




Super large-bore ingestion of clot (SLIC) leads to high first pass effect in thrombectomy for large vessel occlusion

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ABSTRACT

Background Super large-bore aspiration (SLBA) has shown high rates of complete clot ingestion.

Objective To report the initial clinical feasibility, safety, and efficacy of this novel SLBA insert combination—super large-bore ingestion of clot (SLIC) technique for stroke.

Methods We performed a retrospective review of three comprehensive stroke center databases. The SLIC technique entails a triaxial assembly of an 8 Fr 0.106" Base Camp catheter, 0.088" catheter extender (HiPoint), and an insert catheter (Tenzing 8) that completely consumes the inner diameter of the 0.088" SLBA catheter. The HiPoint catheter is delivered over the Tenzing 8 to the face of the embolus, which is withdrawn, while aspirating through the Base Camp and HiPoint catheters as a single assembly.

Results Thirty-three consecutive patients with large vessel occlusion were treated with SLIC. The median age was 70 years (30–91) and 17 were male (51.5%). The median presenting National Institutes of Health Stroke Scale score and Alberta Stroke Program Early CT score was 21 (1–34) and 8 (5–10), respectively. There was 100% success in delivering the 0.088" catheter to the site of the occlusion. The successful revascularization rate (modified Thrombolysis in Cerebral Infarction (mTICI) score $\geq 2B$) was 100% within a single pass in most cases (82%). Final mTICI $\geq 2C$ was achieved in 94.1% of occlusions, with 73.5% mTICI 3 recanalization. The rate of first pass effect in achieving excellent reperfusion (mTICI $\geq 2C$) was 70.5%. There were no adverse events or postprocedural symptomatic hemorrhages.

Conclusions Our initial experience with the SLIC technique resulted in achieving a first pass effect (mTICI $\geq 2C$) in 70.5%. Navigation of the SLBA catheter extender over the Tenzing insert was successful and safe in this early experience.

INTRODUCTION

Direct aspiration¹ has been shown to be equivalent to stent retriever thrombectomy for patients with a large vessel occlusion (LVO) for recanalization² and clinical outcomes.³ However, without complete ingestion of the clot, much of it remains outside the catheter and can be a source of distal emboli.⁴ Super large-bore

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The field of mechanical thrombectomy is rapidly moving towards first pass efficacy, meaning achievement of single pass recanalization scores of TICI 2c and TICI 3. It is known that first pass efficacy is a predictor of good clinical outcome in patients undergoing mechanical thrombectomy.

WHAT THIS STUDY ADDS

⇒ This study evaluates a recently added tool to the neurointerventional armamentarium for rapid reperfusion with excellent first pass efficacy by clot ingestion. Clot ingestion is key for reducing, possibly even eliminating, the occurrence of distal emboli during the mechanical thrombectomy procedure. Here, we present the initial experience of three experienced, high volume neurointerventional centers in using the novel Super Large Bore Aspiration (SLBA) insert combination for acute ischemic stroke treatment due to large vessel occlusion. The Super Large-bore Ingestion of Clot (SLIC technique) has shown high rates of complete clot ingestion resulting in excellent first pass efficacy and reperfusion rates using this new 0.088-inch super large bore catheter.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE AND/OR POLICY

⇒ The preliminary data obtained from three experienced and high-volume neurointerventional centers is very promising. A prospective trial (SUMMIT MAX) is currently ongoing which randomizes patients to this new clot ingestion technique versus standard contact aspiration with the aim to prove non-inferiority. The use of large bore catheters for clot ingestion during mechanical thrombectomy is supposed to be an easy-to-use platform that offers improved delivery of the large bore catheter to the target vessel. It is our hope that the simplicity of this catheter platform will allow for a more rapid and increased first pass reperfusion.



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aspiration (SLBA) catheters, designed to reach the middle cerebral artery (MCA) with inner diameters of 0.088", have shown complete ingestion of clots in vitro, including challenging fibrin rich clots.^{5,6} It has been shown in a case report that SLBA is technically feasible.⁷ Recently, a novel 0.088" catheter extender (catheter extension on a wire)⁶ has been cleared for access to the cerebrovasculature (HiPoint, Route 92 Medical, San Mateo, California, USA). The unique insert catheter (Tenzing 8, Route 92 Medical) completely consumes the inner diameter of the catheter extender, facilitating delivery.⁸ We sought to review the preliminary experience with the super large-bore ingestion of clot (SLIC) technique for stroke across three large academic medical centers in consecutive patients. Our hypothesis is that SLIC with complete clot ingestion may improve the first pass effect.⁹

MATERIALS AND METHODS

Data collection and analysis was performed under an institutional review board approved protocol (UMass Neuro IR Registry H00001860). Given the retrospective nature of the study, no patient consent was required.

In this three-center initial experience, we retrospectively evaluated 33 consecutive patients treated for acute ischemic stroke between February 2021 and January 2022 with an off-label use of a US Food and Drug Administration (FDA) approved device. The Route 92 Medical 088 access system is currently approved as a catheter facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system, according to the FDA indication for use. The device is not approved as an intracranial aspiration catheter for mechanical thrombectomy.

Patient selection for endovascular treatment was based on advanced imaging with head non-contrast computed tomography, CT angiography and/or CT perfusion. Patients included in this series were found to have a large cerebral vessel occlusion with viable ischemic penumbra (6–24 hours) in the vascular territory supplied by the occluded target artery. Clinical and procedural data of the group of patients undergoing SLIC thrombectomy were extracted.

SLIC technique

The SLIC technique for stroke entails a triaxial assembly with an 8 Fr 0.106" guiding catheter (Base Camp), a 0.088" 62 cm catheter extender (HiPoint) (online supplemental figure 1), and a diameter matching, self-centering insert catheter (Tenzing 8) (online supplemental figure 2). The Base Camp can be used as a sheath or through a 9 Fr sheath (online supplemental figure 3) and is advanced over a matching navigation catheter. In certain cases, due to marked aortic arch tortuosity, the Base Camp was advanced into the distal common or internal carotid artery (ICA) over a VTK catheter. The Tenzing insert catheter is used to navigate the HiPoint to the clot then, while pulling the insert out, the 0.088" catheter progresses into the clot and ingests it, as the Tenzing is removed (figure 1 and online supplemental video 1). The suction thrombectomy, applied through the Base Camp catheter and 0.088" HiPoint as a single assembly, is directly transferred to the clot, resulting in a physical ingestion of the whole embolus (figure 2 and online supplemental video 2).

Data collection and analysis

Demographic, clinical and imaging variables were collected (table 1). National Institutes of Health Stroke Scale (NIHSS) score at admission and baseline modified Rankin Scale (mRS) were recorded. The degree of vessel occlusion at presentation

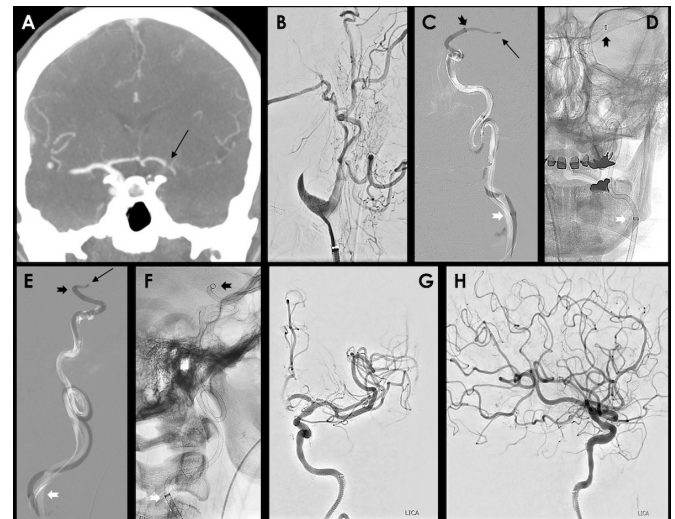


Figure 1 (A) Head CT angiography on coronal view demonstrating the occlusion site at the level of the left internal carotid artery (ICA) terminus (black arrow). (B) Lateral fluoroscopy image showing pseudo-occlusion of the left ICA in relation to the intracranial ICA occlusion. (C) Frontal fluoroscopic image showing severe tortuosity of the left ICA cervical segment, with tip of the Tenzing 8 delivery catheter within the clot (black arrow), the tip of the HiPoint 088 catheter within the proximal left middle cerebral artery M1 segment (black arrowhead), and Base Camp guide catheter at the origin of the cervical left ICA (white arrowhead). (D) Frontal single shot image demonstrating mild progression of the tip of the HiPoint 088 catheter (black arrowhead) after retraction of the Tenzing 8 delivery catheter. (E) and (F) Lateral fluoroscopy and single shot images in the same setting. (G) and (H) Anteroposterior and lateral fluoroscopy image showing the post single-pass recanalization of the left intracranial ICA vascular occlusion.

and after treatment was defined by the modified Thrombolysis in Cerebral Infarction (mTICI) classification¹⁰ reported by the operator. Puncture to recanalization time, evidence of symptomatic intracranial hemorrhage or presence of embolization in previously unaffected vascular territories were also recorded. Successful revascularization was defined as postprocedural mTICI score $\geq 2B$. Puncture to recanalization time was defined as the time from groin access to at least mTICI 2B revascularization. Symptomatic intracranial hemorrhage was determined as the presence of post-treatment hemorrhage on CT with associated worsening of the NIHSS score ≥ 4 points on clinical examination.

RESULTS

Patient demographics and procedural data

Between February 2021 and January 2022, 33 consecutive patients presenting with LVO eligible for thrombectomy and in whom vascular anatomy was deemed favorable to accommodate the system were treated with the SLIC (table 1). One center enrolled patients over the entire time frame between February 2021 and January 2022, the other center between February 2021 and November 2021, and the last center included patients from November 2021.

The overall size of the intracranial ICA and MCA was evaluated on CT angiography and if deemed appropriate based on visual criteria, the 088 system was used. One patient underwent a simultaneous bilateral treatment of both anterior circulation large vessel occlusions (left ICA and right MCA). The median age was 70 years (30–91) and 17 were male (51.5%). The median

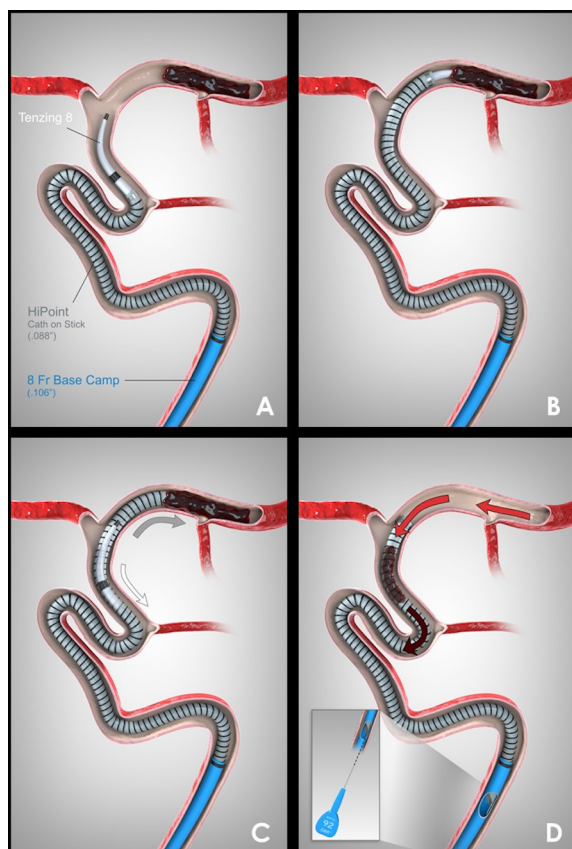


Figure 2 (A) Super large-bore ingestion of clot (SLIC) platform: 8 Fr 0.106" Base Camp catheter (blue) placed at the level of the cervical internal cerebral artery, 0.088" HiPoint catheter extender (gray-black striped) and tapering Tenzing 8 insert catheter (white with two black distal markers). (B) The Tenzing 8 insert catheter is used to navigate the HiPoint to the site of occlusion, without crossing the clot and reducing any ledges, which allows for seamless transition through the extra-intracranial vasculature. (C) While pulling the insert out, the 0.088" catheter progresses into the clot. (D) The suction thrombectomy, applied through the Base Camp catheter and 0.088" HiPoint (catheter on a stick) as a single assembly, is directly transferred to the clot, resulting in a physical ingestion of the whole embolus.

presenting NIHSS score was 21 (1–34). One patient was treated, despite an NIHSS value below the standard threshold of 6, for an extensive area of penumbral mismatch noted on CT perfusion. The mean pre-stroke mRS score was 0.9 (0–4). Twelve patients (36%) received intravenous thrombolysis. Median Alberta Stroke Program Early CT score was 8 (5–10). The sites

Table 1 Patient demographics and procedure information

No	33
Age (years), mean±SD	70±12.5
Sex, n (%)	Male: 17 (51.5%); Female: 16 (48.5%)
Occlusion site, n (%)	MCA: 17 (50%); ICA: 17 (50%)
Presenting NIHSS score, median (range)	21 (1–34)
Baseline mRS score, median (range)	0.9 (0–4)
ASPECTS, median (range)	8 (5–10)
tPA, n (%)	12 (36.4%)
ASPECTS, Alberta Stroke Program Early CT Score; ICA, internal carotid artery; MCA, middle cerebral artery; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; tPA, tissue plasminogen activator.	

Table 2 Thrombectomy results

Number of passes, median (range)	1 (1–2)
First pass effect (mTICI ≥2C), n (%)	24 (70.5%)
Time (puncture to final recanalization), mean±SD (min)	20.4±7
Adjunctive device used, n (%)	4 (11.8%)
Final mTICI	
mTICI 2B	2 (5.9%)
mTICI 2C	7 (20.6%)
mTICI 3	25 (73.5%)
mTICI, modified Thrombolysis In Cerebral Infarction.	

of occlusion were almost slightly more prominent at the level of the MCA (53%) than at the ICA (47%), with significant preponderance of the left laterality (64.7%).

The overall successful revascularization rate (mTICI ≥2B) was 100%. First pass efficacy in achieving mTICI ≥2B, ≥2C, or 3 was 82.3%, 70.5%, and 64.7%, respectively. In four cases (11.8%), it was necessary to use a stent retriever or lower profile aspiration catheter (M2 branch) to achieve better reperfusion (from mTICI 2B to 2C (n=3); from mTICI 2B to 3 (n=1)). The average time from groin puncture to achieve mTICI ≥2B and final recanalization was 14.4 min (6–31 min) and 20.4 min (10–37 min), respectively (table 2).

No intracranial vascular dissection or perforation were noted. No embolization in previously unaffected vascular territories or symptomatic postprocedural intracranial bleeding were observed. There were two cases (6.0%) of asymptomatic subarachnoid hemorrhage on the post interventional CT scan, which resolved on follow-up imaging and left no clinical sequelae.

Discharge NIHSS score was available for 29 patients (87.9%) and ranged from 0 to 19. Mean NIHSS score was 4. Five patients died (15.2%). Four of these patients presented with severe strokes (NIH stroke scale scores of 20, 26, 32, and 32). The patients had moderate and large stroke burdens. The patients' families elected to pursue comfort measures only. One patient had an underlying history of malignancy and was rapidly decompensated owing to recurrent embolic strokes. The patient's family choose to pursue comfort measures only.

A discharge mRS score of 0–2 was seen in 14 patients (42.4%). One patient improved from a baseline mRS score of 1 to 0 at discharge. Eight patients (24.2%) returned to their baseline neurological function at discharge (mRS score range 0 to 4).

DISCUSSION

The gold standard in the emergent treatment of acute ischemic stroke due to IVO is mechanical thrombectomy, performed using different approaches: stent retriever, aspiration,^{11 12} or a combination of both.¹³

The SLIC technique using the super large-bore aspiration catheters with the Route 92 Medical system entails a triaxial platform that is reduced to a single rotating hemostatic valve with the use of a catheter extender navigated over the Tenzing insert catheter. In our preliminary experience, we were able to advance this super large-bore system to the site of the occlusion without crossing the distal aspect of the clot in all cases. The advantage of not needing to cross the complete clot to bring up the super large-bore catheters is less or no disruption of the clot as that correlates with the size of the microcatheter used to cross the clot.¹⁴ Another unique feature of the novel Tenzing 8 insert catheter is that it almost completely consumes the entire inner diameter of the 0.088" catheter,

thus reducing any ledges, which allows for seamless transition without getting caught on the origins of side branches, such as the ophthalmic artery.

Once the 0.088" SLBA catheter is within the clot, the Tenzing insert is removed. Removal of the Tenzing creates a void which, by the law of conservation of mass, requires this void to be replaced. The void will be filled by the clot in which the SLBA was placed (online supplemental video). Essentially, removal of the Tenzing in this system is equivalent to using a syringe/pump to create a vacuum.

As seen previously in the in vitro experiments,^{5,6} SLIC is capable of complete clot ingestion of even tough fibrin-rich clots. The act of ingestion leaves no embolus attached to the tip of the aspiration catheter, hence decreasing the chance of distal emboli or reocclusions. In our preliminary clinical experience, this translated to a high rate of first pass efficacy of 70.5% for excellent reperfusion (mTICI \geq 2C). A recent real-world large registry showed that the first pass effect rate to achieve excellent reperfusion was 40.5%.¹⁵ The SLIC technique represents an innovative technology to dramatically improve the first pass effect. However, larger clinical evidence is needed to confirm our promising preliminary results.

A first-in-man experience outside the United States with multiple versions of the Route 92 Hi-Point was recently presented.¹⁶ Caldwell *et al* described three different aspiration systems, while using incremental calibers of the aspiration catheters from large-bore aspiration catheters (0.070") to SLBA (0.088"). In the third phase of their study, which has a comparable technique to our study for use of SLBA, the first pass reperfusion rate of mTICI \geq 2B was 80%, which is nearly identical to our data (82.3%). Moreover, Caldwell *et al* reported a first pass reperfusion rate resulting in excellent reperfusion (mTICI \geq 2C) of 55%, which is less than the rate (70.5%) reported herein. In the first-in-man experience, 25% of cases required adjunctive devices. As our experience with this system grows, we found no primary lesion that required adjunctive devices to achieve mTICI 2B recanalization, and in 11% of cases adjunctive devices were required to recanalize more distal occlusions to improve final reperfusion (mTICI 2B to mTICI \geq 2C). Although this was a preliminary experience, the SLIC technique was also faster in achieving groin puncture to mTICI \geq 2B recanalization (20 min) in comparison with Caldwell *et al* (26 min) and other aspiration trials such as ASTER (38 min)¹⁷ and COMPASS (22 min)¹⁸ while uniformly using the largest commercially available 088 platform for primary aspiration. The mean time from groin puncture to clot contact with the 0.088" catheter assembly was 14 min (6–31 min). We compared first pass reperfusion rate of the data presented in the current study with 80 cases performed between January 2019 and November 2020 using our prior workflow—namely, balloon guide catheter coupled with distal aspiration and stent retriever thrombectomy.¹¹ With SLIC, we observed a better first pass reperfusion rate of 82.3% vs 56.3% for mTICI \geq 2b and 70.5% vs 48.8% for mTICI \geq 2c.¹⁹

Our study has many limitations, notably it is a small retrospective case series. Due to the limited supply of devices, more patients could not be treated with SLIC. We sought to reduce the impact of patient selection bias by including consecutive patients with ICA terminus or M1 occlusions from three academic centers that actively maintain clinical databases. Moreover, since these patients were recently treated, a reported 3-month mRS score is not available. A randomized clinical trial evaluating this technology has been approved by the FDA (SUMMIT MAX) and will be necessary to confirm the excellent technical and angiographic outcomes of the super large-bore aspiration insert

catheters combination technique observed in our early clinical experience, and to confirm the clinical benefit of first pass effect.

SUMMIT MAX is a prospective, randomized (1:1), controlled, interventional clinical trial to Evaluate the Safety and Effectiveness of the Route 92 Medical MonoPoint Reperfusion System for Aspiration Thrombectomy in patients with acute ischemic stroke, which aims to prove non-inferiority of the Route 92 medical reperfusion system for the revascularization rate achieved in comparison with the AXS Vecta aspiration system (Stryker Neurovascular). Up to 220 patients will be enrolled in up to 30 institutions in the USA and New Zealand. Further details are available online at <https://clinicaltrials.gov/ct2/show/NCT05018650>.

CONCLUSIONS

Preliminary experience with the SLIC technique using super large-bore aspiration catheters as a first-line thrombectomy treatment demonstrated 100% efficacy and safety in successfully accessing the intracranial occlusion with an 0.088" aspiration device, with first pass efficacy of 70.5%.

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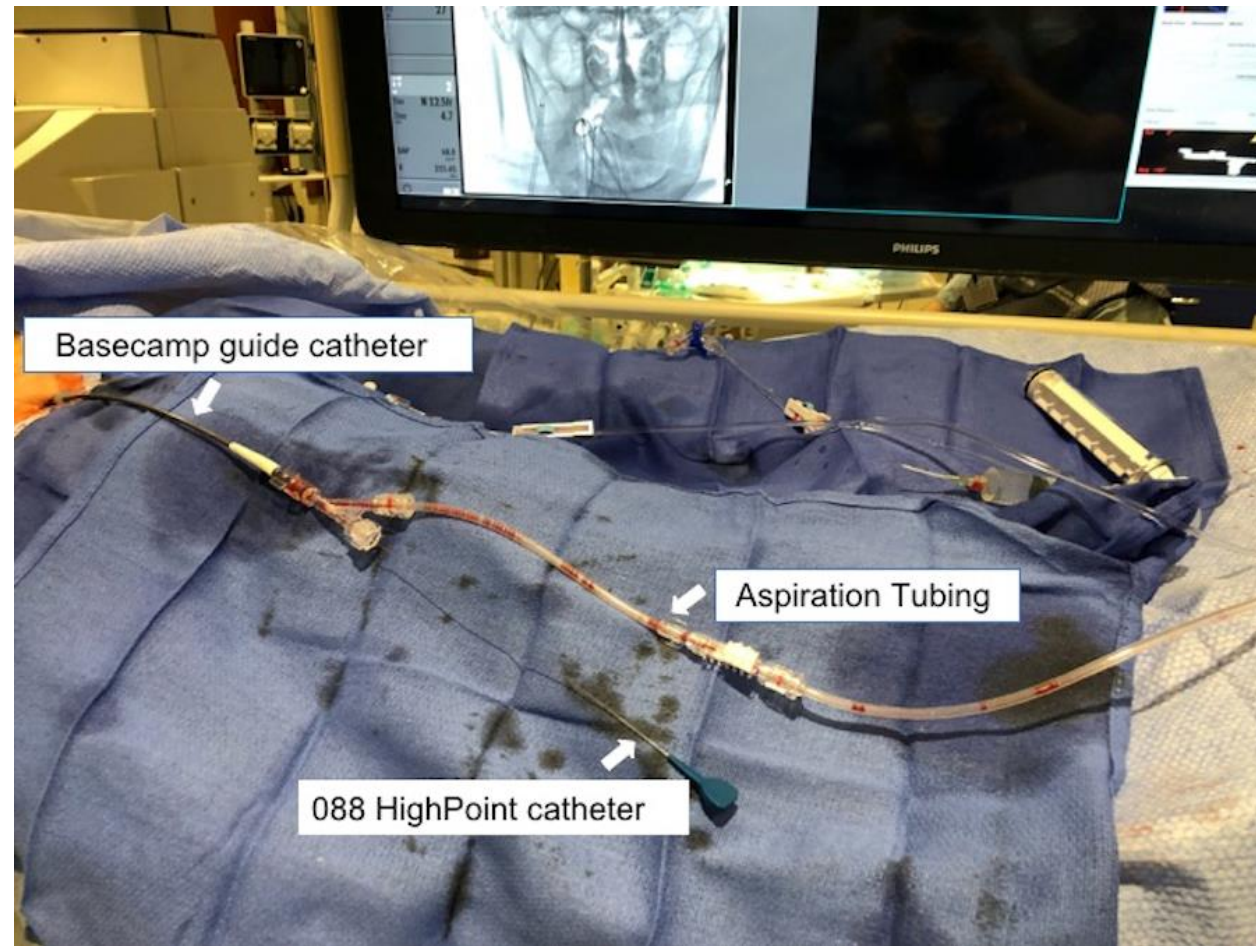
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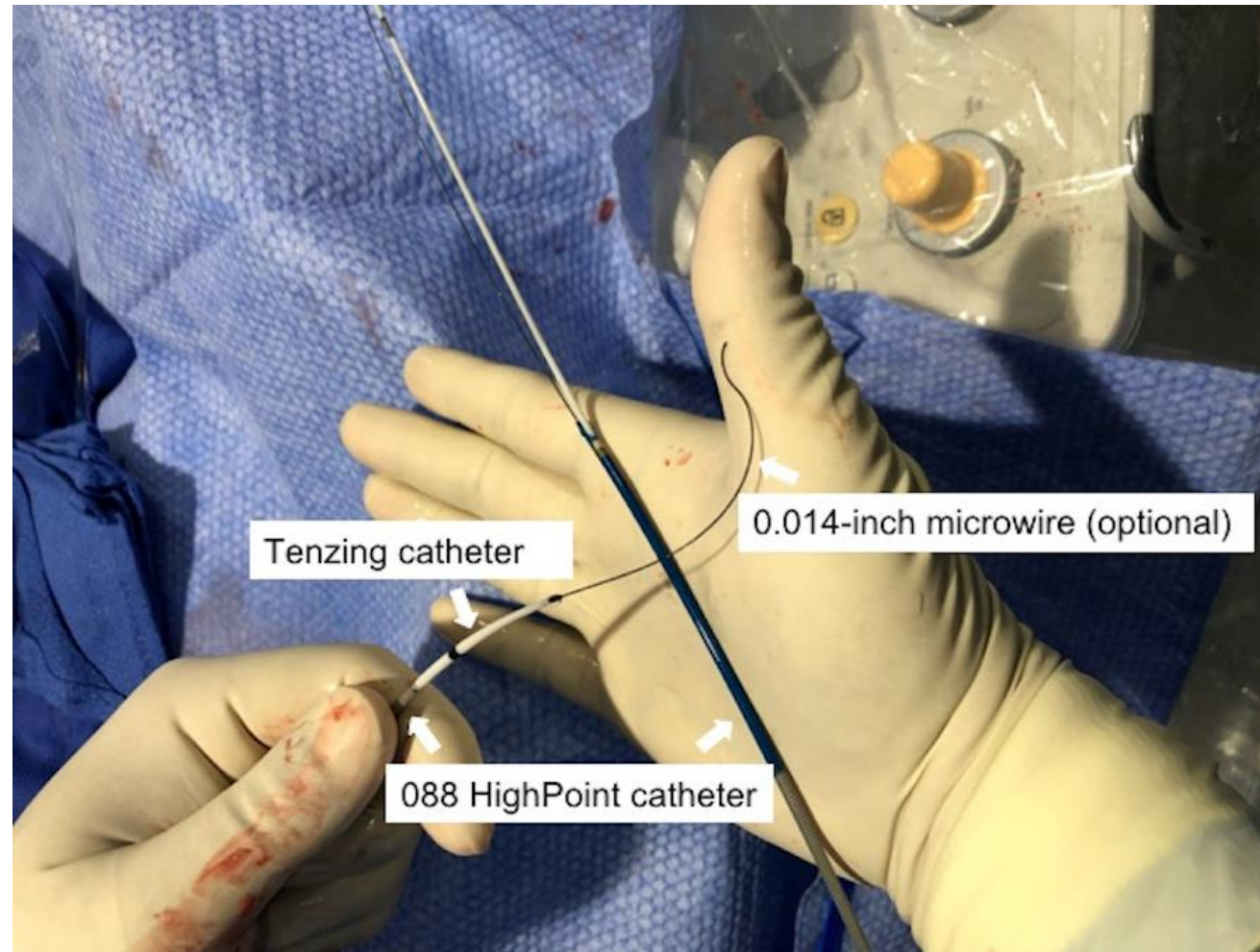
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Supplemental Figure 1 shows the 8 Fr 0.106" guiding catheter (Base Camp) and 0.088" 62 cm catheter extender (HiPoint) connected to the aspiration tubing in preparation for the thrombectomy pass.



Supplemental Figure 2 shows the assembly of the 0.088" 62 cm catheter extender (HiPoint) with the self-centering insert catheter (Tenzing 8) as well as an optional 0.014-inch microwire.



Supplemental Figure 3 shows the 8 Fr 0.106" guiding catheter (Base Camp) inserted into the right femoral artery via a 9 French femoral sheath.

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4	Consulting fees	<input checked="" type="checkbox"/> None						

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5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None <table border="1"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
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ICMJE DISCLOSURE FORM

Date: 5/24/2022

Your Name: Gustavo M Cortez, MD

Manuscript Title: Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

Manuscript Number (if known): Click or tap here to enter text.

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ICMJE DISCLOSURE FORM

Date: 5/24/2022

Your Name: G. Dabus MD

Manuscript Title: Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

Manuscript Number (if known): Click or tap here to enter text.

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4	Consulting fees	<input type="checkbox"/> None						

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
		Medtronic, Microvention, Cerenovus, Penumbra, Stryker, InNeuroCo, Route 92	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
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ICMJE DISCLOSURE FORM

Date: 5/24/2022

Your Name: Matthew J. Gounis PhD

Manuscript Title: Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

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		Naglireiter MDDO, Neurogami, Philips Healthcare, Progressive Medical, Pulse Medical, Rapid Medical, Route 92 Medical, Stryker Neurovascular, Syntheon, ThrombX Medical, Wallaby Medical, the Wyss Institute and Xtract Medical	
3	Royalties or licenses	<input checked="" type="checkbox"/> None	
4	Consulting fees	<input type="checkbox"/> None	
		Alembic LLC, Astrocyte Pharmaceuticals, BendIt Technologies, Cerenovus, Imperative Care, Jacob's Institute, Medtronic Neurovascular, Mivi Neurosciences, phenox GmbH, Q'Apel, Route 92 Medical, Stryker Neurovascular, Wallaby Medical	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
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ICMJE DISCLOSURE FORM

Date:5/24/2022

Your Name:Ricardo A. Hanel, MD, PhD

Manuscript Title:Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

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	committee or advocacy group, paid or unpaid	<div>Cerebrotech</div> <div>eLum</div> <div>Endostream</div> <div>Three Rivers Medical Inc</div> <div>Scientia</div> <div>RisT</div> <div>Blink TBI</div> <div>Corindus</div>	
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ICMJE DISCLOSURE FORM

Date: 5/24/2022

Your Name: Anna Luisa Kuhn MD PhD

Manuscript Title: Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

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ICMJE DISCLOSURE FORM

Date: 5/24/2022

Your Name: Francesco Massari MD PhD

Manuscript Title: Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

Manuscript Number (if known): Click or tap here to enter text.

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ICMJE DISCLOSURE FORM

Date: 5/24/2022

Your Name: Varun Naragum MD

Manuscript Title: Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

Manuscript Number (if known): Click or tap here to enter text.

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ICMJE DISCLOSURE FORM

Date:5/24/2022

Your Name:Ajit S. Puri MD

Manuscript Title:Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

Manuscript Number (if known):Click or tap here to enter text.

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4	Consulting fees	<input type="checkbox"/> None <div> <div>Medtronic Neurovascular, Stryker Neurovascular, Balt, Q'Apel Medical, Cerenovus, Microvention, Imperative Care, Agile, Merit, CereVasc and Arsenal Medical</div> <div></div> <div></div> <div></div> </div>	
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ICMJE DISCLOSURE FORM

Date: 5/24/2022

Your Name: Jasmeet Singh MD

Manuscript Title: Super Large-bore Ingestion of Clot (SLIC) Leads to High First-Pass Effect in Thrombectomy for Large Vessel Occlusion

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