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Simulation in Transcutaneous Injection Laryngoplasty Using a 3D-printed Laryngeal Injection Task Trainer (LITT)

ABSTRACT

Objective: To develop a low-cost 3D-printed Laryngeal Injection Task Trainer (LITT) for simulation of transcutaneous injection laryngoplasty and evaluate its effectiveness among trainees.

Methods:

Design: Cross-Sectional Time-Motion Study and Post-Training Evaluation Survey
Setting: Tertiary University College of Medicine Anatomy Laboratory
Participants: Five residents and 2 consultants in Otolaryngology-Head and Neck

Surgery were trained using a LITT fabricated through three-dimensional printing of cartilage models and silicone molds through the UP SIBOL Greenhouse and the Philippine General Hospital Craniomaxillofacial Prosthesis Unit. Participants were asked to perform transcutaneous laryngeal injection on the LITT. The duration in performing the procedure from palpation of landmarks to injection of material was measured in seconds and recorded. After the simulation workshop, participants were asked to evaluate the subjective experience with surgical simulation using the modified Michigan Standard Simulation Experience Scale (MiSSES).

Results: The mean time in performing transcutaneous laryngeal injection across different training levels for either trans-cricothyroid or trans-thyrohyoid approach was not statistically significant. Mean time in performing transcutaneous laryngeal injection between 2 approaches, the trans-cricothyroid approach (79.32 seconds with SD 34.89) and the trans-thyrohyoid approach (35.16 seconds with SD of 10.88), was statistically significant. Using the MiSSES tool for evaluation of the simulation training, majority of the participants agreed that the LITT allowed self-efficacy in performing the procedure, had adequate fidelity in terms of its characteristics and components, had high educational value in training participants for knowledge and skills on transcutaneous laryngeal injection and that the simulation provided good teaching quality. For the overall rating, all participants concurred, with 83.3% of participants answering strongly agree and 16.7% of participants responding somewhat agree, that the simulation experience was helpful in knowledge and skills development on transcutaneous laryngeal injection. On final evaluation of the LITT, 75% of the participants responded that it can be used in training but should be improved slightly.

Conclusion: The laryngeal injection task trainer (LITT) had an acceptable fidelity, educational value, teaching quality to improve self-efficacy in performing transcutaneous injection



laryngoplasty - with points for improvement in terms of model and set-up stability, color accuracy and consistency of the visual indicator. It is recommended that the LITT be also used for future workshops and possibly further validation studies after applying the points for improvement gathered from this simulation study.

Keywords: *simulation-based training; 3D-printing; transcutaneous laryngeal injection; injection laryngoplasty; trans-cricothyroid; trans-thyrohyoid*

Simulation-based training has increasingly become a recognized method of teaching in medicine. Acquisition of skills and surgical competence are no longer solely developed through the traditional apprenticeship model of training. Surgical skills can also be taught in the laboratory using simulation models.^{1,2} Simulation models enable an operator or trainee to reproduce a certain situation artificially. In terms of medical training, these models can be utilized as an alternative experiential learning to actively synthesize theoretical knowledge with skills without the risk of patient safety compared to an apprenticeship model.²

The use of animal or human cadavers has traditionally been the mode for simulation of certain procedures.³ While human cadaveric models have accurate anatomy, these are not readily accessible and can be quite expensive to set up in simulation laboratories or courses. Animal models are also widely used but structures differ from human anatomy in several ways. Non-cadaveric simulation models on the other hand, utilize materials ranging from household items to 3D-printed cartilage models and silicone soft tissue simulators.^{3,4,5} There are different kinds of simulation models, and these can be categorized according to fidelity – or how similar they are in real life or situational context.² These include low- and high-fidelity models, simulation within working theatres, simulated patient role-play, computer-based simulators, box-trainers and basic suturing models.⁶ With the advent of 3D printing technology, newly developed anatomical models and task simulation trainers have flourished over the past 20 years. Using data derived from medical imaging such as in computed tomography, layer-by-layer manufacturing can be done to fully construct a prosthetic structure or model.⁷ The material of objects depends on printer capability and can generally be made from plastic, resin and even metal, to name a few. Three-dimensional printing is now revolutionizing medical simulation learning in anatomy, pathology and procedural skills by providing anatomic and surgical relevance physically.⁷ Task trainers made of 3D-printed and silicone models may also be more accessible to trainees and can continue to guide them even after completion of such courses, thus boosting confidence in performing certain procedures. Given the

promise of simulation-based medical training, research towards its use is paramount to see whether it also improves patient outcomes.⁶

Three-dimensional-printed models for simulation-based training in Otolaryngology have also emerged and the most widely described in literature are 3D-printed temporal bones. Models for anatomic instruction and procedural training have also been developed for the sinonasal and skull base and the larynx.⁸ These models may be used for training to develop competency in certain procedures. One skill that can be taught using simulation models is transcutaneous laryngeal injection, an office-based procedure in laryngology. This study aims to develop a low-cost 3D-printed Laryngeal Injection Task Trainer (LITT) for the simulation of transcutaneous injection laryngoplasty and evaluate its effectiveness among trainees.

METHODS

This is a non-clinical, cross-sectional study using mixed methods involving a time-motion study and post-training evaluation surveys on surgical simulation using an investigational laryngeal injection task trainer. With University of the Philippines Manila Institutional Review Board Approval (UPMREB 2024-0423-01, the study was conducted at the University of the Philippines Manila - College of Medicine Anatomy laboratory. Participants included residents and consultants of the Department of Otolaryngology-Head and Neck Surgery of the Philippine General Hospital. Consultants of the Department of Otolaryngology-Head and Neck Surgery who were facilitators for this task station during the workshop were not included.

Fabrication of Laryngeal Injection Task Trainer

An open-source resource for the stereolithography (STL) files for a 3D larynx model and soft tissue silicone molds was downloaded from the link in the published study by Lee *et al.*⁹ (<https://wikifactory.com/@3dlaryngology/3d-larynx-surgery-trainer/files>). Using the Ultimaker Cura version 5.0.0 open-source 3D printing program (Ultimaker B.V., Geldermalsen, Netherlands), all downloaded STL files were viewed, and printer settings were adjusted for thermoplastic polyurethane (TPU) filament for the larynx model and resin filament for the silicone molds printed with an Ultimaker S3 fused deposition modeling (FDM) 3D printer (Ultimaker B.V., Geldermalsen, Netherlands) for the larynx cartilage and a Formlabs Form 3 resin printer (Formlabs Inc., Massachusetts, USA) for the silicone molds. The open-source model STL files and software previously mentioned were used to generate the virtual design of the laryngeal models in coordination with the UP Surgical Innovation and Biotechnology Laboratory (UP SIBOL) Greenhouse. Three-dimensional printing of cartilage models and silicone molds, and casting of the silicone components were done

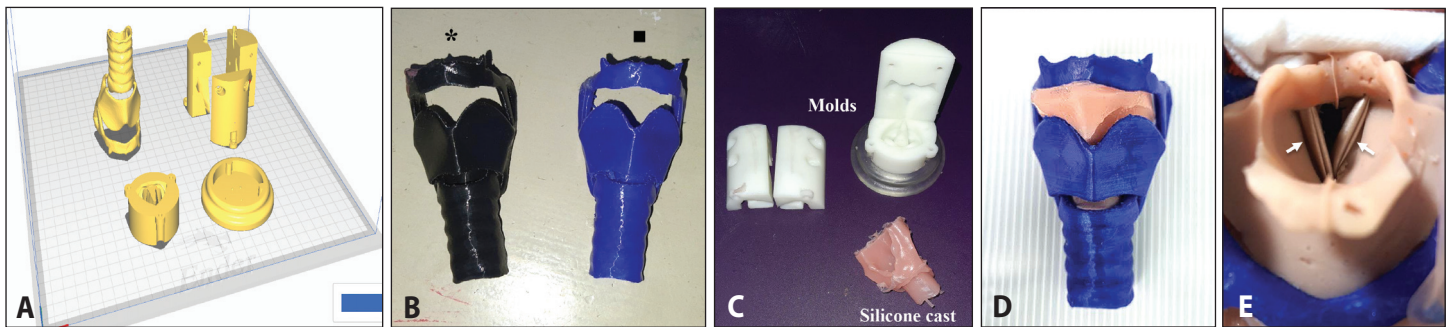


Figure 1. Process of 3D printing of laryngeal cartilages and endolaryngeal molds. **A.** Loading of STL files to an open source program prior to 3D printing; **B.** Prototypes of 3D printed laryngeal cartilages (Asterisk – PLA filament; Square – TPU filament); **C.** Assembled 3D-printed mold for casting silicone endolaryngeal components; **D.** the final 3D silicone endolarynx; silicone endolarynx placement inside the 3D printed laryngeal cartilage; and **E.** Placement of latex balloon (indicated by arrows) as a visual indicator for the vocal cords and paraglottis

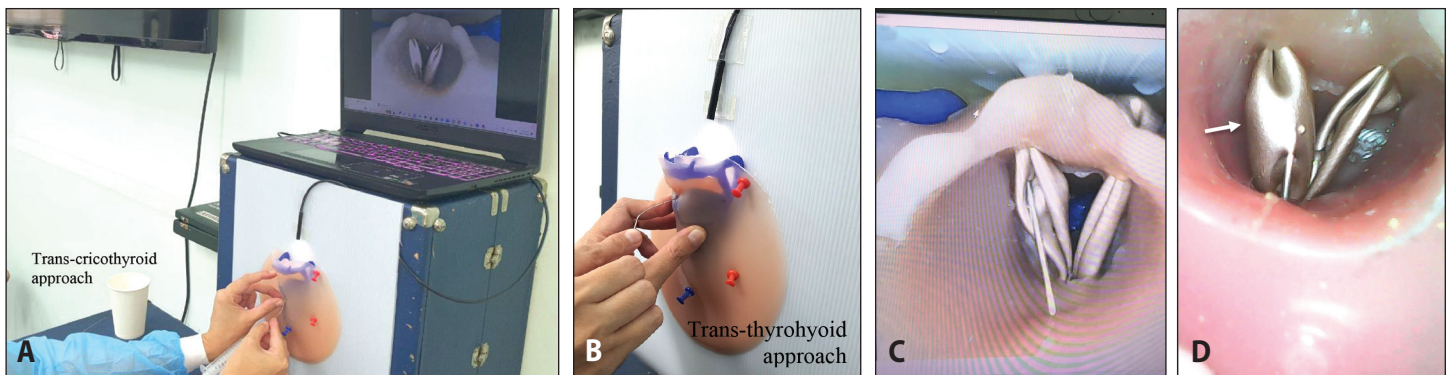


Figure 2. Final set-up during simulation for transcutaneous laryngeal injection using the Laryngeal Injection Task Trainer (LITT). **A.** Set-up with the LITT model fixed to a board and a system with a borescope and laptop used as a video monitor. Transcutaneous injection done via trans-cricothyroid approach; **B.** Transcutaneous injection via the trans-thyrohyoid approach; **C.** Positioning of the needle towards the latex balloon (paraglottis) using the trans-thyrohyoid approach; and **D.** Injection of material as indicated by the expanded latex balloon (arrow).

in the UP SIBOL Greenhouse (fabrication laboratory) and the Philippine General Hospital Craniomaxillofacial Prosthesis Unit. (Figure 1A and B)

The resin-printed endolarynx mold components shown in Figure 1A were assembled as illustrated in Figure 1C. Ecoflex™ 00-30 silicone material (Smooth-On, Inc., Macungie, PA, USA) was injected inside the assembled mold and cured for 24 hours. After curing, the newly shaped silicone endolarynx was carefully removed from the disassembled mold casing. (Figure 1C) The silicone endolarynx was placed inside the 3D-printed laryngeal cartilage. (Figure 1D) To replicate the vocal folds with an easily identifiable visual cue, a brown-colored thin latex balloon was inserted at the level of the laryngeal opening of the silicone cast. (Figure 1E)

To simulate the external neck, an outer skin cover was fabricated. For the outer skin cover of the neck, a 5 mm thick silicone layer was cured over a flat-surfaced template. It was then wrapped around the endolarynx-cartilage model and the edges secured to an upright support with tape. A total of 3 models were produced. A prototype was initially checked for quality and durability prior to the training course. (Figure 1E)

Simulation using the Laryngeal Injection Task Trainer

The simulation-based training on transcutaneous injection laryngoplasty was facilitated during a scheduled workshop using the laryngeal injection task trainer LITT. The set-up included the 3D laryngoplasty model attached to a plastic corrugated board in upright position, a 3.5m AN97 Micro USB borescope (Shenzhen Wellwin Technology Co., Ltd, Guangdong, China) attached to a ASUS TUF Gaming A15 laptop (ASUSTeK Computer Inc., Taipei, Taiwan) to simulate an endoscopy tower. The Open Broadcaster Software (OBS) Studio version 27.2.4 (Lain Bailey, Arizona, USA) was used to project and record the camera screen as seen in Figure 2A. A facilitator was assigned during the simulation to observe and assess the participants and coordinate the debriefing. A co-facilitator was also assigned to assist during the simulation. The liquid material for injection (commercial distilled water) was loaded in a 5 ml syringe attached to a gauge 23 spinal needle.

Initially, the plan for the objective assessment during the workshop was to assign participants into two groups: 1) Participants first perform the transcutaneous injection via the trans-cricothyroid and trans-thyrohyoid approach using the LITT, making three attempts for each



approach to practice the steps followed by performing the task on a soft-embalmed cadaver; and 2) Participants perform laryngeal injection using only the soft-embalmed cadaver, via the trans-cricothyroid and trans-thyrohyoid approach, with one attempt for each approach. However, during the workshop, the first few participants encountered problems with the soft-embalmed cadaver model while attempting to perform the task. Upon palpation of landmarks on the soft-embalmed cadaver by participants, the vocal cords tended to move midline, obstructing the view of the needle and necessitating repeated application of an endotracheal tube to position the vocal cords in an abducted position. This made it inconsistent for comparison, thus cadaveric simulation was entirely omitted, and all participants proceeded to perform transcutaneous laryngeal injection on the LITT only.

The participants were asked to perform transcutaneous laryngeal injection on the LITT, with one attempt for each approach (trans-cricothyroid and trans-thyrohyoid approach). The duration in performing the procedure - from palpation of the landmarks to insertion of the needle in the neck via the cricothyroid membrane (*Figure 2A*) or thyrohyoid membrane (*Figure 2B*), to visualization of the needle and insertion onto the vocal cords (*Figure 2C*), to injection of the material and withdrawal of the needle (*Figure 2D*), for each attempt was measured in seconds and recorded.

Evaluation of Laryngeal Injection Task Trainer

A short debriefing regarding the simulation was done. After the training workshop, a survey questionnaire was distributed to the participants using a modified Michigan Standard Simulation Experience Scale (MiSSES)⁹ – an open source validated modular qualitative tool (available from: <http://www.med.umich.edu/umcsc/research/MiSSES.doc>), to evaluate subjective experience with surgical simulation in transcutaneous laryngeal injection.

Data Analysis

The time in seconds was recorded for each participant in performing both the trans-cricothyroid and trans-thyrohyoid approach of transcutaneous injection laryngoplasty. The mean performance time for each of the approaches was taken per year level of residency training. One-way analysis of variance (ANOVA) (Jeffreys's Amazing Statistics Program, version 0.19.1, University of Amsterdam, Amsterdam, Netherlands) was used to compare the mean time of performing the task across year level of training, and paired t-test (Jeffreys's Amazing Statistics Program, version 0.19.1, University of Amsterdam, Amsterdam, Netherlands) to compare the mean time in doing the transcutaneous laryngeal injection between the two approaches.

RESULTS

A total of 27 participants were recruited for the study - with a mean age of 32; 16 were male and 11 were female. Twenty-five (25) participants were part of residency training – 7 (1st year); 7 (2nd year); 6 (3rd year); and 5 (4th year). There were two laryngology consultants who participated in the simulation. The number of transcutaneous injection laryngoplasty procedures done previously by the participants was recorded and illustrated in *Table 1* - showing that only two of the residents had prior experience in performing transcutaneous laryngeal injection before the study. Consultants who participated had experience of at least 10 procedures done prior to the study. All 27 participants were able to complete the procedure.

The mean duration of performing transcutaneous laryngeal injection via trans-cricothyroid and trans-thyrohyoid approach across different years of training respectively were the following: 96.86 and 33.00 seconds for Y1 residents, 68.86 and 38.29 seconds for Y2, 89.50 and 37.83 seconds for Y3, 57.20 and 30.60 for Y4, and 37.50 and 20 seconds for the consultants – a general trend of decreasing performance time with increasing training experience was seen.

One-way analysis of variance (ANOVA) was used to check for any significant difference in performance time among different year levels of residency only for the two types of approaches. For the trans-cricothyroid approach, the f-ratio value was 1.80484 and p-value was .177184. For the trans-thyrohyoid approach, the f-ratio value was 0.66859 and the p-value was .580741. Both sets of results for both approaches among the different resident year levels were not significant at $p < .05$.

Paired t-test was used to check statistical difference of the mean performance time of all resident participants between the two injection laryngoplasty approaches performed. Mean performance time was 79.32 seconds with SD of 34.89 for the trans-cricothyroid approach and 35.16 seconds with SD of 10.88 for the trans-thyrohyoid approach. Mean difference of the trans-cricothyroid to the trans-thyrohyoid approach was 44.16 (95% CI - 29.22-59.10); the two-tailed P value was less than .0001 so the time difference was statistically significant.

Table 2 summarizes the participant evaluation of the laryngeal injection task trainer in six domains using the modified MiSSES. Only 24 of the 27 participants provided complete answers in the survey after the activity and on following them up after a week. Majority of the participants agreed that the LITT allowed self-efficacy in performing the procedure, had adequate fidelity in terms of its characteristics and components, had high educational value in training participants for knowledge and skills on transcutaneous laryngeal injection and the simulation provided good teaching quality. For the overall rating, all participants concurred - with 83.3% of participants answering strongly

Table 1. Demographic data of participants in the study according to year level of training and number of transcutaneous injection laryngoplasty procedures done

Position/ Year Level	No. of Participants	Number of laryngeal injections done		
		0	1 to 10	More than 10
Year 1 Resident	7	7	0	0
Year 2 Resident	7	7	0	0
Year 3 Resident	6	5	1	0
Year 4 Resident	5	4	1	0
Consultant	2	0	0	2
Total	27	23	2	2

Table 2. Evaluation per domain of the transcutaneous laryngeal injection simulation on the laryngeal injection task trainer (LITT) using the modified Michigan Standard Simulation Experience Scale (MiSSES) (responses= 24/27)

Domain	Evaluation (%)					
	Don't know	Strongly disagree	Some-what disagree	Neutral	Some-what agree	Strongly agree
Self-Efficacy						
The LITT helped improve my knowledge	-	-	-	-	20.8	79.2
The LITT helped improve my confidence at performing transcutaneous laryngeal injection	-	-	4.2	8.3	45.8	41.7
The LITT helped improve my ability to transcutaneous laryngeal injection	-	-	-	4.2	41.7	54.2
The LITT helped improve my ability to transcutaneous laryngeal injection independently	4.2	-	12.5	8.3	54.2	20.8
Fidelity						
The simulator used has adequately realistic characteristics/features	4.2	-	4.2	4.2	58.3	29.2
The simulation environment is adequately realistic	-	-	12.5	12.5	41.7	33.3
Realism of cartilage components was adequate	4.2	-	4.2	8.3	45.8	37.5
Realism of endolarynx mold was adequate	4.2	-	4.2	12.5	29.2	50
Educational Value						
The LITT is a good training tool for knowledge in transcutaneous laryngeal injection	-	-	-	4.2	16.7	79.2
The LITT is a good training tool for skills in transcutaneous laryngeal injection	-	-	-	-	12.5	87.5

Teaching Quality						
Instructor(s) were knowledgeable about the topic	-	-	-	-	4.2	95.8
Instructor(s) were able to convey material in a way that was understandable to	-	-	-	-	12.5	87.5
The learning materials (readings, presentations) improved my understanding of transcutaneous laryngeal injection	-	-	-	-	16.7	83.3
The resources we used improved my understanding of transcutaneous laryngeal injection	-	-	-	-	12.5	87.5
Overall Rating						
Overall, this simulation experience was helpful regarding knowledge and skills development on transcutaneous laryngeal injection	-	-	-	-	16.7	83.3

agree and 16.7% of participants responding somewhat agree, that the simulation experience was helpful in knowledge and skills development on transcutaneous laryngeal injection. On final evaluation of the LITT using the modified MiSSES tool, 75% of the participants responded that it “can be used in training but slight improvements should be made,” 16.7% responded that “the simulator requires minor adjustments before it can be considered for use in training,” and 4.2% each responded that “the simulator can be used in training with no improvements made,” or that “the simulator requires extensive improvements before it can be considered for use in training.”

DISCUSSION

Developing skills among trainees in certain procedures through simulation-based training is gaining recognition as it offers experiential learning without the risk for patient safety.⁶ One procedure that can be taught through simulation-based training is transcutaneous laryngeal injection, an office-based procedure performed commonly for management of unilateral vocal fold paralysis, glottal insufficiency or vocal cord atrophy. This can be performed via several approaches, including via the trans-cricothyroid membrane or via the trans-thyrohyoid membrane approach.¹⁰

In this study, simulation of transcutaneous laryngeal injection using both approaches were done on LITT with relative ease of understanding



and use. When performing this procedure, palpation of the landmarks was important prior to insertion of the needle to the neck and onto the vocal cords, where the material was then injected until sufficient medialization of the vocal cord was achieved. Based on this conceptual workflow, the 3D-printed laryngeal injection task trainer was able to simulate the steps from landmark palpation to portraying adequate medialization of the vocal cords.

Using the open-source models and files provided by Lee *et al.*,⁴ the model backbone for the laryngeal injection task trainer was readily accessible and easily replicable. The slight differences in our production of the 3D prints for the molds compared to the study of Lee *et al.*⁴ were due to the variable capabilities of the available models of the 3D printer in the institution and the type of filament material used. Commercial models of printers, capable of printing a variety of materials from polylactic acid (PLA), thermoplastic polyurethane (TPU) to resin, are more available these days so issues with reproducibility can be lessened. The same can be said with the silicone materials used for soft tissue replication in the model. Although more accessible nowadays, the pricing may still be an issue especially if working on a minimal budget. The other larynx models for transcutaneous injection in the literature have used some form of indicator during injection – an audible tone via an electronic thyroarytenoid (TA) module in the model of Ainsworth *et al.*,³ and a visual cue in the form of an expandable latex balloon to mimic the vocal folds, placed inside a standard-size toilet paper tube in the study of Cabrera-Muffly *et al.*,⁵ creating a low cost laryngeal simulation injector. The electronic sound module was more difficult to adopt since it requires more advanced technical skill and costing to produce. For this study, the long latex balloon was incorporated into the silicone endolarynx model to provide a visual cue in the simulation for adequate vocal cord medialization. The concern with this additional feature was the need to constantly replace the balloon to maintain the integrity of its expansion during succeeding attempts in simulation training. All in all, the LITT was easily accessible, replicable and low cost at around PhP 2,000 (USD 35) compared to higher end models or courses.

Based on the results of the study, there was a general trend of decreasing time in performing the transcutaneous laryngeal injection as the training level or experience became higher. However, there were no significant differences across residency training levels for both approaches. For all participants, attempts with the trans-thyrohyoid approach were shorter in duration compared to the trans-cricothyroid approach, with a mean difference of 44.15 seconds. The mean duration between the two approaches were statistically different. This might be due to several factors mentioned by the participants - the needle tip was more easily visualized in the trans-thyrohyoid approach given that

it was more proximal to the endoscopic camera and had less structures obstructing its full view compared the trans-cricothyroid approach which had the needle more distal to the camera and was underneath the glottic opening. In addition, several participants relayed some difficulty in palpating the area of the cricothyroid area and thus positioning the needle. This may be seen as an issue of fidelity for the simulation model.

The subjective assessment of the surgical simulation using the modified Michigan Standard Simulation Experience Scale (MiSSES) has several domains for evaluation as described by Seagull and Rooney - these are self-efficacy, fidelity, educational value, teaching quality and overall rating.¹⁰ Self-efficacy addresses issues of participant knowledge, confidence, and ability to work independently using the simulation model and most of the attending participants agreed that the LITT improved their knowledge, confidence and ability in performing an injection laryngoplasty. A few were neutral or disagreed that it improved their confidence in ability. This may be due to the previously mentioned difficulty in palpating the landmark, thereby increasing the time in doing the task. Suggestions by the participants to help increase confidence and ability were performing more than one attempt and doing comparison procedures with an actual patient.

Evaluation of fidelity pertains to suspension of disbelief, visual characteristics, tactile characteristics, procedural authenticity among others. Most participants agreed that the simulator had adequate realistic features of the silicone skin and endolarynx, TPU cartilage and environment in general. However, around a quarter of the participants were either unsure or disagreed that the simulator had acceptable realism. Simulator characteristics mentioned by participants that need improvement include stability to be maintained in an upright position, palpability of landmarks such as the cricothyroid, and color of the printed components to reflect actual cartilage components.

All participants agreed to varying degrees that there was significantly good educational value and teaching quality of the LITT and recommended that it should be used for teaching and practicing laryngeal injection prior to performing it to actual patients. There was also good feedback on the overall quality of the simulator build. Participants highlighted the importance of increased time of exposure and number of attempts in using the LITT, consistent stability of the upright positioning of the model during the simulation using a more rigid support, and the palpability of the landmarks especially the cricothyroid. One important factor that affected the performance of participants during the attempts was the expandability of the latex balloon – this visual indicator would consistently have poor performance if it were not replaced after every injection attempt due to the perforations made on the surface.

By taking the participant suggestions into account, the LITT can

be improved in several ways: 1) Securing the silicone skin using pins or thumbtacks instead of just tape against a sturdier back support such as a corkboard or thick illustration board to maintain a more consistent upright position; 2) Printing the laryngeal cartilage using a cream or whiter filament of a sturdier material such as polylactic acid (PLA) to increase fidelity and maintain accessibility to the cricothyroid membrane; and 3) Replacing the latex balloon with a more sustainable, sturdier yet still expansile material such as a small-sized foley catheter (French 8) to eliminate the effort and time to frequently change the visual indicator due to perforations.

Limitations of this study include the unforeseen problems with the cadaver set-up which led to on-the-spot changes of methodology and comparison of the study groups. Another significant limitation was the number of participating consultants which did not reach the minimum number needed to include the group for statistical analysis. Hence, only the resident groups were statistically assessed.

For future studies, it is recommended to separate the validation studies from comparative investigations to minimize issues with methodology. A study of a cadaveric simulation for transcutaneous injection laryngoplasty can also be done separately prior to comparison studies with 3D simulation. Recruitment of more consultant participants with experience in the procedure can be done to further give power to the statistical analysis. For the objective evaluation of participant

performance, the Objective Structured Assessment of Technical Skill (OSATS)¹¹ which had been used already for surgical simulation training in the literature is suggested to be utilized aside from the basic time recording of the procedure. The LITT is recommended for use in future workshops and further validation studies after applying the points for improvement gathered from this simulation study.

In conclusion, 3D model-based simulation can be a good method of training individuals for certain procedures in laryngology such as transcutaneous injection laryngoplasty. Using the present available literature, a laryngeal injection task trainer could be fabricated by modifying open-source blueprints to also include a visual indicator during simulation training. The LITT had acceptable fidelity, educational value, teaching quality to improve self-efficacy in performing injection laryngoplasty - with points for improvement in terms of model and set-up stability, color accuracy and consistency of the visual indicator. Residents-in-training at any year level should have no significant issue in using the LITT. In general, the LITT can be used at any given time by a trainee as it is relatively low-cost, reproducible, easily set-up, portable, and requires no patient interaction. Furthermore, it can be used repeatedly to improve confidence and ability to do several approaches to laryngeal injection such as trans-thyrohyoid and especially trans-cricothyroid with only minor upkeep and maintenance.

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