

Process Improvement in Stroke Care

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Rapid technologic advances in endovascular therapy have provided neurointerventionalists with more effective mechanical thrombectomy tools to treat acute ischemic stroke.

With the release of the MR CLEAN results supporting the efficacy of mechanical thrombectomy, clinicians have turned their focus to optimizing the continuum of stroke care and improving outcomes for all stroke patients. Standardized stroke protocols have come into use to reduce the time to recanalization, address inefficiencies, and enable the delivery of more timely care. Where door-to-puncture times for patients used to be more than 1 hour, facilities are now able to bring patients to the angiography suite in vastly reduced times. Discussions have also extended to patient triage in the field and readiness of stroke centers. It has been well supported that for every 30 minutes without intervention, the probability of a good clinical outcome decreases by 12%.¹ With time improvements across the continuum of stroke care, there is potential for drastic improvements in outcomes for an even larger number of patients.

Institutions have been honing in on three important time intervals: door to CT, CT to puncture, and puncture to revascularization. A variety of changes are being instituted via standardized protocols, including: (1) use of a standardized table setup to ensure appropriate materials are present for thrombectomy; (2) timely patient processing upon arrival to the emergency department; and (3) streamlined preoperative preparation to avoid delay in time to puncture. These changes have led to improved door-to-groin puncture times, as demonstrated by Abbott Northwestern, where mean door-to-groin puncture times improved from 73 to 22 minutes.² Abbott Northwestern adopted a standardized table setup that is detailed here in the case report by Dr. Kayan and Dr. Delgado. Similar results were obtained at Swedish Medical Center, where a standardized stroke protocol was instituted in the summer 2013. When the data from



2012 to 2015 were evaluated, door-to-recanalization times decreased from 131 to 84 minutes, with 60% of the time savings realized from standardizing the thrombectomy procedure to aspiration alone front line.³ As the clinical team moves quickly to prepare for patient arrival, the use of protocols and checklists ensures that as soon as the patient gets to the angiography suite, the team is ready to perform the intervention.

THE IMPACT OF ACE™68 ON THROMBECTOMY

A direct aspiration as a first-pass technique (ADAPT) has provided neurointerventionalists with an efficient and effective method for removal of large vessel occlusions (LVOs). Aspiration as a first-pass technique has continued to gain adoption, and new devices will likely increase the success rate of aspiration, further translating to better patient outcomes. Penumbra has continually focused on optimizing its aspiration system, powering ACE™ large-bore reperfusion catheters with the full-vacuum Pump MAX™ and Hi-Flow aspiration tubing.

In line with continual performance improvement, Penumbra has developed an even more advanced large-bore reperfusion catheter with the new ACE™68.

TIME SAVINGS WITH ACE™68 AND THE PENUMBRA SYSTEM

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Penumbra engineered the ACE68 Reperfusion Catheter with a 0.068-inch lumen on a new tracking technology platform. Sixteen transition zones and an extended flexible distal shaft allow for an optimal tracking profile to enable easy navigation through difficult tortuosity. These technologic improvements have translated to even shorter procedure times, along with highly successful Thrombolysis in Cerebral Infarction (TICI) 2b/3 results with aspiration alone.⁴ The ACE68 is able to remove large clot burdens, reducing the need for adjunctive devices and allowing for cost savings. Abbott Northwestern observed significant improvements with each successive generation of the ACE Reperfusion Catheter.⁴ In their 100-patient experience, successful revascularization using

aspiration alone was achieved in 65% of patients with ACE™60, 88% with ACE™64 (Penumbra, Inc.), and 100% with ACE68.⁴ Penumbra's focus on continually improving the only aspiration system cleared by the US Food and Drug Administration has allowed for effective use of aspiration as the go-to therapy for stroke interventions.

1. Khatri P, Yeatts SD, Mazighi M, et al. Time to angiographic reperfusion and clinical outcome after acute ischaemic stroke: an analysis of data from the Interventional Management of Stroke (IMS III) phase 3 trial. *Lancet Neurol*. 2014;13:567-574.
2. Kayan Y, Delgado Almandoz J, Young M, et al. Process improvement in door-to-groin puncture times at a comprehensive stroke center shows a trend towards reduced mortality at 90 days. Poster presented at: SNIS Annual Meeting; July 25-29, 2016; Boston, MA. Available from authors upon request.
3. Frei D, McGraw C, McCarthy K, et al. A standardized neurointerventional thrombectomy protocol leads to faster recanalization times [published online November 3, 2016]. *J Neurointerv Surg*.
4. Delgado Almandoz J, Yasha K, Young M, et al. ACE aspiration is an effective first-line treatment for acute ischemic strokes in the anterior circulation. In: Proceedings from the ABC-WIN Seminar; January 15-17, 2017; Val d'Isere, France. Available from authors upon request.

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Standardization of our stroke treatment protocol has allowed for significant improvements in treatment times. By utilizing the following three core time-saving processes, my team and I have been able to reduce door-to-puncture times from 66 to 47 minutes and puncture-to-revascularization times from 65 to 37 minutes¹:

- Prenotification of the arrival of a stroke patient
- Dedicated stroke team preparing for intra-arterial therapy in parallel
- Standardization of the thrombectomy procedure

Standardization of the thrombectomy procedure has presented the greatest potential for time improvements. ADAPT has been adopted as our first-line strategy and has been implemented in our protocol, calling for use of a large-bore ACE68 Reperfusion Catheter to be tracked over a 3MAX™ Catheter (Penumbra, Inc.) to the face of the clot. Three attempts are made with aspiration, ensuring that each attempt applies aspiration for a full 90 seconds. Following this approach with ACE68 has allowed me to achieve greater success with aspiration alone, therefore enabling decreased procedure time and reduced device cost.

CASE REPORT

A man in his early 60s presented with right hemianopsia, right visual field deficit, and right-sided weakness. A posterior cerebral artery (PCA) occlusion was identified on CT, and the patient was brought to the angiography suite at

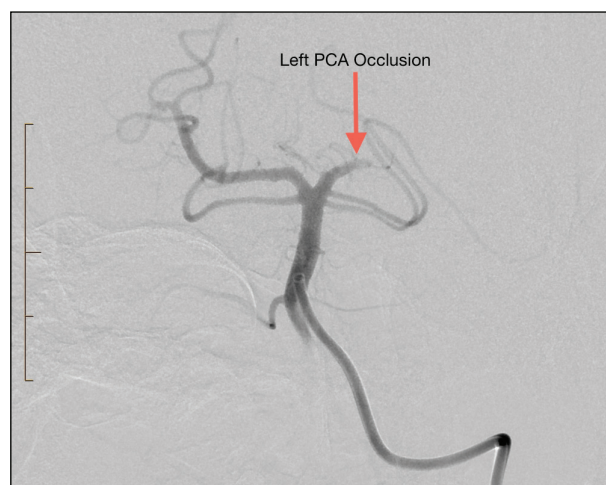


Figure 1. Occlusion in the left PCA.

1:00 PM with the interventional team readied for thrombectomy. Groin puncture occurred 18 minutes later, and an LVO was identified in the P1 6 minutes after groin puncture.

A Neuron™ MAX 088 guide sheath (Penumbra, Inc.) was used to provide a stable platform to advance the ACE68 catheter to the face of the clot. Two passes were made with the ACE68, achieving TICI 3 recanalization at 1:34 PM, a result of 16 minutes from puncture to revascularization.



Figure 2. Revascularization of the left PCA.

1. Frei D, McGraw C, McCarthy K, et al. A standardized neurointerventional thrombectomy protocol leads to faster recanalization times [published online November 3, 2016]. *J Neurointerv Surg*.

Process Improvement Using ACE68



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Disclosures: Dr. Kayan is a consultant to Penumbra, Inc. and MicroVention; Dr. Delgado is a consultant to Penumbra, Inc.

Safe and effective endovascular treatment of acute ischemic stroke is dependent on prompt intervention. After a systematic analysis of our process of taking patients to the angiography suite, we standardized key steps, including the institution of a stroke bag containing all necessary devices to perform efficient thrombectomy procedures (Figure 1A). From January 2013 to December 2015, we attempted 108 mechanical thrombectomy procedures. Both the mean and median door-to-groin puncture times in 2015 were significantly reduced from the previous 2 years (35 min vs 89 min and 22 min vs 73 min, respectively; $P < .001$). There was a trend toward reduced mortality at 90 days (16% vs 26%; $P = .166$).¹

Penumbra's ACE Reperfusion Catheters, Hi-Flow aspiration tubing, and Pump MAX are the most important components of our stroke bag. ADAPT using ACE has been our go-to therapy for several years when treating LVOs. Recently, we looked back at 100 consecutive patients with anterior circulation LVOs who were treated with ACE as first-line therapy. Advances in ACE catheters have improved performance and efficiency.

Of 100 consecutive patients, 84 were treated with aspiration alone, with the remaining 16 patients requiring rescue using the Solumbra technique. Looking at generational improvements from ACE60 to ACE64, and now to ACE68, successful revascularization using aspiration alone occurred 65%, 88%, and 100% of the time, respectively.² Additionally, improved trackability allowed for a reduction in puncture-to-reperfusion time from 48.2 minutes with the ACE60 to 29.9 minutes with the ACE64 and ACE68.² Based on our experience, we are very confident in the reliability of ADAPT using the ACE68 catheter.

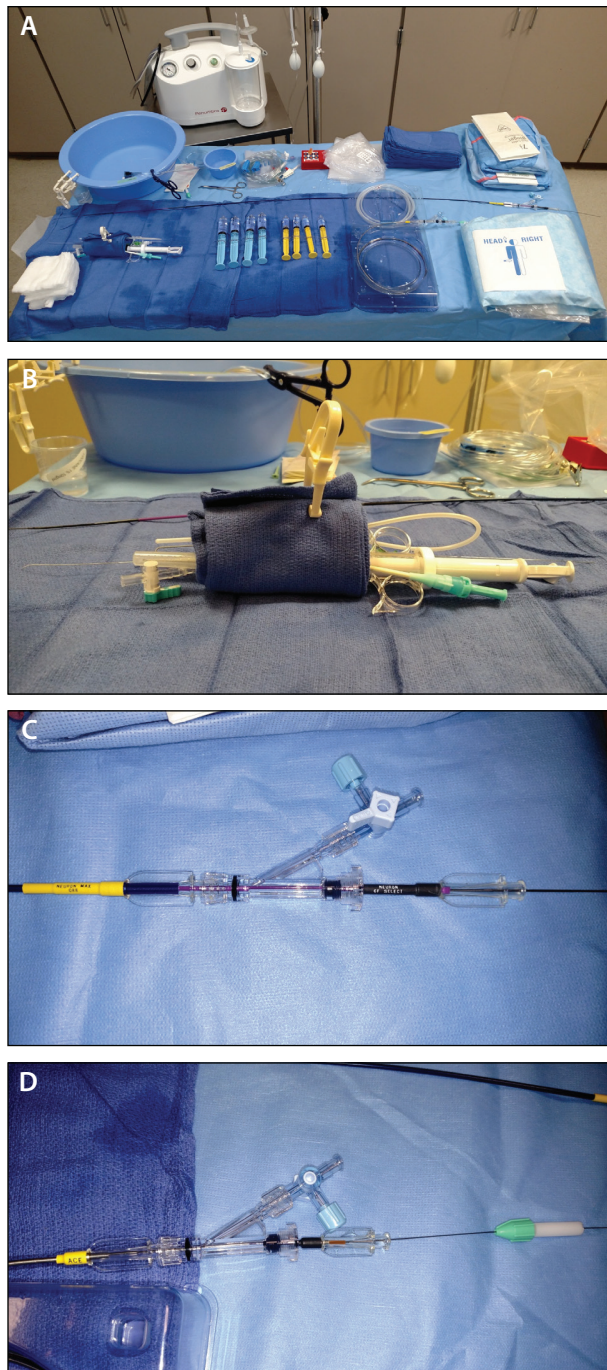


Figure 1. Stroke table with all items necessary for thrombectomy including Pump MAX™ (A). Case setup using a prearranged “access burrito” for improved efficiency: an 8-F short sheath, micropuncture set, and lidocaine 1% (B). A 90-cm Neuron™ MAX™, Penumbra Select H1 or Simmons, 0.035-inch Glidewire® (Terumo Interventional Systems)—all prearranged coaxially prior to the patient’s arrival (C). An ACE Reperfusion Catheter, 3MAX, 0.016-inch Headliner® (MicroVention)—again all prearranged coaxially (D).

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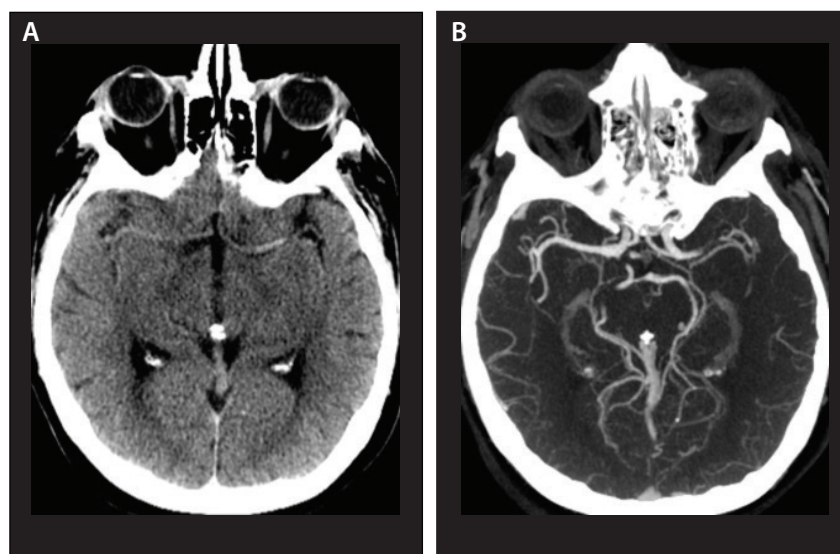


Figure 2. Initial CT (A) and CTA (B).

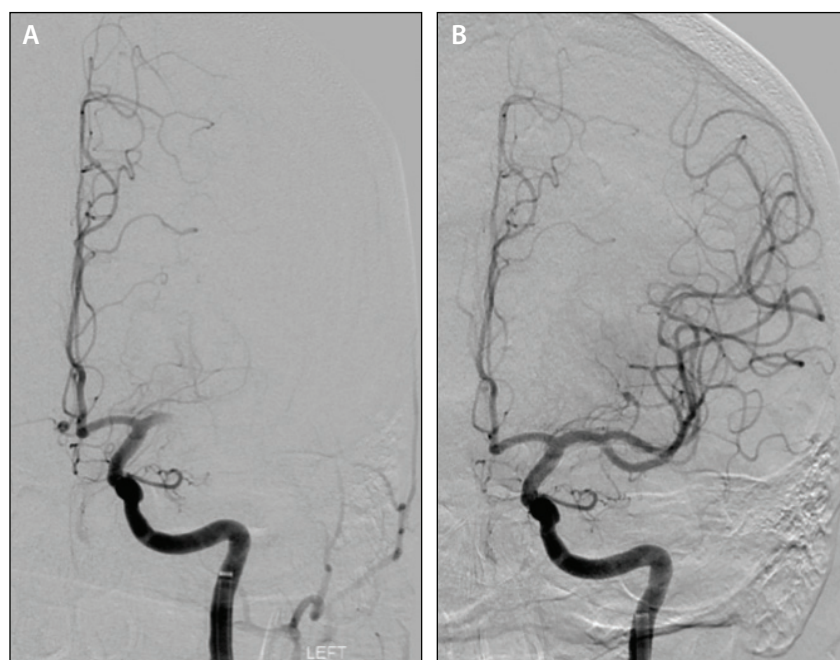


Figure 3. Left M1 occlusion (A). Revascularization of the MCA (B).

CASE REPORT

A woman in her late 60s experienced sudden-onset aphasia and right-sided weakness immediately after subclavian artery stenting. Her initial National Institutes of Health Stroke Scale (NIHSS) score was 21, and her Alberta Stroke Program Early CT Score (ASPECTS) at noncontrast CT was 10. CTA of the head confirmed an occlusive thrombus in the M1 segment of the left middle cerebral artery (MCA) (Figure 2).



Figure 4. Thrombi removed by the ACE™68 Reperfusion Catheter.

We decided to proceed with intervention using our standardized stroke setup (Figure 1). Under conscious sedation, a Neuron MAX 088 guide sheath was positioned in the distal internal carotid artery at the skull base. Utilizing a 3MAX Catheter, an ACE68 was successfully navigated to the thrombus in the M1 segment. TICI 3 recanalization was achieved with a single pass (Figure 3), resulting in the removal of several intact clot pieces (Figure 4) in 11 minutes from puncture to reperfusion.

The NIHSS score was reduced to 0 on postprocedure day 1. She was sent home on post-procedure day 2, and at 1 month, her modified Rankin Scale score was 1.

1. Kayan Y, Delgado Almandoz J, Young M, et al. Process improvement in door-to-groin puncture times at a comprehensive stroke center shows a trend towards reduced mortality at 90 days. Poster presented at: SNIS Annual Meeting; July 25-29, 2016; Boston, MA. Available from authors upon request.
2. Delgado Almandoz J, et al. ACE aspiration is an effective first-line treatment for acute ischemic strokes in the anterior circulation. Presented at: ABC-WIN Seminar; January 15-20, 2017; Val d'Isere, France. Available from authors upon request.



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Disclosures: Dr. Berlet is a consultant to Penumbra, Inc.; Dr. VanEpps has no disclosures.

Our institution has followed the evolution of stroke care and adopted ADAPT as our primary approach for mechanical thrombectomy. ACE68 has improved upon the original ACE tracking technology to provide outstanding deliverability along with an even larger lumen for effective clot removal when paired with the Hi-Flow aspiration tubing and Pump MAX.

CASE REPORT

A woman in her late 60s presented to the hospital in the evening with aphasia and hemiparesis. Her NIHSS score was 19, and her ASPECTS at noncontrast CT was 9 (Figures 1 and 2). CTA of the head confirmed a large thromboembolus in the left MCA (Figure 3), and she was taken to the angiography suite for intervention.

ACE68 was navigated over a 3MAX Catheter to the thrombus in the M1 (Figure 4). TICI 3 recanalization was achieved in 14 minutes from puncture to reperfusion with a single pass. The NIHSS score was reduced to 3 on postprocedure day 1 during which time the patient was walking, talking, and passed a swallow test. She was able to resume a normal diet

and expects a strong recovery. Figure 5 shows the MRI 48 hours after revascularization.

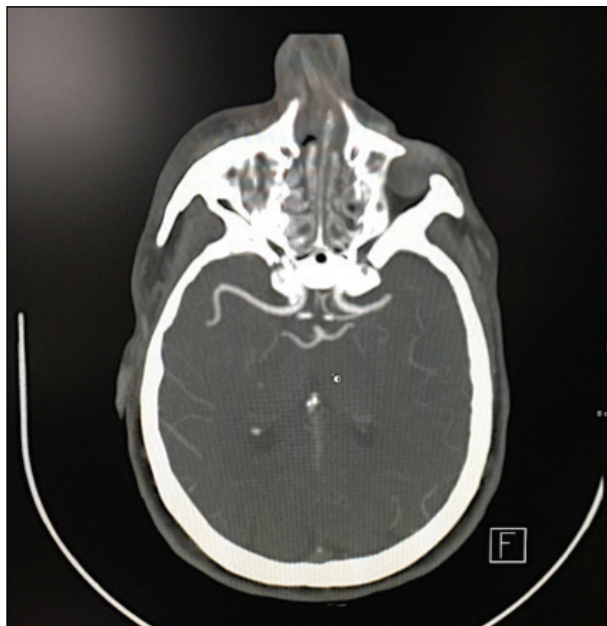


Figure 2. Initial CT.



Figure 3. Left M1 occlusion.

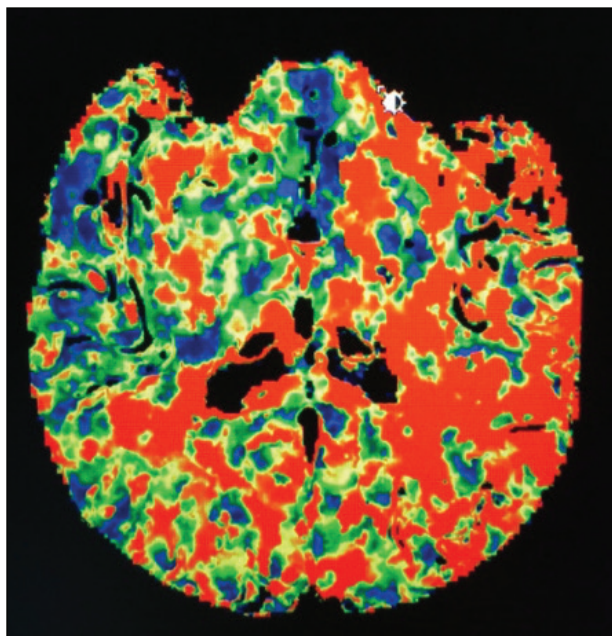


Figure 1. Initial CT perfusion.



Figure 4. Revascularization of the MCA.

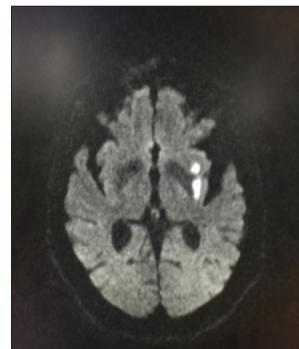


Figure 5. MRI 48 hours after revascularization.

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Disclosures: None.

For the past few years, ADAPT has been my standard approach for mechanical thrombectomy. With Penumbra's comprehensive system for stroke, I've found the best success coupling the Neuron MAX 088 guide sheath for access with Penumbra's new ACE68 Reperfusion Catheter and Hi-Flow tubing for maximum aspiration. The advancements made with the Penumbra System have allowed me to achieve even better puncture-to-revascularization times, as noted in the following case.

CASE REPORT

A woman in her early 40s with a past medical history of mitral valve replacement on warfarin had discontinued warfarin in preparation for a gynecologic procedure. The day after the gynecologic procedure, she experienced stroke symptoms of left-sided weakness and confusion with time of onset at 7:00 AM. She was taken directly to CT. Both CTA and CT perfusion were performed, which confirmed the presence of a right M1 occlusion along with viable penumbra (Figure 1A). The patient was brought to the angiography suite 1 hour later for intervention.

Access was achieved using a Neuron MAX 088 guide sheath, placing it at the high cervical. The ACE68



Figure 1. M1 occlusion (A). Revascularization of the middle cerebral artery (B).

Reperfusion Catheter was tracked over a 3MAX Catheter to the face of the clot with ease. With one pass, the clot was ingested and TICI 3 recanalization was achieved (Figure 1B). Total time from puncture-to-reperfusion was 12 minutes. The patient's symptoms resolved on the table and she returned to normal function. ■

Disclaimer: The opinion and clinical experiences presented are for informational purposes only. The results may not be predictive for all patients. Individual results may vary depending on a variety of patient-specific attributes.