DEPARTMENT OF
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UNIVERSITY OF WISCONSIN–MADISON

NEONATAL 22-23-WEEK PREMATURE INFANT SIMULATION MANNEQUIN

BME 200/300 - Final Report

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Abstract

Neonatology is an exciting and developing field. Studies and developments based on the various phases of gestation are mitigating complications surrounding preterm birth. This project focuses specifically on 22-23-week neonates. These infants are considered extremely premature and resuscitation is 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 mannequins that accurately and reliably represent neonates born at this stage of gestation. There are currently no neonatal mannequins 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 mannequin that includes three critical components. This includes IV access, realistic anatomical structures 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 mannequin 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 should occur many times over the fabrication timeline. With the team's efforts, a neonatal mannequin 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 this project is to send more families home with their newborn babies, specifically extremely premature babies. 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 24 weeks, the survival rate ranges to 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 difficult ethical decision often varying from case to case and parent to parent, doctors are advised not to attempt resuscitation before 25 weeks of gestation [2]. Even if the infant manages to survive, the risk of permanent disability is high for infants born before 25 weeks gestational age [2]. Further, due to the rarity of extremely premature infants, doctors often do not have experience handling and resuscitating infants at 22-23 week gestational age. If a simulation mannequin with all necessary components for resuscitation techniques coupled with realistic skin texture existed, doctors could practice on that mannequin, so that when a real, high risk 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 mannequin, 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 mannequins on the market, but none that accurately simulate a 22-23 week premature infant and satisfy the client's desires. Trucorp has a TruBaby X mannequin 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 neonates due to the larger size of the 5 month

infant mannequin. 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 for 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 Mannequin, 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, 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 mannequin, 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 week gestational age.

Problem Statement

There are currently no 22-23 week neonatal simulation mannequins 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 mannequin 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

Most 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. Preterm births are the leading cause of infant mortality in industrialized countries. Of all births, around 11% are preterm, and those account for 60-80% of infant 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. In this stage is the first big step in being able to complete gas exchange. The ability to complete the gas exchange circuit, however, 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 of gestation, which lays the basis for gas exchange. 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. While the lungs are underdeveloped compared to a full term infant, the anatomical structure between preterm and full term infants is approximately the same. While scaled down, most preterm infants share the same anatomical features and dimensional ratios as full term infants. 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]. This makes it impractical to scale down an adult model that may already exist. The chest cavity of 22-23 week premature infants is similar to that of a full term infant, but just much smaller. In addition, infants of this age 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 because of its fragility.

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 resuscitation of neonates born extremely premature. 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 mannequin 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 mannequin, to 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 mannequin should be less than

30.5 centimeters, and a weight of 400-500 grams.The client also requested that the skin be made more lifelike, as a premature infant's skin is more malleable, sticky, and gelatinous than a full-term infant or an adult.

III. Preliminary Designs

Model with IV Insertion & LED Resuscitation Component

This design for a 22-23 week neonatal mannequin features IV insertion capabilities and electronic resuscitation features, making this model a top-of-the-line resuscitation-training device that is both durable and cost-effective for educational use.

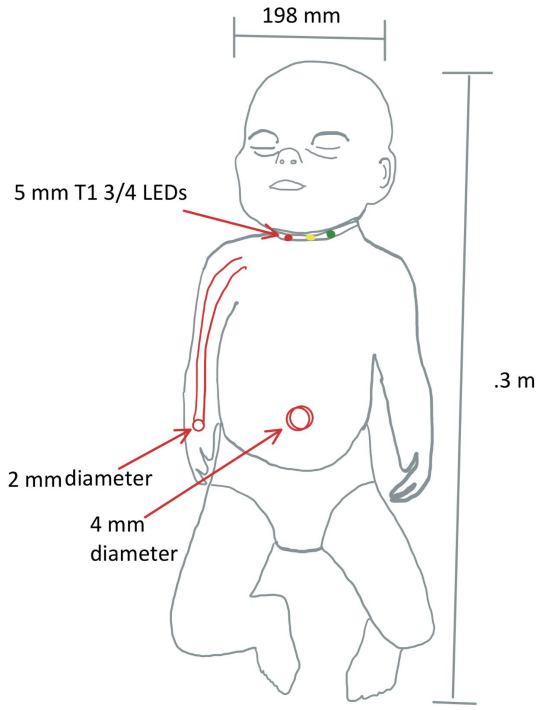

Figure 1: Model with IV Insertion & LED Resuscitation Component

This design features an LED and pressure sensor circuit, connected to the chest cavity, that detects proper and improper resuscitation technique via Arduino software [8]. After the sensor picks up on the pressure applied, the Arduino categorizes the resuscitation as proper, approaching improper, or improper, and an LED is lit with its respective category. Green shows proper technique; yellow indicates

potentially improper technique, and red indicates improper technique. This allows for direct feedback for those training on the device to practice their resuscitation strategies and potentially save more premature neonatal infant lives.

The durability aspect comes from the materials that have a high elastic modulus, and will not wear as easily as more brittle materials. The IV line will be a small tube of plastic that will allow for multiple reinsertions of 2 mm IV line. Additionally, an umbilical line hole will be included for similar umbilical cord insertion. Finally, the skin would be made out of silicone, which, as an elastomeric polymer, can withstand more extensive use in comparison to more gelatinous polymers.

Realistic Chest Cavity Model With Intubation

This neonatal model includes many physical features, including realistic limbs, chest cavity, and multiple IV insertion points to make the model as realistic to a 22-23 week neonatal infant as possible, given the design team's time constraint.

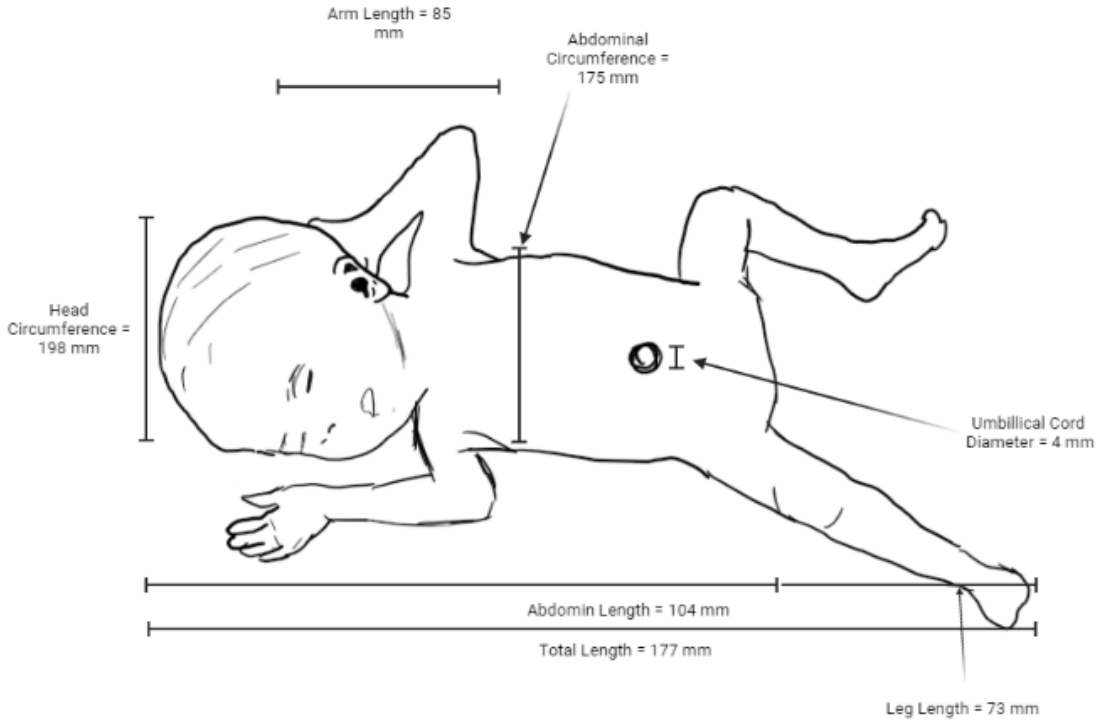

Figure 2: Realistic Chest Cavity with Intubation Model

This mannequin features a composite of polymers for the skin to make the mannequin's skin model as accurate as possible to premature infant skin. The inner layers of the skin model will be made of a gelatinous polymer such as a hydrogel made out of gelatine, agar, or polyvinyl alcohol. The outside of the gelatinous polymer will be sealed with an elastomer–such as silicone or polyurethane–that allows for the hydrogel to be more durable, stretchable, skin-like, and prevents evaporation of the water used to make the gelatinous polymer. This mannequin will also have airbrushing and realistic coloration to make the mannequin as life-like as possible. Additionally, limbs will have a skeleton system with realistic joints to allow for accurate movements.

The chest cavity of the mannequin will be a realistic, air-bag system. It will also feature an accurate ribcage to encapsulate the mannequin's respiratory system. The mannequin will also include IV insertion and intubation holes in the umbilical cord and mouth. Electronics that allow for mimicking the rise and fall of breathing will also be included.

Model With Fluid Pockets

This model is very similar to the realistic chest cavity model with the composite polymer skin and electronic respiration system. The main difference is the inclusion of liquid proof pockets that allow liquids to be drawn through the IV insertion lines and umbilical cords, allowing those who work with neonates to practice drawing fluids from neonatal infants in critical condition.

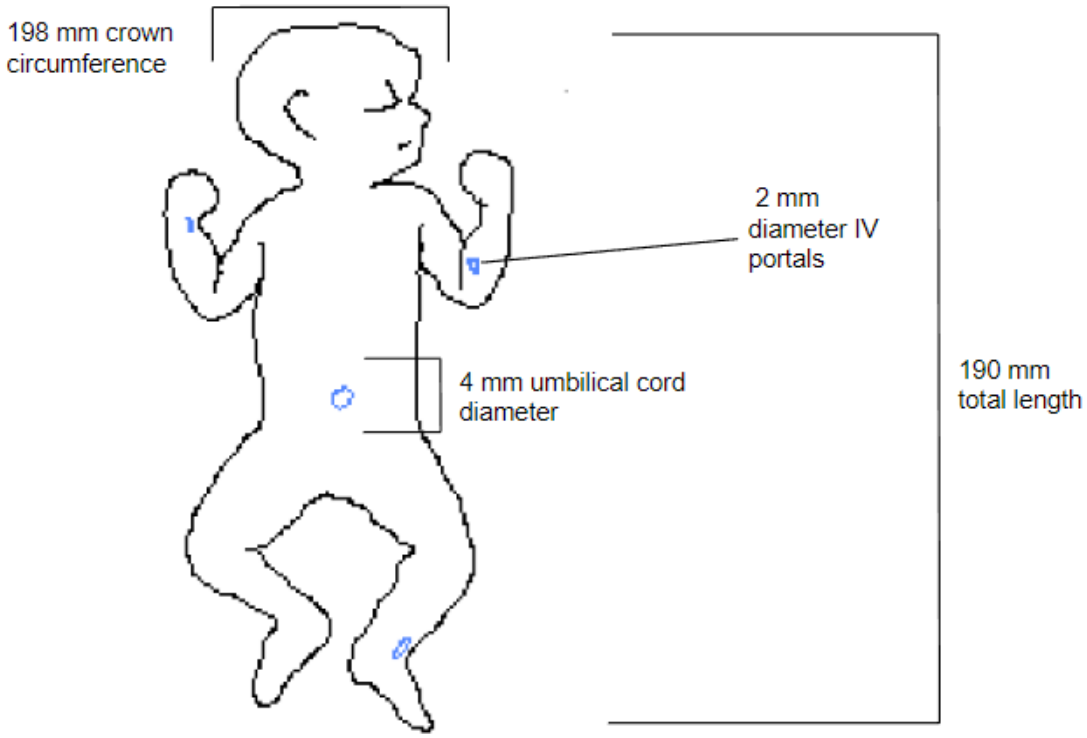

Figure 3: Model with Fluid Pockets

IV. Preliminary Design Evaluation

Design Matrix

The 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 was evaluated based on the client's requirements, what was most readily accomplishable in a semester, and by how readily the design team can fabricate the model with the amount of background knowledge that the design team has.

Texture is how accurately the skin model on the mannequin mimics that of a true premature neonate's skin. Usability is how effective the mannequin serves as a training device. This concerns whether it has the proper design components for educational purposes or not. This criteria also determines if the mannequin is durable enough for training use. Cost is how cost effective the design is to make in comparison to competitors with more costly mannequins. Size and weight refers to how accurately the model portrays 22-23 week neonatal dimensions and weight. Realism is how life-like the mannequin is,

and finally feasibility and reproducibility is how effectively the design team can fabricate the model during the time constraint of the semester.

Each of these criteria were weighted by what was determined to be the most important criteria which were texture, usability, and cost. The next highest criteria were size and weight, which, while important for the mannequin, these dimensions could be impacted by the inclusion of external bulky electronics and mechanical components. The lowest criteria were realism and feasibility given a general lack of research in this realm, and the fact that the team will be making one final prototype during the span of the semester.

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

	Design 1: Model with IV Insertion & LED Resuscitation Component	Design 2: Realistic Chest Cavity Model w/ Intubation	Design 3: Model w/ Fluid Pockets
Texture(25)	3/5 (15)	5/5 (25)	4/5 (20)
Usability(25)	4/5 (20)	2/5 (10)	3/5 (15)
Cost(25)	2/5 (10)	3/5 (15)	2/5 (10)
Size/Weight(15)	3/5 (9)	2/5 (6)	3/5 (9)
Realism(5)	4/5 (4)	5/5 (5)	4/5 (4)
Feasibility/ Reproducibility (5)	3/5 (3)	2/5 (2)	2/5 (2)
Total (100)	61	63	60

Proposed Final Design

Ultimately, the team chose Design 2: Realistic Chest Cavity Model with Intubation. This design scored the highest based on the design matrix criteria. This model's hydrogel and elastomer composite skin, in combination with realistic joints and additional details in the skin design, would give it the most

realistic texture. It is the most cost efficient, as fluid pockets pose the threat of damage in Design 3, and Design 1 is more costly due to the amount of sensors and lights that would need to be purchased. Design 2 is more realistic overall than either of the other designs. Design 1 becomes too heavy with the inclusion of all proposed electronics. Design 3, due to its fluid pocket, cannot include some of the necessary electronic components for realism.

V. Fabrication/Development Process

Materials

Our final design consisted of three essential components. The first is the mold used to shape the neonatal mannequin skin, the second is the mannequin skin tissue biomaterial, and the third is the inflating lung mechanism. For the mold, the team elected to use Nylon-12. This polymer was chosen because it fulfills several requirements. It is relevantly heat-resistant, as it withstands temperatures up to 280^{o} F and would thus prevent the risk of deformation of the mold. We used this material to 3D print a mold designed digitally through Mesh Maker. The material for this was provided by MakerSpace. The neonatal mannequin's skin was made from Sylgard 184. This silicone elastomer was poured in layers into the Nylon-12 mold and cured in this mold in order to hold the form of the neonate. Finally, the team chose to utilize a relatively simplistic design for the lungs of the neonate. This plastic tubing and balloon model is able to accommodate the intubation materials, and is able to inflate with the input of air. This tubing and balloon was provided by Dr. Elgin.

Methods

The first step in building the prototype was to 3D scan Premature Anne at the MakerSpace. Then, the file was processed and sent to the team. From there, the members modified the files using a combination of SolidWorks, MeshMixer, and Blender to remove the limbs from the scan, slice it in half, and then extrude a box so that the scan became the negative space. The team 3D printed the mold at the MakerSpace. Meanwhile, the team began to test skin materials to use for the prototype. It was determined that the Sylgard 184 would suffice for the design. Opposingly, the agar retained too much moisture to adhere to the Sylgard 184, and therefore, was not used in the mannequin. The next prototyping step was to mix and pour the Sylgard 184 into the mold. The solution consisted of a 10:1 ratio between the base and the curing agent. It was then cured at 280^{0} F in an oven. Afterwards, a balloon mechanism was inserted to

simulate a breathing mechanism, and the two halves of the molds were glued together. The balloon mechanism consisted of a tube that was able to fit the required 2 mm intubation tube, a balloon, and a rubber band connecting the two such that it was airtight.

Final Prototype

Figure 4: Final prototype made out of Sylgard 184 with intubation tubing and balloon mechanism

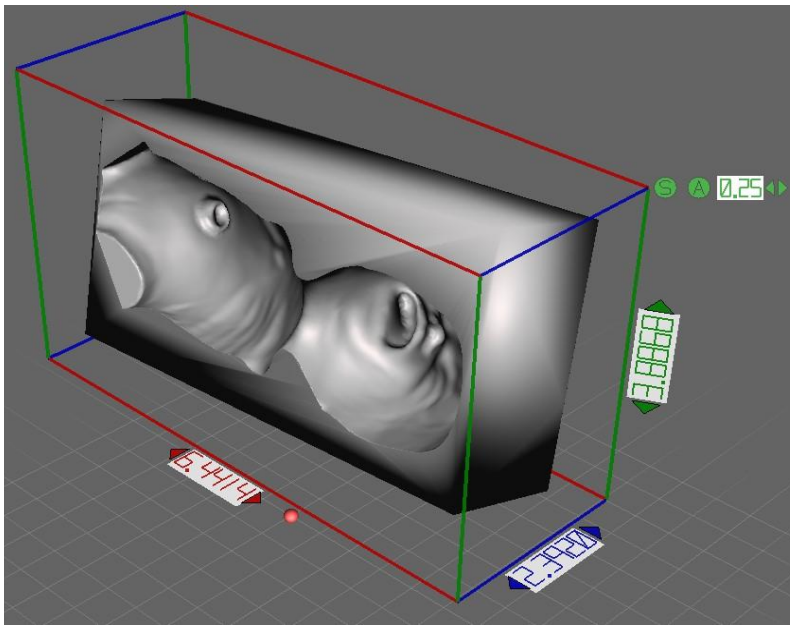

Figure 5: Scaled-down, nylon mold created using Blender and Meshmixer. The units of dimension are displayed in mm.

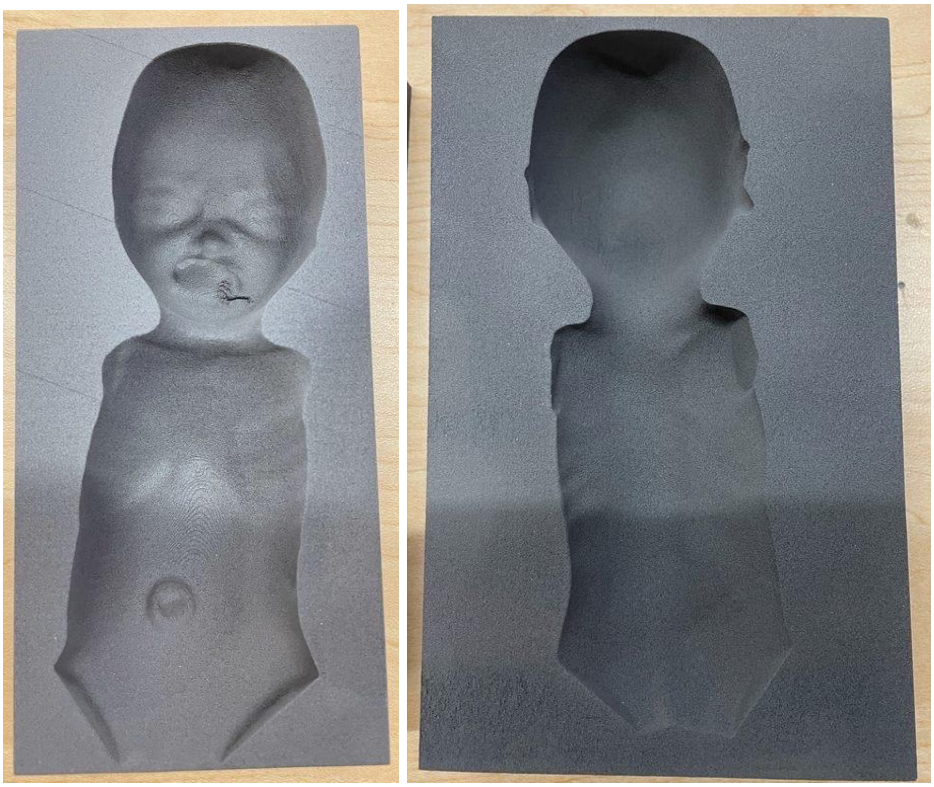

Figure 6: Finalized nylon mold for prototype.

The team's final design for the semester project can be seen in Figure 4. The design was generated by pouring layers of Sylgard 184 into a larger printed mold from Figure 5 and Figure 6. Within this there was a chest and head cavity as well that creates space internally in the mannequin for the inclusion of extra components. The design includes a balloon mechanism to mimic lungs made out of a rubber water balloon that is fastened around a plastic 2 mm tube. This mechanism sits in a chest cavity and the tube exits from the "mouth" of the mannequin's face. Intubation can be done by inserting a tube into the mouth tube and blowing air which allows the balloon to inflate and mimics a rising and falling baby's chest. The team's goals of including color, joints, and electronics were not fulfilled as the main goal for the semester was to create realistic skin with the proper texture.

Testing

Testing of the mannequin prototype consisted of two different testing categories. The first was mechanical testing of our prototype's skin model. The mechanical properties of the skin were evaluated in two different ways, with the Sylgard-184 elastomer undergoing a tensile test, and the agar hydrogel undergoing compression testing. Next, usability testing was performed qualitatively by design team members. The following passages will summarize the protocol and purposes of the design team's choice in testing.

A tensile test is a test used to characterize the mechanical properties of a material where a controlled, tensile load is applied until failure. Data collected by this test can be used to determine the yield strength, ultimate tensile strength, Young's modulus, and more. The design team chose to conduct this experiment using an MTS machine, triplicating the results by testing three different samples of the Sylgard elastomer. Once data was collected according to protocol (in appendix), the data was analyzed for the Sylgard-184 samples' elastic moduli and ultimate tensile strength. This helps determine the effectiveness of our selected material for external skin use of the training mannequin.

A compression test is similar to a tensile test as it is used to characterize the mechanical properties of a material. The difference between the tests is that instead of a tensile load being applied, a controlled, compressive load is applied until failure. Compression testing of three agar hydrogel samples was conducted (as shown in the appendix) to identify the elastic modulus and ultimate compressive strength of the agar hydrogel material chosen. While not requiring as high of an elastic modulus as the external skin layers, appropriate strength should still be considered for mannequin use.

Finally, usability testing was conducted qualitatively by design team members to assess comfortability using the mannequin. In this testing, team members attempted to intubate the mannequin using the tube provided by the client; blow into the intubation tube to see if the balloon mechanism inflated to mimic rescue breaths used in CPR; and, finally, the chest of the mannequin was pressed on to mimic chest compressions for resuscitation. This testing was performed not quantitatively given that none of the design team members are familiar with formal resuscitation techniques. Future work reflecting on this testing process demonstrates an understanding of how this testing could be improved through quantifying results and establishing a more effective testing procedure.

VI. Results

To determine whether the prototype adhered to the design criteria, three tests were conducted. The first was tensile testing of the Sylgard 184, the elastomer used for the prototype. The second test was compression testing of the agar hydrogel. The third test was usability testing conducted by the members of the team to determine whether the mannequin could be successfully intubated.

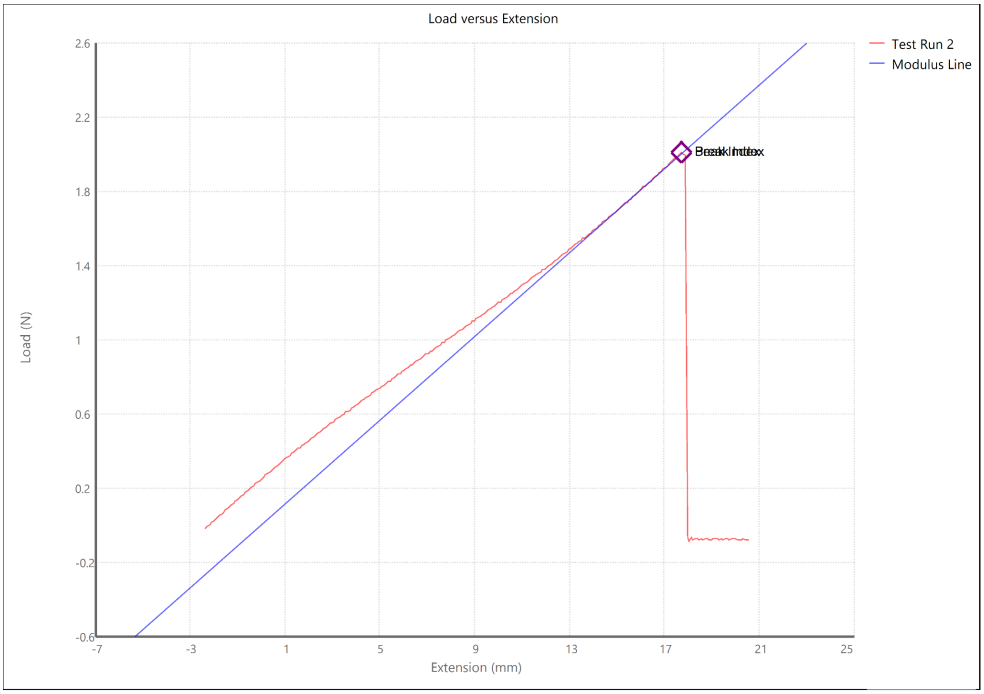

Figure 7: Data from one run of tensile testing of Sylgard 184

Tensile testing was used to determine whether the Sylgard 184 that was cured and poured by the team met the industry standard specifications. Performed to determine whether the selected elastomer can

stretch to a point that shows it can be effectively used in future prototypes and mannequins. Industry standards claim that for bulk Sylgard 184, the Young's Modulus should be 1.32-2.97 MPa [11]. When testing on three samples was conducted, the team found that the material was able to withstand an average of 2.0 N. From this value, a Young's Modulus was calculated to be about 0.11 MPa. This is significantly lower than the industry specified values, and the team believes that this may have been a result of improper degassing prior to pouring the material in the mold.

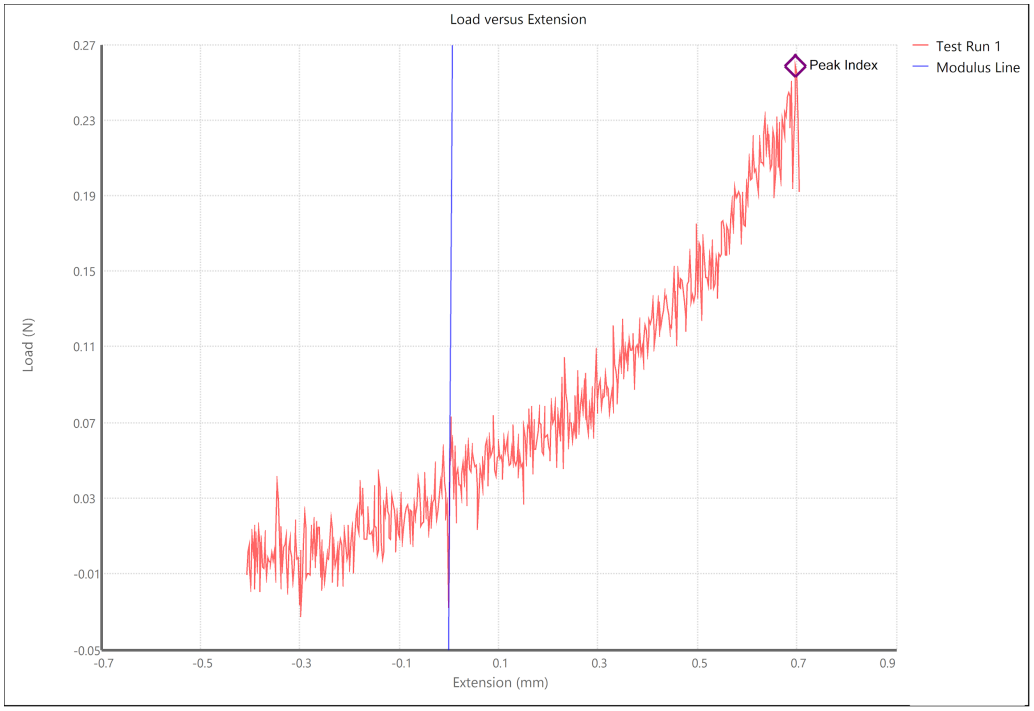

Figure 8: Data from one run of compression testing of agar hydrogel

Compression testing was performed to determine whether agar that was mixed and created by the team met industry standards. The comparison to standards was used to determine if the selected hydrogel can withstand enough force to be used effectively in future mannequins and prototypes. Industry standards claim that for bulk agar, the Young's Modulus should be between 30 and 700 kPa [12]. When testing on three different samples was performed, the team found that the material was able to withstand an average maximum compressive force of 0.25 N. From this the Young's Modulus that was calculated was 360 kPa. This falls within the standards that were determined by industry. However, the material was not actually used in the final prototype due to it not attaching to the elastomer properly.

Once the prototype was completed, members of the team attempted to intubate the mannequin and ensure that there was a rise and fall of the mannequin's chest. Additionally, members identified how

easy or difficult it was to interact with the mannequin. This was not quantified in any manner but was used to identify potential pain points that can be improved upon in coming semesters. Members identified that the balloon was inflating and that it was easy to perform these types of actions when the mannequin was lying face up on a table. However, actual handling of the mannequin was difficult as the material was sticky and the halves threatened to come apart with more forceful handling. These are points that the team believes can be improved in the future.

VII. Discussion

The results of tensile testing on three samples of Sylgard 184 was that the material was able to withstand an average of 2.0 N. From this value, the Young's Modulus was calculated to be about 0.11 MPa. This is lower than industry standards, and thus should be improved upon in future prototypes. One reason for this failure that the team has considered is that the material was not put into the degasser for long enough. Each time additional material was cured, the mixture was placed into the degasser for 30 min. The team believes that if the time that the material spends in the degasser is increased to 45 min to 1 hour, there might be significant loss of bubbles and thus an increase in tensile strength of the material. The air bubbles that were left in the samples and thus the prototype could be a reason that the material failed much sooner than expected.

The results of the compression testing on agar was that the material was able to withstand an average maximum compressive force of 0.25 N. From this value, the Young’s Modulus that was calculated was 360 kPa. While this fell within the industry standards defined, the team opted not to use the material between layers of Sylgard. This is because the material would not properly bind to the elastomer. The agar’s texture ended up being too wet and slimy so it was difficult to cure layers of elastomer over the top without compromising the integrity of the material. Thus, the team decided to just use multiple layers of the elastomer rather than sandwiching the agar between layers of Sylgard 184. However, the team believes that agar can be used in the future by using a chemical acrylation process and using reagent grade agar instead.

From usability testing it was determined that while the mannequin can be intubated to a somewhat successful degree, it is difficult to determine how noticeable the rise and fall of the chest should be. To aid in this, the team hopes that in the future, the prototype can be handed off to teams of medical professionals who can provide their feedback from their own usability testing. Additionally, the team determined that the material was too delicate where it had been attached together from the two halves of the mold. As a result, the team believes that in the future, improvements can be made to the

attachment of the two halves. This might be fixed by leaving the halves somewhat uncured and then adding a thin layer of uncured Sylgard 184 on each half and curing the halves together.

Due to the time constraints of the semester, the team was not able to fulfill creation of all of the components that were identified in the design matrix. In the future the team would like to explore the addition of limbs and tubing as well as the inclusion of some electrical components.

As far as testing goes, the team would like to continue MTS testing on newer, improved samples. This would include testing of an elastomer-hydrogel complex rather than performing tests on the materials separately. Additionally, the team would also like to expand what usability testing entails and allow for medical professionals or medical students to interact with the prototype and determine what aspects need improvement and what aspects are working as desired. Because of the lack of literature on infants that are born at 22-23 weeks of gestation, a lot of the work that the team has conducted has been based on what was supplied by the client. As a result, the client and other teams of medically knowledgeable people providing feedback would give the team more direction in terms of how the project should progress in future iterations.

Ethical considerations that the team followed were ISO 13485 which ensures that the team follows ethical design practices as well as including proper documentation while putting the customer and patients first [13]. The team also considered ISO 14971 which is in regards to risk management [14]. The team ensured that there would be no injury or poor response when handling the mannequin. This was crucial as the mannequin is to be used in medical and educational settings to simulate a real medical experience.

VIII. Conclusions

Neonatal resuscitation in infants born extremely premature is relatively rare as the survival rate for these infants is very low. Currently, there are no simulation mannequins on the market specific to 22-23 weeks gestation, which does not allow medical professionals the ability to practice medical procedures including resuscitation and IV insertion. Oftentimes, a medical professional’s first experience with a neonate this small requiring resuscitation is in a high stakes and chaotic environment within the hospital. To increase confidence and reduce stress, the team has developed design ideas to create a realistic mannequin that includes aspects for medical professionals to practice.

To do so, 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. A previous design team was able to create a mold and develop an adequate design, though it did not include any of the criteria that was discussed above. Thus, the team has worked to create a design to improve on the previous group's successes and shortcomings.

The team's final design sought to include realistic neonatal skin by using a gelatinous, elastomer material. This was developed by pouring the silicone elastomer–Sylgard 184–into the 3D printed mold of the mannequin. In addition to the outer skin, the mannequin also consisted of a balloon on the inside of the thoracic cavity which, once inflated, would allow the movement of the chest cavity as well as any intubation required. During testing, however, it was concluded that the Young's Modulus of the Sylgard 184 tested (0.11 MPa) was not in the range of the industry specifications. Additionally, the elastomer curation was not as expected, resulting in inconsistencies of parts of the outer layer's appearance and the retention of air bubbles. Despite these aspects interfering with the handling of the mannequin, the team was still successful in improving the texture of the outer skin by increasing the level of stickiness, making the material more closely resemble that of a neonate. Additionally, the team was also able to perfect the size of the mannequin and improve intubation applications from the previous group.

In a future continuation of the project, the team would like to try using a different material for the 3D printed mold as that could have also altered with the final texture of the skin. The team hypothesizes that there might have been a chemical interaction between the Sylgard 184 and the nylon of the mold. The team also looks to improve upon the fusion of the two halves of the mold as well as adding color to the elastomer such that the mannequin looks more similar to an actual preterm infant. Additionally, increasing the testing and seeking medical professionals' opinions on the usability testing would allow for further improvements to the design. In terms of the skin, the team would like to improve on the bubbles, and increase the durability of the outer layer. The team would also prefer to add a middle layer to provide a more skin-like texture, as was decided in the final design.

IX. References

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X. Appendix

A. Product Design Specification (PDS)

Function:

The simulation mannequin must be representative of a premature infant born at 22-23 weeks of gestation. The mannequin must be able to be intubated, which means that a breathing tube must be able to be placed into the mannequin’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 mannequins 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 mannequin 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 mannequin 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 mannequin, 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 mannequin 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.

b. *Safety*:

I. *User Safety* - Any electronics included in the mannequin must be enclosed and remain at a temperature low enough to ensure that the user is not experiencing any discomfort.

c. *Accuracy and Reliability*:

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

II. The mannequin 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 mannequins is between 3 to 5 years of frequent usage.

e. *Shelf Life*:

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

f. *Operating Environment*:

I. The mannequin will be used as a training model in hospitals and teaching facilities.

g. *Ergonomics*:

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

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

h. *Size*:

I. The length of the mannequin should be roughly 1 foot when measuring from the “head” of the mannequin to the opposite side.

i. *Weight*:

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

j. *Materials*:

I. The mannequin must involve a skin-like material on the external surface. Electronic components should also be encased within this material.

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

I. The mannequin 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.

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[1].

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 that wish to educate their students on the intubation of neonatal infants. The students and medical professionals using the product would prefer if the mannequin 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 mannikin 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 mannikin does not incorrectly train medical students in how to intubate the neonatal infant patient.

d. *Competition*:

I. There are many other neonatal intubation mannequins on the market today. These include, but are not limited to, models from Universal Medical Inc.[5], Laerdal Company [4], and Trucorp[5].

B. Expenses and Purchases

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Skin								
Slyguard Silicone Elastomer	Needed to make the layer of ski	WPI		11/4/2022	1	$286.00	$286.00	https://www.wpiinc.com/sylg18
Agar Agar Powder	Needed to make the protective	The Seaweed Solution		11/4/2022	1	$14.99	$14.99	https://www.amazon.com/Agar-
Petri Dishes	Needed to work on differnt conc	LabAider		11/13/2022	1	$14.98	$14.98	https://www.amazon.com/Steril
3D Printing								
Mold	Needed mold in order to make r	Makerspace		11/22/2022	1	$123.00	$123.00	
							$0.00	
						TOTAL:	**$438.97**	

C. Testing Protocols

Skin Molding

1. Mix 1 gram of Sylgard 184 Base with .10 grams Sylgard 184 Curing Agent in a petri dish.
2. Transfer the solution to a baking sheet.
3. Place the baking sheet with the solution in an oven at 280° F for half an hour.
4. Remove the sample and note imperfections (such as areas that are not fully cured).
5. Calibrate the MTS machine, preparing the tension test.
6. Place the Sylgard 184 sample in the pincers of the MTS machine.
7. Begin the test.
8. Record the data from the MTS test.
9. Repeat steps 1-8 for two additional samples.

Agar Compression Testing Protocol

Compression testing is a mechanical test to characterize the mechanical properties of the desired material. This involves applying vertical load over time, measuring the displacement of the material, and creating a

stress-strain curve from this data until mechanical failure. This makes it easy to characterize the elastic modulus of the agar hydrogel and its greatest load it can hold before failure.

The protocol is as follows:

1. Select 3 samples of agar hydrogel of appropriate thickness and area for use on the MTS machine.
    1. Ensure that the sample selected is as uniform as possible and is consistent among the other samples.
2. Attach appropriate compression testing plate heads onto the load cells.
3. Power up the MTS machine if not already on and open the MTS software. Open a new test.
4. For each sample, do the following...
    1. Measure and record the length, width, and thickness of the agar sample.
    2. Write this information in the appropriate text-entry prompts of the MTS software for your new test.
    3. Place the sample centered on the compression plates.
    4. Double-check that everything looks right before running the test.
    5. Unlock the machine and select the run test.
    6. Collect compression testing data until failure–this should look like a sudden dip in displacement on the stress-strain graph.
    7. Stop the machine and take a picture of a sample where you believe failure to be located.
5. Use data analysis to identify the elastic modulus and ultimate strength.