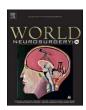
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Benchtop simulation of the retrosigmoid approach: Validation of a surgical simulator and development of a task-specific outcome measure score

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ARTICLE INFO

Keywords: Neurosurgery Education Model validation Simulation training Retrosigmoid craniotomy Microvascular decompression

ABSTRACT

Background: Neurosurgical training is changing globally. Reduced working hours and training opportunities, increased patient safety expectations, and the impact of COVID-19 have reduced operative exposure. Benchtop simulators enable trainees to develop surgical skills in a controlled environment. We aim to validate a high-fidelity simulator model (RetrosigmoidBox, UpSurgeOn) for the retrosigmoid approach to the cerebellopontine angle (CPA).

Methods: Novice and expert Neurosurgeons and Ear, Nose, and Throat surgeons performed a surgical task using the model – identification of the trigeminal nerve. Experts completed a post-task questionnaire examining face and content validity. Construct validity was assessed through scoring of operative videos employing Objective Structured Assessment of Technical Skills (OSATS) and a novel Task-Specific Outcome Measure score.

Results: Fifteen novice and five expert participants were recruited. Forty percent of experts agreed or strongly agreed that the brain tissue looked real. Experts unanimously agreed that the RetrosigmoidBox was appropriate for teaching. Statistically significant differences were noted in task performance between novices and experts, demonstrating construct validity. Median total OSATS score was 14/25 (IQR 10-19) for novices and 22/25 (IQR 20-22) for experts (p < 0.05). Median Task-Specific Outcome Measure score was 10/20 (IQR 7-17) for novices compared to 19/20 (IQR 18.5-19.5) for experts (p < 0.05).

Conclusion: The RetrosigmoidBox benchtop simulator has a high degree of content and construct validity and moderate face validity. The changing landscape of neurosurgical training mean that simulators are likely to become increasingly important in the delivery of high-quality education. We demonstrate the validity of a Task-Specific Outcome Measure score for performance assessment of a simulated approach to the CPA.

1. Introduction

Simulation models are becoming a staple teaching adjunct in neurosurgery owing to the changing landscape of neurosurgical training. Neurosurgical trainees worldwide have reported a lack of training and limited opportunities to operate as core personal challenges to development.^{1,2} Such concerns are not incidental – lack of surgical experience limits skill development which may lead to increased risk of operative morbidity and mortality.^{3,4} This decline in training opportunities is multifactorial. Firstly, in recent decades there has been a greater emphasis on patient safety coupled with an increased expectation of surgical performance and outcome.^{5,6} These changes have shifted the

Abbreviations: OSATS, Objective structured assessment of technical skills; VR, Virtual reality; AR, Augmented reality; 3D, Three-dimensional.

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educational paradigm from the apprentice-based Halstedian approach of "see one, do one, teach one" to a more cautious approach. Secondly, the introduction of legislation pertaining to maximum working hours in both the USA and Europe has led to a reduction in the working week for neurosurgical trainees. Thirdly, developments in minimally invasive and endovascular interventions have shifted many procedures toward interventional neuroradiologists, such as aneurysm coiling versus clipping. Finally, the deleterious impact of the COVID-19 pandemic upon neurosurgical training internationally has been well documented. S-11

Cadaveric workshops, technical skills workshops, and clinical fellowships have been employed to enable trainees to hone their surgical skills in the face of reduced training opportunity. However, these can be costly and organisationally challenging. In recent decades, high-fidelity simulation models have increasingly been used as a teaching adjunct, enabling trainees to familiarise themselves with operative scenes in a controlled and safe environment. 12 This is particularly pertinent for complex subspecialty neurosurgical approaches such as the retrosigmoid approach to the cerebellopontine angle (CPA). The efficacy of neurosurgical simulation models in improving surgical skill is well documented, as several neurosurgical simulators have been shown to confer wider benefits to clinical practise and reduced rates of surgical complications. 5,13,14 Simulation models may also provide an answer to imbalanced training opportunities seen in low and middle income countries, as the advent of three-dimensional (3D) printed neurosurgical models has enabled rapid and economic development of high-fidelity training models. 15-17

Evidently, neurosurgical simulation models have a wide range of positive impacts upon training. It is imperative, however, that new neurosurgical simulation models undergo validation before adoption. Several frameworks for model validation exist, though a widely accepted framework is the assessment of face, content, and construct validity. Face validity evaluates the realism of a the simulator; content validity refers to the utility of the simulator as a training modality; and construct validity refers to whether the model can accurately delineate between differing levels of surgical experience. ¹⁹

Currently, there are no validated simulation models for the retrosigmoid approach to the CPA. We aim to validate the RetrosigmoidBox (UpSurgeOn S.r.l., Milan), a benchtop simulation model of the retrosigmoid approach to the CPA by establishing its face, content, and construct validity. The scope of validity focus is for use of the RetrosigmoidBox in simulation and training workshops pertaining to the retrosigmoid approach to the CPA. Further, we aim to develop and validate a Task-Specific Outcome Measure scoring system specific to a simulated approach to the CPA.

2. Methods

Reporting guidelines for surgical simulation validity studies as published by Van Nortwick et al were followed in this publication. Approval was granted for model validation by an University College London Research Ethics Committee (reference number 17819/001).

2.1. Model

The RetrosigmoidBox is a high-fidelity benchtop simulator which recreates a typical retrosigmoid approach to the CPA (Fig. 1). The model consists of a retrosigmoid craniotomy window, cranial nerves III to XII, vertebral arteries, the basilar artery, posterior-inferior cerebellar artery, anterior-inferior cerebellar artery, superior cerebellar artery, right cerebellar hemisphere, brainstem, mammillary bodies, and the posterior skull base. The RetrosigmoidBox is manufactured using silicones and resins via 3D printing technology and a tailored manufacturing processes, to replicate the physics of live anatomical structure. Additional components of the RetrosigmoidBox that were not used in this study include virtual reality features and replaceable bone covers (Fig. 1A) which can be used to practice the craniotomy phase.

2.2. Participants

Twenty participants from Neurosurgical and Ear, Nose, and Throat (ENT) surgical backgrounds were recruited from a single tertiaryacademic neurosurgical centre, during a cross-specialty one-day simulation event relating to lateral skull base approaches. Subjects were derived from multiple institutions across the United Kingdom, with convenience sampling applied to those present at the simulation course. Participants were categorised as either novice (defined as post-graduates in training or junior roles) or expert (defined as consultant lateral skull base surgeons). Novices included senior house officers (post-graduate years 2-4 equivalent) and registrars (resident equivalent). A sample size of fifteen novices and five experts was chosen in-keeping with current literature for general neurosurgical benchtop simulator validation studies assessing construct validity, of which the median number of participants involved is 15 (IQR 10-21), and the median proportion of experts as a proportion of total participants is 24% (IQR 16%-43%). No power calculations were performed. Demographic data was collected from participants, including age, gender, surgical training grade, dominant hand, and approximate number of retrosigmoid approaches performed. Years of surgical experience was collected post-hoc (defined as years in a recognised training programme, post-training fellowship, and consultant post).

2.3. Surgical task

Participants were asked to perform a surgical task using the RetrosigmoidBox – exposure of the CPA and identification of the trigeminal nerve

Participants were provided with a standard microsurgical instrument set. The task was performed microscopically using a ZEISS Kinevo 900 operating microscope (Carl Zeiss Co, Oberkochen, Germany). Operative videos were recorded and stored on a secure hard drive. Completion of the task was signalled by the participant touching the nerve they had identified as the trigeminal nerve with Spetzler-Malis bipolar forceps (Fig. 1D).

2.4. Outcomes: face and content validity

Expert participants were asked to complete a post-task questionnaire which reviewed face and content validity (Supplementary Digital Content 1). Face validity was quantified in Part 1 of the questionnaire, featuring questions pertaining to the realism of the RetrosigmoidBox; content validity was assessed in part 2, featuring questions regarding the perceived usefulness of the RetrosigmoidBox as a teaching construct. 5-point Likert scales were used throughout (1 = Strongly Disagree, 2 = Disagree, 3 = Neither Agree nor Disagree, 4 = Agree, 5 = Strongly Agree). Quantitative data for face and content validity is presented descriptively. Median response was used as a measure of central tendency.

2.5. Outcomes: construct validity and development of a task-specific outcome measure scoring system

Construct validity was assessed through post-hoc blinded review of anonymised recorded operative videos. Participant operative videos were cut down to approximately 2 minute videos. Each participant's surgical technique was scored using modified Objective Structured Assessment of Technical Skills (OSATS) criteria, in accordance with existing simulation model validation theory. ^{19,21–23} Secondly, authors scored each video using an in-house developed Task-Specific Outcome Measure scoring system (Supplementary Digital Content 2). Since no unifying surgical workflow guideline exists for the retrosigmoid approach to the CPA, Task-Specific Outcome Measures were generated from Intercollegiate Surgical Curriculum Programme (ISCP) workflows for microvascular decompression, literature review, and following consultation with expert authors. ^{24–26}

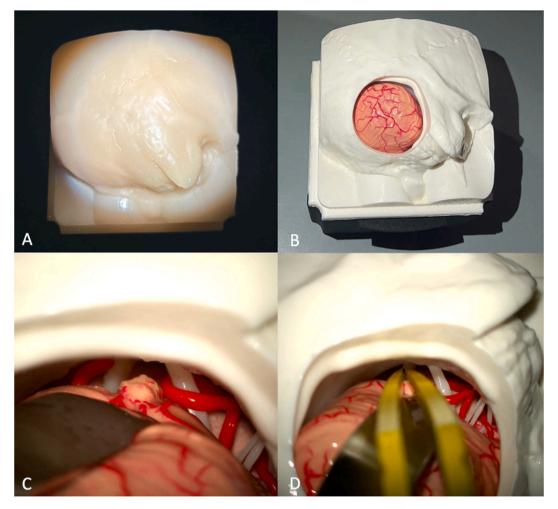


Fig. 1. The RetrosigmoidBox (UpSurgeOn) with replaceable bone cover (A) and without (B); C) operating microscope view of RetrosigmoidBox with cerebellum retracted to expose the CPA; D) completion of the operative task signalled by participant identification of the trigeminal nerve. The replaceable bone covers were not used during the task.

Data was collected using 5-point Linear scales for each OSATS and Task-Specific Outcome Measure scoring question (Supplementary Digital Content 2). Responses were assigned a numeral rank from 1 to 5. Median response to each scoring question was calculated as a measure of central tendency. Median values for each question were used to generate a total OSATS score out of 25 and Task-Specific Outcome Measure score out of 20 for each participant. Statistical comparison between novice and expert groups' OSATS and Task-Specific Outcome Measure score was performed using Mann–Whitney U, with a p value < 0.05 denoting statistical significance. Interrater reliability was calculated utilising intraclass correlation coefficients, with a value of >0.8 suggesting a high degree of interrater reliability. Data was analysed using GraphPad (GraphPad Software Inc, California, USA) and StataMP, Version 17.0 (StataCorp LLC, Texas, USA).

2.6. Secondary outcome: time to task completion

Time to task completion was recorded as a secondary outcome. Task beginning point was standardised to the first moment of contact with the RetrosigmoidBox, and the end point was identification of the trigeminal nerve (or nerve suspected to be the trigeminal nerve) with forceps.

3. Results

Five experts and fifteen novices were included. The novice group comprised six registrars (residency equivalent), eight senior house officers (post-graduate year equivalent) and one senior fellow (senior resident equivalent). Table 1 shows participant baseline characteristics.

3.1. Face and content validity

Questions assessing face and content validity can be found in Supplementary Digital Content 1, Part 1 and 2 respectively. Results are shown in Table 2. Overall, 100% (15/15) novices and 80% (4/5) experts stated that they would use the model again.

Table 1 participant demographics, *= years of neurosurgical experience defined as years in a recognised training programme, post-training fellowship, and consultant post.

	Novice	Expert
n	15	5
Gender M:F	7:8	5:0
Age (median $+$ IQR)	32	51 (45-56)
	(28-34)	
Handedness R:L	15:0	5:0
Years of surgical experience* (median + IQR)	3 (0-6)	22 (17-27)
Approximate no. of retrosigmoid approaches	1 (0-3)	200
independently performed (median + IQR)		(138-500)

Table 2Face and content validity responses.

	Median response (IQR)	% Agree or Strongly Agree
Face Validity		
The brain tissue looked realistic	Neither Agree nor Disagree (Disagree - Agree)	40%
The blood vessels looked like real vessels	Agree (Neither – Agree)	80%
The cranial nerves looked like real nerves	Agree (Neither – Agree)	60%
The brain tissue felt realistic	Disagree (Disagree – Neither)	20%
The blood vessels handled like real vessels	Agree (Disagree – Agree)	60%
Content Validity		
The craniotomy window was indicative of a typical retrosigmoid craniotomy	Agree (Agree – Strongly Agree)	80%
The approach to the CPA was realistic and appropriate for teaching	Strongly Agree (Agree – Strongly Agree)	100%
Origin and course of the cranial nerves was realistic and appropriate for teaching	Agree (Agree – Strongly Agree)	100%
Overall, the model is useful as a training tool for the retrosigmoid approach	Strongly Agree (Agree – Strongly Agree)	100%

3.2. Construct validity

Construct validity was determined through post-hoc analysis of surgical microscopic videos by five blinded reviewers using OSATS and Task-Specific Outcome Measures (Supplementary Digital Content 2). Total OSATS and Task-Specific Outcome Measure scores were calculated for each participant. Median total OSATS score was 14/25 (IQR 10–19) for novices and 22/25 (IQR 20–22) for experts (p < 0.05, Mann–Whitney U) (Fig. 2A). Median Task-Specific Outcome Measure score was 10/20 (IQR 7–17) for novices compared to 19/20 (IQR 18.5–19.5) for experts (p < 0.05, Mann–Whitney U) (Fig. 2B). All experts (5/5) correctly identified the trigeminal nerve, compared to 47% (7/15) of novices. Scores for experts and novices for the individual components of the OSATS and Task-Specific Outcome Measure scores can be found in Supplemental Digital Content 3. Interrater reliability was 0.92 (CI 0.86–0.97) for OSATS, and 0.96 (CI 0.92–0.98) for Task-Specific Outcome Measures.

Median time to task completion was 1 min 50 s (IQR 1 min 11 s–5 min 18 s) for novices and 36 s (IQR 22 s–2 min 10 s) for experts (p > 0.05, Mann–Whitney U) (Fig. 3). When analysing only those who correctly identified the trigeminal nerve, there remained no statistically significant difference between Experts and Novices.

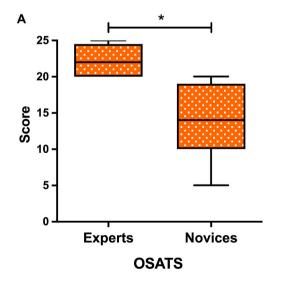
4. Discussion

4.1. Key findings

We present a model validation study for a high-fidelity benchtop simulator for the retrosigmoid approach, using a focused surgical task amongst novices and experts. To the authors' knowledge, this is the first validation study of a simulation model for the retrosigmoid approach. Our data reviewed face, content, and construct validity of the retrosigmoid simulator.

Face validity refers to the realism of the simulator, encompassing both visual and tactile realism. 19 Visually, experts reported a high degree of realism in appearance of the model blood vessels and cranial nerves, and a low degree of realism in appearance of brain tissue. In contrast, participants were ambivalent when commenting on the feel of the simulator, with the feel of brain tissue scoring particularly low. Based on these responses the RetrosigmoidBox showed a moderate degree of face validity, with appearance of brain tissue and force-feedback elements of tissue being areas for improvement. Limited tactile realism is a common criticism of benchtop simulators, as the creation of fragile and realistic brain tissue and vessels must be balanced against the need for durability. These concerns do not necessarily impact the utility of the simulator in teaching - simulator models are commonly used for training surgeons in the early stages of the learning curve who will benefit from processing of procedural steps and mental rehearsal, features unaffected by haptic realism. Iterative improvement of the RetrosigmoidBox should focus upon improving face validity, including improved appearance and tactile realism of brain tissue. Presence of arachnoid and bleeding vessels would further increase the realism of the simulator.

Response from our expert participants confirmed the utility of this simulator as a teaching adjunct, confirming content validity. Experts unanimously agreed that the simulator was appropriate for teaching the approach to the CPA, that the model's origin and course of cranial nerves was appropriate for teaching, and that the RetrosigmoidBox was



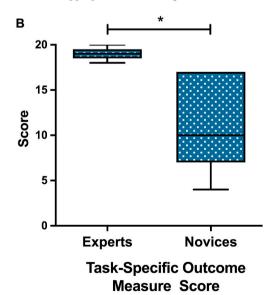


Fig. 2. OSATS and Task-Specific Outcome Measure score for novices and experts. Caption: Fig. 2: Median, interquartile range, and minimum and maximum values for total OSATS (Fig. 2A) and Task-Specific Outcome Measure (Fig. 2B) scores for participants. Maximum score was 25 for OSATS and 20 for Task-Specific Outcome Measure scores *=p<0.05, Mann–Whitney U.

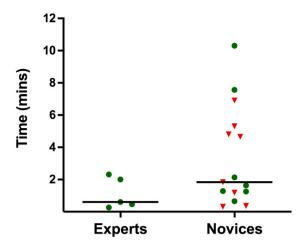


Fig. 3. Time to task completion. Caption: Fig. 3: Median and individual values for time to task completion. Task beginning point was standardised to the first moment of contact with the RetrosigmoidBox with a surgical instrument. Task completion defined as identification of the trigeminal nerve, or nerve suspected to be the trigeminal nerve. Green circles indicate participants who correctly identified the trigeminal nerve, red triangles indicate participants who did not. No statistically significant difference was noted between experts and novices (p = 0.16, Mann Whitney U). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

useful as a training tool for the retrosigmoid approach. The model does, however, lack features which would enhance its usefulness as a training tool. For example, lack of cerebrospinal fluid (CSF) and arachnoid reduces realism and limits the ability of trainees to practise crucial steps such as enabling CSF egress from the cisterna magna to encourage cerebellar relaxation, and arachnoid dissection.

The surgical simulator was able to adequately distinguish between experts and novices for a set surgical task, demonstrating construct validity. Statistically significant differences were noted between experts and novices for both OSATS score and Task-Specific Outcome Measure scores. Furthermore, all experts were able to correctly identify the trigeminal nerve compared to under half of novices.

Finally, we demonstrate the validity of a novel scoring system, the Task-Specific Outcome Measure score, for assessment of a simulated approach to the CPA and identification of the trigeminal nerve. Task-Specific Outcome Measure scores correlated significantly with the established OSATS scoring system demonstrating concurrent validity, and showed similar ability to detect statistically significant differences between novice and expert participants.

4.2. Comparison to current literature

The modern neurosurgical training climate of reduced operative exposure and shorter working-weeks render simulation more important than ever. ^{2,6} Simulators circumvent many issues faced by neurosurgical trainees and enable safe and deliberate practice, detailed and immediate feedback, and repeated practice; features crucial in the attainment of expert performance. ^{6,27,28} It is unsurprising, therefore, that the neurosurgical community has seen a sharp rise in the number of commercially available simulators in the past decade. ⁵

At present, simulation options for trainees recreating the retrosigmoid approach are largely limited to cadaveric surgical skills courses and animal models. ²⁹ Further, existing simulation models for the retrosigmoid approach have not been validated. Bovine and swine cadavers have been used to simulate the retrosigmoid approach, with both found to be valuable teaching adjuncts. ^{29,30} These have not been validated and carry the issues associated with animal model use including anatomic variation, lack of target pathology, and ethical concerns. ⁶ Recently, 3D printed benchtop simulators have become increasingly commonplace,

with evidence suggesting that these models are able to accurately represent neurosurgical pathology.^{5,31} Martinez, et al. describe the development of a 3D printed biomimetic retrosigmoid craniotomy model; and Graffeo, et al. describe 3D printed models demonstrating the retrosigmoid approach. 32,33 These models show significant promise, though neither have undergone validation. 32,33 Rubio et al. used cadaveric specimens to create a virtual reality (VR) interactive 3D volumetric model of the retrosigmoid approach.³⁴ This VR simulator, however, has not been validated. Oishi et al. describe the development of 3D virtual models from pre-operative MRI scans in patients undergoing microvascular decompression for trigeminal neuralgia. 35 Whilst VR simulation models are promising, evidence has demonstrated that a lack of haptic feedback limits skill acquisition. ³⁶ However, VR models have been validated with intra-simulation performance metrics correlated to operative skill.³⁷ In a post-covid climate, VR may represent a widely accessible means of operative rehearsal for the retrosigmoid approach.36

Validity assessment is essential to ensuring that quality is maintained, particularly given the variability in validity testing seen for neurosurgical simulators.⁵ Future validation studies should employ a standardised approach to validity testing to ensure robust methodology and greater translational benefits.³⁶

In this study we have demonstrated the validity of a novel Task-Specific Outcome Measure scoring system tailored to our surgical task. Tailored scoring systems enable tailored assessment. In contrast, established scoring systems such as OSATS provide a more general assessment of surgical performance, and are susceptible to missing procedure-specific measures of performance. It is unsurprising that task-specific outcome scales are increasingly adopted in neurosurgical simulation. ^{38,39}

Future simulation assessment may benefit from the integration of artificial intelligence (AI). Research in this emerging application of AI has demonstrated the ability of AI to distinguish level of surgical expertise. 40,41 In time we may witness a paradigm shift in surgical simulation assessment from subjective means towards standardised automated systems. AI in surgical simulation carries its own unique problems, yet is uniquely suited to this application in its ability to process and contextualise numerous performance metrics, and would free up the need for experts, a limited and costly resource. 42 Further research is warranted in this promising area.

4.3. Strengths and limitations

The methodology employed in this research draws upon contemporary definitions of face, construct, and content validity, encompassing the use of experts to ensure a robust validation framework. ^{5,18} This study compared expert and novice performance to assess construct validity, a key feature of validation that is frequently absent from validation studies. ¹⁸ The task chosen minimised variance, having been created following literature review, expert consultation, and review of Intercollegiate Surgical Curriculum Programme protocols.

Number of participants and novice to expert ratio were in keeping with existing literature. Operative video scoring was conducted in a blinded fashion, and scoring systems were based upon precedence in the literature. The Further, peer-rated operative skill rating for surgical videos has been proven to be a valid assessment of surgical ability. Interrater reliability was significant suggesting a high degree of internal validity. Finally, efforts to enhance immersion were employed to enhance the realism of the task, such as performing the task in a neurosurgical theatre.

Limitations of this research must be considered. First, the task did not encompass the craniotomy phase of the retrosigmoid approach, a key component of a retrosigmoid approach, and a step able to be reproduced using the UpSurgeOn simulator. Secondly, whilst this research describes a robust validation process, validity testing was constrained to the simulation setting only. Translational impacts such as clinical

improvements, patient outcomes, and skill retention were not assessed. ⁴⁴ Several additional validity tests were not employed in this research, including assessment of predictive validity. ²⁰

5. Conclusion

This research demonstrates that the UpSurgeOn RetrosigmoidBox benchtop simulator has a high degree of content and construct validity. Experts unanimously agreed that the RetrosigmoidBox was appropriate for teaching adjunct for the retrosigmoid approach to the CPA and identification of the trigeminal nerve. Iterative improvement of the RetrosigmoidBox should focus upon improving face validity, including improved appearance and tactile realism of brain tissue. Fundamental changes in the delivery of neurosurgical training on a global scale mean that benchtop simulation models, such as the one described, are essential in the delivery of high-quality education.

Further, we have demonstrated the validity of a Task-Specific Outcome Measure score for the performance assessment of a simulated approach to the CPA. Future validation studies should employ a standardised approach to validity testing to ensure robust validation and maximise translational benefits. Future surgical scoring systems may benefit from the integration of AI to provide automated and standardised feedback.

Funding

The authors report no funding source for this work. Health Education England Covid Training Recovery Programme Fund subsidised the cost of attendance to the simulation day for London based neurosurgical trainees.

CRediT authorship contribution statement

Simon C. Williams: Data curation, Investigation, Formal analysis, Methodology, Writing – original draft, preparation, Writing – review & editing. Razna Ahmed: Data curation, Formal analysis, Writing – review & editing. Joseph Darlington Davids: Writing – review & editing. Jonathan P. Funnell: Writing – review & editing. John G. Hanrahan: Writing – review & editing. Hugo Layard Horsfall: Writing – review & editing. William Muirhead: Methodology, Writing – review & editing, Supervision. Federico Nicolosi: Writing – review & editing. Lewis Thorne: Methodology, Writing – review & editing, Supervision. Hani J. Marcus: Conceptualization, Methodology, Writing – review & editing, Supervision. Patrick Grover: Conceptualization, Methodology, Writing – review & editing, Supervision.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: FN is the founder and CEO of UpSurgeOn. We acknowledge that this presents a conflict of interest, though confirm that the author's role was limited to manuscript review. We confirm that publication is original research, and is not a commercial advertisement.

Acknowledgements

We would like to thank Health Education England for their financial support for trainees attending the course, made available as part of the COVID-19 Recovery Surgery Scheme. We also thank the Margaret Spittle Foundation.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.wnsx.2023.100230.

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