DOI: 10.1111/cid.12781

ORIGINAL ARTICLE

WILEY

Immediate loading of multiple splinted implants via complete digital workflow: A pilot clinical study with 1-year follow-up

Xi Jiang DMD | Ye Lin DMD | Hong Y. Cui BS Med Tech | Ping Di DMD

Department of Oral Implantology, Peking University School and Hospital of Stomatology, Beijing, People's Republic of China

Correspondence
Ping Di, Department of Oral Implantology, Peking University, School and Hospital of Stomatology, Beijing 100081, People's Republic of China.
Email: diping2008@163.com

Funding information
Program for New Clinical Techniques and Therapies of Peking University School and Hospital of Stomatology, Grant/Award Number: PKUSSNCT-18A13; Capital's Funds for Health Improvement and Research, Grant/Award Number: CFH,2018-2-4102

Abstract

Background: Complete digital workflow attracts more attention in implant dentistry.

Objectives: To explore the feasibility and short-term clinical results of immediate loading of multiple implants with fixed temporary bridges (2-4 teeth span) by complete digital workflow, and to evaluate the three-dimensional (3D) deviation of digital impression comparing with traditional impression method.

Material and Methods: A total of 31 partial edentulous patients (16 females and 15 males) were recruited in this study. Digital impressions were taken immediately after implant placement, and implant-supported splinted temporary bridges were fabricated through a full digital approach (model free) and delivered within 24 hours. Final restorations were finished 4 months after surgery via traditional impression technique. Subjects were followed 1 year after treatment. 3D impression deviations were analyzed by comparing the digital and conventional impression methods. Time costs for the full digital approach were recorded. Implant survival rate, marginal bone levels were evaluated.

Results: All the recruited subjects finished this study. Seventy-four implants were surgically placed and immediately loaded with 34 temporary bridges fabricated through a full digital approach. Digital impression deviation compared with traditional impression method was 27.43 ± 13.47 μm. Time costs for chair side and laboratory were 32.55 ± 4.73 and 69.30 ± 10.87 minutes, respectively. Marginal bone alterations were −1.58 mm and −1.69 mm at the time of 4 and 12 months after surgery. The implants had a survival rate of 100% at the 1-year follow-up time.

Conclusions: Immediate loading of multiple implants in partial edentulous (2-4 teeth span) patients with full digital approach is clinically applicable. The 3D discrepancy between digital and traditional impression is within clinical acceptable range.

KEYWORDS
accuracy, digital impressions, immediate loading, implants, partial edentulous

1 | INTRODUCTION

Implant-supported restorations have significantly changed prosthetic treatment concepts and proven their long-term clinical success.[1] To fabricate and provide the implant-supported superstructure, the three-dimensional implant position, the surrounding hard and soft tissue in addition with the antagonists are transferred to the dental laboratory. This is mostly done by the traditional impression and stone model technique with impression coping and implant analogue. However, the conventional prosthetic workflows are criticized with economic, technical, and patient-related compromises. Traditional impression techniques are associated with transfer problem caused by shrinkage, separation of the tray and the impression material, and distortion due to variable layer thickness.[2] Suffocation hazard, taste irritation, and gagging may interfere with the impression taking process and cause unpleasant patient experience. In addition, traditional lab process involves a time-consuming and complex manufacturing step with expensive manpower and equipment, a long list of materials with inconsistent quality, waste products as well as high experience dependence.

The precise fit of prosthesis on dental implant is crucial. The mobility of dental implants only exists because of flexibility of the bone, which is less than 5 μm.[3] This rigid osseointegration and interfaces between various prosthetic components preclude any error adaptation. Improper fit of units may contribute to both potential mechanical and biological complications.[4,5] Digital dentistry technique including digital impression, computer-aided design, and computer-aided manufacture (CAD/CAM) provide an alternative methodology to fabricate dental prosthesis, which may eliminate the above-mentioned shortcoming and minimize the misfit of the conventional lab work.[6]

The digital impressions play an important role in this workflow because they are the first step toward a full digital line of prosthetic fabrication. The direct digitalization using an intraoral scanner seems to be the most logical way to start the digital workflow and CAD/CAM technique, which may completely eliminate the traditional impression and cast methods.[7]

However, besides in vitro laboratory investigations, the clinical scientific evidence of using intraoral scanning instead of traditional impression and model technique on implant prosthesis is very low. Current evidence only supported the clinical application of digital impression in single-unit implant restoration.[8-11] To the authors' knowledge, no clinical study could be identified for multiple implants-supported bridges.[12]

Immediate loading of multiple implants with temporary prosthesis is now considered as a predictable treatment with comparable implant survival rate compared to conventional loading protocol.[13] Immediate functional[14] or nonfunctional[15] loading were both with promising clinical results. However, for better stability during the healing stage, splinted temporary restorations were often the first choice. Therefore, accurate transfer of the interimplants position is crucial for the fabricating of splinted multiple implants-supported superstructure and the prerequisite for its passive fit so as the success of immediate loading.

The primary aim of this clinical study is to investigate the feasibility and short-term clinical results of immediate loading of multiple implants with fixed temporary bridges (2-4 teeth span) by completely digital workflow, moreover, to compare and explore the interimplants spatial discrepancy between conventional impression method and the intraoral scanner.

2 | MATERIALS AND METHODS

Ethics approval was obtained from the local ethical committee (Institutional Review Board of Peking University School and Hospital of Stomatology, Approval Number: PKUSSIRB-201523074). The study was conducted in accordance with the Helsinki declaration of 1975 as revised in 2000. Patients who seek for implant placement at the department of oral implantology were screened for their eligibility form September 2016 to December 2017.

The inclusion criteria were set as follows:

- Multiple adjacent teeth missing or to be extracted in low-esthetic demanding zone (mandible, morals, and second premolar in the maxilla).
- Adequate alveolar ridge width and height to bear the dental implants in healed ridge and extraction socket.
- Implant insertion torques were at least 20N·CM.
- The patients were willing to participate in this study and no systematic or local conditions that would preclude them from implant therapy. Smokers were not excluded from this study.

The exclusion criteria were:

- Implant site involved the maxillary frontal area (first premolar to first premolar).
- Bone augmentation procedures (eg, sinus lift, guided bone regeneration, ridge splitting, block graft) were need. Intrasocket grafting was not excluded from the study.
- Lack of adequate width of keratinized mucosa.
- One implant could not reach the insertion torque of 20N·CM.

Patients who met these criteria were informed about the study and signed the informed consent. The presurgical evaluation included clinical examination and radiographic analysis of the edentulous area. Adequate bone volume, soft tissue condition, and restorative space were confirmed before intervention.

3 | CLINICAL PROCEDURES

3.1 | Implant surgery

Prior to surgery, prophylactic antibiotic therapy (cefuroxime 0.25 g) was started 1 hour before surgery, and patients rinsed with 0.2% chlorhexidine solution for 1 minute. The surgical site was anesthetized on both the buccal and palatal/lingual aspects using Primacaine Adrenaline (Produits Dentaires Pierre Rolland, Acteon Pharma Division, Merignac, France). Conventional crestal incisions were applied, followed by the reflect of full thickness soft tissue flap in healed ridge. Sequential osteotomy and implant insertion were performed according to the manufacture's guidelines (Camlog Screw-Line Implant, Camlog Biotechnologies AG, Basel, Switzerland). In case of immediate implant, the unsalvageable teeth were extracted, and bony wall of the extraction socket were exposed. Implants were placed within the socket, the gap between the implant body and socket bone wall was grafted with bone substitute (Bio-Oss Collagen; Geistlich Pharma AG, Wolhusen, Switzerland). The insertion torch of each implant was recorded. If the primary stability of all the implants exceed 20N·CM, immediate functional loading via full digital approach were planned.

3.2 | Digital impression

After suturing of the soft tissue flap, digital impression was immediately obtained with the Trios scanner (3shape, Copenhagen, Denmark) according to the manufacture's recommendation. First, the full arch of the surgical site was scanned with the connection of healing abutments; second, the antagonist full dentation was scanned; then, the healing abutments were replaced with scanbodies (Camlog Scanbodies, Camlog Biotechnologies AG, Basel, Switzerland), tightened by hand. Local area around the implants was scanned including the scanbodies and adjacent teeth. Lastly, the scanbodies were disconnected and replaced by healing abutment, and bite registration was digitalized. The whole costed time during the process of digital impression was recorded.

3.3 | CAD/CAM process

A model-free fabrication process was adopted in a local dental lab. Data were transferred to CAD software (Dental system, 3shape, Copenhagen, Denmark) for the virtual design of a screw-retained full-contour splinted temporary bridges. After completion of the virtual design, the STL file of the restoration was then sent to a CAM machine (Organical Multi, Organical CAD/CAM GmbH, Berlin, Germany) to mill a full-contour temporary restoration of polymethyl methacrylate (PMMA) (Organic PMMA, Organical CAD/CAM GmbH, Berlin, Germany). The provisional bridge was delivered and manually screwed onto the implants within 24 hours postsurgery. The occlusion was checked and adjusted, if needed. Centric occlusion and centric relation contacts were guarantee, nonaxis forces due to lateral movement were eliminated. And the lab and chair-side time for temporary restoration fabrication and delivery were recorded (Figure 1).

3.4 | Final restoration and follow-up

Four months after implant surgery and immediate loading, traditional impressions (splinted pick-up technique) were taken, and the final restorations that were designed as splinted zirconia bridge cemented on individualized titanium abutments were delivered. Patients were revisited at 1 year after surgery (Figure 2). Peri-implant marginal bone levels were evaluated by peri-apical x-ray at the time of immediate loading with temporary bridge, final restoration delivery (4 months postsurgery) and 1-year follow-up (Figure 3).

3.5 | Accuracy evaluation

The accuracy of digital impression was evaluated by comparing 3D position of virtual scanbodies from intraoral scanner and lab scanner. In detail, Scanbodies, same with intraoral scan, were mounted on the implant analogs in the master cast, which was fabricated for the final restoration manufacturing via conventional impression method, at the same position

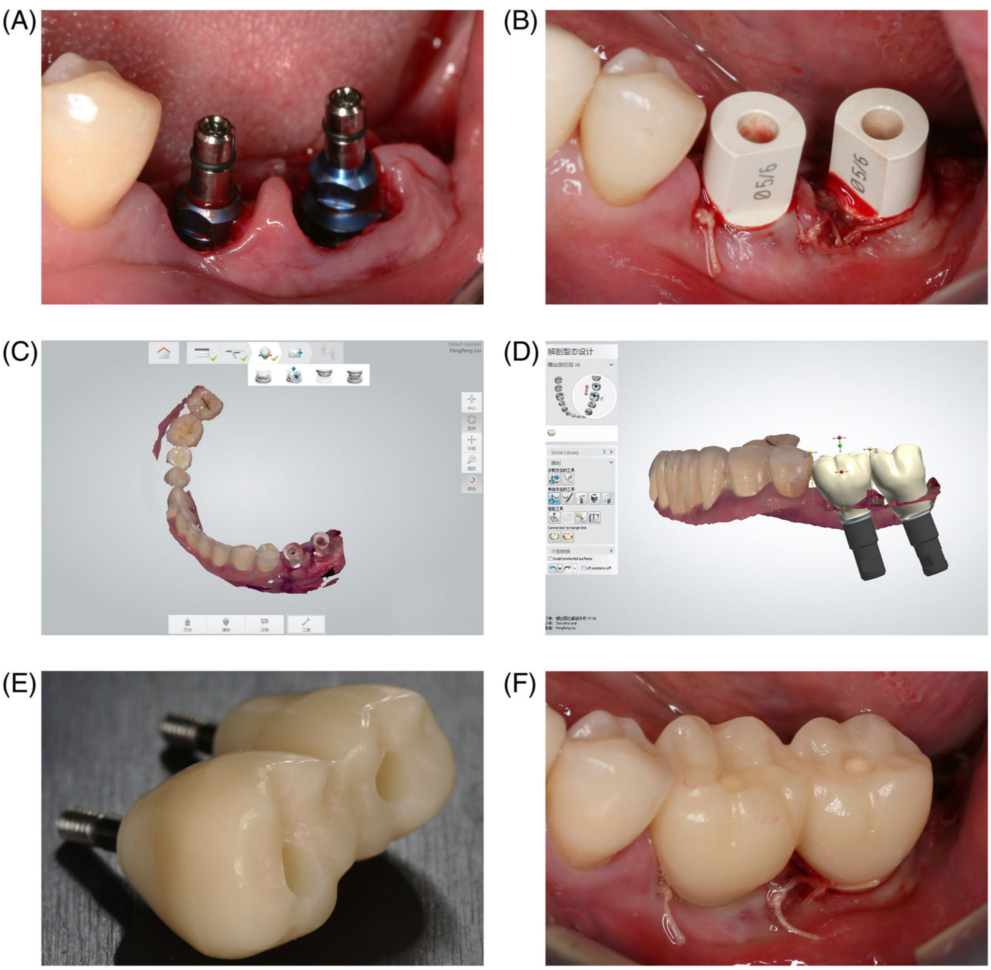

FIGURE 1 Clinical and lab procedures of full digital approach for immediate loading of multiple adjacent implants. A, Two adjacent implants were surgically placed in the posterior mandibular extraction sockets. B, Scanbodies were mounted onto the implants after suturing. C, Digital impressions were taken by intra oral scanner, the 3D positions of the scanbodies were captured. D, Restoration for immediate loading was designed by CAD software. E, Screw-retained splinted temporary bridges of PMMA was milled by CAM machine. F, Temporary restoration was screwed onto the implants. CAD, computer-aided design; CAM, computer-aided manufacture; 3D, three-dimensional

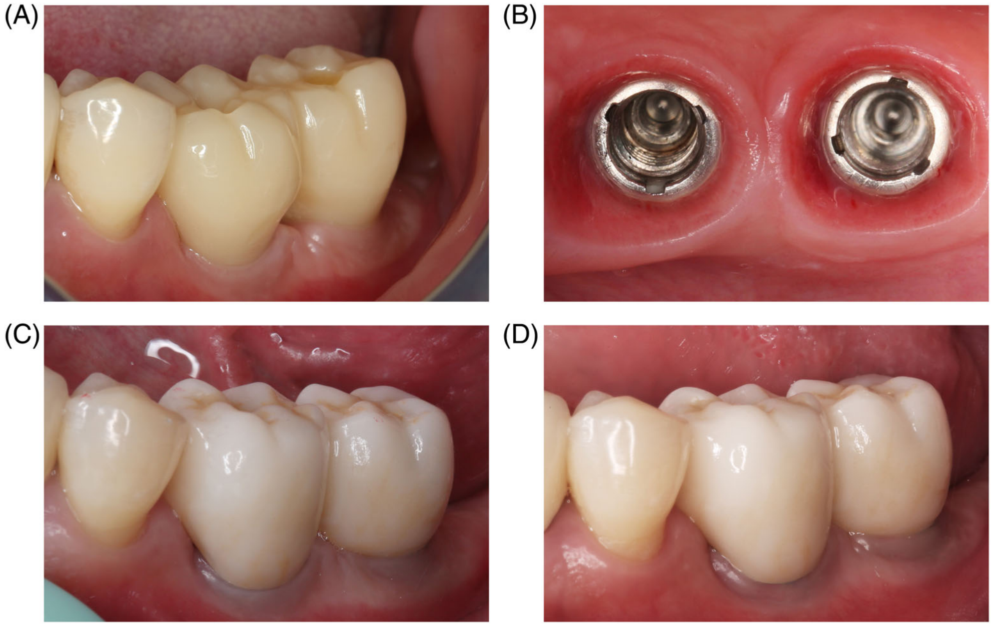

FIGURE 2 Healing and final restoration. A, Clinical view after 4 months of healing. B, Soft tissue profile after removal of temporary bridges. C, Final restoration in place. D, Clinical situation at 1-year follow-up

and digitalized by lab scanner (D800, 3shape, Copenhagen, Denmark). Both the data files from intraoral scanner and lab scanner were transferred into STL files and imported into metrology software (Geomagic Qualify 12, 3D Systems, Rock Hill, South Carolina). For comparison, the standard CAD file of scan body was aligned to all the scanbodies in the STL files, using character-fit algorithm. Then, the aligned scanbodies were saved as new files. As the interimplant position is the most important aspect for implant-supported splinted bridge, the accuracy evaluations were done between the new files containing solely scanbodies, which excluded all the other irrelevant parts of the models.[16] Best-fit algorithm was used to superimpose the two files from lab scanner and intraoral scanner, with the tolerance set at 0.001 μm. Then, a 3D comparison was done, the absolute mean deviation from the mean positive and negative deviation was used to evaluate the accuracy (Figure 4).

3.6 | Statistics

All measurements were recorded in an Excel 2013 spreadsheet (Micro-soft Corporation, Redmond, Washington), and transferred to SPSS version 13.0 (SPSS, Inc, Chicago, Illinois) for statistical analysis. Descriptive statistics (means and standard deviations) were calculated for each clinical, radiographic, and digital parameter.

4 | RESULTS

Thirty-six patients were initially eligible for this study. Thirty-five subjects accepted the invitation, and of these, four patients were excluded due to lack of implant primary stability. The rest 31 subjects, 16 females, and 15 males, with ages of 50.77 ± 12.80 years old were finally recruited and finished this study. A total of 74 implants (56 implants in healed ridge and 18 implants in extraction sockets) were installed and immediately loaded with 34 temporary bridges fabricated via the full digital approach. Demographic and distributional properties were summarized in Table 1.

4.1 | Clinical findings

No implants were lost during the 1-year follow-up period resulting the implant survival rate of 100%. One temporary bridge showed

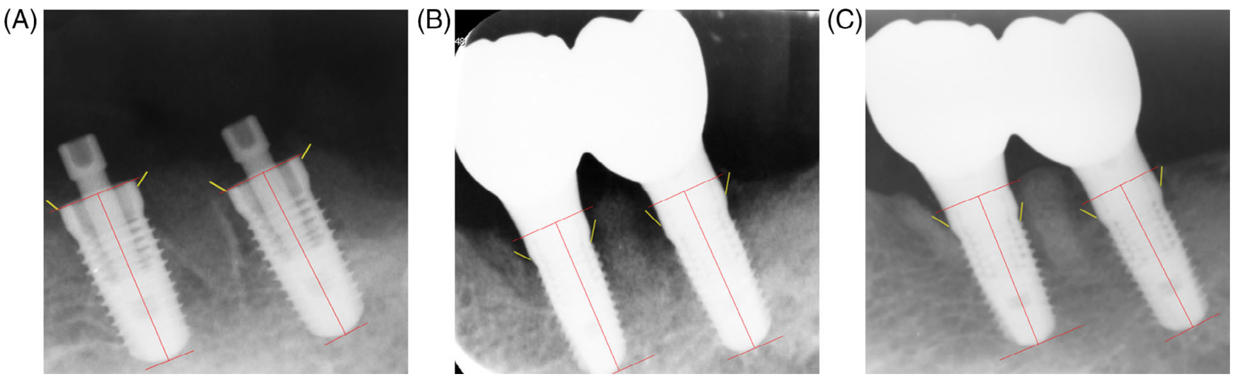

FIGURE 3 Periapical x-ray. Yellow short lines indicate the mesio and distal marginal bone levels. The red line section between the coronal and apical horizontal lines indicates the length of the implant, which was used as calibration for marginal bone resorption measurement. A, Immediate loading after surgery. Note the radiolucency of the PMMA bridge. B, Final restoration delivery after 4 months of healing. C, One-year follow-up

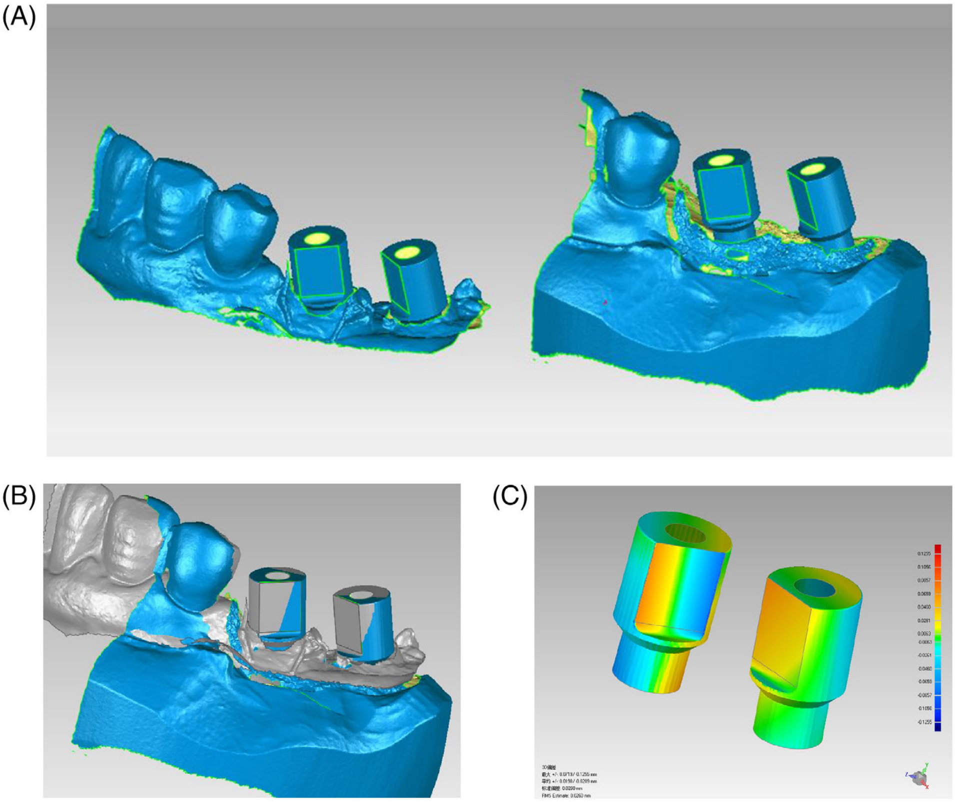

FIGURE 4 Accuracy evaluation by comparing STL files from intraoral scanner and lab scanner. A, STL files from the intra oral scanner (left) and lab scanner (right), note the scanbodies have been replaced by standard CAD files. B, Three-dimensional superimposition of the two files. C, To eliminate irrelevant part, only the scan bodies were resuperimposed and analyzed. CAD, computer-aided design

screw loosening at 6 weeks postsurgery, which was re-tightened, and the implants were healed uneventful.

The time cost for digital impression taken was 17.90 ± 2.77 minutes. The time for CAD design and CAM milling were 33.24 ± 7.18 and 36.06 ± 5.83 minutes, respectively. The duration for chair-side adjustment and delivery of the temporary bridge was 14.65 ± 4.64 minutes (Table 2).

TABLE 1 Demographic and distributional characteristics of participants and implants

Study participants	**31**
Implants	74
Temporary bridges	34
Age(years)	
Mean ± SD	50.77 ± 12.80
Range	27-77
Gender (n, %)	
Female	16 (51.61%)
Male	15 (48.39%)
Implant sites (n, %)	
In healed ridge	56 (75.68%)
In extraction socket	18 (24.32%)
Surgical area	
Posterior maxilla	9 (26.47%)
Posterior mandible	19 (55.88%)
Frontal mandible	6 (17.65%)

4.2 | Radiological findings

Marginal bone level changes (n = 74) were −1.58 ± 0.40 mm at the 4 months follow up, and −1.69 ± 0.38 mm at the 1-year postsurgery compared with the base line of immediate postsurgery. Marginal bone levels can be stably maintained after the initial 4-month bone remodeling phase (Figure 5).

4.3 | Accuracy evaluations

The 3D deviation (n = 34) between the intraoral scanner and lab scanner was 27.43 ± 13.47 μm, ranging from 12.19 to 54.87 μm.

5 | DISCUSSIONS

The present study provided good short-term clinical results of complete digital workflow (model free) for immediate loading of multiple implants supporting fixed temporary bridges regarding implant survival and marginal bone levels. The 3D implant positions were also compared between traditional impress-cast technique and digital impression, revealing clinical acceptable discrepancy.

Implant dentistry has been continuously benefitting from digital technique in recent years. The introduction of CAD/CAM had facilitated the workflow of the fabrication process and demonstrates a significant improvement in accuracy compared with conventional casting technique.[17] Regarding the whole restorative phase of implant rehabilitation, a hybrid conventional/digital method, which means conventional

TABLE 2 Time costs of full digital approach in clinics and laboratory

Time costsMean ± SD (min; n = 31)	Clinics		Laboratory	
	Intraoral scanning	Chair-side restoration delivery	CAD design	CAM fabrication
	17.90 ± 2.77	14.65 ± 4.64	33.24 ± 7.18	36.06 ± 5.83
Total	32.55 ± 4.73		69.30 ± 10.87	

Abbreviations: CAD, computer-aided design; CAM, computer-aided manufacture.

impression, plaster cast, extra oral indirect digitalization by lab scanner, and then CAD/CAM to fabricate the prosthesis, is still the clinical routine, offering a reliable solution from single unit to full arch implant-supported framework.[18,19]

In the context of rapid spread of digital technique in implant dentistry, to avoid the multistep of impression taken and establishing a more standardized, simplified, complete digital approach became an attractive treatment concept, however, the available evidence for complete digital workflow of implant restoration is very limited.[12]

Beuer et al. reported the application of intraoral scanning system to restore single posterior teeth.[20] They captured the 3D position of the implant immediately after its insertion during the surgery, then the implant was left to heal submergely. A screw-retained one-piece abutment crown was fabricated without a physical model and delivered at the time of secondary-stage surgery. This procedure allowed only two clinical visits to complete an implant rehabilitation, besides, biological benefit of avoiding repeatedly detach the healing abutment was provided. However, only one case was reported, no other information can be compared with the present study, except the digital impression were both taken during the surgery.

Lee et al. evaluated the clinical performance of single implant restoration with intraoral laser scanner. A total of 36 patients were restored with a single crown cemented to an individualized abutment fabricated with CAD/CAM. Marginal integrity, interproximal contact and occlusal adjustment time were evaluated, and the authors conclude the clinical success of digital impression for the prosthetic phase of single implant restoration.[11] Joda et al. compared the digital workflow (intraoral scanning, CAD/CAM fabrication) and conventional pathway (classical open tray impression, standardized abutment plus Porcelain Fuse to Metal crown) of 20 cases, regarding clinical

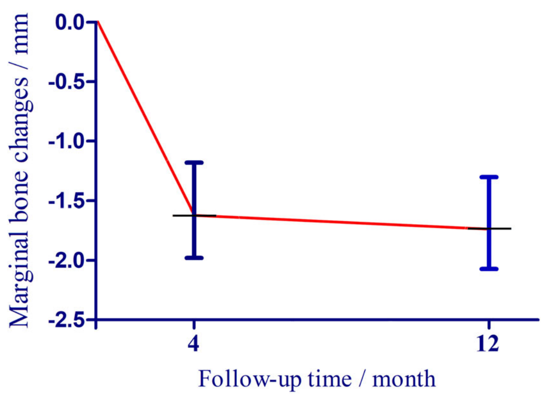

FIGURE 5 Marginal bone alterations during the 1-year follow-up period

performance and efficiency. They found that digital workflow with intraoral scanning can provide predictable accuracy and threefold more efficiency than the conventional pathway.[12] These previous clinical studies provided clinical feasibility of complete digital workflow starting with intraoral scanning, However, only single unite implant restoration were involved, which is the major difference compared with our study with multiple implants. Therefore, direct comparison cannot be made between our work with previous studies.

To the authors' knowledge, this is the first clinical study using digital impression to fabricate splinted implant restoration in partial edentulous patients without a physical model. This full digital workflow introduced a very efficient way to deliver a temporary bridge for immediate loading of multiple adjacent implants. Conventional approach for immediate loading often involved impression taking, cast pouring and temporary bridge fabrication, or by relying a prefabricated acrylic shell intraorally and refine it extraorally.[14] Both approaches were time-consuming, requiring lots of man-made steps and most of all, imported higher risk of contaminating the fresh surgical wound by impression material or relying substances. However, considering the following factors: lack of solid clinical evidence of digital impression for multiple implants rehabilitation, veneering is needed in some cases and the inexperience for lateral occlusal design of current CAD software, the final restorations were fabricated by conventional impression and stone cast technique.

The scanning time during the surgery and chair-side time for restoration delivery were 17.90 ± 2.77 and 14.65 ± 4.64, respectively, which was longer than those in the previous study. Joda and Bragger reported average scanning time was 13.4 minutes and chair time for prosthesis delivery was 7.4 minutes.[10] This discrepancy for clinical time-efficiency might be cause by different scanning range (full arch vs local area), scanner brands (Tiros vs iTero), edentulous span (single tooth vs multiple teeth), restoration type (temporary bridge vs final restoration), and in addition, obtaining a clear and clean environment immediate after implant placement is more difficult and time-consuming for scanning and restoration delivery compared with healed site.

All the implants were immediately functional loaded and survived in the 1-year follow-up in the present study. Radiographic examination revealed stable marginal bone levels. This clinical outcome is in agreement with other clinical studies concerning immediate loading in partial edentulous patients by conventional approach with the same[15,21] or longer follow-up period.[14,22] A higher torque has been considered for immediate functional loading. At least 20N·CM for splinted implants was suggested by previous studies.[15,23] The present study confirmed that implant with insertion torch over 20N·CM can be successfully integrated with immediate functional loading. In another clinical study of immediate loading of splinted posterior implants, 25 of 36 implants' insertion torque were less than 15N·CM, and the author concluded insertion torque values did not compromise successful osseointegration.[14]

Accuracy for implant restoration is always the key issue for long-term success. As the introduction of CAD/CAM processing, errors of fabricating prosthesis were greatly reduced. The main concern of inaccuracy in full digital approach lies on the intraoral scanning process. Very few clinical studies evaluated the accuracy of digital impressions of dental implants. Chair-side adjustment time,[10] marginal fit evaluation by clinical inspection[11] and radiographic examination,[24] were used as indirect parameters reflecting the accuracy of the full digital approach.

Direct accuracy evaluations of digital impression on dental implants mostly comprised of in vitro studies in models. As defined by Ender and Mehl, accuracy consists of two parameters: trueness describes how far measurement deviate from the actual object, while precision describes how much the various test scans differ from each other.[25] According to recent systematic review, mainly based on in vitro studies, the trueness varied from 6 to 337 μm depending on different scanners, scanning length, scanbody visibility, and operator's experience.[12,26,27] However, it is difficult to determine the clinically acceptable degree of misfit for implant-supported prosthesis. Jemt proposed a limit of 150 μm to prevent long-term complications,[28] some believed 100 μm to be acceptable,[29] while others took this threshold to a more demanding level of 30 and 75 μm.[30,31] As these numbers also included the errors of the fabrication process, scanning deviation must be below this threshold.

In the present study, the exact trueness of intraoral scan cannot be measured, as acquiring actual position of placed implants in patient's mouth has no standard methods. The indirect digitalization by impression-cast and lab scanner has been proved clinically success from single unit implant restoration to full arch framework, therefore, data from lab scanner were set as the reference for comparison, which do not imply indirect digitalization has the better accuracy than the intraoral scanner.

Deviation in this study was 27.43 ± 13.47 μm, which was within the threshold of clinical acceptance and also in accordance with 19 and 33 um deviation in two in vitro studies of complete edentulous patients with the same scanner[16,32] and 64 μm deviation from partially edentulous models of two implants.[33] Several clinical cases reports have applied the intraoral scanner to fabricate multi-implant-supported framework and indicated the potential possibility to use digital impression as a clinical routine.[24,34,35]

However, in a recent clinical study with 36 partial edentulous patients, digital impression exhibited least accuracy with linear errors ranging from 160 to 270 μm, and the authors conclude it is not suitable to fabricate a well-fitting restoration with digital impressions.[36] An in vitro study also supported this conclusion.[37] The inconsistency of these results might be caused by various factors, such as different number and distribution of implants, types of intraoral scanning system, choice of digitalization methods, reference data, and evaluation methods. Until now, no consensus can be made regarding digital impression in fabricating multiple-implant-supported restoration.

Although our preliminary results supported the application of full digital approach in immediate loading of multiple adjacent implants in partial edentulous patients, limitations in this study cannot be ignored. No control group was included and only the temporary not the final restorations were fabricated. The radiolucent temporary bridges preclude the inspection of potential improper fit of the restoration from x-ray. High elasticity of PMMA may also survive the incomplete passive fit when tightening the screw. Further researched are needed to confirm the clinical feasibility and accuracy of digital impression in multiple-implant rehabilitation in partial edentulous patients.

6 | CONCLUSIONS

Complete digital workflow is a clinically feasible approach to facilitate immediate loading of multiple adjacent implants (2-4 teeth span) in partial edentulous patients in respect of implant survival rate and marginal bone alterations. The 3D discrepancy between digital and traditional impression is within clinical acceptable range.

ACKNOWLEDGMENTS

The authors thank all the staff in the department of oral implantology for helping us to finish this clinical study. Special appreciations to Shanshan Zhao for her dedicated work in lab. This study was supported by Program for New Clinical Techniques and Therapies of Peking University School and Hospital of Stomatology (2018-16).

CONFLICT OF INTEREST

The authors declare no conflict of interest regarding this clinical study.

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How to cite this article: Jiang X, Lin Y, Cui HY, Di P. Immediate loading of multiple splinted implants via complete digital workflow: A pilot clinical study with 1-year follow-up. *Clin Implant Dent Relat Res*. 2019;21:446–453. https://doi.org/10.1111/cid.12781