Carovac: The Carotid Clot Vacuum

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Clinical Need

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- Stroke:
  - 5th leading cause of death in the United States
  - Kills 130,000 people every year - 1 out of every 20 deaths
- Ischemic stroke:
  - Accounts for 87% of all strokes
  - Major leading cause of neurological disability
  - Chance of disability increases as the time between stroke onset and treatment increases

Background & Goal

Current treatments
- tPA:
  - Most successful within 3 hours of stroke onset
  - Non-ideal for patients on blood thinners or with larger clots
- Mechanical thrombectomy:
  - Most successful within 6 hours of stroke onset
  - Procedure could be long and has risk of causing secondary strokes

Project Objective:
- Entry through carotid artery rather than femoral artery
  - Reduces procedure time
  - Reduces complexity of procedure and risk of causing further clots

Methods

Prototype Design

Novel Aspiration Sheath Design (Figure 3)
- Added “teeth” to the design of the aspiration sheath
  - Prevent clot backflow similar to a heart valve

Prototype
- 3D printed mold for sheath at 3x scale (Figure 4)
- Used Smooth-On silicone to create new aspiration sheath
- Combined smaller sheaths to create a full length catheter

Filter (Figure 5)
- Distal filter ensuring that no clot fragments travel downstream and cause further clotting
  - Roughly 100 um pore size catches small clot fragments while still allowing for blood to flow
  - Self-deploying nitinol design

Circuit (Figure 6)
- Peristaltic pump gives constant flow rate at levels matching the Reynold’s Number of arterial blood flow in the body

Testing Results

COMSOL Analysis
- Addition of “teeth” creates a significant pressure drop between the front of catheter and behind the teeth to successfully prevent backflow of aspiration material

Sensitivity Analysis
- Entrance through the carotid artery reduces necessary aspiration pressure when compared to the femoral artery

Regulatory Analysis

- Conceptually novel but functionally similar; FDA will deem it to be “substantially equivalent” (SE) through Premarket Notification Application
- Situationaly reimbursed by Medicaid and Medicare

Future Work

- Develop manufacturing technique for the teethed catheter as well as the nitinol filter
- Improve testing criteria and measure aspiration efficiency and completeness
- Develop incision closure and clot signaling technology

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References

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