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AJNR Am J Neuroradiol 2008, 29 (2) 247-252
doi: https://doi.org/10.3174/ajnr.A0790
http://www.ajnr.org/content/29/2/247

ORIGINAL RESEARCH

Occlusion Length Is a Crucial Determinant of Efficiency and Complication Rate in Thrombectomy for Acute Ischemic Stroke

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BACKGROUND AND PURPOSE: Although mechanical thrombectomy (MT) has an encouragingly high recanalization rate in treating stroke, it is associated with severe complications of which the underlying factors have yet to be identified. Because MT is a mechanical approach, the mechanical properties of the thrombus might be crucial for its success. The present study assesses the effect of thrombus length on the in vivo effectiveness and complication rate of MT.

MATERIALS AND METHODS: Angiography and embolization of 21 cranial vessels with radiopaque whole-blood thrombi 10, 20, and 40 mm in length (7 occlusions each) were performed in 7 swine. MT was carried out using a distal snarelike device (BCR Roadsaver) with proximal balloon occlusion. A total of 61 retrievals were attempted.

RESULTS: In the group of 10-mm occlusions, 77.8% of the attempts achieved complete recanalisation. For longer occlusions, the success rates decreased significantly to 20% of attempts for 20-mm occlusions (odds ratio [OR], 14; 95% confidence interval [CI], 2.2–89.2) and 11.1% for 40-mm occlusions (OR, 28; 95% CI, 3.9–202.2; $P < .005$). The low success rates were largely due to complications associated with thrombus compaction during retrieval. Similarly, the rate of thromboembolic events increased from 0% in 10-mm occlusions to 14.8% in 40-mm occlusions.

CONCLUSIONS: MT using a distal device proved to be a fast, effective, and safe procedure for recanalizing short (10-mm) occlusions in the animal model. However, occlusion length emerged as a crucial determinant for MT with a significant decrease in recanalization success per attempt and increased complication rates. These findings suggest limitations of MT in the clinical application.

Recent studies have examined whether mechanical thrombectomy (MT) can accelerate the process of recanalization, increase the recanalization rate, and even expand the window of opportunity compared with the established treatment of intravenous and intra-arterial thrombolysis (IAT).[1-5] Some authors report a benefit from MT compared with thrombolysis.[6-11] The clinical results of MT are exceedingly variable and include severe complications, such as dissection and vessel perforation.[7,10] Still, the high recanalization rates indicate that MT has the potential to become an alternative treatment option for acute cerebrovascular stroke.

Most newly introduced MT devices are distal devices that approach the thrombus proximally but are then advanced by guidewire and microcatheter past the thrombus where they are unsheathed to apply the main force to the distal base of the thrombus.[7,10,12] Some distal devices use supplemental aspiration through the balloon or guiding catheter to reduce the risk of thromboembolism during retrieval. Several basket-like and coil-like distal devices are available commercially, including the Catch device (Balt, Montmorency, France), the Merci Retrieval System (Concentric Medical, Mountain View, Calif), and the newly developed BCR Roadsaver device[13] (Terumo, Tokyo, Japan; Fig 1).

The literature on IAT and MT has not examined the possible influence of mechanical properties, such as thrombus length, on their efficiency and safety. The occlusion length might influence the success especially for MT in 2 aspects: an increasing amount of thrombotic material has to be retrieved by the device, and the proportionally larger surface of the thrombus to the vessel wall increases the friction and, therefore, the force necessary to retrieve the thrombus.

To date, the precise clinical settings for successful application of MT have not been defined,[14] but the occlusion length might have a major impact on its indication for clinical use. To elucidate this correlation, the present study uses an animal model of radiopaque whole-blood thrombus[15,16] to evaluate the in vivo effectiveness of a distal approach (BCR Roadsaver device) with regard to thrombus-device interaction, retrieval success, and complication rate as related to occlusion length.

Methods

Animals

Seven swine ranging in weight from 42 to 49 kg were used. General anesthesia was maintained with a 2% isoflurane and 2 L/min N_2O inhalant. Expired carbon dioxide levels were kept between 30 and 35 mm Hg. The animals were euthanized after the experiments. All of the procedures were approved by the responsible local animal care committee.

Thrombus Preparation

To replicate occlusion lengths in human stroke, thrombi 3 mm in diameter and 10 mm and 20 mm in length (as measured in the hanging position) were generated. Although unlikely in the clinical setting, 40-mm-long thrombi were used in an additional study group to evaluate the general principle and limitations of distal MT. Literature is

Received March 11, 2007; accepted after revision June 18.

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DOI 10.3174/ajnr.A0790

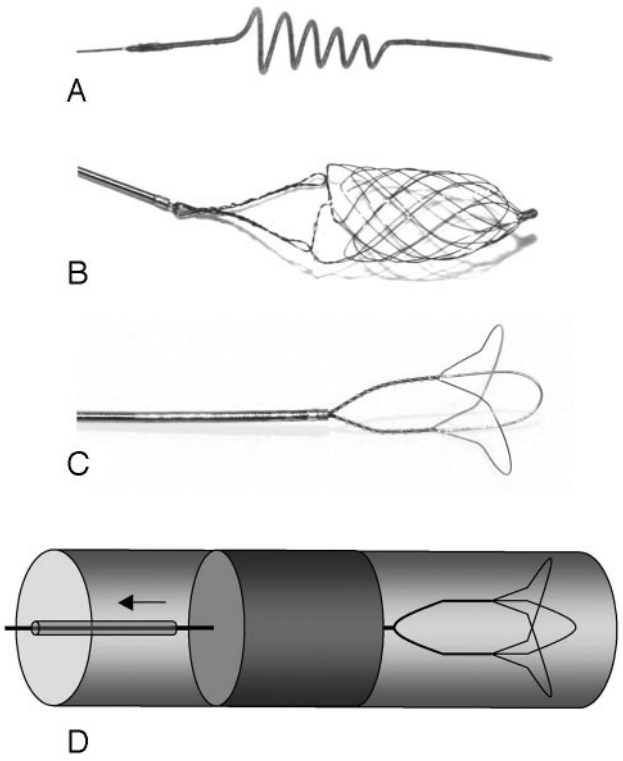

Fig 1. Comparison of distal devices. The Merci device (*A*) has a coil-like shape; the Catch device (*B*) has significantly more filaments forming its basketlike shape than the BCR Roadsaver device (*C*) with its complex snarelike shape. *D,* The device is delivered using a microcatheter and is unsheathed behind the clot, where force is applied to the distal base of the thrombus.

still vague on the mechanical aspects on thrombi and emboli in acute cerebrovascular stroke. Predominately whole-blood thrombus, or "red thrombus," is found in the occluded vessel.[17] However, the consistency of thrombus can differ in the clinical setting, and some groups have evaluated the harder or calcified clot and its influence on mechanical recanalization.[18]

For the present study, whole-blood thrombus was created. The clot was prepared for selective thromboembolization by mixing 10 mL of autologous blood with 25 IU of bovine thrombin (Dade Behring, Newark, Del). To increase x-ray absorption, 1 g of barium sulfate was added. After mixing for 10 seconds, the blood was injected into a 3 mm silicone tube (Clinico Medical, Bad Mersfeld, Germany) and incubated for 60 minutes at room temperature. The radio-opacity allowed visualization of thrombus movement in real time, as well as detection of the dislocation of fragments to peripheral vessels. The thrombus was then washed extensively in physiologic saline solution and incubated for a further 20 minutes before application.

Study Protocol

Surgery was performed through a groin approach on each animal for preparation of the common femoral artery (CFA) and vein (CFV) under general anesthesia. A 10F catheter sheath (Arrow International, Reading, Pa) was introduced into the CFA and continuously flushed with heparinized physiologic saline (10 IU/mL). A central venous catheter was placed in the CFV for constant venous access.

A biplane high-resolution angiography system (Toshiba CAS500, Tokyo, Japan) was used for selective intra-arterial digital subtraction angiography of the branching of the common carotid artery (CCA), the internal carotid artery (ICA), the lingual artery (LA), and the maxillary artery. Selective angiography was done on the LA and ICA. Two to 4 vessels per animal were occluded. The choice of vessels was balanced between the different groups. The mean vessel size was 2.9 mm (range, 2.3–3.4 mm) with no significant differences between the study groups ($P = .94$). After thrombus application, the guiding catheter was removed for 5 minutes to restore arterial flow and allow embedding of the thrombus.

The BCR (blood clot retriever) Roadsaver device was used for MT (Fig 1). The device consists of 3 distal loops mounted at a microwire. The diameter of the unfolded loops is 3.5 mm. The device was delivered using a microwire (SilverSpeed 14; ev3, Irvine, Calif) and a 2.9F microcatheter. Retrieval of the microcatheter initially liberated the device. To capture the thrombus at its distal end, the microcatheter was again advanced toward the device. As recommended for the device, the retrieval procedure was performed under proximal balloon occlusion using an 8F balloon guider (Balt) in the CCA. In addition, proximal aspiration was applied through the balloon catheter using a 50-mL syringe.

Retrieval of the thrombus was limited to 5 attempts per vessel occlusion. If after 5 attempts no recanalization was achieved, retrieval was rated as failed. During the study, a total of 21 vessels (11 LA and 10 ICA) were occluded, and 61 retrieval attempts were made. Follow-up angiography was performed to evaluate the recanalization rate and detect potential complications. A late (30 minutes) follow-up angiogram distinguished between vasospasm and dissection.

The following data were collected: 1) thrombus movement and distal dislocation, fragmentation, and thromboembolization; 2) recanalization rate using the Thrombolysis in Myocardial Infarction scale (TIMI; 0–3)[19]; 3) success rate and time per attempt; 4) number of vasospasms after successful recanalization graded as follows[20]: 0 = no narrowing, 1 = slight narrowing (<25% reduction in lumen diameter), 2 = moderate narrowing (25%–50% stenosis or 50%–75% stenosis affecting only a short vessel segment), and 3 = severe narrowing (50%–75% stenosis affecting a long vessel segment or any stenosis >75%); 5) site where thrombotic material was lost during retrieval; and 6) vessel dissection or perforation.

Analysis of variance was used to reveal differences between the study groups. The odds ratio (OR) and 95% confidential interval (CI) were used to evaluate the probability of successful thrombus retrieval and embolization rate with the different occlusion lengths.

Results

Efficiency and Complications for 10-mm Thrombi

A total of 7 vessel occlusions with 10-mm thrombi were treated. Nine retrieval attempts were needed to achieve complete recanalization (TIMI 3) in all of the occlusions (7 of 7; 100%; Table). To express the efficiency, the mean number of attempts necessary to attain 1 recanalization was calculated. Nine attempts were necessary to achieve recanalization of the 7 occlusions, or every 1.3 attempts (9 of 7) led to total recanalization. The percentage of attempts achieving TIMI 3 was 77.8% (7 of 9). In 2 attempts, the thrombotic burden was not reduced, not even achieving removal of thrombus fragments. The mean time per attempt was 10.6 minutes (SD: ±2.7), and the mean time for recanalization was 13.6 minutes. Initial passage of the clot with the microcatheter to unsheathe the device never led to distal dislocation of thrombotic material. In addition, no thromboembolic events occurred in other vessels dur-

Results for mechanical thrombectomy as related to thrombus length

Variable	Occlusion Length, mm			Level of Significance
	10	20	40	
Total number of attempts	9	25	27	NA
Mean time per attempt (±SD), min	10.6 (± 2.7)	11.5 (± 4.3)	11.8 (± 3.1)	$P = .67$*
Total recanalization rate, TIMI 3, %	100	71.4	42.9	
Success rate for partial clot removal, %	77.8	68.0	55.6	$P = .43$*
10 vs 20 mm				OR, 1.6 (95% CI, 0.3–9.8)
10 vs 40 mm				OR, 2.8 (95% CI, 0.5–16.0)
20 vs 40 mm				OR, 1.7 (95% CI, 0.5–5.3)
No. of attempts per successful recanalization	1.3	5	9	$P < .005$*
No. of attempts achieving TIMI 3, %	77.8	20.0	11.1	
10 vs 20 mm				OR, 14.0 (95% CI, 2.2–89.2)
10 vs 40 mm				OR, 28.0 (95% CI, 3.9–202.2)
20 vs 40 mm				OR, 2.0 (95% CI, 0.4–9.4)
Thromboembolism rate during passing procedure, %	0	4.0	7.4	$P = 0.67$*
Thromboembolism in other vessels, %	0	4.0	14.8	$P = 0.24$*
10 vs 20 mm				
10 vs 40 mm				
20 vs 40 mm				OR, 4.2 (95% CI, 0.4–40.2)

Note:—OR indicates odds ratio; 95% CI, 95% confidence interval; NA, not applicable.
* ANOVA.

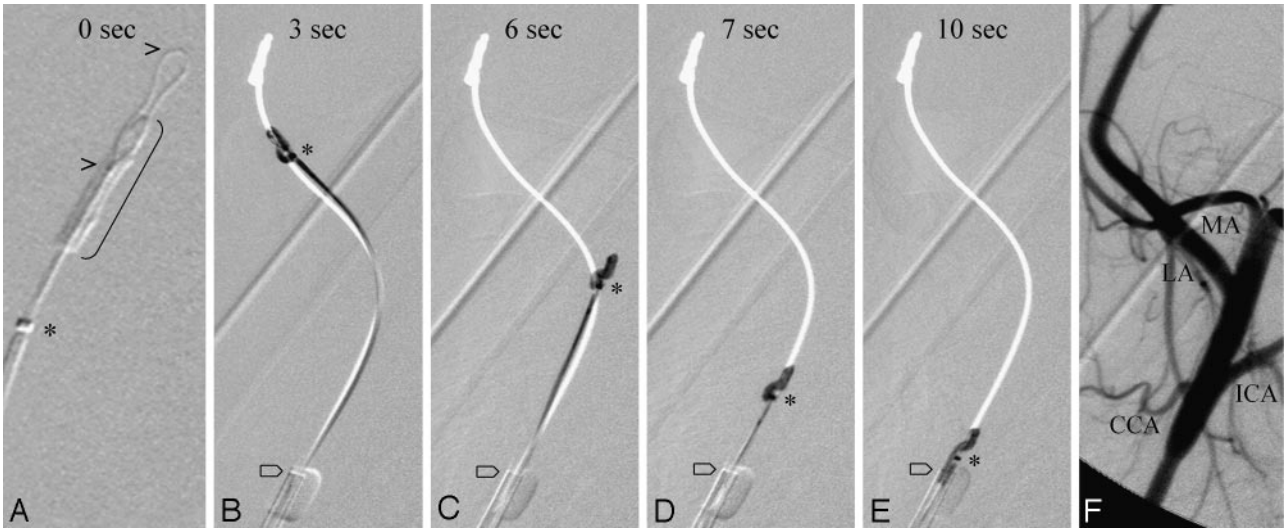

Fig 2. Magnified image of initial 10-mm thrombus; the microcatheter (*) is positioned proximal to the thrombus (]) with the device unsheathed (upper and lower markers >) distal to the thrombus (*A*). *B–D,* During initial retrieval, the device partially catches the thrombus without significant elongation of the vessel. *C* and *F,* Minor dislocation of thrombus and device is visible at the junction of the lingual and maxillary arteries. *E,* Elongation of the thrombus in proximity to the balloon catheter (*open arrow*) illustrates the effect of the additional proximal aspiration. Total retrieval was achieved.

ing retrieval. The vasospasm rating was high (mean grade, 3); no vessel dissection or perforation was encountered.

Thrombus-Device Interaction for 10-mm Thrombi

Evaluation of the thrombus-device interaction revealed that the BCR Roadsaver device efficiently encased the 10-mm thrombi. In all of the successful attempts, half of the thrombotic material was caught in the device, and half was pushed sideways to the microcatheter and partially compressed by the pulling maneuver (Fig 2). The thrombus, however, was still prone to flow, as proximal balloon occlusion was applied to collateral flow. Use of supplemental aspiration through the balloon catheter produced elongation of the thrombus in proximity to the catheter and often succeeded in partial or complete removal of the thrombotic material from the device (Fig 3).

Efficiency and Complications for 20-mm Thrombi

A total of 7 vessel occlusions with 20-mm thrombi were treated and 25 attempts were made and achieved complete recanalization (TIMI 3) in 5 occlusions (71.4%). A mean of 5 attempts was necessary to achieve 1 successful recanalization, and the percentage of attempts achieving TIMI 3 was 20% (5 of 25). This rate is significantly lower than that for 10-mm thrombi (OR, 14; 95% CI, 2.2–89.2). The device removed some thrombotic material in 17 (68%) of 25 attempts; in the other 8 attempts it retrieved no material. The mean time per attempt was 11.5 minutes (SD, ±4.3), a time not significantly different from that for 10-mm thrombi ($P = .67$).

One attempt (4%) resulted in the distal dislocation of a small thrombus fragment during the initial passage with the microcatheter. In another attempt (4%), the thrombus

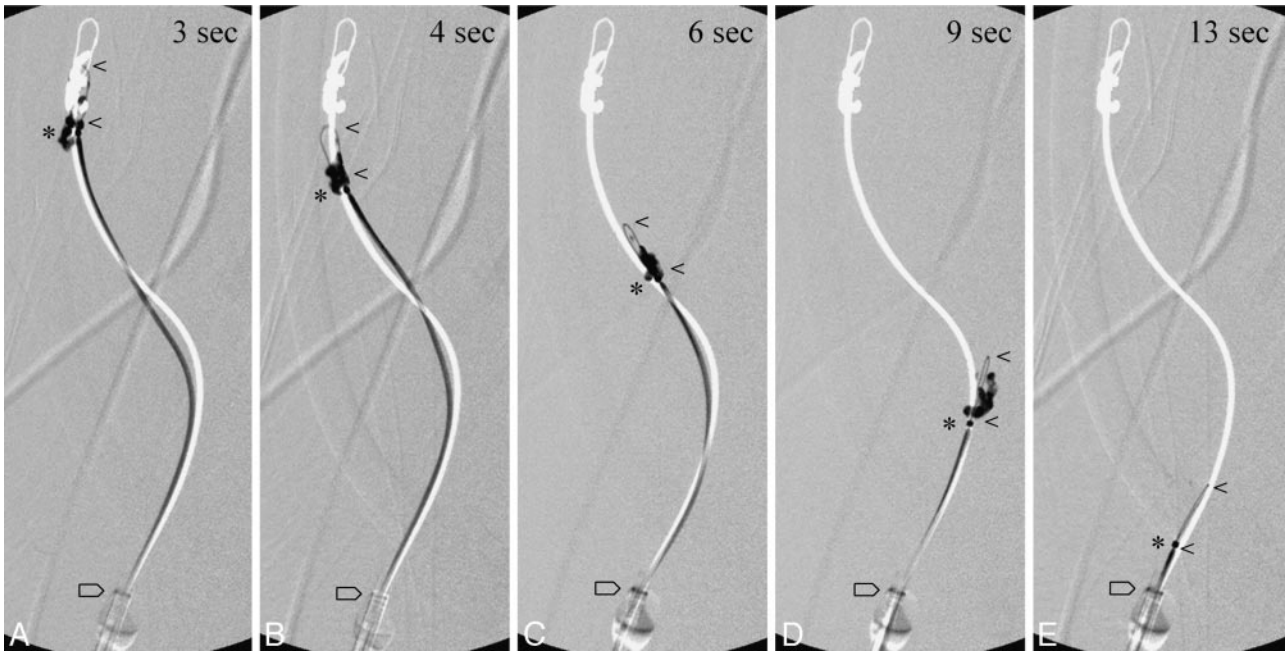

Fig 3. Retrieval of the 10-mm thrombus. *A,* The distal device (upper and lower markers <) enters the thrombus. *B* and *C,* Approximately half of the thrombotic material is carried within the device; the other half is either pushed sideways to the microcatheter (*) or proximal to the device and is prone to collateral flow (*D*). *E,* The supplementary proximal aspiration sucks the entire thrombus from the device into the balloon catheter (*open arrow*) to achieve total recanalization.

fractured during retrieval, triggering thromboembolic events in other vessels. The vasospasm rating was also high (mean grade, 2.8); no vessel dissection or perforation was found.

Efficiency and Complications for 40-mm Thrombi

A total of 7 vessel occlusions with 40-mm thrombi were treated; 27 attempts resulted in complete recanalization (TIMI 3) of 3 occlusions (42.9%). A mean of 9 attempts was necessary to achieve 1 total recanalization; the relation of attempts achieving TIMI 3 to the total number was 11.1% (3 of 27). This is a significantly lower success rate than for 10-mm thrombi (OR, 28; 95% CI, 3.9–202.2) but not significantly different from that for 20-mm thrombi (OR, 2; 95% CI, 0.4–9.4). Some thrombotic material was removed in 15 (55.6%) of 27 attempts; in the other 12 attempts no thrombotic material was retrieved. This rate did not differ significantly from that for 10-mm and 20-mm thrombi ($P = .43$). The mean time per attempt was 11.8 minutes (SD, ±3.1), a time not significantly different from that for the other study groups ($P = .67$).

In 2 attempts (7.4%), a small thrombus fragment was dislocated distally during initial passage with the microcatheter. The number of thromboembolic events in other vessels was clearly elevated to 14.8%, not reaching statistical significance ($P = .24$; Table). The vasospasm rating was again high (mean grade, 3); no vessel dissection or perforation occurred.

In none of the study groups did a device fracture or become lost. No vessel dissection or perforation was found during control angiography.

Thrombus-Device Interaction of 20-mm and 40-mm Thrombi

The interaction of 20-mm thrombi and 40-mm thrombi with the device was similar: after the device was positioned distal to the thrombus, a small distal portion of the thrombus was caught inside the device, whereas the major proximal portion was compressed and pushed sideways to the microcatheter either by the renewed forward movement of the microcatheter or by the pulling maneuver during retrieval (Fig 4). If the compressed thrombus was mobilized, no further compression occurred during retrieval. The proximal thrombus was prone to (collateral) flow and to shearing at the tip of the guiding catheter (Fig 5). If the thrombus was not mobilized, during subsequent retrieval attempts the device did not catch the compressed thrombus, nor was it easy to retrieve through the occluded vessel. The increase in force necessary to slip the device through the thrombotic material caused the occluded vessel to elongate (Fig 6). The device was then retrieved empty or containing only small fragments of the thrombus.

Discussion

MT is not yet an established treatment option on par with thrombolysis. Although the high recanalization rates achieved in some studies are encouraging, severe complications, such as thromboembolic events, have been observed of which the underlying causes remain unidentified. Because MT is a mechanical approach, the mechanical properties of the thrombus, such as the length, might be crucial to its success. None of the numerous studies published on IAT and stroke treatment has focused on thrombus length. This omission can be attributed on the one hand to the difficulty of determining occlusion length in the clinical setting (eg, administering contrast injections proximally and distally to the occlusion site) and on the other hand to a lack of alternative treatment options. Any evaluation of MT (using either a proximal or distal device) to determine the optimum tradeoff between efficiency and complications must, therefore, focus on the mechanical properties of the thrombus. In the present study, we used an animal

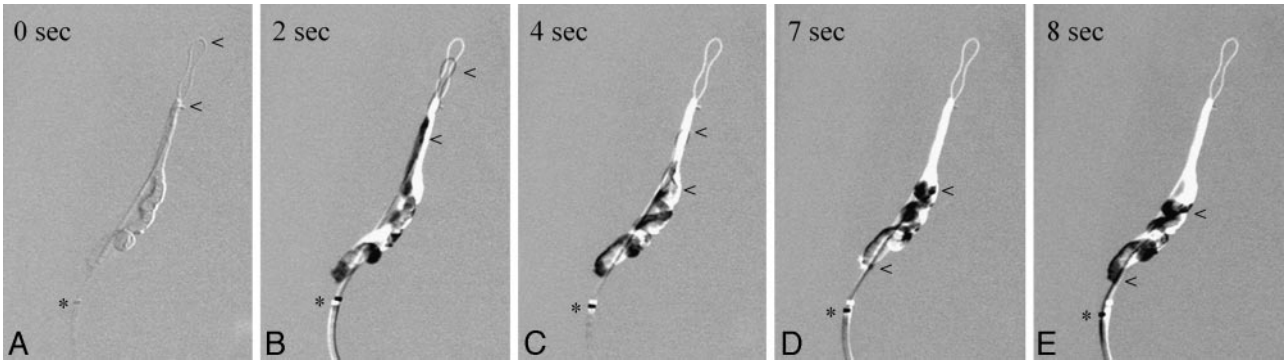

Fig 4. *A,* During the retrieval attempt of the 40-mm thrombus, the device is unsheathed distal to the thrombus. *B,* The device (upper and lower markers <) enters the thrombus. *C–E,* The thrombotic material is progressively compressed between the device and the microcatheter (*).

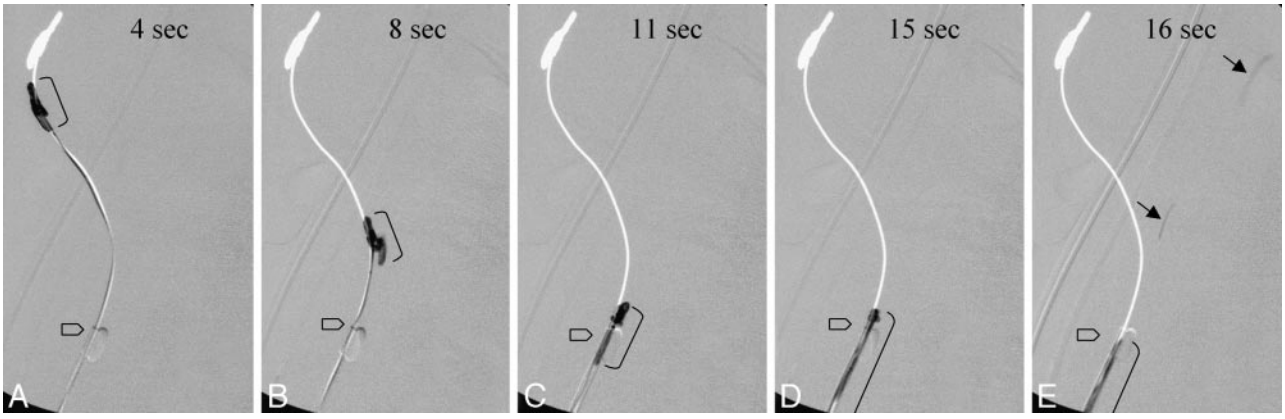

Fig 5. The 40-mm thrombus (]) is initially mobilized within the carrying vessel (*A*) and partially compressed sideways to the microcatheter (*B*). *C,* The thrombus enters the balloon catheter (*open arrow*); compression of the thrombus causes the distal part to stick at the tip of the balloon catheter. The thrombus is elongated (*D*) and finally fractures with consequent thromboembolization (⟶) into other major vessels (*E*). A major potion of the thrombus is retrieved to the balloon catheter.

model to evaluate in vivo one important aspect of vessel occlusion, the thrombus length.

For short occlusions (10-mm thrombus), in our experience the most clinically relevant, the BCR Roadsaver device achieved fast and efficient recanalization of the occluded vessels. No distal dislocation of the thrombus or thromboembolic events were observed. These results emphasize the potential of MT in general and of the device that we used (BCR Roadsaver) in particular in the setting of acute stroke. They also show for the first time that the thrombus length has a significant influence on the retrieval rate. In short occlusions (10-mm thrombus), the device achieved complete recanalization of all of the occlusions, with a low mean number of attempts needed to achieve recanalization (1.3) and a high percentage of successful attempts (77.8%).

The results for retrieval of 20-mm thrombi did not differ significantly from those for 40-mm thrombi, both being significantly worse than those for 10-mm thrombi. This finding indicates that the borderline of efficiency lies somewhere between 10 and 20 mm, within the range of possible clinical occlusions. Complications such as distal dislocation of thrombotic material also increased slightly with thrombus length. The thromboembolic events into other vessels increased from 0% in the 10-mm thrombus group to 7.4% in 20-mm thrombus group, with a rise to 14.8% in the 40-mm thrombus group. These events are clinically important, because they might worsen the neurologic status of the patient by occluding a so-far-unaffected vascular territory. However, this increase in complication rate did not quite reach statistical significance in the present study.

The decrease in recanalization rate and increase in complication rate parallel to thrombus length can be attributed to the thrombus-device interaction. Although most small thrombi are caught in the device, large thrombi are usually compressed by the device and pushed proximally to it.

The compression of large thrombi during retrieval increases the diameter of the thrombus, thereby increasing the already higher friction between it and the vessel wall. One consequence of this is elongation of the vessel during retrieval of long thrombi. From our point of view, the compression of the thrombus, therefore, reduces the retrieval rate and increases the stress on the vessel wall. This finding is consistent with the results of a previous study on MT in vivo.[16]

Once a long thrombus is mobilized, the proximal portion is prone to flow and to shear off at the guiding catheter. The additional aspiration recommended for the Roadsaver device proved to be effective in proximity to the balloon catheter but did not totally eliminate thromboembolic events associated with long thrombi. It must be emphasized, however, that to evaluate the general principle of distal MT, we designed the present study so as to test it at its limits, with 40-mm thrombi probably exceeding the limits of clinical probability. Even in these extreme cases, no safety issues with the Roadsaver device were observed.

Severe vasospasms after recanalization were encountered in all of the study groups, a finding consistent with previous studies.

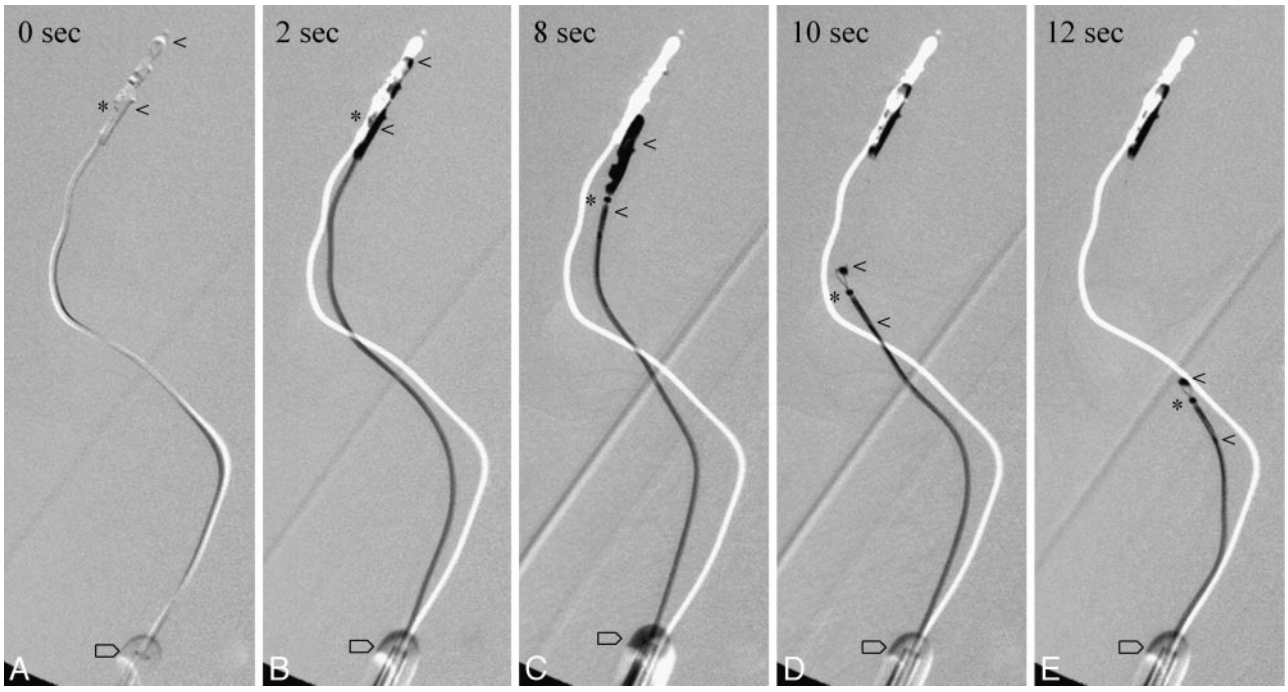

Fig 6. *A,* The device (upper and lower markers <) is unsheathed distal to the 40-mm thrombus. *B* and *C,* During the retrieval attempt, the device enters the compressed thrombus, and the pulling force causes marked elongation of the carrying vessel. The device finally slips through the thrombus catching only a minor fragment (*D*), which is retrieved together with the microcatheter (*) to the balloon catheter (*open arrow, E*).

We consider the high mean vasospasm ratings, independent of thrombus length or visible stress to vessel walls during retrieval, as a limitation of the animal model. In our view, the relatively "young" vessels of our model had a higher tendency to vasospasm, which may have led to the high rate. The high vasospasm rate might even obscure differences between our study groups. On the other hand, the vasculature provides less tortuosity than the human anatomy. This might facilitate the application and retrieval process during MT and overestimate the success rate due to lower friction compared with the applications in humans. Furthermore, the chosen whole-blood thrombus provides a soft consistency; however, retrieval success might differ depending on the thrombus consistency.

Conclusions

MT using a distal device proved to be a fast, effective, and safe procedure for recanalizing short (10-mm) occlusions in the animal model. Occlusion length emerged as a crucial determinant for MT; for occlusions of longer length (20 and 40 mm), compaction of the thrombus led to a significant decrease in recanalization success per attempt and increased complication rates. These findings underline the need to evaluate the occlusion length in patients and suggest limitations of MT in the clinical application.

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