# Piezoelectric-Driven Hernia Repair Mesh Mechanically Loaded with Ultrasound For Soft Tissue Healing

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## Background

Annually there are over 1 million hernia repair surgeries performed in the USA.[1,2] Hernias occur when part of an organ, typically the intestines, protrudes through a weakened location in the abdominal wall (**Figure 1a**). Hernias can present in any age, demographic, and physical condition patient. It is standard for the surgeon to use a hernia repair mesh to help hold the compromised tissue together, depending on the location of the hernia and patient condition (**Figure 1b**). However, rate of recurrence for hernias after using a synthetic mesh are currently high. For example, in the most common type of hernia repair, ventral hernia repair, hernia recurrence rates can range from 24% to 43% in tobacco users or people with diabetes.[3] Physiological level ES has shown beneficial effects in improving healing in both hard and soft tissue regeneration. Piezoelectric materials have the capability of producing low level electrical signals from mechanical loading to help speed healing.[4]

Combining the novelty of piezo elements to create an electrically active hernia repair mesh for faster healing prospects is conducted in this study through simulated transcutaneous mechanical loading of the piezo element with therapeutic ultrasound.

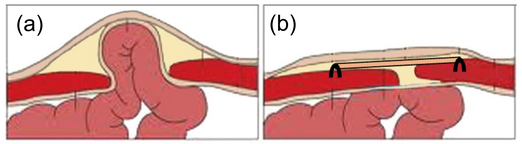



**Figure 1.** (a) Hernia (b) Hernia Repair Mesh

## Methods

Medical grade polypropylene (PP) hernia repair mesh (PPKM505 0.125 mm monofilament, 1.3 x 1.5 mm pores 58 GSM, SurgicalMesh™ Division, Textile Development Associates, Inc.) was cut to a dimension of either 24 mm x 80 mm or 20 x 60 mm, gold sputter coated (GSC) (EMS150RS Quorum) and autoclaved at 120˚C for 30 minutes. The mesh then underwent a wetting ladder with ethanol and sterilized water to increase hydrophilicity and then incubated overnight in 40% fetal bovine serum (FBS) for protein adsorption to promote integrin binding. The prepped mesh was then electrically connected together and linked to the piezo element that was embedded in silicone. Mouse NIH 3T3 fibroblast cells (ATCC, Manassas, VA) were plated on 6-well plates at 150,000 cells per well, incubated at 37˚C with 50 RPM for 7 hours, and then moved to a stationary incubator at 37˚C for the remainder of the study. The media was Dulbecco's Modified Eagle Medium (DMEM) with 10% FBS and 1% Streptomycin. The cells on the mesh were loaded electrically via the voltage released by the piezo elements. The piezo elements were mechanically loaded twice daily through an ultrasound phantom with a clinical ultrasound machine (Chattanooga Intelect TranSport). More specifically, the ultrasound machine was 15 seconds on and 15 seconds off for 10 minutes, twice daily.

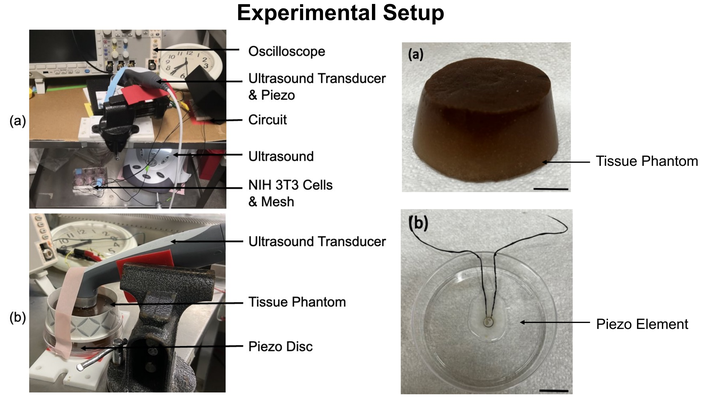
For the temporal studies, one ultrasound intensity was chosen (0.5 W/cm$^2$) and conducted over a period of 5- & 7-days (**Table 1**). The initial metric was a Live/Dead Viability/Cytotoxicity Kit (Thermo Fisher Scientific, Waltham, MA). The experimental groups were: (1) PP mesh, no ES (2) GSC PP mesh, no ES, (3) GSC PP mesh, ultrasound intensity 0.5 W/cm$^2$.

**Table 1.** Temporal viability study experimental groups.

| Number | Experimental Group (*n*=3) | Electrical Loading (Ultrasound Intensity) | Number of Stimulation Days |
|---|---|---|---|
| 1 | GSC PP Mesh | No ES | 5 |
| 2 | GSC PP Mesh | 0.5 W/cm$^2$ | 5 |
| 3 | PP Mesh | No ES | 5 |
| 4 | GSC PP Mesh | No ES | 7 |
| 5 | GSC PP Mesh | 0.5 W/cm$^2$ | 7 |
| 6 | PP Mesh | No ES | 7 |

## Results

**Experimental Setup**




The temporal viability studies showed viability with cellular growth on all three experimental mesh groups: PP mesh, GSC mesh, and GSC mesh with ES for the 5-day study (**Figure 2**) and the 7-day study. **(Figure 3).**

**Results:**

5-Days of Stimulation

- Controls showed similar amounts of live & dead cells adhered to the mesh.
- GSC PP ES mesh appeared to have more live cells on the mesh then both controls.

7-Days of Stimulation

- PP & GSC PP controls increased in the amount of cellular growth on the mesh compared to the 5-day study.
- GSC PP ES group had similar levels of live cells on the mesh & had fewer dead cells compared to the GSC control group.

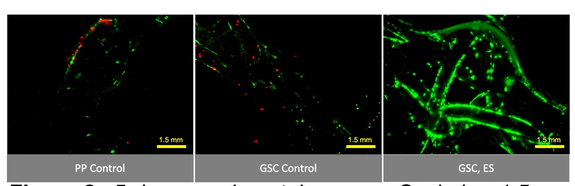



**Figure 2.** 5-day experimental groups. *Scale bar 1.5 mm.*

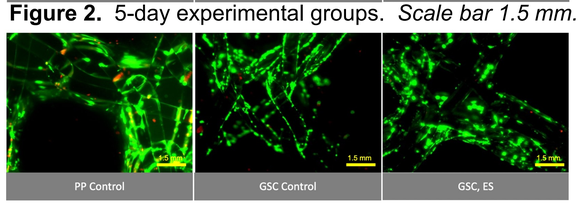



**Figure 3.** 7-day experimental groups. *Scale bar 1.5 mm.*

## Discussion

Initial viability results showed promising outcomes for the ES hernia repair mesh for soft tissue healing after 5- & 7-days. However, a small complication arose with the GSC mesh where the some of the GSC gold target did not stay adhered to the mesh. This can be seen in **Figure 4,** where the dark flakes are floating gold.

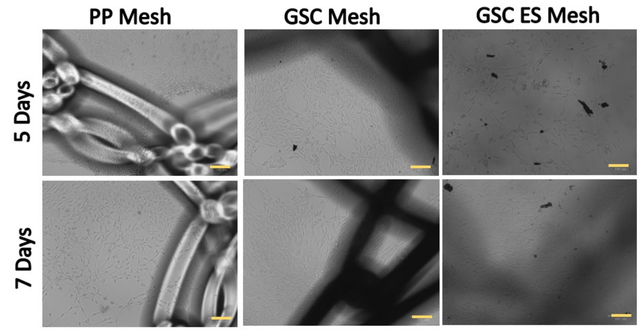



**Figure 4. Brightfield images of 5- & 7-day experimental groups.** ***Scale bar 100 µm.***

This could be due to how the mesh was handled prior to sputter coating. More tests are necessary to conclude the cause of the flaking.

## Conclusions

While the initial viability results show promise for the transcutaneous mechanically loaded hernia repair mesh, the viability studies would need to be conducted again with an electrode that does not have gold flaking occur. An added measure of 14-days of stimulation will be added as well as an ultrasound intensity study.

Future Work

- Determine cause of gold flaking on mesh
- Repeat temporal viability studies
  - Add in another time point of 14-days of stimulation
  - Add in additional experimental groups for ultrasound intensity viability study (ex: 0.5 , 1.0, & 2.0 W/cm$^2$)
  - Include a total collagen assay for matrix formation quantification
- Conduct a Scratch Assay to Assess Time-To-Closure of a Wound
  - QPCR of key wound healing marker (fibroblast growth factor (FGF))

## Acknowledgments

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SHARPhub an initiative of BBCetc

## References

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