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A Validated 3D Printed Laryngeal Suturing Simulator for Endoscopic Laryngeal Cleft Repair

Running title: Laryngeal Cleft Simulator

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Abstract

Objectives

Endoscopic laryngeal cleft repair (ELCR) with endolaryngeal suturing is an advanced surgical skill. This study objective was to assess the validity of 3-dimensionally (3D) printed laryngeal suturing simulator for ELCR.

Study Design

Development and validation of a simulator for ELCR.

Methods

A ELCR model was developed using 3D printed and readily available materials. Participants were surveyed before and after a simulation session using five-point Likert scale questions. Performance data was assessed using blinded expert video review and rated using a novel objective structured assessment of technical skills (OSATS) for endoscopic laryngeal suturing.

Results

Twenty-one participants ranging from residents to attendings completed the simulation session. Survey respondents reported on a five-point Likert scale that the model was "easy to use" and "quite realistic" (both mean of 4). Confidence improved significantly in 86% of participants ($p<0.01$). Overall OSATS scores (out of a total 55) showed a median improvement in technical skills of 11.7 points ($p=0.004$). OSATS demonstrated good intra-rater ($\kappa=0.689$ and 0.677) and moderate inter-rater ($\kappa=0.573$) reliability. Completion times improved from first to last suture by

a median time of 512 seconds to 350 seconds (decrease of 202 seconds, p=0.002). Participants with no prior ELCR experience improved more than those with in vivo experience.

Conclusion

This study demonstrates validity of a simulator utilizing 3D printed larynges for ELCR. A novel OSATS for endoscopic laryngeal suturing was successfully implemented. Confidence, technical skills, and completion times improved with use of the model across a variety of participants.

Lay Summary

A 3D printed model of a congenital airway anomaly was designed and successfully used by surgeons of all training levels. The simulator increased surgeon confidence, improved technical surgical skills, and reduced operation completion times.

Keywords: Laryngeal cleft, endoscopic suturing, 3D printing, simulation, education

Level of Evidence: N/A

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Introduction

Laryngeal clefts are congenital upper airway malformations that result in a deficiency of tissue between the laryngotracheal complex and esophagus. They are relatively rare, occurring in approximately 1 in 10,000 to 1 in 20,000 live births, but are being diagnosed with increasing frequency.[1,2] The most common grading system for laryngeal clefts is the Benjamin and Inglis classification, which ranks clefts from type one to type four depending on anatomic depth.[3] Type one and type two clefts, which extend either to the level of the vocal cords or partially into the cricoid, respectively, are the most prevalent.[4]

While some laryngeal clefts may be asymptomatic or can be managed conservatively, most undergo surgical intervention for definitive treatment of dysphagia and aspiration.[2,5] Historically, these were repaired with open surgery, however, the vast majority of laryngeal cleft repairs are now performed endoscopically.[2,4,5] Similar endoscopic procedures (e.g. interarytenoid suture augmentation) are also becoming more widely used for dysphagia treatment in patients with normal anatomy. Endoscopic endolaryngeal suturing, such as that used in endoscopic laryngeal cleft repair (ELCR), is an advanced and technically challenging surgical skill. It can be difficult to gain competency in ELCR within the course of a residency or fellowship program, placing otolaryngology trainees at risk of graduating with technical deficiencies.[6]

Surgical simulation is widely used in modern surgical education to augment technical training.[7] It allows for practice of procedural and situational skills in a low-stress environment that does not affect patient morbidity and mortality. Additionally, simulation removes the time constraints of live operating, and allows for repetition, reflection, and real time feedback. Within the field of otolaryngology, simulators including both physical models and virtual reality have

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been described in every subspecialty.[8] Airway surgery, including laryngeal surgery, is no exception to this trend, but no validated simulators have been described for ELCR.

Utilizing a combination of readily available and three dimensional (3D) printed materials, we developed a realistic training model for ELCR. A novel endoscopic laryngeal suturing objective structured assessment of technical skills (ELS-OSATS) was developed to evaluate performance of simulated ELCR. We hypothesized that this model would improve both user confidence and competence in technical skills.

Methods

Model Development

An ELCR simulator was created with two main components: a silicone laryngeal cleft model and a positioning framework for simulated endoscopic surgery.

For the model, digital modeling software (Mimics/3-Matics [Materialise, Leuven Belgium]) was used to virtually create atypical airway anatomy from a normal CT scan to develop a laryngeal cleft construct. Cleft depth was placed to a level below true vocal cords, representing a type two cleft. This was then used to produce a three-dimensional (3D) mold and printed on a Flashforge 3D printer (Zhejiang, China) using polylactic acid (PLA) material (Figure 1a). Dyed silicone and Slacker additive (Macungie, Pennsylvania) was cured in the molds to create the soft tissue framework. True vocal cords were painted white using silicone paint to aid in realism and differentiation from surrounding tissue (Figure 1b).

A framework was created using a hospital standard plastic supply bin, rolled surgical towels, duct tape, and a large Lindholm laryngoscope (Figure 2a). Holes were cut in the sides and bottom of the bin to accommodate the laryngeal model. The cleft model was then stabilized

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using a temporal bone holder (Figure 2b) and placed into the framework housing the laryngoscope to complete the simulator (Figure 2c).

When used with a microscope or endoscope, the simulator re-created an ergonomically similar set-up to a patient in suspension laryngoscopy in the operating room (Figure 2d). Standard micro laryngeal instruments were then used to perform ELCR. The view of the cleft model through the simulator imitated the view of the larynx during an ELCR on a real patient (Figure 3).

OSATS Development

A novel ELS-OSATS tool was developed for the assessment of endoscopic suturing skills used during ELCR (supplemental Figure 1) using a modified Delphi method. The development panel was composed of expert pediatric otolaryngologists from three institutions who perform ELCR regularly in their practices. Similar to other OSATS used in otolaryngology, this included both task-specific and global operative performance sections.[9,10] The task-specific portion was developed by polling the expert panel and dividing the operative procedure of endoscopic endolaryngeal suturing into compartmentalized steps required to successfully complete the procedure. Finalized steps included microlaryngeal instrument handling, endoscopic suturing (further divided into tissue tension and support and appropriate suture placement with regard to depth and position), endoscopic knot tying, and use of the endoscopic knot pusher. The global-operative performance portion of the scale was developed using the American College of Surgeons OSATS global rating scale.[11,12] All specific items (five for task-specific performance as listed above, and six for standard global operative performance) were rated on a five-point Likert

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scale with one representing poor performance and five representing outstanding performance, for a total of 55 possible points.

Data Collection

Internal Review Board approval was obtained from Seattle Children's Hospital and the University of Washington to test the simulator on live participants. The model was implemented at a simulation station for teaching and practice of ELCR at the annual Northwest Airway Course. Participants consisted of a mix of resident, fellow, and attending otolaryngologists. Prior to simulator use, participants watched a five-minute instructional video on ELCR using the simulator. Study participation was voluntary, and all participants at the course had scheduled time with the simulator.

Each simulation consisted of a 10-minute session in which participants performed ELCR on the models. Additional equipment used included an operating microscope (Zeiss, Oberkochen, Germany) and standard microlaryngeal instruments (Karl Storz, Tuttlingen, Germany). Suture repair was completed using 6-0 polydioxanone suture (PDS, Ethicon, Inc., Somerville, New Jersey), with five knots per suture throw. Participants were encouraged to place as many sutures as possible within the time limit. Each participant completed either one or two sessions, which were videorecorded. Participants completed surveys before and after sessions rating their confidence with performing laryngeal suturing on a five-point Likert scale, with one being no confidence, to five being complete confidence (supplemental Figure 2). Surveys also detailed their training level, prior experience with in vivo ELCR, self-evaluation of each suture throw, and opinion of realism and ease of use of the simulator.

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Deidentified video recordings were edited to extract first and last suture throw for each participant. Each participant therefore had a pre-simulator use video (first suture throw) and a post-simulator use video (last suture throw of their last session). Videos of each individual suture throw were then reviewed in a randomized, blinded fashion by two pediatric otolaryngology attendings. Each suture throw was ranked using the ELS-OSATS. The videos were re-randomized and re-evaluated by the same reviewers six months after initial review for intra-rater comparison.

Data Analysis

Statistical analyses were performed on participant self-evaluation of confidence, ELS-OSATS scores, and suture completion time. Independent t-tests were used to compare completion time and ELS-OSATS scores by experience level at the initial attempt. The Wilcoxon signed-rank test was used to compare ELS-OSATS scores as well as changes in survey responses between attempts (i.e. first to last suture throw). A paired t-test was applied to compare completion times between attempts. Cohen's κ testing was used to assess inter-rater and intra-rater reliability of ELS-OSATS rankings.

Results

Simulation sessions using the ELCR model were performed by a total of 21 otolaryngologists, including 16 residents (76%), two fellows (10%) and three attending physicians (14%). Residents comprised of trainees from clinical post-graduate year (PGY) two (n=6, 28.5%), three (n=6 28.5%), and four (n=4, 19%). Fellows were both PGY six (n=2, 10%). Attendings ranged from two to ten years in practice (n=3, 14%).

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All participants completed a simulation session with the model at least one time and all completed at least one suture throw during their session(s). A completed suture throw was defined as endoscopic passage of the needle through supraglottic tissue and endoscopic tying of one to five knots. Out of the full cohort who completed one throw (n=21), 76% (n=16) completed two suture throws, and 14% (n=3) completed three suture throws. Of the participants who completed only one suture throw (n=5), three attempted but did not complete a second throw during the allotted time.

All participants completed the survey for a 100% response rate. Overall, the simulator was rated as "easy to use" and "quite realistic", both with a mean response rate of four. All participants either "agreed" or "strongly agreed" (four or five on five-point Likert scale) that otolaryngology trainees would be better prepared for ELCR after using the simulator.

Participants reported confidence increased significantly after using the simulator, improving a mean of one full Likert point from "basic comfort with steps" (2/5) to "intermediate confidence with all steps" (3/5) ($p<0.001$, Figure 4). Self-assessment of individual suture throws attempts also improved by a full point between first and second attempts ($p=0.008$, Figure 4). No statistically significant improvement was seen between second and third attempts due to insufficient power (n=3).

ELS-OSATS data (maximum total of 55 points) obtained from the blinded reviews demonstrated a significant overall score improvement in skill of 11.7 points when comparing first to last suture throws (increase of median score from 26.0 [IQR 12.3-34.3] to 37.7 [IQR 28.9-49.4], $p=0.004$) (Figure 5, Table 1). Improvement was also seen when breaking down ELS-OSATS into global operative performance ($p= 0.02$) and ELCR task-specific performance ($p= 0.03$). Calculated completion times of each suture throw from video review also showed

improvement from a median time of 512 seconds to 350 seconds (decrease of 202 seconds, IQR 15-298, p= 0.02, Figure 6).

Inter-rater and intra-rater reliability were also calculated from the blinded reviewer data (Table 2). Intra-rater reliability showed good agreement for rater one (κ= 0.677) and for rater two (κ= 0.689). Inter-rater reliability was shown among all OSATS categories, with an overall moderate concordance (κ= 0.573). Breakdown by OSATS categories is detailed in Table 2.

Performance and confidence did differ by participant experience level. When stratifying by PGY year, initial confidence levels varied widely but correlated strongly with prior in vivo ELCR experience ($p<0.0001$). Participants with no prior experience, who never observed or participated in ELCR, had both greater subjective and objective improvement than those with some experience (≥1 in vivo ELCR). The group with no experience (n=7) had an even greater improvement in confidence (1.5 points), compared to the group with experience (n=9, $p<0.01$). This group also increased in median overall ELS-OSATS scores by 12.1 points (IQR 1.3-18.5) as opposed to 10.5 points (IQR 0-18) for experienced participants (p=0.04) and improved in completion time by 269 seconds (IQR 254-421) as opposed to 55 seconds (IQR 0-192) ($p<0.001$, Table 2).

Discussion

Endoscopic suturing for ELCR requires advanced surgical skills which can be difficult both to learn and to teach. Limitations in training opportunities exist due to the single-operator nature, operative time constraints, and low case volumes. Additionally, the vast majority of patients undergoing these operations are infants or young children, making other factors such as anesthetic time even more important. Even over the course of an entire residency or fellowship,

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otolaryngology trainees may lack sufficient exposure to in vivo ELCR to gain competency. Surgical simulation using ELCR models offers a realistic way to develop these skills, which may ultimately translate to improved surgical proficiency and more effective training when applied to live patient opportunities. Our described surgical simulator represents the first report of a validated tool to improve user confidence and surgical skills for ELCR.

The simulator was successfully implemented among a group of otolaryngologists ranging from junior residents to attendings, indicating its feasibility. Participants overall rated the simulator as "quite realistic" (Likert scale median of 4) and the majority (n=15, 72%) strongly agreed (Likert scale 5) that otolaryngology trainees would be better prepared for ELCR after using the simulator. These patterns were corroborated by expert attending physicians who perform ELCR regularly in their practice (n=3), showing face validity.

Both an increase in subjective confidence and a statistically significant improvement in objective measures using a novel ELS-OSATS were observed after use of the simulator. ELCR specific aims were identified and successfully performed on models, including laryngeal tissue handling, endoscopic suture placement, endoscopic knot tying and use of the endoscopic knot pusher, and endoscopic suture cutting. The ELS-OSATS showed sufficient inter-rater and intra-rater reliability to indicate its utility in assessing these ELCR task specific performance as well as global operative performance for endoscopic suturing. Objective improvement was seen in overall scores ($p= 0.004$), and both for global operative performance ($p= 0.02$) and ELCR task-specific performance ($p= 0.03$). These results collectively demonstrate content validity of the ELCR simulator.

Construct validity, defined as the degree to which the test items identify the quality, ability, or trait it was designed to measure[13], was also shown by comparing users of varying

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experience levels. Participants with no experience with in vivo ELCR started off with lower skill levels on ELS-OSATS and confidence and improved in both categories by a larger margin than those with more experience. Time to completion also showed greater improvement in novice participants. These results indicate that incorporating surgical simulation for ELCR early on in training may be valuable.

Model validity was also shown when assessed by Messick framework, another proposed method of demonstrating simulator validity. This system assesses five specific sources: content, response process (i.e. quality control), internal structure (e.g. reliability), relations with other variables, and consequences of the assessment.[14] Evaluation of content of the simulator and OSATS was conducted by expert otolaryngologists who regularly perform ELCR in their practice. Response process was ensured by providing a standardized instructional video to participants as well as by having the videos randomized and blinded prior to review. Internal structure was assessed using Cohen's kappa metrics for inter-rater and intra-rater reliability. Relation to other variables was determined statistically comparing scores and completion times between groups with different training level and in vivo ELCR experience.

One other laryngeal cleft model has been described in the literature by Kavanaugh et al.[15] This model included a laryngeal cleft among a library of pediatric laryngeal pathologies constructed with various 3D printing materials. They showed that silicone-based material was the most mechanically similar to live tissue but did not evaluate the use of the simulator for training purposes.

Our model provides not only a validated way to practice ELCR, but also offers several other benefits over other described airway simulation models. Printing the mold as opposed to the larynges themselves allowed for faster, more cost-effective production of multiple models.

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Material cost for the 3D printed mold and silicone larynges was less than $10, not including production labor costs, dependent on who is producing the model. Each model can be reused for multiple simulations. In our experience, the tissue quality was adequate for 30-40 suture throws. The mold also makes model development portable and easily replicable, and they can be shared with institutions that may not have advanced 3D-printing capabilities.

Limitations in this study exist mainly in its relatively small sample size and the subjective nature of survey-based results. In particular, including more experienced attending surgeons in future work may help strengthen the validity of the model. Additionally, data was only collected from one institution which may contribute to additional implicit bias. We also acknowledge that creation of models like this require high-cost resources including a 3D printer. While these technologies are becoming more widely available and more cost effective, they still involve a moderate upfront investment, space dedication, and specialized technical expertise for development. Options including inter-institutional collaborations and design sharing may help mitigate these constraints. Further testing is needed to demonstrate predictive validity of this model showing how it affects operative performance for in vivo ELCR.

Conclusion

This study demonstrates face, construct, and content validity of a simulator for endoscopic ELCR. A novel OSATS for endoscopic laryngeal suturing was concurrently developed and implemented. Both subjective perceived confidence and objective technical skills improved with use of the model across a variety of participants. Completion times per endoscopic suture throw decreased by over three minutes on average between first and last

attempt with the simulator. This data shows that use of the simulator is a useful adjunct in surgical training and practice for ELCR.

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Tables

Table 1: Median ELS-OSATS and completion time data for all participants overall and compared between participants with no prior experience and participants with some experience (≥1 in vivo ELCR). * indicates $p < 0.05$.

	First Suture Throw			Last Suture Throw			Change from First to Last		
	Total (n=16)	No Experience (n=7)	Some Experience (n=9)	Total (n=16)	No Experience (n=7)	Some Experience (n=9)	Total (n=16)	No Experience (n=7)	Some Experience (n=9)
Total ELS-OSATS (maximum 55)	26.0	21.1	28.6	37.7	33.2	39.1	11.7*	12.1*	10.5*
Task-Specific Performance (maximum 25)	11.0	9.9	11.8	16.4	14.6	17.8	5.4*	4.7*	5.9*
Global Operative Performance (maximum 30)	14.3	11.3	16.7	20.1	18.6	21.3	5.8*	7.3*	4.5*
Completion Time (seconds)	512	630	428	350	361	373	202*	269*	55*

Table 2: Inter-rater and intra-rater reliability for ELS-OSATS compared between blinded video reviewers.

	Cohen's κ		
	Task Specific Performance	Global Operative Performance	Overall Performance
Inter-Rater Reliability			
Reviewer 1 versus Reviewer 2	0.560	0.581	0.573

Intra-Rater Reliability			
Reviewer 1	0.682	0.665	0.677
Reviewer 2	0.688	0.680	0.689

Figure Legends

Figure 1

A 3D printed mold of a type 2 laryngeal cleft (a) used to fashion laryngeal cleft models out of dyed silicone (b).

Figure 2

A framework for housing the model created from readily available materials (a), into which a stabilized laryngeal model (b) is placed to complete the simulator for laryngeal cleft repair (c). When used with a microscope, the simulator re-creates an ergonomically similar set-up to a patient in suspension laryngoscopy in the operating room (d).

Figure 3

Endoscopic view of the laryngeal model (bottom) compared to an in vivo larynx (top) before and after endoscopic suturing.

Figure 4

Participant survey data ranking self-assessed confidence before and after simulator use on a five-point scale. Median overall improvement was one point.

Figure 5

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ELS-OSATS results (maximum of 55 points) compared between first and last suture throws as calculated via blinded review. Median overall improvement was 11.7 (21%).

Figure 6

Completion time between first and last suture throws. Median overall improvement was 202 seconds (3 minutes 22 seconds).

Supplemental Figure 1: ELS-OSATS

The endoscopic laryngeal suturing objective structured assessment of technical skills (ELS-OSATS) used to evaluate performance of simulated endoscopic laryngeal cleft repair. Similar to other OSATS used in otolaryngology, it contains both task-specific and global operative performance sections, for a total of 55 possible points.

Supplemental Figure 2: ELCR Simulator Survey

Surveys administered to study participants before and after ELCR simulator use. Questions evaluate participant demographics and experience level, opinions on model realism and utility, and confidence with performing laryngeal suturing.

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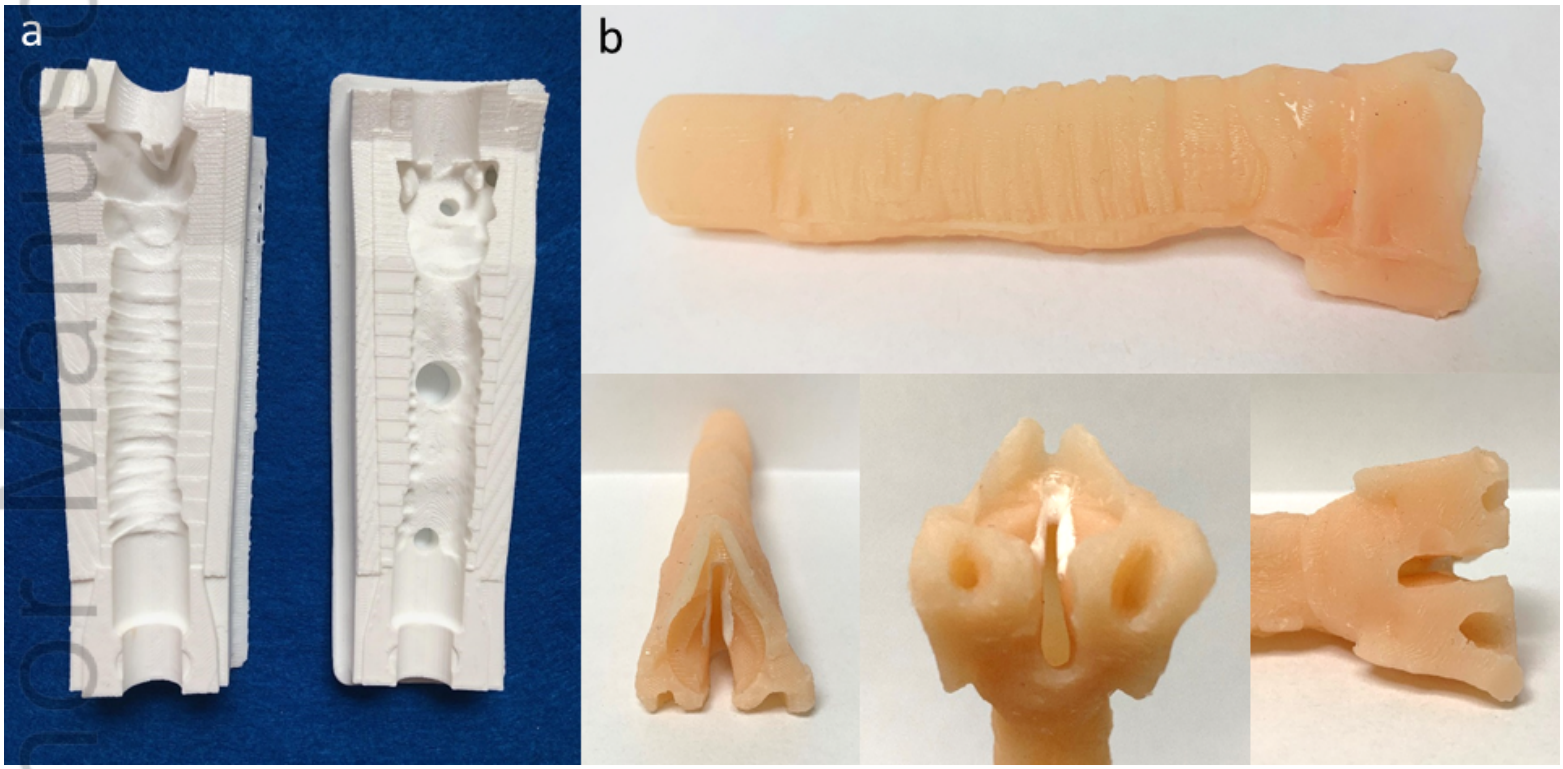

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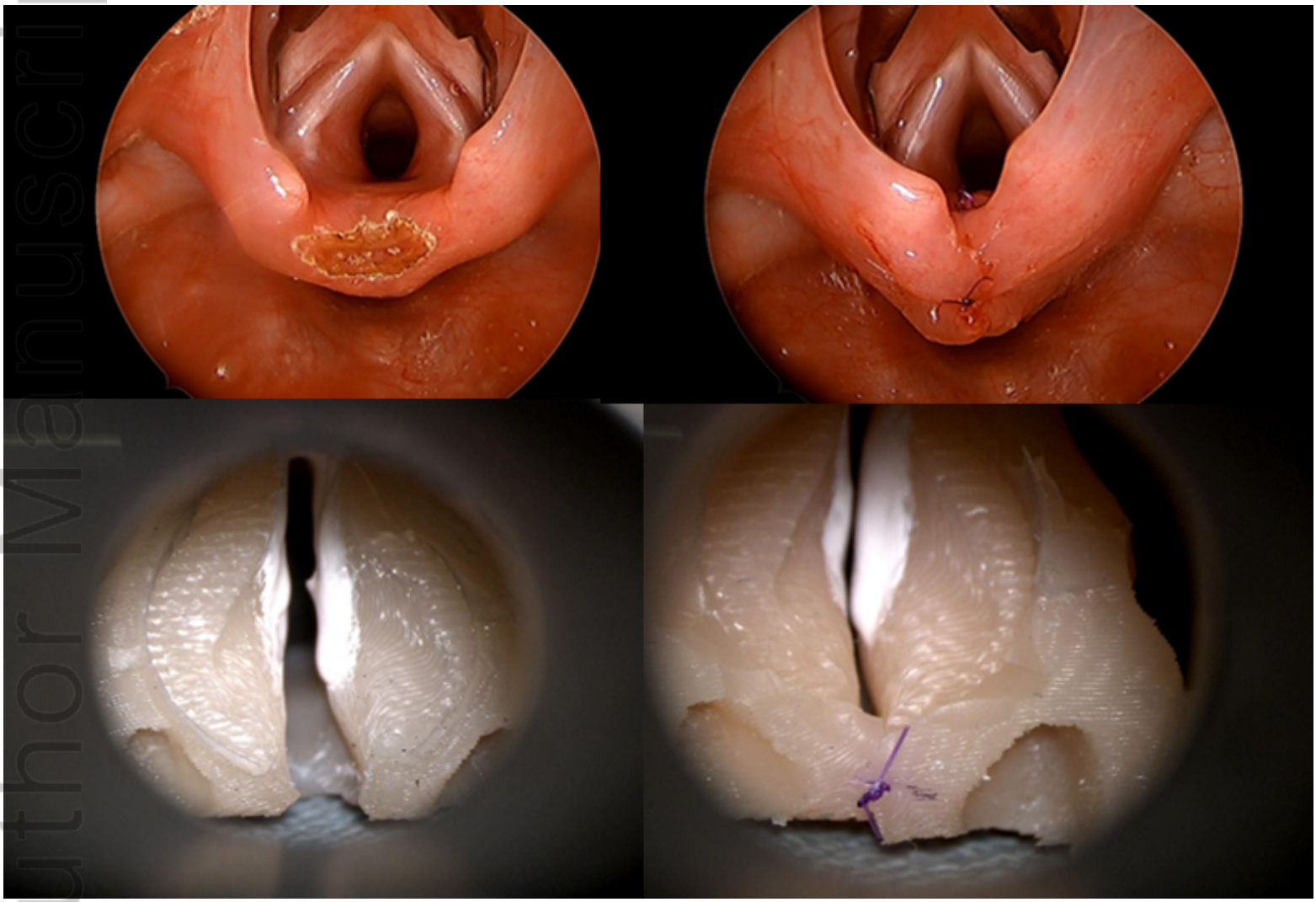

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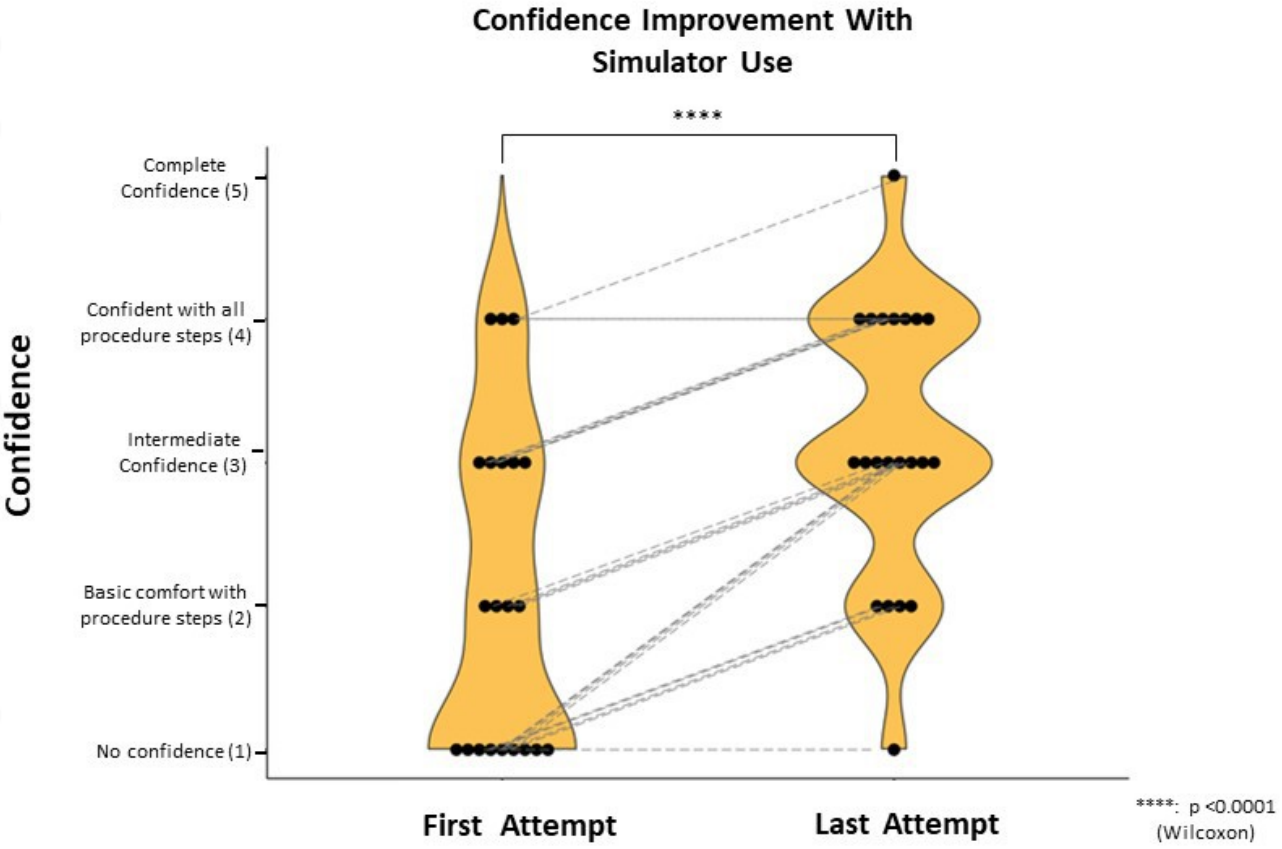

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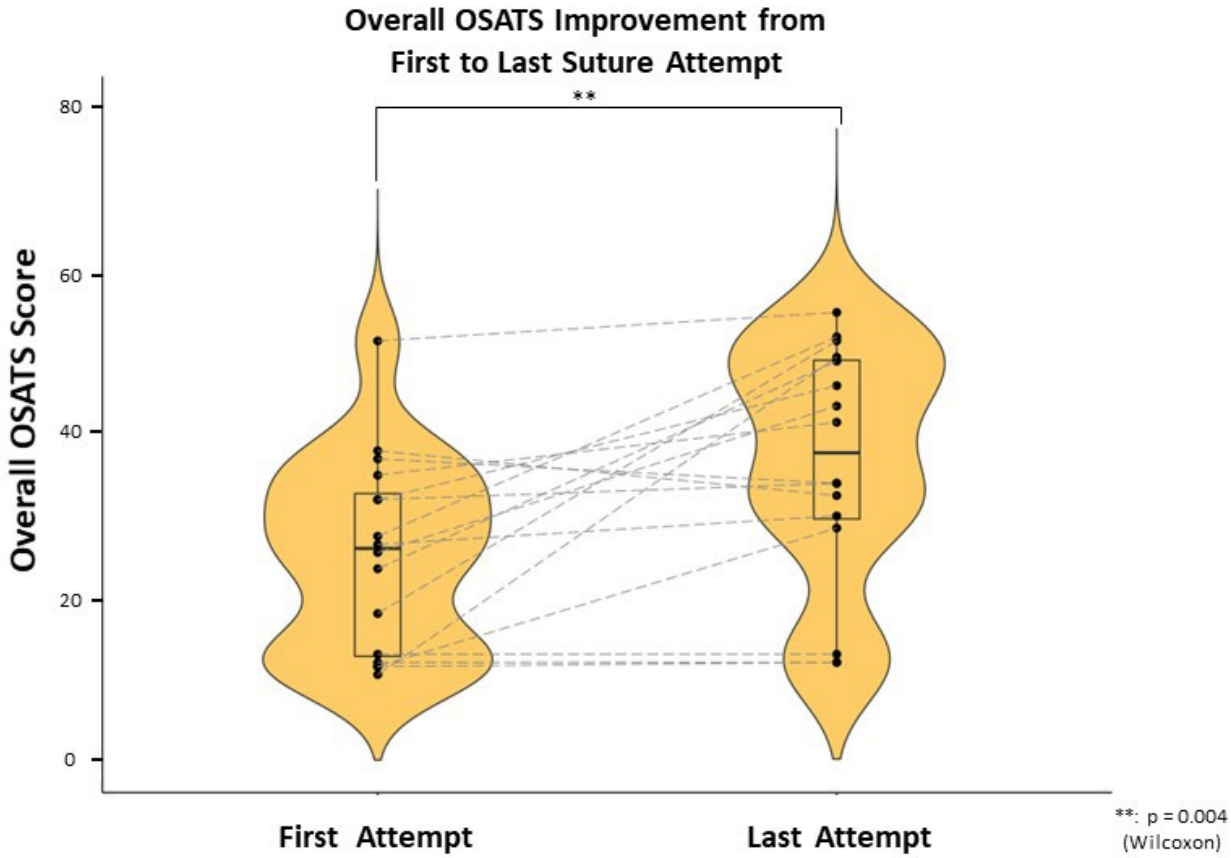

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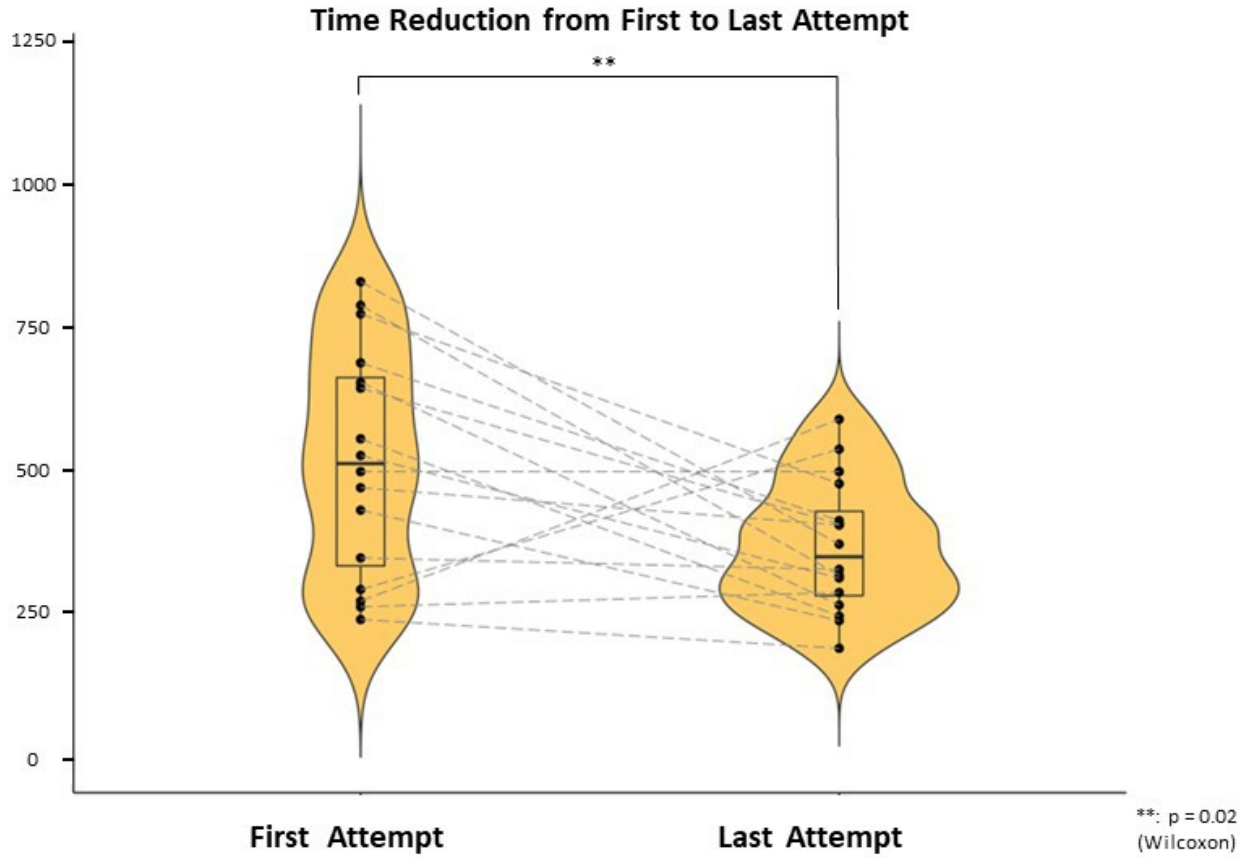

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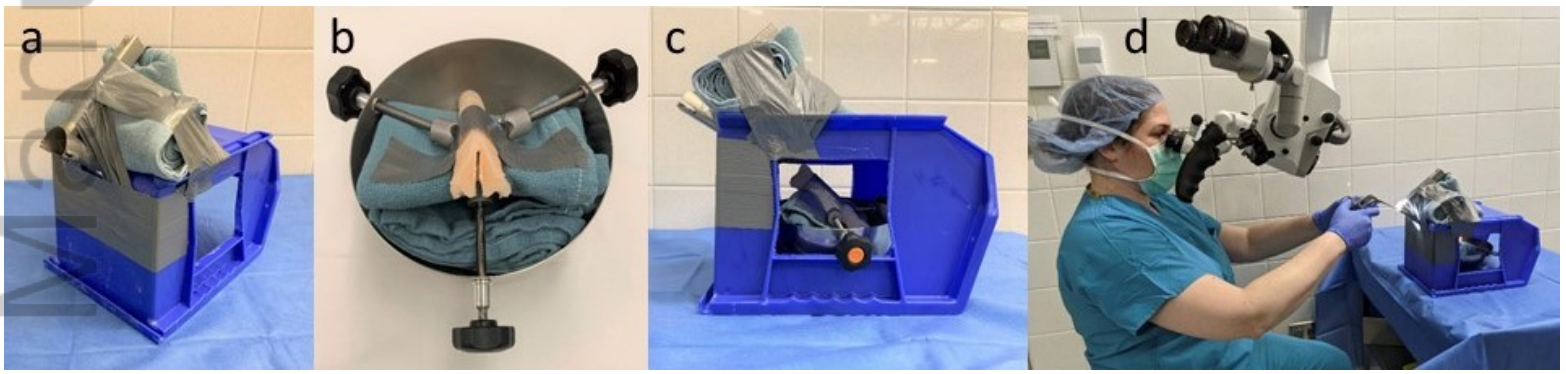

LARY_30320_NEW Figure 2.jpg