Development of a Novel Ultrasound Probe Body Interface

Impact of Increased Access to Point-of-Care Ultrasound on Diagnostic Imaging Capabilities of Developing Countries

A Thesis Prospectus In STS 4500 Presented to The Faculty of the School of Engineering and Applied Science University of Virginia In Partial Fulfillment of the Requirements for the Degree Bachelor of Science in Biomedical Engineering

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

In busy hospital practices, procedures such as auscultation, where doctors examine cardiac and abdominal irregularities, are typically performed with the use of a stethoscope. While this method allows for diagnosis, it is limited by the fact that there is only auditory information available. In a study performed by a group of researchers from Texas Tech University, a mix of 89 health care professionals were tasked to detect various sounds using three different types of stethoscopes. Of the three, doctors using the high-end stethoscope performed the best, correctly identifying all of the sounds 69% of the time (Mehmood et al., 2014). In recent years, point of care ultrasound (POCUS) has gained increasing popularity (Sippel et al., 2011). The advantage of using a POCUS over a stethoscope is that it can scan the heart, lungs, abdomen, soft tissue, and musculoskeletal system. In most cases, the images obtained by the POCUS offer comparable or better images than an x-ray machine (Sorensen & Hunskaar, 2019). Due to the versatility and quality of POCUS imaging, it serves as a viable auscultation method as it allows for real time visual feedback and more accurate diagnosis of issues such as lung obstruction or irregular heart beats (Lewis, 2019). Dr. Ahmad (UT Galveston) claims that in the near future, POCUS will be an essential part of a doctor's everyday carry. He also advocates for the use of the device due to its ability to instantaneously transfer images to other doctors when second opinions are needed (Hall, 2018). With a traditional cart based ultrasound costing \$30,000, POCUS is a much more affordable option for doctors, costing only \$2,000 (Kuttler, 2018).

Another advantage of POCUS is that it allows for bedside imaging without having to transport the patient to the radiology room, see Figure 1 (Arnold et al., 2020). Despite significant advantages, the largest drawback of POCUS imaging comes from the gel that serves as the

interface between the device and the patient. In its current form, ultrasound gel is inefficient as it has to be wiped off and reapplied between each image. This process vastly reduces the number of hospital patients that are able to be seen each day. With these problems in mind, the goal of the capstone project is to develop a reusable alternative to the current gel that will make POCUS a more viable alternative to the stethoscope in procedures such as auscultation.



Figure 1. A point of care ultrasound device (Thoma, 2013)

Technical Topic

In its current form, the doctor uses the smaller side (bell) for lower frequency sounds, and the larger side (diaphragm) for higher frequency sounds, see Figure 2 (Ultrascope, 2021). There are a number of potential spots for sound to be obstructed while traveling from the chestpiece to the eartips such as outside noise entering the tubing, that factor into the diagnostic limitations.

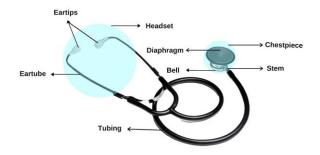


Figure 2. The parts of the stethoscope (Rudolf, 2021)

As previously mentioned, one of the major barriers preventing POCUS from being a widespread and utilized alternative to the stethoscope is the current ultrasound probe-body interface. Ultrasound gel is a sticky, single use, gel substance made of a mixture of water and propylene glycol (Premier Ultrasound, 2014). Because auscultation requires listening to multiple areas of a patient's body, the ultrasound gel would need to be wiped off between each application on a new body part. This is a long and tedious process that busy hospital practices cannot afford to take on. In addition, the gel is cold and often uncomfortable for patients. To remedy this, some doctors choose to warm the gel prior to application which adds to the total time for the procedure (Annis, 2021).

In an effort to overcome this limitation, a novel ultrasound interface made of a double network hydrogel will allow for a reusable medium with comparable image quality. The hydrogel will be crosslinked with polyacrylamide and alginate. Each of these substances have been shown to have low cytotoxicity, making it safe to apply to the skin (Yi et al., 2020). Because the hydrogel is primarily composed of water, the interface will not impede ultrasound transmission. The reusable nature of the hydrogel will allow for easy application and removal, which will reduce the time it takes to complete the procedure. By closing the gap between the

time it takes to perform the exam, POCUS will be able to serve as a more accurate diagnostic tool without compromising patient throughput.

To determine the success of the double network hydrogel, it will be analyzed in terms of its biocompatibility, the material durability, and total time to perform auscultation in comparison to the stethoscope. Because the hydrogel will be in contact with patient skin, it is essential that the polymers used will not cause a negative reaction during the procedure. Both polyacrylamide and alginate have been shown to have low levels of toxicity (International Journal of Toxicology, 2005). The mechanical properties of the double network hydrogel make the surface very tough and resisitant to tearing. This will aid in the capability of repeated uses of the material. Finally, while the time of the procedure with the POCUS will not be less than that of the stethoscope, it will close the gap created by the current gel procedure.

It is expected that by successfully developing te double network hydrogel, doctors will be able to increase their imaging efficiency and overall patient throughput. While my technical project focuses on the development of a reusable point of care ultrasound probe-body interface, my research interest is focused on the implementation of point of care ultrasound in developing countries and the impact it will have on diagnostic imaging capabilities.

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Analyzing the effects of increased access to diagnostic imaging

For my thesis, I will answer the following research question: How should point-of-care ultrasound be introduced into developing countries to ensure successful implementation? Diagnostic imaging is currently significantly limited in developing countries. In 2016, a team of researchers from Stellenbosch University conducted a study to evaluate the disparity in the number of imaging devices in Tanzania vs. South Africa. The results of the study found that in the public sector, Tanzania has 5.7 general radiography devices per 1 million people. This is far short of the World Health Recommendation of 20 devices per 1 million people. South Africa, on the other hand, spends a significant amount more on healthcare and has 19.7 general radiology devices per 1 million people (Ngoya et al., 2016). By answering this research question, strides can be made towards closing the gap in diagnostic imaging between developing and developed countries.

Various forms of data will be collected to develop an answer to the question. To start, I will collect data on healthcare spending in the United States, Tanzania, Uganda, and Afghanistan. Looking at these countries' healthcare spending will provide insight to why the developing countries are unable to afford the medical devices they need. Data on previous attempts for medical device donation in Tanzania, Uganda, and Afghanistan will also be collected. This data will information regarding what the major successes and pitfalls have been in getting devices implemented in these countries. Case studies will be performed to analyze this data and determine where there need to be improvements in the donation process to ensure successful donations moving forward. By analyzing the prior cases and healthcare spending, the proper implementation process can be determined to ensure improvement of healthcare in developing countries.

Conclusion

Stethoscopes are an inaccurate technology that could be replaced by point-of-care ultrasound. Real time image formation and more reliable and accurate diagnoses set POCUS apart as the ideal candidate for auscultation examinations. Currently, the single use nature of ultrasound gel makes it less efficient and more time consuming than the stethoscope in busy hospital practices. It is proposed that the development of a double network hydrogel consisting of polyacrylamide and alginate will provide a reusable ultrasound medium that produces comparable image quality. This technology will increase the efficiency of POCUS, in turn making it a more viable alternative to the stethoscope. The impact of this technology will be increased patient throughput in busy hospital practices as well as more accurate diagnoses which will increase overall patient health. The research topic aims to evaluate the impact of POCUS introduction in developing countries on diagnostic imaging capabilities. It is expected that by answering this question, the need for increased POCUS accessibility will become more apparent.

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