Arterial Coupler Re-Design: Adjustable Stent/Cuff Anastomosis

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Presentation Overview

- Problem Statement
- Background
- Product Design Specifications
- Design Considerations
- Final Design
- Testing Plans
- Future Work
- References and Acknowledgments

Problem Statement

Current Arterial Anastomosis

- 30-60 minutes with high expertise
- Risk of thrombosis, leakage, operation failure
- Existing couplers not suitable for arteries

Refined Aim

- Suture-minimized
- Expandable
- 2 - 5 mm vessels
- No contact with inner lining
- Overall: Reduce operative time while ensuring patency and biocompatibility

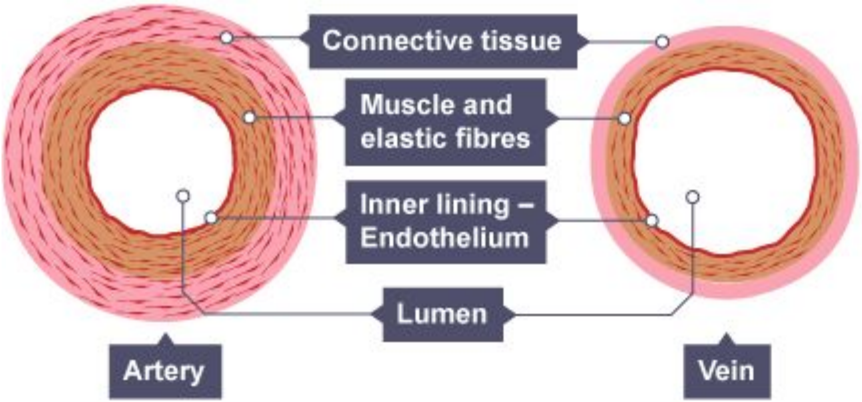

Figure 1: Structural comparison of veins and arteries [1]

Current Arterial Anastomosis Procedure

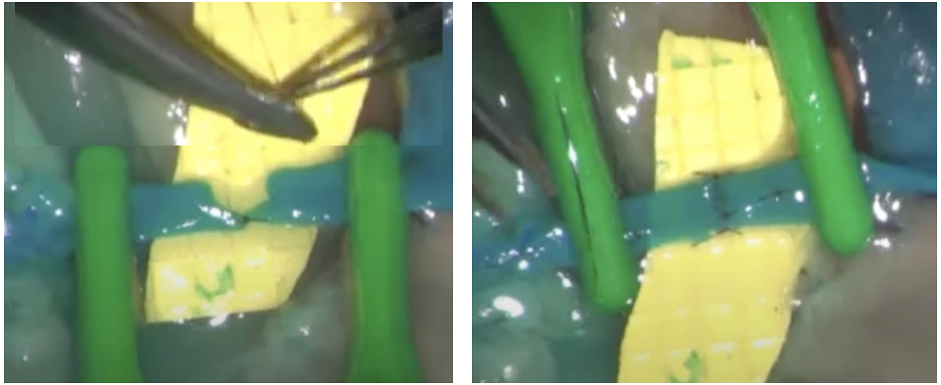

Figure 2: Client provided images of microanastomosis [2]

Method

- Hand suture technique at the millimeter scale
- Total of 6+ sutures depending on vessel and artery size

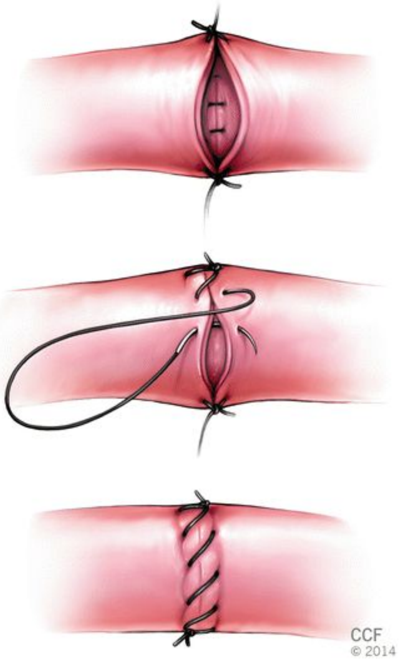

Figure 3: Suture technique for microanastomosis [3]

Background - Impact

Improve Patient Outcomes

- Faster repair → reduced ischemia times [4]

Clinical Relevance

- Reconstructive, transplant, and trauma surgeries

Efficiency

- Minimize times and complications → minimize costs

Standardize Care

- Reduces variability in procedure and outcomes

Expand Accessibility

- Simplified procedure → less experienced surgeons can execute → quality care to more patients [5]

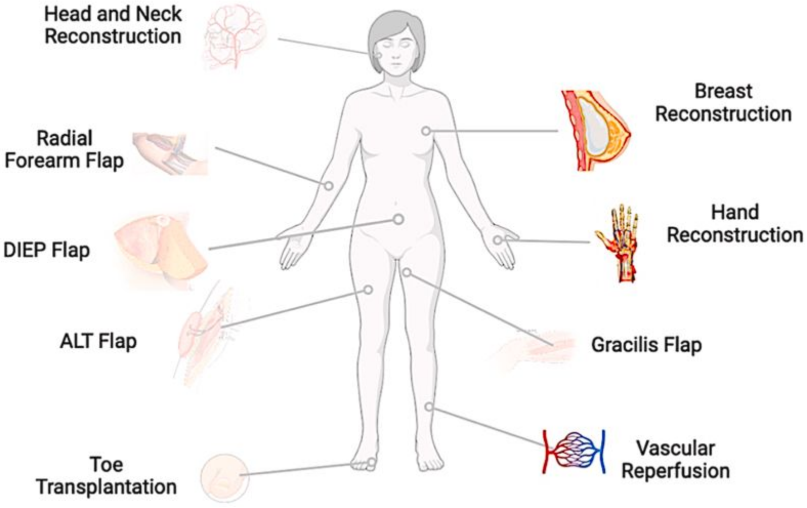

Figure 4: Potential impacts for sutureless microvascular anastomosis [5]

Background - Current Methods & Designs

Hand Sewn Sutures

- Gold standard, 30-60 minutes [6]
- Demanding and challenging learning curve

Venous Coupler Device

- Reduce time to ~7.5 minutes [6]
- Easy to use, high patency rate [7]
- Not ideal for arteries [8]

Figure 5: Venous Coupler Procedure Steps [9]

Figure 6: GEM Venous Coupler [10]

Background - Current Methods & Designs

Magnetic Compression Anastomosis (MCA)

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

External Cuff Methods

- Evert vessel ends over tube
- Risks stenosis, loss of compliance, and thrombosis [14]

Intraluminal Stents / Dissolvable Scaffolds

- Shorten procedure time
- Risks thrombosis and stenosis [15]

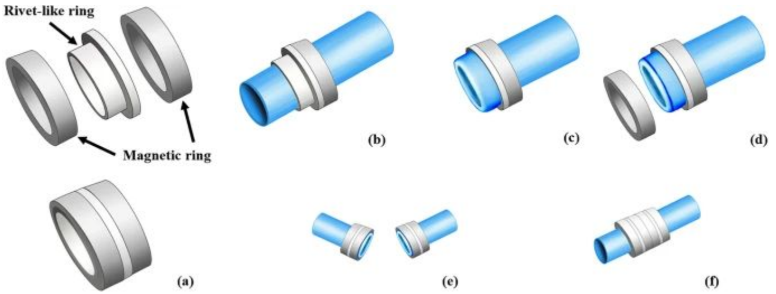

Figure 7: Working mechanism magnetic compression anastomosis [16]

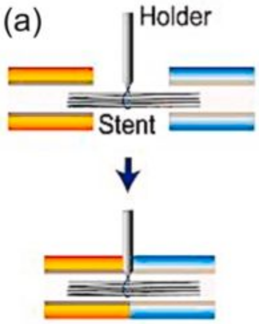

Figure 8: Intraluminal Stent Mechanism [5]

Product Design Specifications

Client Requirements

- *Adjustable* - Can expand or contract with **2-5 mm arteries**
- *Efficient* - Procedure completion in **< 20 minutes** [6]
- *Safe* - Lifelong implant, withstand **160-200 mmHg**
- *Sterile* - **Single use**, EO sterilization, smooth edges
- *Reliable* - Maintain patency ≥ **95%** immediately after, ≥ **90%** after 7 days
- *Usable* - Ergonomic, low learning curve for surgeons
- *Materials* - Biocompatible metals (316L SS, Nitinol) [17]
- *Cost* - Within **$1,000** budget, benchmark couplers **$250-$400** [18]
- *Standards* - Meets **FDA Class II** and ISO requirements

Design 1: Sock Clamp

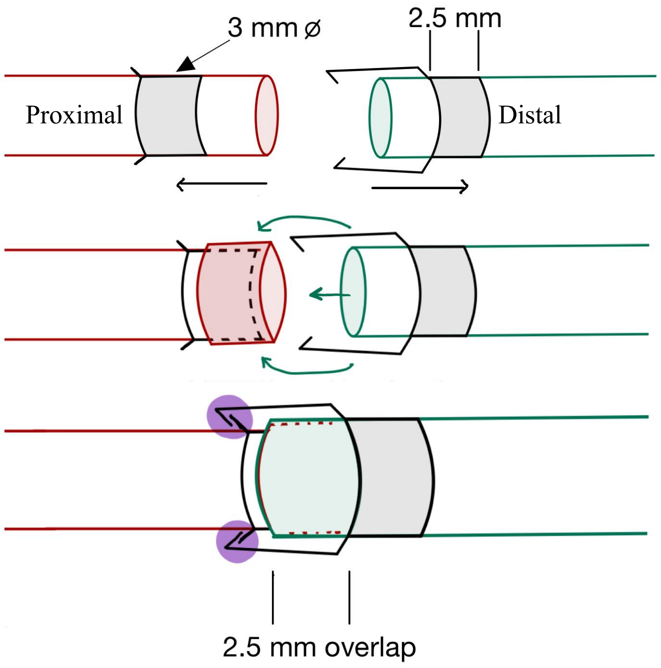

Figure 9: Sock Clamp Design

Pros:

- Sutureless
- Quick arterial connection
- Intima contact

Cons:

- Attachment to both ends
- Non-adjustable
- Clip durability

Design 2: Spike Stent

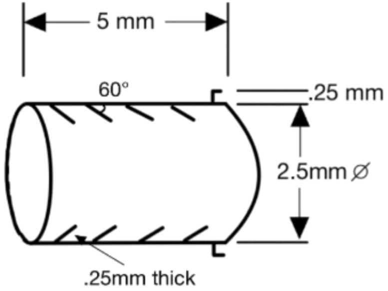

Figure 10: Spike Stent Dimensions

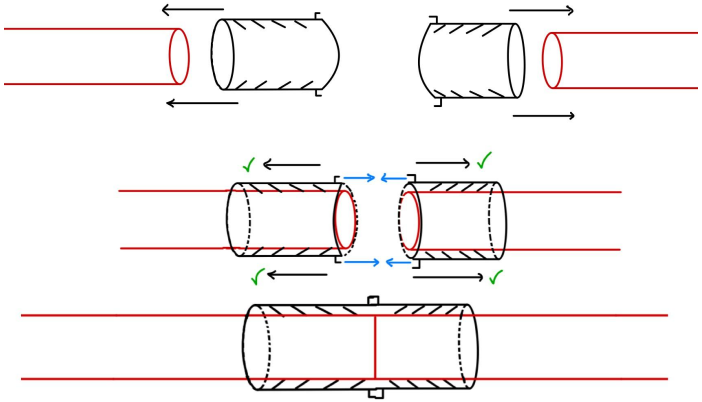

Figure 11: Spike Stent Application

Pros:

- Quick application
- Sutureless
- Low machining and material cost

Cons:

- Potential arterial damage
- Intima contact
- Adjustability
- Attachment to both ends

Design 3: Expandable Nitinol Stent

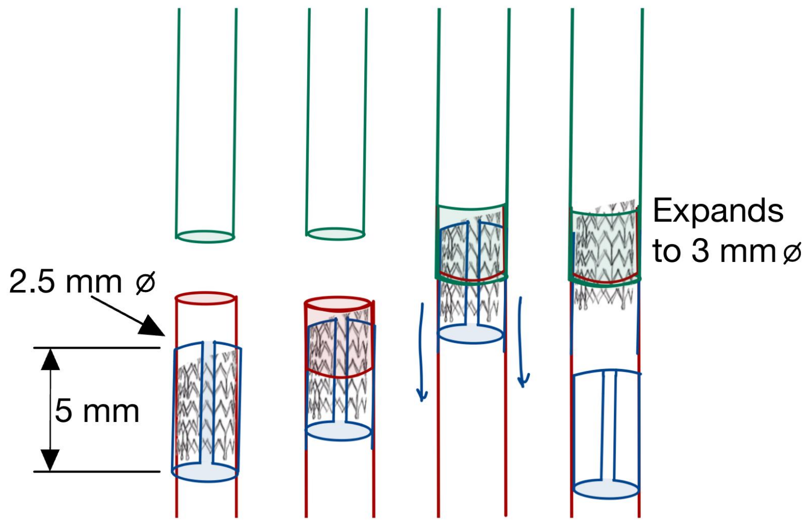

Figure 12: Expandable Nitinol Stent Application

Pros:

- High pressure tolerance
- Adjustable diameter during implantation
- Strong intima-intima contact

Cons:

- Material is more difficult to source and more costly
- Post-deployment adjustability
- Securing suture

Design Matrix Criteria

1. Efficiency

Implant time < 20 second

2. Adjustability

Diameter had ability to expand after implantation

3. Intima Contact

Sufficient contact between inner walls of artery ends

4. Durability

Withstands biological environment

5. Safety

Design geometry avoids risk of harm

6. Manufacturability

Material source and design machinability

7. Cost

Client provided budget is $1,000

Design Matrix

Arterial Coupler Device							
		Sock Clamp		**Spike Stent**		**Expandable Stent**	
Criteria	**Weight**	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Efficiency	25	3	15	2	10	4	20
Adjustability	20	1	4	1	4	4	16
Intima Contact	15	5	15	2	6	5	15
Durability	15	4	12	3	9	3	9
Safety	10	4	8	2	4	4	8
Manufacturability	10	4	8	3	6	3	6
Cost	5	4	4	4	4	3	3
Total (Out of 100):		66		43		77	

Table 1: Design Matrix

Final Design: Expandable Stent

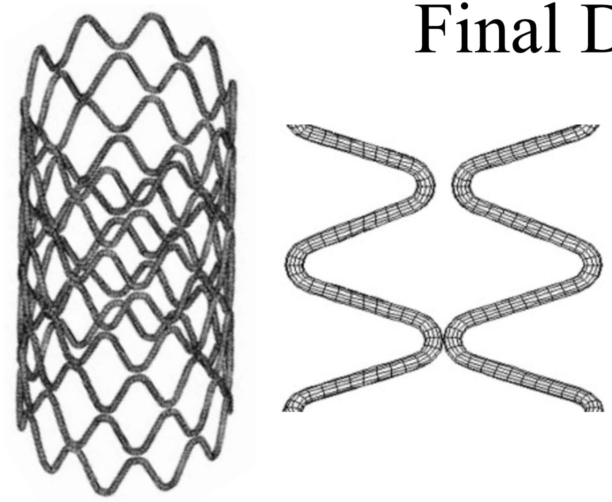

Figure 13: Example Nitinol Stent Geometry [19]

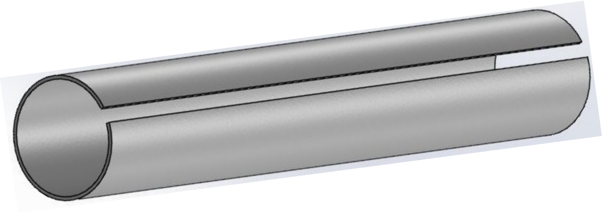

Figure 14: Loader Tube Design

Stent Component:
- Nitinol Stent
- OD: 3 mm
- ID: 2.9 mm
- Strut Width: 0.1 mm
- Stent Height: 20 mm

Loader Tude Component:
- PTFE Tubing
- OD: 2.5 mm
- ID: 2.4 mm
- Tubing Width: 0.1 mm
- Tubing Height: 20 mm

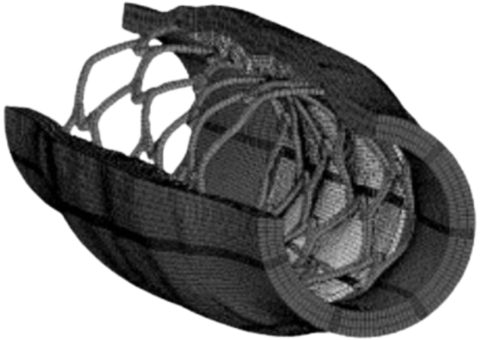

Figure 15: Example Nitinol Stent Geometry [19]

Planned Testing

- Implantation trials on chicken thighs arteries to evaluate usability
- Conduct trials of dyed saline for leakage and patency
- Compare overall implantation time against hand-suturing
- Perform finite element analysis (FEA) to predict stress concentrations and guide design refinement

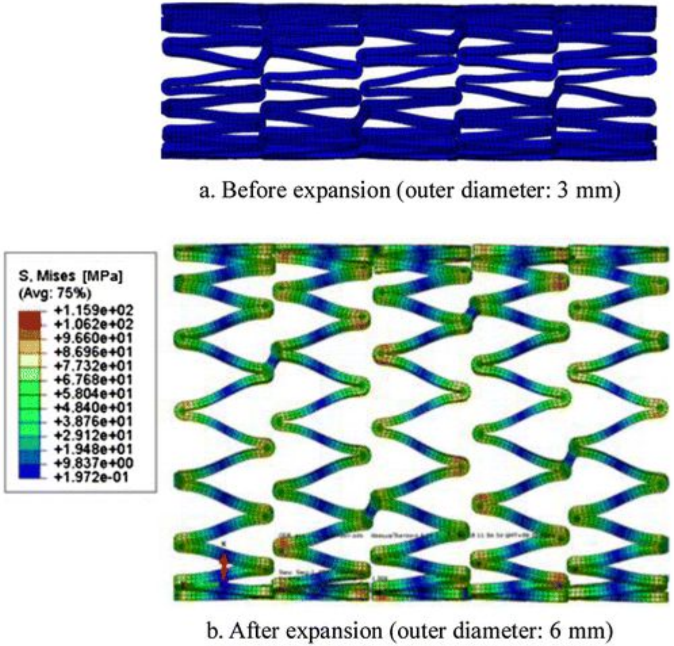

Figure 16: Finite element analysis of the stent before (a) and after (b) expansion [20]

Future Work

- Ensuring a consistent seal ends may be challenging
- Loader tube will require design iterations
- Implantation trials for consistency and reproducibility
- Flow testing to assess durability under long operations
- Biocompatibility of nitinol and PTFE validation
- Surgeon feedback to guide prototype development

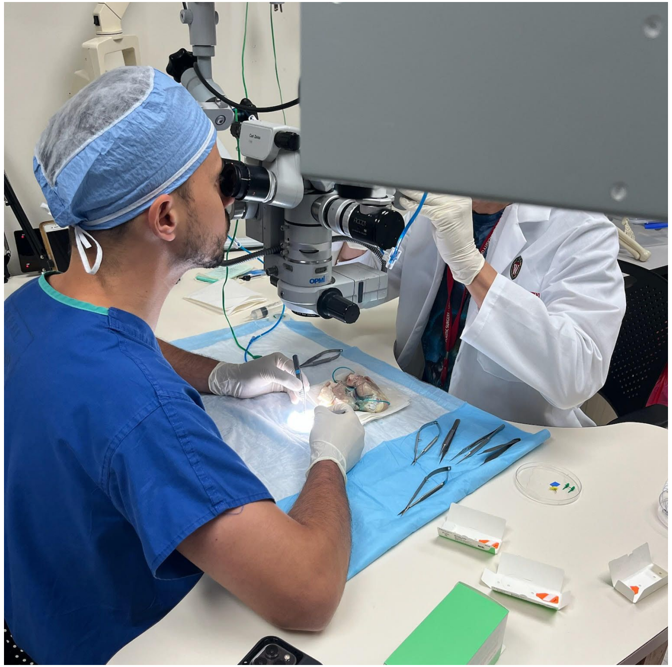

Figure 17: Dr. Weifeng Zeng teaching resident anastomosis technique on chicken thigh

Acknowledgements

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Questions