The Doppler Dot - September 2017
Product Design Specifications

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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.

References

Mickle, M., Rothfuss, M. and Gimbel, M. (2013). *Implantable doppler blood flow monitor and doppler probe*. US20130116575 A1.

Corrigan, R. (2014). *Radial compression hemostasis band with doppler confirming vascular patency*. US20140142615 A1.