DEVELOPMENT OF AN ARRAY BASED, TRIANGULATION APPROACH TO FETAL HEART RATE MONITORING FOR MULTIPLE GESTATION PREGNANCIES

AN ANALYSIS OF THE PULSE OXIMETER THROUGH A SOCIAL CONSTRUCTION OF TECHNOLOGY FRAMEWORK

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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October 27, 2023

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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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General Research Problem: Closing the Gaps within Healthcare

How does differing from the "norm" influence patient experiences and outcomes in clinical settings?

Developments in medical technology have contributed to the improvement in health outcomes for millions of individuals. Nevertheless, gaps persist, such as the technical limitations of the current Doppler ultrasound (US) fetal heart rate (fHR) monitor. Doppler US transducers experience frequent periods of signal loss and are only capable of accurately focusing on a single heart rate; challenges arise in the discernment of multiple distinct heart rates within close proximity, which is common in multiple gestation pregnancies. Multiple gestation pregnancies, such as twins, triplets, and higher order pregnancies, are categorized as higher risk, resulting in premature births, contributing to lower birth weights and smaller sizes for gestational ages (Gill et al., 2023). With the fetal and maternal mortality rates being 2-3 times higher for African-American women and infants than their white counterparts showing a clear relationship between race and outcomes (Hoyert, 2023). Considering the obvious health disparities in pregnancies, complex sociotechnological improvements must be made to the Doppler US transducers to improve multiple gestation infant outcomes in order to begin closing the gaps. The leading accepted method for evaluating fetal health *in utero* is the fHR monitoring (Hamelmann et al., 2020). However, this technology is only well adapted for a traditional singleton pregnancy and presents major reliability concerns with measuring fHRs in multiple pregnancies. Additionally, the monitor itself puts the birthing person in additional discomfort due to the monitor covering the lower back obstructing the site for epidural administration to manage the pain associated with childbirth (Hamelmann et al., 2020).

Furthermore, advancements in medical technology, being socio-technical in nature, are susceptible to racial biases in both development and implementation by healthcare professionals. This bias is evident in pulse oximeters calculating an overestimation of the blood oxygen levels of individuals with darker skin pigmentations (Sudat et al., 2023). The structural racism woven into the fabric of society has influenced the development of technologies. The advancements in healthcare diagnostic and treatment technology are often clinically tested on homogenous groups, primarily non-hispanic white males. Therefore, the flaws in current technologies, especially in diagnosing people of color, contribute to delayed treatments and worse outcomes. To address these systemic issues, there is a critical need for the medical system to reevaluate the certification process for new and existing technologies. Since many medical technologies were invented and shaped by the "standard" patient therefore, marginalizing those that did not fit into this standard. This reassessment should be inclusive, considering the diverse experiences of individuals based on gender and race, to ensure that advancements in medical technology benefit everyone equitably.

Technical Research Question: Array Based Triangulation Approach to Fetal Heart Rate Monitoring for Multiple Gestation Pregnancies

How can Doppler ultrasound transducers be modified to more accurately calculate and differentiate fetal heart rates in multiple gestation pregnancies?

Multiple gestation (twins, triplets, etc.) births account for approximately 3% of all live births in the United States (Gill et al., 2023). A significant proportion of these births are preterm, leading to low birthweight and additional health complications for the newborns. Given the heightened risk associated with multiple gestation pregnancies, technological advancements are necessary for improving fetal monitoring. As previously mentioned, the predominant method for assessing fetal health during labor and delivery is fHR monitoring. Doppler ultrasound (US) functions as the *de facto* technology for fHR monitoring in clinical practice (Hamelmann et al., 2020). Utilizing Doppler US, fHR deviations from the healthy range of 110 to 160 beats per minute (bpm) may serve as indicators of potential issues such as insufficient oxygen supply or other serious conditions for the fetus (Pildner von Steinburg et al., 2013).

Despite the widespread use of the Doppler US, there are known limitations. These consist of inaccurate beat-to-beat estimation of fHR, frequent periods of signal loss, particularly severe in the case of multiple gestations, and restriction of efficient epidural administration due to lower back obstruction. Epidurals are commonly used medical interventions for pain management during labor and delivery. Moreover, the current design of fHR monitors is tailored towards measuring a single heart. In multiple gestation pregnancies, the close proximity of the fetal hearts *in utero* poses challenges in isolating and differentiating each fHR using the traditional method. Therefore, to test our experiment we must develop a physical model capable of replicating the tissues of the maternal abdomen during pregnancy. This necessitates the insertion of sound-emitting devices into phantom gel engineered to replicate the acoustic impedances of the abdominal tissues. Concurrently, there is continuing modification of an existing algorithm designed to accurately identify and distinguish multiple heart rates without necessitating device repositioning.

This project aims to address these challenges through the following objectives: improving the integration of sound-emitting devices into a phantom gel, designed to mimic the tissue layers of a birthing person abdomen, redesign the method for securing the device to the maternal abdomen the Doppler US device to ensure compatibility with epidural placement, and continue the development of an advanced algorithm for accurate triangulation of multiple fetal heart rates. These tasks will be completed via the following methods.

Initially, my team and I will develop a phantom gel model that is capable of replicating the acoustic impedances of the main layers of the abdomen. The tissue layers we have chosen to recreate are the uterine lining, adipose (fat) tissue, muscle (abdominal) tissue, and skin tissue. In addition to replicating the acoustical impedances, the phantom gel will also mimic the thickness of these layers to account for an accurate depth and tissue interference. The phantom gel will most likely be produced using a gelatinous mixture to reduce costs and allow for easier creation. An array of sound-emitting devices (minimum of three) will later be implanted within the phantom gel to produce fetal heart rates and the heartbeat of the pregnant person. In order to calculate the acoustical impedances of the phantom gel, we will measure the density and use the speed of sound in gelatin. A drawback in this design is the inability to accurately replicate fetal movements, which often occurs *in utero,* during these measurements; however, we plan to mitigate this simplification by creating multiple phantom gels with varying sound-emitting devices placements.

The second phase of our experiment will be to design and create a Doppler US monitoring device capable of differentiating and measuring at least two fetal heart rates within the uterus. Measurements will be taken from several locations across the gel to collect the most amount of data in the abdomen. We will test the efficacy of the device by comparing the measured heart rate outputs from the device with the known inputs from the sound-emitting devices. A final aspect of the project is to redesign the method for physically securing the device to the birthing person. The current method requires that a strap be wrapped over the abdomen and lower back of the individual leading to an obstruction when attempting to administer an epidural for pain management during labor and delivery. Through shadowing labor and delivery, as well as interviewing OB/GYNS at UVA Health, we will determine the functionality and requirements for securing the device. Our success with this project will allow for further experimentation eventually leading towards human testing and increased comfort for the birthing person.

An Analysis of the Pulse Oximetry Through a Social Construction of Technology Framework

How have inaccuracies in pulse oximetry readings affected treatment and outcomes of patients with darker skin pigmentations?

Pulse oximeters have become indispensable in healthcare, as a quick and noninvasive medical diagnostic way to measure an individual's blood oxygen saturation (SpO_2). Blood oxygen saturation is a widely used metric in clinical settings as oxygen is influential on several major organ systems (Hafen & Sharma, 2023). However, as the COVID-19 pandemic has come to an end, concerns regarding the accuracy have emerged as studies showed that African Americans experienced higher rates of under detection of hypoxemia (Sudat et al., 2023). This led to statistically significant differences in their time to recognition of treatment eligibility having clinical consequences since, hypoxia was the leading cause of in-hospital mortality during the COVID-19 pandemic.

Furthermore, the pulse oximeter functions by emitting 2 different wavelengths of light, red and infrared (IR) (660 and 940 nm) through the skin. These wavelengths are absorbed by the oxygenated and deoxygenated hemoglobin in the blood and the differences in absorption are used to calculated SpO_2 (Tekin et al., 2023) A significant discrepancy for these devices is the inaccuracies in calculation of SpO_2 for individuals of darker skin pigmentations (Sudat et al., 2023). SpO_2 levels for African-American patients are frequently over-estimated due to unavoidable interaction of melanin, the pigment responsible for skin color, with the wavelengths transmitted through the skin (Cabanas et al., 2022). This interaction leads to miscalculations in blood oxygen levels which affect the clinical interventions taken, such as how much and when supplemental oxygen should be administered.

Due to the structural racism that is deeply rooted in all parts of American society has been influential in the development of this technology. The breakthrough of the pulse oximeter was invented back in the 1970s by Takuo Aoyagi in Japan, a country of nearly homogeneous racial makeup with lighter skin tones (Severinghaus, 2007). Unfortunately, structural racism in the US has limited the inclusion of diverse groups in clinical trials, therefore when the device was introduced in the US it was primarily tested on individuals with lighter skin tones for decades (El-Galaly et al., 2023). The medical community has had unfounded theories regarding the genetic and physical differences between non-hispanic whites (NHW) and non-hispanic blacks (NHB) that have existed since slavery in the US. Early doctors and researchers would justify the unequal treatment of African Americans through medically unproven stereotypes such as denser bones and higher pain tolerances (Habib, 2023). Though now when a medically proven physical difference has an effect on their treatment very little has yet been done to resolve this discrimination. Additionally, following the COVID-19 pandemic the prevalence of this bias created by pulse oximeters has become increasingly reported and few groups have begun to address these disparities. My analysis of pulse oximeters will take the science, technology, and society theory of social construction of technology (SCOT), which states that culture and society shape technological developments rather than technology shaping society (Pinch & Bijker, 1984). I argue that the structural racism in the United States heavily influenced the guidelines and the design specifications for the pulse oximeter creating a disparity for African-American patients. Through a deeper inspection of the societal views towards people of color the SCOT framework will help show the influence society has had on the development and testing of the pulse oximeter. To prove this hypothesis I will be using an assortment of articles discussing structural racism in the US, the pulse oximeter functionality, the influence on COVID-19, and the current ways this issue is being addressed.

Conclusion

Through the STS research paper the complex interactions between society and the development and implementation of pulse oximeters can be evaluated. This analysis will be done using a SCOT framework to understand the social and cultural influences that have shaped pulse oximeters and the resulting effects of their influences. The technical project discussed in this paper will deliver a novel ultrasound phantom gel capable of replicating the abdominal tissues of a pregnant person while also producing a novel Doppler US fHR monitor that will successfully detect and differentiate the heart rates between at least two fetuses *in utero*. The combined effort of the STS and technical projects will attempt to address the issues related to medical technologies and their preference towards treating the traditional patient. Although the topics are inherently independent, the understanding of the racial and ethnic implicit biases that were used in designing the pulse oximeter can guide the ethical development of the proposed Doppler ultrasound systems.

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