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CHAPTER 6

SPLINTLESS SURGERY: DOES PATIENT-SPECIFIC CAD-CAM OSTEOSYNTHESIS IMPROVE THE ACCURACY OF LE FORT I OSTEOTOMY?

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ABSTRACT

Background. The purpose of this study is to analyse the accuracy of maxillary positioning in orthognathic surgery using patient specific CAD-CAM osteosynthesis plates. Pre-operative 3D virtual plans were translated to Le Fort I osteotomy procedures.

Methods. A retrospective case study of three patients was conducted. Virtual surgical planning was used for each case based on a CBCT, using Simplant O&O. Patient specific CAD-CAM drilling guides and osteosynthesis plates were produced for maxillary positioning and fixation. Maxillary placement accuracy was evaluated by virtual comparison of the pre-operative planning and post-operative CBCT images.

Results. Three patients (average age: 40 years) underwent the patient specific osteosynthesis procedure as part of their bi-maxillary osteotomy treatment. Post-operative analysis of the three cases showed an average deviation of $1.3 \pm 1.4$ mm from the pre-operative planning, at the level of the upper dentition.

Conclusion. This method enables intra-operative positioning of the maxilla, independent of the condylar/mandibular position and requires no extra-oral reference points. The study demonstrates that this method results in accurate maxillary placement.
INTRODUCTION

Three dimensional (3D) planning of orthognathic surgery is already widely utilized in clinical practice, especially for the treatment of asymmetrical maxillofacial deformities. Surgical outcome in these cases depends on proper planning and on proper translation of the treatment plan to the actual surgical procedure (1). Correct positioning of the maxilla, after a Le Fort I osteotomy, in the transversal and sagittal plane is usually guided by an intermediate splint (2, 3). The vertical dimension is generally determined using intra-or extra oral reference points (4). Intra oral reference points are usually marked on the bone above and below the osteotomy line. The most commonly used extra oral reference point is a nasion screw or glabella pin. These parameters can cause inaccuracy in the positioning of the maxilla as can the splint, the vertical positioning error, intra operative condylar sag and condylar posterior pressure (5). Reported alternatives for the positioning of the maxilla are 3D printed guides, used intra operatively, and a tooth or bone borne, to guide the maxillary movement (2). These can be used in conjunction with pre-bend plates (6). This study aims to develop and evaluate a novel method for maxillary positioning, independent of the amount of condylar sag. To realise this, patient specific osteosynthesis plates and placement guides were developed. Patient specific osteosynthesis or splintless maxillary repositioning have been reported (7, 8) but this study aims to introduce a patient specific method that requires no additional tissue removal or changes in surgical procedures and includes post-operative accuracy analyses. The primary outcome measure is the maxillary position based on cone beam computed tomography (CBCT) analysis.

PATIENTS AND METHODS

The medical ethical committee of the University Medical Center Groningen has approved the use of the patient specific osteosynthesis and this study conforms to the Declaration of Helsinki principles for ethical medical research.

A retrospective case study of three patients, whereby the patients were treated using patient specific CAD-CAM osteosynthesis plates, was conducted by the department of Oral and Maxillofacial Surgery at the University Medical Center Groningen. All patients met the following inclusion criteria: 1) patients required a Le-Fort I osteotomy as part of a combined orthodontic/surgical treatment plan, 2) they had not undergone previous maxillary or mandibular orthognathic surgeries, 3) craniofacial anomalies/syndromes were absent. The patient group consisted of 2 females and 1 male with an average age of 40 years (range: 21-60 years).
Data acquisition
A 3D scan of the craniofacial area was performed using CBCT imaging (i-CAT, Imaging Sciences International, Hatfield, USA). All output files were generated in digital imaging and communications in medicine (DICOM) format. A virtual model of the dentition was obtained using the Lava™ Chairside Oral Scanner (3M™ ESPE™, St. Paul, USA). This scanner gives stereolithography (STL) output files. The virtual dentition models were projected and superimposed on the CBCT images using Simplant O&O (Simplant, Kessel, Belgium) and the contours were aligned.

Virtual planning
After segmentation of anatomical structures on the augmented model, virtual osteotomies were carried out using the custom planar application and repositioning tool in the software. Positioning of the maxilla was based on pre-determined clinical data and virtual analysis. The virtual surgical planning was completed by indicating the preferred locations for the plate- and screw fixation on the zygomatic and paranasal buttresses, guided by the bone thickness as interpreted from the CBCT images (9).

CAD/CAM osteosynthesis
Generation of virtual planning STL files enables the design and fabrication of medical grade titanium miniplates using CAD-CAM techniques (Createch Medical, Mendaro, Spain). The design of the plates is based on the size and shape of conventional titanium L-plates used with le Fort I osteotomies (Figures 1 and 2). The indicated screw locations are used as the basis to design the plate, following the contour of the maxillary bone, which aids in the translocation towards the final position. A drill- and cutting guide is designed (Figure 1) to enable accurate placement of the patient specific CAD-CAM osteosynthesis plates. These guides are printed in 3D using stereo lithographic techniques (layer- wise polymerisation of liquid resin) and the plates are manufactured using a five axis milling machine. A 3D intermediate splint is fabricated (Simplant, Kessel, Belgium) as a fail-safe; this provides the surgeon with a means to switch to conventional translation methods when the maxillary position is being questioned, after using the CAD-CAM plates. This splint is based on the surgical planning and therefore contains the same degree of translocation as that planned with the CAD-CAM plates. All guides and osteosynthesis plates are sterilized using regular hospital sterilization means.

Surgical procedure
The surgery includes a conventional Le Fort I approach through a vestibular incision of the maxilla, exposing the maxillary bone. Subsequently, the cut- and drilling guide is fixated on the dentition using wire around the orthodontic braces. The guide abuts on
the contour of the bone and indicates the Le Fort I bone cut and the drilling locations for all the screws. Maxillary translocation is already accounted for in the guide. Once the guide is in place (Figure 3), the screw holes are drilled and the cutting line is indicated using a marker pen. The osteotomies are made according to this line. The fixation plates are then positioned guided by the drill holes and fixated with commercially available 1.5 mm osteosynthesis titanium screws (KLS Martin Group, Tuttlingen, Germany). See Figure 4. The mandible is repositioned using a conventional bilateral sagittal split osteotomy guided by the final 3D printed splint and fixated using titanium miniplates and 2.0 mm screws (KLS Martin Group, Tuttlingen, Germany). Figure 5 demonstrates the final occlusion after the procedure.

**Figure 1** - Dentition supported drill and osteotomy guide.

**Figure 2** - Surgical 3D patient specific CAD-CAM osteosynthesis plates

**Measurements on superimposed 3D models**

The primary outcome measure is the maxillary position based on analyses of CBCT images. A post-operative 3D- CBCT scan is made to evaluate the repositioning. All planning and postoperative files are anonymised. The Simplant software is used to render 3D structures of the skull, maxilla and mandible, using the same Hounsfield threshold values as in the virtual planning. The pre-operative intra-oral scan of the dentition is matched with the post-operative CBCT dental contours to make-up a post-operative augmented model. The STL planning and surgical outcome files are exported to Geomagic Qualify (3D systems, Rock Hill USA). The 3D treatment plan is matched
with the post-op data on both zygomatic bones, the supra orbital rims and the foramen magnum, based on an iterative closest point (ICP) algorithm. All measurements are performed by one observer (JK) who is not involved in the surgical treatment. Following each superimposition, colour-coded distance maps are constructed to measure the amount of displacement of the maxillary dentition. The mean distance of displacement is calculated for each patient.

RESULTS

Three patients, average age 40 years, received bimaxillary osteotomy treatments including the CAD-CAM osteosynthesis. All the cases underwent ventralization of the maxilla and the 2nd and 3rd cases also had dorsal downgrafting of the maxilla. No switches were made to conventional, splint guided, repositioning in this study. Post-operative analysis of the three cases with surface based matching, using the ICP principle, demonstrated an average deviation from the pre-operative planning, of 1.3 ± 1.4 mm Euclidian Distance on the dentition area. Post-operative CBCT images were taken as part of regular follow-up, within approximately two weeks after surgery. Figure 6 shows the mean distance between the superimposed models of the pre-operative orthognathic planning and the postoperative augmented model (the post-operative CBCT scan matched the intra-oral scan of the dentition). The distance map of the superimposed models demonstrated the distances were positive, in the ventral direction. This indicates that the position of the maxilla was more forward than the virtual planning.
The initial design of the dentition-supported guides in the first patient was felt to be too flexible, resulting in too much freedom of movement and potential placement error. Increasing the rigidity of the guides, which was regulated during the fabrication process, restricted the degrees of freedom during placement in patients 2 and 3. Additional fixation holes in the guides enabled improved fixation to the orthodontic brackets with a metal wire, which was considered as rigid by the surgeon. The guide provided good support during the drilling of the screw holes and did not allow any noticeable deviation in terms of angulation.

**Figure 6** - Dentition colour distance maps: patient 1. (left), 2. (middle) and 3. (right). The legend on the right reflects the distance between the pre-operative (planning) and post-operative imaging of the dentition. Note that differences represented by the colors are in XYZ-planes.
DISCUSSION

The objective of this study was to introduce and evaluate a patient specific CAD-CAM osteosynthesis plate, as a translation tool, from a virtual Le Fort I treatment plan to surgical intervention. The average deviation of the post-operative maxillary dentition, compared to the treatment plan, was $1.3 \pm 1.4$ mm.

The accuracy in the first patient was noticeably less compared to the second and third patient. In the first patient, the design of the drilling guide was too bulky, leading to less accurate positioning of the guide. The bulky guide was also slightly flexible. Retrospectively, this was regarded as too flexible with a risk of bending during seating and therefore introducing inaccuracies.

The guide design was adjusted and less bulky in the second and third patients resulting in an average deviation of $0.85 \pm 1.15$ mm in both patients. Proper positioning of the guides requires a regular surgical approach and when these guides are designed correctly the surgical access is reconcilably minimal (Figures 1 and 2).

One observer (JK), who was not directly involved in the surgical treatment, manually positioned the intra oral scan of the anatomical outline of the dentition in the axial, coronal and sagittal plane in the CBCT. This process is visual and seems accurate, but no accuracy validation was performed at this stage. Different methods are reported for creating composite models for 3D virtual planning, which always introduces small errors when combining CBCT images with dentition models (10, 11). This error is, however, equally present in the CAD-CAM or conventional 3D splint methods.

Kwon et al. reported that the accuracy of maxillary osteotomies using conventional articulator fabricated splints is $1.17 \pm 0.74$ mm. They compared the accuracy of maxillary osteotomies using 3D printed splints derived from virtual planning, and found it to be $0.95 \pm 0.58$ mm (12). The accuracy between those techniques and our technique seems to be comparable, but there is a difference in the direction of the discrepancy between the methods. The maxilla of the Kwon et al. articulator patient was positioned more posteriorly compared to the planned position. It seems logical to assume that this is related to the fact that the patient was in a supine position during the surgery which may have led to the condyles being in a retruded position and thereby the maxilla being in a more posterior position than was planned (8). The Gander et al. (8) study reports a comparable method as reported here for patient specific osteosynthesis, but however, does not report a quantification of their post-operative accuracy as was shown in this study. The method reported by Polley et al., on the other hand, which reports adequate
translation from virtual planning to the actual patient, does not include manual plate bending; this was not the case here. The Polley et al. study also lacks exact accuracy analysis (13). The results of the complete procedure in our study quantify an average deviation of 1.3mm from the planning. Comparable results are reported by Mazzoni et al. (7), after analysing 10 patients. However, the guide design in this study differs in that it is dentition fixated and not bone supported.

The advantage of the method described in this manuscript is, therefore, that the plates do not require to be bent manually and the guides assure cohesion between the screw locations and the osteotomy.

This study reveals that a specific indication for using patient specific CAD-CAM osteosynthesis plates are cases requiring a posterior maxillary down graft, often combined with a counter clock rotation of the maxilla-mandibular complex (14). In such cases, the repositioning of the maxilla will not cause many bony interferences. Furthermore, fabricating a conventional splint is difficult for the cases requiring a semi-adjustable articulator because simulating the exact hinge axis of the mandibular condyle is not easy and virtual planning and splint fabrication will probably not overcome this issue (12).

**CONCLUSION**

The main advantages of this method are that the intra operative positioning of the maxilla is independent of the condylar/mandibular position and that there is no need for extra-oral reference points. The patient specific CAD-CAM osteosynthesis plate is a promising technique as it translates a 3D virtual orthognathic treatment plan to an actual patient Le Fort I osteotomy accurately.
REFERENCES


