Carovac: The Carotid Clot Vacuum

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BIOMEDICAL ENGINEERING
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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

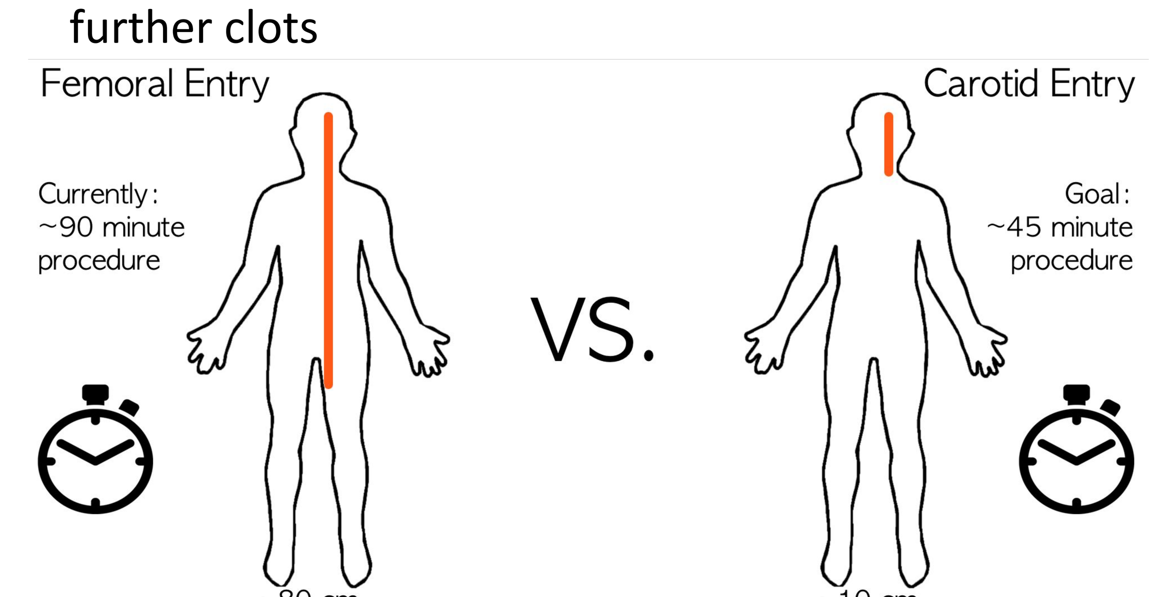
Background & Goal

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

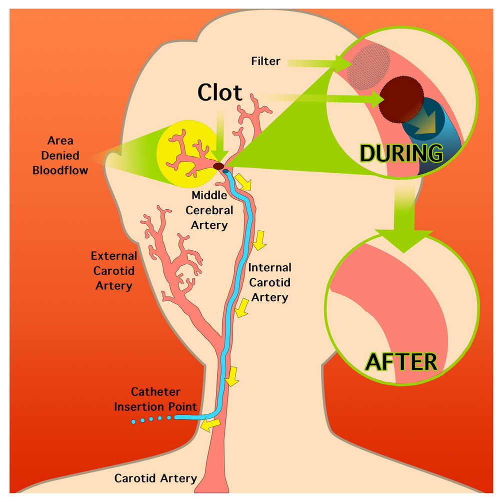
Project Objective:

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



^ Figure 1: Comparison of procedural time required for femoral entry vs. carotid entry

- Innovative aspiration-aided clot removal device
  - Permits safe navigation through cerebral vessels
  - Allows only unidirectional travel of clots
- Novel filter design
  - Captures potential clot fragments
  - Avoids damaging vessel linings

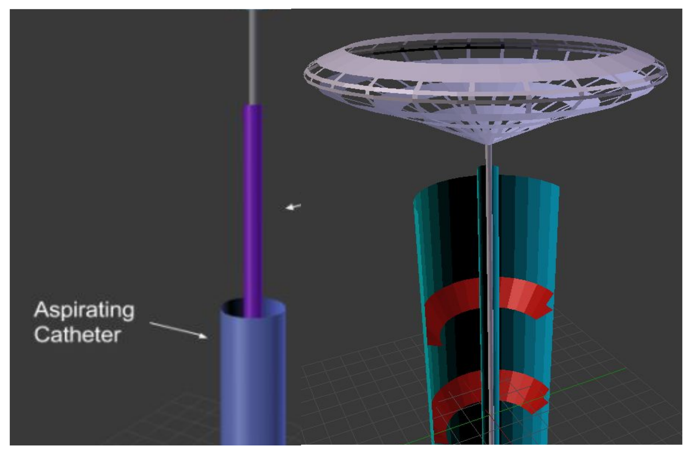


^ Figure 2: Schematic demonstrating clot removal process via carotid route

Prototype Design

***Novel Aspiration Sheath Design* (Figure 3)**

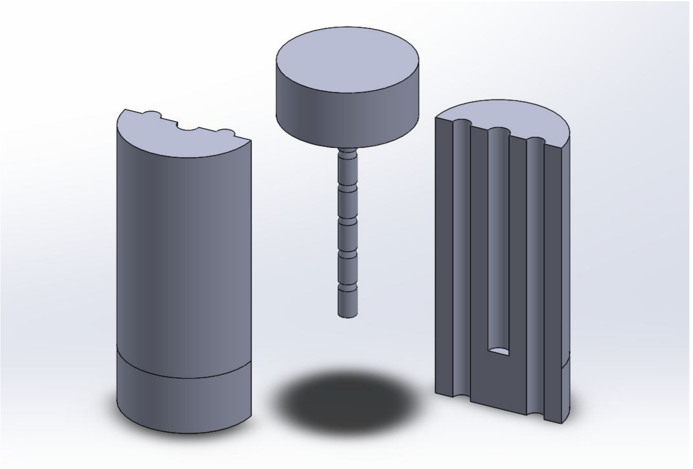
- Added "teeth" to the design of the aspiration sheath
  - Prevent clot backflow similar to a heart valve



^ Figure 3: CAD Model of Aspiration Sheath and Filter

Prototype

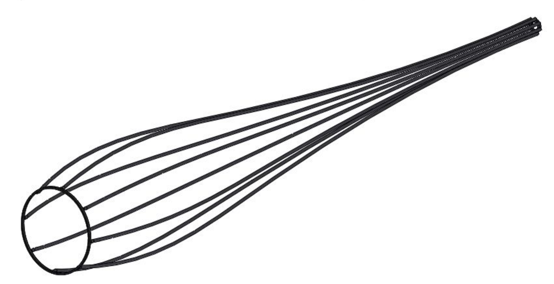
- 3D printed mold for sheath at 3x scale (Figure 4)
- Used Smooth-On silicone to create new aspiration sheath
- Combined smaller sheaths to create a full length catheter



^ Figure 4: Catheter Mold Prototype in SolidWorks

***Filter* (Figure 5)**

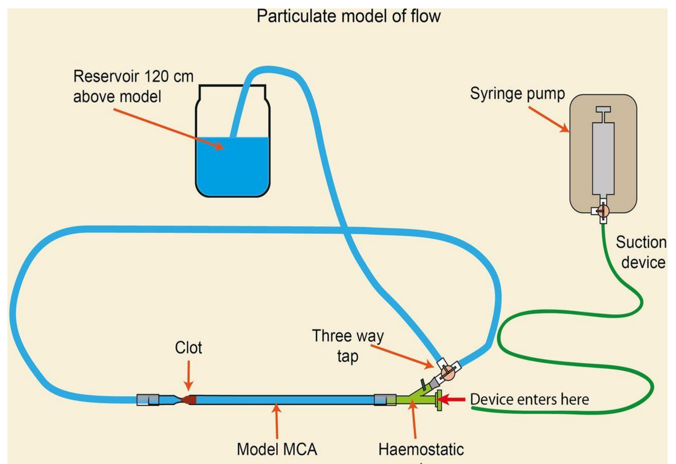
- Distal filter ensuring that no clot fragments travel downstream and cause further clotting
- Roughly 100 um pore size catches small clot fragments while still allowing for blood to flow
- Self-deploying nitinol design



^ Figure 5: Filter Prototype in Solidworks

***Circuit* (Figure 6)**

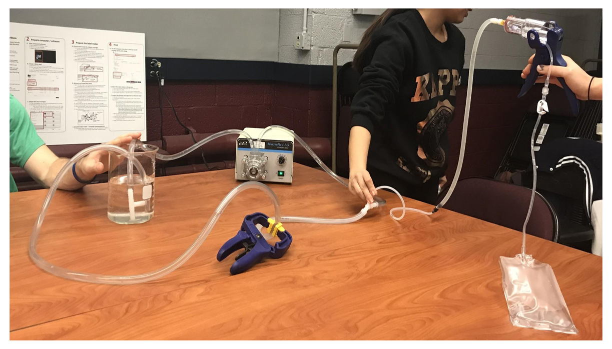
- Peristaltic pump gives constant flowrate at levels matching the Reynold's Number of arterial blood flow in the body



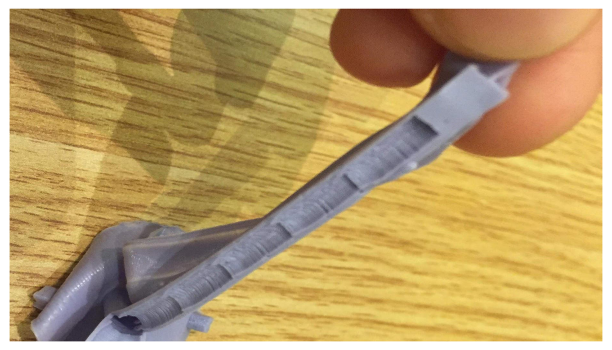
^ Figure 6: Schematic of blood flow circuit

Methods

^ Figure 7: Segmented Silicone Aspiration Sheath



^ Figure 8: Assembled Blood Flow Circuit



^ Figure 9: Cross Section of Aspiration Sheath with Teeth

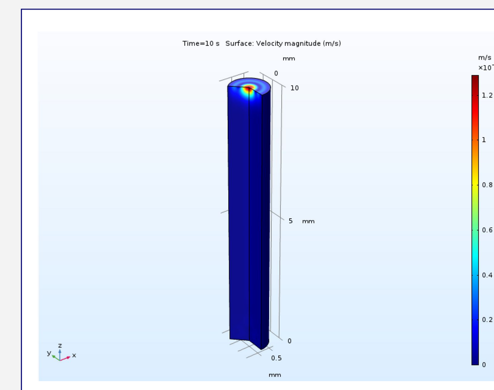
Novel Aspiration Sheath

- Catheter mold designed in SolidWorks then 3D printed
- Molds were covered with *Parafilm M*™ to prevent silicone leakage
- Mold filled with *Ecoflex 00-30* silicone mixture and allowed to cure for at least 24 hours
- Hardened silicone segments were fixed together with *Sil-poxy®*
- Blood flow circuit designed using peristaltic pump, rubber piping, and luer lock connectors

Filter

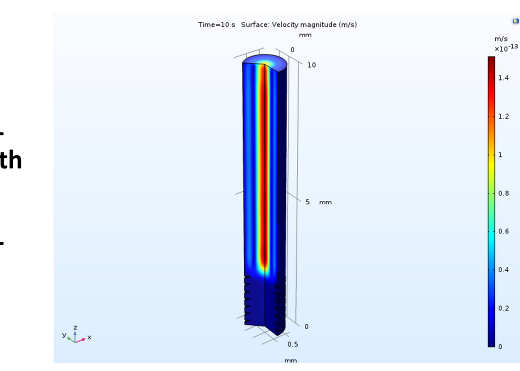
- Initial filter mock-up created with stainless steel
- Second scaled-up filter prototype crafted from nitinol & heat-treated to hold shape
- To-Scale filter drafted in SolidWorks for future development and COMSOL analysis

Testing Results



< Figure 10: COMSOL Analysis without teeth

> Figure 11: COMSOL Analysis with teeth

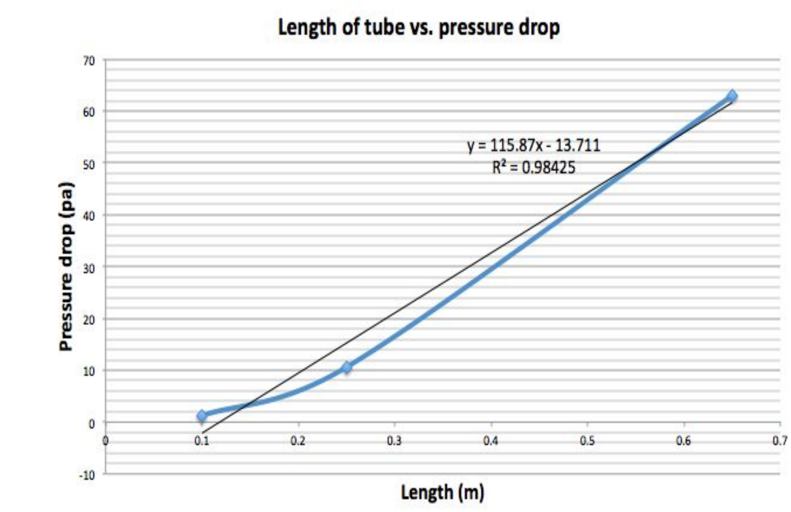


COMSOL Analysis

- 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



^ Figure 12: Graph of Pressure Drop as a Function of Length

Regulatory Analysis

- Conceptually novel but functionally similar; FDA will deem it to be "substantially equivalent" (SE) through Premarket Notification Application
- Situationally 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

Acknowledgments

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