

Piloting 3D technologies as a surgical simulation suite for patient-specific cochlear implantation surgeries in pediatrics

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Abstract

Background: Cochlear implants (CIs) help restore hearing in patients with severe to profound hearing loss. High-fidelity simulation tools may enhance surgical preparedness, patient safety, and training opportunities. This study validates the use of patient-specific 3D models in a virtual reality (VR) simulation environment (CardinalSim) and 3D printed as preoperative rehearsal tools for pediatric CI surgery.

Methods: A cross-over study was conducted with five pediatric CI cases referred to a pediatric cochlear implant centre. Participants included attending surgeons and trainees. CT-derived models were imported to VR simulations and used to make 3D printed replicas of each patient's temporal bone. Participants completed simulations using VR, followed by the corresponding printed model, with surveys collected after each. Trainee performance was assessed using standardized competency rating scales, and simulation metrics were recorded. After surgery, participants completed a clinical impact questionnaire. Preoperative metrics were compared to intraoperative performance. Primary outcomes were the face and content validity of both modalities.

Results: VR and 3D printed models demonstrated strong face and content validity. VR facilitated anatomical orientation and time efficiency, while 3D models offered superior tactile realism. Simulation times increased progressively from VR to printed models to surgery, reflecting growing task complexity. Participants reported improved confidence and surgical preparedness following simulation.

Conclusion: Patient-specific VR and 3D printed simulations offer complementary benefits for preoperative planning and surgical training in pediatric CI cases. These tools represent promising, scalable solutions for enhancing safety and performance in complex pediatric otologic surgery.

Trial Registration: Clinical trial number - not applicable.

Introduction

Hearing loss negatively impacts speech and language development in pediatric patients if not managed early in development (1,2). Cochlear implants (CI) can restore hearing in pediatric patients with severe-profound hearing loss when they are unresponsive to traditional hearing aids. These surgically implanted devices electrically stimulate the cochlear nerve, improving hearing in patients with both unilateral and bilateral deafness (3,4).

To assess whether a cochlear implant is feasible for a patient, and to plan the surgical procedure, medical professionals use magnetic resonance imaging (MRI) and computed tomography (CT)(5). Despite extensive planning, this surgical procedure is considered high risk (6,7). The rate of complications from CI surgery is between 3.7% to 24.6%, with minor complications occurring most frequently (8). Even with extensive education, many surgical trainees feel that their training did not adequately prepare them with the hands-on skills required to complete some surgeries (9,10). As such, many new surgeons opt for fellowships to supplement their residency training (11,12). In order to maximize surgical performance and reduce risks to patients, additional training adjuncts are imperative.

Surgical trainees learn anatomy through cadaveric dissection and surgical techniques through observing surgeries and performing components of surgical procedures under supervision (12). While cadaver use is seen as the gold standard in anatomical education (13), cadaver usage has decreased in medical education (14) due to financial, ethical and supply limitations (15–18). These factors are compounded by it being more challenging to procure pediatric cadavers. While some educational programs utilize smaller adult bodies to simulate pediatric anatomy, this does not provide an accurate educational opportunity (18,19). Surgical trainees also learn by observing experienced surgeons, but their ability to perform components of surgical procedures is limited by the high stakes nature of surgery (20). These factors highlight the need for novel opportunities for medical curriculums to standardize medical education and allow surgical trainees to hone their CI surgical skills and anatomical knowledge in a low-risk environment. Moreover, there is growing appetite across Canadian residency training programs for alternative training adjuncts, including virtual reality–based approaches, to support this need (21).

Over the last five years, surgical simulation has become increasingly popular, particularly in Otolaryngology – Head & Neck Surgery (OHNS) training. Utilizing patient CT scans, condition-specific, and patient-specific anatomical models can be developed and deployed as virtual surgical simulations in virtual reality (VR) or as surgical simulations with physical models (22–27). Alternatively, anatomical models based on CT datasets of cadaveric specimens have been used to develop VR simulators to facilitate a better understanding of temporal bone anatomy (26,27), simulate cochlear implant surgery with (28) or without (29) electrode insertion. This allows medical education to be standardized, and by creating unique simulations allows surgical trainees to prepare for individual anatomical variability. Amongst VR simulators, CardinalSim was recognized as a potentially useful tool for developing surgical plans and reducing complications during cochlear implantation surgery although the impact of use on surgical skills was not assessed (27). CardinalSim is a high fidelity virtual simulation that was developed to accurately simulate OHNS surgeries enabling surgeons to practice surgical skills on patient specific virtual temporal bones while receiving haptic feedback (30–32). While this tool has been established as a surgical training tool (31), its use as a tool to prepare surgeons for pediatric cochlear implantation has not been concretely established as it has only been used retrospectively with a small pediatric sample (30). Studies with 3D printed anatomical models have also been useful tools in OHNS surgical training. Specifically, studies have found that using 3D printed models prior to surgery can improve bone drilling performance (22) reduce operating time and costs (23), improve surgical planning (23), reduce complications (23) and accurately replicate anatomy for educational purposes (24,25). While studies utilizing printed 3D printed anatomical models do exist, the anatomical accuracy and the fidelity of the models is low.

In this study, we sought to explore how the consecutive use of both virtual anatomical models in CardinalSim and physical high-fidelity pediatric patient-specific 3D printed models for cochlear implant drilling simulations impacted the surgical skills of surgical trainees.

Study Objectives:

Our observational study aimed to validate the use of patient-specific anatomical models in preparation for pediatric cochlear implant surgery. Specifically, we aimed to validate the use of both CardinalSim and 3D printed models as tools to be used in surgical simulation. The hypothesis was that CardinalSim and 3D printed bone models meet acceptable standards for face and content validity required for preoperative simulation of cochlear implantation surgeries. Our secondary hypothesis was that both methods enhance the surgeons' experience during the preoperative planning and improve inter-team communication. However, we anticipated finding differences between surgeons' preferences of the two modalities.

Methods

Trial Design

This was a prospective observational trial of multiple educational interventions (physical and virtual patient-specific simulations) for surgical trainees.

Selected Patients & Study Participants

Patient cases selected for the simulation were recruited from a tertiary care pediatric hospital cochlear implant team located in Vancouver, Canada between August 2022, and October 2022. A verbal consent script was used to obtain permission from patients, or their delegate, to use their medical images for surgical simulation in advance of their surgery, inclusion in the research study, and publication of results. Only patients who were enrolled in the study, and who underwent surgery during the study period were included in the study. Abnormal, urgent, and deferred surgical cases were excluded from the study. Figure 1 illustrates the patient recruitment process for the study.

Figure 1 - Patient enrollment. Three patients were enrolled in the study which resulted in 5 surgical simulations (2 bilateral cases, 1 unilateral case).

Participants in the study included two staff otolaryngologists, one surgical fellow and one surgical resident at a pediatric cochlear implant centre.

Anatomical Modelling & Simulation Setup

CT datasets from referred and consented patients were used to generate patient-specific anatomical models. For each case, 3D reconstructions were created using a combination of manual and automated segmentation techniques, following our standardized anatomical modeling workflow (33). Key anatomical structures—namely the temporal bone, cochlea and semicircular canals, ossicles, oval and round windows, tympanic membrane, facial nerve, sigmoid sinus, and tegmen—were identified and segmented. Figure 2 a-c provides a graphical representation for the anatomical modelling process.

When structures were not clearly visible in the CT scans, regions of interest were manually delineated using established anatomical landmarks. Once segmentation was complete, the attending otolaryngologist for the case was consulted to validate the anatomical accuracy and ensure correct interpretation of the medical images. Once validated, the 3D reconstruction was exported as both .nrrd and .3mf for use in CardinalSim and 3D printing, respectively.

Figure 2 - A graphical presentation of the technical anatomical processing and study flow. The process starts by (a) importing the computer-tomography (CT) dataset; (b) Images will then be analyzed through a combination of manual and automated algorithms, called Segmentation; (c) the virtual model provides a visual representation of significant anatomical structures; (d) the virtual model is imported into the CardinalSim environment for group simulation; (e) the 3D printed model is taken into the simulation room for group simulation.

CardinalSim Developed through a multi-institutional effort, CardinalSim is a virtual surgical rehearsal platform that allows users to practice their surgical approach on a patient-specific level (31,34). Using the TouchTM haptic device (3D Systems, Rock Hill, South Carolina, United States) to simulate a surgical drill, participants were instructed to perform a cochlear implantation surgery, as seen in Figure 2d. CardinalSim was run on consumer-grade computer hardware, with Microsoft Windows 10 Pro operating system (Microsoft, Redmond, WA). In this study, an nVIDIA (Santa Clara, CA) GeForce RTX 2080 Ti coupled with an Intel (Santa Clara, CA) 11th Gen Core i9, and 64GB of DDR4 RAM was used. Participants viewed the surgical scene on a passive LG (Seoul, South Korea) 3D monitor with virtual reality glasses. CardinalSim offered the ability to translate, rotate and zoom in/out of the virtual temporal bone model. Conventional 2D views and an endoscopic view were also supported in the simulation environment. Participants had access to nine burr sizes using either a diamond burr or a cutting burr. Prior to the session, participants underwent a five-minute introduction to the simulator, and study staff trained in using CardinalSim were present during the session to alleviate technological issues.

3D Printed Anatomical Models A physical replica of the patient-specific anatomy was created using a 3D printer (J720, Stratasys, Ltd, Minnesota, USA). The mechanical properties and the appearance of the anatomical structures of the temporal bone were replicated utilizing a combination of proprietary print materials; this included a combination of Agilus and Vero materials (white, yellow, magenta, cyan, black). Cavities were filled with SUP706 material. Table 1 provides a detailed description of the print settings on GrabCad Print (GrabCad, Massachusetts, USA). While the color information for the soft tissues were manipulated to ensure visual contrast with the surrounding background, color information for the bony anatomy (ossicles and temporal bone) was directly imported from the segmentation software Mimics (Materialise, Leuven, Belgium). Each 3D-printed bone was placed inside the a temporal bone holder with adjustable screw-in clamps to ensure accurate positioning, that resembles the position of the patient on a surgical bed. Participants had access to cutting burrs size 2-5mm or diamond burrs size 1.5-4mm with irrigation, Medtronic[®] otologic drill. Otologic suction (3,5,7 Fr, 18 and 20 gauge) were used to clear drilling dust. Zeiss[®] Surgical Microscope equipped with a side-mounted teaching monitor, allowing for real-time observation and supervision by attending surgeon was available.

Table 1 - Print settings for 3D printing of temporal bone on a J720 printer.

Anatomical Structure	Color				Shore- A Level	Strength	Base & Core Options
	R	G	B	A			
Sigmoid	0	0	255	0.09	40	Lite	Body appearance
Tegmen	255	255	0	0.09	40	Lite	Body appearance
Tympanic Membrane	255	255	0	0.09	40	Lite	Body appearance
Round Window	0	255	0	0.09	40	Lite	Body appearance
Oval Window	0	255	0	0.09	40	Lite	Body appearance
Facial Nerve	0	255	0	0.09	40	Lite	Body appearance
Temporal Bone						Lite	Body appearance
Ossicular Chain						Lite	Body appearance

Surgical Simulations

All study participants attended the simulation training within 1 week of the patient's upcoming scheduled cochlear implant surgery. Surgical simulation training sessions were 2 hours and consisted of conducting cochlear implant surgery to the point of a cochleostomy with the haptics-enabled virtual reality simulation (CardinalSim) followed by a simulation on the 3D printed model, as seen in Figure 3. Each drilling session consisted of 3 stages: (i) the resident performing the mastoidectomy up to incus identification, (ii) the fellow drilling the facial recess, and (iii) the staff otolaryngologist performing the cochleostomy. In some cases where a step was not completed sufficiently, correction was made by the next participant (eg. If the mastoidectomy performed by the resident was not satisfactory, the fellow would update the mastoidectomy before moving on to the facial recess). To replicate pragmatic surgical scenarios, the staff otolaryngologists were able to provide feedback throughout to the resident and fellow. After completing each step of the simulation, participants filled out a survey on their experience. Data for the surgical simulations was collected at the pediatric cochlear implant centre.

Transfer of Skills to Patient Surgery

After the simulation training experience, participants performed the cochlear implant surgery within 1 week. The staff otolaryngologists decided whether the resident and fellow were adept to complete each phase previously assigned in the simulation (ie. Resident = mastoidectomy; fellow = facial recess; staff = cochleostomy). To replicate pragmatic surgical scenarios, participants were able to provide feedback and guidance to each other throughout the procedure. Discussions that took place during the surgery including feedback and guidance were recorded for further analysis. After completing the surgical procedure, participants filled out a survey on their experience.

Outcomes

Five cases from three patients (one unilateral, two bilateral) were included in this study. All outcomes were assessed for each of the cases. For each case a resident, a fellow, and a staff surgeon participated in the simulation.

Primary Outcome

Face and Content Validity - Participants were asked to complete a face and content validity questionnaire on the CardinalSim and 3D printed models using Research Electronic Data Capture (REDCap). The questionnaire was adapted from the surgical simulation literature and is provided in the supplementary materials (28,32,33). Items were rated using a 5-point Likert scale, with 1 representing "strongly disagree" and 5 representing "strongly agree". Questions were organized according to domain with 5 domains for face validity (the appearance of anatomy, haptic feedback, ergonomics, depth perception, and overall quality) and 6 domains for content validity (anatomy, surgical planning, drilling technique, instrument navigation and movement, hand/eye coordination, and overall learning utility).

Secondary Outcomes

Surgical Competency of Trainees - The surgical competency of trainees was assessed using the traditional competency rating scale used by the Royal College of Physicians and Surgeons. Staff were asked to rate the fellows and residents using a REDcap questionnaire at 3 timepoints: after simulation with CardinalSim, after simulation with 3D printed models, and after the actual operation. Competency involved a 5-item Likert scale with items from 1 representing "I had to do" to 5 representing "I did not need to be there". The survey is provided in the supplementary materials. Videos were recorded with participant consent during the simulation. The operating room was not video recorded. All feedback that was provided to the resident and fellow during the procedures was recorded. The type and count of the feedback is presented.

Procedural Metrics - Procedural metrics included the simulation start time, end time, active time, and feedback provided during the procedure. Start time was defined as the time of the first contact for drilling. End time was defined as the moment the participant indicated that the procedure was complete. Active time included the total time for active drilling, not including time spent discussing the case or changing instruments.

Perceived Clinical Impact - Participants were asked to complete a questionnaire on perceived clinical impact using REDcap. The questionnaire was adapted from the 3D modeling literature (33), considering the simulation environment (3D printed and CardinalSim) as a training event using Kirkpatrick's Four

Levels of Training Evaluation (37). The questionnaire is provided in the supplementary materials. Items were rated using Likert scales across domains of reaction, learning, behavior, and results. The resident and fellow were asked 12 questions in total, and the staff were asked 24 questions in total.

Sample Size and Analysis Methods

Cases for this study were enrolled from a convenient sample of eligible patients and surgical teams. The results of the qualitative open-ended responses were coded using a rapid analysis framework (38). This framework involved summarizing the comments in a table and then consolidating summaries on broad themes or categories with supportive quotes to indicate key findings. Results are reported using the Consolidated Standard Reporting Trials (CONSORT) guidelines.

Results

Three patients participated in this study, with two undergoing bilateral surgery. Their demographics are reported in Table 2.

Table 2 - Case Demographics

Case Number	Patient Number	Age (Year)	Surgical Side	Etiology of Sensorineural hearing loss	Pertinent medical history that may impact cochlear implant surgery
1	1	9	Left	Unknown	Previous surgery for drum perforation and resulting middle ear cholesteatoma, no recurrence during CI surgery
2	2	1	Left	Hypoplastic cochlear nerve	
3	2	1	Right	Hypoplastic cochlear nerve	
4	3	1	Left	GJB2* (35delG)	
5	3	1	Right	GJB2* (35delG)	

* GJB-2 Gap junction beta 2, homozygous for c.35delG variant.

The participants in this study included two staff otolaryngologists, one fellow, and one resident surgeon (N = 4). The demographics of the study participants are reported in Table 3.

Table 3 - Participant Demographics

Participant Characteristics	Total population (n/4, %)
Seniority Level	
Resident (PGY 2)	1 (25)
Fellow	1 (25)
Staff	2 (50)
Sex	
Male	4 (100)
Dominant Hand	
Right-handed	4 (100)

Face and Content Validity Survey

Shown in Table 4, the content of the simulator was suitable to practice cochlear implantation surgeries for both the CardinalSim and 3D printed models. Participants stated:

"[the models provided a] better understanding of the abnormal anatomy, [and it was] easier to understand the CT imaging after working on the models". -Fellow

"[the models are] very helpful as a teaching tool, particularly for the junior resident who had basically no experience drilling a temporal bone". -Staff

Of note, CardinalSim trended toward higher scores on domains of usefulness for learning patient anatomy (CardinalSim, median = 2 strongly agree IQR 1; 3DP, median = 1 agree IQR 1) and surgical simulation (CardinalSim, median = 2 strongly agree IQR 1; 3DP, median = 1 agree IQR 2) . A fellow stated:

"overall, in terms of bone drilling and exposing the incus, the model was very helpful in predicting how much to drill and to have a clear picture of the anatomical structures that are needed to expose the incus". - Fellow

On the other hand, 3D printed models trended toward higher scores on domains of haptic feedback (CardinalSim, median = 0 neutral IQR 2; 3DP, median = 2 strongly agree IQR 1), realistic depth perception (CardinalSim, median = 1 agree IQR 3; 3DP, median = 2 strongly agree IQR 1), and effectiveness for practicing instrument navigation and movement (CardinalSim, median = 1 agree IQR 1; 3DP, median = 2 strongly agree IQR 0), practicing hand-eye coordination (CardinalSim, median = 1 agree IQR 1; 3DP, median = 2 strongly agree IQR 0), and as an overall effective teaching tool (CardinalSim, median = 1 agree IQR 1; 3DP, median = 2 strongly agree IQR 1). Participants stated:

“the tactile feedback of the 3D printed model was much closer to the real bone[and] in terms of size it was much more real.” -Fellow

“[we] preferred 3D printed, as CardinalSim doesn’t provide the tactile or depth perception that you get from the 3D printed model.” -Staff

Table 4 - Responses to face and content validity surveys for CardinalSim and 3D printed models (-2 = strongly disagree, -1 = disagree, 0 = neutral, 1 = agree, and 2 = strongly agree)

Item	Median (IQR)	
	CardinalSim	3D Printed
The appearance of the temporal bone anatomy is realistic	1 (1)	1 (1)
Drilling provides realistic haptic feedback.	0 (2)	2 (1)
The simulation suite is ergonomic.	1 (1)	1 (1)
The simulation suite provides realistic depth perception.	1 (3)	2 (1)
The overall quality of the simulation suite is excellent.	1 (0)	1 (1)
The simulation suite is useful for learning patient anatomy.	2 (1)	1 (1)
The simulation suite is useful for surgical planning.	2 (1)	1 (2)
The simulation suite is an effective tool for practicing drilling technique.	2 (1)	2 (1)
The simulation suite is an effective tool for practicing instrument navigation and movement.	1 (1)	2 (0)
The simulation suite is an effective tool for practicing hand-eye coordination.	1 (1)	2 (0)
The simulation suite is an overall effective teaching tool.	1 (1)	2 (1)

Surgical Competency

As shown in Table 5, the resident competency scores did not improve over time, with the staff rating their performance as 1 “I had to do” across the three timepoints. The fellow competency scores followed a similar pattern.

Table 5 - Surgical competency of the trainees (fellow and resident) across the three timepoints. Competency was scored on a 5 step likert scale: 1 = I had to do, 2 = I had to talk them through (ie, able to perform some tasks but requires repeated directions), 3 = I had to prompt them from time to time (ie, demonstrates some independence, but requires intermittent prompting), 4 = I needed to be there in the room just in case (ie, independent but needs assistance with nuances of certain situations), and 5 = I did not need to be there I needed to be there in the room just in case (ie, independent but needs assistance with nuances of certain situations).

	Median (IQR)		
	CardinalSim	3D Printed	Operating Room
Resident	1 (1)	1 (2)	1 (1)
Fellow	2 (2)	3 (1)	2 (2)

As shown in Table 6, the median amount of feedback by both the resident and the fellow received decreased when going from the CardinalSim simulation (Resident, median = 8 IQR 4; Fellow, median = 2 IQR 1) to the 3D printed simulation (Resident, median = 4 IQR 7; Fellow, median = 1, IQR 3), but greatly increased when going from the 3D printed simulation to the operating room (Resident, median = 14 IQR 4; Fellow, median = 11 IQR 1).

Table 6 - Median counts of feedback received by residents and fellows.

Item	Median (IQR)		
	CardinalSim	3D Printed	Operating Room
Resident	8 (4)	4 (7)	14 (4)
Fellow	2 (1)	1 (3)	11 (1)

Note: The resident was provided feedback by the fellow and staff. The fellow was provided feedback by the staff. The staff did not receive feedback.

We analyzed the feedback that the resident and fellow received across all three timepoints, and found trends in feedback related to drilling direction (Table 7). Other feedback was provided to residents and fellows on anatomical orientation, model orientation, drilling technique, drilling direction, patient orientation, and irrigation suggestion. Fellows received additional feedback about control of bleeding, and timing.

Table 7 - Counts and frequencies of feedback received by residents and fellows during each of the three timepoints. Feedback is separated into 8 overarching themes.

AO		MO		DT		DD		PO		IS		CB		T		
Resident																
	Count, n/15	Frq., %	Count, n/4	Frq., %	Count, n/26	Frq., %	Count, n/95	Frq., %	Count, n/6	Frq., %	Count, n/5	Frq., %	Count, n/0	Frq., %	Count, n/0	Frq., %
CS	7	47%	3	75%	3	12%	26	27%	-	-	-	-	-	-	-	-
3DP	1	7%	1	25%	8	31%	21	22%	3	50%	3	60%	-	-	-	-
OR	7	47%	-	-	15	58%	48	51%	3	50%	2	40%	-	-	-	-
Fellow																
	Count, n/4	Frq., %	Count, n/3	Frq., %	Count, n/5	Frq., %	Count, n/44	Frq., %	Count, n/0	Frq., %	Count, n/0	Frq., %	Count, n/1	Frq., %	Count, n/2	Frq., %
CS	-	-	1	33%	2	40%	8	18%	-	-	-	-	-	-	-	-
3DP	-	-	2	67%	2	40%	4	9%	-	-	-	-	-	-	-	-
OR	4	100%	-	-	1	20%	32	73%	-	-	-	-	1	100%	2	100%

*[-] indicates no recorded responses

**CS=CardinalSim, 3DP=3D printed, OR=operating room, AO=anatomical orientation (confirmation of the location of anatomical structures), MO=model orientation (adjustments to the position of the model for improved visibility), DT=drilling technique (adjustments to the drill bits, angles, or stroke technique while drilling), DD=drilling direction (suggestions for where to drill and in which direction), PO=patient orientation (adjustments to the position of the patient/model for increased visibility), IS=irrigation suggestion (suggestions for increasing or decreasing the irrigation level for improved visibility), CB=control of bleeding (suggestion for when to control bleeding), and T=timing (comments on the speed at which steps are being completed)

Procedural Metrics

The median times that the resident, fellow, and staff spent on each step of the cochlear implant during the CardinalSim simulation, 3D printed simulation, and in the operating room are shown in Table 8. The active times represent the amount of time spent actively drilling. The total time represents the amount of time spent completing the entire step, which includes procedures such as adjustments to the drill bit, irrigation, and discussion among the clinical team. The time that the fellow and staff spent making corrections to the resident's work on the mastoidectomy and the fellow's work on the facial recess, respectively, is also shown in Table 8. The participants spent the least amount of time on each step of the cochlear implant surgery during the CardinalSim simulations, followed by the 3D printed model. The most amount of time was spent in the operating room.

Table 8 - Total time spent (minutes) on the cochlear implant procedure across seniority and each of the three timepoints.

	CardinalSim	3D Printed	Operating Room
	Median(IQR)	Median(IQR)	Median(IQR)
RESIDENT			
Mastoidectomy	7.00 (IQR 8.00)	14.00 (IQR 12.00)	27.00 (IQR 13.50)
FELLOW			
Mastoidectomy correction	1.00 (IQR 1.50)	1.00 (IQR 5.50)	9.00 (IQR 6.50)
Facial recess	4.00 (IQR 2.50)	13.00 (IQR 10.50)	37.00 (IQR 21.00)
STAFF			
Facial recess correction	0.0 (IQR 1.00)	0.00 (IQR 4.00)	0.00 (IQR 5.00)
Cochleostomy	2.00 (IQR 2.00)	3.00 (IQR 1.50)	8.00 (IQR 6.50)

*[-] indicates no recorded times

Perceived Clinical Impact

In this study, participants primarily shared the simulator with their colleagues (n=15 (5 cases, 3 timepoints), 100%), and used the models for pre-surgical planning (n=15, 100%). Overall, we found staff and trainees reacted positively to the simulator (both CardinalSim and 3D printed), acquiring knowledge and skills from the simulator, and reporting that they applied the learnings to the surgeries (Table 9). Participants also reported direct results from the simulation with respect to building consensus amongst the clinical care team, the trainees understanding of the proposed surgery and potential complications, and the staff’s ability to anticipate procedural complications (Table 9).

“[the models] stimulated dialogue amongst the team. You go over the anatomy in greater detail than we normally would do with just the CT”. -Staff

“the chorda tympani nerve was not identified on either model, however, it was quite apparent and skeletonized in the patient and as a result great care was taken to preserve it which took more time [for us to do the procedure in the operating room]. I would have allowed the resident to drill either way, however, having watched him drill yesterday I had great confidence in his drilling today and was surprised about the time”. -Staff

In two of the cases (2/5, 40%), the models were perceived to accurately display the anatomy as portrayed by the preoperative medical images. In one case, the cortical mastoid was accurately depicted but when it came to the facial recess, the deepness of the round window niche was shown by CardinalSim and the CT image, but not within the 3D model. The facial nerve was also inaccurately depicted in the model compared to the intraoperative findings in this case. In the other case, the posterior canal didn’t represent the actual images, which was thought to be due to inflammation in the middle ear. Recommendations were made by the respondents to use more vibrant colors for the facial nerve for easier recognition during simulation.

Our qualitative responses indicated that the most significant changes resulting from the resident using the simulator to perform the mastoidectomy were improved confidence in drilling within the operating room (n = 3), improved understanding of anatomy (n=2), and improved understanding of drilling margins (n=2). The resident said:

“[the simulator] Increased [my] confidence in drilling.”

“[the simulator] greatly improved understanding of complex anatomy and boundaries of the surgery”

The most significant changes for the fellow who performed the facial recess were a better understanding of the radiological anatomy (n=2), improved understanding of the drilling margins and surgical approach (n=2), and improved confidence while drilling (n=1). The fellow said:

“Better understanding of the radiological anatomy”

“Boosting [my] confidence to drill significant amounts of bone to expose the incus without being concerned.”

“Understanding the amount of drilling needed and the size of [the] mastoidectomy needed.”

For staff, the most significant changes were improved confidence in trainees (n=3), improved ability to predict and plan for challenges in the operating room (n=3), and improved understanding of abnormal anatomy (n=1). The staff said:

“It built the resident’s confidence. It relaxed myself by watching the resident drill on this side. And it is just cool to drill ahead of time.”

“More extensive discussions around how to approach challenging cases, in particular how to approach facial recess.”

“Knowing the anatomy before we got there beyond CT [imaging] (although the facial nerve was questionable).”

In the end, participants would recommend the simulator to their colleagues (13/15, 87%), but preferred the 3D printed models alone (12/15, 80%) for cochlear implant simulations, over CardinalSim alone (0/15%, 0%), or the combination of both models (3/15, 20%).

Table 9 - Responses to the clinical impact survey.

	Count, n/N	Frequency, %
Kirkpatrick Level 1: Reaction		
Overall, my preferred preparation method is:***		
3D printed model only	12/15	80%
CardinalSim + 3D Printed model combination	3/15	20%
Would you recommend the simulator to your colleagues?***		
Yes	13/15	87%
No	2/15	13%
Did this simulator meet your expectations?***		
Yes	6/15	40%
Somewhat	6/15	40%
No	3/15	20%
Did this model provide the value you anticipated?***		
Far exceeds	1/15	7%
Exceeds	5/15	33%
Meets	2/15	13%
Meets some	7/15	47%
Does this simulator accurately display the anatomy as portrayed by the preoperative medical images?*		
Yes	3/5	60%
No	2/5	40%
Did you notice any difference(s) between this simulator and intraoperative findings?*		
Yes	4/5	80%
No	1/5	20%
Kirkpatrick Level 2: Learning		
Do you think your own understanding of the patient's condition and the anatomical structure was enhanced by this simulator?***		
Yes	13/15	87%
No	2/15	13%
From your perspective, how do you think this simulator impacted your ability to anticipate procedural difficulties?***		
Significantly increased	1/15	7%
Somewhat increased	12/15	80%
No effect	2/15	13%
From your perspective, how do you think this simulator impacted your confidence with the overall diagnosis and clinical care plan?***		
Somewhat increased	4/15	27%
No effect	11/15	73%
From your perspective, how do you think this simulator impacted your ability to explore different treatments that would not have otherwise been pursued?*		
No effect	5/5	100%
Kirkpatrick Level 3: Behaviour		
What type of model did you use?***		
3D printed	15/15	100%
CardinalSim	15/15	100%
Was this simulator shared with patients and families?		

No	5/5	100%
Was this simulator shared with the clinical care team?		
Yes	5/5	100%
Please indicate who you shared the simulator with on the clinical care team.***		
Surgeon(s)	5/5	100%
Was this simulator shared with trainees?		
Yes	5/5	100%
Was this simulator shared with others?		
No	5/5	100%
Did you use this simulator as part of preoperative planning?***		
Yes	13/15	87%
No	2/15	13%
Please indicate how you used the simulator for planning:***		
For surgical or interventional simulation	11/15	73%
As a visual aid for intraoperative orientation	4/15	27%
For assessing the likelihood of success or failure of the surgical strategy	2/15	13%
Other	3/15	20%
Kirkpatrick Level 4: Results		
From your perspective, how do you think this 3D model impacted the following communication metrics: Consensus amongst clinical care team about the proposed treatment plan*		
Significantly increased	1/5	20%
Somewhat increased	2/5	40%
No effect	2/5	40%
From your perspective, how do you think this 3D model impacted the following communication metrics: Length of time to define the individual's surgical or interventional plan*		
Somewhat increased	2/5	40%
No effect	3/5	60%
From your perspective, how do you think this 3D model impacted the following communication metrics: Trainee's understanding of the proposed surgery and potential complications*		
Significantly increased	2/5	40%
Somewhat increased	3/5	60%
From your perspective, how do you think this simulator impacted procedural/intraoperative time?*		
No effect	4/5	80%
Somewhat increased	1/5	20%
From your perspective, how do you think this simulator impacted fluoroscopy/radiation exposure?*		
No effect	5/5	100%
From your perspective, how do you think this simulator impacted blood loss?*		
No effect	5/5	100%
From your perspective, how do you think this simulator impacted anesthetic and other medication usage?*		
No effect	5/5	100%
From your perspective, how do you think this simulator impacted anticipating potential complications?*		
Significantly increased	2/5	40%
No effect	1/5	20%
Somewhat decreased	2/5	40%

From your perspective, how do you think this simulator impacted human resources used (ie, operative assistance and other support staff)?*		
No effect	5/5	100%
From your perspective, how do you think this simulator impacted time spent on preoperative planning?***		
Significantly increased	9/15	60%
Somewhat increased	4/15	27%
No effect	1/15	7%
Somewhat decreased	1/15	7%

[-] indicates no recorded responses

*indicates questions that were only asked to the staff

***indicates questions that were asked to the resident, fellow, and staff

Discussion

We validated the use of a pediatric patient-specific surgical simulator including both CardinalSim and 3D printed temporal bone models in a rehearsal environment. To our knowledge, no research has yet studied the combined benefits of virtual reality and 3D printed models for surgical simulation of cochlear implant surgery in a pediatric setting.

Face and Content Validity

Overall, face and content validity for the simulator were achieved over the tested domains, however, some minor differences existed between the two types of models. The haptic feedback, realistic depth perception, and effectiveness for practicing instrument navigation and movement, practicing hand-eye coordination, and overall effectiveness as a teaching tool were face and content validity domains that the 3D printed models scored higher than the CardinalSim models. Specifically, the tactile feedback and size of the 3D printed models were found to mimic the real bone more realistically than the CardinalSim models. Our simulator scored better than other authors who have found temporal bone simulators to provide unrealistic haptic feedback and have an uncomfortable design (35,36,39), however, the haptics of CardinalSim was the lowest rated item tested. Despite the differences between the models and the actual patient's anatomy, the trainees in our study reported acquiring skills and learnings from each of the simulations that transferred over to the surgery. We reiterate the conclusions of other authors (9), that while haptics technologies are improving, a perfect replica of the human temporal bone may not always be necessary for trainees to build strong otologic surgical skills. Our study shows that combinations of virtual reality technologies and 3D printed models complement each other, and future research should explore the parameters for optimal training to achieve specific learning outcomes in medical training.

Surgical Competency of Trainees

The surgical competency of the trainees did not improve from the initial use of CardinalSim to their final performance in the operating room, and in fact we saw increases in feedback provided in the operating room. In comparison to previous work (40), our study uniquely studied the performance of the trainees within patient specific simulated surgical environments, followed by performance with real patients in the operating room. There are multiple reasons why competency did not show improvement in the operating room. First, the simulator provided an opportunity for trainees to deliberately practice each patient's specific surgery, but complex interactions and contextual factors involved in the actual care of a live patient can often not be reproduced and measured within simulated settings (41). These elements would add to pressure in the operating room and lead to increased feedback provided to trainees. Second, at the time this study was designed, no comprehensive assessment tools existed for evaluating simulation performance in cochlear implant (CI) surgery. Therefore, we adopted the Entrustable Professional Activity (EPA) framework, which offers a global rating approach to assess competency. Competency related to specific steps (such as drilling of the posterior wall of the auditory canal, the widening of the posterity tympanotomy, and round window exposure) could have been missed, and future studies should consider the use of a more contemporary instruments, such as the newly developed CI Surgery Assessment Tool (30). Ultimately, the competency measures assessed may not be indicative of the model's value for educating and preparing trainees, especially in the context of our other results.

Procedural Metrics

Despite the lack of improvement to competency indicated, our results indicate that the simulator provided an opportunity for trainees to deliberately practice each patient's specific surgery, while protecting patients from potential harm. Our procedural metrics indicate that residents who were involved in the study were given opportunities to perform the mastoidectomy within the operating room accompanied by greater levels of entrustment and confidence from supervising faculty. Other research has shown that simulations can reduce the risk of errors in the OR (42), therefore one potential explanation is that

staff are witnessing less critical errors and gaining more confidence in the performance of trainees overtime. Future research should compare staff perception of trainees aptitude after using the simulation suite in comparison to standard training.

Perceived Clinical Impact

We found that the simulator was perceived to be an effective teaching tool, specifically in regard to learning patient anatomy and surgical planning. Overall, all participants reported the simulator to increase their understanding of the patient's condition and the anatomical structure. We found that because the CardinalSim component allowed participants to zoom in and out, it allowed for reversal of steps and greater control of visualization which served as an advantage for teaching residents about the patient anatomy. Yet when drilling, the 3D printed component was perceived to be most useful due the better haptics and ability to use the actual surgical tools in the induction room to perform the simulation. Overall the 3D printed models were the preferred model for preparing for cochlear implant surgeries. Our findings contrast Awori et al. (2023) who found virtual reality models to be preferred over 3D printed models by pediatric residents and nurse practitioners understanding cardiac anatomy and pathophysiology (15,43). We conclude that CardinalSim may be best used as a tool for understanding of the patient's condition and the anatomical structure, whereas 3D printed models may be best used in surgical and interventional simulation where realism is a critical component of the practice dynamic. Future research should further study the longitudinal benefits of using virtual models in conjunction with 3D printed models across the learning paradigm for ear anatomy and cochlear implant surgical rehearsal.

Notably, in some cases, the 3D models decreased the staff's ability to anticipate procedural difficulties. This was because there were some differences between some of the simulators and what was eventually seen intraoperatively. The location of the facial nerve was not accurately replicated in the model leading to increased time within the operating room. Facial nerves are not visible on the CT scans, although their pathway can be and have to be manually segmented based on expert consultation. The limitation of the facial nerve modeling being based on subjective interpretation for cochlear implantation simulation is one major limitation of the simulator's reliance on CT scan imaging for abnormal anatomy, and further research is required to find alternative methods for more accurate placement.

Limitations

There are several limitations to this study. First there are limitations to the survey given to the staff to assess the surgical competency of the resident and fellow. Other investigators should consider this survey for future studies assessing competency as an outcome for cochlear implant simulators.

The surveys used in this study relied on participants self-reporting measures for the clinical impact of the CardinalSim and 3D printed surgical simulations. The nature of self-reported results may introduce bias and limit the reliability of the qualitative results reported in the study. The results may have instigated social desirability which consists of self-deception and impression management. In this case, participants may have intentionally or unintentionally reported incorrect responses, omitted responses, or altered the magnitude of responses to create a false front and present themselves in what they felt was a more favorable manner.

This study evaluated a small sample of surgeons including two staff otolaryngologists, one fellow and one resident. The small sample may bias results and may influence the generalizability of the results to the larger surgical community using CardinalSim and 3D printed models for surgical simulation. The sample size means we can only present trends, and we cannot test for statistically significant findings. As we tested both model types in succession and made comparisons between the models throughout, the reported results may have been influenced by the simulation sessions as well as prior experiences thus causing confounding effects that our study design did not control for. Results may be misrepresented due to these biases.

Conclusion

This study represents a step towards establishing the usage of both CardinalSim and 3D printed models for patient-specific preoperative planning and surgical education for cochlear implant surgeries with 3D printed models tending to be favored by medical teams when compared to the CardinalSim software. Skills obtained from utilizing both of these two simulations transferred over to the operating room for surgical trainees. Overall, the preliminary use of the combination of virtual and physical patient specific anatomical models for preoperative simulation of cochlear surgeries was promising, with positive results for face and content validity and the ability to apply the models to medical training. These technologies are promising as educational tools for surgical trainees of all levels preparing for cochlear implant surgeries.

Declarations

Ethics approval and consent to participate

Ethics approval for this study was obtained from UBC C&W Research Ethics Board (H21-03224). All study participants provided their consent using an electronic consenting form. A verbal consent script was used to obtain permission from patients, or their delegate, to use their medical images for surgical simulation in advance of their surgery, inclusion in the research study.

Consent for publication

A verbal consent script was used to obtain permission from patients, or their delegate, to use their medical images for publication of results.

Availability of data and materials

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Competing Interests

The authors declare that they have no competing interests.

Authors' contributions

Sima Zakani: Conceptualization; Methodology; Software; Validation; Formal analysis; Investigation; Data curation; Writing – original draft; Writing – review & editing; Visualization. Chelsea Stunden: Project administration; Formal analysis; Writing – original draft; Ethics submission preparation. Puneet Khosa: Investigation; Data curation; Formal analysis; Writing – original draft. Justin Lui: Methodology; Software; Writing – review & editing. Amjad Tobia: Methodology; Investigation; Writing – review & editing.

Kaishan Aravinthan: Investigation; Writing – review & editing. Mark Felton: Conceptualization; Methodology; Supervision; Funding acquisition; Resources; Investigation (patient recruitment); Writing – review & editing. Frederick K Kozak: Conceptualization; Methodology; Supervision; Funding acquisition; Resources; Investigation (patient recruitment); Writing – review & editing. John Jacob: Conceptualization; Methodology; Supervision; Funding acquisition; Formal analysis; Writing – review & editing.

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Figures

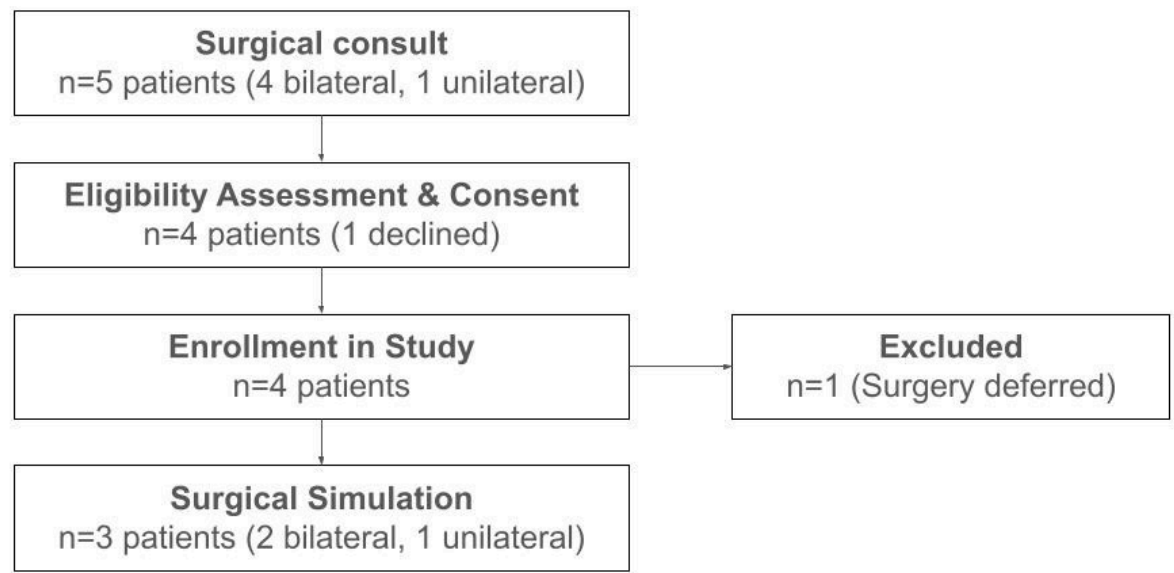


Figure 1

Patient enrollment. Three patients were enrolled in the study which resulted in 5 surgical simulations (2 bilateral cases, 1 unilateral case).

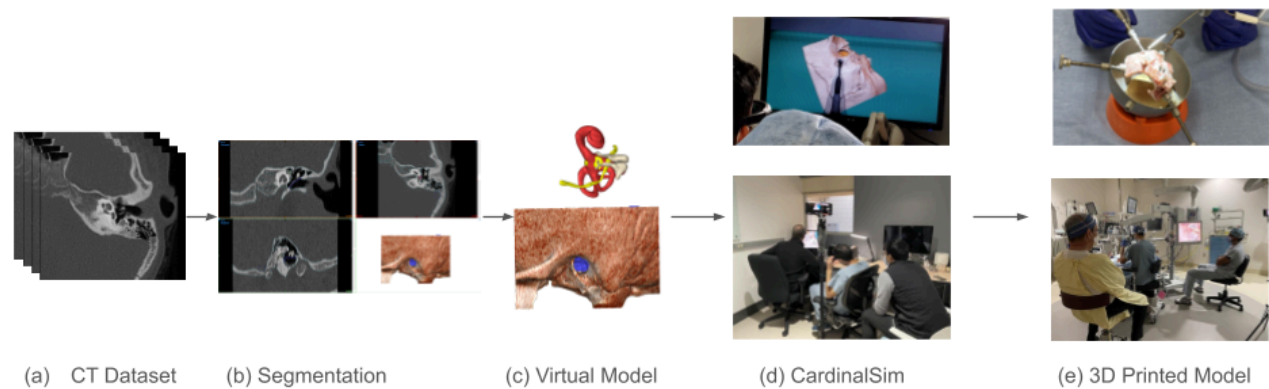
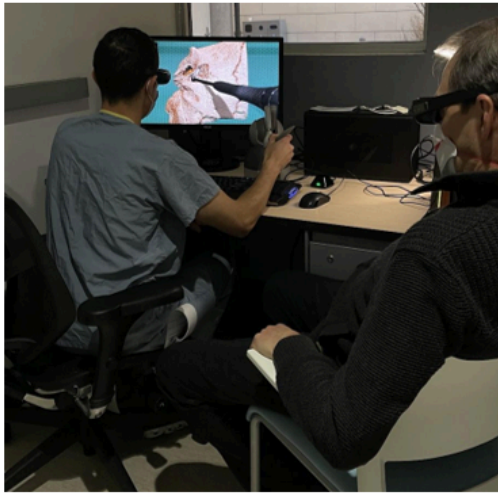


Figure 2

A graphical presentation of the technical anatomical processing and study flow. The process starts by (a) importing the computer-tomography (CT) dataset; (b) Images will then be analyzed through a combination of manual and automated algorithms, called Segmentation; (c) the virtual model provides a visual representation of significant anatomical structures; (d) the virtual model is imported into the CardinalSim environment for group simulation; (e) the 3D printed model is taken into the simulation room for group simulation.



(a)



(b)

Figure 3

Surgical simulation setup. Participants by conducting cochlear implant surgery with the haptics-enabled virtual reality simulation (a) followed by a simulation on the 3D printed model (b). In each session the staff otolaryngologist was present to observe competency and provide feedback.