Adjustable Coupler for Arterial Anastomosis

Preliminary Product Design Specifications

BME 400 | Lab 306

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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, whereas the device should be 10.0 mm to 20.0 mm to prove device 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 ($V = 2\pi^2Rr^2$, 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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