Experimental Model Evaluation of Filter Trapping After Embolectomy Using the Merci System —Supplemental Technique for Merci Retrieval Procedure—

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Abstract

Examination of embolectomy using the Merci® Retrieval System using experimental stroke models demonstrated that aspiration is not adequate to remove larger clots. The effectiveness of filter trapping was examined using the same models. A silicone model of the carotid artery system with model blood clot was incorporated in a laboratory pulsatile flow system. Embolectomy was performed using the Merci Retrieval System. Any clot not evacuated through the balloon guide catheter was trapped with a distal protection filter device developed for cervical stenting. The clot could not be sucked into the guide catheter by the recommended procedures in nine of 15 trials. Trapping failed in only one trial, in which the clot passed through a gap between the edge of the filter orifice and the inner model lumen. A clot was withdrawn to the catheter tip trapped across the edge of the orifice frame in one trial, and a very large clot was trapped across the filter orifice in two trials. Even clots made by the same method showed variation in properties, especially hardness, which may affect the effectiveness of aspiration. The aspiration procedure recommended for the Merci Retrieval System did not remove the large clots formed by embolectomy. The trapping procedure using a filter device without an orifice frame was effective to solve this problem.

Key words: stroke, embolectomy, extraction, retrieval, filter

Introduction

Endovascular reconstruction for hyperacute thromboembolic stroke achieves lower recanalization rates than atherosclerotic stroke,^{1,7,8)} and is one of the factors contributing to the dismal prognosis. This poor result may be related to the occurrence of acute occlusion against a background of poor collateral circulation. In addition, the volume of thromboembolus is far larger than that of atherosclerotic thrombus,^{7,8)} and the effect of thrombolysis is variable depending on the characteristics of the thrombus.^{2,9,11)} Supplemental procedures and devices have yielded moderate results, such as disruption,²⁴⁾ percutaneous transluminal angioplasty,^{16,23,31)} stenting,²⁵⁾ and aspiration,¹²⁾ or particular devices such as the snare,^{3,9,20,30)} but none has been established as the optimum method.

Recently, the commercial Merci retrieval device

was approved for foreign body extraction and intracranial thrombectomy.¹³⁾ According to the MERCI phase 1 trial, successful recanalization with mechanical thrombectomy was achieved in 12 of 28 patients, and with additional intra-arterial tissue plasminogen activator in 18 of 28 patients with embolism and thrombosis with atheromatous plaque.⁴⁾ Our previous model study of the Merci® Retrieval System found that further refinements of the retrieval device are needed for capturing and holding the embolus, and the aspiration procedure is not always successful.

The present study evaluated various devices for trapping the embolus using the experimental model.

Materials and Methods

I. Procedures and devices

The devices for this experimental procedure con-

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Fig. 1 Devices for this experimental procedure consist of the retrieval device, filter protection device, and flow control guide catheter. **Merçi® Retrieval System (upper):** The Merçi® Retriever is delivered by the Merçi® Microcatheter. The Merçi® Balloon Guide Catheter is used to facilitate the insertion and guidance of delivery catheters. The balloon provides temporary vascular occlusion during extraction procedures. **Spider™ Embolic Protection Device (middle):** This device has originally been developed as a distal protection device for the cervical stenting procedure. This device has no orifice frame. **RX ACCUNET™ Embolic Protection System (lower):** This device has also been developed as a distal protection device. This device has an orifice frame. US 10 cent coin (diameter, 17.9 mm) (left).

sist of the retrieval device and the filter protection device (filter device) introduced through the flow control guide catheter (Fig. 1). The Merçi® Retriever (Fig. 1 upper) is the key component of the Merçi® Retrieval System (Concentric Medical, Mountain View, Calif., U.S.A.) and is designed to engage and capture the occlusive thrombus in the retrieval process. The Retriever uses the superelastic property of memory shaped nitinol (nickel titanium). The Retriever is a tapered wire with five helical loops of decreasing diameter (from 2.8 mm to 1.1 mm) at the distal end available as the X5 and slightly stiffer X6 with proximal wire diameter of 0.012 and 0.014 inches, respectively. The X6 was adopted in this experiment. The Merçi® Microcatheter has a 3F outer diameter that tapers to 2.4F and a single lumen designed to navigate and deliver the Merçi Retriever under radiographic guidance. The Merçi® Balloon Guide Catheter (BGC) is used to facilitate the insertion and guidance of an intravascular catheter into the selected blood vessel in the peripheral neurovasculature. The balloon provides temporary vascular occlusion during angiographic procedures. The

balloon is made of soft compliant silicone with diameter/length of 10 mm × 10 mm and maximum inflation volume of 10 cm³ with proximal flow control. The catheter has a 9F outer diameter with 0.085-inch inner diameter.

The Spider™ Embolic Protection Device (ev3, Minneapolis, Minn., U.S.A.)¹⁹⁾ (Fig. 1 middle) was mainly adopted as the filter device, with the RX ACCUNET™ Embolic Protection System (Guidant, Santa Clara, Calif., U.S.A.)²¹⁾ (Fig. 1 lower) used for several trials with comparison. The present study used devices with the following specifications. The Spider distal embolic protection system has a crossing profile of 3.1F, and consists of four components: capture wire, delivery catheter, stylet, and recovery catheter (which is not needed in this procedure). The capture wire is a Teflon-coated 0.014-inch stainless steel wire that is convertible from 320 cm length for use with rapid-exchange systems, with a 1.2 cm atraumatic floppy tip, and a heparin-coated nitinol mesh filter with a pore size of 196 μm, varying in diameter from 7 mm. The delivery catheter is a 2.9F polyethylene catheter used with the inner polyethylene stylet, which provides a tapered transition from the delivery catheter to the guidewire. The RX ACCUNET consists of a filter with guide wire, delivery sheath (3.5F), and recovery catheter (5.5F). The filter basket consists of a polyurethane filter with a pore size of 120 μm over a nitinol basket with 7.5 mm diameter and 3.7F profile. The guide wire is a Teflon-coated 0.014-inch nickel titanium distal core/stainless steel wire that is convertible from 190 cm length with a 3 cm radio-paque tip. The RX ACCUNET guide wire is advanced with the filter basket and the delivery sheath as a unit during positioning.

II. Experimental system

A silicone model of the carotid system was created by the loose wax technique^{5,21,26,27)} and incorporated in an experimental pulsatile flow system with full length channel. The embolic material (clot) consisted of blood sampled from humans or pigs and stood for more than 24 hours with added liquid coil. Neither human nor animal donors had received any drug affecting bleeding or coagulation. Endovascular thrombolysis is ordinarily not indicated for intracranial carotid artery embolism, but is often adopted for middle cerebral artery embolism, although both types are common causes of major stroke. Therefore, we created two models in which the clots were injected from the side channel of the flow system and positioned at the carotid T portion (10 trials) or the horizontal portion of the middle cerebral artery (5 trials).

Fig. 2 Silicone embolism model system: The experimental set-up consists of a portable angiography unit and pulsatile flow system. The hydraulic pressure of the upper reservoir tank creates a steady mean flow. The pulsatile flow generated by the velocity-controlled servomotor pump is superimposed on the steady mean flow. Collateral retrograde flow from the external carotid system to the occluded internal carotid system is also reproduced. Simulation of the clinical procedure is carried out using the portable angiography system with road mapping function.

The experimental set-up consisted of a portable angiography unit and pulsatile flow system (Fig. 2). The hydraulic pressure of the upper reservoir tank created a steady mean flow. The pulsatile flow generated by the velocity-controlled servomotor pump was superimposed on the steady mean flow. Collateral retrograde flow from the external carotid system to the occluded internal carotid system was also reproduced. Simulation of the clinical procedure was carried out using the portable angiography system with road mapping function. Systolic, diastolic, and mean pressure, and pulsation rate were measured proximal to the model. The side channel which allows introduction of the intraluminal 9F catheter was positioned before the silicone model. The series of procedures were performed as closely as possible with clinical practice under fluoroscopy. If problems arose, the models could be inspected directly. The angiographic image and direct view were recorded by two video-cameras and transmitted to a video-monitor, where the investigator could follow the course of the intervention.

III. Procedures

The fundamental retrieval process followed the procedure which Concentric Medical recommends for the Merci Retrieval System.²²⁾ After the BGC was placed into the internal carotid artery, using

Fig. 3 Photograph (left) and fluoroscopic image (right) showing the Merci® Retriever has ensnared a clot (arrow), and the clot with liquid coil (arrowhead) before loading (right upper quarter of a circle). US 10 cent coin (diameter, 17.9 mm).

standard cerebral catheterization techniques, the microcatheter was guided into the occluded vessel and passed beyond the clot. The Retriever was advanced to allow two to three distal loops of the helix to exit the microcatheter distal to the clot. The Merci Retriever was then retracted to contact the clot, and the proximal loops were then deployed within the clot. The BGC balloon was inflated to control system flow during removal of the clot and the Merci Retriever rotated five times clockwise to further ensnare the clot (Fig. 3). The Merci Retriever wire and the microcatheter hub were then held together, suction applied through the lumen of the balloon guide catheter using a 20-ml syringe, and the Merci Retriever with the ensnared clot and the microcatheter were simultaneously and slowly withdrawn together into the guide catheter (Fig. 4A). The microcatheter and the Merci Retriever were then removed from the guide catheter, which was aspirated to ensure complete evacuation of any clot fragments (Fig. 4B). If the occlusion persisted, then the procedure could be repeated up to a few passes of the Merci Retriever. If the clot could not be retrieved, the clot was transferred to the tip of the BGC by refluxing the system flow.

The filter trapping procedure was then followed for the remaining clots and fragments. The filter device co-axially folded in the delivery catheter was navigated to the petrosal portion of internal carotid artery, then the delivery catheter was retracted to deploy the filter (Fig. 4C). The BGC was deflated, allowing the antegrade internal carotid flow to resume and to trap the floating clots into the filter (Fig. 4D). The filter device was withdrawn gently and fixed on the catheter tip, and then removed as a

unit (Fig. 4E).

The effectiveness of aspiration and filter trapping, the dynamics of the embolus, and the maneuverability of devices were evaluated by inspection of the radiographic and video images. The angiography,

Fig. 4 Photographs (upper row) and fluoroscopic images (lower row) of the filter trapping procedure. **A:** The Merci® Retriever with the ensnared clot and the microcatheter are simultaneously and slowly withdrawn together into the guide catheter. **B:** The microcatheter and the Merci Retriever are then removed from the guide catheter, which is aspirated to ensure complete evacuation of any clot fragments. **C:** The filter device co-axially folded in the delivery catheter is navigated to the petrosal portion of internal carotid artery, and deployed there. **D:** The balloon is deflated, allowing the antegrade internal carotid flow to resume and to trap the floating clots in the filter. **E:** After confirming trapping, the filter device is withdrawn carefully and fixed on the catheter tip, and then removed as a unit.

simulation of the maneuver, and evaluation were performed by two specialist neurosurgeons.

Results

Table 1 summarizes the experimental results using the Merci Retriever and the Spider. The retrieval procedure was successful in only three of 10 trials in the carotid artery. Clots were dislodged at the carotid siphon or the carotid-cavernous and petrosal portions, and re-ensnared at least three times, but all these trials ended in failure. Aspiration failed in six trials and the four other clots could only be aspirated by repetition of aspiration and flushing. The retrieval procedure was successful in two of five trials in the middle cerebral artery, and aspiration was successful in two trials.

Direct inspection found some mechanical disruption and fragmentation of clots during the retrieval and retraction procedures. Fragmentation became more frequent with increased number of retrieval procedures. All clots not trapped by the retrieval procedure were transferred to the top of the guide catheter by reversal of the flow system. All floating clots were easily migrated by very slight flushing or contact with devices. The reproduced collateral retrograde flow with slight aspiration from the guide catheter achieved ready proximal transfer of the clots and fragments. Even clots made by the same method showed variable properties, especially hardness, which may influence the effectiveness of aspiration.

Filter trapping was performed for the nine trials in which aspiration failed, and the clot could be extracted in eight trials (Fig. 4C-E). No clot was pushed by the delivery catheter distal to the position of filter deployment. Trapping failed in one trial, in which the clot passed through a gap between the edge of the filter orifice and the inner model lumen. A clot was withdrawn to the BGC tip trapped across the edge of the orifice frame in one trial, and a very

Table 1 Results of retrieval and trapping procedures using the Merci® Retriever and the Spider™

Carotid T portion model:

Retrieval procedure: 10 trials		Aspiration: 10 trials		Filter trapping: 6 trials	
success	failure	success	failure	success	failure
3 trials	7 trials	4 trials	6 trials	5 trials	1 trial

Horizontal portion of the middle cerebral artery model:

Retrieval procedure: 5 trials		Aspiration: 5 trials		Filter trapping: 3 trials	
success	failure	success	failure	success	failure
2 trials	3 trials	2 trials	3 trials	3 trials	0 trial

Fig. 5 Photograph of filter trapping using the RX ACCUNET™. The clot (arrowheads) is trapped between the filter frame and the inner lumen of the model. When the device is retracted, the clot passes through the gap and escapes.

large clot was trapped across the filter orifice in two trials. After deflating the balloon and resuming the antegrade flow, some clots attached to the catheter tip or wire of the filter device for a while, but were eventually freed and trapped. None of the trapped clots could be sucked into the BGC, so were removed by trapping between the catheter tip and filter orifice followed by withdrawal of the whole unit.

The RX ACCUNET was also evaluated using the same experimental system. The principal clots could not be trapped by the filter in all four trials. The clots became attached to the frame in front of the orifice and all or part of the clots were liberated and migrated distally during trapping or withdrawal (Fig. 5).

Discussion

The stump pressure, which is about 60% of blood pressure in normal balloon occlusion under flow control,⁶⁾ causes retrograde flow into the guide catheter.¹⁰⁾ Therefore, thrombosis remnants may be carried on the reflux flow to the catheter tip without aspiration, even a large clot liberated during withdrawal, except for embolus which is attached or lodged in the vascular lumen. The stenting procedure for cervical carotid stenosis incorporates protection from the arteriovenous shunt which also utilizes this reflux.¹⁷⁾ The aspiration procedure is intended to attract tiny debris and some clots into the guide catheter, and may also attract floating fragments in the intracranial vessels. Therefore, the aspiration procedure is also important as a sup-

plemental method to concentrate clots and fragments at the catheter tip.

Our evaluation of the effectiveness of aspiration for the embolus found the results were not as good as the MERCI Trial Procedure Guide suggests.²²⁾ Clots of the size to occlude the carotid or middle cerebral artery could be aspirated into the 9F guide catheter but required considerable negative pressure. Including the experiments using other retrieval devices, we examined this procedure more than 20 times, and clots were not aspirated in about half of the trials. Even clots made by the same method showed variation in properties, especially hardness, which may account for the failure. The properties of clinical embolic material may show even more variation. Moreover, even if the clot could be aspirated, whether the clot could be completely aspirated was not confirmed, as the remaining radiolucent clot is not easy to identify by fluoroscopy or angiography.

The present study suggests that some provision should be made for trapping clots in the extraction maneuver for stroke. The distal balloon,^{14,17,28)} filter,^{15,17,18,21,29)} and arteriovenous shunt with flow reversal¹⁷⁾ are available for protection during cervical stenting, but we adopted filter trapping as the others are related to aspiration. The Filter Wire Exv (Boston Scientific/Medi-tech, Natick, Mass., U.S.A.)¹⁵⁾ and Neuroshield™ (MedNova, Horsham, U.K.)¹⁵⁾ show the best retrievability, and the Spider¹⁹⁾ and Neuroshield¹⁸⁾ have excellent steerability and stability. The object of trapping in this study was not debris but certain sizes of clot. We assumed that any filter which had a frame in front of the orifice would be inadequate, and so mainly investigated the Spider as a filter without frame, and the RX ACCUNET with frame and structurally similar to the Neuroshield for comparison. The study demonstrated as expected that a filter without frame was essential to capture the larger clots. So far as we know, the only filter devices with suitable structures are the Spider and Filter Wire.

The aspiration performance of the Merci Retrieval System was examined using experimental models. Clots of a size likely to occlude the carotid or middle cerebral artery were not effectively removed by aspiration. Trapping of the clots with a filter device without orifice frame was effective, as long as no gap was present between the filter and inner lumen. These findings were obtained in the laboratory, and are not immediately applicable to clinical practice. Embolectomy is a promising strategy for the endovascular treatment of acute thromboembolic stroke, so we hope that the manufacturers will refine the devices and procedures.

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Commentary

Acute thromboembolic attack in the cerebral vasculature is a serious problem that should be corrected as an emergency base. Although the treatment of acute thromboembolic occlusion of major cerebral arteries has evolved, the dissolution or disruption of this dangerous material is not yet satisfactory. The landmark study from the National Institute of Neurological Disorders and Stroke³⁾ recommends intravenous recombinant tissue plasminogen activator as a first-line treatment for the patient with acute ischemic stroke within 3 hours. The overall recanalization rate, however, was reported to be between 16.8% and 38%.¹⁾ Data also support the benefit of intra-arterial thrombolysis in patients with acute stroke treated within 6 hours of symptom onset.²⁾ Both intravenous and intra-arterial fibrinolysis sometimes fail to achieve recanalization. As a result, mechanical alternatives are available to attempt to achieve rapid revascularization and reperfusion in patients with symptomatic ischemic stroke. The MERCI Trial Investigators (ref. 22 of this article) reported that the MERCI Retriever can restore vascular patency during acute ischemic stroke within 8 hours of stroke symptom onset.

In this study, the authors performed examination of embolectomy using the Merci Retrieval System in experimental stroke models and demonstrated that aspiration is not adequate to remove larger clots. The present study also displayed that the trapping procedure using a filter device without an orifice frame is effective to solve this problem.

The Merci Retrieval System is in an ongoing state of development, and this article could give invaluable clues to the manufacturers for the refinement of this device.

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In the era of local fibrinolytic therapy using tissue plasminogen activator (t-PA), active embolectomy treatment is not always performed. However, theoretically, there is no doubt that the retrieval of the clot and complete recanalization of the occluded artery within the therapeutic time window will produce good outcome by minimizing the infarction area. In addition, as a matter of course, clot retrieval therapy without fibrinolytic agent has a lower risk of hemorrhagic complication that is considered as an unavoidable adverse event in t-PA treatment. Therefore, the incentive for developing active embolectomy treatment is not necessarily low in the clinical scene. Indeed, in clinical practice, we occasionally face acute iatrogenic occlusion of the main cerebral artery during angiography (not only the cerebral angiography but also other angiography such as coronary angiography). In such cases, active embolectomy using conventional angiographical technique including physical breakage of the clot using a catheter and guidewire is frequently performed.

In this experimental paper to evaluate the performance of the Merci system including new devices, it is clearly revealed that this excellent system is useful and effective to retrieve the clot. Under ideal experimental conditions, the Merci system showed good performance (high success rate of clot retrieval) to retrieve the clot. This is quite encouraging information for endovascular treatment.

As I have mentioned, this experiment was performed "under ideal experimental conditions," so this paper does not necessarily offer an optimistic view of application of this system to clinical practice. Firstly, the embolic material (clot) used in this experiment was produced by only blood, so the clot was quite soft and fresh that is easy to evacuate and break. Secondly, in this experiment system, there was no risk of vessel wall perforation by the wire that often causes a serious risk of complication in the patient.

However, this Merci system is now the most promising and effective candidate to perform aggressive clot retrieval. Indeed, as cited in this paper, there are some papers that show the Merci system has a quite good success rate of clot removal in clinical cases. I expect that clinical trials using the Merci system will be conducted in Japan.

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