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WILEY
Validity Testing of a Three-Dimensionally Printed Endoscopic Sinonasal Surgery Simulator

Mohamedkazim M. Alwani, MD; Thomas J. Svenstrup, BS; Elhaam H. Bandali, MS; Dhruv Sharma, MD; Thomas S. Higgins, MD; Arthur W. Wu, MD; Taha Z. Shipchandler, MD; Elisa A. Illing, MD; Jonathan Y. Ting, MD, MS, MBA

Objectives/Hypothesis: To assess the face, content, construct, and concurrent validity of the PHACON Sinonasal Surgery Simulator (SNSS).

Study Design: Prospective cohort study.

Methods: A total of 12 otolaryngology residents were recruited to perform sinonasal surgery on the simulator followed by cadaveric heads. Resident performances were recorded and de-identified. Face and content validities were evaluated based on 5-point Likert scale questionnaires. The recordings were evaluated by extramural expert rhinologists based on a validated Global Rating Scale (GRS). These results were analyzed and compared to assess construct and concurrent validity.

Results: The appearance of anatomic structures was rated as realistic by 75% of all participants, while only 30% and 41.7% rated the mucosal and bony tissues as realistic, respectively. A total of 91.7% of participants found the model useful for teaching anatomy, while 66.7% said it was useful for teaching operative technique. Construct validity was confirmed by showing significant differences in performance between the novice and experienced groups. Concurrent validity was confirmed by showing significant correlation between performance on the model and gold standard (i.e. cadaver head).

Conclusions: This study demonstrates the face, content, concurrent, and construct validity of a 3D-printed SNSS. Although this model has the potential to be a valuable tool in endoscopic sinus surgery training for otolaryngology residents, improvements are required with respect to the quality of simulated mucosal tissue as well as the simulated anatomy of the frontal-ethmoid compartment.

Key Words: Endoscopic sinus surgery, simulation training, surgical simulation, PHACON, simulator validity.

Level of Evidence: NA

INTRODUCTION

The endoscopic approach is currently considered the gold standard approach in the surgical management of sinonasal disease. Furthermore, the innovation of a wide range of telescopes and technical equipment has broadened the applicability of endoscopic sinonasal surgery (ESS). However, safe ESS continues to remain a complex undertaking due to the vicinity of the sinonasal region to the skull base and orbit. In addition to detailed knowledge of sinonasal anatomy, surgeons require a specific set of specialized surgical skills which involves the use of operative instruments and endoscopes with 2-dimensional (2D) views in a vascularized 3-dimensional (3D) labyrinth that is centered around critical structures. In light of the complexity of sinonasal anatomy and the non-intuitive nature of endoscopic instrumentation, novice trainees often face a significant learning curve prior to achieving proficiency at ESS.

The successful navigation of this learning curve in the setting of patient safety concerns presents a challenging paradigm in high-stakes surgical education. Traditionally, surgical technique has been taught by cadaveric dissection and/or intra-operative instruction. However, with the advancement of computing, materials, and manufacturing technology, several high-fidelity simulators have been developed, validated, and deployed in surgical training. Subsequently, surgical simulation training (SST) has seen an exponential rise in popularity. This is mainly because simulation training provides a low-risk, low-stress practice arena, where trainees are at liberty to develop their psychomotor and decision-making skills without the risk of poor patient outcomes.

Regardless of the design and complexity, any educational simulator must demonstrate validity as a training tool prior to formal deployment. With regard to simulation of ESS, previous studies have validated various simulation...
models using structured face validity (realism of simulator), content validity (skills transposition via simulator), construct validity (differentiation of skill levels), and concurrent validity (comparison to gold standard) studies. The purpose of this study was to assess the face, content, construct, and concurrent validities of a 3D-printed Sinonasal Surgery Simulator (SNSS) to establish its utility as a surgical training tool for otolaryngology residents.

MATERIALS AND METHODS

Simulator

The PHACON Sinus Trainer (Leipzig, Germany), consisting of a replaceable sinus module fixated in a mannequin head (Figs. 1 and 2), was utilized for ESS simulation. The replaceable sinus module was composed of synthetic tissue that mimics sinus mucosal and bony anatomy. Figure 3 provides an endonasal endoscopic view of the simulator. The simulator platform also provides an image-guidance navigation system based on computed tomography data of the sinus module (image guidance was not employed on the simulation day due to technical difficulties).

Participants

Twelve otolaryngology residents were enrolled in the simulation study after Institutional Review Board exemption was obtained. The 12 resident trainees consisted of PGY 2 to PGY 5 residents, with three residents at each level of training. Face and content validity were analyzed by all participants, while construct and concurrent validities were applied for resident trainees only. All participants had either observed, assisted, and/or performed ESS in a supervised operating room setting.
Participants had any previous experience using the sinus simulator during the course of their residency training. None of the participants had any previous experience using the sinus simulator.

Setup
Participants received a standardized orientation of the simulator, as well as an information packet explaining the goals of the study, a schedule, general instructions, the sequence of surgical steps, and face and content validity assessment questionnaires. Participants first performed a sequence of steps on one side of the simulator. Participants then performed an identical sequence of steps on a cadaver head while preserving laterality. Surgical performances on the simulator and the cadaver heads were recorded and saved for later evaluation. A key was developed to de-identify video recordings. Due to technical issues, the simulator navigation system was not utilized on the simulation day. No image-guidance was utilized for cadaver head dissection.

Table I: Modified Global Rating Scale.

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1. Uncinectomy | a. Identification of uncinate and boundaries  
b. Incision of uncinate with backbiter or sickle knife  
c. Removal of uncinate with forceps or debrider |
| 2. Maxillary antrostomy | a. Identification of natural ostium of maxillary sinus  
b. When indicated, enlargement of ostia by removal of posterior fontanelle |
| 3. Anterior ethmoidectomy | a. Identification of bulla  
b. Removal of bulla with mucosal preservation with forceps or debrider  
c. Removal of anterior cells with identification of boundaries (middle turbinate, basal lamella, lamina papyracea) |
| 4. Posterior ethmoidectomy | a. Low entrance into basal lamella with preservation of horizontal strut  
b. Removal of posterior ethmoid cells with identification of skull base, superior turbinate |
| 5. Sphenoidotomy | a. Entrance via posterior ethmoids at inferomedial triangle or entrance through natural ostium  
b. Enlargement of sphenoid ostia  
c. Demonstration of internal carotid, optic nerve location |
| 6. Frontal sinuostomy | a. Atraumatically removes bony partitions in the frontal recess  
b. Defines the skull base and orbital wall |

Table II: Face Validity Questionnaire Responses.

<table>
<thead>
<tr>
<th>Task</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>≥Agree, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Appearance of anatomical structures is realistic.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>7</td>
<td>2</td>
<td>75.0</td>
</tr>
<tr>
<td>2. The mucosal tissue feels realistic.</td>
<td>0</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>30.0</td>
</tr>
<tr>
<td>3. The bony tissue feels realistic.</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>41.7</td>
</tr>
<tr>
<td>4. Depth perception is realistic.</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>6</td>
<td>83.3</td>
</tr>
<tr>
<td>5. Instruments application is realistic.</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>6</td>
<td>83.3</td>
</tr>
</tbody>
</table>

Face and Content Validity
A five-item Likert scale questionnaire was utilized to evaluate face validity. Global content validity was also evaluated using a five-item Likert scale questionnaire. Text-specific content validity was evaluated utilizing a modified fifteen-item questionnaire. All questionnaires were completed in full by all participating trainees.

Construct and Concurrent Validity
De-identified video recordings were analyzed by two extramural fellowship-trained attending sinus surgeons. The evaluators were blinded to all participant demographics, including training level. Performances were then graded using a modified Global Rating Scale (GRS) shown in Table I. Each component of the GRS was scored on a scale of 1 to 5, with a score of 1 implying “unable to perform”, a score of 2 – 4 implying “able to perform majority of task”, and a score of 5 implying “able to perform easily with good flow”. The GRS scores were analyzed using Analysis of Variance (ANOVA) testing with mixed effects model to establish construct validity between junior trainees (PGY 2 and PGY 3) and senior trainees (PGY 4 and PGY 5). The GRS ratings on the simulator were then compared to GRS ratings on the cadaver head for each task-specific measure to assess concurrent validity using Pearson’s correlation. All statistical analyses were performed using SPSS 22 (IBM Corp., Armonk, NY). Statistical significance was defined with a p value < 0.05.

RESULTS
Face Validity
Face validity was evaluated by all participants (n = 12). Responses for the face validity questionnaire are summarized in Table II. A total of 83.3% (n = 10) of the participants agreed or strongly agreed that depth perception and application of instruments was realistic, while 75.0% (n = 9) of participants agreed or strongly agreed that the appearance of anatomical structures is realistic. However, only 30% (n = 4) of evaluators agreed that the feel of the mucosal tissues was realistic, and only 41.7% (n = 5) of the evaluators agreed or strongly agreed that the feel of the bony tissues was realistic.

Content Validity
Content validity was also evaluated by all participants (n = 12). Responses for the global content validity questionnaire are summarized in Table III. All participants agreed or strongly agreed that the simulator is useful for improving hand-eye coordination. A total of 91.7% of participants...
(n = 11) reported that the model is useful for teaching surgical anatomy and is useful as an overall training tool. Of the 12 participants, 11 participants (91.7%) agreed or strongly agreed that the simulator is useful for surgical planning, while only 8 participants (66.7%) agreed or strongly agreed that it is useful for improving operative technique.

### TABLE III.
Content Validity Questionnaire Responses.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>&gt;Agree, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global content validity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. This model is useful for teaching anatomy.</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>2. This model is useful for teaching surgical planning.</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>3. This model is useful for improving operative techniques.</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>4. This model is useful for improving hand-eye coordination.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>5. This model is useful as an overall training tool.</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Task-specific content validity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. This model helps to develop camera skills needed for ESS.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>2. This model helps to develop skills needed for nasal endoscopy.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>3. This model helps to develop basic injection fundamentals needed for ESS.</td>
<td>0</td>
<td>1</td>
<td>8</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>4. This model helps develop dexterity, accuracy, and precision with instruments.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>5. This model helps to develop fundamentals involved in maxillary antrostomy.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>6. This model helps to develop fundamentals involved in ethmoidectomy.</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>7. This model helps to develop fundamentals involved in sphenoidotomy.</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>8. This model helps to develop skills needed for frontoethmoid recess exploration and frontal sinusotomy.</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>9. Use of this model will increase resident competency when used to train residents prior to their first ESS.</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>8</td>
</tr>
</tbody>
</table>

ESS = endoscopic sinusonal surgery.

Fig. 4. Comparison of task performances by junior and senior residents to test construct validity. PGY = postgraduate year.
Responses for the task-specific content validity questionnaire are also summarized in Table III. All participants agreed or strongly agreed that the model helps to develop camera skills; helps to develop skills for nasal endoscopy; and helps to develop dexterity, accuracy, and precision with instruments. A total of 11 evaluators (91.7%) agreed or strongly agreed that the model will increase resident competency when used to train residents. Although 75% of evaluators (n=9) agreed or strongly agreed that the simulator helps to develop fundamentals involved in maxillary antrostomy, only 3 evaluators (25%) agreed or strongly agreed that the model helps to develop injection fundamentals and only 6 evaluators (50%) agreed or strongly agreed that the model helps develop skills for frontoethmoid recess exploration and frontal sinusotomy.

**Construct Validity**

Construct validity was tested by comparing the PGY 2 and 3 resident group to the PGY 4 and 5 resident group. Blinded extramural simulator evaluations of the video recordings for each resident were compared using the 2-sample t-test. The combined overall mean ± SD for PGY 4 and 5 group on the modified Global Rating Scale (GRS) was significantly higher as compared to the combined overall mean ± SD for PGY 2 and 3 group (4.1 ± 0.6 vs. 3.3 ± 0.3; P < .001). Additionally, ANOVA testing for each of the items on the validated checklist revealed a statistically significant difference between the PGY 2 and 3 group and the PGY 4 and 5 group as demonstrated in Figure 4, with the exception of sphenoidotomy.

**Concurrent Validity**

Each task-specific measure on the GRS was found to demonstrate statistically significant concurrent validity (P < .05) across performances on the cadaver and simulator as assessed by Pearson’s correlation coefficient. Anterior ethmoidectomy (r = 0.799), frontal sinusotomy (r = 0.776), and sphenoidotomy (r = 0.684) achieved the highest correlation coefficients with P values <.0001 as summarized in Table IV.

**Inter-rater Reliability**

Inter-rater agreement between the two blinded extramural evaluators was assessed using Kendall’s coefficient of concordance, which indicated a high degree of inter-rater agreement (W = 0.82).

**DISCUSSION**

In light of increasing ethical awareness, medicolegal concerns, complexity of surgical procedures, and healthcare costs, surgical trainees are encountering a new set of challenges in achieving surgical proficiency and competency within a defined training period. In order to mitigate these educational challenges, several studies across multiple surgical specialties have investigated the utility of surgical simulation training and have demonstrated positive results. This success emanates from the provision of a practice arena for aptitude testing, early skills acquisition, and advanced skills training, prior to immersing surgical trainees into the performance arena. A large component of the recent paradigm shift in surgical simulation training stems from advancements in computing and manufacturing technology which, in turn, have increased access to high-fidelity, anatomically accurate synthetic and computerized simulation models including 3D-printed and virtual reality simulators.

The PHACON Sinus Trainer provides a physical bench simulator composed of an adult-sized mannequin head that allows for the use of real-world ESS instruments, as shown in Figure 1 and Figure 2. Though not used in our study, the model can be integrated with navigation software that allows the learner to correlate a two-dimensional endoscopic image with its three-dimensional spatial orientation. The mannequin head is fitted with a “Sinus Patient” which is an individual, replaceable, 3D-printed module composed of synthetic tissue that mimics sinonasal mucosal and bony anatomy. The head’s framework is based on standard computed tomography imaging of a human specimen. The trainer provides an opportunity to simulate sinonasal surgery on a life-sized sinonasal cavern using actual surgical tools with the aim of simulating the haptic feel of a real tissue.

Although evaluators in our cohort consistently validated the appearance of anatomical structures, depth perception, and instrument application, face validity score was found to be lowest for haptic feedback from mucosal tissues. This is consistent with findings reported by Alrasheed et al., whose 3D-printed sinonasal simulator demonstrated the realism of mucosal tissue as the weakest feature. This consistency in low face validity scores for mucosal tissue haptic feedback invites further work on the part of innovators and manufacturers to explore different material compositions to simulate mucosa. On the contrary, unlike results published by Alrasheed et al. demonstrating high validity scores for haptic feedback of bony dissection, only 41.7% of evaluators in our cohort agreed that the bony tissue haptics of PHACON Sinus Simulator simulated were realistic. This difference is likely due to materials choice with Alrasheed et al. finding success with VeroWhitePlus RGD835 (Stratasys Ltd., Eden Prairie, MN). Our findings demonstrate consistently high scores for content validity, with evaluators being particularly impressed by the model’s ability to help develop: skills for rigid nasal endoscopy, endoscopic hand-eye coordination,
and judgment for choosing appropriate instrumentation. Overall, all evaluators agreed that the model is useful for developing hand-eye coordination, and 91.7% of evaluators stated that the PHACON Sinus Simulator is useful as an overall training tool. Notably, the mucosal injection module received the lowest scores for content validity. This finding is consistent with low face validity scores for mucosal tissue and was associated with the poor haptic feedback of needle penetration and planar hydro-dissection. Furthermore, the frontoethmoid exploration and frontal sinusotomy module also received low content validity scores with only 50% of evaluators agreeing that the model helps develop skills for these tasks. Although this is superior to findings reported by Steehler et al. (50% vs. 20%), there remains a significant potential for improvement on these tasks, and a minor re-evaluation of simulator design to address this module is warranted.6

Our study confirms construct validity of the simulator with senior residents (PGY 4 and PGY 5) outperforming junior residents (PGY 2 and PGY 3) consistently on all task modules, with the exception of sphenoidotomy where the opposite was true. Though the cause for this anomaly in expected results remains difficult to discern definitively, the low content validity scores for the sphenoidotomy module may be a contributing factor. Furthermore, our study also confirms concurrent validity in that level-appropriate resident performances were remarkably similar on the simulator and cadaver heads for all modules. These findings are crucial in qualifying the PHACON Sinus Simulator as a high-fidelity simulator.6,18

Limitations of this study include a small number of participants who belonged to a single training institution. This increases the potential of a response bias for face and content validity appraisal, as well as potentially compromising external validity of task performance. Furthermore, our study did not evaluate the translation of the skills gained using this simulator model in real ESS. Prospective studies are required to evaluate the transfer of skills from ESS simulation training sessions to the operating room. Additionally, interruptions during resident performances eliminated our ability to correlate resident performance times between different levels and between the simulator and cadaver. To mitigate rater bias for construct validity, two extramural expert evaluators who were blinded to participant demographics were utilized. Inter-rater reliability was determined using the Kendall's coefficient of concordance which revealed a high degree inter-rater reliability of 0.82 (a Kendall's coefficient of 1 infers perfect inter-rater reliability).

CONCLUSION
This study demonstrates the face, content, concurrent, and construct validity of a 3D-printed sinonasal surgery simulator. Although this model has the potential to be a valuable tool in endoscopic sinus surgery training for otolaryngology residents, improvements are required with respect to the quality of simulated mucosal tissue as well as the simulated anatomy of the fronto-ethmoid compartment.

BIBLIOGRAPHY