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Evaluation The Accuracy Of Three-Dimensional Virtual Surgical Planning For Maxillary Positioning In Orthognathic Surgery: Prospective Clinical Study

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I. Introduction

A person's face is the most visible aspect of their appearance and is what other people focus on, during social interaction. Those with severe malocclusions may have been stared at, bullied, discriminated, against most of their lives. Even when their condition may evoke a sympathetic response there may be an unintentional, negative non-verbal response from others which may be difficult for those people to suppress. As a result of these negative experiences, people with a facial deformity may go on to exhibit shyness and defensiveness in social situations, which compounds their social difficulties [(1)].

Deformity is a term used to refer to any distortion of any part of the body. The term dentofacial deformity is described as a type of deformity that affects primarily the jaws and dentition, and its prevalence is variable, depending on genetic and social factors [(2)].

Important advances have occurred in the last years in terms of diagnosis and planning instruments, as well as in surgical techniques, instruments, and materials used, which have made orthognathic surgery a safe procedure, as well as accessible to an important part of the population [(3)].

The main objective of the orthognathic surgery is to correct dentofacial deformities, functional and aesthetic problems. Its success depends not only on surgical techniques, but also on an accurate and detailed treatment plan [(4,5)].

Two-jaw orthognathic surgery, Lefort I osteotomy of the upper jaw combined with sagittal split ramus osteotomy (SSRO) or intraoral vertical ramus osteotomy (IVRO) of the lower jaw, is an efficient procedure to correct severe dento-maxillofacial deformities [(6,7)].

The success of two jaw surgery relies on surgical technique and accurate surgical planning [(8,9)]. Conventional treatment planning for two-jaw surgery involves diagnosis with 2D cephalometric radiograph, face-bow transfer and model surgery on plaster dental cast, and fabrication of intermediate and final occlusal splint [(10,11)].

There are several three-dimensional (3D) VSP protocols, such as the Computer-Aided Surgical Simulation (CASS) [(1,12)], which represents a paradigm shift in surgical planning for patients with dentofacial deformities [(1,13)]. Using cone beam computed tomography (CBCT) scans and software programs, a computerized composite skull model of the patient is generated to accurately represent the dentition, the skeleton and the soft tissues.

Virtual surgical planning and Rapid Prototyping (RP) technology offers new possibilities to obtain a comprehensive 3D evaluation of the dental arches and the surrounding skeletal structures to simulate different surgical plans and predict the corresponding results, as well as to facilitate the transfer of the virtual surgical plan to actual outcome using 3D-printed splints and guiding templates [(14,15)].

Aim of study

This study aims to evaluate the accuracy of 3D virtual surgical planning for maxillary positioning and orientation in orthognathic surgery via comparison of preoperative planning and postoperative actual results.

II. Patients And Methods

Patient Selection

This study will be conducted on eleven (11) patients requiring orthognathic surgery ,Patients who have abnormalities of the jaws that cannot be corrected with conventional orthodontics, attending to the outpatient clinic of the department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Ain Shams University. The research protocol will be reviewed and accepted by the ethical committee of the Faculty.

Before the study, the number of patients required in simulated compared to postoperative was determined after a power calculation according to data obtained ***(Li et al., 2015)***. In the study, distance to FHP "mm" regarding UI in simulated mean was 50.2±4.67 and in postoperative mean was 49.5±4.71, and mean difference 0.60±0.07 with a large effect size (f = 0.775). A sample size of 11 patients in the study group was determined to provide 80% power for independent samples T test at the level of 5% significant and Confidence interval 95% using G. Power 3.19.2 software.

Statistical analysis:

The collected data will be, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 23.0

Descriptive statistics were done for numerical parametric data as mean±SD (standard deviation) and minimum & maximum of the range and for numerical non parametric data as median and 1st& 3rd inter-quartile range, while they were done for categorical data as number and percentage.

Inferential analyses were done for quantitative variables using Paired sample t-test of significance was used when comparing between related sample with parametric data and Comparison between differences by time for non-parametric data using Wilcoxon Signed-Rank Sum test with non parametric data.

Inferential analyses were done for qualitative data using Chi square test for independent groups. The level of significance was taken at P value <0.050 is significant, otherwise is non significant. The p-value is a statistical measure for the probability that the results observed in a study could have occurred by chance.

Inclusion Criteria

1. Patients with maxillary deformities
2. Patients with no medical compromising conditions.
3. Both sexes will be accepted.
4.Age range of patients 18-30 years

Exclusion Criteria

1.Patient with bone and syndromic diseases. (Diabetes, Syndromic patients)
2. Vulnerable groups (prisoners, orphans, disabled, ...).

(The study will be conducted in accordance with ethical principles, including the approval from research ethical committee in ASU. The study protocol will be explained to all prospective candidates, and a written informed consent will be received from each patient before participation).

Case Preparation

Patient will undergo routine clinical and radiographic (Lateral, Cephalometric, Panorama) as well as orthodontic consultation in the outpatient clinic .

Preoperative Cone Beam Computed Tomography (CBCT) scan showing the entirety of the facial skeleton will be taken for all the patients. The Digital Imaging and Communications in Medicine (DICOM) data and STL data will be imported into an analytic software for 3D reconstruction and virtual model surgery.

Dental Impressions will be recorded. The digital dental models will be created by scanning the plaster dental models to replace the occlusal surface of the teeth in the CBCT images. The digital dental model will be then recorded in STL (standard triangulation language) extension.

3D virtual surgical planning (VSP) will be executed and surgical wafer exported as a Stereolithography file (STL) to be printed using a 3D printer.

Surgical Procedure

The procedure will be performed under general anesthesia via nasal intubation.

Incisions for Le Fort I osteotomy are to be done, osteotomy performed above the level of the dental roots the maxillary position adjusted according to the Model Plan and checked with the repositioning occlusal wafers. Fixation in adjusted position will be carried out with screws and miniplates.. Patient will be instructed to wear the Wafer in position fixed by Elastics for 7 days. Wound is closed by 4-0 Vicryl.

Postoperatively patients will be covered by an Amoxicillin-Clavulanic acid antibiotics, an appropriate Non-Steroidal Anti-Inflammatory Drug (NSAID) and steroids.

Method of evaluation:
Accuracy of the VSP will be assessed by comparing the VSP with the actual postoperative outcome.
The superimposition of planning and postoperative will be performed in 3D software.
VSP and postoperative images will be approximated using three reference points.

Statistical analysis:
Inter-observer reliability assessment

Inter-observer reliability were qualified using the weighted Kappa, it has a value between +1 and -1, where 1 is total positive linear correlation, zero is no linear correlation, and -1 is total negative linear correlation.

Statistical package

Values were presented as mean and range values. Data were explored for normality using Kolmogorov-Smirnov test of normality. The results of Kolmogorov-Smirnov test indicated that data recorded values were normally distributed. Therefore, paired sample t-test was used to compare between Plan and Post.

The significance level was set at $p \leq 0.05$. Statistical analysis was performed with SPSS 23.0 (Statistical Package for Scientific Studies, SPSS, Inc., Chicago, IL, USA) for Windows.

III. Results:

The study included eleven patients with ranged age 19 to 25 years mean 21.91±1.87 years old, complaining from skeletal maxillary deformity. Seven Females and four Males patients were included. All of them underwent Lefort I and BSSO osteotomy for the maxilla and the mandible respectively.

All patients were assessed clinically, radio-graphically and had photographs taken as a baseline record before any surgical intervention. Type of surgery and amount of the required skeletal movement were then decided and evaluated in the virtual plan. CT scan were taken before surgery (T0) and at the first follow up visit after surgery (T1). Patient's gender, age, type and amount of maxillary skeletal movement are presented in table 1.

Table 1: Shows demographic data, patient age, sex and type, amount of maxillary movement.

Demographic data	Total cases (n=11)
Sex	
Male	4 (36.4%)
Female	7 (63.6%)
Age "years"	
Range	19-25
Mean±SD	21.91±1.87

Case number	Age (years)	Gender	Type and amount of maxillary movement
Case 1	23	Female	Advancement 6mm
Case 2	21	Male	Advancement 9mm
Case 3	24	Male	Advancement 7mm
Case 4	19	Female	Impaction 8mm
Case 5	20	Female	Advancement 10mm
Case 6	23	Female	Advancement 5mm
Case 7	22	Male	Impaction 7mm
Case 8	20	Female	Advancement 10mm + Impaction 6mm
Case 9	23	Female	Advancement 8mm
Case 10	25	Male	Advancement 4mm
Case 11	21	Female	Advancement 5mm

Radiographic assessment of the accuracy of waffers:

After superimposition of the postoperative 3D model over the virtually planned one, the distance between the selected points (the most inferior-mesial point of upper central incisor, upper canine tip and the mesiobuccal cusp tip of upper first molar) and the three planes of space for both the virtual plan and the actual outcome were measured.

The mean of the measured distances for each plane was compared between the virtual plan and the actual postoperative to assess the accuracy of waffers in planning transfer to the theatre. Two assessors undertaken the CT analyses, each one of them collected two separate sets of records.

The results showed non statistically significant difference between the virtual plan and the actual postsurgical outcome. Only minor inaccuracies were present; none of these discrepancies affected the clinical result for the sample included in this study.

Inter-observer reliability:

The inter-observer reliability was assessed by weighted Kappa, which was 0.947, indicating almost perfect agreement between the two assessors.

Accuracy in the Mediolateral direction in relation to FHP:

Assessment of the points distances to the FHP in the virtually plan 3D model (mean=45.72mm, SD=8.49mm) in the comparison to the postoperative 3D model (mean=45.80mm, SD=8.54mm) showed a non-significant statistical difference where P=0.186. The mean difference between each “Plan” pint and its counterpart “Post” point was 0.076±0.056mm (Table 1, Figure 1).

Table 1: Showing the mean ± SD values, of measurements from the “Plan” and “Post” landmark points to the FHP.

	FHP		Paired sample t-test			
	Mean	±SD	MD	±SE	t-test	p-value
Virtual Plan	45.72	8.49	0.076	0.056	1.355	0.186
Postoperative	45.80	8.54				

P-value >0.05 is insignificant difference

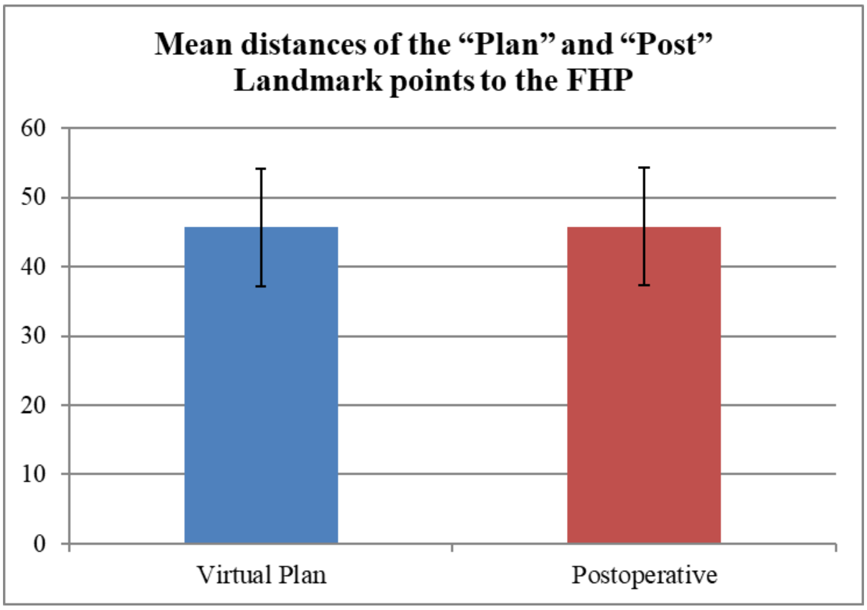

Fig. (1): Bar chart representing measurements from the “Plan” and “Post” Landmark points to the FHP (Mean±SD).

Accuracy in the Mediolateral direction in relation to MSP:

Assessment of the points distances to the MSP in the virtually plan 3D model (mean=17.09mm, SD=8.54mm) in the comparison to the postoperative 3D model (mean=17.10mm, SD=8.49mm) showed a non-significant statistical difference where P=0.877. The mean difference between each “Plan” pint and its counterpart “Post” point was 0.009±0.055mm (Table 2, Figure 2).

Table 2: Showing the mean ± SD values, of measurements from the “Plan” and “Post” landmark points to the MSP.

	MSP		Paired sample t-test			
	Mean	±SD	MD	±SE	t-test	p-value
Virtual Plan	17.09	8.54	0.009	0.055	0.156	0.877
Postoperative	17.10	8.49				

P-value >0.05 is insignificant difference

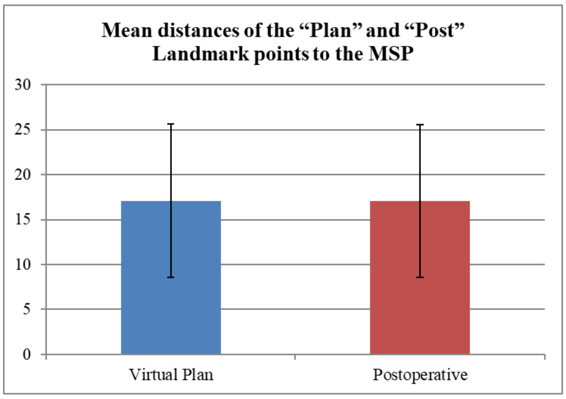

Fig. (2): Bar chart representing measurements from the "Plan" and "Post" Landmark points to the MSP (Mean±SD).

Accuracy in the Mediolateral direction in relation to CP:

Assessment of the points distances to the CP in the virtually plan 3D model (mean=55.85mm, SD=12.39mm) in the comparison to the postoperative 3D model (mean=55.85mm, SD=12.36mm) showed a non-significant statistical difference where P=0.960. The mean difference between each "Plan" pint and its counterpart "Post" point was 0.003±0.067mm (Table 2, Figure 2).

Table 3: Showing the mean ± SD values, of measurements from the "Plan" and "Post" landmark points to the CP.

	CP		Paired sample t-test			
	Mean	±SD	MD	±SE	t-test	p-value
Virtual Plan	55.847	12.39	0.003	0.067	0.050	0.960
Postoperative	55.850	12.36				

P-value >0.05 is insignificant difference

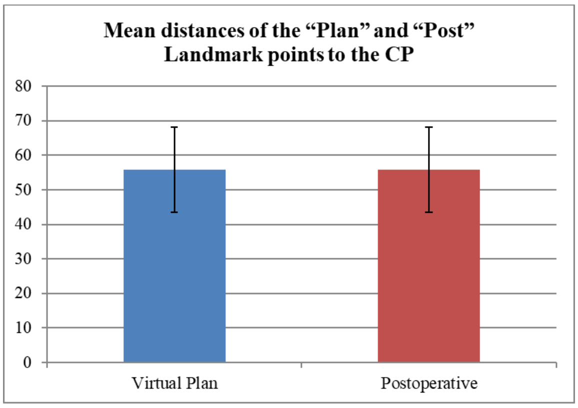

Fig. (3): Bar chart representing measurements from the "Plan" and "Post" Landmark points to the CP (Mean±SD).

IV. Discussion:

Tonin et al. [16] conducted a retrospective and observational study on 70 patients of both sexes, who were submitted to bimaxillary orthognathic surgery between 2015 and 2019.

They then evaluated the accuracy of 3D virtual surgical planing (VSP) for the maxillary positioning. The result indicated that there no significant statistical differences were found for liner and angular measurements between the Planned and postsurgical outcomes (P>0.05).
All overlapping points presented values within the range considered clinically irrelevant (<2mm;<1°).

Stokbro et al. [17] also made a survey on 30 patients they are also evaluated the influence of segmentation on positional accuracy and transverse expansion and genioplasty in placement of the chin segment. The virtual surgical plan was compared with the postsurgical outcome by using three linear and three rotational measurements. The influence of maxillary segmentation was analyzed in both superior and inferior maxillary repositioning. In addition, transverse surgical expansion was compared with the postsurgical expansion obtained. An overall, high degree of linear accuracy between planned and postsurgical outcomes was found, but with a large standard deviation. Rotational difference showed an increase in pitch, mainly affecting the maxilla. Segmentation had no significant influence on maxillary placement. A posterior movement was observed in inferior maxillary repositioning. A lack of transverse expansion was observed in the segmented maxilla independent of the degree of expansion.

Schneider et al. **(18)** perform a prospective randomized trial to compare conventional (csp) versus customized VSP in bimaxillary orthognathic surgery. The VSP appears to be a more accurate method for orthognathic treatment planning with significant differences in the angle outcome (SNA $p < 0.001$; SNB $p = 0.002$; ANB $p < 0.001$). There were significant differences in splint accuracy in favor of CAD/CAM splints ($p = 0.007$). VSP significantly reduced the duration of operation ($p = 0.041$).

Sun et al. **(19)** present and discuss a workflow regarding computer-assisted surgical planning for bimaxillary surgery and intermediate splint fabrication. Three different modalities were utilized to obtain this goal: cone beam computed tomography (CBCT), optical dental scanning, and 3-dimensional printing. A universal registration block was designed to register the optical scan of the wax bite to the CBCT data set. Integration of the wax bite avoided problems related to artifacts caused by dental fillings in the occlusal plane of the CBCT scan. Fifteen patients underwent bimaxillary orthognathic surgery. The printed intermediate splint was used during the operation for each patient. A postoperative CBCT scan was taken and registered to the preoperative CBCT scan. The difference between the planned and the actual bony surgical movement at the edge of the upper central incisor was 0.50 T 0.22 mm in sagittal, 0.57 T 0.35 mm in vertical, and 0.38 T 0.35 mm in horizontal direction (midlines). There was no significant difference between the planned and the actual surgical movement in 3 dimensions: sagittal ($P = 0.10$), vertical ($P = 0.69$), and horizontal ($P = 0.83$). In conclusion, under clinical circumstances, the accuracy of the designed intermediate splint satisfied the requirements for bimaxillary surgery.

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