Arterial Coupler Re-Design: Adjustable Stent/cuff Anastomosis

Preliminary Product Design Specifications

BME 400 | LAB 308

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September 18, 2025

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 120/80 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 without structural deformation. Typical arterial blood pressures range from 120/80 mmHg (systolic/diastolic) [7].

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 ^{o}C [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 ^{o}C. Irreparable damage to organs can occur when body temperatures are outside of 32.2-41.1 ^{o}C [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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