31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Testing of Neurosurgical Needle Steering via Duty-Cycled Spinning in Brain Tissue in Vitro

Davneet Minhas, Johnathan A. Engh, and Cameron N. Riviere, *Member, IEEE*

***Abstract*—A technique for steering of flexible bevel-tipped needles through tissue, providing proportional control of trajectory curvature by means of duty-cycled rotation or spinning during insertion, has been presented previously, and tested in vitro in gelatin samples. The present paper presents the results of testing under more authentic conditions. Thirty-two needle insertions were performed in cadaver brain tissue. Needle insertion was controlled interactively by the surgeon, adjusting parameters intraoperatively as needed based on fluoroscope images acquired at intervals of 1-2 cm of insertion depth. The average target acquisition error was 1.80 ± 1.33 mm.**

I. Introduction

More than 18,000 Americans develop intraparenchymal brain tumors each year, and over 13,000 die from primary brain tumors each year [1]. Long-term survival is rare. Total resection is often impossible because the tumors grow in a diffuse manner into the surrounding parenchyma. Treatment that combines surgical resection with chemotherapy and radiotherapy is common, though this is generally not curative [2].

A growing area of research for adjuvant therapy of these tumors is known as compartmental or local therapy, which is the application of therapeutic agents directly to the target zone in and around a brain tumor [3]. Local anti-tumor therapy has the advantage of bypassing the blood brain-barrier, which can facilitate higher dosage of the administered agent with less risk of systemic side effects. The major disadvantage of local anti-tumor therapy is the requirement of an operation to deliver the treatment, a disadvantage that may be minimized by the use of minimally invasive techniques such as needle-based intervention.

Compartmental therapy was first popularized by the use of chemotherapeutic wafers such as Gliadel (MGI Pharma Inc.). After surgical tumor resection, a wafer is implanted in the residual cavity, and as it degrades, chemotherapeutic particles are released. However, only marginal benefits have been reported so far in multiple randomized trials [4-6]. As a result, interest has grown in the delivery of local therapies deep to the resection bed of a tumor through the use of microcatheters [7]. The best-known such technique is convection-enhanced delivery (CED) [3, 8]. In CED, large therapeutic molecules may be infused into the interstitium using pressurized infusion through a microcatheter, circumventing the blood-brain barrier. CED has shown promise in multiple clinical trials for patients with malignant brain tumors [9-11].

One of the challenges in CED is the regulation of drug distribution. One solution to this problem involves microinjections through multiple catheters along multiple linear trajectories in order to achieve more uniform drug concentrations. However, each transection of the pia increases 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 can minimize this risk, facilitating drug delivery into a large number of points in sequence through a single entry point and a single proximal portion of the trajectory.

Recent years have seen an increasing amount of research in the area of steering of flexible needles through tissue [12-15]. Some of these techniques are less suitable for use in the brain due to their reliance on significant tissue deformation [12, 13]. 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. Webster et al. exploited this phenomenon, describing steering of the needle by controlling the orientation of the shaft during insertion [15]. We have adapted this technique for brain tissue, augmenting it with a novel means for controlling the amount of bending during insertion to provide proportional control of steering [16]. A straight or linear trajectory can be achieved with a bevel-tipped needle by spinning the needle during insertion (in fact, of course, the trajectory is helical, but can be made practically straight given appropriate choices of rotation speed and insertion speed). Relatively complex three-dimensional trajectories can then be envisioned by combining short segments, some straight and some curved, as desired. Following this concept to its logical conclusion, it is possible to generate trajectories with intermediate amounts of curvature by spinning the needle with a duty cycle, taking care that during the spinless portion of each cycle the bevel is returned to its original orientation. Lower spinning duty cycles produce curvatures closer to the

Manuscript received April 7, 2009. This work was supported in part by Simeon M. Jones, Jr. and Katharine Reed Jones Fund and the Walter L. Copeland Fund of The Pittsburgh Foundation, and by the National Science Foundation (grant no. EEC-9731748).

D. Minhas is with the Department of Biomedical Engineering, Carnegie Mellon University, Pittsburgh, PA 15213 USA (e-mail: dminhas@cmu.edu).

J. A. Engh is with the Department of Neurological Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA 15213 USA (e-mail: EnghJA@upmc.edu).

C. N. Riviere is with the Robotics Institute, Carnegie Mellon University, Pittsburgh, PA 15213 USA (e-mail: camr@ri.cmu.edu).

curvature attained without spinning, whereas higher duty cycles produce curvatures closer to a straight line. Once again, insertion speed, rotation speed, and duty cycle period can be chosen so as to create a trajectory that appears smooth, rather than as a concatenation of straight and curved segments. The efficacy of this approach has been demonstrated previously in vitro in needle steering trials using gelatin phantoms [16], and a kinematic model of the process has been developed [17]. As a test of efficacy in a more authentic setting, the present study reports the results of testing using human cadaver heads.

II. Methods

A. Equipment

The needle-steering system is shown in Fig. 1. The base of the system is a linear slide driven by a lead screw with a screw pitch of 0.1", 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. The design is thus similar to that in [18]. A Luer-Lok™ fitting attached to the rotational motor is used to hold the needle in place. An adjustable aluminum bracket was constructed in order to interface the needle steering system with a Leksell G stereotactic head frame (Elekta, Inc.) for ease of use.

The needle-steering system is controlled using a graphical user interface that allows selection of the needle tip orientation, insertion speed, rotation speed, insertion acceleration, rotation acceleration, duty cycle, and duty cycle period. Parameters can be selected preoperatively and also adjusted intraoperatively in real time.

To maximize the attainable curvature or steering angle in tissue as soft as the brain, a custom needle prototype was developed previously in order to increase the cross-sectional area of the tip while minimizing the stiffness of the needle shaft [16]. This prototype was used in the present experiment. The custom needle prototype consists of a 14G stainless-steel needle tip with a 10º bevel attached to a 29G nitinol main shaft (Nitinol was chosen for its high elasticity). In addition, the tip was bent 15º, further increasing the effective cross-sectional area.

B. Experimental Procedure

The needle-steering system was tested *in vitro* in cadaver brain tissue, in a total of 32 individual navigation trials (16 in each of two cadaver heads, obtained under institutional committee approval). The specimens were previously frozen, and then thawed for the experiment. Fixative agents were not used, so as to avoid the effects of such agents on the mechanical properties of the tissue. Each head was placed in ear pins for rigid fixation, and a burr hole craniostomy was performed. Navigation was performed via C-arm fluoroscopy using a previously described technique [19]: in each trial, a target point was selected in preoperative fluoroscope images. The needle was then inserted partially towards the target, without spinning, in the field of view of the C-arm (Philips BV Pulsera). Fluoroscopy was again utilized 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 90º 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. During spinning segments, the rotational speed was 120 rpm. At intervals of roughly 1-2 cm, needle insertion was paused and a fluoroscopic image was recorded. The duty cycle of the needle-steering system was then adjusted, when needed, in order 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. Each trial represents a single monotonic insertion; partial retraction and reinsertion in order to improve the target acquisition was not performed. The post-processing software of the Pulsera C-arm was then used to draw a line on the display between the endpoint of the needle and the target point. This line was then measured in order to obtain the target acquisition error.

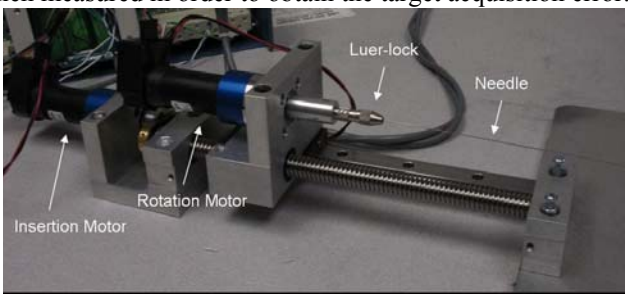

Fig. 1. The prototype needle steerer, showing the motors used for insertion and for rotation.

III. Results

For the 32 trials performed, the target acquisition error was 1.80 ± 1.33 mm. Fig. 2 presents the final fluoroscopic image from a typical trial. Each trial was begun with a duty cycle of either 0% or 100%, depending on the location of the target with respect to the entry point. However, during each insertion trial, intraoperative adjustments were made in order to minimize the target acquisition error. The number of such adjustments ranged from one to ten. On average, 3.7 adjustments per needle insertion were made to either the duty cycle or the needle tip orientation in order to reach the target. Insertions with more adjustments to the trajectory tended to take more time and generally involved deeper targets, as expected. Completion time ranged from 11 s to 124 s, with an average of 46 ± 28 s.

The minimum and maximum completion times corresponded to minimum and maximum linear target depths of 26.07 mm and 110.88 mm, respectively. Because the needle trajectories were curved, insertion lengths were

greater than actual target depths. The corresponding minimum and maximum insertion lengths were 26.60 mm and 112.99 mm, respectively. The average target depth was 71.66 ± 21.57 mm, whereas the needle insertion length was 73.80 ± 21.90 mm. The minimum difference between depth and insertion length was 0.06 mm, and the maximum difference was 14.75 mm.

Naturally, the difference between target depth and insertion length typically corresponded to the "target angle," i.e., the angle between the normal to the skull at the entry point and the vector from the entry point to the target. The target angle varied from a minimum of 1.0° to a maximum of 45.3°. The mean target angle was 15.0° ± 11.4°.

IV. Discussion

The results indicate at an elementary level the feasibility of accurate needle steering in the brain. The heterogeneity of the tissue of the cerebral parenchyma makes the trajectory of a flexible needle difficult to predict with accuracy. The conventional solution for percutaneous procedures such as brain biopsy is to use a rigid biopsy needle which will not be deformed by the surrounding brain during insertion. Although all trajectories through the brain must be linear using this approach, the endpoint of the needle is both accurate and reproducible. However, certain lesions in the brain are difficult to approach using a linear trajectory. More importantly, if a "treatment zone" involving multiple injection sites is the intended target of therapy, multiple trajectories are required in order to inject the area. In the case of primary brain tumors, which usually recur within 2 cm of the resection bed, coverage of the peritumoral area could be envisioned using a steerable needle, by treating a certain point, then retracting slightly and steering to the next point, and so on. Although needle steering in the present experiment was operated by the surgeon in an interactive or manual control mode, a more important control mode for the device in the future will involve integration of the control system with neuroimaging data and intraoperative tracking of the needle, with which the system could then execute preoperative plans in a semiautonomous fashion under the supervisory control of the surgeon, using the tracking signal for feedback control. Fluoroscopic "snapshots" were utilized in this study, but real-time image guidance would be preferable.

This study is a proof of concept; much remains to be done before the approach is clinically viable. The present cadaveric study does not address the question of pathologic changes incurred within the brain parenchyma as a result of the needle passage. The safety of brain tissue and blood vessels during needle passage must be demonstrated. Avoidance of tissue damage due to the rotating tip is a crucial issue [20]. The potential for damage is primarily a function of the tip velocity (including rotational velocity) and the specific geometry of the tip. Future research will include biomechanical modeling of needle insertion at various velocities of insertion and rotation, in order to determine both a safe needle design and appropriate operational limits on velocity. Further tissue studies in vitro will then validate the modeling results. The goal is to obtain a symptomatic hemorrhagic rate no greater than that resulting from standard rigid stereotactic brain biopsy needles (1.2% for 2.1 – 2.5mm-diameter needles, according to a large retrospective study [21]).

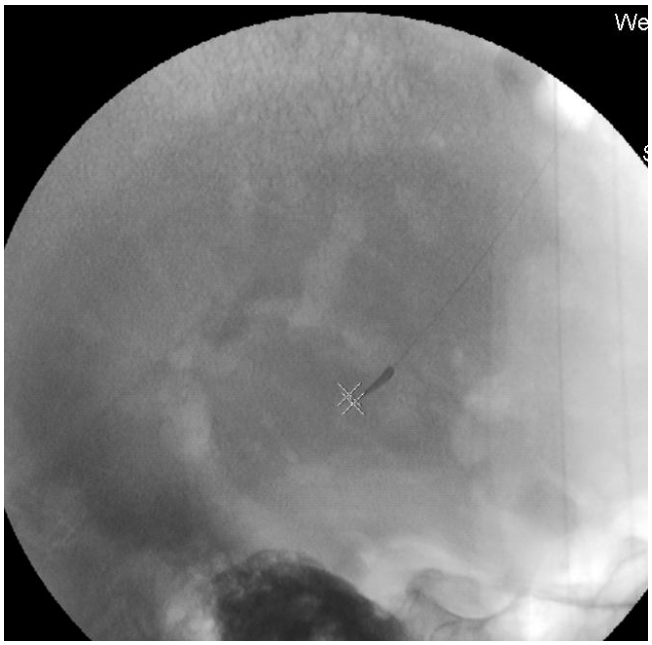

Fig. 2. Final fluoroscopic image from a typical trial, including the marked line between the final tip position and the target, both of which are marked with an ×.

Potential applications of this technology are not limited to oncology. Such a system could be used to create a nonlinear trajectory for brain biopsy. In deep brain stimulation or ablation, a misplaced probe could conceivably be retracted a centimeter or so, then redirected to a better target along a curved trajectory. Targeted delivery of regenerative agents along the path of white matter fascicles could be also envisioned using this technology following head trauma or cerebrovascular injury.

References

[1] A. Jemal, T. Murray, A. Samuels, A. Ghafoor, E. Ward, and M. J. Thun, "Cancer statistics, 2003," *CA. Cancer J. Clin.,* vol. 53, pp. 5-26, 2003.

[2] I. F. Dunn and P. M. Black, "The neurosurgeon as local oncologist: cellular and molecular neurosurgery in malignant glioma therapy," *J. Neurosurg.,* vol. 52, pp. 1411-1422, 2003.

[3] M. Westphal and P. M. Black, "Perspectives of cellular and molecular neurosurgery," *Neurooncology,* vol. 70, pp. 255-269, 2004.

[4] H. Brem, S. Piantadosi, P. C. Burger, and et al., "Placebo-controlled trial of safety and efficacy of intraoperative controlled delivery by biodegradable polymers of chemotherapy for recurrent gliomas," *Lancet,* vol. 345, pp. 1008-1012, 1995.

[5] S. Valtonen, U. Timonen, P. Toivanen, and et al., "Interstitial chemotherapy with carmustine-loaded polymers for high-grade gliomas: a randomized double-blind study," *Neurosurgery,* vol. 41, pp. 44-49, 1997.

[6] M. Westphal, D. C. Hilt, E. Bortey, P. Delavault, R. Olivares, P. C. Warnke, I. R. W. Jaaskelainen, and Z. Ram, "A phase 3 trial of local chemotherapy with biodegradable carmustine (BCNU Gliadel wafers)

in patients with primary malignant glioma," *Neurooncology,* vol. 5, pp. 79-88, 2003.
[7] National Institute of Neurological Disorders and Stroke (NINDS) and National Cancer Institute, "Report of the Brain Tumor Progress Review Group." NIH Publication Number 01-4902, 2000.
[8] W. A. Hall, E. Rustamzadeh, and A. L. Asher, "Convection-enhanced delivery in clinical trials," *Neurosurg. Focus,* vol. 14, pp. 1-4, 2003.
[9] J. H. Sampson, G. Akabani, G. E. Archer, D. D. Bigner, M. S. Berger, A. H. Friedman, H. S. Friedman, J. E. Herndon, S. Kunwar, S. Marcus, R. E. McLendon, A. Paolino, K. Penne, J. Provenzale, J. Quinn, D. A. Reardon, J. Rich, T. Stenzel, S. Tourt-Uhlig, C. Wikstrand, T. Wong, R. Williams, F. Yuan, M. R. Zalutsky, and I. Pastan, "Progress report of a Phase I study of the intracerebral microinfusion of a recombinant chimeric protein composed of transforming growth factor (TGF)-α and a mutated form of the *Pseudomonas* exotoxin termed PE-38 (TP-38) for the treatment of malignant brain tumors," *J. Neurooncol.,* vol. 65, pp. 27-35, 2003.
[10] S. J. Patel, W. R. Shapiro, D. W. Laske, R. L. Jensen, A. L. Asher, B. W. Wessels , S. P. Carpenter, and J. S. Shan, "Safety and feasibility of convection-enhanced delivery of Cotara for the treatment of malignant glioma: initial experience in 51 patients," *Neurosurgery,* vol. 56, pp. 1243-1253, 2005.
[11] S. Kunwar, "Convection enhanced delivery of IL13-PE38QQR for treatment of recurrent malignant glioma: presentation of interim findings from ongoing phase 1 studies," *Acta. Neurochir. Suppl.,* vol. 88, pp. 105-111, 2003.
[12] S. P. DiMaio and S. E. Salcudean, "Needle insertion modeling and simulation," *IEEE Trans. Robot. Autom.,* vol. 19, pp. 864-875, 2003.
[13] D. Glozman and M. Shoham, "Image-guided robotic flexible needle steering," *IEEE Trans. Robot.,* vol. 23, pp. 459-467, 2007.
[14] S. Okazawa, R. Ebrahimi, J. Chuang, S. E. Salcudean, and R. Rohling, "Hand-held steerable needle device," *IEEE/ASME Trans. Mechatron.,* vol. 10, pp. 285-296, 2005.
[15] R. J. Webster, III, J. S. Kim, N. J. Cowan, G. S. Chirikjian, and A. M. Okamura, "Nonholonomic modeling of needle steering," *Int. J. Robot. Res.,* vol. 25, pp. 509-525, 2006.
[16] J. A. Engh, G. Podnar, D. Kondziolka, and C. N. Riviere, "Toward effective needle steering in brain tissue," in *Proc. 28th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc.*, 2006, pp. 559-562.
[17] D. S. Minhas, J. A. Engh, M. M. Fenske, and C. N. Riviere, "Modeling of needle steering via duty-cycled spinning," in *Proc. 29th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc.*, 2007, pp. 2756-2759.
[18] R. J. Webster, III, J. Memisevic, and A. M. Okamura, "Design considerations for needle steering," in *Proc. IEEE Int. Conf. Robot. Autom.*, Barcelona, 2005, pp. 3599-3605.
[19] D. Stoianovici, J. A. Cadeddu, R. D. Demaree, H. A. Basile, R. H. Taylor, L. L. Whitcomb, W. Sharpe, Jr, and L. R. Kavoussi, "An efficient needle injection technique and radiological guidance method for percutaneous procedures," *Lect. Notes. Comput. Sci.,* vol. 1205, pp. 295-298, 1997.
[20] M. A. Meltsner, N. J. Ferrier, and B. R. Thomadsen, "Observations on rotating needle insertions using a brachytherapy robot," *Phys. Med. Biol.,* vol. 52, pp. 6027-6037, 2007.
[21] M. Field, T. F. Witham, J. C. Flickinger, D. Kondziolka, and L. D. Lunsford, "Comprehensive assessment of hemorrhage risks and outcomes after stereotactic brain biopsy," *J. Neurosurg.,* vol. 94, pp. 545-551, 2001.