Driving Innovation in Pediatric ENT

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Customizing Surgical Simulation Using 3D printing

Surgical Simulation

Surgical simulation has become more widespread in response to a call for standardization of surgical training and implementation of competencies into the surgical curriculum. At the same time, there have been significant improvements in simulation technologies, allowing more realistic simulators. The premise of surgical simulation is very attractive - the trainee is allowed to practice a skill in a low pressure environment while decreasing risk to patients. It would also open the door to objective measures that can assess surgical trainees' experience levels. Current methods of assessing if a trainee has experience performing a procedure relies on the number he or she has performed during residency., a distinction that is unclear due to self-reported number of procedures done.

To determine if the surgical simulator is adequate for training, validation must be performed. This evaluation must dissect different aspects of the model to assess for face and construct validity. Face validity is the subjective measure of how physically similar the simulation is to real-life [1]. Construct validity measures whether the simulation tests the skill it is supposed to test. In the past, construct validity has been measured by time to completion of a given procedure or surgical skill. Decreasing times meant that the simulation was working, or that it held some construct validity[2]. This posed an issue, as the time to completion may not reflect the overall quality or mastery of a skill. It is recommended that outcome parameters for measuring simulator validity should be based on the analysis of expert surgeons' decisions and actions during procedures [3]. It is not uncommon to compare the performance of an experienced surgeon versus a novice to adequately assess for construct validity. Regardless of the simulator, the ultimate goal is whether the simulation can improve resident education and patient outcomes.

The objective of this chapter is to describe the new developments and recent implementation of 3D printing methods in surgical simulation in pediatric otolaryngology

3D Printing

Additive manufacturing, or 3D printing, is a relatively new technology that was initially developed in the early 1980s. In 1984, Chuck Hull of 3D Systems Corporation filed a patent for a prototype system based on the process known as stereolithography. Hull is credited with creating the STL (STereoLithography) file format that is widely used in 3D printing software. Recently, the price of 3D printers has decreased significantly, as low as $100 for certain consumer models (Peachy Printer). Cost of materials have also decrease significantly over the last 5 years. Common 3D printing materials range from $0.048/g for acrylonitrile butadiene styrene (ABS), to $0.107 for high impact polystyrene (HIPS) [4]

The process of 3D printing begins with modeling, with most clinical applications relying on high resolution CT or MRI scans. Data from these scans is exported to 3D printing software and converted into STL files. These files are translated into code instructing the printer to construct the object in 3 dimensions in a layer-by-layer method. Most printers typically print at 100 um (250 DPI) thickness per slice, although printers exist that can print as thin as 16 um (Objet Connex 3D Printer, Stratasys).

After modeling, the materials to be used must be considered. The materials available are different depending on the type of 3D printer. The most commonly used printers in simulation of bone and soft tissue of the head and neck involve fused deposition modeling printers and inkjet-like 3D printers. Fused deposition modeling printers use plastic wire usually one to two millimeters in diameter fed through a heating element and extruded onto flat working surface. The extruded plastic immediately cools and hardens, and a 3D object is created in a layer-by-layer manner. Inkjet printers use various powders or resins that are finely sprayed and set using UV light.

Both types of printers have advantages and disadvantages, based on the application. Fused deposition modeling printers are more limited in their selection of materials, mostly hard plastics that are suitable for simulating bony tissue. The inkjet printers use materials of a greater variety of textures and softness, as well as realistic color reproduction. These types of printers are better suited for the fabrication of soft tissues, such as mucosa or septal cartilage, although the reproduction of these tissues is still not very visually realistic.

With certain applications, supporting material is needed to fill space. Any stalactite-like structure requires supporting material, because during the printing process part of the model would be unsupported. This material is typically removed mechanically or dissolve chemically after printing. In cases where the supporting material is encased, such as within the mastoid air cells, it cannot be evacuated until during the dissection of the model.

Some applications make use of 3D printed molds later casted using silicone. This allows for relatively inexpensive simulation of soft tissue, whereas direct printing of soft tissues requires more expensive equipment and materials.

Shore Hardness

Materials used for 3D printing are often characterized based on their Shore durometer rating. Shore durometry is a measure of the hardness of a material, which may generally be defined as a material’s resistance to permanent indentation. The scale was originally defined by Albert Ferdinand Shore, who developed a device used to standardize testing of material hardness in 1920.

Several different scales exist for measuring durometer to accommodate for materials with different properties. For example, comparing a hard plastic material with a soft, rubbery material would produce misleading results if they were judged on the same scale. The ASTM D2240-00 testing standard calls for a total of 12 scales, depending on the intended use. Each scale rates a given material with a value between 0 and 100, with 100 indicating the maximum hardness level for a given scale (**Table 1**).[5]

Table 1. Shore Hardness Scales of household materials

	Extra soft	Soft	Medium Soft	Medium Hard	Hard	Extra Hard
Shore **00**	0 10 20 30 40 50 60 70 80 90 100					
Shore **A**	0 10 20 30 40 50 60 70 80 90 100					
Shore **D**	0 10 20 30 40 50 60 70 80 90 100					
Household items	Gummi Candy gel sole	rubber band	eraser	tire tread	shoe heel	hard hat

The actual value produced by a scale correlates directly with the depth of indentation in a material after application of force. The basic Shore test device uses a hardened indenter, a calibrated spring, a depth indicator, and a flat presser foot. Different scales will vary the maximum force applied and indenter shape as appropriate for the material to be tested. The most common scales used are A and D. Scale A is the durometer scale most appropriate for soft, vulcanized rubbers and other elastomeric materials. Scale D is more appropriate for hard plastics, such as the plastics used in protective headgear used in construction. For the purposes of choosing materials to mimic human tissue, a lower shore hardness value correlates with softer tissues, such as cartilages or mucosa surfaces. Higher shore hardness values correlate with bony tissue.

FDM Print Materials

ABS is a commonly used material for 3D printing (**Table 2**). It is a polymer composed of varied proportions of 3 monomers: acrylonitrile, butadiene, and styrene. Changing the composition of each component alters the characteristics of the end product, making it possible to alter the heat-resistant or durability properties of the material. For the purposes of 3D printing bone and other hard biomaterials, ABS is very attractive. It has a glass transition temperature of about 105 Celsius, meaning that it is able to be extruded from a 3D printer nozzle at that temperature and then quickly cool into a more solid state. The resulting material is rigid, making it effective for applications such as hard casings of electronics or human temporal bone models. A major downside of ABS is the strong odor and harmful gas released when heated, such as with an otologic drill.

Table 2 Shore Hardness Scale values of silicone rubber used in 3D printing.

Material	Shore Hardness
ABS	75 **D**
HIPS	50 **A**
PLA	80 **D**
SE	10 **A**

Another popular material used in FDM 3D printers is polylactic acid (PLA). This material differs from ABS in numerous ways. The material itself is derived from corn starch, is easier to print with, and does not produce noxious fumes when heated. It also may be mixed with many different materials to alter its characteristics in a way that ABS cannot. For example, PLA may be mixed with finely milled chalk to produce a material which can mimic stone (LAYBRICK, CC Products). PLA is slightly less stable in hot temperatures due to its glass transition temperature of 60 Celsius.

Filler Materials

One technical drawback of 3D printing is that free hanging structures cannot be printed without supporting material. For example, if a printer were trying to print a stalactite-like structure, the inferior tip of the stalactite would be unsupported by anything during printing. This is addressed by the use of supporting materials printed in void spaces that can be dissolved with solvents that will not dissolve the primary building material. High impact polystyrene (HIPS) is used with ABS prints and may be dissolved with limonene. Polyvinyl acetate (PVA) is used with PLA prints and may be dissolved in water.

Inkjet type Printers

There is a greater variety of materials that are available for use with inkjet-type printers. These printers use powder cartridges that are deposited in layers and set using UV light. Models resembling soft tissue cartilage has been created using plaster powders [6]. Furthermore, these printers tend to have a wider range of material colors to choose from, but they are still not able to accurately capture the visual appearance of human flesh. These printers are also costlier to use than their FDM counterparts, both because the printers themselves and the materials used for printing are expensive. The types of powders and resins that exist are too numerous to describe in detail, and many formulations are proprietary and not readily publicized.

Applications

Educational model for myringotomy and tympanostomy tube insertion.

Myringotomy is one of the most common surgical procedure performed in pediatric patients. Various simulations models have been developed ranging from high fidelity to low cost low fidelity. Our designed a model using a combination of 3D printed structures and 3D printed molds for silicone (**Figure 1**). The model has several different configurations due to its modularity, to account for variations in patient anatomy, such as external auditory canal diameter and angle of the tympanic membrane. This allows the instructor to customize the model depending on the skill or experience of the student. We designed our to replicate all steps of the procedure including removing ear wax and suctioning the middle ear fluid. This allowed us to experiment with different viscosities of fluid to adequately simulate middle ear effusions.

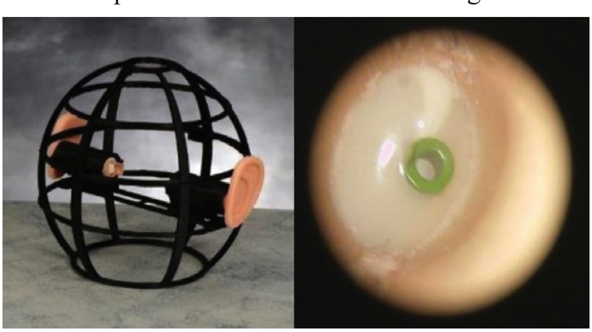

Figure 1. Image of modular Tympanostomy tube simulator.

The particular model created by our group used polylactic acid (PLA) for the direct printing process, as well as casted silicone rubber. This method bypasses one of the weaknesses of FDM printing, which is the ability to print with materials similar to soft mucosal tissue. The only directly 3D printed component of the simulation model was the head-shaped holding frame. A high performance silicone was used to replicate the soft tissue of the pinna and tympanic membrane. The parts were all designed based on previously described anatomic measurements using a Solid Edge ST7 CAD system (Siemens, Plano, Texas). The group used a Makerbot Replicator Desktop 3D Printer, a fused deposition modeling type 3D printer, to create the cast of the external auditory canal and molds for the silicone rubber components. The goal of the model was to develop a highly realistic inexpensive, modular and reusable simulation model. The total cost of the model was $32.16 for all the components. The tympanic membrane is the only non-reusable component of the model, but it only costs $0.07.

Validation was performed using a 14 item questionnaire relating to face and content validity. The results reflected favorably upon the myringotomy model.

Pediatric Laryngeal Simulation model

Another relatively new application of 3D printing is in the simulation of complex pediatric airways. Critical airway cases are relatively rare, providing residents with few opportunities to familiarize themselves with the associated challenges. Moreover, some pediatric airway conditions are so uncommon that a resident may not see an" adequate" number of cases during their training. Current airway simulation models are designed for acquisition of basic skills, using manikin models which are stiff and less flexible tissue as compared to a real patient. Current available models are designed to practice intubation and bronchoscopy rather than procedures that require cutting and suturing since the models are expensive and their parts not disposable. We developed our 3D printed model to accurately represent soft tissue characteristics, while replicating pediatric specific airway conditions such as laryngomalacia, subglottic cysts and laryngeal clefts (**Figure 2**).

The model was also created using a combination of direct 3D printed structures and casted silicones. A fused deposition modeling type printer was used to create the directly printed structures and the molds. The model was adapted from a CT scan and then processed using 3D-Slicer Software 4.0 (Cambridge, MA).

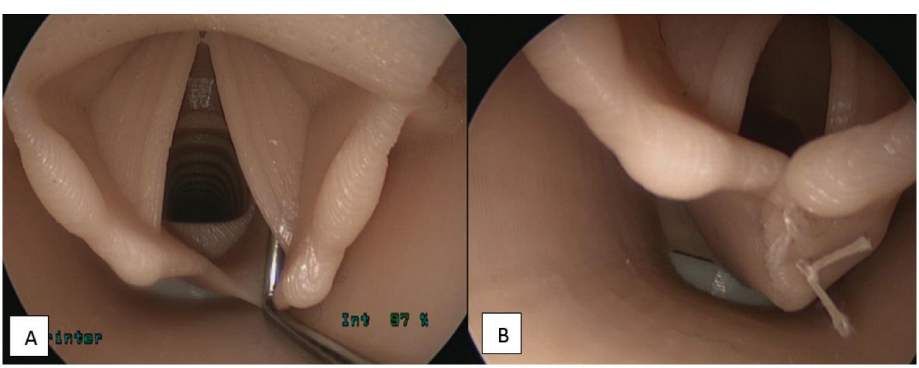

Figure 2. Image of a Type 1 laryngeal cleft before and after repair.

Various abnormal airway conditions were developed based on this initial model, including laryngomalacia, laryngeal cleft, subglottic stenosis, and subglottic cysts. Validation of this model was done using a 12-item Tissue Likeness Scale which was developed taking into consideration laryngoscopic procedures.

Orofacial Cleft Repair Surgery Simulation

Orofacial clefts are the most common congenital birth defect, with approximately 1:600 children born affected by this congenital malformation. The surgery is very complex, requiring ambidexterity that may only be acquired through many hours of practice. Traditionally, trainees are given experience intraoperatively. However, this can increase operative time by as much as 104% We developed a new 3D cleft palate model that uses a combination of directly printed bony structures and casted silicone rubber to simulate mucosa. The hard palate is made of PLA, and molds of the soft palate and mucosal surfaces were made and filled with silicone rubber (Dragon Skin) (**See Figure 3**). To develop a high fidelity model the tensor veli palatini (TVP) was simulated using silicone elastomer and its tendon hooking around the Hamulus. The neurovascular bundle exiting the greater palatine foramen was also included in this model. [7]

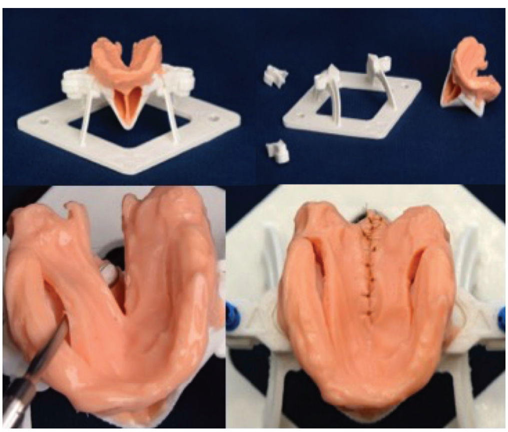

Figure 3. Image of cleft palate simulator.

Major upsides to this model include the relatively inexpensive price of $10. Validation was done subjectively by otolaryngologists after they performed a von Langenbeck palatoplasty to repair the incomplete cleft palate on the model.

Temporal Bone Simulation

Temporal bone simulation using 3D printing is perhaps the most established form of surgical simulation in pediatric otolaryngology. The anatomy of the mastoid air cells is extremely complex and crucial to understand in otologic surgery that requires dissection of the temporal bone [14-16]. Most authors use CT scan data imported to 3D printing software. Materials can vary widely and depend on the types of printers available to an institution. The more complex models use a variety of different materials of different colors in order to simulate important anatomical structures such as the facial nerve or sigmoid sinus [8]. Face validity of this model was accomplished using a 9 point Likert scale questionnaire with 10 items.

Some authors opted to use the common ABS plastic used in many 3D printing applications [9] with HIPS used as supporting material. Multiple problems appeared in their model, perhaps the most concerning being the noxious smell created by the heat exposure of the otologic drill. The major advantage to using ABS is that the printers that can use ABS are relatively inexpensive, as well as the material itself. The 3D printers used to create better validated models containing different colored structures within the model may be as high as $60,000 [10] and used proprietary powder and resin materials that cost >$400 per canister [11]. We believe, however, there are ways of decreasing the costs of the models by combining different manufacturing techniques with 3D printing.

One author demonstrated the use of surgical simulation by an established otolaryngologist performing surgery on a challenging 8-year old case [10]. A model of the child's temporal bone was created based on CT scan data and then printed using an inkjet-type printer that utilized materials of varying properties to allow for simulation of hard and soft tissue. The model was found to be an accurate representation of the patient's anatomy, as noted by objective measurements of the distance between important landmarks. No formal validation study was performed on this model. Overall, the internal fidelity of 3D printed models is accurate [12] and should be considered a useful adjunct to cadaveric dissection.

Other Applications

A novel application is the use of 3d printing in simulation of auricular reconstruction [13]. Currently, the most common technique for auricular reconstruction is carving an auricular cartilage framework from autogenous cartilage. However, significant morbidity can be associated with technical errors in carving, there are few opportunities for trainees to gain experience performing this procedure. There are other currently existing options for simulation of this procedure, which include various root vegetables, cadaveric costal cartilage, or dental impression material. 3D printed costal cartilage is used to simulate this tissue, with the advantages including a patient-specific simulation, more realistic materials, and reduction in cost.

A high-resolution CT scan was obtained from the patient, which was then converted and exported to a 3D modeling software. A negative model was created based on this exported CT scan. The negative model was then 3D printed. The 3d printed negative model was this filled with varied mixtures of silicone and pure cornstarch. The model was validated by 3 independent microtia surgeons, which were defined as individuals having performed at least 50 microtia reconstructions. The surgeons rated the 2:1 silicone: starch ratio as being superior to both the 5:6 ratio and MEMOSIL-2, a dental impression material that has previously been used for similar applications [5, 8].The model was determined as being superior to existing models with greater tissue likeness using a 5 point Likert scale.

Mono-material paranasal sinus phantom for endoscopy training

Endoscopy sinus surgery simulation first originated from a study done by Yamashita *et al* in 2004 [17]. The model consisted of 5 components made of plastic that are assembled into a complete model of the sinuses. Users commented positively on the training model as compared with a cadaver or real patient. The phantom cost $2000 USD.

Another model developed more recently is the SIMONT (Sinus Model Oto-Rhino Neuro Trainer, Recife, Brazil), which includes two special materials that simulate both bony and soft tissue, as opposed to the Yamashita model. It involved a 3D printed model that is able to be used for endoscopic sinus surgery simulation with navigation. The material used to simulate soft tissue structures was Neoderma, a material with mucosa-like properties. SIMONT costs $400-$1000.

Similarly, another model developed by Ossowski *et al* [18] was found to improve procedure performance time in medical students trained on the model as opposed to students not trained on the model. The students that received training using the model also demonstrated a reduction in pain in the procedures done on real patients, as compared to non-trained students.

This phantom was 3D printed using ABS, then several artificially introduced fiducial markers were placed in various locations within the model to help with endoscopy-CT registration [6]. The major advantage to this model as compared to predecessors is its cost. The model was qualitatively assessed by endoscopic sinus surgery surgeons using a zero-degree rigid endoscopy. There were no objective measures taken to validate the model's use among surgical trainees.

Conclusion

The technology behind 3D printing in surgical simulation is still in its infancy, relatively speaking. The most popular consumer 3D printers available, as well as the most affordable, have only been around since 2009 (Makerbot Cupcake CNC). The relative paucity of new developments on the topic of this chapter is a reflection of its novelty. Currently validation studies done using 3D printed prototypes vary widely in their criteria. We recognize that there has yet to be a standardized tool for assessing a 3D printed module's effectiveness in resident education.

Furthermore, there exists a limitation on the types of materials available for use in 3D printing. FDM printers are somewhat restricted in printing softer, more pliable materials. Powder or resin inkjet printers are still fairly expensive and may not replicate how tissue looks visually. As a result of these limitations, surgical simulations have been restricted in the types of cases that are able to be simulated and the fidelity of the models. Despite these limitations, 3D printing has had a promising role in the training of residents and will only become better with time.

One of the fascinating aspects of 3D printing is the open-source nature of the technology, meaning that "prints" are available as digital files and may be freely used by anyone. This may allow large multi institutional studies using the same model and may allow the best models to become part of a standardized curriculum. A cornerstone of 3D printing has been that the free flow of ideas afforded to us by computers and 2D printers should be accessible in 3 dimensions. Limited access to medical education and restrictions on cadaver usage in some parts of the world may make aspects of surgical training difficult or impossible. While gaining experience through performing procedures on real patients will never be able to be replaced by this technology, it may become an integral way for the medical community to share ideas or create new technologies. It may also allow for standardization of resident training by allowing for realistic and inexpensive assessment modules. The technology is promising and will hopefully lead to great advances in the medical field as a whole.

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