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RESEARCH ARTICLE

Development and Validation of a 3-Dimensional Flexible Laryngoscopy Training Simulator

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ABSTRACT

The objective of this study was to validate the use of a 3-Dimensional Flexible Laryngoscopy Training Simulator. This is a simulation device development and validation study. Anonymized CT scan data from a head/neck CT of a patient with normal anatomy was imported and a head/neck digital model was created. A 3D simulation model was printed using a stiff (Stratasys Vero) and flexible (Stratasys Agilus) material combination with a ShoreA hardness value of 60. Novices and experts were instructed and provided 5 trials to pass the laryngoscope. The videos of the first and the last trial were recorded and evaluated by three different evaluators. Performances were measured by the amount of time spent and precision of the task. Repeated measures of ANOVA and generalized linear model with binomial proportion was used were utilized to analyze the data. The post training scores were statistically significantly higher than pre training scores (Mean: 15.57 vs. 13.01, $p < 0.0001$) controlling for trainee experience. The time taken to complete a successful pass post training was statistically significantly lesser than pre training (Mean: 62.55 secs vs. 36.36 secs, p-value = 0.0007) controlling for individual's experience. The odds of becoming skilled at the task was 4 times higher post training in comparison to pre training, controlling for individual's experience (OR: 4.05, p-value: 0.0026). The 3-Dimensional Flexible Laryngoscopy Training Simulator is a valid trainer for both novice and experienced individuals. The simulator can improve technical skill performance and is critical for medical training.

Keywords: Simulator, Laryngoscopy, vocal folds

1 Introduction

Flexible laryngoscopy is a primary diagnostic tool for evaluation of patients with otorhinolaryngologic abnormalities [1]. Many medical care providers including speech-language pathologists, otolaryngologists, anesthesiologists and emergency medicine physicians perform flexible laryngoscopy as emergency or elective procedures [2]. However, training standards for this commonly used procedure vary widely by training program,[2] often leading to hesitancy on the part of the provider, especially newly graduated medical professionals to perform these procedures in clinical settings due to inadequate skills or comfort level [3].

Teaching process standardization can help prevent unintentional negative outcomes such as poor exam quality, errors, inaccurate diagnoses, patient discomfort and injury. Simulation models are widely used as valuable tools to strengthen various skills by creating a safe and comfortable replica of clinical environment for frequent practice [4]. Simulation training has been shown to improve patient care and management of complicated cases across various procedures including bronchoscopies [5, 6] ,laparoscopicsurgeries [7] and other procedures [8-10]. Otolaryngologic training programs often use simulators to assist with procedural learning [11-14]. This training may be especially useful for skill building and aptitude assessment in trainees without any prior experience. In the related field of speech-language pathology, simulator training is less common. Speech-language pathologists and medical practitioners perform many similar procedures as their otolaryngology colleagues, including flexible and rigid laryngoscopy for vocal fold visualization and swallow assessments.

The purpose of the current study was to develop and validate a flexible laryngoscopy training simulator. We sought to determine if endoscopy performance improved following simulator training and if performance gains were dependent on trainees' past endoscopy experience. The ultimate goal is to develop a comprehensive medical education simulator program with less reliance on human participants for use across medical sub-specialties.

2 Methods

2.1 Simulator Development

Emory University Institutional Review Board approval was obtained prior to the study (IRB00114511). Anonymized CT scan DICOM (Digital Imaging and Communications in Medicine) data from a head/neck CT of a patient with normal anatomy was imported into Mimics version 21 (Materialise™, Plymouth, MI). The patient was a 52 year old female who underwent CT scan for other medical reasons and had no laryngeal pathology or findings. The head/neck digital model was created by first thresholding air in the airway lumen with a Hounsfield density above -1000 and below -125. The remaining tissues were grouped into a voxel mask to represent an aggregate of soft tissue and bone. The soft tissue/bone voxel mask was converted into a surface .STL representation within Mimics and the resulting .STL triangle mesh was refined/remeshed in 3-matics (MaterialiseTM) version 13.

The resulting STL model was imported into GrabCAD version (free 3D printing software) and sliced for input into a Stratasys J750 multijet printer (Stratasys Ltd, Eden Prairie, MN). A 3D simulation model was printed on the Stratasys J750 using a stiff (Stratasys Vero) and flexible (Stratasys Agilus) material combination with a ShoreA hardness value of 60. This model was used for all simulation purposes. Figure 1 shows the simulator set up.

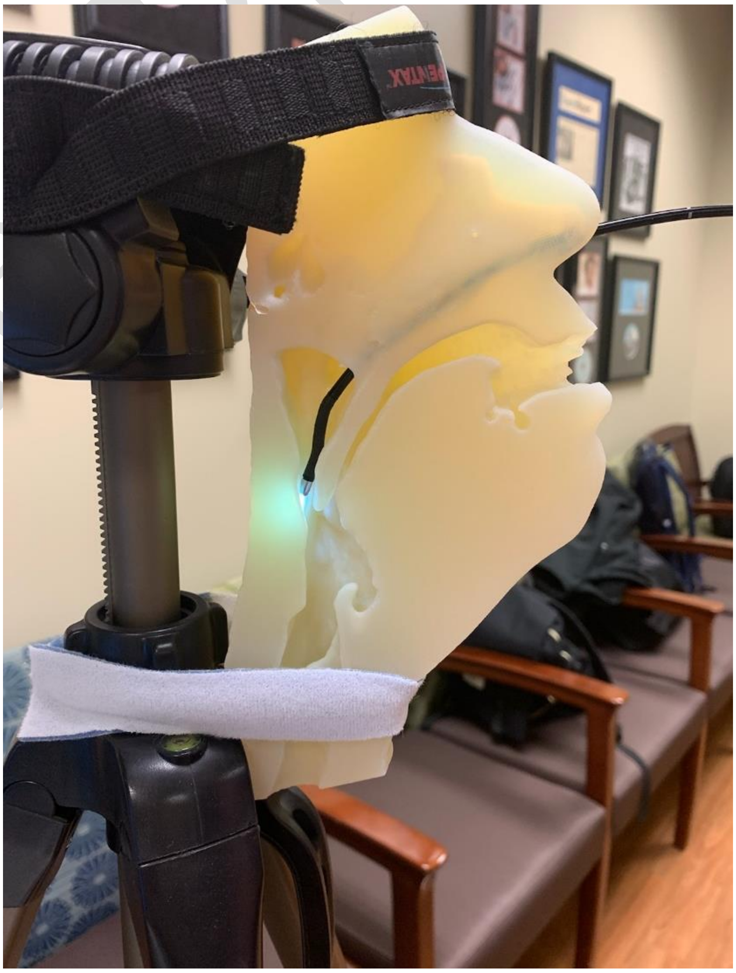

Figure 1: *Flexible Laryngoscopy Training Simulator Set-up*

2.2 Participants

A convenience sample was used for this cohort study. Participants were recruited from attendees of a speech-language pathology endoscopy training course. The training course allowed an easy access to the sample population. Participants were divided into two groups based on endoscopy experience: novice (< 20 lifetime total endoscopy passes) and experienced (> 20 lifetime total endoscopy passes). All participants (novice and experienced) passed the endoscope through the simulator. A successful pass terminated with the endoscope positioned above the centered vocal folds. Participants repeated the training five times. Based on previous simulation studies, four to six trials ia considered an acceptable number for simulator training. [15]. The first pass was recorded as the 'pre-test' and the fifth repetition was considered as 'post-test'. An expert endoscopist assisted in set-up for the participants but did not guide the pre and post-test passes, nor were they involved in rating the training sessions.

2.3 3D Simulator Training

A flexible video naso-pharyngo-laryngoscope (Model # VNL9-CP, PENTAX Medical, Montvale, NJ) was used by all participants for all training trials. The laryngoscope was attached to a video processor (VIVIDEO Video Processor [CP-1000], PENTAX Medical, Montvale, NJ). Training sessions were digitally recorded and saved with a unique, non-identifying participant ID.

2.4 Data Collection

No demographic information were collected. Videos (pre- and post-test) were recorded for all the participants starting from entrance into nasal cavity to centered vocal cords. The videos were analyzed by three different raters for error(s) and rater's perception of change in confidence of the participant to perform endoscopy after the trials. All raters were fellowship trained laryngologists. The exam time taken to complete one complete exam was evaluated by the research coordinator (See Appendix 1 for the data collection form).

2.5 Statistical Methods

The videos were randomized to be evaluated by three different raters using the evaluation form (Appendix 2). A score was created by combining the Likert scales of questions 1, 2, 3 and 5. The higher the score the better. A generalized linear model was used to analyze time taken to complete the procedure. Repeated measures of ANOVA were utilized to analyze the continuous outcome and generalized linear model with binomial proportion was used to evaluate the binary outcomes.

3 Results

Twenty-one participants enrolled in the study. Of those, 16 were novice and 5 were experts. Each participant generated two videos (pre-post training), for a total of 42 videos.

The post training scores were statistically significantly higher than pre-training scores (Mean: 15.57 vs. 13.01, p <0.0001) controlling for trainee experience. However, there was no difference between the scores of experienced and novice individuals controlling for the training type (pre or post) (p-value = 0.06).

The time taken to complete a successful pass post training was statistically significantly lesser than pre training (Mean: 62.55 secs vs. 36.36 secs, p-value = 0.0007) controlling for individual's experience. Similarly, experienced individuals took less time to center the vocal cords than novice individuals (Mean: 39.8 secs vs. 59.12 secs, p-value = 0.02). Table 1 shows time taken to perform the procedure stratified by individual's experience.

The odds of capturing the vocal folds in the center of the screen did not differ after training and did not depend upon individual's experience. The odds of becoming skilled at the task was 4 times higher post training in comparison to pre training, controlling for individual's experience (OR: 4.05, p-value: 0.0026).

Table 1: *Time taken to perform the procedure (Pre –post) stratified by experience level*

Time	Experienced		Novice	
In seconds	Pre	Post	Pre	Post
	50.6	29.00	72.9	45.3

4 Discussion

The flexible laryngoscopy training simulator was useful for both experienced and novice individuals. The participants required less time to perform the procedure post training, independent of their baseline experience level. The individuals made less errors and passed the scope with minimal scope redirection post training, suggesting that the participants became skilled at performing the task controlling for their individual experience.

Evidence that simulation can improve technical skill performance is critical for medical training. This need is heightened in instances when training on human subjects may be difficult, such as with the COVID-19 pandemic or in the case of procedures that may cause pain or discomfort when not performed by a skilled technician. Pandemic restrictions placed on personal protective equipment utilization, number of providers allowed in clinical spaces at a time, extra time required for room turnover and cleaning, and limits on number of patients seen per day as well as on healthy volunteers allowed in clinic [16-18] all reduced the opportunity for flexible laryngoscopy training. The data here and in similar studies show that simulators are valuable tools to build skill and confidence in providers, while reducing risk to patients or volunteers. Future studies should investigate if simulation training for flexible laryngoscopy also improves patient safety, comfort and diagnostic outcomes.

5 Conclusion

The results of the study indicate effective flexible laryngoscopy learning amongst both skilled and beginner population, with decreased procedural time and being skilled at the task. This, in turn will help in reducing patient examination time and procedural discomfort. The laryngoscopy training simulator has a great potential to help mitigate learning gap between the theoretical and practical knowledge, for residents, medical students, otolaryngologists, and last but not the least – speech language pathologists.

6 Declaration

6.1 Funding

This work was supported by the Dean's Imagine, Innovate and Impact (I3) Education Grant from the Emory University School of Medicine

6.2 Ethical Approval

Emory University Institutional Review Board (IRB) approval was obtained prior to the study (IRB00114511).

6.3 Informed Consent

Since this is a minimal risk study, oral consent obtained from the subjects and was approved by the IRB.

6.4 Competing Interests

The author declares that no potential conflict of interest exists related to this article

How to Cite this Article:

Will be updated in the final version.

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Appendix 1: Rater evaluation form

3-D Simulator study Form

Total time Taken in seconds (Entry to vocal folds centered) ________

1. Did the scope inappropriately contact any of the structures in the nose? (turbinate, septum)?

   ☐1 (many times, had difficulty steering) ☐2 ☐3 (one or two instances) ☐4 ☐5 (no difficulty navigating this portion)

2. Did the endoscope inappropriately contact the posterior pharyngeal wall?

   ☐1 (many times, had difficulty steering) ☐2 ☐3 (one or two instances) ☐4 ☐5 (no difficulty navigating this portion)

3. Did the endoscope inappropriately contact the supraglottic (epiglottis, false vocal folds)?

   ☐1 (many times, had difficulty steering) ☐2 ☐3 (one or two instances) ☐4 ☐5 (no difficulty navigating this portion)

4. Were the vocal folds centered on the screen at the end of the exam?

☐Not Centered ☐ Centered

5. Did the endoscopist maintain a smooth trajectory with minimal redirection to access the oropharynx to view the larynx?

   ☐1 (many times, had difficulty steering) ☐2 ☐3 (one or two instances) ☐4 ☐5 (no difficulty navigating this portion)

6. Subjectively, what was the overall confidence of the endoscopist?
   ☐Novice/Tentative/Uncertain ☐ Skilled/Decisive/Certain