# Validation of a three-dimensionally printed simulator for training in endoscopic sinonasal surgery*

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## Abstract

**Background**: The ability to incorporate different materials in the construction of 3-D printed models has resulted in the ability to mimic a variety of anatomical structures such as cartilage, mucosa and bone. The aim of this study was to evaluate the face and content validities of a model as a training tool for endoscopic sinus surgery.

**Methods**: Twenty-six delegates and ten teaching faculty members were invited to complete a post-hoc questionnaire survey. The survey consisted of a 22-question 5-point Likert scale to assess the model's realism (face validity) and its effectiveness as a training tool (content validity).

**Results**: Over 80% of the delegates agreed or strongly agreed that the appearance of anatomical structures within the model was realistic and mimicked actual sinus anatomy. In addition, a similar proportion agreed or strongly agreed that the application of instruments on the composite materials of the model realistically mimicked bone. All faculty agreed that the model was useful to develop hand-eye coordination and was a useful training tool for endoscopic sinus surgery. Overall, the sinus model received high scores regarding its use for training surgeons, especially to develop camera and instrument handling skills.

**Conclusion**: The results of this study suggest that otolaryngology doctors in their early or intermediate stage of training would benefit most from a clinical-based modular programme. The model requires further development in areas such as the realism of mucosa, incorporation of sinonasal pathology and having more complex anatomy to be useful for the training of more advanced surgeons.

**Key words**: sinonasal, septum, polyps, 3D printing, training

## Introduction

Due to cost and restricted access to human cadaver specimens, alternatives such as animal-based models have previously been evaluated as potential platforms for post-graduate surgical training [(1)]. Despite being a valuable training tool for developing hand-eye coordination and camera handling skills, the lack of normal sinonasal anatomy places limits on its utility to train otolaryngology surgeons in endoscopic sinus surgery. The recent global lockdown due to the COVID-19 pandemic have further restricted training opportunities in the clinical workspace as well as availability of post-graduate instructional courses.

Rapid advancements in 3D printing technology have enabled high-fidelity models to be fabricated. The use of different materials in the construction of these models has resulted in the ability to mimic a variety of anatomical structures such as cartilage, mucosa and bone [(2)]. The aim of this study was to evaluate the face and content validities of a 3-D printed model as a training tool for ENT doctors in endoscopic sinus surgery.

## Materials and methods

### Simulator

The PHACON Sinus Trainer (Phacon GmbH. Leipzig, Germany), consisting of a replaceable sinus training cassette secured in a mannequin head holder, was utilised for endoscopic sinus

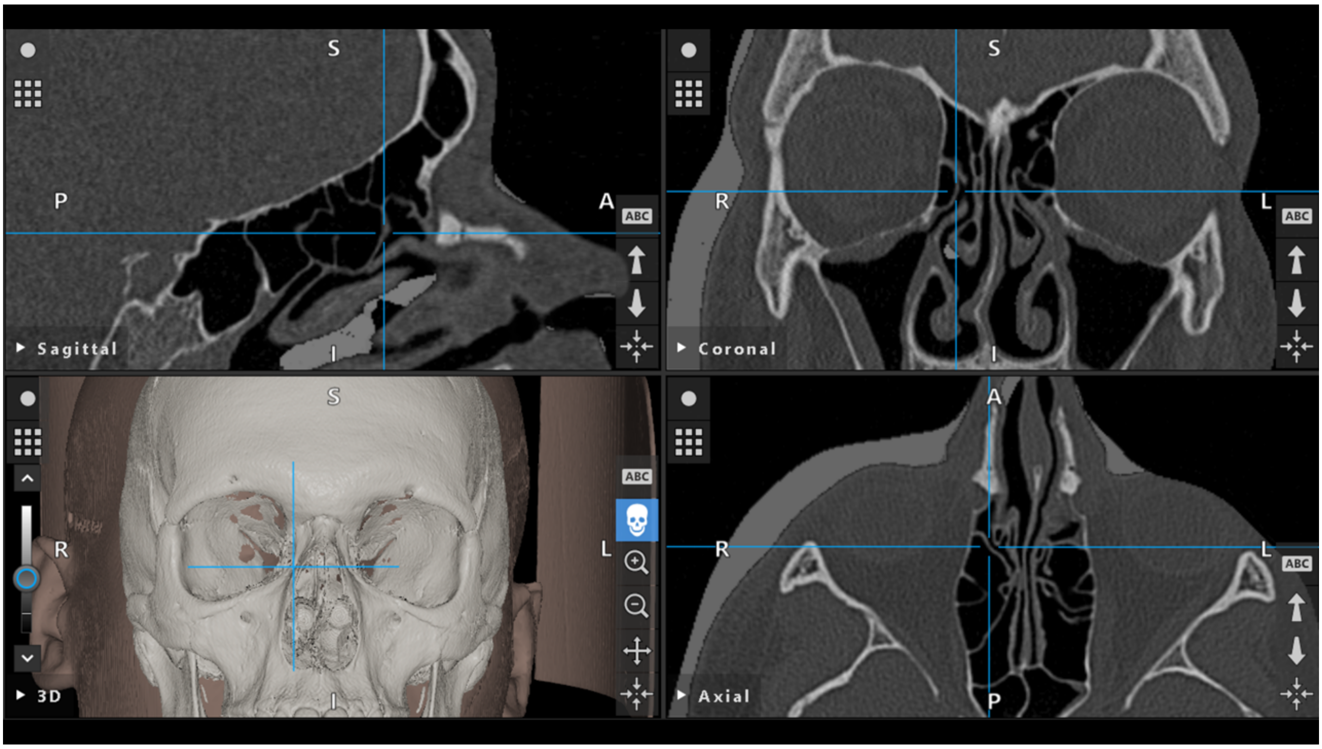


Figure 1. Screenshot of the multi-planar reconstruction of the CT scan used for 3D printing of the sinus training cassette.

surgery (ESS) simulation. The 3D printed sinus training cassette is based on CT scan data with precise anatomically accurate bony architecture of the sinonasal air cells overlain with silicone to mimic mucosa (Figure 1) [3]. These models were fabricated to include the sphenopalatine artery, lamina papyracea, and simulated nasal polyps made from silicone.

### Participants

Delegates of the ESS course undertook a series of simulated dissection, supervised by ten faculty members, over a two-day period. Each delegate was assigned to a work station equipped with the PHACON Sinus Trainer (Figure 2), 4mm 0° endoscope connected to a monitor and camera system, sinus surgery instruments (Karl Storz, Tuttlingen, Germany) and Straightshot™ microdebrider handpiece (Medtronic Inc., Jacksonville, FL, USA). None of the delegates had any previous experience using the PHACON Sinus Trainer.

The course programme was divided into modules; each designed around a clinically-themed, interactive presentation and culminating in a demonstration (key steps, video) of the surgical procedure (Table 1). Progression through the modules was paced and supervised by members of the teaching faculty which consisted of ENT surgeons with an interest in rhinology. Delegates were instructed to start on the left side of the model before proceeding to the right side. At the end of each course, all delegate and teaching faculty were invited to provide course feedback which included a questionnaire survey (Table 2). The survey consisted of a 22-question 5-point (5, strongly agree; 4, agree; 3, neutral; 2, disagree; 1, strongly disagree) Likert scale based on that used by previous groups to assess non-cadaveric dissection model's realism (face validity) and its effectiveness as a training tool (content validity) [4].

### Statistical analysis

Statistical analysis was performed using the SigmaPlot software package version 12 (Systat Software Inc., CA, USA). A p value $<0.05$ was considered statistically significant.

### Ethical considerations

Human ethics committee approval was not required. Equipment utilised during the course was supported by Karl Storz and Medtronic.

## Results

### Face validity

Data from returned responses was collated from two ESS courses held between 4 – 6 May 2022. Twenty-six complete datasets from course delegates were available for analysis. Overall, over 80% of the delegates agreed or strongly agreed that the appearance of anatomical structures within the model was realistic and mimicked actual sinus anatomy (Table 2, Figure 3). In addition, a similar proportion agreed or strongly agreed that the application of instruments on the composite materials of the

Table 1. Stepwise progression through the training modules during the course.

| Module | Clinical theme | Simulated endoscopic sinus surgery |
|---|---|---|
| 1 | Nasal polyps | Polypectomy |
| 2 | Epistaxis | Sphenopalatine artery ligation |
| 3 | Chronic rhinosinusitis | Uncinectomy, antrostomy, ethmoidectomy |
| 4 | Nasal obstruction | Septoplasty, turbinoplasty |
| 5 | Epiphora | Dacryocystorhinostomy |
| 6 | Inverted papilloma | Medial maxillectomy |
| 7 | Fungal sinusitis | Sphenoidotomy |
| 8 | Mucocele | Frontal sinusotomy, mini-trephine |

model realistically mimicked bone. However, less than half of the delegates (46%) agreed or strongly agreed that the mucosal tissues was realistic, while nearly a quarter (23%) disagreed with this statement.

### Content validity

Responses for the global content validity questionnaire are summarised in Table 1. The majority of delegates (92%) agreed or strongly agreed that the training model was useful for learning sinonasal anatomy as well as developing hand-eye coordination needed for endoscopic sinus surgery. A similar proportion reported that the model was useful for planning surgery and for improving operative techniques. There was high level agreement to statements that the model was a useful training tool for surgeons.

Responses for the task-specific content validity questionnaire are also summarized in Table 2. Over 90% of delegates agreed or strongly agreed that the model was relevant to developing essential skills needed for endoscopic sinus surgery such as handling the camera and instruments. There were similarly high levels of agreement that the model was helpful in developing an understanding on a range of specific operative procedures from basic (e.g., maxillary antrostomy, ethmoidectomy, sphenopalatine artery ligation) to more advanced (e.g., sphenoidotomy, medial maxillectomy) techniques.

### Responses according to stage of training

The collated responses were also stratified according to the stage of post-graduate otolaryngology training which was declared by the delegates at the time of course registration (Figure 3). These were defined as early (n = 7), intermediate (n = 10) and latter (n = 9) years training. The overall mean (± standard deviation) of all responses for early years trainees was significantly higher when compared to the intermediate and later years

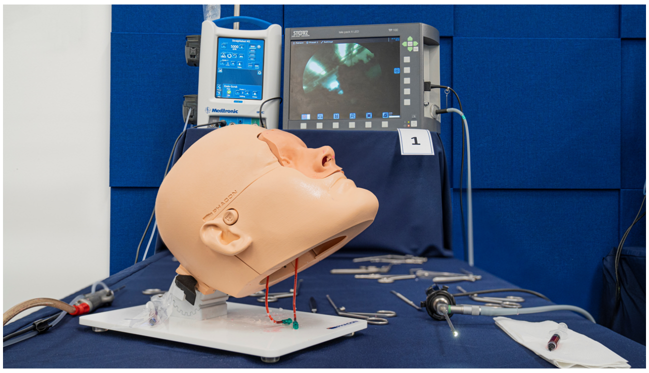

Figure 2. Workstation with PHACON Sinus Trainer and training cassette in situ.

delegates (4.4 ± 0.2 vs. 4.1 ± 0.3 vs. 4.0 ± 0.3; $P < 0.05$). There was no difference observed in the returned responses between the intermediate and later years training cohorts.

### Faculty feedback

Although the ratings from the teaching faculty (n = 10) were high for the model's fidelity and its effectiveness as a training tool, the realism of mucosal tissue had the lowest mean score (Figure 4). All faculty agreed that the model was useful to develop hand-eye coordination and was a useful training tool for endoscopic sinus surgery. Overall, the sinus model received high scores regarding its use for training surgeons, especially to develop camera and instrument handling skills. While task-specific rating scores remained high for more basic sinus surgery techniques, a greater proportion of the teaching faculty (15%) disagreed or were neutral that the model was useful for developing advanced sinus techniques such as dacryocystorhinostomy or frontal sinus surgery.

## Discussion

### Synopsis of key/new findings

Improvements in 3-D printing technology have enabled the fabrication of composite models, such as the PHACON Sinus Trainer, which are not only lifelike but provide realistic haptic feedback to mimic a variety of human tissue characteristics such as mucosa, bone, cartilage, muscle and skin. The restrictions and limitations imposed on surgical training opportunities during the COVID-19 pandemic, both in the workplace environment and availability of post-graduate courses, have provided a catalyst to re-evaluate how surgeons can be trained [5,6]. While many 3-D printed simulator models have been described in the literature and therefore potentially available for training purposes, most are not fabricated on a large scale or easily available commercially [2].

This study examined the face and content validity of the PHACON Sinus Trainer. The results suggest this high-fidelity 3-D

Table 2. Summary of feedback from all course delegates.

| | Feedback | Strongly disagree: 1 | Dis agree: 2 | Neutral: 3 | Agree: 4 | Strongly agree: 5 | Mean rating score (SD) |
|---|---|---|---|---|---|---|---|
| | | Number of responses (%) | | | | | |
| Face validity | 1. Appearance of anatomical structures is realistic | 0 (0) | 2 (8) | 1 (4) | 18 (69) | 5 (19) | 4.0 (1.2) |
| | 2. The mucosal tissue feels realistic | 0 (0) | 6 (23) | 8 (31) | 11 (42) | 1 (4) | 3.3 (0.7) |
| | 3. The bony tissue feels realistic | 0 (0) | 1 (4) | 12 (3) | 72 (19) | 12 (3) | 3.9 (1.2) |
| | 4. Depth perception is realistic | 0 (0) | 3 (12) | 1 (4) | 8 (31) | 14 (53) | 4.3 (1.1) |
| | 5. Instruments application is realistic | 0 (0) | 1 (4) | 1 (4) | 12 (46) | 12 (46) | 3.9 (1.0) |
| Global content validity | 6. This model is able to mimic actual sinus anatomy (high fidelity) | 0 (0) | 2 (8) | 3 (12) | 19 (72) | 2 (8) | 3.9 (1.2) |
| | 7. This model is useful for learning sinonasal anatomy | 0 (0) | 1 (4) | 1 (4) | 15 (58) | 9 (34) | 4.2 (1.1) |
| | 8. This model is useful for learning surgical planning | 0 (0) | 1 (4) | 3 (12) | 13 (50) | 9 (34) | 4.2 (1.0) |
| | 9. This model is useful for improving my operative techniques | 0 (0) | 0 (0) | 2 (8) | 14 (54) | 10 (38) | 4.3 (1.1) |
| | 10. This model helps develop my hand-eye coordination needed for endoscopic sinus surgery | 0 (0) | 2 (8) | 0 (0) | 9 (34) | 15 (58) | 4.3 (1.3) |
| | 11. This model is useful as an overall training tool | 0 (0) | 2 (8) | 0 (0) | 13 (50) | 11 (42) | 4.4 (1.2) |
| | 12. This model is an adequate training platform for future surgeons | 0 (0) | 2 (8) | 2 (8) | 12 (46) | 10 (38) | 4.1 (1.0) |
| Task-specific content validity | 13. This model correlates with the essential skills needed for endoscopic sinus surgery | 0 (0) | 2 (8) | 0 (0) | 15 (58) | 9 (34) | 3.8 (1.0) |
| | 14. This model helps to develop camera skills needed for endoscopic sinus surgery | 0 (0) | 0 (0) | 1 (4) | 11 (42) | 14 (54) | 4.7 (1.2) |
| | 15. This model helps to develop camera skills needed for nasal endoscopy | 0 (0) | 1 (4) | 1 (4) | 12 (46) | 12 (46) | 4.3 (1.1) |
| | 16. This model helps develop dexterity, accuracy, and precision with instruments | 0 (0) | 2 (8) | 1 (4) | 10 (38) | 13 (50) | 4.2 (1.1) |
| | 17. This model helps to develop fundamentals involved in sphenopalatine artery ligation | 0 (0) | 2 (8) | 1 (4) | 14 (54) | 9 (34) | 4.1 (1.0) |
| | 18.This model helps to develop fundamentals involved in maxillary antrostomy | 0 (0) | 0 (0) | 3 (12) | 15 (58) | 8 (30) | 4.2 (1.0) |
| | 19.This model helps to develop fundamentals involved in ethmoidectomy | 0 (0) | 1 (4) | 3 (12) | 15 (58) | 7 (26) | 4.0 (1.0) |
| | 20. This model helps to develop fundamentals involved in sphenoidotomy | 0 (0) | 2 (8) | 1 (4) | 13 (50) | 10 (38) | 4.1 (1.0) |
| | 21. This model helps to develop skills needed for frontoethmoid recess exploration and frontal sinusotomy | 0 (0) | 1 (4) | 2 (8) | 15 (58) | 8 (30) | 4.1 (1.0) |
| | 22. This model helps to develop advanced sinus techniques for less common procedures e.g. medial maxillectomy, dacryocystorhinostomy | 0 (0) | 1 (4) | 2 (8) | 16 (62) | 7 (26) | 4.1 (1.1) |

printed model can serve as an effective tool for training in endoscopic sinus surgery. This simulator allows for development of hand-eye coordination in endoscopic camera skills and, training on the use of both cold steel and powered sinus instruments.

### Strengths of the study

The current PHACON Sinus Trainer model has evolved to include synthetic nasal mucosa, polyps and sphenopalatine artery. In addition to undertaking simulated endoscopic polypectomy, the training module provided delegates the opportunity of setting up a microdebrider and understanding the interactions between the various blade settings with soft tissue; an essential technical knowledge for any surgeon undertaking endoscopic sinus surgery [7]. We believe that the present course programme is a paradigm shift from conventional dissection courses which typically emphasises on stepwise progression of anatomical dissection. Although our training programme was based on clinically relevant themes, progression through each module was associated with increasing complexity of surgical dissection and technical skill. Completion of all modules was designed to maximise the potential of the simulator (Table 1).

The larger cohort of delegates in this study allowed for the retur-

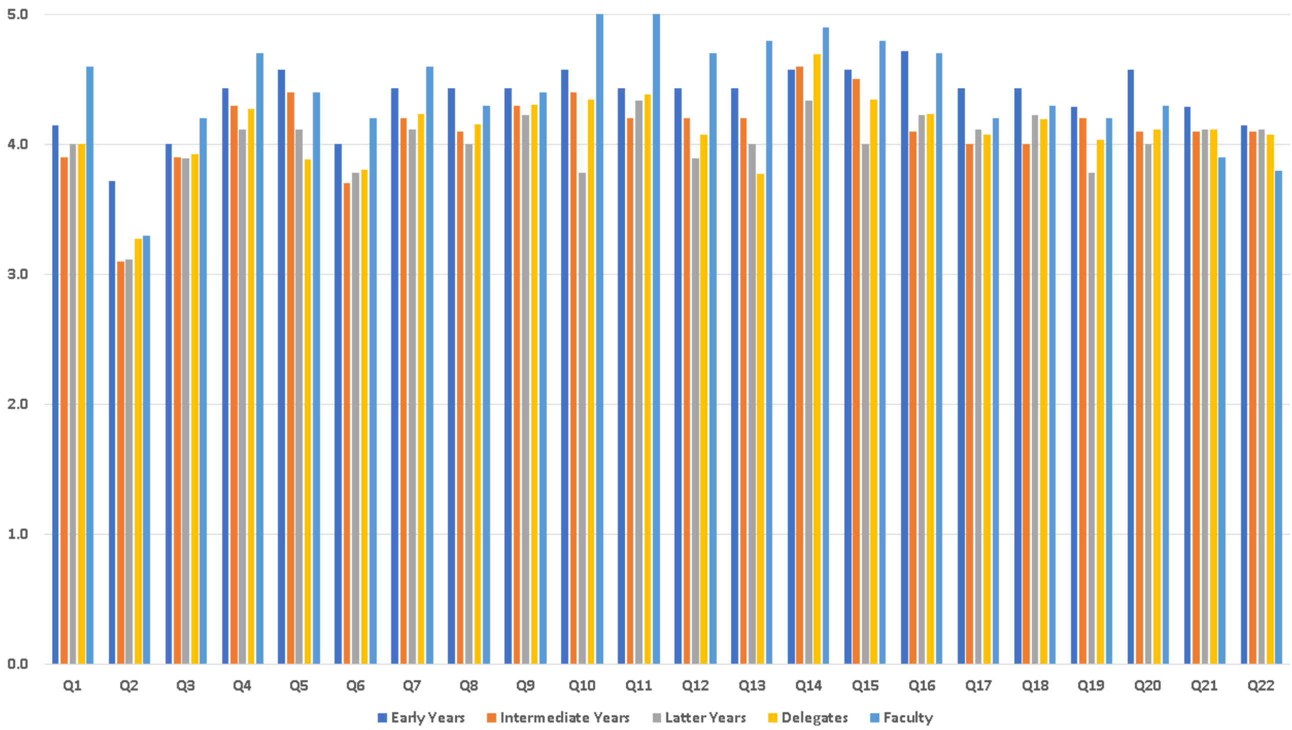


Figure 3. Summary of responses from all delegates.

ned responses to be stratified according to the level of training, and comparison with the teaching faculty. Although there was general concordance in the responses provided by the course delegates, some interesting differences were observed in both face and content validity. For example, the realism of nasal mucosa scored the lowest among latter years trainees (Figure 3). This could be because these trainees have previously attended dissection courses utilising cadaver specimens or have more clinical experience in undertaking nasal septal and endoscopic sinus procedures.

### Comparisons with other studies

A previous study reported on the face and content validity of the PHACON Sinus Trainer from 12 post-graduate ENT doctors [3]. The published results corroborate with the present study in the appearance of anatomical structures, depth perception, and instrument application; although face validity rating score was similarly lowest for mucosal tissue [8]. The authors of another study opined that the weakest feature was the realism of the mucosa in their high-fidelity model. They also noted the difficulty of flap elevation as the simulated mucosa was strongly attached to the nasal septal cartilage and bone which did not reproduce the force needed in real surgery [9].

### Clinical applicability of the study

High-fidelity surgical simulators are recognised as an invaluable tool for training and education [2]. Three-dimension printing technology is not only increasingly affordable but with faster printers, mass-production is therefore feasible. While current technological advancements do not yet permit the shifting of benchmarks away from human cadaver as the ideal platform for surgical training, the utility of sinonasal models such as those used in the present study cannot be ignored. For example, the latest training models developed by PHACON and Fusetec have incorporated a variety of simulated pathology including nasal polyps, inverted papilloma and deviated septum which cadaveric specimens do not normally have. As these models are designed from actual fine-cut CT scans, real patients' scans could be utilised to develop models with more complex sinonasal anatomy and inflammatory load to challenge the different skill sets or experience of surgeons [10]. This is a paradigm shift from human cadaveric specimens where complex paranasal sinus anatomy is uncommon or undiscovered unless dissected.

A further benefit offered by the model is the opportunity for training in hand to eye co-ordination in a simulated setting. Instrument manipulation in a safe and effective manner as well as endoscope handling skills can be improved with this model without the risk of inadvertent injury to critical patient structures such as the orbit and skull base by the novice ENT surgeon in the operating theatre. The ability for surgeons to undertake repeated surgical dissection on 3-D printed models has been reported to result in significant improvement in the individual's ability to perform the surgical dissections for the different

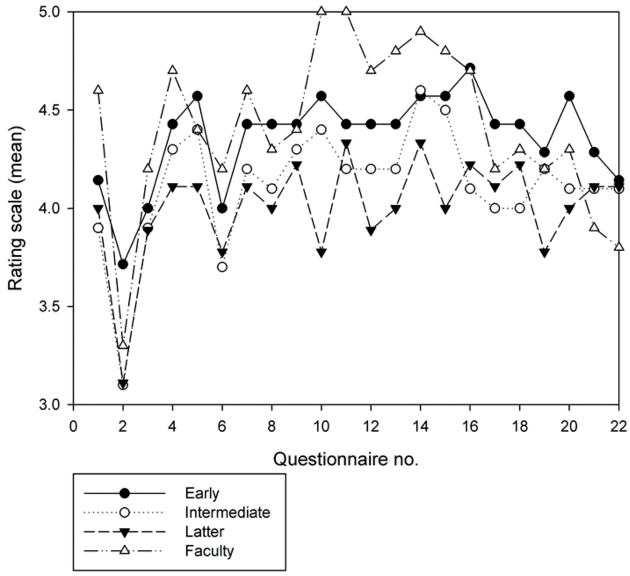


Figure 4. Comparison of mean scores of each question between different stages of training and faculty.

sinuses, progress of surgery and completeness of the surgical dissection [10].

The quality of human cadaver tissue at the time of dissection varies widely with the embalming technique. While fresh-frozen tissue is regarded as being superior in appearance and tissue handling when compared to formalin-fixed or Thiel-processed specimens degrades more rapidly once thawed. Unlike models which can be mass-produced, human cadaveric tissue is not as easily available. Furthermore, the use of models for surgical training is not bound by the regulatory requirements and restrictions typically mandated when using human cadaveric tissue. Storage and handling of human tissue can also be difficult and expensive, whereas used training cassettes can be discarded in general waste or appropriate recycling bins.

Mass production of these models ensure uniformity in the anatomical variants and simulated pathology encountered by all attendees of the training event. Delegates benefit from being able to benchmark their progress against their peers during the course and faculty dissections that are being demonstrated [10,11]. At present, the model does not have variations in the anatomy of the frontal sinus. Complex anatomical configurations are not present, and thus represents a drawback that it cannot be considered a model to train complex frontal sinus surgery such as Draf 2A, 2B or 3. Despite the many benefits, however, barriers to adoption exists; not least the cost of these models. The PHACON Sinus Trainer with a training cassette cost approximately €2,000 each [12]. Although this cost may be comparable to human cadaver specimens, it should be acknowledged that the durable plastic sinus trainer can be reused indefinitely. Furthermore, the inability to replicate nasal mucosa accurately may dissuade course organisers from considering an alternative to human cadaver specimens.

## Conclusion

While the current model does not replace human cadaveric tissue, it is a credible tool for surgical skills training in endoscopic sinus surgery. The results of this study suggest that otolaryngology doctors in their early or intermediate stage of training would benefit most from a clinical-based modular programme. The model requires further development in areas such as the realism of mucosa, incorporation of sinonasal pathology and having more complex anatomy to be useful for the training of more advanced surgeons.

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None.

## Authorship contribution

SCL: Concept and design of study. Data analysis and drafting of manuscript. AS: Data analysis and drafting of manuscript. NCT: Data analysis and drafting of manuscript.

## Conflict of interest

AS is the International Medical Affairs Director for Medtronic ENT. SCL and NCT have none to declare.

## Funding

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