



The Doppler Dot

BME 200/300

October 11th, 2017

Client: Dr. Nicholas Albano

Advisors: Dr. Naomi Chesler and Ms. Ashley Mulchrone

Team Members: Crysta Frank (Team Leader), Luke Hetue (BWIG), Anna Keller (BPAG), Luke Le Clair (Communicator), Jacob Mundale (BWIG), Galen Riley (BSAC)

Abstract

Currently, patients undergoing reconstructive surgery are awakened every hour, as a result of medical staff monitoring the triphasic signal of the artery to the newly reconstructed tissue. This arterial signal is monitored via Doppler ultrasonography, which measures blood velocity by analyzing the frequency by which the produced sound waves deflect off the blood cells. Frequent monitoring of arterial blood flow is crucial in detecting ischemia and decreasing the potential damage to the newly operated tissue due to ischemia. If the tissue is too ischemic the tissue risks necrosis, therefore it is imperative that the tissue in question be operated on immediately to be salvaged. The challenge of this project is to create a device that can adhere to a patient's skin, reduce or eliminate the mess of the current ultrasonic gel, and maximize patient comfort. Currently, the medical staff use Doppler probes with ultrasonic gel to be the medium that conducts the sound. The patient is often bothered by the application and cleanup of the gel. The proposed solution is to create a device that can contain the gel and adhere to the patient's skin, marking the location of the desired artery. This will reduce the time that nurses spend looking for the artery, reduce the mess, and increase patient comfort.

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Introduction

Problem Statement

Frequent monitoring of arteries is essential to reconstructive surgeons and arguably more essential to patients; however, it is not always sufficient to simply feel for blood pressure of the arteries of concern at the surface of the patient's skin. This is due to the stress often put on arteries in tissues that are operated on in reconstructive surgery, causing blood pressure to be too faint to physically feel. Therefore, reconstructive surgeons must resort to the use of the pencil Doppler to monitor blood flow, up to six centimeters under the skin. Although this device is highly accurate and reliable, it is also highly inconvenient, for the pencil Doppler requires the use of ultrasound transmission gel. Often, the medical staff must awaken patients once an hour in order to use the pencil Doppler to ensure specific tissues still have sufficient blood flow through their operated tissue. This not only places heightened stress on the patient, but the ultrasonic gel will also remove any prior mark applied to the patient that located the artery of concern. Thus, the client seeks to find a device that would be capable of attaching to the skin and remain firmly in one position so as to superficially identify the location of the artery while also allowing the transmission of the sound waves (8-9.1 MHz) of a pencil Doppler. The other option the client would be willing to pursue is a device that could be directly attached to the patient that is capable of transmitting hemodynamic data via a receiver that could be plugged into a pre-existing device and unplugged when not in use.

Impact

Reconstructive surgery is a major procedure that often requires a surgeon to modify the vascular system within the patient by moving and redirecting arteries to ensure the new/transplanted tissue will survive and receive sufficient blood-flow. Thus, the survival of the tissue is dependent upon the vascular surgeon's ability to operate on arteries and because it is difficult to maintain precision when operating on small, fragile parts, patients must undergo hourly monitoring after having the surgery. Due to the nature of current monitoring procedures, it is common for the nurses to awaken the patients, disrupting their sleep, and making it more stressful for the patient that is recovering. In addition, under current procedure, nurses can struggle to locate or hear the triphasic arterial blood flow signal beneath the patient's tissue. This can lead to repetitive disruptions and the aid of more advanced help from a surgeon if the nurses are unable to locate the artery. These factors increase the difficulty of the nurse's job and place additional, unnecessary stress on the patient. Ideally, the final device would eliminate patient disturbances, reduce the time and energy spent locating the artery, and have further uses beyond the UW hospital. The device is intended to make the continuous monitoring of arterial blood flow from any type of surgery easier.

Existing Devices

The most widely used product is the liquid hydrogel. It can only be applied to an area of the body where the skin is intact. Prior to the use of the transducer, this gel is spread over the area that will be viewed or listened to, thereby acting as the conductive medium between the

transducer and skin. The use of ultrasonic gel is highly effective in conducting sound waves as compared to air. Also, the gel has a low viscosity and therefore a liquid nature. It must be wiped off the patient after each procedure [1].

Solid hydrogels are already on the market as well. HydroAid has created a solid hydrogel pad that is versatile on open wounds. It is a 6 cm x 10 cm x 3 mm rectangular pad that can be placed over irregular surfaces that can transmit robust signals from an area that could not be examined with the standard hydrogel [2]. HydroAid and similar products are described as disposable and require the additional use of liquid gels if the planned procedure is scheduled to be long, around 45 minutes [3].

Some solid hydrogels have also been taken a step further and some include adhesive properties. SonoFAST markets a pad that attaches directly to the ultrasound transducer. It consists of 3 layers: a lubricated layer that will be in contact with the patient's skin, an internal conductive layer, and the adhesive layer that will attach to the instrument's transducer. This pad eliminates the mess that would be created by the liquid hydrogel but cannot mark the location of the blood vessels being monitored. Beyond this, the SonoFAST pad is similar to other existing solid hydrogel pads and needs to be disposed of after every use and cannot sustain functionality over a long period of time, anything exceeding 45 minutes [4].

Background

Research

Up to 5% of reconstructive surgery patients experience complications from irregular perfusion, or drainage of blood at the surgery site. If this abnormality is not corrected in a timely manner, prolonged ischemia to the operated tissue will lead to tissue necrosis. Restriction of blood flow may be a result of either thrombosis or pinching of an artery [5]. In the case that blood flow is not re-established a phenomenon, known as no-reflow, occurs. The resulting severity of damage to the tissue is correlated with the total time that the operated tissue lacks blood flow. Therefore patients are monitored hourly to ensure the operated tissue is healthy and no emergency procedures need to be performed [6].

The pencil Doppler functions by directing sound waves in the direction of an artery and then receiving the returning signal to determine fluid velocity [7]. The Doppler must be used in conjunction with an ultrasound gel as the gel is a more conductive medium than air for the transmitted signals [8]. Although the cleanup of solid gels is minimal, they do not transmit sound reliably in prolonged procedures, which the current procedure requires [9]. In addition, it is important to note that the pencil Doppler has significant operator dependence. Nurse turnover during a typical hospital stay for reconstructive patients (5-6 days) results in inconsistent readings. This exemplifies the importance of permanently marking the location of the arterial signal on the patient [6].

Considering these elements and the clients product requirements, materials which hold the strongest potential to be used in the design include: Pros-Aide II Adhesive, Formlabs Flexible Resin, Formlabs Durable Resin, and Aquasonic hydrogel. Pros-Aide II is a paint on adhesive used for prosthetics. It has been determined to be safe for skin and is hypoallergenic [10]. The Flexible Resin produced by Formlabs has been recommended for wearable prototyping, it is a versatile material that is able to bend and compress. The Durable Resin produced by Formlabs is wear-resistant, strong, and has the ability to deform slightly when compressed [11].

Client Information

The client, Dr. Nicholas Albano, is a plastic surgery resident at the University of Wisconsin School of Medicine and Public Health. He graduated with his MD from the New York University School of Medicine in 2015. His goal is to improve the post-op monitoring of his patients.

Design Specifications

The performance requirements outlined in the Design Specifications document create the backbone of the project. These requirements include the abilities of accurately and reliably alleviating stress on the patient, conducting ultrasound waves, and marking the location of the strongest triphasic signal. In addition, the device must be safe for the patients who will be using the device in the hospital, and for the doctors and nurses who are administering it. The device must have a service life of five days and at least a year shelf life. Finally, it needs to follow the

sterilization requirements of the hospital; thus, it will most likely need to be disposable after each use. For more information on the Design Specification document see Appendix A.

Preliminary Designs

Disposable Hydrogel Adhesive Patch

Design 1 consists of a solid hydrogel material covered with an adhesive patch. An external Doppler probe would then be used to monitor the patient's arterial signal. The Doppler waves would then be able to travel through the patch into the patient. While the gel would be able to conduct sound effectively, the adhesive patch may not conduct sound as well as just the gel. This could pose a challenge when listening for a signal.

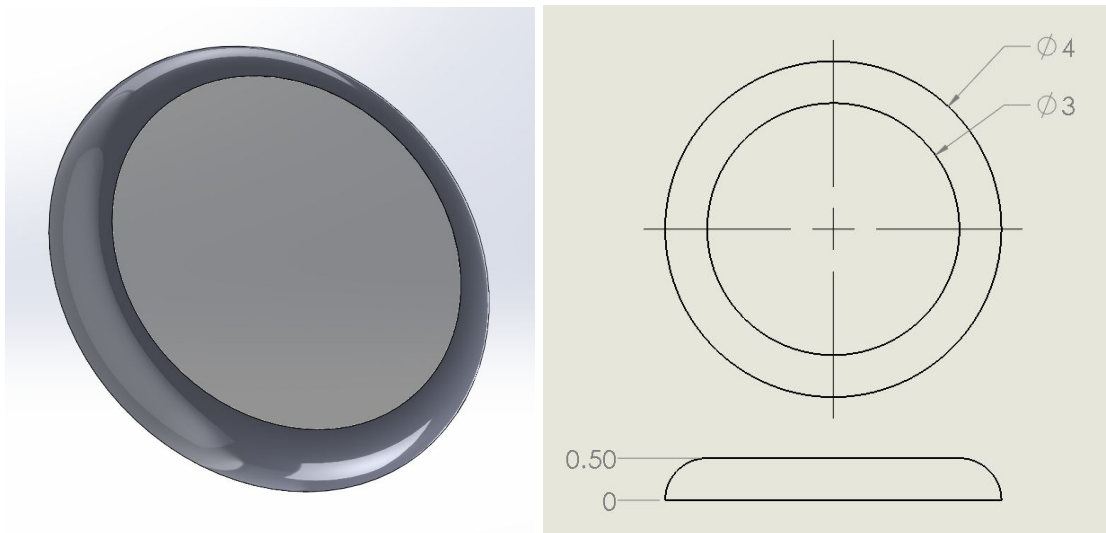


Figure 1: Disposable Hydrogel Adhesive Patch (Design 1) - all units in centimeters

Reusable Doppler with Disposable Hydrogel Patch

The second design consists of a solid hydrogel patch with an embedded Doppler probe. This is then covered with an adhesive patch. The Doppler probe will have wires (not shown) that come out of the patch. These wires will then be able to connect to a device that will analyze the sound of the patient's blood flow. This is similar to the current device; however, the current Doppler probes are made to be held in the medical professional's hand. This makes the probes larger than what would be used in this design. In addition, the smaller Doppler probe would be able to be reused once the patch is removed from the patient.

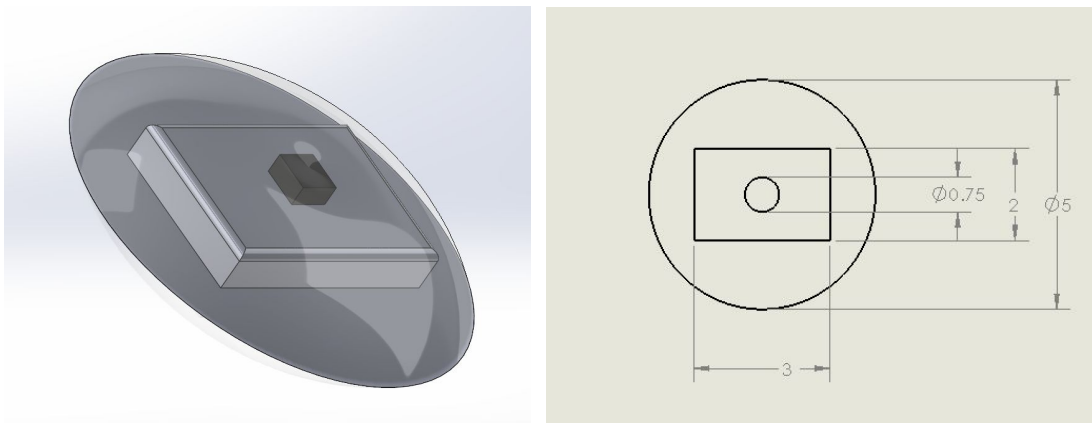


Figure 2: Reusable Doppler with Disposable Hydrogel Patch (Design 2) - all units in centimeters

Disposable Hydrogel Adhesive Container

Design 3 contains the ultrasonic gel that is currently used for Doppler probes. It is made of a 3D printed resin. An external Doppler probe is inserted into the gel in order to pick up arterial blood flow. This design has a removable cap to keep the gel from drying out or spilling.

The removable cap will help the liquid gel last for the required amount of time that it has to remain on the patient. If the gel does dry out, a nurse can easily add more without much discomfort to the patient. This design has an adhesive bottom to stick to the patient's skin.

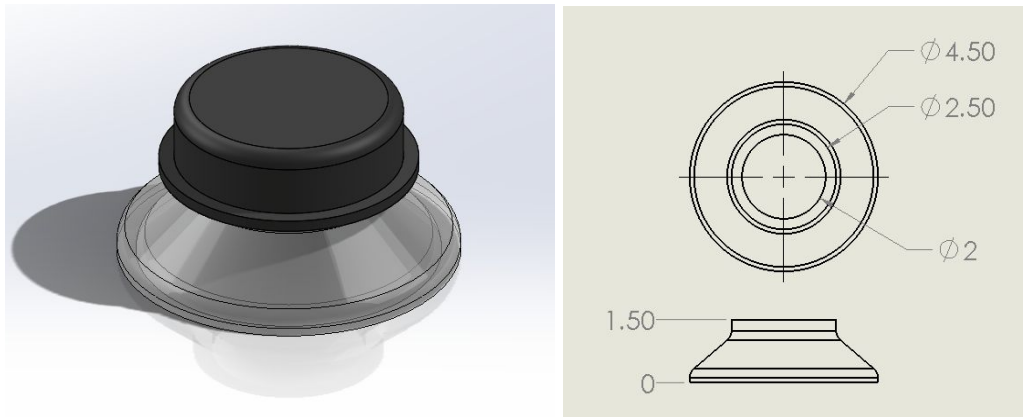

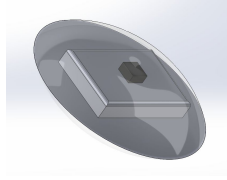
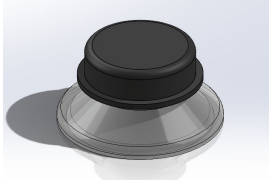


Figure 3: Disposable Hydrogel Adhesive Container (Design 3) - all units in centimeters

Preliminary Design Evaluation

Design Matrix

Table 1: Design Matrix

	Design 1: Disposable Hydrogel Adhesive Patch 		Design 2: Reusable Doppler with Disposable Hydrogel Patch 		Design 3: Disposable Hydrogel Adhesive Container 	
Effectiveness (30)	4/5	24	4/5	24	5/5	30
Patient Comfort (25)	4/5	20	4/5	20	3/5	15
Ease of Use for Nurses (15)	4/5	12	2/5	6	4/5	12
Service Life (10)	2/5	4	3/5	6	5/5	10
Cost (10)	5/5	10	3/5	6	4/5	8
Safety (10)	5/5	10	4/5	8	5/5	10
Total (100)	80		70		85	

The matrix above compares the 3 preliminary designs on important criteria in order to decide which design is the best. A variety of criteria were used to compare the designs based on the needs of the client. Effectiveness is weighted the highest due to its importance. Effectiveness is rated on the ability of the gel to conduct the sound waves and the ability of the patch to adhere to skin. Design 3 was rated the highest of the three designs because the gel has already been proven to accurately and reliably conduct the sound waves.

The second most important criteria to consider is patient comfort. The two hydrogel patches tied for the highest score in this category because they both have a small diameter and remain close to the body, whereas design 3 has a small diameter, but it protrudes 1.5 cm from the body. This will cause more discomfort to patients because it may inhibit their everyday activities.

Ease of use for nurses is also an important aspect to consider because the nurses need to use the device every hour. Design 2 scored the lowest due to the difficulty of adjusting the Doppler probe to find the signal. If the Doppler was no longer placed directly over the artery, the nurse would need to remove the top adhesive layer in order to move the Doppler to the right spot. For the other 2 designs, the nurse would simply have to place the probe in a different spot on the patch.

The client required that the patch be able to stay on the patient for at least 5 days. Therefore, service life is an important aspect to consider in the matrix. The third design scored the highest in this category. The first 2 designs both require a solidified gel. The solidified gel is more likely to dry out within 5 days and not be able to conduct the sound waves.

The next criteria to consider is cost. Design 1 is the least expensive design. Design 3 is more expensive because 3D printing is involved. The second design is the most expensive due to the Doppler device inside.

The last criteria to consider is safety. Design 2 was ranked the lowest in this category because it has wires coming from the Doppler which could get tangled and cause a safety concern for the patient. After ranking all the designs using the weighted criteria, it was concluded that design 3 ranked the highest.

Proposed Final Design

The final design features a container that will have an interior diameter of 4 cm with reference to the bottom of the container. The thickness of the container will be 5 mm throughout the entire container, to ensure it has enough surface area to stick the patient and to ensure the design is robust enough to contain the ultrasonic gel. The container will be 3D printed out of a “Flexible Resin” made by Formlabs because there is easy access to this material it has proven itself as being effective with regard to other wearable devices. The “Flexible Resin” is also suitable for the final design because its moldability will improve the patient’s comfort and its flexibility will improve fit and tack to irregular surfaces on the patient’s body. The final design also features a rubber cap that will allow the nurse to take readings as needed while also being able to seal the ultrasound gel within the container. This is desirable because the cap will help reduce any mess by confining the gel within the container. Furthermore, the lid will allow the gel to remain on the patient without drying out and will eliminate the need to reapply and then remove the gel from the patient every time the nurse takes a reading. The container itself will be

secured to a Tegaderm adhesive film via a paint on adhesive that will be able to stay attached during periods of intense/frequent motion and perspiration. Thus, this adhesive will be capable of keeping the container stuck to the patient for 5 days even if the patient is moving around and/or perspiring. The actual adhesive the team will be using is called Pros-Aide II. This adhesive is hypoallergenic, atraumatic when removed, and proven to be effective when used with makeup and prosthetics. Finally, by having the container attached directly over the artery being monitored for the duration of the hospital stay, it will act as a semi-permanent marker and reduce the number of instances where the artery in question cannot be located by the nurse.

Fabrication/Development Process

Materials

The material of the prototype was a key aspect of the design. Two different adhesives were used. First, the Tegaderm film was used to cover the skin in order to ensure no maceration of the skin occurs. The Tegaderm film is a hypoallergenic, water-resistant adhesive used in hospitals. It has good oxygen and moisture vapor permeability, but is impermeable to liquids and bacteria [12]. The other adhesive used was Pros-Aide II Adhesive. This is a paint on adhesive used to hold the gel container to the Tegaderm film. The material used for the gel container was Flexible Resin. This flexible material was chosen in order to maximize comfort for the patient. Lastly, the conventional liquid hydrogel that the medical staff use with the doppler dot in the

hospital was used in order to conduct the doppler signal. A detailed list of materials and budget can be found in Appendix B.

Methods

The creation of the team's prototypes started with creating a three dimensional model of the part in the software Solidworks. After the team created and properly dimensioned a three dimensional model of the Hydrogel Container, they created a .STL file, which stores only the surface geometry data that describes a three dimensional mode. The team then uploaded this .STL file into a 3D slicing software called PreForm. This software was created by Formlabs and works in conjunction with Formlabs' 3D printer. In PreForm, the team selected the materials they wanted to use while 3D printing, and customized the orientation of the parts they printed as well as the number, size, and placement of support structures. After preparing the orientation of the parts the team wanted to print and their corresponding support structures, they sent the PreForm file to the 3D printer. Before beginning the print, the resin tank needed to be changed so that the correct resin was being used. In this case, the team was using the Flexible Resin made by Formlabs. After the tank was changed, the base plate warmed so that the resin was at a temperature between 31 to 35 degrees celsius.

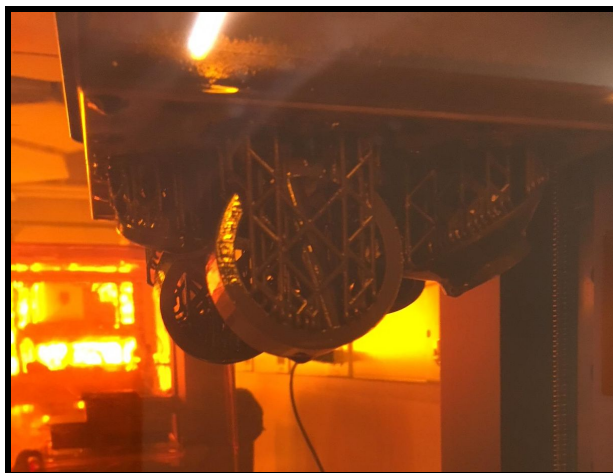


Figure 4: Image of 3D Printing Process

After the resin was at the optimal temperature required for printing, the part began to print layer by layer. It took roughly four and a half hours to print one Hydrogel Container. After the print was finished, the product was placed in two solution baths for 10 minutes each and then



cured for approximately one hour under an ultraviolet light. After the curing process had concluded, the support structures were carefully removed from the 3D printed parts using snipping tools. Once the support structures were removed, the team was left with the 3D

printed prototype.

Figure 5: Image of the Curing Process

Final Prototype

Pictured on the following page is the team's Final Prototype after being 3D printed with Formlabs' Flexible Resin. The surface finish is fairly smooth and all of the edges have been filleted as can be observed. Overall, the design is sleek, safe, and effective.



Figure 6: Image of 3D Printed Final Prototype

In Figure 7, the team has a 3D model of the final Hydrogel Container design that was created in Solidworks. When juxtaposing Figure 6 (physical 3D printed prototype) with this 3D computer model, it is evident that the design the team fabricated is the design they intended to produce.

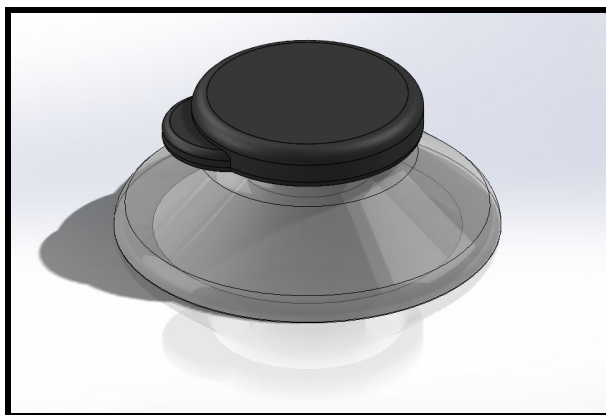


Figure 7: Solidworks 3D Model of Final Design

Viewing Figure 8, one can see exactly how the Doppler Pen is intended to fit inside of the Hydrogel Container. It may be difficult to see, but the Doppler Pen can measure hemodynamic data within a four centimeter diameter. A clearer depiction of this can be viewed in the Appendix under section C: Doppler Pen and Hydrogel Container Calculations.

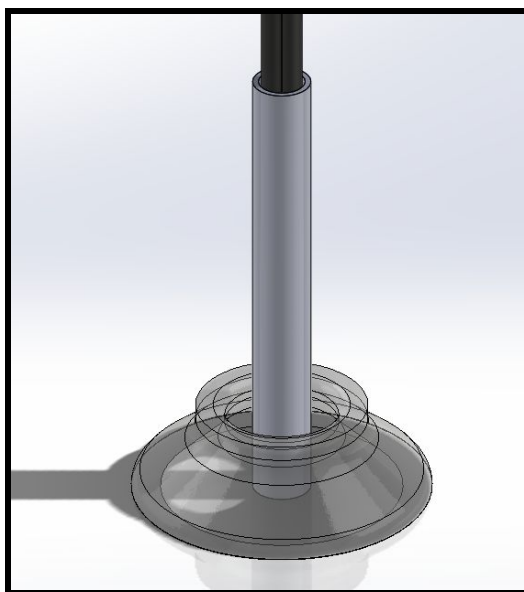


Figure 8: Solidworks 3D Model of Doppler Pen Inserted in Container

As shown in Figure 9, the dimensions of the final Hydrogel Container design are labeled with units of centimeters. While creating this design the team was hoping to keep the profile of the container as low as possible while still maintaining the accessibility of a four centimeter diameter area with the doppler pen. Also, the team wanted to ensure the design had enough surface area along the bottom ring of the Hydrogel Container to obtain enough adhesive contact points, so that the container would be securely adhered to the patient.

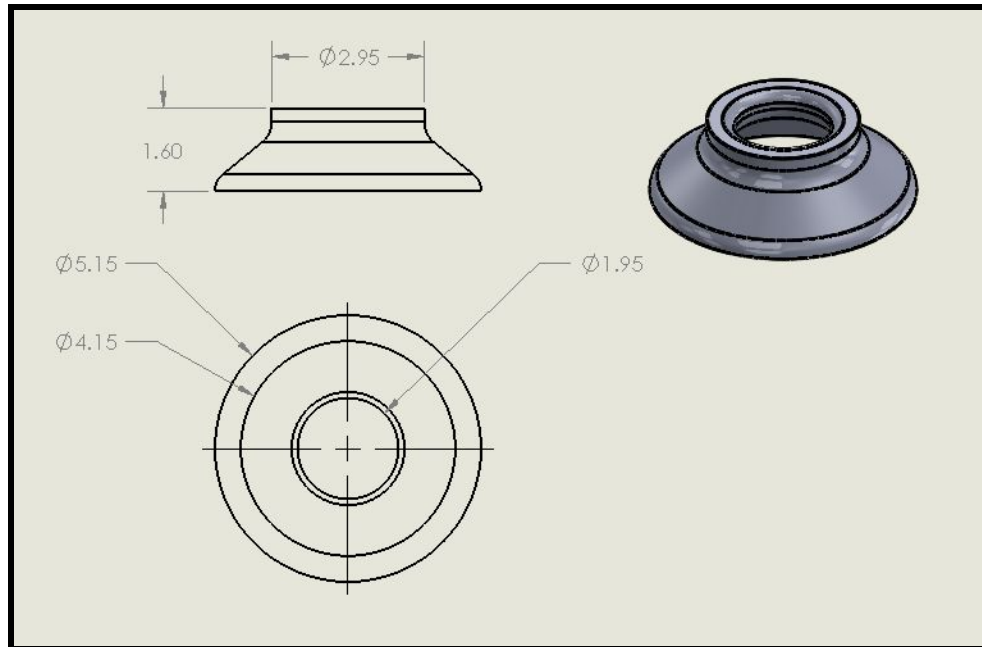


Figure 9: Dimension of the Hydrogel Container

Viewing Figure 10, one can clearly understand the important dimensions (labeled in centimeters) regarding the design of the Hydrogel Container's cap. In this design one can see that the team used a friction fit (or a transition fit) to secure the cap to the Hydrogel Container. Essentially, the inside diameter of the cap and the outside diameter of the opening of the hydrogel container have the same exact diameter. Thus, because tolerances exist and due to the flexible nature of the material we used, the cap is able to fit over the opening of the Hydrogel Container and remain in place due to frictional forces acting between the two components.

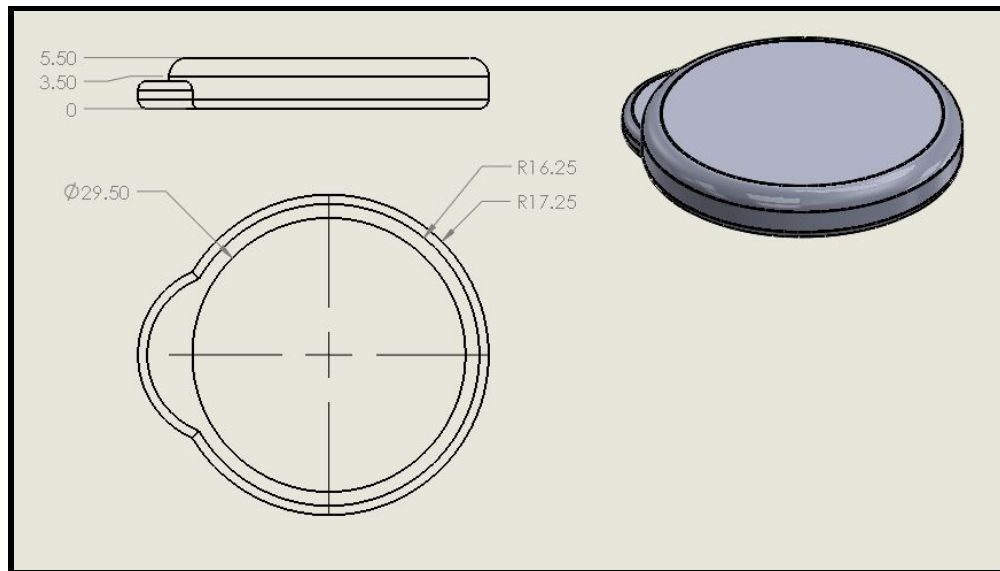


Figure 10: Dimensions of the Cap to the Hydrogel Container

Testing

The first test that was completed was the adhesive longevity test. In this test, the Tegaderm was adhered to the subject for five days. The subject was instructed to maintain his daily routine to simulate the most movement a patient would experience. This was performed to show that the Tegaderm adhesive had the ability to adhere for the required amount of time of 5 days. After the Tegaderm was removed, a second test was performed to test the strength of the Pros-Aide adhesive. This test was conducted in much the same way as the Tegaderm adhesive test. The Tegaderm was placed on the subject's skin. The device was then adhered to the Tegaderm using the Pros-Aide adhesive. This test will show whether the Pros-Aide adhesive is strong enough to secure the device to the Tegaderm for 5 days. Additionally, these tests will give insight into the comfort of wearing the device and removing it, which is an important aspect of the design specifications.

The second test that was performed was a peel test to determine the force required to remove the device from the Tegaderm. Tegaderm was placed on the subject's skin. The device was then adhered to the Tegaderm using Pros-Aide. The device was then pulled using a dynamometer in order to measure force. Multiple trials were performed at 180° (horizontal) and 90° (vertical). This test will show how the force required to remove the device compares to the force required to remove a bandaid. The goal is for the forces to be similar so that the device removal discomfort is at a medical standard.

The third test was an evaporation test. This was performed with two identical mass scales each with Tegaderm and approximately 3g hydrogel. On one scale, the device was placed over the hydrogel and capped. Both scales were left alone for 5 hours with mass readings taken every 15 minutes. This test will show whether the device is successful at reducing evaporation. It is important that the device reduce evaporation in order to decrease patient discomfort. Currently, the medical staff has to add liquid hydrogel to the patient every hour. The goal of this device is to reduce the number of times that the medical staff is required to add gel to the patient; therefore, reducing the amount of time the medical staff spends disrupting the patient.

The final test that was performed was a speed comparison test. Conventionally, the medical staff mark the location of the artery after finding it the first time with pen. Removing the liquid hydrogel after use of the doppler removes the mark as well. After multiple uses of the doppler there is no longer a mark over the artery. In order to simulate this, we performed a test with the best case scenario of the conventional method that included there being a mark over the artery, and then also the worst case scenario with no mark over the artery. These two methods were then compared to the use of the new device. First, an artery on the subject was found. The

subject then moved around and time passed to simulate natural movement of the artery. Then the process of listening for the artery signal was timed for each of the three methods. The test for each case was repeated by four subjects three times each on the same subject. This test will show the efficiency of each method. The client didn't require that the method reduce the time it takes the medical staff to listen to the arterial signal, but he did require that it reduce patient discomfort. Increasing the amount of time the medical staff has to spend disrupting the patient, will increase the patient's discomfort. Therefore, the results must show that the device doesn't take the medical staff longer to use than it does with the conventional method.

Results

During the adhesive longevity test, the Tegaderm remained secured to the subject's skin for 5 days. The device fell off only after intense movement from the subject on the fifth day. This showed that the Pros-Aide adhesive is strong enough to adhere given the activity level of the patients. Additionally, the subject reported no concern of discomfort with wearing and removing the Tegaderm. The device didn't restrict subject movement, but the cap was found to come off on occasion.

Results from the peel test showed that the average force required to remove the device was 3.02N in the 180° test and 2.91N in the 90° test. Each trial ranged between 2.6N to 4.0N which is similar to the strength of a Band-Aid brand adhesive [13]. This shows that the device has the ability to remain adhered to the Tegaderm, while still being able to be removed easily at the end of the patient's stay.

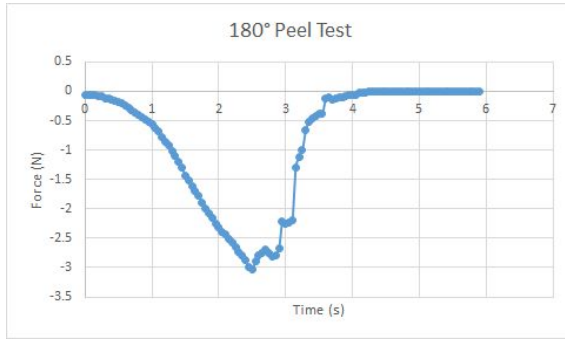


Figure 11: 180° Peel Test Average

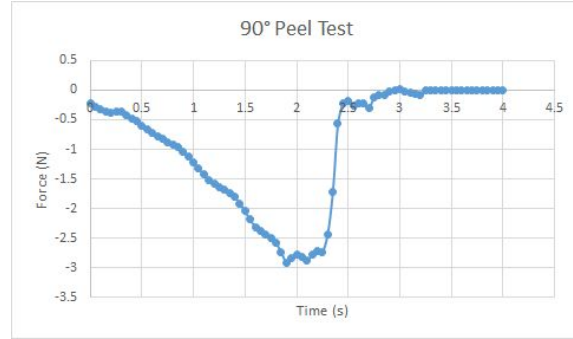


Figure 12: 90° Peel Test Average

Results from the evaporation test showed that 21% of the uncapped hydrogel had evaporated while 5.7% of the capped hydrogel evaporated. Extrapolating forward, the uncapped hydrogel would have completely evaporated after about 22.6 hours while the capped hydrogel would have completely evaporated after 75.5 hours. This shows that the capped device drastically reduces the amount of evaporation of hydrogel.

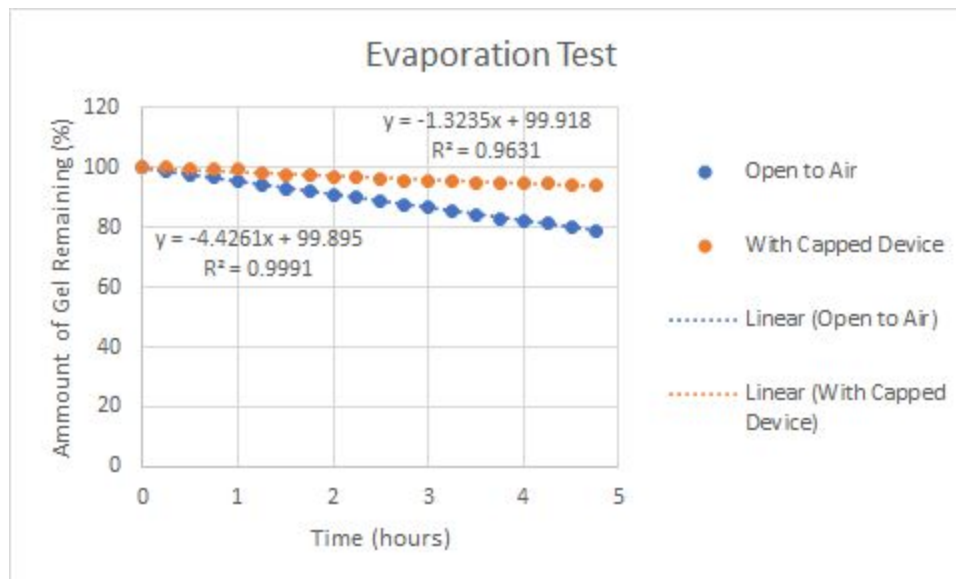


Figure 13: Evaporation of Hydrogel

Results of the speed comparison test showed that the device reduced the amount of time needed to find the arterial signal. On average, it took the team 39.95 seconds to find the arterial signal without a mark, 33.31 seconds with a mark, and 20.27 seconds with the device marking the location of the artery. With the limited amount of time that the team had to perform these tests, the trial with the device ended up with a large standard deviation. Therefore, the speed test shows that the time to find the arterial signal with the device is at least as fast as the time it took to find the arterial signal with a mark. According to the client, the team only needed to show this and not that the device made the process faster.

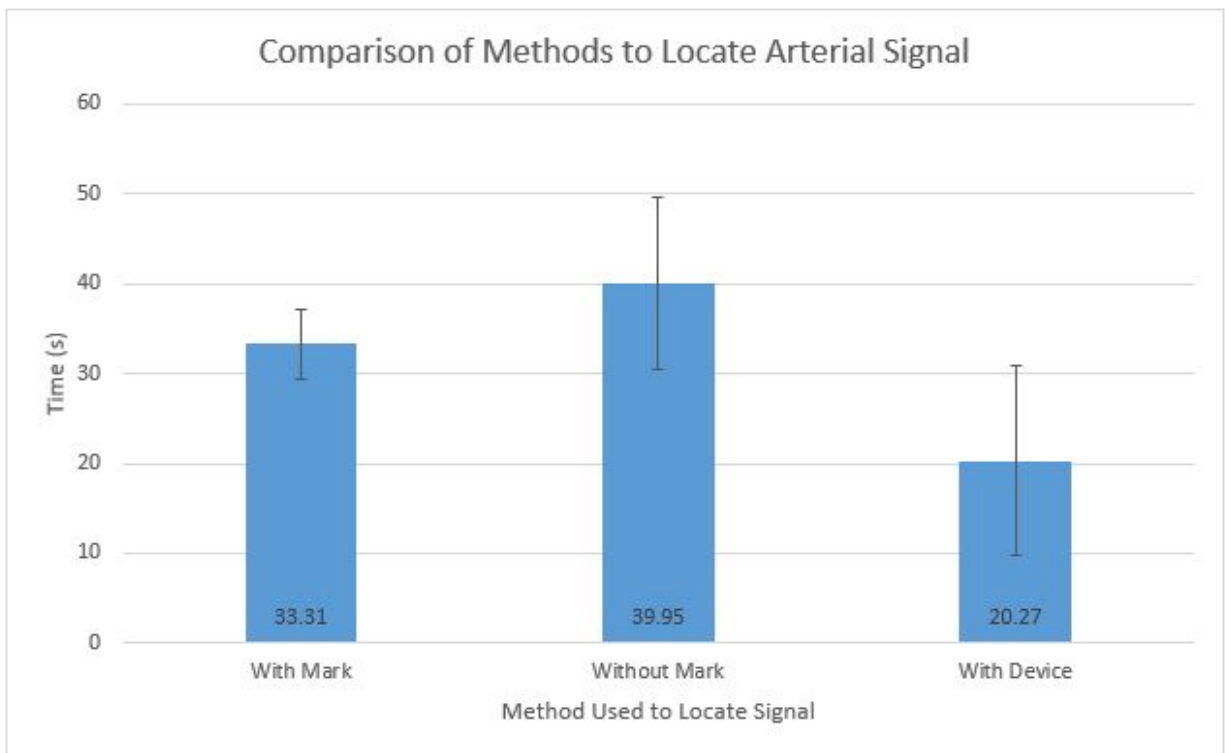


Figure 14: Time to Find Arterial Signal

Discussion

Results showed that the device will last the required five days of use. The device also has the ability to be removed at the end of the trial with no trauma to the patient. However, no solid results can be drawn from the speed comparison test. The team wanted to show that finding the arterial signal with the device was at least as fast as finding the signal with a mark on the patient. In reality, this can only be truly tested with trained medical staff on real patients.

As of now, no testing has been performed on medical patients. It is to be hoped that the device will be used on patients in the future. If this is the case, FDA regulations must be kept in mind for any future changes to the device. At some point in the future, the device will need to be tested on patients. At this stage, HIPAA laws and regulations will come into effect and must be considered by those doing the testing. As previously mentioned, the development of this device has the potential to help many patients make a full recovery without the unnecessary loss of tissue while minimizing patient discomfort.

At this point, FDA regulations were not taken into account while designing and construction our device. Before patient testing can be implemented, FDA approval must be given. If they have different requirements, then some aspects of the device must be changed to meet those requirements. At this moment, the team has not looked into FDA regulations so the device may or may not be ready for clinical trials.

Sources of Error

The first test conducted determined that both adhesives could last for five days. The team only ran one trial for each adhesive. One trial may not be enough to make an accurate assumption that the adhesive works for five days. That could be one potential source of error.

For the peel test, the Pros-Aide adhesive may have not dried completely when the test was performed. This means that the actual adhesive strength may be stronger or lighter than what results showed. In addition, the speed at which the device was pulled off may have played a part in how much force the device could withstand.

Since the data for the evaporation test was extrapolated, there could be error in that test. In an ideal situation, the hydrogel would be left out until it evaporated; however, the team did not have the time or resources to keep monitoring the test for longer than what was tested. In addition, the heat from the patient's skin may speed up evaporation. Ideally, the team would like to test the device on a patient to see how quickly the hydrogel evaporated.

Ideally, the speed test would be performed by medical professionals on a reconstructive patient. Since the team did not have the authorization for this kind of testing, team members found arterial signals on each other. This could have a large source of error. Since the people ultimately using the device will be professionals, it would be ideal for those people to test the device. Beyond this, each member of the team only performed the test a few times. Much larger data sets are required to perform thorough statistical analyses of data. The source of error and ambiguity in this test could be drastically reduced by having this test redone many more times to

increase the sample size and hopefully create normality in our data. The team would have liked to get this testing data in order to have more robust results.

Conclusions

Overview

In reconstructive surgeries, reattached blood vessels can become damaged and lose their functionality. Therefore, it is important to monitor a patient's blood flow for several days after the surgery is completed. This process can be bothersome to the patient who should be resting after having an invasive surgery. It can be difficult for doctors and nurses to consistently find the correct artery. Once found, there is often a mess that is created when using the Doppler probe in conjunction with the the liquid hydrogel. The client wishes to develop a device that can attach to a patient's skin, mark the location of an artery, and effectively conduct sound in the range of a Doppler probe. This will help to reduce or even eliminate the mess created by the Doppler probe and hydrogel. In addition, this will make the process of monitoring blood flow easier for both the nurses and the patients.

The final design solves all of these problems. By having an adhesive bottom, it can easily attach to the patient's skin and mark the location of the artery. Due to its design, it will also contain the hydrogel and therefore reduce the mess. In addition, since this design uses the gel that is currently used to transmit Doppler waves, there will be no problem with the device

conducting sound. The device has a removable cap allowing the gel to be easily accessed and resealed. Overall, this design meets all of the goals that were outlined by the client.

Future Work

Currently, in addition to using Doppler probes, doctors also assess the patient's skin color and temperature. These are other measures that they use to verify blood flow. In a patient with decreased blood flow, the skin will grow cold and change colors. In the future, an additional adhesive ring may be added around the outside of the device. This device would be able to monitor the patient's skin temperature to ensure that there is adequate blood flow to the target tissue. This would help the doctors and nurses to measure another variable at a glance to ensure the full recovery of the patient.

In addition, some graduate students at MIT have developed a new type of hydrogel. This hydrogel does not dry out, is adhesive, and can be embedded with electronics [14]. This hydrogel alone meets the client's requirements. Results from the evaporation test of the hydrogel container device found that the liquid gel would still evaporate after 3 days of being in the container. This hydrogel developed by MIT solves the problem of having to reapply liquid hydrogel and would therefore be very beneficial in the design. Additionally, the gel could be embedded with a Doppler and simply be plugged in by medical staff to monitor the patient's blood flow. This would significantly reduce disruption of the patient.

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Appendix

A: Product Design Specifications

Client: Dr. Nicholas Albano

Advisor: Dr. Naomi Chesler and Ashley Mulchrone

Team: Crysta Frank - cfrank5@wisc.edu (Team Leader)

Luke Le Clair - lleclair@wisc.edu (Communicator)

Galen Riley - griley@wisc.edu (BSAC)

Jacob Mundale - mundale@wisc.edu (BWIG)

Luke Hetue - hetue2@wisc.edu (BWIG)

Anna Keller - akeller5@wisc.edu (BPAG)

Date: Tuesday, December 5th, 2017

Function

Frequent monitoring of arteries provides surgeons with essential data pertaining to the successfulness of the the surgery. In many scenarios it is not sufficient or even possible to feel a pulse in the artery of concern. The lack of a pulse, which simply means the blood flow through the artery is too faint to feel, can be the result of many scenarios including, but not limited to, the added stress experienced by the artery after surgery, an artery that may still be recovering, or an unsuccessful surgery. When a pulse cannot be detected, surgeons need to resort to other methods in order to monitor blood flow through the previously operated on artery. To do so, medical staff utilize a medical instrument known as a pencil Doppler that allows them to listen to the blood flow within the artery. The technology relies on a hydrogel, which transmits frequencies produced by a mechanism in the doppler pencil. These ultrasound frequencies then bounce off of moving blood cells flowing through the artery and travel back to the receiver where they are analyzed. The receiver is composed of two piezoelectric crystals that vibrate at specific rates based on the returning frequencies that strike the receiver. A computer then analyzes the

vibration rates of the piezoelectric crystals and produces a pattern of noises perceptible to humans. Thus, when monitoring the blood flow through an artery, the medical staff is capable of hearing a triphasic signal that correlates to the dilation of the artery as blood passes through the artery. Although this device is highly accurate and reliable, the process of applying the ultrasound transmission gel and finding the location of the artery can be tedious and inconvenient with regard to the patient's sleep pattern. Measurements must be taken by medical staff at a rate of once per hour during the first twenty four hours following the surgical procedure. Hence, the medical staff is looking for a way to take blood flow measurements while disturbing the patient as little as possible. Furthermore, the medical staff is looking for a way to superficially mark the location of the artery for the duration of the patient's five day hospital stay.

Client requirements

This product...

- Must be able to detect and monitor blood flow in arteries.
- Must have an in service lifespan of five days.
- Must be attached directly to the patient's skin.
- Must minimize the extent to which the patient will be disrupted during measurements.
- Must be comfortable.
- Must be disposable.
- Could be equipped with a skin temperature indicator to increase usefulness..

Physical and Operational Characteristics

a. Performance requirements: The device must be able to alleviate the stress and/or discomfort of patients being monitored by a doppler pencil. To achieve this goal, the device will eliminate the need to clean the hydrogel from the patient after each use of the doppler. The product must still be able to conduct the ultrasound waves as before so as to ensure the pencil doppler is capable of receiving and analyzing the triphasic signal. Additionally, our product must mark the location on the patient with the strongest signal from the artery of interest. Safety is also an important factor, both for the patient and for the doctors and nurses who are using it. Thus, it needs to follow the sterilization requirements of the hospital and should not include any sharp edges, nor should it be made out of any materials that are toxic when they come in contact with a person's skin.

Lastly, the device must have a service life of five days. This means that for five days the adhesives, the gel, and the device itself must be able to withstand constant use and movement.

b. Safety: Since this device will be used in a hospital setting, it must follow all the safety guidelines the hospital has in place. This means it must not cause any harm to the patient or the person administering it. The components of the device include a Tegaderm film adhesive, another adhesive substance known as Pros-Aide, and finally a hydrogel container constructed out of FormLabs' "Flexible Resin." The Tegaderm film adhesive, which protects the patient from maceration caused by prolonged exposure to the hydrogel, and the Pros-Aide adhesive are both proven to be hypoallergenic and atraumatic when removed from a person's skin. Thus, because Tegaderm is already widely used in the medical field and because Pros-Aide is proven effective and safe in the world of makeup and prosthetics, we have decided they would be safe to use in a hospital setting. Similarly, we opted to use a flexible resin when fabricating our hydrogel container, because it will improve comfort, but the material's flexibility will also help improve patient safety. Similarly, when designing the part, we ensured all of the edges were filleted so as to ensure the patient and medical staff alike would not have to interact with any sharp edges. Finally, because the materials we decided to use to create our product are relatively inexpensive, our product would likely be treated as a disposable medical device, which means we do not have to worry about a sterilization process for multi patient use.

c. Accuracy and Reliability: The device needs to be very reliable. Lack of accuracy or reliability would cause the on-duty nurse to alert a the on-call medical staff of a possible life-threatening condition which would cause unnecessary stress to the patient and the surgeons.

d. Life in Service: The device will be adhered to the patient for the duration of 5 days, during which it must remain attached and functional. The adhesives will have to keep the hydrogel container secured to the patient for the entire time and be robust enough to stay adhered despite any movement, perspiration, or use, that it might experience.

Furthermore, the hydrogel container will undergo constant opening and closing of the cap as well as exposure to hydrogel for these 5 days. Thus, it is important that the cap and the hydrogel container are robust enough to withstand five days worth of opening and closing cycles as well as normal measurement use.

e. Shelf Life: The Tegaderm film adhesive, the Pros-Aide adhesive, and the Hydrogel Container will all be stored separately. The Tegaderm film adhesive as well as the Pros-Aide adhesive have their own packaging and shelf life conditions and parameters. The Hydrogel Container will have a shelf life of about one year. Formlabs did not specify how long 3D printed products made from flexible resin would maintain their structural integrity and flexible properties, but according to their website the material should not begin to denature for over a year. Ultimately, we intend on having the Hydrogel Container stored in a cool, dry environment with limited to no exposure to sunlight.

f. Operating Environment: The device will be used by medical staff and it is intended to be placed on the surface of a patient's skin near or directly over a surgical site. Similarly, the Hydrogel Container will be filled with a hydrogel for the duration of the patient's hospital stay, so our product will be operating in a particularly wet environment.

g. Ergonomics: The device must be straightforward and eliminate the time consumption and stress of the procedure currently associated with obtaining hemodynamic data. The device must also be comfortable for the patient to wear/use and should not cause additional pain or irritation to the patient. Thus, we have implemented the Tegaderm adhesive film patch to prevent maceration of the skin. Similarly, we have ensured the adhesives are hypoallergenic and atraumatic when removed. Finally, the device is to be fabricated out of a flexible resin to improve comfort and the design will have smooth and filleted edges so as to ensure the safety of the patient and the medical staff.

h. Size: The device will be a circular container that has an outermost diameter of 5.15 centimeters and a height of 1.6 centimeters. The inside diameter at the base of the container will be 4.15 centimeters. This inside diameter has this dimension, because arteries are often subject to natural movement and through experience, our client suggested that the artery can be displaced by up to 2 centimeters in any direction. The

inside diameter of the top of the opening will be 1.95 centimeters, because given the size of the doppler pen being used by the medical staff (one centimeter in diameter), the depth of the top opening (half of a centimeter) and the angle between the skin of the patient and the interior wall of the container (fortyfive degrees), the medical staff member collecting the hemodynamic data will be able to access the full range of area within the hydrogel container to obtain successful measurements.

i. Power Source: Our product is to be operated without the requirement of a power source.

j. Weight: The device is designed to be as lightweight as possible without sacrificing structural integrity and strength. The reason, the device is designed to be lightweight is because it will be adhered to a patient, thus the lighter our device is, the less adhesive strength will have to be exerted to keep it attached to our patient. Our client did not specify an official weight requirement, however, we feel that our design should not weigh more than three grams.

k. Materials: The first material we are using is an adhesive film known as Tegaderm produced by 3M. Next, we are utilizing another adhesive agent called Pros-Aide that will be used to adhere the Hydrogel Container to the Tegaderm film that will be directly attached to the patient's skin. Lastly, we will fabricate our Hydrogel Container out of a flexible resin produced by Formlabs that has 3D printing capabilities.

l. Aesthetics, Appearance, and Finish: We want the device to be aesthetically pleasing, thus we want to ensure our design is refined and very sleek. We also want to ensure that the device has a smooth surface finish so that it will not be likely to cut or harm anyone who interacts with the device.

Production Characteristics

m. Quantity: Our final design did not entirely meet all of the design specification our client wanted us to meet. For example, when using the Hydrogel Container, one would have to refill the container with Hydrogel at least once during the patient's stay, because it takes about three days for the hydrogel to completely evaporate. Similarly, our design did not include a temperature indicator that was intended to help the medical staff measure the skin temperature of the patient, which is another way to measure how successful the surgery was with regard to getting blood to the transplanted tissue.

Ultimately, we do not want to mass produce a product that does not entirely satisfy our client. For the time being we have two functional prototypes.

n. Estimated Cost: A package of four Tegaderm film adhesive patches is estimated to cost approximately \$7.13, which means the cost per patch is about \$1.78. A two ounce bottle of Pros-Aide II adhesive will cost approximately \$13.30. Finally, the Hydrogel Container and the Lid have a combined volume of 12.65 mL. To use a 3D printer found in the Makerspace in Wendt Commons, it will cost \$2.53 to print a single hydrogel container. Thus, the per unit cost to produce a useable Hydrogel Container is around \$5.00 if you were to use 70 cents worth of Pros-Aide adhesive per Hydrogel Container.

Miscellaneous

o. Standards and Specifications: For this semester, we will not require FDA approval, however, before producing our product on a larger scale it would be wise to obtain an FDA approval.

p. Patient-Related Concerns: Currently, the main concern is to not wake the patient as they sleep. With current methods, the patient is woken up every hour as the nurses measure blood flow. In addition, the device will need to be comfortable as it will remain on the patient for several days. Finally, we want to prevent maceration of the patient's skin at all cost, because by prevent maceration we are decreasing the likelihood that the patient contracts an infection.

q. Competition: Many vascular doppler devices already exist. One of the most common practices now is to use an implantable doppler. This device is a cusp that directly attaches to a vein or artery that monitors blood flow through the vessel. The cusp contains a transducer that sends and receives signals into the blood vessels and will wirelessly transmit the readings to an external source for monitoring (Mickle, M., Rothfuss, M. and Gimbel, M. 2013). In talking with the client, Dr. Albano has stated that these devices are very hard and precarious to implant. Beyond this, after the device is no longer necessary it is removed by simply pulling the cusp off of the blood vessel. This creates a risk of tearing the vessel and cutting off the newly transplanted tissue from the blood source.

Vascular dopplers do not need to be internal; external devices exist and this is one of the design's constraints. Currently, there is an external doppler that wraps around the wrist. This radial design is able to monitor vascular flow in the wrist and adapt it's pressure based on the current readings as to not constrict the vessel being monitored

(Corrigan, 2014). This device is external but restricted to the wrist. The client wishes to be able to have a device that could be placed anywhere on the body and have accurate readings that are obtained as non-invasive as possible.

Lastly, our group found an article that described a group of researchers at MIT who created a hydrogel that will not dry out. (Chu, 2016). Furthermore, the researchers have also proved this hydrogel's capabilities with embedded electronic devices. This hydrogel that resists dehydration could be directly applied to our design project, because a relatively easy, yet expensive solution to our client's design requirements would be to implant a doppler device within the hydrogel and then adhere the hydrogel to the patient's skin.

r. Customer: Dr. Albano, a plastic surgery resident at UW Hospital, is looking for a device to simplify the process of obtaining arterial blood flow readings. He is looking for the device to be external and minimally invasive for the patients.

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B: Cost of Materials

The client provided a budget of \$100. The team stayed below budget with a total of \$30.18 in expenses. A list of the materials is below.

Description	Supplier	Part/Model #	QTY	Date	Price	Total
Pros-Aide II Adhesive The Sequel, 2 fl oz	MakeupMedly	PA1PROSII2OZ	1	10/31/17	\$13.30	
Torbot GRICKS Double-Sided Adhesive Disc 1/2" I.D. X 4" O.D.	Home Health Care Products	GR150112	1	11/09/17	\$16.88	
Tegaderm Film	Client via the UW Hospital		8	11/21/17	\$0	
Flexible Resin 3D Printed Container	Formlabs at UW-Madison Wendt Makerspace		6	11/4/17	\$0	
Liquid Hydrogel	Professor Amit Nimunkar		1	9/27/17	\$0	\$30.18

C: Doppler Pen and Hydrogel Calculations

