Arterial Coupler Re-Design: Adjustable Stent/Cuff Anastomosis

Team Members: Sofia DeCicco, Jackie Behring, Ally Rausch, Arshiya Chugh, Daniel Pies
Clients: Dr. Jasmine Craig & Dr. Weifeng Zeng | Advisor: Darilis Suarez-Gonzalez | BME 400, Fall 2025
College of Engineering, University of Wisconsin–Madison

Background Information / Motivation

Arterial Anastomosis

- Microsurgical connection of two arteries to restore blood flow
- Broad clinical applications
- Hand suturing limitations:
  - Requires highly precision
  - Time consuming process
  - Prone to variability

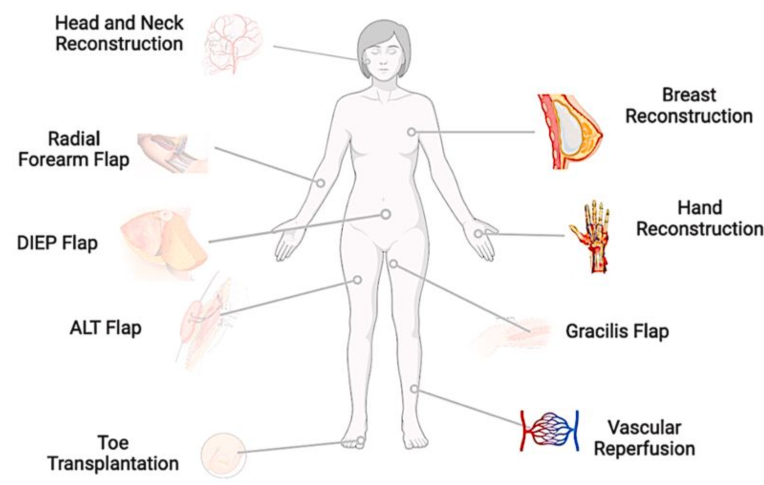


Figure 1: Procedures, and their locations, involving arterial anastomosis [1].

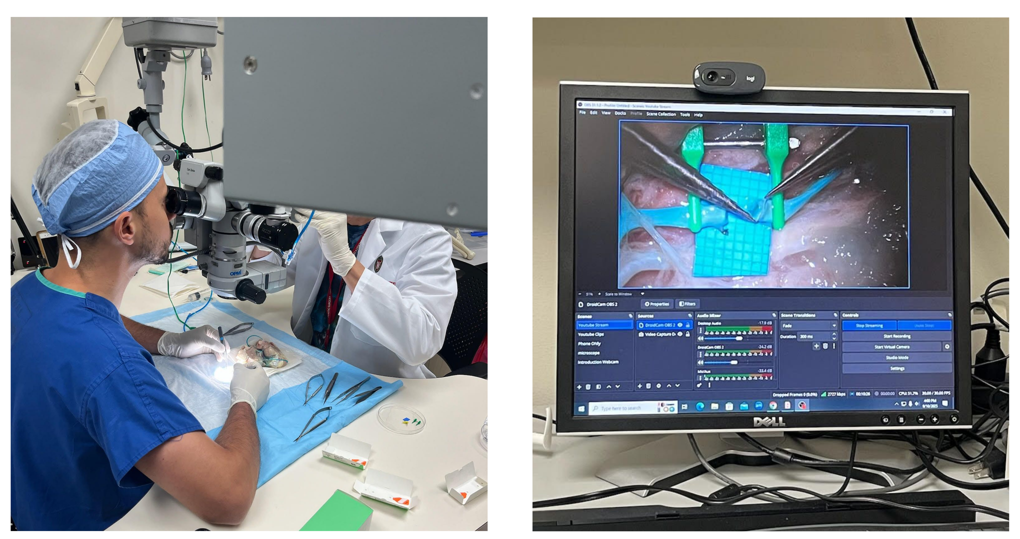


Figure 2, 3: Current arterial anastomosis procedure.

Motivation

- Faster arterial repair which reduces ischemia time [2]
- Reduced surgical time and complications helps minimize costs and improve patient outcomes
- A more consistent technique reduces variability
- A simplified procedure that can be executed by less experienced surgeons, increasing accessibility [1]

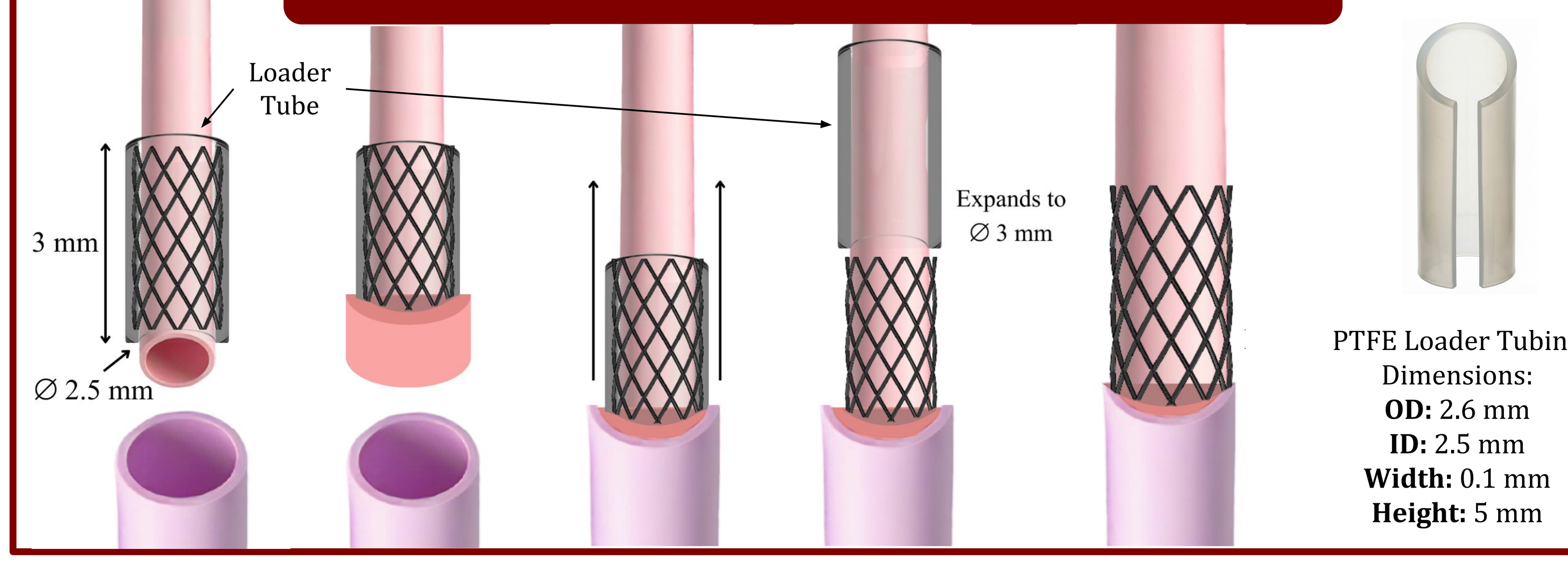
Problem Statement

Microsurgical arterial anastomosis is a cornerstone of reconstructive surgery, enabling tissue transfer and limb salvage. Current techniques are highly time consuming, technically demanding, and are highly dependent on surgeon expertise. Suturing vessels as small as 1 mm can take even the most experienced surgeons 30-60 minutes, extending operating times and jeopardizing tissue viability. Existing stent-based approaches introduce complications by contracting the vessel lumen and lack adaptability across the wide range of vessel diameters encountered in clinical practice. There is a critical need for a biocompatible, adjustable, and easy-to-use device that can reliably reduce operative time while maintaining vessel integrity and minimizing complications.

Design Specifications

- Can expand or contract with **2-5 mm arteries**
- Procedure completion in **< 20 minutes** [3]
- Lifelong implant, withstand **160-200 mmHg**
- **Single use**, EO sterilization, smooth edges
- Ergonomic, low learning curve for surgeons
- **≥ 95%** initial patency and **≥ 90%** after 7 days [4]
- Biocompatible metals (316L SS, Nitinol) [5]
- Within **$1,000** budget with benchmark couplers **$250-$400** [6]
- Meets **FDA Class II** and ISO requirements

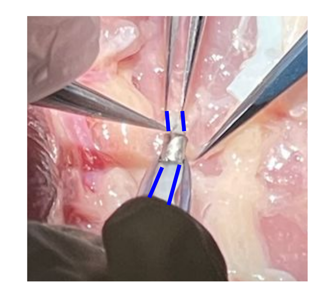
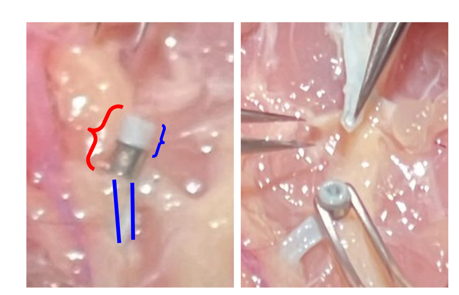
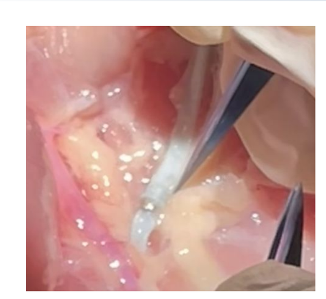
Proposed Design Process



Testing and Results

Feasibility Testing: Ensure Feasibility of Design using Rigid Tubing

Dimensions
ID: 2.31 mm
OD: 2.54 mm
Height: 3mm

	Image	Acceptance Criteria	Key Notes
Feed Artery Through Tubing		• Artery end passes w/out snagging, tearing, or visible intimal abrasion.	• Blunt cut from prototyping was highlighted as an area of risk • Stent will be electropolished and smoothed to reduce sharp edges
Evert Artery		• Artery can be everted without tearing or overstretching • No spontaneous rolling back	• Smooth tubing resulted in too much recoil ◦ Stent texture will be more rigid ◦ Spikes/pegs may need to be added to design
Pull Opposing Artery End		• Second artery can be pulled over the device with ease • Second artery does not roll back once secured on device	• Suture will be applied in actual procedure to secure whole assembly • OD of device must be less than ridgid tube in compressed state
Flow Test		• No leakage at implant site with added flow • Flow remains laminar or minimally disturbed	• Need to test flow at upper end of arterial pressure 200 mmHg • Overall process was not completed in 20 seconds

Solidworks Testing: Simulation under Arterial Flow and Pressure

Assumptions:

- Transmural Pressure = 100 mmHg - Typical MAP in small-medium human arteries at rest
- A flow velocity of 0.2m/s in a 3 mm diameter artery corresponds to ~84 mL/min in volumetric flow and a mass flow of 0.0015kg/s

Areas of Highest Wall Shear Stress

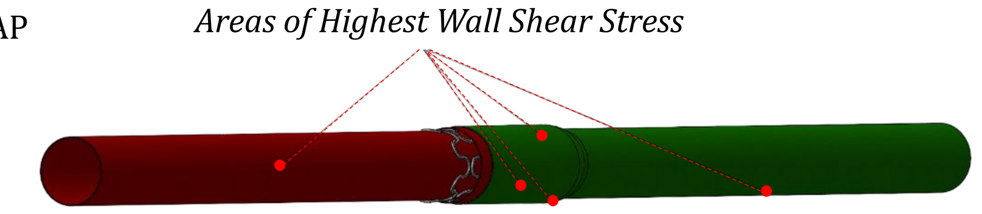
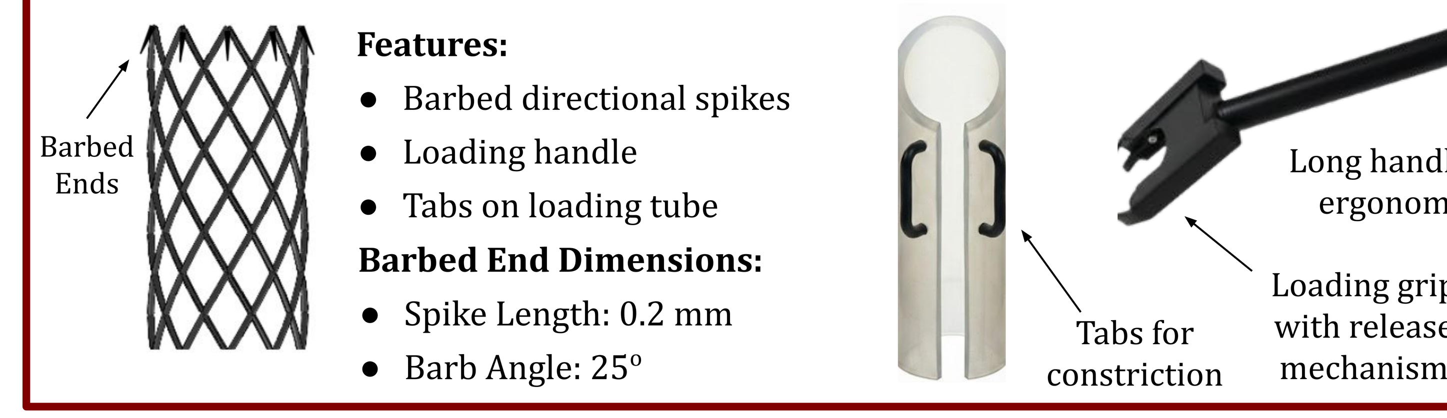


Figure 4: Wall shear stress from fluid flow simulation.

Configuration	Hoop Wall Stress of Conducted Study (kPa)	Hoop Wall Stress of Literature Range (kPa)	Result
Single Artery Wall (0.5mm)	39.5	20-100 [7]	Within physiological arterial range
Nitinol Stent (.11mm)	184	182* [8]	Slightly above typical stented-artery averages, well within safe mechanical capacity of Nitinol
Full Stack (4.22mm)	53.3	8.1-60*	Within typical single-artery ranged

Table 1: Hoop stresses for 3mm artery configuration.
** Model-based estimate; literature only gives qualitative/MPa-scale design limits for Nitinol stents*

Proposed Final Prototype



Features:

- Barbed directional spikes
- Loading handle
- Tabs on loading tube

Barbed End Dimensions:

- Spike Length: 0.2 mm
- Barb Angle: 25°

Discussion

Artery Insertion

- No snagging or tearing
- Minor localized abrasion, need for electropolishing
- Internal diameter allows atraumatic vessel guidance

Eversion Performance

- Minimal overstretching; no rollback
- Low friction; slight texturing or added rigidity needed
- Spike improves grip of everted vessel

Opposing Artery End

- Second artery end can be pulled over device
- Clinical use will still require a confirmatory suture
- Device functions as a reliable scaffold for alignment

Flow Testing

- No leakage at implant site under flow; laminar pattern maintained
- Minor leakage only occurred when sharp edges were present

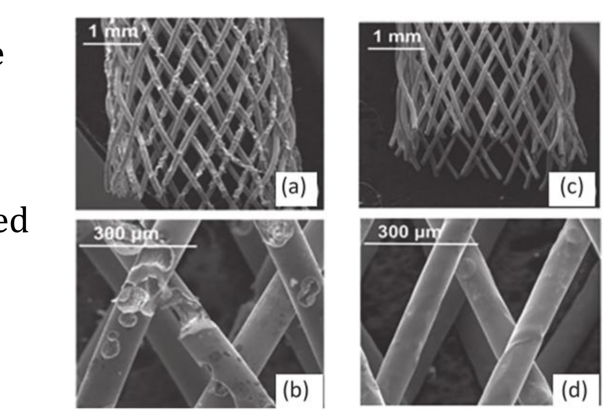


Figure 5: Images showing unpolished versus electropolished [9].

Future Work

Future Modifications

- Fabricate full Nitinol prototype and evaluate electropolished edge quality and controlled radial expansion
- Improve vessel retention by adding or testing micro-texture or anchoring features
- Refine geometry and surface finish
- Integrate final suturing interface

Future Testing

- Assess complete anastomosis workflow
- Quantify flow performance via leak rate, pressure drop, and flow patterns
- Conduct evaluations on ex vivo arterial models
- Verify prototype robustness across vessel diameters

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Acknowledgements

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