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Construct Validity of a Low-Cost Medium-Fidelity Endoscopic Sinus Surgery Simulation Model

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Objective: Assess construct validity of a low-cost medium-fidelity silicone injection molded model task trainer for endoscopic sinus surgery (ESS) training.

Methods: Fellowship-trained rhinologists, otolaryngology attendings, and otolaryngology residents at various levels of training performed sinus endoscopy and seven procedures on the model. Construct validity was evaluated by comparing novice to various levels of experienced performance using a validated checklist.

Results: Thirty-two subjects participated in this study. Otolaryngology attendings and postgraduate year (PGY) 3 to 5 otolaryngology residents significantly outperformed PGY 1 to 2 otolaryngology residents on most tasks in the task-specific checklist.

Conclusions: This study demonstrated the construct validity of the low-cost medium-fidelity ESS model.

Key Words: Endoscopic sinus surgery, simulation, three-dimensional printing, model task trainer, validation, resident education.

Level of Evidence: NA

INTRODUCTION
Simulation-based education has become an increasingly important supplemental component of surgical training. The traditional learning model for surgery involves residents observing attending surgeons in the operating room, followed by supervised practice with gradual attainment of independence. Yet, this traditional model is constrained by concerns of patient safety, limited work hours, and subjective assessment of surgical skills.1,2 Simulations allow trainees to acquire surgical skills in a safe environment that is conducive to repeated deliberate practice and objective graded feedback without the concern of patient outcomes or complications.

Supplemental skill acquisition through simulations would be particularly advantageous in endoscopic sinus surgery (ESS) training. ESS has limited case volumes and higher trainee complication rates due to the anatomical complexity of nasal sinuses.3 Different forms of ESS simulation and model task trainers are available for otolaryngology trainees of various training levels. A novice learner may acquire basic endoscopic skills using more accessible and affordable models.4–6 An advanced learner could benefit from high-fidelity models such as cadavers and virtual reality with haptic feedback.7,8 However, these latter models are constrained by high cost, high maintenance, and limited availability.

Simulation models should be validated prior to use for resident education. Validity of training devices is outlined by benchmarks that include face, construct, and content validity. Face validity is established when experts subjectively agree on whether the test meets its training objectives. Content validity is defined when experts subjectively agree on whether the test properly reflects the steps and skills used in the targeted procedure. Construct validity is defined as the ability of the test to differentiate between novice and expert performance.9

Chang et al. developed a low-cost, medium-fidelity silicone injection molded ESS model task trainer and established its face and content validity.10 The purpose of this study is to assess the construct validity of this model to establish its potential for use in otolaryngology training programs.

MATERIALS AND METHODS
A low-cost, medium-fidelity ESS model (Fig. 1) was developed for ESS technique training and detailed previously.10 In summary, the mold is three-dimensionally (3D) printed on an entry-level printer, and silicone is injected into the molds. The model can be...
constructed with relatively low active assembly time of less than 2 hours and a low per unit cost of $20.55 USD. Trainees are able to practice three-pass sinus endoscopy and seven procedures that simulate ESS procedures. These procedures are: inferior turbinectomy, maxillary sinus and frontal sinus balloon dilation, uncinectomy, maxillary antrostomy, anterior ethmoidectomy, and intranasal suturing of the middle turbinate.

Institutional review board (IRB) exemption was obtained from Georgetown University (IRB 2016-0702) and University of Texas Health Science Center San Antonio (IRB HSC20150639E). Otolaryngology residents, general otolaryngologists, and fellowship-trained rhinologists from multiple otolaryngology training programs were recruited to this study. The participants were categorized into three subgroups: 1) novice for postgraduate year (PGY) 1 to 2 otolaryngology residents, 2) competent for PGY 3 to 5 otolaryngology residents, and 3) expert for attending general otolaryngologists and fellowship-trained rhinologists. Each subject’s training level and number of ESS cases experienced were recorded.

Each participant performed three-pass endoscopy and the seven procedures on the sinus model using zero- and 30-degree endoscopes and endoscopic instruments of their choosing. The participants’ performances were recorded and marked with the corresponding participant information. The recordings were de-identified, randomized by task, and reviewed independently and in a blinded fashion by three fellowship-trained rhinologists. The recordings were graded for ESS operative competency on a Likert scale of 1 to 5 (1 = unable to perform, 3 = able to perform majority, 5 = performs easily with good flow) using the task-specific checklist (Supporting Fig. S1) developed and validated by Lin et al.11

Interrater agreement between the three blinded expert reviewers measured by Kendall coefficient of concordance indicated moderate-to-substantial agreement between the evaluators for all tasks in the checklist (range, 0.61–0.78).12 Table I shows internal consistency of the task-specific checklist evaluated by Cronbach α, which demonstrated fairly good agreement ranging from 0.80 to 0.98.

The mean Likert scores for each task in the task-specific checklist for the three subgroups are illustrated in

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**Fig. 1.** Assembled sinus surgery simulation model. (A) Outside view. (B) Labeled endoscopic view (left nasal cavity).

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### RESULTS

Thirty-two participants were enrolled in this study. Of those, three were fellowship-trained rhinologists; four were general otolaryngologists; and 25 were otolaryngology residents. Due to time constraints, two participants were unable to complete the anterior ethmoidectomy and intranasal suturing tasks. One participant lacked documentation of demographic information and was removed from the evaluation. The participants were categorized into three subgroups: 1) faculty (n = 7), 2) PGY 3 to 5 (n = 8), 3) and PGY 1 to 2 (n = 16). The PGY 3 to 5 group had an average experience of 114 ESS cases, whereas the PGY 1 to 2 group had 13 participants with no ESS experience and three participants with minimal ESS experience.

Interrater agreement between the three blinded expert reviewers measured by Kendall coefficient of concordance indicated moderate-to-substantial agreement between the evaluators for all tasks in the checklist (range, 0.61–0.78).12 Table I shows internal consistency of the task-specific checklist evaluated by Cronbach α, which demonstrated fairly good agreement ranging from 0.80 to 0.98.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Task</th>
<th>Cronbach’s α</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inferior turbinectomy</td>
<td>Identify</td>
<td>0.90</td>
</tr>
<tr>
<td></td>
<td>Cut</td>
<td>0.91</td>
</tr>
<tr>
<td></td>
<td>Straight</td>
<td>0.95</td>
</tr>
<tr>
<td>Balloon maxillary</td>
<td>Identify</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td>Balloon</td>
<td>0.90</td>
</tr>
<tr>
<td>Balloon frontal</td>
<td>Identify</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>Balloon</td>
<td>0.92</td>
</tr>
<tr>
<td>Uncinectomy</td>
<td>Identify</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>Incision</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td>Removal</td>
<td>0.90</td>
</tr>
<tr>
<td>Maxillary antrostomy</td>
<td>Identify</td>
<td>0.98</td>
</tr>
<tr>
<td></td>
<td>Removal</td>
<td>0.94</td>
</tr>
<tr>
<td>Anterior ethmoidectomy</td>
<td>Identify</td>
<td>0.81</td>
</tr>
<tr>
<td></td>
<td>Removal</td>
<td>0.93</td>
</tr>
<tr>
<td>Intranasal suturing</td>
<td>Suture</td>
<td>0.79</td>
</tr>
</tbody>
</table>

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Figure 2. There were 31 participants: seven attendings, eight PGY 3 to 5 otolaryngology residents, and 16 PGY 1 to 2 otolaryngology residents. Two participants in the PGY 1 to 2 subgroup were unable to complete the anterior ethmoidectomy and intranasal suturing of the middle turbinate tasks and were not reflected in the mean scores of the respective tasks. Participants were graded on a Likert scale (1–5) for each task. (A) Mean scores for each task in the task-specific checklist by subgroups: attending, PGY 3 to 5, PGY 1 to 2. (B) P values of Tukey pairwise subgroup comparisons of task-specific checklist scores, where symbols denote statistical significance (P < 0.05). INS = intranasal suturing; PGY = postgraduate year.

Methods

The medical educational environment is changing as educators try to apply scientific- and research-proven methods to teach surgical skills. Residents are expected to learn more in less time with the 80-hour weekly limit. Further, the current apprenticeship model of surgical training results in only sporadic opportunities to perform specific tasks. The role of simulation has generally increased in otolaryngology, although implementation into actual rhinology curricula has lagged. As such, it is important that validated simulators are available for use in resident training.

This study demonstrated construct validity of the low-cost, medium-fidelity ESS model task trainer because the model distinguishes between expert and novice performance. Attendings had significantly (P < 0.05) higher mean scores compared to PGY 1 to 2 residents in all tasks except for identification of the bulla, for which there was no significant difference (P = 0.1387). The most significant differences were seen in inferior turbinate (mean score difference 2.2586, 95% confidence interval [CI] (1.2155 to 3.3024), P < 0.0001) and uncinate incisions (mean score difference 1.7292, 95% CI (−0.867 to 2.5913), P < 0.0001) tasks. Postgraduate year 3 to 5 residents outperformed PGY 1 to 2 residents in four out of seven procedures: inferior turbinatectomy, frontal balloon sinus dilation, uncinctomy, and anterior ethmoidectomy. No significant (P < 0.05) mean score differences were identified between attendings and PGY 3 to 5 residents in any task on this model.

Discussion

The medical educational environment is changing as educators try to apply scientific- and research-proven
benefit from high-fidelity models that require anatomic knowledge such as a frontal sinus anatomy module and trainers that more closely mimic the haptic feedback of human tissue and the complexity of sinonasal anatomy. The McGill virtual reality simulator showed that senior residents significantly outperformed junior residents for the ESS performance metrics of quality, efficiency, and safety. The Madigan ES3 used a virtual reality platform with trainees, showing that those with training increased operative confidence while they reduced operative times and surgical errors. Although it would be ideal to practice on these advanced systems before stepping into the operating room, cost considerations limit availability of these trainers to most residency programs.

Cadaveric ESS simulators have high anatomical fidelity and can also be tailored for specific training goals such as cerebrospinal fluid leak repair. However, cadaver-based education can be constrained by limited availability, single-use utility, high costs, and technical staff needed for maintenance, as well as ethical and cultural concerns surrounding use of human cadavers. Sheep heads have also been utilized as a simulator due to anatomical similarity to human paranasal sinuses; however, this use faces similar constraints as the cadaveric specimen.

The advantage of the current model is that the mold is printed on an entry-level 3D printer, and the model can be easily constructed with a reasonable amount time (less than 2 hours of active handling) and low costs ($20.55 USD per two nasal cavities). Three-dimensional printed teaching resources are being developed for ESS and other specific surgical procedures such as craniotomies, cerebral aneurysm surgery, and transcranial endoscopic ear surgery. Advantages of 3D printing include creating training models for different anatomical structures and pathological conditions, which could lead to building personalized patient models for preoperative planning.

Whether using low-fidelity models, high-fidelity models, or cadavers, simulation-based education offers valuable training opportunities for trainees of various surgical skill levels. The ultimate validation benchmark (albeit rarely achieved) for a learning tool is predictive validity, defined as whether the tool can predict surgical skill performance in the operating room. Research has shown that skills acquired during ESS simulation training translate into improved performance in the operating room. The low-cost sinus surgery task trainer developed by Harbison et al. demonstrated that participants completing a simulation-based education improved their ESS checklist scores for cadaveric uncinate and maxillary antrostomy. Residents who trained with the virtual reality-based Madigan ES3 system were quicker and made fewer mucosal injection errors during in vivo ESS procedures and completed the tasks significantly faster compared to residents without Madigan ES3 training experience; however, injections are different than the actual performance of ESS. These findings provide evidence supporting the use of validated simulations in ESS training curricula. Future studies should evaluate the predictive validity of this sinus task trainer to assess the transfer of simulator-acquired skills into the operating room.

Limitations of this study include the small test group size (n = 31) leading to a wide range in the ESS experience levels within the competent subgroup of PGY 3 to 5 residents. Postgraduate year 3 residents are beginning to gain significant exposure to sinus surgeries, whereas PGY 5 residents are at their final year of otolaryngology training, operating with increased independence, and often directing junior residents. Further, this medium fidelity model appears most useful for novices rather than for those with more surgical experience in ESS. It is plausible that high-fidelity models are more useful for more experienced trainees. Additionally, this study did not address predictive validity for the transfer of simulator-acquired skills to the operating room, which is the gold standard for any simulator, although not demonstrated for the vast majority of surgical simulators. Nonetheless, the production of a low-cost and validated model that is widely available to residency programs worldwide is an important step in the right direction of encouraging use of meaningful simulation in residency training.

CONCLUSION

ESS simulators are a valuable supplement to otolaryngology resident education. This low-cost, medium-fidelity silicone injection molded sinus model has construct validity, as demonstrated by its ability to distinguish between novice and expert endoscopic operative performance.

Acknowledgment

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The views expressed herein are those of the authors and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, the Department of Defense, or the U.S. government.

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