Original research

Comparative study of intracranial access in thrombectomy using next generation 0.088 inch guide catheter technology

Devin V Bageac ,[1] Blake S Gershon ,[1] Jan Vargas,[2] Maxim Mokin ,[3] Zeguang Ren,[3] Deeksha Chada,[1] Aquilla S Turk,[2] M Imran Chaudry,[2] Raymond D Turner,[2] Johanna T Fifi,[1] Tomoyoshi Shigematsu,[1] Reade De Leacy[1]

[1]Department of Neurosurgery, Mount Sinai Health System, New York, New York, USA
[2]Department of Neurosurgery, Prisma Health, Greenville, South Carolina, USA
[3]Neurosurgery and Brain Repair, University of South Florida College of Medicine, Tampa, Florida, USA

Correspondence to
Dr Reade De Leacy, Department of Neurosurgery, Mount Sinai Health System, New York, New York 10029-657, USA; rdeleacy@gmail.com

Received 23 February 2021
Revised 5 May 2021
Accepted 9 May 2021
Published Online First 26 May 2021

ABSTRACT

Background Most conventional 0.088 inch guide catheters cannot safely navigate intracranial vasculature. The objective of this study is to evaluate the safety of stroke thrombectomy using a novel 0.088 inch guide catheter designed for intracranial navigation.

Methods This is a multicenter retrospective study, which included patients over 18 years old who underwent thrombectomy for anterior circulation large vessel occlusions. Technical outcomes for patients treated using the TracStar Large Distal Platform (TracStar LDP) or earlier generation TRX LDP were compared with a matched cohort of patients treated with other commonly used guide catheters. The primary outcome measure was device-related complications. Secondary outcome measures included guide catheter failure and time between groin puncture and clot engagement.

Results Each study arm included 45 patients. The TracStar group was non-inferior to the control group with regard to device-related complications (6.8% vs 8.9%), and the average time to clot engagement was 8.89 min shorter (14.29 vs 23.18 min; p=0.0017). There were no statistically significant differences with regard to other technical outcomes, including time to recanalization (modified Thrombolysis In Cerebral Infarction (mTICI) ≥2B). The TracStar was successfully advanced into the intracranial internal carotid artery in 33 cases (73.33%); in three cases (6.67%), it was swapped for an alternate catheter. Successful reperfusion (mTICI 2B-3) was achieved in 95.56% of cases. Ninety-day follow-up data were available for 86.67% of patients, among whom 46.15% had an modified Rankin Score of 0–2%, and 10.26% were deceased.

Conclusions Tracstar LDP is safe for use during stroke thrombectomy and was associated with decreased time to clot engagement. Intracranial access was regularly achieved.

To cite: Bageac DV, Gershon BS, Vargas J, *et al*. *J NeuroIntervent Surg* 2022;**14**:390–396.

INTRODUCTION

Outcomes following thrombectomy for emergent large vessel occlusive stroke (ELVO) are inversely related to the procedure time.[1 2] Analysis of data from randomized clinical trials reveals that this association is driven primarily by the time between initial imaging and adequate reperfusion.[3] The interval between groin puncture and time of first clot contact can contribute significantly to the overall procedure time, and thus rapid guide catheter navigation from the aortic arch to the intracranial internal carotid artery (ICA) may improve thrombectomy outcomes.

A major impediment to rapid reperfusion is tortuosity of the cervical and skull base vasculature, which is independently associated with an increased time to first pass.[4 5] Notably, approximately 40% of patients undergoing endovascular thrombectomy in the setting of ELVO display significant vascular tortuosity.[6]

Even in the absence of pathology, normal angulation within the intracranial ICA and vertebral arteries can be barriers to safe intracranial advancement when using most conventional guide catheters. Evidence suggests that advancing a 0.088 inch (2.24 mm) guide to the petrocavernous junction can shorten procedure time and improve outcomes, likely by potentially reducing the path length of clot retrieval and increasing flow arrest during remote aspiration, as well as providing support for navigating aspiration catheters distally.[7 8] For these reasons, a flexible 0.088 inch guide catheter that can decrease time to clot engagement and facilitate distal access may lead to improvement in the quality of thrombectomy.

We present a multicenter, retrospective, matched cohort study evaluating the safety of stroke thrombectomy using a novel 0.088 inch guide catheter designed for navigation to the intracranial vasculature, with secondary analyses conducted to evaluate efficacy endpoints.

METHODS

This multicenter retrospective study was approved by the Institutional Review Board at each participating center. The study complies with the Health Insurance Portability and Accountability Act. Cases were performed by eight separate proceduralists at three US health centers.

This study proceeded in two phases. First, a single-arm retrospective review was conducted in order to evaluate clinical outcomes in thrombectomy patients treated with the TracStar Large Distal Platform (TracStar LDP) (Imperative Care, Campbell, CA) or earlier generation TRX LDP (Imperative Care, Campbell, CA). These platforms differ only in their available lengths (95 cm and 105 cm vs 90 cm, respectively), and the term 'TracStar LDP'

will be used to refer to both unless otherwise specified. Second, a matched cohort analysis was performed to compare the safety profile of the TracStar LDP to other commonly used guide catheters, with secondary analyses conducted to detect differences in technical efficacy.

Inclusion criteria for this study encompassed patients older than 18 years of age who underwent endovascular thrombectomy for large vessel occlusive stroke affecting the anterior circulation. Patients were excluded if angiography demonstrated no ELVO or if the decision was made not to proceed with thrombectomy. The data collection period extended from August 2019 to February 2020.

For the single-arm review, baseline clinical characteristics, procedural details, and clinical outcomes were collected by review of patient records. Patient imaging was prospectively adjudicated by fellowship trained neurointerventionalists. Pre- and post-procedural ASPECTS (Alberta Stroke Program Early CT Score) were determined using non-contrast CT imaging obtained immediately before and 1–3 days following thrombectomy. Evidence of post-procedural hemorrhage 24–72 hours following thrombectomy was evaluated on post-procedural CT if MRI was not available.

For the matched cohort comparison, patients treated with the TracStar LDP were matched 1:1 with patients treated using other guide catheters during the data collection period. Matching criteria included occlusion location (regardless of laterality) and the usage of angioplasty±stenting. Univariate testing was carried out to ensure groups were balanced across relevant baseline characteristics including aortic arch type, occlusion laterality, and vascular tortuosity. A group of heterogenous control guide catheters was selected in order to compare TracStar to the general safety profile of devices commonly used in neurointerventional practice.

The primary outcome measure was defined as the proportion of device-related complications. This study was not designed to test for superiority of the TracStar LDP with regard to technical efficacy, but secondary outcome measures for efficacy were collected and analyzed, including guide catheter failure, time between groin puncture and clot engagement, time between groin puncture and modified Thrombolysis In Cerebral Infarction (mTICI) 2B+recanalization, fluoroscopy time, total number of passes, and final mTICI recanalization score. Guide catheter failure was defined as failure to maintain stable positioning within the cervical ICA, or use of an alternative guide catheter at any point after initial access was attempted. After testing for group balance, univariate statistical analyses were carried out using Mann-Whitney U test, χ^2 test or unpaired t-test as appropriate with a significance threshold of $p<0.05$.

Vascular tortuosity was classified in three orthogonal plains on preprocedural CT angiography according to a modification of the criteria set forth by Metz *et al*, as illustrated in figure 1.[9] Vascular kinks were categorized into three subgroups: (1) less than 30°, (2) between 30° and 60°, and (3) between 60° and 90°. Vessels that made a complete 360° turn were counted as a loop. All tortuosity located between the aortic arch and the petrocavernous junction was included in the classification. Logistic regression was performed in order to determine the relationship between the number of <90° turns and the time from groin puncture to clot engagement.

The position of the TracStar LDP throughout the procedure was determined by prospective evaluation of fluoroscopic images obtained during thrombectomy. For the purposes of this study, segments of the ICA are described via an adaptation to the criteria set by Lasjaunias and Berenstein, as depicted in figure 2.[10] The intracranial ICA was defined as originating at the vessel's medial turn within the petrous bone (horizontal petrous segment). In all TracStar cases, the target position for LDP placement was defined as the intracranial ICA at or beyond this segment. It was not common practice among any of the participating institutions to advance any of the control guide catheters beyond the vertical petrous ICA. Within the TracStar group, a post hoc logistic regression was performed in order to investigate a potential association between distal LDP placement and final recanalization grades.

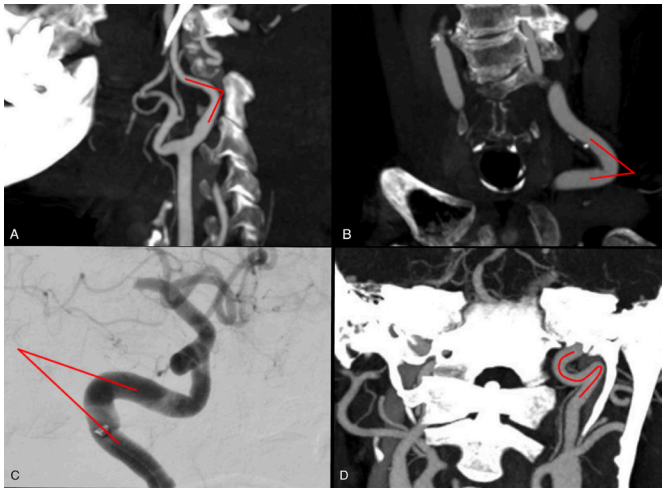

Figure 1 CT angiography maximum intensity projections (A, B, D) and DSA right ICA injection (C) showing examples of vascular tortuosity grades (indicated in red). (A) Sagittal view of 60°–90° ICA turn. (B) 30°–60° CCA turn. (C) <30° ICA turn. (D) ICA loop. CCA, common carotid artery. DSA, digital subtraction angiography; ICA, internal carotid artery.

Thrombectomies were performed via femoral artery access under monitored anesthesia care unless general anesthesia was indicated by the patient's clinical status. TracStar was introduced through an 8 or 9 French (Fr) sheath in the right femoral artery in all cases, and navigated to its final position using a coaxial selecting catheter. All thrombectomies were performed using direct aspiration techniques with or without subsequent stent retriever use at the discretion of the proceduralist.

RESULTS

TracStar single-arm clinical outcomes

Forty-five patients treated using the TracStar LDP were included in the final analysis of this retrospective study. Table 1 summarizes patient demographics and baseline clinical characteristics. Within the patient cohort, 42.22% were female, and the median age was 76.5 years (IQR 62.75–85.25). A prior history of stroke was present in 24.55% of patients. Baseline modified Rankin Score (mRS) was 0 in 68.89% of patients, 1–2 in 22.22%, and 3 in 8.89%.

Clinical presentation and imaging data are summarized in table 2. The median time between last known well and groin puncture was 5.08 hours (IQR 3.24–13.57). Patients had a median presentation NIHSS (National Institutes of Health Stroke Scale) of 16 (IQR 11–19) and a median ASPECTS of 9 (IQR 8–10). Of the large vessel occlusions, 55.56% occurred at the M1 segment of the middle cerebral artery (MCA), 13.33% occurred at the M2 segment, and 31.11% occurred at the ICA terminus.

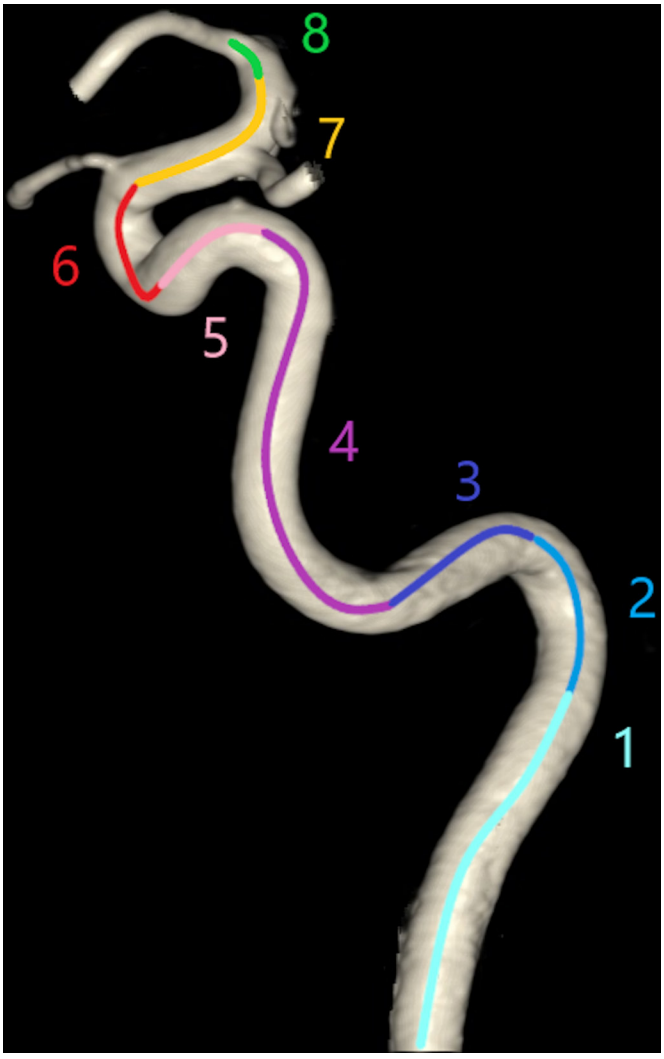

Figure 2 Right ICA angiographic reconstruction showing segmentation criteria used to determine the highest point reached by TracStar LDP. (1) Cervical, (2) vertical petrous, (3) horizontal petrous, (4) ascending cavernous, (5) horizontal cavernous, (6) paraclinoid, (7) supraclinoid, (8) ICA terminus. ICA, internal carotid artery; LDP, Large Distal Platform.

Table 3 summarizes post-procedural outcomes. Median post-procedure ASPECTS was 7 (IQR 5–9). Intraparenchymal hematoma consistent with ECASS (European Cooperative Acute Stroke Study) parenchymal hematoma type 1 (PH-1) was observed in eight patients (17.78%), but none were symptomatic. Median 24 hour NIHSS was 9 (IQR 4.5–14). Ninety-day follow-up data were available for 39 patients (86.67%). Among patients with available follow-up data, 46.15% had a 90 day mRS of 0–2, 43.59% had a 90 day mRS of 3–5, and 10.26% were deceased.

Matched-cohort comparison

Forty-five patients treated with other commonly used guide catheters were selected to act as a control group for the 1:1 matched cohort analysis presented in table 4. Patients were matched based on the site of occlusion regardless of laterality (ICA, M1 MCA, or M2 MCA), as well as the use of angioplasty±stenting. Guide catheters used in the control group included Neuron MAX (n=31; Penumbra Inc, Alameda, CA), Ballast 088 Long Sheath (n=9; Balt USA, Irvine, CA), AXS Infinity LS PLUS (n=2; Stryker, Portage, MI), Walrus Balloon Guide Catheter (n=1; Q'Apel, Fremont, CA), FlowGate2 Balloon Guide Catheter (n=1; Stryker, Portage, MI), and 8Fr Flexor Shuttle Sheath (n=1; Cook Group, Bloomington, IN).

Univariate analysis revealed no significant differences between TracStar and control groups with regard to relevant procedural characteristics including anesthesia type, aortic arch type, occlusion laterality, vascular tortuosity, or first-pass technique.

Results of the matched cohort analysis are summarized in table 5. Analysis of the primary outcome measure revealed that the TracStar LDP was non-inferior to other commonly used

Table 1 Patient demographics and clinical baseline for TracStar group

Total patients (n)	45
Age (median, IQR)	76.5 (62.75–85.25)
Sex (n, %)	
Female	19 (42.22)
Race (n, %)	
Black or African American	9 (20)
White	22 (48.89)
Other	9 (20.00)
Unknown	5 (11.11)
Ethnicity (n, %)	
Hispanic or Latino	8 (17.78)
Past medical history (n, %)	
Prior stroke	11 (24.44)
Cardiac arrhythmia	14 (31.11)
Cardiovascular disease	11 (24.44)
Congestive heart failure	6 (13.33)
Diabetes	17 (37.78)
Hematologic disorder	1 (2.22)
Hyperlipidemia/hypercholesterolemia	19 (42.22)
Hypertension	31 (68.89)
Illicit drug use	1 (2.22)
Myocardial Infarction	2 (4.44)
Renal failure	2 (4.44)
Valvular disease	2 (4.44)
Dementia	4 (8.89)
Cancer	3 (6.67)
Smoking status	
Current smoker	1 (2.22)
Former smoker	8 (17.78)
Medications before admission	
Antiplatelets	21 (46.67)
Anticoagulants	12 (26.67)
Antihypertensives	21 (46.67)
Statins	12 (26.67)
Baseline mRS	
0	31 (68.89)
1	5 (11.11)
2	5 (11.11)
3	4 (8.89)

mRS, modified Rankin Score.

Table 2 Clinical presentation

Time from last known well to groin puncture (hours) (median, IQR)	5.08 (3.24–13.57)
Presentation NIHSS (median, IQR)	16 (11–19)
Presentation ASPECTS (median, IQR)	9 (8–10)
5 (n, %)	2 (4.44)
6 (n, %)	1 (2.22)
7 (n, %)	5 (11.11)
8 (n, %)	11 (24.44)
9 (n, %)	9 (20)
10 (n, %)	17 (37.78)

ASPECTS, Alberta Stroke Program Early CT Score; NIHSS, National Institutes of Health Stroke Scale.

guide catheters with regard to safety. Device-related complications occurred in 6.8% of the TracStar group (95% CI 1.4% to 18.3%) and 8.9% of the control group (95% CI 2.4% to 21.2%). In the TracStar group, all three device-related complications manifested as asymptomatic groin hematomas that resolved with conservative management. In the control group, there were two cases of cervical vessel dissection, one case of flow-limiting ICA vasospasm, and one case of asymptomatic groin hematoma, which was managed conservatively. Vessel dissections in the control group were managed conservatively without the need for stenting, and the case of vasospasm resolved following injection of intra-arterial verapamil. The LDP or guide catheter failed to reach the ICA at similar rates in both groups (6.67% in TracStar vs 13.33% in control, p=0.291).

The average time from groin puncture to clot engagement was 8.89 min shorter in patients treated with TracStar LDP when compared with the control group (14.29 min vs 23.18 min; p=0.0017). There was no significant difference in mTICI 2B+ or mTICI 2C+ recanalization time, fluoroscopy time, number of passes to achieve mTICI 2B+, final mTICI score, or complication rates. It was not common practice at the participating institutions to advance any of the control guide catheters beyond that vertical petrous ICA; thus statistical testing for differences in the highest point reached was omitted in order to reflect the fact that more distal access in the TracStar group should not be interpreted to mean that distal access was attempted and failed in the control group.

Table 3 Post-procedural outcomes for the TracStar group

Approximate 24 hour ASPECTS (median, IQR)	7 (5–9)
Subarachnoid hemorrhage (n, %)	6 (13.33)
Hemorrhagic conversion (n, %)	15 (33.33)
HI-1 (hemorrhage infarction type 1)	6 (13.33)
HI-2 (hemorrhage infarction type 2)	1 (2.22)
PH-1 (parenchymal hematoma type 1)	8 (17.78)
PH-2 (parenchymal hematoma type 2)	0 (0)
Malignant increase in ICP	1 (2.56)
24 hour NIHSS	8 (4–14)
* mRS at 90 days (±21 days) post procedure	
0–2	18 (46.15)
3–5	17 (43.59)
Deceased	4 (10.26)

*6 patients (13.3%) were lost to follow-up. Percentages were calculated with regard to available follow-up.
ASPECTS, Alberta Stroke Program Early CT Score; ICP, intracranial pressure; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale.

Table 4 Procedural characteristics of matched cohorts

	TracStar (n=45)	Control (n=45)	P value
Anesthesia (n, %)			0.5318
MAC	35 (77.78)	38 (84.44)	
General	9 (20)	5 (11.11)	
MAC converted to general	1 (2.22)	2 (4.44)	
Arch type (n, %)			0.8321
Type I	18 (40.00)	16 (40.00)	
Type II	17 (37.78)	17 (37.78)	
Type III	7 (15.56)	9 (20)	
Unable to assess	3 (6.67)	3 (6.67)	
Bovine arch (n,%)	4 (8.89)	10 (22.22)	0.073
Vessel tortuosity			
Number of turns 90°–60° (n)	54	65	
Number of turns 60°–30° (n)	18	15	
Number of turns <30° (n)	4	4	
Number of 360° loops (n)	5	4	
Occlusion at first pass (n, %)			1
ICAT	6 (13.33)	6 (13.33)	
M1	25 (55.56)	25 (55.56)	
M2	14 (31.11)	14 (31.11)	
Left sided occlusion (n, %)	25 (55.56)	31 (68.89)	0.19
Technique used at first pass (n, %)			0.1338
First pass aspiration	36 (80)	41 (91.11)	
First pass aspiration and stent retriever	9 (20)	4 (8.89)	
Angioplasty and stenting			1
Angioplasty	1 (2.22)	1 (2.22)	
Stenting	1 (2.22)	1 (2.22)	
Angioplasty and stenting	1 (2.22)	1 (2.22)	

ICAT, internal carotid artery thrombus; MAC, monitored anesthesia care.

The TracStar was successfully advanced beyond the vertical petrous ICA segment in 33 cases (73.33%). Post-hoc analysis of the TracStar group revealed a non-significant trend towards an association between intracranial LDP positioning and excellent reperfusion, such that with each increasing level beyond the vertical petrous segment, the odds of mTICI 2C+ reperfusion increased by a factor of 1.55 (95% CI 0.94 to 2.57, p=0.086).

DISCUSSION

In this matched cohort analysis study, the use of TracStar LDP in an unselected group of patients undergoing thrombectomy for anterior circulation ELVO was associated with a non-inferior safety profile and significantly shorter time between groin puncture and clot engagement when compared with other commonly used guide catheters. There were device-related complications in 6.8% of TracStar cases compared with 8.9% of control cases, indicating non-inferiority by assessment of the lower limit of 95% confidence (1.4% vs 2.4%). All complications associated with TracStar were asymptomatic groin hematomas, likely attributable to the fact that the use of TracStar requires placement of

Table 5 Matched cohort comparison

	TracStar (n=45)	Control (n=45)	P value
Device related complications (n,%)			0.857
Vessel dissection	0 (0)	2 (4.44)	
Flow limiting vasospasm	0 (0)	1 (2.22)	
Groin hematoma*	3 (6.67)	1 (2.22)	
Non-device related complications (n, %)			0.71884
Vessel dissection	0 (0)	1 (2.22)	
Embolism to new territory	0 (0)	1 (2.22)	
Wire perforation	1 (2.22)	1 (2.22)	
Guide catheter failure	3 (6.67)	6 (13.33)	0.291
Time from groin puncture to clot engagement (min) (mean, SD)	14.29 (7.88)	23.18 (16.43)	**0.00171**
Time from GP to 2B+recanalization (mean, SD)	33.02 (26.85)	39.91 (29.51)	0.2045
Fluoroscopy time (min) (mean, SD)	26.08 (17.3)	27 (20.19)	0.8225
Total number of passes (mean, SD)	2.56 (1.74)	2.49 (1.55)	0.97
Final mTICI score (n, %)			
2B+	43 (95.56%)	42 (93.33%)	0.65
2C+	32 (71.11%)	30 (66.67%)	0.65
Highest point reached by initial guide catheter (n, %)			–
Guide failure	3 (6.67)	6 (13.33)	
Cervical ICA	5 (11.11)	32 (71.11)	
Vertical petrous	4 (8.89)	7 (15.56)	
Horizontal petrous	8 (17.78)	0 (0)	
Ascending cavernous	10 (22.22)	0 (0)	
Horizontal cavernous	7 (15.56)	0 (0)	
Paraclinoid	5 (11.11)	0 (0)	
Supraclinoid	1 (2.22)	0 (0)	
ICA terminus	1 (2.22)	0 (0)	
M1 MCA	1 (2.22)	0 (0)	

*All hematomas were small, asymptomatic, and resolved with conservative management.
†Defined as failure to reach the ICA or swap to alternative guide catheter.
GP, groin puncture; ICA, internal carotid artery; MCA, middle cerebral artery; mTICI, modified Thrombolysis In Cerebral Infarction.

a groin sheath, which is not a requirement for most of the other guides in the control group.

The average time from groin puncture to clot engagement was 8.89 min shorter in patients treated with TracStar LDP (14.29 min vs 23.18 min; p=0.0017); however, this difference was not accompanied by a statistically significant decrease in time from groin puncture to mTICI 2B+recanalization (33.02 min vs 39.91 min; p=0.205). As this study was designed primarily to assess safety, it was not sufficiently powered to identify small differences in these efficacy timepoints. Nonetheless, our finding of decreased time to clot engagement may serve to support further study with regard to a potential decrease in time to reperfusion.

There were no significant differences between groups with regard to failure of the guide catheter to reach the ICA. The TracStar LDP was safely advanced beyond the vertical petrous segment of the ICA in 73.33% of cases (figure 3). Procedure-related complications in the TracStar LDP group included one instance of microguidewire perforation unrelated to the LDP, and three small asymptomatic access site hematomas, all of which resolved with conservative management.

In three cases (6.67%), the TracStar LDP was swapped for an alternate guide catheter after failed attempts to access the cervical ICA. In all three cases, a perceived lack of catheter support was cited as the rationale for the swap, and the procedure was completed from the same approach. All three support-related swaps occurred within the first two use-cases for the interventionalists in question, and likely represent the learning curve associated with proximal navigation using the long 14.5 cm distal flexible zone of the TracStar LDP.

The design of the TracStar LDP differs from those of commonly used guide catheters in ways that bear relevance to technical considerations. First, with available lengths of 95 cm and 105 cm, it is longer than most conventional guides. As such, it should be paired with intermediate catheters that are long enough to ensure an adequate working length, especially if the TracStar is not advanced intracranially. Second, the distal flexible segment is 14.5 cm in length, significantly longer than those found in guides such as the Neuron MAX (4 cm) or AXS Infinity LS (9.5 cm). For this reason, interventionists found that single-maneuver advancement of the TracStar from the arch to a 'stable landing zone' in the distal cervical ICA was important for ensuring catheter stability. The coaxial technique was used to maximize support provided by the selecting catheter and 0.038 inch guidewire, followed by advancement of the TracStar LDP under roadmap guidance to identify potential obstacles. Using this technique, the entire 14.5 cm flexible segment was able to achieve safe distal purchase within the carotid vasculature.

Among patients with available follow-up at 90 days, the rate of good functional outcomes (46.15% mRS ≤2) and mortality (10.26%) were similar to those in other real-world series.[11–14] Successful recanalization was achieved in all but two cases (mTICI 2B-3 95.56%), and complete recanalization (mTICI 2C-3) was achieved in 71.11%. These rates are higher than those published in similar real-world datasets.[13 15 16]

Post-hoc analysis revealed a trend suggestive of an association between distal guide catheter placement and complete recanalization. Though not statistically significant, there are multiple theoretical bases that merit further investigation into this potential association. First, distal guide placement provides more support for navigation of thrombectomy devices to the face of the clot, and decreases the path length between engaged thrombus and final evacuation through the guide catheter. This decreases the number of turns across which the clot is retrieved, and thus potentially reduces the rate of fragmentation and distal embolus.

Second, distal placement may allow for local flow limitation achieved by aspiration through the guide. This may particularly be the case for when the guide can be advanced beyond the level of posterior communicating artery or ICA terminus, through which collateral flow is thought to increase the rates of distal embolus in in vitro studies.[17] Increased rates of first pass recanalization achieved through use of balloon guide catheters are thought to be due to these flow-arrest and suction reversal effects,[18 19] though balloon guides carry with them limitations on size and flexibility.

The clinical relevance of distal guide placement has been demonstrated by Ansari *et al* in their evaluation of the GUide sheath Advancement and aspiRation in the Distal petrocavernous internal carotid artery (GUARD) technique.[7] In their study, a 6 Fr 0.088 inch distal guide sheath was advanced past the skull base into the horizontal petrous ICA to augment thrombectomy. When compared with a propensity matched

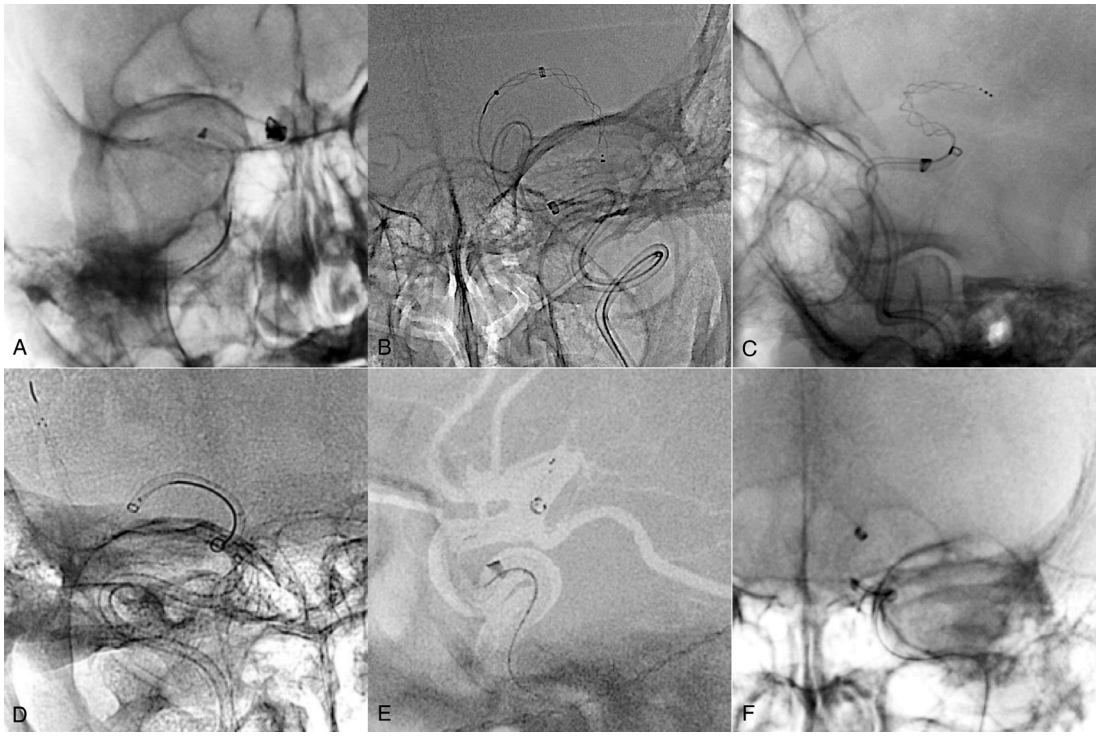

Figure 3 Fluoroscopic images demonstrating the highest point reached by TracStar in select cases. (A) AP view showing TracStar positioned within the right M1 MCA during thrombectomy. (B) AP view showing TracStar in the left horizontal petrous segment after navigating an ICA loop at the skull base. (C) Lateral view showing TracStar in the right supraclinoid segment after navigating three consecutive 60°–90° turns. (D) AP view showing TracStar in the right horizontal cavernous segment after navigating a <30° turn at the skull base. (E) Lateral view showing Tracstar positioned within the horizontal cavernous segment after navigating a <30° turn at the posterior genu of the cavernous ICA. (F) AP view showing TractStar positioned at the ICA terminus. AP, anteroposterior; ICA, internal carotid artery; MCA, middle cerebral artery.

'standard thrombectomy' control group, distal guide placement achieved significantly higher successful mTICI ≥2B reperfusion rates (98% vs 80%, p=0.015) and improved functional mRS ≤2 outcomes (67% vs 43%, p=0.04), with independent effects of the GUARD technique confirmed in a multivariable logistic regression model. Successful reperfusion rates were similar to those demonstrated in the present study. While these findings support the notion that distal guide placement during thrombectomy is beneficial, their study design did not allow for determination of the number of cases in which guide advancement was unsuccessful, or not attempted due to safety concerns. Additionally, advancement of the guide in their technique relied on support provided by prior stent retriever deployment and clot aspiration through a distal access catheter. After each pass using the GUARD technique, the guide was retracted back into the cervical or vertical petrous ICA. In the present study, distal access is achieved without this additional support.

The present study demonstrates that distal intracranial ICA access using a TracStar LDP catheter is safe and feasible. Future investigations may include an evaluation of the safety and efficacy of direct aspiration though a similarly designed 0.088 inch guide catheter in the distal ICA or proximal M1 segments. In vitro studies have already demonstrated higher rates of first-pass recanalization,[20] and lower rates of distal embolization,[21] with direct aspiration through an 0.088 inch lumen when compared with a standard 6 Fr intermediate. If similar results are safely reproducible in vivo, it may translate to a meaningful improvement in patient outcomes.

This study is limited primarily by its retrospective matched cohort design. Differences in technical outcomes cannot be interpreted as causal, and the study was not designed to investigate group level differences with regard to clinical outcomes. Likewise, the effect of intracranial placement cannot be separated from the effect of other elements of catheter design because, as it stands, the authors are not aware of an 0.088 inch catheter against which to safely compare rates of distal access beyond the vertical petrous ICA. Although the previously discussed study of the GUARD technique did advance an 0.088 inch guide into the cavernous ICA, they explicitly noted a case of guide-related ICA dissection resulting from aggressive advancement. In the absence of an alternative 0.088 inch guide catheter designed with the intention of distal intracranial access, the present series is offered as an early evaluation of the feasibility of distal access. Additionally, this study is limited by the lack of a validated system for grading vascular tortuosity as it pertains to endovascular access above the aortic arch. The system employed here, which considers simply the turn-angle required for catheter advancement, was adapted from criteria set forth in 1961, long before the modern neuroendovascular era. It is known that angulation alone is not sufficient to predict difficulty in catheter navigation. For example, steep angulation in proximal segments of the innominate or common carotid arteries prolongs the time from groin puncture to clot engagement significantly more than similar angulation in more distal segments of the ICA.[22] While the methods of quantifying arterial angulation in this study does offer a means by which to capture relative tortuosity, future studies would benefit from a more neuroendovascularly-relevant grading scale correlated directly to the time between groin puncture and clot engagement.

CONCLUSION

The results of this multicenter retrospective study demonstrate that the TracStar LDP is safe and effective for use during thrombectomy for ELVO, and is associated with a significantly shorter time between groin puncture and clot engagement when compared with other commonly used guide catheters. The TracStar LDP allowed for reliable navigation of proximal vessel tortuosity, and access to the distal intracranial ICA was regularly achieved. Rates of successful recanalization were comparable to optimum techniques published to date.

Contributors Substantial contributions to the conception or design of the work: RDL, DVB, JV, MM. Acquisition, analysis, or interpretation of data for the work: RDL, DVB, BSG, DC, JV, MM. Drafting the work or revising it critically for important intellectual content: All listed authors. Final approval of the version to be published: All listed authors. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: All listed authors.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests JV reports consulting agreements with Integra Life Sciences and Corindus Vascular Robotics. MM reports grants funding from the National Institutes of Health (NIH R21NS109575), consulting agreements with Medtronic and Cerenovus; stock options in Serenity Medical, Synchron, Endostream, and VICIS; and an affiliation with the JNIS editorial board. RDT reports consulting agreements with Siemens Healthineers, Johnson and Johnson, Q'Apel Medical, Rebound Therapeutics, Echovate, Viseon; stock holdings in Q'Apel Medical, Rebound Therapeutics, Echovate, Viseon, Synchron, Endostream Medical; and royalty fees from the Medical University of South Carolina. MIC reports consulting agreements with Terumo Microvention, Johnson and Johnson, Imperative Care, Medtronic Neurovascular; stock holdings in Q'Apel Medical, RIST Neurovascular, Echovate, Viseon, Synchron, Endostream Medical, and royalty fees from the Medical University of South Carolina. AST reports consulting agreements with Blockade Medical, Cardinal Consulting, Cerebrotech, Corindus Vascular Robotics, Medtronic Neurovascular, Endostream Medical, Terumo Microvention, Penumbra, Siemens Healthineers, Imperative Care, Three Rivers Medical, Vastrax, Shape Memory, Stryker Neurovascular, Serenity Medical, 880 Medical, Q'Apel Medical; stock holdings in Cerebrotech, Corindus Robotics, Endostream Medical, Imperative Care, Three Rivers Medical, Vastrax, Shape Memory, Synchron, Serenity Medical, BlinkTBI, Echovate, RIST, Apama, Pipe Therapeutics; is the Chief Medical Officer of Corindus Robotics; co-foundership of Imperative Care, Vastrax, National Education and Research (NEAR) Center, Neuro Technology Investors (NTI), Pipe Therapeutics; and board membership for BlinkTBI. JF reports equity in Imperative Care and an affiliation with the JNIS editorial board. RDL reports a consulting agreements with Imperative Care, Cerenovus, Siemens Healthineers; equity in Synchron, Endostream and Q'Apel Medical; and an affiliation with the JNIS editorial board. DVB, BSG, DC, RZ, and TS have no competing interest to report.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

ORCID iDs
Devin V Bageac http://orcid.org/0000-0002-4183-2829
Blake S Gershon http://orcid.org/0000-0002-6441-2552
Maxim Mokin http://orcid.org/0000-0003-4270-8667

REFERENCES

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;13:567–74.
2 Alawieh A, Vargas J, Fargen KM, *et al*. Impact of procedure time on outcomes of thrombectomy for stroke. *J Am Coll Cardiol* 2019;73:879–90.
3 Ribo M, Molina CA, Cobo E, *et al*. Association between time to reperfusion and outcome is primarily driven by the time from imaging to reperfusion. *Stroke* 2016;47:999–1004.
4 Snelling BM, Sur S, Shah SS, *et al*. Unfavorable vascular anatomy is associated with increased revascularization time and worse outcome in anterior circulation thrombectomy. *World Neurosurg* 2018;120:e976–83.
5 Kaymaz ZO, Nikoubashman O, Brockmann MA, *et al*. Influence of carotid tortuosity on internal carotid artery access time in the treatment of acute ischemic stroke. *Interv Neuroradiol* 2017;23:583–8.
6 Benson JC, Brinjikji W, Messina SA, *et al*. Cervical internal carotid artery tortuosity: a morphologic analysis of patients with acute ischemic stroke. *Interv Neuroradiol* 2020;26:216–21.
7 Ansari SA, Darwish M, Abdalla RN, *et al*. Guide sheath advancement and aspiration in the distal petrocavernous internal carotid artery (GUARD) technique during thrombectomy improves reperfusion and clinical outcomes. *AJNR Am J Neuroradiol* 2019;40:1356–62.
8 Gross BA, Dolia J, Tonetti DA, *et al*. Ballast and NeuronMax in stroke thrombectomy. *J Neurointerv Surg* 2020;12:neurintsurg-2020-016039.
9 Metz H, Murray-Leslie RM, Bannister RG, *et al*. Kinking of the internal carotid artery. *Lancet* 1961;1:424–6.
10 Lasjaunias P, Berenstein A. Arterial Anatomy: Introduction. In: Lasjaunias P, Berenstein A, eds. *Surgical Neuroangiography: 1 functional anatomy of craniofacial arteries*. Berlin, Heidelberg: Springer Berlin Heidelberg, 1987: 1–32.
11 Jovin TG, Chamorro A, Cobo E, *et al*. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med Overseas Ed* 2015;372:2296–306.
12 Goyal M, Demchuk AM, Menon BK, *et al*. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med* 2015;372:1019–30.
13 Deb-Chatterji M, Pinnschmidt H, Flottmann F, *et al*. Stroke patients treated by thrombectomy in real life differ from cohorts of the clinical trials: a prospective observational study. *BMC Neurol* 2020;20:81.
14 Berkhemer OA, Fransen PSS, Beumer D, *et al*. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med* 2015;372:11–20.
15 Volny O, Krajina A, Belaskova S, *et al*. Mechanical thrombectomy performs similarly in real world practice: a 2016 nationwide study from the Czech Republic. *J Neurointerv Surg* 2018;10:741–5.
16 Mokin M, Abou-Chebl A, Castonguay AC, *et al*. Real-world stent retriever thrombectomy for acute ischemic stroke beyond 6 hours of onset: analysis of the NASA and TRACK registries. *J Neurointerv Surg* 2019;11:334–7.
17 Yoo AJ, Andersson T. Thrombectomy in acute ischemic stroke: challenges to procedural success. *J Stroke* 2017;19:121–30.
18 Jeong DE, Kim JW, Kim BM, *et al*. Impact of balloon-guiding catheter location on recanalization in patients with acute stroke treated by mechanical thrombectomy. *AJNR Am J Neuroradiol* 2019;40:840–4.
19 Brinjikji W, Starke RM, Murad MH, *et al*. Impact of balloon guide catheter on technical and clinical outcomes: a systematic review and meta-analysis. *J Neurointerv Surg* 2018;10:335–9.
20 Fitzgerald S, Ryan D, Thornton J, *et al*. Preclinical evaluation of millipede 088 intracranial aspiration catheter in cadaver and in vitro thrombectomy models. *J Neurointerv Surg* 2021;13:447–52.
21 Arslanian RA, Marosfoi M, Caroff J, *et al*. Complete clot ingestion with cyclical adapt increases first-pass recanalization and reduces distal embolization. *J Neurointerv Surg* 2019;11:931–6.
22 Knox JA, Alexander MD, McCoy DB, *et al*. Impact of aortic arch anatomy on technical performance and clinical outcomes in patients with acute ischemic stroke. *AJNR Am J Neuroradiol* 2020;41:268–73.