Accuracy and Safety of In-House Surgeon-Designed Three-Dimensional Printed Patient Specific Implants for Wafer-Less Le Fort I Osteotomy

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Abstract

The design and fabrication of three-dimensional (3D) -printed patient-specific implants (PSIs) for orthognathic surgery are customarily outsourced to commercial companies. We propose a protocol of designing PSIs and surgical guides by orthognathic surgeons-in-charge instead for wafer-less Le Fort I osteotomy. The aim of this prospective study was to evaluate the accuracy and post-operative complications of PSIs that are designed in-house for Le Fort I osteotomy. The post-operative cone beam computer tomography (CBCT) model of the maxilla was superimposed to the virtual surgical planning to compare the discrepancies of pre-determined landmarks, lines and principal axes between the two models. Twenty-five patients (12 males, 13 females) were included. The median linear deviations of the post-operative maxilla of the x, y and z axes were 0.74 mm, 0.75 mm and 0.72 mm, respectively. The deviations in the principal axes for pitch, yaw and roll were 1.40°, 0.90° and 0.60°, respectively. There were no post-operative complications related to the PSIs in the follow-up period. The 3D-printed PSIs designed in-house for wafer-less Le Fort I osteotomy are accurate and safe. Its clinical outcomes and accuracy are comparable to commercial PSIs for orthognathic surgery.

Introduction

Patients with dentofacial deformities suffer from reduced quality of life and low self-esteem as the consequences of poor function and aesthetic ^[1, 2]. Such deformities are also known to be related to temporomandibular joint pain and obstructive sleep apnoea ^[3, 4]. Correction by orthognathic surgery has become a routine procedure in most oral and maxillofacial surgery centres in the world. The traditional method of surgical planning involves transferring the patient's jaw record through mounted stone models of the dentition, and through mock surgery on the stone models to simulate the surgical procedures, and to fabricate surgical wafers that are used to guide the intra-operative surgical movements ^[5]. However, significant errors could be incorporated in each step of the planning process which could affect the execution and ultimately the outcomes of the orthognathic surgery ^[6].

With the development of orthognathic planning software and three-dimensional (3D) imaging technology such as cone-beam computed tomography (CBCT) and intraoral scanning systems, virtual surgical planning (VSP) is made possible and has broadened the boundary of orthognathic surgery ^[7]. VSP allows visualisation of the bony structure in a 3D perspective. Advancement in 3D printing further expand the possibilities in this field. The surgical wafers can be designed and printed by 3D printers after VSP, which in theory reduces the potential source of error from the transfer of records and laboratory-related variables ^[8-10]. However, no matter laboratory made or 3D-printed, the use of a wafer to position the osteotomised maxillary segment in Le Fort I osteotomy relies on the mandible, which is a mobile unit at the temporomandibular joints. It is therefore inevitable to have certain discrepancies from the planned movement when the wafer is used, in particular the vertical dimension of the jaw positioning ^[9, 11].

The concept of wafer-less positioning and fixation of Le Fort I osteotomy was developed to solve the wafer-related inaccuracies. Several studies have shown patient-specific implants (PSIs) planned and fabricated by commercial companies achieved good accuracy ^[12-14]. However, outsourcing the design and production of PSI has several drawbacks - such as long turnaround time (12), high cost (15,16), and the surgeon's lack of control in designing the implant. These disadvantages of commercial PSIs may limit its application and adoption, particularly in lower-income countries or teaching institutes.

With the popularisation of computer-aided design / computer-aided manufacturing (CAD-CAM) technology and further advancement of 3D printing, it is predicted that the cost of 3D printing for metal will become more affordable.

There is also a push for open source VSP programs and design tools to allow more surgeons to plan and design PSIs for orthognathic surgery and head and neck reconstruction ^[15–17]. The legislation and accreditation of approved PSIs and other implantable medical products in different countries are expected to change when the technology is further matured, so more patients may benefit from the PSI technologies but could not afford the commercial PSIs.

Our centre initiated a research project to develop self-designed PSIs for head and neck surgeries ^[17]. For orthognathic procedures, a protocol was set for surgeons of the Le Fort I osteotomy to design PSIs and surgical guides in-house. The feasibility, accuracy and safety of such PSIs are yet to be proven and verified. Therefore, this study aimed to evaluate the accuracy and post-operative complications of in-house surgeon-designed surgical guides and PSIs for wafer-less positioning of the maxilla in Le Fort I osteotomy.

Materials And Methods

Study design

This was a prospective study on the accuracy and post-operative complications of patients treated with in-house surgeon-designed PSI for wafer-less Le Fort I osteotomy. Patients with dentofacial deformity under the care of Oral and Maxillofacial Surgery, Faculty of Dentistry, The University of Hong Kong were recruited. The inclusion criteria were: (1) patient age 18 years or older; (2) Le Fort I osteotomy as part or whole of the orthognathic procedure; and (3) in-house surgeon-designed patient specific implant and surgical guide were planned for the Le Fort I osteotomy. The exclusion criteria were: (1) patients who were pregnant; (2) systemic conditions or diseases that affected normal bone healing; and (3) patients who were unable to take the preoperative and postoperative CT/CBCT scans; and (4) patients who had previous orthognathic surgery. This study was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority of Hong Kong West Cluster (ref no.: UW16-315). This study conformed to the Declaration of Helsinki.

Virtual surgical planning (VSP)

All patients were assessed preoperatively by the chief surgeon with the same protocol. Clinical measurements, clinical photographs in the neutral head position, and study models were performed for treatment planning. CBCT scans of the whole skull region were also taken. The preoperative CBCT image was imported into Proplan CMF 3.0 software (Materialize, Leuven, Belgium) for 3D model reconstruction and virtual surgery. The images were then segmented to remove artefacts and ensure adequate bony surfaces are exposed for design and fabrication of the PSI. The orientation of the virtual skull image is based on multiple factors: the neutral head position, the facial midline determined during clinical examination, and the Frankfort plane of the 3D cephalometry analysis. Virtual surgery was performed in the program and movements were determined based on the clinical findings. Outcome was verified and predicted with digital simulation.

In-house surgeon-designed PSIs and surgical guide

After completing the VSP, the PSIs and surgical guide were designed on the planned maxilla model by the surgeon-in-charge, using Materialise 3-matic 12.0 software (Materialise, Leuven, Belgium). The fixation screws were positioned to avoid any vital structures and tooth roots. The patient-specific fixation plate was designed to fit passively onto the surface of the virtual maxilla (Figs. 1a-c). By reverse engineering, the planned maxilla was registered back to its original position together with the fixation screws. A patient-specific surgical guide was then designed to incorporate the existing screw holes on the maxilla (Fig. 2a-c). The completed design was sent to printing with selective laser

melting (SLM) technology from Grade 2 pure titanium. Removal of supporting units and smoothening of the edges were performed. Lastly, the PSI and surgical guide were autoclaved and sterilised before the surgery.

Surgical Procedures

A standard exposure for the Le Fort I osteotomy was performed. After vestibular incision, the lateral wall of maxilla, infraorbital foramen, the pyriform aperture were exposed. The patient-specific titanium surgical guide was placed to ensure passive fitting and temporarily secured with titanium screws (Fig. 3a). The screw holes of the surgical guide were drilled, and the osteotomy at the anterior maxillary wall was marked. The guide was then removed.

Osteotomies at the lateral nasal wall, the lateral maxillary wall and the nasal septum were completed with osteotomes. Posterior separation was performed by tuberosity cut. The maxilla was down fractured and mobilized. Bone interferences were removed according to the surgical movement. The patient-specific titanium fixation plate was placed and secured with 6mm titanium screws using the pre-drilled screw holes (Fig. 3b). The positioning of the maxilla was cross-checked with the planned movement and its occlusal relation to the mandible.

After the Le Fort I osteotomy, other orthognathic procedures were performed where indicated. The wounds were closed in layers. Standard medications that include analgesics and antibiotics were prescribed.

Assessment of post-operative accuracy

Postoperative CBCT scans were taken 1 month after the surgery. The VSP was superimposed onto the postoperative CBCT model of the maxilla to assess the accuracy of the PSIs. The 3D models were first aligned in Proplan CMF by superimposing an area that was outside the surgically treated region - the frontal part of the skull. The models were then imported into Materialise 3-Matic and aligned again using global registration until the average distance error after 50 iterations was less than 0.01mm.

Four sets of measurements were made to evaluate accuracy: (1) The linear deviation between the planned and actual postoperative models of the skull along maxilla dental reference points (Fig. 4a); (2) the linear deviation along the x- (horizontal), y- (anteroposterior), z- (vertical) axis and xyz-axis; (3) the inter-canine and inter-molar distances of the planned movement and the actual post-operative models; (4) the angular deviations of the principal axes in terms of pitch, roll, and yaw between the planned and postoperative models. The pitch was measured as the angle between the Frankfurt plane and the occlusal plane; the roll as the angle between the horizontal line and occlusal plane; and the yaw as the angle between the mid-arch and mid-sagittal planes (Fig. 4b). The definitions of all the points, lines and principal axes used are listed in Table 1.

Table 1
Definition of reference point, lines and planes for measurement of linear and angular deviation.

Point	Definition
11i	The most inferior and mesial point of the incisal edge of maxillary left central incisor
21i	The most inferior and mesial point of the incisal edge of maxillary right central incisor
13	The cusp tip of the right maxillary canine
23	The cusp tip of the left maxillary canine
16	The mesio-buccal cusp tip of the right maxillary first molar
26	The mesio-buccal cusp tip of the left maxillary first molar
PorR	Superior margin of the right external acoustic meatus
PorL	Superior margin of the left external acoustic meatus
OrL	Most inferior point of the left orbital rim
Nas	Most anterior point of the frontonasal suture, at which it intersects with the internasal suture
Midpoint	Midpoint of most medial and inferior points of 11 and 21
Line	
Intermolar	Distance between points 16 and 26
Intercanine	Distance between points 13 and 23
Transverse	Line between PorL and PorR
Plane	
Frankfurt	Plane through PorL, PorR and OrL
Occlusal	Plane through 16, 26 and Midpoint
Mid-sagittal	Plane through Nas, normal to line Transverse
Mid-arch	Plane through Midpoint and normal to line Intermolar

Post-operative complications relating to PSIs

Post-operative complications of the PSIs that include infection or exposure of the PSIs, loosening of screws, or incidences that led to removal of the PSIs post-operatively were recorded at post-operative 6 weeks and 6 months.

Statistical Analysis

All statistical analyses were performed using the software SPSS version 25.0 (SPSS Inc., Chicago, IL, USA). Kolmogorov-Smirnov and Shapiro-Wilk test were used for normality test. Descriptive statistics were used to report the accuracy of the maxilla position in terms of translation and rotation. Absolute values were used for description and subsequent analyses. Mann-Whitney U Test was used to investigate the difference in deviation between one-piece Le Fort I and two-piece Le Fort I. Wilcoxon signed-rank tests were used in comparison between deviation in pitch, yaw and roll. A 5% probability level was taken as the cut-off for statistical significance. Adjustment of p-value with Bonferroni Test were done in multiple group comparisons to reduce the possibility of Type I errors.

Results

Twenty-five patients (12 females and 13 males) with a mean age of 26.4 years (SD 5.4 years, ranged 18–41 years) were recruited in the study. The majority of the patient presented with maxillary hypoplasia (80%) with or without maxillary canting. Sixteen patients had Le Fort I osteotomy in one piece and 9 patients received a two-piece Le Fort I osteotomy. The demographic information, diagnoses and treatment received are presented in (Table 2).

Table 2
Summary of demographic information of patients.

	% (n)
Gender	
Male	48 (12)
Female	52 (13)
Maxillary Diagnosis	
Maxillary hypoplasia	80% (20)
Maxillary Canting	32% (8)
Vertical maxillary excess	8% (2)
Dentoalveolar hyperplasia	4% (1)
Anterior open bite	4% (1)
Le Fort I Osteotomy	
1 piece	64% (16)
2-piece	36% (9)

Accuracy of the linear measurements

The absolute median deviation from planned position of maxilla were 0.74 mm on the x-axis, 0.75mm on the y-axis and 0.72 mm on the z-axis. The median translation deviation was 1.75 mm (xyz-axis). The mean deviation of the actual versus planned maxillary position at the x, y and z axes were 0.91mm (S.D. 0.72mm), 1.12mm (S.D. 1.09mm) and 1.08mm (S.D. 0.96mm), respectively. The absolute median deviation of inter-canine and inter-molar distance were 0.54 mm and 0.98 mm, respectively (Table 3). Boxplot of the absolute linear deviation at different landmarks of maxilla in terms of x-, y-, z- axes is shown in Fig. 5. Boxplots of the absolute linear deviation at different landmarks of maxilla, inter-canine and inter-molar distance are shown in Figs. 6 and 7.

Table 3. Overview of the absolute median linear and angular deviation of maxilla.

Maxillary position Landmark in the maxilla	Mean (S.D.) and median deviation (in mm)							
	x-axis		y-axis		z-axis		xyz-axis	
	Mean (S.D.)	Median	Mean (S.D.)	Median	Mean (S.D.)	Median	Mean (S.D.)	Median
11i	0.88 (0.13)	0.74	1.25 (0.22)	1.09	1.23 (0.23)	0.73	2.20 (0.28)	1.79
21i	0.78 (0.13)	0.66	1.07 (0.22)	0.87	1.20 (0.22)	0.96	2.00 (0.28)	1.72
13	0.96 (0.15)	0.80	1.07 (0.22)	0.75	1.18 (0.19)	0.71	2.11 (0.26)	2.26
23	0.96 (0.14)	0.73	1.14 (0.22)	0.83	1.01 (0.21)	0.64	2.09 (0.25)	1.70
16	1.06 (0.18)	0.86	1.03 (0.21)	0.54	0.91 (0.12)	0.78	2.01 (0.22)	1.71
26	0.81 (0.13)	0.63	1.17 (0.24)	0.69	0.98 (0.17)	0.78	2.09 (0.22)	1.96
Mean (S.D.)	0.91 (0.72)		1.12 (1.09)		1.08 (0.96)		2.08 (1.24)	
Median	0.74		0.75		0.72		1.75	
Lines (in mm)	Mean (S.D.) (in mm)				Median (in mm)			
Inter-canine distance	0.76 (0.14)				0.54			
Inter-molar distance	1.12 (0.16)				0.98			
Orientation	Mean (S.D.) (in degree)				Median (in degree)			
Pitch	3.03 (0.66)				1.40			
Yaw	1.12 (0.16)				0.90			
Roll	0.88 (0.16)				0.60			

* Kolmogorov-Smirnov and Shapiro-Wilk test were performed to evaluate the normal distributions of the data on the linear deviations. The median values and subsequent statistical analyses for skewed data were used.

Accuracy of the principal axes angles

The deviations of the principal axes between the post-operative maxilla models and the planned models were measured. The median deviation of the pitch, yaw and roll planes were 1.40°, 0.90° and 0.60°, respectively (Table 3). Wilcoxon signed-rank tests were used to investigate any differences between pitch, yaw and roll. Statistically significant differences were found between pitch versus yaw ($p = 0.01$), and pitch versus roll ($p = 0.001$) (Table 4). Boxplot was produced for absolute angular deviation from the planned position of the maxilla. (Fig. 7)

Table 4
Result of Wilcoxon
Signed-rank Tests
showing multiple
comparison between
pitch, yaw and roll.

Group	p-value
Pitch – Yaw	.010
Pitch – Roll	.001
Roll - Yaw	.193

Comparison between one-piece Le Fort I and two-piece Le Fort I

Mann-Whitney U tests were used to compare the difference in linear and angular deviation between one-piece and two-piece Le Fort I groups. No statistically significant difference was found in all landmarks, inter-canine, inter-molar distance, and principal axes. ($p > 0.05$) (Table 5).

Table 5
Result of Mann-Whitney U Tests
showing comparison between one-
piece and two-piece Le Fort I.

Parameter	p-value
11i	.657
21i	.506
13	.279
23	.222
16	.437
26	.096
inter-canine distance	.677
inter-molar distance	.560
Pitch	.890
Yaw	.597
Roll	.211

Post-operative complications

No cases were presented with infection or exposure of the PSIs, loosening of screws, or incidences that led to removal of the PSIs up to post-operative 6 months.

Discussion

This study aimed to evaluate the accuracy of in-house surgeon-design PSIs and cutting guides for wafer-less positioning of the maxilla in Le Fort I osteotomy. The key findings of this study were 1) the median deviations of the actual maxilla when compared to the planned position in the x, y and z axes, and the inter-canine and inter-molar lines were less than 1mm, which indicate an accurate positioning of the maxilla by the cutting guides and PSIs ; 2) the deviations of the principal axes in pitch, yaw and roll were 1.40°, 0.90° and 0.60°, respectively, with pitch significantly less accurate than the other two orientations; 3) there were no difference in accuracy of using PSIs in Le Fort I osteotomy in one-piece or two-piece; and 4) there were no post-operative complications of the PSIs for the Le Fort I osteotomy during the 6-months review period.

Traditional orthognathic surgery planning and execution relies on facebow transfer, stone model surgery, and laboratory-made wafers for positioning of the osteotomized jaws. The inevitable errors of manual record taking and transfer as well as the inadequacy of the articulator to simulate the mandibular movement have proved to be the causes of inaccurate surgical execution [6, 18]. The advancement in virtual planning is a significant breakthrough in orthognathic surgery as it allows surgeons to visualise the bony structure pre-operatively and to plan the surgical movement with precision. Combined with 3D printing, surgical wafers can now be constructed without the need of laboratory transfer of records, thus reducing the potential errors during the process [8]. However, these 3D-printed wafers still led to discrepancies from planned movement due to their reliance on the mandible for the fixation of the maxillary segment. [19]. Imperfect fitting of the surgical wafer to the occlusion, or the difference in the condyle position during the scanning process are also possible errors of a wafer-guided orthognathic surgery [20, 21].

In order to avoid the errors from using a surgical wafer, the concept of wafer-less orthognathic surgery has blossomed. Wafer-less surgery with PSI enables accurate placement of the maxilla independent of the condyle or mandible, and without the need for extraoral reference points. [22]. Several studies on commercial company-designed and fabricated PSIs have demonstrated great potentials. It was shown that these PSIs enabled precise positioning and fixation in maxillary osteotomy [13] with adequate strength and stability [23]. Furthermore, wafer-less PSIs improved the accuracy, predictability and surgical time of orthognathic surgery [24].

However, there are drawbacks of PSI made by commercial companies: 1) the high cost, 2) the long turnaround time that spans from 4 to 6 weeks; and 3) and the surgeon's lack of control in designing the implant. We discovered that by having our surgeons design the PSI in-house, the disadvantages of contracting commercial PSI can be overcome.

The accuracy of PSIs is one of the most important factors in determining their adoption. Accuracy is measured by comparing the difference between the planned model and the actual postoperative jaw position in linear and angular dimensions. In a systematic review on the accuracy of VSP in orthognathic surgery, it was agreed that linear deviations of less than 2 mm (xyz-axis) between the planned and actual post-operative models were considered acceptable. [24]. It was also stated in the review that the angular accuracy of pitch, yaw and roll of VSP were up to 2.75°, 1.7° and 1.1°, respectively [24]. Previous studies on the accuracy of commercial PSIs showed the difference between planned and actual models were around 1mm [12]. In this study, it is shown that in-house surgeon-designed PSIs could match commercial PSIs in terms of accuracy in the linear angulations. In addition, the deviations of the median angular measurements in pitch, roll and yaw were extremely low (0.6° – 1.4°); indicating the execution of the orthognathic planning was precise.

Another novel finding of this study was that there were no differences in accuracy of PSIs in one-piece or two-piece Le Fort I osteotomy. The cases that require multiple segmentation of Le Fort I (3 or 4 pieces) were not analysed as

these procedures are not common in many centres around the world. Moreover, multi-segmentation of Le Fort I may be better fixed with the use of a surgical wafer and customised arch bar, instead of the sole application of PSIs.

One major advantage of designing PSIs in-house is the time saved. In our centre, surgeons receive trainings to design PSIs. On average, a trained surgeon requires only 3 to 4 hours to conduct VSP and design the surgical guides and PSIs for a case. The designs are then sent out for printing, and the products are typically ready in 7 working days. This in-house process is significantly more time-efficient than outsourcing the PSIs to be designed and made. With less time required to prepare for surgery, patient waiting time for operation is shortened and a turnover of cases is higher. Another advantage of designing in-house is that the surgeons can implement specific design features into the PSIs and surgical guides according to their personal preferences. It is also particularly beneficial for junior surgeons to understand the challenges of a case through the planning and designing process.

Safety, as reflected in the incidence of surgical complications, is an important factor to consider when implementing a new treatment modality. Rückschloß et al. suggested that VSP using PSIs can help reduce the risk of post-operative complications such as nerve injury or damaged dental roots because surgeons are able to mark out these structures and plan for the depth of penetration into bone^[25]. In this study, there were no cases that presented with infection or exposure of the PSIs, loosening of screws, or incidences that led to removal of the PSIs in the early postoperative period. It proves that the in-house surgeon-designed PSIs are safe for use. An extended follow-up is required to observe if there are any long-term complications.

In conclusion, this study shows that in-house surgeon-designed 3D-printed PSIs for wafer-less Le Fort I osteotomy are accurate in the execution of VSP, with minimal discrepancies in all linear and angular measurements. The pitch is relatively less accurate when compared to the yaw and the roll. There were no complications observed in the early post-operative period. In-house surgeon-designed 3D-printed PSIs can be an alternative to commercial PSIs for wafer-less Le Fort I osteotomy as it shortens the preparation time of surgery, and potentially reduces the surgical cost of the patient or the institute.

Declarations

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AUTHOR CONTRIBUTIONS STATEMENTS

All authors responsible for design of study and acquisition of data. YYL, JKCL, ATCL, NEZT and KPYL analyzed data. JKCL, ATCL, NEZT and KPYL drafted the article. YYL, SWA, DTSL and YXS approved the final manuscript.

COMPETING INTERESTS STATEMENTS

The authors declare no conflicts of interest.

ETHICS DECLARATIONS

Ethical Approval: Ethic approval was granted by the local institutional review board (HKU/HA HKW IRB UW16-315).

Patient Consent: Written informed consent was obtained from all participants

OTHER INFORMATIONS

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DATA AVAILABILITY

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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Figures

Figure 1

(a-c). The patient-specific fixation plate was designed to fit passively onto the surface of the virtual maxilla

Figure 2

(a-c). The patient-specific surgical guide was then designed to incorporate the existing screw holes on the maxilla, and marked the amount of bone removal.

Figure 3

(a-b). 3a. The patient-specific titanium surgical guide was placed to ensure passive fitting and secured with titanium screws temporarily. The screw holes were then pre-drilled; 3b. After mobilization of the maxillary segment and removal of bony obstacles, the patient-specific titanium fixation plate was tried in and secured with 6mm titanium screws using the pre-drilled screw holes.

Figure 4

(a-b). 4a. Overlay of planned position (blue) and postoperative position (grey) and corresponding reference points; 4b. Overlay of planned position (white) and postoperative position (red) and various angular measurements.

Figure 5

Boxplot of the absolute linear deviation at different landmarks of maxilla in terms of x-, y-, z- axes.

Figure 6

Boxplot of the absolute deviation in inter-canine and inter-molar distance.

Figure 7

Boxplot of the absolute angular deviation from the planned position of the maxilla.