A Disposable Robot for Intracerebral Hemorrhage Removal[1]

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1 Background

Intracerebral hemorrhage (ICH) is a life-threatening condition that happens when a blood vessel in the brain ruptures causing blood to flow into the brain tissue and form a hematoma, compressing the brain. ICH affects around one in every 50 people in their lifetime, and approximately 40% of them will die within the first month after the ICH [1]. Treatment for ICH often involves the use of drugs, with surgical approaches sometimes employed to remove the hematoma. Since decompression is known to improve brain conditions [2], it is logical to assume that surgical decompression would lead to better surgical outcomes. However, surgery does not change mortality rates for typical patients. We hypothesize that this may be due to the damage to healthy tissue required to create an open corridor for conventional surgical tools to reach the hematoma. This process is currently similar to that used in open brain surgery for tumor removal in cancer patients.

Based on this hypothesis, we seek to build a device that enables decompression of the brain with minimal damage to brain tissue. There have been some previous attempts to decompress ICH through less invasive approaches (see Ref. [3] for further discussion and references), but none of them has yet demonstrated significant clinical outcomes benefits for typical ICH patients. In this paper, we follow the steerable needle approach introduced by Burgner et al. [3], in which curved concentric tubes are used to aspirate the hematoma through a needle-sized entry path through the brain. The system described in Ref. [3] consists of a large, autoclavable robot that deploys one stiff, straight outer cannula, and a precurved inner Nitinol tube. By translating both tubes and rotating the inner tube (three total degrees-of-freedom), the robot is able to reach the surgical site through a needle-size opening in the brain. Our contribution in this paper is to design and build a new, disposable robot for controlling the inner cannula and Nitinol tube. The new robot is compact and low cost, following the general paradigm of Ref. [4] (though with a different mechanical design) which was originally introduced for thermal ablation of tumors and brachytherapy seed implantation, but has not been applied to ICH aspiration.

2 Methods

The main goal of our design is to make the robot simple and inexpensive so that it can be disposable. This eliminates the need for cleaning between cases, and may thus provide a smooth path to commercialization. Based on this, the robot is designed to be compact, low-cost, and with few moving parts. We also include sensors to facilitate a homing procedure, which was discussed, but left to future work, in the robot described in Ref. [3].

As shown in Figs. 1 and 2, the new robot contains two carriages, each of which actuates one tube. The carriages translate on two v-shaped tracks (1), on the inside of the casing. Each carriage has four V-wheels (2), which fit snugly on the tracks and stabilize the carriage. The v-shaped tracks and wheels are chosen because they provide the carriages with enough support to overcome forces and moments expected in surgery, while being low-cost. Two DC motors (3) and (4) are mounted on the inner tube carriage to enable both translation and rotation, while one motor is included on the outer tube carriage to provide translation only.

A system of gears converts the motor torques to rotation of the inner tube and translations of the carriages. In the case of rotation, the gear (5) on the motor rotates the gear attached to the inner tube, thus changing the orientation of the tube. For translation, the spur gear (6) meshes with the linear rack (7) on the bottom of the casing. Turning the gear applies thrust to the carriage. This gear is located directly beneath the tube, to avoid applying unwanted torque to the carriage during translation. Spur gears are chosen for their simplicity, reliability, and low cost. The gaps between the carriages and casing walls function as pathways for wires connecting electronics to an external computer and power to the motors.

As described in Ref. [3], it is useful to be able to swap tubes during a single procedure, so that tubes of different curvatures may be used sequentially. To achieve this, we employ a quick-release mechanism, which enables users to easily change tubes

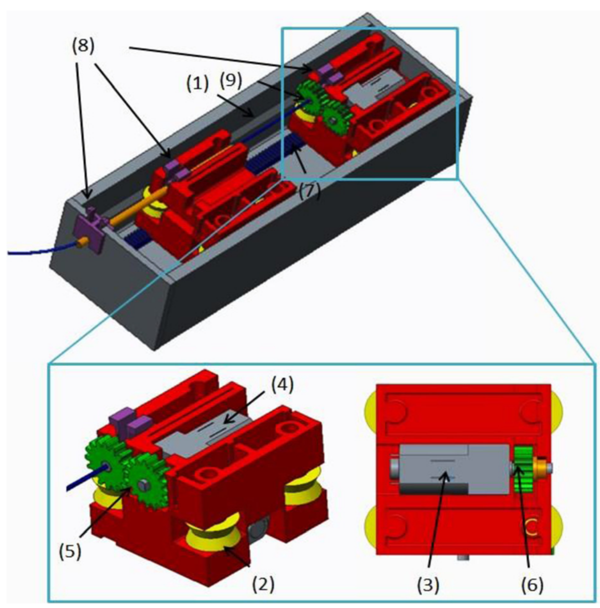

Fig. 1 CAD drawings of the robot are shown. On the top is an isometric view of the assembled robot. On the bottom left is the isometric view of the inner tube carriage. On the bottom right is the bottom view of the inner tube carriage.

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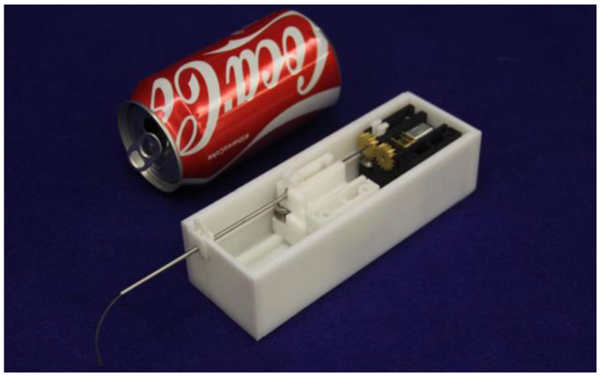

Fig. 2 The assembled robot is shown with only the mechanical components and motors included. The sensing systems described have been designed, but not yet implemented on the prototype.

during a procedure. To change tubes, the physician unlocks all three locks (8), releasing both tubes. Another set of tubes can then be inserted and locked in place. Overall, the prototype contains a small number of moving parts, which was a design objective to reduce cost and complexity.

To ensure safety, redundant sensors are used and compared during surgery for each degree-of-freedom such that the surgery can be aborted if a sensor fails (i.e., if the two ever disagree with one another). In addition to the motor encoders, an angular position magnetic sensor and two linear position magnetic sensors with accuracy up to ± 0.1 mm are used to measure rotation of the tube and translation of both carriages. The angular magnetic sensor is installed on the gear and the adjacent wall, while the linear magnetic sensors are installed on the walls of the casing and the sides of the carriages.

In addition to the redundant relative sensors mentioned above, additional magnets and hall sensors that act as limit switches are used to home the robot. The magnets are embedded in the gear (9) attached to the inner tube and the bottom of the two carriages. The hall sensors are installed onto the wall of the carriage facing the gear (9) and the bottom of the casing. During the homing procedure, the two carriages and the tube move and rotate until the hall sensors produce a signal indicating that the home position has been reached.

Our system employs a control scheme similar to that of Ref. [3], with a control board that interfaces with sensors and provides motor commands. The control board also interfaces with a computer, generating the motor control signals.

3 Results

The prototype shown in Fig. 2 was 3D printed and assembled with low-cost, off-the-shelf parts. The whole robot is designed such that it can ultimately be injection molded, further reducing the final cost. In this work, the carriage was printed in one piece, but in an injection molded version, it will be the combination of two parts that are molded separately and snapped together. The casing was also made from three simple parts. The off-the-shelf parts used in the robot include the outer tube, v-wheels, sleeve bearings, spur gears, and motors. The various sensors described are not currently integrated into the prototype, but will be added in the near future. The total cost for all the off-the-self parts, including mechanical components, motors, and sensors in our prototype was approximately \$70, not including the nitinol tube (even in low quantities, nitinol tubing currently averages approximately \$85/foot [5]). The exact final manufactured cost is still to be determined and depends upon a number of factors, but is likely to be under \$100 with economies of scale in component ordering.

The overall size of the robot is 160 mm $\times$ 54 mm $\times$ 40 mm. The robot is intended to be mounted to a passive, lockable support arm, with a suction tube connected to the proximal end of the inner tube. Details of the surgical workflow and intended image guidance approach are presented in Ref. [3].

4 Interpretation

The results described here are promising but there is still much work to be done before this device is finalized. First, the sensing systems described in this paper must be implemented on the prototype. Next, we plan to test the entire system by conducting phantom hematoma removal experiments, repeating the experiments performed in Ref. [6]. Since we intend the robot to ultimately be made with injection molding, the molded robot must be manufactured and assembled and further evaluations and experiments performed to test the accuracy, robustness and safety of the robot. While the final cost of the injection molded robot is still to be determined, the prototype presented in this paper can in principle be made at a cost that is amenable to a disposable robot approach.

In conclusion, we have presented a robot designed for ICH removal that is low-cost, compact, and uses few moving parts. A disposable robot approach has the potential to help facilitate clinical adoption of the concentric tube technique for ICH decompression.

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