The catheter tip distensibility substantially influences the aspiration force of thrombectomy devices

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SUMMARY

Background A direct aspiration first pass thrombectomy (ADAPT) is a fast-growing technique for which a broad catalog of catheters that provide a wide range of aspiration forces can be used. We aim to characterize different catheters' aspiration performance on stiff clots in an *in vitro* vascular model. We hypothesize that labeled catheter inner diameter (labeled-ID) is not the only parameter that affects the aspiration force (asp-F) and that thrombus-catheter tip interaction and distensibility also play a major role.

Methods We designed an experimental setup consisting of a 3D-printed carotid artery immersed in a water deposit. We measured asp-F and distensibility of catheter tips when performing ADAPT on a stiff clot analog larger than catheter labeled-ID. Correlations between asp-F, catheter ID, and tip distensibility were statistically assessed.

Results Experimental asp-F and catheter labeled-ID were correlated ($r=0.9601$, $p<0.01$). The relative difference between experimental and theoretical Asp-F (obtained by the product of the tip's section area by the vacuum pressure) correlated with tip's distensibility ($r=0.9050$, $p<0.01$), evidencing that ADAPT performance is highly influenced by catheter tip shape-adaptability to the clot and that the effective ID (eff-ID) may differ from labeled-ID specified by manufacturers. Eff-ID showed the highest correlation with experimental asp-F ($r=0.9944$, $p<0.01$), confirming that eff-ID rather than labeled-ID should be considered to better estimate the device efficiency.

Conclusions Catheter tip distensibility can induce a significant impact on ADAPT performance when retrieving a stiff clot larger than the device ID. Our findings might contribute to optimizing thrombectomy strategies and the design of novel aspiration catheters.

INTRODUCTION

Mechanical thrombectomy is a minimally invasive procedure, rapidly growing worldwide, that provides the best clinical outcomes in ischemic strokes due to large vessel occlusion [1]–[3]. A direct aspiration first pass technique (ADAPT) is an emergent thrombectomy strategy that provides safe and rapid revascularization. Its effectivity has accelerated the development of endovascular devices [4].

The ADAPT approach generally consists of navigating a large-bore catheter through the vascular anatomy to reach the occlusion site, where the catheter tip is positioned close to or in direct contact with the proximal aspect of the thrombus. The catheter is then connected to a syringe or aspiration pump that generates vacuum pressure to either aspirate the thrombus through the catheter or engage it for subsequent retrieval.

The main approaches to evaluate the performance of aspiration devices in the literature are computational fluid dynamics analysis [5], [6], experimental flow rate measurements [7], [8], and studies related to aspiration force (asp-F) and vacuum pressure [9]–[11]. Technical evaluations by several authors suggest that the aspiration performance of commercially available devices is highly correlated to the labeled inner diameter (labeled-ID) of the catheter tip. Hence, the higher the catheter labeled-ID, the higher the asp-F [7]–[10], [12]. Recently, Yaeger et al. [10] studied the asp-F generated by an aspiration pump through several commercial catheters and found a correlation coefficient of 0.981 between catheter labeled-ID and the measured asp-F. Nevertheless, the same study reported that Stryker Cat 6 (labeled-ID = 0.06 in, asp-F = 130.57 ± 4.12 mN) and Penumbra 5MAX (labeled-ID = 0.054 in; asp-F = 132.24 ± 3.92 mN) delivered similar asp-F despite the significant difference in their labeled-ID, which suggests that catheter labeled-ID may not be the only parameter that determines asp-F.

The goal of this study is to determine whether catheter tip mechanical behavior impacts ADAPT performance. For this purpose, we define catheter tip distensibility as the capability of a device to enlarge its ID when it is interacting with a thrombus that cannot be completely ingested due to its size and stiffness. In this work, we evaluated the asp-F of several thrombectomy catheters, the percentage of catheter tip widening as a measure of tip distensibility, and the correlation between them.

METHODS

Catheters

The following thrombectomy catheters were evaluated: Penumbra 5MAX (labeled-ID = 0.054 in), ACE 68 (labeled-ID = 0.068 in) and JET 7 (labeled-ID = 0.072 in) (Penumbra, Inc, CA, USA), Microvention Sofia (labeled-ID = 0.055 in) and Sofia Plus (labeled-ID = 0.070 in) (Microvention, CA, USA), Stryker AXS Cat 6 (labeled-ID = 0.060 in), and Cat 7 (labeled-ID = 0.068 in) (Stryker, MI, USA), Medtronic React 68 (labeled-ID = 0.068 in) and React 71 (labeled-ID = 0.071 in) (Medtronic, MN, USA).

Experimental setup

A custom-made methacrylate deposit constituted the experimental setup with a connector at the bottom part, a 3D printed carotid artery model, a silicone tube simulating the femoral artery attached to a hemostatic valve, and a tubing system that connects all mentioned components. **Figure 1** depicts the setup.

Regarding the *in vitro* carotid artery model, we selected a set of computed tomography angiography (CTA) images from an anonymized stroke patient. We then performed medical segmentation to get the 3D mesh of the common carotid artery, internal carotid artery (ICA), and proximal ramifications of the external carotid artery. This preliminary model was further processed to be printable, and it was manufactured by stereolithography, a 3D-printing technique that uses photoreactive resin and

UV light to create the desired geometry. Softwares utilized in the manufacturing process were 3D Slicer [13], [14], Autodesk Meshmixer [15], and PreForm (Formlabs, Inc, MA, USA). The carotid artery was printed with a commercially available Elastic 50A resin by a high-resolution desktop 3D Printer, Form 3 (Formlabs, Inc, MA, USA).

The stiff clot analog was likewise 3D printed with the Elastic 50A resin; it was created with a conical geometry of 20 mm length x 5 mm diameter at the base (distal end) that progressively reduces at 4:1 length-diameter ratio until reaching the tip (proximal end). In all cases, the clot analog was partially introduced into the catheter, simulating the scenario where a thrombus cannot be completely aspirated but needs to be engaged by negative pressure and retrieved into the guiding catheter.

Aspiration force study

Concerning the experimental preparation, the experimental setup was filled with water, and the carotid artery model was coupled to the connector in the deposit. The clot analog's distal end was attached to the load cell using a suture thread, and the entire clot was inserted into the terminal ICA, partially occluding the vessel.

Asp-F were measured with a Zwick-Roell Zwick-line Z0.5TN universal testing machine (Zwick-Roell, Ulm, Germany) equipped with 5 N load cell operating in traction mode controlled by testXpert II software (Zwick Roell Group Ltd., Ulm, DE). We introduced the selected catheter through the hemostatic valve for each measurement and navigated it to reach the proximal end of the clot in the ICA. As a vacuum generator, we used a 60-cc syringe connected to the catheter's proximal end through a three-way valve. Once that aspiration started, the thrombus was engaged into the catheter, and the load cell started to shift at 1 mm/s in the opposite direction to aspiration. Simultaneously, the device's force on the clot to resist the detachment was monitored to determine the peak value of asp-F. Each set of experiments per catheter was replicated 20 times (N = 20).

Catheter tip mechanical behavior analysis

Catheter tips' mechanical behaviors were characterized by the mechanical testing machine operating in compression mode. **Figure 2A** depicts the experimental setup. Briefly, the catheter was subjected to a gripper 3 mm below the tip, the distal end of the conical clot was glued to the upper plate of the Zwick Roell machine, and its tip was positioned concentrically to the catheter tip.

Compression mode tests were configured as follows (**figure 2B**): the initial height position (h0) of the clot analog was adjusted, so its diameter matched the labeled-ID of each catheter. For this purpose, we shift the upper plate towards the device until the load cell detected the minimum changes in force, which meant that the clot was in contact with the catheter's inner walls; once a test started, the upper plate descending velocity towards the catheter was set to 0.25 mm/s, and the measurement was configured to finalize once the compression force matched the peak value determined in the asp-F study for each specific catheter. The testXpert II software registered the distance traveled by the upper plate from the initial height position, which corresponded to the clot's additional length inserted into the catheter tip. Hence, the effective ID (eff-ID) was defined as the catheter's ID when maximum asp-F was applied (**equation 1**):

$$effID = D_{clot(h0)} + \Delta L \frac{D}{L_T} \quad \text{(Eq. 1)}$$

Where $D_{clot(h0)}$ was equal to labeled-ID of each device, ΔL is the distance travelled until achieving the peak asp-F of each catheter, and $\frac{D}{L_T} = \frac{5\ mm}{20\ mm}$ is the conical clot's base diameter by length. The eff-ID allowed us to calculate the percentage of catheter tip widening (ΔID**)** as a parameter to quantify devices' distensibility.

Statistics

Experimental asp-F were presented as mean ± standard deviation. T-student test with a confidence interval of 95 % was used to analyze asp-F delivered by catheters with the same labeled-ID, namely, ACE 68, Cat 7, and React 68.

Under the simulated scenario where there was no backflow through the catheter because of the occluded tip, the theoretical asp-F transmitted through a catheter is defined by **equation 2**.

$$aspF = P \times A \quad \text{(Eq. 2)}$$

Where P, which has a constant value of 89.74 ± 0.34 kPa, is the vacuum pressure generated by a 60 cc syringe [10], and A is the section area of different catheter tips. We calculated the relative difference between the experimental and theoretical asp-F (ΔForce) and conducted a bivariate correlation to find the Pearson's correlation coefficient between ΔForce and ΔID measured from catheter tip distensibility study. Correlations between catheter's asp-F, labeled-ID and eff-ID were determined likewise using SPSS Statistics (IBM Corp., NY, USA).

RESULTS

Experimental asp-F of thrombectomy catheters in the carotid model under flow arrest scenario is shown in **Figure 3A**. The observed experimental asp-F ranged from 210 to 470 mN (**table 1**). The correlation between the experimental asp-F and the catheter labeled-ID was confirmed by a Pearson's coefficient of 0.9601 ($p<0.01$). Amongst all devices, React 71 delivered the highest asp-F (455.43 ± 9.76 mN). Amongst catheters with the same lab ID (0.068 inches), experimental asp-F generated by Cat 7 (382.23 ± 5.26 mN) was higher than the experimental asp-F generated by React 68 (vs. 373.65 ± 14.18 mN; $p<0.05$). Both catheters showed higher experimental asp-F than ACE 68 (338.10 ± 5.69 mN; $p<0.001$)

Theoretical asp-F calculated from the product of vacuum pressure and the section area of the catheter tips are shown in **Table 1** and plotted in **Figure 3A**. ΔForce was defined as the relative difference between the experimental asp-F and the theoretical asp-F for a given labeled-ID. The device that showed the minimum ΔForce was ACE 68 (60.80 %), followed by Sofia 5F (62.89 %) and 5 MAX (64.88 %). React 71 (98.68 %) showed the highest ΔForce.

The catheter tip distensibility, observed when a stiff clot analog is aspirated, ranged between 14.69 % (Jet 7) and 24.76 % (React 71). **Figure 3B** shows ΔForce versus ΔID. Both variables showed a Pearson's correlation coefficient of 0.9050 ($p<0.01$), suggesting that catheter tip distensibility explains the discrepancy between measured (experimental) and expected (theoretical) asp-F. **Figure 3C** presents experimental asp-F versus eff-ID. Both variables are correlated with a Pearson's coefficient of 0.9944 ($p<0.01$).

DISCUSSION

In this study, we simulated an ADAPT scenario where a stiff clot larger than catheter ID cannot be directly aspirated and instead has to be engaged into the catheter tip for retrieval. Our results showed that overall labeled-ID correlated with the achieved experimental asp-F, however, we observed that larger catheters did not necessarily lead to the highest asp-F, or catheters with identical labeled-ID showed up to 13.05 % variability in their experimental asp-F. Our findings, in line with previous publications [10], confirm that labeled-ID is not the only factor determining the experimental asp-F of a device and therefore, additional variables should be considered.

Long et al. [16] presented a novel catheter design and demonstrated that a larger proximal ID could [17] also increase the eff-ID of the catheter and consequently, the asp-F. Boisseau et al. [12] re-

ported in their review that, besides catheter labeled-ID, other factors like the use of cyclical aspiration [18], [19] or balloon guide catheter [17], the contact angle between clot and catheter [20] and the clot composition [21] may influence the success of aspiration.

Several studies have reported that ADAPT may be more effective for fibrin-rich clots than for red blood cell-rich ones [12], [21], which suggests that thrombus-catheter tip biomechanical interaction has a significant influence on the recanalization rate. Our experiments identified that the catheter tip distensibility plays a significant role when applying the ADAPT technique to a stiff clot, generally both fibrin-rich and calcified types [22]. The tip distensibility may vary depending on materials used to manufacture the outer layer of the catheter; whereas React 68's outer jacket materials are based on a mix of polyamide and polyether, ACE 68 and Cat 7 add polyurethane to that mix*, and, therefore, increasing the tip's resistance to strain* and possibly the overall structural support*."*

By quantifying the distensibility of the tip, we were able to differentiate the catheter labeled-ID from the eff-ID, which is an experimental variable that also takes into account the mechanics of clot-catheter tip interaction. As aspiration devices may present a substantial tip distensibility, eff-ID should be considered to estimate the device efficiency rather than the labeled-ID specified by the manufacturer. Thus, our findings can be insightful for device selection criteria if we could identify thrombus' stiffnesses before the interventional procedure.
With a closer glance at Figure 3B, we observe that the correlation coefficient between ΔForce and ΔID was excellent ($r= 0.905$; $p<0.01$) meaning that the difference between the expected and observed forces is mainly explained by the tip's distensibility. After adjusting the data for tip distensibility, only 0.56% of the ΔForce remains unexplained (figure 3C). Therefore, at least in our experimental model, the impact of other features on ΔForce, such as the clot-catheter inner wall friction (that could also increase asp-F) is residual.
Several studies evaluated commercially available pumps: Froehler et al. [9] reported that Penumbra Max, ASPIRE device, and 60 cc syringe generate similar vacuum pressures (26-28 inHg); Yaeger et al. [10] conducted a technical comparison between Penumbra Jet Engine, Penumbra Max, Microvention Gomco, Stryker Medela, and 60 cc syringe. They concluded that Penumbra Jet Engine generated the highest vacuum pressure (28.8 ± 0.10 inHg), although the others were close (26-27 inHg); and Gross et al. [23] validated in an *in vitro* model and clinically that aspiration with a 60 cc syringe is as effective as Penumbra Max. Thus, results obtained in our tip force measurements using a manual aspiration syringe might be valid if commercially available pumps with comparable vacuum pressures are applied.

Limitations

The main limitation of this work is the clot mimic's stiffness, which may significantly differ from thrombus retrieved from stroke patients. Therefore, we aim to synthesize clot analogs that better reproduce physiological clot biomechanics in the following stages of our device evaluation studies. Furthermore, the influence of other variables such as catheter-vessel ratio and the concomitant presence of a stent retriever will be analyzed in future works.

CONCLUSIONS

When retrieving stiff thrombi with ADAPT, the difference between the theoretical asp-F according to labeled-ID and the measured asp-F is mainly explained by their tip's mechanical flexible behavior. Our results may help in the optimization of thrombectomy strategies and the development of novel aspiration catheters.

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Competing interests
The authors declare no competing interests.

Contributorship
JL, OC, MR conceived the design, performed the experiments, analyzed the data, and drafted the manuscript. AT, MDL, PC and EE made contributions to data interpretation and critical review for intellectual content.

Data sharing
All data are available upon reasonable request to the corresponding author.

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Catheter	labeled-ID (in)	Experimental Asp-F ± SD (mN)	Theoretical Asp-F (mN)	ΔForce (%)	ΔID (%)	eff-ID (in)
5 MAX	0.054	218.62 ± 4.66	132.60	64.88	17.93	0.064
Sofia 5F	0.055	224.06 ± 7.53	137.55	62.89	16.32	0.064
Cat 6	0.060	286.65 ± 5.28	163.70	75.11	17.95	0.071
React 68	0.068	373.65 ± 14.18	210.26	77.71	19.12	0.081
ACE 68	0.068	338.10 ± 5.69	210.26	60.80	16.08	0.079
Cat 7	0.068	382.23 ± 5.26	210.26	81.79	18.83	0.081
Sofia Plus	0.070	392.21 ± 12.27	222.81	76.03	18.53	0.083
React 71	0.071	455.43 ± 9.67	229.22	98.68	24.76	0.089
Jet 7	0.072	396.75 ± 9.49	235.72	68.31	14.69	0.083

Table 1. Aspiration force (Asp-F) and catheter tip mechanical behavior analysis. LabID is the catheter inner diameter specified by device manufacturers, theoretical Asp-F was calculated by applying **eq. 2**, ΔForce is the relative difference between experimental and theoretical Asp-F, ΔID obtained from **eq. 1** is a parameter that quantifies catheter tip's distensibility and eff-ID is the catheter ID considering thrombus-device mechanical interaction.

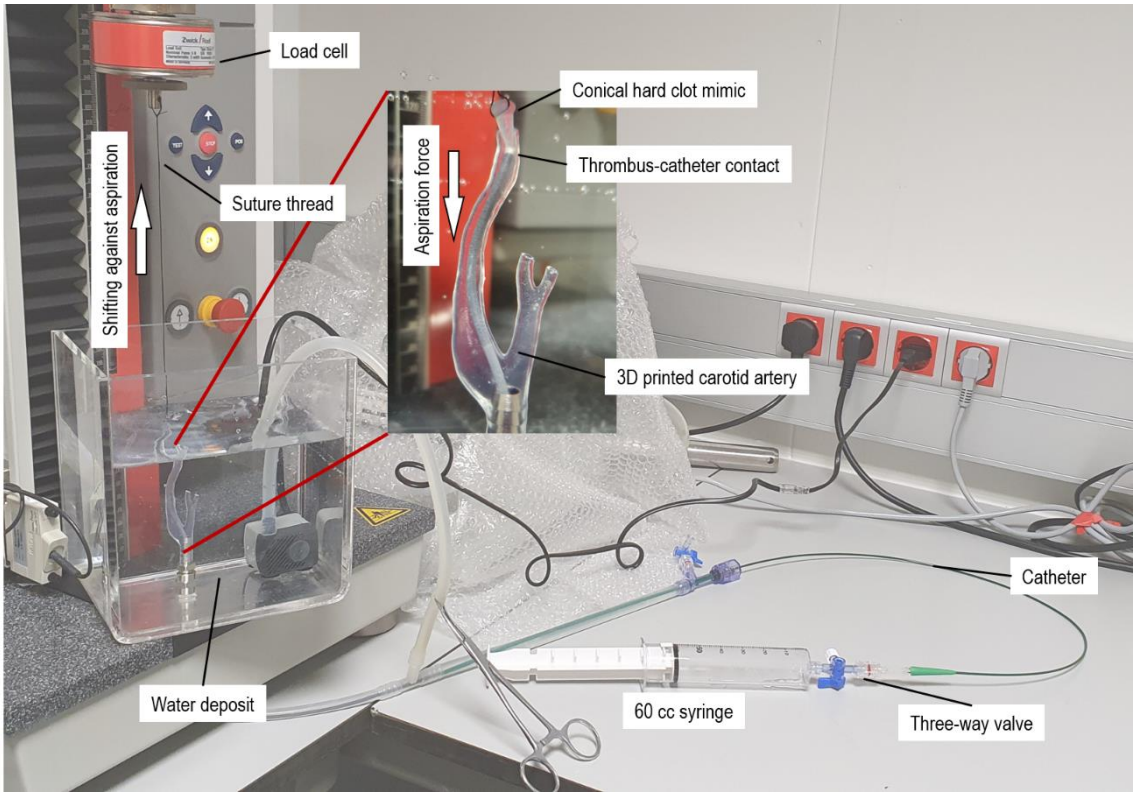

Figure 1. Experimental setup to measure aspiration forces exerted by thrombectomy catheters on a stiff clot mimic.

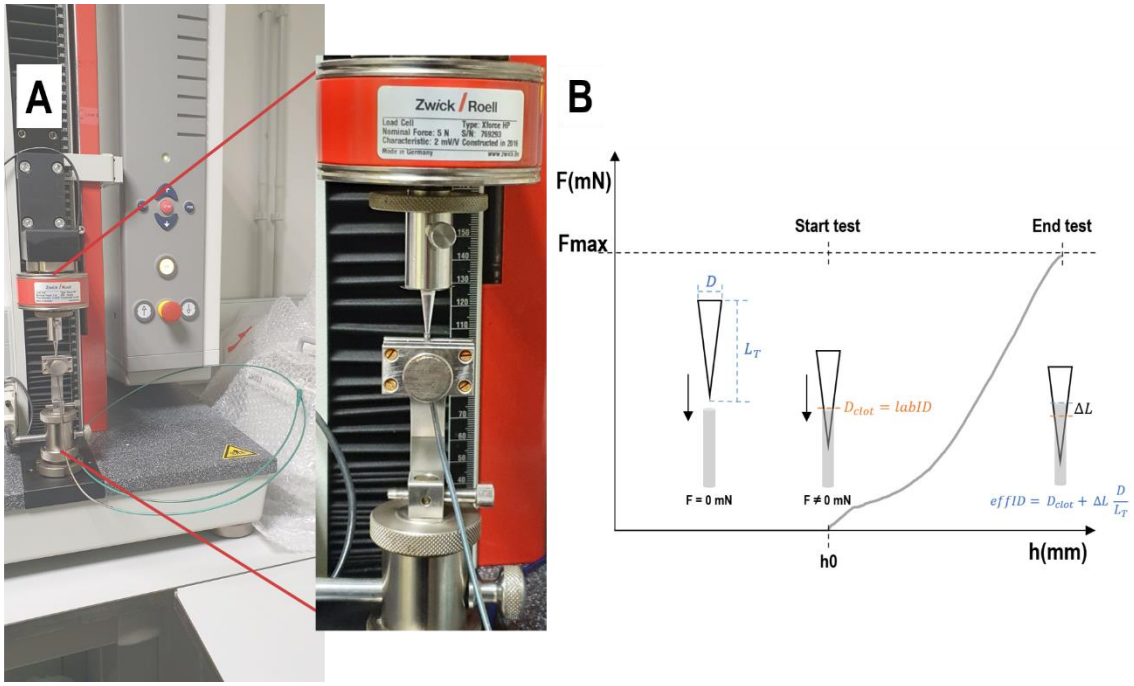

Figure 2. A) Experimental setup to determine catheters tip distensibility, B) force (F) vs. height position (h) concept plot, and the distinction between different stages of compression test to find the effID. D and L_T are the base diameter and the total length of the conical thrombus, D_{clot} is the clot mimic diameter at the beginning of the test, ΔL is the additional length inserted into the device and Fmax is the experimental aspF determined for each catheter.

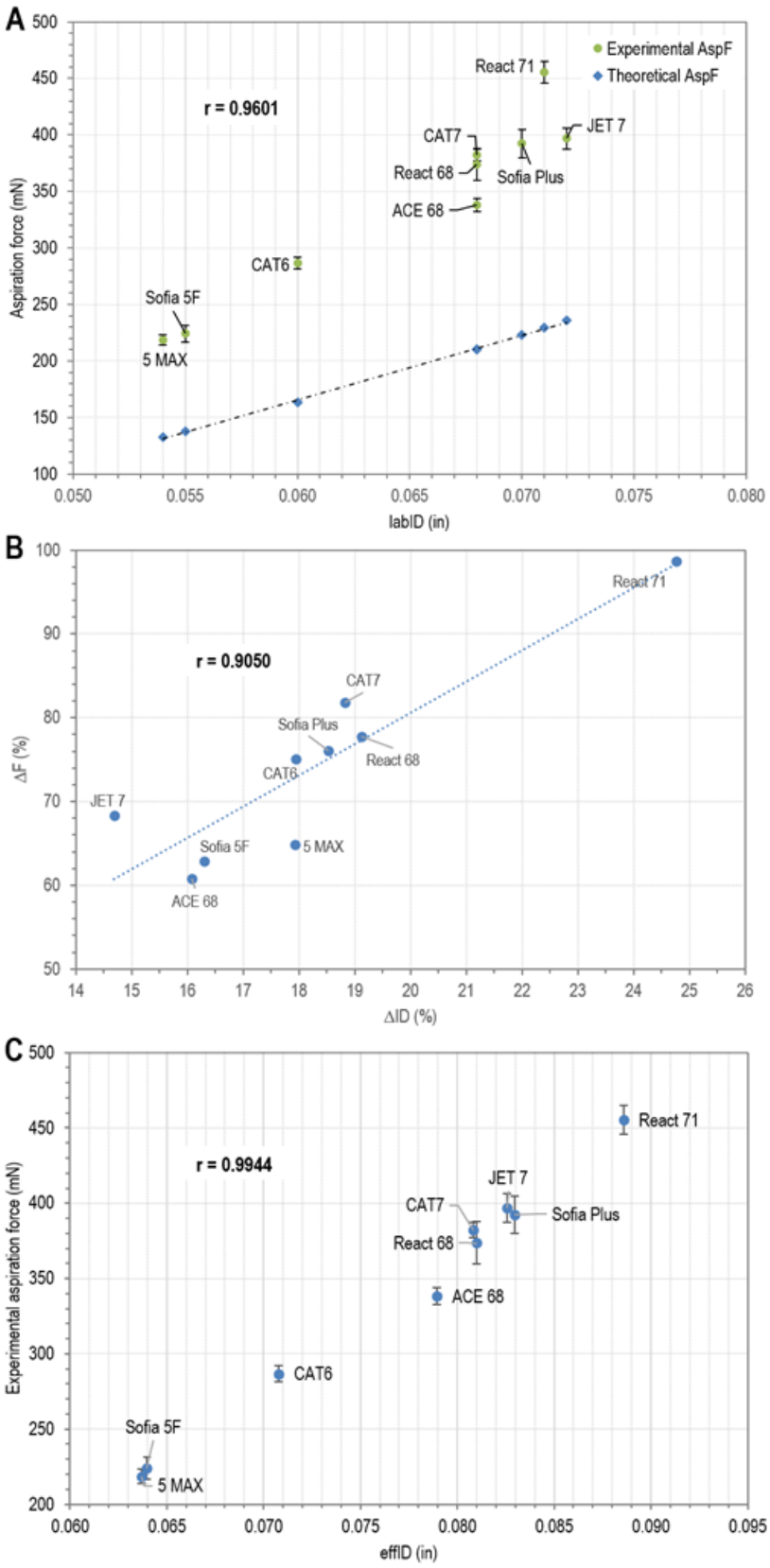

Figure 3. A) Experimental vs. theoretical AspF; B) the relative difference between measured and expected AspF is correlated to catheter tip distensibility; C) effID is a better parameter to estimate AspF than ID specified by manufacturers.