Systemic Sclerosis Calcinosis Outcomes with Wearable Ultrasound Technology (SCOUT)

#23

CALCIVIEW

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Clinical Problem

Calcinosis is a common and debilitating manifestation **secondary** to **systemic sclerosis (SSc)**, affecting up to one third of patients and leading to **pain, ulceration, infection, and functional impairments**[1]-[3]. There is a critical need for **noninvasive, point-of-care technologies** that can reliably **detect, quantify, and map calcinosis in SSc**, particularly in the hands and forearms where disease burden is highest [1][2]. Recent advances in **wearable ultrasound technology**, have enabled imaging with high spatial resolution and tissue conformity, but have not yet been applied to SSc-related calcinosis [9]-[11].

Mission Statement

SCOUT aims to innovate a viable device that will help with the early diagnosis of calcinosis in patients with systemic sclerosis. Our team values innovation, integrity, and quality, all of which are critical in our mission to develop our device. Together, alongside our patients and mentors, we are committed to closing the gaps in healthcare access for underserved communities and ensuring medical solutions are equitable and accessible to all.

Market Analysis

SSc Market Size: **USD 2.74 billion in 2025** and has an anticipated compound annual growth rate calcinosis affects **35-40% of patients with SSc, estimating at roughly 2.5 million people worldwide.** [13]

Number of Patients Affected: Calcinosis affects **35-40% of patients with SSc**, estimating at roughly **2.5 million people worldwide.**

Product Concept and Design

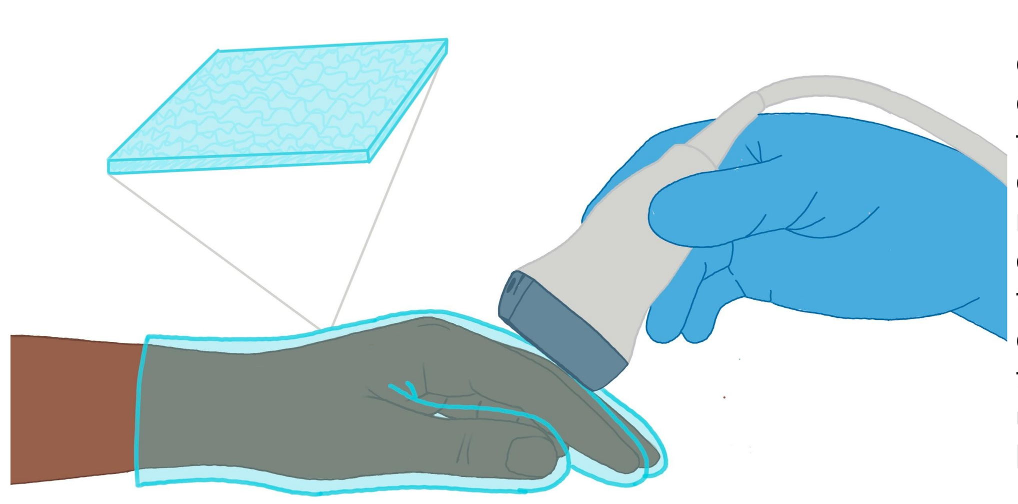


Figure 1. The product concept is composed of a hydrogel material chemically modified to improve the fidelity of ultrasound imaging of calcinosis deposits. The hydrogel material will be tuned to match the electric impedance of the skin and soft tissue, minimize reflection or noise caused by the presence of calcium in the skin, and be adaptable to existing ultrasound workflows to minimize burdens to clinical integration.

Technical Modeling

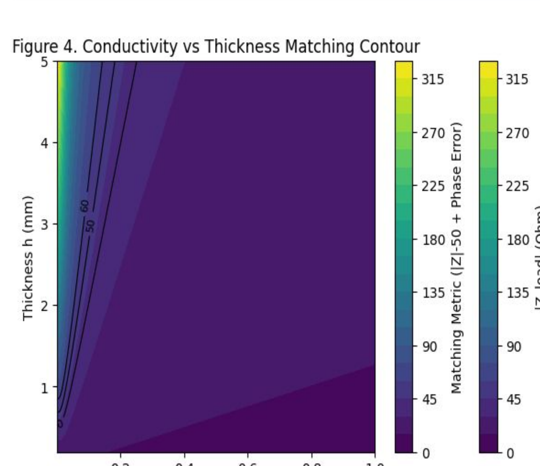


Figure 2. Power-transfer efficiency η(f) across frequency for the representative case

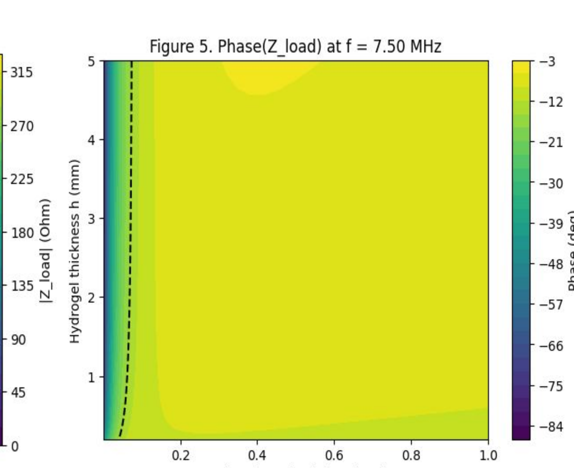


Figure 3. Contour map of ∣Zload∣ at the center frequency (e.g., 7.5 MHz) as a function of hydrogel conductivity σh (x-axis) and thickness h (y-axis)

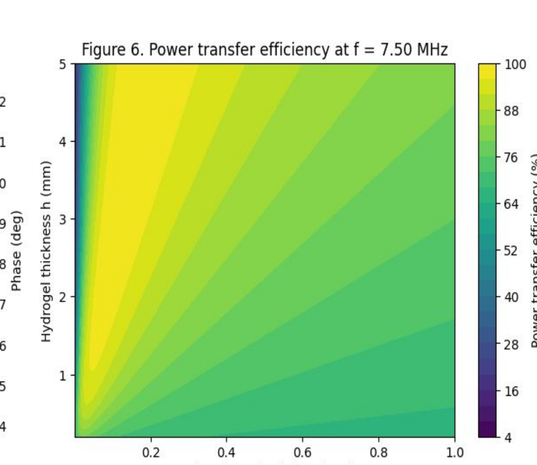
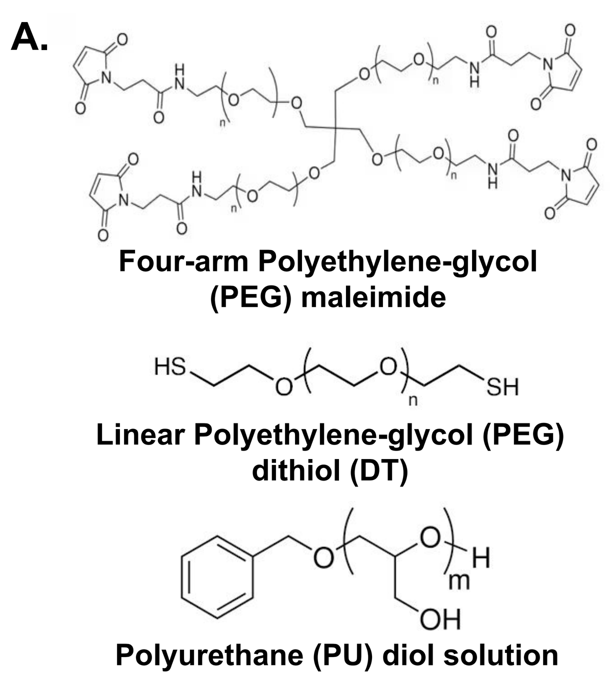


Figure 4. Contour map of phase of Zload at center frequency vs σh and h

Physical Prototyping

A.



B.

ID	wt%	R
A1	0.06	2.5
A2	0.1	2.5
A3	0.14	2.5
B1	0.06	3
B2	0.1	3
B3	0.14	3
C1	0.06	3.5
C2	0.1	3.5
C3	0.14	3.5

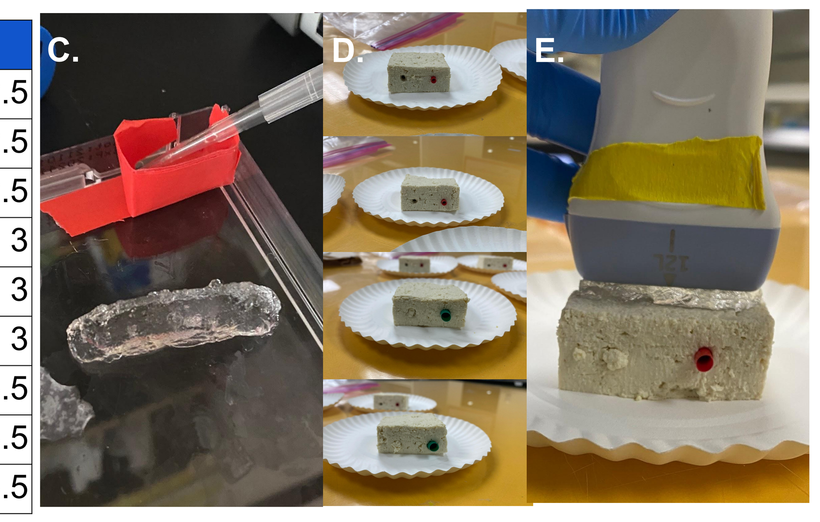


Figure 5. A. Molecular structures of selected polymers for hydrogel fabrication. **B.** Table of gelation combination IDs varying by polymer wt% (0.06, 0.10, 0.14) and polymer PEG:PU ratio R (2.5:1, 3:1, 3.5:1). **C.** Final gel prototype outside of mold. **D.** Phantom models at varying calcinosis volumes and depths. **E.** Final hydrogel prototype in use with ultrasound probe and phantom model.

Results

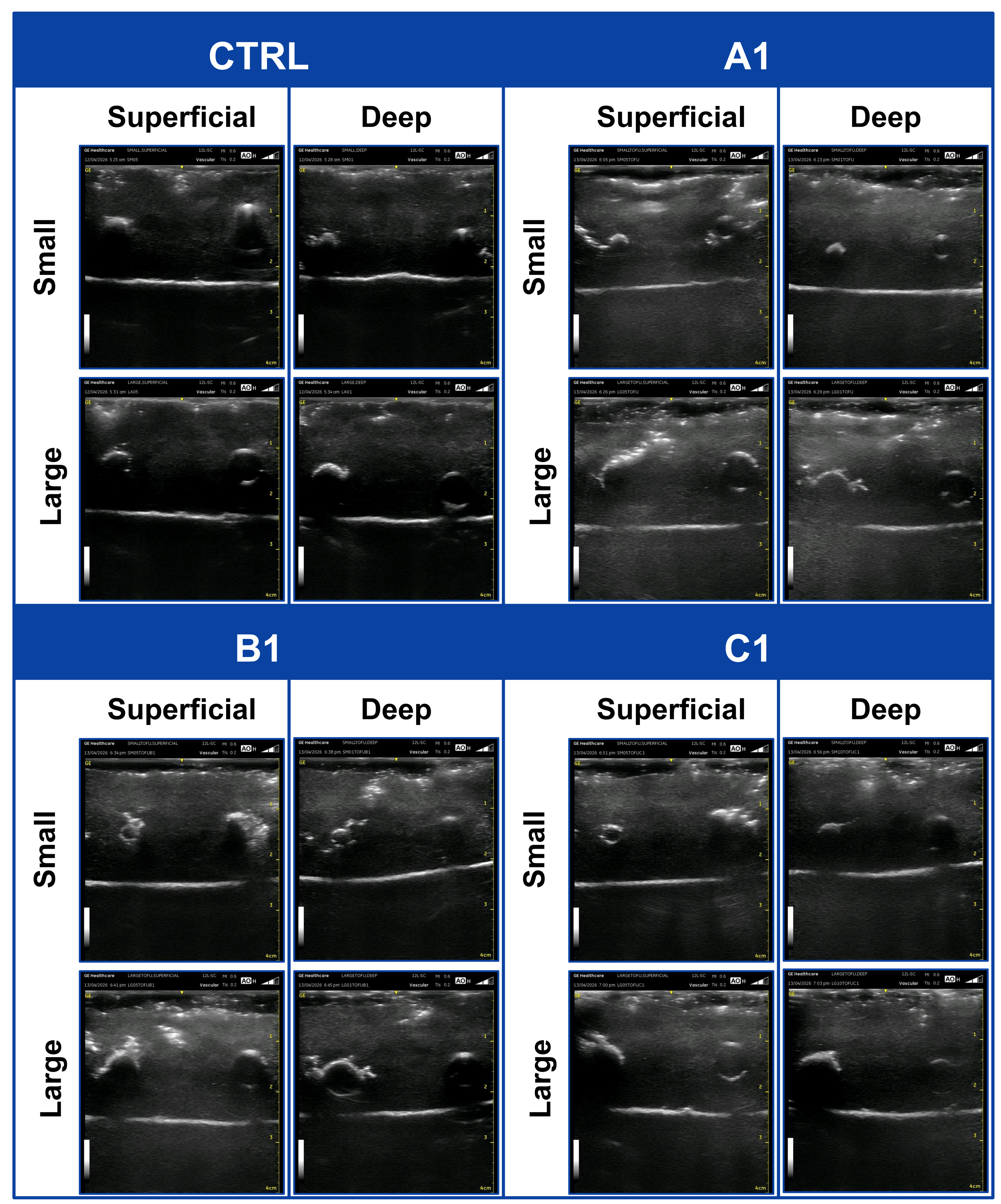


Figure 6. Ultrasound images produced on varying calcinosis volumes and depths. CTRL refers to commercial ultrasound gel, A1 refers to the 6 wt% 2.5:1 PEG:PU gel, B1 refers to the 6 wt% 3:1 PEG:PU gel, and C1 refers to the 6 wt% 3.5 PEg:PU gel. Small and Large refer to the diameters of simulated calcinosis lesions (5 mm and 8mm respectively). Superficial and Deep refer to the depths at which the simulated calcinosis lesions were implanted (5 mm and 10 mm respectively). Straws of identical diameters were imaged alongside the calcinosis lesions as a control.

Final Product Specifications

Specification	Target Range	Validation Need
Hydrogel Sheet Thickness	10 mm	Optimal thickness for signal propogation
Hydrogel Polymer Composition	3:1 PEG:PU	Optimal ratio of tunable polymer (PEG) to mechanical integrity maintenance (PU)
Hydrogel Weight Percentage	6 wt%	Maximal water retention for optimal signal retention
Sheet Dimensions	43mm x 8mm x 10mm	Minimum dimensions to cover surface of ultrasound probe to conserve material in initial prototyping
Final Sheet Volume	3440 uL	Minimum volume provided selected dimensions and thickness

Analysis

A.
$$Detectability\ Score = \frac{Detected\ Area}{Expected\ Area}$$

B.

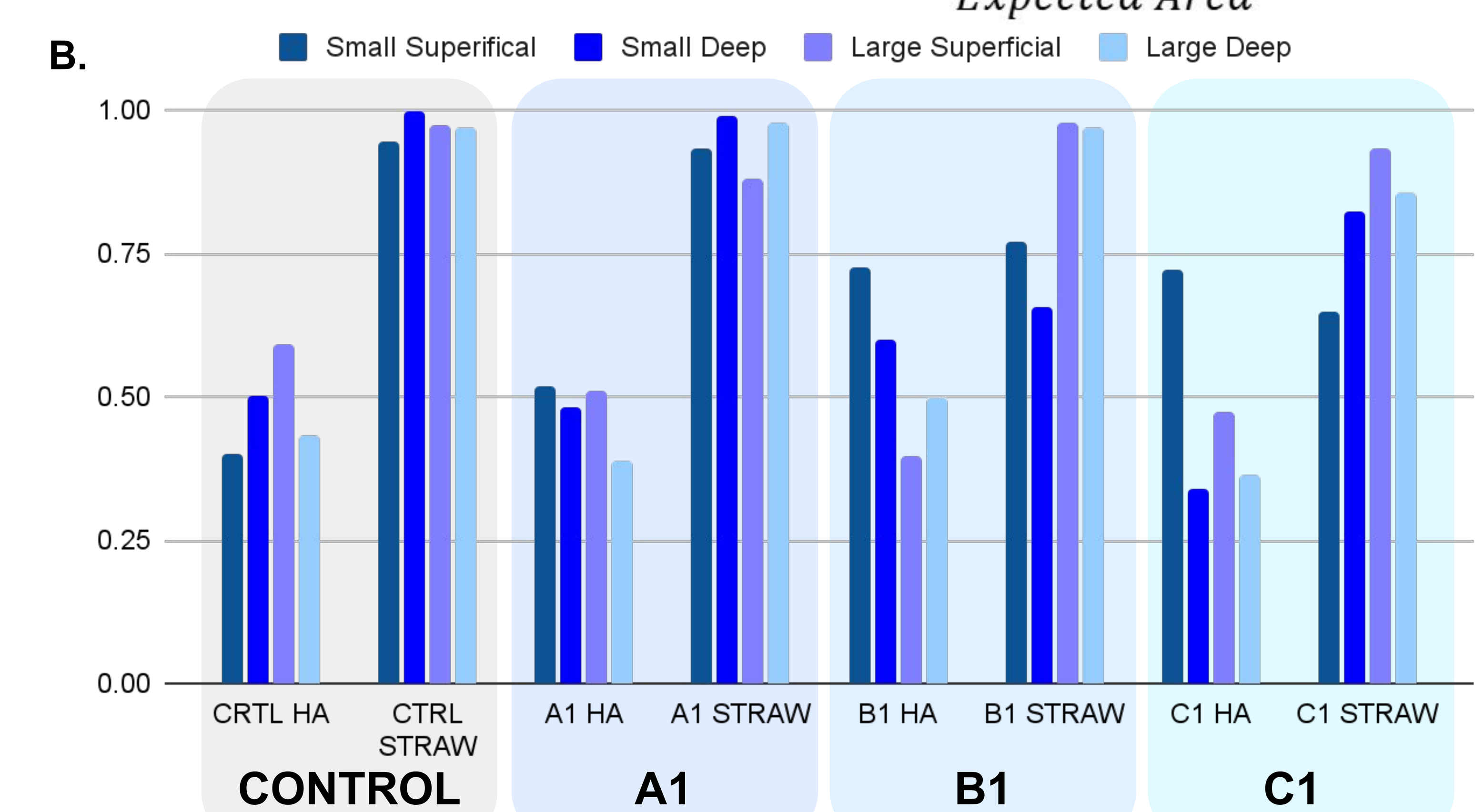
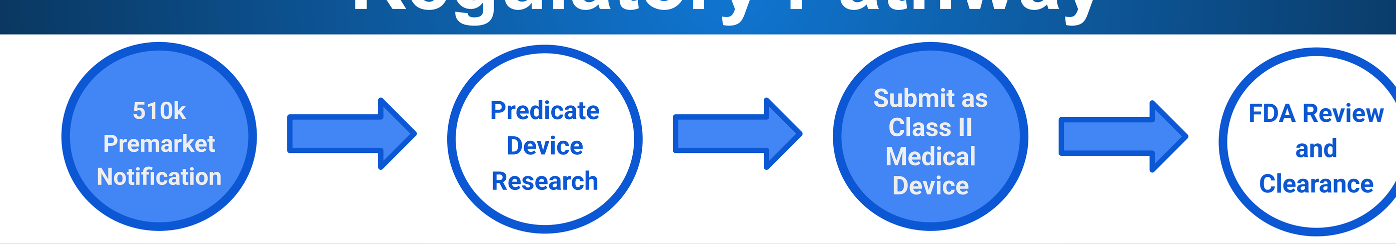
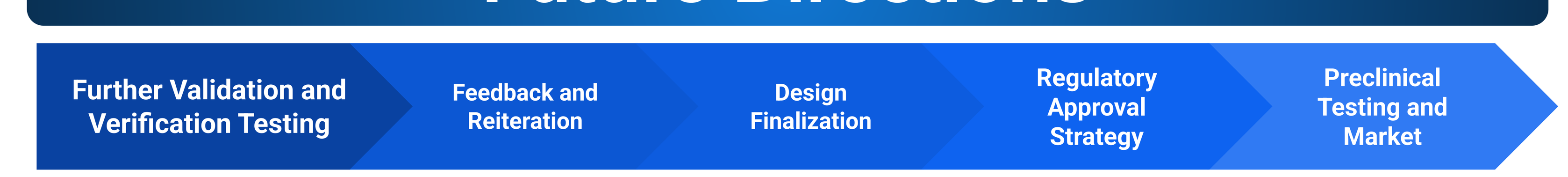


Figure 6. A. Equation utilized to quantify detectability score of experimental hydrogel formulations. **B.** Detectability of embedded inclusions across imaging conditions. Bar chart showing normalized detectable area (detected area divided by expected inclusion area) for straw controls and calcinosis analogs under both commercial ultrasound gel and hydrogel conditions. Results are grouped by gel (control, A1, B1, C1) inclusion size (small, large), depth (superficial, deep). Detectability serves as a quantitative proxy for imaging fidelity, with higher values indicating improved visualization of target features.

Regulatory Pathway



Future Directions



Acknowledgements, Design History File, and References

We would like to thank our mentors Dr. Nagaraja, Dr. Sohn, Dr. Verma, and Dr. Pham for their guidance, expertise, and support throughout this project. We would also like to thank Dr. Vernon, Professor Sobrado, and the rest of the School of Biological and Health Systems Engineering for providing us the opportunity and resources to pursue impactful engineering work.