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Minimally-Invasive Intracerebral Hemorrhage Removal Using An Active Cannula

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***Abstract*— The high incidence of intracerebral hemorrhages, together with a 40% mortality rate, provide strong motivation for enhancements in the treatment methods available to physicians. To minimize the disruption to healthy brain tissue associated with gaining access to the surgical site that is imposed by traditional open or endoscopic surgical intervention, we propose a new minimally-invasive, image-guided, robotic approach that provides articulation within the lesion at the tip of a needle. In this paper we present a biocompatible and sterilizable robot, together with an image-guidance approach designed to deliver the tip of the needle accurately to the blood clot and to move it within the clot, to aspirate it. An experimental evaluation demonstrates removal of 92% of the target clot tissue in a proof-of-concept phantom study.**

I. Introduction

Every 40 seconds, a person in the United States has a stroke [1]. Intracerebral hemorrhage (ICH) is the second leading cause of stroke, representing a large portion of the total economic burden, morbidity, and mortality of strokes [2], with a 40% mortality rate [3]. An intracerebral hemorrhage occurs when a hematoma (i.e. a blood clot) causes increased pressure in the brain. A critical factor in the treatment of ICH is time, with every second between the start of bleeding and the application of treatment reducing the patient's odds of survival. Another critical factor is the cost/benefit analysis associated with the collateral damage to healthy tissue involved in surgical exposure of the clot, for removal. This calculation eliminates many patients as surgery candidates, and forces doctors to adopt a "watchful waiting" approach and hope that drugs can reduce intracranial pressure before brain damage becomes too severe. The 40% mortality rate underscores the drawbacks of both surgery and watchful waiting, which have comparable clinical outcomes [4]. These factors motivate the new, minimally invasive approach we propose in this paper.

This approach builds upon and extends a great deal of early research in the field of medical robotics on robotic assistance for stereotactic procedures. Indeed, the very first surgical robot was designed specifically for delivering needles to precise locations within the brain [5]. Since then, there has been a great deal of subsequent research on this topic, which is reviewed in [6], [7], [8]. While these stereotactic robots have been used for many applications – essentially anything that can be accomplished by accurate placement of the tip of a needle at a desired location – simple needles are not well-suited to ICH evacuation. This is because ICH evacuation requires movement of the tip of the device within the lesion, rather than a single placement followed by aspiration. Based on this, ICH was an early motivation for the development of bevel-steered needles [9], [10]. However, bevel-steered needles have yet to be demonstrated in realistic ICH experiments, even in phantoms. This is due to curvature limitations that thus far preclude sufficient deflection *within* the hematoma, combined with the unsolved challenge of adapting the needle to carry an interventional tool suited to ICH removal, or even a sufficiently large diameter aspiration channel. Brain tissue is soft compared to the tissue phantoms typically used in needle steering experiments, and only very thin needles have thus far been sufficiently flexible to achieve steering in it [10].

To satisfy the need to manipulate the interventional tool within the hematoma, an early robotic approach to ICH removal involved endoscopic brain surgery combined with the use of a straight morcellator to debulk the clot [11]. It was shown in phantom studies that while the robot added a few minutes to the overall surgery, it enabled surgeons to remove the clot with significantly less damage to the brain tissue immediately surrounding the clot. Despite this clear benefit, robotic assistance has yet to become routinely used in treating ICH. One contributing factor may be that the surgical approach to the clot itself – which requires an open pathway to be created through brain tissue so that straight instruments can be manipulated at the surgical site – remained the same as in standard endoscopic neurosurgery. It has recently been suggested that the most significant problem in ICH removal is the trauma associated with accessing the surgical site, and that if the lesion could be debulked from within by an articulated tool at the tip of a needle, patient outcomes might be significantly improved [12]. It was this suggestion that inspired the system described in this paper.

Our new minimally invasive, image-guided, robotic approach involves essentially the same level of trauma to healthy tissue required for brain biopsy, which is far less than in open or endoscopic brain surgery. The system aspirates the clot through a type of needle that can achieve tip articulation

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within the clot, called an active cannula. Also called a concentric tube continuum robot, this device consists of multiple concentric tubes that translate and rotate inside one another [13], [14], [15]. In this study, we use a version of the device similar to that previously used in soft tissue targeting applications in [16], [17], [18], [19], which consists of two tubes, the outer of which is straight. The straight tube initially acts exactly as an image-guided biopsy needle does, delivering the tip of the device to the hematoma, after which the precurved inner tube can be deployed and used as the aspiration channel to remove the clot. Then, through coordinated movement of the two tubes (insertion and retraction of the outer, combined with insertion, retraction, and axial rotation of the inner) the tip of the device can be moved within the hematoma to debulk it.

II. The Current Clinical Perspective on ICH

Intuitively, hematoma evacuation should result in improved patient outcomes due to relief of pressure on an at-risk volume of brain tissue near the hematoma. Similarly, faster resolution of deficits should lead to more rapid mobilization and discharge, thus exposing the patient to fewer potential complications in the postoperative hospital environment. Unfortunately, these benefits are not seen in studies of operative evacuation of intracerebral hematomas, except in highly selected "optimal" patients. These patients tend to have small, superficial lesions, and a good preoperative performance status, which does not represent the majority of ICH patients [20], [21], [22], [23], [24]. In standard open procedures where the brain substance is cut with electrocautery, tubular retraction systems with or without endoscopic assistance and Archimedes screw-type devices have been attempted with minimal improvement in outcomes [25], [26], [21].

A proportion of this failure may be due to permanent injury which is irreversible even with evacuation. However, it is known that there is an at-risk volume of brain tissue which may be salvaged and returned to pre-injury function if its conditions are optimized. The majority of these hemorrhages occur as a result of lipohyalinization (a thickening of the vessel wall that leads to bleeding) of small superiorly projecting perforating vessels off of the circle of Willis at the base of the brain. Thus, anatomically, the hematoma is deep in the brain and any superoinferior operative trajectory of any significant dimension will result in more tissue volume disruption than would be saved by hematoma evacuation. This results in only superficial lesions being candidates for evacuation and may be partially responsible for the lack of encouraging data. Although there have been several minimally invasive surgical approaches proposed, such as locally delivered ultrasound with thrombolysis and endoscopic aspiration of the clot [27], [28], these have only been applied in small case studies and have not been adopted as the standard treatment for ICH. In fact, there remains no approved treatment method that clearly decreases the morbidity and mortality of ICH [2].

However, aspiration through a stereotactic robot with articulation capability at the tip of the needle, informed by a three-dimensional representation of the hematoma, has the potential to enable removal of these lesions with significantly less tissue disruption than is currently required. The proposed cannula used in the experimental section of this paper is smaller in diameter than standard stereotactic biopsy needles (which are 2.2mm in diameter) routinely utilized in this anatomic location with an acceptable complication rate of less than 2% [29]. We believe that this will enable relatively safe evacuation of these common lesions and lead to improved patient outcomes.

III. System Overview

Our image-guided robotic system (Fig. 1) incorporates a sterilizable robot for controlling a two-tube active cannula (described in Section IV), a head-mounted trajectory guide working in concert with optical tracking to enable image guidance (discussed in Section V), a passive arm, and a suction device enabling aspiration of the clot through a tube connected to the back of the cannula. The procedure for using this system to remove an intracerebral hematoma is to first mount the trajectory guide onto the patient's skull as shown in Fig. 1, and then align it with the desired target using the image-guidance system, as described in Section V. These steps mimic the standard clinical workflow for image-guided brain biopsy using the Medtronic, Inc. Navigus clinical image guidance system.

The robot, which has been autoclaved and is sterile, is then mounted to the passive arm. The motor pack is bagged and attached to the sterile robot. Following this, the robot and the trajectory guide are coupled together, aligning

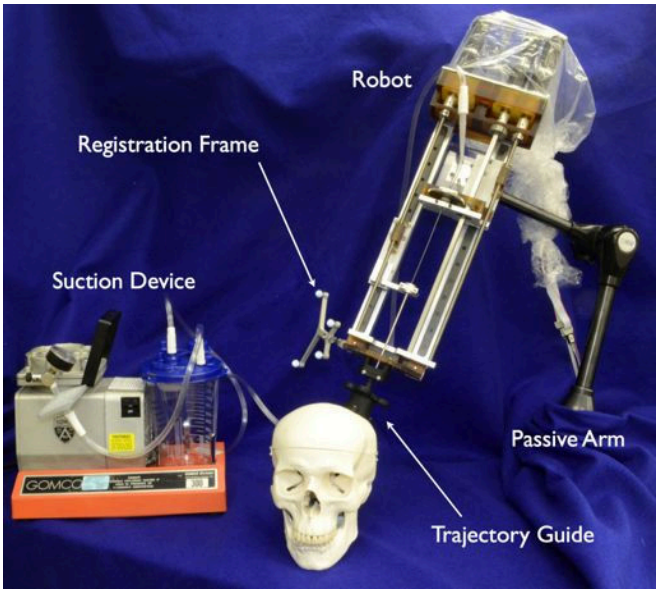

Fig. 1: The complete system is shown attached to a phantom skull with the trajectory guide. The robot is supported with a passive arm, and a suction device is attached to the robot to aspirate the hematoma. The motor pack attached to the robot is bagged for sterility, while the rest of the robot is autoclavable. The optical tracker used for image guidance is not shown, although the rigid body it tracks can be seen attached to the robot.

the robot with the desired trajectory into the brain. The inner tube is attached to a standard clinical suction device, enabling aspiration. The cannula is then deployed to the clot using the robot's motors, excavating it by extending the curved inner tube out of the straight outer tube, and then performing coordinated movements of both tubes according to a preoperative plan. Once the interior of the clot has been debulked, both tubes are retracted and the robot is detached from the trajectory guide.

IV. Robot Design

The ICH robot was specifically designed to be suitable for human clinical trials. Thus, we designed for sterilizability, biocompatibility, usability, and safety. The robot is designed to deliver an active cannula consisting of two tubes to the blood clot and then manipulate those tubes as necessary to debulk the clot. During this process, suction is used to aspirate the clot through the innermost tube of the active cannula. While many prior actuation units have been designed for concentric tube robots, this is the first robotic version (a manual version without motors was described in [17]) of which we are aware that is fully sterilizable and operating-room ready. It is constructed entirely from autoclavable and biocompatible components, with a modular motor pack that can be bagged.

We designed the robot to have three degrees of freedom (see Figs. 1 and 2) with one motor to control linear translation of a straight, stiff, stainless steel outer tube, and two others that control translation and rotation of a precurved, flexible (nitinol) inner tube (see Fig. 3). Both linear motions are accomplished using lead screws to translate two separate carriers (one for each tube, see Fig. 2) via a threaded block attached to each carrier, with the carriers riding on two linear slides. A square shaft is used to transmit rotary motion to the inner tube carrier, and spin the tube via a gear train (see Fig. 2). Both the lead screws and the square shaft are controlled by a motor pack at the rear of the device that consists of motors mounted to a motor plate which can be attached and detached easily from the robot.

To make the robot both biocompatible and sterilizable, we used only stainless steel, aluminum, PEEK, and Ultem, all of which can withstand autoclave sterilization. Before OR use, the stainless steel will be passivated, and the aluminum anodized. To create a sterile barrier around the motors, a sterile bag and bag clamp were included in the design (see Fig. 4). The bag is secured to the robot with the bag clamp, and the section of the bag that encompasses the motor plate is removed. To enable transmission of motor actuation across the sterile/non-sterile barrier (the back plate of the robot), we used an Oldham coupling, a strategy similar to that used on the da Vinci Surgical System (Intuitive Surgical, Inc., USA) for the same purpose, which works on the basis of creating a tortuous path from the non-sterile region to the sterile region (see Fig. 5).

The robot was designed to enable several precurved inner tubes to be used in sequence in a given surgery if needed to cover a geometrically complex hematoma. Thus, we provide a quick-release mechanism for the tubes as shown in Fig. 6. Each tube is bonded to its respective hub using biocompatible and autoclavable Loctite M-21 HP. We also provided a quick-release for the carriers so that in an emergency, the tubes can be retracted rapidly by disengaging the carriers from the lead screws (see Fig. 7).

V. Image-guidance for ICH

Evacuation of ICH is usually supported by image-guidance using the preoperative computed tomography (CT) images of the patient. An optical or electromagnetic tracking system enables localization of tracked instruments and visualization of their pose, with respect to images. In our robot-assisted ICH evacuation procedure, we intend to accomplish registration using exactly the same method used by modern clinical image guidance systems, namely a surface scan of the face, followed by alignment of the facial points scanned with the corresponding surfaces in the CT images, using surface-based registration.

Once the registration of the patient is established, we adapt the needle alignment technique of the Navigus system (Medtronic, Inc., USA), a commercially available neuron-avigation system that was developed for brain biopsies and deep-brain stimulation. Fig. 8 illustrates the method of aligning the insertion trajectory. First an osteotomy is performed by the surgeon. After opening of the dura, the base of the trajectory guide is attached to the skull using three titanium screws. The trajectory stem, used to align the active cannula with the target location, is then snapped onto the base and loosely secured in place with the locking ring. An alignment probe is inserted into the trajectory stem, which enables visualization of the insertion trajectory in the image-guidance system (see Fig. 8b) and adjustment of it as desired. The locking ring is then securely tightened to fix the trajectory stem in place, and the alignment probe removed. Next, the robot (attached to a passive arm) is moved into the surgical field and the robot front plate is coupled to the trajectory

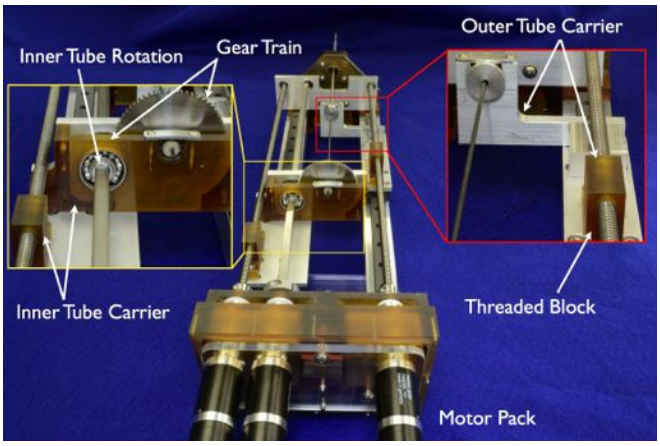

Fig. 2: The robot uses lead screws to translate the carriers via a threaded block. The carriers, which hold the tubes, travel along a linear track. The inner, precurved tube is rotated with a square shaft attached to a small gear that meshes with the large gear attached to the tube hub.

Fig. 3: The tubes are permanently attached to hubs using a biocompatible glue and can be autoclaved. The inner, precurved tube also has a gear attached to the hub to rotate the tube.

stem. The trajectory stem has a flat in it that aligns with a flat on the robot front plate, enabling physical registration of the robot with the trajectory stem. The active cannula then passes through the trajectory stem and into the brain, along the desired trajectory.

VI. Workspace Case Study

We conducted the following feasibility study to determine the ability of a two-tube active cannula to access a hematoma. This study began with an anonymized ICH patient CT image dataset (see Fig. 9). We segmented the skull and the hematoma in the CT images (0.5 mm inplane resolution, 5 mm slice thickness) and created surface models using 3D Slicer. This patient suffered from a hematoma with an overall volume of about 30.2 cm^3. We then determined a straight access path to the hematoma and selected an inner tube curvature. The left image shows the straight access to the hematoma and an overlay of the workspace of a cannula with an inner tube curvature of 0.05 mm^{-1} on the hematoma.

Fig. 4: The motor pack is bagged to ensure sterility of the robot for clinical use. (a) The motor plate, shown here, is removed from the robot to allow the bag to be attached with the aluminum bag clamp. (b) After the bag clamp is attached, the portion of the bag inside the bag clamp is removed, enabling the motors to subsequently attach to the Oldham couplings. (c) The motor plate is reattached and the bag pulled over it. The robot is now sterile.

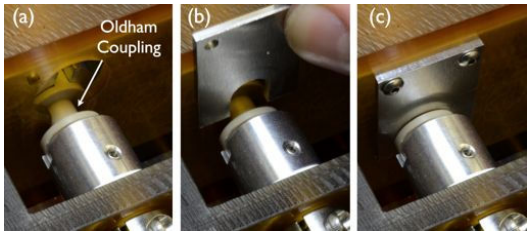

Fig. 5: An Oldham coupling is used to transfer rotation of the motor shaft through a tortuous path to the sterile lead screws and square shaft for translation and rotation of the cannula tubes. (a) Oldham coupling made from PEEK plastic. (b) An aluminum plate is brought down over the Oldham coupling and secured in place. (c) The aluminum plate creates the tortuous path between the non-sterile bagged motor pack and the sterile robot.

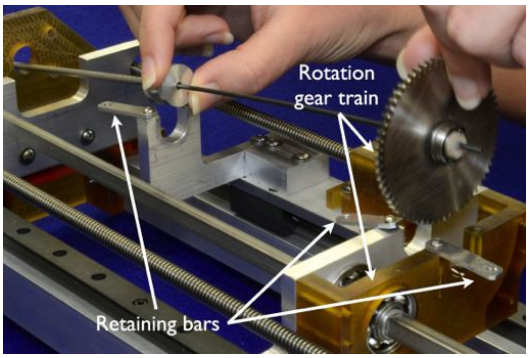

Fig. 6: Quick-release mechanism for the tubes. Either tube may be quickly released from the mechanism by removing a screw and swinging a retaining bar out of the way. This enables one to change the inner tube during a surgery if multiple tubes with different curvatures are to be used in sequence.

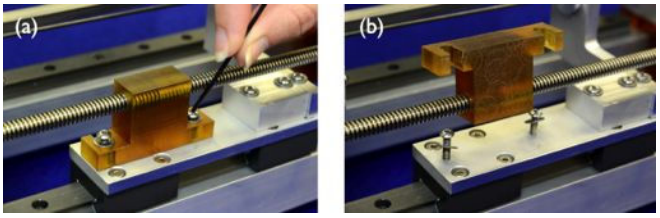

Fig. 7: Quick-release mechanism for carriers enabling them to be detached from the lead screws and manually slid backward, for manual rapid tube retraction. The mechanism works by (a) loosening holding screws, followed by (b) swinging the threaded block away from the carrier.

This active cannula is capable of accessing all areas within the hematoma. The left image appears pixelated due to the 5 mm slice thickness, and the fact that the axial images have been stacked and then re-sliced in the sagittal direction to create the image.

We note that hematomas in the brain vary in size and shape, meaning that for optimal performance, the curvature of the inner tube must be selected based on the requirements of the specific clot geometry exhibited by a given patient. We believe that a set of discrete tube shapes will be capable

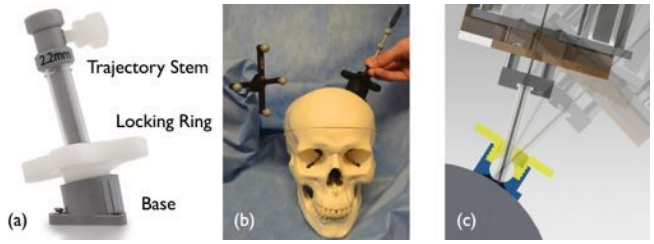

Fig. 8: Image-guidance is achieved by adaptation of (a) a commercially available neuronavigation system (Navigus, Medtronic Inc.), which consists of a bone anchored base, to which a trajectory stem is attached by a locking ring. (b) A tracked pointer is inserted through the trajectory stem and used to align the stem with the desired trajectory, after which the locking ring secures it in place. (c) The robot attaches to the stem, aligning the cannula insertion trajectory. The image shows three overlaid poses, with two being semi-transparent.

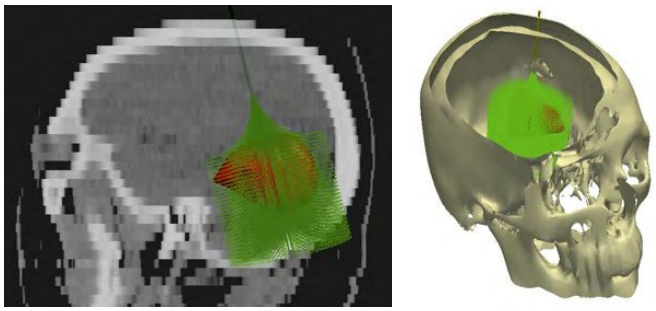

Fig. 9: Example patient case. Left: Sagittal CT slice view with 3D model of the hematoma (red). The active cannula approaches the hematoma through a straight access path and the achievable workspace is visualized (green). Right: The workspace of the active cannula covers the hematoma.

of covering the majority of hematoma shapes, and note that complex hematoma shapes may be approached sequentially, using first one tube precurvature for the inner tube, and then removing it and inserting another with a different precurvature.

VII. Experimental Evaluation

In order to illustrate the use of our robotic system for aspiration of intracerebral hematomas, we conducted a phantom study. This experiment used a red phantom, simulating a blood clot, encased in a clear phantom, simulating brain tissue (see Fig. 10). The clear phantom was made from 10% by weight Knox gelatin (Kraft Foods Global Inc., USA), and the red phantom was made from Jell-O gelatin. This made the tumor much softer than the surrounding brain tissue. This phantom is similar to the phantom described in [11]. The trajectory stem was aligned in a straight path to the center of the blood clot and secured using the locking ring. The robot was then affixed to a passive arm (MA60003, NOGA, USA) and attached to the trajectory stem using the procedure outlined in Section V. We then inserted the straight, stiff outer tube to the clot, with the inner tube retracted fully inside it. The inner tube was then advanced into the clot to aspirate it in the manner described previously. Path planning for the tip of the cannula was done manually, with an operator specifying a series of joint space positions for the robot based on visual observation of the removal progress. The robot was able to remove 92% of the 112.6 g clot, determined by initially measuring the amount of red gelatin added to the phantom, and then scooping out and weighing all remaining red gelatin after the intervention.

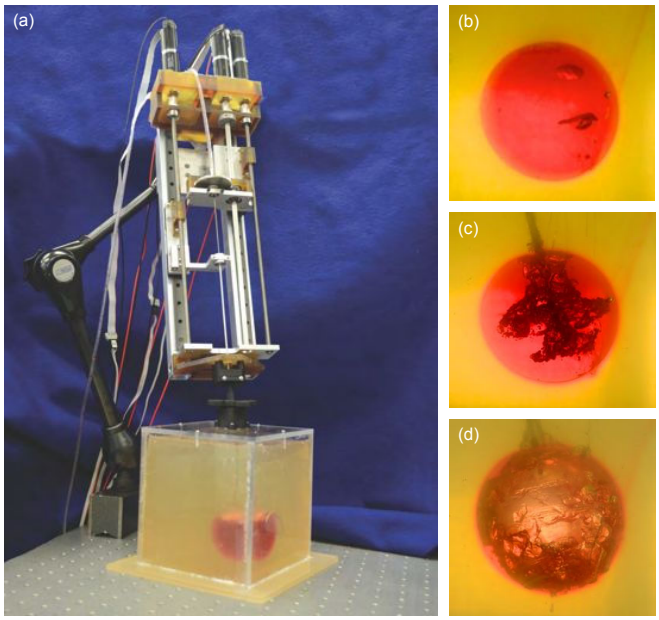

Fig. 10: Phantom experiment. (a) The robot is attached to the passive arm and secured to the trajectory guide which is mounted onto the top of a acrylic box. The active cannula is deployed to the clot and the aspiration tube is used to debulk the clot. (b) The blood clot is shown prior to beginning the experiment, (c) progress midway through the removal experiment, and (d) the same area after aspiration.

VIII. Discussion

The robotic approach presented in this paper represents a promising new minimally invasive option for brain decompression in intracerebral hemorrhage patients. The new sequential paradigm involving removing and replacing tubes during the surgery differs from the prevailing design paradigm for concentric tube robots in endonasal surgery [30], cardiac surgery [31], lung surgery [32], and targeting in brain ventricles [33], where a single, more complex robot is used. These prior design approaches have assumed that one specific collection of tubes must cover all desired points or volumes relevant to a particular patient and surgical procedure, for the entire duration of the surgery. The idea was that the tubes would be physically shape set by a heat treatment process after planning and before surgery, to attain the curvatures selected by the design algorithm.

In contrast, ICH removal is an emergency procedure that cannot tolerate a delay of 10 to 20 minutes to heat set a desired shape into each component tube. Thus, for ICH and similar applications, it is useful to use a concentric tube robot that is rapidly assembled from an initial, pre-made set of "basis tubes", which are already curved and available in the operating room. We imagine a design algorithm selecting a small number of these basis tubes, which will then be inserted through one another to create the interventional device. This approach would be conceptually similar to the interchangeable instrument set available with the da Vinci robot, in that many different instruments would be available during surgery.

When using these tube combinations, we note that if optical visualization within the lesion is needed, we can introduce a chip-tip camera through the outer tube to the blood clot, and that in this case it may be desirable to use two robots at the same time. We also note that intraoperative ultrasound may be useful for monitoring the progress of clot aspiration.

Lastly, we note that motion planning for the tip of the cannula within the clot is an open research topic that we intend to address in future work. In the experiments in this paper, we

simply performed this planning procedure manually, under direct visualization of the clot (Fig, 10b-d). In an actual surgical case, particularly with a clot more complex than a sphere or tubes with shapes more complex than constant curvature, it will be useful to develop automated motion planning algorithms to ensure that the tip of the cannula visits all reachable points within the clot as rapidly and safely as possible.

IX. Conclusion

In this paper we introduced a steerable needle approach to treating ICH designed to replace open surgery with a needle-based procedure. We presented the design of a sterilizable and biocompatible robot, an image-guidance approach, and experimental results demonstrating the concept. Our experiment in a gelatin phantom showed that 92% of a spherical phantom clot could could be removed with a two-tube active cannula.

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