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Radial Artery Model for Catheterization Procedures

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Radial Artery Model for Catheterization Procedures

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Abstract— The purpose of this project was to create a radial artery model that is usable under ultrasound that would reduce complications during catheterization procedures. Each year, over one million of these procedures are done and complications can affect the outcomes of the patient. Using ultrasound during these procedures is an upcoming way to reduce these complications and improve the outcome that a patient will have.

Keywords—radial, artery, angioplasty, ultrasound, catheterization

I. INTRODUCTION
The clinical problem area our group is addressing within the cardiac field is the need to reduce the rate of complications that occur during catheterization procedures. The purpose of this project was to design a product that would reduce procedural complications in patients receiving radial artery catheterization procedures to improve patient outcomes. Approximately, 1 million cardiac catheterizations are done each year in the United States [2]. The procedural complications include artery spasms (34%, ~340,000 patients), perforation (1%, ~10,000 patients), and location (30%, 300,000 patients) [2],[3]. When utilizing ultrasound, the first attempt placement success rates jumped 44% to 65% [3]. Current solutions to this issue involve using better imaging techniques, training models and devices that increase physician experience, and pre-dilation of the arteries. Using an imaging technique such as in-tra-vascular ultrasound guidance has been shown to reduce failure by nearly 50% in comparison to usual care [4].

II. USER NEEDS
To address lowering the failure rate of stent placement procedures, our group conducted interviews with professionals that have experience in the cardiac field and with these procedures. Since these interviewees had different professional backgrounds in the cardiac field, the questions were tailored to what each individual had knowledge of. Our first interview was with a nurse working on an intensive cardiac care floor. Our second interviewee was a physician assistant. We then interviewed a cardiologist at OSU Wexner Medical Center. From these interviews, we determined several customer requirements. These are listed in Appendix A. The requirements we believed mattered most included: the device should reduce the likelihood of stent deployment failure, the device should be relevant to current surgical techniques, the device should interface properly with the relevant surgical tools used during stent deployment, and they should perform as well or better than similar devices.

III. DESIGN INPUTS
During the design inputs phase of the project our group was tasked with extracting engineering requirements, creating a QFD (Quality Function Deployment), and conducting a risk assessment for our project. Our risk assessment is discussed later in this report. Engineering requirements for our design were extracted from the customer requirements that were created during the user needs stage. These requirements are physical and performance characteristics that we wanted to achieve for our product. These requirements address the user needs in measurable terms. The full list of engineering requirements and the customer requirements they are derived from can be found in Appendix A.

The QFD for this stage is used to ensure that we effectively identify and prioritize the needs and expectations of the customer. On the left of the QFD, we have our customer requirements and our extracted engineering requirements are located at the top of the QFD. The QFD also compares these requirements to products that are currently on the market. Our
completed QFD can be found in Appendix B. Once our group completed the QFD, several conclusions were made to better assist us throughout the project. The product that had the highest rating in the competitive analysis and competitive technical assessment was the United Biologics Angio-Suite which is an anatomical training model. This product performed as well or better than similar devices, is non-invasive, and reusable. When rated for the engineering requirements, this product had high scores in accurate patient anatomy, anatomical accurate vasculature, biocompatibility, reusability, and non-invasiveness. Our group also concluded that we could improve on cost and having accurate entry anatomy. The United Biologics training model offers a high-end model that is anatomically relevant, and we want to keep the cost under this. Along with this, despite having accurate entry anatomy being something to improve upon, it was not something that would be a top priority since this could increase cost and training time as well as causing issues with reusability.

IV. DESIGN PROCESS
To choose a design concept, our team brainstormed several potential ideas, created a QFD to compare these ideas, and then created a parts design matrix. Our brainstorming process was a collaborative effort where we would each propose ideas or add to ideas already stated. During our brainstorming, we had to keep in mind that we were focusing on “prevention.” Once we completed brainstorming, we had several potential design ideas as a result: a virtual reality training simulator, a physical training model, a delivery system with a camera.

The QFD used during the design process compares our design concepts to our engineering requirements. Each score is based on importance and how well that idea would meet each requirement. After scoring, it was determined that a physical model using transparent material would best meet our requirements. We also chose to focus on one artery to model with one location for insertion. Another conclusion that was made from the QFD was the lowest scoring requirements were dependent on the material used. To choose the material that was best for what we our model, research on arterial mechanics was done.

During this time, our group met with a researcher from Cleveland Clinic’s Vascular Core Laboratory. After this meeting, while we still aimed to reduce surgical complications through physician training, the way in which we are hoping to achieve this is through a different approach. This approach would still be a physical model but with a realistic skin segment access point on the forearm that would go to the radial artery. This model would also be usable under ultrasound. V. DESIGN OUTPUTS
Design outputs are derived from engineering requirements and specifications of the model. Many of these were dependent on the material we chose. For example, the model needed to have similar mechanical properties to that of human arteries. Through research we found that meant our material had to comply with a Youngs modulus of 1.55 +/- 1Mpa and a tensile strength of 2 +/- 1.5 - 1.0 Mpa [1]. Other requirements were not so much dependent on the material itself, but how that material was able to be maintained once 3D printed. Another important requirement our device had to comply under ultrasound. This meaning that we would be able to see the radial artery and other parts of the forearm under ultrasound. This could only be tested using an ultrasound machine which our group was able to use through the help of NEOMED.

To comply with many of these design considerations, our group used 3D modeling software which not only helped to visualize the device but also aided in 3D printing of the arteries and bones, and making any necessary changes before development. Images of these drawings can be seen in Appendix D, E, and F.

VI. DESIGN VERIFICATION
The verification process ensures that the design outputs have met the engineering requirements from the Design Inputs stage.

After completing verification testing, three of our inputs passed, three failed, and two were unable to be verified. The passing inputs included: the device is less than 40 pounds, the arteries in the model have similar mechanical properties to human arteries, and the model can interface with sutures. The verification test of the model can interface with sutures was done by suturing onto the skin layer of the model to see if the skin was able to be sutured. The verification test for the arteries having similar mechanical properties was done through research and analytical modeling and calculations. The inputs that failed to meet their requirement included: the model being anatomically accurate, the access point being anatomically accurate, and the model having the ability to interface with a catheter. These requirements not being met at this time were due to the thermal expansion of the 3D printing material. Through research we learned that the internal diameter of the radial artery is around 2.5 +/- 0.5 mm and the external artery diameter is 3.25 +/- 0.5 mm. At this time, we had only printed one artery due to time constraint. When the 3D print was made the diameters for both the inner and external diameter were taken. This caused the artery diameter for the inner diameter to be slightly larger than what was allowed for the conformance criteria. The inner diameter was measured at 4.84 mm. To fix this issue, we scaled the mesh...
file and ordered a new 3D print to see if the artery diameter would meet the specification. The requirements we were able to verify during our testing were the reusability of the device and the device being able to use under ultrasound. To verify ultrasound testing, we collaborated with students at NEO MED who were able to get us in contact with individuals who would let us access an ultrasound machine. However, we were unable to do this before the review of this phase.

VII. MEDICAL DEVICE
The final medical device that was constructed is an anatomical model of the human forearm containing the radius, ulna, and the radial artery. The bones of the radius and ulna were created by 3D printed parts of white PLA 3D print filament. The radial artery was created by natural latex tubing that had a 2 mm inner diameter and a 3 mm outer diameter. The radial artery was filled with fluid to simulate blood. The fluid contained water and red food coloring. There was also surrounding soft tissue which was made from Ecoflex 00-10 super soft platinum silicone. This device is designed to be used as a training model for the user to practice ultrasound-guided radial artery catheterizations. The model is capable of being used under ultrasound in that the structures contained within the model are visible under ultrasound such as the radial artery and bones. The design also features a skin layer that provided the user with the ability to suture a catheter to the surface of the model after insertion. This provides a much more clinical feel as some physicians prefer to suture the catheter down in clinical cases to prevent migration of the catheter out of the artery.

VIII. VALIDATION TESTING
Validation testing is done to ensure that the device meets the customer requirements established in the User Needs phase. The validation tests we are to complete involves the testing of the device under ultrasound, a mock catheterization, and a puncture test. Validation under ultrasound was completed at NEO MED. The procedure involved applying gel to our model and using the ultrasound machine to see if we can see the radial artery under the ultrasound. This test was validated because we were able to clearly differentiate between the artery, bone, and needle that was being inserted into our model. During the mock catheterization procedure, the medical student was able to identify the radial artery and needle on the ultrasound machine. Upon insertion of the needle, she said that the feel was similar to human tissue. This can be seen in Appendix G and Appendix J. To validate that the model was similar to human skin, our group used an Instron machine to determine the force required to puncture the model. Under similar conditions, pig skin has been shown to puncture at a force of 1.6N. [1] When our model was tested, the puncture force was measured as 0.98N. This difference can be accounted for by the Tissue Mimicking Material (TMM) being isotropic and homogenous while human tissue is anisotropic and heterogenous. The results of this test can be seen in Appendix I.

IX. RISK MITIGATION PROCESS
The risk mitigation process was completed using an FMEA (failure mode and effect analysis). The FMEA compares four products: an anatomical training model, an intravascular ultrasound catheter, a light and stent delivery system, and a pre-dilation catheter. For each of these products, the FMEA contains their function and potential failure modes. It also has the causes and effects of these failures. It also assigns a risk priority number which is used to systematically classify and prioritize risk. Along with this, the FMEA contains how these risks can be mitigated. During the design process phase, design outputs phase, and medical device phase a dFMEA (design failure mode and effect analysis) was created and updated with each phase. This dFMEA identifies different components of the device and lists their potential failure modes. For each failure mode, potential effects of failure, potential causes of failure, suggested mitigations, severity, occurrence, detection, and RPN (risk priority number) is also listed. These dFMEA’s aided in the design process as the risks are attempted to be mitigated through product design. During the medical device phase, a final version of the dFMEA was created and used in a risk mitigation summary. This summary listed each risk and a summary of it, the risk’s RPN and risk level, and how the risk was mitigated. The residual risk was then compared to the overall benefits of the device which was determined to outweigh the remaining residual risks. The majority of risks for this device were not personal injury, but rather damage to the device itself. Through material selection and proper design these risks were minimized and thus the overall benefit outweighed the residual risk. The materials included white PLA 3D print filament, ecoflex 00-100 super soft platinum silicone, natural latex tubing, PLA 3D print filament, and synthetic skin sheets. The risk mitigation summary also includes a section to identify the focus of future risk mitigation activities. Our FMEA can be seen in Appendix K.

X. MARKETING AND MANUFACTURING CONSIDERATIONS
The perceived market for this anatomical model are hospitals and training programs for cardiologists for stent placement and angioplasty procedures. The research shows that there about 1 million radial artery catheterization procedures performed each year. [2]. It is becoming more prevalent for cardiologists to perform angioplasties through the radial artery. The problem is there is not training models that allow surgeons or cardiologists to practice this procedure on. That is why the market is high for these models due to the large number of stent placement surgeries that take place each year.

XI. SUMMARY FEASIBILITY DISCUSSION
We as a team believe that the design of our anatomical training model did satisfy the need of a model to help in the success rate of stent placement procedures. That is because we
were able to create a model that was functional under ultrasound which allow the surgeon or cardiologist to be able to see the radial artery before performing the catheterization procedure. This allows a higher success rate for the ability to properly find the artery which in turn lowers the number of procedural complications during the stent placement procedure. We as a group believe our model can be demonstrated as a prototype because it is able to be used under ultrasound. It is also able to be used by a surgeon or cardiologist, with the use of ultrasound, find the radial artery and be able to perform a stent placement procedure.

XII. Discussion, Lessons Learned, and Conclusions
The major issue that took place during our design process was the shift in our model. Originally during the first stages of the design process our team was focused on creating an anatomical training model that was based on the entire arm going in through the coronary artery. After discussion with Dr. Paul Bishop we shifted our approach to an anatomical training model of just the forearm focusing on an access site through the radial artery for catheterization procedures. It will also be able to be functional under ultrasound. Our team then had to add and revise the design matrices, FMEAs, and QFDs to factor in the new requirements and needs for our new design approach. This caused a small setback in the design process which could have caused us to not be able to complete all the verification tests that were needed for our design. This caused us to realize the importance of time management to allow for products to be produced on time and for design tests to verified completely.

XIII. Future Work
The future opportunities include further validation training from surgeons or cardiologists to allow for validation of our model. That concludes that the further work that needs to be done includes cardiologists performing the radial artery catheterizations on our model for validation. This would allow for our anatomical training model to be implemented into training programs for surgeons. We would also like to add pulastile flow and additional vasculature to the model to add to the realism of the anatomical training model.

XIV. Individual Roles and Responsibilities
This project served as a way for us to use previous knowledge gained in classes and co-op experiences during our time at the University of Akron. This project took us through the process of identifying a clinical need.

Ben Stalls: During this project, Ben Stalls conducted research to help identify a clinical problem. Ben then interviewed cardiologist Dr. William Marshall to gain a better understanding of how the clinical problem impacts those who work in the field. Also, Ben performed market research to understand the potential impact that our project’s solution can have and how many lives this will help. Ben helped to derive engineering requirements from our customer needs, and then explored the positive and negative correlations between these engineering requirements. By examining these correlations, the team was able to identify potential bottlenecks that might occur in the design process before reach the prototyping stage. Ben performed a technical competitive assessment in which existing products that can be used to solve our clinical problem, are ranked against each other using our engineering requirements. This helps our team identify areas that existing products perform well, as well as areas that could be improved upon. Ben has worked with the team to generate and brainstorm concept designs. Ben has researched arterial vessel mechanics and the effect that vessel tortuosity has on the mechanical properties of arteries. Ben has done 3D mesh modeling to construct arterial phantoms that can be used for molding a prototyping. Also, research has been done on materials that can be used to simulate the mechanical properties of arterial walls. Ben has worked to use 3D CAD files to construct a mold to create a physical anatomical model of the human forearm, the bones contained within, and the radial artery. Ben has corresponded with the university’s departments to purchase the materials required to manufacture the model. Ben has corresponded with students and staff at NEOMED to evaluate the model’s usability under ultrasound and the model’s ability to provide an accurate representation of ultrasound-guided radial artery catheterization.

Kyla Beville: During this project Kyla Beville interviewed Dylan Galford who is a nurse on the Intensive Cardiac Care floor at the Ohio State University Wexner Medical Center. By conducting this interview, the team was able to gain knowledge on complications that can occur during cardiac procedures and what steps are taken to mitigate those complications. Kyla also contributed to the creation of the engineering requirements document. This allowed the team to group the customer requirements with their respective engineering requirement. She also helped in identifying the co-relationships between the customer and engineering requirements as well as the technical correlations that are present in the QFD. This helped the team determine which requirements heavily relied on another and where are project could be impacted when going into the design concepts phase. Kyla helped in contributing ideas to the brainstorming process. Along with this, she helped the team in determining which concept would best fit the requirements outlined in earlier stages of the project. She then helped in the generation of the Design Specifications document which outlines the purpose of the device created during this project. Kyla then helped in the creation of the Bill of Materials. This document provides information on materials used for the model such has where they were sourced, pricing, and typical lead time. Throughout the project, Kyla also helped in keeping the Gantt chart up to date. This helped the team stay on track during each phase of the project so that milestones could be reached before the gate reviews. Kyla was also the main author of the final report that was submitted to the Williams Honors College.

Mitchell Gagnon: During this project Mitchell assisted in the development of interview questions in the beginning phase of the project which allowed the team to gather valuable information to understand the current needs of the relevant...
Mitchell then assisted in the creation of various user needs that would outline the problems that our device seeks to solve. Mitchell also assisted in creating the engineering requirements. These requirements are measurable requirements for the device that were translated from the initial user needs. Mitchell then assisted the team in the creation of the QFD to determine the positive and negative relationships between different customer requirements (user needs) and engineering requirements, as well as how important it is for each requirement to be in the device. In the design phase Mitchell participated in the brainstorming activities for the medical device as well as creating the FMEAs. Brainstorming helped the team to identify solutions to the problems from the user needs as well as narrowing down the ideas for the device. The FMEAs compared the risks of different product designs initially, and listed risks for the product once a design was decided upon. These risks were accompanied by their probable cause, effects, and suggested mitigations, verification activities, and validation activities. Mitchell created a table listing engineering requirements, how each will be verified, the passing verification criteria, and the result of each requirement’s testing. This showed the team how to properly verify the engineering requirements while keeping track of results, especially in the case of a failed verification. Mitchell also participated in the ultrasound testing of the device at NEOMED with assistance from our group of NEOMED students and Ben.

Maya Ariza: During this project, Maya Ariza contributed to the idea generation of what specific part of cardiac care we as a team were going to focus on. We chose the idea of stent placement in cardiac care. Next, she came up with interview questions and interviewed Amanda Duncan, a physician assistant for a cardiologist in the Cleveland Clinic. From that she contributed to the generation of customer requirements from the answers she received in the interview with Amanda Duncan. Then she helped to come up with the engineering requirements from the customer requirements that were generated in the first gate. Then she helped with the production of the QFD based on the engineering and customer requirements that helped to compare the two and the technical relationship between the engineering requirements. She also contributed to the writing of the honors proposal report. Then she helped in the creation of ideas for our final project. As a group we did this by brainstorming. Then after the brainstorming, she assisted in the production of another QFD that was necessary to decide on the best approach for the final project idea. Then she assisted in creating the Bill of Materials which listed out the information for the materials which included prices, units, and typical lead time. Then she assisted in writing the final honors report and the script for the video of our project.

XV. PROFESSIONAL AND ETHICAL RESPONSIBILITIES
This anatomical training model has considered the impact of the engineering solution for global, economic, and societal contexts. This project considered the global effects because from research we learned that around 1 million radial artery catheterizations procedures are performed each year in the United States [2]. With this research in mind, through the creation of this anatomical training model we are hoping to assist in the lowering of failure rates. The lowering of failure rates will be because the training model will allow cardiologists to practice radial artery catheterizations with the help of ultrasound. When the cardiologist goes to perform the actual procedure, this practice will help to provide the cardiologist with training to cause the success rates to increase. This will also help with the economic concerns because if a training model assists in the increase of the success rates of radial artery catheterizations, then the number of surgeries that are needed for correction decreases. This would cause the amount of money medical insurance and patients would have to pay each year.

XVI. ACKNOWLEDGEMENTS
We would like to thank Dr. James Keszenheimer, Dr. Paul Bishop and Steve in their help with the creation and collaboration for our project. We would also like to thank our readers Dr. Zhang and Dr. Yun for their criticism of our papers to help us produce the best documents as possible. Lastly, we would like to thank NEOMED for their assistance in our project to help us test the model itself and its usage under ultrasound.

REFERENCES
### Appendix A. List of Engineering requirements derived during Design Inputs Stage

<table>
<thead>
<tr>
<th>Category</th>
<th>Customer Requirement</th>
<th>Engineering Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>User/Patient/Clinical and Performance Characteristics</strong></td>
<td>The device should be comfortable to handle, in regards to weight and size, comparable to similar devices</td>
<td>Weight, Dimensions, Ease of Use</td>
</tr>
<tr>
<td></td>
<td>The device should accurately portray tortuous and non-tortuous arteries</td>
<td>Anatomically Accurate Vasculature</td>
</tr>
<tr>
<td></td>
<td>The device should accurately portray various arteries</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The device must accurately portray a patient’s anatomy</td>
<td>Accurate Entry Anatomy, Anatomically Accurate Vasculature</td>
</tr>
<tr>
<td></td>
<td>The device should accurately portray insertion points</td>
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<td></td>
<td>The device should reduce the likelihood of stent deployment failure</td>
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<td></td>
<td>The device should perform as well or better than similar devices</td>
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<td></td>
<td>The device should be relevant to current surgical techniques</td>
<td>Accurate Entry Anatomy, Anatomically Accurate Vasculature, Device Interfacing</td>
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<tr>
<td></td>
<td>The device must be reusable</td>
<td>Reusability, Repeatability</td>
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<td></td>
<td>The device must be non-invasive</td>
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<tr>
<td><strong>Privacy and Security</strong></td>
<td>The device must comply with HIPPA requirements</td>
<td>Cost, Secure Data</td>
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<tr>
<td><strong>Safety</strong></td>
<td>The device should have no unintended pinch points</td>
<td>Cost</td>
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<td>The device should have no unintended sharp corners</td>
<td>Cost, Biocompatible</td>
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<td></td>
<td>Biocompatibility of used materials must be previously proven</td>
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<td></td>
<td>The device must be able to be cleaned</td>
<td>Maintenance Interval, Cost</td>
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<td></td>
<td>The device must be able to be disinfected</td>
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<tr>
<td><strong>Ease of Use</strong></td>
<td>This device should allow for easy transportation compared to similar devices</td>
<td>Weight, Dimensions</td>
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The device should not require extensive training for qualified surgeon use.

<table>
<thead>
<tr>
<th>Training Time, Ease of Use</th>
<th>Cost</th>
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<tr>
<td>The cost of the device should be comparable to or less than existing devices</td>
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Appendix B. QFD Diagram for Design Inputs highlighting correlations between Customer and Engineer Requirements with comparisons to current products on the market.

Appendix C. QFD Diagram for Design Process phase which compares ideas generated during brainstorming to Engineering Requirements.
<table>
<thead>
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<th>Engineering Requirements (Quality Characteristics)</th>
<th>Parts Design (Concepts)</th>
<th>Method of Modeling</th>
<th>Visual Feedback</th>
<th>Tactile Feedback</th>
<th>Accessed Artery</th>
<th>Location of Insertion</th>
<th>Target Values</th>
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Appendix D. Cross-section of 3D model used for visualization and 3D printing
Appendix E. Entire 3D model used for visualization before development.

Appendix F. 3D image of model cut in half. This was used to print the radial artery and bones that are incased in the model.
Appendix G. Image of the model under ultrasound. The radial artery and bones are shown.
Appendix H. Image of ultrasound machine used at NEOMED.
Appendix I. Results of force to puncture testing.

Appendix J. Image of model under ultrasound showing bones, artery, and needle.
Appendix K. FMEA used to determine risks associated with our model and how to mitigate those risks.

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Diagram:
- Needle
- Artery
- Bones

Legend:
- Needle
- Artery
- Bones