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Fully digital versus conventional workflow for horizontal ridge augmentation with intraoral block bone: A randomized controlled clinical trial

Ning Zhu DMD | Jiayu Liu DMD | Ting Ma DMD | Yu Zhang DMD | Ye Lin MD

Department of Oral Implantology, Peking University School and Hospital of Stomatology & National Clinical Research Center for Oral Diseases & National Engineering Laboratory for Digital and Material Technology of Stomatology & Beijing Key Laboratory of Digital Stomatology, Beijing, China

Correspondence
Yu Zhang, Department of Oral Implantology, School and Hospital of Stomatology, Peking University, 22 Zhongguancun South Avenue, Haidian District, Beijing 100081, China.
Email: zhang76yu@163.com

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Abstract

Objectives: To compare the outcome and efficiency of the computer-aided intraoral block bone grafting procedure with those of the conventional technique for the augmentation of horizontal ridge defects.

Materials and Methods: A total of 28 patients with single missing tooth in esthetic zone with class IV horizontal alveolar bone defect in need of dental implant restoration were recruited. Computer-aided design of the implant restoration and intraoral block bone grafting was performed for all the participants. The patients were randomly and equally divided into guide and control groups. A fully guided bone harvesting, trimming, and grafting surgery was executed in the guide group. The control group patients underwent surgery without any guide. After 6 months, all the patients underwent implant placement. The primary outcomes were the root mean square estimate (RMSE) values between the outer contours of the actual implanted and planned bone block as well as the RMSE values between the inner surface of the implanted bone block and the original bone surface of the recipient site immediately after surgery. The secondary outcomes were the trimming time of bone block and the surgery-associated complications. The postoperative visual analog scale (VAS) of pain, swelling, and mouth opening difficulty was recorded.

Results: All 28 patients underwent intraoral block bone grafting, followed by the placement of implant after 191.8 ± 19.69 days. The RMSE values between the outer contours of the implanted and planned bone blocks were significantly lower in the guide group (0.37 ± 0.16 mm) as compared to those in the control group (0.72 ± 0.29 mm) ($p = 0.0007$). The RMSE values between the inner contours of the graft block and original bone at the recipient site were lower in the guide group (0.35 ± 0.15 mm) as compared to those in the control group (0.48 ± 0.17 mm) ($p = 0.043$). The duration of bone block trimming was shorter in the guide group (401.51 ± 97.60 s) as compared to the control group (602.36 ± 160.57 s) ($p = 0.0005$). In the control group, two patients received secondary bone grafting, one patient experienced bleeding of donor site and temporary hypoesthesia of the lower lip and chin skin, and one patient developed temporary sensitivity of the adjacent tooth.

Conclusions: As compared to the conventional procedure, the fully digital workflow in the present study seemed to be a more accuracy and effective protocol for

horizontal ridge augmentation with intraoral block bone. Trial registration: Chictr.org.cn (ChiCTR2000036390).

KEYWORDS
bone harvesting, dental implants, digital technology, horizontal alveolar ridge augmentation, intraoral block bone grafting

What is known

- Intraoral block bone grafting is considered highly reliable for reconstruction of severe horizontal ridge defects.
- Alveolar ridge augmentation assisted by digital technology is helpful for improving the predictability and surgical efficiency and reducing complications.
- There is a lack of research on the use of digital technology to assist horizontal ridge augmentation with intraoral block bone grafting.

What this study adds

- Using digital workflow, prosthetically driven intraoral block bone grafting can be achieved accurately and efficiently.

1 | INTRODUCTION

The ideal function and esthetics of dental implant restoration depend on placement of the implant. Bone augmentation is necessary for the correct positioning of an implant as well as the esthetic reconstruction of alveolar contour in cases of an atrophic alveolar bone.[1,2] Common bone augmentation techniques include guided bone regeneration (GBR)[3] and autogenous bone block grafting.[2,4,5] Benic and Hämmerle suggested a staged approach for bone augmentation with autogenous block bone and implant placement for the classes IV and V bone defects characterized by reduced width or height of the ridge, which decreased the primary stability of the implant in the correct prosthodontic position.[3]

Autogenous bone grafts can be obtained from intraoral or extraoral donor sites.[6] Intraoral bone harvesting is associated with less trauma, shorter anesthesia time, lower complication rate, lower cost, and superior quality of the regenerated bone as compared to extraoral bone harvesting, thereby making it more widely used.[7,8] Intraoral bone grafting from the ascending mandibular ramus is considered the most reliable method for the reconstruction of severe alveolar defects.[9–11] However, the presence of teeth and mandibular canal make the anatomical structure of the mandible complicated. Lacking reference position information for intraoral block bone harvesting might result in either inadvertent injury to the critical anatomical structures or limited obtained graft quantity.[1,10,12] The damage of anatomical structure could result in postoperative complications, such as numbness, neurosensory disturbances, and postoperative discomfort. Osman and Atef[13] proposed a digital bone harvest guide for reducing the technical sensitivity and postoperative complications of bone block harvesting from the chin bone. De Stavola and colleagues[14,15] reported a computer-guided mandibular harvesting procedure to safely obtain a sufficient volume of block bone. These studies indicated that surgical complications could be reduced. The volume of harvest bone could be controlled using the digital guide for block bone harvest.[16]

Traditional free-hand bone block grafting depends solely on the experience of the surgeon and lacks orientation with the definitive prosthesis and prosthetically driven tissue augmentation target shape, resulting in the unsatisfactory predictability of the outcomes related to bone augmentation and implant restoration.[1] Moreover, an inadequate fit between the block graft and recipient area might lead to the ingrowth of connective tissues between them, thereby hindering successful graft integration.[17,18] In order to improve the results of bone block grafting procedures, Collins and colleagues[17] provided a surgical stent with the buccal surface of the planned definitive restoration to help positioning and contouring block bone grafts. Misch[19] suggested designing a replica of the target bone block graft as a template on the bone defect gypsum model to help in determining the dimensions and contours of the bone graft needed. Pham Dang and colleagues[18] used digital technology to reconstruct and print a 3-dimensional model of the recipient area in order to improve the fit between the graft and the recipient's bone; this model was referred to trim the graft intraoperatively.

We previously reported the feasibility and workflow for the prosthetically driven fully digital-guided intraoral bone block grafting guide for the augmentation of atrophic ridges.[20] The use of digital technology might help directly design the target contour of the bone defect area, obtain a 3-dimensional model of the planned bone block, virtually move the 3-dimensional model to the donor site to select the suitable bone harvesting site, and propose corresponding guides for the entire augmentation operation. At the same time, the use of a guide might improve the operational efficiency and postoperative outcomes. Therefore, this randomized-controlled clinical trial aimed to compare the effects of a proposed prosthetically guided fully digital combined guide for the intraoral block bone grafting[20] with that of the conventional free-hand surgery.

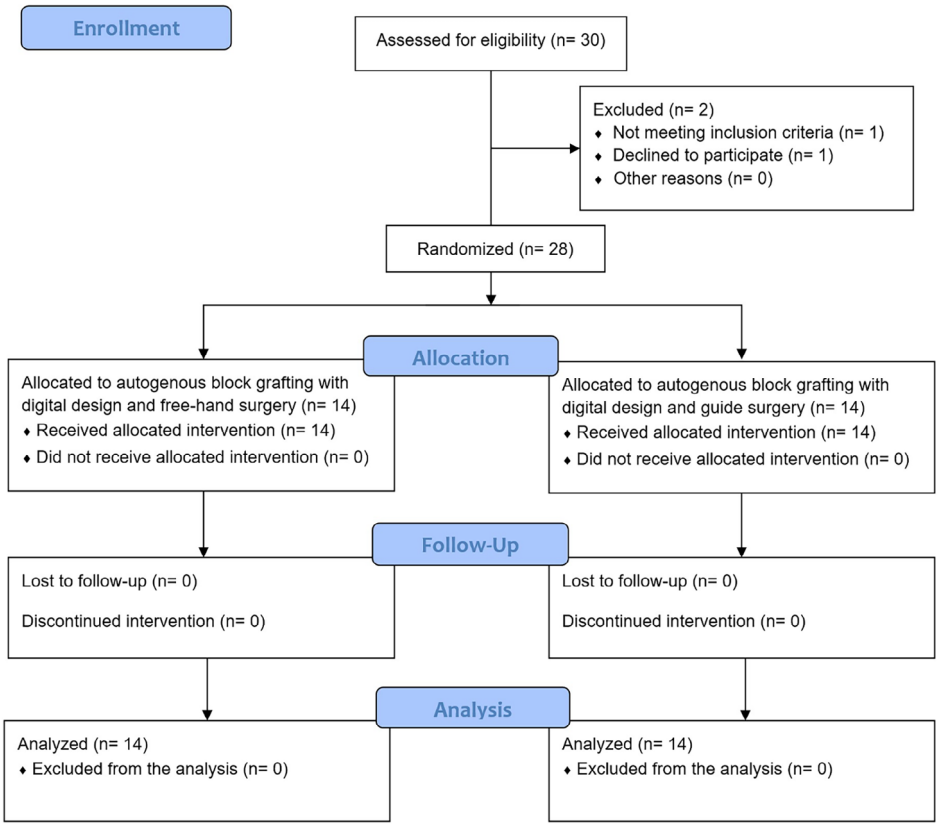

FIGURE 1 CONSORT 2010 flow diagram

2 | MATERIAL AND METHODS

2.1 | Study design

This randomized-controlled clinical trial was approved by the Institutional Review Board of Peking University Hospital of Stomatology, Beijing, China (Approval No. PKUSSIRB-202056085), and was registered at the Chinese Clinical Trial Registry (Registration No. ChiCTR2000036390). In accordance with the principles of the Declaration of Helsinki, written consent was obtained from the patients after providing them with a detailed explanation of this study. The current study was conducted as per the CONSORT clinical trial guidelines and the study flowchart is shown in Figure 1.

2.2 | Inclusion and exclusion criteria

The criteria for inclusion of patients in this study were as follows: (1) a single missing tooth with horizontal alveolar bone defect (class IV, Benic and Hämmerle classification)[3] in esthetic zone in need of dental implant restoration; (2) a missing tooth for more than 3 months; (3) patients having sufficient block bone available from the mandibular ramus.

The criteria for exclusion of patients from this study were as follows: (1) patients with a medical history of systemic diseases, such as uncontrolled diabetes, affecting the surgery outcomes, such as bone or wound healing; (2) patients with a known history of mental illnesses; (3) pregnant or lactating female patients; (4) patients with untreated periodontitis; (5) patients with untreated pulp lesions of the adjacent teeth; (6) heavy smokers; and (7) patients with poor oral hygiene.

2.3 | Calculation of the sample size

A literature review provided insufficient data to compare with the current study. Therefore, a contour root mean square estimate (RMSE) of 0.82 ± 0.31 mm was obtained by reviewing 10 recent free-hand block bone grafting procedures performed by the same surgeon (Y. Z.) in this study. An RMSE of 0.50 ± 0.15 mm was assumed for the guide groups and calculated using PASS11 software ($\alpha = 0.05$, power = 0.80), containing 12 patients per group. Then, the sample size was increased to 14 patients per group to prevent the potential loss of follow-up.

2.4 | Randomization, allocation concealment, and blinding

The current study enrolled a total of 28 patients who consecutively visited the Peking University School and Hospital of Stomatology, met the inclusion criteria, and were scheduled to undergo intraoral bone block grafting for augmentation of the atrophic ridges. The block randomization was performed using SAS 9.4 software with a block

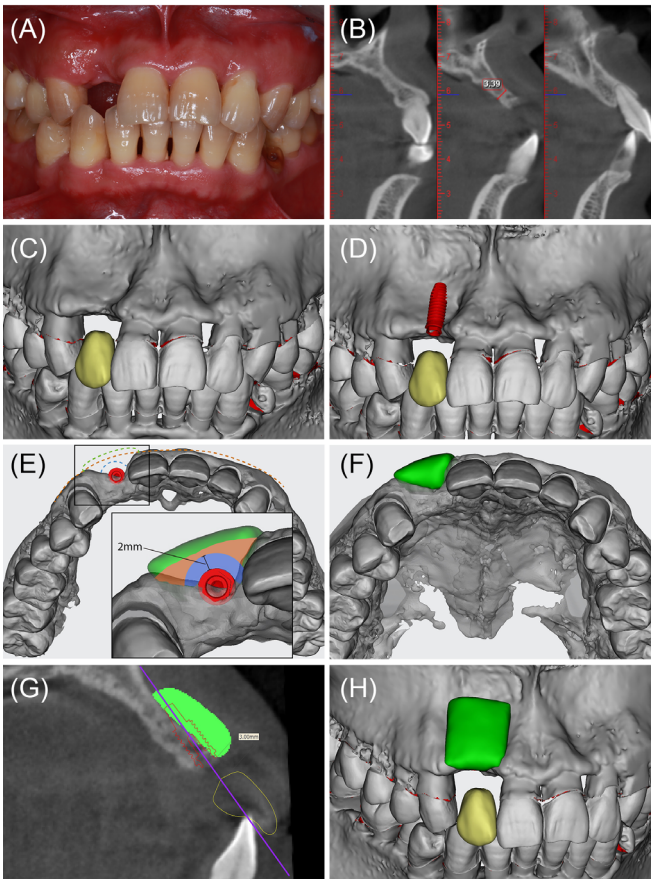

FIGURE 2 Target restorations, implants, and graft designs. (A) preoperative intraoral photo; (B) preoperative imaging data; (C) designed definitive prosthesis (yellow); (D) designed definitive implant (red); (E) target bone block design, ensuring 2 mm of bone thickness (blue) buccal to the implant (red), and that the bone contour (orange) was in line with the adjacent and contralateral teeth and was appropriately over-sized (green); (F) occlusal view of the target graft; (G) sagittal view of the definitive prosthesis (yellow), definitive implant (red), implant long axis (purple) and target graft(green); (H) front view of the target graft

size of 4. The patients were equally divided into two groups. The envelope method was used to conceal the grouping scheme. A researcher opened the envelopes after receiving signed consent from the patients. Both the participants and outcome assessors were blinded to the grouping allocation.

2.5 | Treatment procedures

2.5.1 | Design procedure

The specific techniques for designing the guide and surgery are reported in a previous study.[20] Briefly, the jawbone models of the patients were obtained preoperatively using cone-beam computed tomography (CBCT, ProMax 3D, Planmeca Oy) scanning. Dentition surface information was obtained by scanning the mounted diagnostic

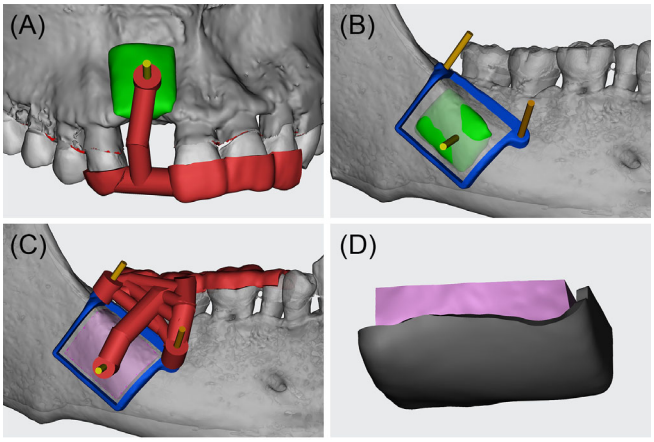

FIGURE 3 Computer-aided design. (A) Graft fixation screw (yellow), graft guide (red); (B) target bone block (green) and graft fixation screw (yellow) moved to the donor site, osteotomy guide (blue) and guide retention screws (orange); (C) tooth-supporting positioning device at donor site (red); (D) virtually harvested bone block (pink) and trim guide (gray)

casts or intraoral scanning (TRIOS; 3Shape A/S). For both groups, the definitive prosthesis was designed using design software (Dental System; 3Shape A/S) (Figure 2A–C) and then used for designing the definitive implant (Figure 2D). The target bone block graft was then designed to ensure at least a 2-mm bone-width buccal for the implant. The bone contour was designed according to the adjacent tooth and contralateral bone contour and an appropriately oversized block was planned, considering its possible resorption (Figure 2E–H). A safe donor area in the mandibular ramus, which was distant from the critical anatomic structures, was mapped. The target graft was then moved to the safe donor site in a way that would require minimal trimming while maintaining sufficient bone volume. This method was followed in both the guide and control groups.

For the guide group, the graft guide (Figure 3A), osteotomy template (Figure 3B), tooth-supporting positioning device at the donor site (Figure 3C), and trim guide (Figure 3D) were designed. The designs were interactively prepared using 3-dimensional image software (Mimics Medical 20.0) and reverse engineering software (Geomagic Studio 2015). The osteotomy template was printed using a cobalt–chromium alloy, while the other guides were printed using photopolymer resin.

2.5.2 | Surgical procedure

The patients received prophylactic antibiotic therapy (Cefuroxime Axetil tablets 0.5 g or Roxithromycin capsules 0.3 g in case of allergy) 1 h before surgery and 0.12% chlorhexidine gargles for 30 s thrice for the oral cleansing.

In the guide group, the tooth-supporting positioning device and graft guide were placed before surgery to confirm their correct seating at their respective sites. The recipient site was exposed to local

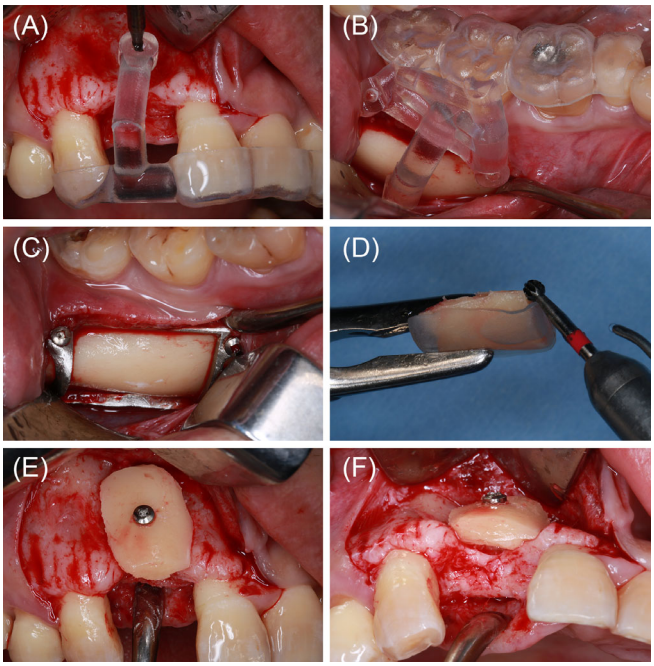

FIGURE 4 Surgery. (A) graft guide at the recipient site; (B) tooth-supporting positioning device at donor site; (C) the osteotomy guide was fixed on the donor site; (D) a trim guide was used to trim bone block; (E and F) implanted bone block

anesthesia and the graft guide was placed at the recipient site to complete drilling (Figure 4A). At the donor area, the incision was designed based on the range of the tooth-supporting positioning device, and the locating holes in the donor's bone were drilled through the drilling rings of the positioning device using a fissure bur (Figure 4B). Subsequently, the osteotomy template was placed on the drilled holes in the donor's bone and checked if the tissue surface of the template fit well with the bone surface. The template was then directly fixed to the bone surface using screws (Figure 4C). The graft was then harvested using a piezoelectric device and a fissure bur according to the internal faces of the osteotomy template. The work tip scale of the piezoelectric device was used for the operation according to the planned osteotomy depth of each osteotomy plane. The harvested graft was trimmed based on the trim guide (Figure 4D) and then fixed directly at the recipient site in the drilled holes in the bone block and the recipient area using titanium screws (Figure 4E,F). Finally, the flaps were sutured.

For control group patients, the same surgeon performed the surgery without a template based on the imaging data and digital graft design with the dental UNC15 probe for measurements. The graft was harvested using a piezoelectric device and dental fissure bur. The depth of osteotomy was approximately equal to the thickness of the cortical bone. The graft was trimmed and checked by repeatedly placing it on the recipient site to observe its contour and fitting until the implantation position was determined. Finally, the holes were drilled in the graft and at the recipient site, and the graft was fixed in the holes using screws.

After the surgery, all patients were prescribed to take Cefuroxime Axetil tablets (0.25 g twice per day for 7 days) or Roxithromycin

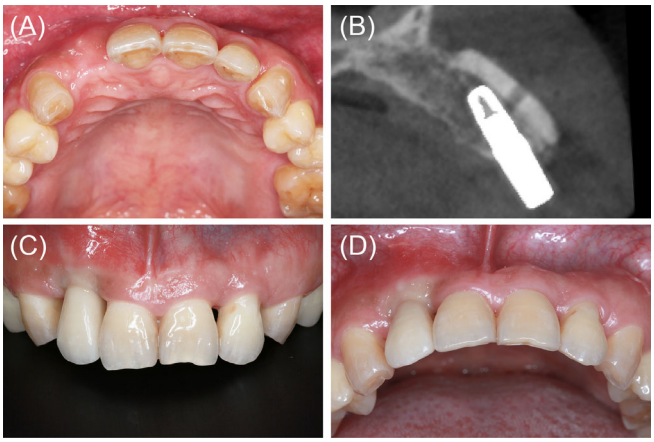

FIGURE 5 Six months after block bone grafting: (A) intraoral photo; (B) implant; (C–D) screw-retained restoration

capsules (0.15 g twice per day for 7 days) in case of allergy, and Ibuprofen sustained-release capsules (0.3 g twice per day for 5 days). The patients were advised to rinse their mouths with 0.12% chlorhexidine gargles for 7 days.

After following up for 6 months (Figure 5A), the fixation screws were removed, and the dental implant was placed (Figure 5B).[2] If the bone was deemed insufficient for the long-term stability of the implant, a second bone augmentation was performed, and the bone augmentation method was selected based on the healed alveolar ridge. Then, after 6 months of implant placement, dental prosthetics were performed (Figure 5C,D).

2.6 | Outcome variables and measures

2.6.1 | Primary variables

RMSE between the outer contours of the designed and actual implanted bone blocks immediately after bone grafting

The jaw model, which was reconstructed immediately after bone augmentation surgery using CBCT, was superimposed on the preoperative jaw model based on the corresponding unchanged surface features and registered using the Geomagic software with the "Best Fit Alignment" (iterative closest point algorithm) command. The two paired models were then trimmed, and only the outer surface contours of the designed and the actual graft were selected for a 3-dimensional deviation analysis. The outer contours of the designed and actual graft were set as the reference and test models, respectively. Next, the "Deviation" command, which could generate a 3-dimensional color-coded mapping, showing the differences between the two models, was applied. The deviations were reported as the shortest distance from the test model to any point on the reference model. Different colors were used to indicate the number of deviation ranges on the mapping. The congruency of the two models was estimated by comparing the RMSE of the test and reference models.

RMSE between the inner contours of the graft block and original bone at the recipient site immediately after bone grafting

CBCT was used to reconstruct the corresponding surface models of these two immediately after bone grafting and RMSE was calculated using the method described in the previous section.

Thickness and volume of the implanted bone block

The bone block graft model was reconstructed immediately after the bone augmentation surgery. Mimics software determined the maximum thickness and volume of the implanted bone block.

2.6.2 | Secondary variables

Complications

The pulp vitality of the adjacent teeth at the donor site was determined preoperatively and 1 day postoperatively using an ice stick. The patients were regularly followed up to monitor changes in pulp vitality. The peripheral tissues at the donor site were examined preoperatively and 1 day postoperatively using the pointed-blunt test. The patients were regularly followed up to monitor the presence of paresthesia. After 6 months of bone block grafting, the presence of secondary bone augmentation and the success of the implant placement were recorded during the implant placement surgery.

Efficiency

The bone harvesting time during the bone graft surgery was calculated using a timer to measure the duration from the beginning of the donor area incision to the finish of bone block harvesting. The time for guide placement was included in the study group. Similarly, the bone block trimming time was calculated to measure the duration from the finish of bone block harvesting to its placement at the recipient site.

Postoperative discomfort

Immediately after the surgery, the visual analog scale (VAS) was used to assess pain during surgery. On postoperative day seventh, VAS was used to assess the short-term postoperative pain, swelling, and mouth opening difficulty. All the patients were informed of these assessments preoperatively.

All the assessments were performed by the same examiner at the specified time points. The data were measured by the trained and calibrated examiner independently of the surgeon, in a single-blinded manner.

2.7 | Statistical analysis

Fisher's exact test and independent sample *t*-test or Mann–Whitney *U*-test were used for categorical and continuous data, respectively. The categorical data were expressed in frequency and percentage, while continuous data were expressed as means ± standard deviations. IBM SPSS 26 and GraphPad Prism 8 software were used for the statistical analyses and $p < 0.05$ was considered significant for all the tests.

3 | RESULTS

A total of 28 patients, equally divided into two groups, were included in this study. Patients' details regarding their sex, age, and recipient site are listed in Table 1. All the participants successfully underwent implant placement after 191.8 ± 19.69 days of bone block grafting.

3.1 | Primary end point

The RMSE between the outer contours of the designed and actual implanted bone blocks immediately after bone grafting in the guide group and the control group was 0.37 ± 0.16 mm and 0.72 ± 0.29 mm, respectively ($p = 0.0007$, independent sample *t*-test) (Figure 6A–C).

The RMSE between the inner contours of the graft block and original bone at the recipient site immediately after bone grafting was 0.35 ± 0.15 mm and 0.48 ± 0.17 mm in the guide and control groups, respectively ($p = 0.043$, independent sample *t*-test) (Figure 7A–C).

The maximum thickness of the implanted bone block in the guide and control groups was 4.64 ± 0.42 mm and 4.26 ± 0.59 mm, respectively ($p = 0.0594$, independent sample *t*-test).

The volumes of the implanted bone block in the guide and control groups were 348.1 ± 67.42 mm^3 and 264.9 ± 38.00 mm^3, respectively ($p = 0.0004$, Mann–Whitney *U*-test).

3.2 | Secondary end points

3.2.1 | Complications

In the control group, one patient developed bleeding in the donor site 6 h after the surgery and displayed hypoesthesia symptoms in the lower lip and chin on the side of the bone harvesting area on the first postoperative day. The range of hypoesthesia, which was detected using the pointed-blunt test, was approximately 2 cm × 2 cm of the side of the chin in the donor area, which reduced to approximately 1 cm × 1 cm after 3 months and disappeared after 6 months. Another patient in the control group experienced sensitivity in the tooth adjacent to the donor site. The pulp vitality test showed that the tooth was more sensitive than before the surgery, which had returned to normal at the 3-month postoperative examination without pulp treatment. The patients in the guide group showed no complications, such as changes in the pulp vitality or paresthesia of the adjacent teeth, and no wound dehiscence or infection occurred in both the groups.

In the control group, two participants underwent secondary bone grafting by GBR with particulate deproteinized bovine bone and resorbable collagen membrane during the surgery for implant placement. The implants were placed after 193.1 ± 17.85 days of bone

TABLE 1 Distribution of the demographic and site characteristics

	Group	*N*	*X*	SD	*p*-value
Patients	Guide	14			
	Control	14			
Sex (male/female)	Guide	7♂/7♀ (50/50%)			0.704[a]
	Control	5♂/9♀ (36/64%)			
Age (years)	Guide	14	39.21	14.98	0.662[b]
	Control	14	36.93	12.19	
Recipient sites (incisor/canine/premolar)	Guide	9I/2C/3P			0.257[a]
	Control	8I/0C/6P			

Abbreviations: ♂, male; ♀, female; *X*, mean; SD, standard deviation.
[a]Fisher's exact test.
[b]Independent sample *t*-test.

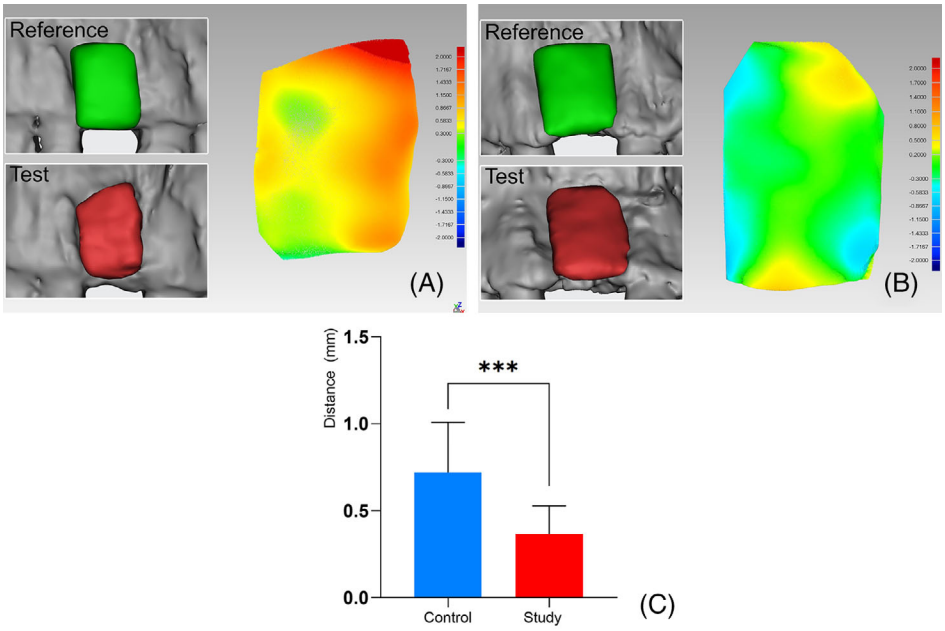

FIGURE 6 Contour evaluation. (A) One case in the control group; the green one on the left side indicates the designed block; the red one on the left side indicates the actual implanted block, and the image on the right side shows the comparison chromatogram between the two outer contours; (B) one case in the guide group; (C) bar graph of the root mean square estimate between the outer contours of the implanted and the planned bone block in the control group and the guide group

grafting in all patients in the control group patients according to the original plan. Conversely, none of the guide group patients required secondary bone grafting, and according to the original plan, the implants were placed after 190.5 ± 21.97 days after bone grafting in all 14 patients.

3.2.2 | Efficiency

Based on the independent sample *t*-test, the total bone harvesting times, including the guide placement time, in the guide and control groups were 609.17 ± 99.97 s and 670.90 ± 139.55 s, respectively ($p = 0.1901$, Figure 8A). The bone block trimming durations in the guide and control groups were 401.51 ± 97.60 s and 602.36 ± 160.57 s, respectively ($p = 0.0005$, Figure 8B).

3.2.3 | Postoperative discomfort

Based on the patients' responses to the VAS questionnaire, there were no statistically significant differences in the during surgery pain as well as postoperative short-term pain, swelling, and mouth opening difficulty (Table 2).

4 | DISCUSSION

This randomized controlled trial compared the outcomes and efficiencies of intraoral block bone grafting, which was performed with and without a template.[20] The results showed that the use of a guide template might make the postoperative graft contours more consistent with those of the preoperative design. Moreover, the use of a guide

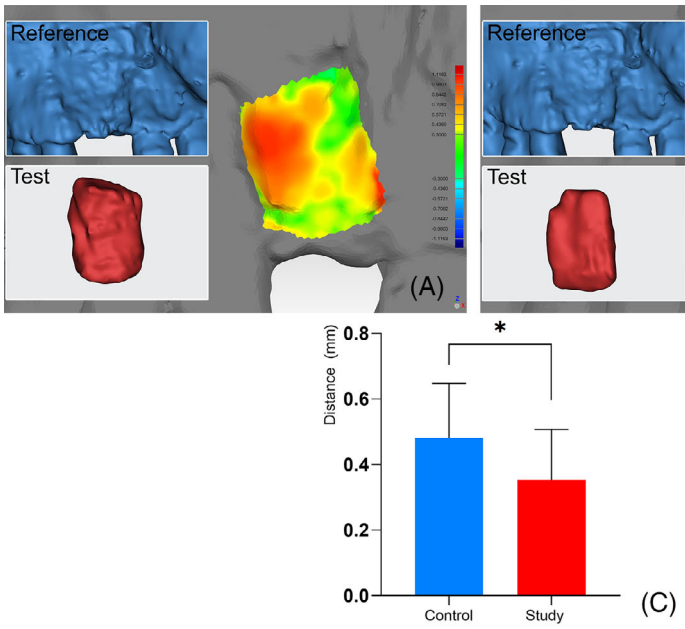

FIGURE 7 Fit evaluation. (A) One case in the control group; the blue one on the left indicates the original bone of the recipient site; the red one on the left indicates the inner fitting surface of the actual implanted bone block, and the image on the right side shows the chromatogram of the fit between the two inner contours; (B) one case in the guide group; (C) bar graph of the root mean square estimate between the implanted bone block and the original bone surface

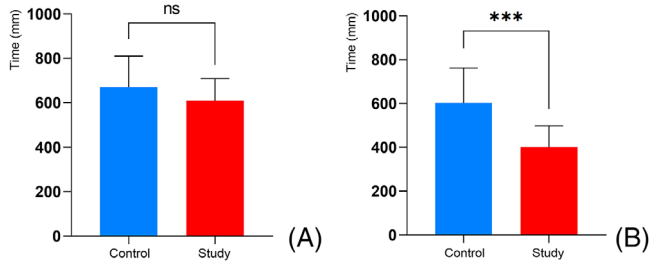

FIGURE 8 (A) Bar graph of the bone harvesting time of the two groups; (B) bar graph of the bone trimming time of the two groups

template could also shorten the time required for trimming of the graft.

Autogenous bone is considered the gold standard for the augmentation of the alveolar ridge.[21] The staged surgical approach of autogenous bone grafting is the most reliable option to avoid the initial instability of implants in the correct position by the insufficient alveolar bone volume.[3] Autogenous block bone grafting is often associated with unpredictable results of bone augmentation, difficulty in controlling the volume and trimming of the harvested bone block, and complications.[6,22,23] A high technical sensitivity is required to harvest, trim, and fix a bone block suitable for the recipient site in traditional bone grafting due to the lack of precise preoperative planning and intraoperative guidance.[1] This might result in a bone graft of poor shape and size, which can affect the prosthetically driven implantation and esthetic outcomes. A poor fit between the graft and the recipient site may also happen, which might be unfavorable to the stabilization of the graft, leading to the ingrowth of connective tissue between the bone graft and recipient area, thereby preventing the successful graft integration.[6]

Computer-aided technology has been widely used to achieve precise, minimally invasive, and safe surgical results to place the implant.[24–27] In bone augmentation surgery, the application of digital technology to assist particulate bone augmentation using a titanium mesh has achieved relatively good results.[28–31] However, unlike the titanium mesh, which can be bent and shaped easily, using digital technology to shape and position the block bone can be difficult. Since accurate bone grafting is indispensable, it is necessary to use digital technology to make block bone grafting as controllable and precise as those of guided implant surgery. In this study, the trim and graft guides, which were compatible with the bone harvest guide, were used in the guide group. The graft guide was designed based on the prosthetically driven target bone block and fixation screws of the designed graft. Then, the target graft was virtually moved to the donor area. The site, requiring the least trimming of the harvested bone block, was identified, and a split-type bone harvest guide was designed, which included a tooth-supporting positioning device and an osteotomy template. Finally, the 3-dimensional bone shape, which required trimming, was obtained by applying the "Boolean operation" to the virtually cut graft and recipient site, thereby designing the trim guide. The 3-dimensional design of the target graft and assistance provided by the intraoperative guide was expected to result in the accurate augmentation of bone, avoiding insufficient bone volume and secondary bone grafting. This also avoided excessive bone grafting, which was extended beyond the contour of the bone arch and guarded the soft tissue at the recipient site from excessive tension as well as avoiding unnecessary bone harvesting.[30]

In this study, the consistency between the actual contour of the graft and the preoperative plan was evaluated by reconstructing the immediate postoperative jawbone model and superimposing it on the preoperative design using the unchanged parts of the jawbone as references. The measured RMSE values between the outer contours of the actual graft and the preoperative design in the guide group were smaller than those in the control group. Specifically, the RMSE values in the guide and control groups were 0.37 ± 0.16 and 0.72

TABLE 2 Postoperative reaction VAS (0–100) results in the control and guide group

Evaluation indicators	Guide group	Control group	Difference (95% CI)	*p*-value
Pain during surgery (VAS)	7.64 ± 4.77	9.64 ± 6.57	−2.00 (−2.46, 6.46)	0.365[a]
Post-op pain (VAS)	21.99 ± 6.16	23.87 ± 8.96	−1.88 (−7.85, 4.09)	0.524[a]
Post-op swelling (VAS)	40.92 ± 12.29	44.19 ± 13.08	−3.27 (−13.13, 6.59)	0.501[a]
Post-op trismus (VAS)	37.96 ± 15.16	36.22 ± 11.14	1.74 (−8.60, 12.07)	0.733[a]

Note: Difference between means (guide-control), *p*-value between the groups.
Abbreviation: VAS, visual analog scale.
[a]Independent sample *t*-test.

± 0.29 mm ($p < 0.001$), respectively, indicating that using the combination of guides could improve the predictability and outcomes of the block bone grafting procedure as compared to the conventional free-hand surgery. Numerous studies have compared the differences between two 3-dimensional models using RMSE values.[16,20,27,32] The 3-dimensional shape of the required implanted bone block and bone harvesting site were also designed for the control group and provided to the surgeon for reference. This might provide more guidance to surgeons than the routine imaging data, thereby improving surgical outcomes. At the same time, it was worth noting that the volume of the implanted bone block in the guide group was more than that of the control group ($p < 0.001$), which might be due to the ability of the surgeon to perform the surgery using the guides without worrying about the surgical safety, thereby adequate bone volume was obtained in the guide group. However, in the absence of a guide, the harvested bone volumes were lower due to the surgeon's concern about damage to the anatomical structures.

On the other hand, the trim guide was expected to improve the fit between the graft and recipient area. In the past, good shaping of the graft was highly dependent on the experience and surgical skills of the surgeons in free-hand surgeries. This procedure requires the surgeon to observe the graft and exposed recipient area during surgery and repeatedly try to determine a proper position for the implant to achieve intimate contact, which might lead to making multiple revisions.[2,17] This whole process lacks predictability, and the patients need to cooperate during the repeated opening of their mouths and reflection of the flap. Moreover, there is also a risk of contamination of the graft and recipient area. Before the final fixation of the graft, the free graft and recipient site needed to be perforated, during which, the graft might drop, become contaminated, or get fractured due to clamping instruments. To assist the trimming of the bone blocks, Pham Dang and colleagues[18] used resin materials for the 3-dimensional printing of the reconstructed jawbone model and placed the harvested bone block on the model, which was then trimmed based on its fit with the model. This method could assist in the trimming of bone blocks to a certain extent, thereby reducing the risk of repeated reflection of the gingival flap. However, it is an indirect auxiliary method and cannot directly limit the trimming of the graft. A direct digital trim guide could aid in bone block grafting, which had not been reported before. In the guide group, the surgeons do not need to place the graft at the recipient site to identify the need for further trimming during the surgery, but they can fix the bone block directly at the recipient area through the drilled holes in the bone block and the recipient area. The RMSE values, which were calculated immediately after surgery between the graft and original bone surfaces, were smaller in the guide group as compared to control group (0.35 ± 0.15 mm vs. 0.48 ± 0.17 mm, $p < 0.05$), indicating that using the combination of guides could improve the fit between the graft and the recipient site. Meanwhile, it was worth noting that the use of a trim guide could achieve a result that was better than that of the conventional surgery, requiring repeatedly opening the flap and putting the graft back into the recipient site for comparison.

Besides, using the trim guide could significantly improve the efficiency of bone block trimming. The statistical analysis of the surgery duration indicated that the in vitro trimming duration of the harvested bone block was significantly shorter in the guide group as compared to the control group (401.51 ± 97.60 s vs. 602.36 ± 160.57 s, $p < 0.001$). This might be due to various reasons, such as avoiding the repeated placement of the graft at the recipient area for observation as well as drilling the bone block and recipient site when the bone block is in vitro, in addition to the use of the trim guide and virtual design of the graft as a reference, indicating the trimming site. This might also be due to the more suitable dimension and shape of the bone blocks harvested using the harvest guide, requiring a lesser trimming. The shortening of the trimming duration was beneficial to maintaining its biological activity. In addition, there was no statistically significant difference observed between the bone harvesting durations of the two groups. The bone harvesting durations of the guide group were recorded from the beginning of incision at the donor area to the finish of bone block harvesting, including the time required for the insertion of guide for the tooth-supporting positioning device, perforating the bone, and removing of the guide, as well as the time required for the insertion and fixation of the osteotomy template and use of the osteotomy instrument. Similarly, the bone harvesting duration in the control group was recorded from the beginning of the donor site incision to the finish of bone block harvesting, including the use of probes to measure length, intraoperative observation of imaging data and preoperative plan, and use of osteotomy instruments. There was no statistically significant difference in the total bone harvesting duration between the two groups, indicating that the use of the guide, which could be tried on preoperatively, did not increase the surgery time consumption.

Researchers have used digital technology to reduce the complications associated with bone grafts and developing the bone harvest guide. Osman and Atef[13] described a bone harvest guide, which was solely dependent on the bone surface for its placement. This method required a larger contact area between the guide and bone surface as

well as a longer surgical incision with increased surgical damage. At the same time, it could be easily affected by the location and field of view of the donor site and could not be easily placed accurately. De Stavola and colleagues[14,15] described a bone harvest guide, which used the tooth positioning part, designed integrally with the osteotomy part of the guide, to improve the accuracy of guide positioning. However, the integrating design could be easily limited by the path of insertion. On one hand, the use of complete crown information to achieve precise positioning was difficult. On the other hand, the tooth positioning part could not be confirmed before surgery, thereby might preventing the intraoperative use of the guide. In addition, the guide was made up of non-metallic materials having a large volume, which increased the scope of the incision and chances of trauma. In order to solve this issue and achieve an accurate positioning using the complete crown information, the previous one-piece type to a split design was altered. The split design allowed the tooth positioning appliance to be tried on preoperatively. In this study, the guide was used successfully for all 14 patients in the guide group. In addition, to reduce the flap size and trauma and provide the surgeons with more operating space, the osteotomy guide was made up of metal and fixed with screws.[33] The surgeon could use the tooth-supporting positioning device to guide the position of the incision as well as use the drilling holes on the bone surface to position the osteotomy guide quickly.

In this study, one patient in the control group showed bleeding and lower lip and chin numbness postoperatively. Another patient developed hypoesthesia in the tooth adjacent to the donor site, and the pulp vitality test showed a more sensitive response as compared to that of the preoperative results. The guide group showed no such complications. These results were consistent with those of the previous studies.[9,10,14,34–37] Comparing the patients' responses to the VAS questionnaire between the two groups showed no significant difference in terms of during surgery pain as well as postoperative short-term pain, swelling, and difficulty of mouth opening, indicating that the use of the guide did not increase the trauma of surgery or postoperative reactions.

It is worth noting that the surgeon in this trial has more than 20 years of surgical experience and was very proficient in free-hand intraoral bone block grafting. However, for the novice surgeons, lacking experience, the digitally aided methods, which rely less on experience, might be more conducive to better outcomes, higher efficiency, lower incidence of complications, and milder postoperative reactions as compared to free-hand surgeries.

In conclusion, the sequential use of the combination of digital guides could make the entire intraoral block bone grafting procedure controllable, improve the predictability of the bone augmentation outcomes, and reduce the grafting trimming duration as compared to the conventional free-hand surgery.

This study had certain limitations. First, the small sample size of participants might be a reason for the lack of statistical significance in the differences between the groups. Second, the surgeon, who performed the surgical procedures, was an experienced surgeon. Although this was beneficial for controlling the variables, the advantage of the guides compared to the free-hand surgery might be more obvious if a novice surgeon performs both techniques. Third, the indication of the guides was a bone defect suitable for repair by the intraoral block bone grafting, exhibiting a relatively regular shape of the recipient site and availability of an adequate bone volume at the donor site. In addition, the design and fabrication of the guides increased the time and economic costs.

5 | CONCLUSIONS

During the observational period, for a tooth missing with horizontal alveolar ridge defects, the guides for intraoral block bone harvesting, trimming, and placement using a fully digital workflow could help in achieving more accurate and predictable surgical results as compared to those of a free-hand operation. The digital intraoral block bone grafting procedure might provide a feasible and repeatable workflow to precisely control the contours of the block bone grafts and improve surgical efficiency.

AUTHOR CONTRIBUTIONS

Ning Zhu: Investigation, data analysis, data interpretation, drafting article, and project administration. **Jiayu Liu**: Investigation, project administration. **Ting Ma**: Investigation, project administration. **Yu Zhang**: Concept, design, resources, critical revision of article, and supervision. **Ye Lin**: Concept, critical revision of article, approval of article.

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CONFLICT OF INTEREST

Ning Zhu and Yu Zhang developed the guide used in this study and two Chinese patents were obtained (patent No. ZL 2021 10 133 908. X; ZL 2021 20283836.2). There are no additional conflicts of interest to report.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Ning Zhu https://orcid.org/0000-0002-9298-9359

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