Pilot Validation of a 3-Dimensional Printed Pituitary Adenoma, Vascular Injury, and Cerebrospinal Fluid Leak Surgical Simulator

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BACKGROUND AND OBJECTIVES: Endoscopic skull base surgery is a subspecialty field which would benefit significantly from high-fidelity surgical simulators. Giving trainees the opportunity to flatten their learning curve by practicing a variety of procedures on surgical simulators will inevitably improve patient outcomes.

METHODS: Four neurosurgeons, 8 otolarynologists, and 6 expert course faculty agreed to participate. All participants were asked to perform a transsphenoidal exposure and resection of a pituitary adenoma, repair a cerebrospinal fluid (CSF) leak, control a carotid injury, and repair a skull base defect. The content, face, and construct validity of the 3-dimensional printed model was examined.

RESULTS: The heart rate of the participants significantly increased from baseline when starting the carotid injury simulation (mean 90 vs 121, $P = .029$) and significantly decreased once the injury was controlled (mean 121 vs 110, $P = .033$, respectively). The participants reported a significant improvement in anxiety in facing a major vascular injury, as well as an increase in their confidence in management of major vascular injury, resecting a pituitary adenoma and repair of a CSF leak using a 5-point Likert scale (mean 4.42 vs 3.58 $P = .05$, 2 vs 3.25 $P < .001$, 2.36 vs 4.27 $P < .001$ and 2.45 vs 4.0 $P = .001$, respectively). The mean Objective Structured Assessment of Technical Skills score for experienced stations was 4.4, significantly higher than the Objective Structured Assessment of Technical Skills score for inexperienced stations (mean 3.65, $P = .016$).

CONCLUSION: We have demonstrated for the first time a validated 3-dimensional printed surgical simulator for endoscopic pituitary surgery that allows surgeons to practice a transsphenoidal approach, surgical resection of a pituitary adenoma, repair of a CSF leak in the diaphragma sellae, control of a carotid injury, and repair of skull base defect.

KEY WORDS: Pituitary adenoma, Pituitary surgery, Surgical simulator, Vascular injury

The use of surgical simulators to augment neurosurgical training is becoming more widespread, with multiple simulation tools becoming available over the past 10 years. The reasons for the increased use of surgical simulators in neurosurgery include reduced working hours, increased number of trainees, reduced operative time, and increased complexity of surgical cases.[1]

ABBREVIATION: OSATS, Objective Structured Assessment of Technical Skills.

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Skull base surgery is a subspecialty field which benefits significantly from high-fidelity surgical simulators. The initial learning curve is steep, and consequences for surgical misadventure are extreme. Giving trainees the opportunity to flatten their learning curve by practicing a variety of procedures on surgical simulators will inevitably improve patient outcomes.

Valentine and Wormald[2] developed an endoscopic sheep model that enables simulation of internal carotid injury with a sinus model trainer. The advantage of this simulator is the realism created in the vascular injury scenario, particularly with regards to pathophysiology of hemostasis. However, this model requires a large animal laboratory and local expertise in preparing the sheep for a course, which limits the models' accessibility.

Donoho et al[3] demonstrated a simulator that involved cannulating cadaver heads through their anatomy laboratory and then perfusing the carotid artery with assistance from a perfusionist. They calculated the costs associated with a "training success" but did not include the cost of establishing an anatomy laboratory and developing the expertise in this technique.

A variety of other surgical simulators using 3-dimensional (3D) printed models have become available, such as the UpSurgeOn TNS Box that was validated in December 2022 by Newall et al.[4] Similarly, Lee et al[5] in 2022 demonstrated development of a 3D printed model to simulate approaches for endoscopic endonasal and transorbital surgery. These models did not allow simulation of pathology or any operative steps like cerebrospinal fluid (CSF) leak repair or vascular injury management. Narayanan et al[6] in 2015 demonstrated development of a 3D printed model to simulate endoscopic management of platybasia but was limited to this pathology.

We present a new 3D printed model and a preliminary pilot validation in its use as a surgical simulator for pituitary adenoma resection, internal carotid artery injury management, and CSF leak repair and/or reconstruction.

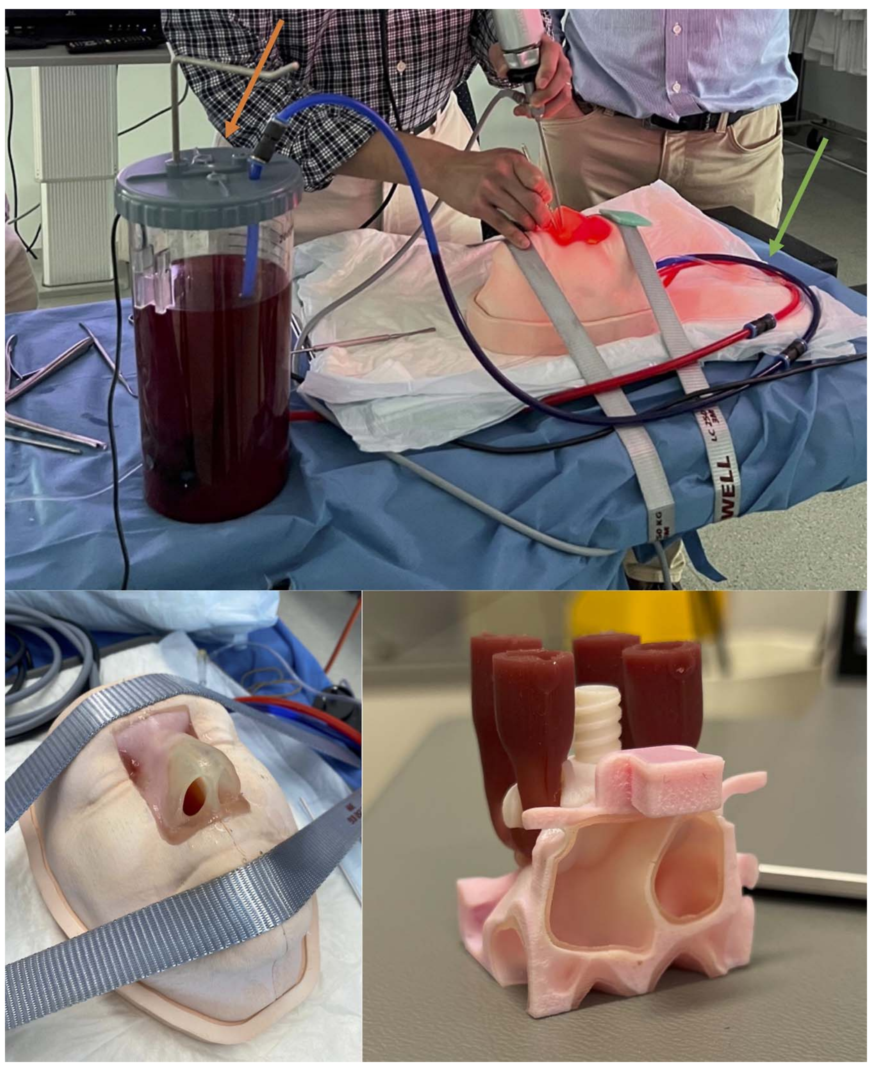

FIGURE 1. *The pituitary adenoma, vascular injury, and CSF leak repair surgical simulator. Top image demonstrates the appearance of equipment when completely set up. The green arrow indicates that "artery" and "venous" perfusion tubes that connect to the blood reservoir and pump, shown with orange arrow. The clear tubing indicated by the green arrow connects to an intravenous bag that acts as the CSF reservoir. Bottom left image is a view surgical simulator. Bottom right is a view of the sphenoid cassette which connects into the back of any sinus model with connections for vascular and CSF simulations. CSF, cerebrospinal fluid.*

TABLE 1. Learning Goals for Participants in the Endoscopic Pituitary Surgery Course

Sinonasal access	• Raise a rescue flap that then is converted into a nasoseptal flap • Perform a wide sphenoidotomy and posterior ethmoidectomy to allow large exposure of the sella • Remove rostrum and drill down anterior face of sella
First pituitary model	• Safely remove the soft suctionable tumor within the cavernous sinus • Repair a CSF leak in the diaphragma sellae using the bathplug technique with chicken fat • Control an easily accessible and visible anterior carotid injury with a chicken muscle patch
Second pituitary model	• Remove the firm and adherent tumor invading the cavernous sinus • Repair a large CSF leak in the diaphragma sellae using the bathplug technique with chicken fat • Control a challenging medial carotid injury with a muscle patch

CSF, cerebrospinal fluid.

METHODS

Model

The pituitary adenoma resection model was purchased from Fusetec. The models were manufactured using 3D printer technology based on the axial computed tomography scans of patients with pituitary neuroendocrine tumors.

The models are manufactured from multiple materials and are printed using 0.0125 mm slices with proprietary voxel-based software integration. To facilitate realistic haptic feedback, bone and skin are constructed with a Shore Hardness (D) 83 to 86 and Shore Hardness (A) 28 to 33, respectively.

The model is based on the functional endoscopic sinus surgery model previously validated by Wormald et al[7] to form the paranasal component of the model. The current model includes a detachable modular sphenoid sinus cassette which contains a sella, diaphgrama sellae and carotid arteries. The diaphragma sellae was constructed from a blend of photopolymers and enabled connection with an intravenous bag of fluids to simulate a CSF leak at a physiological intracranial pressure, when disrupted. The carotid arteries were constructed from platinum cured silicone rubber and connected to an external pump. When activated this enabled pulsatile blood flow within the carotid arteries, thereby simulating the high-flow/high-pressure vascular event as described by Valentine et al.[8] There was a total of 2 sphenoid sinus cassettes each with varying degrees of cavernous sinus invasion of the pituitary adenoma and varying tumor consistencies, from soft to firm and adherent. Figure 1 demonstrates the model when set up for use, as well as the face model and sphenoid cassette.

Participants

All participants at the 1st Endoscopic Pituitary Surgery Course in Adelaide, Australia, were offered the opportunity for involvement and provided a participant information sheet. Four neurosurgeons and 8 ENT surgeons agreed to participate and provided direct informed consent. The surgeons were a variety of trainee registrars (residents) and consultant surgeons. The local institutional review board had approved the study to be conducted. Precourse information was collected regarding previous experience with endoscopic pituitary surgery and the management of major vascular injuries. This was assessed with a precourse questionnaire, see **Supplemental Digital Content 1**, http://links.lww.com/ONS/B102.

Surgical Task

The surgical tasks were provided to the participants on the day of the course. Before commencement of their dissections, the surgical task was demonstrated initially in a live dissection provided by 2 of the expert course faculty. The learning goals for participants are outlined in Table 1.

Figure 2 demonstrates the steps to be completed using the surgical simulator, and Video demonstrates the model being dissected by 2 of the faculty.

Face Validity

Face validity was assessed by a postdissection questionnaire provided to the expert faculty and all participants. The questionnaire was graded using a Likert scale.[9] See the questionnaire in **Supplemental Digital Content 2, 3 and 4**, http://links.lww.com/ONS/B103, http://links.lww.com/ONS/B104, and http://links.lww.com/ONS/B105.

To assess the heart rate response during the vascular injury component of the model, a chest strap heart rate monitor (Chest Strap Fitness Sport Diving EM) was fitted to participants for the duration of the dissection. Peak heart rate was measured at a variety of time points during the dissection: baseline, during dissection, first carotid injury, after first reconstruction, second carotid injury, and after second reconstruction. Participants were also provided a questionnaire to complete at the end of the course using a Likert scale to rate their anxiety regarding vascular injuries before and after completing the course. See **Supplemental Digital Content 4**, http://links.lww.com/ONS/B105.

Content Validity

Content validity was assessed by the same postdissection questionnaire as for face validity using a 5-point Likert scale.[9] See **Supplemental Digital Content 2**, http://links.lww.com/ONS/B103.

Construct Validity

Construct validity was assessed using post procedural video recordings of the dissection. These were reviewed by one of the expert authors. This was completed in a blinded fashion, and one of the video recordings included the demonstration station performed by 2 of the expert faculty from earlier in the day. Participants' operative performance was assessed using a modified Objective Structured Assessment of Technical Skills (OSATS) criteria.[10] See **Supplemental Digital Content 5**, http://links.lww.com/ONS/B106.

Statistical Analysis

A one-sided paired Student *t*-test was used to compare changes in heart rates for participants during different stages of the dissection. A 2-sided paired t-test was also used to compare changes in precourse and

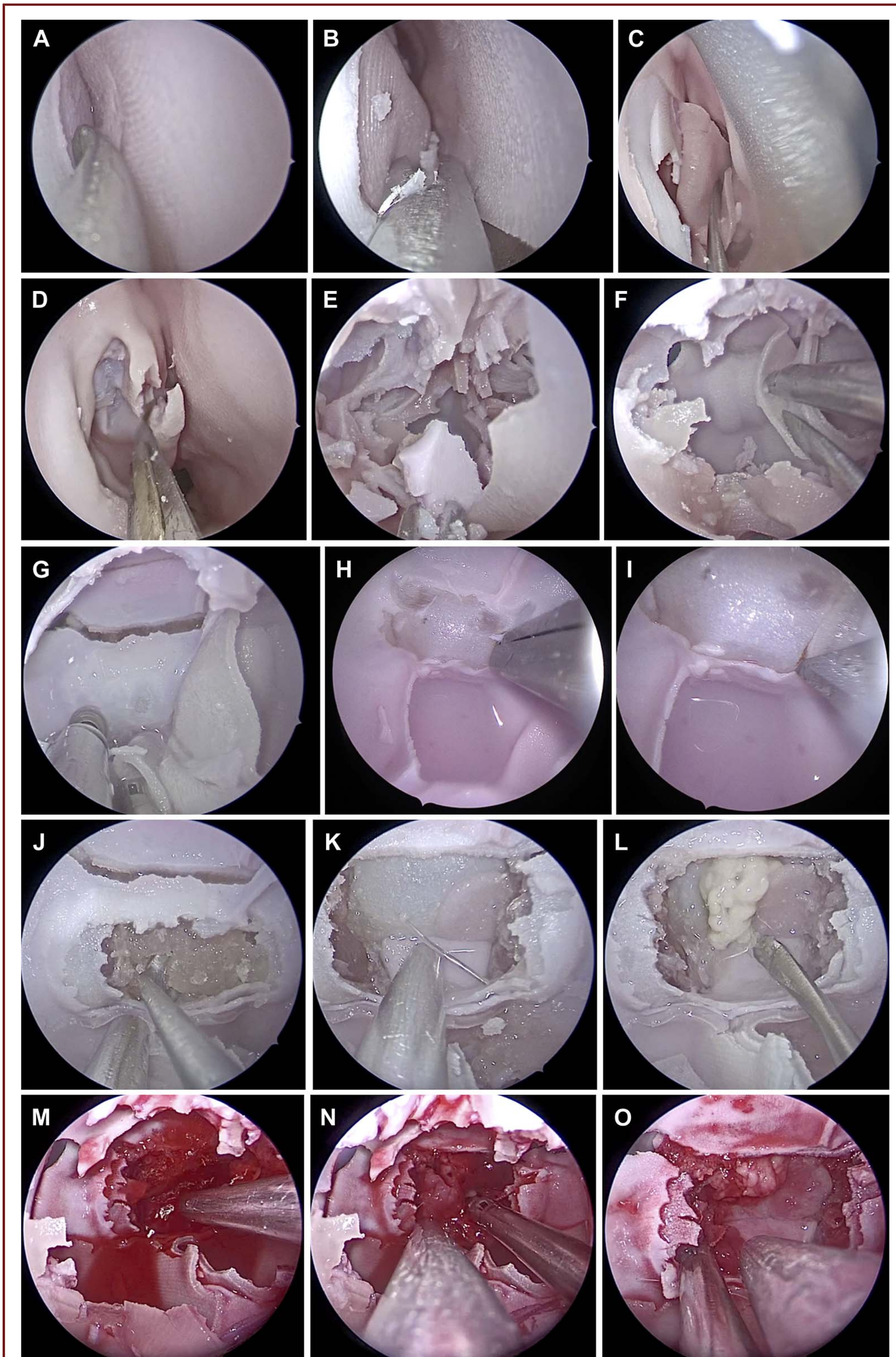
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FIGURE 2. *The steps to be completed using the surgical simulator A-N.* **A**, *Incising through septal mucosa and beginning to raise a nasoseptal flap;* **B**, *removal of left sided septal spur;* **C**, *complete raising of nasoseptal flap and storing in the nasopharynx;* **D**, *bilateral middle turbinectomies;* **E**, *removal of the sphenoid rostrum;* **F**, *peeling the sphenoidal mucosa off the face of the sella;* **G**, *high-speed drill to thin the bone over the sella;* **H**, *Kerrison-Rongeur to complete exposure of sella;* **I**, *durotomy;* **J**, *resection of the pituitary adenoma;* **K**, *injury to the diaphragma with subsequent CSF leak;* **L**, *repair of CSF leak using the bathplug technique with chicken fat;* **M**, *injury to the carotid artery;* **N**, *use of two-surgeon four-hand approach to managing major vascular injury and placement of a harvested chicken muscle patch; and* **O**, *successfully control the hemorrhage. CSF, cerebrospinal fluid.*

postcourse questionnaire responses completed by participants. A 2-sample *t*-test was used to compare the mean scores for OSATS between experienced and inexperienced groups.

RESULTS

Study Size and Participant Characteristics

Participants were grouped into teams of 2 surgeons per station, with a total of 6 stations and 12 surgeons. Owing to the unequal number of neurosurgeons and ENT surgeons, one station had 2 ENT surgeons. A variety of consultant and trainee surgeons participated in the course.

One participant had observed a carotid injury, but no participants had ever been involved in managing a carotid injury during an endoscopic endonasal case.

To allow OSATS assessment the surgical teams were dichotomized into experienced and nonexperienced groups. An experienced group was defined as having a combined experienced of more than 50 endoscopic pituitary surgeries, regardless of specialty. Inexperienced groups had a combined experienced of <50 cases as the primary surgeon. This yielded 2 groups of experienced surgeons and 4 groups of inexperienced surgeons. All surgeons in the experienced cohort were consultant surgeons.

The individual experience of the participants is demonstrated in Table 2. Heart rate data and self-rated questionnaire data were dichotomized into experienced and inexperienced surgeons. An experienced surgeon was defined as having completed more than 10 cases, whereas an inexperienced surgeon was defined as having completed <10 cases.

Face Validity

Heart rate monitoring data were available for 10 participants. The heart rate of the participants significantly increased from baseline to when starting the carotid injury simulation (mean 90 vs 121, SD 21.5 vs 22.5, $P < .001$). There was a significant reduction in heart rate once the bleeding from the carotid artery injury was controlled from when it first occurred, and the surgeons had moved onto the next assigned task of reconstructing the skull base defect (mean 121 vs 110, SD 22.5 vs 17.3, $P = .038$). The heart rate was significantly higher when surgeons were first exposed to the vascular injury scenario compared with the second time they were exposed in the subsequent model suggesting some level of comfort (mean 121 vs 108, SD 22.5 vs 23.4, $P = .012$). Heart rate during initial dissection pre carotid injury was not significantly different from dissections after management of both carotid injuries during skull base reconstruction (Figure 3).

Postcourse questionnaire data were available for 12 participants regarding vascular injury and 11 participants for pituitary adenoma resection and CSF leak repair competence. On average participants reported a significant improvement in anxiety in facing a major vascular injury (mean 4.42 vs 3.58 $P = .05$) and a significant improvement in their self-rated confidence in being able to manage a major vascular injury (mean 2 vs 3.25 $P < .001$). All participants reported improvements in their confidence in undertaking a pituitary adenoma resection and a CSF leak repair (mean 2.36 vs 4.27 $P < .001$ and 2.45 vs 4.0 $P = .001$, respectively) (Figure 4).

Examining the 7 participants who had completed <10 cases (inexperienced) demonstrated significant changes in baseline heart rate compared with during the first carotid injury (mean 93 vs 113.1,

TABLE 2. Baseline Demographic Information Divided by Experienced and Inexperienced Surgeons

	Number of cases				
Surgeon experience	**<10**	**10-30**	**30-50**	**50-75**	**75-100**
Experienced (n = 5)					
Number of endoscopic pituitary surgeries performed	0	2	2	1	0
Number of endoscopic pituitary surgeries assisted	1	0	0	3	1
Inexperienced (n = 7)					
Number of endoscopic pituitary surgeries performed	7	0	0	0	0
Number of endoscopic pituitary surgeries assisted		5	2	0	0

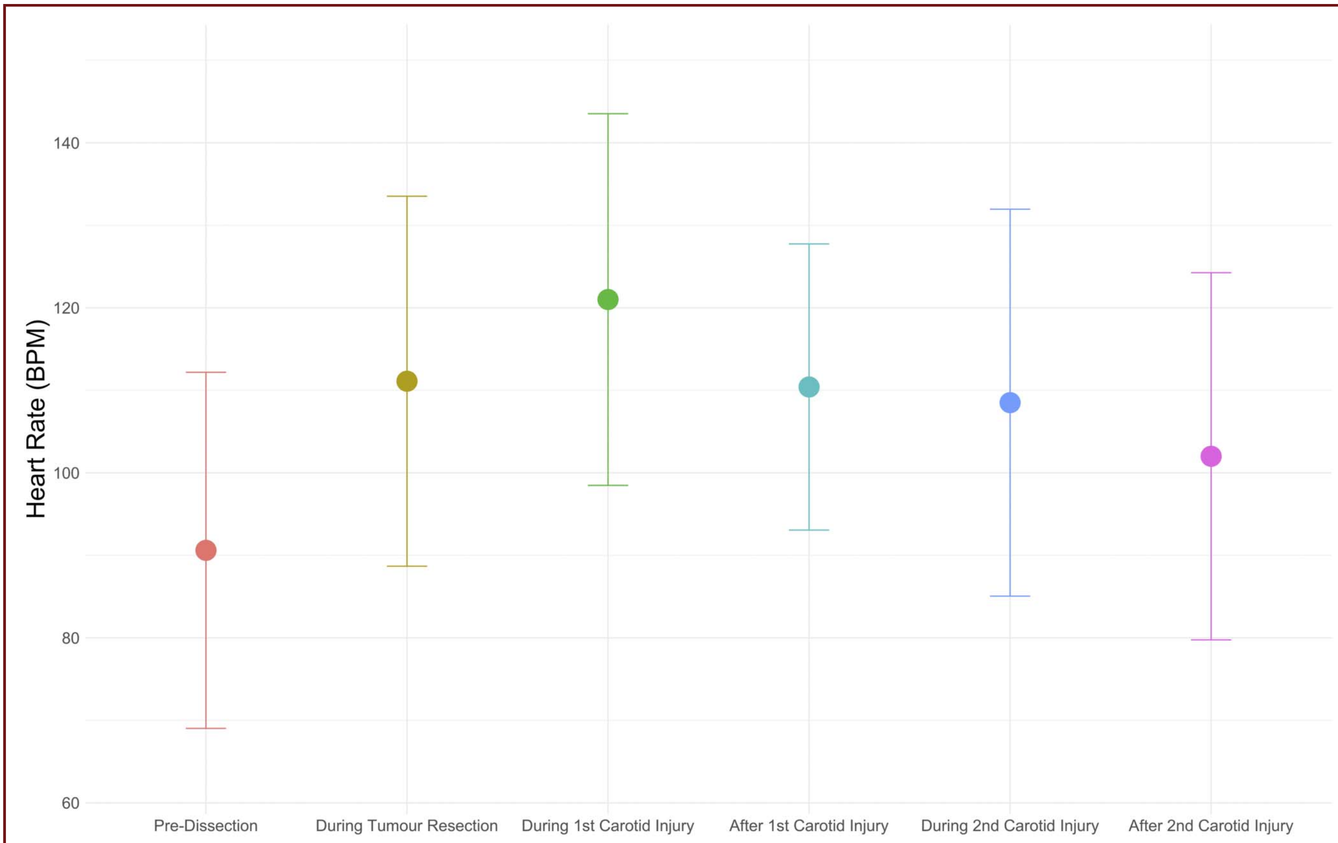

FIGURE 3. *Dot plots demonstrating the changes in heart rate of participants between different time points during the dissection. BPM, beats per minute.*

SD 25 vs 24.8, P = .022), heart during carotid injury and after control (mean 123 vs 111, SD 22.7 vs 19.7, P = .042), heart rate during the first carotid injury and during the second injury (mean 123 vs 113, SD 22.7, 26.3, P = .043), anxiety regarding management of carotid injuries (mean 4.29 vs 3.57, P = .047), confidence with management of pituitary adenoma resection (mean 2 vs 4.4, P = .001), and confidence with CSF leak repair (mean 2.1 vs 4.1, P = .004).

Examining the 5 participants who had completed more than 10 cases (experienced) demonstrated a significant change in baseline heart compared with during the first carotid injury (mean 85 vs 106, SD 12.2 vs 19, P = .027). The remaining outcomes demonstrated the same trends as the cohort but were not significant: heart rate during carotid injury compared with after (mean 115 vs 108, SD 25.8 vs 13.3, P = .646), heart rate during the first carotid injury and during the second carotid injury (mean 115 vs 97, SD 25.8 vs 11.9, P = .262), anxiety regarding management of carotid injuries (mean 4.6 vs 3.6, P = .089), and confidence with management of CSF leaks (mean 3 vs 3.75, P = .058).

Content Validity

Six of the course faculty, all experienced endoscopic skull base, and pituitary surgeons scored the model 4.73 of 5. The mean score for tissue handling was the lowest at 4.3. The remaining domains examined included anatomic accuracy, appropriate learning goals for the model, and whether the model would be beneficial for ENT and neurosurgical trainees. All of these domains had a mean score of 4.8.

Construct Validity

The mean OSATS score for experienced stations was 4.4 and inexperienced was 3.65 (P = .016).

DISCUSSION

To the authors' knowledge, this is the only surgical simulator that allows surgeons to practice an endoscopic transsphenoidal approach, pituitary adenoma resection, repair of a CSF leak through a diaphragma sellae tear, control of a carotid injury, and reconstruction of the defect in a single 3D printed model.

Participants experienced a significant increase in their heart rate during the first simulated carotid injury compared with their baseline. Interestingly this is despite still being shown what the simulation would look like by the masterclass dissection earlier in

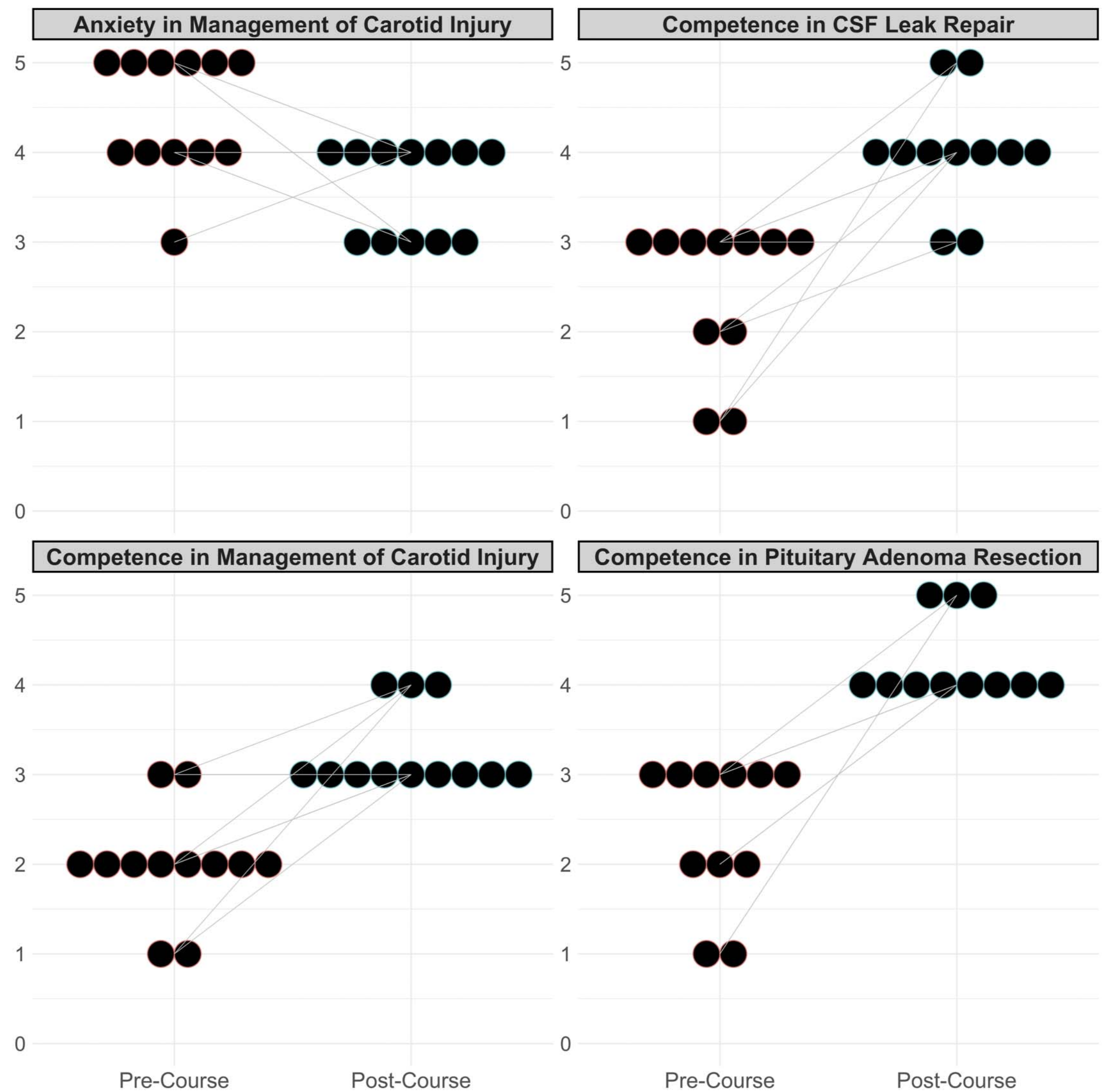

FIGURE 4. *Dot plots demonstrating the change in self-rated anxiety and competence for management of carotid injury and management of pituitary adenoma resection and CSF leak repair. CSF, cerebrospinal fluid.*

the day. It is noteworthy that participants' heart rates were significantly higher during the first carotid injury compared with the second carotid injury, which demonstrates the value of simulation training on a surgeon's stress response, as opposed to active observation of the same task.

When dichotomizing the participants into experienced and inexperienced groups, it demonstrated that the changes in heart rate, confidence in management of carotid injury, pituitary adenoma resection, and CSF leak repair followed the same trends as the whole cohort, except they were no longer significant. This is likely a reflection of the participants experience; however, owing to the small sample size, this is unclear.

The results of the OSATS for the surgical stations demonstrate a significantly higher score in surgical teams who had completed in combination over 50 endoscopic pituitary surgeries. However, owing to the small sample size, (2 stations vs 4 stations) the strength of this result is unclear. Furthermore, because of the small sample size, a regression analysis between the OSATS score and precourse experience could not be performed.

The ability to effectively train junior ENT and neurosurgeons is significantly enhanced by incorporating all these surgical steps into one model and allowing the 2 surgeons to practice the ergonomics of operating together and improving their communication. A major benefit of the model is the modularity of the design with the sphenoid cassette that can be changed repeatedly for increasingly complex and anatomically diverse pathology. Other significant benefits of this model include reduced costs compared with cadavers because of no requirement of disposal or acquisition, biohazard risk, and availability as models are printed to order.

There are a variety of surgical simulators currently available, with a subset of these models being validated as surgical simulators. They can be broadly categorized as cadaveric, live animal, virtual, and 3D printed plastic models.

Donoho et al[3] published an article in 2019 examining the costs associated with using a validated perfusion-based internal carotid artery injury simulation during endoscopic skull base surgery. This simulator involved cannulating cadaver heads through their anatomy laboratory and then perfusing the carotid artery with assistance from a perfusionist. To train 72 surgeons over 6 training sessions to manage an internal carotid injury it was estimated to cost 19 800 USD. Donoho et al[3] calculated the cost required to achieve a training success ranged between 452.94 and 1139.29 USD. Importantly, this does not include the cost of establishing an anatomy laboratory and developing the expertise in this technique. The 3D printed models in the authors' endoscopic pituitary model course have comparatively lower costs.

The consumable components include the pituitary tumor cassette and anatomically specific sinus trainer, valued at 225 USD and 325 USD, respectively.

Valentine and Wormald et al have published on the development of a large animal vascular injury simulator designed to train surgeons for the management of carotid artery injury during endoscopic endonasal approaches.[11,12] This simulator has demonstrated efficacy in teaching delegates how to safely manage this life-threatening complication. They examined outcomes for delegates who encountered a carotid artery injury after completing the course and compared the outcomes with historical measures. Of the 118 delegates who had attended the course, there were 9 major vascular injuries. All patients survived, and no patient had permanent neurological disability[11] which was a significant improvement on the historical management of these injuries.

3D printed surgical simulators appear to be the most promising types of simulators currently being developed. Newall et al[4] published a validation of the UpSurgeOn TNS Box in December 2022. This 3D printed model allows participants to perform a transsphenoidal approach and demonstrated significant results regarding face, content, and construct validity. Unfortunately, the model does not have capacity to simulate CSF leak repair, vascular injury management, or pituitary adenoma resection.

Our study demonstrated preliminary validation of this 3D printed pituitary model based on the significant data obtained when assessing face, content, and construct validity at a surgical skills course. Further research with a broader variety of surgeons is required to completely validate the model.

Limitations

The main limitations of this study relate to the small number of participants, which limited the depth of statistical analysis. However, the purpose of the study was to demonstrate the preliminary validity. Despite the small number of participants, the analysis demonstrates significant results.

Because of the way the course was conducted, it was not possible to accurately score the time taken to control the carotid injury or quantify the volume of blood lost. Further research will involve task specific OSATS to demonstrate improvement in certain tasks with repeated exposure to the model.

In addition, there is a potential for bias as 2 of the authors have financial disclosures relating to the company that produces these models. This was accounted for by blinding all experts to the data analysis to minimize any potential cognitive bias. Fusetec was not involved in sponsoring the course at which this research was conducted.

CONCLUSION

We have demonstrated for the first time a 3D printed surgical simulator that allows surgeons to practice a transsphenoidal approach, surgical resection of a pituitary adenoma, repair of a CSF leak in the diaphragma sellae, control of a carotid injury, and repair of skull base defect. The significant results for assessing face, content, and construct validity demonstrate this is a valid surgical simulator. Replicating this validation process with more participants and a broader range of participant experience is required for future research.

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Disclosures

Peter-John Wormald is a consultant for FuseTec, Medtronic, Karl Storz, Neilmed and Stryker, and a shareholder in Chitogel; Alkis J. Psaltis is a current consultant for Medtronic and Karl Storz, previously a consultant for Fusetec in 2021, shareholder for Chitogel, and speaker for GSK, Sanofi and Sequiris. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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Supplemental Digital Content 1. Precourse demographic data questionnaire.
Supplemental Digital Content 2. Postcourse questionnaire completed by faculty to rate face and content validity.
Supplemental Digital Content 3. Postcourse OSATS as determined by expert authors reviewing recorded videos of participants.
Supplemental Digital Content 4. Precourse and postcourse questionnaire completed by participants to rate subjective confidence with vascular injury.
Supplemental Digital Content 5. Precourse and postcourse questionnaire completed by participants to rate subjective confidence with pituitary adenoma resection and CSF leak repair.
VIDEO. Demonstration of the surgical steps on one of the 3-dimensional printed models.

COMMENTS

The authors describe a unique 3D simulation model for endonasal approaches and evaluate its role as a training tool for creation of a nasoseptal flap, resection of a synthetic pituitary adenoma, repair of a cerebrospinal fluid leak, and repair of a carotid injury. They show both objective and subjective improvement in trainee comfort with management of carotid injury thus helping further validate the use of such a model. Importantly, this synthetic model is available commercially and an order of magnitude less costly than traditional cadaveric or synthetic models which can improve access to training for both US and international surgeons. The validation of a training paradigm and consideration of its cost/benefit ratio are also key to scaling a training platform for surgeons. The authors should be commended on discussing these various challenges for implementing a surgical training platform. I look forward to seeing how this approach can be expanded in the future.

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