DEPARTMENT OF
Biomedical Engineering
UNIVERSITY OF WISCONSIN–MADISON

NEONATAL 22-23-WEEK PREMATURE INFANT SIMULATION MANIKIN

BME 200/300 - Preliminary Report

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Client: Dr. Timothy Elgin

Advisor: Dr. Kristyn Masters

Team Members:

Loukia Agoudemos	Team Leader
Sophia Finn	Communicator
Charlie Fisher	BWIG
Abbie Schaefer	BSAC
Tanishka Sheth	BPAG

Abstract

Neonatology is an exciting and developing field. Studies and developments based on the various phases of gestation are mitigating complications surrounding birth. This project focuses specifically on 22-23-week neonates. These infants are considered extremely premature and resuscitation is very rarely performed. As the field has developed, it has become possible to resuscitate neonates born this premature. These neonates are rare, and thus medical professionals often have minimal experience with these infants. This creates a demand for medical simulation manikins that accurately and reliably represent neonates born at this stage of gestation. There are currently no neonatal manikins for infants born between 22-23 weeks, the earliest model represents a neonate born at 25 weeks. The team has been tasked with creating a neonatal simulation manikin that includes three critical components. This includes IV access, realistic anatomical aspects that allow for proper intubation, and central umbilical line placement. The team's current solution aims to expand on previous work. The main goals for this semester are to include limbs for IV access, a realistic chest cavity, to allow for the manikin to be intubated, and to improve how realistic the skin texture is. To ensure the group delivers a satisfactory device, testing will be conducted on mechanical and skin components, and client evaluation will occur many times over the fabrication timeline. With the team's efforts, a neonatal manikin that accurately models a 22-23 week premature infant will be designed to save lives of at-risk preterm infants and send more home with their families.

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I. Introduction

Motivation

The broad goal of the project is to send more families home with their babies, specifically with babies that are born extremely prematurely. Infants that are brought home when born extremely premature are unlikely miracles [1]. An extremely premature infant is defined as one who is born before 28 weeks of gestation [2]. At 25 weeks gestational age, the survival rate is around 59% - 86%. At 23 weeks, the survival rate ranges from 31% - 78%. The survival rate for an infant born at 23 weeks of gestation is 1% - 64%, and the survival rate of infants born at 22 weeks drops to less than 10% [2]. This project focuses on infants born at 22-23 weeks of gestation, who have a relatively low chance of survival. Currently, although it is a hard ethical decision often varying from case to case and parent to parent, doctors are advised not to attempt resuscitation before 25 weeks [2]. Even if the infant manages to survive, the risk of permanent disability is rather high for infants born before 25 weeks of gestational age [2]. Further, due to the rarity of extremely premature babies, doctors often do not have experience handling and resuscitating infants at 22-23 weeks of gestational age. If a simulation manikin with all necessary components for resuscitation techniques, coupled with realistic skin texture existed, doctors could practice on manikin so that when a real, high-intensity premature delivery occurs, they would be well-versed in resuscitating a 22-23 week neonatal infant. With the introduction of a cost-effective and realistic simulation manikin, extremely premature infants can have a higher rate of survival due to an improved training experience for doctors worldwide.

Existing Devices and Current Methods

There are a couple of infant manikins on the market, but none that accurately simulate a 22-23 week premature infant. There are a couple of neonatal infant manikins on the market but none that fully satisfy the client's desires. Trucorp has a TruBaby X manikin that simulates a 5-month-old infant. TruBaby X has a chest that rises and falls with proper intubation, full chest recoil when performing CPR, multiple insertion points, and fluid pockets beneath insertion points to simulate real bodily fluids [3]. Practicing resuscitation techniques on TruBaby X would be ineffective for doctors trying to gain experience resuscitating extremely premature babies due to the larger size of the 5-month infant manikin. The second competing design is Universal Medical's C.H.A.R.L.I.E, which simulates an infant at birth. C.H.A.R.L.I.E. stands for the first letter of each of its most notable features. The 'C' stands for

compressions and cardiac, the ‘H’ stands for heat compatible, the ‘A’ stands for airway and arterial access via the umbilicus, the ‘R’ means resuscitation, ‘L’ means laryngeal mask capable of oxygen use or PPV, the ‘I’ represents intravenous, intraosseous, and intubation, and the ‘E’ stands for ECG [4]. Although C.H.A.R.L.I.E. simulates an infant at birth, the size is still much bigger than a 22-23 week premature infant. The final competing design is Laerdal’s Premature Anne manikin, which is most similar to this semester’s project. This design is a 25-week premature baby that can be intubated through the nose and mouth and includes a chest cavity that rises and falls, umbilical cord access, and multiple locations for IV insertions [5]. At just 2-3 weeks away from the team’s desired infant manikin, Premature Anne is still significantly bigger than a 22-23 week premature baby. Further, the skin does not accurately represent the thin, gelatinous skin of an infant at 22-23 weeks of gestational age.

This project is also a continuation of the semester prior. The prior group was able to create a mold design but was unable to create a functioning prototype. Many of the aspects from last semester’s design will be carried over to this semester, including the PDMS skin texture and the mold design that was created. However, last semester’s team experienced difficulties with the material of the skin interacting negatively with the material of the mold.

Figure 1: *Prototype from last semester’s group*

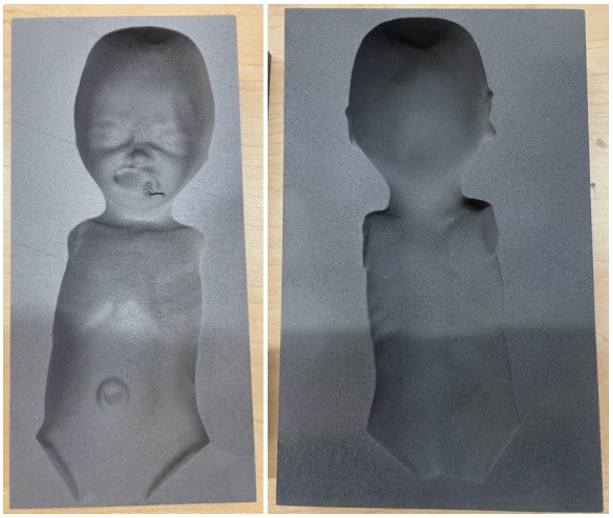

Figure 2: *Mold created from Nylon 12 from last semester's group*

Problem Statement

There are currently no 22-23 week neonatal simulation manikins on the market, though it is vital for medical professionals to practice the skills needed to resuscitate an infant at this age. As a result, it is critical to develop a simulation for medical personnel to practice their skills and ease the learning curve to learn in an environment that is less chaotic and high stakes than the first real event. This simulation manikin must be able to be intubated, support central umbilical line placement, and include IV access. Including a chest cavity and rib structure that allows for additional training in thoracentesis and pericardiocentesis would be ideal.

II. Background

Relevant Biology and Physiology

22-23 week premature infants are approximately 1 foot long and weigh between 0.9-1.1 pounds on average. Due to their small size, doctors often do not attempt resuscitation. 11% of births are preterm, yet are the leading cause of mortality in industrialized countries, accounting for 60-80% of deaths. The more premature the infant is the higher risk for pulmonary abnormalities and infections. Babies born at 22-23 weeks of prematurity are in the canalicular stage of lung development, which is between 23-26 weeks. This stage is the first big step in being able to complete gas exchange, however, the ability to

complete the gas exchange circuit does not complete until between 24-26 weeks, meaning infants born at 22-23 weeks are not able to properly breathe on their own. The conducting airways and terminal bronchioles are formed in this stage, which lays the basis for gas exchange. However, neonates born in this stage are equipped with poor lung elasticity, which reduces the functional residual capacity (FRC) of the lungs. This decreases the lung volume and increases the desaturation of the blood. One similarity that preterm infants have with term infants is their anatomical structure, while scaled-down, most preterm infants share the same anatomical features and dimensional ratios. For example, the thoracic cavity, while different from an adult's thoracic cavity where there are distinguishable ribs, an infant has a more cone-like thoracic structure [6]. The chest cavity of 22-23 weeks premature infants is similar to that of a full-term infant, but just much smaller. In addition, they also have gelatinous, sticky skin that tears very easily [7]. This means that when life-saving operations are performed, the skin is often damaged or torn in the process.

Client Information

The client, Dr. Timothy Elgin is a neonatal physician affiliated with the UW Department of Pediatrics, who is passionate about improving the education surrounding the resuscitation of neonates born extremely prematurely. He requires the team to fabricate a prototype model that satisfies the needs of medical professionals training to develop proper resuscitation practices.

Design Specifications

The customer base for this product is medical schools and training hospitals that wish to educate their students on the intubation of premature neonatal infants. As it will be used for training, it would be preferable if the manikin is easy to handle, but maintains accurate difficulty when demonstrating resuscitation in premature infants born at 22-23 weeks of gestation. Due to this, the client’s requirements included having the ability to put a synthetic breathing tube (2.00 -2.50 mm diameter) in the mouth of the manikin, attach a synthetic umbilical cord, and practice vital signs. Additionally, the base had to be pressure resistant and needed expandable lungs to replicate breathing. Some additional design requirements were a shelf life of 3-5 years, the manikin should be less than 30.5 centimeters, and a weight of 400-500 grams (refer to PDS). The client also requested that the skin be made more lifelike, as a premature infant's skin is more malleable than a full-term infant’s or an adult’s.

III. Preliminary Designs

PVA Casted Mold

PVA was determined to be an acceptable design for the mold because of its ability to dissolve in water. It is often used as a support structure for 3D printing. As a result, it would be a breakaway mold that could be used when curing the manikin. However, because of its breakaway component, it would not be used multiple times and instead is a single-use mold that would need to be reprinted every time.

Tough PLA

Tough PLA was determined to be an acceptable design for the mold because it is one of the most commonly used plastics for 3D printing. It is heat resistant and would be able to withstand the curing process for PDMS, which is the material that will be poured and cured in the mold. Additionally, it is durable and can be reused for multiple prototypes.

Nylon Mold

Nylon was determined to be an acceptable design for the mold because it is extremely heat resistant. It was also the material used in the prior semester for this project. However, the Nylon had interactions with the PDMS and did not yield the desired results. Thus, it would only be a viable option if PDMS was not the chosen skin material.

PDMS Coating on Ballistics Gel

This design for the 22-23 week neonatal manikin strikes a balance between the tactile experience and realism that the properties of PDMS provides and the durability and additional realistic properties that ballistics gel provides. 3D printed PVA that is in the shape of the trachea and chest cavity will be placed in the ballistics gel solution before curing in a fashion where it is easily removed afterward. This will leave behind the desired cavities for intubation. Using the mold, the team will first fabricate the ballistics gel base. Then the team will cure a thin layer of PDMS over the ballistics gel at room temperature due to the low melting temperature of the ballistics gel.

PDMS Only

This is the same design for the neonatal manikin as in the semester. This design consists of thin layers of PDMS being cured on top of one another in the mold. Each layer will be cured at 300° for ten minutes at a time. A 3D-printed PVA in the shape of the trachea and chest cavity would be placed in the mod during the curing process, and then removed afterward to leave the cavity behind for intubation.

Sleeve Coating

This design consists of a PDMS sleeve that can be slipped on and off of a more durable, PVA neonatal manikin. This allows the PDMS covering to be replaced as needed and provides accurate texture to only the locations of the manikin that will be made contact with during intubation.

Intubation and Shell

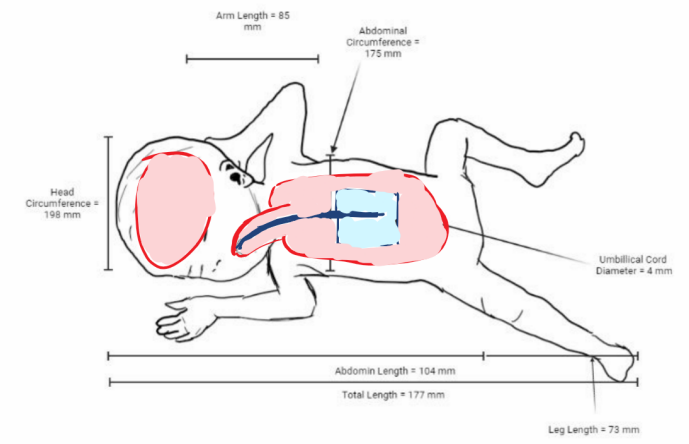

Figure 3: *Drawing of the Intubation and Shell design idea.*

This design uses a PLA-printed chest and belly cavity. This allows the chest cavity to have solid support within the manikin. Within this cavity, an infant-sized CPR bag would be placed within it to replicate the lungs. The airways would be molded with silicone to include a realistic mouth and esophagus. This design was previously used in this design project at a different university.

Balloon Lungs

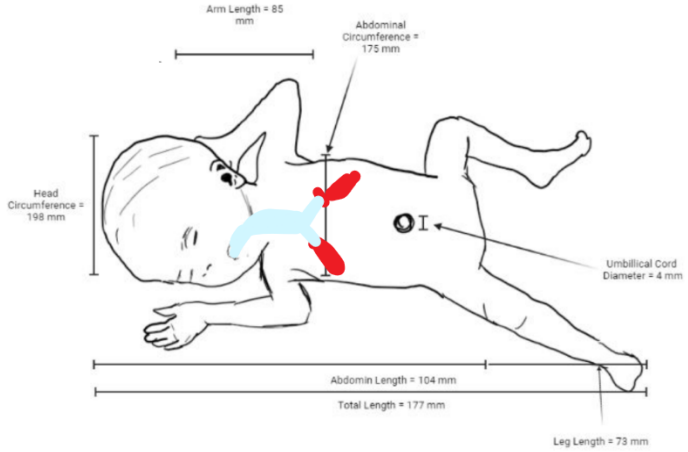

Figure 4: *Drawing of the Balloon Lungs design idea.*

The balloon lungs include a breathing tube with T-connectors to mimic airways. These "airways" would be connected to two small balloons which can inflate and deflate to replicate breathing. These balloons would represent the lungs. This idea is simplistic in that it does not include any skeletal components.

Mock Airway and Skeleton

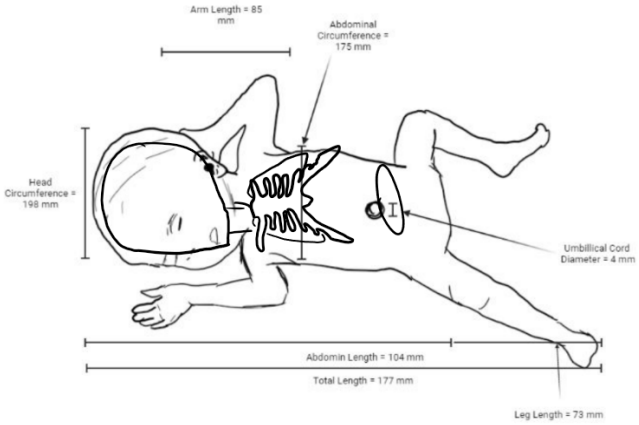

Figure 5: *Drawing of Mock Airway and Skeleton design idea.*

The mock airway and skeleton design includes a 3D-printed skull and skeleton within the manikin. This structure would be created out of an elastic-plastic such as polyurethane. Furthermore, there would be accurately sized lung-air bags for the rise and fall of the lungs.

IV. Preliminary Design Evaluation

Design Matrix

A design matrix is a tool employed by the design team to evaluate preliminary designs in terms of important selected criteria. The criteria chosen by the design team were evaluated based on the client's requirements, what was most readily accomplishable in a semester, and the amount of background knowledge that the design team has.

Heat resistance is how well the material resists melting when placed in environments with high temperatures. Cost is how cost-effective the material is compared to other alternatives. Durability is how capable the material is to withstand wear and tear depending on what is outlined by the client's specifications. Detail capturing is how well the material will be able to portray smaller intricacies of the design such as facial features. Feasibility is how capable the team is to create the design over the course of the semester. Ease of use is how easy the material is to turn into the design and how simple usage is by the users.

Each of these criteria was weighed by what the team determined to be most important. Heat resistance was considered the most important because the material must be able to withstand the curing temperatures of the biomaterial. Cost, durability, and detail capturing were the next most important because it was critical to include the most features while withstanding usage over a few years. Keeping the cost low allows for the design to be reproduced as necessary. Feasibility was the next most important aspect because it determines how capable the team is to create and complete the design. Ease of use was least important because the mold is only being used to give the model shape and will not be used after the prototype is created unless needed to create more prototypes.

Table 1: *Design matrix evaluating 3 feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores out of 5.*

	Design 1: PVA Casted Mold	Design 2: Tough PLA	Design 3: Nylon Mold
Heat Resistance (25)	3/5 (15)	4/5 (20)	5/5 (25)

Cost (20)	2/5 (8)	5/5 (20)	4/5 (16)
Durability (20)	4/5 (16)	5/5 (20)	4/5 (16)
Detail Capturing (20)	4/5 (16)	5/5 (20)	4/5 (16)
Feasibility (10)	3/5 (6)	4/5 (8)	1/5 (2)
Ease of Use (5)	3/5 (3)	4/5 (4)	1/5 (1)
Total (100)	64	92	76

Additionally, the team evaluated various designs for the material and composition of the neonate manikin itself. Six different criteria were used for this evaluation: texture, usability, cost, durability, realism, and feasibility/reproducibility.The texture is how well the material composition replicates the tactile experience of the skin of a premature infant. Usability is how easily the manikin can be used to simulate intubation. Cost is how economical the price of the manikin is compared to other options. Realism is how realistic the manikin looks and feels. Feasibility/Reproducibility is a measure of how complex the fabrication process will be and how easily it can be repeated with a high degree of precision if necessary.

The team determined that texture, cost, and usability were the most important. This is due to the fact that the client's main complaint about other designs on the market is that they have a very artificial, plastic feel rather than the hydrated and elastic feel of a premature infant. Cost is important due to the fact that another challenge of acquiring neonatal intubation manikins is that they are not accessible. For example, Premature Anne from Laerdal costs $2,999 [4]. The team thus is prioritizing the design of a manikin that is more affordable. Usability was also ranked as the most important due to rollover complications from the previous semester. The most challenging issue was that the previous design had low usability, as it was not easily intubated or handled.

Durability was ranked as the next most important criterion. This is because a large component of determining whether the manikin is functional or not is designing it in such a way that it can handle its function of intubation. This will be done repeatedly to the manikin throughout its lifespan, and thus it must be able to withstand the necessary amount of pressure for intubation many times.

The lowest-ranked criteria were realism and feasibility/reproducibility. This is because, one, the team decided that the aesthetics of the manikin were not as important at this stage of development as the functionality of the manikin. The team also wanted to concentrate efforts on perfecting one fabrication process before fine-tuning it for reproducibility.

Table 2: *Design matrix evaluating 3 ideas for the manikin. Evaluation of feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores out of 5.*

	Design 1: PDMS Coating on Ballistics Gel	Design 2: PDMS Only	Design 3: Sleeve Coating -Thicker silicone sleeve on top of hard plastic body
Texture(25)	5/5 (25)	3/5 (15)	4/5 (20)
Usability(25)	5/5 (25)	3/5 (15)	4/5 (20)
Cost(25)	4/5 (20)	5/5 (25)	2/5 (10)
Durability(15)	4/5 (12)	2/5 (6)	3/5 (9)
Realism(5)	4/5 (4)	2/5 (2)	5/5 (5)
Feasibility/ Reproducibility (5)	4/5 (4)	5/5 (5)	2/5 (2)
Total (100)	90	68	66

The team also evaluated several design ideas for the inner workings of the manikin. This includes a system for intubation and faux lungs. The designs were evaluated based on five criteria which were ranked based on what the team determined to be most important for the project's functionality. The most important criterion was realism, which is how accurately the airway mechanism mimics breathing (normally and during resuscitation). This also evaluates the accuracy and realism of the structure of the inner workings. Because the manikin is primarily going to be used for intubation, it is critical that the inner workings provide a realistic imitation of breaths and chest rising and falling. This is complemented by usability, which is how easy the manikin's features are to use. The realism is dependent on how simple the breathing mechanism is to operate by the user.

The next most important criterion was cost. This is because the manikin needs to be low cost in order to create numerous functional prototypes, and be created within the cost constraints of the semester. Durability and feasibility were the lowest because they are not necessary for functionality, but are required for the reproduction of prototypes and extended usage. Durability is important because the manikin should have a shelf life of about 3-5 years, meaning that the inner workings should be able to withstand semi-constant use for this time period. Feasibility and reproducibility are important for the

project because the team should be able to develop a prototype within the semester and this prototype should be easy to recreate in future iterations.

Table 3: *Design matrix evaluating 3 ideas for the inner workings. Evaluation of feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores out of 5.*

	Design 1: Intubation and Shell	Design 2: Balloon Lungs	Design 3: Mock airway and skeleton
Feedback Mechanism/ Realism (25)	4/5 (20)	4/5 (20)	5/5 (25)
Usability(25)	4/5 (20)	4/5 (20)	5/5 (25)
Cost (20)	3/5 (12)	5/5 (20)	2/5 (8)
Durability (15)	3/5 (9)	3/5 (9)	4/5 (12)
Feasibility/ Reproducibility (15)	3/5 (9)	5/5 (15)	2/5 (6)
Total (100)	70	84	76

Proposed Final Design

Ultimately, the team chose to combine the highest scoring designs from each matrix to create the final design. The manikin's skin will be created out of ballistics gel which will be coated with a layer of cured PDMS. Ballistics gel will increase the durability of the design while PDMS will maintain the skin-like texture that is required for realism. This model will also include limbs that will allow for IV access. The inner workings will be created by using balloons and tubing to simulate lungs that can rise and fall with the introduction of air. Finally, the mold to create this design will be created from tough PLA, which is heat resistant enough to withstand the curing process and should have no chemical interactions with the skin materials during curing.

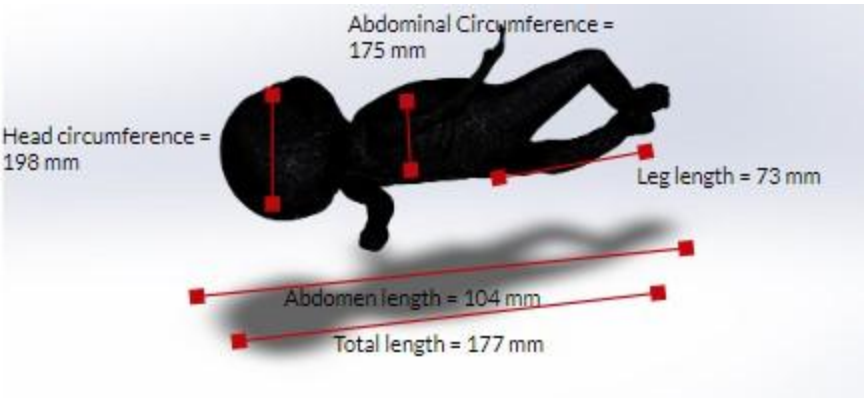

Figure 6: *SOLIDWORKS visualization of what the final design should look like after completion*

V. Fabrication/Development Process

Materials

The final mold design aims to use Ultimaker's Tough PLA from the UW-Madison Makerspace to 3D print. The mold will be composed of two halves that split the neonate in half along its coronal plane. This will allow for the inner workings and chest cavity to be placed within each half before sealing both halves together. The skin and exterior of the manikin will be created with ballistics gel for durability and a PDMS coating cured overtop for texture. The inner workings will use small balloons to represent premature lungs. These will be connected to tubing which will replicate the trachea.

Methods

The design team will begin by using the mold design that was created by one of the members last semester. The mold is split in half, so the team will also consider how the two halves will be joined together–either through a zipper or a hydrogel-compatible glue, like a tissue adhesive. The ballistics gel for the skin will be created by mixing ballistics gelatin powder with water. The ratio of this will be 10% gelatin by mass [8]. Once the ballistics gel mixture is created, it will be poured layer by layer into the mold. Once the gel has reached about midway through one half of the mold's cavity, a 3D printed snowman shape will be placed into the mold to hold the space for the chest cavity. The ballistics gel will be poured once more until the mold's cavity is completely filled. After this, the PLA will be removed from the material and the chest cavity will be intact. After the gel has set, the layer of PDMS will be cured on top of the ballistics gel. The PDMS will be allowed to cure at room temperature for a number of days so as not to melt the ballistics gel. Once the skin of the manikin has set, the inner workings will be

created. The inner workings will be created by using breathing tubing with a T-connector to mimic airways. At the ends of these, two small balloons will be attached to mimic lungs. Additionally, tubing will travel up the trachea to the mouth of the infant to provide a resuscitation avenue. Once this breathing mechanism has been placed into the manikin, the two halves of the manikin will be sealed together with either PDMS or a tissue adhesive.

Testing

Testing conducted during the course of this design project will ensure the best outcome of the final prototype. This will also help the design team identify areas of weakness for future design improvements.

The first testing conducted by the group will involve testing of the chosen skin materials, ballistics gel and PDMS. In order to identify the optimal formulation of ballistics gel, gels made with different concentrations of gelatin will be compression tested on a MTS machine. The formulation that best matches the elastic modulus of 17.8 kPa and the physical properties of a 22-23 week neonate's skin will be the formulation the team moves forward in prototyping with [9]. Similar testing will be conducted with the PDMS with a tensile strength test. The best concentrations for each of the materials will move forward in the prototyping stage.

Next, usability testing will be conducted to assess the effectiveness of the team's prototype. First will be intubation testing. This will involve all members of the design team and the client attempting to intubate the prototype with the laryngoscope, place an umbilical line, and insert IVs in locations of IV insertion. This will be tested against the control manikin, Premature Anne. Quantitative data such as time taken to complete this will be assessed as well as quantitative –such as comfort level and success– will be recorded. Other ideas for evaluating the prototype will be continuously considered throughout the project development phase with feedback from the team's client.

VI. Results

Results will be analyzed using standard deviation, statistical significance and percent error for the compression testing of the ballistics gel and tensile strength test for the PDMS. When the team finds the most realistic formulation in terms of replicating the 17.8 kPa elastic modulus for the baby's chest, this will be the formula used to construct the final prototype [9]. The team will also appraise the results of the tensile strength testing of the PDMS and determine if the results are accurate enough to successfully mimic 22-23 week old skin. If not, the team will reevaluate the choice of material. Overall, if the tests

yield results deemed adequate, then the fabrication of the prototype will ensue. Otherwise, different materials will be considered, graded, and tested accordingly.

VII. Discussion

In the testing of the skin quality of the manikin, if the group finds that the skin is damaged or that any noticeable deformations have occurred, another material may be chosen. If it is found that the ballistics gel and PDMS create an unwanted reaction when in contact or if the group has extended difficulty coating the ballistics gel with the PDMS, modifications to the design may be made. These modifications could include alterations to the material choices or adjusting the attachment method through such ways as texturing the ballistics gel surface.

The purpose of this product is to allow for medical professionals to experience realistic training to prepare them for real life neonate procedures. Therefore it is essential that the manikin maintains as much realism as feasible given the time frame and budget constraints. As each individual infant is unique, one potential source of error is that it is impossible to create a manikin that accounts for all variations of neonates. To combat this error our team has decided upon a design that represents characteristics maintained by a majority of 22-23 week old infants, while also considering future work that can be done to potentially create interchangeable parts to diversify our manikin [6] [7]. Another potential source of error is that the analysis of the skin testing can include MTS testing which could result in possible sources of error due to placement and amount of force being used to shear.

Throughout the group's research/testing, one of the main ethical considerations is that the final product and prototypes are safe to handle and do not pose a threat to the users. Such dangers could potentially include overheating of the electronic components to dangerous temperatures or usage of toxic materials that could harm the user.

VIII. Conclusions

Medical procedures performed on extremely premature infants are relatively rare as the survival rates for these infants is very low. For this reason, it is essential that medical professionals have adequate training on neonates so that when strenuous situations are encountered they feel more confident in their capabilities. Currently, there are no simulation manikins on the market representing infants of 22-23 weeks gestation, causing there to be a lack of adequate training for neonatal procedures such as resuscitation, intubation, and IV insertion. Oftentimes, a medical professional's first experience with resuscitation of a neonate this small is in a high stakes and chaotic environment within the hospital. To

better prepare medical professionals for these different scenarios, the team has developed design ideas to create a realistic neonatal manikin for simulated practice.

The final design seeks to replicate a true neonate through the incorporation of realistic, elastomer skin. This will be developed by coating the ballistics gel manikin core with PDMS to create the gelatinous texture the team is looking to mimic. Additionally, a new mold that includes limbs will be created which will be vital to the inclusion of IV access ports on the manikin's feet and arms. This will allow for the insertion of a 2mm IV tube. Market research was conducted, and the proposed final design was chosen after comparison to competing designs on the market. The team developed three design ideas, and determined a final design based on weighted scores in various design criteria. The previous team was able to create a mold and develop an adequate design, though it did not include any of the criteria that were discussed above. Thus, the team has worked to create a design to improve on the previous group's successes and shortcomings.

If the team was able to do this portion of the project again, there would have been a greater emphasis on meeting with the client to involve him more in the design process and ensure that the progress of the team continues to be on track with his vision.

Moving forward, the team will first focus on 3D printing the mold for the torso portion of the manikin and then molding the ballistics gel within it. To complete the next aspects of the project, the team will divide up responsibilities amongst members to work on testing ways to coat the ballistics gel with PDMS, creating molds for the limbs of the neonate, and creating an airway that can be utilized for intubation practice. Once this is complete the different components of the manikin will be assembled to create the final prototype. The team will then perform testing to determine whether the manikin is functioning as desired. Finally, necessary revisions will be determined and changes will be made to the final design for final testing.

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X. Appendix

A. Product Design Specification (PDS)

Neonatal 22-23-Week Premature Infant Simulation manikin: PDS

2/10/2023
Client: Dr. Tim Elgin
Advisor: Dr. Kristyn Masters
Team Members: Loukia Agoudemos, Sophia Finn, Tanishka Sheth, Charlie Fisher, and Abbie Schaefer

Function:

The simulation manikin must be representative of a premature infant born at 22-23 weeks of gestation. The manikin must be able to be intubated, which means that a breathing tube must be able to be placed into the manikin's trachea. Additionally, the chest cavity and rib cage must be created so as to include further procedural training for medical professionals in thoracentesis and pericardiocentesis. As there is a lack of simulation manikins for infants born this premature, it is critical to develop one that allows for medical personnel to be able to practice resuscitation techniques. Using a simulation manikin with similar characteristics and technology that makes it seem more lifelike allows the medical professionals to practice in a less chaotic and stressful environment. It is essential for medical personnel to have access to a training manikin such as this as it will allow neonatology to further advance and resuscitation to be possible for infants born at even younger gestational times.

Client requirements:

I. Length should be less than 30.5 cm
II. Improve skin texture of previous models
III. Ability to put synthetic breathing tube (2.00 -2.50 mm diameter) in mouth of manikin, to attach a synthetic umbilical cord, and to be able to practice vital signs
IV. Base has to be able to handle breathing mask and bag practice, therefore pressure resistant
V. Weight around 400-500 grams
VI. Expandable lungs that replicate neonatal breathing
VII. The more prototypes the better

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*:

I. The manikin must be able to last between 3-5 years and production cost must remain low to maintain reproducibility. It should also maintain similar characteristics to a real infant born at

22-23 weeks of gestation and include anatomically relevant structures.

II. According to a study conducted by Dr. Douglas Campbell and colleagues, high-fidelity simulation manikins for neonatal resuscitation prove more effective for practicing intubation on neonates. Such manikins include features such as breathing, crying, seizing, displaying cardiac and respiratory status, etc [1].

III. Standard procedure for neonatal resuscitation include the following:

A. Receive 30 seconds of intermittent positive pressure for adequate resuscitation and minimizing mask leak.

B. Withstand the chest compression pressure of standard chest compression techniques employed– 3 chest compressions to 1 breath. .

1. Force applied by two thumbs at a right angle to the chest with fingers clenched in a fist.

2. Thumbs applying force to the sternum with fingers encircling the chest and back for support.

b. *Safety*:

I. *User Safety* - The manikin is intended to be utilized in a low risk, learning environment. Any electronics included in the manikin must be enclosed and remain at a temperature low enough to ensure that the user is not experiencing any discomfort. Users should be informed of any characteristics of the manikin that are deemed as dangerous prior to operation.

c. *Accuracy and Reliability*:

I. The skin that is included on the manikin must be lifelike and resemble that of an extremely premature infant.

II. The organs, limbs, and other body parts that compose the manikin must replicate a realistic infant in such qualities as material, size, and location on the baby.

III. The manikin should be an accurate anatomical representation of an infant born at 22-23 weeks of gestation.

d. *Life in Service*:

I. Typical use for simulation manikins is between 3 to 5 years of frequent usage.

II. If deemed necessary, certain parts of the manikin can be replaced without requiring full manikin renewal.

e. *Shelf Life*:

I. Batteries and electronics within the manikin must be able to last for the full lifetime of the model.

II. It is essential that the materials and components of the manikin will not deteriorate in the storage environment over several years.

f. *Operating Environment*:

I. The manikin will be used as a training model in hospitals and teaching facilities. This includes such

areas as simulation centers and classrooms. The manikin will encounter temperatures rarely straying from room temperature (68 °F and 77 °F) in these environments.

g. *Ergonomics*:

I. The medical personnel using the simulation manikin must be able to perform resuscitation procedures without hindrance.

II. The manikin should be easy to use without exceedingly complicated electronic components that must be manipulated by the user.

h. *Size*:

I. The length of the manikin should be roughly 1 foot when measuring from the "head" of the manikin to the opposing end near the feet.

i. *Weight*:

I. The manikin should be between 400 and 500 grams which does not include added electrical components.

j. *Materials*:

I. The manikin must involve a skin-like material on the external surface. It is essential that the materials of the manikin simulate real human anatomy in such qualities as texture, thickness, and finish. Electronic components should also be encased within this material. The materials must be non-toxic and be safe to be in contact with human skin over prolonged periods of time.

k. *Aesthetics*, *Appearance, and Finish:*

I. The manikin must look similar to an infant born between 22-23 weeks of gestation in both size and shape.

II. Additional aesthetics should not add any adverse effects to the experience nor add any extra weight.

2. Production Characteristics

a. *Quantity*:

I. The client requires a single prototype. With successful creation of one prototype, more will be needed.

b. *Target Product Cost*:

I. Cost should be low enough to be reproducible, and be created within a couple thousand dollars. Market prices of competing models as well as the cost of materials and labor will be considered when assigning a retail value to the manikin.

3. Miscellaneous

a. *Standards and Specifications*

I. ISO 13485: This standard states that the organization must ensure quality medical devices from design to manufacturing and so on. This is achieved through ethical design that puts the customer and patient first, following standards, having adequate documentation, and so on[2].

II. ISO 14971: This standard states that risk management and design with risk considerations must

be conducted by the design team. This involves risk evaluation and the implementation of risk control by the design team[3].

b. *Customer*:

I. The customer base for this product is medical schools and hospitals that wish to educate their students on the intubation of neonatal infants. The students and medical professionals using the product would prefer if the manikin is easy to handle but at the same time reflect the higher difficulties in resuscitation for premature infants of 22-23 weeks of gestational age.

c. *Patient-related concerns*:

I. The patients that this manikin is supposed to simulate, the neonatal infant, would best benefit from this device if it is quite comparable to their likeness. Therefore, the patient-related concern is that the neonatal infant manikin does not incorrectly train medical students in how to intubate the neonatal infant patient.

d. *Competition*:

I. There are many other neonatal intubation manikins on the market today. These include, but are not limited to, models from Universal Medical Inc.[5], Laerdal Company[4], and Trucorp[6]. However none of the current models on the market represent infants younger than 25 weeks of gestation.

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any quantitative information without references came directly from the client, Dr. Elgin

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B. Expenses and Purchases

The team has not yet made any purchases.