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SYSTEMATIC REVIEW

Effectiveness of Mouthguards for the Prevention of Orofacial Injuries and Concussions in Sports: Systematic Review and Meta-Analysis

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Abstract

Background Sport activities can account for up to one-third of all orofacial injuries. Mouthguards (MGs) have been proposed as a way to reduce these injuries.

Objectives To present a systematic review and meta-analysis of the effectiveness of MGs for the prevention of sports-related orofacial injuries and concussions.

Methods Using specific search terms, PubMed, Ovid Embase, and the Cumulative Index to Nursing and Allied Health Literature were searched to find studies that (1) contained original quantitative data on MGs and orofacial injuries and/or concussions, (2) included groups involved in sports or exercise activities, (3) included MG users and non-MG users, and (4) provided either risk ratios (RRs) and 95% confidence intervals (95% CIs) comparing injuries among MG users and non-MG users, or data that could be used to calculate RRs and 95% CIs.

Results Twenty-six studies met the review criteria. Investigations employed a variety of study designs, utilized different types of MGs, used widely varying injury case definitions, and had multiple methodological weaknesses. Despite these limitations, meta-analyses indicated that the use of MGs reduced the overall risk of orofacial injuries in 12 cohort trials (summary RR [nonusers/users] = 2.33, 95% CI 1.59–3.44), and 11 trials involving self-report questionnaires (summary RR [nonusers/users] = 2.32, 95% CI 1.04–5.13). The influence of MGs on concussion incidence in five cohort studies was modest (summary RR [nonusers/users] = 1.25, 95% CI 0.90–1.74).

Conclusion These data indicate that MGs should be used in sports activities where there is significant orofacial injury risk.

Key Points

Athletes wearing mouthguards have less than half the risk of orofacial injuries compared to athletes not wearing mouthguards.

Mouthguards do not appear to reduce the risk of concussions in sport activities.

Mouthguards should be used in all sports where there is significant risk of orofacial injury.

1 Introduction

Athletes participating in many types of sporting activities are exposed to considerable risk of orofacial injury and concussion. A United States (US) Surgeon General's report on oral health listed sports as one of the major causes of oral and craniofacial injuries, accounting for up to one-third of all sports-related injuries [1]. The incidence of orofacial injury in sports has been widely reported [2], but there are considerable differences among studies with regard to injury case definitions, level of play, populations examined, methods of

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data collection, time period over which injury data were collected, and sports investigated. Retrospective surveys of various groups of athletes have found that 10–70% of athletes report having experienced at least one orofacial injury during participation in sports [3–11]. There are also methodological issues that complicate comparisons among concussion studies [12], and it is acknowledged that concussion rates are influenced by multiple factors, including sport and competition level [13]. At the US collegiate level, concussions treated by medical personnel made up 6.2% of all treated injuries, with the highest rates in men's wrestling, men's ice hockey, women's ice hockey, men's American football, women's soccer, and women's basketball (in that order) [14]. Concussion rates in high school and college sports were about five to six times higher in competition compared to practice sessions [14, 15]. In the Youth Risk Behavior Survey, 15% of US high school students self-reported a sports-related concussion [16]. Both orofacial injuries and concussions can have considerable long-term functional, psychological, and financial consequences.

Since the early 20th century, mouthguards (MGs) have been promoted as a way to reduce the incidence of orofacial injuries and concussions [17–19]. The American Society for Testing and Materials defines a MG as "a resilient device or appliance placed inside the mouth (or inside and outside), to reduce mouth injuries, particularly to teeth and surrounding structures" [20]. A MG generally separates the upper and lower dentition and at least a portion of the teeth from the adjacent soft tissue. MGs are generally classified into three types. Stock MGs are those sold over the counter and not shaped to an individual's dentition. They are essentially U-shaped devices with a central channel for the teeth and ridges on both sides. Stock MGs are held in place by clenching the teeth and they are generally not recommended by dentists. A second type, the boil-and-bite MG, consists of thermoplastic material. The device is immersed in hot water to soften it, placed in the mouth, and then shaped to the dentition with finger, tongue, and bite manipulation. Custom-made MGs are produced in dental laboratories from impressions of the athlete's mouth and the fit is generally checked by a dentist [21–23].

MGs are hypothesized to reduce the likelihood of orofacial injuries and concussions through several mechanisms. First, during direct forceful horizontal impact to the mouth MGs may prevent fracture or dislocation of the teeth by separating the mandibular (inferior) and maxillary (superior) teeth and absorbing or redistributing the impact forces over a broader area. Second, during traumatic jaw closures (vertical impacts), MGs may protect against mandibular bone fractures by stabilizing the mandible and absorbing the impact force. Third, MGs may reduce laceration and bruising of soft tissue by separating the teeth from the soft tissue, thus inserting a protective layer between hard and soft tissue. Finally, MGs 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 [24–26].

MGs have been widely advocated for use in sports [27–29], and this has led to their adoption as mandatory equipment in some sports [30–33], although with a varied history of success [32, 34]. Both the National Collegiate Athletic Association (NCAA) and National Federation of State High School Associations (NFSH) currently require MGs for field hockey, American football, ice hockey, and lacrosse [30–32], with the NFSH additionally requiring MGs for wrestlers with dental appliances. Among medical societies, the American Dental Association (ADA) Council on Scientific Affairs endorses the use of properly fitted MGs for reducing the incidence and severity of sports-related dental injuries [35]. ADA Council on Scientific Affairs and the ADA Council on Access, Prevention, and Interprofessional Relations specifically recommend that properly fitted MGs be worn in 29 sports and activities including acrobatics, baseball, basketball, bicycling, boxing, equestrian events, field events, field hockey, American football, gymnastics, handball, ice hockey, in-line skating, lacrosse, martial arts, racquetball, rugby, shotputting, skateboarding, skiing, skydiving, soccer, softball, squash, surfing, volleyball, water polo, weightlifting, and wrestling [29].

While there have been a number of reviews on the effectiveness of MGs for the prevention of orofacial injuries and concussions [21–23, 29, 36–40], only two of these [19, 40] have been systematic reviews with meta-analyses, attempting to answer the simple question of whether or not MGs reduce the incidence of orofacial injuries and/or concussions. Several new investigations on this topic have recently been published. In this paper, we describe the results of an update to our 2007 systematic review and meta-analysis [19] examining whether or not MGs reduce the risks of orofacial injuries and concussions during sports activities.

2 Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used to guide this research [41]. Specific details of our review protocol are described below.

2.1 Information Sources and Search

The National Library of Medicine's PubMed, Ovid Embase, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) were searched to find studies that had examined MGs and orofacial injuries and/or concussions. Orofacial injuries were defined as tooth fractures, luxations, or avulsions; lacerations of soft tissue; fractures of facial bones; and/or injuries to the temporomandibular joint area [24]. Keywords used in the search included {(mouthguards OR mouth protectors OR tooth protectors OR mouthpiece) AND (injury OR concussion OR orofacial)}. The reference lists of obtained articles and other reviews found in the search [22, 38–40] were examined for other articles not found in the retrieval services. The final search was completed in August 2018. One author was successfully contacted to clarify data in their study [42] and three other authors did not respond to requests. The results of the search and selection process were documented in a PRISMA flow diagram [41] (Fig. 1).

2.2 Study Selection and Data Extraction

To determine the effectiveness of MGs in preventing injuries, studies were included in the review if they (1) contained original quantitative data on orofacial injuries and/or concussions, (2) included groups involved in sports or exercise activities, (3) included MG users and non-MG users, (4) provided either risk ratios (RRs) and 95% confidence intervals (95% CIs) comparing injuries among MG users and non-MG users, or data that could be used to calculate RRs and 95% CIs, and (5) were written in English. Studies were not included if (1) they involved activities other than sport or exercise, (2) they compared different types of MGs and did not have a non-MG group, (3) they lacked original, quantitative injury data, or (4) all or most (≥ 95%) of the athletes in the study wore MGs. To guide the data extraction, a spreadsheet was constructed that contained the study

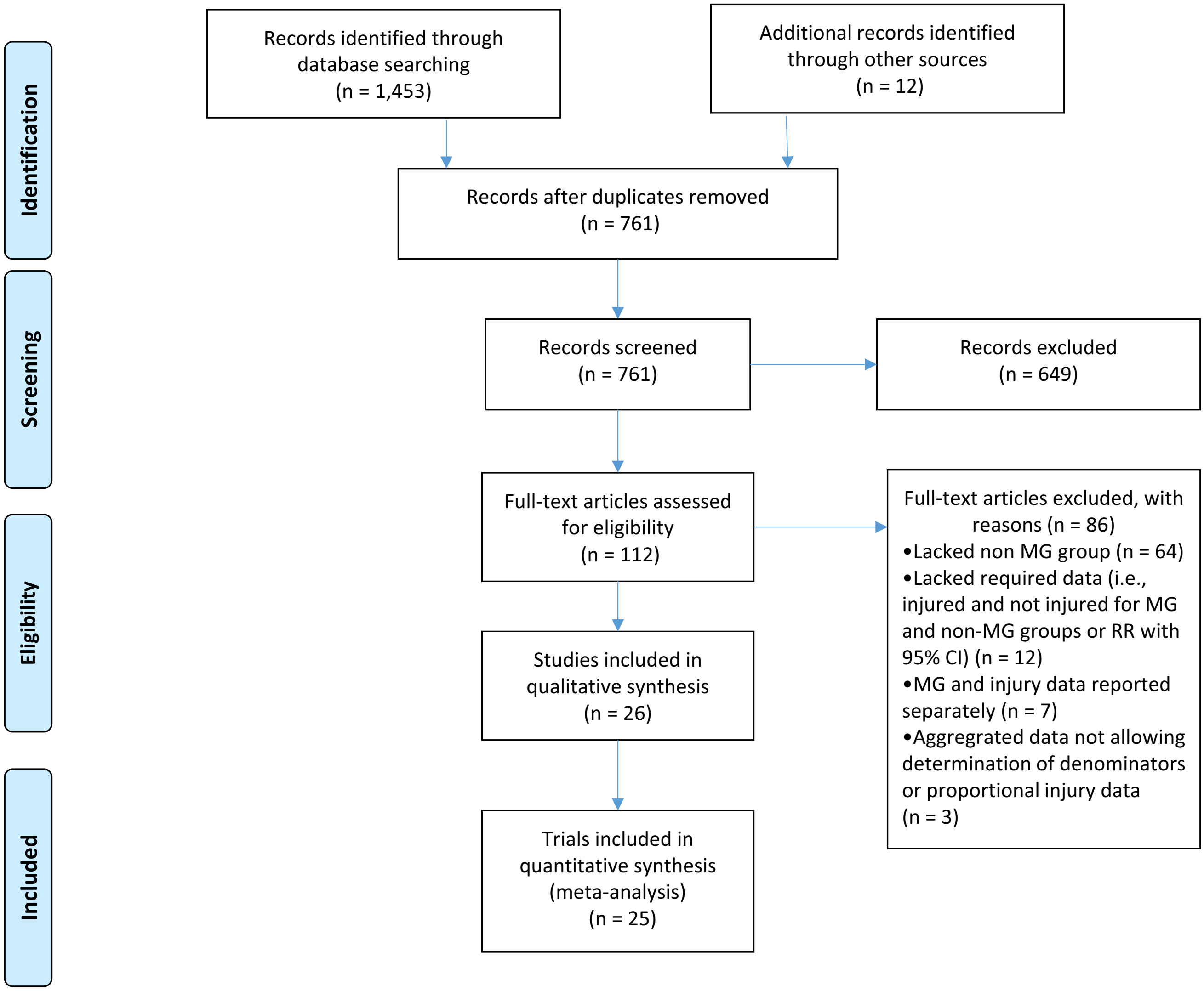


Fig. 1 PRISMA flow diagram. *MG* mouthguard, *RR* risk ratio, *95% CI* 95% confidence interval

name, study design, country where the data were collected, sport/exercise activity, sample sizes, injury definition, type of MG, data collection methods, injury outcomes, and numerical results.

2.3 Methodological Quality

Methodological quality of the studies was assessed using the checklist of Downs and Black [43]. The five major areas rated by the checklist were (1) reporting quality, (2) external validity, (3) bias, (4) confounding (selection bias), and (5) statistical power. The checklist had 27 items, most of which were rated on a two-point scale as either "yes" (1 point) or "no" (no point). One item (relating to reporting quality) had a highest possible score of 2. For the purposes of this review, the single statistical power question was reduced from a possible score of 0–5 to a score of 0 or 1. Thus, the maximum possible total score was 28. Two authors independently rated each of the selected articles. Following the independent evaluation, the reviewers met to examine the other reviewer's scores and to reconcile differences. The final consensus score of the reviewers served as the methodological quality score. Scores were converted to a percent by dividing the raters' score for the article by 28 and multiplying by 100%.

2.4 Summary Measure

The summary statistic was risk based, specifically, the RR with its 95% CI. The RR was the ratio of the risk of injury in MG nonusers to that of MG users calculated as follows:

$$\frac{\text{Injured MG nonusers/total MG nonusers}}{\text{Injured MG users/total MG users}}$$

In cases where an article provided RRs and 95% CIs these were used directly. For many studies, data had to be reanalyzed to obtain RRs. This could be readily done if the article contained the four pieces of data needed in the formula above. When reanalysis was necessary, the Open Source Epidemiologic Statistic Calculator (OpenEpi, Verson 3.01) was used to obtain RRs and 95% CIs [44]. If the sample size in any cell was less than 5, Yates' correction was applied. In studies where there were no injuries in a particular group, a value of 0.5 was added to each cell and this was used to estimate the RR and 95% CI [45]. Where incidence measures reported were rate-based (i.e., based on injuries per athletic exposure or injuries per unit of time) rather than risks, RR and 95% CIs were back-calculated from the Chi square statistic [44].

2.5 Meta-Analyses and Assessment of Publication Bias

The Comprehensive Meta-Analysis Statistical Package, Version 3.2 (Biostat, Englewood, NJ, USA) was used to perform the meta-analysis. Separate analyses were performed for: (1) cohort studies involving orofacial injuries, (2) questionnaire (survey) studies involving orofacial injuries, and (3) cohort studies involving concussions. The meta-analysis produced a summary RR and 95% CI that represented the pooled results from all of the RRs and 95% CIs in individual investigations. Heterogeneity of the RRs was assessed using the Q- and the I^2-statistics [46]. Heterogeneity was the degree of variability in the RRs used in a particular meta-analysis. If heterogeneity was significant, a random model was selected for the meta-analysis; if heterogeneity was not significant, a fixed model was selected.

The Comprehensive Meta-Analysis Statistical Package, Version 3.2 was also used to examine publication bias using funnel plots [47], Begg and Mazumdar correlations [48], and the trim and fill procedure [49]. Funnel plots are graphs of each study's logarithm (log) RR against a measure of precision such as the standard error (driven primarily by sample size). Studies with larger sample sizes tend to cluster near the top of the plot and near the pooled (summary) log RR while smaller studies are generally near the bottom of the graph. If publication bias is present, the bottom of the plot tends to show a higher concentration on one side since studies with smaller samples are more likely to be published if they had larger effect sizes. Funnel plots, while useful visual indications of possible publication bias, have been criticized because of subjectivity of interpretation and differences that arise with different choices of axes [50, 51]. Thus, additional statistical indicators of publication bias were examined. The Begg and Mazumdar test [48] calculates the rank order correlation between the treatment effect and standard error. A significant correlation suggests that publication bias exists. The trim and fill procedure [49] adjusts the funnel plot through an iterative process, removing studies concentrated on one side of the plot, reinserting the "trimmed" studies on the other side of the plot, and imputing their counterparts on the original side of the plot. A new RR and 95% CI is estimated that includes these hypothetical missing studies.

3 Results

Figure 1 shows the PRISMA diagram indicating the number of publications included and excluded at each stage of the literature search and selection process. There were 112 full text articles retrieved for further examination after inspecting titles and abstracts. After reviewing these, 26 articles were found to meet the inclusion criteria. Three of these articles reported on Phildelphia high school American football players at various times (before and after MGs were mandatory); data from these three investigations were combined to obtain a single RR and 95% CI [52–54]. One study [55] reported separately on MG use in American football and ice hockey players and these two sports were included separately in the analysis.

3.1 Characteristics of Selected Studies

Table 1 provides a summary of the methodology and results of the 26 selected studies arranged by date of publication. Study designs included non-randomized prospective cohort intervention studies [42, 54, 56–61], non-randomized retrospective cohort studies [55, 62], one-group ecological intervention studies [33, 52, 53, 63], cross-sectional surveys [24, 25, 64–72], and a single randomized prospective cohort investigation [73]. One-group ecological interventions compared injuries in groups of athletes before and after the introduction of MGs. Cross-sectional surveys involved athlete recall of injuries and MG use and both measures were assessed at the same time within the same questionnaire. Team-level interventions provided MGs to entire teams and compared those teams to other teams that did not have MGs. Sport activites included American football [52–57, 64], rugby [33, 42, 58, 61, 70, 73], basketball [59, 63, 66, 68], ice hockey [55, 60], field hockey [71], handball [24], taekwondo [67], and studies that examined a number of different sports [25, 62, 65, 69, 72]. All three types of MGs were included in the reviewed studies, with most studies including MGs of any type [24, 25, 33, 42, 61, 63–66, 68–72], and a minority of studies ($n = 7$) rreporting exclusively boil-and-bite, [57, 62, 67] custom [73], or both boil-and-bite and custom [52–54]. Three studies did not clearly state the type of MG [55, 58, 60].

Injury case definitions varied widely, as shown in the fifth column of Table 1. In orofacial injury investigations, some studies appear to have included only injuries to the teeth [24, 25, 33, 52–54, 56, 57, 62–64, 67, 70, 72], while other studies appeared to include any orofacial injury [42, 55, 58, 59, 65, 66, 68, 69, 71, 73]. Most studies examining concussions [42, 58–60] did not provide criteria for determining the injury, and one study [65] apparently used loss of consciousness as an indicator. Only one study utilized [61] used consensus criteria ratified by an international group [74].

The last column of Table 1 shows the methological quality scores, which were relatively low, ranging from 34% to 68% of available points. The mean ± standard deviation was 49 ± 9%. Only five studies [33, 42, 62, 63, 73] scored ≥ 50% and only two [42, 73] scored > 60%.

Most studies [24, 25, 33, 42, 52–58, 61, 62, 64–72] required a secondary data analysis (as specified in Methods, Sect. 2.5) to statistically compare injury differences between MG users and nonusers by calculating RRs and 95% CIs. For three studies [59, 63, 73] a secondary analysis was not necessary, but it was conducted so the investigations could be more easily compared to other studies. Original data were obtained from one author [42] to directly calculate RRs and 95% CIs, and one study provided the appropiate RR and 95% CI [60].

Some investigations [52–54, 73] compared groups wearing MGs to groups that were composed of both non-MG users and some MG users. Despite problems with designs of this type, if injury rates were lower in the group of exclusive MG users this implies the protective effect was at least as large as the magnitude of the effect observed in the study. That is, the MG users in the “non-MG user group” would be expected to lower the injury incidence in the “nonuser group” (if MGs reduced injury incidence), thus reducing the magnitude of the observed MG effect. Other studies allowed comparison of injuries in “frequent MG users” to those of non-MG users [24, 71]. In this case the frequent users may not have been wearing MGs during an injury, but similar to the above situation, the effect of the MG would be at least as large as the effect observed in the study. In this case, the frequent user not wearing the MG during an injury would increase the injury incidence in the frequent user group.

3.2 Meta-Analysis and Publication Bias

Figure 2 shows the forest plots of the 12 cohort and one-group ecological intervention trials that examined the effectiveness of MGs for the prevention of orofacial injuries. Table 2 shows the summary statistics and Fig. 3a the funnel plot. Both the Q- and I^2-statistics suggested considerable heterogeneity among the RRs (Table 2), so a random-effect model was employed for the meta-analysis. Groups not wearing MGs had over twice the risk of an orofacial injury compared to those wearing MGs. The funnel plot (Fig. 3a) indicated that many studies fell to the right of the log of the summary RR suggesting that studies with smaller effects may exist on the left, but had not been published (indicative of potential publication bias). The rank order correlation was not significant, but the trim and fill procedure suggested that five studies might be “missing” from the left side of the graph. After inserting the “missing” studies on the left with the trim and fill procedure (Fig. 3b) the new imputed RR was lower, with narrower 95% CIs (last column Table 2), but there was still a protective effect from wearing MGs.

Figure 4 shows the forest plot of the 11 survey studies that queried athletes on orofacial injuries and MG use. Table 2 shows the summary statistics and Fig. 3c the funnel plot. Both the Q- and I^2-statistics indicated considerable heterogeneity among the RRs (Table 2), so a random effects model was employed. As with the cohort/ecological studies, groups not reporting MG wear had over twice the risk of

Table 1 Characteristics of studies on the effectiveness of mouthguards for the prevention of orofacial injuries and concussions

Study	Study design	Country: player level, activity	Sample sizes	Injury definition	MG type	Data collection	Injury incidence (%) or injury rate (injuries/exposures)	Methodological quality score (%)
Schoen 1956 [56]	Prospective cohort (team-level intervention)	USA: HS American football	151 MG users; 244 non-MG users	Damage to hard structures of the mouth	Custom latex and mouth-formed shell liners	Inspections by dentist at beginning and end of American football season	MG users = 0%, non-MG users = 11.9% ($p < 0.01$)	38
Moon and Mitchell 1961 [57]	Prospective cohort (team-level intervention)	USA: HS American football	64 MG users; 240 non-MG users	Dental damage	Boil-and-bite	Forms completed by coaches after each injury	MG users = 0%, non-MG users = 10.4% ($p = 0.01$)	48
Cohen and Borish 1958 [54] Cohen and Borish 1961 [53]; Cohen 1962 [52]	One-group ecological intervention	USA: HS American football	2923 MG users; 596 non-MG users	Tooth damage	Boil-and-bite or custom	Not clear	MG users = 0.1%, non-MG users = 3.5% ($p < 0.01$)	41
Dunbar 1962 [55]	Retrospective cohort (team-level intervention)	USA: HS American football and ice hockey	American football: 96 MG users; 160 non-MG users. Ice hockey: 42 MG users; 92 MG non-users	Mouth trauma	Not clear	Not clear	American football: MG users = 0%, non-MG users = 1.9% ($p = 0.72$). Ice hockey: MG users = 0%, non-MG users = 3.3% ($p = 0.87$)	34
Bureau of Dental Education 1963 [64]	Cross-sectional survey	USA: HS American football	39,370 MG users; 5053 MG non-users	Tooth damage	Any	Cross-sectional questionnaire sent to HSs	MG users = 1.5%, non-MG users = 2.1% ($p < 0.01$)	39
Blignaut et al. 1987 [58]	Prospective cohort	South Africa: collegiate rugby	321 players, 555 exposures[a]	1.Mouth, tooth, lip damage 2.Concussion	Not specified, but stated that dentists provided 95% of MGs	Form completed by trained examiners after each match	(1) Mouth, tooth, lip injury MG users = 4.6%, non-MG users = 4.7% ($p = 0.97$) (2) Concussion MG users = 3.1%, non-MG users = 2.6% ($p = 0.68$)	43

Table 1 (continued)

Study	Study design	Country: player level, activity	Sample sizes	Injury definition	MG type	Data collection	Injury incidence (%) or injury rate (injuries/exposures)	Methodological quality score (%)
McNutt et al. 1989 [65]	Cross-sectional survey	USA: junior and senior HS athletes, 18 sports	2167 MG users; 303 non-MG users	1.Oral trauma 2. Concussion (LOC)	Any	Preseason structured interview of athletes about past injuries and MG use (self-reported)	1) Oral trauma MG users = 2.5%, non-MG users = 55.1% ($p < 0.01$) 2) Concussion MG users = 1.3%, non-MG users = 11.9% ($p < 0.01$)	41
Maestrello-deMoya et al. 1989 [66]	Cross-sectional survey	USA: HS basketball	43 MG users; 977 non-MG users	Orofacial damage	Any	Questionnaire mailed to coaches, completed by athletes (self-reported)	MG users = 4.7%, non-MG users = 32.0% ($p < 0.01$)	46
Labella et al. 2002 [59]	Prospective cohort	USA: men's collegiate basketball	50 colleges: 8663 exposures with MGs, 62,273 exposures without MGs	1.Tooth FX, luxations, avulsions, mandible/maxilla FX 2.Concussion	Custom or boil-and-bite	Athletic trainers completed weekly web-based injury form	1) Tooth FX injury: MG users = 0.12/1000 exposures[a], non-MG users = 0.67/1000 exposures ($p = 0.08$) 2) Concussion MG users = 0.35/1000 exposures, non-MG users = 0.55/1000 exposures ($p = 0.61$)	46

Table 1 (continued)

Study	Study design	Country: player level, activity	Sample sizes	Injury definition	MG type	Data collection	Injury incidence (%) or injury rate (injuries/exposures)	Methodological quality score (%)
Marshall et al. 2005 [42]	Prospective cohort	New Zealand: club rugby	240 men, 87 women, 12,252 athletic exposures[a]	1.Teeth, mouth and jaw damage 2.Concussion	Any	Weekly telephone interviews of participants for events which required medical attention and loss of ≥ 1 day of play	1) Teeth, mouth, jaw injury MG users = 0.45/1000 exposures, non-MG users = 0.61/1000 exposures ($p = 0.73$) 2) Concussion MG users = 2.12/1000, non-MG users = 0.91/1000 exposures ($p = 0.16$)	68
Finch et al. 2005 [73]	Prospective cohort (team-level randomized trial)	Australia: club rugby	111 custom MG users; 190 controls (MG users and non-users)	Head or orofacial damage	Custom in MG group; any or none in control group	Trained team members collected data during play	MG users = 1.8/1000 h play, non-MG users and some MG users = 4.4/1000 h play ($p < 0.01$)	64
Quarrie et al. 2005 [33]	One-group ecological intervention	New Zealand: any rugby players	121,900 players in 1998 (first mandatory MG use but without enforcement); 120,900 players in 2003 (mandatory MG use with enforcement capability)	Dental injury claims	Any	Accident compensation database containing dental injuries and cause of injury	1998 (early mandatory MG use without enforcement) = 1.8%, 2003 (mandatory MG use with enforcement capability) = 1.2% ($p < 0.01$)	48
Benson and Meeuwisse 2005 [60]	Prospective cohort	USA: pro ice hockey	1006 players in 30 NHL teams (not clear how many using MGs)	Concussion	Not clear	Equipment managers and NHL personnel documented MG use and play time during season games; physicians recorded concussions	MG users = 39 injuries, non-MG users = 33 injuries (injury incidence or rates not provided, just risk ratio)	46

Table 1 (continued)

Study	Study design	Country: player level, activity	Sample sizes	Injury definition	MG type	Data collection	Injury incidence (%) or injury rate (injuries/exposures)	Methodological quality score (%)
Cetinbas et al. 2006 [25]	Cross-sectional survey	Turkey: university soccer, ice hockey, karate	90 MG users; 31 non-MG users	Dental trauma	Any	Self-reported on questionnaire	MG users = 0%, non-MG users = 51.6% ($p < 0.01$)	41
Tulunoglu and Ozbek 2006 [67]	Cross-sectional questionnaire	Turkey: semi-pro/amateur taekwondo	66 MG users; 153 non-MG users	Dental trauma	Boil-and-bite	Self-reported on questionnaire	MG users = 25.8%, non-MG users = 12.6% ($p < 0.01$)	45
Cohenca et al. 2007 [63]	One group ecological intervention	USA: women's collegiate basketball	48 players in 1996–1999 (MGs not mandatory); 72 players 2000–2005 (MGs mandatory)	Dental trauma requiring medical attention and loss of ≥ 1 day of play	Any	Medical personnel reported to surveillance system	1996–1999 (MGs not required) = 8.3%, 2000–2005 (MGs required) = 2.8% ($p = 0.35$)	50
Kemp et al. 2008 [61]	Prospective cohort	England: pro rugby	757 players total but not totally clear	Concussion	Any	Medical personnel reported injuries weekly	MG users = 4.0 injuries/1000 h play, non-MG users = 5.8 injuries/1000 h play ($p = 0.44$)	61
Zadik and Levin 2009 [62]	Retrospective cohort	Israel: recreational athletes, ball games, martial arts, and other sports	93 MG users; 179 non-MG users	Dental FX, luxations, subluxations during sports	Boil-and-bite	Reported on questionnaire after MGs provided	MG users = 8.6%, non-MG users = 11.7% ($p = 0.43$)	54
Frontera et al. 2011 [68]	Cross-sectional survey	Brazil: national teams, men's basketball	27 MG users; 361 non-MG users	Orofacial trauma (soft tissue, teeth, and mandibular trauma)	Any	Self-reported on questionnaire	MG users = 8.0%, non-MG users = 53.2% ($p < 0.01$)	57
Tiwari et al. 2014 [69]	Cross-sectional interview	India: pro athletes, 7 contact and 7 noncontact sports	80 MG users; 240 non-MG users	Front tooth and soft tissue damage	Any	Self-reported in personal interview	MG users = 60.0%, non MG users = 37.1% ($p < 0.01$)	48
Liew et al. 2014 [70]	Cross-sectional survey	Malaysia: tournament rugby players	142 MG users; 314 non-MG users	Rugby-related dental trauma	Any	Self-reported on questionnaire	MG users = 33.8%, non-MG users = 22.9% ($p = 0.02$)	54
Vucic et al. [71]	Cross-sectional survey	Netherlands: junior and senior club field hockey	862 MG frequent users; 437 non-MG users	Orofacial trauma	Any	Self-reported on questionnaire	MG frequent users = 12.8%, non-MG users = 23.8% ($p < 0.01$)	59

Table 1 (continued)

Study	Study design	Country: player level, activity	Sample sizes	Injury definition	MG type	Data collection	Injury incidence (%) or injury rate (injuries/exposures)	Methodological quality score (%)
Bergman et al. 2017 [24]	Cross-sectional survey	Croatia: pro handball	28 MG frequent users; 72 non-MG users	Dental trauma (socket bleeding; tooth FX, luxation or avulsion)	Any	Self-reported on questionnaire	MG frequent users = 17.9%, non-MG users = 23.6% ($p = 0.72$)	61
Galic et al. 2018 [72]	Cross-sectional survey	Croatia: young athletes (5–19 year old), water polo, karate, taekwondo, handball	94 MG users; 135 non-MG users	Dental trauma	Any	Self-reported on questionnaire	MG users = 10.6%, non-MG users = 15.6% ($p = 0.29$)	50

USA United States of America, *HS* High School, *MG* mouthguard, *LOC* loss of consciousness, *FX* fracture, *pro* professional, *NHL* National Hockey League

[a] An athletic exposure was one athlete involved in one game

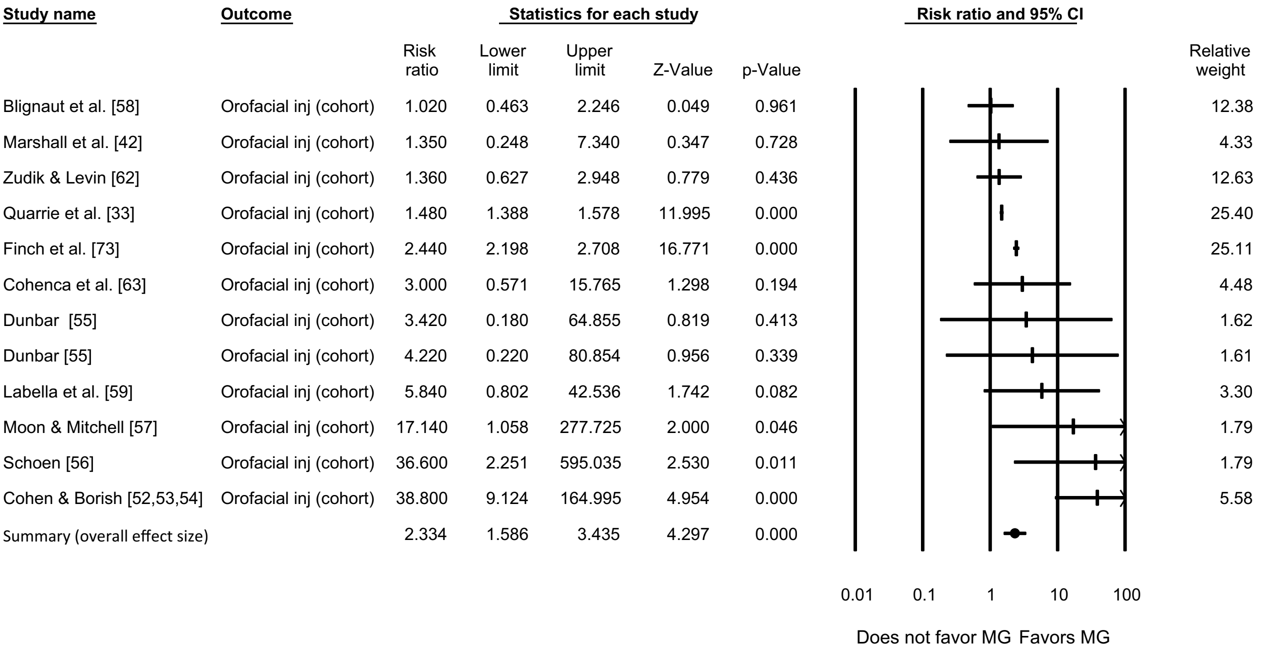
an orofacial injury compared to those who reported wearing MGs. Minimal publication bias was suggested since the funnel plot had a similar number of studies on both sides of the graph, the rank order correlation was not significant, and the trim and fill procedure suggested no "missing" studies (Table 2).

Figure 5 shows the forest plot of the five cohort studies examining the effectiveness of MGs for the prevention of concussions. Table 2 shows the summary statistics and Fig. 3d the funnel plot. One concussion study [65] was not included in this meta-analysis because it was the only one that had examined concussions through a self-reported cross-sectional questionnaire. If that study [65] was included in the meta-analysis with the cohort studies the RR (non-MG users/MG users) was 1.58 and 95% CI 0.65–3.86 (random model because of significant heterogeneity, $I^2 = 90\%$). For the five cohort studies, both the Q- and I^2-statistics indicated a low level of heterogeneity (Table 2), so a fixed effect model was employed. There was little difference in concussion risk between groups wearing and not wearing MGs. The funnel plot had a similar number of studies on both sides of the graph, but the rank order correlation was significant, suggesting publication bias. Despite this, the trim and fill procedure suggested no missing publications.

4 Discussion

This study found that MGs users had a considerably lower risk of orofacial injury compared to individuals who did not wear a MG, but the effect of MGs on concussion risk was minimal. There was some suggestion of publication bias for the orofacial injury cohort investigations, but when the hypothetic "missing studies" were imputed in the analysis through the trim and fill procedure, the favorable effect of MGs was still retained. There was considerable heterogeneity among the orofacial injury studies, but this was expected given the variations in study designs, injury definitions, sports involved, and other factors [75]. With the addition of nine new investigations [24, 25, 62, 63, 68–72], the risk reduction for orofacial injuries was larger than we found in our previous meta-analysis [19]. For concussions, only two new investigations were found [60, 61] and there is still no definitive evidence that MGs influence concussion risk.

There is some debate over whether randomized studies should be combined with non-randomized studies in meta-analysis [76, 77]. This concern centers on unidentified sources of confounding in non-randomized studies and other factors that might modify risk. However, unrecognized confounders can exist in both types of investigations. To be a confounder, the variable must cause the outcome or be associated with it, which can occur in either type of study design, although unrecognized confounders are generally assumed



Study name	Outcome	Risk ratio	Lower limit	Upper limit	Z-Value	p-Value	Relative weight
Blignaut et al. [58]	Orofacial inj (cohort)	1.020	0.463	2.246	0.049	0.961	12.38
Marshall et al. [42]	Orofacial inj (cohort)	1.350	0.248	7.340	0.347	0.728	4.33
Zudik & Levin [62]	Orofacial inj (cohort)	1.360	0.627	2.948	0.779	0.436	12.63
Quarrie et al. [33]	Orofacial inj (cohort)	1.480	1.388	1.578	11.995	0.000	25.40
Finch et al. [73]	Orofacial inj (cohort)	2.440	2.198	2.708	16.771	0.000	25.11
Cohenca et al. [63]	Orofacial inj (cohort)	3.000	0.571	15.765	1.298	0.194	4.48
Dunbar [55]	Orofacial inj (cohort)	3.420	0.180	64.855	0.819	0.413	1.62
Dunbar [55]	Orofacial inj (cohort)	4.220	0.220	80.854	0.956	0.339	1.61
Labella et al. [59]	Orofacial inj (cohort)	5.840	0.802	42.536	1.742	0.082	3.30
Moon & Mitchell [57]	Orofacial inj (cohort)	17.140	1.058	277.725	2.000	0.046	1.79
Schoen [56]	Orofacial inj (cohort)	36.600	2.251	595.035	2.530	0.011	1.79
Cohen & Borish [52,53,54]	Orofacial inj (cohort)	38.800	9.124	164.995	4.954	0.000	5.58
Summary (overall effect size)		2.334	1.586	3.435	4.297	0.000	

Fig. 2 Forest plot of cohort studies examining effects of mouthguards on orofacial injuries. *MG* mouthguard, *inj* injury, *95% CI* 95% confidence interval

Table 2 Summary statistics for meta-analyses examining effects of mouthguards on orofacial injuries and concussions

Outcome	Studies (n)	Summary RR (95% CI)	Q-statistic p value	I^2 (%)	Begg and Mazumdar statistics		Trim and fill procedure	
					Rank order correlation	p value	Trimmed and imputed studies (n)	Imputed RR (95% CI)
Orofacial injury (cohort studies)	12	2.33 (1.59–3.44)	< 0.01	88	0.17	0.23	5	1.68 (1.14–2.47)
Orofacial injury (questionnaire studies)	11	2.32 (1.04–5.13)	< 0.01	98	0.36	0.06	0	NA
Concussion	5	1.25 (0.90–1.74)	0.35	10	− 0.70	0.04	0	NA

RR risk ratio, *95% CI* 95% confidence interval, *NA* not applicable (no studies were trimmed so RR and 95% CI were not imputed)

to be balanced across both arms (groups) in most large trials. A review of empirical studies indicated that meta-analysis based on observational (non-randomized) and randomized trials generally produce similar effect sizes [76]. In the present meta-analyses, it was decided ad hoc to combine randomized and non-randomized studies for these reasons. There was only one randomized study available in the literature [73]. The RR for this randomized trial [73] was 2.44 (95% CI 2.19–2.71) while that of the pooled results was 2.33 (95% CI 1.59–3.44), reflecting a similar RR but larger 95% CI for the pooled effect. The larger 95% CI can be considered to reflect the larger uncertainty due to many factors including type of sport, player position, injury definitions, and other issues. However, the meta-analytical estimate, although less precise, can be viewed as having better external validity due to the inclusion of these diverse populations and the known selection factors that affect the generalizability of randomized trials.

The methodological quality scores ranged widely from 34 to 68%, and were generally low, averaging less than half of the available points. Scores in early trials conducted before the year 2000 ranged from 34 to 48% (mean ± SD = 41 ± 5) while those after 2000 ranged from 41 to 68% (mean ± SD = 53 ± 8). Early studies [52–57, 64] often did not clearly state a study purpose/hypothesis or perform any statistical analysis of the data. There was only

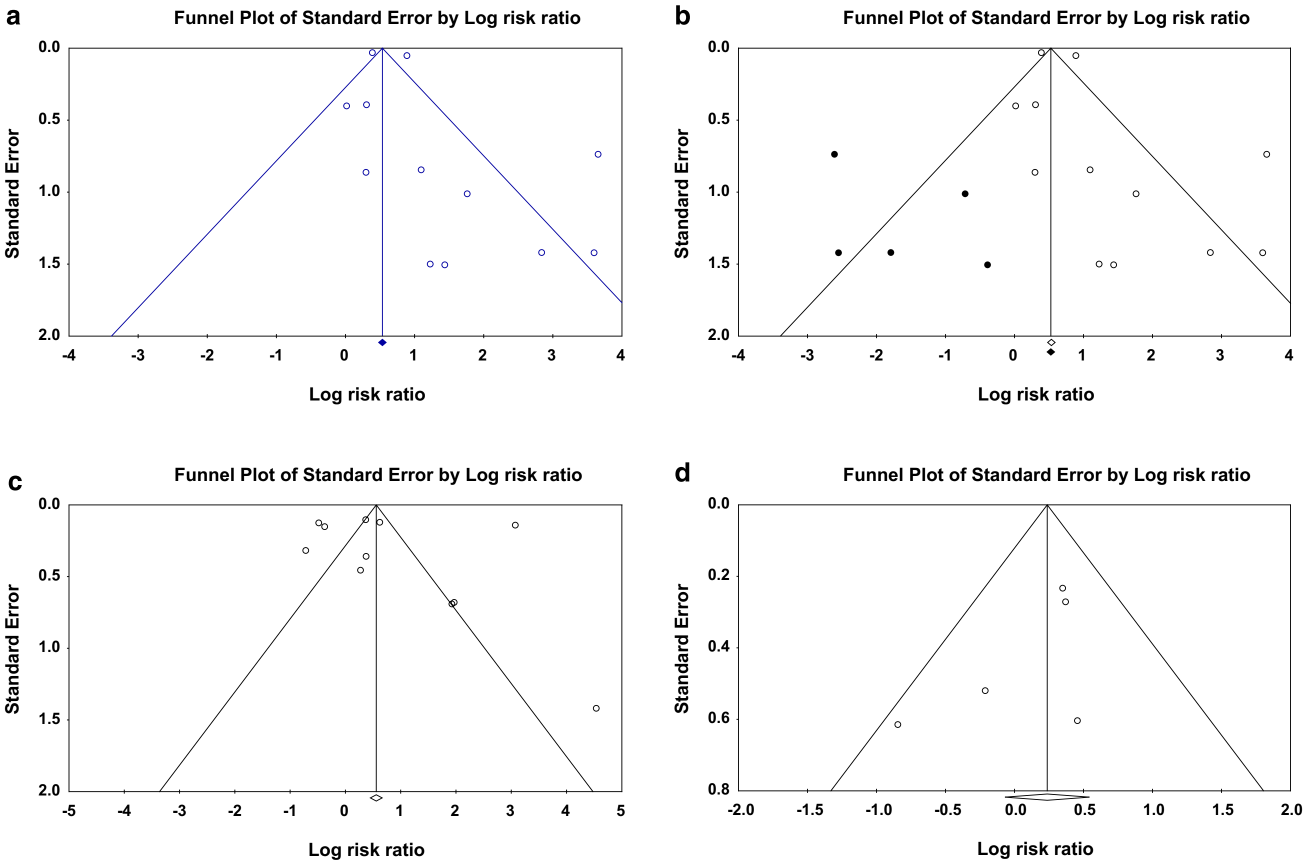
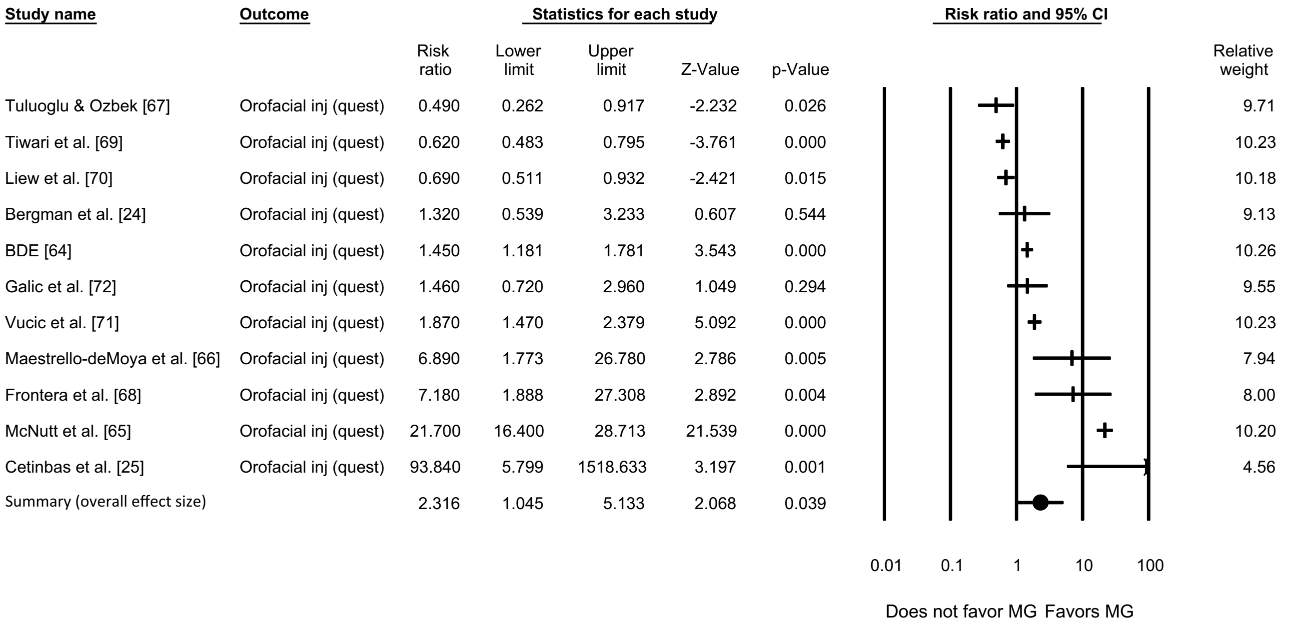


Fig. 3 Funnel plots of studies involving mouthguards and injuries. **a** Cohort studies on mouthguards and orofacial injuries; **b** cohort studies on mouthguards and orofacial injuries showing studies imputed with the trim and fill procedure (closed circles represent imputed values); **c** questionnaire studies on mouthguards and orofacial injuries; **d** cohort studies on mouthguards and concussions. Diamonds below vertical axis represent summary log risk ratio with 95% confidence intervals

one randomized study, and as it is impossible to conduct a blinded study of MGs virtually all studies were scored low when blinding and randomization were considered in the Downs and Black [43] rating system. The methodological quality scoring performed in this review suggests that future studies examining the effectiveness of MG for prevention of orofacial injuries and concussions could be improved by more comprehensive descriptions of study participants and outcome measures; presentation and analysis of potential confounders; quantitative reporting of adverse events associated with MG use; appropriate multivariable statistical analysis; compliance monitoring; and improved reporting of design-phase power analyses.

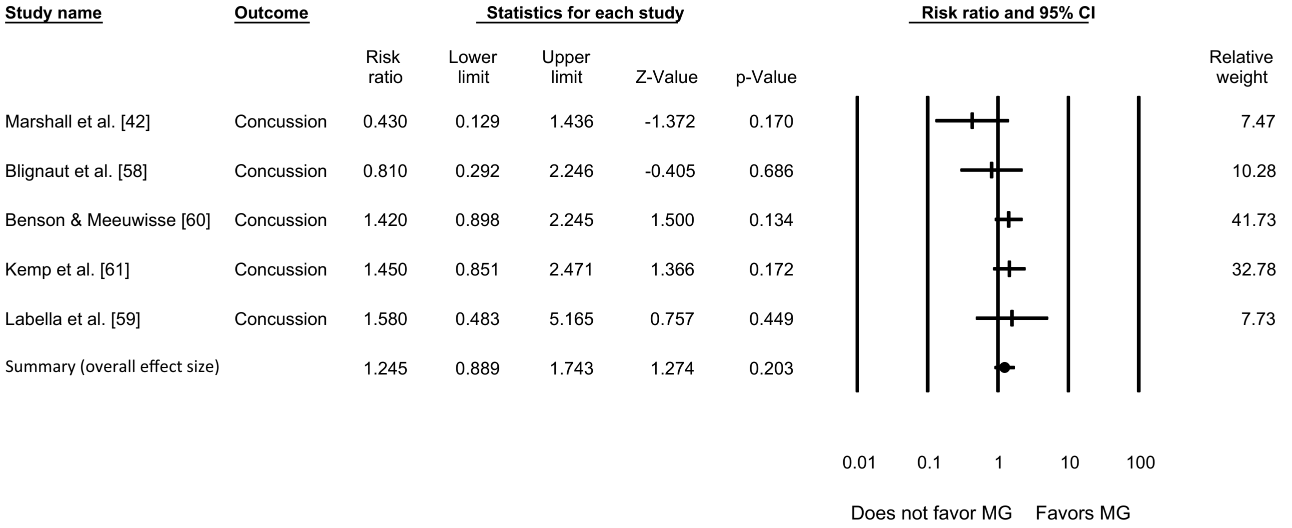
Studies involving questionnaires asked athletes to remember their MG use and previous injuries. Studies of this type are methodologically weak because of potential recall bias, social desirability bias, errors in self-observation, and errors in recall of events [78, 79]. Further, some individuals may have started using a MG after an orofacial trauma and questionnaires usually did not consider this. Nonetheless, there were a relatively large number of questionnaire studies and the results tended to support the findings from the cohort investigations, although the confidence intervals were considerably wider because of the greater variability between studies.

With regard to concussions, there were several investigations that used study designs or outcome measures that could not be included in this review, but nonetheless found that MGs did not influence concussion incidence or factors related to concussions. A case–control study [80] of young ice hockey players found that at the time of injury, 74% of concussed player ($n = 143$) and 78% of non-concussed players ($n = 156$) were wearing MGs (odds ratio = 1.23, 95% CI 0.68–2.22). Another investigation [81] of athletes suffering sport-related concussions (sports not specified) examined a battery of neurocognitive tests (related to attention, memory, reaction time, and information processing speed) and post-concussion symptoms (headache, nausea, balance dizziness, etc.). The investigators compared results among those wearing and not wearing a MG at the time of injury and found



Study name	Outcome	Risk ratio	Lower limit	Upper limit	Z-Value	p-Value	Relative weight
Tuluoglu & Ozbek [67]	Orofacial inj (quest)	0.490	0.262	0.917	-2.232	0.026	9.71
Tiwari et al. [69]	Orofacial inj (quest)	0.620	0.483	0.795	-3.761	0.000	10.23
Liew et al. [70]	Orofacial inj (quest)	0.690	0.511	0.932	-2.421	0.015	10.18
Bergman et al. [24]	Orofacial inj (quest)	1.320	0.539	3.233	0.607	0.544	9.13
BDE [64]	Orofacial inj (quest)	1.450	1.181	1.781	3.543	0.000	10.26
Galic et al. [72]	Orofacial inj (quest)	1.460	0.720	2.960	1.049	0.294	9.55
Vucic et al. [71]	Orofacial inj (quest)	1.870	1.470	2.379	5.092	0.000	10.23
Maestrello-deMoya et al. [66]	Orofacial inj (quest)	6.890	1.773	26.780	2.786	0.005	7.94
Frontera et al. [68]	Orofacial inj (quest)	7.180	1.888	27.308	2.892	0.004	8.00
McNutt et al. [65]	Orofacial inj (quest)	21.700	16.400	28.713	21.539	0.000	10.20
Cetinbas et al. [25]	Orofacial inj (quest)	93.840	5.799	1518.633	3.197	0.001	4.56
Summary (overall effect size)		2.316	1.045	5.133	2.068	0.039	

Fig. 4 Forest plot of questionnaire studies examining effects of mouthguards on orofacial injuries. *MG* mouthguard, *inj* injury, *quest* questionnaire, *95% CI* 95% confidence interval



Study name	Outcome	Risk ratio	Lower limit	Upper limit	Z-Value	p-Value	Relative weight
Marshall et al. [42]	Concussion	0.430	0.129	1.436	-1.372	0.170	7.47
Blignaut et al. [58]	Concussion	0.810	0.292	2.246	-0.405	0.686	10.28
Benson & Meeuwisse [60]	Concussion	1.420	0.898	2.245	1.500	0.134	41.73
Kemp et al. [61]	Concussion	1.450	0.851	2.471	1.366	0.172	32.78
Labella et al. [59]	Concussion	1.580	0.483	5.165	0.757	0.449	7.73
Summary (overall effect size)		1.245	0.889	1.743	1.274	0.203	

Fig. 5 Forest plot of cohort studies examining effects of mouthguards on concussions. *MG* mouthguard, *95% CI* 95% confidence interval

little difference between the two groups in neurocognitive function or symptoms [81].

While the evidence in this review does not support the use of MGs for concussion protection, this does not preclude the possibility that there may be some types of MGs or some MG designs that may be more effective for this purpose. In this review it was not possible to determine if one type of MG was more effective for concussion prevention than another because only one concussion study specified the type of MGs investigated (i.e., both custom or boil-and-bite) [59] while others investigated MGs without disaggregation by type [42, 61, 65] or were not clear on the type [58, 60]. With regard to design, it has been hypothesized that if MGs are properly fitted (custom type) with 3–4 mm of thickness posteriorly they may be more effective for concussion prevention [82]. The expert opinion from the first International Sports Dentistry Workshop in 2016 suggested that MGs should cover the distal portion of the maxillary first molar with a thickness of 3 mm at the outside surface facing the lips and cheek (labially), 3 mm contacting the biting surface (occlusally), and 2 mm facing the roof of the mouth (palatally), and that the bite be bilateral and balanced [28]. It seems very probable that custom-fit MGs are far more likely to routinely fulfill these parameters over the course of the sport season, relative to boil-and-bite or off-the-shelf generic fit MGs. Further epidemiologic research of good methodological quality is still needed on the topic of MGs and concussions. There is also a need for biomechanical studies examining the role of MGs in mitigating the forces transmitted to the head in mandible and non-mandible impacts.

Compliance with the use of MGs was an important issue considered as a point in the methodological quality review; however, compliance was reported in less than half of the cohort studies reviewed here. In some cohort investigations the study procedures were such that there was relatively high confidence that athletes were wearing or not wearing MGs during the injury [42, 59]. In other cohort studies the measures of compliance were of variable quality. An investigation involving American football players found that only 40% were still using MGs at the end of the season [57]. A study of rugby players reported that after MGs became mandatory for New Zealand rugby, 93% reported wearing them in games, but only 46% in practices [33]. Among amateur athletes provided a free boil-and-bite MG, only 34% reported using them during sports activites [62]. Despite this, all three investigations [33, 57, 62] found a protective effect from MG use suggesting the effect may be larger if compliance was more universal. Compliance has also been shown to be relatively low in other investigations that were not a part of this review. For example, in one study of NCAA ice hockey players, athletic trainers estimated that only 63% of athletes consistently used MGs in competition [34]. In a study of Italian rugby players only 54% reported wearing their MGs at all times in training and competition [83]. Even when MGs were provided free of charge, usage rates were low [62, 84]. One study [85], using logistic regression and data obtained from a questionnaire, found that risk of oral injury among rugby players decreased as the frequency of MG use increased. Taken together, these data suggest that mandatory enforcement of MG use, potentially with penalities for non-compliance, could further reduce the incidence of orofacial injuries.

5 Conclusions

Despite differences in injury definitions and low methodological quality of some studies, this review suggests that MGs offer significant protection from orofacial injuries. Meta-analyses indicated that the overall risk of an orofacial injury was more than twice as great when athletes involved in many different sports were not wearing a MG. On the other hand, the current evidence indicates that MGs have little impact on reducing the incidence of concussions. The methodological quality of future studies could be improved by better descriptions of study participants, clear injury case definitions, consideration of potential confounders, quantitative reporting of adverse events, multivariable statistical analysis, monitoring of compliance, and consideration of statistical power. MGs should be used in all sport activities where there is significant risk of orofacial injury.

Data Availability The datasets generated during this review are available from the first author on reasonable request.

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Compliance with Ethical Standards

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Conflict of interest Joseph Knapik, Blake Hoedebecke, Georgia Rogers, Marilyn Sharp, and Steven Marshall declare that they have no conflicts of interest relevant to the content of this work.

Disclaimer The opinions or assertions contained herein are the private views of the author(s) and are not to be construed as official or as reflecting the views of the Army or the Department of Defense.

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