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Research Article

Digital workflow for high-risk, low-volume procedure simulation

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Abstract

Introduction: The effectiveness of simulation in medicine for teaching and assessing procedural skills is well documented; however, simulation technologies are not always available due to the high cost of simulators and lack of specific training. With the advances in digital modeling and 3D printing, we can create less expensive, more specific, and more readily available models to represent these tricky procedures, allowing for more robust training of our medical professionals.

Methods: The process begins with a radiological scan that is segmented to capture the anatomies associated with the desired condition. We tested two different methods for fabrication; one made on a multi-material poly jet printer and the other using a selective laser sintering (SLS) TPU printer.

Results: Our first method produced a model that was not adequate for our use case. The second method produced a model that worked for our use case and captured the geometry well. The SLS printer proved more durable, mechanically accurate, and feasible for simulating massive hemoptysis than method 1. This model was used in the airway management simulations with the PCCM Fellows and was deemed exempt by COMIRB 21-3067, the institutional review board of the University of Colorado Denver | Anschutz Medical Campus.

Conclusion: Our method proved to be successful in producing models that are high-detailed, inexpensive, and reproducible to teach specific medical procedures.

Keywords: 3D Printing, Bronchoscopy, Medical Education, Engineering, Hemoptysis

Introduction

For thousands of years, simulations have been used by doctors for training before performing high-risk procedures on patients [1]. Due to changes in healthcare and academic environments, as well as the introduction of new technologies, we have seen an increase in the use of simulation for education and competency assessment [2]. Recent advances in medical imaging combined with digital modeling and additive manufacturing have led to high-quality representations of anatomical structures with diverse mechanical properties to capture patient variability for education and training [3]. Despite the clinical utility of 3D-printed models, however, several technical challenges prevent their widespread adoption, particularly concerning the demanding requirements of materials for complex medical simulations.

Procedural training using simulation is of particular importance for clinical scenarios that are high-risk, such as emergent presentations of life-threatening conditions, especially when these are not frequently encountered. There are several high-risk, low-volume (HRLV) procedures that physicians completing Pulmonary and Critical Care Medicine (PCCM) training are expected to manage, however, it is unlikely that trainees will have enough exposure in the routine course of 18-24 months of clinical training to become proficient. In an attempt to provide more educational opportunities, an increasing number of programs are turning to simulation as it has many benefits, including improving technical and non-technical skills required for clinical practice and improving procedural outcomes without putting the safety of the patient at risk [4,5]. However, a review of PCCM fellowship programs across the country shows that 51.1% of respondents reported no dedicated training for HRLV procedures [5,6].

Simulation in PCCM is officially recommended by anesthesia and pulmonology societies as a standard form of education and practice [7]. There is an increase in simulation products for HRLV procedures on the market, specifically for bronchoscopy training. When reviewing these different products, Fielding et al. determined the 3 most important considerations while developing a bronchoscopy simulator are anatomical accuracy, fidelity (the degree of representation) to actual clinical scenarios, and cost. These products cover the range from low-fidelity, low-cost models to high-fidelity, technology-laden simulators with data feedback systems, which are costly at over $100,000 [8]. Many of the lower-fidelity simulators, which are more widely used, focus on a limited scope or one specific task. For the most engaging learning experience, the simulation needs high levels of realism, making the event resemble the actual clinical experience as closely as possible [9], and representing the nuanced visual and tactile cues.

Current simulation manikins are governed by the paradigm of traditional manufacturing, where the volume of units sold and the simplicity of parts determines a successful product on the market [10]. This leads to manikins that have simple representations of anatomy and only simulate procedures that are frequently encountered, including low-risk high-volume (LRHV) procedures. With design and engineering software, and the advances and availability of 3D printing, there is an opportunity to create higher fidelity modules that represent anatomy accurately and can be more specifically tailored to less common conditions. Processes like this can make the creation of complex parts more accessible and affordable, providing consumers with better options.

We propose a method that will elevate the fidelity of the current simulation products on the market by 3D printing detailed models from anatomy in a radiological scan, to create add-on models that represent less common conditions with great detail and specificity. Our method will cover the segmentation required to make the initial model, as well as the digital manipulations and fabrication choices that allowed us to successfully simulate PCCM conditions. The first clinical scenario we chose to represent was massive hemoptysis, requiring learners to perform procedures for proper airway management. The simulations were conducted with no issues or interruptions due to the model and were easy to repeat. We believe this same method can be used for other HRLV procedures seen within PCCM and other areas of healthcare, such as central venous catheter placement, intraosseous access, endobronchial ultrasound and biopsy, and pleural procedures. The evaluation of our simulation by pulmonary fellows was deemed IRB-exempt by the COMIRB 21-3067.

Methods

All imaging was de-identified sample data downloaded from 3D Slicer Medical Imaging Software (3D Slicer) [11]. The sample data and derivative models were not used clinically and therefore the requirement for individual informed consent was waived. The sample Digital Imaging and Communications in Medicine (DICOM) data was acquired from a Computed Tomography (CT) scanner. Each model consisted of data solely from one imaging session and was chosen for printing with the guidance of a Board Certified Pulmonologist.

This method followed the standard approach for generating a standard tessellation language (STL) file native to most, if not all, medical segmentation software as described in Jacobson et al. [12]. In this process (**Figure 1**) the DICOM was first cropped to isolate the desired anatomy and reduce the file size. A flood-filling threshold algorithm was used to create a mask within a desired range of grayscale values. In this process, each voxel is converted through a binary process to a solid if the value of the voxel is within the specified range. An offset tool was used to expand the mask normally to the outer mesh boundary and create a hollow feature with a defined thickness. The resulting segmentations were exported to STL using the native export module. In this process each voxel is converted to a triangle, therefore the number and size of triangles are dictated by the voxel size of the segmentation label map representation's geometry as described in Jacobson et al.

Method 1: Printing multi-materials with Objet

The resulting STL model, described in the methods overview, was imported into open-source voxel-based modeling software. As seen in **Figure 2**, a free paint mode uses local operations to edit field material properties of the underlying voxelized model while maintaining topological purity from the imported STL. It was used to create a dual material model where specific elements could be defined with different properties. Each material was exported to STL using a split isosurface mesh command, which exported isosurfaces of the material mixing ratio trimmed by the shape channel. The resulting files contained two sets of STL files representing the two material channel isosurfaces.

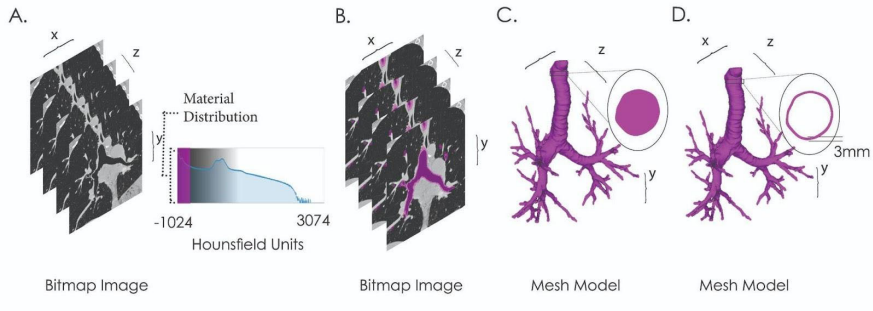

Figure 1. General workflow for the conversion of DICOM data to 3D mesh model. The model creation process begins with **a)** uploading the DICOM files from the CT scan into 3D Slicer. The scans will then go through the process of segmentation **b)** using the threshold values to mask the airway. **c)** A margin expansion operation is performed on the mesh to expand the segment beyond the airway walls, and then **d)** a hollow operation is used to define a uniform wall thickness of 3 mm.

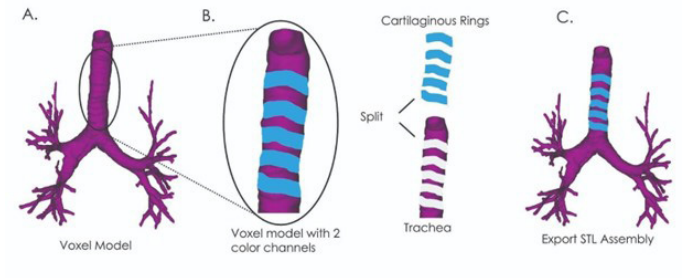

Figure 2. Workflow for multi-material methods. For method 1 **a)** the STL file was loaded into an open-source, voxel modeling software and converted into a voxel model. **b)** A free-paint operation was used to select the cartilaginous rings and change the material channel, making a two-material model. The two material channels were separated using a Split Iso-surface command and **c)** exported as two separate mesh bodies.

Models shown herein were printed on a commercially available Objet Connex 260 (three-material) printer. AgilusClear (RGD810) was used as a soft transparent material to represent the lung parenchyma while VeroMagenta (RGD851) was used to represent the rigid cartilaginous rings.

Method 2: Printing in TPU with EOS P770

The STL model created in the methods overview was imported into CAD 3D modeling software [12], where minor geometry manipulations were performed on the model (**Figure 3**). These manipulations consisted of adding a hooked coupling element and enlarging the outer surface of the opening to allow for a sleeve connected to the simulator. We ensured these manipulations would not make changes to the internal surface of the model, to keep the features true to the original data, and provide an accurate view from the perspective of the bronchoscope. The model was then connected to drip lines and an IV bag to simulate blood flow.

The successful models were used in simulations of massive hemoptysis and foreign body retrieval and tested against screen-based simulation methods with a group of Pulmonary fellows by COMIRB protocol 21-3067.

Results

The DICOM images were loaded into 3D Slicer and cropped down to isolate the airway of the patient. The cropped files were segmented to the 3rd pulmonary branch generation by using the flood fill tool with an intensity tolerance = 30 Hounsfield value units and a neighborhood size = 0.8 pixels, this resulted in a solid mask representing the inner surface of the airway. Using the margins and hollow tool, we expanded the mask by 3 mm and shelled the model defining the wall thickness as 3mm. This created a 3D model while still preserving the details of the internal wall that the bronchoscope will view.

For method 1, the STL file was imported into Autodesk Monolith [13], a voxel-based modeling software, so we could separate the model into two materials. The free paint function was used to define the cartilaginous rings as a separate model, which was then separated using a split isosurface command, creating two STL files. With an assembly of two STL files, we imported the model into GrabCAD Print and defined the material properties such that the cartilaginous rings would be a 70:30 mix of veroMagenta to Agilus and the airway body would be solely Agilus.

Method 2 produced models of adequate detail and more resilience. The resulting model was printed on an SLS Printer EOS P770 with the EOS TPU 1301 material. The TPU 1301, per manufacturer specs, has a shore hardness of 95A and elongation at a break of 250%. The post-processing of the model required air blasting to clear out the bulk of the powder, and multiple water baths to remove the final layers of fine particles. Because of the properties of the TPU and the geometry of our model, we were able to simulate the compliance of bronchial tissue while still holding the form of the airway (**Figure 5**). This allowed for a more appropriate feel while maneuvering and placing tools like the flexible bronchoscope and the bronchial blocker. Another benefit of the laser-sintered TPU is that it creates a watertight model, and when printed with closed tips, our airway was able to hold fluid. This was important for our

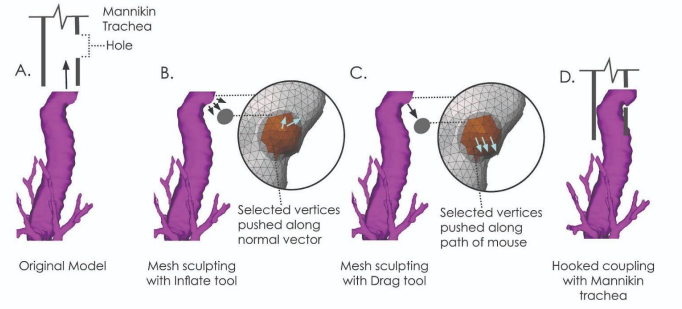

Figure 3. Manipulating the mesh to improve connection to the simulation mannikin. The 3D printed model needs to connect with the upper airway of a simulation mannikin **a)** but the original model had no easy, reliable method of maintaining that connection. By using some mesh sculpting tools like **b)** inflate and **c)** drag, we created a hook coupling to fit through the hole present in the mannikin trachea **d)** and can withstand axial forces from the bronchoscope.

simulation of massive hemoptysis, as it allowed us to control the flow and direction of fluid through the model, simulating blood flow in the airway.

The 3D printed model was integrated, post-printing, with IV drip needles into the tips of the 3rd generation pulmonary branch following the methods laid out in Osswald et al [6]. These IV needles were connected to a standard clinical IV bag with drip rate limiters. This IV bag was filled with a mix of saline, cornstarch, and dye to simulate blood.

As a test case, we partnered with our collaborator in PCCM to put together a multipart simulation event for training the fellows on lower airway emergencies where the airway model was utilized to simulate the management of massive hemoptysis and foreign body retrieval. For foreign body retrieval, an airway was mounted on a board, and learners practiced retrieving foreign objects using a bronchoscope and retrieval tools. For the simulation of massive hemoptysis, a simulation manikin (Laerdal SimMan 3G) provided the representation of the upper airway but did not have a visually accurate lower airway. Our 3D-printed model connected to the manikin's upper airway just below the vocal cords, creating a seamless transition from upper to lower airways, from the point-of-view of the bronchoscope. The manikin was set up in a hospital bed in the intensive care unit and was connected to IV tubing carrying fake blood. A script for three different scenarios was created by a Board Certified Pulmonologist, designed to test fellows on multiple skills required for proper clinical management. Fellows were split into groups of 2 or 3 and each took turns as the lead clinician for all scenarios. In each round, the fellows were evaluated by 2 board-certified pulmonologists on their management of the clinical scenario. Because of the design of the airways, the simulation of massive hemoptysis was easily adapted to each scenario by changing the input of flow of fake blood into various IV tubing lines. This simulation allowed fellows to practice identifying the source and location of the bleeding, and to intervene using clinical tools. Procedures performed on the manikin and airway model included endotracheal intubation, mainstem bronchus intubation, bronchoscopy, and placement of endobronchial blockers.

A survey was conducted after the simulation was complete, and the results demonstrate the effectiveness of engaging learners and improving understanding as compared to other educational methods such as screen-based simulation. **Figure 7** shows the results of the survey.

Discussion

For each model that was printed using Method 1, we observed problems with color saturation, material fatigue, and delamination between material assemblies. The mixing ratios of Agilus30 Clear and VeroMagenta did not linearly translate to the corresponding visual and mechanical results. As a result, the models required a significantly higher ratio of VeroMagenta before becoming visually apparent, as seen in **Figure 4**. This resulted in a stiffer material and more brittle model with 2 orders of magnitude difference in elastic modulus. In our attempt to represent the cartilaginous rings with a higher durometer material, we saw issues of delamination at the interface of the two materials after minor wear and tear. Such models may be appropriate for applications requiring fine and delicate precision training, where breakage and tear is a critical metrics to test. The workflow described here solves problems that constrain traditional biomedical 3D-printing approaches, including the introduction of thresholding artifacts, time costs with segmentation, computationally limited file sizes, the artificial filtering or obscuring of data, and the inability to print small-scale variations in optical transparency and mechanical gradients. Although the models used in this study successfully mimicked grayscale gradients present in native tomography data, recent advances in high-spatial-resolution CT and MRI scanning, photorealistic volumetric rendering algorithms [14], and full-color bitmap-based printing approaches will allow much more life-like 3D-printed depictions of patient-specific anatomy and is an area of active research.

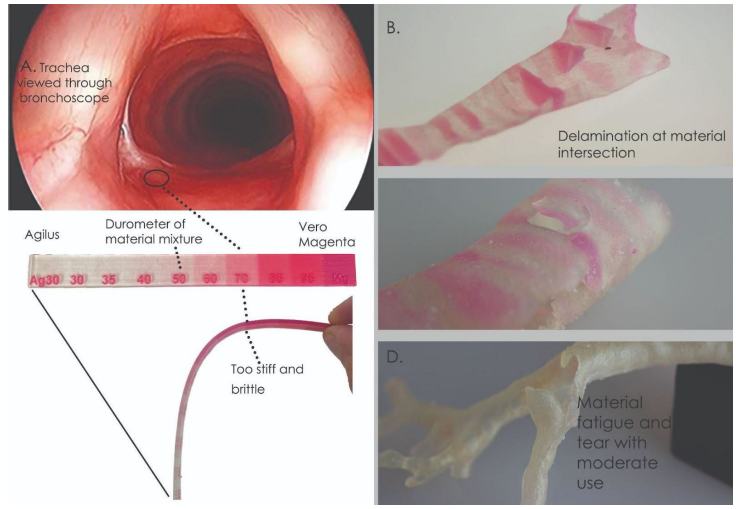

Figure 4. Exploration of color saturation and material mixing with Agilus30 and VeroMagenta materials. The target pigment was chosen from an image taken with the bronchoscope **a)** that represents healthy tissue of an airway. We printed a sample strip that demonstrates the final look and feel of the two materials being mixed at different ratios. The results of mixing these two materials led to multiple failure modes in the final model **b-d)**.

Method 2 produced geometrically accurate models with the appropriate form and rigidity to withstand our use case (**Figure 5**). A benefit of this style of printing is that it can create water-tight models which allow us to manage fluid flows for our simulation of massive hemoptysis. Simulating a complex procedure can be difficult with many moving parts, but with our system, we were able to run multiple clinical scenarios with bleeding from different sites without having to manipulate the model in between (no additional connections/disconnections, no removing and replacing the model, etc.) The model seamlessly allowed for smooth flow through the clinical scenarios (**Figure 6**), creating realistic stress and high cognitive load for the fellows learning to navigate through the airway under pressure. The fellows were provided a survey after the simulation to better understand their experiences and how they compared to screen-based simulations. While 68.75% of the fellows agreed that screen-based simulations are helpful, 94.11% said that they prefer physical 3D model simulators over screen-based equivalents. The 3D model simulation excelled at improving the spatial-temporal ability of the fellows, and making the simulation and experience more lifelike, with respective scores of 4.59, 4.76, and 4.94 on the Likert scale. This initial data support the use of 3D-printed anatomical models for simulation because it gives students a hands-on, lifelike experience while learning the nuances of a specialty procedure. To further improve our data, we will need to run more simulations and collect more survey data.

With the various styles of 3D printing (SLS, FDM, PolyJet, etc…), we demonstrate the ability to represent characteristics important to simulation, such as visual accuracy with multiple colors and material compliance for tactile procedures. As 3D printers become more widely available, workflows like this will help to fill the gap in medical education, allowing for more detailed and specific experiences for procedural training. By lowering barriers to the visualization of fine details in bio-realistic 3D-printed models, we hope to broaden access to this technology for a wide range of medical professionals and patients. While our work has established the workflow for the simulation of massive hemoptysis and foreign object retrieval, the same process can be applied to many other HRLV procedures like intraosseous access, central venous catheter, endobronchial ultrasound and biopsy, and various pleural procedures. When combined with high-resolution biological imaging data, multi-material medical 3D printing has the potential to improve training, enhance communication, and open new research avenues in precision medicine.

Our method of 3D-printed patient-specific models for clinical training demonstrates the ability to create precise and realistic medical simulations of complex issues. By incorporating patient-specific data with a digital modeling and fabrication workflow we demonstrate the extensibility and adaptability of our process to numerous situations. Furthermore, the digital process described herein can impact the function of the final 3D-printed model without modifying the topological fidelity, the extent of which can vary widely as a function of the fabrication strategy employed and/or the skills of the operator utilizing the simulation model.

Conclusion

Here, we have shown a method for designing and fabricating higher fidelity add-ons for simulation mannequins, to improve the training of fellows in HRLV procedures within PCCM. As

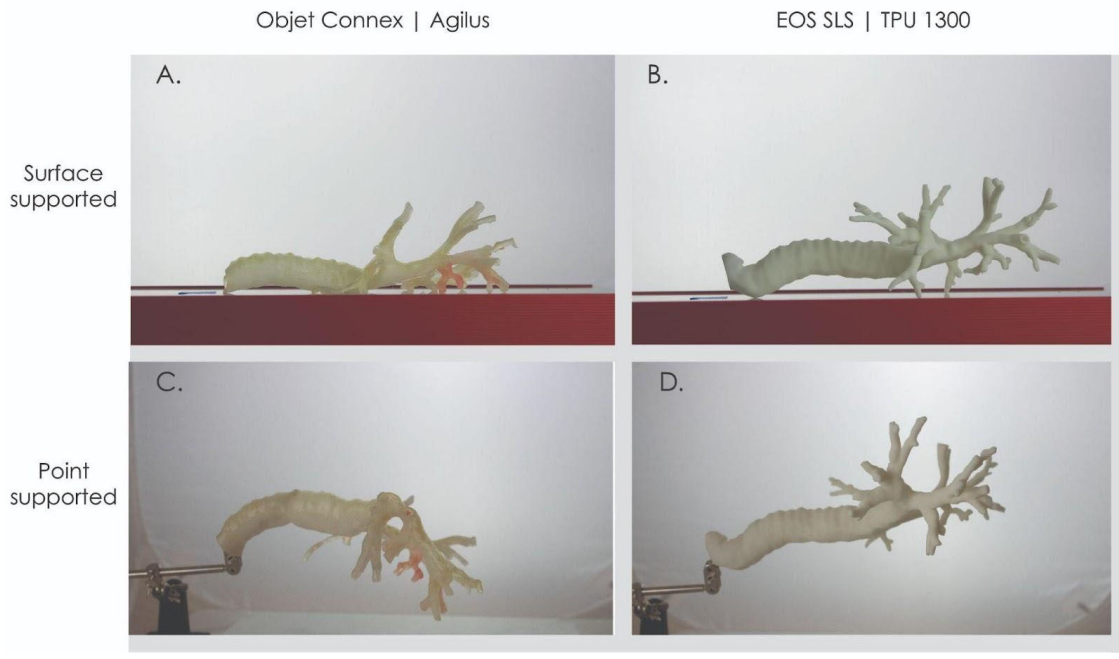

Figure 5. Comparing the printed models from each method. Although the geometry was the same, the models behaved in very different ways due to the materials. With the model laying flat on a surface **a)** we see that the multi-material model cannot keep its shape and collapses under its weight, unlike the **b)** TPU model. Similar results are seen when the models are held at one end **c-d)**.

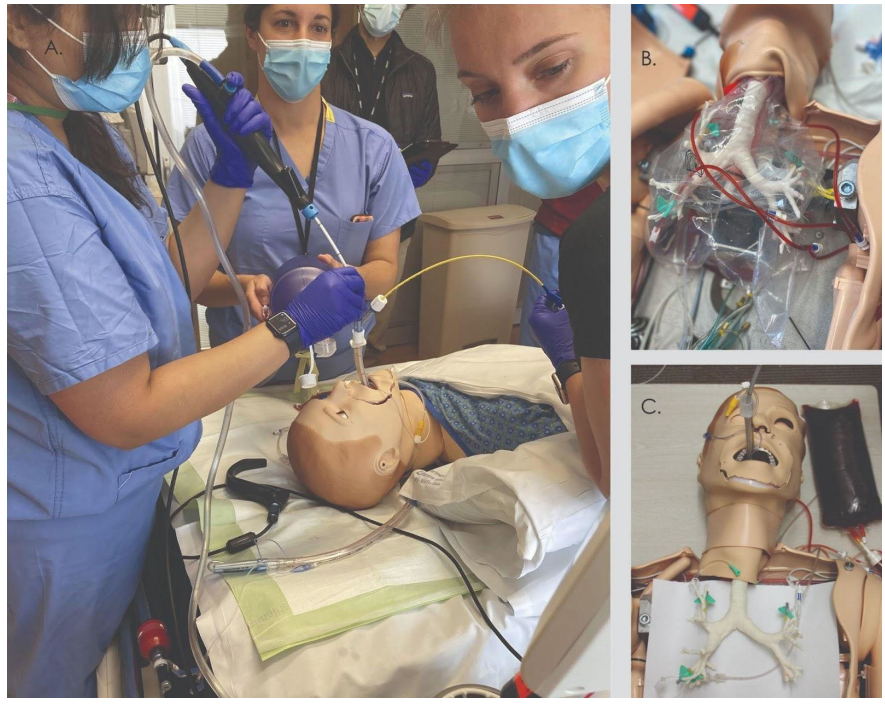

Figure 6. Live simulation with a group of PCCM fellows being evaluated by a Board Certified Pulmonologist. Multiple clinical scenarios were conducted with the **a)** mannikin in an ICU bed. The airway model was placed inside the mannikin and **b)** connected to the upper airway. A blood bag with a drip line was connected to the airway model at one of the three defined sights.

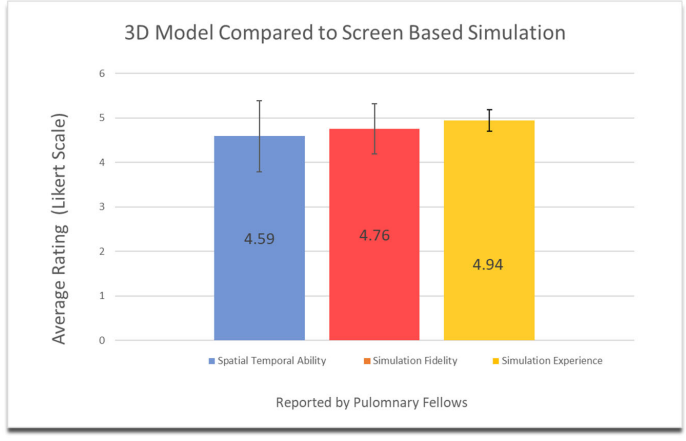

Figure 7. Survey results from Pulmonary Fellows. The Fellows were asked a series of questions relating this 3D model simulation experience to their experience with other modalities of learning (2D images, screen-based simulation, etc.) The responses were analyzed and displayed to show the general trends of the group.

simulation becomes an increasingly important part of procedural education, we must find ways to improve access to higher-fidelity learning tools, to improve medical education and patient outcomes. With the use of design and engineering tools and 3D printing, we were able to create a workflow that will allow for an accurate representation of anatomy for more detailed and specific training of less common, but extremely important procedures. This data has shown that our methods improved the educational experience and engagement as compared to traditional, screen-based simulations, but will require further research to understand its effectiveness in improving competency overall.

Acknowledgments

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Author Disclosure Statement

Nothing to disclose.

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