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ACCURACY OF PROPLAN CMF R 3.0.1 VERSUS PLANMECA ROMEXIS R 6.4.1; IN THE FABRICATION OF OCCLUSAL REPOSITIONING SPLINTS FOR ORTHOGNATHIC SURGERY; RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Objectives: This study aimed to compare the accuracy of two software programs, Proplan CMF R 3.0.1 and Planmeca Romexis R 6.4.1, for fabricating occlusal repositioning wafers for bimaxillary orthognathic surgery.

Materials and Methods: Our research was conducted on 18 patients with skeletal deformities. Patients were randomly distributed into two groups: the control group, where 9 patients were planned by Proplan CMF R 3.0.1; and the study group, where 9 were planned by Planmeca R 6.4.1. All the patients underwent bimaxillary orthognathic surgery. Each patient received 2 CT scans preoperatively and 1 month postoperatively. Materialize 3-matic software was used to identify discrepancies between the virtual treatment plan and the outcome by superimposing the planned STL model with the postoperative one.

Results: The deviations measured with Romexis were slightly higher than those with Proplan. However, the results had no significant differences ($p > 0.05$). Both programs effectively fabricated splints accurately enough to transfer the virtual planning to the operation theater. The mean differences between the planned and postoperative positions of the maxilla and mandible were 0.37 and 0.48 mm.

Conclusion: This study supports the accuracy of both software programs (Proplan and Romexis) for splint fabrication for bimaxillary orthognathic surgery. However, further research is needed to refine software algorithms to reduce the observed minor variations.

KEYWORDS: Bimaxillary Orthognathic surgery, Planmeca Romexis R 6.4.1, Proplan CMF R 3.0.1, Materialise 3-Matic, Repositioning Splints.

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INTRODUCTION

Orthognathic surgery (OGS) is a complex surgery that requires high precision. It can be difficult to achieve high accuracy in OGS, but advances in technology have made this easier [1] [2]. Since the 1980s, full-arch maxillary occlusal splints have been used to position bone fragments after OGS surgery [3].

For many years, OGS treatment planning was done using 2D cephalometric analysis, dental casts, and model surgery. Model surgery allowed surgeons to plan the surgery outside of the body, which helped them to create rigid inter-occlusal wafers [4].

These wafers were used during surgery to reposition the teeth and skeletal segments into their planned positions. However, this traditional planning method was imprecise and time-consuming [4]. The modern use of computer technology in OGS planning has revolutionized the field.

Computer-aided design and manufacturing (CAD/CAM) software can now be used to create accurate and customized occlusal splints. These splints are used to transfer the preoperative surgical plan to the patient during surgery[5]. The goal of OGS is to create a functional occlusion and improve facial aesthetics. However, the definition of an ideal aesthetic is subjective and may vary between the clinician and the patient [6].

After proper OGS planning, the outcome of surgery will depend on the accuracy of transferring the plan to the patient. Occlusal splints are the classic and most used method for surgical transfer [7]. Splints are used in OGS surgery to transfer the preoperative surgical plan and to reposition the jaws into the required optimized occlusion [8].

Recent developments in dentomaxillofacial imaging using computed tomography (CT) and cone beam CT (CBCT) have allowed for further developments in CAD/CAM software. Advances in computer technology have led to the development of a variety of algorithms and software for 3D virtual planning of orthognathic surgery [9].

The main advantages of 3D planning include the creation of a virtual skull and teeth, and the direct production of digital and physical splints. This leads to more accurate planning, time savings, and better results [10].

This study aimed to compare the accuracy of two software programs, Proplan CMF R 3.0.1 and Planmeca Romexis R 6.4.1, for fabricating occlusal repositioning wafers for bimaxillary orthognathic surgery.

MATERIALS AND METHODS

The study was conducted in accordance with ethical principles, including the approval from research ethical committee in Ain Shams University. The study protocol was explained to all prospective candidates, and a written informed consent was received from each patient before participation. The study was conducted on 18 patients with skeletal deformities were randomly selected from the outpatient clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Ain Shams University. Criteria of patients' selection were as follows:

Inclusion criteria:

- Patients who have skeletal maxillary and mandibular discrepancies requiring bimaxillary orthognathic surgery.
- Patients who are free from any systemic disease that may affect normal healing and predictable outcome.
- Patients with no signs or symptoms of temporomandibular joint disorders.

Exclusion criteria:

- Patients who are younger than 18 years old.
- Intra-bony lesions or infections may delay osteotomy healing.

- Smokers.
- Patients receiving chemotherapy or radiotherapy.
- Conditions such as: cleft lip-palate or craniofacial deformities, systemic or coagulative illnesses, pregnancy, and any regular medication therapy (such as antiphlogistic), with the exception of oral contraceptives.

All the patients included in this study passed through this standardized protocol for the patient's preparation (assessment and planning), surgical procedure, and postoperative analysis:

1- Thorough diagnosis, clinical assessment and comprehension of the primary concerns and demands of the patients; to reach a preliminary treatment plan estimation.

2- A panoramic radiograph was taken to evaluate the overall state of the teeth, the existence of intrabony lesions, or any impacted teeth, while lateral cephalometric radiographs were taken and traced to corroborate the initial diagnosis.

3- Extra oral photo documentation: frontal, lateral (profile), three quarter (45°). All photos are taken in rest and smile positions.

4- Intraoral photo documentation: dental occlusion (frontal, right, and left lateral views), and occlusal views for both arches.

5- Intra oral scan by 3Shape intra oral scanner TRIOS 4 (Copenhagen, Denmark) for both arches (maxilla and mandible) for each patient of each group.

6- Print the scans into 3D printed models (Proshape Dental Model Resin, Turkey).

7- Optical scan using a 3Shape desktop 3D laser surface scanner E2 (Copenhagen, Denmark); one for the maxillary model alone, the second for the mandibular model alone, and the third for both models positioned in the target occlusion; then they are saved as a Standard Tessellation Language (STL) file.

8- Computed Tomography (CT) was performed for each patient.

9- DICOM data is digitally transferred to the planning software Planmeca Romexis R 6.4.1 CMF surgery(Orthognathic software) was used for the study/intervention group and ProPlan CMF R 3.0.1 (DePuy Synthes®/Materialize®) for the comparator/control group for segmentation virtual three-dimensional reconstruction of the facial skeleton, and occlusal splint (wafer) fabrication.

10- Superimposition of the scanned maxillary and mandibular teeth to the DICOM data for better resolution for stent fabrication.

11- Cephalometric analysis for confirmation for our clinical diagnosis and treatment plan.

12- Internal meetings for treatment planning via virtual means.

13- Maxillary Lefort I osteotomy is done to split the maxilla from the skull base.

14- Customized intermediate splints are designed with computer assistance (CAD).

15- Bilateral Sagittal Split Osteotomy (BSSO) is done on the right and left sides of the jaws to separate the body from the ramus.

16- Customized final occlusal splints manufactured with computer assistance (CAM).

17- Our protocol always addresses the maxilla first and is corrected with the intermediate wafer; the BSSO is fixed after the final occlusion is set with the final wafer.

18- Postoperative CT scan of the patient after 1 month.

19- ProPlan CMF software is used to import the planned preoperative CT scan, segment it, and export it as STL model.

20- ProPlan CMF software is used to import the postoperative CT scan, segment it, and export it as STL model.

21- Materialise 3-matic Industrial software is used to assess and compute the correctness of both STL models, as well as identifying discrepancies between the virtual treatment plan (prior to surgery) and the outcome following it (postoperative); by superimposition of the planned STL model with the postoperative one for each group.

Post operative assessment:

A CT scan was acquired one month after the operation. DICOM files of the real postoperative situation were imported into the Mimics Medical 19.0 and subsequently transformed into three-dimensional models through rendering. The preoperative virtual planning was rendered as STL 3D model (by Proplan for the control group and Romexis for the comparative group).

The real postoperative and preoperative 3D models were exported to the 3- Matic Medical 11.0 software. The 3- Matic software was used to superimpose the 3D models of the [preoperative virtual planning] and the [actual postoperative]. This was done by employing several unaltered significant points (landmarks) on the cranium, such as the sella turcica (S), Nasion (N), and infraorbital and supraorbital foramina. To superimpose/ overlay the data, the "N-Point registration tool" was utilized; it was then followed by the "Global registration tool" to improve precision.

Identifying the transverse/ axial plane/ Frankfort Horizontal Plane (FHP) through infraorbital and porion points. The longitudinal/ median plane, which is perpendicular to the FHP, which is the mid-sagittal plan (MSP) that passes through the midline landmarks as: N, posterior nasal spine (PNS), and anterior nasal spine (ANS).

The coronal/ frontal plane (CP) which bisects the human body into dorsal and ventral surfaces through and perpendicular to the transverse and axial planes. These are the 3 planes of space which were identified for both the virtual preoperative and postoperative 3D models for both the control and comparative groups.

Following the overlay, 5 unchanged reference landmarks were identified on both maxilla and mandible of both the virtually relocated and real postoperative ones, which maintained identical positions. They are the canine tips, mesiobuccal cusp tips of the 1st molars, and the most inferior mid-point on the incisal edge of the central incisors. All these points were identified on maxilla and mandible bilaterally.

Distances between each point and the three planes of space were measured in both 3D modes, the virtually planned preoperatively and the real postoperative one. By analyzing both measures, we figured out if there was any variation from the virtual plan in all 3 planes which could affect the overall cosmetic and functional results. Also, assess how accurate were the splints in converting the virtual plan to the operation theater by analyzing the CT.

These figures showed the exported models from Proplan (Planned) [control group] (Fig. 1, 2), the same steps will be repeated to the exported models from Romexis (Planned) [Study group], while the post operative exported models are always exported from Mimics for both groups also with the same steps of distance measurements for both the maxilla and mandible.

To evaluate the accuracy of the 3D-printed occlusal wafers in transferring planning to the operating room, the mean of the measured distances for every plane was compared between the virtual and the real postoperative plans. Two independent observers examined the CT data sets of 18 clinical patients in order to confirm the approach that is now being presented and assess how well 3D planning was translated to the patients.

The previous steps were completed separately by both observers to ascertain the inter-observer variability. After four weeks, one observer repeated the steps to evaluate intra-observer variability.

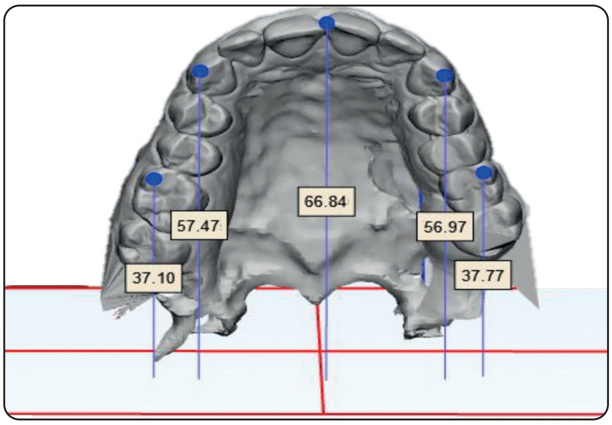

Fig. (1) Measurement of the distance from the previously mentioned points to the coronal plane in the planned model for maxilla which exported from Proplan to the 3 Matic

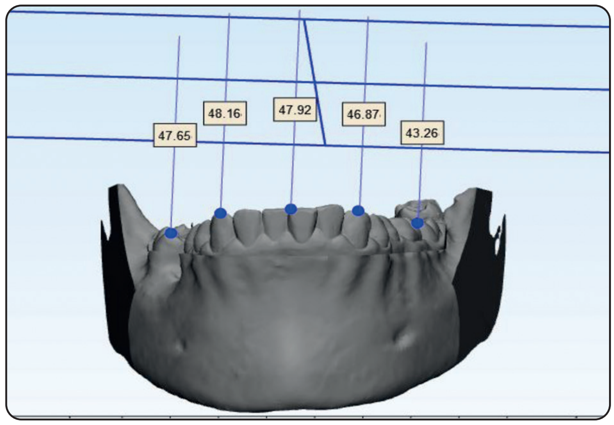

Fig. (2) Measurement of the distance from the previously mentioned points to the FHP plane in the planned model for mandible which exported from Proplan to the 3 Matic.

Then, calculating the mean differences of the surgical displacement for the maxillary, and mandibular segments. Evaluations were done on the translations; left/ right (regarding the MSP), cervical/ caudal (according to the FHP), and anterior/ posterior (regarding the CP).

Statistical analysis:

Categorical data were presented as frequency and percentage values and analyzed using the chi-square test. Numerical data were presented as mean and standard deviation values. They were examined for normality by viewing the distribution and using Shapiro-Wilk's test. Age data were found to be normally distributed and analyzed using an independent t-test. Other data were non-parametric and were analyzed using the Mann-Whitney U test. The significance level was set at $p<0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.4.1 for Windows.

RESULTS

Linear deviations

Intergroup comparison and summary statistics for linear deviations (mm) are presented in Table (1).

Within both arches and different planes, the deviations measured with Romexis were higher than those of Proplan. However, the differences were not statistically significant ($p>0.05$).

TABLE (1) Intergroup comparison and summary statistics for linear deviations (mm).

Arch	Plane	Deviation (mm) (Mean±SD)		p-value
		Proplan	Romexis	
Maxillary	**Horizontal (FHP)**	1.13±0.29	1.37±0.36	**0.133ns**
	Coronal (A/P)	1.11±0.08	1.18±0.24	**0.929ns**
	Sagittal (L/R)	0.39±0.10	0.45±0.09	**0.100ns**
Mandibular	**Horizontal (FHP)**	1.15±0.17	1.36±0.27	**0.130ns**
	Coronal (A/P)	1.33±0.37	1.54±0.40	**0.286ns**
	Sagittal (L/R)	1.19±0.27	1.25±0.15	**0.723ns**

ns not significant.

DISCUSSION

Three-dimensional treatment planning in orthognathic surgery enables surgeons to conduct virtual osteotomies before the actual procedure, facilitating a more predictable correction of dysgnathia [11]. Proplan CMF R 3.0.1 and Planmeca Romexis R 6.4.1 are two software programs that were used in this study to compare how accurate, easy to use, and fast they are at fabricating occlusal repositioning wafers for bimaxillary orthognathic surgery.

Moreover, virtual surgical planning facilitates the assessment and forecasting of soft tissue outcomes. It facilitates an approximate prediction of the soft tissue reaction to maxillomandibular relocation as a basic geometric transformation, without accounting for precise mechanical models and tissue characteristics [12].

The application of 3D printers in orthognathic surgery is prevalent and includes the fabrication of splints, surgical guides, pre-bent plates, patient-specific implants and plates, and 3D models. In contrast to the conventional approach, the digital occlusal splint offers superior precision, reliability, and consistency, along with enhanced quantitative control and efficiency [13].

Hernandez-Alfaro et al. acquired surface images of the dental arches using an intraoral digital scanner. When the scans were combined with the patients' CT images for the creation of an intermediate CAD/CAM splint, the accuracy and consistency of the procedure were evaluated; this resulted in a high overall accuracy and an error of less than 1.5 mm between the intraoperative intermaxillary relationship and the virtual intermaxillary position [12].

The 18 patients with skeletal deformities in this study underwent BSS and Lefort-I osteotomies on the mandible and maxilla, respectively. Proplan CMF R 3.0.1 was used to plan 9 patients (group I = control group), while Planmeca Romexis R 6.4.1 was used to plan the other 9 patients (group II = study group).

Previous studies have used two methods to assess skeletal changes during orthognathic treatment: using distance maps to assess differences between the surface of the planned and postoperative jaw segments [14], [15], and calculating both linear and angular differences between points of reference through cephalometric analysis [16, 17].

The most widely used technique is linear and angular measurements, which are susceptible to human mistake and depend on precisely identifying cephalometric landmarks, as it is necessary be done both on the preoperative and postoperative models [12].

The findings of the present investigation shown remarkable repeatability of the software programs [Proplan and Romexis] in planning and [3-Matic] in quantifying bone displacements between two CT datasets.

In this study, the translation discrepancies (vertical, anteroposterior, and lateral) were measured by 3-Matic by conventional calculation of linear differences between reference points (1st method).

The [conventional linear method] is less accurate than [matrices comparing] one; the mistake induced by the identification of cephalometric landmarks varied from 0.02 mm to 2.47 mm [18].

As the same landmarks had to be recognized twice, the overall landmark recognition inaccuracy was considered the summation of individual landmark identification errors, which can easily surpass the clinically relevant error margin of 0.5 mm [18].

Two ways may be utilized to eliminate the landmark identification mistake, the fully automatic landmark recognition [19], [20] or the deletion the necessity of landmark based measurement.

The linear method was used (rather than cephalometry) to determine the accuracy of splints to transfer virtual planning into surgical reality was examined linearly by measuring the distance in all three planes from five repeatable points.

These points were the canine and mesiobuccal cusp tips of the 1st molars bilaterally and the midpoint on the incisal edge of the central incisors on the maxilla to evaluate the three-dimensional precision of the maxillary position [21]. Also, all these points were exactly identified on the mandible to evaluate the 3D accuracy of the mandible position.

The linear deviations between the virtual plannings and the postoperative outcomes of the two software programs, Proplan and Romexis, were assessed by 3-Matic software.

As shown in Table 1, the deviations measured with Romexis were slightly higher than those of Proplan across all planes (horizontal, coronal, sagittal) for both maxillary and mandibular arches. However, the differences were not statistically significant ($p > 0.05$).

The mean differences between the planned (Proplan and Romexis) and the postoperative position of the maxilla and mandible were 0.37 and 0.48 mm respectively. This is in line with Stokbro et al. who examined thirty patients who underwent bimaxillary orthognathic surgery and determined that all mean linear discrepancies for the maxilla and mandible were within 0.5 mm (no statistically significant difference) [22].

Although different software systems may produce modest discrepancies in measurement results, they are generally within acceptable clinical limits. This implies that, while Romexis had higher deviations than Proplan, the difference was not significant enough to indicate a meaningful discrepancy between the two programs.

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