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A Hybrid Ultrasonic and Microsuction Approach for Minimally Invasive Thrombectomy to Treat Ischaemic Stroke

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Abstract

Approximately 87% of all stroke cases are caused by Ischaemic stroke. Ischaemic stroke occurs when blood flow to a part of the brain is reduced or completely blocked due to an arterial obstruction, leading to cerebral ischaemia. Mechanical thrombectomy and IV Thrombolysis are the two reperfusion therapies, which are time critical to treat Ischemic stroke. Thrombectomy devices that are available now are limited in their ability to treat small, tortuous vessels, and thrombolytic drugs carry a significant haemorrhagic risk. To overcome these challenges, we develop a hybrid ultrasonic microsuction catheter that combines mechanical vibration through a piezoelectric transducer(PZT) with microsuction aspiration to facilitate clot disruption and removal. The PZT induced mechanical oscillations will then densify the fibrin network and will release the entrapped red blood cells and then the microsuction will aspirate the loosened fragments, reducing embolic risk. Finite embolic simulations indicate safe violations and amplitudes and suction flow rates capable of effective clot removal without damaging vessel walls. This study offers a promising new direction for thrombectomy devices to treat Ischaemic stroke, pulmonary embolism, and peripheral thrombosis [1-4].

Keywords: Ischaemic Stroke, Mechanical Thrombectomy, Microsuction, Ultrasonic and Simulation

1. Introduction

Stroke is a sudden neurological deficit caused by an interruption of blood supply to the brain or by bleeding within the brain, resulting in acute loss of brain function due to neuronal injury or death [5]. There are three types of stroke: Hemorrhagic stroke, Ischaemic stroke, and Transient Ischaemic Attack. Ischaemic stroke is the most common type of stroke and occurs when blood flow to a part of the brain is reduced or completely blocked due to an arterial obstruction, leading to cerebral ischemia [6]. The obstruction may be caused by a thrombus forming within a cerebral artery or an embolus originating elsewhere in the body and traveling to the brain [7]. Hemorrhagic stroke occurs when a weakened blood vessel ruptures and causes bleeding into or around the brain tissue [8]. The increase in intracranial pressure and reduced cerebral perfusion can lead to brain damage. Hemorrhagic stroke is commonly associated with hypertension, aneurysms, or vascular malformations[9]. Transient ischemic attack (TIA) is a temporary episode of neurological dysfunction which is caused by a brief interruption of blood flow to the brain [10]. Symptoms typically resolve completely within a short time and do not cause permanent brain injury, but TIAs are important warning signs of an increased risk of future stroke [11]. Stroke is the leading cause of death and disability, with Ischaemic stroke comprising approximately 85% of cases. Management of Ischaemic stroke is usually divided into acute treatment and secondary prevention. Acute treatment should be given quickly to avoid severe and permanent consequences because brain tissue dies rapidly when blood flow is interrupted Roughly 1.9 million neurons die every minute if an Ischaemic stroke is untreated. The center of this area, where the blood supply is blocked, is called the infarct core. Surrounding this core is a zone called Ischaemic Penumbra The brain cells in the penumbra are not dead yet. They are weak and not working properly because they have too little blood and oxygen. However, these cells can still be saved if blood flow is restored quickly and it can result in persistent paralysis due to motor cortex damage, aphasia if language areas of the brain are affected, visual loss from occipital or optic pathway involvement, and cognitive impairment when association areas of the brain are damaged. The devices that are currently available for mechanical thrombectomy include stent retrievers and aspiration catheters Chemical thrombolysis, such as tissue plasminogen activator(TPA), usually has a risk of systemic haemorrhage [5-19].

Machine learning is now proving to be effective in overpowering the limitations of traditional medical approaches by improving precision, diagnosis in healthcare and remote monitoring. In addition, robotics is helping disabled people to regain mobility through newer technologies such as robotic prosthetics and assistive devices helping them to perform daily tasks, which was once impossible . To address limitations of thrombolysis, we developed a hybrid ultrasonic microsuction catheter that leverages piezoelectric actuation to disrupt clots while using integrated suction to remove debris mechanically. This approach combines simplicity with the potential to access distal vessels safely and efficiently. applicable criteria that follow [20,21].

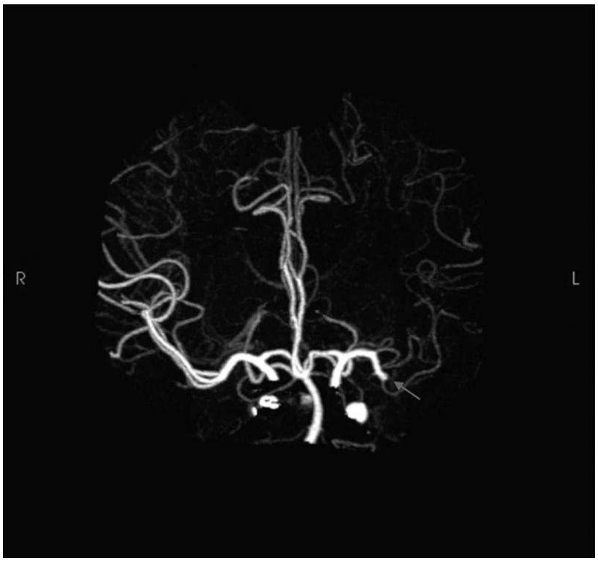

Figure 1: CT-Angiography Demonstrating an Abrupt Occlusion of The Patient'sleft Middle Cerebral Artery

2. Methodology

2.1. Ultrasonic Actuation in Biomedical Devices

Ultrasonic actuation uses piezoelectric transducers (PZT) to produce the mechanical vibrations and these vibrations are in the ultrasonic range which means that they are too high for humans to hear. When these vibrations are applied to a blood clot they will help loosen the clot by shaking its structure. The vibrations can make the fibrin network (the fibers that hold the clot together) more compact and move the trapped red blood cells, which will then finally make the clot easier to break apart and remove.

2.2. Microsuction Mechanisms

Microsuction is a suctioning technique that uses gentle negative pressure (suction) through a very small catheter tube, which will be inserted from a radial artery or a femoral artery [22]. When microsuction is used together with ultrasonic vibrations, the vibrations first break the clot into smaller pieces then the suction removes these fragments from the blood vessel. This will help to prevent pieces of the clot from traveling further in the bloodstream and causing further blockages elsewhere.

2.3. Design Optimization

2.3.1. Microsuction Module

There is a small channel inside the catheter connected to a micropump and this pump creates adjustable suction between 50 and 150 mmHg to pull out the loosened clot fragments. For safety, small pressure sensors are placed near the catheter tip and along the suction path. These sensors constantly measure the pressure inside the vessel and the catheter. Then the measurements are sent to a control system through the sensors MEMS (Micro Electro Mechanical Systems) so that the doctor can adjust the suction level if necessary and ensure the procedure is done safely.

2.3.2. Catheter Shaft

The catheter shaft is made from biocompatible and MRI compatible polymers, which are materials that are safe for the body and can be used during MRI imaging [22]. The shaft is designed to move through the twisting blood vessels of the brain. It has a tapered shape and it is wider near the handle and narrower at the tip having the diameter of about 2–3 mm at the proximal end for strength and support and about 1 mm at the distal end so it can reach very small blood vessels without causing any damage.

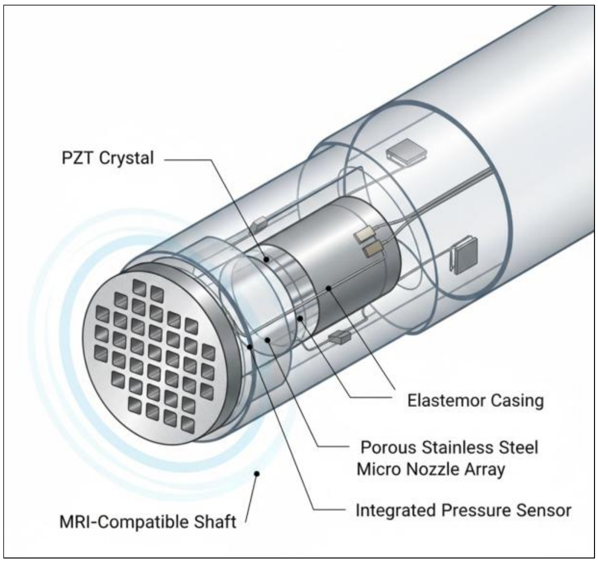

Figure 2: Catheter with Piezoelectric Transducers (PZT)

2.4. Actuator Tip

The tip of the catheter will contain a piezoelectric crystal that produces ultrasonic vibrations and these crystals are protected by a waterproof elastic material so that it can safely work inside the body. The device generates vibrations between 20 kHz and 50 kHz, which is strong enough to break up the blood clots but gentle enough to avoid damaging the blood vessel walls. The tip also has a porous stainless steel micro nozzle structure and this design is made in such a way that it can help direct the ultrasonic energy toward the clot and allow broken clot fragments to be removed easily. small brain vessels. The simulations helped predict how the device would interact with clots and blood vessels before testing it in real patients [24]. The simulations focused on whether the ultrasound vibrations could break the clot and if the suction

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could remove the broken pieces of the clot safely.

2.5. Structural Fem Simulation

In this simulation, we created a computer model of a small brain blood vessel. The vessel was about 1–3 mm wide and 20 mm long, which is similar to real cerebral vessels and we placed a blood clot inside the vessel which blocked 80–100% of the vessel. The vessel wall was modeled as a flexible material and the clot was modeled in soft and firm clot. The catheter tip contained a piezoelectric crystal (PZT) that produces ultrasonic vibrations between 20–50 kHz and these vibrations moved the catheter tip by 5–15 micrometers, which helped in breaking the clot. To simplify the simulation, the ends of the blood vessel were kept fixed.

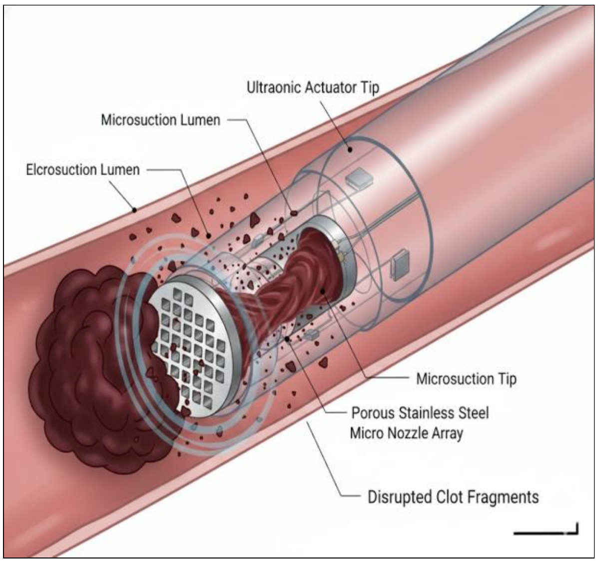

Figure 3: Architectural Layout of The Ultrasonic Catheter

The simulation showed that the ultrasonic vibration caused the clot to become denser in some areas and move red blood cells inside it and helped in weakening the clot structure. The stress applied to the vessel wall stayed below 50 kPa and the results also showed that the soft clots deformed 20–35% more than firm clots when exposed to the same vibration, which may suggest that the device may need to adjust vibration frequency and amplitude depending on the clot type.

3. Limitations

3.1. Mechanism of Action

In this procedure, a catheter is carefully guided through the blood vessels from the Femoral artery or Radial artery using medical imaging, such as X-ray or fluoroscopy and a special dye is injected to make the blood vessels visible on X-ray. The Neurointerventionalist moves the catheter until it reaches the location of the blood clot that is blocking the vessel. Once the catheter reaches the clot, a small device inside it called a PZT transducer is turned on and then this device produces ultrasonic vibrations. The vibrations will help in compressing the fibrin fibers that hold the clot together and release the red blood cells trapped inside it. As a result, the clot becomes weaker and easier to break apart. After the clot is loosened then the catheter has a microsuction system and this suction creates a small negative pressure that pulls the broken clot material into the catheter so it can be taken out of the blood vessel. The vibration and suction can work at the same time or one after the other. The procedure is repeated until the doctor confirms through the imaging that the normal blood flow has returned and the vessel is open again.

3.1. Simulation And Feasibility Study

We used a computer simulation program called COMSOL Multiphysics to test whether the Hybrid Ultrasonic Microsuction Catheter could safely remove blood clots from There were some simplifications made in the simulation. The clot was modeled as a smooth cylinder but real clots often have irregular shapes and mixed materials. The blood vessel ends were fixed, which might slightly overestimate the stress on the vessel wall. The simulation also did not include heat produced by ultrasound, which could affect tissues during long procedures.

3.2. CFD Simulation of Microsuction

In this simulation, the blood behaved like a Newtonian fluid with a viscosity of 3.5 cP and the vessel walls were rigid. The catheter applied suction pressure between 50 and 150 mmHg and this created flow rates of about 0.5–2 ml of blood per second and the simulation tracked clot fragments sized 50– 500 micrometers. The results showed that more than 90% of clot fragments were successfully aspirated when the suction settings were optimized and the shear stress on the vessel wall remained below 10 Pa.

3.3. Limitations

This simulation also had some simplifications. Blood was treated as a Newtonian fluid, even though real blood behaves differently under changing flow conditions. The simulation also did not include pulsating blood flow from the heartbeat. Clot fragments were modeled as rigid spheres, but in reality they are soft and deformable, which could affect how easily they are removed.

3.3.1. Coupled Vibration Suction Simulation

Finally, we combined both simulations to see how vibration and suction work together. The results showed that when the ultrasonic vibration and suction were synchronized, the device could remove about 60–80% of the clot volume in one cycle. The risk that fragments would escape and travel to other vessels (embolization) was less than 10%, and the stress on the vessel wall remained below 50 kPa, which suggests the safety of this method.

4. Future Work

Future work will focus on testing and improving the hybrid ultrasonic microsuction catheter. The device will be tested in the laboratory experiments using artificial blood vessels and clot samples that are designed to behave like real clots and these tests will measure how well the catheter can break up clots and how well it can suction them out and also how its fluid flow behaves during the process. Then the catheter will be tested in models that can mimic the shape and structure of real blood vessels to see its interaction with the vessel walls. After the laboratory tests, the device will also be studied in animal models for safety and accuracy. At the same time, we will explore combining the catheter with robotic or navigation systems, which could help doctors control the catheter more precisely and adjust its movement

5. Conclusion

Machine learning and robotics is now proving to be effective in overpowering the limitations of traditional medical approaches by improving precision, diagnosis in healthcare and remote monitoring [22]. Therefore, this study describes a new medical device designed to help remove blood clots that cause ischemic strokes. An ischemic stroke happens when a blood clot blocks a blood vessel in the brain and prevents blood from reaching brain tissue. We created a very small catheter, which is a thin tube that is guided through blood vessels from femoral and radial artery. First, it uses ultrasonic vibrations that will help in weakening and breaking apart the blood clot then the device uses gentle micro suction removing them from the blood vessel. Before building it, we used computer simulations to test how it would work, where it showed that the catheter could break up and remove clots effectively while still staying within safe limits so that it does not damage the blood vessel walls. The study is an early step, which will be followed by the next stages which will involve laboratory experiments and testing in preclinical studies to confirm that the device works accurately and safely.

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