Evaluating the Feasibility and Accuracy of Digitizing a Maxillary Defect Model Simulating Various Trismus Conditions

Yuan Gao, BDS, DDS
Mariko Hattori, DDS, PhD
Manjin Zhang, DDS, PhD
Mahmoud E. Elbashti, BDS, MSc, PhD
Yuka I. Sumita, DDS, PhD

Department of Maxillofacial Prosthetics, Tokyo Medical and Dental University (TMDU), Tokyo, Japan.

Purpose: To compare the feasibility and accuracy of using intraoral scanners to digitize a maxillary defect model simulating various trismus conditions. Materials and Methods: Four intraoral scanners were used to digitize a maxillary defect model simulating four different degrees of trismus (mouth opening = 10, 20, 30, and 40 mm), and the scanned areas were compared. The scans were also superimposed on each other for precision analysis and on reference data for trueness analysis using 3D evaluation software. Two-way ANOVA was used to compare area, precision, and trueness among scanners and among conditions. Results: The surface area for which 3D data were obtained by the intraoral scanners ranged from 2,672 to 6,613 mm². Significant differences were observed between the scanners (P < .001) and between the trismus conditions (P < .001), with a smaller scanned surface area in severe trismus (10 mm). Trueness ranged from 0.033 to 0.301 mm, and precision from 0.022 to 0.397 mm. Significant differences in trueness and precision values were found among the scanners (P = .001 and P = .001, respectively), but not the trismus conditions (P = .260 and P = .075, respectively). Conclusion: Although trueness and precision differed between intraoral scanners, digitization of the maxillectomy model simulating various trismus conditions appears to be feasible from the perspective of accuracy with all of the scanners used. The smaller scanned surface area in the severe trismus condition was due to lack of data on the defect site in that condition. Int J Prosthodont 2022 December 9. doi: 10.11607/ijp.7842. Online ahead of print.

Conventional methods for producing prostheses are widely and successfully used, but the inevitable errors that can occur when obtaining impressions, creating castings, and digitizing the defect with laboratory scanners means that errors can potentially occur during the manufacturing process. There are many possible reasons for these potential errors, including poor elastic strain and permanent strain of the impression, impression distortion, inappropriate disinfection of the impression, separation of impression materials from the impression tray, deformation of the conventional impression before pouring and storage of the impression for potential castings, and remanufacture of casts and dies.

In recent years, the most prominent change in the dental field has undoubtedly been the development of digital dentistry. From the 1980s, CAD/CAM ceramic restorations were used to enable dentists and technicians to complete all-ceramic crowns, fixed dentures, and implants in a digital flow. Since CAD/CAM applications were introduced to the dental field, technology has been developed to create intraoral digital impressions from which high-resolution data of prepared teeth can be obtained. These intraoral scanning systems were provided as an alternative, simplified method for impression-taking. These systems can also speed up the manufacturing process.
process and overcome the shortcomings of conventional impressions.\textsuperscript{20} Proper visualization of the digitized data also plays an important role in prosthetics because it offers interactive treatment planning in relation to the delivery of definitive prostheses.\textsuperscript{21,22}

In some recent studies, intraoral scanner (IOS) devices were used to capture images of the mucosa, suggesting their feasibility and accuracy.\textsuperscript{23–28} To date, digital technologies have led to considerable progress not only in general prosthetics, but also in specific areas such as maxillofacial prosthetics.\textsuperscript{24,25} Taking impressions via conventional methods is challenging for maxillectomy patients and carries the risk of aspiration and impaction of the impression material, as well as the impression deformation associated with large maxillary defects.\textsuperscript{29} Therefore, using IOS devices to take impressions is considered easier and safer than conventional methods for these patients. However, there are some difficulties and deficiencies that still need to be resolved when obtaining intraoral digital impressions. In previous studies, researchers showed that obtaining intraoral digital impressions is not the same as the steady and accurate working process of extraoral laboratory scanners.\textsuperscript{30,31} A major problem that persists when using intraoral digital impression systems in the fabrication of maxillofacial prosthetics is that the scanner tip shifts during the scanning procedure. This shifting might affect the accuracy of scanning the defect area.\textsuperscript{26}

IOS devices are a possible alternative to conventional methods for taking impressions in patients with trismus. Trismus is a condition that prevents the mouth from fully opening. This condition can be either congenital or acquired and may result from surgical treatment of orofacial cancers, trauma, burns, Plummer-Vinson syndrome, scleroderma, radiotherapy, etc.\textsuperscript{32,33,34} The limited maximum opening of the mouth with trismus creates challenges in prosthetic treatment. Several studies have described the difficulties encountered in dental procedures because the limited mouth opening in trismus makes it difficult to access the oral cavity, especially when making impression trays and when inserting and removing dentures.\textsuperscript{35,36,37} Using IOS devices could be one way for dentists to offer an alternative method for impression-taking that can help with successful treatment in these patients.

To evaluate whether IOS devices could be a feasible and accurate method to use in patients with trismus, the accuracy of the scans obtained must be investigated. Trueness and precision are the two parameters that describe the accuracy of a measurement method.\textsuperscript{17,20} Trueness is defined as the closeness of agreement between a large test dataset and a true or accepted reference dataset\textsuperscript{38,39} and is measured as potential deviation between the two datasets.\textsuperscript{23} Precision is defined as the closeness of agreement between all test datasets acquired from the same object by the same scanner.\textsuperscript{39} Both trueness and precision can be applied to procedure information to confirm the repeatability of scans obtained by a scanner.\textsuperscript{23,40,41}

Trismus is common among patients undergoing maxillofacial prosthetic rehabilitation, and therefore the model of a maxillectomy patient with trismus was used as the research object in this study. The suitability of using IOS devices for taking digital impressions in trismus cases can be confirmed only through multiple comparisons between different IOS devices. Thus, the purpose of this study was to measure the surface area of a digitized maxillectomy defect simulating trismus at different degrees of mouth opening. This study also aimed to compare the feasibility and accuracy (ie, trueness and precision) of digitizing the maxillectomy defect simulating the different trismus conditions with four different IOS devices. The null hypothesis was that no significant difference would be found between the different opening conditions or IOS devices in the trueness or precision of the digital impressions.

**MATERIALS AND METHODS**

Four IOS devices were used in this study: Cerec (Cerec Omnicam, Dentsply Sirona), Trophy 3DI Pro (Yoshida Dental); Trios 3 (3Shape), and True Definition (3M Espe).

The dimensions of the active head portions were 16 × 16 mm for Cerec; 16 × 13 mm for Trophy 3DI Pro; 19 × 20 mm for Trios 3; and 16 × 14 mm for True Definition.

**Preparation of Maxillectomy Model**

A maxillary model (Prosthetic Restoration Jaw Model, PRO2002-UL-UP-FEM-28, Nissin) was used to prepare a maxillectomy model. Artificial teeth from the first premolar to the second molar were removed, and a part of the left side of the maxillary model was curved using a carbide bar to create an Aramany Class II defect\textsuperscript{42} (dimensions: 39.575 × 26.561 × 20.232 mm) extending from the first premolar to the second molar on the left side. The defect was mechanically polished (Big Silicone Point HP R2, Shofu) (Fig 1).

**Reference Scan**

Reference data were obtained by scanning the model with an industrial scanner (ATOS III Triple Scan 8MP, GOM; measurement inaccuracy = 0.001 μm; mean temperature 22°C ± 1°C). This involved calibrating the device according to the manufacturer’s instructions, then placing the model on the scanner platform. The model was scanned with accuracy data (trueness and precision) exported as a standard template library (STL) file. The scanned reference data were named R1.
Setting the Trismus Condition

The maxillectomy model, a normal mandibular model (Prosthetic Restoration Jaw Model, PRO2002-UL-UP-FEM-28, Nissin), and a phantom head (Simple Manikin II, Nissin) were used to simulate a patient. The maxillary and mandibular models were set with simulated mucosa (Oral Cavity Cover, Nissin) and connected to the phantom head (Fig 2).

The models, simulated mucosa, and phantom head were attached to the workbench using a mounting unit set (Bench Mount SPM III, Nissin). After the phantom set was fixed in place, the degree of jaw opening was measured along the standard midline between the maxillary and mandibular incisors at four simulated positions: 10 mm to represent severe trismus; 20 mm to represent moderate trismus; 30 mm to represent mild trismus; and 40 mm to represent no trismus. To adjust the degree of opening parallel to the standard midline, a maximum interincisal opening measuring instrument (OraStretch MIO Scale, Cranio Rehab) was used (Fig 3).

Position 0 (P0) of the measuring instrument was placed on the occlusal plane at one of the mandibular central incisors and then placed on the occlusal plane of the corresponding maxillary central incisor. P0 was always used as the base point to adjust the degree of jaw opening. After measurement was completed, the scanning process was started.

Scanning Procedure

The aforementioned four IOS devices were used for the scanning procedure. All of the IOS devices were placed under the same conditions in the same room, which excluded the influence of extraneous light and was maintained at a constant temperature (mean temperature: 22°C ± 1°C). The scanning procedure started at the incisors on the buccal side. The scanner tip was used to capture the contour of the model, which involved scanning the mucosal region (including the palate) and considering the actual situation of the degree of jaw opening and the whole dental arch by following the crest to the other side. Finally, the stitching gap at the palate was minimized by moving the scanner tip over the palate in a zigzag pattern. After the first scanning procedure was completed, the scanning system software displayed any possible missing areas on the main screen, and these areas were continually scanned until no missing areas remained. The model was subjected to the same scanning procedure five times at each of the four degrees of jaw opening. As a result, the scanner system exported 20 files. After completing the 20 rounds of scanning, the maxillectomy model, normal mandibular model, and phantom head were returned to the original position, and then a second round of scanning was performed using another IOS device. Scanning all four degrees of jaw opening with the same...
model using the four different IOS devices generated a total of 80 STL files.

**3D Deviation of Datasets**

A 3D comparison process was carried out next, which required the use of industry-certified software to convert the Cerec dataset into the STL file format. For True Definition and Trios 3, STL files were provided by the manufacturers. For Trophy 3DI Pro, it was possible to export the dataset to STL file format. Trueness was measured (as defined previously) for the reference datasets (R1) and one of the five scan datasets (S1) obtained for each degree of jaw opening. The same measurement was taken for the other evaluations (S2 through S5). Then, precision was measured (as defined previously) for two of the five scan datasets obtained for each degree of jaw opening (S1 through S5). After 80 digital impressions were made and classified, the STL files were sent to 3D analyzing software (spGauge, Armonicos; Fig 4a). The datasets were superimposed on each other using the software’s best-fit function. Then, the entire 3D comparison (x, y, and z coordinates) was automatically performed (Fig 4b). Finally, the software’s selection and cutting tools were used to eliminate the area not related to the study (Fig 4c).

After eliminating that area, the area of the scan data was identified by directly selecting the scan data. The final dataset was then visually inspected as follows. After using the software function “deviation analyzing,” a color map of the data analysis was exported. The color map enabled identification of the areas of high and low agreement (Fig 4d). Then, results of the 3D error assessment and the maximum, mean, and median deviation for each degree of opening were generated. An analysis report was displayed directly on the screen, from which distances between the
vertices of the corresponding models were calculated (including the mean ± SD).

Statistical Analyses
Using the 3D data, including the mean ± SD, statistical analysis was carried out to determine both precision and trueness. Because mean and SD values were used in the analyses, two values were obtained for each comparison; that is, one value from the comparison of the reference dataset to the scan dataset for trueness, and one value from the comparison of two different scan datasets for precision. Thus, 10 values for each degree of jaw opening were obtained for the trueness comparisons (each IOS dataset [n = 5] compared to R1; 2 deviation values per comparison), and 20 values were obtained for the precision comparisons (each IOS dataset [n = 5] compared to each other dataset obtained using the same IOS; that is, dataset 1 was compared to dataset 2, dataset 1 was compared to dataset 3, . . . dataset 4 was compared to dataset 5, etc, resulting in a total of 10 comparisons with 2 values per comparison obtained).

To evaluate the effect of accuracy on the maxillectomy model, interaction terms between the main effects (scanner and degree of trismus) were included in the model to detect differences between the equipment. The least-squares mean of the main effects (scanner and trismus) and interaction effects (95% CI) were calculated, and the results were plotted in a box plot. Shapiro-Wilk test was used to examine the normal distribution of each value. Two-way ANOVA was used to evaluate differences among all of the comparisons between the IOS devices and between the different degrees of jaw opening. Tukey adjustment was used for post hoc multiple-group comparisons. In addition, relevant comparisons were made between the results of the maxilla and mandible using the different scanners (eg, the results of the maxilla using the Cerec scanner vs those using the Trophy 3DI Pro scanner). Statistical software (SPSS version 19.0.0, IBM) was used to perform all calculations, with statistical significance among the groups set at P < .05.

RESULTS
The 3D analysis showed that not all of the IOS devices were suitable for making digital impressions of the trismus maxillectomy model. Visual analysis of the superimposed dataset of the maxilla included digital mismatches at the teeth, palate, gingiva, and other regions (Fig 5).

All of the data acquisition and matching procedures were successful except when using Cerec and True Definition. Cerec could not scan the mucosa or defect surfaces at any degree of opening, so no Cerec data could be obtained. With True Definition in the 10-mm opening condition, the scanned area was small and stitching was incomplete; these scans ended in error, so no scan data were obtained. With Trophy 3DI Pro and Trios 3, digital impressions were obtained for all degrees of opening.

Figure 6 shows that, in the 10-mm opening condition, the mean surface area obtained by Trophy 3DI Pro was 3,185.4 mm² (range: 2,955 to 3,488), and that obtained by Trios 3 was 2,825.8 mm² (range 2,672 to 2,969). For the 20-mm opening, these values were 4,655.8 mm² (range: 4,413 to 4,892) and 4,441.4 mm² (range: 4,336 to 4,531), respectively; and that of True Definition was 6,460 mm² (range: 6,428 to 6,552). For the 30-mm opening, the respective values were 6,548.4 mm² (range: 6,511 to 6,596); 6,161.6 mm² (range: 6,069 to 6,244); and 6,601 mm² (range 6,589 to 6,613). For the 40-mm opening, the respective values were 6,533 mm² (range: 6,421 to 6,612), 6,566.2 mm² (range: 6,545 to 6,582), and 6,604 mm² (range: 6,589 to 6,613). Significant differences were observed between the areas scanned by
the IOS devices ($P < .001$) and between all degrees of opening ($P < .001$), except for the 40-mm opening.

Figure 7 shows the trueness measurements of the scan data. In the 10-mm opening condition, the median trueness taken by Trophy 3DI Pro was 0.254 mm (range: 0.134 to 0.299), and that taken by Trios 3 was 0.071 mm (range: 0.033 to 0.13). For the 20-mm opening, these values were 0.226 mm (range: 0.133 to 0.301) and 0.092 mm (range: 0.042 to 0.13), respectively; and that of True Definition was 0.058 mm (range: 0.045 to 0.069). For the 30-mm opening, the respective values were 0.195 mm (range: 0.119 to 0.212), 0.136 mm (range: 0.063 to 0.246), and 0.053 mm (range: 0.042 to 0.068). For the 40-mm opening, the respective values were 0.169 mm (range: 0.133 to 0.222), 0.104 mm (range: 0.051 to 0.193), and 0.053 mm (range: 0.044 to 0.062). Data analysis revealed statistically significant differences in the trueness values among all IOS devices under the same degree of opening ($P = .001$); however, no significant differences were found among unsigned differences for the degrees of opening ($P = .260$).

Figure 8 shows the precision measurements of the scan data. In the 10-mm opening condition, the median precision taken by Trophy 3DI Pro was 0.186 mm (range: 0.087 to 0.397), and that taken by Trios 3 was 0.089 mm (range: 0.022 to 0.158). For the 20-mm opening, these values were 0.199 mm (range: 0.099 to 0.318) and 0.085 mm (range: 0.014 to 0.162), respectively; and that of True Definition was 0.039 mm (range: 0.026 to 0.059). For the 30-mm opening, the respective values were 0.147 mm (range: 0.079 to 0.242), 0.165 mm (range: 0.056 to 0.242), and 0.042 mm (range: 0.019 to 0.077). For the 40-mm opening, the respective values were 0.160 mm (range: 0.097 to 0.232), 0.098 mm (range: 0.026 to 0.163), and 0.032 mm (range: 0.024 to 0.049). Data analysis revealed statistically significant differences in the precision values among all IOS devices under the same degree of opening ($P = .001$). However, the unsigned comparisons among scans showed no significant differences in precision for the degrees of opening ($P = .075$).

**DISCUSSION**

To the present authors’ knowledge, this is the first study to simulate trismus in vitro in order to investigate the surface area and accuracy of 3D impressions obtained by different IOS devices for a maxillectomy model. The results demonstrate that digitization is feasible. These results led to partial rejection of the null hypothesis because there were significant differences in trueness and precision among the IOS devices.

Scanning was possible in trismus that was not severe. For the 40-mm opening, the surface area measurements were not significantly different, and the area basically covered the entire maxilla, including the dentition, hard palate, and soft palate. However, for the 10-, 20-, and 30-mm openings, the area was smaller and the data were partially missing due to lack of space for scanning—but this observation was limited to only the Trophy 3DI Pro and Trios 3. The True Definition scanner captured a larger area than the other two IOS devices for the 20-mm opening, and the area was almost the same for the 30- and 40-mm openings, but it could not complete scanning for the 10-mm opening. [AU: Please see query in Results.] One reason for the differences in scanning area measurements is the different shape of the IOS tip. Under the same opening condition, the area captured by each IOS differs according to the shape of the scanner tip. Another reason is that different IOS devices have different recognition and sensitivity when scanning the palatal soft tissue. Currently, IOS devices are used to fix restorations rather than removable partial dentures and complete dentures. Previously, IOS devices have performed better with teeth than with palatal soft tissue in relation to recognition and accuracy.

The 3D analysis showed that the True Definition scanner performed better in all conditions, except for the 10-mm opening (Figs 6 to 8). Trios 3 showed an average performance, while the Trophy 3DI Pro showed mid to low performance, and no data could be obtained on the maxillectomy defect in any of the trismus conditions using Cerec. Because True Definition had significantly higher trueness and precision than the other three IOS devices, this scanner appears to be more suitable for moderate trismus conditions. However, True Definition should not be used for severe trismus, as the other two IOS devices performed better. The higher accuracy of the True Definition was possibly due to its substantially smaller tip (16 x 14 mm). However, the significance of this detail remains unclear because the IOS devices differed...
The results indicate that the IOS devices were able to take digital impressions for trismus patients at different degrees of jaw opening. However, as mentioned above, no scan data could be obtained using Cerec. In other studies, Cerec systems have required the use of powder to increase the opacity of the surface and to produce a uniform reflection that increases the quality of the impression.\textsuperscript{1,11,38} In the present study, powder was not used for Cerec scanning because it was not mentioned in the manufacturer instructions. Further investigation is required to determine approaches to scanning mucosa using Cerec.

In previous studies, computerized optical impressions of the maxillectomy defect model using IOS devices seemed to provide reliable and accurate results.\textsuperscript{25,26} Also, digitizing the edentulous maxillectomy defect models with an IOS in vitro was found to be feasible and accurate.\textsuperscript{9} Accurate reproduction of the shape of oral tissue is necessary in digital dental treatment. A recent study specified that an error of less than 0.3 mm at the 99.5\% most deviating aspect of model scans would be clinically acceptable.\textsuperscript{40} In the present study, trueness of the digital impressions of the trismus maxillectomy model obtained by the IOS devices ranged from 0.053 to 0.254 mm, and precision from 0.039 to 0.199 mm, so accuracy of the IOS devices used is considered to be within the clinically acceptable range. These results suggest that using IOS devices is a suitable alternative to conventional methods for obtaining digital impressions in trismus patients with different degrees of mouth opening.

Although several studies have compared the accuracy of digital impressions, few in vitro and in vivo studies have measured the feasibility and accuracy of full-arch images obtained by IOS devices. Braian and Wennerberg compared the accuracy of five IOS devices for scanning edentulous and dentate complete-arch mandibular casts, and both the precision and reliability were low in complete-arch scanning, especially for edentulous patients.\textsuperscript{17} However, in another study by Elbashti et al, digital impressions of maxillectomy defect models using an IOS seemed highly accurate and reliable.\textsuperscript{26} These conflicting results could be explained by different accuracy assessments, including different master models or different scanning procedures. In the trismus conditions in the present study, the results showed comparable accuracy to the results of Elbashti et al.\textsuperscript{25}

The present results demonstrated that the larger the degree of opening, the greater the area investigated when using the same IOS. Some studies have shown that the larger and more complicated the scan area, the lower the accuracy. When the scanning range is gradually expanded, more images will be merged, which might cause progressive distortion of the scanned data and lower accuracy.\textsuperscript{17,23,38} In the trismus conditions in the present study, it was difficult to scan some parts using the IOS device, but some of these parts could still be captured by chance. Those parts that did lack sufficient scan data could result in low accuracy. In the nontrismus condition, most parts were easily scanned, providing sufficient scan data to stitch the images together, and some parts were captured many times so that more accurate data were obtained. However, in the trismus conditions, not all of the scanned parts were stitched together to form an entire plane because the data were lacking in some regions. Therefore, the coverage of the scanned area was higher and the chance
of random error during the scanning procedure was lower than in the nontrismus condition. Factors that could also result in low accuracy are the experimenter’s scanning technique, different identification by the IOS devices, and limitation of the analysis software. In the 10- and 20-mm conditions, trueness and precision varied more than in the other two conditions. Accuracy was not significantly different between the different conditions. Thus, the results of trueness and precision showed that the trismus conditions did not affect the measurement accuracy of the digitized maxillectomy model when using the same IOS.

In previous studies, the optically challenging environment of the oral cavity led to reduced scanning accuracy in vivo.\textsuperscript{18,19,20,23,25} Therefore, while results obtained in vivo can be considered a better solution than in vitro, the clinical accuracy might be lower.\textsuperscript{18,19,20,23,25} In the present study, a curved model simulated a real maxillectomy defect and was located in a phantom head with simulated mucosa in the various trismus conditions but did not fully replicate an actual clinical situation. The maxillectomy patient’s oral cavity is complex, and scanning access can be restricted by various structures, including hard tissues (e.g., teeth), soft tissues, surrounding oral structures, and even fixed restorations. In similar in vivo studies, accuracy is influenced by clinical variables, including the presence of saliva, light conditions, humidity of the oral environment, intermittent acquisition, and tongue and soft tissue movement.\textsuperscript{17,25,30,31} How to improve the IOS devices and make them more suitable for patients with trismus should be considered.

CONCLUSIONS

Within the limitations of this in vitro study, the following conclusions were drawn:

1. It was possible to digitize the maxillary defect model in moderate and mild trismus conditions using the IOS devices; however, not all scanners could be used in the severe trismus condition.
2. In the severe trismus condition, the area of the scanned surface was smaller than in the other conditions due to lack of data on the defect site.
3. The scanned surface area of the maxillectomy model was significantly different between the different scanners.
4. Different trismus conditions did not affect the accuracy when scanning the maxillectomy model.
5. Although accuracy differed significantly between the different IOS devices, all were accurate within the clinically acceptable range.

ACKNOWLEDGMENTS

This work was partially supported by the Promoting Leading Edge Research in Oral Science project at Tokyo Medical and Dental University and by the Japanese Dental Science Federation (JDSF-DSP1-2020-208-2). This study was presented at the 36th Annual Meeting of the Japanese Academy of Maxillofacial Prosthetics (JAMP), held in Sendai, Japan, June 26–28, 2019. Trophy 3D! Pro was loaned free of charge by Yoshida Dental Trade Distribution, Co. The authors report no conflicts of interest.

REFERENCES


