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RESEARCH ARTICLE

Assessing the Strength and Ease of Wearability of a 3D Printed Mouthguard: A Pilot Study

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Abstract

Background: Orofacial and dental injuries in sports primarily affect the upper lip, maxilla, and maxillary incisor teeth, with the latter being involved in 50-90% of dental trauma cases. Such injuries can have serious repercussions for children and their families, including pain, psychological distress, and high economic costs. The Academy of Sports Dentistry (ASD) and the International Association of Dental Traumatology (IADT) strongly recommend the use of well-fitted, customised mouthguards to decrease the risk of these injuries. **Aim:** To evaluate the strength and ease of wearability of a 3D printed mouthguard using polylactic acid. **Methodology:** 30 subjects of both genders in the age group 18-35 years involved in sports activities were enrolled for the study. Rubber base impressions were made, models were poured, data were processed, and a 3D model of a customised mouthguard was printed using polylactic acid. The manufactured mouthguard was tested for hardness, strength and ease of wearability. **Results:** The average impact strength (Izod Test) of the mouthguards was 105.62 J/m, and the average hardness value (Rockwell Test) was found to be 103.67 HRA. **Conclusion:** 3D printed mouthguards, fabricated with 100% infill density, exhibit adequate impact strength and moderate hardness, offering comfort and protection from sports-related orofacial injuries to players.

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1. INTRODUCTION

Sports activities often subject athletes to substantial impacts and collisions, which are responsible for nearly 18% of sports-related injuries, with dental trauma being notably prevalent. Contact sports have been identified as the leading cause of orofacial injuries. Survey data highlights that wrestling reports the highest percentage of orofacial injuries (83.3%), followed by boxing (73.7%), basketball (70.6%), karate (60.0%), jiu-jitsu (41.2%), handball (37.1%), football (23.3%), judo (22.3%), and field hockey (11.5%)[1,2]. Untreated dental trauma, particularly in children with permanent teeth, can significantly diminish their quality of life compared to those without injuries[3]. The Academy of Sports Dentistry (ASD) and the International Association of Dental Traumatology (IADT) emphasise the importance of using customised mouthguards[4]. Ensuring proper alignment of the maxillary and mandibular arches during the mouthguard fabrication process is crucial for effectively absorbing and distributing impact forces, which helps mitigate the risk of injury[5]. By providing a protective layer between the upper and lower jaws, mouthguards can decrease the likelihood of condylar displacement injuries and reduce the chances of concussions[6,7].

Mouthguards have traditionally been designed to prevent injuries on the lips, protecting oral tissues from bruising and cuts and preventing traumatic dental injuries like crown/root fractures, luxation injuries, and avulsions. Also, they protect the mandible from injuries like fractures and dislocations[8]. A custom-fitted mouthguard plays a key role in preventing tooth fractures and dislocations by cushioning the teeth from direct impact. It also redistributes the shock from forceful impacts, reducing the likelihood of jaw fractures[9]. Additionally, the mouthguard minimises soft tissue injuries by separating the teeth from the adjacent oral tissues. Latest scientific evidence emphasises the mandate of wearing a 3.0 millimetre thick, well-fitted mouthguard to decrease the risk of concussion injuries. It absorbs the shock forces resulting from jaw impacts, which would otherwise be transmitted to the brain[10,11].

2. MATERIALS AND METHODS

A pilot study was conducted in the outpatient department of a dental college in collaboration with an engineering college in North-East India on 30 subjects of the age group 18-35 years of both genders involved in sports activities like boxing, martial arts, wrestling, karate, basketball, handball and cricket. Institutional ethical clearance was obtained A/206/REB/Prop(FP)/172/100/12/2022.

2.1 Inclusion Criteria

- Individuals aged 18–35 years.
- Subjects actively involved in organised or recreational sports activities with a potential risk of oro-facial injury.
- Subjects with a minimum of 28 teeth in the maxillary arch are adequate for fabrication and retention of a customised mouthguard.
- Subjects with healthy oral and periodontal status.

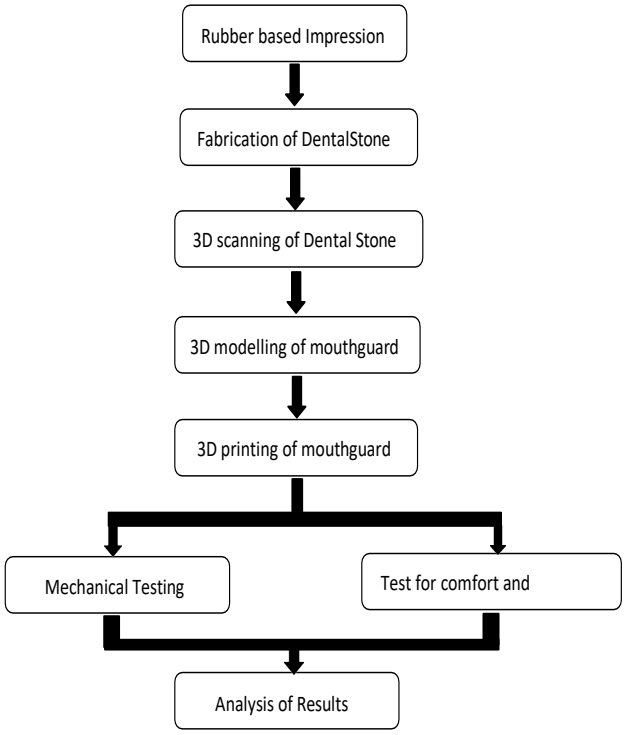


Figure 1. Flow chart of processes involved.

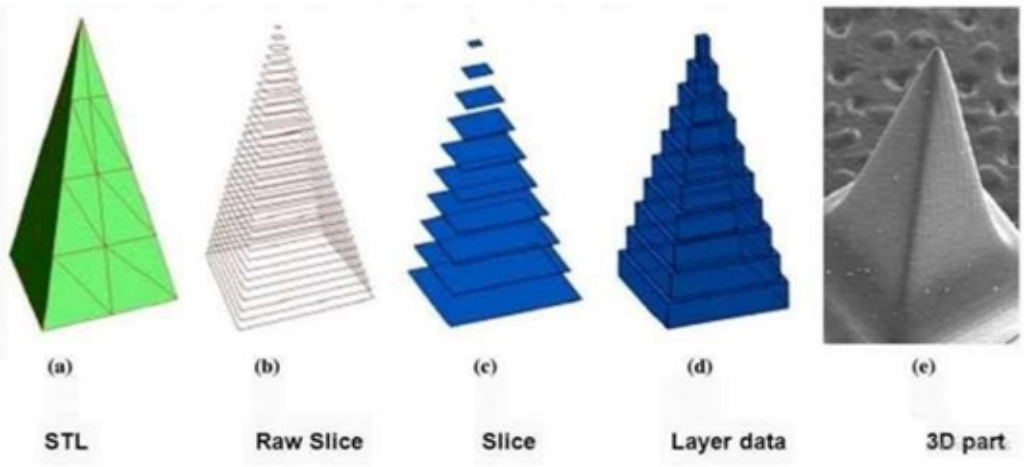


Figure 2. Step-by-step conversion of STL files into a 3D model (working principle of Slicing software).

- Subjects willing to undergo dental impressions, intraoral examination, and trial of the customised 3D printed mouthguard.

2.2 Exclusion Criteria

- Subjects with active dental caries, untreated periodontal disease and oral infections.
- Subjects with missing maxillary anterior teeth, extensive prosthodontic rehabilitation or orthodontic appliances.
- Subjects with temporomandibular joint disorders, severe malocclusion or parafunctional habits.
- Subjects with systemic conditions or disabilities.
- Participants unwilling or unable to provide informed consent or comply with study requirements. Top of Form

Before the commencement of the study, the researchers were trained and standardised by using models and photographs depicting the possible range of observations demonstrated on several subjects in the Outpatient Department (OPD) for a period of one week. Informed written consent was obtained. Before starting the examination. All participants rinsed their mouths with plain water. They were made to sit comfortably on the dental chair. A rubber base impression of the maxillary and mandibular arches was made. A model was poured in dental stone, which was scanned and converted to a 3D CAD model using a 3D scanner (Creality Scan Raptor) and converted to an STL file format. Ultimaker Cura (Figure 2), which is a slicer software, was used to convert the 3D model in STL format into Geometric code (G-code) language for the 3D printer with parameters listed in Table 1.

The data was processed, and a 3D model of the mouthguard was printed using polylactic acid (Figure 3). The polylactic acid is a biodegradable material and

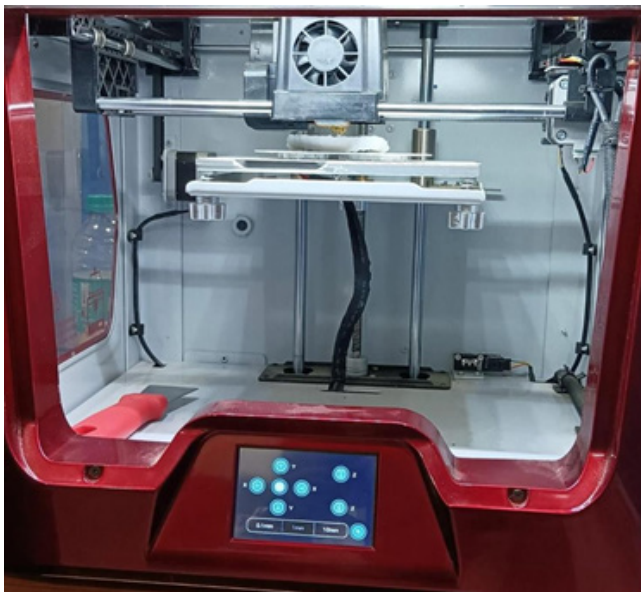


Figure 3. 3D printing of the mouthguard.

Table1. Printing parameters of the customised mouthguard

Parameters	Value
Infill Density	100%
Extruder Temperature	200 oC
Printing Speed	30 mm/sec
Layer Height	0.1 mm
Infill pattern	Triangle
Bed Temperature	50 oC
Line Width	0.4 mm

can be easily produced from renewable sources like sugar cane, sugar beet and corn starch and was hence utilised. The data was processed, and a 3D model of the mouthguard was printed with the fused deposition modelling technique. The impact test of the 3D printed mouthguard was carried out using an un-notched Izod test type E (Figure 5a), and the Rockwell hardness test was used for measurement of the hardness of the mouthguard (Figure 5b).

The subjects were recalled, and the fit of the mouthguard was tried. They were requested to wear it for five minutes (Figure 4). During this time, the



Figure 4. Subject wearing a 3D printed mouthguard.

subject was questioned about the ease of wearability in terms of breathing and speech and was asked to fill a questionnaire (Appendix). The mouthguard was then removed and stored in cold water. An effort was made to motivate the patient about the necessity of wearing mouthguards in sports-related activities and good oral hygiene practices. The data acquisition was coded and not identified by name to maintain the confidentiality of the subjects. A flow chart of the entire process involved in this research is illustrated in Figure 1.



Figure 5. **(a)** Izod Impact Test; **(b)** Rockwell Hardness Test.

Table 2. Results from the Izod Impact test and Rockwell Hardness test

Izod Impact Test (J/m)				Rockwell Hardness Test			
Test 1	Test 2	Test 3	Average	Test 1	Test 2	Test 3	Average
105.66	105.30	105.91	105.62	104	103	104	103.67

3. RESULTS

The 3D printed mouthguards were fabricated using a 100% infill density to ensure consistency with the required standard size for testing. The models were then subjected to two tests: the Izod impact test and the Rockwell hardness test. The results of the Izod impact test (J/m) and Rockwell Hardness test (HRA Scale) for each of the three tests are presented in Table 2. The average impact strength (Izod Test) of the mouthguards was 105.62 J/m, and the average hardness value (Rockwell Test) was found to be 103.67 HRA. These results suggest that the 3D printed mouthguards have a relatively high impact resistance and moderate hardness, suitable for typical use in sports as protective gear.

4. DISCUSSION

This pilot study aimed to assess resistance to impact using the Izod impact test and surface hardness using the Rockwell hardness test of a 3D printed mouthguard with polylactic acid. The gold standard for fabrication of mouthguards is ethylene vinyl acetate using thermoforming processes[12]. However, the most common material for 3D printing is plastic in nature. Different polymer materials that may be employed include Acrylonitrile Butadiene Styrene (ABS), Polycarbonate (PC), Polylactic Acid (PLA), High-Density Polyethene (HDPE), PC/ABS, Polyethene Terephthalate (PETG), Polyphenyl Sulfone (PPSU), and High-Impact Polystyrene (HIPS)[13]. Polylactic Acid (PLA) with a pro of 1.75 mm, a filament which is an enhanced version of PLA in terms of strength, durability, smoothness, temperature resistance and toughness, was used. It also has the added advantage of affordability, availability, relatively low toxicity, and low printing temperature. Its low thermal expansion coefficient plays a crucial role in achieving dimensional accuracy, as it impacts both expansion and contraction. Additionally, the strong interlayer bonding in PLA contributes to maintaining model dimensions[14]. Although Polylactic Acid (PLA) is a biodegradable material and is generally regarded as biocompatible, all components used in fabrication should comply with relevant regulatory standards, such as FDA/medical-grade material requirements for prolonged oral contact. The effect of additives on toxicity, degradation behaviour, and microplastic release should therefore be studied in future studies.

An effective customised mouthguard should possess adequate mechanical properties, including sufficient impact strength, resilience, and optimal hardness to absorb and dissipate traumatic forces without deformation or fracture. In addition, the material must be biocompatible and non-toxic, with minimal potential for degradation during prolonged intraoral use. Good hygiene practices, including ease of cleaning and disinfection, are also essential to maintain oral health and long-term usability.

The average Izod impact strength of the 3D printed mouthguards was found to be 105.62 J/m in the present study, indicating that the mouthguards possess moderate resistance to impact.

The average Izod impact strength of the 3D-printed mouthguards was 105.62 J/m, indicating moderate resistance to impact. Previous studies have reported that ideal custom-fitted sports mouthguards should possess adequate impact absorption capacity along with flexibility and comfort comparable to EVA materials, which typically exhibit hardness values of 80–85 Shore A. Mouthguards fabricated with approximately 4 mm thickness demonstrate an optimal balance between protection and wearer comfort[15].

This result is important because a mouthguard must be able to absorb and dissipate impact forces to protect the wearer's teeth and jaw from potential injury. The relatively high impact strength observed in this study suggests that the printed mouthguards are likely to offer a sufficient level of protection during moderate impact events, such as contact sports. The results are consistent with findings from previous studies on 3D printed polymeric materials, which have demonstrated that the impact strength can be influenced by factors like the infill percentage, material type, and printing parameters[16,17]. In this study, the use of 100% infill likely contributed to a more solid and durable mouthguard, potentially leading to the higher impact strength observed compared to mouthguards printed with lower infill densities.

The Rockwell hardness test yielded an average hardness value of 103.67 HRA, indicating that the mouthguards exhibited a moderate surface hardness. Hardness is a key factor in determining the comfort and fit of a mouthguard. A mouthguard that is too hard might feel uncomfortable or irritate the mouth, while a too-soft mouthguard might not provide sufficient protection against impact. The observed hardness is within the typical range for mouthguard materials used in both conventional and 3D printed products[18,19]. However, the impact of material hardness on user comfort, fit, and retention needs to be evaluated through further clinical trials since the effectiveness and ease of wearability of the mouthguard during long-term use were planned for future study. Ultimaker Cura, an open-source software, was used in the present study. The advantage is that it is compatible with routinely used 3D printers, common 3D formats of files such as STL, OBJ, X3D, 3MF and image file formats such as BMP, GIF, JPG, and PNG[20,21]. Excessive use of the mouthguard causes wear and tear, which will increase the chances of absorption of micro and nano plastics in the human body. Microplastics and nanoplastics can cause inflammation and tissue damage that can affect the sports person's performance[22]. Permissible filler materials and colours are added to the material to enhance the aesthetics of the manufactured materials[23].

5. CLINICAL SIGNIFICANCE

Polylactic Acid (PLA) 3D printed mouthguards have the advantage of strength, precision and production efficiency. Since PLA is a biodegradable thermoplastic material, it can be fitted precisely with the help of digital manufacturing techniques. Advanced materials and biobased composite PLA, reinforced with elestormers, nanofiber materials can be used to strengthen the inner layer and soften the outer layer to provide comfort when using the mouth guard.

6. LIMITATIONS AND FUTURE RESEARCH

This pilot study has several limitations that should be addressed in upcoming research work. First, the sample size was small, and the results may not be fully representative of the broader population of 3D printed mouthguards. Larger sample sizes and more rigorous testing would help ensure the reliability and validity of the results. Additionally, while the Izod and Rockwell tests provide valuable insights into the material properties, they do not fully account for the mouthguard's overall fit, comfort, or performance in real-world conditions. Clinical trials that assess user satisfaction, retention, and long-term durability in athletes or patients would be essential to better understand the practical applications of 3D printed mouthguards.

The increasing adoption of 3D printing for Customised Mouthguards (CMGs) highlights the need for extensive research on suitable printable materials and fabrication techniques to ensure optimal clinical performance and ease of wearability for the athlete. Factors such as mechanical strength, shock absorption capacity, dimensional accuracy, durability, wear resistance, hygiene maintenance, and long-term intraoral biocompatibility must be critically evaluated in future studies. To further enhance the performance of 3D printed mouthguards, future studies should explore variations in material composition, layer height, infill patterns, and post-processing techniques, as these factors could impact both the mechanical and

functional properties of the mouthguard. Additionally, incorporating biomechanical testing such as pressure distribution and retention force testing could provide more insights into the comfort and effectiveness of these mouthguards under real-world conditions. Moreover, investigating different types of materials (e.g., flexible resins, elastomers) or hybrid printing techniques (combining rigid and flexible materials) may help optimise the balance between durability, impact protection, and comfort, ultimately improving the overall performance of 3D printed mouthguards. In addition, the potential for material degradation, toxicity, and microplastic release during prolonged use requires further investigation, especially when modified filaments, additives or colours are added. Also, finite element analysis (FEA) studies can help in understanding stress distribution, force dissipation, and deformation patterns in mouthguards during impact.

7. CONCLUSION

The results of this pilot study demonstrate that 3D printed mouthguards, fabricated with a 100% infill density, exhibit reasonable impact strength (105.62 J/m) and moderate hardness (103.67 HRA). These findings suggest that 3D printed mouthguards are durable and capable of providing adequate protection and ease of wearability. Also, the findings of the present study contribute to the growing body of knowledge on 3D printed protective devices and pave the way for the development of customizable, cost-effective mouthguards for sports.

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APPENDIX I

Questionnaire

- Do you currently wear a mouthguard during sports activities?

☐ Yes ☐ No

- How comfortable did you find the 3D-printed mouthguard while wearing it for 5minutes?

☐ Very comfortable ☐ Somewhat comfortable ☐ Neutral ☐ Uncomfortable ☐ Very uncomfortable

- Did you experience any irritation or discomfort in your mouth while wearing the mouthguard?

☐ Yes ☐ No

- If yes, please describe:_____
- How would you rate the overall fit of the mouthguard in your mouth?

☐ Excellent ☐ Good ☐ Fair ☐ Poor

- Did the mouthguard stay in place securely while you wore it?

☐ Yes ☐ No

- How would you rate the retention (ability to stay in place) of the mouthguard?

☐ Excellent ☐ Good ☐ Fair ☐ Poor

- Did you need to adjust or reposition the mouthguard frequently?

☐ Yes ☐ No

- Were you able to breathe easily while wearing the mouthguard?

☐ Yes ☐ No

- Did the mouthguard interfere with your ability to speak?

☐ Yes ☐ No

- Did you experience any difficulty in opening and closing your mouth with the mouthguard?

☐ Yes ☐ No

- How protected did you feel wearing the mouthguard during physical activity?

☐ Very protected ☐ Somewhat protected ☐ Neutral ☐ Not very protected ☐ Not protected at all