

Splintless surgery: does patient-specific CAD-CAM osteosynthesis improve accuracy of Le Fort I osteotomy?

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Abstract

To analyse the accuracy of maxillary positioning after Le Fort I osteotomy, we retrospectively assessed the outcome in three patients (mean (range) age 40 (21 – 60) years) who had been treated with patient-specific CAD-CAM osteosynthesis plates as part of a bimaxillary osteotomy. Virtual surgical planning in each case was based on cone-beam computed tomography (CT) (Simplant® O&O, Dentsply Implants NV, Kessel-Lo, Belgium), and patient-specific CAD-CAM drilling guides and osteosynthesis plates were produced for maxillary positioning and fixation. We evaluated the accuracy of the placement by virtual comparison of the preoperative and postoperative images. In the upper dentition, postoperative analysis showed a mean (SD) deviation of 1.3 (1.4) mm from the preoperative plan. The method enables accurate placement of the maxilla, independent of the condyle or mandible, without the need for extraoral reference points.

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Introduction

Three-dimensional planning of orthognathic surgery is already widely applied, particularly for the treatment of patients with asymmetrical maxillofacial deformities, and good outcomes depend on careful planning being translated to the actual operation.¹ Correct positioning of the maxilla after Le Fort I osteotomy in the transverse and sagittal planes is usually guided by an intermediate splint,^{2,3} and the vertical dimension is generally measured using intraoral or extraoral reference points.⁴ Intraoral reference points are usually marked on the bone above and below the osteotomy

line. The most commonly used extraoral reference point is a nasion screw or glabella pin. These variables, however, can cause inaccurate positioning of the maxilla, as can the splint, errors in vertical positioning, intraoperative condylar sag, and posterior pressure from the condyle.⁵ Reported alternatives are intraoperative 3-dimensional printed guides, and tooth or bone-borne guides,² which can be used with prebent plates.⁶

We aimed to develop and evaluate a new method of positioning the maxilla that was independent of the amount of condylar sag. To realise this, patient-specific osteosynthesis plates were used. Patient-specific osteosynthesis or splintless maxillary repositioning has previously been reported,^{7,8} but our method enables the postoperative analysis of accuracy, and does not require the removal of additional tissue or a change in the surgical approach. The primary outcome measure was the position of the maxilla evaluated on cone-beam computed tomography (CT).

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Patients and methods

The Medical Ethics Committee of the University Medical Centre, Groningen, approved the use of patient-specific osteosynthesis, and the study conformed to the principles of the Declaration of Helsinki.

We retrospectively studied three patients (2 women and 1 man, mean (range) age 40 (21–60) years) who were treated with patient-specific CAD-CAM osteosynthesis plates at the Department of Oral and Maxillofacial Surgery at the University Medical Centre, Groningen. All patients received Le Fort I osteotomy as part of combined orthodontic and surgical treatment; they had not had previous operations on the maxilla or mandible, and had no craniofacial anomalies or syndromes.

Data acquisition

Three-dimensional scans of the craniofacial area were done using cone-beam CT (i-CAT, Imaging Sciences International, Hatfield, USA), and all output files were generated in digital imaging and communications in medicine (DICOM) format. We used the Lava™ Chairside Oral Scanner (3 M ESPE, St Paul, USA) to produce stereolithographic output files to obtain a virtual model of the dentition. This was projected and superimposed on the cone-beam CT using Simplant® O&O (Dentsply Implants NV, Kessel-Lo, Belgium) and the contours aligned.

Virtual planning

After segmentation of the anatomical structures on the augmented model, we made virtual osteotomies using the custom planar application and repositioning tool in the software. The position of the maxilla was based on the predetermined clinical data and virtual analysis. The completed virtual plan indicated the preferred locations for the plates and screws on the zygomatic and paranasal buttresses, which were guided by the thickness of the bone as interpreted from the cone-beam images.⁹

CAD-CAM osteosynthesis

The generation of stereolithographic files in virtual planning enables the design and fabrication of medical-grade titanium miniplates using CAD-CAM (Createch Medical SL, Mendaro, Spain). Our plates were based on the size and shape of the conventional titanium L-plates used in Le Fort I osteotomies (Figs. 1 and 2). They followed the contour of the maxillary bone, and the design was based on the sites of the screws, which aided in their translocation to the final position. A drill and cutting guide (Fig. 1) enabled accurate placement. The guides were made on a 3-dimensional printer using stereolithographic techniques (polymerisation of liquid resin in layers) and the plates manufactured using a five-axis milling machine. An intermediate 3-dimensional splint was

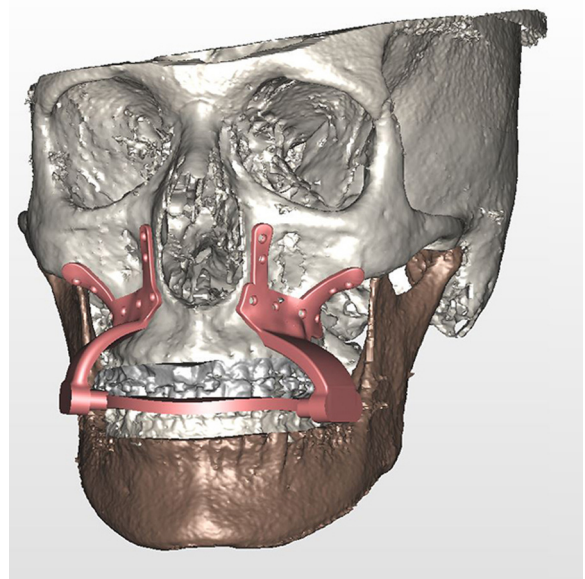


Fig. 1. Dentition-supported drill and osteotomy guide.

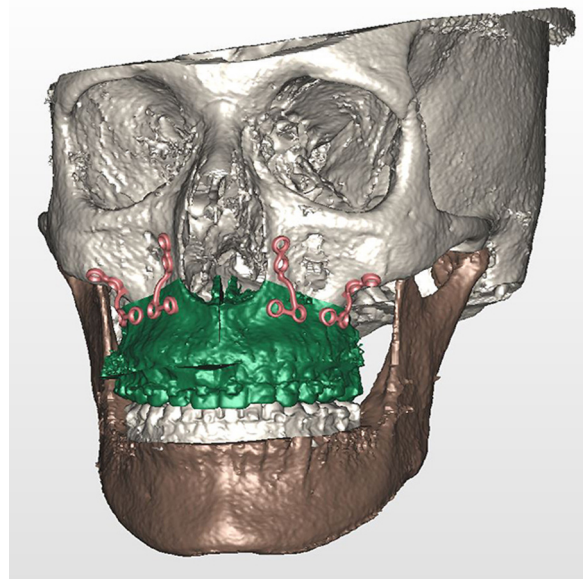


Fig. 2. Surgical 3-dimensional customised CAD-CAM osteosynthesis plates.

also made (Simplant®, Kessel-Lo, Belgium) to enable the surgeon to switch to conventional methods if the position of the maxilla was questioned after use of the CAD-CAM plates. The splint was based on the surgical plan and therefore permitted the same degree of translocation as was planned with the CAD-CAM plates. All guides and osteosynthesis plates were sterilised using standard methods.

Surgery

The surgery included a conventional Le Fort I approach through a vestibular incision in the maxilla to expose the

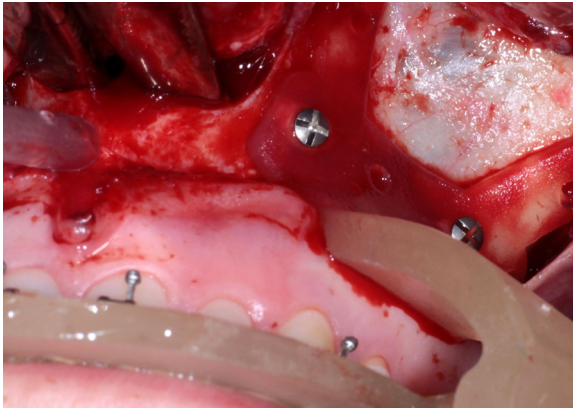


Fig. 3. Dentition-supported guide during operation.

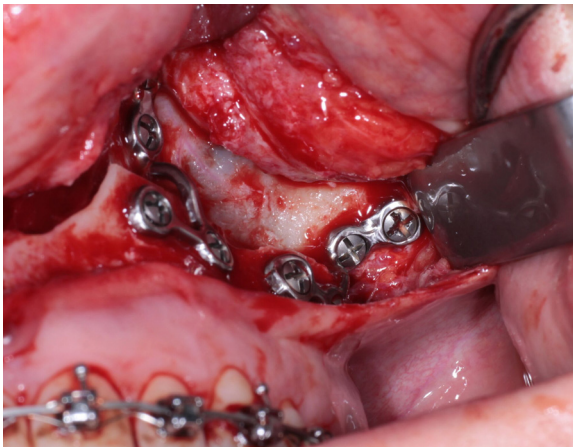


Fig. 4. Osteosynthesis after placement of screws.

bone. We fixed the guide to the teeth with wires around the orthodontic braces so that it abutted the contour of the bone and indicated the Le Fort I cut as well as the drilling sites for all the screws. Maxillary translocation had already been accounted for in the guide. When the guide was in place (Fig. 3), we drilled the screw holes and marked the cutting line with a marker pen. The osteotomies followed this line. We then positioned the plates using the drill holes as a guide, and fixed them with commercially available 1.5 mm osteosynthesis titanium screws (KLS Martin Group, Tuttlingen, Germany) (Fig. 4). Guided by the final 3-dimensionally printed splint, conventional bilateral sagittal split osteotomy was done to reposition the mandible and it was fixed with titanium miniplates and 2.0 mm screws (KLS Martin Group, Tuttlingen, Germany). Fig. 5 shows the final occlusion.

Measurements on superimposed 3-dimensional models

We based the primary outcome measure on a comparison of the preoperative and postoperative cone-beam images. All

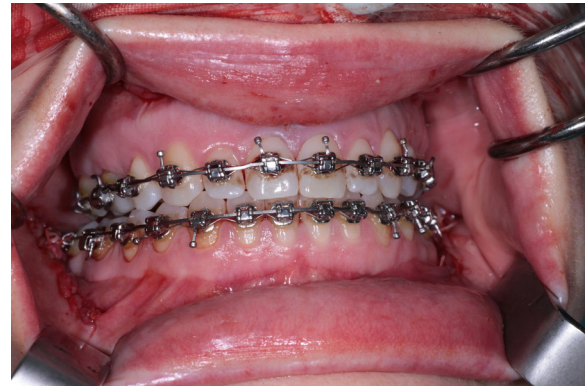


Fig. 5. Occlusion at the end of the procedure.

planning and postoperative files were anonymised. We used the Simplant® software to render 3-dimensional structures of the skull, maxilla, and mandible. After matching the preoperative intraoral scan of the dentition with the postoperative scan to make a postoperative augmented model, we exported the planning and surgical outcome files to Geomagic Qualify (3D Systems, Rock Hill, USA). The 3-dimensional treatment plan was matched with the postoperative data on both zygomatic bones, the supraorbital rims, and the foramen magnum, according to an iterative closest point algorithm. All measurements were done by one observer (JK) who was not involved in the surgical treatment. After each superimposition, we constructed colour-coded distance maps to measure how much the maxillary dentition had been displaced, and calculated the mean distance of displacement for each patient.

Results

All three patients had bimaxillary osteotomies that included CAD-CAM osteosynthesis and advancement of the maxilla. The upper side of the maxilla had been lowered in the second and third cases. No operations had to switch to conventional, splint-guided techniques. Postoperative analysis showed a mean (SD) deviation from the preoperative plan of 1.3 (1.4) mm (Euclidean distance on the dentition). Postoperative cone-beam CT scans were taken as part of regular follow-up within about two weeks of the surgery. Fig. 6 shows the mean distance between the superimposed preoperative and postoperative models (the postoperative scan matched the intraoral scan of the dentition).

We noticed that the initial design of the dentition-supported guide used in the first patient was too flexible, as it allowed too much movement and could have caused errors in placement. Use of more rigid guides in the other two patients restricted the degrees of freedom during placement, and the addition of more holes improved wire fixation to the orthodontic brackets. The guides provided good support while the screw holes were being drilled and did not allow any noticeable deviation in terms of angulation.

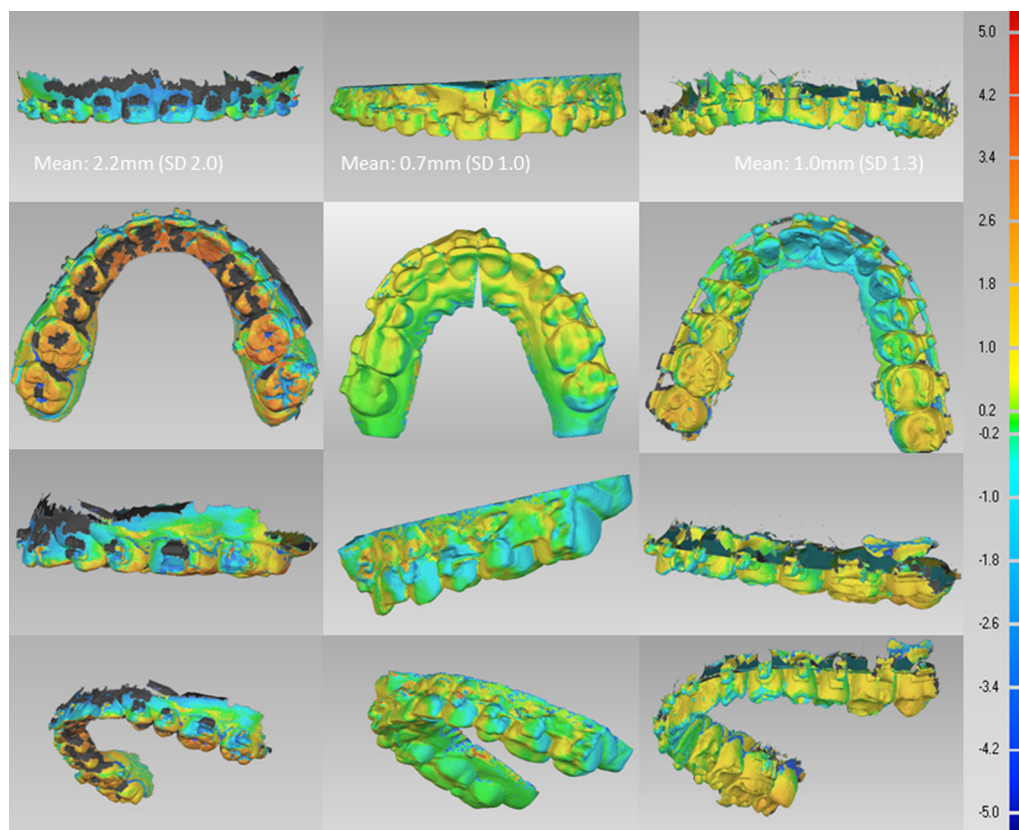


Fig. 6. Colour distance maps (left: case 1; middle: case 2; right: case 3). The scale on the right indicates the distance between the preoperative and postoperative images of the dentition. Note that differences shown by the colours are in the XYZ-planes.

Discussion

Our objective was to introduce and evaluate a patient-specific CAD-CAM osteosynthesis plate that can be used to translate a virtual Le Fort I treatment plan to the operating theatre. The mean (SD) deviation of the postoperative maxillary dentition from the plan was 1.3 (1.4) mm.

Positioning in the first patient was less accurate than in the others because the bulky, flexible drilling guide led to less precise positioning and could have bent during seating.

The less bulky design used in the other patients resulted in a mean (SD) deviation of 0.85 (1.15) mm. Proper positioning of the guides requires a standard surgical approach and when designed correctly, access is minimal (Figs. 1 and 2).

One observer (JK), who was not directly involved in the operation, manually positioned the intraoral scan of the anatomical outline of the dentition in the axial, coronal, and sagittal planes. This was done by eye and seemed accurate, but we did not validate the accuracy at this stage. Different methods have been reported for the creation of composite models for 3-dimensional virtual plans, and they always introduce small errors when cone-beam CT is combined with dentition models.^{10,11} This error is, however, equally present in both the CAD-CAM and conventional methods.

Kwon et al reported that use of conventional articulator splints for maxillary osteotomies resulted in a mean (SD)

accuracy of 1.17 (0.74) mm. They compared the accuracy of operations using 3-dimensional printed splints derived from virtual plans, and found it to be 0.95 (0.58) mm.¹² Although their results are comparable with ours, there is a difference in the direction of the discrepancy. In patients treated with conventional articulators, the maxilla was more posterior than the planned position, and it seems logical to assume that if the patient was supine during the operation, the condyles may have retruded and caused the maxilla to be in a more posterior position than was planned.⁸

The method reported by Gander et al for patient-specific osteosynthesis is comparable with ours, however they did not quantify postoperative accuracy.⁸ Polley and Figueroa reported adequate translation from the virtual plan to the actual patient, but they included manual bending of the plates, which was not the case in our study, and did not precisely analyse accuracy.¹³ The results reported by Mazzoni et al in 10 patients are comparable with ours, but the design of the guide differs from ours as it was fixed to the dentition and not to the bone.⁷

In our method the plates do not need to be bent manually and the guides ensure cohesion between the sites of the screws and the osteotomy.

Our study shows that patient-specific CAD-CAM osteosynthesis plates are specifically indicated in patients who require a posterior maxillary downgraft, often

with counter-clockwise rotation of the maxillomandibular complex.¹⁴ In such cases, repositioning of the maxilla will not cause many bony interferences. Fabrication of a conventional splint for patients who require a semi-adjustable articulator can be difficult because it is not easy to simulate the exact axis of the hinge of the mandibular condyle, and virtual planning and fabrication of a splint will probably not overcome this.¹²

The main advantages of our method are positioning of the maxilla independent of the condyle or mandible, and the fact that extraoral reference points are not needed. The technique accurately translates a 3-dimensional virtual treatment plan to an actual Le Fort I osteotomy.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients' permission

We obtained the patients' consent to publish the data.

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