J Osaka Dent Univ 2023 (April); **57 (1)**: 41−46.

Thermoforming accuracy of mouthguards incorporating digital dental technology into the conventional fabrication procedure

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The fit of mouthguards fabricated using working models produced by a 3D printer based on impressions taken with an intraoral scanner were compared with the fit of those fabricated by conventional methods, i.e. mouthguards formed on plaster models using a pressure thermoforming machine. A maxillary dentition model was used as the master model. A total of 20 working models were replicated with hard plaster. The master model was scanned using an intraoral scanner, and 10 working models were produced using a 3D printer. A pressure thermoforming machine was used for 10 of the working models, and a vacuum former was used for the other 10. Mouthguard sheets were formed on 10 plaster models and 10 3D printer models using a pressure thermoforming machine. Similarly, the mouthguard sheets were formed on 10 plaster models using a vacuum former. The fit of the mouthguards fabricated by thermoforming on the working model fabricated by the 3D printer was not comparable to that of those fabricated by the conventional method. However, it was better than that of the mouthguards fabricated using the vacuum former. We concluded that, the fit of the mouthguards fabricated by thermoforming on a working model fabricated by a 3D printer is clinically acceptable. (J Osaka Dent Univ 2023; 57: 41-46)

Key words: Mouthguard; 3D printer; Intraoral scanner

INTRODUCTION

Traumatic orofacial injuries commonly occur during basketball, soccer, and other athletic activities.[1, 2] Recently, mouthguards have become a key component of the safety equipment used to reduce the risk of oral injury during athletic activities. Numerous studies have suggested that mouthguards have preventive effects against sports-related traumatic injuries. Various experimental studies have been conducted to confirm their efficacy. Additionally, mouthguards are thought to reduce the risk of sports-related concussions (SRCs) due to their shock absorption capability. However, there is mixed evidence that mouthguards prevent SRCs.[3-6] A previous systematic review that analyzed four studies evaluating the effectiveness of mouthguards in preventing SRCs reported that the results of these studies were inconsistent.[7] Of the four studies, one reported that mouthguard use was associated with a reduced incidence of SRC and loss of consciousness,[8] whereas the remaining studies reported they had no beneficial effects that in preventing SRCs. A later systematic review that analyzed five studies that evaluated the benefit of mouthguards revealed a negative incidence rate ratio of 0.81 for the incidence of SRC. However this was not statistically significant ($p=0.18$).[9]

Custom-made mouthguard production requires working models of the upper and lower jaws and occlusal impressions, all of which require considerable storage space. Although the working models should be stored for future use, it is very difficult to determine when to dispose of the plaster cast models that may deteriorate. Therefore, there is a need for digital impressions using an intraoral scanner to fabricate mouthguards. This fabrication method could significantly improve efficiency.

Computer-aided design/computer-aided manufacturing (CAD/CAM) systems for dental prosthetics have advanced remarkably in the past decade.[10] It has been reported that the accuracy of dental prosthetics fabricated by conventional indirect methods with no more than a 100 μm gap is not significantly different from the accuracy of those fabricated by newly developed dental CAD/CAM systems.[11] We previously suggested custom-made homemade cloth masks assisted by a CAD/CAM system if there is a shortage of surgical masks[12] and reported a case for which new dentures were manufactured by incorporating digital dental technology with conventional methods to reduce the burden on edentulous patients with severe dementia.[13] Although mouthguards can be fabricated with soft materials using a 3D printer, this technique has not been used commercially to date in Japan. The material for making denture bases with a 3D printer cannot be used because the pharmaceutical approval review has yet to be obtained. Therefore, at present, it is necessary to incorporate dental digital technology into the fabrication process of conventional methods, rather than using a digital workflow for the entire process, to improve the safety and efficiency of fabrication of mouthguards. This study aimed to compare the fit of mouthguards fabricated using working models produced by a 3D printer based on impressions taken using an intraoral scanner with the fit obtained by conventional methods.

MATERIALS AND METHODS

A maxillary dentition model (D51 FE-500 A-QF; Nissin, Tokyo, Japan) was used as the master model, with the height of the central incisor trimmed to 20 mm and the proximal buccal root of the first molar to 18 mm according to Takahashi *et al.*[14] The impression of the master model was taken using a dental alginate impression material (Tokuyama A-1α; Tokuyama, Tokyo, Japan). The working model was made of hard plaster (Newplastone II; GC, Tokyo, Japan) and embedded in silicon impression material (Duplicone; Shofu, Kyoto, Japan). A total of 20 working models were replicated with hard plaster, trimmed to the same dimensions as the master model, and allowed to dry overnight. A pressure thermoforming machine (Erkopress 300 Tp; Erkodent, Pfalzgrafenweiler, Germany) was used for 10 of the working models, and a vacuum former (Erkoform 3D Motion; Erkodent) was used for the remaining 10.

The master model was scanned using an intraoral scanner (TRIOS 3 intraoral scanner; 3 Shape, Copenhagen, Denmark), and 10 working models were fabricated using a 3D printer (Asiga MAX UV; Asiga, Sydney, Australia) using dental light-curing resin (Freeprint Model T; Detax, Ettlingen, Germany) at 100 μm per layer. After cleaning with isopropyl alcohol, final polymerization was performed in a dental polymerizer (Asiga Flash; Asiga), followed by trimming to the same dimensions as the master model.

Mouthguard sheets (Erkoflex; Erkodent) with a thickness of 4 mm were formed on 10 plaster models and 10 3D printer models using a pressure thermoforming machine. Similarly, the mouthguard sheets were formed on 10 plaster models using a vacuum former.

The thermoforming accuracy of the mouthguards was measured according to Abe *et al.*[15] First, the weight of the formed mouthguard sheet and the model together was measured. Then, an addition-type silicone fit-testing material (Fit Checker; GC) was placed on the inner surface of the mouthguard sheet and then formed on the models for 3 min with finger pressure. The surplus fit-testing material was removed, and then the weight of the formed mouthguard sheet, the models, and the remaining fit-testing material was measured (Fig. 1). The weight of the fit-testing material remaining between the mouthguard sheet and the model was used as the measure of fit accuracy, which was compared among the three conditions: the pressure-formed

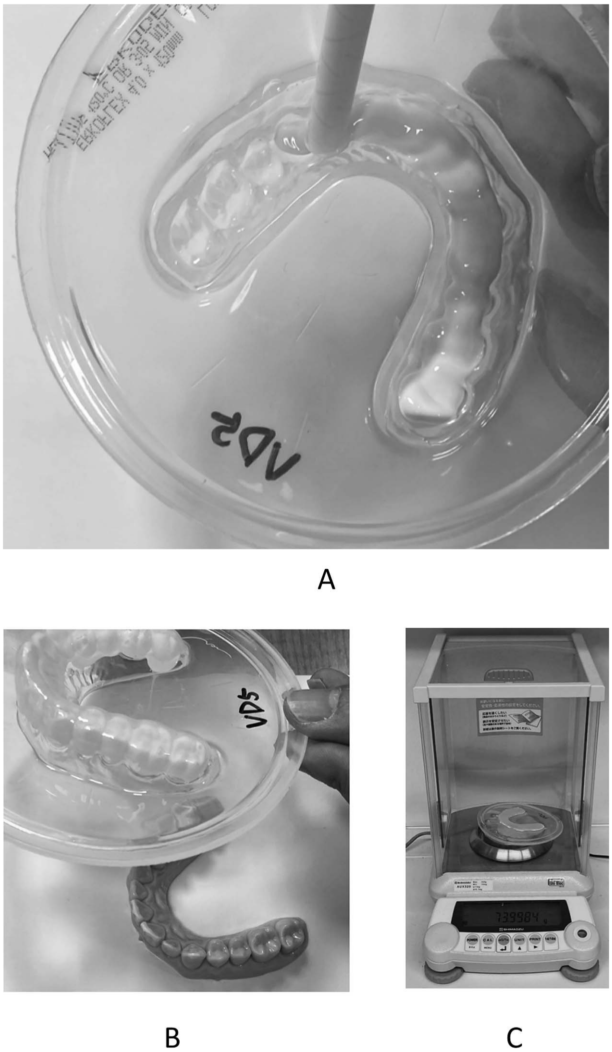

Fig. 1 Procedures for measurement of the fit of the mouthguard; (A) placement of the fit-testing material into the mouthguard after molding, (B) pressure contact on the master model by finger pressure, and (C) weighing the fit-testing agent remaining between the mouthguard and the master model.

sheet to the plaster model (pressure condition), the pressure-formed sheet to the 3D printer model (3D printer condition), and the vacuum-formed sheet to the plaster model (vacuum condition). The differences between the conditions were compared using the Mann-Whitney U test.

Additionally, the systematic bias was estimated using Bland-Altman plots of the means of the paired measurements of a sample against differences between the two measurements to investigate the intra-rater reliability. Fixed bias was assessed by 95% confidence intervals (CIs) of the differences between the measurements. Proportional bias was assessed by regression analysis of the scatterplots. For additional details on the analysis, refer to previous studies.[16, 17] All data were analyzed using SPSS Statistics 20 (IBM, Tokyo, Japan) at a significance level of 5%.

RESULTS

The thermoforming accuracy was visually confirmed by pouring hard plaster inside the mouthguard sheet (Fig. 2). The pressure condition had the highest thermoforming accuracy among the three conditions. The average weight of the fit-testing material in the 3D printer condition was 1.88 g, which was heavier than that in the pressurized condition (1.56 g) but lighter than that in the vacuum condition (2.05 g) (Fig. 3).

Table 1 shows the summary of the intra-rater reliability. In the Bland-Altman plots, the 95% CIs indicated a lack of fixed bias (range included zero) (Fig. 4). Furthermore, regression analysis of the scatterplots indicated a lack of proportional bias (insignificant probability). These results suggest that the measuring method used in this study had excellent intra-rater reliability.

DISCUSSION

This study compared the fit of mouthguards fabricated using working models produced by a 3D printer based on impressions taken with an intraoral scanner with the fit of mouthguards fabricated by conventional methods. The fit of the mouthguards fabricated using the working models produced by the 3D printer was not comparable to that of the mouthguards fabricated using the conventional method, that is, using dried plaster working models. However, the fit was better than that obtained using a vacuum former on a similar plaster working model. Based on these results, we think that the fit of mouthguards fabricated by thermoforming on the working model fabricated by a 3D printer is clinically acceptable.

The fabrication process for mouthguards is not as complex as that for dental prosthesis, such as

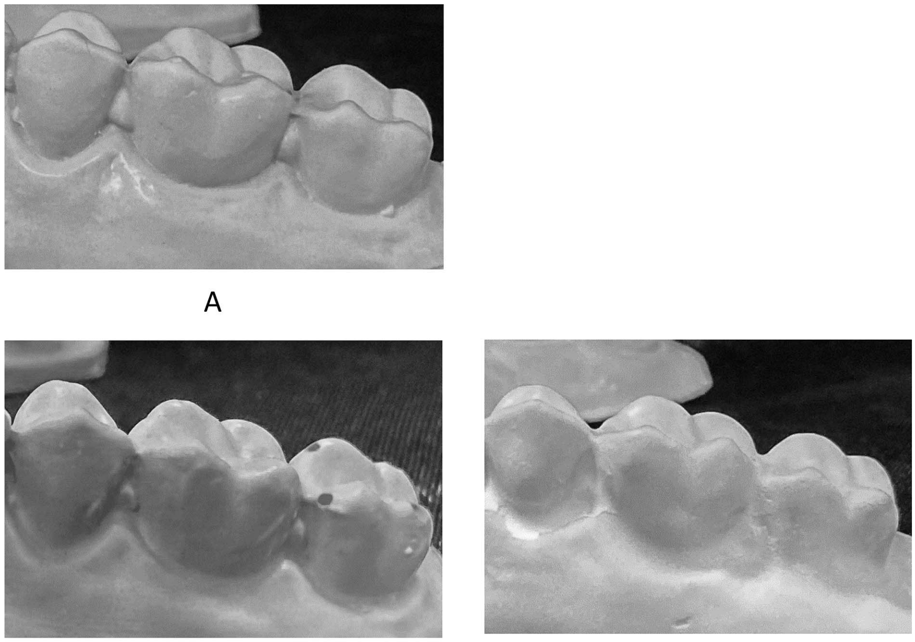

Fig. 2 the Accuracy of thermoforming by pouring hard plaster inside the mouthguard sheet under three different conditions. (A) the pressure-formed sheet on the plaster model (pressure condition), (B) the pressure-formed sheet on the 3D printer model (3D printer condition), and (C) the vacuum-formed sheet on the plaster model (vacuum condition).

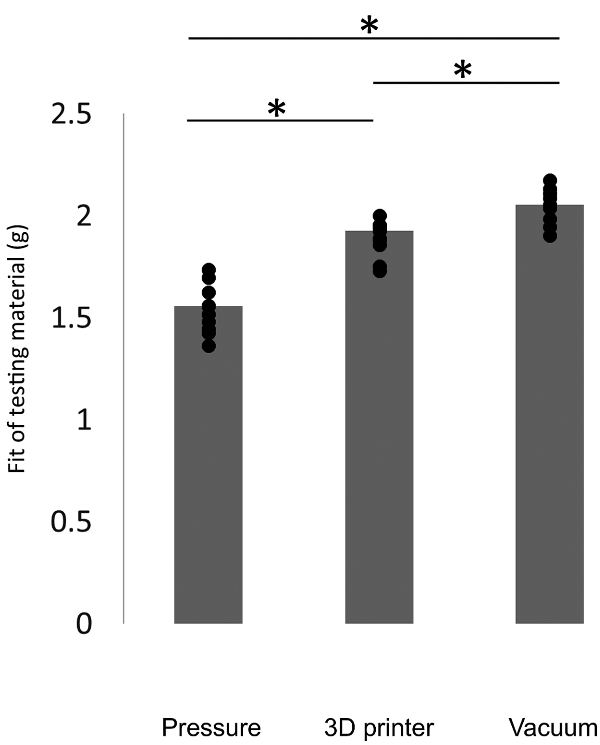

Fig. 3 The mean of the fit-testing material in the 3D printer condition was 1.88 g, which was heavier than that in the pressurized condition (1.56 g) but lighter than that in the vacuum condition (2.05 g) (*p＜0.05).

Table 1 Summary of statistical analyses

Weight of remaining fit-testing material		
Intra-rater reliability		
Measurement 1	Measurement 2	P
1.56±0.12	1.55±0.13	0.99
Fixed bias		
Mean difference	95% CI	
0.01	−0.27 to 0.29	
Proportional bias Regression coefficient		
−0.014		0.97

(g)

metal crowns, bridges, and removable dentures. However, it is time-consuming and costly to take impressions and fabricate working models. Working models can be stored, but depending on the duration and location of storage, there are concerns about the deterioration and hygiene of the models. For these reasons, the process of mouthguard fabrication should be simplified. However, no significant improvement over conventional methods has

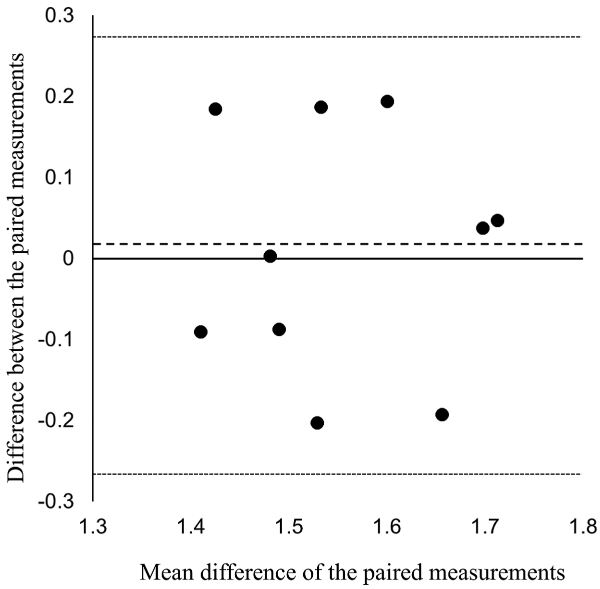

Fig. 4 Bland-Altman plots of intra-rater reliability for measuring the fit-testing material, with the mean difference and 95% confidence interval. The mean of two measurements for each sample was plotted against the difference between these measurements to assess systematic bias.

been reported.

Optical impression taking using an intraoral scanner has various advantages over conventional methods that use impression materials. The digital data of the dentition and surrounding tissues obtained by scanning can be easily stored and transferred. However, since the mouthguard is essentially designed on a 3D designing tool, neither plaster nor an articulator is needed. In addition, if the 3D data of the mouthguard's morphology is stored, it can be duplicated without taking another impression or occlusion if there are no changes in the dentition. However, at present, the question remains whether soft materials that can be used in 3D printers can be used in the oral cavity. The cost of production is also still unrealistic. Therefore, it would be best to create a hybrid model as shown in this study, in other words, a working model created by an optical impression and a 3D printer, together with a sheet formed by the conventional thermoforming method.

Intra-examiner reliability is the reliability when one examiner evaluates multiple participants. In this study, the fit of the 10 mouthguard sheets was evaluated by one examiner twice. An intra-class correlation coefficient value is considered good if reliability is 0.7 or more.[18, 19] Therefore, the measurement method in this study has sufficient statistical reliability.

CONCLUSION

The fit of mouthguards fabricated by thermoforming on a working model fabricated by the 3D printer was not comparable to that obtained by the conventional method. However, it was better than that of mouthguards fabricated using the vacuum former. Therefore, the fit of the mouthguard fabricated by thermoforming on the working model fabricated by the 3D printer is considered clinically acceptable.

Acknowledgements
The authors would like to thank the following individuals for their assistance in this study. Mr. Shinsuke Matsuda gave us valuable advice and aided us in handling the dental laboratory equipment based on his experience as a laboratory technician. Dr. Kazuki Sako taught us how to process the data. Dr. Tomohiko Okamura assisted with the measurements. We thank all members of our department for their advice on draft preparation. This research was supported by KAKENHI (Grant-in-Aid for Scientific Research No. 19K19964, 21K11350) to Y. Tanaka, and by the Mizuno Sports Promotion Foundation.

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