Three-Dimensional Biomodeling in Complex Mandibular Reconstruction and Surgical Simulation: Prospective Trial

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ABSTRACT

Background: Mandibular reconstruction is challenging for experienced and resident surgeons. Three-dimensional (3D) biomodeling creates accurate physical models of patients' craniofacial skeletons, which can potentially assist reconstruction. However, this capacity has not been objectively examined.

Objective: The purpose of this study was to assess 3D biomodels in performing and learning mandibular reconstruction through surgical simulation.

Design: Prospective cohort study.

Setting: Tertiary care academic referral centre.

Methods: Ten experienced and 10 naive resident surgeons were asked to bend and fixate a titanium reconstruction plate, for a standardized anterior hemimandibular defect, on a 3D biomodel by freehand or 3D biomodel-assisted means. Participants were randomized to which technique was performed first. Twenty-four to 48 hours later, participants performed the opposite technique.

Main Outcome Measures: Accuracy was measured by anterior mental projection and intercondylar and interangular splay. The results per technique were compared to a complete (control) mandible. The time of reconstruction and usability of each technique, as per an International Standards Organization-based questionnaire, were also determined.

Results: Three-dimensional biomodel-assisted reconstruction led to plates with statistically indifferent projection and splay compared to the control (p < .05) for both groups. Conversely, freehand constructs significantly deviated in projection and splay for either group (p < .05). No difference in reconstruction time by technique was found (p < .05). Usability favoured 3D biomodel-assisted bending, with significantly higher ratings in either group (p < .05).

Conclusions: Three-dimensional biomodels provide a usable and accurate means of mandibular reconstruction for experienced surgeons. Moreover, when used in surgical simulation, they provide an effective tool for teaching residents.

SOMMAIRE

Contexte: La reconstruction de la mandibule se montre une intervention particulièrement difficile pour les chirurgiens chevronnés et les résidents en chirurgie. La biomodélisation tridimensionnelle (3D) permet la reproduction de modèles physiques, précis du squelette craniofacial; cette propriété pourrait faciliter la reconstruction, mais elle n'a jamais été examinée objectivement.

Objectif: La présente étude avait pour objectif d'évaluer les biomodèles 3D dans l'apprentissage et la réalisation de la reconstruction de la mandibule dans le cadre de simulations d'intervention chirurgicale.

Type d'étude: Il s'agit d'une étude prospective de cohortes.

Lieu: L'étude a été menée dans un centre spécialisé universitaire de soins tertiaires.

Méthodes: Nous avons demandé à 10 résidents expérimentés en chirurgie et à 10 résidents débutants en chirurgie de courber et de fixer une plaque de reconstruction en titane pour corriger une perte de substance hémimandibulaire antérieure uniformisée, soit à
main levée sur un biomodèle 3D, soit par manipulation assistée par un biomodèle 3D. Les participants ont été dirigés au hasard vers l’une des deux techniques, puis ont appliqué l’autre, de 24 à 48 heures plus tard.

**Principaux critères d’évaluation:** La précision était mesurée sur l’incidence mentonnier antérieure et sur les écartements incondylien et interangulaire. Les résultats obtenus pour chacune des techniques ont été comparés avec ceux obtenus pour une mandibule complète (témoins). De plus, le temps de reconstruction et la convivialité de chacune des techniques ont été évalués à l’aide d’un questionnaire conçu d’après les normes de l’Organisation internationale de normalisation.

**Résultats:** La reconstruction assistée par biomodèle tridimensionnel a permis le façonnement de plaques ayant une incidence et des écart statistiquement indifférents par rapport à la reconstruction du témoin (p < .05), dans les deux groupes. Par contre, la reconstruction à main levée s’éloignait de manière significative de l’incidence et des écarts prévus, dans l’un ou l’autre des deux groupes (p < .05). Il n’y avait pas de différence en ce qui concerne le temps de reconstruction exigé par chacune des techniques (p < .05). Quant à la convivialité, elle penchait nettement en faveur de la manipulation assistée par biomodèle 3D, et ce, dans les deux groupes (p < .05).

**Conclusions:** Les biomodèles tridimensionnels offrent aux chirurgiens chevronnés un moyen convivial et précis de reconstruction de la mandible. De plus, utilisés dans les simulations d’intervention chirurgicale, ils se montrent un bon outil d’enseignement aux résidents.

**Key words:** mandibular reconstruction, rapid prototyping, three-dimensional biomodeling, three-dimensional printing, usability

Mandibular defects following oral cancer surgery often require intricate and composite reconstructions. The goals of reconstructions are contour restoration while maintaining condylar relationships with adjacent structures, which results in preservation of aesthetics, oral competence, mastication, articulation, and allows for dental implantation. The gold standard of reconstruction has become osteocutaneous free tissue transfer with titanium plate fixation. The bony segments of the free flap are shaped to replace the resected portion of the mandible and are fastened with titanium plates. When the outer cortex of the mandible is intact, the plate is shaped intraoperatively by bending it to the mandible prior to mandibulectomy. However, when tumours violate the outer cortex of the mandible, the reference points for plate bending are lost. Consequently, the surgeon must resort to "freehand" bending, where the desired curvature is estimated based on the opposing, intact maxilla.

To aid in challenging craniofacial reconstructions, some surgeons have added three-dimensional (3D) biomodeling to their armamentarium of surgical tools. The concept of biomodeling was formalized in 1998 and was recently redefined as "an entity that replicates the geometry or morphology of a biological structure, which can be realized in either a computer-based form or a solid physical form." To obtain a 3D biomodel in physical form, a class of technologies known as rapid prototyping (RP) is employed. RP involves translating medical imaging data, such as computed tomographic (CT) scans, to 3D replicas of an anatomic structure via a 3D printer. Photopolymer materials are jetted in ultrathin layers onto a platform, which is then lowered by fractions of a millimetre so that the next layer may be applied. Each layer is immediately cured with ultraviolet light, thus producing fully cured models that may be used as soon as the printing process is complete. These models are accurate up to 0.016 mm and require 1 hour per centimetre of height being built to be produced.

By using computer-aided drafting (CAD) software to manipulate CT scan data, an entire craniofacial skeleton or a selected portion of one may be printed. Moreover, mirror images of portions may be created. In the case of a large tumour violating the outer mandibular cortex, the involved hemimandible may be deleted from the CAD images, and a mirror image of the uninvolved section may be used to recreate the expected mandibular form. In the case of a tumour extending through the anterior mandible, the CAD software can be used to create a best estimate of the native mandible based on reference points along the maxilla and uninvolved mandible. These models can then be used as templates for mandibular reconstruction plate bending.

Although 3D biomodels have been used by surgeons since the 1990s, there is a paucity of prospective, objective data supporting their use in craniofacial surgery. The advantages of biomodels are postulated to be shortened operating time and improved efficiency, increased plate bending accuracy, improved surgical planning and surgeon comfort, better patient education and informed consent, allowance of teaching demonstrations and surgical simulation, and user-friendliness. However, many of these advantages have yet to be confirmed.

This study set out to objectively and subjectively evaluate the utility of 3D biomodeling in the reconstruction
of a large mandibular defect. Two groups of subjects were tested: experienced craniofacial surgeons (group 1) and resident surgeons (group 2). The focus of group 1 was to determine the accuracy and usability of 3D model-assisted plate bending compared to freehand bending in experienced surgeons. Group 2 was used to determine the utility of 3D models in surgical simulation and learning mandibular reconstruction in surgical trainees. As such, the purpose of this study was to evaluate 3D biomodels in performing and learning complex mandibular reconstruction through surgical simulation.

Methods

Ethics approval was granted by the University of Alberta's Health Research Ethics Board (HREB). Patient information, consent, and data collection forms were reviewed and approved. The study was conducted at a tertiary care academic referral centre.

Research Questions

To assess the utility of applying 3D biomodels to performing and learning complex mandibular reconstruction, the following research questions were devised:

1. Does 3D biomodel-assisted mandibular reconstruction plate bending result in more accurate constructs compared to freehand bending?
2. Is 3D biomodel-assisted mandibular reconstruction plate bending more efficient compared to freehand bending?
3. Is 3D biomodel-assisted mandibular reconstruction plate bending more usable than freehand bending?
4. Is mandibular reconstruction easier to learn via 3D biomodel-assisted plate bending than via freehand techniques?

Participant Recruitment and Enrollment

Group 1 (Experienced Surgeons)

This group consisted of surgeons who perform craniofacial surgery, including mandibular reconstruction, in their practice via traditional, freehand methods. The purpose of this group was to determine the impact of 3D biomodels on plate bending accuracy and efficiency by surgeons who are accustomed to freehand bending. As such, a direct assessment of 3D biomodel usability, with an established baseline, could also be made. All potential craniofacial surgeons in the Edmonton, Alberta, area from 2008 to 2010 were contacted via telephone and e-mail to participate in the study. Ten surgeons met the criteria listed below and agreed to be enrolled:

1. Practicing head and neck, plastic, or oromaxillofacial surgeon
2. Mandibular reconstruction included in the practice
3. Performed at least 20 mandibular reconstructions using a reconstruction plate

The exclusion criterion for experienced surgeons was using 3D biomodels in mandibular reconstruction in their practice.

Group 2 (Residents)

The second group included residents at the University of Alberta, who will be trained in craniofacial surgical techniques as part of their program. This group was intended to assess the ease of learning mandibular reconstruction with the aid of a 3D biomodel. A recruitment e-mail was sent out by a divisional secretary to all surgical residents at the University of Alberta. The first 10 respondents who met the criteria listed below and were willing to participate were enrolled:

1. University of Alberta surgical resident in a training program, which includes craniofacial surgery (ie, otolaryngology–head and neck surgery or plastic surgery)
2. Having participated in or performed at least five craniofacial operations
3. Being familiar with the use of titanium plates, a surgical drill, plate benders, plate cutters, and plate fixation with screws

Exclusion criteria for residents were as follows:

1. Having performed or assisted in mandibular reconstruction
2. Having used 3D biomodels in craniofacial surgery

Prior to enrolment, the study coordinator (P.T.D.) completed a checklist of the above criteria with each potential participant. Those who met the criteria then received verbal and HREB-approved written information regarding the purpose, benefits, and risks of the study. Following the information session, the participants signed an HREB-approved consent form.

Participant Groups and Randomization

Participants of each group were randomized to first perform either freehand or 3D biomodel-assisted mandibular
reconstruction plate bending. A balanced, randomized sequence was created for each group using an online computer-based random number generator. This sequence was then translated onto cue cards that were kept in the generated order in a sealed, opaque envelope. An equal number of participants in each group performed 3D biomodel-assisted bending first. Randomization occurred after informed consent was obtained and just prior to beginning the trial by pulling out the next cue card from the envelope.

**Study Protocol**

After randomization, the participant was given standardized verbal and written instructions of the trial. These included a description of the materials provided and the primary objective: to bend and fixate a mandibular reconstruction plate to a standardized defect on a 3D biomodel with the greatest accuracy possible. The plate was to be bent along the inferior border of the mandible, as it would be on a patient. Accuracy was defined as mimicking the contour of the expected native mandible in terms of curvature, projection, and splay. Participants were instructed to take as much time as necessary to achieve this goal.

Participants were given an incomplete 3D biomodel of a patient’s craniofacial skeleton with a section from the right angle to the left midbody of the mandible missing. This skeleton was put together for the participants on a 3D platform (Figure 1A) into which the maxilla fit (Figure 1B) and the pieces of the mandible were snapped into place (Figure 1, C and D). A version of the skeleton with a complete mandible, which fit into the platform, was created as a control (Figure 1E). Lastly, a complete version of the craniofacial skeleton was also provided to participants performing the 3D biomodel-assisted technique (Figure 1F). The 3D biomodel was based on a CT scan of a patient with a large tumour.

**Figure 1.** Three-dimensional biomodels. A, Platform. B, Platform with maxilla. C and D, Platform with maxilla and standardized mandibular defect. E, Platform with maxilla and complete mandible (control). F, Complete craniofacial skeleton.
violating the outer and anterior mandibular cortex (Figure 2).

Participants were also provided with a standard set of instruments: one plate bender, two rotating plate cutters, one fixed-handle guarded screwdriver, one 2.4 mm titanium microvascular plate with an angle to the right (5 × 17 holes), four 2.4 mm × 12 mm titanium self-tapping cortex screws (Synthes, Inc., West Chester, PA), and one power drill (Craftsman, Belleville, ON) with a 1.8 mm drill bit (Synthes, Inc.). An assistant (P.T.D.) was available to hold and hand over instruments, much like a scrub nurse would in the operating theatre.

Participants in group 1 (experienced surgeons), who were performing the freehand technique, were asked to perform the reconstruction as they would in their practice. Those performing 3D biomodel-assisted bending were instructed to use the complete 3D model (see Figure IF) as a guide to bend the reconstruction plate directly on. Participants in group 2 (residents) were shown a 5-minute instructional video demonstrating the technique that they were about to perform. The videos consisted of the senior author (H.S.) demonstrating either the freehand or the 3D biomodel-assisted technique using the same tools provided to the participants. The videos were unscripted and filmed in an operating room to simulate a real-life teaching environment. All participants were instructed to fixate the bent plate to the incomplete model in a position that they deemed to be as accurate as possible. Ideally, fixation would have been performed with four screws on either side of the defect; however, owing to funding constraints, participants were asked to use two screws on each side. Participants were permitted to remove the fixated plate and reapply it as many times as necessary should the initial results be unsatisfactory.

Following the final instructions/videos, the participant was given an opportunity to familiarize himself or herself with the instruments for 2 minutes. As soon as the participant picked up an instrument, a digital, computerized timer (Apitec Timer, version 6.3.1, Apitec, Berkeley, CA) was started. Once the participant was satisfied with the reconstruction, he or she was asked to announce “Done,” and the timer was stopped. The time was recorded in minutes:seconds. The completed reconstruction was then measured as described below.

Twenty-four to 48 hours following the first trial, the participant repeated the reconstruction task using the opposite technique to what they were randomized. That is, if he or she performed freehand the first day, the 3D biomodel-assisted technique would be performed on the second day. Following the second trial, the participant completed the Mandibular Reconstruction Techniques Usability Questionnaire (Table 1 and Table 2).

**Outcome Measures**

**Primary Outcome**

The accuracy of mandibular reconstruction plate bending was the primary focus of this study and was assessed by measuring (1) anterior mental projection (AMP), (2) intercondylar splay (ICS), and (3) interangular splay (IAS). AMP was defined as the perpendicular distance from the midpoint of the 3D model platform to the posterior edge of the mandibular reconstruction plate, with the model still sitting in the platform (Figure 3, A and B). This measurement was obtained using calipers, a standard surgical ruler, and an “L” square ruler to ensure that the measurement was taken perpendicular to the platform. ICS was defined as the shortest distance between condyles with
Table 1. Mandibular Reconstruction Techniques Usability Questionnaire Results, Part 1: Direct Technique Comparison

<table>
<thead>
<tr>
<th>Question</th>
<th>Technique</th>
<th>Group 1 (Experienced Surgeons)</th>
<th>Group 2 (Residents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Which technique of mandibular reconstruction would you prefer to use in your practice?</td>
<td>Freehand</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>2. Which technique of mandibular reconstruction did you find more efficient?</td>
<td>3D model</td>
<td>90</td>
<td>100</td>
</tr>
<tr>
<td>3. Which technique was more difficult to use?</td>
<td>Freehand</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>4. Which technique was easier to learn?</td>
<td>3D model</td>
<td>70</td>
<td>100</td>
</tr>
<tr>
<td>5. Which technique would you prefer to use in teaching residents?</td>
<td>Freehand</td>
<td>80</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>3D model</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Freehand</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>3D model</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>Freehand</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>3D model</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Secondary Outcomes

In addition to the accuracy of reconstruction, the efficiency and usability of using 3D biomodels were assessed:

1. Efficiency: time of reconstruction as measured during the trials
2. Usability: a Mandibular Reconstruction Techniques Usability Questionnaire based on International Standards Organization (ISO) standards was devised to determine the subjective usability of 3D biomodels in mandibular reconstruction (see Table 1 and 2). The ISO is an

Table 2. Mandibular Reconstruction Techniques Usability Questionnaire Results, Part 2: Rating of Mandibular Reconstruction Techniques

<table>
<thead>
<tr>
<th>Question</th>
<th>Group 1 (Experienced Surgeons)</th>
<th>Group 2 (Residents)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean Ratings on a 10-Point Likert Scale</td>
<td>p Value</td>
</tr>
<tr>
<td>1. Please rate the ease when learning</td>
<td>Freehand</td>
<td>6.5</td>
</tr>
<tr>
<td></td>
<td>3D model</td>
<td>3.6</td>
</tr>
<tr>
<td>2. Please rate your efficiency when using</td>
<td>Freehand</td>
<td>5.7</td>
</tr>
<tr>
<td></td>
<td>3D model</td>
<td>2.6</td>
</tr>
<tr>
<td>3. Please rate your comfort level when using</td>
<td>Freehand</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td>3D model</td>
<td>2.1</td>
</tr>
<tr>
<td>4. Please rate your accuracy when using</td>
<td>Freehand</td>
<td>4.9</td>
</tr>
<tr>
<td></td>
<td>3D model</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Ratings range from 1 to 10. A rating of 1 is equal to the best possible outcome, and a rating of 10 is equal to the worst possible outcome.
The organization is responsible for setting reliable and reproducible standards for a wide variety of industries and technologies. Unfortunately, no ISO guidelines exist for freehand or 3D biomodel-assisted mandibular reconstruction. As such, a novel questionnaire based on established ISO 9241-11 usability standards, was created. These validated ISO standards define usability as the “extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.” The specific users were defined as experienced surgeons and resident surgeons. The specific goals were defined as per the research questions above. The context of use was complex mandibular reconstruction as defined above.

The questionnaire was divided into two parts: direct technique comparison and rating of techniques (see Table 1 and Table 2). Questions were devised to separately assess the effectiveness, efficiency, and satisfaction of using each reconstruction technique as studies have shown these domains to be independent of one another. Effectiveness was assessed with surrogates of technique accuracy and ease of learning. Efficiency was directly defined. Satisfaction was reflected in terms of technique preference and comfort. In part 1 of the questionnaire, participants were asked to compare techniques by choosing one over the other. In part 2, participants were asked to rate each technique on 10-point Likert scales for each question. A rating of 1 was considered to be the most congruent or agreeable value with the question being asked. Conversely, a rating of 10 was considered the least congruent or agreeable value with the question being asked. For example, a rating of 1 for questions pertaining to efficiency would indicate that the technique was the most efficient technique possible, whereas a rating of 10 would be the least efficient technique possible.

3D Biomodel Creation

A standardized helical CT scan of one patient’s craniofacial skeleton was obtained in 1 mm axial slices with 0° gantry. The Digital Imaging and Communication in Medicine (DICOM) format data were then imported into Mimics 13.1 (Materialise, Leuven, Belgium). After saving a complete 3D craniofacial skeleton, the mandible was segmented from the skull. The complete skeleton and the separate skull and mandible were then exported as individual STL files into Freeform 10 (SensAble, Woburn, MA) for further segmentation and manipulation. Based on haptic input, the mandible was further sectioned to remove a portion from the right mandibular angle to the left midbody. Also, unnecessary areas of the skull were removed to create a maxilla. This left six saved pieces: a complete craniofacial skeleton, a copy of the maxilla of the skeleton, a copy of the complete mandible of the skeleton,
and a copy of the mandible missing the portion from the right angle to the left midbody.

A platform into which the maxilla and sectioned mandible would fit securely was created with a series of lofting and Boolean operations using a combination of Rhinoceros 3D (McNeel & Associates, Seattle, WA) and Freeform.

All individual pieces were then exported as STL files from Freeform to a 3D printer (Invision SR 3D printer, 3D Systems, Rock Hill, SC) using Visijet SR200 Plastic (3D Systems). This multijet modeler is similar to an ink-jet printer in that it deposits material in successive, thin layers to build the 3D models from computer data. One 3D model of the complete craniofacial skeleton, complete model, complete maxilla, and platform was printed. Additionally, two pairs of the mandibles with the missing section were printed for each participant.

Statistical Analysis

For each participant group, the results of AMP, ICS, and IAS for freehand and 3D biomodel-assisted techniques were compared to the control mandible using a one-sample t-test. The results of AMP, ICS, IAS, and time of reconstruction for freehand and 3D biomodel-assisted techniques were compared to each other using an independent samples t-test. Furthermore, the results of trial 1 and trial 2 for each group were compared to each other using two independent samples t-tests. The results of part 2 of the Mandibular Reconstruction Techniques Usability Questionnaire were also compared using an independent samples t-test. Statistical significance was set as p < .05. All statistical analyses were performed with SPSS Statistics 17.0 (SPSS Inc, Chicago, IL).

Results

Ten experienced craniofacial surgeons completed both trials and comprised group 1. All were male with an average age of 44.7 years (range 35–55 years). The average time since completion of residency was 10.2 years (range 1–22 years).

Table 3 demonstrates the plate bending accuracy of group 1 by technique of mandibular reconstruction compared to the control mandible. Freehand reconstructions were consistently retrognathic with an average AMP 6 mm posterior to the expected position. This is a statistically significant difference compared to the control. Conversely, 3D biomodel-assisted plate bending led to AMPs mimicking the control mandible with no statistically significant deviation. When using freehand bending, experienced surgeons created constructs that were significantly splayed. The average ICS was 6 mm and the IAS was 3 mm lateral of the control. However, reconstruction plates bent with 3D model assistance were not statistically different from the control in terms of ICS and IAS. All accuracy measures were significantly different between techniques, with 3D model–assisted constructs showing greater accuracy versus the freehand bends (p < .05). Lastly, accuracy measures were compared by the order of the technique performed, that is, attempt 1 versus attempt 2. There was no statistically significant difference in AMP (p = .74), ICS (p = .63), or IAS (p = .16) based on whether the experienced surgeons performed freehand or 3D biomodel–assisted reconstruction first or second.

Ten residents completed both trials and comprised group 2. Eight were male and two were female, with an average age of 29.1 years (range 26–35 years). The average time since completion of medical school was 2.5 years (range 8 months–3.8 years).

Table 4 demonstrates the plate bending accuracy of group 2 by the technique of mandibular reconstruction compared to the control mandible. Freehand reconstructions were consistently and significantly prognathic with an average AMP of 3 mm protruding beyond the expected mentum. Conversely, the AMP with 3D biomodel–assisted
Table 4. Mean Mandibular Reconstruction Measurements from Group 2 (Residents)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Freehand</th>
<th>3D Model</th>
<th>3D Model versus Freehand</th>
<th>p Value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (cm)</td>
<td>Distance, cm</td>
<td>p Value</td>
<td>Distance, cm</td>
<td>p Value</td>
</tr>
<tr>
<td>Anterior mental projection</td>
<td>8.5</td>
<td>8.8 (0.2)</td>
<td>.01</td>
<td>8.6 (0.2)</td>
<td>.27</td>
</tr>
<tr>
<td>Intercondylar splay</td>
<td>7.9</td>
<td>7.1 (1.0)</td>
<td>.03</td>
<td>8.1 (0.4)</td>
<td>.18</td>
</tr>
<tr>
<td>Interangular splay</td>
<td>7.8</td>
<td>7.2 (0.7)</td>
<td>.03</td>
<td>7.8 (0.2)</td>
<td>.67</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(5.7–8.5)</td>
<td>(–1.14 to –0.07)</td>
<td>(7.6–8.8)</td>
<td>(–0.11 to 0.49)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(6.0–8.1)</td>
<td>(–1.16 to –0.10)</td>
<td>(7.5–8.1)</td>
<td>(–0.13 to 0.19)</td>
</tr>
</tbody>
</table>

Plate bending showed no statistically significant difference compared to the control. With freehand bending, residents created constructs that were significantly antisplayed. The average ICS was 8 mm and the IAS was 6 mm medial of the control. Meanwhile, reconstruction plates bent with 3D model assistance were statistically indifferent in terms of splay measures compared to the control. All accuracy measures were significantly different between techniques, with 3D model-assisted constructs showing, once again, greater accuracy compared to the freehand counterparts (p < .05). The accuracy measures were compared by the order of the technique performed. No statistically significant difference was detected in AMP (p = .14), ICS (p = .98), or IAS (p = .68) when the first and second attempts at reconstruction were compared.

Table 5 shows the time required to complete mandibular reconstructions. The craniofacial surgeons required an average of 11.1 minutes longer to bend a reconstruction plate with a 3D biomodel than by freehand methods; however, this was not found to be a significant difference (see Table 5). Residents, however, required an average of 8.9 minutes longer with the freehand method than with 3D model assistance. This was not a significant difference (see Table 5). When the order of technique was compared, there was no statistical difference in the time of reconstruction required based on which technique was performed first or second (group 1, p = .27; group 2, p = .63).

Group 1 rated the usability of 3D biomodel assistance significantly more favourably than the freehand technique in most domains tested (see Table 1 and Table 2). Similarly, nearly all of group 2 found the 3D biomodel-assisted method of learning and performing mandibular reconstruction to be more usable than the freehand method (see Table 1 and Table 2). Moreover, they rated the 3D biomodel-assisted method significantly more favourably than the freehand technique in each domain tested (see Table 1 and Table 2).

Discussion
Previous studies have hypothesized that 3D biomodel-assisted plate bending used in craniofacial surgery, including mandibular reconstruction, will provide several distinct advantages over freehand plate bending. The first part of this study focused on evaluating how well experienced surgeons can adapt to using 3D biomodels in complex mandibular reconstructions. This group consisted of surgeons who are comfortable and experienced in freehand mandibular reconstruction but do not use 3D model assistance. This was not a significant difference (see Table 5). When the order of technique was compared, there was no statistical difference in the time of reconstruction required based on which technique was performed first or second (group 1, p = .27; group 2, p = .63).
intuitive as having a 3D model to base plate bending on should lead to consistently accurate plate bending, whereas freehand bending will be highly dependent on surgeons' preferences, skill, and experience.

Some surgeons may argue that it is undesirable to bend a reconstruction plate to conform to the inferior edge of the native mandible, as is attempted with 3D biomodel assistance. The reason is that such plates will include the projection of the mentum, which is often anterior to the maxillary incisors. Although this type of reconstruction is best at restoring the cosmetic appearance of the neo-mandible, it may be positioned too far anterior to allow for proper occlusion if osseointegrated dental implantation is desired. One solution would be to use a “double-barrel” reconstruction with one part of the bone following the mandibular contour and the other placed opposite the maxillary alveolus. This technique provides a thicker mentum but will increase the bone stock available for implantation. The effect will be a neomandible with accurate contour, appearance, and preserved dental function. Another option would be to bend the plate at the level of the mandibular alveolus, thus ensuring good opposition of the construct with the maxillary alveolus. This alternative, however, may not impart an ideal cosmetic outcome.

Two measures of splay were used to determine plate tension and torsion. ICS reflects distal spatial changes resulting from proximal compressive forces of the reconstruction plate and can be prone to wide deviations with even small over- or underbending. IAS reflects proximal changes resulting from torsional forces of the plate and is much more resilient to compression. As such, greater plate bending inaccuracies are needed to cause discrepancies from the control. When using freehand bending, experienced surgeons created constructs with significantly more ICS and IAS compared to the control mandible. However, the ICS and IAS of reconstruction plates bent with 3D model assistance were not statistically different from the control. Once again, 3D biomodel-assisted plates showed consistent results with narrower standard deviations and confidence intervals. The clinical translation is that patients undergoing freehand mandibular reconstruction will be prone to tensional and torsional forces placed on their condyles and temporomandibular joints (TMJs). Consequently, they will be prone to malocclusion, TMJ pain or dysfunction, and poor bony union. In addition, the added forces on the reconstruction plate may weaken it over time, leading to plate fracture and undesirable and unpredictable bone remodeling. It is important to note that these results are despite the condylar relationships being stabilized by the platform (see Figure 1), much as they would be by an external fixator in the operating theatre. Therefore, the idea that 3D biomodel-assisted reconstruction eliminates the need for external mandibular fixation or intermaxillary fixation is supported.

When comparing 3D biomodel-assisted bending to freehand bends, all accuracy measures demonstrated a statistically significant difference between techniques \( p < .05 \), thus further supporting the improved accuracy when using a 3D biomodel.

It is given that 3D biomodels provide exceptional spatial understanding of anatomic relationships. Thus, pre- and intraoperative planning should be improved. As such, it has been hypothesized that 3D biomodel mandibular reconstruction will save operating time. The craniofacial surgeons tested in this study required on average 11.1 minutes longer to bend a reconstruction plate with a 3D biomodel than by freehand methods. This difference was not statistically significant and is not likely clinically significant. This result opposes that of Toro and colleagues, who showed a 1.5-hour decrease in surgical time when using a 3D biomodel in mandibular reconstruction. This difference can be explained by the surgeons being unfamiliar with the technique and potentially trying to be “too perfect” with their reconstructions. The wider range of times and confidence intervals for the 3D biomodel-assisted reconstructions further supports this idea. With practice, it is possible that the surgeons would become more efficient with the 3D models.

When assessing the usability of the 3D biomodel-assisted method, the majority of experienced surgeons preferred the 3D biomodel method to the freehand method for learning, teaching, efficiency, and overall use. Furthermore, experienced surgeons rated the 3D biomodel-assisted method significantly more favourably than the freehand technique for technique learning, efficiency, and accuracy \( p < .05 \). However, the surgeons felt quite comfortable with both techniques \( p < .05 \). This may be a reflection of extensive experience with the freehand method and having limited exposure to 3D biomodel assistance during this trial. Overall, the questionnaire shows that 3D biomodel-assisted mandibular reconstruction is a highly usable technique, as per ISO standards. These results are supported by the pioneering work of D'Urso and colleagues.

Part 2 of this study focused on using 3D biomodels as surgical simulation tools in the learning of complex mandibular reconstruction. The subjects, residents, had never performed mandibular reconstruction and had a
presumably equal baseline of plate bending skills. The instructional videos shown to the residents were designed to recreate the teaching that occurs in the operating theatre.

The accuracy of reconstruction was used as a measure of the effectiveness of learning mandibular reconstruction. When using the freehand method, residents bent significantly more prognathic plates than when using the 3D biomodel-assisted method. However, the 3D biomodel-assisted plates showed no significant difference in AMP compared to the control, and the measures were tightly bound to the average, as shown with a narrow standard deviation and confidence interval.

Mandibular constructs performed by residents were significantly splayed laterally, demonstrating very narrowly bent plates. Once again, the clinical implication will be poor TMJ function, malocclusion, and plate weakening. Furthermore, the increased inferior tension will cause greater lateral forces on the condyles, leading to potentially worse symptoms. The difference in projection and splay measures is further highlighted when comparing techniques directly ($p < .05$).

Despite being naive to mandibular reconstruction, the residents were able to create, with 3D biomodel assistance, accurately bent mandibular reconstruction plates for a complex defect. This objectively supports the utility of the 3D models as a teaching and surgical simulation tool as these novice surgeons quickly and accurately learned the reconstructive technique.

When comparing the residents' time of reconstruction, there was no statistically significant difference between techniques. However, the mean increase of 8.9 minutes with the freehand technique shows improved efficiency in learning mandibular reconstruction with a 3D biomodel. Furthermore, the accuracy per unit time of plate bending would greatly favour the 3D biomodel-assisted technique.

Nearly all residents found the 3D biomodel-assisted method of learning and performing mandibular reconstruction to be more usable than the free-hand method. The consensus was that the technique was easier to learn, more efficient, and perceptibly more accurate. Furthermore, residents rated the ease of learning, comfort, efficiency, and accuracy of 3D biomodel-assisted bending more highly than the freehand version ($p < .05$). Not only does this support the use of 3D biomodels in teaching, but it also promotes their usability in surgical simulation as even novice surgeons quickly feel comfortable with the technique.

Potential criticisms of this study include the results being limited by the number of participants, applying a nonvalidated questionnaire, "training bias," and "faking bias." With a small number of participants, the chance of making a type 1 error becomes more likely. However, statistical differences in primary outcomes that were not significant were accompanied by closely clustered results, whereas significant differences were not. This suggests that although a small number of participants were included, the differences in accuracy of reconstructive technique were strongly associated with the technique used. Usability results followed a similar pattern.

Unfortunately, a validated questionnaire for 3D biomodel-assisted surgery does not exist. Therefore, to minimize bias, ISO standards were applied with direct estimation methods of subjective outcomes. This is a common testing method when validated scales are lacking. Such questionnaires are easy to comprehend and have shown reliability and reproducibility in reflecting perceptions of effectiveness.

Some may claim that surgeons may seek professional advantage with self-promotion by associating themselves with "cutting-edge" technology. As such, they alter their performance or "fake it" to promote the technique that will ultimately improve self-advertising. However, the surgeons in this study belong to a public health care system, and no such advantage exists.

Lastly, by testing naive subjects with a novel technique, there is a potential for intrastudy training or adaptation. Participants may perform better with each subsequent attempt of reconstruction as they develop skills and experience with previous trials. This is especially true with trainees at the steeper end of the learning curve, such as residents. Therefore, one may expect there to be a difference in the accuracy results between first and second plate bending attempts, regardless of the technique used. In contrast, all comparisons for accuracy and time of reconstruction between the first and second plate bending attempts, for either group, were statistically insignificant. This supports the notion that the results are highly dependent on the actual mandibular reconstruction technique.

Conclusion

This study is the first to provide objective and subjective evidence supporting the use of 3D biomodels in complex mandibular reconstruction. It demonstrates that 3D biomodel-assisted mandibular reconstruction leads to accurate plate bending when performed by experienced and even naive, novice surgeons compared to traditional, freehand methods. Although the time to reconstruction was not shown to be statistically different between techniques, the usability was rated more favourably for
3D biomodel-assisted bending by both groups tested. Lastly, these results support the utility of 3D biomodels in teaching, learning, and simulating complex mandibular reconstruction.

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