This is an Accepted Manuscript for *The Journal of Laryngology & Otology*
DOI: 10.1017/S0022215124001853

Feasibility and Validation of a Synthetic Airway model for in-situ Laser Dissection

Authors: Thomas Daniel Milner[1]

Jiak-Ying Tan[2]

Elaine Baird[3]

William Andrew Clement[4]

Jenny Montgomery[1]

Saleh Okhovat[1]

Affiliations: 1. Department of Otolaryngology, Queen Elizabeth University Hospital, Glasgow

2. Department of Otolaryngology, NHS Lothian, Lauriston Building, Edinburgh.

3. Department of maxillofacial prosthetics, Queen Elizabeth University Hospital, Glasgow

4. Department of Paediatric Otolaryngology, Royal Hospital for Children, Glasgow

Correspondence: Mr Thomas Daniel Milner

Department of Otolaryngology, Queen Elizabeth University Hospital, 1345 Govan Road, Glasgow. G51 4TF

Tel: 0141 201 1100

Email: tommilner1@doctors.org.uk

Authorship Statement:

Mr. Milner and Mr. Okhovat designed, participated, acquired data and analysed the data. Mrs. Baird supported designing the study. Mr. Clement and Mrs Montgomery supervised the project. Ms Tan drafted the manuscript with Mr. Milner, Mrs. Baird, Mr. Okhovat, Mr. Clement and Mrs Montgomery revised the manuscript. Mr. Milner agrees to be accountable for all aspects of the work.

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Declaration Statement:

We have no conflict of interest to disclose. We confirm that this work is original and has not been published elsewhere, nor is it currently under consideration for publication elsewhere. It was presented at the American Head and Neck Society 11th International Conference on Head and Neck Cancer which was held from 8th to 12th July 2023.

Abstract:

Introduction:

This study measured the effectiveness of an in-house designed, cast silicone airway model in addressing the lack of easily accessible, validated Transoral laser Microsurgery (TLM) simulation models.

Methods

Participants performed resection of two marked vocal cord lesions on the model. The model underwent face, content and construct validation assessment using a 5-point Likert scale questionnaire measuring the mean resection time for each lesion, and the completeness of lesion excision. Comparative analyses were performed for these measures.

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Results

13 otolaryngologists participated in this study. The model achieved validation threshold on all face and content measures (median ≥4). Construct validation was demonstrated by the improvement in mean resection time between lesion one and two (86s vs 54s; W=11, p=0.017), and mean resection time was lower amongst more senior otolaryngologists (61.5s vs. 107.1s, W=11, p=0.017).

Conclusions

This is a low-cost, easily reproducible, high-fidelity synthetic airway model, demonstrating face, content and construct validity.

Keywords

Laser, Endoscopy, Larynx, Head and Neck Surgery

Introduction:

Transoral Laser Microsurgery (TLM) is the recommended surgical treatment for early glottic malignancy (T1a) and demonstrates similar oncological outcomes in comparison to radiotherapy for T1b and T2 glottic malignancies [1]. As a consequence, TLM is a key component of the otolaryngology surgical curriculum[2]. However, TLM proficiency requires the development of operative skills that are typically novel to the surgical trainee, and a detailed understanding of laser application and safety. Studies have shown that there is a significant correlation between surgeons' experience and TLM overall complications [3, 4]. It is, therefore, essential to provide optimal training opportunities to shorten the operative learning curve, and to develop proficiency in TLM.

Practical simulation has been increasingly incorporated into surgical training programs, catalyzed by the change in medical environments, reduced working hours, advancement of medical and simulation technologies, an increasing emphasis on patient safety and the emergence of a digital era in surgical training [5, 6]. Surgical simulation allows the opportunity to enhance surgical curricula in a safe and cost-effective manner. This need was further enhanced by the restricted operative opportunities posed by the COVID pandemic [7-9].

Traditionally, laryngology surgical simulation has utilized animal models or human cadavers [10-13]. However, use of these resources can be cost-prohibitive and requires consideration of ethical implications. Furthermore, the availability of surgical lasers and microscopes in environments equipped to allow cadaveric or animal model dissection is

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

limited. Synthetic models bypass the ethical considerations presented by animal/cadaveric models and have the potential to allow in situ simulation in the operating theatre environment. A recent systemic review described laryngeal simulators for laryngeal microsurgery but none of these were tested for laser surgery [14]. There is limited availability of synthetic models for laser surgery practice in the literature, with only one article, published in German, describing an interventional synthetic gelatinous laryngeal model (IMOLA) [15]. Identifying this, the authors aimed to design a low-cost, high fidelity and easily reproducible synthetic silicone laryngeal model with 3D printing to simulate laser surgery in in-situ in the theatre environment.

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Methods

Model Design

The initial template for model construction required a 'negative' of a patient's airway. In order to obtain the optimal template, CT neck images were reviewed in several patients, allowing identification of the ideal larynx: a normal laryngeal airway, with a good glottic opening on the captured images, but with satisfactory vocal cord definition. Using a 3D printer, a 'negative' airway template was generated out of resin.

Silicone was chosen as the ideal 'positive' cast material, providing a suitably realistic texture in comparison to human mucosal tissues. Several silicone products were trialed, including Steramould (Carl-Zeiss, www.detax.de), and Smooth-On Dragon Skin™ 10 Medium, Fast and Very Fast (Bentley Advanced Materials, www.benam.co.uk). The ideal silicone was found to be Smooth-On Dragon Skin™ 10 Fast. Silc Pig Silicone Pigments (Bentley Advanced Materials, www.benam.co.uk) were used to generate a pink color, similar to laryngeal mucosa. A 60mm diameter cylindrical metal frame was sourced (Gerton table leg, IKEA), with the length cut to match the size of the negative airway model (95mm). Multiple silicone casts were created, with Vaseline applied to both the 'negative' airway template and the metal frame to allow easy removal of the cast. The Vaseline was washed from the silicone casts prior to use with the laser.

Silicone Laser Safety

All silicone product designers were contacted to request a safety data sheet, and to clarify the safety of their product during combustion. Smooth-on Dragon Skin™ was confirmed

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

to produce no known harmful substances following combustion, and the company confirmed that they had safely performed laser cutting of the product previously.

An initial safety test was performed in situ, under the supervision of the NHS Greater Glasgow & Clyde (NHS GGC) Fire Safety Officer, to confirm the safety of the product with the CO2 operative laser.

Study Design

Anterior and posterior glottic 'lesions' were created on the superior surface of the right vocal cord on each model with the use of a permanent marker. The models were suspended with the use of a retort stand, and an operating laryngoscope was similarly held in position. Operative drapes and wet swabs were placed around the laryngoscope, and a protective wooden shield was placed behind the model to prevent distal laser damage. A SimMan model was placed behind the protective board and an anaesthetic machine placed next to the operating table to generate realism (Figure 1(a)). A CO2 laser and microscope were set up in the standard fashion.

A total of 13 otolaryngology trainees and consultants were each provided with a model. The participant then performed resection of the two vocal cord 'lesions' using laryngeal microscopic instruments (Integra MicroFrance, custsvcuk@integralife.com) and the CO2 laser (Figure 1(b) and 1(c)). A pre-study questionnaire assessed participant grade, seniority (junior = Specialty Trainee 4 to 6, senior = Specialty Trainee 7, 8 and consultant), degree of exposure to endolaryngeal laser surgery and simulation, and level of confidence with endolaryngeal laser surgery.

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Model Validation

The model underwent face, content and construct validity assessment. Face and content validity were assessed with a 14-question, 5-point Likert scale questionnaire assessing the degree of agreement with statements about the model. A score of 1 was least agreeable, whilst a score of 5 was most agreeable.

Construct validity was assessed by comparing the time taken for each participant to excise each lesion, and by assessing the completeness of excision of each lesion.

Face, content and construct outcome measures were assessed according to surgeon seniority, degree of exposure to endolaryngeal laser surgery and level of confidence with endolaryngeal laser surgery.

Wilcoxon signed rank tests and Chi-squared tests were used to assess model outcomes. Statistical analyses were conducted using R statistical software version 2.15.2 (http://www.r-project.org)

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Results

Demographic Data

13 participants comprised seven junior otolaryngology trainees (ST3-ST6), three senior trainees (ST7-8), one specialty senior clinical fellow and two consultants. They were categorized into two groups – junior (ST3-6) and senior (ST7- consultant) to generate comparatively sized groups. Within the junior group (n=7), 5 individuals had no endolaryngeal laser experience, while 2 individuals reported between 10-20 cases, and none of this group had undergone endo-laryngeal laser surgery simulation. In the senior group (n=6), all surgeons had endolaryngeal laser experience ranging from 1-5 cases up to >20 cases, and three participants had experience in laryngeal laser simulation.

Face Validation

The face validation outcomes revealed all participants agreed or strongly agreed that the overall realism of the synthetic larynx model closely resembled endolaryngeal laser practice, achieving a median score of 4, sufficient for validation. The anatomic arrangement of the synthetic larynx, the tissue feel of the vocal cords, the resemblance of the microlaryngeal instrumentation of the model, the use of the laser and the accuracy of laser cordectomy of this model were also assessed, and achieved the pre-requisite median validation score of 4. These data are displayed in Figure 2.

Content Validation

As per Figure 2, participants all agreed or strongly agreed that the laryngeal model aided in practicing laser resection of laryngeal lesions, with an overall median score of 5

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

demonstrating that the model attained the required threshold for content validity. Furthermore, median scores of 4 demonstrated that the model attained content validity for components of the operation: teaching laryngeal surgical anatomy and principles of endolaryngeal surgery, improving microlaryngeal instrumentation familiarity, and improving economy of movement and operative skills. Finally, participants also strongly supported the usefulness of the model to learn the safe use of laser in a controlled setting (median score of 5).

Construct Validity

Participants were asked to dissect two vocal cord lesions. The mean time required for laser resection of the first lesion was 86s (range= 45 – 149s). The time required for the second lesion showed a significant improvement with an average time of 54s (range= 27-118s) (W=11, p=0.017). Junior trainees demonstrated greater improvements in dissection time (mean= 43.4s) compared to the senior trainees or consultants (mean= 18.7s). However, this was not significant (W=9.5, p=0.12) (Figure 3 & 4). The mean time required for the senior group to complete laser resection for both lesions was 61.5s (range= 45-85s), while the mean time required for the junior group was 107.1s (range= 49-149s), representing a significant difference (W=11, p=0.017). In terms of excision completeness, 10 out of 26 specimens demonstrated complete excision (38.5% of specimens). Comparing completeness of excision between junior and senior participants, the junior group attained a lower completeness of excision (28.6%) in comparison to the senior group (50%), although the data were not statistically significant (X^2=1.254, p=0.263). (Figure 5). Finally, when comparing the questionnaire outcomes according to

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

seniority, laser experience and laser confidence, it was found that the tissue was deemed to be more realistic by more senior otolaryngologists, and the microlaryngeal instrumentation deemed to be more realistic amongst those with more laser experience and more confidence using the laser.

Model Reception

11 of the 13 participants agreed or strongly agreed that the model allowed them to demonstrate their endolaryngeal surgical skills accurately, and 12 participants reported feeling more confident to perform endolaryngeal laser resection safely after using the model. All of the participants agreed that the simulation model was a useful training tool, and that it will help increase the confidence of trainees in performing endolaryngeal laser resection. The majority of participants (9/13) also felt there were not sufficient simulation models available to practice microlaryngeal surgical skills and endolaryngeal laser resection in the current training program.

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Discussion

This study describes the development of a low-cost, high fidelity endolaryngeal laser model, that has demonstrated face, content and construct validity. Participants determined that the model had sufficient verisimilitude to the human larynx, and that the steps of the operation were sufficiently similar to endolaryngeal surgery to reach the required validation threshold. In addition, there was a statistically significant difference in dissection time required between lesion one and two, demonstrating an improvement in performance through practice on model, and the model dissection time was lower amongst more senior operators, highlighting that the model is able to delineate between experience levels in terms of operative time (construct validity). This supports the three-stage skill acquisition theory proposed by Fitts and Posner, whereby the development of psychomotor competencies is highly dependent on sustained deliberate practice over many years with regular feedback from experienced surgeons and constant self-reflection within a learner-centered learning environment[16-18]. Trainees in the modern era have suffered from reduced training opportunities within their surgical training, in part due to the restriction in working hours, the re-structuring of surgical training resulting in a shortened training pathway, and in more recent years the COVID-19 pandemic[5, 6, 8, 9, 17, 19]. It is therefore paramount to enhance the learning environment, through the use of validated simulation models such as this endolaryngeal model, to allow trainees to progress in their acquisition of skills.

The majority of the participants agreed that there is a lack of validated laryngeal models available to practice microlaryngeal laser resection. According to the face validity

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

assessment result, the silicone larynx simulation model showed high structural fidelity as compared to a patient's larynx. A literature review on materials used for human skin models by Dabrowska *et al*. (2016) stated that silicone has a refractive index that is similar to human skin, is easily manipulated, and has a high safety and stability profile [20]. Dragon Skin was the silicone chosen for the casting of the current laryngeal model as it represented a suitable mucosal texture and appearance, while having been demonstrated to be laser safe by the company. This material was also used to create a 3D model for bladder cancer in a recent study[21].

It is important that surgical models allow trainees to feel that they are able to practice the key components of an operation. This study has indicated that participants felt the model allowed them to develop their TLM skills, with the model demonstrating content validity. This included improving manual dexterity and economy of movement when using the laser micromanipulator, an operative skill that is not mimicked in any other surgical procedure. As the provision of endolaryngeal laser simulation models is relatively limited, with the majority of available models being cadaveric or animal models [10-13, 15], the ability of trainees to practice use of the laser micromanipulator is often restricted, due to the cost considerations, and safety challenges of using an operative laser in a simulation environment suitable for cadavers/ animal tissue. The suitability of this model for in situ operative simulation would allow trainees greater access to laser simulation, while maintaining model fidelity.

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

As stated, the model demonstrated construct validity through the analyses of mean time taken to complete the laser resection, both between lesions, and between seniority cohorts. However, the study also analyzed improvement in dissection time, and dissection accuracy between junior and senior trainees. While both of these analyses demonstrated trends towards improved outcomes in the senior group, neither were significant. Due to the oncological indication of many TLM procedures, it is important that any model allows an analysis of accuracy. When reviewing outcomes amongst patients with early laryngeal cancer undergoing endolaryngeal surgery, a higher number of revision surgeries necessitated by positive dissection margins was noted amongst surgeons with less experience[4]. While it was evident within this study that dissection accuracy was assessable through analysis of the specimen margin, further study would be required to ensure that the model is able to delineate between skill levels.

The authors acknowledge some limitations presented by the endolaryngeal model described in this study. Firstly, the synthetic model lacks the tissue planes present within the glottis, and it was not possible in this study to develop a 'lesion' with depth. This could be incorporated into future models, although the primary aim of this study was to develop a low-cost model that allowed sufficient fidelity to result in skill acquisition. Due to the challenges of cadaveric laser surgery, and the lack of availability within our region, it was not possible to assess this silicone larynx model against cadaveric tissue. Cadaveric tissue is the gold standard for surgical simulation due to its ability to simulate the authentic tissue handling experience, providing high haptic fidelity. Of note, a recent systemic review has suggested that there is no good quality evidence to support the use of

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

cadaveric simulation, instead of synthetic models, to improve short-term skill acquisition among trainees [22]. The authors, therefore, believe the current synthetic model is a reliable low-cost model that can replace cadaveric tissue to aid trainees in overcoming the learning curve in laser resection. The study design also necessitated small numbers of participants, due to the limitations in course space availability. Despite this common limitation of simulation studies, the model still demonstrated validity, and statistical significance, suggesting adequate power.

Summary

1. TLM has a deep learning curve where there is correlation between proficiency and TLM complications.
2. Silicon is the material-to-use in providing suitable realistic tissue texture along with good fire safety profile.
3. This study demonstrated the 3D-printing CT-derived silicon model is a low cost, easily reproducible with good face and content validity.
4. There was a significant reduction in resection time between lesion one and two, especially in the junior cohort, demonstrating good construct validity of the model.
5. One of the limitations of the synthetic model is the lack of tissue planes present within the glottis.

Conclusion

This silicone synthetic simulation model is a useful educational tool to help trainees to flatten the learning curve in TLM. It is a safe and cost-effective simulation model. Further studies aim to create models with better haptic fidelity by incorporating tissue planes and in-built tumors for laser surgery simulations. The team also aim to democratize education and training opportunities by providing current models to ENT trainees from other regions.

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Acknowledgements

We thank NHS Greater Glasgow and Clyde for providing theatre facilities and microscopic equipment.

Financial Support

Funding for the project was obtained through the NHS GGC Head and Neck Surgery Endowment Fund.

Competing Interests

All authors declared no conflict of interest.

Ethical Standards

All patients consented to the use of their CT images for the construction of 3D ‘negative’ airway templates.

Project approval was obtained from the NHS GGC Department of Otolaryngology, the NHS GGC Fire Safety Officer, and the Theatre Department at the Royal Hospital for Children, Glasgow.

References

1. Jones TM, De M, Foran B, Harrington K, Mortimore S. Laryngeal cancer: United Kingdom National Multidisciplinary guidelines. *J Laryngol Otol* 2016;**130:**S75-s82
2. Otolaryngology Curriculum. In: https://www.iscp.ac.uk/iscp/curriculum/otolaryngology-curriculum/1-introduction/ 2023]
3. Vilaseca-González I, Bernal-Sprekelsen M, Blanch-Alejandro J-L, Moragas-Lluis M. Complications in transoral CO2 laser surgery for carcinoma of the larynx and hypopharynx. *Head & Neck* 2003;**25:**382-8
4. Bernal-Sprekelsen M, Blanch J-L, Caballero-Borrego M, Vilaseca I. The learning curve in transoral laser microsurgery for malignant tumors of the larynx and hypopharynx: parameters for a levelled surgical approach. *Eur Arch Otorhinolaryngol* 2013;**270:**623-8
5. Shahzad S, Anwar I. Apprenticeship Model in 21st Century's Surgical Education: Should it Perish? *Archives of Surgical Research* 2021;**2:**1-3
6. Evans CH, Schenarts KD. Evolving Educational Techniques in Surgical Training. *Surg Clin North Am* 2016;**96:**71-88
7. An NHS under pressure In: https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/pressures/an-nhs-under-pressure 2023]
8. Clements JM, Burke JR, Hope C, Nally DM, Doleman B, Giwa L, et al. The quantitative impact of COVID-19 on surgical training in the United Kingdom. *BJS Open* 2021;**5:**zrab051

https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

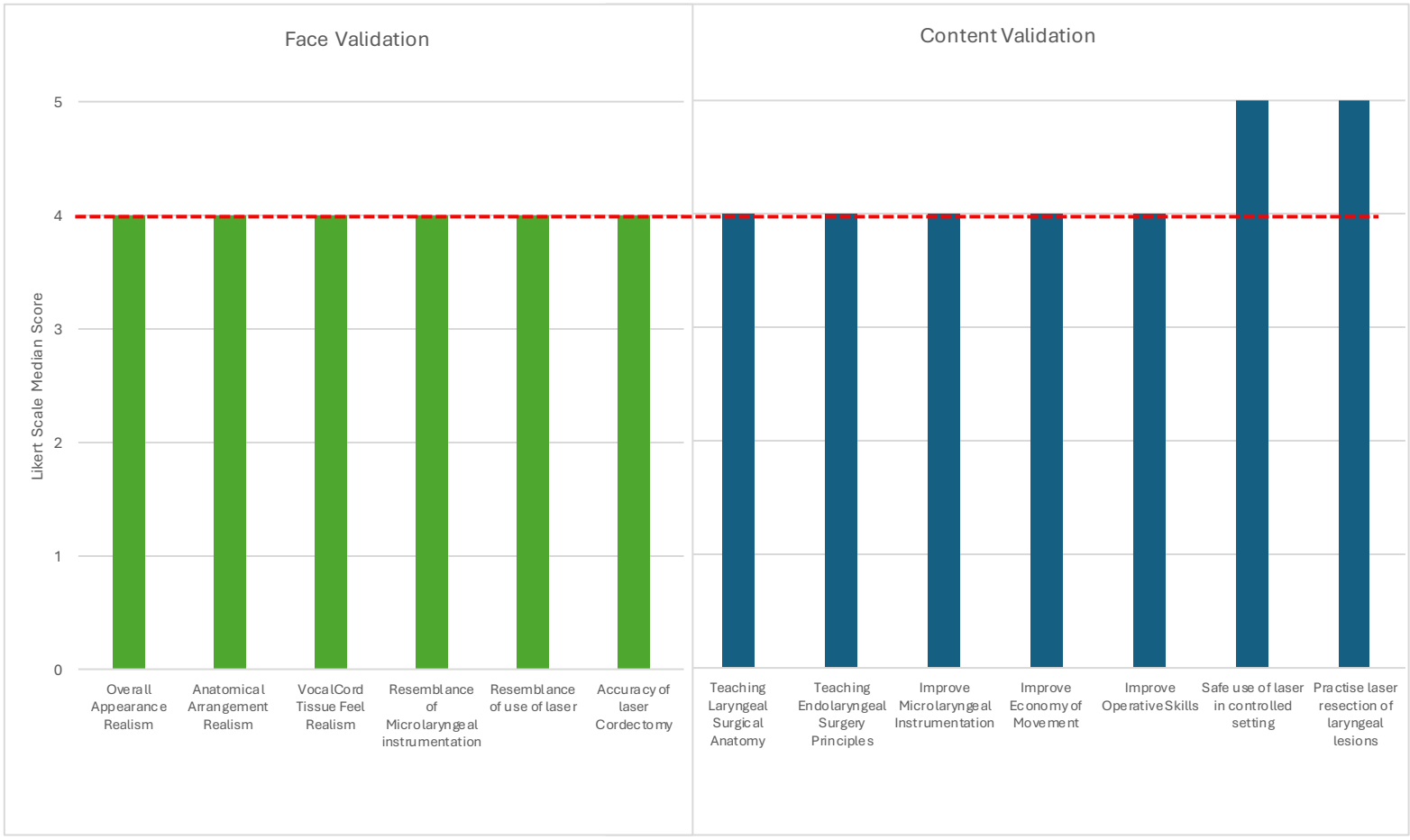
9. Hope C, Reilly JJ, Griffiths G, Lund J, Humes D. The impact of COVID-19 on surgical training: a systematic review. *Tech Coloproctol* 2021;**25:**505-20
10. Chan CY, Lau DPC. Simulators and models for laryngeal laser surgery and laser myringotomy. *Laryngoscope* 2016;**126:**2089-91
11. Bressler SE, Adkins LK, Dunham ME, Walvekar RR, Jung JP, Belgodere JA, et al. A modular surgical simulator for microlaryngoscopy using standard instruments and the carbon dioxide laser. *Laryngoscope Investig Otolaryngol* 2022;**7:**1065-70
12. Chang J, Wu X, Kahng PW, Halter RJ, Paydarfar JA. Cadaver head holder for transoral surgical simulation. *Laryngoscope* 2018;**128:**2341-4
13. Hoffman MR, Kletzien H, Dailey SH, McMurray JS. Simulation of KTP Laser-Based Zenker Diverticulotomy with a Porcine Model and Laryngeal Dissection Station. *OTO Open* 2017;**1**
14. Pankhania R, Pelly T, Bowyer H, Shanmugathas N, Wali A. A systematic review of low-cost simulators in ENT surgery. *J Laryngol Otol* 2021;**135:**486-91
15. Stasche N, Quirrenbach T, Bärmann M, Krebs M, Harrass M, Friedrich K. [IMOLA -- a new larynx model for surgical training. Education in transoral laser microsurgery of the upper airways]. *Hno* 2005;**53:**869-72, 74-5
16. Fitts PM, Posner MI. *Human performance*. Belmonth, California Brooks/Cole Publishing Company, 1967
17. de Montbrun SL, Macrae H. Simulation in surgical education. *Clin Colon Rectal Surg* 2012;**25:**156-65

18. White C, Rodger MWM, Tang T. Current understanding of learning psychomotor skills and the impact on teaching laparoscopic surgical skills. *The Obstetrician & Gynaecologist* 2016;**18:**53-63
19. Jones F, Passos-Neto C, Braghiroli O. Simulation in Medical Education: Brief history and methodology. *Principles and Practice of Clinical Research Journal* 2015;**1:**56-63
20. Dąbrowska AK, Rotaru GM, Derler S, Spano F, Camenzind M, Annaheim S, et al. Materials used to simulate physical properties of human skin. *Skin Research and Technology* 2016;**22:**3-14
21. Smith GT, Lurie KL, Zlatev DV, Liao JC, Ellerbee Bowden AK. Multimodal 3D cancer-mimicking optical phantom. *Biomed Opt Express* 2016;**7:**648-62
22. James HK, Chapman AW, Pattison GTR, Griffin DR, Fisher JD. Systematic review of the current status of cadaveric simulation for surgical training. *Br J Surg* 2019;**106:**1726-34

Figure I: Simulation set-up including laryngoscope in retort frame (a), microlaryngoscopy view (b) and theatre environment (c).

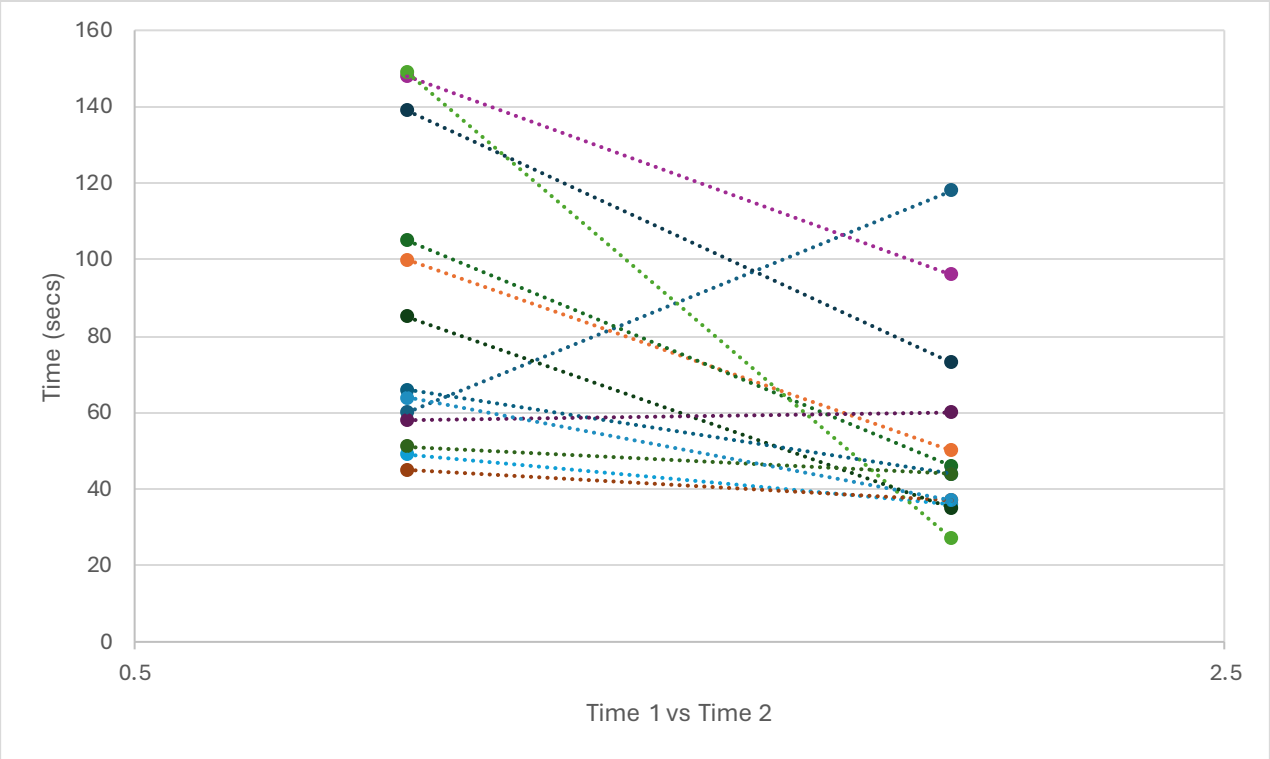
https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Figure II: Validation bar chart – Bar chart demonstrating median Likert scores for face validation questions. The validation threshold is demonstrated (red dashed line)



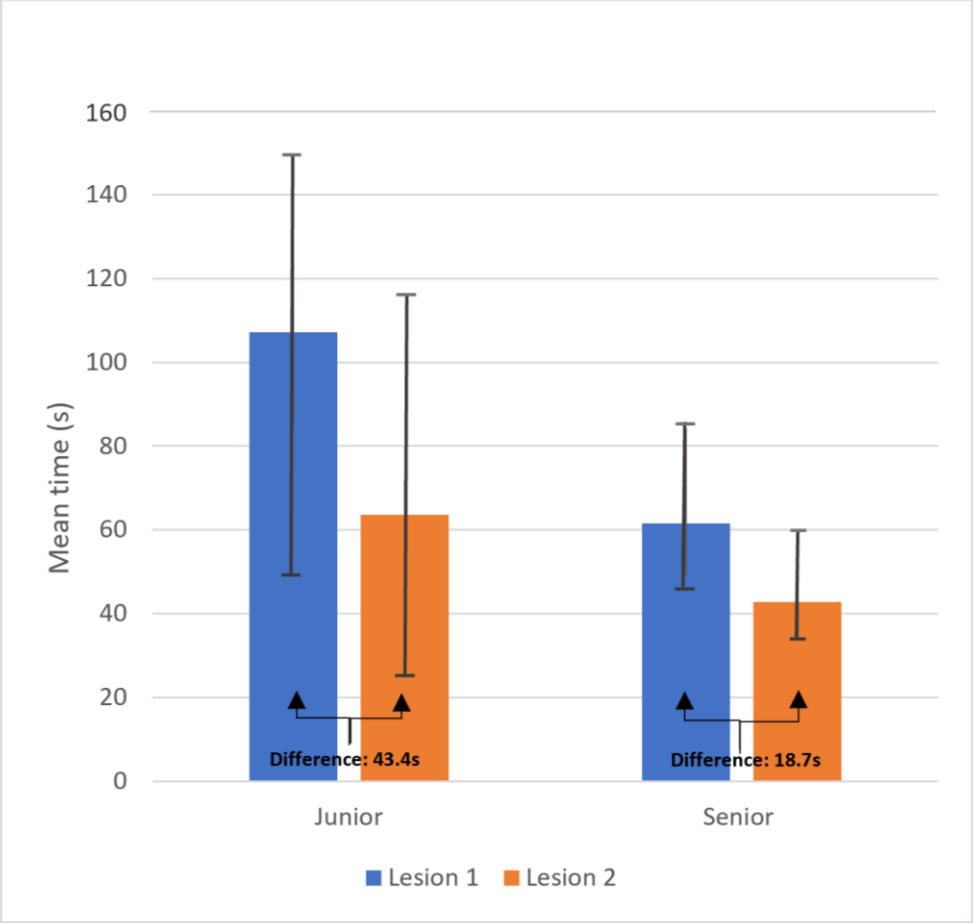
https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Figure III: Individual excision time between lesion 1 vs. lesion 2



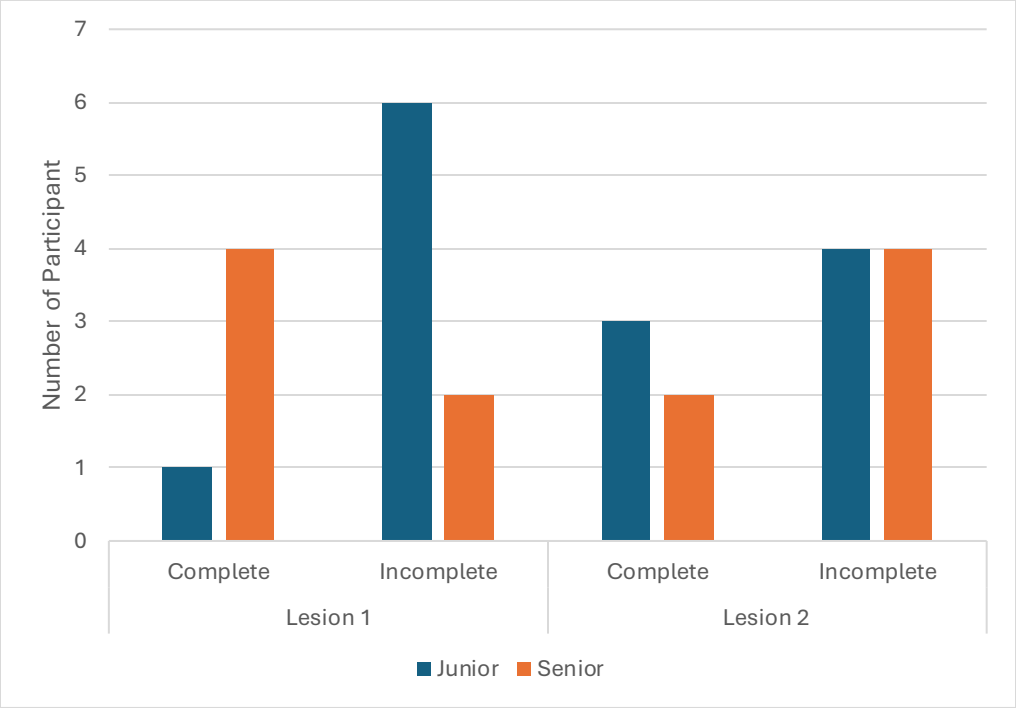
https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Figure IV: Mean dissection time, stratified by lesion and seniority



https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press

Figure V: Number of complete excisions, stratified by lesion and seniority.



https://doi.org/10.1017/S0022215124001853 Published online by Cambridge University Press