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Original Article

Evaluation of the Partial Re-Sheathing Technique with the Solitaire Stent Retrieval System *In Vitro* Model and a Representative Case

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Objective: Vascular injuries are severe complications associated with endovascular thrombectomy. In the present study, we evaluated the re-sheathing technique with the Solitaire stent retrieval system to overcome these complications.
Methods: We examined the diameter and resistance to retrieval of the Solitaire FR device (6 × 20 mm) during full and partial deployment *in vitro* model. We also examined a representative case in which the re-sheathing technique was used.
Results: We found that the Solitaire device spread elliptically during partial deployment. As the length of the partially deployed device decreased, the maximum diameter also decreased. The distal half of the stent retained 80% of the maximum diameter of the partially deployed Solitaire. The resistance to retrieval was significantly higher during full deployment (mean ± standard deviation; 0.32 ± 0.04 kg) than during half deployment (0.22 ± 0.04 kg) (Mann–Whitney U test; p = 0.006). The re-sheathing technique was used in the representative case due to the high resistance to retrieval, which enabled recanalization without extravasation.
Conclusion: In cases of high resistance to retrieval, minimal re-sheathing may be useful for capturing the thrombus without increasing the risk of vascular injury.

Keywords ▶ re-sheathing technique, Solitaire stent, *in vitro*

Introduction

In the Solitaire with the Intention for Thrombectomy as Primary Endovascular Treatment (SWIFT PRIME) trial, endovascular thrombectomy was performed with the Solitaire FR (Medtronic Neurovascular, Irvine, California, USA) or Solitaire 2 (Medtronic Neurovascular) device. Intra-arterial treatment is effective for emergency revascularization in patients with proximal intracranial arterial occlusion due to ischemic stroke.[1)]

However, there is a significant correlation between complications and unfavorable clinical outcomes.[2)] The subarachnoid hemorrhage (SAH) had occurred in 4% of patients who had received treatment with a stent retriever with intravenous tissue plasminogen activator (t-PA) in the SWIFT PRIME trial[1)] and in 16.2% of patients who had undergone mechanical thrombectomy with the Solitaire device as first-line treatment.[3)] Safety and high recanalization rates are important in thrombectomy using stent retrievers.

A stent retriever is usually deployed by unsheathing. The device then passively expands into its original shape, at which point the indentations of the stent struts interact with the thrombus.[4)] To improve apposition of the stent retriever to the vessel wall, the push and fluff [5)] and active push deployment[4)] techniques have been described for the Trevo Retriever (Stryker Neurovascular, Mountain View, CA, USA) which has a closed-cell stent-like shape.[5)] The Solitaire device has an open-ring structure with folded overlapping rims.[4)] The active push deployment technique is also effective for the Solitaire device.[4)]

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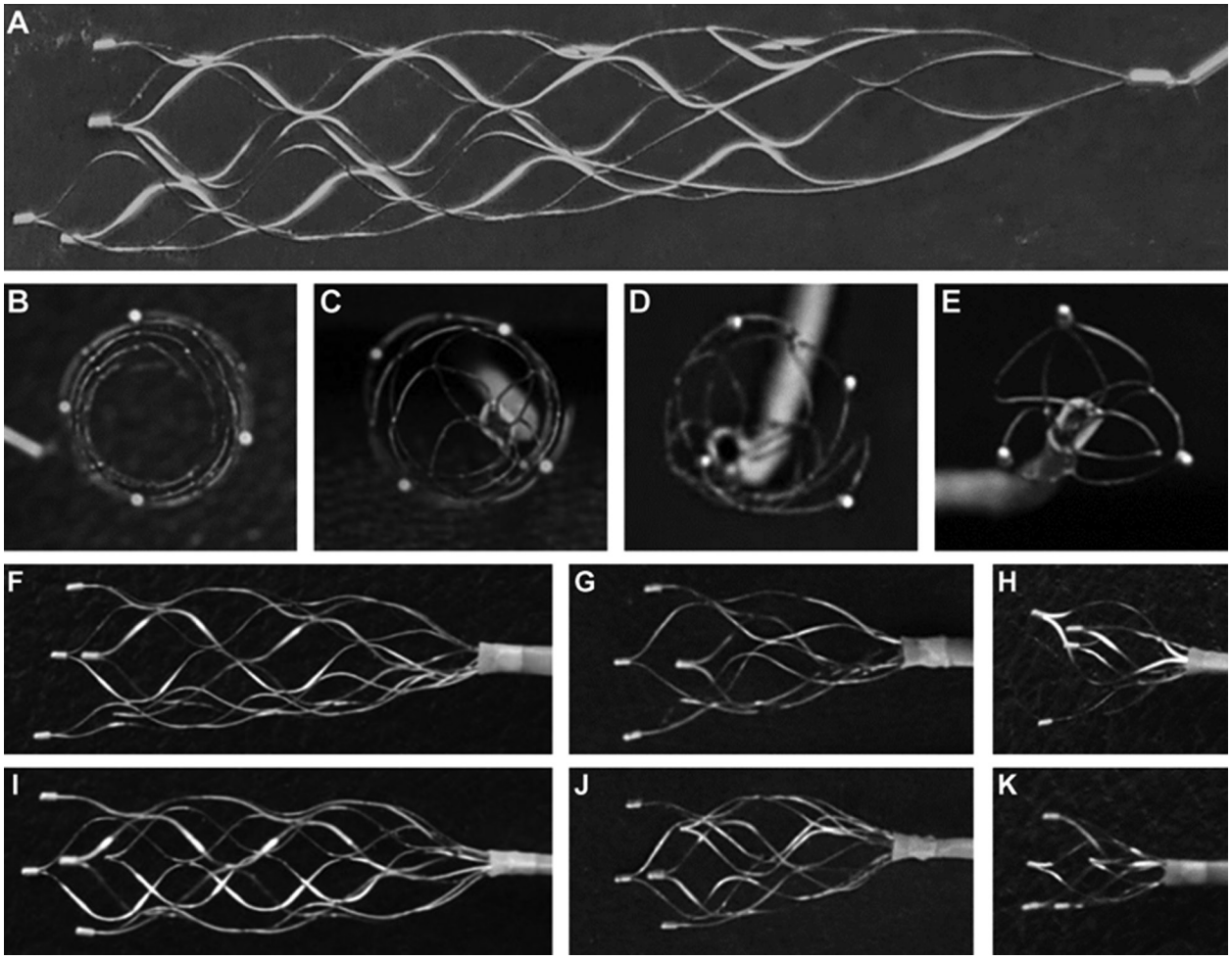

Fig. 1 (**A**) Full deployment of the Solitaire device (diameter: 6 mm, usable length: 20 mm, total length: 31 mm). Short-axis view of full deployment (**B**), three-fourths (**C**), half (**D**), and one-fourth (**E**). Long-axis view from the direction of the large diameter in the three-fourths (**F**), half (**G**), and one-fourth (**H**). Long-axis view from the direction of the narrow diameter in the three-fourths (**I**), half (**J**), and one-fourth (**K**).

In addition to the full deployment technique, partial deployment or re-sheathing techniques have also been reported.[6,7] The partial deployment was used to remove the thrombus at the M2/3 bifurcation of the middle cerebral artery (MCA). They deployed half the working length of the stent retriever with adequate length to engage the thrombus and avoided unnecessary length of stent deployment across the sharp angles of the vessel.[6] The re-sheathing technique with the Solitaire device, which was achieved by pushing the aspiration catheter, secured the thrombus within the stent and decreased the distance over which the thrombus needed to travel.[7]

An *in vitro* study has described the characteristics of various stent retrievers;[8] however, to the best of our knowledge, no study has examined the partial deployment or re-sheathing status with the Solitaire device *in vitro* model. In the present study, we investigated the effects of the re-sheathing technique with the Solitaire device by evaluating changes in diameter and resistance to retrieval *in vitro* model. We further evaluated a representative case in which recanalization was achieved via the re-sheathing technique.

Materials and Methods

In vitro model

We evaluated the Solitaire FR device (6 × 20 mm) (**Fig. 1A**); however, due to limited resources, only one Solitaire system was used for all evaluations. All tests were performed at room temperature.

Changes in the diameter of the Solitaire device due to partial deployment

We investigated changes in the diameter of the Solitaire system based on whether the device had been fully or partially

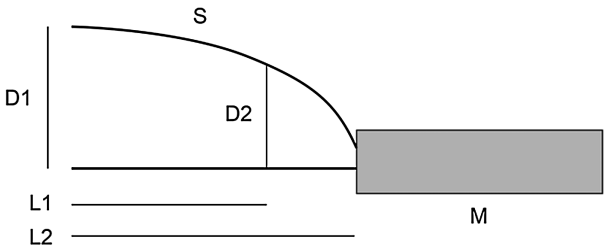

Fig. 2 Schematic diagram illustrating the measurement method for the percentage of the device's length that retained 80% of its maximum diameter (D1, maximum diameter of the partially deployed Solitaire device; D2, 80% of maximum diameter; L1, length measured from the tip of the Solitaire device that retained 80% of the maximum diameter of the partially deployed Solitaire device; L2, length of the partially deployed Solitaire device; S, Solitaire device, M, microcatheter). The percentage of length that retained 80% of the maximum diameter was obtained by calculating L1/L2 × 100.

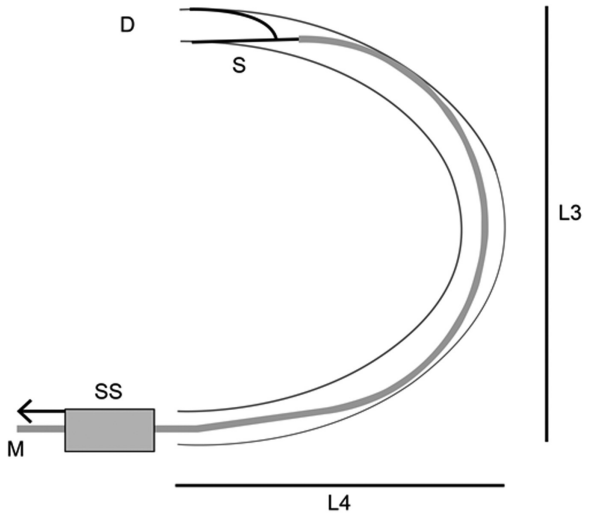

Fig. 3 Schematic diagram illustrating the silicone tube model used to evaluate resistance to retrieval (L3 = 60 mm; L4 = 50 mm; D = 2.5 mm; S, Solitaire device; M, microcatheter; SS, the position of the spring scale). We deployed the Solitaire device at the opening of the silicone tube. We evaluated the resistance by pulling the spring scale in the direction indicated by the arrow.

deployed. A Marksman microcatheter (Medtronic, Minneapolis, MN, USA) was used to deliver the Solitaire device. For partial deployment, length was measured from the tip of the Solitaire device to the tip of the microcatheter. We observed the changes in diameter on the short- and long-axis photographic images under the following three length conditions: three-fourths, half, and one-fourth deployment. The diameter was measured at the site where the outer edge of the stent spread. During full deployment, the Solitaire device opens concentrically (**Fig. 1B**). However, during re-sheathing, the device spreads elliptically (**Fig. 1C–E**). Therefore, we evaluated the long-axis images in the re-sheathing condition based on the direction of the large diameter, as well as the narrow diameter. We measured the maximum diameter near the tip of the device in each situation.

When evaluating the long-axis images, we defined the percentage of the device's length that retained 80% of its maximum diameter as follows: (length measured from the tip of the Solitaire device that retained 80% of the maximum diameter of the partially deployed Solitaire device)/(length of the partially deployed Solitaire device) × 100 (**Fig. 2**). The diameter and length were measured by an investigator blinded to the study results using Image J software (National Institutes of Health, Bethesda, MD, USA).

Resistance to retrieval

For the *in vitro* model, we used a curved silicone tube with an inner diameter of 2.5 mm (**Fig. 3**). We measured the length of partially deployed Solitaire device by unsheathing the device. After measuring the length, we fixed the delivery wire of the Solitaire device and a microcatheter. We deployed the Solitaire device at the entrance of the silicone tube and connected a spring scale with a microcatheter. We removed the Solitaire system by directly pulling the spring scale. The maximum scale value during retrieval was recorded. Retrieval and reading of the scale were performed by different investigators who remained blinded to the study results. Resistance to retrieval was examined under two conditions: Full deployment and half deployment. Experiments were repeated seven times for each condition.

Representative case

We retrospectively collected data from the medical records of patients with acute ischemic stroke caused by a proximal intracranial anterior circulation lesion, who exhibited tortuous anatomy, and had received intra-arterial treatment using the re-sheathing technique at an institution between January 2016 and July 2016. The study was approved by the ethics committees of the institutions.

Statistical analysis

Mann–Whitney U tests were used to compare data from the full and partial deployment conditions. Data are presented as the mean ± standard deviation. The level of statistical significance was set at $p < 0.05$. Statistical analyses were performed using Excel Statistics software (BellCurve for Excel, version 2.14 for Windows; Social Survey Research Information Co., Ltd., Tokyo, Japan).

Table 1 Change in the diameter of the solitaire device during partial deployment

	Maximum diameter (mm)	Percentage of the device's length that retained 80% of its maximum diameter (%)
Large view		
Three-fourths	5.7	69
Half	5.4	57
One-fourth	4.5	68
Narrow view		
Three-fourths	5.0	81
Half	4.6	72
One-fourth	3.8	54

Large view: Evaluation of long-axis images based on the direction of the large diameter. Narrow view: Evaluation of long-axis images based on the direction of the narrow diameter. Percentage of the device's length that retained 80% of its maximum diameter: (length measured from the tip of the Solitaire device that retained 80% of the maximum diameter of the partially deployed Solitaire device)/(length of the partially deployed Solitaire device) × 100.

Results

In vitro model

Changes in the diameter of the Solitaire device due to partial deployment (Fig. 1) (Table 1)

During partial deployment, the Solitaire device spread elliptically. As the length of the partially deployed device decreased, the maximum diameter decreased. The percentage of the device's length that retained 80% of its maximum diameter ranged from 54% to 81%. The distal half of the partially deployed Solitaire device was more likely to maintain a constant diameter than the proximal half which exhibited pronounced decreases in diameter.

Resistance to retrieval (Fig. 4)

The resistance to retrieval was measured seven times for each condition. The resistance to retrieval was significantly higher for full deployment (0.32 ± 0.04 kg) than for half deployment (0.22 ± 0.04 kg) (Mann–Whitney U test; $p = 0.006$).

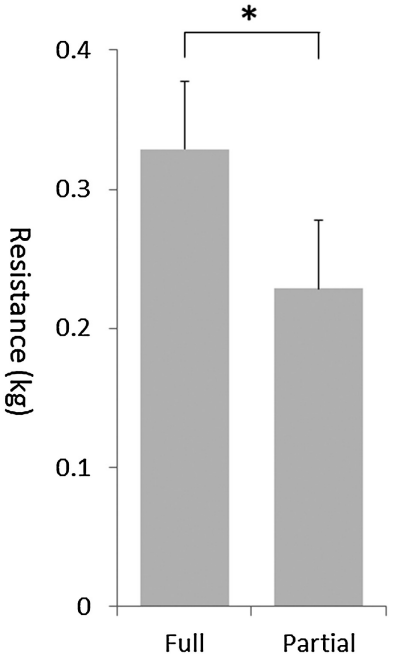

Fig. 4 Resistance to retrieval. Bar graph showing values measured using the spring scale. The average values for the full and half partial deployment were 0.32 ± 0.04 kg and 0.22 ± 0.04 kg, respectively. Error bars represent the standard deviation across subjects. *p <0.05, Mann–Whitney U test.

Case Presentation (Fig. 5)

The patient in the present study was a 90-year-old woman who lived at home and had experienced sudden left hemiparesis. She was diagnosed with cerebral infarction and underwent intravenous t-PA and endovascular therapy.

Tortuous anatomy was observed between the aortic arch and the internal carotid artery (ICA). Digital subtraction angiography (DSA) revealed occlusion of the right MCA. We could not advance the guiding catheter and intermediate aspiration catheter further due to common carotid artery (CCA) loop formation. We advanced the Marksman microcatheter and deployed the Solitaire FR device (6 × 30 mm). Prior to retrieval, the guiding catheter was placed on the proximal side of the loop formation in the CCA. When we attempted to retrieve the Solitaire device, the guiding catheter moved distally to the ICA, and the loop formation of CCA was stretched. However, the resistance to retrieval prevented movement of the Solitaire device. To avoid the risk of vascular injury, we decided to use the re-sheathing technique by pushing the microcatheter. The Solitaire device was retrieved without further pulling on the delivery wire. Recanalization of almost all the MCA territories was achieved without extravasation and SAH in sylvian fissure.

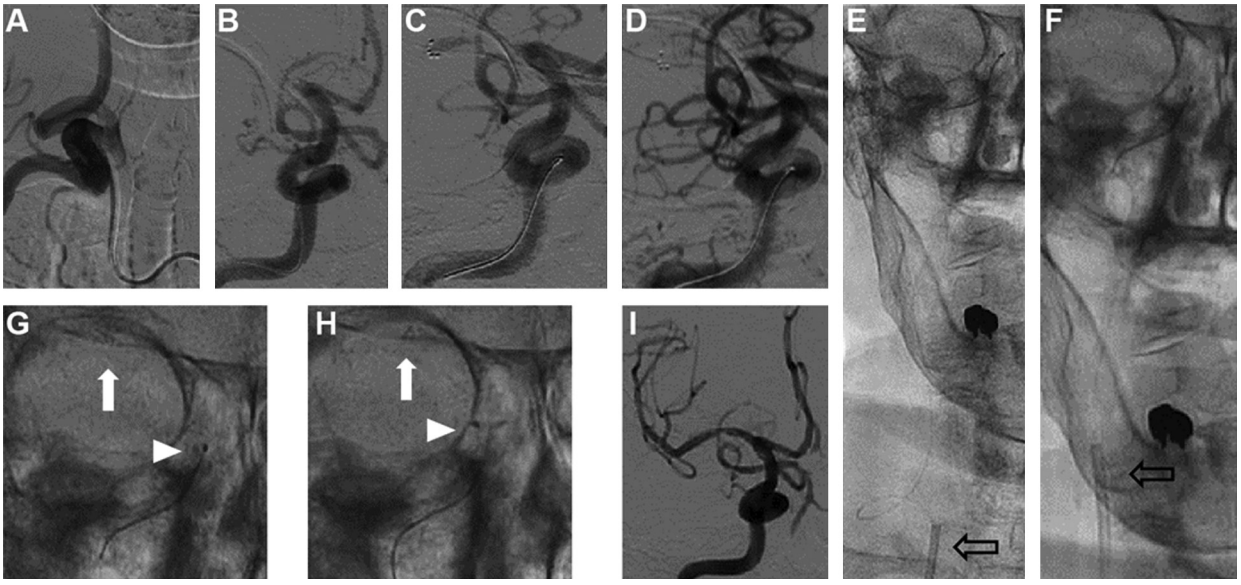

Fig. 5 Representative case. (**A**) DSA (anteroposterior view) showing tortuosity and loop formation in the right CCA. (**B**) DSA (anteroposterior view) showing occlusion of the right MCA. Tortuous anatomy was also observed between the petrous and ophthalmic segments of the ICA. The horizontal portion of the cavernous segment of the ICA exhibited a mediolateral course. (**C**) DSA (anteroposterior view) showing immediate, partial reperfusion following full deployment of the Solitaire device (6 × 30 mm). (**D**) DSA (anteroposterior view) showing early loss of immediate reperfusion. Fluoroscopy (anteroposterior view) showing guiding catheter (open arrow) placement on the proximal side of loop formation at the CCA (**E**) and moving distally towards the ICA during retrieval (**F**). However, the resistance to retrieval was too high to enable movement of the Solitaire device. (**G**) Fluoroscopy (anteroposterior view) showing the tip of the Solitaire device (arrow), and the tip of the microcatheter (arrowhead) was placed at the proximal side of the cavernous segment of the ICA before re-sheathing. (**H**) Fluoroscopy (anteroposterior view) showing the tip of the Solitaire device (arrow); the tip of the microcatheter (arrowhead) had moved to the distal side of the cavernous segment of the ICA by re-sheathing. The Solitaire device was retrieved following re-sheathing. (**I**) DSA (anteroposterior view) showing recanalization of the MCA without extravasation. CCA: common carotid artery; ICA: internal carotid artery; DSA: Digital subtraction angiography; MCA: middle cerebral artery

Discussion

When partially deployed, the Solitaire device spread elliptically as opposed to concentrically. Re-sheathing resulted in a decrease in diameter and resistance to retrieval of the Solitaire device. The distal half of the partially deployed Solitaire device retained 80% of its maximum diameter. Additionally, we demonstrated the usefulness of the minimum necessary re-sheathing technique in a representative case. To the best of our knowledge, the partial deployment status of the Solitaire device *in vitro* model was described by the present study for the first time.

As the length of the partially deployed Solitaire device decreased, the maximum diameter decreased; however, the percentage of the device's length that retained 80% of its maximum diameter did not decrease proportionately and ranged from 54% to 81%. The partially deployed device manifested a non-concentric shape on the short-axis view. Therefore, it is important to recognize that the diameter of the partially deployed Solitaire device depends not only on the length from the tip of the Solitaire device but also on the part of the Solitaire device.

As the Solitaire system relies on direct clot retrieval, there is a risk of arterial injury when employing the device.[9] Defects of the internal elastic lamina and denudation of the wavy endothelial surface have been observed in animal models.[9] SAH due to vessel rupture is among the most severe complications associated with endovascular thrombectomy. SAH does not typically occur following vessel perforation;[5] however, resistance to retrieval may stretch the affected artery and accompanying vein, resulting in SAH.[3] Use of the re-sheathing technique resulted in decreases in both the length and diameter of the Solitaire device, which may explain the decrease in resistance to retrieval. Additionally, the radial pressure exerted by stent retrievers on the vessel wall is inversely proportional to the length of the deployed stent.[8] Therefore, the re-sheathing technique could minimize the risk of vascular injury.

However, the re-sheathing technique may be associated with a decreased recanalization rate due to decreases in the diameter of the device and fragmentation of the thrombus. Expansion of the Solitaire device compresses the thrombus against the vessel wall, leading to immediate restoration of blood flow, the rate of which subsequently decreases. This

decrease may be caused by migration of the thrombus through the stent struts over time.[10] Early loss of immediate reperfusion has been associated with a higher rate of final successful reperfusion.[11] Therefore, it is important to first achieve adequate radial force to the thrombus. In a previous report on the partial deployment of the stent retriever, half the working length of the stent retriever was deployed; it was of adequate length to engage the thrombus.[6] Since the maximum diameter decreases during partial deployment, we speculate that if the Solitaire device is partially deployed from the beginning of the procedure, the initial expansion may be inadequate. We speculate that it is more effective to first fully deploy the Solitaire device to achieve adequate indentation of the thrombus. If the resistance to retrieval remains too high, minimal re-sheathing could be performed to minimize the risk of vascular injury while ensuring thrombus removal. The minimal re-sheathing may decrease the risk of the fragmentation of the thrombus. We presented only one case with the usefulness of the re-sheathing technique as the rescue method to overcome high resistance to retrieval. Although the partial deployment or re-sheathing techniques has also been reported,[6,7] The further large-scale validation studies are required to evaluate the safety and efficacy of this technique. Additionally, we will evaluate whether or not the re-sheathing technique is more optimal than semi-deployed technique from the beginning of the procedure to treat vessels with distal and tortuous anatomy.

Limitations

The present study has limitations. The manual retrieval of the Solitaire device and visual judgement of stent diameter have influenced the reproducibility of our results. As we used a silicone tube with a consistent diameter of 2.5 mm for the resistance experiments, the Solitaire device was relatively oversized. Furthermore, the vessel anatomy in this study did not correspond to that of vessels with varying diameters. Future studies should evaluate this technique in greater detail using more precise equipment under variable conditions.

In addition, we used only one Solitaire system for all evaluations due to limited resources. In the study of the resistance to retrieval, the standard deviation of the scale was small; however, it is possible that the re-utilization of the stent retriever changes the characteristics of the Solitaire system. Solitaire system has several types, such as 6 × 30 mm and 4 × 20 mm. The utility of the combined aspiration and stent retrieval technique for thrombectomy has been reported.[7,12,13] The stent was withdrawn and/or re-sheathed into the larger intermediate type catheter.[7,12,13] In future studies, we aim to compare various types of stent retrievers including Trevo type and larger intermediate catheters for more applicable data.

The resistance to retrieval could be changed by employing different deployment technique. The push and fluff [5] and the active push deployment[4] techniques are used to increase the radial force exerted on the thrombus by actively pushing the stent retriever. In our experiments to evaluate the resistance to retrieval, the Solitaire system was evaluated in the unsheathed status, and not in the re-sheathing status. The delivery wire of the Solitaire system was kept at the same place in each condition. We speculate that the radial force between the unsheathed and re-sheathing status of the Solitaire device may change less markedly than that during the push and fluff and active push deployment status. We will confirm the difference of the stent retrieval system condition in various deployment techniques.

Conclusion

During re-sheathing, the Solitaire device was spread elliptically. Re-sheathing resulted in a decrease in the diameter of the stent and resistance of stent retrieval. The distal half of the partially deployed Solitaire device retained 80% of its maximum diameter. The findings of the present study indicate that minimal re-sheathing of the Solitaire device may be useful in cases where high resistance is encountered during retrieval.

The study was approved by the ethics committees of the institutions (Permission number: 2018-1 and 19-1102). The study was performed in accordance with the guidelines of these committees.

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Disclosure Statement

The authors of this study declare no conflict of interest.

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