BME 200/300 (Biomedical Engineering Design)
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Project #33: Umbilical Cord Model for Umbilical Vein Catheterization Training

MID-SEMESTER REPORT

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Abstract

The goal of this design project is to develop a training model that mimics the human neonatal abdomen, focusing primarily on the internal anatomical course of the umbilical vein and the external texture of the abdomen. This model would be used for umbilical vein catheterization training, incorporating real umbilical cords. Currently, there are two existing models in the market which have been deemed unsatisfactory: one due to its price, and the other because of inadequate mimicry of the umbilical cord placement in a newborn. The purpose of this project is to bridge the insufficiencies of these devices by creating a design that will stabilize a real umbilical cord during the training procedure.

Problem Statement

The American Academy of Pediatrics Neonatal Resuscitation Program (NRP) requires training for thousands of physicians and medical staff involved in the delivery of newborns. Placement of an intravenous catheter in the umbilical vein of the cord stump in a distressed newborn is one way to provide life saving medication. Catheterization training on a model can help to improve on this skill outside of the delivery room. Developing a model that not only improves on negative aspects of the existing models but also meets or exceeds the positive aspects of those models, will create a positive learning experience for trainees before the critical situation arises. This means that the design model must mimic the umbilical vein path within an infant, like the Laerdal model, while being simple to prepare and compatible with an umbilical cord like the "baby bottle" model. All this must be done while ensuring stability of the cord and maintaining a high safety level associated with the handling of human tissue and blood-borne pathogens.

Background Materials

ANATOMY OF THE UMBILICAL SYSTEM

While in the uterus, the fetus is connected to the mother through the umbilical cord and placenta. The umbilical cord carries all nutrient and waste from fetal metabolism to and from the infant, respectively. The umbilical cord itself has an average length, at term, of 56 cm and is free to move with the baby. The cord normally has three blood vessels running its length: two arteries and a vein. These three vessels and the allantoic duct are surrounded by the Wharton's jelly. This gelatinous substance is composed mostly of hyaluronic acid and is rich in stem cells. The small arteries spiral around the vein until the umbilicus of the fetus where they diverge. The arteries are responsible for carrying deoxygenated blood away from the fetus while the vein brings oxygenated blood from the mother to the baby. The umbilical vein is larger in diameter and has thinner walls, compared to the umbilical arteries. At the umbilicus, the umbilical vein diverges from the arteries. The arteries descend towards the legs and terminate at the femoral arteries, while the umbilical vein ascends through the abdominal cavity to the portal vein of the liver, which leads into the inferior vena cava. At birth, the umbilical cord is severed and clamped. Specifically, the umbilical vein and arteries collapse on themselves and eventually turn into ligaments. The umbilical vein turns into a ligament extending from the umbilicus to the ligamentum venosum separating the two lobes of the liver.

UMBILICAL VEIN CATHETERIZATION

When a newborn infant is in critical condition, it is often necessary to infuse medication as quickly as possible in order to save the infant's life. The fastest way to do this is to start an intravenous line through the umbilical vein. To do this, a clinician must unclamp the umbilical cord and cut it down to 1-2 cm above the skin surface. This ensures that the line inserted into the vein will meet minimal twisting as it passes into the abdomen. A 5 or 8 French catheter is most often used because of the small umbilical vein diameter. Before the catheter is inserted, the clinician will wrap a small tie around the cord to stop any bleeding once the catheter is inserted. When inserted, the catheter enters only about 5 cm. If the catheter is inserted too far, it could pierce through the portal vein or make its way to the heart. To check the orientation of the catheter, the clinician draws back a small amount of blood into the syringe. If no blood enters the chamber, or if resistance is met, then the clinician must attempt to insert the catheter again or fix the orientation. This is to ensure that the catheter has not punctured through the wall of the vessel, or that it is not suctioned to the side wall of the vessel.

An umbilical vein catheter should only be used as a temporary line; this is due to many different reasons. One reason is that the umbilical vein and cord begin to deteriorate after birth. The weakened vessel could tear or fuse with the line if it is left inside for too long. Another reason is that with the cord open to the environment, an entryway is provided for bacteria and other pathogens. Also, septic shock can occur in severe cases.

CATHETERIZATION TRAINING & CURRENT PRODUCTS

Umbilical vein catheterization is very seldom used, only for very severe cases of shock or cardiopulmonary failure. Because of this rarity, few clinicians ever get to practice their skills on actual infants. Training on proper umbilical vein catheterization technique is required by the American Academy of Pediatrics and thousands of medical staff and physicians must attend the Neonatal Resuscitation Program. The design team participated in a mock training organized by the client. This training used the more widely accepted umbilical catheterization training model, the "baby bottle" model.

The "baby bottle" model consists of a small infant bottle with the nipple excised about halfway down. This baby bottle is filled with Pedialyte and red food coloring to simulate blood. A section of real umbilical cord is slipped through the hole and the end submerged in the Pedialyte. The training proceeded very similarly to the procedure explained above, except for several complications. One complication that made the procedure very difficult was the poor stabilization of the cord by the nipple. The cord was free to rotate and translate with respect to the baby bottle nipple. This made it difficult to insert the catheter without pushing the cord into the bottle or rotating it around its longitudinal axis. If the hole in the nipple was made smaller, the nipple compressed the cord too much. This in turn constricted the veins and made it very difficult to pass the catheter through the vessel smoothly. In the mock training, the catheter punctured through the vessel and side wall of the cord. Another complication was that the blood in the cords had not been washed out and had begun to clot, making it very difficult for the catheter to pass through the vein. Neither of these complications is present in the actual procedure, because the blood is still fresh and the cord is firmly secured in the abdomen of the newborn.

This model was also a very poor representation of an infant's abdomen. The bottle is thin and cylindrical and gives no place for the trainees to rest their hands. It is nothing like what is encountered in a real procedure. Having so many differences makes the training less useful. If the model simulates the real procedure more, there would be less shock when encountering the real thing. With a procedure that is already stressful to begin with limiting, the amount of change the clinician experiences would be ideal.

There are several other products available for trainers to practice on. Two models seem to be the most popular substitutes to the "baby bottle" model. One of the models is offered for purchase through Laerdal. This company manufactures many different training models for a multitude of procedures. The umbilical vein catheterization model is named Baby Umbi and is a plastic baby manikin with an extendable rubber umbilical cord and faux blood reservoir, as shown in Figure 1. This model solves the problem of having a model that is more like an actual baby, although the umbilical cord is nothing like a real cord. It is made of rubber and can stand on its own without any support, unlike a real umbilical cord. The vessels are also much larger and straighter then the vessels in a real umbilical cord, making the training unrealistic. Baby Umbi also has a very high price tag for a model that does a poor job representing the actual procedure.

Figure 1: Baby Umbi by Laerdal

Figure 2: Variation on the baby bottle model using vinyl tubing as umbilical cord mimic

Another model that is used sometimes is a variation of the "baby bottle" model. This model uses vinyl tubing of different diameters to mimic the umbilical cord and vessels, as shown in Figure 2. This is an ever poorer model than the baby bottle model; not only is the cord-holding apparatus still a glass bottle, but the real cord tissue has been replaced by a mimic that is unlike an actual umbilical cord in many ways.

It is evident that the current models available do a poor job of simulating umbilical vein catheterization training. This reiterates the need for a new umbilical vein catheterization training model.

Client's Requirements & Design Constraints

The design must incorporate a real, fresh umbilical cord. An actual umbilical cord is preferred to artificial blood vessels, to mimic the umbilical vein as it twists and curves inside the infant's body. The use of a real umbilical cord requires that the model's "umbilicus" be able to accommodate different cord sizes. One of the most immediate concerns is stabilization of the cord, which is where the current model in practice fails. In the proposed design model, the cord must neither rotate nor translate internally or externally from its stabilized position while the training is in progress.

Actual umbilical vein catheterization involves verification of the depth of catheterization. This is accomplished by drawing back blood through the vein to indicate access to the circulatory system. The model should therefore include a fake-blood reservoir to serve this purpose.

To give the trainees the most realistic practice, the final model should mimic both the size and texture of the neonatal abdomen, hence materials for the outer surface must have similar characteristics to that of human flesh. Yet, safety must be emphasized. There can be no sharp edges that could puncture the umbilical cord, the "abdomen", the medical gloves, or the skin of the trainee. Doing so would expose the trainee to possible blood-borne pathogens.

The ergonomics of this prototype require that the final model be both reproducible and user-friendly. The model should not take a significant amount of time to set up, and should be easily portable and simple to use. In addition, the design and construction of the model must comply with FDA regulations and the American Academy Pediatrics NRP guidelines.

Design Components

The prototype design is to be comprised of three design components: architecture, stabilization, and materials. The architecture of the design is the general size and shape of the model. The design must resemble either the neonatal abdomen, or an entire infant's body in reflection of reality. This model must also include a blood reservoir below or within the structure itself. Also within the structure, there must be a means by which the catheter can follow, so as to anatomically mimic the path of the umbilical vein.

The stabilization of the design is the component that connects the umbilical cord to the model. Being that the current training model fails at maintaining a stable cord during the catheterization training procedure, it is of great importance that stabilization of the cord is achieved. This entails a mechanism that does not allow the cord to rotate, slip, or move during the training procedure.

The design materials chosen must provide support for the model, at the same time mimicking the texture of human flesh. They should also be sterilizable or disposable after use.

Ideas for Architecture

The team came up with three models in accordance with the design constraints. Each model seeks to address some, if not all, of the design aspects, such as the location of the blood reservoir and the layout of the internal "vein". A code name was given for each idea.

Model 1 (Salad Bowl) cuts the body of the model into anterior and posterior halves as shown in Figure 3. The posterior half is to be made of a red, hard, transparent material, while the anterior half serves as the "abdomen". The biggest advantage of this model is that trainees are able to see the depth of catheterization through the posterior half, so that no blood reservoirs are needed. However, it must be emphasized that blood reservoirs do serve as an important training tool for depth verification.

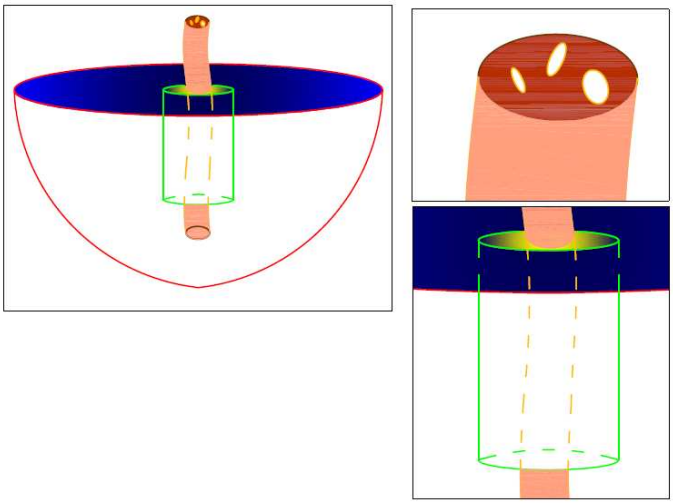

Figure 3: Model 1 (Salad Bowl)

Model 2 (Pommel Horse) requires a single piece of dome-shaped support that is hollow inside, as shown in Figure 4. The thickness of the support will have to depend on the elasticity and softness of the material. A hole will be punctured in the dome to allow placement of the cord. The cord will extend into the dome cavity for not more than 1 cm. To lead the catheter to the blood reservoir, a plastic tubing that mimics the anatomical course of the umbilical vein can be fixed to the proximal end of the cord. The blood reservoir will be the baby bottle model, except that the nipple must be replaced by the plastic tubing. To fix the baby bottle and support in place, a tray needs to be placed at the bottom to keep both components at the same level. The biggest disadvantage of this model is the complexity of putting the components together, though the components are independent of each other.

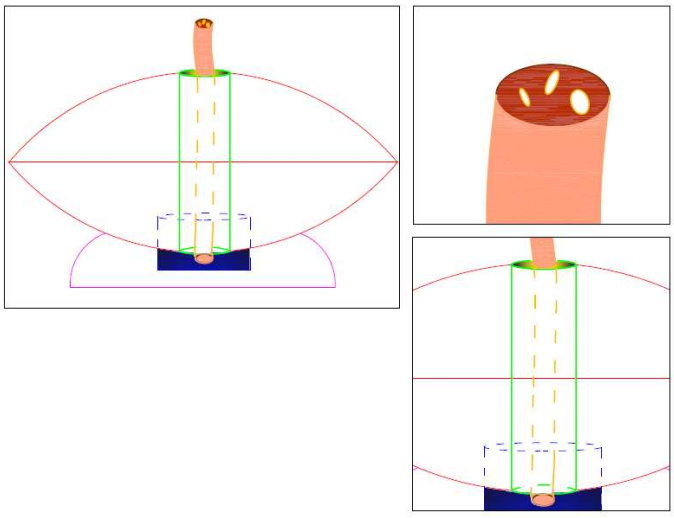

Figure 4: Model 2 (Pommel Horse)

Model 3 (Gel Cushion) cuts the model into left and right halves as shown in Figure 5. Each half is made entirely of gel, and can be carved to mimic the anatomical course of the umbilical vein. To prevent leakage of tissue fluids into the gaps formed when the halves are put together, a plastic tubing can be laid along the tunnel. The most attractive aspect of this model is that it can be very easily put together due to its simplicity. However, designing the mold and selecting an appropriate material prove to be a huge challenge. Also, should any mistakes be made during the design process, the mold has to be re-constructed.

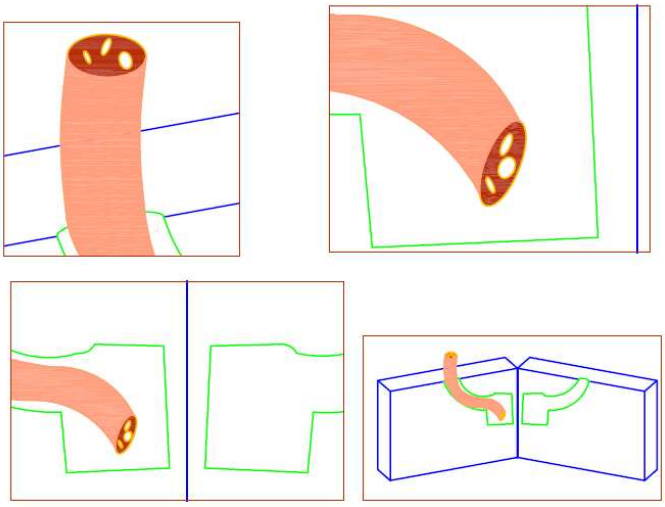

Figure 5: Model 3 (Gel Cushion)

Design Matrix for Architecture

One of the criteria included in the design matrix was functionality, which describes the adaptability of the model to different cord sizes and its ability to incorporate a blood reservoir and distinguish abdominal anatomy. Safety was also included, describing the ability of the device to provide a harmless learning experience for the trainees. Another criterion was user-friendliness, which involves the complexity of usage; the device must be logical upon approach and very self-explanatory and familiar. Also, the architecture must be reproducible so that it would be simple to backtrack when mistakes are made during the construction process. Reproducibility also entails the complexity of construction, and the availability of materials for various parts of the model.

Model 1 (Salad Bowl) does not exactly exhibit functionality qualities, but the design is the simplest and most reproducible. Model 2 (Pommel Horse) provides great mimicry of the abdominal cavity. Moreover, the fact that its multiple components are independent of each other eases backtracking during construction. Model 3 (Gel Cushion) has some anatomical relationships to the real scenario, but the two halves coming together may allow reservoir liquid or cord pathogens to leak through the gel in spite of the plastic tubing. Also, because the model requires so much extraneous material and an intricate mold design, it is harder to reproduce in an efficient and durable manner.

Based on the presumption that gel is the chosen material and that gel is absorbent, model 3 is the least safe due to its extensive usage of gel. In contrast, model 1 does not involve a blood reservoir, and model 2 encases the blood reservoir in a chamber. Both minimize the risk of tissue fluid leakage. However, the membrane covering of model 1 renders the support collapsible should too large a force be exerted on it. It is also susceptible to penetration by sharp objects. Hence, model 2 prevails in terms of safety.

From these design/model assessments, the following design matrix was created and the "Pommel Horse" was chosen as the best model that fit the client's needs and was realistic. The design matrix is shown in Table 1 on the next page.

CRITERIA	WEIGHT	MODEL 1 *(Salad Bowl)*	MODEL 2 *(Pommel Horse)*	MODEL 3 *(Gel Cushion)*
Functionality	40%	10%	90%	80%
Safety	30%	70%	80%	50%
User-Friendliness	20%	80%	50%	30%
Reproducibility	10%	90%	75%	70%
TOTAL	**100%**	**50%**	**78%**	**60%**

Table 1: Design Matrix

Ideas for Materials

There are two main challenges regarding this aspect of the design. First, the material has to suitably mimic the abdomen of an infant, so as to provide greater realism during the catheterization training process. Secondly, the material also has to be easily disposable or sterilizable after use. This is to minimize the risk of transmission of blood-borne pathogens, since the training involves handling of real human tissue.

One of the initial ideas that the team had in mind was to use silicone as the base material for the model. With its well-known application in breast implants, the material's mimicry of human tissue was not an issue. Silicone would also be readily available and relatively inexpensive to purchase should the team decide to use it. However, the fact that it would be hard to shape the material to resemble that of the model in mind limited the applicability of silicone. Furthermore, the team did not have prior experience with silicone and was not sure of its physical and chemical properties.

Another idea was to use ballistic gelatin to construct the model. Due to its close simulation of the density and viscosity of human and animal muscle tissue, ballistic gelatin is used as a medium for testing of firearms ammunition. This same property would also be ideal to mimic the abdomen of an infant. The materials for making the gel are also readily available and inexpensive. However, a few limitations were observed. Firstly, the process of making the gel from its base materials is a long and tedious one. This begs the question of whether the new model would actually be more user-friendly than the current "baby bottle" model, and whether trainers/trainees would be willing to go through this longer process. In addition, the hardened gel tends to stick to its mold, making it hard to remove cleanly.

As an alternative, the team considered using foam, such as those found in toy nerf footballs. The foam was found to be neither too hard nor too soft, and could provide a suitable simulation of the abdomen of an infant. It is also easily obtainable and very cheap. The main advantage of this material over the others is its ease of use. The foam does not have to be shaped or made; using the shape of a football would be sufficient (one just has to cut the nerf ball in half). A hole can also be easily cut into the nerf ball to allow placement of the umbilical cord and stabilization structure. One limitation of using foam is that it can absorb tissue fluid. Hence, blood from the umbilical cord may be absorbed by the foam. To address this issue, the team proposed to use a non-absorbent covering (such as plastic) to cover the entire model.

After careful deliberation of the pros and cons of each material, the team decided to choose foam as the material for the model, specifically that found in a nerf football.

Ideas for Stabilization

The stabilization method has to address the primary issue of fixing the umbilical cord to the architecture model to prevent any inward/outward slipping or rotations about the cord's longitudinal axis. Additionally, it also has to include the ability to incorporate cords of different sizes, as well as keeping the cord intact and in place without damaging it.

INITIAL STABILIZATION IDEAS

The team set out by subdividing the stabilization approach into two components: cord-level stabilization (CLS) and gel-level stabilization (GLS), with the initial assumption that the model would be made of gel. CLS involved attaching a structure to the umbilical cord to prevent it from slipping and rotating, while GLS dealt with fixing the entire CLS structure (with cord attached) onto the model itself.

One GLS idea incorporated two screw-like mechanisms which were hollow to allow fixing of the CLS structure and umbilical cord. The two mechanisms could then be slotted into the hole in the architecture model from opposite ends and stabilized using a locking mechanism. One such mechanism would be that found in BNC cables, but it was decided that that would be too complex a design for the training model.

Another GLS idea involved using a hollow metal cylinder with both ends open to accommodate the cord and CLS structure. This idea was based on the assumption that gel would be used for the model architecture. The metal cylinder would have retractable rods at both ends; these are initially retracted, but after insertion into the model's cavity, a worm gear mechanism causes the rods to come out and pierce into the gel, stabilizing the structure. Alternatively, the rods need not be retractable. In this case, the structure would be placed into the mold with the gel forming around it.

The first CLS idea that the team considered was that of using two rings with "microhooks" along the inner surface. Instead of using microhooks though, larger structures like "long teeth" were suggested. These long teeth would be adequately flexible to accommodate cords of different sizes; thicker cords would bend but not break the teeth, while thinner cords could still be held by the teeth. To prevent slipping or rotation of the cord, it would be inserted into the rings such that their teeth pointed in opposite directions. However, the danger of the teeth puncturing the cord exists. Also, the availability of such a device and possible complexity involved in creating one led the team to consider alternatives.

The second CLS idea involved half-cylindrical clamps holding the umbilical cord in place. These clamps would have frictional material along the inner surface (in contact with the cord) to prevent movement of the cord. The clamp would be adjustable to adapt to different cord sizes. Building on this initial idea, the team suggested using a retort stand and clamp, such as those found in chemistry laboratories. This idea would infuse both CLS and GLS, since the clamp can hold the cord at a desired height above the model, without worrying about stabilizing the cord-model interface. Frictional material would still be used to coat the inner surface of the clamp to provide a firm grip on the cord. However, this mechanism might cause the cord to be gripped too tightly, such that the vessels are constricted and catheterization impeded. Also, the bulky setup of the retort stand and clamp might be a hindrance when carrying out the procedure.

The third CLS idea was to use a thermally-responsive metal spring for the umbilical cord to be inserted into. The diameter of the spring would be temperature-dependent, such that an increase in temperature would increase its diameter. A cord would be slid into the lumen of the spring in its expanded state. Upon cooling, the spring would contract and fuse with the cord, holding it tightly. The screw-like mechanism that results can also be used to fix the cord onto the model. However, the viability of the idea is undermined by the fact that the spring would have to be at high temperatures (introducing risks associated with handling the material), and the properties of the cord might change when in contact with such temperatures. Experiments would also have to be carried out to determine the thermal responsivity of the spring and whether it can adapt to accommodate different cord sizes without penetrating the umbilical cords.

EVOLUTION OF IDEAS AFTER CONSULTATION WITH CLIENT

The team brought the brainstormed ideas to the table during the subsequent meeting with the client. It was evident, after the client's suggestions and preferences were discussed, that some of the prior ideas were not applicable and new considerations would have to be undertaken. The decision to use foam as the material for the model's architecture also mandated some changes to the initial ideas and rendered the term "gel-level stabilization" invalid.

An idea that the team considered was to use an adhesive material to secure the umbilical cord to the model. The adhesive material had not been determined yet, but had to be able to provide frictional contact with the cord to prevent it from slipping or rotating. This idea would be simple, since it involved simply "wrapping" the cord with a material and making the material adhere to the main model body.

In view of the client's preference for having a compressible insert rather than a rigid screw-and-socket mechanism, and in alignment with the adhesive approach, the team proposed a new idea of "wrapping" gelatin around the umbilical cord, thereby forming a compressible insert. This "cord-in-gel" approach would involve making the gel in a cylindrical container, and immersing the cord centrally into the container before the gel hardens (care has to be taken not to place the cord in when the temperature is still too high; this could "cook" the cord and change its properties). The cord can be held suspended in the gel by piercing a stick through its top, and placing the stick on the top of the container. Once the gel sets, the closed end of the container would be cut off to expose the cord. This entire structure would be inserted into the model, with the container acting as a support. In this way, both stability and accommodation of different sizes can be accomplished. However, this structure would only be effective if the gel adheres well to the cord; experiments are in the process of investigating the frictional properties of the cord-gel interface.

Another idea that the team considered was the "sphygmometer" approach. In this model, an air pad (e.g. a baby blood pressure cuff) would be connected to a manual hand pump (e.g. a nose aspirator) and inserted into the hole in the model's architecture. This device would be secured permanently to the model body. To prevent contamination of the entire model, a plastic sheet would be used to cover the model, including the hole for the placement of the umbilical cord. Where the sheet covers the hole, frictional material such as sandpaper would be secured to it. This would prevent the cord from slipping or rotating. As cords of different sizes are inserted, the air pad would be inflated by manually squeezing the hand pump. This inflation causes the cord to be held in place. The amount of inflation can be controlled either by a valve or a clamp. This idea is limited by the fact that it would be hard to tell when sufficient pressure is being exerted to hold the cord in place. As a result, the cord could be held too tightly such that catheterization cannot be carried out properly.

Currently, the team has limited the choices down to the "cord-in-gel" and "sphygmometer" approaches. Experiments are being carried out to determine the feasibility of both mechanisms, as well as to further investigate the effects of the respective limitations of the ideas.

Design Matrix for Materials & Stabilization

No design matrix was created for these two design components since the ideas were actively being revised. As explained before, experiments are currently being carried out to verify the feasibility of each idea before a final design is chosen.

The Final Solution

Discussions with the client revealed that "Pommel Horse" and foam are indeed the best architectural model and material. With regards to stabilization, the "cord-in-gel" and "sphygmometer" approaches remain equally competitive. As mentioned, experiments are being carried out to determine which approach is better for catheterization training. The preliminary design for the final model is shown in Figure 6.

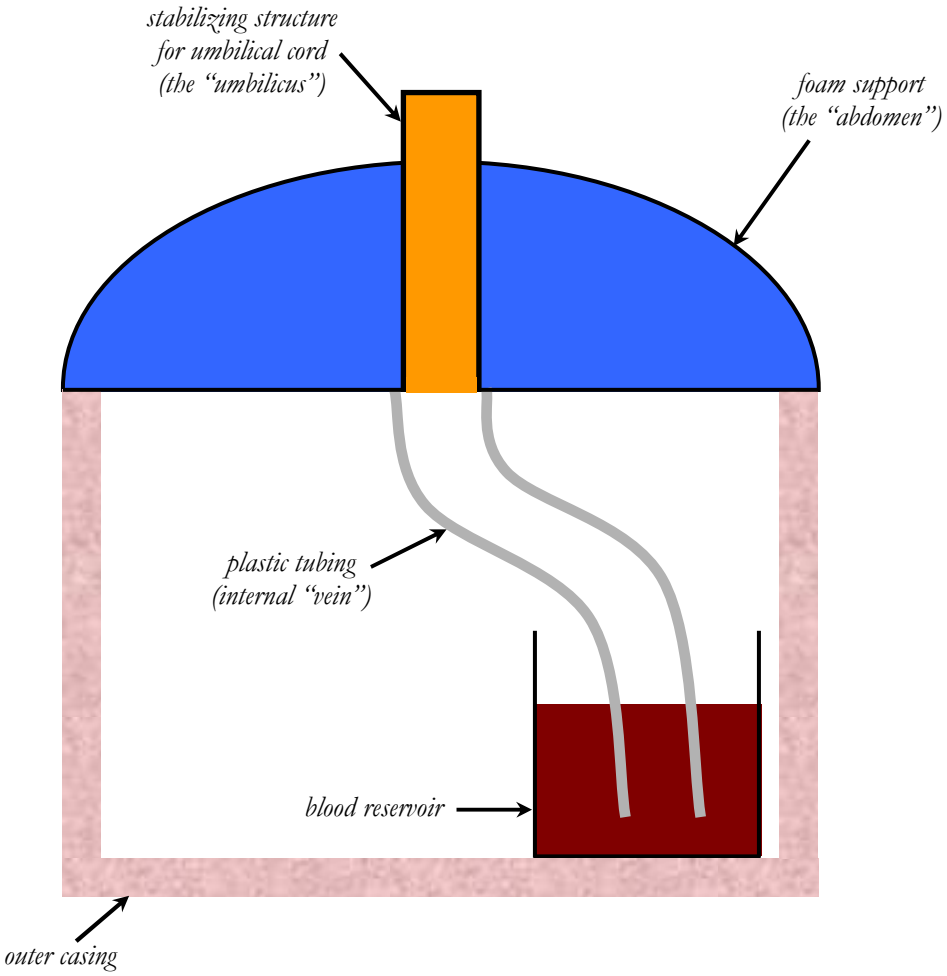

Figure 6: The final solution

Current & Potential Difficulties

ABOUT THE FOAM SUPPORT

The current way to drill a hole in the foam support is via cutting with a penknife. The resulting hole is oblique and does not have a smooth wall. It is also difficult to enlarge the hole using a penknife. A more efficient method is needed so that a smooth, uniform tunnel can be made perpendicular to the base of the foam support. Besides, the current foam support does not mimic the neonatal abdomen accurately in terms of size.

ABOUT THE STABILIZING STRUCTURE

Both approaches have potential difficulties. In the "cord-in-gel" approach, the cord tends to stick to the walls of the gel solution container and hence does not suspend centrally in the container. The current container (a 50-ml Falcon centrifuge tube) is also too hard to be easily cut. Furthermore, fixing the gel under low temperatures may alter the cord properties.

In the "sphygmometer" approach, the current blood pressure cuff is meant for babies and requires an automated pumping machine to modulate the air pressure within the cuff. Hence, there is no valve in the air tube to ensure unidirectional flow of air. A nose aspirator, which is practically a manual air pump, is currently used to pump air into the blood pressure cuff. However, it does not have a valve nor an inlet for air to enter during pumping, causing the air pressure between the cuff and the aspirator to equalize when the aspirator is relaxed. Besides, it is difficult to control the normal stress acting on the umbilical cord by the blood pressure cuff since there is no quantification of the air pressure in the cuff. To stabilize the cord, the friction (or shear stress) must be sufficiently high. This can either be achieved by increasing the normal force, the coefficient of friction, or both. Due to the risk of collapsing the umbilical vein, the normal force (or normal stress) should be limited. Thus the better way is to increase the coefficient of friction between the "umbilicus" and the cord. Yet, comparison between various frictional materials requires the administration of a known amount of normal force. Here, the issue of air pressure quantification surfaces again.

ABOUT OTHER COMPONENTS

No potential difficulties have been identified for other components of the final model.

Future Work

Future work revolves around finding solutions to the potential difficulties. Table 2 on the next page summarizes the plan to resolve each difficulty. It is noteworthy that this plan is not final, but involves iterative experimentation until the optimal functions are achieved. The main challenge is to identify the better of the two stabilization approaches. Besides verifying the feasibility of each approach, both must pass through the catheterization challenge − the final stabilizing structure must pose no difficulties in catheter insertion and navigation beyond those on the trainee's part. Lastly, the model must be improved in areas other than functionality: safety, user-friendliness and reproducibility. Only when all design criteria are reasonably satisfied can the model be considered a prototype.

DIFFICULTY	PROPOSED SOLUTION
Drilling the "umbilicus" smoothly, uniformly, and perpendicular to the base of the foam support	Attempt to cut the hole using a proper electric drill with variable drill bits, a cookie cutter, or a hot-wire styrofoam cutter
Inaccurate "abdomen" size	Use a larger-than-required foam support and shape it
Suspending the umbilical cord in a cylindrical container without it sticking to the walls	Use a larger cylindrical container, preferably with a diameter between 3 cm and 4 cm
Cutting the cylindrical container	Use an electric saw to cut the current container, or use a container with softer material
Changes in tissue properties of the umbilical cord under low temperatures	Experiment with temperatures between −20°C and 4°C to find the optimum temperature for gel fixing without affecting the cord
Air pressure equalization between the blood pressure cuff and the nose aspirator, and no inlet for air in the nose aspirator	Design a valve that is able to release air pressure and ensure unidirectional air flow and attach one to the air tube and one to the nose aspirator (for air inlet)
Quantification of normal stress acting on the umbilical cord by the blood pressure cuff	Fix a strain gage or any other appropriate pressure meter between the cord and the blood pressure cuff

Table 2: Proposed solutions for current and potential difficulties in the final solution

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APPENDIX : PRODUCT DESIGN SPECIFICATIONS

PROJECT TITLE:

Umbilical Cord Model for Umbilical Vein Catheterization Training
(Project Number: 33 / Project Code: umbilical)

INITIAL PROBLEM STATEMENT:

The American Academy of Pediatrics Neonatal Resuscitation Program (NRP) is required training for thousands of physicians and medical staff who attend the delivery of newborns. Placement of an intravenous catheter in the umbilical vein of the cord stump in a distressed newborn is one way to provide life saving medication and is a skill that is essential to the NRP course. Hands-on training in the placement of an umbilical venous catheter has received increased attention and emphasis since the 2005 update of the NRP course.

Currently, two models for hands-on training are available. Some companies make newborn models for CPR that also have artificial umbilical cords (e.g. Laerdal). These models appear to inadequately mimic placement in a real cord and are very expensive. Alternatively, the American Academy of Pediatrics recommends using sections of an umbilical cord obtained after delivery. The cord section is placed in a glass baby bottle with part of the nipple cut off so the cord extends about 1/2 an inch from the top of the nipple. While this model has the advantage of using a real cord, the cord is secured poorly and thus does not adequately mimic placement in a newborn.

The client's design idea is to make a support for real umbilical cords that would more closely mimic the umbilical stump of a newborn. The model could be made out of a material that might mimic the abdominal wall, such as ballistic grade gel, and might perhaps have two halves that clamp around a section of real cord. The model could mimic the curves of the umbilical vein after it enters the body, making placement more realistic. Ultimately, this model, which would best be quite inexpensive and disposable, could be marketed to the over 25,000 individuals in the US who teach NRP and would likely represent a vast improvement over the "baby bottle" model.

REVISED PROBLEM STATEMENT:

To construct a model optimized for use in the umbilical vein catheterization training program, a suitable method is to be devised to firmly hold a fresh umbilical cord in place. In addition, the model needs to accurately mimic the external texture and internal structure of the human neonatal abdomen.

CLIENT REQUIREMENTS:

- Real human umbilical cords are to be used. Fresh specimens can be obtained from Meriter Hospital, but should be used within 1 to 2 days before they are no longer deemed suitable for safe handling.
- The model should mimic the anatomical course of the umbilical vein within the abdominal cavity with adequate mechanical stability, and also mimic the external texture of the neonatal abdomen.
- Fake blood should be incorporated for two functions that aid the training: verification of catheter depth, and location of umbilical vein on the stump.
- The model should be either disposable or sterilizable.
- The model should be equally or more user-friendly than the current baby bottle model without loss of functionality.

DESIGN REQUIREMENTS:

1. Physical & Operational Characteristics

a. **Performance Requirements:** The components of the model must be disposable or sterilizable as its usage involves physical contact with human tissue which poses a risk of blood-borne pathogen transmission. If it is to be sterilized, it must be able to sustain at least 45 training sessions, which is the annual training frequency under the NRP.

The internal structure and external texture of the model must mimic the neonatal abdomen without compromising the stability of the umbilical cord. Axial rotation about the "umbilicus" should not exceed 10 degrees, and axial translation should not exceed 5 mm. Radial stress must be controlled such that the umbilical vein is not overly compressed to allow catheterization with minimal resistance. This is dependent on the specific size of the cord used. In essence, radial stress must be variable.

Trainees should primarily be challenged in the navigation within the umbilical vein. As the vein is convoluted only outside the body, the umbilical cord itself cannot be used to substitute the course of the vein within the body. Hence, a separate mechanism must be used to mimic the anatomical course of the umbilical vein within the body.

The fake blood must always be disposed after usage, though its container can be sterilized and re-used.

b. **Safety:** The model must not contain sharp edges. Materials used must be non-toxic, and preferably be disposable. If the model is to be sterilized, materials must be carefully chosen such that any tissue fluids or remnants adhered to the model can be easily removed.

c. **Accuracy & Reliability:** The model must accurately represent the neonatal abdomen immediately after birth. Radial stress acting on the cord, if any, should be calibrated to avoid excessive compression and the consequent tightening of the umbilical vein. The calibration must be valid for at least 45 training sessions.

d. **Life in Service:** If the model is designed to be disposable, it should be able to sustain usage of about 2 hours. If it is designed to be sterilized, it must remain reusable for at least 1 year after the first use.

e. **Shelf Life:** At least 5 years under room conditions. Umbilical cords must only be obtained at most 1 day before each training session.

f. **Operating Environment:** Normal clinical or laboratory environment, but must be handled under sterile conditions.

g. **Ergonomics:** The trainee should insert the catheter at least 5 cm into the umbilical vein in order to pass the "umbilicus". The amount of force used must not be too high so as not to puncture the cord. The model should be placed at least 10 cm from the edge of the working platform, with no sharps within a radius of 30 cm.

h. **Size:** The rough dimensions of the entire model should be between 10 cm and 20 cm in height, and between 15cm and 40 cm in length or breadth. The inlet for the umbilical cord should be between 2 cm and 5 cm in diameter, and between 4 cm to 8 cm in length. The blood reservoir should be able to fit within the "abdomen" while being able to contain at least 10 ml of fake blood.

i. **Weight:** Between 500 g and 1 kg, such that it is sufficiently stable on the working platform, yet easily handled by the trainee.

j. **Materials:** One fresh human umbilical cord per use. A soft material (such as foam) that can retain its shape after compression should be used as the "abdomen". If this material is porous and able to retain moisture, a waterproof material must be used to cover the "abdomen". The "umbilicus" should not be rigid so as to accommodate various cord sizes. The internal "vein" that leads the catheter to the blood reservoir must not be easily penetrated by the catheter, and must be easily shaped to mimic the anatomical course.

k. **Aesthetics, Appearance & Finish:** Only the texture of the model needs to resemble the neonatal abdomen. Other aesthetic features such as colour and shape are secondary.

2. Production Characteristics

a. **Quantity:** 1 reproducible model for this project. At the manufacturing level, the number of units produced must be sufficient to sustain at least 45 training sessions a year, whether or not it is designed to be disposable or sterilizable.

b. **Target Product Cost:** Yet to be determined.

3. Miscellaneous

a. **Standards & Specifications:** The design and construction of the model must comply with FDA regulations and the American Academy of Pediatrics NRP guidelines.

b. **Customers:** Any clinical institution that is involved with NRP umbilical vein catheterization training.

c. **Patient-Related Concerns:** The donor of the umbilical cords must remain anonymous to the designers and users of the model.

d. **Competition:** The recommended baby bottle model currently used in NRP, the vinyl-tubing baby bottle model, and "Baby Umbi" from Laerdal.