Doppler Dot

BME 200/300

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Abstract

Currently, patients undergoing reconstructive surgery are awakened every hour so that nurses can monitor blood flow to the newly reconstructed tissue. If the blood flow is not monitored correctly, the newly-placed tissue could die. It may be difficult for nurses to find the artery as it often moves under the tissue. In addition, the signal may be very weak making it hard to find. This can cause discomfort to the patient as the nurse attempts to find the artery. Often, the on call doctor needs to be paged just to find the arterial signal. 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 gel, and maximize patient comfort. Currently, doctors and nurses use Doppler probes with hydrogel to conduct the sound. This creates a mess and can bother the patient significantly. 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 blood vessels and arteries is essential to reconstructive surgeons; however, it is not always sufficient to simply feel for blood flow through specific vessels and arteries of concern. This is due to the stress often put on arteries and vessels in tissues that are used in reconstructive surgery, causing blood flow to be too faint to feel. Therefore, reconstructive surgeons often resort to the use of the pencil Doppler to hear blood flow, up to 6 cm 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 nurses must awaken patients once an hour in order to use the pencil Doppler to ensure specific tissues still have blood flow in both arteries and veins. This not only places heightened stress on the patient, but the gel will also remove any markings prior that located the vein/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 mark the location of the artery or vein while also being capable of transmitting 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 and be capable of transmitting hemodynamic data via a receiver that could be plugged into a preexisting device and unplugged when not in use.

Impact

Reconstructive surgery is a major procedure that often requires a surgeon to modify the internal plumbing within the patient by moving and redirecting arteries and veins 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 extremely small arteries and because it is difficult to maintain precision when operating on small, fragile parts, patients must undergo hourly monitoring, after having surgery. Due to the nature of current monitoring procedures, it is common for the nurses to accidentally awaken the patients, disrupting their sleep and making it more difficult for the patient to focus on healing. In addition, under current procedure, nurses can struggle to find or hear the triphasic arterial blood flow signal beneath the patient's tissue. This can lead to more poking and prodding and even 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 potentially have further uses beyond the UW hospital. The device is intended to make any form of necessary arterial blood flow location in any type of surgery easier and more accurate.

Existing Devices

The most widely used product is the liquid hydrogel. It can be applied to a closed area of the body. Prior to the use of the transducer, this gel is spread over the area that will be viewed or listened to. It allows the transducer to maintain secure contact with the body and eliminates air

pockets that would block the transmitted signals before they entered the patient's body. Due to its liquid nature, the gel becomes runny and must be wiped off with a towel after the procedure [1].

Solid hydrogels are already on the market as well. HydroAid has created a solid hydrogel pad that is versatile over virtually any part of the body including open wounds. It is a 6 cm x 10 cm x 3 mm rectangular pad that can be placed over irregular surfaces that can produce robust signals from an area that could not be locally examined [2]. Similar products are described as disposable and require the additional use of liquid gels if the planned procedure is scheduled to be long [3].

Solid hydrogels have also been taken a step further and some include adhesive properties. SonoFAST has 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 also would not be able to 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 can not sustain functionality over a long period of time [4].

Background

Research

Although less than 5% of reconstructive surgery patients experience perfusion, or drainage of blood at the surgery site, the result of restricted blood flow to the flap will quickly

lead to cell death in the attached tissue if not corrected in a timely manner [5]. In the case that blood flow is not reestablished a phenomenon, known as no-reflow, occurs. The resulting severity of damage to the tissue is correlated with the total time that the flap lacks blood flow. Therefore patients are monitored hourly to ensure the flap is healthy and no emergency procedure needs to be performed [6].

The Pencil Doppler functions by first directing sound waves into the direction of blood flow and then receiving the return signal to determine fluid velocity [7]. The Doppler must be used in conjunction with an ultrasound gel as it eliminates air pockets which would have otherwise interfered with the transmitted signals [8]. Although the cleanup of solid gels is minimal, they do not transmit sound reliably in prolonged procedures, which the device requires [9]. In addition, it is important to note that the device 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 marking the location of the strongests thoracic 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: P-DERM Skin Contact Acrylic Adhesives, Formlabs Flexible Resin, Formlabs Durable Resin, and Aquasonic hydrogel. P-DERM is a 0.18mm thick silicone gel adhesive tape that is composed of high adhesion silicone gel coated onto a polyurethane carrier that is designed for skin contact. Overall, this product features “excellent instantaneous tack,” “atraumatic removal from skin,” and it 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 ability to accurately and reliably alleviate stress to the patient, conduct sound waves, and mark 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

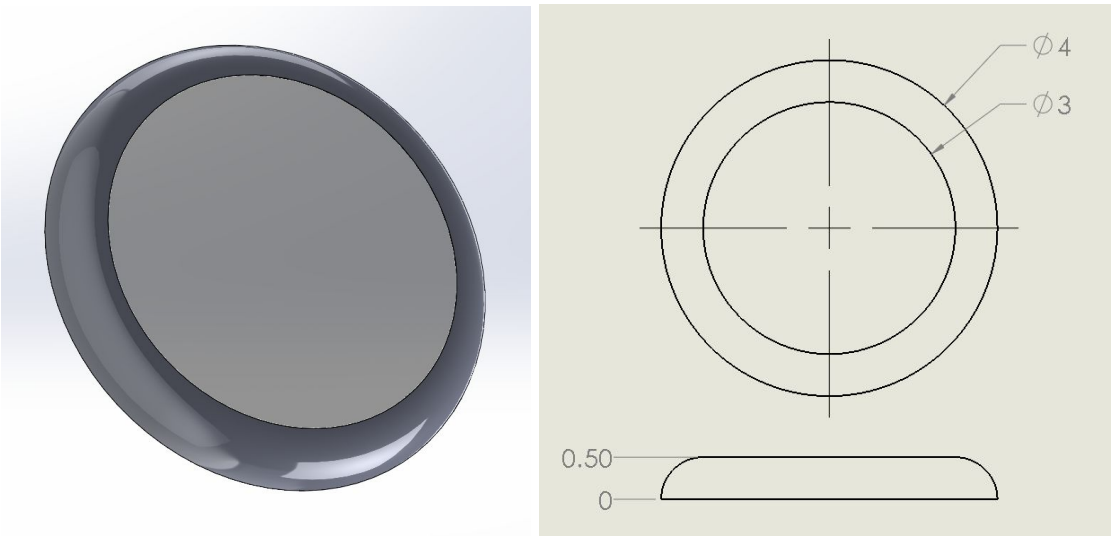


Figure 1: Disposable Hydrogel Adhesive Patch (Design 1)

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 blood. The Doppler waves would then be able to travel through the patch into the patient. While the gel would be able to transmit sound effectively, the adhesive patch may not transmit sound as well as just the gel. This could pose a challenge when listening for a signal.

Reusable Doppler with Disposable Hydrogel Patch

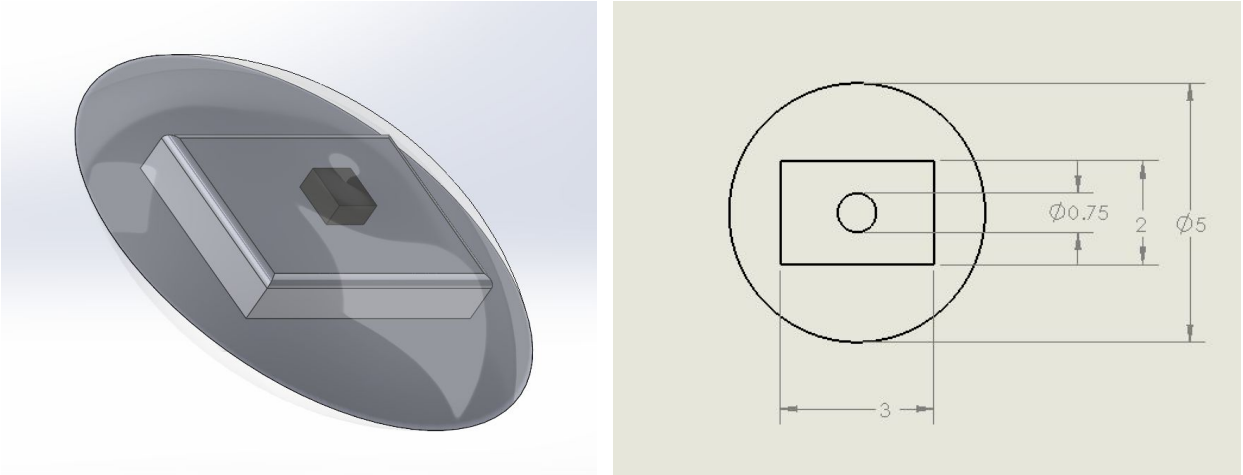


Figure 2: Reusable Doppler with Disposable Hydrogel Patch (Design 2)

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 caregiver'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.

Disposable Hydrogel Adhesive Container

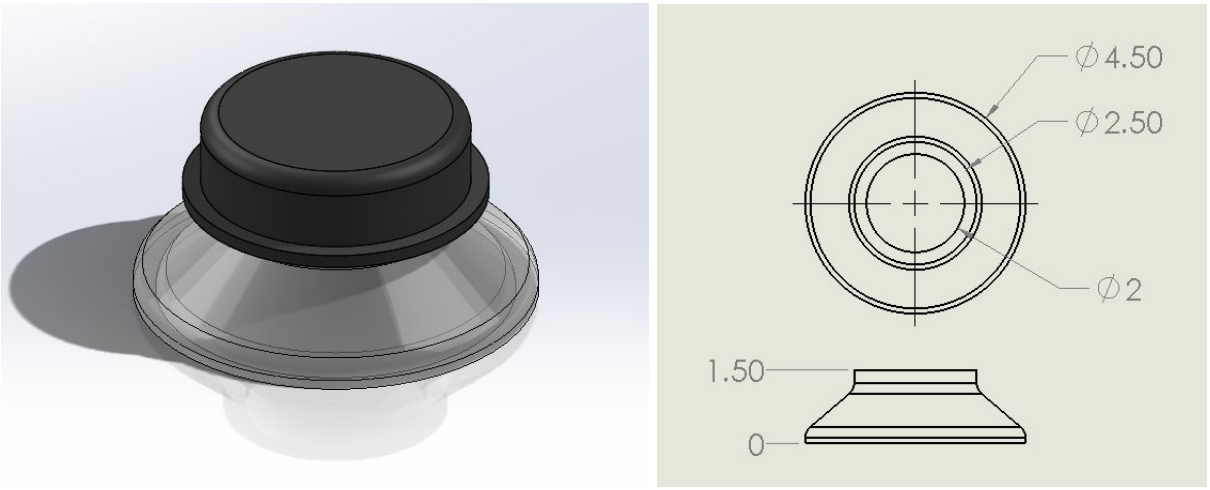


Figure 3: Disposable Hydrogel Adhesive Container (Design 3)

Design 3 contains the hydrogel 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 device to last for the required amount of time that is 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.

Preliminary Design Evaluation

Design Matrix

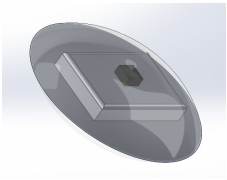
	Design 1: Disposable Hydrogel Adhesive Patch 		**Design 2:** Reusable Doppler with Disposable Hydrogel Patch 		**Design 3**: Disposable Hydrogel Adhesive Container 	
Effectiveness **(30)**	4/5	24	4/5	24	5/5	30
Patient Comfort **(25)**	4/5	20	4/5	20	3/5	15
Ease of Use for Nurses **(15)**	4/5	12	2/5	6	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**	

Table 1: Design Matrix

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 3 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 2 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 3-D 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 hydrogel. The container will be 3-D printed out of a "Flexible Resin" made by Formlabs, because there is easy access to this material and because this material has proven itself as being effective with regard to other wearable devices. The "Flexible Resin" is also suitable for the final design, because its malleability 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 rubberized cap that will allow the nurse to take readings as needed, while also being able to seal the hydrogel/ultrasound gel within the container. This is desirable, because the cap will help reduce the mess by confining the gel within the container. Furthermore, the lid will allow the gel to remain on the patient without drying out and it will eliminate the need to reapply and then clean off the gel every time the nurse needs to take a reading. The container itself will have an adhesive strip fitted to the flat, circular, underside of the container and the adhesive will be similar to that found on kinetic tape which is designed to stay attached to a human body during periods of intense/frequent motion and perspiration. Thus, this adhesive will likely 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 we will be using is one

made by P-DERM that is hypoallergenic, atraumatic when removed, and P-DERM claims it has "excellent tack" [10]. Lastly, by having the container stuck to the desired spot on the patient (directly over the artery being monitored) for the duration of their hospital stay, it will act as a semi-permanent marker and hopefully reduce the number of instances where the artery in question cannot be located by the nurse.

Discussion

As of now, no testing has been performed. 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 as the device is being built. 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. If testing shows that the device effectively transmits sound, then this would mean that further improvements can be made on the device in order to monitor different signs of decreased blood flow. As previously mentioned, the development of this device will help many patients make a full recovery without the unnecessary loss of tissue.

Sources of Error

As of right now, there has not been any testing. In the future, it is hoped that the device will be tested to ensure it's accuracy and reliability. One anticipated source of error could be using different amounts of gel. Different amounts of gel could affect the ability of the Doppler

to conduct sound. This error could be resolved by measuring out a specific quantity of gel for every test of the device. This would make each test consistent and eliminate this source of error.

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. 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. In addition, this will make the process of monitoring blood flow easier for both the nurses and the patients.

The proposed 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 Doppler gel 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 sealed or accessed. Overall, this design meets all of the goals that were outlined.

Future Work

Currently, in addition to using Doppler probes, doctors also assess the patient's skin color and temperature. This is another measure that they use to verify blood flow. In a patient with decreased blood flow, that skin will grow cold and change colors. In the future, an adhesive ring can 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.

References

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Appendix

A. Product Design Specifications

Function

Frequent monitoring of blood vessels and arteries is essential to reconstructive surgeons; however, it is not always sufficient to simply feel for blood flow through specific vessels and arteries of concern. This is due to the stress often put on arteries and vessels in tissues that are used in reconstructive surgery, causing blood flow to be too faint to feel. Therefore, reconstructive surgeons often resort to the use of the pencil Doppler to hear blood flow, up to 2 mm 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 nurses must awaken patients once an hour in order to use the pencil Doppler to ensure specific tissues still have blood flow in both arteries and veins. This not only places heightened stress on the patient, but the gel will also remove any prior markings that located the vein/artery of concern. Thus, our 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 mark the location of the artery or vein while also being capable of transmitting the sound waves (8-9.1 Mhz) of a pencil Doppler. The other option our client would be willing to pursue is a device that could be directly attached to the patient and be capable of transmitting hemodynamic data via a receiver that could be plugged into a preexisting device and unplugged when not in use.

Client requirements

- Be able to hear blood flow in arteries and veins
- Skin temperature indicator
- Approximately 5 day lifespan
- Attach directly to patient
- Minimize patient disruption

Physical and Operational Characteristics

a. Performance requirements: The device must be able to alleviate stress to the patients. This can be done by removing the messy gel process currently necessary for conducting the sound waves and reducing the chance of waking the patients up by probing them with the doppler. Therefore, the created product must still be able to conduct sound waves in order for the pencil doppler to pick up the signal. Additionally, it must mark the location on the patient where the strongest signal of the vessel of interest is. It 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 also has a requirement to last five days. This means that for five days the adhesive and the device itself must be able to withstand constant use and movement. Finally, it needs to follow the sterilization requirements of the hospital; thus, it will most likely need to be disposable after each use.

b. Safety: Since this device will be used in a hospital setting, it must follow all the safety guidelines the hospital has in place. It must not cause any harm to the patient or the person administering it. One thing to keep in mind is sanitation/sterilization of the device between patient use. Also, making sure the device won't cause the doctors/nurses

to be exposed to any body fluids from the patient. And lastly, the device itself must not be made of a material that could scratch/cut the patient or cause exposure of harmful chemicals to the skin.

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 physician of a possible life-threatening condition which would cause unnecessary stress to the patient and physician. However, if the device were to fail in such a way that it was falsely detecting blood flow and hence fail to alert the on-duty nurse of the situation, the patient's life could be jeopardized.

d. Life in Service: The device will be left attached to the patient for the duration of 5 days, it must remain unmoved and unchanged. It will undergo constant use for these 5 days.

e. Shelf Life: Although the device will most likely be disposable, it must remain viable in storage, this could be up to a year. It will be stored in a cool, dry environment with limited to no exposure to sunlight.

f. Operating Environment: The device will operate on the surface of the patient's skin near the surgical site while the patient is hospitalized.

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.

h. Size: The device will most likely be a thin circular patch with a radius of 2 cm.

i. Power Source: Our group is currently in the brainstorming phase, we have not yet determined the final design of our device. It is entirely possible that our device will not require a power source. It is also possible that our device will draw power from the computer it will be interacting with, or it might even need to run off of small, inexpensive, lightweight batteries. We cannot adequately provide an answer to what power source we will be using until we have a finalized design we plan on pursuing.

j. Weight: The device should be lightweight in the sense that it should not weigh more than a few grams. As of yet there is no official weight requirement for this device. However, because this device will most likely be fashioned to the patient by using an adhesive material, it will most definitely be easier to keep a lighter device securely fashioned to the patient when compared to a heavier device that will likely have a larger tendency of falling off. Furthermore, based upon a general consensus, it has been hypothesized that a lighter device will be more comfortable for a patient to use than one that is "heavier."

k. Materials: Our group is currently working closely with our client while doing in depth research to find materials that will be suitable and safe to use within our design. At this point we are not even sure if the materials we need exist. More research as well as a finalized design will be required in order to properly describe the materials we need.

l. Aesthetics, Appearance, and Finish: We want the device to be aesthetically pleasing, thus during the design phase, we want to ensure our design is refined and very sleek. We

also want to ensure that the device is smooth so that it will not be likely to cut or harm any users.

Production Characteristics

m. Quantity: If our group succeeds at creating a product capable of replacing the current pencil doppler technology, large quantities of these devices will need to be produced. After a patient has been released from the operating room after undergoing vascular surgery, it is a requirement that their hemodynamic data be closely monitored for 5 days after the operation. Thus, every patient that undergoes vascular surgery will require at least one of our devices per surgery. If other hospitals/health care professionals feel as though their patients could also benefit from our product we may need to consider the mass production of our device.

n. Estimated Cost: Currently there are no devices that perform the same tasks that we would like to accomplish so it is hard to define a price. The final product will likely be disposable so we would like to keep costs to an absolute minimum.

Miscellaneous

o. Standards and Specifications: For this semester, we will not require FDA approval, however, it will need to be FDA approved at some point. This should be kept in mind and we should proceed as if we are looking for 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.

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, the removal is just pulling the cusp off. 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.

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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