Team Venture

Direct aspiration thrombectomy catheter for clot removal

Team Name

Thrombectomers

University

Vanderbilt University

Team Members:

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Executive Summary

In order to specifically treat thrombi that may cause ischemic stroke, a technique called direct aspiration thrombectomy has been developed. It uses the idea of a vacuum force to siphon a clot from blocking an artery using a catheter, leading to the removal of the threat to the patient. Our team proposes the construction of a dynamic model that will allow physicians to mimic thrombectomies in an adult, and optimize the thrombectomy procedure, improving quality of care and surgery success.

Our team intends to use the model to increase thrombectomy efficacy by increasing the vacuum force at the tip of the aspiration catheter. The proposed solution is increasing intracranial pressure (ICP) in order to increase the vacuum that we are able to pull at the tip of the catheter. The flow model designed is composed of a box, representing the cranial cavity, with silicone tubes, representing the vasculature, running through the box. A clot is simulated by completely or partially occluding the tube so as to severely restrict flow. The pressures on either side of the clot and inside the box (ICP) are measured, providing us with the data necessary to study the effect of increasing ICP on the vacuum force at the tip of the catheter.

There is the possibility of using computer simulations to mimic direct aspiration thrombectomy procedures. Bekker et al. (1999) used a computer simulation to understand the effects of anesthesia on cerebral blood flow and intracranial pressure.[1] Although this type of method may be easier to implement and result in lower expenses,

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4010388/

performing real time procedures is likely to improve the efficacy of the surgery, making our proposed model a better solution for the medical industry.

We believe that people will choose our solution over others because to our knowledge, this phenomenon has never been modeled, and is entirely unique. Flow models of the cranial cavity have been designed before, however our design combines accuracy with simplicity and portability to guarantee an exceptional product.

This device is not intended to be used with therapeutic function. The primary function of this device is to model and test various parameters of the cranial environment as they relate to surgical procedures. Thus, the target of this device is in research settings. FDA approval will not be necessary to bring this device to the market. Additionally, since this will not play a role in patient healthcare directly, no Medicare and Medicaid consideration exist.

Once commercially available, our product would be available to neurosurgeons, researchers, and medical device companies. We would provide our model for approximately $400 directly to hospitals and medical schools who intend to use it for practice thrombectomies as well as selling it directly to the medical device companies. We would also sell the model for a discounted price to nonprofit organizations who desire to help third world countries improve hospital conditions.

Description of Problem to be Solved

In the recent history of the United States, there has been a large amalgamation of deaths resulting from strokes, causing many medical practitioners to scramble to find ways to treat this notorious disease before it causes further damage to the population. Strokes can result from two main mechanisms, either through an ischemic or hemorrhagic route. Nearly 85% of strokes go through an ischemic pathway, which means a blood vessel in the brain is occluded, leading to a lack of blood flow and oxygen to an area of the brain. This pathology can either occur through a thrombus, or blood clot, developed in the brain, or an embolus, which forms in other areas of the body and then lodges in a brain artery.[2]

In order to specifically treat thrombi that may cause ischemic stroke, a technique called direct aspiration thrombectomy has been developed. It uses the idea of a vacuum force to siphon a clot from blocking an artery using a catheter, leading to the removal of a threat to the patient.[3] Many medical providers have, however, wished for a way to determine the best way to determine what type of parameters are necessary to accurately remove the clot, especially under different pressures and flow rates in the brain. To conquer this problem, we propose the construction of a dynamic model that will allow physicians to mimic thrombectomies in an adult, improving quality of care and the surgery's success.

[2] https://www.mayoclinic.org/diseases-conditions/stroke/symptoms-causes/syc-20350113
[3] https://www.ncbi.nlm.nih.gov/pubmed/28409731

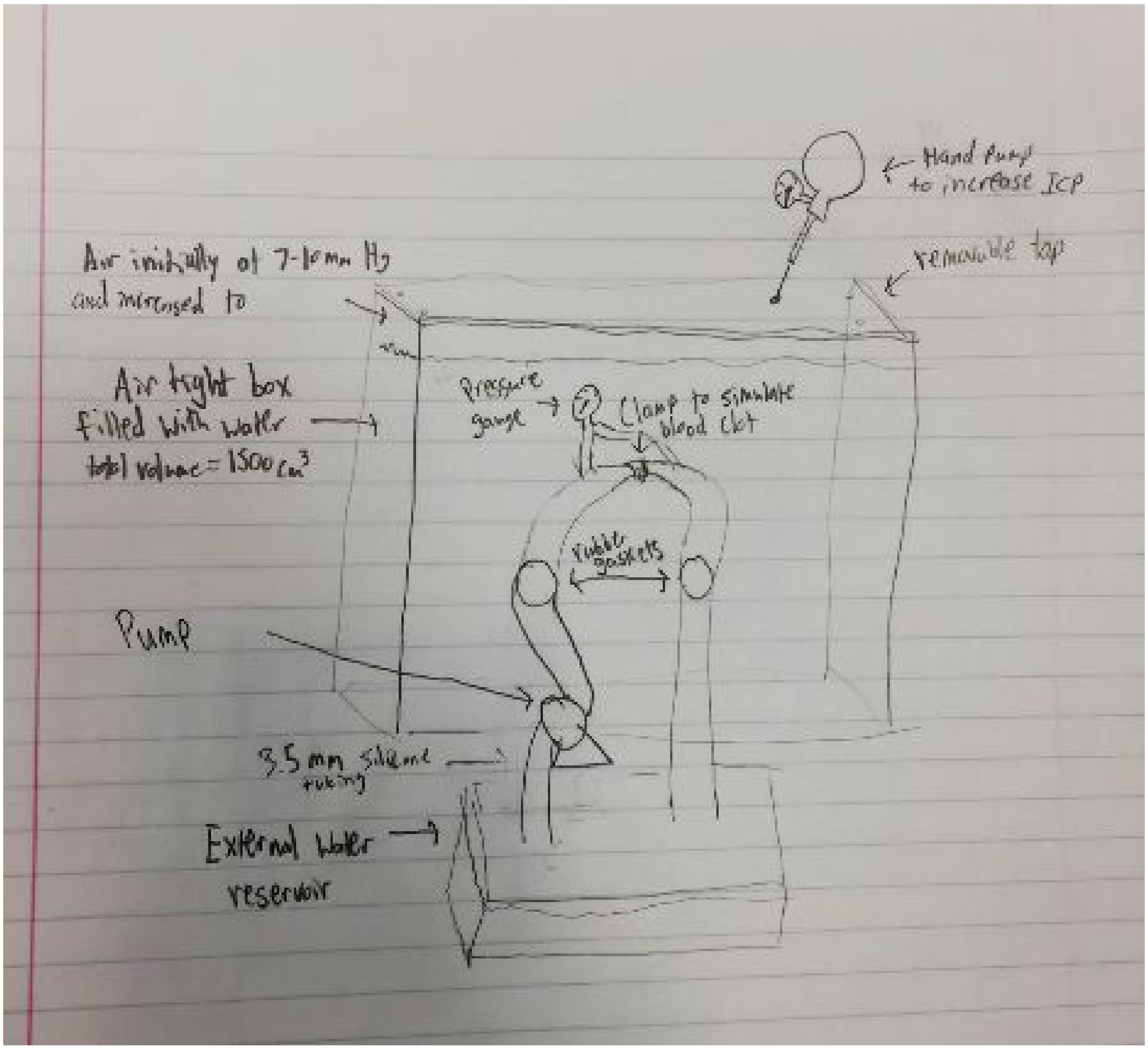
Project Objective Statement

Our team intends to address the issue of ineffective thrombectomy procedures by creating a model of the cranial cavity in order to test different cranial conditions and optimize the thrombectomy procedure. Our intention is to increase thrombectomy efficacy by increasing the vacuum force at the tip of the aspiration catheter. Because vacuum force is a product of the vacuum pressure at the tip of the catheter and the cross-sectional area of the catheter, vacuum force can be optimized by increasing the vacuum pressure. Current aspiration methods already provide the maximum vacuum pressure physically possible (the inverse of the pressure at the tip of the catheter); however, this can theoretically be optimized by increasing the intracranial pressure (ICP).

According to the Monro-Kellie Doctrine, ICP can be increased by adding to the volume of blood in the cranial cavity. One possible method of increasing brain blood volume would be restricting blood flow in both the external and internal jugular veins. This could result in an increase in the vacuum force exerted onto the blood clot, and allow for easier removal with the catheter.

In order to investigate the magnitude of the effect on vacuum force, a flow model is required. The flow model is a box representing the cranial cavity with silicone tubes representing the vasculature running through the box. A clot is simulated by completely or partially occluding the tube so as to severely restrict flow. The pressures on either side of the clot and inside the box (ICP) are measured, providing us with the data necessary to study the effect of increasing ICP on the vacuum force at the tip of the catheter.

Documentation of the final design:



Estimated Manufacturing Costs

Total Model Cost: $210.20 for small scale orders

- Container: $20, Air-tight plexiglass box with removable lid
  - Parts: $15
  - Labor for assembly: $5
- Tubing: $42.50, $16 for large-scale orders. Both a flow model and accessory tubes.
  - Silicone flow model estimations: $40 small scale, $15 for large scale
  - Silicone tubing: $2.50 small scale, $1 for large scale
- Sealants: $2.20, $0.30 large scale. Making the container air tight
  - Gaskets: $2 small scale, $0.25 large scale
  - Waterproof glue: $0.20 small scale, $0.05 large scale
- Expandable plastic bladder: $5. Used to raise ICP.
- Syringe: $0.50, 30 mL syringe to press water into plastic bladder.
- Pressure Gauge: $40, 2 30 mm Hg pressure gauges.
- Pump: $100

Potential Market

The primary purchasers of this product would be members of the scientific and engineering community that are interested in using a model of the cranial cavity in the context of blood flow and pressure control. The purchasing customers would be the purchase coordinators of various labs around the nation, both private and public. The end users of the device would be research assistants, technicians, investigators, and research students.

The model can have many applications, including optimization of surgical technique, as demonstrated by the scope of this project. However, applications can also include development of more effective diagnostic tools based on parameter measurements within the model.

The market size would be as large as the number of labs interested in buying the model for purposes of cranial pressure research. In the United States, there are about 3500 practicing neurosurgeons[4] and about 17,000 neurologists[5]. This device would be marketed to these neurosurgeon-scientists and neurologist-scientists. Additionally, this device could be marketed toward medical device companies looking to demonstrate efficacy of their products. Finally, the direct aspiration thrombectomy model could be used in medical schools or physician residency programs to train surgeons in thrombectomy. The selling price would be about $400. Distribution channels would be through scientific journal publications and scientific new articles sources. Additionally, distribution could be accomplished by partnering with a biomedical device company.

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[4] http://www.aans.org/pdf/Legislative/Neurosurgery%20IOM%20GME%20Paper%2012%2019%2012.pdf
[5] https://www.aan.com/PressRoom/Home/PressRelease/1178