Biomaterials Redesign of Microvascular Anastomotic Coupler

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To: Zoe Hopkins, Blaze Grossman, Emily Wolfert

Executive Summary

The key factors in the redesign of this part include the use of biomaterials, the redesign of the part geometry to include these biomaterials, and the proposition of production scale manufacturing methods suitable for these redesigns. The choice of biodegradable material was guided by previous literature, during which we found the PLGA polymer used in similar predicate devices with a biodegradability timeline similar to our goals. The model of coupler serving as the inspiration for the redesign utilizes two very strong but bioinert materials, polyethylene, and stainless steel. These high strength materials can withstand much greater forces than the biodegradable bulk material chosen for the redesign, so features of the old design were modified for robustness. This included to realize this new design on a production scale, the two most promising possibilities include injection molding with the PLGA polymer or additive manufacturing using stereo lithography printers and biodegradable resins. The commonality of these two processes is the ability to make complex shapes while retaining isotropic materials in the final part, which is essential for the strength of small features such as the pins.

Key customer requirements for anastomotic procedures include successful attachments of vessels and low rates of dehiscence. These requirements are related to our coupler by successful attachment rate, max force withstood by coupler before assembly separates, max forces withstood by vessels before ripping.

Different models of the coupler device were tested in assembled orientation with one blood vessel surrogate engaged. In both models, tensions upwards of 100N were experienced without a signal failure of the pins. This demonstrates that the pins are exceptionally stronger when assembled into the opposite coupler than when unengaged.

Another factor in the improvement of the device is the time taken to film an implementation of the device using dissected cow arteries. The first round of prototypes required several people to affix the coupler and blood vessels and required additional processing of the cow arteries in the form of puncturing pilot holes for the spikes. Overall, the procedure took about an hour to perform. The latest model of prototypes was operated on in only a half hour and required only one person to perform the procedure. The improved placement and orientation of the spikes allow for much easier puncturing of the arterial wall for smoother attachments.

Previous Content

Introduction

This Test Plan Report is an up-to-date summary of the biomaterials redesign of microvascular anastomotic coupler device. It includes our statement of work, network diagram, indications for use, budget, customer requirements, specification development, intellectual property assessment, conjoint analysis, morphology, concept evaluation, conceptual model, and our prototype manufacturing plans. For this report we updated our detailed design to the current iteration and the manufacturing plans to show in more detail how our device is produced. Finally, we added test plans to show how we plan to meet our engineering specifications and make sure the Coupler works as intended.

Statement of work

Summary

The femoral artery bypass procedure currently contains a bottleneck in the suturing of blood vessels together, also known as anastomosis. To decrease this step in the procedure would dramatically reduce the critical path and overall length of procedure, resulting in fewer complications during surgery. This project compares predicate devices for suturing and anastomosis in providing a solution for the end-to-side anastomotic technique that is key to femoral bypass surgery as well as others. An anastomotic coupler system is redesigned for the incorporation of biomaterials and will be constructed, tested, and implanted over the course of this project. Testing will consist of cytotoxicity, finite element analysis, and biodegradability. Implantation will be performed to demonstrate efficacy of the connection using animal sourced blood vessels.

Introduction

Our project is based upon an automatic blood suturing device. We want to improve the way surgeons and doctors go about fixing blood vessels/ arteries during femoral artery bypass, Peripheral artery disease causes a narrowing of the blood vessel but by doing a vessel graft, it creates a new path for blood to flow through. Our idea will save time in the OR and allow for blood to easily go through the system again. The overall problem was firstly examined more closely by our sponsors of the BICEP program. This statement provides an overview of the already existing technology developed to ease the procedure of suturing blood vessels and how we plan to enhance this process through our own product. In the end section there is a description of how the project is managed and how our roadmap for the next few months looks like and then everything will be concluded but before diving into that, we have some background information.

Background

This project was proposed by a student of the BICEP program who shadowed vascular surgeries. The two predominant surgeries that informed the design of the proposed device were Carotid Thromboendarterectomy with Patch Angioplasty and Femoral Artery bypass. The main observation made when observing both procedures was the excessive amount of time spent suturing blood vessels together. As a general trend of surgery, the amount of time spent in operation exponentially increases the risk for complications to arise. As such, it is desirable to reduce the amount of time spent on the bottleneck step of suturing. The connection of two blood vessels together is medically known as anastomosis. The golden standard for this procedure has remained relatively unchanged since its inception. Throughout the literature review of anastomotic procedures, it stood out that while sutures are the current gold standard for vascular anastomotic procedures, they are unideal due to the rigorous training required for mastery and the time needed to perform them. A possible solution to decreasing the time of these procedures was to shift the scope from sutures towards other methods of anastomotic connection. An example of this shift is seen in the practice of intestinal anastomoses, which more often utilize staples for their relative ease of use compared to sutures. Vascular anastomoses

are too small for the convenience of staples to be practical. However, an alternative method to sutures exists as coupling devices. These options were explored throughout our literature review of predicate devices.

The first predicate device considered was the Proxisure Automatic Suturing Device can produce interrupted or running stitches and can be inserted laparoscopically for use in minimally invasive surgeries. A downside of this device is that the size would need to be scaled down for vascular surgery, which may require redesign of mechanisms that are already too small to be further miniaturized. It is intended for use on flat or slightly contoured surfaces, which may indicate it could not be optimized for the hyper-contoured shape of a cylindrical blood vessel. [1]

A predicate device that steers away from the use of sutures is an expandable Nitinol cuff sewn onto the end of a Dacron prosthesis. The expandable cuff would be shrunk for easy insertion into the proximal end of the descending aorta, and the flexibility of the device would provide constant radial pressure outward from the middle of the lumen. This pressure outwards would be opposed by a pair of ligations on the outside of the vessel, which would press the artery into the expandable cuff and hold the suture in place. This design would be favorable for its ease of operation. To perform the anastomosis, the surgeon only needs to perform two ligations which are drastically easier than suturing and would comparably require much less time. The downside is that this is optimized for end-to-end anastomoses and there was no apparent route to incorporate it into an end-to-side anastomoses. [2]

Another device that informed this design was the Synovis Vascular Coupling System for End-to-End anastomosis. This design produces an efficacious connection between arteries in the animal models studied but would remain in vivo without degrading. While not indicated in the report, this may lead to impingement of nearby structures or chronic inflammation over time. While the workflow for implementation seemed easier than producing sutures, the device requires auxiliary too for implementation, which adds complexity to the procedure that would preferably not be necessary. This coupler could also only be used for end-to-end anastomoses, limiting its range of applications. However, the efficacious anastomosis produced with this device encourages the further exploration of couplers. [3] See *Appendix c.*

The “New Absorbable Microvascular Anastomotic Devices Representing a Modified Sleeve Technique” is an end-to-end anastomotic coupler that offered significant design insights. This device is an improvement on previous anastomotic couplers in that the rings used to hold arteries together are incredibly compact in size and are biodegradable. The inside ring holds one vessel in an inside-out state while the outer ring holds the other vessel overlapped on the first. Extensive in vivo analyses from this study emphasized the importance of intima-to-intima contact for the remodeling of blood vessel walls and demonstrated the impressive biodegradability of PLGA polymer. Both considerations were key in the proposed solution of this project. However, this design overall was not suitable due to its restriction to end-to-end anastomoses and because of the decrease in functional length of the blood vessels due to the process of folding them inside out. [4] See *Appendix d.*

The most attractive previous development found is the Microvascular Anastomotic Coupling System from Synovis. This approach offers the reduced complexity of a coupler system and provides intima to intima contact of the anastomosed vessels while offering the improvement of being useful for side-to-end anastomosis. This innovation revolves around the rings that hold the two vessels in a partially inverted state, which offers the essential intima-to-intima contact without sacrificing as much functional length of the vessels as full inside-out inversion. The primary downside to this device is the ring and pins are not absorbed after implantation, which over time could lead to inflammation or even migration which could jeopardize the efficacy of the anastomosis and would impinge on surrounding anatomy as well as the anastomosed vessel itself. This consideration is revisited later in the project. [5] See *Appendix e.*

Research of different patented applications similar to our idea showed that there are already different approaches to solve the problem of anastomotic procedures taking a lot of time and concentration for the surgeon to perform. Most of the applications, however, concentrate on end-to-end anastomosis and they are not able to assist with end to side or side to side procedures. With our approach we want to change that as one of the biggest differences to the existing patents. Also, we want to implement the use of biodegradable materials for the coupling device which then can be left

alone in the body for the arteries to heal and after the healing is done the device does not need to be surgically removed again.

Some of the testing regulations we will be following to test are the ISO standards outlining tests for cytotoxicity, biocompatibility, and FEA.

Our sponsors relayed to us that this summer when working for BiCEP they saw that this would have really helped the doctors in the OR, and they thought it would have immediate effects on the time spent in surgery.

Objectives

This design project will consist of a redesign of the Microvascular Anastomotic Coupler for the implementation of biomaterials.

The goal of this project is to reduce time spent during the operation of femoral artery bypass without sacrificing the anastomotic connection's efficacy. While intended specifically for FAB, the end-to-end anastomosis procedure applies to other procedures such as cerebrovascular and coronary artery bypass procedures.

This project will include an analysis of biomaterial properties compared to materials currently used.

Customer requirements for this device consist of shorting the procedure time of FAB while preserving efficacy of the anastomosis. A customer requirement to improve on the predicate device is the coupling system's biodegradability.

Table 1: Engineering Specifications Table

Spec. #	Parameter Description	Requirement or target (unit)	Tolerance	Risk	Compliance
1	Rate of successful attachments	95%	± 3	H	T, S
2	Max Force Withstood by coupler before assembly separates	22.5N	± 1	H	T
3	Max Force withstood by vessels before Ripping	15N	± 1	H	T
4	Amount of diff. Procedures applicable to	2 types	Min	L	T, S

The first key customer requirement involves the procedure sparking the inspiration for this project, the femoral artery bypass. This procedure requires the ability to perform an end-to-side anastomosis in the addition of a bypass to the femoral artery.

Mechanisms of dehiscence include either the couplers not holding together after being mated or the vessels ripping off their pins. To quantify these modes of failure, we added the specifications of Force Required to Separate Couplers and the Force of Tension Withstood Until Vessel Rips.

The specification for Attachment Success Rate measures the ease of use for physicians utilizing the device in a way that is suitable for our testing capabilities.

The scope of this project has evolved into comparing different features of the basic model. As such, we are keeping the size of the couplers consistent throughout the iteration process. Thus, the engineering specification of Minimum vessel able to be Operated On was not in our scope to test.

The first specification we plan to meet will be the total steps in a surgery our product will take to be used for connecting blood vessels. We will measure this specification by performing surgery on animal arteries to test out how many steps it will take in the end. Also, we can check the patents we looked on for end-to-end anastomosis since the procedure is quite similar to checking our specification.

The time to perform surgery will also be checked by performing surgery on animal arteries and then analyze how much time an experienced surgeon will need for the same procedure. This is a high-risk specification since the amount of time needed for the surgery is equivalent to a higher risk of failure. Since a long surgery means more concentration for the surgeon and there can be more mistakes the longer it takes.

Another specification is the time to degrade in vivo. We want our product to be biodegradable so that it can stay in the body for the healing process and in the end does not even have to be removed. We will test this specification by doing a biodegradability test and then we just measure how long it takes for our device to degrade over time. This one is also a high-risk specification because if the degradation is too fast, the blood vessels may not be healed yet. Additionally, if it takes too long there could be risk for blood clots and other complications.

The next specification we want to meet is to have a minimum diameter of blood vessel possible to work with. We can just test this requirement the same way as all the others by performing surgery on animal arteries. Inspection of the diameters of our prototype is also possible.

We then also want our product to be applicable to different procedures. The number of procedures applicable can also easily be tested by trying different surgeries with the device and comparing them to comparable products to see where we can use our device.

Finally, we want a low rate of dehiscence at the blood vessels. This can be tested by inspection of the blood vessel after implementing our product or after performing the animal surgery. This last specification is high-risk as well since it is especially important that the blood vessels are properly connected in the end. Otherwise, it can lead to inner bleeding real fast.

Project Management

For this project, we expect to finish our planning stage over the next few weeks, then begin to order parts and hopefully build a prototype.

We plan to do ISO test 9000 to check biodegradability, biocompatibility, and FEA testing. We also plan to start testing the Cal Poly meats cow arteries they will hopefully donate to us. This plan will give us a unique chance to test out the product and show that it has potential before the end of winter quarter.

In terms of the next steps, we want to get our designs down on paper so we can order the material we need/ get them up in CAD so we can 3D print. We hope to have these done by the end of November.

For our network diagram we have a plan to connect with doctors, research biocompatibility and biodegradability, and design our rough sketches. Then we want to finalize the sketches, plug them into CAD, and run the FEA tests. Lastly, we would print the sketches, test on the animal arteries, and then run the biodegradability tests.

Conclusion

We wrote this Statement of Work to inform the reader of our project, past devices that are similar, the way we will develop and test, and hopefully how we hope it helps people. Our product will be a Microvascular Anastomotic Coupler. We hope that this device consists of shorting the procedure time of FAB while preserving the efficacy of the anastomosis.

Network Diagram

Attached below is our network diagram. It shows our timelines and when we expect to have deliverables started and completed.

	Task Name	Duration	Start	Finish	Predecessors	Resource Names
1	Connect with doctors	2 wks	Thu 10/6/22	Wed 10/19/22		ENGR4 -R330,laptops,sam
2	Research on biodegradability and biocompatibility	4 wks	Thu 10/13/22	Wed 11/9/22		ENGR4 -R330,laptops,sophie
3	status update memo #1	4 days	Wed 10/19/22	Mon 10/24/22		ENGR4 -R330,laptops,Nick
4	Quiz #2	6 days	Wed 10/19/22	Wed 10/26/22		ENGR4 -R330,laptops,sam
5	FMEA assignment	6 days	Wed 10/19/22	Wed 10/26/22		ENGR4 -R330,laptops,Nick
6	Conceptual Model	6 days	Thu 10/27/22	Thu 11/3/22	5	ENGR4 -R330,laptops,sam
7	Conceptual design review presentation	4 days	Thu 10/27/22	Tue 11/1/22	5	ENGR4 -R330,laptops,sophie
8	conceptual design report	4 days	Thu 10/27/22	Tue 11/1/22	5	ENGR4 -R330,laptops,sophie
9	conceptual design review peer question	3 days	Fri 11/4/22	Tue 11/8/22	6,7,8	ENGR4 -R330,laptops,Nick
10	peer evaluations	4 days	Wed 11/2/22	Mon 11/7/22	7	ENGR4 -R330,laptops,Nick
11	team health assessment	4 days	Wed 11/9/22	Mon 11/14/22	6,7,8,9	ENGR4 -R330,laptops,Nick
12	status update memo #2	4 days	Tue 11/15/22	Fri 11/18/22	3,5,6,7,8,9,10,11	ENGR4 -R330,laptops,sam
13	status update memo #3	6 days	Mon 11/21/22	Mon 11/28/22	12	ENGR4 -R330,laptops,sam
14	risk and hazard assessment	4 days	Tue 11/29/22	Fri 12/2/22	13	ENGR4 -R330,laptops,sophie
15	quiz #3	6 days	Thu 10/27/22	Thu 11/3/22	4	ENGR4 -R330,laptops,sophie
16	critical design review presentation	11 days	Mon 12/5/22	Mon 12/19/22	14	ENGR4 -R330,laptops,Nick
17	critical design report	11 days	Mon 12/5/22	Mon 12/19/22	14	ENGR4 -R330,laptops,sam
18	critical design review peer questions	3 days	Tue 12/20/22	Thu 12/22/22	16,17	ENGR4 -R330,laptops,sophie
19	yellow tag	30 days	Thu 10/6/22	Wed 11/16/22		sam,the hangar,red tag
20	winter project plan	4 days	Fri 12/23/22	Wed 12/28/22	18	ENGR4 -R330,laptops,Nick
21	design notebook	33 days	Thu 10/6/22	Mon 11/21/22		ENGR4 -R330,laptops,sophie
22						
23	Manufacturing first batch of 3D-printed prototypes	26 days	Tue 12/6/22	Tue 1/10/23		3rd party manufacturing firm,Cris sion,Resin material, 3d resin printer
24	Updated Project plan	3 days	Tue 1/10/23	Thu 1/12/23		laptops,ENGR4 -R330,Nick
25	Second batch of cal poly blood vessel samples	14 days	Tue 1/10/23	Fri 1/27/23		Cal poly meats,transport bags,sam
26	Tensile Strength Testing	3 days	Wed 1/11/23	Fri 1/13/23	23	tensile strength tester,3d printed parts,BMED Lab,sophie
27	Updating/reevaluating design if necessary	2 days	Sat 1/14/23	Mon 1/16/23	26	ENGR4 -R330,laptops,sam
28	Status Update Memo 1	3 days	Fri 1/13/23	Tue 1/17/23	24	ENGR4 -R330,laptops,Nick
29	3D-print second batch of updated models	6 days	Tue 1/17/23	Tue 1/24/23	27	3d resin printer,3rd party manufacturing firm,Cris sion, Resin material
30	Status Update memo 2	5 days	Wed 1/18/23	Tue 1/24/23	28	ENGR4 -R330,laptops,Nick
31	2nd round of Tensile Strength Testing	3 days	Wed 1/25/23	Fri 1/27/23	29	3d printed parts,BMED Lab,tensile strength tester,sophie
32	Updating/reevaluating design if necessary	3 days	Sat 1/28/23	Tue 1/31/23	31	ENGR4 -R330,laptops,sam
33	Test Plan Presentation	5 days	Wed 1/25/23	Tue 1/31/23	30	ENGR4 -R330,laptops,Nick
34	Test Plan Report	5 days	Wed 1/25/23	Tue 1/31/23	30	ENGR4 -R330,laptops,Nick
35	Functional prototype Video	5 days	Wed 1/25/23	Tue 1/31/23	30	ENGR4 -R330,laptops,Nick
36	Implementation of device with real blood vessels	14 days	Wed 2/1/23	Mon 2/20/23	25	3d printed parts,MaVR Lab,surgical equipment,sam
37	3D-print third batch of updated models necessary	5 days	Wed 2/1/23	Tue 2/7/23	32,33,34,35	3d resin printer,3rd party manufacturing firm,Cris sion, Resin material
38	Peer Evaluations	6 days	Wed 2/1/23	Wed 2/8/23	33,34,35	ENGR4 -R330,laptops,Nick
39	Team Health Assessment	6 days	Wed 2/1/23	Wed 2/8/23	33,34,35	ENGR4 -R330,laptops,Nick
40	Ethics reflection	7 days	Wed 2/1/23	Thu 2/9/23	33,34,35	ENGR4 -R330,laptops,Nick
41	3rd round of Tensile Strength Testing if necessary	5 days	Wed 2/8/23	Tue 2/14/23	37	3d printed parts,BMED Lab,tensile strength tester,sophie

Figure 1: Network Diagram: Tasks, Duration and Resources Part 1

42	Status Update memo 3	3 days	Fri 2/10/23	Tue 2/14/23	38,39,40	ENGR4 -R330,laptops,Nick
43	Quiz #1	5 days	Fri 2/10/23	Thu 2/16/23	42	ENGR4 -R330,laptops,Nick
44	Status Update memo 4	3 days	Fri 2/17/23	Tue 2/21/23	42	ENGR4 -R330,laptops,Nick
45	Biomaterial comparison/evaluation/prove of concept summarized	6 days	Tue 2/21/23	Tue 2/28/23	36,41	ENGR4 -R330,laptops,sophie
46	Status Update Memo 5	5 days	Wed 2/22/23	Tue 2/28/23	44	ENGR4 -R330,laptops,Nick
47	Manufacturing instructions document	6 days	Tue 2/28/23	Tue 3/7/23	36,41	ENGR4 -R330,laptops,sophie
48	Status Update Memo 6	5 days	Wed 3/1/23	Tue 3/7/23	46	ENGR4 -R330,laptops,Nick
49	Design Review Presentation	5 days	Wed 3/8/23	Tue 3/14/23	48	ENGR4 -R330,laptops,Nick
50	Senior Project Design Report	5 days	Wed 3/8/23	Tue 3/14/23	48	ENGR4 -R330,laptops,Nick
51	Design Notebook	7 days	Wed 3/8/23	Thu 3/16/23	48	ENGR4 -R330,laptops,Nick
52	Peer evaluations	7 days	Wed 3/8/23	Thu 3/16/23	48	ENGR4 -R330,laptops,Nick
53	Expo Poster	7 days	Wed 3/8/23	Thu 3/16/23	48	ENGR4 -R330,laptops,sophie

Figure 2: Network Diagram: Tasks, Duration and Resources Part 2

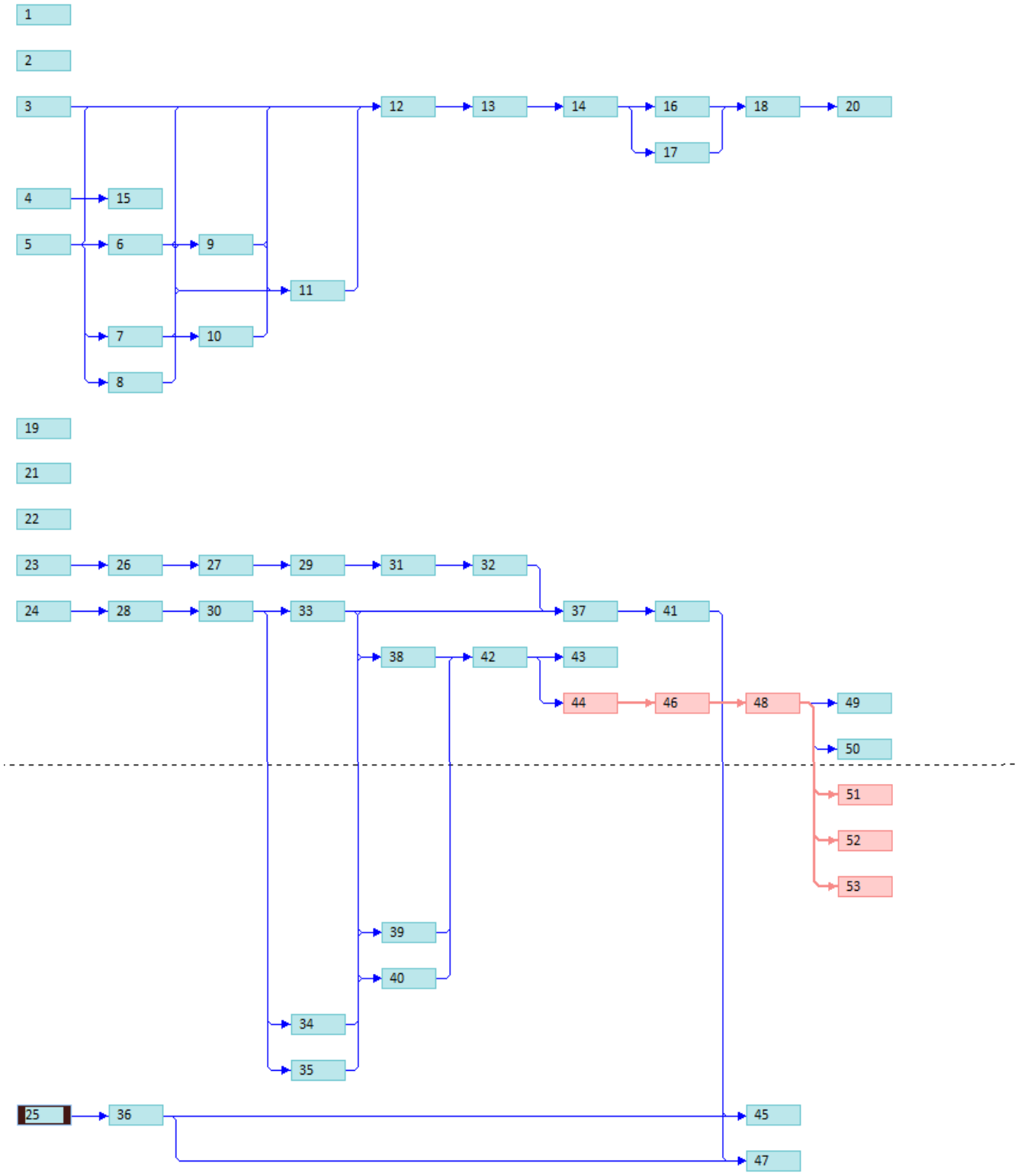


Figure 3: Network Diagram: Critical Path

Indications for Use

The Microvascular Anastomotic Coupler system is indicated for relief in patients with peripheral artery disease, specifically plaque buildup in the femoral artery encountered in microsurgical procedures only in the peripheral vascular system. It is intended for use with veins and arteries having an outside diameter no smaller than 4 mm and no larger than 10 mm.

The Microvascular Anastomotic Coupler system is indicated for relief in patients with peripheral artery disease in need of a popliteal artery bypass with vein graft. This would aid in reducing time spent suturing in surgery and avoid occlusion resulting in increased profusion to the lower extremities.

Budget

The budget was revised to fit the latest test and manufacturing procedures. This includes Resin, which we need for our 3D SLA-printing. Also, we also need blood vessel mimics for the testing *and the CalPoly Meats blood vessels will not be enough for that purpose.*

Table 2: Project budget

Item	Purpose	Unit	Quantity	Cost/Unit	Total Cost
Resin for 3D-print	True size prototype	50	4	$1	$200
Blood vessel surrogates	Used for vessel grip testing	1	1	$15	$15

Customer Requirements

Our customer requirements were made by thinking about what is most important to our customers and what this device will aim to satisfy. In many surgeries involving some form of anastomosis, such as femoral artery bypass and renal transplantation, practicing the traditional parachute suture method can be an exceptionally delicate and time-consuming step, bottlenecking the workflow of the entire procedure. The level of proficiency required to produce an efficacious anastomosis using sutures is high and the learning curve required to reach it can be steep. Long procedure times are generally detrimental due to the increase in costs of procedure and the exponential increase in complication rate that coincide with procedure time. A product meant to assist in these surgeries would need to satisfy the requirements of creating an efficacious anastomosis, reducing the skill needed to perform the procedure, and reducing the overall time of procedure.

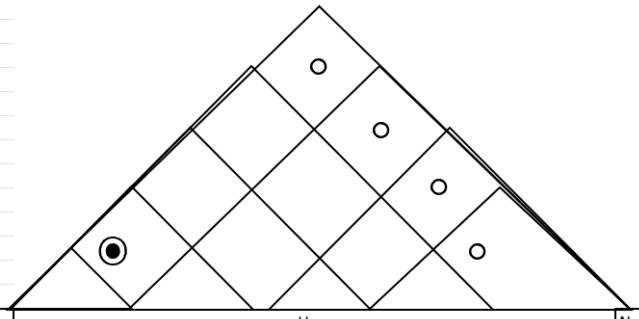
Specification Development (House of Quality)

The customer requirements of reliability and ease of use necessitate a design the is robust and consistent in performance. These requirements are translated to the tangible specification of the rate of successful attachments of the vessel to the coupler in the setup phase of the operations. The two main modes of failure that will be recorded upon attachment of vessel to coupler are the pins breaking and the vessel ripping. The pins could break due to excessive force required that could be the fault of various design shortcomings such as the robustness of the pin attachment to the ring and the force applied when piercing the vessel with the spike of the pins.

Another consideration of reliability lies in the assembly of the couples after their individual connection. The failure of the anastomosis may result from either the couplers not holding the vessels together with enough strength or the vessels ripping at some point after assembly. The engineering specifications gathered from this consideration are the max force

of tension before the couplers are pulled apart from each other when mated and the max force of tension before the vessel rips out of the assembly.

Ideally this coupler will be useful for both end to end anastomosis and end to side. This specification will be met throughout the iterative design process of the pin geometries. There is more tension when pulling the side of a vessel through the ring compared to the whole vessel itself, therefore the pins must be placed as radially inward as possible while still being able to pull the vessel over the connecting faces.



◉ = 9
o = 3
Δ = 1

		Who		How					Now				
		Surgeons/doctors/nurses	Patient	Rate of Pins brekaing upon attachment	Rate of Vessels ripping upon attachment	Amount of Diff. Procedures applicable to	Force of Tension to pull apart couplers	Force of Tension to rip apart vessels	1 = very bad 5 = very good ✕ = Hand Sutures ⧓ = Proxisure Automatic Suturing ▲ = Biodegradable Couplers - Sleeve Technique ✠ = MAC Synovis				
What				∨	∧	∧	∨	∨					
				%	types	types	N	N	1	2	3	4	5
Implementation Procedure	Easy for Suregoen to perform	30	5	◉	◉				✕		▲⧓✠		
	fast to attach	25	20	o	o				✕		⧓	✠	▲
Efficacy	Reliable	10	25				◉	◉				✕⧓▲✠	
	Biodegradable	5	20						✠				✕▲⧓
	Miniaturizable	10	10							⧓			✕✠▲
Anastomy the application is u	Capable of patching	5	5			Δ			▲✠				✕⧓
	Capable of end-to-end	5	5			Δ			⧓				✕✠▲
	Capable of End-to-side	10	10			Δ			⧓▲				✕✠
Importance		urgeons		38.12154696	38.12154696	2.209944751	9.944751381	9.944751381					
		Patients		12.88343558	12.88343558	2.45398773	27.60736196	27.60736196					
Hand Sutures				7.272727273	7.272727273	9.090909091	21.81818182	21.81818182					
Proxisure Anastomotic Suturing				20.63492063	20.63492063	7.936507937	19.04761905	19.04761905					
Biodegradable Couplers - Sleeve Technique				17.56097561	17.56097561	3.414634146	17.56097561	17.56097561					
MAC Synovis				21.08108108	21.08108108	5.945945946	19.45945946	19.45945946					

Figure 4: House of Quality

Intellectual Property Assessment

In our Intellectual Property Assessment, we investigated patents that are similar to our first design idea and discussed if there would be any patent infringements through our design. Certain Keywords were used to start the search for similar patents shown in figure 4.

U	A61B 17/11	· for performing anastomosis; Buttons for anastomosis
	A61B 2017/1103	· · ~~Approximator~~*{Approximator}*
	A61B 2017/1107	· · *{*for blood vessels*}*
	A61B 2017/111	· · *{*with means for removing a constriction after performing anastomosis*}*
U	A61B 17/1114	· · {of the digestive tract, e.g. bowels or oesophagus}
	A61B 2017/1117	· · · *{*adapted for discharge after necrotisation, e.g. by evacuation, expulsion or excretion*}*
	A61B 2017/1121	· · *{*adapted for performing tissue or graft eversion*}*
	A61B 2017/1125	· · *{*Forceps, specially adapted for performing or assisting anastomosis*}*
	A61B 2017/1132	· · *{*End-to-end connections*}*
	A61B 2017/1135	· · *{*End-to-side connections, e.g. T- or Y-connections(Y-shaped blood vessel prostheses A61F 2002/065)*}*
	A61B 2017/1139	· · *{*Side-to-side connections, e.g. shunt or X-connections*}*
	A61B 2017/1142	· · *{*Purse-string sutures*}*
U	A61B 17/115	· · Staplers{for performing anastomosis in a single operation}
	A61B 2017/1157	· · · *{*applying the staples radially*}*

Figure 5: Keywords used to find initial relevant Cooperative Patent Classifications

Patents that are similar to our design idea:

The invention claimed is:

1. An anastomosis clip for connecting a first vessel with a second vessel,

wherein the first and second vessels each have a vessel wall with an outer surface,

wherein the anastomosis clip comprises:

a first attachment portion,

a second attachment portion,

a hinge having a pivot axis and configured to couple the first attachment portion to the second attachment portion such that the first attachment portion and the second attachment portion are movable relative to one another around the pivot axis between i) a closed position and ii) an open position, and

a retainer ring which is moveable relative to the first attachment portion as well as to the second attachment portion and which is configured to lie, in use, between the outer surfaces of the vessel walls of the first and second vessels;

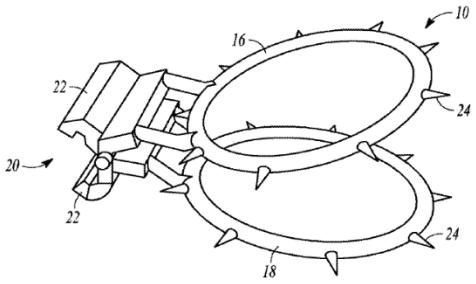


FIG. 1A

Figure 6: US-11259809-B2 March 1st, 2022: Blood vessel connectors and methods for blood vessel connection

The device above is about connecting two vessels to each other. The vessels are put over the spikes and then like a clip the spikes are connected to each other. This patent claim could be infringed on by having a similar holding mechanism for our device since spikes are quite an uncomplicated way to hold things in place. We would address this issue by using biodegradable materials for the device which then means we can leave it in the patient's body, and it does not have to be removed in the end. Also, by updating the design to fit more than two blood vessels we could go around the infringement.

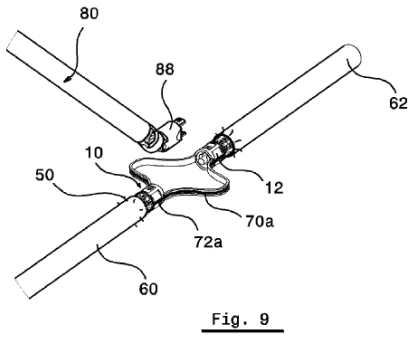


Fig. 9

1. An anastomosis device, comprising:

a) a support housing having an interior chamber and having a longitudinal axis, said support housing having a compliant flexible section, and a plurality of suture needles mounted on an outer surface of said compliant flexible section, said plurality of suture needles being aligned with, and around, said longitudinal axis;

b) an introducer including a circular disc section rigidly affixed to said support housing adjacent to an end of said compliant flexible section, said circular disc section having a diameter selected to match an interior diameter of an anatomical tubular structure undergoing an anastomosis process; and

c) a deformation mechanism mounted in said interior chamber and configured such that when said introducer is seated in said anatomical tubular structure and said deformation mechanism is activated said deformation mechanism including a cam head section bears outwardly away from said longitudinal axis against an interior surface of said compliant flexible section to drive said plurality of suture needles radially outwards away from said longitudinal axis forcing said plurality of suture needles to pierce through a wall of said anatomical tubular structure simultaneously around a circumference of said anatomical tubular structure.

Figure 7: US-8911458-B2 Dec 16th, 2014: Device for performing end-to-end anastomosis

The patent shown is used for end-to-end anastomosis and is used in minimal invasive surgery. It includes a camera, needles for suturing and a rod where the arteries will be connected. We could infringe on the claim that our product will also be a rod mechanism where the arteries are connected. Also, the suturing method can be infringed as a claim if ours is like the one shown in this patent. To prevent this, we will try to implement a design where not only is an end-to-end anastomosis possible but other blood vessel branches can be connected to the ones we already connect.

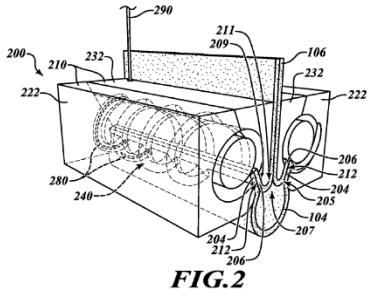


FIG.2

What is claimed is:

1. An apparatus comprising:

an eversion mechanism configured to engage a first external surface of a receiving passage adjacent a first opening in the receiving passage in order to create a receiving flange presenting a first interior face;

a donor support mechanism configured to support a donor passage with an opening in an end in an everted position that forms a donor flange presenting a second interior face, and further configured to present the second interior face of the donor flange against the first interior face of the receiving flange to present a passage juncture;

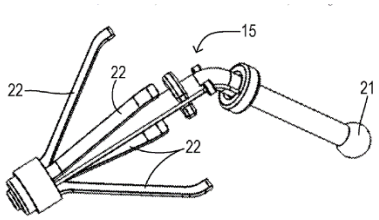
a first opposing guide section configured to be disposed along a first exterior surface of the receiving flange;

a second opposing guide section configured to be disposed along a second exterior surface of the donor flange, wherein opposing interior surfaces of the first and second opposing guide sections define a helical channel; and

a suturing mechanism configured to motivate a filament through the helical channel around the passage juncture to suture the second interior face of the donor passage to the first interior face of the receiving passage.

Figure 8: US-11141161-B2 October 12th, 2021: Full eversion anastomosis juncture formation and suturing

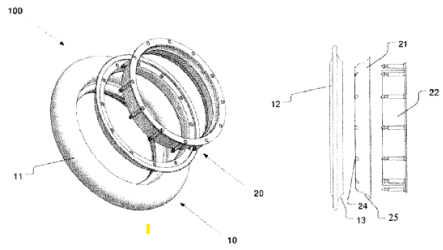
This patent shows a different suturing technique whereas a blood vessel is sutured to a donor vessel. This patent could be infringed on by using a similar suturing technique for our own device. This could be avoided by using a different type of connecting method where we only try to connect around one circumference of the vessel and not the entire length.



A stabilization tool supports a blood vessel for suturing during cardiovascular surgery. The support vessel may typically be part of an artificial graft used in replacing an aortic arch. The stabilization tool has a central shaft with a mounting element at a first end. A plurality of retractable arms have their distal ends affixed to a second end of the central shaft. The retractable arms are movable between a nested position flanking the central shaft and a range of extended positions wherein proximal ends of the retractable arms are spaced away from the central shaft. A closing ring is slidable over the retractable arms from a deployed position adjacent the second end of the central shaft to a retracted position spaced away from the second end to move the retractable arms.

Figure 9: US-10531947-B2 January 14th, 2020: Great vessel graft suturing aid

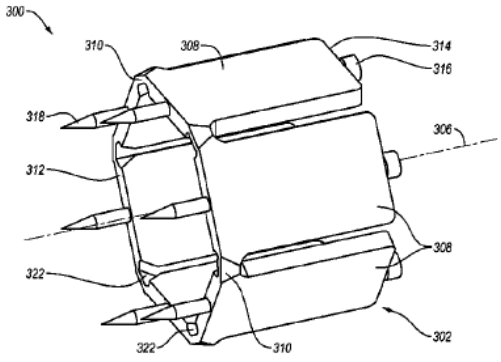
This device is about a tool to support stabilization of a blood vessel for suturing. We might infringe on this patent by having a similar supporting/holding mechanism for our device. This can be easily solved though by having more than just the stabilization component but also the component of connecting the blood vessels, which makes it a new invention.



A device (**100**) for arrangement on the side wall of an intestine is provided. The device (**100**) comprises a first member (**10**) and a second member (**20**) of a generally hollow open configuration. The first member (**10**) comprises an elastic part (**11**), with a first and a second axial end, and a rigid support part (**12**), arranged at the first axial end of the elastic part (**11**). The second member (**20**) comprises a first and a second axial end, said first end of the second member (**20**) matching the shape of the second axial end of the elastic part (**11**), such that an intestine wall may be uniformly distributed between the second axial end of the elastic part (**11**) and the second member (**20**). The device (**100**) also comprises a connection member (**30**) for connecting the rigid support part (**12**) and the second member (**20**) to each other. A method for arranging said device at the side wall of a tubular structure, and a connector (**200**) for connecting two devices (**100**) is also provided.

Figure 10: US 9743931 B2 August 29th, 2017: Device and a method for anastomosis

This patent could be infringed on by making a similar part for connecting more than one blood vessel to each other and using a similar method to connect the branching vessels. Since this invention, however, is for anastomosis of an intestine there should be no problem since our device is used in a separate way.



Methods, devices, apparatus, assemblies, and kits for performing a vascular anastomosis are disclosed. A device for a vascular anastomosis includes tissue engaging portions that can move between at least two configurations. In some embodiments, the tissue engaging portions move without the aid of moving parts, while in other embodiments the tissue engaging portions extend from one or more movable wings. The tissue engaging portions may be separated by a first distance when in a pre-deployment configuration and by a second distance when in a deployed configuration. A method includes engaging a plurality of tissue engaging members of a coupling device against first end tissue. After selectively engaging the tissue engaging members and first end tissue, the first end tissue is stretched by at least moving the tissue engaging members. The stretched first end tissue is coupled to the second end tissue by mating the coupling device to a mating anastomosis device.

Figure 11: US 9642623 B2 May 9th, 2017: Methods, devices, and apparatus for performing a vascular anastomosis.

This device again uses a similar technique like the first patent that we looked at. It also uses spikes to connect blood vessels together and hold them in place. Again, would our design be for connecting more than one blood vessel and our device should be biodegradable in the end.

Conjoint Analysis

We utilized conjoint analysis to test how the different iterations scored compared to each other when presented to our peers.

Customer	Rank (Y)	RoM (x1)	Knots (x2)	Handling (x3)
1	1	1	1	1
	2	1	2	2
	4	2	1	2
	3	2	2	1
2	1	1	1	1
	3	1	2	2
	4	2	1	2
	2	2	2	1
3	3	1	1	1
	1	1	2	2
	2	2	1	2
	4	2	2	1
4	2	1	1	1
	3	1	2	2
	1	2	1	2
	4	2	2	1
5	1	1	1	1
	3	1	2	2
	2	2	1	2
	4	2	2	1
6	1	1	1	1
	3	1	2	2
	2	2	1	2
	4	2	2	1
7	1	1	1	1
	2	1	2	2
	3	2	1	2
	4	2	2	1

Attribute	Variable	1	2
Range of Motion	X1	180°	120°
Ties Knots	X2	Yes	No
Hanlding	X3	One Handed	Two

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.679135104
R Square	0.46122449
Adjusted R Square	0.393877551
Standard Error	0.88640526
Observations	28

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	3	16.14285714	5.380952381	6.848484848	0.001707995
Residual	24	18.85714286	0.785714286		
Total	27	35			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-0.714285714	0.88640526	-0.805822964	0.428257398	-2.543736256	1.115164828	-2.543736256	1.115164828
RoM (x1)	1.142857143	0.335029697	3.411211462	0.002293489	0.451389833	1.834324453	0.451389833	1.834324453
Knots (x2)	1	0.335029697	2.984810029	0.006433615	0.30853269	1.69146731	0.30853269	1.69146731
Handling (x3)	4.79571E-17	0.335029697	1.43143E-16	1	-0.69146731	0.69146731	-0.69146731	0.69146731

Figure 12: Conjoint Analysis

Both Range of Motion and Knot Tying have coefficients with corresponding p-values below 0.05, indicating the importance weighted to them by the model is statistically significant. Of those two variables, the coefficient for Range of Motion is larger, indicating that Range of Motion is the greatest predictor of whether customers will like the combination of features.

Morphology

Our morphology document shows different iterations of our device idea with the corresponding images.

Table 3: Morphology

Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Creating Bifurcation for End-to-side functionality	Mate of one vessel directly to side of other	Rigid T-Joint intermediate	Vascular Prosthetic intermediate		
Holding blood vessels in place	Sutures	Outer Ring + Metal Pins	Outer Ring + Pins of same material	Inner ring + ligation	Inner Ring + Outer ring
Coupler Does not remain in the body	Biodegradable materials	Follow-up procedure for coupler removal			
Vessel contact	Intima-to-intima contact: Full inside out inversion in one vessel, overlapped by another vessel	Intima-to-intima contact: Flared orientation in both vessels	Non-overlapping end to end with space in between	Mated with cross sections	
Handle	No handle	Handle for holding	Handle for holding and transitioning vessels		

Table 4: Morphology in sketch format

FEMORAL GRAFT	PROXIMAL DISTAL T-JOINT GRAFT	PROX. DIST. PROSTHETIC GRAFT		
SUTURE "PARACHUTE"	PINS ARE SECONDARY MAT.	PINS SAME MAT. AS RING	VESSEL COUPLER Ligation	INNER RING OUTER RING
INSIDE-OUT SLEEVE INT-INT CONACT	FLARED ENDS MEET INT-INT CONACT	INTEMEDIATE NON-OVERLAPPING	X-SECTIONAL ENDS MEETS NON-OVERLAPPING	
NO SPECIAL HOLDER	HOLDER	HOLDER + CONNECTOR		

The first function was chosen to specify the device to be useful for side-to-end anastomosis. This can be accomplished by holding one vessel directly to the side of another or by having an intermediate material bridge the gap between them. Another function is the method of fastening the vessels. Ideally, a method besides sutures would be used, which could consist of various methods. A function that could affect the potential of the vessels to heal together is the way they are mated. For this function, we prioritize intima to intima contact due to its demonstrated efficacy in previous anastomotic device evaluations. The last consideration explored in the morphology was how the vessels are fixed throughout the procedure.

Concept Evaluation (Pugh Charts)

In our concept evaluation we put together three prototypes out of our morphology and compared them to each other through Pugh Charts.

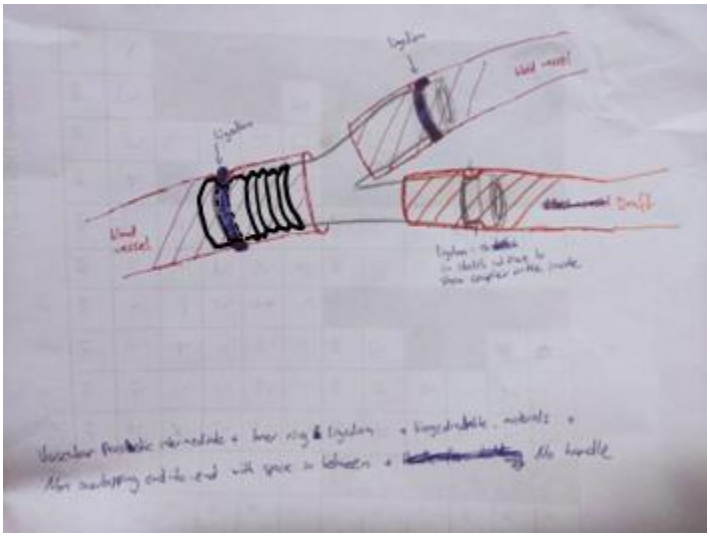


Figure 13: Vascular Prosthetic with Ligation

This concept sketch was realized by combining the functions vascular prosthetic intermediate, inner ring & ligation, biodegradable materials, non-overlapping end-to-end with space in between and no handle. It was developed to function as a prosthetic which will reside inside of the blood vessels throughout the healing process. The blood vessels and the draft should grow together surrounding the prosthetic and when everything is healed up you just have to wait for the device to biodegrade and nothing will be left inside of the vessels that could risk another arteriosclerosis. For holding the blood vessels in place on top of the product ligations will be used. As for holding the device there is no holder implemented in the design since the prosthetic can easily be held in place by a surgical plier.

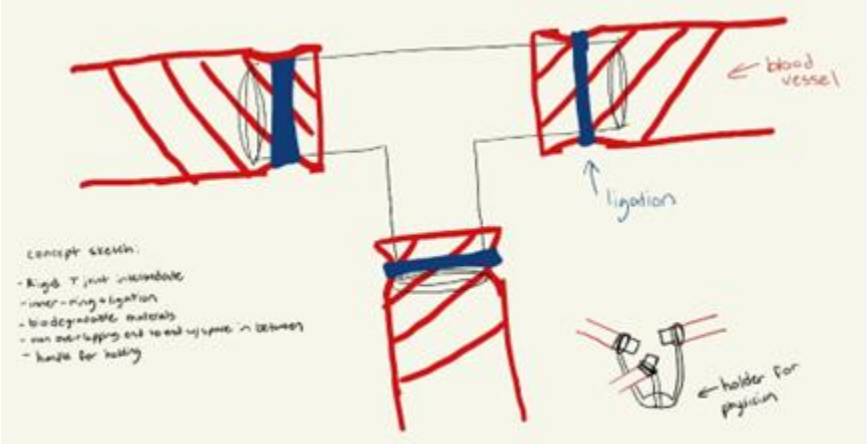


Figure 14: Rigid T Joint Prosthetic with Ligations

This concept sketch was put together by combining a rigid T-joint intermediate, inner ring + ligation, biodegradable materials, non-overlapping end-to-end with space in between and a handle for holding. We are thinking that this device will function as a prosthetic that will degrade. Because of the biodegradable material we are using, nothing will remain long term wise in the vessel relieving the risk for arteriosclerosis. Ligations will be used on top of the T joint and the blood vessels to keep them in place. The handle displayed in the bottom right corner is used to make the operation easier for the physician. The ligations combined with the handle should make it quite easy to learn and keep the time spent doing sutures low.

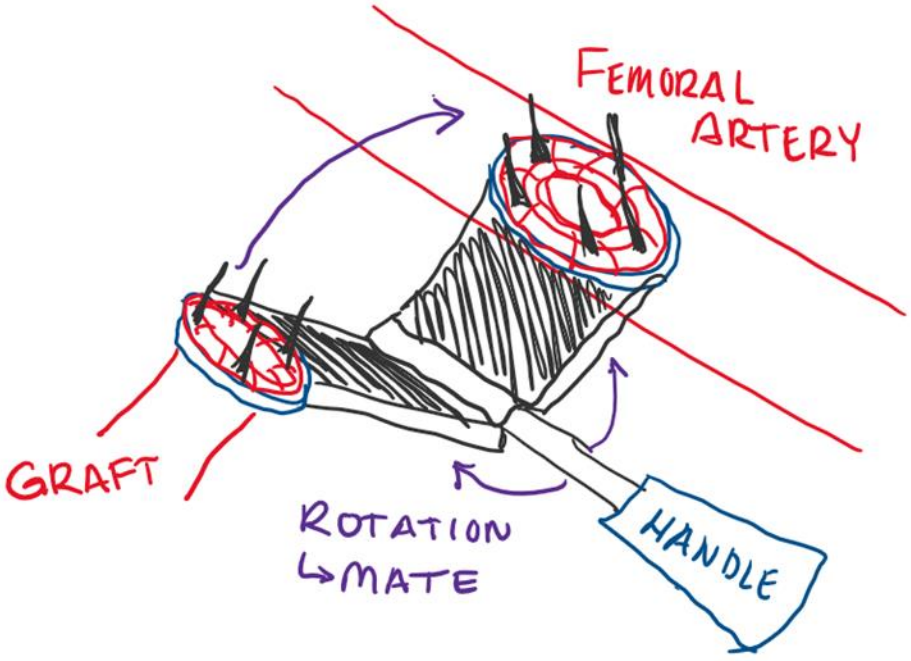


Figure 15: Biodegradable M.A.C

This concept utilizes a direct side-to-end Coupler with no intermediate where the vessels mate with flared ends. The handle serves dual function of holding the vessels in place with also connecting the individual coupler halves during anastomosis. The spikes in the coupler rings must hold the vessels in their flared orientation and resist the shear force the vessels would respond with. As such, the secondary material chosen for the pins is a biodegradable metal, most likely of magnesium base. When combined with a biodegradable polymer as the choice for the ring, the implant will be fully biodegradable, allowing the vessels to remodel to each other without the downsides of impingement or chronic inflammation affecting the anatomy surrounding the implant.

Pugh Charts

The following analysis is based on our Pugh Charts which can be seen in *Appendices f – n.*

Although remarkably similar, we found the M.A.C. to have a slightly more complexity than both ligation-connected intermediates in terms of steps to complete due to the need to visually confirm the flared orientation of the blood vessels during their fixation to the coupler rings. However, based on previous studies evaluating the use of the Synovis M.A.C., we hypothesized the alternatives to have insignificant differences in total procedure time on the scale of comparison to suturing. Furthermore, this extra complexity of flaring the blood vessels provides vast benefits in the efficacy of connection due to its necessity in establishing intima-to-intima contact. This led us to believe that the vascular prosthetic would provide a more natural path of flow than the Rigid T-joint. It would also be less impinging on the surrounding anatomy due to the flexibility of the prosthetic.

A consideration in the evaluating the vascular prosthetic and the Rigid T-Joint that we felt unable to adequately judge was the efficacy of connection. We are confident about the efficacy of the M.A.C. due to its property of introducing intima to intima contact. With both intermediate materials, however, the efficacy would rely on either of two unknowns.

One of these unknowns would be the capabilities of the endothelium and exterior vasculature to remodel enough to bridge the gap between where each blood vessel is attached to the coupler.

The second unknown is the efficacy of the vasculature-to-coupler connection. It was hypothesized that the introduction of porosity or a surface roughness would promote cell adhesion and strengthen the merging of the vessels to the coupler. In the case of the prosthetic, the seamless weave of the tube naturally includes exceptionally high surface area to promote cell adhesion for the same benefits.

Conceptual Model

SolidWorks was used to produce a generic model for the Design of the Anastomotic Ring Coupler with pins of the same material as the ring. The CAD displays the model of a through hole in the ring with cylindrical pins. The drawing view illustrates the cross-sectional view used to display various geometries of pins and slots.

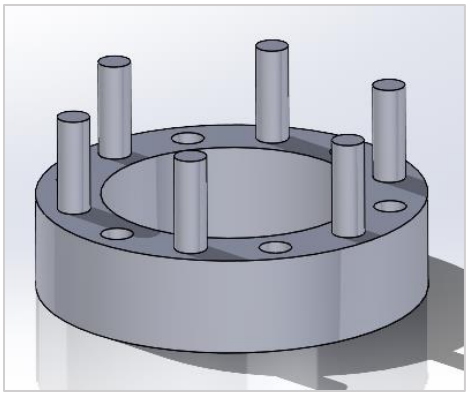


Figure 16: Assembly of Coupler Rings

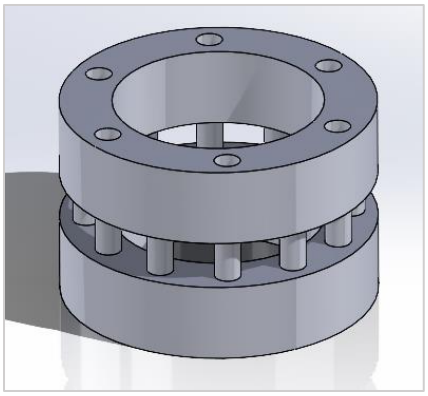


Figure 17: Individual Anastomotic Ring

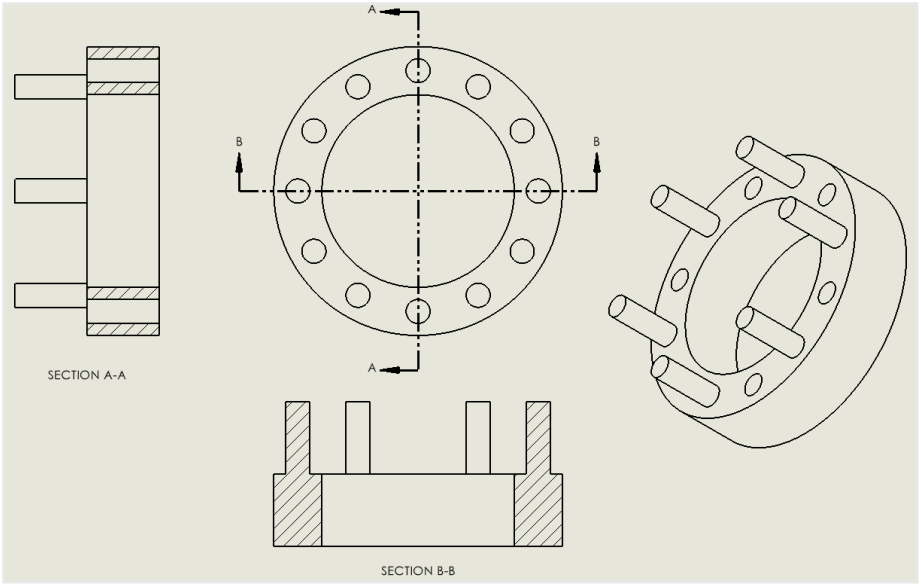


Figure 18: Drawing of Individual Pins

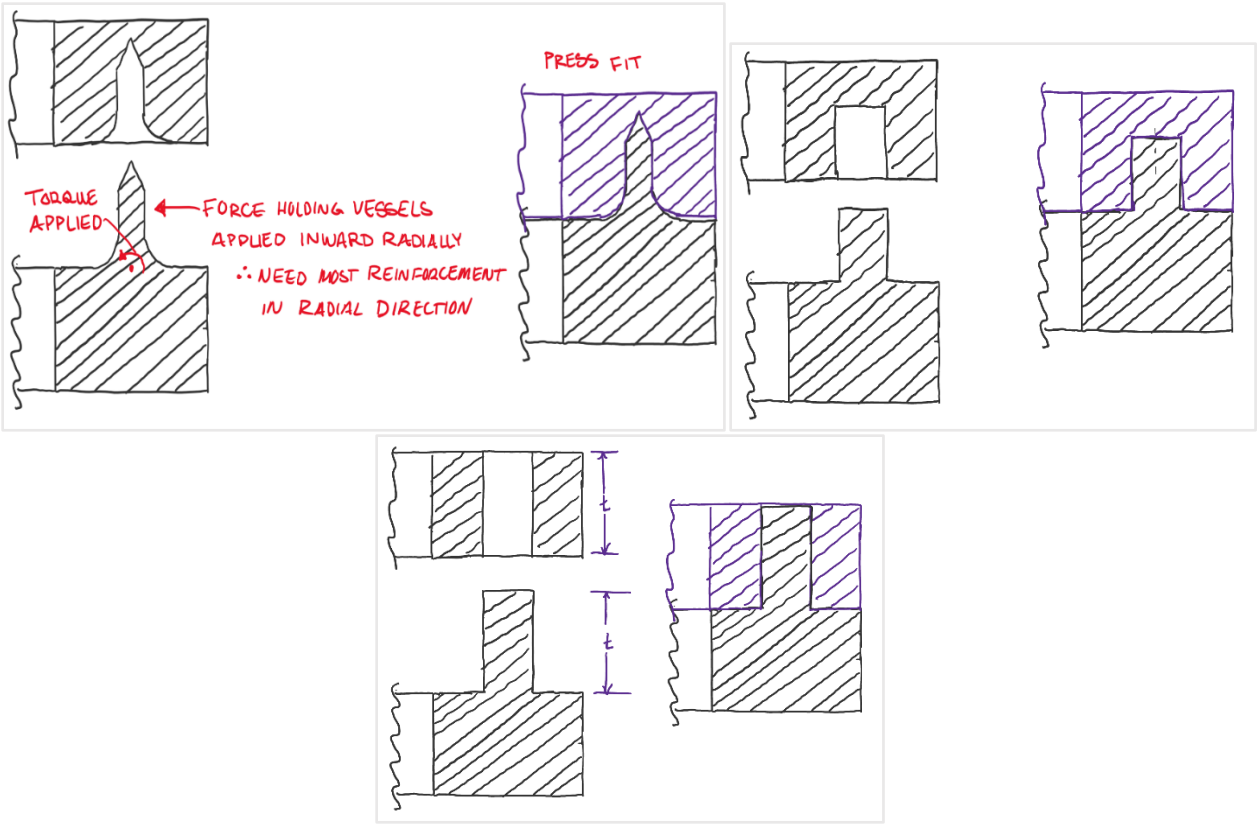


Figure 19: Pin Geometries. A) Filleted with spike B) Wide Pin
C) Through Pin

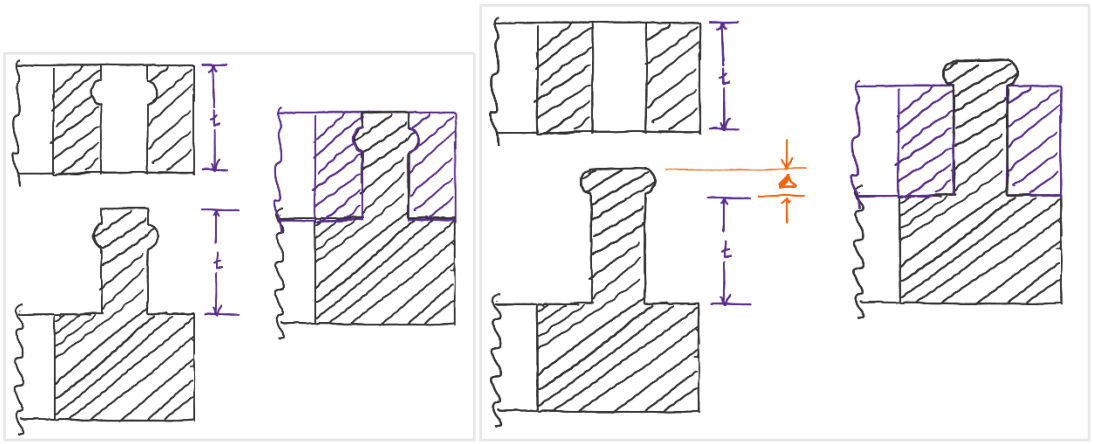


Figure 20: Pin Geometries. D) Male Female Interlocking E) Through Male

Concept analysis consisted of producing cross-sectional views of different pin geometries for comparison. The construction of the CAD model inspired the question into whether creating such a complex geometry at the small scale would be possible. Another consideration is whether the polymer pins could be designed in a way to have enough strength to not break off. Further concept generation needs to be explored to satisfy the three main functional purposes: 1) holding vessels in flared orientation, 2) holding rings together, and 3) making the pins strong enough to not fail.

The design we have created thus far is a solid design and we think it could work well but we will also be paying close attention to the strength of the individual pins of the ring, the sizing of the pins and how they fit, and the geometry of the pins and if we need to investigate new shapes to improve our model.

Detailed Design

The final design of the Anastomotic Biodegradable coupler will consist of a single solid body with pins directly attached to the rings. A single assembly consists of two identical pieces with their pins and holes interconnected. Iterations of this design test the different fits that will result in the mate that is easiest to connect while still able to hold itself together. Following testing will confirm whether the additional surface area of a knurling texture on the face of the rings will hold the walls in place with better friction. This added grip is intended to remove load from the small diameter pins to prevent tearing of the artery walls.

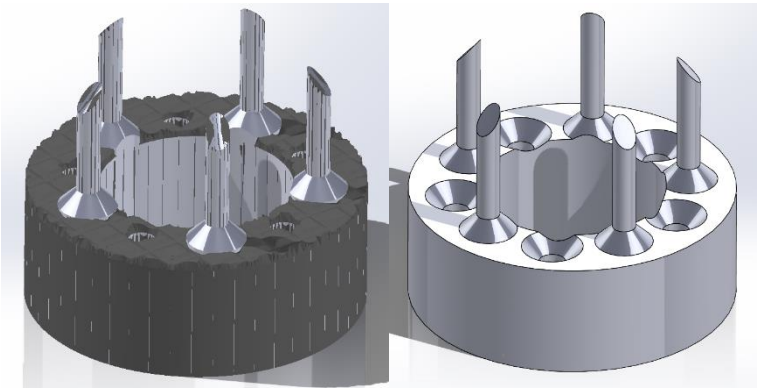


Figure 21: Image of Model A Mesh showing Knurled Surface Texture

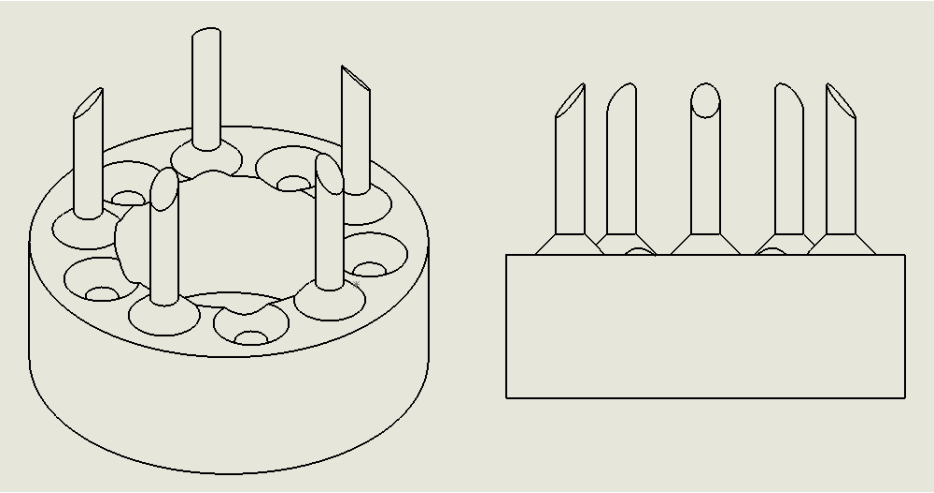


Figure 22: Drawing of Model A

Table 5: First Iteration Parameters for different Prototype Models

Model	A	B	C	D	E	F	G	H
Clearance (mm)	0.75	1.00	1.25	1.00	1.00	1.00	1.00	1.00
Face to Bump (mm)	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
Face to Notch (mm)	2.75	3	3.25	3	3	3	3	3
Bump/Notch Fit	Perfect	Perfect	Perfect	Clearance	Interference	Perfect	Perfect	Perfect
Notch Diam (mm)	0.8	0.8	0.8	0.8	0.7	0.8	0.8	0.8
Bump Diam (mm)	0.8	0.8	0.8	0.7	0.8	0.8	0.8	0.8
Pin/Hole Fit	Perfect	Perfect	Perfect	Perfect	Perfect	Clearance	Interference	Perfect
Pin Diam (mm)	1	1	1	1	1	1	1.1	1
Hole Diam (mm)	1	1	1	1	1	1.1	1	1
Knurling	None	None	None	None	None	None	None	Present

Table 6: Second Iteration Parameters for different Prototype Models

Model	G	H	I	J
Hole Resize (%)	115	125	135	145
Pin Diam (mm)	1	1	1	1
Hole Diam (mm)	1.15	1.25	1.35	1.45

A significant feature throughout the iterative design process was the optimization of the spike's point. This design depends on the use of polymers as bulk material due to their biodegradable properties, but with this comes a significant compromise in mechanical properties. To overcome this problem, the orientation of the spikes was changed as the following images show.

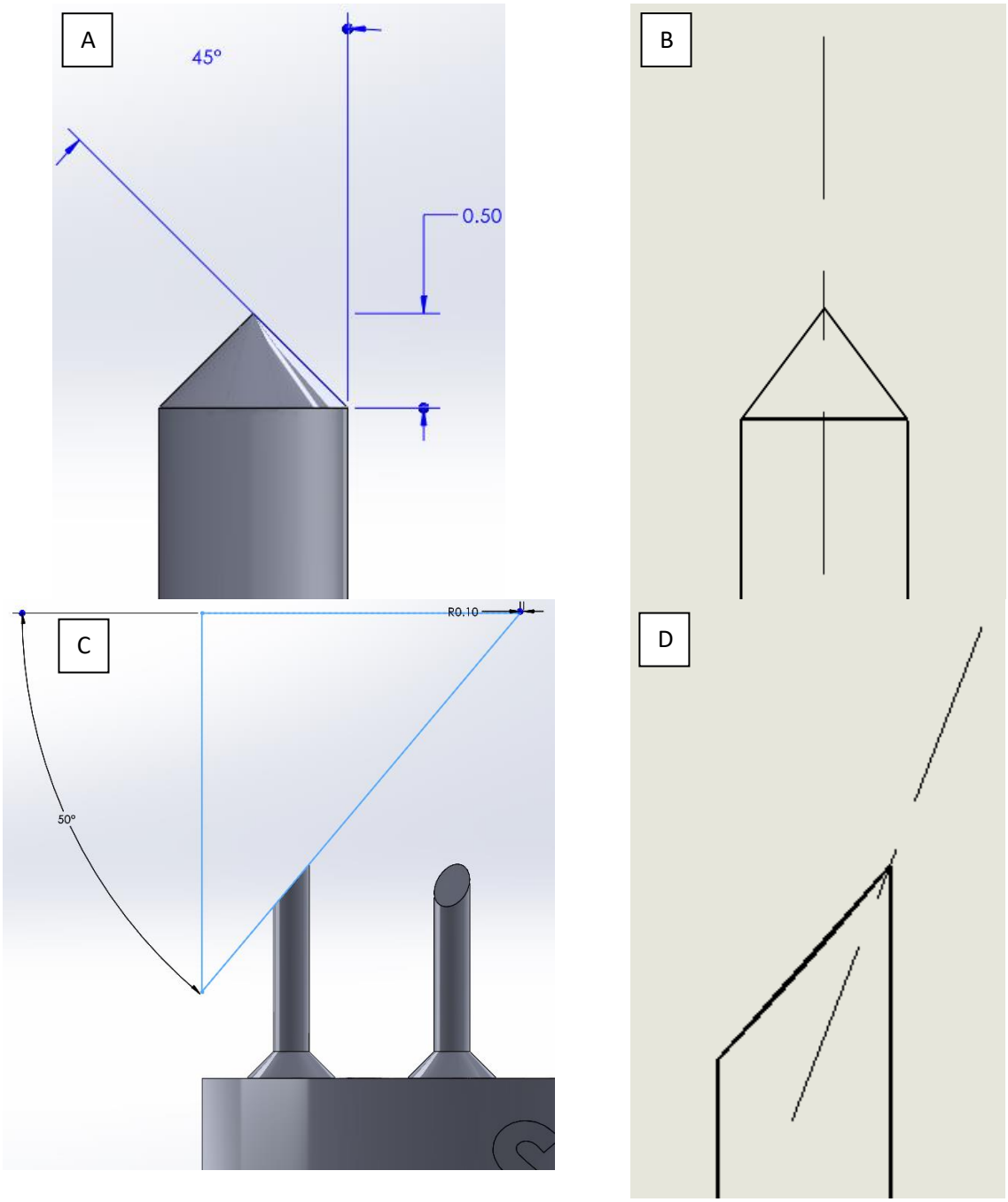


Figure 23: Spike Design. A) Old spike geometry. B) Old Angle of point apex. C) Latest spike geometry. D) Latest Angle of point apex.

In the newer pin geometry, the point is formed by a revolved triangle cut. This places the point of the spike at the most radially inward part of every pin. The first advantage of this orientation is that the point of the spike is angled radially inward, creating a functionally sharper point against the tented vessel during implementation. The second advantage is that the vessel does not need to be stretched as far to reach the point of the spike. This factor is likely to increase the ease of operation, as the vessel has a limited capacity to stretch.

Prototype Manufacturing Plans

Our team has decided to print our device on a Resin 3D printer. The specific printer we use is the Elegoo Saturn 2. The first step to achieving this will include perfecting our solid works model. Then we use Lychee Slicer where we choose our printer and use the standard resolution settings with an x- and y-axis resolution of 28,5 µm and a z-axis resolution of 50 µm. To facilitate the production of prototypes through SLA printing, two key design-for-manufacturing features are added that are not essential to the function of the part. A chamfer rides along the bottom face of the part and a radially symmetric set of channels connect both the center hole and the pin holes to the outside.

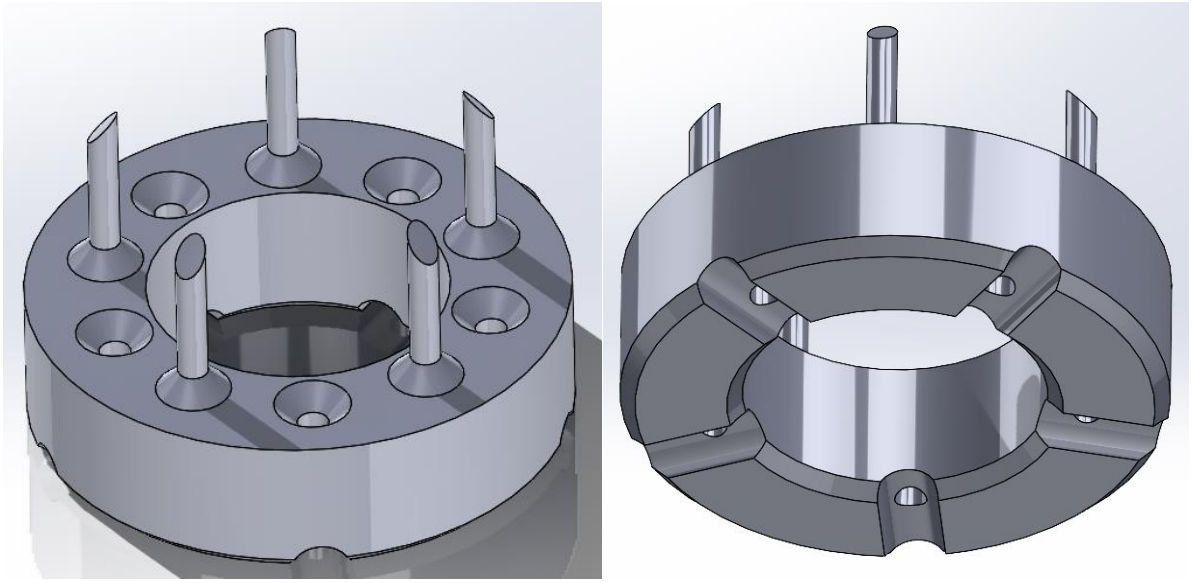


Figure 24: Microvascular Anastomotic coupler with design for manufacturing features

The parts are oriented on the print bed chamfer side down and placed with about 5 millimeters of space between them. Post processing consists of washing the models in isopropyl alcohol to remove the remaining resin. After removing the residual resin, the print is cured with a UV light source. Due to the parts' small size, one plate can print 64 individual models, allowing rapid iterative testing of the different parameters to be compared.
These prototype models will be printed using the Elegoo Photopolymer Resin that has similar mechanical properties to that of our final biodegradable polymer, PLGA, as seen in table 16. The PLGA ratio we looked at has an L/G ratio of 10/90. These prototypes will be of accurate scale due to the exceptionally high resolution of SLA printers. SLA printing produces isotropic parts, as opposed to the anisotropic parts formed in typical additive manufacturing methods. Therefore, these prototype iterations will retain the chosen bulk material's mechanical properties for accurate testing performance.

The printer used for the resin printing process is owned by a private party who is willing to help with the project. The estimated cost of the printing pieces will be at 50ct per piece, but an invoice will be sent at the end of the prototyping and testing phase for a clarification of printing, post processing, and shipping costs.

The prototype manufacturing method being utilized has inherent limitations in dimensional accuracy. In the first round of prototype iterations, every single model had an interference fit between the pins and the holes, even those designed to be clearance fits. Therefore, these model's designs required revisions to make the couplers combinable.

Metric analysis was performed to inform the design of hole diameters in the second iteration of prototypes. Due to the small feature size, hand measurements with calipers are not sufficiently accurate. The first iteration prototypes and a known scale of 5 mm were imaged using a confocal microscope and analyzed using ImageJ software. The scale was used to calibrate a relation between pixel count and true size. Images of the scale and the parts were taken with the exact same microscope configuration from the same distance to maximize accuracy (see appendix o). Several measurements were taken of different prototype hole diameters and averaged. This average was compared to the designed parameter and the difference was used to inform the resizing of the hole for the second round of prototype iterations *(table 16*). The true holes of the printed parts were ~13% smaller than designed be average. The pins only deviated from the designed size by ~3.4%. In the second iteration of prototypes, the size of the pins was left the same and the size of the pins was incrementally increased across the models (see table 16).

Table 7: Metric Analysis of First Iteration Prototypes

	Designed Size (mm)	Measured Size (mm)	Diff = Designed - measured (mm)	Revised size = Designed + Difference (mm)	% Increase	% Dev
Model A Hole	1.1	0.99	0.11	1.21	110	
Model A Pin	1.0	0.97	0.03			3
Model B Hole	1.0	0.891462	0.108538	1.108538	110.8538	
Model B Pin	1.0	0.97	0.03			3
Model C Hole	1.0	0.844583	0.155417	1.155417	115.5417	
Model C Pin	1.1	1.07	0.03			2.727
Model D Hole	0.8	0.680071	0.119929	0.919929	114.991125	
Model D Pin	0.8	0.75	0.05			6.25
Model E Hole	1.2					
Model E Pin	1.2	1.17	0.03			2.5
Model F Hole	1.0					
Model F Pin	1.0	0.97	0.03			3
Average					112.85	3.41

Table 8: Material Properties Comparison Table for PLGA and 3D-print Resin

Material	**PLGA**	**3D-print Resin**
E modulus (MPa)	2.5 - 6	1.5 -9
Elongation (%)	300 - 350	65 - 300
Tensile Strength (MPa)	8 - 13	4 - 20
flexural strength (MPa)	11	120 - 140
flexural modulus (GPa)	6	3.1 – 3.5
shear modulus (MPa)	65- 150	/

As mentioned above our manufacturing plans are only for our prototype which is used to test our device since the resin has comparable properties to our PLGA. With our printing method the Resin also has isotropic properties which will be the case in the final manufacturing process. The PLGA version of our prototype is supposed to be manufactured via injection molding.

Instruction for Use

Our coupling device is very straightforward to use. The following instructions will be done on one half of the coupler device first and then repeated on the other half of the coupler with the blood vessel we want to connect to the first one. First, there is a big hole that fits the outer diameter of the blood vessel in the middle of the prototype where we put it through as the first step. After putting the blood vessel through the device, it is stretched and pulled over the first pin of the coupler. The pin will perforate the blood vessel, and thus connect it and keep it in place. Then you pull the vessel over the pins that are across from the first one also connecting it to those. This makes it easier to connect the last two pins compared to connecting the blood vessel in circular sequence. In the end the blood vessel is attached to the last two pins and now is ready to be mated to the other half of the coupling device. As previously mentioned, the other half follows the same instructions to also connect a blood vessel to the pins. Now after there are two blood vessels connected to the two halves of the coupling device, we can join the blood vessels together. The spikes on one half pierce the blood vessel on the other half and fit into the matching holes to connect the two parts to each other. The parts are held together through a press fit of the pins and holes.

In our final part all of this is done by surgeons who connect those two blood vessels together in the human body while doing surgery. All the surgical procedures to get to the point of connecting two blood vessels and finish the surgery after connecting the vessels are not included in these Instructions for Use. It is however necessary to mention that our device will need some preparation and cleanup work to be fully implemented.

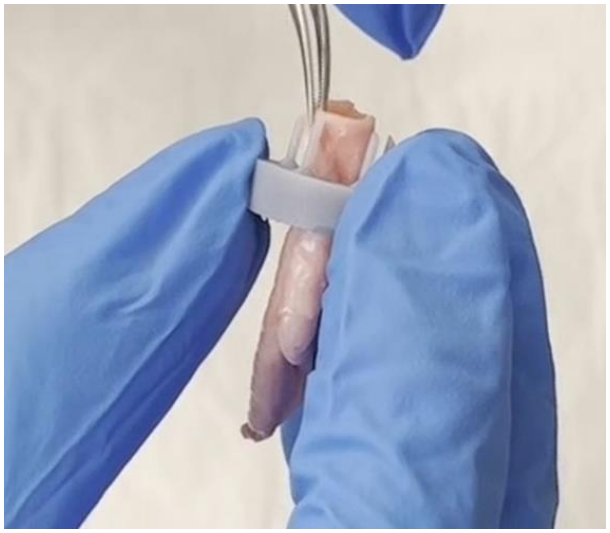


Figure 25: First step of assembly: Pulling blood vessel through middle hole.

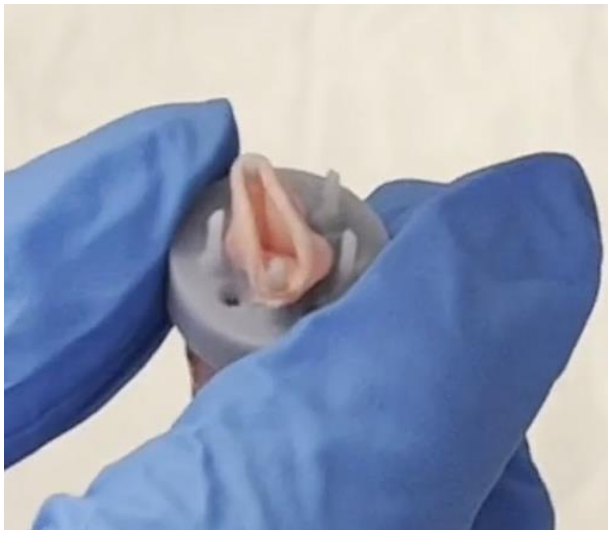


Figure 26: Second step of assembly: Connecting of pins.

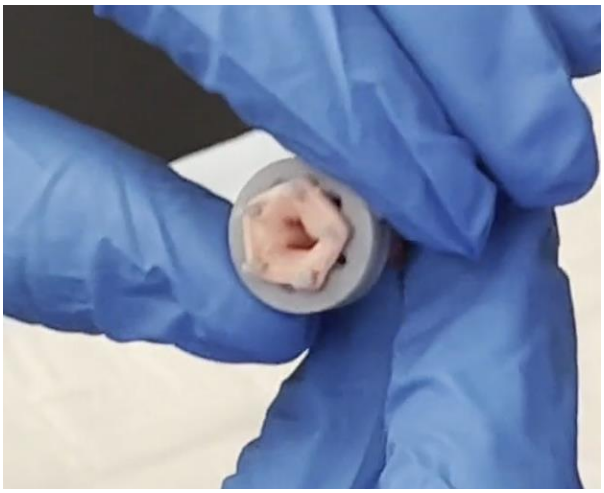


Figure 27: Third step of assembly: First completed coupler half.

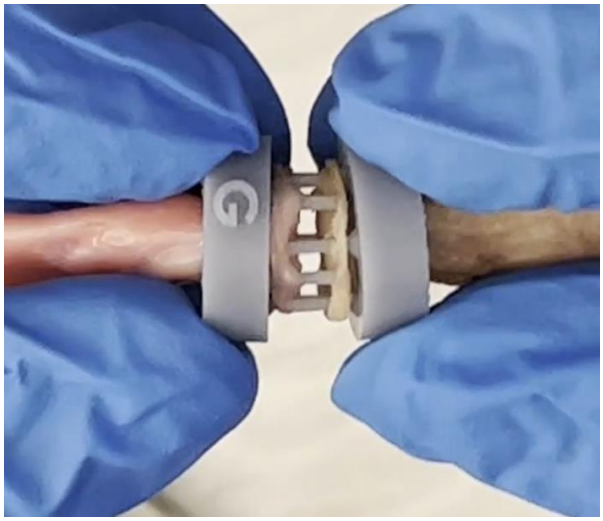


Figure 28: Fourth step of assembly: Coupler arrangement before mating.

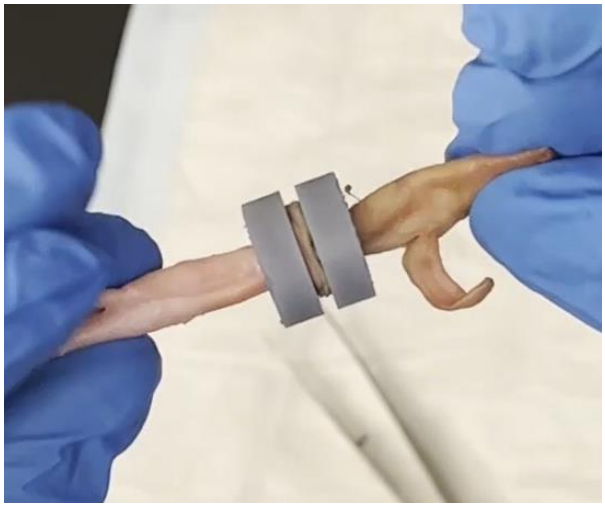


Figure 29: Full assembly.

Test protocols

Test 1: Connection force testing

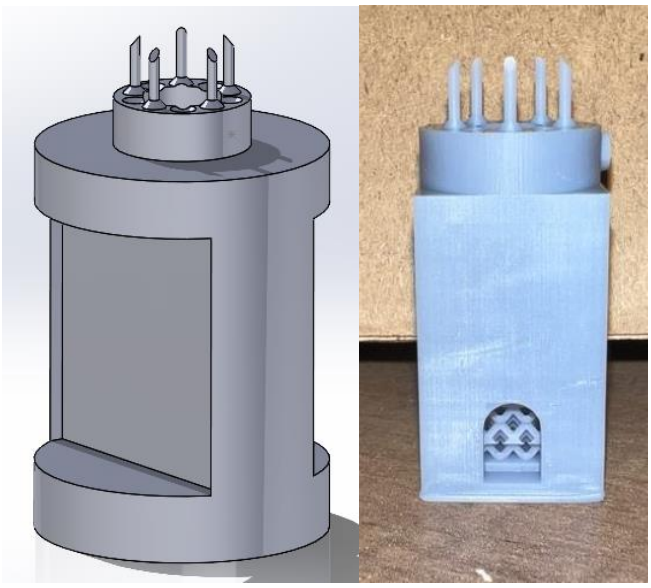


Figure 30: Connection Force Testing Fixture: Solid works first sketch (left), Model used in Testing (right)

A key customer requirement of the couplers is to have a low rate of dehiscence. One key failure mode of dehiscence, the testing is designed to work against, is the couplers separating due to poor fit. After the second iteration of prototypes, with the metric analysis resizing, are inspected for fits, the best model based on the force required to pull them apart will be compared to the Ultimate Tensile Stress where blood vessels would rip which we calculated later in this document. This requirement can be tested with the Instron Tensile Tester using custom coupler parts designed to have space for the native Instron clamps to grip.

As mentioned above the equipment for the test will be the Instron Tensile Tester and custom models of the best fitting prototypes with added material for the native Instron clamps to grip. Those modified prototypes can be seen in figure 25. Additionally, a thin cardboard piece with a thickness of 2mm will be added to create a small gap between the couplers which would also naturally occur because of the blood vessel between the two faces of the coupler. Personnel required for this test will initially be BMED ISA Pierce until our group has had sufficient supervised practice to perform all testing ourselves.

The test starts with clamping one of the modified prototypes into the bottom clamp of the Instron Tensile Tester and connecting the second half of the coupler with the clamped one. After this the top half of the coupler can also be secured to the top vise of the Instron. After assembly, the clamps will be adjusted to not introduce a high compressing force which could distort our results in the end. Therefore, the starting force must be below ±0.3N before starting the Pull. Since our device just needs to be pulled apart until the pins are disengaged or ripped, we will pull a total distance of 6 mm.

Data will be acquired as tensile force in the system over time as the custom prototype is pulled apart from each other, and the peak tension before the couplers are pulled apart will be the key piece of data.

The expected outcome for this test is that the couplers will withstand a tension of 22.5N. The force was calculated out of Ultimate Tensile Stress where the blood vessel would rip. [6] To this force we applied a safety factor of 1.5. The calculation from Stress to Force is found in appendix p.

Given that our first prototypes were unable to be pulled apart with our hands, this test will not be held to a contingency plan but rather will be an optimization based on the comparison of models deemed best fitting candidates after review of the second round of prototype iterations. The best fitting candidates will be compared in a group of n = 25.

Test 2: Vessel Grip and Pin Strength Testing

Some key customer requirements for the anastomosis method are to be reliable and easy for the surgeon to attach. A translation of these requirements to engineering specification can be the rate of success when attaching the blood vessels to the pins. Two potential failure modes during this step would be breaking the pins, indicating that the coupler itself is not reliable, and the blood vessels ripping, indicating that too much force is required during attachment and the process is not easy enough.

The attachment of a Latex blood vessel surrogate to the coupler in end orientation will provide a pass-fail test for attachment. The failure criteria for this test will qualitatively be defined by either the pins breaking upon attachment or the vessel ripping.

To attach the blood vessel surrogates to the coupler we need to start with pulling the surrogate through the hole of the coupler. Then the surrogate is pulled over the first pin and the pin will poke a hole through the wall thus introducing the first connection. After this the blood vessel is pulled over the pins across from the first pin also connecting them with the pins pinching holes through the surrogate. In the end the remaining pins are connected to the blood vessel.

After the attachment portion of this test, the attached coupler is mated to a matching unattached coupler. In this assembled orientation, the vessel walls will be compressed by both faces of the coupler. The parameter targeted by the next portion of this test is the coupler assembly's ability to hold the blood vessels after assembly without them ripping. A custom fixture (figure 26: Vessel grip test fixture) will be attached to the bottom of the Instron and support the assembly from the top. The vessel attached to the assembly will be gripped in the native Instron clamps above. The data acquired will be the max force withstood by the vessel before it is ripped out of the assembly. The expected outcome for this comparison is for the additional feature of knurling on mating face of the rings to increase the max tension withstood by a blood vessel by reallocating load away from the small and pointy pins. The control group (n=25) will consist of rings with no surface texture, and the experimental group (n=25) will consist of couplers that have a knurled surface on the face of the ring but are identical to the control group otherwise.

The equipment for the test will be the Instron Tensile Tester, the custom fixture Vessel Grip Test Fixture, the different prototype models being compared, and Latex blood vessel surrogates to pull on.

Data will be acquired as tensile force in the system over time as the fixtures are pulled apart from each other, and the peak tension before failing will be the key piece of data.

For the first few tests the tensile test instructor Pearse will be present for training purposes and after a few supervised tests we will be able to perform them on our own. Our team member responsible who overlooks the testing will be Sophie.

If the pins fail at a rate that does not meet the criteria for the successful attachment rate, this will warrant a further geometric revision of the pins and their attachment to the rings. If the latex blood vessel surrogates fail at a rate that does not meet the criteria for the successful attachment rate, this will warrant a resizing of the ring and repositioning of the spikes to pull on the vessels with less outward radial force.

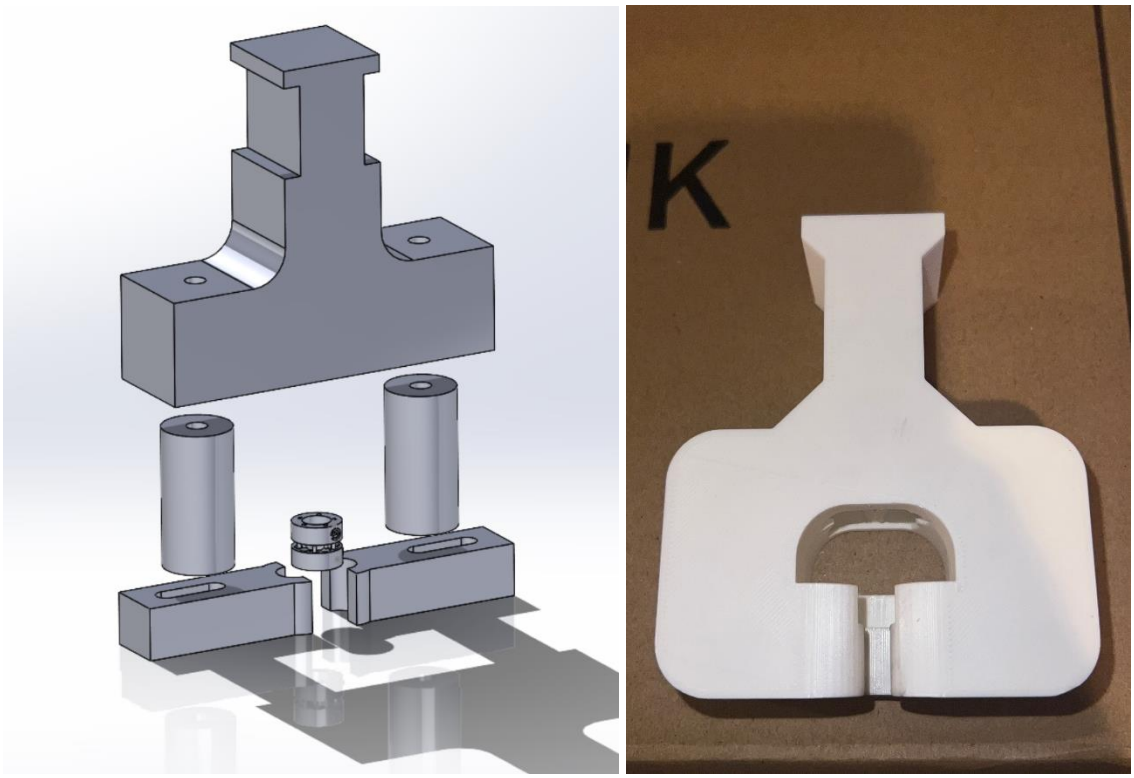


Figure 31: Vessel Grip Test Fixture: Solid works first sketch (left), Fixture used in Testing (right)

Test Network diagram

All our next steps to start the testing procedures are listed below in the test network diagram and will be completed before the final report is due.

	Task Name	Duration	Start	Finish	Predecessors	Resource Names
1	Print new iteration of coupler	4 days	Thu 2/2/23	Tue 2/7/23		Engr 4 - R330,laptops,sam
2	order surrogate blood vessels	4 days	Thu 2/2/23	Tue 2/7/23		Engr 4 - R330,laptops,sam
3	order materials for testing fixtures	4 days	Thu 2/2/23	Tue 2/7/23		Engr 4 - R330,laptops,sam
4	manufacture testing fixtures	5 days	Wed 2/8/23	Tue 2/14/23	3	Machine Shop,fixture materials,nick
5	start first connection force tests	4 days	Wed 2/15/23	Sat 2/18/23	4,1	BMED lab,fixture,3D-print parts,sophie
6	evaluate testing results	3 days	Sun 2/19/23	Tue 2/21/23	5	Engr 4 - R330,laptops,nick
7	start first vessel grip and pin strength testing	4 days	Wed 2/22/23	Sat 2/25/23	6,1,2,4	BMED lab,fixture,3D-print parts,surrogate blood vessels,sophie
8	evaluate testing results	3 days	Sun 2/26/23	Tue 2/28/23	7	Engr 4 - R330,laptops,nick
9	start second connection force tests	4 days	Wed 3/1/23	Sat 3/4/23	6,8	3D-print parts,BMED lab,fixture,sophie
10	evaluate testing results	3 days	Sun 3/5/23	Tue 3/7/23	9	Engr 4 - R330,laptops,nick
11	start second vessel grip and pin strength testing	4 days	Wed 3/8/23	Sat 3/11/23	8,10	3D-print parts,BMED lab,fixture,sophie,surrogate blood vessels
12	evaluate testing results	3 days	Sun 3/12/23	Tue 3/14/23	11	Engr 4 - R330,laptops,nick

Figure 32: Test Network Diagram: Tasks, Schedule & Resources

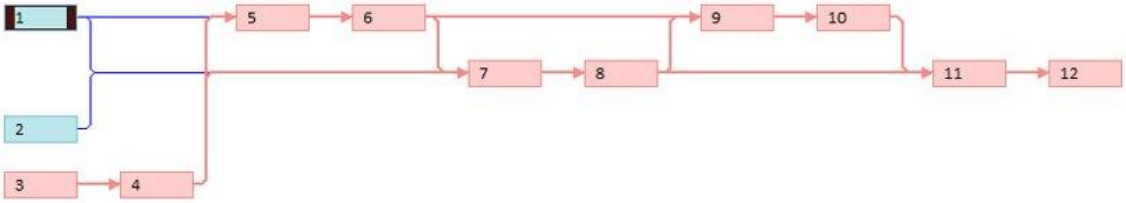


Figure 33: Test Network Diagram: Critical Path

Testing Data and Analyses

Test 1: Connection force testing

The results of our test did not meet our initial expectations. We had anticipated that the coupling system, incorporating a 2mm spacer set between the two halves of the coupler, would be over an average tensile force of 22.5N. However, our findings indicated that only prototypes 19 and 21 exhibited a favorable outcome, with separation forces of 70N and 40N, respectively. Most of the other specimens averaged a maximum tensile force of around 2-4N which meant the parts had nearly no interference fit to keep them together. With 2 out of 26 specimens failing to achieve a Tensile Force over 22.5N we had a failure rate of around 92%. Prototype 19 and 21 indicated however that if the interference fit is good, we could achieve better results in the future. Notably, our manufacturer experienced some issues with their printing process during the production of these prototypes, which we believe significantly impacted the fit of the coupling system. A few days after the first test, we received a new set of prototypes for the second test that displayed considerably enhanced grip strength. Unfortunately, these new prototypes lacked the requisite fixture necessary for compatibility with our first test design. Because of this, we only have our initial test data and could not rerun the test to achieve better results than in the first run. Solutions to improve the testing results in the future are to replace the added material for the Instron to grip with a fixture that can hold the normal couplers without any added material. It is possible that the added materials and printing time to produce the modified parts for the grip test increased the variability of the manufacturing process leading to poor fits.

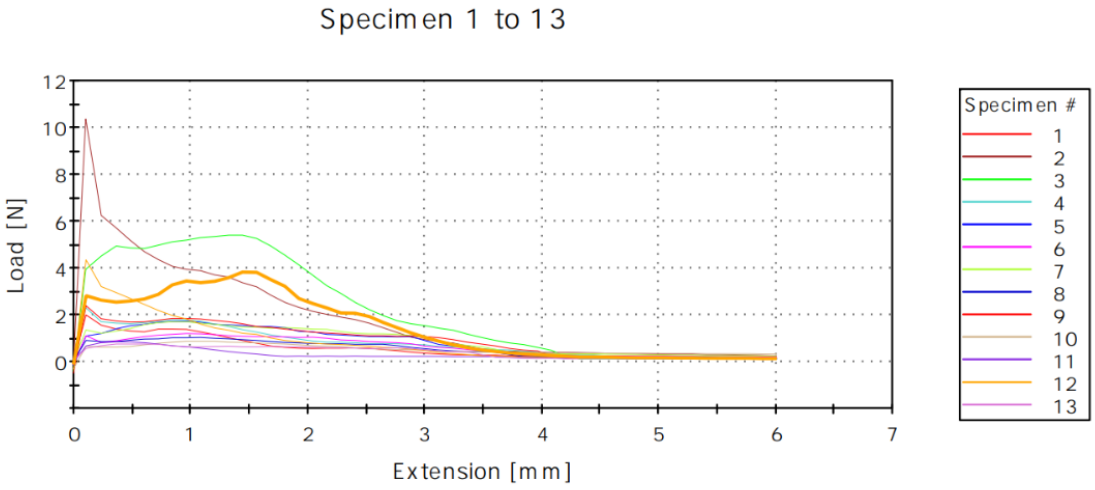


Figure 34: Test 1 results (part 1)

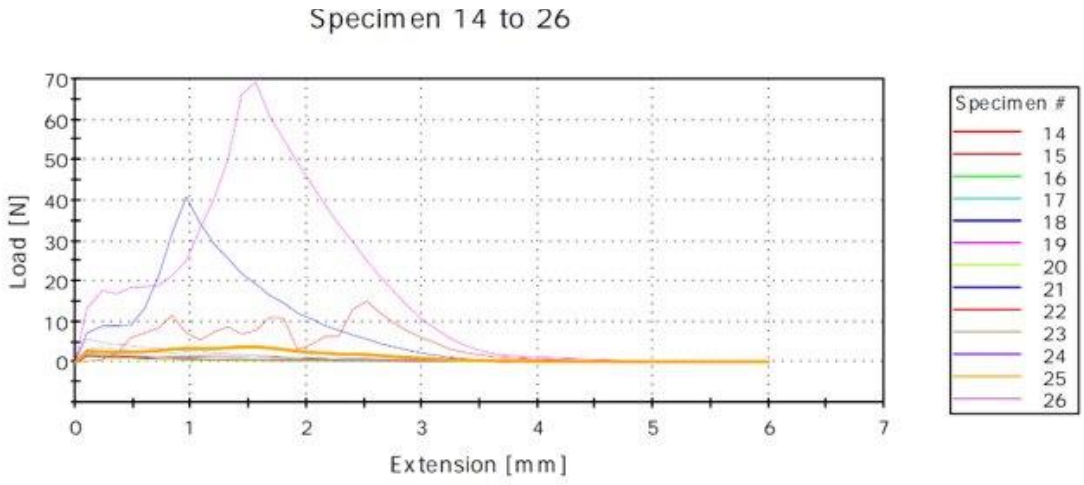


Figure 35: Test 1 results (part 2)

Test 2: Vessel Grip and Pin Strength Testing

Test 2 yielded positive outcomes. We utilized silicone tubing with an inner diameter of 7mm, an outer diameter of 10mm, a selective wall thickness of 1.5mm, and cut the tube to a length of 2.5 inches. During the preparatory phase, we encountered setbacks, as the tubing appeared to be too thick for our prototype size and too difficult to pull over all 5 pins without the pins failing, which indicates that our pins may be not strong enough to keep a blood vessel in an intima-to-intima position without failing before connecting the second part of the device. Since it worked with the real blood vessels we used in previous assemblies and in our Indications for Use Instruction below, it could just be a poor choice of surrogate tubing for our test. Nevertheless, through strategic problem-solving, we succeeded in devising a method to divide the tubing opening into five strips, which we could then attach to one side of the disc. Overall, the test furnished compelling evidence of the strength and durability of our device when both sides of the coupler were engaged. The sharp falls that appear on the graphs below denote instances where the silicone tubing ruptured from the coupler, while the smoother lines represent instances where the tubing only stretched until it eventually slipped from the fixture of the Instron machine.

Specimens 1 to 25 are models with smooth surfaces in between the pins, whereas specimens 26 to 50 have the knurled surface feature. We can observe that in nine instances the tubing ruptured where the coupler had the smooth surface. Most of them ruptured at a Load between 90 to 100N. The rest of the tubing did not fail and reached around 90N before it slipped out of the fixture because the downward pull was too strong. This means that 36% of the tubing failed while using the smooth surface feature.

While testing the knurled surface feature we can identify only four instances of the tubing rupturing around a load of 75 to 90N which is lower than most of the ruptures occurring at specimens 1 to 25. Also, the tubing slipped out of the fixture earlier than with the smooth surface finish around loads of 70 to 80N. Concluded we can see that the tubing connected to knurled surface prototypes has a failure rate of 16%.

Since not all the 50 specimens could be tested until failure and the Load each half of the specimens reached was also different there is no conclusive evidence that the knurling or smooth surface had a significant impact on the failure rate of the couplers. However, it seems that the specimens with knurled surface features impacted the elasticity of the tubing. The tubing connected to the knurled surface feature couplers shows slippage at a far lower load than the tubing connected to the couplers with smooth surfaces. This suggests the couplers with a knurled surface finish may hold the compressed portion of the vessels tighter, allowing less material to stretch out of the sandwiched portion of the assembly and effectively decrease the length of the vessel across which the tension was distributed. Couplers with a knurled surface may be better than couplers with a smooth surface since the blood vessels should stay in place for improved healing results and lower chances of leaking.

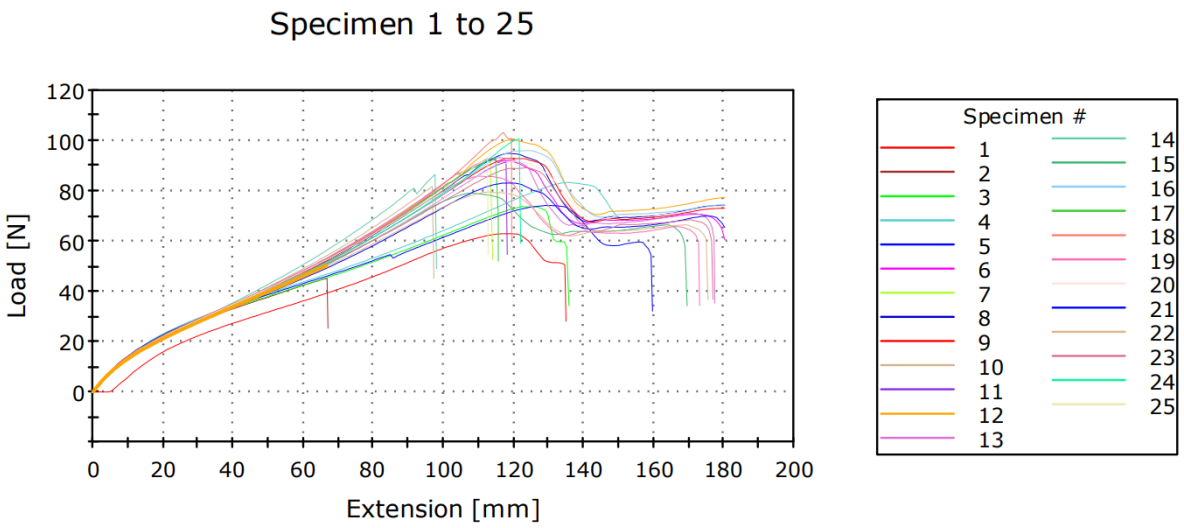


Figure 36: Test 2 results (part 1)

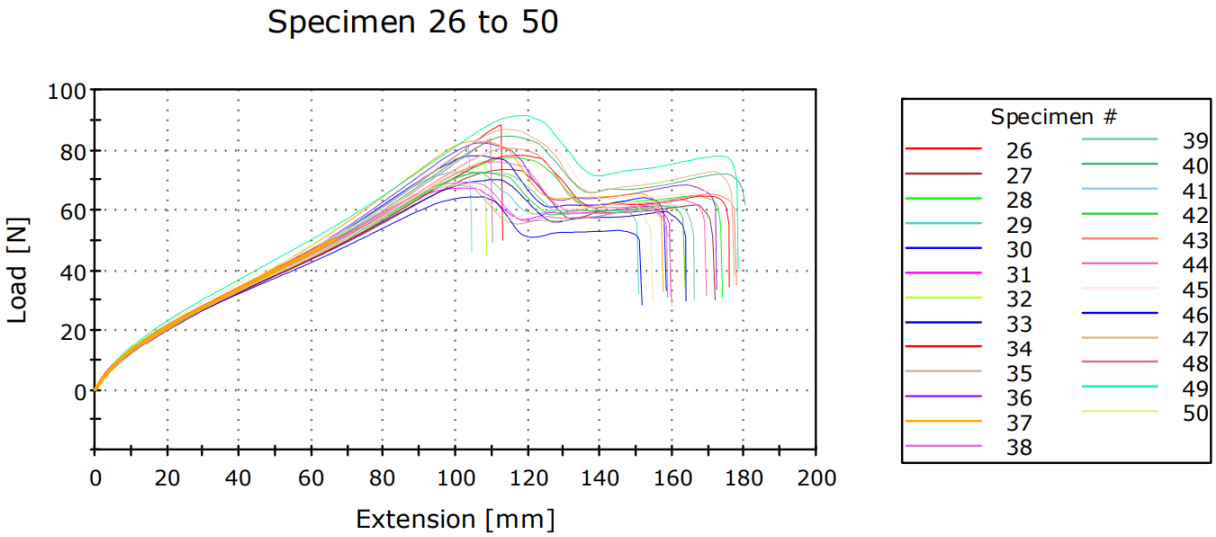


Figure 37: Test 2 results (part 2)

Conclusions

In conclusion, it is evident that there are key areas for improvement in our design. Our initial test underscored the significant impact that minor manufacturing changes can have on the fit of the coupler, potentially leading to life-threatening internal bleeding. That is why even after witnessing the improved interference fits for our second test there should still be a safety feature that makes sure, that even if the interference fit is not as strong as it should be, to keep the two coupler halves connected. One design idea to improve the connection could be a clip as an additional part to the coupler that would be added to the coupler after the blood vessels are attached and the two halves connected. There could be an indentation on both surfaces without pins where the clip just had to be attached to keep the two parts in their compressed position.

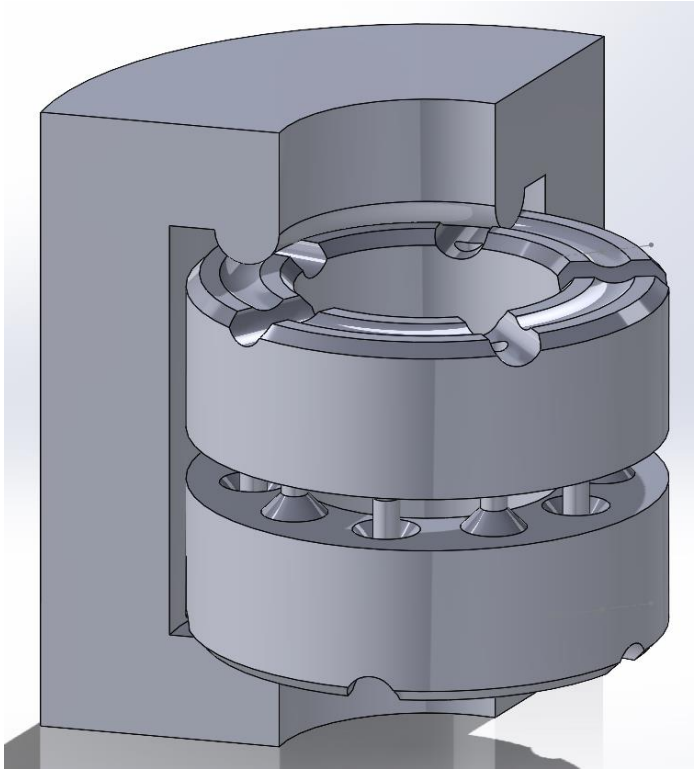


Figure 38: Possible future clip design

One potential design alteration that could be considered involves implementing conical pin holes, which would ensure that the necessary interference fit is achieved. It is important to note that thorough testing and refinement would be required to determine if any of these proposed design changes effectively enhance the fit of the couplers and satisfy the required connection force specifications. We must reiterate, however, that the current design was created for testing purposes only due to budgetary constraints. Furthermore, the surrogate resin used for testing is not PLGA, the intended material, and changing the material could yield different results. Additionally, we aim to injection mold the coupler in the future, which could enhance the consistency of the coupling devices, as opposed to the 3D resin printing, we used for our prototype.

The results from the second test provide favorable feedback concerning our design decisions. Despite exerting a substantial amount of force, the pins and coupler demonstrated remarkable durability, with no instances of breakage recorded, and only the surrogate blood vessels failing. Moreover, the pins proved sufficiently robust to penetrate through blood vessels effortlessly, without experiencing any breakage during assembly while utilizing actual blood vessels.

Regrettably, the surrogate blood vessels lacked the necessary elasticity to be fitted over our pins without damaging the pins, prompting a consideration of redesign options aimed at enhancing the robustness and thickness of the pins to withstand greater shear forces or by purchasing surrogate vessels with a more similar thickness to native vessels.

Discussion

During early stages of prototype manufacturing, there was a high rate of failure in early parts due to parts falling off the printing bed. Parts were also much wider at the bottom than designed, an effect known as “elephant’s foot.” The suction cupping effect occurs when using an SLA printer to produce a cylinder. Due to the prevalence of through holes in our part for the vessel and the pins, there was a large amount of adherence to the screen in the SLA printer. After a new layer is cured, the bed of the printer is pulled upwards away from the screen to make space for resin. If there are any enclosed hollow spaces, the air will create a suction force as it is pulled away from the screen by the bed and cause “elephant’s foot”.

To address these issues, structural supports were added. Offsetting the parts from the board using supports prevents the formation of closed spaces throughout the printing process and separates the bottom face of the part from the printing bed. Later iterations of prototypes were printed without supports in favor of other design modifications. The use of supports solved the suction cup and elephant’s foot issues, but unnecessarily added printing time, material cost, and post processing time to remove supports. These problems were solved by the addition of two key design features. Channels were added to expose the center hole and outside the part to allow fluid to enter the center hole as the bed pulls the cylinder away from the SLA screen. These channels also remove the bottom portion of the ring’s through holes, preventing them from being deformed or entirely closed where the part adheres to the base plate. Champers were added to the bottom face of the part to offset the effects of elephant’s foot.

A significant setback in the iterative design process was our implementation of two changes to the manufacturing method at once. The Structural supports and the metric analysis resizing were implemented over same iteration of prototypes, leading to our tolerances falling on the opposite side of the spectrum by consisting entirely of clearance fits. Following the establishment of a consistent manufacturing process, another round of metric analysis was conducted with the aim of pinpointing a new size for the pin holes.

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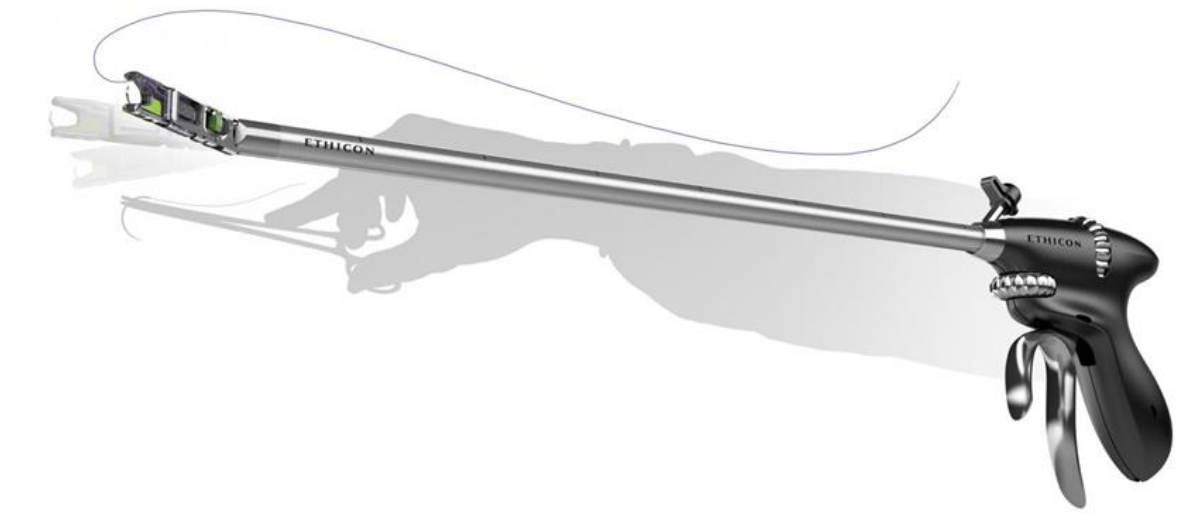
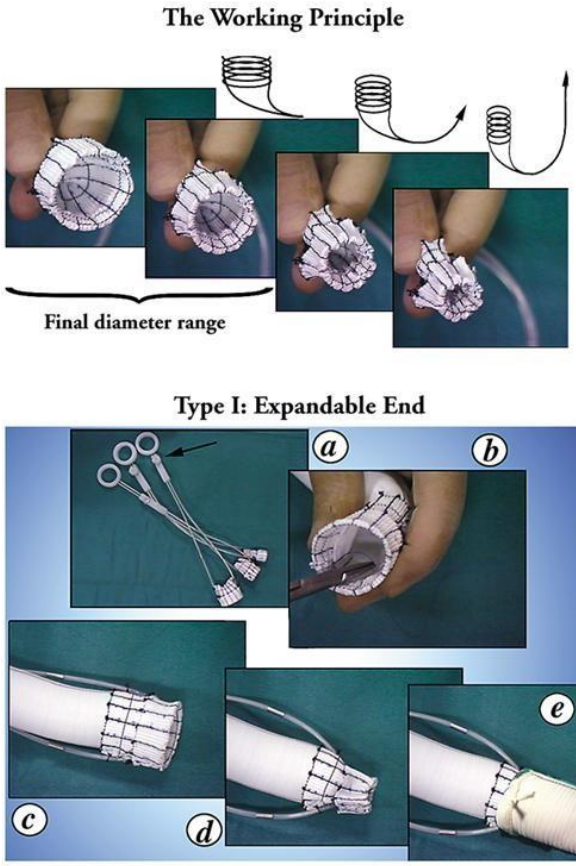
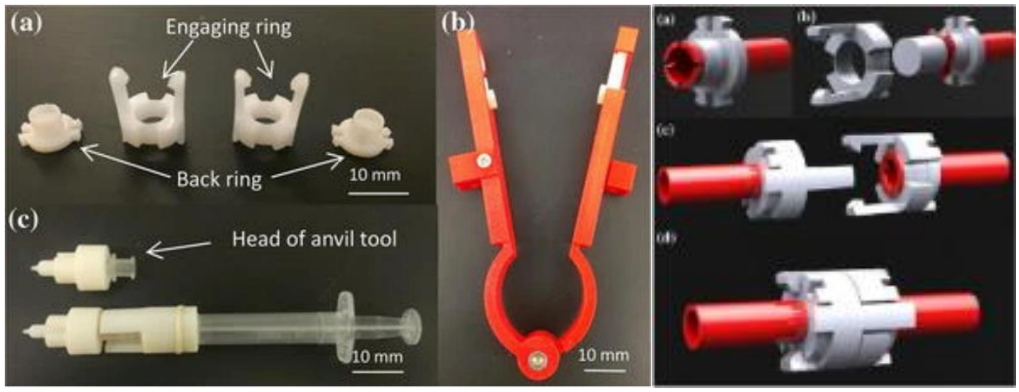
Appendices



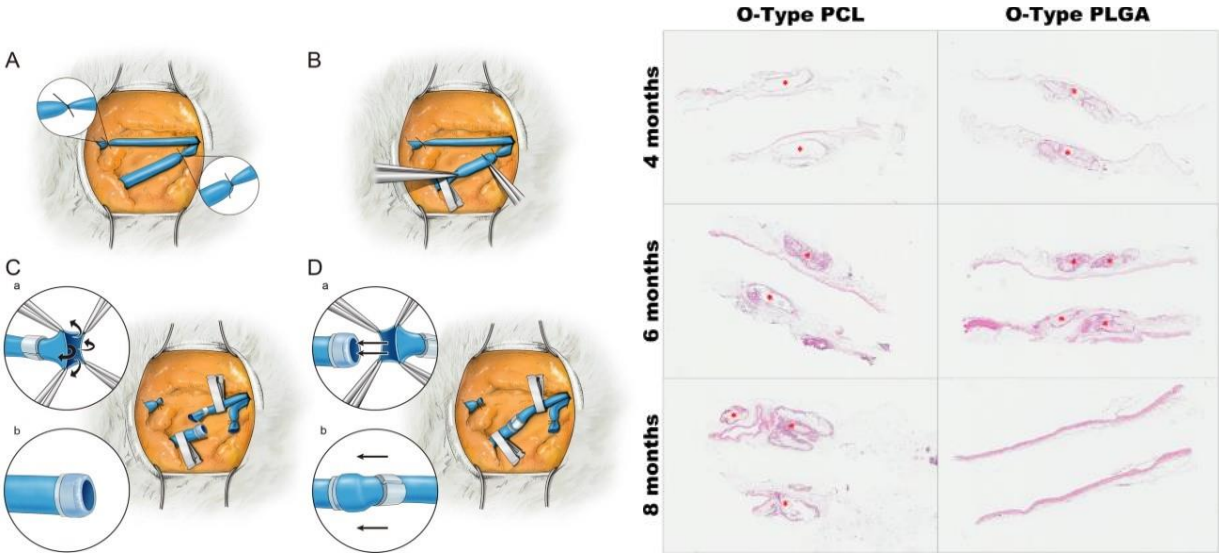
Appendix a: Proxisure Device [1]



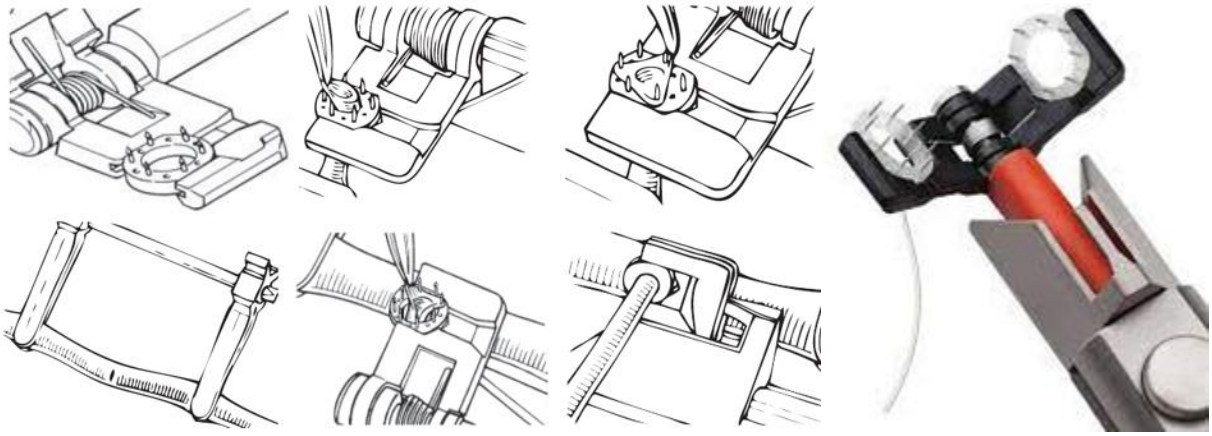
Appendix b: Improved Device for Sutureless Aortic Anastomosis [2]



Appendix c: Vascular Coupling System for End-to-End Anastomosis [3]



Appendix d: New Absorbable Microvascular Anastomotic Devices Representing a Modified Sleeve Technique: Evaluation of Two Types of Source Material and Design [4]



Appendix e: Microvascular Anastomotic COUPLER System [5]

Issue: Choose method and device for anastomosis		Biodegradable M.A.C.	Vascular Prosthetic with Ligation	Rigid T Joint Prosthetic with Ligations
Steps to Complete	5	DATUM	1	1
Biodegradable	20		-1	-1
Time to Perform Surgery	30		0	0
Minimum Vessel Diameter	15		-1	-1
Intima-to-intima contact	25		-1	-1
Impingement on Surroundings	5		0	-1
	100		-55	-60

Appendix f: Pugh Chart Biodegradable M.A.C. Samuel

Issue: Choose method and device for anastomosis		Biodegradable M.A.C.	Vascular Prosthetic with Ligation	Rigid T Joint Prosthetic with Ligations
Steps to Complete	7	DATUM	1	1
Biodegradable	18		-1	-1
Time to Perform Surgery	25		0	0
Minimum Vessel Diameter	20		-1	-1
Intima-to-intima contact	25		-1	-1
Impingement on Surroundings	5		0	-1
	100		-56	-61

Appendix g: Pugh Chart Biodegradable M.A.C. Sophie

Issue: Choose method and device for anastomosis		Biodegradable M.A.C.	Vascular Prosthetic with Ligation	Rigid T Joint Prosthetic with Ligations
Steps to Complete	5	DATUM	1	1
Biodegradable	25		0	-1
Time to Perform Surgery	30		0	0
Minimum Vessel Diameter	15		-1	-1
Intima-to-intima contact	15		-1	-1
Impingement on Surroundings	10		0	-1
	100		-25	-60

Appendix h: Pugh Chart Biodegradable M.A.C. Nick

Issue: Choose method and device for anastomosis		Vascular Prosthetic with Ligation	Biodegradable M.A.C	Rigid T Joint Prosthetic with Ligations
Steps to Complete	5	DATUM	-1	0
Biodegradable	20		1	0
Time to Perform Surgery	30		0	0
Minimum Vessel Diameter	15		1	0
Intima-to-intima contact	25		1	0
Impingement on Surroundings	5		1	-1
	100		60	-5

Appendix i: Pugh Chart Vascular Prosthetic Samuel

Issue: Choose method and device for anastomosis		Vascular Prosthetic with Ligation	Biodegradable M.A.C	Rigid T Joint Prosthetic with Ligations
Steps to Complete	7	DATUM	-1	0
Biodegradable	18		1	0
Time to Perform Surgery	25		0	0
Minimum Vessel Diameter	20		1	0
Intima-to-intima contact	25		1	0
Impingement on Surroundings	5		1	-1
	100		61	-5

Appendix j: Pugh Chart Vascular Prosthetic Sophie

Issue: Choose method and device for anastomosis		Vascular Prosthetic with Ligation	Biodegradable M.A.C	Rigid T Joint Prosthetic with Ligations
Steps to Complete	5	DATUM	-1	0
Biodegradable	25		0	1
Time to Perform Surgery	30		0	0
Minimum Vessel Diameter	15		1	0
Intima-to-intima contact	15		1	0
Impingement on Surroundings	10		1	-1
	100		35	15

Appendix k: Pugh Chart Vascular Prosthetic Nick

Issue: Choose method and device for anastomosis		Rigid T Joint Prosthetic with Ligations	Vascular Prosthetic with Ligation	Biodegradable M.A.C
Steps to Complete	5	DATUM	0	-1
Biodegradable	20		0	1
Time to Perform Surgery	30		0	0
Minimum Vessel Diameter	15		0	1
Intima-to-intima contact	25		0	1
Impingement on Surroundings	5		1	1
	100		5	60

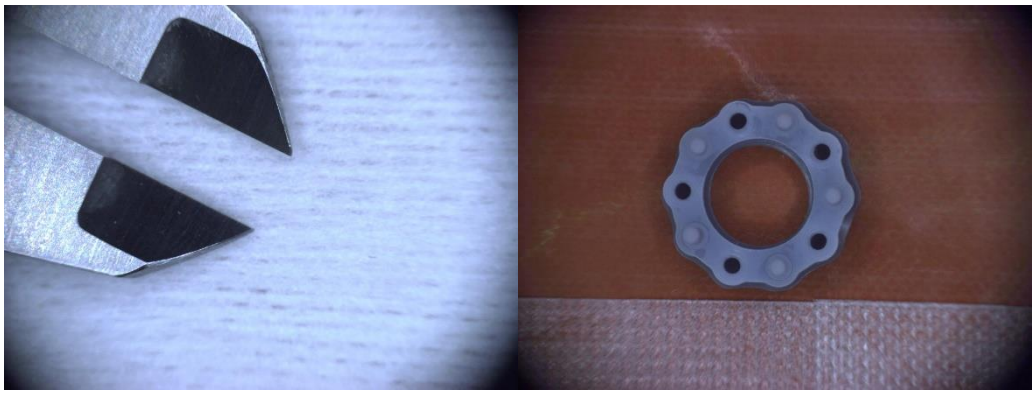
Appendix l: Pugh Chart Rigid T Joint Samuel

Issue: Choose method and device for anastomosis		Rigid T Joint Prosthetic with Ligations	Vascular Prosthetic with Ligation	Biodegradable M.A.C
Steps to Complete	7	DATUM	0	-1
Biodegradable	18		0	1
Time to Perform Surgery	25		0	0
Minimum Vessel Diameter	20		0	1
Intima-to-intima contact	25		0	1
Impingement on Surroundings	5		1	1
	100		5	61

Appendix m: Pugh Chart Rigid T Joint Sophie

Issue: Choose method and device for anastomosis		Rigid T Joint Prosthetic with Ligations	Vascular Prosthetic with Ligation	Biodegradable M.A.C
Steps to Complete	5	DATUM	0	-1
Biodegradable	25		1	1
Time to Perform Surgery	30		0	0
Minimum Vessel Diameter	15		0	1
Intima-to-intima contact	15		0	1
Impingement on Surroundings	10		1	1
	100		35	60

Appendix n: Pugh Chart Rigid T Joint Nick



Appendix o: Metric Analysis Images

Longitudinal Ultimate Tensile Stress: 391 kPa

0.001 Newton per square Millimeter = 1 Kilopascal

UTS = 0.391 Newton per square Millimeter

Ac: 38.33 mm^2

Longitudinal Force = Stress * Area = 0.391 N/ square Millimeter * 38.33 mm^2 = 14.98703

Appendix p: Blood Vessel Tension Calculations