Neonatal 22-23-Week Premature Infant Simulation Manikin

Preliminary Report

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Abstract

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 has been requested by the client, Dr. Timothy Elgin. Currently, there are no affordable 22-23-week manikins on the market. There are a couple designs close in age and some in testing, but none that are known to satisfy the client's requirements listed above. The team's goal this semester is to expand on previous work, from both a University of Iowa design team and the design teams at 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 MTS testing, a blind touch test by the client, Dr. Elgin, and his colleagues, and using tape 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. This contributes to the overarching motivation of the project, which is to counter the traditional limits of viability and ultimately send more families home with their babies.

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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, 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, physicians often do not attempt resuscitation on infants born this extremely premature. 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]. In order to soften the learning curve for medical personnel and ultimately send more babies home with their families, a simulation manikin is needed that allows physicians, residents, and fellows to practice the resuscitation techniques needed to successfully resuscitate extremely preterm infants before their first high-stress, real-life event.

Existing Designs

Laerdal Medical's Premature Anne:

Premature Anne 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 as it is representative of an infant born at 25 weeks gestation instead of 22-23 weeks gestation. Additionally, the skin is durable but unrealistic 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 [3].

Figure 1: Laerdal Medical's Premature Anne During Training Simulation [3]

Lifecast Body Simulation's Micro-Preemie Manikin:

Lifecast's Micro-Preemie Manikin anatomically represents an infant born at 22-23 weeks gestation. This manikin supports training such as intubation and ventilation, umbilical line placement, and nasogastric tube placement. Micro-Preemie Manikin was made by a design team at Elstree Studios in collaboration with Dr. Alok Sharma, a neonatologist, and it 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. Micro-Preemie Manikin does not have IV access [4].

Figure 2: Lifecast Body Simulation's Micro-Preemie Manikin [4]

Problem Statement

There are currently no known 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 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 30.5 cm in length and weigh between 400-500 g. They have very thin, wet, gelatinous skin that can tear easily. 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 prevent 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 extremely premature infant 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 [5].

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 [6].

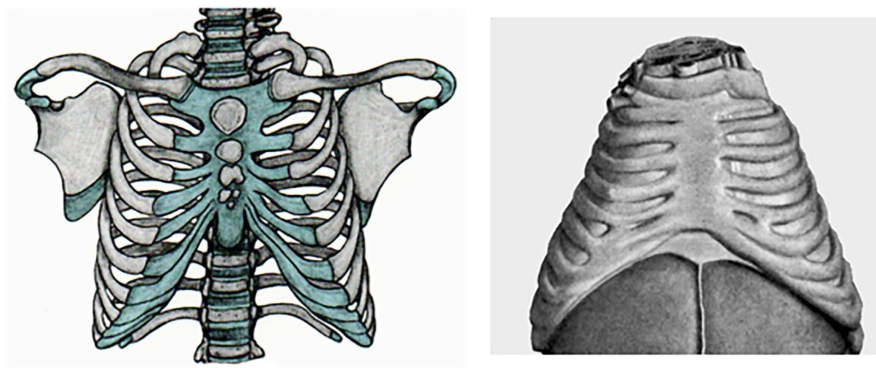


Figure 3: Anatomy of Chest Cavity of an Adult (left) vs Anatomy of Chest Cavity of a Newborn (right) [6]

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. With this in mind, the Young's modulus of adult skin is reported to be between 4.6 MPa and 20 MPa [7]. 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 400-500 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.

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. This attachment style would allow the limbs to be rotated similarly to true, anatomical human movement.

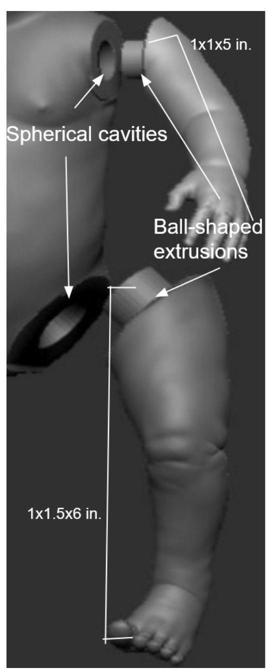


Figure 4: Ball and Socket attachment design [8].

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.

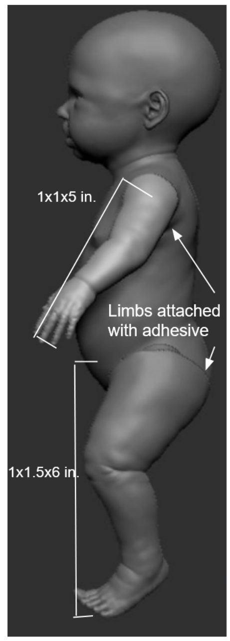


Figure 5: Glued attachment design [8].

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.

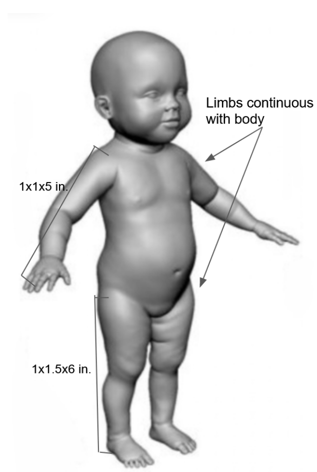
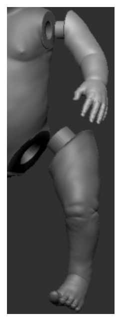


Figure 6: Combined with body mold attachment design [9].

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)	*4/5*	4	*4/5*	4	5/5	5
Cost (5)	*4/5*	4	*4/5*	4	5/5	5
Total: 100	**65**		**77**		**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). 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 and **cost** of each design was also considered, and the combined mold scored the highest in both categories because it has fewer components than the other two designs.

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 [10]. When cured, PDMS has a Young's modulus that ranges from 3.51 MPa to 5.13 MPa [11], 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 [12], though these will be tested with different additives to determine the closest similarity the synthetic skin can reflect to neonates.

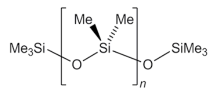
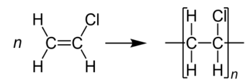
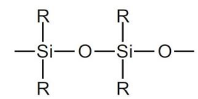
Hand-Painted Silicone

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 [13]. 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 and a yield strength of 2.4 MPa to 5.5 MPa [12] while also having a maximum elongation of 700% [13].

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:** Polydimethylsiloxane (PDMS) 		**Design 2:** Polyvinyl Chloride (PVC) 		**Design 3:** Hand-Painted Silicone 	
Stickiness (20)	*5/5*	20	*4/5*	16	4/5	16
Elasticity (20)	*5/5*	20	*5/5*	20	5/5	20
Ease of Fabrication (20)	*4/5*	16	*4/5*	16	4/5	16
Safety (15)	*5/5*	15	*5/5*	15	3/5	9
Durability (10)	*3/5*	6	*4/5*	8	5/5	10
Cost (10)	*2/5*	4	*5/5*	10	5/5	10
Appearance (5)	*4/5*	4	*5/5*	5	5/5	5
Total: 100	**85**		**90**		**86**	

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 inert 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 [14].

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, all materials scored full points; PVC and silicone for their elastic properties (see section Skin Material section above), and the fact that additives can be used to influence this property [14]. PDMS scored full points for its elastic properties that are also able to be changed via mixture ratios.

Ease of fabrication is an important consideration for producing the manakin 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, PDMS, PVC, and hand-painted silicone scored the same because all are likely to involve a mixture that would need to be cured prior to use [15].

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 must be nontoxic and inert. PDMS and PVC scored full points in this category because they are generally inert substances with no toxins [10], [16]. The hand-painted silicone, however, scored lower because silicone is not inert, and not as stable [17].

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 [17]. PVC ranked second, with a shelf life of at least 10 years [18], and PDMS scored lowest due to a shelf life of only 24 months [10].

Cost, as mentioned, is considered for skin replacements in addition to initial fabrication. Consequently, PDMS scored the lowest because it is the most expensive of the three materials, while PVC and hand-painted silicone both scored higher since they are less expensive.

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, silicone and PVC scored highest since they are easily pigmented, and PDMS scored lower as it is not commonly pigmented, and could be an obstacle in the future.

From evaluation of each of these skin materials, PolyVinyl Chloride (PVC) was chosen for the skin material. 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 and Methods

For fabrication of the limbs and body, molds of the manikin will be 3D printed; there will be separate molds for the trunk/head and limbs. Ecoflex 00-30 with flesh-colored coloring will be used to fill the mold completely (see Appendix B: Ecoflex Protocol for the full fabrication protocol of the manikin body). Skin fabrication will take place in a wet lab and involve a mixture and cure time. PVC will be the main ingredient used in the skin material, as determined by the skin material design matrix. An exact protocol will be decided on in the coming weeks and will be included in the final report.

Testing

To test the materials for the skin, three tests will be performed: MTS testing, tape test, and blind testing of medical personnel. MTS testing will be done on both Ecoflex and PVC to evaluate that the material characteristics are within ranges outlined in the PDS (Appendix A). A tape test will be utilized by checking if lifting a piece of tape off the outer layer of skin causes a tear. Tearing will be considered a success for the material durability, as neonatal skin is thin and will tear easily. Additionally, skin samples in petri dishes will be prepared to ask medical personnel in the neonatology division, including the client, Dr. Elgin, to determine the material most similar to that of a true neonate's by feeling each of the samples with their eyes closed. Their eyes will be closed so that the appearance does not affect their decision, just the texture and stickiness of the material.

Discussion

Ethical Considerations

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.

Future Work

Since this project is multi-facetted with several different components, there are many avenues for future work. As the team will be focusing on the external fabrication for this semester, the majority of work on internal physiology and anatomy will be explored in the future. This includes ventilation, intravenous modeling, respiration, internal organs, and all electronics that would be housed inside the model to allow for accurate simulations and feedback. Future work will also focus on improving ease of fabrication by lowering cost of materials and increasing efficiency in creating the model.

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 made to 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 is 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 will use 3D printed molds of the head, body, arms, and legs. An inexpensive, durable material, such as Ecoflex, will be used for the bulk of the prototype and will be cured in the 3D printed molds. The gel-like prototype will then be coated with a layer of PVC skin to simulate the real feel of skin of an extremely premature infant. 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.

References

[1] S. R. Walani, "Global burden of preterm birth," International Journal of Gynecology & Obstetrics, vol. 150, no. 1, pp. 31–33, 2020, doi: 10.1002/ijgo.13195.

[2] A. Cavolo, B. Dierckx de Casterlé, G. Naulaers, and C. Gastmans, "Physicians' Attitudes on Resuscitation of Extremely Premature Infants: A Systematic Review," Pediatrics, vol. 143, no. 6, p. e20183972, Jun. 2019, doi: 10.1542/peds.2018-3972.

[3] "Premature Anne," Laerdal Medical. https://laerdal.com/us/products/simulation-training/obstetrics-pediatrics/premature-anne/ (accessed Sep. 20, 2023).

[4] "Lifecast Body Simulation | Surgical Manikin." https://www.lifecastbodysim.com/micro-preemie-manikin (accessed Sep. 20, 2023).

[5] J. Kattwinkel, R. S. Bloom, American Academy of Pediatrics, and American Heart Association, Eds., Textbook of neonatal resuscitation, 6th ed. Elk Grove Village, Ill.?] : [Dallas, Tex.? American Academy of Pediatrics ; American Heart Association, 2011.

[6] J. A. Vilensky and C. A. Suárez‐Quian, "Newborn anatomy," Clinical Anatomy, vol. 35, no. 1, pp. 15–18, 2022, doi: 10.1002/ca.23774. [Online]. Available: https://onlinelibrary.wiley.com/doi/10.1002/ca.23774. [Accessed: Oct. 11, 2023]

[7] M. Pawlaczyk, M. Lelonkiewicz, and M. Wieczorowski, "Age-dependent biomechanical properties of the skin," Postepy Dermatol Alergol, vol. 30, no. 5, pp. 302–306, Oct. 2013, doi: 10.5114/pdia.2013.38359.

[8] "Realistic baby Techino parts separately 3d print | 3D Print Model," CGTrader. Accessed: Oct. 02, 2023. [Online]. Available: https://www.cgtrader.com/3d-print-models/science/astronomy-physics/realistic-baby-techino-parts-separately-3d-print

[9] "Baby T Pose with 5 Subdivision Levels Quad Mesh | 3D model," CGTrader. Accessed: Oct. 02, 2023. [Online]. Available: https://www.cgtrader.com/3d-models/character/child/baby-t-pose-with-5-subdivision-levels-quad-mesh

[10] "Polydimethylsiloxane | PDMS | Cas 63148-62-9 | Connect Chemicals." https://connectchemicals.com/en/product-finder/polydimethylsiloxane (accessed Oct. 02, 2023).

[11] R. Ariati, F. Sales, A. Souza, R. A. Lima, and J. Ribeiro, "Polydimethylsiloxane Composites Characterization and Its Applications: A Review," Polymers (Basel), vol. 13, no. 23, p. 4258, Dec. 2021, doi: 10.3390/polym13234258.

[12] Ashby, Mike. "Material Property Data for Engineering Materials," 2021.

[13] "All About Silicone Rubber - Properties, Applications and Uses." Accessed October 9, 2023. https://www.thomasnet.com/articles/plastics-rubber/about-silicone-rubber/.

[14] "Polyvinyl Chloride PVC," *British Plastics Federation*. https://www.bpf.co.uk/plastipedia/polymers/PVC.aspx (accessed Oct. 02, 2023).

[15] "Plastic Fabrication: The Complete Guide," *Wee Tect*. https://www.weetect.com/plastic-fabrication-the-complete-guide/ (accessed Oct. 02, 2023).

[16] "Chemical resistance," *ECVM*. https://pvc.org/about-pvc/pvcs-physical-properties/chemical-resistance/ (accessed Oct. 02, 2023).

[17] H. Busch, "Silicone toxicology," *Semin Arthritis Rheum*, vol. 24, no. 1 Suppl 1, pp. 11–17, Aug. 1994, doi: 10.1016/0049-0172(94)90104-x.

[18] "Shelf Life of Rubber Products - Interstate Specialty Products," Mar. 29, 2019. https://www.interstatesp.com/shelf-life-of-rubber-products/ (accessed Oct. 02, 2023).

Appendix

<u>Appendix A: Product Design Specifications</u>

<u>Function:</u>

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.

<u>Client requirements:</u>

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.

<u>Design requirements:</u>

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 ±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℃ to 25℃ 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℃ to 25℃ 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℃ and 25℃, 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 PreemieNatalie [8]
            a. PreemieNatalie 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-Preemie 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.

References

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

[1] “Reiteration of Existing OSHA Policy on Indoor Air Quality: Office Temperature/Humidity and Environmental Tobacco Smoke | Occupational Safety and Health Administration.” https://www.osha.gov/laws-regs/standardinterpretations/2003-02-24 (accessed Sep. 21, 2023).

[2] J. Lee et al., “Evaluation of the proper chest compression depth for neonatal resuscitation using computed tomography,” Medicine (Baltimore), vol. 100, no. 26, p. e26122, Jul. 2021, doi: 10.1097/MD.0000000000026122.

[3] M. Pawlaczyk, M. Lelonkiewicz, and M. Wieczorowski, “Age-dependent biomechanical properties of the skin,” *Postepy Dermatol Alergol*, vol. 30, no. 5, pp. 302–306, Oct. 2013, doi: 10.5114/pdia.2013.38359.

[4] H. S. Moon, J. S. Burm, W. Y. Yang, and S. Y. Kang, “Prognosis of Full-Thickness Skin Defects in Premature Infants,” Arch Plast Surg, vol. 39, no. 5, pp. 463–468, Sep. 2012, doi: 10.5999/aps.2012.39.5.463.

[5] 14:00-17:00, “ISO 13485:2016,” ISO, Jun. 02, 2021. https://www.iso.org/standard/59752.html (accessed Sep. 21, 2023).

[6] 14:00-17:00, “ISO 14971:2019,” ISO, Jul. 14, 2020. https://www.iso.org/standard/72704.html (accessed Sep. 21, 2023).

[7] “Premature Anne,” Laerdal Medical. https://laerdal.com/us/products/simulation-training/obstetrics-pediatrics/premature-anne/ (accessed Sep. 20, 2023).

[8] “Laerdal Global Health - PreemieNatalie Preterm Simulator,” Laerdal Medical. https://laerdal.com/us/products/simulation-training/obstetrics-pediatrics/preemienatalie/ (accessed Sep. 20, 2023).

[9] “Lifecast Body Simulation | Surgical Manikin.” https://www.lifecastbodysim.com/micro-preemie-manikin (accessed Sep. 20, 2023).

Appendix B: Ecoflex Protocol

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

Outer shell

Materials needed:

1. smooth-on body double release cream
2. PLA print of half baby (right and left)
3. Internal mouth and throat mold (left and right)
4. Internal abdominal cavity mold (left and right)
5. Ecoflex 00-30
6. Flesh-colored Silc Pig coloring
7. Metal wire
8. Hot glue gun
9. 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 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)
- Preceding 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