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New Technology in Treating Hemorrhagic Stroke: Is a New Gold Standard on the Horizon?

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There is an unmet need in the United States and abroad for the treatment of hemorrhagic stroke. But now, this deadliest, costliest and most debilitating form of stroke with no surgical standard is experiencing a paradigm shift. New and growing peer-reviewed published evidence showing improved morbidity and mortality with early intervention of hemorrhagic stroke is gaining wide attention by neurosurgeons from across the U.S. and Europe, where technologies used in a new ICH surgical approach just gained CE Mark.

Hemorrhagic stroke has always been “the other stroke” with no proven surgical answer. It carries early mortality rates ranging from 35%-52%¹ and an estimated associated cost of care and productivity losses at approximately \$12.7 billion annually²⁻⁴. While hemorrhagic stroke accounts for only 20% of all strokes in the U.S., its affects are devastating with only 10%-25% of patients returning to functional independence.^{2,3}

Evidence from the more common ischemic stroke that makes up the other 80% of stroke occurrences has taught practitioners that “time is brain” and early invention has a direct impact on patients’ functional and cognitive recovery. Although less recognized, the same principle applies to ICH, where different mechanisms of secondary brain damage also occur in the first few hours after incident onset.⁴ Despite clinical evidence from early clinical trials with MISTIE and STICH supporting the role of early hematoma evacuation, surgical intervention for supratentorial ICH remains unproven and is rarely performed or performed only after the patient is in decline.⁵ Consequently, approximately 95+% of ICH-based care involves medically managing symptoms.

Patented technology advancements by [NICO Corporation](#) have been combined to create a systematic standardized surgical approach using standardized technologies to overcome both historical and current neurosurgical challenges in ICH evacuation procedures. The two missing critical elements to surgical intervention are a non-



NICO BrainPath Technology

disruptive standardized surgical approach to accessing the ICH and using standardized technologies for safe and maximum clot evacuation.

The new technologies that answer these unmet needs include the [BrainPath](#) and [Myriad](#), both FDA-cleared devices. BrainPath is a navigation-compatible, port-based technology already used in more than 5,000 procedures. It provides minimally disruptive access to deep regions of the brain and is the first and only device that creates a path to the target by using a parafascicular, trans-sulcal surgical approach versus cutting through critical brain fiber tracts⁶. The Myriad is an automated, multi-functional resection tool that has been used in more than 11,000 surgery procedures. It is used through the BrainPath sheath for clot evacuation. These technologies improve the applicability and evidence that early surgical ICH evacuation can potentially lead to improved functional recovery.⁷



NICO Myriad tissue and clot removal device

What these technologies provide is a surgical approach that establishes a standardized methodology to treating ICHs, as evidenced in a published paper highlighting a two-year, multi-center pilot study of 39 patients with clot evacuation by 15 neurosurgeons uniformly trained on the technologies and approach. The authors reported no new deficits, no surgical deaths, and over 90% clot removal, resulting in a statistically significant GCS improvement.⁸ The results were replicated by Cleveland Clinic in a prospective study of 18 patients where 65% of patients had an active bleed successfully managed – providing an ultra-early treatment option without the need for clot stability prior to surgery.⁹ Total hospital length of stay also compared favorably to other recent studies, suggesting a meaningful cost benefit exists.

Typically, in my experience and in the experience of many vascular neurosurgeons, the belief is that the earlier the clot is accessed, the better opportunity for improved recovery for the patient. For ICH, two key goals emerge once non-disruptive access is achieved: Gain maximum clot evacuation and don't create additional bleeding.⁷ The Myriad device, unlike a sucker, is capable of removing both fibrous and liquefied clots because it combines and automates two important tools – scissors and suction. The surgeon is able to toggle between gently sucking near delicate structures and controlled cutting or scissors when the clot is cross-linked ([view surgical procedure videos HERE](#) using these technologies). This capability is what achieved unprecedented 95% clot evacuation with no new surgical deficits in published literature.⁹

Despite the positive results of the initial case series, retrospective and prospective studies, and the widely accepted benefit of this new surgical approach for subcortical lesions, Level I evidence supporting the use of these techniques in ICH is needed for the approach to become supported by standard of care guidelines. This information, coupled with the successes of past trials, led to the development of a larger multi-center, randomized, adaptive clinical trial called ENRICH (Early Minimally-invasive Removal of IntraCerebral Hemorrhage). ENRICH includes 25 major academic and community centers that will compare standard medical management to early surgical hematoma evacuation using minimally invasive parafascicular surgery in the treatment of acute spontaneous

supratentorial intracerebral hemorrhage. The trial is led by Emory University School of Medicine and Grady Memorial Hospital in Atlanta.

To date, a total of [18 peer-reviewed papers and abstracts](#) that included 221 cases have been published on the clinical experiences and outcomes when using the BrainPath Approach for access and evacuation of ICH. This evidence, and the support of major academic healthcare centers like Sutter Eden, Emory University, Johns Hopkins, Cleveland Clinic, Cedars-Sinai, and Indiana University currently participating in the ENRICH trial, gives a high level of confidence that the standardized approach and technologies are in prime position to help ICH patients who have no proven surgical option for treatment and may eventually provide a new gold standard of care in ICH.

For specialists who want access to education on the BrainPath Approach, training is available at various healthcare institutions in the United States, as well as the annual course and meeting of the Subcortical Surgery Group (SSG). I encourage you to take advantage of these training courses [HERE](#) or at the upcoming SSG course [HERE](#). Educational opportunities like these will go a long way to solidifying that the BrainPath Approach could become the new gold standard in treating patients with hemorrhagic stroke.

References

- ¹Macellari F, Paciaroni M, Agnelli G, Caso V. Neuroimaging in intracerebral hemorrhage. *Stroke*. 2014;45:903-8.
- ²Adeoye O, Broderick JP. Advances in the management of intracerebral hemorrhage. *Nat Rev Neurol*. 2010; 6:593-601.
- ³Andersen KK, Olsen TS, Dehlendorff C, Kammersgaard LP. Hemorrhagic and ischemic strokes compared: Stroke severity, mortality, and risk factors. *Stroke*. 2009;40(6):2068-72.
- ⁴Sahni R, Weinberger J. Management of intracerebral hemorrhage. *Vascular Health and Risk Management*. 2007;3(5):701-709.
- ⁵Zammar SG, Zimmerman RS, Tiano MM, Bendok BR. Time is brain and so is less blood: The hyperacute period after intracerebral hemorrhage. *Neurosurgery: Science Times*. 2015; 76(6): N12.
- ⁶Kassam AB, Labib MA, Bafaquh M, et al. Part I: The challenge of functional preservation: An integrated systems approach using diffusion-weighted, image-guided, exoscopic-assisted, transsulcal radial corridors. *Innovative Neurosurgery*. 2015;3:5-23.
- ⁷Ritsma B, Kassam AB, Dowlathshahi D, Nguyen T, Stotts G. Minimally invasive subcortical parafascicular transsulcal access for clot evacuation (Mi SPACE) for intracerebral hemorrhage. *Case Rep Neurol Med*. 2014;2014(102307): 4 pages.
- ⁸Labib MA, Shah M, Kassam AB, et al. The Safety and Feasibility of Image-Guided BrainPath-Mediated Transsulcal Hematoma Evacuation: A Multicenter Study. *Neurosurgery*. 2016.
- ⁹Bauer AM, Rasmussen PA, Bain MD. Initial Single-Center Technical Experience With the BrainPath System for Acute Intracerebral Hemorrhage Evacuation. *Operative Neurosurgery*. 2016.