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DESIGN OF A WEARABLE ULTRASOUND PATCH WITH SOFT AND CONFORMAL MATCHING LAYER

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ABSTRACT

Ultrasound is a safe, noninvasive diagnostic technique used to measure internal structures such as blood vessels and the velocity of blood flow in the human body. The ability to continuously measure blood flow in major cerebral arteries would enable the early detection of medical problems such as stroke. However, current ultrasound technology consists of rigid, hand-held probes that are arduous to use, sensitive to movement, and are primarily designed for intermittent, instead of continuous use. Here, we describe the design of a wearable ultrasound patch for continuously measuring blood flow velocity through the middle cerebral artery (MCA) that can be assessed from the temple region of the head. The wearable ultrasound patch is composed of an array of piezoelectric elements that are wired together using flexible electrical conductors and encapsulated in an elastic substrate. To improve ultrasound energy transfer, a soft and conformal composite matching layer is introduced. The matching layer consists of gallium-based liquid metal (LM) microdroplets dispersed in a silicone elastomer. The acoustic impedance of the matching layer can be tuned by varying the volume loading of LM. The wearable ultrasound patch will provide new opportunities to continuously measure blood flow velocity and ultimately enable early detection of medical problems such as stroke.

Keywords: ultrasound, wearable electronics, acoustic impedance, liquid metal

1. INTRODUCTION

Wearable electronics that can continuously monitor human physiology and activity have emerged as a viable platform for enabling remote patient monitoring of traditional vital signs such as pulse rate, body temperature, and respiration rate [1,2]. Such devices will play an increasingly important role in medical diagnoses and care decisions alongside the traditional roles of healthcare practitioners, ultimately enabling prompt treatment of acute events, resulting in reduced morbidity and mortality. However, these wearable sensors are primarily limited to recording signals on the surface of the skin.

Transcranial Doppler ultrasound is a safe, noninvasive, and portable diagnostic technique that can be utilized to measure hemodynamic changes in major cerebral arteries, and can be used as an indication of cardiovascular health [3-5]. For continuous monitoring, wearable ultrasound patches have recently been introduced enabling noninvasive, continuous imaging of internal organs and arteries [6-8]. To create a conformal, skin-like device, piezoelectric elements can be mounted on elastic substrates and wired together using stretchable electrical conductors, offering improved wearability as compared to existing rigid ultrasound probes [7]. However, the stretchable ultrasound device is not compatible with existing rigid backing and matching layers, resulting in low energy transfer into tissue. Alternatively, a thick bioadhesive couplant layer can be utilized to adhere a rigid ultrasound probe to the skin, allowing integration with existing rigid backing and matching layers [8]. However, this approach is ultimately limited to a few square centimeters due to the rigid ultrasound probe.

Here, we introduce the design of a wearable ultrasound patch with an array of piezoelectric elements encapsulated in an elastic substrate with a soft and stretchable, mechanically compatible matching layer (**Figure 1**). The patch can be placed on the temple region of the head and the array of piezoelectric elements can be used to identify a suitable location for measuring cerebral blood flow velocity without the need to manually reposition the device.

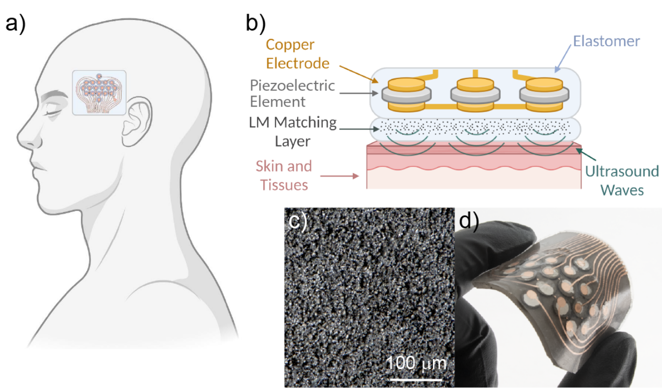

FIGURE 1: (A) ILLUSTRATION OF THE WEARABLE ULTRASOUND PATCH LOCATED ON THE TEMPLE REGION OF THE HEAD. (B) EXPLODED VIEW SCHEMATIC ILLUSTRATION OF THE PATCH SUMMARIZING THE LAYOUT. (C) MICROGRAPH OF THE SOFT AND CONFORMAL MATCHING LAYER. (D) PHOTOGRAPH OF THE WEARABLE ULTRASOUND PATCH. (A-B) SCHEMATIC ILLUSTRATIONS WERE CREATED USING BIORENDER.COM.

2. MATERIALS AND METHODS

A wearable ultrasound patch was designed that conforms to the temple region of the human head. The patch includes an array of piezoelectric elements, which are independently addressable. The array of elements enables the device to locate the MCA without the need for manual repositioning. The embedded piezoelectric elements act as both the senders and receivers of the ultrasound signal. To improve ultrasound energy transfer into tissue, a soft and conformal acoustic matching layer was designed and characterized. The matching layer is composed of LM microdroplets dispersed (≤ 50% by volume) in a silicone elastomer. The acoustic impedance of the matching layer can be tuned by varying the volume loading of LM.

2.1 Wearable Ultrasound Patch Design

The wearable ultrasound patch shown in Figure 1 consists of eighteen piezoelectric elements embedded in a soft silicone elastomer (PDMS; Sylgard 184, Dow Corning). A detailed exploded view schematic illustration shown in **Figure 1B** summarizes the layout of the wearable ultrasound patch. Flexible copper electrodes are fixed to the top of each element using conductive epoxy (8331D, MG Chemicals) and connected to an ultrasonic pulser/receiver circuit, allowing the elements to be independently addressable. The bottom of the elements is connected to a common ground using an interconnected flexible copper grid. The entire flexible circuit is then encapsulated in PDMS. To improve the ultrasound energy transfer into tissue, the flexible circuit is bonded to a soft and conformal matching layer. A micrograph of the matching layer is shown in **Figure 1C** and consists of LM microdroplets embedded in PDMS matrix.

To determine the layout of the ultrasound patch, the temple location of the Doppler signal for the MCA was recorded from several test scans using a handheld ultrasound device with a 2 MHz probe (Doppler BoxX, Compumedics Gmbh, Singen, Germany). The elements were then arranged in a pattern within a bounding box created by the best signal locations on the scans (**Figures 1 A, D**). The individually addressable array of piezoelectric elements will allow the wearable device to locate the MCA by beamforming without the need for manual repositioning of the device.

2.2 Wearable Ultrasound Patch Fabrication

The fabrication of the ultrasound patch shown in **Figure 2** was adapted from Wang, et al [7]. First, the matching layer is spin processed to the optimal quarter-wavelength thickness on a glass substrate and cured at 100 °C for 1 hour (**Figure 2A**). Details about the fabrication of the matching layer can be found in Section 2.3. Next, a 1/2 oz flexible copper clad sheet (FR8510R, DuPont) was placed on a sacrificial elastomer substrate for laser patterning utilizing a UV laser micromachining system (Protolaser U4, LPKF) [9]. After laser patterning, debris was cleaned from the surface of the electrodes with isopropanol and the excess copper was removed from the elastomer substrate as shown in **Figure 2B-C**. The copper electrodes were then transferred to the flexible matching layer using a water-soluble tape (Aquasol), shown in **Figure 2D**. A stencil mask was then placed over the copper electrodes and a thin layer of conductive silver epoxy was blade coated onto the electrode surface (**Figures 2E-F**). The stencil mask was then removed. This process was repeated for the top electrodes and transferred to a PDMS substrate without LM. The piezoelectric elements were then placed on the uncured silver epoxy as shown in **Figure 2G** and sandwiched between the top and bottom copper electrodes. The device was placed in an oven at 80 °C for 40 minutes to cure the conductive epoxy. After curing, the entire device was encapsulated with PDMS and cured at 80 °C for 1

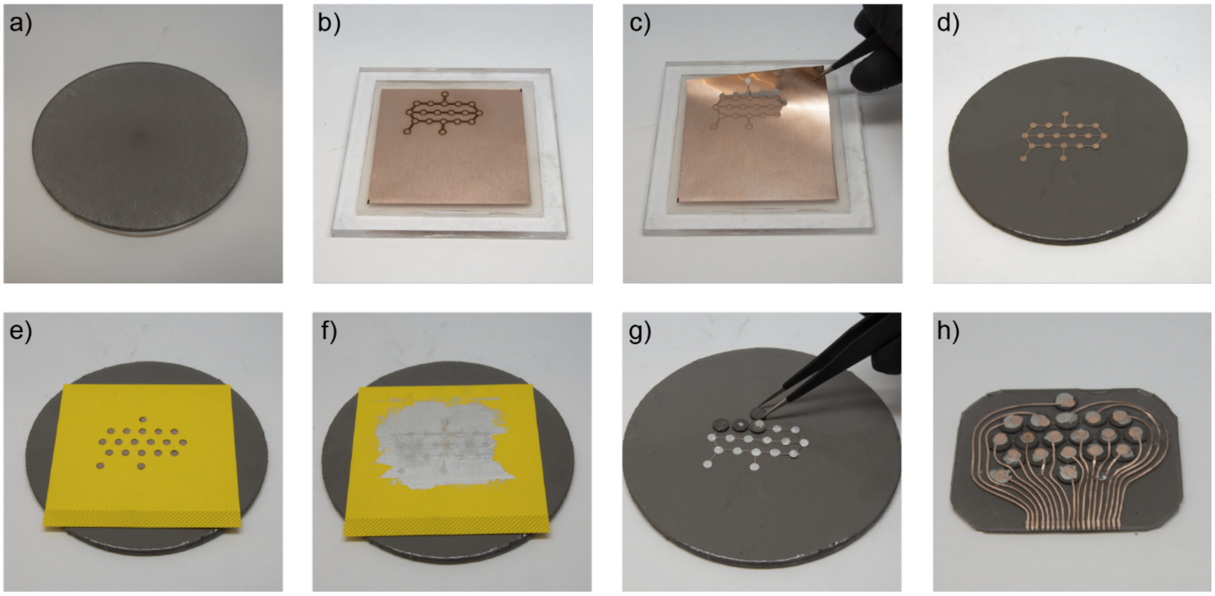

FIGURE 2: FABRICATION PROCESS FOR THE WEARABLE ULTRASOUND PATCH. (A) THE ACOUSTIC MATCHING LAYER WAS FIRST SPIN-PROCESSED TO THE DESIRED THICKNESS. (B) A FLEXIBLE COPPER CLAD SHEET WAS PROCESSED ON AN ELASTOMER SUBSTRATE AND PATTERNED USING A UV LASER. (C) AFTER LASER PATTERNING, THE SUBSTRATE WAS CLEANED AND THE EXCESS COPPER CLAD WAS REMOVED. (D) THE ELECTRODE WERE TRANSFERRED TO THE MATCHING LAYER. (E) A STENCIL MASK WAS APPLIED TO THE BOTTOM ELECTRODES AND (F) CONDUCTIVE SILVER EPOXY WAS BLADE COATED ONTO THE ELECTRODES. (G) THE PIEZOELECTRIC TRANSDUCERS WERE PLACED ONTO THE EPOXY-COATED ELECTRODES AND SANDWICHED BETWEEN THE TOP AND BOTTOM ELECTRODES. (H) THE ENTIRE DEVICE WAS THEN ENCAPSULATED WITH PDMS.

hour in a pressure chamber at 40 PSIG resulting in the final wearable device shown in **Figure 2H**.

2.3 Acoustic Matching Layer Design and Fabrication

Acoustic matching layers are a critical component that improve the transfer of ultrasound energy from the transducer to the imaged medium (tissue). Typically, these matching layers are made of metal particle-polymer composites [10]. However, these rigid layers are not compatible with flexible and/or stretchable wearable ultrasound patches.

$$Z = \rho \cdot c \tag{1}$$

The acoustic impedance (Z) of a material is determined by the density (ρ) of the material and the speed of sound (c) through the material as shown in **Equation 1** [12]. Most flexible materials, such as silicone-based elastomers, have relatively low densities resulting in low acoustic impedance values that are similar to human tissue. Gallium-based liquid metal (eutectic gallium indium, EGaIn) droplets ($\rho = 6.25$ g/ml) were embedded into a silicone elastomer to create a soft and conformal matching layer that has an elastic modulus (E) similar to human skin ($E < 1$ MPa) [11]. The acoustic impedance of the matching layer can be tuned by changing the volume loading of EGaIn within the elastomer matrix.

The optimal acoustic impedance of the acoustic matching layer (Z_m) is the geometric mean of the piezoelectric material ($Z_1 = 22$ MRayl) and the imaged medium ($Z_2 = 1.5$ MRayl), shown in **Equation 2** [12]. For the wearable ultrasound patch, the optimal acoustic impedance was determined to be 5.74 MRayl. The optimal thickness for the matching layer is a quarter-wavelength, or 200 µm.

$$Z_m = \sqrt{Z_1 \cdot Z_2} \tag{2}$$

The LM matching layer is fabricated by first preparing the PDMS-LM emulsion by combining the PDMS oligomer with LM at a 0.9:1 volume ratio that is shear mixed with an overhead mixer at 2,200 RPM for 20 minutes, which results in LM droplets with a diameter of approximately 1 µm. The PDMS curing agent is then added to the emulsion at a 10:1 oligomer/curing agent ratio and mixed/degassed in a planetary mixer (SpeedMixer DAC 400.2 VAC, FlackTek; 1000 RPM for 1 minute). For LM volume loadings less than 50%, additional PDMS oligomer/curing agent was added to dilute the mixture to the appropriate volume loading. The matching layer is spin processed to the desired 200 µm thickness and cured at 100 °C for 1 hour.

Samples for acoustic impedance characterization were created by casting the uncured LM-silicone emulsion into a 30 mm x 30 mm x 1.5 mm elastomer mold and cured at 100 °C for 1 hour.

3. RESULTS AND DISCUSSION

The acoustic properties of the soft and conformal matching layer were measured at several LM volume loadings from 0 to 50%. For each sample the density was measured gravimetrically using a density determination kit (**Figure 3A**). As expected, we see a linear increase in density as the volume loading of LM is increased from 0 to 50%. Next, the speed of sound of the samples was measured using a transmission-through method (**Figure 3B**). An immersed transducer (2.25 MHz flat, 0.5-inch diameter, IR-0208-S, Harisonic) was driven by a Panametrics 500 PR pulser/receiver. The emitted pulse traveled through a sample of known thickness and was received by another immersed transducer (3.5 MHz flat, 0.5-inch diameter, IR-0308-S, Harisonic). The signal from the receiving transducer was sampled using a digital oscilloscope (TBS2074B, Tektronix, Beaverton, OR), and the speed of sound in the material was calculated. We observed that the speed of sound decreased with increasing volume loading of LM as predicted by the Wood's model shown in **Equation 3** [13]. The theoretical speed of sound (c_{Wood}) is calculated from the LM density (ρ_f), PDMS matrix density (ρ_m), LM volume loading (ϕ), and compressibility of the PDMS matrix (χ_m), and LM filler (χ_f).

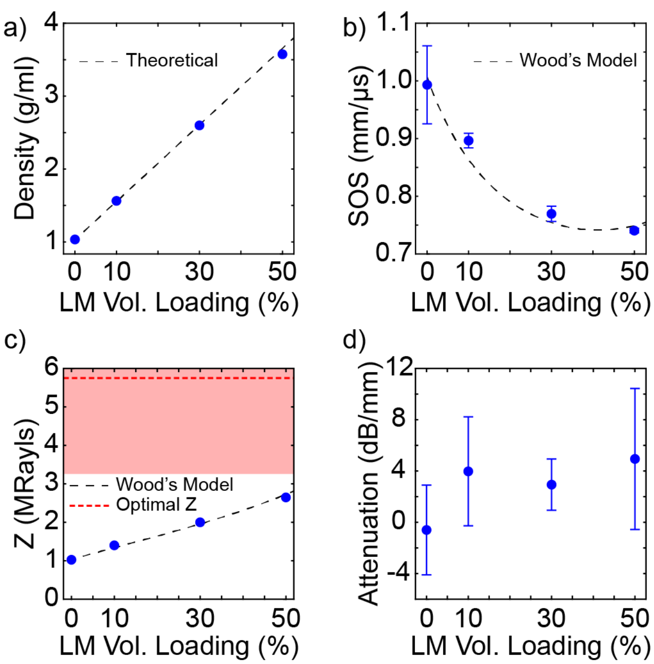

FIGURE 3: SOFT AND CONFORMAL LM-PDMS COMPOSITE MACTHING LAYER (A) MASS DENSITY, (B) SPEED OF SOUND THROUGH THE COMPOSITE, (C) ACOUSTIC IMPEDANCE, AND (D) ATTENUATION COEFFICIENT VERSUS LM VOLUME LOADING. ERROR BARS SMALLER THAN DATA POINTS ARE NOT SHOWN. (C) DASHED RED LINE INDICATES OPTIMAL ACOUSTIC IMPEDANCE FOR MATCHING LAYER. THE SHADED REGION (3.26 TO 10.12 MRAYL, UPPER BOUND NOT SHOWN) DENOTES ACOUSTIC IMPEDANCE VALUES FOR WHICH TRANSMITTED INTENSITY IS >= 90% OF THE MAXIMUM POSSIBLE TRANSMITTED INTENSITY, AS GIVEN BY EQUATION 2.

$$c_{Wood} = \frac{1}{\sqrt{[(1-\phi)\rho_m+\phi\rho_f]\cdot[(1-\phi)\chi_m+\phi\chi_f]}} \qquad (3)$$

The acoustic impedance of the composite material was then determined using **Equation 1** (**Figure 3C**). The PDMS matrix without any LM had the lowest acoustic impedance. The LM-PDMS composite showed an approximately linear increase in acoustic impedance as the LM volume loading was increased from 0 to 50%. The optimal acoustic impedance of 5.74 MRayls is shown by the red horizontal dashed line in **Figure 3C**. The shaded region (3.26 to 10.12 MRayl, upper bound not shown) denotes acoustic impedance values for which transmitted intensity is >= 90% of the maximum possible transmitted intensity, as given by Equation 2. Finally, the attenuation coefficient for the samples at the piezoelectric element's center frequency (2.75 MHz) was measured by using the same setup as described for speed of sound measurement and comparing received pulses with and without the sample present. Frequency-dependent attenuation was then calculated from these data by the method of reference [8] and was averaged over the center frequency and the four nearest frequencies (2.225, 2.2375, 2.2625, and 2.275 MHz) to reduce variability due to noise (**Figure 3D**).

The 2.75 MHz center frequency of the piezoelectric element (1-3 Composite, 2 MHz, 250 µm fiber diameter, 65% random fill factor, 6 mm diameter, Smart Material Corp., Sarasota, FL) was found by calculating the Fourier transform amplitude spectrum for a single received pulse (**Figure 4**). We observe a negligible increase in the attenuation coefficient as the LM volume loading is increased from 10 to 50%. This data illustrates that LM-PDMS composites offers an alternative solution to the rigid metal particle-polymer composite acoustic matching layers for integration with flexible and/or stretchable wearable ultrasound patches.

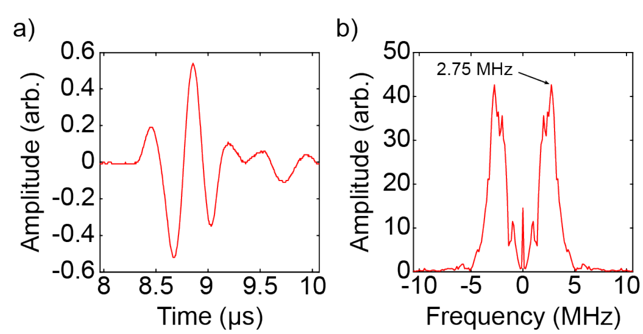

FIGURE 4: (A) PULSE PRODUCED FROM A SINGLE ELEMENT WHEN CONNECTED TO A PANAMETRIC PULSER/RECEIVER. (B) AMPLITUDE SPECTRUM OF A SINGLE ELEMENT SHOWING A PEAK FREQUENCY OF 2.75 MHz.

4. CONCLUSION

In summary, we have introduced the design of a wearable ultrasound patch with a soft and conformal acoustic matching layer. The array of piezoelectric elements will enable the identification of the optimal location for measuring cerebral blood flow velocity without the need to manually reposition the device. This device provides a path towards creating an ultrasound device for long-term hemodynamic monitoring that would enable the early detection of medical problems such as stroke. Additionally, we demonstrated that LM can be utilized as a filler in an elastomer matrix to tune the acoustic impedance. Future work will focus on optimizing the acoustic properties of the matching layer to achieve the desired acoustic impedance of 5.74 MRayls. Furthermore, we will characterize the advantage of the soft and conformal matching layer while measuring the blood flow velocity of the MCA in human subjects.

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