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Abstract: This retrospective study aimed to assess the accuracy of prebent plates and computer-aided design and manufacturing osteotomy guide for orthognathic surgery. The prebent plates correspondent to the planning model were scanned with a 3-dimensional printed model for guide design and used for fixation. Forty-two patients who underwent bimaxillary orthognathic surgery using computer-aided design and manufacturing intermediate splint with the guide (guided group: 20 patients) or with conventional fixation under straight locking miniplates (SLMs) technique (SLM group: 20 patients) were analyzed. A deviation of the maxilla between the planned and postoperative positions was evaluated using computed tomography, which was taken 2 weeks before and 4 days after the surgery. The surgery time and the infraorbital nerve parasthesia were also evaluated. The mean deviations in the mediolateral (x), anteroposterior (y), and vertical directions (z) were 0.25, 0.50, and 0.37 mm, respectively, in the guided group, while that in the SLM group were 0.57, 0.52, and 0.82 mm, respectively. There were significant differences in x and z coordinates (P < 0.001). No significant difference in the surgery duration and paraesthesia was seen, suggesting the present method offers a half-millimeter accuracy for the maxillary repositioning without increasing the risk of extending surgery duration and nerve complication.

Key Words: Computer-aided design and manufacturing osteotomy guide, 3-dimensional printing, guided surgery, orthognathic surgery, prebent plate

Traditional treatment planning for orthognathic surgery using an intermediate splint made from a dental plaster cast model, face-bow, and articulator is likely to cause errors that prevent accurate positioning during surgery. Recent developments in 3-dimensional (D) printing, computer-aided design and computer-aided manufacturing (CAD/CAM) technology have extensively benefited orthognathic surgery. Many authors have reported the beneficial effects of CAD/CAM-based patient-specific surgical guides and intermediate splints for accurate maxillary repositioning, which is the most important factor for the success of orthognathic surgery.1–6 However, the use of the CAD/CAM intermediate splint for maxillary surgery has often caused some errors because of the mobility of the mandible and temporomandibular joint, particularly in patients with unstable condyle-fossa relations and repeated intraoperative measurement for maxillary repositioning.7–9 Therefore, the accuracy of CAD/CAM-guided surgery remains to be determined, although it is obviously more accurate than traditional surgery. We previously reported a simple technique using a straight locking miniplate (SLM) for accurate maxillary repositioning without any intraoperative measurement.8,9 As the SLM technique defines the relationship between the maxilla and mandible during surgery, the combination of SLM and CAD/CAM intermediate splints reflects the virtual surgical planning during surgery as a simplified. Accordingly, a comparison of this simplified maxillomandibular relation reproducible method, SLM technique, with fully guided surgery with osteotomy and plating guide could precisely evaluate the accuracy of the guided surgery because both methods use a CAD/CAM-based intermediate splint. A 3D-printed intermediate splint allows us to evaluate the accuracy of the surgery because the splint reproduces the planned position of the maxilla, even though the osteotomy and plating procedures are performed manually. This study aimed to compare the accuracy of 2 maxillary repositioning methods for orthognathic surgery: prebent plates and CAD/CAM osteotomy guide and SLM technique. The osteotomy and plating guide were designed based on prebent plates corresponding to the 3D surgical planning model and then printed with a 3D printer. A CAD/CAM-based intermediate splint was used in both methods. The maxillary position was 3D evaluated and cephalometric analysis was performed. The surgery time up
to the maxillary positioning and the infraorbital nerve paraesthesia were also evaluated. The deviation between the planned and actual surgery of both method and difference of them were calculated.

**METHODS**

**Study Design, Surgical Planning, and Simulation**

This retrospective clinical study was approved by the ethical committee of Yokohama City University (approval number, B201000050). We obtained the data of skeletal Class II or III patients who underwent bilateral sagittal split osteotomy (BSSO) and Le Fort I osteotomy (LI) at the Department of Oral and Maxillofacial Surgery, Yokohama City University Medical Center. A computed tomography (CT) scan was performed using a 64-slice CT scanner (Aquilion 64; Toshiba Medical Systems) 2 weeks before surgery (T0) and 4 days after surgery (T1). The patients were scanned while seated with a natural head position in centric occlusion. The imaging conditions were as follows: 120 kVp, 300 mA, 750 ms exposure time, and 0.5 mm thickness. Computed tomography data were exported in digital imaging and communications in medicine format and rendered to 3D virtual models using ProPlan CMF software (Materialise) to generate 3D craniomaxillofacial models. The dental casts were scanned with a scanner (3 shape TORIOS 3) and recorded on the virtual model using point-based and surface-based superimposition in the stereolithography (STL) files in ProPlan CMF software. Next, virtual LI and BSSO were performed, and the bony segments were virtually repositioned to correct the maxillomandibular relationship.

**Design and Construction of Surgical Guides and Intermediate Splint**

After the virtual LI, the virtual intermediate splint with the maxilla of the LI segment in the planned position was fabricated using Form 2 (Formlabs) with biocompatible photopolymer resin (Surgical resin; Formlabs). The repositioned maxillary model was exposed by 3D printing and bent 4 titanium locking miniplates (Synthes) were fixed to the bony surface and gap on printing 3D model. Finally, the maxillary models with prebent plates were scanned using a laser scanner, and the STL data were imported into the ProPlan CMF software. The cutting and screw guide were created using the ProPlan CMF software. The left and right surgical guides were designed based on planned osteotomy with imported STL date of plates and manufactured surgical guide, which included cutting line, bone of the interfering part, and screw holes 2.0 mm in diameter with 3D printing (Fig. 1). The surface of the surgical guide in contact with the bone was not polished to maintain accuracy.

**Evaluation**

The accuracy of the surgical repositioning of the maxilla was evaluated by comparing the planned maxilla and the actual postoperative maxilla in 3D objects. The preoperative and postoperative facial bones were superimposed with ProPlan software using an alignment tool in semiautomatic registration at the anterior cranial base that used surface-based rigid registration using the iterative closest point algorithm. Next, the preoperative maxilla was superimposed onto the postoperative maxilla. Repositioning distances were planned according to the following 3 reference planes: the Frankfort horizontal plane was referenced as the axial plane; the midfacial plane was referenced as the sagittal plane, defined perpendicular to the Frankfort horizontal plane, passing through the central landmarks of the nasion and sella; and the coronal plane was referenced perpendicular to the Frankfort horizontal plane and midfacial plane through the sella. Maxillary movements were evaluated at the 6 landmarks along with x-, y-, and z-coordinate axes; following, midpoint of the upper central incisor (U1), bilateral upper canine (RU3, LU3), and the most inferior point of the

**FIGURE 1.** The prebend plates and surgical guides. (A) The computer-aided design and manufacturing repositioned the maxillary model and the prebend 4 titanium plates. (B) The cutting and screw guide (orange objects) were created with the preoperative maxilla (green object) using the ProPlan CMF software.

**FIGURE 2.** Intraoperative application. (A) The surgical guide fitting with one screw on the maxillary surface. (B) The prebend titanium plates were fixed after repositioning to the planned maxilla.

**Surgical Procedure**

All surgeries were performed under general anesthesia by a nationally certified specialist oral and maxillofacial surgeon. The maxilla was exposed using the conventional LI osteotomy approach. The surgical guide was fixed onto the exposed maxilla with one screw fixation (Fig. 2). All screw holes were drilled, and the cutting lines were marked following the surgical guide. The osteotomy lines were cut using an ultrasonic cutting instrument and a reciprocating saw. The guide was removed, and the same operation was performed on the other side. After conventional downfracture of the maxilla, the maxilla was moved to the planned position matching the 4 prebent plates and holes were drilled after the removal of the bony interferences. Finally, the screws were fixed to 4 prebent titanium plates, which fitted the planned maxilla after maxillomandibular fixation (MMF) with an intermediate splint (Fig. 2). After Le Fort I osteotomy using a reciprocating saw, MMF was performed using a centric relation splint. The SLM was fixed bilaterally to the zygomatic buttress above the LI osteotomy borderline and proximal segment of the mandible. They were secured with 2 screws on each side. The SLM maintains the vertical distance between the skull base and mandible and can reproduce centric condylar positioning throughout the surgery. The SLM and screws were removed from both sides, and a downfracture was performed. When the maxilla was moved to the planned position, the screw holes were fitted accurately at the upper side of the SLM holes after the removal of bony interference using MMF with an intermediate splint. In this situation, MMF with an intermediate splint was performed, and the SLM was refixed using 4 screws. Finally, 4 titanium miniplates were bent, fitted with the maxilla, and fixed.
mesial cusp of the crowns of a bilateral upper first molar: (RU6, LU6), and posterior nasal spine. Furthermore, the surgery time of the maxilla (from incision to maxillary repositioning and fixation plates) and postoperative hypoesthesia in the infraorbital nerve were evaluated in both groups.

**Statistical Analysis**

The maxillary repositioning between the 2 groups (CAD/CAM surgical guides with prebent plates and SLM) was compared using the Wilcoxon rank-sum test. The planned and postoperative measurements in each group were also compared using the Wilcoxon rank-sum test. Differences were considered statistically significant at P-value < 0.05. Statistical analyses were performed using JMP 12 (SAS Institute Inc.). Each measurement was performed twice by the same surgeon, and the mean was recorded.

**RESULTS**

Forty-two consecutive patients from 2018 to 2020 were included in this study. The patient profiles of both groups are summarized in Supplementary Digital Content 1 (Table 1, http://links.lww.com/SCS/F69). Their age ranged from 16 to 44 years. None of the patients had a history of congenital facial deformities or other midfacial surgeries. The surgical guide group was 22 patients, which included 4 cases of skeletal class II, 13 cases of skeletal class III, and 5 cases of ≥4 mm facial asymmetry. Although, the SLM group were 20 patients including 5 cases of skeletal class II, 10 cases of skeletal class III, and 5 cases of ≥4 mm facial asymmetry. Comparisons between the guided and SLM groups are shown in Figures 3–5. The mean overall absolute deviation of 6 landmarks for the guided group was significantly smaller than that of the SLM group on the x- and z-axes (Fig. 3). The absolute deviation values of the guided and SLM group were 0.25 and 0.57 mm on the x-axis (mediolateral direction), 0.50 and 0.52 mm on the y-axis (anteroposterior direction), and 0.37 and 0.82 mm on the z-axis (vertical direction), respectively. The value of the x and z-axes of the guided group were significantly smaller than those in the SLM group (P<0.001; Fig. 3). The mean signed deviation values of the 3 axes of the guided group were within a half-millimeter, whereas that of the SLM group was within a millimeter (Fig. 4).

The overall maximum overcorrection and undercorrection of signed deviation were 1.44 and −1.49 mm in the guided group and 1.78 and −1.99 mm in the SLM group. The mean signed value deviation on the x-, y-, and z-axes in the guided group were −0.1 to −0.2, 0.30 to −0.50, and 0.25 to −0.25 mm, respectively. Although the mean signed value deviation on x-, y-, and z-axes in the guided group were −0.50 to −0.50, 0.30 to −0.50, and 0.25 to −1.0 mm, respectively. The signed value on the z-axis of the SLM group showed undercorrected deviation compared with the other axes of both groups (Fig. 4).

The mean absolute deviation of each 6 landmarks for the guided group was <0.5 mm, while those of the SLM group were 0.50 to 1.00 mm (Fig. 5). The deviations of all landmarks in the guided group were significantly smaller than those in the SLM group (P<0.01; Fig. 5). The actual deviation (signed value) on x-, y-, and z-axes of all landmarks are shown in

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**FIGURE 3.** The absolute value deviation between planned maxilla and postoperative maxilla in all patients. Comparison of computer-aided design and manufacturing surgical guide with prebent plates and SLM. SLM indicates straight locking miniplates.

**FIGURE 4.** The signed value deviation between planned maxilla and postoperative maxilla in all patients. Comparison of computer-aided design and manufacturing surgical guide with prebent plates and SLM. SLM indicates straight locking miniplates.

**FIGURE 5.** The absolute value deviation between planned maxilla and postoperative maxilla at various landmarks. Comparison of computer-aided design and manufacturing surgical guide with prebend plates and SLM. SLM indicates straight locking miniplates.
Figure 4. No significant difference was seen in the specific landmarks/axis (Supplementary Digital Content 1, Table 2, http://links.lww.com/SCS/F69).

There were significant differences in the duration of surgery up to the maxillary movement (Supplementary Digital Content 1, Table 3, http://links.lww.com/SCS/F69). The mean surgery duration of the maxilla in the guided group was 28 minutes shorter than that in the SLM group (Supplementary Digital Content 1, Table 3, http://links.lww.com/SCS/F69). There were no differences between the 2 groups regarding hypoesthesia of the infraorbital nerve (Supplementary Digital Content 1, Table 3, http://links.lww.com/SCS/F69), and paresthesia resolved completely within 6 months in both groups.

**DISCUSSION**

The present study demonstrated that the use of prebent plates scanned osteotomy and platting guide achieved a half-millimeter accuracy for the maxillary positioning. The accuracy in mediolateral and vertical directions were 0.25 and 0.37 mm, which were significantly smaller than the nonguide surgery. Even the deviation in the anteroposterior direction was 0.5 mm although it was not significantly different. Because Bai et al. first reported orthognathic surgery with a CAD/CAM surgical guide, studies on the accuracy of guided surgery have been reported. According to their reports, the average deviation of the prebent plate technique with the CAD/CAM intermediate splint was 1.5 mm, and the average deviation of the patient-specific implant technique was 1.02 mm. However, the accuracy of the proposed method was less than a half-millimeter. Our method used a 3D printing model of the maxilla based on virtual surgical planning. Plate prebending was performed on the printed planning model, and thereafter the prebend plates on the model were directly scanned as they fit each other. Therefore, information on screw-hole location and directions, as well as osteotomy lines, were precisely reproduced in the surgical guide, resulting in a half-millimeter accuracy of the surgical plan. Other researchers also used prebent plates; however, their guide to determine the screw-hole location was a combined unit with an intermediate splint. The guide was integrated with the intermediate splint, indicating that the position was defined by the intermediate splint rather than the screw-hole guide. Our screw-hole guide was combined with only the osteotomy guides. Therefore, the drilling positions were not defined by the intermediate splint position, indicating that the setting of our guide was simple. The intermediate splint is ultimately unnecessary because the correspondence of the prebend plates guarantees the position of the maxilla. However, the intermediate splint was fabricated and used because the splint could provide planned occlusal information and intermaxillary fixation made it easier for the surgeon to place the prebend plates on the maxilla, that is, the intermediate splint acted as a supportive device to consolidated the accuracy in the present procedure. The deviations of the present method were <0.5 mm for all landmarks, indicating that the maxillary position was 3D and precisely defined with the present guide despite the different planned repositioning distances. Among the 3 coordinate axes, the x-, y-, z-axes, the y-axis showed the least accuracy compared with the x- and z-axes, similar to previous reports of guided surgery. The possible cause of this discrepancy is the difficulty in visually judging the anteroposterior suitability of the guide to the bone surfaces, unlike the mediolateral and vertical directions.

The other cause of maxillary repositioning error other than the surgical technique in the prebend plate scanned guide procedure is an extra deformation of titanium miniplates after scanning caused by the release of the residual stress of titanium in the process of manual prebending. In particular, the residual stress increases when the number of the banding angle of the plates increases. During preoperative preparation, the plates may be bent several times to fit well to the surfaces of the planned maxillary model, resulting in plate deformation. In addition, the manually prebend plates were more fragile because of microfractures, and fragile points caused by manual bending, which decreased their resistance. Therefore, excessively prebend and thick plates should not be used to achieve accuracy.

**The SLM technique is one of the condylar repositioning methods, and a simplified technique that reproduce the relationship between the mandibular ramus and buccal buttress during surgery.** We previously reported that the condylar position accuracy of SLM during the orthognathic surgery was a submillimeter in distance and half a degree in rotation after sagittal split ramus osteotomy, indicating that the technique is a reliable tool for accurate positioning even in the maxilla during orthognathic surgery. The present study used SLM with CAD/CAM intermediate splint and achieved 0.5 to 1.0 mm accuracy, which is a relatively reliable value although it was inferior to the accuracy of prebend plates and CAD/CAM osteotomy guide. Pietzka et al. showed that maxillary repositioning accuracy for CAD/CAM generated splints in combination with temporary mandibular fixation, which is considered to be a technique similar to the SLM technique. According to their report, the median deviation was −0.62 mm, which was mostly the same accuracy as the present result although their undercorrection and overcorrection were −4.48 and 3.67 mm, whereas those of the present result were −1.99 and 1.78 mm, which were mostly half as variability as those of their results. Among the mean deviation in x, y, and z directions, the accuracy of SLM in the z-, vertical direction, was relatively inferior to the other direction. Furthermore, the range of under and overcorrection on the z-axis of the SLM was relatively large compared with other directions. These results suggest that SLM is a promising tool but has a weak point in determining the vertical position of the maxilla.

The SLM technique maintained a 3D relationship between the mandibular ramus and buccal buttress. However, because of the mobility of the mandible and temporomandibular joint, SLM was not able to fix the maxilla-mandibular relationship completely, particularly in patients with unstable condyle-fossa relations. To reproduce the relationship, locking plates were temporally fixed on the surface of the buccal buttress. Accordingly, the position on the y-axis, the anteroposterior direction, was particularly reproducible. In fact, the present results demonstrated that the accuracy of SLM on the y-axis was mostly equal to that of the guide. Although, because of the reference
point, which is on the buccal buttress, to reproduce the maxilla-mandible relation is in front of the maxilla, the accuracy of maxillary positioning at the posterior part could be worse. In other words, this discrepancy could be more precisely improved by guided surgery. The surgical guide in the present study does not depend on mandibular mobility and is not affected by the condyle-fossa relationship and condylar head condition. The guide was based on the scanned prebend plates bent on the virtual planning model, suggesting not only the plate fitting but osteotomy line and plating direction accomplish to reproduce the maxillary position as the surgical planning.

ProPlan CMF software showed highly precise matching of the postoperative and preoperative skull base, with a median deviation of only 0.03 to 0.07 mm CT slice thickness of 0.5 to 1.0 mm. Furthermore, for each landmark indicated on the planned maxillary object, a corresponding landmark in the preoperative position was automatically generated by the ProPlan CMF. Therefore, Using ProPlan CMF software reduced the manual point selection error and measurement error.

The present study demonstrated that prebend plate and CAD/CAM osteotomy guide could be reliable surgical tool. However, the limitation of this study was the small number of patients with class II malocclusion and facial asymmetry compared with class III malocclusion. Further investigations with larger sample sizes for each jaw type and long-term stability are required to determine its precise accuracy, appropriate indication, and predictivity.

CONCLUSIONS

The use of the scanned prebend plate-based surgical guide offers a predictive and accurate method for maxillary repositioning. The present guided surgery showed a half-millimeter accuracy in all 3D coordinate axes with fewer complications, such as longer operation time and inferior orbital nerve palsy, suggesting that this method is a reliable surgical technique for accurate orthognathic surgery.

REFERENCES