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CLINICAL RESEARCH

Accuracy and feasibility of 3D-printed custom open trays for impressions of multiple implants: A self-controlled clinical trial

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ABSTRACT

Statement of problem. Three-dimensionally printed custom open trays have become a popular option in clinical implant dentistry because of advantages such as individualization, efficiency, and effectiveness. However, clinical evidence on their accuracy and feasibility is lacking.

Purpose. The purpose of this clinical study was to evaluate the accuracy and feasibility for impressions of multiple implants by using 3D-printed custom open trays versus conventional custom open trays.

Material and methods. Twenty-two partially edentulous individuals needing impression making for restorations supported by multiple implants were enrolled. Two types of custom open trays were made for each participant, a 3D-printed tray (test) and a conventional tray (control). With a splinted technique, silicone definitive impressions were obtained with the 2 custom open trays and poured with Type IV dental stone. Impression accuracy (primary outcome) was evaluated by measuring linear distances and the marginal gaps between the implant replicas and verification devices on the test and control casts. Clinical tray fit, impression quality, and cast quality were rated by an independent technician through a visual analog scale (VAS). The fabrication time and cost of the 2 types of custom open trays were recorded. The feasibility of 3D-printed trays was determined from these outcomes. The paired Student *t* test and Wilcoxon rank-sum tests were used for statistical analysis (α=.05).

Results. For impression accuracy, no statistically significant difference was found between test and control groups (P>.05). In terms of clinical tray fit, impression quality, and cast quality, no statistically significant difference was found (all P>.05). Regarding fabrication time and cost, the test group (57.65 ±6.49 minutes, 0.37 ±0.07 United States dollars [USD]) exhibited superiority over the control group (101.96 ±2.92 minutes, 4.41 ±0.37 USD) (both P<.001).

Conclusions. Within the limitations of this study, the 3D-printed custom open trays were clinically accurate, efficient, and cost-effective for impressions of multiple implants. (J Prosthet Dent 2022;128:396-403)

An accurate impression is essential for the fabrication of a precisely fitting implant-supported prosthesis, which is critical for the long-term success of the restoration.[1-6] Impression accuracy is affected by impression technique,[7-10] impression material,[11] impression coping design,[12,13] the type of impression tray,[14-18] and the experience of the operator.[19] The impression material should be tightly bonded to the tray, which should be sufficiently rigid to support the dental stone without deformation.[18] Therefore, proper tray design is a prerequisite for an accurate impression and a resulting accurate cast.[14,15,20] Impressions of multiple implants require a more precise and meticulous impression-making technique,[7,21,22] and the open tray and splinted technique have been advocated in recent systematic reviews.[7,21,23,24]

Conventionally, to obtain splinted impressions, open trays are made by dental laboratory technicians on diagnostic casts. The procedure is time-consuming and labor-intensive, cast storage is problematic,[25,26] and a diagnostic impression usually requires a dedicated visit, prolonging the prosthetic workflow. The actual clinical utilization rate of custom trays has been reported to be limited.[20,27] With the growing demand for dental

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Clinical Implications

The 3D-printed custom open tray is a feasible alternative to the conventional custom open tray and should be considered for dental practice.

implants worldwide, a simplified and efficient method of making custom open trays is needed to expedite clinical practice.

The use of 3D-printing technology has become popular in dentistry,[25,28-32] and 3D-printed custom open trays have been described.[33-36] From an in vitro study, Liu et al[25] reported that the accuracy of 3D-printed custom open trays (polylactic acid, PLA) for multiple implants was slightly better than that of conventional custom open trays (light-polymerized acrylic resin). However, the authors are unaware of a clinical investigation on the accuracy and feasibility of 3D-printed custom open trays for multiple implants.

The purpose of the present clinical study was to compare the impression accuracy of multiple implants made with 3D-printed custom open trays with that of conventional custom open trays. To determine the clinical feasibility of 3D-printed custom open trays comprehensively, the clinical tray fit, impression quality, cast quality, fabrication time, and cost were all compared. The null hypothesis was that no significant difference would be found in accuracy and feasibility between 3D-printed custom open trays and conventional custom open trays for impressions of multiple implants.

MATERIAL AND METHODS

This prospective self-controlled, comparative clinical trial was conducted from September 2018 to December 2019 at Peking University School and Hospital of Stomatology, Department of Oral Implantology. Ethical approval was granted by the School and Hospital of Stomatology, Peking University (PKUSSIRB-201839138), and all participants provided informed consent. It was registered on the Chinese Clinical Trial Registry (ChiCTR1800015285). Twenty-two participants with healed multiple implants on the same arch (2 of whom had a single implant on the involved arch nonadjacent to the multiple implants to be restored) were enrolled. Sample size was based on a pilot study and the sample size chart for paired comparison.[37] The other inclusion criteria included no mobile teeth in the same jaw, normal mouth opening, and older than 18 years. The exclusion criteria comprised any teeth in the same jaw showing mobility 1 or higher, limited mouth opening, strong oropharyngeal reflex, undergoing orthodontic treatment, uncontrolled systemic disease, pregnancy or lactation, and poor compliance. The study design is illustrated in Figure 1. An 8-item visual analog scale (VAS) (Table 1), which was the rating reference of the clinical tray fit (item 1), the impression quality (item 2 to 6), and the cast quality (item 7, 8), had been developed before the trial based on pertinent literature.[38-41]

At the first appointment, 2 preliminary impressions, 1 implant-level and 1 healing abutment-level, were made with stock trays and polyvinyl siloxane (Silagum-Putty; DMG) for each participant. The implant-level impression was poured, and then a conventional custom open tray was fabricated on the diagnostic cast with light-polymerized urethane methacrylate resin (Lightplast-Platten; Dreve Dentamid GmbH). The latter was scanned (Ex-pro; Hangzhou Shining 3D), and then an open tray was digitally designed in a dedicated software program (SV Individual Tray; Hoteamsoft Co Ltd) based on the scan data. Then, a desktop fused deposition modeling (FDM) 3D-printer (Lingtong III; SHINOTECH) printed the tray from PLA (PLA; Beijing Baden Technology Co, Ltd), a renewable and biodegradable material.[42] The fabrication time and material cost of the 2 trays were recorded. The design procedures of the 3D-printed custom open trays are presented in Figure 2.

At the second appointment, after the fit of the 2 custom trays had been verified intraorally by using the VAS (Table 1), 2 silicone definitive impressions were made by using the open tray and splinted technique, as described previously.[25] The specified new nonengaging impression copings were connected with autopolymerizing acrylic resin (Pattern Resin; GC Corp) and sectioned 24 hours beforehand (For the 2 single implants, 2 engaging impression copings were used.). The manufacturer's recommendations for working and polymerization time were followed. The minimum time interval between the 2 impressions was 5 minutes. A pair of test and control impressions are seen in Figure 3. Additionally, left and right interocclusal records (Rapid soft; Coltène) were made (Fig. 4). A verification device having appropriate interproximal contacts was fabricated intraorally by resplinting another set of prepared nonengaging impression copings (Fig. 5A). After a designated dental laboratory technician (Qiang Hao) had assessed the 2 impressions with the VAS (Table 1), the 2 impressions were poured with Type IV dental stone (Fujirock EP; GC Corp) in a standard protocol.[25] The 2 definitive casts were inverted onto a glass slab to flatten the base after pouring. Then, the paired casts were rated with the VAS (Table 1).

Accuracy was assessed after the casts had been stored for 24 hours, including linear distance measurements and the marginal gaps between the implant replicas and verification devices on the test and control casts. First, 2 holes were drilled in each interocclusal record with a pointed-end bur (Fissure Carbide Bur HP; Shofu Inc), the record was repositioned on the cast, and 4 points were marked through the 4 holes (Fig. 4B): right-distal (RD),

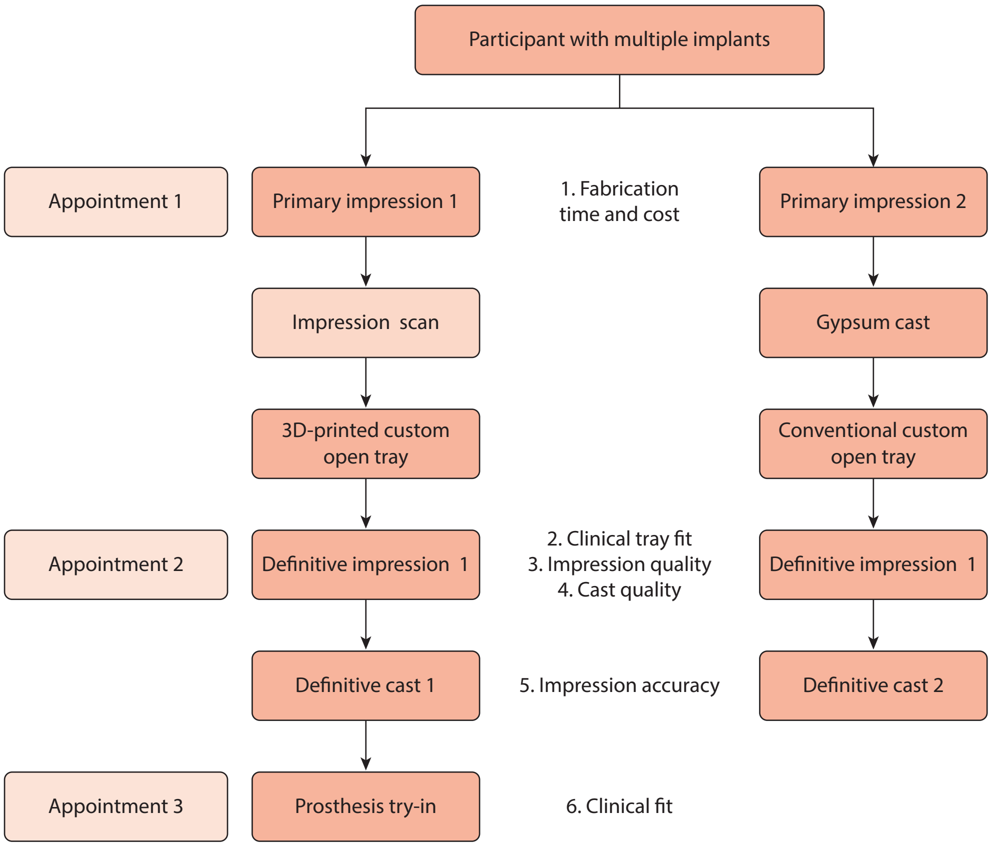

Figure 1. Study design.

right-mesial (RM), left-mesial (LM), and left-distal (LD). The cast was then placed on the operating platform of a calibrated stereomicroscope with a resolution of 1 μm (SmartScope MVP 200; Quality Vision International Inc), and distances were measured under ×48 magnification between RD-LD, RD-LM, RM-LD, and RM-LM (Fig. 3C). Measurement error of the method ranged from 8 to 12 μm (10 repeated measurements on 3 pairs of casts). After the passivity of the verification device had been verified on 2 corresponding casts with the aid of a reusable adhesive (Blu-tack; Bostik) and a microscope sample flattener (obtained from Leitz, now discontinued), the casts were laterally stabilized on a square glass plate and transferred onto the platform with the long axis of the posterior coping-replica complex parallel to the platform and perpendicular to the long axis of the stereomicroscope. The gap between the posterior unsecured impression coping and replica was measured at the buccal interface with the 1-screw test[43] under ×110 magnification (Fig. 5B). For each measurement, the mean of 10 repetitions was calculated and used as the value. Then, the casts were returned to the dental laboratory, and the prostheses were fabricated on the test casts. At the third appointment, the fit was verified both clinically and radiographically, and the prostheses were delivered to the participants.

Table 1. VAS for clinical tray fit, impression quality, and cast quality (1 to 10 numeric rating scale with anchors: 1, poor; 5, good; 10, excellent)

Items
1. Clinical tray fit
2. Bonding between tray and impression material
3. Completeness, clearness of impression
4. Stability of impression copings
5. Tears, voids, or bubbles
6. Potential of multiple pouring
7. Completeness and clearness of cast
8. Stability of implant replicas

VAS, visual analog scale.

All the clinical procedures were performed by an experienced prosthodontist (P.D.), and all the laboratory work was done by a certified dental laboratory technician (Zhichun Zhang), in an environment with a temperature of 23 ±2 °C and a humidity of 50% ±10%. All the impressions and casts were scored by another experienced dental laboratory technician (Qiang Hao). All the 3D-printed custom trays were designed by a postgraduate dental student (X.Y.). All the accuracy measurements were made by an experienced examiner (Y. Li).

A statistical analysis was implemented by using a software program (IBM SPSS Statistics, v20.0; IBM Corp) (α=.05). Differences in the interlandmark

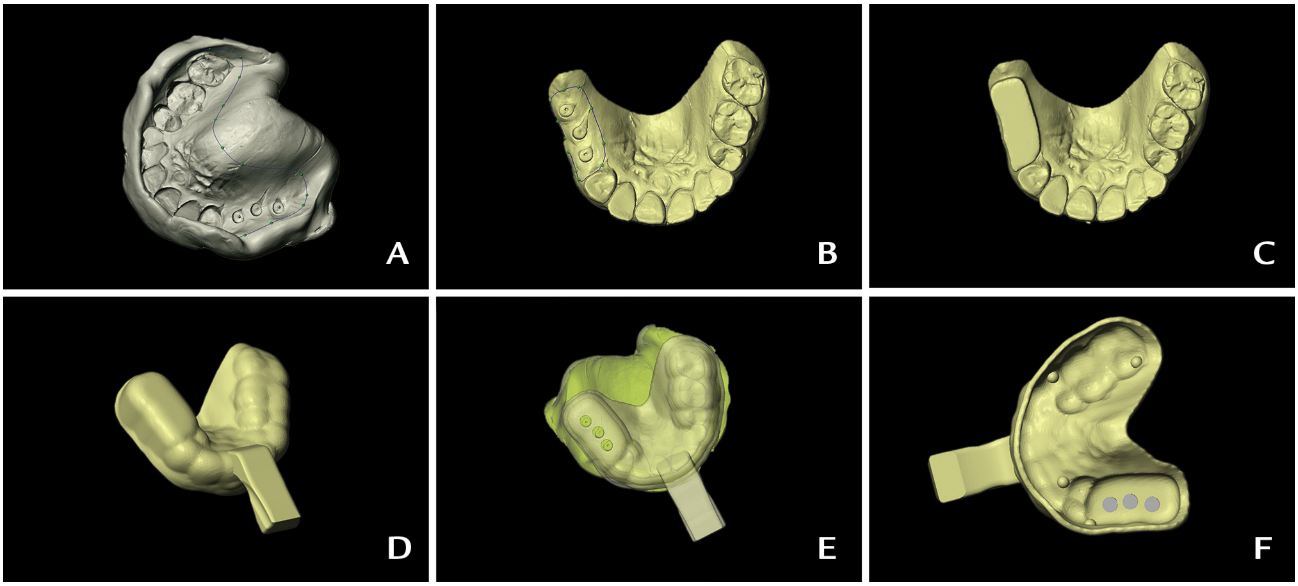

Figure 2. Design procedures of 3D-printed custom open tray. A, Extract boundary line. B, Circle implant area. C, Elevate implant area. D, Create tray. E, Make holes corresponding to impression copings. F, Add tissue stops.

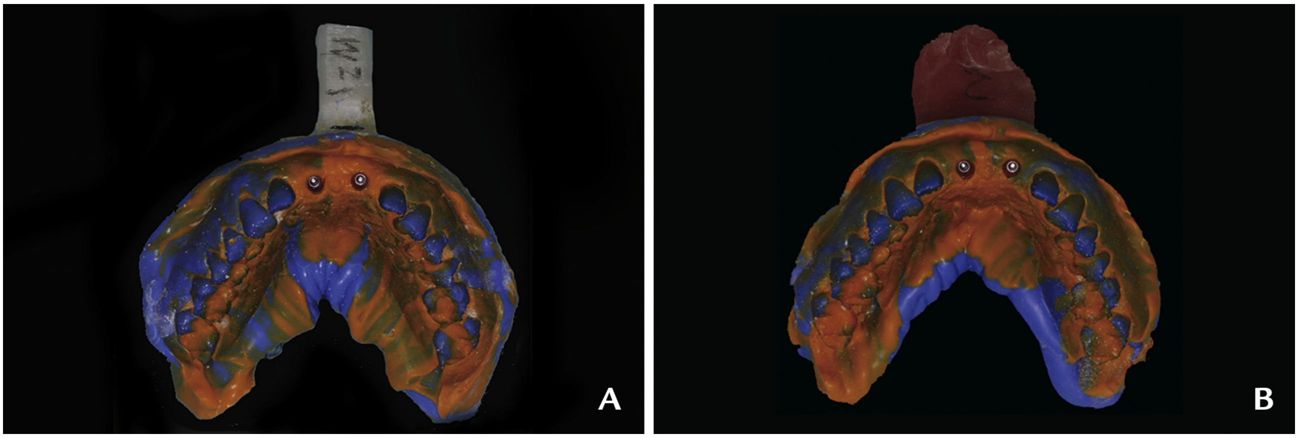

Figure 3. Paired definitive impressions. A, Impression made with 3D-printed custom open tray. B, Impression made with conventional custom open tray.

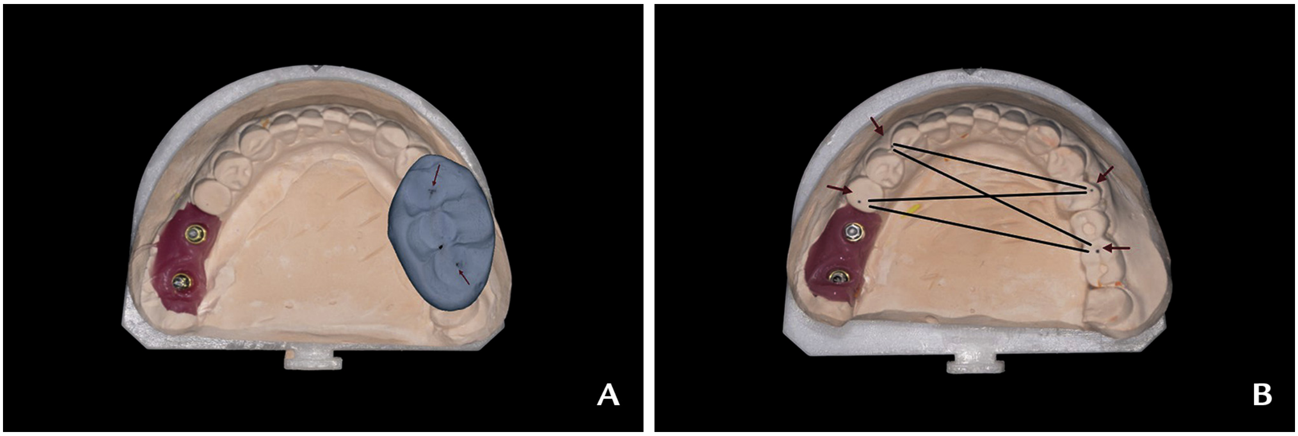

Figure 4. Interlandmark linear distance measurement. A, Repositioned interocclusal record. *Red arrows* indicate drilled holes. B, Landmarks marked (*red arrows*).

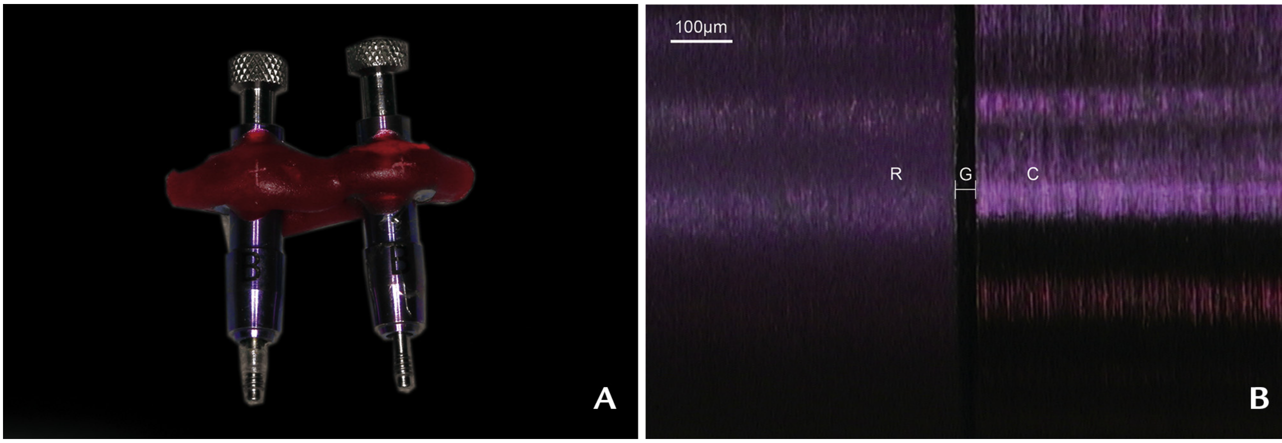

Figure 5. Marginal gap measurement of coping-replica specimen. A, Verification device. B, Stereomicroscope image of coping-replica interface (original magnification ×110). C, impression coping; G, marginal gap; R, implant replica.

distances were assessed by paired Student *t* test after Shapiro-Wilk tests had evaluated the normality of the data. The intraclass correlation coefficient (ICC) was used to assess the consistency between paired inter-landmark distances of the test and control groups. The Wilcoxon rank-sum test was used to evaluate the secondary outcomes: clinical tray fit, impression quality, cast quality, fabrication time, and cost (α=.05).

RESULTS

The descriptive data of participants are shown in Table 2. All prostheses showed adequate clinical fit and were delivered without complications.

The Shapiro-Wilk test indicated normality (P>.05) for the linear distances across both groups. The differences (test minus control) ranged from -25 μm to 37 μm, and the average of absolute differences was 15.4 μm (Fig. 6). The paired Student *t* test showed no significant differences between the 2 groups (P>.05) (Table 3). High ICC values further demonstrated strong consistency between the 2 groups (Table 4). Twenty-five verification devices attained passivity on both test and control casts. No statistical difference in marginal gaps was found between the test group (31 ±3 μm) and control group (32 ±3 μm) (P>.05) (The 2 Camlog verification devices were excluded in gap measurement for homogeneity.). For clinical tray fit, impression quality, and cast quality, the differences were not statistically significant (all P>.05) (Table 5).

The fabrication time difference of the test (57.65 ±6.49 minutes) and control group (101.96 ±2.92 minutes) was statistically significant (P<.001) (Fig. 7A). The cost was significantly lower in the test group (0.37 ±0.07 United States dollars [USD]) than that in the control group (4.41 ±0.37 USD) (P<.001) (Fig. 7B).

Table 2. Description of participant data

Parameter	Participants (N=22)
Mean ±SD age	53 ±10 years
Sex ratio	41% men
Dental arch	Maxilla 10, mandible 13
Implant site	M 32, PM 21, IC 4
Implant System	NA 53, C 5
Prothesis design	Splinted crown 25 (NA 23, C 2) Single crown 2 (NA 1, C 1)

C, Camlog; IC, incisors; M, molar; NA, Nobel Active; PM, premolar; SD, standard deviation.

DISCUSSION

Based on the results of the study, the null hypothesis that no significant difference would be found in accuracy and feasibility between 3D-printed custom open trays and conventional custom open trays for impressions of multiple implants was accepted.

The comparable accuracy of the 2 types of custom open trays shown in this study was consistent with that of Liu et al,[25] who reported that the mechanical strength of PLA and the bond to the impression materials were excellent. The clinical fit of the prostheses fabricated on test casts was supplementary evidence for the accuracy of the 3D-printed custom open trays. Chen et al[31] and Sun et al[32] reported that impression thickness with 3D-printed custom trays was more uniform than that with conventional custom trays, which improved impression accuracy. The satisfactory clinical accuracy and performance of the 3D-printed custom trays in the present study was consistent with these reported characteristics.[25,31,32]

Research on the accuracy of impression trays has been with in vitro experiments and is sparse, and the authors are unaware of clinical trials on the newly developed 3D-printed custom open trays. Assessments have included linear deviation, angular deviation, 3D surface deviation,

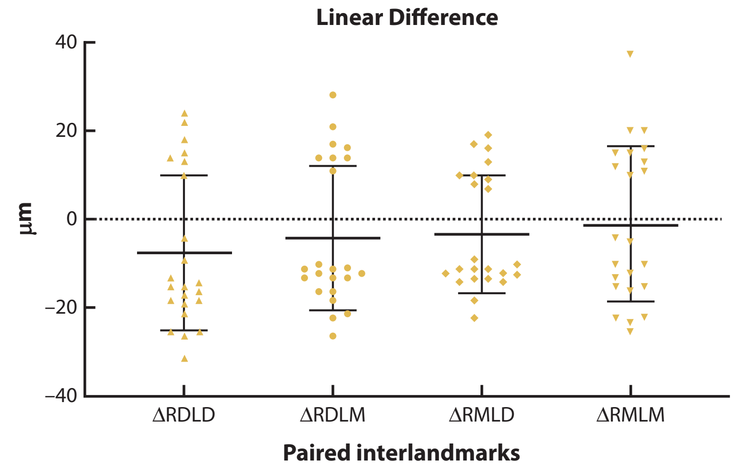

Figure 6. Linear difference distribution (mean ±standard deviation) of 4 interlandmark distance (test minus control). Control, conventional custom open tray; Test, 3D-printed custom open tray.

Table 3. Mean ±SD linear difference between test and control casts for 4 interlandmark distances (μm)

Paired Interlandmarks	Mean ±SD	$Mean_{ABS}$ ±SD	*P*
RD-LD	-7.36 ±17.33	17.48 ±6.19	.082
RD-LM	-3.91 ±16.27	15.65 ±4.95	.877
RM-LD	-3.17 ±13.06	12.65 ±3.70	.332
RM-LM	-1.00 ±17.54	15.69 ±7.15	.787

ABS, absolute value; control, conventional custom open tray; LD, left distal point; LM, left mesial point; RD, right distal point; RM, right mesial point; SD, standard deviation; test, 3D-printed custom open tray.

Table 4. Consistency between test casts and control casts for 4 interlandmark distances

Consistency	RD-LD	RD-LM	RM-LD	RM-LM
ICC	1.000	1.000	0.989	1.000

ICC, intraclass correlation coefficient; LD, left distal point; LM, left mesial point; RD, right distal point; RM, right mesial point.

Table 5. Evaluation of clinical tray fit, impression quality, and cast quality (full score of "clinical tray fit," "impression quality," and "cast quality" was 10, 50, 20)

Rating Item	Test	Control	*P*
Clinical tray fit	8.91 ±2.11	9.57 ±1.44	.180
Impression quality	43.48 ±2.35	42.83 ±2.53	.317
Cast quality	18.04 ±2.50	17.83 ±2.53	.763

Control, conventional custom open tray; Test, 3D-printed custom open tray.

marginal misfit, and strain analysis, of which linear deviation has been preferred.[21,23,24] In previous studies, reference points were either determined by geometric features or artificially made on models, and distances were measured by using equipment with different resolution, including digital calipers,[30] microscopes,[10,17] profile projectors,[13] and scanners.[19] Damodara et al[14] measured linear distance between anatomic locations on dental casts, reporting a measurement error of approximately 14 μm. Hansen et al[17] measured reference points on a reference model, reporting an error range of 4 to 25 μm. Vigolo et al[13] used landmarks based on geometric features, reporting an ICC of 0.978. However, it was difficult to make landmarks in the participant's mouth in the present clinical trial, and the anatomic locations of the teeth or oral cavity were not always consistent. Under such circumstances, repositioned interocclusal records were adopted to mark reference points. The measurement error of this study ranged from 8 to 12 μm, comparable with that of previous studies.[13,14,17] Additionally, the ICC above 0.98 also indicated that the method was reliable.

The marginal misfit between components has been another standard accuracy assessment method, typically by measuring the gaps between superstructures and implants.[6,9] However, the present study was designed to evaluate the impression tray type, independent of the subsequent superstructure fabrication. For a straightforward comparison, nonengaging impression copings were connected intraorally to be verification devices, wherein each coping and matched replica constituted a specimen exhibiting a vertical gap between the mating surfaces (Fig. 4B).

The predominant implants used were Nobel Active (conical connection). As the purpose of the study was to investigate whether the impression tray type influenced impression accuracy, mainly assessed by linear distances on casts, 2 participants with 5 Camlog implants (tube-in-tube internal connection) were also enrolled. The gap measurement between components was not measured because if differs with different implant systems to some extent.

The 3D-printed custom open tray is more time-efficient, less labor intensive, and less expensive and is made with a renewable material. These qualities were reported in a clinical trial similar to the present study.[29]

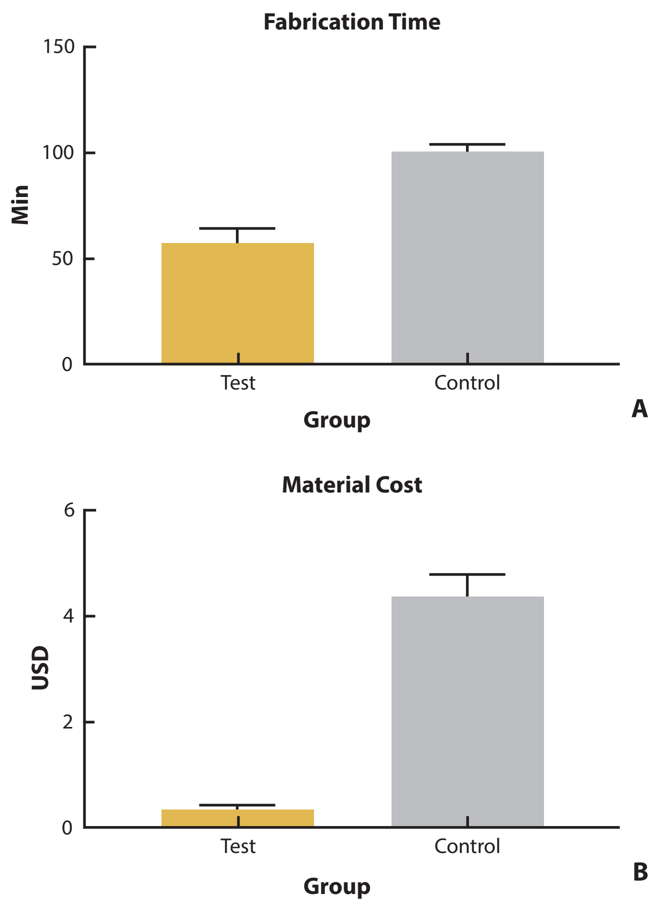

Figure 7. Tray fabrication comparison of test and control group (mean ±standard deviation). A, Fabrication time; B, Material cost. Control, conventional custom open tray; min, minutes; Test, 3D-printed custom open tray.

In view of the design of a 3D-printed custom tray, the workflow in the present study was simplified and time-efficient, taking a skilled operator about 3 to 7 minutes with the dedicated software program. In previous reports,[33-35] the preliminary impression needed pouring and the custom open tray design made with the physical diagnostic cast. Moreover, the procedures used in those reports required switching between different sophisticated software programs, additional time, and a longer learning curve. The workflow described by Li et al[36] was based on digital implant plan data and only applicable to patients who had received computer-assisted implant surgery. In the present workflow, no additional data or preparation were needed, a convenient healing-abutment level preliminary impression initiated the custom open tray, and a definitive impression could be made 1 hour later at the same visit. This user-friendly workflow for 3D-printed custom open tray could be applicable for different clinical circumstances, regardless of implant location or system.

The definitive impression could be made at the same appointment as for the preliminary impression, eliminating an additional visit for definitive impression making. Additionally, the laboratory steps and the prosthetic workflow could be streamlined and expedited, with improved patient acceptance and satisfaction with the decreased associated costs, appointments, and shortened treatment time.

This study compared tray fabrication, clinical performance, and accuracy between 3D-printed custom trays and conventional custom open trays and identified the clinical accuracy, clinical feasibility, and clinical potential of the 3D-printed custom open tray. Limitations of the study included that the referenced conventional custom open tray did not provide an exact trueness.

CONCLUSIONS

Based on the findings of this clinical study, the following conclusions were drawn:

1. The 3D-printed custom open trays showed comparable accuracy and clinical performance as conventional custom open trays for impressions of multiple implants.
2. The 3D-printed custom open trays required less labor, less fabrication time, and lower cost than the conventional custom open trays.
3. The 3D-printed custom open trays were suitable for clinical application.

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CRediT authorship contribution statement

Xulan Yang: Software, Formal analysis, Writing - original draft, Visualization. **Yanping Liu:** Software, Writing - review & editing. **Yuan Li:** Investigation, Validation. **Yijiao Zhao:** Methodology, Software. **Ping Di:** Conceptualization, Project administration, Funding acquisition, Resources, Supervision.

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