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A new approach of splint-less orthognathic surgery using a personalized orthognathic surgical guide system: A preliminary study

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Abstract

The purpose of this study was to evaluate a personalized orthognathic surgical guide (POSG) system for bimaxillary surgery without the use of surgical splint. Ten patients with dentofacial deformities were enrolled. Surgeries were planned with the computer-aided surgical simulation method. The POSG system was designed for both maxillary and mandibular surgery. Each consisted of cutting guides and three-dimensionally (3D) printed custom titanium plates to guide the osteotomy and repositioning the bony segments without the use of the surgical splints. Finally, the outcome evaluation was completed by comparing planned outcomes with postoperative outcomes. All operations were successfully completed using the POSG system. The largest root-mean-square deviations were 0.74 mm and 1.93° for the maxillary dental arch, 1.10 mm and 2.82° for the mandibular arch, 0.83 mm and 2.59° for the mandibular body, and 0.98 mm and 2.45° for the proximal segments. The results of the study indicated that our POSG system is capable of accurately and effectively transferring the surgical plan without the use of surgical splint. A significant advantage is that the repositioning of the bony segments is independent to the mandibular autorotation, thus eliminates the potential problems associated with the surgical splint.

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Competing interests
None.

Ethical approval
The study was approved by the ethics committee of the hospital prior to the study.

Patient consent
Informed consent was obtained from each patient before enrollment.

Keywords

custom plate; 3D printing; orthognathic surgery; splint-less; computer-aided surgical simulation

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The repositioning of maxillary and mandibular segments is essential for aesthetic and functional outcomes in orthognathic surgery. With the giant leap in three-dimensional (3D) computer-aided surgical simulation (CASS) technology development, surgeons are now able to simulate and test various surgical plans in a computer until the best possible outcome is achieved[1]. To transfer the surgical plan to the patient at the time of the surgery, the surgical splint technique has been traditionally used to reposition the jaw[2]. To date, the accuracy of using digital surgical splints manufactured by computer-aided design and manufacturing (CAD/CAM) technique has been significantly improved[3]. Nonetheless, the position of maxilla is still dependent on mandibular autorotation, no matter whether maxillary or mandibular surgery is performed first. The instability of the mandibular condyle-fossa relationship is a potential problem that may directly affect the placement of the maxillary segment at the desired position.

With the aim of eliminating the above-mentioned problem, a number of methods have been reported for independently repositioning the maxillary bony segment[4–8]. However, a disadvantage is that the placement and removal of the drilling and repositioning templates may further complicate the surgical procedure and increase the operating time. In addition, it may cause additional harm to patients because some screw holes are specifically drilled for fixing surgical templates. Furthermore, these surgical templates are usually bulky. The attached templates may interfere with the fixation of titanium surgical plates. Finally, the construction material of these surgical templates is not rigid and may be deformed intraoperatively, directly affecting the accuracy of the surgical outcomes. Therefore, how to practically and effectively transfer virtual three-dimensional (3D) plan to the patient at the time of surgery still poses a challenge.

To this end, the purpose of this study was to develop and validate a splint-less approach for double-jaw orthognathic surgery. This approach utilized a personalized orthognathic surgical guide (POSG) system, which comprised a set of cutting guides and 3D printed custom titanium fixation plates for both Le Fort I and bilateral sagittal split osteotomies (BSSOs). The cutting guides were first used to predrill screw holes and guide osteotomies. The custom plates were then used to reposition and stabilize the bony segments as planned, without the use of surgical splints or any additional tool such as surgical navigation.

Patients and methods

Patients treated in our department between June and September 2015 were randomly selected using a random table to participate to this prospective study. The inclusion criteria were (1) patients who were diagnosed with dentofacial deformity and scheduled to undergo bimaxillary orthognathic surgery of their treatment; (2) patients who were scheduled to undergo a computed tomography (CT) scan as a part of their diagnosis and treatment; and (3) patients who agreed to participate in this study. Exclusion criteria were (1) patients who suffered from craniofacial syndrome; (2) patients who had previous orthognathic surgery;

(3) patients who had previous maxillary or mandibular trauma; and (4) patients who required segmentalized bimaxillary surgery. The study was approved by the hospital ethics committee prior to the study (approval number [2015] 026). Informed consent was obtained from each patient before the enrolment.

A total of 10 patients were enrolled in the study, five males and five females. Their median age was 22 years (range 18–27 years). Two patients were diagnosed with skeletal class II deformity and eight were diagnosed with skeletal class III. Six of the class III patients also combined with facial asymmetry.

Surgical planning following CASS protocol

A preoperative CT scan of patient's head was acquired with 1.25 mm slice thickness in the supine position (GE Healthcare, Fairfield, CT, USA). A wax occlusal bite was used to slightly separate the maxilla and mandible and maintain the centric relation. The CT data were imported into planning software (ProPlan 2.0, Materialise NV, Leuven, Belgium) to generate 3D maxillary and mandibular models. The digital dental models were generated by scanning a set of stone dental models using a high-resolution laser surface scanner (SmartOptics AS, Bochum, Germany). The digital dental models were then incorporated and merged into the 3D skull model, replacing the less-than-accurate CT teeth[9–12]. This resulted in a computerized composite skull model with accurate rendition of both the bony structures and the teeth.

The composite skull model was then positioned in a unique reference frame[1,11–15]. In this study, the *nasion* was defined as the origin of the reference frame for the composite skull model, with the *x*-axis running in mediolateral direction, the *y*-axis in anteroposteriorly direction, and the *z*-axis in inferosuperior direction. The midsagittal (YOZ) plane was a vertical plane that best divides the face into right and left halves based on clinical examination and neutral head posture (NHP) records[12,16]. The axial (XOY) plane was the horizontal plane passing through *nasion*, dividing the head to the upper and lower parts. The coronal (XOZ) plane was the vertical plane that was perpendicular to the other two planes.

After the reference frame of the composite skull model was established, a Le Fort I osteotomy and a BSSO, with or without genioplasty, were simulated in the computer based on clinical examination, cephalometric analysis, and 3D measurements following the standard CASS planning routine[11,14,17–19]. During the virtual planning, the translational movement of the Le Fort I segment was from −0.8 mm to 3.1 mm along the *x*-axis, −3 mm to 3.9 mm along the *y*-axis, and −2.0 mm to 3.9 mm along the *z*-axis. The rotational movement of the Le Fort I segment was from −4.2° to 6° in pitch, −3.2° to 3.5° in roll, and −7.6° to 3.9° in yaw. The movements of the mandibular distal segment translational movement were based on the maximum intercuspation to the maxillary teeth using an occlusal template[12,16].

Design and intraoperative utilization of the POSG system

Once the computerized surgical plan was finalized, the POSG system was designed in the computer. The 3D models of the bony segments, in both their initial and planned positions, were imported into Geomagic Studio (Geomagic, Research Triangle Park, NC, USA). The POSG system included a maxillary set and a mandibular set. Each set consisted of a pair of cutting guides and a pair of custom fixation plates. All the designs, namely the geometry and placement position of the cutting guides and the fixation plates, were approved by the surgeons prior to the surgery. Stereolithography (STL) files of all guides and fixation plates were exported for manufacturing process using two 3D printers. The maxillary cutting guides and both maxillary and mandibular custom plates were manufactured by an electron beam melting (EBM) titanium 3D printer (A1 system, Arcam AB, Gothenburg, Sweden) using Ti6AIV4 alloy. The mandibular cutting guides were fabricated by a laser sintering 3D printer (3D Systems, Rock Hill, SC, USA) using photosensitive resin.

Maxillary set

Design—The purpose of the cutting guides was to assist the surgeon in performing the osteotomy and pre-drilling the screw holes that would be automatically reposition the Le Fort I segment to the planned position in conjunction with the use of 3D printed custom plates. The right and left maxillary cutting guides were designed to perfectly fit and cover the surgically exposed bony surface of the maxillozygomatic buttress and the anterior maxillary walls to a maximal extent. This was to ensure that the guides could be anchored intraoperatively at the exact same locations as planned with the maximum stability. During the designing process of the cutting guides, all 3D models of the bony segments were located at their original positions (Fig. 1A). The upper portion of the guide was designed like a flat “U” shape, and the lower portion was designed like an inverted flat “U” (Fig. 1B). They were rigidly connected with a solid vertical bar in the middle. The inferior margin of the upper portion, and the superior margin of the lower portion indicated the Le Fort I osteotomy line (the left guide in Fig. 1B), and ostectomy lines if applicable (the right guide in Fig. 1B). A total of 11 2.0-mm screw holes, five on the upper portion and six on the lower, were designed on each cutting guide. These 11 screw holes not only were used for temporary fixing the cutting guide, but also served as the repositioning bony reference landmarks. It is important to note that all screw holes should be designed carefully to avoid damaging the roots.

The custom fixation plates served as both the maxillary repositioning guide and titanium plates. The custom plates also included a left and a right plate. During the designing process of the custom plates, all 3D models of the bony segments were located at their final planned positions (Fig. 2A). The upper portion of the plate was designed to fit the bony surface above the Le Fort I osteotomy line using the exact same five screw holes that had previously been used for the cutting guide (Fig. 2B). The lower portion was designed to fit the surface of the osteotomized Le Fort I segment at its final position using the same six screw holes that had also previously been used for the cutting guide. Therefore, this combination of the pre-drilled screws and the custom plate would automatically bring the osteotomized Le Fort I segment to its final planned position[7,8]. In addition to the 11 repositioning screw holes, extra screw holes were also added to the plate in case they were needed to further stabilize the plate intraoperatively.

Surgery

At the time of the surgery, the anterior wall of the maxilla was routinely exposed through an intraoral incision. The maxillary cutting guides were placed onto the planned position based on the unique surface geometry of the maxillozygomatic buttress and the anterior maxillary walls as designed. The 11 screw holes were drilled using the predetermined screw holes on the guides, which were then temporarily fixed in place using the screws. The osteotomy/ ostectomy then started as planned (Fig. 1C). Once the cutting lines were clearly marked, the cutting guides were removed and the Le Fort I osteotomy was completed.

Next, the 3D printed custom maxillary fixation plates were adapted, one on each side, to reposition the Le Fort I segment to the planned position. The 11 screw holes on the bones used for temporary fixing the cutting guides were used again as the bony reference landmarks for repositioning Le Fort I segment (Fig. 1D). The upper portion of the custom plate was first firmly installed on the maxilla above the osteotomy line by aligning the corresponding five screw holes on the plate to the bone (Fig. 2C). Afterwards, the osteotomized Le Fort I segment was moved and rotated till all the remaining corresponding six screw holes on bone and plate were aligned. This would automatically bring the Le Fort I segment to its final planned position as the screws were placed into the appropriate screw holes and tightened (Fig. 2D). Additional screws might be applied as indicated, or in case any of the repositioning screw holes was stripped.

Mandibular set

Design—The concept of designing and using the mandibular set was the same as the maxillary one. The right and left mandibular cutting guides were designed to fit the buccal surface of the mandibular body where the sagittal split osteotomy took place. During the designing process of the cutting guides, the proximal and distal segments were located at their original positions (Fig. 3A). The cutting guide consisted of upper and lower portions. The upper portion was a tooth-borne splint for quick and accurate installing the guides intraoperatively (Fig. 3B). The lower portion was the guide for marking the cutting line(s) for vertical osteotomy and ostectomy. It was designed fixed to the bony surface using six 2.0-mm screws, three on each side of the cutting line (Fig. 3B).

The right and left custom fixation plates served as not only titanium plates, but also the mandibular distal and proximal segments' repositioning guide. The custom plates were designed to use the same six screw holes that were previously used by the cutting guides. During the designing process of the custom plates, the proximal and distal segments were located at their finally planned positions (Fig. 4A,B). The custom plates were designed to fit onto the bony surface of both distal and proximal segments at the planned position across the vertical osteotomy line, and placed along external oblique line of mandible as routine method of fixing sagittal split osteotomy. When the screws were placed into the corresponding screw holes and tightened, the custom plates would automatically bring the distal and proximal segments to their final planned position (Fig. 4C,D).

Surgery

The buccal bony surface of the mandible was exposed as a routine sagittal split osteotomy. First, the mandibular cutting guide was installed using the tooth-borne splint portion of the guide. Second, the lower portion of the guide was temporarily fixed with titanium screws through the designed screw holes on the guide. The planned margins for vertical osteotomy/ostectomy were then marked by a pencil (Fig. 3C,D). Once the cutting guide was removed, the sagittal split osteotomy was completed as usual. Finally, the distal and proximal segments were fixed together using the custom plates and screw holes that were used by the cutting guide (Fig. 4C,D). As the screws were tightened, the distal and proximal segments were automatically aligned to their final planned positions without the use of surgical splint.

Outcome evaluation

A postoperative CT scan was acquired 3 days after the surgery. During the scanning, the occlusion was maintained at maximum intercuspation without the use of elastic traction. The postoperative CT scans represented the actual postoperative surgical outcomes. Outcome evaluation started after all the postoperative CTs were completed and collected. The digital dental models were also incorporated and merged into the postoperative CT model as a composite model. This is feasible because the segmentalized cases were excluded, and the postoperative CT scan was acquired shortly after the operation. The dentition of the digital dental models remained the same as the preoperative ones. The CASS surgical plan used for surgery represented the planned surgical outcomes. The accuracy of POSG system was assessed by comparing the planned outcomes to the actual postoperative out-comes[1,14,20,21]. The primary outcome measurements were the positional and orientational differences between the planned and postoperative maxillary and mandibular dental arches, the mandibular body, and the proximal segment. The first three measurements were done with the models registered at the cranium. The last measurement of the proximal segment placement was done with the models registered at the mandibular body to remove the confounding factor of the mandibular distal segment's position. The secondary outcome measurements were the linear differences between the planned and postoperative positions of the maxillary and mandibular midlines, the chin, and the gonial angle.

Both the planned and the actual postoperative CT models were imported into a computer animation software, 3DS Max (Autodesk Inc, San Rafael, CA, USA). The postoperative CT scans were segmented in two parts: the cranium-midface and the mandible. The proximal segments were not segmented from the distal segment. The outcome evaluation was completed by first digitizing a group of anatomical landmarks on both planned and postoperative models. The postoperative models were then registered to the planned models. The differences in position and orientation were finally calculated between these landmarks. The evaluation was completed together by two examiners (B.L. and S.S.) independent of each other. The results of intraclass correlation coefficient with absolute agreement definition for landmark coordinates ranged from 0.96–0.98, indicating a high degree of absolute agreement. Therefore, the landmark coordinates between the two examiners were averaged. The detailed evaluation procedure is described as follows.

Step 1: To digitize landmarks

We adopted the premise that three points are sufficient to define the position and orientation of an object in 3D space[1,14]. Therefore, three landmarks were digitized on each object. The details of the landmarks are listed in Table 1 (Fig. 5).

Step 2: To register the postoperative models to the planned ones

Using our previously validated method[1,14], the registration was completed by superimposing the area of each model that was not moved by surgery, that is the cranial region. The planned models were kept static, and served as targets. On the planned models, we initially hid all the landmarks and the bony segments that were moved during planning, i.e., Le Fort I segment and mandible. Only the region that had not been moved, i.e., cranium, was visualized. In addition, since the postoperative mandibular model is a single piece, during the process of registering the postoperative mandibular model to the planned one, the planned proximal segments were marked hidden. These precautions were done to avoid operator's bias during registration. The postoperative CT models were registered to the planned models using the surface-best-fit method. Finally, after the registration was completed, all hidden landmarks for the maxilla were displayed and their raw coordinates were recorded.

Step 3: To calculate the differences using descriptive statistics

To measure the differences between the planned and postoperative positions, the raw coordinates of all landmarks were first tabulated in Excel (Microsoft Corp, Redmond, WA). Afterwards, the centroid of each object (maxillary dental arch, mandibular dental arch, mandibular body, and proximal segment) was calculated following our previously developed method[14]. They were then paired with the planned and postoperative outcomes, and categorized according to dimensions (mediolateral (x), anteroposterior (y) and superoinferior (z)), and locations (maxillary dental arch, mandibular dental arch, mandibular body, right proximal segment, and left proximal segment). The linear differences between the planned and postoperative outcomes were calculated in x, y, and z dimensions. The angular differences were also calculated in pitch (the rotation around the x-axis), roll (the rotation around the y-axis), and yaw (the rotation around the z-axis). In addition, the differences in maxillary midline, mandibular midline, and chin were calculated in x-coordinates only using the paired raw coordinates. Finally, the discrepancies in the gonial angle were calculated in x, y, and z dimensions using the paired raw coordinates.

Since there were only 10 patients included in this report, only descriptive statistics, including root mean square deviation (RMSD)[14], mean, standard deviation (SD), 95% confidence interval (CI), were used to present the data. To help interpret the results of the accuracy measurements, we considered positional differences between the planned and postoperative outcomes, of less than 2 mm to be clinically insignificant[22,23]. We also considered orientation differences of less than 4° to be clinically inconsequential[24]. However, for maxillary dental midline position, the most noticeable parameter, we used a more stringent threshold of 1 mm.

Results

All the double-jaw surgeries were completed successfully using our POSG system without the use of surgical splint. All the patients achieved good final occlusion without postoperative elastic traction. There was no sign of abnormal bleeding, breakage of the custom plates, or any difficulty in using the POSG system. The surgical time ranged from 120 to 200 minutes (median 160 minutes), and it took 30–60 minutes (median 40 minutes) to plan the surgery using CASS, and an additional 70–95 minutes (median 80 minutes) to design the POSG system. All the patients healed uneventfully with no wound dehiscence, and achieved a good postoperative final occlusion without elastic traction. All temporary postoperative nerve paresthesia of the lower lip, if any, was fully recovered within 1–3 months.

Primary outcome measurements

The results of the primary outcome measurements were presented in Table 2. For the maxillary dental arch, the largest positional and orientational differences between the planned and postoperative outcomes in RMSD were 0.74 mm and 1.93°, respectively. In addition, for the mandibular dental arch, the largest positional and orientational differences in RMSD were 1.10 mm and 2.82°, respectively. Furthermore, for the mandibular body, the largest positional and orientational differences in RMSD were 0.83 mm and 2.59°, respectively. Finally, for the proximal segment, the largest positional and orientational differences in RMSD were 0.98 mm and 2.43°, respectively.

Secondary outcome measurements

The results of the secondary outcome measurements were presented in Table 3. The maxillary dental midline, the mandibular dental midline and the chin deviations in RMSD were only 0.32 mm, 0.74 mm, and 0.70 mm, respectively. The RMSD of the gonial angle deviation was 1.65 mm.

Discussion

An optimal surgical plan for orthognathic surgery is the plan that can be accurately transferred to the patient at the time of the surgery[17,25]. The results of this study showed that our POSG system is capable of accurately and effectively transferring the computerized surgical plan in the operating room, without the use of surgical splints. The differences between the planned and postoperative outcomes were minimal with no clinical meaningfulness. There were a few recent reports on custom titanium plates for maxillary osteotomy[26– 28]. Philippe[26] described a case report, in which the customized mini-plate was used to reposition and fix the maxilla. All four custom mini-plates at the bilateral nasofrontal and zygomatico-maxillary buttresses were joined together as a single unity. Gander et al.[27] described a design of three-unit patient-specific implants (PSIs) for a two-segment Le Fort I osteotomy in a case report. Two units of the PSI anchored on bilateral alveolar zygomatic buttress while the middle unit enfolded around the anterior nasal aperture. The PSIs were fabricated using laser-sintered technique, and the cutting guide was made of polyamide. Preoperative cone beam (CB)CT scans were superimposed to the postoperative ones for quality control. However, no quantitative evaluation was performed. Mazzoni et al.[28] described a case series of 10 patients in which they used CAD/ CAM surgical cutting guides and titanium fixation plates to correctly reposition the maxilla. Customized titanium plates consisted of two separate parts that could fit the surface of bilateral anterior wall of the maxilla. The surgical outcomes were evaluated by superimposing the postoperative CBCT to the virtual plan. They found all seven patients were less than 2 mm. However, the anterior wall of the maxilla, instead of the nasofrontal and zygomatico-maxillary buttresses, were mostly used to fix the customized fixation plates in this study. Nonetheless, to our knowledge, there is no report of the splint-less method using custom titanium plates for mandibular surgery. Subsequently, there are no reports of quantitative evaluation on the utilization of custom titanium plates for bimaxillary surgery using translational and orientational measurements.

Our POSG system is designed for both maxillary and mandibular surgery, and validated with quantitative evaluation. Our POSG system has several advantages. The first advantage is to allow surgeons precisely duplicating the osteotomy and removing the bony collisions between the segments at the time of the surgery exactly as planned in the computer. The second advantage is that the rigidity of the titanium plates ensures the correct position of the bony segments. The solid custom plates can be fixed only when the bony segments are correctly aligned as planned. This is especially beneficial to the maxillary impaction or setback surgery, in which the bone collisions must be removed prior to the repositioning of the bony segment. The third advantage is allowing surgeons to precisely drill only one set of screw holes for both cutting guides and automatically repositioning the bony segments to the planned positions in conjunction with the use of custom titanium plates. Ultimately, the repositioning of the bony segments is independent to the mandibular autorotation, thus eliminates the potential problems associated with the traditional surgical splint, even that is made by CAD/CAM technology.

There are also some limitations of this system. It is difficult to intraoperatively modify the preoperative surgical plan. All the surgical procedures, including the osteotomy and the repositioning, are predetermined by the surgical guides and custom plates. In addition, the material for the custom plates are very hard. They can be barely re-bent during the surgery. Therefore, the accuracy of presurgical planning becomes even more important. All the bony collisions should be removed using the cutting guides prior to reposition the bony segments.

In the future, prospective studies with larger patient sample size are necessary to further validate this system. In addition, a study will be designed to compare the accuracy of using the POSG system to the CAD/CAM surgical splint. Moreover, the cost-effectiveness of custom plates will be evaluated. Finally, the mechanical properties of 3D printed titanium plates will be tested and compared before the surgery and after the custom plates are removed 6 months postoperatively. Of the note, this is our clinical routine to remove the surgical plates 6 months after the orthognathic surgery.

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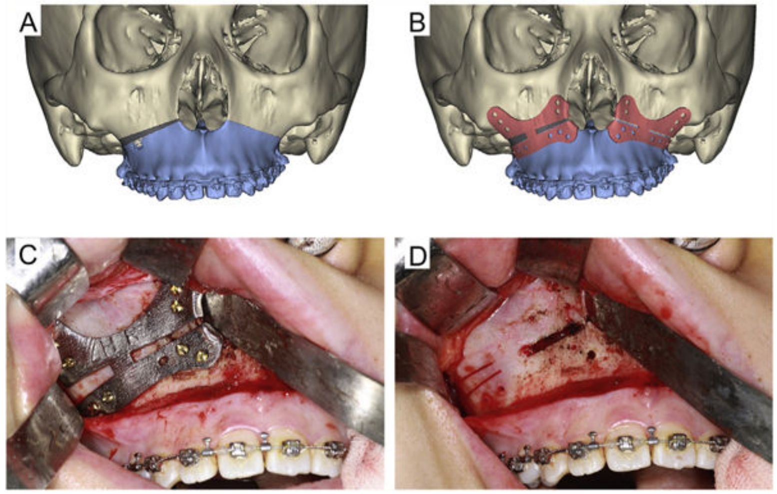

Fig. 1.

The design and use of the cutting guides in the maxillary set of the POSG system. (A) The virtual maxillary Le Fort I osteotomy was simulated. However, at this stage, the Le Fort I segment was at the initial position. (B) The cutting guides were designed based on planned cutting of osteotomy and ostectomy. The upper portion of the guide was designed like a flat "U" shape, while the lower portion was designed like an inverted flat "U". They were rigidly connected in the middle. The inferior margin of the upper portion, and the superior margin of the lower portion indicated the osteotomy and ostectomy line(s). In addition, 11 screw-hole (2.0 mm in diameter), five above and six below the cutting line, were designed on each guide. These screw holes were also used for adapting 3D printed custom plates in the next step. (C) The cutting guide was temporarily fixed in place using screws. (D) The cutting lines could guide the saw blade to accurately perform the osteotomy and ostectomy as planned. Once the cutting guides were removed, the screw holes left on the bony surface were preserved as the bony reference landmarks for the next step.

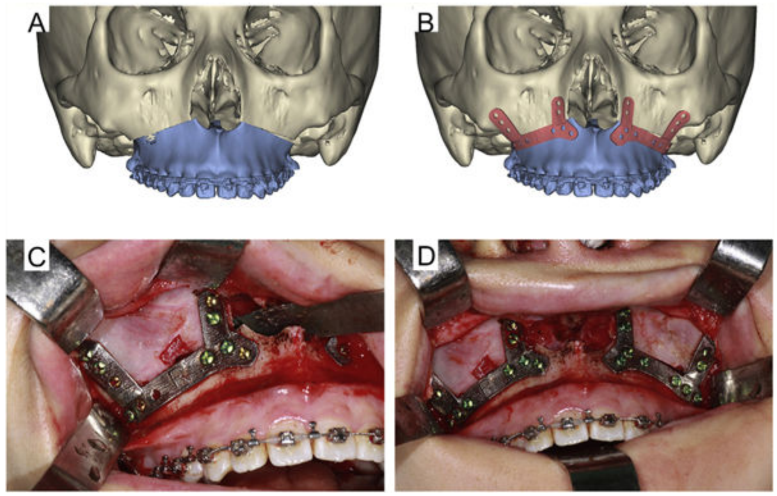

Fig. 2.

The design and use of the custom plates in maxillary set of the POSG system. (A) The maxillary Le Fort I segment were repositioned at the final planned position based on clinical examinations, cephalometric analysis and 3D measurements. (B) The upper portion of the custom plate was designed to fit the bony surface above the Le Fort I osteotomy line using the exact same five screw holes that were previously used for the cutting guide. The lower portion was designed to fit the surface of the osteotomized Le Fort I segment at its final position using the same six screw holes that also previously used for the cutting guide. Finally, extra screw holes were designed on the plate in case for any reason. (C) The maxillary custom plate was firmly fixed onto the maxilla using the screw holes above the osteotomy line on each side. Then, the predetermined locations of the screw holes on custom plates automatically brought the Le Fort I segment to its planned position as the screws were placed into the corresponding screw holes and tightened. (D) The fixation of the maxilla was completed when bilateral custom plates were fixed.

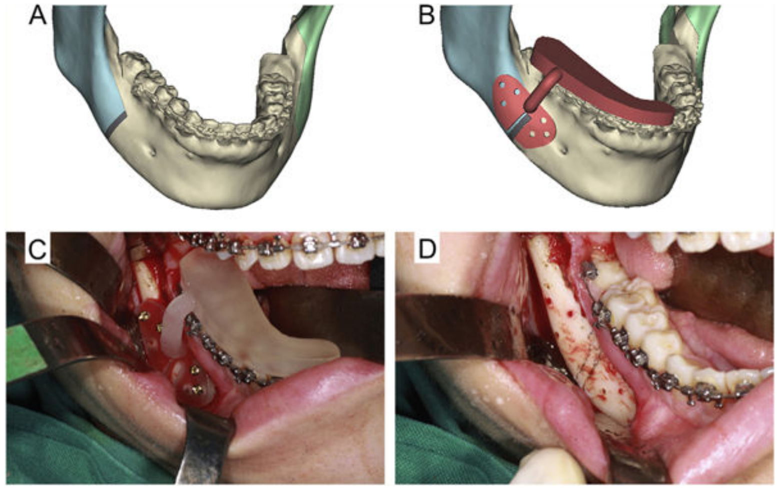

Fig. 3.

The design and use of the cutting guides in the mandibular set of the POSG system. (A) BSSO was simulated in CASS planning. The collision area between the distal and proximal segments was marked for removal. (B) The upper portion was a tooth-borne splint for quick and accurate installing the guides intraoperatively. The lower portion was the guide for marking the cutting line(s) for vertical osteotomy and ostectomy. It was designed fixed to the bony surface using six 2.0-mm screws, three on each side of the cutting line. (C) The lower portion of the cutting guide was temporarily fixed in place with screws through screw holes, while the upper portion was fixed using teeth-borne splint. (D) The planned margins for vertical osteotomy/ ostectomy were then marked by a pencil.

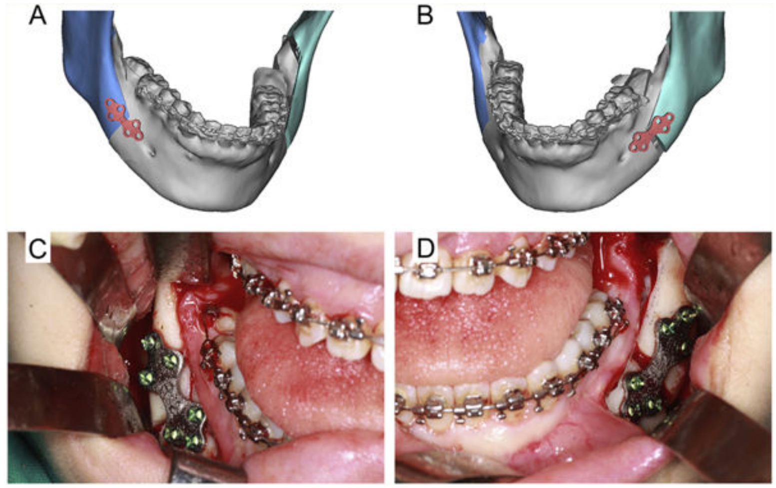

Fig. 4.

The design and use of the custom plates in the mandibular set of the POSG system. (A,B) The mandibular custom plates were designed based on the distal and mandibular proximal segments at final position. The same screw holes, used for cutting guides, were used for custom plate fixation. (C,D) Bilateral custom plates were fixed. As the screws were tightened, the distal and proximal segments were automatically aligned to their final planned positions without the use of surgical splint.

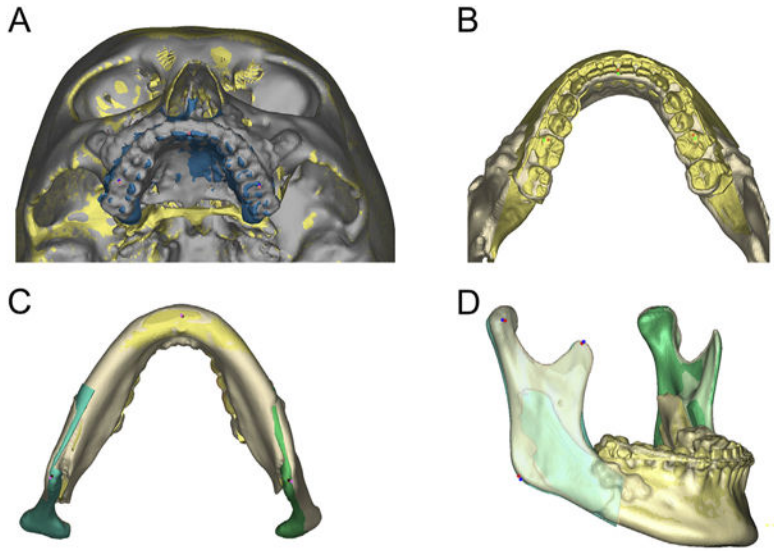

Fig. 5.

Landmarks used for evaluation. (A,B) Landmarks used for evaluating the maxillary and mandibular dental arches. (C) Landmarks used for evaluating the placement of mandibular body. (D) Landmarks used for evaluating the placement of mandibular proximal segments.

Table 1

Primary and secondary outcome measurements and their landmarks.

Measurement	Landmark 1	Landmark 2	Landmark 3
Primary outcome measures			
Linear and rotational differences of maxillary dental arch	Upper dental midline between the 2 maxillary central incisal embrasure	Right mesiobuccal cusp of the upper 1st molar	Left mesiobuccal cusp of the upper 1st molar
Linear and rotational differences of mandibular dental arch	Lower dental midline between the 2 mandibular central incisal embrasure	Right mesiobuccal cusp of the lower 1st molar	Left mesiobuccal cusp of the lower 1st molar
Linear and rotational differences of mandibular body	Pogonion	Right gonion	Left gonion
Linear and rotational difference of proximal segment	Midpoint between the lateral and medial poles of the condyle	Coronoid	Gonion
Secondary outcome measures			
Linear difference of maxillary dental midline	Maxillary dental midline	N/A	N/A
Linear difference of mandibular dental midline	Mandibular dental midline	N/A	N/A
Linear difference of chin	Pogonion	N/A	N/A
Linear difference of gonial angle	Gonion	N/A	N/A

Table 2

Accuracy (root mean square deviation (RMSD), mean, standard deviation (SD) and 95% of confidence interval (CI)) of positional and orientational differences between the planned and postoperative outcomes (primary outcome measurements).

		Orientational difference (degree)								
		RMSD	Mean	SD	95% CI		RMSD	Mean	SD	95% CI
Maxillary dental arch	Mediolateral	0.38	−0.18	0.35	(−0.43 0.07)	Pitch	0.67	0.11	0.69	(−0.39 0.60)
	Anteroposterior	0.74	−0.54	0.53	(−0.92 −0.16)	Roll	0.57	0.02	0.60	(−0.41 0.45)
	Superoinferior	0.60	0.33	0.53	(−0.05 0.71)	Yaw	1.93	−0.83	1.83	(−2.14 0.48)
Mandibular dental arch	Mediolateral	0.58	−0.33	0.50	(−0.69 0.03)	Pitch	1.65	0.45	1.67	(−0.75 1.65)
	Anteroposterior	1.10	−0.67	0.92	(−1.33 −0.02)	Roll	0.91	−0.07	0.95	(−0.75 0.61)
	Superoinferior	0.78	0.38	0.72	(−0.14 0.89)	Yaw	2.82	0.26	2.96	(−1.86 2.38)
Mandibular body	Mediolateral	0.50	0.00	0.52	(−0.38 0.37)	Pitch	1.60	−0.51	1.60	(−1.65 0.64)
	Anteroposterior	0.76	0.15	0.79	(−0.42 0.71)	Roll	2.59	0.40	2.70	(−1.53 2.33)
	Superoinferior	0.83	−0.26	0.83	(−0.85 0.33)	Yaw	0.93	−0.48	0.84	(−1.08 0.12)
Mandibular proximal segment (left)	Mediolateral	0.98	−0.10	1.03	(−0.83 0.64)	Pitch	2.45	1.39	2.12	(−0.13 2.91)
	Anteroposterior	0.80	0.23	0.82	(−0.35 0.82)	Roll	1.08	0.01	1.14	(−0.80 0.83)
	Superoinferior	0.75	−0.10	0.79	(−0.67 0.46)	Yaw	2.01	0.49	2.06	(−0.98 1.96)
Mandibular proximal segment (right)	Mediolateral	0.69	−0.18	0.70	(−0.68 0.32)	Pitch	2.43	−1.66	1.85	(−3.01 −0.37)
	Anteroposterior	0.52	0.05	0.54	(−0.34 0.44)	Roll	1.74	−0.59	1.73	(−1.83 0.64)
	Superoinferior	0.94	−0.28	0.94	(−0.95 0.40)	Yaw	2.10	0.26	2.20	(−1.31 1.83)

Table 3

Accuracy (root mean square deviation (RMSD), mean, standard deviation (SD) and 95% of confidence interval (CI)) of positional differences between the planned and postoperative outcomes (secondary outcome measurements).

		Positional difference (mm)			
		RMSD	**Mean**	**SD**	**95% CI**
Maxillary dental midline	Mediolateral	0.32	−0.01	0.34	(−0.27 0.22)
Mandibular dental midline	Mediolateral	0.74	−0.44	0.63	(−0.89 0.01)
Chin	Mediolateral	0.70	−0.03	0.74	(−0.53 0.53)
Gonial angle (left)	Mediolateral	1.37	−0.45	1.37	(−1.43 0.53)
	Anteroposterior	1.25	0.47	1.22	(−0.41 1.34)
	Superoinferior	1.56	−0.62	1.50	(−1.70 0.45)
Gonial angle (right)	Mediolateral	1.18	0.47	1.14	(−0.35 1.29)
	Anteroposterior	1.32	0.19	1.37	(−0.79 1.17)
	Superoinferior	1.65	−0.02	1.74	(−1.26 1.23)