Early experience of wafer-free Le Fort I osteotomy with patient-specific implants in cleft lip and palate patients

Merta, Minna

2023-02

Merta , M , Heliövaara , A , Leikola , J & Suojanen , J 2023 , ' Early experience of wafer-free Le Fort I osteotomy with patient-specific implants in cleft lip and palate patients ' , Journal of Plastic, Reconstructive & Aesthetic Surgery , vol. 77 , pp. 78-86 . https://doi.org/10.1016/j.bjps.2022.10.051

http://hdl.handle.net/10138/355760
https://doi.org/10.1016/j.bjps.2022.10.051

ELSEVIER

JPRAS
An International Journal of Surgical Reconstruction
www.JPRASurg.com

Early experience of wafer-free Le Fort I osteotomy with patient-specific implants in cleft lip and palate patients

Minna Merta[a], Arja Heliövaara[b], Junnu Leikola[b], Juho Suojanen[a,b,*]

[a] *Päijät-Häme Joint Authority for Health and Wellbeing, Department of Oral and Maxillo-Facial Surgery, Lahti, Finland*
[b] *Cleft Palate and Craniofacial Centre, Department of Plastic Surgery, Helsinki University Hospital and Helsinki University, Helsinki, Finland*

Received 15 September 2021; accepted 26 October 2022

KEYWORDS
Le Fort I osteotomy;
Orthognathic surgery;
Patient-specific implants (PSI);
Virtual surgery;
Cleft lip and palate

Summary *Purpose:* The use of virtual surgical planning and patient-specific saw and drill guides combined with customized osteosynthesis is becoming a gold standard in orthognathic surgery. The aim of this study is to report preliminary results of the use of virtual surgical planning and the wafer-free PSI technique in cleft patients.
Materials and methods: Patient-specific saw and drill guides combined with milled patient-specific 3D titanium alloy implants were used in reposition and fixation in Le Fort I osteotomy of 12 cleft patients. Surgical information was retrieved from hospital records. Pre- and post-operative lateral cephalograms were analyzed.
Results: In 10 of 12 cases, the implants fitted as planned to predesigned drill holes and bone contours with high precision. In one patient, the mobilization of the maxilla was too demanding for virtually planned advancement, and the implants could not be used. In another patient, PSI fitting was impaired due to an insufficient mobilization of maxilla and tension on PSI fixation with screws. After the surgery, the mean advancement of the anterior maxilla (point A) of all patients was 5.8 mm horizontally (range 2.7–10.1) and −3.1 mm vertically (range −9.2 to 3.4). Skeletal relationships of the maxilla and mandible could be corrected successfully in all patients except for the one whose PSI could not be used.

Head of Department: [a]Eeva Kormi, [b]Patrik Lassus
* Corresponding author at: Cleft Palate and Craniofacial centre, Department of Plastic Surgery, Helsinki University Central Hospital, P.O. Box 281, 00029 Helsinki, Finland.
E-mail address: juho.suojanen@helsinki.fi (J. Suojanen).

https://doi.org/10.1016/j.bjps.2022.10.051

Conclusions: Virtual surgical planning combined with PSI is a possible useful clinical adjunct for the correction of maxillary hypoplasia in cleft patients. Large maxillary advancements and scarring may be cause problems for desired advancement and for the use of implants.

Introduction

Computer-aided design (CAD) is more often used in surgery. Developments of virtual surgical planning, patient-specific implants (PSI), and saw and drill guides have been progressive during the past few years. PSI can be milled or laser sintered from a selection of medically approved composites or alloys. Especially complex three-dimensional (3D) structures such as facial skeletons have been successfully reconstructed with PSI.[1,2] The main benefit of these implants is the possibility to restore the anatomy in high fidelity, while the main problems are associated with biocompatibility of CAD-CAM (computer-aided manufacturing) materials.[1,3]

Orthognathic surgery is conventionally based on two-dimensional (2D) cephalometric analysis combined with the clinical findings of the patient's soft tissue quality and facial appearance. The accurate positioning of the maxilla perioperatively is demanding, especially in patients with craniofacial deformities and with unilateral and bilateral clefs of lip and palate with severe maxillary hypoplasia, asymmetries, multiple missing teeth with constricted maxillary dental arches, alveolar bone defects, and scar tissue from previous operations. Earlier reports have demonstrated that PSIs are accurate and functional tools for reposition and fixation after Le Fort I osteotomy in nonsyndromic patients.[4-7] In fact, the wafer-free, drill guide, and PSI-based technique are reported to be more accurate in maxillary repositioning as compared to the conventional tooth-bearing wafer technique.[8-11] In mandibular sagittal split osteotomy,[12,13] the benefits of PSI are found to be more limited.

The need for orthognathic surgery varies according to the cleft type. According to the recent literature, 30–69.6% of patients with bilateral cleft lip and palate (BCLP)[14-18] and 5.6–48.3% of patients with unilateral cleft lip and palate (UCLP) need orthognathic surgery.[14-16,18,19] For patients with isolated cleft palate (CP), the need for orthognathic surgery is lower at 0–13.2%.[14,16,18,20] Since the need for orthognathic surgery in syndromic and nonsyndromic cleft patients is rather high, and midline asymmetries as well as horizontal, vertical, and transversal problems often exist, and the anatomy in cleft area is challenging, the use of virtual surgical planning combined with PSI could be expected to be beneficial. To our knowledge, there are no comparative studies of the use of PSI in cleft patients.

The aim of our preliminary study is to report the results of the use of virtual surgical planning and wafer-free PSI technique of Le Fort I osteotomy in 12 cleft patients.

Material and methods

Surgery and virtual planning

The patients were operated on at the Helsinki University Central Hospital from January 2016 to September 2020 by the same surgical team. Altogether 12 cleft patients needing maxillary correction were virtually designed with surgeons and senior cleft orthodontists using the Planmeca ProModel™ system (Planmeca Ltd., Helsinki, Finland). All patients were imaged with computed tomography (CT) preoperatively, with a slice thickness of 1 mm and a gantry tilt of 0°. Dental casts with target occlusion were shipped to the company, where they were digitally scanned, and the formed STL-file was then fused to imported CT DICOM-data. Virtual osteotomies were designed interactively online with company engineers using CAD software provided by the company. Saw and drill guides that had been 3D printed as well as milled PSIs were designed and manufactured individually for each patient by Planmeca Oy, Helsinki, Finland. Dentition-based CAD/CAM wafers were preordered for safety reasons in each case, even though the surgery was planned as wafer-free. The wafers and drill guides are medical use approved printing material.[4] PSI were fixed with 5-7 mm screws (1.85 mm Matrix screws by DePuy Synthes or 2.0 mm screws by KLS-Martin). All bimaxillary surgery cases ($n = 7$) were planned using the maxilla-first protocol. The preoperative 3D planning of the virtual operation was performed using Planmeca Romexis® (Planmeca Oy, Helsinki, Finland) and 3D Systems Geomagic Freeform (3D-Systems, Rock Hill, South Carolina, U.S) software. All patients received speech and language assessment.

Cephalometrics and orthodontics

All patients were imaged with CT 3 months (SD 1.6 months) preoperatively. Immediate postoperative lateral cephalometric radiographs were taken 1–3 days after surgery with the head positioned according to the Frankfort horizontal plane with molar teeth occluded and lips in repose. Postoperative CTs were not taken because of radiation.

For the cephalometric analysis, the preoperative 3D CT was converted to a 2D lateral cephalogram using the Romexis Imaging program (Planmeca Romexis, version 6.0.0.778). The pre- and post-operative cephalograms were digitized by the same orthodontist using the Planmeca Romexis Cephalometric Analysis module. The subsequent pre- and post-operative cephalometric tracings were super-

Table 1 Patient characteristics.

Subjects	Sex	Age at Operation	Type of Cleft/dg	Earlier craniofacial operations and techniques
1	M	20	CLA, BOFS-syndrome (Branchio-oculo-facial syndrome)	Primary lip repair 4mo (Millard). Alveolar bone graft 9y.
2	F	39	CP	Previous operations abroad, unknown age. Le Fort I osteotomy.
3	M	21	UCLP	Primary lip repair 3mo (Millard), palatal repair 9mo (Bardach). VPI surgery (pharyngeal flap, Hogan) 5y. Alveolar bone graft 9y.
4	F	23	CP	Primary palatal repair 9mo (Bardach)
5	F	17	UCLP, CHARGE-syndrome	Primary lip repair 3mo (Millard), palatal repair 14mo (Bardach). VPI surgery (pharyngeal flap, Hogan) 5y. Resection of pharyngeal flap 5y and 9y because of sleep apnea. Alveolar bone graft 9y.
6	F	16	UCLP	Primary lip repair 7mo (Millard), palatal repair 25mo (Bardach). Alveolar bone graft 11y.
7	F	18	CLA	Primary lip repair 4mo (Millard). Secondary lip correction 6y. Alveolar bone graft 9y.
8	M	24	UCLP	Primary lip repair 3mo (Millard), palatal repair 10mo (Bardach). Alveolar bone graft 10y.
9	F	18	BCLP	Primary lip repair 4mo (Millard), palatal repair 9mo (Bardach). Secondary lip repair 5y. Rhinoplasty 6y. Alveolar bone grafts 13y, 14y, and 16y.
10	F	13	UCLP	Primary lip repair 4mo (Millard), palatal repair 10mo (Bardach). VPI-surgery (Furlow double-opposing Z-plasty) 12y. Alveolar bone graft 12y.
11	F	16	UCLP	Primary lip repair abroad, unknown age. Primary palatal repair 12mo (Bardach). Alveolar bone graft 9y. Fistula closure 11y.
12	F	17	CP	Palatal repair 9mo (Bardach). VPI surgery (Furlow double-opposing Z-plasty) 10y.

Abbreviations: F, female; M, male; mo, months; y, years; VPI surgery, surgery for velopharyngeal insufficiency.
BCLP, bilateral cleft lip and palate; CLA, cleft lip and alveolus; CP, isolated cleft palate, UCLP, unilateral cleft lip and palate;.
VPI surgery, surgery for velopharyngeal insufficiency.
Typical findings in syndromes:.
BOFS-syndrome (Branchio-oculo-facial syndrome): skin anomalies on the neck, malformations of the eyes and ears, and distinctive facial features.
CHARGE-syndrome: coloboma, heart defects, atresia choanae, growth reduction, genital abnormalities, and ear abnormalities.

imposed by a Sella-Nasion (SN) plane in order to measure the surgical changes in the maxillo-mandibular position. All measurements were corrected for cephalometric enlargement. As postoperative CTs could not be taken, the accuracy of the amounts of the virtually planned horizontal and vertical surgical changes of the maxillary and mandibular positions was not compared. Only angular measurements were used in comparing the preoperative virtual predictions and actual surgical results.

All patients were given orthodontic treatment with fixed appliances before and after the osteotomy. Intermaxillary elastics were used during postoperative orthodontics.

Results

Surgery

The mean age of 12 patients operated on was 20.2 years (range 13–39). Three patients were male and 8 patients were females; 7 had UCLP (58.3%), 1 BCLP (8.3%), 3 CP (25%), and 1 cleft lip and alveolus (CLA) (8.3%). The material included 2 patients with syndromes (CHARGE and BOFS-syndromes). Patient characteristics and information about the earlier operations can be seen in more detail in Table 1. All patients underwent one-piece Le Fort I osteotomy. Seven of the patients were operated on with two-jaw surgery (Table 2). Bimaxillary osteotomy was necessary for the correction of maxillary hypoplasia with facial asymmetries, canting of the occlusal plane, severe anteroposterior discrepancy, and bimaxillary retrusion.

No major technical problems on medical modeling, virtual surgical planning, or PSI generation were detected. During operation, the PSI fitted bone contours and predesigned drill holes with high precision in 10 patients. In one patient (number 2), the PSI could not be used due to an insufficient mobilization of the maxilla for virtually planned advancement. This patient's osteosynthesis was performed freehand with conventional mini-plates, and maxillary retrognathia was accepted as a result. This patient had previously had a Le Fort I operation, but no further information was available about the other earlier operations as the patient had lived abroad. Previous fixation plates were removed at the start of the new operation. Velopharyngeal insufficiency (VPI) was noticed pre- and post-operatively. In another patient (number 10), PSI fitting was impaired due to an insufficient mobilization of maxilla and tension on PSI fixation with screws. In this patient, the expected advancement could not be achieved. After the surgery, there was an edge-to-edge bite. This patient had the largest difference between the virtually simulated prediction and the actual postoperative SNA angle (3.2°) of the patient series.

In 2 patients (numbers 3 and 8), the mobilization of the maxilla was highly challenging. These patients were the ones with the largest postoperative horizontal advancements of the maxilla, 10.1 mm, of the patient series. Despite that, PSI fitted bone contours with high precision and could be used for osteosynthesis. In one patient (number 8), the splint was used to secure accurate positions to PSIs. In one patient (number 3), the previous pharyngeal flap had to be cut in order to mobilize the maxilla sufficiently. Postoperatively, surgery for VPI was needed. Postoperative speech corrective surgery for 2 patients (numbers 2 and 3) was performed with a secondary Furlow procedure (double-opposing Z-plasty) 14 and 15 months after the osteotomy.

No major complications were observed. One patient suffered from postoperative epistaxis. In 2 patients, delayed wound closure was observed, but no reoperations were needed. A patient case is presented in Figure 1A, B, C, D, and E.

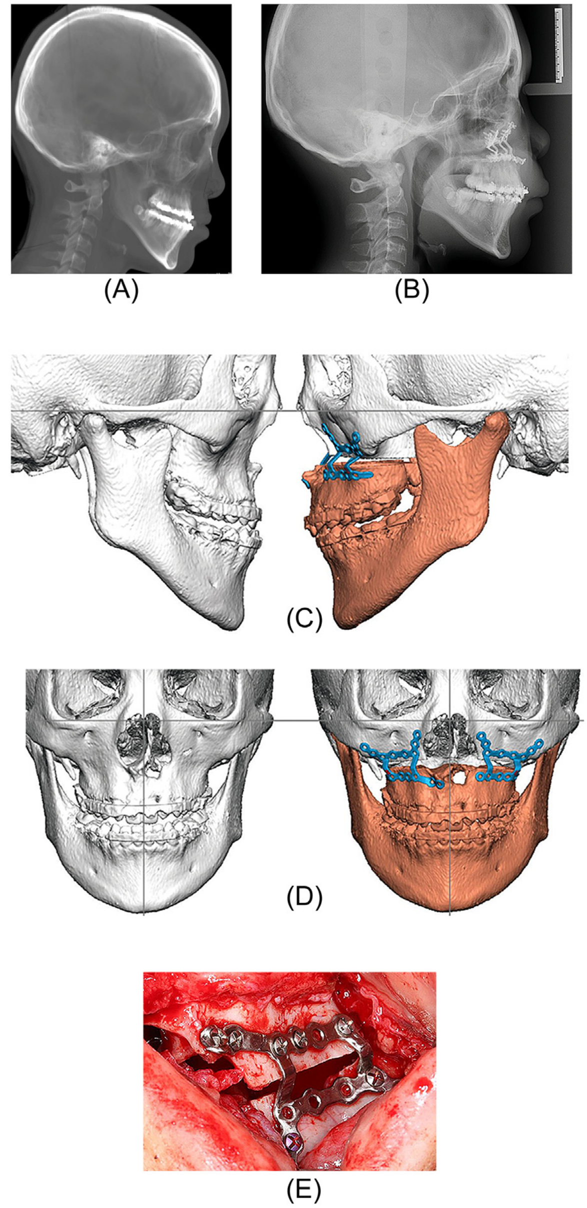

Figure 1 A-E. Patient case
Sixteen-year-old female with a left-sided UCLP (case 11). Maxilla (point A) was moved 7.1 mm forward, 0.6 mm downward, and 0.5 mm to the right side **(Figure 1A, 1B, and 1C).** The PSI in the cleft side was planned to cross the alveolar cleft to get more support (**Figure 1D and 1E**). The PSI fitting in surgery was excellent, and there were no complications after surgery either. The DBX putty was used in surgery for augmentation. The clinical result including facial profile and occlusion was good.
A. 3D CT taken before surgery changed to 2D lateral cephalometric picture. The picture was taken with wax wafer in mouth to get mandible to condyle position
B. Lateral cephalometric picture taken at first postoperative day
C and D. 3D plan of the surgery and PSI. The PSI in the cleft side was planned to cross the alveolar cleft to get additional support
E. The PSI in its planned position during surgery.

Cephalometrics

After the surgery, the mean advancement of the anterior maxilla (point A) of all patients was 5.8 mm horizontally

Table 2 Surgical procedures.

Subjects	Type of operation	PSI fitting and surgical limitations	Complications	Augmentation	Maxillary point A horizontal	advancement point A vertical	Mandibular point B horizontal	advancement point B vertical
1	Bimax	PSI fitting excellent	Postoperative epistaxis 1 pop	DBX putty	2.7	−9.2	−8.2	2.0
2	Le Fort *I* + genioplasty	PSI not usable, due to insufficient mobilization of maxilla	VPI surgery (Furlow) 15mo postop.	DBX putty	3.9	3.4	3.2	2.9
3	Bimax	PSI fitting excellent. Palatoplasty cut for maxillary mobilization.	VPI surgery, (Furlow) 14mo postop.	DBX putty	10.1	−4.9	0.5	1.8
4	Bimax	PSI fitting excellent	None	None	4.0	2.3	7.7	2.5
5	Le Fort I	PSI fitting excellent	None	DBX putty	3.7	−5.2	−4.1	−2.7
6	Bimax	PSI fitting excellent.	None	DBX putty	7.1	−3.1	4.9	−7.1
7	Bimax	PSI fitting excellent.	Delayed wound closure on left SRO	None	2.7	−1.4	3.2	−0.2
8	Bimax	PSI fitting excellent. Mobilization of maxilla challenging.	None	DBX putty	10.1	−7.2	−5.5	−2.2
9	Le Fort I	PSI fitting excellent.	Delayed wound closure on left side	DBX putty	9.0	−1.2	−2.2	−0.4
10	Le fort I	PSI fitting impaired to predesigned drill holes due to tension. PSI usable.	None	DBX putty	3.7	−7.2	−3.0	−0.1
11	Le Fort I	PSI fitting excellent.	None	DBX putty	7.1	−0.6	1.6	2.4
12	Bimax + rhinoplasty	PSI fitting excellent.	None	None	NA	NA	NA	NA
				Mean	5.8	−3.1	−0.2	−0.1
				SD	2.9	4.0	4.8	3.0
				Max	10.1	3.4	7.7	2.9
				Min	2.7	−9.2	−8.2	−7.1

The maxillary (point A) and mandibular (point B) horizontal and vertical advancements measured from superimpositions of cephalometric tracings. Abbreviations: Bimax, combined Le Fort I osteotomy and bilateral sagittal ramus osteotomy; PSI, patient-specific implant; mo, months; SRO, sagittal ramus osteotomy; DBX, commercial demineralized bone matrix derivate from DePuy Synthes, VPI surgery, surgery for velopharyngeal insufficiency; point A, the most concave point of anterior maxilla; point B, deepest point on the anterior contour of the mandibular alveolar arch.

Table 3 Mean pre- and post-operative changes in cephalometric parameters of all patients.

Mean	Preop.	SD	Postop.	SD
SNA (°)	73.6	4.6	80.6	4.9
SNB (°)	76.8	7.5	77.2	6.4
ANB (°)	−3.2	6.5	3.4	3.1
SN/MP (°)	38.7	10.4	39.2	8.8
PL/MP (°)	27.9	7.0	25.6	7.5
LAFH/TAFH (mm)	56.4	2.3	56.1	2.4
UI/SN (°)	102.9	11.1	101.2	10.2
LI/MP (°)	88.4	9.1	88.3	8.9

Abbreviations: SNA, angle between Sella-Nasion-A-point; SNB, angle between Sella-Nasion-B-point; ANB, angle between A-point-nasion-B-point; SN/MP, angle between Sella-Nasion line and Mandibular plane (Go-Me); PL/MP, angle between Palatal plane (ANS-PNS) and Mandibular plane; LAFH/TAFH, ratio of lower anterior facial height (ANS-Me) and total anterior facial height (N-Me); UI/SN, angle between long axis of the upper incisor and Sella-Nasion line; LI/MP, angle between long axis of the lower incisor and Mandibular plane.

(range 2.7-10.1) and −3.1 mm vertically (range −9.2 to 3.4) (Table 2). In the vertical direction, a positive value represents the movement of the maxilla to a more cranial position, and a negative value represents movement to a more caudal position. In one patient (number 12), the original CT could not be converted to a lateral cephalogram because of the change in the X-ray storing system. For this patient, the preoperative 2D cephalometric data is missing, and the cephalometric measurements could not be made. The mean pre- and post-operative SNA, SNB, and ANB angles were 73.6, 76.8, and −3.2°, and 80.6, 77.2, and 3.4°, respectively (Table 3). Postoperatively, the angle ANB was positive, and the maxillomandibular skeletal relationships could be corrected in all patients except for the one, whose PSI could not be used (number 2). When PSI were used, the differences of the virtually simulated predictions of these angles and the actual postoperative angles varied between 0 and 3.4° (Table 4). Statistical analyses were not performed because of the small and heterogeneous samples.

Discussion

Surgery

To our knowledge, there are no reports of the use of PSI in cleft patients, although the typical facial characteristics of a patient with a cleft that may be addressed surgically involve 3D deficiencies in the infraorbital, zygomatic, maxillary, and alveolar regions.[21] In reference to orthognathic issues, the maxilla is deficient in all dimensions, and there is displacement with constriction of the maxillary dental arch.[21] No major technical problems on medical modeling, virtual surgical planning, or PSI generation were detected in this study. In patients with dentofacial dysplasia, it has been demonstrated that PSIs are accurate and functional tools for reposition and fixation after Le Fort I osteotomy.[4-7] Recent literature shows that the wafer-free, drill guide, and PSI-based technique are more accurate in maxillary repositioning as compared to the conventional tooth-bearing wafer technique.[8-11] A cleft patient's bone surface morphology may greatly differ from the retrognathia or open bite of the Le Fort I patients without clefts. However, there were no problems with virtual model interpretation clinically, with the cutting and drilling guide, or with PSI fitting perioperatively in most of the patients. One PSI pair among the 12 operated patients was not usable due to an insufficient mobilization of the maxilla as compared to the original plan. This is a known phenomenon that is sometimes present in cleft patient surgery and in conventional wafer-based technique. In selected cases, especially with large advancements, 2 final wafers with different advancements can be ordered. This same patient had previously had a Le Fort I operation, but no information was available about the earlier operations as the patient had lived abroad. Palatal scarring and the quality of palatal tissue are the most important considerations for predicting the difficulty with surgery and relapse associated with midface advancement.[22] In cleft patients, maxillary bone can be remarkably thin. During the VSP precise screw, holes might be difficult to determine. To avoid perioperative challenges, it is possible to add extra screw holes to PSI to prevent this issue. In 10 cases, the PSI fitted with high precision, and we found them to be highly helpful for accurate repositioning of the maxilla, since predrilled screw holes are obvious landmarks for the designed position of the maxilla. Specific surgical procedures, such as pharyngeal flap, may cause decreased ability to mobilize and stabilize the advanced maxilla.[23] In our series, a previous pharyngeal flap was cut during osteotomy in one patient, and postoperative VPI surgery was performed.

Cephalometrics

Preoperatively, the patients of this study had maxillary and/or bimaxillary retrusion, crossbite, and asymmetries. The mean cephalometric postoperative maxillary advancement (point A) of was 5.8 mm horizontally and −3.1 mm vertically. The mean horizontal advancement was slightly larger than the mean (4.0 mm) in our unit reported earlier.[24] However, the individual variation was large. In other Finnish maxillofacial units treating dentofacial dysplasia patients, over 5.0 mm advancements were regarded as large advancements.[7] The preoperative mean value of the angle ANB (sagittal maxillo-mandibular relationship) was −3.2°, which reflects the need for orthognathic surgery. Postoperatively, the angle ANB was positive (mean 3.4°), and skeletal relationships of the maxilla and mandible could be cor-

Table 4 Differences in cephalometric angles (in degrees) between the virtual prediction and the actual early result in patients with PSI.

Subjects	Preoperative simulation SNA	Postoperative actual result SNA	Difference	Preoperative simulation SNB	Postoperative actual result SNB	Difference	Preoperative simulation ANB	Postoperative actual result ANB	Difference
1	82.2	81.2	1.0	79.1	77.3	1.8	3.1	3.9	−0.8
3	83.6	83.2	0.4	80.7	80.0	0.7	2.9	3.2	−0.3
4	77.3	76.8	0.5	69.5	69.5	0.0	7.8	7.3	0.5
5	75.1	74.2	0.9	73.1	71.0	2.1	2.0	3.2	−1.2
6	76.1	76.3	−0.2	73.8	74.0	−0.2	2.3	2.3	0.0
7	83.0	85.1	−2.1	80.4	79.1	1.3	2.6	6.0	−3.4
8	89.6	87.8	1.8	89.0	87.4	1.6	0.6	0.4	0.2
9	80.3	81.2	−0.9	73.0	72.6	0.4	7.3	8.6	−1.3
10	81.1	77.9	3.2	77.5	76.6	0.9	3.6	1.3	2.3
11	72.1	72.8	−0.7	68.4	68.4	0.0	3.7	4.4	−0.7
12	86.0	86.7	−0.7	83.3	84.2	−0.9	2.7	2.5	0.2
Mean	80.6	80.3	0.3	77.1	76.4	0.7	3.5	3.9	−0.4
SD	5.1	5.1	1.4	6.2	6.0	0.9	2.2	2.5	1.4
Max	89.6	87.8	3.2	89.0	87.4	2.1	7.8	8.6	2.3
Min	72.1	72.8	−2.1	68.4	68.4	−0.9	0.6	0.4	−3.4

Abbreviations: SNA, angle between Sella-Nasion-A-point; SNB, angle between Sella-Nasion-B-point; ANB, angle between A-point-Nasion-B-point.

rected in all patients except for the one, whose PSI could not be used due to scar tissue and insufficient mobilization.

In bimaxillary orthognathic surgery in patients without clefts, the success criteria for computer-aided surgical simulations have been set for 2 mm for the linear and 4° for the angular differences.[25,26] When PSI were used in our patients, the angular differences in this study were smaller than 4° (0–3.4 mm), and we conclude that the technique used in this study provides a reproducible 3D method for the prediction of postoperative angular maxilla-mandibular relations. As postoperative CTs were not taken because of radiation, only angular measurements were compared. The lack of analyzing the accuracy of the virtual surgical planning and the amount of maxillary and mandibular movements is a limitation of this paper. However, clinically relevant differences between conventional cephalometric radiographs and measurements performed on 3D models constructed from CBCT scans have been reported.[27-29] Moreover, the evaluation of change in maxillary position after orthognathic surgery is complicated by the fact that conventional cephalometric landmarks on the maxilla may be affected by the procedure.[30]

Only a few reports exist of the accuracy of virtual surgical planning in orthognathic surgery in patients for clefts.[31,32] According to Wang et al. (2020), virtual surgical planning was successfully transferred to actual surgery with the help of 3D printed surgical splints in 90 patients with clefts.[31] Most of the linear differences in the study were below 2 mm, and all angular differences were below 4°[31] Wu et al. (2019) compared the 3D postsurgical outcomes of 50 patients with cleft lip and palate following maxillary major (≥ 5 mm) and minor (< 5 mm) advancement with the “waferless” technique.[30] Discrepancies of all rotational surgical correlations (roll, yaw, and pitch) were positively correlated to the degree of planned surgical movement.[32]

Orthognathic surgery is often one of the final procedures in the cleft patient’s rehabilitation. The purpose is to achieve functional, long-term, stable occlusion, harmonious facial appearance, and improved self-esteem. The clinical results of our patients were satisfactory. According to this preliminary study with a small number of patients, in most cases, the PSI fitted with high precision, which assumably made surgeries easier and faster. No major complications were observed. Although the cost of the operations was not our study subject, it is true that PSIs are more expensive compared to stock plates. Some additional savings might come due to assumably shorter operation time and less frequent re-operations.[6] Cost efficiency of PSI needs further studies. Final conclusions of the technique can be drawn after the accuracy of the virtual planning, long-term effects, and skeletal stability have been analyzed.

Conclusion

PSI serve as a possible useful clinical adjunct for wafer-free reposition after Le Fort I osteotomy in cleft patients. However, large mobilization of maxilla can be a challenge and must be kept in mind in virtual surgical planning. There were no technical errors in medical modeling of cleft patients’ CT data for virtual surgical planning, drill and cutting guides, or PSI manufacturing despite aberrant bone morphology in PSI and surgical guide-related surfaces.

Ethical Approval

The protocol of this retrospective study was approved by the Hospital District of Helsinki and Uusimaa (HUS/917/2021) and adhered to the principles outlined in the Declaration of Helsinki.

Financial support

This work is financially supported by the Emil Aaltonen Foundation, Finnish-Norwegian Medical Foundation, Finnish Medical Foundation, Finnish Dental Society Apollonia, Paulo Foundation, Päivikki and Sakari Sohlberg Foundation, and Helsinki University Hospital Funds.

Conflicts of interest

Authors JS and JL have participated in congresses, where attendance fees were in part or in total supported by DePuy-Synthes or KLS-Martin.

Acknowledgments

We would like to thank Jani Horelli, Alexander Brink, Tomas Fering, Tuomas Pöysti, and Ville Salonen in Planmeca for technical assistance.

References

1. Stoor P, Suomalainen A, Lindqvist C, et al. Rapid prototyped patient specific implants for reconstruction of orbital wall defects. *J Craniomaxillofac Surg* 2014;**42**:1644–9.
2. Järvinen S, Suojanen J, Kormi E, et al. The use of patient specific polyetheretherketone implants for reconstruction of maxillofacial deformities. *J Craniomaxillofac Surg* 2019;**47**:1072–6.
3. Kärkkäinen M, Wilkman T, Mesimäki K, Snäll J. Primary reconstruction of orbital fractures using patient-specific titanium milled implants: the Helsinki protocol. *Br J Oral Maxillofac Surg* 2018;**56**:791–6.
4. Suojanen J, Leikola J, Stoor P. The use of patient-specific implants in orthognathic surgery: a series of 32 maxillary osteotomy patients. *J Craniomaxillofac Surg* 2016;**44**:1913–16.
5. Heufelder M, Wilde F, Pietzka S, et al. Clinical accuracy of waferless maxillary positioning using customized surgical guides and patient specific osteosynthesis in bimaxillary orthognathic surgery. *J Craniomaxillofac Surg* 2017;**45**:1578–85.
6. Suojanen J, Järvinen S, Kotaniemi KV, et al. Comparison between patient specific implants and conventional mini-plates in Le Fort I osteotomy with regard to infections: no differences in up to 3-year follow-up. *J Craniomaxillofac Surg* 2018;**46**:1814–17.
7. Kotaniemi KVM, Heliövaara A, Kotaniemi M, et al. Comparison of postoperative skeletal stability of maxillary segments after Le Fort I osteotomy, using patient-specific implant versus miniplate fixation. *J Craniomaxillofac Surg* 2019;**47**:1020–30.
8. Kraeima J, Schepers RH, Spijkervet FKL, et al. Splintless surgery using patient-specific osteosynthesis in Le Fort I osteotomies: a randomized controlled multi-centre trial. *Int J Oral Maxillofac Surg* 2020;**49**:454–60.

9. Jones JP, Amarista FJ, Jeske NA, Szalay D, Ellis E 3rd. Comparison of the accuracy of maxillary positioning with interim splints versus patient-specific guides and plates in executing a virtual bimaxillary surgical plan. *J Oral Maxillofac Surg* 2022;**80**:827–37.
10. Rückschloß T, Ristow O, Müller M, et al. Accuracy of patient-specific implants and additive-manufactured surgical splints in orthognathic surgery - A three-dimensional retrospective study. *J Craniomaxillofac Surg* 2019;**47**:847–53.
11. Karanxha L, Rossi D, Hamanaka R, et al. Accuracy of splint vs splintless technique for virtually planned orthognathic surgery: a voxel-based three-dimensional analysis. *J Craniomaxillofac Surg* 2021;**49**:1–8.
12. Suojanen J, Leikola J, Stoor P. The use of patient-specific implants in orthognathic surgery: a series of 30 mandible sagittal split osteotomy patients. *J Craniomaxillofac Surg* 2017;**45**:990–4.
13. Suojanen J, Järvinen S, Hodzic Z, et al. No differences in infections between patient-specific implants and conventional mini-plates in mandibular bilateral sagittal split osteotomy - Up to 3-year follow-up. *J Craniomaxillofac Surg* 2019;**47**:1181–4.
14. Good PM, Mulliken JB, Padwa BL. Frequency of Le Fort I osteotomy after repaired cleft lip and palate or cleft palate. *Cleft Palate Craniofac J* 2007;**44**:396–401.
15. Daskalogiannakis J, Mehta M. The need for orthognathic surgery in patients with repaired complete unilateral and complete bilateral cleft lip and palate. *Cleft Palate Craniofac J* 2009;**46**:498–502.
16. Voshol IE, van der Wal KG, van Adrichem LN, Ongkosuwito EM, Koudstaal MJ. The frequency of Le Fort I osteotomy in cleft patients. *Cleft Palate Craniofac J* 2012;**49**: 160–166.
17. Heliövaara A, Leikola J, Hukki J. Craniofacial cephalometric morphology and later need for orthognathic surgery in 6-year-old children with bilateral cleft lip and palate. *Cleft Palate Craniofac J* 2013;**50**:e35–40.
18. Dalle Ore C, Schoenbrunner A, Brandel M, et al. Incidence of Le fort surgery in a mature cohort of patients with cleft lip and palate. *Ann Plast Surg* 2017;**78**:S199–203.
19. Heliövaara A, Rautio J. A comparison of craniofacial cephalometric morphology and the later need for orthognathic surgery in 6-year-old cleft children. *J Craniomaxillofac Surg* 2011;**39**:173–6.
20. Antonarakis GS, Watts G, Daskalogiannakis J. The need for orthognathic surgery in nonsyndromic patients with repaired isolated cleft palate. *Cleft Palate Craniofac J* 2015;**52**:e8–e13.
21. Phillips JH, Nish I, Daskalogiannakis J. Orthognathic surgery in cleft patients. *Plast Reconstr Surg* 2012;**129** 535e–48e.
22. Turvey TA VW, Fonseca RJ. Maxillary advancement and contouring in the presence of cleft lip and palate. In: Turvey TA, Fonseca RJ, editors. *Facial clefts and craniosynostosis. Principles and management*. Philadelphia: WB Saunders; 1996. p. 441–503.
23. Wolford LMCD. End-stage reconstruction in the complex cleft lip/palate patient. In: Turvey TA, Fonseca RJ, editors. *Facial clefts and craniosynostosis. Principles and management*. Philadelphia: WB Saunders Company; 1996. p. 504–36.
24. Harjunpää R, Alaluusua S, Leikola J, Heliövaara A. Le Fort I osteotomy in cleft patients: maxillary advancement and velopharyngeal function. *J Craniomaxillofac Surg* 2019;**47**:1868–74.
25. Hsu SS, Gateno J, Bell RB, et al. Accuracy of a computer-aided surgical simulation protocol for orthognathic surgery: a prospective multicenter study. *J Oral Maxillofac Surg* 2013;**71**:128–42.
26. Zhang N, Liu S, Hu Z, et al. Accuracy of virtual surgical planning in two-jaw orthognathic surgery: comparison of planned and actual results. *Oral Surg Oral Med Oral Pathol Oral Radiol* 2016;**122**:143–51.
27. van Vlijmen OJ, Maal TJ, Bergé SJ, et al. A comparison between two-dimensional and three-dimensional cephalometry on frontal radiographs and on cone beam computed tomography scans of human skulls. *Eur J Oral Sci* 2009;**117**:300–5.
28. van Vlijmen OJ, Maal T, Bergé SJ, et al. A comparison between 2D and 3D cephalometry on CBCT scans of human skulls. *Int J Oral Maxillofac Surg* 2010;**39**:156–60.
29. Gribel BF, Gribel MN, Frazäo DC, McNamara JA Jr, Manzi FR. Accuracy and reliability of craniometric measurements on lateral cephalometry and 3D measurements on CBCT scans. *Angle Orthod* 2011;**81**:26–35.
30. Houston VJ, Jones E, James DR. A method of recording change in maxillary position following orthognathic surgery. *Eur J Orthod* 1987;**9**:9–14.
31. Wang Y, Li J, Xu Y, et al. Accuracy of virtual surgical planning-assisted management for maxillary hypoplasia in adult patients with cleft lip and palate. *J Plast Reconstr Aesthet Surg* 2020;**73**:134–40.
32. Wu TJ, Lee YH, Chang YJ, et al. Three-dimensional outcome assessments of cleft lip and palate patients undergoing maxillary advancement. *Plast Reconstr Surg* 2019;**143** 1255e–65e.