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Penumbra System® for Intracranial Mechanical Thrombectomy

Experts discuss the effectiveness of this system for the fast and efficient removal of intracranial thrombi.

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Disclaimer: Physician authors were not compensated for the writing of this article.



Early revascularization of large vessel occlusions (LVOs) is known to improve clinical outcomes in selected patients with acute ischemic stroke (AIS).¹ Since its release in 1995, tissue plasminogen activator (tPA)

was the only FDA-approved early treatment modality for AIS. However, only a fraction of patients receive intravenous tPA due to the restrictive 3- to 4.5-hour treatment time window after the onset of symptoms. Also, intravenous tPA has been shown to be less effective in removing LVOs.² Such limitations have led to the rapid evolution of mechanical thrombectomy devices.

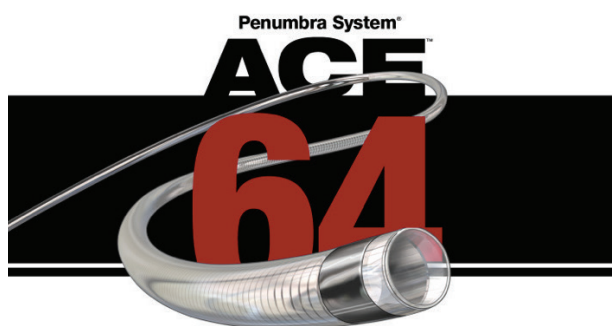
Early thrombectomy began when neurointerventionists manipulated microwires in attempts to dislodge thrombus. Since then, we have seen tremendous innovation: the Merci® retrieval system (Stryker Neurovascular), the original Penumbra System® (Penumbra, Inc.), stent retrievers, and the newest Penumbra System with ACE™ and ACE™ 64 reperfusion catheters.

MR CLEAN was the first randomized controlled trial (RCT) to show that patients who receive both intravenous tPA and endovascular therapy have significantly improved clinical outcomes compared with patients who receive only intravenous tPA. The trial studied 500 patients with AIS caused by proximal LVOs in the anterior circulation (as confirmed by CT angiography

[CTA], MRA, or digital subtraction angiography) and a National Institutes of Health Stroke Scale (NIHSS) score ≥ 2 .³ Subsequent RCTs have confirmed these findings.⁴⁻⁶

Since the publication of the positive RCT data, many physicians have used a direct aspiration as a first-pass technique (ADAPT) to revascularize patients. When using this technique, the operator places a 6-F-long sheath as far distally into the internal carotid artery





(ICA) (for anterior thrombi) or into the distal V2 segment (for posterior thrombi) as safely as possible. In general, the largest caliber reperfusion catheter is selected in order to maximize engagement with the thrombus. The reperfusion catheter is delivered over a microcatheter and a 0.016-inch microwire directly to the thrombus. After positioning the reperfusion catheter, the microcatheter and wire are then removed. The Penumbra pump provides full vacuum, enabling the reperfusion catheter to aspirate and remove the thrombus.

ADAPT is possible due to advanced engineering technology that allows catheters close to 6-F in outer diameter to be advanced to the site of occlusion. The latest reperfusion catheter from Penumbra, ACE64, offers a large distal inner lumen and excellent trackability, while the Penumbra pump provides constant vacuum to maximize clot engagement and removal during the procedure. The ADAPT FAST study, which used mostly previous-generation SMAX™ and SMAX ACE™ devices (Penumbra, Inc.), reported > 97% revascularization rates (thrombolysis in cerebral infarction [TICI] 2b/3), no instances of emboli to new territory (ENT), and groin puncture to revascularization times of 37 minutes or less.¹

Another mechanical thrombectomy approach involves the use of a stent retriever, either in combination with local aspiration (“Solumbra” technique) or with a balloon guide catheter (BGC). During the Solumbra technique, a reperfusion catheter is advanced over a microcatheter to the site of occlusion and left at the face of the thrombus. A stent retriever is deployed through the microcatheter, and the microcatheter is removed, leaving the stent retriever in place. Under aspiration, the stent retriever is removed.

A recent independent study reported improved clinical outcomes (modified Rankin Scale score ≤ 2 at 90 days) with ADAPT compared with the Solumbra technique.⁷ This encouraging finding warrants further investigation but suggests that direct aspiration with the Penumbra System, when used frontline as part of ADAPT, enables the safe, effective, and efficient removal of thrombi from the neurovasculature. ADAPT is

also known to have significantly lower associated procedure costs, hospitalization costs, and lengths of stay compared with the Solumbra technique.⁸

BGCs are designed to arrest antegrade flow in order to maximize clot capture during stent retrieval. During the procedure, a BGC is advanced into the proximal ICA. A stent retriever is deployed, and the balloon of the BGC is inflated to arrest flow in the carotid artery when the stent retriever is retrieved into the BGC.

ENT occurs when fragments of the thrombus are released during thrombectomy, causing embolization to previously unaffected territories. The combination of a stent retriever and BGC is known to contribute to ENT rates of 9% to 10%.^{3,9,10} A substudy of the North America Solitaire Acute Stroke registry evaluated the role of BGCs in patients treated for AIS with the Solitaire™ stent retriever (Medtronic, Inc.) and reported that BGCs offer no statistically significant decrease in ENT rates or distal thrombi.¹¹ Moreover, the addition of localized aspiration may reduce the incidence of ENT due to its ability to remove clot en masse. In one retrospective analysis, the use of a stent retriever/aspiration combination resulted in a 6% ENT rate—a noticeable decrease from a stent retriever/BGC combination.¹²

The following cases highlight the effective clot removal, fast revascularization times, and favorable safety profiles of ADAPT.

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ADAPT causes minimal clot fragmentation and often allows for the extraction of the occlusive embolus en bloc with a single pass. The minimization of ENT is a significant advantage of using ADAPT.

CASE REPORT

A 61-year-old man arrived to the emergency department and presented with several hours of diplopia, dizziness, and right upper extremity weakness. The patient underwent an initial CT scan at approximately 4:30 PM (Figure 1). At 9:30 PM, an LVO was detected with CTA (Figure 2).

The patient was transferred to the neurovascular intensive care unit at Swedish Medical Center in Englewood, Colorado, arriving to the angiography suite at 2 AM. Groin puncture occurred 10 minutes after arrival, and the thrombus was identified 15 minutes later (Figure 3).

At the time of arrival, the patient was well outside of the time window for intravenous tPA, so the decision was made to treat the occlusion mechanically using an ACE64 device. A 3MAX™ catheter (Penumbra, Inc.) was used to provide support to navigate ACE64 to the thrombus. With one pass, the clot was removed intact (Figure 4). The final angiogram, 18 minutes later, showed that all of the thrombus was successfully removed, there was no ENT, and the patient achieved TICI 3 recanalization (Figure 5).

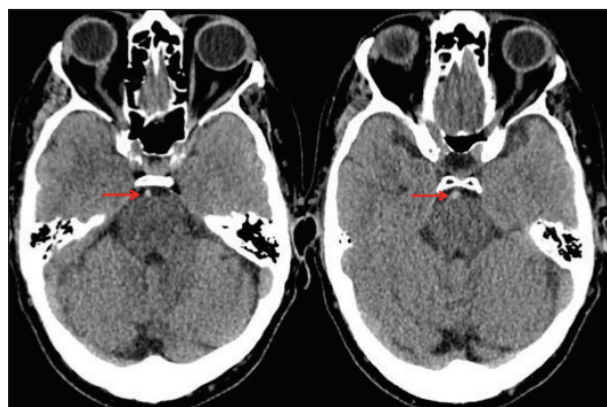


Figure 1. Initial CT scan.

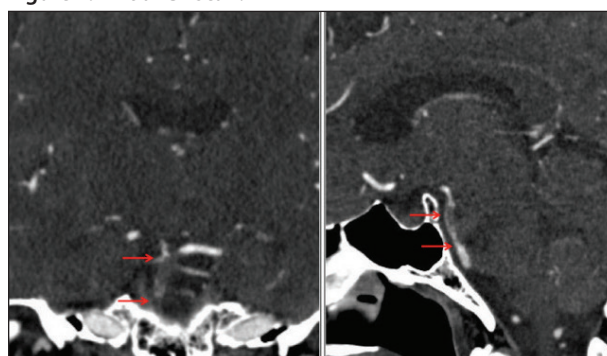


Figure 2. CTA confirming an LVO.

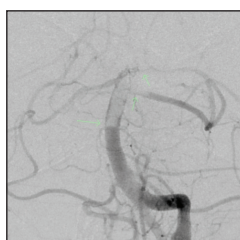


Figure 3. Angiogram showing the occluded basilar artery.

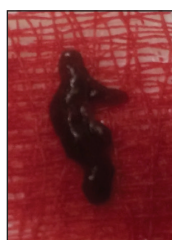


Figure 4. Clot removed intact using ACE64.

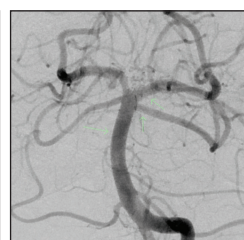


Figure 5. Final angiogram showing TICI 3 recanalization of the basilar artery.



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The availability of more flexible, large-bore reperfusion catheters make ADAPT a novel revascularization strategy.

CASE REPORT

A 76-year-old woman with a history of hypertension woke up at 8:30 AM with “stroke symptoms,” as

described by her husband. The exact time of onset is unknown. At the emergency department, the patient

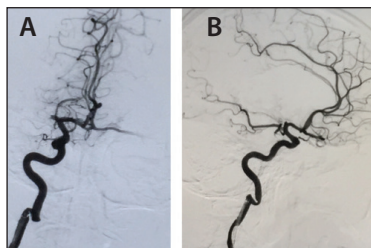


Figure 1. Occluded right MCA. Anteroposterior (AP) view (A), lateral view (B).

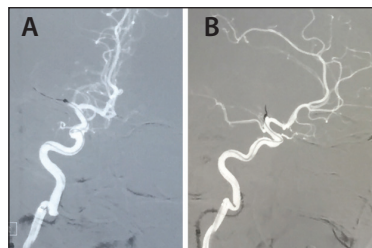


Figure 2. The 5MAX ACE device is navigated to the right MCA. AP view (A), lateral view (B).

presented with a modified NIHSS score of 10, with left hemiplegia, facial droop, and neglect. Imaging showed a dense right M1 segment, large right middle cerebral artery (MCA) penumbra, and proximal right M1 occlusion. Ten minutes later, the patient received intravenous tPA while in CT.

The patient was transferred to the interventional radiology suite where groin puncture was initiated within minutes. A right M1 occlusion was confirmed (Figure 1).

We decided to use ADAPT by delivering the 5MAX ACE catheter to the occlusion (Figure 2) over a 3MAX reperfusion catheter and a Fathom™ wire (Boston Scientific Corporation).

One pass of the 5MAX ACE catheter resulted in TICI 3 flow to the MCA (Figure 3). Groin puncture to recanalization time was 18 minutes. Closure was successful with a StarClose SE® arterial closure system (Abbott Vascular). Prior to leaving the interventional radiology suite, the patient demonstrated improved motor skills with a modified NIHSS score of 5.

Twenty-four hours later, CT images showed that the

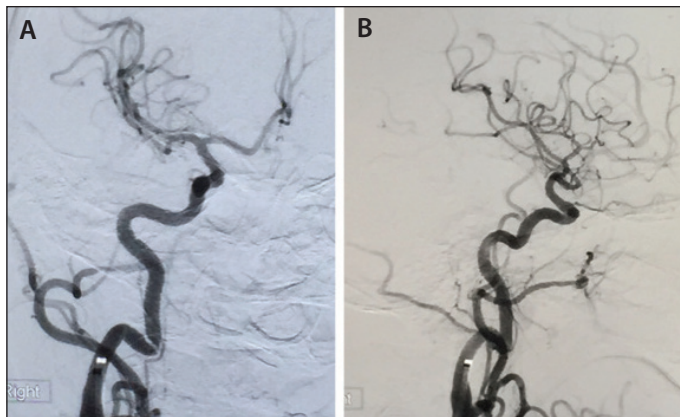


Figure 3. Successful revascularization of the right MCA. AP view (A), lateral view (B).

right MCA was no longer hyperdense and that there was no evidence of infarct or hemorrhage. She had a modified NIHSS score of 2 for left arm weakness and facial droop.

Forty-eight hours later, MRI images showed small lacunar infarcts in the right lentiform nucleus and caudate, with a modified NIHSS score of 0.



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Dr. Baxter has disclosed that he is a consultant to Penumbra, Inc.

Improved reperfusion catheters have accelerated our ability to achieve higher recanalization rates than ever before. Today, the operator rarely has to completely traverse the occlusion or deploy adjunctive devices. The catheter can be advanced to the level of the thrombus over the 3MAX catheter and any microwire. Inability to aspirate further confirms optimal positioning of the catheter relative to the thrombus. The microcatheter and wire are removed, and aspiration is applied using the Penumbra pump.

CASE REPORT

A 32-year-old woman with a history of smoking and hypertension presented with aphasia, right hemiplegia, and left gaze preference. Her initial NIHSS score was 20. Imaging confirmed an LVO in the left MCA (Figure 1). The patient was given 73.6 mg of intravenous tPA.

Groin puncture occurred 2 hours and 52 minutes from symptom onset. TICI 3 recanalization was achieved 14 minutes later, with one pass of the ACE64 catheter (Figure 2). After 24 hours, her NIHSS score decreased to 1. The patient's modified Rankin Scale score was 0 at 90-day follow-up.

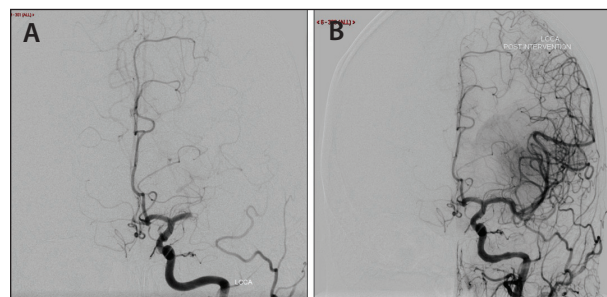


Figure 1. Occluded left MCA (A) and revascularization of the left MCA (B).

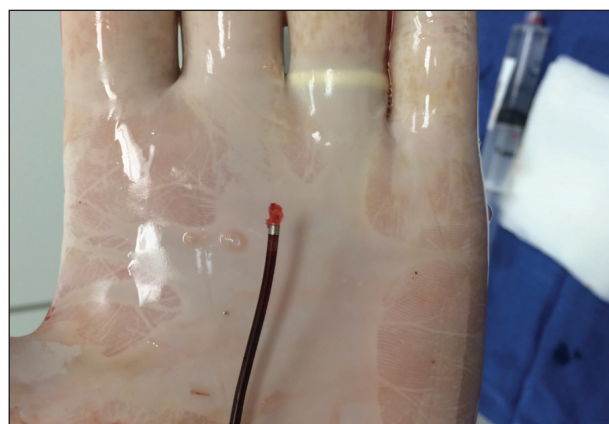


Figure 2. Clot removed from the MCA using the ACE64 catheter.

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CASE REPORT

A 92-year-old woman arrived to the emergency department, presenting with acute right-sided hemiparesis, left gaze deviation, and severe aphasia. According to the patient's daughter, they were sitting together about to have lunch at 11:00 AM, when she suddenly slumped over to the right and could not speak. The patient arrived at our center via ambulance at 11:27 AM. The stroke response team brought her directly from triage to the CT imaging suite. Her initial NIHSS score was 21.

The patient's past medical history was significant for hypertension, coronary artery disease, and diabetes mellitus. Three weeks earlier, the patient had fallen and hit her head, and at the time, the family was told that she had a contusion. She was also recently diagnosed with atrial fibrillation and treated with metoprolol for heart rate control; she was not anticoagulated. At baseline, the patient was independent and took care of all her own needs without assistance.

An initial CT scan of the head demonstrated a dense left MCA with an Alberta Stroke Program Early CT Score (ASPECTS) of 8 (Figure 1). CTA confirmed a proximal left MCA occlusion. The patient was not a candidate for intravenous tPA due to her history of recent head trauma, as previously mentioned. She was transferred to the interventional suite for mechanical thrombectomy at 12:10 PM.

The patient was placed under monitored anesthesia care, and using a right common femoral approach, a 6-F, 90-cm Neuron™ MAX 088 guide sheath (Penumbra, Inc.) was placed. We attempted to deliver the Neuron MAX 088 guide sheath over a 125-cm Simmons Select catheter into the left ICA. Despite using a variety of guidewires of variable stiffness, all of our attempts failed. In this patient, advancing a stable guide platform into the left carotid artery was challenging due to tortuous anatomy and a type III arch (Figure 2). Each time we advanced the Neuron MAX device, the system prolapsed into the ascending aorta. A 4-mm X 15-mm TransForm™ occlusion balloon catheter (Stryker Neurovascular) and a 0.014-inch Synchro2® guidewire (Stryker Neurovascular) were advanced through the 125-cm Simmons catheter into the proximal external carotid artery. The TransForm balloon was inflated in the facial branch of the external carotid artery. The

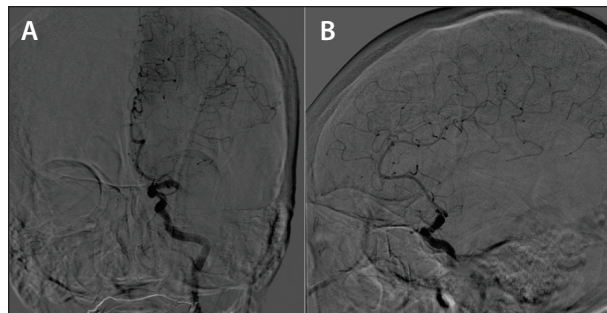


Figure 1. Left MCA occlusion. AP view (A), lateral view (B).

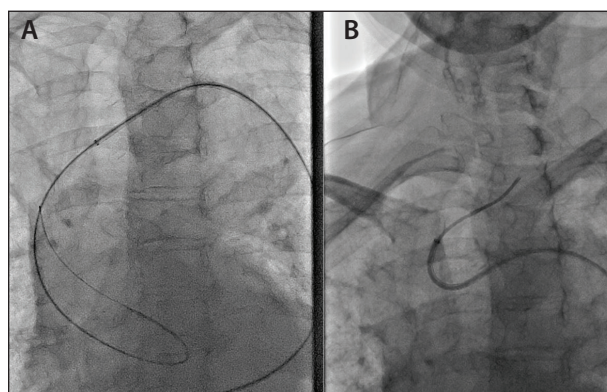


Figure 2. Reformatting the Simmons Select catheter and type III arch (A). The Simmons Select catheter engaged in proximal left common carotid artery (B).

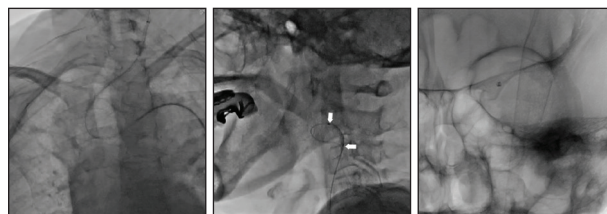


Figure 3. The 5MAX ACE in position.

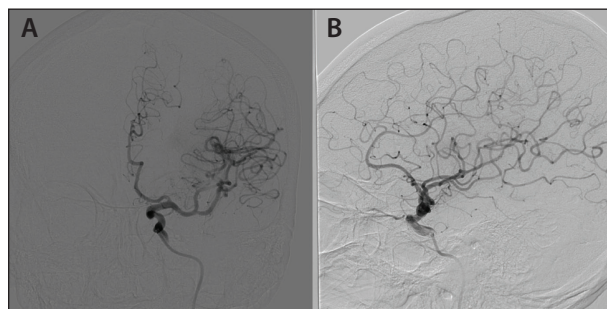


Figure 4. Recanalization of MCA. AP view (A), lateral view (B).

inflated balloon and its associated catheter were used to anchor the system, allowing for delivery of the Neuron MAX 088 device into the common carotid artery. A 5MAX ACE catheter was delivered to the



Figure 5. CT imaging at 24 hours.

occlusion site (Figure 3) over a Velocity® microcatheter (Penumbra, Inc.) and a 0.014-inch Synchro2 wire. The clot was engaged at 1:35 PM.

Using aspiration alone, TICI 3 recanalization was achieved after 2 minutes (Figure 4). The patient's symptoms started to improve: she began moving her right side, and her speech returned. Shortly after the procedure, her NIHSS score was down to 12. At 24 hours, the patient had a mild residual facial droop and right upper extremity drift with a NIHSS score of 2. A CT scan of the brain showed no evidence of infarct or hemorrhage (Figure 5). She was started on apixaban 2.5 mg by mouth twice daily and was discharged on hospital day 4 with a NIHSS score of 1.



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In order to create a stable platform for the SMAX ACE catheter, the Neuron MAX guide sheath should be delivered as far distally into the cervical or proximal petrous ICA as possible. The largest size reperfusion catheter that the vessel can accommodate should be used in order to engage the maximum amount of thrombus.

CASE REPORT

An 83-year-old man arrived to the emergency department 3 hours after presenting with left hemiplegia, dysarthria, right gaze preference, and a NIHSS score of 15. CTA and CT perfusion imaging confirmed an LVO in the right ICA (Figures 1 and 2).

The patient was given a full dose of intravenous tPA, and we decided to aspirate using the SMAX



Figure 1. Initial CT scan.

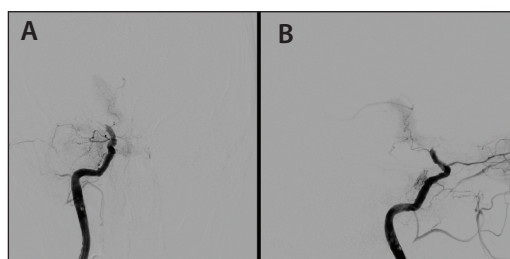


Figure 2. Occluded right ICA. AP view (A), lateral view (B).



Figure 3. Advancing the SMAX ACE catheter to the thrombus (A, B); revascularization of the right ICA (C).

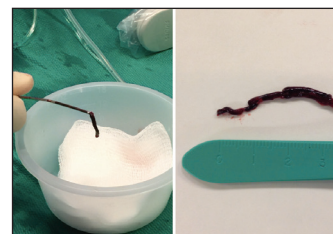


Figure 4. The SMAX ACE catheter removes thrombus intact from the right ICA.

ACE catheter (Figures 3 and 4). TICI 3 recanalization was achieved 30 minutes after groin puncture, and 48 hours later, his NIHSS score decreased to 2 (Figure 5).

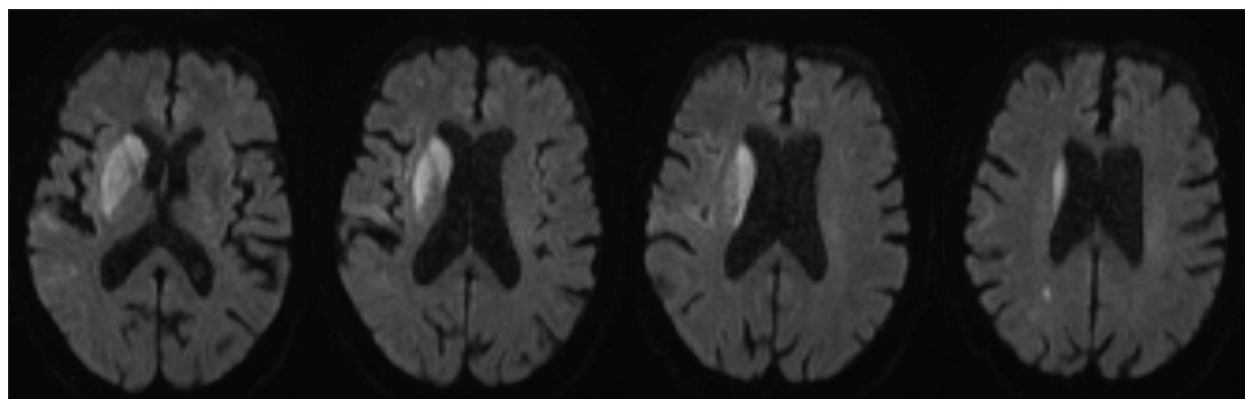


Figure 5. MRI 48 hours postoperative.

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CASE REPORT

A 40-year-old woman, last known well at 11:00 AM, arrived to the emergency department presenting with right MCA syndrome and an NIHSS score of 28. CTA showed an occluded right M1. The patient was given intravenous tPA but decompensated clinically, requiring intubation prior to being transferred to Lahey Hospital & Medical Center.

Intervention began at 2:00 PM. A right M1 occlusion was

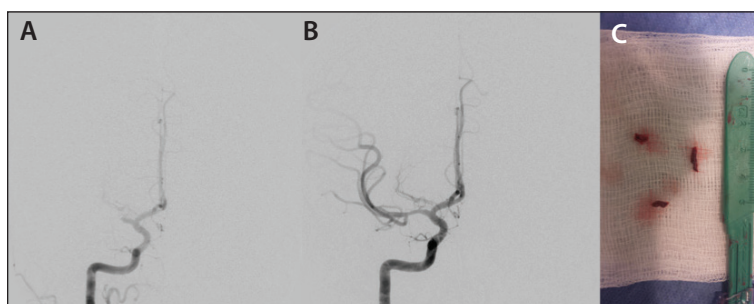


Figure 1. Occluded right MCA (A); revascularization of the MCA (B); removed thrombi (C).

confirmed via angiography (Figure 1). We decided to use a 5MAX ACE catheter delivered over a 3MAX catheter to aspirate the thrombus. Groin puncture to TICI 3 recanalization time was 33 minutes. The patient's NIHSS score at discharge was 0.

CONCLUSION

The Penumbra System with ACE and ACE64 reperfusion catheters is a proven, safe, and effective go-to device to achieve revascularization in patients with AIS secondary to LVO. ACE technology offers superb trackability and a large inner lumen that maximizes thrombus engagement and offers versatility if adjunctive devices are needed. We look forward to the continued evolution of thrombectomy approaches and believe that the Penumbra System deserves strong consideration as a primary frontline tool to treat AIS. ■