What Is the Accuracy of Bimaxillary Orthognathic Surgery Using Occlusally-Based Guides and Patient-Specific Fixation in Both Jaws? A Cohort Study and Discussion of Surgical Techniques

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Purpose: The development of advanced digital orthognathic surgical protocols requires investigation to determine the accuracy of surgical outcomes. This report's purpose is to quantify 3-dimensional linear discrepancies between simulated and actual results for double-jaw orthognathic surgery utilizing occlusally-based guides in conjunction with patient-specific fixation in both jaws.

Methods: This retrospective cohort study assessed the accuracy of double-jaw orthognathic surgery, in all cases performed by 1 surgeon between May 2019 and January 2021, utilizing occlusally-based guides and patient-specific fixation plates in both maxillary and mandibular surgeries. The primary outcome was absolute linear discrepancy between virtually-planned and surgically-achieved maxillary and mandibular position in 3 dimensions. Secondary outcomes were relative (directional) discrepancy, to assess if protocols erred in 1 direction of each surgical axis. Sequencing of bimaxillary surgery, age, and sex were covariates. Absolute and relative linear differences at A-point, B-point, and pogonion were evaluated using *t* tests. Descriptive statistics were amassed, and results were analyzed to determine if discrepancies differed from a null hypothesis of 2-mm error.

Results: Forty-nine patients were enrolled, consisting of 25 males and 24 females with a mean age of 24.8 years. Thirty-five single-piece and 14 multipiece LeFort I osteotomies, 49 bilateral sagittal splits, and 35 genioplasties were studied; there were 22 maxilla-first and 27 mandible-first surgeries. Mean A-point absolute discrepancies of 0.57 (95% confidence interval: 0.41-0.73), 0.37 (0.24-0.50), and 0.45 (0.33-0.57) mm were observed in horizontal, transverse, and vertical planes, respectively. B-point discrepancies were 1.15 (0.79-1.52), 0.62 (0.47-0.78), and 1.14 (0.91-1.38) mm. Pogonion discrepancies were 1.29 (0.86-1.73), 0.85 (0.64-1.06), and 1.24 (1.00-1.49) mm. All P values were <.001. Sequencing of bimaxillary surgery did not alter absolute differences (P = .2 to >.9) with A-point discrepancies consistently smaller than B-point and pogonion discrepancies regardless of sequencing. Mandible-first surgery was associated with posterior directional error; both sequences were associated with superior directional error at B-point and pogonion.

Conclusion: Bimaxillary orthognathic surgery utilizing a patient-specific protocol in both jaws produces results highly reproducible to planned simulated surgery and accurate below a 2-mm hypothesis, with maxillary discrepancies approaching 0.5 mm and mandibular discrepancies approaching 1 mm.

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The success of orthognathic surgery in achieving a functional and harmonious facial skeleton is predicated on the surgeon's ability to properly diagnose deformity, design surgical movements, and execute preoperative plans in the surgical arena. Traditional methods used for years have relied on hand-fabricated splints and stock hardware, bent to anatomical requirements intraoperatively, in order to reposition the jaws and fixate osteotomies in their desired positions. Articulator-based protocols for surgical simulation and splint fabrication are effective in establishing stable occlusion; however, they introduce sources of inaccuracy, and 3-dimensional repositioning osteotomies are difficult with respect to bodily and angular discrepancies.[1-3]

It is only natural that, over time, oral and maxillofacial surgeons have sought to reduce the deviation between treatment plan and surgical result. Just as the use of external points of reference was identified as instrumental in reducing error in maxillary repositioning in early orthognathic surgery protocols,[4,5] modern technological advances have allowed surgeons to use digital techniques to achieve accurate results. Today, surgeons incorporate digital workflows, computer-assisted surgical planning, and 3-dimensional printed surgical splints in their orthognathic surgical protocols. Virtual treatment-planning protocols are advantageous in that they permit surgeons to evaluate patients radiographically in 3 dimensions; reliably diagnose pitch, roll, yaw, and linear deformities; identify issues with centric relation; and trial multiple surgical plans to determine an optimal plan to achieve desired results. Surgical splints fabricated using computer-aided design and manufacturing (CAD/CAM) have demonstrated high success rates at achieving discrepancies of 2 mm or less, an accepted margin of error in orthognathics.[6]

Comparable or improved accuracy has been demonstrated between virtual and conventional surgical planning techniques, with demonstrated margins of error less than 2 mm in anterior-posterior, vertical, and transverse dimensions with both techniques.[7] Some studies have reduced surgical discrepancy to approximately 1 mm with the use of computer-generated splints[8,9] and have demonstrated that computer-aided treatment plans yield improved subjective craniomaxillofacial skeletal harmony over conventional techniques.[10]

Further development of patient-specific technology has allowed the introduction of custom titanium plates used in conjunction with either bone-borne or, as in the cohort study discussed in this report, occlusally borne osteotomy guides. One in vitro study using occlusally-based resin guides has achieved maxillary repositioning within 0.5 mm of preoperative plan using a splintless protocol.[11] In 1 randomized trial using occlusally-based resin guides, patient-specific osteosynthesis demonstrated superior accuracy of patient-specific hardware in splintless maxillary surgery, compared to splinted stock plate controls.[12] In vivo applications using titanium bone-borne maxillary guides have reliably achieved ≤2 mm differences,[13] with some authors reporting median discrepancies below the 1 mm margin using bone-borne titanium guides.[14] Technological adaptation in computer-aided and patient-specific surgery suggest that 1 mm may be the future threshold for accuracy for orthognathic surgeons.

The authors of this manuscript are not aware of any previous reports on the accuracy of double-jaw surgery using patient-specific fixation plates in both jaws. As such, the purpose of this study was to quantify the discrepancy between simulated digitally planned and actual patient results in double-jaw guided osteotomies using occlusally-borne osteotomy guides and patient-specific fixation hardware. The authors hypothesize that patient-specific protocols will demonstrate accuracy in bimaxillary surgery below a 2 mm threshold in both jaws. The specific aims of the study were to quantify discrepancies between planned and achieved bodily movements at anterior midline skeletal reference points (A-point, B-point, pogonion) in 3 dimensions, to determine if directional trends in surgical discrepancies existed to suggest consistent and predictable errors attributable to technique, and to assess whether sequencing of surgery (maxillary or mandibular first) had a measurable effect on discrepancies in maxillary or mandibular repositioning.

Materials and Methods

This study was approved by the Institutional Review Board of New York Presbyterian Hospital (#20-10022854-02). This study abides by the Helsinki Declaration guidelines for human subject research.

STUDY SAMPLE AND DESIGN

To address the research purpose, the investigators designed and implemented a retrospective cohort study design. The study population was composed of all patients who presented with skeletal malocclusion to the private practice of 1 surgeon (J.M.N.) and who were subsequently treated for orthognathic surgical correction at the NewYork-Presbyterian Hospital/Weill Cornell Medical Center between May 2019 and January 2021.

To be included in the study sample, patients had to be treated with double-jaw orthognathic surgery: LeFort I osteotomy and bilateral sagittal split mandibular ramus osteotomy, with or without concomitant genioplasty. Patients requiring either single-piece or multipiece LeFort I osteotomy were studied. Additional inclusion criteria were the use of a patient-specific protocol incorporating intraoperative occlusal-borne maxillary and mandibular guides 3D printed in resin using the stereolithography (SLA) technique and patient-specific 3D-printed titanium fixation plates.

Patients were excluded as study subjects if their specific skeletal facial deformities or personal goals of treatment dictated single-jaw surgery or if they were treated with a different protocol from the guided technique described in this report (eg, unguided surgery with the use of CAD/CAM splints and stock fixation plates, a technique commonly used by the senior author prior to May 2019; or guided surgery with the use of titanium guides and patient-specific fixation plates, a technique introduced after January 2021). One patient was excluded because of technical problems in overlaying preoperative and postoperative computed tomography (CT) data.

Surgical Planning

All patients underwent presurgical treatment planning according to the surgeon's protocol, which included facial landmark measurements, cone beam CT in centric relation, digital occlusal records, maxillomandibular occlusal record, and intraoral and facial photography. Presurgical records were taken within 1 month of the planned surgical date.

All operations were subsequently planned by the surgeon via virtual surgical planning sessions (3D Systems, Littleton, CO) with the same experienced biomedical engineer. These sessions included the design of tooth-borne custom osteotomy guides with predictive holes for the placement of patient-specific fixation hardware following the osseous movements in accordance with the virtual plan. All guides were fabricated with resin using SLA processing. Patient-specific 3D-printed maxillary (1.7 mm system, 0.8 mm profile) and mandibular (2.0 mm system, 1.2 mm profile) titanium plates (Facial iD; Stryker Craniomaxillofacial, Kalamazoo, MI) were designed to achieve the planned linear movements as well correction of pitch, roll, and yaw deformities of maxillary and mandibular segments. Hardware design and SLA guide predictive holes were planned to avoid injury to vital structures in the surgical field (inferior alveolar and infraorbital nerves, incisive neurovascular bundle, tooth roots, maxillary sinus, and nasal cavity). By virtual planning using the patient's CT scan, each desired plate design could be adapted directly to the anatomical contours of the patient. The patient-specific plates were created through additive manufacturing via a 3D printing process using titanium powder (laser rapid manufacturing). Cases were planned to include the use of computer-printed interim and final occlusal surgical splints rather than following a splintless protocol.

Surgical Protocol

The utilization of intraoperative surgical guides with patient-specific hardware required modification of standard maxillary, mandibular, and genial surgical protocol.

LeFort I osteotomy. Following placement of an external nasion reference and exposure of the maxilla in usual fashion, an occlusally-borne SLA osteotomy guide for 1 hemimaxilla was placed in a passive manner with removal of all soft-tissue interferences. Next, maxillomandibular fixation (MMF) was established using either surgical lugs (fixed orthodontic cases) or MMF screws (clear aligner cases). The use of intraoperative MMF was predicated on the rationale that occlusally borne guides fabricated to simultaneously capture both maxillary and mandibular dentition would provide additionally intraoperative stability over a protocol capturing only single-jaw occlusion. Furthermore, the use of MMF served an additional checkpoint before proceeding: Poor fit of a surgical guide would indicate to surgeons that an occlusal discrepancy (eg, improper enameloplasty, bracket interference) or soft-tissue impingement (eg, cuff of attached gingiva or periosteal tag) existed and required correction.

A single 1.7-mm fixation screw was placed to the maxilla to secure the guide to the maxillary osseous contours and prevent mobility or flexion of the resin guide (Fig 1). Guided screw holes were prepared over the nasomaxillary and zygomaticomaxillary buttresses through holes placed in the guide. Guides were generally designed with 8-12 screw holes per hemimaxilla, for adaptation and placement of two 4- to 7-hole fixation plates. An osteotomy of the anterior maxilla was then performed through the guide slot in the resin guide; for impaction cases, the guides incorporated 2 parallel or wedge osteotomies for placement and excision of interpositional bone and superior repositioning. MMF was released and re-established for preparation of the contralateral maxilla in identical fashion. Following removal of the guide, anterior maxillary osteotomies were extended to the lateral and pterygomaxillary regions. The maxilla was then downfractured, and osseous reduction protocols proceeded in standard fashion.

The patient was then placed in MMF via an occlusal splint, and the right and left piriform plates were placed to assess proper vertical dimension and

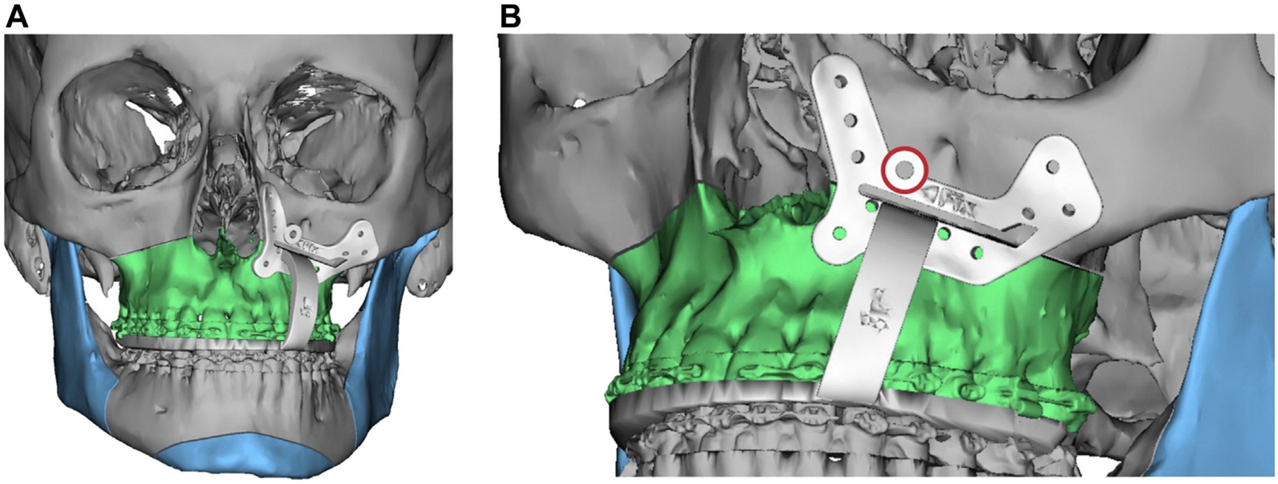

FIGURE 1. *A*, Maxillary occlusal-based guide with predictive osteotomy and screw-hole placement. *B*, The *red circle* indicates site of temporary fixation screw. Unmarked holes indicate sites of predictive screw holes to align with patient-specific plates following completion of planned osseous repositioning. Slot cutout informs osteotomy position.

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identify any bony interferences. Any interferences that prevented passive 3-dimensional positioning were removed. Predrilled screw holes passively and properly aligning with each plate both above and below the osteotomy confirmed that proper bony mitering and vertical position had been achieved. An external reference mark further confirmed proper vertical length of the midface: As the accuracy of mandibular surgery in maxilla-first sequencing is predicated on correct maxillary vertical dimension, the authors utilized external reference to ensure that the maxilla was placed passively into final vertical position and that compression of segments or torquing of plates did not compensate for small bony interferences. Following these confirmation steps, all 4 plates were applied and secured with 1.7 × 4-mm-long screws.

Bilateral sagittal split osteotomy. Mandibular exposure and placement of medial and sagittal osteotomies were prepared in standard fashion. A mandibular SLA guide was placed following removal of soft-tissue impingements, and MMF was established. Following placement of a single 2.0-mm fixation screw to ensure close adaptation of guide to bone, 6 screw-hole osteotomies were prepared, and buccal corticotomy was performed (Fig 2). Ninety-degree drills were used to access proximal screw-hole sites. In similar fashion to maxillary impactions, guides for mandibular setback surgery permitted 2 parallel or convergent corticotomy lines for planned resection of the

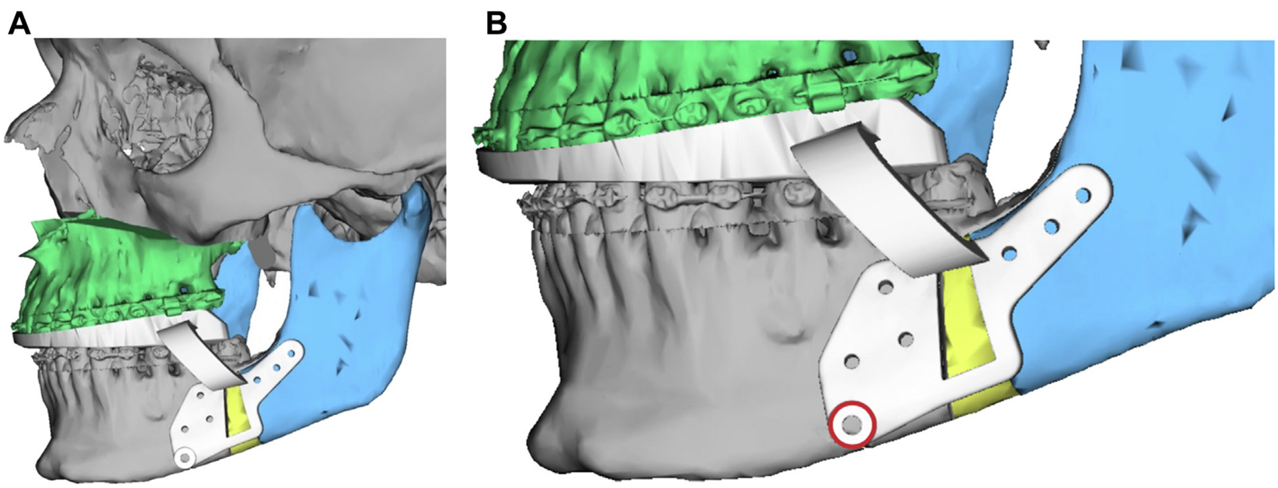

FIGURE 2. *A*, Mandibular guide based off of interim occlusal position. *B*, The *red circle* indicates site of temporary fixation screw. Unmarked holes indicate sites of predictive screw holes to align with patient-specific fixation plates following completion of planned osseous repositioning. *Yellow shading* indicates guided buccal cortical resection for planned mandibular setback.

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proximal segment bone. Buccal corticotomies marked in MMF were completed to depth following removal of guides. MMF was released, the sagittal split was completed, and contralateral guide was re-established for preparation of the other sagittal split osteotomy in identical fashion. Placement of mandibular patient-specific fixation plates occurred with the patient in MMF with an occlusal splint. During manual seating of the mandibular condyle, proper plate orientation, fit, and absence of bony interferences were verified by alignment of predrilled distal segment screw holes with the plate now fixated to the proximal segment.

Genioplasty. Following the removal of soft-tissue impingements, two 2.0-mm screws were placed to secure the occlusal-borne genioplasty marking guide to the symphysis of the mandible while in MMF. Following preparation of the 8 screw-hole osteotomies (for two 4-hole "C"-shaped paramedian plates), an anterior mandibular horizontal osteotomy was performed through the guide slot. The guide was then removed, and the symphyseal osteotomy was completed. The genial transport segment was then secured to a separate occlusal-based repositioning guide with 2-mm screws placed into the positioning holes. Patient-specific fixation plates were applied to the symphysis and secured with 1.7-mm screws placed into the predictive holes (Fig 3).

VARIABLES

The primary outcome variable studied was surgical discrepancy, defined as the absolute linear difference between the planned and achieved position of midline anterior facial anatomical landmarks (A-point, B-point, pogonion) in 3 dimensions. The secondary outcome variable was relative (directional) difference, to determine if guided protocols erred consistently in 1 direction of each of 3 surgical axes. Surgical sequencing (maxilla-first or mandible-first) was a covariate studied for its impact on surgical discrepancies. Additional covariates studied included age and sex. Maxillary segmentation (single-piece, multipiece osteotomies) was not studied as a covariate due to sample size limitations.

DATA COLLECTION METHODS

Postoperative cone-beam computed tomography scan of the maxilla and mandible was attained within 10 days following surgery in accordance with the surgeon's routine postoperative surgical protocol. For each patient, the same experienced biomedical engineer overlaid the postoperative cone-beam computed tomography scan on the preoperative scan modified with planned computer-simulated surgical movements. The scan alignment was verified utilizing the Geomagic Design X software (Rochester Hills, MI); the software synchronized the position of preoperative and postoperative scans on the basis of upper midface osseous contours and bony landmarks that were

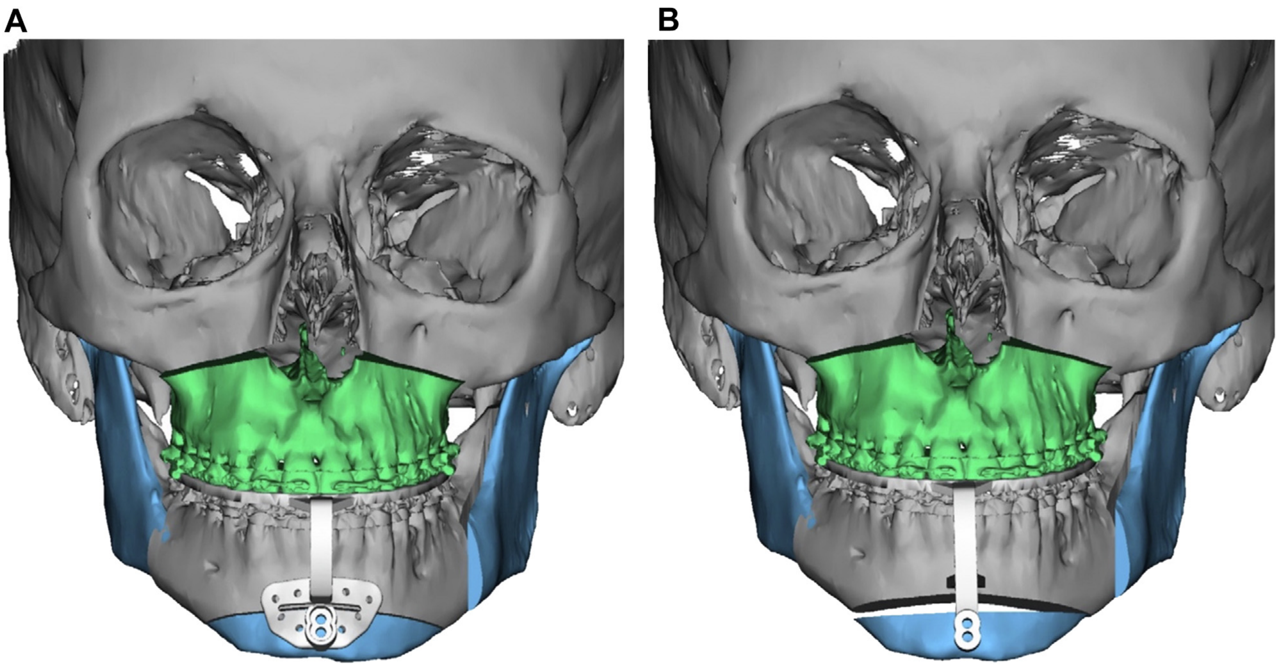

FIGURE 3. *A*, Genial marking and cutting guide based on patient's final occlusion. Midline screw holes are for guide stabilization. Parasymphyseal holes indicate predictive position of patient-specific plates following genial segment repositioning. *B*, Positioning guide for stabilization of genial segment during plating.

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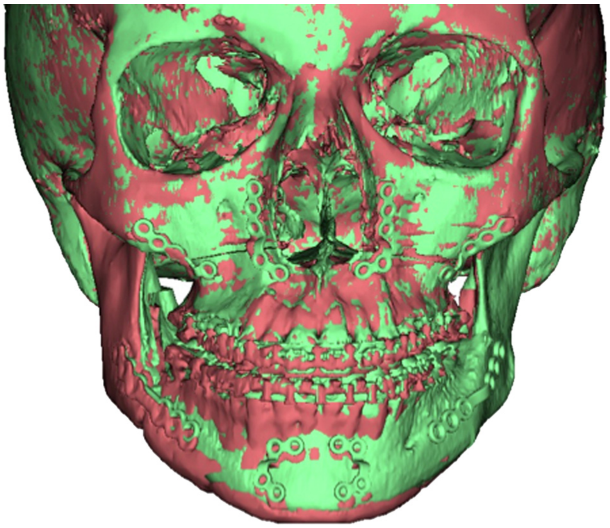

FIGURE 4. Overlaid preoperative and postoperative cone-beam computed tomography (CBCT) data with custom fixation plates.

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not involved in the surgical movements (orbital rims, maxilla superior to LeFort I osteotomy level), a reference region unchanged by surgery (Fig 4). Optimization of alignment in unchanged anatomy permitted analysis of discrepancies between planned and actual surgical results in the operative field.

The anatomic landmarks utilized for the comparative analysis were A-point, B-point, and pogonion. For each landmark, planned linear movements in the horizontal (anterior/posterior), transverse (left/right), and vertical (up/down) planes were recorded on the basis of the virtual surgical planning session. These points were digitally identified by the engineer and remained fixated to each individual osteotomy through the alignment process. Thus, there was no error in A-point, B-point, or pogonion location attributable to human identification error because each anatomical landmark was selected once, and its location remained fixed to the local anatomy of preoperative and postoperative dentate segments. The location of the landmarks was compared between preoperative (planned virtual anatomy) and postoperative (achieved anatomy) time points to assess discrepancies in the osseous position following surgery. Subtraction of planned movements from actual postoperative values was performed to quantify the linear difference in millimeters. In no cases did fixation hardware overlie or obscure anatomical landmarks; for example, all genioplasties were performed with 2 para-midline C-shaped plates so that B-point and pogonion were not obscured.

Table 1. DESCRIPTIVE STATISTICS: DEMOGRAPHICS AND PROCEDURE CLASSIFICATION

Total patients	49	
Sex: M/F	25/24	
Mean age: all/M/F, yr	24.8/25.6/24	
Median age: all/M/F, yr	21/21/21	
Sequencing		
	Maxilla first	22
	Mandible first	27
LeFort I osteotomy		
	Single piece	35
	Multipiece	14
Genioplasty		35

Abbreviations: F, female; M, male.

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In order to identify directional trends in data such as consistent underachievement or overachievement of desired movements, and to avoid statistical canceling of positive and negative error, both the magnitude and direction of discrepancies were recorded. To achieve this, a consistent nomenclature scheme was created in which positive values were assigned to movements in the anterior, leftward, and downward directions; negative values were assigned to movements in the posterior, rightward, and superior directions. Thus, positive values for offset variables indicated anterior, leftward, or downward overcorrection, and negative values indicated error in the opposite vectors. For each of the 3 anatomical landmarks and in each of 3 planes, both relative (positive or negative) and absolute (magnitude) values were calculated.

DATA ANALYSIS

Descriptive statistics were tabulated to determine age, sex, and procedure performed for each patient. Planned values of osteotomy movements at each anatomical landmark, in 3 planes, were recorded for the entire cohort of patients. Relative (directional) and absolute (magnitude) linear differences at A-point, B-point, and pogonion in each of the anterior-posterior, left-right, and superior-inferior planes were calculated by a subtraction method for each patient. The mean values and 95% confidence intervals were calculated; P values were determined using 1-sample 1-tailed (absolute differences; H_0: d = 2 mm; H_a: d < 2 mm) and 1-sample 2-tailed (relative differences; H_0: d = 0 mm; H_a: d $\neq$ 0 mm) t tests. To assess the impact of case sequencing as a covariate, these calculations were repeated for maxilla-first and mandible-first cohorts. Utilizing Welsh 2-sample t tests, A-point, B-point, and pogonion absolute and relative differences were compared across sequencing cohorts, and P values calculated to determine significance. To assess the impact of patient age and sex as covariates, a linear regression model was used, and beta values were calculated.

Table 2. PLANNED ABSOLUTE MOVEMENTS AT A-POINT, B-POINT, AND POGONION IN THREE DIMENSIONS

	A-point, mm	B-point, mm	Pogonion, mm
Anterior/posterior	4.7 (2.9)/4.6/2.8-6.8/0.1-13.0	6.1 (4.7)/5.2/2.2-8.4/0.1-20.7	6.7 (6.8)/5.0/1.5-8.1/0.1-28.6
Left/right	0.75 (0.62)/0.60/ 0.16-1.17/0.00-2.21	1.98 (1.69)/1.65/1.00-2.49/ 0.11-9.34	2.37 (2.16)/1.54/ 0.84-2.99/0.18-9.79
Up/down	1.40 (1.14)/1.05/ 0.55-2.10/0.00-5.81	2.35 (2.09)/1.69/0.85-3.43/ 0.03-10.02	2.91 (2.43)/1.97/ 0.85-4.83/0.03-9.97

The values in each cell are given as: mean (SD)/median/IQR/min.-max.

Abbreviations: IQR, interquartile range; min.-max, minimum-maximum values; SD, standard deviation.

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A linear regression model was additionally utilized to calculate the correlation between planned and achieved movements across all patients in each plane; and to further quantify the correlation between planned and achieved movements in the anterior-posterior plane on the basis of planned magnitude of movement. Throughout the statistical analysis, cases in which genioplasty was performed were not isolated, in order to minimize statistical dilution. As such, the pogonion position attributable to guided genioplasty was not studied alone. Similarly, multipiece LeFort I osteotomy cases were not isolated from single-piece ones. It is noted that sequencing of double-jaw surgery was not randomized and remained at the discretion of the surgeon.

Results

A total of 49 (25 male, 24 female) subjects were included in the cohort study with mean and median ages of 24.8 and 21 years, respectively. There were 22 maxillary-first and 27 mandibular-first surgical cases, comprising a total of 35 single-piece LeFort I osteotomies, 14 multipiece LeFort I osteotomies, 49 cases of bilateral mandibular sagittal ramus osteotomies, and 35 genioplasties. Patient demographics and distribution of surgical procedures are reported in Table 1.

In the anterior-posterior dimension, the median planned movement at A-point was 4.6 mm; at B-point, 5.2 mm; and at pogonion, 5.0 mm. Maximum planned movement at A-point was 13.0 mm; at B-point, 20.7 mm; and at pogonion, 28.6 mm. A summary of planned absolute movements of A-point, B-point, and pogonion in 3 surgical planes is reported in Table 2.

The use of patient-specific surgical guides and customized internal fixation hardware resulted in high-fidelity reproduction of virtual treatment plans in 3 dimensions. When studied across all 49 bimaxillary cases (Table 3), mean absolute differences at A-point were 0.57 mm (anterior/posterior), 0.37 mm (left/right), and 0.45 mm (superior/inferior); at B-point, 1.15 mm (A/P), 0.62 mm (L/R), and 1.14 mm (S/I); at pogonion, 1.29 mm (A/P), 0.85 mm (L/R), and 1.24 mm (S/I). All absolute differences were significant ($P < .001$) against a null hypothesis value of 2 mm.

In both mandible-first and maxilla-first sequence cohorts, absolute differences at each anatomical point and in each directional plane were significantly ($P < .05$) less than 2 mm (Tables 4 and 5). The sequencing of double-jaw surgery did not have a statistically significant effect on absolute differences observed at A-point, B-point, or pogonion across any of the 3 surgical dimensions ($P = .14$ to >.90, Table 6) when cohorts were compared for accuracy. After controlling for other covariates such as age and sex (Table 7), the effect of sequencing remained nonsignificant.

Reduced discrepancies were seen in the maxilla regardless of the first jaw operated (Tables 4 and 5). For example, in the anterior-posterior dimension, the mean A-point errors of 0.58 mm (maxilla first) and 0.57 mm (mandible first) were consistently smaller in magnitude than the mean B-point errors of 0.95 mm (maxilla first) and 1.31 mm (mandible first). In the anterior-posterior dimension, A-point errors were not found to be smaller in maxilla-first cases ($P > .9$), and B-point errors were not reduced in mandible-first cases. Vertically, A-point (0.54 mm, maxilla first; 0.38 mm, mandible first; $P = .2$), B-point (1.17 mm, maxilla first; 1.12 mm, mandible first; $P = .9$), and pogonion (1.34 mm, maxilla first; 1.16 mm, mandible first; $P = .5$) errors were similar across surgery sequencing.

Relative difference calculations were used to determine if surgical techniques consistently erred in 1 direction in each of the 3 surgical planes. Across all cases, there were significant ($P = .02$-.05, Table 3) negative mean relative differences in the anterior-posterior plane: A-point, −0.27 mm; B-point, −0.58 mm; pogonion, −0.54 mm. These negative values indicate that posterior error was favored over anterior error using this surgical protocol; thus,

Table 3. RELATIVE AND ABSOLUTE DIFFERENCES BETWEEN VIRTUAL PLAN AND SURGICAL OUTCOME AT A-POINT, B-POINT, AND POGONION OF ALL CASES

All Cases (n = 49)	Relative Differences (H_0: d = 0 mm; H_a: d $\neq$ 0 mm)			Absolute Differences (H_0: d = 2 mm; H_a: d < 2 mm)		
Surgical plane	A	B	Pogonion	A	B	Pogonion
Anterior/ posterior	−0.27 (0.76) (−0.56, 0.21) [−0.49, −0.05] *P* = .02	−0.58 (1.63) *(−1.10, 0.50)* [−1.05, −0.12] *P* = .02	−0.54 (1.91) *(−1.13, 0.66)* [−1.09, 0.01] *P* = .05	0.57 (0.57) *(0.21, 0.77)* [0.41, 0.73] *P* < .001	1.15 (1.28) *(0.50, 1.13)* [0.79, 1.52] *P* < .001	1.29 (1.50) *(0.44, 1.46)* [0.86, 1.73] *P* < .001
Left/right	0.12 (0.57) *(−0.10, 0.29)* [−0.04, 0.28] *P* = .15	0.10 (0.82) *(−0.51, 0.65)* [−0.13, 0.34] *P* = .38	0.12 (1.12) *(−0.59, 0.82)* [−0.20, 0.44] *P* = .45	0.37 (0.45) *(0.09, 0.47)* [0.24, 0.50] *P* < .001	0.62 (0.54) *(0.25, 0.79)* [0.47, 0.78] *P* < .001	0.85 (0.73) *(0.44, 1.04)* [0.64, 1.06] *P* < .001
Up/down	−0.11 (0.61) *(−0.49, 0.19)* [−0.28, 0.07] *P* = .22	−0.92 (1.08) *(−1.81, −0.14)* [−1.23, −0.61] *P* < .001	−0.95 (1.17) *(−1.56, −0.40)* [−1.29, −0.62] *P* < .001	0.45 (0.42) *(0.12, 0.66)* [0.33, 0.57] *P* < .001	1.14 (0.83) *(0.53, 1.81)* [0.91, 1.38] *P* < .001	1.24 (0.85) *(0.66, 1.56)* [1.00, 1.49] *P* < .001

Values are given as mean difference (standard deviation) in mm (interquartile range in mm) [95% confidence interval, mm] *P* value.

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Table 4. RELATIVE AND ABSOLUTE DIFFERENCES BETWEEN VIRTUAL PLAN AND SURGICAL OUTCOME AT A-POINT, B-POINT, AND POGONION OF CASES SEQUENCED MAXILLA-FIRST

Maxilla-First (n = 22)	Relative Differences (H_0: d = 0 mm; H_a: d ≠ 0 mm)			Absolute Differences (H_0: d = 2 mm; H_a: d < 2 mm)		
Surgical plane	A	B	Pogonion	A	B	Pogonion
Anterior/posterior	−0.13 [−0.48, 0.21] *P* = .43	−0.02 [−0.54, 0.49] *P* = .93	0.10 [−0.54, 0.73] *P* = .76	0.58 [0.35, 0.81] *P* < .001	0.95 [0.68, 1.23] *P* < .001	1.15 [0.79, 1.52] *P* < .001
Left/right	0.11 [−0.06, 0.28] *P* = .19	0.09 [−0.34, −0.52] *P* = .66	0.17 [−0.44, 0.78] *P* = .57	0.27 [0.15, 0.39] *P* < .001	0.70 [0.41, 0.99] *P* < .001	1.03 [0.63, 1.43] *P* < .001
Up/down	−0.20 [−0.52, 0.11] *P* = .19	−0.89 [−1.38, −0.39] *P* < .001	−0.93 [−1.52, −0.34] *P* = .004	0.54 (0.50) [0.31, 0.76] *P* < .001	1.17 [0.81, 1.53] *P* < .001	1.34 [0.95, 1.74] *P* < .001

Values are given as mean difference in mm [95% confidence interval, mm] *P* value.

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Table 5. RELATIVE AND ABSOLUTE DIFFERENCES BETWEEN VIRTUAL PLAN AND SURGICAL OUTCOME AT A-POINT, B-POINT, AND POGONION OF CASES SEQUENCED MANDIBLE-FIRST

Mandible-First (n = 27)	Relative Differences (H_0: d = 0 mm; H_a: d ≠ 0 mm)			Absolute Differences (H_0: d = 2 mm; H_a: d < 2 mm)		
Surgical plane	A	B	Pogonion	A	B	Pogonion
Anterior/posterior	−0.38 [−0.68, −0.09] *P* = .01	−1.04 [−1.76, −0.32] *P* = .01	−1.07 [−1.90, −0.23] *P* = .01	0.57 [0.32, 0.81] *P* < .001	1.31 [0.67, 1.96] *P* = .02	1.41 [0.66, 2.16] *P* = .06
Left/right	0.13 [−0.15, 0.41] *P* = .34	0.12 [−0.17, 0.40] *P* = .40	0.08 [−0.26, 0.43] *P* = .62	0.45 [0.24, 0.66] *P* < .001	0.56 [0.39, 0.74] *P* < .001	0.70 [0.50, 0.91] *P* < .001
Up/down	−0.03 [−0.23, 0.17] *P* = .76	−0.95 [−1.37, −0.53] *P* < .001	−0.97 [−1.39, −0.56] *P* < .001	0.38 [0.24, 0.51] *P* < .001	1.12 [0.78, 1.46] *P* < .001	1.16 [0.83, 1.48] *P* < .001

Values are given as mean difference in mm [95% confidence interval, mm] *P* value.

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Table 6. COVARIATE ANALYSIS OF SURGICAL SEQUENCING ON ABSOLUTE DIFFERENCES BETWEEN VIRTUAL PLAN AND SURGICAL OUTCOME

	A-Point			B-Point			Pogonion		
	Maxilla-First	Mandible-First	*P* Value of Means	Maxilla-First	Mandible-First	*P* Value of Means	Maxilla-First	Mandible-First	*P* Value of Means
Anterior/posterior	0.58/0.48 [0.27, 0.76]	0.57/0.33 [0.20, 0.77]	>.9	0.95/0.82 [0.60, 1.12]	1.31/0.75 [0.44, 1.27]	.3	1.15/1.02 [0.50, 1.50]	1.41/0.74 [0.38, 1.38]	.5
Left/right	0.27/0.18 [0.07, 0.42]	0.45/0.27 [0.12, 0.58]	.15	0.70/0.54 [0.27, 0.80]	0.56/0.55 [0.18, 0.77]	.4	1.03/0.81 [0.54, 1.25]	0.70/0.62 [0.34, 0.98]	.14
Up/down	0.54/0.42 [0.11, 0.88]	0.38/0.26 [0.12, 0.54]	.2	1.17/0.98 [0.62, 1.70]	1.12/0.76 [0.52, 1.62]	.9	1.34/1.13 [0.74, 1.65]	1.16/0.89 [0.59, 1.51]	.5

Values are given as mean of absolute differences, mm/median [IQR] of absolute differences, mm.
IQR, interquartile range.

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Table 7. COVARIATE ANALYSIS OF AGE AND SEX ON ABSOLUTE DIFFERENCES BETWEEN VIRTUAL PLAN AND SURGICAL OUTCOME

Dimension	Covariate	Beta	95% Confidence Interval	*P* Value
Anterior/posterior	Age	0.01	−0.01, 0.03	.5
	Male (vs female)	0.00	−0.41, 0.40	>.9
	Maxilla first (vs mandible first)	−0.06	−0.48, 0.36	.8
Left/right	Age	0.01	0.00, 0.02	.3
	Male (vs female)	−0.15	−0.35, 0.05	.13
	Maxilla first (vs mandible first)	0.10	−0.11, 0.30	.4
Up/down	Age	−0.01	−0.02, 0.01	.4
	Male (vs female)	0.15	−0.11, 0.41	.3
	Maxilla first (vs mandible first)	0.16	−0.11, 0.43	.2

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maxillary advancement was preferentially underachieved rather than overachieved. In mandibular surgery where both advancement and setback were planned, posterior error does not implicate overcorrection or undercorrection of deformity. There was no statistically significant trend identified (P = .15-.45) in the direction of relative errors in the left-right plane. In the vertical plane, there was a statistically significant (P < .001) negative relative difference at B-point (−0.92 mm) and pogonion (−0.95 mm), indicating that mandibular position, on a whole, was more superior than planned and that surgical protocol favored superior over inferior error.

When evaluating relative error across maxilla-first and mandible-first cohorts, much of the posterior error identified in all-case cohort at A-point, B-point, and pogonion is attributable to mandible-first surgery. In maxilla-first surgery, the anterior-posterior relative errors are near zero (A: −0.13 mm; B: −0.02 mm; pogonion: −0.10 mm) with nonsignificant P values (.43-.93). However, in mandible-first surgery, there were negative (posterior) relative differences of −0.38 mm (P = .01), −1.04 mm (P = .01), and −1.07 mm (P = .01) at A-point, B-point, and pogonion, respectively. Table 8 depicts covariate analysis of sequencing on relative differences. At B-point (P = .022) and pogonion (P = .027), relative errors are significantly more negative (posterior) in mandible-first surgery; this significance was not identified at A-point (P = .3). Nonsignificant (P = .3->.9) impact of sequencing on relative errors was also found in the left-right and vertical planes.

Table 8. COVARIATE ANALYSIS OF SURGICAL SEQUENCING ON RELATIVE DIFFERENCES BETWEEN VIRTUAL PLAN AND SURGICAL OUTCOME

	A-Point			B-Point			Pogonion		
	Maxilla-First	Mandible-First	*P* Value of Means	Maxilla-First	Mandible-First	*P* Value of Means	Maxilla-First	Mandible-First	*P* Value of Means
Anterior/posterior	−0.13/−0.12 [−0.53, 0.39]	−0.38/−0.25 [−0.64, 0.05]	.3	−0.02/−0.14 [−0.80, 0.79]	−1.04/−0.61 [−1.27, −0.14]	.022	0.10/0.26 [−0.90, 1.01]	−1.07/−0.51 [−1.21, −0.06]	.027
Left/right	0.11/0.06 [−0.07, 0.27]	0.13/0.04 [−0.13, 0.36]	.9	0.09/0.24 [−0.43, 0.69]	0.12/0.10 [−0.42, 0.61]	>.9	0.17/0.49 [−0.56, 0.94]	0.08/0.06 [−0.49, 0.69]	.8
Up/down	−0.20/−0.04 [−0.62, 0.13]	−0.03/−0.07 [−0.38, 0.22]	.3	−0.89/−0.98 [−1.70, 0.02]	−0.95/−0.76 [−1.62, −0.42]	.8	−0.93/−1.08 [−1.65, −0.03]	−0.97/−0.86 [−1.51, −0.46]	>.9

Values are given as mean of relative differences, mm/median [IQR] of relative differences, mm. IQR, interquartile range.

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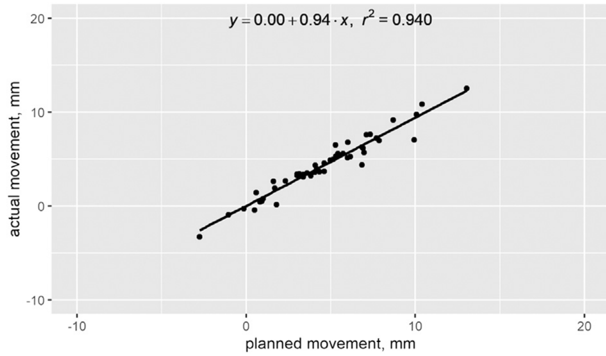

FIGURE 5. Regression analysis of the relationship between planned and actual movements at A-point, all cases, in the anterior-posterior plane.

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A regression analysis was performed to characterize the relationship between planned and achieved surgical movements in the anterior-posterior plane, across the spectrum of magnitudes of linear movements represented in the cohort. The following linear regressions were calculated:

- A-point: actual movement = 0.94*planned movement, $r^2 = 0.940$ (Fig 5)
- B-point: actual movement = 0.87*planned movement – 0.59, $r^2 = 0.960$ (Fig 6)
- Pogonion: actual movement = 0.89*planned movement – 0.15, $r^2 = 0.950$ (Fig 7)

Covariate analysis found that age, sex, and bimaxillary sequencing had no statistically significant effect on absolute differences (Table 7).

While this study was designed to assess bony position over a quantified occlusal relation, none of the study patients required revisionary corrective jaw

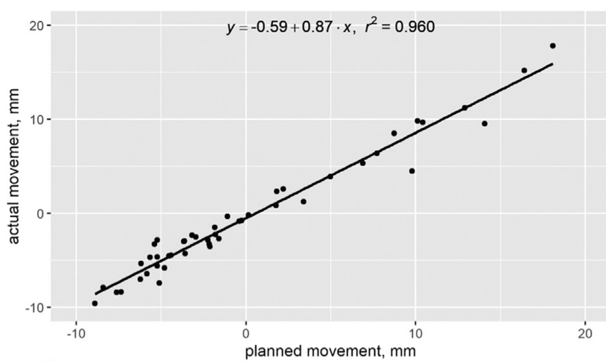

FIGURE 6. Regression analysis of the relationship between planned and actual movements at B-point, all cases, in the anterior-posterior plane.

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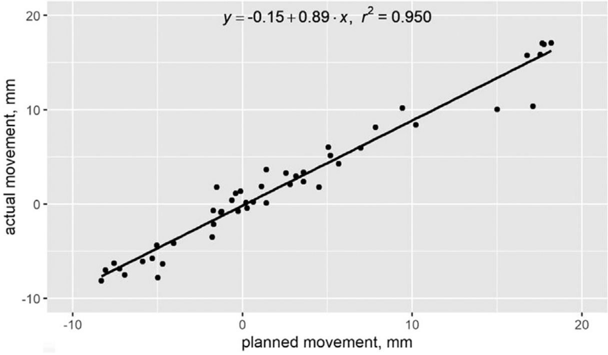

FIGURE 7. Regression analysis of the relationship between planned and actual movements at pogonion, all cases, in the anterior-posterior plane.

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surgery as the result of a malocclusion. Additionally, in no case did the surgeon need to abandon the guided protocol because of poorly-fitting surgical guides or fixation plates.

Discussion

In the first large-sample cohort assessing double-jaw orthognathic surgery using patient-specific guided protocols, this cohort study sought to quantify, in 3 dimensions, discrepancies between planned and achieved surgical anatomies of the maxilla and mandible. The authors hypothesized that patient-specific protocols would demonstrate bimaxillary accuracy below a 2-mm threshold. Further goals included study of directional trends in error and the impact of sequencing on error in double-jaw orthognathics. In the cohort studied, patient-specific protocol using occlusally borne SLA resin guides and patient-specific fixation plates permitted high-fidelity reproduction of digitally planned facial movements for maxillary and mandibular surgeries performed in conjunction with one another for patients requiring double-jaw orthognathic correction of skeletal facial deformities. The results demonstrate that guided orthognathic surgery with patient-specific fixation plates allows for reliable reproduction of the planned osteotomy movements with errors approaching 0.5 mm in maxillary surgery and 1 mm in mandibular surgery, with 3-dimensional linear accuracy at each of A-point, B-point, and pogonion being significant ($P \leq .05$) below the 2-mm hypothesized threshold. Comparable absolute differences were seen regardless of sequencing of surgery, and maxillary surgery was found to be more precise than mandibular surgery. Additionally, regression modeling indicated high correlation values for A-point, B-point, and pogonion positioning across a diverse cohort of patients undergoing wide-ranging magnitudes of orthognathic correction.

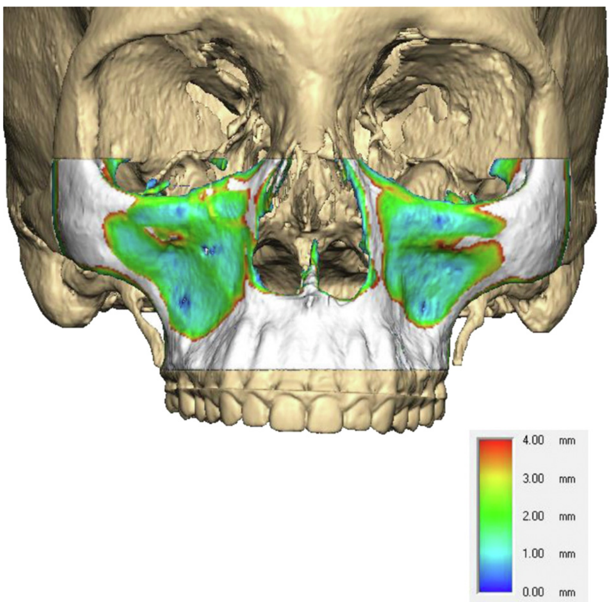

FIGURE 8. Identification of nasomaxillary and zygomaticomaxillary buttress position via bone depth scale.

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In the vertical plane, the results identified significant all-cohort negative (superior) relative differences at B-point and pogonion in both maxilla-first and mandible-first surgery. As these superior errors were isolated to mandibular surgery and not evident at A-point in either cohort, the authors hypothesize that superior mandibular error may be attributable to over-equilibration of occlusion or to the use of light orthodontic elastics in the early postoperative period.

In the horizontal plane, negative (posterior) relative differences were identified in the mandible-first cohort at each of A, B, and pogonion locations. The authors theorize that this may be due, in part, to patient selection and the nonrandomness of sequence in this study: Mandible-first surgery was more commonly selected in patients with class II malocclusion and steep occlusal planes, patients associated with a higher degree of relation-centric occlusion variability that may have manifested with errors in record taking.

The protocols we described in this report differ from those in other literature in which splintless surgery was performed. At this center, the use of both external maxillary reference points via nasofrontal K (Kirschner) wire placement and occlusal maxillomandibular splints was maintained. These devices were used intraoperatively in conjunction with guided technology to serve as additional confirmatory checkpoints to verify accuracy of bony position given that guided surgical protocols were newly introduced and not yet verified in their accuracy. Furthermore, this surgical protocol uses SLA resin occlusally-based osteotomy guides that are designed to capture maxillo-mandibular relation at the moment of osteotomy; they are fabricated in accordance with planned sequencing of surgery (maxilla first, mandible first, etc.) and relate osteotomy position to the position of both jaws rather than to only single-jaw anatomy. In second-jaw surgery, resin guides capture the bimaxillary intermediate occlusion, predicted by first-jaw surgical guides and set by first-jaw patient-specific fixation plates.

During guided surgery, it is critical to obtain passive seating of the hardware with elimination of any bony interferences during the LeFort I and sagittal split osteotomies. This is with the goal of minimizing torquing of hardware during placement which could potentially lead to discrepancies in accuracy of jaw position. This protocol uses 4 plates per maxilla, rather 1 or 2 conjoined plates, in order to reduce the likelihood of plate flexion that may compensate for bony interferences and thus introduce small errors.

In guided surgery using this protocol, the accuracy of the custom plates is predicated on accurate condylar positioning in planning sessions, and thus reliable records-taking in centric relation. In the majority (estimated at 90%) of jaws included in this series, predrilled guided screw holes in the distal segment of the second jaw passively aligned with plates when the proximal segment and condyle were seated (maxilla first) or the entire maxillomandibular complex was seated (mandible first). When discrepancies were noted, they were generally 1 mm or less. The authors propose possible etiologies for observed discrepancies: errors in predictive condylar position from virtual planning sessions secondary to condylar positioning during CT data acquisition and unidentified bony interferences during either maxillary or mandibular surgery leading to nonpassive plating. Record-taking error may be introduced in the form of slight protrusion anterior to centric relation (incomplete attainment of centric relation), unidentified centric occlusion position, unstable occlusion causing shifting, and multiple condylar positions.

In examples of intraoperative discrepancy, the surgeon's subjective feel when seating the condyle in centric relation was given priority over predrilled guided holes. While data were not available, it is estimated that on approximately 10% of cases, 1 or more holes were redrilled when plating the second jaw. As such, plating the second jaw while in MMF via occlusal splint remains essential.

Custom contouring of plates allows for optimal bone-to-plate contact and reduces even minor torquing of bony segments that occurs with imperfect bending of stock hardware, a source of discrepancy in orthognathic surgery. Custom plates are modifiable intraoperatively with bending techniques, but in the authors' experience, this is rarely necessary and did not occur in any of the cases in this report. The use of patient-specific plates has additional benefits to surgeons and patients beyond accuracy of reproducing planned bony movements. During planning meetings, surgeons collaborate with engineers to place screw holes in the optimal position to capture best-possible bone stock while avoiding injury to vital structures such as inferior alveolar nerve, mental or infraorbital foramina, tooth roots, and maxillary sinus (Figs 8 and 9). The resulting plate architecture may be unusual (Fig 10) relative to the traditional stock plate design, but it allows the

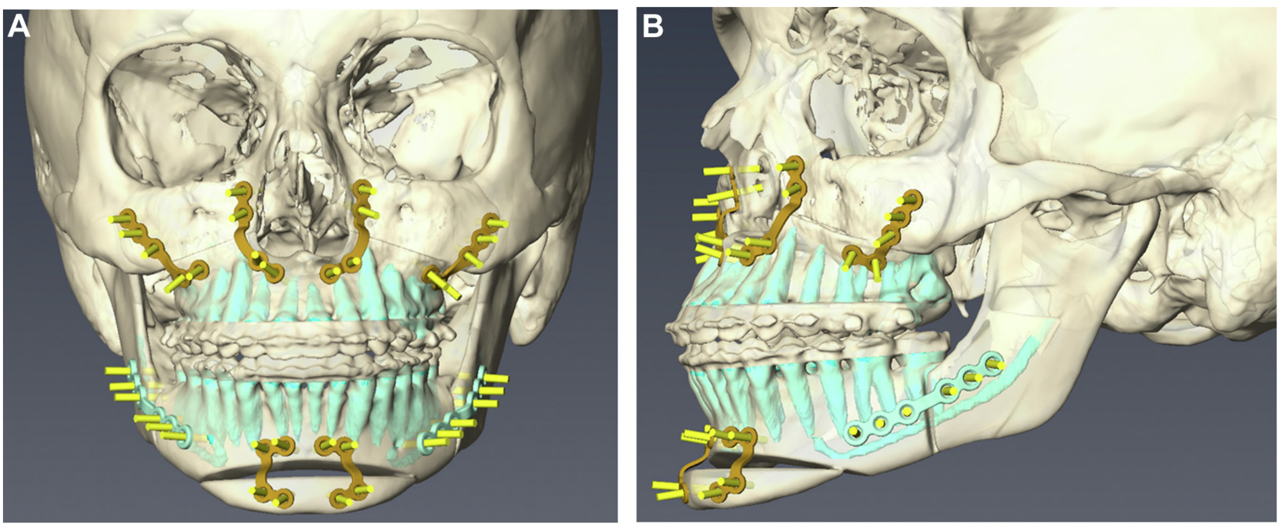

FIGURE 9. *A*, Design of patient-specific fixation plates minimizes risk of injury to vital structures, coronal view. *B*, Design of patient-specific fixation plates minimizes risk of injury to vital structures, sagittal view.

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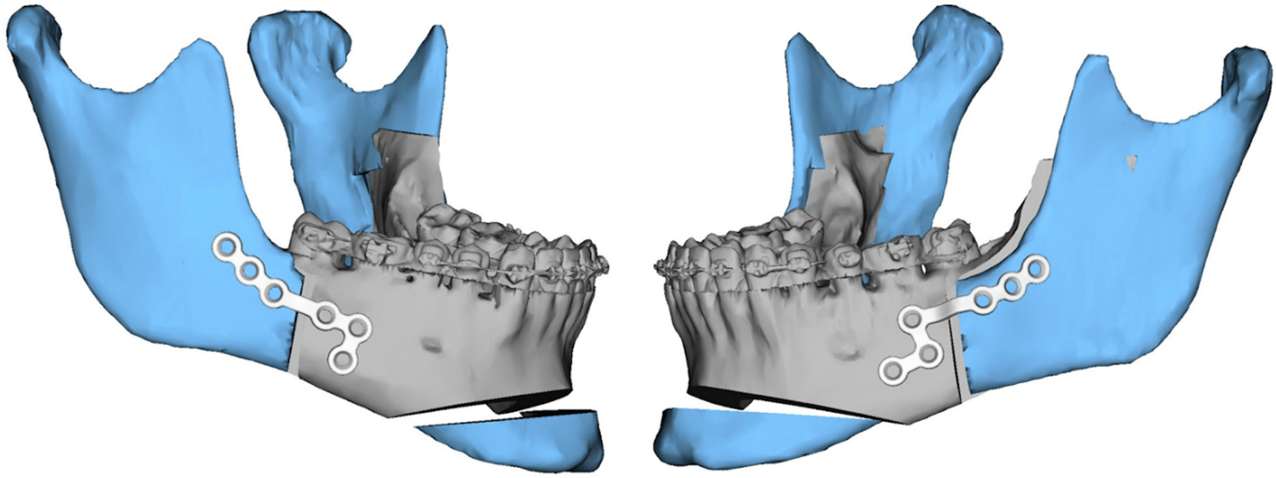

FIGURE 10. Patient-specific fixation plates from same patient, demonstrating asymmetric configurations designed to avoid inferior alveolar nerve, mental foramina, and tooth roots.

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surgeon to utilize regions of high quality and thickness while avoiding vital structures. The long-term stability of orthognathic surgery utilizing patient-specific hardware will be a subject of future research.

While the accuracy achieved with guided orthognathic surgery is promising, the use of SLA predictive guides and patient-specific fixation hardware is not without surgical drawbacks. As resin guides have a certain degree of flexion, or play to them, intraoperative obstructions (soft-tissue impingement, occlusal mis-seating, bony interferences) can be inadvertently camouflaged by guide flexion; these sources of error may lead to reduced accuracy of guided surgery and plate adaptation. Additionally, the SLA resin may permit nonparallel drilling of screw holes or may itself yield to a surgical bur, each presenting an opportunity for imprecisely placed predictive holes and thus some degree of error. Furthermore, guide size necessitates increased surgical exposure, including slightly larger incisions and periosteal stripping, relative to traditional techniques. Surgical protocols for guided techniques require frequent application and removal of MMF although added operative time may be balanced by time savings in not having to bend plates intraoperatively. Surgeons must also weigh the increased costs and production times required for use of a custom platform against the clinical relevance of accuracy, the frequency of replating, and the frequency of revisionary surgery. It is our hope that future research may quantify such variables.

The authors acknowledge that this cohort study is in part limited by the lack of a matched control group, as data were not available to compare the primary surgeon's patient-specific results with a cohort of same-surgeon patients treated with the use of previous analog (model surgery and hand-fabricated splints) or virtual (CAD-CAM splints with stock fixation hardware) protocols. Such control groups, if available, would have provided increased isolation of the variable of patient-specific protocol. Additionally, a larger sample size would be required to properly power the study to evaluate transverse dimension (eg, multipiece LeFort osteotomies) or the accuracy of patient-specific genioplasty alone. Finally, in assessing the results of this cohort study, it is important to consider that the fundamental goal of orthognathic surgery is a functional stable occlusion, rather than osseous accuracy alone. While this study was not structured to evaluate planned and achieved occlusal relationships, such information would be of paramount clinical value to orthognathic surgeons.

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