Case series

Use of a large-bore 088 intracranial access support catheter for delivery of large intracranial devices: case series with the TracStar LDP in 125 cases

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ABSTRACT

Background The delivery of neuroendovascular devices requires a robust proximal access platform. This demand has previously been met with a 6Fr long sheath (8Fr guide) that is placed in the proximal internal carotid artery (ICA) or vertebral artery segments. We share our experience with the first 0.088 inch 8Fr guide catheter designed for direct intracranial access.

Methods We retrospectively reviewed a prospectively maintained IRB-approved institutional database of the senior authors to identify all cases where the TracStar Large Distal Platform (LDP) was positioned within the intracranial vasculature, defined as within or distal to the petrous ICA, vertebral artery (V3) segments, or transverse sinus. Technical success was defined as safe placement of the TracStar LDP within or distal to the described distal vessel segments with subsequent complication-free device implantation.

Results Over the 41-month study period from January 2020 to June 2023, 125 consecutive cases were identified in whom the TracStar LDP was navigated into the intracranial vasculature for triaxial delivery of large devices, 0.027 inch microcatheter and greater, for aneurysm treatment (n=108, 86%), intracranial angioplasty/stenting (n=15, 12%), and venous sinus stenting (n=2, 1.6%). All cases used a direct select catheter technique for initial guide placement (no exchange). Posterior circulation treatments occurred in 14.4% (n=18) of cases. Technical success was achieved in 100% of cases. No vessel dissections occurred in any cases.

Conclusion The TracStar LDP is an 0.088 inch 8Fr guide catheter that can establish direct intracranial access with an acceptable safety profile. This can be achieved in a wide range of neurointerventional cases with a high rate of technical success.

INTRODUCTION

The delivery of neuroendovascular devices requires a catheter access platform which features robust proximal and distal support, and trackability through tortuous vasculature.[1–4] These requirements have been commonly met by the use of a triaxial system consisting of a guide catheter, intermediate catheter, and a microcatheter system.[5 6] An 0.088 inch (8Fr) guide catheter is often used in these set-ups to provide proximal support while traversing the aortic arch and large proximal vessels, with smaller diameter intermediate catheters used to provide distal support closer to the site of intervention.[7] The proximal and distal support provided by the guide and intermediate catheters offers enhanced distal control of microsystems and device deployments.[8 9]

Previous 0.088 inch guide catheters have been limited by their stability and trackability into the intracranial vasculature.[10–14] This limitation prevents distal placement and enhanced stability for the delivery of large neurointerventional devices. The TracStar Large Distal Platform (LDP) (Imperative Care, Campbell, California, USA) is the first ever supportive 0.088 inch guide catheter with a hyperflexible tip designed to track to the intracranial vasculature.[3] This catheter is 105 cm in length and has a unique angled tip, and proprietary durometer transitions facilitate navigation into the cavernous internal carotid artery (ICA) which offer improved stability across major vessels and may provide improved stability for the delivery of large diameter neurointerventional devices. Furthermore, intracranial positioning of an 0.088 inch guide may provide a similar level of distal support to triaxial systems and enable a simplified biaxial system to be used in some cases.[3 12] In this case series we report our experience in 125 consecutive cases using the TracStar LDP according to the PROCESS guidelines.[15] To date, this is the largest report of the safety, effectiveness, and potential advantages of using a triaxial system with intracranially positioned 0.088 inch guide catheters to support a variety of large device neurointerventions.

METHODS

Patient selection

We retrospectively reviewed a prospectively maintained IRB-approved (MetroWest Medical Center IRB: 2020–039) institutional database of the senior authors to identify all cases where the TracStar LDP was used between January 2020 and June 2023. In all cases the TracStar LDP was the initial catheter of choice and not a back-up after failure of a different device. We included all consecutive patients in which the TracStar LDP was positioned within or distal to the petrous ICA, V3 segment of the vertebral artery,

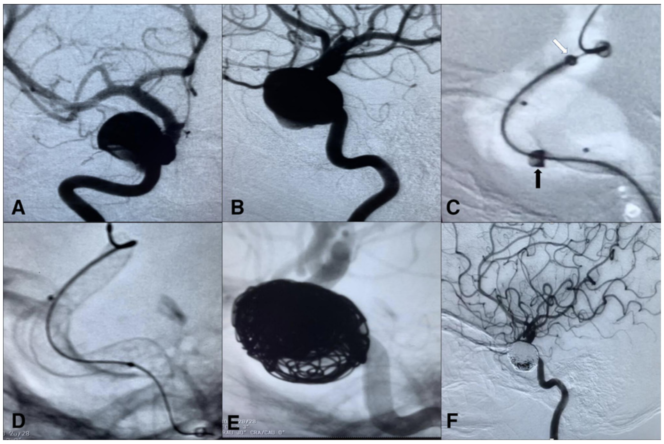

Figure 1 (A,B) A symptomatic adult patient underwent flow diversion for a 25 mm cavernous aneurysm. (C) A Surpass flow diverting stent (white arrow) and the TracStar LDP guide catheter (black arrow) were brought to the anterior genu of the cavernous internal carotid artery (ICA) segment. (D, E) Deployment of the Surpass flow diverting stent with adjunctive coil embolization was performed. (F) Final angiography with contrast stasis showing no evidence of vessel irregularities along the length of the ICA where the TracStar LDP was navigated.

or the transverse sinus, depending on the location of the target lesion.

Procedure details

All patients receiving an endoluminal construct were started on dual antiplatelet therapy in the week preceding the procedure and had a platelet reactivity unit (PRU) value drawn preoperatively. All cases were completed using a femoral access approach with an 8Fr femoral sheath (10 cm in length). After gaining vascular access, a 0.035 inch guidewire and direct select catheter were used to advance the TracStar LDP into the ICA or vertebral artery. After positioning, the select catheter and 0.035 inch guidewire were removed and the intermediate catheter and microcatheter were advanced through the TracStar LDP. The triaxial system of catheters was then advanced into the intracranial vasculature (figure 1) and used to facilitate delivery and deployment of either flow diverting stents (FDS), with or without coiling, or vascular reconstruction devices (VRD), with or without balloons.

Use of a triaxial system with a TracStar LDP, intermediate catheter, and microcatheter was not required for this study; however, all cases included in this cohort used this technique. A variety of intermediate and microcatheters were used as part of the triaxial system based on the cerebrovascular neurosurgeon's discretion, pertinent clinical context, and the specific vascular anatomy. The AXS Catalyst 5 (Stryker Neurovascular) and Excelsior XT-27 (Stryker Neurovascular) were the most commonly used intermediate catheters and microcatheters, respectively.

Data collection

Cases were reviewed for the following demographic and clinical data: age, sex, aneurysm characteristics, vessel tortuosity grades, access catheters used and their most distal positions, location of vascular pathology, preoperative PRU value, and pertinent medications. Procedural details collected included the types of devices used (stents, catheters, balloons, microwires) and the most distal location of the guide and distal access catheters. The parent vessel was graded by the following on angiography: cervical ICA tortuosity (corkscrew loop or 90° turn) and cavernous ICA tortuosity (Ia, Ib, II, III, or IV) as previously described.[16] Intraoperative medication use, including heparin, tirofiban, and verapamil, were also recorded.

Outcomes

Procedural outcomes including thromboembolic complications, hemorrhage, hematoma, and vessel dissection were assessed. Technical success was defined as safe placement of the guide catheter within or distal to the petrous ICA (anterior circulation), vertebral artery (V3) (posterior circulation), or the transverse sinus for venous stenting procedures.

Statistical analysis

Discrete datapoints including patient demographics, clinical data, effectiveness, and safety endpoints were summarized with rates. Mean and SE were generally reported for continuous data. All analyses were completed using Minitab 21.4.0 statistical software (Minitab Inc, State College, Pennyslvania, USA).

RESULTS

Patient demographics

Over the 41-month study period the TracStar LDP was used in a total of 125 consecutive patients. Most patients were female (n=94, 75%) and the average age was 65.4±1.3 years. The cervical ICA had no loops in 104 cases (97%). Cavernous segment tortuosity was graded as Ia (n=50, 47%), Ib (n=24, 22%), II (n=13, 12%), III (n=14, 13%), and IV (n=6, 6%) using a previously published scale.[16] Patient demographics and anatomical characteristics are summarized in online supplemental table S1.

Procedural characteristics

Aneurysm treatments were the most common procedure type in this study, accounting for 86% (n=108) of cases. Other procedures in this study included intracranial angioplasty/stenting (n=15, 12%) and venous sinus stenting (n=2, 1.6%). The most commonly used FDS were the Surpass Evolve and Surpass Streamline (Stryker Neurovascular). The average FDS diameter was 3.91±0.07 mm and the average length was 21.4±0.94 mm. VRDs included the Atlas and Wingspan stents (Stryker Neurovascular) and the Precise stent (Cordis). The average VRD diameter was 4.18±0.25 mm and the average length was 19.5±1.28 mm. Additional information describing the treatments and devices used is reported in online supplemental table S1.

A triaxial system with direct select catheter technique for guide placement (no exchange) was used in all cases. Heparin was administered in accordance with standard practice to 86% (n=109) of patients and tirofiban to 16.5% (n=21) of patients. Posterior circulation placement occurred in 14% (n=18) of cases. Technical success was achieved in 100% (n=125) of cases. No symptomatic or flow-restricting vessel dissections occurred in any of the cases. Verapamil was administered in 11% (n=14) of cases of pronounced tortuosity to augment vessel caliber and reduce the chance of inducing vasospasm, and no cases required calcium channel blockers for flow-limiting vasospasm.

DISCUSSION

The TracStar LDP has a unique combination of a stiff proximal shaft designed to provide support in the aortic arch, distal large vessels, and venous sinuses, combined with a long 14.5 cm distal flexible segment that facilitates distal navigation through tortuous anatomy. All cases in this study were able to use the TracStar LDP for distal intracranial navigation. Even in the case of tortuous cervical grading, the TracStar LDP was consistently delivered to the petrous ICA and beyond (see online supplemental table S1). Of the anterior circulation cases, the TracStar LDP was navigated to the petrous segment in the majority of cases and to the cavernous segment or higher in 34% of cases. Even with the relatively large number (n=20) of cases with moderate to severe cavernous tortuosity (cavernous grade III or IV), the TracStar LDP was still successfully navigated to the intracranial ICA and achieved technical success in all cases. More broadly, large-bore guide catheters (in particular TracStar LDP) were used for all large device neurointerventional procedures during the study period. Our group have long been users and proponents of the advantages of triaxial systems with 088 base catheters, and this is routine in our practice.[17]

Despite this study including a wide range of endovascular techniques, cerebrovascular anatomy, and neurointerventional devices, all TracStar LDP cases were a technical success. While there have been previous reports of using the 0.088 inch TracStar LDP in flow diversion, a majority of the cases in these reports used the TracStar LDP as a stand-alone guide catheter in a primarily biaxial system.[3 18] In contrast to conventional biaxial methods, the triaxial system may offer a steadier foundation for precise microcatheter maneuvering into distal intracranial targets and has been shown to be a viable technique for supporting intracranial stent delivery and deployment.[4 17] The intermediate catheters used as part of the triaxial system provide additional distal support close to the target treatment location which enhances system stability and may result in heightened microcatheter responsiveness, contributing to improved procedural safety.[13 19] The use of 0.088 inch guides as part of triaxial systems helps provide the proximal support necessary to deliver larger intermediate catheters to distal vasculature such as the M2, basilar, and superior sagittal sinus, thereby enhancing the level of distal support.[13]

Our experience has made clear several delivery techniques which tend to maximize the chances of successful delivery of the TracStar LDP. First, we tend to position the 5Fr select catheter in the high cervical segment when advancing the TracStar LDP from the arch, as this helps navigate the catheter beyond the highly mobile proximal cervical segment which is more prone to vasospasm. Second, the TracStar LDP is brought intracranially over the 0.058 inch distal access catheter, thereby minimizing the step-off/ledge effect and allowing the TracStar LDP to be tracked with virtually no vasospasm noted in this patient cohort. We feel that the soft nature of the TracStar LDP tip is the most likely source of failure to deliver the device, as it may result in prolapse into wider arches. Hence, advancing the select catheter higher as stated above is essential when navigating wider arches to prevent said prolapse and ensure successful navigation into more distal vasculature. One of the powerful takeaways from this experience is that the learning curve for using the TracStar LDP is quite minimal. This is likely due to the routine use of 0.088 inch catheters in modern thrombectomy procedures performed by nearly all neurointerventionalists. Furthermore, this catheter was designed specifically for deep access.

A triaxial platform with the TracStar LDP positioned in the intracranial ICA and vertebral arteries may further enhance stability when used to support delivery of large intracranial devices, such as the Surpass flow diverters used in this study which measure up to 5 mm in diameter and the larger 8 mm Precise stents used in the venous sinus (online supplemental table S1). While other guide catheters, including Infinity and Ballast (Balt USA, Irvine, California, USA), have most commonly reported distal navigation to the proximal ICA segments such as the high cervical ICA,[17] the present study showed that the TracStar LDP can be consistently navigated more distally to the petrous and cavernous ICA, vertebral artery V3 segment, and transverse sinus with an excellent safety profile shown by the lack of catheter-related complications or hematomas (figure 1 and online supplemental table S1). The higher intracranial positioning that can be achieved with the TracStar LDP makes it a novel addition to the existing arsenal of 0.088 inch internal diameter guide catheters currently available to neurointerventionalists.

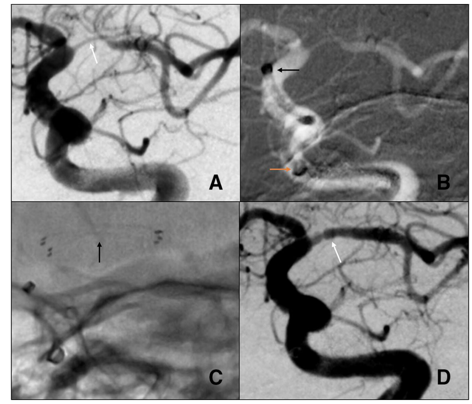

Figure 2 (A) Cerebral angiography of a patient in their 70s, who presented with weakness, showing severe proximal left M1 stenosis (white arrow). (B) In a triaxial platform, the TracStar LDP (orange arrow) was navigated to the vertical cavernous to provide distal support for AXS Catalyst 5 Distal Access Catheter in the internal carotid artery terminus for delivery of a 3×15 mm Wingspan (C, black arrow). (D) Final angiography showing significant improvement in flow to the middle cerebral artery (white arrow).

Use of the TracStar LDP also allowed the successful deployment of Wingspan intracranial stents for the treatment of intracranial atherosclerotic disease (ICAD). The original WEAVE/WOVEN trials used a 6Fr or larger guide for stent delivery, although the details of specific guide catheters were not mentioned.[20 21] A comparative multicenter study delivered a balloon-mounted stent using 6Fr guide catheters for ICAD stent angioplasty.[22] The study cohort described here implanted Wingspan stents that ranged from 2.5 mm to 4.5 mm in diameter using the TracStar LDP with a triaxial platform. The use of the 8Fr guide catheter in a triaxial setting had notable stability in large proximal intracranial vessels without compromising delivery of a large-bore stent deployment system with a balloon catheter (figure 2). This series includes the only reported use of the TracStar LDP guide catheter to enhance the deployment of large Wingspan stents in the treatment of ICAD.

In this retrospective review of prospective cases, we also describe the use of the TracStar LDP for the delivery of large distal VRDs for the management of venous sinus stenosis.[23] A single case series of 58 patients exists that describes the successful use of the TracStar LDP for venous sinus stenting.[23] In a biaxial platform, the TracStar LDP was navigated to the transverse sinus for the deployment of VRDs as large as 10 mm in diameter.[23] In the series described here, the TracStar LDP catheter was positioned in the transverse sinus in two cases to deliver the 8×40 mm Precise Pro RX (Cordis, Miami Lakes, Florida, USA) with a triaxial system. Enhanced stability was achieved in both cases by using a triaxial system and was performed without procedural complications. Use of the TracStar LDP in a triaxial platform may enhance platform trackability for the delivery of large VRDs and support venous sinus stenting.

Study limitations

This report is subject to limitations inherent to retrospective and non-randomized studies. Although the study demonstrated the safety of the TracStar LDP for distal access in flow diversion, stenting for ICAD, and stenting for venous sinus stenosis, its safety profile in other neurointerventional procedures remains to be determined. Furthermore, our experience is that of a single group of experienced practitioners at a single center and therefore future research should focus on externally validating our institutional findings.

CONCLUSION

Based on our experience, the use of the TracStar LDP in triaxial systems is a safe and effective approach for the delivery of large neurointerventional devices and helps to enhance distal access in intracranial aneurysm management. The TracStar LDP is a valuable addition to the armamentarium of neuroendovascular access technology as it provides enhanced distal stability in large intracranial vessels and facilitates the successful treatment of aneurysms, ICAD, and venous sinus stenosis.

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Contributors JKC and DAZ assisted with the conception and design of the manuscript. JKC, BMM, DAZ, and JCCdB drafted and revised the manuscript for important intellectual content. JKC, DAZ, BMM, and JCCdB assisted with the data acquisition and analysis. JKC, NBB, MTB, SS, GPC, LML, and ALC reviewed the important intellectual content presented in the manuscript. ALC, MWK, and FJL performed treatment procedures and critically revised the important intellectual content. All authors read and approved the final manuscript.

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Table S1. Case Summary and Procedural Details

	Number / Average (Range)	% (all cases) / SE
Demographics		
Total Cases	125	
Age (years)	65.4 (22-90)	±1.26
Female Sex	94	75%
Circulation		
Aneurysm Treatment (Total)	108	86%
Anterior	98	91%
Posterior	10	9.3%
ICAD Stenting (Total)	15	12%
Anterior Circulation	9	60%
Posterior Circulation	6	40%
Sinus Stenting (Total)	2	1.6%
Anatomy		
Cervical Grade		
0	104	97%
1	3	2.8%
Cavernous Grade		
Ia	50	47%
Ib	24	22%
II	13	12%
III	14	13%
IV	6	5.6%
Access and Catheters		
Catheter System		
Triaxial	125	100%
Case Characteristics		
PRU	60.4 (2 - 250)	
Medications		
Heparin	109	86%
Tirofiban	21	16.5%
Verapamil	14	11%
TracStar LDP™ Position		
Petrous	71	57%
Vertical Cavernous	25	20%
V3	16	13%
Horizontal Cavernous	9	7.2%

Supraclinoid	2	1.6%	
Transverse Sinus	2	1.6%	
Distal Intracranial Catheter used			
Cat 5	110	88%	
AXS Vecta 71	9	7.2%	
SOFIA	7	5.6%	
AXS Vecta 46	1	0.8%	
Phenom Plus	1	0.8%	
Distal Intracranial Catheter Position			
Supraclinoid	22	17%	
Horizontal Cavernous	38	30%	
M1	38	30%	
V3	8	6.3%	
Basilar Junction	5	3.9%	
V4	3	2.4%	
ICA Terminus	2	1.6%	
Vertical Cavernous	2	1.6%	
Superior Sagittal Sinus	2	1.6%	
M2	1	0.8%	
Petrous	1	0.8%	
A1	1	0.8%	
AICA	1	0.8%	
Paraclinoid	1	0.8%	
Microcatheters Used		(% of category)	
Excelsior XT 27	43	57%	
Excelsior SL 10	17	23%	
Headway 21	12	16%	
Phenom 27	6	8.0%	
Headway Duo 156	3	4.0%	
Headway 27	3	4.0%	
Phenom 21	1	1.3%	
Devices			
Number of Devices per Total Cases	1.15		
Total Number of Flow Diverters	106		
Total Number of VRD	37		
Total Number of WEB	1		
Diameter by Flow Diverter Type (mm)			
Surpass evolve (n = 47)	4.20 (3-5)		± 0.08
Surpass stream (n = 37)	3.92 (3-5)		± 0.11
FRED (n = 15)	3 (2.5-5)		± 0.18

Pipeline Flex (n=7)	3.92 (2.75-5)	± 0.38
Diameter by Other Stents/Devices (mm)		
Neuroform Atlas (n = 15, out of 20)	4.0 (3-4.5)	± 0.28
Wingspan (n = 14, out of 15)	3.57 (2.5-4.5)	± 0.30
Precise (n = 2)	8	
WEB SL (n = 1)	8	
Access Related Complications		
Groin Hematoma	0	0%
In Situ Thrombus Formation	0	0%
Vasospasm	0	0%
Iatrogenic Vessel dissection	0	0%
Procedural Success	125	100%