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ORIGINAL ARTICLE

Characterization of mouthguards: Impact performance

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Abstract

Background/Aim: It is difficult to characterize the impact behavior of mouthguards on the basis of their components. Impact behavior tests should be performed on mouthguard formed to simulate their intra-oral performance. The aim of this study was to compare the impact behavior of six models of mouthguards using a standardized experimental protocol.

Material and methods: Four commercially available mouth-formed mouthguards (SDI™, Gel Nano™, Opro Shield Gold™ and Kipsta R300™), one mouth-formed mouthguard prototype and one custom-made mouthguard were tested. The procedures recommended by the manufacturers (injecting procedure for custom-made mouthguard and “boil-and-bite” procedures for mouth-formed mouthguards) were used to adapt five samples per model on steel jaws. Impact performances were assessed according to labial aspect thickness and maximum contact load (FMax) during impact using a drop tower.

Results: SDI™ and Opro Shield Gold™ had the thinnest labial aspect thickness ($P < .01$), followed by the Gel Nano™ and the Kipsta R300™ ($P < .01$) with a thickness of about 3 mm. The prototype and custom-made mouthguard were thicker (almost 4 mm). The custom-made mouthguard, the Kipsta R300™ and the prototype had the best impact performances, but the labial aspect thickness of the Kipsta R300™ was significantly lower than that of the custom-made mouthguard and the prototype. Analysis of force curves and position of the mouthguard on the impacted zone showed that the Kipsta R300™ was less well adapted.

Conclusion: Thickness and impact performance are not sufficient criteria to characterize performance of mouthguards.

KEYWORDS

impact behavior, polymer structure, polyvinylacetate polyethylene copolymers, standardization

1 | INTRODUCTION

There are three types of mouthguard (MG): the stock type, the mouth-formed type and the custom-made type.^{1,2} The stock MGs currently available have evolved little since the design of the first unfitted MG.³ The main difference lies in the constituent material, which has benefited from technological developments: firstly cork, sponge or rubber, then polyvinyl chloride or polyurethane, and finally polyvinylacetate

polyethylene copolymers (PVAc-PE copolymers).³⁻⁶ This type of MG is simply placed over the maxillary dental arch of the athlete, resulting in poor retention with the risk of its loss during activity¹ and the possibility of becoming wedged in the airway.^{5,7}

The mouth-formed type represents nearly 90% of all MGs worn by athletes.⁸ The technique of adaptation by thermomodeling (“boil and bite”) increases the temperature of the MG material to allow it to be adapted to the athlete’s mouth. The custom-made type is made after

an impression has been taken of the maxillary dental arch⁷ or both the maxillary and mandibular dental arches.⁹⁻¹² This impression must be performed by a dental practitioner to verify the records of the dental arch and the surrounding tissues,⁴ as well as to assess the increase in vertical dimension and lower jaw position.⁹⁻¹² A custom-made MG is considered to be more protective and to offer better wearability than the other types.^{1,4,13}

Whatever the type or method of manufacture, MGs designed for sport or leisure activities are considered as personal protective equipment.¹⁴ Therefore, all types of MG have to be approved for the highest level of protection for a reasonably foreseeable risk during use. Various parameters should be taken into account to evaluate their level of performance. The level of protection has mainly been expressed in terms of impact behavior,^{15,16} which is directly related to the thickness of the material.^{15,17-19}

Various protocols have already been proposed to evaluate impact performance such as tests on samples,^{20,21} on sheets^{18,19,22-24} and on MGs.²⁵⁻³⁰ However, it is difficult to characterize the impact behavior of MGs on the basis of their components (mono-/multi-, sample or sheet). It would be better to perform such impact behavior tests on their structure, especially for "boil-and-bite" MF-MGs which are modeled by the athlete himself.

For this reason, an impact behavior study should be based on a protocol common to all MG types after fitting. Thus, the aim of this study was to evaluate the impact behavior of four commercially available mouth-formed MGs, one mouth-formed prototype and one "standardized" custom-made device. The hypothesis was that impact criteria (thickness and maximum contact load) are sufficient to assess the performances of MGs.

2 | MATERIALS AND METHODS

Manufacture of the maxillary and mandible steel models was based on the standard adult working model series ANA-4 (Frasaco GmbH, Tett nang, Germany): upper and lower model jaws in stable intercuspation (28 teeth).

Four commercially available MF-MGs were used for this study: SDI™ (Techniques Actuelles France, Le Meux, France), Gel Nano™ (Shock Doctor North America, Minnetonka, MN, USA), Opro Shield Gold™ (Opro, Hertfordshire, UK) and Kipsta R300™ (Oxylane, Villeneuve d'Ascq, France), respectively, named SDI, GN, OSG and KR300 in the study. They were purchased locally (Bordeaux, France). SDI, GN and OSG are bicomponent MF-MGs, and the KR300 is a mono-component MF-MG. A fifth EVA-type bicomponent thermo-plastic MF-MG (named "Prototype" in this study) was also tested.³¹ The five MF-MG models were thermomodeled on steel jaw models and according to the respective manufacturer's guidelines for commercial models and prototypes. A 400-N force was applied to the steel jaw during modeling using a specific device (described in^{25,32}), in accordance with the maximal bite force reported in the literature.^{33,34} This customized device was designed to apply a force (400 N) with a mass and a lever system on the top plate of the maxillary steel model, which is guided by two rods (avoiding any rotation of the mouthguard).

All MGs were fitted on the same day under the responsibility of the same dentist. Five MGs were formed for each model.

Five CM-MGs were supplied by the dental operator and made on the steel jaws model using the procedure described by Poisson et al.³⁵:

- Take irreversible hydrocolloid impression of maxillary and mandibular steel arches which includes the entire mucobuccal borders.
- Make dental casts from the impressions.
- Record temporo-mandibulo-maxillary relationship.
- Make CM-MG by PVAc-PE copolymer injection: pressure machine J100 Evolution™ (Pressing Dental, Euromax, Monaco), PVAc-PE copolymer cartridge Corflex orthodontic™ (Pressing Dental, Euromax, Monaco) injected at 160°C for 15 minutes according to the manufacturer's recommendations.
- Place CM-MG in steel jaws, then examine and eventually modify the buccal borders while repositioning the lower jaw and airway space.

The following essential requirements were applied at all times^{15,19,28,36-38}:

- The CM-MG enclosed the maxillary teeth as far as the distal surface of the second molars and had a minimum thickness of 3 mm on the labial aspect, a minimum of 2 mm on the occlusal aspect from canine to molar, a minimum of 4 mm on the incisal edges of the maxillary incisors and 1-2 mm on the palatal aspect.
- The labial border was first extended to within 2 mm of the reflection of the buccal sulcus of the maxillary dental arch and then to the cervical third of the labial aspect from the canine to second molar mandibular teeth.
- The palatal border was extended about 10 mm above the gingival margin.

All MG models are shown in Figure 1.

The degree of retention of the MGs was tested classically.³⁹ Each MG was placed on the maxillary steel model. Then, the steel model was manually turned over. The MG had to stay in position on the maxillary arch during 30 seconds when only subjected to its own weight. The result was "Retention" if it stayed in position and "Insufficient retention" if not.

The ability of MGs to absorb energy and limit the force transmitted to teeth is directly linked to the thickness of the MG where the impact occurs.²⁵ The labial aspect thickness (LAT) corresponded to the mean value of the incisal third and the cervical line of the labial aspect. Thicknesses were measured using a Dial Caliper (Maestra, Talleres Mestraitua, Bilbao, Spain) with a measuring range of 0-10 mm and a 0.05-mm accuracy. Thickness values at the level of the impact zone were also used to determine the impact performance of the MGs.

To characterize the impact response, the MGs were positioned between the steel jaws using a 400-N preconditioning bite force and the ensemble was set up on a drop tower.²⁵ Briefly, a 2-kg projectile mounted on a falling carriage was raised to 0.20 m and then released to impact the MG with a hemispherical steel impactor (16 mm diameter) as shown in Figure 2. Force was measured with a piezoelectric load sensor

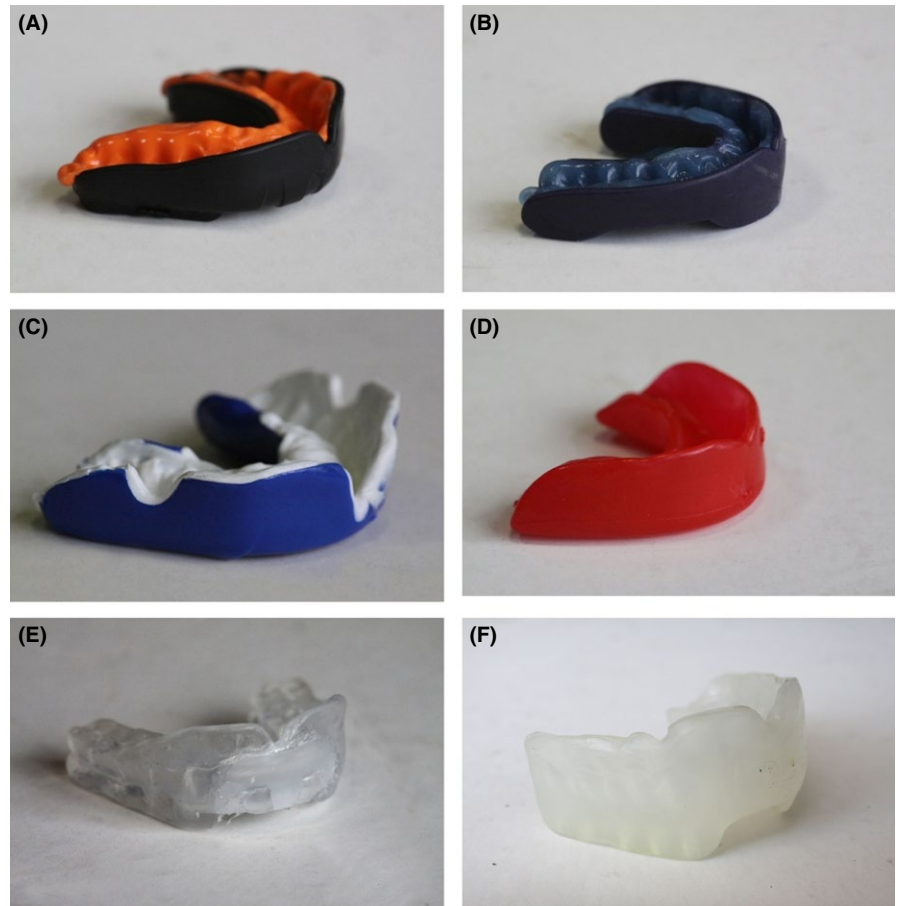


FIGURE 1 Six MG models: (A) SDI, (B) GN, (C) OSG, (D) KR300, (E) Prototype, and (F) CM-MG

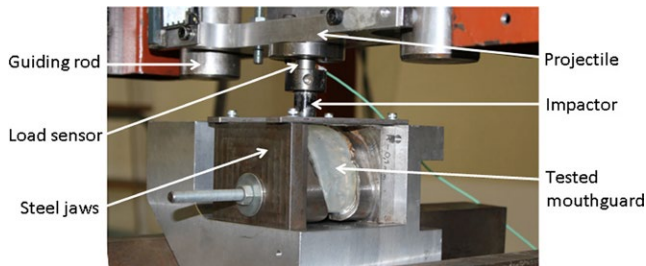


FIGURE 2 Impact device setup on the drop tower

mounted on the impactor (9011A, Kistler, Winterthur, Germany) using a 2.5-kN range,²⁵ and the signal was digitized by a National Instruments card acquisition at a frequency of 30 kHz. The incisal cushion was chosen for this test because it is the zone where the most severe injuries occur around the upper central incisors.⁴⁰⁻⁴² To ensure the same impact loading conditions for all MGs, all impacts were made on the right incisal cushion (only one test per sample). Then, force vs time curves were plotted. The maximum contact load (FMax), corresponding to the maximum value of force vs time curve, was obtained.

TABLE 1 Labial aspect thickness (LAT) and maximum contact load (FMax)

	N	LAT (mm)			FMax (N)		
		Mean	SD	Coefficient of variation	Mean	SD	Coefficient of variation
SDI	5	2.68	0.08	3.0 a	>2500	//	//
GN	5	3.07	0.11	3.6 b	1516	48	3.2
OSG	5	2.66	0.06	2.3 a	2268	307	13.5
KR300	5	3.16	0.12	3.8 b	1314	89	6.8 a
Prototype	5	4.45	0.13	2.9	1338	58	4.3 a
CM-MG	5	3.81	0.20	5.2	1407	44	3.1 a

Means in a given column with the same letters (a, b) are not significantly different.

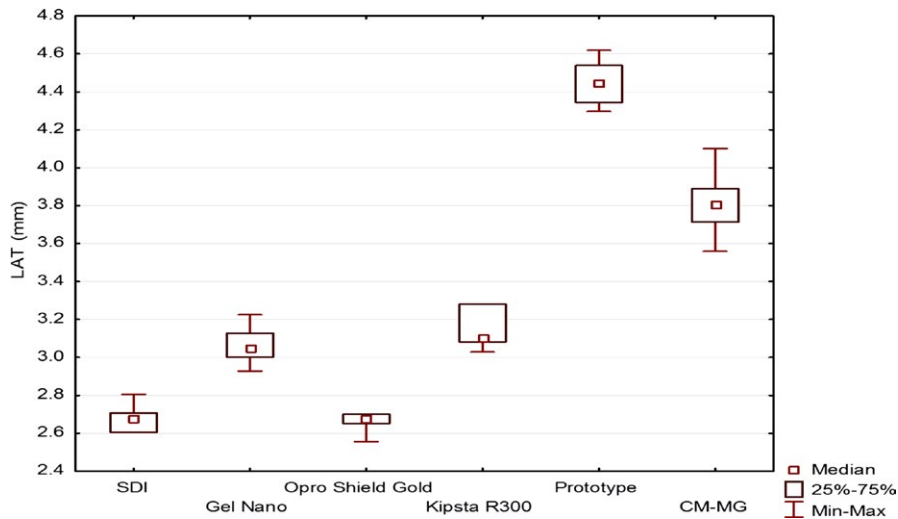


FIGURE 3 Labial aspect thickness according to model (mm)

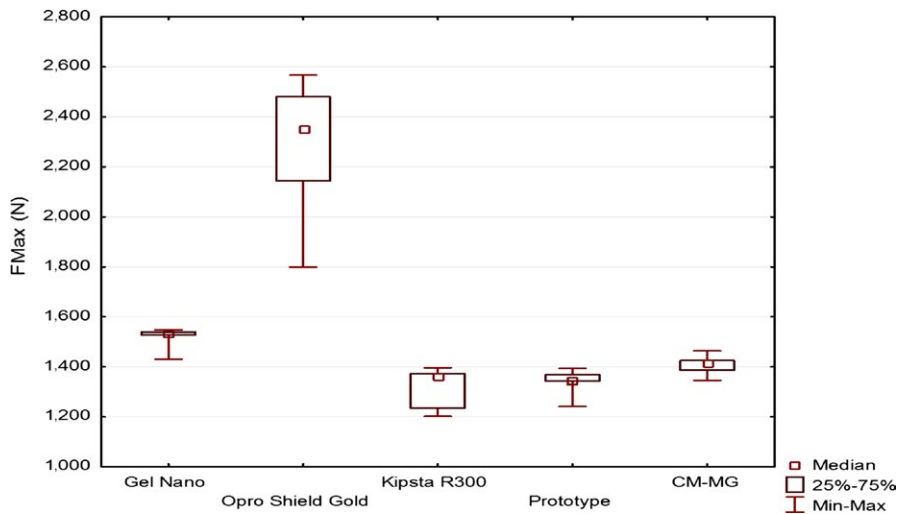


FIGURE 4 Maximal force (FMax) transmitted during impact test per model (N)

The level of adaptability was evaluated on a sagittal section of the MG placed on the maxillary arch model in plaster. The criterion used was the size of the space between the underside of the MG and the labial surface of the maxillary central incisor, with a small free space indicating good adaptability.^{3,43}

Impact performance data analysis consisted of comparisons of LAT and FMax by Kruskal-Wallis ANOVA and the Mann-Whitney U Test. All statistical analysis was performed using Statistica v10 (StatSoft, Inc., Tulsa, USA). A value of $P < .05$ was used as an indicator of statistical significance.

3 | RESULTS

The degree of retention was insufficient for the OSG and the KR300: fall of the MGs from the maxillary arch during the retention test.

Labial aspect thickness (LAT) and maximum transmitted force were used to assess impact performance (Table 1). Two MF-MGs had the thinnest LAT ($P < .01$), (SDI and OSG), followed by the GN and KR300 ($P < .01$) with a thickness of about 3 mm (Figure 3). The remaining MGs (Prototype and CM-MG) were thicker (almost 4 mm).

For maximum transmitted force (Figure 4), no data were available for the SDI because the maximum load reached during the impact was higher than 2500 N. The OSG and GN had intermediate mean values of 2267 N and 1516 N, respectively. All the other MGs (KR300, Prototype and CM-MG) had about the same mean FMax of about 1350 N. The differences between both groups were significantly different ($P < .02$).

Figure 5A presents the evolution of force as a function of time for each MG type. Only one curve was plotted per MG owing to the good repeatability of mechanical behavior. The structural response of all MGs appeared to be elastic (linear relationship between load and time). At the beginning of the rising load, a toe region was present for OSG, KR300 and the Prototype (Figure 5B).

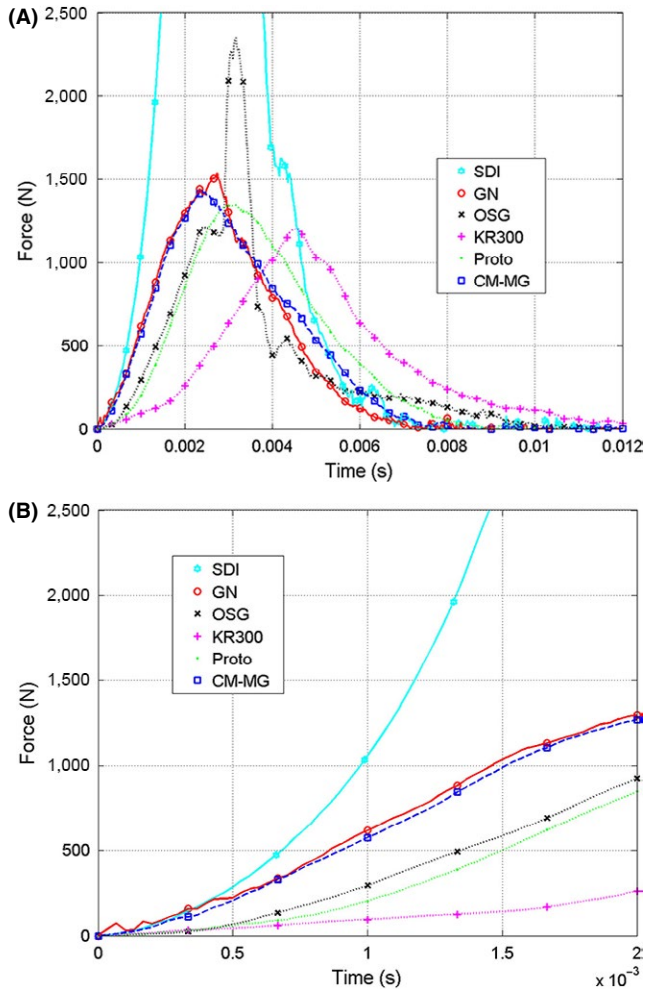


FIGURE 5 (A) Force vs time for all MGs tested. (B) Same as in (A) but with expanded time scale

The free space between the underside of the MG and the plaster model was 0, 0, 0, 0.48, 0.72 and 2.65 mm for the SDI, GN, CM-MG, Prototype, OSG and KR300, respectively (Figure 6).

4 | DISCUSSION

The aim of this study was to assess the impact performance of MGs. As the oral and dental tissue types and various models of resin jaws are known to influence this type of assessment,^{25,28} the MGs were mounted on steel jaws, which cannot be deformed during the experimental procedure.

Impact behavior differed considerably between the MGs tested. These differences were due not only to the materials but also to other criteria such as thickness and the geometry/shape of the MG. The most effective MG is one that limits the force transmitted to the maxillary dental arch. According to the tests in this study, the CM-MG, the K300 and the prototype had the best performance (Figure 4). Table 1 shows the GN, OSG and SDI had significantly lower impact performances. Figure 5A shows that the maximum effort of the SDI exceeded the

maximum value of 2.5 kN chosen for the study. Moreover, post-test observation of the SDI showed a perforation, resulting in direct contact between the impactor and the steel jaw. Thus, the SDI did not meet the performance criteria for the study.

The bi-component MGs did not perform better (FMax) than the mono-component ones. The main objective of bi-component MGs is to guarantee a minimal thickness after the fitting procedure.^{8,44}

The thickness and force absorption properties of MG materials are widely thought to be linked.^{16,18–20} Previous studies have already defined the decision threshold for the thickness of MGs.^{15,19,36} For the labial aspect, a minimum thickness of 3 mm has been proposed.¹⁵ The thickness measurements were assessed at the level of the upper right central incisor because the upper central incisors are the teeth that are the most traumatized in sport.^{40–42} The thickness of the palatal aspect was not considered in this study because it has minimal effect on impact behavior.⁴⁵ The SDI and the OSG had a mean of thickness of less than 3 mm, which might explain their limited impact performance (Table 1). Statistical analysis showed that the prototype and the CM-MG were the thickest and had the best impact performance. The GN and the KR300 did not differ significantly in terms of the thickness of the labial aspect but the latter had better impact performance. Finally, the KR300 was thinner than the CM-MG and the prototype, but its performance was equivalent. This result is not in accordance with the literature, suggesting that other parameters are involved.

Three of the tested MGs (KR300, Prototype and CM-MG) had the same performance at maximum load but a difference in behavior to reach it: KR300 and Prototype were able to move under the effect of the impact to touch the labial aspect of the steel jaw (see two slopes on the curves—Figure 5B). Figure 6D–F shows a free space (FS) between the labial aspect of the MG and the buccal face of the upper incisor. The FS was large with the KR300, whereas it was small with the Prototype and absent with the CM-MG. The KR300 proved to be poorly adapted to the shape of a steel jaw. It behaved like a standard MG (type I) with all the drawbacks: poor retention and risk of becoming wedged in the airway.^{3,43} This is due to the modeling procedure which does not respect the thermal properties of the material.⁴⁶ When the temperature in the core (occlusal temperature) of the material does not reach the melting temperature, thermomodeling is superficial and affects only the outer layers,^{8,44} which leads to a poor fit.⁴³ This can result in a large free space (FS) between the tooth and the labial aspect of the MG, as with the KR300 (Figure 6D).

Finally, even though the thickness and the impact performance of a given MG might be suitable, its wearability and thermomodeling process also have to be characterized to make it efficient.

In conclusion, thickness and impact performance are not sufficient criteria to describe the performance of mouthguards.

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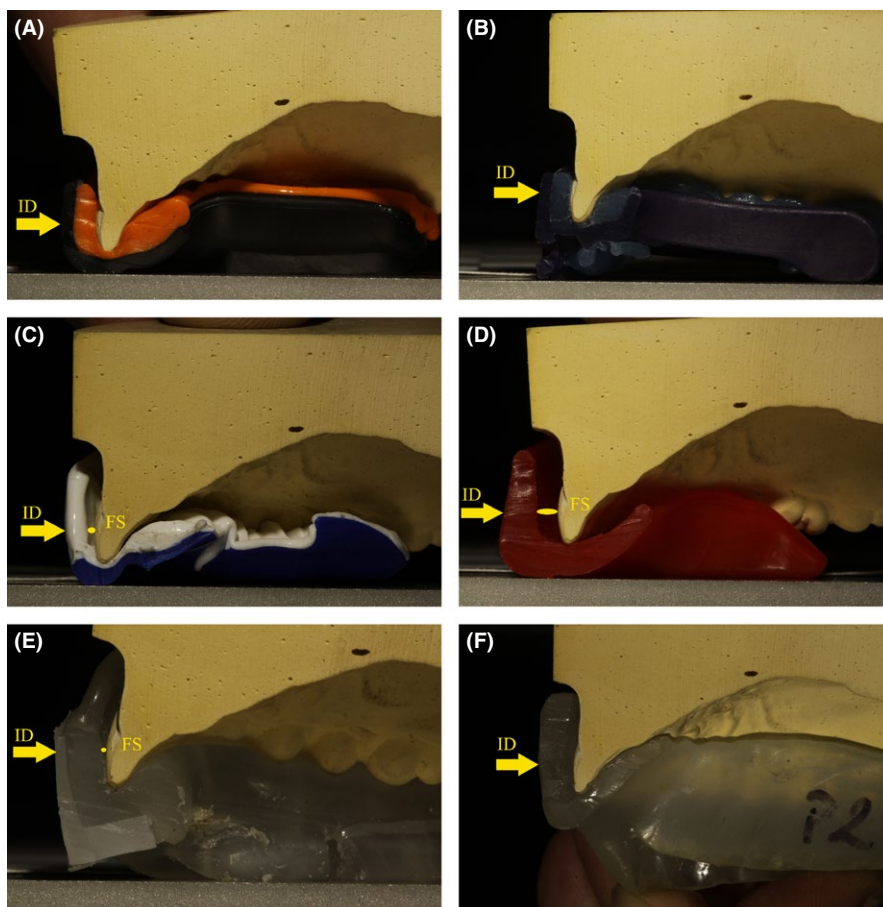


FIGURE 6 Cross section on sagittal plane by impact zone (FS: free space, ID: impact direction) for (A) SDI (no free space), (B) GN (no free space), (C) OSG, (D) KR300, (E) Prototype, and (F) CM-MG (no free space)

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CONFLICT OF INTEREST

The authors confirm that they have no conflict of interest.

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