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Research Paper
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Three-dimensional planning accuracy and follow-up protocol in orthognathic surgery: a validation study

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Abstract. The purpose of the study was to propose and validate a three-dimensional (3D) tool for the assessment of orthognathic surgery planning accuracy and postoperative follow-up. A total of 15 patients (four male, 11 female; mean age 29.6 years) with skeletal class II and III, who underwent bimaxillary surgery were recruited for the study. All patients had preoperative computed tomography (CT), and cone-beam computerized tomography (CBCT) scans 1–6 weeks and 6 months postoperatively. The data was exported to a customized stepwise module developed in Amira software resulting in the accuracy being presented as translational and rotational differences between the planning and the actual outcome. To evaluate the reliability of the proposed method, intra-class correlation coefficient (ICC) was applied at a 95% confidence interval on the translational and rotational output of two observers. The inter- and intra-observer reliability were found to be high (ICC range: 0.94–0.98) with mean variability of less than 0.4mm and 0.7° for translational and rotational movements for both planning accuracy and follow-up protocols. The study provides a reliable, quantitative and time-efficient method for evaluating the accuracy of virtual surgical planning and postoperative follow-up.

Key words: virtual surgical planning; orthognathic surgery; follow-up; surgical accuracy.

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Recent advances in three-dimensional (3D) technology and rapid prototyping (RP) have led to the development of objective techniques for diagnosing, treatment planning, predicting outcomes and follow-up of orthognathic surgery patients[1,2]. This has improved the understanding of the complex 3D anatomy of the dental and craniofacial region.

Three-dimensional simulation to predict the post-surgical outcome plays a vital role in improving the actual surgical outcome and, in addition, in improving patients' quality of life by achieving suitable aesthetics and functional results[3]. Therefore, it is essential to compare the accuracy of virtual to real surgical outcome so that any undesirable results can be addressed objectively. The most important step in predicting the accuracy of post-surgical outcome is interrelated to the registration and alignment of the pre- and postoperative computed tomography (CT)/cone beam computer tomography (CBCT) scans[4].

Various methods have been proposed in the literature for comparing the accuracy of the virtual 3D planning to the actual surgical procedure[2,4–6]. These methods can be categorized into cephalometry based or registration based. The central demerits of those suggested methods have been the human error related to cephalometric landmark placement[7], time inefficiency or the usage of multiple software for assessing the accuracy of surgical planning in orthognathic surgery[4].

Currently three accepted registration methods exist in the literature: landmark based registration (LBR)[8], surface-based registration (SBR)[9] and voxel-based registration (VBR)[10]. LBR involves a higher degree of human error relying on identification of landmarks and inter-observer variations,[7] whereas surface-based registration (SBR) is dependent on the accuracy of 3D scanned models and the quality of the segmentation from CT/CBCT scans[11]. VBR is a technique by which pre- and postoperative CT/CBCT scans of patients can be superimposed automatically based on the volumetric similarities between the two scans[10]. Hence, VBR is considered the gold standard for registration as it is regarded the least variable method[12,13].

Gaber et al.[14] recommended a protocol for the 3D postoperative accuracy evaluation based on their systematic review. The protocol consisted of applying VBR on the anterior cranial base for aligning and registering the two scans, hence eliminating human error related to landmark identification and placement, followed by an automated or semi-automated evaluation with translational or rotational assessment. They insisted on validating the protocol via inter- and intra-observer reliability tests.

Baan et al.[5] suggested the application of a software, OrthoGnathicAnalyser, for the translational and rotational assessment, whereas the remainder of the steps in the protocol were carried out by an additional software, Maxilim (Medicim NV, Mechelan, Belgium). Stokbro and Thygesen[4] suggested the application of two free open-source software and the protocol was time consuming as suggested by the authors.

Recent methods applied in orthognathic surgery are more focused towards the planning aspect and no 3D protocol exists for objective quantification of long-term postoperative follow-up. Relapse studies have either been based on 2D or 3D cephalometry[15,16] carrying the risk of human error. Literature lacks evidence on the availability of a time-efficient and a solely software-based protocol for analysing the 3D movements in orthognathic surgery.

Therefore, the aims of this paper were to propose and validate a cephalometric-free semi-automatic 3D tool and protocol to compare the 3D virtual planning with the actual surgery outcome and assessment of postoperative follow-up after orthognathic surgery.

Materials and methods

Ethical Approval

This study was conducted in compliance with the World Medical Association Declaration of Helsinki on medical research. Ethical approval was obtained from the Ethical Review Board of the University Hospitals Leuven (reference number: S57587). Informed consent was not required for this retrospective study as patient-specific information was kept anonymous.

Patients and radiographic examination

Fifteen patients (four male, 11 female, mean age 29.6 years) with skeletal class II and III, who underwent orthodontic treatment and bimaxillary surgery (Le Fort I and bilateral sagittal split osteotomy (BSSO)) without genioplasty during the period 2015–2016, were recruited from the Department of Oral and Maxillofacial Surgery, University Hospitals Leuven, Leuven, Belgium. The inclusion criteria included patients within the age range of 18–55 years, accessibility to patients' preoperative, immediately postoperative (1–6 weeks) and 6 months postoperative CT/CBCT scans and presence of virtual surgical planning used for the fabrication of 3D-printed intermediate wafers. Exclusion criteria were previous history of oral and maxillofacial surgical intervention, presence of craniofacial anomalies such as cleft lip and/or palate, craniosynostosis, hemifacial microsomia and other syndromic diseases.

The study included a total of 45 scans (15 preoperative CT scans, 15 CBCT scans at 1–6 weeks postoperative, and 15 CBCT scans at 6 months postoperative). The details of the systems used are shown in Table 1 including one CT system and two different CBCT systems (16 scans with CBCT1 and 14 scans with CBCT2). All scans were carried out using a standardized protocol (Table 1) as described by Stratis et al.[17].

Virtual 3D planning protocol

Virtual 3D planning was performed in PROPLAN software (Materialise, Leuven, Belgium). The preoperative CT patient Digital Imaging and Communications in Medicine (DICOM) images were imported into the software where composite models of maxilla and mandible were created. The movements of the maxilla defined by the surgeon were planned to create the intermediate splint while the final splint was fabricated as described by Shaheen et al.[18]. The composite models of the maxilla in original and final positions were exported as stereolithography (STL) files to be used in the accuracy-assessment protocol.

Surgical Technique

All bimaxillary surgeries were executed by the same surgical team. Surgical procedure involved maxillary Le Fort I osteotomy[19] followed by Hunsuck/Epker modification of BSSO[20,21]. Maxilla was fixed with two L-shaped miniplates and monocortical screws on each side. In addition, BSSO fixation was carried out using two miniplates and monocortical screws transorally for each split[22].

Postoperative Assessment Protocols

Two semi-automatic protocols were developed in Amira software (version 6.3.0, Thermo Fischer Scientific, Merignac, France) in a user-friendly wizard module instructing the user at every step. The first protocol was designed for accuracy assessment of the maxilla after bimaxillary surgery by comparing the immediate postoperative scan to the preoperative virtual planning. The second protocol was intended for following up the patient 6 months, 1 year and 2 years postoperatively. The steps and details of the accuracy assessment protocol and the follow-up protocol, explained with the 6 months postoperative data, are described in the following subsections.

Accuracy assessment protocol

Step 1: Import DICOM images. The user imported the preoperative and immediate postoperative DICOM images into the module.

Step 2: Cranial base registration. The postoperative images were registered onto the preoperative anterior cranial base using rigid VBR with mutual information[23–25] as shown in Fig. 1.

Table 1. Acquisition settings for the computed tomography/cone beam computed tomography systems used.

	CT	CBCT 1	CBCT 2
System	Siemens Somatom Definition Flash	Planmeca Promax 3D Max	Newtom VGi-evo
System's origin	Siemens AG, Erlangen, Germany	Planmeca, Helsinki, Finland	Newtom, Verona, Italy
Total mAs	855	216	15.3
Potential (kV)	120	96	110
Slice thickness (mm)	0.75	0.6	0.3
Field of view (mm^2)	–	230 × 260	240 × 190

CBCT, cone beam computer tomography; CT, computed tomography.

Step 3: Registration of the maxillary segments. To overcome the human error associated with cephalometric landmarking, the preoperative maxillary segment was registered to the postoperative maxillary segment[5]. Maxillary segments were manually outlined on the registered postoperative model avoiding the inclusion of the titanium plates, followed by the selection of the same area in the preoperative model. The selection area from the two parts did not have to be identical as the VBR algorithm overcame this limitation (Fig. 2). The transformation matrix (TM1) acquired after the registration was used in the next step.

Step 4: Calculation of 3D translational and rotational displacements. The STL of the virtually planned maxillary segment and the preoperative maxillary segment were imported into the module (both segments were identical except for the position). The transformation matrix (TM1) obtained in the previous step was applied to the preoperative maxillary STL to reposition it to the actual achieved position.

Three landmarks were placed on the occlusal surface to construct the occlusal plane of the planned maxillary segment (midpoint of the incisal edge and mesiobuccal cusps of the first molars left and right). These landmarks represented the orientation of the maxilla in 3D coordinates. The planned maxillary segment was then superimposed on the postoperative achieved maxillary segment using SBR to obtain a new transformation matrix (TM2). This TM2 was applied on the three landmarks to reposition them to the achieved

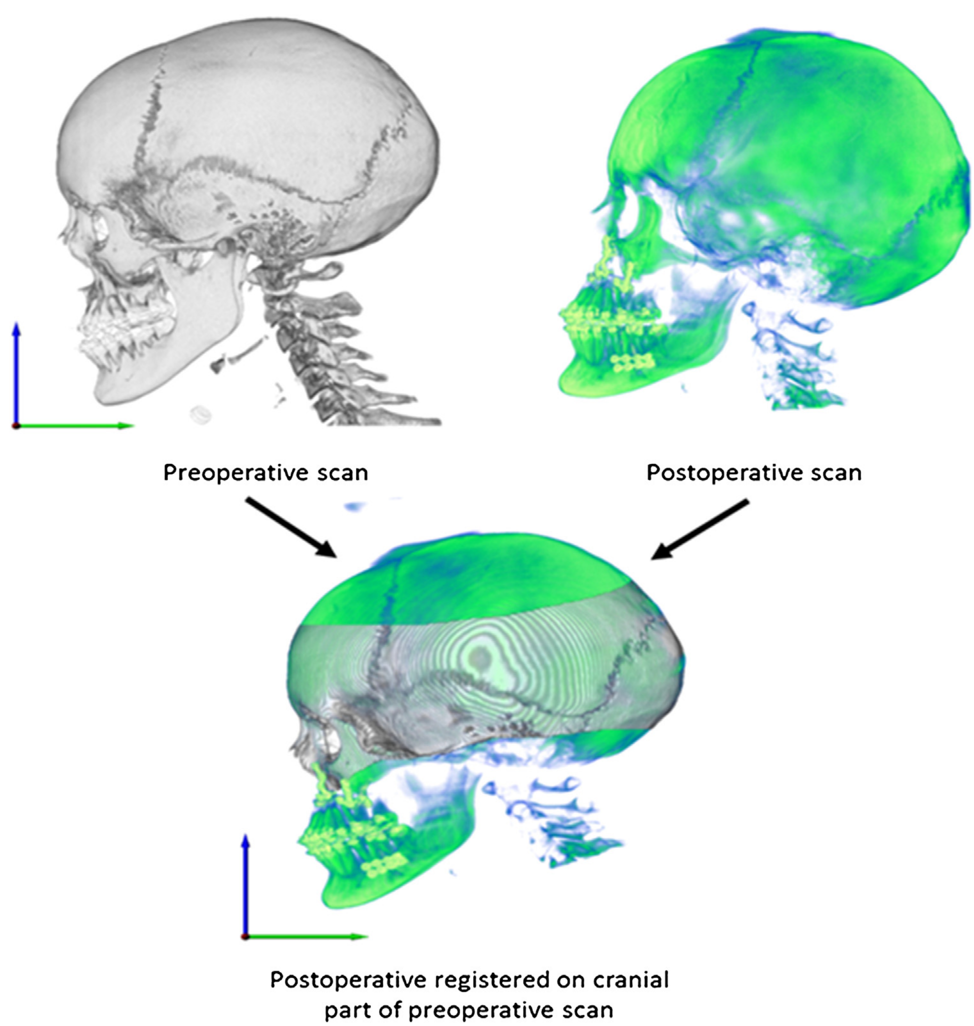

Fig. 1. The postoperative scan (green) registered on the preoperative scan (grey) based on the preoperative anterior cranial base using rigid voxel-based registration.

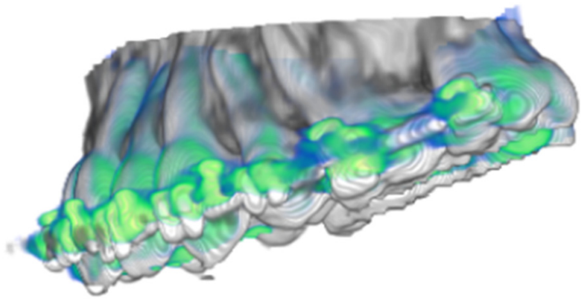

Fig. 2. The preoperative maxillary segment (grey) registered on the registered postoperative maxillary segment (green) using rigid voxel-based registration.

position. These six points, i.e. three points on planning object and the corresponding three points on achieved position, were further analysed using singular value decomposition (SVD) algorithm written in Python and integrated into the Amira wizard module. The output of this step was the 3D clinical accuracy assessment of the translational and rotational movements that represented the 3D error in six degrees of freedom. The translational measurements included: left/right (L/R), anterior/posterior (A/P) and intrusion/extrusion (I/E). The rotational measurements were categorized into pitch, roll and yaw. The interpretation of these measurements was previously described by Baan et al.[5].

Step 5: Data export. The registered postoperative images were exported and saved in DICOM format as well as the maxillary achieved segment (saved as STL) to be used in the follow-up protocol.

Follow-up protocol

The protocol included objective assessment of 6 months postoperative scans. The module involved repetition of all the steps as mentioned in the accuracy assessment protocol, except step 4, by treating the registered postoperative as the preoperative data and the follow-up as the postoperative. During step 4, the maxillary achieved segment was imported as the preoperative STL and duplicated. One copy represented the planning model and the other copy was transformed into the achieved position. The calculations were then applied to these two objects to analyse the stability of the maxillary segment in a period of 6 months. The registered follow-up images and the maxillary achieved segment were then exported as explained in step 5 of accuracy assessment.

Observers

All data were assessed by two observers. Repetition of the assessment was performed 1 month after the first session by both observers for calculating the inter- and intra-observer reliability. Time taken by both observers for applying accuracy assessment and follow-up protocol to every patient was recorded during all sessions.

Statistical Analysis

Data were analysed using MedCalc statistical software (version 12.0, Ostend, Belgium). Intra-Class Correlation Coefficient (ICC) was applied at a 95% confidence interval for assessing the inter- and intra-observer reliability of planning accuracy and follow-up (where <0.50 = poor reliability; 0.50–0.75 = moderate reliability; 0.75–0.90 = good reliability; >0.90 = excellent reliability)[26]. The mean, absolute mean and standard deviation were also calculated for all the data.

Results

Table 2 illustrates the validation of both accuracy assessment and follow-up protocols via the inter- and intra-observer tests using ICC for translational and rotational movements at a 95% confidence interval. Accuracy assessment ICC showed an excellent reliability (0.97–0.98) with mean absolute differences of 0.33–0.34 mm for translational and 0.42–0.63° for rotational movements. The follow-up ICC was 0.94–0.95 with mean absolute differences of 0.25–0.30 mm and 0.31–0.39° for translational and rotational movements, respectively.

Table 3 demonstrates the accuracy of the assessment and follow-up protocols related to translational and rotational movements of the maxilla and the time required for the specific modules for all 15 cases. The mean time for both modules was within the range of 9.4–10.9 min.

The mean indicates the direction of the error while the absolute mean quantifies the magnitude of the error. For the accuracy assessment protocol, the I/E measurement showed the least reliable measurement (mean = -0.9 mm; absolute mean = 1.1 mm). The overall translational movements for both protocols showed a mean of ≤ -0.3 mm and absolute mean of 1 mm. The overall rotational movements were within 1.6°. For the follow-up protocol, the overall mean absolute error was 0.5 mm for the translational movements and 0.7° for the rotational movements, which were considered more stable compared to the accuracy-assessment protocol.

Discussion

Virtual 3D planning in orthognathic surgery has been an area of interest for the past few years. Various methods have been proposed for assessing the accuracy of virtual planning, but to date no consensus has been reached as to which method is the most reliable, user friendly and least time consuming. Literature also lacks evidence on application of software for follow-up accuracy assessment. Based on Gaber et al.'s[14] recommendations, the following study was carried out to introduce a new technique for evaluating the precision of planning versus actual surgery and follow-up.

The inter and intra-observer reliability (ICC) were high for both protocols (0.94–0.98) with inter and intra mean variability

Table 2. Inter- and intra-observer interclass correlation coefficient (ICC) results with mean absolute difference (AD) and standard deviation (SD).

	Accuracy assessment reliability				Follow-up reliability			
	Translational		Rotational		Translational		Rotational	
	ICC	Mean AD ± SD (mm)	ICC	Mean AD ± SD (°)	ICC	Mean AD ± SD (mm)	ICC	Mean AD ± SD (°)
Inter-observer	0.97	0.33 ± 0.36	0.97	0.42 ± 0.41	0.94	0.25 ± 0.18	0.94	0.31 ± 0.32
Intra-observer	0.98	0.34 ± 0.44	0.98	0.63 ± 1.1	0.95	0.30 ± 0.37	0.95	0.39 ± 0.44

Table 3. Results of the accuracy assessment and follow-up protocols for the 15 patients.

			Translational movements (mm)			Rotational movements (°)		
		Time (min)	L/R	A/P	I/E	Pitch	Roll	Yaw
Accuracy assessment protocol	Mean (SD)	9.4 (2.1)	0.2 (1.0) −0.3 (1.4)	−0.2 (1.8)	−0.9 (1.1)	−1.2 (2.9) −0.3 (2.2)	0.1 (1.0)	0.2 (2.2)
	Absolute mean (SD)		0.8 (0.6) 1.0 (1.0)	1.2 (1.3)	1.1 (0.9)	2.3 (2.1) 1.6 (1.6)	0.8 (0.6)	1.6 (1.5)
Follow-up protocol	Mean (SD)	10.9 (3.3)	−0.1 (0.7) −0.1 (0.7)	−0.2 (0.8)	0.1 (0.6)	0.3 (1.4) 0.1 (0.9)	−0.1 (0.7)	0.0 (0.4)
	Absolute mean (SD)		0.5 (0.5) 0.5 (0.5)	0.6 (0.5)	0.5 (0.3)	1.1 (0.8) 0.7 (0.7)	0.5 (0.5)	0.3 (0.2)

A/P, anterior/posterior; I/E, intrusion/extrusion; L/R, left/right; SD, standard deviation.

of less than 0.4mm and 0.7° for translational and rotational movements, respectively. The ICC was slightly lower for the follow-up module (0.94–0.95) compared to the planning (0.97–0.98) but still both modules were found to have excellent agreement. This might have been related to the unavoidable minor teeth movement during the finishing stage of the postsurgical orthodontic treatment[27]. Nevertheless, VBR counteracted these minor dental changes as registration was based on volumetric information of the whole arch. A similar study by Baan et al.[5] exhibited an ICC of 0.97–0.99 for the maxillary region with their 3D tool OrthoGnathicAnalyser. Stokbro et al.[4] demonstrated an ICC of ≥0.99 based on only intra-observer reliability.

In the current study, a state-of-the-art stepwise module was established using a single software for validating the accuracy of planning and follow-up. The module was considered semi-automated and user friendly because it consisted of 12 steps in the form of a fully automated wizard requesting the user to either import objects or press next, apart from only four steps: highlighting the cranial base part, the pre- and postoperative maxilla and pointing to the three landmarks on the preoperative maxilla. However, the highlighting was carried out as drawing on the screen for all parts with the mouse facilitating the user interaction. The accuracy of highlighting and drawing of maxilla and cranial base was independent of operator experience as it relied on a VBR algorithm. Furthermore, literature suggests VBR to be a reliable and accurate method for anterior cranial base registration[28]. The time taken for each module was around 10min (Table 2) as compared to similar studies which either failed to provide the time duration of the assessment procedure or were considered to be time consuming[5]. The time taken for cranial base registration ranged between 1 and 5 min. Our method compared with various open-source software studies was found to be less time consuming and within the same accuracy range[4]. Time is the least documented and most ignored factor related to the assessment methods, therefore we deemed it necessary to be addressed.

The translational and rotational differences (<2 mm and <4°) in accuracy assessment and follow-up protocols were considered to be clinically insignificant[29]. These minor variations can be considered more reliable as compared to the less accurate 3D cephalometric measurements[4]. A high-resolution STL of the maxilla was used to facilitate the placement of three landmarks on the maxillary teeth during the SBR step in accuracy assessment protocol which were deemed adequate for orienting the maxilla in 3D coordinates and reconstructing the occlusal plane. The main role of this maxillary segment STL was to avoid the human error by automatically repositioning the landmarks without user interference from one position to another, i.e. for the accuracy-assessment protocol, from preoperative position to the actual outcome position and from actual outcome position to planned position; furthermore, for the follow-up protocol, automatically repositioning landmarks from immediate postoperative position to achieved 6 months postoperative position.

All 15 cases involved in the study showed similar range of accuracy for follow-up irrespective of the type of CT/CBCT device and image acquisition settings used for acquiring the scan. For instance, patients having preoperative CT and postoperative CBCT showed the same amount of accuracy when compared with patients having only CBCT scans and vice versa. This was confirmed by the excellent ICC results (≥0.94). Moreover, the mean absolute difference of inter- and intra-observer reliability for accuracy assessment (translation: ≤0.34 mm, rotation: ≤0.63°) and follow-up (translation: ≤0.30 mm, rotation: ≤0.39°) methods was found to be highly accurate, proving that the type of scan had no effect on the methods applied as no digitization was needed and the registration (VBR) was based on volumetric similarities.

This study had certain limitations. The quantitative analysis only involved the maxillary movements for validating the method, thereby, further analysis is required for assessing the application of the method in maxillary segmental osteotomy, mandibular region (BSSO) with or without genioplasty. For the follow-up module, the study was only limited to 6 months postoperative cases. We hypothesize that the above-mentioned method is applicable for long-term follow-up by comparing 1-year follow-up to 6 months and 2 years to 1 year to check for relapse as dental changes within these periods would be minimal. However, additional studies are required to confirm this hypothesis.

In conclusion, the study provides a reliable, user-friendly and time-efficient method for evaluating the planning and follow-up accuracy, hence improving the standards in orthognathic surgery.

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Patient consent. Not required.

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