



Department of
Biomedical Engineering
UNIVERSITY OF WISCONSIN-MADISON

Adjustable Coupler for Arterial Anastomosis

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Clients: Dr. Jasmine Craig and Dr. Weifeng Zeng

Advisor: Professor Justin Williams

Overview

- I. Background
- II. Current Design and Flaws
- III. Summary PDS
- IV. Design Ideas
 - A. Crank Expansion
 - B. Exterior Wedge
 - C. Plier-Assisted Stent
 - D. Elastic Clamp
- V. Final Design Matrix
- VI. Future Work + Testing
- VII. References and Acknowledgments

Problem Statement

Motivation

- Arterial anastomosis procedures are **time-intensive** and require high levels of **precision**
- Anatomical and **physiological differences** in veins and arteries **prevent** use of coupler

Goal

- Develop novel **coupler** device to minimize surgery **duration** and **skill** required
 - Adjustable
 - Minimize leakage
 - Minimize trauma

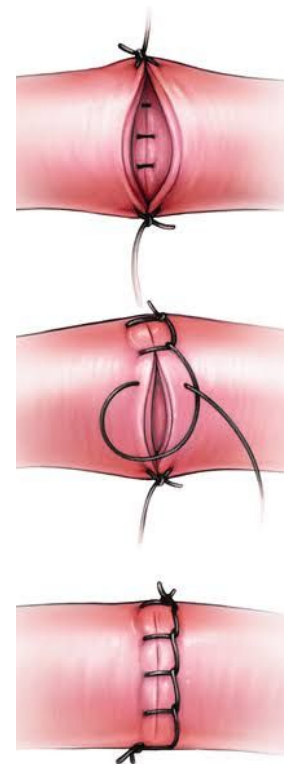


Figure 1: Arterial Anastomosis [1] 3

Client Description & Background

- Clients: Dr. Jasmine Craig and Dr. Weifeng Zeng
- Arterial anastomosis: **connection** of two arteries to restore blood flow
- Current procedures
 - Hand-sewn
 - **Coupler**
- Limitations
 - **Thickness** and elasticity
 - High intraluminal pressure
 - Spasm tendency

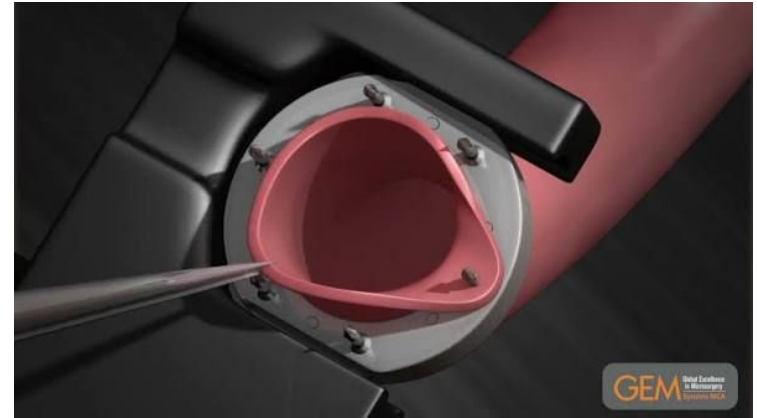


Figure 2: GEM Coupler Procedure [2]

Current and Competing Designs

GEM Coupler Device

- 8% of procedures required troubleshooting [3]
- Necrosis at coupler interface
- No adjustability



Figure 3: GEM Coupler Procedure Video [2]

Catie King

Hand-sewn by surgeon

- Requires intensive training and specialization
- Time consuming

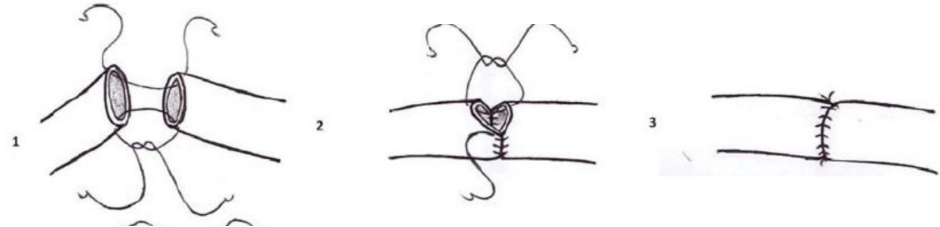


Figure 4: Steps to perform end-to-end vascular anastomosis [4]



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PDS Summary

Function and size

- End-to-end arterial coupling w/o vessel trauma
- Adjustable: expands and compresses by 30% of original size
- 10-20 mm diameter for proof-of-concept

Mechanical requirements

- Leak-free under static and pulsatile flow
- Withstand > 3.64 N of axial tensile stress
- Withstand up to 26.7 kPa for hypertensive patients

Safety and materials

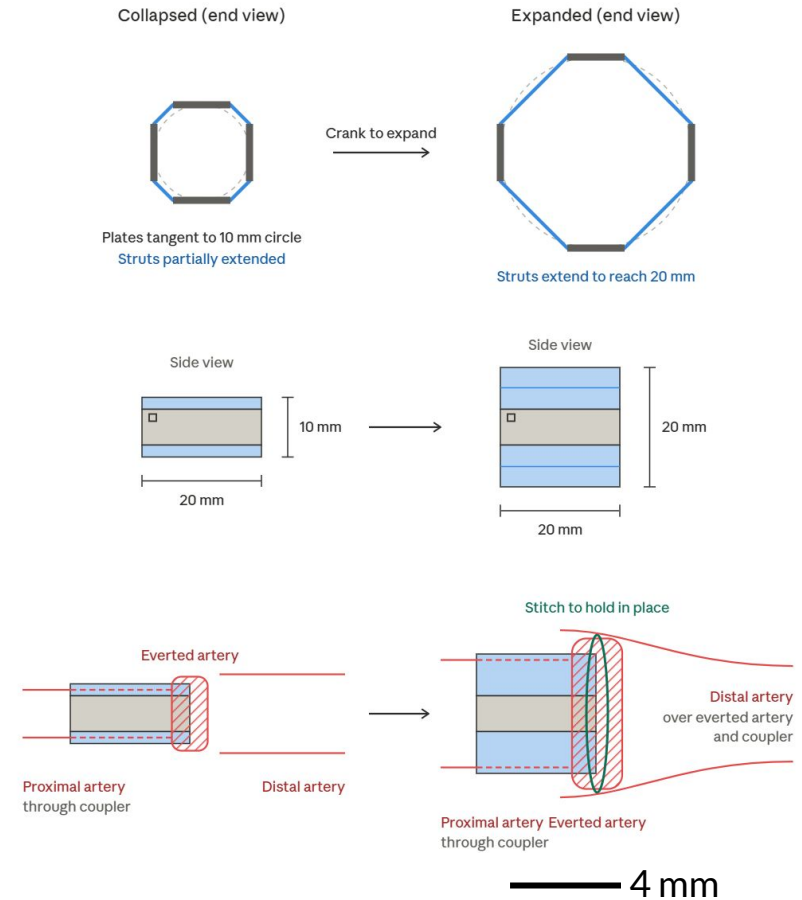
- Biocompatible (ISO 10993)
- Sterile packaging (ISO 11607) and 3-year shelf life
- Class II device, 510(k)
- Must not harm patient

Miscellaneous

- Usable by less specialized surgeons
- \$500 starting budget

Crank Expansion

- Crank tool pushes four plates outward, sliding struts fill the gaps
- Proximal artery passes through and everted over its end
- Distal artery is secured with a single circumferential stitch



Plier-Assisted Stent

- Manually expand artery
- Stent placed within artery
- Suture used to connect second artery

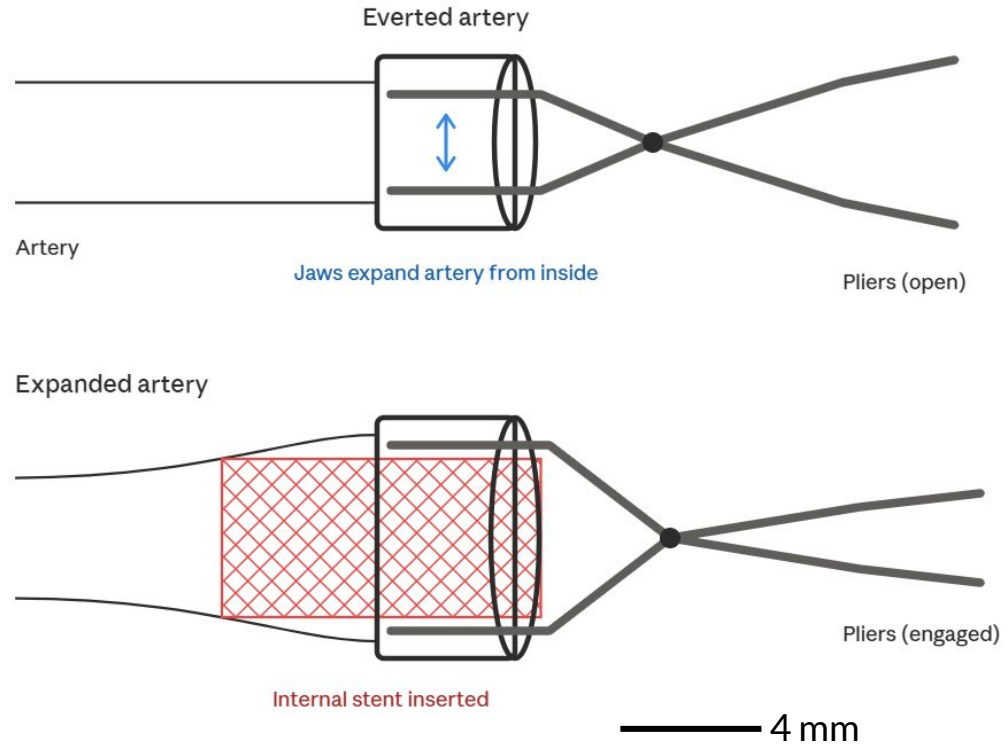
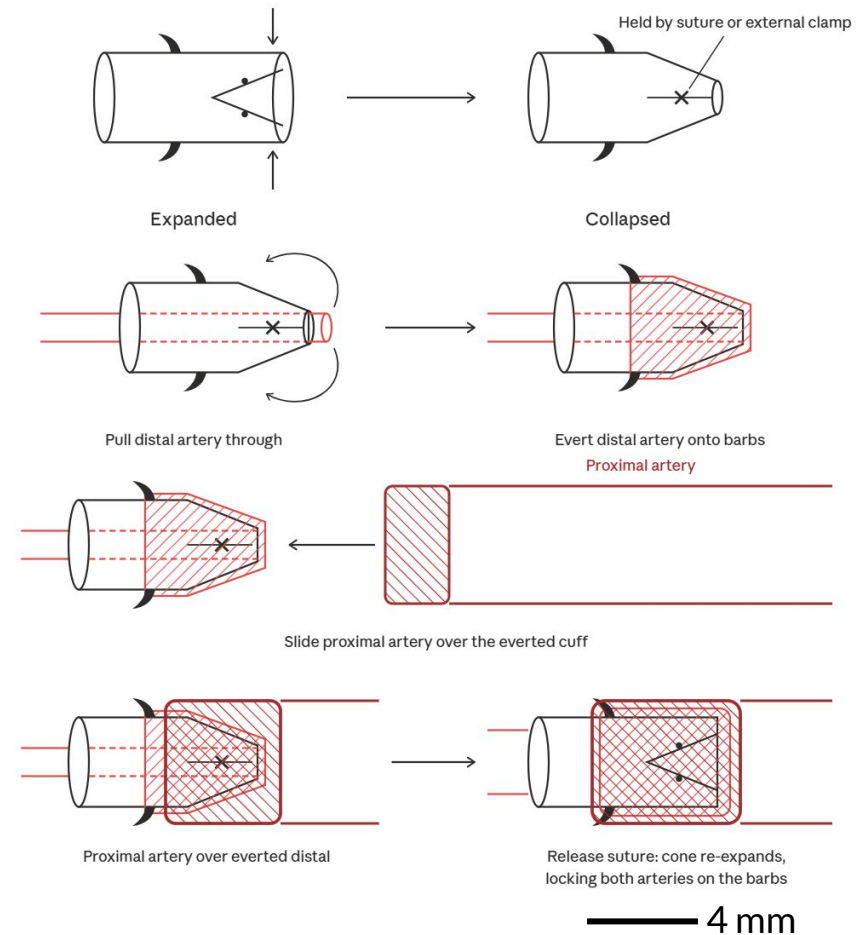


Figure 6: Plier-Assisted Stent Design

Exterior Wedge

- Wedge design allows for a range of diameter via compression
- Barb holds everted artery in place
- Returns to original shape after procedure



Elastic Clamp

- Elastic ring allows expansion
- Two clamps hold artery together
- Similar placement to current devices

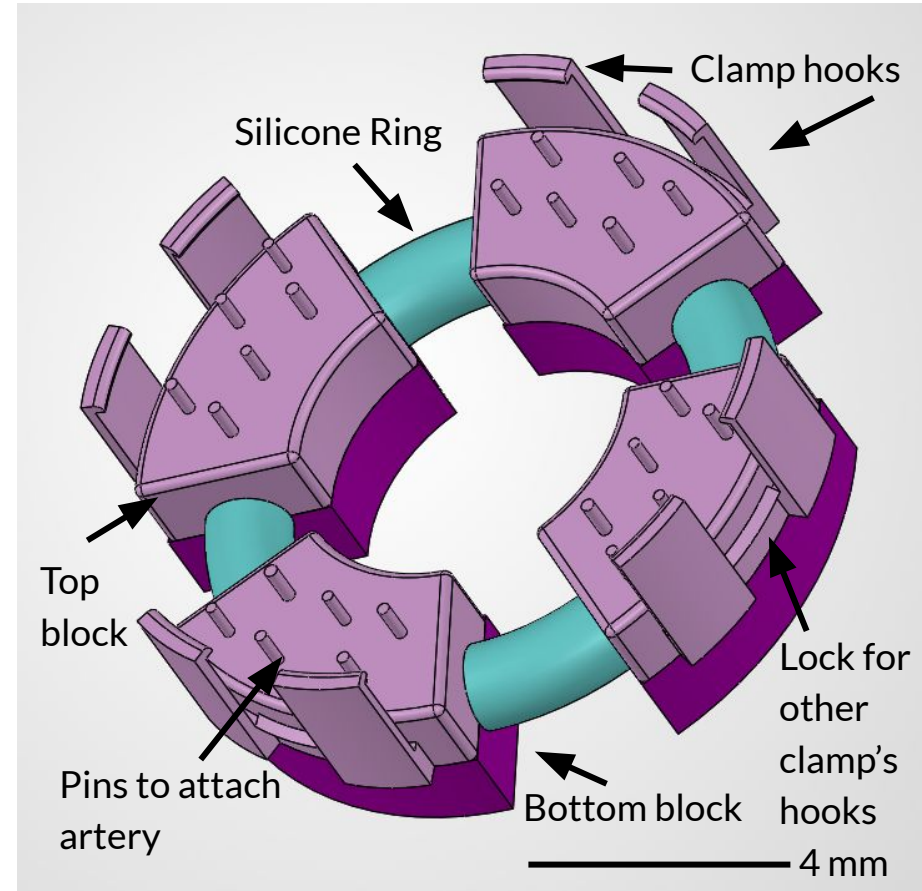


Figure 8: One half of the arterial elastic clamp design

Design Matrix

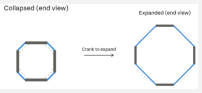
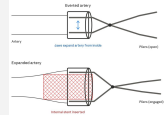
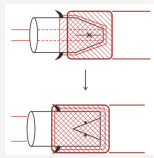
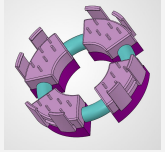
		Design 1: Crank Expansion 		Design 2: Plier- Assisted Stent 		Design 3: Exterior Wedge 		Design 4: Elastic Clamp 	
Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Adjustability	30	2/5	12	3/5	18	2/5	12	4/5	24
Efficiency	20	4/5	16	2/5	8	3/5	12	4/5	16
Ease of Use	15	2/5	6	3/5	9	4/5	12	4/5	12
Safety	10	2/5	4	2/5	4	4/5	8	4/5	8
Durability	10	2/5	4	3/5	6	3/5	6	3/5	6
Fabrication	10	2/5	4	2/5	4	5/5	10	4/5	8
Cost	5	3/5	3	2/5	2	5/5	5	4/5	4
Total (Out of 100)		49		51		65		78	

Table 1: Arterial Coupler Design Matrix

Final Design

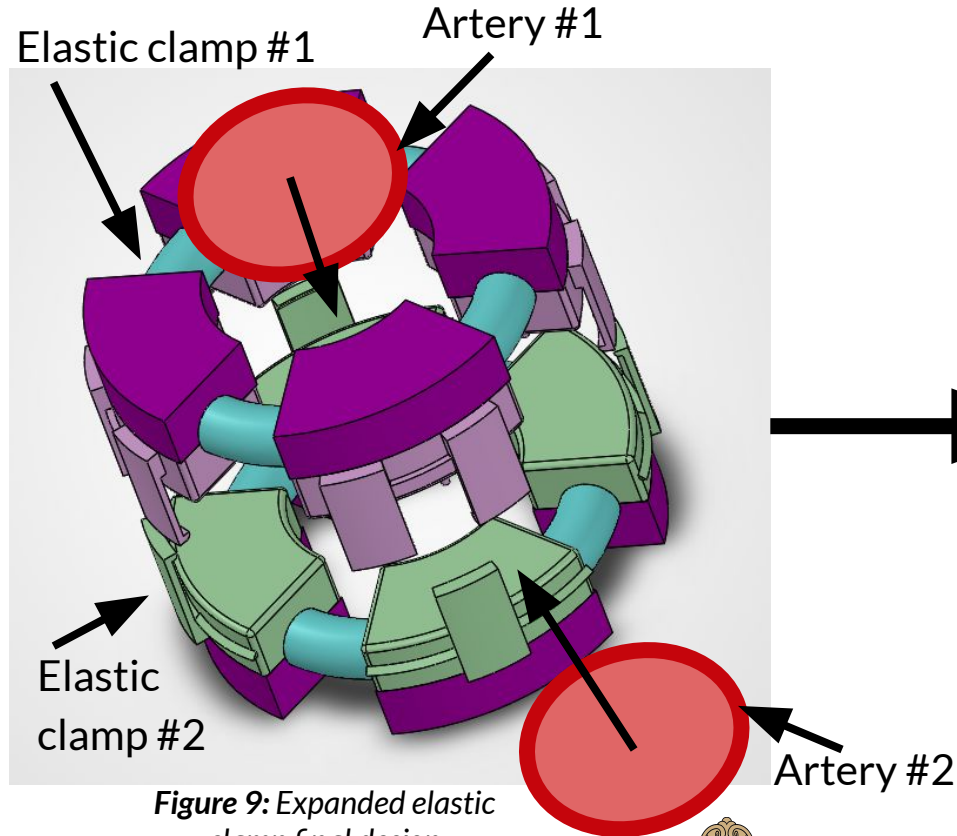


Figure 9: Expanded elastic clamp final design

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Inner diameter
allows blood flow

Aligned
elastic rings

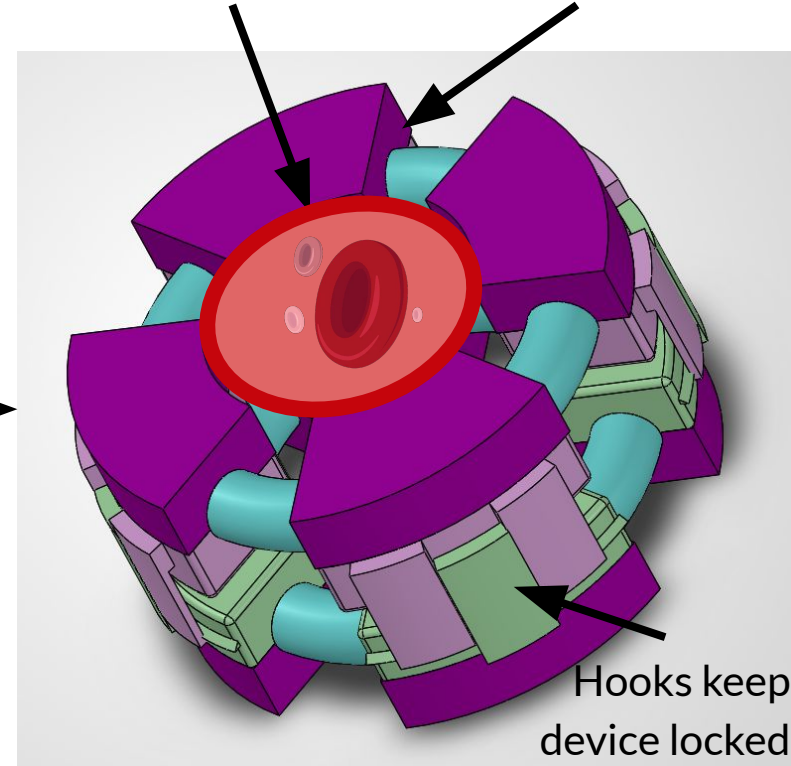


Figure 10: Combined elastic clamp final design

Testing

- **Leakage and patency testing**
 - Dyed saline testing on synthetic tubing and chicken thigh arteries [5]
 - Acceptance Criteria: no leakage under static or pulsatile conditions
- **Hydrostatic Pressure Testing**
 - Syringe pump testing
 - Acceptance Criteria: withstand systolic blood pressure of 120-140 mmHg and diastolic blood pressure of 80-90 mmHg [6]

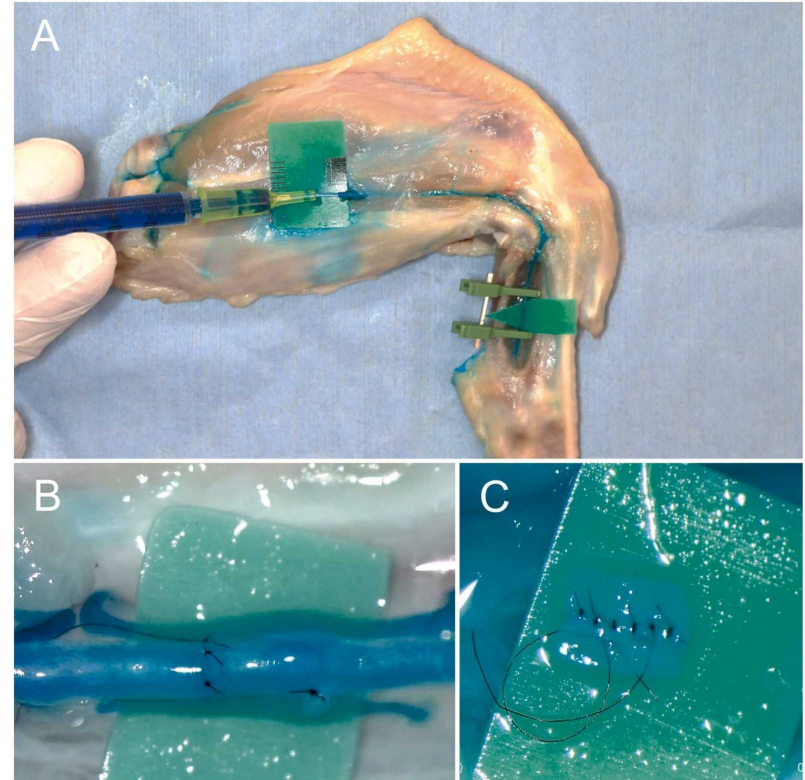


Figure 11: Dyed water injected into chicken wing [7]

Testing

- **Tensile Testing**
 - MTS tensile pull-test
 - Acceptance Criteria: Failure force of >100 gf pull force
- **Efficiency and Usability Tests**
 - Compare overall implantation time of our device vs. existing methods
 - Acceptance Criteria: time reduction using our device



Figure 12: MTS machine [8]

Future Work

This Semester:

- Finalize design focused on adjustability
- Create a working prototype scaled up to 10-20 mm

Next Semester:

- Focus on miniaturization
- Work on making design bioresorbable
- Conduct testing



Acknowledgements

Clients: Dr. Jasmine Craig & Dr. Weifang Zeng
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References

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