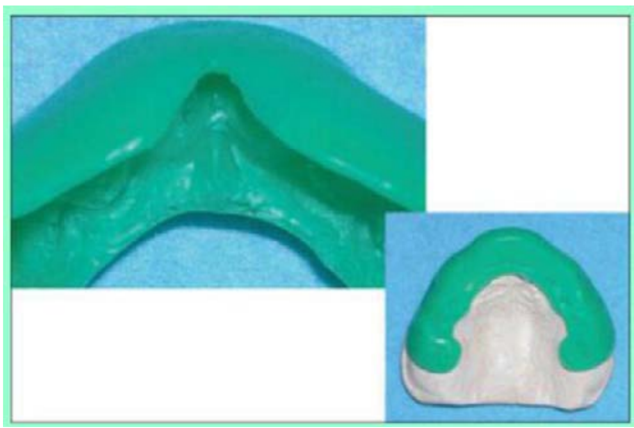


Figure 4-7. Mouthguard sheet is cut and trimmed, the occlusion is adjusted on the model and using a Burner or a Gas torch and a Super-sheet (Molten Medical co. Ltd, Osaka, Japan) polished.

Figure 4-8. Final adjustments in the mouth.

STUDY NO.5-1 : DOES HARD INSERTION AND SPACE IMPROVE SHOCK ABSORPTION ABILITY OF MOUTHGUARD.

The original article [80]

ABSTRACT

Mouthguards are expected to reduce sports-related orofacial injuries. Numerous studies have been conduced to improve the shock absorption ability of mouthguards using air cells, Sorbothane, metal wire, or hard material insertion. Most of these were shown to be effective; however, the result of each study has not been applied to clinical use. The aim of this study was to develop mouthguards that have sufficient prevention ability and ease of clinical application with focus on a hard insertion and space. Ethylene vinyl acetate mouthguard blank Drufosoft and the acrylic resin Biolon. Three types of mouthguard samples tested were constructed by means of a Dreve Drufomat air pressure machine: the first was a conventional laminated type of EVA mouthguard material; the second was a three layer type with acrylic resin inner layer (hard-insertion); the third was the same as the second but with space that does not come into contact with tooth surfaces (hard + space). As a control, without any mouthguard condition (NOMG) was measured. A pendulum type impact testing machine with interchangeable impact object (steel ball and baseball) and dental study model with the strain gages applied to teeth and the accelerometer to the dentition were used to measure transmitted forces. Statistical analysis (ANOVA, $P < 0.01$) showed significant differences among four conditions of NOMG and three different mouthguards in both objects and sensor. About acceleration: in a steel ball which was a harder impact object, shock absorption ability of about 40% was shown with conventional EVA and hard-insertion and about 50% with hard + space. In a baseball that was softer compared with steel ball, a decrease rate is smaller, reduction (EVA = 4%, hard-insertion = 12%, hard + space = 25%) was admitted in the similar order. A significant difference was found with all the combinations except for between EVA and hard-insertion with steel ball (Tukey test). About distortion: both buccal and lingual, distortions had become small in order of EVA, hard-insertion, and hard + space, too. The decrease rate is larger than acceleration, EVA = 47%, hard-insertion = 80% or more, and hard +space = 98%, in steel ball. EVA = 30%, hard-insertion =75%, and hard + space = 98% in baseball. And a significant difference was found with all the combinations (Tukey test). Especially, hard + space has decreased the distortion of teeth up to several percentages. Namely, acceleration of the maxilla and distortions of the tooth became significantly smaller when wearing any type of mouthguard, in both impact objects. But the effect of mouthguard was clearer in the distortion of the tooth and with steel ball. Considering the differences of mouthguards, the hard-insertion and the hard + space had significantly greater buffer capacity than conventional EVA. Furthermore, hard + space shows quite high shock absorption ability in the tooth distortion. Namely, hard + space has decreased the distortion of teeth up to several percentages in both impact objects.

INTRODUCTION

Maxillary front teeth often receive direct horizontal impacts. So it is assumed that more than 90% of sports-related teeth injuries had contained this area [13, 15-17, 76, 91]. Influences of these injuries reach not only a functional problem but also an aesthetic and a mental matter. While, a lot of other organizations damages can be recoverable by appropriate treatment and the natural healing power. But teeth fracture, dislocation and so on never recover naturally. Moreover, an endurance of teeth after treatment does not return thoroughly to intact teeth level. Treated teeth, which used a metal post-core or crown etc, became easy to receive a secondary injury, because of its' high elasticity modulus. Furthermore, after the slight injuries such as enamel clack, tooth concussion and so on, it is assumed that after effects such as pains and the necrosis of pulps were seen by about 25% [92].

It is assumed that mouthguards are effective to a reduction and a prevention of these injuries by many sports dentist. Hundreds of studies have been conduced to improve the shock absorption ability of mouthguards using air cells [93], a sorbothane [57], a metal wire[66] , a sponge [59], or a hard material [31, 67]. Most of these study showed these materials or fabrication methods were effective. However, the results of each study have not been applied to clinical use. In addition, many sports-related orofacial injuries have still happened though the Mouthguard is used. So the aim of this study was to develop a mouthguard that has sufficient prevention ability and ease of clinical application with focus on a hard insertion and space.

MATERIALS AND METHODS

Ethylene vinyl acetate (EVA) mouthguard blanks used were Drufosoft and acrylic resin sheets were Biolon (Dreve-Dentamid GMBH, Unna, Germany). Three types of mouthguard samples tested (Figure 5-1) were constructed by means of a Dreve Drufomat (Type SO, Dreve-Dentamid) air pressure machine: a conventional laminated type of EVA mouthguard material (EVA 3 + 3; Figure 5-1b), a three layer type with the acrylic resin inner layer (hard-insertion; Figure 5-1c), a similar type as the second B but with a space that does not come into contact with the tooth surface (hard +space; Figure 5-1d). The actual thickness of each mouthguards at the impact points was approximately 3.0 mm. And without any mouthguard was used as a control (NOMG; Figure 5-1a). Three mouthguards were made for each three type and the impact tests described as below were carried out three times for each mouthguard.

Same pendulum type impact testing system used in our series of studies [29, 55, 79] (with interchangeable impact object; steel ball and baseball) and a dental study model (D17FE-NC.7PS, Nissin, Tokyo, Japan) with strain gages (KFG-1-120-D171-11N30C2: Kyowa, Tokyo, Japan) applied to the teeth and the accelerometer fixed to maxilla (AS-A YG-2768 100G, Kyowa) were used to measure transmitted forces (Figure 5-2.). Measured mechanical forces by means of the strain gauges and the accelerometer were amplified, converted and analyzed. Then, means and standard deviation were calculated for each variable evaluated. Shock absorption ability (%) was calculated against the control as well. Statistical comparison was made using a one-way (ANOVA) test. And Tukey multiple comparison test was used for further comparisons ($P < 0.01$), using SPSS (SPSS Japan Inc., Tokyo, Japan).

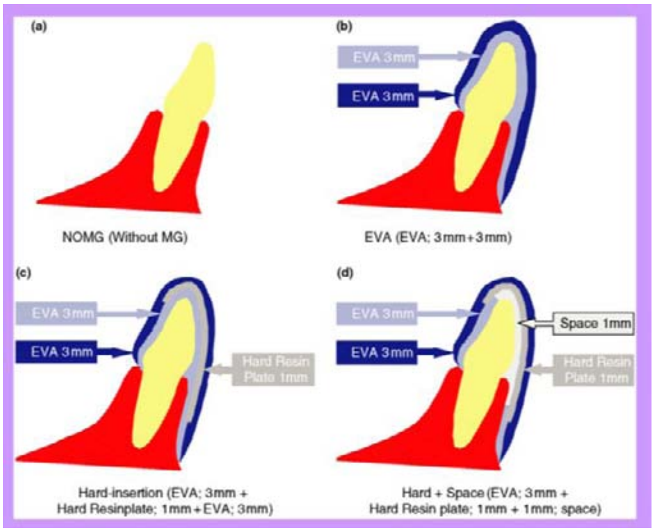


Fig. 5-1. Three types of mouthguards: (b) conventional laminated type of EVA mouthguard material (EVA 3+3), (c) three layer type with the acrylic resin inner layer (hard-insertion), (d) similar type as the second (b) but with a space that does not come into contact with the tooth surface (hard + space). And without any mouthguard was used as a control (NOMG) (a).

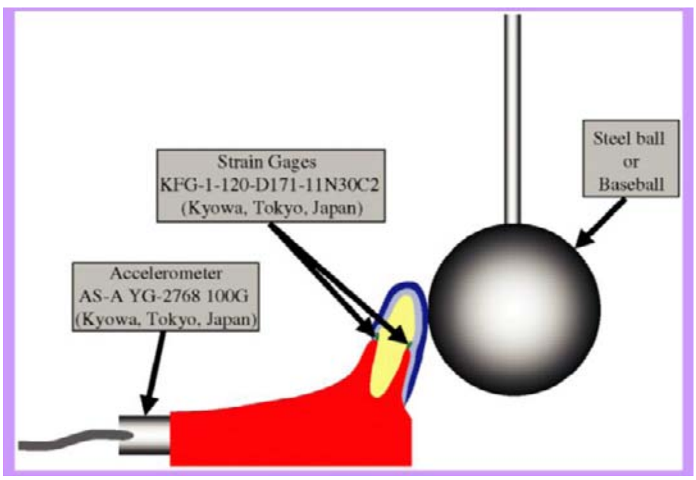


Fig. 5-2. Specially designed devices to measure the shock absorption ability of mouthguard and a dental study model.

RESULTS

Waveform of the Distortion

The distortion waveforms of four conditions at the buccal cervical with steel ball are showed in Figure 5-3. The waveform consisted of two peaks. The first peak seems to be generated, when impact object was hit. And it seems that second peak originated in the impact caused after teeth moved in space where correspond to the periodontal ligament. And the first peak is analyzed as the impact power. The waveform of the NOMG was sharp and strong compared with wearing any types of mouthguards. Waveforms were become smooth by wearing mouthguards. The tendency was clear in the order of EVA, hard-Insertion, and hard + space. Hard + space showed almost flat waveform.

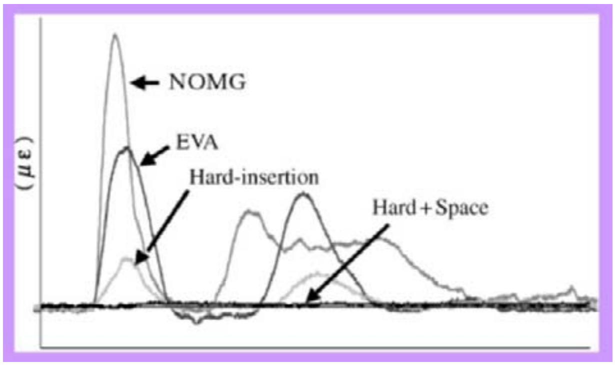


Fig. 5-3. Distortion of waveforms of four conditions at buccal cervical with a steel ball. The waveform of the NOMG was sharp and strong compared with wearing any types of mouthguards. Waveforms became smooth by wearing mouthguards. The tendency was clear in the order of EVA, hard insertion, and hard + space. Hard + space showed almost flat waveform.

The Acceleration and Distortion each Measuring Point and Object

Transmitted forces of acceleration and distortion of each measuring point are showed in Figures 5-4 to 9. And absorption ability (%) and results of Tukey test are also in each Figure.

Acceleration with the steel ball which was a harder impact object, shock absorption ability of about 40% was shown with EVA and hard-insertion, and about 50% with hard + space. With the baseball that was softer compared with steel ball, a decrease rate is smaller, but a reduction was admitted in the similar order (EVA = 4%, hard-insertion = 12%, hard + space = 25%). Statistical analysis (ANOVA, $P < 0.01$) showed significant differences among four conditions of NOMG and three different mouthguards with both the steel ball and the baseball. And significant differences were found with all the combinations except for between EVA and hard-insertion with the steel ball (Tukey test, $P < 0.01$).

Distortion with the steel ball, both buccal and lingual distortion became small in order of EVA, hard-insertion, and hard + space, too. A decrease rate is larger than acceleration, EVA = 47%, hard-insertion = 80% or more, and hard +space = 98%, with the steel ball. EVA = 30%, hard-insertion = 75%, and hard + space =98% with the baseball. Thus, hard + space decreased the distortion of teeth up to several percentages. Statistical analysis (ANOVA, $P < 0.01$) showed significant differences among four conditions of NOMG and three different mouthguards, in both measuring point and objects. And a significant difference was found with all the combinations (Tukey test).

DISCUSSION

Many researches to improve the impact absorption ability of the mouthguard by using some intermediate layers or by improving the mouthguard material itself have been conducted. Among them, only one paper reported negative results [31]. All other researches insisted on having improved the impact absorption abilities of the mouthguard by their methods.

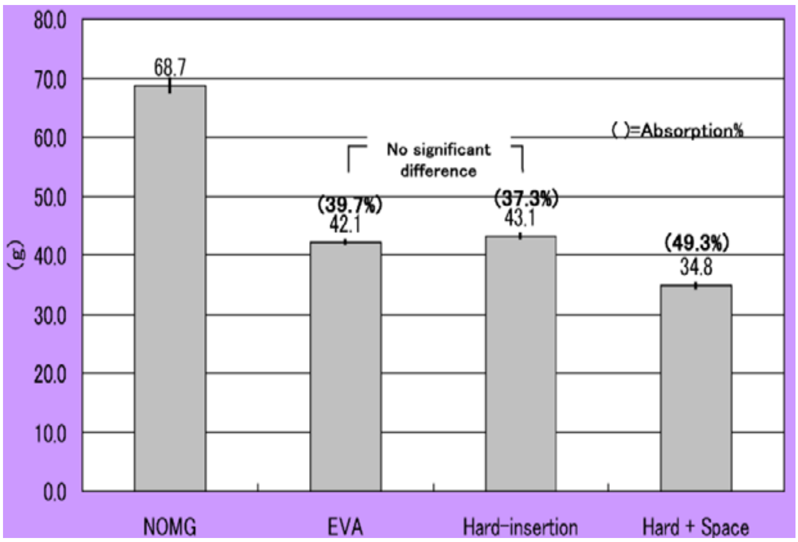


Fig. 5-4. Steel Ball acceleration.

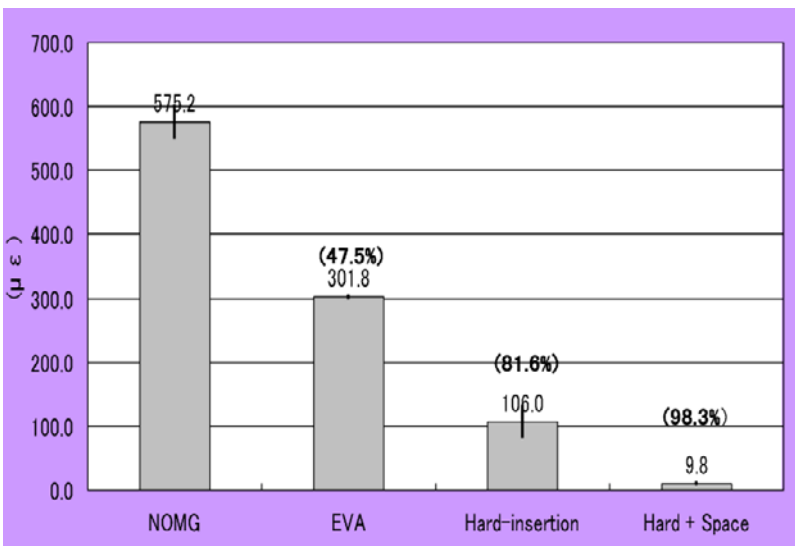


Fig. 5-5. Steel Ball distortion (buccal cervical).

Modified mouthguard material with an inclusion of air cells in a 4 mm thick EVA reduced transmitted forces by 32% when compared with traditional EVA mouthguards of the same thickness [68] . An intermediate layer of sorbothane (a visco-elastic polyurethane that has been used in sports and orthopedic applications because of its shock-absorbing properties) reduced a peak force significantly than a comparable thickness EVA mouthguard [57]. A half-round arch wire strengthener extending between the first molars embedded in a double layer EVA mouthguard was the most efficient[66] . Bilaminated mouthguard with a piece of sponge as an intermediater showed the highest shock absorption (49%) [59]. Hard layers of EVA insert reduced energy absorption when compared with a control sheet of the EVA without the hard insert [67].

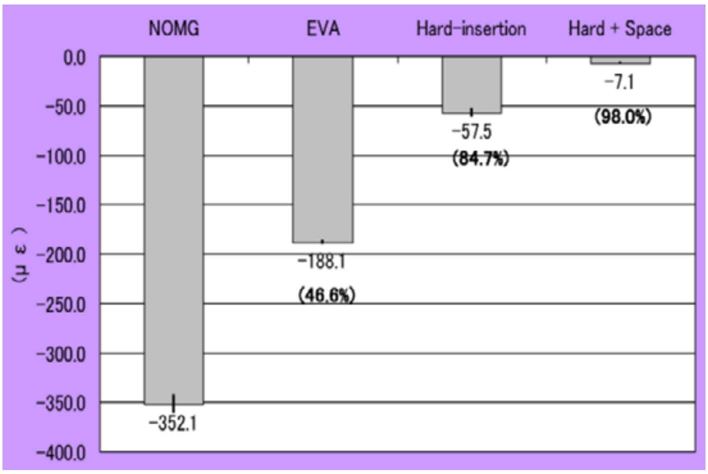


Fig. 5-6. Steel Ball distortion (palatal cervical).

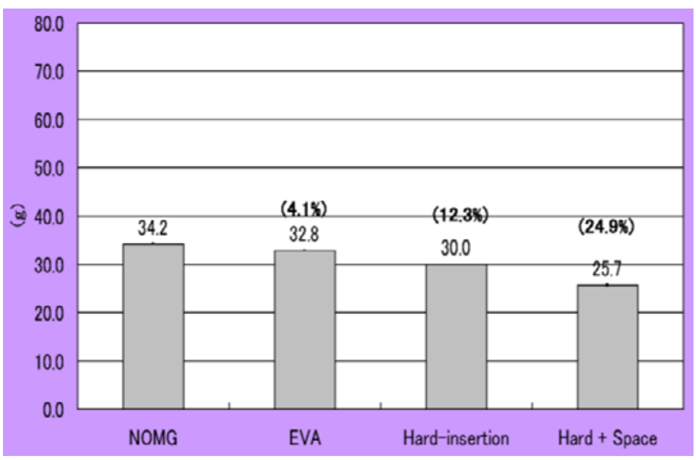


Fig. 5-7. Baseball acceleration.

However, these were not the methods, which was able to apply to clinical easily or not used routinely. Additionally, because half-round arch wire and hard material outer layer are used, they are not necessarily safe. So these methods are, to our knowledge, not being used now.

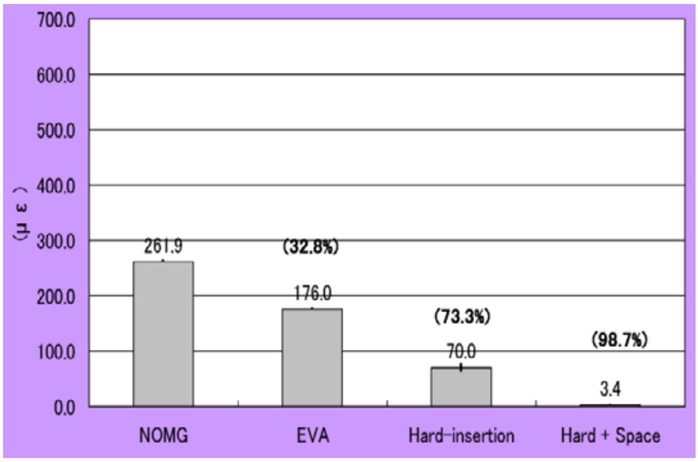


Fig. 5-8. Baseball: distortion (buccal cervical).

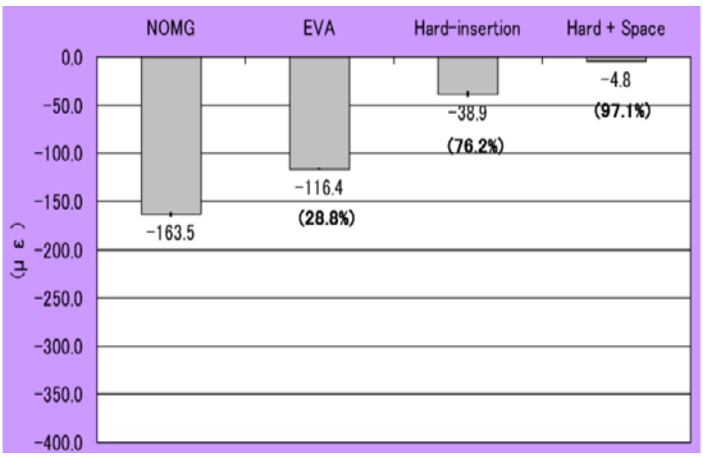


Fig. 5-9. Baseball: distortion (palatal cervical).

Consequently, this present study was planned and conduced to develop a mouthguard that has sufficient prevention ability and ease of clinical application with focus on a hard insertion and space. By means of a pendulum type impact testing machine with interchangeable impact object [29, 55, 79] and dental study model with the strain gages applied to teeth and the accelerometers to the dentition[90].

As the result, distortions of the tooth and acceleration of the maxilla became significantly smaller when wearing any type of mouthguard, in both steel ball and baseball impact objects. But the effect of mouthguard was clearer in the distortion of the tooth. Considering the differences of mouthguards, hard-insertion and hard + space had significantly greater buffer capacity than conventional EVA. Furthermore, hard + space shows quite high shock absorption ability in the tooth distortion. Namely, hard + space has decreased the distortion of teeth up to several percentages in both impact objects.

Only the buffer ability of a material thickness contributes a prevention level for horizontal direct impact force in a lot of conventional mouthguard. If the mouthguard have the impact absorption ability of 80-90% [27, 29, 55] which are the highest values of previous studies. It is difficult to protect all sports related teeth and orofacial bone injuries.

However, in this present study, the impacted energy was distributed backward and decreased an amount of the destructive energy to teeth by using hard inner layer. In addition to this effect, the mouthguard material can bend in applied space between mouthguard and teeth, and energy should be absorbed greatly while mouthguard transforming. Therefore, it is considered that the distortion was hardly transmitted to the tooth in this impact power level. And if the impact power is so strong and mouthguard cannot bear it, for this situation, hard inserted materials will break down and absorb the much energy at the moment. So the injury might be preventable or reduced with this type of hard + space mouthguard.

This distinct improvement by hard + space is achieved with small design change and easy to clinical use. So we should recommend and produce this type of mouthguard in consideration of the type of sports (ice hockey, cricket, women's lacrosse, etc.), level and condition of player's mouth condition (with fractured and repaired tooth, tooth with veneer metal crown, porcelain facing crown, implant prosthetics, fixed partial denture, etc.). In addition, we should conduct well-formed prospective studies on the field that evaluate whether this type of mouthguard is sufficient to reduce incidence or severity of orofacial sport-related injuries.

CONCLUSION

Within the limit of this laboratory study, the acceleration of the maxilla and the distortions of the tooth became significantly smaller when wearing any type of mouthguard, in both steel ball and baseball. But the effect of mouthguard was clearer in the distortion of the tooth and with steel ball. Considering the differences of mouthguards, the hard-insertion and the hard + space had significantly greater buffer capacity than conventional EVA. Furthermore, hard (acrylic inner layer) + space (between the tooth surface and mouthguard material) showed quite high shock absorption ability in the tooth distortion. Namely, hard + space has decreased the distortion of teeth up to several percentages in both impact objects.

STUDY NO.5-2 : A FABRICATION METHOD OF A MOUTHGUARD WITH HARD INSERTION AND SPACE.

A fabrication method of a type aimed at the protection against front teeth, especially maxillary central incisor, is shown in Figure 5-10 to 16

Figure 5-10. First EVA material is pressed on upper a model.

Figure 5-11. Remove first material on the teeth to obtain "Space" in order to protect the teeth.

Figure 5-12.Removed "Space" should be filled with a silicon patty in order to maintain the space during second and third layer material pressing.

Figure 5-13. Model with first material and silicon patty is buried with granule to diminish a undercut as much as possible.

Figure 5-14. An acrylic plate is pressed as the intermediate material. Materials without necessity are cut, and the form is timed.

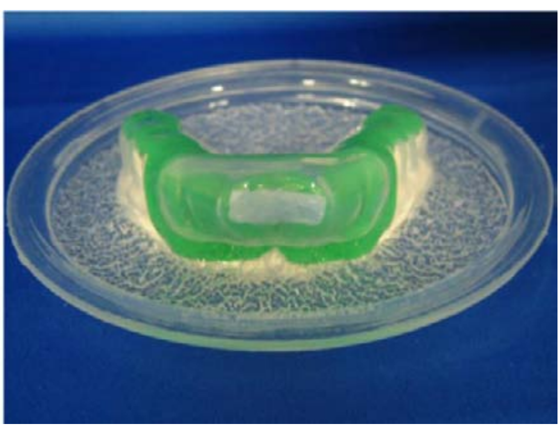


Figure 5-15. Third EVA layer is laminated

Figure 5-16. The completed mouthguard is on the model.

Figure 5-16. Total buccal thickness of hard insertion and space area is only about 3mm thickness. First green EVA material is not available on the half of central incisors.

STUDY NO.6 : CAN MOUTHGUARDS PREVENT MANDIBULAR BONE FRACTURES AND CONCUSSIONS? A LABORATORY STUDY WITH AN ARTIFICIAL SKULL MODEL.

The original article [38]

ABSTRACT

Some sports' accidents are responsible for inflicting traumatic brain injuries and mandibular bone fractures when impacts occur to the chin. It is often thought that mouthguards can prevent many of these injuries. However, such assertions may be insufficient without adequate research. It is therefore necessary to establish a systematic method of investigation to solve this problem. In the present laboratory study, tests were performed using pendulum impact equipment and an artificial skull model connected to strain gages and accelerometers to simulate and measure the surface distortions related to bone deformation or fractures and the acceleration of the head related to concussions. As impacts, direct blows to the mandibular undersurface were applied. As a result, wearing a mouthguard decreased ($P < 0.01$) the distortion to the mandibular bone and the acceleration of the head significantly compared with not wearing a mouthguard (54.7%: to the mandible - measured at a total of three different points, 18.5%: to the head measured at a total of three different points). Within the limits of this study, the following conclusions were drawn: The present measuring system in this study was able to evaluate the distortion to the mandibular and the acceleration of the head from the direct blow to the mandibular undersurface. Mouthguards can reduce distortion to the mandibular and the acceleration of the head from the same blow. So mouthguards might have the possibility to prevent mandibular bone fractures and concussions. However, further well-designed and exhaustive studies are vital to show that mouthguards reduce the incidence of concussions and mandibular bone fractures.

INTRODUCTION

The overwhelming majority of surveys stress the significant protective ability of mouthguards to teeth, soft tissue and orofacial traumas. It was the research carried out on early American football that showed it most clearly. Stenger et al. [94] reported that full facemasks reduced dental and mouth injuries to almost half and with the addition of mouthguards the number of these injuries decreased to 1.4%. Since the use of mouthguards was made compulsory for American high school football in 1962 and for American college football in 1974, the number and severity of dental injuries among these athletes have dramatically decreased [78, 95].

In other sports, Morton and Burton[96] reported that, 272 high school rugby players were fitted with custom-made mouthguards. Among the total 31 players reported receiving damage to the mouth during one season. Of these 31 players, 20 were wearing mouthguards at the time of the accident and most received soft tissue lacerations and bruising, and five suffered minor teeth fractures. On the contrary, 13 fractures were recorded in 11 players who were not wearing mouthguards. Morrow et al.[97] studied orofacial injuries among female basketball players during the 1990-1991 season. The injury rate was 2.8% for those who wore mouthguards and 30.3% for those who did not wear them. Maestrello-de moya and Promosch[53] also surveyed high school basketball players in Florida, and determined that injuries increased 6.8 times when mouthguards were not used.

Thus many researchers have showed the effectiveness of the mouthguard in sports; however the spread of suitable mouthguards is still slow. This seems to suggest that a lot of preventable dental related sports injuries continue to occur. One reason for this is that players might not recognize the advantages of mouthguards and may not have had a properly produced mouthguard for their age, the kind of sports they played, or their level of participation in sports. Knowledge is especially short concerning the relationship between mandibular bone fractures, concussion prevention and mouthguards.

It has long been thought that concussions are associated with a range of injuries that are generally diagnosed on the basis of medical signs and symptoms present at the time of an impact. A concussion has been described in clinical terms as a syndrome characterized by immediate and transient post-traumatic impairment of neural function, such as alteration of consciousness or disturbance of vision or equilibrium, and other signs and symptoms because of the involvement of the brain stem. The assumed cause is a rapid distortion and movement of the brain according to acceleration as well as more critical subdural hemorrhage etc [98]. However, neither the impact power nor the acceleration of the head in sports' injuries is that strong if compared with accidental falls and traffic accidents [99]. Therefore, the kind of brain damage easily generated by sport is thought to be concussions. Not surprisingly, surveys seem to suggest that there are a great number of concussions found in various sports.

In contact sports, it is said that one in every 20 players experienced a concussion during a season [76]. Gerberich's [100] investigation into secondary school sports' injuries and revealed that 19% of players reported having had a concussion with 69% of them returning to play sports the same day. Garon[16] reported that among junior high school athletes more than a third of the concussions were reported in sports other than football. Although this situation continues, the symptoms associated with a concussion are assumed to be transitory in general. As a result, concussions tend to be disregarded as serious injuries. However, players with a prior history of a concussion had a four to six time's greater risk of a second concussion than that of the player without a prior history [100-103]. Furthermore, the effects of concussion seem to be cumulative, and lead to post concussion syndrome[85]. Thus, this has important implications for sports where concussion associated injuries are common.

Concussions occur even when there is no direct blow to the head [104]. While it is said that an impact to the brain is indispensable for a concussion to occur, it does not necessarily have to be a direct blow [99]. One report sited that the most common cause of a concussion in sport was a blow to the mandible [13].

Therefore, the mouthguard might have some benefits in preventing concussions. The first benefit is the dissipation of the forces delivered to the maxilla, skull, and temporomandibular joint complex when the mandible receives a blow [59, 60, 105, 106]. The second benefit is the stabilization of the skull through increased neck muscle activity when clenching, which may be enhanced with the presence of a mouthguard [107, 108]). The third benefit is gained with an alert mandibular position by wearing a mouthguard which can distract the condyle from their fossa [39, 94].

However, as clinical evidence, only the retrospect surveys and some case study reports suggested that mouthguards may protect athletes from concussions [16, 109]. In contrast, a prospective study in the American college basketball league and American football showed that custom-fitted mouthguards did not significantly affect the rates of concussion [20, 43].

When we pay attention to concerning laboratory studies now; Hickey [60] first indicated the effectiveness of the mouthguard with tests carried out on cadaver. However, ethical considerations make it difficult to duplicate or continue such experiments or to use such methods now.

With these considerations in mind, a variety of simulation experiments are being planned, and being executed. De Wet et al. [59] conducted experiments using a modal hammer with a built-in load cell and a skull model with strain gauges and accelerometer sensors mounted in various positions on the maxilla and inside an artificial skull. They could not get appropriate results concerning the deformation of bone from the strain gauges and accelerometer sensors. But only the input force with the modal hammer was able to show the mouthguards effectiveness. The impact attenuation rate after an impact, on a dry skull, was also reported and led to the assumption that there was an absorption ability to some degree[105]. Sumiyoshi et al. [106] reported that after the impact to the mandibular was analyzed using a finite element method, the impact force was reduced to the maximally incisor tooth, nose and a reduction in the number of concussions when using a mouthguard. Moreover, in other papers[107, 108] it was reported that the mouthguard was effective in reducing the impact of punches to the head in boxing. However, to continue such testing methods nowadays would be fought with greater ethical difficulties than before, especially if trying to obtain dry human skulls and the necessary specialized equipment for testing.

In regard to mandibular bone fractures, a number of reports [82, 107, 108] argue on the effectiveness of using mouthguards. Takeda et al. [79] showed the possibility that a defective mouthguard in occlusion increases mandibular bone fractures, i.e. the design and or materials of the mouthguard can reduce mandibular bone fractures etc. Therefore, a lot of mandibular bone fractures can occur causing serious problems extending over one's whole life. There are many reports concerning mandibular bone fractures related to sports, which are common traumas to the maxillo-facial region and often cause additional brain damage. There are also many cases that result in types of temporomandibular disorders, after mandibular bone fracture treatment has been carried out. When a tooth germ is in a fracture line, either abnormalities related to shape or eruption were frequently observed [110]. Moreover, even if an injury does not result in a bone fracture, there is the possibility that traumatic changes will occur in the temporomandibular joint [111]. Also, in children's jawbone fractures, especially in simultaneous fractures of the mandible and joint areas, dentition and jaw deformity emerged at a high rate later[77]. Therefore, the influence of such injuries on everyday sports life and athletic ability, and so on after an injury, is immeasurable.

In this laboratory study, the mouthguard is examined for its effectiveness or lack of effectiveness on the surface distortion of the mandible in relation to mandibular bone fractures and the acceleration of head related to concussions by means of a pendulum impact testing device and an artificial skull model [79]. At the same time, we hope to establish a systematic approach to testing that can be used in the future, and which is the basis of our present trials.

While considering further well-designed prospective studies are essential to show that mouthguards considerably reduce the incidence of concussions and mandibular bone fractures.

MATERIAL AND METHODS

The measuring methods and systematic approach were almost the same as our previous series of studies [29, 55] i.e. the pendulum device with a steel ball (approximately 300 g) attached as the impact object was employed and hit the center surface of an acrylic resin plate fixed to the left second premolar of the mandibular bone of an artificial skull model (ZA20; 3B Scientific International, Co. Ltd, Niigata, Japan) from below. This model had the occlusion adjusted carefully and the temporo-mandibular space filled with acrylic resin. The mandibular was attached to the maxilla with three springs. An electromagnet was used to control the release of the impact ram in order to concentrate the force over a small area and make the distance with the target precise (Figure 6-1). And strain gauges (KFG-1-120-D171-

11N30C2; Kyowa Electronic Instruments Co., Ltd, Tokyo, Japan) were applied to three labial aspects of the mandible (right premolar region, left premolar region and left mandibular angle region) to measure the surface distortion relating to bone deformation or fracture. Three single-direction accelerometers (AS-A YG-2768 100G, Kyowa) were fitted to three points (the parietal region = frontal plan, the frontal region = sagittal plan, and the temporal region = horizontal plan) to measure the acceleration of the head, in relation to concussions, as three-dimensional objects (Figure 6-1).

Measured mechanical forces by means of the strain gauges and the accelerometers were amplified and then converted into an electric output voltage and stored as data. Then, means and standard deviation were calculated for each variable evaluated. Statistical comparisons were made using a Student's t-test in each measured region ($P < 0.01$), using SPSSR (SPSS Japan Inc., Tokyo, Japan).

The mouthguard blanks used were Drufosoft (Dreve-Dentamid GMBH, Unna, Germany) with a 3.0 mm thickness. The mouthguard tested samples (Figure 6-2) were constructed of 2-layer-laminations by means of a Dreve Drufomat (Type SO; Dreve-Dentamid) air pressure machine on a stone model impressed with alginate material. The actual thickness after lamination with adjustments made for the normal spatial relation of the teeth when the jaws were closed was approximately 3.0 mm on the first molar. To obtain uniform thickness, the same operating steps (including the constant heating time: 150 s.) were used. Three mouthguards were made and the impact test was carried out three times. Therefore, nine impacts were recorded in total.

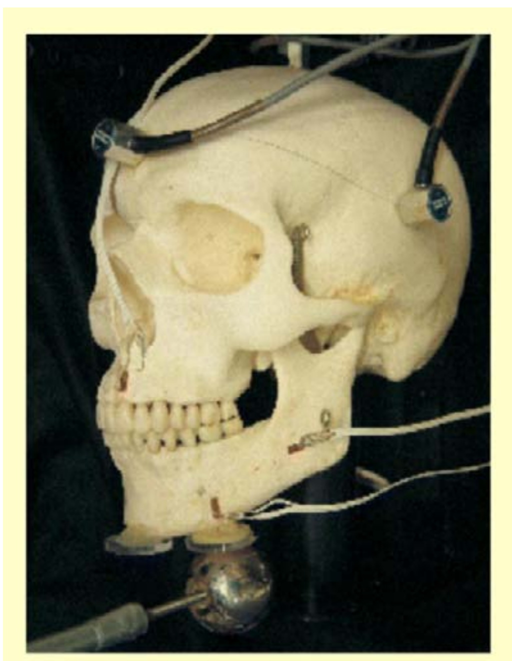


Figure 6-1. Artificial skull model sensors were applied with the pendulum impact device.

Figure 6-2. Pressure laminated Ethylene vinyl acetate (EVA) mouthguards were used in the experiments.

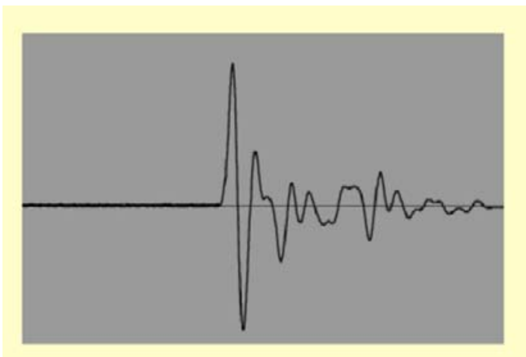


Figure 6-3. Typical waveform of the acceleration of the head from the parietal region without a mouthguard.

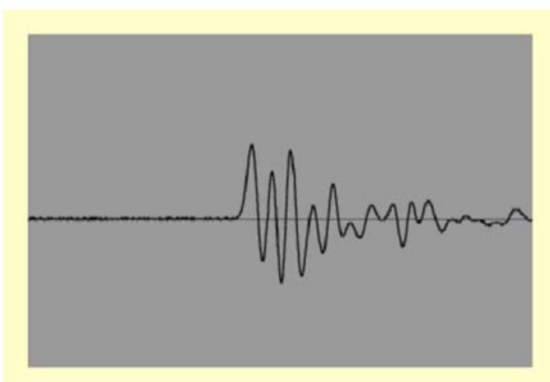


Figure 6-4. Typical waveform of the acceleration of the head from the parietal region with a mouthguard. The waveform without a mouthguard was sharp and strong compared to with a mouthguard.

RESULT

The Waveform from the Acceleration of the Head and the Distortion on the Mandible

Typical acceleration waveforms on the parietal region with and without mouthguards are illustrated in Figures 6-3 and 4.

Fitting the mouthguard decreased the amplitude of the impact. Similar tendencies were observed at other measurement points.

Distortion to the Mandible

The results of the three measurement points with the total shown in Figure 6-5, and the results of the t-tests ($P < 0.01$) and absorption capacity (%).

The distortion recorded, without a mouthguard, to the right premolar was 149.0 με, the left premolar was 494.7με, the left mandibular angle was 358.5με, and the total was 1002.2με. The distortion recorded, with the mouthguard, to the right premolar was 102.3με, the left premolar was 135.8με, the left mandibular angle was 215.4με, and the total was 453.5με. Thus, the maximum distortions were reduced when wearing a mouthguard than without wearing one by 31.3-72.5% at each measurement point and 54.7% approximately in total. Furthermore, the distortion to the mandible was significantly reduced, with a mouthguard, at all the measurement points including the total.

The Acceleration of the Head

The results of the three measurement points and the total are shown in Figure 6-6, with the results of the t-tests ($P < 0.01$) and absorption capacity (%).

The acceleration, without the mouthguard, of parietal region was 58.8 g, the temporal region was 23.2 g, the frontal region was 128.2 g, and the total was 210.2 g. In contrast, the acceleration, with the mouthguard, of the parietal region was 31.0 g, the temporal region was 15.2 g, the frontal region was 125.1 g, and the total was 171.3 g. Thus, the maximum acceleration was reduced when a mouthguard was fitted, in contrast to the tests being conducted without them, by 2.4-47.3% at each measurement point and 18.5% approximately in total. Moreover, the acceleration was significantly reduced, with the mouthguard, to the parietal and temporal regions.

DISCUSSION

The impact or shock force is thought to be force that is applied to a target together with a change in speed during a short duration of time. Generally speaking, the power is very big

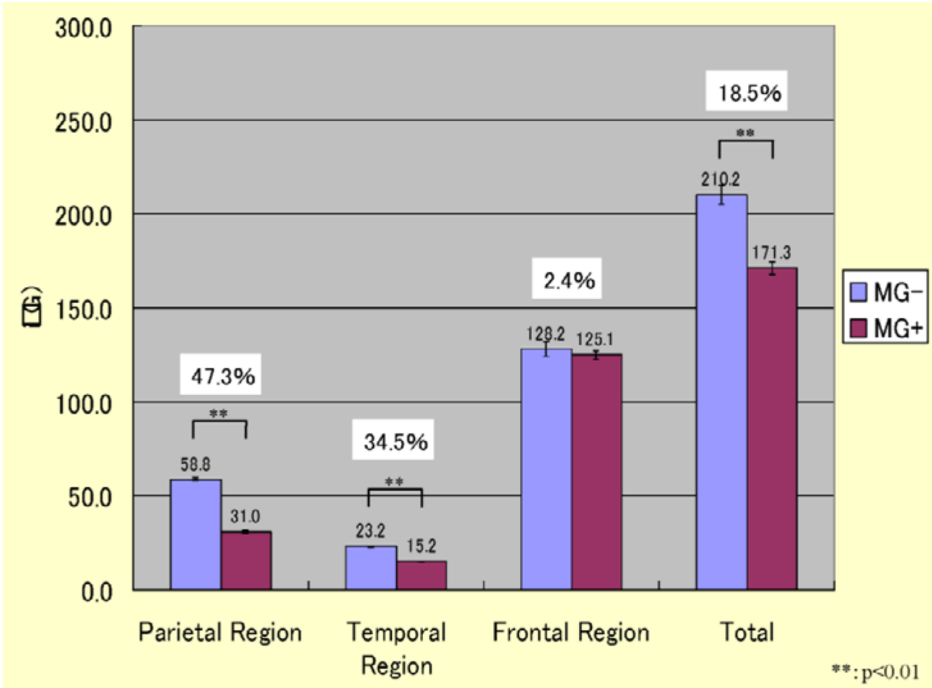


Figure 6-5. Distortion of the mandible was compared with and without a mouthguard.

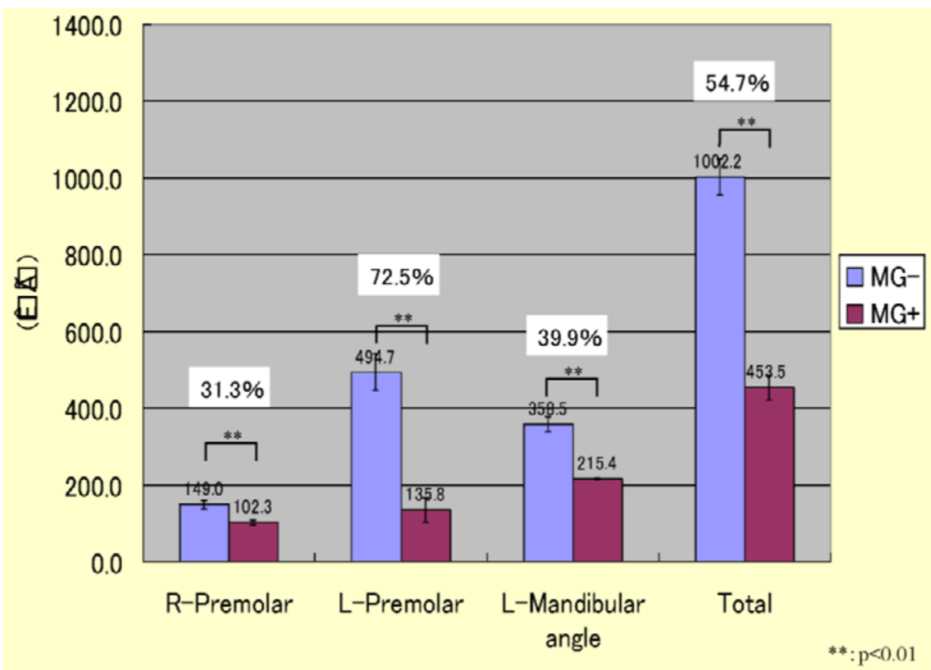


Figure 6-6. Acceleration of the head compared with and without a mouthguard.

and duration is very short. Additionally, the total power is invariable, even before and after the impact. Therefore, when the impact power is applied to a human body, there are two quite different results. If the energy is not great enough to cause damage to the body, it is consumed as heat energy by the viscosity characteristics of joints or soft tissue. In the case where the energy is much greater, it changes to a destructive energy which causes damage to the soft tissue, the dislocation and the fracture of teeth, fractures of the bones and so on [50]. Therefore, as in many sports, it is prohibited to collide with an opponent during play or to hit one's opponent with an instrument. However, accidentally or intentionally, a collision or a blow will occur in most sports. In contact sports such as rugby, American football, boxing and sumo wrestling etc., collisions cannot be avoidable, because contact is a characteristic part of how they are played. As a preventative measure the use of a mouthguard is expected to protect not only the orofacial area but also to prevent or minimize the occurrence of concussions.

The responsibility is on researchers to supply the necessary scientific proof. For that, well-designed prospective studies are necessary to show that mouthguards reduce the incidence of concussions and mandibular bone fractures. But, as a laboratory study, it is also necessary to establish a method that examines the quality and effectiveness of mouthguards.

Despite this, as described above, there is no method by which the effectiveness of the mouthguard concerning concussions and mandibular bone fractures can be easily examined.

Therefore, for the spread of mouthguards in the future, the establishment of a reliable method that can answer questions such as, ‘What type of mouthguard is appropriate for preventing craniofacial injuries?’ or ‘How can we as dentists make reliable mouthguards for each player?’ are crucial.

Thus, in the present study, the test was performed to clarify the effectiveness of mouthguards in regard to concussions and mandibular bone fractures by means of a pendulum impact testing device and skull models. As a result, wearing a mouthguard (MG+) decreased the acceleration of the head and the distortion in the mandibular bone compared with not wearing one (MG-). This was the same result as reports[16, 39, 53, 59, 60, 78, 86, 94-96, 105, 106, 109, 112, 113] suggesting that the effectiveness of mouthguards was not only to protect the teeth and dentitions but also to prevent injury to the surrounding bone and skull and reduce the likelihood of concussions. It is thought that the effectiveness of mouthguards against the impact power applied to the mandible depends on three factors as described above. They are the dissipation of the impact forces to the maxilla, skull, and temporomandibular joint complex when the mandible receives a blow [59, 60, 105, 106], the stabilization of the skull through increased neck muscle activity when clenching with mouthguard[86, 112], and gained with an alert mandibular position by wearing a mouthguard which can separate the condyle from their fossa. It seems that, needless to say, these results depend on the dissipation of the impact forces with mouthguard [39, 94]. Usually when the impact force to the orofacial region exceeds the physical resistance strength of an athlete's body the result is an injury. At this time, a large amount of kinetic energy is caused in the body. To absorb this energy, the teeth, periodontal tissue, the bones or the temporomandibular joints, etc. are destroyed [114]. Therefore, we only have to decrease the amount of kinetic energy in the body, to prevent injuries, by using mouthguards.

Furthermore, the impact power depends on certain conditions, such as the type of sports' participation, gender, age and so on. Consequently, the necessary thickness, hardness and everything else associated with mouthguards will depend on each athlete and or sport. In other words, each sport and each player that plays in each sport requires an individualized mouthguard that is made from appropriate materials and designs custom made by a learned sports-dentist. Any mouthguard materials and designs available should always be examined and considered in light of the newest study methods available.

CONCLUSION

Some sports have been responsible for traumatic brain injuries and mandibular bone fractures caused by repeated blows to the chin. It is commonly believed that the mouthguard protects against these injuries. However, this revelation by itself is not sufficient. Therefore, it is necessary to establish a standardized method of experimentation to solve this problem. In the present laboratory study, the tests were performed using pendulum impact equipment and an artificial skull model. However, it is necessary to take further well-designed prospective studies into consideration to show that mouthguards reduce the incidence of concussions and mandibular bone fractures.

Within the limits of this study, the following conclusions were drawn: (i) The present measuring system in this study was able to evaluate the distortion to the mandibular and the acceleration of the head from a direct blow to the mandible. (ii) Mouthguards can reduce distortion to the mandibular and the acceleration of the head from a direct blow to the mandible in the artificial skull model. (iii) Mouthguards might have the possibility of preventing mandibular bone fractures and concussions.

STUDY NO.7 : ARE ALL MOUTHGUARDS THE SAME AND SAFE TO USE? THE INFLUENCE OF OCCLUSAL SUPPORTING MOUTHGUARDS IN DECREASING BONE DISTORTION AND FRACTURES.

The original article.[79]

ABSTRACT

The safety benefits of mouthguards have been demonstrated in many studies, with many authors and sports dentists strongly recommending the wearing of mouthguards. However, wearing a mouthguard with incorrect occlusion might cause a variety of problems. It comes as no surprise that a traumatic blow to the chin, while wearing an insufficient mouthguard, might result in severe distortions to the mandibular bone, and bone fractures. The aim of this study was to clarify how ineffective insufficient occlusal supporting mouthguards are and how dangerous they can be to use. Consequently, in this study, occlusal supportive areas were varied and accelerations of head and distortions of the mandible were measured using an artificial skull model and a pendulum impact device. As a result, the distortions of the mandible tended to increase as the supported area decreased. On the contrary, accelerations of the head decreased as the occlusion part decreased. This is because, a lot of impact energy was consumed in the distortion of the mandible; accordingly, it seemed that only a little destructive energy was transferred to the head. From this study, it would seem that wearing a mouthguard, which is insufficient in the occlusion, has the potential of causing a bone fracture of the mandible. Consequently, mouthguards should have proper occlusion.

INTRODUCTION

With the number of people taking part in various sports worldwide increasing, mouthguards, as protective equipment, has attracted the attention of athletes and many others connected with sports. Until now, the efficiency of mouthguards to protect against trauma has been demonstrated in hundreds of studies, not only in epidemiological research, but also in experimental methods [25, 31, 59, 60, 63, 65, 66, 69, 86, 93, 106, 112, 115, 116] Mouthguards decrease the incidence of injuries to both the teeth and lips, and reduce the severity and prevalence of jaw fractures and concussions [39, 86, 106, 112, 117]. Not surprisingly, many authors and sports dentists, alike, have strongly recommended the wearing of mouthguards.

As a result of the growing number of sports and participants, sports-related injuries also appear to be increasing in proportion. In the current situation, seven sports have already taken initiatives to make the wearing of mouthguards compulsory, i.e. boxing, American football, rugby, kick-boxing, karate (Kyokushin), inline hockey and women's lacrosse (except for boxing, as per the rules, mouthguards are not applied for all the ages, levels and gender) in Japan. Furthermore, in other sports, such as K-1 and sumo-wrestling, mouthguards are gradually becoming more accepted among some participants.

But, any organization does not specify for a type of mouthguard should be used. So, one negative aspect of making the wearing of mouthguards compulsory in all sports is most players seem to wear inefficient mouthguards, such as a low safety and bulky boil-and-bite type or a too thin one-layer vacuum type.

In addition, it was envisaged that using these types of mouthguards might cause various problems, especially when using mouthguards with improper or insufficient occlusion. First, a traumatic blow was applied to a chin while wearing an insufficient mouthguard; it was easily suspected severe distortions might occure in the mandibular bone lead to increasing the chance of bone fractures. Secondly, it was also suspected that these types of mouthguards might cause temporomandibular arthritis. To keep these types of mouthguards in position, players need to continuously clench during a game or practice. This has the potential to cause large stress or even an overload to the neuromuscular system resulting in temporomandibular arthritis.

In the present study, we concentrated on the first problem. The aim of this study was to clarify how ineffective insufficient occlusal mouthguards are and how dangerous they can be to use. Consequently, in this study, occlusal supportive areas were varied, and accelerations of head and distortion of the mandible were measured using an artificial skull model and a pendulum impact device.

MATERIALS AND METHODS

Materials and methods employed in this study were almost the same previously mentioned No6 study [38], except for mouthguards' occlusion. Namely, mouthguard blanks used were Drufosoft and test samples were constructed of 2-layer-laminations (about 3mm thickness on a first molar) by means of a Dreve Drufomat After occlusal adjustment, the mouthguards were cut in position central, distal of left and right canine and distal of left and right second premolar, to test the following occlusal conditions. The six occlusal conditions tested were [1](76|MG), [2](7-4|MG), [3](7-1|MG), [4](7-|-3MG), [5](7-|-5MG), [6](7-|-7MG). (Figure 7-1). Three mouthguards were made and impact tests were conducted three times on each one.

RESULTS

Distortion in the Mandible

The results of two measurement points (left premolar, near the hit point; right premolar) and the total of the two measured points are shown in Figures . 7-2 to 4.

When measuring the two premolar points for distortion, it was revealed that as the occlusal area decreased, the distortion increased as below. On the left premolar, it increased from 134.8με in 7+7MG to 255.8με in 76|MG. In addition, 76|MG showed approximately two times the amount of distortion to that of 7+7MG. The right premolar showed a similar tendency with the distortion ranging from 108.2με in 7+7MG to 148.2με in 76|MG. As for the total, it increased from 814.8με in 7+7MG to 1281.1με in 76|MG. Statistical analysis (ANOVA) showed that differences in occlusal areas effect the distortion in all two-point tests conducted, as well as the total distortion recorded ($P < 0.01$). Furthermore, there were significant differences between 7+7MG and all other MG except for 7+5MG in left premolar and total (Tukey's test).

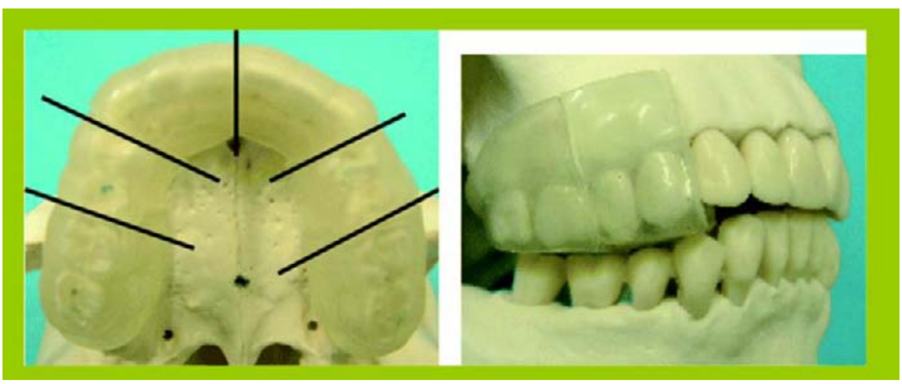


Fig. 7-1. The mouthguard was cut in position central, distal of left amd right canine and distal of left and right second premolar, to test occlusal conditions (left) and 7-4 MG mouthguars is in position (right).

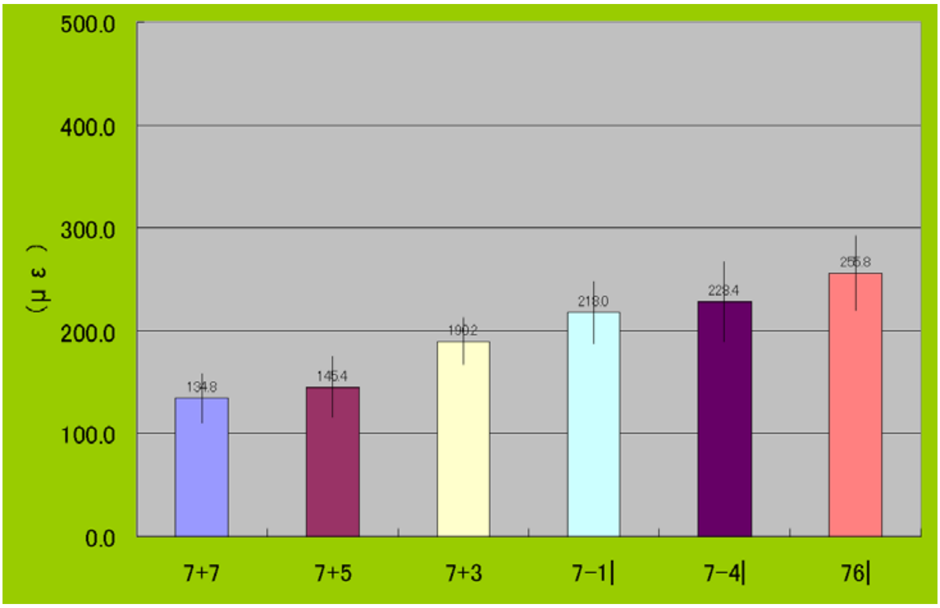


Fig. 7-2. Distortion on the mandible (left premolar, NHP): On the left premolar, it increased from 134.8 in 7+7 MG to 255.8 in 76| MG. In addition, 76| MG showed approximately two times the amount of distortion to that of 7+7 MG.

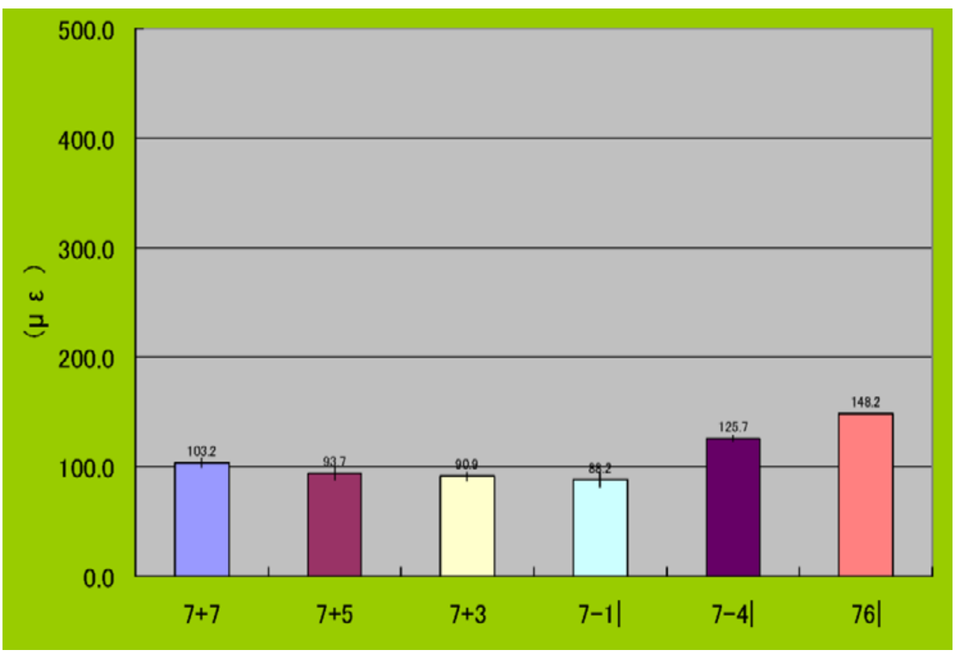


Fig. 7-3. Distortion on the mandible (right premolar): The right premolar showed a similar tendency with the distortion ranging from 108.2 in 7+7MG to 148.2με in 76| MG.

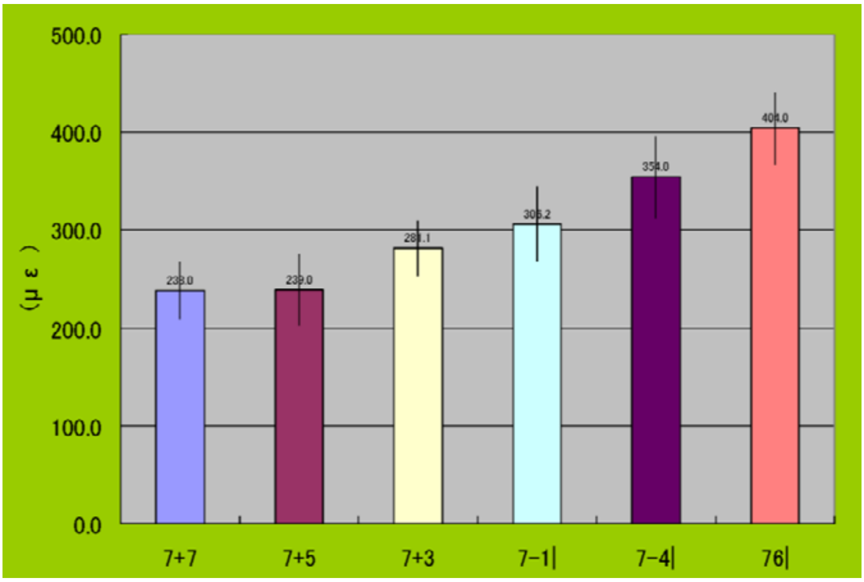


Fig. 7-4. Distortion on the mandible (total): As for the total, it increased from 814.8με in 7+7MG to 1281.1με in 76│MG.

Acceleration on the Head

Accelerations of the head are shown in Figure 7-5.

The acceleration of the head decreased as the occlusion areas decreased from 170.8 G in 7+7MG to 148.3 G in 76|MG. Statistical analysis of both the ANOVA and Tukey's test showed similar results as mandibular distortions.

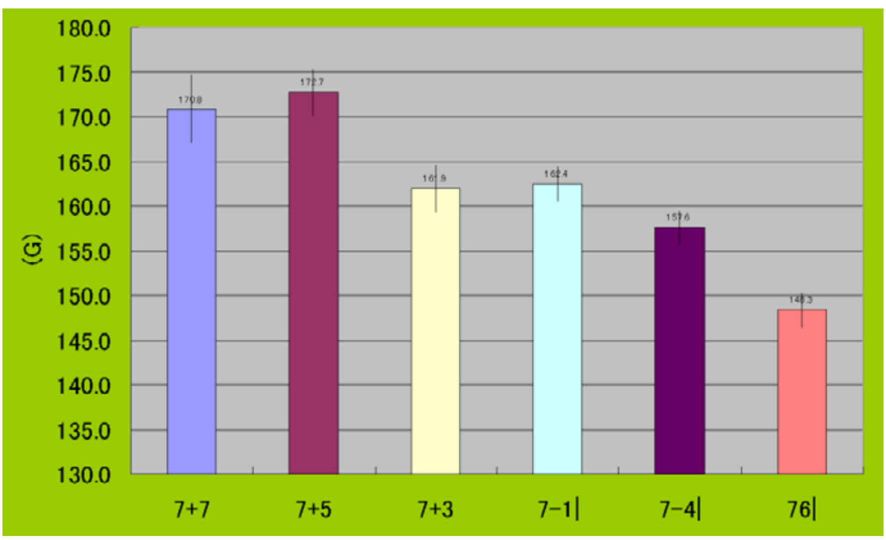


Fig. 7-5. Acceleration in the head. The acceleration of the head decreased as the occlusion areas decreased from 170.8G in 7-│-7MG to 148.3in 76│MG.

DISCUSSION

In many sports it is prohibited to collide with an opponent during play or to hit one's opponent with an instrument. However, in some sports a collision or blow will sometimes, accidentally or intentionally, occur. In contact sports, such as rugby, American football, boxing, and sumo-wrestling, collisions cannot be avoided as contact with opponents is expected and is a characteristic part of how they are played. Therefore, trauma is not a situation that can be avoided in all sports. The oro-facial area, where trauma to the teeth, jawbone, and so on occur frequently, is not exceptional. So, the use of mouthguards is expected to prevent injuries. Moreover, preventing concussion is also expected [60] [39, 86, 106, 112, 117] when using mouthguards that absorb shock energy and promote neck muscle activity [86, 112].

However, the comfort [1], safety, and so on of mouthguards are strongly influenced by the types available and the quality of manufacturing. So it is dangerous to assume that all types of mouthguards have the same level of protection. When a mouthguard has insufficient occlusal protection, the athlete is likely to sustain a mandibular fracture when hit in the jaw. This is likely to occur either if the mouthguard is manufactured incorrectly like many "boil and bite" types or a one layered custom made mouthguard. Especially, it is difficult to manufacture a mouthguard correctly when the patient has an open bite or severe malocclusion [34, 89].

Consequently, in this study, the authors concentrated on insufficient mouthguard occlusion with the purpose of examining the influence of different occlusal conditions of mouthguards on oro-facial safety. Testing was carried out using a skull model and a pendulum-type device to measure distortion to the mandible, and head acceleration.

This study illustrated that when an impact was applied to the mandible, the partial or total distortion of the mandible significantly increased as the supported area of the mouthguard decreased. In particular, a mouthguard such as 67|MG with insufficient occlusal contact showed almost double the amount of distortion compared to a mouthguard with an appropriate occlusal relationship (7+7MG). Of course, 7+7MG offered the most protection with 7+5MG at almost the same level of safety, but all other mouthguards, at 7+3MG or offering less occlusal support were viewed as being inappropriate.

When you pay attention to the acceleration of the skull, the acceleration decreased as occlusal area decreased. On the surface, this might appear to be a positive result. However, it was viewed that wearing a mouthguard with fewer occlusal supported areas, at the time of impact, meant that a lot of energy was consumed in the distortion of the mandible. Accordingly, it appeared that only a small portion of the energy from the point of impact was transferred to the head.

Thus using improper occlusal-supported mouthguards severely increased distortion, and so, logically, the possibility of mandibular bone fracture might increase. So, mouthguards should be made by dentists to ensure good occlusal relationships. The player should have good occlusal contact over a large area when biting mouthguard even lightly. This can only be done if an impression of the apposing arch is made to establish occlusal relationship and incisal guidance. Mass-produced mouthguards cannot fulfill these requirements and, as mentioned above, even custom made but too thin one-layered vacuum-type mouthguards are not adequate. Consequently, the conventional and modified [34]pressure-laminated mouthguard and the improved vacuum fabrication method [89] that allows enough occlusal thickness is strongly recommended at this time. The other types of mouthguards should only be used on a temporary basis until the ideal mouthguard can be constructed.

Information and recommendations that athletes wear an appropriate mouthguard is crucial. As participation in sports is so widely spread across society, all dentists (not only those involved in sports dentistry) have an obligation to inform their patients, who participate in various sports, of the benefits of wearing a mouthguard that gives appropriate occlusion, such as the laminate type, as much as possible. It is also necessary to have players understand the importance of both having regular examinations, at least once every season, and the need for having adjustments or remakes done to their mouthguard when a transformation takes place, a hole wears through, or when any nonconformity occurs to the mouthguard while in use or after the teeth have been treated. Equally, there is a need to spread information, to dentists and dental technicians alike, as to which manufacturing methods are appropriate for mouthguards in order to carry forward the knowledge of an efficient type of mouthguard to players, teachers, trainers, coaches, and so on. Any attempts for a more complete health management system by various groups, teams, and/or school units will be a substantial contribution to reducing sports injuries. To establish an environment where players can only use an appropriate mouthguard is surely the goal we should all aim for.

CONCLUSION

In this study, we took up the problem of occlusion as one of the ill effects of insufficient and inadequate mouthguards that are readily available for use by unsuspecting athletes from various sports.

The results of this study suggest that wearing poor quality mouthguards increases the possibility of distortion of the mandibular bone after impact resulting in increased fracture potential. There will always be the fear of causing a bone fracture to the mandible, if athletes continue to wear mouthguards that are insufficient in the area of occlusion, and thus are inadequate to protect properly. Therefore, we should not blindly follow directives from manufacturers who promote the use of mass-produced or thin one-layer-type mouthguards. There is an obvious need to recommend that players should avoid using the boil-and-bite type. Again, mouthguards should have proper occlusion that is precisely adjusted by well-trained dentists.

THE ENTIRE SUMMARY

We recognize that an ideal mouthguard will provide significant benefits in reducing the impact force caused either by a direct or an indirect oro-facial trauma and will also reduce the occurrence of concussion to the brain. Consequently, we have recommended wearing mouthguards to athletes and continue to be active in this area. The acceptance of mouthguards and the use of them are increasing. However, regrettably, not all mouthguards are sufficient to ward off serious injuries. The comfort, safety, and so on is strongly influenced by the types and the quality of manufacturing. So it is dangerous to assume that all types of mouthguards have the same level of protection. The player should have good occlusal contact over a large area when biting mouthguard even lightly. This can only be done if a mouthguard made by dentist or dental technician carefully. Mass-produced mouthguards cannot fulfill these requirements. Consequently, the conventional and modified pressure-laminated mouthguard and the improved vacuum fabrication method that could allow enough protection are strongly recommended at this time. Again, mouthguards should have proper occlusion that is precisely adjusted by well-trained dentists.

ACKNOWLEDGMENT

I sincerely thank the journal of Dental Traumatology and Blackwell Publishing, and Japan Prosthodontic Society for allowance to use our accepted articles to publish in this book. I also sincerely thank co-workers, Department of Sports Dentistry, Tokyo Dental College, Connell Wayne Regner, for their cooperation. I would like to thank Associate Professor Jeremy Williams, Tokyo Dental College, for his editing of the English of part of this manuscript.

REFERENCES

[1] DeYoung, AK; Robinson, E; Godwin, WC. Comparing comfort and wearability: custom-made vs. self-adapted mouthguards. *J Am Dent Assoc*, 1994, 125, 1112-1118.

[2] Bahr, R; Holme, I. Risk factors for sports injuries: a methodological approach. *Br J Sports Med*, 2003, 37, 384-399.

[3] Lephart, SM; Fu, FH. Emergency treatment of athletic injuries. *Dent Clin North Am*, 1991, 35, 707-717.

[4] Echlin, PS; Upshur, RE; Peck, DM; Skopelja, EN. Craniomaxillofacial injury in sport: a review of prevention research. *Br J Sports Med*, 2005, 39, 254-263.

[5] Newsome, PR; Tran, DC; Cooke, MS. The role of the mouthguard in the prevention of sports-related dental injuries: a review. *Int J Paediatr Dent*, 2001, 11, 396-404.

[6] Hayrinen-Immonen, R; Sane, J; Perkki, K; Malmstrom, M. A six-year follow-up study of sports-related dental injuries in children and adolescents. *Endod Dent Traumatol*, 1990, 6, 208-212.

[7] Borssen, E; Holm, AK. Traumatic dental injuries in a cohort of 16-year-olds in northern Sweden. *Endod Dent Traumatol*, 1997, 13, 276-280.

[8] Levin, L; Friedlander, LD; Geiger, SB. Dental and oral trauma and mouthguard use during sport activities in Israel. *Dent Traumatol*, 2003, 19, 237-242.

[9] Petersen, PE; Bourgeois, D; Ogawa, H; Estupinan-Day, S; Ndiaye, C. The global burden of oral diseases and risks to oral health. *Bull World Health Organ*, 2005, 83, 661-669.

[10] Love, RM; Carman, N; Carmichael, S; MacFadyen, E. Sport-related dental injury claims to the New Zealand Accident Rehabilitation & Compensation Insurance Corporation, 1993-1996: analysis of the 10 most common sports, excluding rugby union. *N Z Dent J*, 1998, 94, 146-149.

[11] Beachy, G. Dental Injuries in Intermediate and High School Athletes: A 15-Year Study at Punahou School. *J Athl Train*, 2004, 39, 310-315.
[12] Finch, C; Braham, R; McIntosh, A; McCrory, P; Wolfe, R. Should football players wear custom fitted mouthguards? Results from a group randomised controlled trial. *Inj Prev*, 2005, 11, 242-246.
[13] Chapman, PJ. The prevalence of orofacial injuries and use of mouthguards in Rugby Union. *Aust Dent J*, 1985, 30, 364-367.
[14] Marrow, J. The prevention of tetanus: which direction for improvement? *Arch Emerg Med*, 1986, 3, 221-223.
[15] Lombardi, S; Sheller, B; Williams, BJ. Diagnosis and treatment of dental trauma in a children's hospital. *Pediatr Dent*, 1998, 20, 112-120.
[16] Garon, MW; Merkle, A; Wright, JT. Mouth protectors and oral trauma: a study of adolescent football players. *J Am Dent Assoc*, 1986, 112, 663-665.
[17] Kvittem, B; Hardie, NA; Roettger, M; Conry, J. Incidence of orofacial injuries in high school sports. *J Public Health Dent*, 1998, 58, 288-293.
[18] Cornwell, H; Messer, LB; Speed, H. Use of mouthguards by basketball players in Victoria, Australia. *Dent Traumatol*, 2003, 19, 193-203.
[19] Jalleh, G; Donovan, RJ; Clarkson, J; March, K; Foster, M; Giles-Corti, B. Increasing mouthguards usage among junior rugby and basketball players. *Aust N Z J Public Health*, 2001, 25, 250-252.
[20] Labella, CR; Smith, BW; Sigurdsson, A. Effect of mouthguards on dental injuries and concussions in college basketball. *Med Sci Sports Exerc*, 2002, 34, 41-44.
[21] Godwin, WC; Craig, RG. Stess transmitted through mouth protectors. *J Am Dent Assoc*, 1968, 77, 1316-1320.
[22] Going, RE; Loehman, RE; Chan, MS. Mouthguard materials: their physical and mechanical properties. *J Am Dent Assoc*, 1974, 89, 132-138.
[23] Bishop, BM; Davies, EH; von Fraunhofer, JA. Materials for mouth protectors. *J Prosthet Dent*, 1985, 53, 256-261.
[24] Yamamoto, T. Experimental studies on properties of mouth protector: evaluation of various materials dynamic energy absorption test with electrical shock sensor (in Japanese). *Tsurumi Shigaku*, 1989, 15, 335-342.
[25] Park, JB; Shaull, KL; Overton, B; Donly, KJ. Improving mouth guards. *J Prosthet Dent*, 1994, 72, 373-380.
[26] Auroy, P; Duchatelard, P; Zmantar, NE; Hennequin, M. Hardness and shock absorption of silicone rubber for mouth guards. *J Prosthet Dent*, 1996, 75, 463-471.
[27] Craig, RG; Godwin, WC. Properties of athletic mouth protectors and materials. *J Oral Rehabil*, 2002, 29, 146-150.
[28] Aoyama, N; Katayama, Y; Kawamata, T; Maeda, T; Mori, T; Yamamoto, T; Kikuchi, T; Uwahodo, Y. Effects of antioxidant, OPC-14117, on secondary cellular damage and behavioral deficits following cortical contusion in the rat. *Brain Res*, 2002, 934, 117-124.
[29] Takeda, T; Ishigami, K; Jun, H; Nakajima, K; Shimada, A; Ogawa, T. The influence of the sensor type on the measured impact absorption of mouthguard material. *Dent Traumatol*, 2004, 20, 29-35.

[30] Hercus, MJ; Hoffmann, AA. Does interspecific hybridization influence evolutionary rates? An experimental study of laboratory adaptation in hybrids between Drosophila serrata and Drosophila birchii. *Proc Biol Sci*, 1999, 266, 2195-2200.

[31] Bemelmanns, P; Pfeiffer, P. Shock absorption capacities of mouthguards in different types and thicknesses. *Int J Sports Med*, 2001, 22, 149-153.

[32] Craig, GB Jr.; Hickey, WA. Current status of the formal genetics of Aedes aegypti. *Bull World Health Organ*, 1967, 36, 559-562.

[33] Agapie, T; Diaconescu, PL; Cummins, CC. Methine (CH) transfer via a chlorine atom abstraction/benzene-elimination strategy: molybdenum methylidyne synthesis and elaboration to a phosphaisocyanide complex. *J Am Chem Soc*, 2002, 124, 2412-2413.

[34] Takeda, I. An Improved Single-Layer Type Full Balanced Occlusion Mouthguard with Partial Lamination for the Mixed Dentition Players. *J pediatric dental are*, 2005, 11, 33-36.

[35] Maeda, M; Takeda, T; Nakajima, K; Shibusawa, M; Kurokawa, K; Shimada, A; Takayama, K; Ishigami, K. In search of necessary mouthguard thickness. Part 1: From the viewpoint of shock absorption ability. *Nihon Hotetsu Shika Gakkai Zasshi*, 2008, 52, 211-219.

[36] Soporowski, NJ. Fabricating custom athletic mouthguards. *J Mass Dent Soc*, 1994, 43, 25-27, 62-23.

[37] Walilko, T; Bir, C; Godwin, W; King, A. Relationship between temporomandibular joint dynamics and mouthguards: feasibility of a test method. *Dent Traumatol*, 2004, 20, 255-260.

[38] Takeda, T; Ishigami, K; Hoshina, S; Ogawa, T; Handa, J; Nakajima, K; Shimada, A; Nakajima, T; Regner, CW. Can mouthguards prevent mandibular bone fractures and concussions? A laboratory study with an artificial skull model. *Dent Traumatol*, 2005, 21, 134-140.

[39] Winters, JE. Sr. Commentary: Role of Properly Fitted Mouthguards in Prevention of Sport-Related Concussion. *J Athl Train*, 2001, 36, 339-341.

[40] Barth, JT; Freeman, JR; Winters, JE. Management of sports-related concussions. *Dent Clin North Am*, 2000, 44, 67-83.

[41] McCrory, P. Do mouthguards prevent concussion? *Br J Sports Med*, 2001, 35, 81-82.

[42] Ranalli, DN; Demas, PN. Orofacial injuries from sport: preventive measures for sports medicine. *Sports Med*, 2002, 32, 409-418.

[43] Wisniewski, JF; Guskiewicz, K; Trope, M; Sigurdsson, A. Incidence of cerebral concussions associated with type of mouthguard used in college football. *Dent Traumatol*, 2004, 20, 143-149.

[44] Mihalik, JMMA; Rivera, EM; Pardini, JE; Guskiewicz, KM; Collins, MW; Lovell, MR. Effectiveness of mouthguards in reducing neurocognitive deficits following sports-related cerebral concussion. *Dent Traumatol*, 2007, 23, 14-20.

[45] Mihalik, JP; McCaffrey, MA; Rivera, EM; Pardini, JE; Guskiewicz, KM; Collins, MW; Lovell, MR. Effectiveness of mouthguards in reducing neurocognitive deficits following sports-related cerebral concussion. *Dent Traumatol*, 2007, 23, 14-20.

[46] Materials, ASfTa. Standard practice for care and use of mouthguards. 1986, 323, 697-680.

[47] Academy, fSD. Frequently Asked Questions. http://wwwsportsdentistry-asdorg/faqsasp, Accessed Mar. 18, 2009.

[48] Cathcart, JF. Mouth protectors for contact sports. *Dent Dig*, 1951, 57, 346-348.
[49] Cohen, A; Borish, AL. Mouth protector project for football players in Philadelphia high schools. *J Am Dent Assoc*, 1958, 56, 863-864.
[50] Satoh, T. Where does the impact power applied to the human body go? (in Japanese). *J Japan Soc Biomechanics*, 1990, 14, 68-72.
[51] Flanders, RA. Mouthguards and sports injuries. *Ill Dent J*, 1993, 62, 13-16.
[52] Webster, DA; Bayliss, GV; Spadaro, JA. Head and face injuries in scholastic women's lacrosse with and without eyewear. *Med Sci Sports Exerc*, 1999, 31, 938-941.
[53] Maestrello-deMoya, MG; Primosch, RE. Orofacial trauma and mouth-protector wear among high school varsity basketball players. *ASDC J Dent Child*, 1989, 56, 36-39.
[54] Holmes, C. Mouth protection in sport in Scotland--a review. *Br Dent J*, 2000, 188, 473-474.
[55] Takeda, T; Ishigami, K; Shintaro, K; Nakajima, K; Shimada, A; Regner, CW. The influence of impact object characteristics on impact force and force absorption by mouthguard material. *Dent Traumatol*, 2004, 20, 12-20.
[56] Anderson, JOA, F. M. Classification, etiology and epidemiology. *Textbook and color atlas of traumatic injuries to the teeth*, 3rd edn. Copenhagen: Munksgaard, 1994, 151-180.
[57] Bulsara, YR; Matthew, IR. Forces transmitted through a laminated mouthguard material with a Sorbothane insert. *Endod Dent Traumatol*, 1998, 14, 45-47.
[58] Cummins, NK; Spears, IR. The effect of mouthguard design on stresses in the tooth-bone complex. *Med Sci Sports Exerc*, 2002, 34, 942-947.
[59] de Wet, FA; Heyns, M; Pretorius, J. Shock absorption potential of different mouth guard materials. *J Prosthet Dent*, 1999, 82, 301-306.
[60] Hickey, JC; Morris, AL; Carlson, LD; Seward, TE. The relation of mouth protectors to cranial pressure and deformation. *J Am Dent Assoc*, 1967, 74, 735-740.
[61] Hoffmann, J; Alfter, G; Rudolph, NK; Goz, G. Experimental comparative study of various mouthguards. *Endod Dent Traumatol*, 1999, 15, 157-163.
[62] Jagger, R; Milward, P; Waters, M. Properties of an experimental mouthguard material. *Int J Prosthodont*, 2000, 13, 416-419.
[63] Johnston, T; Messer, LB. An in vitro study of the efficacy of mouthguard protection for dentoalveolar injuries in deciduous and mixed dentitions. *Endod Dent Traumatol*, 1996, 12, 277-285.
[64] Low, D; Sumii, T; Swain, MV; Ishigami, K; Takeda, T. Instrumented indentation characterisation of mouth-guard materials. *Dent Mater*, 2002, 18, 211-215.
[65] Warnet, L; Greasley, A. Transient forces generated by projectiles on variable quality mouthguards monitored by instrumented impact testing. *Br J Sports Med*, 2001, 35, 257-262.
[66] Watermeyer, GJ; Thomas, CJ; Jooste, CH. The protective potential of mouthguards. *J Dent Assoc S Afr*, 1985, 40, 173-177.
[67] Westerman, B; Stringfellow, PM; Eccleston, JA. The effect on energy absorption of hard inserts in laminated EVA mouthguards. *Aust Dent J*, 2000, 45, 21-23.
[68] Westerman, B; Stringfellow, PM; Eccleston, JA. Beneficial effects of air inclusions on the performance of ethylene vinyl acetate (EVA) mouthguard material. *Br J Sports Med*, 2002, 36, 51-53.

[69] Westerman, B; Stringfellow, PM; Eccleston, JA. EVA mouthguards: how thick should they be? *Dent Traumatol*, 2002, 18, 24-27.
[70] Oikarinen, KS; Salonen, MA; Korhonen, J. Comparison of the guarding capacities of mouth protectors. *Endod Dent Traumatol*, 1993, 9, 115-119.
[71] Morii, H. A study on mouth protector-Influence of mouth protectors on the shock absorption ability of bovine teeth.(in Japanese) *Nihon Univ Dental J*, 1998, 72, 331-338.
[72] Maeda, M. Study on mouth protectors-Physical properties of the polyolefin polymers (in Japanese). *Jpn prosthodont Soc*, 1994, 38, 372-382.
[73] Andreasen, FM; Andreasen, JO. Treatment of traumatic dental injuries. Shift in strategy. *Int J Technol Assess Health Care*, 1990, 6, 588-602.
[74] Yamamoto, T. [Experimental studies on properties of mouth protector: evaluation of various materials dynamic energy absorption test with electrical shock sensor]. *Tsurumi Shigaku*, 1989, 15, 335-342.
[75] Yoshifuku, y. Impact forces of fighting techniques. (in Japanese). *J Sports Sci*, 1987, 6, 252-258.
[76] Morrow, RM; Kuebker, WA. Sports dentistry: a new role. *Dent Sch Q*, 1986, 2, 11-13.
[77] Tanaka, N, Hayashi, S, Suzuki, K, Uchide, N, Tomitsuka, K, Hirata, Y, Yoshimasu, H; Amagasa, T. [Clinical study of maxillofacial fractures sustained during sports and games]. *Kokubyo Gakkai Zasshi*, 1992, 59, 571-577.
[78] Powers, JM; Godwin, WC; Heintz, WD. Mouth protectors and sports team dentists. Bureau of Health Education and Audiovisual Services, Council on Dental Materials, Instruments, and Equipment. *J Am Dent Assoc*, 1984, 109, 84-87.
[79] Takeda, T; Ishigami, K; Ogawa, T; Nakajima, K; Shibusawa, M; Shimada, A; Regner, CW. Are all mouthguards the same and safe to use? The influence of occlusal supporting mouthguards in decreasing bone distortion and fractures. *Dent Traumatol*, 2004, 20, 150-156.
[80] Takeda, T; Ishigami, K; Handa, J; Naitoh, K; Kurokawa, K; Shibusawa, M; Nakajima, K; Kawamura, S. Does hard insertion and space improve shock absorption ability of mouthguard? *Dent Traumatol*, 2006, 22, 77-82.
[81] Francis, KT; Brasher, J. Physiological effects of wearing mouthguards. *Br J Sports Med*, 1991, 25, 227-231.
[82] Dorney, BD; V. Richer, T. Signature mouthguards. *Phillip J*, 1994, 9, 311-319.
[83] Padilla, R; Dorney, B; Balikov, S. Prevention of oral injuries. *J Calif Dent Assoc*, 1996, 24, 30-36.
[84] Padilla, RR; Lee, TK. Pressure-laminated athletic mouth guards: a step-by-step process. *J Calif Dent Assoc*, 1999, 27, 200-209.
[85] Woodmansey, KF. Athletic mouth guards prevent orofacial injuries: a review. *Gen Dent*, 1999, 47, 64-69; quiz 70-61.
[86] Takeda, TIK; Tsukimura, N; Shimada, A; Futomi, Ohki, K; et al. Study on the relation between the stomatognathic system and the systemic condition - effect of the mouthguard on boxing punch Part 2 (in Japanese). *J Japn Soc Clin Sports Med*, 1996, 13, 1152-1160.
[87] Jarvinen, S. Incisal overjet and traumatic injuries to upper permanent incisors. A retrospective study. *Acta Odontol Scand*, 1978, 36, 359-362.

[88] Jarvinen, S. Traumatic injuries to upper permanent incisors related to age and incisal overjet. A retrospective study. *Acta Odontol Scand*, 1979, 37, 335-338.

[89] Nakajima, K; Takeda, T; Kawamura, S; Shibusawa, M; Nara, K; Kaoru, N; Ishigami, K. A vacuum technique to increase anterior thickness of athletic mouthguards to achieve a full-balanced occlusion. *Dent Traumatol*, 2008, 24, 50-52.

[90] Takeda, T; Ishigami, K; Nakajima, K; Naitoh, K; Kurokawa, K; Handa, J; Shomura, M; Regner, CW. Are all mouthguards the same and safe to use? Part 2. The influence of anterior occlusion against a direct impact on maxillary incisors. *Dent Traumatol*, 2008, 24, 360-365.

[91] Josefsson, E; Karlander, EL. Traumatic injuries to permanent teeth among Swedish school children living in a rural area. *Swed Dent J*, 1994, 18, 87-94.

[92] Komatu, E; Kuriu, Y; Sasano, T; Hanazawa, K; Marumo, M; Sanjo, D. A clinical statistical study of traumatized teeth. (in Japanese). *Jpn j Oral Diag/ Oral Med*, 1988, 1, 136-140.

[93] Westerman, B; Stringfellow, PM; Eccleston, JA. An improved mouthguard material. *Aust Dent J*, 1997, 42, 189-191.

[94] Stenger, JM; Lawson, EA; Wright, JM; Ricketts, J. Mouthguards: Protection against Shock to Head, Neck and Teeth. *J Am Dent Assoc*, 1964, 69, 273-281.

[95] Sane, J. Comparison of maxillofacial and dental injuries in four contact team sports: American football, bandy, basketball, and handball. *Am J Sports Med*, 1988, 16, 647-651.

[96] Morton, JG; Burton, JF. An evaluation of the effectiveness of mouthguards in high-school rugby players. *N Z Dent J*, 1979, 75, 151-153.

[97] Morrow, R; Binci, T; Seals, P; Barnwell, G. Oral injuries in southwest women's basketball players. *Ahletic Training*, 1991, 26, 344-345.

[98] Kawamata, K. How do it become it if the concussion is repeated? When can the player return? *J Japn Soc Clin Sports Med*, 2002, 19, 637-643.

[99] Taguchi, S. When do you diagnose as the concussion? *J Japn Soc Clin Sports Med*, 2002, 19, 609-613.

[100] Gerberich, SG; Priest, JD; Boen, JR; Straub, CP; Maxwell, RE. Concussion incidences and severity in secondary school varsity football players. *Am J Public Health*, 1983, 73, 1370-1375.

[101] Gronwall, D; Wrightson, P. Cumulative effect of concussion. *Lancet*, 1975, 2, 995-997.

[102] Kelly, JP; Rosenberg, JH. Diagnosis and management of concussion in sports. *Neurology*, 1997, 48, 575-580.

[103] Wilberger, JE. Minor head injuries in American football. Prevention of long term sequelae. *Sports Med*, 1993, 15, 338-343.

[104] McCrory, P; Johnston, K; Meeuwisse, W; Aubry, M; Cantu, R; Dvorak, J; Graf-Baumann, T; Kelly, J; Lovell, M; Schamasch, P. Summary and agreement statement of the 2nd International Conference on Concussionin Sport, Prague 2004. *Br J Sports Med*, 2005, 39, 194-204.

[105] Kumazawa. Research on attenuation of occlusal forces in a human dry skull - Effect of mouthguards. *Kanagawa Shigaku*, 1992, 26, 412-419.

[106] Sumiyoshi. Efficacy of mouthguards against sports injuries- finite element method analysis supposing contusion of the chin. *Nihon Koukuu geka gakkai zasshi*, 1996, 42, 1192-1196.

[107] Takeda, I; Tsukimura, Shimada, Futomi, Toyoshima, et al. Study on the relation between the stomatognathic system and the systemic condition - effect of the mouthguard on boxing punch. *J Japn Soc Clin Sports Med Care*, 1996, 12, 569-578.
[108] Takeda, I; Tsukimura, Shimada, Futomi, Ohki, et al. Study on the relation between the stomatognathic system and the systemic condition - effect of the mouthguard on boxing punch Part 2. *J Japn Soc Clin Sports Med*, 1996, 13, 1152-1160.
[109] de Wet, FA; Badenhorst, M; Rossouw, LM. Mouthguards for rugby players at primary school level. *J Dent Assoc S Afr*, 1981, 36, 249-253.
[110] Suei, F; Taguchi, Wada Prevalence of tooth follicles involves in young persons and their prognosis. *J Jpn Stomatol Soc*, 1993, 42, 739-744.
[111] Ishikawa. *Dental Pathology*, Revised Edition, 1982, 344-345.
[112] Takeda, TIK; Tsukimura, N; Shimada, A; Futomi, Toyoshima, T; et al. Study on the relation between the stomatognathic system and the systemic condition - effect of the mouthguard on boxing punch (in Japanese) *J Japn Soc Clin Sports Med Care*, 1996, 12, 569-578.
[113] Piccininni, PM. Mouthguard and concussion prevention: International Symposium on Concussion in Sports. *BrJ Sports Med*, 2001, 35, 375.
[114] Satoh. Where does the impact power applied to the human body go? *J Jpn Soc Biomechanics*, 1990, 14, 68-72.
[115] Greasley, A; Imlach, G; Karet, B. Application of a standard test to the in vitro performance of mouthguards. *Br J Sports Med*, 1998, 32, 17-19.
[116] Greasley, A; Karet, B. Towards the development of a standard test procedure for mouthguard assessment. *Br J Sports Med*, 1997, 31, 31-35.
[117] Dorney, B. Mouthguard protection in sports injury. Case report. *Aust Dent J*, 1994, 39, 372.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 131-160
ISBN: 978-1-60876-223-1

Chapter 3

PARTICULATE RESPIRATORY PROTECTION – OVERVIEW, EMERGING ISSUES AND RESEARCH NEEDS

Samy Rengasamy*[*], *Ziqing Zhuang, Raymond Roberge and Ronald E. Shaffer
National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 626 Cochrans Mill Road, P.O. Box 18070, Pittsburgh, PA 15236.

ABSTRACT

This chapter is a brief review of respiratory protective devices for harmful airborne particulates. Particles in the breathing air present serious health hazards to civilians and workers in occupational settings. To reduce the inhalation of particles, respiratory protection is required when other control measures are not feasible or not yet implemented. For many years respiratory protection devices were used in industrial workplaces to minimize particulate exposures, then extended to other workplaces including healthcare. Respirators are required to reduce the exposure to airborne infectious diseases, including severe acute respiratory syndrome (SARS), pandemic influenza and multi-drug resistant diseases because implementation of administrative and engineering controls is not always feasible. Similarly, bioterrorism incidents involving viruses, bacteria and spores require respiratory protection. Another emerging area of concern is the recent technological developments in the nanotechnology industry for producing engineered nanomaterials. Nano-sized particles may potentially be more toxic than equal quantities of larger-sized particles.

The exposure to harmful nonbiological and biological aerosols can be addressed by proper selection of air-purifying respirators (APRs) recommended by regulatory agencies and other organizations. The National Institute for Occupational Safety and Health (NIOSH) and other standards organizations have developed performance standards for APRs. The NIOSH-certified APRs will provide expected protection levels when properly used. However, these devices do not fit all wearers equally well and impose varying

[*] Corresponding author: Phone: 412-386-6853, Fax: 412-386-5250, Email: ARengasamy@cdc.gov

levels of discomfort when fitted to the face. Poor fit of a respirator causes face seal leakage and compromises the respiratory protection levels. To address this issue, NIOSH has recently characterized face sizes and shapes characteristic of the current U.S. work force and developed new respirator fit test panels. Advanced respirator design for different facial features could improve respirator fit leading towards consistent protection.

Also, the physiological impact of some forms of respiratory protective equipment upon wearers has not been adequately examined. Re-use of disposable equipment is also an issue of recent importance given that supplies of disposable respirators may be insufficient in a pandemic-like setting. Recent technological developments have produced nanofibers which can be employed for producing efficient filters. Similarly, antimicrobial components can be incorporated into the filter media used for respirators to kill/ inactivate the microorganisms, as they pass through or are captured in the filter. The need for further research and developments in the different areas of respiratory protection are discussed.

I. INTRODUCTION

Particles are generated by a wide variety of natural, domestic, and industrial activities including construction, agriculture, and mining. Environmental particles are associated with a broad spectrum of acute and chronic health effects ranging from irritation to death (WHO 2000). Indoor air pollution also contributes to the increase in risks of respiratory diseases (WHO 2005). Similarly, workplace airborne contaminants are associated with diseases including pneumoconiosis, cancer, asthma and allergic alveolitis (WHO 1999; Hoet et al. 2004). The health effects of particulates are primarily reduced by implementing engineering (fume-hoods, biosafety cabinets, containment systems) and administrative controls. However, these measures may not be sufficient to reduce the inhalation of nonbiological as well as biological particles including multi-drug resistant tuberculosis, SARS, and avian and pandemic influenza viruses. Thus, respiratory protection is an essential line of defense to reduce the inhalation of harmful nonbiological and biological aerosols. In the United States, over three million workers are required to wear respirators in 282,000 establishments (BLS/NIOSH 2003) as a consequence of their work.

The increased production of engineered nanoparticles in workplaces also raises concern on their effects on human health and environment. Nanoparticles are defined as particles with at least one dimension <100 nm. Nanoparticles are generated by various natural as well as industrial processes including combustion, milling and grinding (Biswas and Wu 2005). Engineered nanoparticles are intentionally produced with specific properties including shape, size, surface and chemistry to meet specific applications in different areas (Biswas and Wu 2005). The chemical and physical properties of engineered nanoparticles can differ from the properties of the bulk form of the same materials. Workers generating or handling engineered nanoparticles in some situations have been shown to be exposed to high levels of nanoparticles (Bello et al. 2009). Exposures to different levels of nanoparticles have been shown to produce respiratory and systemic health effects in animal models (Maynard and Kuempel 2005; Oberdorster et al. 2005; Schulte et al. 2008; Fanning et al. 2009; Shvedova et al. 2009). The characteristics of engineered nanomaterials present new challenges to understand and manage potential health risks to workers in different workplaces.

Figure 1. Various types of NIOSH-approved respirators (with permission from manufacturers Moldex, Kimberly Clark, MSA, and North Safety Porducts).

Respiratory protection is a complex, dynamic and evolving field addressing filtration, face seal leakage, physiology and other factors necessary to support the use of respirators for protection against various types of particulates. Respirator manufacturers, standard development organizations and government regulators need to work together to develop "easy to use" respirators that provide maximum protection while minimizing burden to workers. This chapter provides an overview of respiratory protection programs and current research areas. The chapter concludes with an update on recent advances in biocidal filters, nanofilters, and other possible improvements to respiratory protection equipment.

II. Elements of Respiratory Protection Program

Types of Respirators

Two main classes of respirators namely air-purifying and air-supplied respirators are used for respiratory protection in workplaces. Air-purifying respirators (APRs) remove contaminants from ambient air while supplied-air respirators use breathing grade air from a source other than ambient air. Tight-fitting air-purifying respirators are divided into half-facepiece and full-facepiece respirators. Half-facepiece respirators cover the face from the nose to under the chin area, and full-facepiece respirators fit on the entire face covering from the hairline to under the chin area **(Figure 1)**. Among the APRs, some are called disposable filtering facepiece respirators (FFRs) because the entire respirator is made up of the filter material and discarded after use. Elastomeric APRs have replaceable filter materials. APRs are also classified as non-powered and powered based on how air is presented to the filter material. Wearers of non-powered respirators including FFR inhale ambient air by breathing. In the case of a powered air-purifying respirator (PAPR) a blower is used to force ambient air through the filters to the face mask inlet covering.

The air-supplied respirators include self-contained breathing apparatus (SCBA) and supplied-air respirators (SAR). SCBA user carries a source of respirable air in a tank which can supply air for limited times. In the case of SAR, the respirable air source is connected to the respirator up to 300 feet airline hose.

For protection against particulate hazards the most commonly used respirators are APRs, FFRs in particular. The remainder of the chapter will focus on APRs.

Respiratory Selection / Assigned Protection Factor (APF)

The Occupational Safety and Health Administration (OSHA) requires that NIOSH-approved respirators be used for respiratory protection against particulates where administration and engineering controls do not reduce worker exposure below some regulatory limit or target level (OSHA 2008). NIOSH certifies N (non-oil resistant), R (oil resistant), and P (oil proof) particulate filtering respirator types 95, 99, and 100 with minimum filtration efficiencies of 95%, 99%, and 99.97%, respectively. Respirators are tested for filtration performance under "worst-case" test conditions (e.g., 85 L/min flow rate, charge neutralized particles, etc.) by measuring the maximum penetration values throughout 200 mg aerosol loading (Federal Register 1995). According to the NIOSH respirator certification test protocol, N type respirators are tested with polydisperse NaCl aerosol particles with a count median diameter (CMD) of 75±20 nm (NIOSH 2007a), while P and R type respirators are tested with polydisperse dioctyl phthalate (DOP) aerosol particles with a CMD of 185±20 nm (NIOSH 2007b).

Respirator selection process for a given workplace is based on the assigned protection factor (APF) for the respirators (Federal Register 2006). The APF of a respirator reflects the level of protection that a properly functioning respirator used in the context of an OSHA-compliant respiratory protection program would be expected to provide to a population of properly fitted and trained users. The APFs provide employers information when selecting respirators for protection against contaminants in workplaces (Federal Register 2006). The APF takes into account all expected sources of facepiece penetration including penetrations through the face seal, filter and valve leakage. For example, an APF of 10 for a respirator means that a user could expect to inhale no more than one tenth of the airborne contaminant present in a given workplace. Proper selection of respirators using APFs is an important component of the respiratory protection program. **Table 1** shows OSHA assigned APFs for different types of respirators. Appropriate respirators are selected based on the criteria described in the NIOSH respirator selection logic based on toxicologic, safety and other relevant information (NIOSH 2004). Selection of respirators for infectious aerosols requires consideration of expert opinion in addition to the traditional exposure assessment approaches. Further, a respirator selection method for infectious aerosols has been described (McCullough and Brosseau 1999). The toxicity of bioaerosols was determined from risk ranking proposed by a variety of organizations including Centers for Disease Control and Prevention (CDC), National Institute of Health (NIH), European Commission, Canadian Laboratory Centre for Disease Control and the World Health Organization (WHO). A ranking of airborne concentration of bioaerosols was obtained from the individual's activity, room volume and airflow rates. From the concentration and toxicity ranks, a minimum APF was determined and the corresponding respirator class suggested.

Respirator Training

OSHA requires employers to provide effective training to employees who are required to use respirators (OSHA 2008). OSHA also requires that all new employees should receive training within the last 12 months immediately prior to joining a respiratory protection program. Employers are required to evaluate proper implementation of the respirator program. The training must be comprehensive, understandable, and recur annually and more often if necessary. Employers shall ensure that employees learn how to inspect, don and doff, and check face seal leaks of the respirator.

Table 1. Assigned protection factors (APFs).

Type of respirator [1]	Quarter mask	Half-mask	Full face-piece	Helmet/ hood	Loose-fitting face-piece
1. Air-purifying respirator (APR)	5	10	50	-----	-----
2. Powered air-purifying respirator (PAPR)	-----	50	1,000	25/1000[2]	25
3. Supplied-air respirator (SAR)					
Demand mode	-----	10	50	-----	-----
Continuous mode	-----	50	1,000	25/1000[2]	25
Pressure demand and other positive pressure mode	-----	50	1,000	-----	-----
4. Self-Contained Breathing Apparatus (SCBA)					
Pressure mode	-----	10	50	50	-----
Pressure demand and other positive pressure mode	-----	-----	10,000	10,000	-----

[1] The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[2] The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. The level of performance can be demonstrated by performing a workplace protection factor (WPF) or simulated workplace protection factor (SWPF) study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

Fit Testing

Respiratory protection is dependent on minimizing both the penetration of particles through filter media as well as leakage around the face mask interface. The high filtration efficiency levels measured for particulate respirators under laboratory test conditions do not necessarily imply high levels of respiratory protection in workplaces. Face seal leakage is a major component of the total inward leakage of particles. For tight fitting APRs, a proper seal between the respirator sealing surface and wearer's face is crucial to reduce leakage. Several studies demonstrated the importance of fit-testing for achieving highest levels of simulated workplace protection factors (Coffey et al. 1999a; Zhuang et al. 2003). OSHA requires fit testing annually either by a qualitative or a quantitative method (OSHA 2008). OSHA-accepted qualitative methods employ the use of isoamyl acetate (IAA), saccharine, Bitrex™ and irritant smoke along with the wearer's senses for determining respirator fit pass/fail criteria. Quantitative fit factor measurements utilize instrumentation to determine leakage using aerosol particle concentration and negative pressure measurements to provide a numerical assessment.

III. Filtration Performance

Filtration Mechanisms

Particles are captured by fibrous filters through interception, impaction, diffusion and electrostatic mechanisms. According to the single fiber theory, mechanical filters capture particles >300 nm size by interception and inertial impaction mechanisms, while Brownian diffusion efficiently filters <200 nm particles (Hinds 1999). However, the intermediate size particles, where none of the mechanisms are dominant, show maximum penetration through filters. The size of the particles at the minimum efficiency is the most penetrating particle size (MPPS). Many studies have shown that the MPPS for mechanical filters is >100 nm (Lee and Liu 1980; Lee and Liu 1982). The MPPS is dependent on several factors including filter charge, particle charge, fiber diameter, packing density and flow rate (Lee and Liu 1980; Lee and Liu 1982; Martin and Moyer 2000). Developments in filter technology enabled the introduction of electric charges onto filter media by corona or triboelectric charging mechanisms to enhance particle capturing efficiency. Electret filters capture particles via coulombic attraction and polarizing forces in addition to other common filtration mechanisms (Hinds 1999). Electret filters are designed with less weight and are widely employed in respirators because of the tremendous increase in filtration efficiency with only modest increase in resistance (pressure drop). Electret filters shift the MPPS towards smaller size (<100 nm) particles (**Figure 2**) (Martin and Moyer 2000; Balazy et al. 2006a; Huang et al. 2007; Rengasamy et al. 2007; Rengasamy et al. 2009).

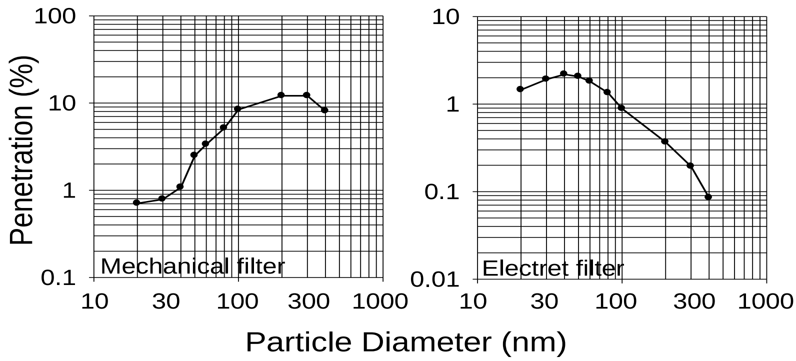


Figure 2. Typical penetration curves for mechanical and electret filters.

Filtration Efficiency

The filtration performance of APRs against particulates has been reviewed in detail elsewhere and only a cursory review will be provided here (Hodous and Coffey 1994; Brown 1995; Rengasamy et al. 2004; Shaffer and Rengasamy 2009). Most studies published in literature employed particulate N95 and P100 FFRs because of their widespread use in many workplaces. For simplicity, these research studies measured the initial penetration levels of polydisperse or monodisperse particles for a short time, such as one minute. The laboratory filtration performance of N95 and P100 FFRs is well-characterized for various size ranges of particles (Qian et al. 1998; Martin and Moyer 2000; Balazy et al. 2006a; Rengasamy et al. 2007; Rengasamy et al. 2008; Eninger et al. 2008a; Eshbaugh et al. 2009). Most of these studies measured the penetration of solid and liquid aerosol particles of different size monodisperse or polydisperse aerosols. The penetration levels were within the NIOSH allowed penetration levels for the different types of respirators at 85 L/min flow rate and the MPPS was in the 50 nm range. One research group reported monodisperse NaCl particle as well as MS2 virus aerosol particle penetration levels > 5% for the MPPS (50 nm observed in the studies) for one of the two N95 FFR models tested in their studies (Balazy et al. 2006a; Balazy et al. 2006b). Subsequent studies measured the filter penetration levels for five N95 FFR models using monodisperse NaCl particles from 20 nm to 400 nm (Rengasamy et al. 2007). Some models showed penetration levels up to 5.2% at the MPPS (40 nm observed in the study) which was not statistically different from 5%. One study reported 3-5% penetrations at the MPPS (approximately 40-60 nm) for N99 FFRs (Eninger et al. 2008a). The discrepancy between the penetration levels measured by the NIOSH particulate test method and other studies can be explained by the difference in the test methodologies. NIOSH respirator certification employs polydisperse aerosols (NaCl, 75±20 nm CMD and DOP, 185±20 nm CMD) for penetration measurements throughout 200 mg loading. Particle penetration is obtained by measuring light scattering of particles using a photometric technique, which is not sensitive to particles <100 nm (Eninger et al. 2008b). On the other hand, many researchers measured penetration levels of different size monodisperse particles for a shorter time using highly sensitive equipment with no loading.

Several of the investigators measured monodisperse aerosol penetrations for durations as low as one minute using a sensitive particle number-based method for the <100 nm particle range (Martin and Moyer 2000; Balazy et al. 2006a; Rengasamy et al. 2007; Eshbaugh et al. 2009). Recent studies attribute particle number, as well as surface area, to the harmful health effects of humans (Donaldson et al. 1998; Schulte et al. 2008; Waters et al. 2009). This indicates that number- and/or surface area-based test methods for respirator testing should be considered for future "worst-case scenario" test methods for contemporary filter media used in respirators.

There have also been several reviews on respiratory protection against biological aerosols (Hodous and Coffey 1994; Rengasamy et al. 2004). Biological aerosol particle penetration measurement is complicated because of the need for a specially-designed experimental set up. Several studies showed that biological aerosols behave the same way as inert aerosols with respect to filtration (Willeke et al. 1996; Brosseau et al. 1997a; McCullough et al. 1997; Eninger et al. 2008c). In one study, bacterial penetrations were compared with those of spherical corn oil particles of the same aerodynamic particle sizes (Willeke et al. 1996). The authors showed that respirator filters had the same penetration values for spherical *Streptococcus salivarius* of 0.8-1.0 μm diameter and spherical corn oil particles (0.9-1.7 μm diameter). This finding was confirmed using *Mycobacterium abscessus* aerosol and similar size polystyrene latex (PSL) particles (Brosseau et al. 1997a; McCullough et al. 1997). Recent studies showed that size-fractionated physical penetration of MS2 virus was similar to the viable penetrations in the electrical mobility diameter (22-29 nm) of MS2 virus (Eninger et al. 2008c).

Because of their small size, questions have been raised against the performance of APRs against nanoparticles generated in the workplace. A recent review discussed the current knowledge and limitations (Shaffer and Rengasamy 2009). Furthermore, NIOSH published recommendations for respiratory protection against nanoparticles (NIOSH 2009). The primary concern was that the thermal velocity of small size particles can exceed their capture velocity (Dahneke 1971) leading to increased worker exposure. This suggests that small size particles approaching molecular sizes may not be captured and that thermal rebound of particles <10 nm size will increase penetration levels as predicted (Wang and Kasper 1991). However, single fiber filtration theory predicts that small size particles will be effectively captured by diffusion. Studies were needed to measure the performance of filter media in general and filters used in APRs in particular to determine single fiber filtration theory predicted performance for particles below <10 nm size.

To better understand the penetration of smaller size nanoparticles, experimental studies used glass fiber, composite and membrane filters and challenged them with monodisperse silver (4-10 nm) and dioctyl phthalate (32-420 nm) aerosols to measure particle penetrations at different face velocities (VanOsdell et al. 1990). Penetration levels decreased with decreasing particle size and there was no evidence for thermal rebound for particles of 4 nm size at face velocities up to 15 cm/s. Further studies showed no measurable thermal rebound of particles until 3 nm size (Ichitsubo et al. 1996). The authors also showed that the penetration of nanoparticles below 2 nm was higher than the theoretical results, thus suggesting thermal rebound. A recent study confirmed the thermal rebound for particles <2 nm size at a face velocity of 2.5 cm/s (Kim et al. 2006). Recent studies using different test systems confirmed the absence of any thermal rebound effect for particles >2 nm size (Heim et al. 2005; Kim et al. 2007a). These studies indicated that respirators made from fibrous filter media would be efficient for capturing particles down to 2 nm.

Historical measurements of respirator efficiency have used aerosol particles >20 nm size, and the lack of information for smaller size particle penetration has remained a concern. Recently, the filtration efficiency of respirators against smaller size particles <20 nm was investigated to determine if any thermal rebound effects could be observed. The filtration performance of respirators against NaCl nanoparticles in the 4.5 nm to 10 μm range aerosols was investigated using one model each of NIOSH-approved N95 and CE-marked European FFP1 respirators (Huang et al. 2007). The authors showed that particles below 10 nm were collected efficiently by the respirators. Another study employed monodisperse silver nanoparticles in the range of 4-30 nm to measure penetration levels for NIOSH-approved N95 and P100 respirators (Rengasamy et al. 2008). Filtration performance of five models of N95 and two models of P100 increased with decreasing particle size down to 4 nm with no thermal rebound. Similar trends in penetrations were obtained for two models each of Conformite Europeen (CE)-marked FFP2 and FFP3 respirators (Rengasamy et al. 2009). All the respirators tested in the study showed no deviation from single fiber filtration theory for particles as small as 4 nm.

Filter Degradation

Filtration performance of FFRs exposed to physical processes and chemicals in workplaces was not well understood until recently. Intermittent aerosol particle loading onto electret filters was shown to decrease filtration efficiency (Moyer and Bergman 2000). Electret filter degradation by gamma- (Walsh and Stenhouse 1998) and X-ray- radiations (Janssen et al. 2003) have been described. In another study, UV irradiation of one N95 and one P100 FFR for up to 8 hrs showed that the penetration levels remained within NIOSH allowed levels (Viscusi et al. 2007). The authors also showed that microwave treatment up to two minutes had no significant changes in filtration performance on the two models tested. Some studies showed that electret filter media degrade at temperatures up to 65°C and relative humidity (RH) up to 90% (Ackley 1982). In other studies, dry heat at a temperature of 80°C for one hour (Viscusi et al. 2007) and dry heat up to 90°C for one hour (Viscusi et al. 2009) showed no visible damage or significant change in filtration efficiency for N95 and P100 FFRs.

Electret filters have been shown to undergo filtration performance degradation upon exposure to certain chemicals. For example, exposure to oils such as DOP decreased the filtration performance of electret filters by mechanisms including neutralization and masking of charge (Tennal et al. 1991; Barrett and Rousseau 1998). Liquid isopropanol treatment increased particle penetration levels with a shift in the MPPS towards higher diameter size particle indicating the removal of electric charges (Chen et al. 1993; Chen and Huang 1998; Martin and Moyer 2000). The removal of electric charges from liquid isopropanol-treated electret respirators was confirmed by electrostatic force microscopy measurements (Kim et al. 2007b). Some studies attributed swelling and dissolution of low-molecular weight polymers for the increase in particle penetrations (Myers and Arnold 2003). In contrast, no measurable release of particles from isopropanol-treated FFRs was reported (Rengasamy et al. 2009). Interestingly, some studies demonstrated that organic solvents in vapor form did not degrade electret filters (Jasper et al. 2006). While great progress has been made, further studies are still needed to better understand the mechanism of electrical charge removal by different treatments.

IV. Particle Leakage

Face seal leakage is a major component of total inward leakage of particles in addition to particle penetration through filter media. Until recently, the relative contribution of face seal leakage to total inward leakage was not well understood for tight fitting APRs. To address this issue, various studies have been conducted with both manikin head forms, and human subjects performing a set of exercises simulating workplace maneuvers in the laboratory, and with subjects performing their normal work activities in real world workplaces.

Face Seal Leakage with Manikin Head

Several studies measured particle leakage into the breathing zone using a manikin set up (**Figure 3)** (Cooper et al. 1983; Tuomi 1985). The respiratory protection by common clothing and household items such as handkerchief and toweling materials was also studied using a manikin head (Cooper et al. 1983). The authors showed 0-65% leakage around the face/mask interface, and 0.6-39% penetration through filtering media at a flow rate of 37 L/min, indicating that leakage is significantly contributing to particle penetration. In another manikin study, face seal leakage produced higher levels of penetration for particles >5 µm diameter (Tuomi 1985). Subsequent studies showed that aerosol penetration through the filter was strongly dependent on particle size and flow rate, while particle leakage was dependent strongly on particle size and less strongly on pressure drop (Hinds and Kraske, 1987). Based on their results, a model was developed to predict the overall penetration as a function of particle size for any work rate and overall total mass penetration and exposure aerosol size distribution (Hinds and Bellin 1987).

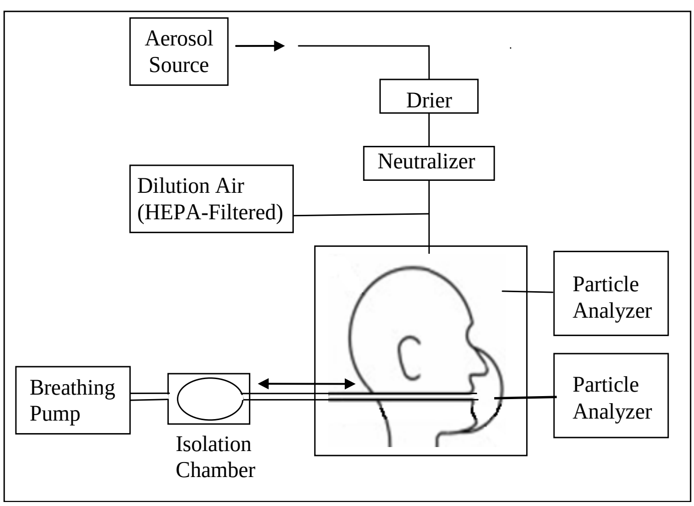


Figure 3. A typical manikin set up to measure particle penetration through filter and face seal.

Some studies compared the face seal leakage of aerosols with gases. In a manikin study, face seal leakage was measured as a function of leak size and particle size with polystyrene latex (PSL) particles and acetone vapor as challenge agents (Myers et al. 1991). Leakage of PSL particles decreased with increasing diameter size from 0.36 to 2.5 µm. The authors also showed that the leakage of acetone vapor was higher than that of PSL particles, indicating that a gaseous challenge agent may be better for fit testing purpose. This possibility was tested with PSL (0.72 µm) particles and vapors including sulfur hexafluoride (SF_6) and isoamyl acetate (IAA) using a manikin head form (Gardner et al. 2004). The simulated respiratory fit factor measurements for PSL particles correlated with those for SF_6 and IAA, suggesting that submicron particle leakage was similar to that of vapor challenges.

Simulated Workplace Protection Factor (SWPF)

Artificial static leaks introduced in manikin head studies may not represent the more dynamic leaks created while a respirator-worn human face is moving during normal work activities (Krishnan et al. 1994; Janssen and Weber 2005; Janssen et al. 2007). Because of the difficulties in measuring particle leakage for subjects wearing respirators in a real workplace, SWPF measurements are made in laboratories using test exercises designed to simulate normal workplace activities. SWPF is measured as the ratio of test atmosphere aerosol concentration outside to the inside of a properly functioning respirator worn properly by a subject in the laboratory.

Several studies investigated the SWPF for N95 FFRs (Coffey et al. 1999b; Coffey et al. 2004; Zhuang et al. 2005). In one study, the performance of 20 N95 FFRs and one elastomeric respirator with replaceable filters was measured in a laboratory setting using a PortaCount Plus (Coffey et al. 1999b). The 95th percentile of the total penetration with fit-testing for all of the respirators combined was 4%, which indicated higher than expected protection levels for N95 respirators. However, the 95th percentile of the total penetration was 33% without fit-testing indicating the importance of fit testing to achieve high levels of workplace protection. In a similar study, 12 N95 FFRs passing a PortaCount Plus fit test method showed 5th percentile SWPF value ≥10 (Coffey et al. 2004). Further studies confirmed this finding by measuring the SWPF for 18 models of N95 (Zhuang et al. 2005). The results showed geometric means (GM) of SWPF 25 and 22 for men and women, respectively. Using a similar methodology, Lawrence and colleagues measured the SWPF for N95 elastomeric and N95 FFRs (Lawrence et al. 2006). For N95 elastomeric and FFRs, the GM values were 35.5 and 20.5 with 5th percentile values of 7.3 and 3.3, respectively. None of these devices as a group provided the expected protection levels for a half-facepiece respirator.

Recently, the SWPF for particles <100 nm was investigated for four different models of N95 FFRs using an Electrical Low Pressure Impactor (ELPI) (Lee et al. 2008). In general, the protection factor (PF) increased with increase in particle size. The authors obtained GM values of 21.5 for four commercially available N95 FFR models (A, B, C, and D) over the eight particle size ranges tested in the study. Nine samples of N95 FFRs for each model A, B, C, and D were tested and the PF values were <10 for 13.9%, 63.95%, 11.1% and 22.2% of the respirators, respectively, suggesting that the OSHA assigned APFs may overestimate their measured PF. Similarly, PF values <10 were reported for some N95 FFRs in a previous study

(Coffey et al. 2004). Interestingly, PF values were less for particles in the 40-200 nm range compared to 200-1300 nm range (Lee et al. 2008). The increasing concern on nanoparticle exposure in workplaces suggests that further studies are needed to better understand the workplace protection factor (WPF) for nanoparticles.

Workplace Protection Factor (WPF)

WPF is a measure of the protection provided in a workplace, under the conditions of that workplace, by a properly selected, fit tested and functioning respirator while it is properly worn and used (AIHA et al. 1985). The number of WPF studies is limited because of the difficulties in simultaneously measuring the contaminant concentrations inside and outside of the respirator on subjects working in real workplaces.

Several studies measured the WPF for different types of APRs used for protection against particulates. In one study the WPF of N95 FFRs in a steel foundry was evaluated (Janssen et al. 2007). Individual WPF values ranged from 5 to 753. The GM was 119 with a 5th percentile value of 19 showing a consistent performance of FFRs with the APF for half-facepiece respirators. Another study investigated the WPF of half-facepiece non-powered air purifying elastomeric respirators equipped with P100 filters in a steel foundry (Zhuang et al. 2003). The GM of the WPFs values was 920 with a geometric standard deviation (GSD) of 17.8 ensuring expected protection levels. On the contrary, one study showed WPFs <10 for N95 FFRs against microorganisms in the 0.7-2 µm and 2-10 µm range sizes representing most bacteria and most fungi, respectively, in agricultural farms (Lee et al. 2005). The low WPF values obtained for some microorganisms are less than the APF value of 10 expected for FFRs. The low WPF values are in agreement with the SWPF obtained for some N95 FFRs (Lawrence et al. 2006). Studies on WPF in healthcare environment are not available to assess the effectiveness of respirators against infectious microorganisms in that occupational setting (Radonovich et al. 2008). However, the low concentration of infectious aerosol particles in healthcare facilities makes WPF measurement difficult.

Fit Test Panels, Anthropometric Analysis, Respirator Design

As noted earlier, face-fitting characteristics are by far the most important aspect for tight fitting respirators to ensure the reliability and level of the protection they offer. Yet, until recently the database of facial dimensions that was used for sizing respirators to fit workers' faces was more than three decades old. For example, the respirator fit test panels used by NIOSH for respirator certification are based on the 25-subject panels developed by the Los Alamos National Laboratory (LANL) in the early 1970's based on U.S. military personnel data. The changing U.S. demographics have resulted in the test panels becoming less representative of the current U.S. workforce of respirator users. Problems with the LANL panel have been reported elsewhere (Zhuang et al. 2005).

In 2001, NIOSH initiated a study to develop an anthropometric database of the heads and faces of civilian respirator users in the U.S. workforce to update the respirator fit test panels. A total of 3,997 subjects were recruited from industries and public services in which workers routinely or occasionally use respirators. Although the sampling plan did not call for sampling specific geographic regions, subjects were obtained at 41 separate sites, located in 8 states from the east to west coasts of the United States. All subjects were measured for 21 dimensions using traditional measurement tools, and 1013 of the total were scanned with a state-of-the-art 3D scanner (Zhuang and Bradtmiller 2005). The researchers established a database containing anthropometric measures that are representative of U.S. population who rely on respirators to prevent work-related respiratory illnesses, injuries, and death.

Based on the data collected, two new fit test panels for half- and full-face respirator fit testing were developed (Zhuang et al. 2007). One of the new panels (NIOSH bivariate panel) included the same linear measurements used in the LANL panel currently used by NIOSH in the respirator certification program (**Figure 4**). The other panel was based on establishing the appropriate facial features by using principal component analysis (PCA) to identify the combination of facial dimensions that best represented the variation among the faces in the data set (**Figure 5)**. The new panels have been incorporated into the International Organization for Standardization (ISO) respiratory protective devices standards (ISO 2009). The use of the new bivariate panel to assess respirators ability to fit a range of facial sizes has been considered in the concept development of a total inward leakage requirement for respirator certification (NIOSH 2007). Based on the new anthropometric data collected, five digital 3-D headforms representative of the current U.S. work force have also been developed (Zhuang et al. 2010).

A similar anthropometric survey of Chinese civilian workers was conducted in 2006 (Du et al. 2008). A total of 3000 subjects (2,026 male and 974 female) between the ages of 18 and 66 years old was measured using traditional techniques. Through comparison with the facial dimensions of American subjects, the study indicated that Chinese civilian workers have shorter face length, smaller nose protrusion, larger face width and longer lip length. Two respirator fit test panels were developed specifically for Chinese workers with the same techniques used to create the NIOSH panels (Chen et al. 2009). Another research group collected facial anthropometric data on 451 Chinese university students and teachers and found that Chinese may have shorter and wider facial characteristics than American civilian workers and military personnel (Yang et al. 2007)

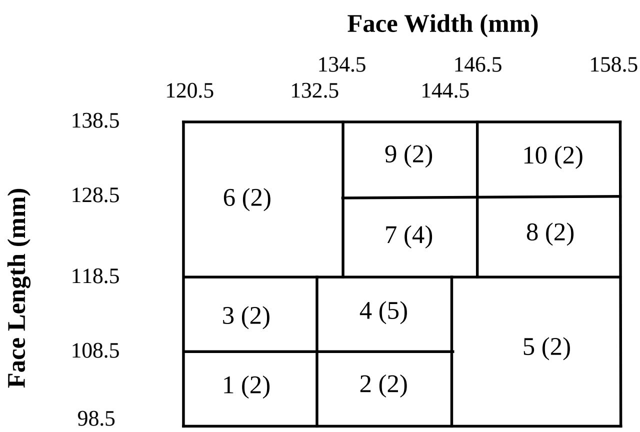


Figure 4. NIOSH fit test panel based on face length and face width. The numbers in each cell represent cell number and the numbers in parentheses indicate the number of subjects to be sampled from each cell.

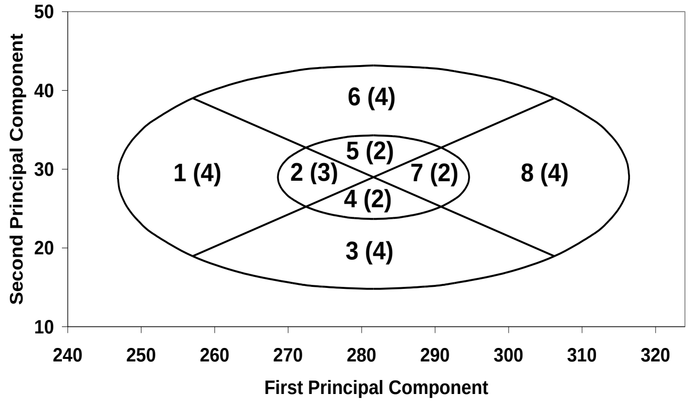


Figure 5. NIOSH fit test panel based on two principal components. The numbers in each cell represent cell number and the numbers in parentheses indicate the number of subjects to be sampled from each cell.

In the 2007 Institute of Medicine (IOM) report, “Assessment of the NIOSH Head and Face Anthropometric Survey of U.S. Respirator Users***”,*** the IOM recommended that "NIOSH [...] perform research to determine which facial features have the greatest impact on respiratory protection of face masks in the workplace, using quantitative measures." (IOM 2007). To address these concerns, NIOSH has developed a research roadmap documenting short- and long-term strategies for facial anthropometrics and respirator fit research.

V. Physiological Impact of FFRs on Wearers

Only a modest amount of data exist on the physiological burden associated with FFRs by workers at low-to-moderate work rates (e.g., healthcare workers, nursery care staff, etc.). There are also few human studies addressing the overall physiological impact of air-purifying respirators (APR) and their impact on wearers will not be included in this review. The impact of wearing a FFR may be manifested as an increase in heart rate (HR), breathing rate (f_B), tidal volume (V_T), minute ventilation ($\dot{V}_E$), or any combination of these parameters. FFR use also results in breathing gas mixtures that have carbon dioxide (CO_2) and oxygen (O_2) levels significantly different from those found in the ambient atmosphere (Caretti and Coyne 2008). FFR also increases the work of breathing because of the need of the wearer to overcome the resistance of the filter media and the increased physiological burden of the respirator dead space ($V_{D\ resp}$). The increase in inspiratory resistance is a dominant effect (Martyny et al. 2002) and, if significant, can result in hypoventilation (Lafferty and McKay 2006). Treadmills have been used in most of the studies to investigate the impact of FFR use on physiological parameters (**Figure 6**).

Breathing Resistance

Breathing resistance in FFRs is a function of filter media parameters (e.g., packing density of fibers, orientation of fibers, thickness of the filter, particulate loading), degree of airflow (higher airflows generally result in greater resistance), and FFR fit (leakage associated with poor fit will impact resistance). Resistance to airflow in FFRs is moderated by decreasing air velocity through manipulation of the shape of the FFR to increase surface area (e.g., duckbill FFR, pleated FFR, etc.). Also, the use of electrically charged (electret) filter fibers results in more efficient FFR that are thinner and offer less resistance to airflow. NIOSH breathing resistance maximums for FFR are 35 mm and 25 mm H_2O pressure, respectively, for inhalation and exhalation at a constant flow rate of 85 L/min (OSHA 2008). One study documented FFR-associated average peak inhalation and exhalation pressures of 1.24 cm and 1.19 cm H_2O pressure, respectively, at a moderate work rate using subjects who did not routinely use FFR (Jones 1991). Others have suggested that the work of breathing associated with the use of FFR is minimal (Fennelly and Nardell 1998).

Breathing Rate (f_B)

Use of respiratory protective equipment generally results in a variable increase in the breathing rate (f_B) that is a factor of the respirator's filter resistance, dead space, work rate, physical fitness of the wearer, respirator-induced anxiety and CO_2 retention (Lange 2000; Szeinuk et al. 2000; Martyny et al. 2002). As the f_B increases, there is less time, per breath, for O_2 extraction and CO_2 expulsion. Previous respirator studies utilized exertion levels (e.g., industrial workers with air-purifying respirators) that are greater than those of many of today's FFR wearers (e.g., healthcare workers, etc.) (Harber et al. 2009), consequently there is little data with respect to current FFR use. Studies using past generation FFRs suggested that low resistance FFRs with small $V_{D\ resp}$ preferentially result in an increase in f_B over V_T because it is more energy efficient (for respirators with small $V_{D\ resp}$ compared to larger $V_{D\ resp}$) and might offer the advantage of increased heat dissipation (Jones 1991). Wearing a N95 FFR for four hours at sedentary activity increased the breathing rate by two breaths per minute over baseline values (Kao et al. 2004). Further improvements in FFR design could bring about decrements in breathing resistance and, by extension, decrease the impact on f_B.

Figure 6. Measurement of physiological parameters of a subject wearing a FFR walking on a treadmill (with permission from NIOSH).

Heart Rate (HR)

Use of respirators places a physiological burden on the user that can affect the heart rate. Wearing a N95 FFR during qualitative fit testing of approximately 30 minutes duration (Lafferty and McKay 2006) or during low to moderate treadmill exercise over 80 minutes (Li et al. 2005) did not significantly increase HR. Further studies are needed to address the cardiovascular impact of FFR worn over periods of several hours.

Tidal Volume (V_T)

Tidal volume (V_T) is the amount of air inhaled or exhaled in each breath and is an indicator of the level of respiratory exertion. Increase in the work of breathing can be manifest as an increase in V_T, breathing rate, or both. The effect of $V_{D\ resp}$ on the FFR user is an increase in V_T (or f_B) (James 1976; Caretti and Coyne 2008). Relatively small amounts of $V_{D\ resp}$ can increase V_T. (Jones 1991); respirators with >100 mL of dead space cause a compensatory increase in the depth of respiration (Hinds and Bellin 1993). Wearing a FFR adds its dead space ($V_{D\ resp}$) to the anatomical V_D of the respiratory tract, functionally resulting in the creation of significantly augmented physiological V_D and the associated increased physiological burden and compensatory requirements. Human respiratory V_D averages 1 mL per pound of body weight. Average $V_{D\ resp}$ of a FFR is dependent upon its configuration (e.g., cup, duck bill, flat fold) and the facial anthropometic features of the wearer. The resultant compensatory increase in V_T ranges from 50% - 90% of the $V_{D\ resp}$ (for respirators having a $V_{D\ resp}$ of 100 mL or more) (James 1976). Duck bill and cup-shaped FFR have greater $V_{D\ resp}$ than flat fold N95, but the $V_{D\ resp}$ differences of these various FFR upon the physiological burden of wearers has not been evaluated in depth. For example, it is theoretically possible that the lower $V_{D\ resp}$ associated with flat fold FFR might offer physiological benefit when worn over extended periods or during intense physical activity.

Respirator Dead Space ($V_{D\ RESP}$) Gases

The $V_{D\ resp}$ of FFR serves as a repository for exhaled and inhaled gases and houses mixtures that are significantly different from the ambient atmosphere (Caretti and Coyne 2008). Inhalation of CO_2 that is higher, or O_2 that is lower, than ambient levels results in compensatory mechanisms to maintain the body's acid-base status within its normally tight boundaries. OSHA ambient workplace standards for CO_2 are <0.5% (as an eight hour time-weighted average), and <19.5% O_2 is considered oxygen deficient (though some have argued, not without merit, that partial pressures should be the dominant consideration rather than O_2 percentages). Interestingly, previous studies have noted that the microenvironment of FFR (i.e., $V_{D\ resp}$) does not conform to the OSHA ambient workplace standards. Lafferty and McKay measured $V_{D\ resp}$ gases during N95 FFR qualitative fit testing exercises and noted mean CO_2 levels of 4.2% (±0.4%) and mean O_2 levels of 15.5% (±0.6%) (Lafferty and McKay 2006). Huang and Huang (2007) taped N95 FFRs to the faces of volunteers (to eliminate face seal leakage) and reported mean $V_{D\ resp}$ O_2 levels as low as 15.21% (±0.21) (Huang and Huang 2007). Thus, it is quite evident that the microenvironment gases of the

FFR can have significant impact on the wearer and additional research is warranted to attempt to address more fully this physiological burden.

Oxygen Saturation

Oxygen saturation (SaO_2) reflects the percentage of hemoglobin binding sites occupied by O_2. Normal SaO_2 levels range from 95% - 100% at sea level. The impact on SaO_2 of wearing an FFR has been studied to a limited degree. One study noted that SaO_2 decreased <1% while wearing an N95 FFR during qualitative fit testing exercises. This correlates with a recent study of surgeons wearing surgical masks (Beder et al. 2008) that noted the SaO_2 baseline of 97.3% declined to 96.3%, a finding that was significant only during surgical procedures > 60 minutes duration. A drop in arterial O_2 of 9 mm Hg, following four hours of FFR wear during hemodialysis, has also been reported (Kao et al. 2004). More data will be required before the full effect of FFR on O_2 parameters is fully elucidated.

Effect of FFR use on CO_2 Levels

Normal carbon dioxide levels in arterial blood range from 35-45 mm Hg pressure. Exhalation causes the expulsion of metabolically-produced CO_2 to the environment, but the use of FFR results in the retention of variable amounts of CO_2 in the $V_{D\ resp}$ that is subsequently re-breathed with successive inhalations. Unfortunately, the impact of this re-breathed CO_2, while wearing FFR, has not been studied in significant detail. Future studies will need to address effects on CO_2 following longer periods of wear and at higher work rates. Also, the impact on CO_2 of different FFR models (e.g., duck bill, flat fold, cup shaped) will need to be investigated.

VI. Emerging Issues

Respirator Shortage/Reuse

Exposure to airborne infectious diseases including the SARS and influenza virus can be reduced by using respiratory protection devices and are often recommended by various public health agencies. During the outbreak of SARS in 2003, large numbers of different size respirators were needed to meet the demand because policy indicates that FFRs worn by healthcare workers should be discarded after examining an infectious patient. Recently, experts predicted the occurrence of an influenza pandemic and a possible shortage of respirators for healthcare personnel and civilian population. The need for more than 90 million N95 FFRs for the protection of healthcare workers against a 42-day influenza pandemic outbreak is predicted (IOM 2006; CDC 2006). In addition, respirators are needed for workers in other sectors and may also be used by the civilian population. Most healthcare facilities only keep a limited number of respirators in stock (Roberge 2008). For these reasons, the U.S. and other countries have stockpiled the most commonly used respiratory devices. The performance of respirators after long-term storage is not well understood, nor is the degree of risk posed by a respirator exposed to an infectious aerosol (e.g. act as a fomite). One possible option to extend supplies would be to decontaminate an FFR and reuse it, which needs further research on evaluating the effects of decontamination on FFR performance. These issues will be discussed in the next three sections.

Storage

OSHA requires that the employer shall ensure that respirators are stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and that they shall be packed or stored to prevent deformation of the facepiece and exhalation valve (CFR 2003). The storage of respirators should be in accordance with any applicable manufacturer instructions.

The effect of long-term storage of FFRs on filter performance was not investigated until recently. In one study, lifetimes between 1.8 to 2.3 years were calculated for two corona-charged polypropylene filters under high voltage conditions (Motyl and Lowkis 2006). The authors showed that conditioning the samples at a higher humidity influences the changes of the equivalent voltage and the life time of the electret filter. Recently the long-term storage of 21 models of N95 FFRs for at least 6 to ~10 years in warehouses at 15-32^{o}C and relative humidity (RH) 20-80% was studied (Viscusi et al. 2009). These FFRs were tested for initial, as well as maximum penetrations with 200 mg NaCl loading according to the NIOSH particulate respirator certification protocol (Federal Register 1995). Nineteen out of 21 models showed <5% initial, as well as maximum penetration levels. The results from this study indicated that storage for up to 10 years will likely maintain the filtration performance of FFRs. Further studies are needed to better understand the aging effect of the other components of the respirator (e.g. straps, sealing surfaces).

Microbial Contamination and Survival

The survival of microorganisms in the contaminated respirators is a potential health problem should respirators be reused. Microbial contamination of past generation respirators stored in humid environments facilitated microbial growth and increased particle penetration, especially if the filter material is biodegradable (Lacey et al. 1982; Pasanen et al. 1993). In one study, 18 types of respirators and 5 surgical mask models were challenged with different microorganisms and then the percentage of culturable microorganisms recovered from filters was calculated (Brosseau et al. 1997b). A wide variation in the culturability of *Mycobacterium abscessus* (1-60%), *Staphylococcus epidermidis* (0-100%) and *Bacillus subtilis* (87-100%) was obtained after 5 days storage.

Further studies with N95 FFRs using *Mycobacterium smegmatis* showed that the microorganism survived only three days even under ideal growth conditions (Reponen et al. 1999). The authors also reported that the viability of *Pseudomonas fluorescens*, a vegetative bacterium was lost in 3 days, while *Bacillus subtilis*, a spore-forming bacterium remained viable for 13 days (Wang et al. 1999). Both organisms failed to multiply and grow. These studies suggested that respirators exposed to different microorganisms need careful consideration before potential reuse.

Decontamination

Cleaning and decontamination are important steps in disinfecting respirators other than disposable FFR, which can reduce the spread of diseases during reuse of a respirator by the same or a different user. Respirator maintenance, cleaning and disinfection are required for respirator reuse in the workplace (CFR 2003). Employers must provide for the cleaning and disinfecting, storage, inspection, and repair of reusable respirators used by employees. Employers also must provide each user a respirator that is clean, sanitary and in good working order. Respirator cleaning and disinfection involve removal of components as recommended by manufacturer, washing with a mild detergent in warm water, rinsing thoroughly, drying and reassembling of components before reuse. Decontamination generally involves additional treatment to kill infectious organisms that have been captured by the filter. However, decontamination of disposable FFRs was not considered until recently.

An Institute of Medicine (IOM) report recommended that Department of Health and Human Services (DHHS) sponsor and/or conduct research on simple decontamination procedures for FFRs to meet the demand during a pandemic influenza (IOM 2006). One recent paper took a step toward addressing this issue by reporting the investigation of the filtration performance of two FFR models exposed to ten different decontamination methods (Viscusi et al. 2007). Liquid hydrogen peroxide at 3% for 30 min, vaporized hydrogen peroxide or UV irradiation for up to 8 hours resulted in penetration levels <5% with no significant damage to both N95 and P100 FFRs. On the other hand, bleach treatment up to 5.25% (sodium hypochlorite) concentrations for 30 min showed stiffening of the respirators and tarnishing of the nose pad, with no significant increase in particle penetration levels.

The effectiveness of a variety of decontamination methods for microorganisms applied to FFRs have been investigated (Fisher et al. 2009; Vo et al. 2009). For example, in one study (Fisher et al. 2009), FFR coupons (circular discs, 5 cm^2) were loaded with MS2 aerosol particles and exposed to different concentrations of bleach for 10 minutes. MS2 virus was maximally inactivated at 0.6% bleach and did not vary with the protein concentration in the suspension medium. However, bleach at 0.0006% effectively inactivated MS2 in growth medium containing low, but not high concentration of protein. This suggested that high protein concentration is likely to inhibit the decontamination effect of bleach. Steam treatment was also found to be effective for decontamination of MS2 on filter coupons and was not affected by protein concentration in the suspension medium.

Several decontamination methods including ozone (Kharde and Yousef 2001), chlorine dioxide (EPA 2007), low pressure oxygen-based plasmas (Hury et al. 1998), L-gel (Raber and McGuire 2002) and other technologies (EPA 1994) have been used for decontamination of microorganisms on different substrate materials, but not on respirators. Further research on potential decontamination technologies for FFRs and other types of APRs contaminated with microorganisms should be conducted.

VII. RECENT DEVELOPMENTS

Biocidal Filters

Handling contaminated respirators may present potential problems of virus transmission. To prevent the spread of infection, a report by the Institute of Medicine (IOM) suggested the need for research in the development of antimicrobial masks that can inactivate the virus (IOM 2006). Respirators incorporated with antimicrobial agents such as iodine, silver, quaternary ammonium and ozone-like compounds can inactivate/kill microorganisms. Some studies showed significant removal/inactivation of MS2 virus aerosol when passed through iodinated filters (Heimbuch et al. 2004; Heimbuch and Wander 2006), while others failed to demonstrate a significant inactivation (Eninger et al. 2008c). The discrepancy between the results obtained in the above studies appears to be due to the difference in the test methodologies employed for measuring the viable virus particles. Iodinated filters were found to be effective for various bacterial species including *Bacillus subtilis, Escherichia coli and Micrococcus luteus* (Lee et al., 2008a; Ratnesar-Shumate et al., 2008). A recent study investigaged MS2 virus decontamination efficacy of respirators using coupons from four manufacturers representing four different antimicrobial agents (Rengasamy et al. 2009). The authors showed that the viability of MS2 was significantly decreased at high temperature and high humidity storage conditions by the iodinated antimicrobial respirator coupon, with no significant effect for the other antimicrobial respirtor coupons. The antimicrobial efficacy of the filter materials for different microorganisms remains to be determined.

Antimicrobial technology in related areas may be applied to respirators. For example, antimicrobial clothing materials incorporated with N-hydantoin derivatives (Sun and Sun 2003) and quaternary ammonium salt (Kim and Sun 2001) were effective for microbial decontamination. The application of similar technologies may be exploited for respirators.

Nanofiber Filters

The non-woven industry generally considers nanofibers as having a diameter less than 0.5 µm with a large surface area-to-volume ratio (Wang et al. 2008). Nanofibers are widely produced by electrospinning (Teo and Ramakrishna 2006) and melt-blown or multi-component fiber spinning techniques (Ward 2005). The physical characteristics of nanofibers, including diameter, surface area and basis weight, have been reported (Grafe and Graham 2002). The increased surface area of nanofibers makes them potential candidates for particle filtration applications. Respirators containing nanofiber filter media have potential to offer excellent filtration performance without an increase in filter air flow resistance. Respirators with smaller air flow resistance are potentially more comfortable to wear for extended periods of time.

Polypropylene nanofibers generated by melt-blown technology were investigated for their collection efficiency against various size particles (Podgorski et al. 2006). The authors showed that addition of thin nanofiber (diameter, 0.74-1.41 µm) layers to the polypropylene filter considerably increased the filtration efficiency, especially in the 200 nm range (MPPS) and 2.6 times increase in the quality factor (QF). QF is a metric of filter performance represented as a ratio between filter efficiency and pressure drop. This finding was confirmed by measuring the figure of merit (also known as QF) for nanofiber (diameter, 0.15 µm) filters (Wang et al. 2008). The authors showed that nanofiber filters had better figure of merit for particles >100 nm compared to conventional fiberglass filters. However, for particles <100 nm, nanofiber filters did not perform better than conventional filters. Application of nanofibers for respiratory protection needs further investigation.

Novel Respirator Designs

Although respirators are designed to provide a good fit on the human face, some exhibit considerable leakage under working conditions (Coffey et al. 1999a; Zhuang et al. 2003). Developments in better sealing respirators will enhance respiratory protection in workplaces. Toward this goal, NIOSH recently sponsored a workshop to discuss the current state of APR fit and to suggest future technologies that could lead to improved fitting APRs (UMSPH 2008). Recently, some manufacturers have designed masks with adhesives on the face sealing periphery to provide a tight seal on the face of a wearer. Others combined a transparent material with the filter for adjusting the fit of the respirator to the face. Another report discussed new technologies that offer potential improvement for facial seal, cooling and filtration (Richardson et al. 2008). Further improvements in simplifying donning and doffing procedures for respirators are needed.

CONCLUSION

The need for respiratory protection against biological aerosols such as influenza and SARS, and nonbiological particulate hazards including nanoparticles is growing. Data from several research studies show that respirators approved by NIOSH and other organizations meet their expected filtration performance levels. These respirators efficiently capture particles as small as 4 nm under stringent test conditions with no deviation from single-fiber filtration theory. Most of the respirators on the market are electret filters with enhanced particle capturing efficiency without significant increase in breathing resistance. The MPPS for the FFRs was in the <100 nm range as expected for electret filters.

In spite of the high filtration efficiency levels reported for respirators, face seal leakage remains a major concern to achieve expected levels of respiratory protection in workplaces. WPF and SWPF studies continue to report varying results on the fitting of FFRs to workers faces. Face seal leakage studies using manikin models with artificial static leaks may be of limited value to address workplace protection against particulates. Several studies attempted to delineate the relationship between face seal leakage and particle size with no consistent pattern. Some of the SWPF studies obtained protection factors around 20 for the commonly used N95 FFRs which exhibited variability in achieving those protection factor levels. WPF measurements in a variety of different actual workplaces provided varying protection levels for similar respirators. Many investigators reported WPF values of >10 for APRs, while WPF value of <10 was obtained in one study. Concerns about nanoparticle leakage suggests the need for further studies on measuring WPF for nanoparticles <100 nm. Fit testing is necessary to ensure that the user is wearing the correct respirator size and model to provide expected levels of protection.

To reduce leakage, design of good fitting respirators is needed. Update of the database of facial feature measurements of workers representing the U.S. workforce instead of the data for the military personnel enabled NIOSH to develop new fit test panels to improve the design of better fitting respirators.

The physiological impact of respiratory protective equipment upon wearers needs further investigation. Recent research has indicated elevated levels of CO_2 and reduced O_2 concentrations could impact the physiological response of users. Further research is needed to assess the impact on user comfort and tolerability issues.

Long-term storage of respirators is needed to meet the demands during pandemic events. Further research on respirator degradation, microbial contamination and decontamination are important to address emerging respirator needs. Technological advances produced biocidal, and nanofiber filters which may be considered for respiratory protection. Further research in similar innovative technologies could provide better respiratory protection to workers through improved fit, better filtration performance, reduced physiological burden, and improved comfort and tolerability.

DISCLAIMER

The findings and conclusions of this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health. Mention of a commercial product or trade name does not constitute endorsement by the National Institute for Occupational Safety and Health.

REFERENCES

Ackley, M. W. (1982). Degradation of electrostatic filters at elevated temperature and humidity. *Filtration Separation*, *22*, 239-242

American Industrial Hygiene Association (AIHA), Respiratory, Protection, Committee (1985). Respirator performance terminology. *Am Ind Hyg Assoc J*, *46*, B22-B24.

Balazy, A., Toivola, M., Adhikari, A., Sivasubramani, S. K., Reponen, T. & Grinshpun, S. A. (2006b). Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks? *Am J Infect Control*, *34*, 51-57.

Balazy, A., Toivola, M., Reponen, T., Podgorski, A., Zimmer, A. & Grinshpun, S. A. (2006a). Manikin-based performance evaluation of N95 filtering-facepiece respirators challenged with nanoparticles. *Ann Occup Hyg*, *50*, 259-269.

Barrett, L. W. & Rousseau, A. D. (1998). Aerosol loading performance of electret filter media. *Am Ind Hyg Assoc J*, *59*, 532-539.

Beder, A., Buyukkocak, U., Sabuncuoglu, H., Keskil, Z. A. & Keskil, S. (2008). Peliminary report on surgical mask induced deoxygenation during major surgery. *Neurocirurgia*, *19*, 121-126.

Bello, D., et al. (2009). Exposure to nanoscale particles and fibers during machining of hybrid advanced composites containing carbon nanotubes. *J Nanopart Res*, *11*, 231-249.

Biswas, P. & Wu, C. Y. (2005). Nanoparticles and the environment. *J Air Waste Manag Assoc*, *55*, 708-746.

Brosseau, L. M., McCullough, N. V. & Vesley, D. (1997a). Mycobacterial aerosol collection efficiency of respirator and surgical mask filters under varying conditions of flow and humidity. *Appl Occup Environ Hyg*, *12*, 435-445.

Brosseau, L. M., McCullough, N. V. & Vesley, D. (1997b). Bacterial survival on respirator and filters and surgical masks. *J Am Biol Safety Assoc*, 32-43.

Brown, R. C .(1995). Protection against dust by respirators. *Int J Occup Safety Erg*, *1*, 14-28.

Bureau of Labor Statistics/National Institute for Occupational Safety and Health (BLS/NIOSH) (2003). *Respirator Usage in Private Sector Firms*, 2001. Washington, D.C.: U.S. Department of Labor/Bureau of Labor Statistics and U.S. Department of Health and Human Services/Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health, 2003, 67 and 219.

Caretti, D. & Coyne, K. M. (2008). Unmanned assessment of respirator caron dioxid levels: comparison of methods of measurement. *J Occup Environ Hyg*, *5*, 305-312.

CDC (2006). Estimated number of masks needed, by type and setting, for a severe influenza pandemic. DHHS, Centers for Disease Control and Prevention. Atlanta.

CFR (2003). Respiratory protection. U.S. Government Printing Office, Office of the Federal Register, Washington, DC., 441-442.

Chen, C. C. & Huang, S. H. (1998). The effects of particle charge on the performance of a filtering facepiece. *Am Ind Hyg Assoc J*, *59*, 227-233.

Chen, C. C., Lehtimaki, M. & Willeke, K. (1993). Loading and filtration characteristics of filtering facepieces. *Am Indust Hyg Assoc J*, *54*, 51-60.

Chen, W., et al. (2009). New respirator fit test panels representing the current Chinese civilian workers. *Ann Occup Hyg 53*, 297-305.

Coffey, C. C., Campbell, D. L. & Myers, W. R. (1999a). Comparison of six respirator fit-test methods with an actual measurement of exposure in a simulated health care environment: Part III--Validation. *Am Indust Hyg Assoc J*, *60*, 363-636.

Coffey, C. C., Campbell, D. L. & Zhuang, Z. (1999b). Simulated workplace performance of N95 respirators. *Am Indust Hyg Assoc J*, *60*, 618-624.

Coffey, C. C., Lawrence, R. B., Campbell, D. L., Zhuang, Z., Calvert, C. A. & Jensen, P. A. (2004). Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J Occup Environ Hyg*, *1*, 262-271.

Cooper, D. W., Hinds, W. C., Price, J. M., Weker, R. & Yee, H. S. (1983). Common materials for emergency respiratory protection: leakage tests with a manikin. *Am Indust Hyg Assoc J*, *44*, 720-726.

Dahneke, B. (1971). The capture of particles by surfaces. *J. Colloid. Interface Sci.*, *37*, 342-353.

Donaldson, K., Li, X. Y. & MacNee, W. (1998). Ultrafine (Nanometre) particle mediated lung injury. *J Aero Sci*, *7*, 533-560.

Du, L., et al. (2008). Head and face anthropometric survey of Chinese workers. *Ann Occup Hyg*, *52*, 773-782.

Eninger, R. M., Adhikari, A., Reponen, T. & Grinshpun, S. A. (2008c). Differentiating between physical and viable penetrations when challenging respirator filters with bioaerosols. *Clean-Soil, Air, Water*, *36*, 615-621.

Eninger, R. M., Honda, T., Adhikari, A., Heinonen-Tanski, H., Reponen, T. & Grinshpun, S. A. (2008a). Filter performance of N99 and N95 pacepiece respirators against viruses and ultrafine particles. *Ann Occup Hyg*, *52*, 385-396.

Eninger, R. M., Honda, T., Reponen, T., McKay, R. & Grinshpun, S. A. (2008b). What does respirator certification tell us about filtration of ultrafine particles? *J Occup Environ Hyg*, 286-295.

EPA (1994). Guide to cleaner technologies. Alternatives to chlorinated solvents for cleaning and degreasing. EPA/625/R-93/016 Office of Reseach and Development, United States Environmental Protection Agency, Cincinnati, OH.

EPA (2007). Anthrax spore decontamination using chlorine dioxide. *Pesticides: Topical & Chemical Fact Sheets*. http://www.epa.gov/pesticides/factsheets/chemicals/chlorine-dioxidefactsheet.htm(last accessed February 18, 2009).

Eshbaugh, J. P., Gardner, P. D. & Richardson, AW .(2009). N95 and P100 respirator filter efficiency under high constant and cyclic flow. *J Occup Environ Hyg*, *6*, 52-61.

Fanning, E. W., et al. (2009). Particulate Matter (PM) Research Centers (1999–2005) and the Role of Interdisciplinary Center-Based Research. *Environ Health Perspect*, *117*, 167-174.

Federal Register (1995). Respiratory Protective Devices. *Final Rules and Notice*, *60*, 30335-30398.

Federal Register (2006). Assigned Protection Factors: Final rule. 71, 50121-50192 http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=18846 (last accessed February 18, 2009).

Fennelly, K. P. & Nardell, E. A. (1998). The relative efficacy of respirators and room ventilation in preventing occupational tuberculosis. *Infect Cont Hosp Epidemiol*, *19*, 754-759.

Fisher, E., Rengasamy, S., Viscusi, D. J., Vo, E. & Shaffer, R. E. (2009). Development of a test system to apply virus containing particles to air permeable materials for the evaluation of decontamination procedures for filtering facepiece respirators. *Appl Environ Microbiol*, *75*, 1500-1507.

Gardner, P. D., Hofacre, K. C. & Richardson, A. W. (2004). Comparison of simulated respirator fit factors using aerosol and vapor challenges. *J Occup Environ Hyg*, *1*, 29-38.

Grafe, T. H. & Graham, K. M. (2002). Polymeric nanofibers and nanofiber webs: A new class of nonwovens. *In: International Nonwoven Technical Conference* (Joint INDA -TAPPI Conference). September 24-26,2002, Atlanta, GA.

Harber, P., et al. (2009). Multidomain subjective response to respirator use during simulated work. *J Occup Environ Med*, *51*, 38-45.

Heim, M., Millins, B. J., Wild, M. & Meyer, J. (2005). Filtration efficiency of aerosol particles below 20 nanometers. *Aeros Sci Tech*, *39*, 782-789.

Heimbuch, B. K., Laventure, G., McDonald, R., Burr, E., Proudfoot, E. & Wander, J. (2004). Antimicrobial efficiency of iodinated individual protection filters. U.S. Air Force Research Laboratory. Tyndall Air Force Base, Florida. Report for Contract No. AFRL-ML-TY-TP-2004-4561.

Heimbuch, B. K. & Wander, J. (2006). Bioaerosol challenges to antimicrobial surface treatments: Enhanced filter efficacy against MS2 coli phage of air filter media coated with polystyrene-4-methyltrimethylammonium triiodide. U.S. Air Force Research Laboratory. Tyndall Air Force Base, Florida. Report for Contract No. AFRL-ML-TY-TP-2006-4527.

Hinds, W. C. (1999). *Properties, behavior, and measurement of airborne particles*, 2nd Edition. Wiley-Interscience Publication, John Wiley & Sons, Inc., New York, New York.

Hinds, W. C. & Bellin, P. (1987). Performance of dust respirators with facial seal leaks: II. Predictive model. *Am Indust Hyg Assoc J*, *48*, 842-847.

Hinds, W. C. & Bellin, P. (1993). The effect of respirator dead space and lung retention on exposure estimates. *Am Indust Hyg Assoc J*, *54*, 711-722.

Hinds, W. C. & Kraske, G. (1987). Performance of dust respirators with facial seal leaks: I. Experimental. *Am Indust Hyg Assoc J*, *48*, 836-841.

Hodous, T. K. & Coffey, C. C. (1994). The role of respiratory protective devices in the control of tuberculosis. *Occup Med*, *9*, 631-657.

Hoet, P. H., Bruske-Hohlfeld, I. & Salata, O. V. (2004). Nanoparticles - known and unknown health risks. *J Nanobiotechnol*, *2*, 12.

Huang, J. T. & Huang, V. J. (2007). Evaluation of the efficiency of medical masks and the creation of new medical masks. *J Int Med Res*, *35*, 213-223.

Huang, S. H., Chen, C. W., Chang, C. P., Lai, C. Y. & Chen, C. C. (2007). Penetration of 4.5 nm to 10 µm aerosol particles through fibrous filters. *J Aero Sci*, *38*, 719-727.

Hury, S., Vidal, D. R., Desor, F., Pelletier, J. & Lagarde, T. (1998). A parametric study of the destruction efficiency of Bacillus spores in low pressure oxygen-based plasmas. *Soc Appl Microbiol*, *26*, 417-421.

Ichitsubo, H., Hashimoto, T., Alonso, M. & Kousaka, Y. (1996). Penetration of ultrafine particles and ion clusters through wire screens. *Aero Sci Tech*, *24*, 119-127.

Institute of Medicine (IOM) (2006). *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu*. Washington, D.C.: National Academies Press www.iom.edu/CMS/3740/ 32033/ 34200.aspx (last accessed February 18, 2009).

Institute of Medicine (IOM) (2007). *Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users*. Washington, D.C.: National Academies Press http://www.iom.edu/CMS/3740/29900/43806.aspx (last accessed April 28, 2009).

International Organization for Standardization (ISO) TS 16976-2 (2009). Respiratory Protectrive Devices – Human Factors – Part 2: Anthropometrics.

James, R. S. (1976). *Physiological effects of breathing resistance and equipment dead space in respiratory protective devices: status of the problem*. National Institute for Occupational Safety and Health Publication No. 77-161. Washington, D.C.: U.S. Government Pringitn Office.

Janssen, L. L., Bidwell, J. O., Mullins, H. E. & Nelson, T. J. (2003). Efficiency of degraded electret filters: part I. Laboratory testing against NaCl and DOP before and after exposure to workplace aerosols. *J Int Soc Res Prot*, *20*, 71-80.

Janssen, L. L., Nelson, T. J. & Cuta, K. T. (2007). Workplace protection factors for an N95 filtering facepiece respirator. *J Occup Environ Hyg*, *4*, 698-707.

Janssen, L. L. & Weber, R. (2005). Effect of pressure drop on respirator face seal leakage. *J Occup Environ Hyg*, *2*, 335-340.

Jasper, W., et al. (2006). Effect of xylene exposure on the performance of electret filter media. *J Aero Sci*, *37*, 903-911.

Jones, J. G. (1991). The physiological cost of wearing a disposable respirator. *Am Indust Hyd Assoc J*, *52*, 219-225.

Kao, T. W., Huang, K. C., Huang, Y. L., Tsai, T. J., Hsieh, B. S. & Wu, M. S. (2004). The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage disease. *J Formos Med Assoc*, *103*, 624-628.

Kharde, M. A. & Yousef, A. E. (2001). Decontamination of a multilaminated aseptic food packaging material and stainless steel by ozone. *J Food Safety*, *21*, 1-13.

Kim, C. S., Bao, L., Okuyama, K., Shimada, S. & Niinuma, H. (2006). Filtration efficiency of a fibrous filter for nanoparticles. *J Nanopart Res*, *8*, 215-221.

Kim, J., Jasper, W. & Hinestroza, J. (2007b). Direct probing of solvent-induced charge degradation in polypropylene electret fibres via electrostatic force microscopy. *J Microscopy*, *225*, 72-79.

Kim, S. E., Harrington, M. S. & Pui, D. Y. H. (2007a). Experimental study of nanoparticles penetration through commercial filter media. *J Nanopart Res*, *9*, 117-125.

Kim, Y. H. & Sun, Y. (2001). Durable antimicrobial finishing of nylon fabrics with acid dyes and a quaternary ammonium salt. *Text Res J*, *71*, 318-323.

Krishnan, U., Willeke, K., Juozaitis, A., Myojo, T., Talaska, G. & Shukla, R. (1994). Variation in quantitative respirator fit factors due to fluctuations in leak size during fit testing. *Am Ind Hyg Assoc J*, *55*, 309-314.

Lacey, J., Nabb, S. & Webster, B. T. (1982). Retention of actinomycetes spores by respirator filters. *Ann Occup Med*, *25*, 351-363.

Lafferty, E. A. & McKay, R. T. (2006). Physiologic effects and measurement of carbon dioxide and oxygen levels during qualitative respirator fit testing. *J Chem Health Safety*, *13*, 22-28.

Lange, J. H. (2000). Health effects of respirator use at low airborne concentrations. *Med Hypoth*, *54*, 1005-1007.

Lawrence, R. B., Duling, M. G., Calvert, C. A. & Coffey, C. C. (2006). Comparison of performance of three different types of respiratory protection devices. *J Occup Environ Hyg*, *3*, 465-474.

Lee, J. H., Wu, C. Y., Wysocki, K. M., Farrah, S. & Wander, J. (2008). Efficacy of iodine-treated biocidal filter media against bacterial spore aerosols. *J Appl Microbiol*, *105*, 1318-1326.

Lee, K. W. & Liu, B. Y. H. (1980). On the mimimum efficiency and the most penetrating particle size for fibrous filters. *Air Pollution Cont Assn*, *30*, 377-381.

Lee, K. W. & Liu, B. Y. H. (1982). Experimental study of aerosol filtration by fibrous filters. *Aero Sci Tech*, *1*, 35-46.

Lee, S. A., et al. (2005). Respiratory protection provided by N95 filtering facepiece respirators against airborne dust and microorganisms in agricultural farms. *J Occup Environ Hyg*, *2*, 577-585.

Lee, S. A., Grinshpun, S. A. & Reponen, T. (2008). Respiraory performance offered by N95 respirators and surgical masks: Human subject evaluation with NaCl aerosol representing bacterial and viral particle size range. *Ann Occup Hyg*, *3*, 177-185.

Li, Y., et al. (2005). Effects of wearing N95 and surgical facemasks on heart rate, thermal stress and subjective sensations. *Int Arch Occup Environ Health*, *78*, 501-509.

Martin, S. B. Jr. & Moyer, E. S. (2000). Electrostatic respirator filter media: filter efficiency and most penetrating particle size effects. *Appl Occup Environ Hyg*, *15*, 609-617.

Martyny, J., Glazer, C. S. & Newman, L. S. (2002). Respiratory protection. *New Engl J Med*, *347*, 824-830.

Maynard, A. D. & Kuempel, E. D. (2005). Airborne nanostructured particles and occupational health. *J Nanopart Res*, *7*, 587-614.

McCullough, N. V. & Brosseau, L. M. (1999). Selecting respirators for control of worker exposure to infectious aerosols. *Infect Cont Hosp Epi*, *20*, 136-144.

McCullough, N. V., Brosseau, L. M. & Vesley, D. (1997). Collection of three bacterial aerosols by respirator and surgical mask filters under varying conditions of flow and relative humidity. *Ann Occup Hyg*, *41*, 677-690.

Motyl, E. & Lowkis, B. (2006). Effect of air humidity on charge decay and lifetime of PP electret nonwovens. *Fibers and Textiles in Eastern Europe*, *14*, 39-42.

Moyer, E. S. & Bergman, M. S. (2000). Electrostatic N-95 respirator filter media efficiency degradation resulting from intermittent sodium chloride aerosol exposure. *Appl Occup Environ Hyg*, *15*, 600-608.

Myers, D. L. & Arnold, B. D. (2003). Electret media for HVAC filtration applications. *Int Nonwovens J*, *12*, 43-54.

Myers, W. R., Kim, H. & Kadrichu, N. (1991). Effect of particle size on assessment of faceseal leakage. *J Int Soc Res Prot Fall*, 6-12.

NIOSH (2004). NIOSH Respirator Selection Logic. DHHS (NIOSH) Publication No. 2005-100. Cincinnati, OH.

NIOSH (2007a). Procedure No. TEB-APR-STP-0059, Revision 2.0. Determination of particulate filter efficiency level for N95 series filters against solid particulates for non-powered, airpurifying respirators standard testing procedure (STP). DHHS, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh. http://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059.pdf (last accessed November 18, 2009).

NIOSH (2007b). Procedure No. TEB-APR-STP-0051, Revision 2.0. Determination of particulate filter efficiency level for P100 series filters against liquid particulates for non-powered, airpurifying respirators Standard testing procedure (STP). DHHS, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh. http://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0051.pdf (last accessed November18, 2009).

NIOSH (2007). Technical concept for half-mask respirator total inward leakage performance requirements and test methods. http://www.cdc.gov/niosh/npptl/resources/certpgmspt/meetings/062607/pdfs/RevisedTechnicalConcept01172007.pdf (last accessed February 18, 2009).

NIOSH (2009). Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered NanomaterialsApproaches to Safe Nanotechnology. An Information Exchange with NIOSH. http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf NIOSH Publication No. 2009-125 (last accessed February 18, 2009).

Oberdorster, G., et al. (2005). Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy. *Particle Fibre Toxicol*, *2*, *8*, 1-35.

OSHA (2008). Respiratory protection 29 CFR 1910.134. Occupational Safety and Health Administration. Washington, D.C. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards (last accessed February 18, 2009).

Pasanen, A. L., Keinanen, J., Kalliokoski, P., Martikainen, P. I. & Ruuskanen, J. (1993). Microbial growth on respirator filters from improper storage. *Scand J Work, Environ Health*, *19*, 421-425.

Podgorski, A., Balazy, A. & Gradon, L. (2006). Application of nanofibers to improve the filtration efficiency of the most penetrating aerosol particles in fibrous filters. *Chem Engg Sci*, *61*, 6804-6815.

Qian, Y., Willeke, K., Grinshpun, S. A., Donnelly, J. & Coffey, C. C. (1998). Performance of N95 respirators: filtration efficiency for airborne microbial and inert particles. *Am Indust Hyg Assoc J*, *59*, 128-132.

Raber, E. & McGuire, R. (2002). Oxidative decontamination of chemical and biological warfare agents using L-gel. *J Hazard Mat B*, *93*, 339-352.

Radonovich, J. L. J., Hodgson, M. & Cohen, H. J. (2008). Do respirators protect in health-care workers from airborne infectious diseases? *Res Care*, *53*, 1660-1664.

Ratnesar-Shumate, S., Wu, C. Y., Wander, J., Lundgren, D., Farrah, S., Lee, J. H., Wanakule, P., Blackburn, M. & Lan, M. F. (2008). Evaluation of physical capture efficiency and disinfection capability of an iodinated biocidal filter medium. *Aero Air Qual Res*, *8*, 1-18.

Rengasamy, A., Verbofsky, R., King, W. P. & Shaffer, R. E. (2007). Nanoparticle penetration through NIOSH-approved N95 filtering-facepiece respirators. *J Int Soc Res Prot*, *24*, 49-59.

Rengasamy, A., Zhuang, Z. & BerryAnn, R. (2004). Respiratory protection against bioaerosols: Literature review and research needs. *Am J Infect Cont*, *32*, 345-354.

Rengasamy, S., Eimer, B. & Shaffer, R. E. (2009). Comparison of nanoparticle filtration performance of NIOSH-approved and CE marked filtering-facepiece respirators. *Ann Occup Hyg*, *53*, 117-128.

Rengasamy, S., King, W. P., Eimer, B. & Shaffer, R. E. (2008). Filtration performance of NIOSH-approved N95 and P100 filtering-facepiece respirators against 4-30 nanometer size nanoparticles. *J Occup Environ Hyg*, *5*, 556-564.

Rengasamy, S., Fisher, E. & Shaffer, R. E. (2009). Evaluation of the survivability of MS2 viral aerosols deposited on filtering facepiece respirator samples incorporating antimicrobial technologies. *Am J Infect Control*, (in press).

Reponen, T. A., Wang, Z., Willeke, K. & Grinshpun, S. A. (1999). Survival of mycobacteria on N95 personal respirators. *Infect Cont Hosp Epidemiol*, *20*, 237-241.

Richardson, A. W., Hofacre, K. C. & Gardner, P. D. (2008). Technology survey for enhancement of chemical,biological, radiological, and nuclear respiratory protection. In. U.S. Army Edgewood Chemical Biological Center Report for Contract No. SP0700-00-D-3180, Task No. 558, ECBC-CR-094.

Roberge, R. (2008). Effect of surgical masks worn concurrently over N95 filtering facepiece respirators: extended service life versus increased user burden. *J Pub Health Manag*, *14*, E19-26.

Schulte, P. A., Geraci, C., Zumwalde, R., Hoover, M. & Kuempel, E. (2008). Occupational risk management of engineered nanoparticles. *J Occup Environ Hyg*, *5*, 239-249.

Shaffer, R. E. & Rengasamy, S. (2009). Respiratory protection against nanoparticles: A review. *J Nanopart Res "Special issue: Environmental and Human Exposure of Nanomaterials" 11*, 1661-1672.

Shvedova, A. A., et al. (2009). Mechanism of pulmonary toxicity and medical applications of carbon nanotubes: two faces of Janus? *Pharmacol Ther*, *121*, 192-204.

Sun, Y. & Sun, G. (2003). Novel refreshable N-halamine polymeric biocides: Grafting hydantoin-containing monomers onto high performance fibers by a continuous process. *J Appl Polymer Sci*, *88*, 1032-1039.

Szeinuk, J., Beckett, W. S., Clark, N. &, Hailoo, W. L. (2000). Medical evaluation for respirator use. *Am J Indust Med*, *37*, 142-157.

Tennal, K. B., Mazumder, M. K., Siag, A. & Reddy, R. N. (1991). Effect of loading with an oil aerosol on the collection efficiency of an electret filter. *Particulate Sci Technol*, *9*, 19-29.

Teo, W. E. & Ramakrishna, S. (2006). A review on electrospinning design and nanofibre assemblies. *Nanotech*, *17*, R89-R106.

Tuomi, T. (1985). Face seal leakage of half-masks and surgical masks. *Am Indust Hyg Assoc J*, *46*, 308-312.

University of Minnesota School of Public Health (UMSPH) (2008). NIOSH No Fit Test Respirator Workshop. November 6, 2008, Pittsburgh, PA. http://cpheo.sph.umn.edu/ mcohs/courses/nofit/. (last accessed March 18, 2009).

Van Osdell, D. W., Liu, B. Y. H., Rubow, K. L. & Pui, D. Y. H. (1990). Experimental study of submicrometer and ultrafine particle panetration and pressure drop for high effficiency filters. *Aero Sci Tech*, *12*, 911-925.

Viscusi, D. J., Bergman, M. S., Sinkule, E. & Shaffer, R. E. (2009). Evaluation of the filtration performance of 21 N95 filtering facepiece respirators after prolonged storage. *Am J Infect Cont 37, 381-386*

Viscusi, D. J., Bergman, M. S., Eimer, B. & Shaffer, R. E. (2009). Evaluation of five decontamination methods for filtering facepiece respirtors. *Ann Occup Hyg 53*, 815-*827.*

Viscusi, D. J., King, W. P. & Shaffer, R. E. (2007). Effect of decontamination on the filtration efficiency of two filtering facepiece respirator models. *J Int Soc Res Prot*, *24*, 93-107.

Vo, E., Rengasamy, S., & Shaffer, R. E. (2009). Development of a test system to evaluate procedures for decontamination of respirators containing viral droplets. *Appl Environ Microbiol*, *75*, 7303-7309.

Walsh, D. C. & Stenhouse, J. I. T. (1998). Parameters affecting the loading behavior and degradation of electrically active fiber materials. *Aero Sci Tech*, *29*, 419-432.

Wang, H. C. & Kasper, G. (1991). Filtration efficiency of nanometer size aerosol particles. *Aero Sci Tech*, *22*, 31-41.

Wang, J., Kim, S. C. & Pui, D. Y. H. (2008). Investigation of the figure of merit for filters with a single nanofiber layer on a substrate. *J Aero Sci*, *39*, 323-334.

Wang, K., Reponen, T. A. & Willeke, K. (1999). Survival of bacteria on respirator filters. *Aero Sci Tech*, *30*, 167-173.

Ward, G. (2005). Nanofibres: media at the nanoscale. *Filtration & Separation*, *42*, 22-24.

Waters, K. M., et al. (2009). Macrophage response to silica nanoparticles are highly conserved across particle sizes. *Toxicol Sci*, *107*, 553-569.

Willeke, K., Qian, Y., Donnelly, J., Grinshpun, S. & Ulevicius, V. (1996). Penetration of airborne microorganisms through a surgical mask and a dust/mist respirator. *Am Indust Hyg Assoc J*, *57*, 348-355.

World Health Organization (WHO) (1999). Hazard prevention and control in the work environment: *Airborne dust*. World Health Organization Occupational Health WHO/SDE/OEH/99.14, http://www.who.int/occupational_health/publications/airdust/en (last accessed February 18, 2009).

World Health Organization (WHO) (2000). Quantification of the health effects of exposure to air pollution. Report of a WHO Working Group. European Centre for Environment and Health, Bilthoven, Netherlands. EUR/01/5026342. E74256. http://www.euro.who.int/document/e74256.pdf (last accessed February 18, 2009).

World Health Organization (WHO) (2005). Indoor air pollution and health. Fact sheet No 292. WHO Media Centre. http://www.who.int/mediacetre/factsheets/fs292/en/print.html (last accessed February 18, 2009).

Yang, L., Shen, H. & Wu, G. (2007). Racial differences in respirator fit testing: A pilot study of whether American fit panels are representative of Chinese faces. *Ann Occup Hyg*, *51*, 415-421.

Zhuang, Z., Benson, S. & Viscusi, D. (2010). Digital 3-D headforms with facial features representative of the current U.S. workforce. *Ergonomics* (in press).

Zhuang, Z. & Bradtmiller, B. (2005). Head-and-face anthropometric survey of U.S. respirator users. *J Occup Environ Hyg*, *2*, 567-576.

Zhuang, Z., Bradtmiller, B. & Shaffer, R. E. (2007). New respirator fit test panels representing the current U.S. civilian workforce. *J Occup Environ Hyg*, *4*, 647-659.

Zhuang, Z., Coffey, C. C. & Ann, R. B. (2005). The effect of subject characteristics and respirator features on respirator fit. *J Occup Environ Hyg*, *2*, 641-649.

Zhuang, Z., Coffey, C. C., Jensen, P. A., Campbell, D. L., Lawrence, R. B. & Myers, W. R. (2003). Correlation between quantitative fit factors and workplace protection factors measured in actual workplace environments at a steel foundry. *Am Indust Hyg Assoc J*, *64*, 730-738

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 161-179
ISBN: 978-1-60876-223-1

Chapter 4

NEURODEVELOPMENTAL TREATMENT APPROACH IN CEREBRAL PALSY

***Maria Teresa Botti Rodrigues dos Santos*[a*], *Felipe Scalco Manzano*[b] *and Renata de Oliveira Guare*[a]**

[a]Discipline of Dentistry, Persons with Disabilities Division, Post Graduation Professor, Universidade Cruzeiro do Sul, São Paulo, Brazil.

[b]Lar Escola São Francisco, Rehabilitation Center, São Paulo, Brazil.

ABSTRACT

Background: Cerebral palsy (CP) describes a group of movement and posture developmental disorders causing activity limitation, caused by nonprogressive disturbances occurring in the developing fetal or infant brain. Complex limitations in self-care functions, such as feeding, dressing, bathing, mobility and the ability to coordinate muscle action to maintain normal posture and to perform normal movements, may also occur. The goal in providing treatment for disabled individuals is to treat the patient in the safest and most efficient manner possible. For some disabled people, comprehensive dental services would be impossible without the more restrictive management techniques. The classic neurodevelopmental treatment (NDT), focus on sensorimotor components of muscle tone, reflexes and abnormal movement patterns, postural control, sensation, perception and memory.

Objective: Describe some methods opening facilitates access to internal surfaces of the maxillary molars, important for dental treatment as well as for preventive care procedures in disabled patients, such as cryotherapy and botulinum toxin A injection. And evaluate the electromyographic (EMG) activity of right and left anterior temporalis and masseter muscles during mandibular resting position in individuals with CP on dental chair, before and after assistive stabilization (NDT).

* Corresponding author: Discipline of Dentistry, Persons with Disabilities Division, Universidade Cruzeiro do Sul, Rua Constantino de Souza, 454, apto 141 zip code: 04605-001, São Paulo – SP – Brazil,Email: drsantosmt@yahoo.com.br, Tel. +55(11) 9972.2301, Fax. +55(11) 5093.0865

Method and Materials: A group of 32 spastic CP individuals of both genders, aged 8 to 14 years old (10.1 ± 3.6), were evaluated. The EMG signals of electric activity were obtained using a 8-channel module (EMG System do Brasil Ltda ®, Sao Jose dos Campos, SP, Brazil) from the bilateral anterior temporalis and masseter muscles in two stages (S1 and S2), stored and analyzed as root-mean-square with values expressed in microvolts. The individuals were firstly positioned on dental chair in their usual seating position with no assistive stabilization or head control (S1). After one week the same individuals were evaluated and positioned according to the NDT (S2). The nonparametric Wilcoxon t test, with significance level of 95%, was used to compare the EMG activity of the muscles on two stages.

Results: The right and left anterior temporalis muscles showed a statistically significant reduction in EMG activity ($p<0.001$ and $p<0.001$) after postural stabilization (S2), and the same pattern was observed for the right and left masseter ($p<0.001$ and $p<0.001$) (S2).

Conclusion: The assistive stabilization decreases the electromyographic activity of right and left anterior temporalis and masseter muscles during mandibular resting position due to the inhibition of the pathological postural reflexes in individuals with cerebral palsy, facilitating dental care and preventive measures.

Keywords: Cerebral Palsy, Neurodevelopmental Treatment (NDT), Cyotherapy, Botulinum Toxin, Electromyographic Activity(EMG), Temporalis, Masseter.

INTRODUCTION

Cerebral palsy (CP) describes a group of movement and posture developmental disorders causing activity limitation, caused by nonprogressive disturbances occurring in the developing fetal or infant brain.[1] This condition is the most common cause of severe physical disability in childhood[2], with an estimated prevalence of 2.4 per 1000 children.[3] CP motor disorders may be accompanied by disturbances of sensation, cognition, communication, perception and seizure disorders[1]. Complex limitations in self-care functions, such as feeding, dressing, bathing, mobility and the ability to coordinate muscle action to maintain normal posture and to perform normal movements, may also occur.[4]

Symptoms of movement disorders include voluntary muscles tonus and reflexes accentuation, and the manifestations of involuntary movements during the execution of voluntary movements and while maintaining posture.[5] The manifestations are observed not only in skeletal limb muscles but also in the orofacial, cervical and head muscles [6] and when they hold their jaw open, such as during tooth cleaning and dental treatment.[5]

Dentistry plays a special role in total patient care for children who present disabilities, since by reducing additional causes of oral infection and, maintaining the teeth, these children can enjoy mastication and nourishment. Even though, to exam the oral cavity in these patients can be a huge problem. In order to facilitate access to internal surfaces of the maxillary molars, important for dental treatment as well as for preventive care procedures in disabled patients, some opening methods, such as cryotherapy and botulinum toxin A injection, are used. Besides, the oral tissues must be protected with the use of oral shield in self injury behavior usually present in these individuals.

• Cryotherapy

Spasticity is a frequent motor disorder present in congenital or acquired lesions of the central nervous system, and affects millions of people worldwide.[7] It may be incapacitating in itself, affecting the musculoskeletal system and limiting normal motor function. Initially, it impairs a comfortable positioning of the individual, making daily activities, such as feeding, walking, transportation and hygiene care, more difficult to achieve. When left untreated, it causes contractures, rigidity, displacement, pain and deformities.[8- 9]

It is a motor disorder characterized by the hyper-excitability of the velocity-dependent lengthening reflex, with deep reflex increment and muscle tone increase.[10]

Spasticity appears in clinical situations such as strokes (cerebral vascular accident), cerebral palsy (CP), spinal cord lesions, neoplasm, cranial-encephalic trauma, heredo-degenerative and demyelinizating diseases, among other alterations of the upper motor neuron.[7] Among the several physiopathological mechanisms involved, one must cite the loss of the descending inhibitory influences (via spinal reticulum) caused by lesions in the cortical-spinal tract on the control of muscle lengthening reflex pathways (myotactic). The loss of the descending inhibitory influence results in the increase of the excitability of the gamma spindle motor neurons and alpha motor neurons.[11]

The difficulties observed not only by dentists but also by caregivers regarding oral hygiene of patients with CP are due to the presence of spasticity in the masticatory musculature acting restrictively on the buccal opening. A number of studies have observed and analyzed the oral status of these population and the results have suggested that dental caries and periodontal disease have a higher incidence in individuals with CP, especially those with more severe motor impairment .[12-14]

Physiologically, muscle tonus, spasticity and muscle spasm are reduced by action on the muscle spindle itself, when muscle temperature drops. Local cooling, by a neural mechanism, increases the excitability of alpha neurons, while decreases that of gamma motor neurons, and when utilized, it facilitates the contraction of the antagonist musculature.[15]

Thermal sensations, as well as pain stimuli, transit in non-myelinized fine afferent nervous fibers of low conductive velocity. When submitted to lower temperatures, these fibers have their conduction decreased.[16]

Cryotherapy is a technique that is widely employed to decrease inflammatory reactions and pain, which also presents a tonus inhibitory action.[16]The face is a region of thinner epidermis, which facilitates the effects of cryotherapy.

The oral cryotheraphy is applied with sliding movements with a gauze-wrapped ice cube, with back and forth movements parallel to the muscular fiber of the subjacent masseter, bilaterally. Each movement covered the entire area, and the massage lasted one minute. (Figure 1)

The increase in inter-incisal distance after oral cryotherapy is observed due to the presence of a higher concentration of muscle spindles in masseter[17], and the sliding movements with ice over this region potentialized the inhibitory action of the spindle, allowing the function of the antagonist musculature of jaw elevators already mentioned by Wittink *et al*.[18] (Figure 2)

Figure 1. Application of oral cryotheraphy.

Figure 2. Increase inter-incisal distance after oral cryotherapy.

• Botulinum Toxin A Injection (BTX-A)

Since the early 80's, BTX-A, a powerful neuromuscular function blocker, has been used in conditions requiring specific muscle relaxation. The initial articles about botulinum toxin reported its use in the treatment of strabismus[19- 20], and its use was later extended to the treatment of conditions of local dystonia such as blepharospasm, spasmodic torticollis, spastic dysphonia, and spastic hypertonia. [21-23]

Afterwards, it was used in the treatment in the spasticity of the limbs, in patients with stroke, in the adductor of the hip in multiple sclerosis and many muscles in the cerebral palsy. [24-25]

Systemic side effects and local complications are uncommon with BTX-A. Systemic side effects are rarely reported, generally not dose related, and can include transient weakness, nausea, and pruritus.[26] There have been no reported cases of systemic toxicity. Locally diffusion of the toxin into adjacent muscular structures, with their subsequent and inadvertent inhibition can occur.

The masticatory muscle spasticity that causes changes in the stomatognathic system also requires treatment.

The masseter and temporalis muscles can be treated with botulinum toxin type A (BTX-A) neuromuscular block. The muscle locations are determined according to the anatomical reference map with the help of the electrical nerve stimulator and muscles palpations. Puncturing is then performed with an electrode needle connected to the electrical stimulator. With the needle inserted into the muscle, an electrical stimulus is sent to the tip of the needle making the muscle contract, thus permitting its accurate location. The masseter muscle is injected with 150 units and the temporalis muscle with 75 units of BTX-A applied bilaterally. A commercially available BTX-A (Dysport® 500 units) was used (Figure 3, Figure 4).

Figure 3. Application of botulinum toxin type A in masseter muscle, under general anesthesia.

Figure 4. Application of botulinum toxin type A in masseter muscle.

Freund et al.[27] reported that the injection of BTX-A into the masseter and temporalis muscles of patients without neurological impairment, diagnosed with temporomandibular dysfunction, yielded several significant findings. First was a reduction in both subjective pain (VAS) and tenderness in some patients. In all cases of pain reduction, the improvement was noted to coincide with the objective and subjective weakening of the masticatory muscles and not before. The possible mechanism was the result of reduction in the maximum contractile force of the injected muscles (alpha motor neuron inhibition) and a reduction in the resting muscle tone (gamma efferent inhibition).[28]

The decrease in hypertonia of the masseter and bilateral temporalis muscles, pain reduction upon palpation and increase of the interincisal opening observed after BTX-A injection may have been due to the same mechanism as described by Filippi, Errico and Santarelli [28].

The pathophysiology of bruxism after brain injury has not been well described. The complications of chronic bruxism include dental wear (Figure 5), temporomandibular joint destruction, and pain. [29] Traditionally, bruxism has been treated with mouth guards to prevent dental wear. However, several factors contraindicate the use of these devices in individuals with spastic tetraplegia, among them the early age of most patients, the impossibility of voluntary removal by the individual, large gingival growth causing a decrease of the clinical crown in the cervical-occlusal direction, presence of convulsive crises, pathological oral reflexes such as vomiting and tonic bite, and especially the alteration in intra-oral sensitivity.

Because the primary muscles involved in bruxism are the temporalis and masseter, it is postulated that weakening these muscles with BTX-A would resolve the condition. [29]

Trauma to soft tissues occurs due to the abrupt mandibular closing movement caused by the spasticity of jaw elevators, resulting in mandibular locking with repetitive interposition of soft tissues between the masticatory surfaces. This condition is reversed by the reduction of hypertonia.

The reduction of the interincisal distance caused by muscle contraction prevents hygiene and feeding, as well as the detection of bacterial plaque and calculus (Figure 6).

With respect to hygiene, a significant improvement is reported by the family member/caregiver regarding the manipulation of the oral cavity, due to the reduction in muscle tonus resulting from the application of BTX-A to the masticatory muscle.

Figure 5. Dental wear due to chronic bruxism.

Figure 6. Intra oral aspects of a patient with cerebral palsy, showing accumulate calculus

Botulinum toxin A injection is a well tolerated, safe and effective procedure for the treatment of children with spastic-tetraplegia cerebral palsy, resulting in improvement of muscle hypertonia, pain, bruxism, range of mouth opening, oral hygiene, and soft tissue trauma. (Figure 7)

Figure 7. Increased inter-incisal distance after Botulinum toxin A injection

• Oral Shield

Masticatory movements of the mandible are rhythmic and automatic. Mastication is a voluntary act controlled by the motor cortex of the precentral gyrus and also has an automaticity component. Coordination of the mandibular movements is associated with the cerebral cortex, the reticular formation, and the extra pyramidal systems. Tongue movements during mastication appear to be based on a functional relationship between the mesencephalic nucleus of the trigeminal nerve and the hypoglossal nucleus.[30]

Self-inflicted injuries have been described[30] as uncoordinated myotonic activity of selected masticatory muscles and tongue following neurological damage in comatose patients, in individuals with moderate to severe neurological impairments, such as cerebral palsy, and those with insensitivity to pain. The chewing movements produced are clenching spasms, biting, gnawing, and less often, bruxing.[31]

Self-injurious behavior (SIB) in the form of lip chewing is a common occurrence among developmentally disabled patients.[32] It has been reported in patients who have cerebral palsy, autism, epilepsy, and mental retardation.[33] It has also been reported in patients with mental and emotional conflicts, such as hate, jealousy, frustration, feeling of inferiority, etc.[34] Several syndromes and congenital conditions have been associated with SIB, including Lesch-Nyhan syndrome, Cornelia de Lange, Rett Syndrome, XXXXXY syndrome, XYY syndrome, and neuropathies.[35] Among severely and profoundly mentally-impaired individuals, the prevalence of some form of SIB approaches 40%.[36] (Figure 8 , Figure 9)

Figure 8. Intra oral aspects of lip trauma.

Figure 9. Intra oral aspects of lip trauma.

Various management methods of lip trauma have been suggested, depending on the severity, frequency and cause of injury. They include medication, behavioral techniques, and use of oral appliances or dental extractions.[37]

Dental extractions have also been advocated in certain cases of SIB[38], since they act as a suppression mechanism of the trauma origin.

SIB treatment in the form of lip biting in developmentally disabled individuals has been the focus of several reports using different oral appliances to prevent or inhibit SIB.[39-40] When an appliance is indicated to prevent oral trauma it has to deflect traumatized tissues away from the occlusal table, permitting mandibular movement, enabling daily oral care, and allowing healing of the injured tissues. It also has to be easily fabricated, to be comfortable and not to pose a risk to the patient.[41] Hanson et al.[41] recommendations considered the number of missing teeth that could compromise the oral appliance retention, as well as the presence of seizures, involuntary and clenched jaw movements, spasms, and feeding patterns, that could result in the displacement of the appliance, consequently creating a potential choking hazard. The caregivers' ability to manage the oral shield also has to be taking into account when it is prescribed.

The oral shield can be made by dental surgeons through buccal mandibular and maxillary arch impressions of the individuals with oral trauma. An acrylic plaque can be made of autopolymerizing acrylic resin used as an oral screen, covering all mandibular teeth occlusal surfaces and covering all the buccal maxillary and mandibular arches until the mucobuccal fold. On the appliance midline, a terminal can be made using the same material in order to facilitate caregivers' introduction and removal. The aim of the appliance fixation to the occlusal surface was to avoid displacement, and prevent aspiration, making it safe and stable. The appliance buccal extension is intended to separate soft tissues. Muscle and frenal attachments reliefs should be carefully ensured at the installation. The oral screen is placed to verify proper fitting and continuous use can be indicated depending on the necessity. (Figure 10 and 11)

The caregivers might receive instructions to remove the appliance twice a day to perform oral hygiene and cleanse the appliance. Periodic examinations must be performed to monitor lower lip, tongue and gum status.

Figure 10. Oral shield applied to patient showed in Figure 8.

Figure 11. Oral shield applied to patient showed in Figure 9.

Figure 12. Traumatic dental injury in 11 tooth.

Traumatic dental injury (TDI) in children and adolescents is a common problem and many authors have reported it in nondisabled individuals. [42-46] Studies regarding TDI prevalence have described it as varying from 7.3%[47], 10.9%[48], 11.7%[49], 15.4%[50], 20.4%[51], 23.3% [52], 33.2%[46], to 58.6% [53].

TDI can frequently lead to tooth lesions, affecting both supporting dental structures and hard tissues. [54] Besides these local injuries, dental trauma can, directly or indirectly, influence people's lives, affecting their appearance, speech, and teeth position, reinforcing the assertion that traumatic dental injuries may cause functional, esthetic, psychological [55] and social problems. [56] (Figure 12)

Falls were associated with loss of stability, while attempting to move from the wheelchair to the bed, bathtub and lavatory seat. Mouthguard appliances with uses ranging from protective to therapeutic could be indicated to prevent oral trauma in CP individuals, respecting patients' understanding, age, feeding ability, spasticity, degrees of masticatory muscles, and caregivers' training.

• Neurodevelopmental Treatment (NDT)

The goal in providing treatment for disabled, physically and mentally challenged, individuals is to treat the patient in the safest and most efficient manner possible.[57] Behavior management techniques currently used in pediatric dentistry include tell-show-do, positive reinforcement, voice control, physical restraint, hand-over-mouth, mechanical restraint, oral premedication, nitrous oxide sedation and general anesthesia.[58] The parents or guardians accept most of these behavior management techniques and explanation enhances their level of acceptance.[58-59] For some disabled people, comprehensive dental services would be impossible without the more restrictive management techniques.[60-61]

Physical therapy interventions include the classic neurodevelopmental treatment (NDT), which focuses on sensorimotor components of muscle tone, reflexes and abnormal movement patterns, postural control, sensation, perception and memory. Handling techniques that control various sensory stimuli have been used to inhibit spasticity, abnormal reflexes and movement patterns and have also been used to facilitate normal muscle tone, equilibrium responses and movement patterns.[62-64]

The aim of the study was therefore to evaluate the electromyographic activity of right and left anterior temporalis and masseter muscles during mandibular rest position, in individuals with CP on dental chair, before and after assistive stabilization.

METHOD AND MATERIALS

A group of 32 non-institutionalized quadriplegic spastic cerebral-palsied individuals of both genders, aged 8 to 14 years old, were evaluated at the dental clinics of the Individuals with Special Needs Discipline (Cruzeiro do Sul University, Sao Paulo, Brazil). A written informed consent for participation and publication was obtained from the adult responsible for each child/individual who agreed on participating in this study.

Electromyographic (EMG) activity was assessed in the dental office, with the individuals sitting upright on a dental chair in a comfortable, well-illuminated, quiet and calm environment during mandibular resting position. They were firstly positioned on the dental chair in their usual seating position (USP) with no assistive stabilization or head control (S1).

After one week, the same individuals were positioned and evaluated according to the neurodevelopmental treatment approach (NDT) (S2), which facilitates responses and normal positions through postures that inhibit reflexes with key control points.[64] (Figure 14).

Figure 13. Patient sat in dental chair in usual seating position with no assistive stabilization or head control.

Figure 14. Patient positioned according to the neurodevelopmental treatment approach.

The assistive stabilization and postural maintenance were achieved through the following techniques: [65]

1. Head was maintained on midline position by one individual of the dental staff over a head support (positioning device) located at the occipital level;
2. Upper members were maintained bent and juxtaposed on midline position, with the help of Velcro straps:
3. Lower members were maintained bent, decreasing the hip angle to 120 degrees in relation to the trunk (coxofemoral angle), by means of soft foam rolls as positioning devices, such as a support under the knees;
4. Mouth was maintained open with the use of mouth props

The EMG signals of electric activity from the bilateral anterior temporalis and masseter muscles were measured during mandibular resting position in two stages (S1 and S2) using a 8-channel module (EMG System do Brasil Ltda ®, Sao Jose dos Campos, SP, Brazil), consisting of a signal conditioner with a band pass filter with cut-off frequencies at 20-500 Hz, an amplifier gain of 1000x and a common mode rejection ratio > 120 dB. All data were processed using specific software for acquisition and analysis (Software AqDados®, version 5.05, Lynx Tecnologia Eletronica Ltda, Sao Paulo, Brazil), a converting plate for A/D 12 bits signal to convert analog to digital signals with a sampling frequency of anti-aliasing 2.0 kHz for each channel and an input range of 5 mV. A disposable active bipolar self-adhesive surface disc Ag/AgCl electrode (MediTrace®, Chicopee, MA, USA) with an active area diameter of 10 mm was also used.

The electrodes were placed parallel to the muscle fibers, with a center-to-center distance of 30 mm, in order to avoid the endplate region and thus obtain stable recordings. They were positioned at the motor point, in each portion of the masseter and anterior temporalis muscles, so that their electrical activity could be adequately assessed. The electrode placement was determined by manual palpation of the muscles, by gently forcing the mouth to close, following the longitudinal alignment and parallel to the muscle fibers direction. The skin underlying the sites was cleaned with alcohol prior to electrode placement. A reference electrode was fixed on the dorsal surface of the right wrist with Velcro tape in order to eliminate possible external interferences.

In all procedures the capture and analyses of EMG signals were carried out as recommended by the International Society of Electrophysiology and Kinesiology.[66] Recordings and analysis of the muscles' electrical activity were obtained with the mandible in the physiological resting position, without any tooth contact. Three consecutive measurements were obtained for 5 seconds each, all on the same day.

The EMG signals were stored and analyzed as root-mean-square (RMS) values expressed in microvolts (μV) in the resting position of each muscle. The means of the three samples of each muscle studied, obtained from each individual, were used to compare the EMG activity of the muscles on two stages using the nonparametric Wilcoxon t test with significance level of 95%.

RESULTS

This study evaluated a group of 32 non-institutionalized individuals with a medical diagnosis of quadriplegic spastic CP. This group was composed of 18 males and 14 females, with a mean age of 10.1± 3.6 yrs.

The mean values expressed as RMS of the anterior temporalis and masseter muscles on S1 and S2, during mandibular rest position of the 32 patients with CP are shown in Table 1.

The right and left anterior temporalis muscles showed a statistically significant reduction in electrical activity after assistive stabilization, and the same was observed for the right and left masseter (P<0.001).

Table 1. Mean ± SD and significance of RMS values of the anterior temporalis and masseter muscles before (S1) and after postural stabilization (S2) during mandibular resting position of 32 individuals with CP.

Muscles		S1	S2	P value
Anterior temporalis	right	5.4±3.3	3.3±1.5	<.001*
	left	6.7±4.0	3.6±1.8	<.001*
Masseter	right	2.7±0.5	2.2±0.8	<.001*
	left	2.9±0.8	2.4±0.5	<.001*

The data were compared by the Wilcoxon T test. (*P<0.001)

DISCUSSION

Several types of physical and mechanical restraints described in the literature have been used in the dental treatment of individuals with disabilities[60]; however, no positioning protocol for dental care at the outpatient clinic level was found, based on the reduction of postural instability accounted for by increased patient global muscle tonus and inhibition of reflexes, such as the asymmetrical tonic neck reflex (ATNR), often observed in patients with CP.[5] The goal of all therapies that individuals with CP undertake is to influence muscle tonus and improve postural alignment through specific handling techniques, and afterward, to work in order to achieve better active participation and practice regarding specific, relevant and functional skills.[63-67] All of the patients studied attend a Rehabilitation Center and are cared for by a multidisciplinary team, consisting of a physiatrist, physical therapist, speech therapist, occupational therapist, among others, and the technique used is the classic NDT approach.[65] Thus, the need to establish a positioning protocol used for dental treatment consistent with the rehabilitation method used during several types of therapy carried out at the rehabilitation center was clear. Based on such techniques, it was proposed that, positioning the patient adequately for dental care at an outpatient clinic level, using the reflex-inhibiting posture concept introduced by Bobath and Bobath[64] could help the dental surgeon to achieve planned treatment goals.

The eletromyographic activity study during mandibular rest position aimed at identifying the electrical activity behaviour of the anterior temporalis and masseter muscles on dental chair, without (S1) and with (S2) assistive stabilization, considering that activation of pathological postural reflexes is responsible for a greater energy expense, and may interfere on the dynamic equilibrium of the masticatory muscles.

The change in muscle tonus in individuals with CP is considered to be caused by disturbances in motor neuron activity in the central nervous system. The entire body muscle tonus is easily accentuated in these individuals and the involuntary movement is induced by various stimuli such as light and sound [6, 68], which are also present during dental treatment.

Surface electromyography provides a noninvasive method to study muscular functions and it is useful in interpreting pathologic states of musculoskeletal or neuromuscular systems. These changes in muscle tonus should be examined using a multichannel surface EMG, which could potentially give a much better insight into motor control disorders.[57-58]

The postures used for assistive stabilization in the present study are based on physiotherapy techniques, i.e. the Bobath[68] concept that the individual should be helped to attain a functional posture that will reduce the emerging pathological reflex activity by stimulating normal muscle tonus.[64]

It should also be pointed out that the increase in muscular and electrical activity, reduces blood circulation (ischemia) and facilitates pain emergence[59] contributing to the greater discomfort generated by a poor sitting position on the dental chair, interfering on dental treatment.

Another method used to reduce this discomfort is the N_20 inhalation, which also can reduce eletromyographic activity, as observed by Yoshida et al.[5] This method has, however, limited indication in severely impaired cerebral palsied individuals, as the ones in the present study. Therefore, the assistive stabilization, which allows dental treatment in the safest and most efficient manner[60], was chosen.

The potential action observed in the muscles studied during the rest position after assistive stabilization was smaller than that observed before postural reflexes inhibition. This result agrees with Sgobbi de Faria and Berzin[61] who found minimum potentials, since their patients received the minimum exteroceptive stimuli.

In addiction to the difference observed on electromyographic activity during assistive stabilization on cerebral palsied individuals, the low RMS values should also be observed. Spaulding et al.[62] had already emphasized the neurological lesion interference or the fiber type abnormalities as responsible factors for the lower RMS values observed on CP individuals when compared to individuals without any neurological lesion. Due to spasticity, the reduction of muscle capillarization and the low oxidative capacity of skeletal muscle fibers brings muscle fatigue and motor units reduction[63], resulting in lower RMS values, as seen on this study. According to Booth et al.[67], on children with spastic cerebral palsy, the muscular function become progressively impaired, with elasticity reduction due to collagen type I accumulation, what could also interfere the low RMS values observed on CP individuals. By means of postural stabilization, the impaired muscles tonus is reduced, facilitating dental treatment, which is expressed by a lower electromyographic activity.

Conclusion

The assistive stabilization decreases the electromyographic activity of right and left anterior temporalis and masseter muscles during mandibular resting position due to the inhibition of the pathological postural reflexes.

Acknowledments

The Ethics Committee of the Federal University of São Paulo / São Paulo School of Medicine (UNIFESP/EPM), Brazil, approved this study (protocol number 0875/04).

References

[1] Bax, M; Goldstein, M; Rosenbaum, P; Leviton, A; Paneth, N; Dan, B; Jacobsson, B; Damiano, D. Executive Committee for the Definition of Cerebral Palsy. Proposed definition and classification of cerebral palsy, April 2005. *Dev Med Child Neurol*, 2005, 47, 571-576.

[2] Kuban, KC; Leviton, A. Cerebral palsy. *N Engl J Med*, 1994, 330, 188-195.

[3] Hirtz, D; Thurman, DJ; Gwinn-Hardy, K; Mohamed, M; Chaudhuri, AR; Zalutsky, R. How common are the "common" neurologic disorders? *Neurology*, 2007, 68, 326-337.

[4] Hurr, JJ. Review of research on therapeutic interventions for children with cerebral palsy. *Acta Neurol Scand*, 1995, 91, 423-432.

[5] Yoshida, M; Nakajima, I; Uchida, A; Yamaguchi, T; Akasaka, M. Effect of nitrous oxide on dental patients with cerebral palsy – using an electromyogram (EMG) from orofacial muscles as an index. *J Oral Rehabil*, 2003, 30, 324-333.

[6] Waldo, EN. *Textbook of Pediatrics*. 12th edition. Saunders:Philadelphia, 1983.
[7] Braun, RM; Bottle, MJ. Treatment of shoulder deformity in acquired spasticity. *Clin Orthop*, 1999, 368, 54-65.
[8] Hinderer, SR; Gupto, S. Functional outcome measures to assess interventions for spasticity. *Arch Phys Med Rehab*, 1996, 77, 1083-1089.
[9] Mall, V; Heinen, F; Linder, M; Philipsen, A; Korinthenberg, R. Treatment of cerebral palsy with botulinum toxin A: funcional benefit and reduction of disability. *Pediatr Rehab*, 1997, 1, 235-7.
[10] Lance, JW. Pyramidal and extrapyramidal disorders. *In Eletromyography in CNS Disorders:central EMG*. Boston: Butterworth, 1984.
[11] Mayer, NH. Clinicophysiologic concepts of spasticity and motor dysfunction in adults with an upper motoneuron lesion. *Muscle Nerve Suppl.*, 1997, 6, S1-13.
[12] dos Santos, MT; Masiero, D; Simionato, MRL. Risk factors for dental caries in children with cerebral palsy. *Spec Care Dentist*, 2002, 22, 103-107.
[13] Rodrigues dos Santos, MT; Masiero, D; Novo, NF; Simionato, MR. Oral conditions in children with cerebral palsy. *J Dent Child*, 2003, 70, 40-46.
[14] Guare R. de O; Ciamponi, AL. Dental caries prevalence in the primary dentition of cerebral palsied children. *J Clin Pediatr Dent*, 2003, 27, 287-292.
[15] Lehmann, JF; DeLateur, BJ. Cryotherapy. In J. F. Lehmann (Ed), *Therapeutic heat and cold*, 4th ed. Baltimore: Williams & Wilkins, 590,1990.
[16] Knight, K. Cryotherapy in Sport Injury Management; ed *Human Kinetics*, 312 1995.
[17] Bakke, M. Mandibular elevator muscles: physiology, action, and effect of dental occlusion. *Scand J Dent Res*, 1993, 101, 314-31.
[18] Wittink, H; Michel, TH; Cohen, LJ; Fishman, SM. Physical Therapy Treatment. In: Wittink H & Michel TH. *Chronic pain managemt for physical therapists*, 1st ed. Boston: Butterworth-Heinemann, 119-153, 1997.
[19] Scott, AB. Botulinum toxin injection of eye muscles to correct strabismus. *Transactions of the American Ophthalmological Society*, 1981, 799, 764-770.
[20] Scott, AB; Kraft, SP. Botulinum toxin injection in the management of lateral rectus paresis. *Ophthalmology*, 1985, 95, 676-683.
[21] Frueh, BR; Felt, DP; Wojno, TH. Treatment of blepharospasm with botulinum toxin. *Archives of Ophthalmology*, 1984, 102, 1464-1468.
[22] Jankovic, J; Orman, J. Botulinum toxin for cranial-cervical dystonia: a double-blind controlled study. *Neurology*, 1986, 36, 120-121.
[23] Ludlow, CL; Nauton, RF; Sedory, SE. Effects of botulinum toxin injections on speech in adductor spasmodic dysphonia. *Neurology*, 1988, 38, 1220-1225.
[24] Koman, LA; Mooney, JF; Smith, B. Management of cerebral palsy with botulinum-A toxin: preliminary investigation. *Journal of Pediatric Orthopedics*, 1993, 13, 489-495.
[25] Silver, RL; Rang, M; Chan, J; De La Garca, J. Adductor release in nonambulant children with cerebral palsy. *Journal of Pediatric Orthopedics*, 1985, 5, 672-677.
[26] Jankovic, J; Schwartz, K. Botulinum toxin injections for cervical dystonia. *Neurology*, 1990, 40, 277.
[27] Freund, B; Schwartz, M; Symington, JN. The use of botulinum toxin for the treatment of temporomandibular disorders: Preliminary findings. *Journal of Oral and Maxillofacial Surgery*, 1999, 57, 916-920.

[28] Filippi, GM; Errico, P; Santarelli, R. Botulinum A toxin effects on rat jaw muscle spindles. *Acta Oto-Laryngologica*, 1993, 113, 400.
[29] Ivanhoe, CB; Lai, JM; Francisco, GE. Bruxism after brain injury: successful treatment with botulinum toxin-A. *Archives of Physical Medicine and Rehabilitation*, 1997, 78, 1272-3.
[30] Guyton, AC. *Textbook of medical physiology*. 7^{th} ed. Philadelphia:Saunders: 1986, p.779-60.
[31] Sheller, B. Self-inflicted oral trauma: report of case. *Spec Care Dentist*, 1992, 12, 28-9.
[32] Willette, JC. Lip-chewing: another treatment option. *Spec Care Dent*, 1992, 12, 174-6. 1992.
[33] Turley, PK; Henson, JL. Self-injurious lip-biting: etiology and management. *J Pedod*, 1983, 7, 209-20.
[34] Winchel, RM; Stanley, M. Self-injurious Behavior: a review of the behavior and biology of self-mutilation. *Am J Psychiatry*, 1991, 148, 306-16.
[35] Chen, LR; Liu, JF. Successful treatment of self-inflicted oral mutilation using an acrylic splint retained by a head gear. *Pediatr Dent*, 1996, 18, 408-10.
[36] Rubin, IL; Crocker, AC. Developmental disabilities: delivery of medical care for children and adults. Philadelphia:Lea & Febiger: 1989, 354-60.
[37] Macpherson, DW; Wolford, LM; Kortebein, MJ. Orthognathic surgery for the treatment of chronic self-mutilation of the lips. *Int J Oral Maxillofac Surg*, 1992, 21, 133-6.
[38] Millwood, J; Fiske, J. Lip-biting in patients with profound neuro-disability. *Dent Update*, 2001, 28, 105-8.
[39] Nurko, C; Errington, BD; Ben Taylor, W; Henry, R. Lip biting in a patient with Chiari type II malformation: case report. *Pediatr Dent*, 1999, 21, 209-12.
[40] Eyssette, M. Dans quels délais se fait la reprise de la marche et fault-il poursuivre la rééducation au-delài du 13^0 mois? *Ann Réadaptation Méd Phys*, 1997, 40, 131-37.
[41] Hanson, GE; Ogle, RG; Giron, L. A tongue stent for prevention of oral trauma in the comatose patient. *Crit Care Med*, 1975, 3, 200-3.
[42] Oliveira, LB; Marcenes, W; Ardenghi, TM; Sheiham, A; Bonecker, M. Traumatic dental injuries and associated factors among Brazilian preschool children. *Dent Traumatol*, 2007, 23(2), 76-81.
[43] Soriano, EP; Caldas Ade, F Jr; Diniz De Carvalho, MV; Amorim Filho Hde, A. Prevalence and risk factors related to traumatic dental injuries in Brazilian schoolchildren. *Dent Traumatol*, 2007, 23(4), 232-40.
[44] Malikaew, P; Watt, RG; Sheiham, A. Prevalence and factors associated with traumatic dental injuries (TDI) to anterior teeth of 11-13 year old Thai children. *Community Dent Health*, 2006, 23(4), 222-7.
[45] Hamdan, MA; Rajab, LD. Traumatic injuries to permanent anterior teeth among 12-year-old schoolchildren in Jordan. *Community Dent Health*, 2003, 20(2), 89-93.
[46] Marcenes, W; al Beiruti, N; Tayfour, D; Issa, S. Epidemiology of traumatic injuries to the permanent incisors of 9-12-year-old schoolchildren in Damascus, Syria. *Endod Dent Traumatol*, 1999, 15(3), 117-23
[47] Zerman, N; Cavalleri, G. Traumatic injuries to permanent incisors. *Endod Dent Traumatol*, 1993, 9(2), 61-4.
[48] Otuyemi, OD. Traumatic anterior dental injuries related to incisor overjet and lip competence in 12-year-old Nigerian children. *Int J Paediatr Dent.*, 1994, 4(2), 81-5.

[49] Josefsson, E; Karlander, EL. Traumatic injuries to permanent teeth among Swedish school children living in a rural area. *Swed Dent J*, 1994, 18(3), 87-94.

[50] Hargreaves, JA; Matejka, JM; Cleaton-Jones, PE; Williams, S. Anterior tooth trauma in eleven-year-old South African children. *ASDC J Dent Child*, 1995, 62(5), 353-5.

[51] Nicolau, B; Marcenes, W; Sheiham, A. Prevalence, causes and correlates of traumatic dental injuries among 13-year-olds in Brazil. *Dent Traumatol*, 2001, 17(5), 213-7.

[52] Soriano, EP; Caldas, AF Jr; Góes, PS. Risk factors related to traumatic dental injuries in Brazilian schoolchildren. *Dent Traumatol*, 2004, 20(5), 246-50.

[53] Marcenes, W; Zabot, NE; Traebert, J. Socio-economic correlates of traumatic injuries to the permanent incisors in schoolchildren aged 12 years in Blumenau, Brazil. *Dent Traumatol*, 2001, 17(5), 222-6.

[54] Andreasen, JO. Etiology and pathogenesis of traumatic dental injuries. A clinical study of 1,298 cases. *Scand J Dent Res*, 1970, 78(4), 329-42.

[55] Rajab, LD. Traumatic dental injuries in children presenting for treatment at the Department of Pediatric Dentistry, Faculty of Dentistry, University of Jordan, 1997-2000. *Dent Traumatol*, 2003, 19(1), 6-11.

[56] Rocha, MJ; Cardoso, M. Traumatized permanent teeth in Brazilian children assisted at the Federal University of Santa Catarina, Brazil. *Dent Traumatol*, 2001, 17(6), 245-9.

[57] Hirata, S; Sakamoto, K; Ookubo, M; Nishigichi, T; Shimazu, A. EMG power spectrum in cerebral palsy. *J Orthopaedic Traumatic Surgery*, 1993, 36, 829.

[58] Ferdjallah, M; Wertsch, JJ. Anatomical and technical considerations in surface electromyography. *Phys Med Rehabil Clin N Am*, 1998, 9, 925-931.

[59] Lund, JP; Donga, R; Widner, CG; Stohler, CS. The pain-adaptation model: A discussion of the relationship between chronic musculoskeletal pain and motor activity. *Can J Physiol Pharmacol*, 1991, 69, 683-694.

[60] Southern Association of Institutional Dentists. Guidelines for dental programs in facilities for the mentally retarded/mentally ill. Asheville, NC: SAID; Oct 17-19, 1990. Available at: http://saiddent.org/modules/14_module6.pdf #search=%22Guidelines%20for%20dental%20programs%20in%20facilities%20for%20the%20mentally%20retarded%2Fmentally%20ill.%20Asheville%22. Accessed April 16, 2008.

[61] Sgobbi de Faria, CR; Bérzin, F. Electromyographic study of the temporal, masseter and suprahyoid muscles in the mandibular rest position. *J Oral Rehabil*, 1998, 25, 776-780.

[62] Spaulding, SJ; White, SC; McPherson, JJ; Schild, R; Transon, C; Barsamian, P. Electromyographic analysis of reach in individuals with cerebral palsy. *Electromyogr Clin Neurophysiol*, 1990, 30(2), 109-115.

[63] Pontén, EM; Stål, PS. Decreased capillarization and a shift to fast myosin heavy chain IIx in the biceps brachii muscle from young adults with spastic paresis. *J Neurol Sci*, 2007, 15, 253(1-2), 25-33.

[64] Bobath, K; Bobath, B. The neurodevelopmental treatment. In: D. Scrutton (Editor). *Management of the Motor Disorders of Children with Cerebral Palsy*. Philadelphia:JB Lippicontt, 6-18, 1984.

[65] Santos, MTB; Manzano, FS. Assistive stabilization based on the neurodevelopmental treatment approach for dental care in individuals with cerebral palsy. *Quintessence Int*, 2007, 38(8) 681-687.

[66] Willians, KR. Standardizing Biomechanical testing in Sport. *Sport*, 1987, 58, 286-287.

[67] Booth, CM; Cortina-Borja, MJF; Theologis, TN. Collagen accumulation in muscles of children with cerebral palsy and correlation with severity of spasticity. *Dev Med Child Neurol*, 2001, 43, 314-320.
[68] Bobath, K. *A neurophysiological basis for the treatment of cerebral palsy*. 2nd edition. Williams Heinemann Medical Books:London,1980.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 181-197
ISBN: 978-1-60876-223-1

Chapter 5

PERFORMANCE ASSESSMENT AND LIMITATIONS OF DISTAL PROTECTION FILTERS FOR CAROTID ARTERY STENTING

Gail M. Siewiorek[1*] and Ender A. Finol[1,2**]

[1]Biomedical Engineering Department, Carnegie Mellon University, Pittsburgh, PA
[2] Institute for Complex Engineered Systems and Department of Mechanical Engineering, Carnegie Mellon University, Pittsburgh, PA.

ABSTRACT

Minimally invasive treatment of cardiovascular disease is becoming an increasingly popular alternative to surgery. In particular, carotid artery stenting (CAS) has gained attention and is also the subject of controversy for the treatment of cerebrovascular disease. Distal protection filters are used during CAS to capture peri-procedural emboli and early clinical trials have shown that they reduce the number of peri-procedural neurological events. The incidence of stroke and death following CAS is similar to that of the gold standard, carotid endarterectomy (CEA). This review focuses on performance and technical assessments of several distal protection filters used today by means of *in vitro* and *ex vivo* experiments, and clinical trials conducted in our laboratory and others. We will also discuss the limitations of these devices and suggest design considerations for future generations of distal protection filters. Parameters such as the ideal pore size, wall apposition and capture efficiency are discussed. In the future, it is likely that CAS and CEA will coexist for the treatment of cerebrovascular disease.

INTRODUCTION

Stroke is the third leading cause of death in the United States, with approximately 1 million stroke-related events each year [1]. About 50% of strokes are due to a buildup of

* Corresponding authors: Phone: 412-268-5213, Fax: 412-268-5229, Email: gail@cmu.edu
** Phone: 412-268-1841, Fax: 412-268-5229, Email: finole@cmu.edu

atherosclerotic plaque in the carotid bifurcation [1]. The recent shift to minimally invasive treatments has given rise to carotid artery stenting (CAS). CAS is a procedure in which the vasculature is accessed percutaneously via the femoral artery. The internal carotid artery (ICA) is revascularized by expansion of a tubular wire mesh over the plaque lesion.

To determine equivalency of CAS and its surgical counterpart, carotid endarterectomy (CEA), several non-randomized and randomized trials have been pursued. According to the North American Symptomatic Carotid Endarterectomy Trial (NASCET), the 30-day stroke and death rate was 5.8% for CEA [2]. Most notably, the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial is the first randomized trial comparing protected CAS and CEA. The 30-day post-procedure primary end-point rate, a composite of stroke, death, and myocardial infarction (MI), was 4.4% for CAS and 9.9% for CEA [3]. The highly anticipated Carotid Revascularization Endarterectomy versus Stent Trial (CREST) has completed enrollment. CREST is a multi-center, randomized clinical trial aimed to assess the efficacy of CAS and CEA in preventing stroke, death, and MI in the short (30-day) term and ipsilateral stroke in the long term (up to 4 years) [4-6]. The CREST lead-in phase, the time to credential potential CAS operators, indicates that octogenarians have increased complication rates following CAS [5].

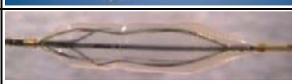
DEVICE OVERVIEW

Despite promising initial results, there is skepticism regarding the efficacy of CAS due to the potential for plaque embolization and occlusion of distal vascular beds. To address this issue, several embolic protection devices (EPDs) have been developed to capture and remove debris dislodged during the procedure. It is generally accepted that embolic protection devices are the standard adjunct for CAS [1]. The World Registry has reported a 2.23% rate of stroke and procedure-related death for protected CAS, compared to 5.29% for unprotected CAS [7].

Currently there are three types of embolic protection devices. The first is the distal balloon occlusion device, which consists of a compliant elastomeric polyurethane occlusion balloon that can be inflated to a diameter of 3 - 6 mm, such as the GuardWire® Temporary Occlusion and Aspiration System (Medtronic, Minneapolis, MN) [8]. It is loaded onto a 0.014-inch hollow nitinol wire with a floppy tip. During CAS, the balloon is inflated distal to the plaque lesion in the ICA to occlude the vessel and block blood flow. Plaque embolized during the procedure is trapped in a stagnant blood column immediately proximal to the inflated balloon. Following stent implantation, the debris and blood column are aspirated and removed from the body. Use of an occlusion balloon is attractive due to a low crossing profile and the ability to capture plaque of all sizes. However, embolization into the external carotid artery (ECA) is feasible, some patients cannot tolerate complete occlusion, and it is not possible to conduct angiographic imaging during the procedure.

The second type of EPD is proximal balloon occlusion or flow reversal device. The device consists of occlusive balloons in the common carotid artery (CCA) and ECA. When inflated, the balloons can either cause blood stagnation similar to the distal occlusion balloon [as achieved by the Mo.Ma™ device (Invatec, Roncadelle, Italy)] or create continuous flow reversal using an external arteriovenous fistula between the femoral artery and vein [as achieved by the Neuroprotection System™ (WL Gore, Flagstaff, AZ)] [9]. Similar to the distal balloon occlusion device, it can protect against particulate of all sizes. In addition, no embolization into the ECA can occur and protection can be achieved without crossing the plaque lesion. The disadvantages of these devices are a large crossing profile and the inability to conduct angiograms.

Table 1. Summary of Embolic Protection Devices.

Name	Picture	Material	Pore Size	Vessel diameter coverage
GuardWire (Medtronic)		Elastomeric material	n/a	3.0-6.0 mm
Mo.Ma (Invatec)		Compliant elastomeric rubber	n/a	13 mm (CCA) 6 mm (ECA)
Neuroprotection (WL Gore)		Compliant material	n/a	12 mm (CCA) 6 mm (ECA)
AngioGuard XP (Cordis)		Nitinol frame / polyurethane membrane	100 µm	3.0-7.5 mm
FilterWire EZ (Boston Scientific)		Nitinol frame / polyurethane membrane	110 µm	3.5-5.5 mm
Emboshield (Abbott Vascular)		Nitinol frame / polyurethane membrane	140 µm	2.8-6.2 mm
RX Accunet (Abbott Vascular)		Nitinol frame / polyurethane membrane	up to 150 µm	3.25-7.0 mm
SpiderFX (ev3)		Nitinol mesh	70-200 µm	3.0-7.0 mm
FiberNet (Lumen Biomedical)		PET (Dacron) fibers	down to 40 µm	3.5-7.0 mm
Rubicon (Boston Scientific)		Nitinol frame / polyurethane membrane	100 µm	4.0-6.0 mm
Interceptor PLUS (Medtronic)		Nitinol mesh	100 µm	5.5-6.5 mm

The third and final type of EPD is the distal protection filter. Numerous distal filters now have FDA approval, including AngioGuard XP (Cordis, Warren, NJ), FilterWire EZ (Boston Scientific, Natick, MA), Emboshield (Abbott Vascular, Abbott Park, IL), RX Accunet (Abbott Vascular, Abbott Park, IL), SpiderFX (ev3, Plymouth, MN), and FiberNet (Lumen Biomedical, Plymouth, MN). Distal filters frequently consist of a 0.014-inch guidewire with a floppy tip. The filter basket itself is composed of several materials. The most common basket is manufactured of nitinol wire struts and a polyurethane membrane with laser cut pores. Other designs consist of a wire mesh (such as SpiderFX) or polymer fibers (such as FiberNet). Once deployed from the delivery catheter, the compressed filter opens and is able to capture any particulate released during CAS. Aspiration of particulates prior to retraction is used with filter designs such as the FiberNet device. After stenting, the filter is retracted into a retrieval catheter, trapping the particulate in the filter basket, and removed from the body. Distal filters have been the focus of research in our laboratory due to the advantage of uninterrupted distal perfusion (and thus the ability to conduct angiograms) over the two types of balloon devices that obstruct normal blood flow. Disadvantages of distal filters include a larger crossing profile than balloon devices, embolization of particles into the ECA and embolization of particles smaller than the pore size of the filter basket, and difficulty navigating severely tortuous or stenosed vessels [8, 10]. See Table 1 for a summary of the embolic protection devices available in and outside of the United States.

PERFORMANCE ASSESSMENT: IN VITRO TESTING

Müller-Hülsbeck *et al.* reported on the first *in vitro* testing of embolic protection devices. A bench-top flow model circulated a 0.9% saline solution at a constant flow rate of 700 mL/min and mean CCA pressure of 78-80 mmHg [11-14]. The carotid artery bifurcation was modeled with straight 5-mm inner diameter silicone tubes having a 35° angle between the ICA and ECA. Either polyvinyl alcohol (PVA) or human plaque particles were injected into the system to simulate embolization. The PVA particles used (average mass 5 mg per size) were small (150-250 μm), medium (250-355 μm), and large (710-1000 μm) sizes [11, 13]. The human plaque particles (average mass 6 mg) consisted of 8-12 fragments ranging in size from 500-1500 μm [12, 14]. The particulates were injected and the capture efficiency calculated for each device (as the percentage of missed particles prior to device retrieval).

The first Müller-Hülsbeck study compared the capture efficiency of GuardWire with AngioGuard (predecessor to AngioGuard XP) using PVA particles with and without aspiration techniques [11]. Overall, GuardWire missed 1.1 mg (7.0%) and AngioGuard missed 0.80 mg (5.0%) of the total particles injected without aspiration. GuardWire missed a larger mass of particles than AngioGuard for small (0.37 versus 0.25 mg), medium (0.28 versus 0.24 mg), and large (0.45 versus 0.31 mg) particles. In a subsequent study, the distal protection filters FilterWire EX (predecessor to FilterWire EZ), Trap (formerly Microvena, Minneapolis, MN), and Neuroshield (predecessor to Emboshield) were tested under the same conditions [13]. Overall, Trap missed the most particles (1.24 mg, 8.2%) and FilterWire EX missed the fewest (0.39 mg, 2.58%). It is worth noting that FilterWire EX's results are dependent on repositioning the filter such that complete wall apposition is visible. If not repositioned, FilterWire EX missed 1.18 mg (7.81%) of particles, making its comparative performance average (performing more favorable than AngioGuard and Trap, but less favorable than Neuroshield and GuardWire Plus). Trap missed the largest mass of particles for small (0.61 mg) and medium (0.41 mg) particles. GuardWire Plus missed the greatest mass of large (0.45 mg) particles. The repositioned FilterWire EX missed the smallest mass of particles for small (0.23 mg), medium (0.11 mg), and large (0.05 mg) particles. Not taking into account repositioning, Neuroshield missed the fewest small (0.28 mg), medium (0.18 mg), and large (0.07 mg) particles. Neuroshield missed significantly less particles than the other devices ($p < 0.001$).

The four distal protection filters used previously (AngioGuard, FilterWire EX, Trap, Neuroshield) were tested with human plaque particles under the same experimental conditions [12, 14]. AngioGuard missed the greatest mass of human plaque (0.27 mg, 4.4%) and Neuroshield missed the smallest mass (0.05 mg, 0.8%). AngioGuard missed significantly more particles than the other devices tested ($p < 0.001$).

Order *et al.* investigated the effect of tortuousity on the capture efficiency *in vitro* of the four distal protection filters tested previously (AngioGuard, FilterWire EX, Trap, Neuroshield) [15]. Normal, mildly tortuous, and severely tortuous geometries were simulated using silicone tubes, with a 6- and 7-cm curved tube replacing a straight segment for the mild and severe configurations, respectively. Overall, AngioGuard missed the most in the mildly (2.54 mg, 16.84%) and severely (3.14 mg, 20.91%) tortuous configurations for small (mild: 1.19 mg, severe: 1.47 mg), medium (mild: 0.78 mg, severe: 0.99 mg), and large (mild: 0.57 mg, severe: 0.68 mg) particles. FilterWire EX missed the least in the mildly (0.45 mg, 2.99%) and severely (0.50 mg, 3.33%) tortuous configurations for small (mild: 0.28 mg, severe: 0.29 mg), medium (mild: 0.12 mg, severe: 0.15 mg), and large (mild: 0.05 mg, severe: 0.06 mg) particles. AngioGuard missed significantly more particles for all particle sizes and all geometries ($p < 0.001$; except large particles in mild or severe configuration, $p = 0.0059$).

Hendriks and colleagues examined the effect four distal protection filters (AngioGuard, FilterWire EZ, RX Accunet, Spider) have on the pressure gradient in a straight single tube set up [16]. A blood-mimicking fluid was circulated in the system with an input pressure of 70 mmHg, resulting in a flow rate of approximately 200 mL/min. Spider had the smallest pressure gradient (1.65 mmHg) while AngioGuard had the largest (8.80 mmHg). RX Accunet had a significantly smaller ($p < 0.0001$) pressure gradient among the polyurethane membrane filters (3.90 mmHg). Spider had a significantly smaller pressure gradient than any filter ($p < 0.0001$). There was a significant correlation between pressure gradient and flow reduction ($r = -0.77$, $p < 0.01$).

Results from Our Laboratory: Performance Assessment – In Vitro Testing

Finol *et al.* tested the capture efficiency of three distal protection filters (AngioGuard XP, FilterWire EZ, RX Accunet) in three silicone tubes with varying inner diameters (5.0-, 5.5-, and 6.0-mm) [17-19] (see Figure 1). The silicone tubes were configured such that it formed a sinusoidal geometry with an angle of approximately 35° between the proximal and distal segments to the apex. The bench-top flow loop circulated distilled water at a flow rate of 360 mL/min and 85 mmHg. Polymer microspheres ranging in size from 297- to 1000-μm (mean 649-μm) were injected into the system and the percentage of particles missed calculated for each device and vessel size. AngioGuard XP missed the largest mass of particles for all three vessel sizes (5.0-mm: 0.66 mg, 8.08%; 5.5-mm: 1.08 mg, 11.83%; 6.0-mm: 1.64 mg, 16.73%). RX Accunet missed the smallest mass of particles for all three vessel sizes (5.0-mm: 0.30 mg, 0.42%; 5.5-mm: 0.02 mg, 0.16%; 6.0-mm: 0.14 mg, 2.13%). AngioGuard XP missed significantly more particles than the other devices for all vessel sizes ($p < 0.05$, except compared to FilterWire EZ in the 5.0-mm vessel: $p = 0.051$).

RX Accunet was tested in a modified bench-top flow loop using a patient-specific flow model manufactured with epoxy resin [20, 21] (see Figure 2). The working fluid, 0.9% saline solution, was circulated at a flow rate of 700 mL/min and 95-100 mmHg CCA pressure. 5 mg of polymer microspheres sized 200-µm, 116-µm, and a combination of 49-, 116-, and 200-µm were injected into the system. RX Accunet missed the fewest 200-µm particles (0.04 mg, 1.1%) and the most 49/116/200-µm particles (0.07 mg, 2.1%).

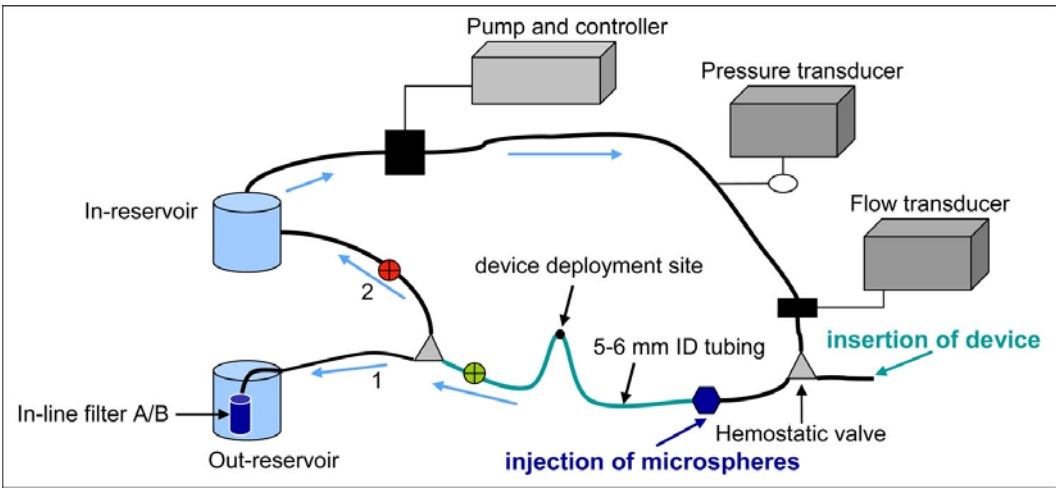


Figure 1. Schematic Diagram of Bench-Top Flow Loop With Sinusoidal Carotid Flow Model.

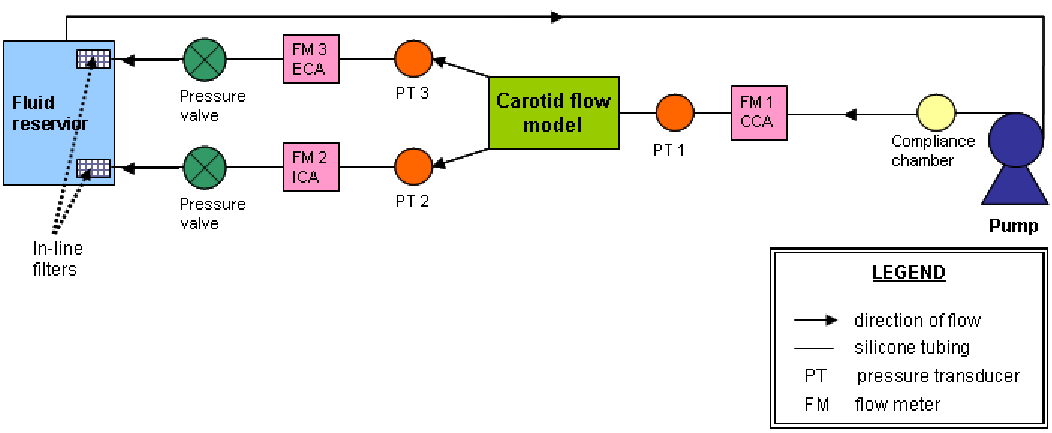


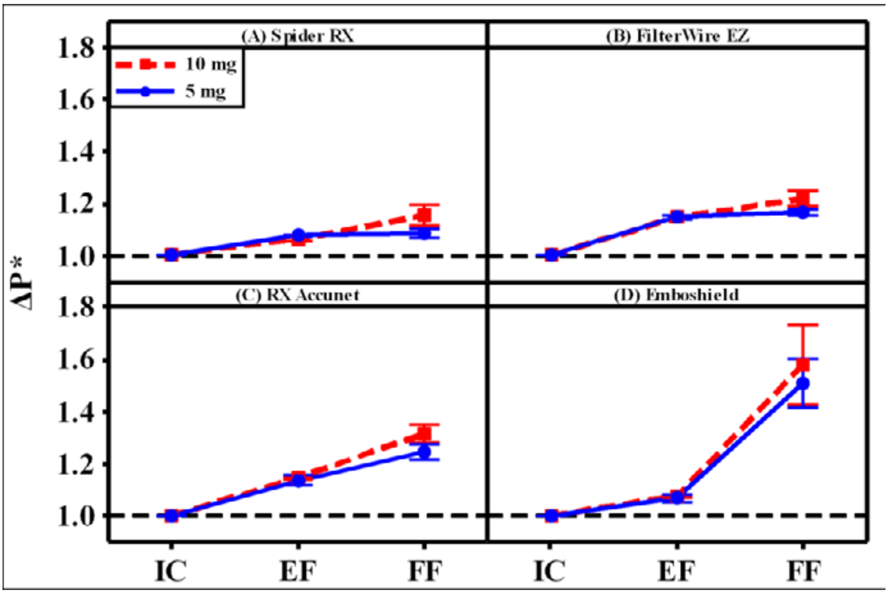
Figure 2. Schematic Diagram of Bench-Top Flow Loop With Patient-Specific or Average Dimension Carotid Flow Model.

The bench-top flow loop was modified a second time to replace the carotid flow model with a silicone phantom having average human dimension and a 70% symmetric ICA stenosis [22-26]. A blood-mimicking solution consisting of 36% glycerol and 64% deionized water was circulated at a flow rate of 737 mL/min and mean CCA pressure of 95 mmHg. Embolization was simulated by injection of 5- and 10-mg of polymer microspheres sized 200-μm, larger than the pore size of the devices tested (AngioGuard XP, FilterWire EZ, Emboshield, RX Accunet, Spider RX). The only exception is Spider RX, which has a variable pore size, and was tested with 300-μm particles. Pressure and flow rate at the CCA, ICA, and ECA were measured at initial, empty filter (deployed distal protection filter prior to particle injection), and full filter (deployed distal protection filter following particle injection) conditions. AngioGuard XP missed significantly ($p < 0.05$, except Emboshield) more particles when injected with 5 mg of microspheres (1.81 mg, 36.3%). Emboshield missed significantly ($p < 0.05$) more particles when injected with 10 mg of microspheres (4.83 mg, 48.4%). It is worth nothing that AngioGuard XP was not tested with 10 mg of particles. Spider RX missed significantly ($p < 0.05$) less particles for both masses (5 mg: 0.01 mg, 0.06%; 10 mg: 0.16 mg, 1.6%). Emboshield had the greatest increase in pressure gradient (+50.7%, 58.1%) and Spider RX had the smallest (+8.1%, +15.5%), for 5- and 10-mg microspheres, respectively. Emboshield had the greatest flow rate decrease (-47.6%, -47.8%) for 5- and 10-mg microspheres. Spider RX had the smallest flow rate decrease (-1.9%) for 5-mg and FilterWire EZ the smallest (-8.2%) for 10-mg. See Figures 3 and 4 and Table 2 for a summary of the effects distal protection filters have on the pressure gradient, flow rate, and vascular resistance in the ICA. See Table 3 for a summary of the results of all published *in vitro* capture efficiency experiments.

Results from Our Laboratory: Design Characteristics Assessment

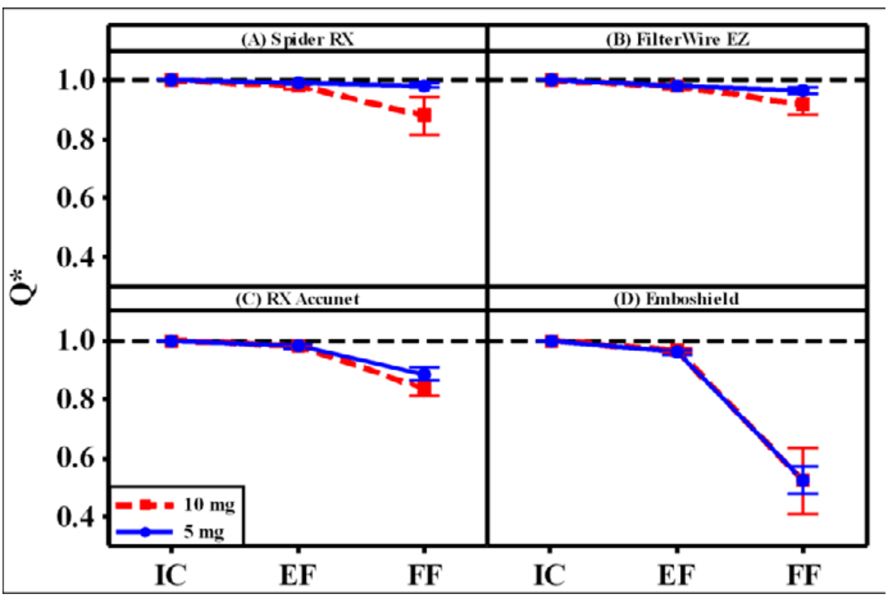
Several design characteristics of five distal protection filters (AngioGuard XP, FilterWire EZ, Emboshield, RX Accunet, Spider RX) were evaluated, including porosity, pore density, and wall apposition [9, 19, 27, 28]. To quantify porosity, an image of the entire filter surface was taken with a Microfire® Microscope Digital CCD camera mounted on an Olympus BX51 upright microscope. A 4x UplanF1 objective with numerical aperture 0.13 was used. Mosaic images were acquired using an automated stage controlled by the software Neurolucida® v5 (MicroBrightfield, Inc., Williston, VT) with a pixel resolution 1.83 μm/pixel. These images were used to count the number of pores and calculate porosity and pore density. Wall apposition was quantified by taking a photograph of the coronal plane of a 5.5-mm inner diameter tube with the appropriate sized device deployed. Any portions of the filter not flush against the tube wall were colored in red to illustrate incomplete apposition.

Porosity was defined as the ratio of the surface area of all the pores to the total surface area of the basket. The former was calculated by multiplying the number of pores by the area for an individual circular pore, knowing the manufacturer’s reported diameter. The latter was estimated by tracing the perimeter of the filter basket using ImageJ 1.38x software. Pore density was defined as the ratio of the number of pores to the total surface area of the basket. Basket length was measured excluding portions of the nitinol struts not covered by the filter membrane. Wall apposition was quantified by taking the ratio of the surface area of the device-wall gap to the total surface area of the vessel cross-section with ImageJ 1.38x.



Change in normalized pressure gradient (ΔP*) with respect to initial condition across the ICA with y error bars for 5- and 10-mg of particles: (A) Spider RX, (B) FilterWire EZ, (C) RX Accunet, (D) Emboshield. IC = initial condition (before device deployment), EF = empty filter condition (device deployed), FF = full filter condition (after particle injection).

Figure 3. Normalized Pressure Gradient Across Distal Protection Filters.



Change in normalized flow rate fraction (Q*) with respect to initial condition across the ICA with y error bars for 5- and 10-mg of particles: (A) Spider RX, (B) FilterWire EZ, (C) RX Accunet, (D) Emboshield. IC = initial condition (before device deployment), EF = empty filter condition (device deployed), FF = full filter condition (after particle injection).

Figure 4. Normalized Flow Rate Fraction Through Distal Protection Filters.

Table 2. Summary of Pressure, Flow Rate, and Vascular Resistance of Distal Protection Filters.

Device	Mass Injected (mg)	Normalized Pressure Gradient	Normalized Fractional Flow Rate	Vascular Resistance
FilterWire EZ	5	+16.6%	-3.5%	+20.5%
	10	+21.8%	-8.2%	+32.7%
Emboshield	5	+50.7%	-47.6%	+194%
	10	+58.1%	-47.8%	+250%
RX Accunet	5	+24.4%	-11.4%	+40.6%
	10	+31.5%	-16.4%	+57.2%
Spider RX	5	+8.1%	-1.9%	+10.1%
	10	+15.5%	-12.1%	+33.0%

Table 3. Summary of All Published *In Vitro* Experiments with Embolic Protection Devices.

Device	Author	Particle Material	Carotid Configuration	Mass Injected (mg)	Results[1]
GuardWire / GuardWire Plus	Müller-Hülsbeck [11, 13]	PVA	Silicone tubes with 35° angle	15.74 [small: 5.24, medium: 5.31, large: 5.19]	1.1 (7.0) [small: 0.37, medium: 0.28, large: 0.45]
AngioGuard / AngioGuard XP	Müller-Hülsbeck [11]	PVA	Silicone tubes with 35° angle	15.94 [small: 5.33, medium: 5.22, large: 5.39]	0.80 (5.0) [small: 0.25, medium: 0.24, large: 0.31]
	Müller-Hülsbeck [13]	PVA	Silicone tubes with 35° angle	15.06 [small: 5.00, medium: 5.03, large: 5.03]	1.21 (8.03) [small: 0.56, medium: 0.39, large: 0.26]
	Müller-Hülsbeck [12, 14]	Human plaque	Silicone tubes with 35° angle	6.01	0.27 (4.4)
	Order [15]	PVA	Silicone tubes with 35° angle; curved 6- and 7-cm ICA	Mild: small: 5.02, medium: 5.00, large: 5.00	Mild: small: 1.19 (23.71), medium: 0.78 (15.51), large: 0.57 (11.30)
				Severe: small: 5.04, medium: 4.97, large: 5.01	Severe: small: 1.47 (29.71), medium: 0.99 (19.92), large: 0.68 (13.57)
	Hendriks [16]	n/a	Single straight silicone tube	n/a	ΔP = 8.80 mmHg
	Finol [17-19]	Polymer	Single curved silicone tube	5.0-mm: 8.76, 5.5-mm: 9.93, 6.0-mm: 11.52	5.0-mm: 0.66 (7.5), 5.5-mm: 1.08 (10.9), 6.0-mm: 1.64 (14.2)

Table 3. (Continued)

Device	Author	Particle Material	Carotid Configuration	Mass Injected (mg)	Results[1]
	Siewiorek [22-26]	Polymer	Average dimension silicone carotid bifurcation; 70% symmetric ICA stenosis	4.99	1.81 (36.3)
FilterWire EX / EZ	Müller-Hülsbeck [11, 13]	PVA	Silicone tubes with 35° angle	15.11 [small: 5.00, medium: 5.04, large: 5.07]	1.18 (7.81) [small: 0.52, medium: 0.37, large: 0.29]
	Müller-Hülsbeck [12, 14]	Human plaque	Silicone tubes with 35° angle	5.99	0.08 (1.3)
	Order [15]	PVA	Silicone tubes with 35° angle; curved 6- and 7-cm ICA	Mild: small: 5.03, medium: 5.00, large: 5.00	Mild: small: 0.28 (5.57), medium: 0.12 (2.4), large: 0.05 (1.00)
				Severe: small: 4.99, medium: 5.01, large: 5.00	Severe: small: 0.29 (5.81), medium: 0.15 (2.99), large: 0.06 (1.20)
	Hendriks [16]	n/a	Single straight silicone tube	n/a	ΔP = 7.95 mmHg
	Finol [17-19]	Polymer	Single curved silicone tube	5.0-mm: 8.08, 5.5-mm: 7.22	5.0-mm: 0.08 (1.0), 5.5-mm: 0.05 (0.6)
	Siewiorek [22-26]	Polymer	Average dimension silicone carotid bifurcation; 70% symmetric ICA stenosis	4.99; 10.0	0.20 (3.9); 0.76 (7.6)
Trap	Müller-Hülsbeck [11, 13]	PVA	Silicone tubes with 35° angle	15.17 [small: 5.08, medium: 5.01, large: 5.04]	1.24 (8.2) [small: 0.61, medium: 0.41, large: 0.22]
	Müller-Hülsbeck [12, 14]	Human plaque	Silicone tubes with 35° angle	6.02	0.16 (2.6)
	Order [15]	PVA	Silicone tubes with 35° angle; curved 6- and 7-cm ICA	Mild: small: 4.97, medium: 5.01, large: 5.00	Mild: small: 0.69 (13.88), medium: 0.45 (8.98), large: 0.27 (5.40)
				Severe: small: 5.05, medium: 5.01, large: 5.02	Severe: small: 0.91 (18.02), medium: 0.53 (10.58), large: 0.37 (7.37)
Neuroshield / Emboshield	Müller-Hülsbeck [11, 13]	PVA	Silicone tubes with 35° angle	15.13 [small: 5.06, medium: 5.03, large: 5.04]	0.53 (3.50) [small: 0.28, medium: 0.18, large: 0.07]

Table 3. (Continued)

Device	Author	Particle Material	Carotid Configuration	Mass Injected (mg)	Results[1]
	Müller-Hülsbeck [12, 14]	Human plaque	Silicone tubes with 35° angle	6.05	0.05 (0.8)
	Order [15]	PVA	Silicone tubes with 35° angle; curved 6- and 7-cm ICA	Mild: small: 5.03, medium: 4.99, large: 5.00	Mild: small: 0.30 (5.96), medium: 0.21 (4.21), large: 0.10 (2.00)
				Severe: small: 5.05, medium: 5.01, large: 5.03	Severe: small: 0.33 (6.53), medium: 0.26 (5.19), large: 0.11 (2.19)
	Siewiorek [22-26]	Polymer	Average dimension silicone carotid bifurcation; 70% symmetric ICA stenosis	5.00; 10.0	1.42 (28.3); 4.83 (48.4)
RX Accunet	Hendriks [16]	n/a	Single straight silicone tube	n/a	ΔP = 3.90 mmHg
	Finol [17-19]	Polymer	Single curved silicone tube	5.0-mm: 7.22, 5.5-mm: 9.58, 6.0-mm: 10.15	5.0-mm: 0.30 (4.2), 5.5-mm: 0.02 (0.2), 6.0-mm: 0.14 (1.4)
	Gaspard [20, 21]	Polymer	Patient-specific epoxy resin carotid bifurcation	200-µm: 3.71, 116-µm: 4.25, 200/116/49-µm: 3.39	200-µm: 0.04 (1.1), 116-µm: 0.06 (1.9), 200/116/49-µm: 0.07 (2.1)
	Siewiorek [22-26]	Polymer	Average dimension silicone carotid bifurcation; 70% symmetric ICA stenosis	5.00; 10.0	0.12 (2.5); 1.46 (14.6)
Spider RX / SpiderFX	Hendriks [16]	n/a	Single straight silicone tube	n/a	ΔP = 1.65 mmHg
	Siewiorek [22-26]	Polymer	Average dimension silicone carotid bifurcation; 70% symmetric ICA stenosis	5.00; 10.0	0.01 (0.06); 0.16 (1.6)

[1] Data are expressed as the mass of particles missed by the device and as a percentage of the originally injected mass in parentheses.

Spider RX had the greatest porosity (50.4%) and Emboshield had the smallest (2.2%). FilterWire EZ had the greatest pore density and Emboshield had the smallest (13.6 and 1.4 pore/mm^2, respectively). Spider RX had the longest basket length and AngioGuard XP had the shortest (17.3 and 5.90 mm, respectively). AngioGuard XP had the greatest wall apposition gap (4.2%) while Emboshield had the smallest (0%). See Table 4 for a summary of the design characteristics of these distal protection filters.

Table 4. Summary of Design Characteristics of Distal Protection Filters.

Device	Pore Size (μm)	Number of Pores	Porosity (%)	Pore Density (pores/mm²)	Basket Length[1] (mm)	Wall Apposition[2] (%)
AngioGuard XP	100	1100	11.3	14.4	5.90	4.2
FilterWire EZ	110	2576	12.9	13.6	13.4	0.65
Emboshield	140	400	2.2	1.4	17.2	0
RX Accunet	up to 150	912	4.5	4.4	15.1	0.075
Spider RX	70-200	1563	50.4	10.0	17.3	0.49

[1] Basket length excludes any metal struts not covered by the polyurethane membrane.

[2] Wall apposition is represented by the device-wall gap, expressed as a percentage of vessel cross-sectional area at the site of device deployment.

PERFORMANCE ASSESSMENT: EX VIVO TESTING

Ohki and associates conducted one of the first investigations to measure the capture efficiency of a distal protection filter in an *ex vivo* apparatus [29]. Neuroshield was tested in eight carotid bifurcation plaques excised from carotid endarterectomy patients. Protected stenting was conducted on the plaques in a bath with an elevated saline bag to flush the lumen of the specimen. Neuroshield captured 88% of the total plaque particles embolized during the procedure. The mean number and maximum size of particles were quantified for three stages of the procedure: released during delivery of the device (3.1 and 500 μm), missed (2.8 and 360 μm), and captured by the device (20.1 and 1100 μm).

Müller-Hülsbeck *et al.* investigated the effect five embolic protection devices (Percusurge [currently GuardWire], AngioGuard, FilterWire EX, Trap, Neuroshield) have on *ex vivo* porcine carotid arteries [30]. A bench-top flow loop circulated 0.9% saline solution at a constant flow rate of 470 mL/min and mean pressure of 91 mmHg. Each device was deployed and subjected to a series of adverse movements (1 cm forward in the cranial direction, 2 cm backward, and 1 cm forward). Vessel wall damage was assessed by histology and the amount of debris captured in a 100 μm filter. Trap generated significantly ($p < 0.001$) more debris (7.51 mg) than the other devices. AngioGuard generated the least debris (4.75 mg).

LIMITATIONS

Although embolic protection devices are routinely used during CAS, three important issues remain unresolved in the design of distal protection filters [9]:

- Ideal pore size of the filtering membrane/basket
- Complete wall apposition even in tortuous geometries
- Obtaining 100% capture efficiency

The ideal pore size of a distal protection filter is contingent upon the threshold of plaque emboli size the brain can tolerate. Masuda *et al.* found that stroke victims had evidence of occluded arterioles ranging in size from 50 to 300 μm resulted in border-zone infarcts [31]. Rapp *et al.* found that fragments <100 μm may cause late neuronal ischemia [32, 33]. This evidence leads to most distal protection filters having a pore size around 100 μm. However, distal embolization may have minor or no clinical manifestation, as indicated by diffusion weighted-MRI (DW-MRI) [34-36]. In addition, no correlation between microembolic signals detected by transcranial Doppler and peri-procedural stroke has been found [37]. The long-term sequelae of silent cerebral infarcts are unknown [9].

In vitro testing by Order *et al.* and Finol *et al.* has demonstrated incomplete wall apposition in tortuous or curved geometries [15, 17-19]. Incomplete wall apposition can be difficult to assess at the time of the procedure. The interventionist is given a false sense of security since the distal protection filter is not functioning as indicated [9].

Finally, the degree to which a filter can capture emboli is dependent on its ability to retain the debris while preserving antegrade flow. The capture efficiency can be improved by altering the design characteristics discussed earlier in this chapter, including pore density, filter shape and length, and filter membrane composition [9]. Increased pore density can increase the filtering ability of the devices while maintaining antegrade flow. Increased filter depth and basket capacity can reduce the incidence of occluded or thrombosed filter baskets. Device membrane composition can increase the capture efficiency of these devices. For example, FiberNet, a distal protection filter that recently obtained FDA approval (in November 2008), is composed of woven polytetrafluoroethylene fibers that allow it to filter particles in two dimensions. This concept may increase capture efficiency in future generations of filters.

One major limitation of *in vitro* testing of embolic protection devices is that their correlation to clinical outcomes is unknown. For example, Siewiorek *et al.* measured an increased pressure gradient and reduced flow in the ICA across all devices due to filter deployment and subsequent capture of emboli that obstructs the filter pores. However, clinical studies are not conclusive regarding the effect of these measurements on the incidence of stroke or death. Casserly *et al.* observed that patients who had a reduction in antegrade flow proximal to the distal protection filter had an increased incidence of stroke or death within 30 days of the procedure (9.5% versus 1.7%, $p = 0.03$) [38]. However, Cieri *et al.* did not observe a difference in complication rates in patients with or without hemodynamic depression, defined as systolic blood pressure < 90 mmHg and/or heart rate < 50 beats/minute [39]. Although the data are inconclusive, interventionists should be cautious to reduce "slow flow" or hemodynamic depression.

CONCLUSION

Carotid artery stenting is a relatively new treatment for extracranial carotid artery occlusive disease. There is consensus in the use of cerebral protection devices to reduce peri- and post-procedural complications. *In vitro* performance assessments can provide an indication as to which device may result in the most favorable clinical outcome and give ideas for development of new, more effective devices. However, the correlation between results of *in vitro* testing and clinical outcome remains unclear. Bench-top testing that more closely mimics the cerebral vasculature, including the Circle of Willis and both left and right carotid arteries, may be helpful for designing and optimizing new devices. Evolving technology including the development of new cerebral protection devices and stents in combination with improvements in training and increased interventionist experience appear to improve CAS outcome. In the near future, the roles of CEA and CAS for the treatment of severe carotid atherosclerosis will likely be defined from the outcome of on-going multi-center, randomized clinical trials. It is likely that CEA will be the treatment for patients with standard surgical risk, while CAS will be reserved for high surgical risk candidates.

ACKNOWLEDGMENTS

The authors would like to thank Dr. Justin C. Crowley and Mr. Corey J. Flynn of Carnegie Mellon University's Department of Biological Sciences and Center for the Neural Basis of Cognition for their invaluable assistance in the acquisition of high-resolution filter images. Dr. Mark Wholey of the University of Pittsburgh Medical Center was a key facilitator of many of the devices tested in our laboratory. Likewise, we thank Dr. Mark Eskandari of Northwestern Memorial Hospital for his relevant discussions on design characteristics of embolic protection filters. Funding for the work conducted in our laboratory was provided in part by the generous support of the Pittsburgh Infrastructure Technology Alliance, the Samuel and Emma Winters Foundation, Carnegie Mellon's Biomedical Engineering Department, Guidant Endovascular Solutions, the John and Claire Bertucci Graduate Fellowship Program, and a National Institutes of Health pre-doctoral training award.

REFERENCES

[1] Bates, ER; Babb, JD; Casey, DE Jr.; et al. ACCF/SCAI/SVMB/SIR/ASITN 2007 clinical expert consensus document on carotid stenting: A report of the american college of cardiology foundation task force on clinical expert consensus documents (ACCF/SCAI/SVMB/SIR/ASITN clinical expert consensus document committee on carotid stenting). *J Am Coll Cardiol*, 2007, 49(1), 126-170.

[2] North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. *N Engl J Med*, 1991, 325(7), 445-453.

[3] Yadav, JS; Wholey, MH; Kuntz, RE; et al. Protected carotid-artery stenting versus endarterectomy in high-risk patients. *N Engl J Med*, 2004, 351(15), 1493-1501.

[4] Hobson, RW; 2nd. Update on the carotid revascularization endarterectomy versus stent trial (CREST) protocol. *J Am Coll Surg*, 2002, 194(1 Suppl), S9-14.

[5] Hobson, RW; 2nd, Howard, VJ; Roubin, GS; et al. Carotid artery stenting is associated with increased complications in octogenarians: 30-day stroke and death rates in the crest lead-in phase. *J Vasc Surg*, 2004, 40(6), 1106-1111.

[6] Hobson, RW; 2nd, Mackey, WC; Ascher, E; et al. Management of atherosclerotic carotid artery disease: Clinical practice guidelines of the society for vascular surgery. *J Vasc Surg*, 2008, 48(2), 480-486.

[7] Wholey, MH; Al-Mubarek, N; Wholey, MH. Updated review of the global carotid artery stent registry. *Catheter Cardiovasc Interv*, 2003, 60(2), 259-266.

[8] Eskandari, MK. Design and development of mechanical embolic protection devices. *Expert Rev Med Devices*, 2006, 3(3), 387-393.

[9] Siewiorek, GM; Eskandari, MK; Finol, EA. The angioguard embolic protection device. *Expert Rev Med Devices*, 2008, 5(3), 287-296.

[10] Kasirajan, K; Schneider, PA; Kent, KC. Filter devices for cerebral protection during carotid angioplasty and stenting. *J Endovasc Ther*, 2003, 10(6), 1039-1045.

[11] Müller-Hülsbeck, S; Grimm, J; Liess, C; Hedderich, J; Bergmeyer, M; Heller, M. Comparison and modification of two cerebral protection devices used for carotid angioplasty: In vitro experiment. *Radiology*, 2002, 225(1), 289-294.

[12] Müller-Hülsbeck, S; Hüsler, EJ; Schaffner, SR; et al. An in vitro analysis of a carotid artery stent with a protective porous membrane. *J Vasc Interv Radiol*, 2004, 15(11), 1295-1305.

[13] Müller-Hülsbeck, S; Jahnke, T; Liess, C; Glass, C; Grimm, J; Heller, M. Comparison of various cerebral protection devices used for carotid artery stent placement: An in vitro experiment. *J Vasc Interv Radiol*, 2003, 14(5), 613-620.

[14] Müller-Hülsbeck, S; Jahnke, T; Liess, C; et al. In vitro comparison of four cerebral protection filters for preventing human plaque embolization during carotid interventions. *J Endovasc Ther*, 2002, 9(6), 793-802.

[15] Order, BM; Glass, C; Liess, C; Heller, M; Müller-Hülsbeck, S. Comparison of 4 cerebral protection filters for carotid angioplasty: An in vitro experiment focusing on carotid anatomy. *J Endovasc Ther*, 2004, 11(2), 211-218.

[16] Hendriks, JM; Zindler, JD; van der Lugt, A; et al. Embolic protection filters for carotid stenting: Differences in flow obstruction depending on filter construction. *J Endovasc Ther*, 2006, 13(1), 47-50.

[17] Finol, EA; Scotti, CM; Verdinelli, I; Amon, CH; Wholey, MH. Performance assessment of embolic protection filters for carotid artery stenting. *Modelling in Medicine and Biology VI*, 2005, 8, 133-142.

[18] Finol, EA; Scotti, CM; Verdinelli, I; Wholey, MH. On the effectiveness of distal protection devices in carotid artery stenting. *Proceedings of the 2005 Summer Bioengineering Conference*, Vail, CO, June 22-26.

[19] Finol, EA; Siewiorek, GM; Scotti, CM; Wholey, MH; Wholey, MH. Wall apposition assessment and performance comparison of distal protection filters. *J Endovasc Ther*, 2008, 15(2), 177-185.

[20] Gaspard, S; Siewiorek, GM; Finol, EA. Performance assessment of a cerebral protection device by in vitro testing and computational fluid dynamics. *Proceedings of the 2006 Summer Bioengineering Conference*, abstract BIO2006-158114, Amelia Island, FL, June 21-25.

[21] Gaspard, S; Siewiorek, GM; Finol, EA. Experimental and computational flow modeling of cerebral protection devices for carotid artery stenting. *J Biomech*, 2006, 39(Suppl. 1), abstract 7194, S308.

[22] Siewiorek, GM; Finol, EA. The effect of embolic protection filters on distal embolization and slow flow condition in carotid artery stenting. *Proceedings of the 2007 Summer Bioengineering Conference*, abstract SBC2007-176534, Keystone, CO, June 20-24.
[23] Siewiorek, GM; Finol, EA. Cerebral protection devices - an in vitro investigation. *Proceedings of the 2007 Biomedical Engineering Society Annual Fall Meeting*, abstract 1591, Los Angeles, CA, September 26-29.
[24] Siewiorek, GM; Finol, EA. Bench-top performance comparison of distal protection devices. *International Journal of Medical Implants and Devices*, 2007, 2(2), 82.
[25] Siewiorek, GM; Wholey, MH; Finol, EA. In vitro performance assessment of distal protection devices for carotid artery stenting: Effect of physiological anatomy on vascular resistance. *J Endovasc Ther*, 2007, 14(5), 712-724.
[26] Siewiorek, GM; Wholey, MH; Finol, EA. Vascular resistance in the carotid artery: An in vitro investigation of embolic protection filters. *J Vasc Interv Radiol*, 2008, 19(10), 1467-1476.
[27] Siewiorek, GM; Finol, EA. Permeability and porosity of embolic protection filters: An experimental study. *Proceedings of the 2008 Summer Bioengineering Conference*, abstract SBC2008-192483, Marco Island, FL, June 25-29.
[28] Siewiorek, GM; Finol, EA. Experimental and computational modeling of permeability of embolic protection filters. *Proceedings of the 2008 Biomedical Engineering Society Annual Fall Meeting*, abstract 66, St. Louis, MO, October 2-4.
[29] Ohki, T; Roubin, GS; Veith, FJ; Iyer, SS; Brady, E. Efficacy of a filter device in the prevention of embolic events during carotid angioplasty and stenting: An ex vivo analysis. *J Vasc Surg*, 1999, 30(6), 1034-1044.
[30] Müller-Hülsbeck, S; Stolzmann, P; Liess, C; et al. Vessel wall damage caused by cerebral protection devices: Ex vivo evaluation in porcine carotid arteries. *Radiology*, 2005, 235(2), 454-460.
[31] Masuda, J; Yutani, C; Ogata, J; Kuriyama, Y; Yamaguchi, T. Atheromatous embolism in the brain: A clinicopathologic analysis of 15 autopsy cases. *Neurology*, 1994, 44(7), 1231-1237.
[32] Rapp, JH; Pan, XM; Sharp, FR; et al. Atheroemboli to the brain: Size threshold for causing acute neuronal cell death. *J Vasc Surg*, 2000, 32(1), 68-76.
[33] Rapp, JH; Pan, XM; Yu, B; et al. Cerebral ischemia and infarction from atheroemboli <100 micron in size. *Stroke*, 2003, 34(8), 1976-1980.
[34] Hauth, EA; Jansen, C; Drescher, R; et al. MR and clinical follow-up of diffusion-weighted cerebral lesions after carotid artery stenting. *AJNR Am J Neuroradiol*, 2005, 26(9), 2336-2341.
[35] Rapp, JH; Wakil, L; Sawhney, R; et al. Subclinical embolization after carotid artery stenting: New lesions on diffusion-weighted magnetic resonance imaging occur postprocedure. *J Vasc Surg*, 2007, 45(5), 867-872, discussion 872-864.
[36] Tedesco, MM; Lee, JT; Dalman, RL; et al. Postprocedural microembolic events following carotid surgery and carotid angioplasty and stenting. *J Vasc Surg*, 2007, 46(2), 244-250.
[37] Crawley, F; Clifton, A; Buckenham, T; Loosemore, T; Taylor, RS; Brown, MM. Comparison of hemodynamic cerebral ischemia and microembolic signals detected

during carotid endarterectomy and carotid angioplasty. *Stroke*, 1997, 28(12), 2460-2464.

[38] Casserly, IP; Abou-Chebl, A; Fathi, RB; et al. Slow-flow phenomenon during carotid artery intervention with embolic protection devices: Predictors and clinical outcome. *J Am Coll Cardiol*, 2005, 46(8), 1466-1472.

[39] Cieri, E; De Rango, P; Maccaroni, MR; Spaccatini, A; Caso, V; Cao, P. Is haemodynamic depression during carotid stenting a predictor of peri-procedural complications? *Eur J Vasc Endovasc Surg*, 2008, 35(4), 399-404.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 199-213
ISBN: 978-1-60876-223-1

Chapter 6

USE OF SEAT BELT BY MINI-BUS DRIVERS IN NIGERIA

[1]Abiodun Olukoga, [2]Kehinde Oluwadiya, [3]Tinu Olukoga and [2]Olusola Odu

[1]University of the West Indies, St. Augustine, Trinidad, WI.
[2]LAUTECH College of Health Sciences, Osogbo, Nigeria.
[3]Norfolk and Norwich University Hospital, Norwich, United Kingdom.

ABSTRACT

Introduction: The use of seat belts was made compulsory for all the occupants of a motor vehicle in Nigeria from January 1, 2003.

Objective: To determine the self-reported use of seat belts by mini-bus drivers in Osogbo, Nigeria and explore the various factors that influence seat belt use, such as the attributes of the drivers and possession of motor vehicle insurance.

Methods: A cross-sectional study of 525 mini-bus drivers in the city of Osogbo, Nigeria using a questionnaire designed for this study. It contained questions on the demographic characteristics of the respondents, the use of seat belt and factors influencing seat belt use such as the driver's normal route (intra-state, inter-state or both intra-state and inter-state) and the possession of motor vehicle insurance.

Results: A very high proportion (49%) of the respondents has been driving a mini-bus for less than 10 years. Most of the drivers (91%) had seat belts in their vehicles. The drivers aged between 25 and 34 years were the majority (46%) of the drivers with seat belts in their vehicles. The presence of a seat belt in the mini-bus was significantly associated with the normal route of travel (X^2=7.959, p<0.05).

It was in only 84% of the respondents that the seat belts in the mini-buses were functional. There was a statistically significant association between the presence of a functional seat belt in the mini-bus and the level of education of the driver (X^2=8.795, p<0.05) and the normal route of travel (X^2=9.965, p<0.05).

Most (85%) of the drivers knew about the regulation that required that they use seat belts while driving. The knowledge of seat belt regulation by the drivers was significantly associated with the number of years of driving a mini-bus (X^2=36.360, p<0.05), normal route of travel (X^2=11.8460, p<0.05) and possession of motor vehicle insurance (X^2=6.051, p<0.05).

Almost all the drivers (95%) were aware of the imposition of a fine when they do not use their seat belts while driving. Drivers aged 25 to 34 years had the highest level of awareness (47%) of the fine for non-use of seat belt when driving and those drivers aged 17 to 24 years had the lowest level of awareness (7%) of the fine. There was a statistically significant association between the age of the driver and the awareness of the imposition of a fine for the non-use of a seat belt when driving (X^2=14.926, p<0.05).

Majority of the drivers always (47%) or sometimes (44%) use a seat belt while driving. Only 9% of the drivers never use a seat belt while driving. The frequency of seat belt use by the drivers was associated with the normal route of travel (X^2=31.718, p<0.05) and possession of motor vehicle insurance (X^2=19.780, p<0.05).

The two main reasons given for the non-use of seat belt by mini-bus drivers were lack of safety consciousness (36%) and inconvenience (32%). Most of the drivers believe that enforcement of the seat belt regulation by the Police and Federal Road Safety Commission (96%), more education (92%) and more reminders (91%) will improve seat belt use by drivers.

INTRODUCTION

Road traffic accidents have been acknowledged as a looming public health epidemic in many countries worldwide, irrespective of their socioeconomic status i.e. whether high-income, middle-income or low-income (Hauswald 1997) (Olukoga 2004a) (Olukoga 2004b) (WHO 2009).

They result in 20 to 50 million non-fatal injuries and account for more than 1.3 million deaths a year. The middle-income and low-income countries in the world currently account for more than 90% of the fatalities from road traffic accidents, although these countries have only 48% of the registered motor vehicles in the world (WHO 2009) (Routley, Ozanne-Smith et al. 2009).

Recent reports of the fatality rates from road traffic accidents are 10.3 deaths per 100,000 in high-income countries, 19.5 deaths per 100,000 in middle-income countries and 21.5 deaths per 100,000 in low-income countries. These respective fatality rates from road traffic accidents show clearly that the rates in low-income countries like Nigeria is double the rates in high-income countries. Hence the problem of road safety is a more serious issue in these low-income countries (WHO 2009) (Sangowawa, Ekanem et al. 2005) (Olukoga 2003) (Olukoga 2007) (Iribhogbe and Osime 2008).

The reduction of injuries and deaths from road traffic accidents is enhanced by the enactment and enforcement of comprehensive and clear legislations on the risk factors such as the use of protective measures like seat belts (Routley, Ozanne-Smith et al. 2009) (Olukoga and Noah 2005). Unfortunately, many countries are failing in these tasks of enactment and enforcement of comprehensive and clear legislations on the various aspects of road safety (Hauswald 1997) (WHO 2009). A recent WHO study showed that only 15% out of 178 countries have laws that are comprehensive with respective to five risk factors of road traffic accidents i.e. speeding, drink-driving, non-use of helmets, non-use of seat belts and non-use of child restraints. There is a very poor degree of enforcement of legislations enacted to address these risk factors. On a scale of 0 to 10, out of 178 countries, only 25% reported the enforcement of their motorcycle helmet-use laws higher than 7, 19% reported the enforcement of their seatbelt laws higher than 7, 13% reported the enforcement of blood alcohol concentration limits higher than 7, 9% reported the enforcement of speed limits higher than 7 and 6% reported the enforcement of their child restraint laws higher than 7. According to the World Health Organisation, only 38% of low-income countries and 54% of middle-income countries require both front-seat and rear-seat passengers in cars to use seatbelts (WHO 2009).

The use of a seat belt reduces the risk of fatalities in a road traffic accident by 40–50% among front seat passengers and by 25–75% among rear-seat car occupants (WHO 2009) (Routley, Ozanne-Smith et al. 2007) (Routley, Ozanne-Smith et al. 2007; Routley, Ozanne-Smith et al. 2008). The enactment and enforcement of mandatory seat-belt laws, as well as appropriate public awareness campaigns have been shown to be very effective in increasing seat-belt wearing rates (WHO 2009) (Olukoga and Noah 2005) (Harris and Olukoga 2005) (Routley, Ozanne-Smith et al. 2009).

The use of seat belts by drivers and passengers in motor vehicles is known to have an influence on the occurrence of road traffic accidents (Lam 2002; Ball, Kirkpatrick et al. 2005). Seat belt use is known to have beneficial effects especially with reduction in injuries and deaths from road traffic crashes (Sangowawa, Ekanem et al. 2005) (Harris and Olukoga 2005) (Oluyemi 2007). Therefore, most countries of the world have laws making seat belt use mandatory for all drivers (Olukoga and Noah 2005). But, there have been reports indicating low compliance of the seat belt laws by commercial motor vehicle drivers including mini-bus drivers (Kim and Yamashita 2007) (Knoblauch, Cotton et al. 2003) (Sullman and Baas 2004).

From January 1, 2003, the Federal Road Safety Commission (FRSC), the regulatory body responsible for road safety issues in Nigeria made the use of seat belts compulsory for all the occupants of a motor vehicle in the country (Ekele, Nnadi et al. 2004) (Iribhogbe and Osime 2008) (Sangowawa, Ekanem et al. 2005; Oluyemi 2007).

According to the World Health Organisation (2009), the reported seat-belt wearing rate for front seat occupants of motor vehicles in Nigeria is 70% (WHO 2009).

OBJECTIVE

The objective of this study was to determine the self-reported use of seat belts by mini-bus drivers in Osogbo, Nigeria. In addition, the various factors that influence seat belt use, such as the attributes of the drivers and possession of motor vehicle insurance were explored.

METHODS

The study adopted a cross-sectional approach. 525 mini-bus drivers in the city of Osogbo, Osun State, Nigeria were invited to participate in the study by completing a questionnaire. 446 of the drivers agreed to participate, giving a response rate of 85%.

A questionnaire designed for this study was administered to all the respondents. It contained questions on the demographic characteristics of the respondents such as age, sex, education and years of driving. Also, there were questions on the use of seat belt and factors influencing this such as the driver's normal route (intra-state, inter-state or both intra-state and inter-state) and the possession of motor vehicle insurance.

DATA ANALYSIS

Data analysis and reporting included frequencies of the basic characteristics and driving profile of the respondents, availability of seat belt, frequency and knowledge of seat belt use and the main reasons why mini-bus drivers do not use seat belts. The associations between the demographic characteristics and driving profile of the respondents, and the availability of seat belt, frequency of seat belt use, knowledge of seat belt regulation and fine for non-use of seat belt were examined using Chi-square.

RESULTS

Basic Demographics of Respondents

Table 1 shows the basic demographics of the 446 responding mini-bus drivers. Majority (46%) of the respondents were between 25 and 34 years old. Those aged 35 to 44 years were 29%. Most of the respondents were males (94%). About 44% of the respondents had primary education and 43% had secondary education. Those drivers without any formal education and those with tertiary education were about 7% respectively.

Table 1. Basic demographics of respondents.

Age (years)	*Freq.*	*Percent*	*95% CI*	
17-24	33	7.8	0.05	0.11
25-34	194	46.0	0.41	0.51
35-44	124	29.3	0.25	0.34
45-75	71	16.7	0.13	0.21
Total	422	100.0		
Sex				
Male	419	94.0	0.91	0.96
Female	27	6.0	0.04	0.09
Total	446	100.0		
Education				
No formal education	30	7.0	0.05	0.10
Primary	188	43.7	0.39	0.49
Secondary	183	42.6	0.38	0.47
Tertiary	29	6.7	0.05	0.10
Total	430	100.0	0.05	0.11

Driving Profile of Respondents

The driving profile of the respondents is described in Table 2. Most (49%) of the respondents have been driving a mini-bus for less than 10 years. About 32% of the respondents have been driving a mini-bus for more than 10 years, but less than 20 years. Only 19% of the respondents have been driving a mini-bus for more than 20 years.

A large proportion (53%) of the responding mini-bus drivers ply their trade only within the state, 21% ply the inter-state route only and 26% ply both the intra-state and inter-state routes.

More than 60% of the mini-bus drivers have motor vehicle insurance and the remaining 36% do not have motor vehicle insurance.

Table 2. Driving profile of respondents.

Years driving mini-bus	*F*	*Pe*	*95% CI*	
0-4 years	8	19.	0	0
5-9 years	1	29.	0	0
10-14 years	9	21.	0	0
15-19 years	4	11.	0	0
>20 years	8	18.	0	0
Total	4	10		
Normal route				
Intra-state only	2	52.	0	0
Inter-state only	9	21.	0	0
Intra-state & inter-state	1	25.	0	0
Total	4	10		
Motor vehicle insurance				
Yes	2	63.	0	0
No	1	36.	0	0
Total	4	10	0	0

Drivers with Seat Belts in Their Vehicles

A very high proportion (91%) of the drivers had seat belts in their mini-buses. Table 3 shows the distribution of drivers with seat belts in their mini-buses. The drivers aged between 25 and 34 years were the majority (46%) of the drivers with seat belts in their vehicles and those drivers between 17 and 24 years had the lowest proportion (8%) amongst drivers with seat belts in their vehicles. There was no statistically significant association between age of the driver and the presence of a seat belt in the mini-bus (X^2=0.328, $p>0.05$).

Most (86%) of the drivers with seat belts in their vehicles had either primary or secondary education and those with no formal or tertiary education were about 14% of the drivers with seat belts in their vehicles. Most of the drivers without seat belts had secondary education (50%) and no driver with tertiary education was without a seat belt. The association between the level of education of the driver and the presence of a seat belt in the mini-bus was not statistically significant (X^2=4.296, $p>0.05$).

Table 3. Drivers with seat belts in their vehicles.

Age	*Yes*	*No*	X^2	*p value*
17-24 years	7.9%	7.5%	.328	.955
25-34 years	45.9%	45.0%		
35-44 years	29.7%	27.5%		
45-75 years	16.5%	20.0%		
Total (N)	381	40		
Education				
No formal education	6.7%	10.0%	4.296	.231
Primary	44.2%	40.0%		
Secondary	41.6%	50.0%		
Tertiary	7.5%	0%		
Total (N)	389	40		
Years driving mini-bus				
0-4 years	19.8%	19.5%	4.733	.316
5-9 years	29.2%	29.3%		
10-14 years	21.8%	17.1%		
15-19 years	11.8%	4.9%		
>20 years	17.5%	29.3%		
Total (N)	400	41		
Normal route				
Intra-state only	51.1%	70.0%	7.959	.019
Inter-state only	22.9%	5.0%		
Intra-state & inter-state	25.9%	25.0%		
Total (N)	401	40		
Motor vehicle insurance				
Yes	64.4%	56.1%	1.110	.292
No	35.6%	43.9%		
Total (N)	399	41		

About 49% of the drivers who had seat belts have been driving for less than 10 years. Drivers who have been driving for more than 10 years but less than 20 years were 44% of the drivers who had seat belts in their mini-buses. The association between the number of years of driving a mini-bus and the presence of a seat belt in the mini-bus was not statistically significant (X^2=4.733, p>0.05).

There were more drivers who ply the intra-state routes (51%) who had seat belts than those who ply the inter-state routes (23%) and those who ply both the intra-state and inter-state routes (26%). The association between the normal route of travel and the presence of a seat belt in the mini-bus was statistically significant (X^2=7.959, p<0.05). More than 60% of the drivers with motor vehicle insurance had seat belts. There was no statistically significant association between the possession of motor vehicle insurance and the presence of a seat belt in the mini-bus (X^2=1.110, p>0.05).

Drivers with Functional Seat Belts in Their Vehicles

It was in only 84% of the respondents that the seat belts in the mini-buses were functioning properly. Table 4 shows the distribution of drivers with functional seat belts in their mini-buses. Majority (46%) of the drivers with functional seat belts in their vehicles were between the ages of 25 and 34 years and the drivers between 17 and 24 years had the lowest proportion amongst drivers with functional seat belts in their vehicles (8%). The association between the age of the driver and the presence of a functional seat belt in the mini-bus was not statistically significant (X^2=3.747, p>0.05).

A majority (86%) of the drivers with functional seat belts in their vehicles had either primary or secondary education and those with no formal or tertiary education were about 14% of the drivers with functional seat belts in their vehicles. The drivers with tertiary education were the least likely to be without functional seat belts in their vehicles. The association between the level of education of the driver and the presence of a functional seat belt in the mini-bus was statistically significant (X^2=8.795, p<0.05).

Table 4. Drivers with functional seat belts in their vehicles.

Age	*Yes*	*No*	*X^2*	*p value*
17-24 years	8.3%	3.2%	3.747	.290
25-34 years	45.7%	47.6%		
35-44 years	29.4%	25.4%		
45-75 years	16.6%	23.8%		
Total (N)	337	63		
Education				
No formal education	6.1%	14.3%	8.795	.032
Primary	43.2%	50.8%		
Secondary	42.9%	31.7%		
Tertiary	7.8%	3.2%		
Total (N)	345	63		
Years driving mini-bus				
0-4 years	19.6%	20.6%	4.698	.320
5-9 years	28.4%	33.8%		
10-14 years	22.7%	13.2%		
15-19 years	11.9%	8.8%		
>20 years	17.3%	23.5%		
Total (N)	352	68		
Normal route				
Intra-state only	49.6%	61.2%	9.965	.007
Inter-state only	24.9%	7.5%		
Intra-state & inter-state	25.5%	31.3%		
Total (N)	353	67		
Motor vehicle insurance				
Yes	64.5%	58.2%	.957	.328
No	35.5%	41.8%		
Total (N)	352	67		

Most of the drivers (48%) who had functional seat belts have been driving for less than 10 years. Drivers who have been driving for more than 10 years but less than 20 years were 35% of the drivers who had functional seat belts in their mini-buses. There were more drivers without functional seat belts in their mini-buses who have been driving for more than 20 years (24%) than all the other categories of drivers except those who have been driving for between 5 and 9 years (34%). There was no statistically significant association between the number of years of driving a mini-bus and the presence of a functional seat belt in the mini-bus (X^2=4.698, p>0.05).

There were more drivers who ply the intra-state routes (50%) who had functional seat belts than those who ply the inter-state routes (25%) and those who ply both the intra-state and inter-state routes (25%). The association between the normal route of travel and the presence of a functional seat belt in the mini-bus was statistically significant (X^2=9.965, p<0.05).

More than 60% of the drivers with motor vehicle insurance had functional seat belts. There was no statistically significant association between the possession of motor vehicle insurance and the presence of a functional seat belt in the mini-bus (X^2=0.957, p>0.05).

Drivers' Knowledge of Seat Belt Regulation

Most (85%) of the drivers knew about the regulation that required that they use seat belts while driving. Table 5 shows the drivers' knowledge of the seat belt regulation in Nigeria. Drivers aged 25 to 34 years had the highest level of knowledge (45%) and those drivers aged 17 to 24 years had the lowest level of knowledge (8%) of the seat belt regulation. The oldest drivers between 45 and 75 years (42%) were more likely to believe that there was no seat belt regulation in Nigeria and there was no driver between 17 and 24 years who did not know of the seat belt regulation. The association between the age of the driver and the knowledge of the seat belt regulation was not statistically significant (X^2=11.416, p>0.05).

Most of the drivers who knew about the seat belt regulation (85%) and those drivers who believed that there was no seat belt regulation (92%) had either primary or secondary education. There was no driver with tertiary education who did not know of the seat belt regulation. There was no statistically significant association between the level of education of the driver and the knowledge of the seat belt regulation (X^2=5.682, p>0.05).

Most of the drivers (47%) who knew about the seat belt regulation have been driving for less than 10 years. Drivers who have been driving for more than 10 years but less than 20 years were 34% of the drivers who knew about the seat belt regulation. Those who have been driving for more than 20 years (67%) were more likely to believe that there was no seat belt regulation in Nigeria and there was no driver who has been driving for less than 5 years who did not know of the seat belt regulation. The association between the number of years of driving a mini-bus and the knowledge of the seat belt regulation was statistically significant (X^2=36.360, p<0.05).

There were more drivers who ply the intra-state routes (51%) that knew about the seat belt regulation compared to those drivers who ply the inter-state routes (24%) and those who ply both the intra-state and inter-state routes (25%). The association between the normal route of travel and the knowledge of the seat belt regulation was statistically significant (X^2=11.8460, p<0.05).

The drivers with motor vehicle insurance were more likely to know about the seat belt regulation (62%) than the drivers without motor vehicle insurance. The proportion of drivers with motor vehicle insurance that did not know about the seat belt regulation was similar to the proportion of drivers without motor vehicle insurance. The association between the possession of motor vehicle insurance and the knowledge of the seat belt regulation was statistically significant (X^2=6.051, p<0.05).

Table 5. Drivers' knowledge of seat belt regulation.

Age	*Yes*	*No*	X^2	*p value*
17-24 years	7.6%	0%	11.416	.076
25-34 years	45.3%	25.0%		
35-44 years	29.5%	33.3%		
45-75 years	17.6%	41.7%		
Total (N)	353	12		
Education				
No formal education	7.7%	8.3%	5.682	.460
Primary	42.0%	50.0%		
Secondary	42.8%	41.7%		
Tertiary	7.5%	0%		
Total (N)	362	12		
Years driving mini-bus				
0-4 years	18.0%	0%	36.360	.000
5-9 years	28.8%	16.7%		
10-14 years	22.6%	8.3%		
15-19 years	11.8%	8.3%		
>20 years	18.8%	66.7%		
Total (N)	372	12		
Normal route				
Intra-state only	50.7%	63.6%	11.840	.019
Inter-state only	24.1%	9.1%		
Intra-state & inter-state	25.2%	27.3%		
Total (N)	373	11		
Motor vehicle insurance				
Yes	61.7%	50.0%	6.051	.049
No	38.3%	50.0%		
Total (N)	371	12		

Drivers' Knowledge of Fine for Not Using Seat Belts

Almost all the drivers (95%) were aware of the imposition of a fine when they do not use their seat belts while driving. Table 6 shows the drivers awareness of the imposition of a fine when they do not use their seat belts when driving.

Drivers aged 25 to 34 years had the highest level of awareness (47%) of the fine for non-use of seat belt when driving and those drivers aged 17 to 24 years had the lowest level of awareness (7%) of the fine. The oldest drivers between 45 and 75 years were all aware of the fine. There was a statistically significant association between the age of the driver and the awareness of the imposition of a fine for the non-use of a seat belt when driving (X^2=14.926, $p<0.05$).

Most of the drivers (86%) who were aware of the imposition of a fine and all the drivers who were unaware of the fine had either primary or secondary education. There was no statistically significant association between the level of education of the driver and the awareness of the imposition of a fine for the non-use of a seat belt when driving (X^2=11.446, $p>0.05$).

Table 6. Drivers' knowledge of fine for not using seat belts.

Age	*Yes*	*No*	X^2	*p value*
17-24 years	7.2%	33.3%	14.926	.021
25-34 years	46.8%	11.1%		
35-44 years	28.5%	55.6%		
45-75 years	17.5%	0%		
Total (N)	400	9		
Education				
No formal education	7.4%	0%	11.446	.076
Primary	44.6%	44.4%		
Secondary	41.7%	55.6%		
Tertiary	6.4%	0%		
Total (N)	408	9		
Years driving mini-bus				
0-4 years	19.8%	33.3%	9.571	.296
5-9 years	29.0%	11.1%		
10-14 years	21.9%	11.1%		
15-19 years	11.4%	0%		
>20 years	17.9%	44.4%		
Total (N)	420	9		
Normal route				
Intra-state only	52.6%	55.6%	1.533	.821
Inter-state only	21.7%	22.2%		
Intra-state & inter-state	25.7%	22.2%		
Total (N)	420	9		
Motor vehicle insurance				
Yes	64.0%	55.6%	.806	.668
No	36.0%	44.4%		
Total (N)	419	9		

Most of the drivers (49%) who knew about the fine for the non-use of a seat belt have been driving for less than 10 years. There was no statistically significant association between the number of years of driving a mini-bus and the knowledge of the fine for the non-use of a seat belt when driving (X^2=9.571, p>0.05).

There were more drivers who ply the intra-state routes (53%) that knew about the fine for the non-use of a seat belt than those who ply the inter-state routes (22%) and those who ply both the intra-state and inter-state routes (26%). There was no statistically significant association between the normal route of travel and the awareness of the imposition of a fine for the non-use of a seat belt when driving (X^2=1.533, p>0.05).

The drivers with motor vehicle insurance were more likely to know about the fine for the non-use of a seat belt (64%) than the drivers without motor vehicle insurance (36%). The association between the possession of motor vehicle insurance and the awareness of the fine was not statistically significant (X^2=0.806, p>0.05).

Frequency of Seat Belt Use

Majority of the drivers always (47%) or sometimes (44%) use a seat belt while driving. Only 9% of the drivers never use a seat belt while driving. Table 7 shows the frequency of seat belt use by the mini-bus drivers. Drivers aged 25 to 34 years were most likely to always (43%), sometimes (47%) and never (56%) use a seat belt when driving. Drivers aged 17 to 24 years accounted for the smallest number of drivers who always (8%), sometimes (7%) and never (6%) use a seat belt when driving. The association between the age of the driver and the frequency of seat belt use was not statistically significant (X^2=4.768, p>0.05).

Table 7. Frequency of seat belt use.

Age	*Always*	*Sometimes*	*Never*	*X^2*	*p value*
17-24 years	8.3%	6.9%	5.6%	4.768	.574
25-34 years	43.0%	47.3%	55.6%		
35-44 years	28.5%	31.9%	25.0%		
45-75 years	20.2%	13.8%	13.9%		
Total (N)	193	188	36		
Education					
No formal education	5.5%	8.1%	10.8%	6.259	.395
Primary	42.8%	45.4%	40.5%		
Secondary	44.8%	38.4%	48.6%		
Tertiary	7.0%	8.1%			
Total (N)	201	185	37		
Years driving mini-bus					
0-4 years	18.5%	20.8%	23.7%	6.972	.540
5-9 years	25.4%	31.8%	39.5%		
10-14 years	23.9%	19.8%	15.8%		
15-19 years	11.2%	11.5%	7.9%		
>20 years	21.0%	16.1%	13.2%		
Total (N)	205	192	38		
Normal route					
Intra-state only	40.3%	63.5%	70.3%	31.718	.000
Inter-state only	30.6%	13.0%	8.1%		
Intra-state & inter-state	29.1%	23.4%	21.6%		
Total (N)	206	192	37		
Motor vehicle insurance					
Yes	74.0%	52.6%	61.1%	19.780	.000
No	26.0%	47.4%	38.9%		
Total (N)	204	194	36		

There were more drivers with secondary education (45%) who always use a seat belt when driving than drivers with other levels of education. More drivers with primary education (45%) usually use a seat belt when driving than drivers with other levels of education. There was no driver with tertiary education who never uses a seat belt when driving. The association between the education of the driver and the frequency of seat belt use was not statistically significant (X^2=6.259, p>0.05).

Those who have been driving between 5 and 9 years were more likely to always (25%), sometimes (32%) and never (40%) use a seat belt when driving than other categories of drivers. Those who have been driving between 15 and 19 years were the least likely to always (11%), sometimes (12%) and never (8%) use a seat belt when driving than other categories of drivers. There was no statistically significant association between the number of years of driving a mini-bus and the frequency of seat belt use when driving (X^2=6.972, p>0.05).

The drivers who ply the intra-state routes were more likely to always (40%), sometimes (64%) and never (70%) use a seat belt when driving than other categories of drivers. The association between the normal route of travel and the frequency of seat belt use when driving was statistically significant (X^2=31.718, p<0.05).

The drivers with motor vehicle insurance were more likely to always (74%), sometimes (53%) and never (61%) use a seat belt when driving than the drivers without motor vehicle insurance. The association between the possession of motor vehicle insurance and the frequency of seat belt use when driving was statistically significant (X^2=19.780, p<0.05).

Main Reasons for Non-Use of Seat Belts

Figure 1 shows the main reason why mini-bus drivers do not use seat belts. The two main reasons given for the non-use of seat belt by mini-bus drivers were lack of safety consciousness (36%) and inconvenience (32%). Other reasons for non-use of seat belt included "drivers feeling safe in big motor vehicles".

Strategies to Improve Use of Seat Belts

Figure 2 shows the strategies that the mini-bus drivers believe will help to improve the use of seat belts. Most of the drivers believe that the enforcement of the seat belt regulation by the Police and Federal Road Safety Commission (96%), more education (92%) and more reminders (91%) will improve seat belt use by drivers.

DISCUSSION

A higher proportion of the drivers in this study were males (94%) compared to the 76% reported by Sangowawa et. al. (2005) for a similar study in Ibadan, Nigeria. However, the study by Sangowawa et. al. (2005) focused on drivers of private motor vehicles unlike this study of drivers of commercial motor vehicles. It is known that there are more male drivers of commercial vehicles, that male drivers have a lower seat belt compliance rate than female drivers and male drivers have a higher risk of being involved in motor vehicle accidents than female drivers (Sangowawa, Ekanem et al. 2005).

Most of the 446 mini-bus drivers (91%) in this study had seat belts in their vehicles. This is similar to the 89% reported by Iribhogbe & Osime (2008) for 114 bus drivers in their study conducted in Benin City, Nigeria who also had seat belts in their vehicles (Iribhogbe and Osime 2008). Also, Sangowawa et. al. (2005) reported that 95% of the 402 vehicles in their study in Ibadan, Nigeria had seat belts for the drivers and front seat passengers (Sangowawa, Ekanem et al. 2005).

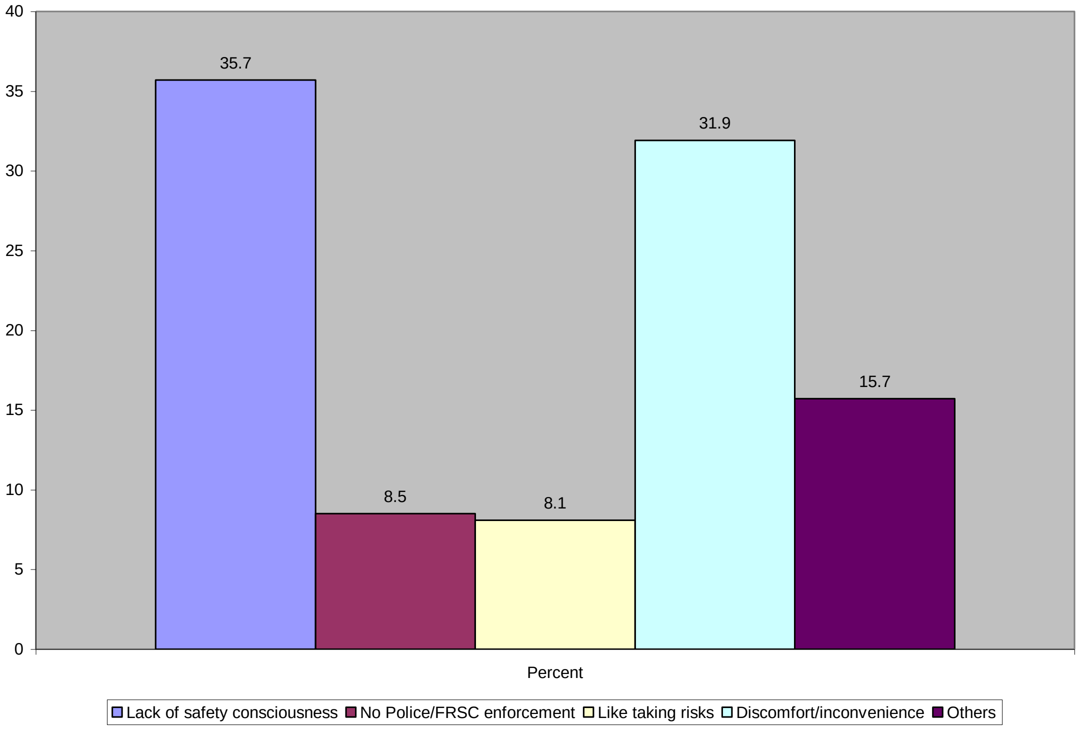


Figure 1. Main reasons for non-use of seat belts.

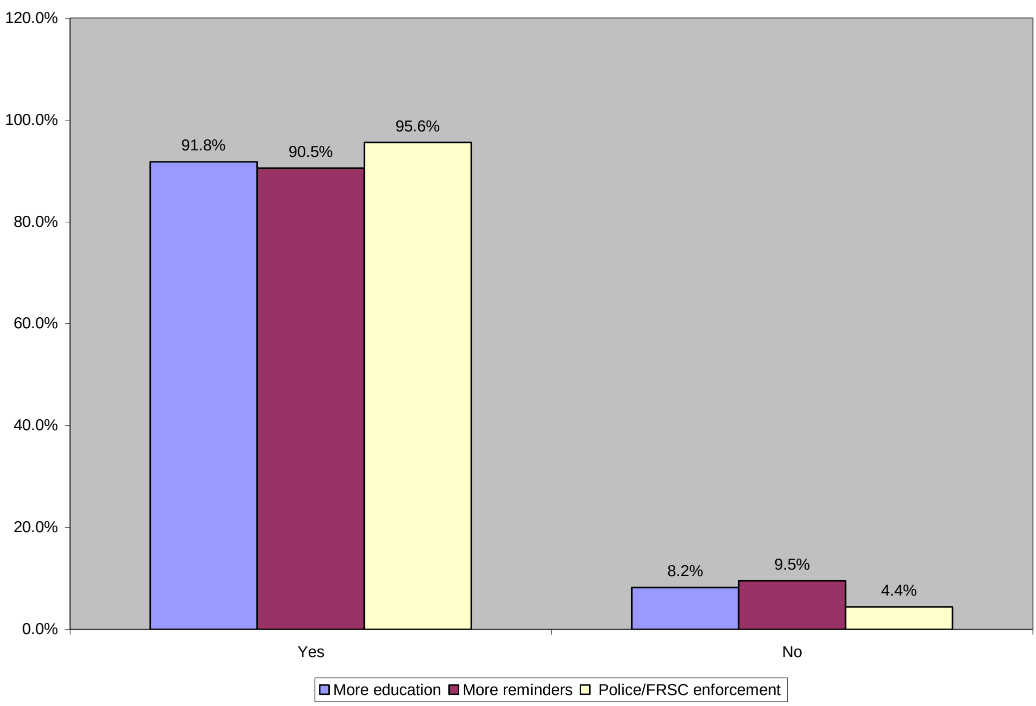


Figure 2. Strategies to improve use of seat belts.

In an observational study of seat belt use in Benin City, Nigeria, Iribhogbe & Osime (2008) reported seat belt compliance rates of 32.5% for bus drivers and 52.3% for all the private and commercial drivers (Iribhogbe and Osime 2008).

The 76% seat belt compliance rate by the mini-bus drivers in this study is much higher than the compliance rates of the bus drivers (32.5%) and all the private and commercial drivers (52.3%) in Benin City, Nigeria (Iribhogbe and Osime 2008). It is also higher than the compliance rates of drivers in University College Hospital, Ibadan (18.9%) and drivers in Ibadan metropolis (48%) in Nigeria (Sangowawa, Ekanem et al. 2005).

Majority of the drivers (70%) who never use a seat belt when driving in this study ply the intra-state routes. This figure is similar to the 67.5% non-compliance rate by intra-city bus drivers in Benin City, Nigeria reported by Iribhogbe & Osime (2008).

Drivers who fail to use their seat belts usually cite discomfort, inconvenience and forgetfulness as their reasons (Routley, Ozanne-Smith et al. 2009). The intra-city bus drivers in the study by Iribhogbe & Osime (2008) based their low compliance rate of the seat belt regulation on inconvenience in light of the fact that they have to stop at frequent intervals to drop off and take on board passengers, as well as the need to assist their passengers with luggage to board or disembark the buses (Iribhogbe and Osime 2008).

Almost all the drivers in this study believe that enforcement of the seat belt regulation by the Police and Federal Road Safety Commission (FRSC) will improve the use of seat belts. This is corroborated by Iribhogbe & Osime (2008) that the actual seat belt compliance rate in Benin City may be lower than the observed figure that they reported. This is because their study was conducted a few days before Christmas, a major festive season during which the Police and Federal Road Safety Commission (FRSC) in Nigeria intensify the monitoring and enforcement of the seat belt regulation. Hence, this higher level of monitoring and enforcement of the seat belt regulation during the study period may have influenced the observance of a higher seat belt compliance rate in their study (Iribhogbe and Osime 2008). The lack of enforcement and the need for more education on the importance of seat belts were also identified as possible factors for the low seat belt compliance rate in Ibadan, Nigeria (Sangowawa, Ekanem et al. 2005).

CONCLUSION

The mini-bus drivers had seat belts in their vehicles that were functional. There was a high level of awareness of the seat belt regulation and the fine for the non-use of seat belts while driving amongst the drivers. Majority of the drivers always or sometimes use a seat belt while driving. Only a very small proportion of the drivers never use a seat belt while driving. About one-third of the drivers attributed the non-use of seat belt by mini-bus drivers to a lack of safety consciousness and inconvenience. The enforcement of the seat belt regulation by the Police and Federal Road Safety Commission (FRSC), more education and more reminders will improve seat belt use by drivers.

REFERENCES

Ball, C. G., Kirkpatrick, A. W., et al. (2005). "Noncompliance with seat-belt use in patients involved in motor vehicle collisions. " *Can J Surg*, *48(5)*, 367-372.

Ekele, B. A., Nnadi, D. C., et al. (2004). "Pregnancy outcome in women involved in road traffic accidents in Sokoto." *Nigerian Journal of Surgical Research*, *6(1-2)*, 46-48.

Harris, G. T. & Olukoga, I. A. (2005). "A cost benefit analysis of an enhanced seat belt enforcement program in South Africa." *Inj Prev*, *11(2)*, 102-105.

Hauswald, M. (1997). "Seat belt use in a developing country: covert noncompliance with a primary enforcement law in Malaysia." *Accident Analysis & Prevention*, *29(5)*, 695-697.

Iribhogbe, P. E. & Osime, C. O. (2008). "Compliance with Seat Belt Use in Benin City, Nigeria." *Prehospital and Disaster Medicine*, *23(1)*, 16.

Kim, K. & Yamashita, E. Y. (2007). "Attitudes of commercial motor vehicle drivers towards safety belts." *Accident Analysis & Prevention*, *39(6)*, 1097-1106.

Knoblauch, R., Cotton, R., et al. (2003). Safety Belt Usage by Commercial Motor Vehicle Drivers. FMCSA, Washington, DC.

Lam, T. L. (2002). "Distractions and the risk of car crash injury: The effect of drivers' age." *Journal of Safety Research*, *33*, 411-419.

Olukoga, A. (2004a). "Cost analysis of road traffic crashes in South Africa." *Injury Control and Safety Promotion*, *11(1)*, 59-62

Olukoga, A. (2004b). "The socioeconomic costs of road traffic accidents in eThekwini (Durban) Municipality, South Africa." *Journal of Interdisciplinary Economics*, *15(3-4)*, 301-308

Olukoga, A. (2007). Trends in road traffic crashes, casualties and fatalities in Malawi. *Tropical Doctor*, *37(1)*, 24-8.

Olukoga, A. & Noah, M. (2005). "The use of seat belt by motor vehicle occupants in South Africa." *Traffic Injury Prevention*, *6(4)*, 398-400.

Olukoga, I. A. (2003). "Pedestrian casualties and fatalities in road traffic crashes in a South African municipality." *Traffic Injury Prevention*, *4(4)*, 355-357.

Oluyemi, A. O. (2007). "Seatbelt Use Survey: A Case Study." *Pakistan Journal of Social Sciences*, *4(6)*, 774-777.

Routley, V., Ozanne-Smith, J., et al. (2007). "Pattern of seat belt wearing in Nanjing, China." *Inj Prev*, *13(6)*, 388-393.

Routley, V., Ozanne-Smith, J., et al. (2008). "China belting up or down? Seat belt wearing trends in Nanjing and Zhoushan." *Accident Analysis & Prevention*, *40(6)*, 1850-1858.

Routley, V., Ozanne-Smith, J., et al. (2009). "Attitudes to seat belt wearing and related safety features in two cities in China." *International Journal of Injury Control and Safety Promotion*, *16(1)*, 15-26.

Sangowawa, A. O., Ekanem, S. E. U., et al. (2005). "Use of Seatbelts by Vehicle Occupants in University College Hospital (UCH), Ibadan, Nigeria." *Annals of Ibadan Postgraduate Medicine*, *3(2)*, 57-62.

Sullman, M. J. M. & Baas, P. H. (2004). "Mobile phone use amongst New Zealand drivers." *Transportation Research Part F: Traffic Psychology and Behaviour*, *7(2)*, 95-105.

WHO (2009). Global status report on road safety: time for action. World Health Organisation, Geneva.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 215-224
ISBN: 978-1-60876-223-1

Chapter 7

MOTORCYCLE HELMET USE IN MAR DEL PLATA, ARGENTINA

[1]Rubén Daniel Ledesma*, [2]Raquel Peltzer, [1]Fernando Poó and [3]Mariana Cremonte
[1]CONICET/Universidad Nacional de Mar del Plata, Argentina.
[2]Universidad Nacional de Mar del Plata, Argentina.
[3]CONICET/CIIPME/Universidad Nacional de Mar del Plata, Argentina.

ABSTRACT

Considerable empirical evidence indicates that helmet wearing effectively reduces motorcycle-related injuries. Nevertheless, in many developing countries the use of this safety device is still low. The aim of this research was to assess the prevalence and possible factors associated with helmet use among motorcycle riders in Mar del Plata city, Argentina. A non-participative, semi-structured observation method was used to assess the prevalence of helmet wearing and to detect factors associated with it. The sample included 1,106 observations of motorcyclists in this city. Data were analyzed through descriptive and inferential statistical methods. A multiple logistic regression model was applied to identify human and environmental predictors of helmet wearing. The general prevalence of helmet use amounted to 36%. Motorcycle passengers were helmeted less frequently than motorcycle drivers were (39.3% vs. only 23.7% passengers). Results of multiple logistic regressions revealed a greater use among women and variations in use depending on weather conditions, type of vehicle ridden, time of day, part of the week (weekday or weekend), and presence of a license plate. Results contributed to a better understanding of the factors involved in helmet use and evidenced the need to make greater efforts to enforce helmet wearing regulations and to intensify motorcycle riders' education.

Keywords: Head protective devices, helmet use, observation, Argentina.

* Corresponding author: Rio Negro 3922, Mar del Plata (7600), Argentina, E-mail: rledesma@mdp.edu.ar, Tel/Fax: 54 223 4716015

INTRODUCTION

In the last couple of years, road traffic injuries have become a major public health concern and a leading cause of death and injury worldwide. Every year, nearly 1.2 million people die as a result of road crashes, and many more are injured or disabled (Peden & Toroyan, 2005). Thus, world concern about traffic crashes and their consequences, such as unintentional injuries, has increased. However, road traffic injuries are not evenly distributed and neither are the resources allocated to address this issue (Peden, McGee & Sharma, 2002). In this regard, high income countries report the lowest rates of road traffic fatalities and more complete data than lower and middle income countries do (Ameratunga, Hijar & Norton, 2006; Norton, Hyder, Bishai & Peden, 2006). In the later, road traffic injuries alone are the second leading cause of death for young adults, second only to HIV/AIDS. In addition to fatalities, injuries account for a considerable degree of disability (Joshipura, Mock, Goosen & Peden, 2004). Moreover, the means of transport leading to a greater number of road traffic injuries differ in each case. In high income countries, the highest proportion of injuries is attributed to motorized four-wheelers, while in low and middle income ones, to motorized two-wheelers (WHO, 2004).

A recent publication issued by the World Health Organization on helmet wearing (2006) gives an account of an increasing number of traffic injuries among motorcyclists in low and middle income countries. The manual also reports a growing proportion of fatalities and injuries among this group. For example, in India 27 % of deaths are caused by traffic injuries among motorcyclists, while in Thailand 70 to 90 %, and in Malaysia 60 %. The WHO's publication observes that the number of road traffic injuries is directly related to the widespread use of two-wheelers in low and middle income countries. In Argentina, despite the lack of systematic and accurate data, some specialized entities have reported an increase in crashes involving two-wheelers (CESVI, 2008). Additionally, it is known that since 2007 the number of motorcycles has significantly grown, exceeding car sales (CIFEMA, 2008).

The danger of being injured in a motorcycle crash is greater for drivers and passengers if they do not use physical protective devices, especially helmets. Bangs in the head and neck constitute the primary cause of death, severe injuries, and impairment among two-wheelers drivers (WHO, 2004). For instance, in Europe, head injuries account for 75 % of deaths whereas, in Malasya, they range from 55 % to 88 % (WHO, 2004). Several studies have shown that helmet wearing is an effective measure to prevent head injuries as well as to reduce the severity of the injuries sustained by two-wheelers riders and passengers (Kulanthayan, Radin-Umar, Ahmad-Hariza, Mohd-Nasir & Harwant, 2000; Mishra, Banerji & Mohan; 1984; Servadei, Begliomini, Gardini, Giustini, Taggi & Kraus, 2003). The World Report on Road Traffic Injury Prevention expounded how helmet use would prevent fatal injuries (WHO, 2004). Hence, it was recommended that countries pass helmet laws and compel drivers and passengers of motorized two-wheelers to comply with them. This implies the need of effective laws on helmet wearing according to manufacturing standards and use regulations (Ichikawa, Chadbunchachai & Marui, 2003; Peek-Asa & Kraus, 1997; Peek-Asa, McArthur & Kraus, 1999). Unfortunately, many countries do not count on such regulations, and if in force, their control and enforcement is insufficient.

As to the variables associated with helmet use rate, it is worth mentioning in the first place, the significance of legislation regulating helmet use. Experiences from different countries indicate that helmet use varies considerably depending on whether it is mandatory or not (e.g., Barrancos Liberatti, Maffei de Andrade & Soares, 2001; Ferrando, Plasència, Orós, Borrell & Kraus, 2000; Servadei, Begliomini, Gardini, Giustini, Taggi & Kraus, 2003). The National Highway Traffic Safety Administration (NHTSA) (2008) contends that "helmet use laws governing all motorcycle riders significantly increase helmet use and are easily enforced because of riders' high visibility" (p.1). Yet, and despite the apparent simplicity of the preceding, it is also necessary to count on continuing police surveillance. In Argentina, for instance, where helmet use is mandatory, control and enforcement are poor and unsystematic. Thus, helmet use rate remains low. Consonant with this, several studies have reported that the lack of surveillance explains why drivers avoid using this device (e.g., Costello, Conrad, Bradshaw, Lamsudin & Kasniyah, 1996; de Hoyos, 2006; Li, Li, Cai, Zhang & Lo, 2008). Hence, it goes without saying that legislation amendment should be supported by proper enforcement.

In spite of the current legislation in force, certain road, environmental and situational variables are tied to differences in helmet use rate. Previous researches found that road type, circulation area, time of day, part of the week and weather conditions were some of the factors connected with helmet use (Barrancos-Liberatti, Maffei de Andrade, Soares & Matsuo, 2003; Conrad et al., 1996; de Hoyos, 2006; Ledesma & Peltzer, 2008; Li et al., 2008; Skalkidou et al., 1999). Overall, drivers are less likely to wear helmets when riding in the city suburbs, in secondary roads, at night and during weekends. Furthermore, helmet use is reduced in good weather conditions, which could be related to comfort. In warmer weather, riders mentioned discomfort when wearing a helmet (Hung, Stevenson & Ivers, 2008; Skalkidou et al., 1999). Conversely, on rainy days, driving with no helmet on was considered complicated.

Likewise, some individual-related variables have been identified as helmet use predictors: gender and age are among these (e.g., Ledesma & Peltzer, 2008; Skalkidou et al, 1999). Previous researches have indicated that male and young people are less likely to wear a helmet. Other individual-related variables influencing helmet use are closely related to the road-user's profile; like having a driver's license or not or the type of vehicle ridden (e.g., Ledesma & Peltzer, 2008; Skalkidou et al, 1999;). Some studies also identify attitudinal variables related to the decision of wearing a helmet (e.g., Bianco, Trani, Santoro & Angelillo, 2005; Germeni, Lionis, Davou & Petridou, 2009; Lowenstein, Koziol-McLain & Glazner, 1997; Reeder, Chalmers & Langley, 1996). For instance, motorcyclists believe that they do not need to wear a helmet when traveling short distances, because, in such case, crashes are unlikely (De Hoyos, 2006; Hung, Stevenson & Ivers, 2008; WHO, 2006). Also widespread is the belief that, under certain conditions, the helmet is not an effective protective device or that it can cause injuries (Germeni et al., 2009; Peltzer, 2006). Other barriers mentioned were: discomfort, vision and hearing disturbance, peer pressure, high helmet cost, and aesthetic issues (Conrad et al., 1996; de Hoyos, 2006; Germeni et al., 2009; Li et al., 2008). Such beliefs, attitudes and common myths reflect the lack of proper information or misinformation on helmet use, although this could also be explained by cultural factors, which could be difficult to modify (WHO, 2006). To sum up, helmet use is a complex, multi-casual behavioral issue influenced by social, cultural and individual-related variables. Thus, it is necessary to examine the situation in each country in the light of its peculiarities.

Argentina counts on a universal helmet use law. Nonetheless and despite the scarce number of studies regarding helmet wearing, low rates have been identified in different geographic regions. Beltramino & Carrera (2007) reported a 12 % wearing prevalence in the city of Santa Fe, while in Buenos Aires such prevalence reached 53% (Luchemos por la Vida, 2006). A study carried out in the city of Neuquén, located to the south of the country, reported a 32 % wearing rate (de Hoyos, 2006). Finally, in Mar del Plata city, 2006 data reported a 40 % wearing prevalence (Ledesma & Peltzer, 2008). Nowadays, considerable efforts are being made to increase helmet use rate; however, reliable and systematic data regarding this issue are still missing. The WHO (2006) has pointed out three reasons why helmet use should be systematically assessed. To begin with, in order to identify the problem and outline its scope. Second, so as to provide arguments to convince policy-makers, and the public in general, about the need to implement a helmet use program. And third, to provide baseline indicators, which are critical when it comes to programs' monitoring. In short, assessing helmet use plays a key role in designing and implementing effective helmet use programs.

In this context, the present study is primarily intended to determine helmet use rate and factors associated with it among motorcycle operators and passengers in Mar del Plata city. The following variables were examined as possible associated factors: (a) riders and passengers' gender, (b) type of vehicle ridden, (c) presence of a motorcycle license plate (compulsory in Argentina), (d) weather conditions, (e) time of the day, (f) part of the week, and (g) place of observation. We hope the present study will provide relevant data to implement measures aimed at increasing helmet use in our community.

METHOD

A non-participative, semi-structured observation method was used to assess the prevalence of helmet wearing and to detect the factors associated with it in the city of Mar del Plata, Argentina. Observations were conducted in seven different points in the city center (suburbs were not contemplated in this study). At each point, observations were made for an hour and each of the following conditions was assessed: (a) day/weekday (b) day/weekend (c) night/weekday (d) night /weekend. The sample totalized 1,106 motorcycle operators (most were males: 87 %). We also recorded 327 motorcycle passengers (most were females: 65%).

Data collection was carried out through an observational record designed and managed by the researchers and a group of students who were doing their grade thesis on traffic psychology. Students were trained beforehand to avoid any possible bias, and they were provided with a written guideline for assistance. To simplify the data collection process, two persons completed the observational procedure at each site. Data were analyzed using descriptive and inferential statistics. In view of the relatively low number of missing values, the pair-wise deletion method was used in some cases. Predictors of helmet use were estimated by a multiple logistic regression model, with the variable helmet use/non-helmet use as dependent and the following as predictors: gender, type of motorcycle, weather conditions (rain), time of day, part of the week, observation site, and presence of a license plate. The dependent variable was coded so that the odds ratio was interpreted as an increase in the helmet use ratio, taking the first category of each independent variable as reference. The logistic regression was computed for drivers and passengers separately. Regarding the drivers' sample, the variable passenger's status (not present, helmeted passenger and non-helmeted passenger) was also introduced as a predictor variable. For the passengers' sample, driver's helmet use/non-use was introduced as a predictor variable.

RESULTS

An overall helmet use rate of 36.0% was obtained. Motorcycle passengers were helmeted less frequently than motorcycle drivers were (39.3% of drivers were helmeted, while only 23.7% of passengers were). It was also noticed that 2% of the riders carried helmets but did not wear them. In addition, when two people were on a motorcycle, only 15% of the times they both wore helmets.

Table 1 shows helmet use rates for drivers and passengers according to some relevant factors. However, for a better estimation of the association between motorcycle helmet use and these factors, the results of the logistic regression analysis were assessed. Table 2 summarizes the most relevant results of the regression model in the drivers' sample. The Hosmer and Lemeshow's goodness of fit test indicates that the model adequately fits the data [$Chi^2(8)$= 4.513, *p*=.808]. The omnibus tests of model coefficients also yield satisfactory results [Chi^2 (17)= 146.280, *p*<.001] . The Nagelkerke's R^2 for the model is 0.20.

Under column *ExpB* in Table 2, the adjusted Odds Ratio (aOR) is shown. Such is the odd that a motorcycle driver in a given category wears a helmet, divided by the odd that a driver in the reference category does not. For example, a female driver is 2.48 times more likely to wear a helmet than a male rider, which is the reference category, keeping the rest of the factors constant. Likewise, an *ExpB* (aOR) of less than 1 indicates a reduction in helmet use when a given condition is compared to the reference category of the same variable. For example, when weekends are compared to weekdays, the aOR is 0.55, indicating a reduction of approximately 45 % (which is derived from: [(aOR-1) * 100] = [(.55 – 1) * 100] = - 45%).

Other relevant results can be summarized as follows. The presence of a passenger wearing a helmet is associated with a lower frequency of helmet use in drivers (aOR= 0.27). Regarding weather conditions, drivers are more likely to wear helmets under rainy conditions than under good weather, aOR=1.81. In terms of vehicle type, a significant reduction in helmet use is estimated for off-road type users, compared to Honda Biz-like riders (aOR=0.28). Conversely, standard motorcycle users are more likely to wear helmets with relation to those driving a Biz-like motorcycle (aOR=2.1). Another vehicle variable strongly connected with helmet use is license plate presence. A reduction in helmet use is observed in vehicles with no plate (aOR=0.45). Controlling for the rest of variables, motorcycle operator helmet use is lower in the evenings and nights than during the day (aOR=0.61). Finally, there are no differences on helmet use rate between the different sites observed.

On the other hand, the results of the logistic regression model for the passengers' sample reveal a significant effect of the driver-helmet-use factor. The odds ratio indicates that motorcycle passengers are less likely to wear a helmet when the driver is helmeted (aOR=0.07). Helmet use among passengers also decreases at night (aOR=0.30) and during the weekend (aOR=0.18). The regression model including only these variables yields a Nagelkerke's R^2 of 0.27.

Table 1. Percentages of helmet use according to the variables studied.

Variable		Observed drivers	% of helmet use by drivers	Observed passengers	% of helmet use by passengers
Gender	Male	956	37.6	115	17.9
	Female	135	48.9	207	36.2
Weather conditions	Not rainy	943	38.2	298	26.0
	Rainy	163	45.7	29	25.1
Type of motorcycle	Biz-like*	566	39.2	188	21.3
	Moped 50cc and Scooter	311	37.9	86	30.2
	Standard	121	47.9	30	26.2
	Custom/Touring/Sport	56	37.9	16	31.2
	Off-road (Cross, Enduro, etc.)	39	17.9	7	0.0
Time of day	Day	525	38.5	136	27.2
	Evening & Night	575	40.1	53	28.2
Part of Week	Weekday	517	40.8	126	18.1
	Weekend	583	37.9	198	27.1
MLP**	Yes	653	45.5	195	41.7
	No	345	27.9	115	18.6

* Honda Biz, Gillera Smash, Guerrero Trip, Motomel Bit. ** Presence of motorcycle license plate.

Table 2. Predictors of helmet use among motorcycle drivers in the city of Mar del Plata, Argentina.

Variable	B	S.E	Wald	df	p	ExpB	IC_l	IC_u
Gender (Ref: Male)								
Female	0.91	0.22	16.36	1	>0.001	2.48	1.60	3.85
Passenger status (Ref: with no passenger)			53.70	2	>0.001			
Helmeted passengers	-1.319	0.214	37.80	1	>0.001	0.27	0.176	0.41
Non-helmeted passengers	1.009	0.307	10.83	1	>0.001	2.74	1.504	5.00
Weather conditions (Ref.: Non- rainy)								
Rainy	0.59	0.27	4.89	1	>0.05	1.81	1.070	3.07
Type of motorcycle (Ref.: Biz-like)			21.72	4	>0.001			
Moped 50cc and Scooter	-0.23	0.17	1.82	1	0.18	0.79	0.565	1.112
Standard	0.74	0.24	9.35	1	>0.01	2.10	1.305	3.38
Custom/Touring/Sport	0.08	0.33	0.05	1	0.81	1.08	0.567	2.05
Off-road (Cross, Enduro, etc.)	-1.29	0.48	7.29	1	>0.01	.28	0.11	0.70
Part of day (ref: Day)								
Evening & Night	-0.49	0.23	4.57	1	>0.05	0.61	0.391	0.96
Part of the Week (ref: Weekday)								
Weekend	-0.59	0.22	7.34	1	>0.01	0.55	0.36	0.85
MLP** (ref: Yes)								
Not	-0.80	0.16	24.22	1	>0.001	0.45	0.32	0.62
Place of observation			8.073	6	0.233			

ExpB: Exp(beta) – Odds Ratio.

IC_l and IC_u: lower and upper values of the 95% confidence interval for the odds ratio.

** Presence of motorcycle license plate.

CONCLUSION

The results of the present study indicate that helmets are not habitually used by motorcyclists in our city, even when their use is compulsory. In the drivers' sample, a helmet use rate of 39.3% is detected, which decreases to 23.7 % in the passengers' sample. This finding is in accordance with that observed in 2006 in our city (Ledesma & Peltzer, 2008). It is also in line with several observational studies previously carried out in different Argentine cities (Beltramino & Carrera, 2007; de Hoyos, 2006; Ledesma & Peltzer, 2008) which evidence a very low rate of helmet wearing. Moreover, in agreement with the WHO (2006), in other Latin-American countries results are coincident. Therefore, much work needs to be done as a means to increase this head protective device use and, hence, reduce the adverse consequences of motorcycle crashes.

Previous researches in cities with low prevalence of helmet use indicate that helmet use seems to be subject to several environmental, situational and personal factors. Our results support this statement. Factors linked to motorcycle helmet use include: rider's gender, motorcycle type, presence of motorcycle license plate, weather conditions, moment of the day, part of the week and number of persons per vehicle. Regarding gender differences, helmets were found to be more extensively worn by women as reported in studies from other countries (e.g., Skalkidou et al., 1999; Li et al., 2008). It is worth noting that it is a well established fact that women are safer drivers and account for lower traffic-related injury rates. Higher male risk of injuries and fatality seems to be related not only to a greater traffic exposure but also to a more risky road behavior (WHO, 2002). Helmet non-use in males can be ascribed to their greater proneness to risky behavior. Further research to address the cultural and psychological basis of gender differences should be conducted. Evidence of socio-psychological factors underling gender differences could provide a basis for effective interventions to promote helmet use.

Helmet use also appears to be associated with some situational factors. Especially, the variation due to climate conditions is significant. The use rate increased under rainy conditions. Helmets seemed to be worn more as a weather protection device than for safety reasons. Some studies have indicated that weather conditions could limit helmet wearing. For example, in warm weather, riders refuse to use them for being uncomfortable (e.g., Hung, Stevenson & Ivers, 2008; Skalkidou et al., 1999). Aside from weather conditions, it was also found that those who rode at night and during the weekends were less likely to wear a helmet, which is consistent with the results obtained from previous studies conducted in other countries (e.g, Barrancos Liberatti et al., 2003; Conrad et al, 1996; Li et al., 2008; Skalkidou et al., 1999). Possible explanations for such findings are that, at night and during weekends, younger people drive motorcycles and recreational use increases while police control decreases. We believe that motorcyclists are inconstant with wearing helmet when they know enforcement is unlikely. Thus, measures to increase permanent police control are necessary.

Likewise, helmet use is associated with some vehicle factors. For instance, the absence of motorcycle license plate is strongly associated with non-helmet use. This is an expected result as the presence of the license plate is an important rule compliance indicator. That is to say, those who drive with no plate are, in fact, violating the traffic law, which could be reasonably associated with non-helmet use. Helmet wearing also varies depending on the type of motorcycle. Personal, social and economic differences could explain variations in the use given to the vehicle, which can influence helmet wearing as well. For example, off-road motorcycles are ridden mostly by young males and for recreational use. Thus, it would be possible to detect fewer helmeted riders on this kind of motorcycles. Moreover, low-income riders use cheaper vehicles and probably cannot afford to buy a helmet. In fact, helmet cost is a major economic constraint that should be taken into account as it could be a barrier to helmet ownership among lower income groups. Indeed, helmet ownership is an effective way to raise helmet use rates. A possible way to promote helmet ownership could be to include approved helmets with each new motorcycle sold, as it was proposed for bicycles (Dannenberg & Vernick, 1993). In Argentina, several state law bills have recently been passed forcing motorcycle shops to include a standard helmet with each motorcycle sold.

Regarding this study limitations, it is important to mention that the logistic regression model could present some estimation problems when applied to cross-sectional studies (Barros & Hirakata, 2003). For that reason, the results of this study should be interpreted with caution and only in terms of associations between variables. Other limitations derive from the fact that it is an observational study. For example, it was not possible to determine if drivers who did not wear helmets, owned or not one. In this regard, the study of individual variables should be deepened through alternative methodologies, such as survey techniques or focus groups, to find out possible economic, motivational and attitudinal aspects related to helmet use. Examples of studies combining observational data with other research methods are those by de Hoyos (2006) and Li et al. (2008).

Finally, we believe that helmet use rate is an indicator of the general road safety situation in a community and of the efforts devoted to face traffic injuries. In our city, as in many other Argentine and Latin-American communities, the absence of sustained action programs is evident. Within this context, actions to increase helmet use cannot be postponed. The need to intensify efforts in order to enforce regulations and promote helmet use among motorcycle riders is evident. In this sense, we believe that the recommendations given by the WHO can serve as a valuable reference for policies' development. We also sustain that it is important to progressively adopt a more integral vision of the transport problem in developing countries, tending not only to improve transit safety, but also to make it more equitable, healthful and sustainable. Measures to promote the safe use of bicycles and to favor the quality and availability of public transport services could contribute to such a change.

REFERENCES

Ameratunga, S., Hijar, M. & Norton, R. (2006). Road-traffic injuries: confronting disparities to address a global health problem, *Lancet*, *367*, 1533-40.

Babio, G. O. & Daponte-Codina, A. (2006). Factors associated with seatbelt, helmet, and child safety seat use in a Spanish high-risk injury area. *The Journal of Trauma*, *60*, 620-6.

Barrancos Liberatti, Ch. L., Maffei de Andrade, S. M. & Soares, D. A. (2001). The new Brazilian traffic code and some characteristics of victims in southern Brazil. *Injury Prevention*, *7*, 190-3.

Barrancos Liberatti, Ch. L., Maffei de Andrade, S. M., Soares, D. A. & Matsuo, T. (2003). Uso de capacete por vítimas de acidentes de motocicleta en Londrina, sul do Brasil. *Pan American Journal of Public Health*, *13*, 33-8.

Barros, A. & Hirakata, V. (2003). Alternatives for logistic regression in cross-sectional studies: an empirical comparison of models that directly estimate the prevalence ratio**.** *BMC Medical Research Methodology*, *20*, 21.

Beltramino, J. C. & Carrera, E. (2007). El respeto a las normas de tránsito en la cuidad de Santa Fé, Argentina. *Pan American Journal of Public Health*, *22*, 141-5.

Bianco, A., Trani, F., Santoro, G. & Angelillo, I. F. (2005). Adolescents' attitudes and behaviour towards motorcycle helmet use in Italy. *European Journal of Pediatrics*, *164*, 207-11.

CESVI Centro de Experimentación y Seguridad Vial (2008). *Estadísticas 2008*. Disponible en: www.cesvi.com.ar

CIFEMA -Cámara de Importadores, Exportadores y Fabricantes de Motovehículos de la Argentina (2008). *Estadísticas*. Disponible en: http://www.cifema.org.ar/

Costello, C., Conrad P., Bradshaw, Y. S., Lamsudin, R. & Kasniyah, N. (1996). Helmets, injuries and cultural definitions: motorcycle injury in urban Indonesia. *Accident Analysis and Prevention*, *28*, 193-200.

Dannenberg, A. L. & Vernick, J. S. (1993). A proposal for the mandatory inclusion of helmets with new children's bicycles. *American Journal of Public Health*, *83*, 644-46.

de Hoyos, G. (2006). Motociclistas jóvenes en la ciudad de Neuquén. In: R. Gelstein, et al. *Aspectos demográficos y sociales de los accidentes de tránsito en áreas seleccionadas de la Argentina*. Buenos Aires: Ministerio de Salud y Ambiente de la Nación.

Ferrando, J., Plasència, A., Orós, M., Borrell, C. & Kraus, J. (2000). Impact of a helmet law on two-wheel motor vehicle crash mortality in a southern European urban area. *Injury Prevention*, 184-8.

Germeni, E., Lionis, C. Davou, B. & Petridou, E. T. (2009). Understanding reasons for non-compliance in motorcycle helmet use among adolescents in Greece. *Injury Prevention*, *15*, 19-23.

Hung, D. V., Stevenson, M. R. & Ivers, R. Q. (2008). Barriers to, and factors associated, with observed motorcycle helmet use in Vietnam. *Accident Analysis and Prevention*, *40*, 1627-33.

Ichikawa, M., Chadbunchachai, W. & Marui, E. (2003). Effect of he helmet act for motorcyclist in Thailand. *Accident Analysis and Prevention*, *35*, 183-189.

Joshipura, M., Mock, C., Goosen, J. & Peden, M. (2004). Essential Trauma Care: strengthening trauma systems round the world. *Injury*, *35*, 841-845.

Kulanthayan, S., Radin Umar, R. S., Ahmad Hariza, H., Mohd Nasir, M. T. & Harwant, S. (2000). Compliance of proper safety helmet usage in motorcyclists. *Medical Journal of Malaysia*, *55*, 40-44.

Ledesma, R. & Peltzer, R. (2008). Helmet Use among Motorcyclists: observational study in the city of Mar del Plata, Argentina. *Revista de Salud Pública*, *42*, 1, 143-145.

Li, L. P., Li, G. L., Cai, Q. E., Zhang, A. L. & Lo, S. K. (2008). Improper motorcycle helmet use in provincial areas of a developing country. *Accident Analysis & Prevention*, *40*, *6*, 1937-1942.

Liu, B., Ivers, R., Norton, R., Blows, S. & Lo, S. K. (2003) Helmets for preventing injury in motorcycle riders. *The Cochrane Database of Systematic Reviews*, *4*. Art.: CD004333.

Lowenstein, S. R., Koziol-McLain, J. & Glazner, J. (1997). The Colorado motorcycle safety survey: public attitudes and beliefs. *The Journal of Trauma*, *6*, 1124-8.

Luchemos por la Vida, Asoc. Civil (2006). *Uso del casco y otros*, *en la ciudad de Buenos Aires (Noviembre del 2006)*. Available on-line: http://www.luchemos.org.ar/

Mishra, B. K., Banerji, A. K. & Mohan, D. (1984) Two-wheeler injuries in Delhi, India: a study of crash victims hospitalized in a neuro-surgery ward. *Accident Analysis & Prevention*, *16*, 407-416.

NHTSA (2008). Traffic Safety Fact Laws. Motorcycle Helmet Use Laws. Retrieved from http://www.nhtsa.dot.gov on march, 2009

Norton, R., Hyder, A., Bishai, D. & Peden, M. (2006). Unintentional Injuries. In *Injuries and Violence*. The International Bank for Reconstruction and Development / The World Bank. Retrieved July 18, 2008, from http://files.dcp2.org/pdf/expressbooks/injurie.pdf#page=4.

Pan American Health Organization (2004). Defunciones por accidentes de tránsito en países seleccionados de las Américas, 1985-2001. *Boletín Epidemiológico*, *25*, 2-5.

Peden, M. & Toroyan, T. (2005). Counting road traffic deaths and injuries: poor data should not detract from doing something!. *Annals of Emergency Medicine*, *46*, 158-160.

Peden, M., McGee, K. & Sharma, G., (2002). *The Injury Chart Book: a graphical overview of the Global Burden of Injuries.* Geneva: World Health Organization.

Peek-Asa, C. & Kraus, J. (1997). Estimates of injury impairment after acute traumatic injury in motorcycle crashes before and after passage of a mandatory helmet use law. *Annals of Emergency Medicine*, *29*, 630-63.

Peek-Asa, C., McArthur D. & Kraus J. (1999). The prevalence of non-standard helmet use and head injuries among motorcycle riders. *Accident Analysis and Prevention*, *31*, 229-233.

Peltzer, R. (2006) Motociclistas Jóvenes en la ciudad de Mar del Plata. In: R. Gelstein, et al. *Aspectos demográficos y sociales de los accidentes de tránsito en áreas seleccionadas de la Argentina.* Buenos Aires: Ministerio de Salud y Ambiente de la Nación.

Reeder, A. I., Chalmers, D. J. & Langley, J. D. (1996). The risky and protective motorcycling opinions and behaviours of young on-road motorcyclists in New Zealand. *Social Science and Medicine*, *42*, 1297-311.

Servadei, F., Begliomini, C., Gardini, E., Giustini, M., Taggi, F. & Kraus, J. (2003). Effect of Italy's motorcycle helmet law on traumatic brainy injuries. *Injury Prevention*, *9*, 257-60.

Skalkidou, A., Petridou, E., Papadopoulos, F.C., Dessypris, N. & Trichopoulos, D. (1999). Factors affecting motorcycle helmet use in the population of Greater Athens, Greece. *Injury Prevention*, *5*, 264-7.

WHO (2002). *Gender and Road Traffic Injuries.* Geneva: World Health Organization.

WHO (2004). *World Report on Road Traffic Injury Prevention*. Geneva: World Health Organization.

WHO (2006). *Helmets: a road safety manual for decision-makers and practitioners*. Geneva: World Health Organization.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 225-232
ISBN: 978-1-60876-223-1

Chapter 8

HIP PROTECTOR DEVISES TO PREVENT HIP FRACTURES OF OLDER ADULTS

[1]Pekka Kannus ***[*]*** ***and [2]Jari Parkkari***

[1]Injury and Osteoporosis Research Center, UKK Institute for Health Promotion Research, Tampere, Finland.

[2]Tampere Research Center of Sports Medicine, UKK Institute for Health Promotion Research, Tampere, Finland.

ABSTRACT

Prevention of elderly people's fractures consists of prevention and treatment of osteoporosis, prevention of falling, and prevention of fractures using injury-site protection. Since great majority of hip fractures are caused by a sideways fall with direct impact on the greater trochanter of the proximal femur, one alternative to prevent the fracture is a padded, firm-shield external hip protector. With this type of two-part design the impacting force and energy are, at the time of the fall-impact, first weakened by the padding part of the protector and then shunted away from the greater trochanter by the shield part of the same.

Following this line, a series of consecutive studies by the Injury and Osteoporosis Research Center at the UKK Institute, Tampere, Finland, have shown that a padded, strong-shield KPH Hip Protector is effective in preventing hip fractures. The results have been encouraging to recommend the protector for high-risk frail elderly people, especially those who have fallen before, had fractures, poor balance and impaired mobility.

The most usual general problem with hip protectors is related to user compliance. Not all elderly people with a high risk of hip fracture will start to use hip protectors. Also, long-term adherence to use the protector can decrease. Therefore, in maintaining the compliance, caregivers' motivation and interest on fracture prevention is of great importance.

* Corresponding author: Injury and Osteoporosis Research Center, UKK Institute, P.O. Box 30, FIN-33501 Tampere, Finland. Tel.: +358-3-282-9336, Fax.: +358-3-282-9200, Email: Pekka.Kannus@uta.fi

INTRODUCTION

Bone fractures of elderly people, especially those affecting the hip or proximal femur, are a true public health problem. Worldwide, over 8 million fractures (over 1.5 million hip fractures) occur annually among persons 60 years of age or older, and the epidemic is likely to worsen during the coming decades along with the rapidly rising number of older adults in both developed and developing countries [10,13,21,25] (Figure 1).

Compromised bone strength or osteoporosis and falling, alone, or more frequently in combination, are the two independent and immediate risk factors of elderly people's fractures through which all the other, more distant risk factors, such as aging, inactivity, poor nutrition, smoking, use of alcohol, diseases, medications, functional impairments and disabilities, operate. Of these two, falling, not osteoporosis, is the strongest single risk factor for a fracture, and when a person falls, the type and severity of falling determine whether or not a fracture occurs [1,10].

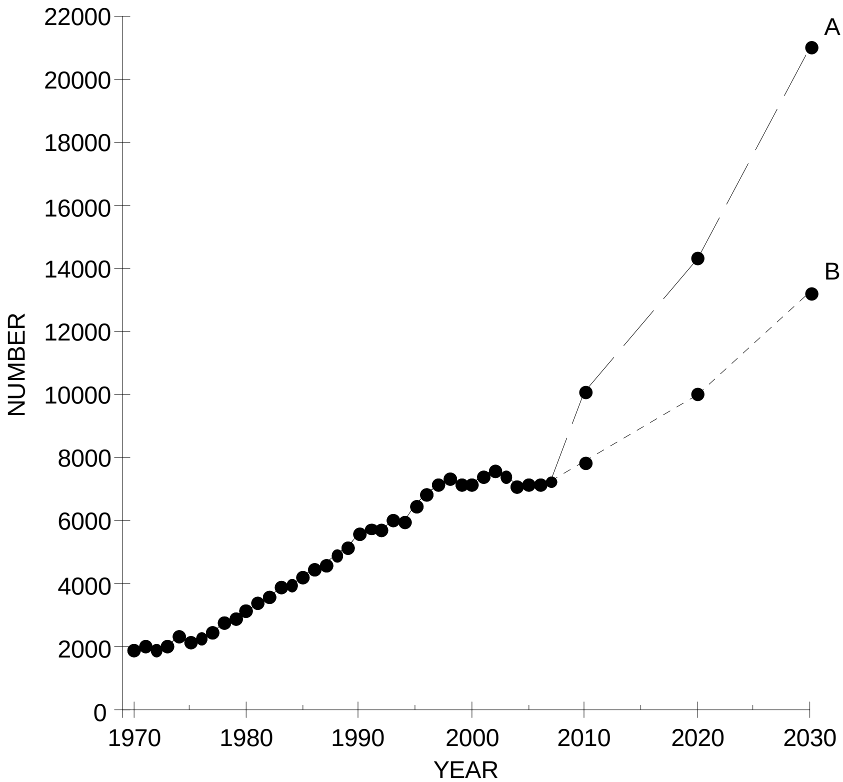


Figure 1. The number of hip fractures in persons 50 years of age or older in Finland from 1970 to 2007 (population size 5.3 million in 2007) and prediction of the fracture development until the year 2030 by two prediction models (A and B). If the age-adjusted fracture incidence per 100 000 50-year-old or older persons continues to rise at the average rate observed in 1970-2007 and the size of this population increases as predicted (from 2.0 million in 2007 to 2.5 million in 2030), the number of hip fractures will be very high, about 21 000, in 2030 (curve A). If, however, the fracture incidence were to become stabilized to the 2007 level, the number of hip fractures in Finland would be about 13 000 in 2030 (curve B).

In view of these findings, it is clear that effective fracture prevention strategies will require additional interventions besides treatment of osteoporosis, such as prevention of falling and prevention of fractures despite osteoporosis and falling (injury-site protection) [1,8,10,11,13,18]. The latter approach has been a key interest at the Injury and Osteoporosis Research Center at the UKK Institute, Tampere, Finland for more than 15 years. Especially, prevention of elderly people's hip fractures has received special attention throughout all these years.

OBJECTIVES

The first objective of our research program on preventing hip fractures has been to find out how hip fracture patients fall, to compare the mechanics of their falls to those falls which do not result in hip fracture, and, in this way, to obtain reliable insight into the etiology and pathogenesis of hip fracture and thus clues for fracture prevention [1]. The second objective has been to create an external hip protector and study its biomechanical efficacy and population-based effectiveness in prevention of hip fractures [2-7]. All of these seven studies have been published in prestigious peer-reviewed international journals [1-7].

METHODS

In the prospective injury mechanism study, 206 consecutive patients with fresh hip fracture and 100 control persons were interviewed and examined at Tampere City Hospital, Tampere, Finland between October 1994 and May 1996. The only inclusion criterion for the case subjects was that the fracture had occurred within 24 hours of the admittance to the hospital. The control persons were admitted from the same community after a fall-injury which did not result in hip fracture. In both groups, the characteristics of the injury were determined by personal interview and clinical examination of the patients within 24 hours of the event [1].

In creation of a hip protector, a large number of various padding materials were first tested biomechanically [2]. After these tests, the researchers (Pekka Kannus, MD, PhD, Jari Parkkari, MD, PhD, and Jussi Heikkilä, orthopedic technician) created and tested biomechanically a shield-type hip protector (KPH Hip Protector, pat. no 96571, www.kphprotector.com, Figure 2) designed to cover the greater trochanter and to both shunt the impact energy away from the greater trochanter and partly absorb the impact energy during the fall on the hip [3]. These biomechanical tests gave the researchers confidence to test the protector in adult male volunteers under forces that could, without the protector, fracture the hip of some of the elderly individuals [4]. Thereafter, acceptability and user adherence with wearing this protector was tested in a 6-month prospective follow-up study in a Finnish nursing home [5], and the force attenuation capacity of the protector was compared with that of 2 other types of hip protectors (Safehip, Safetypants) [6]. Finally, true efficacy of the KPH Hip Protector to prevent hip fractures was tested in a large randomized clinical trial with 653 elderly protector users and 1148 control persons [7].

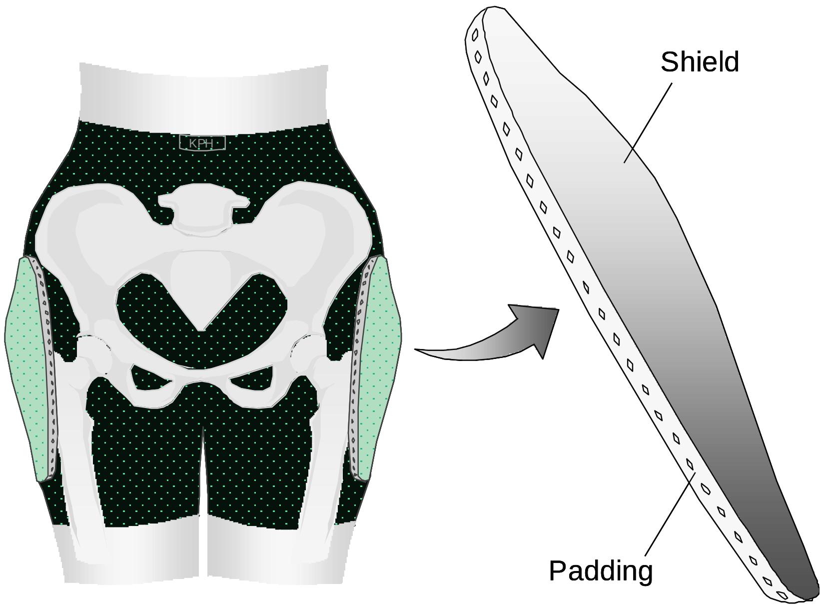


Figure 2. The KPH Hip Protector (Medlogics, Wageningen, The Netherlands, http://www.kphprotector.com) for prevention of hip fracture. The two padded shields are worn in pockets of the undergarment.

RESULTS

The injury mechanism study observed that in 98% of the hip fracture patients, the fracture was a result of a fall [1]. Majority of the patients (81%) reported that the main impact during a fall was directed to the greater trochanter of the femur, while in controls this occurred rarely (3%). In 56% of the hip fracture patients, the occurrence of the impact on the greater trochanter was verified by observing a fresh subcutaneous hematoma on that site, while such a hematoma was rare in the controls (6%) [1]. In a later study, our research team verified that a fall onto the hip is indeed a serious high-impact injury possessing energy to fracture the proximal femur even in young healthy men [8]. This being the case, it is evident that sideways falls can be very dangerous and thus a natural target for prevention of hip fracture.

In the hip protector study series, the research team found that when using reasonable thicknesses of the currently available hip padding materials, the femoral impact force could not be lowered below the theoretical fracture threshold [2,6], and it was concluded that prevention of hip fractures by external protectors should be based on other ideas than hip padding alone (ie, increase in the impact surface, shunting the impact energy away from the greater trochanter, or their combination).

The biomechanical test results of the energy-shunting and energy-absorbing KPH Hip Protector then showed that this type of hip protector can provide an effective impact force attenuation in typical falling conditions of elderly adults by reducing the initial force to the seventh part [3,6], while the other types of hip protectors are clearly less effective [6]. The biomechanical superiority of the KPH Hip Protector has been recently verified by Dutch researchers [17]. In the KPH Hip Protector experiments with adult volunteers, the fall-induced peak impact forces did not cause undue pain to the impacted hip region, and, in all probability, the forces delivered to the proximal femur remained below the range of force capable to fracture the proximal femur of older persons [4].

The 6-month nursing home study revealed that 63% of the elderly persons to whom the KPH protector was introduced wore the protector on a regular basis without major problems [5]. The attitute (ie, education and motivation) of the staff of the institution was believed to be crucial factor for reaching the rather good initial acceptance rate, and then the very high user compliance, for the protector.

Finally, the above noted randomized two-year clinical trial showed that, by intention-to-treat analysis, the risk of hip fracture was 60% lower in the hip protector group than control group (13 hip fractures in the protector group vs. 67 hip fractures in the control group, RH = 0.4, 95% CI 0.2-0.8, p=0.008). By active treatment or efficacy analysis of the hip-protector group, the risk of hip fracture was over 80% lower if the protector was worn at the time of the fall versus the situation where the hips of these people were not protected during the fall (RH = 0.1, 95% CI, 0.03-0.5, p=0.003). According to the protector-to-control group comparison, the number needed to treat (NNT) to avoid one hip fracture was 41 persons for one year (95% CI, 25-115), or 8 persons for five years (95% CI, 5-23). Since the costs of 8 pairs of the KPH Hip Protectors are less than 900 USD and the total first year costs of hip fracture are approximately 20 000 USD [19,24], the protector also turned out to be a very cost-effective (cost-saving) procedure.

CONCLUSION

Our injury mechanism study showed that a typical hip fracture of an older adult is a result of a fall and a subsequent impact on the greater trochanter of the proximal femur. For this reason, we suggest that in addition to the traditional means of preventing osteoporotic fractures (ie, maximising peak bone mass and prevention of age-related bone loss), the prevention strategies of hip fractures should include serious efforts for diminution of the number and severity of the falls of the older persons. Additionally, this over 15-year research project on fracture prevention has provided strong evidence that the number of hip fractures among frail older people can be clearly recuded by the use of an anatomically designed, biomechanically effective-proven KPH Hip Protector (Figure 2). The use of the protector is neither cost-creating nor cost-neutral but clearly a cost-saving procedure.

FINDINGS FROM OTHER HIP PROTECTOR STUDIES

After designing and testing the KPH Hip Protector, many other models of hip pads and devices have been developed, very often, however, without scientifical backup of the biomechanical antifracture efficacy of the model [8-11]. And not surprisingly, results of many randomized clinical studies with these mechanically weaker hip protectors have shown that the risk of hip fracture is not reduced with these devices [9-11,21].

Thus, it is extremely important that a satisfactory hip-protector research and development program should ensure documentation of the biomechanical antifracture efficacy of the selected protector in vitro and in actual falls; continuing with analyses of protector position at the time of fall impact as well as protector compliance and adherence among users; and, ending with a user-control comparison in a randomized clinical trial [11,21]. The most recent international consensus statements on biomechanical testing and clinical trials of hip protectors recommend that intra-individual randomization can also be considered; ie, on random basis, the same person has a true protector on one hip and a sham protector on the other [22,23].

The newest hip protectors that emphasize a thin, soft design seem to seek increased user-comfort and compliance, but this is probably achieved at the cost of reduced force attenuation, efficacy, and safety. In our view, therefore, there is a case for to be made for a regulatory Food and Drug Administration (FDA)-type device approval process. This would be based on a protector-specific application detailing the biomechanical and clinical studies that verify the biomechanical efficacy and clinical effectiveness of the protector in question. Studies with negative results should be included in the application. The entire approval process would be consistent with the requirements of evidence-based medicine and provide important quality control for elderly users and those paying for the products [9].

Recent meta-analyses and systematic reviews on hip protectors have combined the results of all kind of hip pads and devices together and concluded that the use of hip protectors in care homes and institutions of elderly people can reduce the risk of hip fracture by 20-60% [12,13,20]. In more specific cost-benefit studies, in which the results of the KPH Hip Protector studies were used as the basis of the analyses, the conclusion was that external strong-shield hip protectors are a cost-saving intervention in both the US nursing home setting [14] and community-dwelling geriatric population [15]. In Ontario, Canada, a recent cost-benefit analysis showed that a strategy to provide hip protectors to all nursing home residents aged 65 years and over (about 61 000 persons) would result in an overall mean cost savings of 6.0 million Canadian dollars in one year [16]. Thus, hip protectors, especially those including a biomechanically effective-proven strong shield, are clinically and economically a very attractive option for frail elderly people with a high risk of hip fracture.

REFERENCES

[1] Parkkari, J., Kannus, P., Palvanen, M., Natri, A., Vainio, J., Aho, H., Vuori, I. & Järvinen, M. (1999). Majority of hip fractures occur as a result of a fall and impact on the greater trochanter of the femur: a prospective controlled hip fracture study with 206 consecutive patients. *Calcif Tissue Int*, *65*, 183-187.

[2] Parkkari, J., Kannus, P., Poutala, J. & Vuori, I. (1994). Force attenuation properties of various trochanteric padding materials under typical falling conditions of the elderly. *J Bone Miner Res*, *9*, 1391-1396.

[3] Parkkari, J., Kannus, P., Heikkilä, J., Poutala, J., Sievänen, H. & Vuori, I. (1995). Energy-shunting external hip protector attenuates the peak femoral impact force below the theoretical fracture threshold. *J Bone Miner Res*, *10*, 1437-1442.

[4] Parkkari, J., Kannus, P., Heikkilä, J., Poutala, J., Sievänen, H., Heinonen, A. & Vuori, I. (1997). Impact experiments of an external hip protector in young volunteers. *Calcif Tissue Int*, *60*, 354-357.

[5] Parkkari, J., Kannus, P. & Heikkilä, J. (1998). Acceptability and compliance with wearing energy-shunting hip protectors: a 6-month prospective follow-up in a Finnish nursing home. *Age and Ageing*, *27*, 225-229.

[6] Kannus, P., Parkkari, J. & Poutala, J. (1999). Comparison of force attenuation properties of four different hip protectors under simulated falling conditions in the elderly: An in vitro biomechanical study. *Bone*, *25*, 229-235.

[7] Kannus, P., Parkkari, J., Niemi, S., Pasanen, M., Palvanen, M., Järvinen, M. & Vuori, I. (2000). Prevention of hip fracture in elderly people with use of a hip protector. *N Engl J Med*, *343*, 1506-1513.

[8] Kannus, P., Leiponen, P., Parkkari, J., Palvanen, M. & Järvinen, M. (2006). A sideways fall and hip fracture. *Bone*, *39*, 383-384.

[9] Kannus, P., Parkkari, J. & Khan, K. (2003). Hip protectors need an evidence base. *Lancet*, *362*, 1168-1169.

[10] Kannus, P., Uusi-Rasi, K., Palvanen, M. & Parkkari, J. (2005). Non-pharmacological means to prevent fractures among older adults. *Ann Med*, *37*, 303-310.

[11] Kannus, P. & Parkkari, J. (2006). Prevention of hip fracture with hip protectors. *Age and Ageing*, *35-S2*, 51-54.

[12] Parker, M. J., Gillespie, W. J. & Gillespie, L. D. (2006). Effectiveness of hip protectors for preventing hip fractures in elderly people: a systematic review. *BMJ*, *322*, 571-574.

[13] Oliver, D., Connelly, J. B., Victor, C. R., Shaw, F., Whitehead, A., Genc, Y., Vanoli, A., Martin, F. C. & Gosney, M. A. (2007). Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses. *BMJ*, *334*, 82-87.

[14] Honkanen, L., Schackman, B. R., Mushlin, A. I. & Lachs, M. S. (2005). A cost-benefit analysis of external hip protectors in the nursing home setting. *J Am Geriatr Soc*, *53*, 190-197.

[15] Honkanen, L., Mushlin, A. I., Lachs, M. & Schackman, B. R. (2006). Can hip protector use cost-effectively prevent fractures in community-dwelling geriatric population? *J Am Geriatr Soc*, *54*, 1658-1665.

[16] Sawka, A. M., Gafni, A., Boulos, P., Beattie, K., Papaioannou, A., Cranney, A., Hanley, D. A., Adachi, J. D., Cheung, A., Papadimitropoulos, E. A. & Thabane, L. (2007). Could a policy of provision of hip protectors to elderly nursing home residents result in cost savings in acute hip fracture care? The case of Ontario, Canada. *Osteoporosis Int*, *18*, 819-827.

[17] Van Schoor, N. M., van der Veen, A. J., Schaap, L. A., Smit, T. H. & Lips, P. (2006). Biomechanical comparison of hard and soft hip protectors, and the influence of soft tissue. *Bone*, *39*, 401-407.

[18] Järvinen, T. L. N., Sievänen, H., Khan, K. M., Heinonen, A. & Kannus, P. (2008). Shifting the focus in fracture prevention from osteoporosis to falls. *BMJ*, *336*, 124-126.

[19] Zethraeus, N., Strömberg, L., Jönsson, B., Svensson, O. & Ohlen, G. (1997). The cost of hip fracture: estimate for 1709 patients in Sweden. *Acta Orthop Scand*, *68*, 13-17.

[20] Sawka, A. M., Boulos, P., Beattie, K., et al. (2007). Hip protectors decrease hip fracture risk in elderly nursing home residents. *J Clin Epidemiol*, *60*, 336-344.

[21] Kannus, P. & Parkkari, J. (2007). Hip protectors for preventing hip fracture. *JAMA*, *298*, 454-455.

[22] Robinovitch, S. N., Evans, S., Minns, J., Laing, A., Kannus, P., Cripton, P., et al. (2009). Hip protectors: Recommendation for biomechanical testing – an international consensus statement (part I). *Osteoporosis Int*, in press.

[23] Cameron, I. D., Robinovitch, S., Birge, S., Kannus, P., Khan, K., Lauritzen, J., et al. (2009). Hip protectors: Recommendation for conducting clinical trials – an international consensus statement (part II). *Osteoporosis Int*, in press.

[24] Dolan, P. & Torgerson, D. J. (1998). The cost of treating osteoporotic fractures in the United Kingdom female population. *Osteoporos Int*, *8*, 611-617.

[25] Kannus, P., Niemi, S., Parkkari, J., Palvanen, M., Vuori, I. & Järvinen, M. (2006). Nationwide decline in incidence of hip fracture. *J Bone Miner Res*, *21*, 1836-1838.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 233-237
ISBN: 978-1-60876-223-1

Chapter 9

TRAFFIC ACCIDENTS AND HELMETS: A RESEARCH OVERVIEW

Viroj Wiwanitkit
Wiwanitkit House, Bangkhae, Bangkok Thailand 10160.

ABSTRACT

Traffic is a daily activity in all cities around the world, and traffic accidents are considered to be a leading cause of death. Safety apparatus is promoted to help lessen the severity of injuries from traffic accidents. In some countries, car and motorcycle accidents are the main cause of death. Motorcycle accidents often cause head injuries especially when the cycle falls to the ground. The helmet is a specific device developed to protect the head. A research overview of traffic accidents and helmets is the focus of this article.

INTRODUCTION [1 – 6]

Traffic is a daily activity in all cities around the world, and traffic accidents are recognized as a leading cause of death.. Due to the present globalization, several kinds of traffic accidents can be expected, and they can be seen in any country around the world. Because traffic is a way to promote communication, a lot of traffic accidents occur around the world everyday. Due to the number of accidents, communities must consider ways to improve safety. A plan for safety management is needed. Safety apparatus is being promoted to help lessen the severity of injuries from traffic accidents.

A traffic accidents can be a serious event. Car and motorcycle accidents are the main cause of death in many countries. These accidents have become one of the leading causes of death for the world's population. Focusing on the motorcycle, it is considered a risky traffic vehicle, and the cycle and rider have been describe as "flesh covering machine" which is totally different from the car, described as "machine covering flesh". The motorcycle accident is therefore usually serious for the rider. An injury to any part of the body of the motorcyclist can be expected. Of several types of injuries, the head injury is one of the most serious scenarios. Because head is an important organ that can be easily injured, serious disability and death can be expected. The final outcome for the motorcyclist who experiences a serious head injury from a motorcycle accident is usually death.

Considering the motorcycle accident, a head injury can be result if the motorcycle falls to the ground. This increases the chance of the head contacting the ground. Serious injury can be expected. However, there can be many degrees of head injury. Minutely, a small contusion on the head can be observed. This is not common but is considered a lucky scenario. In the more serious outcomes, a fracture and brain injury can be seen. Because the brain is a vital organ contained in the skull or the head, a head injury can easily induce a brain injury. The serious form of brain injury, epidural hemorrhage, can be expected. This is usually accompanied by a lucid interval, and can lead to the death of the affected motorcyclist within a short period. In addition, there can be a more chronic form of brain injury, subarachnoid hemorrhage. This kind of brain injury can also result in death as the final outcome. However, the most serious form of brain injury is crushing of the brain. This is usually due to a truck running over the head, which is the case of sudden death at the site of an accident. This type of accident caused collapse of skull and total brain damage, with sudden death as the acute final outcome.

HELMET: A PREVENTIVE APPARATUS FOR THE MOTORCYCLIST

The helmet is a specific device developed for protection of the head. It can be used in sports such as rugby. However, the widely used indication is for motorcycle riding. Since it covers the head, the helmet can reduce the degree of head injury if an accident occurs. The helmet protects the motorcyclist's head from direct danger. In many countries, helmet usage is mandated by the Traffic Act [7]. The author will hereby summarize important reports on traffic accidents and helmets.

Table 1. Important reports on traffic accidents and helmets

Author	Detail
Mayrose [8]	Mayrose studied the effects of a mandatory motorcycle helmet law on helmet use and injury patterns among motorcyclist fatalities [8].
Hoang et al. [9]	Hoang et al. studied the costs of traumatic brain injury due to motorcycle accidents in Hanoi, Vietnam [9]. dos Santos et al. studied profile of motorcycle accident victims treated at a public hospital emergency department [10].
Sirimaharaj and Pyungtanasup [11]	Sirimaharaj and Pyungtanasup studied the epidemiology of mandibular fractures treated at Chiang Mai University Hospital, Thailand [11].
Ranney et al. [12]	Ranney et al. studied helmet use among 510 injured motorcyclists in a state with limited helmet laws [12].

Table 1. (Continued)

Author	Detail
Mertz and Weiss [13]	Mertz and Weiss reported on changes in motorcycle-related head injury deaths, hospitalizations, and hospital charges following repeal of Pennsylvania's mandatory motorcycle helmet law [13].
Espitia-Hardeman et al. [14]	Espitia-Hardeman et al. reported on impact of interventions directed toward motorcyclist death prevention in Cali, Colombia [14].
Ramli et al. [15]	Ramli et al. studied pattern of maxillofacial injuries in motorcyclists in Malaysia [15].
Kuo et al. [16]	Kuo et al. reported a case of traumatic hyoid bone fracture in patient wearing a helmet [16].
Houston and Richardson [17]	Houston and Richardson reported on motorcyclist fatality rates and mandatory helmet-use laws [17].
Goslar et al. [18]	Goslar et al. reported on helmet use and associated spinal fractures in motorcycle crash victims [18].
Karbakhsh-Davari et al. [19]	Karbakhsh-Davari et al. reported on bicycle-related injuries in Tehran, Iran [19].
Hyder et al. [20]	Hyder et al. reported the results from exploring the economics of motorcycle helmet laws [20].
Rasouli et al. [21]	Rasouli et al. reported on spinal cord injuries from road traffic crashes in southeastern Iran [21].
O'Keeffe et al. [22]	O'Keeffe et al. reported on increased fatalities after motorcycle helmet law repeal [22].
Beltramino and Carrera [23]	Beltramino and Carrera reported on traffic law compliance in the city of Santa Fe, Argentina [23].

Table 2. Important reports on sports and helmets

Author	Detail
Copeland et al. [25]	Copeland et al. said that “Combined tool approach is 100% successful for emergency football face mask removal [24]. Cantu and Mueller reported on brain injury-related fatalities in American football [25].
Marshall et al. [26]	Marshall et al. reported on an ecologic study of protective equipment and injury in two contact sports [26].
Finch et al. [27]	Finch et al. discussed “What do under 15-year-old schoolboy rugby union players think about protective headgear?” [27]
Sane [28]	Sane reported a comparison of maxillofacial and dental injuries in four contact team sports: American football, bandy, basketball, and handball [28].
Sances et al. [29]	Sances et al. discussed the biomechanics of spinal injuries [29].

The author hereby makes suggestions from research overview. Overall, it is well evidenced that the helmet is very useful in efficacy and effectiveness in prevention of head injury for the motorcyclist. In view of cost effectiveness, it also implies a valuable method at low cost. A specific law on helmet use should also be set because the law usually proves to be effective for the control of accidental injuries.

HELMET: A PREVENTIVE APPARATUS FOR THE SPORTMAN

As already mentioned, the helmet is also useful in sports. There are also some reports concerning the use of helmets as a preventive apparatus in sports as summarized in Table 2.

REFERENCES

[1] Chen, CH; Wang, TY; Tsay, PK; Lai, JB; Chen, CT; Liao, HT; Lin, CH; Chen, YR. A 162-case review of palatal fracture: management strategy from a 10-year experience. *Plast Reconstr Surg.*, 2008 Jun, 121(6), 2065-73.

[2] Tunçbilek, G; Işçi, E. Traumatic evulsion of the globe: a very rare complication of maxillofacial trauma. *J Craniofac Surg.*, 2008 Mar, 19(2), 313-5.

[3] Liu, BC; Ivers, R; Norton, R; Boufous, S; Blows, S; Lo, SK. Helmets for preventing injury in motorcycle riders. *Cochrane Database Syst Rev.*, 2008 Jan 23, (1), CD004333.

[4] Hyder, AA; Waters, H; Phillips, T; Rehwinkel, J. Exploring the economics of motorcycle helmet laws--implications for low and middle-income countries. *Asia Pac J Public Health*, 2007, 19(2), 16-22.

[5] Roccia, F; Cassarino, E; Boccaletti, R; Stura, G. Cervical spine fractures associated with maxillofacial trauma: an 11-year review. *J Craniofac Surg.*, 2007 Nov, 18(6), 1259-63.

[6] Hinds, JD; Allen, G; Morris, CG. Trauma and motorcyclists: born to be wild, bound to be injured? *Injury*, 2007 Oct, 38(10), 1131-8.

[7] Ogle, AJ; Tillotson, EA. Should it be the law in Wisconsin that all motorcyclists are required to wear helmets? *J Trauma Nurs.*, 2008 Apr-Jun, 15(2), 43-6.

[8] Mayrose, J. The effects of a mandatory motorcycle helmet law on helmet use and injury patterns among motorcyclist fatalities. *J Safety Res.*, 2008, 39(4), 429-32.

[9] Hoang, HT; Pham, TL; Vo, TT; Nguyen, PK; Doran, CM; Hill, PS. The costs of traumatic brain injury due to motorcycle accidents in Hanoi, Vietnam. *Cost Eff Resour Alloc.*, 2008 Aug 22, 6, 17.

[10] dos Santos, AM; Moura, ME; Nunes, BM; Leal, CF; Teles, JB. Profile of motorcycle accident victims treated at a public hospital emergency department**.** *Cad Saude Publica.*, 2008 Aug, 24(8), 1927-38.

[11] Sirimaharaj, W; Pyungtanasup, K. The epidemiology of mandibular fractures treated at Chiang Mai University Hospital: a review of 198 cases. *J Med Assoc Thai.*, 2008 Jun, 91(6), 868-74.

[12] Ranney, ML; Mello, MJ; Baird, J. Helmet use among 510 injured motorcyclists in a state with limited helmet laws. *Med Health R I.*, 2008 Apr, 91(4), 100-2

[13] Mertz, KJ; Weiss, HB. Changes in motorcycle-related head injury deaths, hospitalizations, and hospital charges following repeal of Pennsylvania's mandatory motorcycle helmet law. *Am J Public Health*, 2008 Aug, 98(8), 1464-7.

[14] Espitia-Hardeman, V; Vélez, L; Muñoz, E; Gutiérrez-Martínez, MI; Espinosa-Vallín, R; Concha-Eastman, A. Impact of interventions directed toward motorcyclist death prevention in Cali, Colombia: 1993-2001. *Salud Publica Mex*, 2008, 50 Suppl 1, S69-77.

[15] Ramli, R; Abdul Rahman, R; Abdul Rahman, N; Abdul Karim, F; Krsna Rajandram, R; Mohamad, MS; Mat Nor, G; Sohadi, RU. Pattern of maxillofacial injuries in motorcyclists in Malaysia. *J Craniofac Surg.*, 2008 Mar, 19(2), 316-21.

[16] Kuo, LC; Lin, HL; Chen, CW; Lee, WC. Traumatic hyoid bone fracture in patient wearing a helmet: a case report. *Am J Emerg Med.*, 2008 Feb, 26(2), 251.e1-2.

[17] Houston, DJ; Richardson, LE. Motorcyclist fatality rates and mandatory helmet-use laws. *Accid Anal Prev.*, 2008 Jan, 40(1), 200-8.

[18] Goslar, PW; Crawford, NR; Petersen, SR; Wilson, JR; Harrington, T. Helmet use and associated spinal fractures in motorcycle crash victims. *J Trauma.*, 2008 Jan, 64(1), 190-6.

[19] Karbakhsh-Davari, M; Khaji, A; Salimi, J. Bicycle-related injuries in Tehran. *Arch Iran Med.*, 2008 Jan, 11(1), 94-7.

[20] Hyder, AA; Waters, H; Phillips, T; Rehwinkel, J. Exploring the economics of motorcycle helmet laws--implications for low and middle-income countries. *Asia Pac J Public Health*, 2007, 19(2), 16-22.

[21] Rasouli, MR; Nouri, M; Rahimi-Movaghar, V. Spinal cord injuries from road traffic crashes in southeastern Iran. *Chin J Traumatol.*, 2007 Dec, 10(6), 323-6.

[22] O'Keeffe, T; Dearwater, SR; Gentilello, LM; Cohen, TM; Wilkinson, JD; McKenney, MM. Increased fatalities after motorcycle helmet law repeal: is it all because of lack of helmets? *J Trauma.*, 2007 Nov, 63(5), 1006-9.

[23] Beltramino, JC; Carrera, E. Traffic law compliance in the city of Santa Fe, Argentina. *Rev Panam Salud Publica.*, 2007 Aug, 22(2), 141-5.

[24] Copeland, AJ; Decoster, LC; Swartz, EE; Gattie, ER; Gale, SD. Combined tool approach is 100% successful for emergency football face mask removal. *Clin J Sport Med.*, 2007 Nov, 17(6), 452-7.

[25] Cantu, RC; Mueller, FO. Brain injury-related fatalities in American football, 1945-1999. *Neurosurgery*, 2003 Apr, 52(4), 846-52.

[26] Marshall, SW; Waller, AE; Dick, RW; Pugh, CB; Loomis, DP; Chalmers, DJ. An ecologic study of protective equipment and injury in two contact sports. *Int J Epidemiol.*, 2002 Jun, 31(3), 587-92.

[27] Finch, CF; McIntosh, AS; McCrory, P. What do under 15 year old schoolboy rugby union players think about protective headgear? *Br J Sports Med.*, 2001 Apr, 35(2), 89-94.

[28] Sane, J. Comparison of maxillofacial and dental injuries in four contact team sports: American football, bandy, basketball, and handball. *Am J Sports Med.*, 1988 Nov-Dec, 16(6), 647-51.

[29] Sances, A Jr.; Myklebust, JB; Maiman, DJ; Larson, SJ; Cusick, JF; Jodat, RW. The biomechanics of spinal injuries. *Crit Rev Biomed Eng.*, 1984, 11(1), 1-76.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 239-243
ISBN: 978-1-60876-223-1

Chapter 10

THE USE OF THE LARYNGEAL MASK AIRWAY IN RABBITS

George M. Kazakos[1*], Ioannis Savvas[1], Tilemachos Anagnostou[1], Irene M. Kazakou[2] and Dimitris Raptopoulos[1]
[1]Clinic for Companion Animals, Faculty of Veterinary Medicine, Aristotle University of Thessaloniki, Greece.
[2]Intensive Care Unit , Venizelio General Hospital of Heraklion, Greece.

ABSTRACT

A major drawback to routine general anesthesia in rabbits is the difficult task of securing airway patency. Intubation of the trachea is technically demanding and time-consuming, sometimes even in the experienced hands. As a result, administration of volatile agents often proves to be difficult, especially when controlled ventilation must be applied. Although laryngeal anatomy of the rabbit differs from that of humans, the LMA designed for use in humans fits well on the rabbit's larynx and provides a good seal around the laryngeal opening.

INTRODUCTION

The rabbit is a standard animal model for biomedical research. Many procedures must be performed under general anesthesia. Anatomic features that complicate airway management in this species include the long and narrow oral cavity, large incisors and sizeable tongue, acute angle between the mouth and the larynx, and limited mobility of the temporomandibular joint. Due to these reasons, orotracheal intubation of rabbits is difficult with a high failure rate especially for the inexperienced staff. Complications of the attempts for orotracheal intubation may include laryngeal trauma, laryngeal spasm upon contact and tracheal damage (Lipman et al. 1997). Special techniques and devices (such as fiberoptic endoscopes and X-

* Corresponding author: E-mail: gkdvm@vet.auth.gr

ray devices) are often used to facilitate endotracheal intubation in rabbits; some researchers have even tried tracheostomy, while others avoid intubation altogether and use alternative methods of inhalational anesthesia administration. One of the commonly used devices is the facemask. Conventional face mask designs do not readily conform to a rabbit's muzlle; they increase mechanical dead space, inhalation of room air, and anesthetic gas pollution, and they do not prevent airway obstruction. The poor seal around the face also makes intermittent positive pressure ventilation (IPPV) difficult. Controlled ventilation of rabbits often is required in research settings (Corleta et al. 1992).

Laryngeal Mask Airway

The Laryngeal Mask Airway (LMA) is a device intended as an alternative to face masks and endotracheal tubes. It consists of an airway tube, a mask, and a mask inflation link. Following insertion into the pharynx and over the laryngeal aperture, the mask forms a direct end-to-end junction between the upper airway and an artificial tube for supplying gas to the bronchial tree. The mask surrounds the hypopharynx and provides a tight seal, making IPPV feasible. The use of the LMA offers some advantages over tracheal intubation. The former is easier for the inexperienced staff members to insert. In fact, the ease of use makes the device an attractive alternative especially in cases of emergency (Davies et al. 1990). Moreover, deviation from the ideal positioning does not preclude excellent functional results in human patients. However, there is concern about an incomplete seal between the LMA and the larynx in humans and laboratory pigs. On the other hand, the inability of the device to completely protect the airway against aspiration of gastric contents is considered to be its main disadvantage when compared with endotracheal intubation (Davies et al. 1990, Patil et al. 1997). Laryngospasm, sore throat, hoarseness, and dysphagia have been reported following LMA use in people. Several features of children (small oral cavity, limited mobility of the lower jaw, and tendency for contact-induced laryngospasm) are reminiscent of difficulties faced by rabbit anesthetists, thereby suggesting why LMAs might have utility as a simpler means of general anesthesia delivery in rabbits.

Literature Review

A review of the recent literature recounting general anesthesia practices in rabbits revealed three full papers and an abstract describing the use of LMAs in this species.

Cruz et al. (2002) found it easier to introduce LMA than endotracheal tube, while a lower dose of the anesthetic induction agent was required. Smith et al. (2004) also compared cuffed and uncuffed endotracheal tubes to LMA in rabbit inhalation anesthesia. It was found that the LMA clearly was a simpler technique for gas delivery, while researchers with formal training but lacking practical experience in general anesthesia of rabbits successfully positioned the LMA in 8- to 12-fold less time than the time required to place an endotracheal tube. This fact suggests that routine LMA use in rabbits likely will afford two important advantages during rabbit procedures requiring general anesthesia: a more stable physiological state (due to rapid restoration of ventilation) and a smoother recovery period (resulting from decreased trauma to the upper airway). Furthermore, the quality of anesthesia provided by the LMA resembled that of the two endotracheal tubes, as indicated by the ability of all the devices to support a surgical plane of anesthesia and to preserve arterial blood pressure, and once positioned, the devices -especially the LMA- were not dislodged by routine manipulations of the animal. However, this is in contrast to our clinical impression, especially when rabbits lay at supine position.

Bateman et al. (2005) compared face masks with LMAs during spontaneous breathing in anesthetized rabbits. They found that although blood gas and airway gas levels did not confirm a significant advantage of LMA use over face masks, two individuals in the face mask group were severely hypercapnic and one of them was hypoxic. A LMA was used successfully to quickly establish control of the previously obstructed airway in both rabbits, with no signs of airway obstruction following correct placement. These observations suggest that although in many rabbits anesthesia can be clinically maintained with a face mask without developing significant airway obstruction, LMA is superior to face mask for airway management in rabbits, and it can be used to correct anesthetic-induced airway obstruction.

Kazakos et al. (2007) tested the feasibility of using the LMA in 50 rabbits during surgery. According to their results useful clinical indices for correct LMA placement are: 1. Detection of unyielding resistance to further advancement during insertion; 2. Vigilant positioning of the black line of the LMA at the midline; 3. Close monitoring of the synchronization of the movements of the reservoir bag with chest wall movements; 4. Observation of sufficient chest wall movements during manual ventilation; and 5. Absence of sound caused by gas escaping in the oral cavity during manual ventilation. Two points were emphasized concerning the process of mask insertion. First, the device must be protected from the rabbit's teeth while in the limited space of its oral cavity. The cuff also needs protection, as previously described for LMA use in dogs and cats. In the same study, this was achieved by inserting the mask through the right interdentium with the aperture facing the upper buccal wall (animal in lateral recumbency) and by advancing it slightly before rotating it so that the teeth would be bypassed and lacerations of the cuff avoided; a similar technique was also followed by Smith et al. (2004). Second, there is an easily overcome mild resistance, possibly due to the narrow caudal oral cavity, encountered as the device is advanced beyond the molars but before the final position, at which point there is an unyielding resistance to further advancement. Finally, early removal of the LMA seemed to be a good practice.

When controlled ventilation was used, Bateman et al. (2005) found that $PaCO_2$ was approximately normal, suggesting that it is possible to deliver effective IPPV to rabbits in dorsal recumbency using a LMA. Unfortunately there was a high incidence of gastric tympanism in this group of rabbits. It was mentioned that the LMA cuff was not inflated in any of the rabbits because the authors' trial study showed that its inflation caused the rabbits' tongues to become cyanotic. This practice could have contributed to the higher incidence of tympanism when IPPV was used.

Although laryngeal anatomy of the rabbit differs from that of humans, the LMA designed for use in humans fits well on the rabbit's larynx and provides a good seal around the laryngeal opening. In Kazakos et al. (2007) study, the size-1 LMA was used in rabbits weighing less than 4 kg and the size-1.5 in larger animals. In four out of fifty rabbits, it was observed cyanosis confined to the tongue; tongue color returned to normal after deflation of the cuff, repositioning of the mask, or removal and use of a smaller size mask. Although arterial blood gas measurements were not performed, the colour of the rest of the mucous membranes was normal, SpO_2 (when the sensor was positioned on the ear) was more than 95%, and other monitored cardiorespiratory parameters were within normal limits. Hence, it was postulated that the likely cause of the cyanosis was the compression of the lingual artery. This phenomenon has also been observed in humans and in ferrets after prolonged (more than six hours) anesthesia. The possibility that tongue cyanosis was caused by a substantial increase in cuff pressure during the course of inhalational anesthesia should probably be excluded, since cyanosis appeared soon after LMA positioning. Based on the findings of this study, the possibility of tongue cyanosis should always be kept in mind. Placing the sensor of a pulse oximeter on the tongue soon after insertion of the LMA may greatly facilitate early diagnosis of lingual cyanosis. In cases of lingual cyanosis, capnography, and buccal tissue perfusion monitoring may also be used to assess pulmonary and cardiovascular function.

When Smith et al. (2004) compared two endotrachal tubes (cuffed and uncuffed) with a paediatric LMA regarding their effectiveness to limit isoflurane emissions, all three devices appeared to emit isoflurane. The isoflurane concentrations measured at the oral commissure with the LMA in place were modestly higher than those obtained with the cuffed and uncuffed endotracheal tubes. Isoflurane was not detected in the operator’s breathing zone. It was proposed that the uncuffed endotracheal tube (usually used to anesthetize birds and reptiles) and the pediatric LMA can be used in rabbits as readily as a cuffed tube.

Apart from the LMA use for administration of inhalational anesthesia in laboratory rabbits, Kazakos et al. (2007) include all the details that veterinarians will need to add this technique to their “rabbit armory”, in the interest of raising the safety of rabbit “dentals” to the standard that is commonly accorded to cats and dogs (Price 2007).

We conclude that the use of the LMA device offers an attractive alternative to endotracheal intubation or to the use of a face mask for maintenance of anesthesia in rabbits under spontaneous-breathing inhalational anesthesia.

REFERENCES

Bateman, L., Ludders, J. W., Gleed, R. D. & Erb, H. N. (2005). Comparison between facemask and laryngeal mask airway in rabbits during isoflurane anesthesia. *Vet Anaesth Analg*, *32(5)*, 280-288.

Corleta, O., Habazettl, H., Kreimeier, U., et al. (1992) Modified retrograde orotracheal intubation technique for airway access in rabbits. *Eur Surg Res*, *24*, 129-132.

Cruz, M. l., Sacchi, T., Luna Spl, Braz Jrc & Cassu Rn. (2000). Use of a laryngeal mask for airway maintenance during inhalation anaesthesia in rabbits. *Vet Anaesth Analg*, *27(2)*, 112-116.

Davies, P. R., Tighe, S. Q., Greenslade, G. L. & Evans, G. H. (1990). Laryngeal mask airway and tracheal tube insertion by unskilled personnel. *Lancet*, *336(8721)*, 977-979.

Kazakos, G. M., Anagnostou, T., Savvas, I., Raptopoulos, D., Psalla, D. & Kazakou, I. M. (2007). Use of the laryngeal mask airway in rabbits: placement and efficacy. *Lab Anim*, (NY), *36(4)*, 29-34.

Lipman, N. S., Marini, R. P. & Flecknell, P. A. (1997). In Anesthesia and Analgesia in Laboratory Animals. In: D. F. Kohn, S. K. Wixson, W. J. White, & G. J. Benson (Eds.), 205-232 (Academic Press, New York).

Patil, V. U., Fairbrother, C. R. & Dunham, B. M. (1997). Use of the laryngeal mask airway for emergency or elective airway management situations in pigs. *Contemp. Top. Lab. Anim. Sci.*, *36(6)*, 47-48.

Price, H. (2007). Intubating rabbits. *Vet Rec*, *26*, 160(21), 744.

Smith, J. C., Robertson, L. D., Auhll, A., March, T. J., Derring, C. & Bolon, B. (2004). Endotracheal tubes versus laryngeal mask airways in rabbit inhalation anesthesia: ease of use and waste gas emissions. *Contemp Top Lab Anim Sci.*, 2004 Jul, *43(4)*, 22-25.

In: Protective Devices: Types, Uses and Safety
Editor: Victor E. Argosyan, pp. 245-248
ISBN: 978-1-60876-223-1

Chapter 11

RESEARCH AND REPORTS ON MEDICAL PROTECTIVE DEVICES IN THAILAND

Viroj Wiwanitkit
Wiwanitkit House, Bangkhae, Bangkok Thailand 10160

ABSTRACT

Medical protective devices are useful for prevention of contact with infectious diseases. There are several kinds of protective devices that are necessary as universal precautions. In a setting with a high prevalence of infectious disease, the focus on these protective devices is of interest. In this chapter, the author will detail and summarize the research and reports on medical protective devices in Thailand, a tropical country.

INTRODUCTION

Medical protective devices are useful to prevent contact with infectious diseases. There are several kinds of protective devices—including gloves, gowns and goggles—that are necessary for universal precautions. In settings with a high prevalence of infectious disease, interest in these protective devices is high. Thailand is a country in tropical Asia with a high prevalence of infectious diseases, so the topic of medical protective devices is an important one there. In this chapter, the author will detail and summarize the research and reports on medical protective devices in Thailand.

GLOVES: IMPORTANT MEDICAL PREVENTIVE DEVICE

Use of gloves, an important medical preventive device, is recommended when coming into contact with conditions that are possibly infectious. Glove wearing is a basic topic in universal precautions. The important research studies on glove use in Thailand are hereby listed, as well as some research on helmets.

Table 1. Some important research on gloves, helmets in Thailand

Authors	Details
Chindawuttigul [1]	Chindawuttigul performed a study of double gloving during operative vaginal delivery [1]. The result of the study showed that the perforation of the gloves in the control group and the experimental group occurred in a significant difference [1].
Pengsaa et al. [2]	Pengsaa et al. performed a study to determine whether using sterile gloves reduces the incidence of nosocomial infection in the neonatal ward of a Thai tertiary hospital [2]. The authors concluded that there was no statistically significant difference in the incidence of nosocomial infection in the infants who received nursing care by using sterile gloves compared to standard care [2].
Aroonpruksakul et al. [3]	Aroonpruksakul et al. studied the leakage of surgical gloves in Siriraj Hospital, Bangkok [3]. According to this work, the high percentage of leakage should forewarn operating personnel of possible contact with diseases, therefore, the authors recommended using double gloves [3].
Sanguansermsri [4]	Sanguansermsri studied the incidence of perforation of double-layer, disposable-latex examination glove in dental clinic, Yasothon Hospital, northeastern Thailand [4]. The study pointed the dentist and the personnel to increase awareness of disposable-latex examination glove usage in dental practice [4].
Rumpradit et al. [5]	Rumpradit et al. performed an evaluation of resteriled gloves [5]. They noted that with the use of new resteriled technique (water-test) leakage rate was reduced [5].
Vongthawatcha [6]	Vongthawatchai studied the rate of glove perforations after using double gloving technique in general surgery [6]. The author suggested that double gloving technique should be applied to prevent the contamination of blood and secretions to surgical health personnel and most gloves could be re-used with reasonable safety [6].
Chongthamawat and Suwanchareon [7]	Chongthamawat and Suwanchareon studied the quality of medical gloves and noted that the medical gloves in Thailand should improve their mechanical properties [7].
Phuenpathom [9]	Phuenpathom studied the road traffic accidents, the use of seat belts and crash helmet for decreasing the severity of accidents [9].
Suputtitada et al. [10]	A study of knowledge and attitude of motorcycle-riders toward helmet in Rayong Province, eastern Thailand was performed. According to this work, although the public knowledge and attitude of the advantages of helmet use was moderately positive, most of the drivers did not desire to use helmets [10]

HELMET: A DEVICE FOR ACCIDENT PREVENTION IN THAILAND

The helmet is a device for prevention of accidents. Although it is not a direct medical preventive device, it is discussed here because it is related to accident prevention which is an important topic in preventive medicine. At present, helmet wearing must be done in Thailand due to the present traffic laws.

GOWN: SUIT FOR MEDICAL PERSONNEL

The gown is the specific suit for medical personnel. It is also recommended that gowns must be worn whenever coming into contact with possibly infectious conditions. However, there is no specific report on the gown as a medical preventive device in Thailand.

GOGGLES: EYE PROTECTION FOR MEDICAL PERSONNEL

Goggles are the specific eye protective device for medical personnel. It is recommended that goggles must be worn when possible spillage of infectious particles is expected, especially for the period during medical procedures. There is only one specific report on goggles as a medical preventive device in Thailand, which focused on goggle usage during delivery [8]. Paisarntantiwong et al. performed a descriptive study to evaluate blood and body fluid splash during vaginal delivery examining incidence rate of splash, factors related to splash and factors related to amount of splash [8]. According to this work, results showed that the splash incidence rate at the front of goggles was high but was not found at the side panel, and the number of splash droplets at the front ranged from one to twenty-three per delivery [8].

CONCLUSION

The research and reports on medical protective devices in Thailand is still lacking and there is a need to promote study in this area.

REFERENCES

[1] Chindawuttigul, S. A study of double gloving during operative vaginal delivery. *Chonburi Hosp J.*, 1993, 18(1), 19-36.

[2] Pengsaa, K; Lumbiganon, P; Taksaphan, S; Pairojkul, S; Sookpranee, T; Kosuwon, P; Panthongviriyakul, C; Noppawinyoowong, J; Sookpranee, M; Bhudisawasdi, W; Wilailuckana, C; Kosuwon, W; Waetasak, P; Namkun, C; Kanteekaew, N; Sithikesorn, J. Do sterile gloves reduce nosocomial infection in the neonatal ward? *J Infect Dis Antimicrob Agents*, 1993, 10(1), 1-7.

[3] Aroonpruksakul, S; Chanchayanon, T; Lertakyamanee, J; Punturuk, S; Jeetaniyom, P. Leakage of surgical gloves in Siriraj Hospital. *Siriraj Hosp Gaz.*, 1995, 47Suppl, 1-9.

[4] Sanguansermsri, C. Incidence of perforation of double-layer, disposable-latex examination glove in dental clinic, Yasothon Hospital. *Med J Ubon Hosp.*, 1995, 16(4), 155-158.

[5] Rumpradit, M; Pungching, A; Potaya, S; Kasetsuwan, P; Khamkosit, S. Evaluation of resteriled gloves in Bhumibol Adulyadej Hospital. *R Thai Air Force Med Gaz.*, 1996, 42(2), 23-28.

[6] Vongthawatchai, P. Rate of glove perforations after using double gloving technique in general surgery. *Commun Dis J*, 1997, 23(3), 431-437.

[7] Chongthamawat, S; Suwanchareon, L. Quality of medical gloves. *Bull Dept Med Serv.*, 1999, 24(4), 189-196.

[8] Paisarntantiwong, R; Thavaramara, T. Goggles for the protection of blood and body fluid during vaginal delivery. *Med J Srinakharinwirot.*, 1997, 4(1), 1-6.

[9] Phuenpathom, N. Seat belts and crash helmets. *R Thai Army Med J.*, 1987, 40(2), 87-92.

[10] Suputtitada, W; Dumpan, T; Promwech, T. A study of knowledge and attitude of motorcycle-riders toward helmet in Rayong Province 1993. *J Prapokklao Hosp Clin Med Educ Cent.*, 1986, 11(1), 9-18.

INDEX

A

B

C

D

G

H

I

J

K

L

M

P

Q

R

S

T

U

V

W

X

Y