Arterial Coupler Re-Design: Adjustable Stent/Cuff Anastomosis

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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

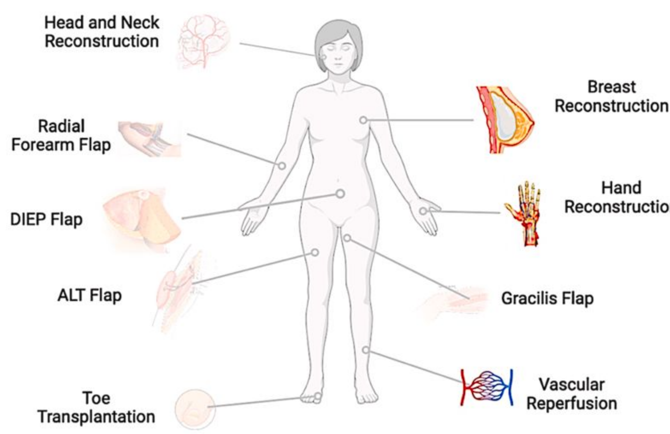


Figure 1: Procedures, and their locations, involving arterial anastomosis [1].

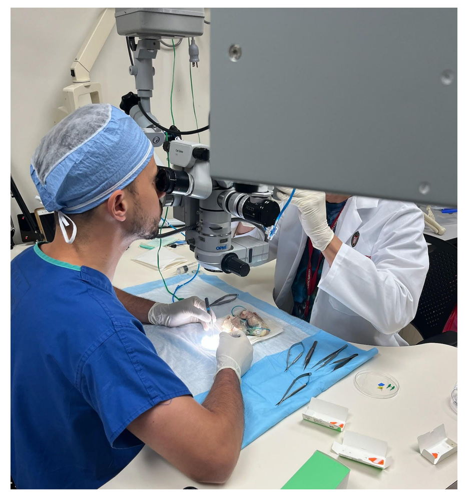
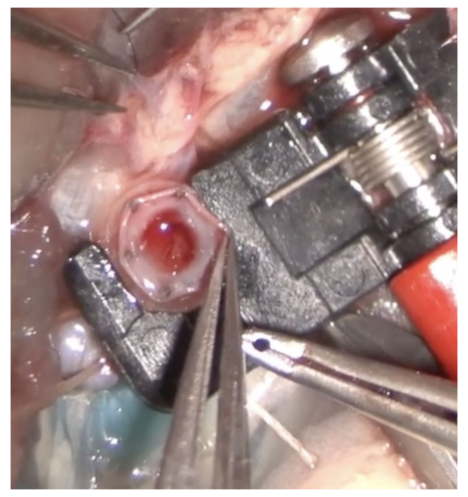



Figure 2, 3: Current arterial and venous anastomosis procedures.

Motivation

- Faster arterial repair which reduces ischemia time [2]
- Reduced surgical time and complications helps minimize costs and improve patient outcomes
- The global anastomosis device market was valued at $4.41 billion in 2025 and is projected to reach $7.07 billion by 2033 [3]
- 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** [4]
- 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 [5]
- Biocompatible metals (316L SS, Nitinol) [6]
- Within **$1,000** budget with benchmark couplers **$250-$400** [7]
- Meets **FDA Class II** and ISO requirements

Proposed Design Process

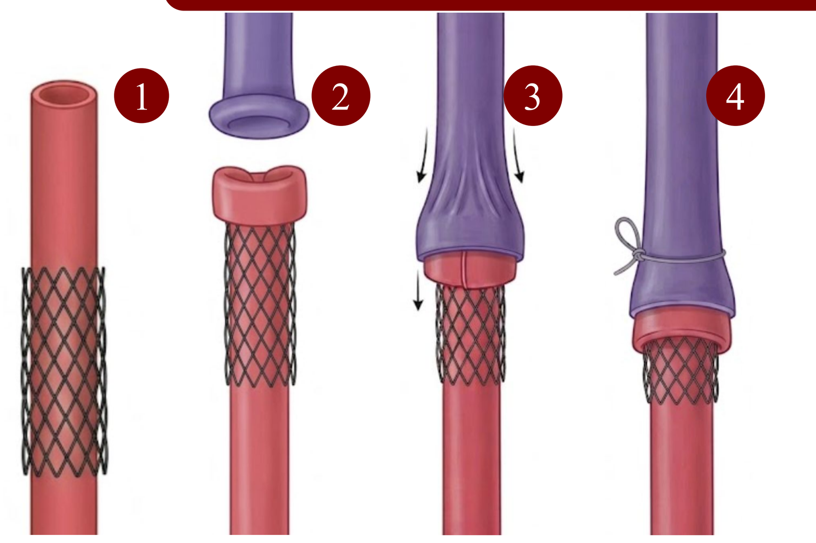


Figure 4: Eversion and insertion procedure.

Step-by-Step Process

1. Insertion
2. Eversion
3. Apposition
4. Securement

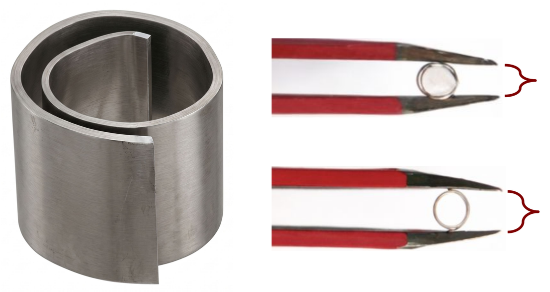
Stent Features

- Micro-texturing prevents rollback
- Adjustable for various vessels
- Reduces procedure time
- Minimizes leakage for improved seal

Testing and Results

Spiral Anastomotic Coupler Objective

Radial diameter is controlled via circumferential suture, allowing the device to be constrained for vessel eversion, then released (cut) to seat against the vessel wall, using a slipknot suture to control expansion.



2.87 mm - Compressed State Diameter

4.19 mm - Uncompressed State Diameter

Figure 5: Close-up of spiral coupler and deployment comparison.

Trial (Vessel Type)	Anastomosis Time	% Time Reduction	% Expansion	Leakage Grade
1 (Vein*)	4 minutes, 50 seconds	−23.4%	4.18%	0
2 (Artery)	2 minutes, 31 seconds	35.7%	15.3%	0
3 (Vein*)	1 minutes, 58 seconds	49.8%	17.0%	0

***Table 1**: Anastomosis time and performance across three trials using spiral coupler.*

** Trials were conducted on available vascular specimens; device diameter was confirmed adjustable to artery-range sizing across all trials. Strip thickness was varied iteratively based on surgeon-reported feedback, 0.0254 mm shim stock was selected for optimal expansion control.*

Spring Testing Objective

Measure the extent of rollback in cuffs with stent-like micro-texturing

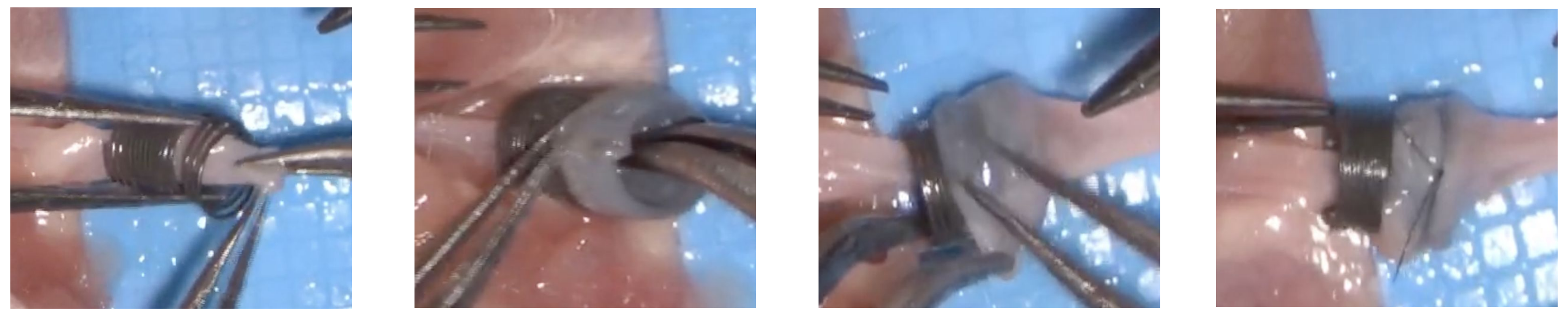


Figure 6-9: Spring arterial anastomosis procedure, showing each critical step.

1 — 2 — 3 — 4

Stent-inspired micro-texturing effectively prevented rollback of the everted artery, maintaining cuff positioning throughout manipulation and demonstrating a clear improvement in mechanical stability over non-textured configurations.

Cuff Material + Vessel Type	% Roll Back
Stainless Steel + Vein	22.9%
Stainless Steel + Vein	16.1%
Stainless Steel + Artery	115.3%
*Nitinol Spring + Vein	0%

***Table 2:** % Roll back per cuff material and vessel type.*

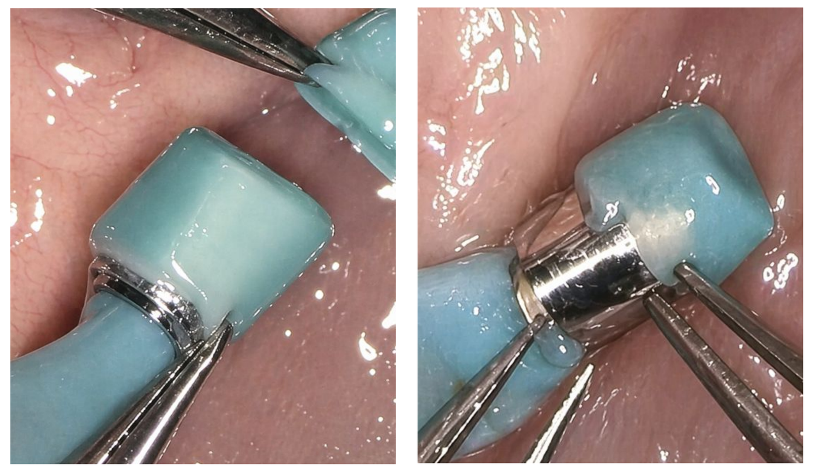


***Figure 10, 11:** Spiral arterial anastomosis procedure.*

Proposed Final Prototype

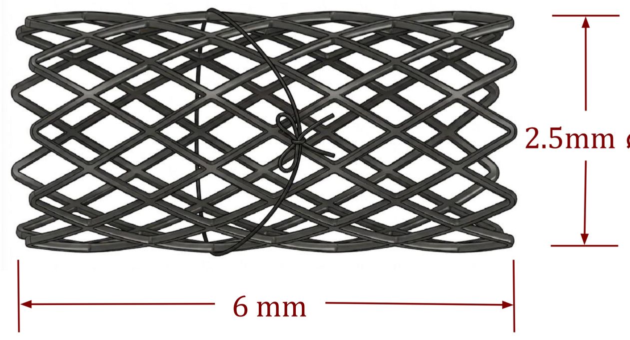


***Figure 12:** Nitinol stent for arterial anastomosis.*

Nitinol Stent with Circumferential Suture

- Microtextured surface provides anti-rollback grip for stable positioning
- Nitinol enables shape memory, restoring the stent to its cylindrical form
- Suture control allows precise contraction and expansion during eversion

Discussion

Procedure Time & Usability

- Procedure time decreased by 60% indicating rapid learning curve across expert, resident, and medical student
- Arterial trial completed faster than initial venous trial despite lower compliance
- Final time (~2 min) reflects 50% reduction vs suturing

Device Deployment

- Compression–eversion–release enabled easier eversion and secure expansion

Eversion Performance

- Minimal overstretching; no rollback observed
- 0.0508 mm thickness balanced flexibility and control

Opposing Vessel End

- Second vessel placement was most challenging step
- Slippage occurred with shorter cuffs; 6 mm length improved retention

Flow Testing

- No leakage (Grade 0) with maintained patency and laminar flow

Future Work

Future Modifications

- Fabricate full Nitinol prototype and evaluate electropolished edges and radial expansion
- Improve vessel retention through micro-texturing or anchoring features
- Refine geometry and integrate a controlled expansion and locking mechanism

Future Testing

- Evaluate full anastomosis workflow across multiple users
- Quantify performance via leak rate, pressure tolerance, and flow patterns
- Test on ex vivo arterial models under physiologic conditions and across vessel sizes

Manufacturing & Scalability

- Identify cost-effective fabrication methods for small-scale Nitinol stents
- Explore vendor partnerships and alternative processes
- Assess trade-offs between precision, scalability, and cost for clinical translation

References

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Acknowledgements

The team would like to thank our clients, Dr. Jasmine Craig and Dr. Weifeng, and our advisor, Dr. Darilis Suarez, for their involvement and support throughout the semester. In addition, thank you to Dr. Puccinelli, Jesse Darley, and the Biomedical Engineering Department for the continued collaboration and resources during this design project.