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Effectiveness and fabrication of mouthguards

REVIEW ARTICLE

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Abstract – Although mouthguards have been suggested as a means for preventing dental traumatic injuries, there are still some controversies over some aspects such as effectiveness in preventing concussions, material selections, method for fabrication, design, side effects and so on. The purpose of this literature review was to clarify differences in opinions with supporting evidence on these issues and find the best guidelines for promoting usage and providing mouthguards with better protective capability and fewer side effects such as difficulty in breathing and speaking.

Introduction

Sports related orofacial traumatic injuries occur frequently among various kinds of sports activities (1). Mouthguards have been utilized by athletes who recognize the need for oral protection during their sports activities, however the frequency of mouthguard usage is still limited. Reasons for not wearing a mouthguard are mainly the discomfort and the difficulty in breathing as well as in speaking (2).

To promote the utilization of mouthguards, properly fitted mouthguards should be fabricated and provided by dental professionals as indicated in the Academy for Sports Dentistry position statements (3). Other than the proper fit, proper outline and occlusion should also be considered.

Although many reports have been published on mouthguards and related matters, there are still some controversies over some aspects such as material selections, method for fabrication, design, side effects and so on.

The purpose of this literature review was to answer following questions and to clarify differences in opinions with supporting evidence.

1. Is the mouthguard effective for preventing or reducing traumatic incidents during sporting events? Which type of mouthguard is most effective?
2. How can we fabricate properly fitted mouthguards?
3. Are mouthguards effective for concussions?
4. Are there any side effects of mouthguards?
5. How can we promote mouthguard usage among athletes?

Efficacy of mouthguards in preventing or reducing traumatic incidents during sports events

Efficacy of mouthguards

Cohenca et al. (4) examined reported injuries to determine the effectiveness of mouthguards in reducing the incidence or severity of dental injuries, and found the incidence rate of basketball players was five times higher than that for American football players for whom mouthguard use is mandatory along with helmets and face masks. Although usage of a mouthguard has been regarded as an effective measure in reducing traumatic injuries during sports events, many reports have been based primarily on questionnaires or subjective opinions among athletes without statistical analysis or a control group (5–8).

An American Dental Association report (9) again indicated that the use of mouthguards can reduce the incidence and severity of sports-related oral injuries, however, it also recommended further study on the effectiveness of currently available mouthguard types and population-based interventions for reducing injuries. The Centers for Disease Control (10) pointed out that there was insufficient research data from randomized controlled trials and identified the need for more high-quality research on the effectiveness of the mouthguard. The lack of acceptable scientific evidence utilizing randomized clinical trials (RCT) was the reason that many of the studies were not valid.

A few studies using proper study designs and statistical analysis, however, have reported the efficacy of the mouthguard in reducing traumatic injuries. Labella et al. (11) reported that mouthguard users had significantly lower rates of dental injuries and soft tissue injuries than nonusers but not for concussions among college basketball players. Finch et al. (12) performed a randomized controlled trial and reported that there was a significant protective effect of custom made mouthguards, compared to commercial mouthguards, during games.

On the other hand, Bingnaut et al. (13) and Maestrello-deMoya & Primosch (6) reported there were no statistically significant differences between wearers and non-wearers of mouthguards with respect to head and neck injuries in general and to oral injuries in particular.

As was mentioned above, there are many reports suggesting the efficacy of the mouthguard in preventing or reducing the severity of dental trauma, however, it is still necessary to have better scientific evidence based on well-controlled study designs.

Biomechanical role of the mouthguard

In order to determine the efficacy of the mouthguard in preventing or reducing the severity of traumatic dental injuries, we have to understand how traumatic injuries occur and how a mouthguard functions during an incident.

Cummins & Spears (14) examined the effect of mouthguard design on stresses in the tooth-bone complex using the finite element model. They suggested that low-stiffness mouthguards absorb shock during hard-object collisions (e.g. baseballs) but may not protect the tooth-bone during soft-object collisions (e.g. boxing gloves). They also suggested reconsidering material and structure of mouthguards to optimize protective capabilities for a range of loads. According to Miura and Maeda's biomechanical study (15), the incisor avulsion starts with the rotation with the center located at the edge of palatal alveolar bone combining the stress concentration at the labial bone. They also suggested if the mouthguard material is too soft, bone with a highly stressed concentrated area will fracture. Miura et al. (16) also demonstrated the direction oriented visco-elastic characteristics of tooth structure under loading, using a multi-scale analysis of stress distribution in teeth, will help in understanding crack propagation during tooth fracture.

Results of these studies suggest that mouthguard material or structure should have rigid stress dissipating capability as well as soft shock absorbing capability to protect the tooth-bone complex during traumatic incidents.

Types of mouthguards

According to the Academy for Sports Dentistry's (ASD) definition, three different types of mouthguards are available now. Type 1 is the stock type, which has no capability to adjust to an individual's morphological characteristics. Type 2 is the so-called mouth-formed or boil and bite type. Both Type 1 and 2 are commercially available and referred to as over-the-counter or on the shelf type. Type 3 is the custom-made mouthguard including the singe layer and the multi layer laminated type.

Seals et al. (17) pointed out that a properly constructed custom-made mouthguard will minimize the common complaints reported by coaches and trainers. They also suggested the need for more education about the types of mouthguards, their merits, and their availability.

Guevara et al. (18) reported that commercially available mouthguards have a higher rebound capability due to the greater thickness in incisal region. Conversely, Park et al. (19) reported that the reduction of thickness during the forming process among commercially available mouthguards was larger than custom made ones. Fakhruddin et al. (20) carried out a population-based, matched case-control study on the use of mouthguards among 12- to 14-year-old schoolchildren, and reported that only 5.5% of children wore mouthguards for school sports, and 20.2% wore protection in league sports. Of those who wore mouth protection, 48.2% wore boil-and-bite mouthguards and 21.4% wore stock-type mouthguards; only 30.4% wore professionally fabricated, custom mouthguards.

Properly fitted mouthguards, specifically custom-made mouthguards, should be recommended in order to reduce common complaints of mouthguards such as difficulty in breathing and speaking. Since a large number of athletes still use commercially available mouthguards, the definition of 'the properly fitted mouth guard' by Academy for Sports Dentistry also include a dentist supervised 'boil-and-bite' (3).

Fabrication of properly fitted mouthguards

Selection of material

Several materials have been suggested for mouthguards, such as: (i) polyvinylacetate-polyethylene or ethylene vinyl acetate (EVA) copolymer, (ii) polyvinylchloride, (iii) latex rubber, (iv) acrylic resin and (v) polyurethane. Craig & Godwin (21, 22) suggested requirements for mouthguard materials based on hardness, impact absorption, tear strength, and water sorption. As Knapik et al. (23) reported that EVA has been predominantly selected for mouthguard fabrication due to the formability and ease of manipulation, though it still has limitations in terms of shock absorption capability and rigidity.

In addition, materials and designs for custom made mouthguards have been investigated to increase the shock absorption capability as well as rigidity.

Addition of some pigment to EVA material may influence the hardness.

Del Rossi et al. (24) examined the difference in fit among EVA materials with different colors on the model. They reported that dark-colored material can provide superior adaptation and more firmly fitting mouthguards than clear material.

Bulsara et al. (25) tested the force transmission through a laminated mouthguard material with a Sorbothane insert with high visco-elasticity. They concluded that a Sorbothane intermediate layer between heat-cured laminated EVA sheets may dissipate the force of impact significantly. Jagger et al. (26) reported that a new silicon material has good potential for use as a mouthguard material. Westerman et al. (27) examined the effect on energy absorption of hard inserts in laminated EVA mouthguards. They found that hard inserts resulted in reduced energy absorption when compared with a control sheet of the same material and approximate thickness but without the hard inserts. Brionnet et al. (28) examined the rugby players' satisfaction with custom-fitted mouthguards made with different materials (silicone rubber and methyl-methacrylate) with a crossover design study. They found there was no significant difference between mouthguards made with the two materials concerning comfort, bulkiness, ability to talk and to breathe, oral dryness and nausea. Westerman et al. (29, 30) also studied the regulated air inclusions or closed foam in the EVA material. However, the materials could not decrease transmitted forces through mouthguards. Takeda et al. (31) suggested that a hard insert and air space between the sheet material and tooth surface can significantly decrease the distortion of teeth.

Shock absorbing capability

Since the effectiveness of mouthguards *in vivo* during studies cannot be easily demonstrated due to ethical reasons, well simulated and validated in vitro model studies or standardized test methods should be established. Several studies have been conducted, such as the simulated jaw model by Greasley et al. (32, 33) and de Wet et al. (34).

Takeda et al. (35) demonstrated the significance of the impact object such as a steel ball, baseball, softball, field hockey ball, ice hockey puck, which influences the amount of transmitted forces through mouthguards. He suggested testing the effectiveness of mouthguards against a specific type of sports equipment. Takeda et al. (36) also indicated the difference in the measured impact absorption ratio of mouthguard materials between sensor types, and the need for using a standard sensor.

Currently EVA is the material of first choice for fabricating custom made mouthguards in terms of availability and ease in manipulation. However, a new material providing the higher shock absorbing capability and rigidity with minimum thickness should be developed and tested in a standardized manner.

Fabrication of mouthguards

In order to achieve a precise fit of the mouthguard, several factors should be controlled during the fabrication process. Since the thermoforming method, using sheet type thermoplastic materials, is the most common method for mouthguard fabrication, factors related to the thermoforming process should be discussed.

Working model

Machi et al. (37) suggested that the palate portion of the impression should not be poured with the stone material for fabricating custom-made mouthguards in order to produce precise working models. Yonehata et al. (38) studied the influence of working cast residual moisture and temperature on the fit of vacuum formed athletic mouthguards. It was found that residual moisture in the working cast was the most critical factor in determining the fit of the mouthguard made by vacuum-forming machines because air trapped between the formed sheet material and model should escape through the working model. The best fit was achieved when the working cast was thoroughly dried and its surface temperature was elevated.

Heating and cooling

Yamada & Maeda (39) reported that the suitable temperature range for forming of the EVA was 80–120°C and the forming process should be completed before reaching the lower limit. Nishida et al. (40) reported that the importance of cooling down the formed sheet material to room temperature in order to avoid the deformation during removal from the model. Machi et al. (41) reported in an experimental study that heterolytic distortion was found in mouthguards removed immediately after the forming process while uniform distortion was found in those removed after the proper cooling period.

Thickness of sheet

Thickness of the mouthguard is a matter of great importance, since the shock absorption capability or energy absorption capability directly depend upon the thickness of mouthguard material.

Required thickness for protection

Westerman et al. (42) examined forces transmitted through EVA mouthguard materials of different types and thicknesses and indicated that transmitted forces were almost the same when the thickness became more than 3 mm. Tran et al. (43) tested tensile strength, elongation, hardness and water absorption of EVA mouthguard materials. They indicated that the thicker 5 mm EVA material was recommended for mouthguards as it displayed the least deformation to load and performed equally as well in the tests as other thicknesses. Westerman et al. (44) indicated that the optimal thickness for EVA mouthguard material with a Shore A Hardness of 80 is around 4 mm. If the thickness increased, while improving performance marginally, results indicated less wearer comfort and acceptance. Maeda et al. (45) tried to determine the minimum thickness required to obtain sufficient energy absorption. From their results, it was suggested that the minimum thickness for EVA mouthguard is 4 mm.

Thickness control during the fabrication process

Thickness of the mouthguard sheet can be changed during the thermoforming process. Park et al. (19) studied EVA materials, varying in thickness and stiffness, while testing their mechanical, thermal, and water-absorption properties. The authors reported that during fabrication, thicknesses decreased from 25% to 50% for the custom-fabricated mouthguards and 70–99% for the commercially available mouth-formed (boil-and-bite) mouthguards. Therefore, commercially available mouthguards are less effective than custom made ones. Bemelmanns & Pfeiffer (46) also examined the shock absorbing effect of the thickness of 'boil-and-bite' and EVA mouthguards layered with silicone or with small hard PVC inserts *in vitro*. They found the boil and bite type was significantly less effective and EVA with PVC inserts had no significant effects.

Thinning of the sheet is particularly critical when it occurs in the area where the external impact is generally exerted, specifically the upper anterior region. Yamada et al. (47) indicated that the thickness rather than the location of the anterior palatal margin of the mouthguard has a significant influence on the reduction of tooth deflection against a horizontal blow. Westerman et al. (42) pointed out the need of avoiding occlusal thinning, especially on the incisal edges since thinning results in the reduction of protection offered by the mouthguard.

Changes in the thickness of formed sheet material are closely related to the working model height or model placement during thermoforming process. Yamada et al. (48) suggested the reduction in sheet thickness formed on the model surface parallel to the sheet surface was smaller than vertical to the sheet surface. Del Rosse & Leyte-Vidal (49) reported a high negative correlation between the model height and the thickness of finished mouthguard sheet, and suggested that the model height should be kept as low as possible. Geary & Kinirons (50) examined the post thermoforming dimensional change (thickness) of EVA thermoformed over dental models under a number of common processing conditions including, model height, inclination, shape and model temperature, model position on the thermoforming platform, plasticizing time and evacuation method. They reported that sheets of 3-mm EVA stretched by 52% during the thermoforming conditions where incisal/cuspal sites were found to be significantly thinner when compared with all other locations measured.

Nakajima et al. (51) introduced an improved fabrication method for increasing the required thickness at the anterior region of the mouthguard using a vacuum type forming machine.

Summary

Citing the previously mentioned reports, the following protocol can be suggested for the thermoforming process of a mouthguard. In order to obtain enough thickness (at least 3 mm) for protection, an EVA sheet with thicker than needed thickness should be selected. The working model should be inclined to where the labial surface of anterior teeth can make a sharp angle to the sheet surface.

Lamination

With the thermoforming technique, it is possible to fabricate multiple layered mouthguards since heated EVA sheets can be fused to each other firmly.

Kenyon & Loos (52) reported that there was a statistically significant patient preference for the double-layered heat- and pressure-laminated mouthguard against a single-layered vacuum-formed EVA mouthguard. With the lamination of EVA sheets, the inclusion of logos, color combinations, and the thickness of the mouthguards can be controlled.

Laminated mouthguards also provide stability. Chaconas et al. (53) suggested that clear thermoplastic material revealed less dimensional change than the polyurethane material and the laminated thermoplastic sheets showed significantly less dimensional change than the other materials tested. Waked et al. (54) studied the effects of aging on the dimensional stability of custom-made mouthguards in vitro. The authors indicated that most of the dimensional change for all mouthguards occurred at the central incisor region, the most important area for the protection of the anterior teeth and the premaxilla. Pressure-laminated mouthguard specimens showed the smallest range of changes at the central incisor region, suggesting potentially improved fit, comfort, and protection. Miura et al. (55) examined the stress concentration during the thermoforming process using three dimensional finite element models. It was also found that the greatest stress accumulation, where most deformations were observed, occurred in the anterior incisal area. In summary, laminated double layer mouthguards have advantages over single-layer ones in terms of longitudinal stability due to lower stress accumulation during the fabrication process.

Design

A great deal of attention has been given to designing mouthguards that are comfortable. Chandler et al. (56) introduced a modified maxillary mouthguard to improve the comfort. Bimaxillary mouthguards (57), however, may still be useful in some cases where the jaw relation should be stabilized. In the design of the mouthguard, it is also necessary to provide a mouthguard that does not interfere with breathing and speech as Gardiner and Ranalli pointed out (2).

Labial side and palatal side

McClelland et al. (58) suggested that comfort is likely to be increased if mouthguards are extended labially to within 2 mm of the vestibular reflection, adjusted to allow balanced occlusal contact, rounded at the buccal peripheries, and tapered at the palatal edges. Maeda et al. (59) reported on the influences of design and finishing of the mouthguard with respect to wearability and retention *in vivo*. The study found significant improvements in comfort, breathing, speaking and swallowing by trimming the palatal margin to the cervical area of the lingual surface of the teeth, finishing all borders so that they are smooth, and adjusting the occlusion of the mouthguard (Fig. 1). No significant difference in retention among different palatal margin designs was found. Maeda et al. (60) also experimentally examined the relation between outline design and retention of mouthguards. In this study, it was found that the outline design did not influence the retention of

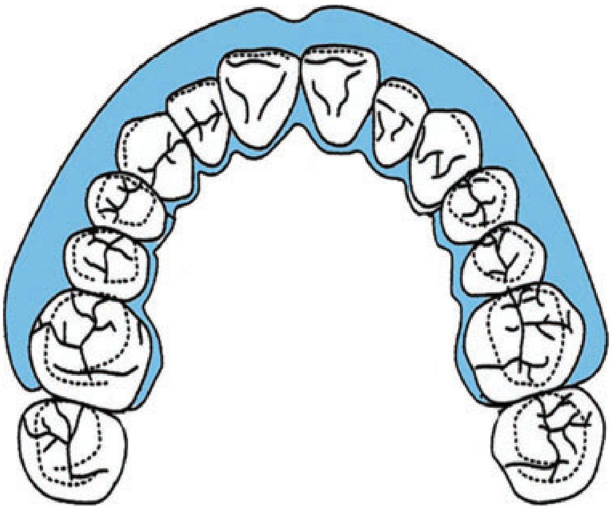

Fig. 1. Significant improvements can be achieved in comfort, breathing, speaking and swallowing by trimming the palatal margin to the cervical area, smooth finishing and occlusal adjustment of the mouthguard. (Adopted and modified from Ref. (59)).

mouthguards as far as the fit was concerned. The reason was that the undercut at the cervical area of molar teeth provided the main retention for the mouthguard.

Occlusion
Since mouthguards cover the occlusal portion of dental arch, the occlusion of mouthguards is another important factor for improving their efficacy.

Takeda et al. (61) discussed the influence of anterior occlusion of mouthguards in protecting the maxillary anterior teeth, indicating that occlusal contacts of the anterior part of mouthguard are necessary for reducing the impact force and tooth distortion. Tsugawa et al. (62) reported the influence of two different mouthguard occlusal surface designs on the performance of female soccer players using a crossover study design and visual analog scale (VAS) questionnaires. They found no statistical difference between the deep intercuspation and the flat occlusal table design in the posterior region of mouthgurads.

There is still need to investigate the influence of occlusion and jaw position for mouthguards on shock absorbing capability, so that the minimum optimal thickness of mouthguard material on the occlusal surface can be determined.

Special design

Orthodontic patients
Special attention should be given to athletes with orthodontic appliances, because they are highly susceptible to soft tissue injuries. Newsome et al. (63) indicated that athletes undergoing orthodontic treatment present a particular problem as they are potentially at greater risk of injury because of increased tooth mobility and the presence of orthodontic appliances. As previously mentioned the fabrication of mouthguards for these patients is problematic. Croll & Castaldi (64) and Maeda et al. (65) suggested modified methods to minimize those problems when fabricating a custom mouthguard.

Diving mouthpiece
As Koob et al. (66) and Hirose et al. (67) indicated that clenching is the greatest risk factor for fatigue while holding the mouthpiece and for pain in the masticatory muscle system after diving. One of reasons for that is the lack of proper design for the holding part of the mouthpiece. Hirose et al. (68) examined the mouthpiece design for diving with the finite element analysis, and suggested an improved design for a diving mouthpiece in terms of the comfort and the strength.

Summary
As in ASD committee on position papers (3), a custom-made mouth guard should be fabricated on the durable accurate cast preferably with a pressure type forming machine, multiple laminations facilitate the use of variable stiffness and insertion of reinforcement materials or team logos. Custom-made mouth guard includes adaptations for the individual athlete, the specific demands of the athletic activity, modifications in the thickness to minimize bulk in non-essential areas, accommodating orthodontic appliances and growth changes, while facilitating ease in breathing, speech and general fit and comfort.

Efficacy of mouthguards for concussion

Although Hickey et al. (69) suggested that a mouthguard could help in reducing the forces of a traumatic impact in a single cadaver skull experiment, this paper has been quoted for many years, and the role of mouthguards in concussion incidents has been controversial due to the insufficient amount of scientific evidence as suggested by McCrory (70).

In an *in vitro* study, Takeda et al. (71) showed that the distortion to the mandibular bone and the acceleration of the head significantly decreased with a mouthguard as compared to no mouthguard.

Labella et al. (11) reported that there were no significant differences between mouthguard users and nonusers in rates of concussions among college basketball players. Mihalik et al. (72) reported that mouthguard use does not decrease the severity of concussion among student-athletes. Knapik et al. (23) also indicate that mouthguards are not effective in preventing concussion based on their literature review.

Regarding the type of mouthguard used in relation to concussion, Wisniewski et al. (73) found no advantage in wearing a custom made mouthguard over a boil-and-bite mouthguard in reducing the risk of cerebral concussion in football players. Similarly, Barbic et al. (74) examined the relation between mouthguard designs and concussion prevention by a multi-center randomized controlled trial with 394 university football and rugby players. Their results also indicated that concussion rates were not significantly different among different types of mouthguards used.

Some studies suggested the use of mouthguards along with the use of other protecting devices such as face shields may contribute to the reduction in the risk of concussion (75, 76) among ice hockey players. Kemp et al. (77) attempted a prospective cohort study on the epidemiology of head injuries in the English professional rugby union and reported that mouthguard and headgear usage was associated with a reduced incidence of concussive injury.

Although most of previous studies did not indicate the effectiveness of mouthguards in reducing the incidence or severity of concussion, it is still better to advise players, particularly in collision sports, to wear a mouthguard as a safety measure in preventing dental injuries.

Side effects and influences of mouthguards

In seventies and eighties, many reports were published discussing the relation between the oral appliance such as the mandibular orthopedic repositioning appliance (MORA) and athletic performance (78–84), however, it is not possible to draw conclusions from these studies due to problems of their study design such as lack of proper controls, and inclusion and exclusion of specific criteria for test subjects. Authors are also seriously concerned about doping issues and athletic performance when the positive influence of certain cases of mouthguard usage is reported.

With respect to oxygen consumption or uptake, Keçeci et al. (85) and von Arx et al. (86) suggested custom-made mouthguards do not have negative effects on the aerobic performance capacity. Francis & Brasher (87) even suggested that although mouthguards may be perceptibly uncomfortable and restrict forced expiratory airflow, they appear to be beneficial in prolonging exercise by improving ventilation and economy. Bourdin et al. (88) also indicated that maxillary mouthguards do not influence physiological parameters, such as visual reaction time, explosive power, ventilation at rest, and ventilation and oxygen consumption during submaximal and maximal exercise.

With these results, it is possible to conclude that wearing properly designed and fitted mouthguards do not influence ventilation and oxygen consumption.

Other side effects of mouthguard usage to be examined further include the possibility of caries development with sports drink intake (89) and disease transmission by contamination of mouthguards (90).

Promotion of mouthguards

In order to increase the usage of mouthguards among athletes, it is of the utmost importance to increase the recognition and understanding of safety measures among not only players but also coaches and related associations. In those sports activities with frequent contacts such as rugby, basketball and so on, mandating of mouthguard usage in certain age groups should be seriously considered (91). For example, mouthguards have been mandated among high school rugby players since 2006 in Japan.

Yamada et al. (92) reported that many soccer athletes had insufficient knowledge about mouthguards and were not concerned about preventing oral injury, although it was, in fact, a common problem in their sport in Japan. They suggested that athletes as well as coaches must be made aware of the high risk of oral injury when playing soccer, rugby, and other contact sports. Berg et al. (93) examined high-school athletic coaches' perceptions about oral-facial injuries and mouthguard use in sports that do not mandate mouthguard use. They indicated that advocacy for mouthguard use should focus on coaches, coaches' associations and rule-making organizations. Maestrello et al. (94) found that many dentists do not think they are responsible for distributing and fabricating the mouthguards.

Newsome et al. (63) suggested in their review that we should promote the use of mouthguards much more, although voluntary use of mouthguards is frequent in some sports such as rugby. Marshall et al. (95) found that equipment usage was highest in those at greatest risk of injury, namely, forwards, male players, and the senior grades in New Zealand rugby players. Jalleh et al. (96) evaluated the mouthguard promotion campaign in Western Australia launched at the start of the 1997/1998 junior rugby union and junior basketball seasons and found an increase in mouthguard usage.

Cornwell et al. (97) studied the knowledge of the value of mouthguards for prevention of injury among Australian basketball players and their experience with orofacial injury, and found that the overall extent of mouthguard use was disappointingly low despite wide recognition of mouthguard value. Muller-Bolla et al. (98) performed a survey among rugby players in France and found that the frequency of mouthguard usage increased among those who had experience of trauma previously.

Onyeaso et al. (99) surveyed coaches with a self-completion questionnaire about oro-facial injuries and mouth protector usage among adolescent athletes in Nigeria. They reported that the majority of coaches agreed on the protective effectiveness of the mouthguard, but they are yet to be adequately informed about mouthguards so as to correctly advise and influence these adolescent athletes.

To promote the usage of mouthguards among players, it is necessary to have strategies such as involving coaches and related personnel who can directly influence players' attitudes along with the proper knowledge of safety measures.

Conclusions

Within the limitation of this literature review, the following conclusions can be made:

1. Mouthguards have been regarded as an effective means for preventing or reducing severity of dental trauma, and further scientific evidence based on the well-controlled experimental designs is necessary to validate the efficacy of athletic mouthguards.
2. In order to achieve the precise fit of the mouthguard, factors related to the thermoforming process, such as working model residual moisture, heating temperature, and so on, should be controlled. By applying the proper design, problems in breathing and speaking with mouthguards can be minimized.

3 Efficacy of mouthguards for concussion prevention is still controversial.
4 Wearing properly designed and fitted mouthguards does not influence ventilation and oxygen consumption.
5 For the promotion of the usage of mouthguards among players, it is necessary to educate coaches and related personnel about the protection afforded by mouthguards.

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