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Three-dimensional spiral-shaping method of microcatheter for paraclinoid aneurysms: assessment using silicone models

Eiki Imaoka[1], Masahiro Nishihori[1], Takashi Izumi[1], Shunsaku Goto[1], Yoshio Araki[2], Kinya Yokoyama[1], Kenji Uda[2], Fumiaki Kanamori[1] and Ryuta Saito[1]

[1]*Department of Neurosurgery, Nagoya University Graduate School of Medicine, Nagoya, Japan*
[2]*Department of Neurosurgery, Japanese Red Cross Aichi Medical Center Nagoya Daini Hospital, Nagoya, Japan*

ABSTRACT

Selecting an appropriate microcatheter tip shape for paraclinoid aneurysms is difficult. Therefore, we devised an original simple and uniform three-dimensional (3D) spiral-shaping method of microcatheter and validated the characteristics and usefulness of this method for coil embolization of paraclinoid aneurysms using patient-specific silicone models. These silicone models were produced based on clinical data from four patients with four paraclinoid aneurysms that underwent endovascular treatment using the 3D spiral-shaping method. These models were classified into four types: superior, medial, inferior, and lateral corresponding to the aneurysm protrusion and locations (C3 or C2 segments by Fisher's classification). Employing a pulsatile pump setup, two operators assessed the following items: navigation methods (pull and wire guiding), catheterization times, microcatheter tip position in the aneurysm, and the feasibility of inserting a framing coil by simple technique compared with three other shapes (straight, 90, pigtail). Three-dimensional spiral-shaped microcatheter could be placed in the medial and inferior type models of C3 segments and superior type model of C2 segment by the pullback method. Catheterization times using a 3D spiral-shaped catheter were significantly shorter than other shaped ones in the superior type models. No significant difference was found in another silicone model. Three-dimensional spiral- and pigtail-shaped catheters tended to position the tip at the center of the aneurysm. In conclusion, 3D spiral-shaped microcatheter was especially effective for the superior projected aneurysm at the C2 segment. The 3D spiral-shaping method can provide easy and secure navigation of the microcatheter into the paraclinoid aneurysms, ensuring optimal positioning for coil insertion.

Keywords: coil, embolization, microcatheter, paraclinoid aneurysm, silicone model

Abbreviations:
3D: three-dimensional
ICA: internal carotid artery

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Corresponding Author: Masahiro Nishihori, MD, PhD
Department of Neurosurgery, Nagoya University Graduate School of Medicine, 65 Tsurumai-cho, Showa-ku, Nagoya 466-8550, Japan
Tel: +81-52-744-2353, Fax: +81-52-744-2360, E-mail: nishihori@med.nagoya-u.ac.jp

INTRODUCTION

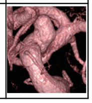
Compared with surgical clipping, endovascular coil embolization for paraclinoid aneurysms has been acknowledged as a less invasive modality and could get favorable outcomes.[1] In recent years, flow diverter stents have become an alternative for coil embolization; however, in some cases, coil embolization is still preferable to flow diverter stents for various reasons, hyporesponder of antithrombotic agents, and delayed aneurysm rupture. Owing to the characteristics of coil embolization for paraclinoid aneurysms, it is challenging to select a suitable microcatheter tip shape and obtain a stable intraaneurysmal position during coil insertion because of tortuous carotid siphons and misalignment between aneurysmal projections and the long axis of an internal carotid artery (ICA). An unsuitable tip shaping of a microcatheter may easily lead to deviation from an aneurysm, making repositioning difficult. Although a few studies have reported several catheter shapes based on the anatomical location of paraclinoid aneurysms, making decisions regarding the catheter shape is still often dependent on the operator's preference and experience.[2-4] Therefore, we devised original, simple, uniform three-dimensional (3D) spiral-shaping methods for paraclinoid aneurysms and were confident of their utility in clinical practice. This study aimed to validate the characteristics of the 3D spiral-shaping method using patient-specific pulsatile silicone models.

MATERIALS AND METHODS

Paraclinoid aneurysm selection for silicone models

Paraclinoid aneurysms that met the following conditions were extracted from our treatment data: maximum aneurysm diameter of 7 mm, secondary diameter of the first coil used of 6 mm, and misalignment between the long axis of the aneurysm and the ICA. Based on these criteria, four aneurysms were extracted from four patients (Figure 1A). Paraclinoid aneurysms were classified based on the aneurysmal projection and location. The aneurysmal projection was defined as a virtual line that crossed between the centers of the aneurysm sac and the aneurysm neck in the anteroposterior view on digital subtraction angiography. We categorized the aneurysms according to the angle formed between the horizontal and virtual lines in four projections: the superior, medial, inferior, and lateral[2] (Figure 1B). We further classified the aneurysm location into two groups (C3 or C2 segments) according to the relative anatomical location of the aneurysm's neck origin, using Fisher's classification.[5] The C3 segment (cavernous segment) starts from the proximal portion of the anterior genu to the origin of the ophthalmic artery. The C2 segment (supraclinoid segment) begins just distal to the origin of the ophthalmic artery and ends at the posterior communicating artery. Based on these criteria, the adopted aneurysms were classified as follows: model 1, medial type at C3; model 2, inferior type at C2; model 3, inferior type at C3; and model 4, superior type at C2. The aneurysm location, projection, size, clinical treatment, and 3D images are shown in Figure 1.

A

Aneurysm models	Aneurysm location	Aneurysmal direction	Neck, dome (mm)	Clinical treatment	Rotational direction of the spiral shaping	3D image
Model #1	Lt. ICA (C3)	Medial	3.7, 7.2 mm	BAC	Clockwise	
Model #2	Lt. ICA (C2)	Inferior	4.0, 7.8 mm	BAC	Clockwise	
Model #3	Rt. ICA (C3)	Inferior	4.5, 8.0 mm	BAC	Counter-clockwise	
Model #4	Lt. ICA (C2)	Superior	3.1, 7.0 mm	BAC	Counter-clockwise	

B

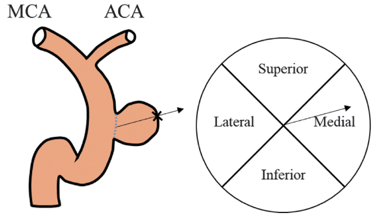


Fig. 1 Characteristics of the paraclinoid aneurysms adopted for the silicone models

Fig. 1A: Characteristics of the paraclinoid aneurysms and rotational direction of the spiral-shaped microcatheter.

Fig. 1B: The aneurysmal direction was defined by four directions (angle formed between the horizontal and virtual lines that crosses between the centers of the aneurysm sac and aneurysm neck); superior, medial, inferior, and lateral.

ICA: internal carotid artery
BAC: balloon-assisted coil embolization
MCA: middle cerebral artery
AC: anterior cerebral artery
3D: three-dimensional

Silicone models of an aneurysm and experimental setup

The raw 3D digital subtraction angiography data, extracted as Digital Imaging and Communications in Medicine files were used to create hollow-vessel models as ordered by an external manufacturer (FAIN-Biomedical, http://fain-biomedical.com). Pulsatile flow and pressure were created by a pulsatile pump, and distilled water with surfactant was added. The pump was set to a pulse, pressure, and temperature of 60 beats per min, 120/80 mmHg, and 37 °C, respectively, assuming an actual clinical situation.

3D spiral-shaping method

In this study, we used the Headway 17 (MicroVention, CA, USA) microcatheter because of its good shape consistency.[6] Initially, a shaping mandrel was made into a 3D spiral shape with a diameter of 5 mm and a pitch of 5 mm (Figure 2A). The operators decided only the rotational direction of the 3D spiral (clockwise or counterclockwise), which was judged by the projection of the aneurysm relative to the ICA. Then, the 3D spiral-shaped mandrel was inserted into a straight microcatheter to be 1 + 1/4 around from the tip (Figure 2B) and was heat-shaped by applying heat 2 cm from the heat source of a hot air gun (Bosch, Gerlingen, Germany) set at 110–120 °C for 60 s and cooled at room temperature for 60 s. After removing the mandrel, the ideal microcatheter shape was a 3D spiral with a rotation diameter and spiral pitch of 7 mm and 7 mm, respectively (Figure 2C). For comparison with the 3D spiral-shaped catheter, we used three catheters of different shapes: straight, preshaped 90°, and pigtail-shaped. We adopted a 2D pigtail shape with a maximum outer diameter of 7 mm, referring to a previous paper on the pigtail-shaped one (Figure 2D).[3,6]

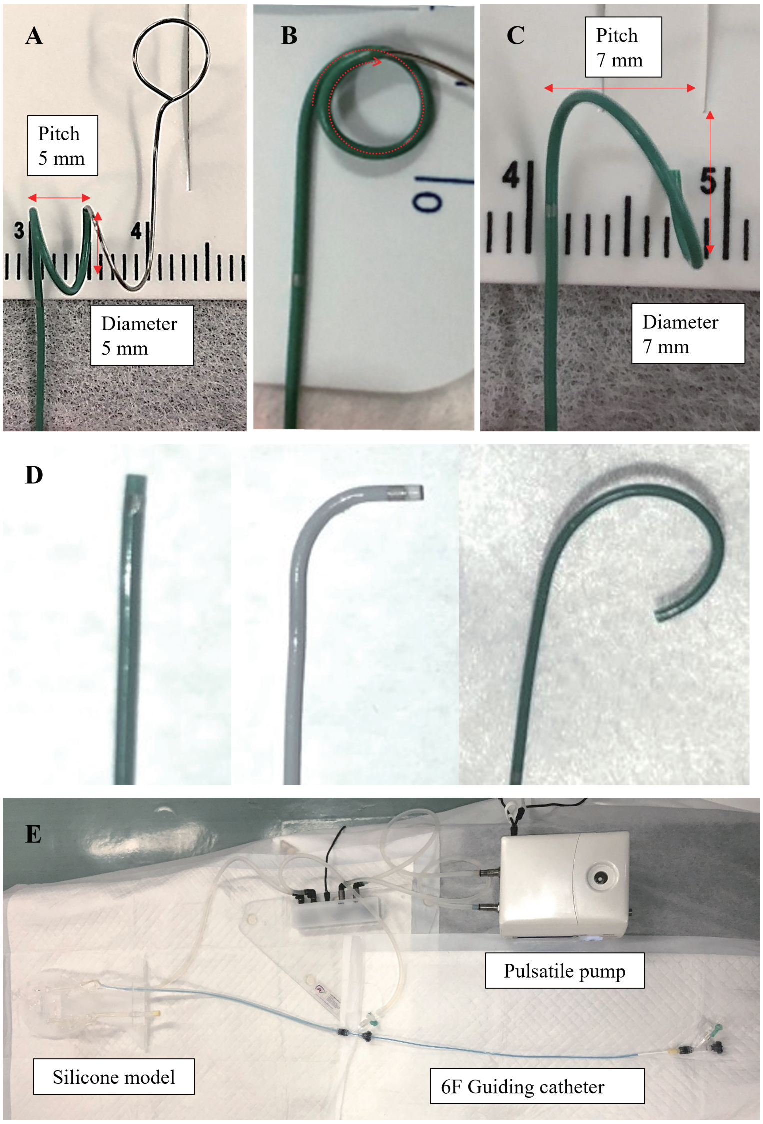


Fig. 2 The three-dimensional (3D) spiral-shaping method, other shapes, and experimental setup

Fig. 2A: Making a shaping mandrel into a 3D spiral shape with a diameter of 5 mm and a pitch of 5 mm.

Fig. 2B: The 3D spiral-shaped mandrel was inserted into a straight microcatheter to be 1 + 1/4 around from the tip.

Fig. 2C: After heat shaping, the ideal microcatheter shape is a 3D spiral with a diameter of 7 mm and a pitch of 7 mm.

Fig. 2D: Photographs of three microcatheters used for comparison: straight, preshaped 90°, and two-dimensional (2D) pigtail-shaped presented in order.

Fig. 2E: Experimental setup.

Assessment items and data analysis

The assessments were performed by biplane angiography using working angles, which had been the actual treatment. Microcatheters were inserted through a 6-Fr guided catheter (Envoy; Codman Neurovascular, Raynham, MA, USA) placed in a position corresponding to a cervical segment of the ICA in all studies (Figure 2E). Two operators with different levels of experience assessed the following items: (1) navigation methods of the microcatheters into the aneurysms (pullback or wire guiding), (2) time needed to guide the microcatheter into the aneurysms, (3) microcatheter tip position, and (4) whether framing coils could be inserted by a simple technique. Initially, the navigation protocol was to advance the shaped microcatheters beyond a targeted aneurysm by wire guiding and pulling back of the shaped microcatheter into the aneurysm after withdrawal of a guidewire tip into the microcatheter; if it failed, then it is advanced it into the aneurysm along the guidewire. Operators were asked to position the microcatheter tip as close to the center of the aneurysm as possible when starting coil embolization. The microcatheter tip position was checked in X-ray images and a good position means that the catheter tip could be placed within 70% of the diameter (equivalent to approximately 50% of the volume) from the center of the aneurysm. The tip position was checked at two arbitrary working angles and evaluated on three grades (excellent, good, and bad). After each microcatheter placement, we tried to insert the target 360 soft 6 mm × 20 cm coil (Stryker, Kalamazoo, MI, USA) as the first coil by a simple technique. If it could not be inserted within 5 min, it was judged as failure. Statistical analyses for the catheterization times for all microcatheters were compared using the Mann–Whitney U test, with Python version 3.7, and $p < 0.05$ was considered significant.

RESULTS

Navigation methods

Table 1 shows the summary of the guiding methods for each shaping and aneurysm projection. Every shaped microcatheter could be inserted into all aneurysm models. Each operator performed the procedure twice, and the results were consistent. The 3D spiral-shaped microcatheter could be placed into the aneurysms using the pullback method in models 1 (medial type), 2 (inferior type), and 4 (superior type). For model 3 (inferior type), only the pigtail-shaped catheter could be implanted in the aneurysm using the pullback method.

Table 1 Navigation methods of microcatheter into aneurysm model

Microcatheter	Model #1 medial	Model #2 inferior (C2)	Model #3 inferior (C3)	Model #4 superior
90°	Pullback	Wire	Wire	Wire
Straight	Pullback	Wire	Wire	Wire
Pigtail	Wire	Pullback	Pullback	Wire
Spiral	Pullback	Pullback	Wire	Pullback

C2: supraclinoid segment by Fisher's classification
C3: cavernous segment by Fisher's classification
Wire: advancing a microcatheter into aneurysm along a microwire
Pullback: positioning naturally in an aneurysm after withdrawal of a guidewire tip into the microcatheter

Catheterization times

Figure 3 shows the catheterization times needed to guide the microcatheter into the aneurysms. No significant difference between each shape was found in model 1 and model 2. For model 3, a pigtail-shaped catheter provided shorter catheterization times (39.5 s, interquartile range (IQR) 30–51.5 s) than a straight one (102.5 s, IQR 64.8–136.8 s, $p = 0.03$). For model 4, a 3D spiral-shaped catheter provided significant shorter catheterization times (46.5 s, IQR 38.3–57 s) than preshaped 90 (220 s, interquartile range 160–270 s, $p = 0.03$), straight (82.5 s, IQR 56–137.5 s, $p = 0.03$), and pigtail-shaped (184 s, IQR 121.8–258.3 s) microcatheters ($p = 0.02$). More experienced operator had significantly shorter catheterization times (57.6 s) than inexperienced ones (130.2 s, $p < 0.01$).

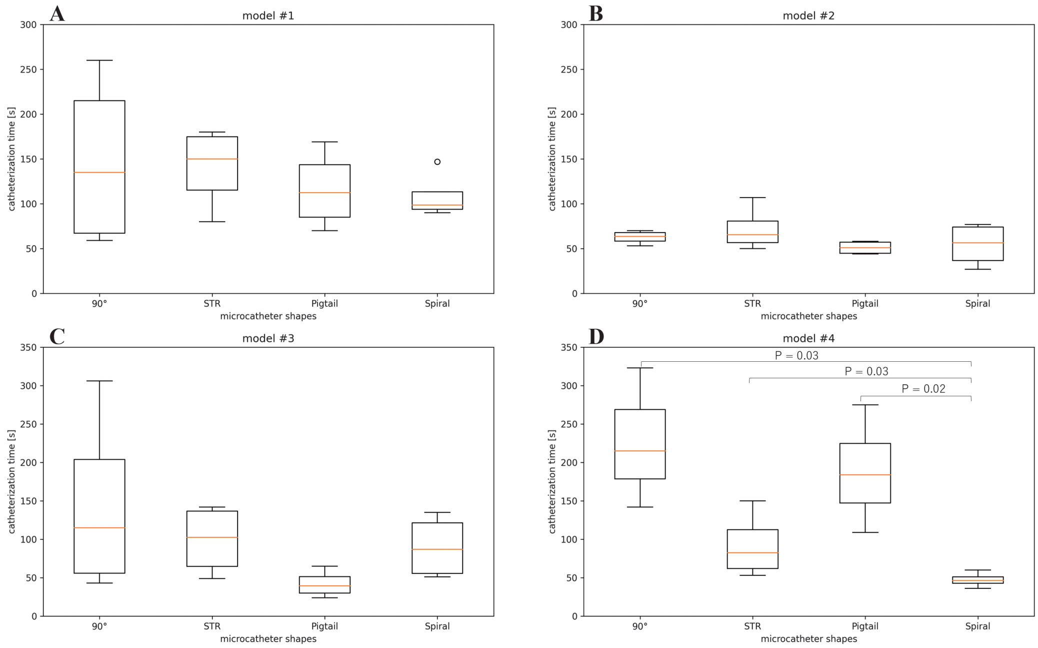


Fig. 3 Boxplot of the catheterization times needed to guide the microcatheter into the aneurysms
Fig. 3A: Model 1 for medial type at C3 segment.
Fig. 3B: Model 2 for inferior type at C2 segment.
Fig. 3C: Model 3 for inferior type at C3 segment.
Fig. 3D: Model 4 for superior type at C2 segment.
STR: straight shape

Microcatheter tip position and coil insertion

Table 2 showed that the tip positions of the 3D spiral-shaped and pigtail-shaped microcatheters tended to be at the center of the aneurysms. The preshaped 90° microcatheter was not suitable for superior projected aneurysms, but was easily adapted to other aneurysm models.

Table 3 shows the results of the coil insertion experiments. The 3D spiral-shaped microcatheters allowed the insertion of the first coil using a simple technique in models 1–3. For model 2, every shaped microcatheter could insert a coil into the aneurysm. On the contrary, for model 4, any microcatheter shape could not enable coil insertion by a simple technique.

Table 2 Evaluation of microcatheter tip position in three grades

Microcatheter	Model #1 medial	Model #2 inferior (C2)	Model #3 inferior (C3)	Model #4 superior
90°	Excellent	Excellent	Excellent	Bad
Straight	Bad	Bad	Good	Good
Pigtail	Good	Good	Excellent	Excellent
Spiral	Good	Excellent	Excellent	Good

C2: supraclinoid segment by Fisher's classification
C3: cavernous segment by Fisher's classification
Excellent: placing the microcatheter tip within 50% of the volume from the center of the aneurysm at two angles
Good: placing the microcatheter tip within 50% of the volume from the center of the aneurysm at one angle
Bad: failing to position the microcatheter tip within 50% of the volume from the center of the aneurysm at any angle

Table 3 Results of the coil insertion experiments

Microcatheter	Model #1 medial	Model #2 inferior (C2)	Model #3 inferior (C3)	Model #4 superior
90°	Failure	Success	Failure	Failure
Straight	Failure	Success	Failure	Failure
Pigtail	Failure	Success	Failure	Failure
Spiral	Success	Success	Success	Failure

C2: supraclinoid segment by Fisher's classification
C3: cavernous segment by Fisher's classification
Success: successful insertion of a first coil (Target 360 soft 6 mm × 20 cm) by a simple technique within 5 minutes
Failure: failing to insert a first coil (Target 360 soft 6 mm × 20 cm) by a simple technique within 5 minutes

DISCUSSION

In this study, we validated the utility of the 3D spiral-shaping method using patient-specific pulsatile silicone models. The advantages of our 3D spiral-shaped microcatheter are as follows: it could be guided for paraclinoid aneurysms in a short time without using wire guidance into them. These findings suggested that this simple and uniform shaping method was highly versatile for safe and easy guiding into the paraclinoid aneurysms.

For the superior projected aneurysm, the catheterization time using the 3D spiral-shaped catheter was significantly shorter than that using other shapes, indicating that it may be one of the ideal shapes. Some previous studies have reported microcatheter shaping methods for paraclinoid aneurysms based on aneurysm projections.[3,4] Kwon et al classified paraclinoid aneurysms into three types, namely, superior, medial, and other, based on the projection and favorable microcatheter shape for each type. They noted the efficacy of an "S"-shaped catheter for superior projected paraclinoid aneurysms. However, details of their original shaping methods were not mentioned in their reports, and the shapes are difficult to reproduce, particularly for inexperienced operators.[3] An “S”-shape catheter can be maneuvered with the first curve from the catheter tip contacting the vessel wall opposite the aneurysm as a support point. Due to the various vascular configurations of carotid siphons, creating suitable “S”-shaped microcatheters requires operator experience to determine the appropriate microcatheter route, support points, and adjustments to the shaping length and angle. Additionally, multiple reshaping attempts may be necessary to adapt to the actual pathway for microcatheter cannulation into the aneurysm. Therefore, inexperienced operators find it challenging to reproduce the “S”-shape microcatheter. On the contrary, a 3D spiral shape is unnecessary when adjusting the shape individually depending on the aneurysm size or vascular running.

To the verify versatility of our method, which appeared to be independent of the individual’s preference or guiding technique, we checked the interoperator variability and catheterization times using 3D spiral-shaped catheters. We found slight variance, suggesting that this shaped catheter could be handled safely by any operators regardless of their ability. This could be explained by the characteristic of the shape, which was allowed to naturally turn toward the aneurysm after withdrawal of the guidewire tip into the microcatheter.

Regarding the catheter tip position in the aneurysm, the 3D spiral- and pigtail-shaped catheter tips tended to be placed in the center of the aneurysms. Nevertheless, no correlation was found between the tip position and the results of coil placement by simple technique. In most failure cases attempted with other shapes, once the microcatheter deviated into the parent artery during coil insertion, repositioning it was challenging. The 3D spiral-shaped catheter could enable coil insertion because it moved and adjusted spontaneously with the best direction to an aneurysm. However, because the poor stability of the microcatheter after its placement due to the few support points on the vessel wall, it tended to easily result in kickback with increased volume embolization ratio and coil insertion force. Therefore, balloon assist techniques should be applied to support the 3D spiral-shaped microcatheter accordingly. In the treatment of aneurysms simulated in the silicone model, the balloon-assisted technique was used in all cases, and the balloon use rate was higher than previously reported.[2,3]

The pulsatile silicone models adopted in this study were excellent in vitro method because multiple examiners can validate the models under conditions close to clinical practice. Until the advent of 3D printing technology, it was difficult to verify whether the catheter shape was optimal. It was not practical to perform several catheterizations into a single aneurysm for clinical validation with the risk of perforation and radiation exposure. Recently, a method of preparing 3D aneurysm and blood vessel models to create tailor-made 3D microcatheter shaping before endovascular treatment has been reported.[7-9] However, it should assume the trajectory of the microcatheter path. Correcting the catheter shape could be difficult if it cannot be as expected as simulated, and applying the results to the treatment of other aneurysms could be limited. Therefore, a reproducible and versatile microcatheter shape should be considered for postoperative validation. Because of the cost and time required to prepare the hollow models and the pump, it is not yet a standard method. In the last few years, there are some reports of computer-assisted microcatheter shaping using simulation, which may be easier than 3D printers.[10] In the near future, if these methods become widespread and sufficient numbers of aneurysm are easily externally validated, such data may lead to the establishment of more generalized shaping methods for cerebral aneurysms.

This study has some limitations. First, the models adopted for this study do not represent all the locations, projections, and sizes of paraclinoid aneurysms. We employed cases in which the direction of the ICA runs and the direction of the aneurysm are misaligned, and the conditions of the aneurysm and neck diameters are the same as much as possible. Therefore, small aneurysms with a maximum diameter of ≤5 mm and cases with stenotic necks or small mother vessel diameters may not be successfully applied. Second, patient-specific thoracoabdominal access route and skull corresponding to the petrous and cavernous portion were not analyzed. These influences the surface friction of the models and microcatheter behavior. Finally, we have not compared custom 3D-shaped catheters for each vascular running. In our opinion, when compared with these, the 3D spiral-shaped ones might be less supported by the vascular wall on the opposite side. However, we could demonstrate in vitro results that were nearly identical to the impressions in clinical practice. We have already treated numerous aneurysms using the spiral-shaped microcatheter and would like to report our clinical results in a future publication.

CONCLUSION

In this study, we validated the utility of the original 3D spiral-shaping method for paraclinoid aneurysms using patient-specific pulsatile silicone models. This method was found to be especially effective for superior projected aneurysms of the C2 segment in our silicone models. This simple and uniform method only requires consideration of the clockwise direction of the spiral catheter toward the aneurysm, and provides easy and secure navigation of the microcatheter into the paraclinoid aneurysm.

CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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