Geometrical comparison between instrumented and non-instrumented mouthguards for rugby: a pilot study

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Abstract: Rugby is a sport with a high injury rate. Much has been done to make the sport safer, particularly in terms of limiting and identifying concussions. Recently, instrumented mouthguards have been developed and used to measure events that may lead to concussion. However, these instrumented mouthguards may not have an appropriate geometry regarding shock absorption and comfort. In addition, there is no specific international standard for instrumented mouthguards. This study proposed a geometric analysis of both instrumented and non-instrumented mouthguards. Ten instrumented mouthguards were analysed and compared with three non-instrumented mouthguards. They were inspected visually, with a 3D envelope scan and with a CT scan. The results showed that the mouthguards did not comply with recommendations such as indentation with the lower teeth which may increase injury or fracture risk.

Keywords: concussion; rugby; instrumented mouthguards; geometry; biomechanics

1. Introduction

Rugby has a significant rate of injuries related to contact and collision between players and with the ground surface. Head and cervical spine injuries account for 14 to 30% [1]. Among these injuries, concussions are of increasing concern [2,3] but the underlying mechanisms are not fully understood. Concussion can be difficult to identify as there is no universal direct external sign [4]. In addition, concussion may occur after repeated low intensity head contacts which are even more difficult to recognize. Consequently, currently there is no universal tool to detect it [5]. This lack of detection may lead to an additional concussion, which can have even more severe consequences. This is called the "second impact syndrome" and can lead to severe brain damage [6].

Recently several instrumented mouthguards (iMGs) have been developed to facilitate the detection of concussions due to high head acceleration events. Some have been evaluated in a laboratory setting [7]. In the field, they were considered to have a good agreement between measurements and actions [8,9], but with some limitations when used in game [10,11]. Regarding their technology, all acceleration components are either directly measured (by accelerometers for linear components) or computed by derivation (by gyroscope for rotational components). The addition of a battery and a Bluetooth connection directly in the IMG makes it a wireless device. All these components change the shape of the mouthguard and can be exposed during players collisions. Located on the upper jaw, those iMG can provide relevant information as they are linked to the skull that holds the brain.

Mouthguards are commonly used in various sports. Their use has been shown to reduce dento-facial trauma [12] as their materials may help to absorb, or at least dissipate, shocks. They have also been found to reduce the severity of concussions, as their wearers may have a reflex to activate neck muscles during dynamic movements [13]. In ice hockey, mouthguard wearers had a 28% reduction in concussion rates [14]. Regarding rugby, World Rugby proposed in 2024 the use of these iMGs to enhance the existing Head Injury Assessment (HIA) to help detect concussions.

Several standards restrict the development of mouthguards, such as the French standard [15]. Numerous articles have been published on geometric concerns questioning its viability in various areas of the iMG [16,17]. A key element of mouthguard design is the fit to the player. To date, three types of mouthguards are available, depending on their fitting process. Type I mouthguards are industrially manufactured, typically made of elastomeric materials, mainly ethylene vinyl acetate (EVA) or polyvinyl chloride, and are not modifiable. Type II industrial mouthguards are made of thermoplastic polymers, mainly EVA. Fitting can be done either directly in the user's mouth (boil and bite method) or based on a geometric model of the user (dental mould or optical scanner based model). These are generic devices that are adapted to a specific geometry. These adaptable devices are the ones currently approved by World Rugby for use in premium-level-HIA matches [18] Type III mouthguards are custom-made intraoral protective devices with all thicknesses controlled. They are more complex to manufacture and should often be made in collaboration between a dentist and a prosthetic laboratory. The manufacturing process of Type I and Type II mouthguards can lead to an inhomogeneous material distribution within the device. This variation may affect both shock absorption (thus safety) and comfort. This study investigates this variability by examining the external and internal geometries of instrumented mouthguards.

As there is no specific standard regarding instrumented mouthguards geometry criteria, the objective of this study was to measure the geometrical characteristics on mouthguards in order to compare instrumented mouthguards with non-instrumented ones. In particular, does the on-board electronics influence the thickness of these mouthguards in critical areas and therefore their shock absorption capacity?

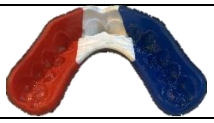
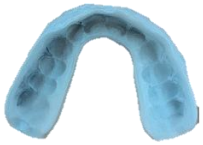
2. Materials and Methods

This pilot study was conducted on adaptable mouthguards (Type II). Ten instrumented mouthguards (iMG), including 7 Prevent Biometrics first version (iMG V1, U20 team) and 3 Prevent Biometrics second version (iMG V2, professional team), were used. The manufacturer produced and adapted the devices for rugby players using individual 3D scans. At the time of the trials, all iMG had already been fitted to each rugby player and were being worn. Three non-instrumented mouthguards (MG) were added, including 2 from elite rugby players and 1 from an amateur player (1 HK protect, 1 Shock Design and 1 Max mouthguard) to create a control group. A synthesis of their characteristics is given in the Table 1.

The external shapes of the MG and iMG were measured using an optical scanner (3Shape® E3 series, 7 µm accuracy). They were coated with a powder scan spray (VITA powder scan spray) to maximise scan quality. Once positioned on the tray, an automated scan path was used to digitise the top and bottom of the MG and then merge them into an .stl file.

Based on the tomographies, the shapes of the sensor cavities were extracted for the iMG V2. Internal shapes were measured using a micro-CT scan (PerkinElmer® Quantum GX2) with the addition of a 0.5 mm aluminum filter plate, an x-ray generator output voltage of 90 kV and an x-ray tube current of 88 mA. The scans were stitched together using a stitching tool. The theoretical accuracy was 172 µm. A DICOM file was extracted and then processed in Slicer 5.2.2 [19] to filter out artefacts and reconstruct the envelope.

Table 1: repartition of studied mouthguards and the measurements realized

Mouthguard type	Number	Rugby player population	Envelope measurement	CT scan	Example picture	Fitting process
MG	3	2 professional players and 1 amateur	Yes	No		Custom fit
iMG V1	7	Under 20 elite players	Yes	Yes		Custom fit
iMG V2	3	Professional players	Yes	Yes		Custom fit

The thicknesses of the areas of interest were measured using both optical and micro-scans. The MG envelope files were processed in MeshLab v2022.02 [20] to isolate the two faces of each area of interest (e.g. vestibular surface). The coordinates of the points in each of these planes were exported. The thickness for each point was then estimated as the Euclidean distance from the nearest point of the opposite area. As the sensors of the iMG V2 are located on one side of the mouthguard, three values were reported, considering all points, those in the sensor (corresponding to s in the Figure1a) area and those in each of both sides without sensor (corresponding to a and c in the Figure1a). The fusion of the envelopes and tomograms was performed using Autodesk® MeshMixer™ software.

Based on a literature review, six geometric criteria were defined as below. To ease understanding, Figure1 illustrates necessary dental vocabulary.

- Criteria 1 (C1), tooth coverage, from the incisors to the distal surface of the second molar [21–23] to preserve teeth and increase comfort.
- Criteria 2 (C2) Mouthguard limit: Labial flange should extend to within 2 mm of the vestibular reflection [24,25], for reducing stress and strain within the teeth. The palatal flange should extend approximately 10 mm above the gingival margin [23,26,27].
- Criteria 3 (C3) Filling of spaces: filling of gaps and possible missing teeth for reducing strain [22]. In the current study, this criteria was visually inspected on the mouthguard.
- Criteria 4 (C4) Occlusal antagonist contact: lower mandibular cusp indentation from canine to 2nd molar as an insufficient occlusion may cause a fracture of the mandible [25,28–30].
- Criteria 5 (C5) Minimum thickness for reducing stress within the teeth. This criteria depends on the area under consideration:
    - vestibular area: from 3 to 4 mm [15,16,23,25,31–33]
    - palatal area: from 1 to 2 mm [16,17,21],
    - occlusal area: from 2 to 10 mm [15,17,33],
    - the incisal margin: from 2 to 4 mm [17,33].
- Criteria 6 (C6) Thickness between teeth and sensors: minimum thickness of 3 mm [34], for avoiding component destruction and preserve teeth. This criteria focus on the thickness named c in the Figure1a.

For criteria C5 and C6, values were compared based on the number of points (in percentage of all points) meeting the criteria, and a boxplot was drawn to facilitate the repartitioning of the thickness values for each area studied.

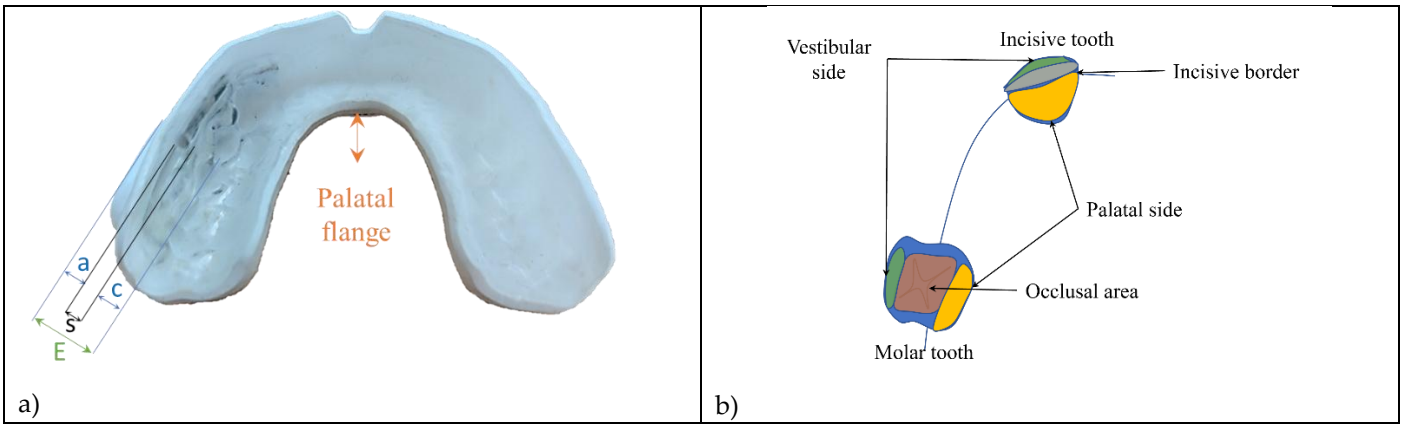


Figure 1: a) definition of thicknesses within the sensor area. E is the overall thickness between the outside and the side in contact with the teeth. a is the thickness between the outside and the sensor. s is the sensor thickness. c is the tickness between the sensor and the side in contact with the teeth. Thus E=a+s+c. b) dental vocabulary for molar and incisive teeth defining palatal (yellow), occlusal (brown) and vestibular (green) sides.

3. Results

No MG or iMG covered teeth up to the distal surface of the second molar (C1). For MG, the mean value of the palatal flange measured on the MGs was 7.4 ± 0.9 mm. All iMG V1 and 2/3 of iMG V2 had a palatal flange too short to be measured (C2). For the other 1/3, the mean value of the palatal flange was 4.5 ± 0.2 mm. Regarding the gaps, they seemed to be filled in all MG and iMG for these geometries (C3). No MG or iMG showed occlusal indentation of the mandibular teeth (C4). With regard to thickness (C5), the values were reported in the Table2, the corresponding mapping in *Figure 2* and the corresponding box plot in *Figure 3* for vestibular thicknesses. *Figure 4* provides details about thicknesses of the V2 iMG regarding the sensor and the surrounding material. Additional thickness results were reporting in the supplementary material, for palatal (*Figure SM1*), occlusal (*Figure SM2*) and incisal (*Figure SM3*) areas. The average sensor thickness (C6) was *s*=2 mm. The average thickness between the sensors and the shell was always less than 3 mm for the internal part, corresponding to *c* in the Figure1a, the thickness between the sensor and the expected position of the tooth.

Table 2: Vestibular, palatine and occlusal thicknesses for MG, iMG V1 and iMG V2. Results values are given in mm. Mean ± SD. The ratios of points verifying the criteria over the total number of points in a given area are expressed as percentages.

Criteria	MG	iMG V1	iMG V2	Target threshold
N	3	7	3	/
Measurement points (x1000)	307 ± 13	65 ± 4	59 ± 2	/
Vestibular thickness (mm)	3.1 ± 0.7 56%	3.5 ± 1.6 58%	3.7 ± 1.6 56%	>3
Palatine thickness (mm)	3.8 ± 0.9 100%	2.6 ± 0.5 100%	4.0 ± 0.7 99%	[1 : 2]
Occlusal thickness (mm)	3.9 ± 0.8 100%	3.1 ± 0.6 98%	4.5 ± 0.6 100%	[2 : 10]
Incisal thickness (mm)	3.7 ± 0.8 100%	3.6 ± 0.5 100%	4.0 ± 0.7 100%	[2 : 4]

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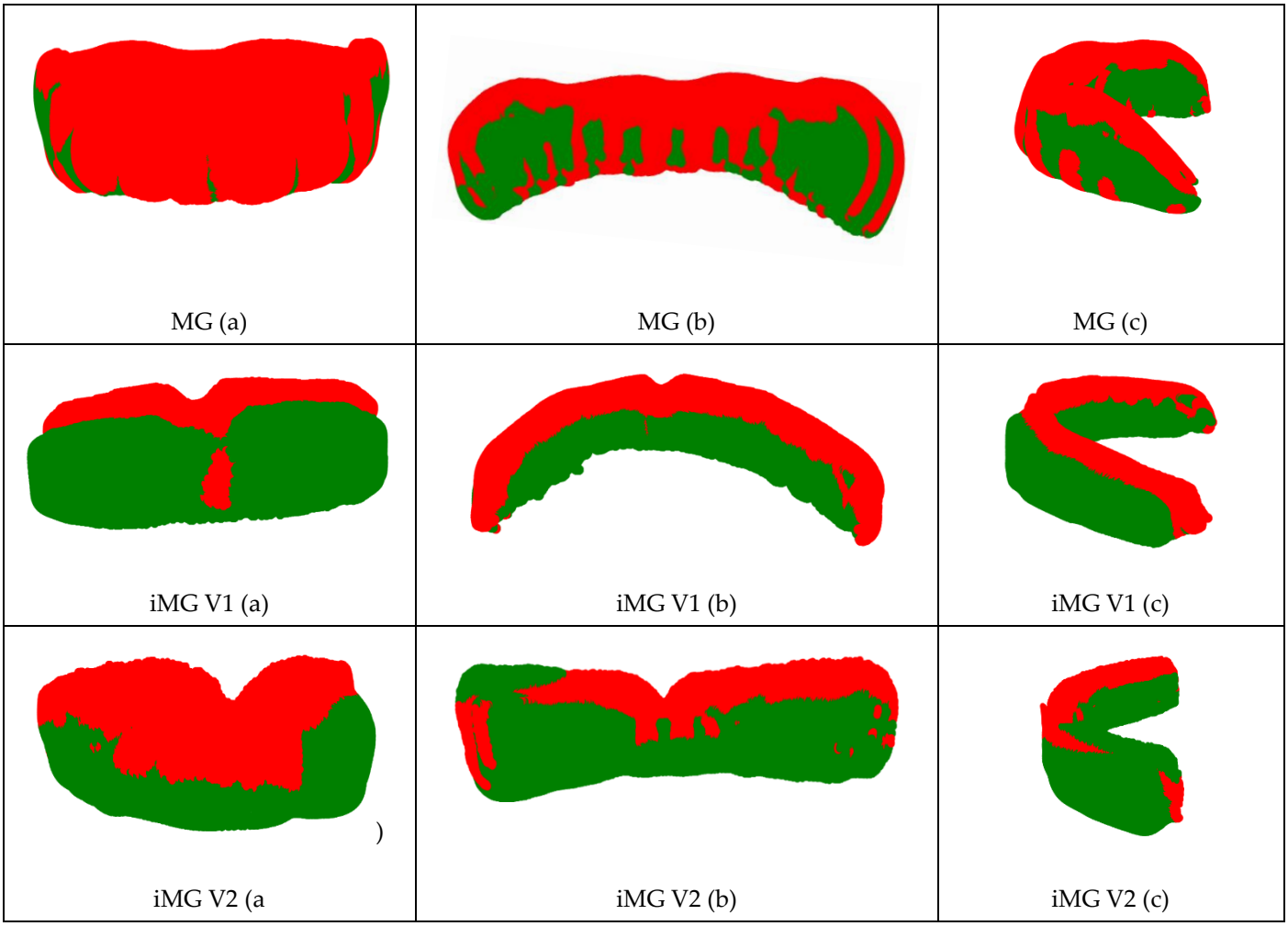

Figure 2 : Mapping of vestibular thicknesses of MG, iMG V1 and iMG V2 ; green areas are thicknesses ≥ 3 mm and red areas are < 3 mm. Front (a), back (b) and 3/4 views (c)

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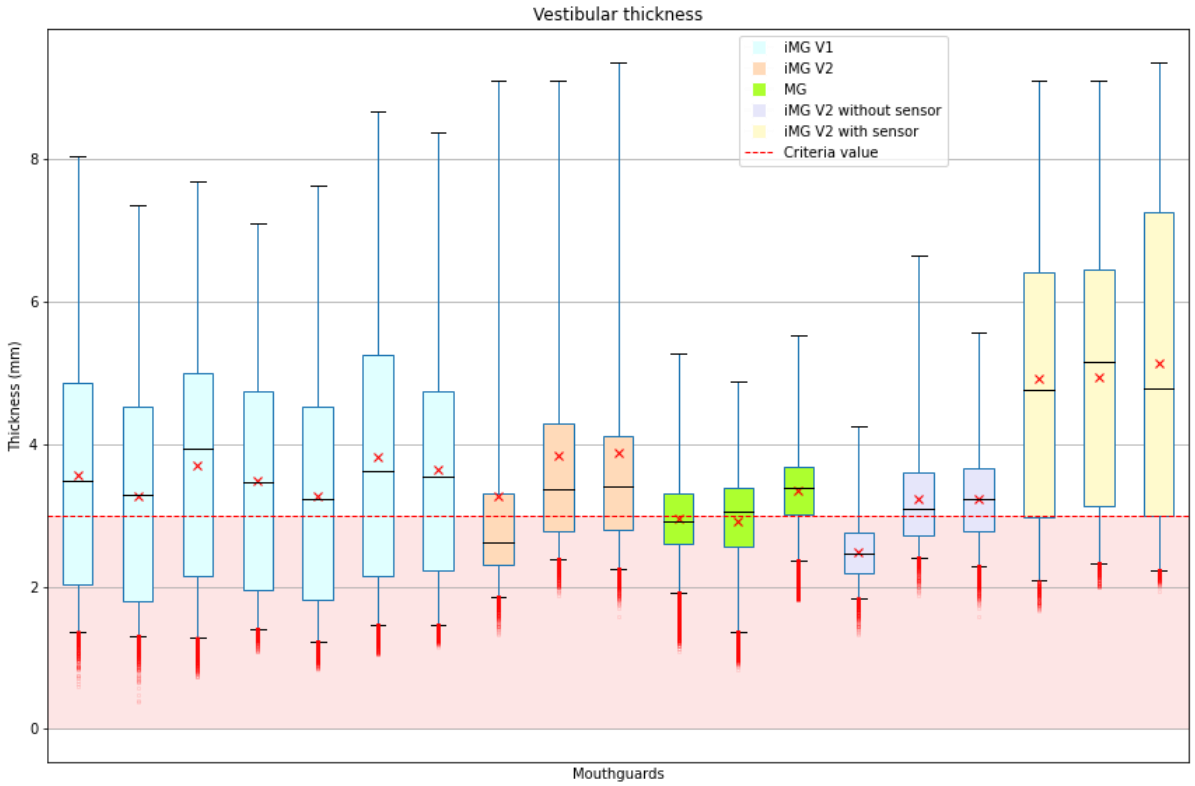

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Figure 3 Vestibular thicknesses of the mouthguards (Table 1 criteria 5-1). The red cross correspond to the mean, the horizontal black line to the median. Boxes limit quartiles. The red dot horizontal line over the figure correspond to the targeted thickness values. Values "without sensors" corresponds to a+c and values "with sensor" corresponds to a+s+c.

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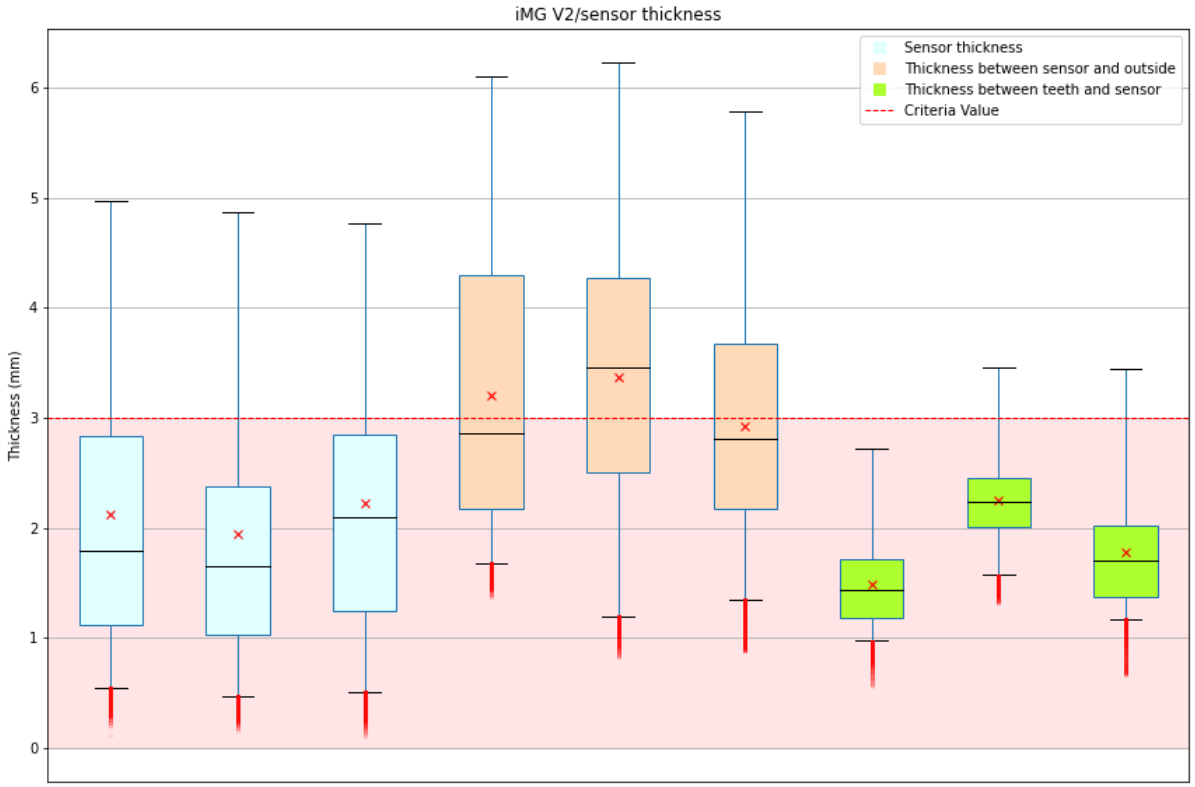

Figure 4: Sensor and mouthguards thicknesses on both sides of the sensors for iMG V2. The threshold was represented by the red area. Thickness between sensor and outside

4 Discussion

The aim of this study was to characterise the geometric specificities of MG and iMG to determine whether they meet current scientific recommendations regarding their geometry for safety and comfort. To date, standards have been focused on non-instrumented mouthguards [15] overlooking the specifics of the instrumented ones. Of the six criteria identified in the literature, four parameters (C1, C2, C3 and C4) can be assessed by simple visual inspection, making them easy to verify directly in clubs. Only the thicknesses, especially in the sensor area, require more specific equipment and can be difficult to measure. However, it was noted that several areas did not meet the requirements on all points, such as vestibular thickness. Regarding occlusal antagonist contact (C4), there was no indentation area between the upper and lower teeth as there was no lower mandibular indentation on the device. The absence of this indentation was shown to increase the risk of mandibular fracture [28,35].

In terms of global geometric parameters, the mouthguards went to the molars, but rarely to all teeth, which can lead to discomfort. More critically, neither MG nor iMG showed an occlusal indentation towards the mandible, contrary to the recommendations of the standards [15]. This lack of occlusion was also shown to increase the distortion of mandibular bone and thus the risk of mandibular fractures [28,29]. To help adapt the occlusion of the mouthguard, the provider's procedures should be modified to include an occlusion adaptation step. This step should be carried out by a trained dentist when giving the mouthguard to the player to ensure an appropriate fit. For thickness, the mean values were often above the thresholds for all criteria. However, they were highly dependent on the area. The upper part of all mouthguards, regardless of technology, was thinner, or the region close to the tooth centres. Thus even if mean values were above criterias, many values were below.

As these devices are often considered to be personalised, one would expect a homogeneous thickness across each area. This would make it easier to validate the criteria and therefore improve safety and comfort. However, the thickness variability, within area, measured in this study, may reflect a lack of personalisation of the device to the user. This resulted in values below the threshold in all configurations for vestibular thickness, for example. Interestingly, this was a problem shared by the mouthguard control group. Critically, the values in the incisor area were below the threshold, even though this area may be at risk. Unlike American football or hockey players who wear a helmet, rugby players may have direct contact over the incisors. Protection of this area should therefore be of even greater concern.

For the iMG V1, the addition of the sensor does not seem to be associated with a significant increase in protective material compared to simple MG. For the V2 version, the addition of thicknesses on both sides of the sensor leads to an overall thickness close to the threshold. However, there is a need for further research as the sensors itself may influence the protective capacity. The parameter defining the thickness between the teeth and the sensors is based on only one study and should be better analysed [34]. In the iMG V2, the placement of all devices on one side led to a drastic increase in the overall thickness of the area. This may result in a lack of comfort for users.

A limitation of this pilot study is the number of mouthguards studied. The heterogeneity of the results only gives us global trends and will benefit from a wider study. This study only included Prevent Biometrics moulded upper jaw 3D scan models iMG, which may have a different geometry than other manufacturers. It also did not include mouthguards that were moulded using a "boil and bite" process, which may be more likely to have an upper/lower jaw match due to their moulding process. However, these were the models currently recommended for elite players by World Rugby. Further research would benefit from the addition of dental scans, which would have helped to determine the actual thickness between the teeth and the outer part of the mouthguard.

No control of the mouthguards use duration was done for this pilot study. Whereas, due to repetitive shocks, material may modify its behavior among time. Especially as the sensors are in the mouth, they may face collision during players contacts. That may modify the thickness and more globally its mechanical behavior. This should be studied to propose an estimation of the product life expectancy regarding its capacity to protect, its capacity to measure and reducing the potential environment impact.

Feedbacks from players should be recorded to better understand its acceptability, and comfort [24,36,37] which may help to increase their wearing time. Qualitative feedbacks from rugby players indicated discomfort in the iMG sensor area, particularly for the V2 version [38].

The field is lacking a clear standards for iMG which would help manufacturers to develop appropriately. Currently the influence of electronic devices addition within this protective device remain unclear, adding ethical concerns [39]. To the best of the author's knowledge, the only study investigating the influence of electronic devices in mouthguards focused

on the ability to keep the electronic device functioning [34]. However, further criteria should address the issue of the potential alteration of shock absorption by these components.

5. Conclusions

Based on the scientific literature, six criteria for analysing the geometry of mouthguards were established. Both the instrumented and non-instrumented adaptable mouthguards tested did not meet all the geometric requirements. The amount of protective material added to the mouthguard to compensate for the sensor insertion did not always seem appropriate. Some missing requirements may lead to a reduction in protection and reduce comfort. The field currently lacks a standard or recommendation to facilitate the manufacture of safe and comfortable instrumented mouthguards.

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Supplementary materials

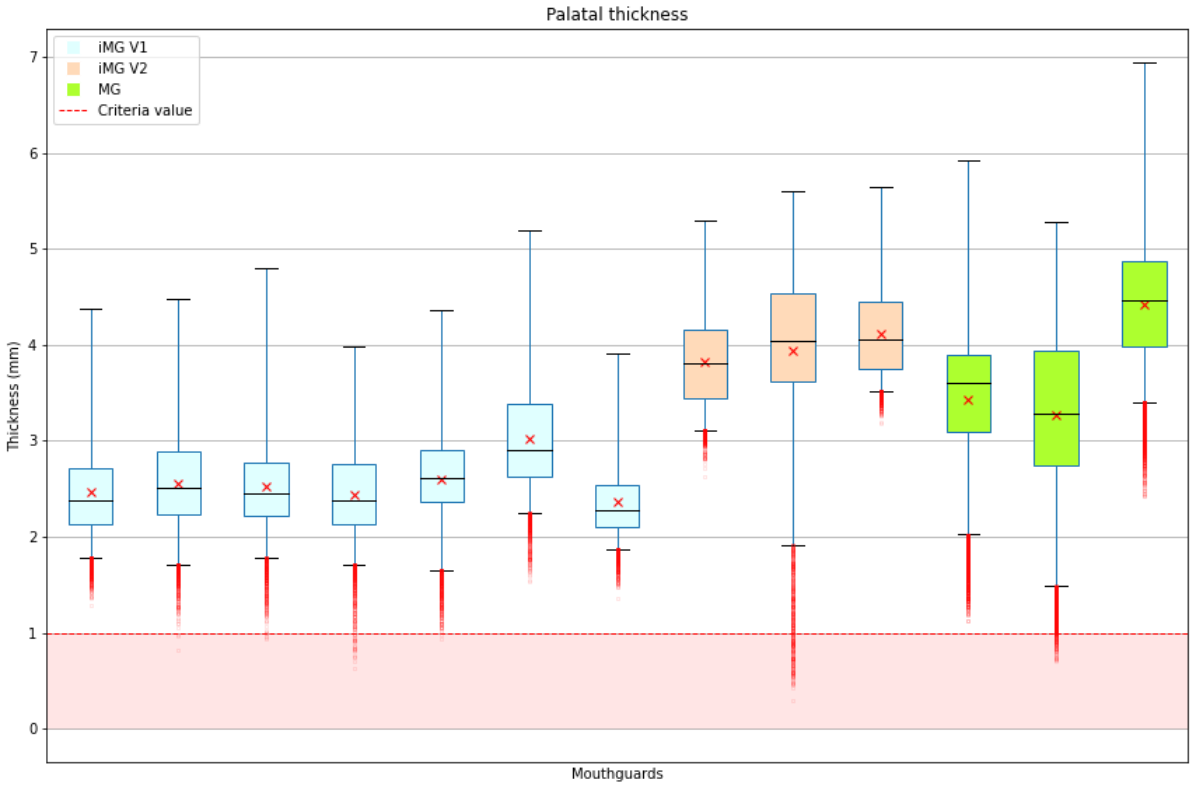

Figure SM1 Palatal thicknesses of the mouthguards (Table 1 criteria 5-2). The red cross correspond to the mean, the horizontal black line to the median. Boxes limit quartiles. The threshold was represented by the red area.

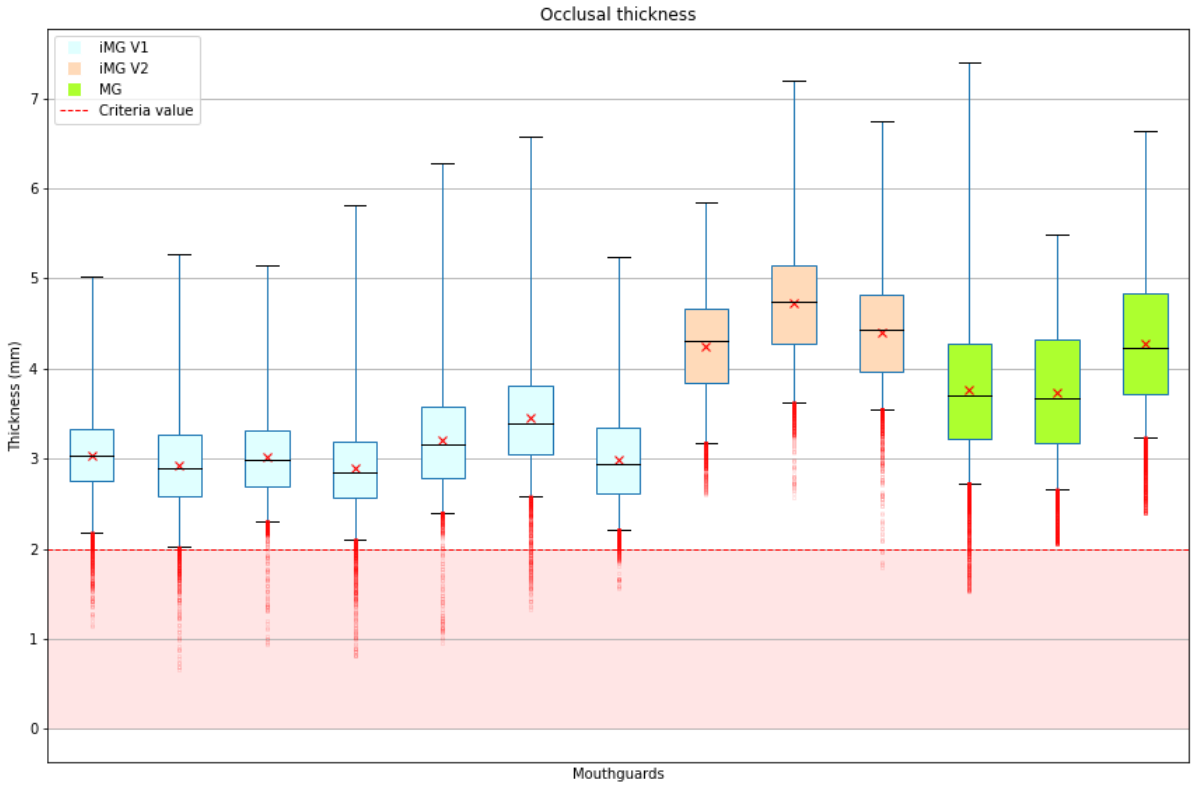

Figure SM2: Occlusal thicknesses of the mouthguards (Table 1 criteria 5-3). The red cross correspond to the mean, the horizontal black line to the median. Boxes limit quartiles. The threshold was represented by the red area.

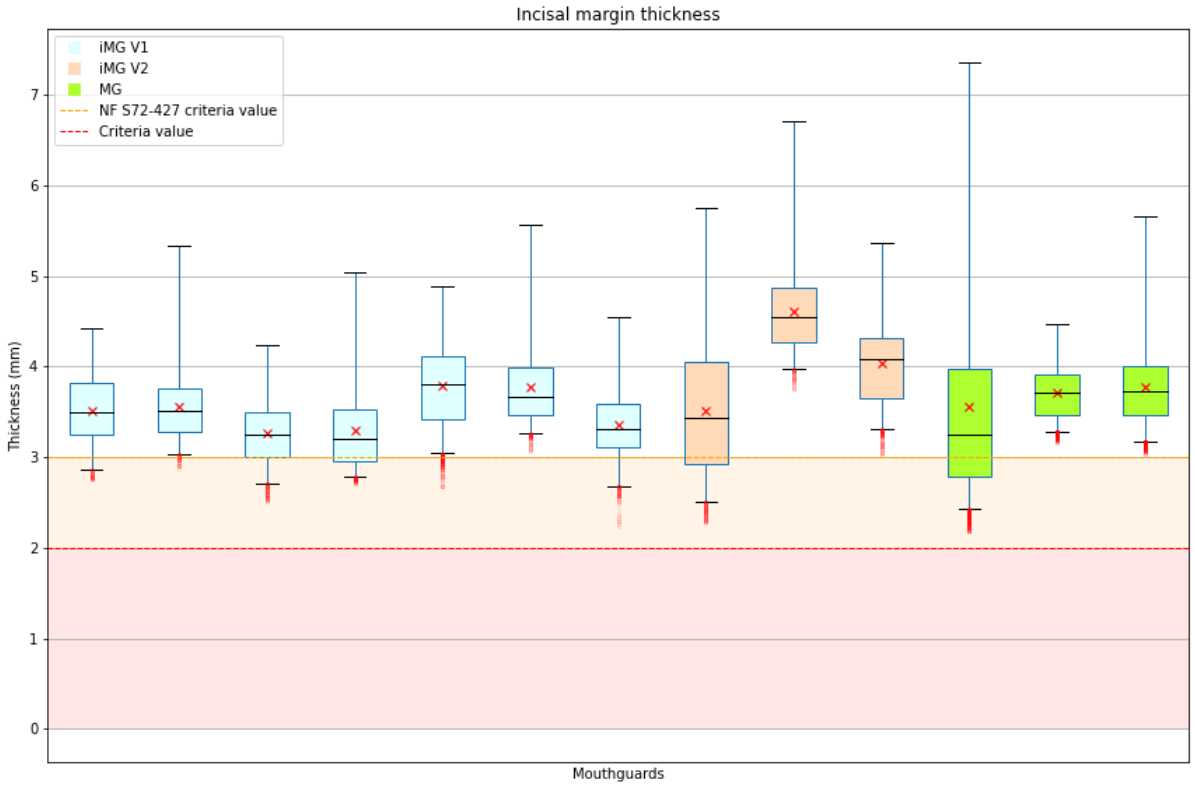

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Figure SM3: Incisal margin thicknesses of the mouthguards (Table 1 Criteria 5-3). The red cross correspond to the mean, the horizontal black line to the median. Boxes limit quartiles. The threshold was represented by the red area.

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