DEVELOPMENT OF A RELIABLE ACOUSTIC COUPLING SYSTEM FOR MEDICAL ULTRASOUND IMAGING

HOW DO DIFFERENT USERS IN THE MEDICAL NETWORK USE ULTRASOUND IMAGING TO MINIMIZE RISK FOR THE PATIENT?

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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 2006, 380 million radiologic procedures and 18 million nuclear medicine procedures were performed in the US; this volume accounts for nearly one-half of the worldwide nuclear medicine procedural use while US patients only comprise of 4.6% of the global population (Crownover & Bepko, 2013). The drastic increase in imaging procedures can be associated with the sixfold increase in annual per capita radiation exposure. This downstream increase in exposure to radiation is a great cause for concern on patient safety and has normalized more intensive risk analysis of incorporating imaging into treatments. However, lack of imaging guidance has contributed to more negative patient experiences along with less accurate treatments as they aren't as precisely targeted (Wagner, 2004). For treatments that require a more localized target in the body, the lack of precision with blind injections can greatly diminish the treatment potency. For example, Lee et al. showed that optimal outcomes were observed in 70% of sonographically guided tendon injections and in only 15% of blind injections (Lee, et al., 2011). Additionally, blind injections can result in increased pain experienced by the patient (Porras & Berkoff). Therefore, both ends of the spectrum have their own pros and cons that need to be evaluated in risk analysis.

One aspect considered in the risk analysis is the necessity of the imaging procedure. Medical professionals from the University of Michigan have investigated the prevalence of over-imaging and how modern society has encouraged this shift (Joy, 2016). Over-testing in low-risk populations can return false positives, detect benign irregularities, and waste unnecessary resources and money. Additionally, the pressure from different actors in the medical network, such as insurance companies and general vs. specialized practitioners can enable unnecessary imaging (Livingston, 2017).

The technical focus of the capstone project is evaluating product reliability and efficacy by assessing different subsystems of an imaging device that falls intermediary on the above mentioned imaging spectrum. The STS focus of this thesis concentrates more on how different actors in the medical network perform risk analysis when choosing existing imaging procedures for patients along with current fallibilities in the system

Technical Report

Ultrasound imaging procedures lie on a spectrum between no imaging guidance to full interventional guidance techniques; both ends carry their own pros and cons. Currently, doctors are forced to evaluate risks and account for pain management, along with patient considerations, when ordering certain types of imaging for patients (Committee on Diagnostic Error in Health Care, 2015). This struggle is in part due to the large number of available test and current gaps in teaching from medical schools. For example, lumbar epidural injections can be performed blindly or with CT fluoroscopic guidance (Wagner, 2004); the former has an increased chance of inaccurate injections and patient pain. Guided injections, albeit ensuring more accurate needle placements and less pain, may not be recommended because of time, radiation dose, low accessibility, and cost (Daniels, 2018). Rivanna is working to create an intermediary device that is able to produce effective and robust 3D images that don't require too interventional of a procedure. The translational function of the device will allow different medical specialties to take advantage of the device's imaging capabilities. By finding a balance between imaging guidance and accuracy, ultrasound imaging can become a more accessible and safer option for patients.

The overall objective of the technical capstone is to assist in the development of a 3D ultrasound imaging. The information below was provided to us by our technical advisor, Zachary Leonard. This objective will be accomplished by evaluating the product reliability and efficacy via test fixtures, that we develop, and subsystem compatibility. The team is expected to develop a test fixture for the motors on which the image-capturing arrays will be performing the sweeps. This fixture will need to evaluate the performance and reliability of the image acquisition hardware along with image analysis to evaluate the produced images. Additionally, the team will develop and evaluate various subsystems of the ultrasound imaging device to ensure high product reliability. Subsystems such as the acoustic coupling fluid system and flex circuit, will be integrated into the device design; the team is expected to optimize subsystem design or choose the best one based on overall compatibility, use-life, and function. The design specifications for the test fixtures will depend on the intended purpose of the image and expectations for its use, which will learn by interviewing employees in the company.

The above objectives will be achieved through external resources (experts in the field), individual research, and in-lab testing. Most Rivanna employees specialize in motor hardware, imaging mechanics, and test fixture design; their feedback and guidance will help focus and shape our individual efforts. A majority of the rationale behind our work will rely on research in certain programming software, such as Arduino or NanoJ, motor mechanics, and design considerations; the research will not only improve our understanding but also reveal what others have done in the past and what techniques have provided the best results. Lastly, we will be able to put our rationales or ideas into practice by testing with the equipment such as experimenting with NanoJ programs on a brushless DC motor and a wired microcontroller.

Current available resources are all the necessary equipment such as motor types, 3D printers, all necessary wirings, sodder tools, etc.

By designing and evaluating the accuracy of the actuator and dosing system, we expect to develop a reliable acoustic-coupling system that assists in obtaining fluoroscopy-like 3D image models.

STS Topic

Medicine is slowly shifting towards a patient-centered care, working towards not only diagnosing and treating any illnesses but also taking into account patient comfort, emotional/mental health, and any minor risks. It's important to value the patient as a human and not view them as a problem that needs to be solved. However, with so many different actors in the medical network, varying in priority and importance, it is easy for that patient focus to be lost behind other facets such as over-reassurance under the guise of maximizing patient survival or optimizing resource usage while minimizing unnecessary waste. The focus of this thesis will be on analyzing the risk analysis procedure in the current system, identifying weak points and fallibilities and what risk they pose to the end user or patient.

The framework used to conduct the investigation in this thesis will be Actor Network Theory (ANT). The different entities and actors in the medical network that impact risk analysis and the drawn conclusions will be analyzed along with the different relationships between them. Additionally, how those relationships change based on the patient's needs and wants will be analyzed.

Over-imaging or over-testing is one of the strongest areas of debate and controversy. It can be caused by many different incentives. Patients who have better access to resources tend to be those who undergo over-imaging; a study by the Department of Veterans Affairs health care facilities found that in two of the same outpatient groups, those with Medicare, compared to those with no healthcare, had an imaging rate that was 3x greater (Joy, 2016). This highlights two problem areas in the system; (1) the inherent discriminative nature of medical insurance can prohibit certain minorities (based on socio-economic status, race, sexual orientation, etc.) from having access to imaging procedures and (2) those who do have more privileged insurance are wasting more resources and potentially experiencing unnecessary risks to their health. James Burke, a neurologist at the University of Michigan stated that nearly half of patients with migraines get unnecessary MRIs, a "pre-emptive action fueled by 'a culture where we like to be reassured'" (Joy, 2016). This societal norm is difficult to diagnose because with more precise and advanced technology, it is difficult to not want to take advantage of those resources to ensure one's health is fully understood. Additionally pressure for medical professionals to undergo imaging procedures continues to instigate this issue; doctors' motivation for prescribing testing is fear or malpractice claims that a problem was overseen. Nearly 52% of the major reasons a doctor orders test is malpractice concerns; this way of thinking rivals the progressive shift towards patient-centered care. It encourages the two problems described above, enabling the disparities in who has access to imaging through unnecessary waste of resources. Additionally, physicians struggle in finding a balance between providing "optimal and compassionate medical care on the one hand, while limiting the unnecessary use of resources on the other" (Litkowsky, 2016).

Additionally, another dimension to risk analysis is focused on direct adverse effects such as radiation exposure or increased risk of introducing carcinoma to patients that drives doctors decisions to ordering tests. This also focuses more on primary care physicians' relationships with radiologists. Authorities in the field such as the U.S. Department of Energy or the American College of Radiology (ACR) have established standard limitations to how much radiation exposure risk patients can healthily experience. An example of a medical resource to assist in appropriate use of imaging is the nine-point scale, set up by the ACR, that uses expert consensus panels to rate test necessity (Crownover & Bepko, 2013).

There is also a disconnect between different actors in the medical network. For example, whole body scans are not recommended by most specialized medical authorities, especially for patients who are asymptomatic or don't present any red flags (Crownover & Bepko, 2013). The FDA prohibits CT system manufacturers from advocating whole-body screening to asymptomatic people (FDA, 2019); however, they're unable to prevent practitioners from that advocacy. The lack of consistency in regulation can easily confuse patients, especially those who aren't familiar with the medical field. With an already existing medical mistrust from the general public, a lack of open and transparent knowledge exchange between medical network actors and the patient can encourage unnecessary imaging procedures. Quick Google searches of whole-body screening recommendations subtly contradict more thorough academic research by implicitly advocating for whole-body screenings without divulging risks such as radiation exposure.

In developing this thesis and investigation, different stakeholders and actors in the medical network were identified: specialized physicians, general practitioners, the Internet, insurance companies and their policies, general public's perspective of medicine, hospital systems, and medical societies. Multiple articles have described the ongoing conflict between how insurance companies and hospitals handle imaging finances and how those policy changes affect patients (Litkowski, 2016) (Livingston, 2017). For example, due to hospitals overcharging, Anthem changed their insurance policy so that they wouldn't cover any imaging cost that were performed at a hospital unless they were deemed necessary; hospitals tend to overcharge for imaging to make up for other financial losses (American Health Imaging, 2018). For the thesis, a more in-depth investigation on how different insurance policies for imaging impact patients and the medical network will be explored via policy document and news articles. Additionally, the relationship between medical societies and specialized vs. general practitioners with respect to imaging protocols will be explore. For example, the American Board of Internal Medicine launched the Choosing Wisely campaign in 2012 to curb use of diagnostic imaging (Litkowski, 2016). Different medical societies and their clinical guidelines will be analyzed along with if and how they're being implemented by practitioners; additionally, if there's a consistency in which types of practitioners are following them will be explored. Google searches will be completed to see the stances that the most accessible/popular websites have on imaging; these are typically the first information patients will receive outside of their doctor. Figure 1 visualizes the actors in the network and how each are related to the patient with respect to imaging (end user). The colors represent proximity of impact with yellow meaning the most direct relation to the patient and blue meaning the most indirect relation. The lines connecting different actors represent their relationship to each other; those with gradients represent a bidirectional connection while a solid color mean a unidirectional connection. Additionally, the degree of gradience can indicate that one actor has higher amount of control in that relationship. For example, at first glance, it can be noted that specialized physicians and hospital systems will have the most direct impact on risk management for a patient's imaging. However, medical societies and the general public won't interact with the patient but will impact actors that interact with the patient. This series of relationships and connections will be more thoroughly explored in the thesis.

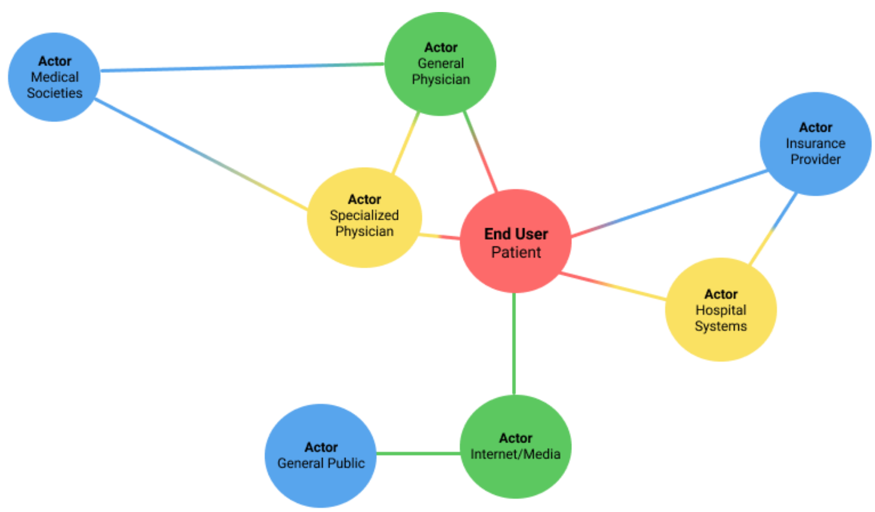

Figure 1: Visualization of different actors in the network and the direction of different relationships with respect to the patient

Next Steps

Capstone related:

- Implement test fixture into existing work (motor software, wiring, flex circuit design)
- Research acoustic coupling fluid and determine design specifications
- Learn more about restrictions regarding device compatibility
- Integrate all subsystems with each other to evaluate product reliability

Thesis related:

- Dive more into this issue with the STS framework: Actor Network Theory
- Identify more of the actors or entities in this framework that impact risk analysis
- Identify more problem areas in the system and back up with more evidence

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