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Original Article

Support and guide performance comparison of balloon guide catheters

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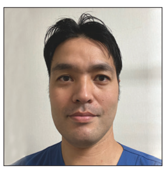

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ABSTRACT

Background: Several types of balloon guide catheters (BGCs) are used in mechanical thrombus retrieval. However, direct comparisons of their supporting and guiding performance have not been reported. We compared the supporting and guiding performance of the Branchor, Flowgate, and Optimo BGCs using a type 3 aorta artificial vascular model.

Methods: An inner catheter was pushed into the artificial vascular model using a linear actuator for the supporting performance evaluation. A previously placed BGC in the internal carotid artery was then intentionally caused to slip. Supporting performance was evaluated by measuring the distance the BGC slipped and generated maximum resistance during Inner catheter insertion. For the guiding performance experiment, a linear actuator was used to guide the BGC into the internal carotid artery of the artificial vessel model. The guiding performance was evaluated by measuring the distance reached by the BGC, maximum resistance generated during insertion of the guiding catheter, and distance the inner catheter slipped. Each experiment was replicated 5 times.

Results: No statistically significant differences were observed in the results of the five supporting performance experiments. However, the results of the first and second experiments suggested that the Optimo offers better supporting performance. In the guiding performance experiment, significant differences were observed, suggesting that the Branchor and Flowgate have superior guiding performance in comparison with the Optimo.

Conclusion: The Optimo offered superior supporting performance, while the Branchor and Flowgate showed better guiding performance than the Optimo.

Keywords: Balloon guide catheter, Mechanical thrombectomy, Performance

INTRODUCTION

Mechanical thrombus retrieval for acute cerebral infarction is an established therapeutic procedure.[1,3,5-8] However, thrombus retrieval and vessel reopening should be performed promptly after onset to improve patient prognosis.[9] A balloon guide catheter (BGC) has been recommended in mechanical thrombus retrieval since these devices can block the antegrade blood flow and prevent embolization distal to the thrombus.[2,4] However, difficulties in guiding the BGC during treatment or slippage of the catheter may extend the time from the start of treatment to retrieval of the thrombus and vessel reopening. No previous studies have compared the guiding or supporting properties of each BGC. Therefore, in this study, we conducted experiments to compare the guiding and supporting performance of three types of BGCs using an artificial vascular model.

MATERIALS AND METHODS

Experimental device

A silicone vascular model of the aortic arch to the neck's internal carotid artery was created to represent a type 3 aorta [Figure 1]. The silicon vascular model was filled with water and a surfactant (Tween 20; Tokyo Kagaku Kougyo, Co. Ltd.) at a concentration of 0.15%. The temperature was then maintained at 37°C using a heater (New Safe Cover Heat Navi 160; GEX Co, Ltd.). A linear actuator (RCS2-SA6R-WA-30-3-400-T2-P-MR; IAI Corporation) was used to create the experimental device that pushed the catheter into the vascular model at a constant rate (1 cm/s). A digital force gauge (FGP-5; Nidec-Simpo Corporation) was attached to the linear actuator to measure the resistance during catheter insertion [Figure 2].

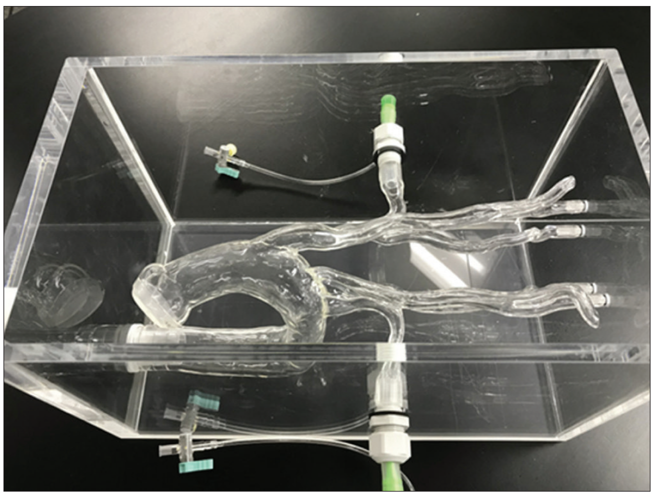

Figure 1: Artificial vascular model A silicone model of a type 3 aorta. The experiment was conducted with the model filled with 37°C water, in which a surfactant had been dissolved.

Support and guide performance evaluation of BGC

For the supporting performance, a BGC was placed in the internal carotid artery, and an inner catheter and a guidewire were passed through it until they touched the wall of the artificial vascular model. Then, the 12-cm inner catheter was pushed forward at a rate of 1 cm/s, which caused the BGC to slip. The distance the BGC slipped and maximum resistance generated when inserting the inner catheter was evaluated. The supporting performance was considered more significant when the distance the BGC slipped was shorter and when the maximum resistance of the inner catheter was higher.

For the guiding performance, a BGC was guided 12cm into the internal carotid artery from the aortic arch at a rate of 1cm/s with an inner catheter and a guidewire placed in the internal carotid artery. The reached distance of the BGC, maximum resistance generated during insertion of the guiding catheter, and distance the inner catheter slipped was evaluated. Guiding performance was considered greater when the distance the BGC reached into the internal carotid artery was longer, the maximum resistance during insertion was smaller, and the distance the inner catheter slipped was shorter.

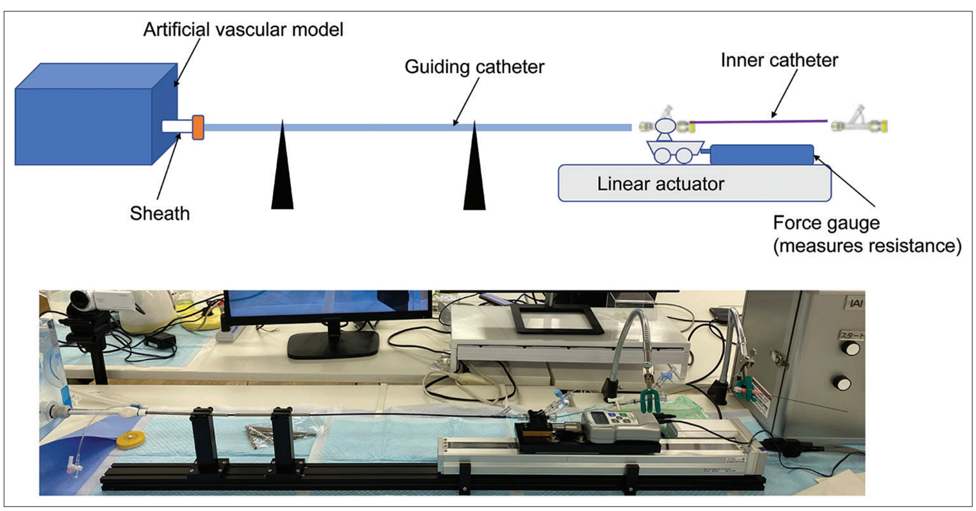

Figure 2: Experimental model A linear actuator was used to create an experimental device that inserted the catheter at a constant rate. A force gauge was attached to the linear actuator to measure resistance during catheter insertion.

Materials used

The BGCs, 9Fr Branchor (Asahi Intecc, Aichi, JAPAN), 8Fr Flowgate (Stryker, Kalamazoo, MI, USA), and 9Fr Optimo (Tokai Medical Products, Aichi, JAPAN) were used, while for the inner catheter and guidewire, 6Fr JB2 130 cm (Medikit, Tokyo, JAPAN) and RADIFOCUS 0.035 in stiff 180 cm (TERUMO, Tokyo, JAPAN) were used, respectively.

Study design

The BGCs' guiding and supporting performance were replicated 5 times each. The same catheter and wire were used in all five supporting performance experiments, after which a new catheter and wire were used for the guiding performance experiments.

Statistical analysis

The results for the three catheter types were examined with the Kruskal–Wallis test, and if significant differences were observed among the three groups, the Steel-Dwass test was added for multiple comparisons. The statistical analysis software used was JMP version 14.2.0 (SAS Institute, Inc., North Carolina, USA).

RESULTS

Table 1 summarizes the results of the supporting and guiding performance experiments. The supporting performance showed no statistically significant differences ($P < 0.05$) between the three groups in the BGC slip distance ($P = 0.06$) or maximum resistance generated when inserting the inner catheter ($P = 0.08$). However, when only 1st and 2nd experiments were examined, the Optimo exhibited a shorter BGC slip distance and higher maximum resistance during catheter insertion than the other two BGCs [Figures 3 and 4]. Regarding the guiding performance experiment, significant differences ($P < 0.05$) were observed in the distance the BGC reached ($P = 0.04$*) and maximum resistance during insertion ($P = 0.009$*) [Tables 1 and 2]. The Branchor reached significantly longer than the Optimo, and the Branchor and Flowgate had significantly smaller maximum resistance than the Optimo.

DISCUSSION

During mechanical thrombectomy for acute cerebral infarction, difficulties in BGC guiding or slippage during treatment may occur occasionally. Such problems with BGCs can delay the start of treatment until vessel reopening, which could significantly influence patient prognosis. In our experiments, we observed differences in the supporting and guiding performance of different BGC types. In general, a BGC has a soft tip and a body that becomes more rigid as it approaches the hand. Factors that regulate BGC support and guiding performance include rigidity, the pattern of rigidity changes from the tip to the hand, and the coating of the catheter's outer wall.

No statistically significant differences ($P < 0.05$) were observed when comparing the five supporting performance experiments. However, in the first and second experiments, the Optimo had a shorter BGC slip distance than the others, and its resistance during inner catheter insertion was higher, suggesting that it offered superior support. The rigidity of the catheter is also critical for evaluating the supporting performance of BGCs; however, the five experiments placed repeated mechanical stress on the catheter, which could have damaged its original rigidity, causing the BGC slip distance to increase and resistance during inner catheter insertion to decrease in the third and subsequent experiments. Considering its original supporting performance, we believe that the Optimo would be effective for cases that require BGCs with a high degree of support performance, such as cases with a sharp bend in the internal carotid artery siphon or peripheral lesions.

In the guiding performance experiment, we observed significant differences ($P < 0.05$) in the reached distance of the BGC ($P = 0.04$*) and maximum resistance during

Table 1 : Results for the supporting and guiding performance of various BGC.

		Branchor	Flowgate	Optimo	*P*-value
Support performance					
Maximum resistance during inner catheter insertion (N)	Median (Range)	0.310 (0.275–0.366)	0.288 (0.252–0.366)	0.357 (0.340–0.526)	0.08
Guiding catheter slip distance (mm)	Median (Range)	85 (83–85)	88 (84–88)	86 (77–87)	0.06
Guiding performance					
Distance the guiding catheter reached (mm)	Median (Range)	31 (25–32)	7 (4–26)	4 (−2–4)	0.04*
Maximum resistance during guiding catheter insertion (N)	Median (Range)	0.69 (0.62–1.44)	0.77 (0.72–1)	1.8 (1.64–1.86)	0.009*
Inner catheter slip distance (mm)	Median (Range)	51 (45–53)	64 (47–66)	64 (60–68)	0.08

The superscript * denotes significant differences ($P<0.05$) between the various BGCs. The table shows the median and range values for assessments from the supporting performance and guiding performance experiments. BGC: Balloon guide catheter

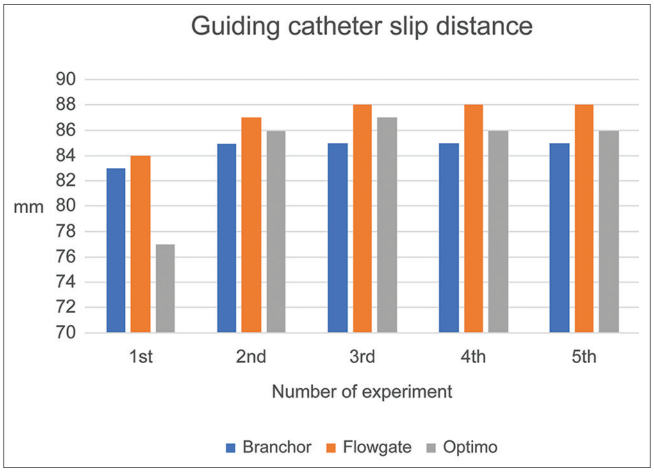

Figure 3: BGC slip distance in the support performance experiment in the first experiment, Optimo's BGC slip distance was shorter than the others. Statistical analysis of all five results yielded no statistically significant differences. BGC: Balloon guide catheter.

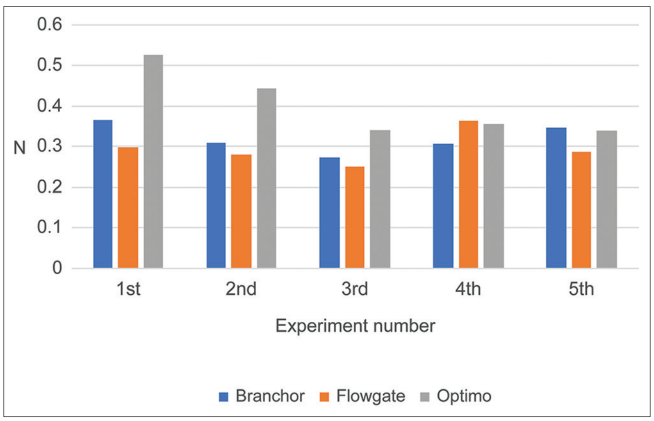

Figure 4: Maximum resistance on the inner catheter in the support performance experiment in the first and second experiments, the maximum resistance on the inner catheter was greater in the Optimo than in the others. Statistical analysis of all five results yielded no statistically significant differences.

Table 2: The results of the Steel-Dwass test.

	***P*-value**
Distance the guiding catheter reached (mm)	
Bronchor – Flowgate	0.09
Bronchor – Optimo	0.03*
Flowgate – Optimo	0.06
Maximum resistance during guiding catheter insertion (N)	
Bronchor – Flowgate	0.9
Bronchor – Optimo	0.03*
Flowgate – Optimo	0.03*

The superscript * denotes significant differences ($P<0.05$) between the various BGCs. The Steel-Dwass test was performed for multiple comparisons. The table shows the results of the Steel-Dwass test

BGC insertion ($P = 0.009$*), with the Branchor reaching significantly longer than the Optimo and the Branchor and Flowgate showing smaller maximum resistance values than the Optimo. This finding indicates that the Branchor and Flowgate would be effective when guiding is expected to be difficult, such as in a type 3 aorta or when the bend from the aortic arch to the internal carotid artery is sharp.

The catheters were inserted at a constant speed using a machine, which differs from the hand movements of actual surgeons. In addition, supporting performance could be improved through balloon inflation, while guiding performance could be enhanced by employing various techniques.[10,11] BGCs are characterized not just by their supporting and guiding performance but by various other factors, such as differences in their effective length and speed at which the balloon inflates and deflates. Ultimately, it may be best to use the BGC type that the surgeon is most familiar with. Still, this experimental assessment of supporting and guiding performance under uniform conditions can be used as a reference for selecting a BGC. No previous reports compared the mechanical guide and support performance of balloon guiding catheters as in our experiment. The experimental device used in this study was to push the catheter in; however, by creating an experimental device that can replicate the operation and closely resemble the surgeon's hand movement, such as by adding rotation, the experiments will be more similar to the actual clinical practice. Suppose the necessary factors for superior guiding and support performance are clarified by evaluating each catheter's guide and support performance. In that case, it will lead to the development of new balloon-guiding catheters with superior guiding and support performance.

CONCLUSION

This study suggests that the Optimo had superior supporting performance, while the Branchor and Flowgate had superior guiding performance. These experiments were conducted with a simple mechanical pushing motion that differs from the movements of an actual surgeon's hands. Building a device that could reproduce an actual surgeon's rotation and other movements could enable assessments that closely resemble a clinical setting. Evaluation of the supporting and guiding performance of different catheters could enable analysis of the elements required to achieve excellent supporting and guiding performance, which could facilitate the development of new catheters that perform well in both aspects.

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Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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