

Article

Exploring Additive Manufacturing for Sports Mouthguards: A Pilot Study

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Abstract

Sports mouthguards play a crucial role in preventing orofacial injuries. Vacuum thermoforming with ethylene-vinyl acetate is the most common fabrication method; however, digital workflows and 3D printing have introduced promising alternatives. This in vitro study aimed to compare mouthguards produced by vacuum thermoforming and 3D printing in terms of precision, trueness and impact resistance. A maxillary plaster model was used to fabricate two groups: thermoformed mouthguards (GTherm, $n = 3$; Playsafe Triple Light, Erkodent™) and 3D-printed mouthguards (GPrint, $n = 3$; high-impact polystyrene via fused deposition modeling). The internal surfaces were scanned with a Medit T500, and precision and trueness were assessed by superimposing STL files using Geomagic software. Ten specimens of each material underwent Charpy impact testing. Data were analyzed with GraphPad Prism. The GPrint group exhibited higher precision (median RMS = 57.8 μm) than GTherm (median RMS = 812 μm), although the difference was not statistically significant ($p = 0.10$). Trueness in GPrint was within acceptable limits (median RMS = 118 μm). In the Charpy test, impact strength was significantly higher in thermoformable-based specimens than in printed ones (mean 17.33 ± 1.96 vs. 14.33 ± 0.65 kJ/m², respectively). Within the study's limitations, 3D-printed HIPS mouthguards showed superior precision and acceptable trueness, whereas thermoformed mouthguards demonstrated significantly greater impact resistance.

Keywords: sports mouthguards; additive manufacturing; 3D printing; vacuum thermoforming; ethylene vinyl acetate (EVA); high-impact polystyrene (HIPS)

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1. Introduction

The use of sports mouthguards has increased over recent decades, leading to a significant reduction in orofacial injuries associated with contact sports [1,2]. Numerous studies investigating the importance of these devices have been conducted, contributing to changes in safety regulations in various sports, including American football, rugby and

boxing, where their use has become mandatory [1,3]. Despite the American Dental Association (ADA) recommending protective devices for more than 20 different sports, the widespread implementation of mouthguards remains challenging. Athletes often report insufficient guidance from coaches, phonation discomfort and perceived impairment of athletic performance as barriers to their consistent use. In addition, financial constraints and the lack of institutional support from clubs have also been identified as contributing factors limiting their adoption [2,3].

The correct use of mouthguards provides protection against numerous common injuries, including coronal dental fractures, avulsions, subluxations and mucosal lesions, as well as fractures of the maxillary and mandibular bones. Such injuries can result in temporary or permanent interruption of sports participation, necessitate complex and costly medical treatments, and, in more severe cases, lead to irreversible functional and esthetic consequences [2,4,5].

According to their molding technique and design, sports mouthguards can be classified into three categories: (i) stock; (ii) boil-and-bite; and (iii) custom-made [1–3,6]. Although the first two are more affordable and convenient, they offer limited adaptation to orofacial tissues and reduced protective efficacy. In contrast, custom-made mouthguards are considered the gold standard, as they are individually fabricated by a dentist in collaboration with a dental laboratory [1]. The process usually involves a conventional analog impression, followed by gypsum model fabrication and vacuum thermoforming, which allows for a precise fit to the individual's oral structures, providing greater comfort and improved impact absorption [3].

Regarding the materials available for custom-made mouthguards, ethylene-vinyl acetate (EVA) is the most widely used. This thermoplastic polymer is highly elastic, flexible, biocompatible and non-allergenic, exhibiting adequate impact absorption through effective force dissipation [3,7–9]. Despite these beneficial properties, EVA presents some limitations, such as dimensional changes due to water-induced expansion in the oral cavity and low rigidity (9 MPa) even at greater thicknesses, which reduce its efficacy in dissipating impact energy and distributing stresses compared to other available materials [7]. To address the limitations of EVA, various strategies have been explored, such as combining it with other more rigid copolymers or reinforcing materials. Modifications have included the incorporation of silver nanoparticles for antibacterial properties and the use of porous rubber, intermediate silicone layers, silicone-nylon mesh, or urethane additives to enhance impact absorption [6]. Alternative approaches have incorporated internal air cells, either alone or combined with hard materials, closed-cell foams, A-silicone interlayers, or honeycomb-structured EVA meshes [6]. In the context of EVA composites, a commercially available product for vacuum thermoforming of sports mouthguards is Playsafe Triple Light (Erkodent™, Pfalzgrafenweiler, Germany). This product is composed of two external EVA layers surrounding a sandwiched cyclo-olefin copolymer (COC) layer—a more rigid and less expandable component, designed to overcome some of the mechanical limitations of EVA alone.

Although custom thermoforming is a reliable fabrication method, it still presents several limitations: (i) dimensional changes, with progressive thickness reduction in critical regions such as incisal edges and cusp tips; (ii) compromised fit accuracy due to deformation from repeated insertion-removal cycles or occlusal loading; and (iii) reduced longevity following exposure to high-impact forces [10,11].

Computer-aided design and computer-aided manufacturing (CAD-CAM) technologies have gained increased popularity in dental medicine, offering reduced fabrication time and cost. Additive manufacturing, or 3D printing, is particularly attractive due to its versatility. Although its application in sports mouthguard production has been reported, the results remain limited and sometimes inconclusive [12].

The additive manufacturing of fully digitally designed sports mouthguards offers a fast, reproducible (particularly in terms of thickness) and individualized solution, while also overcoming some of the disadvantages associated with thermoformed mouthguards, such as thickness loss and delamination. According to Soltanzadeh et al., the main advantages of this approach include the simplification of laboratory procedures with reduced production time, high reproducibility and predictability (as a result of eliminating multiple steps prone to human error), improved adaptation to relevant oral structures, greater accessibility of digital information, and consequently, enhanced communication between the clinician and the laboratory [13].

Several materials are currently being investigated for the additive manufacturing of mouthguards, one of which is high-impact polystyrene (HIPS). HIPS is widely used across various industries due to its excellent mechanical properties and ease of processing. Produced by the radical polymerization of styrene monomer with polybutadiene rubber, HIPS is a thermoplastic polymer with a microstructure composed of an amorphous polystyrene matrix containing spheroidal domains responsible for its opacity, elongation, plasticity under stress and energy absorption. The combination of superior mechanical performance and cost-effectiveness makes HIPS a material of choice for numerous industrial and commercial applications [9,14,15].

Despite being a promising strategy, the additive manufacturing of sports mouthguards still requires further research to validate the biocompatibility of additive materials, their effectiveness in impact absorption and dissipation and their capacity to accurately fit and adapt to the dental arch and adjacent soft tissues [7].

Therefore, the aim of the present study is to compare, *in vitro*, sports mouthguards produced by vacuum thermoforming with those fabricated by 3D printing, with respect to the following parameters: precision, trueness and impact resistance.

2. Materials and Methods

2.1. Experimental Setup and Workflow

Based on a maxillary gypsum model obtained from an anonymized laboratory cast of an individual with a complete dentition (non-identifiable data and therefore exempt from informed consent), the following study groups were established:

- (a) Thermoformed Group (GTherm): vacuum-thermoformed mouthguards fabricated from transparent Playsafe Triple Light plates (Erkodent™, Pfalzgrafenweiler, Germany) with a thickness of 4.1 mm ($n = 3$).
- (b) Printed Group (GPrint): mouthguards fabricated by fused deposition modeling (FDM) using high-impact polystyrene (HIPS) filament [Dowire™, Seixal, Portugal] ($n = 3$).

The experimental workflow is summarized in the schematic diagram shown in Figure 1.

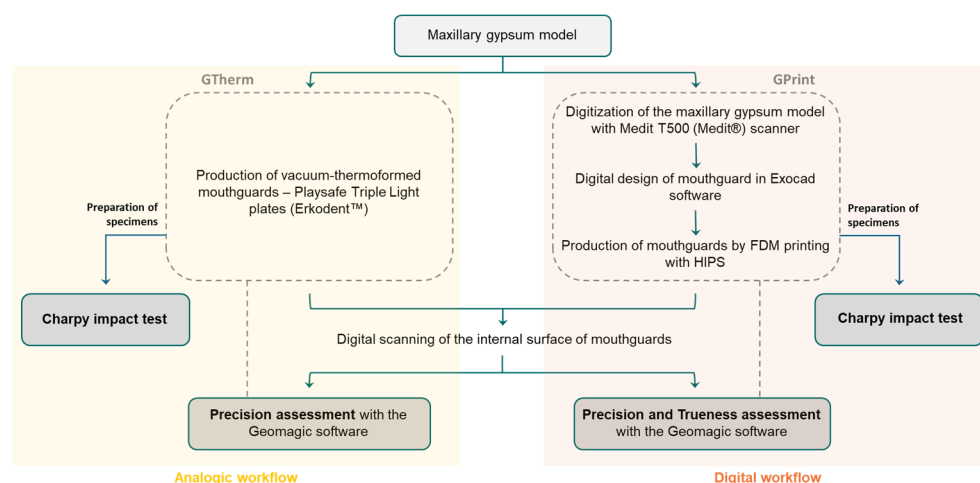


Figure 1. Experimental workflow of the in vitro study. GTherm—group of vacuum-thermoformed mouthguards; GPrint—group of 3D-printed mouthguards; FDM—fused deposition modeling; HIPS—high-impact polystyrene.

2.2. Fabrication of Sports Mouthguards by Vacuum Thermoforming (GTherm)

After blocking out the undercut areas of the maxillary gypsum model used in the study (master model) with wax (Figure 2a), the model was duplicated using a silicone duplicating material [Duplicating silicone A + B, 22 shore, Proclinic™, Barcelona, Spain; (Figure 2b)].

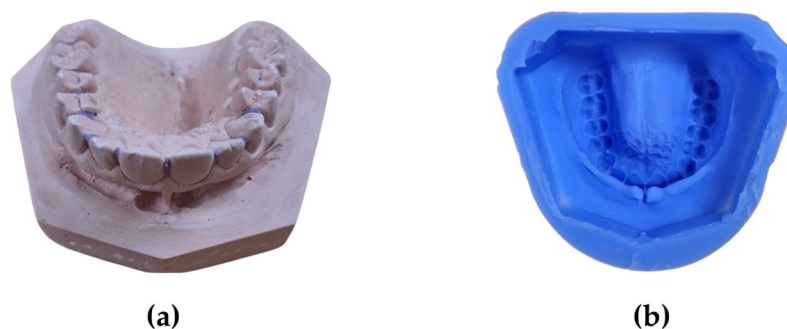


Figure 2. (a) Master gypsum model after blocking out undercuts with wax; (b) Corresponding silicone mold used for cast duplication.

From this silicone mold, three gypsum casts were produced, on which Playsafe Triple Light plates (Erkodent™, Pfalzgrafenweiler, Germany) were vacuum-thermoformed using the Erkoform-3dmotion thermoforming unit [Erkodent™, Pfalzgrafenweiler, Germany; (Figure 3a)].

The thermoforming process was fully automated after selecting the program compatible with the material used (in this case, Playsafe Triple Light plates) and involved the following steps:

- (i) Positioning the gypsum model on the base filled with pellets (Figure 3b), ensuring complete coverage of its lower surface to prevent plate rupture or cracking during thermoforming;
- (ii) Placing the Playsafe Triple Light plate in the heating ring and heating it to 110 °C;
- (iii) Performing automatic, instantaneous forming, followed by a 10 min cooling period.

After cooling, the thermoformed plate with the model was removed from the machine, and the intended trimming margins were marked (Figure 3c). Trimming of the

mouthguard was performed using a handpiece with a diamond bur, followed by polishing with a specific bur designed for thermoformed materials. Final finishing was achieved with an Erkodent flameless heater, which was applied after removal of the thermoformed mouthguards from the model and exclusively at the periphery to gently smooth the trimmed margins (Figure 3d).

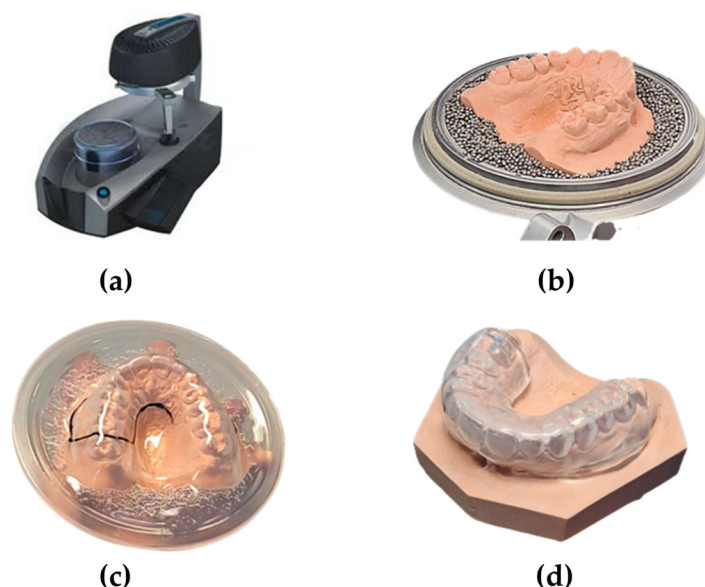


Figure 3. Fabrication of sports mouthguards following the analog workflow (vacuum thermoforming). (a) Erkoform-3dmotion thermoforming unit (Erkodent™, Pfalzgrafenweiler, Germany); (b) Gypsum model positioned on a pellet-filled base; (c) Playsafe Triple Light plate (Erkodent™, Pfalzgrafenweiler, Germany) thermoformed on the model, with marked trimming margins. (d) Finished thermoformed mouthguard after trimming and polishing.

2.3. Digital Fabrication of Sports Mouthguards by 3D Printing (GPrint)

The digital production workflow began with the digitization of the maxillary master gypsum model using a laboratory scanner (Medit T500™, Seoul, Republic of Korea), yielding an STL file of the digital model (Figure 4a). Using this file, the mouthguard was digitally designed in Exocad software (version 3.1), replicating as closely as possible the contours and extension of the thermoformed mouthguards (DigMG). The following design parameters were applied: spacing—0.04 mm; occlusal thickness—2 mm; and smoothing—10 mm (Figure 4b).

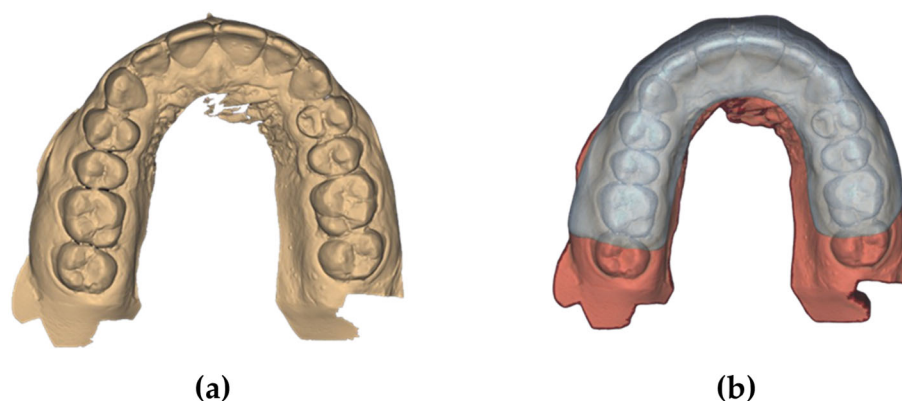


Figure 4. CAD phase of digital mouthguard production workflow. (a) STL file of the digitized maxillary gypsum model; (b) Digital design of the mouthguard in Exocad software (DigMG).

The CAM phase was carried out at the Institute of Science and Innovation in Mechanical and Industrial Engineering (INEGI, Porto, Portugal). From the STL design file, mouthguards were produced by fused deposition modeling (FDM) using an Original Prusa i3 MK3S 3D printer (Prusa Research™, Prague, Czech Republic) with HIPS as the printing material (Figure 5a). Printing parameters, summarized in Table 1, were selected based on the study by Sousa et al. [9]. Supports were applied only to the external surfaces of the mouthguards to maintain a clean internal surface for subsequent evaluation. Three HIPS mouthguards were printed (Figure 5b). After printing, supports were manually removed using pliers and a scalpel, without any additional finishing or polishing.

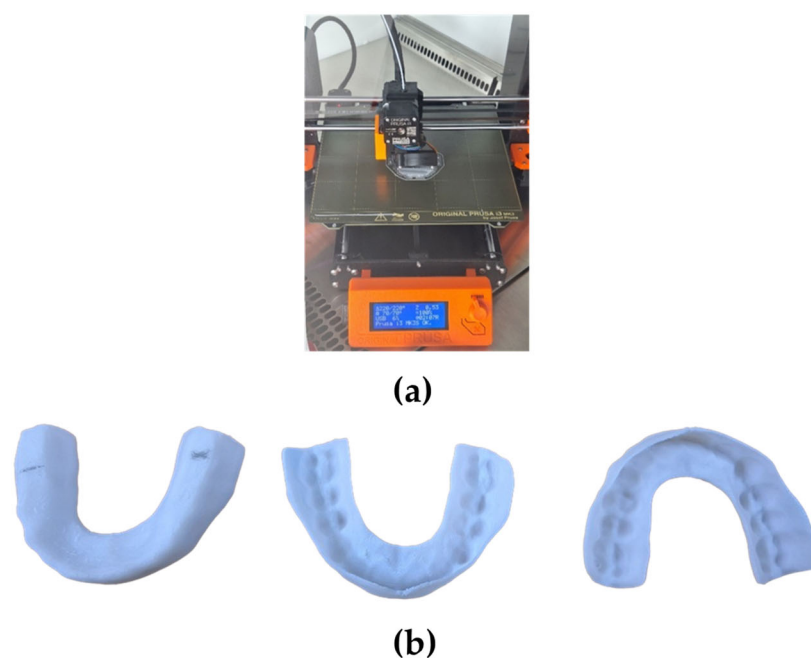


Figure 5. CAM phase of digital mouthguard production workflow. (a) Original Prusa i3 MK3S printer (Prusa Research™, Prague, Czech Republic) at the start of printing a mouthguard; (b) HIPS mouthguards fabricated by FDM after removal of support structures.

Table 1. FDM printing parameters for a sports mouthguard fabricated with HIPS.

Printing Temperature (°C)	Bed Temperature (°C)	Printing Speed (mm/s)	Layer Height (mm)	Final Thickness (mm)
220	70	50	0.1	2

2.4. Digital Scanning of the Internal Surface of Mouthguards for Trueness and Precision Assessment

The internal surfaces of the mouthguards from both groups (GTherm and GPrint) were digitally scanned using a laboratory scanner [Medit T500™, Seoul, Republic of Korea; (Figure 6a)]. Prior to scanning, an anti-reflective scanning spray (CEREC Optispray, Dentsply Sirona™, Charlotte, NC, USA) was applied to the internal surface of each mouthguard (Figure 7). The mouthguards were then stabilized on the scanner platform using a four-pin fixation system (Figure 6b), generating an individual STL file for each specimen (Figure 6c,d).

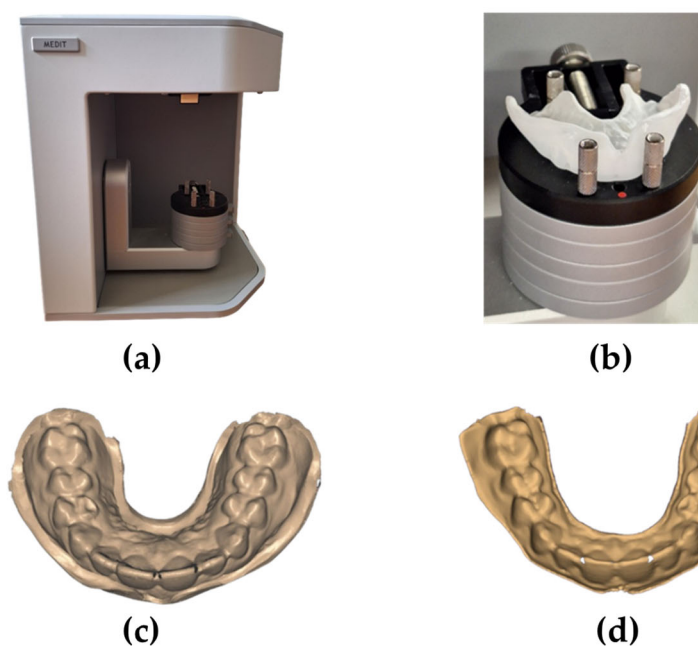


Figure 6. Digital scanning of the internal surface of the fabricated sports mouthguards. (a) Medit T500™ laboratory scanner used for digitization; (b) Detail of mouthguard stabilization using the scanner's four-pin fixation system; (c) STL file of the internal surface of a thermoformed mouthguard; (d) STL file of the internal surface of a 3D-printed mouthguard.

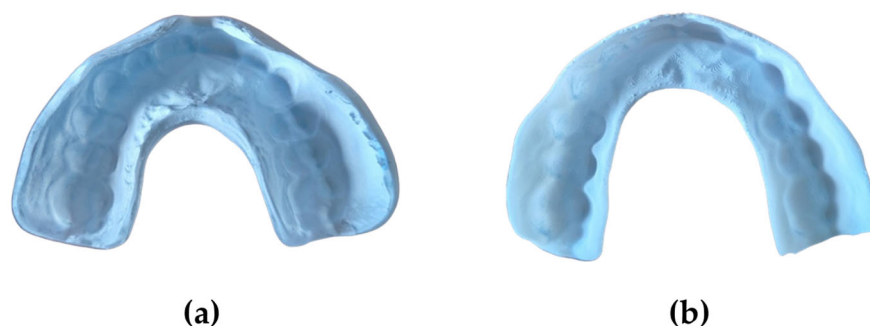


Figure 7. Sports mouthguards after application of the anti-reflective scanning spray. (a) Example of a thermoformed mouthguard; (b) Example of a 3D-printed mouthguard.

The evaluation of trueness and precision was performed using Geomagic Control X software (version 2018; 3D Systems™, Rock Hill, SC, USA). STL files of interest were superimposed using the best-fit alignment algorithm, and mean root mean square (RMS) deviation values (μm) were calculated. Pairwise superimpositions were conducted according to Table 2. Color maps were generated to visualize the degree of alignment across the surface after superimposition, using the following scale: negative deviations shown in blue, positive deviations in red ($\pm 1000 \mu\text{m}$) and deviations within $\pm 100 \mu\text{m}$ highlighted in green.

Table 2. STL file superimpositions performed in Geomagic software (Geomagic Control X, version 2018; 3D Systems, Rock Hill, SC, USA).

Evaluation Parameter	STL File Superimposition
Precision	GTherm1 × GTherm2
	GTherm2 × GTherm3
	GTherm1 × GTherm3
	GPrint1 × GPrint2
	GPrint2 × GPrint3
	GPrint1 × GPrint3
Trueness	DigMG × GPrint1
	DigMG × GPrint2
	DigMG × GPrint3

2.5. Charpy Impact Test

The Charpy impact test was conducted following the general guidelines of ISO 179, except for the specimen length, which was adjusted due to limitations of the testing apparatus:

- Ten specimens of HIPS printed by FDM ('Print'; Figure 8a) were fabricated with dimensions of 60 × 10 × 4 mm, based on an STL file designed in Autodesk AutoCAD 2018 (Autodesk, San Rafael, CA, USA);
- Ten specimens of Playsafe Triple Light ('Therm'; Figure 8b) with dimensions of 60 × 10 × 5.4 mm were cut from a Playsafe Triple Light sheet (Erkodent™, Pfalzgrafenweiler, Germany) that was not subjected to thermoforming.

The test was carried out at a room temperature of 22 °C using a Hounsfield Plastic Impact Machine (Tensometer Ltd., Morland Road, Croydon, England, UK), specifically designed for polymer impact testing. The equipment consists of a variable-weight pendulum, a specimen holder and a graduated dial gauge. Specimens were positioned horizontally, and a 1 lb pendulum was used for each test. Each specimen was struck once, and the values recorded, expressed in lb·ft, were converted to joules (J) using the conversion factor 1 lb·ft = 1.356 J. These values, corresponding to the absorbed energy (E), were used to calculate the impact strength, by dividing E by the cross-sectional area (A) of the specimen before impact, according to the following Equation (1):

$$\text{Impact strength} = \frac{E}{A} \times 1000 \text{ (kJ/m}^2\text{)} \quad (1)$$

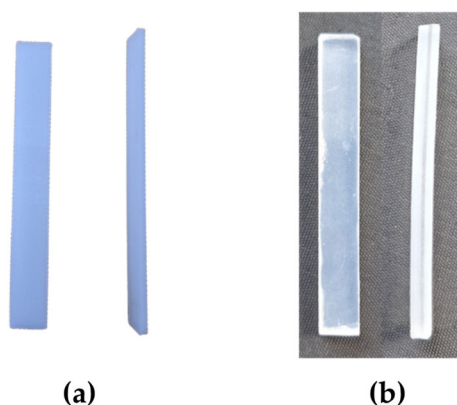


Figure 8. Specimens produced for the Charpy impact test. (a) HIPS-printed specimens; (b) Thermoformable specimens of Playsafe Triple Light (Erkodent™).

2.6. Statistical Analysis

The collected data were analyzed using GraphPad Prism™ software (version 5.0; GraphPad Software Inc., San Diego, CA, USA, 2007). Due to the small sample size used in the precision evaluation, the normality of the results could not be assessed using the available tests (Kolmogorov–Smirnov, D’Agostino–Pearson, or Shapiro–Wilk). Therefore, the nonparametric Mann–Whitney test was applied for comparative analysis between the GTherm and GPrint groups. The data obtained from the Charpy test followed a normal distribution, as verified using the Shapiro–Wilk ($\alpha > 0.05$). In this case, an unpaired *t*-test was performed. Statistical analyses were conducted with a significance level (α) of 0.05, comparing medians or means, respectively, and standard deviations with a 95% confidence interval. A *p*-value < 0.05 was considered statistically significant.

3. Results

3.1. Precision Assessment

Precision was evaluated by superimposing the STL files within the thermoformed group (Figure 9) and within the 3D-printed group (Figure 10). In the resulting color maps, green areas indicate good correspondence between surfaces, blue areas represent negative deviations (i.e., the fabricated mouthguard is smaller than the reference design), and red areas denote positive deviations (i.e., the fabricated mouthguard is larger than the original design). Analysis of these color maps revealed a clear predominance of green areas in the GPrint group, within the ± 100 μm range, when compared with the GTherm group, indicating higher precision in the former.

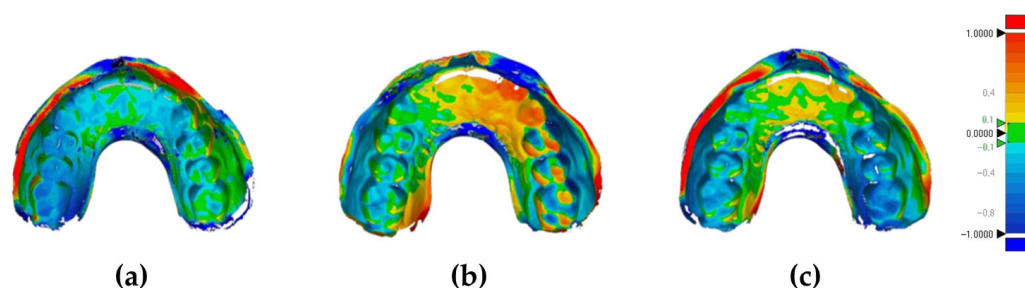


Figure 9. Color maps resulting from the superimposition of STL files of vacuum-thermoformed mouthguards in Geomagic software. (a) GTherm1 $\times$ GTherm2; (b) GTherm2 $\times$ GTherm3; (c) GTherm1 $\times$ GTherm3.

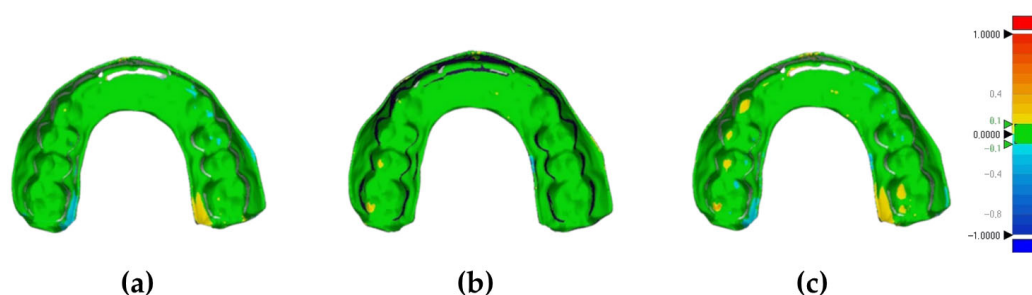


Figure 10. Color maps resulting from the superimposition of STL files of 3D-printed mouthguards in Geomagic software. (a) GPrint1 $\times$ GPrint2; (b) GPrint2 $\times$ GPrint3; (c) GPrint1 $\times$ GPrint3.

These findings are supported by the RMS values (Table 3). Although the differences were not statistically significant ($p = 0.10$), both the median and mean RMS values were

substantially higher in the GTherm group (812 μm and 830.7 μm , respectively) than in the GPrint group (57.8 μm and 54.2 μm , respectively).

Notably, no consistent directional trend in deformation or nonconformance was identified among the vacuum-thermoformed samples (Figure 9), suggesting that the observed deviations fall within the expected variability of the manufacturing process.

Table 3. Quantitative analysis of precision, expressed as RMS (μm), based on digital superimposition of STL files in Geomagic software.

Group	Superimposed Files	RMS ¹ (μm)	Median RMS (μm)	Mean RMS (μm)	Standard Deviation	<i>p</i> -Value ²
GTherm	GTherm1 $\times$ GTherm2	885	812	830.7	47.8	0.10
	GTherm2 $\times$ GTherm3	795				
	GTherm1 $\times$ GTherm3	812				
GPrint	GPrint1 $\times$ GPrint2	57.8	57.8	54.2	7.5	
	GPrint2 $\times$ GPrint3	59.1				
	GPrint1 $\times$ GPrint3	45.6				

¹ RMS—Root Mean Square. ² *p*-value—Mann–Whitney test, considering GTherm vs. GPrint.

3.2. Trueness Assessment

Trueness was evaluated by superimposing the STL file of the mouthguard design (DigMG), used as the reference, onto the STL files of the three printed mouthguards. This analysis was only applicable to the digital production workflow. The resulting color maps showed a predominance of green areas, indicating good correspondence between the files ($\pm 100 \mu\text{m}$), followed by light blue and yellow regions (Figure 11). Quantitative analysis of these results, expressed as RMS values (μm), is summarized in Table 4.

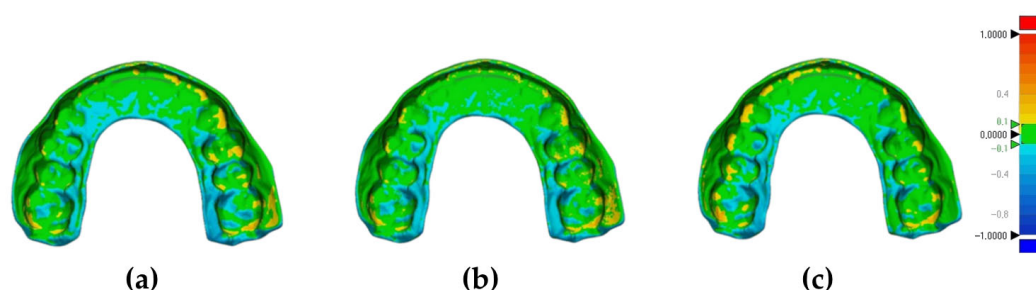


Figure 11. Color maps resulting from the superimposition of the STL file of the digital mouthguard design (DigMG) with the STL files of the 3D-printed mouthguards in Geomagic software. (a) DigMG $\times$ GPrint1; (b) DigMG $\times$ GPrint2; (c) DigMG $\times$ GPrint3.

Table 4. Quantitative analysis of trueness, expressed as RMS (μm), based on digital superimposition of STL files in Geomagic software.

Superimposed Files	RMS ¹ (μm)	Median RMS (μm)	Mean RMS (μm)	Standard Deviation
DigMG $\times$ GPrint1	118	118	121.3	10.4
DigMG $\times$ GPrint2	133			
DigMG $\times$ GPrint3	113			

¹ RMS—Root Mean Square.

3.3. Charpy Impact Assessment

All specimens were individually subjected to the Charpy impact test, and the values recorded were expressed as impact strength (kJ/m^2). Preliminary tests conducted on three HIPS-printed specimens with a thickness of 2 mm resulted in fracture. Based on these

findings, a thickness of 4 mm was selected for the fabrication of the HIPS-printed specimens. As depicted in Figure 12, under the experimental conditions used, the impact strength of the thermoformable specimens (mean 17.33 ± 1.96 kJ/m²) was significantly higher than that of the HIPS-printed specimens (mean 14.33 ± 0.65 kJ/m²) ($p < 0.0007$, unpaired t -test).

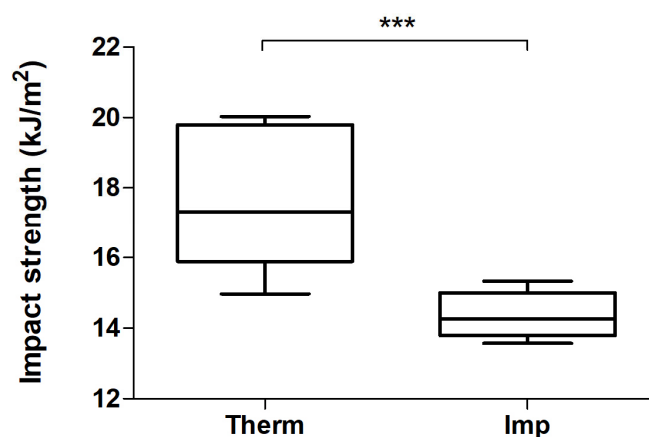


Figure 12. Impact strength (kJ/m²) of thermoformable material (Therm) and HIPS-printed (Print) specimens obtained using the Charpy impact test. Results are presented as mean $\pm$ standard deviation (SD). *** $p < 0.0007$, unpaired t -test.

4. Discussion

Digital production of sports mouthguards has been increasingly investigated in recent years as a means to overcome some of the limitations inherent to the analog workflow, reflecting the broader “digital evolution” observed across multiple fields of dentistry. Additive manufacturing, in particular, has shown great promise [7]; however, its implementation in clinical practice still requires validation and optimization of numerous parameters, not only related to the 3D printing process but also to the mechanical and physical properties of the available materials [9,12].

One of the objectives of this study was to compare sports mouthguards produced by vacuum thermoforming and by 3D printing in terms of precision and trueness, parameters that are essential in any fabrication workflow. To provide context, these two concepts are components of a broader parameter—accuracy. Accuracy refers to the closeness of a measured value to the true value and is determined by its trueness and precision. Trueness represents the closeness between the mean value obtained from a series of measurements and a reference value, reflecting how closely the produced object matches the real dimensions. Precision, on the other hand, describes the closeness between independent measurements obtained under defined conditions, indicating the reproducibility of repeated measurements [16,17].

In our study, although the differences were not statistically significant, thermoformed mouthguards exhibited markedly lower precision than 3D-printed ones, as indicated by higher RMS values and a reduced prevalence of green areas in the color maps of the GTherm group (median: 812 μ m for GTherm vs. 57.8 μ m for GPrint). This difference in precision may be attributed to several factors inherent to the vacuum thermoforming process, including: i) creation of the master model from an alginate impression, a material highly prone to dimensional changes; ii) the predominantly manual nature of the process, which increases the likelihood of human-induced variability; iii) the use of three different gypsum models, produced from a silicone mold, to fabricate each thermoformed mouthguard, potentially affecting precision due to

gypsum expansion during polymerization [12]. Nonetheless, it is worth noting that some limitations of the analog method may have been mitigated through the use of a fully automated thermoforming system (Erkoform-3dmotion, Erkodent™), which minimizes errors related to fluctuations in thermoforming temperature, pressing duration and cooling conditions [18].

Differences in precision between the GTherm and GPrint groups may also have been influenced by experimental factors inherent to the measurement methodology. Notably, the use of a titanium oxide anti-reflective spray was required to opacify the transparent surfaces of the thermoformed mouthguards, facilitating optical scanning [19]. Even with a high-reproducibility blue-light scanner (Medit T500), the depth and extent of the thermoformed mouthguards hindered accurate scanning of the incisal edges, necessitating increased spray application for GTherm. Previous reports indicate that this spray can introduce measurement discrepancies of up to 40 µm, potentially biasing the precision results [17]. Additionally, the Geomagic software's best-fit alignment may not perfectly match STL files, introducing minor errors.

The precision assessment further revealed that no systematic directionality or reproducible pattern of deformation was observed across the bulk of the GTherm samples, suggesting that the observed deviations were largely localized and sample-specific rather than indicative of a uniform or directional nonconformance introduced by the thermoforming process. However, upon closer inspection, the red and dark blue areas consistently originated from the peripheral regions in all superimposed file pairs, which may be attributed to the application of heat during margin refinement. Although heat finishing was applied gently and restricted to the periphery, this step was performed after removal of the mouthguards from the corresponding cast model in accordance with the routine laboratory workflow, rather than as a methodological choice by the investigators. This approach may have introduced additional variability, thereby reducing reproducibility. In contrast, heat finishing with the appliance positioned on the model would likely have provided mechanical support to the internal surface, limiting deformation and improving dimensional stability. If abrasive chemical agents had been used for the final finishing step instead of heat, a different deformation pattern would be expected. Chemical polishing primarily affects the surface layer and margin smoothness without inducing thermal softening or bulk material flow. Therefore, its use may have resulted in reduced peripheral distortion, improved consistency among samples and fewer localized deviations in the superimposition analysis of GTherm. Regarding trueness, this parameter could only be assessed in the GPrint group, as the original digital design (DigMG) was available only for these specimens. For thermoformed mouthguards, evaluating trueness would require comparing the STL file of the master model with the STL of the inner surface of the mouthguard, which yielded excessively high RMS values of no practical significance. In the GPrint group, acceptable trueness results were observed for the 3D printing technique (median: 118 µm), comparable to those reported by Cameron et al. (~110 µm) using similar best-fit superimposition methods [20]. In their study, trueness values were further improved to approximately 50 µm through optimization of printing parameters, suggesting that adjustments to the printing angle and/or speed could similarly enhance trueness in the present work. It should be noted, however, that the printing parameters chosen for the present investigation were based on the preliminary studies of Sousa et al., which provided the best outcomes for these settings [9]. Nonetheless, a more detailed discussion on how these parameters specifically influence the printed material properties would further strengthen the evaluation.

Overall, the precision and trueness values obtained suggest that additive manufacturing of HIPS mouthguards via FDM offers higher reproducibility and lower systematic error than vacuum thermoforming of Playsafe Triple Light sheets, while

maintaining acceptable trueness for 3D printing, a critical aspect of any fabrication workflow.

For athlete safety and comfort, it is essential not only to ensure the precise fit of mouthguards but also to maximize their impact absorption. In this study, thermoformable specimens exhibited significantly higher impact strength in the Charpy test compared to the HIPS-printed specimens. Although Sousa et al. have reported 2 mm as the optimal thickness [9], under our experimental conditions, all specimens of this thickness fractured during a preliminary assay. Therefore, HIPS specimens with a thickness of 4 mm were produced instead.

The results provided by the Charpy impact test can be expressed in various ways, including dissipated energy, absorbed energy, impact strength and damping, among others [9,21,22]. This variability, along with the lack of standardized testing protocols for mouthguards, limits the consistency of data reported in the literature and impairs reliable comparisons across studies [22]. To the best of our knowledge, no investigation has directly compared Playsafe Triple Light (Erkodent™, Pfalzgrafenweiler, Germany) with printed-based mouthguards, and the manufacturer does not provide impact strength values for these thermoforming plates. Accordingly, any further quantitative analysis beyond the scope of the present study would be largely speculative.

HIPS was selected for 3D printing based on previous studies by Sousa et al. [9], which compared different materials for the additive manufacturing of mouthguards. Among the materials evaluated, HIPS exhibited notable thermal stability (up to 400 °C), high flexural and impact strength and relatively low tensile strength [9]. Thinner specimens (2 mm) showed superior performance across most parameters, which guided the STL design for mouthguards.

Despite promising results, HIPS biocompatibility is not fully established, as residual styrene in the polymer is potentially toxic at high concentrations [23]. The biocompatibility of this material has been the focus of ongoing research and improvement, given its considerable mechanical potential. In fact, HIPS modified with different types of particles and dispersed phases may present a reduced risk of adverse reactions when in contact with living tissues [24,25].

This study presents some limitations inherent to its *in vitro* design, which will need to be complemented in the future by *in vivo* clinical studies. The sample size was small, limiting the robustness of the statistical analysis, and the study should therefore be regarded as a pilot investigation. Contrary to recommended protocols, the fabrication of the thermoformed mouthguards did not take into account the opposing dental arch and its corresponding occlusal scheme, as only the internal surface was the focus of analysis. However, this omission may have influenced the final outcome, as the absence of simulated occlusal contact could affect the fit, thickness distribution and overall adaptation of the mouthguards. It should also be noted that the potential influence of the thermoforming process on impact absorption capacity was not assessed, since the Playsafe Triple Light (Erkodent™) sheet used for specimen preparation was not subjected to this process. This explains the measured thickness of the specimens (5.4 mm), prior to any thermoforming procedure. This aspect may be particularly relevant, as one of the main limitations of thermoforming is the reduction in mouthguard thickness in critical areas such as incisal edges and cusp tips [6]. Future work should evaluate the impact resistance on specimens after thermoforming to more accurately represent the performance of clinically fabricated mouthguards. With regard to the impact tests, they present several limitations when compared to real-world sports conditions, such as: i) their inability to replicate the compliance of cranio-mandibular tissues; ii) the absence of standardized testing protocols, which hinders the comparison of results across different studies; and iii) their inability to reproduce realistic sports-related impact scenarios,

thereby limiting their clinical relevance [26]. Such limitations are intrinsic to any in vitro study, providing valuable preliminary information regarding the materials under evaluation. Finally, a limitation of this study is that the comparison between thermoforming and additive manufacturing involved different materials, whose rheological properties influence forming accuracy and mechanical behavior. Although thermoforming the same polymer used for 3D printing (HIPS) would allow a more controlled comparison of fabrication techniques, our aim was to assess additive manufacturing under clinically relevant conditions. Therefore, a well-established vacuum-thermoformable material routinely used in clinical practice was selected for comparison. This approach reflects real-world workflows and highlights the combined material-process interactions relevant to the clinical adoption of 3D-printed mouthguards.

Given the promising results of additive manufacturing in this pilot study, future research should focus on optimizing printing parameters, exploring new or modified materials to improve impact absorption and validating these findings in larger in vitro and, eventually, in vivo trials before clinical implementation. Additionally, it would be valuable to investigate the effects of aging on the biomechanical performance of 3D-printed mouthguards, assess the effect of repeated impacts on the specimens and perform both macroscopic and microscopic analyses of the material post-impact to better characterize its deformation and fragmentation behavior. Finally, biocompatibility and toxicity assessments should also be carried out.

5. Conclusions

The results obtained from this pilot study allow the following conclusions under the tested experimental conditions:

- (i) Additive manufacturing of sports protective mouthguards by FDM using HIPS demonstrates higher precision compared to vacuum thermoforming of Triple Safe Light (Erkodent™) sheets;
- (ii) The trueness of the additive manufacturing process falls within acceptable ranges for 3D printing techniques;
- (iii) The impact strength of Triple Safe Light (Erkodent™) material used in thermoformed mouthguards is significantly higher than that of HIPS processed via 3D printing.

Overall, the collected data suggest that a digital workflow can represent a valuable alternative to conventional analog methods in terms of precision and trueness. However, the development of 3D printing materials with improved impact absorption properties remains necessary.

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Abbreviations

The following abbreviations are used in this manuscript:

ADA	American Dental Association
EVA	Ethylene-vinyl acetate
COC	Cyclo-olefin copolymer
CAD-CAM	Computer-aided design and computer-aided manufacturing
HIPS	High-impact polystyrene
FDM	Fused deposition modeling

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