# Custom-Machined Miniplates and Bone-Supported Guides for Orthognathic Surgery: A New Surgical Procedure



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**Purpose:** Several surgical strategies exist to improve accuracy in orthognathic surgery, but ideal planning and treatment have yet to be described. The purpose of this study was to present and assess the accuracy of a virtual orthognathic positioning system (OPS), based on the use of bone-supported guides for placement of custom, highly rigid, machined titanium miniplates produced using computer-aided design and computer-aided manufacturing technology.

**Materials and Methods:** An institutional review board-approved prospective observational study was designed to evaluate our early experience with the OPS. The inclusion criteria were as follows: adult patients who were classified as skeletal Class II or III patients and as candidates for orthognathic surgery or who were candidates for maxillomandibular advancement as a treatment for obstructive sleep apnea. Reverse planning with computed tomography and modeling software was performed. Our OPS was designed to avoid the use of intermaxillary fixation and occlusal splints. The minimum follow-up period was 1 year.

**Results:** Six patients were enrolled in the study. The custom OPS miniplates fit perfectly with the anterior buttress of the maxilla and the mandible body surface intraoperatively. To evaluate accuracy, the post-operative 3-dimensional reconstructed computed tomography image and the presurgical plan were compared. In the maxillary fragments that underwent less than 6 mm of advancement, the OPS enabled an SD of 0.14 mm (92% within 1 mm) at the upper maxilla and 0.34 mm (86% within 1 mm) at the mandible. In the case of great advancements of more than 10 mm, the SD was 1.33 mm (66% within 1 mm) at the upper maxilla and 0.67 mm (73% within 1 mm) at the mandibular level.

**Conclusions:** Our novel OPS was safe and well tolerated, providing positional control with considerable surgical accuracy. The OPS simplified surgery by being independent of support from the opposite maxilla and obviating the need for classic intermaxillary occlusal splints.

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Achieving high accuracy in orthognathic surgery (OGS) remains challenging. Since the 1980s, full-arch maxillary occlusal splints have been widely used to position bone fragments that have undergone osteotomy. The modern use of computer technology in OGS planning has revolutionized the field, producing a paradigm shift in practice and providing the basis for the development of new surgical solutions. Such computer-aided design (CAD)-computer-aided manufacturing (CAM) technology makes it possible to model OGS procedures to greater accuracy, notably by controlling the position of the condyles and by designing surgical splints.

However, with the current level of development of this technology, the role of the surgeon continues to be critical for achieving the surgical objectives, in particular, vertical, ramus, and condylar positioning. <sup>15</sup> If any of these important steps are not carried out accurately, the final results will not match preoperative planning.

After proper orthognathic planning, outcomes are determined first by the accuracy of transferring this planning to the surgical intervention and second by the stability of the fragments that have undergone osteotomy. For the first step, surgical transfer, occlusal splints are the classic and most commonly used method. However, their drawbacks include lack of accuracy and control, including leaving much positioning in the hands of the surgical team. For the second step, stability, the classic osteosynthesis systems require plate bending and are not always strong enough to counter deforming muscular forces, especially in extensive bimaxillary advancement operations.

We propose that high-rigidity custom-made miniplates designed from the final planning of an OGS case contain all the information required for simultaneous surgical transfer and stabilization, obviating the need for classic intermaxillary occlusal splints and intraoperative measurements. Instead, positioning of both the osteotomies and miniplates would rely on radionavigation systems or bone-supported guides.

The purpose of this study was to present and assess the accuracy of a novel, minimally invasive virtual orthognathic positioning system (OPS), based on the use of bone-supported guides for placement of custom, highly rigid, machined titanium miniplates produced using CAD-CAM technology.

# **Materials and Methods**

STUDY DESIGN

This prospective observational study was approved by the Research Ethics Committee of the Basque Country (protocol No. 2/2004). The inclusion criteria were as follows: adult patients who were classified as skeletal Class II or III patients and as candidates for

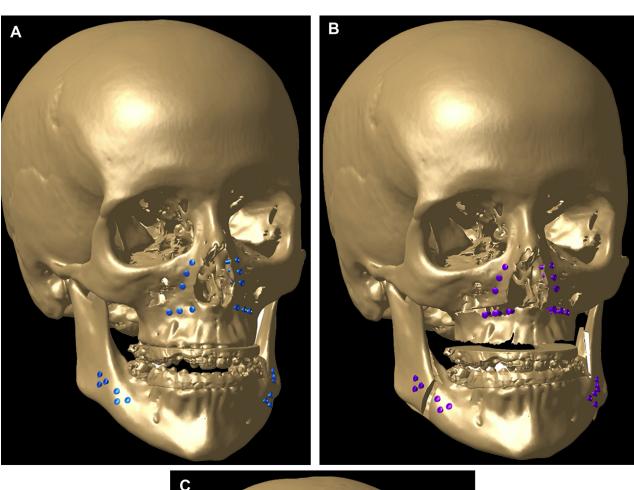
OGS or who were candidates for maxillomandibular advancement as a treatment for obstructive sleep apnea (OSA) after assessment by a multidisciplinary team. The exclusion criteria were cleft lip or palate and skeletal deformities resulting from trauma or degenerative conditions.

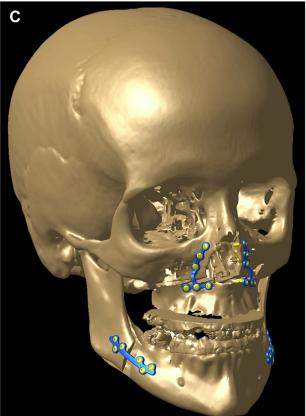
Preoperative photographs were taken, and written informed consent was obtained. The main operator was the first author. The minimum follow-up period was 1 year.

## SURGICAL PLANNING

A reverse-planning process was used in all cases:

- 1) A helical maxillofacial noncontrast computed tomography (CT) scan in central relation was performed (Philips Brilliance CT, 16 detectors; Philips Medical Systems, Best, The Netherlands), with patients in a supine position, holding their breath at the end of expiration and without swallowing, with their tongue against their incisors. The slice thickness was 1 mm. Data were exported into DICOM (Digital Imaging and Communications in Medicine) format. The resulting raw file from the skull was segmented with SimPlant Pro OMS software (Materialise Dental, Leuven, Belgium), which was stored as an stereolithography (STL) file. Subsequently, surface scanning of each dental model arch was achieved with the Lava Scan ST scanner (3M ESPE, Ann Arbor, MI), thereby producing another STL file. The 2 STL files were fused using the SimPlant Pro OMS software with a best-match algorithm for surfaces. A virtual patient was thus generated from each skull's corresponding pair of STL files.<sup>11</sup>
- 2) On the bone surface of the virtual patient, the osteotomy lines and future fixation drill markings were marked in areas of good bone quality, while tooth roots and the path of the inferior alveolar nerve were avoided to maximize safety. We placed a total of 6 to 8 points on each side of the bone surface anterior to the pyriform aperture of the maxilla, leaving some space for the subsequent Le Fort I osteotomy. The same process was carried out for the mandibular bone, with 3 or 4 points being marked on each side of the vertical osteotomy of the mandibular bilateral sagittal split osteotomy. This image was designated CT1 (Materialise Dental), as shown in Figure 1.
- 3) Afterward, virtual surgery was performed on a 3dimensional (3D) digital model of the patient's skull using the same software and following a conventional procedure, <sup>13</sup> obtaining the planning (PL) images. The CT1 and PL images were exported as STL files for the design and





**FIGURE 1.** Reverse planning. A, Areas with good bone quality are defined, and drill holes are located. B, Surgical movements are virtually planned. C, Plates are designed using computer-aided design-computer-aided manufacturing technology adapted to drill hole placement and bone contour.

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- manufacturing of the bone-supported guides and the machining of the custom-made miniplates.
- 4) By use of the STL files from the final digital plan (PL), a set of custom, highly rigid miniplates with a low profile (1.2 to 1.3 mm) were designed to fit the surface of the bone in the final plan, and the osteosynthesis screw holes marked in step 2 were included. These miniplates were designed with CAD-CAM technology using PowerShape software (Delcam, Birmingham, UK) and machined from grade 5 titanium (Createch Medical, Mendaro, Spain).
- 5) Finally, using the STL files from CT1, a set of bonesupported guides were designed to ensure correct intraoperative positioning of the miniplates to transfer the planned movements to the patient. For these, CAD was used to fit the surface in the CT1 image, taking into account the holes marked in step 2 (Delcam and Createch Medical). These guides were manufactured using rapid prototyping technology and were made from a biocompatible photosensitive resin. For the maxilla, they consisted of a bone-supported design adapted to the pyriform aperture. For the mandible, they consisted of an adapted guide with points of contact to the supporting bone joined to an occlusal splint, which enabled stable anchorage. The occlusal splint was designed using the STL files from CT1 and could be used independently as a secondary splint, to achieve better control of the final occlusion in cases in which the original occlusion of the patient was going to be maintained, such as in pure bimaxillary advancements for OSA treatment, as shown in Figure 2.

## SURGICAL TECHNIQUE

Maxillary exposure was obtained by a canine-to-canine incision. Before the Le Fort I osteotomy, bone-supported guides were placed and the planned osteosynthesis screw holes were drilled in the maxilla. The Le Fort I osteotomy with down-fracture was then performed, following the twist technique. <sup>16</sup> Possible bone contact points were removed, and the greater palatine artery pedicles were liberated. The custom miniplates were then fixed to the fragment that had undergone osteotomy. Aided by a wire at the level of the anterior nasal spine, the upper maxilla was mobilized until the holes of the miniplate matched the proximal holes of the Le Fort I osteotomy. Osteosynthesis was performed as shown in Figure 3.

Mandibular exposure was obtained following the conventional technique to perform an Obwegeser-Dal Pont osteotomy. We placed a bone-supported guide, marked the vertical osteotomy using a piezoelectric saw (Mectron, Sestri Levante, Italy), and drilled the holes for the screws. The sagittal split ramus osteotomy was then performed. We created a controlled fracture and reshaped the distal point of the mandibular lingula, when necessary, to avoid contact between bone fragments. Afterward, osteosynthesis was performed by fixating the miniplate first to the ramus and then to the mobile body of the mandible, as shown in Figure 4.

During surgery, maxillomandibular occlusal splints and an osteosynthesis system with conventional miniplates were available, in case we were unable to use the custom OPS. Our OPS does not require intermaxillary fixation.

## POSTOPERATIVE CARE AND FOLLOW-UP

Patients were admitted to our department for postoperative care in a monitored setting, according to routine protocol. Antibiotic prophylaxis was instituted. Patients were followed during clinic visits at least at the 1-week, 1-month, 3-month, 6-month, and 1-year time point, unless required otherwise.

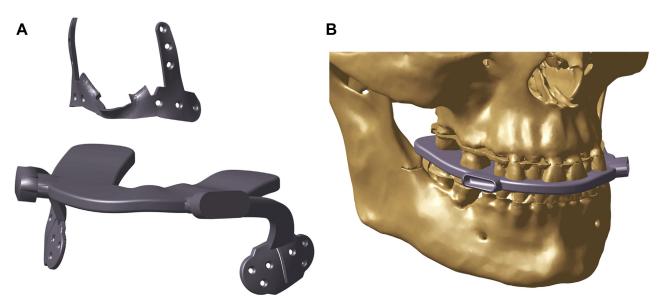
#### **IMAGE ANALYSIS**

One month after surgery, a second CT scan (CT2) was carried out by the same technician using the same protocol on the same machine. The CT2 DICOM dataset was processed to create a 3D model of the postoperative maxillofacial skeleton. The comparison was performed by overlapping the STL files of the PL images and the CT2. First, technicians located the superimposed images relative to the cranial structures that did not undergo variation in their position, such as the cranial vault and orbital rims. Afterward, they isolated the structures to study, notably the upper maxilla, mandibular ramus, and mandibular body. We used PowerShape software (Delcam, Birmingham, UK) and 3D Reshaper software (Technodigit, Genay, France) to calculate the discrepancies using iterative closest point (ICP) surface matching. Because the number of measured points was high, each surface deviation was analyzed using statistical methods and represented on a color-graded scale.

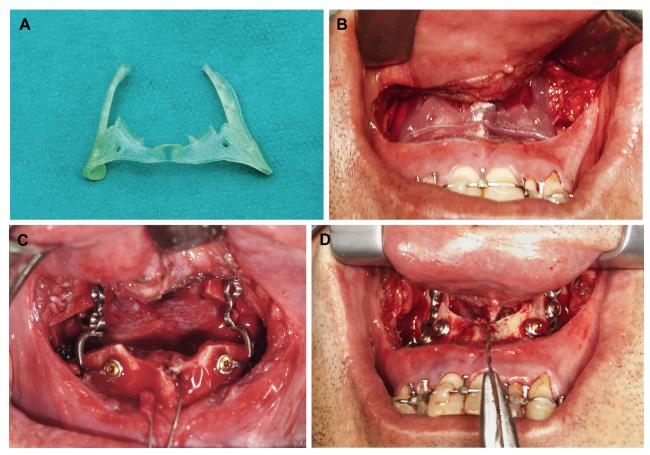
## **Results**

The OPS was successfully used in 6 consecutive patients, as shown in Table 1. The male-female ratio was 5:1, and the mean age was 34.33 years (range, 20 to 45 years). The surgical indications were severe OSA in 4 patients, skeletal Class II in 1 patient, and skeletal Class III and facial asymmetry in 1 patient. Two representative cases are shown in Figures 5 and 6.

We performed bimaxillary surgery in 5 cases and monomaxillary surgery in 1 case. In 2 cases we performed OGS to correct severe malocclusion due to



**FIGURE 2.** A, B, Bone-supported guide design. Part of the mandibular guide can be used as a secondary splint if needed. Brunso et al. Custom Miniplates for Orthognathic Surgery. J Oral Maxillofac Surg 2016.



**FIGURE 3.** A, Upper maxilla guide design. B, Bone surface adaptation of guide and drilling. A small incision is needed. C, Symmetric placement of the plates with screws and the help of a wire in the nasal spine. D, Positioning and osteosynthesis of the maxilla are performed simultaneously as result of the customized plate without an occlusal splint.

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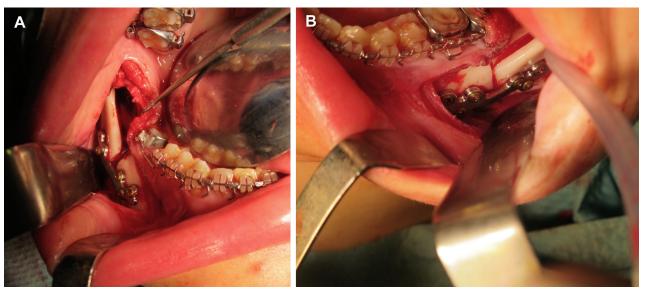


FIGURE 4. A, B, Mandibular osteosynthesis.

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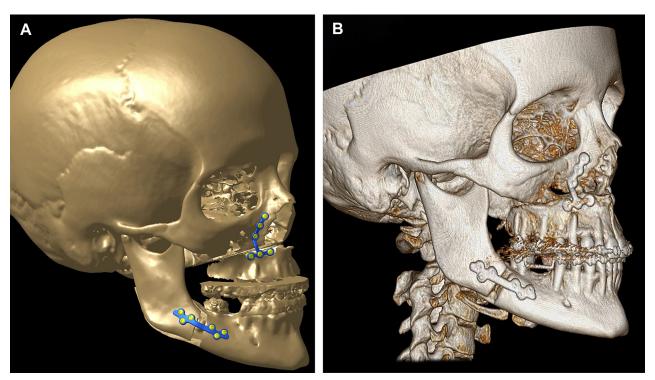
anteroposterior hypoplasia of the maxilla, as well as mandibular asymmetry with prognathism. In the other 4 cases, requiring skeletal correction for severe OSA, we performed 10- to 11-mm maxillary advancements, generally with counterclockwise rotation, depending

on the extent of the retropalatal and retrolingual collapse. Table 1 summarizes the movements performed in each case.

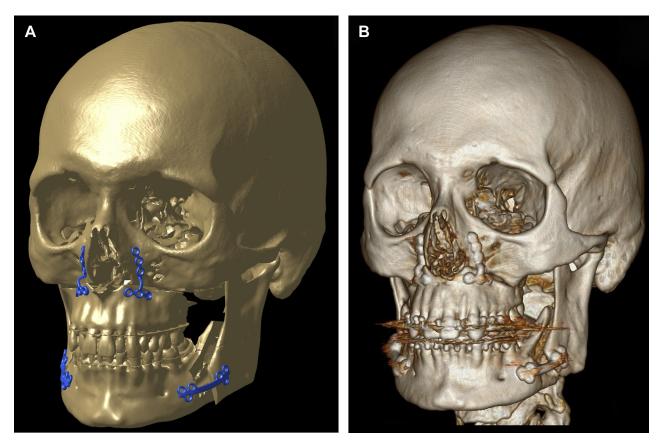
The OPS allows the intervention to start with either the maxilla or the mandible. Nevertheless, we suggest

Table 1. PATIENT DATA									
Patient No.	Gender	Age, yr	Reason for Surgery	Surgery	Follow-Up, mo				
1	M	45	OSA (AHI, 76)	11-mm maxillomandibular advancement and counterclockwise rotation of occlusal plane (4°)	12				
2	M	37	OSA (AHI, 35)	11-mm maxillomandibular advancement and counterclockwise rotation of occlusal plane (5°)	18				
3	М	32	OSA (AHI, 85)	10-mm maxillomandibular advancement, counterclockwise rotation of occlusal plane (5°), and genioplasty (10 mm)	12				
4	M	45	OSA (AHI, 64)	10-mm maxillomandibular advancement and counterclockwise rotation of occlusal plane (8°)	14				
5	F	27	OS	5-mm maxillary advancement, correction of midline, and mandibular surgery for centering and retrusion	15				
6	M	20	OS	10.2-mm monomaxillary advancement of mandible and genioplasty (8 mm)	16				

Abbreviations: AHI, Apnea-Hypopnea Index; F, female; M, male; OS, orthognathic surgery; OSA, obstructive sleep apnea. *Brunso et al. Custom Miniplates for Orthognathic Surgery. J Oral Maxillofac Surg 2016.* 



**FIGURE 5.** A, Preoperative virtual orthognathic surgery planning. B, Final outcome (second computed tomography scan). Brunso et al. Custom Miniplates for Orthognathic Surgery. J Oral Maxillofac Surg 2016.



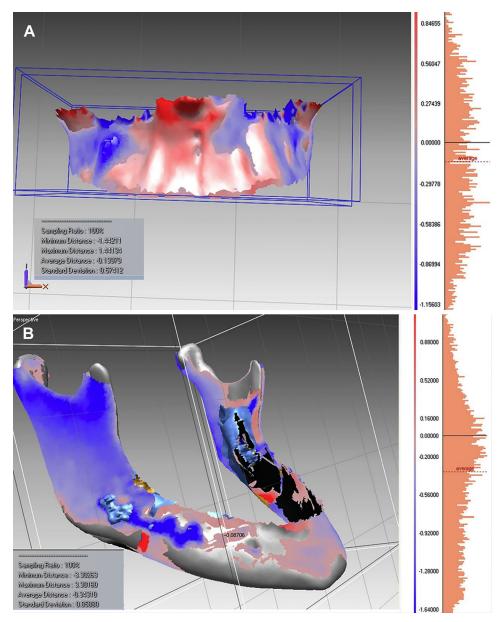
**FIGURE 6.** A, Preoperative virtual obstructive sleep apnea planning. B, Final outcome (second computed tomography scan). Brunso et al. Custom Miniplates for Orthognathic Surgery. J Oral Maxillofac Surg 2016.

starting with the mandible. In the first 4 cases, the operation started on the maxilla, but the marking of the osteotomy line and the drilling in the mandible were performed previously with the bone- and dental-supported guides. In the next 2 cases, the intervention started on the mandible. Starting on the mandible provides the advantage of performing the marking of the osteotomies and the drilling with the mouth closed, fixing the occlusal splint with both dental arches and bringing stability to the structure that rests on the bone. By using this method, intraoral drilling is achieved without the need for a percutaneous approach.

CT scans were analyzed by overlapping the virtual surgery (PL) and postoperative (CT2) images. Accu-

racy was reported in terms of average deviation and SD, as well as the percent frequency of overlap error smaller than 1 mm, as shown in Figure 7. The custom OPS miniplates were found to fit perfectly with the anterior buttress of the maxilla and the mandible intraoperatively. At the level of the maxilla, the SD and average deviation were 0.78 mm and 1.09 mm, respectively, with 71.2% of values within 1 mm. For the mandible, the results were slightly better because the SD and average deviation were 0.69 mm and 0.61 mm, respectively, with 75.3% of values within 1 mm, as shown in Table 2.

We believe that the results of this study are promising given that 82% of the operated maxillae (9 of 11) have



**FIGURE 7.** Precision study obtained by overlapping virtual planning image and final outcome image (second computed tomography scan). *A*, Upper maxilla. *B*, Mandible.

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	SD, m	<u>m</u>	Average Deviation, mm		Error Within 1 mm, %						
Patient No.	Upper Maxilla	Mandible	Upper Maxilla	Mandible	Upper Maxilla	Mandible					
1	0.76	0.74	1.29	0.95	68	71					
2	0.80	0.45	1.42	0.62	66	77					
3	1.13	1.04	1.61	0.54	56	59					
4	0.66	0.39	1.01	0.94	74	72					
5	0.57	0.86	0.14	0.34	92	86					

1.09

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0.71

0.69

undergone large advancements (≥10 mm). We are aware that the number of cases is limited and that we cannot draw conclusions beyond the analysis of each case, but it is important to highlight that greater accuracy was achieved in the smaller advancements than in the larger ones. In the maxillary fragments that underwent less than 6 mm of advancement, an SD of 0.14 mm (92% within 1 mm) was achieved at the upper maxilla and 0.34 mm (86% within 1 mm) at the mandible. In the case of great advancements of more than 10 mm, the SD was 1.33 mm (66% within 1 mm) at the upper maxilla and 0.67 mm (73% within 1 mm) at the mandibular level.

0.78

There were no perioperative complications or signs of intolerance in the postoperative period. The mean length of stay was 4.83 days (range, 3 to 7 days). The mean follow-up period was 14.33 months (range, 12 to 18 months).

# **Discussion**

Table 2. ACCURACY

6

Mean

Our OPS used 4 highly rigid, custom miniplates to achieve simultaneous osteosynthesis and positioning of the maxillary segments: 2 for the frontal process of the maxilla and 2 for the mandibular body. A set of bone-supported surgical guides enabled us to define the osteotomy lines and the exact locations of the osteosynthesis screw holes, irrespective of whether surgery started at the maxilla or at the mandible. The design of the miniplate at the anterior buttress shortened the procedure and helped preserve blood supply to the vestibular flap by reducing the access incision and dissection required.

Several authors have proposed alternative systems for performing OGS without the need for classic bimaxillary occlusal splints. Depending on the method used for repositioning maxillary segments according to the virtual surgical plan, the various positioning systems can be classified into 2 groups: 1) systems used exclusively for repositioning, based on the use of various splints at different time points,

with osteosynthesis being carried out later with conventional osteosynthesis systems, including those described by Zinser et al<sup>18,19</sup> and Polley and Figueroa,<sup>22</sup> and *2)* systems used for repositioning and osteosynthesis in the same procedure, using custom miniplates placed accurately on the bone surface guided by bone-supported surgical guides and/or navigation systems, including those described by Philippe<sup>20,21</sup> and Mazzoni et al.<sup>23</sup>

71.2

0.30

0.61

87

75.3

All of these systems achieve a good level of accuracy, generally higher than that obtained using classic procedures. 1-3,24-27 Most authors agree that these new approaches may be particularly beneficial in cases involving substantial changes in the vertical dimension, regardless of whether there is rotation in the occlusal plane. In such cases, the transfer of the surgical plan to the patient may not be accurate using conventional procedures, because of poor vertical control due to self-rotation of the mandibular condyle in the glenoid fossa. 18-24

Zinser et al<sup>24</sup> compared various different procedures for OGS. This study analyzed the level of accuracy obtained by a complex system of multiple CAD-CAM splints, by intraoperative navigation, and by the classic approach based on the use of intermaxillary occlusal splints. The system with bone guides was the only one that achieved centric relation of the condyles at the temporomandibular joint. The level of accuracy was lower for the mandible with all 3 systems. The study also analyzed the accuracy achieved concerning soft tissues, a type of data that has not been included in any other study, despite this being one of the most important factors during the planning process.

Polley and Figueroa<sup>22</sup> presented a system based on bone-supported guides with occlusal support for positioning the maxillary fragments independently of the opposite maxilla. They subsequently performed osteosynthesis with conventional miniplates.

Philippe<sup>20,21</sup> and Mazzoni et al<sup>23</sup> presented 2 new navigation systems based on osteotomy drilling guides

and custom miniplates generated from titanium powder by direct metal laser sintering. Mazzoni et al offered a waferless solution only for the maxilla that consists of 2 independent guides, 1 for each hemimaxilla, positioned with a navigation tool that allows the drilling of all the osteosynthesis screws. Then, 2 custom-made miniplates allow the positioning and the osteosynthesis of the maxillary fragment. Philippe's system design is similar, but instead of two independent pieces they are joined into a single one, for both the guide and the custom-made miniplate, requiring a larger access incision. 20,21 Compared with machining, layer-by-layer construction of prostheses is potentially less expensive and faster; on the other hand, it may result in lower rigidity and carries a higher risk of contamination.

Custom osteosynthesis systems to be used to transfer information to fragments that have undergone osteotomy should be highly rigid to ensure that they maintain their properties both intraoperatively and postoperatively. In addition, the rigidity of the systems may enable one to reduce the size and number of miniplates required for osteosynthesis, facilitating minimally invasive approaches, one of the cornerstones, together with accuracy and safety, of image-guided surgical interventions.

The planning of an OGS case is essential to achieve excellent outcomes. New 3D technologies allow very good presurgical control of condylar positioning and occlusion. The final result also will be determined by the accuracy with which the surgical team transfers the digital plan to the patient. This operator dependence can theoretically be improved with the ease of use and reliability of the components of the system, including intermaxillary occlusal splints, bonesupported surgical guides, and navigation systems. 19,24,28,29 The OPS may improve on the accuracy achieved using the traditional technique, which involves maxillomandibular occlusal splints and conventional miniplates, because it does away with the need to use the opposite maxilla during the positioning of the maxillary segments, thereby avoiding the potential errors derived from the rotational and translational movements of the condyles. Furthermore, custom miniplates should provide valuable information for accurate vertical control and proper seating of the condyles in centric relation in the glenoid fossa.

Achieving stability of the fragments that have undergone osteotomy and avoiding relapse are the next goals. The rigid fixation has shown its advantages over other osteosynthesis systems, being necessary when lowering movements of the maxilla are performed or in great maxillary advancements.<sup>30</sup> The OPS considers such stability by fabricating the miniplates from highly rigid grade 5 titanium machined

from a titanium block and fixating them to goodquality bone on the anterior midfacial buttress. The custom miniplates are machined to perfectly fit to the surface of the midfacial bone with no need for molding, which would compromise their properties. In theory, these advances should improve on conventional osteosynthesis systems. However, in light of our study's results, it is evident that, by themselves, they are not enough to provide perfect stability, especially when operating near the limits of skeletal movement, such as in cases of great advancements for OSA. In these severe cases, it is highly likely that early adaptive changes occur, especially at the dentoalveolar level, prompted by the surgical intervention itself. Thus it is not surprising that morphologic changes occur between the time of surgery and the time of postoperative CT.31,32

Several factors can play an important role in the early postoperative period, and these will influence final outcomes. Examples include the bone quality, the stability of the achieved occlusion, neuromuscular adaptation or secondary elastic therapy, and temporomandibular joint stability. Improving our knowledge of these factors and their destabilizing effects might represent one of the greatest challenges in OGS.

The procedure presented in this article builds on previous research in which the authors assessed the functionality of a custom, highly rigid osteosynthesis system using CAD-CAM technology for large maxilloadvancements. 33,34 mandibular During successive cases, the surgical guides were continually redesigned to make them more practical and easier to use. The 6 cases presented in this article correspond to the third design, as shown in Figure 8. The initial goal was to avoid having to perform the dental-occlusal scan needed for producing occlusal splints using exclusively bone-supported guides without occlusal support. However, at the mandibular level, such guides forced us to make longer access incisions and, given that the body of the mandible has a flat surface, it was difficult to determine exactly where to place them on the bone surface. These difficulties were overcome in subsequent cases by using a guide with occlusal support, refining our technique, and minimizing the incisions. Because neither intermaxillary fixation nor intraoperative measurements and plate molding are necessary, operating times may shorten considerably as surgeons become familiar with the technique, but like every new procedure, the OPS has a learning curve.

The ease and advantages of the OPS depend on precise surgical technique. Little maneuverability is left if bones are overdrilled, screws have poor purchase, or inaccurate osteotomies are made. We have not faced such situations in any of our cases, but recognize their possibility. Their potential impact can be minimized by

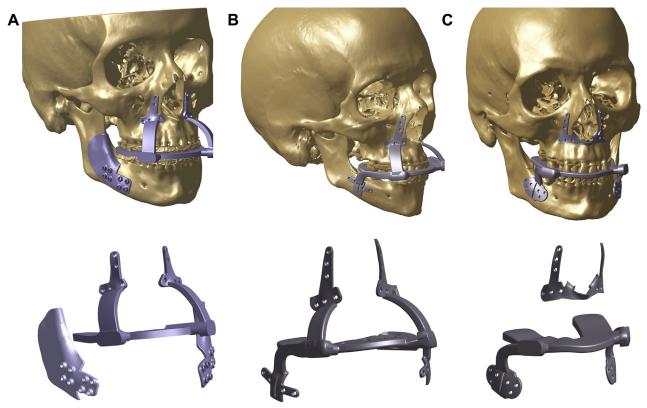


FIGURE 8. A-C, Evolution of guides to final design.

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designing miniplates with at least 6 holes, located over good-quality bone on CT. In addition, it is important to assess potential complications that may arise, case by case. A high risk of anomalous fracture in the region of the bilateral sagittal ramus osteotomy or poor bone quality should prompt a more prudent approach and consideration of other surgical solutions.

This assessment of potential complications also should influence the design of the miniplates, by anticipating potentially insufficient bone contact. With bilateral sagittal ramus osteotomy in large maxillomandibular advancements, there will be premature contact between the lingula of the mandible and the cortex of the mandibular ramus, which will be exacerbated if there is also lateral rotation. When there is only slight contact, this can be resolved by displacing the ramus laterally, with a pivot point on the proximal surface of the mandibular condyle. In the case of larger movements, however, the area of contact should be reshaped.

Although the OPS has potential in any type of OGS, it may be particularly useful in the following cases: *1)* large asymmetry with a substantial vertical component; *2)* likely poor occlusal stability during the postoperative period, regardless of whether this is because of tooth loss or the use of a surgery-first approach; and *3)* anatomic deformities or severe cases that are difficult to treat with conventional osteosyn-

thesis systems. It is hoped that with increased experience, these indications can be broadened and extended to other patient populations as well. We intend to accrue additional outcome data and further realize the potential of this novel technique in OGS.

In conclusion, the novel technique presented in this study was safe and well-tolerated. The OPS provided vertical control and correct condylar positioning with considerable surgical accuracy. This novel technique simplified surgery by being independent of support from the opposite maxilla and obviating the need for classic intermaxillary occlusal splints or intraoperative measurements.

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