Development of Novel Ultrasound Probe-Body Interface

The Case For Capitalism

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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:

The Stethoscope has been used since 1816[19]. It can be used to check a patient for various health conditions. Conditions like[13]: heart murmurs and gallops, heart valve leakage, low blood pressure, check a patient's breathing and find lung abnormalities, ruptured veins, discover abnormal blood flow (bruits), identify bowel sounds, and can even measure the size of a liver. Identifying all of these conditions requires training and experience to try and find out if the whooshing sound you hear is a bruit, a ruptured vein, or your patient's breathing. What initially stopped ultrasound from being more widely used, in everyday medical care, was the size of the machine. Early ultrasound machines from 1960-1997[9] were big bulky machines that needed to be in their own room and couldn't be easily moved into a patient's room. After that time frame they became more mobile and accessible until 2010 when cart and even handheld models became more reliable[9]. Handheld ultrasound devices are now the norm in ultrasound devices and can be used for everything the Stethoscope can be used for and more. These handheld ultrasound devices can also be used to monitor babies in the womb, check the integrity of veins and arteries, and monitor vital organs like the heart and lungs. However, a new barrier to ultrasound's efficient use is the need for the use of ultrasound gel. Ultrasound gel serves as a material interface between the ultrasound probe and the human body, so clear images can be produced without interference from the air. The application and removal of this gel is a time-consuming process. For the general practitioner to examine their patients in a time-effective way, a faster alternative to ultrasound gel must be developed. Materials like PDMS silicone have been proposed as an interface material[1]; yet, no product or material has been designed for the criteria and constraints that is needed to replace ultrasound gel. The goal of this project is to find a suitable material replacement for the ultrasound interface. We first intend to find non-toxic interface materials that can pass FDA sensitization and irritation tests. These materials must have a similar acoustic impedance value to soft tissue to allow for the capture of clear images, and also be able to maintain their physical integrity while being form-fitting to the human body. Second, we intend to test the materials for the clarity of image they produce and to select and develop a prototype to conform to the handheld ultrasound transducer.

Technical Discussion:

The purpose of the ultrasound gel is to get rid of any air between the patient and the ultrasound probe[2]. This is important because air has a different acoustic impedance value than soft flesh. So the ultrasound waves will be distorted when they return to the ultrasound if they travel through the air. Which will then produce a distorted image. As stated before the purpose of this project is to find a replacement for the gel that doesn't require as much cleanup as gel and can be used quickly and efficiently. To start finding an alternative for ultrasound gel me and my partner, Thomas Dugan, began by looking at prior art and various articles that talk about ultrasound gel and suitable replacements.

There are many common ultrasound gels that have been used to give crisp and clear images of ultrasounds. Some of the gels used are: Aquasonic gel, Scriphessco gel, and McKesson gel. The one our Capstone Project Advisor uses is the Parker Aquasonic gel. Ultrasound gel has a similar impedance value of soft flesh. Soft Flesh has an impedance value of 1.63 MRayls[7] and most ultrasound gel is around 1.5 MRayls[7]. This value does not match perfectly but still provides clear images of the body's interior due to having a sufficiently low reflection coefficient. Variants of ultrasound gel do exist, most notably we found a couple of “homemade” versions of ultrasound gel. An interning primary care physician developed a version made by boiling guar gum and water with salt to be used in countries that don’t have ready access to ultrasound gel[4]. Another variant is a gel made with cornstarch, cassava, flour, and salt. Not only are these ingredients more readily available than most ingredients of standard ultrasound gel (like propylene glycol and glycerine). They are simple recipes that can be transported and made in less ideal conditions. However, in the hospital environment, these alternative gel formulations do not fulfill the design goals for this project, as they are essentially another way to make ultrasound gel.

Our approach for a new ultrasound interface differs from prior examples in that we are trying to find a gel pad that can be reusable and time-efficient, minimizing the cleanup after its use. Our intended material design is a silicone elastomer, which must have an acoustic impedance similar to soft tissue, be non-toxic when in contact with skin, and maintain its physical form. Certain silicones are known to be non-toxic and to maintain their physical integrity; the main focus of our project will be to find the impedance values of materials so clear images can be given when used in ultrasound. As previously stated we discovered that the impedance value of soft tissue has been averaged around 1.63 MRayls[7]. We then looked at various materials that have impedance values around 1.63 MRayls and found a material, PDMS silicon, that could be used as viable replacements. We have ordered a couple of samples of possible PDMS hydrogels that have impedance values of similar value and have an Elastic Modulus of around 2.6 MPa. The next step is to acquire all the materials we deemed suitable replacements and test them in the lab and find out if they can be a viable substitute.

We will test the elastic modulus of our samples by putting them in an Instron machine. While the samples all have an elastic modulus of around 2.6 MPa we can alter their elastic modulus by using different levels of crosslinker. To do this we will be altering the amount of crosslinkers in each sample we make by 10% from 70%-100%. So we can find the optimal elastic modulus for our gel. With the more crosslinker added the higher the elastic modulus our gel becomes. We can also bring our samples to medical practitioners and get a peer review of our samples by asking them which amount of crosslinker they like when performing Ultrasound.

The next step of testing is taking our samples and using them in ultrasound so we can see if they are a viable ultrasound interface. We will develop a quantitative test for clarity of ultrasound image using handheld transducers, possibly using wire phantoms. It may be necessary to borrow transducers from ultrasound faculty for testing, as integration of the handheld transducer available may be impractical. With the test we'll develop we can also test to see if the varying amounts of crosslinker affects the ultrasound image.

The next step is determining how selected materials interact with 70% isopropyl alcohol cleaning solution. Since we want our gel to be reusable we must see if there is degradation from the cleaning solution. We will retest its physical properties after each cleaning over time to see if physical integrity is maintained. After testing we will review the images and data we have gathered and see if they can compare to our control of regular ultrasound gel. Within a nine month period we will continue testing like this until we find a suitable replacement.

STS Discussion:

The impacts of this technology, if we are successful, are various, but each would have a positive impact on everyday quality of life. Since the entire goal of this project was to make an easier and more efficient ultrasound interface for everyday clinical use. Our advisor, Dr.

Morikawa started this project because he saw that an improvement could be made when he was performing ultrasound on his patient's. He found that the need to apply and wipe off ultrasound gel from patients was limiting how quickly multiple patient's could get an ultrasound. So he first tried to develop a solution himself and then moved to getting student help in the form of developing a Capstone project.

If we are successful in making a new ultrasound interface we could cut the costs on the ultrasound process itself. Right now a five liter bag of ultrasound gel costs around twenty to twenty-five dollars. With ultrasound gel being needed for multiple appointments every day, pregnancy check ups, monitoring internal organs, and examining the integrity of veins a lot of gel is used. A monthly budget dedicated to purchasing ultrasound is therefore needed to match the material's daily consumption. And while ultrasound gel does have a shelf life of five years, when a bottle has been used it must be used up within twenty eight days. Any longer and the risk of microbial contamination is too high for medical application. However, our gel pad would only need to be purchased once and regularly cleaned in order to be maintained for clinical use. It would only need to be replaced when it physically degrades.

An additional benefit of cutting the cost of an ultrasound means it would turn it into a cheaper medical procedure. Making it more affordable for lower income patients. The benefits of this are obvious, giving more people access to proper medical care will let doctors know more about their patients and treat health conditions before they become a problem. It will also reduce financial strain on families, letting them focus on other financial troubles. Also reducing how long a patient stays at the doctor's office. Freeing up the patient's time so they can get back to their daily life. Contributing to a better quality of life for all patients and doctors.

Early on in the peer review process of our project we were asked about the environmental impact of ultrasound gel and what its impact is and how ours would make it better. We looked into it and found that there is little to no environmental impact from ultrasound gel[13]. Since ultrasound gel is mostly made from water and propylene glycol. While propylene glycol is made from petroleum it is also easily soluble in water[16]. Which means medical practitioners can wipe away the gel from the patient and then they can simply toss it down into the trash. Ultrasound gel can also be easily washed away into the sink if needed. There have also been some advances in developing greener sources of propylene glycol. These developments have found a way to make it from vegetable oils, further reducing ultrasound gel's already small environmental impact[12]. Our new product will also not add to any environmental strain as well. Silicone PDMS can be bio-degraded by the soil and is made from silica found in sand[18]. Therefore silicone does not require any drilling or fracking since it is not an oil product like plastic or propylene glycol.

Another potential benefit of a new ultrasound interface is the potential to change the entire structure of many forms of healthcare. Ultrasound would no longer be relegated to dedicated appointments with giant machines that require tedious setup and cleanup. If we are successful it will turn an ultrasound into a quick procedure to efficiently check the internals of a patient. Ultrasound could be used to accurately identify a patient's wounds in an emergency medical situation. Letting doctors know where the internal bleeding is from a car crash victim, or discovering where a blood clot is in a stroke patient. It will speed up medical appointments so doctors can quickly check on a mother's baby and then go to another patient and monitor their heart, arteries, and veins for perforations. It could also potentially jump start new research into ultrasound. Since ultrasound will become a better tool for diagnosing a patient than a stethoscope, it will therefore be used more in medical situations. Researchers will then see it as a more viable field of study since it would become such a commonly used and essential device.

Research question and methods:

To find a good material to act as our new ultrasound interface we needed to define what would make a good interface. First and foremost a good image clarity as a constraint was selected because that is the primary purpose of ultrasound imaging. We found a paper that discussed measurements for clarity of ultrasound images, and image contrast and contrast-to-noise ratio were two metrics they used to evaluate it[22]. Values for our interface material in this metric will be compared against those found using conventional ultrasound gel, which we don't yet have measurements for. However we do know that a material must have an acoustic impedance value similar to soft tissue in order to produce the image clarity desired. Assuming a constant soft tissue impedance value of 1.63 MRayl, the reflection coefficient (percent of the ultrasound wave's energy that is reflected rather than transmitted) of an interface material with an impedance of 1.3 MRayl is about 0.01 or 1%. This is much larger than the reflection coefficient found using gel, which is 0.009%, but may or may not still be acceptable in the imaging context. We will find out when we compare our samples, which have different reflection coefficients.

Another desirable factor in making an efficient gel pad is that it must be deformable and elastic, so it can form-fit to the body and retain its shape. We will measure this by finding a material's elastic modulus. After examining various gels and materials we found that Sylgard

184, a common PDMS silicone, is slightly deformable and has an elastic modulus of 2.6; we are choosing around 2 MPa for the minimum elastic modulus. Also, medical sponges are easily deformable and have an elastic modulus of around 35 MPa, setting the upper limit for acceptable elastic modulus. Silicones (which we plan to be using) are for the most part unreactive, but we have not determined a suitable test/measurement for chemical degradation. We hope the fact that the gel pad will be deformable and elastic will speed up the ultrasound process since it won't be a gel that will need to be applied and cleaned off the patient versus putting a gel pad on and off a patient.

Conclusion:

If we are successful in developing an alternative ultrasound probe-body interface, then we will allow doctors greater ability to treat patients. Ultrasound would no longer be relegated to dedicated appointments that require tedious setup and cleanup. It could turn into a quick procedure to efficiently check the internals of a patient. Ultrasound could be used to find internal bleeding in emergency medical situations. Doctors could quickly check on the development of a mother's baby and then go to another patient and check their heart, arteries, and veins for perforations. It could also potentially excite new research into ultrasound. Portable ultrasound will become a common replacement for the stethoscope, and used in more medical situations. Researchers will see it as a more viable field of study since it would become such a commonly used and essential medical device.

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