Designing a Novel Ultrasound Probe-Body Interface

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Abstract

The application and removal of ultrasound gel during medical ultrasound imaging is a time consuming and messy process. This project seeks to find a replacement for ultrasound gel used during ultrasound imaging. We sought out to find a material that was reusable, elastic, non-toxic, and chemically non-reactive when used in a clinical setting. A crucial additional requirement is that the acoustic impedance, a physical property of how sound waves travel through materials, of the material should be as similar as possible to the acoustic impedance of soft tissue. To fulfill these requirements our team performed a material search. Polydimethylsiloxane (PDMS) silicone materials were identified as having good acoustic impedances similar to that of soft tissue. Two silicone formulations were identified as non-toxic and were requested from the manufacturer, Sylgard 170 and Sylgard 184. These silicones come in a kit with an elastomer base and a chemical crosslinker, and have tunable physical properties through variable crosslinking. By varying the ratio of crosslinker to base, the stiffness and elasticity of the material was manipulated towards finding the optimal material stiffness for conformation to the ultrasound probe and human body. Different model shapes were tested for the silicone, eventually settling on a hemispherical shape for optimal contact with the probe and body. Durability tests were performed to measure material degradation upon contact with isopropyl alcohol, a common clinical cleaning agent, and image quality tests were performed with wire phantoms to determine suitability for clinical imaging. Sylgard 170 showed great promise as an interface material, observing no degradation and the ability to generate clear images. Future work will focus on tuning the physical properties of prototypes to create a softer material for better conformation between the probe and body.

Keywords: Ultrasound gel, Acoustic Impedance, Polydimethylsiloxane (PDMS), elastomer base, chemical crosslinker

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Introduction

The Stethoscope is a medical device that has been used since 1816. It has been used to check a patient for various health conditions, like heart murmurs and gallops, heart valve leakage, low blood pressure, to check a patient's breathing and find lung abnormalities, ruptured veins, to discover abnormal blood flow (bruits), identify bowel sounds, and can even measure the size of a liver[1]. Identifying all of these conditions requires extensive training and experience to determine if the whooshing sound you hear is a bruit, a ruptured vein, or your patient's breathing. A new technique was found to be necessary: medical imaging.

Medical imaging is a powerful tool in doctors' battle against disease; it allows them to see directly into the body. Medical imaging helps doctors identify disease states that they otherwise would not be able to, which is the first step when treating a patient. One such medical imaging technology is medical ultrasound. Medical ultrasound transducers emit high-frequency sound waves that travel through the body and return, where they are measured by the ultrasound probe and integrated into a two-dimensional image.

Handheld ultrasound devices are now the norm in ultrasound devices and can be used for everything the stethoscope can be used for and more. However, a barrier to ultrasound's efficient use is the need for the use of ultrasound gel[2]. Ultrasound gel serves as a material interface between the ultrasound probe and the human body, so waves do not travel through the air, which would cause

distortion in the image. This is because of a material property called acoustic impedance Z, which determines how sound waves travel through a material. For a constant frequency wave, like that used in ultrasound, acoustic impedance of a material is shown in Equation 1:

$$Z = \rho c \quad [1]$$

where ρ is material density and c is the speed of sound in that material. Acoustic impedance is important for ultrasound because it determines the percent of the sound wave that is reflected or transmitted at the boundary between two materials. The reflection coefficient R defines how much of the sound energy will be reflected at the boundary and is shown in Equation 2:

$$R = (z_1 - z_2)^2/(z_1 + z_2)^2 \quad [2]$$

where z_1 and z_2 are the specific acoustic impedances of the two materials at the boundary, respectively. As seen in Equation 2, if the acoustic impedances of the materials are very different, then the reflection coefficient will be large compared to when the acoustic impedances are more similar. On the other hand, the transmission coefficient T defines the percent of the sound energy that will be reflected at the boundary between two materials and is shown in Equation 3:

$$T = 4z_1z_2/(z_1 + z_2)^2 \quad [3]$$

In order to minimize unwanted wave reflections at the boundary between different materials, the acoustic impedances of the different materials should be as similar as possible. The reflection coefficient R and the transmission coefficient T mathematically add up to 1, describing the percent of the energy of the sound wave that is reflected and transmitted, respectively.

For our application of a material interface between the ultrasound probe and the body, our material should have an acoustic impedance as close to that of soft tissue, which has an average acoustic impedance of 1.63 MRayl[3]. Air has a very low acoustic impedance of 0.0004 MRayls, so contact between the sound wave and the interface of air and soft tissue will lead to a very large reflection coefficient of R≈0.999, and very poor transmission[3]. Having an interface material with an acoustic impedance close to that of soft tissue will allow the sound waves to travel through the interface material and into the soft tissue for imaging as seen in Figure 1.

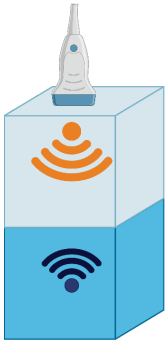

Figure 1: Principle of ultrasound interface. *The ultrasonic transducer (top) sends sound waves through the interface material (middle) and into the soft tissue (bottom), where they are reflected back to the transducer and interpreted. If the waves are reflected at the boundary between the interface and the soft tissue, the soft tissue is not able to be imaged.*

The current solution to the problem of the ultrasound probe-body interface is ultrasound gel. However, issues with ultrasound gel have been raised. The application and removal of ultrasound gel is a time consuming and messy process. For the general practitioner to examine their patients in a time-effective way, a solid alternative to ultrasound gel must be developed. Materials like PDMS silicone have been proposed as an interface material[4]; yet, no material has yet demonstrated the ability 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 and ultrasound transducer. Other criteria for these materials are that they must be reusable over time, which means it must be able to withstand contact with isopropyl alcohol, a commonly used cleaning solution. The material must be non-toxic and be able to pass irritation and sensitization tests required by the FDA, as the material will make frequent contact with patients' skin. The material must be large enough to cover the ultrasound probe and small enough to make contact with specific areas of the human body, required for the context of diagnostic scanning. Second, we intend to test the materials for durability and for the clarity of image they produce and to select and develop a prototype to

conform to the handheld ultrasound transducer.

Materials and Methods

Based on acoustic impedance research by Selfridge[5], PDMS silicone materials were identified as having good acoustic properties. In comparison to the average acoustic impedance of soft tissue of 1.63 MRayl, silicones Sylgard 184 and Sylgard 170 were found to have acoustic impedances of 1.04 MRayl and 1.34 MRayl, respectively[5]. Calculated reflection coefficients for the interface between these materials and soft tissue are around 4% for Sylgard 184 and around 1% for Sylgard 170. KONIX® Sterile Ultrasound Gel, which has been approved by the FDA, has a reported acoustic impedance of 1.49 MRayl, for comparison[6].

Silicone formulations Sylgard 170 and Sylgard 184, manufactured by Dow, were of particular interest because of their non-toxic and stable chemical properties, as well as tunable physical properties through variable crosslinking. Other materials with desirable acoustic properties lacked necessary non-toxic properties, such as Ecothane. Ecothane was rejected as a prospective interface material because, despite its acoustic impedance value of 1.54-1.63, it was not appropriate for human contact in a medical environment and would not be able to be approved by the FDA[7].

Samples of Sylgard 170 and Sylgard 184 were requested from Dow. Both Sylgard 170 and Sylgard 184 come from the manufacturer as kits in two parts, each with an elastomer base (Part A) and a chemical crosslinker (Part B). Both the elastomer base and chemical crosslinkers of Sylgard 170 and Sylgard 184 are viscous liquids. Shown in Figure 2 is the procedure we used for mixing each silicone formulation for developing silicone models.

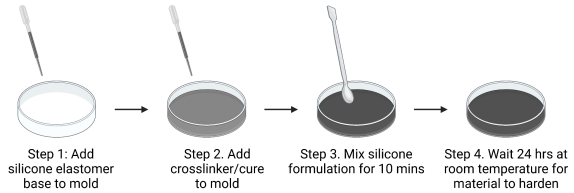

Figure 2: Procedure for mixing silicone models. *The silicone elastomer base is added and weighed, followed by adding and weighing the crosslinker. The formulation is mixed for 10 mins and allowed to cure and solidify for 24 hrs.*

The manufacturer of Sylgard 170 and Sylgard 184 recommends base to crosslinker ratios of 1:1 and 10:1, respectively. Sylgard 170 and Sylgard 184 are used primarily in industry as sealants or encapsulants in electronics, and we assume that these crosslinker to base ratios recommended by Dow are optimized for this purpose. However, upon initial experimentation, it was found that this resulted in silicones that were too hard for our use as ultrasound interface materials.

The tunable physical properties of Sylgard 184 and Sylgard 170 were achieved by variable crosslinking. The more crosslinker used relative to base, the harder and more firm the material became. The less crosslinker used relative to base, the softer the material became, up until a point where the material did not retain its shape and remained as a viscous liquid.

Creation, Prototyping, and Testing of Silicone Models

The first models were largely exploratory in dealing with the new silicone materials. Both the shape and base to crosslinker ratios were in early stages of refinement. The first silicone models were made in the bottom of plastic Solo cups, shown below in Figure 3. Sylgard 184 is a translucent silicone material, while Sylgard 170 is a dark black color.

Figure 3: First models of Sylgard 184 and Sylgard 170, left to right. *The bottom of a plastic cup was used as a mold.*

The first models were made with base to crosslinker ratios near the recommended values by the manufacturer, and were quite hard as a result.

As part of the design process, materials were brought to Advisor Dr. Morikawa and tested with a handheld ultrasonic transducer, in accordance with the intended application. This drove the design process towards softer materials and material shapes that would allow for better conformation with the transducer. In preliminary testing of

image quality, which would be a key criteria for any interface material, the probe was brought into contact with the material interface, and used to image soft tissue. Later, imaging was conducted on wire phantoms submerged in water, as human testing could not continue without IRB approval. Ultimately, the first models did not prove successful in testing of image quality. This is likely due to ridges on the surface of the material, which may have allowed air to enter between the probe and the transducer and caused unacceptable reflection artifacts in the image. In addition, these materials were too hard, indicating too much crosslinker relative to base. For the majority of the duration of this project, base to crosslinker ratios of created models were skewed in the direction of the manufacturer-recommended values, leading to materials that were not soft enough. Early experimentation with base to crosslinker ratios did not lead to substantial difference in material hardness.

The second models were mixed in petri dish molds, shown in Figure 4 below. These were chosen for their wide, flat shape so they would easily conform to the human body when used during ultrasound testing. These had the added benefit of being easy to make due to the ready-made molds.

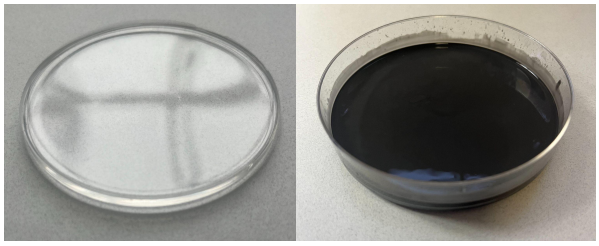

Figure 4: Second models of Sylgard 184 and Sylgard 170, left to right. *A petri dish was used as a mold.*

The second silicone models were also unsatisfactory after initial image quality testing. Base to crosslinker ratios were varied to 3:2 for Sylgard 170 and 5:1 for Sylgard 184, but this did not create a softer material. Efforts to tune the physical properties of the materials were hampered by lack of knowledge of the material at the time, which included not knowing whether Part A or Part B of the kit for Sylgard 170 was the elastomer base or the crosslinker. In testing the second models, it was found that through stacking them on top of each other an image was able to be produced. This; however, in retrospect, was most likely a reflection artifact instead of an actual image of soft tissue.

Theorizing that a certain thickness was needed for a material interface, the third and final models were created, shown below in Figure 5. These were of a hemispherical shape and were made using table tennis balls sliced in half as molds. The theory behind these models was the idea that the rounded part could conform to the human body while the flat top would be where the transducer would be placed.

Figure 5: Third models of Sylgard 184 and Sylgard 170, left to right. *A table tennis ball cut in half was used as a mold.*

In making the third models shown in Figure 5, a volumetric measurement was used to measure how much elastomer base and crosslinker was to be added. First, the radius of the hemispherical mold was measured. For a given base to crosslinker ratio, it was determined using an online calculator[8] the depth of the hemisphere up to which the elastomer base should be filled. After the base was added, the crosslinker was added up to the total volume of the hemisphere. Upon comparison with a mass-based system of measuring amounts of elastomer base and crosslinker, this volume-based system was deemed to be inaccurate and was discontinued in favor of the mass-based approach. Final models of Sylgard 184 and Sylgard 170 both had base to crosslinker ratios of 1:40, although this was a volume measurement and is likely inaccurate. Further mass-based tuning of base to crosslinker ratios has determined that insufficient crosslinking to produce a solid material takes place at a ratio of 15:1 for Sylgard 170. This mass-based base to crosslinker ratio of 15:1 for Sylgard 170 produces a very thick liquid, indicating that the optimal ratio is somewhere less than 15:1.

Regardless, the hemispherical models of Sylgard 184 and Sylgard 170 that were created at volume-based ratios of 40:1 were ready for testing. The Sylgard 184 model was still quite rigid, while the Sylgard 170 was slightly soft and had high elasticity, retaining its original form after deformation.

Durability testing

To test the durability of the materials, two tests were conducted, exposing the samples to CVS 91% isopropyl alcohol. This was for the purpose of seeing if they would degrade under use in a clinical setting. Samples of Sylgard 170 and 184 at different base to crosslinker ratios were used in each test. The first test had the samples cleaned with the isopropyl alcohol each day and then measured in the same spot to determine their thickness. The second test had the samples continuously soaked each day in isopropyl alcohol and removed to record their thickness each day. Material lengths were measured each day in the same spot for the sake of consistency.

Image quality testing

To test image quality associated with the material interface, a handheld ultrasound probe was used to image wire phantoms submerged in water. The submerged wire phantoms functioned as simulated soft tissue, water being acoustically similar to soft tissue. Water has an acoustic impedance of 1.48 MRayls, compared to the average of 1.63 MRayls of soft tissue[9]. The transducer was placed against the silicone interface, with the bottom of the silicone submerged in water.

Results

The two graphs in Figure 6 show the results of our degradation testing. The top graph shows the results for the wiping test and the second graph shows the results of the soaking test. On the x-axis is days, up to 26, and the y-axis shows percent change in material thickness, from the initial value. Base to crosslinker ratios for each silicone formulation are varied, but not significantly, so it is not expected that minor changes in the ratio should be visible in the degradation results. Small spikes in the percent % change of material thickness are attributable to human error in measuring; however, larger trends are expected to be more accurate.

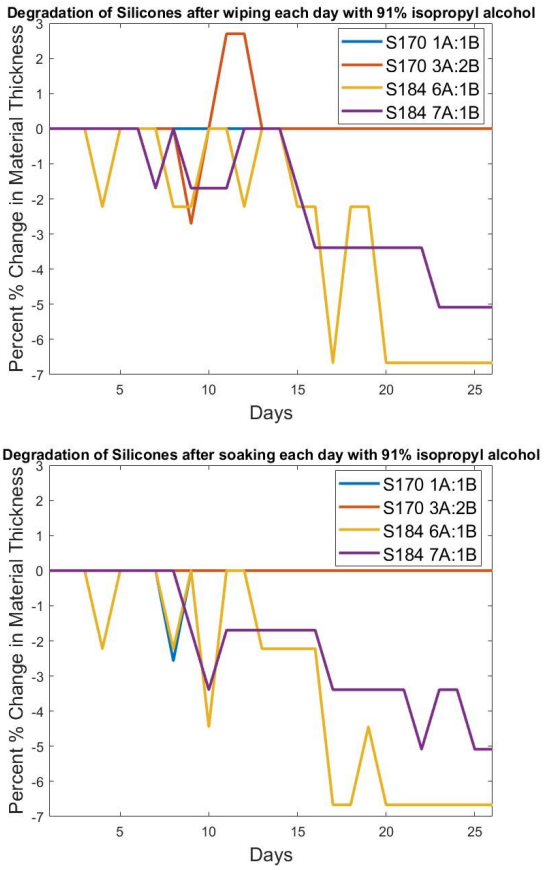

Figure 6: Degradation of silicones exposed to isopropyl alcohol. *Silicones were wiped (top) and soaked (bottom) each day in isopropyl alcohol.*

The results of our degradation testing show significant degradation with Sylgard 184 and no degradation with Sylgard 170. Although there is noise in the data, the major trend for both exposure conditions, wiping and soaking, is degradation with Sylgard 184 and no degradation with Sylgard 170.

The results of the image quality testing are shown below in Figure 7. The imaging setup is shown on the left of the figure. The ultrasound probe is in contact with the interface material, Sylgard 170. Ultrasound gel had to be placed at the interface between the probe and the silicone for an image to be produced. On the right, bright spots on the ultrasound image indicate the position of the submerged wires about 4 cm below the probe in the area where the wires were located, indicating a correct image.

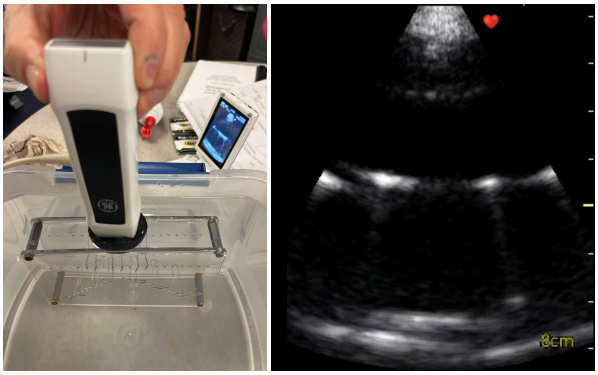

Figure 7: Wire phantom imaging setup (left) and resulting ultrasound image (right). *The ultrasound probe and the material interface Sylgard 170 is being used to image submerged wires, appearing as bright spots in the image on the right.*

In testing the Sylgard 184 with the wire phantom setup, reverberation artifacts were observed and a clear image was not able to be obtained, even with gel at the interface between the probe and the material. This is expected because of the poorer acoustic impedance of Sylgard 184 relative to Sylgard 170.

Discussion

Interpretation of degradation results

As observed in Figure 6, degradation results showed significant degradation of Sylgard 184 and no degradation of Sylgard 170. Additionally, base to crosslinker ratio was not varied widely, and it seemed to have not had an effect on degradation. If base to crosslinker ratios were varied wider, we may have observed an effect on degradation when exposed to isopropyl alcohol. The expectation would be that a higher base to crosslinker ratio, less crosslinker relative to base, would lead to greater degradation. This is because with greater amounts of crosslinking, the polymer network of polydimethylsiloxane (PDMS) molecules is held together tighter, which is expected to lead to less degradation over time. However, this has not been shown, and requires further study.
Another interesting result from the degradation testing is that soaking Sylgard 184 in isopropyl alcohol did not appear to lead to greater degradation than wiping each day with isopropyl alcohol. One would expect that if contact with isopropyl alcohol leads to any degradation in Sylgard 184, that more contact would lead to more degradation in Sylgard 184. This suggests the possibility that it was not contact with the isopropyl alcohol that caused the degradation of the Sylgard 184, but another factor that was not accounted for. It is not known what this factor is, but it could be friction that occurred in wiping the samples and cleaning the isopropyl alcohol off the soaking samples when measurements were conducted. A possible explanation is that Sylgard 184 contracts with time, perhaps due to the delayed effect of the crosslinker within the polymer network of the material. This however is speculative, and should be studied further.

Interpretation of image quality results

It was fortunate that Sylgard 170 observed no degradation after contact with the cleaning solution because Sylgard 170 also was the material that successfully proved itself as a possible interface material. The successful imaging of the submerged wire phantom setup shows proof of concept that Sylgard 170 has a good enough acoustic impedance for the application of medical imaging, as the water component of the wire phantom setup is acoustically similar to soft tissue.

Our final model, Sylgard 170 with a volume-based base to crosslinker ratio of 40:1 (which corresponds to a mass-based base to crosslinker of less than 15:1), was judged to still be too rigid for soft tissue imaging. A solid, air-excluding interface between the probe and the material requires an even softer material. This is why ultrasound gel was needed between the probe and Sylgard 170. We anticipate that an even softer material will eliminate this need for gel between the probe and the material. In terms of the ideal base to crosslinker ratio to achieve this softer material, further testing showed that mass-based base to crosslinker ratios of 15:1 and higher did not crosslink sufficiently and did not hold their shape. The ideal base to crosslinker ratio for Sylgard 170 is unknown, but below 15:1, and should be studied further.
Theorizing on the problem of how to make Sylgard 170 softer, the idea of introducing an additive to the material was suggested. Adding magnesium and sugar were hypothesized to accomplish this goal. There are several problems with this idea. First, detailed reaction and chemical

makeup of Sylgard 170 is proprietary information held by the Dow corporation, and material on the ingredients and reactions undergone in the crosslinking process are unknown, which makes the idea of introducing additives a highly speculative experiment. Also, the introduction of a significant amount of additive may disrupt the homogeneity of the material, which may lead to unsuitability as an interface material. A heterogeneous material essentially has multiple material interfaces inside it, which, if the materials comprising the heterogeneous material have different acoustic impedances, will lead to reflection artifacts inside the material, leading to complete unsuitability as a material interface. It is the opinion of this group that finding the mass-based base to crosslinker ratio for ideal material stiffness is the clearest way towards removing the problem of air at the probe-material interface.

Limitations and future research

Lack of IRB approval hindered our ability to test our silicone materials as they would be used, on human soft tissue. Although the success of Sylgard 170 in imaging the submerged wire phantom setup is a good start, future research should test on soft tissue itself, to see how Sylgard 170 can perform. In addition, a statistical comparison of image quality comparing Sylgard 170 to ultrasound gel should be conducted. This is necessary to prove that our material meets the clinical standard of effectiveness provided now by ultrasound gel.

Another limitation of this study is that Sylgard 170 has not been approved for medical use by the FDA. Ultrasound gel is a class II device regulated by the FDA, and our device would receive the same designation through the 510(k) process. In order for our device to be approved, we would have to show that Sylgard 170 could pass irritation and sensitization tests, as it will come into contact with human skin in clinical use. Sylgard 170 has not been shown yet to be able to pass these tests.

Further research into optimal material shape should be conducted. The idea of emulating an ultrasound probe cover, with the silicone material being shaped to cover the end of the transducer, should be explored. This may allow for better contact between the probe and the material, and between the material and the body.

Significance and innovation of the project

If we are successful in developing an alternative ultrasound probe-body interface, 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 will become a quick procedure to efficiently evaluate the internals of a patient. Doctors could quickly check on a mother's baby and then go to another patient and check their vasculature for perforations. The use of ultrasound could also be broadened for use outside of clinical settings. Ultrasound could be used by EMTs to quickly diagnose heart attacks or to identify where the blockage is in a stroke so that doctors back at the hospital can know where to operate. Finally, this would spur more research into the field of ultrasound since it would become a much more commonly used and essential medical device. Point-of-care handheld ultrasound machines will replace the stethoscope, and be used effectively in more medical situations.

End Matter

Author Contributions and Notes

Paul Deaton and Thomas Dugan contributed equally in writing this paper.

The authors declare no conflict of interest.

Acknowledgments

Dr. Masahiro Morikawa

Professor Timothy Allen

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