Design, Fabrication, and Testing of a Novel End-to-End Vascular Coupling System

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***Abstract*— Microvascular anastomosis is common and necessary during reconstructive and free tissue transfer surgeries. Traditional hand suturing techniques are time consuming, subject to human error, and require complex instruments. Prior attempts including staples, ring-pin devices, cuffing devices, and clips were either more cumbersome, were unable to maintain a tight seal, or did not work for both arteries and veins. To provide a more efficient and reliable vessel anastomosis, a pin-free vascular coupling system that can be used for both arteries and veins was designed and manufactured. A set of corresponding instruments were developed to facilitate the anastomosis process. Both bench testing and *ex vivo* testing were performed to evaluate the operating abilities of the vascular coupling system. Preliminary studies were performed on cadaver pigs.**

I. Introduction

During replantation and free tissue transfer surgeries, it is often necessary to cut and reattach vessels [1]. The current state of the art in microsurgical vascular anastomosis is hand suturing the two cut ends of an artery or vein together using ultrafine techniques with the assistance of an operating microscope [2]. This technique requires specialized training, is time consuming, expensive when considering doctor and operating room time and is subject to a great degree of human error [3]. There have been many attempts to identify alternatives to the current manual suturing technique. Typical examples are staples, clips, cuffing rings, adhesives and laser welding [4,5,6,7,8,9,10,11,12,13], all of which have fallen short due to the lack of biocompatibility, complexity of design and general inefficiency.

A commercially successful approach to simplifying the manual suturing technique exists with the "GEM Microvascular Anastomotic Coupler" (Synovis Micro, Birmingham, AL) [14]. This device makes use of two high density polyethylene (HDPE) rings which are anchored to the cut ends of two veins. The two rings are then brought together to juxtapose the two cut vessel ends, thereby re-establishing the continuity of the vein. Due to the increased wall thickness, elasticity, and intraluminal pressure of arteries over veins, this device has had a limited role in successful arterial anastomosis. Attempts at using this device for arterial anastomosis have only been successful with significant modification, which undesirably adds time and complexity over traditional manual suturing. Another vascular coupling device partially solved the problem by replacing the rigid ring base with a ring having five rotating wings [15]. While this device works well for arteries, it can still require some manual manipulation of the vessel for consistent pin penetration. It is worth noting that most of the current anastomotic devices involve the eversion of the vessel end, which stretches the blood vessel wall and increases the possibility of tearing if pins are used.

The new vascular coupling system provides an easy and efficient installation process without the use of wall-penetrating pins. A set of installation instruments has been developed to facilitate the anastomosis process. Mechanical and *ex vivo* testing have been performed to estimate the functionality and feasibility of the vascular coupling system. Preliminary studies were performed on cadaver pigs.

II. Materials and Methods

A. Coupler design and fabrication

The coupler consists of an engaging ring and a back ring for each vessel end (Fig. 1). In the process of anastomosis (Fig. 2), one end of the vessel is passed through the back ring with about 2mm of vessel extending beyond the edge. The end of the vessel is then clipped (1-2mm) to allow for release of tension at the free edge and easy eversion of the vessel over the back ring. Finally the engaging ring is installed onto the back ring and a friction fit is used to engage the clipped ends of the vessels between the engaging ring and the back ring. The same installation process is performed on the opposite vessel. The two couplers installed on the vessel ends are offset 90°. When connected, the two arms on the engaging rings hook into a groove at the bottom of the opposing back ring to finally lock and secure the two vessel ends to each other.

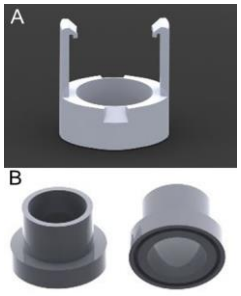

Figure 1 (A) The engaging ring, (B) The back ring.

Research supported by TCIP from University of Utah.

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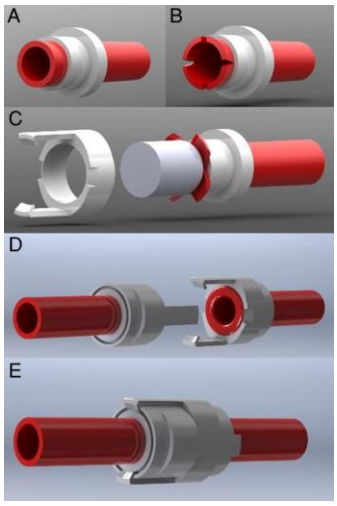

Figure 2 (A) The vessel is passed through the back ring, (B) The end of the vessel is clipped 1-2mm, (C) The vessel end is everted using the temporary placement of an anvil, (D) The engaging rings are installed on both vessel ends, (E) Two vessels are connected.

The device is designed to keep the vessels open and prevent any parts from coming in contact with blood flowing through the vessel, which not only reduces the chance of blockage or collapse at the point of coupling, but reduces the risk of thrombosis.

Coupler prototypes were fabricated and designed to establish the proof of concept. The engaging rings were built from Vero White and polylactic acid (PLA) using 3D printing techniques. Back rings were built from polymethyl methacrylate (PMMA) using laser cutting.

B. *Installation apparatus*

A set of instruments aimed at facilitating the anastomosis process using the coupler were designed and fabricated. The instrument set includes a holder and an anvil instrument (Fig. 3). The holder is used for holding the back ring. In the holder instrument, two anchor arms are connected using the pinned hinge at the end. The difference between the two anchors is that the heads are offset from each other by 90° to allow the two couplers held by the instruments to be locked with each other at the completion of the anastomosis process. Each anchor arm is used for one cut end of the vessel to be anastomosed.

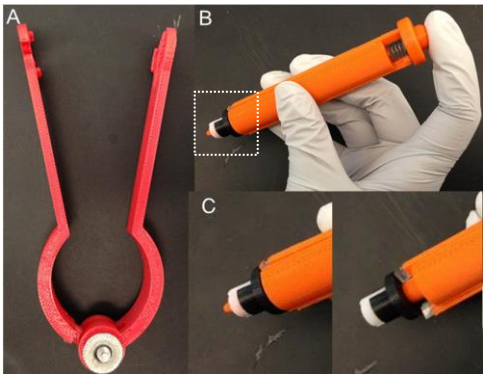

Figure 3 (A) The holder consists of two anchor arms, (B) The anvil tool with engaging ring, (C) A closer look of "Pushing the engaging ring".

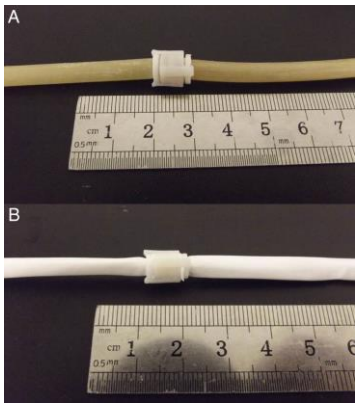

Figure 4 (A) Latex tubing was connected with the couplers, (B) ePTFE tubing was connected with the couplers.

The anvil instrument is a pen-shaped rod with an anvil head (Fig. 3(B)). The engaging ring rests on the outside of the anvil rod and can be pushed onto the back ring by sliding the pen cap back and forth. The anvil instrument has two main functions: (i) the outline of the anvil is designed to evert the clipped vessel end (Fig. 2(C)) and (ii) the pen cap pushes the engaging ring onto the back ring such that the clipped vessel end is fixed between the engaging ring and back ring using a friction fit.

C. *Mechanical testing*

The couplers were tested on both latex tubing and ePTFE tubing with the installation instruments. Latex tubing was selected to simulate the artery due to its relatively similar properties and thick elastic wall. ePTFE was selected to simulate the vein due to its reduced expandability and thin tubing wall. By adjusting the gap between the engaging ring and the back ring, both tubing types were successfully connected with couplers.

A flow test was performed to evaluate the couplers' effects on the flow in the vessel. Two latex tubes were connected with couplers. Another piece of uncut latex tubing with the same length as the coupled one was prepared as a control. Pressurized water was introduced at a rate of 150ml/min- 250 ml/min, which corresponds to a typical range of blood flow rate for arteries with a diameter in the 3-5 mm range, and pushed through both the coupled and control tubes. The pressure before and after the couplers was measured with a pressure gauge.

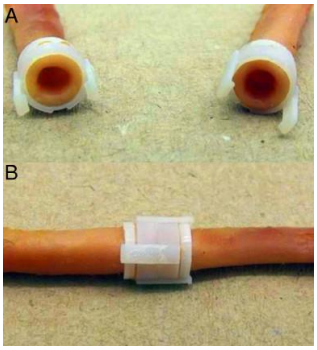

Figure 5 (A) Cross section of human cadaver arterie ends after installation of the engaging ring, (B) Two pieces of human cadaver arteries were connected.

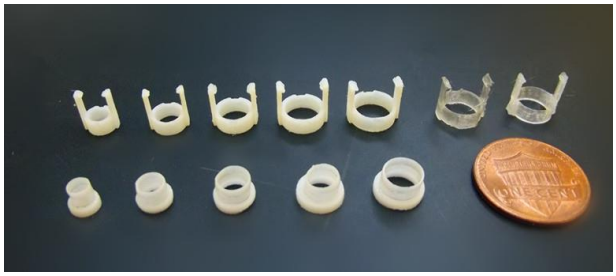

Figure 6 Engaging rings and back rings were manufactured in various sizes for vessels whose outer diameter ranges from 2mm to 6mm.

D. Ex-vivo testing and cadaver animal study

Human cadaver vessels with a 5 mm inner and 6 mm outer diameter were used to test the functionality of the couplers (Fig 5). By adjusting the gap between the engaging ring and the back ring, the couplers are applicable to vessels with different wall thickness.

A qualitative leakage test was performed on two pieces of porcine vessels connected with couplers. One end of the vessel was plugged, and pressurized water was applied from the other end using a syringe. Pressure was increased slowly until the uncoupled portions of the of the vessel expand. Both arteries and veins were tested.

A preliminary study was performed on a cadaver pig using the vascular coupling system and the installation instruments. The aim of the study is to evaluate the functionality of the system in a mock surgery scenario.

III. Results and Discussion

A series of couplers were manufactured and can be used for vessels whose outer diameters are in 2mm-6mm range (Fig 6). Engaging rings were made from both Vero White, a synthetic material used for proof of concept prototyping and PLA with 3D printing techniques. Back rings were made from PMMA with laser cutting.

In testing the functionality of the device, after the engaging ring was installed on the back ring, it was found that the back ring was completely covered with the everted vessel end and was not exposed (Fig 5(A)), the clipped vessel ends were all secured well between the engaging ring and the back ring, leaving a smooth everted vessel intima for the next coupling step.

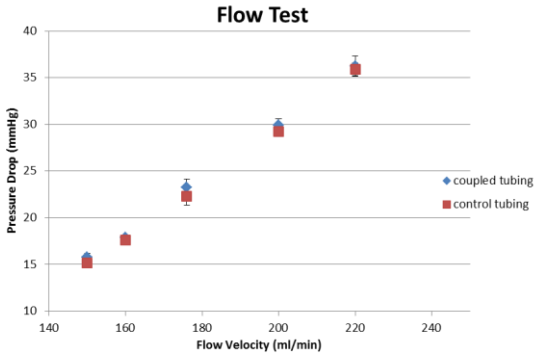

Figure 7 Plot of the flow test data showing the relationship between pressure drop in the tubing versus flow rate across coupled and control tubing.

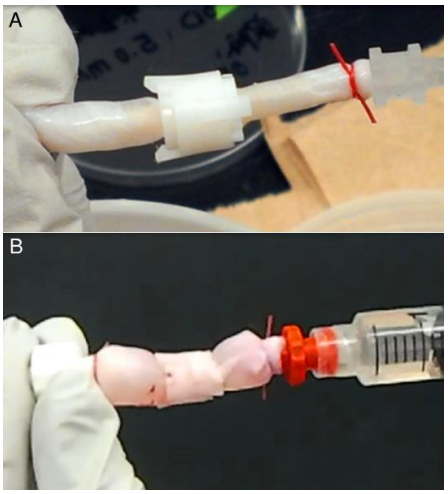

Figure 8 (A) Leakage tests were performed on porcine arteries, (B) Leakage tests were performed on porcine veins.

The coupler flow test results are plotted (Fig. 7) as the pressure difference across the simulated test vessel versus the driving flow rate. The flow test showed that the coupler did not restrict the flow significantly compared to the uncut tubing. These tests were performed multiple times at various flow rates and the differences in pressure drop were minimum, compared with uncut tubing. It can be concluded that the coupler has little effect on the flow.

The coupler leakage test was performed on both porcine arteries and veins. The whole process was recorded and Fig 8 shows the final status of the process. Unbounded portions of the vessel expanded with increasing pressure. There was no leakage found at the coupling point of the vessel during the whole process. A quantitative test is being developed.

A severed renal artery was reconnected in a cadaver pig (Fig 9). The cadaver animal test provided information on the operating abilities of the couplers and the installation instruments in a more realistic environment. The whole anastomosis process was proven to be accomplished in a limited space. In a real surgery, the dimension of the blood vessels will be varying in a certain range. Couplers and instruments that can be used on different sizes of vessels are being developed.

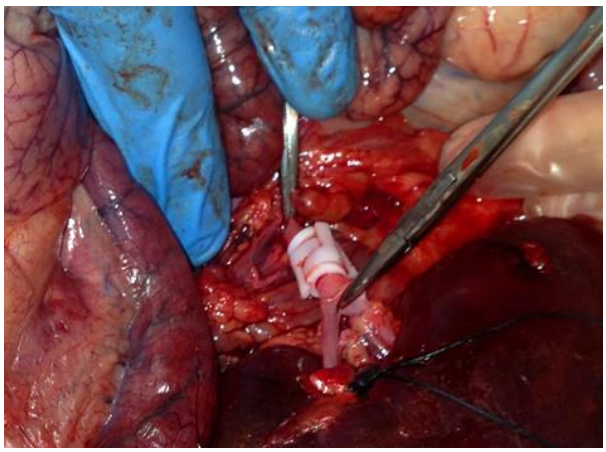

Figure 9 Couplers were installed on the renal arteries in a cadaver pig.

With the new vascular coupling system, the problems of low flexibility and the increased thickness of the arteries are solved and the stress created by everting the end of the artery is relieved by clipping the end of the vessel. Also, by adjusting the gap between the engaging ring and the back ring, the couplers can be used on vessels with the same outer diameter but different wall thickness. The use of couplers without pins reduces the chance of tearing the vessel wall by misplacement of the pins when compared with previous devices that included pins. The proposed device would reduce the time required in the surgery suite and the likelihood of failure of the anastomosis.

IV. Conclusion

A pin-free vascular coupling system and its corresponding instruments were designed, fabricated and tested. The device is easy to use and there is no vessel stretching or damage during the process. The results showed that the new coupler can be used to efficiently perform a vascular anastomosis in cadaver animal models. Future studies will include fabricating the couplers with different biocompatible materials, improving the instruments to adapt to different sizes of vessels and performing *in vivo* tests. The novel vascular coupling system has great potential to be a valuable tool for reconstructive surgery.

Acknowledgment

The authors would like to acknowledge the financial support of Technology Commercialization Project, University of Utah.

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