

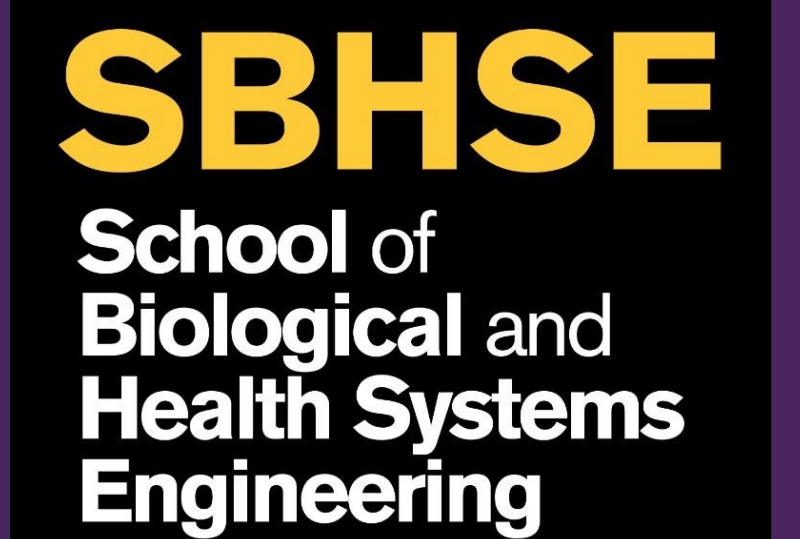


BioSpring: Small-Scale Orthopedic Implantables

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Clinical Need

- 6-9 million people in the United States currently experience scoliosis or other type of spinal deformity due to growth plate issues during puberty and 38,000 patients undergo rigid spinal fusion surgery every year [1].
- 15-30% of all bone injuries in children include fracture through a growth plate [2].
- Current orthopedic implants rely on fully rigid fixation, making them non-ideal for natural longitudinal fluctuations of growth plates, particularly in pediatric patients.
- This rigidity results in stunted or uneven bone growth, poorer recovery outcomes, and challenges in biomechanical compatibility with soft tissues within joint spaces.

Mission Statement

Our mission is to promote bone growth and patient recovery through distraction osteogenesis by integrating small-scale biocompatible springs into existing orthopedic implants.

Project Planning



BioSpring Project Gantt Chart

- This chart outlines the entire project timeline, necessary checkpoints, and is used to track task completion.

Customer Needs + Specifications



BioSpring Project House of Quality

- This chart defines the key technical and customer specifications and evaluates current market competitors against those criteria.

Needs/Metrics	Value
Young’s Modulus	7-12 MPa
Max Load Withstood	35N
Max Spring Deflection	2-3mm
Spring Outer Diameter	2mm
Degradation Rate	<1%/year
Tolerance Matching (mm) with Orthopedic Implants/Standard Surgical Tools	±0.05 mm
Cutoff Total Creep Strain	5% over 2-3 years
Sterility Assurance Level (SAL)	10-6 (1/1,000,000 probability of microorganism being present)

Device Concept

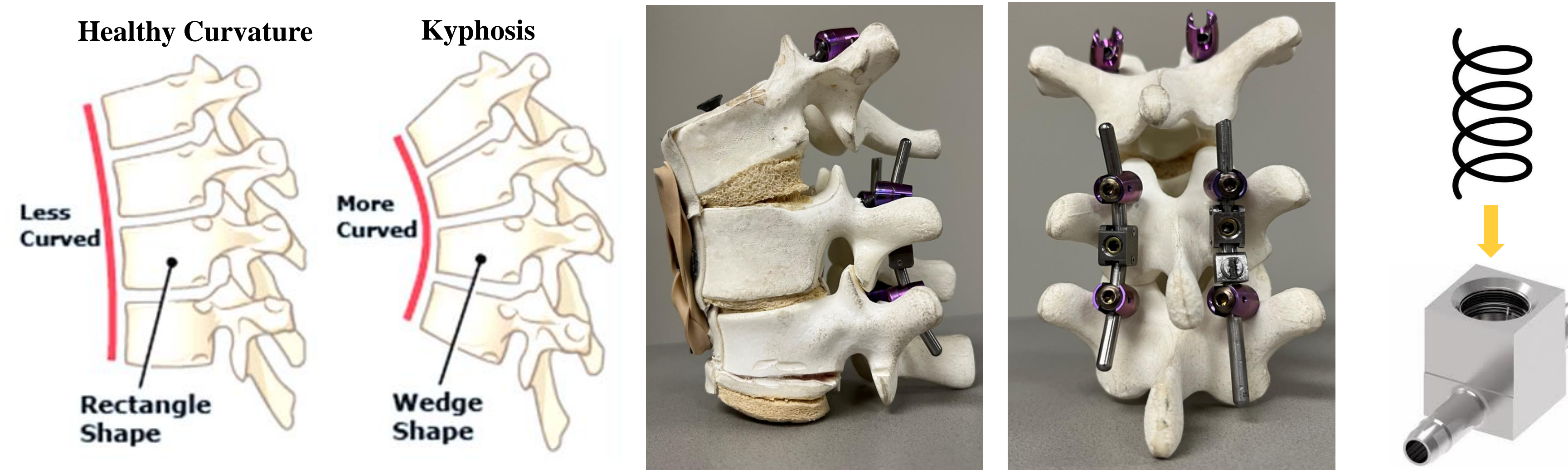


Fig 1a/b. Curvature & Growth Plate Pinching in Spinal Deformities [3].

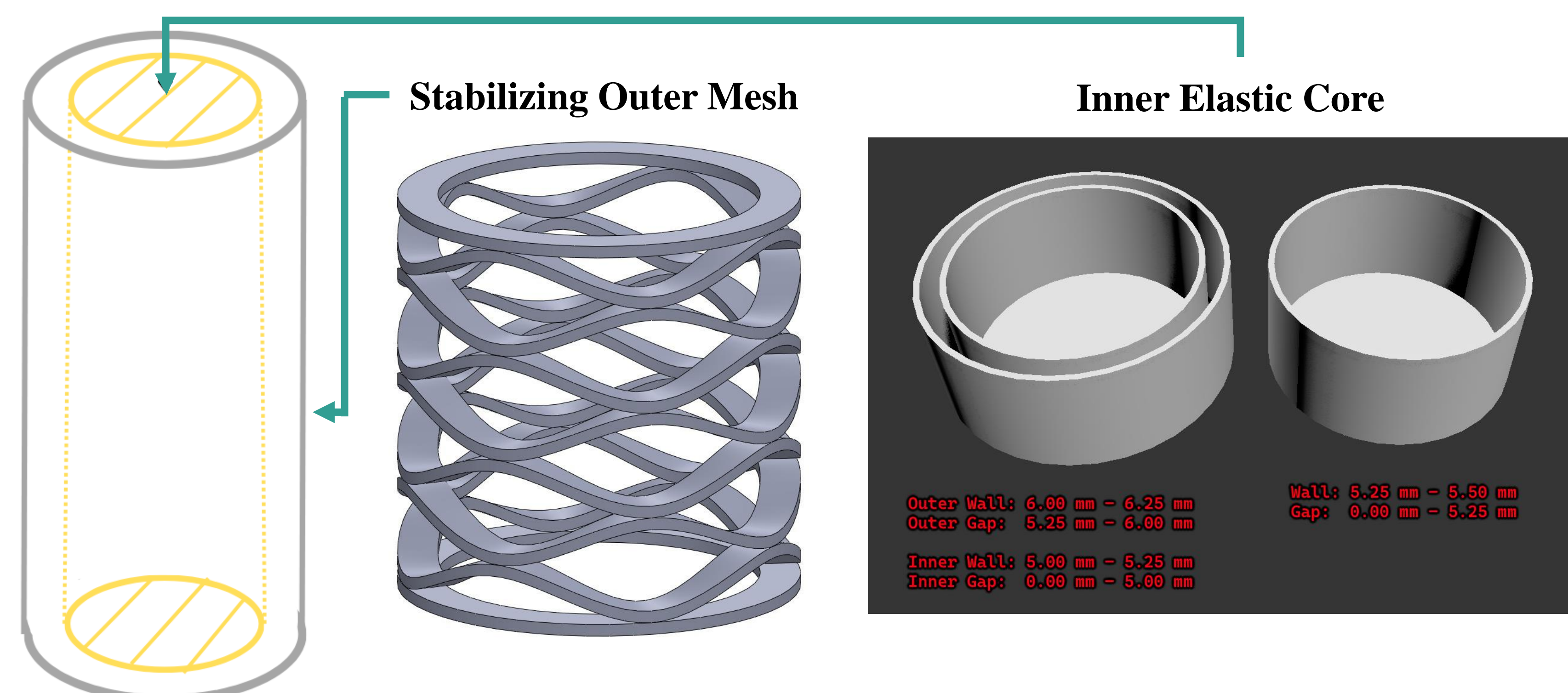
Fig 2a/b. Model of current rigid fixation approach of pediatric kyphosis courtesy of Cameron Jeffers & Dr. Halanski.

The BioSpring is a millimeter-scale double-walled polymeric spring, combining a shape-stabilizing outer mesh with an elastic inner core to enable structural elasticity without obstructive diametric deformation.

Virtual + Technical Modeling

- High compressibility and load-bearing capacity will enhance the linear range of motion and provide consistent passive force to generate distraction around the growth plate and promote osteogenesis

Technical Models	Model Equations
Bacterial Growth on Implants	$\frac{dA}{dt} = r * A (1 - \frac{A}{K}) (1 - \frac{R}{R50})$
Standard Linear Solid Model	$\sigma(t) + \frac{\eta}{E_2} \frac{d\sigma(t)}{dt} = E_1 \epsilon(t) + \frac{\eta(E_1 + E_2)}{E_2} \frac{d\epsilon(t)}{dt}$
Stiffness Degradation	$E(n) = E(0) - E(0)(d + a_2 BS) n^{a_3 + BS}$
Shear & Torsional Stress	$t_{max} = \frac{16Pr}{\pi d^3} (1 + \frac{d}{4r})$
Fatigue Life	$S = \sigma_f \cdot N^{-b}$

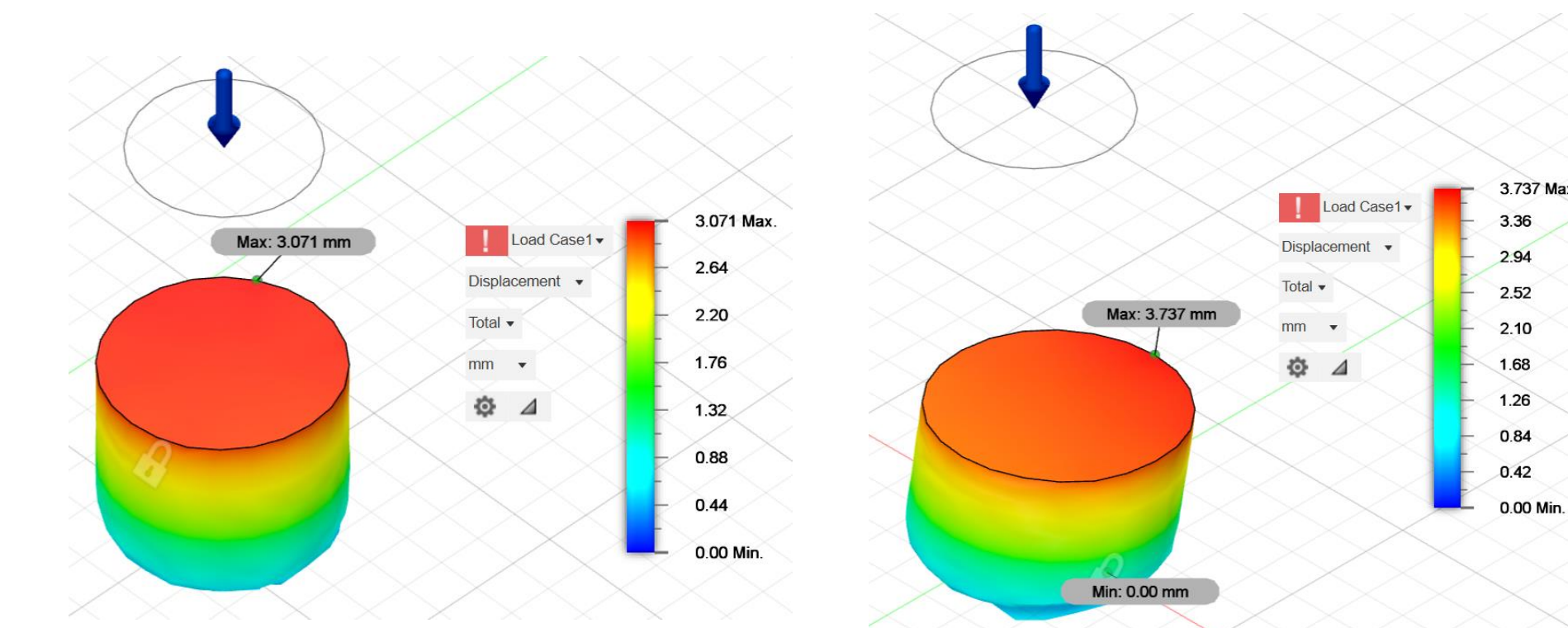


Manufacturing

- For prototyping, Fused Deposition Modeling (FDM) with thermoplastic polyurethane (TPU) filaments will shape the outer geometry, while medical grade silicon rubber casting will form the inner elastic core, allowing rapid, cost-effective iteration in-house.

Material	TPU (Ether, aliphatic, 20% barium sulfate)	Medical Grade Silicon Rubber
Young’s Modulus	0.02 GPa	16.7 MPa
Yield Strength	50 MPa	2.08 - 5.9 MPa
Shear Modulus	15 MPa	511MPa
Poisson’s Ratio	0.48	0.49
Density	1.82g/cm ³	1.23g/cm ³
Cost (USD/lb)	\$4-6	\$20-30

Fig 3a/b. Virtual axial load modeling conducted on both polymers to determine elasticity and deformation characteristics



BioSpring Product Architecture

- This chart outlines the physical components, energy transfer, and essential technical models involved with our design.

Moving Forward

- After customer/market analysis, we have selected this promising design.
- Next steps include advanced technical modeling for validation before ordering materials to perform polymer testing and prototyping.
- 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 for implantable devices.

Acknowledgements

We extend our thanks to Dr. Olivia Burnsed, Dr. Matthew Halanski, Cameron Jeffers, Dr. Bradley Greger, and Dr. Brent Vernon for their continued guidance, trust, and support with the BioSpring project.

