BioSpring: Small-Scale Orthopedic Implantables

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Clinical Need

- ❑ **6–9 million** people in the U.S. experience **scoliosis or spinal deformities** due to growth plate disturbances [1].
- ❑ **38,000+ spinal fusion surgeries** are performed annually to treat severe cases [1].
- ❑ 15–30% of pediatric bone injuries involve growth plate fractures [2].

Works Cited

- ❑ Current implants use **rigid fixation**, which is **non-ideal for growing bone**. Rigid systems can lead to:
  - ➢ Stunted or uneven bone growth
  - ➢ Delayed or impaired recovery
  - ➢ Poor compatibility with soft tissue in joints

Device Concept

The BioSpring is a millimeter-scale force-modulating polymer spring designed to enhance structural elasticity in existing orthopedic platforms to build implants that grow with the patient.

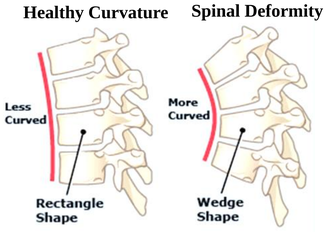


Fig 1. Curvature & Growth Plate Pinching in Spinal Deformities [3].

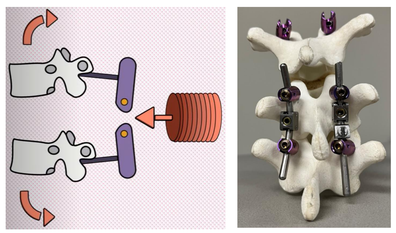


Fig 2. a) BioSpring two-rod approach, b) BioSpring implant device shown on the right.

Specifications + Material Selections

Needs/Metrics	Value
Young's Modulus	50-250 MPa
Load Withstood	35 N
Elastic Compressible Range	1-2 mm
Max Diametric Change at 8N	< 50%
Cell Viability	> 95%
Swelling Ratio	Match or Less than Control
Max Force Generation	Match Control (7-9N)
Shear + Torsional Stress	Less than Control
Manufacturing Cost	Less than Control

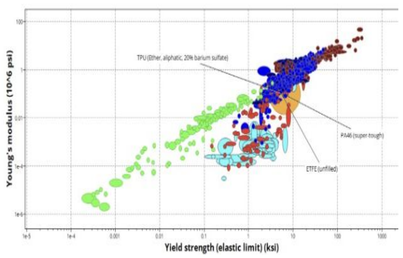
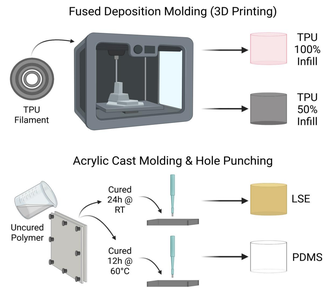


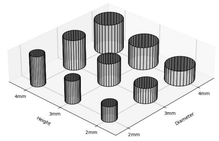
Fig 3. **Material Selection Process via Ansys Granta EduPack.** TPU 20% Barium Sulfate hit the desired yield strength metrics with 98% similarity. Soft polymers were selected due to similar mechanical properties with a larger range of compressibility.

Selected Polymers:

- ❑ Thermoplastic Polyurethane (**TPU**)
- ❑ Polydimethylsiloxane (**PDMS**)
- ❑ Liquid Silicone Elastomer (**LSE**)

Prototyping + Experimental Design





- ❑**4** Material Conditions
- ❑**9** Dimensional Combinations
- ❑**36** Total Unique Experimental Groups

Material Characterization *– How do the materials behave under mechanical stress?*

1. Mechanical Compression Testing

Implantable Feasibility *– How do the materials react to the conditions of the body?*

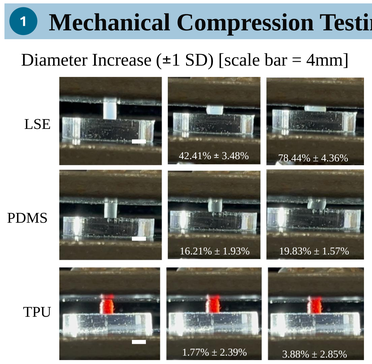
2. Swelling Ratio Testing
3. Cell Viability Testing

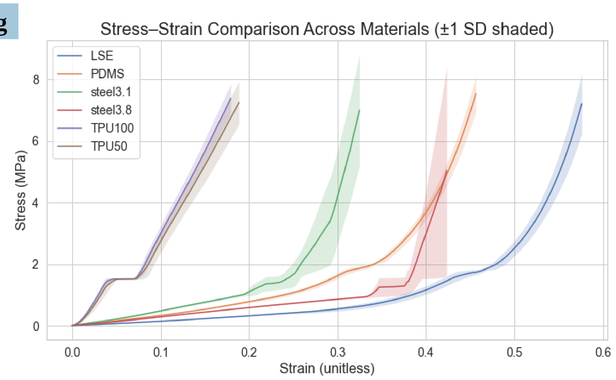
Device Validation *– Can the prototype produce an effective force in the final device?*

4. Integrated Device Testing

Test Systems + Results

1 Mechanical Compression Testing





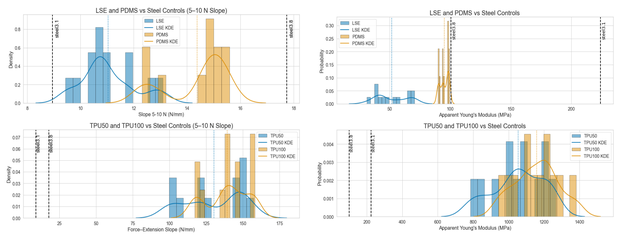
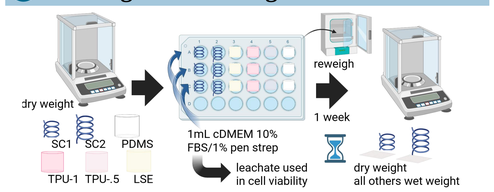


Fig 4: Characterization results. Testing revealed that PDMS and LSE springs exhibited force-extension behaviors that fell between those of the two stainless steel controls and comparable Young's moduli, demonstrating suitable stiffness for dynamic orthopedic loading, while improving on the controls by having a smooth, predictable force response across a longer range of compression, and less slippage. All materials showed diametric deformation within the limits of the screw hole, showing structural compatibility.

2 Swelling Ratio Testing



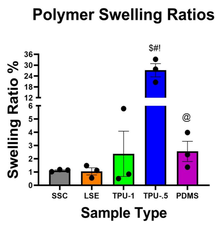
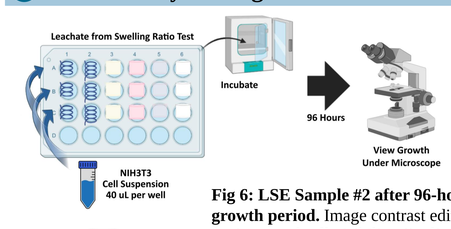


Fig 5: Swelling ratios of various polymer compositions tested for the BioSpring component. All materials except TPU with 50% infill showed a statistically significant reduction in swelling compared to the stainless-steel controls (which had varying geometries), indicating their suitability as low-swelling alternatives for implant integration.

3 Cell Viability Testing



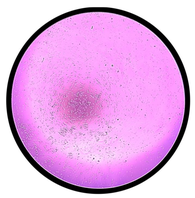
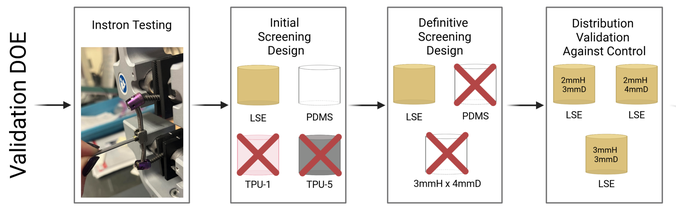


Fig 6: LSE Sample #2 after 96-hour growth period. Image contrast edited for increased cell visibility. Qualitative analysis shows cell proliferation across the stainless-steel control and all polymer samples. Subsequent reruns performed on LSE and PDMS samples over 24-hour period yielded similar results. Future experiments will involve Trypan blue staining with hemocytometers to quantify precise live/dead cell ratios.

Design Validation

4 Integrated Device Validation Testing



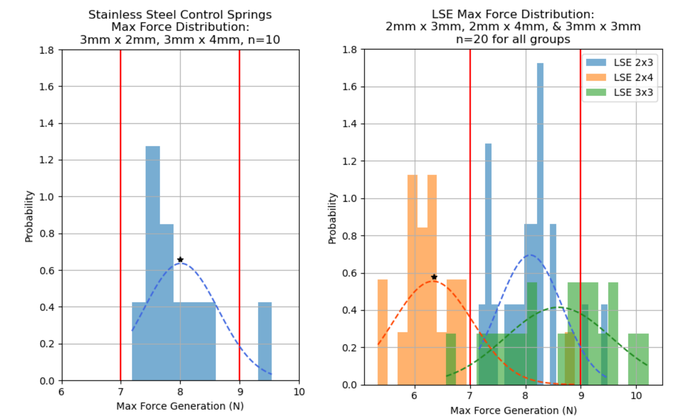
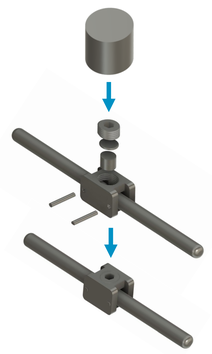


Fig 7: Validation testing. Distribution (n=20) of remaining three experimental groups against control (C) in target range (7-9N). Kruskal-Wallis analysis confirmed significance between groups, post-hoc tests using Holm's method revealed statistical significance shown between Control and LSE 2x4 (***p=0.0039**). C vs LSE 2x3, p = 0.6941 and C vs LSE 3x3, p = 0.3514. LSE 2x3 and 3x3 were **not** statistically different from each other or C, indicating successful fit of target range and need for further testing.

Final Design + Moving Forward



- ❑ Next steps should include investigating **LSE 2x3mm and 3x3mm** with larger sample sizes.
- ❑ We recommend looking into medical-grade manufacturing practices for implantable devices, testing LSE's medical-grade counterpart (medical rubber), and exploring other manufacturing process to decrease dimensional tolerance (injection molding).
- ❑ As a component for implantable orthopedic devices, the BioSpring would be classified as a Class III Biomedical Device and will adhere to the necessary regulations and requirements.

Acknowledgements

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Phoenix Children's

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