Running head: MOUTHGUARD EFFECTIVENESS

Do Intraoral Mouthguards Work?

Written by:

Marwan Al Rayes, Loren Arenson, Devandra Chudasama, Dan Siracusa and Alice Wu

University of Toronto, Faculty of Dentistry

Word Count: 2447

Submitted: April 05, 2007

Abstract

Orofacial injuries are prevalent in contact and non-contact sports. Considering that 13-39% of all dental injuries are sports related (Chisick et al., 2000), the need for effective methods of orofacial protection is crucial. Researchers have proposed that the mouthguard could act as a protective device that can potentially reduce the extent and severity of orofacial injuries. Hence, the effectiveness of mouthguards in reducing sports related orofacial injuries is an area of research that deserves further inquiry.

An evidence-based review was performed to determine if mouthguards are effective in reducing sport related orofacial injuries. A Scopus pilot test, an Ovid systematic search, expert opinions, and a review of reference lists resulted in the compilation of 15 studies intended for critical appraisal. A checklist was utilized to systematically assess the evidence of efficacy of prevention, after which 6 studies met the strict criteria.

Results demonstrated that mouthguards significantly decrease the incidence of dental trauma. Inconclusive evidence was found regarding the ability of mouthguards to reduce soft tissue injury and concussion. Overall, there is fair evidence to suggest the mandatory use of mouthguards in sports related activities. Further research is warranted to confirm these results.

Key words: Mouth guard, mouthguard, mouth protect, tooth protect, teeth protect, injury, trauma, bleed, avuls, sport, athlete, football, baseball, volleyball, basketball, soccer, rugby, hockey, wrestle, bicycle, box, surf, motorcross, swim, lacrosse, and play

Do Intraoral Mouthguards Work?

Orofacial injuries are a group of injuries pertaining to the oral and facial regions of the human body which include dental fractures, dental avulsions, dental luxations, jaw fractures, concussions due to a blow under the chin, and bruising or laceration of the gums, tongue, lips, and cheeks (Kvittem et al., 1999). Considering that 13 – 39% of dental injuries are attributable to sports (Chisick et al., 2000) and that craniofacial injuries comprise one sixth of the total injuries occurring in sports (Nonfatal sports, 2000), it is evident that there is a close relationship between sports and orofacial injuries. The prevalence of orofacial injuries varies depending on the type of sport played, the degree of contact, and the age, gender and geographical location of the subject studied (Kumamoto & Maeda, 2003). For instance, football and rugby have the highest prevalence of orofacial injury at 54% (Kumamoto & Maeda, 2003), males appear to be at greater risk than females (Wisneiwski et al., 2004) and in contact sports, the risk of an individual acquiring and sustaining an orofacial injury is 10% (Flanders,1995). Evidently, treating and preventing sport-related orofacial injuries is of particular importance in light of their pervasiveness and severity.

Orofacial injuries have widespread and problematic implications. Such injuries may impact physical, psychological, social, and economical aspects of life. Physically, orofacial injuries can result in abnormal primary teeth exfoliation, failure in permanent teeth eruption, unfavourable colour changes in teeth, development of painful abscesses, and tooth loss resulting in unaesthetic gaps in the mouth of the injured victim (CDHA, 2005). Cortes, Marcenes and Sheiham (2002) demonstrated that children with traumatic dental injuries suffered psychological and social difficulties, such as emotional problems and alienation. From an economic standpoint, a study by Locker and Maggirias (2004) revealed that treatment costs of sport-related

dental injuries in Ontario was approximately between 22-25 million dollars (US). A cost-benefit analysis conducted by the Academy of General Dentistry in 2005 estimated that fabricating a custom made mouth guard is less than 20 times the cost of treating one avulsed tooth, thus indicating that simple prevention alone can often reduce the huge financial impact of such orofacial injuries.

Protection from sport-related orofacial injuries currently comes in the form of three shielding equipments: mouthguards, face masks, and helmets. Mouthguards will be the focus of this report since they are intraoral and can thus be incorporated into the dentist's procedures. This intraoral device is designed to fit one or both dental arches in order to protect against orofacial injuries during sport activities (JADA Continuing Education, 2006). It is believed that mouthguards help reduce orofacial injuries by acting as impact-absorption devices which dissipate the energy of a traumatic blow, thereby preventing direct force on oral structures (Hoffman et al., 1999). They are also believed to act as a cushion between the mandible and maxilla thereby lessening the severity of injuries related to condylar displacement, such as condylar dislocation and concussion (Winters, 2001). In view of the prevalence, severity, and wide implications of sport-related orofacial injuries, the present report sought to investigate whether mouthguards can be effective in reducing the incidence and frequency of sport-related orofacial injuries.

Method

A systematic method was utilized in order to select, review and critically appraise studies in the literature pertaining to mouthguards.

Search Strategy

Four various search strategies were performed to ensure a thorough review of the literature. First a preliminary pilot search of potential key words was conducted on Scopus (1997 to the present). This preparatory search yielded 63 applicable articles (see Table 1 for Scopus search strategy) and served as a useful method to compile appropriate key words (see Table 2).

The key words were then used in a comprehensive search via Ovid. Several electronic bibliographic databases were searched: Ovid MEDLINE (R)- (1950-February Week 3 2007), Ovid MEDLINE (R) Corrections, Ovid MEDLINE (R) In-Process & Other Non-Indexed Citations- (March 06, 2007), AMED (Allied and Complementary Medicine)- (1985- March 2007), CINAHL- Cumulative Index to Nursing and Allied Health Literature- (1982- March Week 1 2007), All EBM Reviews- Cochrane DSR, ACP Journal Club, DARE, and CCTR, EMBASE (1980- 2007 Week 09), Health and Psychosocial Instruments (1985- January 2007), Journals @Ovid Full Text (March 6, 2007) and Ovid Healthstar (1966- January 2007). This intensive search excluded review articles, articles that were not available at local holdings, in vitro studies and studies that were not published in English. Overall, the Ovid search yielded 310 potentially appropriate articles. It should be noted that several searches were run using variations of the keywords in order to ensure an accurate review of the literature.

In order to supplement our research, experts in the field were consulted. Dr. Robert Zaichick and Dr. Paul Piccininni were contacted and asked to recommend noteworthy literature

on the topic of interest (See list of credentials in Appendix A). The valuable suggestions given helped to facilitate the finding of an additional thirteen potentially applicable articles.

Lastly, cited reference lists of relevant articles obtained via our Scopus search, our Ovid search and expert recommendations were analyzed to reveal an additional six potentially relevant articles (on the basis of the article titles). All duplicate articles were excluded from the reference review.

Determination of Relevance

The abovementioned search strategies produced a total of 392 articles. Of these articles, thirteen were eliminated due to overlap among databases and reference list results, and three were disregarded because they were unavailable for review. 330 and 31 articles were then eliminated by review of the title and abstract, respectively. A list of the articles removed and reasons for exclusion appear in Appendix B. It should be noted that at least two people deliberated and came to an agreement on every decision on whether to include/exclude each study. An article was eliminated if it failed to meet any of the following criteria:

1) The article presented primary research.
    - Review articles, letters, and commentaries were excluded.
2) The study examined the mouthguard effect.
    - If the study solely focused on the attitudes towards mouthguards, the prevalence of mouthguards, or comparisons of the various types of mouthguards it was excluded.
3) The study was done in vivo.
    - In vitro studies were exluded as they do not adequately simulate typical sport conditions (Warnet and Greasley, 2001)
4) The study design was a randomized controlled trial, a cohort study, a case-control study, a cross-sectional study, or a survey.

A total of fifteen articles met the above criteria and were obtained for critical appraisal.

Validity Instrument

These fifteen remaining articles were each scored according to a "Checklist to Assess Evidence of Efficacy of Therapy or Prevention" developed by Leake (1997) (see Table 3). Each article was assessed by two independent reviewers. A mutual agreement was made following discussion within the group whenever discrepancies were noted. The highest possible score on the checklist was 15. An in-depth summary of search results can be found in Table 4.

Results

Six articles that examined whether mouthguards were effective in reducing orofacial injury were retained after critical appraisal. The relevant results are summarized in Table 5. Finch et al. (2005) presented strong evidence to support mouthguard use by means of a randomized control trial (RCT). De Wet et al. (1981) and Morton and Burton (1979) conducted cohort studies which similarly presented findings to support the use of mouthguards. Due to the nature of the study designs, the evidence obtained via these cohort studies was slightly weaker than the results of the RCT. The other three studies analyzed were surveys which demonstrated insufficient findings.

With the number of head/orofacial (H/O) injuries per every 1000 exposure hours to be 4.4 (95% CI 2.2-8.9) in the control group and 1.8 (95% CI 2.2 – 8.9) in the intervention group, Finch et al. (2005) verified that custom-fitted mouthguards provide crucial protection against H/O injuries. Similar findings and conclusions were made by de Wet et al. (1981). Morton and Burton (1981) drew comparisons between wearers and non-wearers, revealing that the severity of oral injuries was reduced, although nonsignificantly, with the use of mouthguards. Marshall et al. (2004) similarly maintained that mouthguards prevent injury. However, their results failed to reach statistical significance. Although Labella et al. (2002) found an inverse relationship

between dental injuries and mouthguards, there was no evidence to suggest protection against soft tissue trauma and concussions. Only the study performed by de Wet et al. (1981) could provide evidence to suggest the effectiveness of mouthguards in preventing concussions. The rest of the studies examined failed to demonstrate such a relationship.

Almost all of the aforementioned studies included tests for statistical analysis and controlled covariates, such as age, gender and division. Finch et al. (2005) used STATA and Poisson regression models, while both de Wet et al. (1981) and Labella et al. (2002) performed Chi square tests. Fisher's test of exact significance and Generalized Poisson regression models were used by Morton and Burton (1979) and Marshall et al. (2004), respectively. Chapman and Nasser (1996) did not conduct any statistical analyses in their studies, and consequently, the significance and validity of their results was weakened.

Discussion

Research suggests that the effectiveness of mouth guards in the prevention of orofacial injuries is generally fair. The evidence proposes that mouth guards significantly decrease the incidence of dental trauma. However, the evidence surrounding its effects on soft tissue trauma and concussions is conflicting. Many of the weaknesses in the literature are a result of weak study designs and inadequately utilized methods.

Our review of the literature revealed one randomized control trial, two cohort studies, and three descriptive surveys. Consequently, the quality of the overall evidence supporting the use of mouthguards was weakened due to limitations inherent in these study designs, such as lack of a control group and non-randomization of participants in groups examined.

It is important to explore the ethical implications associated with studies on the given subject matter. It is arguably unethical to assign participants to a control group and, as a result,

prevent them from wearing a piece of protective equipment. An interesting way of circumventing this dilemma was demonstrated by Finch et al. (2005). They requested that subjects in the experimental group wear the mouthguards given to them. On the other hand, subjects in the control group had the freedom to decide on their own mouthguard practice. Participants in both groups could then be compared.

Despite attempts to establish a control group, there was often an uneven distribution of participants between the test and control groups. Only de Wet et al. (1981) had an even allocation of participants between the test and control group (75 players in each). All other studies analyzed exhibited a greater proportion of test subjects compared to the control group subjects. Of significance are the studies conducted by Morton and Burton (1979) and Chapman and Nasser (1996), in which the test group outnumbered the control group by 201 and 114 participants, respectively. This is an important consideration, as an even distribution between test and control subjects allows one to better document notable differences between the groups. Nonetheless, it should be noted that an adequate sample size was included in all studies.

Another key limitation in these studies is the use of self-report questionnaires to obtain data, such as those used in the study performed by Marshall et al. (2004). By relying heavily on the subject's memory of previous injury and mouthguard use, this technique introduces recall bias which skews the validity of the results.

The studies analyzed were also largely dependent on subject compliance rates. In the event that certain subjects did not adhere to the rules of the study or did not participate for the duration of the study, a skewing of the results would arguably be likely to result. This lack of supervision serves no purpose but to weaken the level of evidence obtained through study.

In order to ensure a sufficient level of validity, it is essential to control for confounding variables. The control of confounding variables by means of a regression analysis typically augments the conclusiveness of a study. The cohort performed by Morton and Burton (1979) failed to take into account potential confounding variables. On the other hand, while studies performed by de Wet et al. (1981) and Marshall et al. (2004) did control for key variables such as occlusion, position, age, and sex, they failed to exercise the benefits of regression analysis. Had these methods been employed, stronger evidence supporting the positive effect of mouthguards on orofacial injury prevention could have been conjured.

Other distinguishing factors which contributed to the overall level of evidence were noted in the articles evaluated. For instance, the standardization of mouthguard fabrication is an essential control that was utilized in the study performed by de Wet et al. (1981). By standardizing the mouthguard, the variability between test subjects was reduced, thus strengthening the evaluated evidence level. The use of supervised questionnaires also played an important role in both cohort studies, most notably in a study of primary school children conducted by de Wet et al. (1981). By implementing supervised questionnaires, the effects of recall bias can be somewhat negated. It is understandable that children at that age may experience difficulty recollecting events in question. By having the questionnaires supervised, the interviewer was able to "walk" the children through the questions, and help alleviate any memory lapses experienced.

A current review of the literature attests that existing scientific expositions regarding H/O injury prevention fail to employ high caliber study designs. Future research documenting the effectiveness of mouth guards should adopt more meticulous study designs, in order to solidify

their conclusiveness. The need to execute a greater number of randomized controlled trials (preferably multi-centered RCTs) is evident given the discontinuity of the present research.

In order to further avoid the shortcomings of previous research, the following suggestions might be adopted:

- Establish studies with larger sample sizes. The greater the number of participants incorporated into a study, the more conclusive evidence one is able to attain.
- Test and control groups should be more evenly distributed to irrefutably determine differences between both sets of subjects.
- Control for confounding variables by implementing regression analyses. Variables of interest one may integrate are class, position on field, age, sex…etc.
- Invoke a standard fabrication for mouthguards. These mouthguards should be fabricated by the same dentist as to diminish variability between test subjects.
- Data collection/interviews should be conducted on site as opposed to being executed by another party, as to diminish errors in data.
- Implement an international meta-analysis. If results are analyzed from a group of studies taken from varying countries, one can arguably create a more accurate data analysis.
- Studies should be conducted in lower socio-economic societies, among whom the prevalence of dental injuries exceeds those in affluent societies (CDHA, 2005). This would assumedly provide a broader sample of injuries to examine, thus increasing sample size and providing more accurate results.

In conclusion, there is fair evidence suggesting that the use of mouthguards significantly decreases the incidence of dental trauma. However, for soft tissue trauma and concussion,

conflicting evidence exists. In 2002, The American Task Force presented weak evidence concerning mouthguard effectiveness (Task Force on Community Preventive Services, 2002). Since then, studies such as the RCT performed by Finch et al. (2005), presented significant evidence suggesting mouthguards do in fact provide some protection against H/O injuries. While we can therefore be more confident in the effectiveness of mouthguards, there are still concerning limitations in much of the existing research. Nevertheless, no study seemed to suggest that mouthguards are a potential risk factor for orofacial injuries. Upon reviewing the evidence, it is apparent that there is no harm, but rather, fair evidence to suggest the mandatory use of mouthguards in sports related activities. Further research needs to be conducted to determine a stronger correlation between mouthguard use and the prevention of orofacial injuries.

References

Academy of General Dentistry. Superstitions: the source of NHL's tooth woes? [online]. [Cited March 2007.] Available from: www.agd.org/consumer/topics/mouthguards/superstitions.asp

CDHA. CDHA Position paper on sports mouthguards. *Canadian Journal of Dental Hygiene (CJDH)* 2005;39(6): 1-18.

Chapman PJ and Nasser BP. Prevalence of orofacial injuries and use of mouthguards in high school Rugby Union. *Australian Dental Journal* 1996; 41: 252-255.

Chisick MC, Richter P, and Piotrowski MJ. Put more "bite" into health promotion: a campaign to revitalize health promotion in the Army Dental Care System. Part I. *The mouthguard, sealant, and nursing caries initiatives. Mil Med*. 2000;165(8): 598-603.

Cortes MI, Marcenes W, and Sheiham A. Impact of traumatic injuries to the permanent teeth on the oral health-related quality of life in 12-14-year-old children. *Community Dent Oral Epidemiol*. 2002;30(3): 193-198.

De Wet FA, Badenhorst M, and Rossouw LM. Mouthguards for rugby players at primary school level. *Journal of the Dental Association of South Africa* 1981; 36: 249-253.

Finch C, Braham R, Mclntosh A, McCrory P, and Wolfe R. Should football players wear custom-fitted mouthguards? Result from a group randomized controlled trial. *Injury Prevention* 2005; 11: 242-246.

Flanders RA. Project Mouthguard. *III Dent J.* 1995;64(2): 67-69.

JADA Continuing Education. Using mouthguards to reduce incidence and severity of sports-related oral injuries. *J Am Dent Assoc* 2006;137(12): 1712-1720

Kumamoto DP and Maeda Y. A literature review of sports-related orofacial trauma. *Gen.Dent*. 2004;52(3): 270-280.

Kvittem B, Hardie NA, Roettger M, and Conry J. Incidence of orofa-cial injuries in high school sports. *J Public Health Dent* 1998;58(4): 288-93.

Labella CR, Smith BW, and Sigurdsson A. Effect of mouthguards on dental injuries and concussions in college basketball. *Medical & Science in Sports & Exercise* 2002; 34: 41-44.

Leake JL, Department of Biological and Diagnostic Sciences, Faculty of Dentistry, University of Toronto. Unpublished document. Course notes DENT 1040Y 2001. The checklist was adapted from Fletcher RH, Fletcher SW, Wagner EH. Clinical epidemiology. The essentials. 3rd ed. Baltimore: Williams and Wilkins, 1996; Sackett DL, Richardson WS, Rosenberg W, Haynes RB. Evidence-based medicine: how to practice and teach. EBM. 2nd ed. New York: Churchill Livingstone, 1997

Locker D and Maggirias J. Costs of traumatic dental injury in Ontario. Health measurement and epidemiology report. Toronto (ON): Community Dental Health Services Research Unit, Faculty of Dentistry, University of Toronto; 2004.

Marshall SW et al. Evaluation of protective equipment for prevention of injuries in rugby union. *International Journal of Epidemiology* 2005; 34: 113-118.

Morton JG and Burton JF. An evaluation of the effectiveness of mouthguards in high-school rugby players. *New Zealand Dental Journal* 1979; 75: 151-153.

Nonfatal sports-and recreation-related injures treated in emergency departments – United States, July 2000-June 2001. *MMWR Morb Mortal Wkly Rep* 2002;51(33): 736-40.

Task Force on Community Preventive Services. Recommendations on Selected Interventions to Prevent Dental Caries, Oral and Pharyngeal Cancers, and Sports-Related Craniofacial Injuries. *Am J Prev Med* 2002;23(1S): 16-80.

Warnet L. and Greasley A. Transient forces generated by projectiles on variable quality mouthguards monitored by instrumented impact testing. *British Journal of Sports Medicine* 2001; 35: 257-62

Winters JE Sr. Commentary: role of properly fitted mouthguards in prevention of sport-related concussion. *J Athl Train* 2001;36(3): 339-41.

Wisniewski JF, Guskiewicz K, Trope M, and Sigurdsson A. Incidence of cerebral concussions associated with type of mouthguard used in college football. *Dent Traumatol*. 2004:20(3): 143-149.

Table 1

Scopus Search criteria

Keywords: - mouthguards - injury
Inclusion: - 1997 – present
Subject Area: - life sciences - physical sciences - health sciences - social sciences

Table 2

Keywords Used in Ovid Systematic Search

Key Words
- Mouthguard$ or mouth protect$ or mouth guard$
- tooth protect$ or teeth protect$
- injur$ or trauma$ or fracture$ or bleed$ or avuls$ or concussion$
- sport$ or athlet$ or football or baseball or basketball or swim$ or hockey or wrestl$ or bicycle$ or box$ or volleyball or surf$ or motocross or ski$ or soccer or lacrosse or rugby or play$

Note: "$" is a truncation technique that retrieves unlimited suffix variation

Table 3

Checklist to Assess Evidence of Efficacy of Therapy or Prevention

1) Was the study ethical?
2) Was a strong design used to assess efficacy?
3) Were outcomes (benefits and harms) validly and reliably measured?
4) Were interventions validly and reliably measured?
5) What were the results?
    - Was the treatment effect large enough to be clinically important?
    - Was the estimate of the treatment effect beyond chance and relatively precise?
    - If the findings were "no difference" was the power of the study 80% or better
6) Are the results of the study valid?
    - Was the assignment of patients to treatments randomized?
    - Were all patients who entered the trial properly accounted for and attributed to its conclusion?

I. Was loss to follow up less than 20% and balanced between test and controls?

II. Were the patients analyzed in the groups to which they were randomized?

- Was the study of sufficient duration?
- Were the patients, health workers, and study personnel "blind" to treatment?
- Were the groups similar at the start of the trial?
- Aside from the experimental intervention, were the groups treated equally?
- Was care received outside the study identified for and controlled for?

7) Will the results help in caring for your patients?
    - Were all clinically important outcomes considered?
    - Are the likely benefits of treatment worth the potential harms and costs?

Table 4

Summary of Search Strategy:

	Search Engine	Steps	Search Strategy	Number of Articles
A	Scopus	N/A	Pilot Study: (“mouthguards” AND “injury”) used as keywords	**63**
B	- Ovid MEDLINE (R) - Ovid MEDLINE (R) Corrections - Ovid MEDLINE (R) In-Process & Other Non-Indexed Citations - AMED - CINAHL - All EBM Reviews - Health and Psychosocial Instruments - Journals @Ovid Full Text - Ovid Healthstar	1	Mouthguard$ or mouth protect$ or mouth guard$	2439
		2	tooth protect$ or teeth protect$	168
		3	1 or 2	2566
		4	injur$ or trauma$ or fracture$ or bleed$ or avuls$ or concussion$	2344878
		5	3 and 4	1444
		6	sport$ or athlet$ or football or baseball or basketball or swim$ or hockey or wrestl$ or bicycl$ or box$ or volleyball or surf$ or motocross or ski$ or soccer or lacrosse or rugby or play$	4453071
		7	5 and 6	1191
		8	limit 7 to English	1087
		9	limit 8 to English language	1087
		10	limit 9 to human	1054
		11	limit 10 to humans	1054
		12	limit 11 to local holdings	627
		13	Limit 12 to “review articles”	113
		14	12 not 13	514
		15	remove duplicates from 14	**310**
C	Experts Opinion	N/A	N/A	**13**
D	Reference lists	N/A	N/A	**6**
E	Total	N/A	N/A	**392**
F	Duplicates from E	N/A	N/A	13
G	Unavailable from E	N/A	N/A	3
H	New Total	N/A	N/A	**376**
I	Title elimination	N/A	N/A	**46**
J	Abstract elimination	N/A	N/A	**15**
K	Final Number of Articles used for evidence based tables	N/A	N/A	**6**

Table 5

Evidence for Efficacy

Author, Date	**Population**	**Intervention**	**Control**	**Outcome**	**Critical Appraisal**	**Conclusion**
Finch et al ., 2005	- 301 football players from 13 teams of the largest district Australian rules - Teams were randomized to a control group and a custom-made mouthguard group - Teams: under 16, under 18, and open (seniors and reserves) - Gender: M - Players were followed for the 2001 playing season - 4 Teams dropped out (for reasons unrelated to the study)	N = 190 Players (4 Senior Teams, 4 Under-16 and Under-18 Teams) Intervention: Each player was provided with a custom-fitted mouthguard and was requested to wear it for the whole season	N = 111 Players (4 Senior Teams, 1 Under-16 and Under 18 Team) Control: Players were not provided with a mouthguard. However, because of ethical reasons, mouthguard use was not restricted in these players.	Rate of Head/Orofacial (H/O) injuries in control group is higher than that in intervention group. - Control: 4.4 injuries / 1000 exposure hours* (95% CI 2.2 – 8.9) - Intervention: 1.8 injuries / 1000 exposure hours* (95% CI 1.1 – 2.9) Adjusted incidence Rate Ratio = 0.56 (95% CI 0.32 – 0.97, p = 0.04) * Exposure Hour = Person hours of playing time	- Study Design (RCT) is the strongest type. - Use of statistical analysis (STATA and Poisson regression models) to control for factors that cause imbalance in the two study groups	Authors' Conclusion: Custom-fitted mouthguards provided significant protection against H/O injuries. Research Design Rating: I (RCT) Recommendation Grade for Action: A
Marshall et al., 2004	- 356 rugby players in New Zealand - data of these players was obtained from the Rugby Injury and Performance Project - Players were followed for the 1993 club season - Levels of competition: seniors, women, colts, schoolboys, and schoolgirls - 52 players were excluded from analysis (for reasons unrelated to the study) - For the remaining 304 players, M = 240 and F = 87.	N = unspecified Intervention: Players who used mouthguards to any degree during the season	N = unspecified Control: Players who did not use mouthguards at all	- Fully adjusted rate ratio (RR) of mouthguard against all injuries combined = 1.1 (95% CI 0.86 – 1.43) - Fully adjusted RR of mouthguard against orofacial injuries only = 0.56 (95% CI 0.07 – 4.63) - Fully adjusted RR of mouthguard against concussions = 1.62 (95% CI = 0.51 – 5.11)	- Follow-up was > 90% complete. - Generalized Poisson regression was used to control for all covariates. - The only study that incorporated female players. - Too few orofacial injuries (6 only) to draw sound conclusion. - Population make-up of both intervention and control groups was not clear. - Fabrication of mouthguard design could have standardized.	Authors' Conclusion: The use of mouthguard appeared to protect teeth, mouth and jaw but slightly increased the risk of concussions. We disagreed since CIs for all findings included 1. The use of mouthguards was neither a preventive nor risk factor for orofacial injuries and concussions. Research Design Rating: III (Survey) Recommendation Grade for Action: I

Author, Date	Population	Intervention	Control	Outcome	Critical Appraisal	Conclusion
Labella et al., 2002	- 50 basketball teams arbitrarily chosen from 40 states and 4 geographic regions of United States - Age: College level - Gender: M - Teams were followed over the course of 1999-2000 season (20 weeks) - 37 teams (74%) reported data for all 20 weeks - 41 teams (82%) reported data for 15 or more weeks	N = 8663 Exposures* Intervention: Use of custom-fitted mouthguard in one exposure * An exposure is defined as one player participating in one practice or contest.	N = 62273 Exposures* Control: No use of mouthguard * An exposure is defined as one player participating in one practice or contest.	- Rate of Concussions = 0.55 (control), 0.35 (intervention) - Rate of oral soft tissue injuries = 1.06 (control), 0.69 (intervention) These two rates are not statistically significant. Rate of dental injuries = 0.67 (control), 0.12 (intervention) $P < 0.05$	- Report of weekly data was entirely based on the trainer of each team. Players were not closely monitored. - Report of data was entirely conducted online and communication with trainers was solely through e-mails. Errors caused by mis-communication or insufficient supervision could be present. - Fabrication of mouthguard design was not standardized. - Classification of injuries was carried out by trainers whom might not have enough medical background to do so. - Chi-square test was used for statistical analysis.	Authors' Conclusion: Custom-fitted mouthguards could significantly reduce the risk of dental injuries but not oral soft tissue injuries and concussions. Research Design Rating: III (Survey) Recommendation Grade for Action: I
Chapman et al., 1996	- 130 Rugby Union football players from a high school in Australia - 16 players in the under-13 team, 17 players in the under-14 team, 17 players in the under-16 team, 63 players in the senior teams - Players were given a questionnaire about history of mouthguard use and details of any orofacial injuries while playing Rugby Union	N = 100% of Players in Senior Teams & 94% of Players in Under-age Teams Intervention: Players wore mouthguards when playing Rugby Union	N = 6% of Players in Under-age Teams Control: Players did not wear mouthguards when playing	- No. of dental injuries = 5 (Control: 4, Intervention: 1) - No. of lacerations = 4 (Control: 2, Intervention: 2) - Statistical Significance not specified.	- No statistical analysis was conducted. - Too few players in the control group. Comparison of data was therefore not valid. - Players needed to recall past injuries, might therefore had recall biases.	Authors' Conclusion: Present study showed a reduced prevalence of dental injuries with use of mouthguards. Research Design Rating: III (Survey) Recommendation Grade for Action: I

Author, Date	Population	Intervention	Control	Outcome	Critical Appraisal	Conclusion
De Wet et al., 1981	- 150 rugby players from 10 primary school teams from South Africa - all had Angle Class 1 jaw relationships - Age: 10-13 - Gender: M - Players were followed for a rugby season (year and length of season unspecified)	N = 75 Players (15 each of 5 schools) Intervention: - Each was provided with a custom-made mouthguard - Placement of mouthguard was done by two operators only - 44 players wore mouthguards for every game - 30 players wore mouthguards regularly (failed to wear for 1-2 occasions) - 1 player disinclined to use mouthguard	N = 75 Players (15 each of 5 schools) Control: Mouthguards were not worn during the games	- Tooth Injuries: 21.3% (non-users), 0% (users) - Lip Injuries: 41.3% (non-users), 18.7% (users) - Other soft tissue injuries: 16% (non-users), 6.7% (users) - Concussion: 12% (non-users), 0% (users) - Injuries of Neck and TMJ: 8% (non-users), 1.3% (users) $P < 0.001$	- Strong Design (Cohort) - Statistical Significance was checked with Chi square test. - Reasons of not wearing mouthguards were recorded. - 2 operators, rather than players themselves, were responsible for placing mouthguards in mouth → minimized incorrect placement - Post-season questionnaires were supervised → reduced errors and loss of follow-up	Authors' Conclusion: All injuries were reduced significantly when using mouthguards. Research Design Rating: II-2 (Cohort) Recommendation Grade for Action: B
Morton et al., 1979	- 272 rugby players from 8 secondary schools in New Zealand - Gender: M - Players were followed from the 1978 season - 51 lost to follow-up (for reasons unrelated to the study)	N = 221 Players Intervention: Each player was provided with a custom-made mouthguard, but only 135 players wore it regularly. 66 players wore mouthguards occasionally and 20 not at all.	N = 20 Players Control: The 20 non-wearers in the intervention group were used as control.	20 wearers and 14 wearers suffered from injuries when playing. - Among the injured wearers, 15 received soft tissue lacerations with no damage to teeth. - Among the injured non-wearers, only 2 received soft tissue lacerations. The rest suffered from tooth fracture. $P = 0.007$	- Strong Design (Cohort) - Control was not strong. (Players who were given the mouthguard but refused to accept it were not a strong control.) - The completion of questionnaires before the season was supervised to reduce error. - Fisher's test of Exact Significance was conducted to control for other variables.	Authors did not draw any conclusion, but result suggested that the severity of injuries was reduced by the use of mouthguards. Research Design Rating: II-2 (Cohort) Recommendation Grade for Action: B

Appendix A

Dr. Robert Zaichick:

- Practicing dentist in Belleville, ON
  - Ex-OHL team dentist

Dr. Paul Piccininni

- President, International Society for Dentistry, Sport and Trauma
- Fellow, Academy for Sport Dentistry
- Member, IOC Medical Commission Games Group
- Member, IIHF Medical Committee
- Team Dentist, Toronto St. Michael's Majors (OHL)
- Sport Medicine Staff - York University

Appendix B

Excluded articles and the reasons for exclusion at abstract stage

Article	**Reason for exclusion**
Onyeaso CO. Oro-facial trauma in amateur secondary school footballers in Ibadan, Nigerian: a study of mouthguards. Odonto-Stomatologie Tropicale 2004; 27: 32-6	Not a study on effectiveness
Onyeaso CO. and Adegbesan OA Oro-facial injury and mouthguard usage by athletes in Nigeria. International Dental Journal 2003; 53: 231-6	Not a study on effectiveness
Lahti H et al. Dental injuries in ice hockey games and training. Medicine & Science in Sports & Exercise 2002: 34:400-2	Examines extraoral not intraoral
Warnet L. and Greasley A. Transient forces generated by projectiles on variable quality mouthguards monitored by instrumented impact testing. British Journal of Sports Medicine 2001; 35: 257-62	In vitro study
Bemelmanns P. and Pfeiffer P. Shock absorption capacities of mouthguards in different types and thicknesses. International Journal of Sports Medicine 2001; 22:149-53	In vitro study
McCrory P. Do mouthguards prevent concussion? British Journal of Sports Medicine 2001; 35:81-2	Not a primary study
DeYoung AK. Mouthguards: preventing sports-related injuries. Journal of Michigan Dental Association 2000; 82:38-9	Not a primary study
Ranalli DN. Prevention of sports-related traumatic dental injuries. Dental Clinics of North America 2000; 44:35-51	Not a primary study
Rodd HD. and Chesham DJ. Sports-related oral injury and mouthguard use among Sheffield school children. Community Dental Health 1997; 14:25-30	Study on frequency and awareness, not effectiveness
Padilla R. et al. Prevention of oral injuries. Journal of the California Dental Association 1996; 24:30-6	Not a primary study
Nowjack-Raymer Re. and Gift HC. Use of mouthguards and headgear in organized sports by school-aged children. Public Health Reports 1996; 111:82-6	Not a study on effectiveness

Porter M. and O'Brien M. The "Buy-Max" mouthguard: oral, peri-oral and cerebral protection for contact sports. Journal of the Irish Dental Association 1994; 40: 98-101	Not a primary study
Croll TP. Custom-fitted protective mouthguards. Journal of Esthetic Dentistry 1992; 4:143-7	Not a study on effectiveness
Stenger JM et al. Mouthguards: protection against shock to head, neck and teeth. Basal Facts 1987; 9:133-9	Case report study
Chapman PJ. Orofacial injuries and the sue of mouthguards by the 1984 Great Britain Rugby League touring team. British Journal of Sports Medicine 1985; 19:34-6	Not a study on effectiveness
Knapik JJ et al. Mouthguards in sport activities: history, physical properties and injury prevention effectiveness. Sports Medicine 2007; 37:117-44	Not a primary study
Adegbesan OA et al. Perception of Nigerian athletes of the use of mouth guards to preven the stresses of sports injury. British Journal of Sports Medicine 2004; 38:685-9	Not a study on effectiveness
Marshal et al. An ecologic study of protective equipment and injury in two contact sports. International Journal of Epidemiology 2002; 31:587-592	Not a study on effectiveness
Hergenroeder, Albert C. Prevention of Sports Injuries. Pediatrics 1998; 101:1057-1063	Not a study on effectiveness
Elkin M. Increased performance using mouthguards-true or false? Journal of the New Jersey Dental Association 1996; 67:74-6	A review, not a primary study
Flanders RA. Mouthguards and sports injuries. Illinois Dental Journal 1993; 62:13-6	A review, not a primary study
Anonymous. Mouthguards are an athlete's best friend. RDH 1992; 12:40-1	A review, not a primary study
Miller et al. Mouthguard use should be encouraged for many sports. Dentistry (Chicago) 1991; 11:21-2	Not a primary study
Chapman PJ. Orofacial injuries and international rugby players' attitudes to mouthguards. British journal of sports medicine 1990;24:156-8	A review, not a study on effectiveness

Chapman PJ. The bimaxillary mouthguard: a preliminary report of use in contact sports. Australian Dental Journal 1986; 31:200-6	Not a primary study
Natt P. Custom made mouthguards for contact sports players. Journal of the Royal Society of Health 1983; 103:180	A review, not a primary study
Koplik B. Mouth guards prevent most oral injuries in contact sports. New York Journal of Dentistry 1974; 44:84-5	A review, not a primary study
Anonymous. Fitted mouthguards afford key protection. Journal of the American Dental Association 1972; 84:531	Not a primary study
Clegg JH. Mouth protection for the rugby football player. British Dental Journal 1969; 127:341-3	Not a study on effectiveness
Quarrie Kl et al. An evaluation of mouthguard requirements and dental injuries in New Zealand rugby union. British Journal of Sports Medicine 2005; 39:650-4	Not a study on effectiveness
Marshall et al. Effectiveness of Protective Equipment In A Cohort Of Rugby Players. American Journal of Epidemiology 1999; 149:S14	Not a study on effectiveness

Excluded articles and the reasons for exclusion at article stage

Article	**Reason for exclusion**
Marshall et al. Use of protective equipment in a cohort of rugby players. Medicine & Science in Sports and Exercise 2001; 33:2131-8	A survey, evidence score below 12
Yamada et al. Oral injury and mouthguard usage by athletes in Japan. Endodontics & Dental Traumatology 1998; 14:84-7	A survey, evidence score below 12
Jennings DC. Injuries sustained by users and non-users of gum shields in local rugby union. British Journal of Sports Medicine 1990; 24:159-65	A survey, evidence score below 12
McNutt T et al. Oral trauma in adolescent athletes: a study of mouth protectors. Pediatric Dentistry 1989; 11:209-13	A survey, evidence score below 12
Blignaut JB et al. Injuries sustained in rugby by wearers and non-wearers of mouthguards. British Journal of Sports Medicine 1987; 21:5-7	A descriptive study, evidence score below 12

Garon MW et al. Mouth protectors and oral trauma: a study of adolescent football players. Journal of the American Dental Association 1986; 112:663-5	A survey, evidence score below 12
Chapmen PJ. The prevalence of orofacial injuries and use of mouthguards in Rugby Union. Australian Dental Journal 1985; 30:364-7	A descriptive study, evidence score below 12
de Wet FA. The prevention of orofacial sports injuries in the adolescent. International Dental Journal 1981; 31:313-9	A survey, evidence score below 12
Anonymous. Orofacial/cerebral injuries and the use of mouthguards by professional athletes in Switzerland. British Dental Journal 2006; 200:499	A survey, evidence score below 12