


Original research

Suction force rather than aspiration flow correlates with recanalization in hard clots: an in vitro study model

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ABSTRACT

Background ANA Advanced Neurovascular Access provides a novel funnel component designed to reduce clot fragmentation and facilitate retrieval in combination with stent-retrievers (SRs) in stroke patients by restricting flow and limiting clot shaving. In previous publications ANA presented excellent in vitro/in vivo efficacy data, especially with fibrin-rich hard clots. We aimed to determine the main physical property responsible for these results, namely suction force versus aspiration flow.

Methods We evaluated in a bench model the suction force and flow generated by ANA and compared them to other neurovascular catheters combined with a SR (Solitaire). Aspiration flow was evaluated with a flow rate sensor while applying vacuum pressure with a pump. Suction force was determined using a tensile strength testing machine and a purposely designed tool that completely seals the device tip simulating complete occlusion by a hard clot. Suction force was defined as the force needed to separate the device from the clot under aspiration. All experiments were repeated five times, and mean values used for comparisons.

Results Aspiration flow increased with the inner diameter of the device: ANA 1.85±0.04 mL/s, ACE68 3.74±0.05 mL/s, and 8F-Flowgate2 5.96±0.30 mL/s (P<0.001). After introducing the SR, the flow was reduced by an average of 0.57±0.12 mL/s. Due to its larger distal surface, ANA suction force (1.69±0.40 N) was significantly higher than ACE68 (0.26±0.04 N) and 8F-Flowgate2 (0.42±0.06 N) (P<0.001). After introducing the SR, suction force variation was not relevant except for ANA that increased to 2.64±0.41 N.

Conclusion Despite lower in vitro aspiration flow, the ANA design showed a substantially higher suction force than other thrombectomy devices.

INTRODUCTION

In recent years, after thrombectomy was confirmed as an effective treatment for acute ischemic stroke,¹ multiple devices have been developed to increase the rates of complete recanalization in the lowest possible number of attempts.^{2–4}

Suction force at the catheter's distal end is thought to be a crucial factor in thrombectomy success. The suction force of the catheter's distal end depends on its bore area.⁵ Catheter technology evolution has

permitted the development of large-bore aspiration catheters with increased navigability.^{6–9}

The ANA Advanced Neurovascular Access (hereafter ANA) provides a novel funnel component designed to reduce clot fragmentation and facilitate retrieval in combination with a stent-retriever (SR) in stroke patients by restricting flow and limiting clot shaving during aspiration and extraction^{10 11} (online supplemental figure SM1).

In a recent study using in vitro three-dimensional phantom models replicating an M1-MCA occlusion, ANA+SR showed significantly better reperfusion rates in a lower number of passes than other commonly used device combinations.¹⁰

A second preclinical study confirmed ANA's efficacy in a swine model and did not reveal safety concerns related to the novel self-expanding funnel in terms of vascular injury.¹¹ In both studies, the improved recanalization rates obtained with ANA were especially relevant when hard fibrin-rich clots were tested. We hypothesize that in conditions in which the occlusion is due to a hard and non-deformable clot, a higher suction force may be more relevant in achieving reperfusion than a high aspiration flow. We aimed to characterize and compare aspiration flows and suction forces generated by different catheters and device combinations.

METHODS

Catheter descriptions

ANA is a thrombectomy device that comprises two coaxial catheters: the funnel catheter and the delivery catheter made from sections of variable stiffness (online supplemental figure SM1). The system is designed to be used in combination with a SR.

The funnel catheter is intended to restrict the blood flow locally during the intervention. The funnel catheter provides significant aspiration that serves as a complementary mechanism to extract the whole clot when combined with retrieval devices. It bears a self-expanding funnel that when unsheathed can expand to the diameter of the landing vessel and adapt to its shape, thereby restricting the blood flow. The funnel is made of a highly flexible polymer cover over a braided radiopaque metallic structure. It is designed to have enough flexibility to adapt to the neurovascular tortuosity while restricting the blood flow.



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Outer Diameter	Catheter	Company	Distal ID* (in)	Proximal ID (in)	Distal Area (in ²)	Length of the tube (cm)
6F**	ANA	Anaconda Biomed, S.L Barcelona, Spain	0.196***	0.047	0.03	138
8F	NeuronMax	Penumbra Alameda, CA	0.088	0.088	0.0061	80
8F	Flowgate2	Stryker Kalamazoo, MI	0.083	0.083	0.005	95
8F	CELLO	Medtronic Minneapolis, MN	0.075	0.075	0.0044	95
6F	NAVIEN 072	Medtronic Minneapolis, MN	0.072	0.072	0.0041	125
6F	ACE68	Penumbra Alameda, CA	0.068	0.068	0.0036	132
6F	4Max	Penumbra Alameda, CA	0.041	0.064	0.0013	139

*Internal Diameter ** Navigation mode *** Funnel fully deployed

Figure 1 Catheters used in the experimental methodology. Proximal and distal cross-sectional areas are given for each device.

The delivery catheter is the device’s external catheter; it has a hydrophilic coating to reduce friction during use and a radiopaque marker at the distal end for angiographic visualization. The catheter materials allow enhanced flexibility at the tip and enough stiffness and pushability of the proximal portion.^{10–12}

The ANA System was compared with other catheters frequently used in mechanical thrombectomy interventions: a long sheath (NeuronMAX), two balloon guide catheters (Cello and Flowgate2), an intracranial support catheter (Navien), and two reperfusion catheters (ACE68 and 4MAX).

The Penumbra NeuronMAX 088 is a long sheath for neurovascular support that gives groin to high cervical access.

Cello and FlowGate2 are balloon guide catheters that offer proximal flow control and a stable platform to facilitate the insertion and guidance of an intravascular catheter. They provide trackability and support. They are indicated for use as a conduit for retrieval devices.

Navien 072 intracranial support catheter is a distal access catheter indicated for introducing interventional devices into the peripheral and neurovasculature.

Penumbra’s 4MAX and ACE68 reperfusion catheters are intended for use in the revascularization of patients with acute ischemic stroke secondary to large vessel occlusion.

The ACE68 catheter is delivered using a coaxial technique. It is designed to navigate tortuous vessels to facilitate clot extraction from proximal large vessels through its large 0.068 inch (1.73 mm) inner lumen with the vacuum power of the Penumbra ENGINE.

The 4MAX Reperfusion Catheter features advance tracking technology that allows access over a solo guidewire for ease of use. The 4MAX Reperfusion Catheter is part of the Penumbra

System and intended for use with Penumbra ENGINE aspiration source and Hi-Flow Aspiration Tubing.

Experimental method

To empirically examine this novel design performance, the ANA was tested against commercially available catheters (figure 1). The catheters were used immediately after removal from the package. All experiments were performed without a SR, and repeated including a SR (Solitaire2 4×40 and 6×20 mm; Medtronic, Minneapolis, MN) to characterize its potential impact on aspiration flow and suction force). The balloons of the balloon catheters were not inflated during the evaluation of their performances.

The proximal and distal cross-sectional areas of the different catheters are represented in figure 1.

Suction force evaluation

In this experiment, the thrombus shape and stiffness were simulated using a polyurethane tool attached to a tensile tester. We refer to this tool as the clot analog. The clot analog was designed to adapt to catheters; it can occlude the inner distal diameter of the catheters selected for this study (online supplemental figures SM2-5). For the evaluation of the suction force of the catheters the following experimental model (online supplemental figures SM2, SM6-7) has been used.

The INSTRON-EQ152 (Instron, Norwood, MA) tensile tester with a 10 N load cell was used. The specially designed clot analog was connected to the load cell. The clot analog occluded the inner distal diameter of the catheters selected for this study (figure 1). Once the clot analog was in place, a vacuum pressure of 500 mmHg was applied using a VacMaxi pump (Apex Medical Corp., New Taipei City, Taiwan) intended for suction. The clot analog was then pulled away from the catheter using the tensile tester at a constant 50 mm/min speed. The force necessary to separate the clot from the tip of the catheter was evaluated. The same clot analog was used for all the experiments. A sample size of five was used, and the mean value of all measurements was used for comparisons.

Aspiration flow evaluation

An ultrasonic flow sensor (Sonotec CO.55/0.35 V2.0, SONOTEC GmbH, Saale, Germany) was connected (online supplemental figure SM8). The aspiration flow experiment was performed in a silicone tube (3 mm internal diameter).

The silicon tube was adjusted to a closed 8F introducer (Terumo) from one side and a sensor from the other side. Once the circuit was assembled, filled with deionized water and no leakage observed, the tested catheter was inserted to a position close to the sensor.

The catheter was connected to the vacuum pump and 500 mmHg of vacuum pressure was applied using a VacMaxi pump (Apex Medical Corp.). The aspiration flow rate was measured in a stationary state for 30 s for each sample.

Balloon lifting experiment

Rubber balloons were filled with 1, 10, 13, 15, and 17 g of water. Vacuum pressure (130 mmHg) was applied through the tested catheter. The tip of the catheter was brought into contact with the balloon apex. The balloon was lifted vertically. A failure was registered if the catheter could not hold the balloon in the air for at least 3 s. Four consecutive attempts were permitted. The maximum weight lifted was

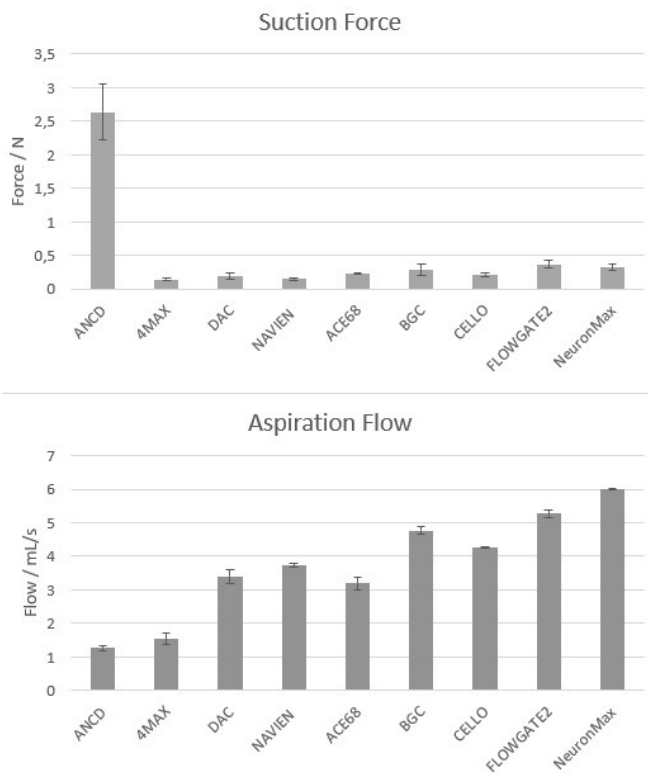


Figure 2 Aspiration flow and suction force (with stent-retriever). ANA has the lowest aspiration flow rate but the highest suction force. Distal access catheter (DAC) refers to the combination of ACE68 and Navien 072, while balloon guiding catheter (BGC) is the combination of 8F Cello and 8F Flowgate2.

noted for each catheter (online supplemental video SM1).

Statistical analysis

Statistical analysis and comparisons were made using the Minitab statistical package (Minitab LLC, State College, PA). Continuous variables were tested for normality using the Anderson–Darling test and presented as mean and SD. Univariate comparisons of means were performed by Student's t-test; a probability value of $P < 0.05$ was considered significant for all the results.

RESULTS

All tests were performed with consistent experimental conditions to limit confounding variables. The results obtained in the aspiration flow and suction force experiments are presented in figures 2 and 3.

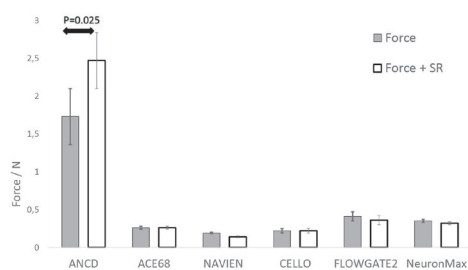


Figure 3 Suction force with stent-retriever (SR) versus suction force without SR. ANA has synergy with the SR.

The achieved aspiration flow rates followed the Hagen–Poiseuille Law ($R^2 = 0.9883$).

The measured suction forces (figure 3) for all tested catheters without a SR (values between 0.11 and 0.42 N) were comparable to those with a SR (0.14–0.37 N) except for ANA in which the force was significantly augmented by the association with the SR (1.69 ± 0.40 N without SR vs 2.64 ± 0.41 N with SR ($P < 0.001$)).

All the catheters tested in the balloon lifting experiment failed to lift 1 g while ANA raised 15 g. A video with the results of the balloon lifting experiment of ACE68 and ANA is included in the online supplemental video SM1.

DISCUSSION

Our study shows that ANA, despite a lower aspiration flow, induces the highest suction force of all tested devices. The dragging force generated when aspiration is applied is highly determined by the contact area between the catheter and the clot. Therefore, ANA distal surface explains ($R^2 = 0.9887$) the superior suction force registered (figure 1). The catheters used were the largest diameters available in the market except for the MAX reperfusion catheter. A 4MAX catheter was used and not a 5MAX to include a broader range of diameters.

The funnel is a braided structure made from a hyperelastic metal alloy covered with a soft elastomeric material. Therefore, the funnel might be compressed if a high enough vacuum is applied. The ability of the funnel to be compressed is useful to grab the clot better. But if the vacuum is too high, the funnel may completely collapse. The collapse would prevent the vacuum from being transmitted to the clot reducing the suction force. The ANA catheter is designed to be used in combination with a SR, which radial force brings additional support to prevent the funnel collapse. In clinical practice, the aspiration should start as the SR's proximal part is entering the funnel's distal portion.

When comparing the suction force of ANA with (2.64 ± 0.41 N) and without (1.69 ± 0.40 N) a SR, we observed a synergistic effect leading to a 56% force increase that was not seen with other devices (figure 3). The radial force needed for ANA to stop the flow is split between the funnel and the SR. The extra radial force of the SR prevents the funnel from collapsing at a high vacuum and explains the highest suction force measured for the ANA+SR combination. This high suction force may be responsible for the observed improved efficacy profile of ANA in terms of complete recanalization when attempting to retrieve hard non-deformable clots.^{10–11} The findings are in line with a recent publication showing that a high catheter to vessel diameter ratio correlates with recanalization.¹³ The design of ANA allowing distal tip expansion up to the target vessel size ensures the highest catheter to vessel ratio in every case. The device is optimized to work in combination with the SR.

A combination of suction force and aspiration flow is needed to extract the clot. The study dispels the paradigm that a higher flow is needed to better retrieve the clot. Aspiration flow during endovascular therapy (EVT) is created to mobilize the occluding clot into the catheter and eventually away from the cerebral vessels.^{14–21} If the flow is maintained, the procedure may be effective, dragging out the whole clot or its fragments. However, if for any reason the aspiration flow is stopped (ie, hard clot occluding the aspiration catheter), the success of the procedure can only rely on the suction force generated at the distal end of the catheter. ANA induces the highest suction force and reduces the probability of fragmentation at the distal end of the clot by protecting its integrity inside the funnel. Our study design represents a clinically relevant approach to what happens in a scenario in which a hard thrombus (rigid material) is completely

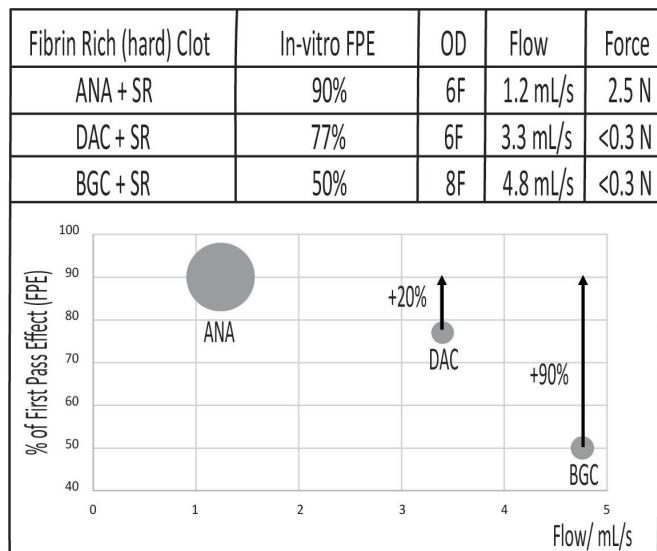


Figure 4 In vitro first pass effect (FPE) versus aspiration flow. FPE data extracted from Sanchez *et al.*⁴ The radius of the circles is directly proportional to the suction force. Highest aspiration flow does not correlate with highest FPE rate in hard clot models. BGC, balloon guiding catheter; DAC, distal access catheter; SR, stent-retriever.

occluding the tip of the catheter. The larger and more flexible tip of the ANA funnel creates an efficient suction trap that also generates local flow arrest. Combining these features may minimize undesired events such as clot separation, fragmentation, or shaving during aspiration and extraction.

In figure 4 the results for ACE68 and Navien 072 were pooled together in the distal access catheter (DAC) category and the 8 French Cello and Flowgate2 results were pooled in the balloon guiding catheter (BGC) category. The figure compares the results of the present study to the results obtained by Sanchez *et al* with hard fibrin-rich clots in phantom models of different tortuosities¹¹: higher aspiration flow does not correlate with higher first-pass recanalization, suggesting that in hard fibrin-rich clots in in vitro models, the suction force is more important than aspiration flow in terms of recanalization. In preclinical observations, the observed increase in suction force with the ANA did not represent an additional procedural risk in endothelial damage.^{10 11}

Previous work has revealed that catheters of varying diameters relay similar vacuum pressures. The suction force theoretical magnitude equals the applied vacuum pressure times the contact area (Force=Pressure×Area).²² Hence, in a rigid catheter system without flow, the force is directly proportional to the pressure. However, if the fluid or the clot is in motion, other variables should be considered. In a flexible catheter obstructed with a clot, the catheter wall’s viscoelastic properties may also play an essential role in the force applied to the clot.⁴ Part of the suction force is lost inside the catheter and does not arrive at the tip. In fluid dynamics, all primary relationships are defined by fundamental equations known as the Navier–Stokes equations. These equations further simplify to relate fluid properties (viscosity), channel geometry (length and inner diameter (ID)), and hydraulic characteristics (aspiration flow and pressure loss) in an equation known as the Hagen–Poiseuille Law (HPL). This relationship applies to nonaccelerating fluid in a tube of consistent diameter.²³

Hagen–Poiseuille Law (HPL):

$$Q = \frac{\pi r^4}{8L} P$$

where Q=volumetric aspiration flow, π =constant pi, r=inner radius (ID/2), ΔP =pressure drop, η =liquid viscosity, and L=length of the tube. According to the HPL, the variable leveraging the most significant effect on the flow-derived vacuum is the device mean ID. As such, even a small increase in ID results in substantial improvement in aspiration flow.⁴

In the standard catheter design with a fixed ID, the flow is directly related to the suction force.

The impact of maximizing the contact area compensates in the ANA the effect of a smaller proximal ID, resulting in a higher suction force despite having a lower in vitro flow. This result may appear counterintuitive because a higher flow is typically associated with a higher suction force. The provided balloon lifting experiment (online supplemental video SM1) is highly illustrative of this.

In clinical practice, the aspiration should start as the SR’s proximal part is entering the distal part of the funnel. The vacuum compresses the funnel but does not entirely collapse it due to the SR radial force. ANA funnel’s ability to be compressed during use further improves the suction force applied to the clot, particularly in combination with a SR. This synergic interaction was not observed with other catheters and could translate into clinical advances in mechanical thrombectomy.

Prior in vitro studies of aspiration catheters have shown that larger IDs exhibit higher tip forces due to larger surface area at the distal end.^{6 22 24} Catheter diameter also directly correlates with thrombectomy success in coronary aspiration thrombectomy in acute myocardial infarction treatment.²⁵ Catheters providing greater force keeping the clot attached to the tip by suction may be more successful in a clinical setting.^{15 18 26} While these studies focused primarily on tip characteristics, the present study explored the overall system performance, including the combination with a SR as is usually done in clinical practice.

Regarding the design selected for the tool to measure the suction force, this was chosen to reduce the friction forces produced by the collapse of the tip during the aspiration. This phenomenon could have a higher impact on the ANA device due to the flexible braided structured design of the bore, which could lead to closer contact with the tool. The authors consider that this fact could potentially benefit clinical practice, creating a trap for the clot when it is inside the catheter tip.

Finally, the balloon lifting experiment is a visual demonstration of suction force. The experiment is not sensitive enough to differentiate between different catheters in the standard range of distal IDs of the commercially available catheters. The experiment visualizes the difference in suction force between ANA and the rest of the catheters that failed to lift the lower weight.

Limitations

This research simulated the thrombus as rigid, with a predefined geometry. The geometry of the tool and the material used could have had an impact on the numerical results obtained.

ANA tip design is very different from the other catheters’ design, hence its interaction with the clot analog may be different.

The suction force is not exclusively linked to the distal area but also with material elasticity.

The balloon lifting experiment was performed with a lower vacuum than is typically used in clinical practice.

CONCLUSION

The expanding tip of ANA confers a substantial increase in suction force compared with other catheters, specifically in combination with a stent-retriever. In conjunction with previous studies, these

results suggest that suction force is more relevant than aspiration flow in terms of efficacy, particularly in hard clots.

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