

Neonatal Intubation Simulation with Virtual Reality and Haptic Feedback

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Abstract

Respiratory distress syndrome (RDS) is a common breathing disorder among premature neonates. Endotracheal intubation is often required to establish a secure airway in these critically ill neonates. Successful intubation, an extremely difficult procedure to perform, requires significant practice and skill. Due to limited clinical opportunities to intubate neonates and ineffective simulation training methods, better training strategies are needed to learn intubation skills. Current training methods, including video instruction and intubation performed on plastic mannequins, fail to emulate the high-stress delivery room environment and the precision required to intubate neonates. Thus, a more realistic training strategy would likely increase physician competency and potentially improve clinical outcomes. Virtual reality (VR), an innovative tool now being used in medicine, provides a realistic method to visually immerse trainees in a non-physical, yet responsive environment. Incorporation of haptic feedback devices allows somatosensory feedback to provide life-like physical sensations. We speculate that medical VR simulations with haptic feedback represent the future of medical training. Integration of a well-designed virtual environment with haptic devices that mimic the neonatal intubation procedure will provide a cost-effective, superior training experience that may improve patient outcomes.

Table of Contents

I. Introduction	3
II. Background 3D Slicer Solidworks Blender Unity	5 8 9 10 11
III. Preliminary Designs Virtual Reality Headsets Standalone VR headsets: Oculus Rift Mobile phone VR headsets: Samsung Gear VR	12 12 12 13
IV. Preliminary Design Evaluation Virtual Reality Headset Design Matrix Proposed Final Design	14 14 17
V. Fabrication Spring 2018: Materials Methods Spring 2018 Prototype Fall 2018 Materials Methods Future Work Testing	19 19 19 21 23 23 24 35 37
VI. Discussion	38
VII. Conclusion	39
VIII. References	42
 X. Appendix A. Problem Design Specifications B. Downloaded Files C. Estimated Costs 	46 46 48 49

I. Introduction

Respiratory distress syndrome (RDS) is characterized by difficulty breathing in neonates and is the leading cause of death for newborns [1,2]. In the U.S. in 2015, infant mortality rates were nearly 6%, with 13.4% of those deaths attributable to RDS [3,4]. Around 7% of infants experience respiratory distress worldwide, with domestic rates closer to 1% [2,5]. RDS prevalence in neonates can range from 10-60% depending on gestation age, with increased rates in premature infants [2,6,7]. According to the World Health Organization, in 2005, nearly 10% of all births were premature, with higher numbers in lesser-developed countries, and it is expected that this number has increased due to a rise in the frequency of Cesarean section procedures [8]. Given the current state of medical technology, these numbers seem surprisingly high.

Currently, RDS is treated via a variety of methods including surfactant replacement therapy, oxygen therapy, and breathing support from a nasal continuous positive airway pressure (NCPAP) machine. For each of these methods, it is often required that a neonatal intubation procedure be performed [9]. While each method is accompanied by its own additional difficulties, neonatal intubation is a difficult procedure to perform. Neonatal intubation must be performed quickly, precisely, and gently. Failure to comply by these guidelines can result in suffocation, tissue damage, or even head trauma [10]. According to a variety of studies, neonatal intubation attempts are often unsuccessful, especially among residents (as would be expected). One study listed success rates of resident intubations as low as 24%, while that of fellows and consultants was closer to 80% [11]. Other studies revealed similar results [12,13].

According to an expert in the field, Dr. Ryan McAdams, one of the primary reasons for poor outcomes is the lack of adequate training methods for physicians. Current methods are mainly restricted to video demonstration and intubation practice on neonate

mannequins [14,15]. Video demonstrations can be useful, but do not emulate the high-stress environment of the delivery room, and do not involve any physical manipulations. Similarly, the hard shelled mannequins with easily identifiable vocal cords, and the stress free environment in which practice intubations are performed provide a poor representation of the actual procedure. Based on the low success rates in residents, it is obvious that these methods are not sufficient and effective training comes primarily from experience. Thus, it would be extremely beneficial to develop more effective and accessible training methods that could improve patient outcomes.

Virtual reality (VR) is an emerging tool in clinical medicine with functionalities ranging from medical training to pain management [16]. Current methods are usually limited to VR alone, but 3D Systems (Rock Hill, SC) produces cutting edge simulations which incorporate haptic feedback devices [17]. The use of haptic feedback motor arms allows developers to give virtual objects apparent physical properties by providing force feedback when an individual "touches" an object in virtual space with the motor arm stylus. VR with haptic feedback provides a possibility to create a wide variety of advanced medical training methods, which will allow for the development of realistic and effective medical training, encompassing the future of medical procedural training. Successful implementation of devices like these could reduce medical training costs, increase patient outcomes, advance medical treatments, and provide avenues by which effective medical training could be implemented in less developed regions of the world.

Neonatal intubation is a difficult procedure with poor patient outcomes, and an increase in procedural efficacy provides an opportunity to substantially decrease infant mortality rates. Current training methods including video instruction and intubation on neonatal mannequins are seemingly inadequate based on procedural success rates among medical residents [11-13]. An advancement in training techniques is thus desirable, and VR with haptic feedback provides a promising alternative to current training methods. The development of a novel VR simulation

that incorporates haptic feedback to accurately emulate a neonatal intubation procedure could greatly improve patient outcomes, reduce medical costs, and expand medical training capabilities far beyond its current state.

II. Background

Dr. Ryan McAdams, our client and chief of neonatology at University of Wisconsin Hospital, is seeking a VR system incorporating haptic feedback to provide a method of neonatal intubation training for emerging physicians. Dr. McAdams has a great deal of experience in this area, having completed a fellowship in neonatology in 2005, and having performed intubations across the globe in parts of Asia and Africa as well as the United States. He stresses the importance of proper preparation before attempting to perform intubations oneself.

Prior to conducting a neonatal intubation firsthand, it is critical that residents and practicing physicians alike receive sufficient training. It is common for preterm infants to weigh less than five pounds [18], leaving these underdeveloped neonates in an incredibly fragile state. The physician's dexterity and precision is vital in preserving an infant's health when performing intubation. The procedure must be conducted gently yet quickly; if performed carelessly, brain bleeds and tracheal scuffing are possible [10]. If done too slowly, the neonate could suffocate [10].

Though technically challenging, intubation is a straightforward procedure, typically requiring around 20 seconds to perform [19]. First, the newborn is laid face-up, with a raised support beneath its shoulders. The head is then tilted upwards, exposing the larynx, and a laryngoscope blade is inserted into the mouth with the nondominant hand. The tongue is scooped or depressed until the vocal cords are visible. Finally, with the dominant hand, the endotracheal tube is inserted through the vocal cords into the trachea, the stylet is removed,

and the tube is secured, allotting a steady flow of oxygen to the lungs via a respirator [20]. See Figure 1 for a visual depiction of a neonatal intubation.

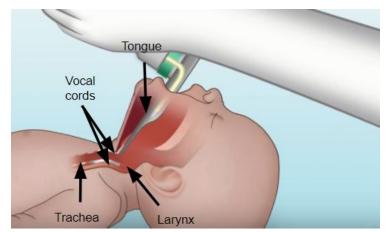


Figure 1: A diagram illustrating the anatomy of an infant's mouth and throat during a neonatal intubation. During insertion, tilting the head is important to keep the pathway to the trachea unobstructed [18].

This procedure is typically rehearsed using roughly proportioned neonate mannequins, which can cost more than \$1000 [21] and do not offer sufficient anatomical accuracy or lifelike texture. Virtual simulations with haptic feedback could offer a promising alternative, allowing precise yet alterable anatomical features to be constructed using CAD software and made tangible via haptic systems.

VR, most commonly used in video games and flight training simulations, has also been used to provide additional realism to medical simulations [22]. The Oculus Rift, manufactured by Oculus (Menlo Park, CA), is regarded as the leading piece of VR display technology in the industry, and is commonly paired with the Unity game engine made by Unity Technologies (San Francisco, California) [23]. While innovative, this technology is not an effective means of procedural training by itself; tactile sensation is necessary when developing the muscle memory and confidence sufficient to conduct a successful operation. Haptic feedback fills this role. Designed to relay intuitive analog feedback to a user's physical input, haptic devices have applications in a wide variety of fields. Haptic technology has become a popular feature in automobiles, video games, and military simulations because of its capability to increase the user's proprioceptive awareness [24]. Unsurprisingly, haptic-driven medical simulations are not a new concept. Haptic feedback devices have been used to quantify the efficacy of virtual procedures performed by physicians as a method of minimizing surgical error. Virtual procedural simulations using haptic feedback have existed for at least ten years, integrating haptic devices manufactured by SenseAble Technologies (Woburn, MA) with detailed models of the human body to give physicians a highly anatomically accurate and consistent method of honing their skills [25]. Systems such as these, which incorporate visual, auditory, and somatosensory feedback, have been successfully implemented in laparoscopy and prostatectomy [26, 27].The PHANToM Touch (now owned by 3D Systems) was one of the first haptic devices available on the market, allowing the user to "feel" virtual elements along a single point of contact manipulated via a stylus integrated with a responsive motor arm [24]. See Figure 2 for a depiction of the PHANTOM Touch.



Figure 2: The image depicts a PHANToM Touch (3D Systems), comprised of a handheld stylus attached to a motor arm. The device interacts with an independent computer running Geomagic software via USB [28].

The PHANToM Touch and its successors, the PHANToM Touch X and the PHANToM Premium, remain the most commercially popular haptic feedback systems on the market and dominate the playing field in medical VR simulations [29,30]. We will be using the PHANToM Touch to simulate procedural motions and generate feedback during VR simulation.

The force feedback provided by the PHANToM stylus is subjective, depending on the pseudo-physics integrated by the developer. A perfect physical simulation using a haptic device is impossible due to its finite processing capabilities. However, algorithms are capable of approximating a wide variety of physical materials. Compressible materials (such as human tissues) are inherently more complex to model than incompressible ones due to their dynamic physical properties, but have been approximated sufficiently to create artificial skin [25].

In order to develop realistic 3D models for the simulation, a series of development platforms must be used. Each platform will be used in conjunction with its strengths and weaknesses: 3D Slicer, a powerful image processing software, will be used to render 2D computed tomography (CT) images into 3D images. Solidworks and Blender, which are used for 3D modelling, will be used to further refine and synthesize props for the virtual environment. Finally, Unity's powerful physics engine will combine all of the virtual components, providing physical attributes to the neonatal model and integrating haptic feedback into the simulation.

3D Slicer

3D Slicer is an open source software platform that is designed for image processing, medical image informatics, and three-dimensional visualization [31]. It can be used for viewing and manipulating 3D Dicom data for integration into 3D modelling software. For this project, it was used to view CT and MRI scans of a neonate's head and upper respiratory tract. The data was segmented into regions of interest such as the trachea and tongue using a manual segmentation tool which allows the user to define

regions of interest (ROIs). Once defined, the ROIs were further refined using built in functionalities such as the thresholding tool which allows the user to extract pixels within a certain intensity range. Once segmented, the ROIs were exported as 3D .STL files. Each 3D model (MRI- and CT-generated) was imported into Blender as separate objects. There, they were refined and will be integrated into a single neonate, with physical constraints (such as joints) pre-defined. It is worth noting that it is critical to import the different anatomical regions as separate objects into Blender because this will allow us to give each object different mechanical properties. Once complete, this process will allow for creation of an anatomically correct neonate model with a mechanically accurate internal anatomy.

Solidworks

Solidworks, manufactured by Dassault Systèmes (Vélizy-Villacoublay France) is a computer aided design software that is free to UW students and used extensively in the medical field to create realistic 3D models. Solidworks has a wide range of advanced surfacing features that will be useful when creating rigid, non-anatomical features within the virtual simulation, such as the virtual tools that the physician will use. Solidworks also supports 2D Drawing, 3D Modeling, Parametric Modeling, Photorealistic Rendering, and 3D viewing. Additionally, Solidworks has 21 writable file types, allowing for compatibility with a wide range of software [32]. See Figure 3 for an example of a SolidWorks model.

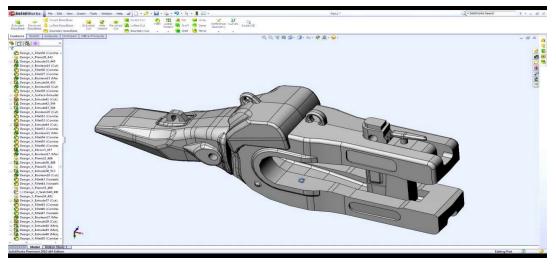


Figure 3: A 3D model created in Solidworks [32].

Blender

Blender (Amsterdam, Netherlands) is a free, open source software used to create visual effects, animation and interactive 3D models [33]. Thus far, Blender has been used to synthesize a realistic 3D model of a neonate for use in the simulation; the exterior skin of the neonate file, which was downloaded from the web, was refined in Blender (and is still in the process of being refined). The internal upper respiratory tract, however, was first isolated in 3D Slicer from CT and MRI data, then exported as a 3D model and subsequently refined in Blender. Blender has also been used to mesh, rig, and texture the final model. Meshing, or the process of converting 3D images into 3D objects, unifies adjacent pixels into sections that can be manipulated as a collective whole. Meshing also entails manually editing the object in order to give it a more realistic shape. The process of rigging provides the model with realistic joints. While rigging, specific sets of vertices are assigned as "bones", which allows the user to set physical constraints which device the relative motion of the different parts of the mesh. The entire bone structure (which would be the entire skeleton in humans) is referred to as the

armature. Finally, texturing will provide the model with a surface "skin" representative of a real neonate, including coloration of the face and interior. Once finalized, the neonate model can be saved as a .blend file and imported directly into Unity.

Unity

Unity is the world's leading real-time gaming/development engine and is used to create half of the world's games [34]. Unity will be used to create the virtual environment and run the simulation. Ultimately, Unity will integrate 3D models made in Blender and Solidworks and allow users to interact with them in real time in a way that emulates the real procedure. Unity plugins and scripts combine the functionality of the haptic device with the properties of the 3D models in the virtual environment [35].

III. Preliminary Designs

Virtual Reality Headsets

There are a wide range of headsets available that are used to create the display in VR systems. They generally fall into two categories: Standalone VR headsets and Mobile phone VR headsets. Standalone headsets tend to be more realistic but more expensive, while mobile phone VR headsets are generally cheaper and feel less realistic.

Standalone VR headsets: Oculus Rift

There are a few standalone VR headsets currently on the market but the Oculus Rift, shown in Figure 4, is the most reasonable for our budget. The Rift costs \$400-500 and has an OLED display. This display has a resolution of 2160 x 1200 pixels and a refresh rate of 90 Hz. The field of view is 110 degrees and has an 8 x 8 feet tracking area when using three sensors. The Rift also comes with custom motion tracked controllers known as Oculus Touch. The controllers have a joystick and button setup that allow for simple gesture mapping based on how the user is holding the controller [37].



Figure 4: An Oculus Rift headset. Dimensions: 184 x 114 x 89 mm [38]

Mobile phone VR headsets: Samsung Gear VR

The most popular mobile phone VR headset is the Gear VR, developed by Samsung (Seoul, South Korea). The Gear VR headset, shown in Figure 5a, costs \$99 but requires a Samsung phone, shown in Figure 5b, to operate, which would increase the price slightly. The super AMOLED display has a resolution of 2560 x 1440 pixels with a 60 Hz refresh rate. The field of view is 96 degrees. The Gear VR headset comes with a remote that allows the user to point and click in the Virtual environment; however, this remote lacks motion tracking capabilities [37].



Figure 5a: Samsung Gear VR Headset. Dimensions: 208 x 123 x 99 mm [39].



Figure 5b: A Samsung phone used with the Gear VR [39].

IV. Preliminary Design Evaluation

Design Criteria (weight)	Oculus Rift	Samsung Gear VR
Cost (35)	2/5 (14)	5/5 (35)
Resolution (20)	4/5 (16)	5/5 (20)
Refresh Rate (20)	5/5 (20)	3/5 (12)
Cranial Tracking Ability (15)	5/5 (15)	4/5 (12)
Versatility (10)	3/5 (6)	4/5 (8)
Total (100)	71	87

Virtual Reality Headset Design Matrix

Table 1: VR headset technologies are compared based on a variety of criteria.Total weight is out of 100.

<u>Cost:</u>

Overall weight: As shown in Table 1, cost is the most important factor because of our client's limited budget. In full-scale production, high-quality headset hardware would be paramount to the product's success. In this stage of development, though, a relatively simple proof-of-concept prototype will suffice. Additionally, a low overall cost will make the system more globally accessible. Cost is weighted at 35% of our total matrix.

Score Rationale: The Samsung Gear VR headset is cheaper than the Oculus Rift by around \$400. Samsung is also more widely established and accessible globally. The Samsung Gear VR earns 5/5 in this category, while the Oculus Rift earns 2/5.

Resolution:

Overall weight: High resolution is vital in making a simulation feel lifelike. Furthermore, neonatal intubation is an incredibly precision-oriented procedure, and visibility issues could compromise the user's experience. Again, however, a proof-of-concept device does not need to operate at full functionality.

Score Rationale: The Samsung Gear VR headset received a higher score because the Samsung Galaxy S6 resolution is higher by 42 percent, with newer phones emerging with even finer resolution [37]. The Oculus Rift is limited to only one resolution. The Samsung VR headset scores 5/5 due its greater resolution, leaving the Oculus Rift with a 4/5.

Refresh rate:

Overall weight: A high refresh rate prevents lag and buffering while simulation is taking place. Refresh weight has been evaluated at 20% of our total matrix.

Score Rationale: In this category the Oculus Rift has a higher refresh rate by 50%, earning it the edge in this category. The Samsung VR headset earns a 3/5 while the Oculus Rift earns a 5/5.

Cranial tracking ability:

Overall weight: The ability to accurately follow the motions of the user's head is highly dependent on the system's hardware. Cranial tracking ability will be crucial in positioning

one's point of reference. The ability to position oneself in VR should be as effortless as possible, as in real life.

Score Rationale: The Oculus Rift has more precise proprioceptive capabilities than the Samsung VR earning it a score of 5/5. Despite this, the Samsung VR still does an excellent job tracking movement, yielding a score of 4/5.

Versatility:

Overall weight: Versatility is evaluated in regards to the headsets interfacing capabilities. In order to emulate a realistic virtual environment, a multitude of third-party softwares will likely need to be incorporated into the virtual system. Thus, the headset needs to be compatible with all software ranging from the gaming engine to the haptic device. In many circumstances, compatibility issues can be worked around, however, earning this category a weight of 10.

Score Rationale: The Samsung Gear VR headset is connected to Google Play, the open-source app store offered by Android. Oculus Rift, however, is run from a Windows operating system. This gives the Samsung Gear VR headset access to a wider range of third party tools and plugins that are not available on a Windows computer.

Proposed Final Design

The final neonatal model will be developed in Solidworks, Blender, and 3D Slicer. Unity, the 3D Systems Touch haptic device, and Samsung Gear VR headset will be used to create the VR simulation and environment. Unity will also be responsible for handling the pseudo physics and material property information sent to the haptic device. This device works alongside 3D Systems OpenHaptics software to attribute physical properties to objects in Unity. OpenHaptics will essentially serve as the liaison between the game engine and the Phantom Touch. When a collision occurs in the virtual environment, OpenHaptics will receive the information and communicate with the Phantom Touch to provide the proper force feedback to the user's hand. Finally, the Samsung Gear VR headset will be used in tandem with a Samsung phone to generate the display. A computer will provide the processing power necessary to run these programs, and the display will be sent to the Samsung phone for projection.

Due to the complex nature of this project, it is worthwhile to reiterate the workflow of the system. Figure 6 shows a flowchart which explains the relationship between all of the various software packages that have been used thus far in the design. Starting from just a CT scan of a neonates inner anatomy, the scan-generated 3D model is then passed into Blender where it is refined. After development is complete in Blender, the file will be imported into Unity where the various virtual objects will be able to interact with one another to make a reactive simulation. Finally, the haptic feedback device is used to allow the user to interact with the 3D environment.

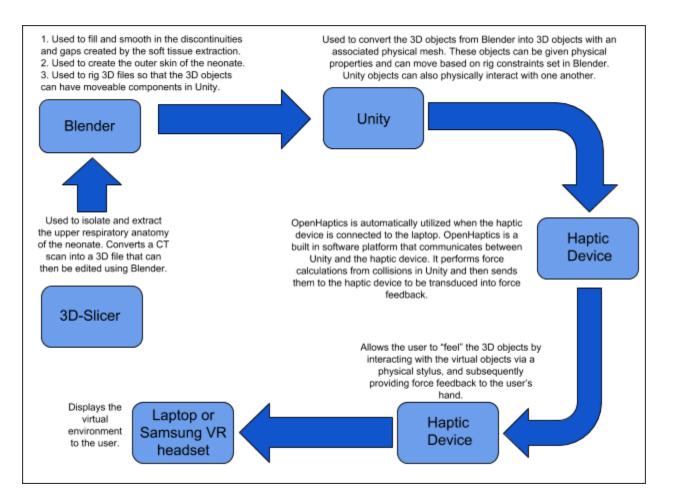


Figure **6**. Diagram illustrating what each software was used for and how they all relate to form our product.

V. Fabrication

Spring 2018:

Materials

In the Spring of 2018 our team began developing a prototype virtual operating room environment using Solidworks, Blender and Unity. Additional realism was added by incorporating medical props available for download at no charge on the internet.

Solidworks, downloaded for free from the UW Campus Software Library, was used to create the simulation's endotracheal tube. Blender, another free software, was used to reorient a virtual character's arms before importing them into Unity. A free version of the powerful game development platform was used to stitch together virtual components into a 3D environment.

A variety of other virtual objects were downloaded from the internet as well. A laryngoscope model and a pair of arms were downloaded for free. Similarly, the Morgue and DeKit assets were downloaded from the Unity Asset Store at no cost. These models were subsequently used to create the final prototype environment. A list of the downloaded files can be found in Appendix B.

<u>Methods</u>

We began constructing the virtual environment using Unity. The room itself was defined as an oblong rectangular prism, while its floor, walls, and ceiling were distinguished by altering their color. We provided the floor a tiled texture by repeatedly inserting small squares separated by thin gaps on all sides. Most props were simply

imported, resized, and placed into the simulation as RigidBody entities. However, some props required more specific alterations.

The user's arms were first reoriented in Blender to more precisely replicate a first-person perspective. Once imported into Unity, the arms' orientation were made dependent on the camera's position, providing the impression that the arms belonged to the user. As downloaded, the arms were flexed which did not appear natural as shown in Figure 7. They were modified to be extended which created a more realistic first person view as shown in Figure 8. Rough hitboxes were defined around the arms to allow the user to interact with RigidBody items.

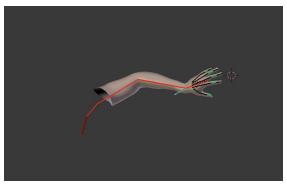


Figure 7: As downloaded, the arm was flexed, appearing slightly awkward and impractical.

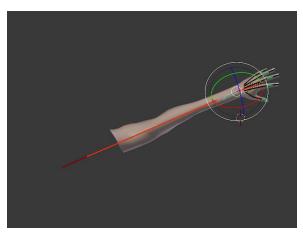


Figure 8: The modified arm model is extended, and more visible from a first-person point of view.

Rather than a RigidBody entity, the deformable sphere (Figure 9) was modelled as a series of vertices and springs. 386 vertices and 1964 springs were used. An arbitrary spring constant was experimentally derived to give the sphere deformable properties. Currently, the sphere is not intended to replicate any aspect of the procedure; it is simply intended to act as a foundation from which we create a semisolid comparable to the tissue found within the respiratory tract of a neonate.

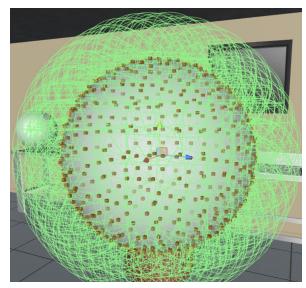


Figure 9: The deformable sphere, pictured above, is comprised of 386 vertices (brown squares) connected by a network of 1964 springs (green threads), whose stiffness can be altered by adjusting Unity's arbitrary spring constant value.

Spring 2018 Prototype

The mock operating room created last spring (Figure 10) includes various props including an operating table, doors, lighting, laryngoscopes (Figure 11), an endotracheal tube (Figure 11), and a deformable sphere (Figure 12). The deformable sphere will be used as a basis for the soft tissue models that will be necessary to create a neonate with realistic textures. Additionally, the arms described above and pictured in Figures 9 and 11 are the main way the user interacts with the environment.



Figure 10: A first person view of the OR scene.

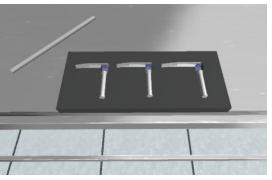


Figure 11: Close up of models for the laryngoscopes and endotracheal tube within the OR scene.



Figure 12: The deformable sphere before and after colliding with the hands.

<u>Fall 2018</u>

Materials

This semester our team began to develop the anatomy that will be used in the final simulation, one of the most time-consuming tasks that must be completed in order to construct the final design. Specifically, we began to refine and rig (give bone-like properties) the outer skin of the neonate, which was modified from a downloadable file on free3d.com [39]. Furthermore, we reconstructed CT and MRI scans of an actual neonate's upper respiratory tract, which were obtained from the client. After comparing the CT- and MRI-generated models, our clients decided that they preferred the CT scan, so we proceeded to refine that model instead of the MRI model. The CT model was integrated with a 3D model of the mouth that was purchased online. The bulk of this development was done in Blender, where the models will continue to be refined in the future.

The team also began to develop a laryngoscope model to interface with the Touch device in Unity. A free downloadable plugin from Glasgow School of Art [40] was used to demonstrate the capabilities of the haptic device; however, this software allows only a single point of contact between the haptic cursor and other colliders in Unity. Thus, a new computational model involving contiguous points of contact along the surface of the laryngoscope is necessary to produce realistic forces and torques in response to a user's input. Unity will also be used for this model, implementing code in C#.

<u>Methods</u>

Blender was utilized to modify the downloaded neonate file. As we will be adding anatomy from the neonatal CT scans, the baby was hollowed out, creating a shell to house future components. The baby was also made symmetrical to streamline future development. This will allow all rigging and texturing to be mirrored across the neonates midline, decreasing the workload. As the 3D baby was not originally symmetric, the baby was divided down the center of the nose and mirrored, deleting half of the original mesh. Additional surfaces were added to fill resulting gaps. The seam connecting the two halves was re-meshed to ensure there were no discontinuities. See Figure 13 for an example to the corrected mesh along the seam. Figure 14 depicts the modifications made to the original 3D baby. As the focus of our project is to provide an accurate simulation of neonatal intubation, the mouth needed to be cut open to allow for an opening and closing mouth/jaw. In order for the mouth/jaw to open and close, the mouth was rigged with deformable and non-deformable bones. In addition to the symmetrization and open mouth, a texture file was found to add color to the baby. The texture file will need adjustments to make the baby more realistic. For example, the baby's eyes will need to be colored to appear closed as would be the case during a real life procedure.

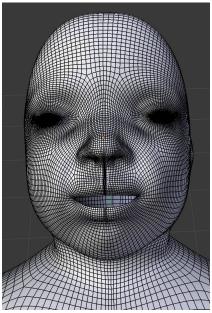


Figure 14: This figure shows the resulting mesh created after mirroring. Mesh lines were extended to ensure no discontinuities existed after integrating the two identical halves.

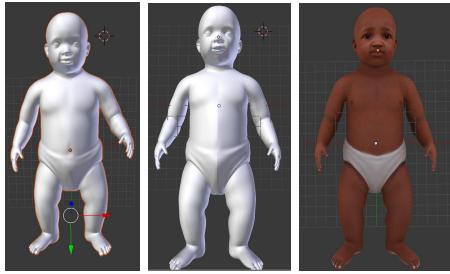


Figure 13: The figure to the left is the original baby. The figure in the middle is our current neonate. Major alterations included making the baby symmetrical to streamline future modifications, and creating an open mouth as intubation will be the focus of our simulation. The figure on the right is the textured version of the neonate.

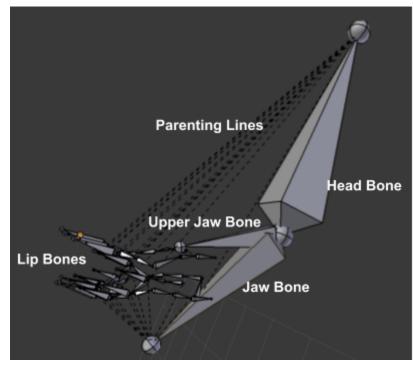


Figure 15: This figure shows shows the armature (bone structure) embedded into the mesh of the baby in order for the mouth and jaw to move naturally.

Figure 15 shows the armature created for the rigging of the mouth and jaw. Parenting involves linking one bone (or groups of bones) to another bone. Parent bones control the movement of the child bones. The non-deformable (parent) bones allow the deformable (child) bones to track the location of the control bones. The head bone is the parent of all bones and like the jaw bones, is not deformable. The lip bones consist of deformable bones outlining the opening of the mouth. Additional deformable bones run along the gums on the inside of the baby shell. These bones were parented to the control bones of the lips. When deformable bones are parented to non-deformable bones, the deformable bones stretch to compensate for the movement of the parent bone. The lower lip bones were parented to the (lower) jaw bone and the upper lip bones were parented to the upper jaw bone so that movement of the jaw bone would cause all of the corresponding lip bones to move. As these are all non-deformable bones, the child bones simply maintain their location with respect to the parent bones. For example, if the parent bone is translated to the left, the child bone will be translated to the left the same amount but respective to its original location.

The armature was then embedded into the mesh of the baby. Embedding the armature will allow the bones to be linked to the mesh of the baby so that if a bone moves, it deforms the surrounding mesh (remember, the mesh is the collection of vertices and edges). The movement of the mesh can be configured several different ways. One way is to manually assign physical weights to vertices within the mesh. The weight can be thought of as a how resistant that vertex is to movement in 3D space. So a heavy vertex will be less likely to move when the vertices surrounding it are pulling on it. The other way to control mesh movement is by auto-assigning weights using a built in Blender functionality. In order to prevent physical weights from impacting future material properties with Unity integration, a mix of auto-assigning and manual selection was used. Trial and error was used to ensure unnatural movements and distortions were kept to a minimum. Figure 16 shows the mouth open and close after rotation of the lower jawbone. When the baby is integrated into Unity, the mouth will be able to open and closed by touch.



Figure 16: This figure shows the open and closed mouth of the baby after rotation of the jawbone.

In addition to the neonatal shell, we have also began to reconstruct the inner anatomy of the neonate. First, a CT scan of a neonate was imported into 3D Slicer, as shown in Figure 17. Next, the trachea, larynx, and vocal cords were segmented using a manual segmentation method in which the user outlines a region of interest. By utilizing built-in thresholding functionality, which allows the user to segment pixels within a specified intensity range, a 3D model of the upper respiratory tract was isolated and subsequently exported to Blender as an .STL file.

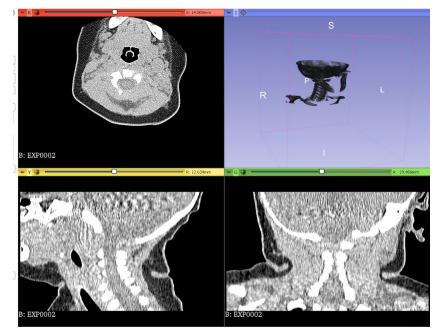


Figure 17: A screenshot of the 3D Slicer viewer, which shows the CT scan of the neonate.

Once in Blender, the model was refined further. As depicted in Figure 18, upon the initial import into Blender, the 3D model was filled with holes and had a rough outer appearance. In order to give the upper respiratory tract a more realistic appearance, both the inner and outer surfaces were smoothed using texturing tools in Blender. Figure 19 depicts the smoothed surface, and while from the outside the object looks less realistic, the figure is shown to exemplify the capability of the smoothing tools in Blender. After modifying and smoothing the rest of the mesh, the outer edge of the larynx and trachea were removed. The finished model is shown in Figures 20 and 21.

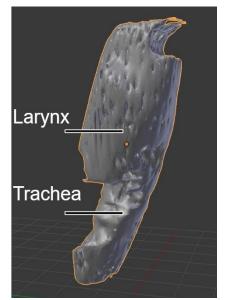


Figure 18: The upper respiratory tract upon the initial importation of the CT into Blender.

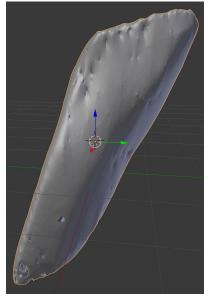


Figure 19: The CT reconstructed upper respiratory tract once smoothed with Blender's texturing tools.

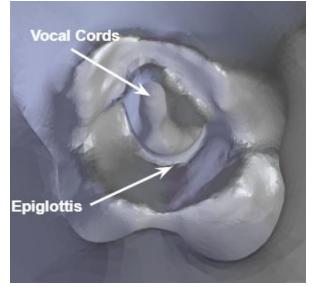


Figure 20: The inner anatomy after refining the initial CT-model.

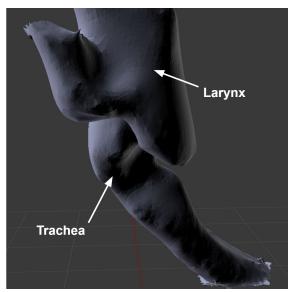
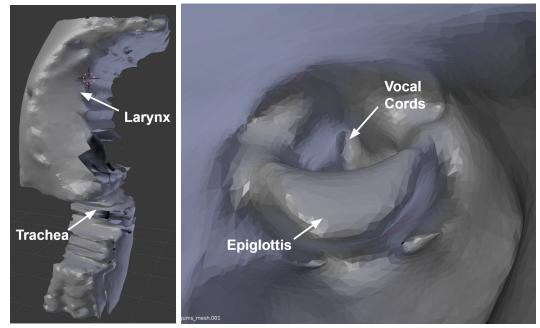


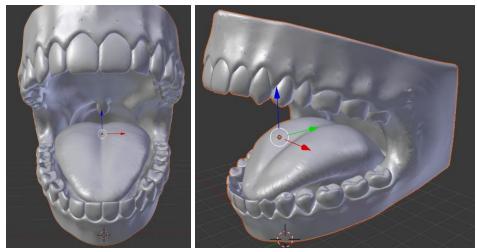
Figure 21: The CT reconstructed upper respiratory tract once the outer shell was removed.

Unfortunately, the CT scan did not capture the front of the neonates mouth. The client hoped to generate the entire inner anatomy of the neonate from 3D images, so we then repeated the process outlined above using an MRI scan. Unfortunately, however, the additional elements that we wished to capture in this scan, the gums and tongue, could not be distinguished in the MRI scan either. The MRI model is shown in Figures 22 and 23.



Figures 22 (left) and 23 (right): The 3D-reconstructed MRI scan is depicted above. The epiglottis is not as well defined in this model, so we chose to continue the rest of the project using the CT scan model.

Since the mouth and tongue could not be visualized using the CT or MRI scans, we had to purchase a model from the internet. The original file is shown in Figures 24 and 25. Since the model was supposed to represent the anatomy of an adult, the model had teeth. The teeth were subsequently removed, and the gums were smoothed to represent those of a neonate, as shown in Figure 26.



Figures 24 (left) and 25 (right): The downloaded 3D model of the mouth had teeth when it was purchased.

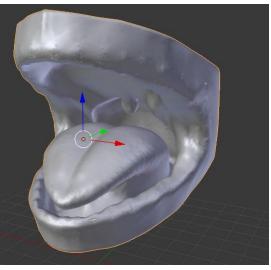


Figure 26: The teeth were removed from the original model and the gums were smoothed to more accurately emulate those of a neonate.

Finally, the refined mouth model was joined with the model of the upper respiratory tract (Figure 21). In order to join these two models, the bottom and back surfaces of the mouth model were removed. After this, the back of the throat was built by manually adding vertices to create a shape that accurately represents the throat. This addition is depicted in Figure 27. After the two models were joined, built-in Blender resurfacing tools were used to smooth the model. The complete model is depicted in Figures 28-32.

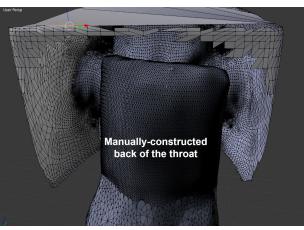
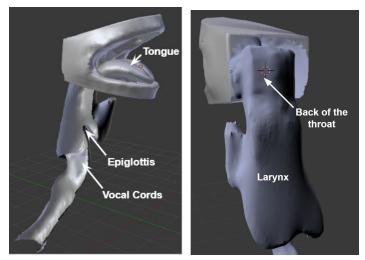


Figure 27: After removing the back and bottom of the mouth model, the mouth and upper respiratory tract models were joined by manually constructing the upper throat.



Figures 28 (left) and 29 (right): A partial cross-section of the complete model is shown in Figure 28, while the complete model is shown from behind in Figure 29.



Figures 30 (left), 31 (middle), and 32 (right): Other perspectives of the completed model are shown above.

Progress in Unity was less tangible. For demonstrative purposes, a 3D model of a laryngoscope was imported into Unity and integrated into the Glasgow School of Art plugin [40], where it could be manipulated using the haptic device and incorporated into several preprogrammed demonstrations (Figure 33). These demonstrations were severely limited in their scope, and still only allowed for a single contact point.

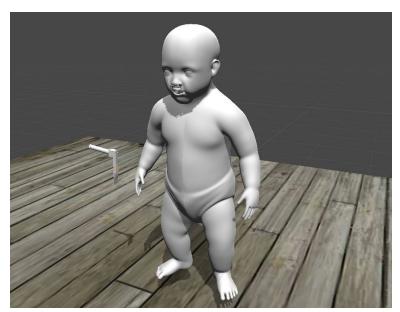


Figure 33: The interactive laryngoscope blade is shown manipulating the exterior shell of the neonate within the plugin developed by Glasgow School of Arts [40].

A more powerful program must be devised to better replicate the behavior of a laryngoscope in real 3D space. Currently, the haptic device can only interact with other virtual objects via a single point. This is undesirable because, obviously, a laryngoscope interacts with a baby via multiple surfaces at once, not through only a single point. Several solutions to this problem are available; 3DSystems advertises a third-party software, SmartCollision (Yokohama, Japan), which may solve the issue entirely [41]. However, pricing is still unavailable, support is limited, and it is unclear whether the software can cooperate with Unity. Alternatively, it is possible to recreate a portion of this software ourselves to fit our specific needs using the guide provided in OpenHaptics by 3DSystems. This route also provides a challenge in that no one on the team has expertise in developing software of such complexity. Nonetheless, due to price restraints, a homemade software will likely be our chosen method of establishing multiple contact points.

As a perfect pseudo-physical model is impossible to create, a point cloud surrounding the laryngoscope will be necessary, acting in place of (or in conjunction with) Unity's mesh system (Figure 34). Depending on the force input of the user, upon collision, each point in contact with an object will exert a force directly opposing the user's motion as well as a moment around a central axis located in the laryngoscope handle. As more points are added, less error arises in the model's response to user input, and therefore it is desirable to maximize point density within the point cloud.

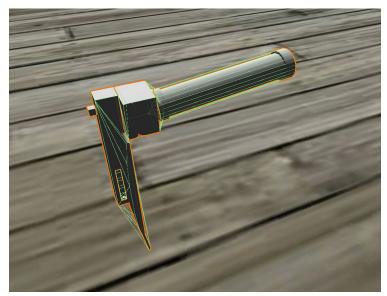


Figure 34: Unity uses a system of meshes to calculate collision physics, parsing the object into triangles, as pictured above. The described haptic software will calculate collisions based on evenly distributed points along the surface of the tool.

Future Work

The next steps in the modification of our 3D neonate will involve rigging the neonate's neck and jaw to move naturally within a VR environment. Additionally, the neonate's face, mouth and the upper respiratory tract will be segmented to allow different material properties to be implemented to each separate tissue area. For example, the cheeks will need to be more compliant than the jaw of the neonate. Separately segmenting these areas, and thus defining them as separate virtual objects, will allow different material properties to be assigned to each object in Unity. Oftentimes, virtual models do not have accurate physical properties. Segmenting will help remedy this issue by allowing for various levels of stiffness in different areas. In order for the neonate to look realistic in the VR simulation, it will need to be textured. Texturing involves refining the surface's shape and color, making the object more realistic. While

the baby looks realistic and the mouth moves without any major distortions, fine tuning will be needed to ensure natural motion. Minor appearance changes will include closing the eyes and fixing the gaps in the coloration of the mesh. The inner anatomy will need to be textured and several sections will be rigged to ensure a realistic appearance and realistic movement constraints.

Our prototype from Spring 2018 will be modified to more closely represent a neonatal OR. The arms will be updated to include realistic animations. Open source hand models from oculus (Figure 35) will be integrated into our existing first-person view using plugins available from Oculus and 3D Systems. These changes will increase the efficacy of the simulation by creating a more realistic training experience.



Figure 35: Textured versions of Oculus Hand Models 1.0 [42].

<u>Testing</u>

Due to time constraints and limited development we have not yet performed testing on the system. Further, evaluating the effectiveness of the final design will be extremely difficult. Proper testing would include finalizing the design and creating a study which compares success rates between residents that had underwent classical intubation training or had been trained using the new system. While this is a future goal, a more realistic form of testing would involve evaluating how well the different components of the design emulate a real procedure. Assessment such as this would need to be done subjectively, and would likely involve recruiting volunteer physicians who had previously performed the procedure to rate the realism of the various components of the simulation. For example, a physician would be asked to rate how well the anatomy of the neonate emulates a real model, and how realistically the tissues deform. Further, as the project progresses we plan on getting input from our clients, Drs. Tomlin and McAdams, about ways to improve the simulation. By repeatedly implementing changes and reevaluating, we will be able to fine-tune the simulation.

VI. Discussion

A successful implementation of the proposed design would drastically change neonatal intubation training and likely spur development of other simulated surgeries. Even if effective, however, accessibility to such advanced training would be limited. Initially, this project was proposed as a means of reducing training costs by avoiding incredibly expensive neonatal mannequins as well as the need for instructor supervision in hopes to provide more widespread accessibility to virtual training while also increasing effectiveness. Upon further investigation, however, access to a relatively high level facility would likely be necessary to run such an advanced simulation. The simulation would require the purchase of the devices outlined previously, such as the haptic feedback devices, VR headset, virtual reality software, and the simulation itself. Most importantly, however, the individual would need access to a powerful server to interface with the system. As mentioned in the background, realistic tissue physics is much more advanced than what conventional VR software is capable of simulating. According to VR specialists Ross Trednick and Kevin Ponto at the University of Wisconsin - Madison, in general, video game physics engines do not operate on lifelike physics models. The incorporation of non-affine transformation physics, in other words, deformable bodies, requires much more advanced physics engines which require extensive processing power. Thus, in order to simulate a high-resolution neonate with realistic physical properties in real time would require the incorporation of a highly advanced processor, most likely in the form of a server. The cost of a powerful server would greatly limit accessibility to VR medical simulations, especially in rural or lower socioeconomic status areas.

Regulatory hurdles also pose a threat to the simulation's eventual position in hospitals and medical schools. Because the simulation's functionality will not directly affect patient health, the FDA does not regulate its use [43]. Obtaining a patent seems to be the more difficult aspect

38

of the product's regulation. Other simulations using haptic feedback and virtual reality have existed for years [25, 26], but it remains possible to defend the virtual models and computational methods utilized in this particular simulation's conception. Once the simulation is proven to be attainable, the first step in this process is approaching WARF to submit an invention disclosure report (IDR). Next, a meeting must be scheduled to discuss the specifics of the intellectual property in a confidential setting. Finally, WARF meets internally to judge whether or not the invention is worth a future investment. If WARF chooses not to fund a patent, independent funding can cost up to \$40,000 [43,44]. Despite these obstacles, the simulation still has the potential to greatly increase medical training effectiveness and thus improve patient outcomes.

VII. Conclusion

Respiratory distress syndrome is a common disease experienced by neonates with remarkably poor clinical outcomes overall. High prevalence of RDS in neonates increases the need for more effective treatments, or alternatively, better training to increase success rates of widely used treatments. The development of a novel medical procedure simulation module which incorporates VR and haptic feedback could be highly beneficial for training effectiveness and thus, patient outcomes. It is also desirable that this system be inexpensive to increase training availability.

The final proposed system will incorporate a multitude of components including a VR headset, two haptic feedback devices, a Samsung phone, an external computer and likely, an external server. The Samsung phone will run the visual component of the virtual reality system and relay information to the computer. The haptic devices will operate in a similar fashion. The computer will subsequently rely on the external server to perform to bulk of the computer processing, and then respond to the haptic devices and phone. The virtual objects will be created using Solidworks, 3D Slicer, and Blender and imported into a scene created in Unity.

39

Finally, virtual-physical properties of the neonatal model will be specified via a custom script in Unity, integrating haptic feedback with the final 3D product.

The complex nature of the proposed system presents an abundance of obstacles that must be overcome. While it is impossible to foresee every challenge that we may face in the creation of the design, it is worth highlighting some of the more obvious limitations and impediments. The first barrier to success lies in the possible compatibility issues between the various software elements. While through preliminary evaluation it seems as if each software will be compatible, it is quite possible that updates in any of the various components could present further obstacles down the road.

The more daunting hurdle will likely be designating realistic physical properties to the virtual objects to ensure that the haptic force feedback feels natural. Not only are there limitations in the motor arms themselves, such as only being able to provide force feedback from a single point at any given time, but the computer modeling of deformable bodies is an extremely challenging process. Given the team's level of expertise, we will need to incorporate existing soft-body physics algorithms in our design, rather than attempt to build them ourselves. Further, to successfully assign physical properties to objects, we will need to create equations which explain how the tissue should deform when forces are applied to it. Extensive research and testing will need to be done to define those equations. Another long term goal is the introduction of multiple difficulty levels to the procedure. For example, by altering parameters such as the airway size, amount of neonatal head movement, or amount of fluid in the throat, the difficulty could be drastically altered.

Such a project is no easy task and will take time and effort. Moving forward we must conquer various aspects of the design in small increments. We will continue our progress on the 3D model of the neonate and the upper respiratory anatomy. Specifically, the 3D models will

40

need to be rigged and textured to look and behave as they would in real-life. In addition, custom Unity scripts will need to be developed in order to incorporate the new hands into the simulation. In the future, we plan to develop viscoelastic models that accurately reflect neonates' soft tissues, in addition to creating a realistic environment incorporating improved visuals and acoustics. The task at hand is tremendous, but represents the forefront of medical technology. In the coming years, it is likely that VR technology will become more prevalent, and will be more easily implementable to increase physician training, lower costs, and ultimately, improve clinical outcomes.

VIII. References

- "Respiratory Distress Syndrome | National Heart, Lung, and Blood Institute (NHLBI)", Nhlbi.nih.gov, 2018. [Online]. Available: https://www.nhlbi.nih.gov/health-topics/respiratory-distress-syndrome. [Accessed: 23-Feb- 2018].
- "Respiratory Disorders of the Newborn" [Online]. Available: https://www.scribd.com/ presentation/31799171/PEDIA2-20100513-Neo-2-Respiratory-Disorders-of-NB. [Accessed: 23- Feb- 2018].
- "Infant Mortality | Maternal and Infant Health | Reproductive Health | CDC", Cdc.gov, 2018. [Online]. Available: https://www.cdc.gov/reproductivehealth/maternalinfanthealth/infantmortality.htm. [Accessed: 23- Feb- 2018].
- "Peristats | March of Dimes", Marchofdimes.org, 2018. [Online]. Available: https://www.marchofdimes.org/Peristats/ViewSubtopic.aspx?reg=99&top=6&stop=119&I ev=1&slev=1&obj=1. [Accessed: 23- Feb- 2018].
- 5. S. Reuter, C. Moser and M. Baack, "Respiratory Distress in the Newborn", *Pediatrics in Review*, vol. 35, no. 10, pp. 417-429, 2014.
- P. A. Robertson, S. H. Sniderman, R. K. Laros, R. Cowan, D. Heilbron, R. L. Goldenberg, J. D. Iams, and R. K. Creasy, "Neonatal morbidity according to gestational age and birth weight from five tertiary care centers in the United States, 1983 through 1986," American Journal of Obstetrics and Gynecology, vol. 166, no. 6, pp. 1629–1645, 1992.
- R. H. Usher, A. C. Allen, and F. H. Mclean, "Risk Of Respiratory Distress Syndrome Related To Gestational Age, Route Of Delivery And Maternal Diabetes," Obstetrical & Gynecological Survey, vol. 27, no. 4, pp. 255–256, 1972.
- Beck, S., Wojdyla, D., Say, L., Pilar Bertran, A., Meraldi, M., Harris Requejo, J., Rubens, C., Menon, R. and Van Look, P. (2010). The worldwide incidence of preterm birth: a systematic review of maternal mortality and morbidity. *Bulletin of the World Health Organization*, 88(1),
- "Respiratory Distress Syndrome (RDS): Treatments National Library of Medicine -PubMed Health", *PubMed Health*, 2018. [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022902/. [Accessed: 10-Feb- 2018].
- 10. OPENPediatrics (2016). "Neonatal Tracheal Intubation" by Lindsay Johnston for OPENPediatrics. [video] Available at: https://www.youtube.com/watch?v=IGTaA_UdIXw [Accessed 31 Jan. 2018].
- 11. Kumar, A. and Vishnu Bhat, B. (1996). Epidemiology of respiratory distress of newborns. The Indian Journal of Pediatrics, 63(1), pp.93-98.
- 12. Haubner, L., Barry, J., Johnston, L., Soghier, L., Tatum, P., Kessler, D., Downes, K. and Auerbach, M. (2013). Neonatal intubation performance: Room for improvement in tertiary neonatal intensive care units. *Resuscitation*, 84(10), pp.1359-1364.
- 13. O'Donnell, C. (2006). Endotracheal Intubation Attempts During Neonatal Resuscitation: Success Rates, Duration, and Adverse Effects. *PEDIATRICS*, 117(1), pp.e16-e21.

 O'Shea, J., Thio, M., Kamlin, C., McGrory, L., Wong, C., John, J., Roberts, C., Kuschel, C. and Davis, P. (2018). *Videolaryngoscopy to Teach Neonatal Intubation: A Randomized Trial*. [online] Available at: http://pediatrics.aappublications.org/content/136/5/912 [Accessed 10 Feb. 2018].

- Kresge, N. (2018). Improving neonatal intubation training to boost clinical competency | Children's National. [online] Innovation District. Available at: https://innovationdistrict.childrensnational.org/improving-neonatal-intubation-training-boo st-clinical-competency/ [Accessed 10 Feb. 2018].
- A. Pourmand, S. Davis, D. Lee, S. Barber and N. Sikka, "Emerging Utility of Virtual Reality as a Multidisciplinary Tool in Clinical Medicine", *Games for Health Journal*, vol. 6, no. 5, pp. 263-270, 2017.
- "3D Printers, 3D Scanning, Software, Manufacturing and Healthcare Services | 3D Systems", *3dsystems.com*, 2018. [Online]. Available: https://www.3dsystems.com/. [Accessed: 24- Feb- 2018].
- 18. Stanford Children's Health", *Stanfordchildrens.org*, 2018. [Online]. Available: http://www.stanfordchildrens.org/en/topic/default?id=low-birthweight-90-P02382. [Accessed: 24- Feb- 2018].
- 19. B. Lane, N. Finer and W. Rich, "Duration of intubation attempts during Neonatal Resuscitation", *The Journal of Pediatrics*, vol. 145, no. 1, pp. 67-70, 2004.
- OPENPediatrics (2016). "Neonatal Tracheal Intubation" by Lindsay Johnston for OPENPediatrics. [video] Available at: https://www.youtube.com/watch?v=IGTaA_UdIXw [Accessed 31 Jan. 2018].
- 2018. [Online]. Available: https://www.anatomywarehouse.com/deluxe-infant-airway-trainer-simulator-a-103467?g dffi=2a24628df7804e7290c4c8aa618951c1&gdfms=B213B79E68E640F0978226453D8 9251A&gclid=CjwKCAiAz-7UBRBAEiwAVrz-9X8gocztC6CExH4fQbHWTbNJohIBrOqco 8vrjBlzthoa2XWn2c5xzhoCmrEQAvD_BwE. [Accessed: 24- Feb- 2018].
- "Oxford Medical Simulation virtual reality training for optimal patient care", Oxford Medical Simulation, 2018. [Online]. Available: https://oxfordmedicalsimulation.com. [Accessed: 24- Feb- 2018].
- 23. "Products Oxford Medical Simulation", *Oxford Medical Simulation*, 2018. [Online]. Available: https://oxfordmedicalsimulation.com/products/. [Accessed: 24- Feb- 2018].
- H. Garden and E. Tech, "How Haptic Technology Works", *HowStuffWorks*, 2018. [Online]. Available: https://electronics.howstuffworks.com/everyday-tech/haptic-technology4.htm. [Accessed: 24- Feb- 2018].
- 25. S. Ullrich, D. Rausch, T. Kuhlen, and S. C. a. A. S. a. G. Welch, "Bimanual Haptic Simulator for Medical Training: System Architecture and Performance Measurements," 2011 2011.
- 26. K. Hagelsteen, A. Langegård, A. Lantz, M. Ekelund, M. Anderberg, and A. Bergenfelz, "Faster acquisition of laparoscopic skills in virtual reality with haptic feedback and 3D vision.," Minimally invasive therapy & allied technologies : MITAT : official journal of the Society for Minimally Invasive Therapy., Oct-2017. [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmed/28367667. [Accessed: 29-Apr-2018].
- 27. 3D Systems. (2018). LAP Mentor VR | 3D Systems. [online] Available at: https://www.3dsystems.com/healthcare/lap-mentor-vr [Accessed 23 Apr. 2018]
- "Touch | 3D Systems", 3D Systems, 2018. [Online]. Available: https://www.3dsystems.com/haptics-devices/touch. [Accessed: 25- Feb- 2018].
- 29. Wai Yu and S. Brewster, "Comparing two haptic interfaces for multimodal graph rendering," Proceedings 10th Symposium on Haptic Interfaces for Virtual Environment

and Teleoperator Systems. HAPTICS 2002, Orlando, FL, 2002, pp. 3-9. doi: 10.1109/HAPTIC.2002.998934

- 30. T. R. Coles, D. Meglan and N. W. John, "The Role of Haptics in Medical Training Simulators: A Survey of the State of the Art," in IEEE Transactions on Haptics, vol. 4, no. 1, pp. 51-66, January-March 2011. doi: 10.1109/TOH.2010.19
- Slicer.org. (2018). 3D Slicer. [online] Available at: https://www.slicer.org [Accessed 7 Oct. 2018].
- Play.google.com. (2018). Samsung VR. [online] Available at: https://play.google.com/store/apps/details?id=com.samsung.android.video360&hl=en [Accessed 17 Feb. 2018].
- 33. B. Foundation, "Home of the Blender project Free and Open 3D Creation Software," blender.org. [Online]. Available: https://www.blender.org/. [Accessed: 07-Oct-2018].
- "Products," Unity. [Online]. Available: https://unity3d.com/unity. [Accessed: 30-Sep-2018].]
- [Assetstore.unity.com. (2018). Unity 5 Haptic Plugin for Geomagic OpenHaptics 3.3 (HLAPI/HDAPI) - Asset Store. [online] Available at: https://assetstore.unity.com/packages/essentials/tutorial-projects/unity-5-haptic-plugin-fo r-geomagic-openhaptics-3-3-hlapi-hdapi-34393 [Accessed 7 Oct. 2018].].
- "Spec Showdown: Oculus Rift vs. Samsung Gear VR", Digital Trends, 2018. [Online]. Available: https://www.digitaltrends.com/virtual-reality/oculus-rift-vs-samsung-gear-vr/. [Accessed: 24- Feb- 2018].
- Amazon.ca. (2018). Amazon. [online] Available at: https://www.amazon.ca/Oculus-Touch-Virtual-Reality-System/dp/B073X8N1YW [Accessed 21 Feb. 2018].
- Play.google.com. (2018). Samsung VR. [online] Available at: https://play.google.com/store/apps/details?id=com.samsung.android.video360&hl=en [Accessed 17 Feb. 2018].
- Free3d.com. (2018). StandingBaby v2 Free 3D Model .obj .stl Free3D. [online] Available at: https://free3d.com/3d-model/standingbaby-v2--119839.html [Accessed 7 Oct. 2018].
- 3D Systems. (2018). Smart Collision | 3D Systems. [online] Available at: https://www.3dsystems.com/scanners-haptics/application-gallery/smart-collision [Accessed 12 Dec. 2018].
- Assetstore.unity.com. (2018). Unity 5 Haptic Plugin for Geomagic OpenHaptics 3.3 (HLAPI/HDAPI) - Asset Store. [online] Available at: https://assetstore.unity.com/packages/essentials/tutorial-projects/unity-5-haptic-plugin-fo r-geomagic-openhaptics-3-3-hlapi-hdapi-34393 [Accessed 12 Dec. 2018].
- [Oculus Hand Models | Developer Center | Oculus", Developer.oculus.com, 2018. [Online]. Available: https://developer.oculus.com/downloads/package/oculus-hand-models/. [Accessed: 07-Oct- 2018].]
- 43. Fda.gov. (2018). Medical Devices. [online] Available at: https://www.fda.gov/MedicalDevices/default.htm [Accessed 12 Dec. 2018].

44. WARF. (2018). Our Process. [online] Available at: https://www.warf.org/for-uw-inventors/our-process/our-process.cmsx [Accessed 12 Dec. 2018].

X. Appendix

A. Problem Design Specifications

Function

The client wishes to develop a virtual simulation environment that accurately models a neonatal intubation procedure. Tentatively, the client desires that a virtual environment be created which mimics the upper respiratory tract, throat, and mouth of a neonate. The virtual system should precisely emulate a clinical environment in order to function as a novel neonatal intubation training method for physicians. Furthermore, the virtual components should be integrated with a haptic feedback motor arm which pairs physical traits to the virtual objects, thus mimicking a clinical procedure with only the use of virtual reality and a portable haptic feedback device. Ultimately, this device should serve as a virtual, but effective, surgery training method.

Client Requirements:

- The virtual environment must accurately emulate the physical and optical characteristics of an infant's head, mouth, and upper respiratory tract.
- A haptic interface must register interactions between the user's physical input and preprogrammed objects, and relay these interactions back to the user via a haptic motor arm.
- The system must include a user-friendly software allowing changes in procedural specifications.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

- The system must be constructed for use in both clinical and rural settings, thus requiring portability and durability.
- The system must be capable of running up to 25 full simulations per day.
- A virtual environment must be capable of simulating neonates in the range of 1-10 lbs.

b. Safety: Any electronic components must be enclosed within appropriate housing to minimize the risk of injury due to electric shock.

c. Accuracy and Reliability: The system must be accurate to .02 mm to compete with current haptic feedback systems and provide a realistic surgical environment.

d. Life in Service: The system must last at least 5 years with minimal maintenance.

e. Shelf Life: The device will be stored inside and will not be exposed to extreme weather conditions. It should not need maintenance while not in use.

f. Operating Environment: The system should be capable of operating in a variety of environments, including clinical and outdoor settings. The virtual simulation will be perfected by using feedback from expert neonatologists to accurately emulate a neonatal intubation procedure.

g. Ergonomics: The device should be intuitive to use and feel very similar to tools used during neonatal intubation such as the laryngoscope and endotracheal tube.

h. Size: The device must be small enough be carried around in a backpack or other case.

i. Weight: The device must weigh less than 40 lbs, light enough to be easily transported in a backpack or other case.

j. Materials: The system will be comprised of a pair of virtual reality goggles, a haptic feedback motor arm, and any computer hardware required to render the environment and power the system.

k. Aesthetics, Appearance, and Finish: The virtual reality should not be blurry. The user should be able to interact with the environment without noticeable buffering.

2. Production Characteristics

a. Quantity: One functional prototype will suffice for BME 400. Ultimately, however, the aim is to provide worldwide accessibility.

b. Target Product Cost: The device should cost under \$5000.

3. Miscellaneous

a. Standards and Specifications: If successful, the device would require IRB and FDA approval to serve as a credible source of medical training.

b. Customer: The system will be used by training physicians who are practicing neonatal intubation procedures. Consequently, they will demand a realistic virtual environment with physical characteristics which accurately model a neonates anatomy and physiology.

c. Patient-related concerns: No concerns should arise from the use of this device as it will serve as an additional form of medical training, not an alternative to current training.

d. Competition: Competition exists among virtual reality platforms, but to our knowledge, there only exists a single haptic feedback system on the market currently, and there are no integrative VR and haptic feedback systems which are used to simulate neonatal intubation procedures.

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Prop	Website name	Author	Filename	Link	
Laryngoscope Blade	3D Warehouse	ProviderOfRandomStargate Stuff	Laryngoscope	https://3dwarehouse.sketchup.com/model/ 515e8861e0f3c2bfdcd154f0c7575f7f/Lary ngoscope	
DefKit asset	Unity Asset Store	Dr. Korzen	DefKit	https://assetstore.unity.com/packages/tool s/physics/defkit-50767	
Morgue scene	Unity Asset Store	Rokay3D	Morgue Room PBR	https://assetstore.unity.com/packages/3d/ enviroents/morgue-room-pbr-65817nm	
Arms	Sketchfab	DavidFischer	First Person Hands Rigged	https://sketchfab.com/models/547a45535f 0c4fe787948f7a7a6a88db	
Baby (modified by the team)	Free3D	printable_models	StandingBaby V2	https://free3d.com/3d-model/standingbaby -v2119839.html	
Mouth and Tongue 3d model (modified by team)	turbosquid	Markuss	Mouth Animated 2.0	https://www.turbosquid.com/3d-models/m outh-teeth-tongue-animation-3d-max/4954 13	
OpenHaptics Plugin	Unity Asset Store	Glasgow School of Art	Unity 5 Haptic Plugin for Geomagic OpenHaptics 3.3 (HLAPI/HDAPI)	https://assetstore.unity.com/packages/ess entials/tutorial-projects/unity-5-haptic-plugi n-for-geomagic-openhaptics-3-3-hlapi-hda pi-34393	
Oculus Hand Models	Oculus / Developers	Oculus	Oculus Hand Models 1.0	https://developer.oculus.com/downloads/p ackage/oculus-hand-models/	

B. Downloaded Files

Table 2: Files that were downloaded and incorporated into the current prototype.

C. Estimated Costs

Material	Approximate Cost	Explanation	Link
Touch Haptic Device	\$2200	This was purchased in order to visualize our simulation.	N/A
Unity Plugins	\$200	In order to develop a life like simulation we may need to purchase more advanced Unity plugins than the ones provided for free. It is impossible to definitively say whether we will need additional plugins, but it is definitely possible that we require more advanced tools as we progress. Functionalities that we may need plugins for include more advance soft-body physics plugins or possibly texture plugins to give provide more realistic texture to the neonate. Finally, if we do end up purchasing such plugins we may also need to buy a monthly Unity subscription (\$30/month). Once again, it's not clear whether this will be required but it's worth mentioning.	One advanced soft body physics plugin can be found here: https://assetstore.unity.com/pa ckages/tools/truss-physics-418 01
Mouth and Tongue 3d Model	\$69	In order to streamline development, models were downloaded because the reconstructed CT and MRI images do not provide very much anatomical-detail of the mouth or tongue.	https://www.turbosquid.com/3d -models/mouth-teeth-tongue-a nimation-3d-max/495413
Total	\$2469		

Table 3: Actual and Estimated costs for simulation development.