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3D-printed pediatric endoscopic ear surgery simulator for surgical training

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A R T I C L E I N F O

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A B S T R A C T

Introduction: Surgical simulators are designed to improve operative skills and patient safety. Transcanal Endoscopic Ear Surgery (TEES) is a relatively new surgical approach with a slow learning curve due to one-handed dissection. A reusable and customizable 3-dimensional (3D)-printed endoscopic ear surgery simulator may facilitate the development of surgical skills with high fidelity and low cost. Herein, we aim to design, fabricate, and test a low-cost and reusable 3D-printed TEES simulator.
Methods: The TEES simulator was designed in computer-aided design (CAD) software using anatomic measurements taken from anthropometric studies. Cross sections from external auditory canal samples were traced as vectors and serially combined into a mesh construct. A modified tympanic cavity with a modular testing platform for simulator tasks was incorporated. Components were fabricated using calcium sulfate hemihydrate powder and multiple colored infiltrants via a commercial inkjet 3D-printing service.
Results: All components of a left-sided ear were printed to scale. Six right-handed trainees completed three trials each. Mean trial time ($n = 3$) ranged from 23.03 to 62.77 s using the dominant hand for all dissection. Statistically significant differences between first and last completion time with the dominant hand ($p < 0.05$) and average completion time for junior and senior residents ($p < 0.05$) suggest construct validity.
Conclusions: A 3D-printed simulator is feasible for TEES simulation. Otolaryngology training programs with access to a 3D printer may readily fabricate a TEES simulator, resulting in inexpensive yet high-fidelity surgical simulation.

1. Introduction

Surgical simulators recreate environments and tasks modeled after surgical procedures with the goal of improving operative skills and patient safety [1]. The duration of surgery is longer with junior trainees, which leads to increased anesthesia administered to the patient and costly operating room time [2–4]. Rehearsal of operative techniques prior to the operating room facilitates a smoother transition. A Cochrane review on use of laparoscopic box simulators for general surgeons showed improvement of technical skills in individuals who have little experience with similar techniques [5]. Additional prospective studies investigating virtual reality and box simulators have shown significant improvement with technical performance in surgery when compared to control groups with conventional residency training [6,7]. Randomized controlled trials using standardized objective assessments have demonstrated strong evidence that simulation is beneficial in surgical training [8].

Transcanal Endoscopic Ear Surgery (TEES) is a relatively new surgical approach with a slow learning curve. In contrast to the binocular microscope, the endoscope allows for improved

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visualization because a wide-angle lens and light source is placed at the distal tip of the instrument. Otoendoscopy was introduced in the late 1960s; however, poor image resolution limited its immediate application [9]. With the introduction of three charge coupled device (CCD) camera systems and high-resolution monitors in the 1990s, endoscopes can provide high resolution imaging and videos of the middle ear. Pioneers of endoscopic ear surgery (EES) espouse its high resolution, magnification, and the newfound ability to look around corners [10]. Specifically, in the pediatric population, recent experience with EES has transitioned from endoscope use strictly for visualization to transcanal approaches using the endoscope for all portions of pediatric middle ear surgeries [10]. The enhanced surgical view resolves the fine details of middle ear structures and their spatial relationships. In some cases, the endoscope has transformed the EAC into a minimally invasive portal for complex middle ear surgery.

Historically, cadaveric temporal bones have been utilized to enhance surgical training in otology. Much of the learning curve involves competency with the surgical drill [11], and surgical training using this model has been shown to directly correlate with surgical skills [12]. Recently, a temporal bone model incorporating artificial cholesteatoma was shown to provide a high-fidelity dissection experience for TEES [13]. Despite the utilization of inexpensive materials, cadaveric tissue remains a resource that is limited in quantity and expensive. Current technology has produced both virtual simulations and alternative materials for temporal bone models [14–16]. Several endoscopic otolaryngologic simulators exist [17,18], however, no non-cadaveric simulators exist for endoscopic ear surgery.

As endoscopic approaches to the middle ear become commonplace in clinical practice, the need for surgical simulation is critical. Given the widespread availability of three-dimensional (3D) printing, the ability to design and fabricate models is now a reality. The current generation of inkjet powder bed printers have the capability of printing at a resolution as low as 89 μm, which means any human structure observed under a microscope or endoscope can be recreated in computer assisted drawing (CAD) software, and readily printed using 3D printing techniques.

Herein, we aim to design and fabricate a reusable 3D-printed TEES simulator. We hypothesize that a reusable 3D-printed TEES simulator can improve the technical skills need for endoscopic ear surgery.

2. Materials and methods

2.1. External auditory canal design

The external auditory canal (EAC) was designed to recreate an anatomically correct entry to the middle ear space. Using anthropometric studies with normative data [19–21], dimensions and angles of the EAC and tympanic membrane were incorporated into the design. Thirty cross sectional images of the EAC were converted into vectors and imported into Autodesk 123D as sketches. Each slice was extruded as a 1 mm thick 3D mesh. Slices were then oriented serially using known ranges of vertical and horizontal bends of the EAC, forming an EAC with a distance of 30 mm (Fig. 1A). The space representing a tympanic membrane (TM) was fashioned using a 2D ellipse, which was then lofted to the last 6 cross sections of the EAC in order to create a 4 mm distance from the TM to the isthmus (Fig. 1C). This formed an interface between the EAC and the TM with a natural contour, including the anterior overhang. Finally, a boolean difference function between this solid mesh and a basic cylinder converted the mesh volume into a canal contained within a support structure (Fig. 1D).

2.2. Middle ear space design

The middle ear space was designed as a dome-shaped testing area (Fig. 2A, B). A dome was chosen because of inherent structural integrity, and because the EAC could interface with the middle ear space at virtually any angle. The dome floor was designed flat, with two rectangular depressions that allowed an interface for modular testing platforms that could be easily exchanged. This floor corresponded to the medial wall of the tympanic cavity. The EAC entered the middle ear space at a 45-degree angle to reflect an accurate orientation for the surgeon. A hinged door on the front side of the dome facilitated the exchange of modular testing platforms for switching simulator tasks (Fig. 2C, D).

2.3. Modular task design

Three “donuts” and two “pegs” were designed for manipulation by endoscopic equipment. Trainees could use alligator forceps (through the EAC) to transfer donuts between pegs. This task was placed on a modular platform that interfaced with the simulated middle ear space floor via two rectangular legs underneath (Fig. 2D).

2.4. Computer assisted drawing and 3D-Printing

Computer Assisted Drawing (CAD) was performed in Autodesk 123D (Autodesk, San Rafael, CA). 2D sketches were converted into vectors using Adobe Illustrator (Adobe Systems, San Jose, CA) and exported as scalable vector graphics (SVG) files. 2D SVG files were imported into Autodesk 123D and extruded as parametric 3D meshes. 3D models were exported as Stereolithography (STL) and Polygon File Format (PLY) files. These files were 3D printed in zp® 151 composite material and ColorBond zbond® 90 fast-curing infiltrant by a Zcorp 650 inkjet 3D printer using the online service, Sculpteo (Paris, France). This type of printer uses an inkjet print head moving across a bed of powder, selectively depositing a liquid binder to harden the powder into consecutive layers in the Z dimension. The zp® 151 high performance composite material has a tensile modulus of 6.405 GPa and tensile strength of 9 MPa. These mechanical properties allow for the creation of robust simulators that can withstand numerous tests without a loss in structural fidelity. Additionally, inkjet printing allows another print head to deposit a colorant simultaneously on the print, allowing for rapid multicolor prints.

2.5. 3D-printed TEES simulator pilot study design

A pilot study of the TEES simulator was conducted using the 3D-printed simulator, rigid endoscopes, and microsurgical equipment. Participants were otolaryngology residents and neurotology fellows with various levels of experience. The simulator task involved the transfer of 3 donuts from one peg to the other, and then back again. Transfer was performed with alligator forceps using a 3 mm, 0-degree endoscope (Karl Storz, Tuttlingen, Germany) for visualization. This task was performed with three serial trials with the dominant hand, followed by three additional trials with the non-dominant hand. Additionally, participants completed a post-simulation survey that asked questions about prior surgical experience (including the number of previous microscopic and endoscopic procedures), along with questions regarding simulator construct validity.

2.6. Statistical analysis

Mean completion times (in seconds) for trials with dominant

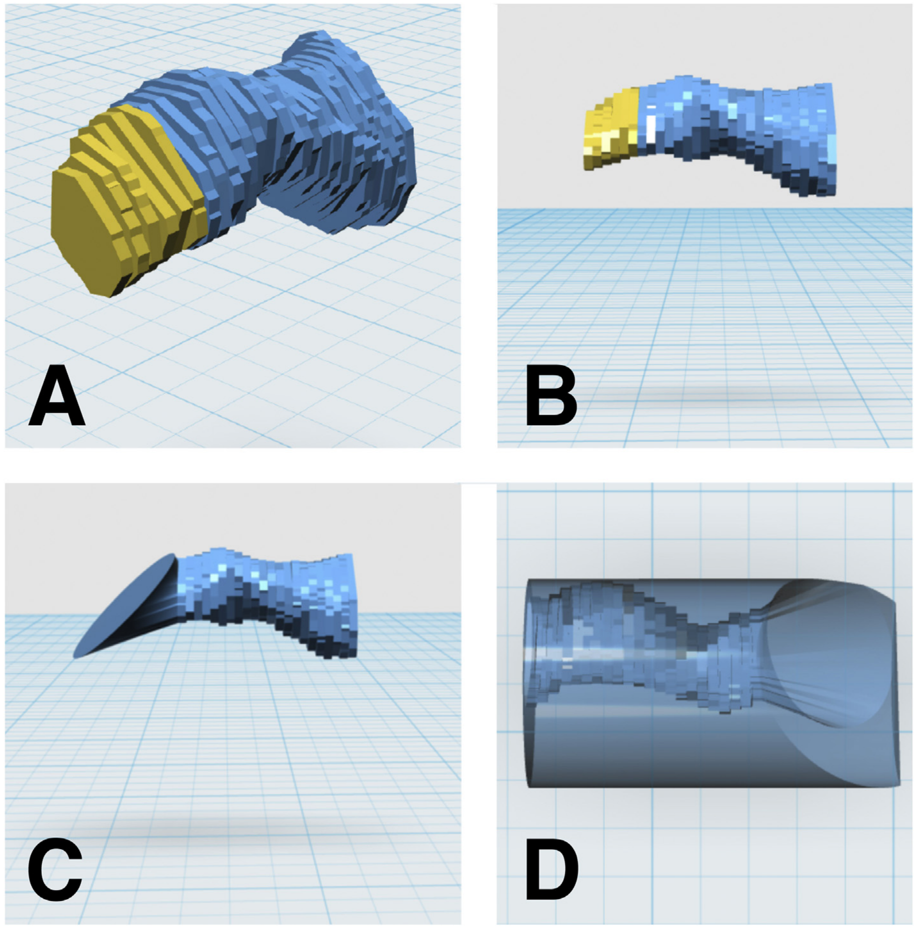

Fig. 1. (A, B) Vectors of cross sectional slices were extruded 1 mm each and arranged serially. The natural bends of a left-sided EAC were formed using normative anatomic data. (A,B) Yellow slices of the proximal EAC were lofted to an ellipsoid shaped tympanic membrane (C). (D) A boolean difference of the solid mesh with a simple cylinder created an EAC with a support structure. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

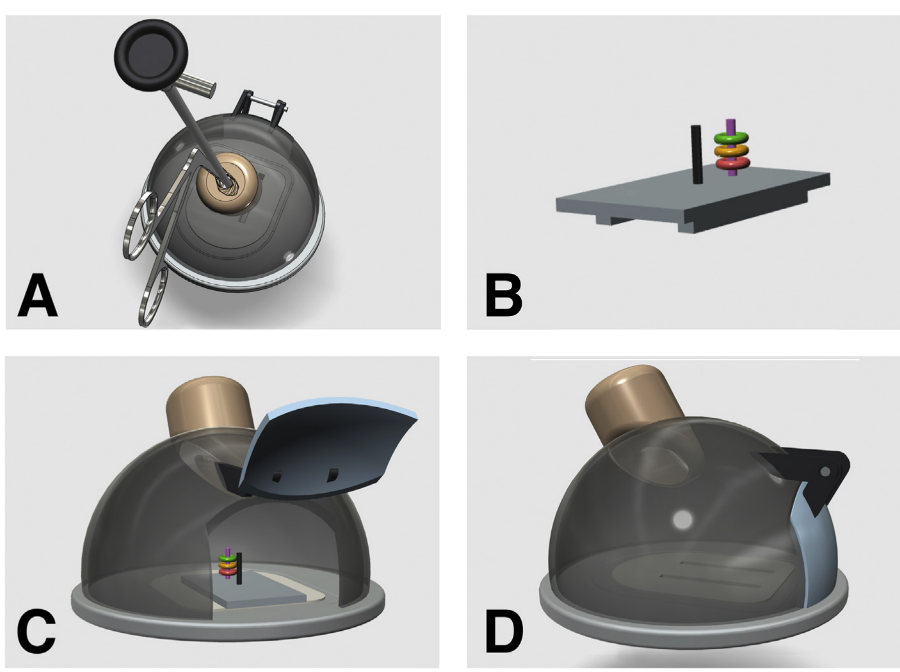

Fig. 2. CAD representation of TEES simulator. (A) The left-sided EAC was angled to facilitate accurate positioning of endoscopic instruments. (B) Donuts and pegs were placed on a modular task platform that fit onto the floor of the middle ear. (C, D) Tasks could be accessed through the hinged door, enabling rapid exchange.

and non-dominant hands were calculated from three time trials on each side. Mean completion times between trainees with 0–3 years and 4–7 years for dominant hand, non-dominant hand, and combined data sets were compared using paired T-tests. Signed rank tests compared the final trial time of each participant with the first trial time. P-values < 0.05 were considered statistically significant. SAS software, version 9.4 (SAS Institute Inc., Cary, North Carolina) was used to perform all statistical analyses.

This study (Study # 909601-1) was deemed exempt from the Massachusetts Eye and Ear Infirmary Studies Committee.

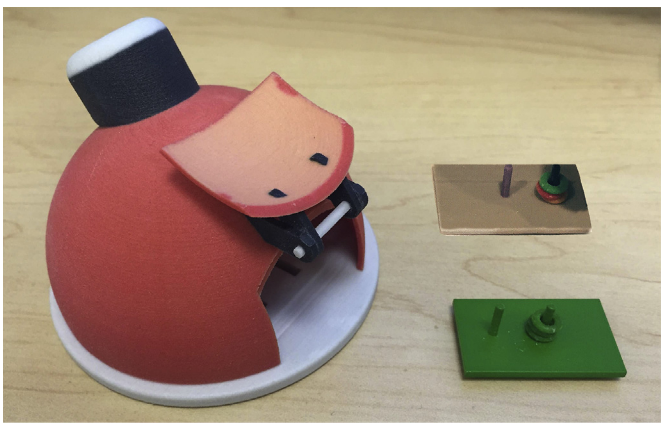

Fig. 3. The 3D printed TEES simulator was printed in full color zp® 151 high performance composite, while simulator tasks were printed in both full color zp® 151 high performance composite and green polylactic acid (PLA). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

3. Results

3.1. 3D-printed TEES simulator

Both the simulator housing and task were 3D printed to scale using a Zcorp 650 inkjet printer for full color through Sculpteo. This model accurately represented average dimensions and angles of EAC anatomy. The simulator was fully functional and allowed for the manipulation of donuts and pegs through the EAC. The hinged door of the dome allowed the modular task to be removed. A more robust model of the task was printed in using fused deposition modeling (FDM) on an Ultimaker 2+ (Ultimaker, Netherlands) with polylactic acid (PLA) filament with the same 1:1 scale (Fig. 3).

3.2. 3D-printed TEES simulator time trial

A timed experiment was devised that required the transfer of donuts and pegs using alligator forceps (Fig. 4). Six right-handed subjects with training ranging from second year resident to otology/neurotology fellow completed 6 timed trials (as described above) (Table 1, Fig. 5). Mean dominant hand trial completion time was shorter for the last trial compared to the first trial ($p = 0.0313$), and for senior residents compared to junior residents (0.0131) (Table 1).

In a post-study questionnaire, all 6 subjects strongly agreed that the simulator exercise provided experience that would be useful during a real TEES procedure.

4. Discussion

A 3D-printed TEES simulator was successfully designed and printed with functional parts that withstood the physical forces of

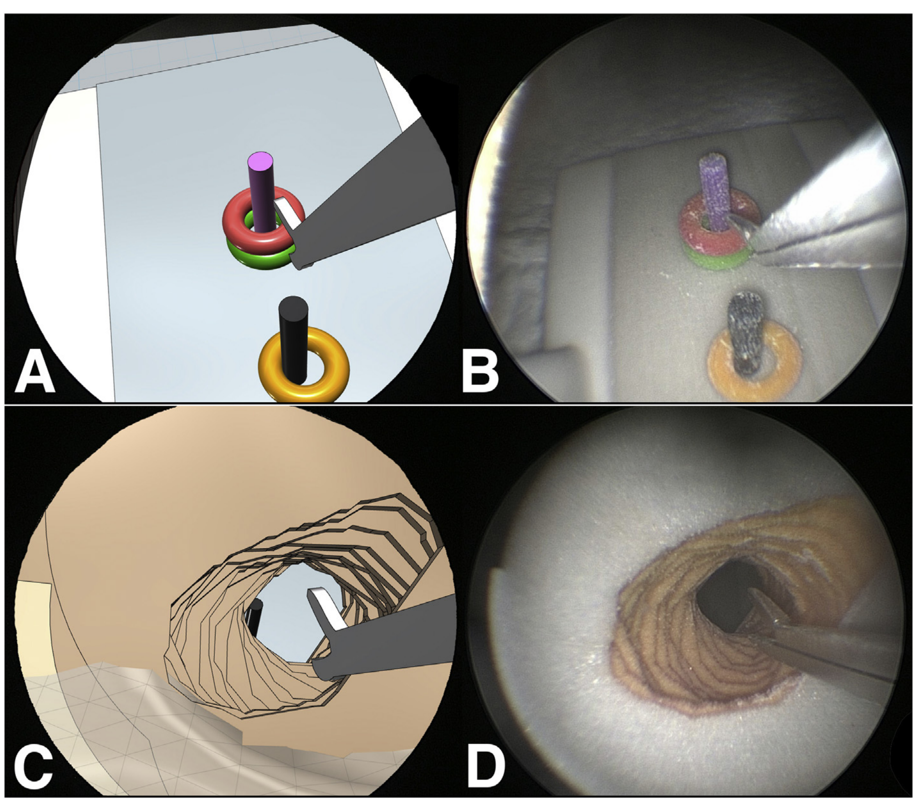

Fig. 4. CAD views of donut and peg task and EAC (A, C) are compared with zero degree endoscope views (B, D), respectively. Using perspective mode in CAD, an accurate rendering of prototypes can be appreciated visually prior to 3D printing.

Table 1
Demographics and surgical experience of trainees.

Subject	PGY year	Prior TEES cases	Dominant hand trial times (sec)				Non-dominant hand trial times (sec)			
			Trial 1	Trial 2	Trial 3	Mean	Trial 1	Trial 2	Trial 3	Mean
01	3	<10	73	39	45	52.33	56	52	68	58.67
02	6	10–50	28.9	17.7	22.5	23.03	50.4	26.1	91.2	55.90
03	5	10–50	37.71	21.51	20.32	26.51	22.34	56.11	49.85	42.77
04	4	<10	32.53	22.96	27.31	27.60	68.93	54.62	34.67	52.74
05	7	10–50	58.61	33.9	29.33	40.61	55.84	64.56	59.29	59.90
06	1	<10	112.17	35.06	41.08	62.77	57.81	50.52	69.29	59.21

Statistical test	Comparison groups	p-value
Signed rank test	Trial 3 vs. Trial 1 for non-dominant hand	$p = 0.3125$
Signed rank test	Trial 3 vs. Trial 1 for dominant hand	$p < 0.05$
T-test	PGY 1–3 vs. PGY 4–7 for overall mean completion time	$p < 0.05$
T-test	PGY 1–3 vs. PGY 4–7 for dominant hand mean completion time	$p < 0.05$
T-test	PGY 1–3 vs. PGY 4–7 for non-dominant hand mean completion time	$p = 0.3281$

Abbreviations: PGY – Post-Graduate Year; sec-seconds; TEES – Transcanal Endoscopic Ear Surgery.

endoscopic equipment. This primary finding provides a proof of concept regarding feasibility using 3D printed materials, and lays the foundation for future design iterations. A single report describing a simulator for middle ear surgery was found in the literature; however, it was not intended for endoscopic use, and had little relevant anatomic parallels to the human middle ear [22]. To date, this is the first simulator intended to develop skills specific to endoscopic ear surgery.

The cost of reusable synthetic materials is much less than cadaveric tissue. 3D printing using an outsourced, online commercial service costs fewer than 100 dollars for a reusable simulator. With in-house printing, the cost of filament material is under 10 dollars per simulator, and a few iterations may be printed per day for rapid prototyping. A recent paper describing pediatric laparoscopic surgery simulation used 3D printing combined with silicone molds for more accurate elastic structural properties [23]. Future iterations of the TEES simulator may incorporate other materials such as inexpensive silicone molds for elastic structures such as the auricle and cartilaginous portion of the EAC.

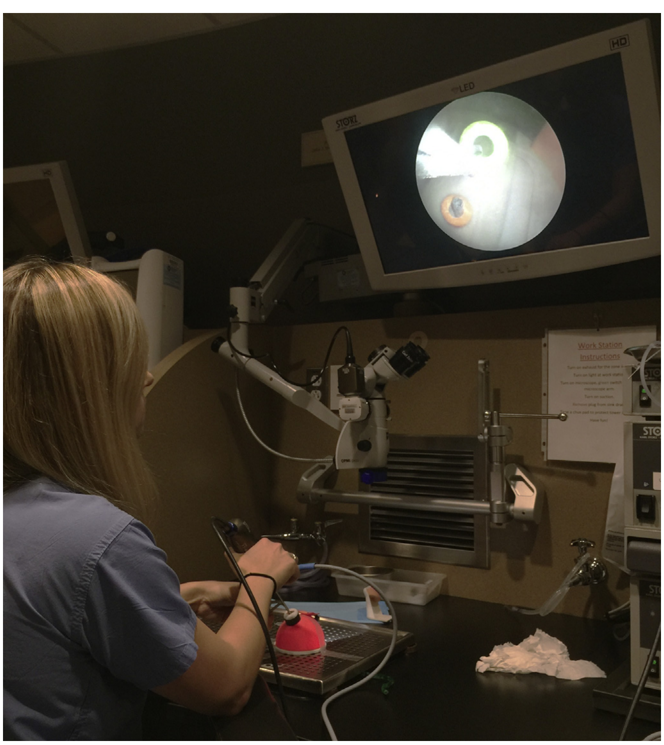

Fig. 5. An otolaryngology resident performs the simulator task with endoscopic assistance. The 3D printed simulator was brought into the surgical training laboratory at our institution, in which participants used endoscopes and microsurgical instruments to complete simulator tasks.

Base material selection is critical for other facets of simulator design beyond cost. The choice of a 3D printed material readily creates anatomically correct structures; particularly with complex geometries. With a 3D printed simulator modeled off of a human EAC, trainees immediately encounter the nuances of horizontal and vertical bends in an anatomically accurate EAC, which would not be achieved as easily via other tubular designs. The simulator designed and implanted in this manuscript is a single unit, ready to use right off the printer bed.

Our pilot study demonstrated construct validity given statistically significant differences between varying levels of experience and rehearsal with the simulator task. Differences in completion times for trainees with four or more years of experience suggests that skill sets required for the simulator may overlap with skills developed in the operating room. It is noted that simulator task completion time decreased precipitously from the first to the third time trial. The simplicity of the first task module with only one repetitive motion may explain the rapid improvement in trainees, in that proficiency is easier to achieve compared to multi-step, TEES procedures. However, preliminary skills developed from simulator experience may prepare trainees for actual surgeries. This notion is supported by the post-simulator subjective questionnaire administered, in which trainees of all ability levels unanimously agreed that skills tested in the simulator are beneficial for endoscopic procedures in the operating room.

Many skills tested in other surgical simulators focus on developing techniques relevant to specific procedures. In general surgery, there is a long history of development and testing surgical skills through basic types of manual dexterity exercises. A review of virtual reality simulators for laparoscopy revealed a wealth of simulators that incorporate haptic feedback on structured, competency-based curricula [24]. Specific skill sets have been developed for each simulator; for example, “basic skills” of navigating cameras and “part-task skills” of dissecting in the LapSim trainer [25].

For the otologic surgeon, our simulator allows for the development of one-handed tasks within the confines of the external auditory canal. The slow learning curve of one-handed navigation alone is enough to recommend simulation as a prerequisite for operating via an endoscopic approach. This fulfills testing of basic tasks. Donuts and pegs test the part-task skill of object manipulation using the alligator forceps with one hand. Anatomic accuracy is less important for this approach, as the goal here is to simply provide trainees with muscle memory for TEES maneuvers. Future iterations of the TEES simulator will implement more anatomically accurate structures within the tympanic cavity if the task calls for them. For example, the ossicular chain and oval window may be designed for an OCR or stapes surgery module. In this latter example, the design is still reduced to its minimal parts, with form following function for part-task skills.

There are a few limitations to this study. First, due to the firmness of materials used, the EAC was reportedly "stenotic". The cartilaginous portion of the EAC had no ability for displacement, and manipulation of endoscopic tools proved to be difficult at times. An expanded EAC or flexible 3D-printing material for this portion would improve simulator design. Secondly, the lack of an external ear with anatomic features such as the tragus took away from both construct and face validity. There was no ability to rest endoscopic equipment on a cartilaginous landmark, and trainees may not have utilized surgical tools in the same way as compared to real endoscopic procedures. Additionally, this beginner TEES simulator is not indicative of a trainee's endoscopic ear surgery proficiency. The transfer of small objects with alligator forceps is but one of many skills needed in TEES, and the slow learning curve comprises the amalgamation of many part-task skills.

In summary, users of a 3D-printed TEES simulator gain experience manipulating instruments in a manner similar to that of the operating room. A reusable model allows trainees to rehearse specific surgical maneuvers prior to a surgical procedure in the operating room. This educational experience is universal to all institutions planning to implement these novel transcanal procedures. Each successive generation of 3D-printed surgical simulators moves us closer to a truly realistic model.

5. Conclusion

A 3D-printed Transcanal Endoscopic Ear Surgery Simulator is feasible for surgical simulation. Residency programs with 3D printer access may readily fabricate a simulator, resulting in an inexpensive but high-fidelity training module.

Conflict of interest

None.

Disclosures

None.

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