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Publication Date
2013-04-01

DOI
10.3791/50299

Peer reviewed

Video Article

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URL: http://www.jove.com/video/50299
DOI: doi:10.3791/50299

Keywords: Biomedical Engineering, Issue 74, Medicine, Bioengineering, Molecular Biology, Anatomy, Physiology, Surgery, Delivery of Health Care, Health Services Research, catheter, microcatheter, deflection, navigation, interventional, Magnetic Resonance Imaging, MRI, lithography, imaging, vascular, endovascular procedures, clinical techniques

Date Published: 4/4/2013

Citation: Hetts, S.W., Saeed, M., Martin, A., Lillaney, P., Losey, A., Yee, E.J., Sincic, R., Do, L., Evans, L., Malba, V., Bernhardt, A.F., Wilson, M.W., Patel, A., Arenson, R.L., Caton, C., Cooke, D.L. Magnetically-Assisted Remote Controlled Microcatheter Tip Deflection under Magnetic Resonance Imaging. *J. Vis. Exp.* (74), e50299, doi:10.3791/50299 (2013).

Abstract

X-ray fluoroscopy-guided endovascular procedures have several significant limitations, including difficult catheter navigation and use of ionizing radiation, which can potentially be overcome using a magnetically steerable catheter under MR guidance.

The main goal of this work is to develop a microcatheter whose tip can be remotely controlled using the magnetic field of the MR scanner. This protocol aims to describe the procedures for applying current to the microcoil-tipped microcatheter to produce consistent and controllable deflections.

A microcoil was fabricated using laser lathe lithography onto a polyimide-tipped endovascular catheter. *In vitro* testing was performed in a waterbath and vessel phantom under the guidance of a 1.5-T MR system using steady-state free precession (SSFP) sequencing. Various amounts of current were applied to the coils of the microcatheter to produce measureable tip deflections and navigate in vascular phantoms.

The development of this device provides a platform for future testing and opportunity to revolutionize the endovascular interventional MRI environment.

Video Link

The video component of this article can be found at http://www.jove.com/video/50299/

Introduction

Endovascular procedures performed in interventional medicine use x-ray guidance as a tool for catheter navigation through vasculature to treat several major illnesses, such as brain aneurysm, ischemic stroke, solid tumors, atherosclerosis and cardiac arrhythmias targeting over one million patients per year worldwide[1-5]. With the use of contrast media, navigation through vasculature is achieved through manual rotation of the catheter and mechanical advancement by the interventionist's hand[6]. However, navigation through small tortuous blood vessels around many vascular bends becomes increasingly difficult, elongating the time before reaching the target site. This poses a problem for time-sensitive procedures such as the removal of a clot in an occluded blood vessel. Additionally, prolonged procedures increase the radiation dose and create the potential for adverse events[7-11]. However, endovascular procedures performed under magnetic resonance imaging may provide a solution.

The strong homogenous magnetic field of an MRI scanner can be exploited for catheter tip navigation by remote control[12,13]. Current applied to a microcoil located at a catheter tip induces a small magnetic moment, which experiences a torque as it aligns with the bore of the MRI scanner[13] (**Figure 1**). If electric current is activated in an individual coil, the catheter tip can be deflected in one plane by remote control. If three coils at a catheter tip are energized, catheter tip deflection can be achieved in three-dimension. Thus, magnetically facilitated steering of a catheter has the potential to increase the speed and efficacy of vascular navigation in endovascular procedures, which could reduce procedure times and improve patient outcomes. In this study, we examined if current applied to a microcoil-tipped endovascular catheter can produce reliable and controlled deflections under MR-guidance as preliminary testing of catheter navigation studies.

Protocol

1. Microcoil Fabrication

1. Obtain a commercially available microcatheter (*e.g.* 2.3F Rapid Transit Cordis Neurovascular Catheter, Raynham, MA) for a substrate.
2. Ensure catheters have no ferrous components, are considered MR-safe, and range in size 2.3-3.0 F.
3. Sputter a titanium adhesion layer followed by a copper seed layer unto a 1 to 2 mm OD insulating tube. Possible materials include polyimide or alumina (Ortech Advanced Ceramics, Sacramento, CA).
4. Electrodeposit a positive photoresist layer using Shipley's PEPR-2400 (currently being sold by DOW Chemical under the name Intervia 3D-P). Electrodeposition results in a uniform coating on the non-planar cylindrical surface.
5. Photoresist is exposed by a unique laser direct-write system (laser lathe, a non-commercial system developed at Lawrence Livermore National Laboratory) in the pattern of the desired coil form (**Figure 2A**). This is a modification of the technique originally described in Malba *et al.*[14]
6. Develop the exposed photoresist in a 1% solution of potassium carbonate at 35 °C.
7. Copper is electroplated through the remaining resist mask to form the desired coil. The system can fabricate both solenoid and Helmholtz (racetrack) copper patterns (**Figures 2C** and **2D**).
8. After copper electrodeposition, remove the resist with hot developer. Remove the copper seed layer, followed by the titanium adhesion layer.
9. Attach the insulating tube to the catheter tip using shrink wrap to complete the assembly. Ensure that the shrink wrap covers the entire coiled tip. To assemble multi-axis catheters place insulating tube structures inside each other as shown in **Figure 2E**.
10. Thread copper wires through the lumen of the microcatheter and solder to the coils at the tip.
11. Modify and shorten a 6 ft RJ11 phone cable to 3 ft in length.
12. Connect the copper wires emanating from the back end hub of the microcatheter to the modified 3 ft phone jack transmission line.

2. Waterbath Setup

1. Make a small hole in the center of the side of a plastic basin about 5 cm from the bottom.
2. Insert a 9F Avanti Cordis vascular sheath (Cordis Endovascular, Miami Lakes, FL) through the hole.
3. Cut the distal tip of the vascular sheath leaving a 4 cm-long piece extending in to the basin.
4. At the end of the sheath, attach a rotating hemostatic or Thuoy-Borst valve to stabilize the location of the microcatheter.
5. Fill the basin with distilled water ensuring complete submersion of the apparatus.
6. Insert the catheter with coiled tip through the vascular sheath and valve.
7. Measure and record the unrestrained length of the microcatheter extending from the valve in to the waterbath.
8. Place the waterbath with microcatheter system within the magnet of the MR scanner and orient with respect to the bore of the magnet.
9. Connect the modified 3 ft phone cable attached to the catheter to a 25 ft RJ11 phone cable transmission line using a 2-way phone jack.
10. Connect the other end of the 25 ft phone cable to a Lambda LPD-422A-FM dual regulated power supply to deliver up to 1 A of current to the device.
11. Place the transmission lines through a waveguide and the power source outside of the MR scanner room outside of the 5 Gauss line.

3. Vessel Phantom Setup

1. Construct a hollow vessel phantom with a Y-shaped intersection from rubber tubing prior to experimentation.
2. Fill the vessel phantom with a 0.0102 M solution of gadopentetate dimeglumine (GdDTPA) (Magnevist, Bayer Healthcare Pharmaceuticals, Montville, New Jersey) in distilled water to create contrast between the phantom vessels and background.
3. Assemble the microcatheter system as outlined in steps 1.1 through 1.9. Connect the catheter to the power supply and position as described in steps 2.9 to 2.11.
4. Position the tip of the microcatheter at the base of the vessel opening.
5. Place the phantom within the magnet of the MR scanner and orient with respect to the bore of the magnet.

4. Magnetic Resonance Imaging

1. Perform imaging with a 1.5T clinical MR system (Siemens Avanto, SW: Syngo B13, Erlangen, Germany; Philips Achieva, SW release 2.1, Cleveland, OH).
2. Apply <50 mA of current to visualize the catheter tip position. Under MRI, a small magnetic moment will be produced at the catheter tip to visualize a distinct artifact of varying shape depending on which coils are energized.
3. Apply variable amounts of current in the range of ±100 mA from the Lambda dual power source to the coils and observe tip deflection (**Figures 3A-3C**) in the water bath setup. Because tip deflection is almost instantaneous, current need only be applied for ~1-2 sec to visualize maximum deflection.
4. Repeat and record consecutive applications of set amounts of current.
5. Repeat step 4.2 while simultaneously pushing the catheter by hand allowing mechanical advancement through the vessel phantom (**Figures 4A** and **4B**). Apply current at the branch point to deflect the catheter tip into the desired vessel. Advance the catheter into the branch vessel by manually pushing the catheter end (**Figure 4C**). Retract the catheter to the vessel bifurcation and repeat in the opposite branch (**Figure 4D**).
6. Acquire MR images using a 2D snapshot-FLASH sequence (TR=30 msec, TE=1.4 msec, a matrix of 256 x128 and flip angle ~30 °).

5. Deflection Measurements

Analyze and measure angle deflections of images captured during water bath experiments with various computer applications (any Digital Imaging and Communications in Medicine (DICOM) Viewer).

Representative Results

From the protocol described above, an angle of deflection between 0 and 90 degrees should be observed from application of 50-300 mA of current delivered simultaneously to both coils of a combined solenoid and Helmholtz coil microcatheter system (**Figure 2E**). An increase in applied current should result in an increase in microcatheter deflection angle, while a reversal in current polarity should result in deflection in the exact opposite direction as observed with positive current (**Figures 5A-5C**). The angle of deflection, however, is dependent upon several parameters. The amount of applied current and the number of coil turns in the solenoid and Helmholtz coils alters the strength of the magnetic moment at the microcatheter tip. Additionally, the strength of the external magnetic field and angle between the magnetic moment of the particle and the external magnetic field dictates the amount of torque experienced by the microcatheter. Lastly, the unrestrained length of the microcatheter tip extending in to the waterbath is another factor that may be altered. Changes to any of these variables will produce modified angles of deflection.

Accurate measurement of deflection angles from MR images can be performed and compared using various types of DICOM viewer software. Advanced deflection can also be tested by successful navigation through a simulated vessel phantom.

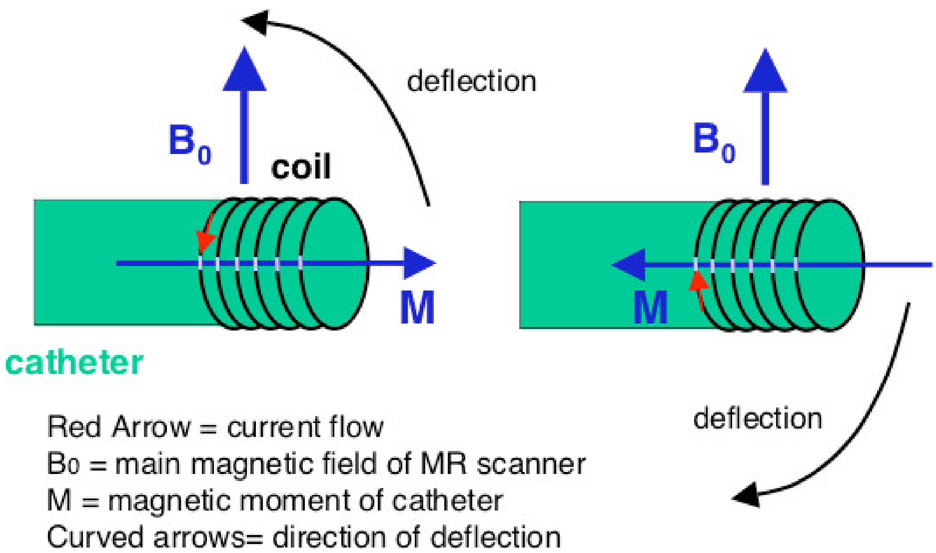

Figure 1. Single-Axis Coil Schematic: Catheter deflection as a result of exploitation of the magnetic environment of the MR scanner. Previously published in Roberts *et al.* 2002[13].

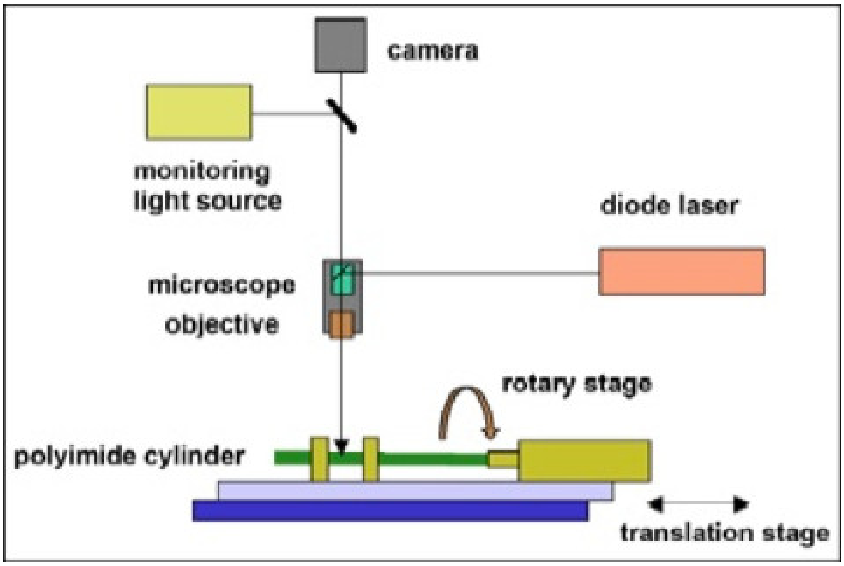

Figure 2A. Laser Lithography Diagram: Setup of laser lithography process. Publication in press (Wilson *et al.* 2013[16]).

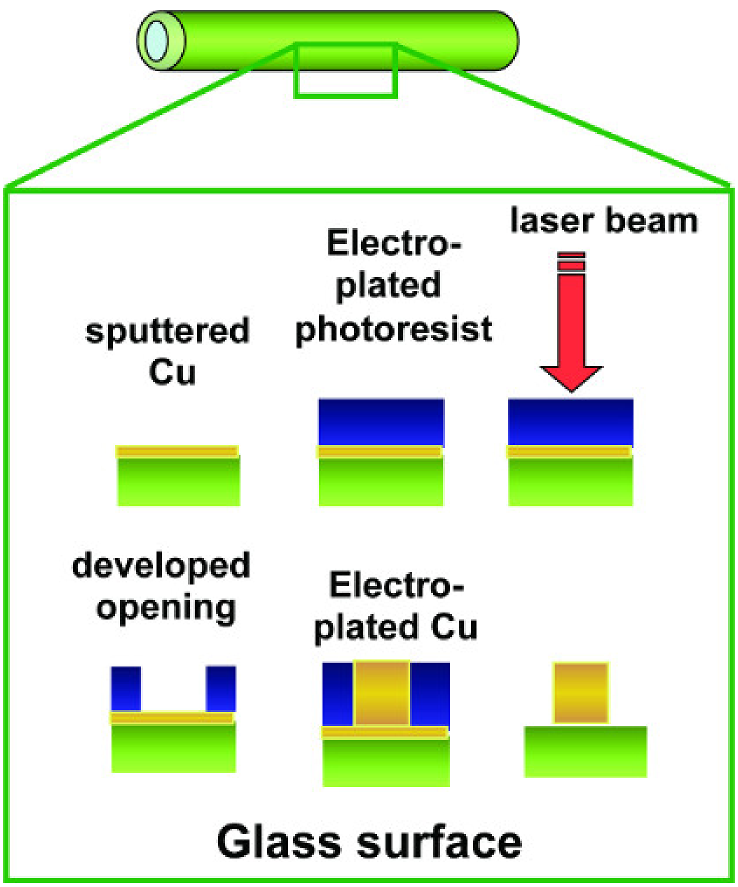

Figure 2B. Laser Lithography Coil Fabrication Diagram: Diagram of the steps involved in laser lathe lithography fabrication of microcoils.

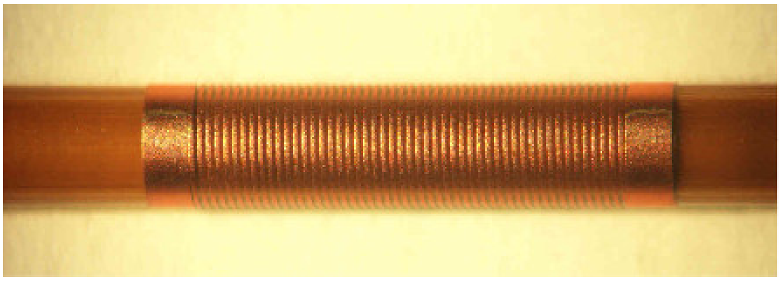

Figure 2C. Solenoid Coil: A microcoil solenoid of 50 turns fabricated on a polyimide tube using lithographic technique called laser lathe lithography. Previously published in Bernhardt *et al.* 2011[15] and Muller *et al.* 2012[16], and in press (Wilson *et al.* 2013[17]).

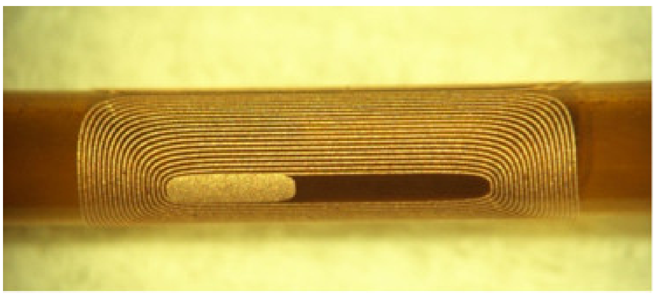

Figure 2D. Saddle Coil: A Helmholtz ("racetrack") microcoil fabricated on the outer wall of a catheter with lithographic technique called laser lathe lithography. Previously published in Bernhardt *et al*. 2011[15] and Muller *et al.* 2012[16], and in press (Wilson *et al.* 2013[17]).

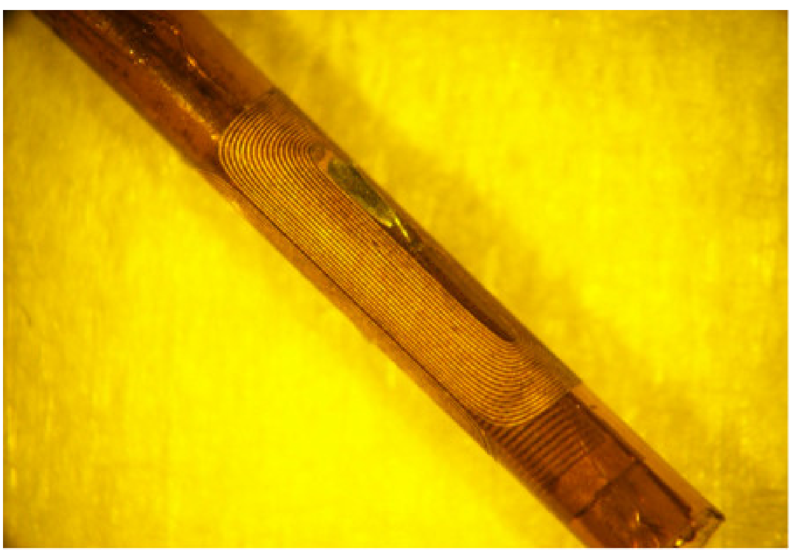

Figure 2E. Combination Coil: A solenoid coil fabricated on a catheter tip placed within a larger tube containing a Helmholtz coil. Simultaneous current application to both coils enables catheter deflection in three-dimensions. Publication in press (Wilson *et al.* 2013[17]).

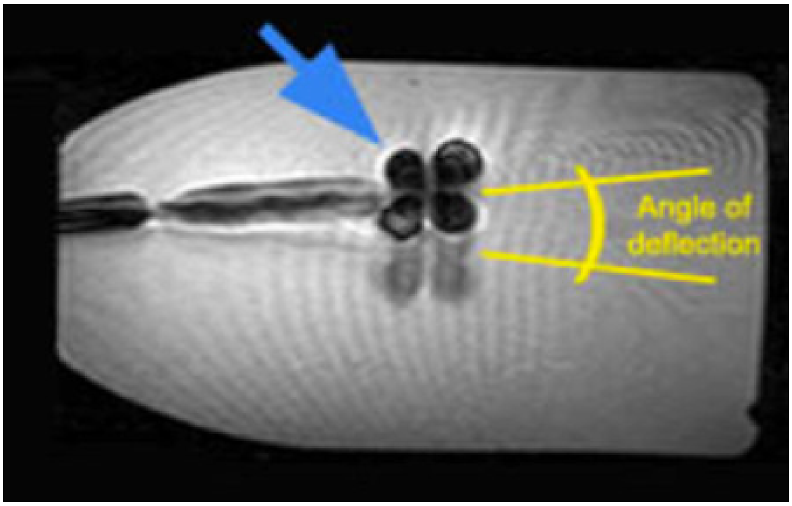

Figure 3A. Catheter Deflection: Catheter tip deflection observable with application of current. Blooming artifact from the energized coil is clearly visible (arrow).

Figure 3B. Anterior-Posterior Catheter Deflection in Waterbath: Application of 50 mA and 100 mA of current resulted in consistent 10 ° and 14.5 ° deflections respectively. Positive current causes tip deflection in the anterior plane, and negative current results in deflection in the posterior plane. Click here to view Figure 3B.

Figure 3C. Right-Left Catheter Deflection in Waterbath: Application of 50 mA and 100 mA of current resulted in consistent 11.5 ° and 17 ° deflections respectively. Positive current causes tip deflection in the right plane, and negative current results in deflection in the left plane. Click here to view Figure 3C.

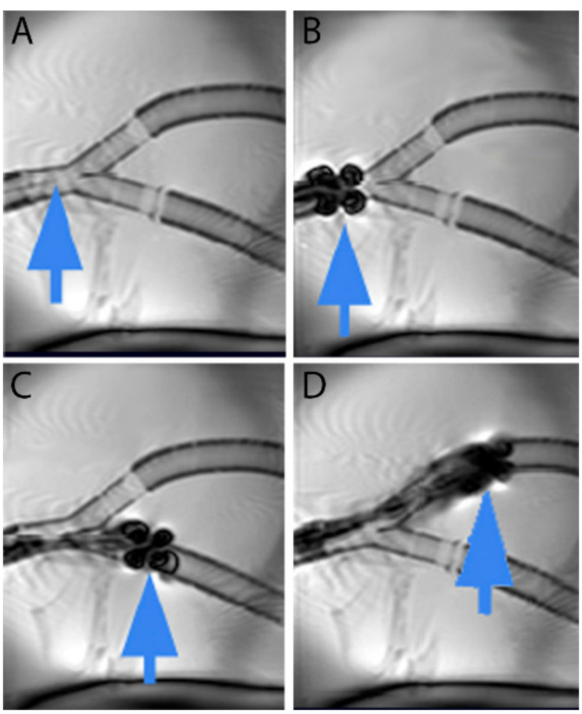

Figure 4. Catheter Steering and Tracking: Controlled catheter deflection and steering through a vessel phantom. Current is applied to the coiled catheter tip producing visualization blooming (arrow). The catheter is mechanically advanced and current (- 45 mA) is applied to cause deflection into the bottom vessel branch **(C)**. The catheter is then retracted to position **(B)**. By reversed current polarity (45 mA), the catheter is deflected and advanced into the top vessel branch **(D)**.

Figure 4B. Catheter Deflection in a Bifurcation Phantom: Current applied to the catheter allows successful targeting and advancement into the left vessel branch of the phantom. The catheter is then retracted to the branching point and directed into the right vessel branch. Click here to view Figure 4B.

Figure 5A-C. Geometric Patterns of Catheter Deflection in a Waterbath: Current is applied to produce deflections within a single plane in all directions. Click here to view Figure 5A, Figure 5B, Figure 5C.

Discussion

Here we describe the protocol for deflection of a microcatheter in a MR scanner. The key parameters for success are accurate application of current and measurement of deflection angle. Inaccurate measurement of deflection angle is the most probable error encountered in this protocol. The angles captured in MR images during the waterbath experiment may differ from actual values due to slight differences in the orientation by which the medium is positioned with respect to the bore of the magnet. To address this issue in the future, images can be captured by MR-compatible fiber optic cameras positioned in two different dimensions. Use of both MR and camera images will provide a more accurate, three-dimensional view of the microcatheter tip.

The quality of images may be improved by altering the parameters under which imaging is performed. A different imaging sequence may be used to determine if an increase in image quality and clarity is experienced. Furthermore, because the transmission lines ran out of the MR scanner control room, the integrity of the magnet room's RF enclosure was sub-optimal possibly reducing image quality. This problem could be ameliorated by placing the power lines through a filter on a penetration panel. Additionally, using the catheter tip microcoils as imaging receiver coils also holds the potential to provide higher resolution images immediately adjacent to the catheter tip. The possibility of using laser lathed catheter tip coils as imaging coils is being explored.

Production of images that are not only better quality, but easier to use to measure precise angle deflection is also possible. Modification of variables that affect angle deflection, as mentioned above, can result in a larger degree of deflection. Additionally, a 3T clinical MR scanner of increased strength may be used in lieu of a 1.5T scanner to increase the range of microcatheter deflection. These changes can produce separation of distinct angle deflection between close intervals of applied current.

Because this protocol aimed to test the ability to control microcatheter deflection, the vessel phantom used was simple and contained a single branch point at approximately 45 °. Now that this capability is established, further testing of microcatheter deflection may be performed in more complex phantoms. Design variables that may be altered include vessel diameter, the angle of vessel branches, and the number of turns within any given path of the phantom. The vessels may also be tapered and the phantom comprised of a different material other than plastic tubing in an effort to more closely mimic human vasculature. In future studies, animal experiments can also be performed to further examine microcatheter navigation ability.

Several limitations of this protocol also exist with regard to the fabrication of microcoils using the Laser Lathe technique. Line width is a function of laser spot size, resist thickness, and pitch. Laser spot size is restricted to a range of three to five microns in diameter, and resist thickness is limited to 25 microns. Furthermore, the thickness of the copper lines is limited by the line width and the resist thickness. Photoresist exposure with the laser direct-write system results in openings or features in the resist that do not have parallel sides. The openings are narrower at the bottom near the seed layer thus limiting the minimum size of the features. Additionally, as lines become thicker, they grow closer to adjacent lines. If lines are too close, the copper seed layer and titanium adhesion layer removal processes are not capable of proceeding uninhibited.

Disclosures

Dr. Hetts has received grant support from Stryker Corporation and is a paid consultant for Silk Road Medical, Inc.

Acknowledgements

Pallav Kolli, Fabio Settecase, Matthew Amans, and Robert Taylor from UCSF, Tim Roberts from University of Pennsylvania

Funding Sources

NIH National Heart Lung Blood Institute (NHLBI) Award (M. Wilson): 1R01HL076486 American Society of Neuroradiology Research and Education Foundation Scholar Award (S. Hetts)

NIH National Institute of Biomedical Imaging and Bioengineering (NIBIB) Award (S. Hetts): 1R01EB012031

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