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The use of patient-specific implants in orthognathic surgery: A series of 32 maxillary osteotomy patients

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ABSTRACT

The use of virtual surgery, patient-specific saw and drill guides, and custom-made osteosynthesis plates is rapidly spreading from deformity surgery to orthognathic surgery. Most of the commercially available systems are using computer-aided design/computer-aided manufacture (CAD/CAM) wafers to produce patient-specific saw guides. However, most plate systems provided are still the conventional "in stock" mini plates that can be individually designed by pre-bending according to the stereolithographic model of the patient. Custom made three-dimensional (3D) printed implants have earlier been demonstrated to be an ideal solution in deformity surgery and in reconstruction of complex posttraumatic cases. In this study, we report the novel use of patient-specific saw and drill guides combined with patient-specific 3D titanium alloy implants as a fixation system in maxillary movement after Le Fort I and bimaxillary osteotomies (n = 32). The implants were individually designed for each patient to follow anatomical structures and to provide exact positioning and stability of the repositioned maxilla.

1. Introduction

The use of computer-aided design (CAD) is rapidly spreading from industry to medicine. Development of patient-specific implants (PSI) in cranio-maxillo-facial surgery has been rapid in the past few years. Especially complex three-dimensional (3D) structures such as orbital walls and parts of the maxilla have been successfully treated by titanium PSI (Stoor et al., 2014). Other materials such as PMMA and several composites have also been successfully used in reconstruction of the skull and the facial skeleton (Ridwan-Pramana et al., 2015; Piitulainen et al., 2014). The main benefit of these reconstructions is restoration of the anatomy in high fidelity. The same industrial CAD process whereby the designer's idea is visualized by creating a CAD model can thus be implemented also in surgery. In surgery, however, the CAD process starts with the patient's computed tomography (CT) data (Rundman et al., 2011).

Orthognathic surgery is usually based on two-dimensional (2D) cephalometric analysis combined with the clinical findings of the patient's soft tissue and smile line. The perfect positioning of the maxilla is sometimes demanding, especially in craniofacial deformity cases, as well as in asymmetry cases in which the maxillary horizontal plane deviates, there is a midline aberration, and a vertical deviation of the inclination of the teeth in the premaxilla. In these severe cases, there is a clear benefit of 3D surgical planning.

The quality of the CAD/computer-aided manufacturing (CAM)-generated wafers has previously been demonstrated to be accurate enough for orthognathic surgery (Schouman et al., 2015). An increasing number of commercial companies are now providing surgical models and 3D design and virtual planning for orthognathic surgery, although with osteosynthesis based on pre-bent stock mini plates. This does not maximize the potential of 3D design and the true patient-specific implants. Earlier reports have demonstrated the clear benefits of 3D printed titanium alloy PSI for the reconstruction of facial defects (Stoor et al., 2014). In this study, we report the use of CAD–CAM patient-specific implants together with virtually designed saw and drill guides for the waferless positioning and fixation of the maxilla after Le Fort I and bimaxillary osteotomies.

2. Material and methods

A total of 32 patients needing maxillary correction were virtually designed with a chief surgeon and orthodontist using Planmeca ProModel system (Planmeca Ltd, Helsinki, Finland). The patients

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underwent operation at the Helsinki University Central Hospital from December 2013 to December 2015. In this process, virtual osteotomies were designed together with the technician using the CAD system provided by the company. 3D printed saw and drill guides as well as patient-specific implants were manufactured individually for each patient by Planmeca (Fig. 1). Also, dentition-based CAD/CAM wafers were preordered for safety reasons in each case. The wafers and drill guides are medical use-approved plastic, and patient-specific implants were titanium alloy as described in more detail earlier (Stoor et al., 2014). Implants were fixed with 6-mm Matrix orthognathic screws (DePuy Synthes). All cases were planned using maxilla-first protocol. The plates were designed to perfectly fit the anatomical contours of the maxilla and the zygoma to generate a "3D lock" (Fig. 2) in which the plate ideally fits only in one position when placed on the repositioned maxilla.

3. Results

The fitting of patient-specific 3D printed plates was in most cases so precise that there would be no need for intermediate wafer maxilla repositioning. However, in all these cases, the wafer was also manufactured for safety reasons. The surgical design of the implants in individual patients can be seen in more detail in Table 1. In all cases except one, the surgery was performed as planned. In one patient, the fitting of the designed plates was not acceptable, which probably resulted from error in the osteotomy design generated by the mandible position during CT.

4. Discussion

The use of 3D design and CAD/CAM wafers combined with pre-bent plates is becoming a common protocol in orthognathic surgery. However, the fixation systems are often still the old stock plates but now pre-bent according to the stereolithography models printed prior to surgery. When using the pre-bent plate technique, the drill holes are not marked in the saw guides. The fitting of these plates is thus not always very precise, allowing a certain degree of freedom in placing them, leading to the mandatory use of wafers. Rapid prototyping and the use of 3D printed PSI have been successful in reconstructive surgery (Stoor et al., 2014; Suomalainen et al., 2015). Only a few surgeons have discovered the benefits of the contouring and 3D locking

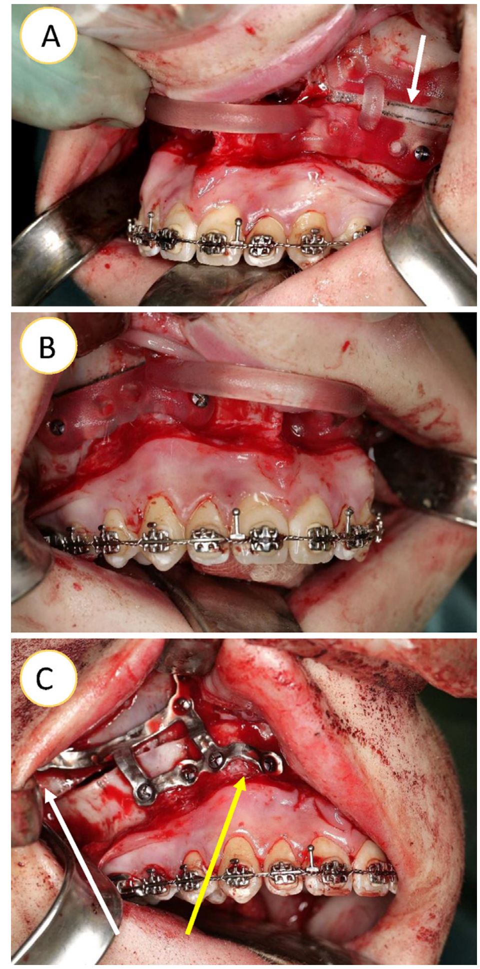

Fig. 2. Use of saw and drill guide and positioning of maxilla with patient-specific plate. The guide is secured to the maxilla (A), and the amount of bone to be removed for impaction is marked (white arrow). The guide can be also left in its place while performing the osteotomy. The holes that are securing the saw and drill guide are the same as those that are later used for screw fixation after repositioning (B). Note the anatomical groove formed by zygomatic buttress (white arrow) and ridge of bone in the canine area (yellow arrow) that are used to generate "anatomical 3D lock" for maxilla repositioning.

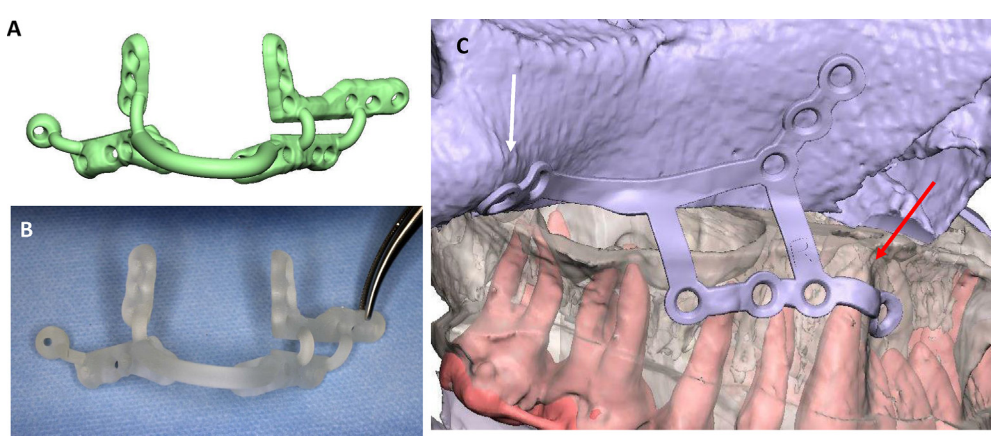

Fig. 1. Virtual planning of the saw and drill guides and patient-specific plates. The drill and saw guide is designed for precise and safe osteotomy lines. On the left side of maxilla, the space is left between the saw guideslots to identify the amount of bone that is needed to remove to generate desired level of impaction, virtual model of the saw and drill guide (A) and actual 3D printed guide (B). In the design of the saw and drill guide as well as the patient-specific plates, the bony surface landmarks and roots of the teeth are identified to generate 3D lock where the plates and guide fit with precision without damaging the roots (C). The zygomatic buttress (white arrow) and shape of the canine root (red arrow) generate natural grooves and ridges where the plate fits only in a relatively small area. If the reduction of the bone is done properly, the plate even alone can be used to reposition the maxilla as designed. In all cases but one, the patient-specific plates could be used. Patient characteristics and plate fitting are summarized in more detail in Table 1.

Table 1
Characteristics of study patients.

Patient no.	Sex	Age (y)	Diagnosis 1	Diagnosis 2	Diagnosis 3	Type of surgery	Movement of maxilla	One piece/segment	Plate fitting
1	M	25	Retrognathia mx.	Cross bite	Anterior open bite	Le Fort I	CW	Two piece	Excellent
2	M	25	Prognathia mnd.	Retrognathia mx.	Cross bite	Le Fort I	Straight + impacion	One piece	Good
3	F	23	Retrognathia mx.			Le Fort I	CCW	One piece	Excellent
4	F	37	Retrognathia mnd.	Distal bite	Large over jet	Bimax	Impaction	One piece	Not usable
5	F	44	Distal bite	Anterior open bite		Bimax	CCW	One piece	Excellent
6	M	28	Retrognathia mx.			Le Fort I	Straight	One piece	Excellent
7	F	22	Retrognathia mx.	Cross bite		Le Fort I	Straight	One piece	Excellent
8	M	25	Prognathia mnd.	Anterior open bite		Bimax	Straight	Two piece	R: Excell. L: good
9	F	24	Retrognathia mx.	Cross bite		Le Fort I	Straight	One piece	Excellent
10	F	48	Retrognathia mx.	Cross bite	Sdr. Waardenburg	Bimax	Straight	Two piece	Excellent
11	F	28	Retrognathia mx.	Asymmetry mnd.	Cross bite	Bimax	Straight	One piece	Excellent
12	M	33	Prognathia mnd.	Asymmetry mnd.	Cross bite	Bimax	Straight	Two piece	Excellent
13	M	24	Retrognathia mx.			Le Fort I	Straight	One piece	Excellent
14	F	19	Retrognathia mnd.	Anterior open bite		Bimax	Impaction	One piece	Excellent
15	F	43	Retrognathia mx.			Le fort I	Straight	Two piece	Excellent
16	F	24	Anterior open bite	Retrognathia mnd.		Bimax	Straight	One piece	Acceptable
17	F	27	Anterior open bite	Retrognathia mnd.	Juvenile Oligoarthritis	Bimax	CCW	One piece	Acceptable
18	M	22	Treacher collins	Retrognathia mnd.		Bimax + PEEK prosthesis	Straight	One piece	Good, see notes
19	F	30	Anterior open bite	Facial asymmetry	Luxation TMJ	Bimax	Impaction	One piece	Excellent
20	F	37	Retrognathia mnd.	Anterior open bite		Bimax	Straight + impaction	One piece	Good
21	F	45	Cross bite			Le Fort I	Straight + down grafting	One piece	Excellent
22	M	27	Anterior open bite	Cross bite		Bimax	CW	Two piece	Acceptable
23	M	21	Anterior open bite			Bimax	CW	One piece	Good
24	F	21	Anterior open bite	Cross bite		Bimax	CCW	One piece	Excellent
25	M	23	Anterior open bite	Cross bite		Le Fort I	CW	One piece	Excellent
26	F	25	Prognathia mnd.	Retrognathia mx.	Cross bite	Le Fort I	Straight	One piece	Acceptable
27	M	37	Acromegaly	Posterior open bite	Cross bite	Bimax (condylotomy)	CW, asymmetrical impaction	Two piece	Excellent
28	F	25	Retrognathia mnd.	Deep bite	Cross bite	Bimax	CW	Two piece	Excellent
29	F	20	Anterior open bite	Retrognathia mnd.		Bimax	CCW	One piece	Excellent
30	F	25	Anterior open bite	Retrognathia mnd.	Retrognathia mx.	Bimax	CCW	Two piece	Excellent
31	M	25	Anterior open bite	Retrognathia mnd.	Retrognathia mx.	Bimax	CCW	Three piece	Excellent
32	M	34	Retrognathia mx.	Prognathia mnd.	Facial asymmetry	Bimax	CCW	One piece	Excellent

Abbreviations: Bimax, bimaxillary osteotomy; CW, clockwise; CCW, counter clockwise; F, female; M, male; mnd, mandible; mx., maxilla; PEEK, polyether ether ketone; Sdr., syndrome; TMJ, temporomandibular joint.

properties of the 3D printed PSI in orthognathic surgery (Gander et al., 2015; Mazzoni et al., 2015).

The conversion of the 3D data to CAD/CAM models has, of course, limitations in anatomic locations with very thin bone constructions or low opacity (Huotilainen et al., 2014). Such errors can be often demonstrated in the base of an orbit or nerve exits where bony lamellae are thin. The error areas, however, are narrow, and even clinical applications using printed patients-specific implants give excellent results (Stoor et al., 2014). In the case of Le Fort I maxillary movement, high-quality bone in zygomatic buttress and apertura piriformis serve as excellent landmarks for surface modeling, which results in precise fitting of the implants. When the CT/cone beam computed tomography (CBCT) manufacturers and PSI manufacturers start to collaborate in the future, presumably the raw data without filters can be used for modeling and the errors will be even less significant. The benefits of 3D planning and virtual surgery, especially in complex cases, are clear; however, it seems that the predictability of soft tissue modeling still poses the most difficult challenges (Tominaga et al., 2016).

5. Conclusion

Based on our current experience in 32 patients and earlier reports (Gander et al., 2015; Mazzoni et al., 2015), the use of CAD/CAM PSI are promising new tools for orthognathic surgery. The CAD/CAM saw and drill guides, together with anatomic landmarks in the maxilla, can be used to design “3D locks” for the PSI, to serve as a tool for precise and stable maxillary repositioning.

Conflict of interest

All authors have participated in congresses where attendance fees were in part or in total supported by DePuy Synthes or KLS-Martin. Juho Suojanen is working in research project where part of the costs is sponsored by Amgen Ltd. The only financial support for this present work comes from Emil Aaltonen Foundation, Tampere, Finland.

Notification

Written informed consent was obtained from the patient presented in the manuscript figures.

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