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Evaluation of a novel 3D-printed custom tray for the impressions of edentulous jaws

Kehui Deng [a,b,c], Hu Chen [a,c], Yong Wang [a,c], Yongsheng Zhou [b,c], Yuchun Sun [a,c,*]

[a] Center of Digital Dentistry, Peking University School and Hospital of Stomatology, Beijing, China
[b] Faculty of Prosthodontics, Peking University School and Hospital of Stomatology, Beijing, China
[c] National Engineering Research Center of Oral Biomaterials and Digital Medical Devices & National Center of Stomatology & National Clinical Research Center for Oral Diseases & Beijing Key Laboratory of Digital Stomatology & Research Center of Engineering and Technology for Digital Dentistry of Ministry of Health, Beijing, China

A R T I C L E I N F O

Keywords:
Accuracy
Custom tray
Edentulous impression
3D printing

A B S T R A C T

Purpose: The purpose of this study was to evaluate a novel 3D-printed custom tray for impressions of edentulous jaws, and to compare it with conventional impression trays.

Methods: Fifteen edentulous patients were enroled to evaluate the accuracy and border extension of a novel custom tray in the shape of a complete denture. Four impressions were made for each patient. Impressions made using novel custom trays were considered the experimental group, impressions made using conventional custom trays were considered the control group, and impressions made using final dentures and non-pressure custom trays were considered the reference groups. The experimental and control groups were compared with the reference groups using three-dimensional (3D) comparison analysis, and the impressions were further divided into regions. The root mean square (RMS) value was calculated to analyse the differences in impression morphology. Additionally, the experimental and control groups were compared to analyse border extension at standard locations.

Results: Compared to the final denture impression as a reference, the diagnostic denture impression (RMS:0.146 $\pm$ 0.024 mm) was closer to the reference than the conventional impression (RMS:0.176 $\pm$ 0.047 mm), with a significant difference only in the secondary stress-bearing area. The border extension of the diagnostic denture impression was slightly longer than the conventional impression; however, the difference was not statistically significant.

Conclusions: The impressions made using the novel custom tray were similar to those made with a definitive complete denture. However, no significant differences were noted when compared with the conventional impressions.

Clinical Significance

A new edentulous impression method is proposed. Compared to the conventional impression, no statistically significant differences were observed in terms of accuracy. However, this novel method can reduce the number of appointment visits. This could be considered to promote the use of digital technology in clinical practice.

1. Introduction

Conventional complete denture restoration requires a primary impression, final impression, jaw relation record, and denture try-in, with the final denture subsequently delivered at the fifth visit [1]. To reduce the number of visits and simplify the treatment process, some feasible techniques have been proposed, such as the one-step impression technique or closed-mouth impression technique [2]. The one-step impression technique can reduce costs and improve efficiency; however, its accuracy is not as good as that of the secondary impression

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* Corresponding author at: Center of Digital Dentistry, Peking University School and Hospital of Stomatology, 22 Zhongguancun Avenue South, Haidian District, Beijing 100081, China.

E-mail address: kqsyc@bjmu.edu.cn (Y. Sun).

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technique, especially for patients with severe alveolar ridge absorption. The secondary impression technique refers to the use of custom trays fabricated based on the primary impression to make a secondary impression, which can obtain better vestibular sulcus morphology to form a border seal in the final denture. The custom tray can be classified as a closed-mouth custom tray or an open-mouth custom tray according to whether the patient opens or closes his mouth during impression-making. The closed-mouth impression technique combines impression making and jaw relation record in a single step, and therefore can reduce the number of visits.

The main difference between the impressions made by closed-mouth and open-mouth custom trays lies in recording the border sealing area morphology. When using open-mouth custom trays to make impressions, passive border moulding is inevitable because of the interference of the handle of the conventional custom tray. When the operator attempts to mould the vestibular tissues manually to simulate muscle movement during mastication, muscular contraction of these tissues does not actually occur [3]; therefore, it is generally believed that active border moulding is more consistent with the actual chewing movement of patients. The closed-mouth impression technique allows for the use of an active method for border moulding because of the lack of external interference, which better reflects the actual vestibular morphology of the mouth in the functional state. Under a moderate occlusal force, the impression can approximately replicate the masticatory function of a complete denture to simulate the morphology of the oral mucosa after compression and deformation. This is particularly true in edentulous jaws with severe absorption of the alveolar ridge. Therefore, dentures fabricated from these impressions can bear a more uniform force during mastication, reducing tenderness caused by local overpressure. In addition, the one-step procedure for impressions and jaw relationships renders the final denture more stable and reduces the number of treatment visits [4,5]. However, the fabrication of closed-mouth custom trays is more complicated than that of open-mouth custom trays, and closed-mouth custom trays are usually used for relining or copying complete dentures [6], thereby limiting their clinical application. In contrast, open-mouth custom trays are simple to fabricate, easy to use, and are widely used in clinical practice.

Digital technology has enabled the incorporation of innovative ideas for the fabrication of complete dentures. The fabrication of the final denture can be digitally realised. Milled denture base bonded milled/commercial teeth or monolithic milled multicolour dentures have higher precision [7], retention, mechanical and surface properties [8], less residual monomer [9], and reduce the time and cost compared with conventional manufacturing [10,11]. Printed dentures have been reported to have less residual monomer [12], close accuracy, biocompatibility and surface roughness, but relatively low mechanical properties with milled dentures [13,14]. Besides, 3D printed dentures are still difficult to accept clinically in terms of aesthetics, compared with milling or traditional dentures [15].Therefore, the 3D printed dentures are generally recommended for immediate or interim dentures, or simply printing the denture base and using the artificial teeth [16].

Custom trays fabricated digitally eliminate the conventional steps of pouring a gypsum model, trimming the model, marking the line, and trimming the tray, simplifying the procedure considerably and improving efficiency [17,18]. In this study, digital technology was used to design and fabricate a new tray that constitutes a closed-mouth tray, where impressions are made, jaw relationships are recorded, and denture try-in is performed in one visit, allowing denture delivery at the third visit. However, the accuracy of this new tray is unknown. Therefore, in this study, impressions made from conventional open-mouth custom trays were used as a control group, and pressure impressions and non-pressure impressions were used as references to evaluate the accuracy and pressure range of impressions made with this new custom tray. The null hypothesis of this study is that there is no difference between the impressions made by the new tray and the conventional custom tray.

2. Materials and methods

2.1. primary impression making

Fifteen edentulous patients were enroled from the Department of Prosthodontics (ethics committee approval no. PKUSSIRB-201838120). The inclusion criteria were as follows: the upper and lower jaws were completely edentulous for more than three months, and the alveolar ridge was classified as Atwood I-III. The experimental workflow is illustrated in Fig. 1. Impression compound (Red, Shanghai Rongxiang Dental Material Co., Ltd.) was used to obtain the primary impressions (Fig. 2a). To record the primary jaw relationship, the rest vertical dimension was measured, and 2 mm was subtracted to obtain the occlusal vertical dimension. The impression compound was loaded on the posterior area of the back of the maxillary tray and placed in the patient's mouth. The patient was asked to bite until the occlusal vertical dimension. Silicon rubber (Type 1, Shandong Huge Dental Material Corporation) can be used to reline the jaw relation to improve alignment accuracy (Fig. 2b). The lip support was adjusted, and aesthetic information, including the midline, lip line, high lip line, and line at the corner of the mouth, was marked (Fig. 2c). A three-dimensional (3D) dental model scanner (Dentscan Y500; Nanjing Geosmart 3D Information Technology Co., Ltd.) was used to scan the impression and jaw relationship, and data were derived in the standard tessellation language (STL) format.

2.2. Design and 3D printing of diagnostic dentures and conventional custom trays

The primary impression and jaw relationship data were imported into a 3D reverse engineering software (Geomagic Studio 2013, Raindrop Geomagic), and the lower impression was aligned on the jaw relation to reconstruct the relationship between the upper and lower jaws (Fig. 3). The impression and aesthetic information data were imported into a complete denture design software (Hoteamsoft Co., Ltd.) to design a closed-mouth custom tray that is similar to a complete denture. This model was called diagnostic complete denture. The margin was reduced by 2 mm to reserve space for border moulding. In addition, a 1-mm space was reserved on the intaglio surface to provide space for the impression material, and hemispherical tissue stops with a diameter of 3 mm were designed on this surface. On the upper diagnostic denture, four tissue stops were placed on the buccal/lingual sides of the anterior arch and on both sides of the alveolar ridge crests of the posterior arch. On the lower diagnostic denture, three tissue stops were located on the alveolar ridge crests of the anterior arch and both sides of the posterior arch (Fig. 3). The diagnostic denture was exported in the STL format.

A conventional open-mouth custom tray was used as the control group. To ensure consistency of the morphology and margin of the intaglio surface of the tray between different groups, the conventional custom tray was designed based on the diagnostic denture in Geomagic by removing the dentition on the diagnostic denture and adding a straight handle to the appropriate place (Fig. 4a-c). Non-pressure trays were designed as a reference group. Holes with a diameter of 3 mm were punched on the conventional custom tray, and their positions were distributed as evenly as possible (Fig. 4d). The designed diagnostic denture and two custom trays (with and without vent holes) were imported into a fused deposition moulding printer (Lingtong II, 0.8 mm diameter nozzle; Beijing Shino) using polylactic acid as the printing material and the printing layer height was set to 0.2 mm for printing.

2.3. Final impression making

At the second visit, a printed diagnostic denture and two custom trays were used to make final impressions for each patient. Border moulding was performed with the diagnostic denture and conventional custom tray using heavy-body silicone rubber (Type 1, Shandong Huge

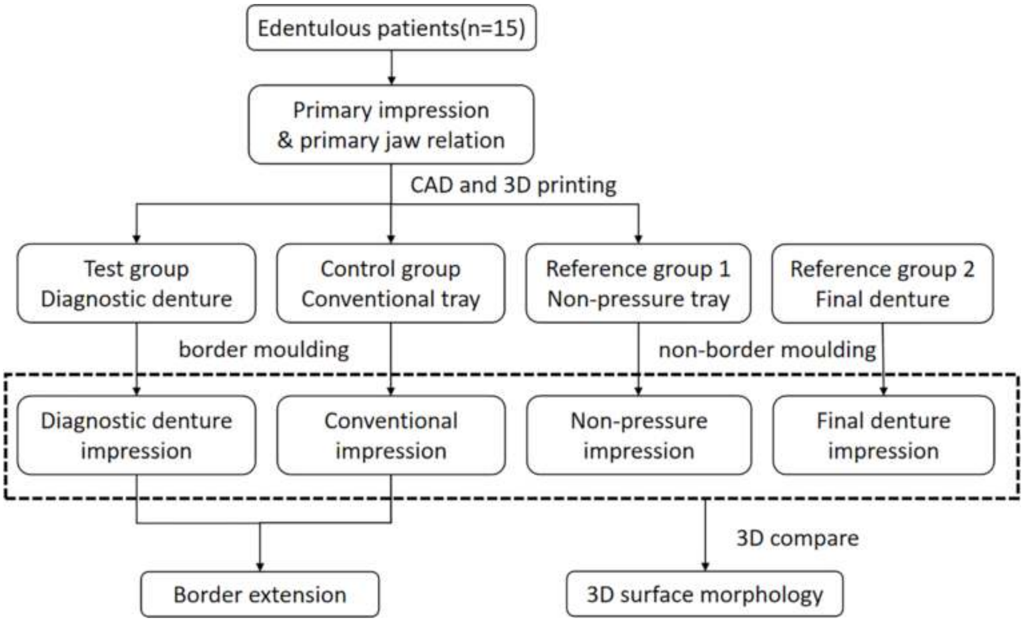

Fig. 1. Flow chart of the experiment.

Fig. 2. Primary impression and primary jaw relation record.
Primary upper impression, (b) primary jaw relationship, and (c) aesthetic information.

Dental Material Corporation). Light body silicone rubber was then used to make a final impression (Type 3, Shandong Huge Dental Material Corporation) (Fig. 5). Impressions made by diagnostic dentures should use the patient's own occlusion; therefore, a balanced occlusion is necessary before impression making. Any occlusal error can be adjusted by grinding the teeth. To obtain the true state of the vestibule and fraenulum during mastication, border moulding should be performed by the patient's own movement, and any passive border moulding with clinician's fingers should be avoided. The border moulding procedure was not performed with non-pressure trays to minimise the pressure on the mucosa. To ensure consistency of the experimental conditions, impressions of the same patient were performed by one dentist in half of a day, and the patient was asked to rest sufficiently between the two operations to allow the oral mucosa to return to its anatomical form. The impressions made by the diagnostic dentures and conventional custom trays were used to create two pairs of dentures for the patient. When the dentures were delivered, one of the two dentures was randomly selected as the tray to make a closed-mouth impression in the occlusion state using light-body silicone rubber. All impressions were scanned to generate 3D data for subsequent morphological analysis.

2.4. 3D data analysis

The data for the four types of impressions were imported into Geomagic. The 3D data were processed preliminarily, including smoothing of the exposed tissue stop area and small bubbles. The non-pressure and final denture impressions were set as the reference data, and the diagnostic denture impression and conventional impression were set as the test data. The best-fit alignment was used to align the data, and then 3D compare commands were performed to analyse the intaglio surface morphology differences. Because of the elimination of the border moulding procedure in the non-pressure tray and final denture groups (no border moulding space in the margin of the denture base), the margin area was not included in the calculations. Furthermore, the maxillary impression was divided into four areas: primary stress-bearing area, secondary stress-bearing area, relief area, and palatal vault. The lower impression was divided into a primary stress-bearing area and secondary stress-bearing area (Fig. 6). To ensure consistency of the analysis area in the same patient, the area boundary drawn on one data point was projected onto the other compared data, after data alignment. In the 3D deviation analysis result, the root mean square (RMS) value, which represents the arithmetic mean of the squares of a group of values, was recorded to avoid positive and negative offsets in the average distance.

Diagnostic denture impressions and conventional impressions were imported into the software (Geomagic Qualify 2013, Raindrop Geomagic) for border area analysis. Conventional impressions were used as the reference data, and diagnostic denture impressions were used as the

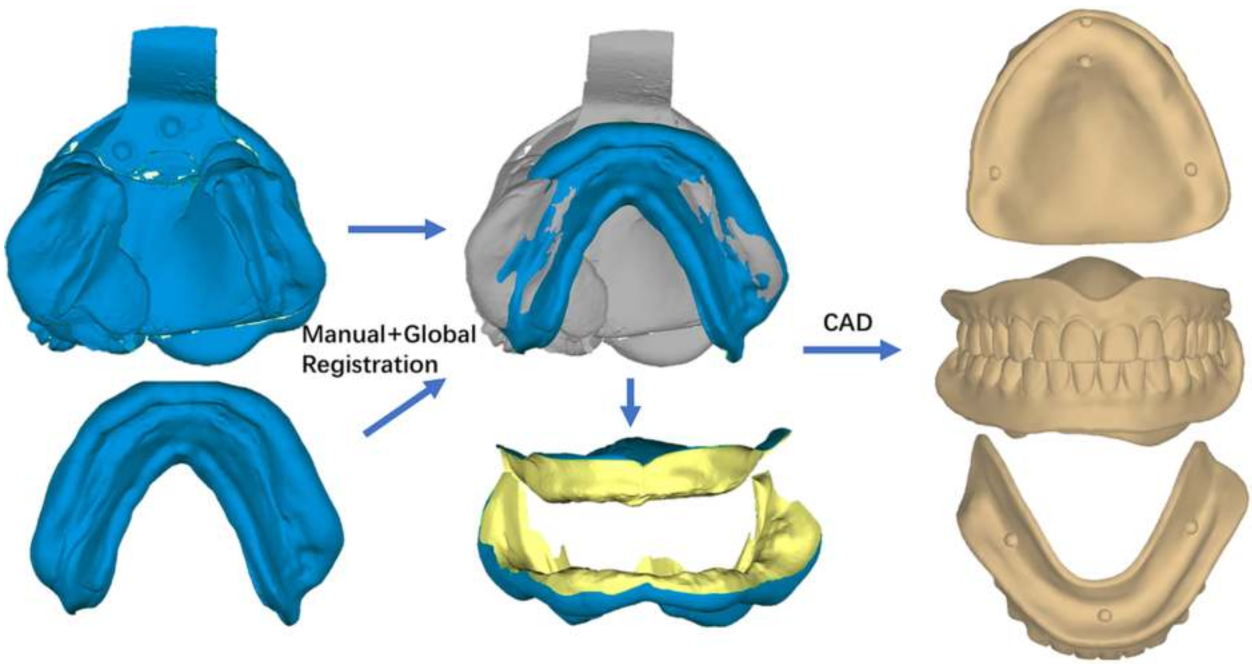

Fig. 3. Design of diagnostic dentures.

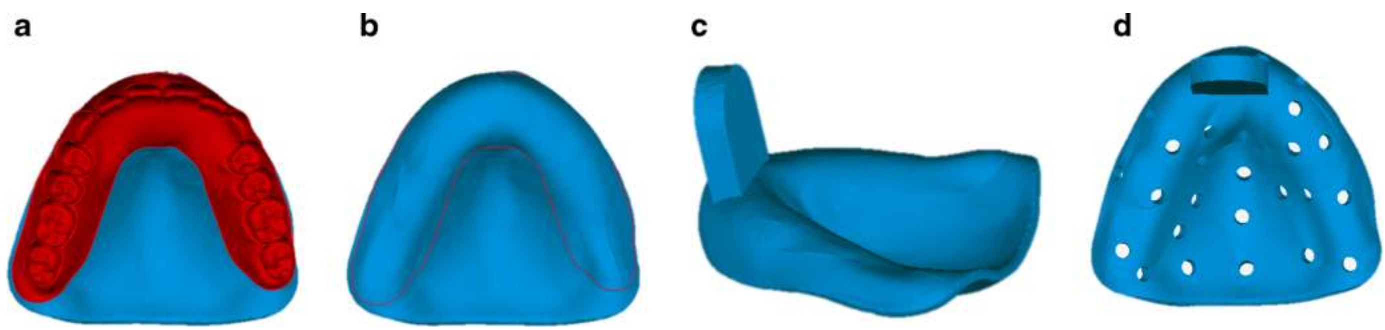

Fig. 4. The design of conventional custom tray and non-pressure tray (upper jaw).
(a) Selection of the dentition part of the diagnostic denture; (b) deletion of the selected part and filling of the deleted patch; (c) importing the tray handle; (d) complete vent holes designed on the tray.

test data. Global registration was used for the data alignment. Border extension curves of impressions were obtained using a pre-constructed plane section view of the position of the canine and first molar (Fig. 7). The distance between the curve vertex of the test and reference data was measured using these cross-sectional views. A positive value indicated that the border extension range of the diagnostic denture impression (test data) was greater, whereas a negative value indicated that the border extension range of the conventional impression (reference data) was greater.

2.5. Statistical analysis

The 3D surface morphology data, including the total area and segmented areas, were entered into a statistical software (IBM SPSS Statistics 20, IBM). Normality testing was performed before the data analysis. A paired *t*-test was used if the data were normally distributed; otherwise, Wilcoxon's signed-rank test was used.

The measurements of border extension were analysed using SPSS Statistics software and classified according to different areas. The anterior and posterior areas were analysed, in which values on the same side of the same jaw were matched for statistical analysis. The buccal and lingual sides of the mandible were analysed and the two sides of the same section were matched for statistical analysis. A paired *t*-test was used if the data were normally distributed; otherwise, Wilcoxon's signed-rank test was used. Additionally, the maxilla and mandible were analysed, and an independent-samples *t*-test was used if the data were normally distributed. Otherwise, the Mann–Whitney U test was used.

3. Results

According to the Atwood classification, the 15 completely edentulous patients included five class I maxillary patients, nine class II maxillary patients, and one class III patient. In addition, three class I mandibular patients, eleven class II mandibular patients, and one class III patient were included.

3.1. 3D surface morphology

Using the final denture impression as a reference, a paired *t*-test was performed for statistical analysis (Shapiro–Wilk (S-W) test, $P > 0.05$). According to the average RMS value, the diagnostic denture impressions were closer to the reference than the conventional impressions, and only a significant difference was noted in the secondary stress-bearing area (Table 1). Using the non-pressure impression as a reference, Wilcoxon's

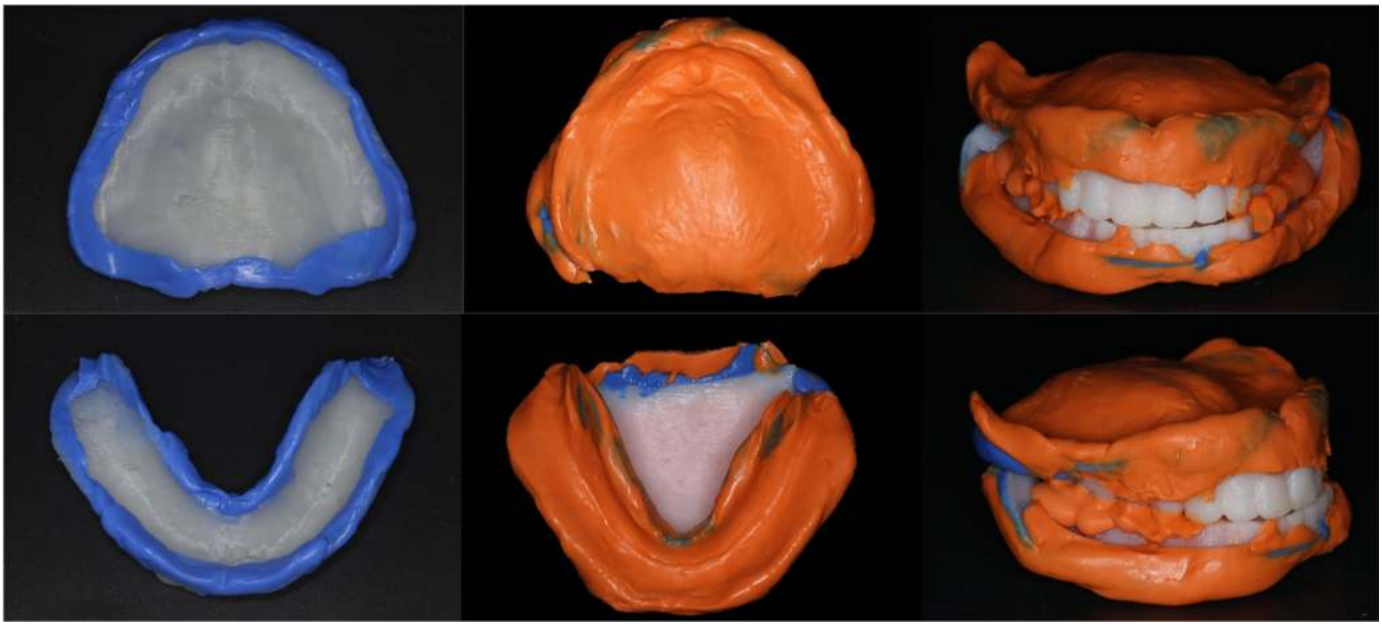

Fig. 5. Border moulding and final impression made by diagnostic dentures.

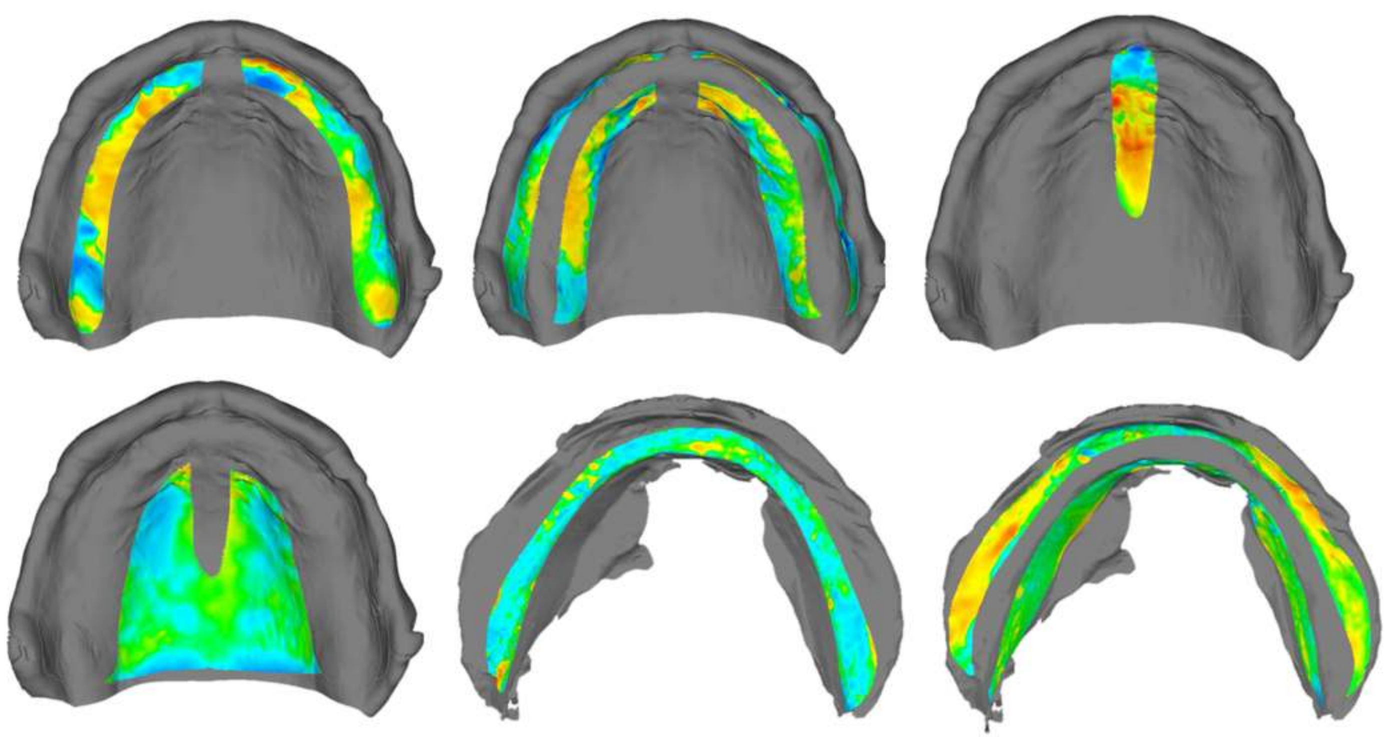

Fig. 6. 3D comparison and division of maxillary and mandibular impressions.

signed-rank test was used for statistical analysis (S-W test, $P < 0.05$). Conventional impressions were closer to the reference, with a significant difference observed in the secondary stress-bearing area of the lower jaw (Table 1).

3.2. Border extension

A positive value indicated that the diagnostic denture impression had a larger extension, whereas a negative value indicated a shorter extension. The mean distances measured at all sites were within $\pm$ 1 mm, with negative values on the buccal and lingual sides of the left canine and on the buccal side of the left molar. However, the difference was significant in terms of a single value, with some reaching 3 mm (Fig. 8). A paired *t*-test was used (Kolmogorov–Smirnov (K-S) test, $P > 0.05$) to analyse the difference between the anterior and posterior areas. Based on the mean value, the posterior area was larger than the anterior area (Table 2). This finding indicates that when making impressions, the posterior area could have a larger extension when diagnostic dentures are used. However, this difference was not statistically significant. A paired *t*-test (K-S test, $P > 0.05$) was used to analyse the differences between the buccal and lingual sides of the mandible. The results showed that the lingual side was significantly longer than the buccal side (Table 2),

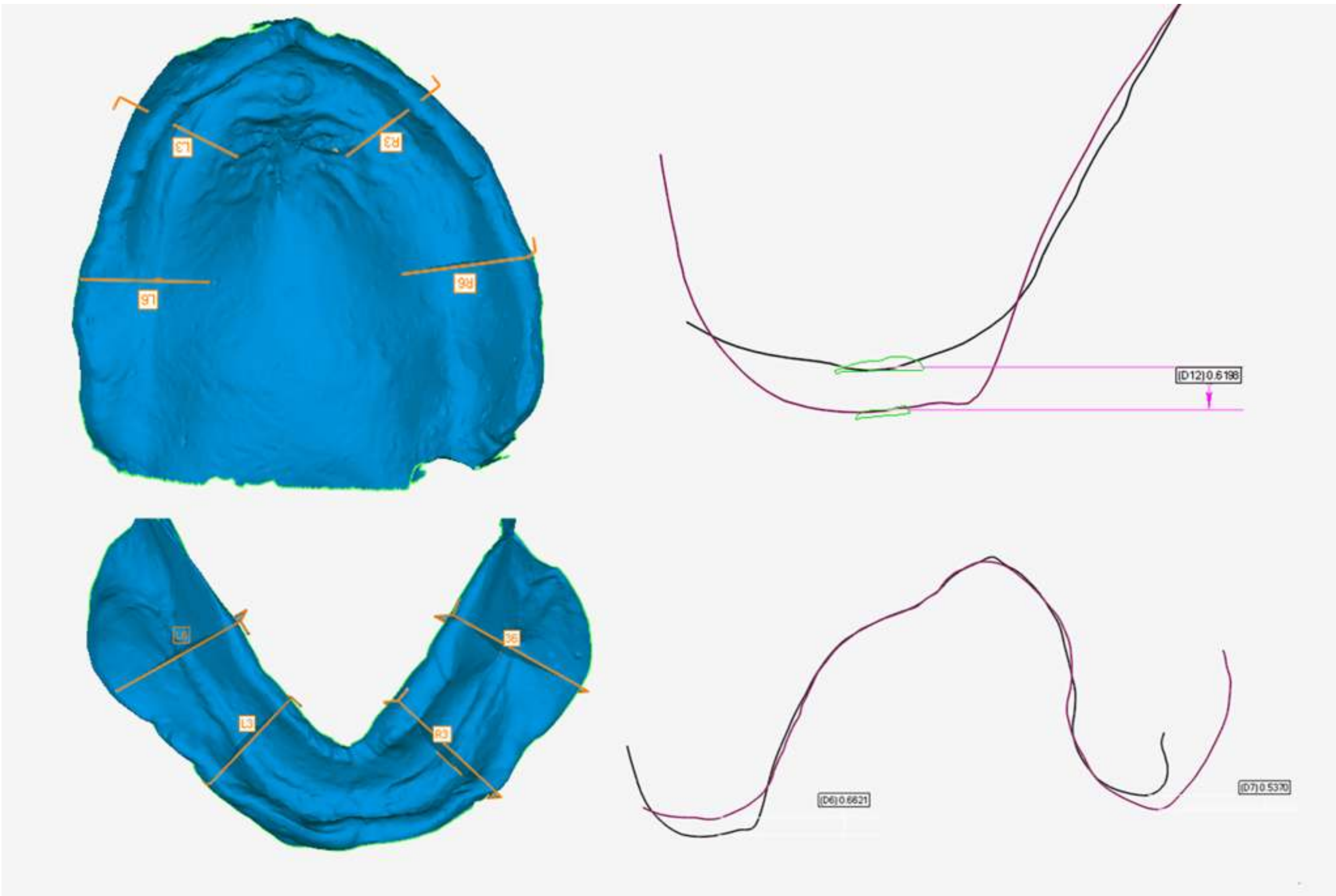

Fig. 7. Impression border extension analysis: construct planes on both sides of the upper and lower jaw impression to extract the boundary for analysis.

Table 1
3D comparison of impressions made from different trays (mm).

Regions		Reference: Final denture impression			Reference: Non-pressure impression		
		Diagnostic denture	Conventional custom tray	*P*	Diagnostic denture	Conventional custom tray	*P*
Upper jaw	Total area	0.146±0.024	0.176±0.047	0.056	0.17±0.046	0.165±0.059	0.551
	Primary stress-bearing area	0.143±0.033	0.145±0.042	0.892	0.158±0.066	0.153±0.077	0.670
	Secondary stress-bearing area	0.154±0.036	0.192±0.064	0.048*	0.175±0.053	0.167±0.075	0.551
	Relief area	0.123±0.033	0.148±0.056	0.104	0.155±0.056	0.16±0.083	0.394
	Palatal vault	0.142±0.03	0.174±0.069	0.163	0.169±0.053	0.161±0.043	0.478
Lower jaw	Total area	0.153±0.046	0.187±0.063	0.062	0.198±0.064	0.181±0.057	0.079
	Primary stress-bearing area	0.149±0.046	0.179±0.07	0.189	0.184±0.058	0.171±0.059	0.363
	Secondary stress-bearing area	0.154±0.048	0.189±0.061	0.039*	0.203±0.069	0.184±0.058	0.044*

* The difference was statistically significant ($P < 0.05$).

indicating that diagnostic dentures could have a larger border extension deviation on the lingual side. An independent-samples *t*-test (K-S test, $P > 0.05$) was used to analyse data from the maxilla and mandible, and no significant differences were found.

4. Discussion

A new closed-mouth tray, called a diagnostic denture, with the shape of a complete denture, was proposed. When it was used as a tray to make impression, the design of the intaglio surface is the key point. The relief space or holes provided for impression material overflow can significantly reduce the pressure [19,20], and a selective pressure impression is recommended for edentulous impressions [21]. Therefore, in this study, 1 mm of impression material space was reserved on the intaglio surface in the design of custom trays, and vent holes were designed on the non-pressure custom tray to minimise pressure reduction. Because the same intaglio surface design was used for diagnostic dentures and conventional custom trays, the difference between the two impressions mainly lies in the method by which the impressions were made, that is, open- or closed-mouth. Rignon-Bret [22] used a complete denture as a custom tray to make a closed-mouth impression, and found that the thickness of this impression was more uniform compared with open-mouth impression, and the force applied in the occlusal state was perpendicular to the occlusion plane and concentrated on the posterior one-third of the area, which is consistent with the masticatory force direction. Therefore, it was suggested that the occlusal force of the patient should be used whenever the upper tray adapts to the occlusion. This is similar to the concept of the diagnostic dentures designed in this study. Specifically, the patient's bite force should be used to make an impression to simulate the stress state of the patient's mastication so that

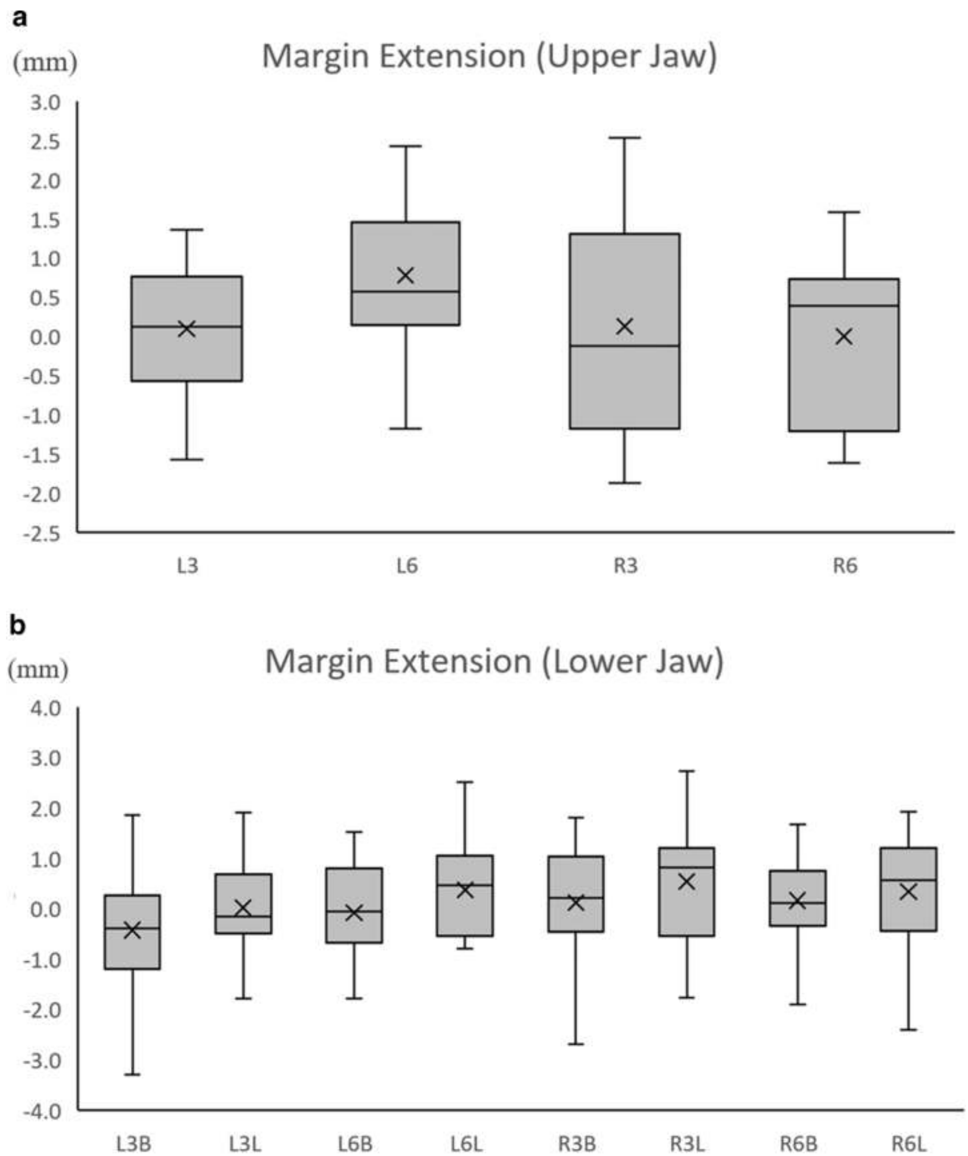

Fig. 8. The border extension of the impression of the (a) upper jaw and (b) lower jaw.
L3, left canine position; L6, left first molar position; R3, right canine position; R6, right first molar position; B, buccal side; L, lingual side.

Table 2
The difference in border extension in different areas.

Position	Mean value (mm)	Standard deviation (mm)	t	df	*P*
Canine	0.04	1.14	−1.641	89	0.104
First molar	0.24	1.01			
Buccal side	−0.10	1.05	−2.299	59	0.025 *
Lingual side	0.28	1.08			
Upper jaw	0.25	1.08	0.94	178	0.348
Lower jaw	0.09	1.08			

* The difference was statistically significant ($P < 0.05$).

the denture fabricated based on this impression has better performance.

In this study, pressure impressions and non-pressure impressions were used to evaluate the difference between impressions made by diagnostic dentures and conventional custom trays. According to the results of the 3D comparison analysis, the diagnostic denture impression was more similar to the impression made by the denture and less similar to the non-pressure impression. This finding suggests that the stress distribution of the alveolar ridge mucosa may be similar to that of complete dentures when making impressions with diagnostic dentures. Furthermore, the analysis of different areas showed a significant difference exclusively in the secondary stress bearing area. Thus, the null hypothesis of this study was rejected. This may be because the mucosa of the secondary stress-bearing area is softer and more prone to displacement under pressure, resulting in a larger deviation compared to other areas. Jung et al. [23] designed an improved closed custom tray and performed a 3D comparison with impressions made by conventional open-mouth custom trays. The results showed that the average mean values of different areas were between 0.03 mm and 0.34 mm, and no significant difference was noted between the two impressions. Zarone et al. [24] compared the differences of different impression materials in making edentulous jaw impression, and the three-dimensional deviation analysis results of the impression were between 0.2 and 0.3 mm. These values are similar to those obtained in this study. To date, no consensus has been reached regarding the accuracy of clinically acceptable edentulous impression. Satoshi [25] showed that after complete denture insertion, the denture base sinks by approximately 0.3 mm when force is applied in the occlusal direction. Therefore, an average 0.3-mm impression deviation is considered acceptable [26].

Border moulding is a key point in the border sealing of dentures. It is generally believed that compared with passive muscle function border moulding, active methods can obtain the true masticated state of the oral vestibule. When using a diagnostic denture, the patient's bite force stabilizes the denture in the mouth, making it easier to perform border moulding without external interference. The lingual side of the diagnostic denture impression was longer than the buccal side, and the difference was statistically significant. This finding could be related to the time and opening/closing state of impressions made using different methods. When making impressions using diagnostic dentures, the tongue fraenulum and surrounding soft tissues were first border-moulded, and then the patient was instructed to bite in a closed state for buccal muscle border moulding. At this time, the patient's tongue was relaxed in a lower position when the mouth was closed, and the impression material still had a certain fluidity, which might have caused extension on the lingual side. When making the mandibular impression using a conventional custom tray, it was held by the dentist's hand. Even if the patient ceases lingual moulding and starts labiobuccal moulding, the tongue may not be completely relaxed in a low position, thereby leading to a relatively short extension. The other measurement points were not statistically different; however, the impressions made by the diagnostic dentures were generally slightly longer than the conventional impressions, which might have been caused by excessive passive border moulding of the open custom trays or the patient's insufficient active muscle function in the closed state. This outcome suggests that, when making a closed-mouth impression, the patient must be instructed to perform muscle movement exercises adequately and exercise in advance if necessary to avoid excessive extension.

Due to the large individual differences in edentulous patients, the impression-making technique also exhibits instability. Additional verification, such as evaluation of the clinical effect of dentures fabricated based on impressions made by diagnostic dentures, is still needed. This study offers guidance for clinical practice. If primary impressions and jaw relations can be obtained during the first visit of edentulous patients, regardless of how these impressions are obtained, the diagnostic denture proposed in this study can be designed and used as a substitute for impression making, jaw relation recording, and try-in denture in conventional complete denture restoration, allowing patients to complete these three steps in one visit.

Although more and more studies have focused on intraoral scanning, it may allow young and less experienced dentists to master edentulous impressions. Nevertheless, owing to the limitation of its principle, intraoral scanning cannot obtain the shape of the vestibular sulcus and the state of slight pressure on the mucosa [27]. For patients with a high alveolar ridge, this methodology could be used to fabricate acceptable maxillary dentures given its relatively low requirement of border sealing, but it cannot be used to fabricate mandibular dentures [28]. Therefore, intraoral scans are currently recommended to obtain primary impressions of edentulous jaws [27]. Final impressions still need to be made using physical trays, and additional tray designs should be further studied and verified.

5. Conclusions

A novel closed-mouth custom tray (diagnostic denture) was digitally designed to make impressions for complete denture restoration. When using the impressions made with the complete denture as a reference, it was seen that the 3D morphology of the impressions made using diagnostic dentures was closer to the reference than conventional impressions. However, no significant differences were noted compared with the conventional impression. A digitally fabricated diagnostic denture can potentially be used to make final impressions in a clinical setting to reduce the number of visits and improve the efficiency of complete denture treatment.

CRediT authorship contribution statement

Kehui Deng: Writing – original draft, Data curation. **Hu Chen:** Software, Writing – review & editing. **Yong Wang:** Validation, Investigation. **Yongsheng Zhou:** Supervision, Project administration. **Yuchun Sun:** Conceptualization, Methodology.

Declaration of Competing Interest

The authors have no financial conflicts of interest.

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