Stent-based anastomotic coupler

Design Team
Nick Cote, Ryan Myers
Matthew Ouellette, Jessica Patel
David Schecter

Design Advisor
Prof. Jeffrey Ruberti
Email: J.Ruberti@neu.edu

Abstract
Microvascular anastomosis is a surgical procedure in which the ends of two blood vessels are connected via hand suturing by a specialized surgeon. A single anastomosis can take 60-120 minutes, extending total surgery time by hours, which drastically increases risk of postsurgical infection and surgeon error due to fatigue. Currently there exists no medical device to expedite the anastomosis of both arteries and veins. The primary objective of this project is to demonstrate proof of concept for a novel microvascular anastomotic coupling device that utilizes a stent to maintain vascular patency while vessel coaptation is achieved. This device would work by inserting a constrained stent at the site of anastomosis, deploying it once the two vessel ends are in contact. Friction forces hold the two vessel ends together while the coaptation is achieved with tissue glue. Stent constraintment mechanisms developed included integrated hook designs, suture constraintment and a brittle sheath design. The brittle sheath design was pursued with both ice and sucrose coatings, as it provides the most biocompatible, manufacturable and reliable constraintment mechanism, while being easily deployable in a timely manner. Preliminary ABAQUS analysis and sheath mold testing provides a positive proof of concept.
The Need for Project

There is a need for a novel anastomotic coupler that drastically reduces surgery time, while also being capable of performing venous and arterial anastomoses.

Microvascular anastomosis is a surgical procedure in which the ends of two blood vessels are connected via hand suturing by a specialized surgeon. A single anastomosis can take 60-120 minutes, extending total surgery time by hours. Increased time of surgery drastically increases the rate of postsurgical infection and surgeon error due to fatigue, in addition to consuming valuable hospital time and resources. In military settings, patients requiring microvascular reconstruction often end up with limb amputations due to lack of time or specialized surgeons in the area. Existing coupling devices on the market reduce the time needed to perform anastomoses, however, are only suitable for use on venous anastomoses; there is a need for a novel anastomotic coupler that drastically reduces surgery time, while also being capable of performing venous and arterial anastomoses.

The Design Project Objectives and Requirements

The primary objective is to demonstrate proof of concept for a novel microvascular anastomotic coupling device that utilizes a stent to maintain vascular patency while vessel coaptation is achieved. This device shall be biocompatible, easy to use, and perform anastomoses rapidly.

Design Objectives

The intent of this project is to design a microvascular anastomotic coupler that utilizes a stent, as required by the project sponsor, to maintain vascular patency (expansion) while vessel coaptation (adhesion) is achieved. The coupler shall allow the anastomosis of both arteries and veins, creating a biocompatible, leak proof connection between two microvascular vessels 2-4mm in diameter. It is desired that the device be easy to operate, simplifying anastomosis procedures so that a highly specialized surgeon is not required to perform the operation, reducing procedure times from 60-120 minutes to below ten.

It should also be noted that the coupler must function properly for only 4 weeks, as collateral blood vessel networks will have formed in grafting procedures by this time.

Design Requirements

The design requirements of this project can be separated into three distinct design challenges: stent selection, stent deployment method, and vessel coaptation method. The critical parameter driving stent selection is the outward pressure the stent can exert on the blood vessel lumen; it must produce a high enough outward pressure to overcome slipping and hold the two ends of the blood vessels together, while not being so high as to injure the lining endothelial cells of the blood vessel.
lumen (175 kPa for veins and 250 kPa for arteries). Additionally, the stent must be small enough to be easily manipulated in microsurgical settings. The deployment method design is dictated by the unique environment in which the stent is being deployed. In traditional stenting procedures a guide wire catheter system is employed, but in an anastomosis surgical setting a catheter system is not applicable as the lesion site is open to the surgeons. As such, it is desired that the stent shall be deployable without an inter-lumen device in such a way that secures each vessel independently, consistently and reliably. This will be accomplished with a nitinol self-expanding stent, as these superelastic, shape memory devices expand to vessel diameters from constrained geometries (Rep. 6). Finally, the coaptation method shall provide a leak proof joint capable of withstanding diastolic and systolic blood pressures.

**Design Concepts Considered**

Three unique mechanisms were considered for the constrainment of the stent: altering stent geometries to incorporate latching hooks, utilizing sutures tied in slipknots to be untied by the surgeon, and a brittle sheath to be fragmented from the outside of the vessel.

**Integrated Hook Designs**

Designs requiring the alteration of stent geometries that integrate constraining mechanisms within the stent weave were initially considered. In the collapsed state, integrated hooks bend towards the central axis of the stent, latching to each other and constraining the stent to its delivery diameter. An applied force causes the hooks to unlatch, allowing the stent to expand. The hooks, made of the same shape memory nitinol as the stent weave, return to their at rest state in line with the stent wall, so as to not induce turbulence in the blood flow. These hooks could be arranged in either an axial or circumferential manner; with an alternative design utilizing the use of external hooks.

**Two Point Suture Constrainment**

The sutured stent design involves constraining both ends of the collapsed stent with surgical suture, that is, one knot on each end of the stent. The sutures are knotted in such a way that pulling the loose end unties the suture easily, deploying the stent. Experimental and FEM analysis disproved the feasibility of the two point suture constraining mechanism (Rep. 11).

**Brittle Cap/Sheath Designs**

This design involves the constraint of a collapsed stent with a
brittle and bioresorbable material, either in the shape of end caps or as a sheath that runs the axial length of the stent. In surgery, the distal end of the device would be inserted into one of the vessels and deployed by applying pressure to the outer surface of the vessel wall, fracturing the coating and deploying that half of the stent. This process is repeated with the other end of the device in the other vessel end. The brittle coating is then absorbed by the vessel walls as healing occurs.

**Recommended Design Concept**

A brittle sheath design will reliably constrain a stent while allowing for extra-luminal, two-sided deployment with minimal vascular manipulation.

**Design Description**

Based on its high biocompatibility, ease of use, and manufacturability, the brittle sheath concept was chosen as the recommended design. Multiple sheath material options were considered including ice, sugar, salt, and poly-L-lactide (PLLA). Ice and sucrose were chosen as potential material options because they satisfy the biocompatibility design requirement, while also being bioresorbable. Due to their differing material properties, these two materials require unique mold designs to create a brittle sheath geometry that facilitates two sided stent deployment without an inter-lumen device. To accomplish this with the ice sheath one half of the length of the ice sheath is smaller in diameter and mass than the other half in addition to featuring raised ribs to increase surface area, thus increasing energy transfer due to heat interactions. The intention of this design is to bias the smaller, ribbed side of the ice sheath to a faster melting time. The smaller side is inserted into one vessel and remains there until melted or fractured by the surgeon, deploying the stent. This process is repeated for the other vessel end. In addition to the outer sheath, the stent has a supportive core of ice which aids in both the manufacturing of the design and to stabilize the temperature of the assembly. Alternatively, the mold for the sucrose sheath does not have raised ribs on one side, but features a ridge separating the two ends of the stent, allowing for two-sided deployment. Once the two vessel ends are contacted with the deployed stent, leak-proof coaptation can be achieved with the application of fibrin tissue glue. To meet the geometric and force stent design requirements, stents ranging from 2 to 4 mm expansion diameter and 20 mm in length were selected, which provided the necessary outward force in testing performed by the project sponsor.
Experimental Investigations
A prototype mold was created to test ice sheath designs in which water is frozen to create an outer sheath. A stent will be deployed into this frozen sheath, inside of which an ice inner core is created. Testing will be performed to determine the melting time for the sheath as well as the sheath’s ability to constrain a stent. Similarly, a prototype mold will be built and used in conjunction with a heated sucrose and water mixture to create a brittle sucrose sheath. The mold will be tested for its ability to constrain a stent as well as the time it takes to dissolve the sucrose when subjected to water.

Analytical Investigations
Mechanical analysis in Abaqus predicted a failure safety factor of 2.96 for the ice sheath based on conservative loading and the yield strength of ice at freezing. Thermal analysis in Abaqus predicted a melting time of about 60 seconds for the ice sheath, which was deemed acceptable (Rep. 10.2.3).

Key Advantages of Recommended Concept
The brittle sheath constrainment mechanism provides the reliable constrainment of a stent, is easy to deploy in a timely manner, and is highly biocompatible as well as readily manufacturable.

Financial Issues
As this is a proof of concept/prototyping phase there were no significant financial issues with the prototype molds. The mold design appears to be easily manufacturable and economically competitive for future generations of the device, as stereolithography enables easy mold fabrication, and the sheath materials (sugar, ice) are readily available.

Recommended Improvements
Testing of the prototype molds revealed room for improvement in the mold design itself, specifically in the reduction of flash. In addition, extra testing is needed to determine the optimal sheath thickness for the desired melting/dissolving time. Potential future designs could include palliative drugs/chemicals in the sheath solution, such as anti-coagulants, steroids, anti-inflammatories.