Ischemic Stroke Clot Removal using Aspirator and Filter from Carotid Artery Entry Point

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Clinical Need

- Strokes are 5th leading cause of death in the America[1].
  - 795,000 cases per year in the United States[4]
  - Ischemic strokes = 87% of all strokes[1]
  - Many ischemic stroke patients > 60 years old[1]
- Immediate medical treatment critical to recovery/rehabilitation for stroke patients
- Current treatment methods (tPA, stent retrievers) can effectively remove/destroy clot and restore blood flow[6,7]
  - Drawback: pieces of clot can break off and travel to other areas of the brain
    - Increased risk of thromboembolism and stroke

Device Design

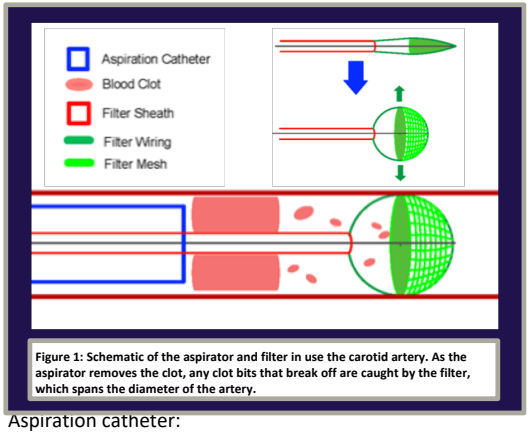

Figure 1: Schematic of the aspirator and filter in use the carotid artery. As the aspirator removes the clot, any clot bits that break off are caught by the filter, which spans the diameter of the artery.

- Aspiration catheter:
  - Description: long flexible tube able to be passed through the vessels to the location of the clot
  - Specifications: 30 cm length, 6 Fr diameter
  - Materials: PTFE
- Filter
  - Description: an umbrella-like basket deployed downstream of the clot to catch clot fragments broken off during aspiration
  - Specifications: 200 µm mesh pore size to catch clots, but allow blood flow
  - Materials: Nitinol, mesh

Device Functionality

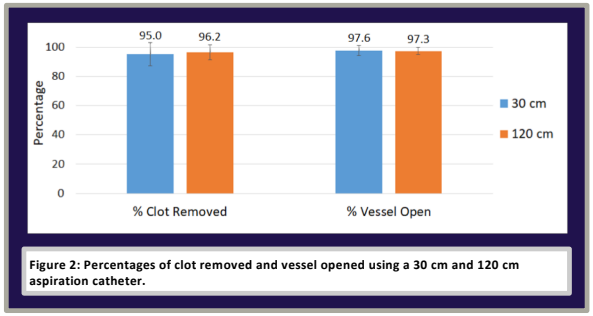

Figure 2: Percentages of clot removed and vessel opened using a 30 cm and 120 cm aspiration catheter.

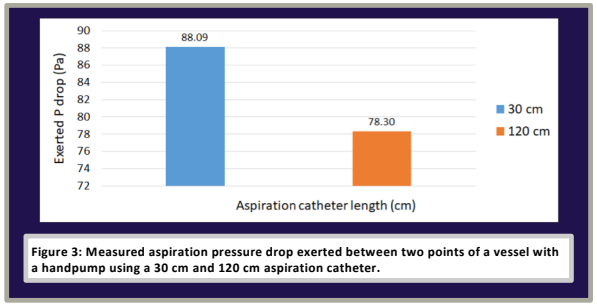

Figure 3: Measured aspiration pressure drop exerted between two points of a vessel with a handpump using a 30 cm and 120 cm aspiration catheter.

- Comparison of aspiration with femoral length (120 cm) and carotid length (30 cm) catheters shows:
  - Comparable percentages of total clot removed (Fig. 2)
  - Comparable blood vessel pressure drops from catheter (Fig. 3)
- Blood flow pressure drop through filter: ~146 Pa
- Retention capacity of filter: 50 µl

Cost and Market Analysis

- **Reimbursement:** Proposed device will be covered
  - Current mechanical thrombolysis techniques covered by most private insurers and Medicare/Medicaid
- **Market segmentation:** 110,000 death/yr = high demand[4]
  - Customers: healthcare providers
  - Payers: insurance companies and medical device companies
  - Users: surgeons operating on patients with acute ischemic stroke- end users less than number of stroke patients
  - Total units sold dependent on system; filter is single use
- **Savings:** Device is similar in price to current systems but will reduce rehabilitation costs due to higher efficacy

Regulation and Patentability

- Regulation
  - Proposed device substantially equivalent to Penumbra Embolectomy Aspiration System (INDIGOTM Aspiration System)[8]
    - Available for use after FDA approval via 501(k)- Possible additional testing in blood vessels and device removal
- Similar Patents
  - US7214237[16]: *Vascular Filter & Improved Strength and Flexibility*
    - No aspirator
    - Mesh cylinder instead of basket shape for filter
  - US9649184[17]: *Slidable Vascular Filter*
    - Filter deployed by screw/thread rather than linearly
    - Functionally similar to proposal, but major differences in style
- Potential Future Competition
  - Devices with more torque control
  - Adhesives to remove clot

Future Work

- Manufacture to-scale filter with nitinol (3D printing)
- Test final model in real-scale *in vitro* studies with blood vessels and bovine blood
- Test final model by *in vivo* trials on animals
- Clinical trials on final model to evaluate efficacy of the model

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