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A novel pressure sensor with an optical system for coil embolization of intracranial aneurysms

Laboratory investigation

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Object. In endovascular coil embolization for an intracranial aneurysm, the excessive pressure created during coil insertion into an aneurysm can cause a catastrophic rupture or dislodge a microcatheter tip from the aneurysm dome, resulting in insufficient embolization. Such undue mechanical pressure can only be subjectively detected by the subtle tactile feedback the surgeon experiences. Therefore, the authors of this study developed a new sensor device to measure the coil insertion pressure via an optical system.

Methods. This novel sensor system consists of a hemostatic valve connected to the proximal end of a microcatheter (Y-connector). The sensor principle is based on an optical system composed of a light-emitting diode (LED) and a line sensor. The latter measures how much the coil-delivery wire slightly bends in response to the insertion pressure by detecting the wire shadow. This information is translated into a given force level. Experimental aneurysm embolization was performed using this optical sensor. A silicone aneurysm model and an in vivo model (porcine aneurysm model) were used in this study. Several surgeons manually performed the coil insertions. The sensor continuously monitored the mechanical force during the insertions.

Results. The sensor adequately recorded the coil insertion pressure during embolization. The presence of the sensor did not hinder the embolization procedure in any way. During embolization in the silicone aneurysm model, a sinusoid pattern of pressure occurred, reflecting actual clinical experience. Similar results were obtained in the in vivo study.

Conclusions. This new sensor device adequately measures coil insertion pressure. This system provides potentially safer and more reliable aneurysm embolizations. *(DOI: 10.3171/2009.1.JNS081181)*

Key Words • intracranial aneurysm • coil embolization • coil insertion pressure • sensor

In recent years, neuroendovascular treatments have been widely used with a variety of improved devices such as microcatheters and microguidewires as well as an enhanced angiographic system. Coil embolization for intracranial aneurysms is one such treatment.

Craniotomy with clipping of the aneurysm neck has been the most conventional therapeutic option for intracranial aneurysms.[16] However, with the reports of improved outcomes after coil embolization for ruptured aneurysms—such as those documented in the International Subarachnoid Aneurysm Trial (ISAT)[10,11] following the development of the Guglielmi detachable coil in 1991[4,5]—and with the rising need for less invasive therapies, coil embolization has spread rapidly over the past 10 years. Furthermore, the development of various new devices, including 3D coils,[2,21] balloon catheters,[8,17] and microstents,[1,3,22] has continued, reducing the difficulties associated with conventional treatment procedures.

Note, however, that coil embolization is always accompanied by a risk of procedural complications, although it is a less invasive treatment than aneurysm neck clipping. In endovascular coil embolization for intracranial aneurysms, the most fatal complication is catastrophic rupture of the lesion, which can indeed result in a poor outcome. Such a rupture is often caused by aneurysm wall perforation by a microcatheter or microguidewire, although excessive pressure during coil insertion can also induce a rupture.[6,7,9,20] Moreover, in the final stage of the procedure, such undue pressure can lead to kickback of the microcatheter tip, and the microcatheter can be unintentionally dislodged from the aneurysm dome, resulting

Abbreviation used in this paper: LED = light-emitting diode.

in insufficient embolization. To avoid such mishaps, it is important to adequately control the coil insertion pressure exerted through the microcatheter. Thus far, mechanical stress caused by coil insertion pressure could only be subjectively detected by the subtle tactile feedback experienced by the surgeon inserting the coil.

Because of these risks, we envisioned a system that would objectively register and quantify the coil insertion pressure to promote safer and more reliable coil embolizations. Therefore, we developed a new sensor device in collaboration with Nagoya University, Nagoya Institute of Technology, and NTN Corporation. Utilizing an optical system, our sensor measures the coil insertion pressure from the bend of the coil-delivery wire. Here, we introduce this novel sensor and present the results of some basic experiments.

Methods

Optical Pressure Sensor System

The new optical coil insertion pressure sensor consists of a hemostatic valve connected to the proximal end of a microcatheter (Y-connector; Fig. 1B and C). The sensor principle is based on an optical system equipped with an LED and 128 detectors of optical line sensors. The optical sensor is set in the space between the portion of the device connecting to the microcatheter (exit part) and the portion that accepts the coil-delivery wire (entrance part). Figure 1D shows a schematic of the device.

We designed a novel shape for the Y-connector. In the usual Y-connector (Fig. 1A), the space between the entrance and exit portions of the delivery wire is linear. In contrast, our device creates a bend in the delivery wire because we intentionally added a little flexure in this space of the device (Fig. 2A and B). Inside this space, the light emitted from an LED casts the shadow of the delivery wire, which synchronizes with the bend in the wire. The optical line sensor detects the change in the position of the delivery wire by measuring the shadow cast—that is, the degree of the bend—according to the coil insertion pressure from a surgeon's fingertip. The darkest point is defined as the position of the bending wire. The line sensor resolution is 63.5 μm (Fig. 2C and D). Positioning data of the bend are transmitted to a control computer box, which automatically translates them into an objective insertion pressure value.

The geometric structure of the sensor is very important for measuring the wire flexion. We determined the geometric shape by experimenting with many prototype sensors. The important geometric parameters in designing the sensor are shown in Fig. 2E: α is the angle between the center lines of the openings, β is the angle the center line makes with the opposing wall, and ρ is the curvature of the wall. If α is 0, the wire will not bend; so, α must be > 0. As α increases, the bending of the wire, due to compressive pressure, increases and the sensitivity increases. Note, however, that an increase in α also increases the friction between the sensor and the wire. If β is $< 90°$, the wire cannot pass through the sensor; it must be $> 90°$ to allow the wire to pass through the sensor. The curvature ρ enables both flexible and hard wires to be measured with the same sensor; it prevents flexible wires from buckling and facilitates bending of hard wires. Note that α, β, and ρ are interdependent parameters. We determined the optimum geometric parameters by making and measuring the prototypes.

At the development stage, the optical sensor was calibrated with a pressure gauge widely used in the engineer-

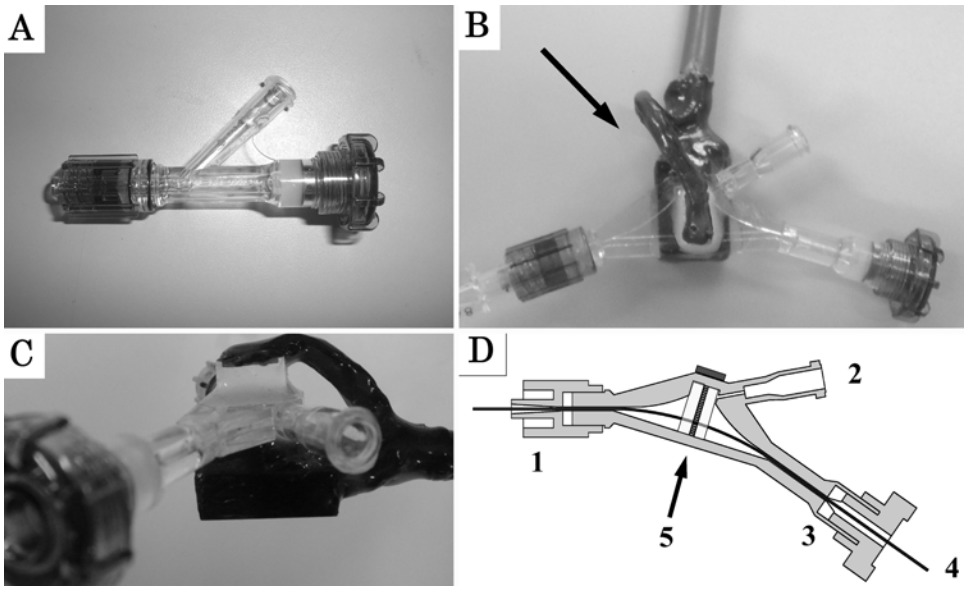

FIG. 1. A: Photograph showing a commercially available Y-connector. B and C: Photographs illustrating the Y-connector with the optical pressure sensor system. *Arrow* indicates part of the optical pressure sensor. D: Schematic showing the optical pressure sensor. 1, part connecting to proximal end of the microcatheter; 2, part connecting to infusion line with normal saline; 3, part to insert into coil-delivery wire; 4, coil-delivery wire; 5, optical pressure sensor.

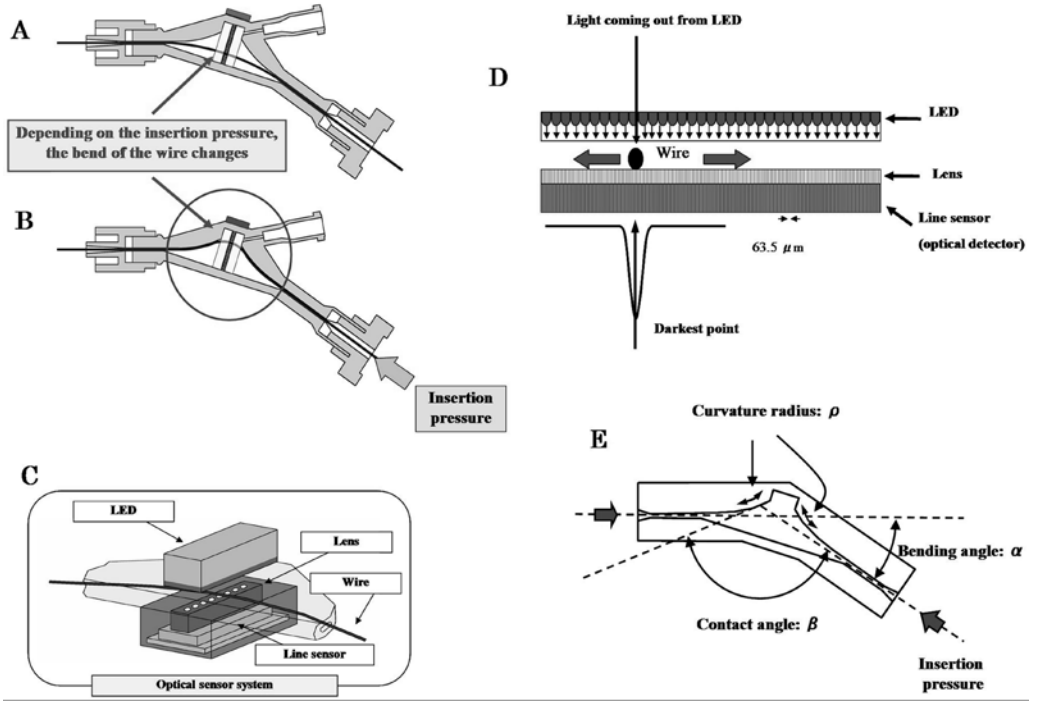

FIG. 2. Schematics showing the optical system. A: Without insertion pressure, the coil-delivery wire does not bend. B: With insertion pressure, the wire bends. Sensor optically detects the position of the bending wire. C: Optical system of the pressure sensor, consisting of LED, lens, and line sensor. D: Line sensor determines the position of the wire by measuring the shadow cast. The darkest point is defined as the wire position, which is translated to insertion pressure. Line sensor resolution is 63.5 μm. E: Geometric structure of the sensor.

ing field to analyze the force of linear objects. The distal part of the coil-delivery wire (without coil) was connected to the pressure gauge, and coil insertion pressure was applied to the proximal part of the delivery wire little by little. We collected data on the relationship between the insertion pressure and the position of the wire shadow, which reflects the wire bend. Note that coil-delivery wires are made of uniform materials corresponding to each of the various kinds of coils. These materials have their own Young modulus, or modulus of elasticity, which defines the correlation between the stress and strain of elastic material. Therefore, the relationship between the degree of coil flexion and the insertion pressure is not so difficult to calculate. We omit here other technical details of the engineering physics of the device, which have been described elsewhere.[12,13]

Indeed, this system can measure coil insertion pressure only at the proximal portion of the wire. Note, however, that according to principles of engineering physics, the pressure detected at the distal tip of the wire is the same as the proximal pressure if the wire is laid in a linear position and without friction. Therefore, it is thought that proximal pressure directly and simultaneously reflects the distal pressure in such an ideal situation. Of course, when any frictional pressure exists, the proximal pressure does not directly reflect the distal pressure. But the pressure measured by the sensor can accurately reflect the proximal pressure, that is, the subtle tactile feedback that the surgeon receives at his or her hand.

Although the hardness and diameter of a coil-delivery wire differ with the various types of coils, the pressure calculation program on our sensor can be changed with the flip of a switch. This device can accommodate any 10-system coil now available in Japan. Pressure values are translated into an optic monitor (color indicator), auditory sensor (speaker), and pressure display monitor (digital numerical value or analog graph). Patents are pending for this device.

Experimental Aneurysm Embolization

Experimental aneurysm embolization was performed using this optical sensor, which continuously monitored the mechanical force during the insertion of coils into the aneurysm. For preliminary study, a silicone dummy aneurysm was used. The whole experimental system is depicted in Fig. 3A. The silicone dummy simulates the shape of a round aneurysm with no branches (Fig. 3B). The dome size was 5 mm in diameter, and the neck length and parent artery diameter were both 3 mm. Several surgeons performed the experimental embolization. Movements of the coil during insertion were observed with a microscope, with the microscopic image reflected on a monitor. For the in vivo study, we fabricated a porcine aneurysm model by surgically transplanting the venous graft and positioning the distal carotid artery to another side of the carotid artery. The dummy aneurysm was ~ 6.3 mm in diameter (Fig. 4). In this article, we analyzed the results of only the first coil insertion.

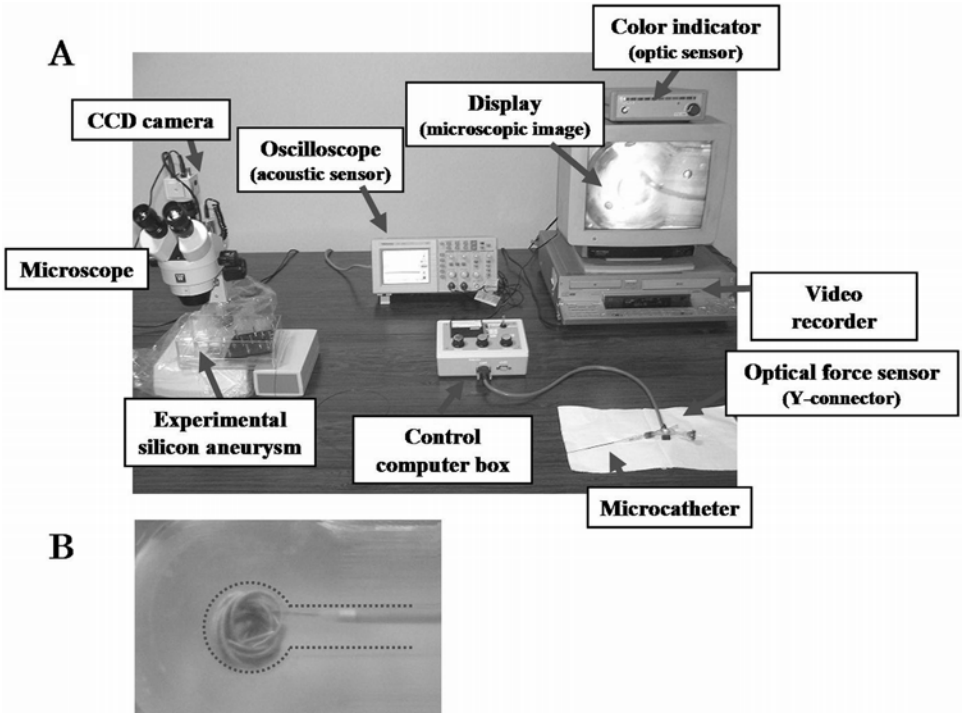

FIG. 3. A: Photograph showing the experimental system for measuring coil insertion pressure with an optical sensor system during embolization in a silicone aneurysm model. B: Photograph of the experimental silicone aneurysm.

Results

The sensor adequately recorded the coil insertion pressure during embolization in both a silicone aneurysm and in an in vivo model. The presence of the sensor did not hinder the embolization procedure in any way.

In the silicone aneurysm model, sinusoid pattern changes in pressure occurred. When the embolization was performed successfully, the maximum insertion pressure did not greatly exceed 0.30 N (Fig. 5). Microscopic imaging was used to monitor coil movement. Coil insertion could be stopped instantaneously and the advance immediately resumed in response to a push-pull-push movement

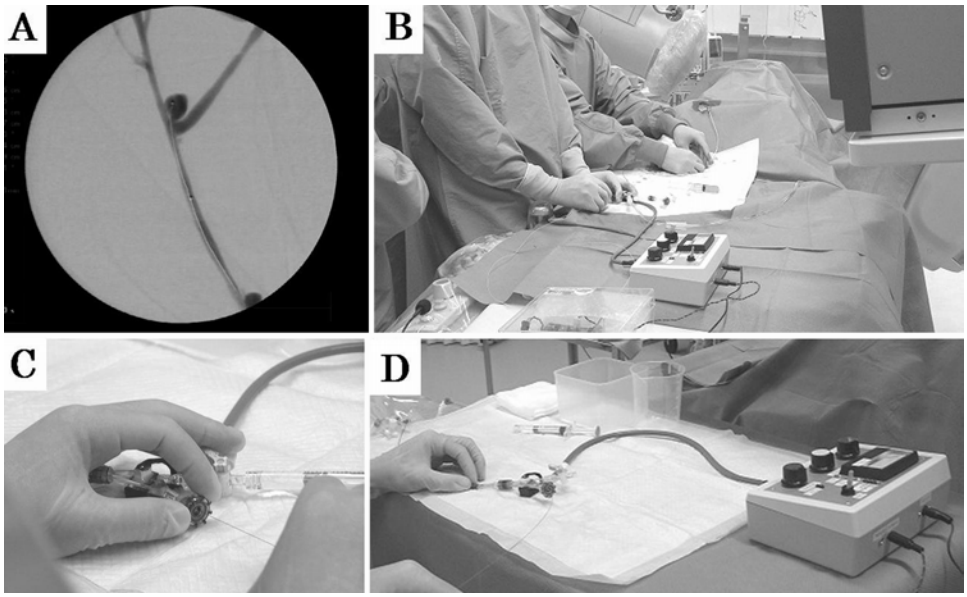

FIG. 4. A: Angiogram showing porcine aneurysm model. Venous graft was surgically transplanted, and contralateral carotid artery was transpositioned at another carotid artery. Aneurysm dome size was 6.3 mm. B–D: Photographs showing in vivo coil embolization with an optical pressure sensor. The presence of the sensor did not hinder conduction of the embolization in any way. This device could be used in the same way as a normal Y-connector.

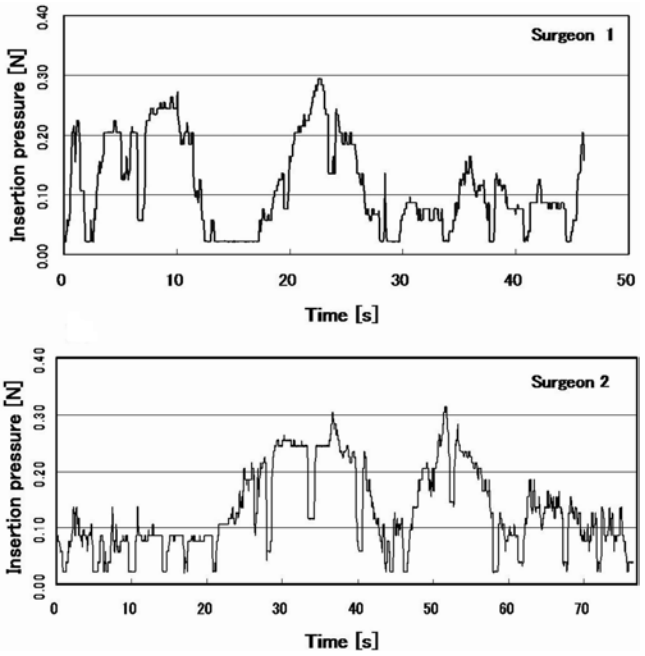

FIG. 5. Representative graphs demonstrating insertion pressures measured by an optical system during embolization in a silicone aneurysm model. The aneurysm dome size was 5 mm, and the inserted coil was 6-mm × 15-cm GDC10-3D. Each panel shows procedures performed by 2 different surgeons. The maximum insertion pressure did not exceed 0.3 N, and a sinusoid pattern of pressure was observed.

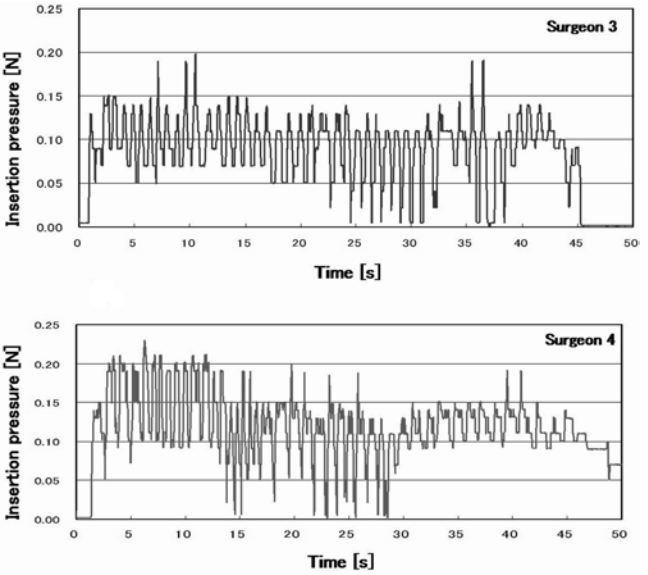

FIG. 6. Representative graphs demonstrating the insertion pressure during in vivo embolization. The aneurysm dome size was 6.3 mm, and the inserted coil was a 7-mm × 18-cm MicroPlex10 complex. Each panel shows procedures performed by 2 different surgeons. The maximum insertion pressure did not much exceed 0.20 N, and a sinusoid pattern of pressure was observed. These results were similar to those obtained with the silicone aneurysm model.

of the surgeon's fingers. The insertion pressure decreased just before coil insertion was momentarily stopped. At the moment that coil advancement was resumed, the pressure was increased by the restart acceleration.

In the in vivo study, changes in the pressure pattern were similar to those in the silicone aneurysm model (Fig. 6).

In some experimental embolizations (both in vitro and in vivo), the surgeon was able to control the coil-insertion speed by using the feedback system of this sensor.

Discussion

Optical Pressure Sensor System

Actually, in coil embolization of an intracranial aneurysm, the mechanical stress on the lesion due to coil insertion pressure can be detected only subjectively through the subtle tactile feedback the surgeon detects via the coil-delivery wire. The surgeon has only been able to describe the insertion pressure as "hard," "stiff," "soft," "smooth," and so forth. Our new sensor device was developed to clarify such ambiguity. It can objectively measure and record the coil insertion pressure via an optical system, which enables the surgeon to objectively evaluate and quantify the coil insertion pressure received by feedback. In addition, other members of the surgical staff can witness the feedback pressure previously detected only by the surgeon. Better cooperative handling is possible when 2 surgeons perform the procedure: one performs the coil insertion while the other controls the microcatheter. Additionally, expert staff can give precise instructions to the surgeon.

The outstanding breakthrough feature of this device is that the coil insertion pressure can be evaluated in the space inside the Y-connector. This system is the first to measure and display the actual subtle pressure applied by the surgeon's fingertips to the very thin wire. In conventional studies, a pressure sensor has been attached to the experimental aneurysm wall itself[14] or to the microcatheter tip.[15,18,19] It has been difficult to measure insertion pressure during an in vivo embolization, because putting a precision sensor on a microcatheter tip is too complicated and expensive. A microcatheter longer than 150 cm with a small distal tip cannot be equipped with a sensor for sufficient sensitivity. Given that this sensor can evaluate the pressure at the proximal portion of the microcatheter far more adequately, it has the potential to revolutionize in vivo coil embolizations and their actual clinical application in the future.

Both digital and analog displays are available for expressing the coil insertion pressure. The pressure data can be transmitted to the control computer and converted into a sound (auditory sensor) as well as a color indicator (optic sensor). After having tried various methods of indicating the pressure, the surgeon seems to prefer looking at the radioscopic monitor during the procedure. It was thought that an auditory sensor would be the most realistic method of keeping the surgeon aware of the coil insertion pressure while simultaneously allowing him to experience the direct feedback in the operation. This device

can also accommodate an alarm system that will alert a surgeon when the insertion pressure spikes dangerously.

The space inside the Y-connector, through which the delivery wire passes, and the sensor itself are never in direct contact, so the sensor has little influence on the coil-delivery wire procedure and is not entirely polluted by blood. Furthermore, the coil-delivery wire remains sterile because it touches only the sensor's interior plastic part but never the optical system itself. In addition, the Y-connector on the new sensor could be used in the same manner as a conventional Y-connector.

Since the sensor part of the Y-connector itself need not be made of special materials, it can be mass produced very inexpensively and even intended as a disposable part.

Experimental Aneurysm Embolization

This device adequately recorded the coil insertion pressure produced during embolization procedures in both a silicone aneurysm model and an in vivo model (porcine aneurysm model). The recorded pressure reflected the actual pressure from clinical experience. When embolization of a silicone aneurysm was successfully performed, the maximum insertion pressure did not greatly exceed 0.30 N. Although the first coil easily slid on the surface of the aneurysm wall, the insertion pressure tended to rise just before the microcatheter was about to "paint"; that is, the tip of the microcatheter moved like a pendulum when the coil slid along and was rolled against the aneurysm wall. The pressure accumulates gradually as coil insertion proceeds and is released at the moment of "painting." Moreover, during embolization, a push-pull-push movement of the surgeon's fingers advances the coil-delivery wire steadily. With this movement, the coil is advanced, stopped abruptly, and soon advanced again. The pressure decreases just before the coil is stopped. Once the coil advance is resumed, acceleration occurs and pressure is likely to increase under that acceleration. Thus, in synchrony with the movement of the surgeon's fingers, increased and decreased forces are generated in turn. This repetitive movement mainly causes repeated changes in the sinusoid pressure pattern in the first coil embolization. In the in vivo study, a similar result was observed.

In the present study, a microcatheter was placed in an almost linear position free of kinks or notable bending so that the frictional pressure exerted when a coil passed inside the lumen of the microcatheter would scarcely affect the result. However, in an actual coil embolization, a microcatheter can often undergo flexures along the route of access. In that situation, our device may not precisely reflect the actual stress on an aneurysm. Therefore, a future area of more detailed research will be the relationship between the flexural condition of a microcatheter and the frictional coil insertion pressure.

Conclusions

We reported on a new coil insertion pressure sensor based on an optical system that adequately measured such pressure. This system provides potentially safer, more reliable aneurysm embolizations.

Disclosure

This study was supported by by NTN Corporation, Osaka, Japan. Yoshitaka Nagano is an employee of NTN Corporation.

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