Arterial Coupler Re-Design: Adjustable Stent/cuff Anastomosis

Final 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 the importance of arterial anastomosis, manual microsuturing is the only method currently used. Manual microsuturing is 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 approximately an 8% risk of thrombosis, leakage, or anastomotic failure, depending on vessel size and other patient factors [2]. These challenges contribute to prolonged ischemia times which, when exceeding 60 minutes, doubles the likelihood of complications occurring [3]. Arterial anastomosis is performed very often as it is a vital part of many procedures, including coronary artery bypass surgery which is performed 400,000 times in a year alone [4]. At a global level, an estimated 5 billion people lack access to safe, affordable surgical care, and in sub-saharan Africa there is roughly one reconstructive surgeon per 10 million people, meaning that patients in low-resource or emergency settings often have no access to microsurgical expertise at all [5]. 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 [6], [7].

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 [8].

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 and Current Methods

The current method for performing arterial anastomosis relies 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 [9]. 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 [10]. 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 [11]. 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 [6].

Figure 1: GEM Venous Coupler [12].

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 [13]. Although they have shown promise in gastrointestinal applications, studies report risks of stenosis, poor alignment, and pressure-induced damage when adapted for vascular use [13],

[14]. 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 [8], [15].

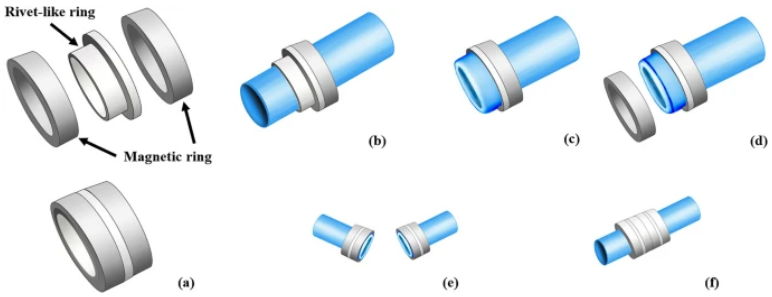


Figure 2: Working mechanism magnetic compression anastomosis [16].

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 [17]. 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 [8].

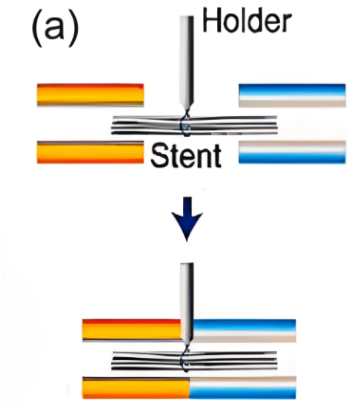


Figure 3: Intraluminal stent mechanism [8].

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 [8]. 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 [18]. These challenges are magnified in emergency and resource-limited settings, where microsurgical expertise is often unavailable [19].

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 [20]. 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 [21], [22].

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

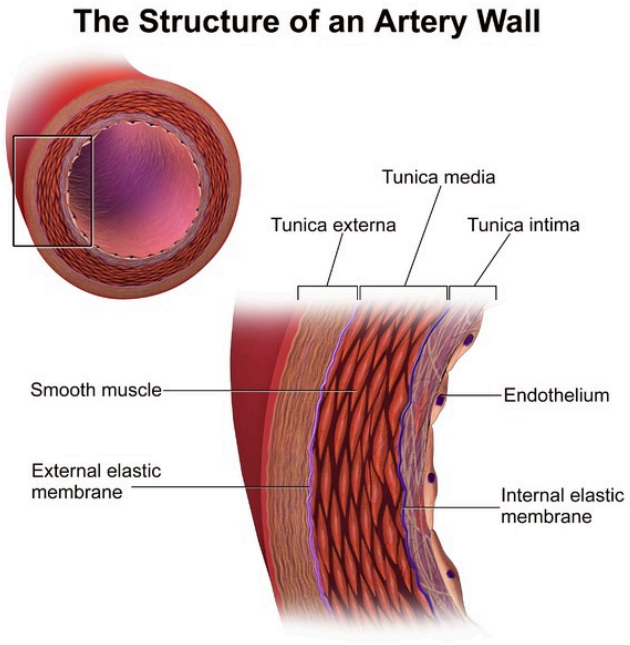


Figure 4: Depicted arterial wall anatomy [23].

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 tunica intima, tunica media, and tunica externa, also referred to as the adventitia, moving from the inner lining to the outer respectively [19]. It is important that intima contact between the two free arterial ends that are being joined is prominent since this mechanism prompts endothelial healing [24]. 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 [25]. The typical artery in this form of microsurgery spans from 0.5-3mm in diameter.

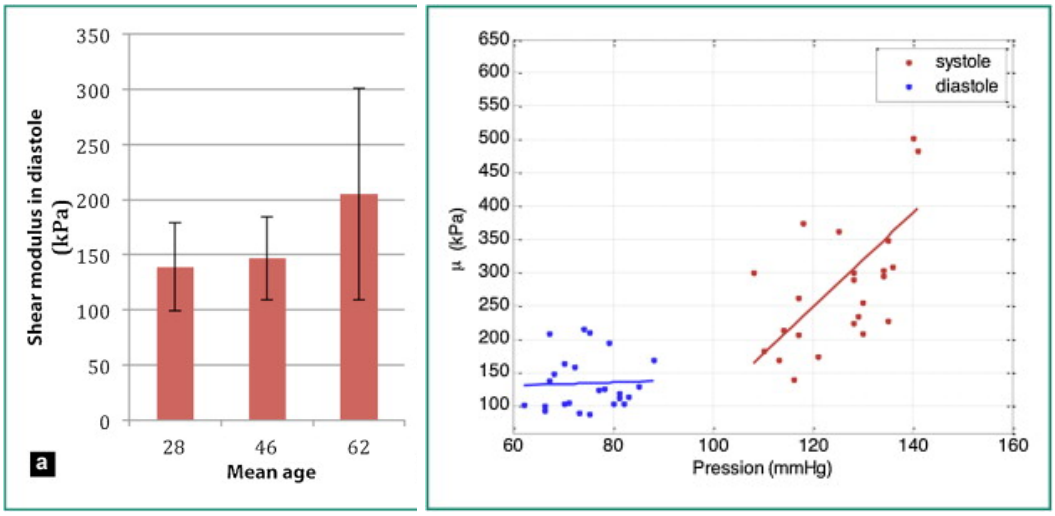


Figure 5: Arterial pressure during diastole and systole [26].

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 5 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 [23]. 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

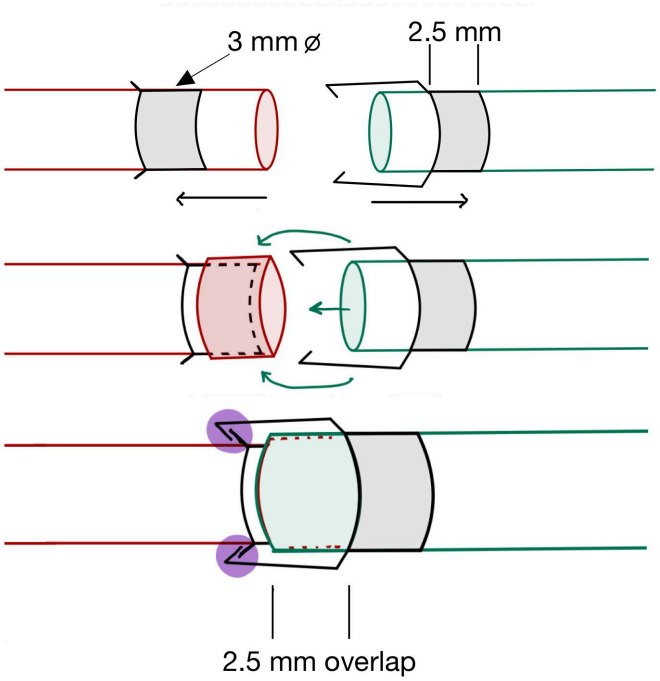


Figure 6: Proposed sock clamp design.

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

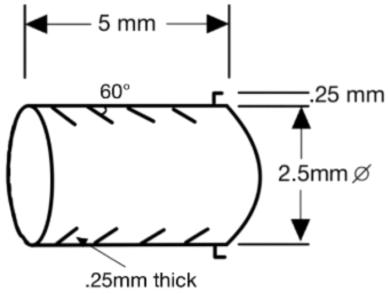


Figure 7: Close-up of directionally spiked cuff.

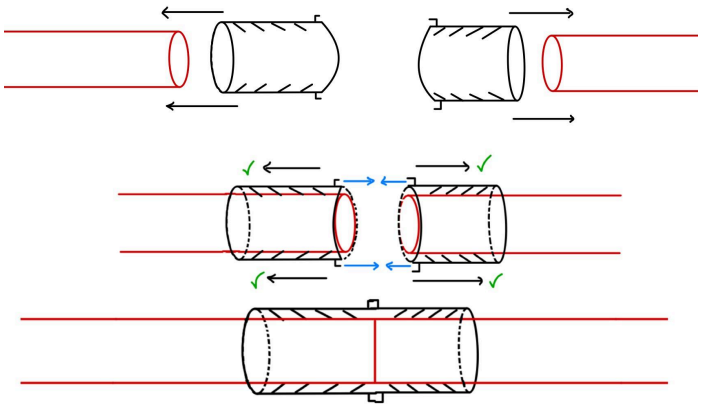


Figure 8: Proposed spike stent design.

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

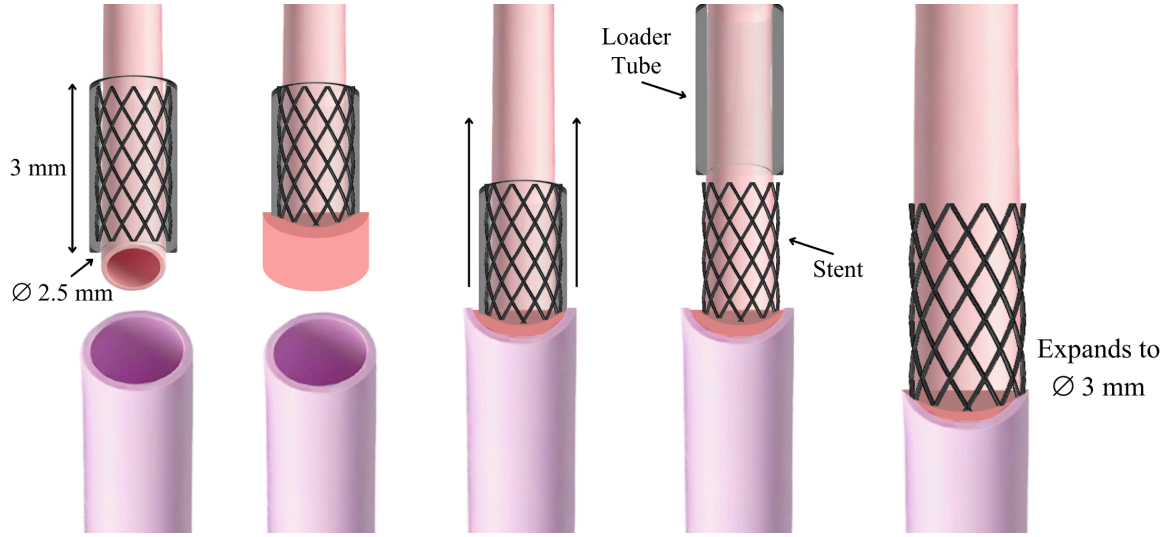


Figure 9: Expandable Nitinol stent application.

The Expandable Stent design is a two aspect 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 [27]. 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. Polytetrafluoroethylene (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 [28]. The stent, machined to 3 mm, will be inserted into the loading tube, which will compress the stent diameter to 2.5 mm, then 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 lavender) 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 3 mm 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

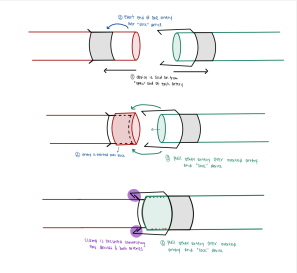
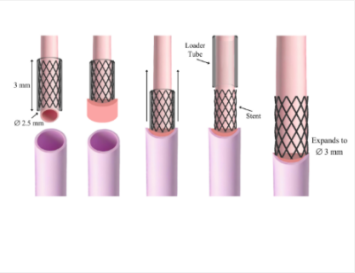
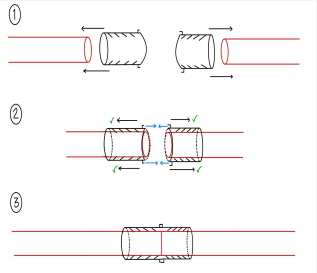
		Design 1: Sock Clamp		**Design 2: Expandable Stent**		**Design 3: SpikeStent**	
							
Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Efficiency	25	3	15	4	20	2	10
Adjustability	20	1	4	4	16	1	4
Intima Contact	15	5	15	5	15	2	6
Durability	15	4	12	3	9	3	9
Safety	10	4	8	4	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

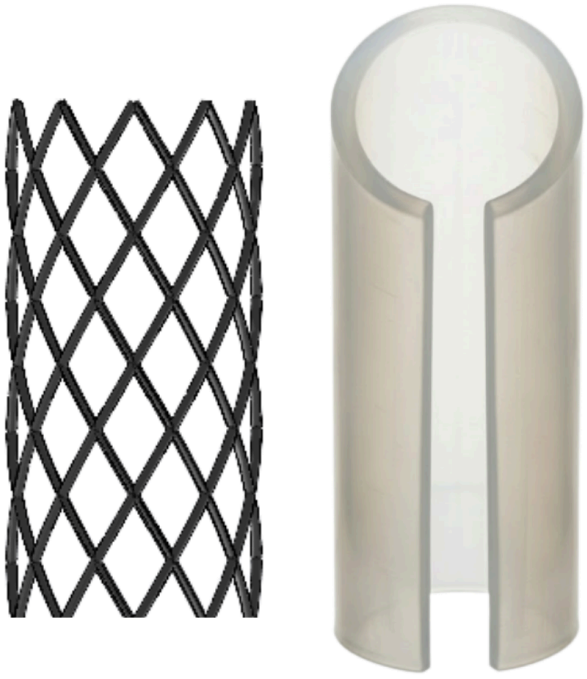


Figure 10: Example Nitinol stent model and accompanying loader tube.

The proposed final design is a nitinol stent that will be inserted into a 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 Nitinol, a biocompatible and corrosion resistant material approved for surgical use. Nitinol was chosen because it provides radial expansion, fatigue resistance, and stable mechanical performance. It is a nickel-titanium shape memory alloy that exhibits superelastic properties that allow it to adjust across multiple vessel diameters [29]. Its ability to expand and contract accommodates arteries across 2-5 mm in diameter while maintaining patency and resisting lumen collapse from pressures up to 200 mmHg. It satisfies the clinical and mechanical requirements of arterial anastomosis by demonstrating hemocompatibility and a safe lifelong implementation, which align with FDA Class II and ISO 10993 standards for blood contacting devices [29], [30].

The loader tube will be fabricated from PTFE due to its low friction coefficient, chemical stability, and biocompatibility in vascular applications [30]. PTFE provides a smooth surface that reduces abrasion during loading and enough rigidity to compress the stent during deployment without damaging the artery.

Nitinol and PTFE satisfy all clinical, mechanical, and regulatory requirements for the final design. Both materials are compatible with ethylene oxide sterilization required by the sterility specifications of the device [31], [32]. These materials support a safe implementation process and a reliable lifelong performance. A detailed list of materials, quantities, and cost estimates will be provided in Appendix II.

Methods

The initial device was modeled and refined in SolidWorks to define stent geometry, optimize vessel fit, and ensure ergonomic access for microsurgeons during anastomosis. CAD modeling allowed evaluation of wall thickness, barbed features, and expansion behavior across the 2-5 mm arterial diameter range before creating physical prototypes.

A scaled up prototype was manufactured using stereolithography (SLA) 3D printing at the UW Makerspace to evaluate the dimensional accuracy, visual alignment, and usability. Resin was selected as the stent material, although it was not mechanically representative, the larger prototype provided a visualization of vessel and loader tube positioning.

A single prototype was fabricated from 316L stainless steel tubing for feasibility testing. A 30.48 cm tube with an inner diameter of 2.31 mm and an outer diameter of 2.54 mm was procured, and the bandsaw in the Design Innovation Lab was used to cut one 3mm segment for testing. The stainless steel edges were sanded down and inspected to reduce sharpness, ensure safe handling, and minimize arterial abrasion during insertion and eversion trials.

Final Prototype

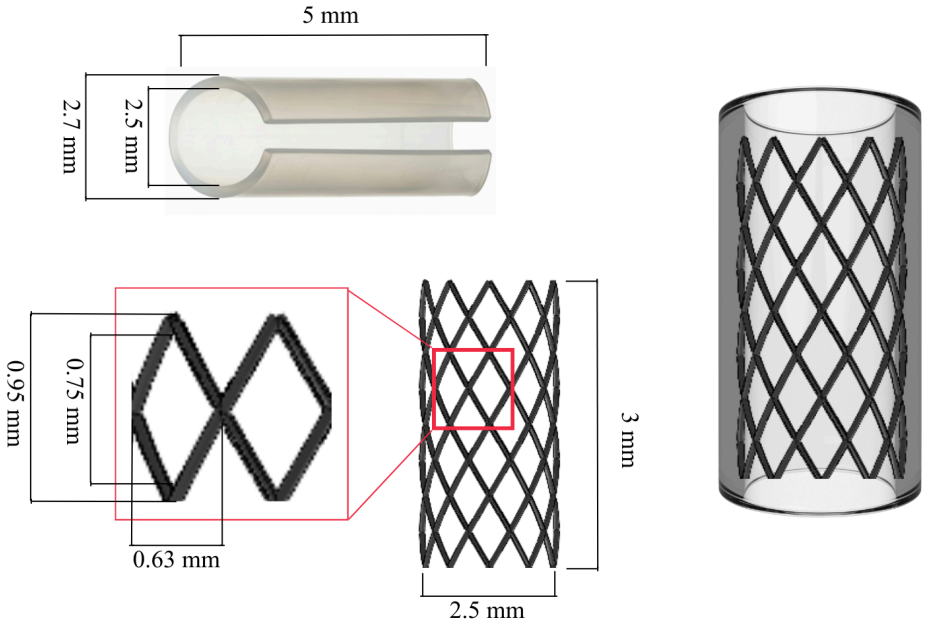


Figure 11: Final prototype with specified dimensions.

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 was feasibility during implantation, leakage resistance, and mechanical fatigue behavior of the device. A secondary focus was placed on SolidWorks fluid-flow modeling to evaluate hoop stresses and confirm that they remained within typical physiological ranges at normal pressures. Additionally, wall shear stress was evaluated under the same conditions to identify regions of elevated shear that could correspond to areas at higher risk for restenosis or flow disturbances.

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.

Feasibility Testing

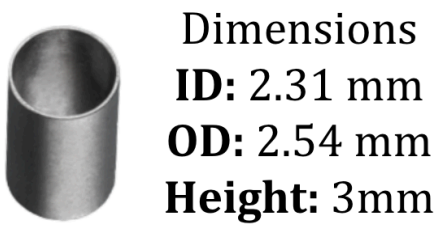


Figure 12: Rigid tubing dimensions used in feasibility testing.

Feasibility testing was performed in the client's laboratory using an early prototype fabricated from 316L stainless steel tubing as seen in Figure 12. This material is resistant to corrosion and

deformation under physiological conditions and pressures up to 200 mmHg [26]. Although Nitinol is the final material for the implant, stainless steel allowed for rapid machining and safe handling during testing. This prototype allowed functional evaluation of the device, including artery insertion, eversion performance, and flow behavior, before manufacturing the full Nitinol implant. The stainless steel model was used to confirm geometry, identify sharp edges, and validate the deployment sequence. Feasibility testing was conducted using the stainless steel prototype discussed in the Methods section.

Operation	Acceptance Criteria
Feed artery through rigid tubing	Artery end passes without snagging, tearing, or visible intimal abrasion.
Evert first artery end over tubing	Artery can be everted without tearing or overstretching. No spontaneous rolling back.
Pull opposing artery end over	The second artery can be pulled over the device with ease. The second artery does not roll back once secured on the device.
Add fluid flow through device	No leakage at implant site with added flow. Flow remains laminar or minimally disturbed.

Table 2: Summary of feasibility testing steps and acceptance criteria.

The steps and acceptance criteria measured through the feasibility testing are summarized above in Table 2. The acceptance criteria was defined based on the design specifications for the final device. Ultimately this testing will confirm the stent concept compatibility with 2–5 mm arteries, smooth and safe manipulation, rapid procedural workflow, long-term patency, and the ability to withstand physiologic pressures up to 200 mmHg. The images presented below in Figures 13-16 were taken during implantation practice with the client on chicken arteries. The chicken arteries are very relevant to human arteries, and are used as vivo models for studying vascular biology [36]. The annotated images are attached to aid in the visual understanding of each image. Solid red lines indicate the tubing that is not covered by an artery. The dotted red line identifies the tubing that is behind or covered by an artery. The blue lines indicate the position of the artery relative to the rigid tubing. Lastly, black arrows represent the direction of fluid flow in our final step of testing.

Original Image *Annotated Image*

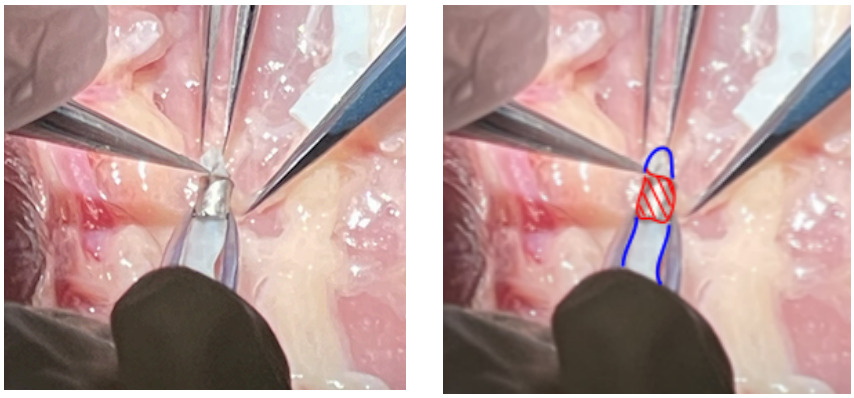


Figure 13: Image of artery being pulled through rigid tubing.

The first step in the feasibility testing involved feeding the artery through the rigid tubing at the fixed diameter. This step was intended to ensure that the artery would be able to fit through the compressed state of the nitinol stent. The first acceptance criteria was defined by the artery being able to pass though without any snagging, tearing, or visible intimal abrasion. In this step, we passed as the artery could safely fit through the 2.3mm inner diameter of the rigid tubing.

Original Image *Annotated Image*

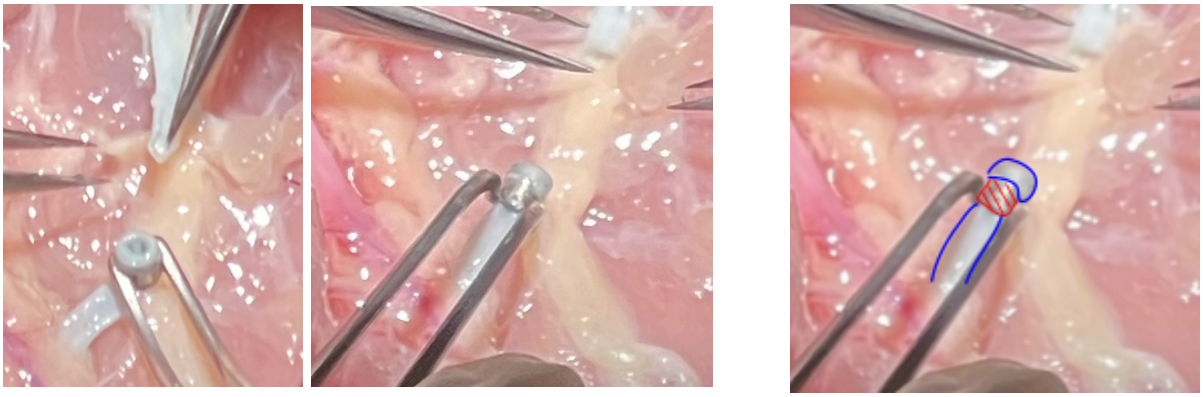


Figure 14: Image of first artery eversion.

The second step was to fully evert the artery over the rigid tubing. A partial failure was observed in this step since the surgeon was able to evert the artery, but only with difficulty. Minor overstretching of the artery end was observed. The outer diameter was too large, requiring more contact with the intima/inner lining of the vessel that is not desired for actual application. The increased intima contact required to evert the artery may contribute to increased thrombogenic risk. The rough cut of the metal

tubing also resulted in more substantial abrasions and damage to the other outer lining of the artery making contact with the tubing. A full failure resulted from the inability of the everted artery to stay in place. There was continuous rolling back unless the artery was held manually. These findings informed two major design revisions: reducing wall thickness to improve evertability and adding a mechanism or texture to better secure the artery. Both changes support the design specification goals of lowering surgeon learning curve and enabling completion in under 20 minutes.

Original Image *Annotated Image*

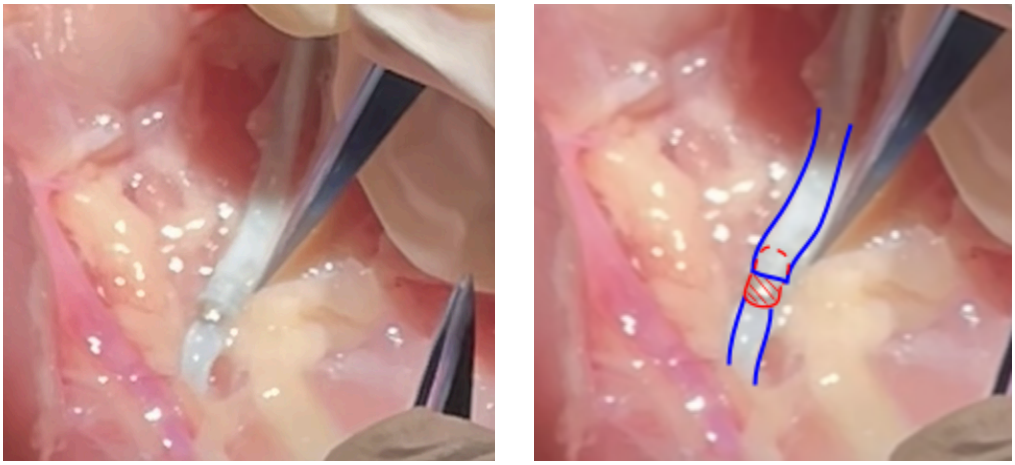


Figure 15: Images of opposing artery pulling over everted artery.

Third, we pulled the opposing artery end over the expanded tubing. Similar issues arose with minor, overstretching and rolling back. More extensive over stretching was observed in this operation now that the outer diameter of the device was increased by the everted artery thickness. The degree of rolling back was reduced now that the artery would make contact with the opposing artery end as opposed to the slippery stainless steel material. Observation from this step further reinforced the need for features that provide better traction during assembly.

Original Image *Annotated Image*

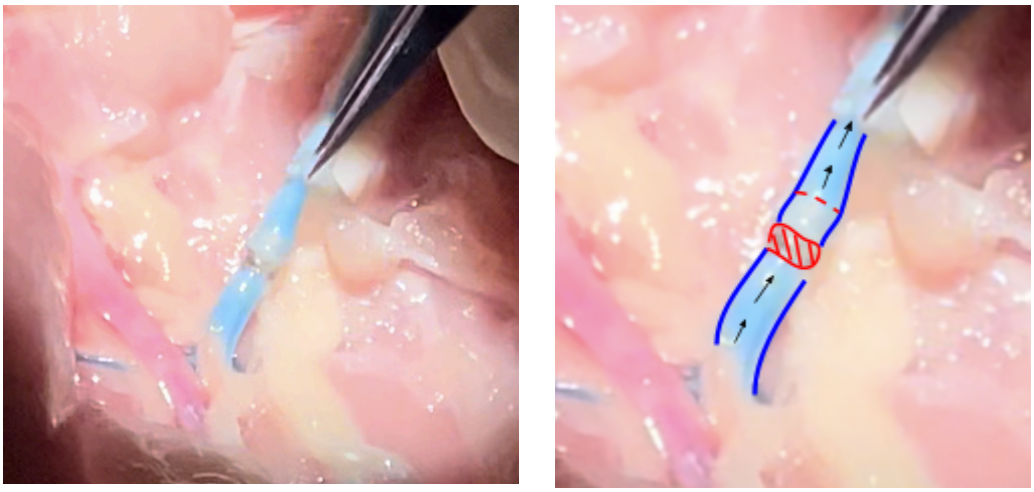


Figure 16: Images of fluid flow through the assembled device.

Finally, we performed a flow test to check for leakage and pressure handling. This test fully passed as no leakage was observed over one minute, and flow remained undisturbed, indicating that the concept can support our long-term patency and hemodynamic requirements. The main limitation of this simulation was the flow pressures that were actually achieved. This test did not reach pressures up to our maximum end of 200 mmHg that the device must be able to withstand. This will require more testing in the future at the greater arterial pressures to ensure our device meets this design requirement.

Overall, these feasibility tests validated the core concept while revealing clear targets for the final design revision: improving arterial grip during eversion and decreasing device thickness. Both changes will help us meet our specifications for usability, safety, performance, and manufacturability.

SolidWorks Simulation

SolidWorks fluid-flow simulations were conducted on the arterial-stent configuration under physiological conditions to quantify the hoop stresses generated by transmural pressure. This analysis was used to determine whether the configuration remained within reported physiological stress ranges at normal pressures to identify concentrations within local stress distributions, preventing potential mechanical failure or vessel injury.

To approximate small- to medium-sized human arteries, 3 different 3 mm long segments were used to represent a single arterial wall (wall thickness of 0.5 mm), a nitinol stent with 0.11 mm strut width, and a full stack of artery-stent-artery-artery representing the final state, picture below in Figure 17. Transmural pressure, which is defined as lumen pressure minus external pressure, was set to 100 mmHg

to represent typical mean arterial pressure at rest [37]. As defined in the product design specifications, physiologic pressures can rise towards 160-200 mmHg during hypertension or systolic surges, however for simplicity pressure was held constant [38]. Blood flow was given a velocity of 0.2 m/s, which corresponds to approximately 84 mL/min in volumetric flow, and 0.0015 kg/s in mass flow. These values were chosen to be consistent with literature values for small arteries [39].

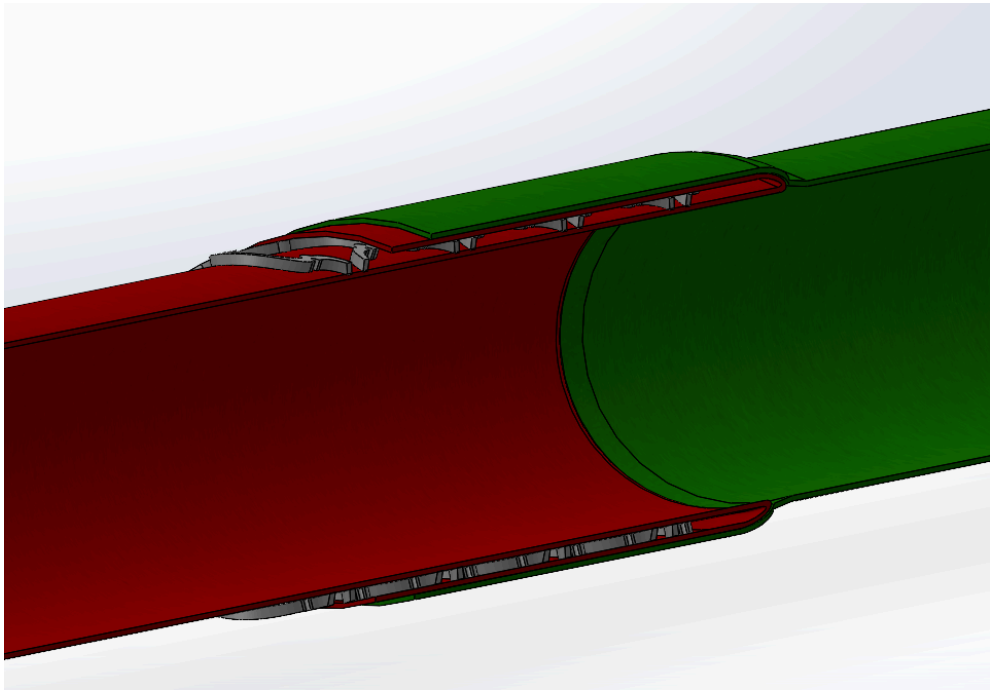


Figure 17: Section view of simulated configuration.

It is important to note that while hoop stress can be calculated using the thin-walled cylinder equation, this only provides localized averages, failing to provide geometry and material-specific information. The SolidWorks simulation, however, allows for visualization of stress distributions across local geometry, allowing evaluations of how wall thickness, stent stiffness, and overlapping regions either concentrate or relieve stress.

The simulated hoop stresses closely matched the expected ranges derived from the thin-walled cylinder estimates and literature values. For the single 0.5 mm arterial wall, the SolidWorks model produced a hoop stress of approximately 40 kPa at 100 mmHg, while the isolated nitinol stent configuration produced a hoop stress of approximately 184 kPa at the same pressure. This value represents a model-based estimate, as literature sources typically provide only qualitative or MPa-scale design limits for Nitinol stents rather than quantitative stress data. When the full artery-stent-artery-artery stack was simulated, the average arterial hoop stress was reduced to roughly 53.3 kPa. This indicates that

the stacked configuration reduced the load such that the arterial wall was operating within typical single-artery ranges. The implications of these stress values for arterial safety and stent performance are elaborated upon in the Discussion Section.

Wall shear stress was evaluated from the SolidWorks testing simulation alongside the hoop stress analysis. The majority of the areas of highest shear stress appeared along the bowed segments of the artery and near the stent overlap region. These high shear stresses were due to changes in lumen geometry and strut intrusions, which accelerate the flow near the walls of the artery and increase velocity gradients. These locations align with regions that are most typically susceptible to restenosis, drastic changes in geometry or other flow disturbances. These areas, pictured below in Figure 18, support that the simulated shear patterns are consistent with expected hemodynamics of the model.

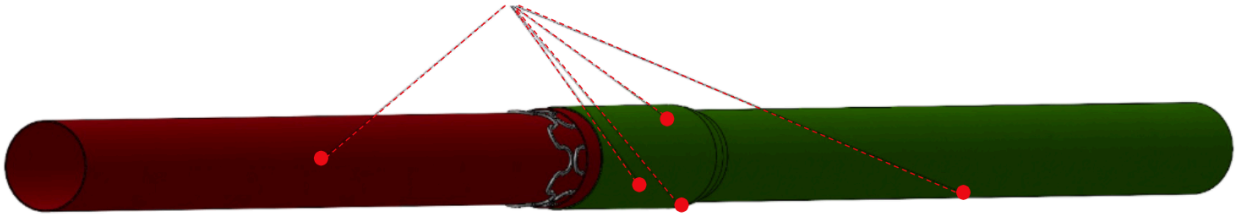


Figure 18: Areas of maximum wall shear stress are shown in red.

Discussion

The goal of this phase of the project was to assess whether the fundamental steps of the anastomosis concept were mechanically feasible using a rigid tubing prototype. Across insertion, eversion, alignment, and flow testing, the results provided initial validation of the core workflow while also revealing specific design limitations that will guide the next iteration.

During insertion trials, the vessel consistently passed through the prototype without snagging, tearing or circumferential deformation which indicated that general geometry of the device supports atraumatic guidance. However, localized abrasion was observed at unpolished edges as it emphasizes the importance of electropolishing and surface finishing in the final Nitinol design. When the edges were smooth, the vessels passed through the tubing without detectable injury. This reinforces that surface quality, not just geometry, is the primary factor influencing insertion safety

Eversion testing demonstrated that the vessel could be folded over the device with minimal overstretching, but spontaneous rollback did occur in several trials. This behavior suggests that while the eversion step is feasible, the current prototype lacks sufficient friction or mechanical engagement to stabilize the everted vessel ends. The smooth tubing used for testing has inherently low surface friction, and these results strongly support the need for integrated anchoring features such as micro-texture or small spikes that can help maintain eversion and prevent slippage during approximation. These

observations also align with prior findings demonstrating that unpolished Nitinol surface can produce micro-burrs and irregularities capable of damaging soft tissue. Figure 19 below highlights the difference between untreated Nitinol struts (a-b) which exhibit debris and surface roughness, and electropolished struts (c-d) which show dramatically smoother profiles suitable for atraumatic vessel contact and reduce the risk of vessel abrasion.

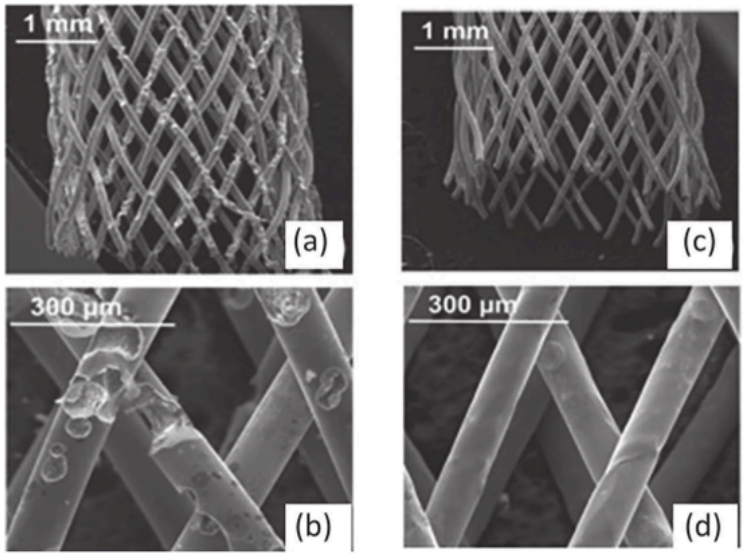


Figure 19: SEM images of Nitinol stents before (a–b) and after (c–d) electropolishing [40].

When pulling the second vessel over the device, the prototype provided adequate structural support to align both arterial segments without requiring excessive force. This confirmed that the device's geometry can facilitate consistent positioning between opposing ends. Despite this, in real clinical implementations, a confirmatory suture would be required to ensure security during postoperative loading. Nonetheless, these findings validate the device's role as a mechanical scaffold for alignment which is critical for reducing variability in manual suturing.

Under steady-state flow, the prototype maintained a sealed interface with no observable leakage when edges were smooth, and flow patterns remained laminar. Leakage occurred only in the presence of sharp or unfinished edges which further emphasizes that surface finishing is essential to creating a reliable seal. These results confirm that the device can support physiologic flow conditions when manufactured with appropriate tolerances and edge quality. Flow testing demonstrated that the prototype maintained a seal interface under physiologic pressures, and flow remained laminar when edges were appropriately smoothed. To complement these benchtop observations, the team performed a preliminary hoop-stress analysis to assess the mechanical safety of both the artery and Nitinol stent during pressurization. The simulated hoop stresses suggest that the arterial recoupler device operates in a mechanically safe range for both the artery and the nitinol stent. A single 0.5 mm arterial wall experiencing around 40 kPa at 100

mmHg falls within the literature range of 20-100 kPa reported for human arteries [41]. The nitinol stent resulted a stress of 184 kPa, which is slightly above the 182 kPa thin-walled estimate, however, this is not a significant cause for concern, as this is still operating well within the mechanical limits of nitinol, implying that there is negligible risk of material yielding or fracturing under normal pressures [42]. This will be a variable to consider when evaluating the device under elevated pressures in the future.Together, these results reinforce the prototype operates safely within expected pressure conditions, though performance at elevated pressure will be an important parameter for future evaluation.

Overall, the rigid prototype demonstrated that the key procedural steps of atraumatic insertion, achievable eversion, vessel alignment, and near leak-free flow are feasible within the intended workflow. At the same time, the tests and results highlighted the necessity for improved retention features and precision manufacturing which will be integral to translating this concept into a functional Nitinol device.

Future Work

Future work will focus on both improving the device design and advancing testing into more realistic physiological environments. The next step is to fabricate a full Nitinol prototype and evaluate key manufacturing characteristics, including electropolished edge quality, surface smoothness, and controlled radial expansion. Insights from these trials will guide refinement of the coupler geometry and inform decisions around surface treatments. Vessel retention will also be enhanced through the addition of micro-textures or anchoring features, and a suture interface will be incorporated so the device integrates seamlessly into the standard anastomosis workflows. In parallel, the team plans to consult with medical device stent representatives to better understand industry fabrication methods, quality standards, and manufacturability constraints. These discussions may also clarify regulatory and production considerations early in the development process. Additionally, the team will also explore micron laser lithography as a potential avenue for producing fine-scale features such as retention spikes, micro-textures, and precision edge-contours all of which are difficult to achieve using conventional machining.

On the testing side, the priority will shift toward assessing the entire anastomosis workflow using the Nitinol prototype, rather than evaluating isolated procedural steps. A key benchmark for clinical feasibility is achieving a total anastomosis completion time of under 20 minutes, and future testing will explicitly measure whether the device enables this target. Furthermore, flow performance will be quantified through leak-rate measurements, pressure-drop analysis, and visualization of flow patterns to determine sealing quality and hemodynamic behavior. Testing will also expand into ex vivo arterial models, enabling more realistic assessments of tissue compliance, handling behavior, and device-artery interaction. Additional trials across a range of vessel diameters will determine whether the prototype

maintains consistent performance and adaptability across clinically relevant conditions. By integrating improved fabrication, industry insight, and comprehensive testing, these efforts will guide the transition from a proof-of-concept prototype to a clinically viable anastomosis device capable of meeting both performance and manufacturability standards.

Conclusion

Microsurgical arterial anastomosis remains one of the most technically demanding steps in reconstructive surgery, often prolonging operative time and relying heavily on surgeon expertise. Current stent-based solutions lack adaptability and can compromise lumen patency, highlighting the need for a vice that is both efficient and physiologically compatible. This project aimed to address these challenges by designing an adjustable Nitinol stent anastomosis device that is capable of guiding two arterial ends into alignment while maintaining patency, reducing variability, and supporting a faster and more consistent surgical workflow.

Testing of the rigid tubing prototype demonstrated meaningful progress towards this challenging goal. The device enabled atraumatic vessel insertion, controllable eversion, stable alignment of opposing artery ends, and laminar flow under physiologic pressures. Observation of localized abrasion and spontaneous rollback revealed opportunities for refinement in edge finishing and vessel retention. Complementary hoop-stress simulations further confirmed that both the artery and stent would operate safely within physiological and material stress limits, suggesting that the concept is mechanically viable for typical arterial pressures. With this, the prototype also highlighted areas requiring further development. Achieving reliable retention will depend on integrating micro textures or anchoring features, and a full workflow evaluation using the Nitinol prototype will be essential to demonstrate that the procedure can be completed in twenty minutes or less.

With continued refinement, expanded testing in ex vivo arterial model, and consultation with medical device stent specialists, this adjustable arterial coupler has strong potential to evolve into a clinically meaningful solution, By reducing procedural complexity and improving consistency, this device will ultimately help shorten ischemia time, minimize complications, and increase the accessibility of microsurgical arterial repair.

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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
304 Stainless Steel Tubing	Miniature, 0.12" OD, 0.01" Wall Thickness - Length 1'	McMaster-Carr	8987K24	McMaster-Carr	8987K24	12/4/2025	1	$8.17	$8.17	Link
304 Stainless Steel Tubing	Miniature, 0.109" OD, 0.012" Wall Thickness - Length 2"	McMaster-Carr	5560K655	McMaster-Carr	5560K655	12/4/2025	1	$4.49	$4.49	Link
304 Stainless Steel Tubing	Miniature, 0.1" OD, 0.009" Wall Thickness - Length 1'	McMaster-Carr	8988K23	McMaster-Carr	8988K23	12/4/2025	1	$9.93	$9.93	Link
									$0.00	
								TOTAL:	**$22.59**	

Appendix III - Design Matrix

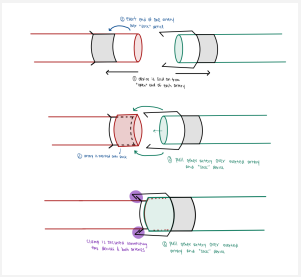
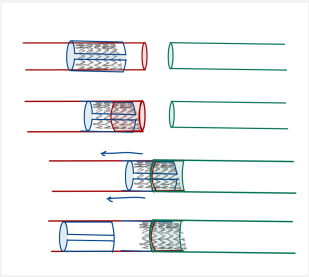
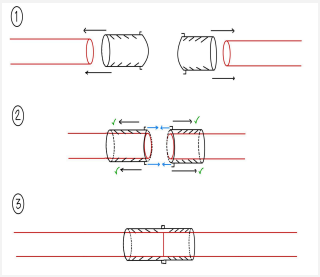
Date: September 26, 2025

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:

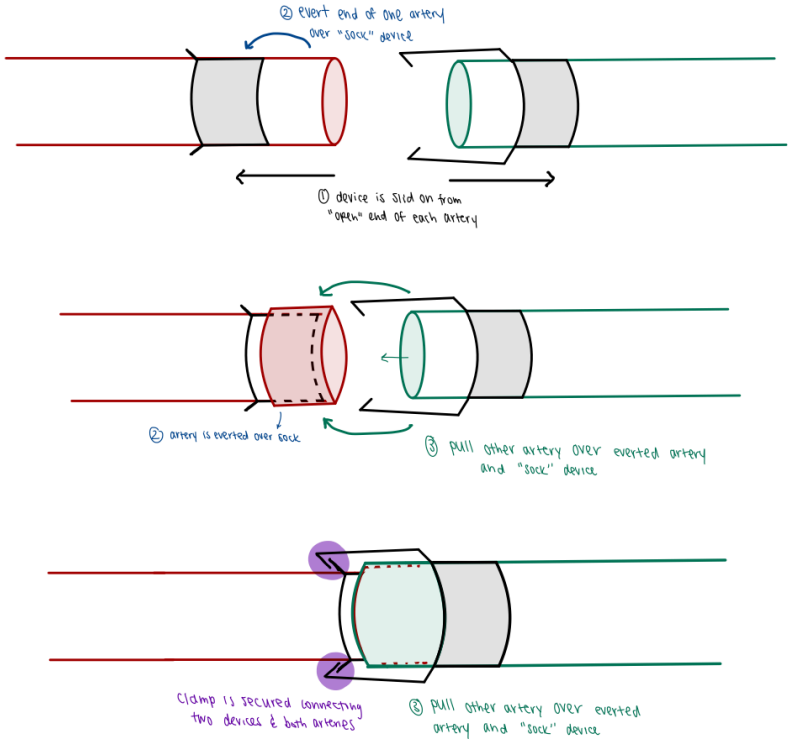


Figure 1: Sock clamp mechanism for sutureless arterial anastomosis.

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:

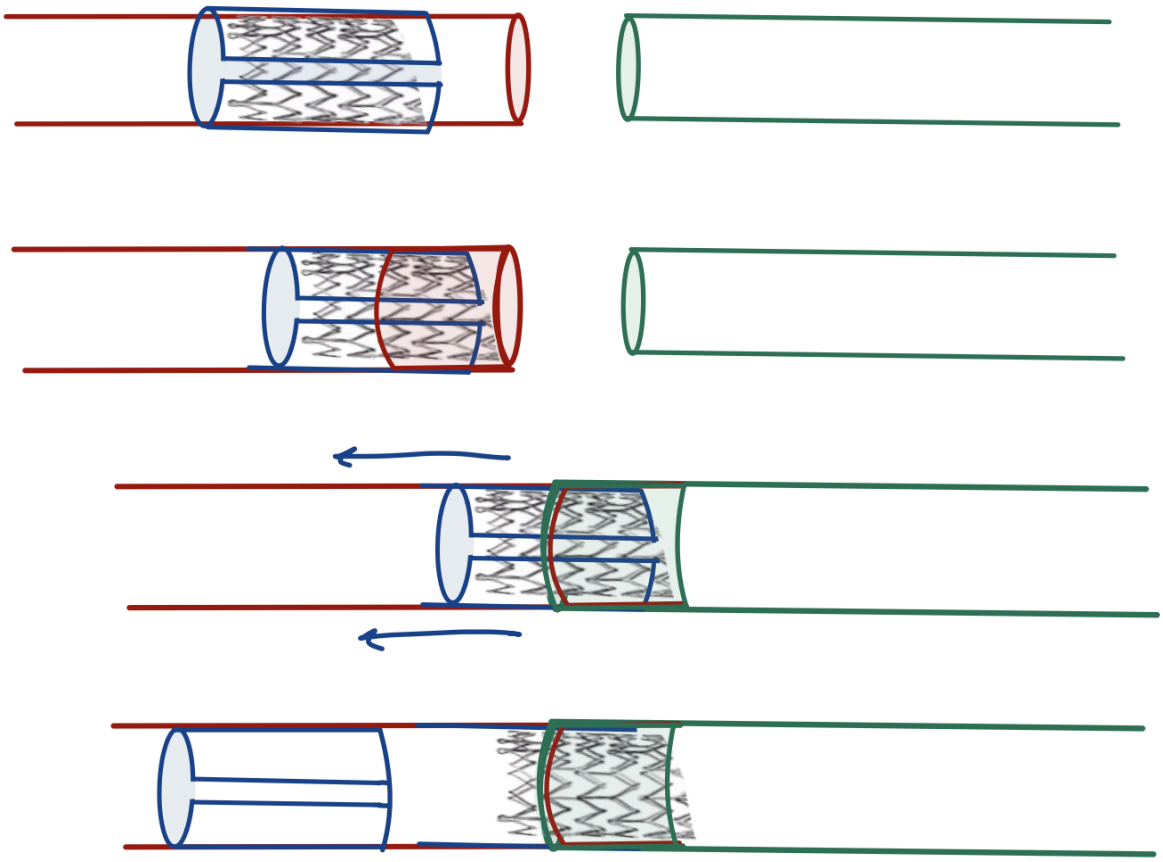


Figure 2: Expandable stent mechanism for sutureless arterial anastomosis.

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:

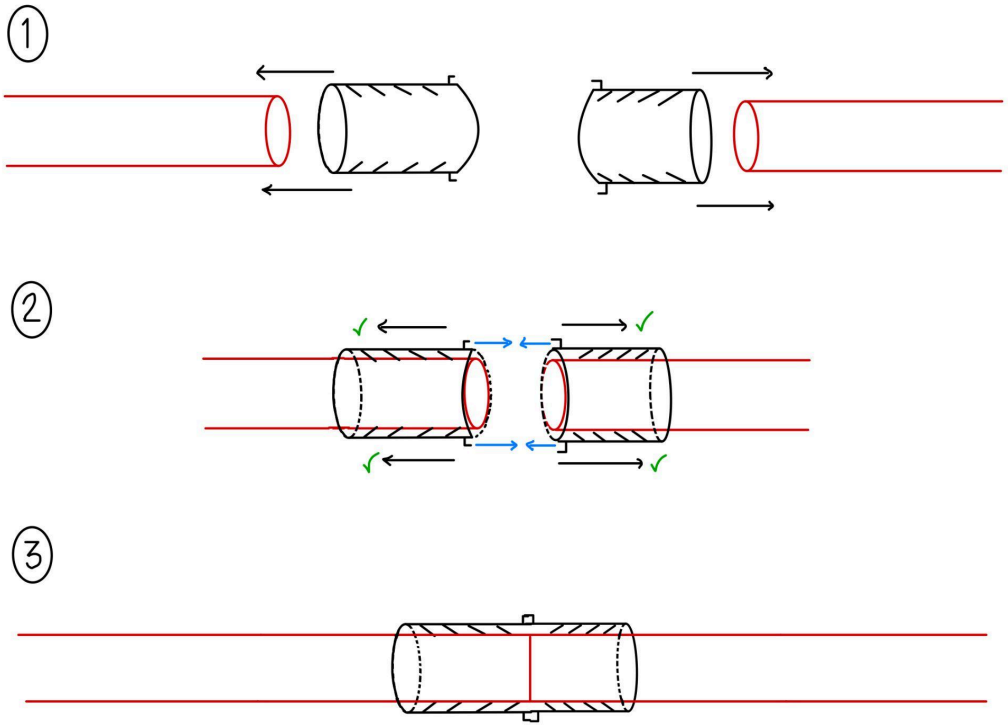


Figure 3: SpikeStent mechanism for sutureless arterial anastomosis.

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.