DEVELOPING A SUTURELESS MITRAL VALVE PROSTHESIS

A novel surgical prosthesis that targets patients with severe mitral annular calcification

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JOHNS HOPKINS
WHITING SCHOOL of ENGINEERING

BACKGROUND

Mitral annular calcification (MAC) is a degenerative condition in which hard calcium deposits accumulate around the opening of the mitral valve. One year mortality of severe MAC can reach as high as 50%.

Calcification impairs valve function, often requiring surgical intervention to replace native valve tissue with a prosthetic valve. This makes the development of more adaptable valve replacements an important unmet clinical need.

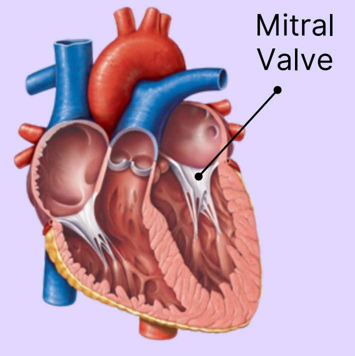


Figure 1: Heart cross-section

Figure 2: Severe MAC (supra-annular view)

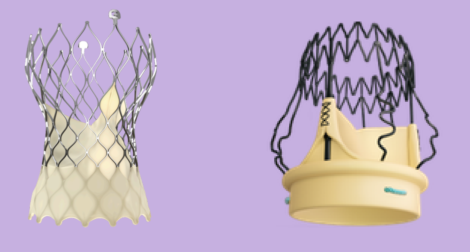
Figure 3: CT scan of severe MAC (supra-annular view)

Sutured Mitral Replacements

On-X (On-X Life Technologies, Inc.) | Mistris Resilia (Edwards Lifesciences)

Sutured prostheses pose high clinical risk due to **time-intensive deployment** and difficulty with suturing through **rigid calcification**.

Sutureless Aortic Replacements



Evolut (Medtronic) | Perceval (Corcym)

The need for a sutureless mitral valve prosthesis remains unmet because calcified mitral valves present unique challenges with their **irregular surfaces, low annulus height, and high blood pressures.**

ACKNOWLEDGEMENTS

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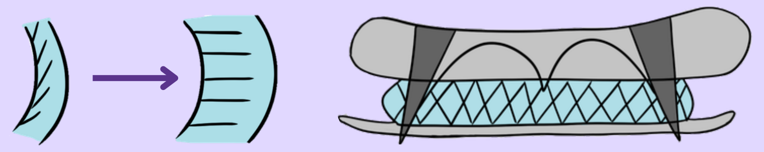
DESIGN EVOLUTION

Problem Definition

To design, prototype, and test a mitral valve prosthetic frame that will house pre-existing leaflets. This frame must achieve **I) manufacturability, II) rapid deployment, III) conformability, and IV) high pressure tolerance.**

V0: Spoke Expansion Within Gel Matrix

Silastic rings engage around MAC and nitinol spokes in gel matrix straighten to conform to annulus

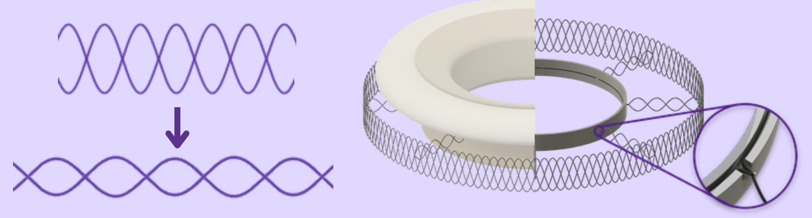


Performance

- ✗ Gel instability (I)
- ✗ Causes torsion (III)
- ✗ Nitinol lacks grip (IV)

V1: Sinusoidal Spokes and Hoop

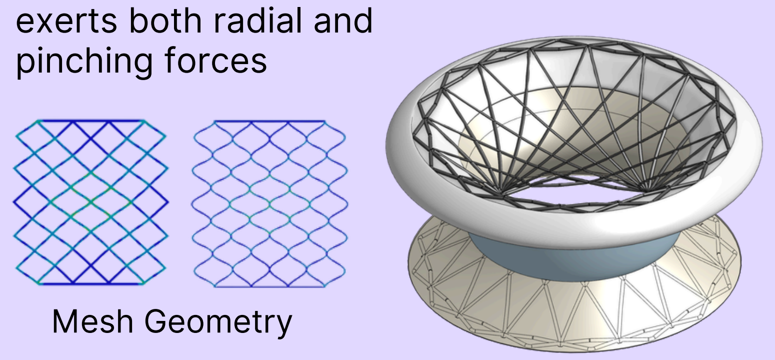
Sinusoidal expansion induces radial force from spokes and circumferential force from hoop



- ✗ Complex nitinol structure (I)
- ✓ Variable wave density (II)
- ✗ Low contact area (IV)

V2: Hourglass Mesh

Nitinol mesh and soft polymer bumper exerts both radial and pinching forces

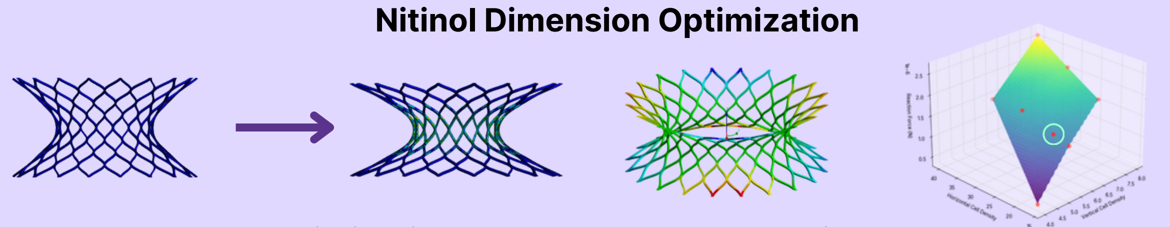


Mesh Geometry

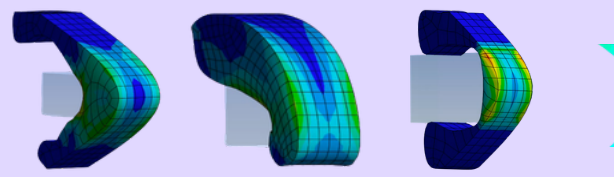
- ✗ Too many elements & high-stress mesh design (I)
- ✓ High flexibility (III)
- ✓ Pinching force (IV)

Finite Element Analysis

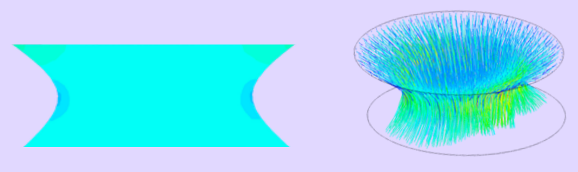
Nitinol Dimension Optimization



Bumper Optimization



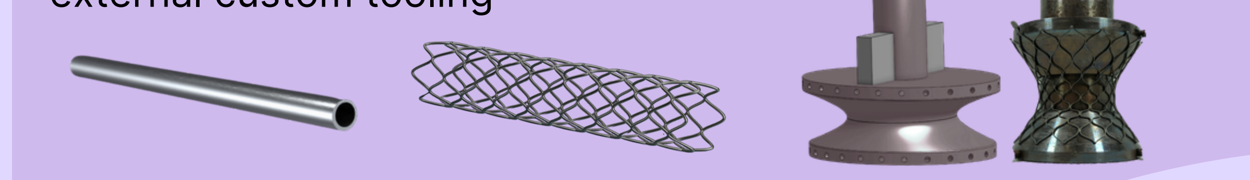
Fluid Flow



RESULTS

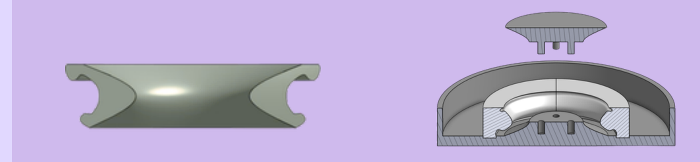
Nitinol Mesh

Nitinol hypotube was laser-cut, expanded, and heat-set with external custom tooling



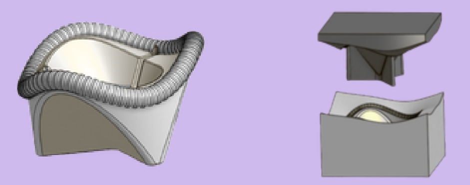
Soft Polymer Bumper

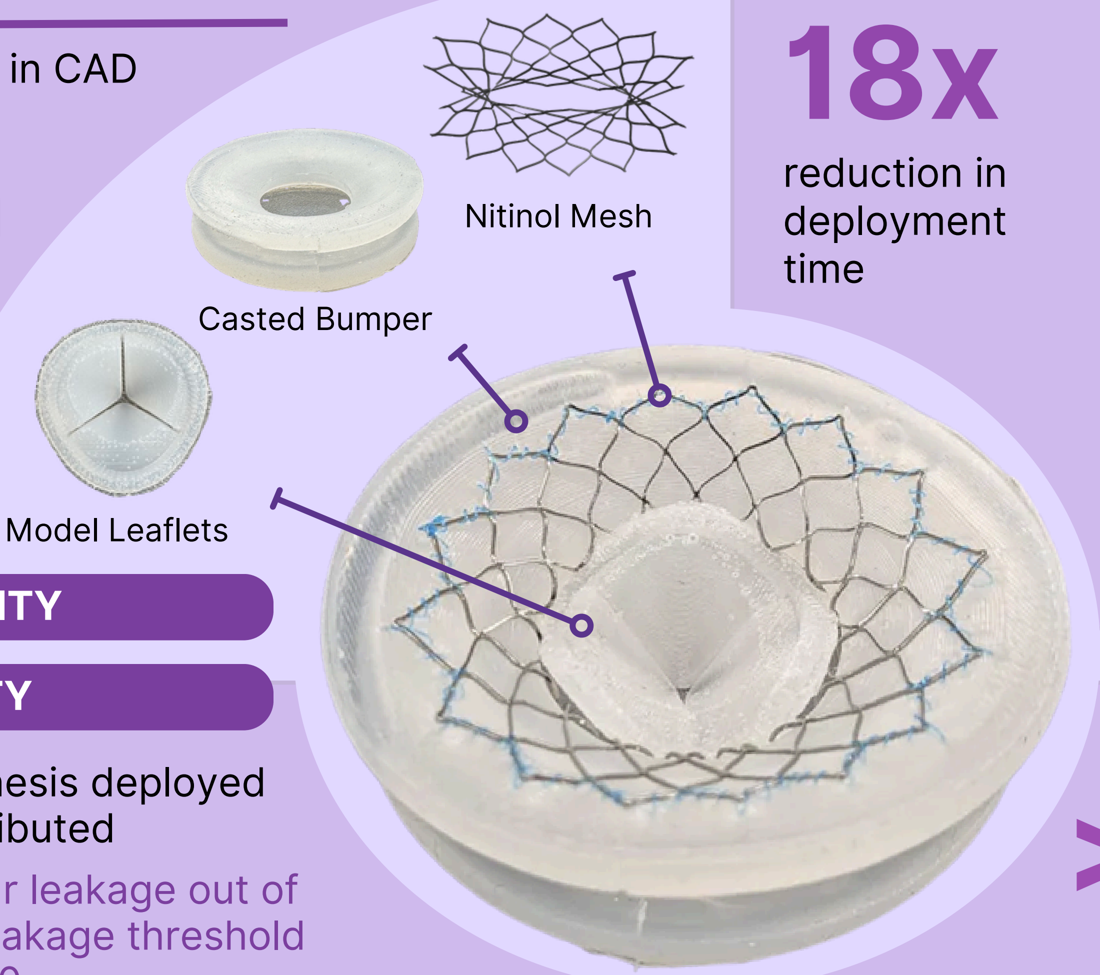
Four-part mold due to overhangs in CAD



Leaflets

Based on tricuspid valve

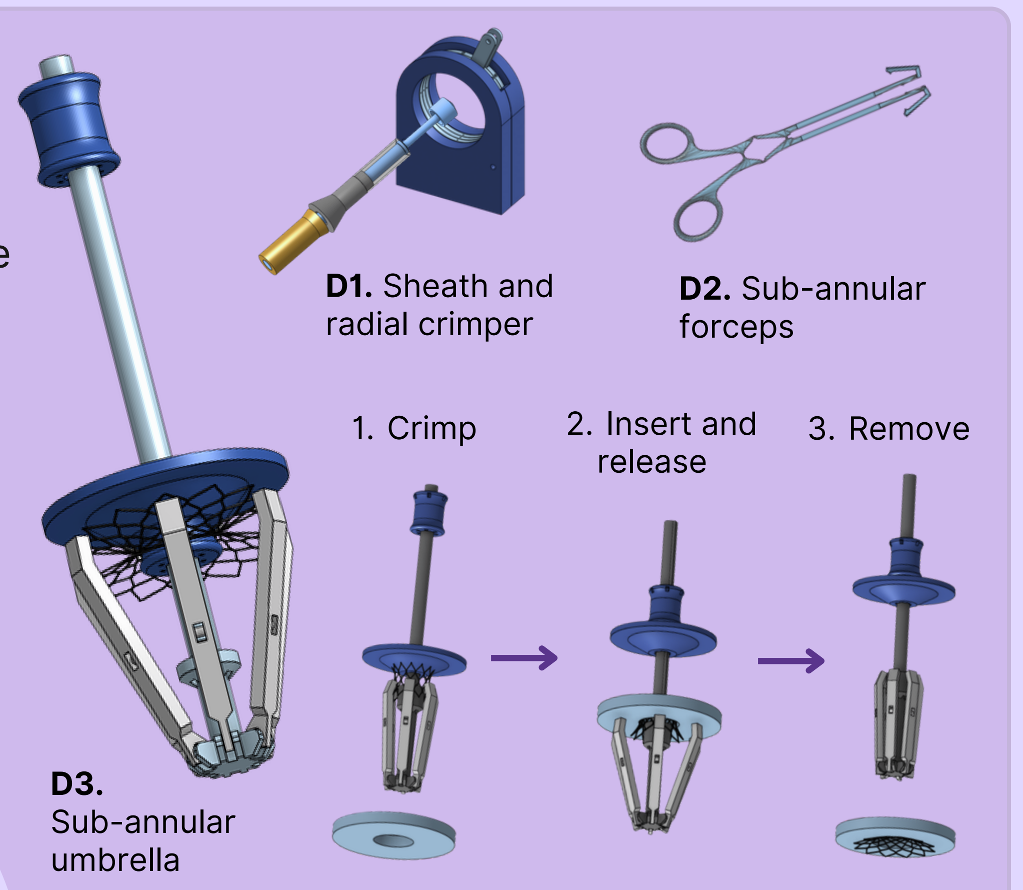




I. MANUFACTURABILITY

40s
average deployment time in valve models

18x
reduction in deployment time



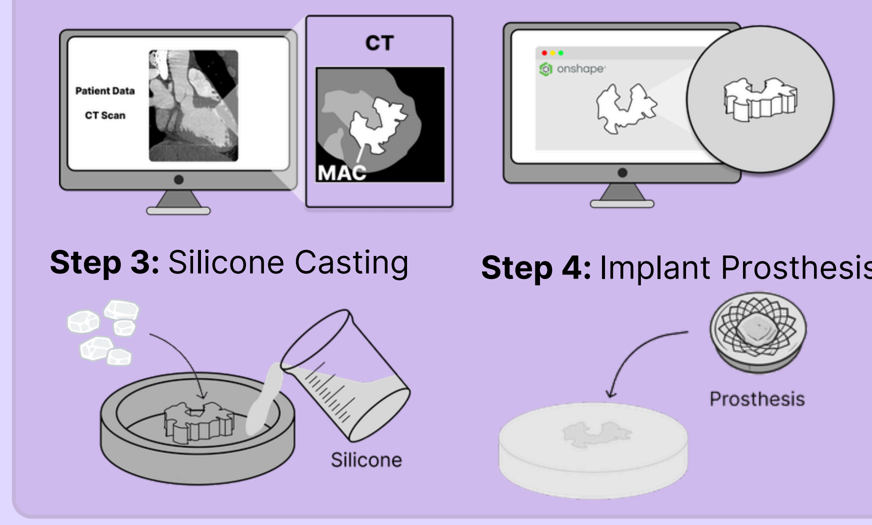
II. RAPID DEPLOYMENT

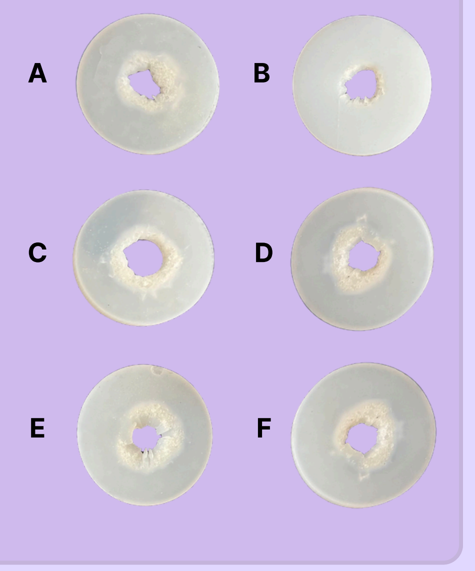
III. CONFORMABILITY

Under 100mmHg pressure, prosthesis deployed in compatible morphologies contributed

~0.7% paravalvular leakage out of 15% total leakage threshold by ISO 5840.

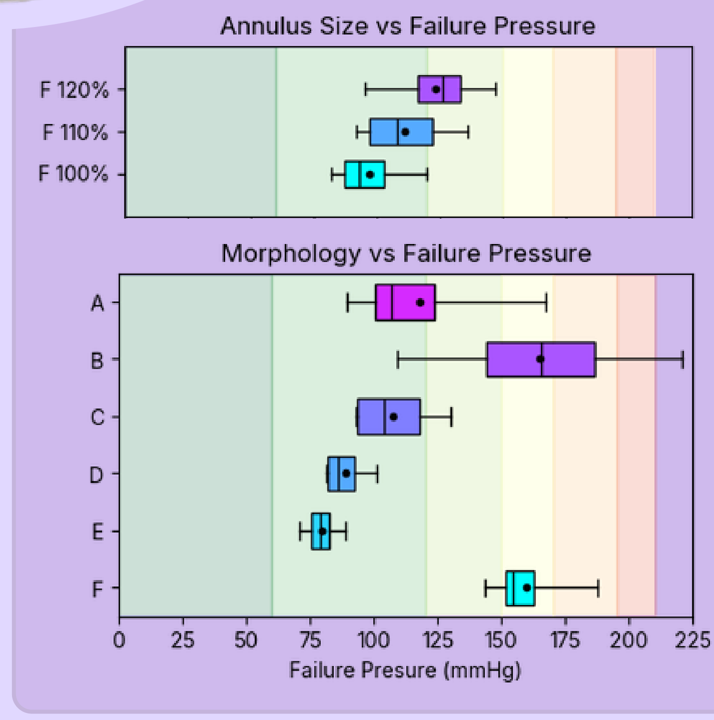
Total Leakage = Transvalvular leakage + Paravalvular leakage



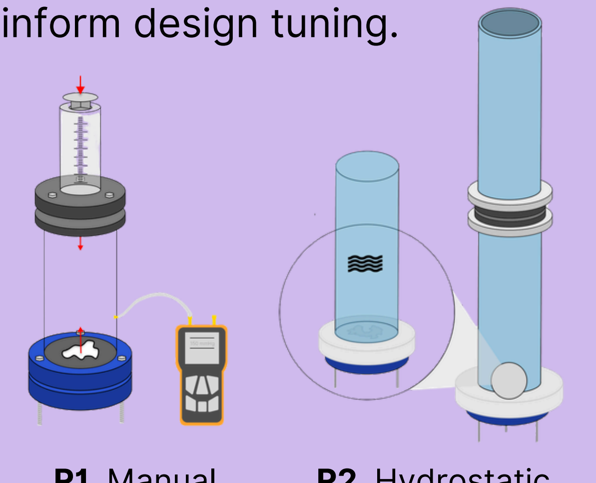


IV. PRESSURE TOLERANCE

>150mmHg maximum tolerance in compatible morphology.



Sizing required for consistent high tolerance. External pulsatile and animal tests will inform design tuning.



R1. Manual actuation | **R2.** Hydrostatic pressure