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Three dimensional assessment of segmented Le Fort I osteotomy planning and follow-up: A validation study

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ABSTRACT

Objectives: The planning accuracy and stability during follow-up of segmented Le Fort I osteotomy, often evaluated using 2D cephalometry and dental cast analysis, is controversial. The aim of this study is to develop and validate a 3D semi-automatic, voxel-based registration assessment protocol to evaluate planning accuracy and stability of segmented Le Fort I osteotomy with individualization of the maxillary segments.

Methods: Preoperative, immediate postoperative and six months postoperative CBCT images were used to evaluate accuracy and stability of the individual segments in 20 patients (13 female; 7 male) who underwent segmented Le Fort I osteotomy. Three translational (left/right, intrusion/extrusion, anterior/posterior) and three rotational (pitch, roll, yaw) dimensions were calculated for each maxillary segment by means of a user-friendly module. Inter- and intra-observer Inter Class Coefficient (ICC) and mean absolute difference (MAD) were calculated.

Results: The inter- and intra-observer reliability ICC varied between 0.93 and 0.99 for the translational and rotational accuracy and stability assessments, indicating excellent reliability. The MAD ranged between 0.21 mm and 0.32 mm for the translational error and between 0.6° and 0.9° for the rotational dimension.

Conclusions: The 3D assessment protocol for accuracy of segmented Le Fort I planning and short-term follow-up, proved to have high reliability with only a small margin of error.

Clinical significance: The proposed 3D assessment protocol allows future in-depth analysis of segmented Le Fort I osteotomy and might implicate future improvement where necessary.

1. Introduction

Segmented Le Fort I osteotomy is a surgical technique that allows correction of moderate transverse discrepancies in addition to vertical and sagittal dimensions. The outcome of this surgical technique, largely based on two dimensional (2D) cephalometry and dental cast model analysis, is contested [1,2]. Proffit et al. [3,4] valued transversal widening of the maxilla as one of the least stable surgical corrections.

Outcome of orthognathic surgery is determined by three consecutive phases [5]. Preoperative diagnosis of dentofacial deformity and surgical planning is crucial [6]. Next, transfer of the planning during surgery, most commonly performed by use of a surgical splint, as well as operative execution is paramount. Finally, postoperative relapse can occur due to muscle and soft tissue interference and as a result of occlusal instability [3,4]. To differentiate in which phase substandard outcome arises, evaluating surgical planning accuracy and long-term follow-up should be separately reported. This allows identifying the cause of poor outcome and improve the treatment planning.

The introduction of three dimensional (3D) technology in orthognathic surgery enabled new methods for evaluating planning accuracy and assessing stability [6–8]. Multiple authors have reported accuracy and stability of segmented Le Fort I osteotomy, often not differentiating the assessment method for segmented and non-segmented Le Fort I osteotomy [5,9–13]. Furthermore, registration-free 3D cephalometry or landmark based registration was frequently applied introducing human error in the reported outcome. Baan et al. [14]. eliminated the necessity for placing landmarks by automatically computing the six degrees of freedom (three translational and three rotational variables) of jaw

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movements using procrustes calculation on the transformation matrices. Shaheen et al. [15] relied on Singular Value Decomposition (SVD) algorithm to analyse the transformation matrices and calculate the translational and rotational changes. Procrustes and SVD are two alternative mathematical shape analyses allowing comparison of two objects. These complex algorithms translate the difference in planned and achieved jaw segments into clinically interpretable translational and rotational values.

Three-D analysis could in particular benefit complex maxillary movements such as segmented Le Fort I osteotomy [16]. Few authors described 3D assessment tools for non-segmented Le Fort I osteotomy [14,17–20]. The applied methodology varied widely according to the systematic review of Gaber et al. [21], therefore, the authors proposed a universal evaluation protocol based on three principles. First, voxel-based registration of the non-operated skull as it is considered the most accurate registration procedure [22]. Second, automated or semi-automated generation of outcome in six degrees of freedom. Third, inter- and intra-reliability tests are urged to demonstrate the validity of the applied 3D method. Following these principles and adapting them to segmented Le Fort I osteotomy, evaluating the individual maxillary segments will provide further insight into the accuracy and stability of segmented Le Fort I osteotomy. To the best of our knowledge, no previous study proposed an assessment 3D registration based protocol that allows evaluating accuracy and stability of the individual maxillary segments following segmented Le Fort I osteotomy

The aim of this study was to develop and validate a 3D semi-automatic, voxel-based registration assessment tool to evaluate planning accuracy and stability of segmented Le Fort I osteotomy with individualization of the maxillary segments.

2. Material and methods

2.1. Patient selection

This study was performed in consent with the World Medical Association Declaration of Helsinki on medical research and the local Ethical Review Board approved this study (B322201526790). The number of included patients was determined following a priori sample size analysis (*GPower 3*.1) based on similar validation studies [14,15,23]. Power analysis calculated that a sample size of minimum 19 patients would give an 80% probability of identifying a significant inter- or intra-observer difference at a statistically significant level of 5%. Therefore, twenty random patients who underwent segmented Le Fort I osteotomy were selected from LORTHOG database. The inclusion criteria involved patients undergoing a 2-piece or 3-piece Le Fort I osteotomy with access to preoperative, immediate postoperative (1–6 weeks after surgery) and 6 months postoperative Cone-Beam Computed Tomography (CBCT; Newtom VGi-evo, Verona, Italy) images. Exclusion criteria consisted of cleft and syndromic patients and a history of maxillofacial trauma.

2.2. Virtual planning protocol

Proplan software (Materialise, Leuven, Belgium) was used to perform digital 3D surgery planning. Composite models of the maxilla and mandible were created based on digital dental models made with 3D intraoral scanner (3Shape A/S, Copenhagen, Denmark) and CBCT Digital imaging and Communications in Medicine (DICOM) images. Next, the surgical movements of the maxilla and mandible were planned followed by the creation of intermediate and final splints as described by Shaheen et al. [24,25].

2.3. Surgical technique

All orthognathic osteotomies were performed by the same surgical team. Surgical indications of the included patients were dual-plane maxilla with anterior open bite, severe proclination of the maxillary incisors and/or transversal maxillary hypoplasia up to 6–7 mm. The surgical procedure consisted of maxillary segmented Le Fort I osteotomy with midline split or segmented 3-piece osteotomy, as described by Meewis et al. [16].. In case of a 3-piece Le Fort I osteotomy, the interdental osteotomy was performed either distal to the lateral incisor or to the canine depending on the patient's specific requirements. Iliac crest bone graft was applied between the maxillary segments. A transpalatal arch was placed perioperatively to stabilize the transversal widening. The maxilla was fixed with four L-shaped miniplates and monocortical screws (KLS Martin, Tuttlingen, Germany).

2.4. Assessment protocol

Two user-friendly tools were developed using Amira software (Thermo Fischer Scientific, Merignac, France). The first protocol allowed determination of the accuracy of the individual maxillary segments following segmented Le Fort I osteotomy by comparing the immediate postoperative scan with the preoperative virtual planning. The second protocol examined postoperative stability by comparing the immediate postoperative CBCT imaging with the six months postoperative scan. These assessment protocols are partially based on the proposed assessment tool for one-piece Le Fort I osteotomy as described by Shaheen et al. [15].. The main difference is the separate registration of the different maxillary segments allowing in-depth analysis of planning accuracy and stability of segmented Le Fort I osteotomy. In the following section, the accuracy and stability assessment protocol are described in more detail.

2.5. Accuracy assessment protocol

Step 1: Registration of cranial base

The preoperative and immediate postoperative DICOM images were imported into the tool. Voxel-based registration (VBR) of the non-operated cranial base was performed [15].

Step 2: Registration of the maxillary segments

The individual maxillary segments are outlined both on the

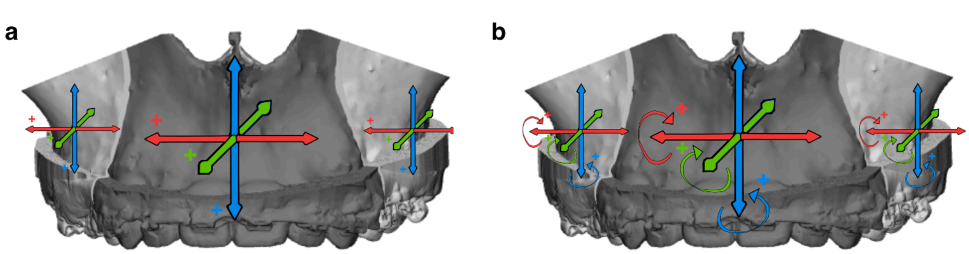

Fig. 1. Interpretation of outcome measurements.
Fig. 1A depicts the interpretation of translational outcome for the individual maxillary segments. The red arrow depicts the left/right movement, the green arrow shows the anteroposterior movement and the blue arrow constitutes the intrusion/extrusion movement. Fig. 1B depicts the rotational displacements. The green arrow constitutes the roll movements with a positive outcome in case of left-inferior displacement of the maxillary segment. The red arrow depicts the pitch movement with a positive value for postero-inferior displacements. The blue arrow depicts the yaw movements with a positive value in case of a postero-left rotation.

Table 1
Planned surgical movements of each maxillary segment.

		Planned maxillary movement					
		Translational (mm ± SD)			Rotational (°± SD)		
		L/R	A/P	I/E	Pitch	Roll	Yaw
2-piece	**Left Segment**	−1.44 (1.14)	3.26 (1.82)	0.98 (2.22)	1.60 (6.34)	−5.35 (3.53)	−4.50 (3.74)
	Right Segment	1.54 (1.10)	2.54 (1.81)	0.21 (1.71)	4.21 (3.88)	−2.97 (2.90)	3.27 (4.24)
3-piece	**Middle Segment**	0.45 (1.14)	2.32 (0.81)	−1.79 (3.98)	5.08 (7.51)	−0.80 (3.30)	0.55 (4.00)
	Left Segment	0.02 (1.46)	2.68 (2.03)	−2.88 (3.51)	3.00 (6.64)	−8.63 (7.94)	−0.40 (5.42)
	Right Segment	0.52 (1.29)	2.24 (2.37)	−3.71 (3.17)	4.76 (6.53)	−8.08 (5.07)	−1.52 (4.01)

Table 1. Planned maxillary movements for each maxillary segments are represented in terms of mean and SD are illustrated. A/P, anterior/posterior; I/E, intrusion/extrusion; L/R, left/right; SD, standard deviation.

preoperative and postoperative 3D scans and matched using VBR. The output of the matching is a transformation matrix (TM1) for each maxillary segment. In case of a 2-piece Le Fort I osteotomy, the left and right maxillae are individually defined according to the surgical split and 2 transformation matrices are resulted. In case of a 3-piece Le Fort I osteotomy, left, right and central maxillary pieces are defined taking into account the location of the interdental osteotomies and 3 transformation matrices are calculated.

Step 3: Calculation of translational and rotational changes

STL-files containing the individual maxillary segments representing their preoperative position created during the preoperative 3D virtual planning were imported. Each STL maxillary segment was repositioned according to the corresponding TM1 to the achieved position and exported as STL-file. Then the STL of the planned maxillary segment was imported and automatically matched to the corresponding STL maxillary achieved segment producing a new transformation matrix (TM2). TM2 was then used to calculate the translational and rotational movements in six degrees of freedom using Singular Value Decomposition (SVD) algorithm [24]. This step was repeated for each individual maxillary segment that was treated as an object producing six measurements per maxillary segment avoiding landmarking errors. The six clinical outcome measurements were interpreted as: left/right (L/R), anterior/posterior (A/P) and intrusion/extrusion (I/E) for translational changes and pitch, roll and yaw for rotational changes. Fig. 1 depicts the interpretation of the outcome measurements.

2.6. Stability assessment

The stability protocol is largely similar to the accuracy assessment. The initial cranial base and maxillary segment registration as described in step 1 and step 2 of the accuracy protocol is performed by superimposing the immediate postoperative CBCT and six month postoperative CBCT. In step 3, only the achieved maxillary STL segment is imported and repositioned according to TM1 to the achieved six month postoperative maxillary position then exported as STL-file. TM1 was used to calculate the translational and rotational changes representing the 6 months stability of the individual maxillary segments.

2.7. Statistics

Twenty patients were assessed independently by two observers (first and second author). One author repeated the examination with a washout period of two weeks. This permitted calculation of inter-and intra-observer reliability by means Intra-Class Correlation Coefficient (ICC) using SPSS (IBM SPSS statistics 27). The following interpretation of ICC values was applied: <0.50 = poor reliability, 0.50–0.75 = moderate reliability, 0.75–0.90 = good reliability, >0.90 = excellent reliability [26]. Wilcoxon signed rank test compared the paired results of the two observers, P-value < 0.05 is considered statistically significant. Mean difference and mean absolute difference of the translational (A/P, I/E, L/R) and rotational (pitch, roll, yaw) movements were determined for each maxillary segment. Relative error was calculated for accuracy and stability measurements relative to the planned and achieved movements respectively.

3. Results

Twenty patients consisting of ten 2-piece cases and ten 3-piece Le Fort I osteotomy cases were included in the study following inclusion/exclusion criteria. Thirteen females and seven males with mean age of 29 years were included. Bimaxillary surgery (Le Fort I osteotomy and Bilateral Sagittal Split Osteotomy (BSSO)) was performed in fourteen patients, six patients underwent mono-maxillary surgery. Mean planned maxillary advancement was 2.32 mm in the segmented patients. In three 2-piece Le Fort I patients intrusion and in five patients extrusion was planned. In five 3-piece Le Fort I patients intrusion and in 3 patients maxillary extrusion was planned. Mean planned pitch of each maxillary segment was clockwise rotated and varied between 1.6° and 5.1°. Table 1 illustrates the planned maxillary movements of the individual maxillary segments. Table 2 describes the inter- and intra-reliability of the planning accuracy and stability assessment protocols. The translational and rotational movements at a 95% confidence interval are described. For the accuracy assessment, excellent inter and intra-observer ICC was found for translational (0.99) and rotational (0.96) calculations. The intra-observer translational and rotational mean absolute differences (MAD) were 0.22 mm and 0.9° respectively. Inter-observer MAD was 0.30 mm for translational and 0.9° for rotational movements. The translational dimension of the stability protocol found an ICC of 0.94 for both inter- and intra-observer groups. Rotational ICC was 0.93 for the intra- and inter-observer reliabilities. Wilcoxon signed rank test determined that the results of the two observers was not statistically significantly different for both assessment protocols: accuracy

Table 2
Inter-and intra-observer interclass correlation coefficient and mean absolute difference.

	Reliability accuracy assessment				Reliability stability assessment			
	Translational (mm)		Rotational (°)		Translational (mm)		Rotational (°)	
	ICC	MAD (SD)	ICC	MAD (SD)	ICC	MAD (SD)	ICC	MAD (SD)
Intra-observer	0.993	0.219 (0.27)	0.955	0.926 (1.19)	0.937	0.321 (0.46)	0.934	0.982 (0.98)
Inter-observer	0.990	0.299 (0.290)	0.962	0.883 (1.07)	0.945	0.246 (0.25)	0.930	0.679 (0.61)

Table 2. Inter- and intra-observer interclass correlation coefficient (ICC) results with mean absolute difference (MAD) and standard deviation (SD). The reliability is separately reported for the accuracy and stability assessment.

Table 3
Accuracy and stability assessment of 2-piece Le Fort I osteotomy.

		Accuracy assessment						Stability assessment					
		Translational (mm)			Rotational (°)			Translational (mm)			Rotational (°)		
		L/R	A/P	I/E	Pitch	Roll	Yaw	L/R	A/P	I/E	Pitch	Roll	Yaw
Left segment	**Mean (SD)**	1.32 (1.43)	0.24 (1.21)	−1.40 (1.28)	−1.64 (5.39)	−2.44 (6.40)	−1.43 (3.80)	−0.09 (0.37)	−0.16 (0.53)	0.05 (0.55)	−0.89 (1.81)	0.27 (1.98)	−0.35 (1.11)
	Absolute mean (SD)	1.32 (1.43)	1.04 (0.57)	1.56 (1.05)	4.30 (3.397)	5.78 (3.24)	2.99 (2.60)	0.31 (0.20)	0.40 (0.37)	0.37 (0.39)	1.45 (1.35)	1.63 (1.02)	0.89 (0.70)
	Relative Error	0.90	0.32	0.84	0.80	1.08	0.64	0.28	0.11	0.24	0.20	0.17	0.14
Right segment	**Mean (SD)**	0.38 (0.89)	0.62 (1.49)	−1.16 (1.22)	0.16 (4.12)	2.47 (3.10)	1.99 (1.86)	−0.13 (0.78)	0.32 (0.70)	0.03 (0.66)	0.05 (2.01)	1.00 (2.87)	−0.70 (1.72)
	Absolute mean (SD)	0.70 (0.643)	1.20 (1.00)	1.30 (1.05)	3.36 (2.10)	3.05 (2.46)	2.17 (1.62)	0.65 (0.39)	0.56 (0.51)	0.49 (0.41)	1.29 (1.47)	1.92 (2.29)	1.16 (1.42)
	Relative Error	0.45	0.44	0.91	0.73	1.01	0.46	0.34	0.18	0.29	0.23	0.70	0.17

Table 3. Results of accuracy and stability assessment of ten 2-piece segmented Le Fort I osteotomy patients. The six degrees of freedom are described for the left and right maxillary segment. Mean absolute error in accuracy error and relapse in follow-up relative to surgically planned movements is shown. A/P, anterior/posterior; I/E, intrusion/extrusion; L/R, left/right; SD, standard deviation.

(translational $P = 0.253$; rotational $P = 0.288$) and stability (translational $P = 0.232$; rotational $P = 0.521$).

The planning accuracy and stability outcome for the six dimensions of the 20 segmented Le Fort I patients as determined by the first observer are depicted in Tables 3 and 4. In 2-piece Le Fort I patients perioperative intrusion/extrusion inaccuracy was the largest translational error with the absolute mean varying between 1.6 and 1.3 mm. In 3-piece patients, the largest surgical error was found in the antero-posterior dimension for the individual maxillary segments (absolute mean between 2.1 mm and 2.6 mm). Mean absolute accuracy error relative to planned movement ranged between 0.2 and 2.2 for translational movements and between 0.5 and 1.1 for rotational movements. The largest error during follow-up was observed for the middle segment with an absolute mean error of 1.4 mm for the intrusion/extrusion dimension and 3.9° for pitch .

4. Discussion

In this study, a 3D semi-automatic, voxel-based registration assessment tool was developed and validated to evaluate outcome of segmented Le Fort I osteotomy. The proposed tool allowed evaluating accuracy of segmented Le Fort I planning and stability and proved to have excellent reliability with only a small margin of error. This study reports a mean ICC ranging from 0.93 to 0.99 for translational and rotational movements. Similar high ICC values have been reported for non-segmented Le Fort I osteotomy indicating solid reliability [14,15,27]. Baan et al. [14]. used voxel-based registration of the cranial base and superimposition of the segmented maxilla and mandible in bimaxillary operated patients. Procrustes shape analysis was performed to calculate translational and rotational accuracy between planned and achieved surgical outcome. Intra- and interobserver ICC of the maxillary measurements were >0.97 indicating excellent reliability for one-piece Le Fort I accuracy assessment. Zinser et al. [27]. described a landmark-based comparison of pre- and postoperative non-segmented Le Fort I osteotomy patients. Hard and soft tissue landmarks and lines were measured twice by two observers reporting a high intra- and interobserver reliability of respectively 0.91 and 0.92. The mean absolute inter- and intra-observer measurement difference of the maxillary segments in this study was less than 0.33 mm for translational errors and less than 1° for rotational errors indicating a reliable assessment protocol and comparable to similar research for one piece Le Fort1 [14,15]. The reliability was comparable for accuracy and stability assessment. In this study, both mean and mean absolute differences were reported. Positive and negative values cancel each other when calculating the mean, however, it is a useful measurement to describe the direction of the error of planning inaccuracies and postoperative relapse. While the mean absolute difference is more meaningful to represent the magnitude of error as shown in the results.

Previous studies reporting outcome of segmented Le Fort I osteotomy used highly variable assessment methods. A distinction is made between registration-free, usually using 3D cephalometry, and registration-based 3D assessment. The literature describes three different types of registration-based evaluation, namely land-mark based, surface-based and voxel-based registration, with the latter generally considered the most accurate method of registration [21,28,29]. De Riu et al. [10] described the rate of alignment of the planned versus achieved correction of facial asymmetry based on cephalometric values in segmented Le Fort I osteotomy patients, without reporting the reliability of the applied assessment. Stokbro et al. [20] applied surface-based registration of the non-operated midface to determine translational and rotational accuracy of segmented Le Fort I osteotomy and Tankersley et al. [30] and Kwon et al. [13] used voxel-based. Kwon et al. [13] applied voxel-based registration of the non-operated cranial base followed by comparing planned and postoperative segmented Le Fort I landmarks according to x,y,z-axis. The intra-observer variability was calculated on seven randomly-selected patients. The method error as standard error ranged

Table 4
Accuracy and stability assessment of 3-piece Le Fort I osteotomy.

		Accuracy assessment						Stability assessment					
		Translational (mm)			Rotational (°)			Translational (mm)			Rotational (°)		
		L/R	A/P	I/E	Pitch	Roll	Yaw	L/R	A/P	I/E	Pitch	Roll	Yaw
Middle Segment	**Mean (SD)**	0.95 (2.82)	−1.89 (4.34)	0.50 (1.16)	−0.57 (6.60)	−0.10 (2.84)	−0.23 (4.11)	0.10 (0.85)	1.23 (1.03)	−0.83 (1.78)	3.57 (3.28)	0.45 (2.14)	−0.23 (1.50)
	Absolute mean (SD)	1.43 (2.59)	2.24 (4.10)	0.99 (0.74)	5.03 (4.02)	2.19 (1.67)	2.48 (3.19)	0.63 (0.55)	1.30 (0.92)	1.41 (1.32)	3.86 (2.90)	1.46 (1.58)	1.14 (0.86)
	Relative Error	2.09	1.06	0.40	0.78	0.93	0.86	0.39	0.49	0.59	0.43	0.36	0.39
Left segment	**Mean (SD)**	1.14 (4.06)	−1.79 (5.81)	0.20 (1.65)	0.53 (5.02)	−3.48 (5.81)	−0.10 (3.52)	−0.19 (0.62)	0.05 (0.59)	−0.21 (0.73)	−0.72 (1.99)	−0.45 (2.10)	−0.33 (0.90)
	Absolute mean (SD)	2.07 (3.63)	2.59 (5.47)	1.05 (1.25)	3.93 (2.91)	5.15 (4.22)	2.12 (2.73)	0.48 (0.41)	0.45 (0.36)	0.56 (0.50)	1.75 (1.06)	1.30 (1.66)	0.73 (0.59)
	Relative Error	2.15	1.04	0.35	0.75	0.66	0.59	0.24	0.12	0.22	0.21	0.11	0.13
Right segment	**Mean (SD)**	1.38 (4.09)	−1.26 (3.65)	0.44 (1.22)	1.99 (5.23)	4.95 (5.22)	0.22 (3.2)	0.22 (0.67)	0.56 (1.65)	−0.81 (1.39)	0.81 (3.94)	1.24 (2.37)	−0.10 (1.56)
	Absolute mean (SD)	2.14 (3.71)	2.08 (3.21)	0.84 (0.96)	4.15 (3.57)	5.92 (3.96)	2.58 (1.72)	0.53 (0.44)	1.05 (1.36)	1.06 (1.19)	2.63 (2.94)	1.55 (2.16)	1.12 (1.04)
	Relative Error	2.00	0.81	0.22	0.73	0.77	0.87	0.27	0.41	0.32	0.29	0.50	0.26

Table 4. Results of accuracy and stability assessment of ten 3-piece segmented Le Fort I osteotomy patients. The six degrees of freedom are described for the middle, left and right maxillary segment. Mean absolute error in accuracy error and relapse in follow-up relative to surgically planned movements is shown. A/P, anterior/posterior; I/E, intrusion/extrusion; L/R, left/right; SD, standard deviation.

from 0.58 to 0.92 mm and was not statistically significant, indicating a reliable assessment method. None of the aforementioned studies clearly reported how the results were obtained, i.e. (semi-) automated. Bengtsson et al. [5,31] reported outcome of 2D and 3D surgical planning, including segmented Le Fort I, after matching the planned maxillary movement with 3D imaging acquired one year postoperatively. This time interval allows a global overview of the obtained outcome but prevents analysis of the timing and origin of inaccuracies and thus impedes improvement proposals. The authors of current study give preference separating evaluation of accuracy with the use of immediate postoperative radiography and investigation of long-term stability.

The largest translational surgical inaccuracies were found in the intrusion/extrusion dimension (absolute mean 1.3–1.6 mm) for 2-piece and in the anteroposterior dimension (absolute mean 2.1–2.6 mm) for 3-piece Le Fort I osteotomies. Translational errors greater than 2 mm require postoperative orthodontic correction and thus are considered clinically significant [32]. The error relative to the planned movements were largest in left/right dimensions (0.4 – 2.2). This can be explained by the relative small planned movements in this direction. Kwon et al. [13]. reported an absolute mean difference of 1.16 mm antero-posteriorly and 1.23 mm vertically. In our study, intrusion/extrusion (1.4 mm) and pitch (3.9°) of the middle maxillary segment were the least stable during follow-up. Future research with a larger patient population are recommended to further explore these inaccuracies.

This study applied voxel-based registration of the non-operated skull base and midface. The preoperative CBCT is merged with the intra-oral scan to further augment the resolution of the 3D reconstruction of the dentition. The semi-automated generation of results largely prevented human error. The individualization of the maxillary segments allows detailed analysis of planning accuracy and stability. The superimposition of the maxillary segments includes the maxillary bone and thus minimizes the influence of postoperative orthodontic treatment on the evaluation of skeletal relapse. Implementation of the proposed assessment tool on a larger cohort study might be able to uncover more precisely if and where inadequate outcome occurs. A systematic error can then be attempted to be resolved as was proposed by Stokbro et al. [20] when an underachievement of 1.5 mm transverse expansion was uncovered. It was suggested that planning of an overexpansion of 1.5 mm might resolve this issue. Alternative solutions might comprise of bone graft application, the use of patient-specific plates or performing augmented-reality surgery.

One limitation of this study was the need for Cone-beam CT radiography which inevitably entails radiation exposure. A study by Stratis et al. [33] reported that CBCT radiography in case of orthognathic patients involves less radiation exposure in comparison to multi-detector CT and is therefore dose-wise justified. The stability evaluation in current study was based on CBCT imaging six months postoperatively. Stability of more than six months following surgery was not evaluated in this study but is expected to be equally reliable as Shujaat et al. [23] proved the reliability of maxillary voxel-based dento-alveolar registration for long term follow-up. The proposed assessment tool was not tested against alternative 3D measurement tools in current study to compare reliability of measurement protocols. The outcome of segmented Le Fort I osteotomy based on the proposed assessment tool was not the subject of current study and is therefore only briefly discussed. The focus of the current study was to validate the 3D assessment tool, hence a sample size of twenty patients was sufficient according to a priori sample size analysis based on similar 3D validation studies [14,15,23]. Future research with a larger study population is necessary to draw clinical conclusions regarding accuracy and stability of segmented Le Fort I osteotomy taking into account the planned maxillary movements.

Conclusion

The aim of this study was to develop and validate a 3D semi-automatic, voxel-based registration assessment tool, to evaluate the outcome of segmented Le Fort I osteotomy for both planning accuracy and long term follow-up. High reliability of the assessment tool regarding planning accuracy and stability of the individualized maxillary segments was reported, allowing future in-depth analysis of this surgical technique and propose improvements where necessary.

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CRediT authorship contribution statement

Oliver da Costa Senior: Conceptualization, Validation, Formal analysis, Writing – original draft. **Lukas Vaes:** Validation, Writing – original draft. **Delphine Mulier:** Writing – original draft, Visualization. **Reinhilde Jacobs:** Writing – review & editing, Supervision, Resources. **Constantinus Politis:** Writing – review & editing, Supervision, Resources. **Eman Shaheen:** Conceptualization, Methodology, Software, Writing – review & editing, Supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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