Design of a Novel Umbilical Venous Catheter with Echogenic Distance Markers for Increased Placement Accuracy

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Abstract

Umbilical Venous Catheters (UVCs) are commonly used in neonatology to administer medications, but complications (such as liver necrosis and arrhythmia) often arise from improper placement of the catheter tip. Currently, radiography is the most common imaging modality used to visualize UVC location, but this results in excess radiation exposure while being more expensive and time-consuming. Point-of-Care Ultrasound (POCUS) has recently emerged for real-time placement guidance and to rapidly verify location, but current UVCs lack sufficient echogenicity and distance markers. The aims of this project include identification of materials to incorporate into UVCs and development of working prototypes to assess the viability of the revised design. Silver-coated microspheres and foam material were identified as experimental conditions and both control and experimental prototypes were created. These prototypes were visualized using a basic ultrasound setup, and it was found that foam material was significantly brighter compared to the control ($p = 0.01204$). The silver-coated microspheres slightly increased brightness, but failed to reach a significant level ($p = 0.1658$). Tensile testing revealed adherence to current medical device regulations and flow rate analysis showed no significant impairment of fluid flow from the inclusion of the distance markers. Application of the experimental conditions to current UVCs and visualization with a clinical ultrasound machine was completed to show small-scale viability and integration into medical practice. While both markers were distinguishable on the modified catheter, the foam tape is considered to be more clearly visible. In summary, foam tape distance markers showed significant improvement of ultrasound visualization and are considered to be more cost-effective and accessible for large-scale manufacturing in the future. Overall, the incorporation of echogenic distance markers into UVCs can help limit the need for radiographic visualization and enable the use of POCUS, ultimately decreasing the risk of complications and improving patient outcomes.

Keywords: Umbilical Venous Catheters, Point-of-Care Ultrasound, Neonatology, Medical Device

Introduction

Umbilical Vein Catheterization

Umbilical Venous Catheters (UVCs) are commonly used in neonatal care to provide central venous access for the first two weeks of life[1]. In the neonatal intensive care unit (NICU), UVCs are recommended for all premature infants with a gestational age less than 28 weeks or weighing less than 1000g[2], as well as infants who are not hemodynamically stable, require mechanical ventilation, or those who cannot receive an alternative form of venous access. All in all, it is estimated that roughly 20% of all NICU patients will require a UVC as part of their care.

After the umbilical cord has been clamped and cut, the UVC can be inserted into the umbilical vein and through the ductus venosus, with the optimal location of the catheter tip at the junction of the inferior vena cava and the right atrium of the heart. However, it is possible for the catheter to shift within the ductus venosus and enter into the portal vein, resulting in liver damage or portal hypertension. It is also common for the catheter tip to migrate further into the right atrium, causing pericardial effusion and cardiac tamponade. If physicians recognize that the catheter has been improperly inserted, it may be partially removed and reinserted, but this increases the risk of Central-line-associated bloodstream infections (CLABSIs)[3]. Studies have shown that complications arise in approximately 13% of all cases of umbilical vein catheterization, almost half of which can be attributed to misplacement of the catheter tip[4].

Standard Placement and Imaging Methods

Currently, placement and insertion depth of the catheter is calculated based upon the distance from the shoulder of the infant to the umbilicus. During the placement process, there are a variety of different techniques to encourage the UVCs to follow the correct path. Manually shifting the liver, placing the infant on their right side, or applying slight compression to the upper

abdomen can align the umbilical vein and ductus venosus to provide a straight path for the catheter to follow[3].

After the catheter has been placed and secured to the umbilical stump, the route of insertion and final placement of the catheter tip is visualized to verify proper placement. Thoraco-abdominal antero-posterior X-rays (TAX) are the current 'standard of care' imaging method, but the anatomical structures visible with radiography are limited to bone[6]. Organs and soft tissues possess very similar radiological densities so there is little contrast between tissue types and minimal details of the vasculature can be seen. As a result, physicians can only estimate the catheter tip location using the vertebrae and diaphragm as reference points. Radiography is also constrained to static imaging, so the placement of the patient and any movement can affect the resulting scan and misrepresent the catheter location relative to the reference points.

Throughout the use of the UVC, TAX must be taken regularly to monitor for tip migration. Therefore, high levels of radiation exposure are also of concern, especially when considering the small body size of the patients. This increased level of exposure has been linked to a higher risk of health complications in later stages of life[5].

Point-of-Care Ultrasound

Point-of-Care Ultrasound is becoming increasingly common as an alternative imaging modality, especially since it can be employed during placement for real-time guidance, as opposed to visualization after the entire placement procedure has been completed. It is also more convenient for clinicians, since the images can be obtained quicker without transportation of the patient. Lastly, there is no risk of radiation exposure as with traditional X-rays.

However, current UVCs lack sufficient echogenic properties to be clearly seen under ultrasound. They can be somewhat distinguished from the surrounding tissue, but the exact tip of the catheter is not clear; depending on the plane of imaging, parts of the catheter body may appear to be the tip. This can cause a misinterpretation of where the catheter tip is located; it may seem that the catheter tip is located in the correct spot but it could actually be placed too high or within the incorrect branch of the vasculature. Therefore, there is a need for the inclusion of echogenic distance markers within the catheter wall so that physicians can easily identify the catheter tip during placement. This will decrease the rate of catheter misplacement and associated complications, while increasing physician confidence and shifting the standard of care toward ultrasound.

Current Design

UVCs are currently produced in two different sizes, 3.5 French (1.17 mm diameter) or 5 French (1.67 mm diameter). The size used for a patient is dependent upon their body weight and anatomical dimensions; generally, infants weighing less than 3.5 kg receive a 3.5 Fr UVC, while 5 Fr catheters are used on those greater than 3.5 kg[1]. The composition of the catheter body varies between different materials. Common choices include polyvinyl chloride (PVC), polyurethane, and silicon-based polymers. There has been no documentation of significant differences in outcomes and occurrence of adverse effects between these materials, but polyurethane and silicone have become the most common for their strength, flexibility, and decreased likelihood of bacterial colonization compared to PVC.

The traditional manufacturing method for UVCs is extrusion, where the chosen material is melted into a viscous liquid and poured into a mold with the desired design specifications. Special antimicrobial coating and lubricants are applied, then the catheters are sterilized and packaged for use[7]. Most UVCs available on the market include distance markings printed on the body of the catheter. Generally, these markings start 5 cm from the catheter tip and are placed every centimeter until 25 cm or the end of the catheter where the luer lock/stopcock is attached. However, these markings do not have echogenic properties and are not distinguishable when viewed under ultrasound. Therefore, the modification of these markers or the addition of new indicators will help achieve the goal of improving visualization.

Project Aims

The first aim of the project is to identify materials that possess echogenic properties and meet the necessary design criteria to maintain functionality. This consists of evaluating previous research on ultrasound visibility of other catheter types and some existing methods or materials that are used to enhance echogenicity. While assessing these different approaches, the conformation of each material to international standards and regulations will also be considered.

Following the identification of the most viable approach, the second aim is to develop a working proof-of-concept catheter prototype that can be used for preliminary testing. The creation of such a prototype will help verify the efficacy of including distance markers while making sure that the addition of these markers will not impair function or structural durability. If necessary, several iterations can be created to improve upon the design and make sure all criteria are met. Given the small scale of the catheter and specialized manufacturing methods used to produce current catheters, these prototypes will likely need to be created on a larger scale. This will help facilitate preliminary testing and following iterations can be scaled down as much as possible with the available manufacturing methods.

Results

Design Criteria

The main design specification and central focus for the project is the improved echogenicity and clear visibility of the catheter and distance markers on an ultrasound scan. Research on the imaging of other catheter types quantified the results using pixel intensity units (PIU) or the grayscale value. An ideal grayscale value is above 150 PIU, since it would be clearly visible and there is high contrast between the catheter and surrounding tissue. Studies regarding other catheter types showed that a grayscale value above 100 is generally classified as visible, so anything within 100-150 PIU will be considered a marginally acceptable value[8].

Secondly, the incorporation of additional material within the catheter wall should have minimal or no impact on the functionality of the catheter. Thus, additional design criteria include maintenance of intact and consistent flow compared to the current standard catheter. This will ensure that the flow of medicine and fluids is not impaired and affect patient care. Ideally, the flow rate of the new catheter design would not be impacted at all, but a flow rate 15% faster or slower than current catheters will be considered acceptable[9]. Furthermore, the structural integrity of the catheter should be comparable to current designs and fulfill the regulatory requirements for UVCs as outlined in ISO 10555-1[10]. This includes meeting a minimum peak tensile force between 10-15 N, depending on the outer diameter of the redesigned catheter prototype.

Other design considerations include degradation resistance and biocompatibility during use. ISO 10993-13 outlines these requirements for medical devices[11]. A variety of medication and fluids are administered through an umbilical central line, some of which can be highly caustic. The materials currently used to form the catheter adhere to these requirements, but any additional materials incorporated as distance markers should undergo testing and be certified to meet these standards. Similarly, the biocompatibility of the materials is also crucial, as they cannot be cytotoxic and elicit immune responses from patients. Since these catheters can remain inserted for up to two weeks, they should be able to withstand all medications and not cause adverse effects due to material choice.

Prototype Testing

Ultrasound Imaging

The prototypes were imaged under a basic ultrasound setup with a single focused transducer attached to a computer-controlled stepper motor on a linear stage. The transducer was attached to a pulser-receiver that simultaneously transmits high-voltage pulses and amplifies the echoes it detects. Using a MatLab program, the transducer was moved in 0.025 cm increments across the top of a water basin containing the prototype for a total distance of 6 cm. Initial data was collected using a 2.5 MHz transducer with a focal depth of 1 in, and a 5 MHz transducer with a focal depth of 0.75 in. The resulting images were reconstructed using Hilbert transforms in MatLab and processed with a finite impulse response filter to remove noise. The results are highlighted in Figure 1 below which shows the ultrasound images and the PIU values measured from the associated images.

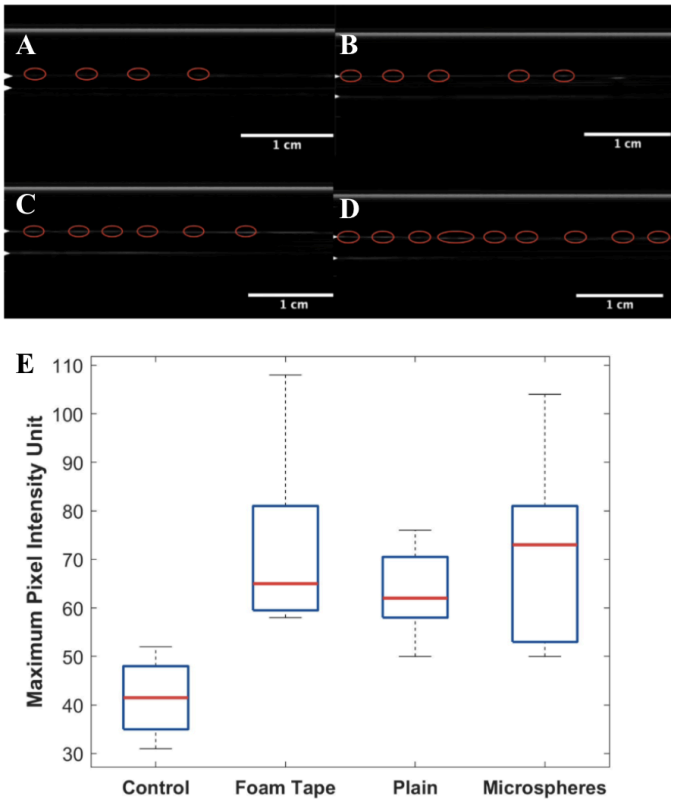

Figure 1: Analysis of Ultrasound Images. *The Ultrasound Images of Control* ***(A)****, Foam Tape* ***(B)****, Plain urethane coating* ***(C)****, and Microspheres* ***(D)*** *are shown above with red circles indicating the areas with increased PIU units. The maximum PIU of each area was obtained and is expressed in the boxplot* ***(E)****.*

The filtered images collected with the 2.5 MHz transducer were found to be clearer and much more suitable for further analysis. Using ImageJ, the scans were converted to 8-bit grayscale images so that the PIUs from the top of each prototype could be identified and analyzed. It was found that the control prototype had an average maximum PIU of 41.5, while its experimental condition, (the foam tape) had a PIU of 72.5. A one-tailed Welch's t-test was performed to determine if the foam tape had a significantly higher average PIU value as compared to the control. A p-value of 0.01204 was obtained, indicating that there was a significant increase in brightness at the $\alpha = 0.05$ significance level.

The PIUs of microsphere-urethane coating experimental condition were compared to those of the plain urethane coating prototype. The plain urethane prototype had an average maximum PIU value of 63.43, while the microsphere condition had a PIU of 71. A one-tailed Welch's t-test was performed to determine if the microsphere-urethane coating had a significantly higher average PIU value as compared to the plain urethane coating. A p-value of 0.1658 was obtained, indicating that there was a not significant increase in brightness at the $\alpha = 0.05$ significance level. In summary, while the microspheres showed a slight increase in average PIU, it was not significant as compared to its control condition and the foam material exhibited the greatest level of brightness.

Tensile Testing & Mechanical Property Assessment

While increasing the echogenicity of the catheter is the primary aim, it is critical to ensure the structural integrity is not compromised by the inclusion of either material. Tensile testing was performed on each of the four prototypes to determine if they would fulfill the minimum requirements of current medical device standards and assess the likelihood of mechanical failure. Using an Instron Testing System, the prototypes were stretched with a displacement rate of 20 mm/min. A value of 15N was determined to be the minimum accepted value of tensile force, as outlined in ISO 10555-1[10] and based upon the diameter of the catheter. Three trials for each condition were performed, and it was found that all prototypes were able to surpass the necessary 15N threshold. The resulting Force vs. Displacement data is shown in Figure 2.

No significant failure (such as breaking or tearing) was observed in any of the prototypes. There were some instances where the prototypes began to slip out of the machine clamps, which can be seen as a drop in force at the end of the trial. However, the prototype had previously surpassed the desired threshold.

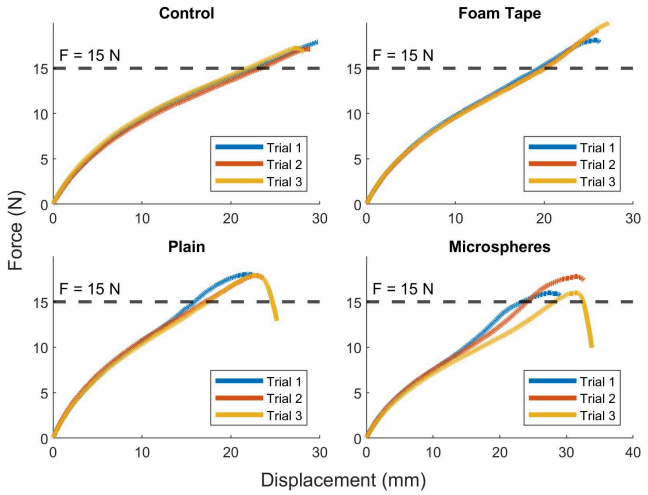

***Figure 2: Tensile Testing Analysis**. Each prototype was stretched with a displacement rate of 20 mm/min and all were able to withstand 15 N of force without failure.*

Flow Rate Analysis

The flow rate was assessed in order to determine if either of the experimental inclusions would impact the functionality of the UVCs. A syringe was used to inject 5 ml of water into the prototype and the amount of time it took for all the liquid to flow out was recorded. Three trials were performed for all four prototypes. As outlined in the design criteria, a tolerable range of flow rate was deemed to be 15% slower or faster than the control groups. The average flow rate of the control was 1.77 ml/s, yielding a range of 1.5 ml/s to 2.03 ml/s for the design constraint. The average flow rate of the foam tape prototype was 1.8m/s, which falls within the accepted range determined by the control. A two-tailed Welch's t-test was performed to determine if the foam tape had a significantly different flow rate as compared to the control. A p-value of 0.8128 was obtained, indicating that there was a not significant change in flow rate at the $\alpha = 0.05$ significance level.

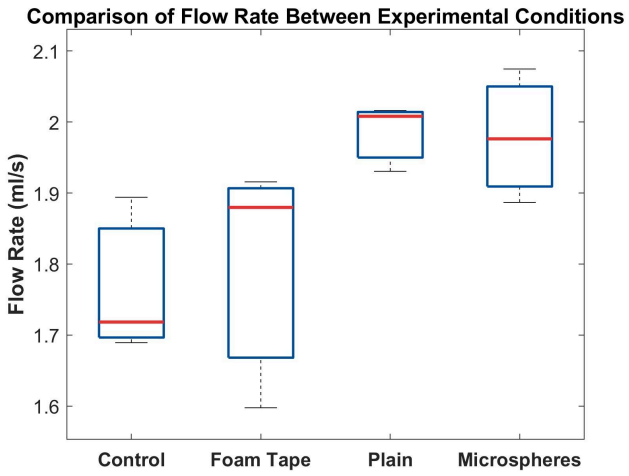

***Figure 3: Flow Rate Analysis**. Each prototype underwent flow rate testing to determine any impact on functionality.*

When comparing the urethane coating prototypes, the average flow rate of the plain urethane coating was 1.98 ml/s, yielding a range of 1.69 ml/s to 2.28 ml/s for the design constraint. The average flow rate of the microsphere-urethane condition was 1.98m/s, which falls within the accepted range determined by the plain urethane coating. A two-tailed Welch's t-test was performed to determine if the microsphere-urethane coating prototype had a significantly different flow rate as compared to the plain urethane control. A p-value of 0.932 was obtained,

indicating that there was a not significant change in flow rate at the $\alpha = 0.05$ significance level. Figure 3 above highlights the flow rate analysis of the four prototype conditions.

Application to Clinical UVCs

Since the prototype testing of both experimental conditions exhibited the potential to increase visibility compared to the current catheters, they were applied to the current UVCs. This would assess the feasibility of each condition on a smaller scale consistent with the standard catheter sizing used in neonatal care. Both conditions were applied to approximately half of the catheter body. The modified UVCs were then imaged with an ultrasound machine to verify the visibility of the distance markers. Figure 4 shows the resulting scans, with the unmodified section of each catheter acting as a control group. The distance markings of both conditions can be distinguished on the surface of the catheter wall, but the foam material is more clearly seen. While both condition showed promise for inclusion as distance markers,

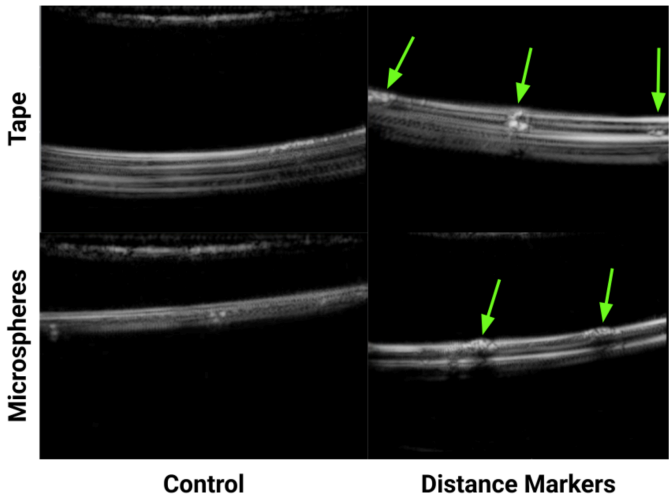

Figure 4: Ultrasound Images of Experimental Conditions applied to standard UVCs. *Foam material and Microsphere-Urethane coating were applied to a standard UVC. The applied material is seen on the catheter body (as indicated by the arrows).*

Discussion

Interpretation of Results

The incorporation of foam material and microsphere-urethane coating both showed increased brightness under ultrasound, but only the experimental condition with the foam tape exhibited significant improvement as compared to its respective control group. The structural integrity and functionality of the catheter prototypes were not impacted by the inclusion of either material, as seen in the results from tensile testing and flow rate analysis. Applying the conditions to standard UVCs showed small-scale feasibility of both conditions, but the foam tape markers were more clearly distinguishable compared to the microsphere distance markers. All of these results indicate that foam material is the more effective distance marker with echogenic properties as compared to the silver-coated microspheres.

The superiority of foam is further justified when considering the cost and accessibility of the material. The silver-coated microspheres were priced at approximately $28/gram, while the foam material can be purchased at a fraction of the cost (around $0.30/gram). There is also a wider variety of foam material available, so the specific density and thickness can be adjusted as necessary to refine the distance marker shape and size. In the future, foam seems to be a more viable option for large-scale manufacturing given its cost-efficiency and wide accessibility.

Significance and Innovation of Project

The addition of echogenic distance markers to UVCs will help reduce the likelihood of adverse effects from misplacement and enable real-time guidance throughout the insertion process. The practice of using POCUS for guidance has proven to be successful in a majority of patients, especially those where a UVC was not able to be inserted with blind placement techniques or X-Ray visualization[12]. Studies have reported a 60% lower incidence of malpositioning with POCUS-guided placement compared to x-ray verification, and there is a lower risk of having to readjust the catheter after insertion[13]. In addition, most medical staff can be easily trained on the use of POCUS for UVC placement, as opposed to the long learning period associated with x-ray[14]. The widespread adoption of POCUS as a visualization method will help conserve NICU resources and improve patient outcomes.

In recent cases that have used POCUS to help place a UVC, different methods have been employed to estimate or guide the internal location of the catheter tip. Small injections of sterile saline are commonly injected during placement, as the turbulence can be seen on an ultrasound scan[15]. Manual compression of the upper abdomen helps align the umbilical vein with the ductus venosus, in order to avoid insertion into the portal sinus[16]. While these techniques have been somewhat helpful for proper placement, the incorporation of echogenic material as distance markers would reduce the need for these procedures and facilitate the insertion process. The inclusion of these materials in future catheter designs will challenge the use of x-ray for UVC visualization and shift clinical practice towards using POCUS as the gold standard of care.

Limitations

Throughout the prototyping process, the researchers encountered some notable limitations that affected the progress and scope of the testing. Perhaps the most impactful was the limited access to machinery and equipment currently used in catheter manufacturing. While it would have been ideal to develop prototypes on the same scale as the clinical standards, it was not feasible with the limited manufacturing techniques available for use. Furthermore, budgetary restrictions constrained the choice of materials for prototyping. When the materials for prototyping were selected, biocompatibility was of the highest concern, but potential products either required specific machinery for production or were far too expensive to fit within the budget.

Related to this, it was initially planned to assess the impact of microsphere weight density in the urethane coating. This would have helped determine the optimal amount of microspheres that would sufficiently increase visibility and identify if there is a level at which increasing the weight density does not improve performance. However, the microspheres were more expensive than anticipated and only a limited quantity could be procured. Therefore, the researchers decided to rely on results from previous studies to inform their choice of microsphere density for prototyping and application to standard UVCs.

Lastly, the researchers had difficulty accessing ultrasound machinery in NICU settings due to time constraints. Therefore, a rudimentary ultrasound setup was used for prototype assessment and only the application of the conditions on the standard catheters was assessed with equipment similar to machines used in clinical care.

Future work and Considerations

The immediate next steps for this project are focused on further assessment of each experimental condition. Although the foam material was deemed to perform better than the microspheres, it is possible that a higher density of microspheres in the urethane coating would achieve comparable or higher levels of brightness. Similarly, all ultrasound imaging was performed using water as a medium so the visibility of either material may vary when viewed within animals or humans. Additional testing within tissue-like phantoms or medical manikins would help address these questions.

Furthermore, alternative manufacturing methods should be considered to achieve complete encasement of the markers within the body of the UVC. Doing so would ensure smooth inner and outer walls of the catheter and limit any potential flow impediment or patient discomfort. This would also lower concerns about the biocompatibility of the materials, since all exterior-facing surfaces could be composed of the standard materials currently in use. These products have already been shown to be biocompatible and pose no risk of cytotoxicity, while also being able to fulfill the necessary design requirements.

Since the overall goal of the project is to facilitate the placement process of UVCs and help improve localization of the catheter tip, the opinions and perspectives of NICU physicians should be continually sought out and incorporated into future design changes. Focus groups that are composed of a wide variety of personnel (doctors, nurses, etc.) should be conducted to address all concerns and suggestions throughout the development process. This will ensure that the final design can be easily used by all care professionals and will not negatively impact the quality of care provided to patients.

Materials and Methods

Materials

The tubing to serve as the inner layer of the prototypes was procured from Amazon, is composed of food-grade pure silicone with a 1.5875 mm inner diameter and a 3.175 mm outer diameter. EVA (Ethyl Vinyl Acetate) Foam tape was purchased from Amazon with 1mm thickness. Silver-coated Polymethyl Methacrylate (PMMA) microparticles were sourced from Cospheric, with an approximate average diameter of 50-80 um and classified as mostly spherical with some agglomeration or tendrils. UreCoat (Smooth-On Store), the two-component polyurethane coating that the microspheres were combined with, was prepared according to the manufacturer instructions. The silicone used as an outer layer on each prototype (SORTA-Clear 18) was also purchased from the Smooth-On Store, is certified to be food and skin safe, and was prepared in accordance with manufacturer recommendations. Although the materials used are not explicitly stated to fulfill biocompatibility criteria according to ISO standards, they were easily accessible and within the budget for this project. Furthermore, the external-facing components are all known to be safe for use in culinary applications, so there are no immediate concerns regarding cytotoxicity.

Methods

Prototype Fabrication

In total, four different prototypes were created: control, foam material, plain urethane coating, and a microsphere-urethane coating. The silicone tubing was sectioned into 10 cm lengths, and each condition was applied every centimeter along the tubing. The foam tape was cut into small dots approximately 1 mm in diameter and attached to the tube with its adhesive backing. The plain urethane coating was prepared according to the manufacturer's instructions: the two components were mixed with a ratio of 100A:10B (by weight) and stirred for three to five minutes to ensure homogeneity. Using a

fine-tip paintbrush, dots of the mixture were applied to the tubing. To make the microsphere-urethane coating, the silver-coated microparticles were added to the prepared plain urethane coating at a 5% weight density and thoroughly mixed to ensure equal distribution of the particles. Similar to the plain urethane, dots of the coating were applied to the silicone tube using a paintbrush. Both the plain and microsphere urethane coatings were allowed to cure at room temperature for around 24 hours to allow it to fully harden.

Following the application of the conditions to the silicone tubing, a thin wire was placed in the tube to keep it straight and prevent silicone from filling the inner space. The tubing segments were then placed in the center of a two-part mold that was designed in Fusion360 and 3D-printed out of ABS plastic (Supplemental Figure 1). The silicone mixture was created according to manufacturer recommendations. The two components were mixed with a ratio of 10g of part A to 1g of part B, with the quantity adjusted to fill the mold completely. The mixture was thoroughly stirred until it reached a uniform viscous consistency. It was then poured into a vacuum flask attached to a vacuum pump and degassed to remove small air bubbles. The silicone mixture was poured around the tubing to completely fill the mold and allowed to cure for 24 hours to reach full hardness. Once it was fully solidified, the prototype was removed from the mold and processed to ensure that the inner lumen was unobstructed on each end and that the excess flashing caused by silicone leaking into the gap between the molds was trimmed off to smooth the outer surface

Application of Test Conditions to Clinical UVCs

Standard clinical-use UVCs were obtained from the NICU and the two experimental conditions (foam tape and microsphere-urethane coating) were applied to sections of the catheter. The catheter with the foam tape condition was a double-lumen catheter made of silicone, and the microsphere-urethane condition was applied to a single-lumen polyurethane catheter. The conditions were applied every centimeter at the current printed distance markers to approximately half of the catheter body, leaving the remaining half unmodified to act as a control. For complete adherence of the foam tape to the catheter, plain urethane coating was used for extra security in addition to the adhesive backing. The microsphere-urethane coating was prepared in the same manner as with the prototypes (5% weight density) and applied with a fine-tip paintbrush. As with the prototypes, both test conditions were allowed 24 hours for complete curing before testing.

End Matter

Author Contributions and Notes

G.K.B and A.B.M performed background research, G.K.B identified materials, G.K.B and A.B.M created prototypes, G.K.B developed testing protocols, G.K.B and A.B.M carried out testing, G.K.B performed statistical analysis, G.K.B and A.B.M wrote the paper.

The authors declare no conflict of interest.

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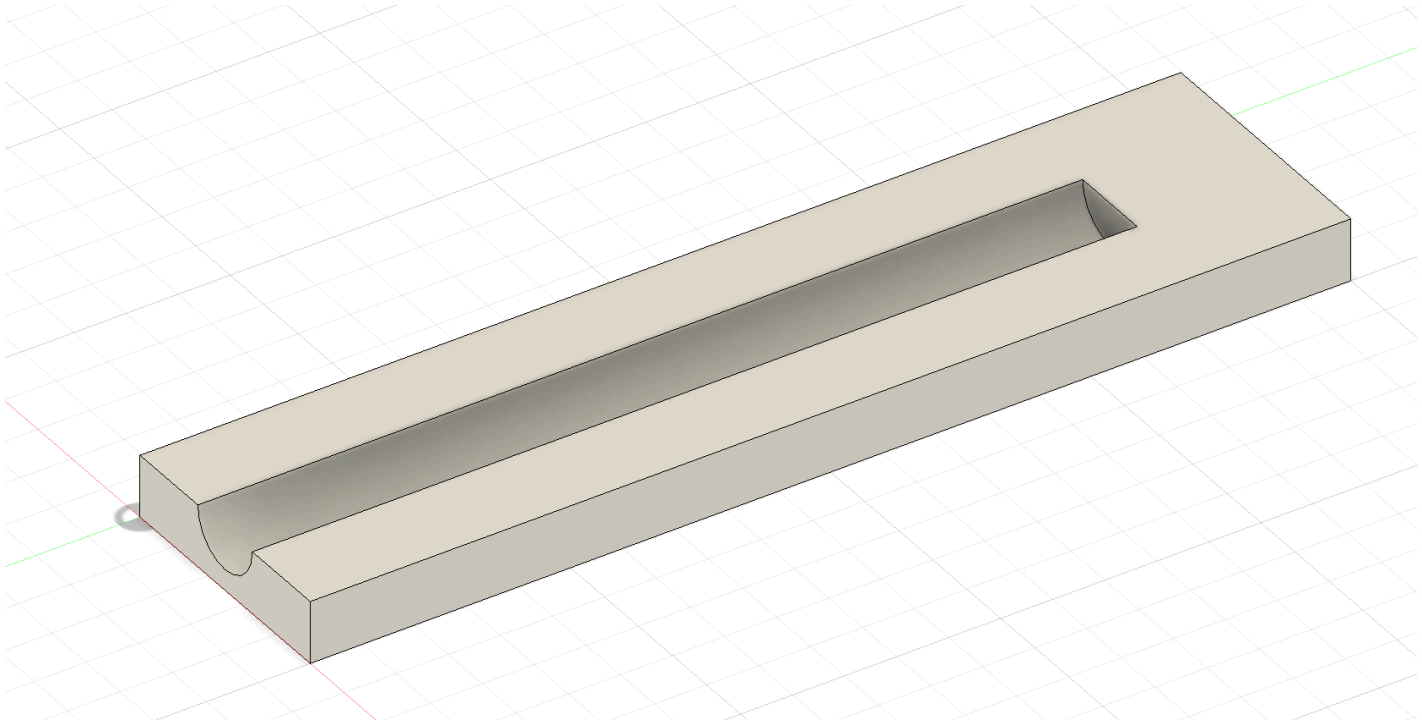
Supplemental Materials



Supplemental Figure 1: CAD Model of Prototype Mold. Two copies of this mold were 3D-printed and secured together to hold the tubing while the silicone cured around it.