Surgical Support System for Cerebral Aneurysm Coil Embolization

1. Introduction

In the medical field, treatments with minimized size of surgery scars to reduce the physical demands of patients are widespread. A typical example of such treatments is a therapy using a catheter. This procedure involves inserting a thin tube called a catheter into a duct of the human body and treating an affected part from inside the duct. Recently, the catheter therapy is also used in the field of treating thin and tortuous cerebral blood vessels, and has been applied to treatments for preventing the rupture of cerebral aneurysm, which is a cause of subarachnoid hemorrhage. Coil embolization shown in Fig. 1 is a procedure that involves blocking the blood flow within the aneurysm by filling the cerebral aneurysm with embolization coils by the combined manipulation of a microcatheter and a coil delivery wire. The manipulation requires the skilled collaboration of two surgeons. Thus, we have developed a new surgical support system that can be operated by only one surgeon. Basic verification for this system was conducted using a silicone dummy aneurysm. The results confirmed that the delivery of the wire at a constant velocity is an effective method for decreasing coil insertion force, and that only one surgeon can perform the same coil embolization procedure. In this paper, we report on the system features and the results of verification.

Endovascular coil embolization is becoming a standard treatment option for people with cerebral aneurysms. The embolization method is the filling of an aneurysm with embolization coils by the combined manipulation of a microcatheter and a coil delivery wire. The manipulation requires the skilled collaboration of two surgeons. Thus, we have developed a new surgical support system that can be operated by only one surgeon. Basic verification for this system was conducted using a silicone dummy aneurysm. The results confirmed that the delivery of the wire at a constant velocity is an effective method for decreasing coil insertion force, and that only one surgeon can perform the same coil embolization procedure. In this paper, we report on the system features and the results of verification.

1) Electric systems which detach the coils from the wire by energizing the delivery wire are widely used.
The procedures of coil embolization are divided into two types: one in which two doctors operate the microcatheter and the wire, respectively, with both of their hands; and the other in which one doctor operates the microcatheter by the left hand and the delivery wire with the right hand. In the latter case, a highly skilled maneuver for simultaneously operating both the catheter and the wire with the left and right hands, respectively, is required. It is therefore often the case that two doctors are involved in the treatment. Mutual understanding between the doctors about “the sense of the wire insertion force felt by the hand” and “pushing and pulling operation of the catheter” is necessary.

In the past, NTN has developed a sensing system for cerebral aneurysm therapy which measures and displays the manual insertion force of the delivery wire working in collaboration with Nagoya Institute of Technology and Nagoya University. As shown in Fig. 2, the sensing system consists of an optical force sensor integrated into a medical device called a Y connector for passing the delivery wire through the catheter. Converting the manual insertion force of the wire into sound pitch and presenting the force audibly provides the circumstance that allows all the medical staff in the operating room to share the same understanding of the provided insertion force.

By extending the function of this sensing system, we developed a cerebral aneurysm coil embolization support device which allows a single doctor to simultaneously and coordinately operate the catheter and the wire as in the two-doctor procedure. In this report, we will discuss the coordinated manipulation of the catheter and the coil, the construction of the developed support device, and the verification results confirming the advantages of this device.

2. Coordinated manipulation of catheter and coils

If the contraction of the volume of a coil lump, called coil compaction, occurs after coil embolization, blood flows back into the aneurysm and the effect in preventing a rupture is lost. In order to prevent coil compaction, the coils need to be inserted into the aneurysm uniformly and densely. The doctor inserts the coils into a site which is estimated not to be densely filled with the coils so that an excessive force is not exerted on the aneurysm.

2.1 Painting phenomenon

Coil embolization is performed by visually observing the state of the aneurysm and the coils with a fluoroscope. To estimate the sites which are not densely filled with the coils, a head-swinging phenomenon called “painting” generated at the tip of the microcatheter shown in Fig. 3 (a) is used. This phenomenon is generated by the interaction between the coils inserted and the inner walls of the aneurysm, in the following manner:

1. Parts of the coils are restrained by the friction between the inner walls of the aneurysm and the coils which have been already inserted.
2. When the coils are inserted further in this state, they start to undergo pressure deformation with the restrained parts as the fulcrums, and the tip of the microcatheter starts to swing (painting).
3. The coils then buckle, and the tip of the microcatheter is released from the restraint by the coils and returns to its original position in the painting movement.

In a space which is densely packed with the coils, the tip of the microcatheter is restrained by the coils, and painting does not occur. In this state, an excessive force is required to insert the coils, and forced insertion may lead to the rupture of the aneurysm.

2.2 Maneuver by two doctors

Two doctors who operate the microcatheter and the delivery wire, respectively, communicate through conversations while checking the fluoroscopic images, and as shown in Fig. 3 (b), insert the coils by the following procedure:

1. During the coil insertion, when no painting is observed and resistance is felt during insertion, the doctor who operates the wire temporarily stops the insertion of the delivery wire.

Note 2) Named so since the movement of the catheter resembles brush strokes.
2.3 Operation of microcatheter

The doctor who operates the microcatheter conducts fine positioning operation of the microcatheter by predicting the degree of bending of the microcatheter in the blood vessel, so that the tip of the microcatheter is not removed from the aneurysm during insertion of the coils. Even in the case where the tip is not moved, the pushing and pulling operations of the microcatheter are necessary. For example, the microcatheter is kept pushed so that the microcatheter is not pushed back during insertion of the coils.

Since the insertion and removal of the microcatheter involve opening and closing of the hemostatic valve (see Fig. 2) of the Y connector, it can be smoothly performed if the hemostatic valve is operated by the left hand while retaining the Y connector, and the microcatheter is operated by the right hand.

3. Developed support device

3.1 Overall construction

Fig. 4 shows the overall construction of this device. In this construction, as in a conventional system, the doctor operates the microcatheter with both hands and operates the delivery wire by a foot switch. The wire is delivered at a constant speed by the wire delivery device. The insertion force of the wire is detected by the cerebral aneurysm sensing system, converted into sound pitch information, and is transmitted to the doctor. The delivery speed is adjusted by a switch. This construction allows performance of coil embolization without a doctor who operates the wire.

Fig. 5 shows the appearance of the sensing system and the wire delivery device. To allow the doctor to check the state of the patient at all times, this mechanism is small in size for use on the surgery table. It also has the function to allow the operator to open the top cover and operate the wire directly by the hand. This function characterizes the system in that it can be used not only to move the delivery wire before insertion of the coils and recover the delivery wire after the coils are detached, but can be also switched to a conventional treatment mode during the operation. zoom
3.2 Wire delivery device

Fig. 6 shows the construction of the developed wire delivery device. A direct-current motor is connected to a driving roller via reduction gears, and drives the delivery wire in the longitudinal direction. To prevent slipping and horizontal shift of a super-thin delivery wire (diameter: about 0.3 mm), a guide rail is provided at the center of the driving roller. A follower roller is attached to the top cover via a thrust spring, and the delivery wire is held between the driving roller and the follower roller by fixing the top cover onto the body part. The maximum insertion speed of the delivery wire is 2.0 mm/s based on measurement results of the insertion speed of manual wire delivery by a doctor.

4. Evaluation of continuous insertion

Fig. 7 shows an experimental evaluation system. A simulated aneurysm was placed in water, and water was injected into a guiding catheter, a microcatheter, a Y connector, and a sensing system. A delivery wire inserted into the catheter was then advanced, and the state of the coil embolus was evaluated by observing it with a microscope. The overall length of the catheter is 1.5 m, and while overall length of the delivery wire is 1.75 m (excluding the coil portions). The simulated aneurysm was formed in the shape of a terminal with a diameter of 4 mm, using a transparent silicone to impart appropriate plasticity and enable observation of the coils inside the aneurysm. The number of the coils inserted was two so that the packing fraction was 20% or higher \(^{13}\), which does not cause coil compaction.

4.1 Speed and insertion force

Table 1 shows the results of coil insertion when inserting the delivery wire at a constant speed. The insertion was conducted with the microcatheter fixed. The coil used was a two-dimensional type which develops into a screw-like shape when it comes out of the catheter tip. The first coil has a development diameter \(^{Note 3}\) of 4 mm, the same as the diameter of the simulated aneurysm, and the second coil has a smaller diameter of 3 mm. The overall length of the first coil was 80 mm, while two different lengths of 60 mm (packing fraction: 21%) and 80 mm (24%) were selected for the second coil for comparison of packing fraction.

The coils were inserted at different speeds varied by 0.5 mm/s. As a result, insertion of the first coil, due to a packing fraction as low as 12%, was successful at the maximum speed evaluated, i.e., 2.0 mm/s. On the other hand, the second coil was not inserted into the aneurysm and pushed out to the parent artery side when driven at a high speed from 1.0 mm/s to 1.5 mm/s or higher. The higher the packing fraction, the lower the upper limit of the speed which allows successful insertion.

Fig. 8 (a) shows the insertion force trend of the delivery wire when the first coil was used. Insertion force is clearly less for the insertion at a constant speed of 1.0 mm/s shown in red than for the intermittent insertion by the manual operation of the doctor shown in blue, the former being about half the latter. The maximum force of the former is also 1/2 or

<table>
<thead>
<tr>
<th>Number of coils inserted [Coil No.]</th>
<th>Coil specification Shape-Diameter-Length [mm]</th>
<th>Volume packing fraction of coils [%]</th>
<th>Wire speed for completed filling coil insertion [mm/s]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2D-4-80</td>
<td>12</td>
<td>0.5～2.0</td>
</tr>
<tr>
<td>2</td>
<td>2D-3-60</td>
<td>21</td>
<td>0.5～1.0</td>
</tr>
<tr>
<td>2</td>
<td>2D-3-80</td>
<td>24</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Note 3) The coils return (develop) to their original two-dimensional (spiral) or three-dimensional (basket-like) shapes once they are out of the catheter tip. The coil diameter at this time is referred to as the development diameter, and the development diameter of the coils inserted is selected depending on the diameter of the aneurysm.
less compared with the latter. A decrease in the insertion force directly leads to a decrease in the risk of a rupture of the aneurysm during insertion of the coils. Therefore, continuous insertion at a constant speed is considered useful.

4.2 Insertion force and developed state

**Fig. 8 (b)** shows the developed states of the coils after being inserted by the manual operation of a doctor (intermittent insertion) and by the wire delivery device (continuous insertion). The development by the intermittent insertion of the doctor resembles the state of the insertion at a low speed of 0.5 mm/s, in which the coil is twisted. In contrast, when the speed is 1.0 mm/s or higher, in which the insertion force became less, the coil was not twisted, and developed into a desirable spiral (cylinder) shape. Such developments can hardly be achieved by human operation. In order to examine the relationship between the insertion force and the developed state in more detail, photographs of the developed states of the coils were taken at one second intervals as shown in **Fig. 9**. The coil used was a three-dimensional coil which develops into a basket shape (development diameter: 4 mm, overall length: 40 mm). Photographing was started when about half of the overall length of the coil was inserted.

In case of 0.5 mm/s, as shown in **Fig. 9 (a)**, sawtooth wave patterns are frequently found in the insertion force trend over time. It can be confirmed from **Fig. 9 (c)** that the developed states of the coils have not changed. This is presumably because static friction force is exerted due to low speed insertion, and the coil is restrained by the wall of the aneurysm. In this rigid state, the insertion force increases in correspondence with the insertion of the coils, and the painting phenomenon occurs at the tip of the catheter.

As shown in **Fig. 8 (a)**, sawtooth wave patterns as in **Fig. 9 (a)** are frequently found with the intermittent insertion by a doctor. This is presumably because static friction is exerted when the insertion is paused, and the coil is restrained by the wall of the aneurysm.

In contrast, in case of 1.0 mm/s, the development state of the coils often changes as shown in **Fig. 9 (d)**, indicating that the coil is sliding and moving on the wall of the aneurysm. In case of wire insertion at a high speed, it is thought that the frictional force is little so that the coil cannot be restrained by the wall of the aneurysm. In **Fig. 9 (b)**, although a sawtooth wave increase of the insertion force, which possibly results...
from the exertion of static friction, is found in part, the insertion force is almost constant at slightly lower than 0.1 N.

5. Evaluation of coordinated manipulation by hand and foot

5.1 Results of coordinated manipulation

Since the second coil cannot be inserted simply by feeding the wire at a constant speed, “manual operation of the catheter” and “foot operation of the delivery wire” by the doctor were added. The results of such insertions are shown in Table 2.

When the overall length of the coil was 60 mm, insertion of the coil was successful at all insertion speeds used in the evaluation (0.5 mm/s to 2.0 mm/s) by additionally employing the manual operation of the catheter. On the other hand, when the overall length of the coil was 80 mm, the gaps between coils were difficult to find even when the doctor moved the tip of the catheter as appropriate since the packing fraction was high, and the coils could not be inserted simply by operating the catheter in some cases.

When there is an indication that the coils are pushed out from the entrance of the arterial aneurysm, stopping of the delivery wire by the foot switch and pulling back operation were additionally performed, and gaps between the coils were carefully searched to complete the insertion.

As mentioned above, it was confirmed that in a state when the packing fraction of the coils is high, a single doctor could manipulate the catheter and the delivery wire coordinately and simultaneously using this system to insert the coils.

Table 2 Delivery wire insertion speeds with collaborative manipulation

<table>
<thead>
<tr>
<th>Coil specification</th>
<th>Manual operation of microcatheter</th>
<th>Foot operation of delivery wire</th>
<th>Wire speed for completed filling coil insertion [mm/s]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape-Diameter-Length [mm]</td>
<td>No</td>
<td>Advance only</td>
<td>0.5~1.0</td>
</tr>
<tr>
<td>2D-3-60</td>
<td>Yes</td>
<td>Advance only</td>
<td>0.5~2.0</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Advance only</td>
<td>0.5</td>
</tr>
<tr>
<td>2D-3-80</td>
<td>Yes</td>
<td>Advance only</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Advance and Retraction</td>
<td>0.5~2.0</td>
</tr>
</tbody>
</table>

5.2 Evaluation of operability

We had four doctors (very skilled to 3 to 4 years of experience) subjectively evaluate the operability of this system. The results are shown below.

(1) Since the insertion force of the coils is audibly presented by a change in sound pitch, the delivery wire can be operated while always checking the state of the coil insertion by fluoroscopic images. The coils are inserted at a constant speed, and it is therefore easy to predict the development movement in the aneurysm.

(2) Compared to wire operation, fine insertion and retraction operations of the catheter based on the observation of painting are comfortable since it is a two-hand operation as in a conventional system.

6. Conclusion

In cerebral aneurysm coil embolization, which has been conventionally performed by two doctors collaboratively, a new support device which can be performed only by a single doctor was developed. This device is small in size for use on the surgery table, and can switch to a normal operation mode performed by the hand of the doctor at any time. The results of the verification conducted using a silicone simulated aneurysm are shown below.

(1) It was confirmed that the continuous insertion at a constant speed requires 1/2 or less the maximum force for inserting the wire than the intermittent insertion by a doctor.

(2) Since the insertion force of the coils is audibly presented, the doctor can operate the catheter by hand and the delivery wire by foot simultaneously while checking the state of coil development by fluoroscopic images as in a conventional system.

(3) Since the delivery wire is inserted at a constant speed, it is easy to predict the coil development in the aneurysm.

In the future, the operability of the system in cases where the shapes of the aneurysms are difficult for coil insertion and the advantages of this system will be verified in further detail in simulated surgery using blood vessel models and animals.
References


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12) http://www.jscas.org/guideline.htm


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