

Neonatal 22-23-Week Premature Infant Simulation Manikin

Final Report

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Abstract

The team's client, Dr. Timothy Elgin, has requested a simulation manikin that resembles an infant born at 22-23 weeks gestation that has the capacity to be intubated, supports central umbilical line placement, allows IV access, and has a rib cage and chest cavity. Currently, there are no affordable and realistic 22-23-week manikins on the market. There are a couple designs close in age and some in testing, but none that have all of the mechanical components desired by the client and none that accurately represent the skin texture of a true neonate. The team's goal this semester is to expand on previous work – from a University of Iowa design team and the design teams at University of Wisconsin - Madison – that have worked on this project, improving the accuracy of the outer layer of skin to have the same texture and elasticity of an infant's born at 22-23 weeks gestation and adding limbs to make the simulation manikin more realistic. The outer layer of the skin will be tested for accuracy using a blind touch test by the client, Dr. Elgin, and his colleagues, and using adhesive to see whether or not the outer layer of skin tears easily. A successful prototype will allow medical personnel to refine the skills needed to successfully resuscitate an extremely premature infant (EPI). This contributes to the overarching motivation of the project, which is to counter the traditional limits of viability and improve resuscitation rates of EPIs.

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Introduction

Motivation

A preterm birth is defined as any live birth that occurs before 37 completed weeks of gestation. Annually, approximately 15 million infants are born preterm worldwide, which is about 11% of all births. Preterm birth is the leading cause of death in children, accounting for 35% of all deaths among newborns. Of all preterm births, only about 5% fall under the category of extremely premature infants (EPIs), which are infants born before 28 weeks of gestation [1].

This project focuses on infants born at 22-23 weeks of gestation. Due to the rarity of these births, for many physicians, residents, and fellows, their first time using the techniques needed to resuscitate an infant this extremely premature is during a real-life scenario. According to a journal article published in 2019, the survival rate of infants born at 23 weeks gestation is between 1% and 64%, and the survival rate of infants born at 22 weeks gestation is less than 10% [2]. Due to the low survival rate and increased risk of disability later in life due to incorrect neonatal resuscitation, such as brain damage and pneumonia, physicians often do not attempt resuscitation on EPIs. In fact, only 0% - 4.4% of surveyed physicians said they would attempt resuscitation of a neonate born at 22 weeks gestation, and only 4% - 47% would attempt resuscitation on a 23-week premature baby [2],[3]. While the decision to resuscitate an EPI is partially an ethical decision made by parents and doctors, the existence of a realistic manikin for medical professionals to practice on could encourage more doctors to attempt resuscitation on infants born at 22-23 weeks gestation. In order to soften the learning curve for medical personnel and ultimately send more babies home with their families, a simulation manikin is necessary.

Existing Designs

There are a few neonatal infant manikins on the market, but none that fully satisfy the client's specifications. Newer designs made to resemble infants born at 22-23 weeks gestation do not have extensive trials or information advertised about them, and existing products pose issues in affordability, accuracy and accessibility.

Laerdal Medical's Premature Anne:

Premature Anne (see Figure 1) is currently on the market as a 25-week premature infant manikin. It is an anatomically correct representation of an infant born at 25 weeks gestation. It is sold either on its own or with a SimPad PLUS that allows physicians to train with different scenarios. This manikin allows for practice suctioning, intubating, and inserting endotracheal, nasogastric, and orogastric tubes. The chest rises and falls with proper technique. It also supports umbilical line placement, and has intravenous (IV) sites in the right saphenous vein, dorsum of the left hand, and the

left antecubital fossa. While this simulation manikin is very advanced and can perform all of the mechanical functions specified by the client, it is too big in the head and abdomen [4]. Additionally, the skin is durable but unrealistic since it is not sticky nor does it tear easily [4], and the cost, which is \$2,999.00 on its own or \$6,899.00 with the SimPad, is much too expensive to meet the client requirements [5].



Figure 1: Laerdal Medical's Premature Anne During Training Simulation [5]

Lifecast Body Simulation's Micro-Preemie Manikin:

Lifecast's Micro-Preemie Manikin anatomically represents an infant born at 22-23 weeks gestation (see Figure 2). This manikin supports training such as intubation and ventilation, umbilical line placement, and nasogastric tube placement, but lacks the ability to practice IV insertion. Micro-Preemie Manikin was made by a design team at Elstree Studios in collaboration with Dr. Alok Sharma, a neonatologist, and is a very new product. As a result, there is no known information about the cost of the prototype. Further, while the skin appears realistic due to the hand-painted silicone, whether or not it feels realistic is unknown [6].



Figure 2: Lifecast Body Simulation's Micro-Preemie Manikin [6]

Past Work

Additionally, this project is continued from previous design teams both at the University of Iowa and UW-Madison. Various aspects of previous designs were adapted, such as the body molds, protocols for using materials, and research done on skin texture and mold design, for use in this semester's design.

Iowa Design Group Final Prototype:

Dr. Elgin was previously employed at the University of Iowa where he had a team of graduate students working on this design project. They created a final prototype of the upper body and head of a 22-24 week infant with realistic infant umbilical veins, arteries, and airway, which can be seen in Figure 3 and Figure 4. Testing, however, determined that the manikin was not capable of intubation and resuscitation. The lungs failed to expand when proper intubation was performed [7]. The manikin was also unrealistic as the prototype was missing limbs and did not have realistic skin, which was qualitatively described by the client as gelatinous, wet, and sticky [4].



Figure 3: Iowa Design Team Final Prototype

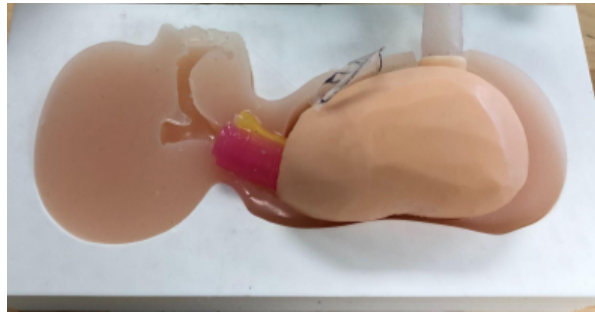


Figure 4: Internal Chest Cavity and Airway of Iowa Design Team Final Prototype

BME Design Spring 2023 Final Prototype:

This project is a continuation from prior semesters at UW-Madison. The spring 2023 team created a manikin using ballistics gel and attempted to use polydimethylsiloxane (PDMS) for the skin but found it would come off during testing. Additionally, the ballistics gel was too stiff, even though the Young's modulus fell within the desired range. Overall, their prototype was unrealistic as it was too small, the skin was an incorrect texture, and it was missing limbs, which can be seen in Figure 5 [8].



Figure 5: BME Design Spring 2023 Final Prototype with Internal Components Inserted

Problem Statement

There are currently no known affordable neonatal manikins on the market made to accurately resemble infants that are born at 22-23 weeks of gestation. Consequently, the first time many physicians, residents, or fellows use the resuscitation skills needed to save an infant born extremely premature is during a real-life scenario. To provide a softer learning curve and to ultimately raise the rate of success of the resuscitation of premature infants, physicians are in need of a neonatal simulation manikin. The manikin must resemble an infant born at 22-23 weeks gestation, have the capacity to be intubated, have IV access, and support central umbilical line placement. Ideally, the manikin will also have a ribcage and chest cavity to allow physicians to practice the techniques needed for thoracentesis and pericardiocentesis procedures.

Background

Relevant Physiology and Biology

Infants born at 22-23 weeks gestation are about 30.48 cm in length and weigh between 400-500 g. They have very thin, wet, gelatinous skin that can tear easily [4]. Due to their thin skin and large surface area compared to body mass, premature infants lose body heat very quickly and require heating upon birth. Further, the tissues of premature neonates are not fully developed and can be damaged by excessive oxygen from intubation. Premature infants need intubation, however, because their chest muscles are weak and are deficient in surfactant, which prevents them from taking effective breaths, and their underdeveloped nervous system may not stimulate them to breathe properly. Finally, their small blood volume makes them susceptible to blood loss and their weak immune system puts them at greater risk for infection. Overall, the resuscitation of an EPI proves to

be very challenging because every scenario is different and the slightest change in technique (i.e. levels of oxygen, heating, compression, etc.) could be the difference between life and death [9].

This project requires an accurate chest cavity of a 22-23 week premature infant in order to practice intubation, compressions, pericardiocentesis, and thoracentesis, so it is important to understand the anatomy of a newborn's chest cavity compared to an adult's. While an adult's chest cavity is more cylindrical shaped and has ribs that wrap around the body, a newborn has a chest cavity that is more cone-shaped and ribs that are in a more horizontal position [10].

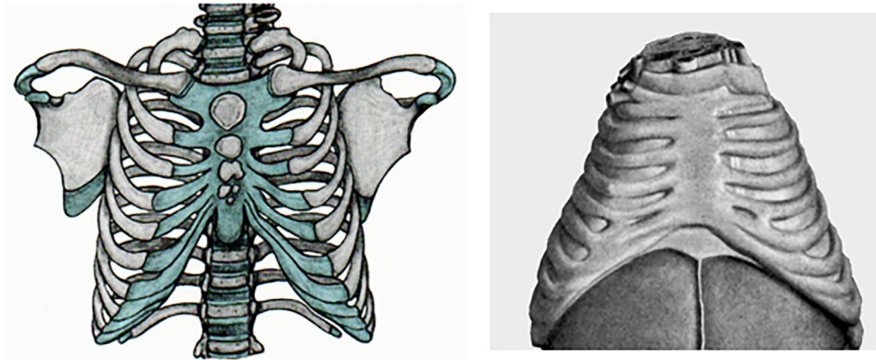


Figure 6: Anatomy of Chest Cavity of an Adult (left) vs Anatomy of Chest Cavity of a Newborn (right) [10]

When researching premature newborns, there are very few literature values cited for mechanical characteristics of various anatomical structures and organs. As a result, literature values for adult humans will be used as a reasonable approximation for prenatal characteristics. Specifically, for skin elasticity, the lower approximation for adult skin was used as an estimate for neonatal skin due to the fact that skin of premature newborns is thinner and more fragile than adult skin, and there is no known value for skin of an infant born at this stage of gestation. With this in mind, the Young's modulus of adult skin is reported to be between 4.6 MPa and 20 MPa [11]. 4.6 MPa will be used as an estimate of the Young's modulus of newborn skin.

Client Information

The client, Dr. Timothy Elgin, is an associate professor at the University of Wisconsin - Madison Department of Pediatrics in the Neonatology and Newborn Nursery Division.

Design Specifications

The client has requested one functioning simulation manikin correctly representing the anatomy of an infant born at 22-23 weeks gestation. The manikin must be no more than 30.48 cm in length, weigh between 400 g - 500 g, and have wet, gelatinous, sticky skin that feels the same as a

real infant would at this gestational age. Further, the manikin must have the ability to be intubated, have IV access, support central umbilical line placement, have a chest cavity that rises and falls with proper intubation, and a correct rib cage for practicing thoracentesis and pericardiocentesis procedures (see Appendix A for full PDS). This semester's work will focus on adding limbs to the body model, and producing skin with a realistic texture.

In addition to meeting the client's requirements, the design must also adhere to ISO standards for medical devices such as ISO 13485 and ISO 14971. ISO 13485 ensures quality medical devices are created from design to distribution. This is achieved through ethical design considerations that put the customer and patient first, and through adequately documenting the entire design process [12]. ISO 14971 is a standard that states that the design team must implement risk management to their design process [13]. This includes assessing risk associated with biocompatibility, electronics, moving parts, and usability, and is applied in the design evaluation process.

Preliminary Designs and Evaluation

Limb Attachment

Ball and Socket

The ball and socket attachment involves a spherical compartment in the body mold where the limb would be inserted. A ball-shaped extrusion at the proximal end of the limb would allow the limb to attach to the trunk of the manikin via insertion. This attachment style would allow the limbs to be rotated similarly to true, anatomical human movement. The ball and socket details would have to be included in the solidworks model to be 3D printed with the cavities and limbs. This would reduce the amount of additional materials used, altering criteria such as ease of fabrication and safety levels as well.

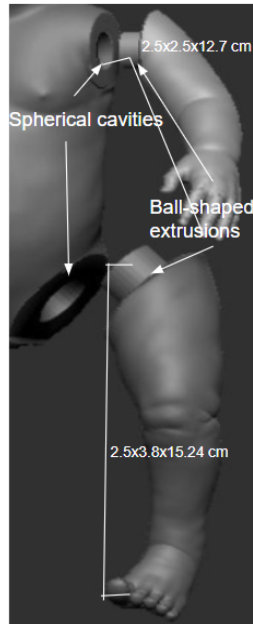


Figure 7: Ball and Socket Attachment Design [14]

Glued

This attachment design involves gluing the limbs to the trunk of the manikin. Consequently, the limbs would not be able to rotate, and would not be detachable. Originally, the plan was to use super glue to attach the EcoFlex 00-30 parts to one another, but after experimentation, it was discovered that both super glue and hot glue do not interact well with EcoFlex 00-30. Therefore, the method was adapted and additional EcoFlex 00-30 was applied and allowed to cure in order to attach the limbs to the cavities.

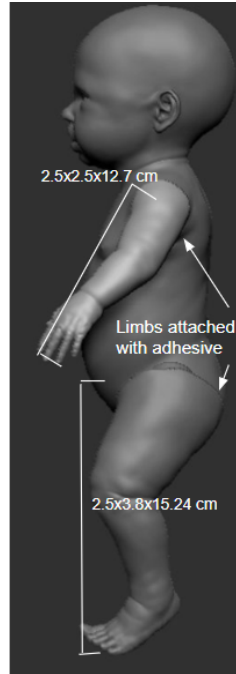


Figure 8: Glued attachment design [14]

Combined with Body Mold

This design would combine the limbs and body into one model. With this attachment, the limbs would not be able to rotate nor detach from the trunk of the manikin. Again, this would have significant implications in the production of the solidworks 3D printed file, and this would potentially alter criteria such as ease of fabrication and safety.

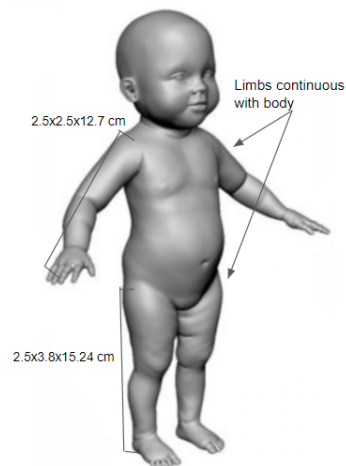





Figure 9: Combined with body mold attachment design [15]

Design Matrix: Limb Attachment

To evaluate the limb attachment designs, a design matrix was implemented (see Table 1 below), and designs were compared based on seven criteria and their respective weight. These criteria are future usability, reproducibility, durability, ease of fabrication, accuracy, safety, and cost. These criteria were chosen based on the scope of the project for this semester, and for future work.

Table 1: Limb Attachment Design Matrix

Criteria:	Design 1: Ball and Socket		Design 2: Glued		Design 3: Combined with Body Mold	
						
Future Usability (20)	4/5	16	5/5	20	2/5	8
Reproducibility (20)	3/5	12	4/5	16	5/5	20
Durability (20)	2/5	8	3/5	12	5/5	20
Ease of Fabrication (15)	3/5	9	4/5	12	3/5	9
Accuracy (15)	5/5	15	3/5	9	3/5	9
Safety (5)	5/5	5	5/5	5	5/5	5
Cost (5)	4/5	4	4/5	4	5/5	5
Total: 100	66		78		76	

Criteria and Weight Explanation

Future usability was ranked highly because this project has many components, and the prototype should be able to incorporate additional components from future design teams. Glued attachment ranked the highest in future usability because separate limb molds allow for easier modification to the limbs (e.g. adding bones and IV access). Combining the limbs to the body mold scored the lowest because any modifications to the limbs, and potentially the head and trunk, would require the manikin to be fully reproduced, making the prototype harder to modify.

Reproducibility was also ranked highly because although the client requires one prototype this semester, the ultimate goal is that it would be mass produced and available to any physician, resident, or fellow looking to improve their neonatal resuscitation techniques. The combined design ranked highest in this category because it ensures each prototype is identical. Meanwhile, the ball and socket design ranked the lowest because the addition of skin material could affect the sockets and impair the mobility of the limbs.

Durability was weighted heavily because the PDS states that the prototype must not lose functionality while remaining in storage for up to two years (see Appendix A). Additionally, since the manikin would be used for a variety of physical simulations, it should be able to withstand human use. The combined mold design has the highest ranking for durability because the whole prototype is one part, whereas the ball and socket design and glued design both have multiple parts, thus increasing the chances of wear and tear where the limbs connect to the body.

Ease of fabrication was weighted the next highest because this is a semester-long project, and only so much can be accomplished. The glued design ranked the highest because it would be the easiest to fabricate, whereas the ball and socket and combined designs would require more CAD processing.

Accuracy in the prototype, which is defined in the design matrix as how close it functions to an actual neonatal infant, is weighted heavily because the client has requested it. For limb attachment, however, accuracy is not weighted as highly as other categories because whether or not the limbs function the way a neonatal infant would does not affect resuscitation. The main need for limbs is so that the prototype feels life-like and that there can be IV access in the hand, foot, and arm. Neither of these require that the limbs move in a realistic way.

Safety of each design must be considered as well. The team does not see any safety concerns with styles of limb attachment, so all designs scored full points in this category.

Cost of each design was also considered, and the combined mold scored the highest as it is most cost effective by reducing material use through eliminating additional limb molds.

Skin Material

Polydimethylsiloxane (PDMS)

Polydimethylsiloxane (PDMS) is a commonly used organic polymer in biomedical applications. PDMS is a silicone-based polymer that has a predisposition to being sticky and tacky. PDMS is inert, non-toxic, and nonflammable which is within the standards of the PDS (Appendix A). The lifespan of PDMS is approximately 24 months when stored properly [16]. When cured, PDMS has a Young's modulus that ranges from 3.51 MPa to 5.13 MPa [17], which encapsulates the value of 4.6 MPa that is being used to represent neonatal skin.

PolyVinyl Chloride (PVC)

PolyVinyl Chloride (PVC) is a synthetic polymer used for many applications including biomedical devices. PVC can be mixed with a variety of additives giving it the advantageous property to vastly vary in flexibility, rigidity, and color. PVC has been used in healthcare applications for artificial skin for emergency burn victims and blood vessels, and in other uses as a rubber due to its flexibility and ease of fabricating. PVC has a Young's modulus rating of 2.1 GPa to 4.1 GPa [18], though these can be tested with different additives to determine the closest similarity the synthetic skin can reflect to neonates. Common plasticizers for PVC often used in medical devices include Diisononyl phthalate (DINP), Dioctyl adipate (DOA), Trioctyl trimellitate (TOTM), and others [19]. These would require further testing to determine the most realistic to neonatal skin.

Hand-Painted Silicone

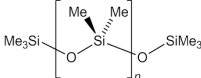
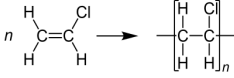
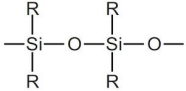
Polysiloxane, otherwise known as silicone, is an elastomer with properties of both plastic and rubber. Silicone has been approved by the FDA in medical products, but potentially can swell after long periods of contact with oil [20]. Silicone is also hypoallergenic and water resistant, but not tear resistant, and can therefore reflect the fragility of a neonate's skin outlined in the PDS (Appendix A). Silicone elastomers have a Young's modulus of 5 MPa to 22 MPa, yield strength of 2.4 MPa to 5.5 MPa [18], and maximum elongation of 700% [20].

Design Matrix: Skin Material

To efficiently and effectively evaluate the materials used for the manikin, a design matrix, seen in Table 2 below, was created with factors ranked by importance. These factors include stickiness, appearance, cost, durability, safety, elasticity, and ease of fabrication. The criteria were selected based on the client's requirements and the team's goals for advancement this semester.

Table 2: Skin Material Design Matrix

Criteria:	Design 1:	Design 2:	Design 3:
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	Polydimethylsiloxane (PDMS)		Polyvinyl Chloride (PVC)		Hand-Painted Silicone	
						
Stickiness (20)	5/5	20	4/5	16	4/5	16
Elasticity (20)	5/5	20	5/5	20	4/5	16
Ease of Fabrication (20)	5/5	20	4/5	16	4/5	16
Safety (15)	5/5	15	5/5	15	5/5	15
Durability (10)	3/5	6	4/5	8	5/5	10
Cost (10)	3/5	6	5/5	10	5/5	10
Appearance (5)	5/5	5	5/5	5	5/5	5
Total: 100	92		90		88	

Criteria and Weight Explanation

Stickiness was ranked highly because of the importance of accurately replicating neonatal skin texture, which will allow clinicians to encounter the feel before a real experience. Of the three materials considered, PDMS scored the highest because of its inherent stickiness, which can be varied with different mixture ratios. PVC and hand-painted silicone ranked lower because they are often described as tacky rather than sticky, though this property can be altered with various plasticizer additives [21].

Elasticity refers to the skin's ability to stretch and conform. This was also ranked highly because the chosen material must be sufficiently elastic to allow accurate resuscitation during compression simulations. In this category, PVC and PDMS scored full points for their elastic properties, and the fact that additives can be used to influence this property [21]. Silicone scored lower because its elasticity is beyond that of the desired specifications, proving to be too elastic (refer to Skin Material section above).

Ease of fabrication is an important consideration for producing the manikin and its replicability, as well as its life-span. Ease of fabrication is how moldable and usable the material is for design and manufacturing purposes along with how easy the skin will be to replace when tearing occurs. For this criterion, PVC and hand-painted silicone scored the same because they involve a mixture that would need to be cured prior to use [22]. PDMS scored higher because of the group's extensive prior experience with the material.

Safety was weighted next highest because the manikin must be safe to use in training applications. Since the skin will be the main layer of interaction, the material the skin is made of should be nontoxic and inert. However, it is reasonable to assume that users will be wearing gloves and applying appropriate care standards, so all materials scored the same for safety.

Durability of the material is important for the shelf-life of skin replacements that will extend the life of use of the manikin. However, durability is linked to the cost of the material since the skin of the manikin is expected to tear and require replacement. With these considerations, hand-painted silicone scored the highest, with a typical shelf life of 20 years [23]. PVC ranked second, with a shelf life of at least 10 years [24], and PDMS scored lowest due to a shelf life of only 24 months [16].

Cost, as mentioned, is considered for skin replacements in addition to initial fabrication. Consequently, PDMS scored lower because it is the most expensive of the three materials, compared to the less expensive silicone and PVC.

Appearance is how accurate the material resembles neonatal skin in pigmentation and texture. While this factor is not a main focus this semester, it is still taken into consideration for future work and how feasible it is to add pigmentation to the skin material. For evaluation, all materials have been known to respond well to pigmentation, so all scored full points.

Proposed Final Design

After consideration of all design ideas, the team chose to use the glued limb attachment method and PDMS as the material to replicate neonatal skin. Additives and fabrication protocols will be determined for use, and skin samples will be prepared for residents and clinicians to feel. With the feedback from medical workers, the fabrication protocol, additives used, and possibly the material itself will be re-evaluated.

Fabrication

Materials

3D printed molds for the body/head were made with polycarbonate (PLC) because it is heat resistant, and if the skin material needs to be cured under heat, it is still possible to use this mold. The molds for the limbs were made using polylactic acid (PLA) since the material is cost effective and printed quickly. The limb molds may be reprinted in the future if they are used for the skin material and need to undergo heat.

The Iowa group chose to use EcoFlex 00-30 for the manikin's body. Other materials considered for fabrication include EcoFlex 00-20, EcoFlex 00-35, Dragon Skin 10 Fast, and Dragon Skin FX Pro. The Iowa group chose to use EcoFlex 00-30 because it has an elastic modulus similar to skin [7].

PDMS was used as the skin material during fabrication. PDMS was chosen mainly for its assumed correct texture of extremely premature neonatal skin. The material is sticky, elastic, and can be mixed with additives to alter the intensity of these properties [16], which is important in replicating the skin texture correctly.

Methods

Fabricating the body of the prototype required ten molds – two halves for the head and abdomen, and two halves for each limb. The mold for the head and abdomen was used from the Iowa group as it met length specifications required by the client. The limb molds were created from STL files of an infant. Equal amounts of Parts I and II of EcoFlex 00-30 (stored at room temperature) were mixed with silicone pigment before being poured into molds (see Figures 10 and 11). Cavities were made by suspending tinfoil in the EcoFlex 00-30 as seen in Figure 12. After 24 hours, the halves of the limbs and upper body were glued together using uncured EcoFlex 00-30 before gluing the limbs onto the upper body also using uncured EcoFlex 00-30.



Figure 10: Body Mold Cavities

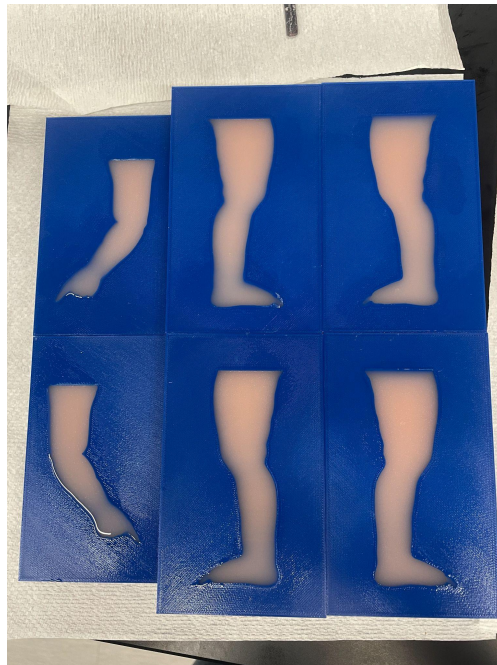


Figure 11: EcoFlex 00-30 Limbs Curing in the 3D Printed Molds

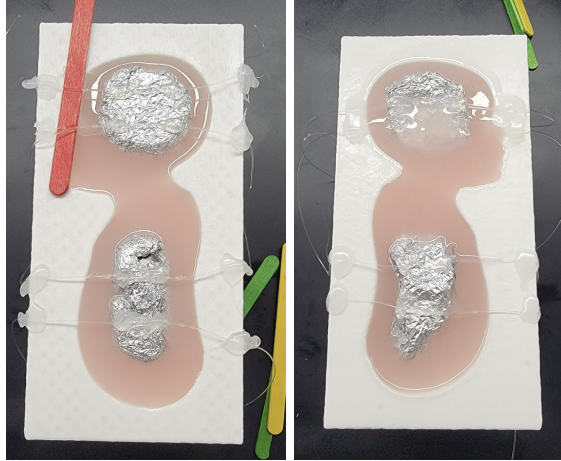


Figure 12: Tin Foil Cavities Inserted into the Mold

Once the body is made from EcoFlex 00-30, the fabrication for the skin can proceed. Because the materials arrived late in the semester, the team did not have time to finalize the fabrication method for the skin material, but we were able to coat a single limb in PDMS. To do this, Sylgard 184 (1:10 mixture of base to curing agent) and 527 were mixed together at a ratio of 1:52 (Sylgard 184:Sylgard 527) before being hand painted onto the leg. This was allowed to cure in a dehydrator for 12 hours at 60 °C. Complete fabrication protocols for skin material and body are in Appendix C.

Final Prototype

For the final prototype, the team created a full size neonatal manikin complete with all four limbs as seen in Figure 13. The body/head was utilized from the previous Iowa group mold and the limbs were fabricated from STL files. The material of the body, representing underlying tissue and muscles, is made of EcoFlex 00-30, and the proposed design had an outer covering of PDMS to simulate the skin of a neonate. The team, however, only had time to coat a single limb with the PDMS as seen in Figure 14. The manikin met specifications of being 24 cm in length and was slightly underweight at 362 g.

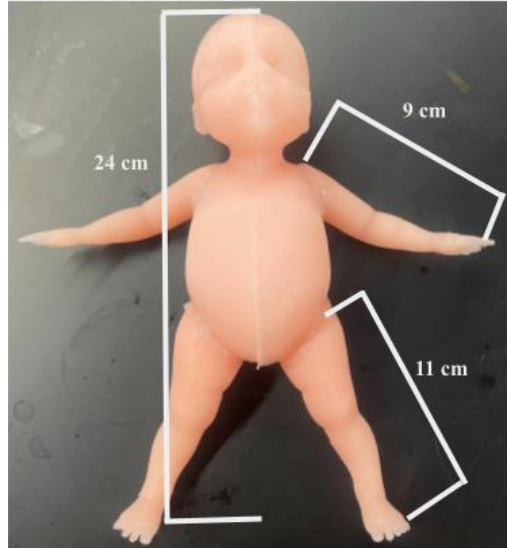


Figure 13: Final Prototype

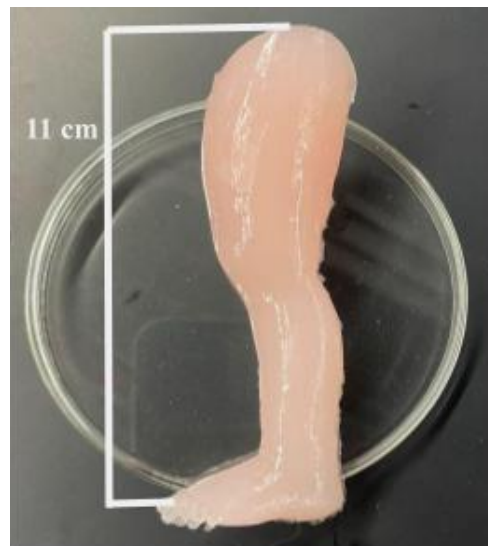


Figure 14: Leg Coated in PDMS Skin Material

Testing

To evaluate the prototype, a Material Testing System (MTS) machine was used to experimentally determine the Young's Modulus of EcoFlex 00-30 by applying a tensile load to the material until slip or failure. Samples of the EcoFlex 00-30 were prepared in petri dishes and cut into rectangular samples. The dimensions of these samples were recorded for later analysis. The samples were loaded into the MTS machine and stretched via the application of a tensile load until the samples broke or slipped from the mounts. Data collected by the MTS machine was exported and analyzed to determine the Young's Modulus of EcoFlex 00-30. The PDMS skin material was not

tensile tested because there are already known literature values for the Young's Modulus of the samples created.

To assess the fabrication of the manikin, the effectiveness of the limb attachment method, and its use in training applications, a usability test was conducted. The usability test involved flipping the manikin from front to back 10 times and performing 3 cycles of 15 compressions. During the testing, a standard of care that would typically be used with extremely premature infants was implemented. It is reasonable to assume that users who will train with the manikin would also use similar standards of care. The manikin was expected to remain in the same condition during usability testing, and no limbs were to detach from the body or split along the middle.

Lastly, to test the skin material, band-aid tear testing was performed to determine if the skin material mimics the fragility of neonatal skin. To perform this test, samples of PDMS were made in petri dishes, and band-aids were applied to the surface of the PDMS. Then, the band-aid was removed, and the skin sample was observed to determine tearing.

A blind touch testing survey was planned and would have been performed given more time. Multiple PDMS skin samples with different additives would have been prepared and brought to the UW Department of Pediatrics where the client, Dr. Elgin, works. Dr. Elgin and his colleagues, who frequently encounter EPIs, would have felt each of the samples and filled out a half sheet survey (see Appendix D) to determine the accuracy of each fabricated skin material. This would have allowed the group to make improvements on the texture of the skin material based on the feedback received. Unfortunately, the PDMS did not arrive in time for this test to be completed this semester.

Results

Following tensile testing, the data collected was filtered to account for noise, and plotted into a stress vs. strain curve (Figure 15) using Matlab software (see Appendix F for full code). From this data, the Young's Modulus was determined by finding the slope of the linear region of the curve. An average value of 0.2766 MPa was obtained, with a standard deviation of 0.2254 MPa. This is outside of the reported values of human skin (4.6 MPa - 20 MPa [11]), but it should be noted that with a small sample size ($n = 3$), the team is unable to confidently make any conclusions about the value of EcoFlex 00-30's Young's Modulus.

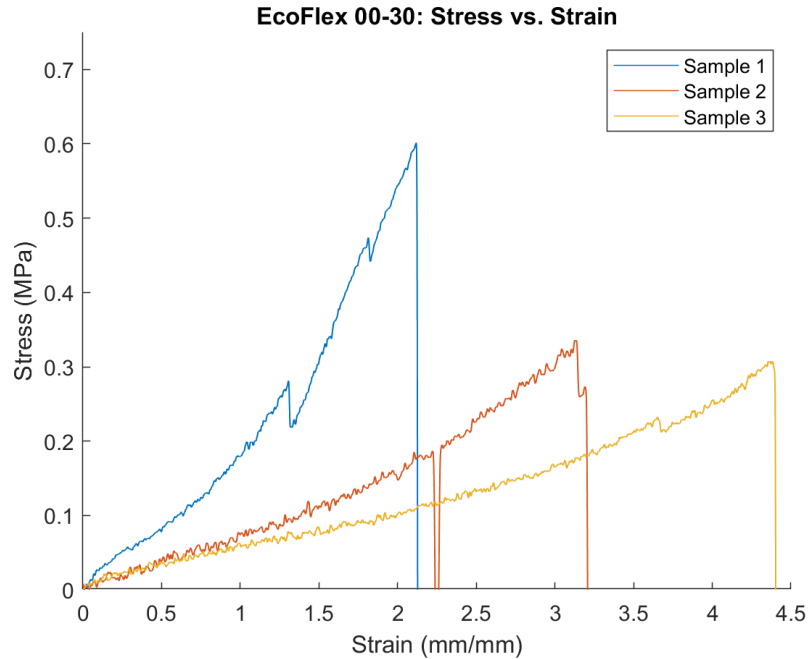


Figure 15: Stress vs. Strain curves of three samples of EcoFlex 00-30

From the usability tests, it was determined that the glued on limb attachment was sufficient for the intended purpose of the manikin. Post-test, all limbs remained fully attached, with no separation between extremity and body. Additionally, the chest was able to retain its shape after the cycles of compressions. This suggests that the manikin will be suitable for resuscitation practices as the chest recoils as expected.

Had the blind skin testing been performed, changes to the skin material would have been made. These changes would be to improve the texture and appearance of the skin material. From the bandaid testing, the team was able to determine that the skin material is accurate in representing the fragility of neonatal skin. When removed, the adhesive bandages tore the skin samples 100% of the time which can be seen in Figure 16. This is representative of true neonatal skin [4], and affirmed the use of PDMS as the skin material.

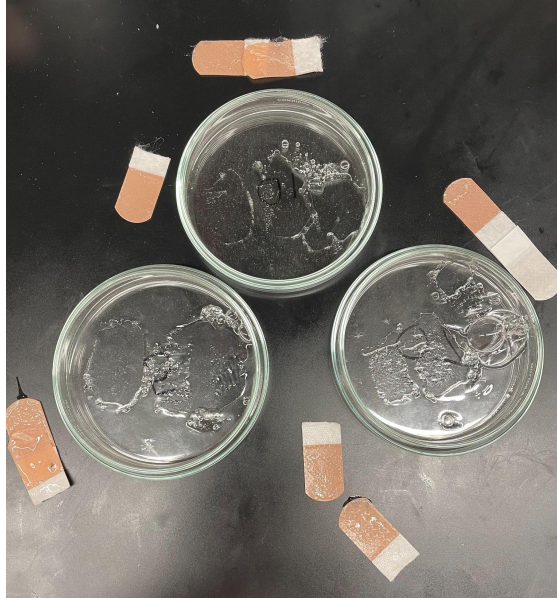


Figure 16: Torn PDMS Skin Samples Post-Band-Aid Testing

Discussion

When designing the manikin, it is necessary to acknowledge limitations in the representation of diverse populations, specifically for skin fabrication. An important use of the manikin includes intravenous insertion on hand, arm, leg, and foot locations. The addition of skin pigmentation to the manikin adds difficulties in accurately representing all premature neonatal infants. Primarily, darker skin poses an increased challenge in locating veins and the point where a user should insert a needle, while lighter skin pigmentation does not pose the same challenge. In consequence, skin pigmentation must be considered as both a factor in accurate representation of a diverse population as well as a differentiating factor in clinical practices.

Because infant mortality rates are so low at such a premature age of gestation, there is little literature on the anatomy and development of a premature infant beyond gestational measurements performed *in vitro*. This created issues while determining measurements for the development of physiology and measurements of the body of the infant along with general background information required for the design project.

As previously stated, the materials did not arrive in time to do thorough testing of the skin. While EcoFlex 00-30 technically follows close to the Young's Modulus of human skin, it is not representative of delicate neonatal skin due to the elongation and has an unrealistic rubbery texture. PDMS was selected not because of its closeness to the Young's Modulus of human skin, but rather because it can more accurately replicate the texture of the neonatal skin.

The prototype's final weight was 362 g which was slightly under the specified 400 g - 500 g. This was considered successful for the design due to the opportunities of future work. With internal

physiology and electronics eventually added, the prototype will most likely be within the designated weight range.

After fabrication, the limb attachment method should be re-evaluated due to the long curing time of the EcoFlex 00-30 causing slipping and rough edges around the limbs. Although the team discovered heat did speed up the curing process, the overall attachment method did not progress smoothly. It is also possible that the mold release used to remove the parts transferred onto the EcoFlex 00-30, making it harder for the limbs to attach. Furthermore, the skin attachment method created a source of error due to the PDMS dripping down the limb and concentrating at the bottom. The skin was then stickier and thicker towards the lower side of the appendage. Because the team was not able to perform the Blind Testing outlined in Appendix D, the realism of the material compared to a neonate is unknown and will have to be determined in Future Work.

Ultimately, this project will require future work to be usable; however, the continuation of this project is vital to increase the survivability rate of premature infants. With a complete prototype following the design specifications, neonatal physicians will be more proficient at neonatal resuscitation and will be more inclined to perform resuscitation to save the lives of premature infants.

Future Work

Due to the immensity of the project and supply chain issues, the team was unable to achieve all of the specifications of this project, leaving opportunities for future work. The team was able to create and attach limbs enabling a more realistic neonate; however, proportions of the mold could be reevaluated along with limb attachment methods to more accurately replicate a 22-23 week old premature infant. Comprehensive testing was unable to be performed with the skin material leaving room for further testing for skin attachment and potential skin material additives. The skin material could be developed by layering different ratios of PDMS on the EcoFlex 00-30 to simulate the layers of human skin, but that was unable to be tested. Furthermore, additional exploration could be done in skin pigmentation to inclusively represent neonates.

Beyond the scope for this semester's goals, areas for future development include airway and lungs for resuscitation, trachea and esophageal cavities for intubation, IV access points, and an umbilical cord. Electronics may eventually be added to the head cavity to provide the user feedback on successful resuscitation.

Conclusion

Infants born at 22-23 weeks gestation are a very rare occurrence, and when infants are born this extremely premature, their survival rate is very low. Currently, there are no known affordable simulation manikins on the market that accurately resemble infants born at 22-23 weeks gestation. The goal of this project is to create a simulation manikin that allows medical personnel to practice the techniques needed to resuscitate a neonate born at 22-23 weeks gestation. The goal this semester was

to add limbs to an already existing body mold and improve the accuracy of the skin texture to be more like that of a true neonate's. The final design used 3D printed molds of the head, body, arms, and legs. An inexpensive, durable material, EcoFlex 00-30, was used for the bulk of the prototype and was cured in the 3D printed molds. The silicone-like prototype would have been covered in a layer of PDMS, but due to materials arriving late, only a limb was coated in the PDMS. While the fabrication could be modified to be more efficient, the prototype accurately represented the size of an infant born at 22-23 weeks gestation. Further, PDMS showed promising characteristics, and further testing should be conducted to determine if it can simulate the sticky, wet, and gelatinous skin of a neonate. The components of the project focused on this semester, the mold and the skin, are important features that aim to fill one of the largest knowledge gaps for medical personnel, which is that the small size and delicate skin of infants born at 22-23 weeks gestation is unlike anything they would have likely experienced working with full-term infants, children, or adults.

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Appendix

Appendix A: Product Design Specifications

Function:

There are currently no affordable neonatal manikins on the market made to resemble infants that are born at 22-23 weeks of gestation. Consequently, the first time many physicians, residents, or fellows use resuscitation skills needed to save an infant born extremely premature is during a real-life scenario. To provide a softer learning curve and to ultimately raise the rate of success of the resuscitation of premature infants, physicians are in need of a neonatal simulation manikin. The manikin must resemble an infant born at 22-23 weeks of gestation in size, appearance, weight, and mechanical function of skin while also having the capacity to be intubated, have IV access, and support central umbilical line placement. Ideally, the manikin would also have a ribcage and chest cavity to allow physicians to practice the techniques needed for thoracentesis and pericardiocentesis procedures.

Client requirements:

- I. The manikin should:
 - A. Have the ability to be intubated, have IV access, and support central umbilical line placement.
 - B. Have a ribcage and chest cavity to allow users to train thoracentesis and pericardiocentesis procedures.
 - C. should resemble an infant born at 22-23 weeks of gestation in size, weight, appearance, and feel.
 1. Manikin should be no more than 30.48 cm in length and should not weigh more than 400 g to 500 g (weight can be adjusted if electronics were to be added).
 2. The skin of the manikin should resemble that of a true premature neonate in texture, thickness, and pigmentation.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements

- i. The manikin should be able to support training in several different care processes including:
 1. IV application (for thoracentesis and pericardiocentesis), central

umbilical line placement, intubation

2. Users should be able to practice these procedures between 3 to 5 times before using skin replacements.
- ii. The manikin would likely be used several days of the week by different people in a training setting.
 1. As the skin of a 22-23-week premature infant is very thin and easily torn, the manikin will need skin replacements on areas of tearing, should they occur. This will allow for an accurate representation of neonatal infant skin.

b. Safety

- i. The team will consider several different materials in an attempt to best replicate premature neonatal skin. Use of these materials may require labeling, standards, and warnings depending on their chemical and physical properties..
- ii. Electrical components in the body cavities, for example, sensors to monitor compressions during resuscitation practice, will require proper safety labeling. This is currently beyond the goal of this semester, and will be considered in the future.

c. Accuracy and Reliability

- i. The chest cavity should always visibly rise when intubation and rescue breathing is properly performed.
- ii. The skin should tear 90% of the time from adhesive tape being placed on the skin and peeled off.
 1. This percentage is permitted to be lowered for the purpose of increasing durability, though the manikin will primarily prioritize accuracy over durability.
- iii. The weight of the model alone should be between 300g and 500g to allow for additional electronics and anatomical structures to be integrated into the design.
- iv. The overall height from head to toe of the manikin should be within $\pm 10\%$ of 30.48 cm.

d. Life in Service

- i. The manikin should be usable for at least two years with use of skin replacements.
 1. The skin of the manikin is expected to tear with use as users train with the model and get experience. As such, skin replacements will be used to fix where tears occur, and should be sufficient for the life of the manikin to be at least two years..

- ii. During training for residents, fellows, and physicians, the model should support use for multiple hours a day, all days of the week.
- e. *Shelf Life:*
- i. When not in use, the manikin should be stored at room temperature: 20°C to 25°C with 20% - 60% humidity [1].
 - ii. The materials of the manikin must not lose realistic texture or physical properties and internal components must not lose functionality while in storage for up to two years.
 - iii. Batteries and electronics must be accessible for replacement as needed or last the duration of the manikin's shelf-life.
- f. *Operating Environment:*
- i. The manikin will be handled in a clinical setting as a training simulator for medical personnel.
 - ii. The manikin will be operating and stored at room temperature: 20°C to 25°C with 20% - 60% humidity [1].
 - iii. The manikin will be exposed to pressure in the thoracic cavity required to depress the chest cavity one-third of the diameter of the chest wall during resuscitation attempts [2].
- g. *Ergonomics:*
- i. The manikin should be used in a clinical, teaching setting, and should be handled with care as a premature neonatal infant would be handled. It should not be used beyond typical neonatal care procedure practices.
 - ii. The skin is extremely delicate, and can tear easily.
 - 1. Tears are expected to occur as medical students learn and get experience with handling newborns.
 - iii. Applied forces include those stated in *f. Operating Environment*, iv.
- h. *Size:*
- i. The manikin should be approximately 30.48 cm in length from head to toe.
 - ii. The manikin's throat cavity should allow for intubation using a 2.0 mm to 2.5 mm diameter breathing tube.
 - iii. The manikin should include a zipper along the length of the back access point for internal maintenance.
 - 1. The skin material is not expected to be present where the zipper is, and should be durable enough to not tear when the zipper is opened and the internal components are handled.

i. Weight:

- i. The weight of the manikin should be between 300 g and 500 g.

j. Materials

- i. No soluble materials should be used for the outer skin layer.
- ii. The skin should resemble premature neonatal skin as accurately as possible.
 1. Initial factors to consider will be thickness, texture, and strength (should tear 90% of the time when adhesive tape is applied and removed). Future work will take pigmentation into account.
 2. Young's Modulus of adult skin is between 4.6 MPa and 20 MPa [3].
 - a. Outer skin layer will be estimated at 4.6 MPa since the skin of a newborn is much more fragile than adult skin.
 - b. Inner material should be minimally degradable and be within the 4 MPa to 20 MPa range, but it is not necessary that this material is fragile.
 3. Accuracy will be assessed through expert opinions via the client and possibly the client's colleagues.

k. Aesthetics, Appearance, and Finish:

- i. The finished manikin should resemble a 22-23-week premature infant as closely as possible in shape, form, and texture.
 1. The manikin should have the same flexibility of skin and tissue as a premature newborn, exhibiting similar softness in the body.
 2. The model's skin should resemble that of a true 22-23-week neonate.
 - a. This texture has been described as thin and wrinkled by experts [4].
 - b. The skin pigmentation should resemble that of a premature infant which is characterized by reddish, transparent skin [4].
 - i. The team recognizes the limitations to the portion of the population that can be accurately represented by one skin pigmentation. This will be taken into account, and the team will work to include as much diversity in the model as possible.
 - ii. In future work, when pigmentation is incorporated into the skin material, it is worthwhile to mention that IV insertion could prove to be more difficult with darker pigmentation.

2. Production Characteristics

a. *Quantity:*

- i. The client currently requires a single prototype. With successful creation of one prototype, more can be produced at a later time.

b. *Target Product Cost:*

- i. The target production cost has some flexibility and ranges from \$500-\$2000.
 1. Manufacturing costs would include materials and fabrication.
- ii. The team's goal is to produce a low-cost manikin that is less expensive than competing models on the market (\$2,000 to \$7,000).

3. Miscellaneous

a. *Standards and Specifications:*

- i. ISO 13485: This standard states that the organization must ensure quality medical devices from design to distribution. This is achieved through ethical design considerations that put the customer and patient first, adherence to standards, and adequate documentation [5].
- ii. ISO 14971: This standard states that the design team must implement risk management to their process. This includes assessing risk associated with biocompatibility, electronics, moving parts, and usability, and controlling for these variables [6].
- iii. OSHA Standard 1910.1000: This standard sets regulation requirements for indoor office temperature and humidity levels: temperature must remain between 20°C and 25°C, and humidity levels must remain between 20% and 60% [1].

b. *Customer:*

- i. The customer is a professor in the department of neonatology and newborn nursery at the University of Wisconsin-Madison. The customer understands that the project is highly theoretical, as there is little literature available on 22-23-week premature neonates. With little engineering background, the customer has also entrusted the team to accurately assess the feasibility of requests. The customer has communicated a preference for accuracy on the manikin's skin texture and thickness.

c. *Patient-related concerns:*

- i. Not applicable.

d. *Competition:*

- i. There are many neonatal manikins on the market. The three premature infant manikins most similar to this project include the following:
 1. Laerdal Medical's Premature Anne [7]

- a. This manikin represents a premature newborn at 25 weeks of gestation.
 - b. The price of Premature Anne is between \$3,000 and \$6,900 depending on what training features are included.
 - c. The skin is durable but not realistic.
2. Laerdal Medical's PremieNatalie [8]
- a. PremieNatalie is meant for nursing mothers to practice breastfeeding.
 - b. The manikin is not realistic in the limbs or trunk, and does not have the skin texture of a premature newborn.
3. Lifecast Body Simulation's Micro-Premie Manikin [9]
- a. This manikin represents a neonate born at 22-23 weeks of gestation.
 - b. There is no information regarding the price, and it is not currently available on the market.
 - c. This manikin does not have IV access.

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

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Appendix B: Material Expenses

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Body Mold	3D printed mold for the body	Makerspace	N/A	N/A	N/A	10/18	1	\$50.60	\$50.60	N/A
EcoFlex 00-30	material for body and limbs	Smooth-On	EcoFlex 0030	Amazon	MFS OEc oFlex30	10/25	2	\$37.38	\$74.76	Link
Flesh-Colored Silicone Pigment Coloring	pigment for the EcoFlex	Smooth-On	88552	Amazon	B005ZH0SFU	10/25	1	\$37.69	\$37.69	Link
Sylgard 527	material for life like skin	Dow Corning	N/A	Amazon	B0711LBBFG	10/25	0	\$149.90	\$0.00	Link
Petri Dishes	used to fabricate skin	Corning Life Sciences	70165-101	Neta Scientific Inc	70165-101	10/25	1	\$104.48	\$104.48	Link
3D Baby STL File	STL file of a baby, will be used to create limb molds	N/A	901910	CGTrader	N/A	10/25	1	\$21.42	\$21.42	Link
Sylgard 527	material for life like skin	Dow Corning		Fisher			1	\$134.81	\$134.81	Link
clay	to make cavities in the body	N/A	N/A	N/A	N/A	12/4	1	\$0.00	\$0.00	N/A
Limb Molds	3D printed molds for the limbs	Makerspace	N/A	N/A	N/A	11/27	1	\$39.04	\$39.04	N/A
glue	to glue on the limbs	N/A	N/A	N/A	N/A	12/4	1	\$0.00	\$0.00	N/A
fishing line	to suspend	N/A	N/A	N/A	N/A	12/4	1	\$0.00	\$0.00	N/A

	aluminum foil to make cavities in the body										
Popsicle Sticks	used for leveling during fabrication	N/A	N/A	N/A	N/A	12/4	1	\$0.00	\$0.00	N/A	
Mold Release	used to coat mold for easy release	N/A	N/A	N/A	N/A	12/4	1	\$0.00	\$0.00	N/A	
Aluminium Foil	to make cavities in the body	N/A	N/A	N/A	N/A	12/4	1	\$0.00	\$0.00	N/A	
								TOTAL:	\$462.80		

Appendix C: Fabrication Protocols

EcoFlex 00-30 Protocol

This protocol was developed by University of Iowa graduate students and will be adapted slightly for use this semester.

Materials needed:

- Smooth-on body double release cream
 - PLA print of half baby (right and left)
 - Internal mouth and throat mold (left and right)
 - Internal abdominal cavity mold (left and right)
 - EcoFlex 00-30
 - Flesh-colored Silc Pig coloring
 - Metal wire
 - Hot glue gun
 - Ruler
-
- Lightly coat the external walls of the mouth and abdominal cavity molds with release cream
 - Cut 6 metal wires the width of the shell mold
 - Using a hot glue gun, secure 2 metal wires parallel to the top surface of to each of the mouth molds spacing them evenly (this will allow the molds to be suspended in the EcoFlex 00-30 without touching the bottom of the shell mold)
 - Warning: if internal molds touch the external body mold there will be a hole in the shell - Following the same process, glue the remaining 4 wires (2 per mold) to the internal abdominal cavity mold
 - Once the glue is set, start to place the right side internal molds in the right side external mold (do the same for the left)
 - Proceeding with caution, use the ruler to make sure all internal components are lined up properly
 - Note: we glued the right mouth and abdominal cavity components together, measured and repeated this process for the left (this helped eliminate some of the placement errors)
 - Once all parts are lined up properly, secure the wires to the external mold using hot glue
 - Use hot glue or a popsicle stick to fill a space for the umbilical cord between the internal abdomen mold and outer shell mold
 - Mix 180g each part A and part B of EcoFlex 00-30 pigmented with “flesh” Silc Pig and pour slowly into the external molds
 - Allow models to sit at least 24 hours before removing molds
 - Halves will be glued together with more EcoFlex 00-30 once all internal components are properly installed

Limb Attachment

Materials are the same as the EcoFlex 00-30 Protocol.

- Once the halves of the body and limbs are glued together, limbs can be attached.
- Wipe the outside of the limbs and body with ethanol to remove the release spray
- Mix equal parts of part A and part B of EcoFlex 00-30 with the Silc Pigment
- Use a spatula to paint a thin layer of liquid EcoFlex onto the limbs
- Slowly heat with a heat gun until the EcoFlex is slightly tacky– be sure that the EcoFlex isn't completely solidified
- Place the limbs in anatomical position and hold while someone uses a heat gun to finish the curing for the EcoFlex until the limbs can be left to cure independently
- It is best to have multiple people help to ensure the limbs are symmetrical
- Add all four limbs and wait for 24 hours to ensure the curing is finalized

Skin Attachment

Materials

- Petri dishes
- Plastic Cups
- Glass Stir Rod
- Scale
- Sylgard 527
- Sylgard 184

- Mix equal parts of Part A and Part B of Sylgard 527
- Stir for 5 minutes with stir rod to ensure well-mixed
- Mix Sylgard 184 base and curing agent in a 10:1 ratio
- Stir for 5 minutes with stir rod to ensure well-mixed
- Mix appropriate amounts of Sylgard 527 and 184 mixtures to achieve desired substrate stiffness:
 - 5 kPa
 - 100% Sylgard 527
 - 10 kPa
 - 98.125% Sylgard 527
 - 1.875% Sylgard 184
 - 20 kPa
 - 95.66% Sylgard 527
 - 4.33% Sylgard 184

- Stir for 5 minutes with stir rod to ensure well-mixed
- Pour 3.5 grams of the mixture into petri dish
- Tilt petri dish to coat uniformly
- Cure in oven for 12 hours at 60°C

Appendix D: Testing Protocols

Skin Tape Testing Protocol

Materials

- Petri dishes
 - 3 skin material samples
 - 9 BandAid
-
- Gather 3 samples of PDMS in separate petri dishes
 - Take a bandaid and press it firmly to the skin sample
 - Wait 30 seconds before carefully removing the BandAid
 - Observe whether the material tears
 - Repeat steps 2-3 for all skin samples, recording tearing

Usability Test

Materials

- Final prototype with limbs attached
-
- Pick up the manikin from a flat surface 10 times as gently as you would handle a true infant
 - Turn the manikin from front to back gently in hands 10 times, always supporting neck
 - Complete chest compressions 15 times in a row for at least three cycles

Tensile Testing

This is performed using a Material Testing System (MTS) machine.

- Open TW ELITE
- Under File name, select new test from template
- Chose Custom template, compression
- MTS EM Tensile simplified
- Open file
- Enter the thickness and width of the sample
- Zero load signal
- Activate kill switch, ensure machine is off
- Place sample in machine
- Turn on machine and unlock crosshead (light should be green)
- Raise until sample is at resting length, when load is small and non-negative
- Zero load and crosshead
- Lock the device
- Press start button on compute
- Run test until failure or slip
- Choose “Yes” when asked to return to zero

- Save file to correct folder
- Push red button to kill the machine
- Remove sample

Blind Testing Neonatal Professionals

Materials

- Blind Testing Survey
 - 3-8 skin material samples
- Arrange separate meeting times with neonatal professionals to prevent bias
 - Have the professional touch the material
 - Provide the professional with the short survey
 - Repeat with multiple professionals
 - Review feedback to determine the future adaptations of skin material

Blind Testing Survey

Neonatal Skin Material

Please feel all samples of skin materials and answer the following questions:

- Rank the samples from best (1) to worst (5)

1: _____ 2: _____ 3: _____ 4: _____ 5: _____

- What could be improved about the best sample? (Circle all that apply)

Stickiness Texture Fragility Other: _____ None

- What was accurate about the best sample? (Circle all that apply)

Stickiness Texture Fragility Other: _____

- Other comments/observations:

Appendix E: Matlab Code

```
%% Load Data
run1 = importdata("RUN11\RUN11.txt").data;
run2 = importdata("RUN2\RUN2.txt").data;
run3 = importdata("RUN3\RUN3.txt").data;
%% Measured Data
a1 = 10 * 1.53; % mm^2
l1 = 67; % mm
a2 = 10 * 0.87; % mm^2
l2 = 45; % mm
a3 = 10 * 1.21; % mm^2
l3 = 57; % mm
%% Data
stress1 = run1(:,2) ./ a1;
strain1 = run1(:,1) ./ l1;
stress2 = run2(:,2) ./ a2;
strain2 = run2(:,1) ./ l2;
stress3 = run3(:,2) ./ a3;
strain3 = run3(:,1) ./ l3;
%% Filtering
d =
designfilt('lowpassfir','filterorder',10,'CutOffFrequency',10,'SampleRate',100);
stress1filt = filtfilt(d, stress1);
stress2filt = filtfilt(d, stress2);
stress3filt = filtfilt(d, stress3);
strain1filt = filtfilt(d, strain1);
strain2filt = filtfilt(d, strain2);
strain3filt = filtfilt(d, strain3);
%% Plotting
figure(1)
hold on
plot(strain1filt, stress1filt, 'DisplayName', 'Sample 1');
plot(strain2filt, stress2filt, 'DisplayName', 'Sample 2');
plot(strain3filt, stress3filt, 'DisplayName', 'Sample 3');
xlabel("Strain (mm/mm)");
ylabel("Stress (MPa)");
title("EcoFlex 00-30: Stress vs. Strain");
legend();
ylim([0 0.75]);
hold off
%% Analysis
E1 = polyfit(strain1(1042:1417), stress1(1042:1417), 1);
E2 = polyfit(strain2(1228:1662), stress2(1228:1662), 1);
E3 = polyfit(strain3(2490:2944), stress3(2490:2944), 1);
```