

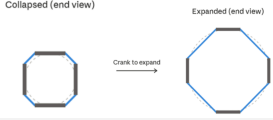
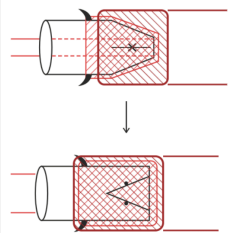
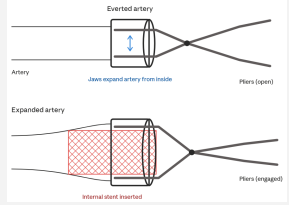
Arterial Coupler Design Matrix							
		Design 1: Crank Expansion 		Design 2: Exterior Wedge 		Design 3: Plier-Assisted Stent 	
Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Adjustability	30	3/5	18	2/5	12	4/5	24
Efficiency	20	4/5	16	3/5	12	2/5	8
Ease of Use	15	2/5	6	5/5	15	3/5	9
Safety	10	2/5	4	4/5	8	2/5	4
Durability	10	2/5	4	3/5	6	3/5	6
Fabrication	10	2/5	4	5/5	10	2/5	4
Cost	5	3/5	3	5/5	5	2/5	2
Total (Out of 100): 100		55		68		57	

Table 1: Design matrix comparing three arterial coupler designs with relevant criteria and scores.

Criteria Descriptions:

Adjustability: Adjustability refers to the device's ability to function across arteries of various diameters. The design should be able to adjust in size to be compatible with two different sized arteries. This feature ensures compatibility with patient-specific anatomies, reducing the risk of stenosis and leakage. The ranking will be based on the adjustment mechanism, the achievable diameter-adjustment range, and the mechanical reliability of the device's adjustment.

Efficiency: Efficiency will be determined by the total time required to implant the device and successfully restore blood flow. Per the clients' requirement, the device should significantly reduce the procedure time compared to current anastomosis methods. Minimizing implantation time had the second-highest rank, as prolonged ischemia can lead to tissue damage and organ failure.

Ease of Use: Ease of use is determined by the device's ergonomic capabilities during use by a surgeon. Due to the technical difficulty of anastomosis procedures, the device should reduce the learning curve and

overall surgical duration. The device should minimize the need for fine motor manipulation and precise alignment while maintaining its functionality. Creating a device that is easier to use will increase the accessibility of the procedure by allowing less specialized surgeons to perform the anastomoses.

Safety: Safety is scored based on design features that predict injury during and after implantation, such as vessel wall trauma (penetration, sharp or rough edges), thrombogenicity (exposed intraluminal material, lack of intima-to-intima apposition), leak risk, biocompatibility of materials based on prior implant use, and the number of deployment steps that could fail or depend on surgeon technique. The safest design will minimize sharp/rough edges and material toxicity, and maximize mechanism simplicity.

Durability: Durability refers to the device's ability to withstand physiological conditions while maintaining structural, physical/chemical, and mechanical properties during and post-surgical procedure. The device must resist fatigue, corrosion, and degradation while retaining its strength, toughness, and elasticity.

Fabrication: Fabrication measures how easily and cost-effectively the device can be produced. The ranking will be based on available materials, processes, and technologies necessary to construct the device. This includes complexity of techniques and their tolerances, scalability, and reproducibility of the device.

Cost: The initial prototype device must be produced within the project's \$500 budget, without compromising functionality or performance. Each design receives a cost score from 5 (estimated prototype cost of \$100 or less) to 1 (more than \$400 and up to \$500), in \$100 steps, with any design exceeding the \$500 budget eliminated before scoring.

Design 1: Crank expansion

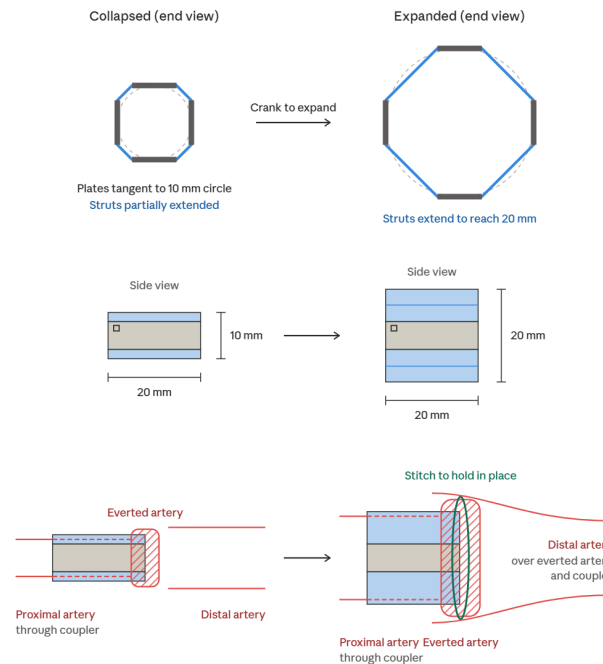


Figure 1: A scaled-up prototype of an expandable coupler is cranked from a 10 mm to a 20 mm diameter, after which the proximal artery is passed through the coupler and everted over its end, the distal artery is drawn over the everted artery and coupler, and a circumferential stitch holds the anastomosis in place (dimensions shown are for the scaled prototype, not the final arterial device).

Design Description: The expandable coupler is a short tube made of four flat plates connected at the corners by sliding struts. The proximal artery is passed through the coupler and folded back over its end, and the distal artery is pulled over the top. A separate crank tool can be used to push the plates outward, sliding the struts out to fill the gaps between them and widening the coupler. After expansion, the plates then lock in place, and a stitch is placed around the overlap holding the connection secure.

Adjustability: This design scored a % for adjustability as the cranking mechanism will allow for an increase in artery diameter, providing consistent blood flow through the connection point. The rigid design will prevent lumen compression after the procedure. Potential concerns with the design arise with repeatability and range of expansion. After one artery is everted over the device, it is expanded. This everted artery may require a device with a small initial diameter in order to achieve eversion. Additionally, the expansion capabilities may not be able to accommodate two arteries with different diameters. Finally, repeating consistent expansion with the device may be difficult, as different arteries could react differently and potentially rupture.

Efficiency: This design scored a % for efficiency, as having an external cranking mechanism allows for a quick and controlled expansion, overall reducing operation time. Additionally, having an external device rather than an internal one minimizes the amount of time it takes to implant the device onto an artery.

Ease of Use: The crank design scored a % for ease of use due to the expected difficulty in attaching the everted walls onto the crank. Additionally, with a small area covering the crank, expanding may prove more difficult than internal methods.

Safety: This design scored a % for safety. Its strengths are intima-to-intima apposition, achieved by everting the proximal artery over the coupler, and an extraluminal position that keeps implant material out of the blood path. These are outweighed by the implant's multiple moving parts (four plates, sliding struts, and a lock), which greatly increase the risk of injury. The sliding struts create pinch points, and the thin plate edges pose a laceration risk at the fold where the artery wraps over the coupler rim.

Durability: This design scored a % for durability as the cranking mechanism involves thin sheets of metal pushing the cylindrical structure outward to increase the device's diameter. The thin sheets of metal are more likely to degrade, corrode, and fail under the compressive forces of the everted and connected artery. However, the bulk of the device's structure can resist degradation and corrosion.

Fabrication: This design scored a % for fabrication as the expansion mechanism requires microfabrication. Consistently creating a device with a functioning mechanism requires expensive industrial equipment. The device also requires multiple moving parts, adding complexity to the fabrication and difficulty in scaling each part appropriately to create various sizes.

Cost: This design scored a % for cost. This device has many small parts with high tolerances, which likely requires high-resolution printing or machining, plus several rounds of iteration to get the sliding fit right.

Design 2: Exterior Wedge

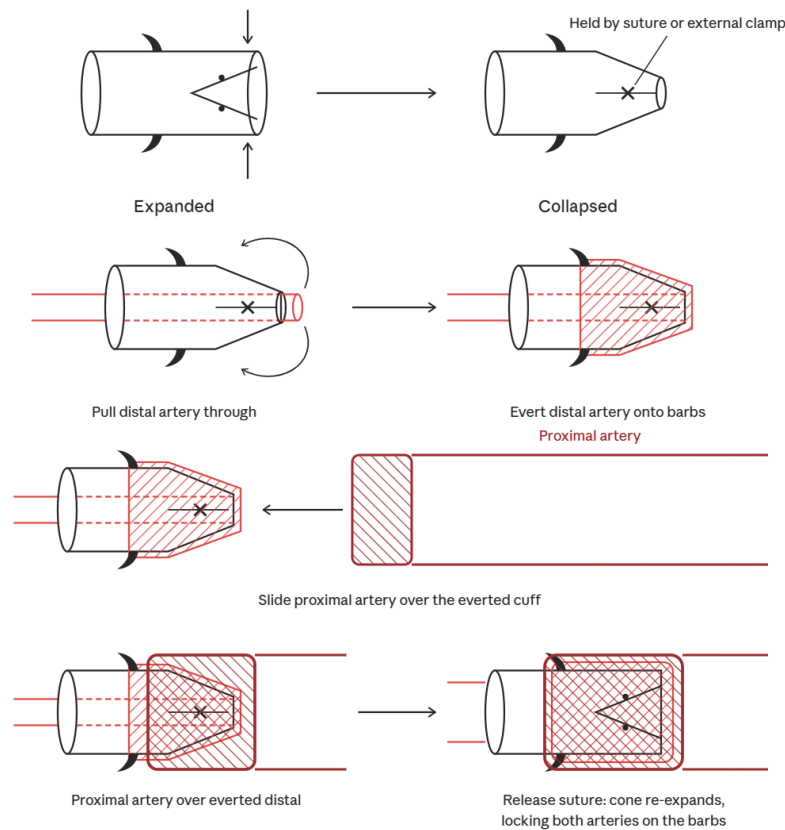


Figure 2: A barbed cylinder with a wedge cut is collapsed into a cone and held with a suture; the distal artery is pulled through and everted onto the barbs, the proximal artery is slid over it, and releasing the suture lets the cone re-expand to lock both arteries in place.

Design Description: The wedged-cone coupler is a barbed cylinder with a V-shaped wedge cut into one end. Pressing the two sides of the notch together closes the V and tapers that end into a cone, which is held collapsed by a suture across the seam or by an external clamp. The distal artery is threaded through the device from the wide end and pulled out through the narrow cone tip. Its free end is then everted back over the outside of the cone and pushed onto the barbs, which point away from the tip so the cuff cannot slide forward off the device. The cone's tapered profile makes the eversion easier, because the vessel is stretched gradually rather than all at once over a blunt edge. Next, the proximal artery is slid over the everted distal cuff. Finally, the suture is cut or the clamp removed, and the cone springs back to its original cylindrical shape. The re-expansion presses both arterial layers outward, so the distal artery is locked on the barbs and the proximal artery is held over it by an interference fit. The result is an intima-to-intima connection with the device outside the blood-contacting surface.

Adjustability: This design scored a % for adjustability. Compression of the wedge allows for adjustability of the device. Large forces from the everted artery and connected artery could result in compression forces on the wedge. A rigid material would be required to maintain blood flow and prevent ischemia.

However, the device could be easily fabricated at various sizes to allow for anastomosis of two arteries with slightly differing diameters.

Efficiency: This design scored a $\frac{5}{5}$ for efficiency. Having the device be external rather than internal overall reduces the time it would take to put the device onto an artery. However, having to manually release the suture and wait for the device to expand may cause user errors, overall reducing the total procedure time.

Ease of Use: The wedge scored a $\frac{5}{5}$ for ease of use due to its simple and tapered design. The tapering allows the wedge to slide into the artery with minimal precision and acts as a guide for insertion. Additionally, once inserted, the expansion requires no manual steps, simplifying the procedure.

Safety: This design scored $\frac{4}{5}$ for safety. As a single piece with no moving parts or deployment tool, it has few mechanical failure points. Its tapered cone allows gradual eversion, which reduces intimal tearing, and greatly achieves intima-to-intima apposition with no device material in the blood path. However, the barbs penetrate the vessel wall and could protrude into the intimal healing interface. The re-expansion force cannot be adjusted, and excess force risks wall injury, while too little could let the proximal artery slip or leak.

Durability: This design scored a $\frac{4}{5}$ for durability. Since it is a single, uniform piece, the device has low risk of corrosion or degradation. The rigid structure provides more radial strength and resistance to internal pressure, but it may be prone to fatigue and fracture. Additionally, the procedure requires the wedged piece of the device into a cone-like structure, which may create internal stress and surface cracks, reducing its durability.

Fabrication: This design scored a $\frac{5}{5}$ for fabrication as it is a simple, single piece. The device can easily be 3D printed in mass quantities. This printing method would decrease the cost per unit. Since the device is a single piece, it can easily be scaled to 2 mm, 3 mm, and 4 mm diameters. The device can be mass-produced at different sizes to provide various options during a procedure.

Cost: This design scored a $\frac{5}{5}$ for cost. A single printed polymer part with no assembly keeps cost low and makes reprinting after each revision cheap, assuming a polymer-based prototype. Using a nitinol/metal version would drop the score significantly.

Design 3: Plier-assisted stent

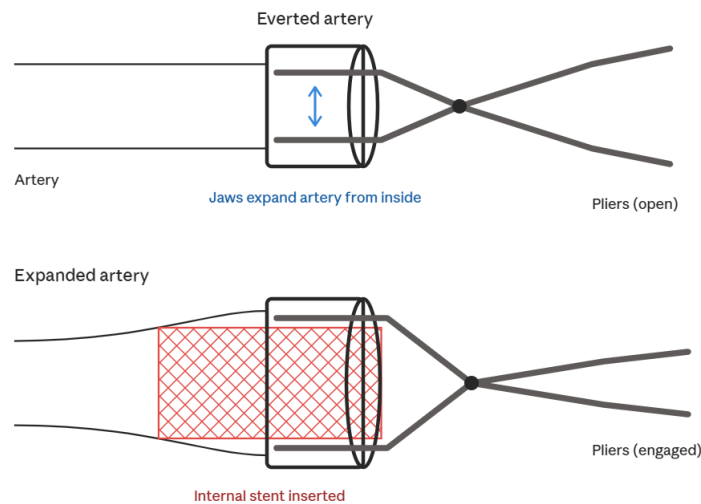


Figure 3: Diagram of the plier-assisted stent design which uses a plier-like device to expand the distal artery to a specified diameter prior to attachment to the proximal artery.

Design Description: Pliers are inserted into an everted, open artery during an anastomosis procedure. The pliers engage, widening the diameter of the artery and allowing a stent to be placed inside the artery. This expanded artery can now be attached to an artery with a larger diameter.

Adjustability: This device scored a % for adjustability since the plier system can be used to expand an artery to a workable diameter. The plier can expand the artery to place a stent device. The plier will require force from the surgeon to expand the artery, but not excessive force that could cause damage to the artery.

Efficiency: This design scored a % for efficiency. Having to manually expand an artery with the pliers increases operation time, as the surgeon will need to be precise in order to work at a small scale and prevent damaging the artery. Additionally, having to place the stent internally will also add to the overall operation time.

Ease of Use: The plier-assisted stent scored a % for ease of use. Using pliers to open and expand the artery is expected to require fine motor precision. However, once expanded, inserting the stent will likely be simple due to the larger opening of the proximal artery.

Safety: This design scored % for safety. The plier tool is simple, and a commercial stent would have established biocompatibility. However, the stent sits inside the lumen, exposing device material to blood and increasing the risk of thrombosis and restenosis. The pliers apply concentrated force directly to the intima, risking tearing. The method of joining the arteries is not defined, so intima-to-intima apposition cannot be confirmed.

Durability: This device scored a % for durability. A stent has many thin struts that are susceptible to fatigue and fracture, especially when it is expanded in a non-uniform way with the plier-like tool. The

interconnected, mesh structure creates numerous stress concentration points prone to mechanical failure, as opposed to more rigid designs.

Fabrication: This device scored a % for fabrication as there are multiple parts that require complex fabrication. The plier device must have tolerances of ~0.5 mm to ensure uniform arterial expansion and to properly fit arteries. The plier also requires fabrication of multiple parts. However, the difficulty of the fabrication results from the stent. The stent requires microfabrication that is both complex and expensive, reducing mass production capabilities.

Cost: This design scored a % for cost. The pliers can likely be adapted from existing instruments at low cost, but the stent is the cost driver. A commercial vascular stent is a prescription device that is expensive and hard for a student team to obtain, and would likely exceed the budget.