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Randomized Clinical Trial of the Accuracy of Patient-Specific Implants versus CAD/CAM Splints in Orthognathic Surgery

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Background: The maxilla position is essential for the aesthetic and functional outcomes of orthognathic surgery. Previous studies demonstrated the advantages of patient-specific implants in orthognathic surgery. However, more data are needed to confirm the superiority of patient-specific implants over surgical splints created with computer-aided design/computer-aided manufacturing (CAD/CAM). This randomized controlled trial aimed to compare the accuracy of patient-specific implants and CAD/CAM splints for maxilla repositioning in orthognathic surgery.

Methods: Patients ($n = 64$) who required orthognathic surgery were randomly assigned to use either patient-specific implants (patient-specific implant group) or CAD/CAM surgical splints (splint group) to reposition the maxilla. The outcome evaluation was completed by comparing virtual plans with actual results. The primary outcome was the discrepancies of the centroid position of the maxilla. Other translation and orientation discrepancies of the maxilla were also assessed.

Results: The authors analyzed 27 patients in the patient-specific implant group and 31 in the splint group. The maxilla position discrepancy was 1.41 ± 0.58 mm in the patient-specific implant group and 2.20 ± 0.94 mm in the splint group; the between-group difference was significant ($p < 0.001$). For the patient-specific implant group, the largest translation discrepancy was 1.02 ± 0.66 mm in the anteroposterior direction, and the largest orientation discrepancy was 1.85 ± 1.42 degrees in pitch. For the splint group, the largest translation discrepancy was 1.23 ± 0.93 mm in the mediolateral direction, and the largest orientation discrepancy was 1.72 ± 1.56 degrees in pitch.

Conclusion: The result showed that using patient-specific implants in orthognathic surgery resulted in a more accurate maxilla position than CAD/CAM surgical splints. (*Plast. Reconstr. Surg.* 148: 1101, 2021.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, I.

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The first two authors contributed equally to this article.

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Orthognathic surgery has been a classic and standard treatment for skeletal dentofacial deformities for decades. The position of the maxilla is essential for aesthetic and functional outcomes of orthognathic surgery. Orthognathic surgery is being reshaped by technological advancements, including digital dental imaging, three-dimensional imaging, computer-aided virtual surgical planning, computer-aided design (CAD) and computer-aided manufacturing (CAM).¹

In recent years, virtual surgical planning has been gradually replacing the traditional surgery model because of its accuracy, efficiency, and flexibility.²

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Virtual planning enables the surgeon to perform osteotomies and move bone segments as needed to optimize the final outcome.^{3,4} It is crucial to accurately execute the virtual plan during the operation to obtain the planned surgical result.⁵ Currently, surgical splinting is still the most commonly used method to translate the virtual plan to the operation field.^{6,7} However, because the positioning of the maxilla depends on a stable condyle-fossa relation, which often cannot be guaranteed, it is difficult to obtain the expected accuracy using the splint technique.

To overcome the limitations of surgical splints, several methods have been developed to maximize the advantages of virtual planning, such as surgical guides, intraoperative navigation, and patient-specific implants.⁸⁻¹⁴ With the development of three-dimensional printing techniques, patient-specific implants have been rapidly applied in craniomaxillofacial surgery since 2013.¹¹⁻¹⁴ Earlier studies have demonstrated that patient-specific implants can obtain good accuracy in translating virtual plans to intraoperative sites in orthognathic surgery, such as for precise repositioning and fixation of the maxilla in Le Fort I osteotomy.¹²⁻¹⁴ However, most of these studies only described the accuracy of the patient-specific implant system and lacked a systematic comparison with a conventional, CAD/CAM surgical splint control group. We designed a randomized controlled trial (Patient-Specific Implants to Increase the Accuracy of the Maxilla Position) to assess whether using patient-specific implants would result in a more accurate maxilla position than using CAD/CAM surgical splints in orthognathic surgery.

PATIENTS AND METHODS

Trial Design

This Patient-Specific Implants to Increase the Accuracy of the Maxilla Position trial was designed as a single-center, randomized, controlled, clinical trial. The trial protocol was developed by the authors and was approved by the human research ethics committee of our hospital. All procedures were performed in accordance with the relevant guidelines and regulations of the hospital.

Participants

Patients who were diagnosed with a skeletal maxillofacial deformity (skeletal class II and III) and required orthognathic surgery, including maxillary surgery, were recruited at their first surgical appointment. The exclusion criteria were previous orthognathic surgery, previous maxillary or mandibular trauma, maxillofacial tumors, segmental maxillary

surgery, oral soft-tissue defects, infections, craniofacial syndromes, bone metabolism disturbances, allergies to titanium implants, and pregnancy. All the participants provided written informed consent.

Sample Size

A sample size calculation was performed to determine the minimal number of patients for the present study. To detect a potential difference of 0.75 mm between the two groups and an assumed SD of 0.92 for each group and with a power of 80 percent at a level of significance of 5 percent, a minimum number of 25 patients were needed for each group. Finally, 64 patients were included in our research after taking a 20 percent dropout rate into account (Fig. 1).

Randomization

After written informed consent was obtained, the patients were assigned randomly by means of a block randomization procedure with the use of a computer-generated list of random numbers to use either patient-specific plates (patient-specific implant group) or CAD/CAM surgical splints (control group). The randomization and allocation were performed by an independent statistician.

The allocation sequence was concealed from the surgeons, enrolled patients, and the researcher. Sealed envelopes were used for sequential numbering. The randomization and allocation procedures were performed at the trial center. All the preoperative preparation procedures were the same between the two groups.

Masking

It was impossible to blind the patient and surgeon to the treatment group for the whole study, especially during the operation. However, the surgeons and researchers were blinded to the treatment group during the virtual planning phase. The doctor performing the clinical examination after the operation was also blinded to the grouping.

Interventions

After the computed tomographic data and digital dental data were obtained, virtual planning began with the use of the standard computer-aided surgical simulation routine for patients in both groups (Fig. 2).^{3,4,8} Once the surgical plan was reviewed and approved by the surgeon, three-dimensional models of the bone segments, in both the initial position and the final position, were imported into CAD/CAM software (Geomagic Studio, Geomagic; Research Triangle Park, N.C.)

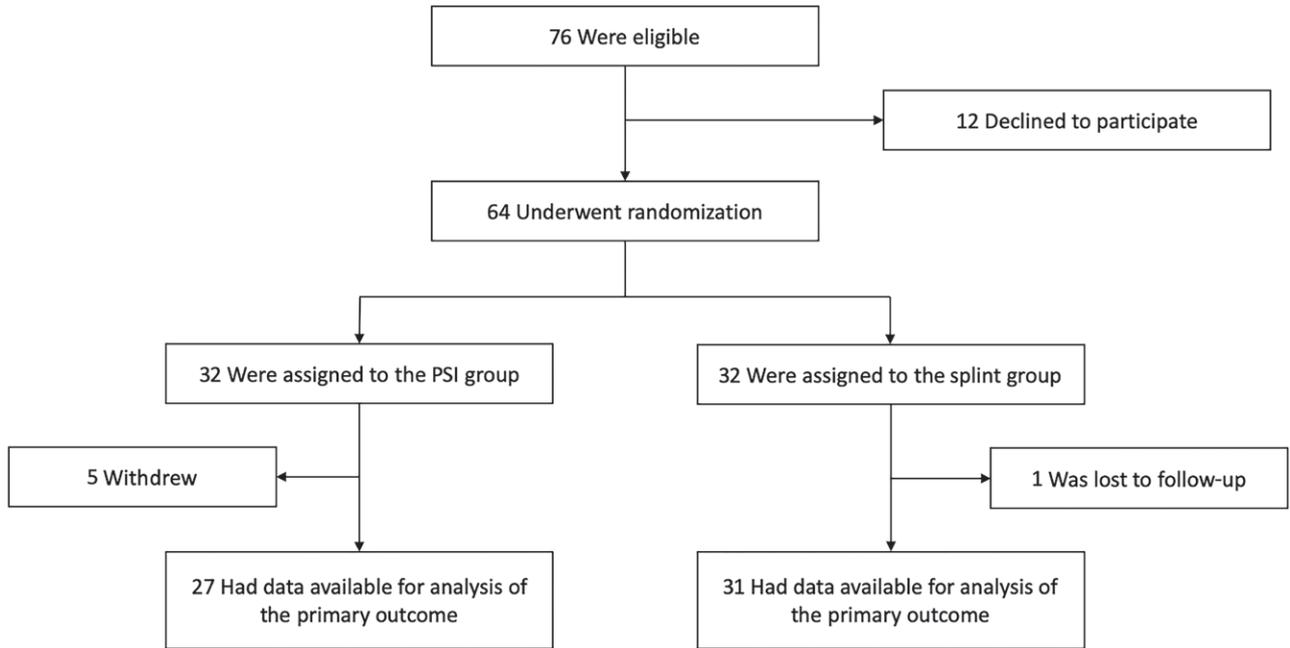


Fig. 1. Enrollment, randomization, and follow-up. *PSI*, patient-specific implant.

to design the surgical splints and patient-specific plates (Fig. 3, above).

For the splint group, surgical splints were designed according to the typical procedure. The mandible-first method was used in the following situations: counterclockwise rotation or inferior repositioning of the maxilla with maxilla-first method resulted in a maximum thickness of the

intermediate splint that exceeded 7 mm, or the condyle was at the anteroposterior position of the temporomandibular joint fossa on the computed tomographic scan.

For the patient-specific implant group, a cutting guide and patient-specific plates were designed for the maxilla surgery. The cutting guide, including both the left and right parts, was

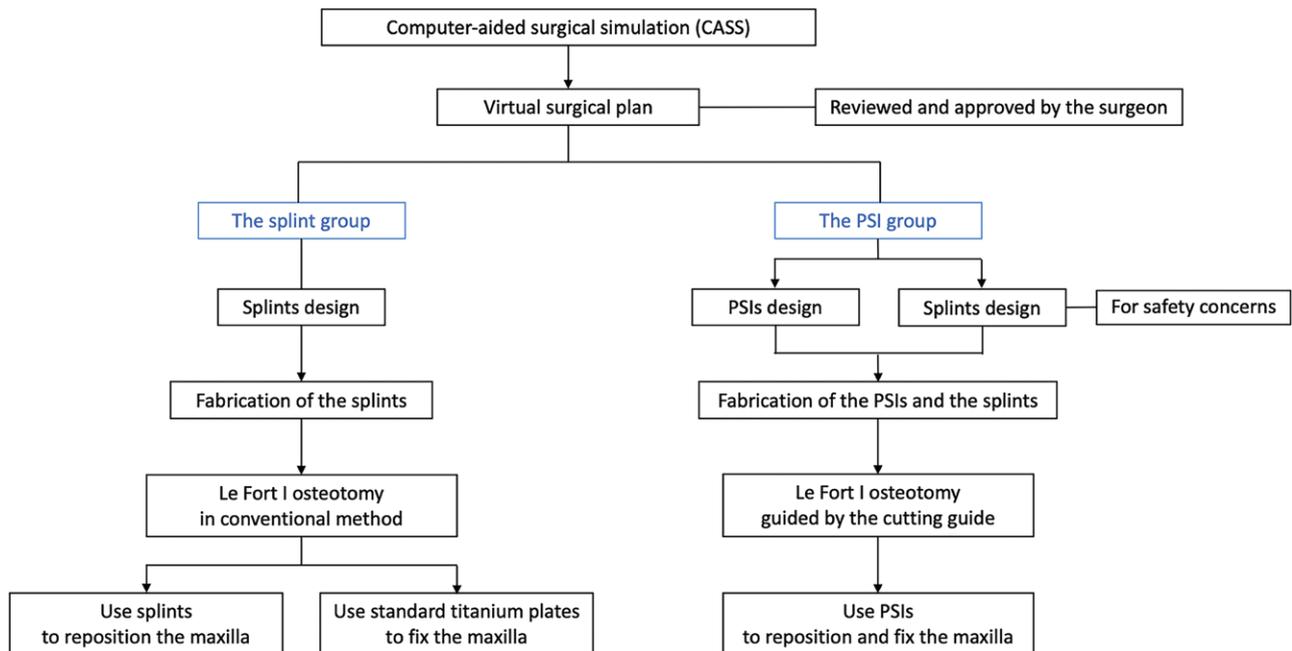


Fig. 2. The flowchart for the design and surgical procedures of the two groups. *PSI*, patient-specific implant.

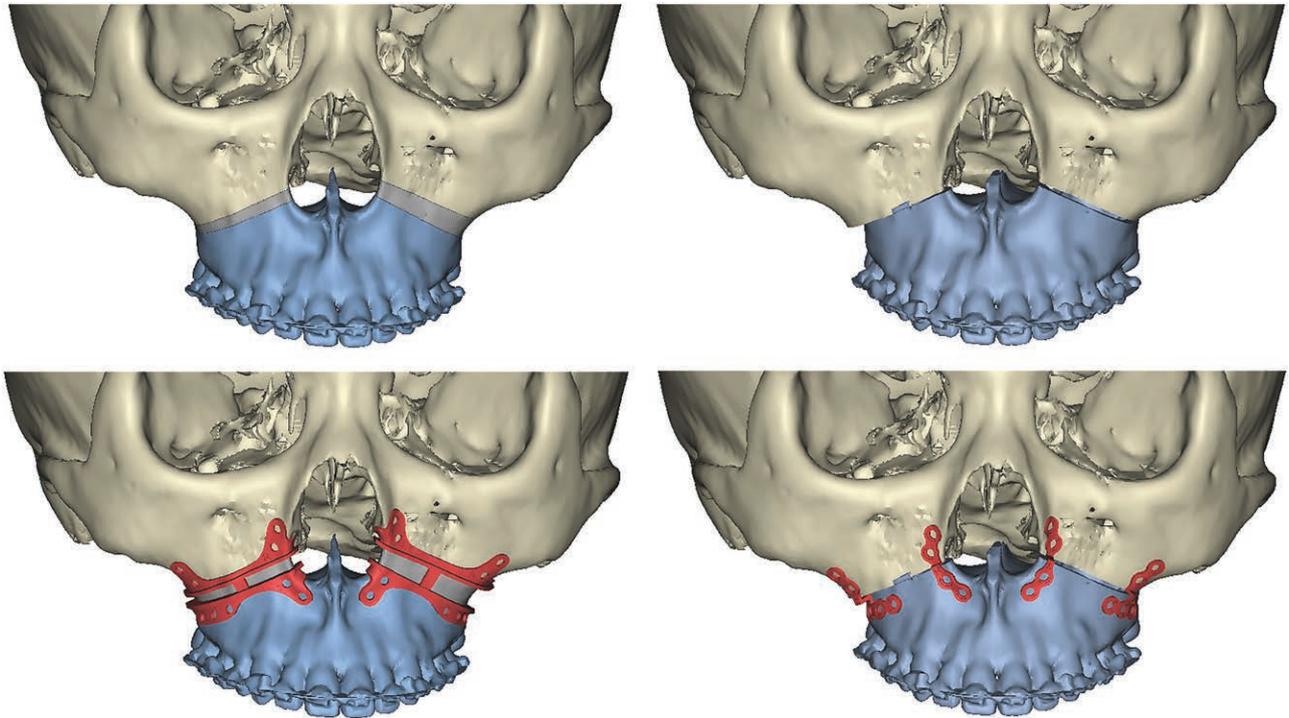


Fig. 3. The virtual surgical plan, the design of the cutting guides, and the patient-specific plates. Le Fort osteotomy (*above, left*) and the repositioning of the maxilla (*above, right*) were simulated. The cutting guides were designed on the maxilla in the initial position (*below, left*). The patient-specific plates were designed on the maxilla in the planned position (*below, right*) (gray, bone collision needed to be removed; red, the cutting guides and the patient-specific plates).

used to guide the osteotomy and screw holes to drill in the patient-specific implant (Fig. 3, *below, left*). In addition, the patient-specific plates were used to simultaneously reposition and fix the maxilla.

Each set of patient-specific plates included four separate customized plates, which were designed to be placed on bilateral zygomatic buttresses and the nasal rim separately. The shape of all four plates fit the bone surface of the maxilla at the planned position. The screw holes on the four plates corresponded with the drill holes on the cutting guide (Fig. 3, *below, right*). When passive fit between the bone surface and plate was achieved and the two sets of screw holes were aligned, the maxilla was brought to the planned position, and the fixation procedure was finished.

The maxilla-first procedure was chosen for all the patients in the patient-specific implant group. The conventional CAD/CAM splints were also prepared for the patient-specific implant group for safety concerns. As in our previous experiences, it was quite difficult to reposition the proximal and distal mandible segments using the customized plates. Therefore, the surgical splint was still used to determine the final occlusion and mandibular position for both groups.

After all the designs were approved by the surgeons, stereolithography files of the guide and patient-specific plate were exported for the manufacturing process using a three-dimensional printer with a selective laser melting technique. Both the splints and the patient-specific implant were sterilized with the regular process before the operation.

Surgery

In the splint group, Le Fort I osteotomy was routinely performed, and the maxilla was down-fractured. Then, the CAD/CAM surgical splints were used to reposition the maxilla according to the traditional procedure, and maxilla fixation was accomplished with standard (in stock) titanium plates.

In the patient-specific implant group, osteotomy was performed, and one set of the screw holes was applied to drill in the maxilla under the guidance of the cutting guide (Fig. 4, *above*). When the maxilla was down-fractured, four customized patient-specific plates were fixed on the maxilla below the osteotomy line using the screw holes predrilled by the cutting guide. Then, the maxilla segment was manipulated until passive fit between the plate and maxilla was achieved and

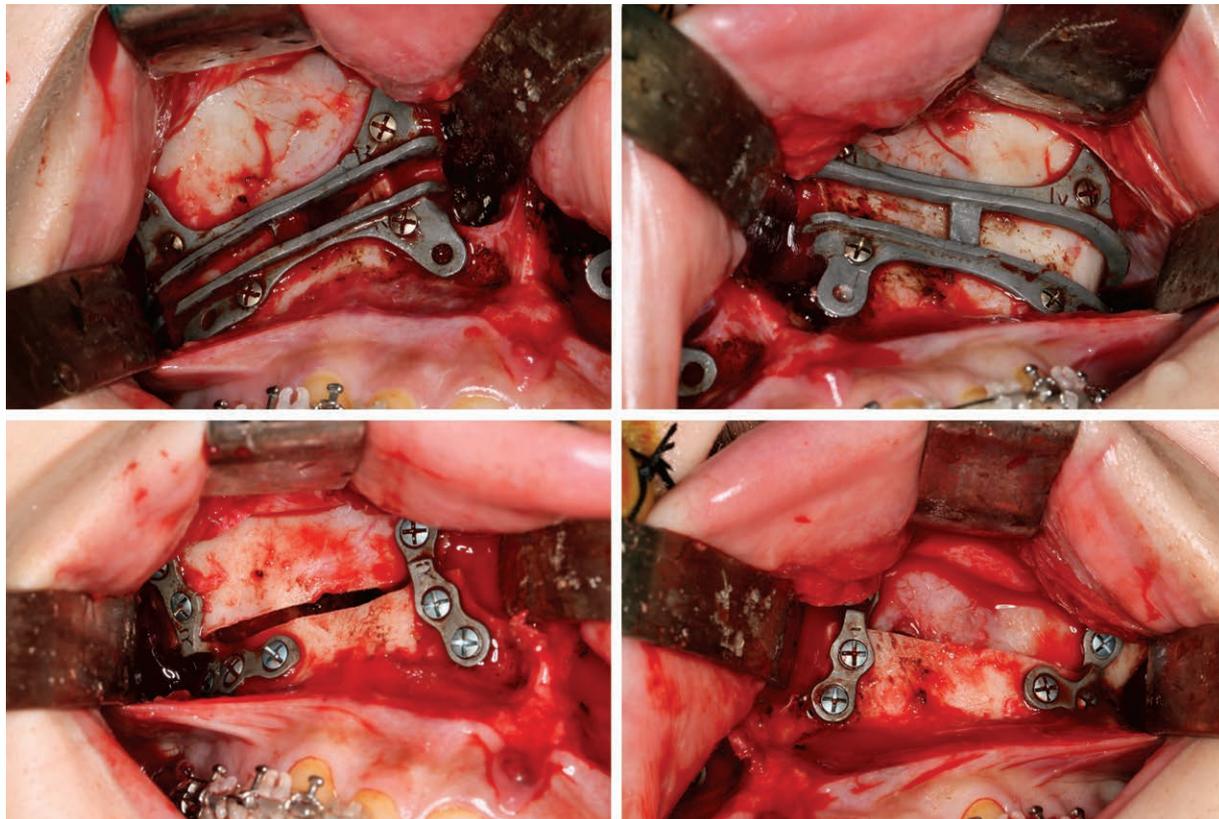


Fig. 4. The cutting guides were placed and temporarily fixed to the bone with screws. The cutting slot in the guide could indicate the removal of the bone collision (*above*). The maxilla was simultaneously positioned and fixed with the use of the patient-specific plate as planned (*below*).

the upper screw holes of the plate were aligned with the predrilled holes on the maxilla. After installing all of the screws, positioning and fixation of the maxilla were simultaneously completed as planned (Fig. 4, *below*). For both groups, the mandible position and final occlusion was determined by the surgical splint.

Accuracy Evaluation

A postoperative computed tomographic scan was acquired within 1 week after the operation to represent the actual surgical outcome. The postoperative skeletal models were generated and imported into computer-aided design software (3-Matic; Materialise NV, Leuven, Belgium) and compared with the virtual plan to assess the surgical accuracy.

Using a semiautomatic fusion tool in 3-Matic, the postoperative models were registered to the virtual plan by surface registration of the skull above the Le Fort I osteotomy. This procedure set the postoperative models into the same coordinate system of the planned models.

The skull model was oriented such that the Frankfurt plane of the skull was parallel to the

horizontal plane (xoy plane), the facial midline was aligned with the sagittal plane (yoz plane), and the coronal plane of the skull coincided with the coronal plane in the software (zox plane). This way, the x axis was in the mediolateral direction, the y axis was in the anteroposterior direction, and the z axis was in the inferosuperior direction (Fig. 5).

Three landmark points of the maxilla segment, the upper incisors and bilateral mesiobuccal cusp of the upper first molar, were digitized on both the planned and postoperative models (Fig. 5). A “reversed” routine developed by Xia et al.¹⁵ and Hsu et al.² was used to ensure that the landmarks corresponded between the planned and postoperative models. The planned models were kept static and served as targets. During the registration, all the landmarks and the maxilla segments were hidden. Only the region above the Le Fort I cutting line was visualized. These precautions were performed to avoid operator bias. The postoperative computed tomographic models were registered to the planned models using the surface-best-fit method. Finally, after the registration was completed, all hidden landmarks for

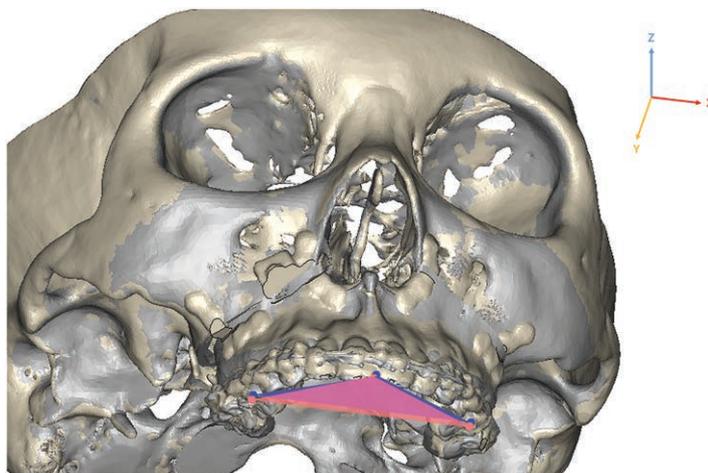


Fig. 5. The postoperative model of the maxilla (*light yellow*) was registered to the virtual plan (*gray*) by surface registration of the skull above the Le Fort I osteotomy. The *x* axis was in the mediolateral (left/right) direction, the *y* axis was in the anteroposterior direction, and the *z* axis was in the vertical (inferosuperior) direction. Three landmark points of the maxilla segment (the upper incisors and bilateral mesiobuccal cusp of the upper first molar) were digitized on both the planned and postoperative models. The coordinates of all landmarks and the centroid of the maxilla segment were used to calculate the discrepancies in the maxilla position between the virtual plan and the postoperative results (*blue*, postoperative model; *red*, virtual plan).

the maxilla segment were displayed and their raw coordinates were recorded.

The coordinates of all landmarks and the centroid of the maxilla segment were used to calculate the discrepancies in the maxilla position between the virtual plan and the postoperative results.² The translation discrepancies were calculated along the *x*, *y*, and *z* axes, and the orientation discrepancies were calculated in pitch (rotation around the *x* axis), roll (rotation around the *y* axis), and yaw (rotation around the *z* axis).

Outcomes

The primary outcome was the discrepancies of the centroid position of the maxilla. The secondary outcomes included translation discrepancies along the three axes, orientation discrepancies around the three axes, and intraoperative blood loss. The translation discrepancies were calculated along the *x*, *y*, and *z* axes and the orientation discrepancies were calculated in pitch (rotation around the *x* axis), roll (rotation around the *y* axis), and yaw (rotation around the *z* axis).

Statistical Analysis

All the analyses were carried out on an intention-to-treat basis. Continuous variables with

normal distributions were presented as the mean (SD); and nonnormal variables were reported as the median (interquartile range). The primary outcome was compared by independent samples *t* tests. The translation discrepancies and orientation discrepancies between the two groups were evaluated using a random-effects generalized linear model fitted with shared frailty to account for intracluster correlation within the same person. The Mann-Whitney *U* test was used for the comparison of the intraoperative blood loss. The frequencies of the categorical variables were compared using Pearson chi-square or Fisher's exact test, as appropriate. The data were analyzed by SAS 9.4 (SAS Institute, Inc., Cary, N.C.). A value of $p < 0.05$ was considered significant.

RESULTS

Trial Participants

From August 1, 2017, to December 31, 2018, a total of 64 patients were recruited and assigned randomly and equally to both groups. After excluding those lost to follow-up ($n = 1$) and those who refused the operation ($n = 5$), 58 patients were included in the primary analysis (27 in the

patient-specific implant group and 31 in the control group).

The flowchart of the study is shown in Figure 1 and the flowchart for the design and surgical procedures of the two groups is shown in Figure 2. The demographic characteristics were similar between the two trial groups (Table 1). Different types of skeletal malocclusion were distributed equally between the two groups.

Primary Outcome

There was a significant between-group difference in the primary outcome, the accuracy of the maxilla position. The maxilla position discrepancy was 1.41 ± 0.58 mm in the patient-specific implant group and 2.20 ± 0.94 mm in the splint group (Table 2).

Secondary Outcomes

For the patient-specific implant group, the largest translation discrepancy was 1.02 ± 0.66 mm in the anteroposterior direction, which indicated that the postoperative maxilla was unexpectedly located posteriorly to the planned position. The largest orientation discrepancy was 1.85 ± 1.42 degrees in pitch, which indicated that the maxilla had an unplanned rotation around the mediolateral (x) axis.

For the splint group, the largest translation discrepancy was 1.23 ± 0.93 mm in the mediolateral direction. The largest orientation discrepancy was 1.72 ± 1.56 degrees in pitch.

There was no significant between-group difference in intraoperative blood loss. The median volume of intraoperative blood loss was 600 ml (interquartile range, 600 to 800 ml) in the patient-specific implant group and 650 ml (interquartile range, 500 to 800 ml) in the splint group.

Safety and Side Effects

No significant differences in serious adverse events were noted between the groups. The incidence of infection was 3.7 percent (one of 27 patients) in the patient-specific implant group and 3.2 percent (one of 31 patients) in the splint group.

DISCUSSION

Our randomized controlled trial showed that using patient-specific implants resulted in a more accurate maxilla position than using surgical splints. The patient-specific implant group showed smaller discrepancies in all three dimensions for both translation and orientation, except for pitch. The largest orientation discrepancy

Table 1. Demographic Characteristics of the Participants

Characteristic	PSI	Splint
No.	27	31
Age, yr		
Mean	23.8	23.6
Range	19–32	19–33
Sex		
Female	15	21
Male	12	10
Classification		
Class II	7	9
Class III	20	22

PSI, patient-specific implant.

Table 2. Maxilla Position Discrepancy in the Two Groups

	PSI Group		Splint Group		p
	Mean	SD	Mean	SD	
Centroid position, mm	1.41	0.58	2.20	0.94	<0.001
Translation					<0.001
discrepancy, mm					
Mediolateral	0.37	0.40	1.23	0.93	
Anteroposterior	1.02	0.66	1.12	0.82	
Superoinferior	0.61	0.44	0.96	0.74	
Orientation					0.246
discrepancy, deg					
Pitch	1.85	1.42	1.72	1.56	
Roll	0.63	0.52	1.25	1.18	
Yaw	0.63	0.44	0.88	0.71	

PSI, patient-specific implant.

was found in pitch for both the patient-specific implant and splint groups. One hypothesis for this result is that all the internal fixation plates, including the customized plates in the patient-specific implant group, were only fixed on the anterior wall of the maxilla, which made a pitch rotation the most likely deviation.

For the patient-specific implant group, the largest translation discrepancy was found in the anteroposterior direction, which might result from the same cause as pitch rotation. For the surgical splint group, the largest translation discrepancy was found in the mediolateral direction. This discrepancy should be given enough attention because an incisor-midline deviation would cause constant complaints from both the patient and the orthodontist after the operation. One possible explanation is that undetected bone collisions might cause a slight lateral shift of the maxilla when it is mounted on the unstable mandible. In addition, it was difficult to evaluate the midline during the operation because of the presence of swelling and soft-tissue deformation.

However, the smallest translation discrepancy was found in the mediolateral direction for the patient-specific implant group. The rigid

customized plates provided accurate control of the maxilla in the mediolateral direction. Bone collisions, which would cause the lateral shift, could directly lead to failure to install the customized plates. Thus, bone collisions could be detected and removed more easily.

Unexpectedly, the smallest translation discrepancy was found in the vertical direction in the surgical splint group. This illustrated that the intraoperative measurements and evaluations, such as checking for incisor exposure, were more reliable than we thought.

Currently, it is well recognized that computer-assisted virtual planning could facilitate orthognathic surgery and improve the surgical result.¹⁶ Therefore, it is essential to accurately set the maxilla at the planned position during the operation to maximize the role of the virtual plan.⁶ Because of the mobile mandible and the temporomandibular joint, the traditional surgical splint technique could be unreliable in the repositioning of the maxilla, especially for patients with unstable condyle-fossa relations.

As CAD/CAM technology has matured, several types of customized surgical guides have been developed to overcome the disadvantages of the surgical splint in maxilla repositioning.^{8,10,17,18} However, the surgical guides have not been widely applied in orthognathic surgery because of its own drawbacks, such as its bulky size, associated slight deformation, and extra time needed for placement and removal.

With the development of three-dimensional metal printing, patient-specific implants could be regarded as an update of customized surgical guides. Because of the titanium material, patient-specific implants are rigid, slim in size, and implantable. Thus, patient-specific implants could reposition and fix the bone segment simultaneously. Attempts to use patient-specific implants in maxilla surgery have been reported since 2013.¹¹

Several previous case series studies evaluated the accuracy of patient-specific plates using the resulting errors from overlapping the planned and postoperative models.^{12,19-21} However, the error of the two overlapped three-dimensional models does not equal the position discrepancy of these two objects and could not fully demonstrate the accuracy of patient-specific implants.

Our previous study used the coordinates of several landmarks to calculate the translation and orientation errors of patient-specific implants for bimaxillary orthognathic surgery and showed that the largest root-mean-square deviations were 0.74 mm and 1.93 degrees for the maxilla

and 1.10 mm and 2.82 degrees for the mandible, respectively.²² Heufelder et al. also reported a cohort study of 22 patients.¹⁴ Five occlusal landmarks were used to compare the planned and postoperative maxilla positions. The median deviation of the maxilla position was 0.39 mm. However, these studies lacked a control group to compare the accuracy of patient-specific implants with that of conventional surgical splints.

Later comparison studies could not strongly prove the superiority of patient-specific implants over surgical splints because of their small sample sizes and retrospective designs. Rückschloß et al.²³ described a comparison study of 18 class III patients (nine with patient-specific implants and nine with splints) treated with the surgical splint method in 2019. The results showed that patient-specific implants could obtain an overall higher accuracy compared with surgical splints, especially for anteroposterior translational movement.

We found several advantages from our experiences during the application of the patient-specific implant technique. Compared with the traditional surgical splint method, the customized plates could completely control the maxilla position without being affected by the unstable mandible and temporomandibular joint. The maxilla position was determined in three dimensions, including in the vertical direction. The internal or external vertical measurement was no longer required.

Compared with CAD/CAM templates, patient-specific implants had simplified intraoperative procedures, as there is no need for fixation and removal of a repositioning guide. Because of its rigid character, titanium guide and patient-specific implants could be easily placed at the unique planned position. In addition, the compact and lightweight design also facilitated its intraoperative use.

In this study, each set of patient-specific plates were designed as four separate plates so that each plate could be placed and fixed separately. Compared to our experiences with other designs in a previous study, the separate design and reduced size of each plate increased the ease of use and required a smaller incision during the operation.

We did not intentionally enroll complex cases in this study, and craniofacial syndromes were also excluded. Although the between-group difference was statistically significant, the actual value of the difference was minor. The accuracy of the splint group was acceptable in this study. When it comes to difficult cases, such as patients with

severe asymmetry or an unstable temporomandibular joint, the accuracy of the splint group would be degraded. We will investigate the superiority of the patient-specific implant over the splint technique for difficult cases in a later study.

In this study, we did not perform a cost-effectiveness analysis. Compared with the conventional splint method, one of the disadvantages of the patient-specific implant is the additional time and economic cost. The design work of the patient-specific implant for one patient will cost 5 hours of a skilled computer-aided design technician. Because of the higher laboratory and manufacturing costs, surgical treatment with patient-specific implants would be more expensive. The other disadvantage is that intraoperative changing of the plan is difficult, which is a common issue for all patient-specific implant techniques.²⁴ If adjustment of the plan is required, the surgeon has to abandon patient-specific plates and complete the operation using standard titanium plates with the conventional method.

All patients in this trial accepted one-piece Le Fort I osteotomy. It is questionable whether the segmental Le Fort I osteotomy for the maxilla would affect the primary and secondary outcomes. These subjects require further investigation.

CONCLUSION

In this randomized, controlled, clinical trial, the use of patient-specific plates in orthognathic surgery resulted in a more accurate maxilla position than the use of CAD/CAM surgical splints.

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