Design and Optimization of the Separated Interface Nerve Electrode for a Freeform Stimulator in Vestibular Restoration

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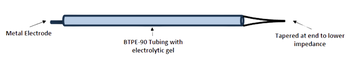
Introduction

Vestibular prostheses aim to restore the sense of balance in individuals with bilateral vestibular dysfunction by delivering electrical stimulation to the vestibular nerve in response to detected head movements. Traditional methods rely on pulsatile stimulation, but freeform or direct current (DC) stimulation can encode a wider range of bi-directional angular velocities, offering a significant advantage for vestibular restoration. However, delivering DC to biological tissue is challenging due to the risk of harmful redox reactions, water electrolysis, and tissue damage at the electrode-tissue interface. To address these challenges, the Freeform Stimulator (FS), developed by Dr. Gene Fridman's Machine Biointerface Laboratory, enables safe delivery of ionic direct current (iDC) through hydrogel-based electrodes that minimize redox reactions. A key component of this system is the Separated Interface Nerve Electrode (SINE), which spatially separates electrochemical reactions from neural tissue. Our project focuses on optimizing the design of the SINE to enhance flexibility, mechanical stability, and consistent ionic current delivery, advancing the long-term safety and performance of ionic neuromodulation technologies.



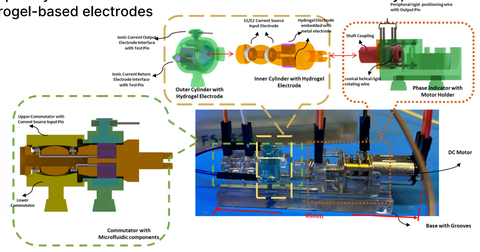


Figure 1. The FS prototype (**right**), developed by the Machine Biointerface Laboratory, is composed of three main modular subsystems: the commutator with microfluidic components, the microfluidic μFS module containing hydrogel electrodes, and the phase indicator with motor holder mounted onto a grooved base. The commutators ensure continuous electrical connections while allowing rotational movement of the μFS, which houses inner and outer hydrogel electrodes (SINEs, **left**) that deliver and return ionic current through embedded metallic interfaces. A phase indicator tracks the absolute rotational position of the electrodes, with motion driven by a DC motor through a shaft coupling. Grooves in the base maintain concentric alignment of rotating parts. The entire device is immersed in mineral oil, functioning as both lubricant and electrical insulator.

Electrical Testing

Electrical testing assessed the ionic conductivity and frequency stability of double network hydrogels formulated with varying $CaSO_4$, MBAA, and sodium alginate concentrations. Resistivity was measured at 100 Hz and 1 kHz using a two-terminal voltage divider setup. At 100 Hz, resistivity generally decreased with increasing calcium sulfate and MBAA concentrations, reflecting enhanced ionic and covalent crosslinking that promoted more continuous ion pathways. Sodium alginate concentration similarly improved conductivity by increasing the charged polymer backbone. At 1 kHz, differences between formulations narrowed, suggesting greater capacitive and polarization effects. Frequency stability was evaluated by calculating ΔResistivity between 100 Hz and 1 kHz. Formulations with intermediate calcium sulfate (10–14%) and MBAA concentrations exhibited the lowest ΔResistivity, indicating greater frequency stability. In contrast, very low or high crosslinker concentrations resulted in higher instability, likely due to disrupted ion conduction networks. These results guide hydrogel formulation for stable ionic current delivery in neuromodulation applications.

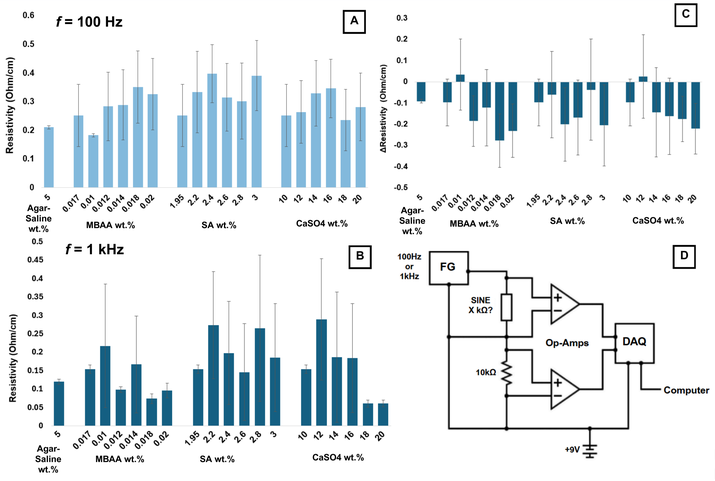


Figure 2. Electrical characterization of double network hydrogels with varying calcium sulfate, MBAA, and sodium alginate concentrations. (**A**) Resistivity measured at 100 Hz across formulations (**B**) Resistivity measured at 1 kHz across formulations (**C**) ΔResistivity, calculated as the difference between 100 Hz and 1 kHz measurements, highlights the frequency stability of each formulation. (**D**) Schematic of the two-terminal voltage divider circuit used to determine resistivity values, featuring a known resistor placed in series with the hydrogel sample.

Stability Testing

To evaluate the water retention properties of candidate hydrogel formulations for SINE optimization, we conducted dehydration testing over a 30-hour period. Previous studies using 5% agar-saline hydrogels with silane additives demonstrated substantial water loss after approximately 24 hours. Building on these findings, we repeated the dehydration testing under controlled environmental conditions to assess improvements in water retention across hydrogels incorporating varying concentrations of calcium sulfate ($CaSO_4$). As shown, the 5% agar-saline control initially retained a higher percentage of water compared to the $CaSO_4$ groups; however, by 24 to 30 hours, hydrogels with 10–16% $CaSO_4$ showed water retention levels comparable to the agar-saline control. In contrast, hydrogels with higher $CaSO_4$ concentrations (18–20%) exhibited accelerated dehydration throughout the test period.

Formulation	Water Retention After 30 hrs. (%)
5% Agar-Saline	96.53
10% $CaSO_4$	96.68
12% $CaSO_4$	95.96
14% $CaSO_4$	95.92
16% $CaSO_4$	95.30
18% $CaSO_4$	96.44
20% $CaSO_4$	95.86

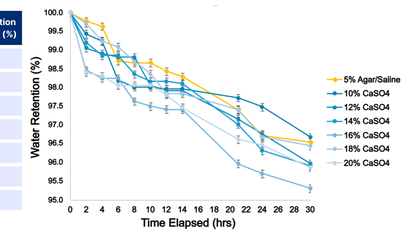


Figure 3. Water retention of hydrogel formulations over a 30-hour dehydration period. Hydrogels composed of 5% agar-saline and varying concentrations of calcium sulfate (10–20%) were tested for water retention under controlled environmental conditions. Error bars represent standard deviation from three independent samples per group.

Fabrication Methodology

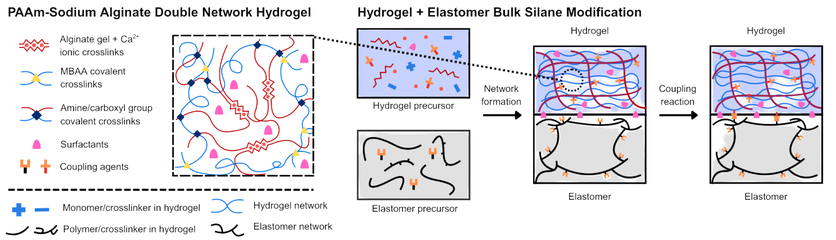
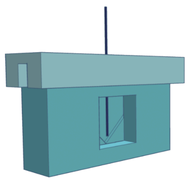


Figure 4. Schematic of double network hydrogel fabrication and bonding to Ecoflex 00-30. Sodium alginate was dissolved with sodium dodecyl sulfate (SDS) and ionically crosslinked using calcium sulfate to form the first network. Acrylamide and MBAA were polymerized via APS and TEMED to create a covalent second network. Ecoflex 00-30 surfaces were treated with TEOVS, while TMSPMA was incorporated into the hydrogel precursor to enable covalent bonding. The resulting hydrogel-elastomer hybrid improves durability, flexibility, and dehydration resistance.

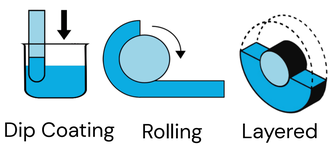
To create a mechanically robust and dehydration-resistant hybrid material, we fabricated a double network hydrogel composed of sodium alginate and polyacrylamide (PAAm), chemically bonded to an Ecoflex 00-30 elastomer substrate. Sodium alginate was dissolved in an aqueous solution containing sodium dodecyl sulfate (SDS) for improved dispersion and ionically crosslinked with calcium sulfate ($CaSO_4$) to form the first network. A second covalent network was established by free-radical polymerization of acrylamide using ammonium persulfate (APS) and N,N,N′,N′-tetramethylethylenediamine (TEMED). To enable stable bonding, 3-(Trimethoxysilyl)propyl methacrylate (TMSPMA) was incorporated into the hydrogel precursor and triethoxyvinylsilane (TEOVS) into the Ecoflex precursor. This dual-silane strategy enhanced covalent bonding at the interface, improving mechanical adhesion and resistance to delamination during dehydration and mechanical stress.

90° Bend Test

90° Bend Test STL used to determine the angle of permanant deformation to the tubing or elastomer coating. BTPE-90 permanently deformed at 90°, while Ecoflex 00-30 returned to original shape



Encasing the Hydrogel:



Mechanical Testing

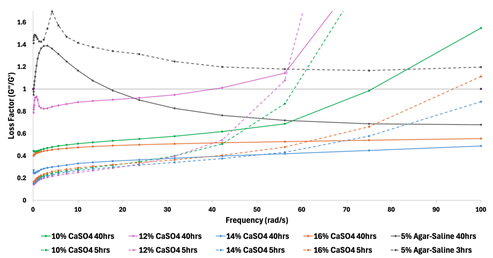
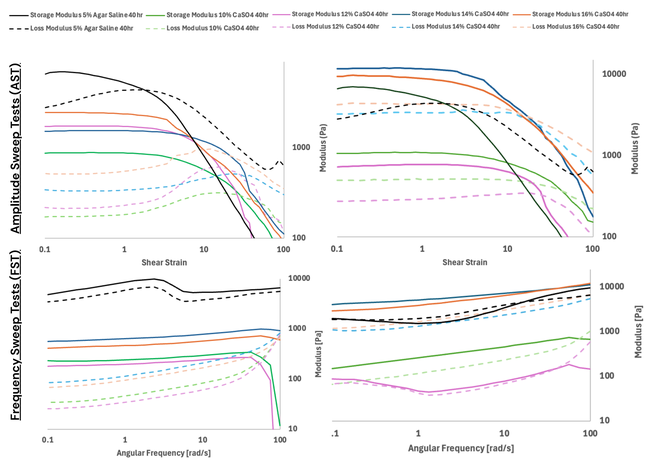


Figure 5. (above), Loss Factor (tanδ) over Frequencies (0–100 rad/s) was measured to assess the balance between energy dissipation and storage within each hydrogel formulation. Higher loss factor values indicate more viscous, energy-dissipating behavior, while lower values reflect more elastic, solid-like performance. Calcium sulfate-based hydrogels exhibited more stable elastic behavior across the frequency range, maintaining low tanδ values. In contrast, the 5% agar-saline control showed greater viscous losses, particularly after 40 hours, suggesting increased structural degradation over time and a shift toward less stable, more energy-dissipative behavior.



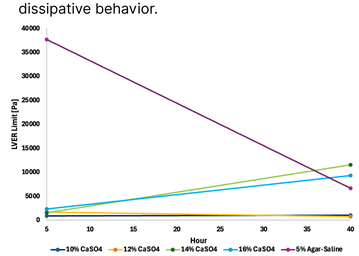


Figure 6. (left), Mechanical Testing and Best Material Selection
Among the tested hydrogels, 14% calcium sulfate demonstrated the most favorable mechanical performance for long-term stability. It showed consistent strengthening over time with limited structural degradation, maintaining a high LVER limit above 9,000 Pa after 40 hours and low energy dissipation across frequencies. In contrast, the 5% agar-saline exhibited rapid mechanical weakening and increased viscous losses, indicating poor durability under dehydration conditions. Based on these results, 14% $CaSO_4$ was selected as the optimal scaffold material for maintaining flexibility, mechanical resilience, and conductivity over extended periods. Amplitude sweep and frequency sweep testing (**above**) further supported these findings, with 14% $CaSO_4$ showing stable modulus values and lower energy dissipation across a broad range of strains and angular frequencies.

Conclusions

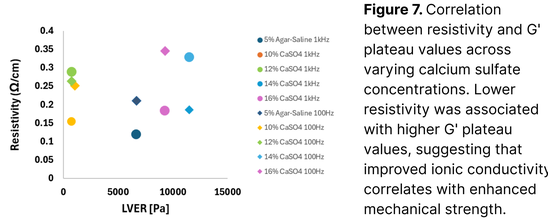


Figure 7. Correlation between resistivity and G' plateau values across varying calcium sulfate concentrations. Lower resistivity was associated with higher G' plateau values, suggesting that improved ionic conductivity correlates with enhanced mechanical strength.

Among the formulations tested, hydrogels containing 10–14% $CaSO_4$ exhibited the most balanced electrical and mechanical performance. Resistivity measurements at both 100 Hz and 1 kHz highlight frequency-dependent behavior, where stability across frequencies is critical for consistent ionic direct current (iDC) delivery in neuromodulation applications. Formulations within this range also demonstrated superior mechanical resilience, maintaining flexibility and structural integrity during extended dehydration periods. Based on these findings, 14% $CaSO_4$ was selected as the optimal composition for further development of the Separated Interface Nerve Electrode (SINE), supporting long-term stability, low impedance, and reliable iDC delivery for vestibular restoration and broader bioelectronic applications.

Acknowledgements

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