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## **Mouthguards in Sport Activities** History, Physical Properties and Injury Prevention Effectiveness

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### Contents

	117
1. Methods Used in the Review and Analysis	119
2. History of Mouthguard Use	120
2.1 Mouthguard Use in Boxing	120
2.2 Mouthguard Use in Football	
2.3 Mouthguard Use in Other Sports	121
3. Physical Properties of Mouthguards	121
3.1 Measurement of Mouthguard Physical Properties	122
3.2 Studies of Mouthguard Materials	123
3.3 Studies on the Protective Capabilities of Entire Mouthguards	130
3.4 Stiffness/Shock Absorption in Relation to Colliding Object and Mouth Characteristics	133
4. Mouthguards and Injuries	
4.1 Methodological Considerations in Injury Studies	134
4.2 Mouthguards and Injury Prevention	138
4.3 Mouthguard Injury-Related Studies not Reviewed	139
5. Conclusions	

### Abstract

Three systematic reviews were conducted on: (i) the history of mouthguard use in sports; (ii) mouthguard material and construction; and (iii) the effectiveness of mouthguards in preventing orofacial injuries and concussions. Retrieval databases and bibliographies were explored to find studies using specific key words for each topic. The first recorded use of mouthguards was by boxers, and in the 1920s professional boxing became the first sport to require mouthguards. Advocacy by the American Dental Association led to the mandating of mouthguards for US high school football in the 1962 season. Currently, the US National Collegiate Athletic Association requires mouthguards for four sports (ice hockey, lacrosse, field hockey and football). However, the American Dental Association recommends the use of mouthguards in 29 sports/exercise activities.

Mouthguard properties measured in various studies included shock-absorbing capability, hardness, stiffness (indicative of protective capability), tensile strength, tear strength (indicative of durability) and water absorption. Materials used for mouthguards included: (i) polyvinylacetate-polyethylene or ethylene vinyl acetate (EVA) copolymer; (ii) polyvinylchloride; (iii) latex rubber; (iv) acrylic resin; and (v) polyurethane. Latex rubber was a popular material used in

early mouthguards but it has lower shock absorbency, lower hardness and less tear and tensile strength than EVA or polyurethane. Among the more modern materials, none seems to stand out as superior to another since the characteristics of all the modern materials can be manipulated to provide a range of favourable characteristics. Impact studies have shown that compared with no mouthguard, mouthguards composed of many types of materials reduce the number of fractured teeth and head acceleration. In mouthguard design, consideration must be given to the nature of the collision (hard or soft objects) and characteristics of the mouth (e.g. brittle incisors, more rugged occusal surfaces of molars, soft gingiva). Laminates with different shock absorbing and stress distributing (stiffness) capability may be one way to accommodate these factors.

Studies comparing mouthguard users with nonusers have examined different sports, employed a variety of study designs and used widely-varying injury case definitions. Prior to the 1980s, most studies exhibited relatively low methodological quality. Despite these issues, meta-analyses indicated that the risk of an orofacial sports injury was 1.6–1.9 times higher when a mouthguard was not worn. However, the evidence that mouthguards protect against concussion was inconsistent, and no conclusion regarding the effectiveness of mouthguards in preventing concussion can be drawn at present. Mouthguards should continue to be used in sport activities where there is significant risk of orofacial injury.

Many types of sports activities put participants at risk of orofacial injury and concussion. The incidence of orofacial injury in sports has been widely reported,<sup>[1-7]</sup> but there are considerable differences among studies with regard to injury case definitions (e.g. chipped or avulsed teeth, tooth and soft tissue lacerations, any injury to the mouth), the populations examined (e.g. professional athletes, collegiate athletes, high school athletes, elementary school children), methods of collecting data (e.g. self-report, emergency room patient records, from coaches or dentists), time period over which injury data were collected (single event, season, career) and the sports examined. Retrospective surveys of various groups of athletes have found that 10-61% have experienced at least one orofacial injury during their participation in sports.<sup>[3,8-31]</sup> There are methodological issues that complicate comparisons among concussion studies,<sup>[32]</sup> but concussion rates appear to vary primarily by sports and competition level. The highest reported rates are in football and ice hockey and the lowest in volleyball; concussion rates are much higher in games than in practice.[32-37]

Mouthguards, also referred to as gum shields or mouth protectors, have long been promoted as a way to reduce the incidence of orofacial injuries and concussions.<sup>[38-41]</sup> The American Society for Testing and Materials has defined a mouth protector as 'a resilient device or appliance placed inside the mouth (or inside and outside), to reduce mouth injuries, particularly to teeth and surrounding structures.<sup>[42]</sup> A mouthguard generally separates the upper and lower dentition and at least a portion of the teeth from the surrounding soft tissue. The protective capability of a particular mouthguard is affected by the geometry of the device as well as the materials used in construction.

Mouthguards are hypothesised to reduce the likelihood of orofacial injuries through several mechanisms. Firstly, they may prevent fracture or dislocation of the teeth by separating the mandibular and maxillary teeth and absorbing or redistributing shock during direct forceful impacts. Secondly, mouthguards may protect against mandibular bone fractures by absorbing shock, redistributing shock and/or stabilising the mandible during traumatic jaw closure. Thirdly, the mouthpiece may reduce the possibility of laceration and bruising of soft tissue by separating the teeth from the soft tissue, thus cushioning and distributing the force of impacts. Finally, it is hypothesised that the mouthpiece may reduce the likelihood of concussion due to a direct blow to the jaw by positioning the jaw to absorb impact forces that would normally be transmitted through the base of the skull to the brain.<sup>[14,16,43-46]</sup>

The wide advocacy of mouthguard use<sup>[47-50]</sup> has led to their adoption as mandatory equipment in some sports.<sup>[51-55]</sup> However, questions can be raised about the most effective type of mouthguard and, more fundamentally, whether there is definitive research evidence that the use of mouthguards actually prevents injuries. While there have been a few reviews on various aspects of mouthguard use,[56-62] none of these reviews has been comprehensive or systematic. The purpose of this article is to present a systematic and detailed literature review on the use of mouthguards in sports and exercise activities. Specifically, this review addresses: (i) the history of mouthguard use; (ii) the physical properties of mouthguards; and (iii) the effectiveness of mouthguards in the prevention of injuries.

# 1. Methods Used in the Review and Analysis

Three distinct literature searches were conducted: one on the history of mouthguard use, a second on mouthguard material and construction, and a third on injuries and mouthguard use. For each topic area, the general procedures were the same. Several retrieval databases were explored to find Englishlanguage studies. These databases included PubMed (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Academic Search Premier, Biomedical Reference Collection (Comprehensive), Cochrane Database of Systematic Reviews and Database of Abstracts of Reviews of Effectiveness. Key words for all three searches included 'mouthguards', 'mouth protectors', 'tooth protectors', 'mouthpiece' and 'gum shields'. For the history of mouthguard use, additional key words were 'boxing', 'football', 'hockey', 'lacrosse', 'history', 'historical', 'prevention', 'American Dental Association' and 'dentists'. For the physical properties of mouthguards, additional key words were 'hardness', 'stiffness', 'tensile strength', 'tear strength', 'water absorption', 'ethyl vinyl acetate (EVA)', 'polyvinylchloride', 'polyurethane' and 'silicon'. To examine the effectiveness of mouthguards for preventing injuries, additional key words were 'injury', 'orofacial', 'dentofacial', 'trauma', 'concussion' and 'cohort studies'. The reference lists of obtained articles were searched for other pertinent articles. Personal contacts were made with some authors to identify other studies, to clarify methods, or to obtain additional data.

Articles on the history of mouthguard use were considered for review if they contained information that would assist in chronicling the development of mouthguards as a device for injury prevention in sports activities. For the review on mouthguard materials and construction, studies were considered for review if they contained original quantitative data on the physical properties of mouthguards (as listed above in the key words).

To determine the effectiveness of mouthguards in preventing injuries, studies were considered for review if they contained original quantitative orofacial injury or concussion data on groups involved in sports or exercise activities. Because we wanted to compare injury risk for mouthguard users and mouthguard nonusers, the article was required to contain four pieces of information: (i) the number of individuals injured while wearing mouthguards; (ii) the number of individuals not injured while wearing mouthguards; (iii) the number of individuals injured and not wearing mouthguards; and (iv) the number of individuals not injured and not wearing mouthguards. Articles were also considered if the four pieces of information could be calculated from the numeric data in the article (in one case an article author supplied the information<sup>[63]</sup>). In many investigations, the required injury data were available within an article but had not been analysed by the authors to determine quantitative differences between mouthguard users and nonusers. In these cases, a secondary data analysis was performed using a Chi-squared test for proportions in EpiInfo 2000, Version 1 (Centers for Disease Control and Prevention, Atlanta, GA, USA) or by manually calculating a Chi-squared for person-time.<sup>[64]</sup> In the Chi-squared test for proportions, if the sample size in any cell was <5, Yates correction was applied.

Because the injury studies were of such variable quality, we developed a scoring instrument to evaluate the methodology of each study. This methodological quality scoring system was modelled on previous systems used for similar purposes.<sup>[65,66]</sup> Six reviewers independently rated each study that met the review criteria on each factor in table I. Following the independent evaluation, the reviewers met to examine the other reviewers' scores and to reconcile major differences. The average score of the six reviewers served as the methodological quality score. In addition, a meta-analysis was performed on the articles that met the review criteria employing a general variance-based method using confidence intervals.<sup>[67]</sup>

#### 2. History of Mouthguard Use

Literature searches using retrieval databases yielded few articles on the history of mouthguard use. This was probably because the retrieval services did not contain older articles that would have been of use in an historical context. Most historical

 Table I.
 Methodological criteria and quality scoring

Criteria	Maximum score
Problem definition and sample	
Statement of research question (prior hypothesis)	5
Source of sample	5
Exclusion of potential participants	5
Power (sample size) calculation	3
Study design and methodology	
Prospective study	10
Retrospective study	4
Selection bias	3
Information bias	3
Description of intervention	6
Comparison of participants with non-participants	4
Appropriateness of methods	12
Addressed possible confounders (e.g. age, gender, fitness, prior injury)	6
Statistical analysis	
Description of statistical tests	6
Use of relative risk or odds ratios	4
Use of confidence intervals or p-values	4
Consideration of confounders	6
Use of multivariate techniques	4
Collinearity	2
Presentation of data	
Demographics	2
Confounders	2
Comparability of groups	2
Tables/graphs	2
Total	100

articles were found in the course of the two other reviews (mouthguard material and construction and mouthguard injury prevention effectiveness) performed as part of this article and/or by searching the reference lists of other articles. Articles were examined and analysed in a chronological sequence to determine how mouthguard use developed in different sports activities.

#### 2.1 Mouthguard Use in Boxing

Boxing was the first recorded sport activity to use mouthguards. Boxers apparently fabricated mouthguard-like devices from cotton, tape, sponge or small pieces of wood. They clenched these materials in their teeth in hopes of providing some shock absorption from the blows to the face. However, the concentration it took to keep these materials on their teeth could draw their attention away from the fight. In many instances, these materials were considered illegal and there were reported cases where the materials were dislodged from the teeth and entered the larynx.<sup>[38,68-70]</sup>

In the 1890s, a London dentist named Woolf Krause put strips of gutta percha (a natural rubberlike resin) over the maxillary incisors of boxers just before they entered the ring.<sup>[71]</sup> In 1919, a fighter named Dinne O'Keefe wore a mouthpiece designed by a dentist, Thomas Carlos, when he fought Jack Britton (the world champion at the time) in Kenosha, Wisconsin.<sup>[72]</sup> Philip Krause (Woolf Krause's son) fabricated perhaps the first reusable mouthpiece which was used by Ted 'The Kid' Lewis during championship fights in the 1910s and 1920s.<sup>[71]</sup> In a fight between Ted Lewis and Jack Britton, Britton complained about Lewis's use of the mouthpiece and boxing officials ruled the mouthpiece could not be used because it was not permitted according to the rules of the game.

In 1927, Jack Sharkey and Mike McTigue fought in an elimination tournament for a chance to face the heavyweight champion, Gene Tunney. By the tenth round McTigue was far ahead in the fight but Sharkey, who was barely able to stand, managed to strike a blow to McTigue's mouth. McTigue's ragged teeth cut his lip so severely that the fight had to be stopped. The contest was awarded to a dazed Sharkey.<sup>[68,71]</sup> Shortly after this fight, boxing officials of the New York State Athletic Commission allowed boxers to use mouthguards.<sup>[38]</sup>

In 1930, the first descriptions of mouthguards appeared in the dental literature. In response to an inquiry by another dentist, three dentists provided information on how to fabricate custom mouth-guards for boxing using dental impressions, wax and rubber.<sup>[69,73,74]</sup> Dr Clarence Mayer, who in 1926 served as the Boxing Inspector for the New York State Athletic Commission, also described how to customise a mouthpiece of similar material.<sup>[38]</sup> A subsequent publication recommended the addition of steel springs to reinforce the soft mouthpieces.<sup>[75]</sup>

#### 2.2 Mouthguard Use in Football

The next sport to adopt mouthguards was football in the US. In the 1940s and 1950s, dental injuries were found to account for 23-54% of all football injuries.<sup>[41,76-80]</sup> A 1950 survey involving 65 major football colleges reported a total of 733 chipped or fractured teeth among  $\approx 4000$  football players.<sup>[41]</sup> Articles began to appear in the dental literature promoting the use of mouthguards in football, and many of these articles provided fabrication techniques.<sup>[39,77-79]</sup> In 1952, Life magazine published an article that included large pictures of several star Notre Dame football players who were lacking incisors.<sup>[81]</sup> This may have focused popular attention on the high likelihood of dental injury in football.<sup>[39]</sup> High schools and colleges began mouthguard pilot programmes, and anecdotal reports in the dental literature suggested that these programmes were successful in reducing the incidence of dental trauma.<sup>[78,82]</sup>

In 1960, the American Dental Association House of Delegates endorsed the use of latex mouthpieces for football and other contact sports.<sup>[40]</sup> The National Alliance Football Rules Committee (composed of the National Federation of State High School Athletic Associations, the National Association of Intercollegiate Athletics, and the National Junior College Athletic Association) mandated mouthpieces for high school and junior college football beginning in the 1962 season.<sup>[40,47,83-86]</sup> The National Collegiate Athletic Association (NCAA) required the use of mouthguards in college football beginning in the 1973 season.<sup>[47,51,87,88]</sup> The current NCAA football regulation requires all players to use an "intra-oral mouthpiece of any readily available colour (not white or transparent) with an FDA-approved base material that covers all the upper teeth."<sup>[54]</sup> Proper fitting of the mouthguard is recommended by the NCAA.

#### 2.3 Mouthguard Use in Other Sports

The state of Minnesota required mouthguards for high school soccer, basketball and wrestling in 1993 but rescinded the requirement about a year later due to community resistance and the presumed lack of data on oral injuries in the selected sports.<sup>[3]</sup> New Zealand currently requires mouthguard use for rugby players of all grades,<sup>[55]</sup> a rule change introduced in 1998.

Besides football, the NCAA now requires mouthguards for ice hockey,<sup>[52]</sup> men's lacrosse<sup>[53]</sup> and women's field hockey. The NCAA and the Amateur Hockey Association have required mouthguards for ice hockey since 1975.<sup>[89,90]</sup> Specific penalties are prescribed for mouthguard nonusers,<sup>[52]</sup> but enforcement and use of mouthguards in ice hockey have not been consistent.<sup>[90]</sup> The NCAA rules for men's lacrosse requires use of "intra-oral mouthpieces of yellow or any other highly visible colour" during play (but not practice).<sup>[53]</sup>

Despite the relatively limited mandatory use of mouthguards in sports, the American Dental Association and the International Academy of Sports Dentistry currently recommends that mouthguards be used in 29 sport or exercise activities. These include acrobatics, basketball, bicycling, boxing, equestrian events, extreme sports, field events, field hockey, football, gymnastics, handball, ice hockey, inline skating, lacrosse, martial arts, racquetball, rugby, shot putting, skateboarding, skiing, skydiving, soccer, softball, squash, surfing, volleyball, water polo, weightlifting and wrestling.<sup>[50]</sup>

#### 3. Physical Properties of Mouthguards

Studies on the physical properties of mouthguards can be classified into two broad groups. The first group involved 19 studies that examined the physical characteristics of various materials used in mouthguards. These investigations examined a large number of properties but did not take into account how the tooth/bone/gingiva complex and how mouthguard construction may influence the protective capabilities, since only materials were examined. The second group of articles comprised 17 studies that examined the shock absorbing capability of the entire mouthguard and provided some insights into favourable mouthguard construction features. These studies considered not only the materials used in construction but also the geometry of the mouthguard and how this might influence the protective capability. However, these studies investigated primarily shock absorbency and seldom measured the breadth of physical properties examined in the mouthguard material studies. Many variables can be expected to influence the effectiveness of the mouthguard, including the material used in construction, the thickness of the protective material, the manner of fabrication, the area of coverage over the teeth and gingiva, characteristics of the protected tissue (teeth/bone/gingiva), and the direction, force and nature of the impact.

#### 3.1 Measurement of Mouthguard Physical Properties

The physical properties of mouthguards that have been examined include shock absorbing capability, hardness, stiffness, tear strength, tensile strength and water absorption. Many of these properties have been measured differently in different studies. It is thus important to outline clearly what is meant by each of these characteristics.

Shock absorbing capability can be broadly defined as the reduction in the impact energy or force transmitted to the surface beneath the mouthguard or material. One measure is the initial rebound of a pendulum or a dropped weight which directly impacts the mouthguard or material.<sup>[91-95]</sup> The degree of rebound is a marker of the amount of impact force absorbed (less rebound, more shock absorption). Another more direct shock absorption quantification is the force measured on a transducer beneath the mouthguard or mouthguard material once a known force (from a pendulum, dropped weight or piston) is applied to the top of the material.<sup>[96-101]</sup> A material with high shock absorbing capability results in a lower peak force or power (force/time) than a material with low shock absorbing capability. Some studies [101-104] hold the impact mass constant, measure acceleration, and calculate impact force (force = mass × acceleration). One study measured only acceleration, but since the mass (steel ball or baseball) and presumably the distance at which the pendulum was released were held constant, the change in acceleration reflects the change in shock absorption ability.<sup>[105]</sup> Other methods related to shock absorbency (strain gauges, energy used in compression) have also been used.<sup>[101,105-107]</sup>

Hardness is the resistance of a material to penetration with a load applied. Hardness can be measured on a number of scales but for the 'softer' materials used in mouthguards, the American Society for Testing and Materials 'A' scale has been used.<sup>[91,92,94,96,108]</sup> Hardness is measured with a device called a durometer that conforms to a particular American Society for Testing and Materials specification (number D2240). Often the commercial name of the durometer is added to the name (e.g. Shore A, Rex A). The durometer has a shaped indenter that applies a specific load to the material and hardness is measured on a scale of 0–100. If the indenter completely penetrates the material, the 'A' hardness is 0 and if no penetration is achieved the reading is 100.

Stiffness is related to hardness and, effectively, as hardness increases so does stiffness. Stiffness is the resistance of a material to deflection by an applied force. Most mouthguard materials have linear elastic properties meaning that the deformation is proportional to the load; once the load is removed the deformation disappears. For materials with linear elastic properties, Young's modulus quantifies stiffness. Young's modulus is the force needed to elongate a material of specified cross-sectional area, most often expressed in N/m<sup>2</sup>. Low stiffness materials have more deformation under load, resulting in increased contact time which in turn reduces peak forces. High stiffness materials have less deformation and tend to distribute the load over a larger area.

Tear strength is a measure of the ability of a material to resist tear forces. Tear strength is usually measured as the amount of force required to tear a notched piece of material divided by the thickness of the material (N/cm). Tear strengths can differ depending on the size of the specimen and the rate of pull. Many mouthguard studies differed in these characteristics (or did not report them); thus, withinstudy comparisons are most appropriate.

Tensile strength is measured in N/cm<sup>2</sup> and is the pull force required to break a material of a specific size. A notched piece of material is placed between two arms and the material is pulled with increasing force until the material breaks.

Water absorption is the amount of water taken up by the material. Two different measures have been used in the mouthguard literature. One measure is simply the increase in total weight, expressed as a proportion of the initial weight (%), after placing the material in water for a selected time and temperature. The other measure is the water absorbed per square centimeter of the material (mg/cm<sup>2</sup>) after placing the material in water for a designated time and temperature.

In general, shock absorbing capability, hardness and stiffness indicate the protective capability of mouthguards and mouthguard materials. Tensile strength and tear strength indicate mouthguard durability, and this is important because the mouthguard is likely to be bitten and chewed by the user. Water absorption suggests the stability of the mouthguard or material in the aqueous environment of the mouth. Mouthguards with high water absorption are likely to retain saliva and oral bacteria.<sup>[92]</sup>

#### 3.2 Studies of Mouthguard Materials

The major materials used in mouthguards are: (i) polyvinylacetate-polyethylene or ethylene vinyl acetate (EVA) copolymer; (ii) polyvinylchloride; (iii) latex rubber; (iv) acrylic resin; and (v) polyurethane.<sup>[92,97,109]</sup> EVA copolymers are the most popular materials, partly because of the ease of custom fabrication.<sup>[92,96,97]</sup> EVA can be formed with little difficulty around a dental cast using vacuum or pressure techniques.<sup>[62,93,110]</sup> The use of polyvinylchloride has come under criticism by the European Union because of presumed links between phthalates (used in polyvinylchloride) and certain chronic conditions.<sup>[111,112]</sup>

Table II shows studies examining the shock absorbing capability of various mouthguard materials; table III presents other physical characteristics including hardness, tear strength, tensile strength and water absorbency. Materials were placed into broad groups for ease of analysis, and to compare the general properties of the materials. However, this sometimes masks subtle differences due to variations in the chemical composition. For example, the properties of EVA can vary depending on the proportion of PVA as well as the type of filler material. More vinyl acetate results in a more flexible, softer, and tougher material while less vinyl acetate results in a stiffer, harder material.<sup>[97]</sup> For this reason, table II and table III also present the ranges for the physical characteristics.

In many reviewed studies only the commercial name of some of the materials was provided.<sup>[91,92,97,98,100-104,106-108,115]</sup> The general category of material (e.g. EVA, polyurethane, latex) often had to be obtained from internet advertising, by calling the manufacturer, or could not be obtained at all. In most cases, it was not possible to determine more discriminating characteristics of the material (e.g. proportion of PVA in EVA, fillers and oils in silicon) because the material was no longer commercially available or because these characteristics were proprietary. A few studies did provide detailed information on some materials, allowing a comparison within different material types.<sup>[93,96,113]</sup>

It is obvious from tables II and III that EVA was the most studied material. As the proportion of PVA in the EVA copolymer increased, shock absorbency increased and water absorbency decreased; however, hardness and tear strength also decreased.<sup>[93]</sup> As the thickness of EVA increased, there was an increase in shock absorbing capability.[97,102,114,115] One study showed that after a thickness of 4mm, there was little additional improvement in shock absorption,<sup>[115]</sup> but another investigation showed substantial and almost linear improvements in shock thickness absorbency as increased through 5.2mm.<sup>[114]</sup> The inclusion of systematic air cells in EVA copolymers improved shock absorbency by 19-32%.[103,104] The inclusion of air cells spaced at random by use of a foam material had no influence on shock absorbency.<sup>[99]</sup>

Compared with EVA, most tested polyurethane compounds had generally similar shock absorbency and hardness but higher tear strength and tensile strength.<sup>[91,92,108]</sup> Polyurethane compounds generally absorbed more water than most EVA compounds.<sup>[91,92]</sup> Sorbathane (a type of visco-elastic polyurethane) laminated between EVA sheets re-

#### Table II. Studies examining mouthguard material shock absorbing capability

Study (year)	Materials	Impactor	Shock absorption measure	Value for shock absorption, range (mean $\pm$ SD), [number of samples tested of similar materials]
Craig and	1. EVA 1.5mm thick <sup>b</sup>	Pendulum (steel ball	Pendulum rebound (amount	1. 58% [1]
Goodwin <sup>[91] a</sup>	2. PU 1.5mm thick	contacted material)	pendulum swung past vertical	2. 47–84% (65 ± 16%) [4]
(1967)	3. Rubber latex 1.5mm thick		after contact with material;	3. 37% [1]
	4. 'Thermoplastic' 1.5mm thick		higher value is more energy	4. 56% [1]
	5. Plastisol (vinyl resin) 1.5mm thick		absorbed)	5. 87% [1]
Going et al. <sup>[92] a</sup>	1. EVA 25mm thick	Pendulum	Pendulum rebound	1. 45–57% (50 ± 4%) [12]
(1974)	2. PU 25mm thick		(% rebound of pendulum;	2. 59% [1]
	3. PVC 25mm thick		100% = no energy absorption,	3. 12–26% (22 ± 4%) [9] <sup>c</sup>
	4. Rubber latex 25mm thick		0% = all energy absorbed)	4. 75% [1]
	5. Acrylic resin 25mm thick			5. 18% [1]
	6. Silicon 25mm thick			6. 73/85% (79 ± 9%) [2]
Loehman et	1. EVA	Pendulum	Pendulum rebound	1. 48/45% (47 ± 2) [2]
al. <sup>[113] d</sup> (1975)	2. PU		(% rebound of pendulum;	2. 59% [1]
	3. PVC		100% = no energy absorption,	3. 12% [1]
	4. Acrylic		0% = all energy absorbed)	4. 18% [1]
	5. Silicon			5. 58-86% (76 ± 12) [6]
Bishop et al. <sup>[93]</sup>	1. EVA (PE, 33% PVA), 3.2mm thick	Drop weight (8g steel	Energy absorbed (calculated	1. 29mJ [1]
(1985)	2. EVA (PE, 28% PVA), 3.2mm thick	ball contacted	from mass, gravity, and	2. 29/29mJ (29 ± 0mJ) [2]
	3. EVA (PE, 24% PVA), 3.2mm thick	material)	rebound of dropped ball;	3. 30/31mJ (31 ± 0mJ) [2]
	4. EVA (PE, 18% PVA), 3.2mm thick		higher values is less energy	4. 31/31mJ (31 ± 0mJ) [2]
	5. EVA (PE, 13% PVA), 3.2mm thick		absorbed)	5. 32mJ [1]
	6. EVA (PE, 8% PVA), 3.2mm thick			6. 32mJ [1]
Park et al.[97]	1. EVA 1mm thick	Drop weight (large	Peak force (force on a	LB/SB:
(1994)	2. EVA 1.5mm thick	steel ball = 473g,	transducer under test material	1. 7605N [1] / 3146N [1]
	3. EVA 2mm thick	drop = 25cm; small	tested when weight struck	2. 3970N [1] / 1908N [1]
	4. EVA 4mm thick	steel ball = 67g, drop	material; lower value is more	3. 2791N [1] / 1743N [1]
	5. EVA 4mm thick; hard material in center	= 86cm)	shock absorption)	4. 2371N [1] / 1028N [1]
				5. 1867N [1] / 1093N [1]

Study (year)	Materials	Impactor	Shock absorption measure	Value for shock absorption, range (mean $\pm$ SD), [number of samples tested of similar materials]
Westerman and Stringfellow <sup>[102]</sup> (1995)	<ol> <li>EVA 1mm thick</li> <li>EVA 2mm thick</li> <li>EVA 3mm thick</li> <li>EVA 4mm thick</li> <li>EVA 5mm thick</li> </ol>	Pendulum (impact energy: heavy = 13J, light = 4J)	Peak force (calculated from accelerometer on pendulum [force = mass × acceleration]; lower value is more shock absorption)	HP/LP: 1. 30.7kN [1] / no measurement 2. 20.1kN [1] / no measurement 3. 13.3kN [1] / 7.6kN [1] 4. 9.8kN [1] / 7.2kN [2] 5. No measurement / 5.9kN [1]
Auroy et al. <sup>[96]</sup> (1996)	<ol> <li>EVA 4.5mm thick</li> <li>Styrol polyolefin 4.5mm thick</li> <li>Stock silicon rubber 4.5mm thick</li> <li>Silicon rubber combinations 4.5mm thick<sup>o</sup></li> </ol>	Pendulum (impact force = 3000N)	Proportion of force absorbed (peak force with material/ peak force without material × 100%; lower value is more shock absorbed )	1. 14/17% (15 ± 2) [2] 2. 19% [1] 3. 8–14% (11 ± 3) [6] 4. 8–20% (12 ± 4) [18]
Westerman et al. <sup>[103]</sup> (1997)	<ol> <li>EVA 4mm thick</li> <li>EVA (2×2×2 air cells, 2mm walls)</li> <li>EVA (2×2×2mm air cells, 1mm walls)</li> <li>EVA (3×3×2mm air cells, 1mm walls)</li> <li>3 and 4 were 4mm thick overall)</li> </ol>	Pendulum (impact energy ≈4J)	Peak force (calculated from accelerometer on pendulum [force = mass × acceleration]; lower value is more shock absorption)	1. 7.6kN [1] 2. 5.5kN [1] 3. 6.2kN [1] 4. 5.1kN [1]
Bulsara and Matthews <sup>[114]</sup> (1998)	<ol> <li>EVA 1.3mm thick</li> <li>EVA 2.1mm thick</li> <li>EVA 3.3mm thick</li> <li>EVA 3.3mm thick</li> <li>EVA 3.4mm thick</li> <li>EVA 4.0mm thick</li> <li>EVA 4.0mm thick</li> <li>EVA 4.3mm thick</li> <li>EVA 5.1mm thick</li> <li>EVA 5.2mm thick</li> <li>EVA 5.2mm thick</li> <li>EVA 4.1.1mm sorbothane, 2.3mm thick</li> <li>EVA + 1.1mm sorbothane, 3.4mm thick</li> <li>EVA + 1.1mm sorbothane, 3.4mm thick</li> <li>EVA + 1.1mm sorbothane, 4.2mm thick</li> <li>EVA + 2.7mm sorbothane, 4.9mm thick</li> <li>EVA + 2.7mm sorbothane, 5.6mm thick</li> </ol>	Drop weight (418.1g mass dropped 10cm)	Peak force (force on a transducer under test material when weight struck material; lower value is more shock absorption)	1. 4109N [1] 2. 3498N [1] 3. 3327N [1] 4. 3091N [1] 5. 2683N [1] 6. 2738N [1] 7. 2183N [1] 8. 2064N [1] 9. 2234N [1] 10. 2126N [1] 11. 1928N [1] 12. 1558N [1] 13. 1345N [1] 14. 1139N [1]

Study (year)	Materials	Impactor	Shock absorption measure	Value for shock absorption, range (mean $\pm$ SD), [number of samples tested of similar materials]
Westerman et al. <sup>[98]</sup> (2000)	<ol> <li>EVA 5mm thick</li> <li>EVA, hard insert at ≈1mm, 4.8mm thick</li> <li>EVA, hard insert at ≈2mm, 4.8mm thick</li> <li>EVA, hard insert at ≈3mm, 4.8mm thick</li> <li>EVA, hard insert at ≈4mm, 4.8mm thick</li> </ol>	Pendulum (impact energy = 1J)	Peak force (force on a transducer located under test material when pendulum struck material; lower value is more shock absorption)	1.10.4N [1] 2.15.1N [1] 3.15.6N [1] 4.13.8N [1] 5.12.1N [1]
Jagger et al. <sup>[106]</sup> (2000)	<ol> <li>EVA 4mm thick</li> <li>Silicon rubber, stock, 4mm thick</li> <li>Silicon rubber, experimental, 4mm thick</li> </ol>	Piston compression at 10 mm/min (forces of 500, 1000 and 1500N)	Energy absorption (energy used in compression; higher value is more energy absorption)	500/1000/1500N: 1. 76J [1] / 670J [1] / 1087J [1] 2. 221J [1] / 427J [1] / 588J [1] 3. 268J [1] / 475J [1] / 597J [1]
Westerman et al. <sup>[104]</sup> (2002)	<ol> <li>EVA 4mm thick</li> <li>EVA (2×2×2mm air cells, 1mm walls)</li> <li>EVA (2×2×2mm air cells, 2mm walls)</li> <li>EVA (3×3×2mm air cells, 1mm walls)</li> <li>3 and 4 were 4mm total thickness)</li> </ol>	Pendulum (impact energy = 4.4J)	Peak force (calculated from accelerometer on pendulum [force = mass × acceleration]; lower value is more shock absorption)	1. 7.6kN [1] 2. 5.5kN [1] 3. 6.2kN [1] 4. 5.1kN [1]
Westerman et al. <sup>[99]</sup> (2002)	<ol> <li>EVA 4mm thick</li> <li>EVA 1% foaming agent 4mm thick</li> <li>EVA 5% foaming agent 4mm thick</li> <li>EVA 10% foaming agent 4mm thick</li> </ol>	Pendulum (impact energy = 4.4J)	Peak force (pendulum force on a transducer located under test material; lower value is more shock absorption)	1. 4.0kN [1] 2. 4.1kN [1] 3. 4.1kN [1] 4. 3.9kN [1]
Westerman et al. <sup>[115]</sup> (2002)	<ol> <li>EVA 2mm thick</li> <li>EVA 3mm thick</li> <li>EVA 4mm thick</li> <li>EVA 5mm thick</li> <li>EVA 6mm thick</li> </ol>	Pendulum (impact energy = 4.4J)	Peak force (pendulum force on a transducer located under test material; lower value is more shock absorption)	1. 15.7kN [1] 2. 11.4kN [1] 3. 4.4kN [1] 4. 4.0kN [1] 5. 3.9kN [1]
Craig and Godwin <sup>[94] a</sup> (2002)	1. EVA 2. Polyethylene foam	Pendulum (impact energy = 1.1J)	Pendulum rebound (% of impact energy absorbed; higher value is more shock absorption)	1. 81–91% (86 ± 4) [5] 2. 87% [1]
Low et al. <sup>[107]</sup> (2002)	<ol> <li>EVA 1mm thick</li> <li>EVA 3mm thick</li> </ol>	Piston compression (micro-indentation)	Energy absorption (portion of area under curve of indentation force vs penetration depth; lower value is more shock absorption)	1. 10–12% (11 ± 2) [2] <sup>e</sup> 2. 13% [1]

Knapik et al.

Study (year)	Materials	Impactor	Shock absorption measure
Takeda et al. <sup>[100]</sup> (2004)	EVA 3mm thick	Pendulum with different objects attached: a. Hard objects (wooden bat, steel ball) b. Soft objects (softball, baseball, field hockey ball, ice hockey puck, cricket ball)	Peak force (pendulum force measured on transducer located under test material; higher value indicates more shock absorption)
Takeda et al. <sup>[101]</sup> (2004)	EVA 3mm thick	Pendulum with different objects attached: a. Steel ball/wooden bat (hard objects) 1. Load cell 2. Accelerometer 3. Strain gauge b. Field hockey ball/ baseball (soft objects)	Variable measures – force for load cell, gravities for acceleration, deformation for strain gauge (value without material minus value with material/value without material × 100%).

a Composition of some commercial materials could not be determined.

Information on thickness was obtained from one of the authors. Information in the original paper is incorrect. b

- С Excludes soft liners.
- Some data are not original. Authors state that some previous data were from Going et al.<sup>[92]</sup> d
- e Only includes force of 50mN.

EVA = ethylene vinyl acetate; HP = heavy pendulum; LB = large ball; LP = light pendulum; PE = polyethylene; PU = polyurethane; PVA = poly vinyl acetate; PVC = poly vinyl chloride; **SB** = small ball.

1. Load cell

2. Accelerometer

3. Strain gauge

Value for shock absorption, range (mean  $\pm$  SD), [number of samples tested

a. Wooden bat 38%, steel ball 62% [2]

b. Softball 1%, baseball 2%, field hockey

ball 4%, ice hockey puck 6%, cricket ball

of similar materials]

4% [5]

Steel ball:

a1. 62% [1]

a2. 81% [1]

a3. 81% [1]

a1. 38% [1] a2 58% [1]

a3. 76% [1] Hockey ball: b1. 4% [1]

b2. 16% [1]

b3. 46% [1]

Baseball: b1. 2% [1] b2. 3% [1] b3. 24% [1]

Baseball bat:

Table III. Studies examining mouthguard material hardness, tear strength, tensile strength and water absorption (empty cell indicates that characteristic was not investigated in the	
study)	

Study (year)	Materials	Hardness <sup>a</sup> range (mean ± SD) [number of samples of similar materials tested]	Tear strength <sup>b</sup> (N/cm) range (mean ± SD) [number of samples of similar materials tested]	Tensile strength <sup>b</sup> (MPa) range (mean ± SD) [number of samples of similar materials tested]	Water absorbency <sup>c</sup> (mg/cm <sup>2</sup> or % weight increase) range (mean ± SD) [number of samples tested of similar materials]
Craig and Godwin <sup>[91] d</sup> (1967)	<ol> <li>EVA 1.5mm thick<sup>e</sup></li> <li>PU 1.5mm thick</li> <li>Rubber latex 1.5mm thick</li> <li>'Thermoplastic' 1.5 mm thick</li> <li>Plastisol (vinyl resin) 1.5 mm thick</li> </ol>	1. 67–90 (80 ± 8) [6] 2. 68–88 (78 ± 9) [4] 3. 35 [1] 4. 75 [1] 5. 66 [1]	1. $245-455$ ( $347 \pm 101$ ) [6] 2. $420-1436$ ( $810 \pm 438$ ) [4] 3. $280$ [1] 4. $280$ [1] 5. $280$ [1]	1. 7-14 (10 ± 3) [6] 2. 19-39 (30 ± 9) [4] 3. 5 [1] 4. 8 [1] 5. 14 [1]	1. 0.01–0.05 (0.03 ± 0.02) [6] 2. 0.47–1.43 (0.76 ± 0.45) [4] 3. No data reported 4. 0.05 [1] 5. 0.08 [1] (Units: mg/cm <sup>2</sup> )
Going et al. <sup>[92] d</sup> (1974)	<ol> <li>EVA 25mm thick</li> <li>PU 25mm thick</li> <li>PVC 25mm thick</li> <li>Rubber latex 25mm thick</li> <li>Acrylic resin 25mm thick</li> <li>Silicon 25mm thick</li> </ol>	1. 68–86 (83 ± 4) [25] 2. 82 [1] 3. 79–85 (82 ± 2) $[10]^{f}$ 4. 66 [1] 5. 92 [1] 6. 25/63 (44 ± 27) [2]	1. $210-368$ ( $310 \pm 42$ ) [25] 2. $350$ [1] 3. $263-735$ ( $574 \pm 120$ ) [10] <sup>4</sup> 4. No data reported 5. $166$ [1] 6. $88/158$ ( $123 \pm 49$ ) [2]	1. 3-20 (11 ± 5) [25] 2. 7 [1] 3. 8-17 (14 ± 3) [10] <sup>1</sup> 4. 17 [1] 5. 9 [1] 6. 2/9 (6 ± 5) [2]	1. 0.13–2.07 (0.48 $\pm$ 0.37) [25] 2. 0.61 [1] 3. 0.32–0.88 (0.63 $\pm$ 0.19) [10] <sup>f</sup> 4. 2.11 [1] 5. 1.38 [1] 6. 0.35/0.36 (0.36 $\pm$ 0.01) [2] (Units: % increase weight)
Loehman et al. <sup>[113]</sup> (1975)	1. EVA 2. PU 3. PVC 4. Acrylic 5. Silicon		1. 280/359 (320 ± 56) [2] 2. 350 [1] 3. 613 [1] 4. 166 [1] 5. 63–151 (112 ± 32) [6]	1. 3/20 (12 ± 12) [2] 2. 7 [1] 3. 9 [1] 4. 9 [1] 5. 3–5 (4 ± 1) [6]	
Bishop et al. <sup>[93]</sup> (1985)	1. EVA (PE, 33%PVA) 3.2mm thick 2. EVA (PE, 28%PVA) 3.2mm thick 3. EVA (PE, 24%PVA) 3.2mm thick 4. EVA (PE, 18%PVA) 3.2mm thick 5. EVA (PE, 13%PVA) 3.2mm thick 6. EVA (PE, 8%PVA) 3.2mm thick		1. 249 [1] 2. $305/384 (345 \pm 56)$ [2] 3. $294/370 (332 \pm 54)$ [2] 4. $395/409 (402 \pm 10)$ [2] 5. $621 [1]$ 6. $749 [1]$		1. 0.35 [1] 2. 0.37/0.37 (0.37 $\pm$ 0.00) [2] 3. 0.31/0.30 (0.30 $\pm$ 0.01) [2] 4. 0.13/0.11 (0.12 $\pm$ 0.02) [2] 5. 0.06 [1] 6. 0.07 [1] (Units: mg/cm <sup>2</sup> )
Wilkinson and Powers <sup>[108]</sup> (1986)	1. EVA 2.0–3.9mm thick 2. 'Soft' PU 2.1–2.8mm thick 3. 'Hard' PU 2.3–3.1mm thick 4. Rubber 2.0–2.2mm thick	1. 75–96 (86 ± 6) [10] <sup>g</sup> 2. 72 [1] 3. 87 [1] 4. 69 [1]	1. 363–542 (436 ± 80) [6] 2. 329 [1] 3. 488 [1] 4. 288 [1]		

Table III. Conte	d				
Study (year)	Materials	Hardness <sup>a</sup> range (mean $\pm$ SD) [number of samples of similar materials tested]	Tear strength <sup>b</sup> (N/cm) range (mean ± SD) [number of samples of similar materials tested]	Tensile strength <sup>b</sup> (MPa) range (mean ± SD) [number of samples of similar materials tested]	Water absorbency <sup>c</sup> (mg/cm <sup>2</sup> or % weight increase) range (mean ± SD) [number of samples tested of similar materials]
Park et al. <sup>[97]</sup> (1994)	<ol> <li>EVA 1mm thick</li> <li>EVA 1.5mm thick</li> <li>EVA 2mm thick</li> <li>EVA 2mm thick</li> <li>EVA 4mm thick</li> <li>EVA 4mm thick; hard material in centre</li> </ol>				<ol> <li>No data reported</li> <li>No data reported</li> <li>No data reported</li> <li>1.40 [1]</li> <li>1.24 [1]</li> <li>(Units: % increase weight)</li> </ol>
Auroy et al. <sup>[96]</sup> (1996)	<ol> <li>EVA 4.5mm thick</li> <li>Styrol polyolefin 4.5mm thick</li> <li>Stock silicon rubber 4.5mm thick</li> <li>Silicon rubber mixtures 4.5mm thick<sup>h</sup></li> </ol>	1. 78/75 (77 ± 2) [2] 2. 82 [1] 3. 28–67 (43 ± 15) [6] 4. 18–70 (42 ± 19) [18]			
Jagger et al. <sup>[106]</sup> (2000)	<ol> <li>EVA 4mm thick</li> <li>Silicon rubber, stock, 4mm thick</li> <li>Silicon rubber, experimental, 4mm thick</li> </ol>	1. 89 [1] 2. 56 [1] 3. 40 [1]	1. 350 [1] 2. 170 [1] 3. 190 [1]	1. 19 [1] 2. 5 [1] 3. 7 [1]	
Tran et al. <sup>[116]</sup> (2001)	<ol> <li>EVA 1mm thick</li> <li>EVA 2mm thick</li> <li>EVA 3mm thick</li> <li>EVA 5mm thick</li> </ol>	1. 85 [1] 2. 84 [1] 3. 84 [1] 4. 84 [1]		1. 17 [1] 2. 15 [1] 3. 12 [1] 4. 9 [1]	<ol> <li>No data reported</li> <li>No data reported</li> <li>No data reported</li> <li>0.98 [1]</li> <li>(Units: % increase in weight)</li> </ol>
Craig and Godwin <sup>[94]</sup> (2002) <sup>d</sup>	1. EVA 2. PVC 3. PE foam	1. 75–81 (77 ± 2) [7] 2. 95 [1] 3. 26 [1]	1. 325–565 (437 ± 88) [5] 2. No data reported 3. 68 [1]		1. 0.14-0.25 (0.19 ± 0.05) [6] 2. 0.30 [1] 3. 4.10 [1]

0

a For entire column, studies measure 'A' hardness; complete penetration = 0, no penetration = 100.

b For entire column, exact methods differed slightly by study.

c For entire column, specimen at 37°C for at least 24 hours.

- d Composition of some commercial materials could not be determined.
- e Information on thickness was obtained from one of the authors. Information in the original paper is incorrect.
- f Excludes soft liners.
- g Includes hard and soft 'sides'.
- h Combinations of various silicon oils and cloth fillers.

EVA = ethylene vinyl acetate; PE = polyethylene; PU = polyurethane; PVA = poly vinyl acetate; PVC = poly vinyl chloride.

(Units: % increase weight)

Mouthguard History, Properties and Effectiveness

sulted in more effective shock absorbency than equal or near equal thicknesses of EVA alone.<sup>[114]</sup>

Latex rubber was a popular material early in the development of mouthguards.<sup>[39,40,117]</sup> However, material studies suggested that this compound has lower shock absorbency, lower hardness, and less tear and tensile strength than EVA or poly-urethane.<sup>[91,92]</sup>

There were few studies of acrylic resins or polyvinylchloride.<sup>[92,94,113]</sup> Available investigations showed that compared with EVA and polyurethane, acrylic materials appear to have higher shock absorbing capability, with lower hardness, lower tear strength, similar tensile strength, and higher water absorption. Compared with EVA and polyurethane, polyvinylchloride is higher in shock absorbing capability, with similar hardness, tensile strength and water absorption.

Silicon rubber compounds have been advocated for use in mouthguards.<sup>[96,113]</sup> The physical properties of this class of compounds can be modified by manipulating the amount of silicon oils and/or filler material to achieve higher shock absorbency than some EVA materials.<sup>[96,106]</sup> However, hardness, tear strength and tensile strength of silicon rubber compounds appear to be lower than EVA, polyurethane or polyvinylchloride.<sup>[96,106,113]</sup> Because of their lower hardness, silicon rubbers are more effective at absorbing shock at lower impact energies.<sup>[106]</sup>

#### 3.3 Studies on the Protective Capabilities of Entire Mouthguards

Because of obvious ethical concerns, no impact studies on the protective capabilities of entire mouthguards have been performed on live human subjects, although one study did examine force damping during weight unloading in human subjects.<sup>[118]</sup> Generally, studies involve a tooth (e.g. plaster cast teeth) or an artificial skull model, but there was no standardisation of these models. In addition, studies differ in terms of impact techniques, anatomical area of impact application, and outcome measures. Table IV shows 17 studies involving entire mouthguards (arranged by year of publication) and how they differ in terms of methodological characteristics and outcomes. In table IV, only studies comparing mouthguard conditions versus no mouthguard are contrasted in terms of the reduction in the outcome measure. Despite the differences in methodology, impact studies have shown that compared with no mouthguard, mouthguards composed of many types of materials reduce intracranial pressure and mandibular deformation,<sup>[45,119]</sup> reduce the number of fractured teeth at a given force,<sup>[44,120,121]</sup> increase the force required to fracture teeth,<sup>[122,123]</sup> decrease forces transmitted to the teeth,<sup>[124,125]</sup> decrease head or tooth acceleration<sup>[45,105]</sup> and dampen impact forces.<sup>[118,126]</sup> However, the force required to fracture teeth may be similar for no mouthguards and custom-made mouthguards if the latter is composed of thin material.<sup>[95,123]</sup>

Although methodological differences among studies must be kept in mind, several general factors emerge that seem to be important for mouthguard construction. As the thickness of the labial area increases, the shock absorbing capability of the mouthguard increases during direct anterior impacts to the incisors.<sup>[44,121,123,124,130]</sup> Labial thicknesses above  $\approx$ 9mm appear to add little additional protective capability.<sup>[121]</sup>

Mouthguard construction can interact with thickness to influence shock absorbing capability.<sup>[44,125,127]</sup> A double layer of material (2mm and 3mm thick) separated by a sponge provided the most effective shock absorption in one study.<sup>[125]</sup> The inclusion of a stainless steel arch or foil has shown equivocal results,<sup>[44,125,128]</sup> but it is reasonable to assume that an arch of this material might assist in distributing forces more evenly across the teeth, and should be investigated further.<sup>[125]</sup> On the other hand, a metal arch may cause additional injury if it escapes the softer mouthguard material and contacts the teeth or soft tissue. Large labial and/or palatal flanges or an exterior air gap cushion do little to reduce the possibility of tooth fracture.<sup>[121]</sup> Materials used to make custom mouthguards can lose considerable thickness during fabrication,<sup>[46,95,110,132]</sup> indicating that the final thickness should be measured and controlled.

Custom-made mouthguards composed of EVA resulted in less tooth deflection (greater cushioning effect) and fewer fractured teeth than boil-andbite mouthguards composed of similar material.<sup>[121,124,128]</sup> However, custom-made mouthguards Table IV. Characteristics of studies examining various outcome measures with and without mouthguards

Study (year)	Model	Mouthguard material	Impactor	Area of impact	Outcome measure	Reduction in outcome measure with mouthguard <sup>a</sup>
Hickey <sup>[119]</sup> (1967)	Cadaver skull	Latex rubber	Piston	Inferior boarder of mandible	<ol> <li>Intracranial pressure</li> <li>Mandibular deformation</li> </ol>	1. 43% <sup>b</sup> 2. 44% <sup>b</sup>
Godwin and Craig <sup>[127]</sup> (1968)	Acrylic/plaster maxillary cast, teeth coated with lacquer	EVA PU Latex Silicon <sup>c</sup>	Pendulum	Central incisors and premolar/molar region	1. Force absorption 2. Lacquer crack patterns	d
Watermeyer et al. <sup>[44]</sup> (1985)	Plaster cast teeth	EVA EVA and steel arch	Pendulum	Incisors	Number of fractured teeth	36-100% <sup>b,e</sup>
Dikarinenen et al. <sup>[123]</sup> (1993)	Plaster cast teeth	EVA PU	Drop weight	Central incisors	Force to cause tooth fracture	0-600% <sup>b,e</sup>
Johnson and Messer <sup>[122]</sup> (1996)	Sheep teeth	EVA	Piston	Central incisors	<ol> <li>Force to cause tooth fracture</li> <li>Lateral luxation</li> </ol>	1. 1335% <sup>f</sup> 2. 90% <sup>f</sup>
Greasley and Karet <sup>[120]</sup> (1997)	Plaster teeth/ rubber composite base	EVA	Drop weight	Central incisors	Number of fractured teeth	43% <sup>g</sup>
Greasley et al. <sup>[121]</sup> (1998)	Plaster teeth/ rubber composite base	EVA EVA/styrene butadiene	Drop weight	Central incisors	Number of fractured teeth	25–92% <sup>e</sup>
deWet et al. <sup>[125]</sup> (1999)	Artificial skull	EVA EVA and steel arch EVA and sponge	Pendulum	Maxillary teeth <sup>h</sup>	Average force over time	26–56% <sup>e</sup>
Hoffman et al. <sup>[124]</sup> (1999)	Metal teeth	EVA	Pendulum	Incisors	Tooth displacement	9–59% <sup>b,e,i</sup>
Guevara et al. <sup>[95]</sup> (2001)	Plaster cast teeth	EVA	Drop weight	Incisors	<ol> <li>Fractured teeth</li> <li>Force absorbed (rebound)</li> </ol>	1. 0–100% <sup>b,e</sup> 2. 17–39% <sup>b,e,j</sup>
Bemelmanns and Pfeiffer <sup>[128]</sup> (2001)	Acrylic resin teeth	EVA EVA with PVC EVA with silicon	Pendulum	Incisors	Tooth displacement	d
Warnet and Greasley <sup>[129]</sup> (2001)	Plaster teeth/ rubber composite base	EVA	Drop weight	Central incisors	<ol> <li>Number of fractured teeth</li> <li>Force over time</li> </ol>	d
Craig and Godwin <sup>[94]</sup> (2002)	Plaster cast teeth	EVA Polyolefin foam	Pendulum	Unclear	Force absorption	72–94% <sup>e</sup>

#### Table IV. Contd

Study (year)	Model	Mouthguard material	Impactor	Area of impact	Outcome measure	Reduction in outcome measure with mouthguard <sup>a</sup>
Cummings and Spears <sup>[130]</sup> (2002)	Computerised finite element analysis	(Computer model)	Simulated soft object impact	Central incisor	Estimated peak tensile stresses in alveolar bone and enamel	d
Takeda et al. <sup>[131]</sup> (2004)	Artificial skull	EVA	Pendulum	Labial aspect of mandible	1. Mandibular displacement 2. Head acceleration	d
Takeda et al. <sup>[45]</sup> (2004)	Artificial skull	EVA	Pendulum	Left second premolar area of mandible	1. Mandibular displacement 2. Head acceleration	1. 55% <sup>k</sup> 2. 19% <sup>l</sup>
Takeda et al. <sup>[105]</sup> (2006)	'Dental study model' <sup>m</sup>	<ol> <li>EVA</li> <li>EVA with hard insert</li> <li>EVA with hard insert and space</li> </ol>	Pendulum	Incisors	Tooth acceleration	Steel ball (hard) 1. 40% 2. 37% 3. 49% Baseball (soft) 1. 4% 2. 12% 3. 25%

a Calculated from available data in article as no mouthguard - mouthguard/no mouthguard × 100%.

- Estimated from graphs in article. b
- Composition of some materials could not be determined. С
- Did not compare mouthguard with no mouthguard; only compared various mouthguard types. d
- Dependent on mouthguard material and construction as discussed in section 3.3. е
- Permanent teeth. f
- 10J drop weight impact, conical head. g
- Exact impact location not well specified in article. h
- Impact at marginal gingiva; uses average damage column in table I. i
- Percentage reduction in rebound calculated as mouthguard no mouthguard.
- Sum of displacement differences in three mandibular regions (range 31-73% reduction). k
- Sum of acceleration differences (mouthguard vs no mouthguard) in three head regions (range 2-47% reduction).
- m Article is not clear on nature of dental model.
- EVA = ethylene vinyl acetate; PU = polyurethane; PVC = poly vinyl chloride.

Sports Med 2007; 37 (2)

Knapik et al.

can differ considerably in the amount of protection offered.<sup>[95]</sup>

The trade-offs imposed by the area of occlusal support was emphasised by Takeda et al.<sup>[131]</sup> In their study, impacts were delivered to the inferior border of the mandible. As the occlusal area increased, mandibular displacement decreased. As the occlusal area decreased, acceleration of the head decreased, since much of the impact force was absorbed by displacement of the mandible. It was suggested that a larger occlusal area be used to reduce mandibular fracture.<sup>[131]</sup> Greater occlusal support also resulted in a faster decay rate of impact forces.<sup>[133]</sup>

## 3.4 Stiffness/Shock Absorption in Relation to Colliding Object and Mouth Characteristics

It is generally assumed that mouthguard material should be moderately hard or stiff with moderate shock absorbing capability.<sup>[91,92,94]</sup> This is assumed to provide optimal protection by redistributing forces over a larger area of tissues (hardness or stiffness) and by reducing forces on the tissues (shock absorption).<sup>[130]</sup> If too hard a material is used, high forces can be transmitted to the underlying tissues; if the material is too soft, it will compress excessively and forces will be delivered to a small area of tissue.

Besides stiffness and shock absorbing characteristics of the material, consideration should be given to the characteristics of the colliding object and the characteristics of the mouth. Almost all studies in tables II through IV have examined hard object collisions involving sudden, high impact forces. These studies model collisions that might be caused by objects like baseball bats, tennis racquets, goal posts, shoe spikes, and the like. In hard object collisions, thicker mouthguards composed of softer material are optimal because a soft material deforms on impact, increasing object contact time and resulting in a decrease in peak force. Soft object collisions are different. In soft object impacts (e.g. softballs, tennis balls, boxing gloves), thicker mouthguards may do little to improve shock absorbency<sup>[100,101]</sup> because the soft object itself deforms on collision and spreads the force over a larger area of tissue. In this case, stiffer materials may be optimal because stiffer materials assist in redistributing the force. Sportsspecific mouthguards may be one solution to the hard versus soft object dilemma, but many sports involve the potential for both types of collisions (e.g. baseball bat and softball; tennis racquets and tennis balls).<sup>[130]</sup>

Besides the impacting object, consideration must be given to the characteristics of the mouth. Different portions of the mouth may require different protective characteristics because of anatomy and tissue characteristics.<sup>[134]</sup> The occlusal surfaces of the teeth are less susceptible to concentrated high forces because of their large surface area which allows a more uniform force distribution. Thus, a softer material with good shock absorbing capability may be appropriate to protect these areas. On the other hand, the incisors are brittle and highly exposed to impact forces that could be concentrated in a small area. An intermediate material with moderate stiffness and moderate shock absorbency would assist in both redistributing forces over a larger surface area and absorbing shock. The gingiva is a soft tissue capable of absorbing some force, and it may be most appropriate to provide stiffer materials here to assist in force redistribution.

One approach to address these numerous considerations may be through the development of special laminates. Mouthguard material laminating techniques are widely available<sup>[59,97,109,110,135]</sup> and offer the possibility that layers with different stiffness and shock absorbing characteristics can be used to customise protective capability. Appropriate laminations might both absorb shock where needed and redistribute forces where this is the optimal solution.

Laminates composed of varying thicknesses of a rigid (stiff) upper layer and soft (less stiff) lower layer (in contact with the teeth/gingiva) have been modelled using finite element analysis.<sup>[134]</sup> In models with laminates of equal thickness (e.g. 2mm thick rigid top layer and 2mm thick soft lower layer), as the stiffness difference between the two layers increased, stress distribution across the teeth also increased; however, the force transmitted to the underlying tissue also increased. Thus, there appeared to be a conflict between stress distribution and shock absorbency.<sup>[91,92,94]</sup> On the other hand, by modelling different thicknesses for the rigid and soft layers, an adequate adjustment between stress distri-

bution and shock absorbency could be achieved. For example, an accommodation between stress distribution and shock absorbency was realised with the top 10% of the laminate rigid and the bottom 90% soft. This accommodation was best achieved when the difference in Young's modulus between the two layers differed by a factor of 1000–10 000.<sup>[134]</sup>

Despite computer modelling,<sup>[134]</sup> studies examining current laminates with different stiffness and hardness characteristics have not been promising. However, it is unclear whether the modulus differences between the rigid and soft layers hypothesised to provide protective effects<sup>[134]</sup> were achieved or even approximated. Westerman et al.<sup>[98]</sup> found that sandwiching a harder EVA layer within softer EVA layers did not improve shock absorbing capability (see table II). However, the hardness difference between the two materials was not large (Shore A hardness 80 vs 90) and the stiffness was not quantified. Greasley et al.<sup>[121]</sup> examined a harder and stiffer material (styrene butadiene, 3mm thick) over an EVA (2mm thick) and found that the number of teeth fractured on impact was similar to a 5mm thickness of the EVA alone. The stiffness/hardness characteristics of the materials were not specified and the ratio of hard to soft material was almost equal. Bemelmanns and Pfeiffer<sup>[128]</sup> laminated a hard polyvinylchloride material between two softer layers of EVA and found little difference in tooth displacement when the laminate was compared with other EVA mouthguards. The moduli of the materials were not specified, and the harder material may not have been optimally placed. Takeda et al.<sup>[105]</sup> placed a 1mm hard insert between two 3mm EVA layers. Compared with two 3mm EVA layers alone, the hard insert resulted in little difference in tooth acceleration when the dental model was impacted with either a steel ball or baseball; however, distortion of the tooth model was reduced  $\approx 60-70\%$  under the same conditions. Thus, there is considerable room for additional research in this area.

#### Mouthguards and Injuries

A total of 69 studies were found that provided original, quantitative data on mouthguard use and injury. Fourteen studies met the review criteria requiring data for mouthguard users and nonusers who were injured and not injured. Table V provides a summary of the methodology and results of these 14 studies arranged in chronological order (date of publication). Two investigations<sup>[86,136]</sup> reported on injuries to Philadelphia high school football players, all whom were wearing mouthguards. These data were combined with mouthguard nonuser data from a previously reported investigation by the same author in the same school system<sup>[137]</sup> examining injury differences in mouthguard users and nonusers.

With a few exceptions,<sup>[63,142,145,146]</sup> most studies required a secondary data analysis (as discussed in section 1) to statistically compare injury differences between mouthguard users and nonusers. For three studies,<sup>[63,145,146]</sup> a secondary data analysis was not necessary but it was conducted so the investigations could be compared more easily with other studies. Original data were obtained from one of the authors for this purpose.<sup>[63]</sup>

#### 4.1 Methodological Considerations in Injury Studies

There was only one prospective group randomised control study,<sup>[146]</sup> with the other investigations involving non-randomised interventions,[137,139] prospective cohorts,<sup>[63,142,145]</sup> one-group ecological interventions,<sup>[55,86,136]</sup> or cross-sectional<sup>[141,143,144]</sup> surveys. The one-group ecological studies compared injuries in groups of athletes before and after the introduction of mouthguards.[55,86,136] The cross-sectional surveys relied on recall of injuries and mouthguard use.<sup>[141,143,144]</sup> Sports activities in the 14 football,<sup>[86,136-141,143]</sup> included studies rugby,<sup>[55,63,142,146]</sup> basketball,<sup>[143-145]</sup> hockey<sup>[140,143]</sup> and a variety of other sports.<sup>[143]</sup> All three types of commercially available mouthguards (stock, boil-andbite and custom<sup>[112]</sup>) were examined in different studies, although custom mouthguards were the most frequently investigated.<sup>[86,136,137,142,144-146]</sup>

The injury case definitions for each study are summarised in the penultimate column of table V. The case definitions varied widely. In fact, only half of the studies explicitly stated their case definition or provided characterisations of the types of injuries included.<sup>[55,63,142-146]</sup> Other studies provided few details beyond a very general injury description.<sup>[86,136-141]</sup>

Study (year)	Study design	Group	No. of participants	Mouthguard type	Data collection	Injury case definitions and injury differences between mouthguard users and nonusers. Percent (%) is proportion of athletes with injuries of the type listed. p-Value is Chi-squared test of hypothesis of no difference between mouthguard users and nonusers <sup>a</sup>	Methodological quality score
Schoen <sup>[138]</sup> (1956)	Prospective cohort	US high school football	151 mouthguard users, 244 mouthguard nonusers	Custom latex and mouth- formed shell liner	'Inspections' (type not specified)	Injury to hard structures of mouth: mouthguard users = 0%; mouthguard nonusers = 11.7% (p < 0.01)	24
Cohen and Borish <sup>[137]</sup> (1958)	One-group ecological intervention	US high school football	84 custom mouthguard users, 596 mouthguard nonusers or stock mouthguard users	Custom or stock	Not clear	Head/face injury: custom mouthguard users = 0%; mouthguard nonusers or stock mouthguard users = $4.4\%$ (p = 0.10) Tooth injury: custom mouthguard users = 0%; mouthguard nonusers or stock mouthguard users = $3.5\%$ (p = 0.16)	21
Moon and Mitchell <sup>[139]</sup> (1961)	Team-level intervention	US high- school football	80 mouthguard users, 240 mouthguard nonusers	Boil-and-bite	Form completed by coaches for each injury	Dental injury: mouthguard users = 0%; mouthguard nonusers = 10.4% (p < 0.01)	30
Cohen and Borish <sup>[136]</sup> (1961) Cohen <sup>[86]</sup> (1962)	One-group ecological intervention	US high school football	2923 mouthguard users (1957–61), 596 mouthguard nonusers (1957)	Boil-and-bite, custom	Form completed by coaches for each injury	Tooth injury: mouthguard users = 0.1%, mouthguard nonusers 3.5% (p < 0.01)	23, 22 <sup>b</sup>

Table V. Contd

Study (year)	Study design	Group	No. of participants	Mouthguard type	Data collection	Injury case definitions and injury differences between mouthguard users and nonusers. Percent (%) is proportion of athletes with injuries of the type listed. p-Value is Chi-squared test of hypothesis of no difference between mouthguard users and nonusers <sup>a</sup>	Methodological quality score
Dunbar <sup>[140]</sup> (1962)	Not clear	US high school football and hockey	Football: 96 mouthguard users, 160 mouthguard nonusers. Hockey: 42 mouthguard users, 92 mouthguard nonusers	Any	Not clear	Football, mouth injury: mouthguard users = 0%, mouthguard nonusers = 1.9% (p = 0.45) Hockey, mouth injury: mouthguard users = 0%, mouthguard nonusers 3.3% (p = 0.60)	16
Bureau of Dental Education <sup>[141]</sup> (1963)	Cross-sectional survey	US high school football	39 371 mouthguard users, 5053 mouthguard nonusers or teams with nonusers	Any	Questionnaire mailed to high schools	Dental injury: mouthguard users = 1.5%, mouthguard nonusers or teams with nonusers = 2.1% (p < 0.01)	18
Blignaut et al. <sup>[142]</sup> (1987)	Prospective cohort	South African university rugby	321 players; 555 exposures <sup>c</sup>	Dentists provided almost 95% of all mouthguards	Player form completed after each match	Head/neck injury: mouthguard users = $15.5\%$ , mouthguard nonusers = $15.8\%$ (p = 0.91) Mouth/lip/tooth injury: mouthguard users = $4.6\%$ , mouthguard nonusers = $4.7\%$ (p = 0.97) Concussions: mouthguard users = $3.1\%$ , mouthguard nonusers = $2.6\%$ (p = $0.67$ )	37
McNutt et al. <sup>[143]</sup> (1989)	Cross-sectional survey	US junior and senior high school students; 18 sports	2167 mouthguard users, 303 mouthguard nonusers	Any	Preseason structured interview about past injuries and mouthguard use	Oral injury: mouthguard users = $2.6\%$ , mouthguard nonusers = $55.1\%$ (p < 0.01) Concussion: mouthguard users = $1.3\%$ , mouthguard nonusers = $11.9\%$ (p < 0.01)	38
Maestrello- deMoya and Primosch <sup>[144]</sup> (1989)	Cross-sectional survey	US high school basketball	43 mouthguard users, 977 mouthguard nonusers	18 stock, 16 boil-and-bite, 9 custom	Questionnaire mailed to coaches, completed by players	Orofacial injury: mouthguard users = 4.7%, mouthguard nonusers = 32.0% (p < 0.01)	30

Table V. Contd

Study (year)	Study design	Group	No. of	Mouthguard	Data collection	Injury case definitions and injury differences	Methodological
			participants	type		between mouthguard users and nonusers. Percent (%) is proportion of athletes with injuries of the type listed. p-Value is Chi-squared test of hypothesis of no difference between mouthguard users and nonusers <sup>a</sup>	quality score
Labella et al. <sup>[145]</sup> (2002)	Prospective cohort	US men's Division 1 basketball	50 colleges; 8663 exposures <sup>c</sup> with mouthguards, 62 273 exposures without mouthguards	Custom	Athletic trainers completed web- based form on a weekly basis	Soft tissue injury: mouthguard users = $0.69/1000$ athletic exposures, mouthguard nonusers = $1.06/1000$ athletic exposure (p = $0.28$ ) Dental injury: mouthguard users = $0.12/1000$ athletic exposure, mouthguard nonusers = $0.67/1000$ athletic exposure (p = $0.02$ ) Dental referrals: mouthguard users = $0/1000$ athletic exposure, mouthguard nonusers = $0.72/1000$ athletic exposure (p < $0.01$ ) Concussions: mouthguard users = $0.35/1000$ athletic exposure, mouthguard nonusers = $0.55/1000$ athletic exposure (p = $0.25$ )	50
Marshall et al. <sup>[63]</sup> (2005)	Prospective cohort	New Zealand rugby	240 men, 87 women; 12 252 exposures <sup>c</sup>	Any	Weekly telephone interview	Teeth/mouth/jaw injury: mouthguard users = $0.45/1000$ athletic exposures, mouthguard nonusers = $0.61/1000$ athletic exposures (p = $0.73$ ) Concussion: mouthguard users = $2.12/1000$ athletic exposures, mouthguard nonusers = $0.91/1000$ athletic exposures (p = $0.16$ )	71
Finch et al. <sup>[146]</sup> (2005)	Randomised group intervention	Australian rugby	111 mouthguard users; 190 controls (mouthguard users and nonuser)	Custom in mouthguard group; any or none in control group	Trained players systematically collected data	Head/orofacial injury: mouthguard users = 1.8 injury/1000 hours of play, mouthguard nonusers = 4.4/1000 hours of play (p < 0.01)	75
Quarrie et al. <sup>[55]</sup> (2005)	One-group ecological intervention	New Zealand rugby	121 900 players in 1998; 120 900 players in 2003 <sup>d</sup>	Any	Rugby-related dental injury claims 1995-2003	Dental claims: <sup>d,e</sup> 1998 (early mandatory mouthguard use) = 1.8%; 2003 (mandatory mouthguard use/enforcement capability) = 1.2% (p < 0.01)	44

a Chi-squared tests involve Yates correction for cell sizes <5.

b First number is for Cohen (1961);<sup>[86]</sup> the second number is for Cohen (1962).<sup>[136]</sup>

c An athletic exposure is one athlete involved in one game or practice session.

d These are years for which denominator data are provided. Methods of estimating player numbers differed slightly in the 2 years.

e Data show a progressive decline in rugby-related dental injury claims from 1996 to 2003. In 1997, mouthguards were mandatory for players under 19 years of age; in 1998, mouthguards were mandatory for all players; in 2003, referees could penalise players for not wearing mouthguards.

Mouthguard History, Properties and Effectiveness

A number of studies<sup>[86,136,137,146]</sup> compared groups wearing mouthguards versus groups composed of both mouthguard nonusers and some mouthguard users. Despite problems with designs of this type, if injury rates were lower in the group of exclusive mouthguard users, this implies the protective effect is at least as large as the magnitude of the effect observed in the study. That is, the mouthguard users in the 'nonuser group' would be expected to lower the injury incidence in the 'nonuser group' (if mouthguards reduced injury incidence), thus reducing the magnitude of the observed mouthguard effect.

The methodological quality scores ranged widely from 16 to 75 as shown in table V. Studies conducted in the 1950s and 1960s received much lower scores (16–30) compared with studies conducted in the 1980s and beyond (30–75). Many of the early studies, where injury case definitions are not clear and the use of mouthguards was still contentious, reported no injuries among the mouthguard users. Later studies reported a number of injuries among the mouthguard users.

Very few studies reported on compliance with use of the mouthguards,<sup>[55,139]</sup> but in some investigations the design was such that it was known whether or not mouthguards were worn for each specific injury.<sup>[63,145]</sup> Some studies involved retrospective questionnaires or interviews that asked athletes<sup>[143,144]</sup> or coaches<sup>[141]</sup> to remember previous injuries and whether or not mouthguards were worn when the injury occurred. These studies would be particularly susceptible to recall bias. It was striking that only one study used a randomised design<sup>[146]</sup> and only two studies performed multivariate analysis controlling for other factors that might influence injury rates.<sup>[63,146]</sup>

#### 4.2 Mouthguards and Injury Prevention

A number of issues complicated the meta-analysis of the injury studies. Some of the more recent studies<sup>[63,145,146]</sup> used athlete-exposures (e.g. one athlete in one game) or athlete-hours of play in the denominator. Athlete-exposures and athlete-hours are sports medicine surrogates for the epidemiological concept of person-time at risk. Studies using athlete-exposures or athlete-hours would need to be excluded from the analysis if the Mantel-Haenszel or Peto meta-analysis methods<sup>[67]</sup> had been used, because those methods require data to complete a  $2 \times 2$  table of a single outcome by treatment for each study. This exclusion could bias the results. Therefore, a general variance-based method was considered that used risk ratios and their confidence intervals.<sup>[67]</sup> However, a problem with this approach was that many of the older studies<sup>[137-140]</sup> reported no injuries in the group of mouthguard users, and risk ratios cannot be determined when one of the cells contains a zero value. To solve this problem, the value of 0.5 was added to each cell and used in the estimate of the risk ratio if any of the cells in the  $2 \times 2$  table contained a zero.<sup>[147]</sup>

Knapik et al.

 
 Table VI. Data used in the general variance based meta-analysis of studies examining influence of mouthguards on orofacial injuries and concussions

Study (year)	Risk ratio	95% CI	
	(nonusers/	00/001	
	users)		
Orofacial injuries			
Schoen <sup>[138]</sup> (1956) <sup>a</sup>	36.60	2.25-594.71	
Cohen et al. <sup>[86,136,137]</sup> (1958, 1961, 1962) <sup>b</sup>	34.33	10.27–114.73	
Moon and Mitchell <sup>[139]</sup> (1961) <sup>a</sup>	17.14	1.06–278.31	
Dunbar <sup>[140]</sup> (1962) <sup>a,c</sup>	4.22	0.22-80.78	
	3.24	0.17-61.42	
Bureau of Dental Education <sup>[141]</sup> (1963)	1.45	1.18–1.78	
Blignaut et al. <sup>[142]</sup> (1987) <sup>d</sup>	1.02	0.46-2.23	
McNutt et al.[143] (1989)	21.72	16.41–28.73	
Masestrello-deMoya and Primosch <sup>[144]</sup> (1989)	6.89	1.77–26.74	
Labella et al. <sup>[145]</sup> (2002) <sup>e</sup>	5.84	0.80-42.42	
Marshall et al. <sup>[63]</sup> (2005) <sup>f</sup>	1.35	0.25-7.39	
Finch et al.[146] (2005)	2.44	2.20-2.71	
Quarrie et al.[55] (2005)	1.48	1.39–1.58	
Concussion			
Blignaut et al. <sup>[142]</sup> (1987)	0.81	0.29–2.23	
McNutt et al.[143] (1989)	9.20	5.70-14.85	
Labella et al.[145] (2002)e	1.58	0.48-5.13	
Marshall et al. <sup>[63]</sup> (2005) <sup>f</sup>	0.43	0.13–1.45	

a 0.5 substituted in each cell to obtain risk ratio.[147]

b Tooth injuries.

- c First row of numbers is for football players, second row of numbers is for hockey players.
- d Mouth/lip/tooth injuries.
- e Dental injuries.

f Data obtained from author to calculate risk ratio.

Table VII. Summary of relative risk (with confidence intervals) of orofacial injury and concussion from meta-analysis using general variance
based method

Analyses	Orofacial injuries		Concussions	
	no. of studies	risk ratio <sup>a</sup> (95% CI)	no. of studies	risk ratio <sup>a</sup> (95% CI)
All studies	13 <sup>b</sup>	1.86 (1.76–1.96)	4	3.94 (2.69-5.80)
Pre-1980 studies	6 <sup>b</sup>	1.64 (1.34–2.00)	0	
Post-1980 studies	7	1.87 (1.78–1.98)	4	3.94 (2.69-5.80)
All non-questionnaire studies	10	1.70 (1.61–1.79)	3	0.82 (0.43-1.58)
Pre-1980 non-questionnaire studies	5 <sup>b</sup>	1.64 (1.34–2.00)	0	
Post-1980 non-questionnaire studies	5	1.70 (1.61–1.80)	3	0.82 (0.43-1.58)

Mouthguard nonusers/mouthguard users

In the Dunbar article,<sup>[140]</sup> football and hockey players were considered separate cohorts; data from three Cohen et al. b articles<sup>[86,136,137]</sup> were combined and considered as a single study.

Separate analyses were performed on the pre-1980<sup>[136,138-141]</sup> and post-1980<sup>[55,63,142-146]</sup> studies because of the generally better methodological quality of the latter. Also, separate analyses were performed eliminating studies that involved retrospective recall of injuries and mouthguard use.[141,143,144]

Table VI shows the relative risk ratios and 95% confidence intervals used in the meta-analysis. Since the three Cohen et al. studies<sup>[86,136,137]</sup> contained information collected on successive years (as noted above), data from these three studies were combined (tooth injuries only). The Dunbar study<sup>[140]</sup> examined independent cohorts of football and hockey players, so each was considered separately; however, whether the study was treated as one cohort or two had little influence on the overall results.

Table VII contains the summary risk ratios and 95% confidence intervals from the general variancebased method. For orofacial injuries, risk is higher among mouthguard nonusers whether considering all studies, considering pre- or post-1980 studies, or when eliminating studies involving retrospective recall. Risk ratios ranged from 1.6 to 1.9 for the different groups of studies examined.

Table VII also shows the risk ratios and 95% confidence intervals derived from the meta-analysis of studies involving concussions. Compared with mouthguard users, the overall risk of a concussion among mouthguard nonusers is very high (risk ratio = 3.9) when all studies are considered. However, eliminating only one study<sup>[143]</sup> that used retrospective recall (average quality score of 38) changed the risk ratio to 0.8, suggesting that concussion risk was higher in mouthguard users. However, given the width of the confidence intervals this should be interpreted as a lack of evidence for concussion prevention.<sup>[148]</sup> The inconsistency among studies is problematic and makes it impossible to determine conclusively whether mouthguards reduce concussion risk at present. Further research of good methodological quality is needed regarding mouthguards and concussion.

#### 4.3 Mouthguard Injury-Related Studies not Reviewed

Numerous studies that had information on both mouthguards and injuries were not considered for review because they lacked one or more required pieces of data. Many investigations contained information on mouthguard users and nonusers who were injured but did not contain the same information on those who were not injured. [8-10,12-16,19,20,22,23,26,149-154] In one case, data was reported on mouthguard users and nonusers who were not injured but the same data was not presented on those who were injured.<sup>[25]</sup>

Some studies reported aggregate data for state or local school systems, and denominator or proportional injury data could not be properly determined.[155-157] Some studies reported aggregated multiple injuries rather than injury incidence (participants with one or more injuries); since Chisquared analysis requires independent data in each cell, an analysis of this type could not be performed.<sup>[158,159]</sup>

One investigation included case studies and did not provide denominator data.<sup>[160]</sup> In other studies, denominator data was not partitioned into mouthguard users and nonusers.<sup>[31,161]</sup> Some investigations contained mouthguard and injury data, but each was reported separately and the two data sets were not combined.<sup>[11,21,24,162-167]</sup> Some studies considered past injuries and 'current' or 'regular' mouthguard use, and it was uncertain whether the mouthguards were worn or not worn in association with the past injury.<sup>[17,18,25,27-30,158,168-172]</sup> In one case, different sample sizes were provided for mouthguard data and injury data, so the two data sets could not be appropriately combined.<sup>[3]</sup>

Some studies compared injury rates among groups wearing different mouthguard types (stock, boil-and-bite, custom) rather than mouthguard users and nonusers.<sup>[83,173-176]</sup> In these investigations, little or no difference was found in injury rates among various types of mouthguards.

#### 5. Conclusions

In the twentieth century, mouthguards progressed from a disposable curiosity used by a few boxers to a highly sophisticated, mandated piece of equipment used by athletes in many physical activities and mandated in some sports. Early, permanent mouthguards were composed of latex rubber but later devices were constructed from EVA, polyurethane, silicon, and other compounds which have improved protective capability and durability. Among these more modern materials, none seems to stand out as superior to another since the characteristics of all the modern materials can be manipulated to provide a range of favourable characteristics. Mouthguard development might best proceed by manipulating shock absorbing and stiffness characteristics of specific materials to achieve protection against hard and soft object collisions while considering the different sports-specific exposure characteristics and anatomy of various oral structures (incisal vs occusal vs gingiva). Additional work on devices to assist in load distribution (e.g. wire bridges) and on the inclusion of systematic air cells in the mouthguard material might also be fruitful.

Studies that have examined injuries among mouthguard users and nonusers are of highly variable methodological quality. However, published research consistently shows that mouthguards offer significant protection against orofacial injuries. Meta-analysis indicates that the overall risk of an orofacial injury is 1.6–1.9 times higher when a mouthguard is not worn, relative to wearing a mouthguard. There is currently insufficient evidence to determine whether mouthguards offer protection against concussion injury, and more work of good methodological quality is needed. Mouthguard use should be promoted in sports activities where there is a significant risk of orofacial injury.

#### Acknowledgements

We would like to thank Ms Ann Marie Gibson for her editorial comments and Ms Stephanie Morrison for her technical review. Mr Kristin Goel and Ms Claudia Coleman assisted us in obtaining many of the references cited in this paper, especially those more difficult to obtain.

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No sources of funding were used to assist in the preparation of this review. The authors have no conflicts of interest that are directly relevant to the contents of this review.

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