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DESIGN OF A MINIATURIZED, AFFORDABLE, AND QUANTIFIABLE VASCULAR DOPPLER

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ABSTRACT

Peripheral artery disease (PAD) results from atherosclerotic plaque deposition on arterial walls causing reduced blood flow to affected tissue and can result in pain, tissue loss, poor wound healing, limb loss, and death. Diagnosis of PAD and clinical assessment of these patients requires the use of a vascular Doppler device. By emitting an ultrasound signal when placed over an artery and measuring the Doppler shift of the signal reflected from moving blood cells, this device produces an audio output descriptive of several blood flow parameters. As shown through multiple rounds of clinician interviews, current vascular Dopplers are expensive, bulky, and lack objective signal analysis. An improved vascular Doppler offering solutions to these problems was designed and prototyped. This prototype demonstrated a reduction in cost and comparable signal quality compared to Doppler devices currently available, and offered an opportunity for future development of automated signal analysis capabilities.

Keywords: vascular Doppler

1. INTRODUCTION

Proper circulation of blood throughout the body is necessary tissue health, wound healing, clotting, immune response, and homeostasis [1]. However, in certain disease states the flow of blood can be diminished, leading to problems with any of the above functions which may threaten life or limb.

A device commonly used to assess clinically significant abnormalities in blood flow is a vascular Doppler. Vascular Dopplers work by sending a pulse wave (PW) or continuous wave (CW) ultrasound signal into a blood vessel and converting the Doppler-shifted, reflected sound wave into audio. This allows the clinician to "hear" the patient's blood flow. Vascular Dopplers aid in diagnosing disease states such as arterial occlusion, arterial stenosis, embolism, thrombosis, arterial dissection, scarring due to repeated injection at a site in an artery, and, most prevalently, peripheral artery disease [2].

Peripheral artery disease (PAD) is the narrowing of blood vessels supplying the limbs due to accumulation of atherosclerotic plaque on the artery wall. This is the same disease process that occurs in coronary arteries of the heart as seen in coronary artery disease. PAD occurs primarily in the legs, but the same atherosclerotic process can also develop in the arteries of the head, neck, chest, and abdomen. This narrowing of the artery increases resistance to flow. The plaque can also rupture, and be carried downstream where it becomes stuck in a smaller vessel or can sometimes completely occlude the artery. The narrowing of the artery and reduced blood flow can lead to signs and symptoms including pain with walking, sores or ulcers, and poor wound healing. If complete blockage of an artery in the feet or legs occurs, as in the case of arterial occlusion, it can lead to gangrene or complete loss of the limb. A reduction in blood flow to the heart and brain is also a possibility, hence if atherosclerosis occurs in the carotid artery, it can cause stroke.

PAD is one of the most common disease states that are diagnosed through the use of vascular Doppler. An estimated 200 million people have PAD worldwide with 8.5 million of them being in the U.S. [3]. Some of the risk factors associated with PAD are high cholesterol, obesity, and old age. While the amount of people with high cholesterol is declining, an increasingly obese (39.8% of the population) and aging population [4] in the U.S. is expected to lead to an increase in PAD over the next decade [3].

Despite the increasing prevalence of PAD, current vascular Dopplers have seen little improvement in the past 20 years. Current devices are large, expensive, and require careful interpretation of audio output that is often times subjective. These limitations make vascular Doppler difficult to use and limit their potential applications.

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2. MATERIALS AND METHODS

In order to determine how to best create this improved vascular Doppler, multiple routes were considered. Initial design criteria were found from multiple rounds of voice of customer (VOC) interviews with clinicians ranging in training level from medical students to specialists such as vascular surgeons and interventional cardiologists. These criteria were weighed on a scale in terms of its feasibility, ease of use, cost, and marketability among other categories. This analysis produced a number of design inputs and outputs that would result in an improved vascular Doppler system. These results are summarized in Figure 1.

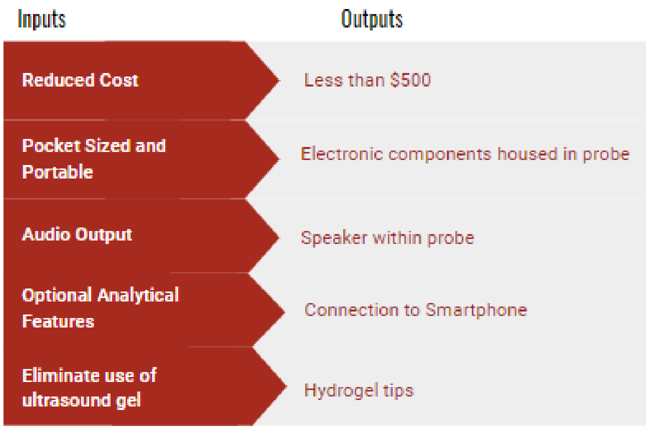

FIGURE 1. Design Inputs and Outputs. Various design inputs and respective design outputs found from the voice-of-customer interviews, competition analysis, and intellectual property analysis.

Features deemed necessary through this process included a sufficient speaker (60-70 dB output), a rechargeable battery (VOC showed a preference toward a reusable device compared to a disposable device), and a pocket-sized housing; all of which were implemented in the first prototype (Figure 2). It was also found that the amount of desired waveform analysis varied by training level: those with less training (medical students and fellows) wanted less waveform analysis features in order to reduce possible distractions and errors, while those with higher levels of training (specialists) were very interested in additional, objective waveform analysis features. Because keeping the device pocket-sized was at the forefront of its design, all components were picked with size in mind and soldered to a printed circuit board (PCB) before being fitted into the housing.

3. RESULTS

To create an improved vascular Doppler, the previous design outputs were combined into a single, compact device. Current vascular Dopplers both on the market and under patent only focus on fulfilling one or two of these improvements and none found were aimed at reducing cost, which would allow for wider use of vascular Dopplers as a non-invasive means of diagnosis. In order to achieve this improved device, all of the components were consolidated into a compact pen-like housing.

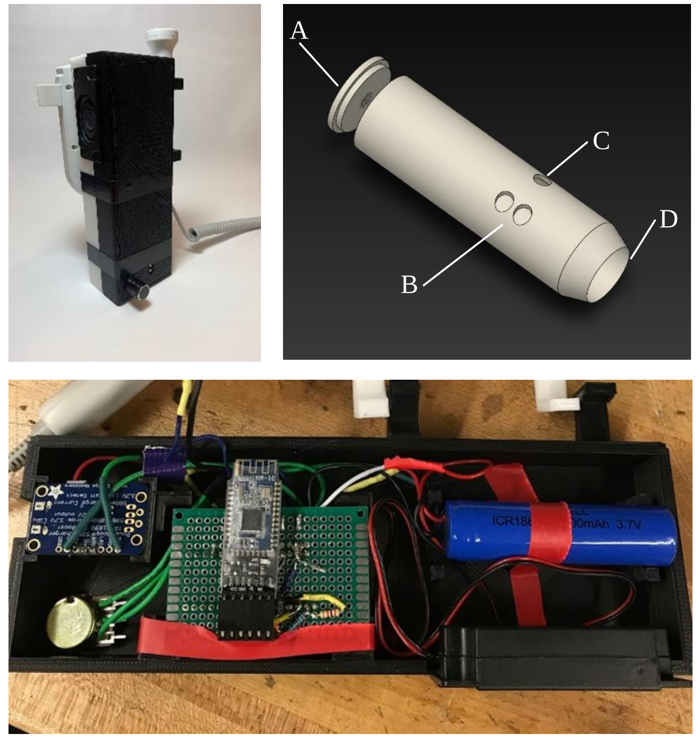

FIGURE 2. Vascular Doppler Prototype. Top Left: The current prototype of the improved vascular Doppler. **Top Right:** A Computer-Aided-Design Model of the next design of the vascular Doppler with parts labeled: A) speaker, B) volume adjustment controls, C) power control, and D) transducer. **Bottom:** Electronic components consolidated and soldered in a 3-D printed housing.

The various additional features including app connectivity, waveform display and analysis, adjustable audio output, and micro-USB recharging were designed to fit within this housing and take up as little space as possible. The app connectivity and waveform analysis circuit was implemented in order to provide users of the device the option to have additional analytical data to support the audio output from the probe, thus, complying with the needs of clinicians of all levels of training. It also reduced the size of the device due to the waveform analysis being able to be offloaded to the phone's processor rather than in the vascular Doppler.

Bluetooth Low Energy (BLE) was chosen as the communication method since it is available in most iOS [5] and Android [6] smartphones based upon the usage of the software in smartphones. Moreover, BLE also satisfies the design output of having a wireless connection spanning at least 10 meters allowing clinicians to maintain use of the device even when moving around during a procedure. The BLE connection currently sends data from the probe to the smartphone through the Blynk app, an interface with the ability to display waveforms, though a standalone app using Android is currently being developed. The PowerBoost 500C from Adafruit was used to build the rechargeable circuit. This board is about the size of a quarter and has a 3.7 volt lithium ion/lithium polymer battery connector allowing it to be powered by any battery with those specifications. The micro USB charging port on top of the board allows for easy charging of the battery as it is a popular format among other mobile devices and would likely be adopted faster than something with a proprietary design. The audio circuit provides the audio output for the blood flow velocity. This consists of an adjustable-volume speaker and audio processing circuit that is connected to the transducer (Figure 2). This enables the user to hear the typical blood flow signal in order to complete any necessary analysis such as ankle-brachial index without the wireless app connection. Additionally, the audio output can be heard across a typical exam room with signals from a potentiometer mapped to provide 8-bit volume control on the device itself.

The transducer is the system that transmits and receives the ultrasonic signal. This is accomplished by using two piezoelectric elements in a continuous wave format where one piezoelectric element is vibrated to produce the ultrasound signal which reflects off of the moving blood particulate and is then received by the second piezoelectric element. Two critical components of the transducer that are open to optimization are the backing and matching material layers. The backing material serves to establish an electrical connection between the piezoelectric elements and circuitry, and also to dampen any unwanted vibrations that may cause aliasing. The matching material's function is to ensure that the ultrasonic wave produced by the piezoelectric elements stays relatively unchanged as it passes through the transducer, across the coupling agent, and into the skin. What matters for this material is its acoustic impedance. For there to be the best sound transmission possible, the acoustic impedance of the matching layer should be as close to that of water as possible. The circuits for communicating with the transducer are based off that of Fuentes et al. [7] and adjusted to the design parameters determined previously. Despite a complete circuit diagram for the oscillator-transmitter and the receiver-demodulator in quadrature, we faced a secondary challenge determining the correct modern components required for the design, considering several components of the design by Fuentes et al. had become obsolete. Hence, a fetal Doppler transducer was used temporarily in the prototype for the transducer circuit.

In order to determine how well the transducer and circuitry worked in its current form, a comparison between our prototype and a vascular Doppler currently being used was performed. For this comparison, our prototype and the widely used Parks Medical Model 811-B vascular Doppler were each used to assess blood flow in the carotid artery of one of the team members. This audio was then recorded and graphed using a spectrograph for analysis. The two spectrographs were made using MSpectralPan from the Melda Audio software and can be seen in figure 4. Both the audio, analyzed qualitatively, and the spectrographs show similar features. The first and second optima representing the blood forward flowing from systole and the blood flowing backwards after the contraction respectively, were very apparent and easy to hear in both audio recordings, though the Parks Medical Model was more distinct. The third

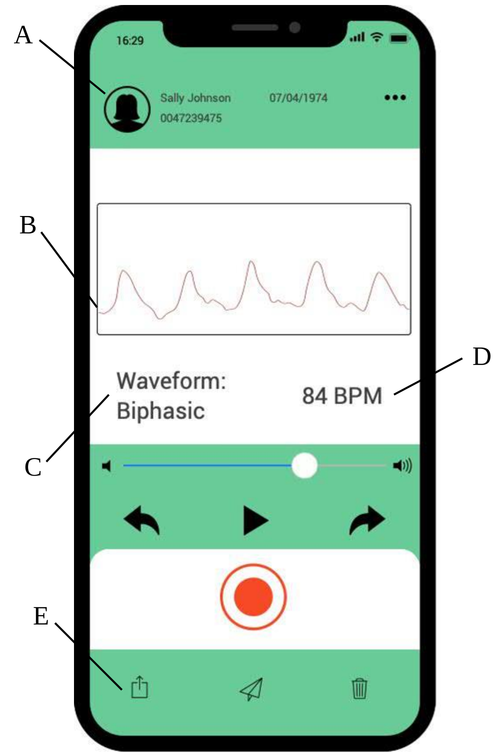

FIGURE 3. Mobile Application Mock-Up. The mobile application would serve as a companion to the BLE-enabled Doppler device and include A) patient summary, B) Doppler waveform display, C) automated waveform interpretation, D) heart rate, E) means to save the Doppler data to the patient's electronic medical record.

optima representing the contraction of the artery due to its compliance was difficult to hear in both audio recordings. It was also noted that there was significantly more noise in our vascular Doppler than the one currently in use.

Both of these qualitative observations can be seen in the spectrographs, as well. The horizontal peaks denote the initial forward-flow phase and the following lower frequency section appeared to correlate with the second backwards-flow phase. As can be seen in the spectrographs, the Parks Medical Model had a much greater difference between these sections. It can also be noted that in our vascular Doppler model, there appears to be a large, relatively consistent band of sound in a mid-frequency range. This is likely noise from both the vascular Doppler and the environment it was recorded in. Both of these phenomena quantitatively reinforce the qualitative observations that the Parks Medical Model had more distinct audio.

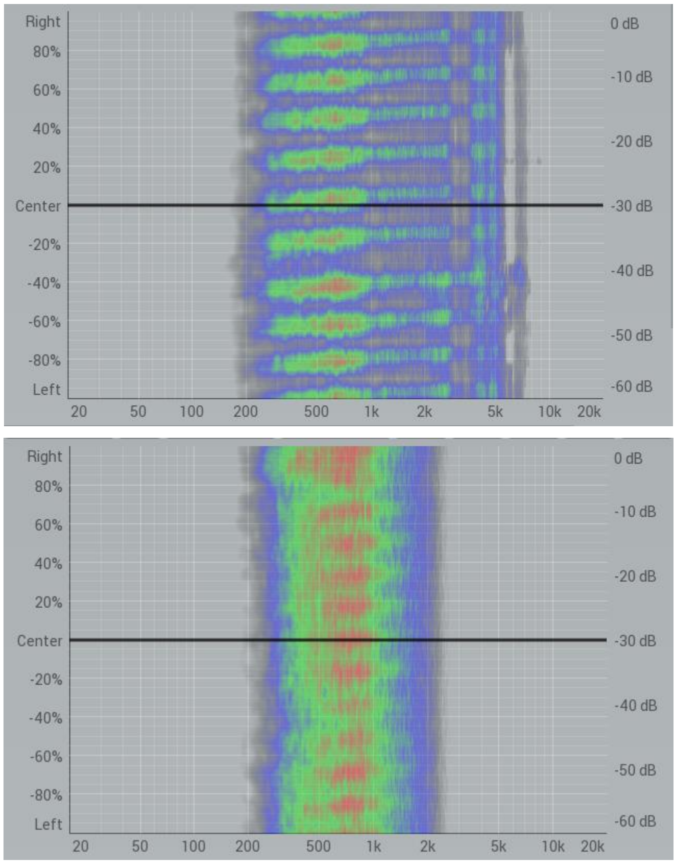

FIGURE 4. Spectrograph Comparison. Top. A spectrograph of an audio recording of the carotid artery from our improved vascular Doppler. The vertical and horizontal axis corresponds to time and frequency in Hertz respectively and the colors correlate to magnitude at the respective frequency and time. **Bottom.** A spectrograph of an audio recording of the carotid artery from a Parks Medical Model 811-B vascular Doppler currently in use at the University of Minnesota's MHealth Hospital.

4. DISCUSSION

An initial prototype of the improved vascular Doppler has been developed. This prototype has verified the feasibility of the improved vascular Doppler through the successful integration of the power/recharging circuit, the audio circuit, the BLE circuit, and a connection to a commercial fetal Doppler transducer.

The prototype is able to discern blood flow and output the corresponding audio signal similar to current devices. Audio from the prototype, however, had more noise and less distinction between the different phases of the blood flow. This difference is possibly due to the lack of any noise reduction software or hardware in our vascular Doppler and the fact that a 4-GHz fetal Doppler transducer is currently being used as the vascular Doppler transducer, while the Parks Medical Model used an 8-Ghz probe. This increase in frequency corresponds to an increase in sensitivity.

Alongside the audio output from the device itself, connection to a smartphone app would display and analyze the waveform, read the patient's heart rate, and allow the physician to save the data to the patient's file among other features.- A mockup of this app and the waveform display can be seen in Figure 3.

One of the major improvements seen even in this initial prototype is the reduced cost. Although it has a reputation among clinicians for having low sensitivity and a poor quality audio output, the most affordable vascular Doppler on the market has a retail price of $399 [8]. The preferred Doppler by most clinicians is the Parks Medical Doppler Model 811-B with a retail price of $710 [9]. The initial prototype of our proposed device can be had substantially cheaper, costing only $126 to produce including a premade transducer. Using a custom designed transducer is estimated to increase production cost to a total of $156 per device in the prototyping laboratory setting. Commercialization of this device would almost certainly lead to even lower production costs and a more affordable retail price. This will allow more clinicians to utilize vascular Dopplers and reduce issues in obtaining vascular Dopplers during procedures due to there being a larger supply in a given clinical setting. Working with manufacturers and customizing the circuitry could likely reduce cost further.

How this prototype addresses the various needs through its features can be seen in table 1. A particularly prominent feature that could be added is a hydrogel tip meant to eliminate the need for ultrasound gel (Table 1). This would act as a faster and more comfortable means of matching audio impedance between the skin and Doppler, and has incited the interest of a number of clinicians. This feature could be applied beyond just

Value Proposition		Proposed Solutions			
		Wireless Connectivity	Rechargeable Battery	In-house Audio	All-in-one Housing
Original Problems To Solve	Scarcity	✓	✓	X	✓
	Limited Portability	✓	✓	✓	✓
	Cost	✓	✓	✓	✓
	Subjective Waveform Interpretation	✓	X	✓	X

Table 1. Value Proposition. The proposed device would solve the four main problems found in current vascular Doppler models of scarcity, limited portability, cost, and subjective waveform interpretation.

the vascular Doppler market, expanding to fetal Dopplers and ultrasound devices. The team is currently verifying this need and will continue to develop the hydrogel tip. Other design aspects that will be improved in the future include improving the BLE connection by reducing and filtering noise, improving connectivity, and improving the conversion of the analog transducer signal to a digital signal to send to the app. The app will also be developed further.

Additional advantages of this prototype over existing Doppler models are found in the device's size and weight. The commonly used Parks Medical Model 811-B has a volume of 1,894 cm^3 and weights 1,360 g. Our prototype offers substantial size and weight reduction with a total volume of 974.5 cm^3 and weighs only 430 g. Comparisons between current devices and the proposed prototype are summarized in table 2.

. This prototype was not optimized for size but was meant to act as a test bed for the other circuits and large volumes were left empty to easily pass wires through. As we continue to iterate on the prototype, the size will be further reduced by optimizing the housing geometry and the packaging of electronics, and by creating custom electronic components rather than using premade ones such as the transducer. The team will also research how different manufacturing techniques could reduce cost, time to build, and size. This includes looking at different means of manufacturing the housing and how this scales with large scale production, how the cost of purchasing parts scales with bulk orders, and whether various systems' circuits (in particular the transducer circuit) could be outsourced to other manufacturers to reduce the cost and production time of the circuits.

	Parks Model 811-B	Prototype Device	Percent Difference
Volume (cm^3)	1,894	974.5	48.6%
Mass (g)	1360	430	69.4%
Cost (USD)	$710	$156	78.0%

TABLE 2. Comparison between Parks Medical Doppler device and prototype. The prototype device offers substantially reduced volume, weight, and cost.

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