Robot-Assisted Intracerebral Hemorrhage Evacuation: An Experimental Evaluation

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ABSTRACT

We present a novel robotic approach for the rapid, minimally invasive treatment of Intracerebral Hemorrhage (ICH), in which a hematoma or blood clot arises in the brain parenchyma. We present a custom image-guided robot system that delivers a steerable cannula into the lesion and aspirates it from the inside. The steerable cannula consists of an initial straight tube delivered in a manner similar to image-guided biopsy (and which uses a commercial image guidance system), followed by the sequential deployment of multiple individual precurved elastic tubes. Rather than deploying the tubes simultaneously, as has been done in nearly all prior studies, we deploy the tubes one at a time, using a compilation of their individual workspaces to reach desired points inside the lesion. This represents a new paradigm in active cannula research, defining a novel procedure-planning problem. A design that solves this problem can potentially save many lives by enabling brain decompression both more rapidly and less invasively than is possible through the traditional open surgery approach. Experimental results include a comparison of the simulated and actual workspaces of the prototype robot, and an accuracy evaluation of the system.

Keywords: continuum robot, active cannula, concentric tube robot, minimally-invasive neurosurgery, robot-assisted surgery

1. INTRODUCTION

An Intracerebral Hemorrhage (ICH) is a hematoma or blood clot that arises in the brain parenchyma, causing increased pressure on the brain (see Figure 1). Strokes occur sufficiently frequently in the United States that one person has one approximately every 40 seconds [1]. ICH is the second most common cause of stroke, and it has a one-month mortality rate of approximately 40% [2]. Thus, ICH accounts for much of the total morbidity, mortality, and economic burden of strokes [3].

A major challenge with ICH is that every minute between the initiation of the hemorrhage and the application of treatment is critical, and time delays dramatically reduce the patient's odds of surviving. One goal of the new robotic approach we propose in this paper is to decrease the time required in the operating room to decompress the brain, transforming an open brain surgery to something comparable to an image-guided needle biopsy procedure.

Another possible reason that the ICH mortality rate is so high is that it is challenging to decompress the brain by removing clots, without damaging surrounding healthy brain tissue in the process. Indeed, at least one study has shown that clinical outcomes are no better whether the clot is surgically removed or not [4] and we hypothesize that the reason for this is the additional trauma associated with accessing the surgical site.

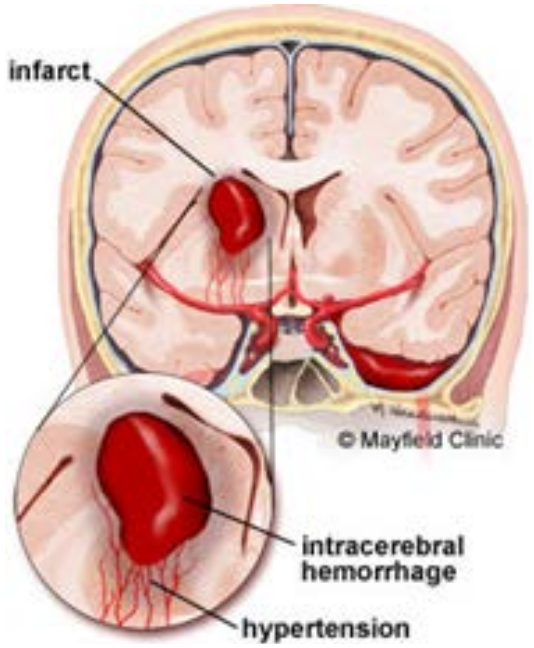

Figure 1.Intracerebral Hemorrhage is a hematoma or blood clot that causes increased pressure on the brain.

Despite this, generally agreed upon guidelines in the medical community indicate that hematomas greater than 3 cm should be operated on, while smaller hemorrhages are treated with drugs and watchful waiting. Surgery is usually supported by image-guidance using the preoperative CT images of the patient, and can include placement of a catheter for drainage of the hematoma after the bulk of the clot is removed. While several minimally invasive surgical alternatives to open craniotomy have been proposed and studied in small case series, such as thrombolysis and endoscopic aspiration of the hematoma [5], ICH remains without an approved treatment proven to decrease morbidity and mortality [3]. The ideal hemorrhage evacuation technique would provide immediate and complete evacuation without traumatizing the brain [6].

In this paper we propose a novel image-guided robotic system to enable aspiration of an intracranial hematoma through a minicraniotomy of the size generally used for image-guided needle placement using modern image guidance systems. This robot delivers an active cannula (a needle-diameter steerable device made from concentric elastic tubes with pre-shaped curvatures) into the clot. Also called concentric tube robots (see Figure 2), these devices have been modeled using beam mechanics. The latest models can describe the space curve of a collection of arbitrarily many concentric tubes, each with a general precurved shape [7], [8]. In this paper we use these robots in a slightly different way than they have been applied in the past. Previously, it has been assumed that one active cannula is available consisting of several tubes whose curvatures must be selected a priori [9–11]. In this paper we consider using multiple active cannulas sequentially, with each consisting of one straight steel delivery tube and one curved nitinol tube. By providing a collection of curved tubes with different precurvatures that are used sequentially rather than simultaneously, we can reduce the complexity of the overall actuation system and provide greater flexibility to select the workspace of the device to match the geometry of the clot to be removed.

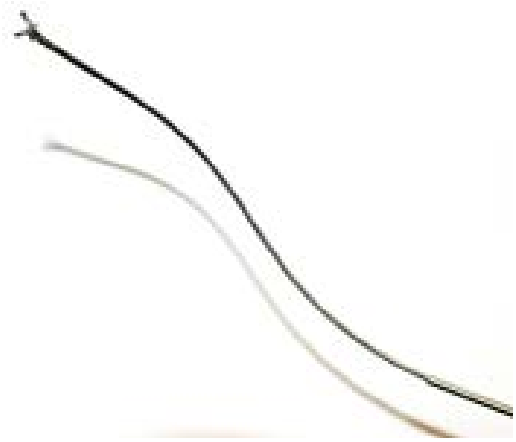

Figure 2. Example active cannula with a gripper inserted through the inner tube to create a miniature manipulator. The gripper can be removed if desired, and for the clot aspiration studies in this paper we use an active cannula without a gripper.

2. Methods

2.1 Tube Actuation System

We have designed and built a robot prototype for ICH evacuation (see Figure 3) that accommodates an active cannula consisting of two tubes (see example tubes in Figure 4). The robot designed to be both autoclavable and biocompatible. It is made from Ultem, PEEK, stainless steel, and aluminum (which can be anodized). The design features a motor pack (not shown) that can be bagged and attached to the end of the robot opposite the concentric tube end effector. For details on this design, see [12]. The robot delivers a two tube active cannula, with an outer tube that is straight and stiff, and an inner tube that is flexible (nitinol) and has a pre-curved section at its tip, as shown in Figure 3. The robot can control the insertion of the outer tube, and both insertion and axial rotation of the inner.

Figure 5 illustrates hemorrhage evacuation using an active cannula. The outer tube follows a straight trajectory from the craniotomy to the hemorrhage. The inner tube with its pre-curvature enables the tip of the cannula to be moved within the hemorrhage so that it can be evacuated via suction. Figure 5b and 5c show two locations for the evacuation of the hemorrhage. The robot is designed such that the inner curved tube can be easily decoupled from the robot and replaced with another tube that features a different precurvature at its tip, while leaving the outer straight tube in place.

2.2 Image Guidance

To enable image-guided delivery of the robot, we adapted the strategy of the Medtronic Navigus system (see Figure 6a), which uses of a bone-anchored base placed over a burr hole in the skull. A trajectory stem attaches to the base with a locking ring. After alignment of the trajectory stem, the robot's front plate is attached to it, enforcing the correct entry path for the active cannula.

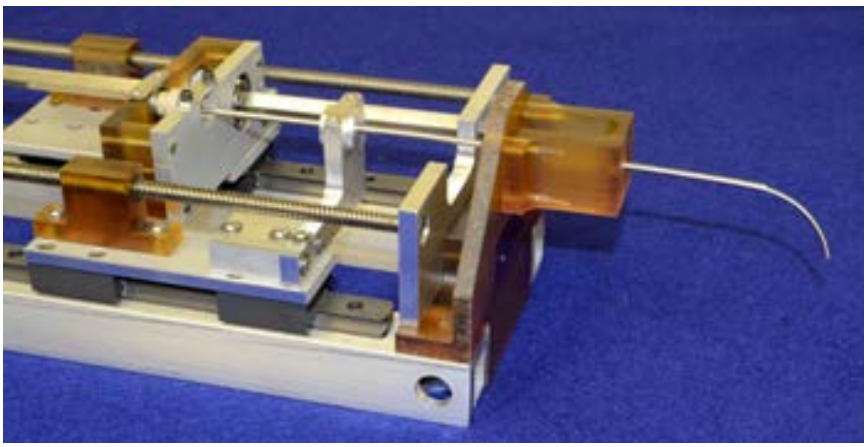

Figure 3. A robot for ICH evacuation that controls insertion of an outer straight stainless steel tube, and insertion and rotation of an inner flexible nitinol tube with a precurved tip. The robot features quick disconnect so that multiple inner tubes can be used during a single surgery. For detailed information on the design of this robot, see [12].

Figure 4. Examples of the tubes that can be used in the robot shown in Figure 3.

The workflow for inserting the robot to evacuate an ICH is as follows: (1) preoperative registration is performed using surface-based registration to align segmented preoperative CT images with a brow scan of the patient, (2) the surgeon then creates a burr hole and attaches the trajectory stem base, (3) the surgeon then uses a tracked probe together with the standard triplanar image view displayed on a monitor to manually adjust the alignment of the trajectory stem (pivoting the ball shown in Figure 6b in its cup), before locking the ball in place using the locking ring, at the desired trajectory, (4) the robot is positioned above the trajectory stem on the passive arm, (5) the active cannula is deployed into the

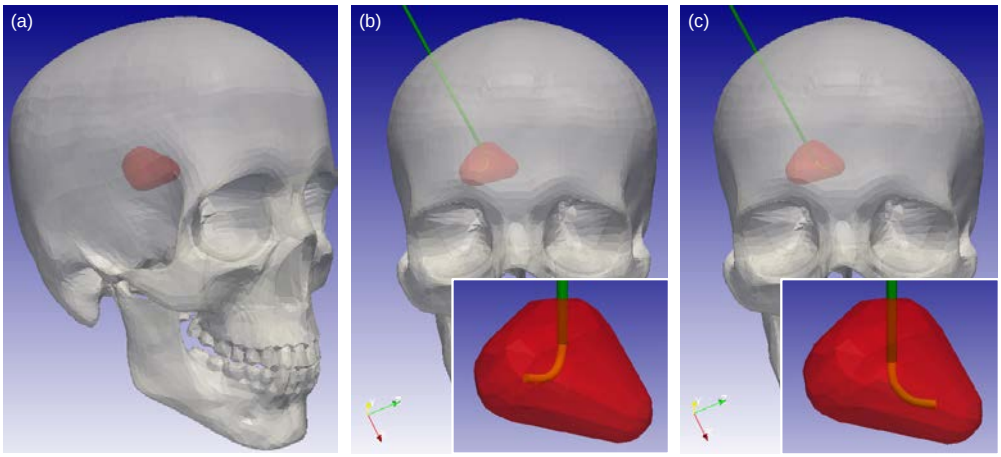

Figure 5. Evacuation of an intracranial hemorrhage: (a) 3D model of the patient's skull and the hemorrhage (red), (b) first planned location for evacuation of the hemorrhage using inner tube with circular curvature (yellow), (c) inserting a different, s-shaped tube (blue) modifies the device's workspace, enabling it to

hematoma, and (6) suction is applied as the cannula tip moves within the hematoma to aspirate the hematoma from within. Optionally, ultrasound can be used to monitor the aspiration process in real-time.

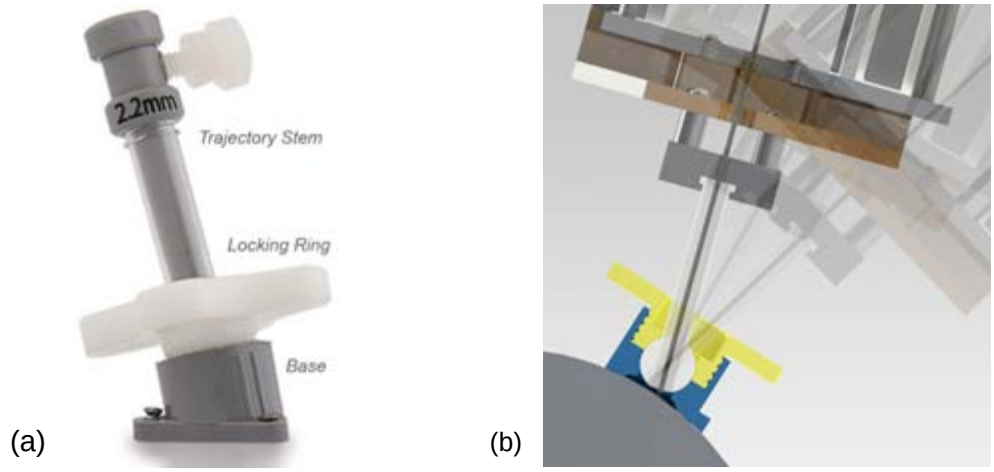

Figure 6. The skull attachment of the robot is adapted to (a) the commercially available neuronavigation system (Navigus, Medtronic Inc.), which consists of a skull bone anchored base, to which a trajectory stem is attached to by a locking ring. (b) The robot attaches to the trajectory stem which allows for pivoting the insertion trajectory. The image shows three overlaid poses.

3. RESULTS

Beginning with an anonymized CT scan of an ICH patient at Vanderbilt Medical Center, we performed an experiment to evaluate the ability of the system described in previous sections to remove a hematoma. In this experiment, we inserted the straight outer tube up to the surface of the clot, and then performed coordinated motion of both tubes to move the tip of the curved tube to all reachable locations within the hematoma. The curved tube remained within the hematoma at all times, and never passed through brain tissue. To replicate the patient anatomy from the anonymized CT scan, we used a two-piece, semitransparent plastic skull (A20/T, 3B Scientific, USA). We segmented the clot from the patient scan and created a mold for a phantom clot it using a rapid prototyping machine. A thin acrylic was placed at the midline of the skull and a hole was laser cut into it to hold the phantom hematoma at the correct height and orientation within the skull. The experimental setup is shown in Figure 7.

A simulated clot was made by molding red gelatin in the rapid prototyped mold. Clear gelatin was molded in the phantom skull, with the simulated clot embedded. The clot was made from Jell-O brand gelatin, with barium added at 0.5 g/ml for contrast enhancement of the clot in CT images. The surrounding gelatin simulating the brain was made from 10% by weight Knox gelatin (Kraft Foods Global Inc., USA). Two inner nitinol tubes (intended to be used sequentially) were precurved via heat treatment to radii of curvature of 19.8 mm and 12.6 mm. An experienced surgeon then selected the entry path for the cannula. The robot was able to remove 83.1% of the clot using both of the curved tubes sequentially. The expected removal percentage, based on the curvatures of the tubes was 80.6%. We believe that tissue deformation is responsible for the experimental results slightly exceeding the theoretical prediction. Suction within the clot causes some shrinking of the clot as material is removed, bringing material within reach of the cannula tip that would not be in reach if the clot rigidly maintained its initial geometry.

4. CONCLUSION

In this paper we have presented a new method for ICH decompression, based on use of an image-guided robotic system. The robot is sterilizable and biocompatible, and designed to deliver an active cannula into a blood clot in the brain, and aspirate it from within. This enables decompression of the brain with trauma comparable brain biopsy. This is the first steerable needle approach for decompressing the brain in ICH. This system also represents a new paradigm in the use of concentric tube robots. Previously, the design of these devices has been considered fixed throughout surgery (i.e. the parameters of all tubes are selected before surgery and no tubes are added or removed from the cannula during surgery). In contrast, here we propose removal of tubes during surgery and introduction of new tubes. This enables much greater freedom in the workspace that can be reached using a relatively simple active cannula, such as the two-tube cannula used

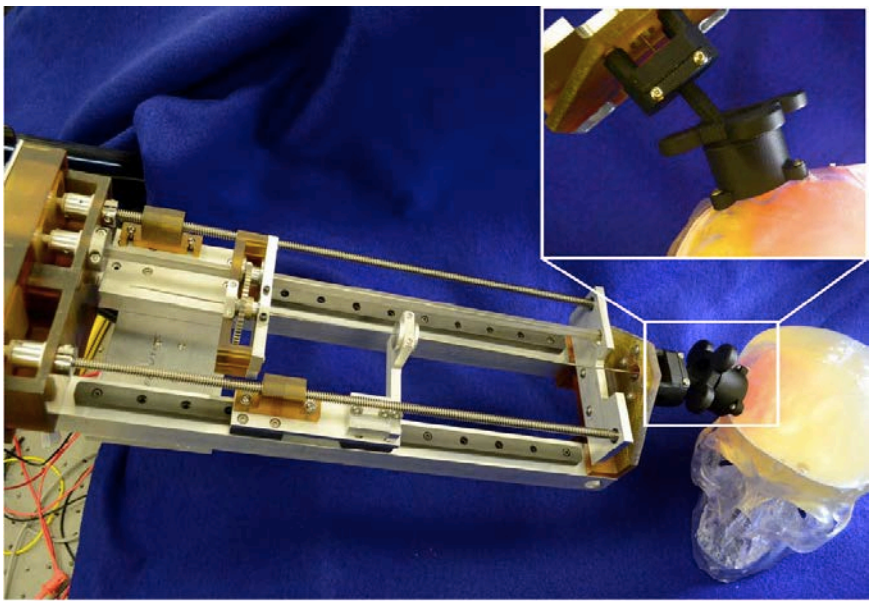

Figure 7. Experimental setup for in vitro phantom experiment. The skull phantom was filled with gelatin. Red gelatin was molded into the shape of a real hematoma taken from a CT scan of an ICH patient, and encased within clear gelatin representing the brain. The robot was then used to remove the clot phantom with an active cannula and suction.

in our experiments in this paper. This has the advantage of enabling a simple actuation system to be used (3 DOF vs. 6 or more DOF), which enables the robot to be low in cost and system complexity. It also has the advantage of enabling these robots to be used in emergency conditions where there is insufficient time for patient-specific design and heat treatment of the tubes to create an optimal cannula for a given patient. If this new approach is as successful in eventual clinical trials as it has been in our initial phantom studies, it may have the potential to save the lives of some of the 40% of ICH patients that die from ICH, and also to reduce the incidence of brain damage in those patients who survive.

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