

A New Method of Microcatheter Heat-Forming for Cerebral Aneurysmal Coiling Using Stereolithography Three-Dimensional Printed Hollow Vessel Models

Sadao Nakajima,* Makoto Sakamoto,* Hiroki Yoshioka,† Tetsuji Uno* and Masamichi Kurosaki*

*Division of Neurosurgery, Department of Brain and Neurosciences, Faculty of Medicine, Tottori University, Yonago 683-8503, Japan and †Department of Neurosurgery, Tottori Prefectural Central Hospital, Tottori 680-0901, Japan

ABSTRACT

Background To perform successful coil embolization of cerebral aneurysms, it is crucial to make an appropriately shaped microcatheter tip for an aneurysm and its parent artery. So far, we manually shaped a mandrel by referencing two-dimensional (2D) images of a rotation digital subtraction angiography (DSA) on a computer screen. However, this technique requires a lot of experience, and often involves trial and error. Recently, there have been increasing reports of manual mandrel shaping using a full-scale three-dimensional (3D) model of an aneurysm and its parent artery output by various types of 3D printer. We have further developed this method by producing a hollow model of an aneurysm and its parent artery with a stereolithography 3D printer and inserting a mandrel inside the model to fit and stabilize a microcatheter tip.

Methods Based on digital imaging and communications in medicine (DICOM) data obtained by rotational DSA, 3D images of an aneurysm and its parent artery were created and converted into standard triangulated language (STL) data. A hollow model was produced by extruding the STL data outward in the normal direction, and then a hole was made at the tip of the aneurysm using these STL data. We output these STL data to a stereolithography 3D printer. After cleaning and sterilizing the model, the mandrel was inserted in the direction of the parent artery through the hole made in the tip of the aneurysm and pushed in, creating the ideal mandrel shape. Twelve cases (14 aneurysms) were included in this study. A microcatheter tip was shaped by this method for patients who were scheduled to undergo coil embolization for an unruptured aneurysm.

Results In 13 of the 14 aneurysms, the microcatheter was easily guided into the aneurysms in one or two trials, the position of the microcatheter tip in the aneurysm was appropriate, and the stability during coil embolization was high.

Conclusion Our method differs from the conventional one in that a hollow model made of resin is produced with a stereolithography 3D printer and that the mandrel is shaped by inserting it retrogradely into the hollow model. Using our new method, it will be possible to shape the tip of a microcatheter suitable for safe and

stable coil embolization without relying on an operator's experience.

Key words cerebral aneurysm; coil embolization; endovascular surgery; microcatheter shape; stereolithography 3D printer

In treating cerebral aneurysms, endovascular coil embolization is currently one of the essential options. Although the advantage of endovascular surgery is that it is minimally invasive, there is a risk of aneurysm rupture during the insertion of microcatheters and coils into the aneurysm.^{1, 2} To perform coil embolization safely and quickly, it is crucial to guide and position a microcatheter into an aneurysm as intended and stabilize the microcatheter without kick-back while coiling.^{3–6}

It is essential to produce the appropriate tip shape for the microcatheter.^{4–6} Pre-shaped microcatheters are commercially available, but they do not always fit the shape of the aneurysm well. The shape and size of the aneurysm, and the direction of the protrusion in relation to the parent artery varies between cases, so the shape of the microcatheter tip needs to be tailored in several cases. Specifically, a mandrel shaped as the parent artery travels based on preoperative images is inserted into the microcatheter's tip, and hot air or high-temperature steam is applied for several seconds to shape the tip of the microcatheter.^{7–9} If the mandrel can be optimally shaped, the microcatheter tip can also be ideally shaped, and aneurysm embolization can be safe and reliable.

However, at present, no theoretical or practical methodology has been established as to how to determine the ideal mandrel shape. Consequently, trial and error are repeated for each case based on the operator's experience. It is difficult to predict how a mandrel should be bent to achieve the ideal microcatheter shape,

Corresponding author: Sadao Nakajima, MD
sd.nakajima@gmail.com

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Abbreviations: D, dimensional; DICOM, digital imaging and communications in medicine; DSA, digital subtraction angiography; STL, standard triangulated language

Table 1. Patient characteristics and assessment of microcatheter shaping

Case	Age	Sex	Location	Diameter, mm	Accessibility	Positioning	Stability	Complication	Adjunctive technique
1	62	F	IC-SHA	6.9	Failure	Good	Stable	No	Stent (enterprise)
2	84	F	IC-PC	14.3	Excellent	Good	Stable	No	Stent (ATLAS)
3	79	F	IC-PC	6.2	Excellent	Good	Stable	No	No
4	65	F	A-com	3.1	Good	Good	Stable	No	No
5	70	F	A-com	2.5	Failure	Poor	Unstable	No	No
			IC-PC	5.5	Excellent	Good	Stable	No	Balloon, Double
6	61	F	IC-PC	4.5	Good	Good	Stable	No	No
7	59	F	A-com	9	Excellent	Good	Stable	No	Stent (ATLAS)
8	39	F	A-com	2.8	Excellent	Good	Stable	No	Stent (ATLAS)
9	61	F	IC-PC	6	Excellent	Good	Stable	No	Double
10	77	F	BA	4.7	Excellent	Good	Stable	No	Stent (LVIS Jr.)
11	60	F	MCA	7	Excellent	Good	Stable	No	Double
12	75	F	IC-AnCho	5.9	Excellent	Good	Stable	No	Double
			IC-PC	7.2	Excellent	Good	Stable	No	Balloon

A-com, anterior communicating artery; BA, basilar artery; F, female; IC-Ancho, internal carotid artery – anterior choroidal artery; IC-PC, internal carotid artery – posterior communicating artery; IC-SHA, internal carotid artery – superior hypophyseal artery; MCA, middle cerebral artery.

and a significant portion of this is based on the operator's experience.

In order to shape a microcatheter appropriately, it is first necessary to accurately grasp the three-dimensional (3D) structure around the lesion. Conventionally, as a method for this, we have viewed rotational DSA images of lesions on a monitor. Recently, we may have viewed full-scale models produced with 3D printers. Although these methods are innovative in understanding the 3D structure of the lesion, they remain the same in determining the appropriate shape of a mandrel. So, we developed a novel method to shape a mandrel appropriately not depending on the operator's experience and skill level. We produced a hollow model of an aneurysm and its parent artery with a stereolithography 3D printer, and we shaped a mandrel by inserting into the hollow model. By using this mandrel, the microcatheter can be easily guided into the aneurysm and shaped to be stable in the vessel.

MATERIALS AND METHODS

Patient selection

This retrospective study was approved by our Institutional Review Board (approval number 20A197), and informed consent was waived. This method was employed in 14 aneurysms of 12 consecutive cases between February 2019 and February 2020, excluding 10 cases in which the shaping of the microcatheter tip was unnecessary

based on a preoperative imaging examination and the cases in which introduction of a flow-diverter was planned (Table 1).

Production of a hollow aneurysm-parent artery model with a stereolithography 3D printer

3D images of an aneurysm and its parent artery were produced using digital imaging and communications in medicine (DICOM) data of rotation digital subtraction angiography (DSA), and were converted into standard triangulated language (STL) data, using 3D visualization and measurement software (Amira®, Thermo Fisher Scientific, Waltham, MA). The STL data were loaded into software editing triangular meshes (Meshmixer®, Autodesk, Mill Valley, CA) and were extruded outward in the normal direction, and a hollow model in which the lumen exactly matches the patient vessel was produced. After a hole was made at the tip of the aneurysm, the STL data were output to a stereolithography 3D printer (Photon®, ANYCUBIC, Shenzhen, Guangdong, China). The XY resolution was 0.047 mm, and Z-axis accuracy was 0.00125 mm. The printing conditions were as follows. The layer thickness was 0.05 mm. The normal exposure time was 1 sec. The off-time was 1 sec. The bottom-exposure-time was 50 sec. The bottom layer comprised four individual layers. The ultraviolet curable resin we used was 3D Printing Resin Clear (WANHAO, Jinhua, Zhejiang, China) (Fig.

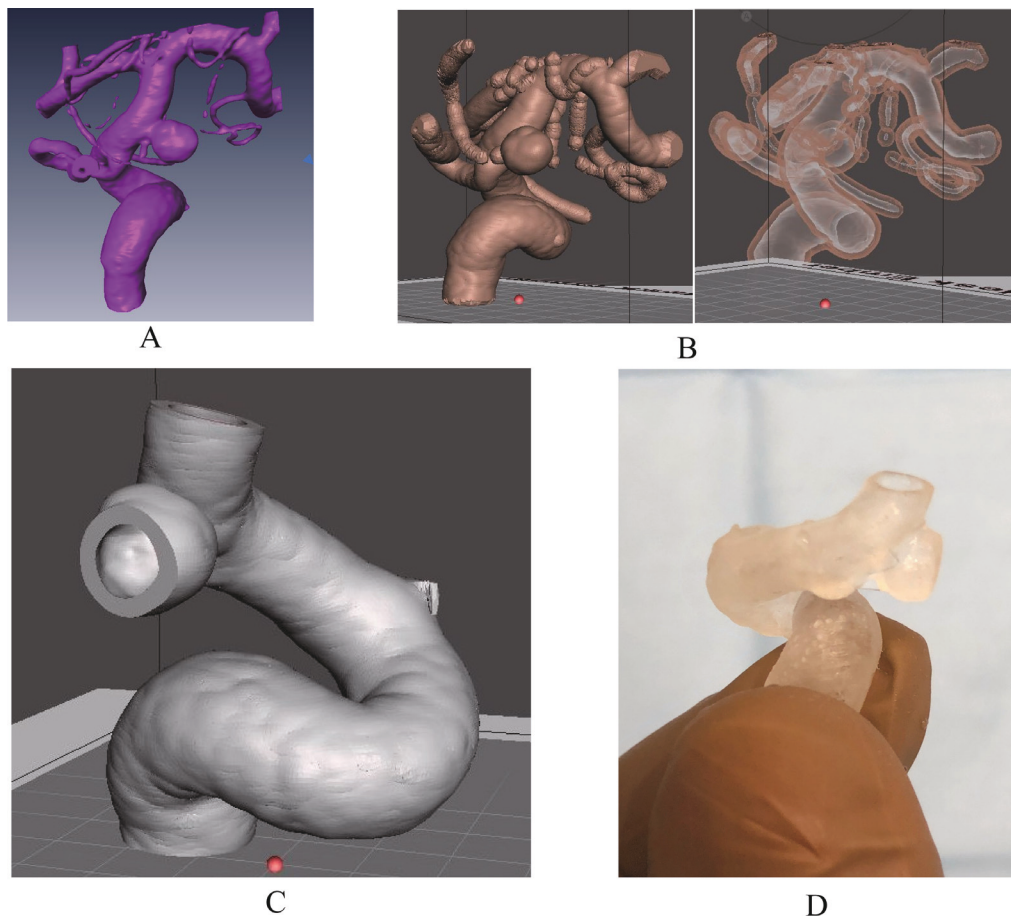


Fig. 1. Production of a hollow aneurysm-parent artery model of case 6. **A:** Create a 3D model based on the DICOM image obtained by rotational DSA. **B:** Convert into STL data and extrude outward in the normal direction to create a hollow model. **C:** Cut unnecessary branches, make a hole in the tip of the aneurysm, and create STL data for 3D printing. **D:** Output a hollow resin vessel model to a stereolithography 3D printer.

1). stereolithography 3D printer can produce a hollow resin vascular model by irradiating an ultraviolet curable resin with ultraviolet rays. The model immediately after printing still had liquid resin attached, so after washing it with alcohol to remove it, secondary curing with ultraviolet light was performed to cure the resin completely. This model was autoclaved and sterilized under the same conditions as used for traditional surgical instruments for neurosurgery. We used HS6610ER1-SR (Getinge, Gothenburg, Sweden), and it took about 18 minutes at 134 degrees Celsius. It took about 30 min to create the final STL data from the DICOM data. It took 2–3 hours to output the STL data to a stereolithography 3D printer and finish cleaning and secondary curing. The total time required for autoclaving was about 100 min.

Shaping a mandrel using the hollow aneurysm-parent artery model

When bringing a sterilized model into the surgical field, caution should be exercised in order to avoid contact with normal surgical instruments as much as possible, and by washing it with clean saline. The saline solution, the equipment used for cleaning, the gloves, and so on were disposed of immediately after use. The mandrel packed together with the microcatheter was inserted through the hole of the aneurysm to the parent artery in the direction opposite to the blood flow. Advancing the mandrel through the hole of the aneurysm made it possible to trace the outer curve of the vascular lumen. The mandrel was inserted as deep as possible until it passed one or two flexions of the parent artery (Fig. 2).

Shaping of the tip of a microcatheter

All microcatheters used were Headway 17® (straight) (Microvention, Tustin, CA). An adequately shaped mandrel was inserted into a microcatheter and exposed to high-temperature air to shape the microcatheter tip. The

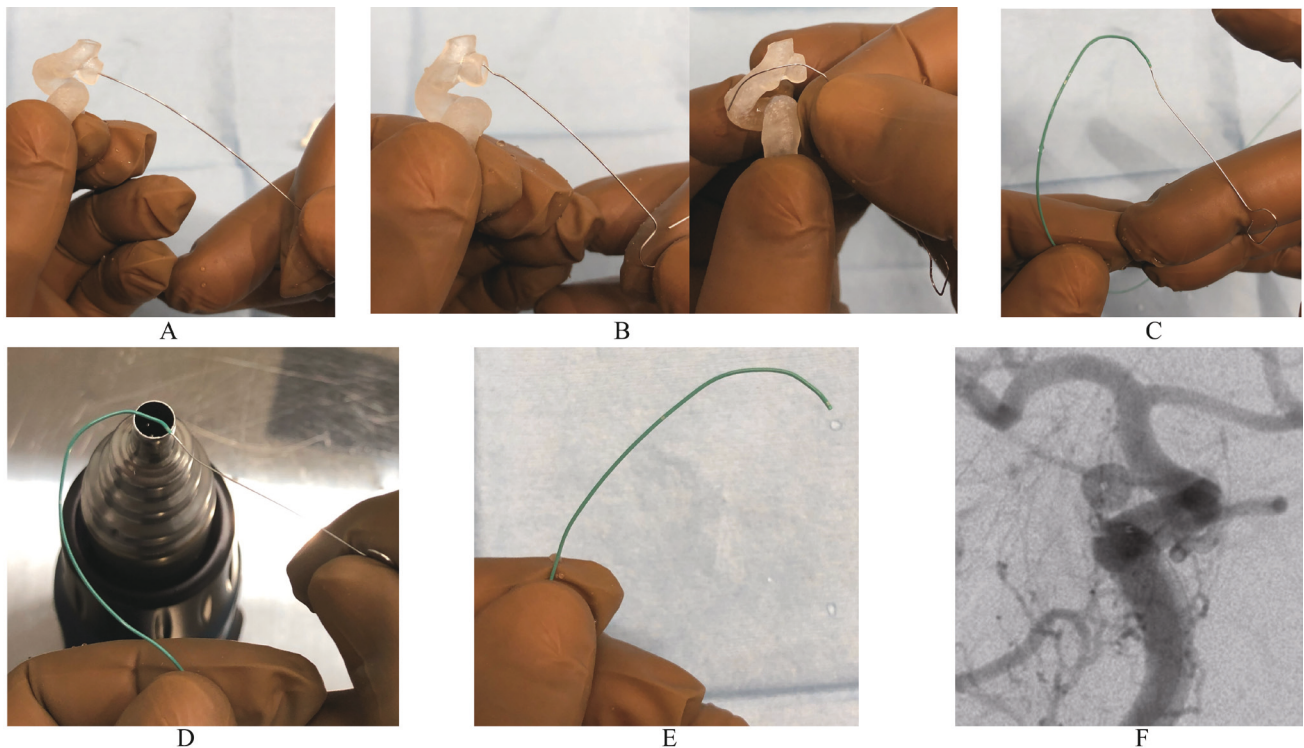


Fig. 2. Shaping the tip of the microcatheter with the hollow aneurysm-parent artery model of case 6. **A:** A mandrel is inserted through the hole at the tip of the aneurysm. **B:** The mandrel is pushed retrogradely through the hole at the tip of the aneurysm to its parent artery in the hollow resin model. **C:** The mandrel is inserted into the microcatheter. **D:** The microcatheter is heat-formed with a hot-air-gun. **E:** The heat-formed microcatheter is looser than the shape of the mandrel. **F:** When inserted into the aneurysm, the microcatheter hits the blood vessel wall and increases tortuosity to enter the aneurysm as intended.

length of the mandrel inserted from the tip of the microcatheter was adjusted so that the tip of the microcatheter was slightly proximal to the center of the aneurysm. We used a hot-air-gun to shape the microcatheter tip at 120 degrees Celsius for 90 sec.⁹

As is well known, the shape of the steam-shaped microcatheter is looser than the original mandrel shape.^{7, 8} However, when the shaped microcatheter was inserted into the patient's vessel, it naturally struck the vessel lumen, increased the degree of flexion, and made it possible to follow a route through the outer curve of the parent artery towards the inside of the aneurysm (Fig. 2). After that, coil embolization was performed using the microcatheter.

Evaluation of the effectiveness of the microcatheter shape

This method's usefulness was evaluated according to four criteria: accessibility, positioning, stability, and complications. The adjunctive technique used together with this method has been added to Table 1. All coil-embolization and evaluations were performed by the co-author who has engaged in endovascular treatment

for about 20 years and has surgical experience in about 2000 cases. In addition, this was not a blind evaluation.

"Accessibility" was evaluated in three stages: "Excellent," "Good," and "Failure." "Excellent" meant that the microcatheter could be placed in the aneurysm in one trial without micro-guidewire navigation, and "Good" meant that the microcatheter could be placed in the aneurysm using a micro-guidewire. "Failure" meant the microcatheter could not be guided into the aneurysm with or without a micro-guidewire, and it was necessary to reshape the tip of the microcatheter or to change the microcatheter.

"Positioning" was evaluated as "Good" or "Poor." "Good" meant that the position of the tip of the microcatheter in the aneurysm was appropriate and as intended, and "Poor" meant that the position of the tip of the microcatheter was not desirable.

"Stability" was evaluated as "Stable" and "Unstable." "Stable" meant that, with the tip of the microcatheter, we were able to complete the procedure without any kickback in the process of embolizing the coil; "Unstable" meant there was kickback and deviation outside the aneurysm during the operation.

RESULTS

Summary

The results are summarized in Table 1. Coil-embolization was performed in 14 aneurysms of 12 patients following this method. By location, there were eight internal carotid artery aneurysms (one paraclinoid, six posterior communicating aneurysm, one anterior choroidal), four anterior communicating aneurysms, one middle cerebral artery aneurysm and one basilar top aneurysm. The average size of the aneurysms was 6.1 ± 2.8 mm.

In 10 of the 14 aneurysms, it was possible to guide the microcatheter to an aneurysm in one trial without using a micro-guidewire. In two aneurysms (cases 4 and 6), the first trial without the micro-guidewire did not allow successful placement in the aneurysm, but the use of the micro-guidewire allowed guidance into the aneurysm easily. In case 1, the microcatheter shaped by the mandrel formed by the hollow model did not have enough flexion, so the mandrel was manually bent farther and another attempt was made. As a result, the microcatheter could be guided into the aneurysm without a micro-guidewire, and coil embolization could be performed without any complication. In case 5, the angle between the aneurysm and the parent artery was extremely steep, and the tip of the microcatheter formed by this method was not sufficiently bent and pointed directly opposite the long axis of the aneurysm. Since it was difficult to shape a small curvature S-shaped catheter with our method, coil-embolization was performed using pre-shaped SL-10® (S-shaped) (Stryker, Kalamazoo, MI).

Regarding the position of the tip of the microcatheter in the aneurysm and the stability of the microcatheter during coil embolization, 13 aneurysms using the

microcatheter shaped by this method achieved good results as intended. No complications related to this procedure were found.

Most microcatheters shaped by this method had good stability and good tip position within the aneurysm, but nine aneurysms required adjunctive techniques because of wide-neck morphology and branching from the neck of the aneurysm. In all cases where double catheterization was performed, the framing coil was embolized with the microcatheter shaped by this method, which was considered the result of demonstrating its stability and good position in the aneurysm. It can also be said that the microcatheter shaped by this method was able to play its role without any problem even if a second catheter, balloon, and stent were used.

Case presentation

A 61-year-old woman (case 6) was noted to have an unruptured aneurysm about 4.5 mm in size at the bifurcation of the right internal carotid artery and posterior communicating artery (Fig. 3).

A 3D model of the aneurysm and the parent artery was created from the DICOM data of the rotational DSA, converted into STL data to form a hollow model, and the tip of the aneurysm was partially cut and output to a stereolithography 3D printer. A mandrel was inserted from the tip of the aneurysm model, and the Headway 17® was formed with a hot-air-gun using this mandrel. A 7Fr. Shuttle sheath® (COOK Medical, Bloomington, IN) was guided to the right internal carotid artery, a distal access catheter [3.2 Fr. TACTICS® (Technocrat Corporation, Aichi, Japan)] was guided to the carotid siphon, and the Headway 17® shaped at the tip was raised from there. At first, the microcatheter was

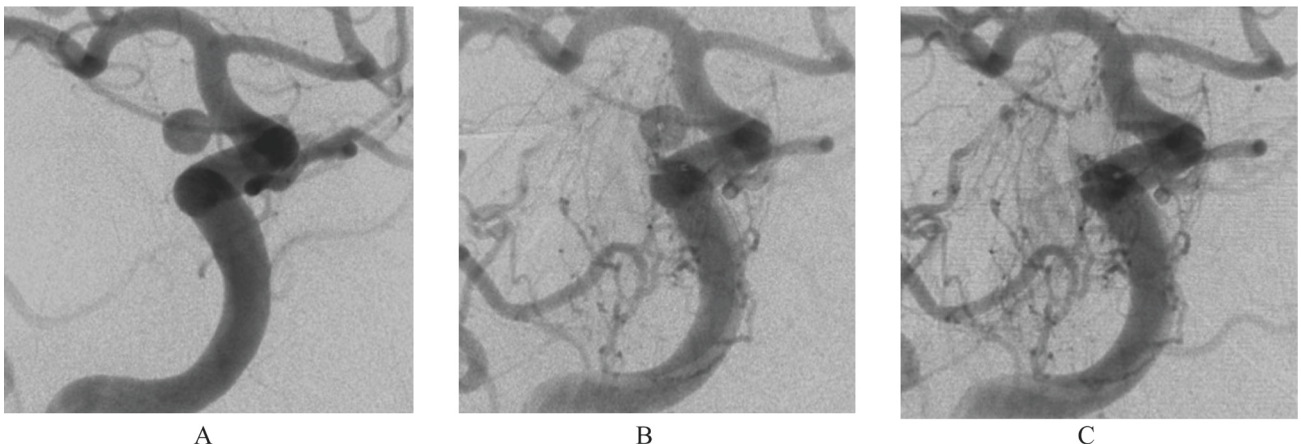


Fig. 3. Intraoperative images of case 6. **A:** Preoperative cerebral angiography showing an internal carotid aneurysm where the posterior communicating artery branches from the neck. **B:** A microcatheter can be inserted into the aneurysm without the guidance of a micro-guidewire. **C:** Postoperative angiography showing that the aneurysm is completely occluded and the posterior communicating artery is preserved.

manipulated using a micro-guidewire, but when it came close to the aneurysm, the microcatheter was advanced into the aneurysm without the guidance of the micro-guidewire. A microcatheter could be easily guided into the aneurysm in the first trial. Embolization was accomplished with this simple technique, from framing to finishing, without kickback of the microcatheter. The posterior communicating artery branched from the aneurysmal neck was preserved, and complete occlusion of the aneurysm was achieved. The microcatheter did not kick back or deviate from the aneurysm consistently throughout the procedure. There were no complications in the perioperative period of embolization (Fig. 3).

DISCUSSION

In recent years, endovascular treatment of cerebral aneurysms, other than coil embolization, has been gradually expanding, especially with a flow diverter. However, indications for a flow diverter for ruptured or bifurcated cerebral aneurysms have not always been shown to be effective, so coil embolization is still the standard treatment for endovascular surgery. One of the essential points in coil embolization is to shape the microcatheter tip into a proper shape and guide it to the appropriate position in the aneurysm.^{3–6} Each patient presents a different structure around a lesion, and it is difficult to predict an appropriate tip shape. As the surgeon's experience increases, it becomes easier to predict the appropriate tip shape. But even the most experienced surgeon may require several trials or perform surgery with an inadequate tip shape. The situation is even more difficult for beginners. There are three reasons for difficulty in shaping a catheter. First, it is difficult to grasp the complex 3D shape of the aneurysm and its parent artery based on the screen's 3D visualization.⁵ Second, it is difficult to predict in advance the shape of a microcatheter that will remain stable during coil embolization.⁵ Specifically, it is thought that the microcatheter is stable when it runs along the periphery of the mother vessel, but the ideal path of the microcatheter is a challenge to predict. Finally, although the position of the microcatheter tip should be slightly proximal to the center of the aneurysm, its control is complicated, and there is a risk of penetration of the aneurysm by the microcatheter or micro-guidewire. Therefore, we conducted research with the aim of developing a microcatheter shaping method for overcoming these three difficulties.

Traditionally, by predicting a 3D structure while checking 2D images,³ the mandrel was shaped not only by bending it by hand, but also by using various articles such as injection needles and resin syringes. Recently,

it has become possible to produce a full-scale model with a 3D printer and shape a mandrel manually while viewing it in the surgical field for more accurate formation.^{4, 6} Although 3D modeling has made it easier to understand the 3D structure of aneurysms and vessels, a great deal of clinical experience is needed to predict which route a microcatheter would ideally follow within the wide vessel lumen. It is also difficult to control where the tip of the microcatheter is placed in an aneurysm having a diameter of only a few millimeters. Even if it is easy to guide a microcatheter into an aneurysm, its effectiveness is rendered useless if the tip of the microcatheter penetrates the aneurysm. The conventional method using a 3D printer is novel in terms of grasping the 3D structure of a lesion, but it can be said that there has been no significant progress in determining the optimum catheter shape and in controlling the position of the tip in the aneurysm from previous methods.

There are two major novelties between the conventional method and our method using a 3D printer. These novelties allow us to solve three difficulties in shaping the catheter. One is that we are producing a hollow model of an aneurysm and its parent artery model, not a solid model. Another point is that we make a hole in the tip of the aneurysm. And our method allows shaping of a sufficiently effective mandrel simply by inserting it into the hollow model without grasping the actual complex 3D structure of the lesion. Our method also allows shaping of the microcatheter, so that it can run along the periphery of the mother vessel and to be stable during coil embolization simply by inserting the mandrel into the hollow model. The operator requires no experience to determine the appropriate route to the aneurysm. Furthermore, another advantage of our method is that it is possible to control where the tip of the microcatheter is located in the aneurysm depending on how far the microcatheter is inserted into the shaped mandrel. In addition to the high stability of the microcatheter, the control of the tip position contributes to reducing the risk of penetrating an aneurysm during surgery and reduces psychological pressure during surgery even for skilled surgeons. Generally, micro-guidewire navigation is required when placing a microcatheter in an aneurysm, but in our method, 71% (10 out of 14 cases) did not require micro-guidewire navigation. Compared with the conventional method, our method provides superior accessibility by the microcatheter to the aneurysm. In 93% of patients (13 of 14 cases), the catheter placed in the aneurysm could be used without changing the position or tip shape until the coil embolization was completed. These results suggest that the catheter tip position was excellent, and the stability was very high.

We believe that shaping a microcatheter using this method can reduce the risks associated with endovascular coil embolization. Intraoperative rupture, one of the major complications of coil embolization, is rare, but if it does occur, both mortality and morbidity become high.^{1,2} Most importantly, we believe that our shaping method allows anyone, regardless of whether they are a novice or an experienced operator, to easily shape the mandrel and shape the microcatheter tip in the same way.

Some things need to be explained about this method. Stereolithography 3D printers have a major advantage in being able to produce models with a higher accuracy than the widely used fused deposition modeling 3D printers where the produced models are sterilized by autoclaving. The model produced by a fused deposition modeling 3D printer is partially melted by the autoclave and loses its shape. However, the problems with stereolithography 3D printers are that handling and maintaining liquid resin are troublesome and that printing requires some expertise. For example, if the model is not oriented properly, the printout may fail, so it is necessary to print out multiple copies with different orientations at the same time. In addition, printouts will always fail if curing resin debris remains in the container, so the container needs to be kept clean at all times.

The second problem is that this method is time consuming. As mentioned above, it takes 4 to 5 hours from DICOM data preparation to completion of sterilization and using it to shape the mandrel. For acute lesions such as ruptured cerebral aneurysms that require urgent treatment, this technique is ineffective. However, for scheduled surgery of unruptured aneurysms, the time it takes to produce a model makes little difference. Even in the case of a ruptured aneurysm, a waiting time of several hours before entering the operating room may be acceptable.

Finally, it can be challenging to pass a mandrel through a hole drilled from the aneurysm tip into a hollow vessel model. Smoothly passing a relatively stiff, straight mandrel through a narrow, steeply bending vessel lumen can be more complicated than expected, and the tip of a mandrel can get caught in the vessel wall, preventing it from moving forward. Fortunately, in the cases presented here, we have been able to insert the mandrel into the lumen of the vascular model rather deeply by using care and some ingenuity, such as bending the mandrel tip. Also when the inserted mandrel is withdrawn, the bend may be extended and straightened. In such cases, the mandrel can be removed by crushing the vessel model with mosquito forceps or other tools. In the future, we would like to examine other shapes

and materials for models in order to make this process easier and more stable.

In conclusion, we developed a novel method to shape a safe and stable microcatheter by producing a hollow model of an aneurysm and its parent artery and inserting the mandrel retrogradely through a hole in the tip of the aneurysm.

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The authors declare no conflict of interest.

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