

Advancing Stroke With STEPS-T Process Improvement and Next-Generation Technology

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Improving stroke outcomes relies on expedient delivery of therapy. In order to improve our door-to-recanalization times, we instituted the STEPS-T program at Valley Baptist, which

stands for stroke triage education, procedure standardization, and technology. Beginning with stroke triage education, a standardized workflow was developed to manage the patient upon arrival to the hospital. This workflow is contingent on the time from symptom onset and directs the patient to the appropriate imaging and therapies (Figure 1).

The second initiative, procedure standardization, begins once the patient is diagnosed with a large vessel occlusion and will receive intra-arterial therapy (Figure 2). It relies on the team dividing up responsibilities and tasks and running preparation in parallel. The first tech will set up the room, prepare devices, and prep the patient once they arrive, while the second tech retrieves patient data and begins recording. The nurse will retrieve the necessary drugs once the patient is draped and will monitor the patient throughout the procedure. The

neurointerventionalist will obtain appropriate consent from the family and focus on proper table positioning. Once the procedure begins, the focus is on performing thrombectomy in the most safe and efficient manner.

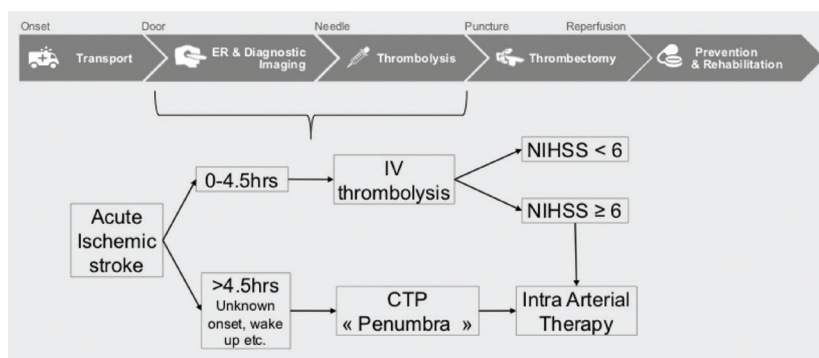


Figure 1. Stroke care pathway.

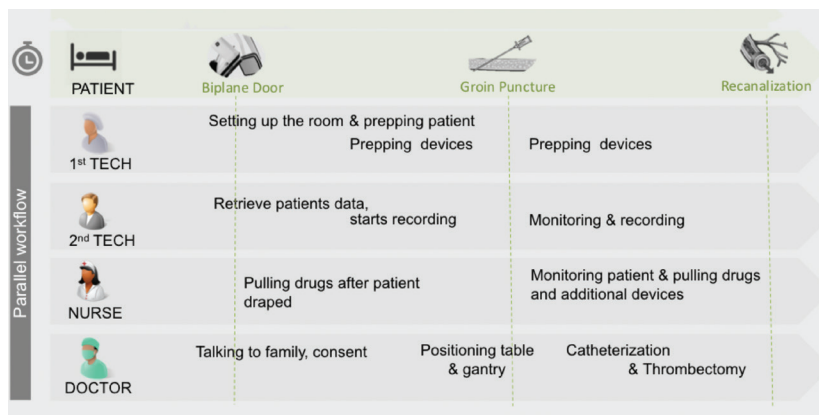
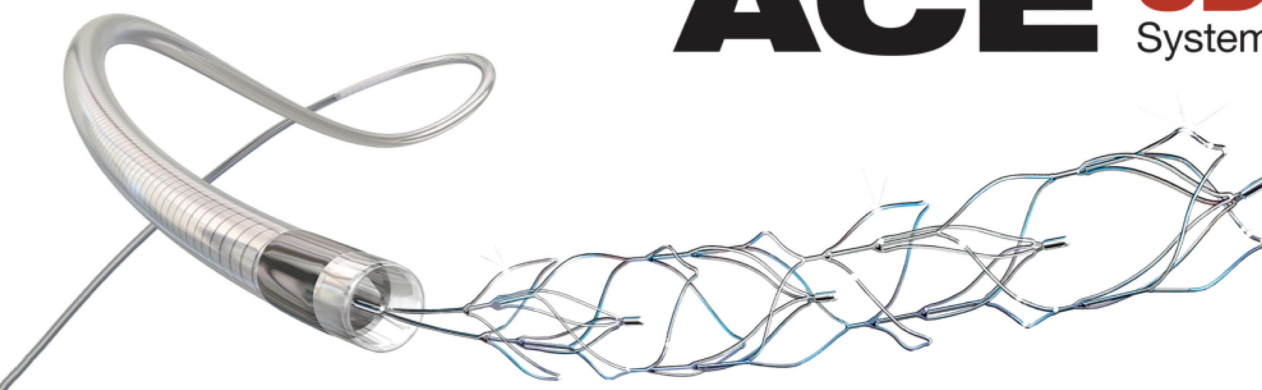


Figure 2. Procedure standardization.

ACE™ 3D™ System



The final initiative comes from optimizing the technology utilized during the procedure. Standardized imaging protocols that have been customized and automated eliminate the need to adjust acquisition, processing, or display settings during the procedure. We have also built out an advanced monitoring and recording system to collect data. Finally, we have adopted a thrombectomy approach that brings about improved angiographic and clinical outcomes, along with improved puncture-to-revascularization times.

For thrombectomy, we utilize combination therapy with the ACE™ 68 Reperfusion Catheter (Penumbra, Inc.) and 3D™ Revascularization Device (Penumbra, Inc.). Early data have suggested that combination therapy with aspiration and a stent retriever provides significant benefits, and recent studies have confirmed this approach. A study from Germany demonstrated the benefits of aspiration for a combination approach with an aspiration catheter and stent retriever.¹ The real-world experience including 450 patients at five high-volume centers in Germany was highly compelling for aspiration used with stent retrievers. The combination approach resulted in a reperfusion rate of 86% compared to the stent retriever and balloon guide group, which demonstrated a reperfusion rate of 65%. Furthermore, a regression analysis was performed that showed that the combination technique, when compared with a stent retriever and balloon guide catheter, had an odds ratio of 3.48. Along with improved revascularization, the data showed a trend toward a lower emboli to new territory rate with the combination approach over the stent retriever and balloon guide approach.¹

The evidence for aspiration, whether used alone as a frontline approach or in combination with a stent retriever, was further advanced at the International Stroke Conference in January 2018.² The COMPASS trial compared the direct aspiration first-pass technique (ADAPT) as a frontline approach against a stent retriever frontline (SRFL) approach. In the SRFL arm, a stent retriever was

combined with a reperfusion catheter in the majority of cases (87%). It is the first trial to include a majority of cases using the most advanced reperfusion catheter, ACE68. The preliminary results were promising, with revascularization rates of modified treatment in cerebral infarction (mTICI) 2b/3 at 91.7% and 89% for the aspiration and stent retriever groups, respectively ($P = .054$). Overall functional outcome at 90 days was 52% for the aspiration group and 49% for the stent retriever group. ($P = .0014$ for noninferiority).²

It is clear that aspiration has a significant role in providing both exceptional angiographic and functional outcomes.

NEXT-GENERATION TECHNOLOGY FOR STROKE

Penumbra launched the 3D Revascularization Device in the summer 2017, introducing a next-generation retrieval device for the treatment of ischemic stroke patients. The 3D device offers a unique architecture including four intraluminal chambers that lock clot centrally within the device for withdrawal into ACE68. This offers several benefits: (1) 3D can be withdrawn into and through ACE68; (2) access with ACE68 can be maintained at the site of the occlusion; and (3) there is potential for reduced clot shearing during withdrawal into ACE68.

These benefits allow for efficient deployment and withdrawal of 3D and open the door for a new technique called **COMPLETE**. COMPLETE alternates between two mechanisms of action—aspiration and 3D—to efficiently engage and remove clot. If clot is still present after 3D is withdrawn through ACE68, aspiration can then be directly applied at the face of the clot with ACE68 to complete the pass. COMPLETE provides the opportunity to utilize two proven techniques for aspiration-based mechanical thrombectomy.

1. Hesse AC, Behme D, Kemmling A, et al. Comparing different thrombectomy techniques in five large-volume centers: a 'real world' observational study [published online September 28, 2017]. *J Neurointerv Surg*.

2. Mocco J, Turk A. A comparison of direct aspiration vs. stent retriever as a first approach (COMPASS): a randomized trial. Presented at ISC 2018: the International Stroke Conference; January 25, 2018; Los Angeles, CA.

CASE REPORTS



Figure 1. The ICA occlusion.

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The patient arrived with an internal carotid artery (ICA) occlusion beginning just past the carotid bulb (Figure 1). I used a Neuron™ MAX 088 long sheath (Penumbra, Inc.) for access and ACE68 to aspirate the clot burden in the ICA. Once the ICA was cleared, an M1 occlusion was still present (Figure 2). I used 3D and ACE68 to retrieve an organized clot from the M1. The result was mTICI 3 (Figure 3), with clot locked within the 3D intraluminal chamber (Figure 4).



Figure 2. The M1 occlusion.



Figure 3. Postprocedure outcome.

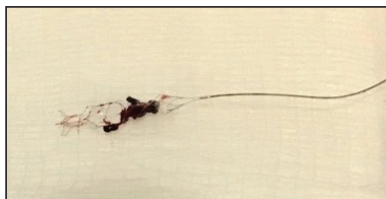


Figure 4. Clot locked in the 3D intraluminal chamber.

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RIA Neurovascular

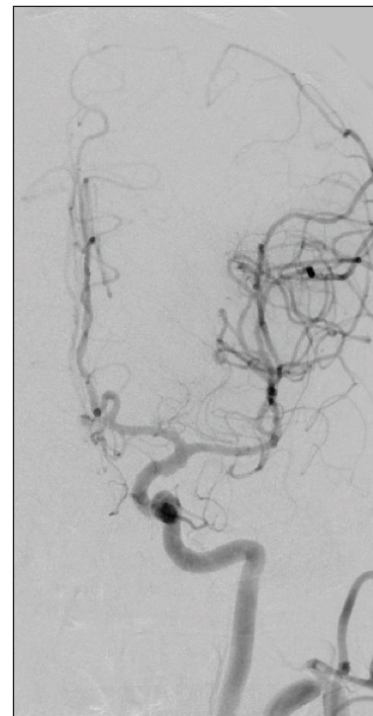
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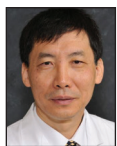
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At Swedish Medical Center, our standard approach is ADAPT, utilizing three passes of aspiration alone before moving to a stent retriever. Although aspiration alone is successful in over 85% of our cases, we still utilize stent retrievers as an adjunctive therapy and an access aid to track ACE68 to the clot when needed.

In this case, the patient arrived with an M1 origin occlusion and a significant loop in his ICA (Figure 1). Due to proximal tortuosity, Neuron MAX was hubbed at the femoral sheath, barely reaching the carotid bulb. This did not provide the support needed to advance ACE68 beyond the ophthalmic artery. We introduced 3D and utilized it as an access aid to “grapple hook” the ACE68 to the face of the clot. Then, we retracted 3D fully through ACE68, retrieving some of the clot in the M1, opening the origin. With ACE68 still in the M1, I quickly transitioned to aspiration alone to COMPLETE the pass, resulting in mTICI 2C (Figure 2). Utilizing both mechanisms of action allowed for a quick transition between aspiration and 3D (Figure 3).

**Figure 1.** The M1 occlusion.**Figure 2.** Proximal M1 occlusion opened with 3D.**Figure 3.** M1 opened with aspiration after 3D.



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I adopted the ADAPT approach in 2012, and it has proven to be effective for the majority of my stroke cases. We recently began to use the new 3D Revascularization Device for the cases where aspiration alone was not sufficient to achieve TICI 2b/3 revascularization. The 3D device has a very unique architecture that is a departure from the previous generation of hollow tube stent retrievers. The intraluminal chambers lock clot within the device, as exhibited in the following report.

In this case, we treated an M1 occlusion with ADAPT (Figure 1). After several passes with ACE™ 64 (Penumbra, Inc.), we introduced 3D through the ACE64 catheter to retrieve the clot. We delivered 3D with a



Figure 1. The M1 occlusion.

Velocity® microcatheter (Penumbra, Inc.) and then removed Velocity completely before commencing aspiration with ACE64 and Pump MAX™ (Penumbra, Inc.). After one pass with 3D, we were able to retrieve a very organized clot that was locked cleanly in the intraluminal chamber (Figures 2 and 3).



Figure 2. Postprocedure result.

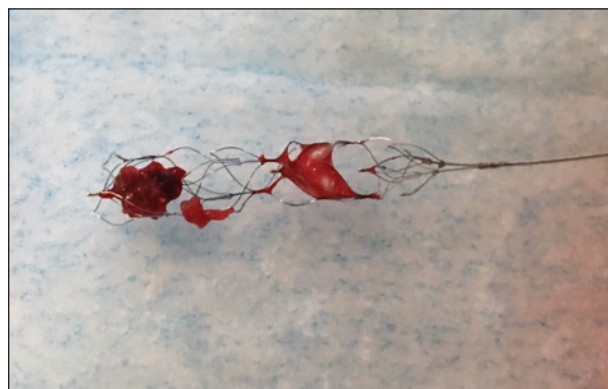


Figure 3. Clot locked cleanly in the intraluminal chamber.

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Disclosures: None.

We typically use ACE68 for the vast majority of our stroke cases with great success. In the past, when a stent retriever was needed, we often used one with the more traditional stent design, which has the metallic tines arranged along the periphery.

In this case, there was a distal carotid and middle cerebral artery occlusion (Figure 1). These types of cases can be challenging due to the large clot burden usually present. I initially used Neuron MAX, ACE68, and a Velocity microcatheter to perform suction thrombectomy, but this was minimally successful, despite multiple passes. I utilized a stent retriever with the traditional stent design, as previously discussed, with concurrent aspiration, but this yielded minimal clot. Knowing the unique design of the 3D with intraluminal chambers, I decided to use it with concurrent aspiration. I was able to capture a significant thrombus

burden and was impressed by the performance of 3D (Figures 2 and 3). ■

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

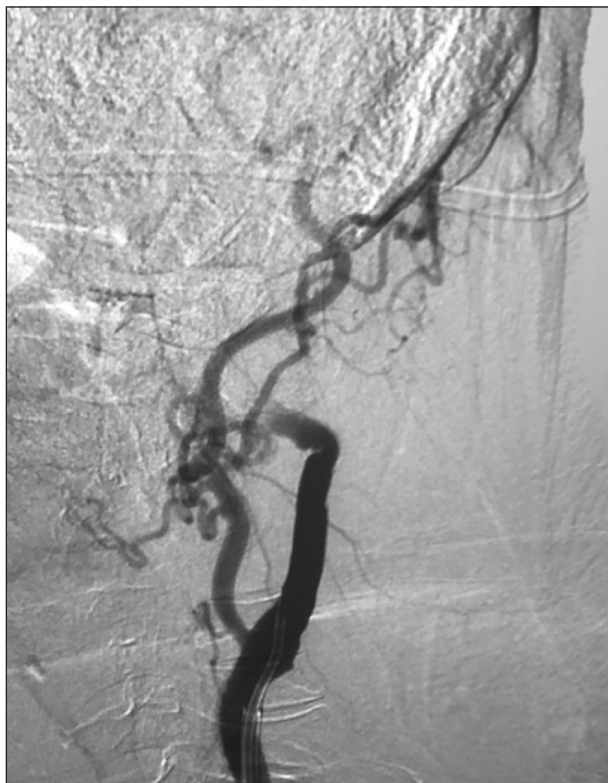


Figure 1. Preprocedure imaging.



Figure 2. Postprocedure result.



Figure 3. Clot burden captured by 3D.