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

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

**FLOW RATE TESTING**

**General Set Up**
- 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

**RESULTS**
- Flowrates of the 5 Pump Prototypes

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

**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

**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
- | 92928, 92929 | Stenting
- | 33990 | Insertion of VAD through percutaneous arteries
- | 37228-37235 | Revascularization of the tibial/peroneal arteries

**MANUFACTURING**

- **Item**
- **Small Batch Cost**
- **Large Batch Cost**
- Physical Parts: $64
- Packaging and Manual: $31
- Assembly: $50
- Sterilization: $140
- Quality Insurance: $310
- Total: $595
- Profit (Sold at $400): -$195

**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.

**PATENTS**
- **Other Patents**
  1. STATORLESS INTRAVASCULAR MICROAXIAL PUMP
  2. METHODS FOR EFFECTING RETROPERFUSION IN A BODY PASSAGE
  3. A METHOD AND APPARATUS FOR BLOOD PUMPING
- **How our Device is Patentable**
  1. Novel: our current technology does not infringe on other patents
  2. Non-obvious: first device to increase blood flow to collateral arteries following a stenting procedure
  3. Useful: will validate usefulness through in-vitro test results

**REFERENCES**