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Original Article

Experimental Validation of Pullout Resistance for Stent Retrievers and Aspiration Catheters

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Objective: Stretching or avulsion of a small perforating artery caused by mechanical traction contributes to intracranial hemorrhagic complications in mechanical thrombectomy, especially for medium and small-vessel occlusions. This study aimed to measure the pullout resistance during stent retriever (SR) traction and aspiration catheter (AC) traction with or without thrombi and characterize the mechanical properties of each device.
Methods: We placed the thrombectomy device in the area corresponding to the insular segment of the middle cerebral artery of a silicon carotid artery model. The thrombectomy device was automatically pulled out at a constant velocity using a horizontal motorized test stand, and pullout resistance was continuously measured 2000 times per second using a digital force gauge. Five types of SRs and two types of ACs with or without thrombus were evaluated. The data were divided into four groups for analysis: SR without clot, SR with clot, AC without clot, and AC with clot.
Results: The line graph was a jagged waveform during SR traction, and it was a gentle curve during AC traction. The maximum pullout resistance was higher in the SR with clot group than the other groups. The coefficient of variation was higher in the SR group than the AC group, with or without clot.
Conclusion: The pullout resistance during SR traction was more fluctuated than that during AC traction. In the presence of a thrombus, pullout resistance for SR was substantially increased, whereas AC resistance was less susceptible to thrombi. The differences in characteristics may reflect differences in the frequency of mechanical traction injury between the devices during clinical use.

Keywords ▶ pullout resistance, stent retriever, aspiration catheter, thrombectomy

Introduction

Stent retrievers (SRs) and aspiration catheters (ACs) are mainly used in mechanical thrombectomy for acute ischemic stroke. Thrombectomy for medium and small-vessel occlusion is becoming widespread as low-profile devices are developed. However, hemorrhagic complications due to stretching or avulsion of small perforating arteries during mechanical traction are a major issue.[1–4] The resistance transmitted to the operator's fingertip when withdrawing thrombectomy devices is the sum of all frictional forces generated by the device, the tortuosity of the vessel, the properties of the thrombi, the thrombi–vessel interaction, and the device–vessel interaction. When the operator feels high pullout resistance, the blood vessels are overstretched due to the retrieval device, which may increase the risk of intraprocedural subarachnoid hemorrhages.

In this study, we experimentally evaluated the pullout resistance of thrombectomy devices under various conditions using an experimental vascular model, an automatic withdrawal machine, and a digital force gauge. The aim of this study was to measure the pullout resistance during SR and AC traction with or without thrombi and characterize the mechanical properties of each device.

Materials and Methods

A commercially available silicon carotid artery model, including two branches of the middle cerebral artery

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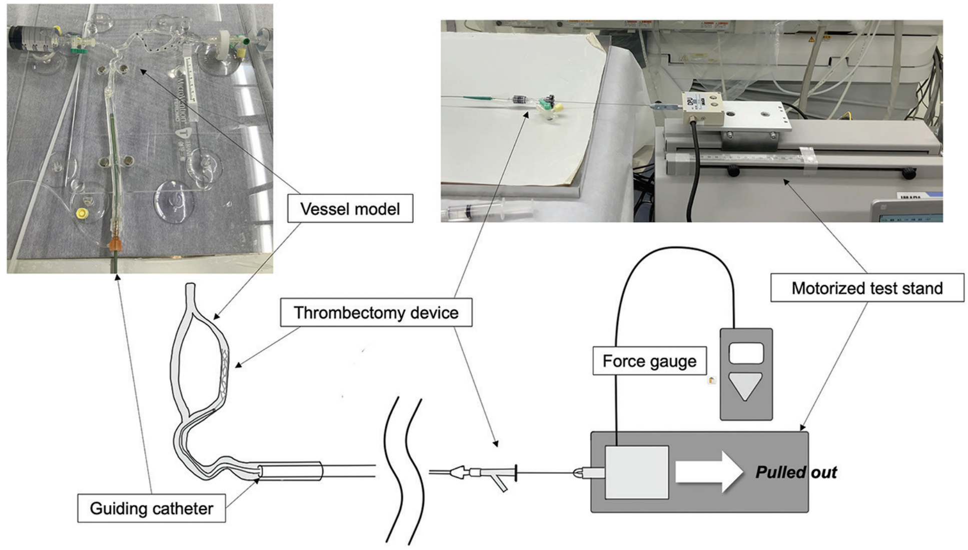

Fig. 1 Photographs and diagram of the thrombectomy device automatic pullout test.

(TrandoMed, Zhejiang, China), was used. The lumen was filled with saline and a guiding catheter (Destination 6F; Terumo, Tokyo, Japan) was placed in the proximal part of the internal carotid artery. We set the start line for pulling out the device in the area corresponding to the insular segment of the middle cerebral artery. The inner diameter was 2.1 mm at the start line. The proximal end of the working length was aligned with the start line for the SR, and the tip of the catheter was aligned with the start line for the AC. The proximal end of the thrombectomy device was fixed to a horizontal motorized test stand (Imada, Aichi, Japan) and automatically pulled out at a constant speed. The traction speed was set a 5 mm/second. Pullout resistance was continuously measured 2000 times/second by a high functionality mode digital force gauge (Imada) connected to the test stand (**Fig. 1**).

To eliminate errors caused by deflection, we used 20-second measurements after the deflection was removed and the pulling force was transmitted to the tip of the devices (after the pullout resistance exceeded 0.2 N). The following five SRs and two ACs were evaluated: Trevo NXT 3 × 32 (Stryker, Kalamazoo, MI, USA), Tron 4 × 20, Tron 4 × 40 (Terumo), Solitaire Platinum 4 × 40 (Medtronic, Irvine, CA, USA), Embotrap II 5 × 33 (Johnson & Johnson, Irvine, CA, USA), and Sofia Flow and Sofia Flow Plus (Terumo). The withdrawal experiment was performed 3 times for each device with and without a thrombus. A clot analog was made with swine blood. Whole blood samples were collected in centrifuge tubes without thrombin. After collection, tubes were stored at room temperature for 24 hours. The resulting blood clot was cut into 5 × 11 mm squares (0.15g) and pushed to the starting line in the vessel model.

We defined the maximum pullout resistance in one trial as R_{max}. The degree of pullout resistance fluctuation is represented by the coefficient of variation (CV) and calculated as CV (%) = (standard deviation/mean) × 100. We divided the data into the following four groups to analyze the differences in SRs and ACs: SRs without clot (SR−), SRs with clot (SR+), ACs without clot (AC−), and ACs with clot (AC+).

We compared pullout resistances between two groups using the Mann–Whitney *U* test. We compared pullout resistance between more than three groups using the Tukey–Kramer Honest Significant Difference test. We used a commercially available statistical software program (JMP 8; SAS Institute, Cary, NC, USA) for analysis. We considered P values of <0.05 statistically significant. The research within our submission has been approved by the ethics institutional review board of Fujieda Municipal General Hospital.

Results

The simplified waveforms for pullout resistance during SR and AC traction are shown in **Fig. 2**. SR traction exhibited a jagged waveform because the pullout resistance increased when the stent part was hooked and stretched at the bend of the vessel and decreased sharply when the stretched stent was released. For AC traction, the pullout resistance increased over time but did not fluctuate much after

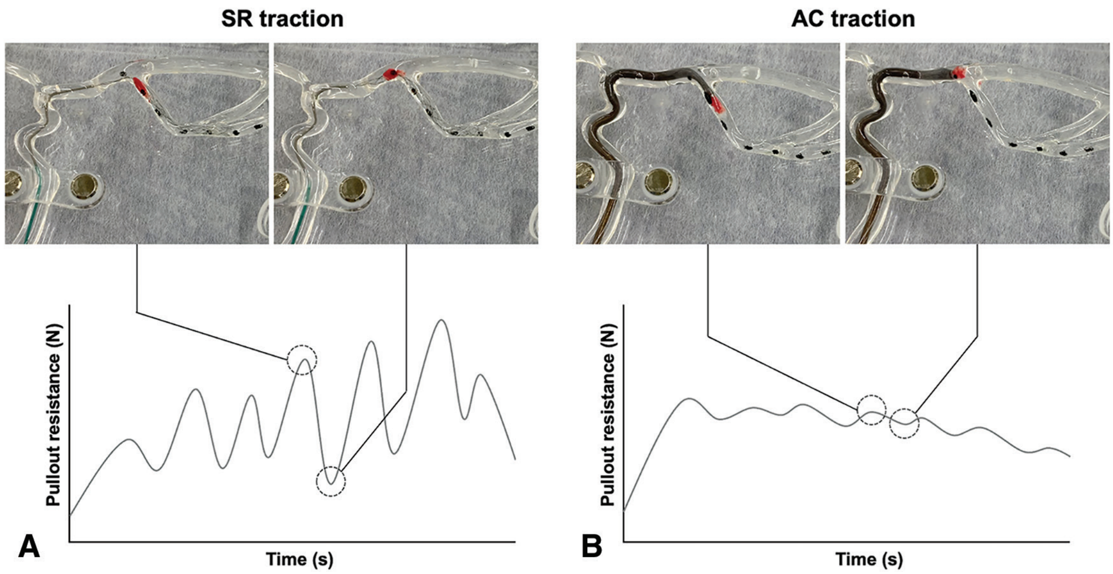

Fig. 2 Representative pictures of the devices and simplified waveforms of temporal changes in pullout resistance. (**A**) SR traction exhibits a jagged waveform because the stent stretches and releases repeatedly. (**B**) AC traction exhibits a gentle curve because the pullout resistance does not fluctuate much. AC: aspiration catheter; SR: stent retriever

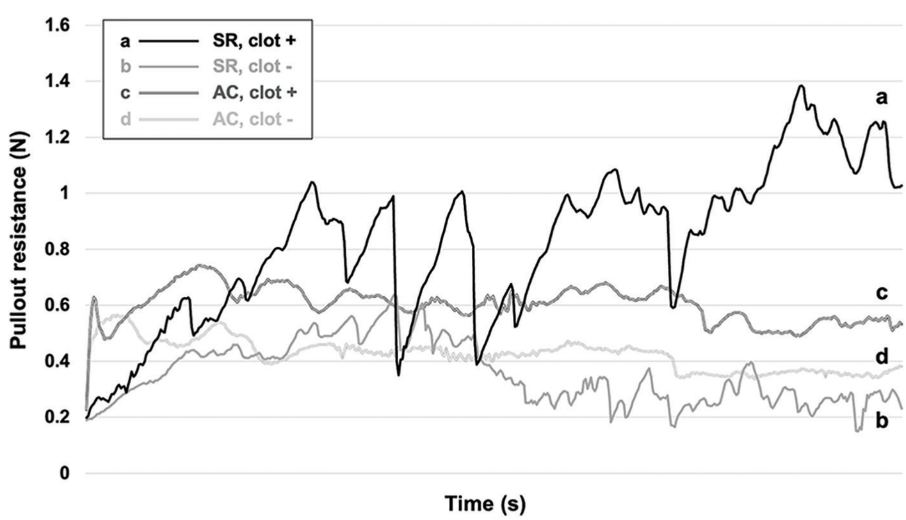

Fig. 3 A representative waveform of temporal changes in pullout resistance for SRs without clot (SR−), SRs with clot (SR+), ACs without clot (AC−), and ACs with clot (AC+). The range on the horizontal axis is 20 seconds. AC: aspiration catheter; SR: stent retriever

reaching the peak value; therefore, the line graph was a gentle curve. This difference was more remarkable in experiments with thrombi. Representative waveforms for SR and AC traction with and without thrombi are shown in **Fig. 3**.

R_{max} was 0.567 ± 0.113N in SR−, 1.369 ± 0.603N in SR+, 0.720 ± 0.124N in AC−, and 0.905 ± 0.098N in AC+ (**Fig. 4**). R_{max} in SR+ was significantly higher than R_{max} in the other groups ($P < 0.05$). Mean pullout resistance was 0.338 ± 0.074N in SR−, 0.690 ± 0.233N in SR+, 0.562 ± 0.133N in AC−, and 0.699 ± 0.088N in AC+. Mean pullout resistance in SR+ was significantly higher than pullout resistance in SR− ($P < 0.05$). CV was 32.4% ± 6.70% in SR−, 38.1% ± 14.0% in SR+, 13.1% ± 4.11% in AC−, and 12.9% ± 4.48% in AC+ (**Fig. 5**). CV was significantly higher in the SR group than the AC group, with or without thrombus (35.3% ± 11.2% vs. 13.0% ± 4.10%, $P < 0.05$). No significant differences in CV were detected between SR− and SR+ or AC− and AC+. The mean values of three tests for the pullout resistance parameters of each device are shown in **Table 1**.

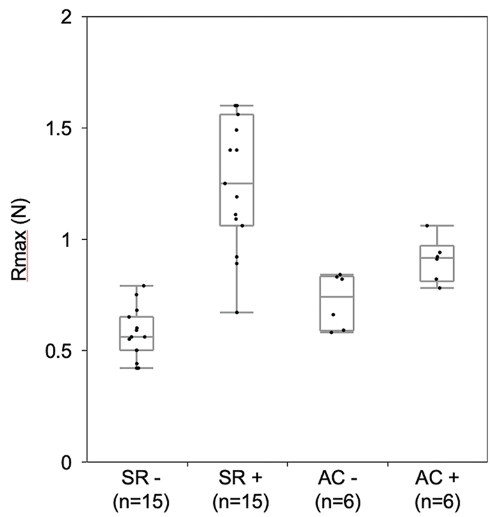

Fig. 4 Box and whisker plots of R_{max} for each group. The horizontal line is the median of the measured values. The top and bottom of the boxes represent the 25th and 75th percentiles, respectively. Whiskers indicate the range from the largest to the smallest observed data points, and cases beyond this range are displayed individually. AC−: stent retriever without clot; AC+: stent retriever with clot; R_{max}: maximum pullout resistance; SR−: stent retriever without clot; SR+: stent retriever with clot

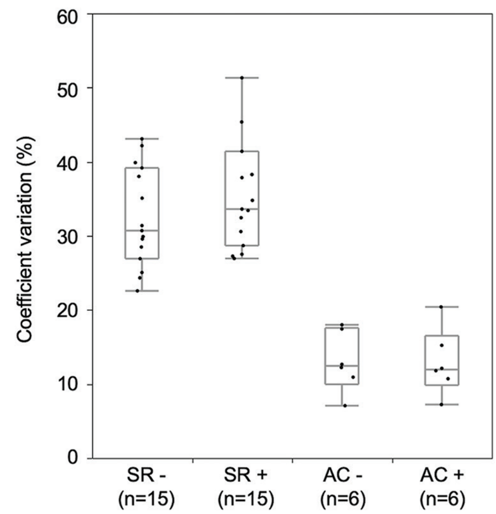

Fig. 5 Box and whisker plots of the CV for each group. The horizontal line is the median of the measured values. The top and bottom of the boxes represent the 25th and 75th percentiles, respectively. Whiskers indicate the range from the largest to smallest observed data points, and cases beyond this range are displayed individually. AC−: stent retriever without clot; AC+: stent retriever with clot; CV: coefficient of variation; SR−: stent retriever without clot; SR+: stent retriever with clot

Table 1 The mean values of three tests for the pullout resistance parameters of each device

	Clot (–)			Clot (+)			
	R_{max} (N)	Mean (N)	CV (%)	R_{max} (N)	Mean (N)	CV (%)	Thrombectomy success
Trevo NXT 3 × 32	0.427	0.253	37.4	1.270	0.605	41.7	0/3
Tron 4 × 20	0.500	0.262	41.7	1.053	0.431	48.0	2/3
Tron 4 × 40	0.583	0.374	28.2	1.093	0.640	30.9	0/3
Solitaire Platinum 4 × 40	0.730	0.417	27.8	2.100	0.992	40.5	1/3
Embotrap II 5 × 33	0.597	0.385	26.9	1.327	0.782	29.4	1/3
Sofia Flow	0.610	0.442	16.0	0.847	0.635	14.3	2/3
Sofia Flow Plus	0.830	0.683	10.1	0.963	0.762	11.5	3/3

CV: coefficient of variation; R_{max}: maximum pullout resistance

Discussion

In recent years, many reports have described mechanical thrombectomy, including a higher intracranial hemorrhage complication rate for medium vessel occlusions compared with the rate for large vessel occlusions.[1,4,5] The hemorrhage rates may be higher because medium and small vessels are easier to have mechanical traction or endothelium damage by interventional maneuvers. Vessel deviations caused by mechanical traction can cause stretching or avulsion of small perforating arteries.[1,2,3] Several retrospective studies demonstrate fewer subarachnoid hemorrhages after thrombectomies using ACs compared with hemorrhages due to SRs.[6–8] In a retrospective review of 465 cases from 13 centers, patients undergoing thrombectomy for M2 segment occlusion were more likely to experience intraprocedural subarachnoid hemorrhages using SRs (9.0%, odd ratio 5.0) and combined technique (9.2%, odd ratio 4.6) compared with patients undergoing thrombectomies using AC (2.1%).[6] Thus, understanding the differences in pullout resistance between SRs and ACs is important. Several reports focused on the pullout resistance of SRs.[9–11] Yokota et al. reported the effects of the structure, length, and diameter of SRs on vessel deviation during SR traction in a vascular model.[9] Ohshima et al. demonstrated that pullout resistance differs depending on the kind of SR and the stent-deployment technique in a vascular model.[10] Our study is the first to examine pullout resistance during SR and AC traction with or without thrombus using a vascular model.

We showed that pullout resistance was relatively constant during AC traction but fluctuated during SR traction; the fluctuation was caused by repeated stent stretching and releasing. The difference in traction between AC and SR is supported by the differences in the CVs for pullout resistance. In the presence of thrombus, the R_{max} and mean pullout resistance during SR traction were significantly higher than the R_{max} and resistance in the absence of thrombus, and the R_{max} in SR+ was the highest of the four groups. These data suggest that when the stent captured the thrombus, it developed a strong frictional force, which might cause a strong vessel deviation in our experiment. **Table 1** shows that the extreme increase in R_{max} and mean pullout resistance in the presence of thrombus was the same for all SRs, although some differences were detected depending on the type, length, and diameter of the SR. This result suggests that the SR capturing a thrombus impacts pullout resistance during SR traction more than the device-dependent differences, such as structure, radial force, length, or diameter.

The R_{max} and mean pullout resistance in the absence of thrombus were higher for AC traction than the R_{max} and resistance for SR traction. However, the increasing degree of pullout resistance caused by the presence of thrombus was smaller in AC traction than in SR traction. Pullout resistance in AC, which takes up part or all of the thrombus, may depend more on the diameter of the catheter than the presence or absence of the thrombus. Even in our experiments, the Sofia Flow Plus, which has a larger diameter, tended to have higher pullout resistance than the Sofia Flow.

The success rates of thrombectomy were 26.7% (4/15) and 83.3% (5/6) for SR and AC tractions, respectively. The SR temporarily captured the thrombus but often released it at the bending portion. This shortcoming may be compensated using the combined technique to prevent the SR from passing through the bend alone. Regarding ACs, the success rate of thrombectomy was 66.6% (2/3) for Sofia Flow with a 1.7 mm of outer diameter and 100% (3/3) for Sofia Flow Plus with a 2.1 mm of outer diameter. Since the inner diameter of the vessel model in which the clot was placed was also 2.1 mm, it may reflect the finding from previous reports that a higher catheter-to-vessel ratio is associated with a higher success rate of clot aspiration.[12]

The clot analog used in this experiment is a red thrombus made from whole blood, which is relatively easy to retrieve. We presume that even higher pullout resistance would occur if we use thrombus types that are more difficult to retrieve, such as collagen-rich thrombi, highly platelet-contracted thrombi, or thrombi with strong vessel wall adhesion.[13–15] This presumption is more feasible in SR than in AC.

We conclude that the higher intraprocedural hemorrhage rate for SR traction can be explained by the higher R_{max} and CV of pullout resistance while the SR, which captures the thrombus, is pulled out. In thrombectomy of medium and small vessels that are vulnerable to mechanical traction, AC use is less likely to affect pullout resistance and may outperform the SR in terms of safety. In addition to the device type and whether the device is capturing a thrombus, we should consider other factors that affect pullout resistance for in vivo thrombectomies, such as hemodynamic stress and anatomical differences, the properties of the thrombus, and the thrombus–vessel interaction.[11,15] This study has some limitations. First, this experiment is under static conditions in a controlled laboratory environment using a single kind of vessel model and thrombus, which may not represent the complexities encountered in clinical settings. Second, withdrawal tests were performed only three times for each device; a higher number of tests may result in more statistical differences.

Conclusion

Pullout resistance fluctuates significantly during SR traction relative to AC traction. In the presence of a thrombus, pullout resistance for SR is substantially increased, whereas resistance for AC is less susceptible to thrombi. These resistance characteristics may be responsible for the differences between the devices in the frequency of mechanical traction injury during clinical use.

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Disclosure Statement

The authors declare that they have no conflicts of interest.

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