Received: 20 September 2022 | Accepted: 25 September 2022

DOI: 10.1002/lio2.945

ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Validation of a three-dimensional printed pediatric middle ear model for endoscopic surgery training

Joshua Anthony Stramiello MD[1] | Stephanie J. Wong MD[2,3] | Raquel Good MS[2] | Alice Tor BS[4] | Justin Ryan PhD[2,5] | Daniela Carvalho MD, MMM[1,2]

[1]Department of Otolaryngology-Head and Neck Surgery, University of California, San Diego, San Diego, California, USA

[2]Division of Pediatric Otolaryngology, Rady Children's Hospital – San Diego, San Diego, California, USA

[3]Department of Otolaryngology-Head and Neck Surgery, Virginia Commonwealth University Medical Center, Richmond, Virginia, USA

[4]Jacobs School of Engineering, University of California, San Diego, San Diego, California, USA

[5]3D Innovations Lab, Rady Children's Hospital, San Diego, San Diego, California, USA

Correspondence
Daniela Carvalho, MD, MMM, Division of Pediatric Otolaryngology, Rady Children's Hospital; Department of Otolaryngology-Head and Neck Surgery, University of California, 3020 Children's Way, MC 5024, San Diego, CA 92123, USA.
Email: dcarvalho72@gmail.com

Funding information
Helen and Will Webster Foundation

Abstract

Objective: The purpose of this study is to assess the anatomical appropriateness of a three-dimensional (3D) printed pediatric middle ear model with a replaceable middle ear unit as an endoscopic ear surgery (EES) simulator.

Methods: Single-blinded, prospective, proof-of-concept study conducted in a simulation operative suite. A simulator was developed through segmentation of source images and multi-material 3D printing. Subjects were asked to point to seven anatomical sites before and after a short anatomy presentation of a human middle ear photograph. They also filled out a survey about the feasibility of the model. Outcome variables included survey scores, pre-anatomy lesson (PreAL) and post-anatomy lesson (PostAL) quiz scores.

Results: There were 24 participants (19 residents, 1 fellow, and 4 attendings), none with self-reported proficiency in EES. The PreAL mean score was 4.42 and PostAL quiz mean score was 5.32 (average improvement of 43% [CI = 17%–70%]; $p = .003$). The higher the level of training, the higher the PreAL scores (0.55 points per year of training; $p = .004$). The subspecialty (otology, other, in-training) was also associated with the PreAL scores ($p = .004$). Total survey score means were 22.8 (out of 30).

Conclusion: The results of our study suggest that our model has adequate anatomical high fidelity to mimic a real, pediatric temporal bone for EES. As 3D printing technologies continue to advance, the quality of ear models has the potential to provide improved surgical training for pediatric EES.

Level of Evidence: 4

KEYWORDS
3D printed, endoscopic ear surgery, middle ear, pediatric, surgical model

1 | INTRODUCTION

Improved surgical outcomes of endoscopic ear surgery (EES) techniques in pediatric patients has led to an increase in its utilization.[1,2]

This work was presented at the 2021 American Academy of Otolaryngology-Head and Neck Surgery Facial Plastics (AAO-HNSF) annual meeting in Los Angeles, CA on October April 5, 2021.

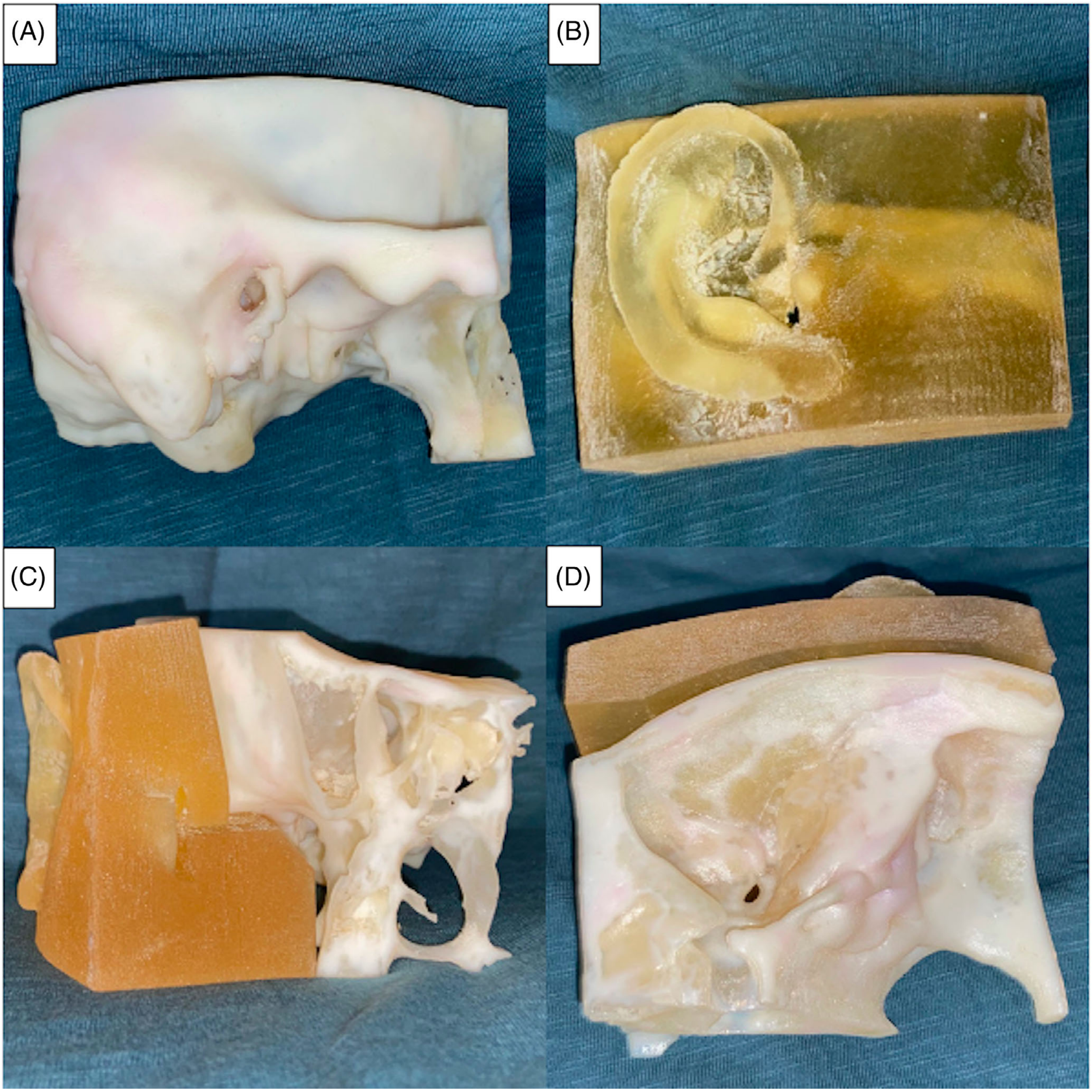

FIGURE 1 High fidelity, 3D-printed pediatric middle ear model. Lateral views, (A) rigid temporal bone and (B) soft tissue made of proprietary plastic photopolymers. (C) Anterior view with soft tissue attached to temporal bone along the zygoma. (D) Superior view of middle fossa, petrous apex, and small portion of posterior fossa

The use of three-dimensional (3D)-printed surgical models for simulation training of residents and fellows in pediatric otolaryngology has been shown to improve self-reported confidence and expertise in the associated practice.[3] In fact, the American Academy of Otolaryngology-Head and Neck Surgery Foundation formed the 3D-Printed Temporal Bone Working Group as a collaborative effort to evaluate 3D-printed ear models for appropriateness of microscopic surgery simulation with reported success.[4] Barber et al. developed an endoscopic pediatric middle ear simulator utilizing a peg-and-ring task, reporting quicker time trials by senior residents, suggesting validity as a surgical simulator.[5]

Our interdisciplinary team of clinicians and engineers developed the first anatomically-correct, high-fidelity, 3D-printed pediatric middle ear model (the authors were unable to identify literature showing precedence in this niche application). The purpose of this study is to assess the appropriateness of this endoscopic middle ear model as a surgical simulator via anatomy testing and real-life surgical tasks by Otolaryngology residents, fellows, and attendings.

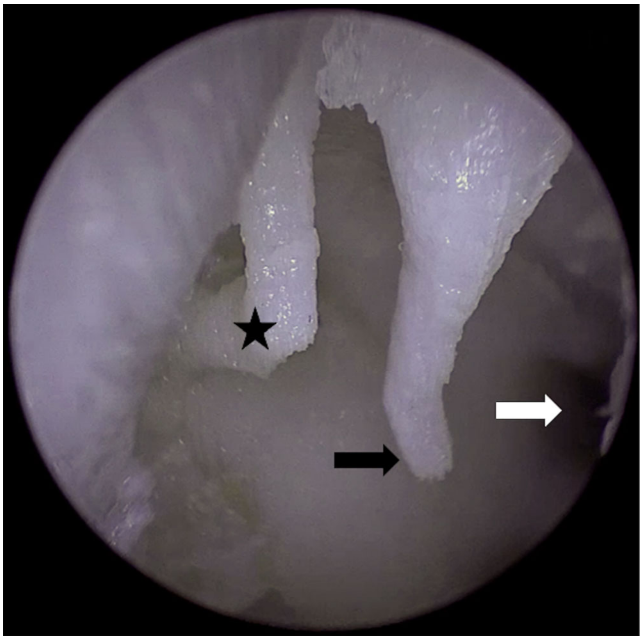

FIGURE 2 Endoscopic view of the lateral middle ear portion of the 3D-printed model. Note the Eustachian tube (white arrow), umbo (black arrow), and incudostapedial joint (black star)

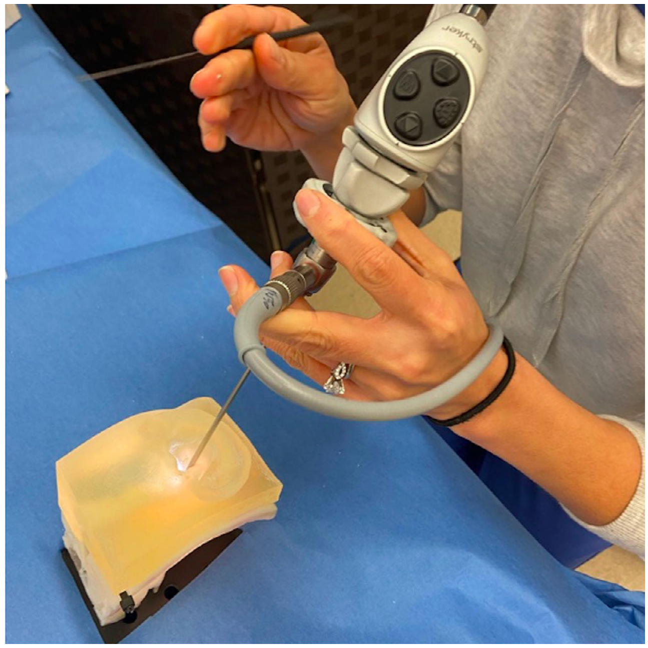

FIGURE 3 Example model set up for anatomy quizzes. Note the participant was supplied with a telescope and Rosen needle

2 | METHODS

This was a single-blinded, prospective, proof-of-concept study conducted in a simulation operative suite on January 8, 2021. We attained Institutional Review Board approval by the University of California, San Diego (UCSD) Human Research Protections Program, project 202070.

A 3D computer model of a right ear was generated through segmentation and reconstruction (Mimics, Materialize) of a computed tomography (CT) scan of a 7-year-old boy with clear delineation of normal temporal bone anatomy. An anatomical 1:1 model of soft tissue and skeletal anatomy (Figure 1) was generated through material jetting 3D printing technology (J750 Digital Anatomy Printer, Stratasys). The model's skeletal anatomy was segmented into a main truncated skull portion and a modular ossicle-focused element. The soft tissue 3D print was designed to fit over the hard tissue prints. The bony and soft tissue anatomy were printed in a photopolymer (trade names of Bone Matrix and Agilus 30, respectively, with additional photopolymers added) to simulate real human tissue and give a more accurate EES experience.

Otolaryngology-head and neck surgery residents, fellows, and attendings from the San Diego area in California were recruited. During recruitment, potential participants were supplied an information sheet discussing the purpose of the study and the novelty of the surgical model. Written consent was required of all participants. No compensation was provided. The proctors were pediatric otolaryngologists with significant experience in performing pediatric EES and were intimately involved with the development of this model. The proctors were blinded to the participants.

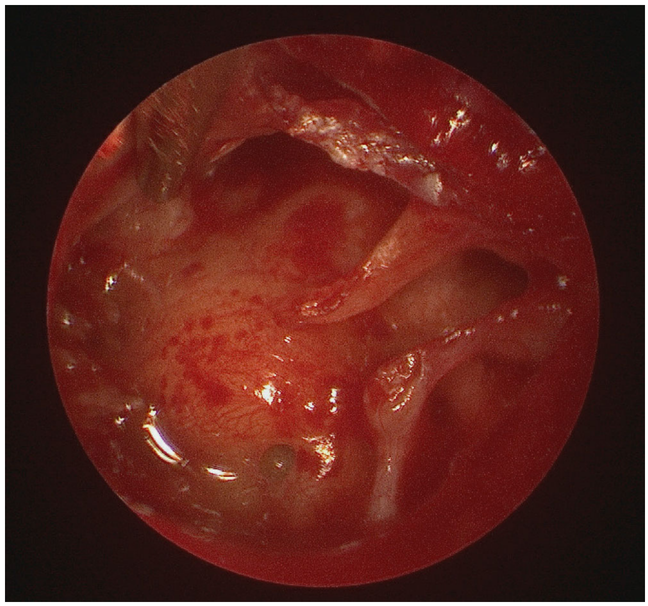

FIGURE 4 Endoscopic image of a left middle ear of a 12-year-old female with no relation to the patient utilized for the 3D model

Participants were presented with the right ear surgical model with normal anatomy (intact ossicular chain) (Figure 2) and asked to place a 30-degree 3 mm scope (10 cm length) into the middle ear (Figure 3). They were also supplied with a Rosen needle to point to the structures in the model. No participants required instruction on instrument use and all were capable of adequately viewing the middle ear endoscopically. As this was an anatomical validation study, the participants were not evaluated on their scope/instrument handling skills. They were then asked to point to seven anatomical sites in the model, which was graded for correctness by a proctor who was blinded to the participants' identities. This was followed by a short 12-point anatomy lesson using a left, endoscopic middle ear photograph (Figure 4) of a 12-year-old female with no relation to the patient who's CT scan was used to build the model. The anatomy lesson consisted of the senior author pointing to and naming 12-specific anatomic sites deemed to be important by expert opinion and included all seven anatomical sites that were asked during the quizzes. The participants were allowed to ask questions during this time. This was performed in groups of three to four participants at a time. Next, within 10 min of the anatomy lesson, a repeat quiz of the same seven anatomical sites was performed using the same parameters as the first quiz. Finally, a non-validated 5-point Likert-scale survey, with a max score of 30, regarding the utility of this model as a teaching modality was answered anonymously by the participants.

Primary outcome was change in pre-anatomy lesson (PreAL) and post-anatomy lesson (PostAL) lesson quiz scores. Secondary outcome was survey score. Independent variables included level of training, sub-specialty, and prior EES experience. Descriptive statistics were derived, and regression and leverage analyses were performed using R (R Core Team) statistical software.

TABLE 1 Participant characteristics

Level of training	Post-graduate year or specialty	Total (%)
Resident	PGY1	4 (21)
	PGY2	4 (21)
	PGY3	4 (21)
	PGY4	3 (16)
	PGY5	3 (16)
	PGY6	1 (5)
Fellow	Otology	1 (100)
Attending	Otology	2 (50)
	Other	2 (50)
Prior ESS experience	Never	17 (71)
	1–2 times	4 (17)
	>2 times	3 (12)

Abbreviations: ESS, endoscopic sinus surgery; PGY, post-graduate year.

3 | RESULTS

There were 24 participants, which included 19 residents, 1 fellow, and 4 attendings (Table 1). Post-graduate year for residents ranged from 1 to 6. Among the fellow and attendings, there were three otologists, one head and neck oncologist, and one rhinologist. The majority of participants (17% or 71%) had no prior experience with EES, while 4 (17%) had performed EES 1–2 times prior, and 3 (12%) had performed EES more than two times prior.

Among the entire group, mean PreAL scores were 4.42 (Std Dev 1.74, $n = 24$) and PostAL scores were 5.32 (Std Dev 1.13, $n = 22$) (Table 2). There was an average improvement of 43% in PostAL scores (CI = 17%–70%; $p = .003$). The higher the level of training, the higher the PreAL scores (0.55 points per year of training; $p = .004$). The sub-specialty (otology, other, in-training) was also associated with the PreAL scores ($p = .004$). The two otology attendings did not perform the PostAL quiz, but had achieved perfect scores on the PreAL quiz despite never performing EES previously. The otology fellow also achieved perfect scores on the PreAL and PostAL quizzes. Effect leverage plot (Figure 5) and analysis of variance testing identified a statistically significant positive slope in PostAL scores based on PreAL scores ($p = .0022$).

The mean total survey score was 22.8 (out of 30, $n = 24$) (Table 3). The lowest scored questions were 1, 2, and 4 (mean 3.46,

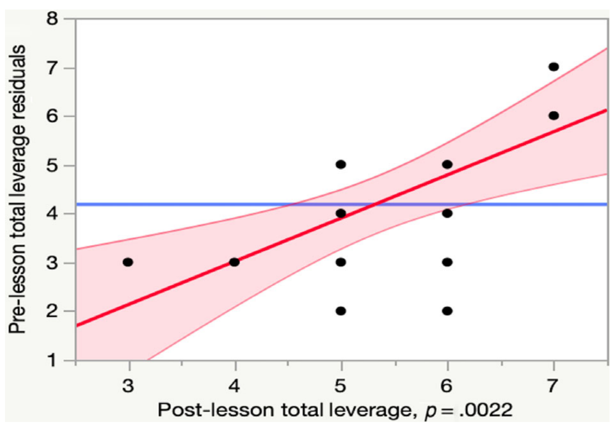

FIGURE 5 Effect leverage plot of pre-anatomy lesson and post-anatomy lesson scores

TABLE 2 Anatomical structures on quizzes

Question no.	Anatomical structures	Total correct PreAL ($n = 24$)	Total correct PostAL ($n = 22$)
1	Promontory	16	17
2	Stapes superstructure	6	10
3	Round window niche	11	15
4	Tensor tympani canal	18	19
5	Lateral process of malleus	17	18
6	Long process of incus	19	18
7	Facial nerve canal	19	20

Abbreviations: PostAL, post-anatomy lesion quiz score; PreAL, pre-anatomy lesson quiz score.

3.25, and 3.63, respectively). Attendings were more likely to answer questions 2, 3, and 5 with a lower score ($p < .025$). Of note, question 6 ("Training with this model would help trainees improve their overall ear surgery skills.") received the highest mean score (4.38).

4 | DISCUSSION

4.1 | Comparisons

A perfect surgical model is contingent upon numerous factors specific to the task and the learner. Some of these include likeness, accessibility, applicability, and durability. Our model was designed with these specific principles in mind, and the main goal of this study was to assess the model's anatomical fidelity.

TABLE 3 Survey questions

1-strongly disagree, 2-disagree, 3-neutral, 4-agree, 5-strongly agree	Mean (Std Dev)
1. This model looks like a real pediatric middle ear model.	3.46 (0.58)
2. This model simulates endoscopic ear surgery just like a human patient.	3.25 (0.66)
3. Training with this model has helped me better understand middle ear anatomy.	3.83 (0.94)
4. Training with this model helped my comfortability with endoscopic ear surgery skills.	3.63 (0.95)
5. Training with this model is an effective way to learn.	4.29 (0.61)
6. Training with this model would help trainees improve their overall ear surgery skills.	4.38 (0.81)

Abbreviation: Std Dev, standard deviation.

In regard to likeness, the specific soft tissue and bony morphology created was derived from a real pediatric patient's CT images. A pediatric temporal bone model was selected for fabrication because the senior author is an academic pediatric otolaryngologist interested in creating more accurate and safer learning experience for trainees interested in pediatric ear surgery. The anatomical fidelity of the printed model was high as evident by the PreAL and PostAL scores. This is confirmed by higher PreAL scores with increasing resident training level, as well as attendings with otology-centric practices. Furthermore, PostAL scores consistently increased at a similar rate despite the participant's having a short lesson on endoscopic middle ear anatomy utilizing a picture of a left ear, while the model was of a right ear. Another important attribute is the tactile likeness, which for our model would include both the bony model firmness, as well as the soft tissue elasticity. The materials used in our model were chosen to mimic the tactile experience of EES in a real patient. These are significant differences between our model and that presented by Barber et al., as their model did not have any likeness to a middle ear, aside from scale.[5]

However, an important strength of Barber et al.'s model is accessibility, which is likely increased compared to ours, due to the simple construction materials. The sophistication of our model is high as it required the skillset of a dedicated 3D printing engineer employed at our children's hospital. This makes accessibility for many institutions more difficult. However, with the continued increased access to 3D printing engineers and firms, obtaining these models are becoming easier with time. Similarly, print time is relatively short, further improving accessibility. One major barrier all middle ear model training

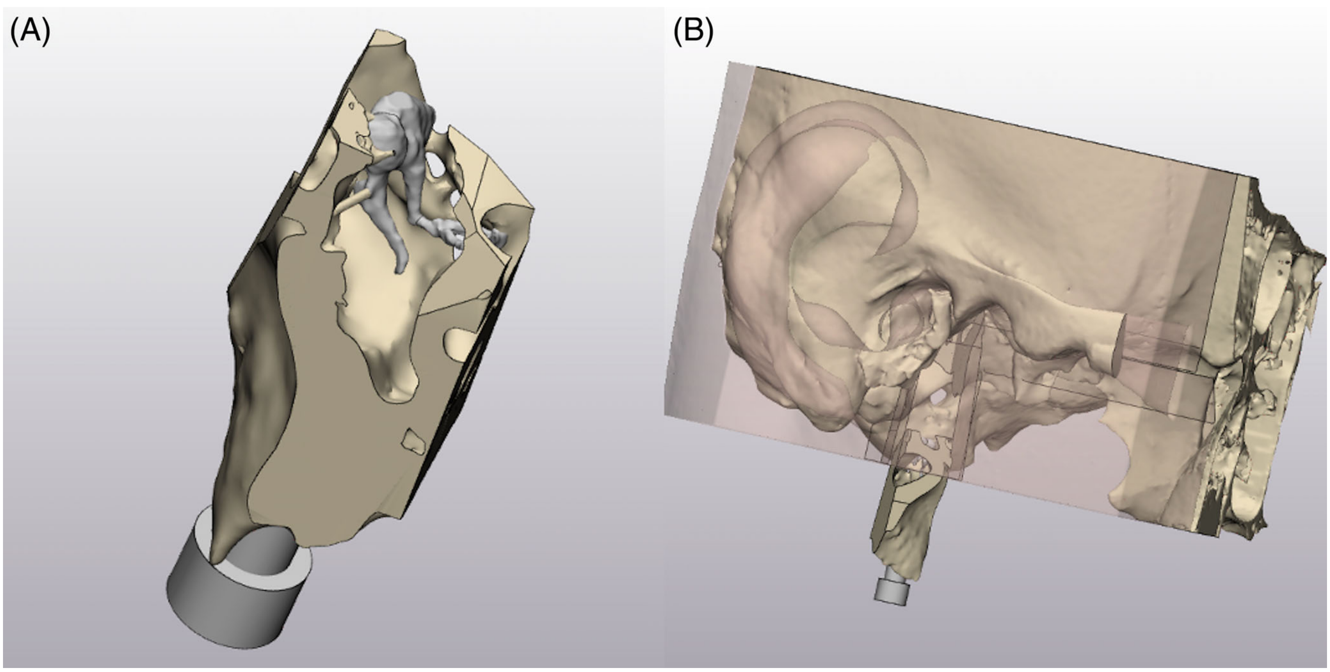

FIGURE 6 Three-dimensional renderings of (A) a normal middle ear central core and (B) assembly of the central core into the temporal bone model

must face is access to surgical instruments. Obtaining dedicated resources towards this should ultimately be an early priority for teaching EES outside of the operating room.

Applicability is difficult to assess in a novel model. Our participants rated all survey questions on the agree side of the Likert scale, painting a positive predilection for teaching. Further testing with skill-based tasks would strengthen our model as an appropriate EES teaching modality.

4.2 | Novelty

We were concerned that the balance of providing a model with strong durability would reduce its likeness as learners may not understand the true fragility of the middle ear initially if it was not consistent with in vivo experience. To provide this likeness, but still attain an important threshold of durability, our model was designed with a central core (Figure 6) containing the middle ear bones that can be exchanged without having to replace the rest of the temporal bone or soft tissue model. Exchange of the core was not required during our study, however, it allowed the ability to quickly repair the model if needed. The small size of the core means very short print times and significant cost savings in materials. Furthermore, this comes with the added benefit of being able to provide differing middle ear circumstances and pathologies. While we did not test these tasks in this particular study, we have successfully created a partial ossicular reconstruction prosthesis (PORP) core complete with 3D-printed PORPs, as well as a cholesteatoma core for future training of EES.

4.3 | Limitations

Significant limitations in our study include the relatively small sample size and the non-validated survey utilized. Similarly, only our proctors were blinded to the participants, and not vice versa. Encouragingly, our data was collected prospectively and attained statistical significance in a manner that suggests a strong likeness to real life anatomy.

4.4 | Prospective efforts

Future endeavors will be focused on improving accessibility and applicability. Providing the appropriate G code to other 3D printing engineers would allow rapid reproduction of the model, increasing access quickly. Installing censors on sensitive anatomy and creating more task-oriented core variability would increase applicability significantly, providing the learner with meaningful tactile and visual feedback in real-time and after. Given the limited access to EES by many resident otolaryngologists, surgical middle ear models may offer a safe and effective tool for learning.

5 | CONCLUSION

The results of our study suggest that our model has adequate high anatomic fidelity to mimic a real, pediatric temporal bone for EES as evident by higher scores per training level, as well as improved scores after an anatomy lesson on a real, but opposite, pediatric middle ear. This was further supported subjectively by the participants on the survey. As 3D printing technologies continue to advance, the quality of ear models has the potential to provide improved surgical training for pediatric EES.

ACKNOWLEDGMENTS
The authors would like to thank the Helen and Will Webster Foundation for their support of the Webster Foundation 3D Innovations Lab at Rady Children's Hospital-San Diego.

FUNDING INFORMATION
None.

CONFLICTS OF INTEREST
None.

ORCID
Joshua Anthony Stramiello https://orcid.org/0000-0001-7941-6276
Daniela Carvalho https://orcid.org/0000-0002-7062-8843

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How to cite this article: Stramiello JA, Wong SJ, Good R, Tor A, Ryan J, Carvalho D. Validation of a three-dimensional printed pediatric middle ear model for endoscopic surgery training. *Laryngoscope Investigative Otolaryngology*. 2022;7(6):2133-2138. doi:10.1002/lio2.945