Arterial Coupler Re-Design: Adjustable Stent/Cuff Anastomosis

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Presentation Overview

- Problem Statement
- Background & Impact
- Competing Designs
- Design Specifications
- Summary of Previous Work
- Evaluation & Lessons Learned
- Proposed Final Design
- Fabrication Plan
- Testing & Evaluation Plan
- Timeline & Semester Goals
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- Other Required Deliverables
- Summary & Next Steps
- References

Problem Statement

Client

- Dr. Jasmine Craig and Dr. Weifeng Zeng
- Plastic surgeons seeking improved arterial anastomosis solutions

Current Arterial Anastomosis

- Procedure requires 30-60 min of high expertise
- Risks: thrombosis, leakage, failure
- Existing couplers unsuitable for arteries

Refined Aim

- Suture-minimized, expandable device
- For 2–5 mm arteries and no intraluminal contact
- Reduced operative time with maintained patency

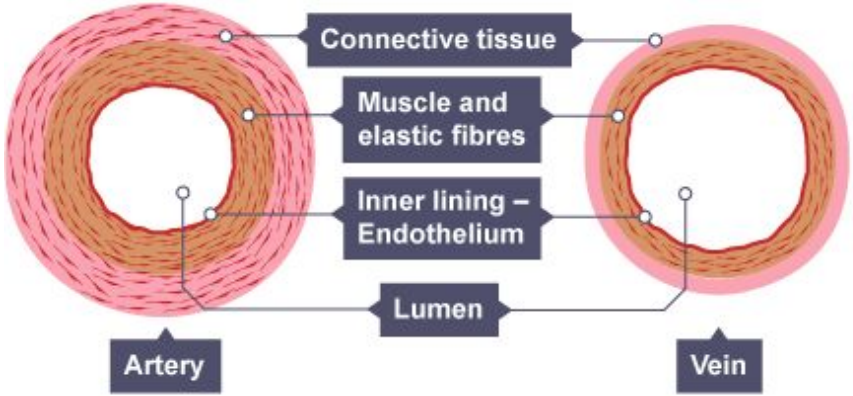

Figure 1. Structural comparison of veins and arteries [1]

Current Arterial Anastomosis Procedure

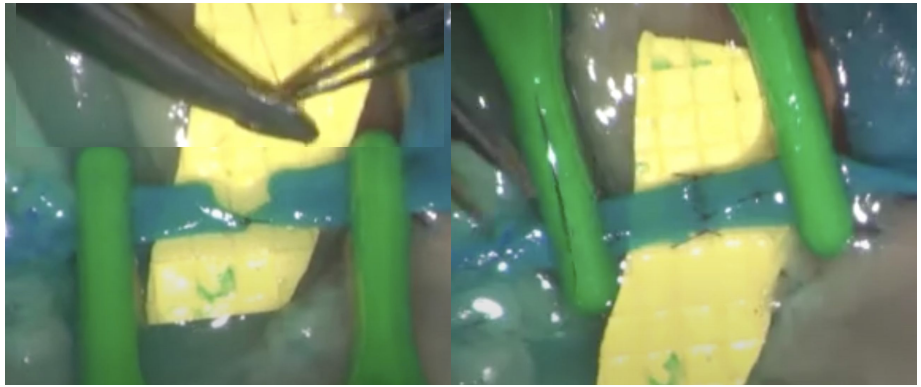

Figure 2 . Client provided images of microanastomosis [2]

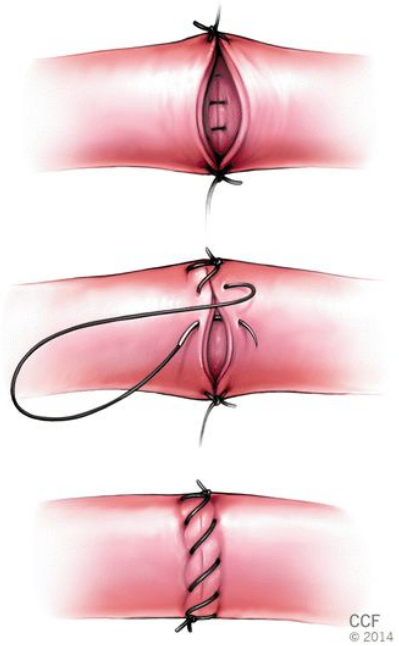

Figure 3. Suture technique for microanastomosis [3]

Current Methods

- Current hand suture technique at the **millimeter scale**
- Total of **6 or more** sutures depending on vessel and artery size

Drawbacks of Methods

- Requires high precision, time consuming, and prone to variability

Background & Impact

Clinical Impact

- Faster repair reduces ischemia time, improving patient outcomes [4]
- Applicable to reconstructive, transplant, and trauma surgeries

System Level Benefits

- Shorter procedures and fewer complications reduce costs
- Standardized technique decreases variability in outcomes
- Simplified workflow expands access to high-quality care [5]

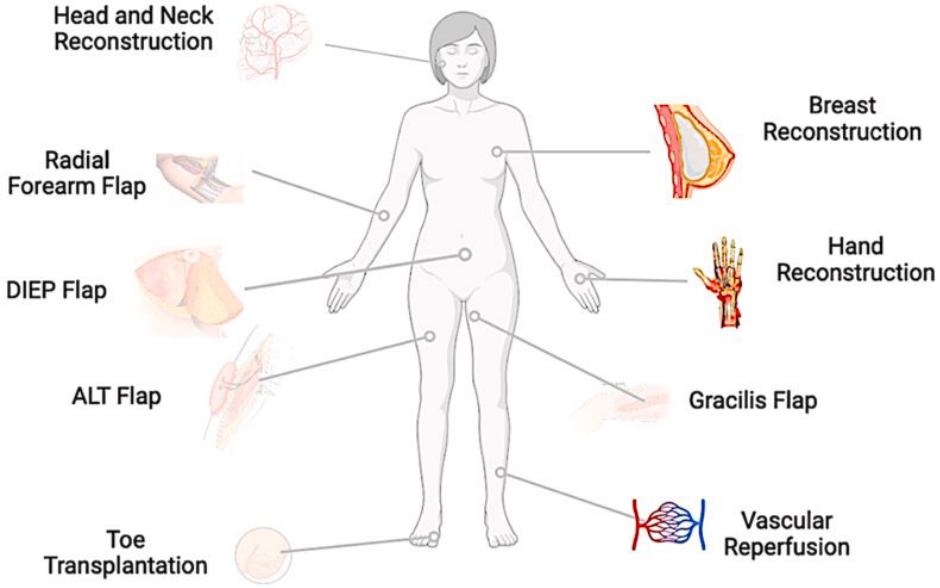

Figure 4. Potential impacts for sutureless microvascular anastomosis [5]

Competing Designs

Overview of Existing Solutions

Manual Microsuturing

- Clinical gold standard, 30 to 60 minutes [6]
- High precision, operator dependent

Venous Anastomotic Couplers

- Reduce time to 7 to 8 minutes [6]
- Easy to use, high patency rate [7]
- Not ideal for arteries [8]

Magnetic Compression Devices

- Rare earth magnets fuse vessel ends [11]
- Proven in GI procedures [12]
- Risks stenosis and misalignment [13]

Figure 5. Venous Coupler Procedure Steps [9]

Figure 6. GEM Venous Coupler [10]

Competing Designs

Overview of Existing Solutions

External Cuff Techniques

- External vessel support
- Standardized alignment
- Risks thrombosis and stenosis [14]

Intraluminal Stent

- Temporary or permanent
- Shortens procedure time
- Risks thrombosis and stenosis [15]

Why Existing Solutions Fall Short

- Fails in small-diameter, high-pressure arteries
- Increases thrombosis risk or lacks durability
- No fast, safe, user-friendly solution

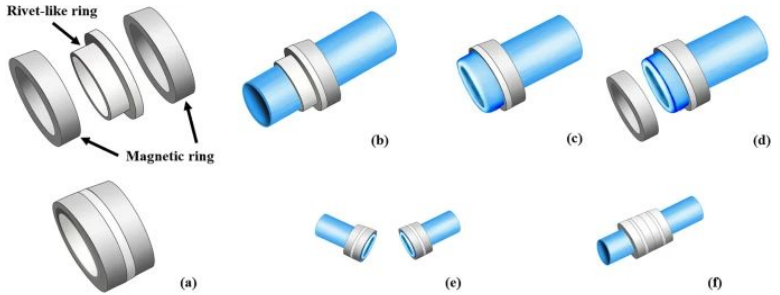

Figure 7. Working mechanism magnetic compression anastomosis [16]

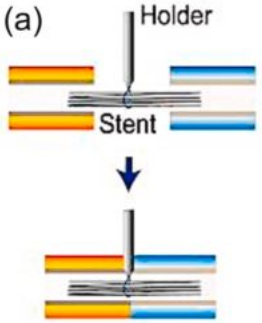

Figure 8. Intraluminal Stent Mechanism [5]

Product Design Specifications

Product Design Specifications

Vessel Size and Performance

- **2-5 mm arteries** (3 mm prototype); ~ **0.3 mm expansion** without recoil
- **< 20 minute** procedure [6]; **> 95%** immediate, **> 90%** (7-day) patency
- Withstands **160-200 mmHg**; enables **intima-to-intima contact**

Safety and Biocompatibility

- **Non-thrombogenic, non-toxic** materials
- Smooth, polished surfaces
- Compatible with **EtO sterilization**

Cost & Usability

- Prototype < $1,000; single-use
- **Low learning curve** for microsurgeons
- Compatible with **standard microsurgical tools**

Product Design Specifications

Regulatory & Standards Considerations

Device Classification

- Anticipated **FDA Class II** medical device
- Intended for vascular anastomosis applications

Biocompatibility

- Meets **ISO 10993** biocompatibility standards
- Evaluated for cytotoxicity, sensitization, and hemocompatibility

Regulatory Pathway

- Designed for **510(k)** regulatory pathway
- Predicate devices: existing vascular anastomosis systems

Summary of Previous Work

Design Approach

- Rigid tube feasibility model used to evaluate insertion, eversion, and alignment
- Simple cylindrical geometry to isolate core handling mechanics
- Dimensions selected to represent small diameter arterial use cases (~ 2-5 mm)

Material & Fabrication

- Rigid stainless steel tubing used as a surrogate feasibility platform
- Selected to provide dimensional stability and repeatable geometry during testing
- Surface finish varied intentionally to assess effects on vessel handling

Demonstrated Feasibility

- Arteries could be inserted and everted without visible tearing
- Alignment of opposing artery ends was achievable
- Basic workflow feasibility was established prior to introducing adjustability

Dimensions
ID: 2.31 mm
OD: 2.54 mm
Height: 3.00 mm

Figure 9. Rigid tube used intentionally as a feasibility platform, not a final design

Evaluation & Testing Results

Rigid Tube Feasibility Results

- Rigid tube testing confirmed arteries could be inserted and everted without visible tearing
- Smooth internal geometry supported atraumatic vessel guidance
- Localized abrasion observed at sharp or unfinished edges
- Some vessel rollback and recoil occurred due to lack of retention features
- Flow testing showed maintained patency with minimal leakage when edges were smoothed

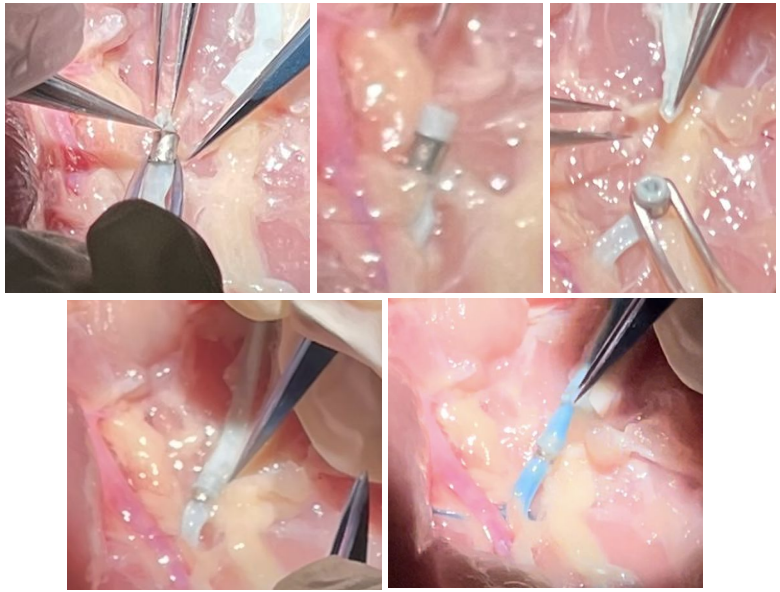

Figure 10. Rigid tube feasibility testing workflow demonstrating artery insertion, eversion over the rigid tube, opposing artery alignment, and final positioning prior to flow testing

Lessons Learned Driving Redesign

Limitations

- Localized abrasion observed at sharp or unfinished edges
- Vessel recoil and rollback occurred due to lack of retention features
- Fixed geometry limited adaptability across vessel diameters

Design Response

- Surface finishing such as electropolishing is required
- Retention features are needed to stabilize the everted vessel
- Introducing adjustability will improve conformity and handling consistency

Proposed Redesign

Figure 11. Image of handling device

Figure 12. Loader tube with handle attachment

Added Components

- Barbed ends to stent
- Thinner strut width
- Loader tub with handles
- Handling device

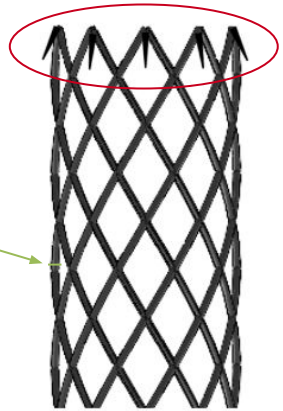

Figure 13. Revisited stent design with barbed edges

Proposed Final Stent Design

Proposed Final Design

Motivation

- Improve stent stability
- Prevent roll back
- Increase stent tissue contact

Dimensions

- ID: 2.40 mm
- OD: 2.45 mm
- Strut Width: 0.05 mm
- Barb length: 0.25mm
- Barb angle: ~ 25°

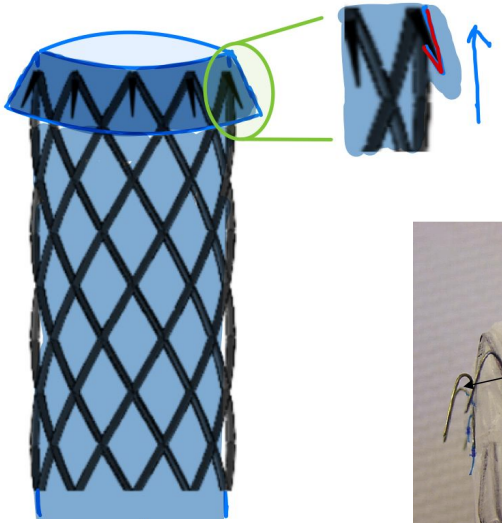

Figure 14. Barbed stent design with artery eversion

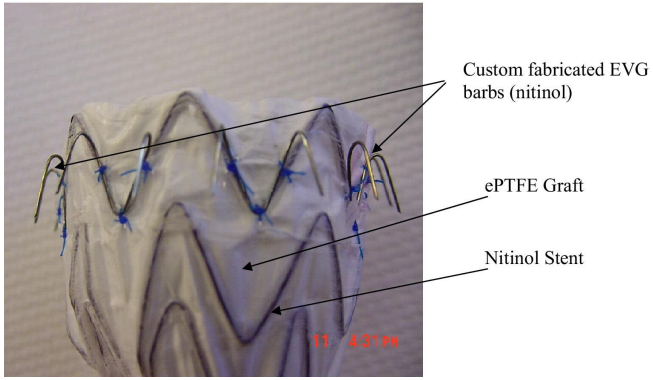

Figure 15. Example of barbed endovascular stent [17]

Stent Fabrication Plan

Stent Fabrication Plan

Material Selection

- Nitinol

Key Fabrication Risks

- Microcracks from laser cutting
- Heat treatment variability
- Surface roughness → thrombosis risk

Final Production

- Outsourced to certified vendor

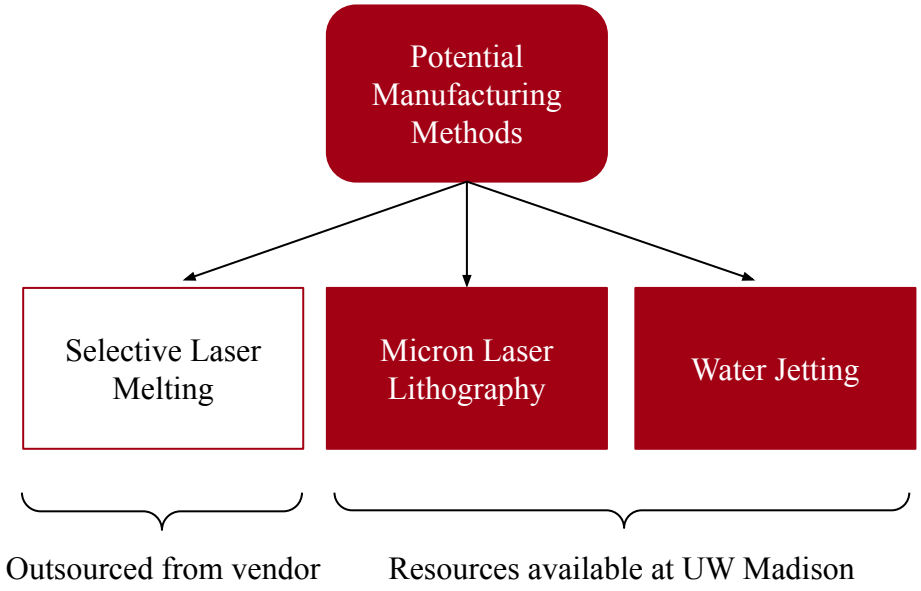

Figure 16. Nitinol stent manufacturing workflow diagram

PTFE Tubing Fabrication Plan

PTFE Tubing Fabrication Plan

Material Selection

- PTFE

Manufacturing Method

- Adjustable stiffness based on additives
- Thin-walled PTFE Tubing
- Rounded edges

Final Production

- Procured from certified vendor

Figure 17. PTFE tubing surrounding a Nitinol stent [18]

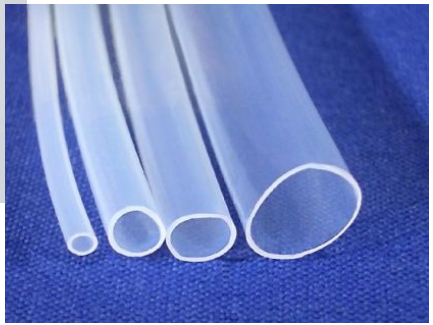

Figure 18. Variety of PTFE tubing dimensions [19]

Testing & Evaluation Plan

1. **Efficiency and Usability Tests**
   a. Time surgeons/residents using recoupler vs. sutures on ex vivo chicken thighs
   b. Data: Time(s), usability score (5-point Likert Scale), failure rate
   c. Acceptance Criteria: >20 minutes, ≥ 4.0/5, <10%

2. **Patency, Leakage, Stenosis Tests (Syringe Pump)**
   a. 80-120 mmHg with dye, grade leaks on scale (0=no leaks, 3=burst) [20], ImageJ % stenosis
   b. Data: Leak grade, patency percentage, percent restenosis
   c. Acceptance Criteria: Grade 0; ≥ 95% patency, < 20% lumen narrowing

3. **Mechanical Integrity, Handling Tests**
   a. Tensile pull-test, deployment test
   b. Data: Failure force (g), misfire rate
   c. Acceptance Criteria: > 100g pull force [5], <5% misfire rate

Timeline & Semester Goals

1. **Major Milestones**
   a. Preliminary Prototype Competition
   b. Efficiency Data Complete
      i. Proves “faster anastomosis”
   c. Leak-Free Patency
   d. Mechanical Reliability Confirmed

TASK	START	END
Fabrication		
Method Selection + CAD	2/6/26	2/20/26
Prototype Build v1	2/20/26	3/6/26
Prototype Build v2	?	?
Efficiency		
Device vs. Suture Testing	3/6/26	3/20/26
Patency		
Leak / Patency Trials	3/20/26	3/27/26
Mechanical		
Deployment Cycles	3/6/26	3/27/26
Deliverables		
Preliminary Report	2/18/26	2/25/26
Executive Summary Draft	3/27/26	4/2/26
Final Executive Summary	4/2/26	4/17/26
Poster Presentation	4/17/26	4/24/26
Final Report	4/20/26	4/29/26

Figure 19. Project timeline showing fabrication, testing, and deliverables

Budget

1. **Spending to Date**
   a. $22.59 - Small Stainless Steel Tubing
2. **Anticipated Future Costs**
   a. Pending Potomac Quote for Stent Cost
3. **Major Cost Drivers**
   a. Fabrication Method
   b. Material
4. **Budget Constraint Compliance**
   a. On track for < $1,000 total

Other Required Deliverables

1. **Documentation Plan**
   a. Photo/video archive of each anastomosis & failure mode
   b. Continued research in LabArchives
2. **User Instructions or Safety Considerations**
   a. Instructions for Use Draft
   b. Cautions/Warnings: Single Use Only, Max 120 mmHg Test
3. **Packaging Considerations**
   a. Sterilization pouches & biocompatible desiccant
   b. Proper labeling: Device ID, sizing & tolerances
4. **Regulatory & Compliance Documentation**
   a. ISO 13485 - QMS for Medical Devices
   b. FDA Class II Roadmap - Vascular Couplers / Anastomotic Devices

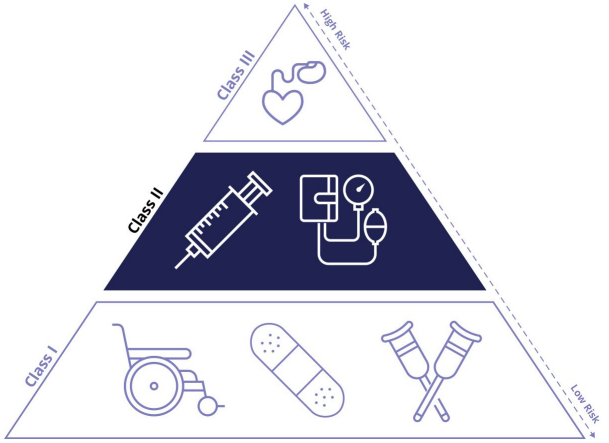

Figure 20. Demonstrated Class II Medical Device [21]

Summary & Next Steps

1. **Validation to Date**
   a. Stent geometries & sizing via hemodynamic modeling and ex vivo tests
   b. Proof-of-concept - stainless steel tubing tests confirmed deployment mechanics
2. **Next Milestones**
   a. Appropriate scale prototype
   b. Efficiency beats suture method
   c. Leak-free patency
3. **Seeking**
   a. Consultation regarding feasibility of outsourcing/fabrication method
   b. Confirmation from client regarding approach to material/fabrication
4. **Journal Article**
   a. Actively coordinating with the client on next steps

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Questions