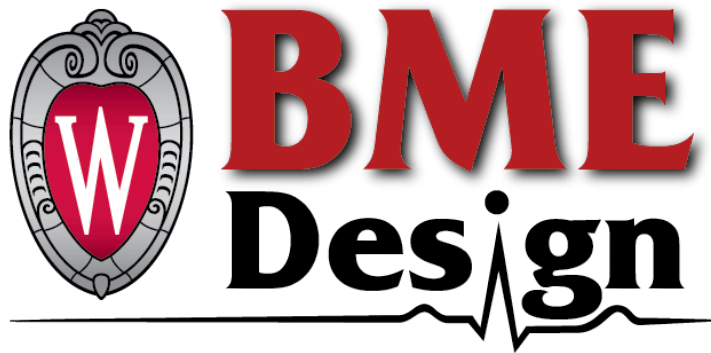




Adjustable Coupler for Arterial Anastomosis
Preliminary Report

BME 400 Design

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Abstract

The growing burden of cardiovascular disease has increased the need for efficient and reliable techniques for arterial reconstruction and anastomosis. Arterial anastomosis is commonly performed using hand-suturing, which requires extensive surgical training and can take 30-60 minutes to complete. Existing sutureless technologies, including venous couplers, magnetic couplers, and intraluminal stents, have limitations related to arterial anatomy, vessel size mismatch, thrombosis, leakage, and vessel damage. The team aims to address these limitations by developing an adjustable arterial anastomotic coupler that reduces procedural time and technical complexity while maintaining vessel integrity. Four preliminary designs were evaluated using a weighted design matrix based on adjustability, efficiency, ease of use, safety, durability, fabrication, and cost. The elastic clamp design received the highest overall score and was selected as the proposed final design. The device consists of opposing clamps connected by an elastic ring that allows the coupler to expand and contract with changes in arterial pressure while maintaining intima-to-intima contact. To evaluate the device, the team will perform leakage and patency, hydrostatic pressure, tensile strength, and efficiency and usability testing. These tests will determine whether the prototype can maintain a secure, leak-free connection under physiological pressures, withstand the required tensile force, and reduce anastomosis time compared with hand-suturing. Results from these tests will guide further design modifications and determine the feasibility of the elastic clamp as an improved approach for arterial anastomosis.

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I. Introduction

A. Motivation and Global Impact

Arterial anastomoses are essential to cardiovascular and organ transplant procedures, enabling the restoration of blood flow within the arteries. The surgery may be performed after removing diseases or damaged tissue, or to create a new pathway around a blockage [1]. Traditionally, arterial anastomosis procedures are hand-sewn, a technique that requires high levels of precision, extensive surgical training, and operative times of 30-60 minutes. Variations in arterial diameter can further complicate anastomosis procedures, as vessel-size mismatch presents challenges for both hand-sewn techniques and coupler devices. While the use of a coupler device is more common with venous anastomoses, some use has been demonstrated in arterial anastomoses. A coupler device utilizes two interlocking rings of pins to interpose arteries, eliminating the need for time-consuming microsuturing. Coupler devices provide benefits such as a decreased thrombosis rate, improved patency, decreased repair time, and reduced ischemia; however, physiologic and anatomic differences in arteries compared to veins offer limitations. Higher thickness, elasticity, intraluminal pressure, and tendency for spasms create a challenging environment for use of a coupler device in arteries. Consequently, troubleshooting is required for 8% of arterial anastomosis procedures when a coupler is used [2].

The growing burden of cardiovascular disease in the United States underscores the need for effective and efficient techniques for arterial reconstruction and anastomosis. The increasing rates of hypertension and elevated LDL cholesterol in the United States contributes to the development and progression of atherosclerotic vascular disease. Notably, nearly half of U.S. adults have hypertension, while approximately one-quarter have elevated LDL cholesterol, highlighting the pervasiveness of these cardiovascular risk factors [3], [4]. As vascular diseases worsen, patients may increasingly require procedures to restore blood flow, including vascular bypass surgery, which relies on arterial anastomosis to reestablish circulation. As a result, the substantial burden of these conditions may contribute to an increased need for effective arterial anastomosis techniques.

The creation of a novel arterial anastomotic coupler that prioritizes adjustability, reduced operative time, and decreased surgical skill requirements could provide significant global benefits. A simplified procedure that maintains adjustability could reduce the need for specialized surgical training while accommodating a wider range of patient anatomies, expanding access to life-saving vascular care in resource-limited settings [5]. Ultimately, the growing burden of cardiovascular disease and the lack of accessible, easily operable arterial couplers highlight a critical need for an improved arterial anastomotic device that can make vascular repair safer, more efficient, and more widely accessible.

B. Existing Devices and Current Methods

Hand-suturing remains the current “gold standard” for arterial anastomosis, despite its technically demanding and time-intensive nature. Beyond the challenges associated with surgical precision and operative time, hand-sutured anastomoses may also carry a greater risk of thrombosis. One comparison of hand-sutured anastomoses and anastomotic couplers found thrombosis rates approximately six times higher in procedures performed using hand-suturing [6]. Although anastomotic couplers have been developed to address some of the limitations of hand-suturing, existing devices are primarily designed for venous anastomoses and do not adequately address the unique challenges of arterial repair. In particular, arteries experience higher rates of calcification than veins, which can increase vessel stiffness and complicate eversion and coupling, potentially compromising the seal between vessels [7], [8].

The Synovis GEM Microvascular Anastomotic Coupler, pictured in Figure 1, is commonly used for venous anastomoses, and has shown improvements in operative duration, patency rates, and ischemia time. Despite its benefits with venous procedures, the GEM coupler is not compatible with arteries due to their physiologic and anatomic properties. The thick walls and rigid calcifications commonly found in arteries can further complicate vessel manipulation during an already technically demanding procedure [2]. Further, the tight compression caused by the rings can pinch the vessels and lead to necrosis.



Figure 1: Synovis GEM Microvascular Anastomotic Coupler [9]

Magnetic couplers, shown in Figure 2, are a less prevalent method that offer a unique solution to anastomosis difficulties, although they lack substantial evidence of success. These devices include “two pairs of magnetic rings and two rivet-like rings” [10] that allow the ends of vessels to come together through the magnetic attraction of the rings. Although magnetic couplers showed initial promise with fast procedural times, their inability to accommodate mismatched vessel sizes, leakage, and interference with medical equipment such as MRIs prevented their widespread adoption.

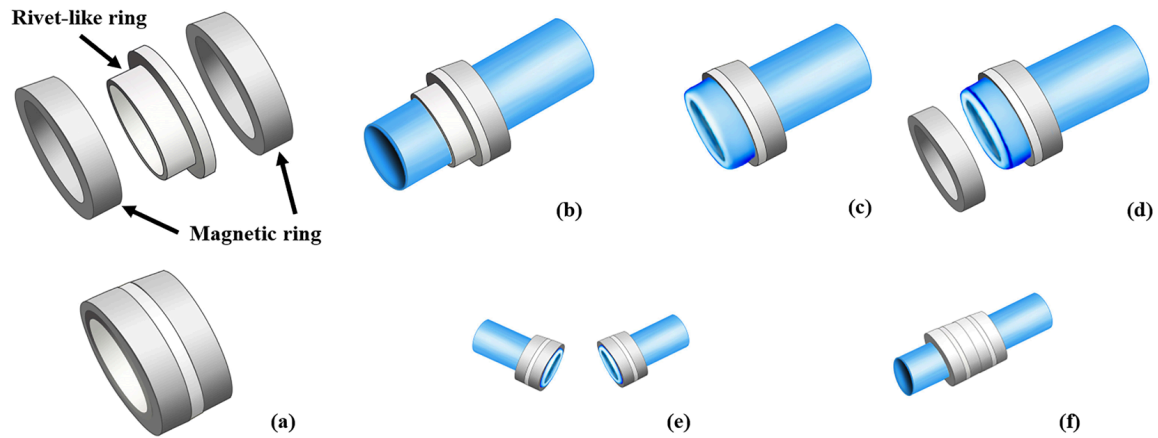


Figure 2: Magnetic Compression Anastomotic Coupler [10]

Intraluminal stents, shown in Figure 3, represent another, less commonly used approach to arterial anastomosis. These devices offer several potential advantages, including eliminating the need for vessel eversion and facilitating relatively straightforward placement. However, their use is associated with significant risks, particularly thrombosis and inflammation. Given the potentially severe consequences of thrombotic complications, intraluminal stents were determined to be unsuitable for the proposed device [10].

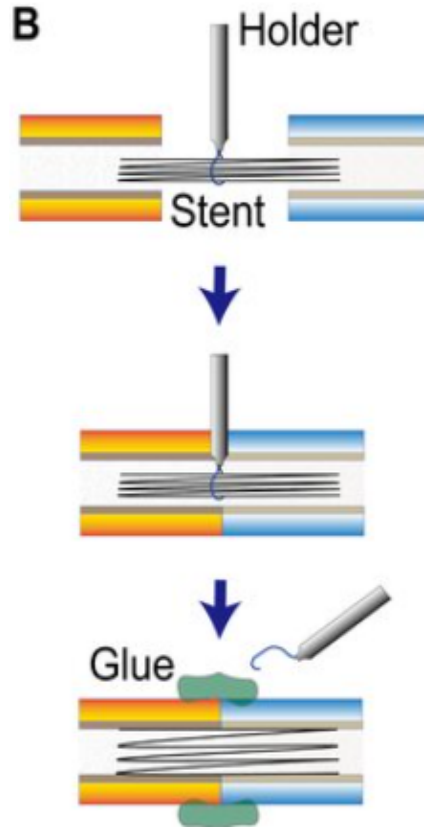


Figure 3: Stent-assisted sutureless microvascular anastomoses [11]

Current solutions for vascular anastomosis fail to address the needs of arterial anastomosis procedures, highlighting a critical gap in the medical device industry. Hand-suturing, venous couplers, and less-popular sutureless methods are limited in their adjustability, and pose a variety of risks such as thrombosis, leakage, and necrosis. It is imperative that a device be developed to mitigate these complications and provide a more efficient surgical method for arterial anastomosis.

C. Problem Statement

Microsurgical arterial anastomosis is a cornerstone of reconstructive surgery, enabling tissue transfer and limb salvage. Current techniques are highly time-consuming, technically demanding, and 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. Alternative methods such as microvascular couplers and stent-based approaches introduce complications and lack adaptability across the wide range of vessel diameters encountered in clinical practice. There is a critical need for a biocompatible, adjustable, and intuitive device that can reliably reduce operative time while maintaining vessel integrity and minimizing complications.

II. Background

A. Biology and Physiology

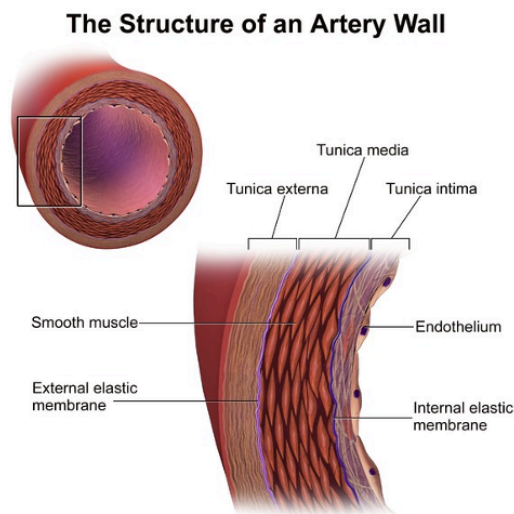


Figure 4: Anatomy of the Artery Wall [12]

Vascular anastomosis is the surgical connection between two blood vessels in the body, like veins and/or arteries, to restore blood flow [1]. While venous anastomosis procedures can be successfully completed with a coupler, arterial anastomosis procedures require hand-suturing due to physiological and anatomical differences between arteries and veins and complications with necrosis and thrombosis.

Arteries are a type of blood vessel that carry blood away from the heart. Figure 4 shows the anatomy of an artery wall including the three layers: tunica intima, tunica media, and tunica adventitia (externa). The tunica intima is the innermost layer and consists of a single layer of endothelial cells surrounded by a connective tissue membrane. The tunica media is thickest and most elastic middle layer, consisting primarily of smooth muscle cells, which regulate blood pressure. The tunica adventitia is the outermost layer that is connective tissue with elastic and collagenous fibers. It is crucial that two free arterial ends are joined with maximum intima-to-intima contact to promote endothelial healing [13]. While intima-to-intima is ideal, contact between the device and intima must be minimized to reduce the risk of coagulation and thrombosis [14].

Veins, which carry blood toward the heart, consist of the same three layers as arteries, but are considerably thinner and less elastic than arterial walls [15]. Veins also operate under lower intraluminal pressures, allowing their walls to be more compliant than those of arteries [16]. In contrast, arteries must withstand higher blood pressures, resulting in thicker walls that are more susceptible to tearing when manipulated. While venous tissue can generally be everted over the

coupler pins without difficulty, the thicker and less compliant arterial walls may be more difficult to evert and may lead to a more dangerous tear. Such damage can compromise the anastomosis and result in significant bleeding due to the higher pressure arteries experience.

Since arteries experience higher pressure than veins, an arterial coupler must strongly consider any possible vessel wall tearing or damage. The device must expand and contract with systolic and diastolic pressure. During systole, the artery can reach a maximum of 140 mmHg, corresponding to a wall stiffness of 500 kPa. During diastolic pressure (60-80 mmHg), the wall stiffness may fall to 80 kPa [17]. The client specified that arterial pressures during microvascular surgery can reach up to 200 mmHg and the device must be suited for this application.

B. Prototype Design and Build Research

Since this device will be implanted into the human body, the materials and geometry of the device must prioritize patient safety. Implanting any device inside the artery may induce many complications including thrombosis, clotting, and stenosis. Therefore, the clients requested a device that remains in the body, but outside of the artery, so the operating environment has high humidity. The materials for the device must be resistant to corrosion and must not degrade before fourteen days to allow for complete arterial attachment.

As stated above in Existing Devices, the GEM coupler is a device that is highly successful in vein anastomosis, partially due to the intima-to-intima contact from the eversion of both ends of the vessel. However, arteries are substantially thicker and stiffer than veins, making the eversion process more difficult and dangerous. This structural difference must be considered in the prototype design.

Another consideration is the previous group that worked on the project in Spring 2026. The proposed design from last semester was an expandable microsurgical stent modeled to accommodate arterial diameters ranging from 2 mm to 5 mm. The device was designed for fabrication in nitinol due to its superelastic properties. However, due to cost and manufacturing constraints, they alternatively created a prototype of a spiral cuff fabricated from stainless steel.

C. Client Information

The clients, Dr. Craig, Dr. Zeng, and Dean Spyres are affiliated with the UW School of Medicine and Public Health. Dr. Zeng is the director of Microsurgery Education at UW-Madison, Dr. Craig is a Plastic Surgery Resident, and Dean Spyres is a research fellow in the Division of Plastic Surgery at UW-Madison [18], [19]. All clients share the mission to make microsurgical education more intuitive and accessible for surgeons and to address disparities in the field of medicine. As a part of their mission, they want to develop a device to simplify and reduce the complications of arterial anastomosis.

D. Product Design Specifications

The device must reduce procedural duration and technical complexity to limit the risk of ischemia and improve ease of use, allowing less specialized surgeons to perform the procedure. The clients provided the team with a starting budget of \$500 for device components, fabrication, and testing.

The device must have an adjustable mechanism that allows expansion and contraction by 30% of its original size to accommodate radial, arterial expansion and relaxation during systolic and diastolic pressure. The clients emphasized the importance of the adjustable mechanism, stating that the team may work at a larger scale (10-20mm diameter) as a proof of concept rather than the typical size performed on (2.0-4.0 mm diameter).

The arterial coupler must demonstrate a 100% success rate, which entails vessel patency, prevention of vessel leakage, and pressure resistance. The long-term patency rate must be greater than 88% and the artery must remain leak-free under static and pulsatile flow [20]. The device must withstand physiological blood pressure of 120/80 mm Hg (16.0/10.7 kPa) and up to 200 mm Hg (26.7 kPa) for patients with extreme hypertension [21], [22]. To ensure secure vessel wall attachment, the coupler must withstand greater than 3.64 N of axial tensile stress to exceed current sutured-anastomosis procedures [23].

Anastomotic and microvascular devices are classified as Class II medical devices and require 510(k) premarket notification [24]. Since the coupler will interact directly with the patient's vasculature, the device must minimize patient risk. Therefore, the device must follow ISO 10993, encompassing chemical and biocompatibility and must remain in sterile packaging according to ISO 11607 until use [25], [26].

Further detail of product design specifications can be referenced in Appendix A.

III. Preliminary Designs

A. Design 1: Crank Expander

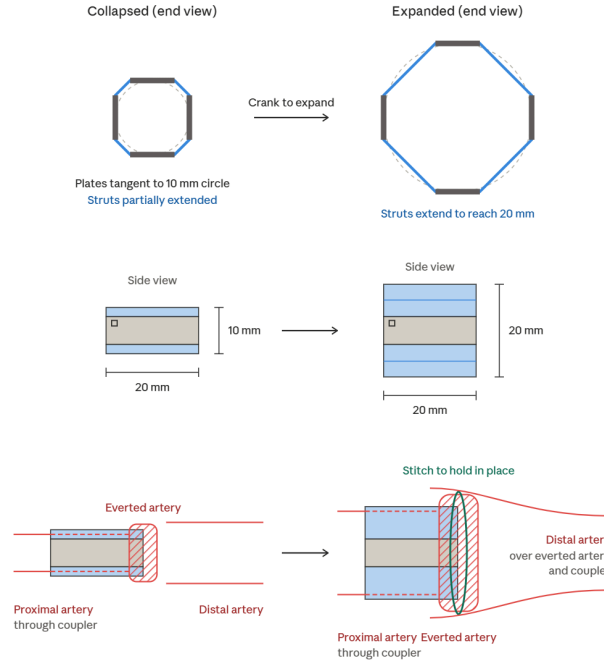


Figure 5: A scaled-up prototype of an expandable coupler is cranked from a 10 mm to a 20 mm diameter. External Crank tool not shown (dimensions shown are for the scaled prototype, not the final device).

The expandable coupler pictured in Figure 5, is a short tube made of four flat plates connected at the corners by sliding struts. The proximal artery is passed through the coupler and folded back over its end, and the distal artery is pulled over the top. A separate crank tool can be used to push the plates outward, sliding the struts out to fill the gaps between them and widening the coupler. After expansion, the plates then lock in place, and a stitch is placed around the overlap holding the connection secure.

This design allows the device to be precisely adjusted to the designated size quickly using an external tool. This fast and controlled expansion provides strong intima-to-intima contact while remaining external to the blood path. This device has several important limitations to consider. The design's fixed diameter in its locked, expanded state does not expand with the vessel as blood flows through the anastomosis site. This lack of compliance, as well as the complicated fabrication to create this design at the desired scale, reduces its feasibility.

B. Design 2: Plier Assisted

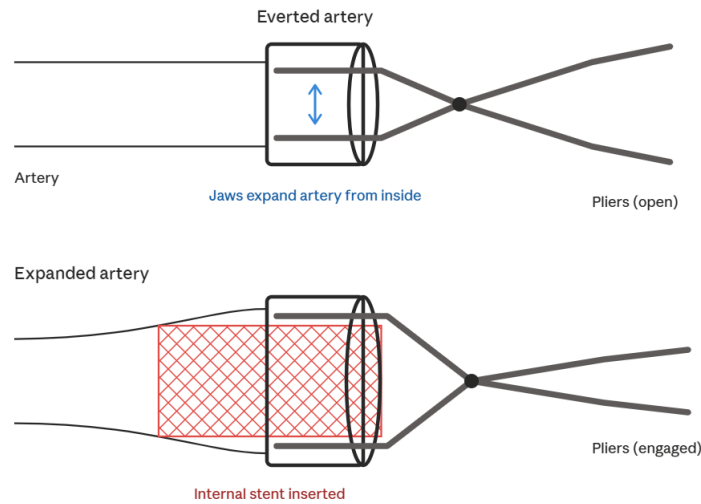


Figure 6: Diagram of the plier-assisted stent design which uses a plier-like device to expand the distal artery to a specified diameter prior to attachment to the proximal artery.

The Plier-Assisted Stent design pictured in Figure 6, utilizes tools that are already available and commonly used in the operating room. During the operation, specialized pliers are inserted into an everted, open artery during an anastomosis procedure. The pliers engage, widening the diameter of the artery and allowing a stent to be placed inside the artery. This expanded artery can now be attached to an artery with a larger diameter.

This approach provides the surgeon with a higher level of control and familiarity throughout the procedure. The plier tool can be adapted from existing instruments with slight modifications to reduce damage to the vessel, and a commercially available stent, with proven biocompatibility, can be combined to size-match the two artery ends. However, this approach places a stent directly in the blood path, which leads to an increased risk of thrombosis and restenosis. Additionally, this design relies on a stent of a fixed diameter that will not expand with the artery. Finally, this relies heavily on sourcing manufactured devices, which would greatly increase cost.

C. Design 3: Exterior Wedge

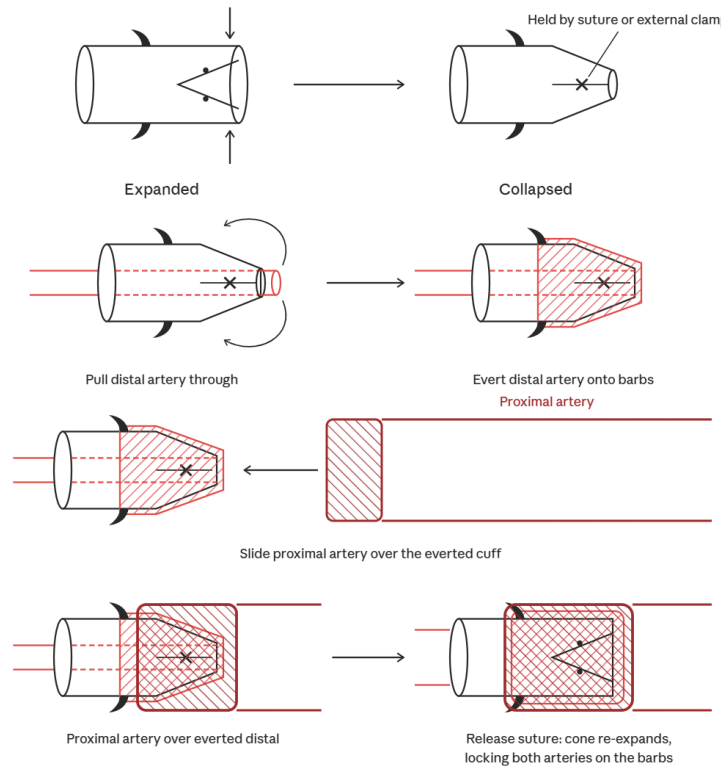


Figure 7: A barbed cylinder with a wedge cut is collapsed into a cone and held with a suture; the distal artery is pulled through and everted onto the barbs, the proximal artery is slid over it, and releasing the suture lets the cone re-expand to lock both arteries in place.

The wedged-cone coupler pictured in Figure 7 is a barbed cylinder with a V-shaped wedge cut into one end. Pressing the two sides of the notch together closes the V and tapers that end into a cone, which is held collapsed by a suture across the seam or by an external clamp. The distal artery is threaded through the device from the wide end and pulled out through the narrow cone tip. Its free end is then everted back over the outside of the cone and pushed onto the barbs, which point away from the tip so the cuff cannot slide forward off the device. The cone's tapered profile makes the eversion easier, because the vessel is stretched gradually rather than all at once over a blunt edge. Next, the proximal artery is slid over the everted distal cuff. Finally, the suture is cut or the clamp removed, and the cone springs back to its original cylindrical shape.

This design emphasizes the need to reduce the difficulty of everting the thick-walled artery. The simplicity of the design allows for fast and cost-effective fabrication while providing excellent intima-to-intima contact and remaining outside of the blood path. However, this design relies heavily on the ability to hold the device in a collapsed state and to release the collapsed state at a designated time. It also has a fixed diameter that does not expand and relies on the traumatic barbs to fixate the artery, increasing the risk of rupture.

D. Design 4: Elastic Clamp

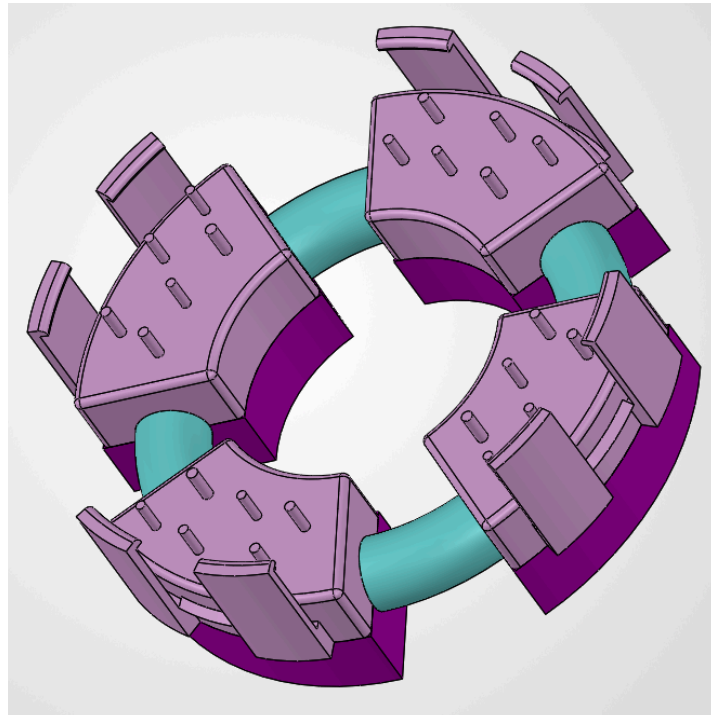


Figure 8: Elastic clamp ring with elastic silicone ring. The silicone ring allows expansion of the device during implantation and increases blood pressure.

The elastic clamp design pictured in Figure 8, consists of two identical ring assemblies, one attached to the end of each artery. Each assembly is built from a continuous circular ring of elastic material with four rigid quarter-circle pieces attached separately around its circumference. The rigid pieces are spaced so that short sections of the elastic ring remain exposed between them, allowing the ring to stretch and recoil as the artery expands and contracts with each heartbeat. During the procedure, the end of each artery is passed through the center of its ring and everted back over the outer cylinder wall, where an atraumatic surface supports the vessel and reduces damage to the arterial wall. Each rigid piece carries an interlocking hook that extends across the gap between the two rings and hooks over the full surface of the opposing ring, securing the connection in both directions. Once joined, the everted ends of the two arteries are held face to face, creating an intima-to-intima connection with the device kept outside the blood-contacting surface. To accommodate arteries of different diameters, the rigid quarter-circle pieces can be designed to attach to elastic rings of different sizes, so only the elastic ring needs to be changed to fit a given artery. See the section titled “Proposed Final Design” for further details.

IV. Preliminary Design Evaluation

A. Design Matrix

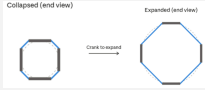
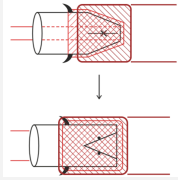
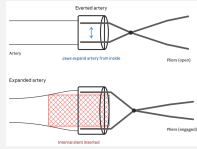
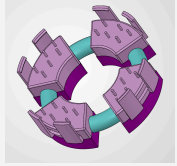
Arterial Coupler Design Matrix									
		Design 1: Crank Expansion		Design 2: Exterior Wedge		Design 3: Plier-Assisted Stent		Design 4: Elastic Clamp	
									
Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Adjustability	30	2/5	12	2/5	12	3/5	18	4/5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

Table 1: Design matrix comparing four arterial coupler designs with relevant criteria and scores.

As shown in Table 1 above, the elastic clamp design ranked the highest overall within the design matrix due to adjustability, efficiency, ease of use, and safety. The elastic clamp design features four connecting clamps with a central elastic ring. Once the arteries are everted onto two clamps, they are connected using opposing hooks. The elastic ring allows compression and expansion based on blood pressure in the flowing artery. Also, the device can be compressed together to improve the arterial eversion. The ability of the ring to change diameter attributes to the high adjustability score. Since this clamping mechanism is simple and does not require suturing, the device scored highly in efficiency and ease of use. However, the surgeon will need to select the correct elastic ring size before the procedure. This will require accurate measurement of the artery diameters. To mitigate potential issues, a kit will be provided with various sizes of the device. This solution will allow surgeons to select the clamp size that is best fit for the two arteries. Finally, the device maintains intima-to-intima contact. Therefore, the device remains outside of the blood-contacting surface, reducing thrombogenicity. The hooks of the device must be designed to not unclasp. Serious complications could arise if the clasp were to unhook, releasing blood from the artery. More details on the criteria ranking and competing designs can be found in Appendix B.

B. Proposed Final Design

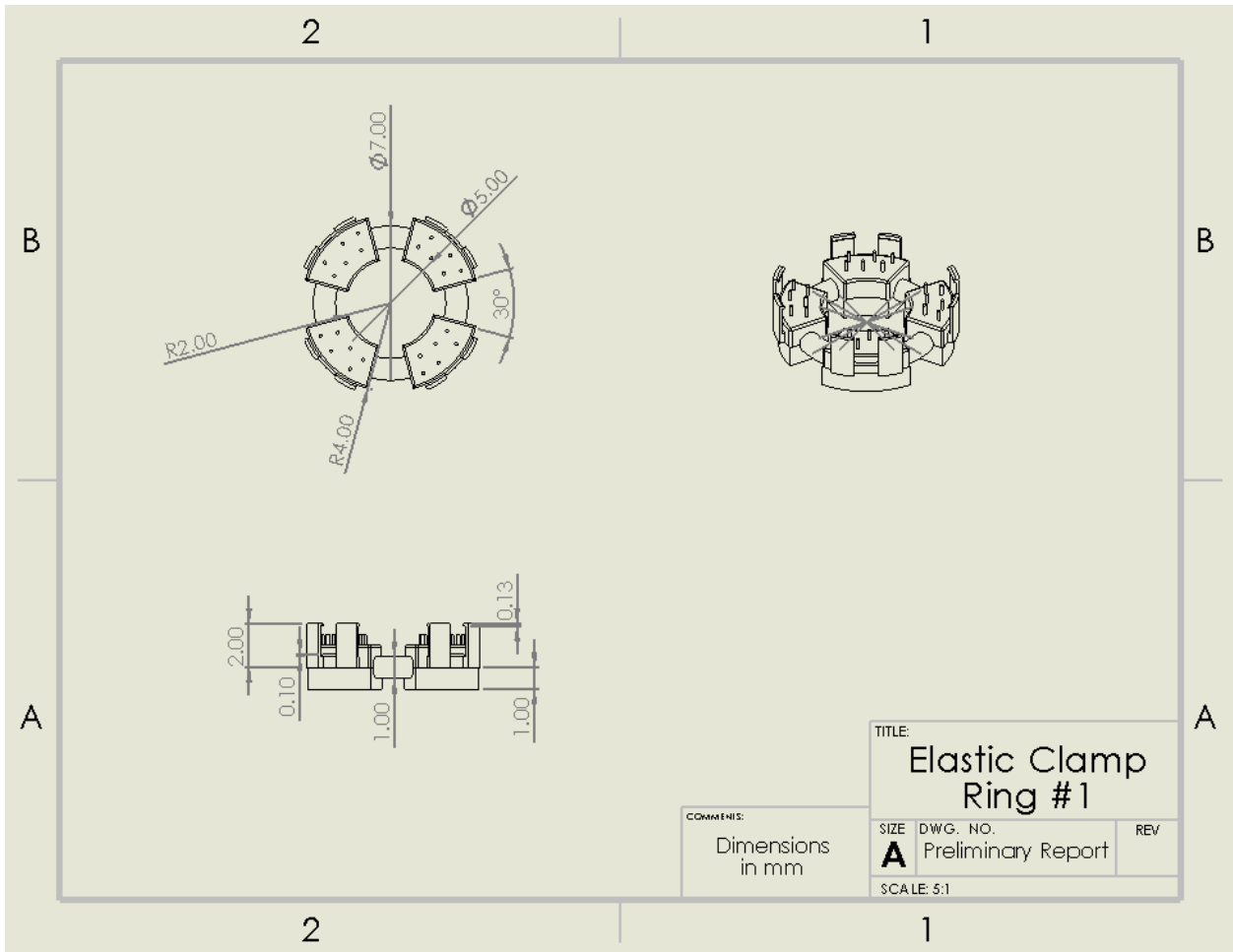


Figure 9: SolidWorks technical drawing of the Elastic Clamp Design.

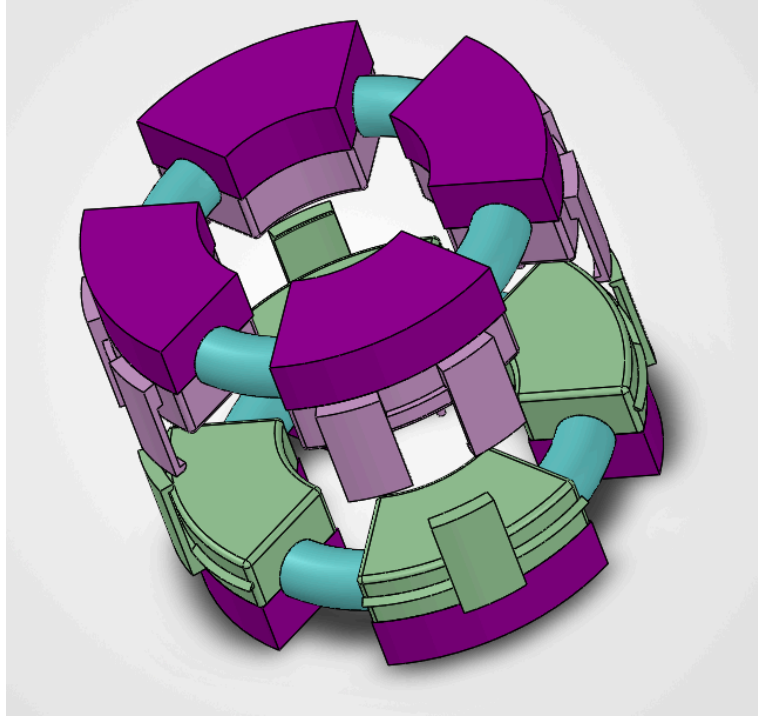


Figure 10. SolidWorks assembly of the final elastic clamp design with both the top and bottom clamp. (Purple) Base connector part. (Light purple) Top connector of clamp #1. (Green) Top connector of clamp #2. (Teal) Elastic ring.

The proposed final design is the elastic clamp. Per client specifications, the device will be scaled to a larger size, with an internal diameter of 10-20 mm. The drawing in Figure 9 depicts an ideal device with an internal diameter of 4 mm. This drawing will be scaled up to develop initial prototypes. The full assembly in Figure 10 features the opposing clamps that will be hooked together. Prototyping of the two parts will allow for analysis of the gap distance between the two faces. This gap will be refined to ensure there is no blood leakage between the everted arteries, and that there is enough space to prevent crushing the everted walls and lock the clamps.

V. Fabrication

A. Materials

The final design will be prototyped using BioMed Clear Resin and a silicone ring. BioMed Clear Resin is not approved for direct, long-term contact with arteries. Further research in long-term biocompatible resources will be conducted to determine the material needed for a potential product. However, the BioMed Clear Resin is available to print on the Formlabs Form 2 printer in the UW-Madison Makerspace. This printer has a resolution of up to 50 microns. The high resolution printing allows the small, complex geometries of the device to be 3D printed.

The silicone ring will be used to provide elasticity to the device. Silicone is a highly biocompatible and chemically inert material. Silicone will be used as an initial ring material as it is both elastic, and can be translated to a final implanted product. Multiple sizes of the silicone ring will be used to test the device at multiple diameters. Based on testing results, a ring with different elasticity may be required and other materials will be considered.

B. Methods

Fabrication of the final prototype will begin by 3D printing the clamps using a Formlabs Form 2 printer. Each part will be printed individually instead of the full assembly: base connector part, top connector of clamp #1, top connector of clamp #2. Next, the silicone ring will be placed in the grooves of four base connector parts. These parts will be aligned along perpendicular diameters. To complete the clamp, the top connector (#1 or #2) will snap onto the pegs of the base connector. This will secure the elastic ring. If the elastic ring slips within the grooves, an adhesive will be used to secure the ring within each clamp piece. The two final clamp parts can be connected using the opposing hooks.

VI. Testing and Results

To evaluate the efficiency, functionality, and mechanical integrity of the arterial coupler, several validation tests will be conducted, including leakage and patency testing, hydrostatic pressure testing, tensile testing, and efficiency and usability testing. These assessments will evaluate the device's performance under simulated surgical and physiological conditions while ensuring a secure mechanical connection between vessel ends. Testing will be performed using synthetic silicone vessels provided by the client, as well as chicken thigh arteries, which have been validated as a suitable vessel model due to their comparable diameter [27].

A. Leakage and Patency Testing

According to the PDS (Appendix A), the coupler must prevent vessel leakage while maintaining vessel patency to minimize the risk of postoperative bleeding or thrombosis. To evaluate the integrity of the vessel seal and confirm continuous flow through the lumen, a dyed saline solution will be circulated through the coupled vessel using a gravity-driven pump to simulate physiological blood flow [28]. The coupled vessel will be visually inspected for leakage and flow obstruction. Any leakage or reduction in flow will indicate insufficient sealing or excessive lumen compression and may require refinement of the device dimensions and compression tolerances.

B. Hydrostatic Pressure Testing

Hydrostatic pressure testing will evaluate the ability of the coupler to maintain a secure mechanical connection under pressures representative of physiological blood pressure without leakage or vessel separation. A syringe pump will be used to pressurize the coupled vessel to the

target pressure range. As stated in the PDS in Appendix A, the device should withstand normal blood pressure of 120/80 mmHg and up to 200 mmHg for patients with extreme hypertension [21], [22]. The coupled vessel will be monitored for separation or deformation throughout testing. Failure at or below the specified pressure range will indicate additional mechanical reinforcement or adjustments.

C. Tensile Testing

To evaluate the mechanical integrity of the coupler and ensure a secure connection between the joined arteries, an axial tensile test will be performed using an MTS testing machine. According to the PDS, the coupler must withstand an axial tensile force greater than 3.64 N to exceed the mechanical strength of current hand-sutured anastomosis procedures [23]. The coupled vessel will be subjected to an increasing axial tensile load until failure or until the specified threshold is reached. Failure below 3.64 N will indicate insufficient mechanical strength and may require refinement of the coupler's locking mechanism, geometry, or material selection.

D. Efficiency and Usability Tests

To fulfill the client's requirements, the device must reduce arterial anastomosis time compared to existing hand-suturing techniques. Minimizing anastomosis time is important for reducing the duration of tissue ischemia, which has been associated with increased complication rates and reduced flap survival [29]. To evaluate the device's surgical usability and efficiency, a user pool of both experienced surgeons and residents unfamiliar with anastomosis procedures will perform arterial anastomoses using hand-suturing techniques and the prototype device. The time required to complete each anastomosis will be recorded for both methods and compared to quantify improvements in procedural efficiency. Qualitative user feedback regarding ease of use, handling, ergonomics, and overall usability will also be collected to identify potential areas for further design refinement.

VII. Discussion

The elastic clamp ranked highest in the decision matrix for adjustability, efficiency, ease of use, and safety. No performance data exist yet, so the findings below describe design rationale, not demonstrated outcomes.

Sutureless anastomotic devices aim to shorten operative and ischemic time and are reported to have higher patency than hand-sewn repair [30]. However, their main documented disadvantages are reduced vessel compliance, stenosis, leakage, and cost [30]. Adapting them for arterial use remains difficult, and an ideal device would also eliminate the need for vessel eversion and reduce thrombosis [23]. This design still requires eversion, but it addresses the compliance problem while keeping the device outside the blood-contacting surface.

In arterial flow, fixed non-expansile rings are proposed to obstruct pulsatile compliance [31]. This constriction is proposed to alter local hemodynamics, create turbulent shear stress, and induce intimal hyperplasia or thrombosis [31], [32]. Compliance matching appears to matter in vivo. In a rabbit carotid end-to-side model, grafts with compliance closer to the native artery showed less anastomotic intimal hyperplasia and higher patency than low-compliance grafts [33]. Rigid rings also cannot adapt to systolic-diastolic pressure changes or size discrepancies without extensive mechanical tailoring [34], [35]. Across coupling devices generally, non-suture devices aborted during surgery required conversion to hand-sewn repair in 8.4% of attempted cases [34].

The elastic clamp addresses this device-tissue compliance mismatch. The arterial attachment regions move with the silicone ring, so the connection can expand and recoil with each heartbeat, and the ring can be swapped to fit different artery sizes. This compliance is a design intent that has not yet been measured. Direct literature on truly radially compliant arterial couplers remains scarce, though emerging bioabsorbable and elastic prototypes target the same limitation [31], [32], [36]. To our knowledge, none of these combine an elastic ring with rigid hooked segments and interchangeable ring sizes. The device is therefore a candidate novel coupler, but that claim needs a systematic patent and literature search before it appears in the final report.

At this stage the research uses bench prototypes only, with no human or animal subjects. For ultimate use, the largest risk is hook failure. If the clasp unhooks, the artery releases blood, which makes the locking mechanism a safety-critical feature. Further prototyping and testing will be used to optimize this part of the design. The silicone ring and rigid pieces would need biological evaluation under ISO 10993-1 or be replaced with other known biocompatible materials prior to any implantation [25]. Device cost is a disadvantage of sutureless technology, and a multi-size kit raises it further [30]. Existing coupler devices were cleared through 510(k) as Class II devices [37]. However, as a novel connector with no suitable predicate, this device could require going through premarket approval.

Several changes will be required once prototyping begins. The gap between the two clamp faces will need refinement so it prevents blood leakage without crushing the everted walls. The hooks will need to be tested and redesigned if necessary, so they cannot unclasp under pulsatile load. The compliance of the ring and attachment region will need to be measured and matched to native arterial tissue. Several sources of error will limit what testing can show. Tolerances in the 3D-printed rigid pieces and variation in silicone stiffness will change both the gap distance and the ring's elastic response. Silicone vessels will not fully reproduce the viscoelasticity or wall thickness of real arteries, so results from them will serve only as an initial estimate for the proof of concept.

VIII. Conclusions

The rise of cardiovascular disease has increased the demand for efficient and reliable methods for vascular reconstruction. Previous anastomosis coupler devices have had great success in reducing the time and skill burden required to safely and effectively join microvasculature compared to the gold standard hand-sutured method. However, these previous devices struggle to address the complications that arterial anastomosis at a microscale creates due to their thick walls and varying blood pressure. These devices are limited by their fixed, inelastic diameters, creating increased pressure, leakage, and stenosis at the anastomosis site and their traumatic vessel attachment methods that increase the risk of thrombosis and vessel damage. The team aims to address these limitations by developing an adjustable arterial anastomotic coupler that reduces procedural time and technical complexity while maintaining vessel integrity. After carefully considering four preliminary designs on key criteria of adjustability, efficiency, ease of use, safety, durability, fabrication, and cost, we will be moving forward with the elastic clamp design. This device uses an expandable, elastic central ring to accommodate for vessel expansion during higher blood pressures, combined with an external clamp system to keep material external to the blood path. While this device does not address the difficult arterial eversion necessary for proper intima-to-intima contact, future device iterations or operative tools will consider this issue. The proposed final design will be tested for leakage and patency, hydrostatic pressure, tensile strength, and efficiency and usability. Results from these tests will guide further design modifications and determine the feasibility of the elastic clamp as an improved approach for arterial anastomosis.

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X. Appendices

A. Product Design Specifications

Function

Arterial anastomosis procedures are traditionally hand-sewn, resulting in a time-intensive and highly precise surgery requiring an advanced level of microsurgical skill. Venous anastomosis procedures often use a coupler device to reduce surgery duration and technical demands; however, applying it to arterial vessels presents additional technical challenges because of differences in anatomy and physiology. Additionally, differences in vessel diameter between the two ends of the anastomosis can further complicate the procedure. The device must provide a method of arterial anastomosis that reduces procedural duration and technical complexity, accommodates differences in vessel diameter, and minimizes trauma to the vessel wall.

Client requirements

- An adjustable anastomotic coupler device capable of connecting two arteries through end-to-end anastomosis.
- Device expansion and compression values that are 30% of the original size.
- Compatibility with blood vessel diameters ranging from 2.0 mm to 4.0 mm.
 - The client requires an initial proof of concept, in which the device should be 10.0 mm to 20.0 mm to demonstrate functionality.
- Scalable device dimensions, allowing for proof of concept as well as microvascular testing.
- Test methods for blood flow leakage, tensile strength, and hydrostatic pressure testing to ensure competitive characteristics with accepted anastomosis methods.
- Lower procedure times compared to current anastomosis methods.
- Proof of concept that is biocompatible with human tissue.

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements

- i. The arterial coupler device will be used during vascular anastomosis procedures and is a single use device. The device must exhibit the mechanical properties suitable for arterial conditions (more detail in the materials section) and must effectively support the surgeons during vascular anastomosis. The coupler device must have a mechanism for adjustability.

b. Safety

- i. As the arterial coupler will directly interact with the patient's vasculature, primary safety considerations focus on minimizing patient risk.
 1. Microvascular anastomotic devices are regulated as Class II devices and require 510(k) premarket notification to receive market clearance. The

labeling must outline where and how the device is intended to be used (e.g., vessel type and diameter) [1].

2. For chemical and biocompatibility, the device must follow ISO 10993-1, -5, -6, -10, -11, which includes cytotoxicity, sensitization, irritation, and systemic toxicity [2].
3. Terminally sterilized implants must follow ISO 11607, requiring sterile packaging to ensure the device remains sterile until use [3].

c. Accuracy and Reliability

- i. The arterial coupler shall demonstrate consistent and repeatable performance for every surgery and must be 100% successful in its use during vascular anastomosis surgery. This entails vessel patency, prevention of vessel leakage, and the ability to withstand the patient's blood pressure without warping or loss of function.
 1. Patency: The coupled anastomosis must allow blood to flow freely through the artery without stenosis or the formation of blood clots. In a study of 25 microvascular anastomoses, the vascular patency was 100%, while the long-term patency rate was 88% [4].
 2. Leak-free: The anastomosis must have no leakage under static or pulsatile conditions.
 3. Pressure resistance: The coupled artery and device must withstand physiological blood pressure without mechanical failure. Physiological blood pressure may range from less than 120/80 mm Hg (16/10.7 kPa) to up to 200 mm Hg (26.7 kPa) for patients with extreme hypertension [5].
- ii. The arterial coupler must have a Reynolds number less than 2000 to ensure consistent laminar flow of blood.

d. Life in Service

- i. The typical duration of an arterial anastomosis surgery utilizing a coupler is 7.3 mins per vessel [4]. The client stated that an ideal final device would be bioresorbable within 2-3 weeks, but the team's prototype may remain in vivo permanently. The arterial coupler is intended for single-use only, and a new, unused device shall be used for each patient.

e. Shelf Life

- i. The device shall be able to remain within sterile packaging for up to 3 years without losing functionality.

f. Operating Environment

- i. Before implantation, the device shall withstand storage conditions of 22.2-25.6°C and a maximum relative humidity of 60% [6].
- ii. During implantation, the device shall withstand handling by surgeons without risk of damage or impacting functionality.
- iii. After implantation, the device shall withstand temperatures of 36.1-37.2°C without losing functionality [7].

- iv. After implantation, the device shall withstand systolic blood pressure of 120-140 mmHg (16.0–18.7 kPa) and diastolic blood pressure of 80-90 mm Hg (10.7–12.0 kPa) without losing functionality [7].
- v. After implantation, the device shall remain intact for 2-4 months before safely degrading [8].

g. Ergonomics

- i. Implantation of the device shall take less than 25 minutes to reduce strain on the surgeon and reduce the risk of ischemia [9].
- ii. During implantation, the product must remain stable to ensure safe and effective end-to-end anastomosis.
- iii. The device shall be capable of being installed by a single surgeon without the application of excessive force.
- iv. The device should be able to be implanted by a first-time user without extensive prior training to reduce the likelihood of user error.
 - 1. An external instruction manual shall be used, as the product is a Class II medical device [10].

h. Size

- i. The prototype shall be scaled up to a diameter of 10-20 mm to facilitate development and testing, with subsequent design iterations targeting progressive miniaturization toward the final intended scale.
- ii. The device shall incorporate an adjustable diameter mechanism capable of accommodating a range of endogenous artery diameters between 2-4 mm.

i. Weight

- i. The implanted device shall weigh no more than the mass necessary to avoid imposing measurable mechanical load on the anastomosis site.
- ii. Weight shall scale with the final device diameter and material density, and cannot be fixed until those parameters are set.
 - 1. Modeling the device as a torus (hoop) with centerline diameter 2-4 mm and cross-sectional thickness 1-2 mm ($V = 2\pi^2 Rr^2$, $R = 1-2$ mm, $r = 0.5-1$ mm), and using common implant material densities (plastics: 900-1450 kg/m³; metals: 4400-8000 kg/m³ [11]), the theoretical device mass ranges from approximately 4.4 mg to 316 mg.
- iii. The device shall be light enough for microsurgical handling and positioning without requiring additional stabilization due to its own mass.

j. Materials

i. Biocompatibility

- 1. The device shall be constructed from materials classified as biocompatible for permanent, blood-contacting implant use in accordance with ISO 10993 [2].
- 2. If any resorbable material is used, the device shall undergo further degradation characterization in accordance with ISO 10993-13 (polymers) or ISO 10993-15 (metals) [2].

ii. Mechanical Properties

1. The device shall use materials with mechanical properties validated against the applicable material standard for the material class selected.
 - a. ASTM D638/D790 for polymers
 - b. ASTM F899/F138 for stainless steel
 - c. ASTM F136 for titanium alloys.
2. The coupler must withstand three primary loading modes under arterial conditions:
 - a. Hoop stress (internal pressure): Design basis of 12.0-18.7 kPa physiologic systolic pressure, with margin toward 26.7 kPa to account for hypertensive patients [\[12\]](#), [\[13\]](#).
 - b. Axial tensile stress (anastomotic pull-apart): Native artery tensile strength is approximately 7.85 ± 3.71 N; sutured anastomoses fail at approximately 3.64 ± 2.2 N [\[14\]](#). The device should exceed the sutured-anastomosis benchmark as a minimum target.
 - c. Wall shear stress: Physiologic arterial shear stress ranges from 1.0-7.0 Pa, site-dependent [\[12\]](#). Rigid rings and protruding elements concentrate stress and disrupt shear patterns at the device-vessel interface, elevating thrombogenic risk [\[15\]](#).

k. Aesthetics, Appearance, and Finish

- i. The device shall present a clean, polished, and professionally finished appearance, with smooth surface texture and uniform coloration to instill confidence in both the implanting surgeon and the patient.

2. Production Characteristics

a. Quantity

- i. The final device is intended to be used once per procedure in order to retain sterility and keep consistent performance.
- ii. The goal for the first semester is to create one working prototype that is scaled up to a diameter of 10-20 mm to demonstrate proof of concept.

b. Target Product Cost

- i. The target product cost per unit should not exceed \$500 as specified by the client.

3. Miscellaneous

a. Standards and Specifications

- i. Anastomotic and microvascular devices are classified as Class II medical devices since the equipment can pose moderate risk to patients during operation [\[10\]](#).
 1. Such devices require 510(k) premarket notification to demonstrate substantial equivalence to an existing, legally marketed device.
- ii. The International Organization for Standardization (ISO) has multiple standards that apply to the development of biocompatible surgical devices and microvascular devices in contact with blood.
 1. ISO 10993 defines requirements for biomaterials if they come in contact with the body [\[2\]](#). The device shall undergo biocompatibility testing covering:
 - a. Genotoxicity (ISO 10993-3)
 - b. Hemocompatibility (ISO 10993-4)

- c. Cytotoxicity (ISO 10993-5)
 - d. Local tissue response following implantation (ISO 10993-6).
 - e. Chemical characterization and extractables/leachables testing (ISO 10993-18)
- 2. ISO 14630 specifies general safety and performance requirements for non-active surgical implants [\[16\]](#).
 - a. Sets baseline requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, and labeling of non-active implants
- 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 [\[17\]](#).
 - ii. Dr. Weifeng Zeng, MD, is an Assistant Scientist and microsurgical instructor at the University of Wisconsin-Madison with a focus on microsurgical education, neural interfacing, and transplantation [\[18\]](#).
 - iii. The clients are seeking a biocompatible, adjustable microsurgical anastomosis device capable of both contraction and expansion. Given their clinical and microsurgical expertise, they prioritize a device that is intuitive to use, reduces operative time, and minimizes procedural complications. For the scope of this semester, adjustability is prioritized over miniaturization.
- c. Patient-related concerns**
 - i. Because the device will come into direct contact with sterile tissue, it is considered a critical instrument and must be sterilized prior to use [\[19\]](#).
 - ii. The most common patient complications associated with anastomosis coupling devices are thrombosis and hematoma, which occurred in 38 of 293 documented cases between 2011 and 2021. Other reported complications were associated with adverse events, including the device functioning differently than expected and difficulties with device connection [\[20\]](#).
- d. Competition**
 - i. The Global Excellence in Microsurgery (GEM) coupler, developed by Synovis, is intended to be used for veins and arteries with a wall thickness of 0.5 mm or less and an outer diameter of 0.8 mm to 4.3 mm. The device requires eversion of the vessel ends, which are secured using pins [\[20\]](#). While this coupler yielded a success rate of 92% in arteries, 8% of the procedures required troubleshooting or reverting to hand sewing due to thrombosis, wall rupture, and arterial vessel thickness preventing eversion [\[21\]](#).
 - ii. Ventrica Magnet Coupler is a prominent magnetic sutureless device for end-to-side anastomosis. This device consists of two pairs of magnetic rings made of sintered neodymium-ferrum-boron materials and two rivet-like rings made of polyetheretherketone. While magnetic couplers have demonstrated significant promise, they require vessel eversion, limiting the usage to only being used in veins. Additionally, the magnetic component can interfere with procedures such as magnetic resonance imaging (MRI) [\[20\]](#).

- iii. A previous University of Wisconsin-Madison biomedical engineering team created a spiral anastomotic coupler to solve this existing problem. Their proposed design was an expandable microsurgical stent modeled to accommodate arterial diameters ranging from 2 mm to 5 mm. However, due to cost and manufacturing constraints, they created a prototype of a spiral cuff fabricated from stainless steel. The proposed procedure consisted of a circumferential suture applied around the cuff to constrain its diameter during the insertion and eversion of the vessel. After positioning the vessel ends, the suture was released, allowing the cuff to expand outward [22].

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B. Design Matrix

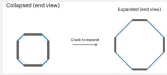
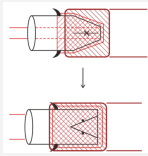
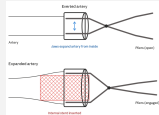
Arterial Coupler Design Matrix									
		Design 1: Crank Expansion		Design 2: Exterior Wedge		Design 3: Plier-Assisted Stent		Design 4: Elastic Clamp	
									
Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Adjustability	30	2/5	12	2/5	12	3/5	18	4/5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

Table 1: Design matrix comparing four arterial coupler designs with relevant criteria and scores.

Criteria Descriptions:

Adjustability: Adjustability refers to the device's ability to fit arteries of various diameters and to move with the artery as blood is pumped through it. The design should adjust in size to be compatible with two different-sized arteries and remain compliant enough to allow the artery to expand and contract with each heartbeat rather than holding it at a fixed diameter. This ensures compatibility with patient-specific anatomies and reduces the risk of stenosis and leakage, as well as intimal hyperplasia associated with compliance mismatch between rigid devices and native arteries. The ranking will be based on the adjustment mechanism, the achievable diameter-adjustment range, the device's compliance relative to the native artery at both diameters, and the mechanical reliability of the device under repeated pulsatile loading.

Efficiency: Efficiency will be determined by the total time required to implant the device and successfully restore blood flow. Per the clients' requirement, the device should significantly reduce the

procedure time compared to current anastomosis methods. Minimizing implantation time had the second-highest rank, as prolonged ischemia can lead to tissue damage and organ failure.

Ease of Use: Ease of use is determined by the device's ergonomic capabilities during use by a surgeon. Due to the technical difficulty of anastomosis procedures, the device should reduce the learning curve and overall surgical duration. The device should minimize the need for fine motor manipulation and precise alignment while maintaining its functionality. Creating a device that is easier to use will increase the accessibility of the procedure by allowing less specialized surgeons to perform the anastomoses.

Safety: Safety is scored based on design features that predict injury during and after implantation, such as vessel wall trauma (penetration, sharp or rough edges), thrombogenicity (exposed intraluminal material, lack of intima-to-intima apposition), leak risk, biocompatibility of materials based on prior implant use, and the number of deployment steps that could fail or depend on surgeon technique. The safest design will minimize sharp/rough edges and material toxicity, and maximize mechanism simplicity.

Durability: Durability refers to the device's ability to withstand physiological conditions while maintaining structural, physical/chemical, and mechanical properties during and post-surgical procedure. The device must resist fatigue, corrosion, and degradation while retaining its strength, toughness, and elasticity.

Fabrication: Fabrication measures how easily and cost-effectively the device can be produced. The ranking will be based on available materials, processes, and technologies necessary to construct the device. This includes complexity of techniques and their tolerances, scalability, and reproducibility of the device.

Cost: The initial prototype device must be produced within the project's \$500 budget, without compromising functionality or performance. Each design receives a cost score from 5 (estimated prototype cost of \$100 or less) to 1 (more than \$400 and up to \$500), in \$100 steps, with any design exceeding the \$500 budget eliminated before scoring.

Design 1: Crank expansion

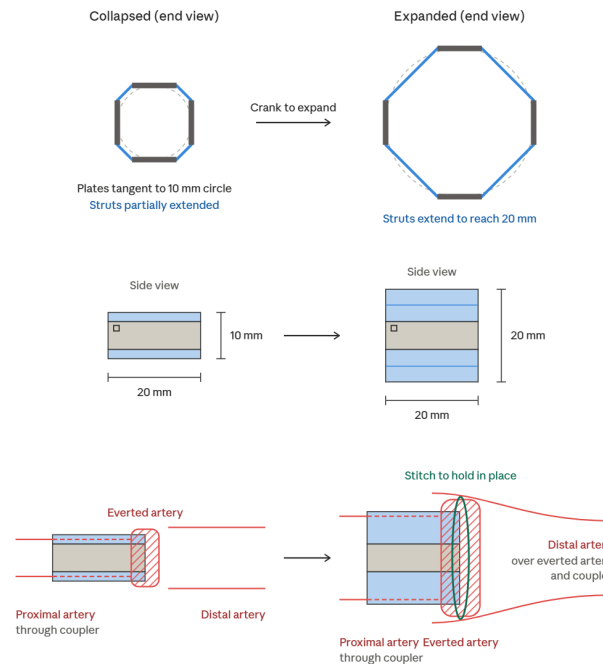


Figure 1: A scaled-up prototype of an expandable coupler is cranked from a 10 mm to a 20 mm diameter, after which the proximal artery is passed through the coupler and everted over its end, the distal artery is drawn over the everted artery and coupler, and a circumferential stitch holds the anastomosis in place (dimensions shown are for the scaled prototype, not the final arterial device).

Design Description: The expandable coupler is a short tube made of four flat plates connected at the corners by sliding struts. The proximal artery is passed through the coupler and folded back over its end, and the distal artery is pulled over the top. A separate crank tool can be used to push the plates outward, sliding the struts out to fill the gaps between them and widening the coupler. After expansion, the plates then lock in place, and a stitch is placed around the overlap holding the connection secure.

Adjustability: This design scored a % for adjustability. The cranking mechanism allows the coupler to widen to match the artery, providing consistent blood flow through the connection point. However, once expanded, the plates lock in place and form a rigid tube, so the artery segment over the coupler cannot expand and contract with each heartbeat. This compliance mismatch between the rigid device and the surrounding artery may increase stress at the connection and the risk of intimal hyperplasia over time. Additional concerns arise with repeatability and range of expansion. The everted artery may require a device with a small initial diameter to achieve eversion, and the expansion range may not accommodate two arteries with different diameters. Finally, repeating consistent expansion may be difficult, as different arteries could react differently to expansion and potentially rupture.

Efficiency: This design scored a % for efficiency, as having an external cranking mechanism allows for a quick and controlled expansion, overall reducing operation time. Additionally, having an external device rather than an internal one minimizes the amount of time it takes to implant the device onto an artery.

Ease of Use: The crank design scored a % for ease of use due to the expected difficulty in attaching the everted walls onto the crank. Additionally, with a small area covering the crank, expanding may prove more difficult than internal methods.

Safety: This design scored a % for safety. Its strengths are intima-to-intima apposition, achieved by everting the proximal artery over the coupler, and an extraluminal position that keeps implant material out of the blood path. These are outweighed by the implant's multiple moving parts (four plates, sliding struts, and a lock), which greatly increase the risk of injury. The sliding struts create pinch points, and the thin plate edges pose a laceration risk at the fold where the artery wraps over the coupler rim.

Durability: This design scored a % for durability as the cranking mechanism involves thin sheets of metal pushing the cylindrical structure outward to increase the device's diameter. The thin sheets of metal are more likely to degrade, corrode, and fail under the compressive forces of the everted and connected artery. However, the bulk of the device's structure can resist degradation and corrosion.

Fabrication: This design scored a % for fabrication as the expansion mechanism requires microfabrication. Consistently creating a device with a functioning mechanism requires expensive industrial equipment. The device also requires multiple moving parts, adding complexity to the fabrication and difficulty in scaling each part appropriately to create various sizes.

Cost: This design scored a % for cost. This device has many small parts with high tolerances, which likely requires high-resolution printing or machining, plus several rounds of iteration to get the sliding fit right.

Design 2: Exterior Wedge

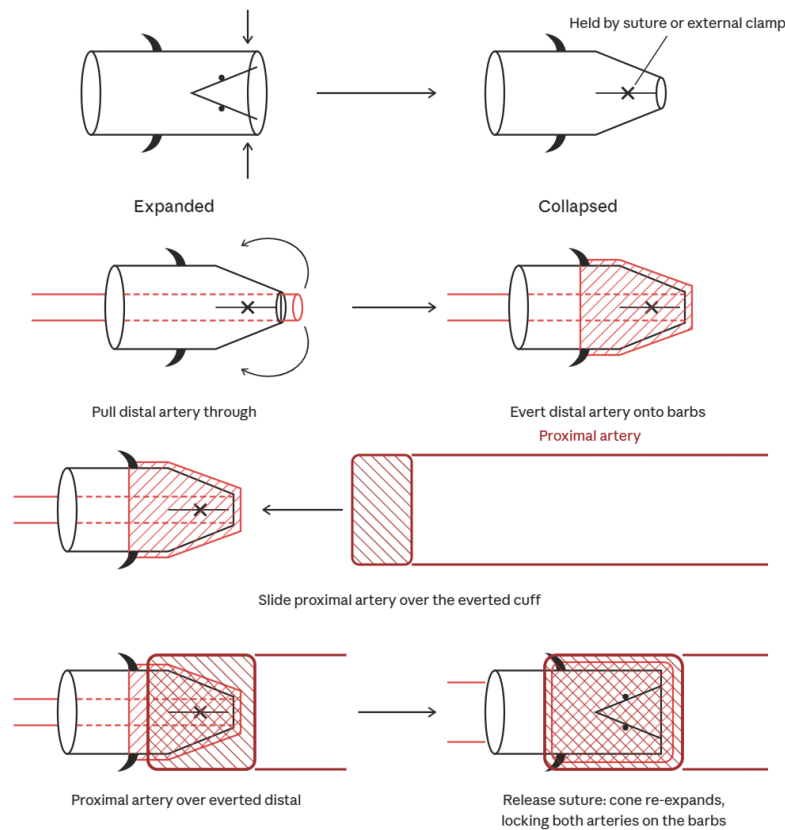


Figure 2: A barbed cylinder with a wedge cut is collapsed into a cone and held with a suture; the distal artery is pulled through and everted onto the barbs, the proximal artery is slid over it, and releasing the suture lets the cone re-expand to lock both arteries in place.

Design Description: The wedged-cone coupler is a barbed cylinder with a V-shaped wedge cut into one end. Pressing the two sides of the notch together closes the V and tapers that end into a cone, which is held collapsed by a suture across the seam or by an external clamp. The distal artery is threaded through the device from the wide end and pulled out through the narrow cone tip. Its free end is then everted back over the outside of the cone and pushed onto the barbs, which point away from the tip so the cuff cannot slide forward off the device. The cone's tapered profile makes the eversion easier, because the vessel is stretched gradually rather than all at once over a blunt edge. Next, the proximal artery is slid over the everted distal cuff. Finally, the suture is cut or the clamp removed, and the cone springs back to its original cylindrical shape. The re-expansion presses both arterial layers outward, so the distal artery is locked on the barbs and the proximal artery is held over it by an interference fit. The result is an intima-to-intima connection with the device outside the blood-contacting surface.

Adjustability: This design scored a % for adjustability. Compressing the wedge allows the device to temporarily narrow for easier eversion, but once released it returns to a fixed diameter, so accommodating different artery sizes depends on fabricating the device in multiple sizes rather than adjusting it during the procedure. This allows anastomosis of arteries with slightly differing diameters but limits the range of

sizes a single device can serve. The V-shaped seam may allow some radial flexing with each heartbeat, giving this design more potential for compliance than a closed rigid tube. However, the material must be stiff enough to resist compression forces from the everted and connected arteries and prevent lumen narrowing. A spring-like material that resists collapse while still flexing at the seam would be considered.

Efficiency: This design scored a 4/5 for efficiency. Having the device be external rather than internal overall reduces the time it would take to put the device onto an artery. However, having to manually release the suture and wait for the device to expand may cause user errors, overall reducing the total procedure time.

Ease of Use: The wedge scored a 4/5 for ease of use due to its simple and tapered design. The tapering allows the wedge to slide into the artery with minimal precision and acts as a guide for insertion. Additionally, once inserted, the expansion requires no manual steps, simplifying the procedure.

Safety: This design scored 4/5 for safety. As a single piece with no moving parts or deployment tool, it has few mechanical failure points. Its tapered cone allows gradual eversion, which reduces intimal tearing, and greatly achieves intima-to-intima apposition with no device material in the blood path. However, the barbs penetrate the vessel wall and could protrude into the intimal healing interface. The re-expansion force cannot be adjusted, and excess force risks wall injury, while too little could let the proximal artery slip or leak.

Durability: This design scored a 4/5 for durability. Since it is a single, uniform piece, the device has low risk of corrosion or degradation. The rigid structure provides more radial strength and resistance to internal pressure, but it may be prone to fatigue and fracture. Additionally, the procedure requires the wedged piece of the device into a cone-like structure, which may create internal stress and surface cracks, reducing its durability.

Fabrication: This design scored a 5/5 for fabrication as it is a simple, single piece. The device can easily be 3D printed in mass quantities. This printing method would decrease the cost per unit. Since the device is a single piece, it can easily be scaled to 2 mm, 3 mm, and 4 mm diameters. The device can be mass-produced at different sizes to provide various options during a procedure.

Cost: This design scored a 5/5 for cost. A single printed polymer part with no assembly keeps cost low and makes reprinting after each revision cheap, assuming a polymer-based prototype. Using a nitinol/metal version would drop the score significantly.

Design 3: Plier-assisted stent

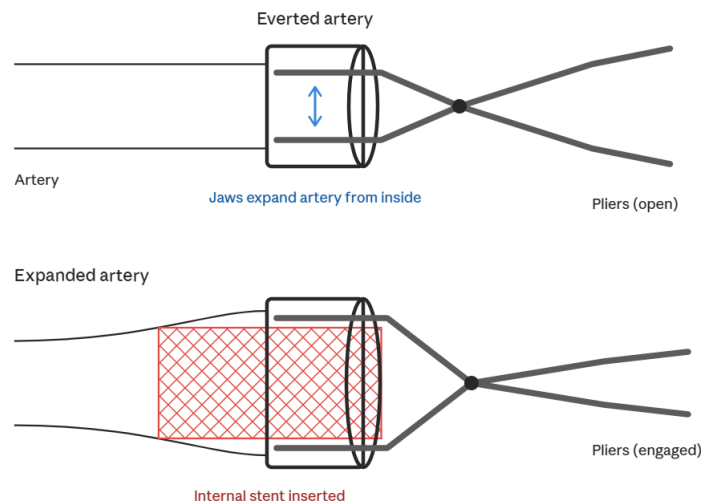


Figure 3: Diagram of the plier-assisted stent design which uses a plier-like device to expand the distal artery to a specified diameter prior to attachment to the proximal artery.

Design Description: Pliers are inserted into an everted, open artery during an anastomosis procedure. The pliers engage, widening the diameter of the artery and allowing a stent to be placed inside the artery. This expanded artery can now be attached to an artery with a larger diameter.

Adjustability: This device scored a % for adjustability. The plier system allows the surgeon to expand the artery to a workable diameter during the procedure, giving it a wide and continuous range of adjustment for connecting arteries of different sizes. The pliers require force from the surgeon to expand the artery, and this force must be controlled to avoid damaging the artery wall. However, a rigid stent would hold the artery at a fixed diameter and create a compliance mismatch with the surrounding vessel. A flexible, self-expanding stent could better allow the artery to expand and contract with each heartbeat. Additionally, stretching the smaller artery to match the larger one may leave its wall stiffer and less able to expand, reducing compliance at the connection.

Efficiency: This design scored a % for efficiency. Having to manually expand an artery with the pliers increases operation time, as the surgeon will need to be precise in order to work at a small scale and prevent damaging the artery. Additionally, having to place the stent internally will also add to the overall operation time.

Ease of Use: The plier-assisted stent scored a % for ease of use. Using pliers to open and expand the artery is expected to require fine motor precision. However, once expanded, inserting the stent will likely be simple due to the larger opening of the proximal artery.

Safety: This design scored % for safety. The plier tool is simple, and a commercial stent would have established biocompatibility. However, the stent sits inside the lumen, exposing device material to blood and increasing the risk of thrombosis and restenosis. The pliers apply concentrated force directly to the intima, risking tearing. The method of joining the arteries is not defined, so intima-to-intima apposition cannot be confirmed.

Durability: This device scored a % for durability. A stent has many thin struts that are susceptible to fatigue and fracture, especially when it is expanded in a non-uniform way with the plier-like tool. The interconnected, mesh structure creates numerous stress concentration points prone to mechanical failure, as opposed to more rigid designs.

Fabrication: This device scored a % for fabrication as there are multiple parts that require complex fabrication. The plier device must have tolerances of ~0.5 mm to ensure uniform arterial expansion and to properly fit arteries. The plier also requires fabrication of multiple parts. However, the difficulty of the fabrication results from the stent. The stent requires microfabrication that is both complex and expensive, reducing mass production capabilities.

Cost: This design scored a % for cost. The pliers can likely be adapted from existing instruments at low cost, but the stent is the cost driver. A commercial vascular stent is a prescription device that is expensive and hard for a student team to obtain, and would likely exceed the budget.

Design 1: Elastic Clamp

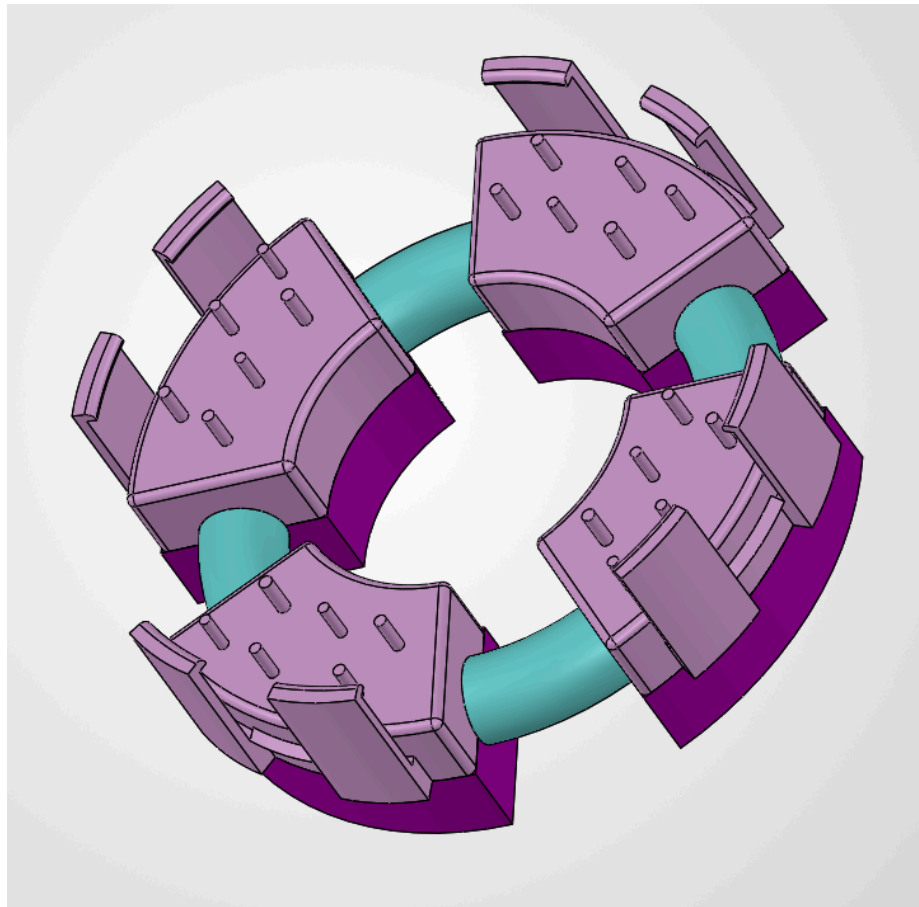


Figure 4: Elastic clamp ring with elastic silicone ring. Silicone ring allows expansion of the device during implantation and increases in blood pressure.

Design Description: The elastic clamp design consists of two identical ring assemblies, one attached to the end of each artery. Each assembly is built from a continuous circular ring of elastic material with four rigid quarter-circle pieces attached separately around its circumference. The rigid pieces are spaced so that short sections of the elastic ring remain exposed between them, allowing the ring to stretch and recoil as the artery expands and contracts with each heartbeat. During the procedure, the end of each artery is passed through the center of its ring and everted back over the outer cylinder wall, where an atraumatic surface supports the vessel and reduces damage to the arterial wall. Each rigid piece carries an interlocking hook that extends across the gap between the two rings and hooks over the full surface of the opposing ring, securing the connection in both directions. Once joined, the everted ends of the two arteries are held face to face, creating an intima-to-intima connection with the device kept outside the blood-contacting surface. To accommodate arteries of different diameters, the rigid quarter-circle pieces can be designed to attach to elastic rings of different sizes, so only the elastic ring needs to be changed to fit a given artery.

Adjustability: This design scored a % in adjustability. The elastic ring allows the device to expand and contract with the artery during each heartbeat, giving it the best compliance of the designs so far. Although the device cannot be adjusted during the procedure, it can be fitted to different arteries by fabricating and stocking elastic rings in multiple sizes, with the same rigid pieces attaching to each ring. However, joining two arteries of different diameters would require two rings of different sizes, and the hook mechanism would need further adaptation to engage reliably across mismatched rings. Compliance is also limited to the exposed elastic sections between the rigid pieces, so the device size would need to be optimized by vessel size.

Efficiency: This design scored a % in efficiency. Once each artery is everted over its ring, the connection is completed by pressing the two rings together until the hooks engage, with no suturing required. This should significantly reduce procedure time compared to hand-sewn anastomosis. The main time cost is everting two arteries, and without pins or barbs to hold the everted tissue, the artery may slip off the ring before the rings are joined, requiring repeated attempts.

Ease of Use: This design scored a % in ease of use. Hooking the two rings together is a simple motion that does not require precise suturing. However, everting each artery over the ring still requires fine motor manipulation, and all hooks on each ring must be aligned with the opposing ring for the connection to secure properly. The surgeon must also choose the correct elastic ring size before the procedure, adding a step that depends on accurate vessel measurement. These issues could be mitigated through the development of an eversion-assisting device or clamping applicator for precise alignment.

Safety: This design scored a % in safety. The intima-to-intima connection keeps all device material outside the blood-contacting surface, reducing thrombogenicity, and the atraumatic surface avoids penetrating the vessel wall. Concerns arise from the hooks, which must be shaped to avoid sharp edges contacting the vessel, and from potential leakage if the elastic sections stretch and open small gaps between the everted arteries. The hooks could also disengage under repeated pulsation if the elastic ring loses tension. Materials chosen for the device must be confirmed to be, biocompatible and mechanically favorable.

Durability: This design scored a % in durability. The elastic ring will undergo many stretch cycles during the healing process, and many elastic polymers lose stiffness or permanently deform under this repeated loading, which could weaken the hold between the hooks and the opposing ring. The bond between the rigid pieces and the elastic ring is also a likely failure point, as it experiences stress with every heartbeat. Durability will depend heavily on the materials selected and should be verified through cyclic fatigue testing.

Fabrication: This design scored a % in fabrication. The modular design simplifies production, since the same rigid pieces can be used with elastic rings of different sizes. However, the device requires two materials joined together, and the hooks must be produced at a very small scale with tight tolerances to engage reliably. A prototype can be easily produced at an enlarged scale using 3D printing for the rigid pieces and a molded elastic material for the ring.

Cost: This design scored a 4% in cost. The estimated prototype cost is between \$100 and \$200, based on resin 3D printing for the rigid pieces and a silicone molding kit for the elastic rings. Producing multiple ring sizes adds some material cost, but both processes are low-cost and accessible through university facilities.