Percutaneous Intracerebral Navigation by Duty-Cycled Spinning of Flexible Bevel-Tipped Needles

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BACKGROUND: Intracerebral drug delivery using surgically placed microcatheters is a growing area of interest for potential treatment of a wide variety of neurological diseases, including tumors, neurodegenerative disorders, trauma, epilepsy, and stroke. Current catheter placement techniques are limited to straight trajectories. The development of an inexpensive system for flexible percutaneous intracranial navigation may be of significant clinical benefit.

OBJECTIVE: Utilizing duty-cycled spinning of a flexible bevel-tipped needle, the authors devised and tested a means of achieving nonlinear trajectories for the navigation of catheters in the brain, which may be applicable to a wide variety of neurological diseases.

METHODS: Exploiting the bending tendency of bevel-tipped needles due to their asymmetry, the authors devised and tested a means of generating curvilinear trajectories by spinning a needle with a variable duty cycle (ie, in on-off fashion). The technique can be performed using image guidance, and trajectories can be adjusted intraoperatively via joystick. Fifty-eight navigation trials were performed during cadaver testing to demonstrate the efficacy of the needle-steering system and to test its precision.

RESULTS: The needle-steering system achieved a target acquisition error of 2 $\pm$ 1 mm, while demonstrating the ability to reach multiple targets from one burr hole using trajectories of varying curvature.

CONCLUSION: The accuracy of the needle-steering system was demonstrated in a cadaveric model. Future studies will determine the safety of the device in vivo.

KEY WORDS: Chemotherapy, Drug delivery, Intracerebral navigation

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A wide variety of neurological disorders are characterized by focal, anatomically definable lesions within the brain parenchyma. Such diseases include brain tumors, stroke, traumatic brain injury, epilepsy, and neurodegenerative disorders. Although many therapies for these disorders are focused on systemic, medical treatments, an alternative method is the delivery of therapeutic agents directly at or around the desired site, which is referred to as compartmental or local therapy.[1] Compartmental therapy was first popularized by the use of chemotherapeutic wafers, most notably Gliadel (MGI Pharma Inc., Bloomington, Minnesota), a surgically implanted carmustine-impregnated wafer. After surgical resection of a malignant primary brain tumor, these wafers are implanted into the residual cavity. As the wafer degrades, chemotherapeutic particles are released into the surrounding parenchyma. However, only marginal benefits have been reported so far in multiple randomized trials.[2-4] As a result, interest has developed more recently in alternative techniques for compartmental delivery of therapeutic particles.

One such technique is the use of microcatheters or needles to infuse therapeutic agents or cells directly into the brain parenchyma.[5] Following the surgical placement of such

ABBREVIATION: CED, convection-enhanced delivery

a catheter, therapeutic particles are infused through the catheter, and the blood-brain barrier is bypassed, allowing for more effective and precise delivery of these particles around the catheter tip. The most well-known of these catheter-based infusion techniques is convection-enhanced delivery (CED).[6,7] In CED, by infusing particles under pressure, much higher particle concentrations are achieved in the interstitial space than by diffusion alone. CED has shown potential in multiple clinical trials, especially for patients with malignant brain tumors.[8-10] However, CED appears to be limited by the difficulties of regulating infusate concentrations in heterogeneous brain tissue,[11] such as is commonly found in and around brain tumors, strokes, and other areas of focal intracerebral abnormality.

One solution to this problem is the placement of multiple catheters through various linear trajectories to achieve more uniform drug concentrations via multifocal infusion. However, each pial transection carries with it the risk of cortical injury and hemorrhage. A versatile steering system which could deliver a catheter tip into a number of points within the white matter could help to alleviate this problem, facilitating drug delivery to a large number of points through a single burr hole. The catheter tip could be steered either using a manipulation system from outside the head, as was demonstrated by the magnetic stereotaxis system,[12-14] or by a system reliant on deformation of the catheter itself as it is inserted into the brain parenchyma. The authors have conceived and designed the latter type of system.

Recent years have seen an increasing amount of research in the area of steering of flexible needles through tissue.[15-18] Some of these techniques are unsuitable for use in the brain because of their reliance on significant tissue deformation.[15,16] One technique that does not involve considerable deformation of tissue is based on the observation that when a relatively flexible bevel-tipped needle is inserted into tissue, the needle tends to bend with a direction and curvature dependent on the bevel angle and stiffness. Exploiting this phenomenon, the needle can be steered simply by controlling the orientation of the shaft during insertion.[18] The authors have adapted this technique for brain tissue, and have augmented it with a novel means for controlling the amount of bending during insertion, thereby providing proportional control of steering.[19] A straight or linear trajectory can be achieved with a bevel-tipped needle by spinning the needle during insertion (in fact, the trajectory is helical, but appears straight if the rotation speed and insertion speed are selected appropriately). Relatively complex 3-dimensional trajectories can then be envisioned by combining short segments, some straight and some curved, as desired. If segments with and without spinning are alternated, the needle can be said to be spinning with a *duty cycle*, where the percentage of the duty cycle indicates the percentage of time that the needle is spinning (eg, a 50% duty cycle consists of alternating spinning and nonspinning segments of equal length). Longer nonspinning segments produce curvatures closer to the maximal natural curvature, whereas longer spinning segments produce curvatures closer to the minimal zero curvature, as seen in Figure 1. Furthermore, the duty cycle period, or the time to complete one spinning segment and one nonspinning segment, can be appropriately minimized to create a curve that appears smooth, as opposed to a concatenation of straight and curved trajectories. The efficacy of this approach has been demonstrated in needle-steering trials using a gelatin phantom.[19] This subsequent study represents a test of the system in vitro using cadaver heads.

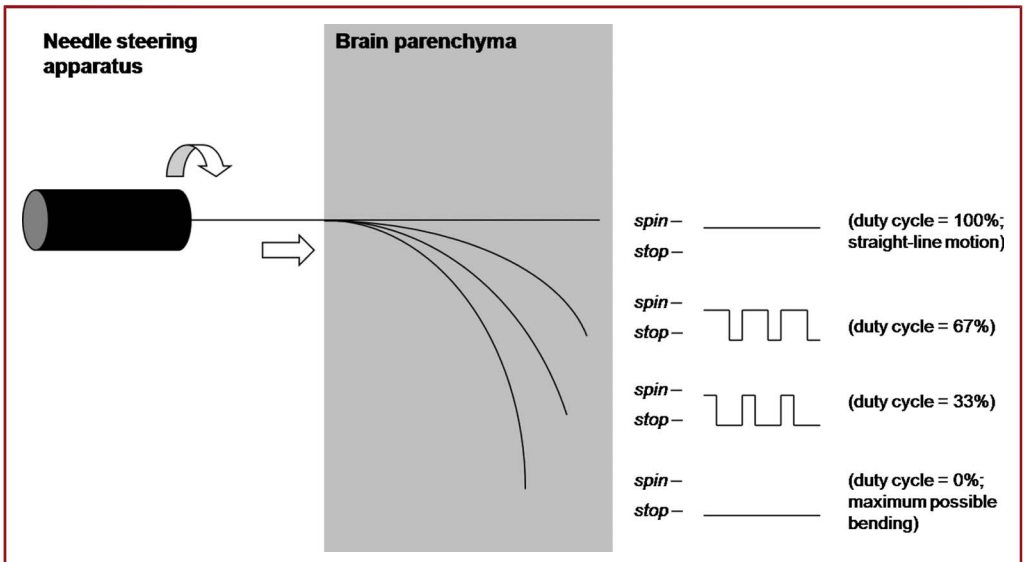

FIGURE 1. *A conceptual drawing of a bevel-tipped needle being inserted into tissue using duty-cycled spinning. Note the inverse relationship between needle curvature and increasing duty-cycled spinning.*

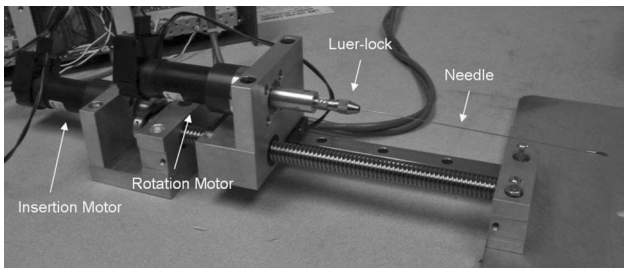

FIGURE 2. *The needle-steering system developed for use in the cadaver trials.*

MATERIALS AND METHODS

The needle-steering system is shown in Figure 2. The base of the system is a linear slide driven by a lead screw with a screw pitch of 0.254 mm, a stroke length of 347 mm, and a total length of 447 mm. The linear slide is actuated by an insertion motor placed at the rear of the device. Mounted onto the slide is the rotational subassembly, which consists of a second motor to rotate the needle. (This design is similar to the report by Webster et al.[20]) A Luer-Lok fitting attached to the rotational motor is used to hold the needle in place. An adjustable aluminum bracket was constructed to interface the needle-steering system with a Leksell G stereotactic head frame (Elekta, Inc., Stockholm, Sweden) for ease of use.

The needle-steering system can be controlled in 2 ways. The first is a graphical user interface in which the end user is able to modify the needle tip orientation, insertion speed, rotation speed, insertion acceleration, rotation acceleration, duty cycle, and duty cycle period. All parameters are modifiable both preoperatively and intraoperatively in real time. This system can be used to execute preplanned trajectories. The second means for control is through a joystick and 3-way toggle switch. The joystick is used to control the needle tip orientation and duty cycle. The needle tip orientation corresponds directly to the joystick orientation, and the duty cycle corresponds to the joystick's distance from its zero position. Joystick zero position provides a duty cycle of 100%, whereas the maximum joystick position provides a 0% duty cycle. The toggle switch is used to advance, stop, and reverse insertion, at a constant insertion speed.

To maximize the attainable curvature or steering angle in tissue as soft as the brain, a custom needle prototype, seen in Figure 3, was developed to increase the cross-sectional area of the tip while minimizing the stiffness of the needle shaft. The custom needle prototype consists of a 14-gauge stainless-steel needle tip with a 10° bevel attached to a 29-gauge hollowed-out nitinol main shaft (Nitinol was chosen for its high elasticity). In addition, the tip was bent 15°, further increasing the effective cross-sectional area.

The needle-steering system was tested in vitro in cadaver brain tissue, in a total of 58 individual navigation trials. Sixteen trials were performed in one cadaver brain, and 42 trials in a second cadaver brain. Each head was placed in ear pins for rigid fixation. A burr hole craniostomy was performed at Kocher's point as measured 11 cm behind the glabella and 2.5 cm lateral to the midline. The burr hole was made using a Midas Rex (Medtronic Midas Rex, Fort Worth, Texas) M8 drill bit, and the dura was opened. Navigation was performed via C-arm fluoroscopy using a previously described technique.[21] In each trial, a target point was selected in preoperative fluoroscope images. The needle was then inserted partially toward the target, without spinning, in the field of view of the C-arm (Philips BV Pulsera, Andover, Massachusetts). Fluoroscopy was again used to ensure that the target lay in the plane in which the needle was curving, and that this plane of needle curvature was perpendicular to the image plane (causing the curved needle to appear straight). At this point the C-arm was then rotated 90° to allow visualization of the progress of the needle toward the target in the plane. An appropriate duty cycle was chosen based on the relation between the target point and the entry point of the needle. The needle was then advanced toward the target at a constant insertion velocity of 0.5 cm/s and rotational velocity of 2 Hz (or 120 rpm). At varying lengths of insertion, needle insertion was paused and a fluoroscopic image was recorded and displayed at a zoom of 1/1. The duty cycle of the needle-steering system was then adjusted, when needed, to optimize the trajectory of the needle toward the target point. Upon reaching the target point as closely as possible, a final fluoroscopic image was recorded. Partial retraction and reinsertion to move the needle closer to the target was not performed to provide a general understanding of the performance of the flexible needle during initial insertion.

The C-arm view was calibrated using spherical fiducials of 4.3-mm diameter. In the final image from each trial, the Measure function of the BV Pulsera postprocessing software was then used to draw a line segment between the end point of the needle and the target point. In the BV Pulsera, these 2 points are selected via point-and-click using a track ball, and the Measure function reports the distance between the points in tenths of millimeters. The point-and-click selection of points introduces a certain degree of error; because of this, measurements were rounded to the nearest millimeter before averaging to obtain the target acquisition error.

FIGURE 3. *The custom needle prototype developed for use in the cadaver trials.*

RESULTS

For the 58 trials performed, the target acquisition error was 2 ± 1 mm. Figure 4 demonstrates a final trajectory in the coronal plane. In this case the trajectory necessary to reach the target point

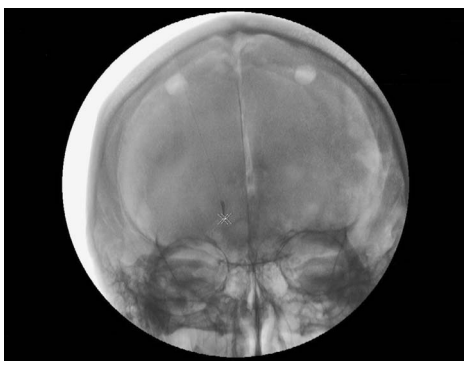

FIGURE 4. *Typical final fluoroscopic image in the coronal plane from a navigation trial in vitro in cadaver brain. The image shows the line drawn in software from the needle tip to the preselected target; each end is marked with a ×.*

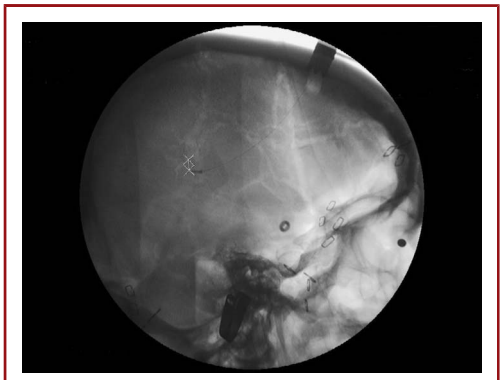

FIGURE 5. *Typical final fluoroscopic image in the sagittal plane from a navigation trial in vitro in cadaver brain. The image shows the line drawn in software from the needle tip to the preselected target; each end is marked with a ×.*

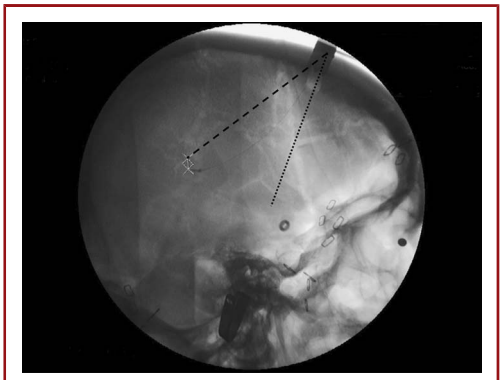

FIGURE 6. *Demonstration of needle entry angle. The dotted line represents the needle insertion vector. The dashed line represents the insertion-target vector. The needle entry angle is the angle between these 2 vectors.*

was fairly linear, so a duty cycle closer to 100% was used. Figure 5 demonstrates a different end trajectory in the sagittal plane. In this case, the trajectory necessary to reach the target point was nonlinear, demanding a high curvature and low duty cycle value, closer to 0%. As can be seen, the target acquisition error in this trial resulted from too low of a maximum needle curvature.

In general, a single constant duty cycle was used, either 0% or 100% depending on the relation between the initial entry angle and the target, for the majority of each needle insertion. However, during each insertion trial modifications were made to minimize the target acquisition error. The number of such adjustments made to the needle trajectory during each insertion trial varied from only a single adjustment to 10 different modifications during one insertion. On average, 4 modifications were made during needle insertion to either the duty cycle or needle tip orientation to achieve the goal. Insertions with a larger number of modifications to the trajectory tended to take longer to perform and tended to have targets selected at greater depths, as expected. The time to complete one insertion trial ranged from 11 seconds to 124 seconds, with an average of 48 ± 28 seconds necessary per trial.

The minimum and maximum insertion trial times correspond to minimum and maximum linear target depths from point of insertion of 26 mm and 111 mm, respectively. However, given the nonlinear nature of the needle trajectories, insertion lengths were consistently greater than actual target depths. The corresponding minimum and maximum insertion lengths were 27 mm and 113 mm, respectively. In general, the depth of a target was 65 ± 21 mm, whereas the needle insertion length was 66 ± 22 mm. Trials did occur, however, in which the difference between the target depth and needle insertion length was both much less and much greater. The minimum difference between depth and insertion length was less than 0.5 mm, whereas the maximum difference was 15 mm.

The differences in target depth and insertion length typically corresponded to the entry angle, with a larger difference being the product of a larger entry angle. As seen in Figure 6, the entry angle is the angle between the needle insertion vector, that is, the direction in which the needle would advance were it completely rigid, and the insertion-target vector, that is, the path a completely rigid needle would have to follow to achieve the target. This entry angle varied greatly in each trial with a minimum of 0° and a maximum of 45°. Over all trials the entry angle was 10° ± 10°.

Control of the needle-steering system was attained through the use of the graphical user interface as opposed to the joystick and toggle switch. The joystick and toggle switch control option was deemed impractical for the cadaver trials given the potential difficulty in maintaining an exact needle tip orientation and duty cycle during insertion pauses for fluoroscopic imaging. Real-time guidance would provide a more reasonable platform for the use of joystick and toggle switch control because pauses during insertion would be unnecessary. However, the most important future control mode for the device probably involves integration of the control system with neuroimaging data and intraoperative tracking of the needle. This would allow the system to execute preoperative plans in a semiautonomous fashion under the supervisory control of the surgeon, using the tracking signal for feedback control of the needle tip.

DISCUSSION

Tissues that effectively deflect a flexible bevel-tipped needle in reproducible fashion would be expected to demonstrate high and homogeneous viscosity. However, the cerebral parenchyma is notable both for its malleability and its heterogeneity. This environment creates a variable low-grade resistance to the passage of a needle or a catheter, which makes a predictable nonlinear trajectory difficult to achieve. The conventional solution for percutaneous procedures such as brain biopsy is to use a rigid biopsy needle that will not be deformed by the surrounding brain during insertion. Although all trajectories through the brain must be linear using this approach, the end point of the needle is both accurate and reproducible.

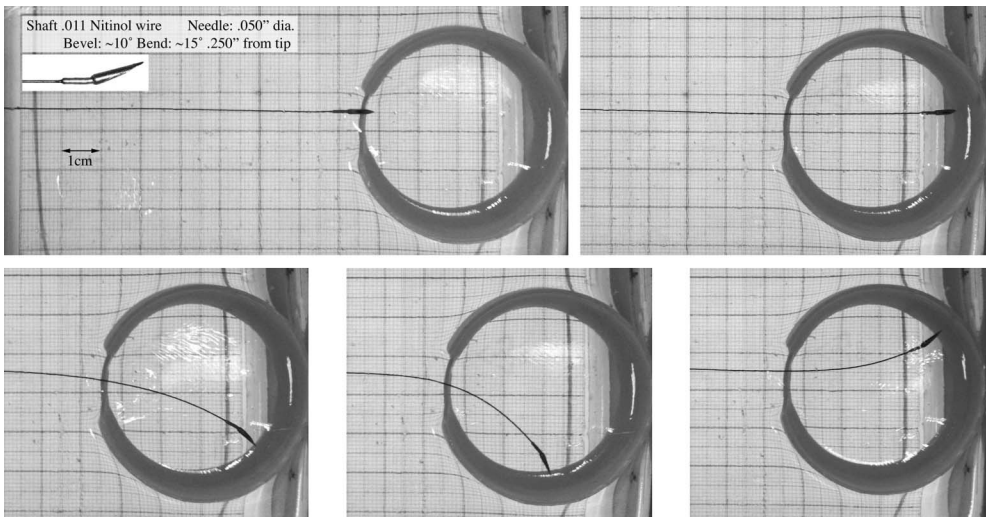

FIGURE 7. *Qualitative demonstration of coverage of a perilesional area using a navigable catheter. The catheter is inserted to a starting point of the target area using a 100% duty cycle trajectory. Subsequent points are achieved by reorienting and inserting the needle using various duty cycles.*

However, certain lesions in the brain are difficult to approach with use of a linear trajectory. More importantly, if a "treatment zone" is the intended target of therapy, multiple trajectories are required to inject the area. In the case of primary brain tumors, which usually recur within 2 cm of the resection bed, coverage of the perilesional area could be envisioned using a navigable catheter, as seen in Figure 7. With improvements in neuroimaging, such a catheter could be capable of recapitulating the curving paths of white matter fascicles themselves. In addition, such a device could be used for cellular implantation within a preplanned 3-dimensional volume [22]

This study is a proof of concept; much remains to be done before the approach is clinically viable. Limitations include the variability of the needle trajectory and the need for constant feedback during insertion. Fluoroscopy was used in this study to confirm an appropriate trajectory and adjust as needed, but real-time image guidance would be preferable. Also, this cadaveric study does not address the possibility of pathological changes incurred within the brain parenchyma as a result of the needle passage, especially following repeated attempts. Nevertheless, this study demonstrates the feasibility of accurate nonlinear needle steering in the brain, provided that some source of image guidance is available.

A paramount concern in the development of intracerebral needle steering is the effect that the spinning needle would have on surrounding brain tissue and blood vessels. Avoidance of tissue damage due to the rotating tip (ie, "coring") is a crucial issue.[23] In clinical use, coring can be avoided completely by limiting the rotation speed relative to the insertion speed. More specifically, coring can be avoided by limiting the angular velocity as follows: $\omega < (v\pi \tan \phi)/d$, where ω is the angular velocity (rad/s), v is the insertion velocity, d is the needle diameter, and ϕ is the bevel angle. Essentially, the potential for damage is primarily a function of the tip velocity (including rotational velocity) and the specific geometry of the tip. Pending studies include biomechanical modeling of the needle trajectories generated at various insertion and rotation speeds in order to design a safe shape for the tip. Further tissue studies in vitro will then validate the modeling results. In addition, nonmetallic shafts are being investigated to develop a probe that offers similar bending performance while still having straight sides, rather than an enlarged or bent tip, thus minimizing local tissue deformation during cannulation. The goal is to obtain a final probe design that yields a symptomatic hemorrhagic rate comparable to that resulting from standard rigid stereotactic brain biopsy needles (1.2% for 2.1- to 2.5-mm diameter needles, according to a large retrospective study).[24]

The potential applications of nonlinear intracerebral navigation are not necessarily limited to oncology. Such a system could be used to create a nonlinear trajectory for brain biopsy. In the setting of deep-brain stimulation or ablative procedures for functional neurosurgery or epilepsy, a misplaced electrode could conceivably be retracted a centimeter or so, then redirected to a better target along a nonlinear trajectory. Finally, targeted delivery of regenerative agents along the path of white matter fascicles could be envisioned using this technology after head trauma or cerebrovascular injury.

CONCLUSION

The feasibility of a nonlinear intracerebral navigation device using a flexible bevel-tipped needle has been demonstrated in vitro. The device is based on the premise of trajectory control solely by appropriate rotation during insertion. This technology

may have the potential to facilitate microcatheter-based compartmental therapy for tumors, strokes, neurodegenerative disorders, and other disorders by enabling precise delivery of therapeutic particles within a predetermined "treatment zone" in and around the region of interest. Further research will be necessary to modify instrument design and assess the safety of the technique in animal models.

Disclosure

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COMMENTS

The authors of this article provide a preliminary report on the use of a flexible needle that can be used to navigate into the brain using a duty-cycle machine to provide a curved trajectory. They use fluoroscopy using cadavers to show the principle. While this is an interesting concept, it awaits the formal use of current methods of imaging (magnetic resonance imaging [MRI], computed tomography [CT]) to determine how useful this will be. One can envision the limitations of trying to get to a target inside the brain using a curved trajectory to avoid pial and ventricular surfaces. Further work from this and other groups should be interesting to see how they can achieve this.

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The authors describe a novel technique of guiding a needle through a cadaveric head. This in vitro study demonstrates the feasibility of guiding a single needle placed via a single burr hole/pial entry to an intracranial target in a nonlinear trajectory. The primary goal of this interesting technique is to minimize cortical hemorrhage when aiming for multiple intracranial targets by limiting pial penetration to a single event. The needle can then be redirected without fully withdrawing and reinserting the needle. While the described methodology is unique, we agree with the authors' conclusions that significant additional study is required before introduction of this technology into routine clinical practice. We have several suggestions in this regard. First, although difficult to prove, there may very well be a correlation between the length of an individual trajectory and the incidence of intraparenchymal vascular injury. Thus, in trying to minimize the risk of a pial hemorrhage, we may be increasing the probability of an intraparenchymal hemorrhage by using a longer curvilinear trajectory. This study cannot be effectively performed without actual clinical trials. Second, while the authors acknowledge the concern of tissue coring due to a spinning needle with a bent tip, limiting the angular velocity will tend to increase the trajectory length to some extent because the needle travels in a spiral fashion. Additional pathologic studies would be indicated to further elucidate any direct increase in parenchymal damage. Providing a smooth surface, a highly flexible constant-diameter unbent bevel-tip needle (which the authors are investigating), would likely provide a significant benefit, if it can indeed be designed. Third, 3-dimensional tracking is mandatory in the human brain. Various methods can be used, including intermittent

but frequent orthogonal biplane fluoroscopic images as well as real-time continuous guidance with magnetic sensors. This can then lead to automated computer algorithms, with intraoperative real-time imaging feedback, which would allow the surgeon to select a x, y, and z target coordinate, as well as draw a trajectory on 2 orthogonal imaging planes (eg, an axial and coronal MR slice). The computer would then automatically translate the surgeon's commands into a series of insertional and rotational velocities (thereby limiting tissue coring), and duty cycles.

Despite the fact that much work remains before clinical introduction of this technique, we believe that the innovative method described by the authors provides a very important step toward safely achieving nonlinear passage of needles or catheters through the brain.

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Sister City: Zürich, Switzerland
Sport is an integral part of Swiss culture and society, making it appropriate for the Fédération Internationale de Football Association (FIFA) headquarters to be located in Zürich. The need for a single body to oversee the game became apparent at the beginning of the 20th century with the increasing popularity of international fixtures. FIFA is responsible for the organization and governance of football's major international tournaments, most notably the FIFA World Cup, held since 1930. Ice hockey and biking are also popular sports in Switzerland.