

BME 200/300 (BIOMEDICAL ENGINEERING DESIGN)
FALL 2007

Project #33: Umbilical Cord Model for Umbilical Vein Catheterization Training

FINAL REPORT

December 11, 2007

TEAM MEMBERS:

Ann Sagstetter (Team Leader)
Padraic Casserly (Team Leader)
Songyu Ng (Communicator)
Angwei Law (BSAC)
Timothy Balmann (BWIG)

CLIENT:

Dr Julie Kessel
Department of Pediatrics, UW-Madison

ADVISOR:

Professor Brenda Ogle
Department of Biomedical Engineering, UW-Madison

Table of Contents

Abstract.....	4
Problem Statement.....	4
Background Information	
<i>Anatomy of the Umbilical System</i>	4
<i>Umbilical Vein Catheterization (UVC)</i>	6
<i>UVC Training & Current Models</i>	6
Client Requirements & Ethical Considerations.....	8
Design Components	
<i>Architecture</i>	8
<i>Stabilization</i>	9
Designing Architecture	
<i>The Salad Bowl Model</i>	9
<i>The Pommel Horse Model</i>	10
<i>The Gel Cushion Model</i>	10
<i>Design Matrix for Architecture</i>	11
Designing Stabilization	
<i>The Screw Concept</i>	12
<i>The Clamp Concept</i>	12
<i>The Cord-In-Gel Concept</i>	12
<i>The Sphygmomanometer Concept</i>	13
<i>Design Matrix for Stabilization</i>	13
The Final Prototypes	
<i>The Cord-In-Gel Model</i>	14
<i>The Sphygmomanometer Model</i>	15

Verification Tests

<i>Tensile Test</i>	17
<i>Catheterization Test</i>	17
Conclusions	18
Future Work	18
References	19
Appendix I: Product Design Specifications	20
Appendix II: Project Expenditure	22
Appendix III: Time Contributions of Individual Members	23

Abstract

Current simulation models used in umbilical vein catheterization (UVC) training programs fail to portray the actual procedure in the delivery room. To provide a more realistic experience for the trainees, two new models were developed, namely the cord-in-gel model and the sphygmomanometer model. Both models have proven to perform better than the current models in terms of their abilities to incorporate and stabilize a real umbilical cord specimen, and to mimic the external texture of the neonatal abdomen.

Problem Statement

Via the Neonatal Resuscitation Program (NRP), the American Academy of Pediatrics trains thousands of clinicians at least 45 times a year to hone their UVC skills. Part of the NRP requires the trainees to perform UVC using a simulation model of the actual procedure. The current model widely used by the NRP is the baby bottle model, which has been deemed unsatisfactory due to its insufficiencies in simulating UVC. A substitute for the NRP baby bottle model, known as “Baby Umbi”, is available in the market. However, due to its steep pricing and inability to incorporate a real umbilical cord, it is inadequate for use in the NRP.

A new simulation model is to be designed and constructed to provide a more realistic experience for NRP trainees, as compared to the current models. Two primary aspects must be optimized to achieve the desired performance:

- 1) *the incorporation and stabilization of a real umbilical cord specimen of not more than 7 cm in length;*
- 2) *the mimicry of the external texture of the neonatal abdomen, inclusive of the umbilicus.*

In addition to the above, the model must be able to perform the fundamental functions which the current models already have. These include the incorporation of a blood reservoir, disposability or sterilizability, biological safety, and user-friendliness.

Background Information

Anatomy of the Umbilical System

Before delivery, the fetus is connected to the mother through the umbilical cord and the placenta. A healthy umbilical cord contains 1 central vein which transports oxygenated blood from the placenta to the fetus, and 2 umbilical arteries which transport deoxygenated blood in the opposite direction. Structural differences between the umbilical vessels include lumen size and wall thickness (Figure 1). From the placenta to the umbilicus, the umbilical vessels intertwine in a helical fashion, and diverge upon entry into the fetus’ abdominal cavity (Figure 2). The umbilical arteries turn inferiorly towards the legs and course around the urinary bladder before joining the internal iliac arteries (and eventually the aorta) approximately at the first sacral (S1) vertebral level. On the other hand, the umbilical vein ascends into the liver and bifurcates at the transverse fissure, branching into the right hepatic lobe and the inferior vena cava.

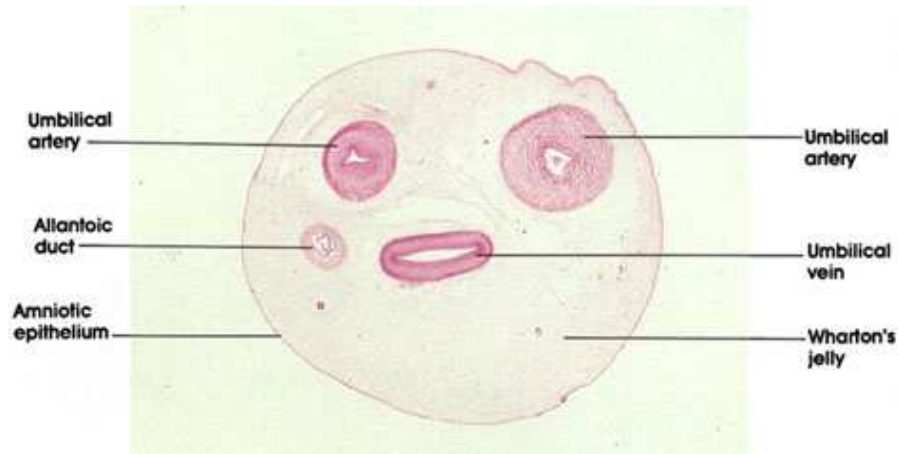


Figure 1: *Histological cross section of the umbilical cord revealing the relative positions of the umbilical vessels*

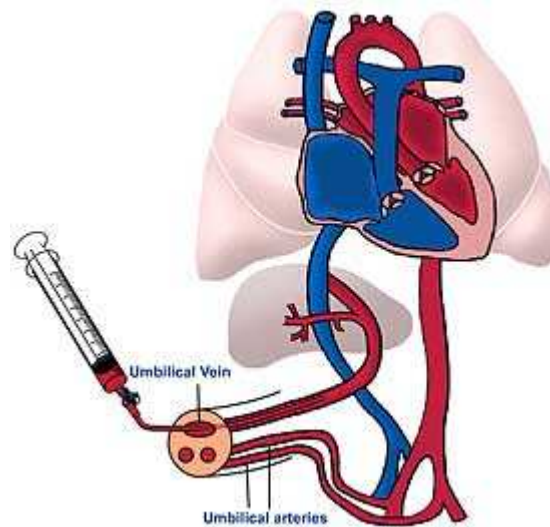


Figure 2: *Schematic of the course of the umbilical vessels upon entry into the neonatal abdomen and the insertion of an umbilical vein catheter*

In the umbilical cord, the umbilical vessels are surrounded by Wharton's jelly, a gelatinous substance that is composed of mostly hyaluronic acid and some collagen and mesenchymal stem cells. Functionally, the Wharton's jelly provides structural support and protection for the umbilical vessels, regulates blood flow, and stores chemicals upon the onset of labor. The allantoic duct, though running in parallel with the umbilical vessels within the umbilical cord, is a remnant of embryonic development and eventually becomes a vestigial structure. Besides the allantoic duct and the umbilical vessels, other macrostructures in the umbilical cord such as nerves and lymphatic vessels are absent.

In a full-term neonate, the umbilical cord is on average about 50 cm long and 2 cm in diameter. The lumen of an umbilical vessel is approximately 1 to 2 mm in diameter.

Umbilical Vein Catheterization (UVC)

During delivery, once the neonate is able to breathe independently, the umbilical cord is doubly clamped at about 2 to 3 cm from the neonatal end and severed between the clamps. This may be performed prematurely (before the neonate can breathe) if the umbilical cord wraps around the neonate's neck and cannot be unwrapped by the clinician. Also, the position at which the umbilical cord is severed depends on the condition of the neonate. If the need for catheterization through any of the umbilical vessels is foreseen, the umbilical cord is cut further away from the neonatal end. Once the umbilical cord is severed, the umbilical stump that remains takes up to 2 to 3 weeks to dehydrate and self-amputate.

UVC is called for when the neonate requires medical intervention via venous access, whether or not it is an emergency. Examples of such situations include shock, cardiopulmonary failure and hypoglycemia, all of which can happen during or after delivery. Venous access allows clinicians to deliver intravenous drugs and perform blood transfusions, as opposed to arterial access which is more commonly employed for blood sampling and monitoring. The umbilical vein is therefore the most direct and painless intravenous route as intact systemic veins need not be accessed and damaged unnecessarily. However, due to the rapid deterioration of the umbilical stump, UVC can only be used temporarily while new routes of venous access are being identified.

During UVC, the clinician carefully inserts a 3.5- or 5-French catheter into the umbilical vein while an assistant stabilizes the umbilical stump with tweezers. The clinician then navigates through the umbilical vein towards the liver, usually up to a depth of about 5 cm beyond the umbilicus. To verify the depth of insertion, the clinician refers to the graduations on the catheter and regularly draws back on the catheter syringe to observe the presence of blood. If blood can be drawn back, the clinician stops advancing and performs the necessary medical procedures.



Figure 3: *Umbilical catheter (3 French = 1 mm)*

UVC Training & Current Models

As neonatal resuscitation is relatively specialized and rare, clinicians are usually not trained in UVC during their normal residency training. This explains why the American Academy of Pediatrics offers the NRP exclusively to train clinicians who may need such a skill. Besides, UVC training is mandatory for clinicians who intend to use it, as UVC is an invasive and challenging procedure.

UVC training under the NRP involves the use of the baby bottle model (Figure 4). The bottle is filled with red dye and Pedialyte solution, while the tip of the nipple is excised to allow the insertion of a real umbilical cord all the way into the solution. The umbilical vein is then catheterized like the actual procedure, with the red solution serving as a blood reservoir for depth verification practice. However, as friction between the rubber nipple and the umbilical cord is very low, the baby bottle model does not prevent rotation and translation of the umbilical cord. This lack of structural support renders UVC difficult, since the umbilical cord moves as the trainee navigates through the umbilical vein. It also increases the tendency for the trainee to apply more force while navigating, which may eventually puncture the umbilical cord (Figure 5). Besides, the NRP baby bottle model does not provide adequate simulation of the neonate's body. During actual UVC, clinicians are able to rest their hands on the neonate's abdomen to improve dexterity and precision. Such contact between the clinician and the neonate is absent in the NRP baby bottle model. Summing all the above factors clearly explains why this model is deemed unsatisfactory for the purpose of UVC training.



Figure 4: *The NRP baby bottle model with and without real umbilical cord specimen*



Figure 5: *Punctured umbilical cord due to excessive force during navigation*

A model that provides contact between the clinician and the neonate exists in the market, and is known as “Baby Umbi” (Figure 6). This product of Laerdal is sold at a price of USD\$396.00 per rubber doll, and USD\$53.00 per set of 3 replaceable umbilical cord mimics. Compared to the NRP baby bottle model which can be purchased below USD\$50.00, “Baby Umbi” is approximately 8 times more expensive. Yet, the major setback of this model is not its price, but the use of umbilical cord mimics instead of real umbilical cords. Unlike the real umbilical cord, the synthetic mimics have much larger “vessels”, provide much more friction, and do not possess the viscoelastic consistency representative of Wharton’s jelly. This model essentially defeats the purpose of simulating UVC, perhaps explaining why the NRP did not adopt this model.



Figure 6: “Baby Umbi” by Laerdal (left: umbilical cord mimics; right: rubber doll)

Client Requirements & Ethical Considerations

The client requires real human umbilical cords to be incorporated and used within 1 to 2 days. The model should mimic the external texture of the neonatal abdomen, and a blood reservoir should be included to contain artificial blood, which simulates the verification of catheter depth in actual UVC. The model should also be either disposable or sterilizable, and be equally or more user-friendly than the current baby bottle model without loss of functionality. More information can be found at the Appendix I.

Cords must be donated anonymously and be treated with respect. Information that may endanger the user must not be made clear in a disclaimer. Designs must be original or properly cited from their respective sources.

Design Components

The design components were split into two main areas – architecture and stabilization.

Architecture

The architecture component dictates the general size and shape of the model. This should resemble either the neonatal abdomen, or an entire infant’s body, in reflection of reality. Suitable materials which sufficiently mimic the texture of the infant abdomen have to be chosen, and they should preferably be sterilizable or disposable after use. The model must also encompass a blood reservoir below or within itself, to allow for verification of catheter placement.

Stabilization

The stabilization component provides the link to connect the umbilical cord to the model. Stabilization entails having a mechanism that does not allow the cord to rotate, slip, or move during UVC training, and is essential since the current NRP training model – the baby bottle model – fails in this aspect. The materials chosen must both provide good stabilization for the cord and be compatible with the model architecture. Similarly, they should preferably be sterilizable or disposable after use.

Designing 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 mimicry of the neonatal abdomen. A code name was given for each model.

The Salad Bowl Model

The first model cuts the main body into anterior and posterior halves (Figure 7). The posterior half is to be made of a red, hard, transparent material, while the anterior half is to be made of a film of gelatin to serve 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.

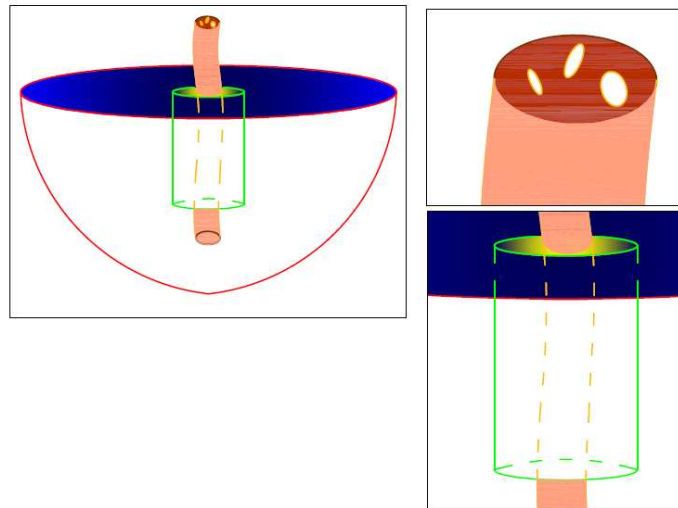


Figure 7: *The salad bowl model (not drawn to scale)*

The Pommel Horse Model

The second model requires a single piece of dome-shaped support that is hollow inside (Figure 8). The thickness of the support will have to depend on the elasticity and softness of the material. A possible material to use is foam, such as those found in toy nerf footballs. Foam can provide a suitable simulation of the neonatal abdomen, and is also cheap and easy to manipulate. 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 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.

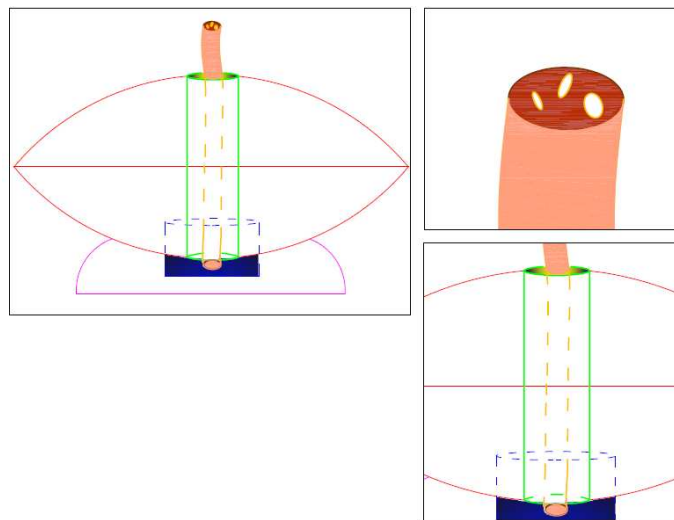


Figure 8: *The pommel horse model (not drawn to scale)*

The Gel Cushion Model

The third model is cut into left and right halves (Figure 9). Each half is made entirely of gelatin, and can be carved to mimic the anatomical course of the umbilical vein, which would provide yet greater realism. Gelatin closely simulates the density and viscosity of human and animal muscle tissue, so it would be suitable as a mimic of the neonatal abdomen. 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 would be a huge challenge. Also, should any mistakes be made during the design process, the mold would have to be re-constructed.

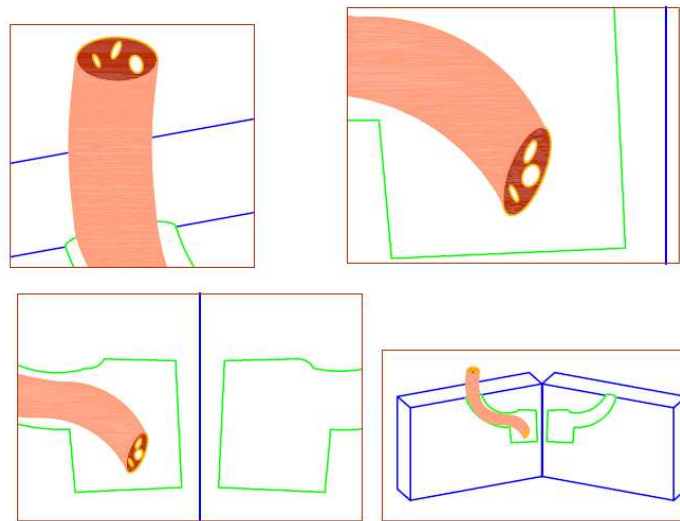


Figure 9: *The gel cushion model (not drawn to scale)*

Design Matrix for Architecture

One of the criteria included in the design matrix was functionality, which describes the ability to incorporate a blood reservoir and mimic the neonatal abdomen. The structure should also provide substantial surface for the user to place his hands – a characteristic that is provided by “Baby Umbi” but not the NRP baby bottle model. 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.

The salad bowl model does not exactly exhibit functionality qualities, but its design is the simplest and most reproducible. Also, unlike the other two models, it does not provide a stable support for the user to place his hands. The pommel horse model provides great mimicry of the abdominal cavity, and the fact that its multiple components are independent of each other eases backtracking during construction. The gel cushion model 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 gelatin is the chosen material and that it is absorbent, the gel cushion model is the least safe due to its extensive usage of gel. In contrast, the salad bowl model does not involve a blood reservoir, and the pommel horse model encases the blood reservoir in a chamber. Both minimize the risk of tissue fluid leakage. However, the membrane covering of the salad bowl model renders the support collapsible should too large a force be exerted on it. It is also susceptible to penetration by sharp objects. Hence, the pommel horse model prevails in terms of safety.

From these design/model assessments, the following design matrix was created and the pommel horse model was chosen as the best model that fit the client’s needs and was realistic (Figure 10).

CRITERIA	WEIGHT	SALAD BOWL MODEL	POMMEL HORSE MODEL	GEL CUSHION MODEL
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%

Figure 10: Design matrix for architecture ideas

Designing Stabilization

Based on the chosen architectural design, several stabilization methods were proposed. Essentially, the stabilization methods have to address the primary issue of fixing the umbilical cord to the architecture model to prevent any translation or rotation of the cord. Additionally, they must also include the ability to incorporate cords of different sizes, as well as keep the cord intact and in place without damaging it.

The Screw Concept

The screw concept incorporates a plug-and-play method, where two complementary screw-like structures (one “male” part on the cord, one “female” part on the architecture model) are stabilized using a locking mechanism. An example of such a mechanism is that found in BNC cables.

The Clamp Concept

The clamp concept involves half-cylindrical clamps holding the umbilical cord in place. These clamps would have a high friction material (HFM) 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, another possibility is to use a retort stand and clamp, such as those found in chemistry laboratories. This idea would allow the cord to be held at a desired height above the model, without worrying about stabilizing the cord-model interface. A HFM 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 Cord-In-Gel Concept

The cord-in-gel concept uses gelatin to stabilize the cord during catheterization. The gel solution is poured into a container to surround the cord. Upon hardening of the gel, the section of the cord that is immersed in the gel would be completely embedded. The gel acts as an adhesive to the cord, stabilizing it at all points on its surface. The concentration of the gel solution can be varied such that a balance between stabilizing force and texture mimicry can be achieved.

The Sphygmomanometer Concept

The sphygmomanometer concept involves the use of a blood pressure cuff to hold the umbilical cord during catheterization. This cuff incorporates an inflatable bladder attached to a rubber hose leading to a valve and bulb, which are used to vary the pressure in the bladder. A HFM can be adhered to the interior of the cuff to provide additional friction between the cuff and the umbilical cord. To keep the inflatable cuff and model free from any biological contamination, a sanitary sleeve can be inserted between the cuff and umbilical cord. This sleeve can be disposed of after each use, thereby reducing the need for disposing of the entire model after a training session.

Design Matrix for Stabilization

One of the criteria included in the design matrix was stability, which describes the ability to fix the cord in place without translation or rotation. User-friendliness was also included, describing the complexity of usage; the device must be logical upon approach and very self-explanatory and familiar. In addition, it should also be easy to construct. Another criterion is materials, which involves the availability of materials for the user to access and obtain.

The screw concept provides good stability for the cord, preventing any translation but allowing slight rotation. The clamp concept, on the other hand, does not have as much precision in controlling the pressure exerted on the cord. Also, the cord is not perfectly cylindrical, hence pressure exerted by the clamp would not be uniform. As a result, stability is compromised. The cord-in-gel concept fully encompasses the cord, not allowing any movement aside from the deformation of the gel itself. The sphygmomanometer concept works similarly to the clamp concept, but because of the cuff's deformability, it is able to wrap around the cord entirely to evenly distribute the pressure on the cord.

Since all models are relatively easy to use, the only characteristic that separates them is the ease of construction. For this, the screw concept fares poorly because the individual parts are difficult to construct and customize in order to accommodate different cord sizes. The clamp concept is relatively easy to construct, but remains difficult to customize. Although both the cord-in-gel and sphygmomanometer concepts are tedious to construct, they can be freely customized to suit the individual cords – a quality that renders these models superior to the others.

The materials required for the screw and clamp concepts are difficult to obtain because they are usually metal alloys. However, this problem is less of an issue for the clamp concept, since clamps can be obtained from laboratories in the hospital. The cord-in-gel and sphygmomanometer concepts, on the other hand, make use of materials that are readily available.

From these design assessments, the following design matrix was created and both the cord-in-gel and sphygmomanometer concepts were chosen to be further pursued (Figure 11).

CRITERIA	WEIGHT	SCREW CONCEPT	CLAMP CONCEPT	CORD-IN-GEL CONCEPT	SPHYGMOMANOMETER CONCEPT
Stability	70%	80%	50%	90%	90%
User-Friendliness	20%	20%	50%	70%	60%
Materials	10%	10%	50%	100%	100%
TOTAL	100%	61%	50%	77%	75%

Figure 11: Design matrix for stabilization ideas

The Final Prototypes

The same foam support is used for both prototypes. To construct the foam support, a 1.75”-diameter hole is drilled into a foam football using an arch punch. Grease is applied to the punch so that friction between the punch and the foam is reduced when the punch cuts into the foam. One side of the foam support is then sliced off (1 to 2 cm from the bottom) to provide a flat base for the prototype to stand. Finally, the foam support is wrapped with a cloth to improve the aesthetic appeal, without covering the hole.

The Cord-In-Gel Model

The cord-in-gel model utilizes 1.75”-diameter Playtex liners, which can be used as containers for the gel solution and also inserts into the foam support. A 2 cm x 13 cm strip of adhesive sandpaper is cut and stuck to the inner surface of the Playtex liner just below its rim. This sandpaper serves to increase surface area for gel adhesion to the smooth Playtex surface. A 7-cm umbilical cord specimen is then suspended in the middle of the liner with a weight tied to the lower end to straighten the cord.

Meanwhile, Knox gelatin is prepared using three packets per 150 ml of hot water. The solution is then continuously stirred until all the gelatin dissolves and left to cool to room temperature. Once cooled, the gelatin is poured into the liner containing the cord, leaving approximately 2 cm of cord exposed. The entire liner is then placed in a large airtight bag and cooled at 2°C overnight.

The next day, the liner is removed from the refrigerator. Using a scalpel, the liner is cut to expose the lower end of the cord. It is then placed into a second Playtex liner, which is filled with 50 ml of water and a few drops of red dye (Figure 12a). The entire unit is inserted into the foam support until the lips of the liners are in contact with the foam (Figure 12b).

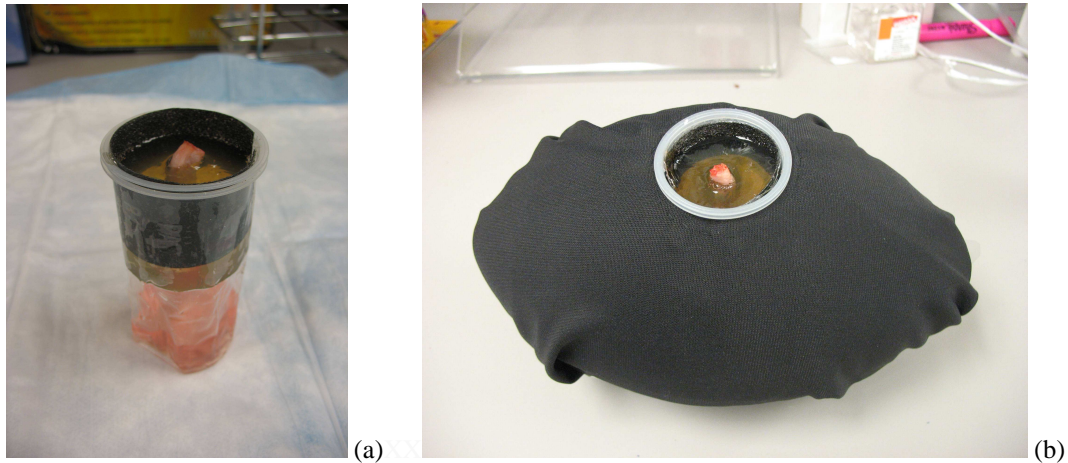


Figure 12: *The cord-in-gel model*

The cord-in-gel model supersedes the efficacy of the baby bottle model, because it completely stabilizes the cord from both rotation and translation during the catheterization, and even resembles an infant's umbilicus. Also, the foam support is superior to "Baby Umbi" since it incorporates real umbilical cords, while maintaining the ability to provide contact between the user and baby.

The Sphygmomanometer Model

The sphygmomanometer model's major functioning component is a Neonate 3 blood pressure cuff. The cuff has a maximum diameter of 3.18 cm, which is a large enough aperture to accommodate any normal cord size. Upon maximum inflation, the cuff's aperture reduces to zero, such that opposite sides of the cuff are touching each other. This cuff is then secured to the inner surface of a plastic tube with a cyanoacrylate-based plastic adhesive. The plastic tube used for this prototype is an 80-ml Medela SpecialNeeds Feeder. A 3.57-mm hole is drilled 4.5 cm from the upper lip of the bottle. This allows the air hose to be attached to the cuff without getting in the way of the catheterization. A small barbed connector joins the air hose to the nipple on the cuff (Figure 13a). A Kendall monoject 12-ml syringe is used to inflate the cuff. To easily attach the air hose to the syringe, a male screw type connector is attached to the air hose. This male connector is inserted into the female connector to form an air tight seal that can be easily detached (Figure 13b).

To increase the friction between the cuff and the cord, strips of 150-grit sandpaper are adhered to the interior of the cuff. These strips are approximately 4.1 cm x 0.3 cm and are glued to the cuff using the same cyanoacrylate-based adhesive. Since the cuff has a tendency to crease upon inflation, the strips of sandpaper are concentrated around the non-creasing sides so that the majority of sandpaper used is in contact with the cord.

To complete the model, the tube is filled with 25 ml of water and a few drops of red dye are added. The entire unit (Figure 14a) is then inserted into the foam support (Figure 14b). Additionally, a 3/8"-hole is drilled into the foam so that the air hose can extend out of the foam.

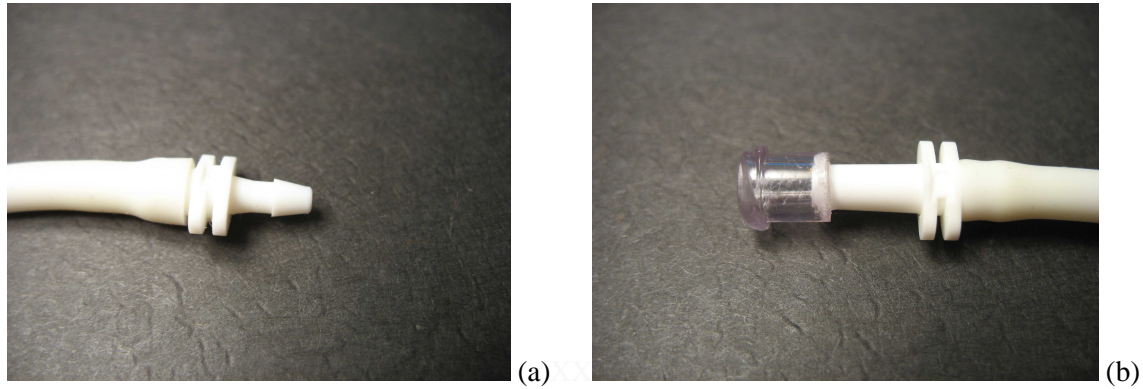


Figure 13: *Hose connections for sphygmomanometer*

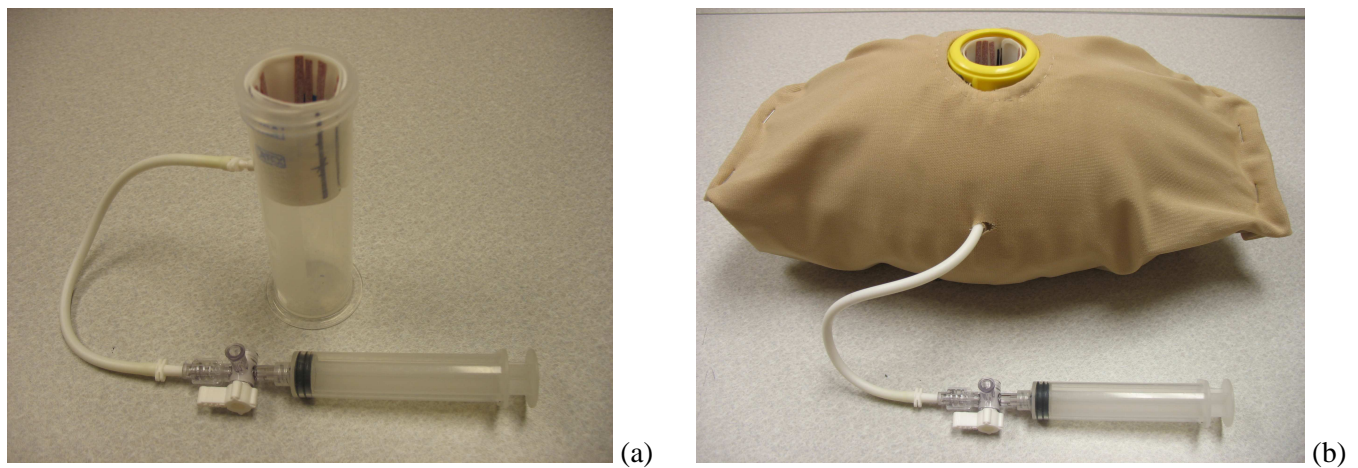


Figure 14: *The sphygmomanometer model*

The sphygmomanometer model is better than the NRP baby bottle model. It is more flexible to use because it is adjustable to any umbilical cord size, whereas the nipple on the baby bottle model must be appropriately cut to hold a specifically-sized cord. The sphygmomanometer model is also effective in prohibiting translation and rotation of the umbilical cord. Also, like the cord-in-gel model, the foam support renders this model superior to “Baby Umbi”.

Verification Tests

In order to compare both the cord-in-gel model and the sphygmomanometer model with the baby bottle model used by NRP, testing was carried out on all three models.

Tensile Test

The tensile test involved using a Newton meter to measure the force required to extract the umbilical cords from their respective stabilizing devices. For the baby bottle model, this stabilizing device is the nipple (with its tip cut off). For the cord-in-gel model, this would be the gel surrounding the cord. For the sphygmomanometer model, the cord is stabilized by the blood pressure cuff. From the results of the tensile test (Figure 15), it can be seen that the cord-in-gel model provided the greatest stability for the cord, where more than 8 N of force was required to pull the cord out from the surrounding gel. The sphygmomanometer model could withstand a maximum tensile force of approximately 3 N before the cord slipped out of the blood pressure cuff. For the baby bottle model, the force required to pull the cord out from the nipple was negligible, since there was very little friction between the nipple and the cord, such that the cord was insufficiently stabilized.

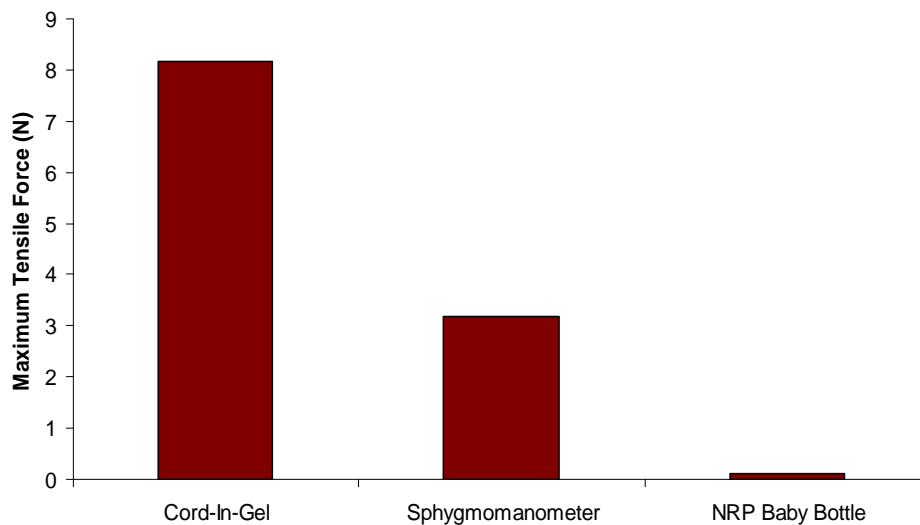


Figure 15: Tensile test results

Catheterization Test

In the catheterization test, all three models were tested side-by-side to determine the proportion of cords that could be catheterized using each model. Different sections from the same umbilical cord were used to test each model; this was to minimize the difference in internal anatomies and amounts of twisting of different cords, although there could still be considerable variance among different sections of the same cord. Each model was subjected to catheterization three times, once each by two team members, and once by the client. The proportion of catheterization successes were then determined (Figure 16). Evidently, the cord-in-gel model was the most successful, allowing catheterization of all the tested cords. The sphygmomanometer model had a slightly lower success rate at 67%, although the sole cord that could not be catheterized was deemed to be overly twisted. For the baby bottle model, it was very hard to catheterize any of the tested cords, resulting in an extremely low success rate. However, it must be noted that the sample size (of 3) in this case was very small; a larger sample size can be used to obtain more accurate results for this test.

MODEL	SUCCESS OF CATHETERIZATION
Cord-In-Gel	100%
Sphygmomanometer	67%
NRP Baby Bottle	0%

Figure 16: Catheterization test results

Conclusions

Clearly, both the cord-in-gel model and sphygmomanometer model are superior to the baby bottle model in terms of stabilizing the umbilical cord and ease of catheterization. Since they utilize a real human umbilical cord, they also provide more realistic training for trainees compared to “Baby Umbi”, which uses artificial cord mimics.

Throughout all the experiments and testing, one factor was identified to be beyond the user’s control in terms of the success of catheterization. Umbilical veins in different cords have different degrees of twisting, which can possibly confound the outcome of the catheterization tests. As mentioned earlier, larger sample sizes can be used to reduce the random error caused by this problem.

Currently, both models are sufficient in meeting the design criteria, but excel in different aspects. The cord-in-gel model, although more cumbersome to set up, performs better at mimicking the umbilicus and stabilizing the cord. The sphygmomanometer model, on the other hand, is more user-friendly in terms of its preparation. It can also be repeatedly used since the cord is not permanently fixed to the stabilizing mechanism. Though the sphygmomanometer model is weaker at stabilization and mimicry, it is believed that this model has greater commercial potential and can be optimized to perform as well as, if not better than, the cord-in-gel model. To ensure a fair comparison of both models, more experiments will have to be carried out.

Current Limitations & Future Work

To understand what future work needs to be done, it is first necessary to identify the aspects of the current models that require improvement and optimize them. Only then is there sufficient evidence for a superior model to be selected.

A major problem with the cord-in-gel model is the large amount of time required to prepare the gel insert. Much of this time can be attributed to suspending and straightening the cord within the gel solution. Currently, a rubber band is tied to each end of the cord segment. On one end, a weight is used to straighten the cord. On the other end, the cord is secured to an external scaffold. It is possible to devise an alternative method to accomplish these so that the process can be simplified. Meanwhile, the sphygmomanometer model can be optimized in terms of cord stability and the ease of catheterization. One possible way is to customize the blood pressure cuff to hold the cord better. Alternatively, a better HFM can be found.

Upon identification of the superior model, one additional feature can be incorporated to further improve the model design: mimicry of the course of the umbilical vein beyond the umbilicus. Currently, both prototypes have their blood reservoirs directly below the umbilicus, which is unlike the anatomical course of the umbilical vein inside the infant's abdomen, since the vein travels from the umbilicus up towards the liver. Incorporating this feature will require increasing the size and reforming the shape of the foam support to accommodate the new path.

Furthermore, it is necessary to acknowledge the possibility that the product may be manufactured on a large scale in the future. Hence, the chosen materials must be compatible with the manufacturing process. The current models, which have been custom-made, require much time to construct, and the users might not be willing to devote that much time to manually set them up. Besides, the chosen materials must be available at bulk manufacturing level.

Lastly, blind testing with actual trainers and trainees is mandatory. Feedback from such professionals is very valuable and can be used to make further modifications on the model.

References

Neonatal Resuscitation Program. American Academy of Pediatrics. Oct 15, 2007. Retrieved from: http://www.aap.org/nrp/images_z_nu/trr5_f62_veinousumbilical.jpg

"Baby Umbi". Laerdal. Sep 14, 2007. Retrieved from: <http://www.laerdal.com.au>

APPENDIX I: PRODUCT DESIGN SPECIFICATIONS

Project Title:

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

Last Updated:

December 11, 2007

Team Members:

Ann Sagstetter
Padraic Casserly
Songyu Ng (Kelvin)
Angwei Law
Tim Balmann

Product Functions:

The product must be able to incorporate and stabilize a real umbilical cord specimen during the UVC training, and to mimic the external texture of the neonatal abdomen.

Client Requirements:

- Real human umbilical cords are to be incorporated and used within 1 to 2 days.
- The model should mimic the external texture of the neonatal abdomen.
- A blood reservoir should be included to contain artificial blood, which simulates the verification of catheter depth in actual UVC.
- 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 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 1 cm. 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. Also, the stabilization mechanism should be able to withstand at least 3 N of force before the cord is uprooted, and the cord must remain catheterizable. The blood reservoir must be designed such that artificial blood can be disposed of after each usage.

- 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 2 days before each training session.
- f. **Operating Environment:** Normal clinical or laboratory environment, but must be handled under biologically safe conditions.
- g. **Ergonomics:** The trainee should insert the catheter at least 5 cm into the umbilical vein. The amount of force used must not be too high so as not to puncture the cord, or exceed the ability of the stabilization mechanism. As a guide, the force that may be encountered is between 3 N and 12 N. 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, without restrictions in depth. 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”, unless the material is to be disposed of. The “umbilicus” should not be rigid so as to accommodate various cord sizes, and must produce considerable friction to hold the cord in place. The path leading the catheter to the blood reservoir must not be easily penetrated by the catheter.
- 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 NRP baby bottle model and “Baby Umbi” from Laerdal.

APPENDIX II: PROJECT EXPENDITURE

SOURCE	ITEM	QUANTITY	TOTAL PRICE (USD)
Dorn True Value Hardware	Med Alo Sandpaper	1 pack of 5	2.49
	HD Velcro Strip	2 packs	2.99
	1½" × 15" Plastic Tubing	1	3.99
	5/8" × 7/8" Plastic Tubing	1	1.58
	5/16" × 1/2" Plastic Tubing	1	1.59
Subtotal (with tax):			14.21
The Home Depot	Adhesive Grip Spray Paint	1	4.92
	1/3' Sandpaper	1	2.47
	Plastic Tubing	1	6.36
	Rubber Gloves	1	3.97
	Epoxy Glue	1	2.97
	6" × 24" Sandpaper Strips	1	5.97
	Grade 36 Sandpaper	1	2.17
Subtotal (with tax):			33.55
Target	Nerf Footballs	2	19.78
	Material for Football Cover	2	39.98
Subtotal (with tax):			63.05
College Library Printing	Poster	1	35.00
	Subtotal (with tax):		
Wal-Mart	Foam Balls	1 pack of 3	3.54
	Vinyl Sheet	2 yd ²	4.88
Subtotal (with tax):			8.88
Capitol Center Foods	Knox Gelatin	14 packs	22.26
	Ziploc Storage Bags	1 box	3.39
	PAM	1	3.39
Subtotal (with tax):			29.13
WalGreens	Playtex Bottle	2	10.98
	Playtex Liners	1 box	5.49
Subtotal (with tax):			17.37
TOTAL:			201.19

APPENDIX III: TIME CONTRIBUTIONS OF INDIVIDUAL MEMBERS

WEEK #	ANN SAGSTETTER	PADRAIC CASSERLY	SONGYU NG	ANGWEI LAW	TIMOTHY BALGEMANN
0	2	3.75	5.5	3.5	4
1	4.75	4	6.25	4.5	4
2	8	10.5	8	7.5	8.5
3	7	4	5.5	5	3.5
4	6	5	5.5	5	5
5	16.5	6	14.5	6.5	9
6	16	17	16	17.25	12.5
7	4.75	2.5	4	4.5	3
8	11.5	9	11.5	9.5	9
9	9.5	5.5	5.5	7	8
10	12	11.5	17	11	9.5
11	21.5	13	19	16.5	20.5
TOTAL:	119.5	91.75	118.25	97.75	96.5