A Mechanical Coil Insertion System for Endovascular Coil Embolization of Intracranial Aneurysms

K. HARAGUCHI¹, S. MIYACHI¹, N. MATSUBARA¹, Y. NAGANO², H. YAMADA³, N. MARUI³, A. SANO⁴, H. FUJIMOTO⁴, T. IZUMI¹, T. YAMANOUCHI¹, T. ASAI¹, T. WAKABAYASHI¹

¹ Department of Neurosurgery, Nagoya University; Nagoya, Japan

² Department of Electronic Control and Robot Engineering, Aichi University of Technology; Gamagōri, Aichi, Japan

³ New Product Development R&D Center, NTN Corporation; Iwata, Japan

⁴ Graduate School of Engineering, Nagoya Institute of Technology, Nagoya, Japan

Key words: intracranial aneurysm, coil embolization, mechanical insertion system, force sensor

Summary

Like other fields of medicine, robotics and mechanization might be introduced into endovascular coil embolization of intracranial aneurysms for effective treatment. We have already reported that coil insertion force could be smaller and more stable when the coil delivery wire is driven mechanically at a constant speed. Another background is the difficulty in synchronizing operators' minds and hands when two operators control the microcatheter and the coil respectively. We have therefore developed a mechanical coil insertion system enabling a single operator to insert coils at a fixed speed while controlling the microcatheter.

Using our new system, the operator manipulated the microcatheter with both hands and drove the coil using foot switches simultaneously. A delivery wire force sensor previously reported was used concurrently, allowing the operator to detect excessive stress on the wire. In vitro coil embolization was performed using three methods: simple mechanical advance of the coil; simple mechanical advance of the coil with microcatheter control; and driving (forward and backward) of the coil using foot switches in addition to microcatheter control.

The system worked without any problems, and did not interfere with any procedures. In experimental coil embolization, delivery wire control using the foot switches as well as microcath-

eter manipulation helped to achieve successful insertion of coils. This system could offer the possibility of developing safer and more efficient coil embolization. Although we aim at total mechanization and automation of procedures in the future, microcatheter manipulation and synchronized delivery wire control are still indispensable using this system.

Introduction

In recent decades, endovascular coil embolization for intracranial aneurysms has undergone marked developments, particularly in adjunctive devices such as coils, stents, and balloon catheters¹⁻⁴. At the same time, procedures have become complicated, and adequate manipulation of microcatheters and coils as well as selection of proper devices is becoming more and more important for efficient and safe embolization. Under such situations, inappropriate manipulation of the devices might even lead to intraoperative rupture of the aneurysm. Although excessive stress on the aneurysm wall appears to be one of the major causes of such catastrophes, there was no means to measure insertion force of the coils or stress on the wall. Matsubara et al. developed and reported the force sensor system to assess the insertion force of the delivery wire of coils objectively^{5,6}. In the experiment, they compared the force pattern of

Figure 1 Schematic diagram indicating the difference in insertion force patterns between manual and mechanical coil embolization for silicone aneurysms (drawn referring to the previous report⁶). A) Manual coil insertion. B) Mechanical coil insertion. C) Mechanical coil insertion with very slow speed. Manual insertion force was a “saw-like pattern” caused by static friction due to a dynamic change in insertion speed. By contrast, mechanical insertion force showed a smaller value as well as a stable and less frequent peak pattern thanks to a continuous kinetic friction state caused by fixed insertion speed. Very slow mechanical insertion showed a greater peak of the force due to the static friction state.

manual insertion with that of mechanical insertion performed at a constant speed. As a result, the mechanical insertion force showed a smaller mean value, more stable pattern, and less

frequent peak (Figure 1). Continuous kinetic friction with fixed speed was assumed to have caused the result.

Recently, technology in robotics has made rapid progress, and has been introduced into various fields of medicine^{7,8}. There is a possibility that coil embolization for intracranial aneurysms could also adopt such robotics or mechanization for safe and appropriate procedures. The good result of mechanical coil insertion cited above could be the beginning of mechanization. Even total automation of coil embolization might be materialized in the future.

Coil embolization is often performed at present by two operators using four hands for accurate manipulation: one operator manipulates the microcatheter, while the other controls the delivery wire of the coil. One of the problems with this method is that synchronization of movements is sometimes very difficult. In particular, beginners may not be able to operate the microcatheter to an appropriate extent or sense the resistance in inserting coils⁹. If these procedures are performed by a single operator, simultaneous and precise control of the coil delivery wire and the microcatheter might be extremely difficult. The present report introduces a preliminary model of a “mechanical coil insertion system” developed in collaboration between Nagoya University, NTN Corporation, and Nagoya Institute of Technology. This device enables a single operator to perform all the procedures involved in coil embolization, using both hands to manipulate the microcatheter while the feet are used to press switches for mechanical driving of the delivery wire at a constant speed. Using this system, a single operator can implement the two-operator-method by himself with little stress on the delivery wire.

Materials and Methods

The mechanical coil insertion system and delivery wire-driving unit

The whole system of mechanical coil insertion is shown in Figure 2A. The delivery wire-driving unit includes the direct current motor connected to the driving roller through the reducer, and the rollers drive the delivery wire at a fixed speed. One of the rollers has a groove so that the fine delivery wire (diameter, 0.3 mm) does not slip in a transverse direction. The

Figure 2 Overview and parts of the mechanical coil insertion system. A) Overview of the mechanical coil insertion system. B) Delivery wire driving unit. C) Delivery wire driving unit connected to the Y-connector and optical coil insertion force sensor. D) Amplifier. E) Foot switches. F) Color indicator showing insertion force. (Figure 2B is reprinted from Nagano Y, Sano A, Matsubara N, et al.¹². Reprint permission has been obtained from the Japanese Society of Computer Aided Surgery).

other roller is fixed on the cover through a spring, pinching the delivery wire between the two rollers when the cover is closed (Figure 2B,C). The foot switches include two buttons for forward / backward driving and are connected to the driving unit (Figure 2E). The operator manipulates the microcatheter with both hands, and controls the delivery wire using foot switches while listening to the tones from the sensor system (described below). The tones indicate the insertion force of the delivery wire. The amplifier is also placed on the operating table, with a dial to adjust the insertion speed

(0.5, 1.0, 1.5, or 2.0 mm/s) (Figure 2D). Patents for the mechanical coil insertion system with foot switches and delivery wire driving unit have already obtained.

Optical coil insertion force sensor

In the mechanical coil insertion system, the delivery wire is driven by rollers not by the operator's hands. Insertion force must therefore be monitored so that the operator can detect excessive stress on the delivery wire, and the coil insertion system includes a force sensor

Figure 3 Optical coil insertion force sensor. The optical line sensor detects the position of the delivery wire and translates it into a force value. When the delivery wire is pushed, it bends inside the Y-connector and the sensor detects the shift of the delivery wire. The amplifier transduces the optical signals to the color indicator, sound output, and force meter.

based on the optical principle (Figure 3). Details of this system have been published elsewhere^{5,10,11}. In this sensor, a remodeled Y-shaped hemostatic valve (Y-connector) is sandwiched between light-emitting diodes and the optical line sensor. When the delivery wire is pushed, it is bent inside the Y-connector, then the shifted position of the wire is translated to a force value. The force is displayed in three

ways: on a meter (Figure 2D), through audible tones (“do, re, mi...”), and a color indicator (Figure 2F).

Experimental coil embolization

Experimental coil embolization was performed using silicone dummy aneurysms. These silicone dummies simulated the shape of round

aneurysms with no branches. The aneurysm dome was 5 mm in diameter, with neck length and parent artery diameter both 3 mm. The tip of a microcatheter (Excelsior SL-10; Stryker, MI, USA) was placed at the center of the aneurysm dome. The microcatheter was placed in an almost linear position to minimize the influence of the frictional force exerted when a coil passed inside the lumen of the microcatheter. Movements of the coil during insertion were observed with a microscope, with the microscopic image reflected on a monitor.

The primary purpose of the experiment was to assess whether the mechanical coil insertion system worked appropriately. We checked whether the delivery wire was driven certainly as the operator expected, whether endovascular surgeons could operate this system easily, and whether the procedures could be performed without any restriction compared to routine clinical procedures.

As mentioned earlier, mechanical coil insertion can be smoother than manual insertion, and our final perspective is total automation of coil embolization. So the secondary purpose is to investigate whether subtle manipulation of the microcatheter and synchronized control of the coil are required when the coil is driven at a fixed speed mechanically. We compared the following three patterns of coil insertion: 1) simple continuous mechanical advance of the delivery wire without microcatheter manipulation; 2) simple continuous mechanical advance of the delivery wire with manual microcatheter manipulation; and 3) driving of the delivery wire (forward / stopping / backward) using foot switches with simultaneous manual manipulation of the microcatheter.

The driving speed of the delivery wire was set at 1.0 mm/s, because a preliminary experiment showed that precise manipulation of the microcatheter is sometimes difficult at faster speeds, while a slower speed can cause larger insertion force affected by static friction⁶. The preliminary experiment also revealed that we could easily achieve insertion of a matched size “first coil” for the empty aneurysm model without any effort using all three methods described above probably due to the shape of the experimental aneurysm model, so we used “partially embolized aneurysm” models. These models were made by inserting a transparent fishing line instead of coils inside the aneurysms, so that subsequently inserted coils could be clearly identified on a monitor. The fishing line was

inserted to the length that could achieve an intended volume proportional to the aneurysm (volume embolized ratio, VER). VERs of the two models used in this experiment were adjusted to 25% and 35%. The coils used in this study were as follows (represented as “coil loop diameter – coil length”): GDC (Stryker) 10 Ultrasoft 3 mm-6 cm and 4 mm-8 cm, or 2D soft 4 mm-8 cm and 5 mm-10 cm for the VER 25% model; GDC 10 Ultrasoft 2 mm-4 cm, 2.5 mm-4 cm, 3 mm-4 cm, and 2 mm-6 cm for the VER 35% model. The coils used were chosen in the same manner as for a clinical situation with these VER values. Experimental insertion was performed five times for each combination of an aneurysm model (VER25% or VER35%) and a coil. All procedures were performed by a single endovascular surgeon. A previous experiment has shown that manual coil insertion force rarely exceeds 0.3 [N]⁵, that is, surgeons feel large resistance to insert when the force exceeds 0.3 [N]. Therefore scores were defined as follows: successful insertion with force ≤ 0.3 [N], 2 points; successful insertion with force > 0.3 [N], 1 point; and failure (defined as the coil or the microcatheter moving outside the aneurysm), 0 points. Mean scores calculated from five repetitions of each trial were statistically compared using Student’s t-test. No ethics committee approval was required for this in vitro experimental study.

Results

The whole system worked appropriately without any problem, and small devices on the operating table did not interfere with any procedures. The delivery wires were accurately controlled by the operator using the foot switches. The operator could stop or start insertion of the coil whenever he wished, and could also gaze at the monitor while manipulating both the microcatheter and coil delivery wire thanks to the tone-presented force sensor. The operating process was quite simple, and endovascular surgeons could use this system without special training.

Mean scores in three insertion methods are shown in Figure 4. When the VER25% aneurysm model and GDC 10 Ultrasoft 3 mm-6 cm coil were used, coil insertion with either of three methods was successfully completed in all five trials (mean scores were all 2 points in each method). This means that the Ultrasoft 3

Figure 4 Comparison of mean scores for the three methods of coil insertion using various coils and aneurysm models. * $p < 0.01$. ** $p < 0.05$. † n.s. Error bars represent standard errors. In general, when the catheter was manipulated manually and the coil was controlled with the foot switches, scores were higher than with other methods. Coil spec is represented as “coil loop diameter – coil length”. VER, volume embolized ratio.

mm-6 cm coil was small and/or short for this aneurysm model. When GDC 10 Ultra-soft 4 mm-8 cm or 2D soft 4 mm-8 cm coils were used, mean scores for simple insertion were less than 1 point. In those situations, manual microcatheter control with or without foot switches helped to obtain significantly higher scores. The GDC 10 2D soft 5 mm-10 cm coil had a relatively large diameter and was long for this aneurysm model, so scores were low even with microcatheter control. However, scores were significantly higher when use of foot switches was added ($p < 0.05$).

Similarly, when the VER35% aneurysm model was used, mean scores with microcatheter control and foot switches were the highest of the three methods, showing significant improvement over both of the other methods except for when Ultra-soft 2 mm-4 cm coils were used. When GDC 10 Ultra-soft 2 mm-4 cm or 2 mm-6 cm coils were used, scores of five trials in each method were all the same (variance and standard error were zero). Mean scores thus showed no significant difference (1 point each) from the GDC 10 Ultra-soft 2 mm-4 cm coil, and the mean score for “Delivery wire control using foot switches with microcatheter manipulation” (1 point) was significantly higher than for the other two methods (0 points) with the GDC 10 Ultra-soft 2 mm-6 cm coil.

In summary, when simple insertion was unsuccessful, microcatheter control worked well to insert coils. Also when scores were low even with microcatheter control, foot switches helped to obtain higher scores. Thus, microcath-

eter control and synchronized coil manipulation were found to be still necessary and important for coil embolization even using our system which can drive the delivery wire at a constant speed.

Discussion

Mechanical insertion of coils

The optical coil insertion force sensor has already been described by Matsubara et al.^{5,6} In their report, mechanical coil insertion force was experimentally compared with manual insertion. Mechanical insertion was performed at a preset constant speed. As a result, mechanical insertion exerted continuous small force, whereas manual insertion showed a larger and frequent peak of the force. Very slow mechanical insertion also showed some peak of the force (Figure 1).

They analyzed the movement of the coil inside the aneurysm model during insertion, and concluded that continuous kinetic friction caused by fixed-speed insertion led the result. That is, constant and not too slow speed maintains a kinetic friction state between the coil and the aneurysm wall, while manual or very slow mechanical insertion causes static friction force that is always larger than kinetic friction force. Their experiment suggested the effectiveness of introducing robotics into endovascular coil embolization, and that was the beginning of our project.

“Four-hands” or “two-hands” method

Currently, in coil embolization of intracranial aneurysms performed by two operators (the so-called “four-hands” method), one controls the microcatheter and the other manipulates the delivery wire of the coil. As a matter of course, mutual understanding and synchronized handling are indispensable for successful procedures. If a discrepancy is present in operator skills, or situations arise in which instantaneous decisions are needed, the microcatheter or the coil can be dislodged and immature rupture may occur due to excessive force against the aneurysm wall. Although some operators manipulate both the microcatheter and delivery wire alone (“two-hands” method), it might be recommended that the operator concentrates on one or the other of these manipulations for precision and delicate control⁹. For example, microcatheter manipulation in tortuous arteries is extremely difficult, because the microcatheter must be pushed or withdrawn more for “bending” in the parent artery. In that situation, two hands are needed for accurate, rapid, and safe control for the microcatheter. Single operators might tend to move the microcatheter roughly, especially when the resistance to insertion is high. Furthermore, the range over which the microcatheter and delivery wire can be moved by one hand within a short time period is limited.

Mechanical coil insertion system

In this setting, we have developed an endovascular coil embolization system allowing precise control of the microcatheter and insertion of the delivery wire at a fixed speed by a single operator.

The mechanical coil insertion system consists of the optical force sensor including the modified Y-connector, delivery wire driving unit, amplifier, and foot switches. The total size of the sensor and driving unit, which are placed on the operating table, is as small as 16×10 [cm], and these do not interfere with procedures. The driving rollers and inner lumen of the Y-connector are kept completely sterile during procedures. In case of an emergency, coil manipulation can immediately be switched to manual by opening the cover of the driving unit and releasing the delivery wire. Auditory presentation of the force enables the operator to watch the behavior of the coil on the monitor during microcatheter manipulation with the hands.

In experimental coil embolization, the operator could move and stop the coil immediately when desired while controlling the microcatheter, an impossible option using a two-operator procedure. We could easily anticipate coil behavior thanks to the fixed insertion speed of the delivery wire, representing another favorable feature of this system. The insertion speed can be controlled easily and finely with the dial on the amplifier.

In our current system, when excessive stress is detected, the operator must stop inserting the coil by manipulating the foot switch. Considering maximum safety, a function to stop the coil automatically when insertion force exceeds a certain value is required. This “auto-stop function” is to be added hereafter.

The importance of combining microcatheter control and coil manipulation (pushing/withdrawing) in the *manual* embolization procedure is widely understood. The results of this experiment indicated that even fixed speed *mechanical* coil insertion requires synchronization of microcatheter and coil movement.

Future perspectives

A future task is to confirm the usefulness of our system with further experiments using complex-shaped aneurysms, tortuous arterial models, and biological aneurysms. We expect that this system could be used clinically and might be helpful for achieving safer and more efficient embolization. In the future, mechanical manipulation of the microcatheter might be able to be established under the force monitor, and even safer procedures could be performed by machines after analysis of appropriate combined control of the microcatheter and the coil, potentially leading to remote-controlled coil embolization or fully automated procedures. In collaboration with industry, our design now includes “foot switches with resistance” to reflect the resistance encountered by the force monitor on the foot switches, and “foot switches with force adjustment” to regulate the insertion force corresponding to pressing power, similar to an accelerator in a car.

Conclusions

We have developed a mechanical coil insertion system for endovascular embolization of intracranial aneurysms, showing good success

without any problems in an in vitro experiment. This system appears useful for allowing a single operator to perform ideal procedures. The present results of the experiment revealed that subtle microcatheter manipulation and simulta-

neous control of the coil delivery wire are still important and required for better coil embolization of aneurysms even when the coil was mechanically inserted at a fixed speed.

References

- 1 Wakhloo AK, Gounis MJ, Sandhu JS, et al. Complex-shaped platinum coils for brain aneurysms: higher packing density, improved biomechanical stability, and midterm angiographic outcome. *Am J Neuroradiol*. 2007; 28: 1395-1400.
- 2 Biondi A, Janardhan V, Katz JM, et al. Neuroform stent-assisted coil embolization of wide-neck intracranial aneurysms: strategies in stent deployment and midterm follow-up. *Neurosurgery*. 2007; 61: 460-468.
- 3 Weber W, Bendszus M, Kis B, et al. A new self-expanding nitinol stent (Enterprise) for the treatment of wide-necked intracranial aneurysms: initial clinical and angiographic results in 31 aneurysms. *Neuroradiology*. 2007; 49: 555-561.
- 4 Ross IB, Dhillon GS. Balloon assistance as a routine adjunct to the endovascular treatment of cerebral aneurysms. *Surg Neurol*. 2006; 66: 593-602.
- 5 Matsubara N, Miyachi S, Nagano Y et al. A novel pressure sensor with an optical system for coil embolization of intracranial aneurysms. Laboratory investigation. *J Neurosurg*. 2009; 111 (1): 41-47.
- 6 Matsubara N, Miyachi S, Nagano Y, et al. Experimental study of generation pattern of coil insertion force using a force sensor system: investigation of friction state between coil and aneurysm wall determined by difference of coil insertion method and insertion speed. *J Neuro Endovasc Ther*. 2010; 4 (2): 84-90. (Japanese article).
- 7 Morel P, Pugin F, Bucher P, et al. Robotic single-incision laparoscopic cholecystectomy. *J Robot Surg*. 2012; 6 (3): 273-274.
- 8 Bertani E, Chiappa A, Ubiali P, et al. Role of robotic surgery in colorectal resections for cancer. *Minerva Gastroenterol Dietol*. 2012; 58 (3): 191-200.
- 9 Kikuchi H. Sentan iryo series 9 Kekkannnai chiryo. Tokyo: Sentan Iryo Gijutsu Kenkyujo; 2004. p. 161-180 (Japanese article).
- 10 Nagano Y, Sano A, Sakaguchi M, et al. Development of force sensor for a linear object. Institute of Electrical and Electronics Engineers Conference on Sensors. Daegu: 2006.
- 11 Nagano Y, Sano A, Sakaguchi M, et al. Development of force sensor for extra-fine and long objects –Application in endovascular coil embolization. *T SICE Transactions of the Society of Instrument and Control Engineers*. 2008; 44: 278-284. (article in Japanese).
- 12 Nagano Y, Sano A, Matsubara N, et al. Development of one surgeon surgery system for cerebral aneurysm coil embolization. *J Jpn Soc Comp Aid Surg*. 2010; 12 (2): 101-107. (article in Japanese).

Shigeru Miyachi, MD, Ph.D.
Department of Neurosurgery, Nagoya University
65 Tsurumai-cho, Showa-ku
Nagoya, Japan
Tel.: +81-52-744-2353
Fax: +81-52-744-2360
E-mail: smiyachi@med.nagoya-u.ac.jp