Evaluation of a Fully Digital, In-House Virtual Surgical Planning Workflow for Bimaxillary Orthognathic Surgery

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Background: The advantages of virtual surgical planning (VSP) for orthognathic surgery are clear. Previous studies have evaluated in-house VSP; however, few fully digital, in-house protocols for orthognathic surgery have been studied.

Purpose: The purpose of this study was to evaluate the difference between the virtual surgical plan and actual surgical outcome for orthognathic surgery using a fully digital, in-house VSP workflow.

Study Design, Setting, Sample: This is a prospective cohort study from September 2020 to November 2022 of patients at the Victoria General Hospital in Halifax, NS, Canada who underwent bimaxillary orthognathic surgery. Patients were excluded if they had previously undergone orthognathic surgery or were diagnosed with a craniofacial syndrome.

Main Outcome Variables: The primary outcome variables were the mean 3-dimensional (3D) (Euclidean) distance error, as well as mean error and mean absolute error in the transverse (x axis), vertical (y axis), and anterior-posterior (z axis) dimensions.

Covariates: Covariates included age, sex, and surgical sequence (mandible-first or maxilla-first).

Analyses: The primary outcome was tested using Z and *t* critical value confidence intervals. The *P* value was set at .05. The 3D distance error for mandible-first and maxilla-first groups was compared using a 2-sample *t*-test as well as analysis of variance.

Results: The study sample included 52 subjects (24 males and 28 females) with a mean age of 27.7 (± 12.1) years. Forty three subjects underwent mandible-first surgery and 9 maxilla-first surgery. The mean absolute distance error was largest in the anterior-posterior dimension for all landmarks (except posterior nasal spine, left condyle, and gonion) and exceeded the threshold for clinical acceptability (2 mm) in 16 of 23 landmarks. Additionally, mean distance error in the anterior-posterior dimension was negative for all landmarks, indicating deficient movement in that direction. The effect of surgical sequence on 3D distance error was not statistically significant (*P* = .37).

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Conclusion and Relevance: In general, the largest contributor to mean 3D distance error was deficient movement in the anterior-posterior direction. Otherwise, mean absolute distance error in the vertical and transverse dimensions was clinically acceptable (< 2 mm). These findings were felt to be valuable for treatment planning purposes when using a fully digital, in-house VSP workflow.

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Orthognathic surgery is a highly complex procedure, and a meticulous surgical plan is critical to the success of the operation. Virtual surgical planning (VSP) has modernized the process of surgical planning and simulation for orthognathic surgery with the use of 3-dimensional (3D) imaging, digital occlusal records, and specialized planning software. With this technique, clinicians can analyse and manipulate the maxillomandibular complex virtually in 3 dimensions. VSP has also enabled the use of computer-aided design and manufacturing of occlusal splints, patient-specific guides, and patient-specific implants (PSIs) to more accurately reproduce the virtual plan in the operating room.

The benefits of VSP for orthognathic surgery have been well established in the literature. Several studies comparing the accuracy of VSP with computer-aided design and manufacturing splints to conventional model surgery have shown that VSP is comparable or more accurate.[1-4] The accuracy of VSP has been especially noted in cases involving a facial asymmetry.[3] Additionally, the operative time tends to be significantly less with VSP than with conventional planning due to the ability to use patient-specific surgical guides.[5]

Currently, several methods exist for implementing computer-aided surgical simulation for orthognathic surgery using patient-specific guides. One common and resource-efficient approach is the use of occlusal splints. In bimaxillary orthognathic surgery, an "intermediate splint" positions the first osteotomized jaw according to the native position of the opposing jaw. A "final splint" is then used to establish the final maxillomandibular relationship. Some authors have proposed using a combination of occlusal splints as well as cutting and positioning templates to more accurately reproduce the virtual plan.[6] Another variation involves 3D printing–simulated postoperative skulls and prebending plates, which are later sterilized and used to position the maxilla during surgery. A further customized protocol involves the use of PSIs. In this technique, drill/cutting guides and a single custom PSI (plate) are used for maxillary repositioning, eliminating the need for an intermediate splint altogether.[7-12] Recent studies have suggested that PSIs are more accurate in reproducing the virtual plan than occlusal splints alone for orthognathic surgery.[7,12,13] Despite the accuracy, PSIs are significantly more expensive than other techniques.

Many of the VSP protocols described previously rely on a third-party company to facilitate the planning process. The main limitations of this protocol are the additional time required to manufacture and transport the surgical guides, as well as the increased cost to the surgeon and/or patient.[14] To circumvent the need for a third party, "in-house" VSP protocols for surgical planning have been suggested. In 2021, Mascarenhas et al described an efficient in-house 3D printing technique for single-jaw orthognathic surgery that took less than 5 minutes to design a surgical splint.[15] In 2020, De Riu et al described a new protocol for in-house management of computer-assisted simulation for bimaxillary orthognathic surgery.[16] This protocol involved pouring stone models, importing a CBCT of the models into an open-source software for processing, then using a second imaging software for surgical simulation. Many authors have evaluated the accuracy of similar in-house VSP techniques;[1,17-19] however, few fully digital in-house protocols have been discussed for bimaxillary orthognathic surgery.

The purpose of this study was to evaluate the difference between the virtual surgical plan and actual surgical outcome using a fully digital, in-house VSP workflow for orthognathic surgery. The investigators hypothesized that this protocol could provide a mean absolute error of less than 2 mm, a commonly used threshold for clinical acceptability.[20] The specific aim of this study was to measure the 3D distance error, as well as the mean error and mean absolute error in the transverse, vertical, and anterior-posterior dimensions, for a series of landmarks between the virtual surgical plan and the actual surgical outcome.

Materials and Methods

STUDY DESIGN

This prospective cohort study recruited patients undergoing orthognathic surgery for the correction of a dentofacial deformity between September 2020 and November 2022. The study was reviewed and approved by the institutional ethics committee, the Nova Scotia Health Authority Research Ethics Board.

SAMPLE

All patients who were scheduled to undergo orthognathic surgery at the Department of Oral and Maxillofacial Surgery at the Victoria General Hospital in Halifax, NS, Canada (Dalhousie University) were invited to participate in the study. Inclusion criteria were patients requiring both maxillary and mandibular surgery (with or without genioplasty), patients undergoing concurrent orthodontic treatment with conventional fixed appliances, and patients undergoing concurrent orthodontic treatment with clear aligner appliances. Patients were excluded if they had previously undergone orthognathic surgery or were diagnosed with a craniofacial syndrome. Patients were invited to participate in the study at the time of their preadmission appointment. All potential benefits and harms related to the study were reviewed and a formal informed consent agreement was signed.

VARIABLES

The primary outcome variable was the mean 3D (Euclidean) distance error as well as the mean error and mean absolute error in the transverse (x axis), vertical (y axis), and anterior-posterior (z axis) dimensions between the actual surgical movement and the virtual surgical plan for each landmark. The mean 3D distance error was calculated as follows:

$$Mean\ 3D\ Distance\ Error = \frac{1}{n}\sum_{k=1}^{n}\sqrt{\left(x_{operation,k} - x_{VSP,k}\right)^2 + \left(y_{operation,k} - y_{VSP,k}\right)^2 + \left(z_{operation,k} - z_{VSP,k}\right)^2} \quad (1)$$

Covariates included age, sex, and surgical sequence (mandible-first or maxilla-first).

Data Collection Methods

The preoperative planning protocol involved a preadmission appointment within 1 to 2 weeks of the surgery date. A detailed examination of the maxillofacial complex was performed and preoperative records were obtained including a panoramic and lateral cephalometric radiograph, a CBCT image (i-CAT FLX V17; DEXIS dental imaging solutions, Quakertown, PA, USA), and a digital impression using an intraoral scanner (Primescan; Dentsply Sirona, Charlotte, NC, USA). CBCTs were obtained using a pre-established protocol that included a 0.3 mm voxel size and 23 × 17 cm field of view image (DAP: 877.6 mGy-cm^2) taken with the patient in maximum intercuspation in the natural head position. The natural head position was achieved by asking the patient to sit upright, looking straight ahead toward a mirror at eye level on the opposing wall.[21]

The CBCT (DICOM dataset) and intraoral scan (STL file) were then imported into a planning program (Dolphin Imaging v11.95 and v12 beta; Patterson Dental, Saint Paul, MN, USA). First, the digital model was superimposed onto the 3D volume using a combination of the auto superimpose function and manual manipulation. The final position of the superimposition was then verified in 3 planes using the slice views. Next, the orthognathic surgery planning module was used to setup and plan the surgery in a stepwise fashion. Steps 1 through 5 involved cropping and clean-up of the STL-converted volume, followed by osteotomizing the jaws and landmark identification (Fig 1). These steps were carried out by a member of the surgical resident team. The final occlusion was set virtually as well as the desired surgical movements based on a Delaire analysis of the lateral cephalometric radiograph.[22] These steps were carried out by the operating resident and reviewed by the staff surgeon. The intermediate and final occlusal splints where then designed in step 8 of the module by the first-year surgical resident.

The finalized splints (STL files) were then optimized for printing with a print preparation program (Preform; Formlabs, Somerville, MA, USA) and printed with an SLA 3D printer (Form 3B; Formlabs, Somerville, MA, USA). Postprint processing included washing (Form Wash; Formlabs, Somerville, MA, USA) and curing (Form Cure; Formlabs, Somerville, MA, USA) of the parts. Finishing and polishing of the parts was carried out by a surgical resident.

All study subjects underwent LeFort I osteotomies (single-piece or multipiece) and bilateral sagittal split osteotomies. Some also underwent a genioplasty if indicated. The surgeries were carried out in the operating room (Victoria General Hospital, Halifax, NS, Canada) under general anesthesia by 1 of the 5 staff surgeons at the Department of OMFS at Dalhousie University and a resident. The prefabricated intermediate splint was used to stabilize the intermediate position for plating. Both mandible-first and maxilla-first approaches were used, depending on the virtual surgical plan. The final splint was then used to stabilize the

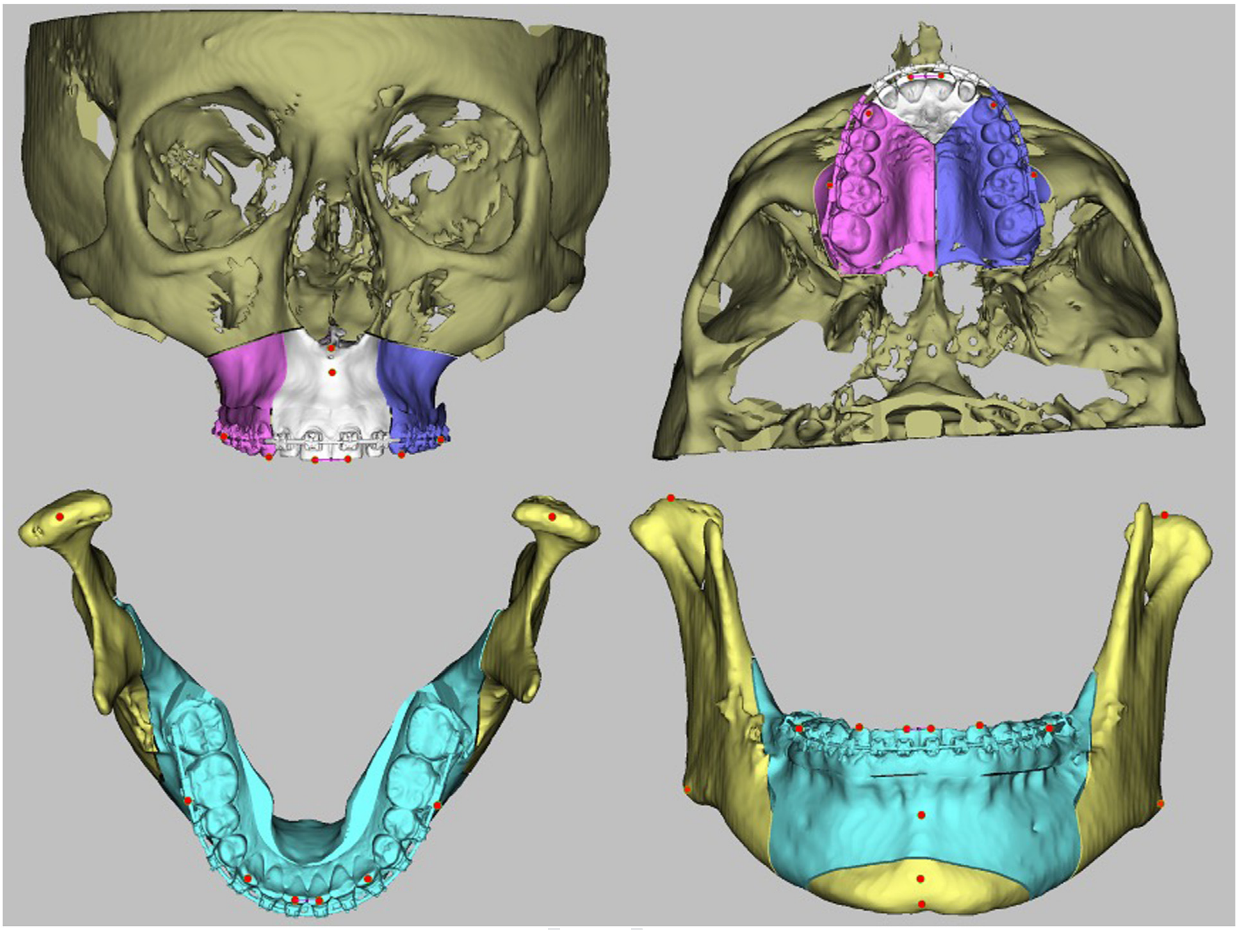

FIGURE 1. The 23 landmarks used to evaluate the postoperative outcome.

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final occlusion for plating. LeFort I osteotomies were fixated with 2.0 mm KLS Martin titanium plates at the level of the nasal aperture and either 2.0 mm KLS Martin plates or wire osteosynthesis at the zygomatic buttresses. Bilateral sagittal split osteotomies were fixated with crescent-shaped 2.0 mm KLS Martin titanium plates. Study subjects were then placed into maxillomandibular fixation with the final splint in place using orthodontic elastics for a period of 2 to 4 weeks postoperatively.

The follow-up protocol generally involved an appointment at 2, 4, and 6 weeks postoperatively. The occlusal splint was removed at either 2 or 4 weeks and a postoperative CBCT was obtained at the same appointment. The same protocol for obtaining the preoperative CBCT was used. The postoperative CBCT DICOM data were then imported once again into Dolphin Imaging software for analysis. The complete workflow for data collection and analysis is illustrated in Figure 2.

The postoperative analysis involved 2 broad steps: registration of the postoperative volume and landmarking of both the preoperative and postoperative volumes. First, registration of the postoperative volume to the preoperative volume was accomplished using a validated, semiautomated, voxel-based superimposition based on the cranial base[23,24] (Fig 3). Next, a series of 23 predefined cephalometric landmarks were labelled using a standardized protocol on the preoperative virtual plan, as well as both the preoperative and postoperative volumes by 2 of 3 independent observers (A.S., T.C., and D.G.). The first 15 cases were landmarked twice by each observer (A.S. and D.G.) on separate occasions for intraobserver reliability calculation purposes.

Evaluation of the preoperative virtual plan involved landmarking in a retroactive fashion in step 5 of the orthognathic surgery planning module by 1 of the 3 independent observers to ensure it was completed according to the standardized landmarking protocol. These landmarks were then automatically carried forward to the previously established virtual surgical plan in step 6 of the planning module. The landmark offsets (planned surgical movements) in 3 dimensions

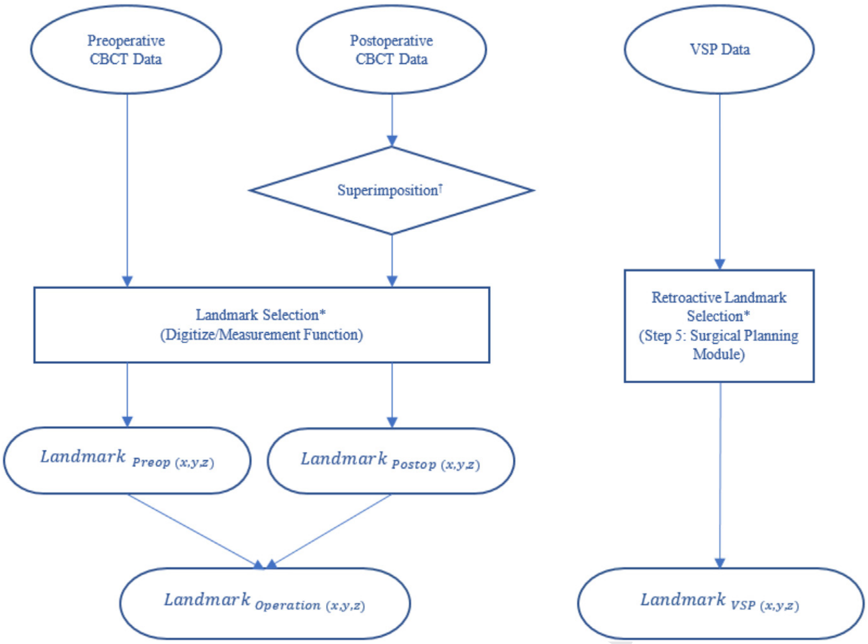

FIGURE 2. Data collection and analysis workflow. † Semiautomated, voxel-based superimposition of the postoperative volume onto the preoperative volume. * 23 cephalometric landmarks using a standardized protocol. Q13

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for each of the landmarks were then exported from the Landmark Offset and Measurement Tables in the form of a linear distance in millimeters.

Evaluation of the postoperative outcome involved landmarking of the preoperative and postoperative volumes using the same standardized protocol. The position of the landmarks in 3 dimensions was then exported from both volumes in the form of x, y, and z coordinates in millimeters. The difference between the postoperative and preoperative landmarks was calculated giving the actual surgical movements in the form of a linear distance in millimeters. For subjects who underwent a genioplasty, landmarks B-point, gnathic, menton, and pogonion were excluded as these were obscured by hardware artifact.

DATA ANALYSES

All statistical analyses were carried out by the Department of Mathematics and Statistics at Dalhousie University, Halifax, NS. A sample size calculation was performed for the mean 3D distance error to detect an error of 2 mm between the planned and actual landmarks with an alpha error of < 0.05 and beta error of 0.2. The sample size needed for statistical power was calculated for each landmark and a sample size of 50 was adequate for most landmarks, including the maxillary central incisor. The results for the sample size calculation are presented in Appendix 1. The interobserver and intraobserver reliability for manual landmark labelling were assessed using the intraclass correlation coefficient (ICC). A 2-way mixed consistency model (ICC [3, 1]) was selected as multiple observers provided measurements on the same subjects, the raters were considered to be a fixed set of raters, and generalization of the results to other raters was not of interest. An ICC between 0.5 and 0.75 represented moderate reliability, between 0.75 and 0.9 represented good reliability, and more than 0.9 was considered excellent. The mean absolute interobserver and intraobserver measurement error was also calculated. The primary outcomes were assessed using a Z critical value confidence interval for the mean 3D distance error as well as the distance error and absolute distance error in the transverse, vertical, and anterior-posterior dimensions across all subjects. A 95% confidence interval was used. A t critical value confidence interval was used to assess the mean 3D distance error for the mandible-first surgery and maxilla-first surgery groups. Once again, a 95% confidence interval was used. In keeping with the literature, a mean absolute error of 2 mm was considered to be the threshold for clinical acceptability.[20] The effect of surgical sequence on 3D distance error was tested using a 2-sample t-test as well as analysis of variance.

Results

PATIENT CHARACTERISTICS

The study sample consisted of 52 subjects (24 males and 28 females) who underwent bimaxillary

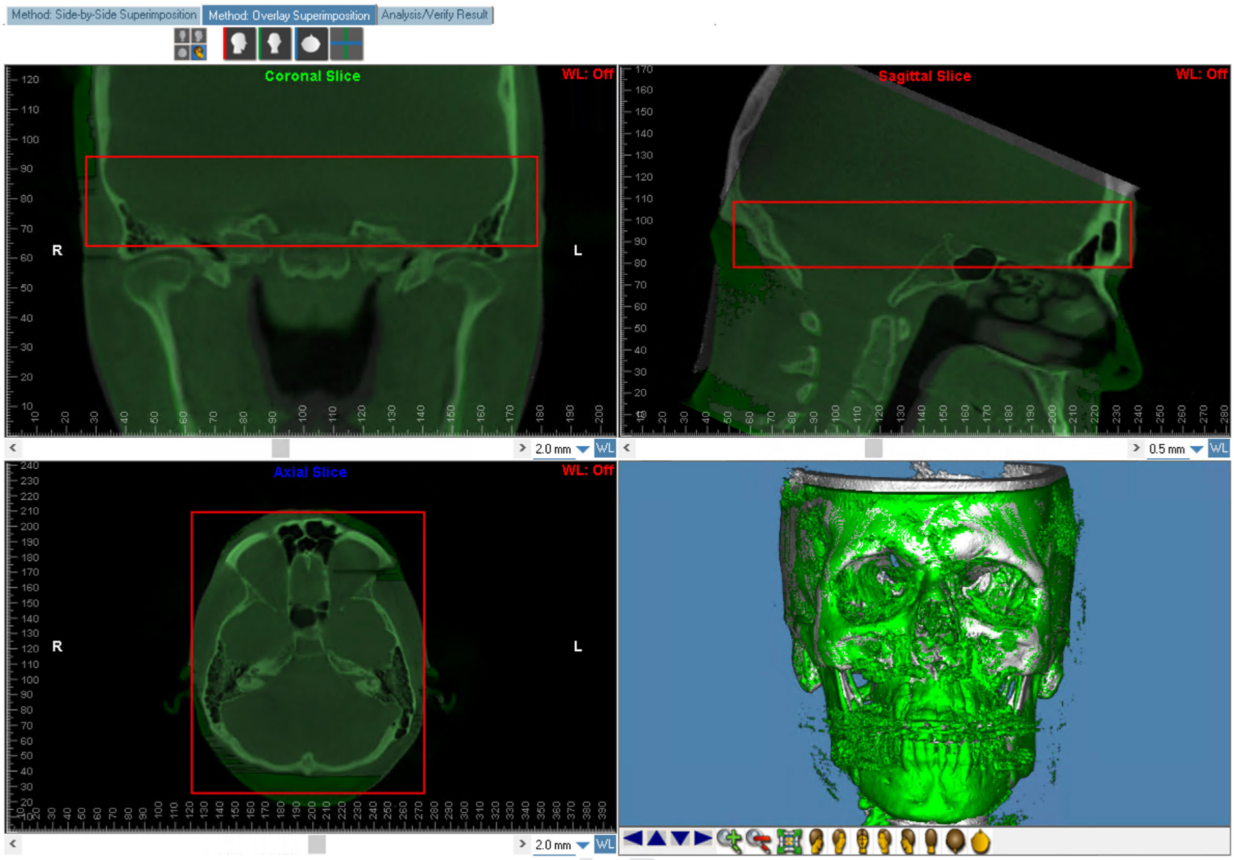

FIGURE 3. Voxel-based superimposition of the postoperative volume onto the preoperative volume.

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orthognathic surgery. The mean age of the sample was 27.7 years with ages ranging from 15 to 65 years. Of these, 11 underwent segmental Lefort osteotomies and 14 underwent concurrent genioplasty. Forty three subjects underwent a mandible-first surgical sequence and nine underwent a maxilla-first surgical sequence. Five subjects underwent maxillomandibular advancement for obstructive sleep apnea.

INTEROBSERVER AND INTRAOBSERVER RELIABILITY

The evaluation of inter-rater and intrarater reliability for landmark labelling is presented in Table 2. The ICC ranged from moderate to excellent and the mean absolute measurement error ranged from 0.37 to 0.52 mm in the transverse dimension, 0.35 to 0.93 mm in the vertical dimension, and 0.43 to 0.69 mm in the anterior-posterior dimension.

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Table 1. PATIENT DEMOGRAPHICS AND OPERATION SEQUENCE

	Operation Sequence			
Study Variable	Mandible-First	Maxilla-First	Total (%)	*P* Value
Sex (%)				
Male	20 (38.5)	4 (7.7)	24 (46.2)	
Female	23 (44.2)	5 (9.6)	28 (53.8)	
Total	43 (82.7)	9 (17.3)	52 (100)	.76
Mean Age (± SD)	27.7 ± 11.3	27.7 ± 16.5	27.7 ± 12.1	.15

Abbreviations: SD, standard deviation.

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Table 2. INTER-RATER AND INTRARATER RELIABILITY FOR LANDMARK LABELLING

	Intrarater Reliability (DG1 and DG2)		Inter-Rater Reliability (DG1 and AS)		Inter-Rater Reliability (DG1 and TC)	
Dimension	ICC[*]	Abs. (mm)[†]	ICC[*]	Abs. (mm)[†]	ICC[*]	Abs. (mm)[†]
X	0.89	0.37	0.80	0.52	0.83	0.38
Y	0.94	0.35	0.93	0.93	0.74	0.57
Z	0.93	0.44	0.94	0.67	0.92	0.43

* Intraclass correlation coefficient. ICC values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values more than 0.90 indicate excellent reliability.

† Absolute measurement error mean in millimeters.

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Primary Outcomes

MEAN 3D DISTANCE ERROR

The Z critical value confidence interval for the mean 3D distance error for each landmark across all subjects is presented in Table 3. The mean 3D distance error was smallest for the left and right condyle landmarks, which were 1.72 and 1.68 mm, respectively. The mean 3D distance error for dental landmarks ranged from 2.79 mm at the left mandibular canine to 3.15 mm at the right maxillary molar. For the left and right maxillary central incisors, the mean 3D distance error was 2.86 and 2.93 mm, respectively. The mean 3D distance error was largest for the bony landmarks and ranged from 3.23 mm at menton to 4.59 mm at anterior nasal spine (ANS).

MEAN DISTANCE ERROR

The Z critical value confidence interval for the mean distance error for each landmark in the transverse, vertical, and anterior-posterior dimensions across all subjects is presented in Table 4 and Table 5 for maxillary and mandibular landmarks, respectively. The mean distance error was negative in the anterior-posterior dimension (z axis) for all landmarks and this result was statistically significant for all landmarks except gnathion (P = .07), menton (P = .06), and pogonion (P = .06).

MEAN ABSOLUTE DISTANCE ERROR

The Z critical value confidence interval for the mean absolute distance error for each landmark in the transverse, vertical, and anterior-posterior dimensions across all subjects is presented in Table 6 and Table 7 for maxillary and mandibular landmarks, respectively. The mean absolute distance error was largest in the anterior-posterior dimension (z axis) for all landmarks except posterior nasal spine, left condyle, and gonion (left and right). For the maxillary central incisors, the mean absolute distance error was less than 1 mm in the vertical dimension (y axis) and less than 2 mm in the transverse (x axis) and anterior-posterior dimensions (z axis).

Table 3. LANDMARK VERSUS MEAN 3D DISTANCE ERROR ACROSS ALL SUBJECTS

	Landmark	Mean (mm)[†]	95% CI[‡]
L1	A-point	4.03	[3.55, 4.50]
L2	ANS	4.59	[3.97, 5.20]
L3	PNS	3.39	[3.01, 3.78]
L4	Mx Canine (L)	2.81	[2.42, 3.20]
L5	Mx Canine (R)	2.86	[2.49, 3.24]
L6	Mx Molar (L)[*]	3.05	[2.63, 3.47]
L7	Mx Molar (R)[*]	3.15	[2.79, 3.52]
L8	Mx Incisor (L)[§]	2.86	[2.49, 3.23]
L9	Mx Incisor (R)[§]	2.93	[2.54, 3.33]
L10	B-point	3.24	[2.72, 3.75]
L11	Condyle (L)	1.72	[1.41, 2.04]
L12	Condyle (R)	1.68	[1.39, 1.98]
L13	Gnathion	3.29	[2.76, 3.81]
L14	Gonion (L)	3.64	[3.02, 4.26]
L15	Gonion (R)	4.22	[3.46, 4.98]
L16	Md Canine (L)	2.79	[2.39, 3.19]
L17	Md Canine (R)	3.08	[2.68, 3.49]
L18	Md Molar (L)[*]	3.05	[2.64, 3.45]
L19	Md Molar (R)[*]	3.12	[2.70, 3.55]
L20	Md Incisor (L)[§]	2.97	[2.60, 3.35]
L21	Md Incisor (R)[§]	2.93	[2.55, 3.31]
L22	Menton	3.23	[2.68, 3.77]
L23	Pogonion	3.36	[2.82, 3.89]

Abbreviations: ANS, anterior nasal spine; CI, confidence interval; L, left; Md, mandibular; Mx, maxillary; PNS, posterior nasal spine; R, right.

* First molar.

† Mean of the 95% confidence interval expressed in millimeters.

‡ Z critical value confidence interval.

§ Central incisor.

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MAXILLA-FIRST VERSUS MANDIBLE-FIRST SURGERY

The t critical value confidence interval for the mean 3D distance error for each landmark for mandible-first surgery and maxilla-first surgery groups are presented in Table 8. The mean of the 95% confidence interval is also shown. The mean 3D distance error for all maxillary landmarks was smaller in the maxilla-first surgery group, while the mean 3D distance error for all

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Table 4. LANDMARK VERSUS MEAN DISTANCE ERROR ACROSS ALL SUBJECTS (MAXILLARY LANDMARKS)

Landmark	Dimension	Mean (mm)†	95% CI‡	*P* Value§
L1 A-point	x	−0.63	[−1.02 to −0.24]	< .01
	y	−0.99	[−1.59 to −0.38]	< .01
	z	−2.73	[−3.28 to −2.17]	< .01
L2 ANS	x	−0.65	[−1.05 to −0.24]	< .01
	y	−0.13	[−0.54 to 0.28]	.52
	z	−3.92	[−4.60 to −3.23]	< .01
L3 PNS	x	−0.45	[−1.00 to 0.11]	.11
	y	1.26	[0.73, 1.78]	< .01
	z	−1.10	[−1.60 to −0.60]	< .01
L4 Mx Canine (L)	x	−0.64	[−1.02 to −0.25]	< .01
	y	0.43	[0.11 to 0.76]	.01
	z	−1.77	[−2.26 to −1.29]	< .01
L5 Mx Canine (R)	x	−0.42	[−0.81 to −0.03]	.03
	y	0.53	[0.23 to 0.83]	< .01
	z	−1.81	[−2.32 to −1.30]	< .01
L6 Mx Molar (L)*	x	−0.86	[−1.25 to −0.47]	< .01
	y	0.62	[0.28 to 0.96]	< .01
	z	−1.86	[−2.40 to −1.32]	< .01
L7 Mx Molar (R)*	x	−0.25	[−0.59 to 0.09]	.15
	y	0.75	[0.43 to 1.06]	< .01
	z	−2.15	[−2.69 to −1.61]	< .01
L8 Mx Incisor (L)‖	x	−0.45	[−0.87 to −0.04]	.03
	y	0.12	[−0.25 to 0.48]	.52
	z	−1.71	[−2.19 to −1.22]	< .01
L9 Mx Incisor (R)‖	x	−0.64	[−1.09 to −0.19]	< .01
	y	0.13	[−0.25 to 0.51]	.49
	z	−1.71	[−2.19 to −1.24]	< .01

Abbreviations: ANS, anterior nasal spine; CI, confidence interval; L, left; Md, mandibular; Mx, maxillary; PNS, posterior nasal spine; R, right.

* First molar.

† Mean of the 95% confidence interval expressed in millimeters. A negative value indicates the actual surgical movement was less than the virtual plan.

‡ Z critical value confidence interval.

§ Null hypothesis was that mean distance error was 0. Benjamini-Hochberg adjusted *P* values were also calculated to control the false discovery rate and results were unchanged.

‖ Central incisor.

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mandibular landmarks was smaller in the mandible-first surgery group except the right condyle, right mandibular canine, and gonion (left and right). Overall, the effect of surgical sequence (mandible-first or maxilla-first) on mean 3D distance error was not statistically significant.

Discussion

OUTCOMES

The purpose of this study was to evaluate the difference between the virtual surgical plan and actual surgical outcome using a fully digital, in-house VSP workflow for orthognathic surgery. The investigators hypothesized that this protocol could provide a mean absolute error of less than 2 mm, a commonly used threshold for clinical acceptability.[20] The specific aim of this study was to measure the 3D distance error, as well as the mean error and mean absolute error in the transverse, vertical, and anterior-posterior dimensions, for a series of landmarks between the virtual surgical plan and the actual surgical outcome.

The mean 3D distance error ranged from 1.68 and 1.72 mm (right and left condyle, respectively) to 4.59 mm at ANS. The smaller error at the condyles was thought to be related to the lesser movement of this landmark during surgery, although this was not tested statistically. The anterior nasal spine is often trimmed intraoperatively. For this reason, ANS was not included in analysis of variance models and its associated distance error results should be interpreted with caution. For the dental landmarks, mean 3D

Table 5. LANDMARK VERSUS MEAN DISTANCE ERROR ACROSS ALL SUBJECTS (MANDIBULAR LANDMARKS)

Landmark	Dimension	Mean (mm)[†]	95% CI[‡]	P Value[§]
L10 B-point	x	−0.52	[-1.01, −0.04]	.03
	y	1.45	[0.75, 2.15]	< .01
	z	−1.27	[-2.04, −0.51]	< .01
L11 Condyle (L)	x	0.29	[-0.06, 0.63]	.10
	y	−0.53	[-0.78, −0.28]	< .01
	z	−0.77	[-1.05, −0.49]	< .01
L12 Condyle (R)	x	−0.32	[-0.57, −0.07]	.01
	y	−0.59	[-0.85, −0.33]	< .01
	z	−0.52	[-0.87, −0.16]	< .01
L13 Gnathion	x	−0.51	[-1.08, 0.05]	.07
	y	1.50	[0.88, 2.12]	< .01
	z	−0.88	[-1.83, 0.06]	.06
L14 Gonion (L)	x	1.70	[0.93, 2.47]	< .01
	y	−0.61	[-1.02, −0.20]	< .01
	z	−1.05	[-1.64, −0.47]	< .01
L15 Gonion (R)	x	−1.37	[-2.35, −0.39]	< .01
	y	−0.76	[-1.27, −0.24]	< .01
	z	−1.21	[-1.91, −0.51]	< .01
L16 Md Canine (L)	x	−0.58	[-0.97, −0.20]	< .01
	y	0.49	[0.15, 0.82]	< .01
	z	−1.81	[-2.27, −1.34]	< .01
L17 Md Canine (R)	x	−0.57	[-0.99, −0.15]	< .01
	y	0.44	[0.07, 0.82]	.02
	z	−1.95	[-2.46, −1.43]	< .01
L18 Md Molar (L)[*]	x	−0.46	[-0.85, −0.07]	.02
	y	0.97	[0.62, 1.31]	< .01
	z	−1.70	[-2.26, −1.14]	< .01
L19 Md Molar (R)[*]	x	−0.44	[-0.84, −0.04]	.03
	y	0.94	[0.59, 1.30]	< .01
	z	−1.92	[-2.46, −1.37]	< .01
L20 Md Incisor (L)[‖]	x	−0.42	[-0.86, 0.02]	.06
	y	0.45	[0.08, 0.81]	.01
	z	−1.92	[-2.36, −1.47]	< .01
L21 Md Incisor (L)[‖]	x	−0.32	[-0.78, 0.14]	.16
	y	0.42	[0.06, 0.78]	.02
	z	−1.83	[-2.28, −1.38]	< .01
L22 Menton	x	−0.43	[-1.00, 0.13]	.12
	y	1.47	[0.88, 2.05]	< .01
	z	−0.93	[-1.89, 0.04]	.05
L23 Pogonion	x	−0.58	[-1.12, −0.04]	.03
	y	1.56	[0.88, 2.23]	< .01
	z	−0.88	[-1.80, 0.05]	.06

Abbreviations: Mx, maxillary; Md, mandibular; L, left; R, right; CI, confidence interval.

* First molar.

† Mean of the 95% confidence interval expressed in millimeters. A negative value indicates the actual surgical movement was less than the virtual plan.

‡ Z critical value confidence interval.

§ Null hypothesis was that mean distance error was 0. Benjamini-Hochberg adjusted *P* values were also calculated to control the false discovery rate and results were unchanged.

‖ Central incisor.

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distance error ranged from 2.79 mm at the left mandibular canine to 3.15 mm at the right maxillary molar. Mean 3D distance error at the left and right maxillary central incisors was 2.86 and 2.93 mm, respectively. There was increased error at left and right gonion (3.64 and 4.22 mm, respectively), which can be

Table 6. LANDMARK VERSUS MEAN ABSOLUTE DISTANCE ERROR ACROSS ALL SUBJECTS (MAXILLARY LANDMARKS)

Landmark		Dimension	Mean (mm)†	95% CI‡
L1	A-point	x	1.19	[1.15, 1.22]
		y	1.74	[1.68, 1.81]
		z	2.83	[2.76, 2.90]
L2	ANS	x	1.27	[1.23, 1.30]
		y	1.10	[1.06, 1.14]
		z	3.95	[3.85, 4.04]
L3	PNS	x	1.62	[1.57, 1.66]
		y	1.74	[1.69, 1.80]
		z	1.70	[1.65, 1.75]
L4	Mx Canine (L)	x	1.17	[1.14, 1.21]
		y	0.92	[0.89, 0.95]
		z	1.99	[1.93, 2.05]
L5	Mx Canine (R)	x	1.17	[1.13, 1.20]
		y	0.92	[0.89, 0.94]
		z	2.12	[2.07, 2.18]
L6	Mx Molar (L)*	x	1.33	[1.30, 1.37]
		y	1.01	[0.97, 1.04]
		z	2.15	[2.09, 2.21]
L7	Mx Molar (R)*	x	1.04	[1.01, 1.06]
		y	1.12	[1.09, 1.15]
		z	2.48	[2.42, 2.54]
L8	Mx Incisor (L)‖	x	1.26	[1.23, 1.30]
		y	0.94	[0.91, 0.98]
		z	1.98	[1.93, 2.04]
L9	Mx Incisor (R)‖	x	1.32	[1.27, 1.36]
		y	0.99	[0.96, 1.03]
		z	1.97	[1.92, 2.03]

Abbreviations: ANS, anterior nasal spine; PNS, posterior nasal spine; Mx, maxillary; Md, mandibular; L, left; R, right; CI, confidence interval.

* First molar.

† Mean of the 95% confidence interval expressed in millimeters.

‡ Z critical value confidence interval.

‖ Central incisor.

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attributed to the increased degree of freedom in positioning the proximal mandibular segment when plating the sagittal split osteotomy. The other bony landmarks in the anterior mandible and maxilla (B-point, gnathion, menton, pogonion, and A-point) were also associated with increased mean 3D distance error. It is possible that some of this error can be attributed to an increased difficulty in consistently labelling these landmarks due to their positions along the curvilinear symphysis and alveolus. Also, by definition, the position of these landmarks will change as the maxillomandibular complex is rotated which may contribute to the increased error.

The mean absolute distance error in both the transverse and vertical dimensions met the threshold for clinical acceptability for all landmarks except B-point, gonion, and pogonion. The mean absolute distance error was largest in the anterior-posterior dimension (z axis) for all landmarks (except posterior nasal spine, left condyle, and gonion) and exceeded the threshold for clinical acceptability in 16 of 23 landmarks. While the mean absolute distance error provides insight into the magnitude of error, the mean distance error provides information on directionality. The results of this study showed that the mean distance error in the anterior-posterior dimension for all landmarks was negative, indicating that there was a general tendency to underadvance (or setback) the maxillomandibular complex compared to what was planned.

In the mandible-first and maxilla-first surgery groups, it was found that the mean 3D distance error for maxillary landmarks was smaller in the maxilla-first surgery group, while the mean 3D distance error for mandibular landmarks except the right condyle, right mandibular canine, and gonion (left and right) was smaller in the mandible-first surgery group. It

Table 7. LANDMARK VERSUS MEAN ABSOLUTE DISTANCE ERROR ACROSS ALL SUBJECTS (MANDIBULAR LANDMARKS)

Landmark	Dimension	Mean (mm)†	95% CI‡
L10 B-point	x	1.43	[1.39, 1.48]
	y	2.14	[2.07, 2.22]
	z	2.44	[2.38, 2.51]
L11 Condyle (L)	x	0.98	[0.95, 1.01]
	y	0.69	[0.66, 0.72]
	z	0.92	[0.89, 0.95]
L12 Condyle (R)	x	0.79	[0.77, 0.81]
	y	0.80	[0.77, 0.82]
	z	1.00	[0.97, 1.04]
L13 Gnathion	x	1.59	[1.54, 1.64]
	y	1.99	[1.92, 2.05]
	z	2.75	[2.67, 2.83]
L14 Gonion (L)	x	2.17	[2.08, 2.26]
	y	1.22	[1.18, 1.26]
	z	1.79	[1.73, 1.85]
L15 Gonion (R)	x	2.47	[2.36, 2.57]
	y	1.49	[1.44, 1.54]
	z	2.27	[2.21, 2.33]
L16 Md Canine (L)	x	1.21	[1.18, 1.24]
	y	1.00	[0.97, 1.04]
	z	1.98	[1.92, 2.03]
L17 Md Canine (R)	x	1.29	[1.25, 1.32]
	y	1.07	[1.03, 1.10]
	z	2.26	[2.21, 2.32]
L18 Md Molar (L)*	x	1.16	[1.12, 1.19]
	y	1.26	[1.23, 1.30]
	z	2.12	[2.06, 2.18]
L19 Md Molar (R)*	x	1.25	[1.22, 1.28]
	y	1.24	[1.20, 1.28]
	z	2.24	[2.18, 2.30]
L20 Md Incisor (L)‖	x	1.38	[1.35, 1.41]
	y	1.06	[1.02, 1.09]
	z	2.09	[2.04, 2.14]
L21 Md Incisor (L)‖	x	1.39	[1.35, 1.42]
	y	1.05	[1.02, 1.09]
	z	2.00	[1.95, 2.06]
L22 Menton	x	1.58	[1.53, 1.63]
	y	1.87	[1.81, 1.94]
	z	2.79	[2.71, 2.88]
L23 Pogonion	x	1.58	[1.53, 1.62]
	y	2.10	[2.03, 2.18]
	z	2.69	[2.61, 2.77]

Abbreviations: CI, confidence interval; L, left; Md, mandibular; Mx, maxillary; R, right.

* First molar.

† Mean of the 95% confidence interval expressed in millimeters.

‡ Z critical value confidence interval.

‖ Central incisor.

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seems logical that the mean error would be smaller in the jaw that is repositioned first given that the intermediate splint is based on an uncut structure. Similarly, it is reasonable that the jaw repositioned second would have a larger mean error given that the final splint is based on a structure that has been modified by surgery. Despite this trend, the analysis of variance for the effect of surgical sequence on 3D distance error was not statistically significant.

In the literature, numerous studies have evaluated the accuracy of outsourced VSP for bimaxillary

Table 8. LANDMARK VERSUS MEAN 3D DISTANCE ERROR FOR MANDIBLE-FIRST AND MAXILLA-FIRST SEQUENCE

Landmark		Mandible-First		Maxilla-First		
		Mean†	95% CI‡	Mean†	95% CI‡	*P* value§
L1	A-point	4.19	[3.66, 4.72]	3.22	[1.94, 4.50]	.13
L2	ANS	4.72	[4.06, 5.39]	3.93	[1.90, 5.97]	.36
L3	PNS	3.57	[3.14, 3.99]	2.57	[1.43, 3.71]	.07
L4	Mx Canine (L)	2.86	[2.40, 3.33]	2.57	[1.67, 3.47]	.55
L5	Mx Canine (R)	2.92	[2.52, 3.31]	2.60	[1.18, 4.02]	.50
L6	Mx Molar (L)*	3.18	[2.68, 3.68]	2.41	[1.68, 3.15]	.18
L7	Mx Molar (R)*	3.31	[2.95, 3.67]	2.42	[0.97, 3.87]	.08
L8	Mx Incisor (L)‖	2.91	[2.50, 3.32]	2.63	[1.48, 3.78]	.53
L9	Mx Incisor (R)‖	2.99	[2.55, 3.42]	2.68	[1.41, 3.94]	.50
L10	B-point	3.01	[2.50, 3.52]	4.16	[2.19, 6.12]	.10
L11	Condyle (L)	1.71	[1.35, 2.07]	1.79	[0.95, 2.64]	.84
L12	Condyle (R)	1.76	[1.40, 2.11]	1.35	[0.88, 1.81]	.32
L13	Gnathion	3.10	[2.53, 3.67]	4.04	[2.38, 5.70]	.21
L14	Gonion (L)	3.78	[3.05, 4.52]	2.96	[1.77, 4.16]	.46
L15	Gonion (R)	4.33	[3.40, 5.25]	3.71	[2.52, 4.90]	.63
L16	Md Canine (L)	2.76	[2.32, 3.20]	2.95	[1.65, 4.25]	.79
L17	Md Canine (R)	3.13	[2.70, 3.56]	2.87	[1.36, 4.37]	.59
L18	Md Molar (L)*	3.02	[2.58, 3.47]	3.15	[1.88, 4.42]	.83
L19	Md Molar (R)*	3.11	[2.65, 3.57]	3.19	[1.67, 4.70]	.95
L20	Md Incisor (L)‖	2.93	[2.51, 3.35]	3.16	[2.01, 4.31]	.71
L21	Md Incisor (R)‖	2.88	[2.46, 3.31]	3.15	[1.99, 4.31]	.66
L22	Menton	3.00	[2.41, 3.59]	4.16	[2.45, 5.87]	.12
L23	Pogonion	3.17	[2.58, 3.75]	4.14	[2.46, 5.83]	.20

Abbreviations: ANS, anterior nasal spine; CI, confidence interval; L, left; Md, mandibular; Mx, maxillary; PNS, posterior nasal spine; R, right.

* First molar.

† Mean of the 95% confidence interval expressed in millimeters.

‡ *t* critical value confidence interval.

§ ANOVA revealed no statistically significant difference between the 2 groups ($P = .37$).

‖ Central incisor.

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orthognathic surgery; however, there is a lack of consensus regarding the most appropriate evaluation protocol for VSP in orthognathic surgery.[20,23] For this reason, a direct comparison of results between studies can be challenging. Hsu et al published a prospective study of 65 consecutive patients using a similar landmark-based evaluation of accuracy as the present study, but used a centroid to represent the maxilla and mandible based on the landmarks.[25] In the maxilla, they reported an error in the transverse, vertical, and anterior-posterior dimension of 0.8 mm, 0.6 mm, and 1.0 mm, respectively. In the mandible, they reported an error of 0.8 mm, 0.6 mm, and 1.1 mm in these dimensions. Baan et al used regional voxel-based registration (R-VBR) to evaluate accuracy, again in the form of a maxillary and mandibular centroid.[26] In the maxilla, they reported an error in the transverse, vertical, and anterior-posterior dimension of 0.49 mm, 1.85 mm, and 1.41 mm, respectively. In the mandible, they reported an error of 0.71 mm, 1.32 mm, and 1.17 mm in these dimensions. In both studies, the threshold for clinical acceptability of 2 mm was met. In the present study, many of the landmarks fell just outside this range, primarily due to an increased error in the anterior-posterior dimension.

Another study by Wilson et al retrospectively analyzed 100 patients who underwent triple-jaw surgery by a single surgeon using a landmark-based evaluation of accuracy.[27] At A-point, they noted an error in the transverse, vertical, and anterior-posterior dimension of 1.23 mm, 1.74 mm, and 1.34 mm, respectively, while the present study found the error to be 1.19 mm, 1.74 mm, and 2.83 mm at this landmark. In the mandible (B-point, pogonion, and menton), they noted a higher degree of error (> 2 mm) in the anterior-posterior dimension, as did the present study. Others have also reported underadvancement with occlusal splint-based VSP.[28-30] Tankersley et al noted a negative mean error of −2.0 mm at the maxillary central incisor with root mean squared deviation of

2.6 mm in the anterior-posterior dimension.[28] While the present study found the mean and absolute error at the maxillary incisor to be slightly less (−1.71 and 1.97 mm, respectively), the same trends were observed. De Riu et al evaluated accuracy using linear and angular measurements on lateral and frontal cephalometric radiographs.[30] Again, they noted a tendency toward underprojection of the jaws and felt that a slight overcorrection during virtual planning could be beneficial.

Overall, it appears that the present workflow for fully digital, in-house VSP can provide a surgical error that is comparable to, or slightly larger than other outsourced VSP protocols published in the literature. Importantly, this in-house workflow tends to underadvance the maxillomandibular complex, while the error in the vertical and transverse dimensions was, for the most part, clinically acceptable. There are several factors that could potentially contribute to this finding. First, if the preoperative CBCT is not obtained in centric relation (as was the case for this study), there is a risk of underadvancement if using a maxilla-first surgical sequence. However, this is unlikely to be a factor in this study as 43 of 52 patients underwent mandible-first surgery and those who did undergo maxilla-first surgery experienced an underadvancement that was comparable to the mandible-first group. Another factor that could influence the degree of advancement is the intraoperative position of the condyle in the glenoid fossa. If the condyle is overseated in the fossa or settles posteriorly under general anesthesia in the supine position, there is a risk of underadvancement. Again, these examples are more relevant to a maxilla-first surgical sequence and are unlikely to be factors in this study for the reasons mentioned above. Additionally, with splint-based surgery, there is no guide for the vertical position of the maxilla. Any deviation from the intended vertical position will cause an unplanned autorotation of the maxillomandibular complex, influencing the final anterior-posterior position. While this is possible, the error in the vertical dimension in this study was found to be small; therefore, an unintended autorotation is unlikely to be the cause. Next, the anterior-posterior discrepancy could be attributed in part to a difference in the planned versus actual osteotomies; however, this was not specifically investigated in this study. Finally, it is possible that some degree of surgical relapse occurred between the time of surgery and the time of postoperative imaging, leading to a perceived underadvancement. While a definitive explanation for this phenomenon was not identified, the general tendency toward deficient movement in the anterior-posterior direction is important to consider. To mitigate this, the authors feel that it may be prudent to slightly overcorrect the anterior-posterior movement during the virtual planning stages by approximately 1 to 2 mm when using this protocol.

Considering these findings, other planning techniques may be indicated when a higher degree of accuracy is required. Kraeima et al performed a randomized controlled trial to evaluate the accuracy of VSP PSIs and splint-based VSP for maxillary orthognathic surgery.[13] They found that the PSI group showed a smaller deviation from the planned position compared to the control group, especially with larger anterior-posterior translations (> 3.70 mm). Abel et al retrospectively evaluated a cohort of 49 patients using PSIs for bimaxillary orthognathic surgery.[31] They reported maxillary discrepancies approaching 0.5 mm and mandibular discrepancies approaching 1 mm. Jones et al performed a retrospective study comparing bimaxillary surgery with PSIs to splint-based VSP and found that at all points, the PSI group was more accurate with nearly all final measurements being within 1 mm of the preoperative plan.[12] Given these findings, it seems as though VSP with PSIs is superior to in-house VSP in terms of accuracy when larger advancements are planned or when a surgical error of less than 1 mm is desired. Of course, the increased cost associated with PSIs needs to be considered.

LIMITATIONS AND AREAS FOR IMPROVEMENT

Regarding the study methods, there were several limitations. First, manual repeated landmark identification on the preoperative and postoperative digital volume is tedious and time-consuming. Also noted previously, the position of some landmarks (A-point, B-point, menton, pogonion, and gnathion) will change as the maxillomandibular complex is rotated, even if by only a small amount. This makes it impossible to truly track the position of these landmarks with repeated landmark identification. To circumvent these issues, some authors have advocated for semiautomatic or automatic voxel-based analysis of surgical outcomes.[23,26,32-34] These techniques rely on R-VBR of the preoperative maxillary and mandibular segments onto to their representative postoperative segments to generate a transformational matrix. The transformational matrix can then be used to calculate the displacement of any number of landmarks on the region of interest. Since the rotational and, more recently, the linear accuracy of R-VBR has been validated for nonsegmental LeFort I and bilateral sagittal split osteotomies by Han et al,[35,36] this technique should be considered for future studies involving analysis of orthognathic surgery outcomes. The second limitation with the study methods is that it is assumed the only movement that occurs between the preoperative and postoperative imaging is due to the surgery itself. However, the use of guiding elastics in the immediate postoperative period prior to imaging invariably contributes to tooth movement that is not accounted for in the study. To remove this variable, an intraoperative image would need to be acquired prior to the insertion of the final occlusal splint, which is impractical. Finally, difficulty in the recording of centric relation (which is especially important in maxilla-first surgery), replicating the planned occlusal adjustments, and reproducing the planned osteotomies all contribute to the observed distance error and are not unique to this study.[37]

There were also limitations related to the study sample. First, all patients who underwent bimaxillary orthognathic surgery were included (with some exceptions, see exclusion criteria). As a result, various surgical movements (advancement, setback, impaction, etc.) were considered and therefore, the trends in surgical error that were observed in the study group may not be representative of each specific type of surgery. Similarly, the degree of surgical movement was not considered. For example, 5 of 52 patients underwent maxillomandibular advancement for obstructive sleep apnea. This patient group underwent significant advancement of the maxillomandibular complex that is nonrepresentative of the typical bimaxillary orthognathic surgery patient and may bias the observed error. While an evaluation of the specific surgical movement and degree of movement were outside the scope of this study, considering these variables in future studies may yield results that are more applicable to specific surgical scenarios.

Relating to the sample size, 14 of 52 patients underwent concurrent genioplasty, leaving a reduced sample size of 38 patients who contributed data for the anterior mandible (see Data Collection Methods). Additionally, only 9 patients underwent maxilla-first surgery. Therefore, findings relating to landmarks in the anterior mandible and a direct comparison of mandible-first and maxilla-first surgery landmarks may not be representative of the larger population.

Q9 In conclusion, the difference between the virtual surgical plan and actual surgical outcome using a fully digital, in-house VSP workflow for orthognathic surgery was evaluated. In general, the largest contributor to mean 3D distance error was deficient movement in the anterior-posterior direction. Otherwise, mean absolute distance error in the vertical and transverse dimensions was clinically acceptable. These findings were felt to be valuable for treatment planning purposes when using a fully digital, in-house VSP workflow.

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Appendix 1. SAMPLE SIZE CALCULATION FOR 3D DISTANCE ERROR

Landmark		Sample Size†	
		SE = 0.2	SE = 0.25
L1	A-point	46	29
L2	ANS	73	47
L3	PNS	46	30
L4	Mx Canine (L)	45	29
L5	Mx Canine (R)	41	26
L6	Mx Molar (L)*	80	51
L7	Mx Molar (R)*	61	39
L8	Mx Incisor (L)‡	37	24
L9	Mx Incisor (R)‡	34	22
L10	B-point	99	63
L11	Condyle (L)	34	22
L12	Condyle (R)	30	19
L13	Gnathion	133	85
L14	Gonion (L)	105	67
L15	Gonion (R)	189	121
L16	Md Canine (L)	38	25
L17	Md Canine (R)	45	29
L18	Md Molar (L)*	48	31
L19	Md Molar (R)*	57	37
L20	Md Incisor (L)‡	38	25
L21	Md Incisor (R)‡	38	24
L22	Menton	130	83
L23	Pogonion	128	82

Abbreviations: ANS, anterior nasal spine; L, left; Md, mandibular; Mx, maxillary; PNS, posterior nasal spine; R, right; SE, standard error.

* First molar.

† Sample size calculation to detect an error of 2 mm between planned and actual landmarks with an alpha error of < 0.05 and a beta error of 0.2.

‡ Central incisor.

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