efemoral: Microaxial Perfusion Pump to Mitigate Critical Limb Ischemia

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MOTIVATION

Background

- Critical limb ischemia (CLI) results from blockages in arteries that impair blood flow to limbs, and can ultimately result in amputation
- 3.5 million American cases projected by the end of 2020[1]

Problem

- Traditional treatments, such as stenting and grafting, clear blockages caused by CLI
- efemoral directly addresses reperfusion to decrease amputation rates, unlike other treatments

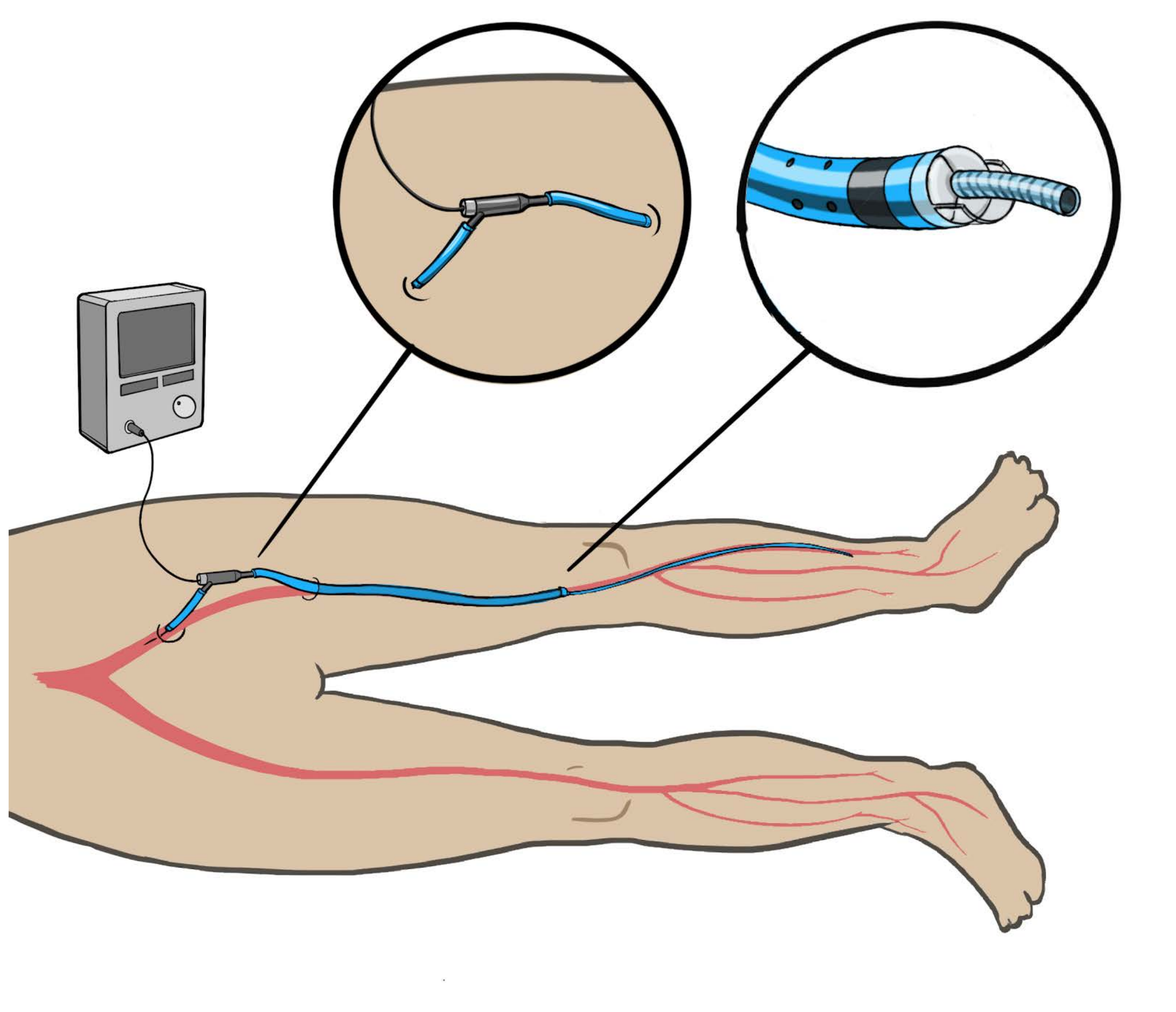

Figure 1: Implantation mechanism with controller, insertion site, and step-down catheter

PROPOSED SOLUTION

- A minimally invasive microaxial perfusion pump
- easily implemented post angioplasty
- Removes blood from femoral artery then reintroduces blood at higher flow rate slightly farther down
- Minimizes stress on blood cells and blood redirection

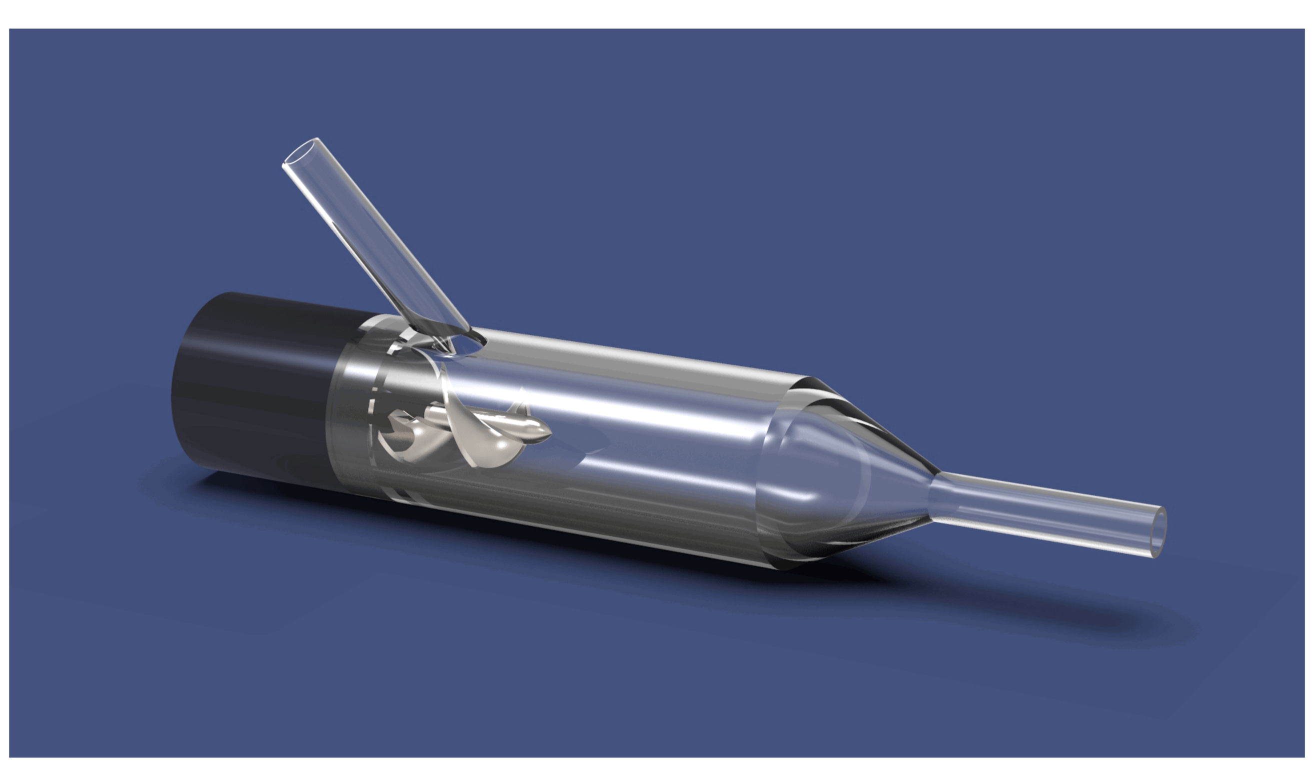

Figure 2: Rendering of pump with motor housing, impeller, and fluid housing

FLOW RATE TESTING

General Set Up

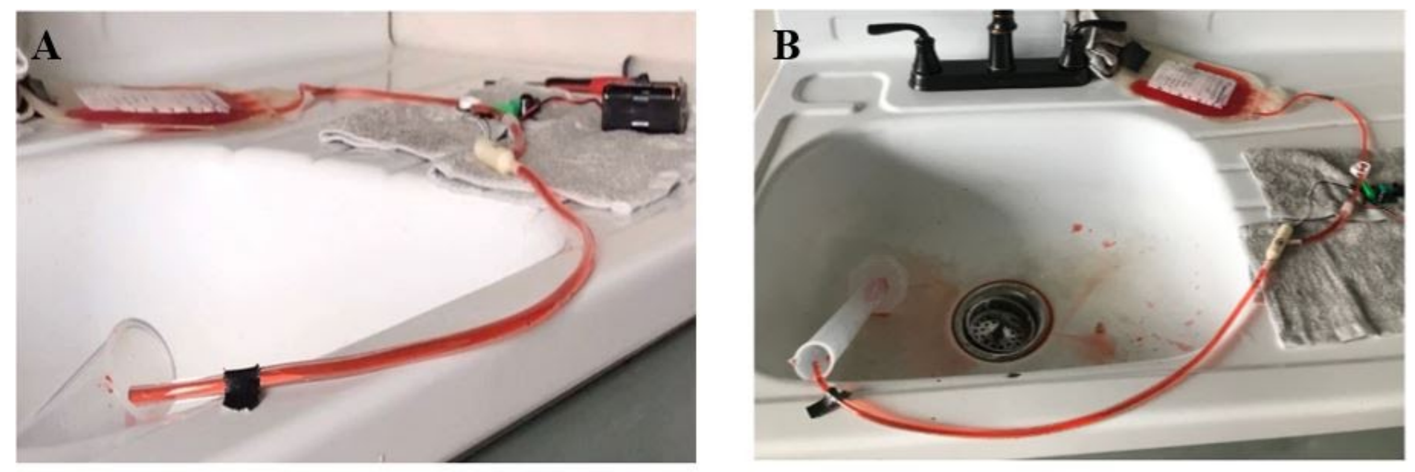

Figure 3: A) A horizontal view of our testing setup. The liquid water supply, pump, and graduated cylinder are all on the same plane. B) A view of our testing setup from above.

RESULTS

- Controls: measured the flowrate of the testing setup for each pump with the motor off
- Raised water supply by 60cm to mimic the gravitational pressure head of the femoral artery.
- Determined that flow driven by this gravitational pressure head alone was about 317.8 mL/min.

Flowrates of the 5 Pump Prototypes

Pump #	Control Flowrate, motor off (mL/min)	Average Flowrate (mL/min)	Standard Deviation (mL/min)
1	16.5	11.0	0.6
2	14.5	3.2	0.8
3	2.5	17.4	6.3
4	No flow achieved. Backflow was greater than forward flow		
5	15.0	16.4	1.3

CONCLUSIONS

- No pumps were able to meet our goal flowrates of 125-250 mL/min
- Significant improvement from our initial prototype that could only achieve flowrate of 6.6 mL/min
- Will need more iterations of redesign and testing to meet our functional requirements
- Once design is finalized, further testing on safety (hemolysis, clotting, pressure of reperfusion) needed before pump can move to animal testing

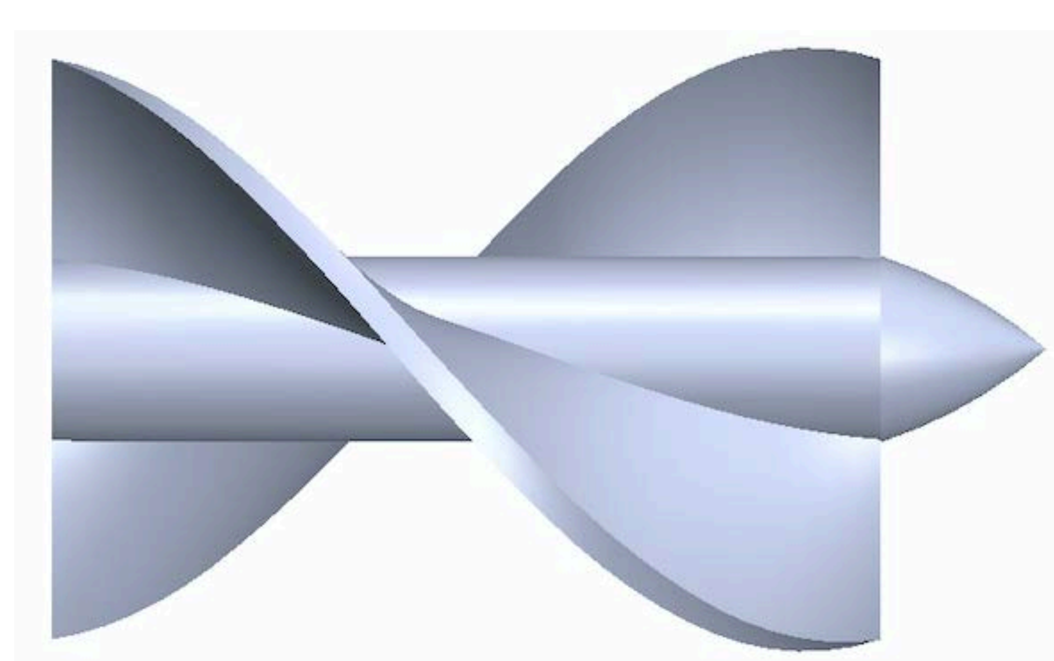

Figure 4: Rendering of the impeller of our best pump, Pump 3. It is a square-edge impeller.

REIMBURSEMENT

- dependent on a patient's condition
- expected to be covered by Medicare/Medicaid.
- Similar products are reimbursable
- our product works in conjunction with those methods

CPT Code(s)	Corresponding Procedure
92920, 92921	Angioplasty[2]
92928, 92929	Stenting[2]
33990	Insertion of VAD through percutaneous arteries[2]
37228-37235	Revascularization of the tibial/peroneal arteries[3]

MANUFACTIRING

Item	Small Batch Cost	Large Batch Cost
Physical Parts	$64	$16
Packaging and Manual	$31	$11
Assembly	$50	$50
Sterilization	$140	$40
Quality Insurance	$310	$10
Total	$595	$127
Profit (Sold at $400)	-$195	$273

COSTS

With a combination of off the shelf and custom fabricated components, it is estimated that the raw cost of this device will be $595 in small batches and closer to $125 in large batches. This raw cost of our device includes physical pump materials, packaging, instructions, assembly, sterilization, and quality assurance. A similar, long term device costs $22,000, so this device can reasonably be sold with a profit of $275 at $400[4].

PATENTS

Other Patents

1. Statorless intravascular microaxial pump[5].
2. Methods for effecting retroperfusion in a body passage[1].
3. A method and apparatus for blood pumping[6].

How our Device is Patentable

- Novel: our current technology does not infringe on other patents
- Non-obvious: first device to increase blood flow to collateral arteries following a stenting procedure.
- Useful: will validate usefulness through in-vitro test results.

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