

Comparison of Actual Surgical Outcomes and 3-Dimensional Surgical Simulations

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Purpose: The advent of imaging software programs has proved to be useful for diagnosis, treatment planning, and outcome measurement, but precision of 3-dimensional (3D) surgical simulation still needs to be tested. This study was conducted to determine whether the virtual surgery performed on 3D models constructed from cone-beam computed tomography (CBCT) can correctly simulate the actual surgical outcome and to validate the ability of this emerging technology to recreate the orthognathic surgery hard tissue movements in 3 translational and 3 rotational planes of space.

Materials and Methods: Construction of pre- and postsurgery 3D models from CBCTs of 14 patients who had combined maxillary advancement and mandibular setback surgery and 6 patients who had 1-piece maxillary advancement surgery was performed. The postsurgery and virtually simulated surgery 3D models were registered at the cranial base to quantify differences between simulated and actual surgery models. Hotelling *t* tests were used to assess the differences between simulated and actual surgical outcomes.

Results: For all anatomic regions of interest, there was no statistically significant difference between the simulated and the actual surgical models. The right lateral ramus was the only region that showed a statistically significant, but small difference when comparing 2- and 1-jaw surgeries.

Conclusions: Virtual surgical methods were reliably reproduced. Oral surgery residents could benefit from virtual surgical training. Computer simulation has the potential to increase predictability in the operating room.

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Le Fort osteotomy advancements and bilateral sagittal split osteotomy (BSSO) setbacks alone and in combination are performed for the correction of skeletal Class III deformities. The conventional treatment planning procedure for these orthognathic surgeries involves making plaster models of the teeth and den- toalveolus. The desired surgical outcome of the den- tition is then determined. A lateral cephalometric ra-

diograph is taken and traced to focus on areas of interest. A relocation plan is then performed. This is frequently performed using computer software. Hard tissue computer predictions from lateral cephalo- grams for orthognathic surgical procedures have been shown to provide accurate hard tissue prediction.^{1,2} They have also been shown to be a reproducible and a quick method of profile prediction that is useful for

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treatment planning and patient presentation.³ Current lateral cephalometric models have also been linked to soft tissues. This allows one to make surgical changes in the hard tissues that are then reflected in the soft tissues.^{4,5} The surgery is then performed on the cast as a mock surgery. From these mock surgery casts, dental splints are created for use during the surgery. The splints are placed on the relocated dentition during the surgery to confirm that the actual surgery matches the model. In this way, the dentition serves as a guide to confirm correct surgical repositioning of the skeletal structures. During preparation for orthognathic surgery, the accuracy of cephalometric tracings and model surgeries is extremely important. The intent is to reduce intraoperative complications and to minimize actual surgical time.

This conventional process is satisfactory but it has a number of limitations. As can be seen above, it is a manual process with multiple steps. It is only a partial view of the actual surgery because the model surgery is not a true mock surgery. It is a repositioning of the dentition to the desired end result to make a splint. It does not involve simulated cuts, or even the necessary components of the craniofacial complex to make such cuts. The relation to the craniofacial complex is loosely made through estimation of the casts to the lateral cephalometric radiograph. The lateral cephalometric radiograph is a 2-dimensional image of a 3-dimensional object (3D). This results in errors of superimposition, distortion, anatomy location, and projection. Vertical positioning of the maxilla is very difficult.⁶ It also requires that one estimate by hand on the cast those movements that have 6 degrees of freedom. This introduces a great deal of inaccuracy.

With the advent of 3D imaging came the possibility for improved diagnosis and treatment planning. Many software systems have been developed that aim to improve surgical treatment and outcomes.⁷ Virtual surgeries can be performed preoperatively.⁸ Craniofacial surgery planners use a patient's individual preoperative 3D cone beam computed tomography (CBCT) scans for making surgical and other predictions. Noguchi and Goto demonstrated that 3D simulated surgical repositioning of bones is helpful for analyzing both bone and soft tissue movements.⁹

The future of cone beam technology to enhance surgical prediction and preparation is very promising. Recent advances in imaging technology have made the acquisition of 3D images more cost-effective and at a reduced radiation dose. This is particularly the case with CBCTs. With the proliferation of CBCT 3D imaging technology, we have seen a concurrent expansion of imaging software programs. These software programs have proved to be useful for diagnosis,¹⁰ treatment planning, and outcome measurement, but precision of 3D surgical simulation still needs to

be tested. The craniomaxillofacial (CMF) application software was developed and surgical navigation components have been validated at the M.E. Müller Institute for Surgical Technology and Biomechanics, University of Bern, Switzerland¹¹ (under the funding of the Co-Me network, <http://co-me.ch/>). Using an existing dataset of pre- and postsurgery CBCT images from the grant Influences on Stability following Orthognathic Surgery (NIDCR DE005215), we compared virtual surgical outcomes with actual surgical outcomes by superimposing the 2 images. Our null hypothesis is that the mean surface distance of the simulated surgical models when superimposed on the actual CBCT of orthognathic surgical patients at the University of North Carolina is 0.5 mm. The voxel size of the images is 0.5 mm; therefore, we anticipate the error in our image superimpositions to be no greater than 0.5 mm. Our aim is to determine whether the virtual surgery performed on the CBCT segmentations can correctly simulate the actual surgical outcome and to validate the ability of this emerging technology to re-create the orthognathic surgery hard tissue movements in 3 translational and 3 rotational planes of space.

Materials and Methods

Fourteen patients who had combined maxillary advancement and mandibular setback surgery and 6 patients who had 1-piece maxillary advancement surgery were selected (11 females and 9 males). Patients ranged in age from 14 to 35 years with a mean age of 21 years. All subjects were taken from a consecutive prospectively collected sample that had 1 of the above-mentioned surgeries on or after November 16, 2004, and consented to participate in a National Institutes of Health-funded project, "Influences on Stability following Orthognathic Surgery" (DE 005215). Patients who had cleft lip and palate, asymmetries, and other craniofacial anomalies were excluded. Rigid fixation was used in all the surgeries.

Image Acquisition

New Tom 3G CBCTs (QR-NIM SRL, Verona, Italy) with the patient in the supine position were obtained before surgery and approximately 4 to 6 weeks after surgery (at splint removal).

IMAGE ANALYSIS PROCEDURES FOR SIMULATION OF SURGERY

Construction of Pre- and Postsurgery 3D Models From CBCT Dataset

Segmentation involved outlining the shape of structures visible in the cross-sections of a volumetric dataset with the New Tom CBCT-3D images. Segmentation of anatomic structures was performed with

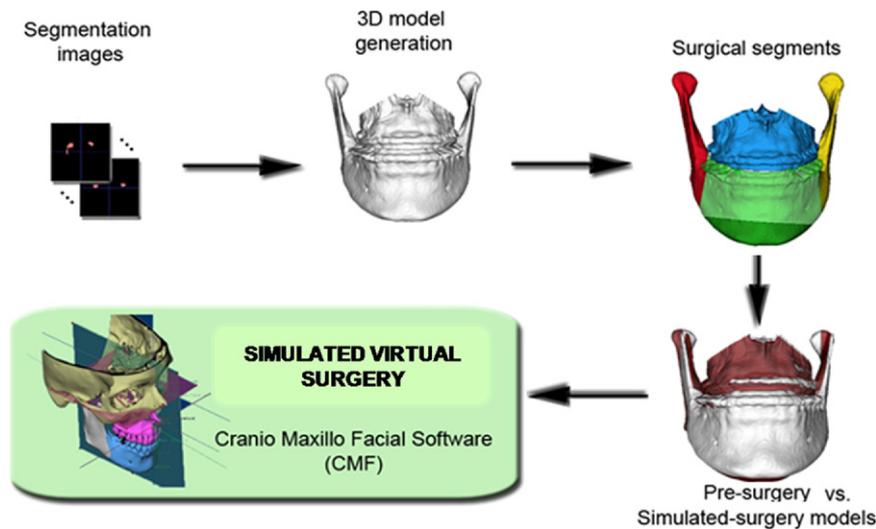


FIGURE 1. Sequence of image analysis procedures used for virtual surgical simulation: After segmentation of anatomic structures, ie, outlining the shape of structures visible in the cross-sections of a CBCT volumetric dataset, the virtual cuts were performed. For each patient, simulated surgery outcomes were created to compare with presurgery and actual surgery models. Virtual cuts matched clinical osteotomy segments that in this example were chin, left ramus, right ramus, mandibular body, and/or maxillary body. The virtual surgical segments were then displaced to determine whether virtual surgery performed on the cone beam CT surface models could correctly simulate the actual surgical outcome.

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ITK-SNAP.¹¹ Three-dimensional virtual models used in this aim were built from a set of ~ 300 axial cross-sectional slices for each image with the voxels reformatted for an isotropic of $0.5 \times 0.5 \times 0.5$ mm. This resolution was used because higher spatial resolution with smaller slice thickness would have increased image file size and required greater computational power and user interaction time. After the segmentation with ITK-SNAP tool, a 3D graphical rendering of the volumetric object allowed navigation between voxels in the volumetric image and the 3D graphics with zooming, rotating, and panning. Image analysis procedures for simulation of surgery are depicted in Figure 1.

Registration of Pre- and Postsurgery 3D Models

The mutual-information approach registers 1 image to another, using a rigid registration to evaluate within subject changes. This task was performed using the registration pipeline within the Imagine Software developed at the University of North Carolina.^{12,13} Our superimposition methods are fully automated, using voxel-wise rigid registration of the cranial base instead of the current standard landmark matching method, which is observer dependent and highly variable. After masking the maxillary and mandibular structures, the registration transform was computed solely on the gray level intensities in the cranial base. Rotation and translation parameters were calculated and then applied to register 3D models.

Surgical Simulation

Surgical simulation was performed with the CMF application software (M.E. Müller Institute for Surgical Technology and Biomechanics, University of Bern, Switzerland). Simulation involved the procedures described below.

Registration. The registered virtual 3D surface models of pre- and postsurgery were converted from .gipl files to .iv files and then imported into CMF.

Simulation of osteotomies. Simulated surgeries were performed on the 3D presurgery models by a single examiner. The cuts for a standard BSSO and maxillary Le Fort I osteotomy were executed by placing points on the presurgery models at the area and in the orientation of the osteotomy cuts. The locations of the surgical cuts were determined by the anatomic characteristics of each patient, such as thickness of the mandibular ramus, position of the mandibular canal, and proximity to the roots of the second molars.

Simulation of surgical displacements. The postsurgical model was used as a surgical guide. This was done by changing the color and reducing the opacity of the postsurgery model, which was superimposed with the presurgery model. The magnitude and direction of the simulated movements were then guided by the registered postsurgical model. Movements for each surgical piece were performed allowing 6 degrees of freedom (anterior-posterior, lateral, superior-inferior, yaw, pitch, and roll).

Quantification of differences between simulated and actual postsurgery models. We computed the surface distances between simulated and actual postsurgery models at specific anatomic regions (condyles, lateral mandibular rami, lateral mandibular corpi, anterior mandibular corpi, chin, lateral maxillary body, and anterior maxillary body).

Statistical Analysis

Student's *t* tests were performed for all 11 regions of interest to test whether the virtual surgeries showed no greater difference than 0.5 mm when compared with the actual surgeries. Student's *t* tests were also performed to test whether the measurements between 2-jaw and 1-jaw surgery patients were statistically significant. Hotelling T^2 was used to test the differences in the amount of movement between 1 and 2-jaw surgery patients. Paired *F* tests were performed to evaluate the difference between right and left lateral rami in patients who received 2-jaw surgeries. Student's *t* tests were calculated to assess the reliability of the 5 patients who received a second virtual surgery.

Results

The virtual surgical models were superimposed on the models of the actual surgical outcomes. This generated visual displays of magnitude, direction, and location of disagreement between models (Fig 2). For all statistical testing, a value of *P* less than .05 was

considered statistically significant. The differences between the superimpositions of the simulated and actual surgery images are shown in Figure 3. The mean difference for the left lateral maxilla was 0.536 mm and the median was 0.515 mm. The mean and median differences were less than 0.5 mm for the superimpositions of all the other regions of interest. The 0.5-mm difference was selected because 0.5 mm is the spatial resolution of the cone beam images. For each region of interest, power was calculated and Student's *t* test was performed to test whether the surface distances between the simulated and the actual surgical models were no greater than 0.5 mm. The results are listed in Table 1. For all 11 regions of interest, there was no statistically significant difference between the simulated and the actual surgical models. The power in the right lateral maxilla, left lateral maxilla, and chin was less than 0.80. The power was greater than 0.96 for all other regions of interest.

In comparing the 2-jaw subjects with the maxillary advancement subjects, Student's *t* test was performed. The results are listed in Table 2. The right lateral ramus was the only region of interest that showed a statistically significant difference when comparing the 2-jaw and 1-jaw surgeries. Hotelling T^2 was performed to test whether 2-jaw surgery translational and rotational displacements were significantly different from maxilla surgery only. There was no statistically significant difference between 2-jaw and 1-jaw surgeries when comparing translational dis-

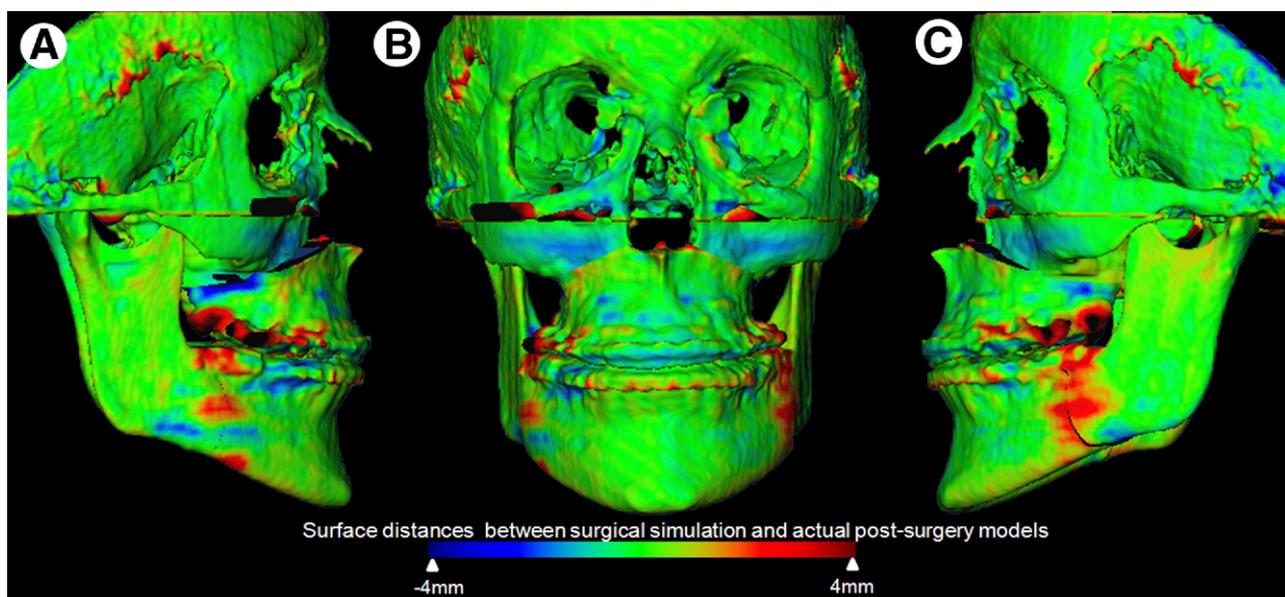


FIGURE 2. Superimposition of virtual surgery and postsurgery models of a patient treated with maxillary advancement and mandibular setback. A, Right lateral view. B, Frontal view. C, Left lateral view. Color maps demonstrate the location, direction, and magnitude of the differences between these models. Note that in the maxilla and mandible except for areas of surgical cuts the surface distances between simulated and actual surgery models are close to 0 mm (green).

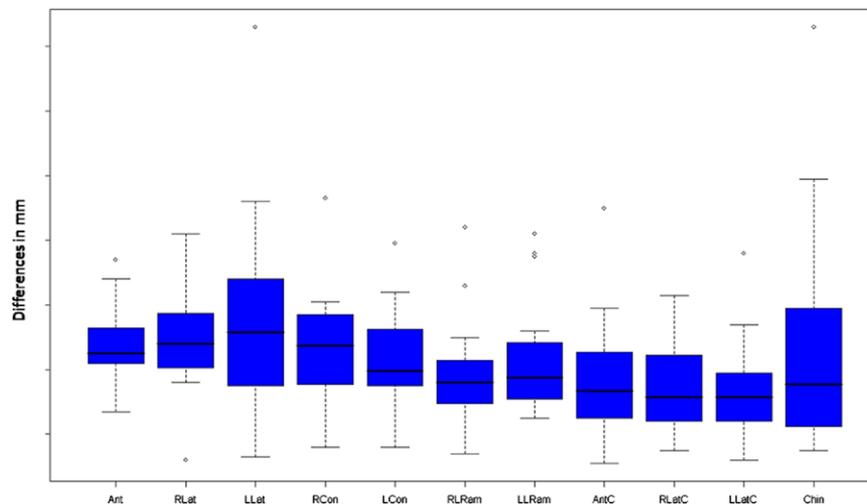


FIGURE 3. Differences between virtual and actual postsurgery models are shown. The x axis shows the 11 regions of interest and the y axis shows the difference in mm between the 2 images. All regions of interest except the left lateral maxilla showed a mean and median difference less than the 0.5-mm spatial resolution of the acquired image (Ant = anterior maxilla, RLat = right lateral maxilla, LLat = left lateral maxilla, RCon = right condyle, LCon = left condyle, RLRam = right lateral ramus, LLRam = left lateral ramus, AntC = anterior corpus of the mandible, RLatC = right lateral corpus of the mandible, LLatC = left lateral corpus of the mandible, Chin = chin).

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placements ($F = 0.80$, $P = .514$) and rotational displacements ($F = 1.18$, $P = .347$), respectively.

In 2-jaw subjects there was very little translational variability in the right and left lateral rami as shown in Figure 4. The left lateral ramus showed greater rotational variability than the right lateral ramus as shown in Figure 5. The median for translational and rotational displacements in all groups was zero, but sig-

nificant individual variability was manifest. Paired F tests were performed to test whether the right and left ramus displacements were significantly different. The F value for translational displacement was 3.2592593 and the probability $> F$ was 0.0633288. The F value for rotational displacement was 1.024251 and the probability $> F$ was 0.4192385. These tests did not demonstrate statistical significance between the right and left lateral rami displacements in 2-jaw surgery patients.

Table 1. COMPARISON OF RESULTS OF VIRTUAL SURGICAL MODELS VERSUS MODELS OF ACTUAL SURGICAL OUTCOMES

	t Value	Probability	t Power
Region of interest			
Anterior maxilla	-0.79167	0.561677	0.962
Right lateral maxilla	-0.18841	0.14745	0.203
Left lateral maxilla	0.538988	0.403845	0.151
Right condyle	-0.8912	0.616033	0.986
Left condyle	-1.85496	0.920813	0.999
Right lateral ramus	-3.27984	0.99606	0.999
Left lateral ramus	-1.81991	0.915435	0.999
Anterior corpus	-3.29165	0.996163	0.999
Right lateral corpus	-5.62111	0.99998	0.999
Left lateral corpus	-5.27873	0.999957	0.999
Chin	-0.45906	0.3486	0.631

Power was calculated. Student's t tests were performed for each region of interest to test whether the difference of the virtual surgical outcomes, when superimposed on the actual surgical outcomes, was less than the image spatial resolution of 0.5 mm.

$P < .05$ was used to determine statistical significance between the 2 images.

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Table 2. COMPARISON OF 2-JAW SURGERY PATIENTS WITH MAXILLARY ADVANCEMENT PATIENTS

	t Value	Probability
Region of interest		
Anterior maxilla	-0.88331	0.388712
Right lateral maxilla	-0.08929	0.929836
Left lateral maxilla	-1.84928	0.080908
Right condyle	0.351947	0.728965
Left condyle	-0.81534	0.425536
Right lateral ramus	2.505062	0.022074*
Left lateral ramus	0.638073	0.53146
Anterior corpus	-1.20006	0.245671
Right lateral corpus	1.633646	0.119702
Left lateral corpus	0.605325	0.552519
Chin	0.100442	0.921104

Student's t tests were performed for each region of interest to test whether there was a difference in the virtual surgical outcomes between 1- and 2-jaw surgery patients.

* $P < .05$ was used to determine statistical significance between the 2 images.

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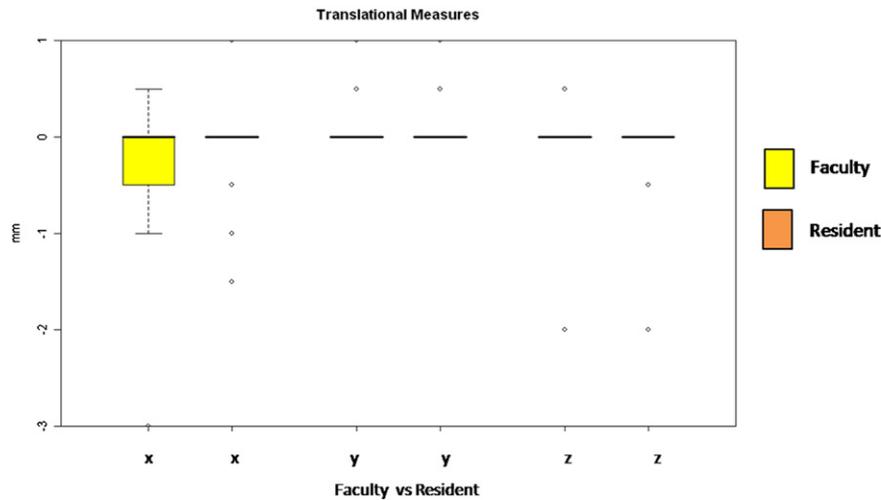


FIGURE 4. Translational movements of the right and left lateral rami during mandibular setback surgery. The faculty member operated on the right side and is always shown in the left of the paired columns (yellow boxplots; x, y, z coordinates). The resident operated on the left side and is always shown on the right of the paired columns (orange boxplots; x, y, z coordinates). Directions of movement in mm: x coordinates, (+)left/(-)right movement; y coordinates (+)anterior/(-)posterior; and z coordinates (+)superior/(-)inferior movement.

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Five of the subjects were randomly selected to have the surgery repeated. The differences between the repeated surgical simulation and the actual surgical outcomes were recorded. These measurements were then compared with the initial differences in measurements for these patients. All of these measurements

showed less than 0.4 mm difference between the initial surgical simulation and the repeated surgical simulation. This is less than the 0.5-mm spatial resolution of the cone beam images. Student's *t* tests were performed and the results are shown in Table 3. There was no statistically significant difference be-

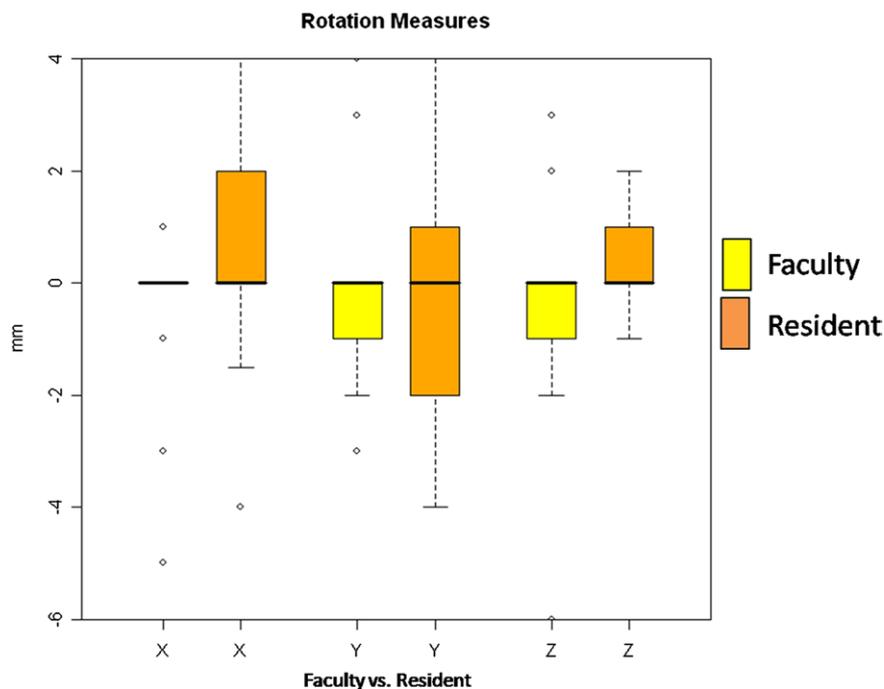


FIGURE 5. Rotational movements of the right and left lateral rami during mandibular setback surgery. The faculty member operated on the right side and is always shown in the yellow of the paired columns. The resident operated on the left side and is always shown on the orange of the paired columns. Amount of rotation in degrees is shown: (+) signifies a clockwise rotation and (-) signifies a counterclockwise rotation. Column X, axial plane or pitch; column Y, sagittal plane or yaw; column Z, coronal plane or roll.

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Table 3. COMPARISON OF MEASUREMENTS BETWEEN THE REPEATED SURGICAL SIMULATIONS AND THE ACTUAL SURGICAL OUTCOMES

	<i>t</i> Value	Probability <i>t</i>
Region of interest		
Anterior maxilla	0.200548	0.850836
Right lateral maxilla	2.046469	0.110131
Left lateral maxilla	1.258634	0.276614
Right condyle	0.043499	0.967389
Left condyle	0.286611	0.788643
Right lateral ramus	0.191565	0.857414
Left lateral ramus	1.152182	0.313421
Anterior corpus	1.617962	0.180981
Right lateral corpus	-0.55405	0.60906
Left lateral corpus	0.202031	0.849752
Chin	-0.18546	0.861896

Five subjects received a second virtual surgery, and measurements for each region of interest were recorded. Student's *t* tests were performed for each region of interest to test the reliability of the repeated surgeries. $P < .05$ was used to determine statistical significance between the 2 images.

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tween the initial and the repeated measurements for any of the regions of interest.

Discussion

Differences between virtual and actual surgical outcomes were measured using a voxel-wise rigid registration of the cranial base. Previous studies have validated this method that has been shown to be more accurate than traditional landmark methods for 3D superimpositions.¹¹ The larger the number of points used for superimposition, the more accurate it becomes.^{14,15} Only 2 of the measured differences between pre- and post-surgery models were greater than 1 mm. All differences were less than 2 mm. Differences of less than 2 mm have been shown to not be clinically significant.¹⁶⁻¹⁸

Presurgical predictions do not necessarily reflect the actual surgical outcomes that are produced. Surgery notes, although helpful, show variation between surgeons as to the estimated amount of movement. Furthermore, surgical notes do not reflect the necessary degree of precision we desire to accurately assess the validity and reliability of the virtual surgeries. Post-surgical models are the best measure of what movements were actually produced in the surgery. Therefore we used the postsurgical models as a guide for positioning of the virtual surgical models. This limits our ability in this study to generalize our results because we cannot say that we were able to predict the surgical outcomes. Future studies can be used to predict surgical outcomes before surgery and assess

whether surgical outcomes and segment movements are better controlled when computer-assisted surgical simulation is performed before surgery. The techniques in this article resulted in an evaluation of the methodology of the computer program itself, allowing assessment and visual display of the location, direction, and magnitude of agreement between virtual and actual surgery models. The difference between the actual surgical displacement values and the measured simulated values was smaller than the CBCT image spatial resolution of 0.5 mm. Computer assisted surgical simulation allowed manipulation of the images in the necessary 6 degrees of freedom to accurately reproduce the actual surgical outcome.

Bi-maxillary surgery has been shown to be more difficult to predict than single jaw surgery.¹⁹⁻²¹ It has been suggested that this is caused by the greater complexity of 2-jaw surgeries. Our research indicates that for the hard tissue structures measured, there was no statistical difference between the 1- and 2-jaw surgery patients. The only exception was the statistically significant displacement of the right lateral ramus in 2-jaw surgery patients. There was also no statistically significant difference in our population in the amount of translation or rotation that was performed in the maxillary body during the surgery. There was also no clinically significant difference between the 2 groups. Three-dimensional surgical planning allows us to overcome many of the limitations of conventional surgical planning. For example, an often-cited difficulty of maxillary impaction surgery is posterior bone removal for vertical positioning of the maxilla. The unpredictability of the necessary bone removal can significantly alter surgical time. Our software allows us to visualize the hard tissue structures in the posterior maxilla and provide better operating room predictability. It allows the surgeon to have a better idea of how much bone removal will be necessary and then plan accordingly (Fig 6).

We demonstrated greater variability in lateral ramus displacement on the left side performed by the surgical residents, while the surgeon performed on the right side. However, the surgery residents' displacement was not statistically significantly different from the attending faculty nor was it considered clinically significant. Increased displacement of the lateral ramus during surgery has the potential for decreased stability of the surgical outcome. It could be valuable to incorporate these emerging technologies into surgical training programs.²² We believe that there is potential for great benefit to residents by allowing them to perform surgical procedures in 3 dimensions before entering the operating room. This allows them to practice procedures as well as to attempt different surgical scenarios. A systematic review of the literature by Gurusamy et al demonstrated that virtual reality train-

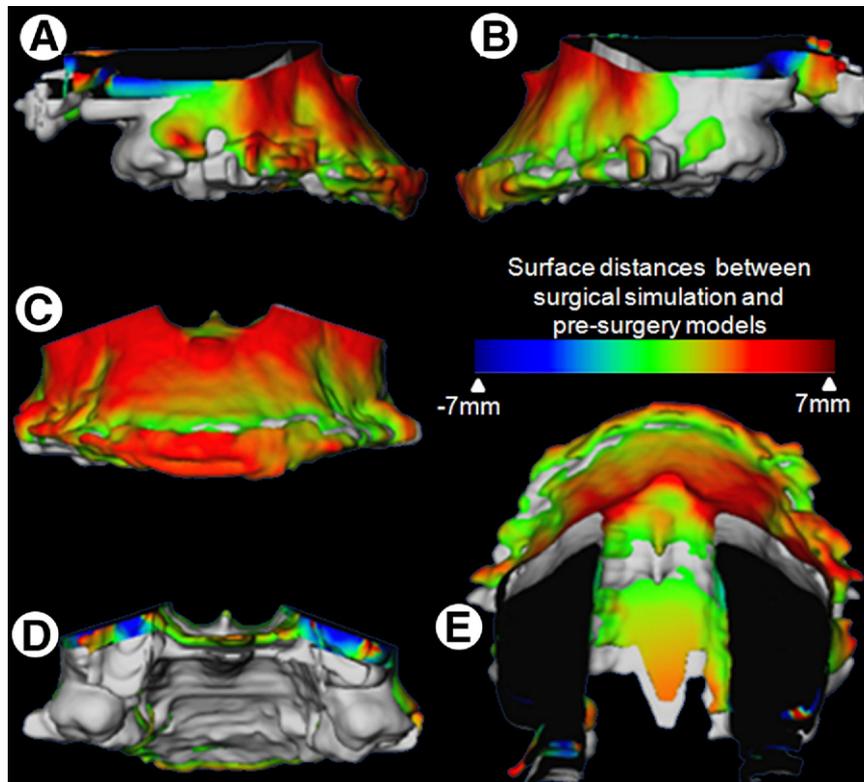


FIGURE 6. Example of a maxillary impaction case in which surgical simulation helped to plan areas and amount of bone removal for impaction. Superimposition of maxillary segment of virtual surgery models and presurgery models of patients treated with maxillary advancement and impaction. A, Right lateral view. B, Left lateral view. C, Frontal view. D, Posterior view. E, Superior view. Gray image is the presurgery model; image with color map is the postvirtual (simulated) surgery image. Color maps demonstrate the location, direction, and magnitude of the differences between these models. Note the dark blue area in the posterior part of the maxilla indicating that 7 mm of posterior bone removal will be necessary during the surgery.

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ing for surgery residents resulted in increased accuracy, decreased operating time, and decreased error.²³ This technology also allows the potential for communication between colleagues and training over distances by sharing digital 3D records.²⁴ We see potential value in surgical resident training for surgical procedures to be supplemented through virtual surgical training.

There has been an explosion in recent years of commercially available programs for 3D virtual surgery and visualization programs. The biggest drawback to these programs is the lack of validation of outcomes. It is desirable that craniofacial skeletal components, occlusion, and soft tissue outcomes are validated.²⁵ This article demonstrated that CMF application software can correctly simulate the actual surgical outcomes of craniofacial skeletal components of patients. However, the CT does not accurately render the teeth with the necessary precision for surgical simulation and splint fabrication.^{26,27} Three-dimensional laser scanning is a noninvasive way to accurately capture the occlusion that has been suggested by multiple groups.²⁸⁻³⁰ These images are then superimposed and merged on the cone beam images.³¹

Using 3D printers, splints can be fabricated from the digital models.³² Soft tissue predictions also lack validation and are extremely difficult to accurately predict in 3 dimensions.^{6,33} Commercially available programs use spring deformation and morphing programs for soft tissue surgical predictions. This is not biomechanically accurate, nor has it been validated.³⁴⁻³⁷ The validation of soft tissue outcomes would greatly improve patient presentation and understanding of surgical outcomes.

Xia et al demonstrated that computer-aided surgical simulation has lower material costs, as well as decreased patient and surgeon time. These investigators foresee even greater time savings by outsourcing the surgical image processing to radiology technicians at imaging centers.³⁸ Our research allowed us to demonstrate that the computer-aided surgical simulations can accurately reproduce with 6 degrees of freedom the actual surgeries performed for Class III correction. This validation of the virtual surgery of hard tissue structures demonstrates the potential for comparable or better surgical outcomes. We see great benefit for this technology in the future as a tool that has been

shown to reduce complication and increase predictability. It allows the surgeon to better predict possible surgical complications and adapt accordingly to mitigate potential difficulties.^{22,39-44} It has also been used to allow more complex surgeries to be successfully performed in a single procedure rather than the previous multiple staged surgeries.⁴¹ Future benefits also include the fabrication of stereolithographic models and surgical splints. These have the potential to greatly reduce intraoperative time, complications, and surgical surprises.⁴¹ The accuracy of computer-assisted surgery has been shown to be within 1 mm when using a referencing splint.⁴⁵ A number of these programs such as the CMF application software that we tested are also equipped with a surgical navigation feature that allows the surgical simulations to be transferred to the operating room.^{36,43,44,46,47} Many such programs, such as CMF, currently take the form of passive intraoperative orientation and tracking systems. In final form there is potential for robotic execution of specific steps autonomously.⁴³ Therefore, we can anticipate the potential for faster, less expensive, and better outcomes through this emerging technology. This rapidly developing technology will have a significant impact on a surgeon's future work.

Three-dimensional diagnosis and treatment planning has great potential for future benefit to patients and surgeons. The validation of these rapidly emerging technologies is paramount. It is particularly valuable to validate craniofacial skeletal components, the occlusion, and soft tissues. Our virtual surgical methods were reliably reproduced. Oral surgery residents could benefit from virtual surgical training. The virtual surgery accurately recreated all surgical movements in three rotational and 3 translational planes of space. One- and 2-jaw virtual surgeries were equally valid and accurate. Preoperative simulation can allow increased predictability in the operating room. Future validation of occlusal and soft tissue components would be very beneficial.

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