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Original research

Efficacy of beveled tip aspiration catheter in mechanical thrombectomy for acute ischemic stroke

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ABSTRACT

Background Direct aspiration thrombectomy techniques use large bore aspiration catheters for mechanical thrombectomy. Several aspiration catheters are now available. We report a bench top exploration of a novel beveled tip catheter and our experience in treating large vessel occlusions (LVOs) using next-generation aspiration catheters.

Methods A retrospective analysis from a prospectively maintained database comparing the bevel shaped tip aspiration catheter versus non-beveled tip catheters was performed. Patient demographics, periprocedural metrics, and discharge and 90-day modified Rankin Scale (mRS) scores were collected. Patients were divided into two groups based on which aspiration catheter was used.

Results Our data showed no significant difference in age, gender, IV tissue plasminogen activator administration, admission NIH Stroke Scale score, baseline mRS, or LVO location between the beveled tip and flat tip groups. With the beveled tip, Thrombolysis in Cerebral Infarction (TICI) 2C or better recanalization was more frequent overall (93.2% vs 74.2%, $p=0.017$), stent retriever usage was lower (9.1% vs 29%, $p=0.024$), and patients had lower mRS on discharge (median 3 vs 4, $p<0.001$) and at 90 days (median 2 vs 4, $p=0.008$).

Conclusion Patients who underwent mechanical thrombectomy with the beveled tip catheter had a higher proportion of TICI 2C or better and had a significantly lower mRS score on discharge and at 90 days.

the force at the catheter tip is directly proportional to the cross-sectional area of the catheter tip, many newer generation catheters feature a larger catheter tip diameter.^{15–17} Additionally, an aspiration catheter with a beveled tip design has recently been developed (figure 1). We report our initial clinical experience in treating large vessel occlusions using these next-generation aspiration catheters.

METHODS

Clinical data

A retrospective analysis from a prospectively maintained database was performed on patients undergoing stroke thrombectomy for large vessel occlusions (middle cerebral artery (MCA) M1 and proximal M2 segments, vertebral or basilar arteries, or the carotid terminus) with direct aspiration thrombectomy at our institution from November 2018 until May 2020 using an institutional review board-approved protocol. Specific parameters captured included age, gender, whether the patient received IV tissue plasminogen activator (tPA), pre-hospital modified Rankin Scale (mRS) score, admission NIH Stroke Scale (NIHSS) score, the location of the vascular occlusion, and Thrombolysis in Cerebral Ischemia (TICI) flow post procedure. The number of aspiration attempts ('passes') made to achieve recanalization of the target vessel and the number of passes made to achieve TICI 2B flow or better and TICI 2C flow or better were recorded, and if a stent retriever was used. Discharge mRS and 90-day mRS scores were collected where available.

All operators selected patients for thrombectomy according to their usual practice. Direct aspiration thrombectomy has been previously described.^{12–13} Briefly, access to the cerebral vasculature requires a 6 French guide catheter. This is advanced as far distally into the internal carotid artery as is safely possible. For posterior circulation thrombi, the guide catheter is navigated into the largest caliber vertebral artery and positioned into the distal V2 segment. A large bore aspiration catheter is navigated to the level of the thrombus over any microcatheter and microwire the operator chooses. Aspiration is applied by use of an aspiration pump. Inability to draw back on aspiration confirms the optimal position of the aspiration catheter abutting the thrombus. At this point, the catheter is slightly advanced to ensure firm engagement with the thrombus, and under aspiration the catheter is withdrawn into the guide catheter.

INTRODUCTION

In recent years several trials have established mechanical thrombectomy as a treatment option in patients with large vessel occlusions.^{1–8} While many of these trials used stent retrievers to achieve recanalization, recent data suggest that direct aspiration as a first pass approach is a viable alternative to stent retriever-based methods.^{9–11} Direct aspiration thrombectomy uses a large bore aspiration catheter to aspirate the thrombus without the use of a stent retriever. If aspiration is unsuccessful, the large bore aspiration catheter can serve as a platform to deliver a stent retriever or other devices.^{12–14}

The renewed interest in mechanical thrombectomy has led to the rapid evolution of catheter technology, with several large bore aspiration catheters now available. Suction force at the tip of an aspiration catheter is thought to be a crucial factor in the success of aspiration thrombectomy, and since



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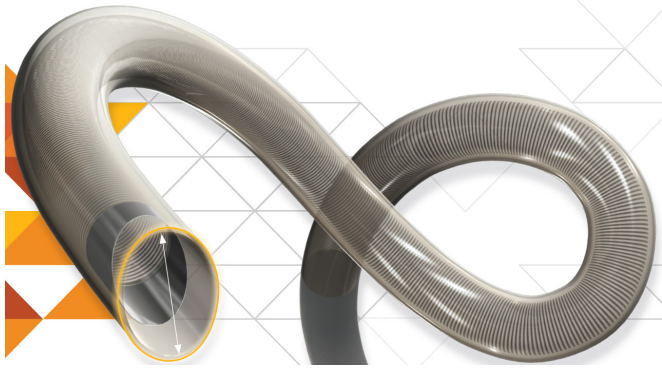


Figure 1 The Zoom71 reperfusion catheter with a beveled tip. Image courtesy of Imperative Care (reprinted with permission).

The large bore aspiration catheters used at our center during the study period included the JET7 (Penumbra, Alameda, California, USA), React71 (Medtronic, Minneapolis, Minnesota, USA), Large Bore Catheter (Cerenovus, Irvine California, USA), Vecta (Stryker Neurovascular, Kalamazoo Michigan, USA), and Sofia Plus (Microvention, Aliso Viejo, California, USA). Additionally, beginning in October 2019, the beveled tip Zoom71 (Imperative Care, Campbell, California, USA) catheter was used. Additional devices were used at the discretion of the operator if first pass failed.

In vitro experiment

To study mechanistically the effect of the beveled tip aspiration catheter, we used a vascular phantom with flow conditions as previously described.¹⁸ To remove confounding variables, a simple tapering tube bent 90° was used as the vascular phantom in which a clot model consisting of thrombin-induced clotting of bovine blood (2.5 NIHU thrombin/mL blood) with the addition of fibrinogen (9 mg/mL blood) and calcium-phosphate apatite (44 mg/mL blood) was introduced to create a large vessel occlusion.¹⁹ The clot measured 3.2 mm in diameter and was 7 mm in length. Flow conditions mimicked those typically found in the human MCA.²⁰ Twenty experiments were conducted with either a Sofia Plus or a Zoom71, randomized one-to-one per device (each device was operated in 10 replicate experiments). We recorded the rate of complete ingestion within the catheter versus corking the clot at the catheter tip followed by retraction. We further measured the rate of complete recanalization after a single attempt. Finally, using a closed system and digital manometer, we recorded the pressure at the catheter tip for both devices, as previously described.²¹ Aspiration was generated using a commercially available vacuum pump (Stryker Neurovascular).

Statistical analysis

Patients were grouped depending on which large bore aspiration catheter was used for thrombectomy. We compared the baseline characteristics of patients such as age, sex, baseline mRS score, and IV tPA administration. The number of attempts to recanalize the target vessel, the number of attempts to achieve TIC1 2B or better and TIC1 2C or better, and whether a stent retriever was used were analyzed. The number of attempts during each procedure were recorded. When comparing all catheters, continuous variables are reported as mean±SD or median (interquartile range) and were tested using a one-way ANOVA or Kruskal–Wallis test, respectively. Discrete variables are reported as

Table 1 Patient demographics for the beveled tip catheter group versus the flat tip catheter group

	Beveled	Flat	P value
N	44	93	
Age, mean±SD	69.4±14.4	67.0±15.8	0.372
Sex, n (%)			0.713
Women	21 (47.73)	40 (43.01)	
Men	23 (52.27)	53 (56.99)	
tPA, n (%)	22 (50)	37 (39.78)	0.274
Admission NIHSS score	44	91	
Median (IQR)	17 (14–21)	19 (15–23)	0.082

NIHSS, National Institutes of Health Stroke Scale; tPA, tissue plasminogen activator.

number (%) and tested using a χ^2 test or Fisher's exact test for small sample sizes ($n < 5$).

Additionally, we grouped patients into those who underwent a thrombectomy using the beveled tip catheter and those in whom the flat tip catheters were used. For these analyses, continuous variables were tested using the Student's t-test or Wilcoxon rank-sum test, and discrete variables were tested using a χ^2 test or Fisher's exact test. Values of $p < 0.05$ were considered statistically significant. All analyses were carried out using R statistical software (The R Foundation, version 4.0.2).

RESULTS

Patient characteristics

There was no significant difference in age, sex, rate of IV tPA administration, and admission NIHSS scores between the beveled tip and flat tip groups (table 1), nor was there a difference between baseline mRS scores between the two groups (table 2). There was no significant difference in the location of vessel occlusion (table 3).

Recanalization efficacy

Recanalization efficacy is summarized in table 4. The percentage of cases in which a stent retriever was used as a rescue device was significantly lower in cases where the beveled tip catheter was used (9.1% vs 29%, $p = 0.024$). Overall, TIC1 2C was achieved in significantly more cases with the beveled tip catheter compared with the flat tip catheters (93.2% vs 74.2%, $p = 0.017$). The beveled tip catheter was able to achieve TIC1 2C or better on first pass in 58.5% of cases compared with 49.3% of cases with flat tip catheters. In cases where TIC1 2C or better outcomes were achieved, there was no significant difference between the percentage of patients who received IV tPA (48.8% for the beveled tip catheter vs 37.7% for the flat tip catheters). There was a trend towards a higher percentage of one pass thrombectomies with the beveled tip catheter compared with the flat tip catheters (56.8% vs 39.8%), but this did not reach statistical significance. When compared with flat tip catheters, the number of passes per procedure was also lower with the beveled tip catheter (1.978 vs 2.47).

Complications

There were four non-access site-related intraprocedural complications, consisting of three dissections and one perforation. There were no complications related to the aspiration catheters in either group.

Table 2 Modified Rankin Scale (mRS) scores on admission, at discharge, and at 90 days for flat tip and beveled tip catheter groups

	Beveled mRS		Flat mRS		P value
	Beveled (n)	Median (IQR)	Flat (n)	Median (IQR)	
Admission	42	0 (0–1)	68	0 (0–1)	0.698
Discharge	44	3 (2–4)	91	4 (3–5)	<0.001
90 Days	28	2 (1–3)	81	4 (2–6)	0.008

Bold text denotes statistically significant findings.

Outcomes

Table 2 compares mRS scores of patients on admission, at discharge, and at 90 days between flat tip and beveled tip catheters. In the beveled tip group the baseline mRS score was available in 42 of 44 cases (95.6%), the discharge mRS was available in all 44 cases (100%), and the 90-day mRS score was available in 28 of 44 cases (63.3%). In the flat tip catheter group the baseline mRS score was available in 68 of 93 cases (73.1%), the discharge mRS score was available in 91 of 93 cases (97.8%), and the 90-day mRS score was available in 81 of 93 cases (87.1%). In cases where data were obtained, patients who underwent thrombectomy with the beveled tip catheter had a significantly lower mRS score on discharge (median 3 vs 4, $p < 0.001$) and at 90 days (median 2 vs 4, $p = 0.008$).

In vitro study

The vacuum generated at the tip of the Sofia and Zoom catheters was the same (631 ± 8 mmHg, $p = 0.97$). The force acting to remove the clot is linearly proportional to the area of the catheter tip, and therefore 15% larger for the Zoom71 device due to the bevel tip.¹⁵ This larger force resulted in complete ingestion of the clot within the Zoom71 catheter in 90% of the experiments compared with 20% of the experiments with the control device ($p = 0.006$). In the one case of failed complete ingestion for the Zoom71 catheter, the angled tip was not oriented 180° with the long axis of the clot. With both devices, complete recanalization was achieved on first pass.

DISCUSSION

We sought to evaluate the effect of a beveled tip aspiration catheter by comparing the performance of similar sized flat tip catheters with the beveled tip Zoom71 catheter. Our results show that, when the beveled tip catheter was used, there was an associated lower number of total aspiration attempts, reduced stent

Table 3 Anatomical locations of vessel occlusion in the flat tip and beveled tip catheter groups

	Beveled	Flat	P value
Total	44	93	
Target vessel, n (%)			0.423
Basilar	2 (4.55)	8 (8.6)	
LICA	5 (11.36)	15 (16.13)	
LM1	18 (40.91)	24 (25.81)	
LM2	5 (11.36)	8 (8.6)	
RICA	0 (0)	10 (10.75)	
RM1	3 (6.82)	21 (22.58)	
RM2	11 (25)	6 (6.45)	
R Vertebral (V4 segment)	0 (0)	1 (1.08)	

Table 4 Thrombectomy results: total number of passes, number of single passes to achieve target recanalization, stent retriever utilization, number of passes to achieve TICI 2B or better and TICI 2C or better, one pass versus multiple passes for target vessel recanalization

	Beveled	Flat	p-value
Number	44	93	
All cases			
Number of passes	87	230	
One pass, n (%)	25 (56.82)	37 (39.78)	0.069
Mean \pm SD	2.0 \pm 1.4	2.5 \pm 1.8	0.079
Stent retriever, n (%)	4 (9.09)	27 (29.03)	0.024
TICI 2B or better			
n	44 (100)	87 (93.55)	0.177
One pass, n (%)*	25 (56.82)	36 (41.38)	0.100
TICI 2C or better			
n (%)	41 (93.18)	69 (74.19)	0.017
One pass, n (%)†	24 (58.54)	34 (49.28)	0.430
tPA, n (%)†	20 (48.78)	26 (37.68)	0.318
Stent retriever, n (%)†	4 (9.76)	15 (21.74)	0.193

Bold text denotes statistically significant findings.

*Reference denominator is number of TICI 2B+.

†Reference denominator is number of TICI 2C+.

TICI, Thrombolysis in Cerebral Infarction; tPA, tissue plasminogen activator.

retriever usage, more frequent TICI 2C or better recanalization, and a lower discharge and 90-day mRS score.

There is evidence that a larger aspiration catheter tip surface area leads to an increase in aspiration power at the tip, an effect that has been postulated to be responsible for a higher first pass efficacy in cardiac thrombectomy.^{22 23} However, there is some debate concerning the impact of larger bore catheters on outcomes.²⁴ In acute ischemic stroke, mechanical thrombectomy performed with the ACE68 catheters also demonstrated higher first pass efficacy compared with the early generation ACE60 and ACE64 catheters.^{15 16} This has led to the development of newer, larger bore aspiration catheters in the 0.071–0.074 inch range. However, with increasing catheter size there is a trade off with navigability into the intracranial vasculature, as larger catheters will eventually be too large to navigate smaller intracranial vessels. One strategy to mitigate this limitation is to introduce a beveled tip catheter, which allows for a higher surface area without necessitating an overall larger diameter catheter (**table 5**).

Force can be described mathematically by:

$$F = P * A$$

Table 5 Comparison of catheter inner diameters (ID) and area of catheter tip

Catheter	Catheter cross-sectional ID (mm)	Area of catheter tip opening (mm ²)
Jet7	1.83	2.63
Large Bore Catheter	1.80	2.55
React71	1.80	2.55
Sophia Plus	1.78	2.48
Vecta	1.88	2.77
Zoom71	1.80	2.94

where F is force, P is pressure, and A is area. Therefore, an increase in area is directly proportional to an increase in force. Our *in vitro* model showed that force acting to remove the clot is 15% larger for the Zoom71 device due to the bevel tip.¹⁵

Another factor that has been linked to the success of thrombectomy in the anterior circulation is the amount of vessel curvature.²⁵ A retrospective review of 159 patients found that mechanical thrombectomy for acute ischemic stroke using stent retrievers was less successful in patients with strongly curved M1 segments.²⁶ In the cardiac literature, the success of aspiration thrombectomy has also been linked to vessel curvature, with more success in straighter segments.²⁷ The angle of interaction between the aspiration catheter and the thrombus has been found to impact the success of mechanical thrombectomy, with an angle of interaction of greater than 125.5 degrees (ie, catheter tip more in line with thrombus face) associated with higher success in clot removal.²⁸ We propose that a beveled tip catheter allows for better alignment along the vessel wall and a higher angle of interaction with the thrombus face. In the *in vitro* study there was one case of failed complete ingestion for the beveled tip catheter in which the angled tip was not oriented 180° with the long axis of the clot, further supporting the role of the angle of interaction.

First pass efficacy has been postulated to be an important measure of procedural success, as reports suggest a correlation between first pass success and good clinical outcomes.¹⁶ In terms of first pass efficacy, the target vessel was successfully recanalized to TICI 2B or better with one attempt in 56.8% of cases with the beveled tip catheter compared with 41.4% with comparable flat tip catheters, although this did not reach statistical significance. While TICI 2B or better has historically been used as a measure of success, we feel that improvements in technology now allow TICI 2C to be achieved in the majority of cases and that this should be the minimal procedural outcome goal that is accepted. The first pass efficacy for TICI 2C or better recanalization was slightly higher for the beveled tip catheter group (58.5% vs 49.3%), and while this was also not a significant difference, it suggests that in cases where TICI 2C or better was not achieved on the first pass, the beveled tip catheter served as a viable platform to deliver smaller aspiration catheters or stent retrievers with which to pursue downstream emboli. The overall TICI 2C or better efficacy with the beveled tip catheter of 93.2% was further supported by the overall lower average number of aspiration attempts and the lower percentage of stent retriever use, which in our practice is used as a second or third line option. The higher percentage of cases achieving TICI 2C or better in the beveled tip catheter group could be an important factor in the significantly lower discharge and 90-day mRS scores seen in the beveled tip catheter group. Finally, a decrease in the number of cases in which a stent retriever was used implies cost savings, which we did not investigate in this study.

Limitations

Our study has several limitations. The *in vitro* model is a simplistic vascular phantom that had 100% first pass success regardless of device. However, both devices were exposed to identical conditions to remove numerous confounding variables to study the mechanism by which the beveled catheter tip engages clot. Our clinical experience is a single-center retrospective experience and the data reported here are observational in nature. A small number of cases were performed with the LBC, Sofia, and the Vecta, which precludes any meaningful conclusions about the individual performance of these catheters. However, there is no evidence to suggest that there should be a difference in clot

ingestion performance due to similar device construction and design.

CONCLUSION

We found the unique design of the Zoom71 beveled tip aspiration catheter appears to translate clinically into a more efficacious thrombectomy device with improved functional outcomes. This is the only study to date detailing this novel device. While the observations are from a single center, the differences observed are significant and warrant a larger multicenter study.

Correction notice This article has been corrected since it appeared Online First. Author name Robert has been corrected from RRobert.

Contributors JV, JB, and AV collected the data and drafted and revised the paper. VA, RMK, and MJG performed the benchtop experiment as well as revised the draft paper. JAE performed the statistical analysis and reviewed the paper. RDT, IC, and AT revised the draft paper.

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