Mechanical Thromboembolectomy for Acute Ischemic Stroke

Comparison of the Catch Thromboectomy Device and the Merci Retriever In Vivo

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Background and Purpose—The purpose of the study was to compare efficacy and potential complications of 2 commercially available devices for mechanical thromboembolectomy.

Methods—Devices were tested in an established animal model allowing the use of routine angiography catheters and thrombectomy devices. Radio-opaque thrombi were used for visualization of thrombus–device interaction during angiography. The Merci Retrieval System and the Catch Thromboembolectomy System were assessed each in 10 vessel occlusions. For every occluded vessel up to 5 retrieval attempts were performed.

Results—Sufficient recanalization was achieved with the Merci Retriever in 90% of occlusions, and with the Catch device recanalization was achieved in 70% of occlusions. Recanalization at the first attempt occurred significantly more often with the Merci Retriever compared to the Catch device (OR, 21; 95% CI, 1.78–248.11). Consequently, significantly more attempts \((P=0.02)\) had to be performed with the Catch device; therefore, time to recanalization was longer. Thrombus fragmentations during retrieval were caused more often by the Catch device compared to the Merci Retriever (OR, 15.6; 95% CI, 1.73–140.84), resulting in a higher distal embolization rate. During retrieval both devices lost thrombotic material at the tip of the guide catheter, which was then aspirated in most cases.

Conclusions—Both distal devices are effective for thromboembolectomy. To avoid loss of thrombotic material and distal embolization, the use of large luminal balloon guide catheters and aspiration during retrieval seems to be mandatory. The design of the Merci Retriever appears to be more efficient during thrombus mobilization and retrieval with less fragmentation compared to the Catch Thromboembolectomy System. (Stroke. 2008;39:1213-1219.)

Key Words: interventional treatment ■ mechanical embolectomy ■ stroke

The low recanalization rate, the limited time window for application, and the increased risk of intracerebral hemorrhage of thrombolysis indicate room for further improvement of stroke treatment. Therefore, the application of mechanical thromboembolectomy for acute stroke treatment is increasing.1–9 All mechanical thromboembolectomy devices are delivered by endovascular access and the occlusion is reached from the proximal side. The various devices can be divided into 2 major groups. Proximal devices such as aspiration catheters attack the thrombus proximally. In contrast, the site of force effect of the distal device (DD) is the distal base of the thrombus.10 Although DD take the same approach, different device shapes have been proposed.11,12 So far no systematic study has been performed evaluating various DD under standardized conditions in vivo.

This study was performed to evaluate 2 clinically established DD already in clinical use, the Catch Thromboembolectomy System (Balt) and the Merci Retrieval System (Concentric Medical, Inc), with regard to efficacy, thrombus–device interaction, and potential complications.

Materials and Methods

Thromboembolectomy Devices

The Catch Thromboembolectomy System consists of a self-expanding basket-like device with a maximum diameter of 4 mm that is fixed at a pusher wire (Figure 1a). The basket and its pusher are positioned in an insertion tube and are delivered through a braided 2.4-Fr microcatheter (Vasco 21+; Balt). The use of a 6-Fr guide catheter is generally recommended. In this study 6-Fr to 9-Fr balloon catheters were used. After placement of the balloon catheter in the common carotid artery a road map was performed and the microcatheter inserted coaxially. Equipped with a microwire (SilverSpeed 14) the microcatheter was navigated into the occluded vessel and the thrombus was passed. After successful placement of the microcatheter beyond the thrombus, the microwire was pulled out and the Catch device was inserted using a Y-shape connector/valve and the
Thrombus Preparation

Thrombus preparation and application were described in a previous study on this animal model. To gain radio-opacity barium sulfate was added to the thrombotic material. Thrombi measured 25 mm in length and were incubated for 1 hour at room temperature before application.

Angiography and Study Protocol

Selective intra-arterial digital subtraction angiography was performed on a biplane high-resolution angiography system (Toshiba CAS 800) with a matrix of 1024×1024 pixels. Iopamidol (Iopamiro 300; Bracco) was used for vessel contrast. After initial angiography of the cranial vessels, selective angiography of the lingual artery and internal carotid artery was performed. These vessels reproduce the anatomic setting of an occlusion of the middle cerebral artery and the basilar artery in human circulation, which are the common localizations for interventional stroke therapy. Mean vessel diameter was 2.6 mm (range, 2.0 to 3.1 mm), corresponding well with the target vessels in humans as well as with the diameter of thrombi extracted from cerebral vessels of stroke patients.

For selective thromboembolization the preformed thrombus was injected into a 7-Fr guide catheter (Guider Softtip; Boston Scientific Target) positioned in the target vessel. After thrombus application the guide catheter was removed for 5 minutes to restore arterial flow and to allow thrombus embedding. The precise localization of the thrombus and complete occlusion of the vessel were assessed by follow-up angiography.

The retrieval attempts were conducted according to the requirements of the manufacturers of the Merci Retrieval System and the Catch Thromboembolectomy System as described previously. All procedures were performed through a balloon guide catheter (Corail, Balt, or Merci, Concentric) placed in the common carotid artery, allowing flow arrest during retrieval. The balloon catheter was continuously flushed with heparinized saline only interrupted during thrombus retrieval. During retrieval only the microwire, microcatheter, and the DD entered the target vessel. For repeated attempts the devices were cleaned, inspected, and, if still intact, reinserted.

The number of attempts to retrieve the thrombus was limited to 5 for each vessel occlusion. After the fifth attempt the clot retrieval was rated as failed. The application time for the initial attempt as well as for the following attempts was recorded.

Each device was evaluated in 10 vessel occlusions. All retrieval maneuvers were documented digitally, assessing thrombus fragmentation and peripheral embolization. Follow-up angiography was performed immediately and 1 hour after the procedure to evaluate recanalization rate, vessel dissection, spasm, or perforation.

Analysis of Data

Conning the movement of thrombus, the following 2 points were analyzed. Thrombus movement, fragmentation, and possible distal dislocation during the passing procedure with the microwire or microcatheter and during delivery of the device were analyzed. Thrombus fragmentation or loss with possible thromboembolization in other vessels during retrieval was also analyzed.

Assessment of Vessel Morphology

Recanalization rate of the carrying vessel using the scale for thrombolysis in myocardial infarction (TIMI; 0 to 3) was evaluated. For statistical evaluation, TIMI grades 0 and 1 were rated as insufficient and TIMI grades 2 and 3 were rated as sufficient recanalization.

Grading of vasospasm in case of recanalization using a scale introduced by Grandin et al was as follows: 0 = no narrowing; 1 = slight narrowing (<25% reduction in lumen diameter); 2 = moderate narrowing (25% to 50% stenosis or 50% to 75% stenosis affecting only a short segment of vessel); and 3 = severe narrowing (50% to 75% stenosis affecting a long segment of vessel or any stenosis >75%). Vessel dissection or perforation was also evaluated.

Retrieval Devices

Retrieval devices were evaluated regarding: success rate and number of attempts to complete thrombus retrieval as well as the application time; total time interval to achieve recanalization; loss of thrombotic
material at the tip of the balloon guide catheter; and feasibility and technical failure.

**Statistical Analysis**

Results of the 2 groups, ie, retrievals performed with the Catch device and Merci Retriever, were compared. Statistical analysis was performed using the Mann–Whitney U test for comparisons of vessel diameters and time intervals. For comparison of recanalization results and the occurrence of complications the $χ^2$ test was used. For both tests values of $P<0.05$ were considered to be significant. OR and 95% CI were used to evaluate the probability of successful thrombus retrieval and embolization rate with the 2 tested DD.

**Results**

Both DD, the Merci Retriever, and the Catch device were applied in 10 vessel occlusions each. Both devices were tested in 4 occlusions of the internal carotid artery and in 6 occlusions of the lingual artery. No significant difference was found between vessel diameters of both groups. A total of 36 retrieval attempts were performed. Initial deployment of the devices distal to the occluding thrombus was feasible in all cases.

**Recanalization Success**

TIMI 2 and 3 recanalizations were achieved in 70% of the occlusions with the Catch device, and in 90% with the Merci Retriever. The Merci Retriever achieved recanalization in the first attempt (9 of 10 occlusions) significantly more often than the Catch device (3 of 10 occlusions; OR, 21; 95% CI, 1.78–248.11). Consecutively significantly more attempts were performed with the Catch device (n=22) compared to the Merci Retriever (n=14; $P=0.02$). Time to recanlization was shorter for the Merci Retriever (13 min; range, 6–28 min) than for the Catch device (20 min; range, 10–50 min). Mean application time per attempt did not differ significantly between both devices (Table).

**Complications**

No vessel dissections or perforations were observed during the study with both devices. Vasospasm rate was equally high for both groups (median vasospasm rate = 3). At follow-up angiography after 1 hour vasospasms usually had resolved, allowing assessment of the recanalization result. Passing maneuvers and deployment of the device caused thrombus fragmentation and distal dislocation in 31.8% of the attempts with the Catch device compared to 28.6% of the attempts with the Merci Retriever (OR, 15.6; 95% CI, 1.73–140.84). Distal thromboembolic events occurred in 40% of occlusions treated with the Catch device compared to 10% of occlusions using the Merci Retriever (OR, 6; 95% CI, 0.53–67.65).

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Complications

- Vessel dissection: 0 vs 0
- Vessel perforation: 0 vs 0
- Vessel spasm, median (range): 3 (3) vs 3 (2–3)

Thrombus fragmentation

| During passage | 7/22 (31.8%) | 4/14 (28.6%) | NS | 0.84† |
| During retrieval | 12/22 (54.5%) | 1/14 (7.0%) | 15.6 (1.73–140.84) | 0.005† |
| Thromboembolic event during retrieval | 4/22 (18.2%) | 1/14 (7.0%) | NS | 0.63† |
| Loss of thrombus at tip of guide catheter | 4/22 (18.2%) | 4/14 (28.6%) | NS | 0.68† |
| Causing thromboembolic event | 1/22 (4.5%) | 0/14 | NA | |
| With successful aspiration | 3/22 (13.6%) | 4/14 (28.6%) | NS | 0.39† |
| Device rupture | 1/22 (4.5%) | 0/14 | NA | |
| Overall thromboembolic event per treated occlusion | 4/10 (40%) | 1/10 (10%) | NS | 0.30† |

*Mann–Whitney U test.† $χ^2$ test. NA indicates not applicable; NS, not significant.
The observation of thrombus movement revealed that thrombotic material was sheared off at the tip of the balloon catheter. This finding was independent from the devices used. However, these fragments could be removed by aspiration in all 4 cases performed with the Merci Retriever and in 3 of 4 cases in which the Catch device was used. Only in these 4 attempts performed with the Catch device was aspiration applied to the guide catheter after the device had been removed.

**Thrombus–Device Interaction**

During the initial passing maneuver the microwire and consecutively the microcatheter passed always between thrombus and vessel wall. A penetration of the thrombus by the microwire or the device was not observed. As a result the Catch device was pulled back in the direction of the vessel wall and was at risk to pass the thrombus sideways. In case of successful thrombus mobilization by the Catch device, only a small part of the thrombus was found to be located inside the basket. Major thrombus parts were located in front of the basket with danger of embolization or loss at the tip of the balloon guide catheter (Figure 3).

In 1 case the Catch device could not be pulled back into the tip of a 6-Fr balloon catheter being blocked by a larger bulk of thrombotic material. Forced attempts to withdraw the device resulted in rupture at the fixation point to the pusher wire (Figure 1a), with consequent embolization of the basket and the thrombus into the maxillary artery.

**Figure 2.** Thrombus retrieval performed with the Catch Thromboembolectomy System. Tip of balloon catheter (*) in common carotid artery is shown. Basket of Catch device (black arrow head) is deployed behind the thrombus (black arrows) in the lingual artery, shown in unsubtracted lateral view of digital subtraction angiography (a). During retrieval, thrombus is pushed in front of the basket and gets compacted (b). Thrombus material does not enter the Catch device. Thrombus fragmentation during retrieval in the occluded vessel (black arrow indicates lost fragment (c).

**Figure 3.** Thrombus retrieval from internal carotid artery using the Catch device, shown in subtracted lateral views of digital subtraction angiography. Balloon catheter (*) placed in common carotid artery. Thrombus (black arrows) is well-mobilized. Note floating part of thrombus when entering a bigger vessel (b). A major part of the thrombus does not enter the basket (black arrow head in c and d). Retraction of basket and thrombus into the 6-Fr guide catheter turned out to be impossible (d).
Because loops of the Merci Retriever are deployed in the thrombus better contact between device and thrombus results. Even if the proximal loops lose the thrombus the latter is caught by the distal loops. This principle works very well in straight vessels. In curved vessels, stretching of the Merci device was noted with increased force on the vessel wall. Consequently, curved vessel segments were stretched (Figure 4c). The Merci Retriever harbors a dynamic aspect with elongation of the corkscrew-like distal part in case of resistance or vessel curves. From a certain moment the resistance is overcome and the device switches to its initial shape (Figures 4,5). Retrieval of the Merci device into the balloon catheter was uneventful in all cases. The aspiration that had to be performed with the Merci retrieval showed to be very effective because thrombotic material was found in the aspiration syringe in many cases. The effect of aspiration was also seen under fluoroscopy: thrombus was aspirated out of the device just in front of the tip of the balloon guide catheter or in those cases in which thrombus was lost at the catheter tip (Figures 5d,e).

Because both devices attack the thrombus from the distal side they are at risk for causing compaction of thrombotic material when pulled back (Figure 2). Compacted thrombus hindered passage in the following attempts with the Catch device in 2 cases and mobilization of the thrombus with the Merci Retriever in 1 case (Figure 4).

**Discussion**

Interest in mechanical thromboembolectomy for acute ischemic stroke treatment is increasing. The Merci study proved mechanical devices to be effective in combination or as an alternative to thrombolysis. Studies evaluating mechanical thromboembolectomy systematically in vivo were lacking until now. Animal studies provide an attractive tool to assess a device in vivo before using it in humans. In this study 2 DD for mechanical thromboembolectomy were evaluated.

Both, the Merci Retriever and the Catch Thromboembolectomy System were found to be effective for revascularization. The Merci Retriever achieved an overall recanalization rate (TIMI 2 and 3) of 90%, and the Catch device achieved an overall recanalization rate of 70%. Interestingly, the Merci Retriever achieved recanalization with the first attempt or failed. Accordingly, time to recanalization was lower then with the Catch device (13 min vs 20 min).

Both DD have to be passed beyond the occluding thrombus. This maneuver was feasible in all occlusions but has the risk of thrombus movement and fragmentation that occurred in nearly equal frequency with both DD. Furthermore, both devices have the dangerous potential to compress the thrombus better contact between device and thrombus results.
bus when pulled back. If retrieval fails, then the passing maneuvers of the following attempts are complicated by the compacted thrombus and by vessel spasm. Both compacted thrombus and vessel spasm might hinder further passing of the thrombus (2 cases with TIMI 0 for the Catch device) or increase the force necessary to mobilize the thrombus. The latter was the reason of failure of the Merci Retriever in 1 case (Figure 4).

Using the Catch Thromboembolectomy System, more attempts were needed leading to significantly more thrombus fragmentations during retrieval (55%) compared to the Merci Retriever (7%; \( P=0.005 \)). As a result distal thromboembolic events occurred more often with the Catch device than with the Merci Retriever. However, retrievals with the Merci Retriever were performed during aspiration, whereas the Catch retrieval was performed only with balloon protection according to the different recommendations of the corresponding manufacturers for the clinical use of their systems. This might have increased the embolization rate for the Catch device.

Both DD are at risk to lose thrombus at the tip of the balloon guide catheter (4 cases each). The lost material could be aspirated in all cases performed with the Merci Retriever and in 3 out of 4 cases performed with the Catch device. In 1 case the Catch device filled with thrombus could not be pulled back into the guide catheter. Finally, the device ruptured and embolized distally. The smaller catheter size (6 Fr) might be responsible for this severe complication. Although the manufacturer recommends the use of guide catheters of 6 Fr and larger, larger balloon catheters seem to be superior when retrieving larger amounts of thrombotic material. In addition, the fixation of the basket at the pusher wire has been improved by the manufacturer of the Catch Thromboembolectomy System.

As observed in a previous study, the microcatheter always passed between the vessel wall and thrombus, and the passing procedure never led to a penetration of the thrombus.\(^ {10} \) Additionally, the Catch device produces a relatively low radial force. As a result, the thrombus is often not caught within the basket-like device but is passed sideways or might be fixed only at the outer surface of the basket. Furthermore, if thrombus volume exceeds the volume of the Catch device parts of the thrombus are floating in the vessel lumen and prone to flow (Figure 3b,c). Consequently, to avoid embolization, proximal balloon occlusion and aspiration during retrieval with the tested devices seems to be essential. This finding is in concordance with the results of a previous study evaluating proximal and distal devices with and without balloon protection.\(^ {10} \)

However, the more complicated delivery process of the Merci Retriever and its higher radial force and corkscrew design allow better engagement of the thrombus, resulting in better thrombus mobilization and a higher recanalization rate, especially during the first attempt. This finding implies faster thrombus mobilization and a higher recanalization rate, design allow better engagement of the thrombus, resulting in balloon protection.\(^ {10} \)

The observed recanalization rate (90%) of the Merci Retriever is much higher than the reported numbers in clinical studies (46% to 63%).\(^ {3,19} \) Differences might be caused by the younger vessels in swine with less tortuosity and atherosclerotic changes, as well as by the different consistence of thrombi. Moreover, procedures in this study were performed with visible thrombi, allowing optimal placement of the devices at and inside the thrombus. Procedures in human stroke will be performed for thrombi that can be depicted only indirectly and might change shape and position during the retrieval procedure, causing lower recanalization rates and increasing risk of complications.

Common complications of the Merci Retriever observed in the clinical Merci studies\(^ {3,20} \) like vessel perforation, dissection, and device fracture were not encountered in our study. This might be a small number effect during this study or biased by the different, “younger,” vessel morphology in the animal model.

An important finding is the stretching of the Merci Retriever in curves and in settings with increased resistance (Figure 4). Elongation of the loops might be hazardous because it reduces retention force to the thrombus.\(^ {21} \) When pulling force exceeded a certain point the device regained its shape, resulting in jump-like dislocations of the device and thrombus. Such sudden movements and stretching of curved vessels might explain unsuccessful retrieval attempts, as well as severe complications observed in the clinical studies.

Both DD provoked a high degree of vasospasm that usually resolved after several minutes. However, this high rate might be explained by the model with vessels prone to spasm.

Limitations

The situation in acute ischemic strokes in humans is very complex and differs from stroke patient to stroke patient. Patient age, vessel status, collateral circulation, occlusion site, cause of stroke, and interrelated thrombus consistency, as well as many further factors, determine the individual situation. The animal model used in this study cannot resemble all different settings. As discussed, the vessels of young swine are less tortuous, have less atherosclerosis, and are prone to vasospasm compared to human head vessels. Thrombi are visible under fluoroscopy to allow assessment of interactions and complications, but this never happens in a clinical situation. To allow comparison between devices, only 1 kind of reproducible thrombus was used. The used whole-blood thrombus prepared with barium sulfate and incubated for 1 hour conforms to a slightly firm clot. Such clot has different mechanical properties compared to hard clot; therefore, the success rate of a mechanical device might be overrated in our model. Additionally, behavior of a given device using this model may differ from the clinical situation.

Conclusion

Both distal mechanical thrombectomy devices are effective for thrombus removal. The findings of the study underline the necessity of balloon occlusion and aspiration to avoid thromboembolic events when using the 2 assessed DD. The mechanical concept of the Merci Retriever seems to be superior to the Catch device with respect to thrombus capture and retrieval, resulting in a higher recanalization rate and shorter time interval to achieve recanalization in the animal model.
Disclosures

None.

References


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*Stroke*. 2008;39:1213-1219; originally published online February 28, 2008;
doi: 10.1161/STROKEAHA.107.495614

*Stroke* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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