Arterial Coupler Re-Design: Adjustable Stent/cuff Anastomosis

Preliminary Report

BME 400 | LAB 308

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Abstract

Arterial anastomosis, the surgical joining of two arteries, is essential for restoring blood flow in cardiovascular, transplant, and reconstructive procedures such as coronary artery bypass grafting, free tissue transfer, and trauma repair. However, the current standard method, manual microsuturing, remains highly time-consuming and technically demanding, often requiring 30-60 minutes of operative time and years of training to master. Even in experienced hands, the method carries risk of leakage, thrombosis, and anastomotic failure, limiting consistency, accessibility, and efficiency in both clinical and emergency settings.

Existing sutureless or mechanical devices, including venous couplers, magnetic compression systems, external cuffs, and intraluminal stents, have shown success in specific contexts but remain unsuitable for arterial use due to thicker vessel walls, greater elasticity, and higher intraluminal pressures. These limitations underscore the need for a suture-minimized, expandable arterial coupling system that can provide secure vessel approximation without compromising flow or biocompatibility.

This project aims to develop a novel arterial coupler that is 3 mm in diameter and capable of expanding 0.3 mm, maintaining mechanical stability without recoil, and avoiding contact with the vessel lumen. The design prioritizes minimized surgical time, ease of use, patient safety, and adaptability to varying vessel diameters (2-5 mm range). Preliminary evaluation includes chicken thigh artery implantation trials, flow testing, and dyed saline trials to verify zero leakage and ensure patency. Additionally, mechanical analysis will be conducted through finite element analysis to assess stress distribution during expansion. If successful, this design could reduce operative time, improve consistency of arterial repairs, and enhance access to safe and efficient arterial anastomosis.

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Introduction

Motivation and Global Impact

Arterial anastomosis is a fundamental procedure across cardiovascular, transplant, and reconstructive surgeries. It enables vital revascularization in coronary artery bypass grafting, free tissue transfer, trauma repair, and organ transplantation. In the United States alone, over 400,000 coronary artery bypass grafts and tens of thousands of microsurgical reconstructions are performed each year, each relying on precise arterial anastomosis to restore circulation and tissue viability [1]. Despite its importance, the current gold standard technique, manual microsuturing, remains highly demanding, time-consuming, and variable between surgeons.

Typical arterial microsuturing requires 30 to 60 minutes of operative time and intensive training to achieve proficiency. Even in expert hands, manual techniques carry the risk of thrombosis, leakage, or anastomotic failure, which can compromise graft patency and patient outcomes. These challenges contribute to prolonged ischemia times, elevated healthcare costs, and limited accessibility, particularly in resource-limited or emergency settings where microsurgical expertise is scarce. Existing alternatives, such as venous couplers, have demonstrated success in low-pressure venous systems but are not suitable for arteries due to differences in wall thickness, elasticity, and hemodynamic load [2], [3].

Developing a reliable, suture-minimized, expandable arterial coupler addresses these systemic gaps by aiming to streamline the anastomosis process, reduce reliance on surgeon skill, and shorten procedure times. By improving procedural efficiency, this device has the potential to reduce ischemic injury, standardize outcomes, and expand surgical accessibility to a broader range of providers. On a global scale, such technology could broaden access to highly technical microsurgical care, reduce postoperative complications, and ultimately improve survival and recovery rates in patients [4].

The societal implications extend beyond individual operations. Enhancing arterial repair efficiency supports faster trauma response, reduces healthcare resource burden, and enables equitable access to life-saving reconstructive and vascular procedures. A sutureless arterial coupler capable of maintaining long-term patency and biocompatibility could represent a significant advancement toward safe, efficient, and universally accessible microvascular surgery.

Existing Devices/Current Methods

Current methods for performing arterial anastomosis primarily rely on hand-sewn microsutures, which remain the clinical standard due to their proven reliability and adaptability across vessel types. However, this approach is time-intensive and is heavily dependent on surgeon expertise. Studies report that manual suturing is associated with high variability in success rates and outcomes, as even minor

misalignments can lead to leakage, thrombosis, or anastomotic failure [5]. These limitations have driven the development of mechanical and sutureless alternatives aimed at improving efficiency, reproducibility, and patient outcomes.

One widely adopted device in venous repair is the GEM Microvascular Anastomotic Coupler (Synovis/Baxter), which uses interlocking rings with metal pins to join everted vessel ends [6]. The coupler has demonstrated high patency rates exceeding 95% in venous systems and reduces operative time to an average of 7.5 minutes compared to traditional hand-sewing [7]. However, the GEM coupler and similar venous devices are unsuitable for arteries because arterial walls are thicker, less compliant, and exposed to higher intraluminal pressures, leading to misalignment and leakage under physiological conditions [2].

Figure 1: GEM Venous Coupler [8]

Alternative designs explored in literature include magnetic compression anastomosis (MCA) systems and external cuff methods. MCA devices use rare-earth magnets to approximate and fuse vessel ends without sutures [9]. Although they have shown promise in gastrointestinal applications, studies report risks of stenosis, poor alignment, and pressure-induced damage when adapted for vascular use [9], [10]. Similarly, external cuff techniques, which evert the vessel over a support tube, reduce operative time but often compromise vascular compliance and have been associated with thrombosis and intimal hyperplasia [4], [11].

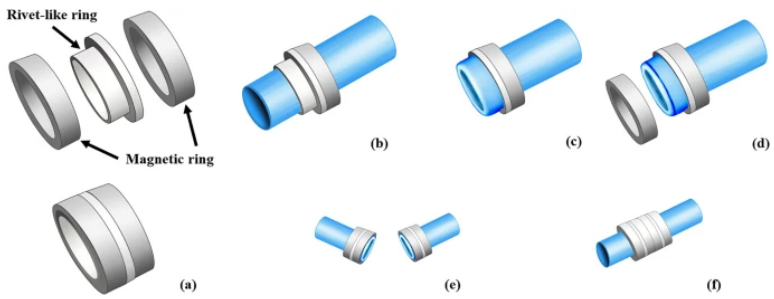


Figure 2: Working mechanism magnetic compression anastomosis [12]

Recent work has investigated placing supportive structures, intraluminal stents, inside the lumen to maintain patency during healing while resorbing over time. These devices can shorten procedure times and do not require eversion but risk disrupting endothelial flow dynamics, provoking thrombosis, and complicating long-term healing [13]. Dissolvable scaffolds, which work to maintain mechanical support during early healing then degrade, seem to be a compelling path as well. Although these scaffolds prevent acute inflammation and thrombosis, challenges remain in tailoring degradation rates, mechanical stability, and biocompatibility concurrently [4].

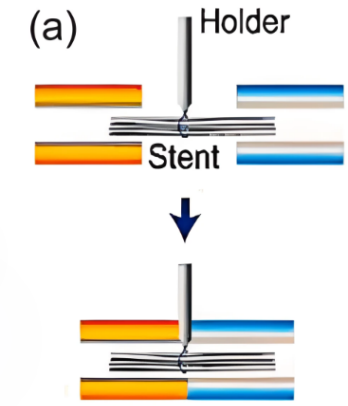


Figure 3: Intraluminal Stent Mechanism [4]

Despite advances, no existing device effectively meets the unique mechanical and biological demands of arterial anastomosis, where precision, elasticity, and long-term patency are critical. The lack of a suture-minimized, expandable arterial coupler represents a clear opportunity for innovation. A design that can expand within a 2-5 mm range, maintain mechanical stability without recoil, and avoid contact with the lumen would bridge a major gap in current surgical technologies. Developing such a device

could significantly reduce operative time, standardize outcomes, and expand accessibility of arterial repair procedures across diverse surgical settings.

Problem Statement

Arterial anastomosis remains one of the most technically demanding and time-consuming procedures in microsurgery, requiring precise alignment and suturing of fragile, small-diameter vessels under high pressure. The current method of manual microsuturing can take up to 30 to 60 minutes per anastomosis and demands years of specialized training to master [4]. Even in expert hands, manual repairs are prone to leakage, thrombosis, or narrowing at the junction, which compromise graft patency and increase the likelihood of reoperation [14]. These challenges are magnified in emergency and resource-limited settings, where microsurgical expertise is often unavailable [15].

Despite decades of innovation, no existing sutureless or mechanical system has successfully replaced hand suturing for arteries. Venous couplers, such as the GEM Microvascular Anastomotic Coupler, achieve high patency and shorter operative times in low-pressure venous systems but fail in arteries due to thicker vessel walls, reduced compliance, and elevated hemodynamic stress [16]. Other sutureless concepts, including magnetic compression, external cuff, and intraluminal stent-based approaches, have shown promise in experimental settings but remain limited by compliance mismatch, risk of thrombosis, and restricted adaptability across vessel sizes [17], [18].

The critical need persists for an expandable, suture-minimized arterial coupling system that can provide secure approximation without intraluminal contact, accommodate diameter dilation (approximately 0.3 mm), and remain stable under pulsatile pressure. A device that meets these criteria would not only reduce operative time and technical dependence but also improve procedural consistency, minimize ischemic injury, and enhance long-term patency. Ultimately, such a system could redefine the standard of arterial repair by offering a faster, safer, and more accessible alternative to manual microsuturing across vascular, trauma, and reconstructive applications.

Background

Biology and Physiology

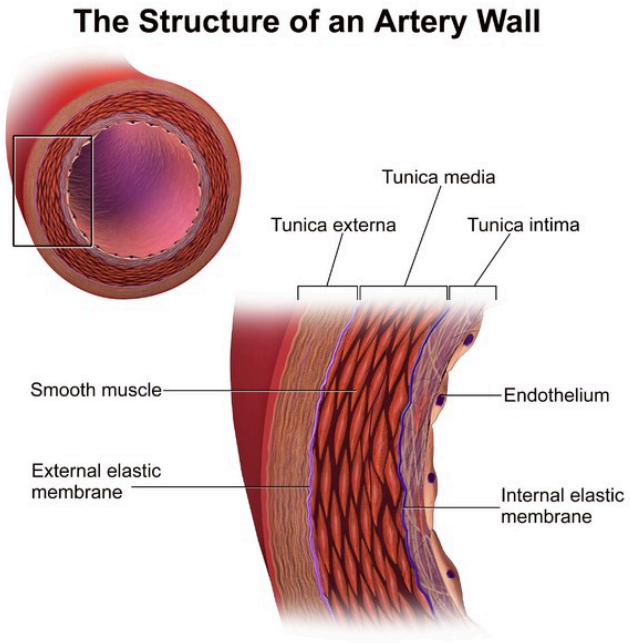


Figure 4: Arterial Wall Anatomy [19]

Initial understanding of arterial anastomosis and current limitations relied heavily on vessel anatomy, endothelial healing, thrombosis risk, and hemodynamics. The arterial wall is composed of the intima, media, and adventitia (externa) moving from the inner lining to the outer respectively []. It is important that intima contact between the two free arterial ends that are being joined is prominent since this mechanism prompts endothelial healing [20]. While intima contact between arterial ends should be maximized, there shall be limited contact between the intima and implantable device since this promotes the risk of coagulation and thrombosis [21]. The typical artery in this form of microsurgery spans from 0.5-3mm in diameter.

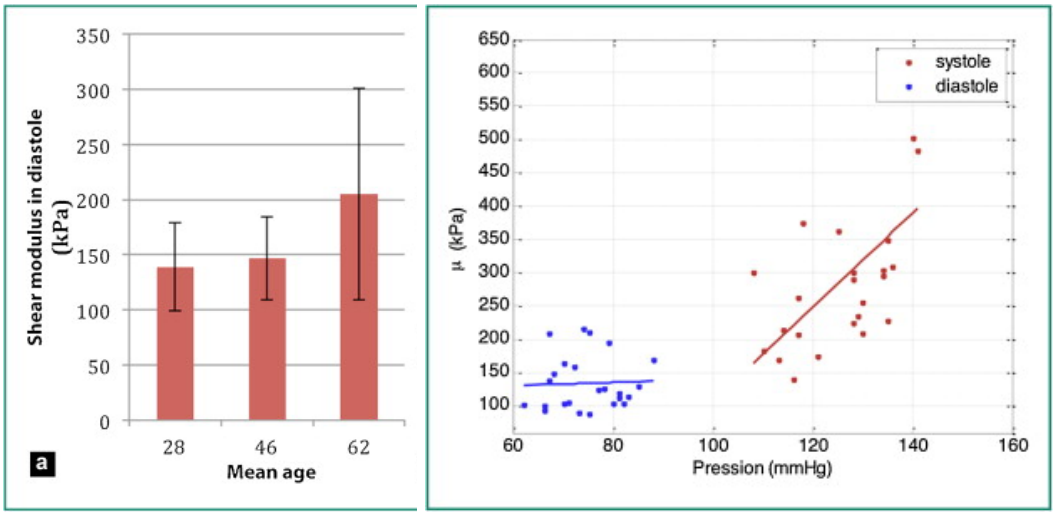


Figure 5: Arterial Pressure During Diastole and Systole [22]

Capturing peak excursions in arterial pressures during microvascular surgery through literature was more scarce, but the client specified that arterial pressures could reach 160-200 mmHg and the device should be suited for this application. The plot in Figure X models arterial wall stiffness in response to diastolic and systolic pressure changes. During systole, arterial pressures reached a maximum of 140 mmHg and this corresponded to a wall stiffness of 500 kPa. On the lower end, stiffness was recorded as low as 80 kPa in response to smaller diastolic pressures. It shall be noted that the obtained diastolic stiffness measurements were separated into respective age groups. Across 30 patients the measured shear modulus increases with age most predominantly in the third age group that covers individuals 55-68 years old. Since the device does not have a target demographic, it must be compatible with a shear modulus ranging from 140 - 210 kPa.

Prototype Design and Build Research

The device will be implanted into the biological system, therefore research surrounding the geometry and material selection must all ensure biocompatibility and patient safety. Since contact with the intima of the artery leads to clotting and thrombosis, all design considerations must position our device outside of the artery. The client requirements specified that the device will be implantable and does not need to degrade over time. For this reason, the considered materials must be resistant to corrosion and degradation in high humidity and liquid environments. Arterial anatomy varies depending on the patient, however, application of our device will be focused on a healthy individual with artery size spanning from 2.5-5mm and peak pressures at 200 mmHg. A common technique for maximizing intima contact is eversion of the artery which is limited by the thickness and greater elasticity of arterial walls [19]. This is a consideration that will limit potential design considerations.

Once a design is in development, the client has chicken arteries available to the team that will allow us to test device implantation and performance. This will measure the overall implantation time expected for our device and compatibility of arterial eversion.

Client Information

Dr. Jasmine Craig, MD, PhD, is a plastic surgery resident at the University of Wisconsin-Madison School of Medicine and Public Health. Dr. Craig's clinical expertise ensures the device aligns with surgical workflows and addresses real-world challenges in vascular reconstruction.

Dr. Weifeng Zeng, MD, is an assistant scientist and microsurgical instructor at the University of Wisconsin-Madison, contributing his expertise in microsurgical education and simulation to guide usability and potential integration into training curriculum.

Production Design Specification

The product design specifications for the adjustable arterial coupler device are derived from client requirements and microsurgical necessities throughout anastomosis. The main function of the device is to securely connect two arteries using a sutureless technique, while maintaining vessel patency and minimizing procedure time. The current procedure takes 30-60 minutes to complete, while the new device must reduce operative time to under 20 minutes. Biocompatibility and structural stability must not be compromised since the device will be permanently implanted in the body throughout the patient's lifetime. The device must resist corrosion in physiological environments while withstanding pressures ranging from 160-200 mmHg. An adjustable coupler ranging in diameters 2-5 mm will be fabricated to account for different size vessels. The coupler should maximize intima-to-intima contact between vessel ends to promote healing and patency, but only engage with the outer surface and avoid interluminal contact to prevent thrombosis.

In addition to these requirements, the device must comply with ISO 10993 biocompatibility standards FDA Class II medical device regulations to ensure that all materials are non-toxic, non-inflammatory, and sterilizable. The device must withstand ethylene oxide (EtO) sterilization without degradation of material properties or loss of function. Each device will be single use and packaged to maintain sterility until it is opened in the surgical field. The device should consider ergonomic techniques and allow for an intuitive operation for both experienced and inexperienced microsurgeons to minimize the challenging learning curve. To ensure ease of use and compatibility with microsurgical tools, the design must not exceed 1 gram, and have a smooth, polished finish without any sharp edges. A minimum shelf life of 3 years will be achieved through appropriate material and packaging selection to maintain

sterility and integrity. To ensure reliable blood flow and minimize risk of thrombosis, it will demonstrate ≥95% immediate vessel patency and ≥90% patency after 7 days in preclinical testing.

One prototype must be produced as the final product and cost under the designated $1,000 budget. The final design will integrate speed and efficiency of existing couplers with the adaptability, biocompatibility, and safety required for arterial applications. Refer to detailed design specifications and data found in Appendix I.

Preliminary Designs and Materials

Sock Clamp

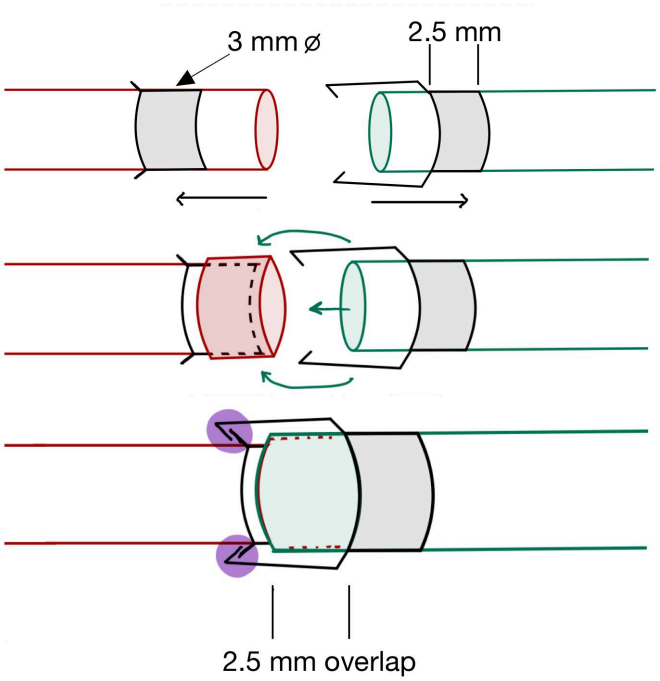


Figure 6: Sock Clamp Design

The first proposed design, the Sock Clamp, shown in *Figure 6* above, features two tubular clamps with clips for locking the arteries together that function similar to a side-release buckle. A suitably strong and biocompatible material, such as Stainless Steel 316L, would be used to ensure no complications with durability or potential thrombosis would occur. One clip uses two small prongs facing away from the cut on the proximal artery (red), while the other clip uses two extending arms reaching out over the end of the distal (green) artery. These clamps would be secured around the perimeter of the arteries using a pressure-based mechanism. The microsurgeon would utilize this device by first fitting the tubular clamps around each artery, then everting the proximal artery back over the clamp. The distal end would then

sleeve over the proximal artery, and the two-point clips would lock together, securing the arteries together. This device eliminates the need for sutures, the most time consuming factor in an anastomosis. The quick arterial connection also allows for excellent intima overlap, facilitating faster regrowth and healing.

Spike Stent

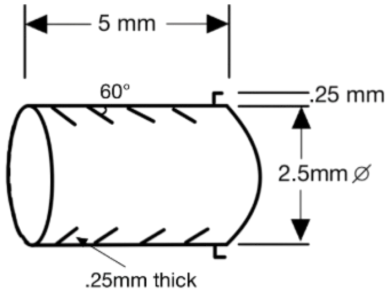


Figure 7: Close-up of directionally spiked cuff.

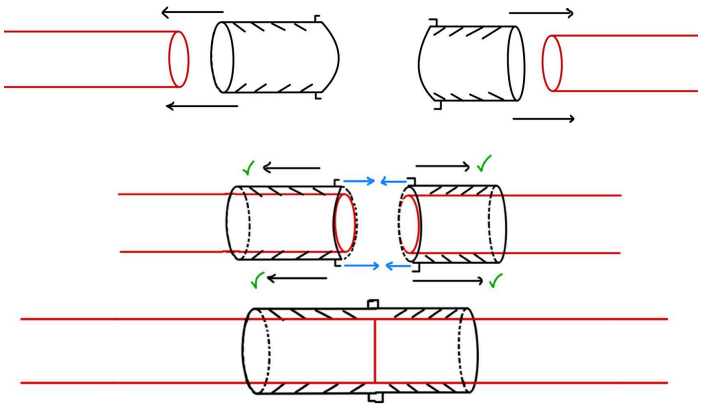


Figure 8: Spike Stent Design

The second design, the Spike Stent, features two directionally spiked external stents, similar to a cuff, surrounding the adventitia of each end of the artery. Machined from a strong, corrosion-resistant, and biocompatible metal, these cuffs and the associated spikes securely anchor the exterior stent in place, minimizing migration while maintaining vessel integrity and biocompatibility. These cuffs, machined to the desired artery size, have small, short spikes, designed for digging into just the adventitial layer surrounding the vessel, avoiding damage to the lumen while preventing the artery from sliding out of the cuff. These cuffs are slid over the arteries until aligned with each end of the cut, as depicted in Figure 8 above. As the directional spikes prevent the cuffs from sliding off of the artery, and the two ends can be joined together via small clips on the exterior of the cuff. This cuffing mechanism allows for a very quick, sutureless process in anastomosis procedures.

Expandable Stent

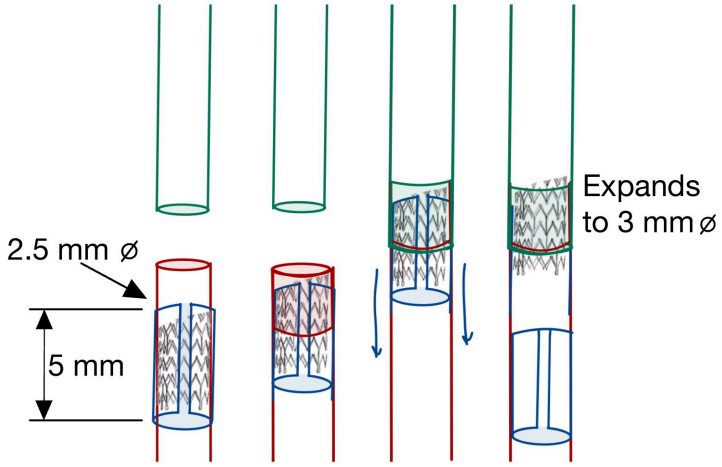


Figure 9: Expandable Nitinol Stent Application

The Expandable Stent design is a two-step design utilizing an expanding nitinol stent housed within a loader tube. This design, pictured above in Figure 9, uses nitinol, a nickel-titanium alloy known for its superelasticity and shape memory, and a material widely used in vascular procedures [23]. The shape memory aspect allows for the stent to be deformed at a cooler temperature, such as the operating room, before returning to its original manufactured shape at near-homeostatic temperatures. The loading tube will be machined from a strong yet flexible material, with a low coefficient of friction being a key requirement. PTFE is a viable choice for this material, as its inherently low friction coefficient gives it antifriction properties. Strength or flexibility limitations of PTFE can also be overcome by adding suitable fillers selected to increase mechanical performance [24]. The stent, machined to 3mm, will be inserted into the loading tube and fit around the proximal artery. The sequence of contact from interior to exterior is artery, stent, then loading tube. At this point, the microsurgeon will then use the loading tube to compress the diameter of the nitinol stent to be smaller than the artery, making for an easier eversion over the device. Once the artery is everted, the distal artery (depicted in Figure 9 as green) is then sleeved over the proximal end. At this point, the loading tube can then be slid away from the junction and off of the proximal artery, leaving the stent to expand back to its 3mm diameter, expanding the arterial lumen, and creating a seal between the arteries. If needed, a suture can then be tied in a clamp-like manner around the junction, reinforcing the seal.

Preliminary Design Evaluation

Design Matrix

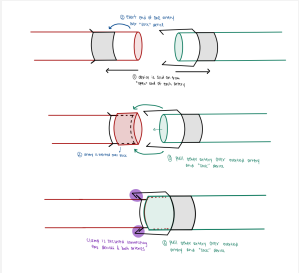
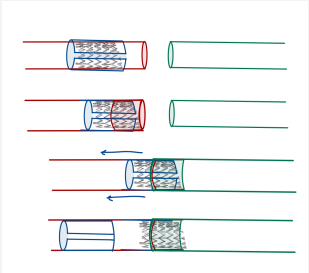
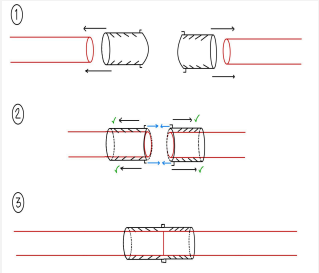
		Design 1: Sock Clamp 		**Design 2: Expandable Stent** 		**Design 3: SpikeStent** 	
Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Efficiency	25	3	15	4	20	2	10
Adjustability	20	1	4	4	16	1	4
Intima Contact	15	5	15	5	15	2	6
Durability	15	4	12	3	9	3	9
Safety	10	4	8	4	8	2	4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

Table 1: Design Matrix Scoring Three Proposed Solutions

The three design concepts were evaluated across seven weighted categories. Efficiency, the most critical, measures implantation time starting the second of arterial clamping and ending once blood flow is successfully restored. Overall implantation time must not exceed 20 seconds to ensure tissue viability. Adjustability assesses the device's ability to be inserted at a smaller diameter and expand to the artery's native size, ensuring anatomical compatibility and reducing leakage or clotting risk. Intima contact measures how well the inner arterial linings align to promote endothelial healing and prevent thrombosis. Durability reflects the device's capacity to maintain structural integrity and function under physiological conditions. Safety evaluates risks of tearing, inflammation, or immune response to favor smooth and biocompatible designs. Manufacturability considers production feasibility and cost-efficiency using

available materials and machining methods. Finally, all designs must meet the budget constraint of $1,000.

This Expandable Stent scored the highest in the three most heavily weighted categories within the design matrix including: efficiency, adjustability, and intima contact. This was the only design option that interacts with only one artery directly improving expected implantation time and efficiency. Nitinol's superelastic and shape-memory properties gives it the ability to be compressed to a smaller diameter while loading into the loader tube and will make eversion of the artery over this reduced diameter easier. Based on stent length, the degree of intima contact can also be controlled and is maximized by this design option. The Expandable Stent scored sufficiently but not the highest in the categories of durability, manufacturability, and cost. This is due to the more complex nature of nitinol as a material choice since it requires laser cutting for stent geometry, shape setting at high temperatures, and electropolishing to smooth surface finish and enhance biocompatibility. The more complex manufacturing procedure and fabrication is the tradeoff for an adjustable and efficient design.

Proposed Final Design

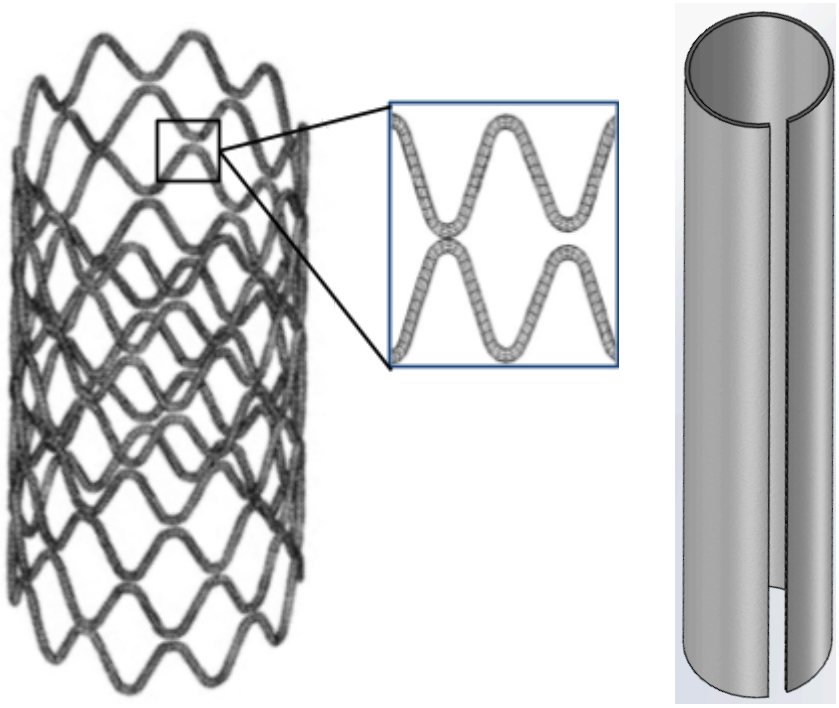


Figure 10: Example Nitinol Stent Model and Loader Tube [25]

The proposed final design is a nitinol stent that will be inserted into a polytetrafluoroethylene (PTFE) loader tube during implantation. During implantation the device will be restricted to the maximum allowable diameter set by the loader tube. Once proper eversion and overlaying of the arterial

ends is complete, the loader tube can be removed and the nitinol stent will have the ability to expand to the machined diameter, set to match the artery. Elastic properties are still maintained in the fully expanded state allowing the device to respond dynamically to deviations in arterial pressures.

Fabrication

Materials

The coupler stent will be fabricated using biocompatible and corrosion resistant materials approved for surgical use. The primary materials under consideration include 316L stainless steel and Nitinol due to their high mechanical strength, flexibility, and clinical history in vascular implants. The 316L stainless steel is resistant to corrosion and deformation under physiological conditions and pressures up to 200 mmHg [26]. Nitinol is a shape memory alloy that exhibits superelastic properties to expand and contract across multiple vessel diameters [27].

The loader tube will be fabricated from PTFE due to its low friction coefficient, chemical stability, and biocompatibility in vascular applications [28]. All materials must comply with ISO 10993 biocompatibility standards and FDA Class II medical device requirements to verify biocompatibility, chemical stability, and hemocompatibility without leachable compound release [29], [30]. A detailed list of materials, quantities, and cost estimates will be provided in Appendix II.

Methods

The initial device will be modeled in SolidWorks to optimize vessel fit, alignment, and ergonomic access for microsurgeons during anastomosis. Early prototypes will be fabricated using stereolithography (SLA) 3D printing at the UW Makerspace to evaluate the dimensional accuracy, visual alignment, and usability. The elastic resin material will be selected to replicate the slight flexibility of the stent, enabling realistic technique and fit testing in the client's laboratory. Following early testing, the feedback will guide design modifications before transitioning to metal fabrication.

Once the dimensions are finalized the metal prototype will be waterjet cut from 316L stainless steel or Nitinol, or outsourced to a precision manufacturing facility capable of achieving microscale tolerances for the 2-5 mm arterial diameter range.

Following fabrication, the prototype will be sterilized using EtO, which is a method compatible with both metals and polymers and used for medical devices with complex geometries [31]. Sterilization procedures will be validated following FDA requirements to ensure complete microbial inactivation and preservation of material integrity in the prototype [32].

Final Prototype

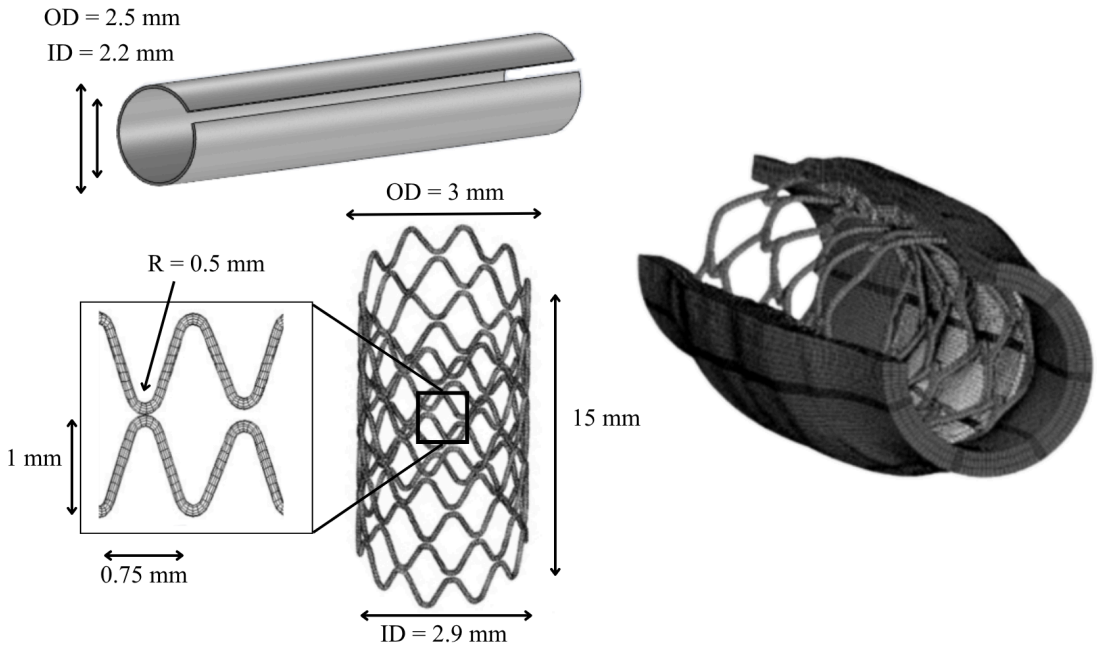


Figure 11: Final prototype with dimensions [25]

Testing and Results

The purpose of testing the prototype is to evaluate the usability, performance, and mechanical effectiveness of the arterial coupler in achieving a secure and efficient vascular connection. The goal of the testing process is to determine how well the device performs under simulated surgical and physiological conditions, specifically assessing its ability to reduce operative and ischemic time while maintaining patency and mechanical integrity. The primary focus of testing will be usability during implantation, leakage resistance, and mechanical fatigue behavior of the device.

To evaluate the surgical usability of the prototype, implantation trials will be conducted using chicken thigh arteries. This model has been validated as an effective microsurgical training and testing platform due to its comparable vessel size and elasticity to small human arteries. It has been demonstrated that the chicken thigh artery model improves microsurgical competence and confidence through repeated practices which makes it a suitable analog for evaluating vascular coupling devices [33]. During this stage, the team will record implantation time, ease of handling, and the ability of the coupler to align and secure the vessel ends properly. Instances of incomplete coupling or tissue tearing will be documented to inform future design iterations.

Following successful implantation, leakage and patency testing will be performed using dyed saline perfusion. The objective of this testing is to verify the formation of a complete seal between vessel

ends and to confirm continuous flow through the lumen under the simulated conditions. Any observed leakage or deformation will indicate the need to refine the sealing geometry or compression tolerance of the device. Ensuring reliable sealing is critical to preventing post operative bleeding or thrombosis in a clinical setting.

The implantation time analysis will directly compare the use of the coupler to conventional hand-suturing techniques. Reducing anastomosis time is essential for limiting ischemic duration, which has been shown to significantly influence outcomes in microsurgical and free flap reconstruction procedures. It was found that extended perioperative ischemia increases complication rates and compromises flap survival [34]. It was also determined that prolonged secondary arterial ischemia can lead to tissue necrosis [35]. By shortening anastomosis time, the coupler has the potential to improve patient outcomes by reducing ischemic risk. These trials will track average procedure time and gather qualitative user feedback to assess usability, ergonomics, and learning curve.

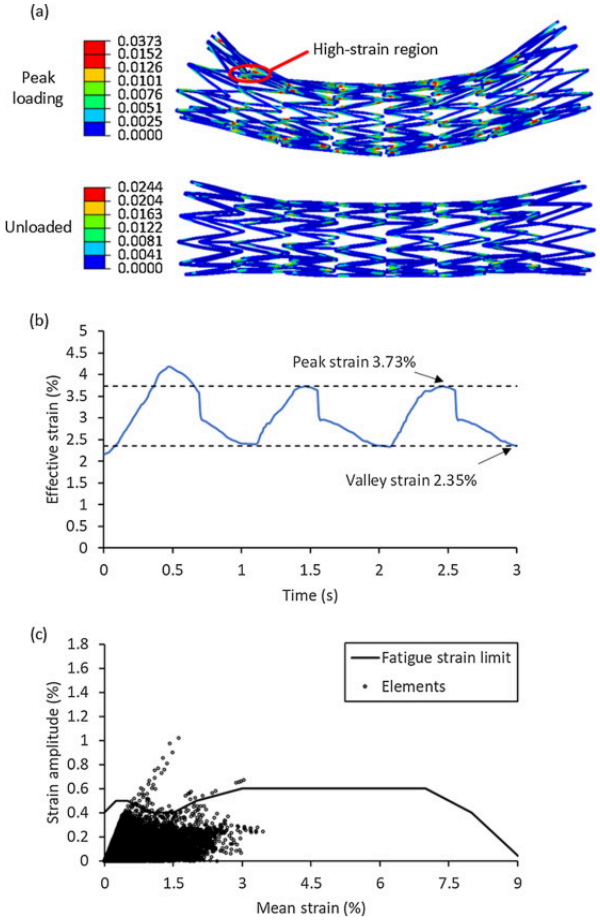


Figure 12: Finite element analysis (FEA) of the coupler illustrating fatigue behavior of nitinol under simulated bending [36].

To analyze the mechanical performance of the design, finite element analysis (FEA) will be conducted to evaluate the stress distribution and fatigue behavior during the expansion of the stent. The coupler's expansion in outer diameter will be modeled to stimulate deployment within small diameter arteries. Fatigue resistance in nitinol stents had been investigated and were subjected to repetitive biomechanical loads [36]. From this, it was found that cyclic bending and torsion were primary contributors to fatigue failure, while pulsatile blood pressure alone posed minimal risk. Incorporating similar computational approaches allows assessment of high stress regions in the coupler and ensures that its nitinol structure can withstand physiology loading without fracture. The results of this analysis, as illustrated in Figure 12 above, demonstrate localized areas of high strain at the inner bends of the stent geometry where peak effective strain reached approximately 3.73% during bending. These findings confirm that bending contributes most to fatigue risk, where strain amplitudes under pulsatile loading remain below the fatigue strain limit. Insights from this analysis will guide future modifications to wall thickness, expansion force, and ring geometry to improve fatigue resistance and durability.

Discussion

Results from testing will determine whether the arterial recoupling device provides an efficient and reliable alternative to the traditional suturing methods currently used in arterial anastomosis. The device is intended to expand the lumen, preventing any potential restenosis, while maintaining vessel integrity and minimizing trauma at the junction. Findings from prototype testing will help assess how well the design achieves these goals and clue the team towards any refinements that are needed to improve overall performance of the device.

During testing, the team will observe and evaluate the effectiveness of the stent and loading tube deployment under realistic handling conditions when performed by microsurgeons. This includes assessing factors such as ease of positioning, expansion, and how well the device is maintained in place without any slippage or leakage. A device that demonstrates consistency in deployment and stability has strong clinical potential, particularly if it reduces anastomosis procedure time, and contributes to an overall simplification of the procedure. Additional testing on cadaver arteries could further validate the device's performance in human vessels and reveal any ergonomic challenges that surgeons could face during use.

Several limitations and potential sources of error may influence the outcomes of early testing. One of the primary challenges is the difference in tissue composition between chicken arteries and human femoral. Chicken vessels are typically thinner, less elastic, and lack the same composition of collagen and smooth muscle layering that is usually found in human arteries [33]. This can alter the mechanical response to expansion forces and device deployment. As a result, findings from animal tissue models may

not fully replicate the behavior of human vasculature under physiological pressures. In addition, variations in vessel diameter between samples could affect the uniformity of the stent's expansion and quality of the seal at the artery ends. Even slight deviations in vessel size or wall thickness may influence the distribution of stress and strain which may lead to inconsistent results across trials.

Variability in deployment force also represents a key source of experimental error. Difference in how microsurgeons handle and actuate the loader tube may affect the rate and magnitude of expansion, which may lead to over or under dilation. Such inconsistencies could compromise both the accuracy of results and the safety of the device if not properly standardized. Furthermore, testing on ex vivo tissue introduces factors such as tissue degradation, dehydration, and loss of homeostatic conditions that can alter compliance and rupture thresholds over time. These changes may affect the mechanical effect observed during deployment.

Finally, material properties of the device itself must be carefully controlled. If the stiffness or recovery behavior of the nitinol structure is not precisely calibrated, excessive radial force or uneven expansion could damage the vessel wall or introduce intimal injury. This highlights the importance of intensive mechanical testing, careful calibration of the expansion mechanism, and consistent validation across several trials to ensure repeatable and safe device performance.

Conclusion

Vascular anastomosis is a critical yet time intensive surgical procedure where precision and consistency directly affect patient outcomes. To address these challenges, the team developed a final design featuring an adjustable self expanding arterial coupler that connects vessel ends. The design utilizes a nitinol ring and PTFE liner to ensure both flexibility and a reliable seal. This will eliminate the need for hand suturing while maintaining luminal patency. This design aims to reduce operative time, minimize ischemic duration, and improve the reproducibility of microsurgical procedures.

Looking ahead, the team will begin implantation trials using chicken thigh arteries to evaluate the ease of deployment and coupling accuracy. Dying saline perfusion testing will then be performed for leakage and flow continuity. Insights from these experiments will guide iterative refinements to the cuff geometry and loader mechanism. In parallel, finite element analysis will continue to evaluate stress distribution and material durability during expansion. Future efforts will integrate surgeon feedback, extended flow testing, and biocompatibility validation to optimize the design for preclinical use and eventual surgical application.

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Appendix

Appendix I - Product Design Specification (PDS)

Introduction:

The following table defines important terms used throughout the document (Table 1).

Term	Definition
Anastomosis	An anastomosis is a surgical connection between two structures. It usually means a connection that is created between tubular structures [1].
Ischemia	an inadequate blood supply to an organ or part of the body, especially the heart muscles [2].
Microsurgery	Microsurgery is a surgical discipline that requires precision to repair or rebuild microscopic parts of the body with specialized tools and procedures [3].
Patency	The condition of being open, expanded, or unobstructed.

Table 1: Definitions of terms used throughout the document.

Function:

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.

Client Requirements:

- The client requires that the team's design is adjustable across artery sizes spanning from 2–5 mm in diameter, either through multiple prototypes or a single adjustable device.

- The client requires that the design only interacts with the outer diameter of the artery and avoids intraluminal placement.
- The device should enable completion of arterial anastomosis within 20 minutes.
- The design should be intuitive to operate and require minimal training for experienced or trainee microsurgeons.
- The client requires that the device remain implanted safely for the duration of the patient's life without loss of function or biocompatibility.
- The device must withstand arterial blood pressures up to 160-200 mmHg without deformation, collapse, or fracture.
- The device must be single-use per surgical procedure, compatible with standard sterilization methods and delivered in packaging that maintains sterility until surgical use.
- The device must avoid sharp edges or burrs that could damage vessels, gloves, or surgical personnel.

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance Requirements*

i. This device should be designed for single use per surgical procedure to ensure sterility and consistent performance.

ii. This device must remain implanted in the patient's body for the duration of their lifespan without loss of function or biocompatibility.

iii. This device will enable anastomosis to be completed in less than 20 minutes, as specified by our client, reducing operative time compared to current suturing methods ranging from 30-60 minutes.

1. In head and neck reconstruction, anastomosis time utilizing coupler devices averages 7.5 minutes, compared to 32.2 minutes with sutured techniques [4].

iv. This device must remain effective under ischemic conditions to ensure perfusion is restored before tissue damage occurs.

1. Reperfusion should occur within 5-6 hours of warm ischemia for limb survival, within 3 hours to minimize functional deficits, and within 10-12 hours of cold ischemia under standard preservation methods [5].

v. As specified by the client, the device will function across a vessel range of 2-5 mm with either multiple prototypes to cover this range or one prototype capable of expanding and contracting between sizes.

vi. This device will maintain patency of the vessel lumen by preventing constriction, collapse, or damage to the intima layer.

vii. The device will accommodate variable arterial stiffness, including changes due to age, smoking, or radiation exposure [6].

viii. This device must have a low learning curve when being used by experienced or training microsurgeons, compared to suturing techniques.

ix. This device must be capable of withstanding arterial blood pressures beyond the typical 120/80 mmHg without structural deformation [7]. Extreme arterial blood pressures range from 160-200 mmHg as provided by our client.

x. This device should avoid placements that promote thrombosis, clotting, or inflammatory response. Intraluminal placement should be avoided, but secure fixation of the vessels is crucial.

1. In head and neck reconstruction, thrombosis occurred in 1.7% of patients with coupler devices, compared to 3.88% with sutured techniques [4].

xi. This device must exhibit corrosion resistance under physiological conditions.

xii. This device must withstand sterilization using ethylene oxide without degradation of material properties or loss of functionality.

b. *Safety*

i. All materials must comply with FDA recognized ISO 10993 standards for biocompatibility, as required for blood-contacting and implantable devices:

1. Materials must be non-toxic, non-inflammatory, and non-thrombogenic, with no leachable chemicals that could enter systemic circulation [8].

ii. The device must avoid sharp edges, burrs, or protrusions that could puncture gloves, damage arterial walls, or injure handlers.

iii. The device must withstand normal arterial pressures, approximately 120 mmHg, without fracture, collapse, or uncontrolled deformation [9].

iv. The device must be compatible with standard sterilization methods (ethylene oxide, gamma irradiation etc.) [10].

v. Validation of sterilization must follow FDA standards, including demonstrating effective sterilization for complex geometries or multi-layered components [10].

vi. Device packaging must ensure sterility until opened in the surgical field.

vii. Device labeling must include clear labeling for size range compatibility and single-use designation.

c. *Accuracy and Reliability*

i. Patency Rates

1. The device should achieve a minimum patency rate of greater than or equal to 95% immediately post-operation and maintain greater than or equal to 90% patency at 7 days in preclinical animal models. Longer-term patency (>30 days) should remain within clinically acceptable ranges greater than or equal to 85%. Patency is the primary indicator of microsurgical success, reflecting the ability of the anastomosis to maintain unobstructed blood flow. Immediate patency rates with traditional suturing and coupler devices consistently exceed 95%, while long-term rates drop modestly due to thrombosis or intimal hyperplasia. For example, a minimally assisted microsurgical technique achieved 95.1% patency (39/41 anastomoses) immediately post-operation [11]. Similarly, anastomotic coupler devices demonstrated 100% immediate patency with long-term patency rates around 88%. Meeting or exceeding these benchmarks ensures clinical viability [12].

ii. Operative Time Reduction

1. The anastomosis procedure should be completed in less than 20 minutes, representing a 3-6x reduction in operative time compared to hand-sewn sutures (30–60 minutes). Shortening operative time reduces ischemia duration, lowers the risk of flap loss, and improves overall surgical efficiency. Traditional microsuturing of 1 mm vessels can take 30–60 minutes, even for skilled surgeons. In contrast, device-assisted approaches in animal models have demonstrated safe completion in under 5 minutes while maintaining patency [13]. By targeting less than 20 minutes in clinical use, the device balances speed with ease of handling and reliability under realistic surgical conditions.

iii. Vessel Diameter Adaptability

1. The device must reliably function with vessels ranging from 2-3.5 mm in diameter, without causing lumen narrowing greater than 10% compared to the native vessel. Even moderate stenoses can create significant pressure gradients and flow reductions if extended in length, as shown in coronary models [14]. Since resistance to flow increases sharply with small decreases in radius,

maintaining lumen patency is essential in microsurgery where target vessels are only 2-3.5 mm.

iv. Leak Prevention and Structural Integrity

1. Beyond patency, leak prevention is critical to avoiding hematoma formation, which can jeopardize flap survival or limb salvage. Microsurgical studies emphasize the importance of watertight closure, with appropriate suture spacing or coupler alignment to prevent leakage. Experimental work using different suture calibers (8-0 to 11-0) in 1 mm vessels has shown that patency and leak prevention are achievable across a range of technical approaches [15]. A device that reliably seals vessels under physiologic pressures while maintaining lumen integrity directly addresses these clinical requirements.

v. User Consistency and Reliability

1. The device should demonstrate less than a 20% variability in operative time and patency outcomes across different users (beginner vs. experienced microsurgeons) and conditions (artery diameters, variable blood pressures). Current microsurgical success is highly dependent on surgeon expertise and learning curves. Experimental data show significant variability in patency rates across techniques and operators, ranging from 80% to 100% in supermicrosurgical models (0.5–0.8 mm vessels) [16]. By minimizing user-dependent variability, this device should be able to provide consistent performance, reduce training burden, and broaden accessibility of microsurgery to surgeons with less specialized experience.

d. *Life in Service*

i. The anastomotic device must maintain structural integrity and patency for at least 2 weeks post-implantation, supporting the vessel during the critical healing phase [17]. The first two weeks after anastomosis are significant for vessel healing, as new tissue forms and the vessel gradually gains strength. Providing mechanical support during this period reduces the risk of leakage or clot formation, ensuring the vessel can handle normal blood flow once it has regained sufficient structural integrity. Maintaining device support through this early healing phase is essential for patient safety and long-term vessel function.

e. *Shelf Life*

i. The device will be free of any batteries, materials, or solutions that will have a set expiration date. Shelf life will therefore be determined by the sterility of the single-use device and package integrity.

ii. About 50% of medical devices are sterilized with ethylene oxide due to its efficiency in sterilizing a variety of polymers, metals, or ceramics that are muti-layered or have difficult geometries [10]. This will be the main form of sterilization considered for the device's shelf life duration.

iii. Sterility of medical devices exposed to ethylene oxide is at most 5 years [18]. This number is limited by packaging integrity, device material, handling and transportation, and environmental conditions. A minimum shelf life of 3 years will be achieved by considering the following:

1. Storing device in a cool and dry environment to prolong sterility. Condensation within packaging due to high humidity can impact sterility of the device.
    a. Maximum relative humidity of 60% [19].
    b. Temperatures range from 72 to 78 oC [19].
    c. Positive air pressure relationship to adjacent areas [19].
2. Using a sealable and durable package to prevent tears that will eliminate sterile barriers.
3. Devices made from hard plastics and metals are less reactive to moisture and temperature maintaining sterility for longer periods of time. Use of softer more porous materials can reduce shelf life sterility.

f. *Operating Environment*

i. In vivo the device will be exposed and must maintain integrity at the following environmental conditions:

1. Human body temperature is within the range of 36.5-37.5 oC. Irreparable damage to organs can occur when body temperatures are outside of 32.2-41.1 oC [20].
2. Maximum arterial flow pressures can span from 80-120 mmHg for a healthy adult [7]:
    a. Largest arterial pressures during systole is ~120 mmHg due to contraction of the heart that drives blood into arteries.
    b. Largest arterial pressure during diastole is ~80 mmHg due to arterial recoil as the heart fills with blood.
3. Full humidity exposure since the device is continually exposed to blood and interstitial fluid. The device must therefore be resistant to corrosion.

4. Arterial diameters can vary with cardiac output such that any device must accommodate this fluctuation and not be too rigid.

ii. During surgical handling in the operating room, the device may be subject to:

1. Sterilization through ethylene oxide which maintains atmospheric pressure of 101 kPa [21].
2. Operating room temperatures average 20 oC to 24 oC and relative humidity exposure of 40% to 60% [22].
3. Device must be easy to handle across all users wearing surgical gloves and removing device from sterile packaging.

g. *Ergonomic*

i. This device should be designed for comfortable, precise operation by microsurgeons while minimizing hand and wrist fatigue during use. Handles, grips, or controls should accommodate a range of hand sizes and enable natural finger and wrist positions. The device should be balanced and stable, supporting fine motor control and repeatable actions for microsurgical coupling. Materials and textures should enhance grip without causing uncomfortability over extended procedures.

h. *Size*

i. The diameters of designs must range from 2 mm to 5 mm with the initial prototype having a diameter of 3 mm, as specified by the client.

ii. Device diameter must expand approximately 0.3 mm once it is implanted and must remain fixed at the expanded diameter without recoil, collapse, or further expansion, as requested by the client.

i. *Weight*

i. The device should have a mass of approximately 0.5 grams per unit (maximum 1 gram) to minimize risk of vessel tension or displacement. This value is based on preliminary design comparisons and will be validated with bench tests [23].

ii. The device should be comfortably supported by standard microsurgical forceps.

j. *Materials*

i. The device should be manufactured utilizing biocompatible materials approved for surgical use, with properties similar to those found in vascular stents. Suitable materials include 316 L stainless steel or Nitinol [24].

1. The design may incorporate a balloon expansion mechanism for adjustable sizing, composed of materials such as nylon or polyethylene terephthalate [25].

ii. The material will be flexible and durable to accommodate variable vessel sizes while maintaining its structure to prevent constriction or collapsation under varying physiological pressures.

iii. The selected material will not contact the arterial lumen, as intraluminal components increase the risk of thrombosis and immune response.

iv. Reabsorbable or dissolvable materials may be considered for future iterations, but are not required for the initial prototype:

1. Drug eluting stents (DES) and resorbable biodegradable stents (RBS) are currently utilized throughout clinical trials. Rapamycin and Paclitaxel are embedded in a polymer matrix coated onto stent wires and released from DES to inhibit the proliferation of smooth muscle cells and reduce restenosis [26].

k. *Aesthetics, Appearance, and Finish*

i. The device should have a professional, modern appearance that conveys quality and precision appropriate for a surgical environment.

ii. Finishes should be smooth, easily sanitizable, and resistant to staining and corrosion.

iii. Components should also be visually consistent with colors and materials that support intuitive use.

2. Production Characteristics

a. Quantity

i. This device is intended to be a single use unit per procedure in order to maintain sterility and consistent performance.

ii. A single prototype will be fabricated by the end of the first month to demonstrate feasibility. Four prototypes covering the 2-5 mm arterial range will be manufactured by the end of the semester.

b. *Target Product Cost*

i. Product cost and manufacturing will not exceed the $1,000 budget allotted by the client.

ii. Current venous couplers on the market span from $250 - $400 per single-use device [27].

3. Miscellaneous

a. *Standards and Specifications*

i. Current Microvascular Anastomotic Coupler Devices on the market are classified as Class II medical devices:

1. The regulatory controls for Class II devices include general controls, special controls, and premarket notification 510(k). If the proposed composition of the biomaterial is substantially equivalent to a predicate device that is active on the market it can gain approval. If not, clinical trials are required for premarket approval [28].

ii. The International Organization for Standardization (ISO) has a couple of standards that apply to the development of an arterial anastomosis device:

1. ISO10993 guarantees biological compatibility of a medical device- ensuring nontoxic, nonthrombogenic, noncarcinogenic, and nonmutagenic effects on the biological system [29].
2. ISO13485 requires that medical devices are monitored by quality management systems. Objective of the standard ensures production of a medical device and related services that meet customer requirements consistently [30].
3. ISO14971 applies risk management monitoring to the design, manufacturing, and life cycle of a medical device [31].
4. ISO11135 monitors the sterility and packaging requirements for the device being exposed to ethylene oxide sterilization [32].

b. *Customer*

i. Dr. Jasmine Craig, MD, PhD, is a plastic surgery resident in the Department of Surgery at the University of Wisconsin-Madison School of Medicine and Public Health. Dr. Craig's clinical insights ensure the device aligns with surgical workflows and addresses real-world challenges in vascular reconstruction [33].

ii. Dr. Weifeng Zeng, MD, is an assistant scientist and microsurgical instructor at the University of Wisconsin-Madison. Dr. Zeng contributes his expertise in microsurgical education and simulation to the project, providing valuable feedback on the device's usability and potential integration into training curriculum [34].

c. *Patient Related Concerns*

i. The device must minimize the risk of blood clot formation and platelet adhesion at the vessel interface during use. Blood is the first tissue to interact with an implanted device, and protein layers that form on the device surface can trigger platelet adhesion and clot formation. Device surfaces with appropriate chemical and physical properties such as hydrophilicity, neutral charge, and specific functional groups can reduce these interactions and lower the risk of thrombosis. This is critical for patient safety and

long-term device performance, ensuring that the device can remain in place without causing adverse blood reactions [35].

d. *Competition*

i. The GEM Microvascular Anastomotic Coupler, produced by Synovis Micro Companies Alliance (Baxter), is the most widely used commercial coupler system in microsurgery [36]. The device uses two interlocking polyethylene rings with pins that evert and appose vessel ends. Clinical studies report high venous patency rates and reduced operative time compared to hand-sewn sutures [37]. However, the device is limited to low-pressure venous systems and is not suitable for arteries due to their thicker, more elastic walls and higher intraluminal pressures, which increase the risk of thrombosis and device failure [38]. In small arteries, practical limitations include ring bulk in tight fields and limited adaptability across small diameter ranges.

ii. Magnetic Compression Anastomosis (MCA) devices use paired rare-earth magnets to approximate tissue via controlled compression [39]. The UCSF Magnamosis platform demonstrates bowel anastomoses with magnet-mediated tissue fusion, and in 2024 the MagDI system received FDA De Novo classification for gastrointestinal (GI) duodeno-ileal anastomosis [40], [41]. Current MCA device sizes are fit for GI lumens but not scalable to 2-5 mm arteries. Other concerns with these devices include potential for misalignment and anastomotic stricture/stenosis [42].

iii. External Cuff techniques evert a vessel end over a short tube/collar and insert it into the opposing end, eliminating sutures and standardizing apposition [43]. Polyethylene cuffs show feasibility in sub-millimeter animal vessels and outline practical construction and handling [44]. Intraluminal approaches, including nickel-titanium (NiTi) shape-memory micro-stents, provide radial support from within and can shorten anastomosis time in preclinical models [45], [46]. The US 575,5772A patent describes a radially expansive vascular prosthesis using a heat-memory alloy ring, while US 9,642,623 B2 outlines an external coupler system designed to secure vessel ends without intraluminal components [47], [48]. However, systematic reviews document recurring drawbacks including reduced compliance at the junction, risks of stenosis or leakage, and potential endothelial injury and hemodynamic disturbance at the interface [49], [50].

iv. A dissolvable sugar-based stent has been proposed as an intra-operative scaffold to hold vessel ends during suturing and then dissolve within 4-8 minutes once flow is restored [51]. This approach addresses handling and speed but is not implantable and lacks arterial in-vivo durability data. Patents such as US 10,285,702B2 and US 20,110,106,118A1

describe absorbable or degradable coupler devices/scaffolds for vascular and microvascular anastomosis [52], [53]. These filings similarly emphasize temporary mechanical support with programmed degradation. However, concerns of degradation rate, mechanical strength during load, and the safety of by-products remains [54].

v. Recent intellectual property (IP) and preclinical work focuses on external/self-expanding couplers, shape-memory alloy (NiTi) rings, and bioresorbable scaffolds for sutureless vascular connections. Most remain pre-clinical, with key open questions on diameter control and compliance matching in smaller diameter arteries and degradation rate/by-product safety over the healing window.

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Appendix II - Material Costs and Analysis

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Nitinol Frame	Nitinol Bare Frame	Lumenous	FRNT0001	Chamfr	LUM84209	10/8/25	1	$275.00	$275.00	Link
High-Density Thread Sealant Tape	PTFE, 0.0032" Thick, 1/4" Wide, 14 Yard Long, White	McMaster-Carr	6802K22	McMaster-Carr	N/A	10/8/25	1	$3.66	$3.66	Link
									$0.00	
									$0.00	
								TOTAL:	**$278.66**	

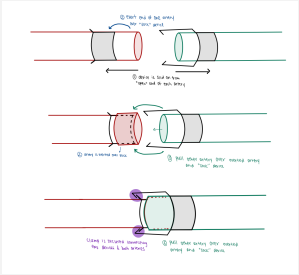
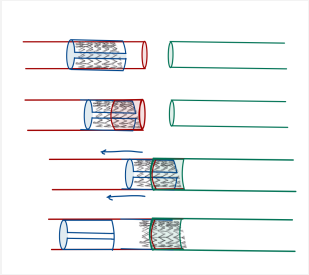
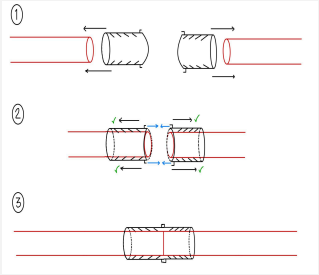
Appendix III - Design Matrix

Date: September 26, 2025

Advisor: Professor Suarez-Gonzalez
Client: Dr. Jasmine Craig
Lab Section: 308
Team Members:

- Allison (Ally) Rausch (Team Leader)
- Sofia Decicco (BWIG)
- Daniel Pies (BSAC)
- Arshiya (Ria) Chugh (BPAG)
- Jacqueline (Jackie) Behring (Communicator)

Design Matrix:

		Design 1: Sock Clamp		**Design 2: Expandable Stent**		**Design 3: SpikeStent**	
							
Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Efficiency	25	3	15	4	20	2	10

Adjustability	20	1	4	4	16	1	4
Intima Contact	15	5	15	5	15	2	6
Durability	15	4	12	3	9	3	9
Safety	10	4	8	4	8	2	4
Manufacturability	10	4	8	3	6	3	6
Cost	5	4	4	3	3	4	4
Total (Out of 100):		66		77		43	

Criteria Descriptions:

Efficiency: Efficiency will be evaluated based on the total time required to implant the device, starting the moment the artery is clamped off and ending when blood flow is successfully reestablished. Because prolonged ischemia can lead to tissue damage, minimizing implantation time is the most critical factor in the success of this device. Per client requirements, the implantation time should be at most 20 seconds.

Adjustability: Adjustability refers to the device's ability to fit securely across a range of arterial diameters. As specified by the client, the preferred design should be pre-set to an intended diameter but capable of expanding dynamically in response to arterial flow and pressure. This feature ensures compatibility with patient-specific anatomies and allows the device to adapt to physiological changes, ultimately reducing the risk of leakage and clotting.

Intima Contact: The degree of intima-to-intima contact between the joined arteries will be a major factor in ranking device performance. Strong and uniform contact is essential for promoting endothelial healing and reducing the risk of thrombosis. Sustained arterial contact is directly tied to long-term patency and patient rehabilitation.

Durability: Durability will be evaluated based on the device's ability to withstand the body's environmental conditions and maintain structural integrity during the operation, preserving required physical properties over its intended lifetime. This includes resistance to fatigue, corrosion, and degradation.

Safety: Safety will be ranked on how likely an injury is to occur during implantation and how likely the device is to harm the patient while implanted. This includes risks such as vessel tearing, clot formation, inflammation, or immune response. The safest designs will minimize sharp edges, toxic materials, or complex deployment mechanisms that increase the chance of adverse outcomes.

Manufacturability: Manufacturability measures how easily and cost-effectively the device can be produced using available materials, processes, and technologies. This includes fabrication complexity, reproducibility, and tolerances, and quality control.

Cost: The device must be produced within the project's budget of $1,000, with careful consideration of material use. The design must stay within budget without compromising functionality and performance.

Design 1:

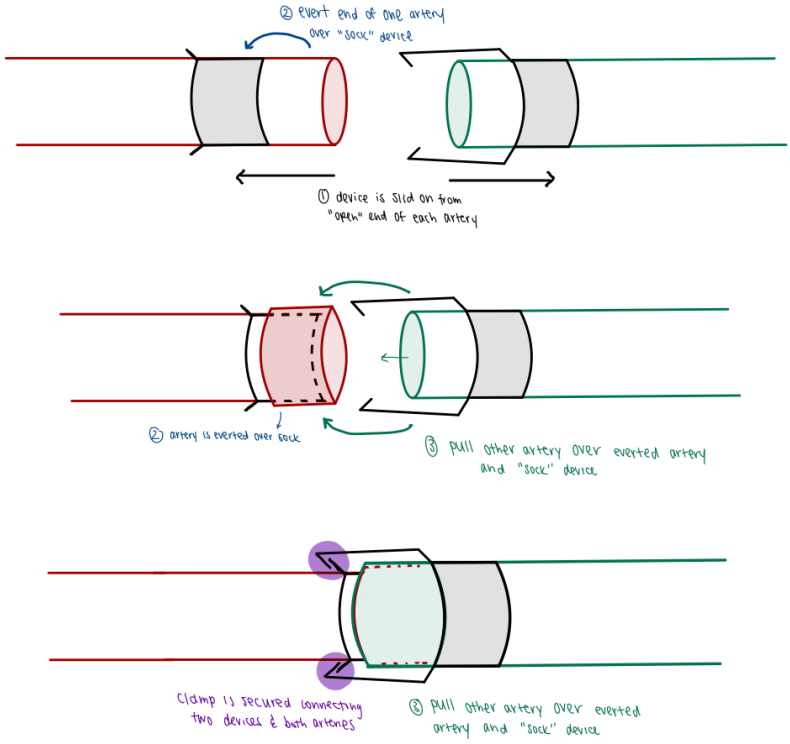


Figure 1: Sock clamp mechanism for sutureless arterial anastomosis.

Design Description: The sock clamp design facilitates arterial anastomosis by using a support sleeve to simplify vessel inversion and alignment. The device is positioned by sliding it onto the open ends of both arteries. One artery is then everted over the sock, exposing its endothelial surface. The opposing artery is pulled over the everted vessel and device, creating direct intima to intima contact between the two arterial ends. Finally, a clamp is secured over the overlap locking the arteries and device to complete the procedures. This approach eliminates the need for sutures, reduces implantation time, and promotes stable vessel contact for improved healing.

Efficiency: This design scored a ⅗ for effectiveness as is it easy to insert the end of the arteries into the two couplers. Once the arteries are everted, the device can simply be clamped together, removing the need for sutures, which are the most time-consuming factor in anastomosis. A significant limitation for the design is the fact that the design requires everting the artery over a fully expanded diameter (~3 mm). Everting the artery over a fully expanded device and then layering the opposing artery over will take more time. Additionally, the clamping mechanism may pose difficulties if there is a variability in the thickness of the artery which may hinder an easy attachment.

Adjustability: This device scored a ⅕ for adjustability, as the rigid design that cannot be compressed easily to make everting the artery of the device easier. The rigid device will only perform at the diameter it was originally designed at.

Intima Contact: This design scored a 5⁄5 for intima contact since it involves everting one end fully and pulling the other artery over this everted position. This maximized intima to intima contact since all of the arterial contact is occurring between the inner lining of each artery. As well, the device avoids direct contact with the intima which can lead to clotting.

Durability: The device scored a ⅘ in durability since the bulk of the device is made from a single compact body. Potential issues may stem from the durability of the clamping mechanism, with the risk of fracturing in use.

Safety: This device ranked a ⅘ for safety since the clamping mechanism provides an added layer of security attaching the two devices together. When blood pressure achieves reading beyond 120 mmHg the device will still be able to withstand these extraneous pressures.

Manufacturability: This device scored a ⅘ in manufacturability since it is overall a uniform body that can be printed in one go. There is the risk of the clamps making manufacturing of the device more difficult due to their extended configuration.

Cost: This device scored a ⅘ for cost since it can be machined or 3D printed with biocompatible materials at a low cost. There may be an increase in price due to the complexity of some design components.

Design 2:

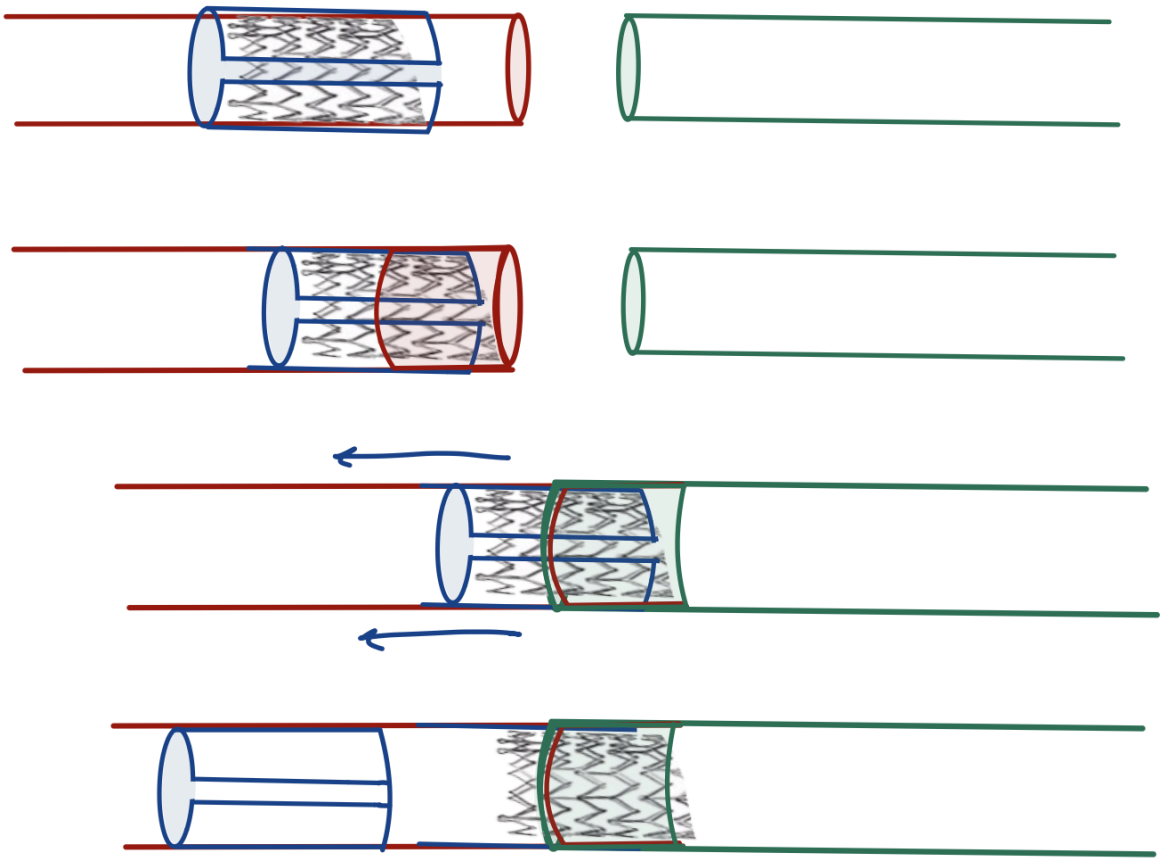


Figure 2: Expandable stent mechanism for sutureless arterial anastomosis.

Design Description: The design connects two arteries using a self expanding stent housed within a delivery device. The stent is first positioned within the lumen of one artery, after which the opposing artery is advanced over the exposed stent. As the stent is eventually deployed, it expands outward to secure both arterial ends against the mesh framework, creating consistent intima to intima contact. Once fully released, the stent maintains vessel alignment and patency without the need for sutures while the delivery device is withdrawn.

Efficiency: This device scored a ⅘ for efficiency since it only involves two components that will intact directly with one artery end as opposed to two. Only needing to attach a device to one end of the artery will decrease the amount of time of the procedure, and the expanding stent will further allow for the loading device to be removed quickly and easily.

Adjustability: This device scored a ⅘ for adjustability since the nitinol stent allows for easy deformation of the material. Initially the device will be loaded into a loader tube that will restrict the diameter of the stent to ~2.5 mm. Expecting the artery in the application is 3 mm, this will allow for easier eversion of the artery over the stent and attachment of the opposing artery over the other end. Once the loader tube is

removed, the nitinol stent will expand to the diameter it was originally manufactured at and hold the artery open.

Intima Contact: This device scored a 5⁄5 for intima contact since it involves fully everting the proximal end and pulling the distal artery over the everted end. This maximizes intima to intima contact, as all of the arterial contact is occurring between the inner lining of each artery. Additionally, the device avoids direct contact with the intima, which can lead to clotting and biocompatibility issues.

Durability: This device scored a ⅗ for durability since the nitinol stent can be easily compressed. While this is a contributing factor to its adjustability, it will have to be machined in a configuration that still maintains mechanical strength in its fully expanded state and does not allow for easy deformation unless held by the loading device.

Safety: This device scored a ⅘ for safety since nitinol is a highly reputable and FDA approved material. The titanium oxide barrier that forms at the top layer of the material prevents nickel ion leaching.

Manufacturability: This device scored a ⅗ for manufacturability since the assembly, laser cutting, and electropolishing process for nitinol stents is more time demanding than the other design options.

Cost: This device scored a ⅗ due to the higher cost of nitinol . The nitinol material itself is not costly but the manufacturing process contributes to increased prices of the fully developed product.

Design 3:

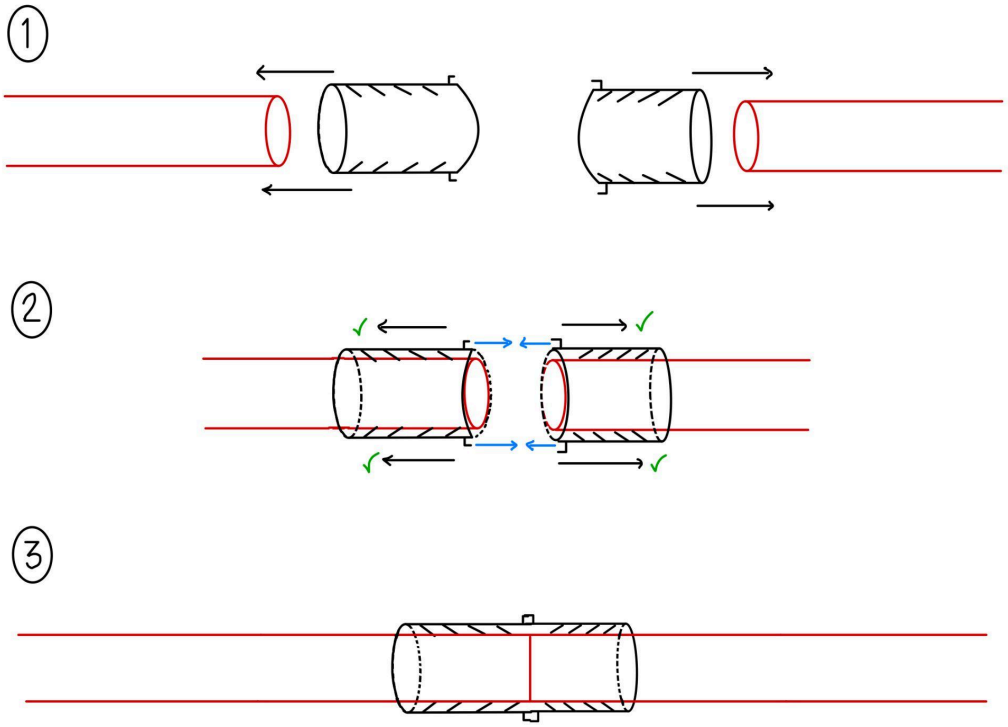


Figure 3: SpikeStent mechanism for sutureless arterial anastomosis.

Design Description: The SpikeStent design secures two arteries using a cylindrical stent with outward facing spikes that anchor the vessel walls. First, each arterial end is advanced over the side of the SpikeStent. The vessels are then approximated at the center where the spikes interlock with the arterial walls to establish stable intima to intima contact. Once both arteries are fully engaged, the device holds them in alignment, maintaining patency without the need for sutures. This approach leverages mechanical fixation to ensure consistent contact and reduce the risk of slippage at the anastomotic site.

Efficiency: This design scored a ⅖ for efficiency since the design poses difficulties when inserting the artery into the stent like structure. Since the artery will not have any outward pressure from fluid flow, pulling the rigid device over the limp vessel will pose a difficulty. The clamps may need to be secured with sutures as well which will add to the overall implantation time and further reduce efficiency.

Adjustability: This design scored a ⅕ for adjustability since it does not allow for any expandable diameter. The device remains rigid and the prongs lining the inner diameter will pose a safety threat of puncturing the arterial wall if the device is compressed.

Intima Contact: This device scored a ⅖, the lowest of the three designs, for intima contact. This design does not require the eversion of one artery end, which may increase efficiency, but allows for very minimal intima contact. With a simple end-to-end connection, overlapping surface area is minimized to just the cross-section of the vessel.

Durability: This device scored a ⅗ for durability due to the clamp mechanism and the prongs lining the interior of the design. Since the prongs will be thin in nature they are more at risk of breaking during manufacturing or application.

Safety: This device scored a ⅖ for safety since the prongs pose a threat of puncturing the arterial wall. This can impact hemodynamic and overall functionality of the artery. If the puncture were to also make contact with the intima it can promote clotting and thrombosis, posing very large safety risks.

Manufacturability: The device scored a ⅗ for manufacturability due to the complex nature of printing the inner diameter of the stent. Given the very small nature of the design it will also be difficult to file down the edges on the prongs to ensure they are not sharp enough to puncture the artery. This device would need to be machined with tight tolerances, further increasing the difficulty of manufacturing.

Cost: The device scored a ⅘ since it can be machined or 3D printed with biocompatible materials at a low cost. There may be an increase in price due to the complexity of some design components.