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3D virtual surgical planning in patients with bilateral cleft lip and palate undergoing premaxilla osteotomy combined with secondary alveolar bone grafting: a retrospective accuracy analysis

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ABSTRACT

This retrospective study evaluates the surgical accuracy of 3D virtual planning and the use of computer-aided design/computer-aided manufacturing splints in premaxillary osteotomy combined with secondary alveolar bone grafting.

The study included all consecutive patients with bilateral cleft lip and palate undergoing a premaxillary osteotomy with secondary alveolar bone grafting treated by the Cleft Team North (the Netherlands) between 2016 and 2023. 3D virtual surgical planning was based on cone beam computed tomography scans and intraoral scans or plaster models. Surgical accuracy was assessed by comparing the planned and postoperative images of the premaxilla through three linear and three angular measurements. Eleven patients were included (mean age: 9.8 years). The mean Euclidean distance between the planned and postoperative outcomes was 1.57 ± 0.79 mm. Linear measurements showed mean differences of 0.74 ± 0.76 mm medio-laterally, 0.65 ± 0.53 mm caudo-cranially, and 0.89 ± 0.70 mm anteroposteriorly. Angular differences were 6.66 ± 5.12° for pitch, 5.09 ± 5.14° for yaw, and 4.61 ± 5.05° for roll. The intra-observer variability was 0.85 ± 0.58 mm and the intraclass correlation coefficient 0.99.

High surgical accuracy can be achieved using 3D virtual surgical planning and computer-aided design/computer-aided manufacturing splints in premaxillary osteotomy combined with secondary alveolar bone grafting.

1. Introduction

Cleft lip and/or palate is the most prevalent congenital orofacial malformation, with varying incidence rates across different populations (Hadadi et al., 2017). In the Netherlands, the prevalence of cleft lip and/or palate is approximately 16.6 per 10.000 live births (Luijsterburg and Vermeij-Keers, 2011). A bilateral cleft lip and palate (BCLP) occurs in 0.025 % of all new-borns and accounts for about 10 percent of all cleft lip and/or palate patients (Luijsterburg et al., 2014).

In patients with bilateral cleft lip and palate (BCLP), the alveolar clefts lead to premaxilla mobility, with the premaxilla articulating superiorly to the vomer bone. Often, this results in protrusion of the premaxilla due to the absence of the sphincter function of the orbicular oris muscle (Bittermann et al., 2016). One of the aims in cleft care is to achieve a complete upper dental arch, enhancing both aesthetics and function. Depending on the patient's age, defect severity and previous treatments, orthopedic treatments such as naso-alveolar molding, orthodontics or surgery may be indicated (Meazzini et al., 2010). In the most severe forms of BCLP the position of the premaxilla remains anterior and superior compared to the adjacent bone. When favourable results cannot be archieved with orthodontic alignment, a premaxillary osteotomy (PMO) combined with secondary alveolar bone grafting (SABG) can be indicated (Bittermann et al., 2016; Schechter and Shetye, 2024).

The purpose of a PMO combined with SABG is to align the maxilla, enhance the success of oronasal fistula closure and promote the

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integration of alveolar bone grafts (Bittermann et al., 2021). The optimal therapeutic strategy for patients with BCLP remains controversial, and there has been no standard protocol for the type and timing of surgical intervention (Hattori et al., 2023). The timing of the procedure is chosen so that the bone graft can support successful eruption of the canines or the permanent lateral incisors, which results in better residual bone volume and reduces the risk of complications at the end of growth (Bittermann et al., 2020). The gold standard for a secondary bone graft is the use of autogenous cortico-cancellous bone from the anterior iliac crest or chin, due to the osteogenic, osteoinductive and osteoconductive properties (Canady et al., 1993; Janssen et al., 2014). Other options are allografts, xenografts and synthetic bone substitutes, such as calcium phosphate-based scaffold (Bajaj et al., 2003; Aalami et al., 2004; De Ruiter et al., 2014; Sharif et al., 2016). The newly formed bone will allow the canines to erupt naturally or be repositioned through orthodontic treatment (Bittermann et al., 2016).

Previously, fixation of the premaxilla in the new position was generally achieved by attaching a dental splint to the mixed dentition in the adjacent lateral maxilla segments with composite or archwire (Rahpeyma et al., 2016; Bittermann et al., 2020). The stainless-steel splint was manually pre-bent and soldered to fit the patient's dental cast model. With the introduction of 3D technology, the use of 3D virtual surgical planning (3D VSP) has now become standard care for patients undergoing orthognathic surgery (Emmerling et al., 2024). 3D VSP offers multiple advantages in orthognathic surgery, including increased accuracy of the procedure, the ability to simulate diverse approaches and procedure types preoperatively, reduced operative time, fewer complications, enhanced postoperative recovery and more predictable outcomes (Adolphs et al., 2014).

A computer-aided design/computer-aided manufacturing splint (CAD/CAM) splint of the repositioned premaxilla is designed and manufactured, based on the 3D VSP. Despite the widespread use of CAD/CAM and 3D VSP (Schepers et al., 2016), there is a lack of research evaluating the accuracy of 3D VSP in patients with BCLP undergoing PMO with SABG. Therefore, the goal of this study was to evaluate the surgical accuracy of PMO with SABG in patients with BCLP using 3D VSP.

2. Materials and methods

In this retrospective cohort study, all consecutive patients with complete BCLP who underwent a PMO combined with SABG between 2016 and 2023 by the Cleft Team North (the Netherlands) were initially evaluated. All patients were treated according to the national cleft lip and palate protocol. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The inclusion criteria were:

- An available preoperative and postoperative cone beam computed tomography (CBCT) scan of good quality, defined as having high resolution, sharpness and no artifacts that could interfere with image interpretation
- A postoperative CBCT scan made before postoperative orthodontic treatment started
- An available intraoral scan of the dentition or an intraoral scan of digitalized plaster models
- An available preoperative 3D VSP, based on either a preoperative intraoral scan or CBCT plaster cast model, using either ProPlan CMF (Materialise Corporation, Leuven, Belgium) or 3-matic Medical (Materialise, Leuven, Belgium) software

The exclusion criteria were:

- A preoperative and/or postoperative CBCT of poor quality
- A postoperative CBCT scan obtained after starting orthodontic treatment
- Not using a CAD/CAM splint

2.1. 3D virtual surgical planning

In 3D VSP for PMO combined with SABG the preoperative CBCT scanning, along with intraoral scanning or digitizing of plaster dental models is used to segment the premaxilla and reposition it virtually, aiming for the most optimal alignment. Preoperative CBCT scanning, along with intraoral scanning or digitizing of plaster dental models was conducted for all patients. 3D models were obtained using ProPlan or 3-matic software. Repositioning of the premaxilla takes place in the three spatial planes (x - medio-laterally, y - caudo-cranially, z - antero-posteriorly). Rotational adjustments are executed along the x-, y-and z-axes (known as pitch, yaw, and roll respectively) (Fig. 1). The dental CAD/CAM splint is designed against the buccal and occlusal surfaces of the upper dentition, based on the 3D VSP. The data is sent to a specialized CAD/CAM company for the design and production of the titanium splint using 3D printing technology. The CAD/CAM splint has a close fit to the dental arch and is intraoperatively fixated to the teeth using dental composite (Clearfil Majesty flow) or orthodontic wire and is removed three months postoperatively (Fig. 2). Following the procedure, a postoperative CBCT scan is conducted to assess the surgical outcome.

2.2. Data collection

The CBCT scans in this study were obtained using a standardized scanning protocol, with settings of 120 KV, 4/5 mA, and a pixel size and slice thickness of 0.4 mm or smaller. The resulting images are stored in Digital Imaging and Communications in Medicine (DICOM) format. An intraoral scan of the dentition was conducted using either the LavaTM Chairside Oral Scanner (3MTM, ESPETM, St. Paul, USA), producing output files in steroid lithography (STL) format, or digitalized traditional plaster models. The following baseline data were collected: age, sex, date of surgery and days between surgery and postoperative CBCT.

2.3. Analysis of study outcomes

The main outcome variable was the difference between the virtual planned position and the surgical obtained position of the premaxilla in the six degrees of freedom (medio-lateral (x), superior-inferior (y) and anterior-posterior (z) translation (mm) and the pitch, roll and yaw rotations (°)). The second outcome of interest was whether there is a correlation between the planned distance and the corresponding accuracy.

3D analysis of the surgical accuracy was performed according to the following steps:

For the measurements, the 3D VSP model, including the original position of the premaxilla and the planned postoperative position of the premaxilla, along with the postoperative 3D model were superimposed.

First, the postoperative model was generated by superimposing the preoperative intra oral scan to the postoperative CBCT scan. The patient's postoperative CBCT scan and preoperative intra-oral scan (STL-file) were imported into ProPlan CMF 3.0 (Materialise Corporation, Leuven, Belgium). The alignment process was repeated twice, with a minimum interval of one week between measurements, by the same observer, who was not involved in the surgical process in order to allow for intra-observer variability analysis.

Secondly, the 3D VSP model (original position and planned position), along with the postoperative 3D model, were imported in into 3-matic version 18.0 (Materialise, Leuven, Belgium) and aligned using surface-based matching. With the pre-operative maxilla serving as reference as its position remained unchanged in position during the

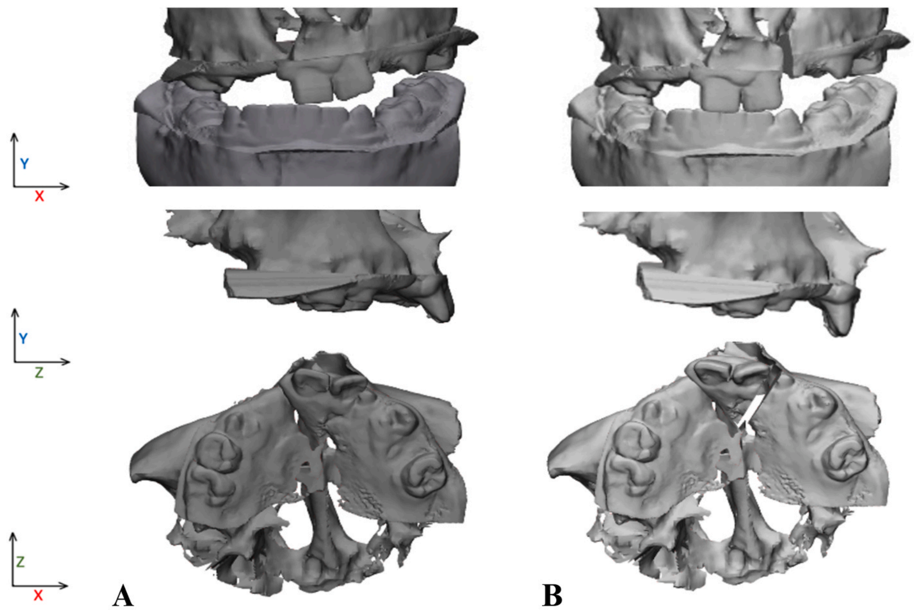

Fig. 1. Bilateral cleft lip and palate 3D model (A, premaxilla in original position; B, premaxilla repositioned with virtual surgical planning for subsequent CAD/CAM splint design.)

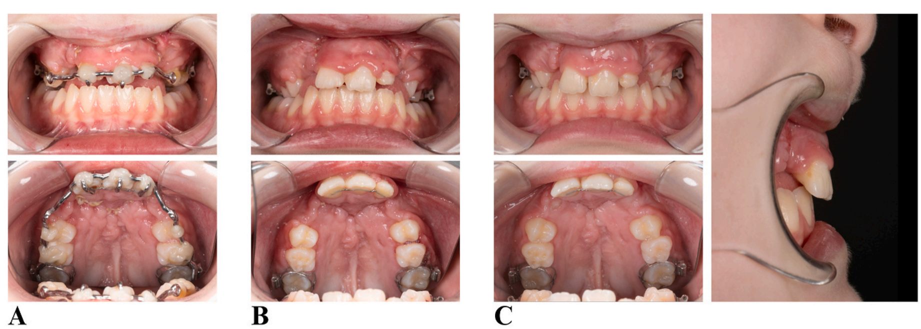

Fig. 2. Postoperative clinical pictures of the repositioned premaxilla (patient 6) (A, one month postoperatively with the computer-aided design/computer aided manufacturing (CAD/CAM) dental splint in place; B, three months postoperatively, after removal of the CAD/CAM splint; C, six months postoperatively.)

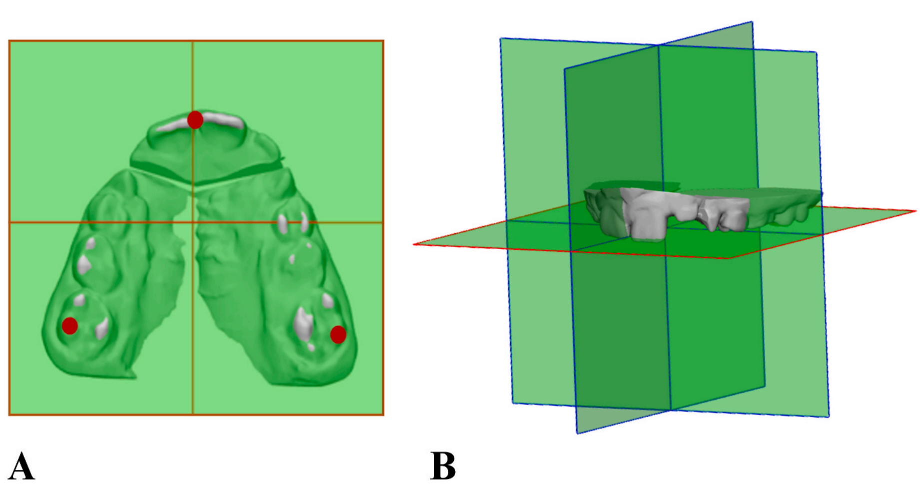

Fig. 3. Coordinate system for measurements (A, occlusal reference plane with landmarks; B, the three planes).

procedure.

To enable measurements between the 3D models within the 3-matic software, a customized coordinate system is manually created based on the surgical planning model. The occlusal plane was identified through the use of specific anatomical landmarks, including the highest points of the distobuccal cusps of the permanent first molars and the incisal edges of the incisors (Ikeda and Yamashita, 2022) (Fig. 3A). Then the sagittal and frontal planes were generated based on the occlusal plane (Fig. 3B).

For linear measurements, the midpoint of the incisal edge of the central incisors (11, 21) serves as a clinically relevant landmark. In addition to the linear measurements in the medio-lateral (x), superior-inferior (y), and anterior-posterior (z) directions in millimeters (mm), the Euclidean distance (mm) for both landmarks between the original and planned position and the planned and postoperative outcome is calculated. The direction of displacement is indicated using negative and positive values.

For angular measurements the rotational error in the sagittal, occlusal, and coronal planes is measured, using the degrees (°) of rotation (pitch, roll, yaw). A reference plane is automatically fit to the premaxilla in 3-matic for the original, planned and postoperative position, selecting the entire mesh. Deviations in these planes are measured both clockwise (+) and counterclockwise (−). For pitch (x), observed from the right side of the maxilla. For yaw (y) from below in the transverse plane and for roll (z) observed from the anterior perspective in the coronal plane.

2.4. Statistics

Statistical analysis was performed in RStudio Version 4.2.3. Descriptive statistics were utilized to explore demographic characteristics of the study population and to determine the mean difference (MD), the mean absolute difference (MAD) and standard deviation (SD) of the accuracy of 3D VSP. The Spearman's correlation coefficient was used to investigate the relationship between the magnitude of displacement and the associated accuracy. The significance level was set at $p < 0.05$. The intra-observer variability, expressed in Euclidean distance (mm) was determined. The intra-observer variability was supported by calculating the Intraclass Correlation Coefficient (ICC), whereby a value of <0.40 is poor, 0.40–0.59 is fair, 0.60–0.74 is good, and 0.75–1.00 is excellent (Cicchetti, 1994). This statistic test is an indicator for the reproducibility of the alignment methodology and the repeatability of the landmark placement. Visual representations of the relationships were displayed through box and whisker plots and a color-coded distance map.

3. Results

Twenty-two patients were initially evaluated. The treatment planning protocol was the same for all patients. Eleven patients were excluded due to the absence of a postoperative CBCT scan (n = 3), not using a 3D VSP CAD/CAM splint (n = 2), missing planning files (n = 2), incomplete radiology data (n = 1), poor quality of the postoperative CBCT (n = 2) and because the postoperative CBCT was taken after the start of orthodontic treatment (n = 1). Eleven patients could eventually be included for analysis.

The cohort was composed of 6 males and 5 females with a mean age at time of surgery of 9.81 ± 1.03 years (8–12 years). The mean time between surgery and CBCT is 43.45 ± 44.48 days (10–136 days). All underwent a PMO combined with SABG with bone from the iliac crest. All procedures were successful and all patients healed uneventful. Patient characteristics are provided in Table 1.

Table 1
Patients included and their relevant parameters. PMO: premaxilla osteotomy.

Patient	Sex	Age	Year	Days between PMO and CBCT
1	female	9	2016	11
2	male	11	2016	11
3	male	10	2018	10
4	male	9	2019	38
5	male	10	2019	136
6	female	8	2020	71
7	female	10	2020	47
8	male	10	2021	11
9	male	12	2021	11
10	female	10	2022	11
11	female	9	2023	121

3.1. Outcomes

The mean difference and mean absolute difference between the original and planned movement and the planned and achieved outcomes of the premaxilla repositioning are presented in Table 2. The highest mean absolute difference for the translational directions between the planned and achieved outcomes was found in the anteroposterior (A/P) (0.89 ± 0.70 mm) plane and in pitch (6.66 ± 5.12°). The highest mean difference between the planned and achieved outcomes was found in the cranio-caudal (S/I) plane (0.26 ± 0.81 mm). The mean difference for pitch (−2.58 ± 8.22°) shows that there is a more counterclockwise position of the premaxilla than planned. The mean linear differences between the planned and the achieved outcome were found to be less than 1 mm. Errors of more than 2 mm were found in 10 % of cases for mediolateral (L/R) translation, 5 % for anterior-posterior (A/P) translation and 0 % for superior-inferior translation. For pitch. 64 % of cases showed an error greater than 4°.

The distribution of the differences between the planned and achieved movements are shown in the box-and-whisker plots below for the absolute mean linear difference, with the data points adjacent to each boxsplot representing the linear measurements of the landmarks (the midpoint of the incisal edge of the central incisors) (Fig. 4) and the absolute mean rotational difference (Fig. 5). The color distance maps of each patient illustrating the difference between the planned and postoperative position of the premaxilla (Fig. 6).

The second outcome of interest was whether there is a correlation between the planned distance and the corresponding accuracy. There is no significant correlation found, given the p-values which are all above 0.05. The intraobserver variability for landmark determination on the 3D model was found to be 0.18 ± 0.14 mm. When the same observer performed two alignments of the 3D model on the postoperative CBCT images with a minimum interval of one week between each assessment, the intraobserver variability was found to be 0.85 ± 0.58 mm. The calculated ICC stands at 0.99. Both indicated a low measurement error and a high intra-rater reliability.

4. Discussion

The aim of this study was to assess the accuracy of 3D VSP for PMO with SABG in patients with BCLP. Accuracy was assessed by virtually comparing the planned and postoperative images of the premaxilla through three linear and three angular measurements. The overall accuracy of the procedure, was found to be less than 1 mm for the three linear movements and less than 7° for the three rotational movements. The euclidean distance between the 3D VSP and the postoperative outcome was 1.6 ± 0.8 mm

The accuracy of 3D VSP has been extensively studied for various orthognathic procedures among non-cleft patients, with clinical criterial for VSP accuracy proposed at <2 mm for linear differences and <4° for angular differences (Hsu et al., 2013; Stokbro et al., 2016; Ritto et al., 2018; Alkhayer et al., 2020). A few studies have compared the accuracy of 3D VSP for Le Fort 1 and bimaxillary osteotomies in class 3 cleft- and non-cleft patients. These studies concluded that the 3D VSP accuracy for cleft patients is almost comparable to that of standard orthognathic procedures, with deviations of less than 2.8 mm and 4° (Wang et al., 2020; Beek et al., 2024; Nys et al., 2023). However, to the best of our

Table 2
The mean difference (MD) and mean absolute difference (MAD) between the original and planned movement and planned and achieved outcomes of the premaxilla repositioning.

		MD ± SD		MAD ± SD	
		Original-planning	Planning-outcome	Original-planning	Planning-outcome
Translational movement (mm)	L/R	−0.82 ± 2.34	−0.18 ± 1.05	1.35 ± 2.06	0.74 ± 0.76
	S/I	0.05 ± 2.71	0.26 ± 0.81	2.07 ± 1.68	0.65 ± 0.53
	A/P	3.07 ± 3.89	−0.13 ± 1.15	3.90 ± 2.99	0.89 ± 0.70
	Euclidean			5.46 ± 2.67	1.57 ± 0.79
Rotational movement (°)	Pitch	−8.76 ± 16.51	−2.58 ± 8.22	16.12 ± 8.46	6.66 ± 5.12
	Yaw	−8.99 ± 16.55	−2.59 ± 6.89	13.0 ± 13.29	5.09 ± 5.14
	Roll	8.94 ± 25.43	−2.15 ± 6.62	14.2 ± 22.64	4.61 ± 5.05

MD, mean difference; MAD, mean absolute difference.
MD: L/R [left (+) or right (−)], S/I [superior (+) or inferior (−)], A/P [anterior (+) or posterior (−)].

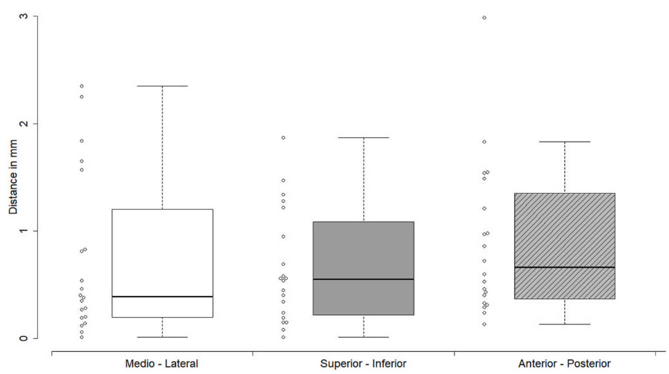

Fig. 4. Linear absolute mean differences (planning versus outcome).

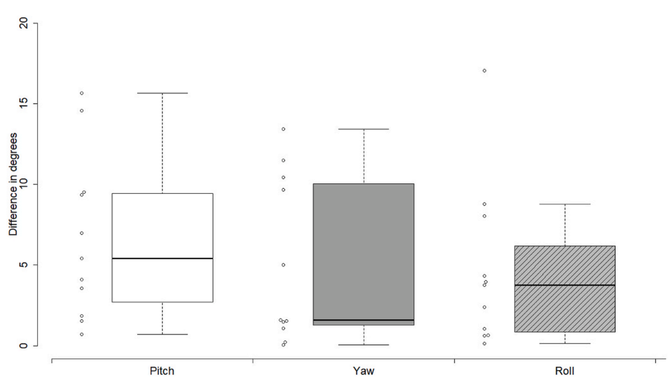

Fig. 5. Rotational absolute mean differences (planning versus outcome).

knowledge, no studies have addressed the accuracy of 3D VSP for PMO combined with SABG for BCLP patients in the current literature.

The anterior/posterior (A/P), cranial-caudal (S/I) translation and pitch rotation have consistently been among the least precise movements in 3D planned orthognathic surgery for both cleft and non-cleft patients (Badiali et al., 2022; Tondin et al., 2022; Nys et al., 2023). This trend is not completely seen in our study: the cranial-caudal (S/I) translation has the best mean absolute linear accuracy (MAD 0.65 ± 0.53 mm), which can be explained by the outliers that are present in the medio-lateral and anterior-posterior planes, which are not observed in the superior-inferior plane. In the medio-lateral (L/R) plane, two outliers of >2 mm are observed and in the antero-posterior (A/P) one large outlier of 2.99 mm is present. No explanation could be found for the outliers. Despite the largest deviation observed in the A/P direction, each linear direction demonstrates an accuracy of less than 1 mm and the Euclidean distance within 2.00 mm. The large planned anterior/posterior (A/P) translation (3.90 ± 2.99) and rotational movement in the pitch (16.12 ± 8.46), suggests a higher likelihood of surgical inaccuracy along this axis. However, this study did not find a statistically significant correlation.

The use of 3D VSP and the CAD/CAM splint is effective in reproducing the position of the reference points (incisal edge), but less effective in controlling angular changes. In this study the difference in pitch was considerably high, with a mean absolute deviation of 6.66°. The MD for pitch (−2.58 ± 8.22°) shows that there is a more counterclockwise rotation of the premaxilla than planned. This higher inaccuracy could possibly be due to the small bone fragment that needs to be repositioned and the anatomy of the palatal part. Another contributing factor could be the attachment of the CAD/CAM splint to the central incisors and lateral sides of the maxilla. This may allow some anteroposterior movement at the top of the premaxilla, resulting in a higher inaccuracy on the x-axis (pitch).

The mean difference (MD) of 0.26 ± 0.81 mm in the cranial-caudal (S/I) translation indicates that, on average, the premaxilla was positioned more superiorly than planned. For PMO, the surgical correction in the vertical direction is more challenging compared to corrections in the posterior, anterior or transverse directions (Padwa et al., 1999). In orthognathic surgery, commonly the vertical height of the upper anterior teeth is measured relative to a fixed point such as the glabella pin (Kraeima et al., 2016). This measurement is not taken in PMO. Additionally, the splint is attached to the lateral parts but not so rigidly that no variation in height is possible. Which may explain this outcome. Another potential issue for the accuracy is that, under the pressure of the often tight upper lip, with bilateral scar tissue, the upper anterior teeth retrude postoperatively after the splint is removed. As a result, the inaccuracy after the splint removal is greater than shortly after the procedure.

The limitations of this study are the small sample size, the retrospective design and the high exclusion rate due to the quality of the postoperative imaging. A PMO with SABG for patients with BCLP is a rare procedure, leading to a scarcity of available data. To determine the procedure's reliability with a high level of confidence, a larger database and fewer exclusions are needed.

The research methodology employed in this study involves the utilization of pre- and postoperative CBCT scans, along with preoperative intra oral scans, to assess the postoperative outcomes. The use of a splint in the surgical procedure introduces scattering artifacts in the postoperative CBCT scans (Minnema et al., 2019). These artifacts affect the quality of the images, leading to potential inaccuracies in the visualization and alignment of anatomical structures. To address this issue, the preoperative intraoral scan is utilized by aligning it with the postoperative CBCT images. However, due to the transitional phase from primary dentition to permanent dentition in patients of this age, and the time gap between the preoperative scans and postoperative CBCT, the ability to accurately evaluate postoperative outcomes may be compromised in such instances.

One option for improving postoperative CBCT quality is the

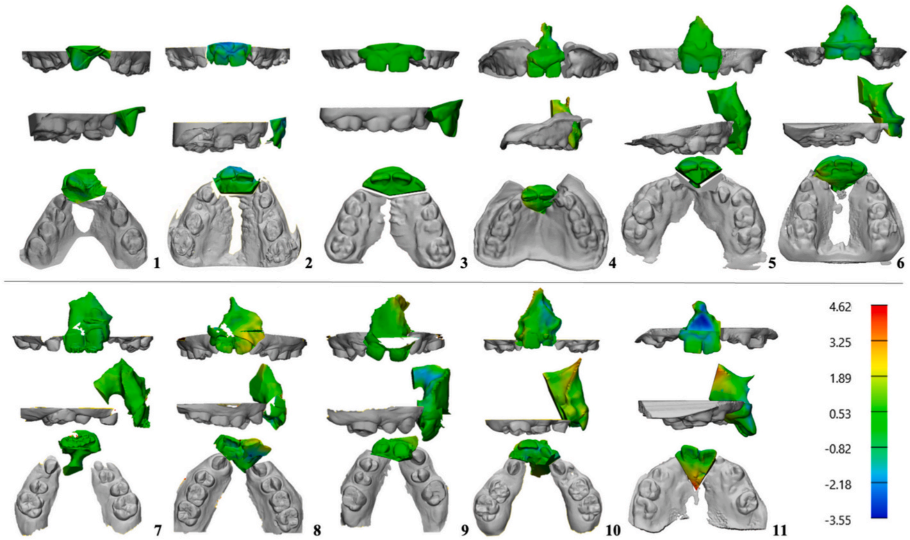

Fig. 6. Color distance map representing the difference in position between the 3D VSP and the postoperative outcome of the premaxilla for each patient in frontal, sagittal and occlusal plane. The scale on the right indicates the variations across the XYZ axes and shows the distance between the 3D VSP and postoperative images with the use of colors (range: −3.55 mm (blue) to 4.63 mm (red). Differences shown by the colors are in the XYZ-planes. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

utilization of artifact removal algorithms specifically designed to target the reduction of artifacts caused by metal or other sources of interference in CBCT images. Studies on the use of artifact removal algorithms show mixed results (Minnema et al., 2019; Goodarzi Pour et al., 2023). For future research, we recommend adding postoperative intraoral scanning as this is the easiest way to improve the accuracy of the measurements. This would further refine the methodology because this approach eliminates inaccuracies caused by the transitional phase of the patients. Furthermore, it allows researchers to gather additional data for analysis without subjecting patients to extra radiation. To obtain a larger cohort within an acceptable period of time, multicenter studies are needed.

The strength of this study is that it addresses a gap in the literature by investigating the accuracy of premaxilla osteotomy, a topic that has not been thoroughly explored in current research and relates the outcomes to routine orthognathic surgery procedures. Secondly, this study uses a methodology where postoperative CBCT scattering has minimal influence in determining accuracy, demonstrating a systematic and innovative approach to the research.

Patients undergo comprehensive orthodontic treatment after PMO with SABG allowing for minor discrepancies to be orthodontically compensated or corrected. While small inaccuracies may have little to no impact on functionality and aesthetics, larger outliers could significantly affect the final outcome for patients with BLCP. Therefore, exploring and understanding the factors that lead to these outliers would be a worthwhile focus for future research.

In a prospective study, further research could be conducted into factors influencing the accuracy of 3D VSP in PMO with SABG, such as previous lip and palate closure, the presence of lateral incisors and additional interventions during the procedure. Moreover, the preoperative orthodontic treatment could possibly influence the accuracy of 3D VSP, as the orthodontic preparation is a crucial factor in successful PMO with SABG (Shirani et al., 2012), as widening the narrow alveolar cleft allows for better surgical access and facilitates earlier grafting of the cleft *(*Kindelan and Roberts-Harry, 1999*)*. It is possible that the use of 3D VSP and a CAD/CAM splint in combination with bone grafting contributes to improved postoperative stability compared to a conventional splint. However, whether this combined approach leads to improves healing outcomes cannot be determined from the current study. Future research could explore the individual and combined effects of VSP and CAD/CAM splints on outcomes, such as graft stability, healing, and osseointegration.

In conclusion, the present study showed that a high surgical accuracy can be achieved, using 3D VSP and CAD/CAM splints for premaxilla osteotomies in patients with bilateral cleft lip and palate. The mean linear difference between planned and achieved outcome differed less than 2 mm. However, the planned rotational movements, especially the pitch, are challenging to achieve.

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References

Aalami, O.O., Wang, J.C., Lenton, K.A., Mathy, J.A., Fong, K.D., Rodrigues, E.D., et al., 2004. Applications of a mouse model of calvarial healing: differences in regenerative abilities of juveniles and adults. Plast. Reconstr. Surg. 114 (3), 713–720. https://doi.org/10.1097/01.prs.0000131016.12754.30.

Adolphs, N., Haberl, E.J., Liu, W., Keeve, E., Menneking, H., Hoffmeister, B., 2014. Virtual planning for craniomaxillofacial surgery–7 years of experience. J. Craniomaxillofac. Surg. 42 (5), e289–e295. https://doi.org/10.1016/j.jcms.2013.10.008.

Alkhayer, A., Piffkó, J., Lippold, C., Segatto, E., 2020. Accuracy of virtual planning in orthognathic surgery: a systematic review. Head Face Med. 16 (1), 34. https://doi.org/10.1186/s13005-020-00250-2.

Badiali, G., Bevini, M., Gulotta, C., Lunari, O., Incerti Parenti, S., Pironi, M., Bianchi, A., Felice, P., Marchetti, C., 2022. Three-dimensional cephalometric outcome predictability of virtual orthodontic-surgical planning in surgery-first approach. Prog. Orthod. 23 (1), 51. https://doi.org/10.1186/s40510-022-00448-x.

Bajaj, A.K., Wongworawat, A.A., Punjabi, A., 2003. Management of alveolar clefts. J. Craniofac. Surg. 14 (6), 840–846. https://doi.org/10.1097/00001665-200311000-00005.

Beek, D.M., Visser, D.J., Chen, Y.H., Baan, F., Nienhuijs, M., Xi, T., 2024. Is there a difference in surgical accuracy following bimaxillary surgery between cleft and non-cleft patients? Clin. Oral Invest. 28 (1), 112. https://doi.org/10.1007/s00784-024-05517-5.

Bittermann, G.K., de Ruiter, A.P., Janssen, N.G., Bittermann, A.J., van der Molen, A.M., van Es, R.J., Rosenberg, A.J., Koole, R., 2016. Management of the premaxilla in the treatment of bilateral cleft of lip and palate: what can the literature tell Us? Clin. Oral Invest. 20 (2), 207–217. https://doi.org/10.1007/s00784-015-1589-y.

Bittermann, G.K., van Es, R.J., de Ruiter, A.P., Frank, M.H., Bittermann, A.J., van der Molen, A.B., Koole, R., Rosenberg, A.J., 2020. Incidence of complications in secondary alveolar bone grafting of bilateral clefts with premaxillary osteotomy: a retrospective cohort study. Clin. Oral Invest. 24, 915–925.

Bittermann, G.K., van Es, R.J., de Ruiter, A.P., Bittermann, A.J., Koole, R., Rosenberg, A. J., 2021. Retrospective analysis of clinical outcomes in bilateral cleft lip and palate patients after secondary alveolar bone grafting and premaxilla osteotomy, using a new dento-maxillary scoring system. J. Craniomaxillofac. Surg. 49 (2), 110–117. https://doi.org/10.1016/j.jcms.2020.12.006.

Canady, J.W., Zeitler, D.P., Thompson, S.A., Nicholas, C.D., 1993. Suitability of the iliac crest as a site for harvest of autogenous bone grafts. Cleft Palate Craniofac. J. 30 (6), 579–581. https://doi.org/10.1597/1545-1569_199_030_0579_sotica_2.3.co_2.

Cicchetti, D., 1994. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instrument in psychology. Psychol. Assess. 6, 284–290.

De Ruiter, A.P., Dik, E., Van Es, R., et al., 2014. Micro-structured calcium phosphate ceramic for donor site repair after harvesting Chin bone for grafting alveolar clefts in children. J. Cranio-Maxillofacial Surg. 42, 460–468.

Emmerling, M.R., Shah, B., Ginzburg, M., 2024. Virtual surgical planning in orthognathic surgery. Curr Surg Rep 12, 26–35. https://doi.org/10.1007/s40137-024-00384-1.

Goodarzi Pour, D., Emami Meybodi, E., Sodagar, K., Emami Meybodi, Z.A., Safari, S., 2023. Effect of metal artifact removal modes on the accuracy of linear measurement around titanium implants by applying different voltages: an original article. BMC Med. Imag. 23 (1), 74. https://doi.org/10.1186/s12880-023-01025-2.

Hadadi, A.I., Al Wohaibi, D., Almtrok, N., Aljahdali, N., AlMeshal, O., Badri, M., 2017. Congenital anomalies associated with syndromic and non-syndromic cleft lip and palate. JPRAS open 14, 5–15.

Hattori, Y., Pai, B.C.J., Saito, T., Chou, P.Y., Lu, T.C., Chang, C.S., et al., 2023. Long-term treatment outcome of patients with complete bilateral cleft lip and palate: a retrospective cohort study. Int. J. Surg. 109 (6), 1656–1667.

Hsu, S.S., Gateno, J., Bell, R.B., Hirsch, D.L., Markiewicz, M.R., Teichgraeber, J.F., Zhou, X., Xia, J.J., 2013. Accuracy of a computer-aided surgical simulation protocol for orthognathic surgery: a prospective multicenter study. J. Oral Maxillofac. Surg. 71 (1), 128–142. https://doi.org/10.1016/j.joms.2012.03.027.

Ikeda, K., Yamashita, S., 2022. A study for determining the inclination of the occlusal plane from the mandibular functional trajectory. Int. J. Dent. 2022, 6713881. https://doi.org/10.1155/2022/6713881. PMID: 35815116; PMCID: PMC9270148.

Janssen, N.G., Weijs, W.L., Koole, R., Rosenberg, A.J., Meijer, G.J., 2014. Tissue engineering strategies for alveolar cleft reconstruction: a systematic review of the literature. Clin. Oral Invest. 18 (1), 219–226. https://doi.org/10.1007/s00784-013-0947-x.

Kindelan, J., Roberts-Harry, D., 1999. A 5-year post-operative review of secondary alveolar bone grafting in the yorkshire region. Br J. Orthod. 26 (3), 211–217. https://doi.org/10.1093/ortho/26.3.211.

Kraeima, J., Jansma, J, Schepers, R.H., 2016. Splintless surgery: does patient-specific CAD-CAM osteosynthesis improve accuracy of Le Fort I osteotomy? Br J Oral Maxillofac Surg 54 (10), 1085–1089. https://doi.org/10.1016/j.bjoms.2016.07.007.

Luijsterburg, A.J., Vermeij-Keers, C., 2011. Ten years recording common oral clefts with a new descriptive system. Cleft Palate Craniofac. J. 48 (2), 173–182. https://doi.org/10.1597/08-150. Epub 2010 Apr 23. PMID: 20500079.

Luijsterburg, A.J.M., Trenning, A.H., Ongkosuwito, E.M., et al., 2014. NVSCA - Registration Cleft Lip and Palate Annual Report. Dutch teams, Dutch Association for Cleft and Craniofacial Anomalies, pp. 1–21, 2014.

Meazzini, MariaCostanza, Lematti, Lara, Mazzoleni, Fabio, Rabbiosi, Dimitri, Bozzetti, Alberto, Brusati, Roberto, 2010. Vertical excess of the premaxilla in bilateral cleft lip and palate patients: a protocol for treatment. J. Craniofac. Surg. 21 (2), 499–502. https://doi.org/10.1097/SCS.0b013e3181cffb4d.

Minnema, J., van Eijnatten, M., Hendriksen, A.A., Liberton, N., Pelt, D.M., Batenburg, K. J., Forouzanfar, T., Wolff, J., 2019. Segmentation of dental cone-beam CT scans affected by metal artifacts using a mixed-scale dense convolutional neural network. Med. Phys. 46 (11), 5027–5035. https://doi.org/10.1002/mp.13793.

Nys, M., Bempt, M.V.D., Shaheen, E., Dormaar, J.T., Politis, C., 2023. Three-dimensional planning accuracy and follow-up of Le Fort I osteotomy in cleft lip/palate patients. J. Stomatol. Oral Maxillofac. Surg. 124 (4), 101421. https://doi.org/10.1016/j.jormas.2023.101421.

Padwa, B.L., Sonis, A., Bagheri, S., Mulliken, J.B., 1999. Children with repaired bilateral cleft lip/palate: effect of age at premaxillary osteotomy on facial growth. Plast. Reconstr. Surg. 104 (5), 1261–1269. https://doi.org/10.1097/00006534-199910000-00004.

Ritto, F.G., Schmitt, A.R.M., Pimentel, T., Canellas, J.V., Medeiros, P.J., 2018. Comparison of the accuracy of maxillary position between conventional model surgery and virtual surgical planning. Int. J. Oral Maxillofac. Surg. 47 (2), 160–166. https://doi.org/10.1016/j.ijom.2017.08.012.

Rahpeyma, A., Khajehahmadi, S., Ghasemi, A., 2016 Apr. Premaxillary osteotomy fixation in bilateral cleft lip/palate: Introducing a new technique. Asian J. Surg. 39 (2), 90–95. https://doi.org/10.1016/j.asjsur.2015.03.016. Epub 2015 Jun 29. PMID: 26138519.

Schechter, J., Shetye, P.R., 2024. Orthodontic treatment of patients with cleft lip and palate from birth through maturity. Semin. Orthod. https://doi.org/10.1053/j.sodo.2024.09.006.

Schepers, R.H., van de Velde, W.L., van Minnen, B., 2016. The three-dimensional printed dental splint in the surgical treatment of malocclusion after polytrauma. Ned. Tijdschr. Tandheelkd. 123 (1), 19–23. https://doi.org/10.5177/ntvt.2016.01.15132.

Sharif, F., Ur, Rehman I., Muhammad, N., MacNeil, S., 2016. Dental materials for cleft palate repair. Mater. Sci. Eng. C Mater. Biol. Appl. 61, 1018–1028. https://doi.org/10.1016/j.msec.2015.12.019.

Shirani, G., Abbasi, A.J., Mohebbi, S.Z., 2012. Need for revision surgery after alveolar cleft repair. J. Craniofac. Surg. 23 (2), 378–381. https://doi.org/10.1097/SCS.0b013e318240fe7f.

Stokbro, K., Aagaard, E., Torkov, P., Bell, R.B., Thygesen, T., 2016. Surgical accuracy of three-dimensional virtual planning: a pilot study of bimaxillary orthognathic procedures including maxillary segmentation. Int. J. Oral Maxillofac. Surg. 45 (1), 8–18. https://doi.org/10.1016/j.ijom.2015.07.010.

Tondin, G.M., Leal, M.O.C.D., Costa, S.T., Grillo, R., Jodas, C.R.P., Teixeira, R.G., 2022. Evaluation of the accuracy of virtual planning in bimaxillary orthognathic surgery: a systematic review. Br. J. Oral Maxillofac. Surg. 60 (4), 412–421. https://doi.org/10.1016/j.bjoms.2021.09.010.

Wang, Y., Li, J., Xu, Y., Huang, N., Shi, B., Li, J., 2020. Accuracy of virtual surgical planning-assisted management for maxillary hypoplasia in adult patients with cleft lip and palate. J. Plast. Reconstr. Aesthetic Surg. 73 (1), 134–140. https://doi.org/10.1016/j.bjps.2019.07.003.