Integrated Master in Dental Medicine

Faculty of Medicine of the University of Coimbra

Overview and systematic review on sports mouthguards

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ABSTRACT

Aims: The three objectives of this work are to make an overview that summarizes the existing evidence about the use of mouthguards concerning different outcomes; to elaborate a systematic review about the comfort and acceptance of mouthguards by the athletes; and to elaborate an experimental project that intends to investigate materials for the manufacture of mouthguards, using 3D printing.

Methods: Two separate researches, guided by a protocol to address the PICO (Population, Intervention, Comparison intervention and Outcome) questions were elaborated: 1. "What is the current evidence regarding the use of sports mouthguards?"; 2. “Does the use of mouthguards in sports practitioners significantly affect the comfort?”. Research has been done in four databases (PubMed, Web of Science, Cochrane and EBSCO). For Overview 8 articles were selected, including only systematic reviews. For the Systematic Review 33 articles were selected including all types of studies except in vitro studies. The methodological quality of studies was assessed with the AMSTAR 2 tool for Overview and with RoB2 and NOS tools for systematic review articles. The experimental project was guided by a protocol created specifically for the study.

Results: Eight studies in the overview evaluated the parameters: cardiopulmonary capacity, prevalence of dentofacial injuries, effectiveness of oral protectors and the effect of different types of protectors on athlete performance. One article evaluated the cardiopulmonary capacity, four evaluated the prevalence of dentofacial injuries, two evaluated the effectiveness of mouthguards and one the effect of different type of mouthguards. The systematic review analyzed thirty-three studies, addressing comfort parameters, difficulty in breathing, speech, xerostomia sensation, nausea, stability, chewing, pain, bulky sensation, jaw fatigue, distraction, protection and acceptance. The results were compared with the help of the VAS scale (Visual Analogue Scale) used by many of the studies. Besides that, the experimental project demonstrated better results for thermoplastic polyurethane with respect to its mechanical properties.

Conclusions: Mouthguards contribute to a lower prevalence of dentoalveolar trauma among athletes. Custom-made mouthguards showed the smallest variety of changes in players' performance. This type of mouthguard had better results in comfort, acceptance, speech interference, breathing difficulty, nausea, mouth dryness, stability and other outcomes denoted by athletes. Preliminary tests, with 3D printed polymers, showed that thermoplastic polyurethanes (TPU) are the materials that present properties similar to the solid polymer normally used in the manufacture of this type of protectors.

Keywords: sports, mouth protectors, trauma and injury, patient comfort, patient satisfaction, acceptance

RESUMO

Objetivos: Os três objetivos deste trabalho são elaborar uma *Overview* que sumarize a evidência existente em revisões sistemáticas sobre o uso de protetores bucais; elaborar uma Revisão Sistemática para se determinar a relação que o uso de protetores bucais com o conforto e aceitação pelos desportistas; e elaborar um projeto experimental que pretende investigar materiais para fabrico de protetores, utilizando a impressão 3D.

Métodos: Foram elaboradas duas pesquisas separadas, orientadas por um protocolo para abordar as questões PICO (População, Intervenção, Comparação e *Outcome*/Resultado): 1. “Qual é a evidência atual sobre o efeito do uso de protetores bucais por desportistas?” 2. “O uso de protetores bucais afeta o conforto durante a prática desportiva?” As pesquisas foram feitas em quatro bases de dados (PubMed, Web of Science, Cochrane e EBSCO). Para a *Overview* foram selecionados 8 artigos, incluindo apenas revisões sistemáticas. Para a Revisão Sistemática foram selecionados 33 artigos, incluindo todos os tipos de estudos exceto *in vitro*. A qualidade metodológica dos estudos foi avaliada com a ferramenta AMSTAR 2 para a *Overview* e com as ferramentas RoB2 e NHI para a Revisão Sistemática. O projeto experimental foi orientado por um protocolo criado especificamente para o estudo.

Resultados: Oito estudos integrantes da *overview* avaliaram os parâmetros: capacidade cardiopulmonar, prevalência de lesões orofaciais, efetividade dos protetores bucais na prevenção de lesões e efeito dos diferentes tipos de protetores na performance do atleta. Um artigo avaliou a capacidade cardiopulmonar, quatro avaliaram a prevalência de lesões, dois avaliaram a efetividade dos protetores e um o efeito dos diferentes protetores na performance. A revisão sistemática realizada analisou trinta e três estudos, tendo sido abordados os parâmetros conforto, dificuldade em respirar e falar, sensação de xerostomia, náusea, estabilidade, mastigação, dor, sensação de “boca cheia”, fadiga articular, distração, proteção e aceitação. Os resultados foram comparados com a ajuda da escala de VAS (*Visual Analogue Scale*) utilizada por muitos dos estudos. O projeto experimental demonstrou melhores resultados para as poliuretanas termoplásticas (TPU), no que diz respeito às suas propriedades mecânicas.

Conclusões: Os protetores bucais contribuem para uma menor prevalência de lesões dentoalveolares em desportistas. Os protetores individualizados obtiveram resultados de menor variação de desempenho dos atletas. Este tipo de protetor revela melhores resultados no que respeita ao conforto, aceitação, interferência na fala, dificuldade respiratória, náuseas, sensação de xerostomia e estabilidade. Os testes preliminares, com polímeros processados por impressão 3D, mostraram que as poliuretanas

termoplásticas (TPU) são os materiais que apresentam propriedades semelhantes ao polímero maciço normalmente utilizado na manufatura deste tipo de protetores.

Palavras-chave: desporto, protetores bucais, trauma e lesão, conforto do paciente, satisfação, aceitação.

Currently, there has been an increase in sports activity, aiming at the physical and psychological well-being of the individual. Consequently, research has been carried out to improve sports practice and prevent injuries resulting from it. In contact sports there are huge injuries that can occur, such as soft tissue lacerations, dental dislocation, dental fractures (especially in the upper anterior teeth), alveolar or temporomandibular joint (TMJ) fractures, concussions, etc.[1, 2] According to data from the National Youth Sports Foundation for the Prevention of Athletic Injury, during a sports season, athletes have a 1/10 risk of facial injury. This type of injury represents 45% of the life risk and an athlete is sixty times more likely to suffer facial trauma when not wearing a mouthguard.

To prevent athletic injury, mouthguards have been created, although their use remains the exception and not the rule. Therefore, it is important to reinforce the relevance of their use and their adaptation to each sport. There are three types of mouth protectors: stock - not customizable; boil-and-bite - the most widely used (the user softens it in hot water and conforms it to the mouth) - and custom-made - individually adapted to the user and requiring an intra-oral impression and a laboratory process.[4]

A mouthguard can suffer various types of damage, most often permanent deformations, fractures, delamination or holes.[5, 6] As an advantage, these types of devices reduce the impact of forces on the oral cavity, both hard and soft tissues. Disadvantages may include poor speech, reduced respiratory efficiency, discomfort and aesthetics.[7] The effectiveness of a mouthguard can be related to the energy absorption of the material, resistance to deformation or comfort of the user.[8] There has been a need for evolution in the current oral protectors, essentially due to poor compliance, the need to use materials with greater protection capacity (thinner) and more sustainable, with less waste of material.

It is known that most athletes, particularly in some sports, are aware of the importance of using a mouthguard, due to its protective effect for the oral cavity. Some authors believe that athletes who use adequate mouthguards are less afraid of injuries and more focused.[9] However, many athletes do not use proper custom-made mouthguards, opting for boil-and-bite type.[10]

Thus, athlete's adherence and perception are important to reduce the number of injuries discussed above.[11] Comfort can be influenced by the adjustment, thickness and extension of the mouthguard.[12] It is important that it does not cause lesions, nausea or dry mouth. Also, it should be retentive and allow good breathing and speech.[12, 13] The fact that there are no regulatory committees for these devices results

in the widespread production of mouthguards which are inadequate and may impair the practice of sports.[14]

Nowadays, it is known that the manufacturing methods of appropriate mouthguards cause a substantial waste of material and are laborious in their preparation. The gold-standard material is still ethylene vinyl acetate (EVA). Until now, the concept of its manufacture was based on the elaboration of plaster models and subsequent manufacture of the protector, using thermoforming machines, which can be of vacuum or pressure.[15, 16] However, this type of production has some disadvantages, such as longer laboratory time, excess of material wasted, etc.

To reduce the problems identified above, improved 3D impression techniques have become a good solution, since there is the possibility of customization / thickness variation in different regions and an individual design can be created. The waste is greatly reduced [17] and it is possible to use materials other than the gold standard EVA.

The addition manufacturing 3D printing consists of incorporating a liquid or powder material into a solid object.[18, 19] The International Organization for Standardization (ISO / TC261), in collaboration with the American Society of Testing and Materials (ASTM), has defined additive manufacturing (AM) as "a process of joining materials to create objects from 3D model data, usually layer by layer as opposed to subtractive manufacturing methodologies". ISO (ISO 17296-2: 2015) has determined seven categories of additive manufacturing - vat-photopolymerization, jetting material, extrusion material, binder jetting, powder bed fusion, sheet lamination and directed energy deposition.[20] With regard to the material extrusion or fused deposition modelling (FDM) technique, this is a 3D printing method based on the extrusion of a thermoplastic material.

Thus, through the analysis of everything that has already been done and realizing the flaws that still exist in sports mouthguards research, the aim of this work is to summarize the existing evidence in more than one systematic review, concerning the use of sports mouthguards and evaluate which results are most addressed (effectiveness of mouthguards, prevalence of trauma, cardiopulmonary capacity, performance, etc.). The second objective is due to the need to prepare a systematic review (SR) in order to answer the question: Does the use of mouthguards in sport affect the comfort reported by practitioners? Finally, trying to overcome some disadvantages reported, an experimental project will be created based on the attempt to manufacture sports mouthguards using 3D printing, with additive technique (FDM), maintaining the ideal mechanical properties and reducing waste.

OVERVIEW ON SPORTS MOUTHGUARDS

METHODS

➢ Criteria for considering reviews for inclusion

The present overview launched from the following research question: What is the current evidence about the use of sports mouthguards?

Eligibility criteria of studies for the present overview was based on the PICO model. The reviews were considered for inclusion if they met the following criteria of population and interventions:

- **Population**: sports practitioners.
- **Interventions**: use of mouthguards.
- **Comparison**: no mouthguards using
- **Outcomes:**

The primary outcomes of interest to this overview were:

1. Acceptance, comfort and perception of the athletes about mouthguards;
2. Comparing different types of mouthguards.

Secondary outcomes included the assessment of:

1. Athletic performance with mouthguards;
2. Prevalence of dento-alveolar trauma;
3. Cardiopulmonary capacity.

Only systematic reviews with or without meta-analysis were included. Revisions that were not written in English, Portuguese or Spanish were excluded. Studies that did not address orofacial injuries or that addressed protective equipment other than mouthguards were excluded.

➢ Search methods for identification of reviews

For the identification of studies to be included in the present review, a detailed search strategy was developed for MEDLINE via PubMed, Dentistry and Oral Sources and

SPORTDiscus Database via EBSCOhost, Web of Science and the Cochrane Central Register of Controlled Trials up to 31 May 2020.

The search strategy was modified for each database and performed by two reviewers.

Table 1 lists the search strategies defined for each database.

The electronic search was complemented by hand search of *Journal of Dental Traumatology*.[21]

PUBMED	
#1 "mouth protectors"[MeSH Terms] OR “mouth protector*”[Title/Abstract] OR "guards mouth"[Title/Abstract] OR "mouthguard*"[Title/Abstract] OR "mouth guard*"[Title/Abstract] OR "mouth protector*"[Title/Abstract] OR "mouth piece*"[Title/Abstract] OR "mouthpiece"[Title/Abstract] OR "oral splint*"[Title/Abstract]	**#2** “systematic review”
#1 AND #2	
EBSCO	
#1 TI = ("mouth protectors" OR "mouth protector" OR "protectors mouth" OR "guards mouth" OR mouthguard OR mouthguards OR "mouth guard" OR "mouth guards" OR "mouth piece" OR "mouth pieces" OR mouthpiece OR mouthpieces OR "oral splint” OR “oral splints”	**#2** “systematic review” OR “meta-analysis”
#1 AND #2	
WEB OF SCIENCE	

#1 TS = ("mouth protectors" OR "mouth protector" OR "protectors mouth" OR "guards mouth" OR mouthguard OR mouthguards OR "mouth guard" OR "mouth guards" OR "mouth piece" OR "mouth pieces" OR mouthpiece OR mouthpieces OR "oral splint" OR "oral splints")	**#2** TS= systematic review
#1 AND #2	
COCHRANE	
#1	MeSH descriptor: [mouth protectors] explode all trees
#2	“mouth protector*”
#3	“protectors mouth”
#4	“guards mouth”
#5	“mouthguard*
#6	“mouth guard*”
#7	“mouth piece*”
#8	“mouthpiece*”
#9	“oral splint*”
#10	“systematic review”
#11	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
#12	#10 AND #11

Tab. 1 - Database and search strategy (31 May 2020).

- **Data collection**

Selection of reviews

After duplicates removal, two overview authors independently screened the titles and abstracts for relevance based on the objectives of each review, population included, interventions and outcomes assessed, and excluded irrelevant reviews. The two authors then assessed the full text of the remaining reviews in order to select the final sample of reviews to be included. There was consensus between the two authors.

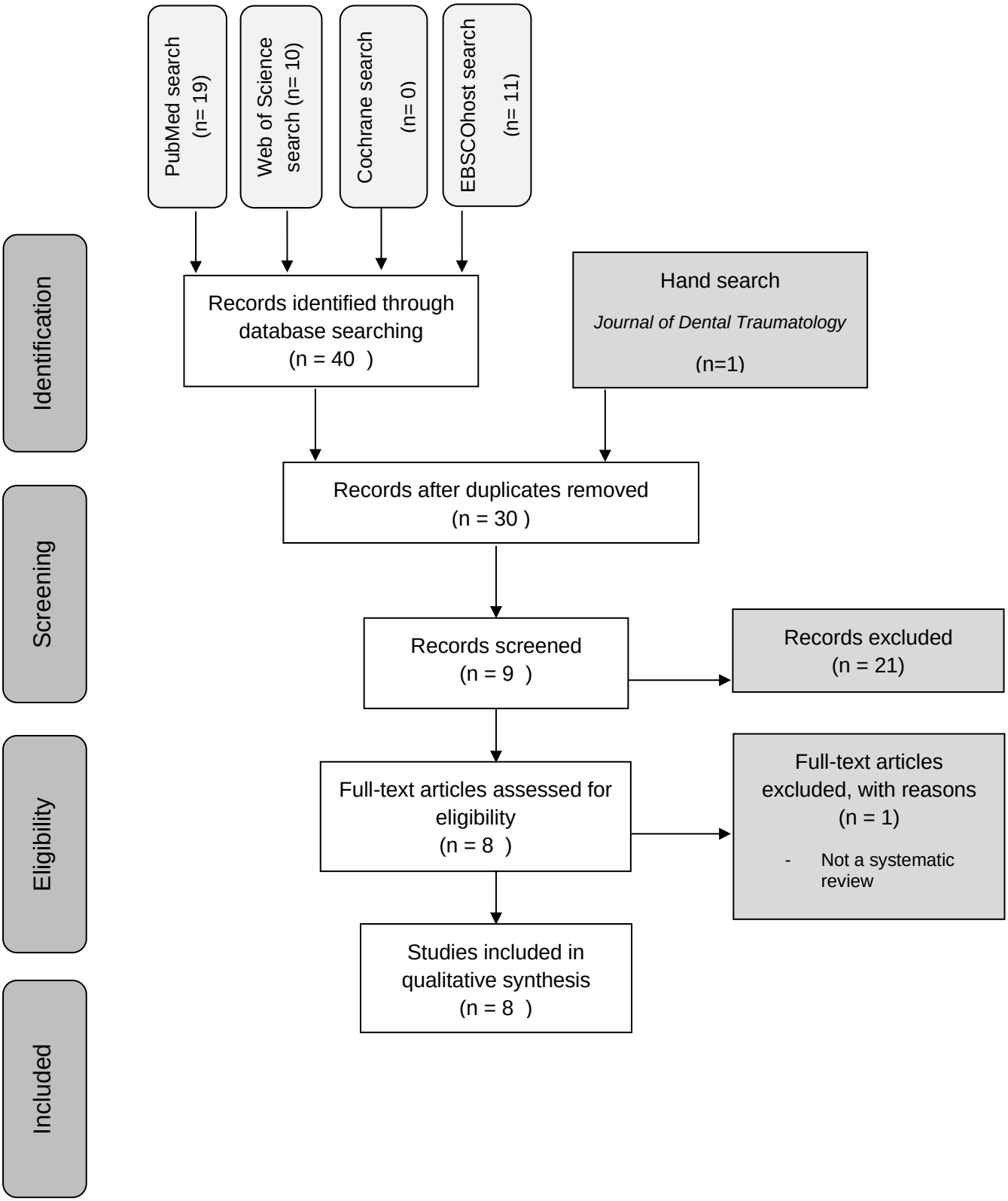


Fig. 1 - Study flowchart and process of selection of the studies.

Data extraction and management

Two overview authors independently extracted the data from each review to specific form containing fields related to the principal features of the review: authors, aims and rationale, number and types of studies, date interval of studies included, study population, interventions, tool used for quality assessment, outcomes, main results with or without meta-analysis and conclusions. Disagreements were debated to achieve consensus.

- **Assessment of methodological quality of included reviews**

The methodological quality of the reviews included was assessed using the AMSTAR 2 measurement tool for appraisal of systematic reviews of randomised and non-randomised studies of healthcare interventions.[22] The rating of the assessment can be high, moderate, low or critically low.

High - zero or one non-critical weakness: The systematic review provides an accurate and comprehensive summary of the results of the available studies that address the question of interest;

Moderate - more than one non-critical weakness: The systematic review has more than one weakness, but no critical flaws. It may provide an accurate summary of the results of the available studies that were included in the review. Multiple non-critical weaknesses may diminish confidence in the review and it may be appropriate;

Low - one critical flaw with or without non-critical weaknesses: The review has a critical flaw and may not provide an accurate and comprehensive summary of the available studies that address the question of interest.

Critically low - more than one critical flaw with or without non-critical weaknesses: The review has more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies.

Reference	Evaluation of risk of bias - AMSTAR2
Caneppele,2017	Low
Cusimano,2010	Low
Fernandes,2019	Moderate
Ferreira,2019	High
Knapik,2019	Moderate
Oliveira,2020	Moderate
Polmann,2020	High
Vucic,2016	Low

Tab. 2. Author's assessment of risk of bias of systematic reviews.

- **Data synthesis and statistical analysis**

Due to the fact that it was not possible to make a statistical analysis of the various outcomes of each systematic review, a descriptive synthesis of the results was made.

The original electronic search in MEDLINE (PubMed), EBSCOhost, Web of Science and the COCHRANE Database of Systematic Reviews (CDSR) retrieved 19, 11, 10 and 0 records, respectively. Hand search identified 1 potentially relevant record. After removing duplicates, 30 records were screened for title and abstract. This analysis allowed the exclusion of 21 records and 9 full texts were retrieved. After critical analysis of the texts, 1 study was excluded (Mascarenhas,2012), because it is not a systematic review. Figure 1 describes the process of identification and selection of the studies.

- **Study characteristics**

The selection process led to the inclusion of eight systematic reviews [23-30], two without meta-analysis [24, 26]. The studies included are summarized in Table 3.

The date range of reviews included was from 2009 to 2020, with studies from 1948 to 2018. Three of the reviews focused on sports practitioners in general [23, 26, 27], three on contact sports athletes [25, 28, 29], one specifically on rugby players [24] and one on field hockey players [30]. All interventions in the studies were related to the use of mouthguards, except for two that addressed dentofacial injuries [28, 29].

Even though there was broad heterogeneity and clinical variation among the selected systematic reviews (SRs), the authors could identify, within the context of the PICO question, three main outcomes based on the interventions assessed:

1. Cardiopulmonary capacity ($VO2_{max}$ - maximum oxygen volume; VE_{max} – maximum ejection volume) [23];
2. Effectiveness of mouthguards in athletic performance, different types of mouthguards [24, 26, 27];
3. Prevalence and different types of dentofacial injuries among sports participants [25, 27-30].

The use of the AMSTAR 2 tool identified 2 high-quality SRs [26, 29], 4 moderate-quality SRs [25, 27, 28] and 2 low-quality [23, 24, 30]. Main reasons for the attribution of moderate quality were absence of the reasons for selecting study types and absence of a list with excluded studies and no description of the source of funding of the studies included in the review, for example. SRs classified as low quality had major methodologic flaws, such as incomplete information of eligibility criteria, inadequate description of the studies included, incorrect evaluation of the risk of bias or not considering the influence of the quality of the studies with the results that may come from the meta-analysis.

First Author (Year)	Date range	Number of studies included and study types	Outcome measures	Outcome measures	Intervention	Meta-analysis
Caneppele,2017	1991-2015	14 RCT	Cardiopulmonary capacity (VO2 max, oxygen uptake; VE max, minute ventilation)	sports practitioners	use of MG	yes
Cusimano,2010	1948-2010	2 RCT, 3 cohorts, 1 ecological, 1 case-control, 3 case-series	Effectiveness of MG and headgear	rugby practitioners	use of MG and/or headgear	no
Fernandes,2019	1998-2017	14 cross-sectional	Prevalence of dento-alveolar trauma	practitioners of contact sports	use of MG	yes
Ferreira,2019	2005-2016	6 RCT, 2 crossover clinical trials, 7 controlled clinical trials	Effect of different type of mouthguards on athletics and performance in athletes.	sports practitioners	use of MG	no
Knapik,2019	1956-2018	8 non-randomized prospective cohort, 2 non-randomized retrospective cohort, 4 ecological, 11 cross-sectional surveys, 1 randomized prospective cohort	Effectiveness of MG, injuries prevention	sports practitioners	use of MG	yes
Oliveira,2020	1985-2018	17 cross-sectional	Prevalence of dentofacial injuries, most frequent types of dentofacial injuries and sports associated	practitioners of contact sports	presence of dentofacial injuries	yes
Polmann,2020	2002-2018	25 cross-sectional, 2 prospective cohort	Prevalence of dentofacial injuries, most frequent types of dentofacial injuries and sports associated	practitioners of contact sports	presence of dentofacial injuries	yes
Vucic,2016	1981-2008	11 cross-sectional	Dentofacial injuries, mouthguard use	field hockey practitioners	use of MG	yes

Tab. 3 – Description of the characteristics of the studies.

- **Interventions**

I. Cardiopulmonary capacity

With regard to cardiopulmonary capacity, the only review that addressed it was based on the analysis of studies that tested respiratory oxygen uptake (VO_{2max}) and ventilation (VE_{max}) in different types of sports practitioners, with specific exercises for this measurement.[23] This study highlights the difference in results depending on the type of mouthguard (MG), since one that is poorly adapted, as may happen in stock and boil-and-bite mouthguards, will need greater contraction of the perioral muscles to remain in position, for example, the need to keep the mouth closed to hold it, which will cause greater difficulty in breathing.

Thus, according to the parameters evaluated in this review, the use of a mouthguard in general affects cardiopulmonary capacity when compared with not using a mouthguard. However, analysing the subgroup that distinguished the type of mouthguard, it was concluded that custom-made mouthguards seems to have no effect on these parameters. The location of the mouthguard was also a factor of analysis, however, due to the low number of studies that tested on the lower-jaw, the influence of arch on the studied parameters could not be estimated.

II. Prevalence of dentofacial injuries

Regarding the prevalence of orofacial trauma, the Vucic (2016) study [30], which includes only studies from 1981 to 2008, reveals in its results that a relatively high proportion (22%) of field hockey players have sustained at least one dentofacial injury in their gaming career. No significant gender differences with regard to the proportion of dentofacial injuries were observed; however, female hockey players had two times higher odds for regular wear of a mouthguard than males. Besides that, the most common causes of dentofacial injuries were a hockey ball (56.5%) and a hockey stick (37.7%). An injured player had two times higher odds of regularly wearing a mouthguard than non-injured players. A significant increase in regular mouthguard use was observed from the 1980s (31.4%) until 2000s (84.5%). The most common complaints about the mouthguard were that it was unnecessary and uncomfortable.

In Fernandes (2019) it was observed that the prevalence of dental trauma within the included studies varied between 7.1% and 71.5% among athletes. Although this percentage varied significantly, ten studies indicated that the prevalence of trauma was less than 40%, depending on the type of sport practiced. Another factor is that the use of mouthguards is not a current habit among sports practitioners such as soccer,

basketball or volleyball. 69.7% of the athletes were affected with trauma during basketball practice, in which only 7% of the total players used mouthguards. [25]

Oliveira (2020) analysed that the overall pooled prevalence of dentofacial injuries among contact sports participants was approximately 30%. Rugby had the highest prevalence of dentofacial injuries. The most common injury was dental injury. [28]

Polmann's review (2020), which was best evaluated, obtained the same percentage of dentofacial injuries among combat sports participants worldwide that Oliveira (2020). Considering sports categories individually, jiu-jitsu presented the highest pooled prevalence of dentofacial injuries (53%) while judo was the sport with the lowest pooled prevalence (25.0%).[29]

As a summary of the mentioned reviews, the use of mouthguards among athletes of contact sports contributes significantly to a lower prevalence of dental trauma.

III. Effectiveness of mouthguards

Cusimano (2010) did not find evidence that headgear and mouthguards prevent neurological injuries in rugby. Nevertheless, this review suggested that there may be a place for better equipment design. [24]

Knapik's review (2019), which was better evaluated and made a meta-analysis, also found that the effect of using MG on the risk of concussion was minimal. This study 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. These data indicates that MGs should be used in sports activities where there is significant orofacial injury risk. [27]

IV. Effect of different type of mouthguards in athletic performance

Ferreira (2019) concluded that custom-made MG with adjusted contacts did not interfere or improve athlete's performance when compared to no use of mouthguard. Besides that, custom-made mouthguards showed the smallest range of changes in players' performance compared with other types of mouthguards. [26]

The present overview aimed to answer to the following question “What is the current evidence about the use of sports mouthguards?” by the analysis of previously published systematic reviews. Although there were few systematic reviews and there was no statistical establishment between them, there were several conclusions that could be drawn.

Thus, the conclusions are:

I. Mouthguards contribute to a lower prevalence of dentoalveolar trauma among athletes of contact sports and the most common injury was dental injury. Furthermore, no significant gender differences regarding the proportion of dentofacial injuries were identified. [30]

II. There is no evidence that headgear and mouthguards prevent neurological injuries in rugby. Moreover, the current evidence indicates that MGs have little impact on reducing the incidence of concussions. [24]

III. The use of a mouthguard in general affects cardiopulmonary capacity when compared with not using a mouthguard. However, custom-made mouthguards seems to have no effect on these parameters. [23]

IV. Custom-made mouthguards with adjusted contacts showed the smallest range of changes in players’ performance compared with other types of mouthguards. [26] There is still some controversy in the studies, as they do not specify whether the tested custom-made mouthguard has contacts adjustment in maximum intercuspation or not, which may cause different results. Kalman (2018) compared boil-and-bite, conventional custom-made and custom-made produced by impressions of the maxilla and mandible, with bite registration and a facebow record. It was concluded that the last MG presented a higher number of occlusal contacts, less increase in vertical dimension and less condylar displacement. The more evenly the forces are distributed, the greater the prevention of injuries.[65] More studies are necessary to know what kind of MG is more comfortable for the athlete.

V. Rugby and jiu-jitsu sports and the hockey ball and hockey stick equipment had the highest prevalence of dentofacial injuries. [28] [29]

VI. The most common complaints about the mouthguard were that it was unnecessary and uncomfortable. [30]

VII. The scientific evidence should be interpreted carefully because there is a great variability in outcome measures and lack of important methodological details.

More studies are necessary with a special focus in the perception of comfort and acceptance of mouthguards by athletes.

Strengths and limitations

The greatest strength of this overview is a correct methodology that intends to explore all the relevant literature (systematic reviews) that exists about mouthguards, always trying to involve two reviewers in searching/evaluation process.

Unfortunately, the considerable methodological heterogeneity of the studies is a limitation. Once the objective of this overview is exploring everything about mouthguards, each study was focused on a theme, resulting in different methodologies, types of studies, outcomes, etc. It will be expectable that a systematic review that addresses retrospective and prospective studies, cross-sectional and longitudinal, randomized and non-randomized studies, etc., will not have the uniformity that would be expected. Through this, we can perceive some evaluations of the AMSTAR 2 tool.

However, this demonstrates that more studies are needed, mainly randomized trials, with significant follow-up periods. So far, in the absence of such uniformity, it is necessary to consider all studies carried out in order to be able to draw practical conclusions, always aware of its limitations.

Implications for clinical practice

Once it has been found that athletes who use mouthguards have less than half the risk of orofacial injuries than those who do not, it is important to create rules and guidelines to make the use of mouthguards mandatory in contact sports, especially in sports where this failure is demonstrated.

For this, it is necessary to make athletes and sports committees aware of this importance and explain the variety of types of mouthguards, including each advantage and disadvantage, accentuating the benefit of using custom-made mouthguards. The presence of a dentist in this awareness would be very important.

Implications for future research

The small amount of systematic reviews on the topic of orofacial traumatology and mouthguards demonstrates that more research is still needed.

Future research should invest in well-designed randomized clinical trials. RCTs should include more comprehensive clinical evidence, including the perception of athletes in the use of mouthguards.

It would also be fundamental to introduce clear criteria to categorize types of mouthguards and standardize the way the athletes' performance is evaluated, so that there is a possibility of a reproducible analysis.

In addition, there is a major failure in studies that are being carried out, because there is not a systematic review that synthesize PROMs. In the end, athletes are the ones who will have to use them. Focusing studies on the prevalence of trauma and which mouthguard is most effective can be irrelevant if athletes just don't feel good about using them, because it could be uncomfortable.

Therefore, our next step should be to understand the main complaints and the advantages that athletes see in mouthguards, in order to focus on presenting the best solution based on scientific evidence that makes them adhere to their use.

SYSTEMATIC REVIEW OF ACCEPTANCE AND COMFORT ON SPORTS MOUTHGUARDS

METHODS

1. FOCUSED QUESTION

A detailed protocol was designed according to the PRISMA (Preferred Reporting Items for Systematic Reviews) statement to answer the following focused question: “Does the use of mouthguards in sport affect the comfort reported by practitioners?“.

According to the PICO method, the topics necessary for the preparation of the strategic research plan were defined, as follows:

- Population: sports practitioners.
- Intervention: use of a customized mouthguard.
- Comparison: not use of a mouthguard or use of a preformed mouthguard.
- Outcome: based on patient reported outcome measures (PROM) like comfort in use, acceptance, performance and approval.

2. PROTOCOL AND REGISTRATION

This systematic review was registered in the Prospero database and was performed according to PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) guidelines (http:// www.prisma-statement.org).

3. INCLUSION AND EXCLUSION CRITERIA

This systematic review considered as inclusion criteria:

1. RCT parallel arm or cross-over design, Controlled Clinical Trials, Non-controlled clinical trials, prospective and retrospective cohort studies, observational and descriptive studies, such as case reports and case series addressing acceptance and comfort on mouthguard use.
2. Patient Reported Comfort in Use, adhesion, satisfaction in use
3. A minimum of 10 participants.
4. English, Portuguese and Spanish language accepted.

The following items were considered as exclusion criteria:

1. References with non-available abstract, abstracts of conferences
2. Reviews, Editorial letters, in vitro and animal studies.

3. Studies not addressing orofacial lesions or addressing protective gear other than mouthguards.

4. SEARCH STRATEGY

For the identification of studies to be included in the present review, a detailed search strategy was developed for MEDLINE via PubMed, Dentistry and Oral Sources and SPORTDiscus Database via EBSCOhost, Web of Science and the Cochrane Central Register of Controlled Trials up to 21 April 2020 (Table 4). There was interest about using grey literature, however, studies were repeated or irrelevant.

The search strategy was modified for each database and performed by two reviewers.

PUBMED		
#1 "sports"[MeSH Terms] OR "sport*"[Title/Abstract] OR "athlete*"[Title/Abstract] OR "athletic*"[Title/Abstract] OR "player*"[Title/Abstract]	**#2** "mouth protectors"[MeSH Terms] OR “mouth protector*”[Title/Abstract] OR "guards mouth"[Title/Abstract] OR "mouthguard*"[Title/Abstract] OR "mouth guard*"[Title/Abstract] OR "mouth protector*"[Title/Abstract] OR "mouth piece*"[Title/Abstract] OR "mouthpiece"[Title/Abstract] OR "oral splint*"[Title/Abstract] OR "splint*"[Title/Abstract]	**#3** "patient comfort"[Mesh] OR "Acceptance and Commitment Therapy"[Mesh] OR "Patient Satisfaction"[Mesh] OR “adherence*”[Title/Abstract] OR “well-being” [Title/Abstract] OR “convenience” [Title/Abstract] OR “contentment*”[Title/Abstract] OR “happiness” [Title/Abstract] OR “satisfaction*”[Title/Abstract] OR “approval*”[Title/Abstract] OR

		“acceptance” [Title/Abstract] OR “performance”[Title/Abstract]
#1 AND #2 AND #3		
EBSCO		
#1 TI = (Sports OR Sport OR Athletic OR Athletics OR Athlete OR Athletes OR Player OR Players)	**#2** TI = ("mouth protectors" OR "mouth protector" OR "protectors mouth" OR "guards mouth" OR mouthguard OR mouthguards OR "mouth guard" OR "mouth guards" OR "mouth piece" OR "mouth pieces" OR mouthpiece OR mouthpieces OR "oral splint" OR "oral splints" OR splint OR splints)	**#3** TI = (“patient comfort” OR comfort OR “acceptance and commitment therapy” OR acceptance OR commitment OR” patient satisfaction” OR satisfaction OR adherence OR “well-being” OR convenience OR contentment OR happiness OR approval OR performance)
#1 AND #2 AND #3		
WEB OF SCIENCE		
#1 TS = (Sports OR Sport OR Athletic OR Athletics OR Athlete OR Athletes OR Player OR Players)	**#2** TS = ("mouth protectors" OR "mouth protector" OR "protectors mouth" OR "guards mouth" OR mouthguard OR mouthguards OR "mouth guard" OR "mouth guards" OR "mouth piece" OR "mouth pieces" OR mouthpiece OR mouthpieces OR "oral splint" OR "oral splints" OR splint OR splints)	**#3** TS = (“patient comfort” OR comfort OR “acceptance and commitment therapy” OR acceptance OR commitment OR” patient satisfaction” OR satisfaction OR adherence OR “well-being” OR convenience OR contentment OR happiness OR approval OR

		performance)
#1 AND #2 AND #3		
COCHRANE		
#1	MeSH descriptor: [Sports] explode all trees	
#2	sport* or athlete* or athletic* or player*	
#3	1# or #2	
#4	MeSH descriptor: [Mouth protectors] explode all trees	
#5	mouth protector* or protector mouth or guards mouth or mouthguard* or mouth guard* or mouth protector* or mouth piece* or mouthpiece* or oral splint* or splint*	
#6	#4 or #5	
#7	MeSH descriptor: [patient comfort] explode all trees	
#8	MeSH descriptor: [Acceptance and Commitment Therapy] explode all trees	
#9	MeSH descriptor: [Patient satisfaction] explode all trees	
#10	adherence or well-being or convenience or contentment or happiness or satisfaction or approval or approvals or acceptance or performance	
#11	#7 or #8 or #9 or #10	
#12	#3 and #6 and #11	

Tab. 4 - Database and search strategy (21 April 2020).

5. STUDY SELECTION

After research, the articles were exported to a reference management program. Duplicates have been removed and two review authors analysed the titles and abstracts. Those that did not meet the inclusion criteria were excluded.

Then, all the full texts were collected and independently assessed by two authors. Inclusion ambiguities were discussed, and there was an agreement between both. (Figure 2)

Studies excluded in the full reading phase are found in Table 5 with the respective justification.

Data were extracted using customized extraction forms and the following data were recorded for each included study: (1) Reference; (2) Study design; (3) Sample size calculation; (4) Objectives; (5) Number of participants; (6) Participant's age and gender; (7) Type of sport; (8) Intervention (use of customized mouthguard); (9) Control group (not used or preformed mouthguard); (10) Number of participants with mouthguard; (11) Material of mouthguard; (12) Thickness of mouthguard; (13) Arch; (14) Outcomes; (15) Use in training or training and game; (16) Use in game; (17) VAS Comfort Index; (18) Comfort reported; (19) Acceptance; (20) Difficulty breathing; (21) Mouth dryness; (22) Speech interference; (23) Tiredness; (24) Nausea; (25) Swallowing; (26) Gingival irritation/ Pain; (27) Bulky; (28) Jaw muscle fatigue; (29) Distracting attention/ Performance degradation; (30) Stability; (31) Bad taste/ thirsty; (32) Loose fit; (33) Chewing/clenching; (34) Discomfort; (35) Effective protection; (36) Disocclusion; (37) Hardness; (38) Overall; (39) Use/not use mouthguard; (40) Type of mouthguard; (41) Reasons for use; (42) Reasons for not use; (43) Reasons to motivate the use; (44) Association use/age.

References	Reasons for exclusion
Gawlak, 2014	Language - Polish
Karaganeva, 2019	Study in vitro
Levin, 2007	It does not address the comfort, acceptance, use. Only address the relationship with previous injuries (occurrence, causes).
Manka-Malara, 2013	Language - Polish

Tab. 5 – Reasons for excluded studies.

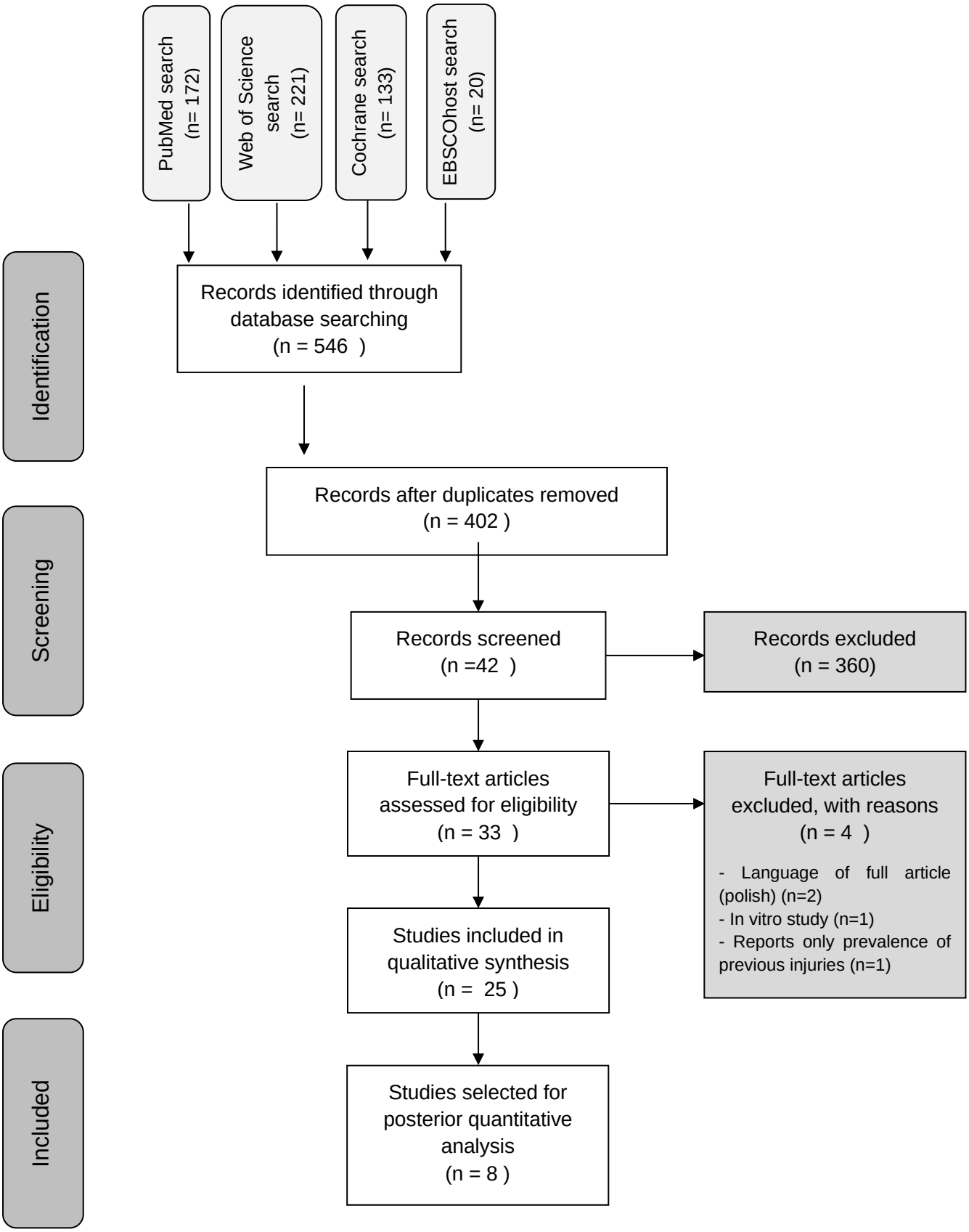


Fig. 2 - Study flowchart and process of selection of the studies

6. DATA COLLECTION

After selecting the studies, data on the following parameters were extracted: reference to author(s) and year of publication, study design, follow up, sample size calculation, objectives, inclusion and exclusion criteria, number of participants and gender, participant's age, type of sport, type and material of the mouthguard, thickness of the mouthguard, arch of the mouthguard insertion, outcomes, comfort and acceptance.

Data was extracted by two authors using specially designed data extraction forms. Disagreements were resolved by discussion and, whenever needed, a third author intervened.

7. ASSESSMENT OF RISK OF BIAS

The Cochrane Collaboration's tool (RoB2, 2019) [31] was used to assess the risk of bias in RCT and crossover studies. Studies were assessed for risk of bias arising from the randomization process (domain 1), risk of bias due to deviations from the intended interventions (effect of assignment to intervention) (domain 2), risk of bias due to missing outcome data (domain 3), risk of bias in measurement of the outcome (domain 4) and risk of bias in selection of the reported result (domain 5).

To assess cohort and cross-sectional studies, the Newcastle–Ottawa Scale (NOS) tool [32] was adapted and used. Three factors were considered to score the quality of included studies: (1) selection of the cohort, (2) comparability of cohorts, and (3) outcome. The quality of the studies (low, some concerns and high risk of bias) was assessed by awarding stars in each domain following the guidelines of the NOS tool. If less than five stars were selected, the article h high risk of bias. If it was between five to six stars, some concerns were considered. If it was more than seven stars, the article had a low risk of bias. (Tables 7-8)

Fig. 3 - Author's assessment of risk of bias of RCT studies

Study ID	Randomization process	Deviations from intended interventions	Mising outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Brionnet, 2001	Some concerns	Low	Low	Low	Low	Low
Collares, 2014	Low	Low	Low	Low	Low	Low
Deyoung, 1994	Some concerns	Low	Low	Low	Some concerns	Some concerns
Duarte-Pereira, 2008	Some concerns	Low	Low	Low	Some concerns	Some concerns
Gomez, 2019	Some concerns	Low	Low	Low	Low	Low
Li, 2020	Low	Low	Low	Low	Low	Low
Queiróz, 2013	Some concerns	Some concerns	Low	Low	Low	Some concerns
Gawlak, 2016	High	High	Low	Low	Low	High
Gawlak, 2014	High	High	Low	Low	Low	High
Gawlak, 2015	High	High	Low	Low	Low	High
Romero, 2018	High	High	Low	Low	Low	High
McClelland, 1999	High	High	Low	Low	High	High

Tab. 6 - Author's assessment of risk of bias of crossover Studies

	Selection					Comparability of cohorts		Outcome				
Study	Representativeness of the exposed cohort	Sample Size	Non-respondents	Ascertainment of the exposure (risk factor)		Main factor	Additional factor	Assessment of outcome		Statistical test	**Total (10/10)**	**Overall Bias**
Andrade,2010	★	0	★	★	★	NA	NA	★	★	★	**7/10**	Low
Andrade,2013	★	0	★	★	★	NA	NA	★	★	★	**7/10**	Low
Bastian,2020	0	0	★	★	★	NA	NA	★	★	★	**6/10**	Some concerns
Boffano,2012	0	0	★	★		NA	NA	★	★	★	**5/10**	Some concerns
Brugesser,2020	0	0	★	★	★	NA	NA	★	★	★	**6/10**	Some concerns
Collins,2015	★	0	★	★	★	NA	NA	★	★	★	**7/10**	Low
Comstock,2005	★	0	★	★	★	NA	NA	★	★	★	**7/10**	Low
Cornwell,2003	★	0	★	★	★	NA	NA	★	★	★	**7/10**	Low
Dileone,2014	0	0	★	★		NA	NA	★	★	★	**5/10**	Some concerns
Gage,2015	0	0	★	★		★	★	★	★	★	**7/10**	Low
Lee,2013	★	0	★	★	★	NA	NA	★	★	★	**7/10**	Low
Lieger,2006	★	0	★	0		NA	NA	★	★	★	**5/10**	Some concerns
Liew,2014	★	0	★	★	★	NA	NA	★	★	★	**7/10**	Low
Matalon,2008	0	0	0	0		NA	NA	★	★	★	**3/10**	High

Tab. 7 - Author's assessment of risk of bias of cross-sectional studies

Study	Selection				Comparability of cohorts		Outcome			Total (9/9)	Overall Bias
	Representativeness of the exposed cohort	Selection of external control	Ascertainment of exposure	Outcome of interest not present at start	Main factor	Additional factor	Assessment of outcome	Follow-up long enough	Adequacy of follow-up		
Eroglu,2016	0	NA	☆	☆	NA	NA	☆	☆	☆	5/9	Some concerns
Hirose,2017	0	NA	☆	☆	NA	NA	☆	☆	☆	5/9	Some concerns
von Arx,2008	0	NA	☆	☆	NA	NA	☆	☆	0	5/9	Some concerns
Walker,2002	0	NA	☆	☆	☆	☆	☆	0	☆	5/9	Some concerns

Tab. 8 - Author's assessment of risk of bias of cohort studies

8. DATA SYNTHESIS

Due to the fact that the studies had a wide variation in the interventions, controls and outcomes studied, an attempt was made to make a simple statistical analysis in order to synthesize and frame the different results, to extrapolate some general conclusions, since many studies used a VAS (Visual Analogue Scale) scale where athletes indicated from 0 to 10 what degree of comfort the mouthguard provided them in different parameters evaluated, for example, difficulty in breathing.

Some studies considered the value 10 as the best evaluation, other studies considered the value 10 as the worst evaluation. In order to have uniformity, the second case was extrapolated so that there was an inversion of the scale. The values of the graphs in Tables 10-15 range from 0 to 12. The latter number is just a ceiling to increase visual perception. 0 means that the mouthguard was worse perceived by the athlete and 10 was the best evaluation.

Statistical analysis was performed resorting to GraphPad 8.4.3. Group comparison was made with the t-student test. Significance level was set at 0.05.

All the results that could not be included in the statistical analysis were synthesized narratively through the conclusions that have been drawn from the various surveys that have been made of the athletes.

The search in MEDLINE via PubMed, Dentistry and Oral Sources and SPORTDiscus Database via EBSCOhost, Web of Science and the Cochrane Central Register of Controlled Trials retrieved 172, 20, 221 and 133 records, respectively. In total, 546 records were obtained.

After removing duplicates, 402 records were screened for title and abstract. This analysis excluded 360 records, 5 full articles were not found, having been excluded, and 4 full-text articles were excluded with reasons. Thus 33 full texts were retrieved.

Figure 1 describes the process of identification of the remaining studies.

1. STUDY CHARACTERISTICS

The characteristics of the thirty three selected studies [14, 33-64] are referenced in Table 9.

Included studies were published from 1994 to 2020. Ten of them were randomized controlled trials (seven crossover), five crossover non-randomized, four cohorts and fourteen cross-sectional studies. The number of study samples ranged from 10 to 1636. From all, only two did not mention the gender of participants [51, 53] and thirteen studies only evaluated one gender (predominantly male). Ages varied from children to adults, with some studies focusing only on a certain age group.

The types of sports mentioned varied a lot, from American football, rugby, handball, basketball, football, martial arts, hockey, swimming, weightlifting, baseball, scuba diving, etc. The type of mouthguard also varied. Seven studies compared the three types of conventional mouthguards - custom-made, boil-and-bite and stock – [33, 36, 44, 46, 50, 59, 61, 64], one compared only the use or not use of a mouthguard [38], one referred to the use of custom-made mouthpiece for scuba-diving [55], two evaluated only boil-and-bite [34, 35], eight only custom-made [14, 39, 41, 49, 54, 57, 60, 63] and five compared the custom-made with boil-and-bite [45, 48, 51, 57, 62]. In relation to the material of the mouthguard, seventeen studies reported it, varying the components from EVA, polyetheretherketone, polyvinylacetatepolyethylene, silicone, methyl-methacrylate, etc. Seven studies reported which thickness they would use, varying between 3 and 4mm [39, 41, 44, 48, 50, 54, 57]. In addition to materials, some studies have also compared different material layouts, alternating thicknesses, decreasing extension or creating ventilated areas. Most of the studies did not explained in which jaw was placed the mouthguard, but the most common was in the upper jaw. Only two

studies used both [39, 55]. Some studies have distinguished between the use of mouthguards only in competitions, only in training or both [37, 38, 44, 58, 59, 64].

Regarding to the assessment of outcomes, four studies used the comfort Visual Analogue Scale (VAS) [39, 41, 47, 49, 63] and other studies adapted this scale.

Author	Year	Type of study	Number of participants	Follow-up	Mean age/ range	Participant's gender	Type of sport
Andrade	2010	cross-sectional	409	-	24.4 ± 5.3	M 55%, F 45%	various
Andrade	2013	cross-sectional	120	-	13-58	M 79.2%, F 20.8%	track and field, judo, football, swimming, basketball, weightlifting, table tennis, volleyball
Bailey	2015	RCT, prospective	15	-	24±1	M 100%	physical agility
Bastian	2020	cross-sectional	75	-	13-18	NR	american football, basketball
Boffano	2012	cross-sectional	65	-	13-39	M 100%	rugby
Braham	2004	RCT	301	-	22.3 (95% conf - 21.6 to 22.9)	NR	american football
Brionnet	2001	RCT crossover	48	8 months	14-18	M 100%	rugby
Bruggesser	2020	cross-sectional	382	-	6-75	M 73.8%, F 26.2%	judo
Collares	2014	RCT crossover	40	2 weeks	15-17	M 100%	football, futsal
Collins	2015	cross-sectional	1636	-	15.9±1.2	M 55.9%, 43.8% F	basketball, baseball/softball

Author	Year	Type of study	Number of participants	Follow-up	Mean age/ range	Participant's gender	Type of sport
Comstock	2005	cross-sectional	234	-	18-52	F 100%	rugby
Cornwell	2003	cross-sectional	496	12 weeks	12-15 and >18	M 67%, F 33%	basketball
Deyoung	1994	RCT crossover	36	4 weeks	NR	M 50%, F 50%	lacrosse
Di Leone	2014	cross-sectional	231	-	24.1±7.1	± M 70%, F 20%	martial arts
Duarte-Pereira	2008	RCT crossover	10	3 weeks	21-23	M 100%	rugby
Duddy	2012	RCT	18	4 weeks	19-23	M 100%	rowing
Eroglu	2006	cohort prospective	22	4 months	15-17	M 50%, F 50%	taekwondo
Gage	2015	cross-sectional	24	2 weeks	32.2±7.3	M 58.3%, F 41.7%	weightlift
Gawlak	2016	cross-over	21	1 year	NR	NR	various
Gawlak	2014	cross-over	21	1 year	16-35	M 100%	martial arts
Gawlak	2015	cross-over	21	1 year	NR	NR	various

Tab.9 - Description of the characteristics of the studies.

Author	Year	Type of study	Number of participants	Follow-up	Mean age/ range	Participant's gender	Type of sport
Gomez-Gimeno	2019	RCT crossover	18	4 weeks	23.7	M 55.6%, F 44.4%	water polo
Hirose	2017	cohort prospective	20	4 weeks	20-52	M 80%, F 20%	scuba diving
Lee	2013	cross-sectional	152	NA	NR	M 71.7%, F 28.3%	taekwondo
Li	2020	RCT crossover	18	3 months	18-30	M 50%, F 50%	various
Lieger	2006	cross-sectional	267	NA	26	M 100%	football, handball, basketball and ice hockey
Liew	2014	cross-sectional	456	NA	22.73±3.98	M 100%	rugby
Matalon	2008	cross-sectional	69	1year	9-12	M 60.9%, F 39.1%	various
McClelland	1999	crossover	22	2 nights	20-26	NR	hockey, squash, football, rugby, box
Queiróz	2013	RCT crossover	25	NA	18-22	F 100%	football
Romero Pérez	2018	crossover	15	NA	20±2	M 100%	american football
von Arx	2008	cohort prospective	13	4 weeks	18-27	M 100%	ice hockey, handball
Walker	2002	cohort prospective	56	2 weeks	7-80	NR	football

2. RISK OF BIAS WITHIN STUDIES

The assessment of the risk of bias of the selected studies is presented in Figure 3 and Tables 6-8.

Ten studies reported the randomization of the tests sequence, however, just three of them reported the method of randomization and how the allocation concealment was performed.

Regarding to the blinding of the participants and intervenient, it was considered that it was not possible to put into practice in almost all studies, since there are cases in which it is possible to perceive the intervention and the control, even without being explained. However, in cases where the intervention and control were two mouthguards in which only the type of material varied, for example, it was considered that the participant would be in a position that could be blind. Regarding the statistic analysers, studies did not mention whether they were aware of the intervention or not.

In the assessment of the domain “incomplete outcome data”, no irregularities were found to be recorded.

Regarding to the domain “Selection of the reported result”, two studies were evaluated with “some concerns” because they were not very clear on that parameter, and one study was consider “high”, because the way in which the intervention was evaluated may not demonstrate the results expected to resolve the initial issue.

In relation to the evaluation of cohort and cross-sectional studies, the main parameter that caused most bias between the studies was "selection". In addition, the design of these types of studies means that they do not have as much quality compared to RCT studies. Still, because of the lack of research on this theme, it was decided to consider it.

3. EFFECTS OF THE INTERVENTIONS

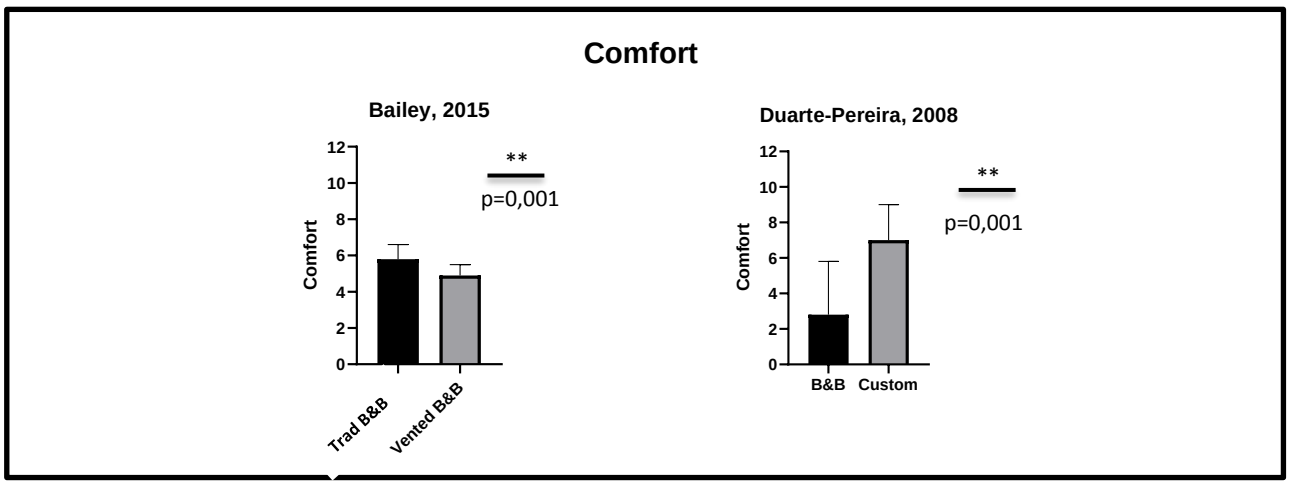
I. Comfort

Approximately 80-90% of the participants considered MGs in general comfortable. [44, 58] In one study, 55% of the athletes did not felt comfortable.[60]

When evaluating the different types of mouthguards, one study reported that 80% considered custom-made MG more comfortable than boil-and-bite [62] and another study almost equalled the comfort levels of these two types, with even

more percentage of participants who considered boil-and-bite more comfortable (42.6% custom-made and 44.1% boil-and-bite). [33]

Table 10 intends to synthesize the perception of comfort felt by athletes in two studies, which one study compared the comfort between traditional and vented boil-and-bite MG and another study compared the custom-made with the boil-and-bite MG. Both relationships proved to be statistically significant, with p=0.001, with superior comfort results in traditional boil-and-bite MG (compared to vented boil-and-bite) and custom-made MG (compared to boil-and-bite).



Tab.10 – Analysis of bar charts of Comfort in traditional boil-an-bite (B&B) vs. vented B&B and in B&B vs. custom-made.

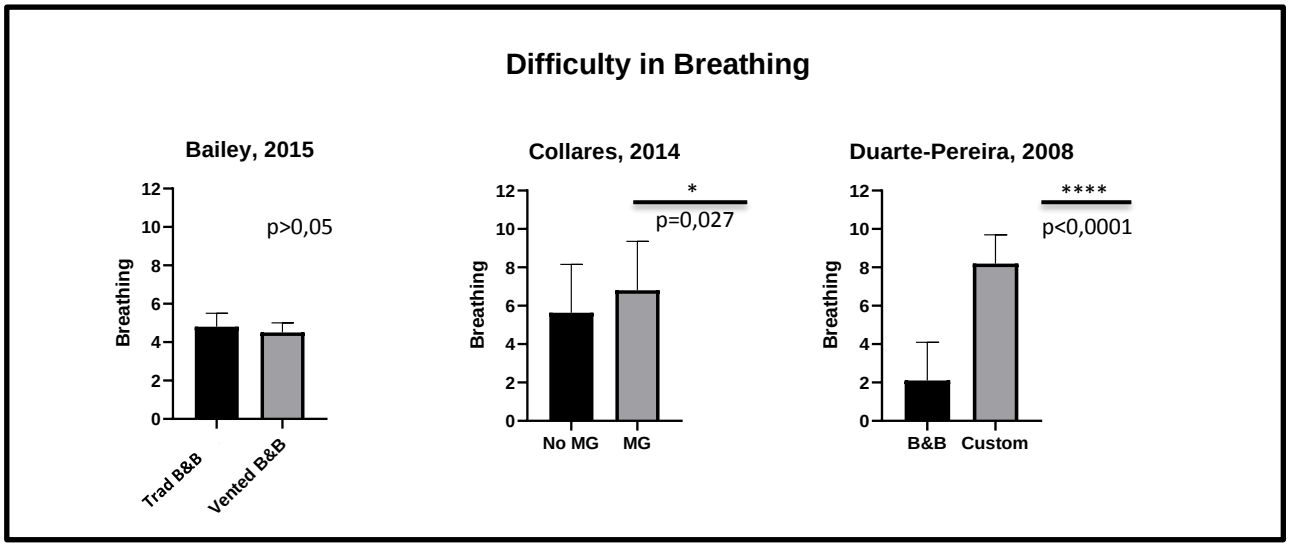
II. Difficulty in breathing

21-44.5% of questioned athletes considered that mouthguards cause difficulty in breathing. [44, 48, 58]

In particular, 10-79% of the athletes considered that boil-and-bite MGs cause difficulty in breathing, 24-36% in stock MGs and 0-38.8% in custom-made. [45, 51, 61, 62]

Table 11 intends to synthesize the perception of difficulty in breathing felt by athletes in three studies, which one compared this outcome between two types of boil-and-bite MGs, one traditional and the other vented, another one compared de general use of a mouthguard and not use, and another study compared boil-and-bite MG with custom-made MG. Last two graphics proved to be statistically significant, with p <0.005, with superior comfort results in traditional boil-and-bite MG (compared to vented boil-and-bite) and custom-made MG (compared to boil-and-bite). Only the first graphic had no statistical significance, since p> 0.05. In the second graphic, there was an increase in recognition by athletes that the use

of mouthguards does not cause as much breathing difficulty as they previously thought before using it. In the last, the custom-made MG had better results in the perception of easier breathing than the boil-and-bite.



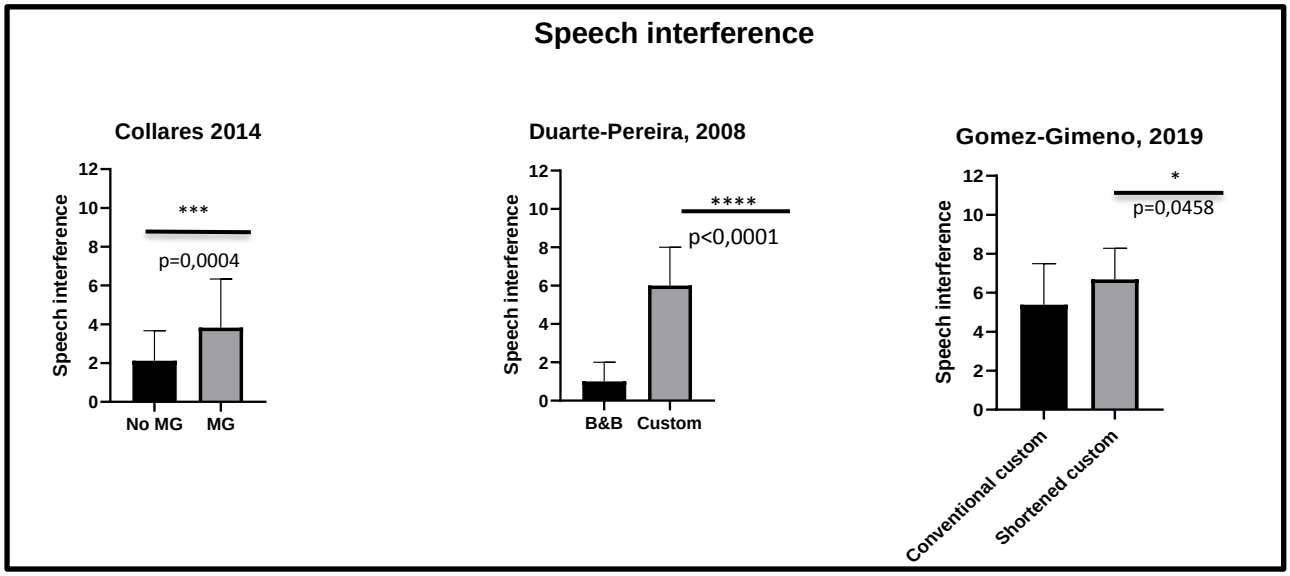
Tab.11 - Analysis of bar charts of Difficulty in breathing in traditional boil-an-bite (B&B) vs. vented B&B, in general mouthguard (MG) use vs. no mouthguard use and in B&B vs. custom-made.

III. Speech interference

In Cornwell (2003), 79% agreed that mouthguards cause speech interference and in Lieger (2006) the percentage was 35%.

Regarding the type of mouthguards, in one of the studies, 100% considered the stock MG as the one that most interferes, followed by the boil-and-bite 79-81% and the custom-made 0-57%.[45, 51, 61, 62]

Table 12 intends to synthesize the perception of speech interference felt by athletes in three studies, which one compared this outcome between general use of a mouthguard and not use, another study compared boil-and-bite MG with custom-made MG and the last one compared conventional custom-made with shortened custom-made. All of them proved to be statistically significant, with $p<0.05$, with worse initial perception of speech interference before using a mouthguard, improving this perception after use. In the second case, boil-and-bite demonstrated to have greater speech interference, and in the third case the shortened custom-made had slightly better results than the conventional one.



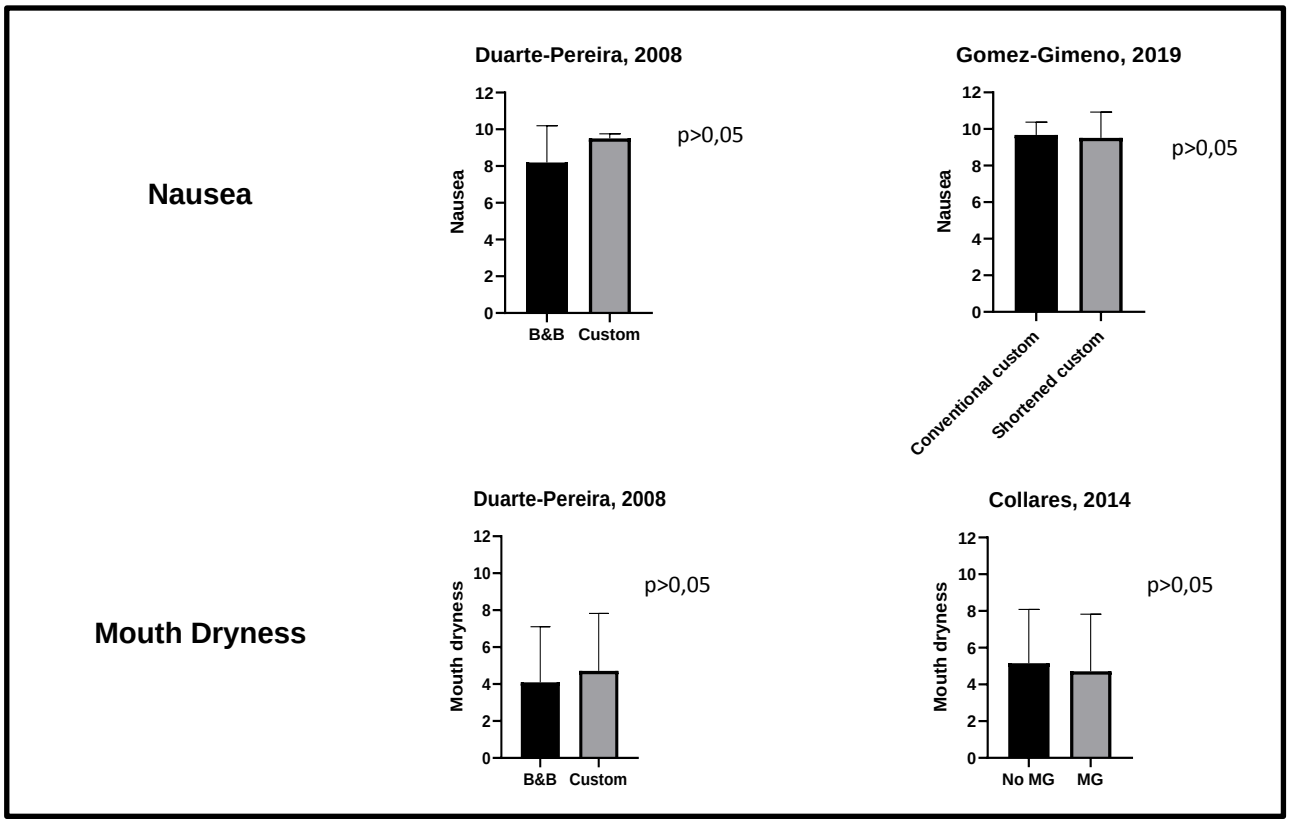
Tab.12 - Analysis of bar charts of Speech interference in no use of MG vs use of MG, in B&B vs. custom-made and in conventional vs. shortened custom-made.

IV. Nausea and mouth dryness

Of the athletes questioned, custom-made mouthguards were considered to be less nauseating or even null and caused less mouth dryness than other mouthguards. [51, 58, 61, 62]

Table 13 intends to synthesize the perception of nausea and mouth dryness felt by athletes in three studies, which one compared these outcomes between boil-and-bite MGs and custom-made MGs, with better results to custom-made.

Other two studies compared conventional custom-made with shortened custom-made and the use of a mouthguard and not use. Results were very similar. All of them did not show statistically significant results, with $p>0.05$.

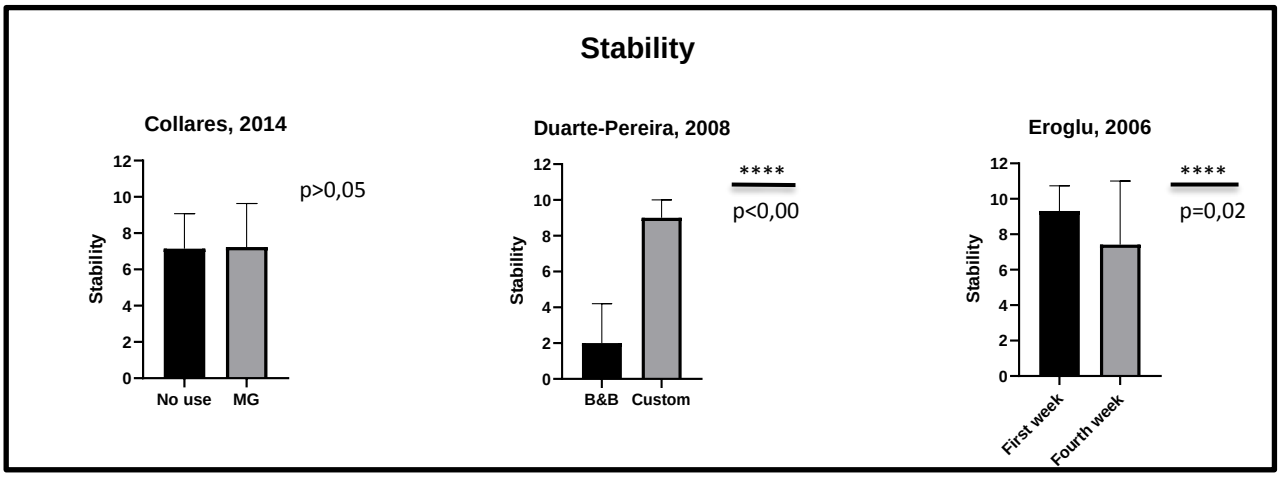


Tab.13 - Analysis of bar charts of Nausea in B&B vs. custom-made and in conventional vs. shortened custom-made. Evaluation of Mouth Dryness in B&B vs. custom-made and with no use of general MG vs. use of MG.

V. Stability and fit

In Romero (2018), custom-made MGs were considered better adapted than boil-and-bite (73% and 27%, respectively). [62] Deyoung (1994) showed that 41.6% of athletes think boil-and-bite loose fit and none consider that this happen with custom-made.[45]

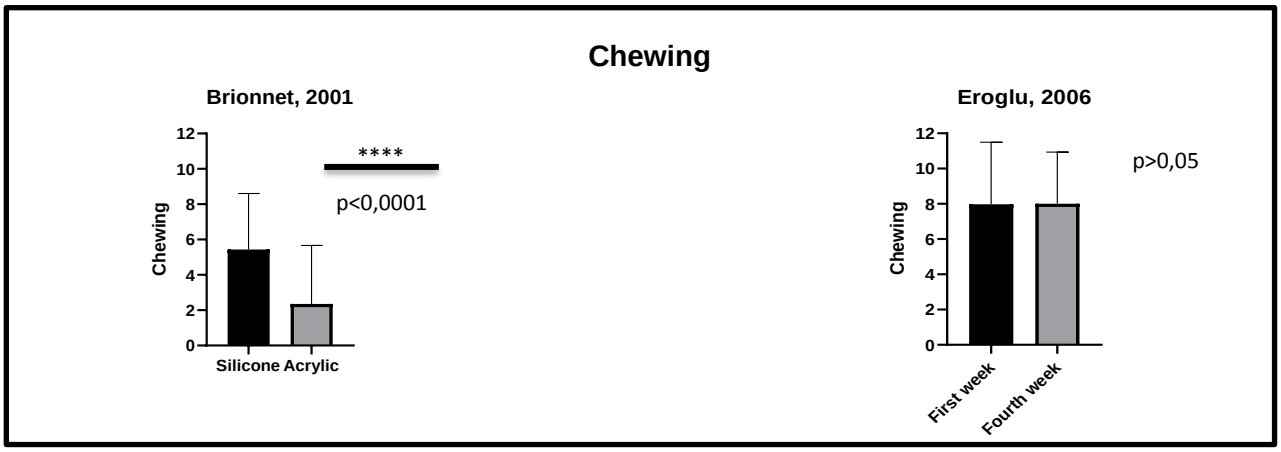
Table 14 intends to synthesize the perception of stability of the mouthguard felt by athletes in three studies, which one compared this outcome between general use of a mouthguard and not use. Other compared boil-and-bite with custom-made and another graphic compared the perception of stability in the first week of use against the fourth week of use. Only the first graphic did not show statistically significant results, with p>0.05. Custom-made MG was considered much more stable than boil-and-bite and, comparing the time interval of using a mouthguard, there was a greater perception of stability in the first week than in the fourth.



Tab.14 – Analysis of bar charts of Stability in no use of general MG vs. use of MG, in B&B vs. custom-made and comparing the use of a general MG in the first week vs. fourth week.

VI. Chewing

Table 15 intends to synthesize the perception of chewing felt by athletes in two studies, which one compared this outcome between silicone and acrylic custom-made MG and another compared the perception of chewing in the first week of use against the fourth week of use. Only the first graphic showed statistically significant results, with $p<0.05$. The silicone MG showed better results than acrylic MG.



Tab.15 - Analysis of bar charts of Chewing in silicone custom-made MG vs. acrylic custom-made MG and comparing the use of a general MG in the first week vs. fourth week.

VII. Irritation/pain, bulky sensation and jaw muscle fatigue

Custom-made mouthguards had better results in these parameters than boil-and-bite MG. [45, 51]

VIII. Distraction in performance

In Queiróz (2013), 35% reported that this occurred only with the use of stock type and 65% with stock and boil-and-bite mouthguards.[61] Di Leone (2014) reported that 8.6% of the athletes considered the custom-made MGs distracting, 25% stock type and 27.7% boil-and-bite.[46]

IX. Effective protection

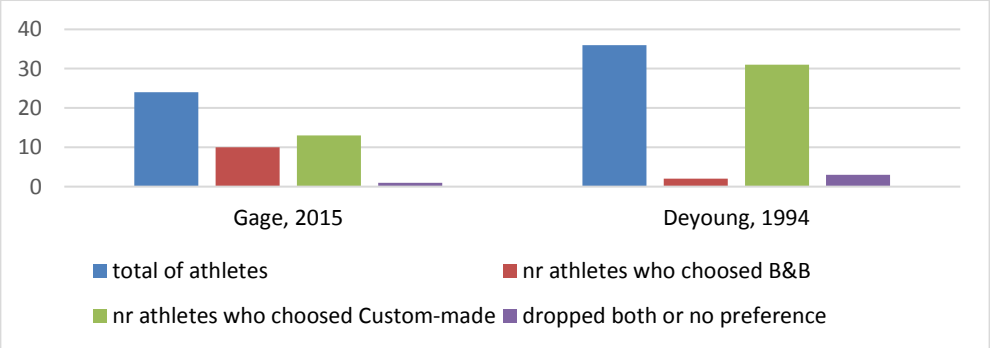
Di Leone (2014) showed that the mouthguards considered by athletes with the greatest protection, in decreasing order, are custom-made, boil-and-bite and stock types (100%, 97.6% and 95%, respectively). [46]

X. Acceptance

The general acceptance of a mouthguard varied between studies, since athletes may consider the mouthguard to be useful, but they end up not adhering to therapy regularly.

However, it was found that the type of mouthguard with greater acceptance was the custom-made, with percentages of 54-94% of satisfaction.[48, 50, 64] In the case of boil-and-bite, all intervenient showed dissatisfaction in Duddy (2012).[48] Walker (2002) results were very identical for custom-made and boil-and-bite (87% and 82%, respectively), with the stock type having 0% satisfaction. [64] In Gage (2015), the percentage of acceptance for custom-made, boil-and-bite and stock was 54.2%, 16.7% and 25%, respectively. [50]

Table 16 compares the acceptance of one type of mouthguard in relation to another - custom-made and boil-and-bite - between two studies. There was a greater number of athletes who chose custom-made MGs. This value was more pronounced in the second study. There were some athletes who showed no interest in any of these types.



Tab.16 - Analysis of choice of the most acceptable mouthguard (custom-made vs boil-and-bite).

OVERALL COMPLETENESS, APPLICABILITY OF EVIDENCE AND LIMITATIONS

The present systematic review aimed to answer to the following question “Does the use of mouthguards in sport affect the comfort reported by practitioners?”.

Throughout this review, it was possible to notice that the use of mouthguards is not yet as instituted as it should be and there is still a lot of disinformation, especially regarding to the most appropriate type of mouthguards. Practically all the studies have reinforced the importance of the dentist in divulging the use of oral protectors for a safer sports practice, emphasizing the custom-made as the most reliable in the prevention of injuries, as well as the important role of sports committees in regulation.

The question that had been proposed in this review was answered in several aspects, since the comfort reported by the athlete goes far beyond its literal meaning. The importance of breathing, speech, nausea, dry mouth, joint pain, stability, performance and concentration will guide the athlete to adhere or not to the use of mouth protection. Sometimes, even before the athlete uses one, he already has a preconceived idea of the problems it may generate, thus starting for an experience that may be immediately condemned to abandon. The "bad reputation" that a mouthguard has makes the youngest athletes feel ashamed to use it, since they use the argument that their colleagues don't have it either.[36, 42, 44]

Some studies have ascertained the reasons that athletes had for not wearing mouthguards, the most common were the cost, forgetfulness, comfort, difficulty in breathing, speaking and closing their lips, some of them did not knew of their existence, teammates do not use them either, it is not mandatory, it is not aesthetic, etc. The athletes who use them give as reasons: the prevention of dentofacial traumas, greater protection, they already had injuries before, they are careful with their teeth, MGs can improve their performance, etc.[33, 36-39, 42, 44, 45, 54, 57, 58, 60]

Thus, the answer to the initial question is “yes”, currently, the use of mouthguards affects the comfort reported by athletes, especially when they are stock or boil-and-bite type. The results showed, almost all, that the custom-made have much better results when compared to the two previous ones, ending up surprising the athletes. These results make sense and have been demonstrated in several studies, since a custom-made mouthguard is specifically designed for a single individual, being fully adapted to their oral cavity, which is not the case of prefabricated mouthguards, which are often more used because they are cheaper and do not require a visit to the dentist.

Therefore, regarding mouth protectors in general, the perception of athletes about their use was many times more negative before experiencing them than after use, which means they had initial low expectations. About three general types of mouthguards, in most of the studies that compared them, their acceptance from the best to the worst was custom-made, boil-and-bite and stock.

In the case of boil-and-bite, one study [35] compared two different types, one traditional and the other vented, and the traditional ended up having better results. Also, in the custom-made results, several types were studied. In one of them, the difference between a conventional and a shortened was evaluated.[54] The shortened mouthguard had a positive difference in speech interference, but no statistically significant difference in nausea perception. In another study, it was studied a custom-made made of silicone and another one made of acrylic, with silicone having better results in terms of chewing the mouthguard.[39]

Comparing the boil-and-bite with the custom-made, in almost all parameters evaluated, the second one was better, sometimes with higher statistical differences.[47] Additionally, Eroglu evaluated the athlete's perception by using the mouthguard one week and then after four weeks [49], and the only statistically significant result was that there was a greater perception of stability in the first week than in the fourth.

Approximately 80-90% of the participants considered MGs in general comfortable. [44, 58] In one study, 55% of the athletes did not feel comfortable.[60] There is some discrepancy in percentages between studies.

About irritation/pain, bulky sensation, jaw muscle fatigue, distraction in performance, and effective protection, most of the studies have reported that custom-made mouthguard is the one with the best results. This results also are valid for speech interference, breathing difficulty, nausea and mouth dryness and stability.

Regarding the type of mouthguards, in one of the studies, 100% considered the stock MG as the one that most interferes, followed by the boil-and-bite 79-81% and the custom-made 0-57%.[45, 51, 61, 62]

Concerning to the acceptance of the mouthguard by the athlete (acceptance/abandonment risk), there was a greater number of athletes who chose custom-made MGs than boil-and-bite type. There were some athletes who showed no interest in any of these types.

Strengths and limitations

The greatest strength of this systematic review is a correct methodology, involving two reviewers in searching/evaluation process.

Since the study designs are so different, there is a greater heterogeneity that might be expected. However, if there is a lack of studies on the subject, it is important to consider them all, providing that these differences are considered.

Implications for clinical practice

Listening athletes and understanding what they think about the use of mouthguards is important in order to have a greater concern in trying to develop a protector that meets their expectations. Being aware of the advantages and disadvantages of different mouthguards makes research into new forms easier. Thus, it is necessary to create a better protective mouthguard, with less thickness and more comfortable. The confection of the mouthguard in the dentist must be more appealing, in the sense of trying to replace the conventional impression by digital resources, ending up being faster and with less waste.

It is important to create guidelines and rules in the different sports so that the use of mouthguards can be the rule and not the exception.

Implications for future research

The few existing articles, the lack of attention to the method of randomization, the design of the studies and the diversity of methodologies and scales of assessment used make necessary further studies to increase the quality of scientific evidence.

Now, knowing which are the weak points of the current mouthguards, it is necessary to find ways to fight them, looking for new materials and ways to make them.

ADDITIVE MANUFACTURING OF SPORTS MOUTHGUARDS

EXPERIMENTAL PROJECT – PILOT STUDY

ABSTRACT

The objectives of the study are to evaluate different commercially available 3D filament printing materials, evaluate structured composition with flexible and rigid materials and evaluate different internal structures (lattice patterns, air layer, etc.).

In a preliminary study we will evaluate the mechanical behaviour of 10 different test pieces, with a different material, internal structure, thickness or print quality each – with ABS and HIPS materials.

For the impact tests, the equipment used will be the pendulum Instron Ceast 9050, with a 5 joule hammer (J), according to the Charpy ISO 179 standard. The test specimens will be prepared with and without notches (1mm) and with different thickness (2, 3 or 4mm).

After completing the preliminary tests, where we assess whether ABS and HIPS are good materials for our study objectives, the TPU material will be added to further tests. Our control group is a test piece with EVA (4mm thickness). New tests will be executed with larger samples and aging tests will be done, using artificial saliva. Then new tests will evaluate the difference between aging or not the test pieces.

The results showed that thermoplastic polyurethanes (TPU) are the materials that present properties similar to the solid polymer normally used in the manufacture of this type of protectors.

KEYWORDS

Mouth protectors, impact test, 3D printing

OBJECTIVES

- Evaluate different commercially available 3D filament printing materials;
- Evaluate structured composition with flexible and rigid materials;
- Evaluate different internal structures (lattice patterns, air layer, etc.).

TYPE OF STUDY

Mechanical impact study.

VARIABLES

Maximum impact force, absorbed energy, qualitative analysis of the presence of fractures before and after aging, contact angle before and after aging and characterization of the material at compression and traction.

INVESTIGATORS

Team at *CEMMPRE*

PI: Prof. Doutora Ana Paula Piedade

Investigator: Ana Messias (PhD), Catarina Pinho (PhD), Micaela Sousa (Master Student), Sara Pina (Master Student)

Team at *Laboratório de ensaios mecânicos da FMUC*

PI: Prof. Doutor João Carlos Ramos

Investigator: Claudia Brites (Lab technician), Sara Pina (Master Student)

SCHEDULE

Procedures/Timing	Month 1	Month 2	Month 3	Month 4
Preparation of the printed specimens				
Impact tests				
Sampling aging process				
Impact tests after aging				
Data collection and analyses				
Writting				

Tab. 17 - Schedule of the project

WORK PLAN

1. MATERIALS

In this study we will evaluate the mechanical behaviour of 4 different test pieces, with a different structure or material each.

Below are presented the materials that will be studied and their different properties.

i. Ethylene Vinyl Acetate (EVA)

It is a thermoplastic co-polymer derived from petroleum available in the form of rigid or flexible flat foil. Higher the content of vinyl acetate, more flexible EVA foils are.

This material will be the control group, because it is considered the gold standard for mouthguards by the literature, especially if it is 4mm thick.

ii. Acrylonitrile butadiene styrene (ABS)

It is a plastic with moderate impact resistance of great use in many industries, such as the automobile or in products of common use.

The high mechanical properties are achieved thanks to the sum of the three blocks that form it: acrylonitrile contributes to hardness, resistance to high temperatures and chemicals and stiffness; butadiene block contributes to toughness, preventing ABS from being fragile in cold environments; styrene provides more rigidity and mechanical strength.

Another advantage of ABS is easier post-processing, because can be sanded, painted or glued and its tensile strength.

There are several types of ABS depending on the quality that is desired.

It will be used the ABS-PRO Natural filament 1.75mm from Dowire®.

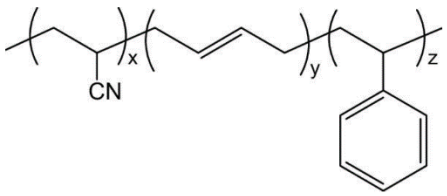


Fig. 4 - ABS chemical structure.

iii. High Impact Polystyrene (HIPS)

HIPS is a thermoplastic obtained by polymerization of high impact resistance. Commonly known as "high impact polystyrene", it is a heat resistant material with good physical properties. This polystyrene is a material suitable for making light and high-quality parts due to the high print resolution and its high impact resistance.

This material presents thermal stability, great impact resistance, chemical resistance and flexibility.

It will be used the HIPS filament 1.75mm from Dowire®

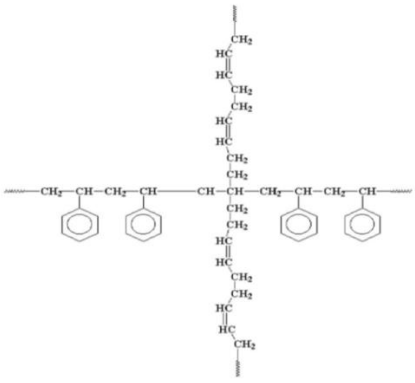


Fig. 5 - HIPS chemical structure.

iv. Thermoplastic Polyurethane (TPU)

TPU (Thermoplastic Polyurethane) is a thermoplastic, more specifically a linear elastomeric polymer belonging to the family of polyurethanes.

This material is characterized by its high resistance to abrasion, to certain chemical elements, to UV rays and low temperatures. This set of properties makes the use of TPU widespread throughout the industry.

This engineering plastic is used in applications that require high resistance to wear and abrasion, such as protection, good shock absorption, resistance to chemical elements (grease, oils, oxygen and ozone) or UV resistance.

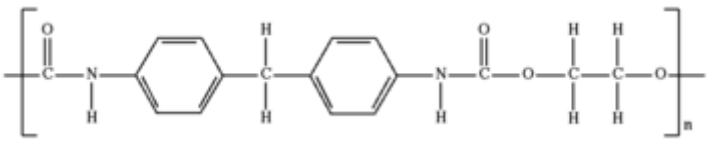


Fig. 6 - TPU chemical structure.

2. IMPACT RESISTANCE EQUIPMENT

For the impact tests, the equipment used will be the Instron Ceast 9050 (pendulum), with a 5 joule hammer (J), according to the Charpy ISO 179 standard.

Fig. 7 - Instron Ceast 9050 equipment.

3. PRELIMINARY TESTS OF IMPACT RESISTANCE

For the preliminary tests, two polymers will be used, because of their high mechanical strength and flexibility, they are easily extruded due to their rheological properties – ABS and HIPS.

Firstly, we will evaluate the mechanical behaviour of 10 different test pieces, with a different material, structure, thickness or print quality each. Table 18 summarizes that.

	MATERIAL									
	HIPS		**ABS**							
Thickness (mm)	2	4	2							3
Notch	no		no	Yes						Yes
Infill (%)	100		100				50		25	100
Quality	LQ		LQ	LQ	NQ	HQ	LQ			LQ

Tab.18 - Composition of test pieces.

Acrylonitrile Butadiene Styrene (ABS) and High Impact Polystyrene (HIPS) test pieces, both supplied by DoWire®, will be printed in the form of rectangular test pieces, with or without a 1mm notch, with the following dimensions: 80x10x4mm and 80x10x2mm.

The influence of the infill and quality printing parameters will be also studied.

Test pieces with 100, 50 and 25% infill will be printed in three different quality types: high quality (HQ) (layer height = 0.06mm), normal quality (NQ) (layer height = 0.01mm) and low quality (LQ) (layer height = 0.02mm).

4. PREPARATION OF THE PRINTED SPECIMENS FOR THE PRELIMINARY TESTS

a) Test pieces without notch

First test pieces will be printed without notch to check if they fractured without the notch.

The dimensions used are 80x10x4mm and 80x10x2mm.

For this case, HIPS and ABS specimens will be printed with Low Quality (LQ) AND 100% infill (note: these are printer parameters).

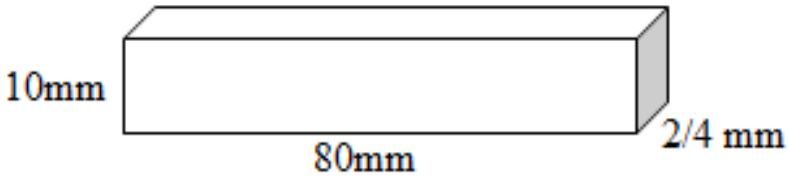


Fig. 8 - Printed test pieces for impact resistance tests without notch.

b) Notched test pieces

Then, test pieces will be printed without a notch to check if they fractured with a notch (note: the notches are not made according to the standard, as the objective is to ensure that they fractured).

The dimensions used are the same as the previous ones with the exception of a 1mm notch (as explained in the figure above).

For this case, only ABS test pieces will be printed. It should be mentioned that the printing parameters are adjusted in order to understand which ones gave the best impact resistance.

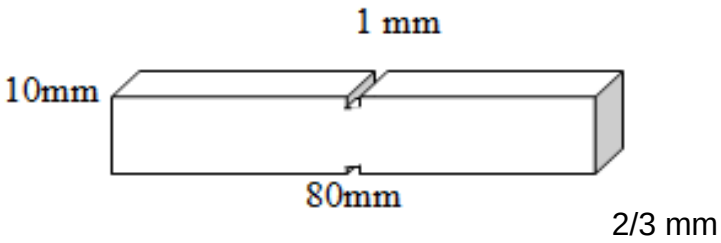


Fig. 9 - Printed test pieces for impact resistance tests with a 1mm notch.

5. IMPACT TESTS WITH LARGER SAMPLES

After completing the preliminary tests, where it was assessed whether ABS and HIPS are good materials for the study objectives, the TPU material was added to new tests. Then, new tests will be executed with larger samples and aging tests will be done, using artificial saliva.

A. Sampling Aging Process*

The thermal and chemical "aging" of the samples will be carried out in a thermocycling device with 500 cycles which will be processed individually as follows:

- The samples will be immersed in artificial saliva at 37º C for 90 minutes.
- Then they will be washed with simple water at 15º C.
- Afterwards, they will be left to dry completely in the air (22º C and HR of 50%) for 90 minutes.

* This process is also subject to validation by means of a pilot test.

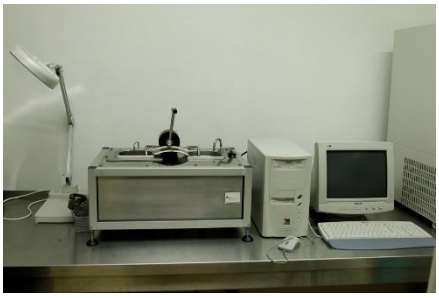


Fig. 11 – Thermocycling device.

B. Impact tests after the aging process

After aging process, the tests will be done to evaluate the difference between aging and not aging of the test pieces.

6. ANALYSIS

For this preliminary study, it is only necessary to analyse the mean and standard deviation of the results obtained.

RESULTS OF PRELIMINARY TESTS

Preliminary results for ABS and HIPS materials are shown in Table 19.

Material	Thickness (mm)	Infill (%)	Quality	Energy absorption (%)	Resilience ($Kg.m^{-2}$)	Energy (J)	Energy (J/mm)	Output
HIPS *	4	100	LQ	15,88	19,87	0,795	0,199	**Complete fracture**
HIPS *	2	100	LQ	6,55	16,39	0,328	0,164	**No fracture**
ABS *	2	100	LQ	8,88	22,23	0,445	0,223	**No fracture**
ABS	3	100	LQ	19,49	24,39	0,975	0,244	**Incomplete fracture**
ABS	2	100	LQ	8,06	20,18	0,404	0,202	**No fracture**
ABS	2	100	NQ	85,49	213,93	4,279	2,140	**No fracture**
ABS	2	100	HQ	41,40	103,60	2,072	1,036	**No fracture**
ABS	2	50	LQ	7,92	19,83	0,397	0,199	**No fracture**
ABS	2	50	LQ	8,49	21,25	0,425	0,213	**No fracture**
ABS	2	25	LQ	9,29	23,26	0,465	0,233	**No fracture**

Tab.19 – Preliminary data. (*) Test pieces without notch.

Both ABS and HIPS are known to be “Engineering materials” due to excellent properties for structural applications. However, considering that the final objective of mouthguards is, simultaneously, protection of the athlete but also comfort and ability to bread correctly other polymers with higher ductility, such as the standard EVA, were tested, in this particular case TPU. The results for the impact tests of the more ductile materials are presented in Table 20.

Material	Quality	Thickness (mm)	Energy absorption (%)	Energy absorption (SD)	Resilience (Kg.m-2)	Resilience (SD)
FlexMark 9 (TPU)	Low Quality	2mm	1,213	0,309	3,037	0,777
		4mm	4,092	1,982	5,122	2,481
FlexMark 9 (TPU)	Normal Quality	2mm	0,888	0,163	2,225	0,407
		4mm	3,143	0,279	3,932	0,347
EVA - Transparent Plate	N.A.	4 - 5 mm	4,543	0,405	5,685	0,508

Tab.20 – Preliminary data.

CONCLUSION

The outcomes of the present overview demonstrated, within all the limitations, that mouthguards contribute to a lower prevalence of dentoalveolar trauma among athletes of contact sports and the most common injury was dental trauma. The type of mouthguard with more advantages in preventing trauma and with better results in comfort and acceptance by athletes was custom-made. The use of a custom-made mouthguard seems to have no effect on cardiopulmonary capacity and showed the smallest range of changes in players' performance compared with other types of mouthguards.

Regarding the systematic review, most of the studies have reported that custom-made mouthguard revealed the best results respecting irritation/pain, bulky sensation, jaw muscle fatigue, distraction in performance and effective protection. This results also are valid for speech interference, breathing difficulty, nausea and mouth dryness and stability. As far as athletes' complaints are concerned, there is still a lot of misinformation about the use of mouthguards that must be improved by their awareness on the part of dentists and sports professionals.

Concerning experimental project, of the polymers tested by 3D printing, and as expected, TPU with higher thickness presents a mechanical performance (in particular, impact resistance) similar to the "standard" EVA-based materials. Therefore, and considering that one of the main characteristics of mouthguards is also the comfort of the athletes, and that this can be achieved by reducing thickness, for further studies the use of multi-materials (TPU+HIPS) can be predicted in order to obtain results similar to those of EVA, but with an optimized thickness.

Since studies of the reviews had several methodologies, more qualified randomized studies are needed as well as mechanical tests with potential printable materials so that the characteristics of mouthguards can be improved.

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There were no conflicts of interest in this project.

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