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Original research

Can micro-guidewire advancement forces predict clot consistency and location to assist the first-line technique for mechanical thrombectomy?

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ABSTRACT

Background The identification of specific clot characteristics before mechanical thrombectomy (MTB) might allow the selection of the most effective first-line technique, thus potentially improving the procedural outcome. We aimed to evaluate if the microwire push forces could extrapolate information on clot consistency and extension before MTB, based on clot mechanical properties.

Methods We measured in vitro the forces exerted on the proximal extremity of the guidewire during the advancement and retrieval of the guidewire through clot analogs of different compositions. In addition, we analyzed the forces exerted on the guidewire to extrapolate information about the location of the proximal and distal extremities of the clot analogs.

Results The maximum forces recorded during the whole penetration phase were significantly different for hard and soft clots (median values, 55.6 mN vs 15.4 mN, respectively; P<0.0001). The maximum slope of the force curves recorded during the advancement of the guidewire for the first 3 s of penetration also significantly differentiated soft from hard clot analogs (7.6 mN/s vs 23.9 mN/s, respectively; P<0.0001). In addition, the qualitative analysis of the shape of the force curves obtained during the advancement and retrieval of the guidewire showed a good potential for the identification of the proximal and distal edges of the clot analogs.

Conclusion Our results demonstrated that it was possible to differentiate between soft and hard clot analogs. Furthermore, force measurements could give important information about the location of the clot extremities. Such an approach might support the selection of the first-line MTB technique, with the potential to improve the outcome.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There is growing evidence that fibrin-rich clots are more difficult to remove than red blood cell-rich clots and require more mechanical thrombectomy (MTB) passes. The identification of specific clot characteristics before the MTB intervention would allow the selection of the most effective first-line MTB technique, potentially improving the procedural outcome.

WHAT THIS STUDY ADDS

⇒ Our findings demonstrated that it was possible to differentiate between soft and hard clot analogs and to identify their proximal and distal edges by measuring the forces exerted on the proximal extremity of the guidewire during advancement and retrieval through the clot analogs.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Such an approach would potentially allow the selection of the most effective first-line MTB technique.

INTRODUCTION

It is well established that clot characteristics influence the mechanical thrombectomy (MTB) outcome.[1] There is growing evidence that fibrin-rich clots are more difficult to remove than red blood cell-rich clots and require more MTB passes. The identification of specific clot characteristics before the MTB intervention might allow the selection of the most effective first-line MTB technique, potentially shortening procedural times. Previous reports have shown that some pre-interventional radiographic signs could be considered as imaging biomarkers, such as the hyperdense vessel sign (HDVS) on CT[2] or the susceptibility vessel sign (SVS) on MRI,[3 4] thus allowing the identification of red blood cell-rich clots. These latter soft clots would be more prone to be removed by stent retriever (STR)-based MTB and, consequently, such an imaging biomarker would allow the selection of this device before the procedure.[2] Other studies have reported on the clot perviousness 'sign', assessed using the pre-interventional CT and CT angiography. The clot perviousness would be in favor of a clot more prone to be removed by direct thromboaspiration (DTA).[5] However, data relating clot perviousness to its histological composition are controversial and it is unclear whether the pervious clot is rich in fibrin or red blood cells.[6 7] Currently, the use of imaging biomarkers is not generally adopted in clinical practice.

We aimed to evaluate a novel approach to extrapolate information on clot consistency and extension before MTB, based on clot mechanical properties.

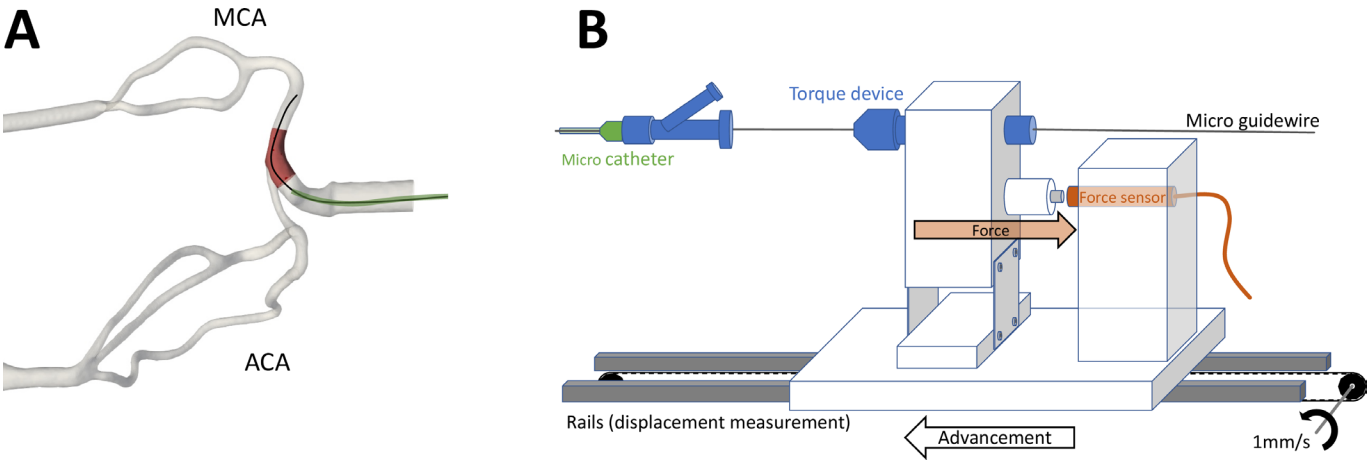

Figure 1 (A) Schematic representation of the vascular model with the clot analog highlighted in red. (B) Schematic representation of the rail-mounted carriage. In particular, visualization of the two blocks: a mobile one mounted on a slat whose movement generated by the distal constraints on the micro-guide is transmitted to the force sensor integrated into the carriage. ACA, anterior cerebral artery; MCA, middle cerebral artery.

We assessed whether the forces exerted on the proximal extremity of the guidewire during the advancement and retrieval of the guidewire through clot analogs (CAs) of different compositions could be used as a surrogate of clot consistency. In particular, we aimed to differentiate between CAs mimicking hard fibrin rich-clots and those mimicking soft red cell-rich clots. In addition, we aimed to investigate whether the analysis of the forces exerted on the guidewire could be used to extrapolate information about the location of the proximal and distal extremities of the CAs. Furthermore, in order to infer what the predictive value of this approach was in terms of the most effective first-line technique, we performed experimental MTBs with STR- and DTA-based techniques using hard and soft CAs according to the clot consistency identified.

METHODS

A dedicated experimental set-up comprising a controlled linear displacement system, one vascular model, and CAs of different consistencies (figure 1) was conceived for the purposes of the study. In the first phase, experiments were aimed at measuring the force needed to advance and retrieve a guidewire through CAs placed into the vascular models to investigate whether the analysis of such forces could provide information on clot consistency and the location of its proximal and distal edges. In the second phase of the study, we aimed to contextualize the force analysis with experimental MTBs. In particular, STR- and DTA-thrombectomy techniques were performed to evaluate the interaction of the MTB devices with clots of different stiffness.

Experimental set-up

Controlled linear displacement system

The system consisted of a mechanical assembly enabling the guidewire to be advanced and retrieved at a constant velocity through the microcatheter and the vascular model. The guidewire was screwed onto a mobile platform. The platform was equipped with a force-measuring sensor and mounted on a carriage, which moved linearly on a rail laid on the experimental bench. An electric motor transmitted the forward and backward motion to a belt connected to the carriage, which moved the whole assembly (figure 1B).

Vascular model

A silicone vascular model was used for the experiments (figure 1A). The model reproduced a realistic vascular anatomy, including the internal carotid terminus, the middle cerebral artery (MCA), and the anterior cerebral artery. The internal carotid terminus measured 4.6 mm in diameter, while the diameter of M1 was around 3 mm. The distance between the carotid termination and the M2 bifurcation was 35 mm. Such a model was intended to reproduce realistic conditions so that the force recorded at the proximal extremity of the guidewire would result from the sum of the force needed to interact and penetrate the CA and the force needed to overcome the additional resistance generated by vessel curves upstream of the CA. The same model was also used to perform the in vitro MTB experiments.

Clot analogs

CAs were produced using a mixture of guar gum and borax according to a method previously reported.[8] Elements were mixed in different concentrations in order to obtain CAs of different stiffnesses. Soft CAs were produced by mixing 2.5% of guar gum and 1.25% of borax, while hard CAs were produced mixing of 4% guar gum and 2% of borax. Before each experiment, mixture consistency evaluations were conducted by performing compression tests using a vertical tensile machine (TVO, Kern Sauter GmbH, Germany) equipped with a force-measuring sensor (FS 2–20, Kern Sauter GmbH, Germany). A mixture of cylindrical samples of 10 mm in diameter and 5 mm in height were compressed to 50% of their initial height. The force value per unit area (mN/mm^2) recorded after 3 min of compression was used for characterization purposes. Soft CAs were considered when compression forces ranged between 3.44 to 3.62 mN/mm^2. Hard CAs were considered when compression forces ranged between 14.67 to 16.63 mN/mm^2.[8] After sample consistency evaluation, CAs of cylindrical shape with a diameter ranging from 5–6 mm were produced. The length of the CAs was adapted in order to obtain the comparable volume for analogs of different consistencies and ranged from 5 to 7 mm.

Description of experiments

Clot consistency evaluation

Before each experiment, a CA was introduced into the vascular model filled with water. Hence, a pressure of 120 mmHg

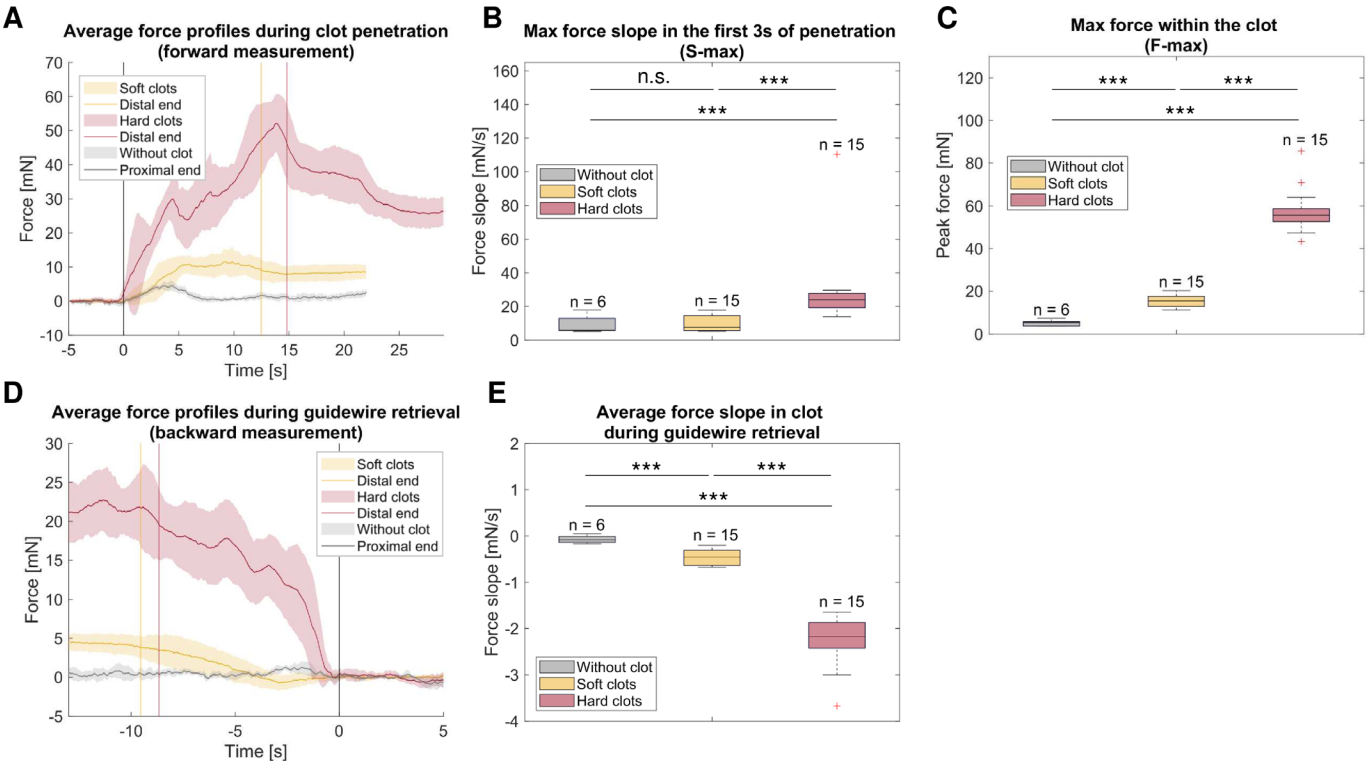

Figure 2 (A) Average force profiles measured in the model during the penetration of both hard and soft clot analogs (CAs) and without clot. (B) Boxplots and statistics for *S*-max. (C) Boxplots and statistics for *F*-max. (D) Average force profiles during retrieval of the guidewire for hard CAs, soft CAs, and without clot condition. (E) Boxplots and statistics for the average force slope in clot for the backward measurement. ***P<0.001.

was applied inside the model using a syringe equipped with a manometer to allow the advancement of the CA. On injection in the model, the CAs reached the carotid termination with the distal portion of the analog protruding in the first segment of the MCA (M1) (figure 1A). Experiments were conducted using a 0.014 inch guidewire (Avigo-Medtronic Neurovascular, Irvine, CA) and a 0.021 inch microcatheter (Phenom 21, Medtronic Neurovascular). In order to maintain the proximal portion of the guidewire and the microcatheter in a straight position during displacements, the models were connected to the linear displacement system with a rigid tube . Experiments were conducted under static flow conditions in order to avoid any disturbance that could influence local physical condition and forces' recording.

At the beginning of the experiments, the microcatheter was manually advanced inside the vascular model 1 mm proximal to the CA. The guidewire was introduced into the microcatheter and advanced up to 10 mm from its distal tip. Thus, the guidewire was connected to the displacement system that advanced and retrieved the guidewire along the model and through the CA at a velocity of 1 mm/s. For the purpose of the study, guidewires' tips were not shaped, but kept straight. Forces were recorded up to 10 mm beyond the CA. The value of the force required to advance the guidewire for the 10 mm inside the microcatheter up to the distal tip was used as a baseline value. Such a baseline corresponded to the force needed to overcome the friction encountered by the guidewire inside the microcatheter during the advancement. The force baseline was subtracted so that the forces resulting from the interaction with the clot were extracted independent of the friction along the previous path. In addition, after each experiment, the guidewire was advanced and retrieved in the vascular model six times in the absence of the CA in order to measure the force related to the friction generated by the interaction between the guidewire and the silicone vessel wall. Forces were measured and recorded while the guidewire advanced into the model through the CA and thereafter during retrieval when the guidewire was retrieved from it. Experiments were video-recorded using two high-definition cameras (Imaging Development Systems GmbH, Germany) oriented to capture the behavior of the guidewire while interacting with the CA.

In vitro thrombectomies

The anatomical vascular model used for CA consistency evaluation was also used to conduct these experiments. Hard and soft CAs were placed at the level of the first portion of the M1 segment and procedures were performed using a large bore aspiration catheter (React 0.071, Medtronic Neurovascular) and a vacuum system (Medela AXS Stryker Neurovascular, Kalamazoo, MI) or using a common STR (Solitaire 4–20, Medtronic Neurovascular). For both techniques, devices were introduced into the model via a guide catheter. When the STR was used, the STR and its microcatheter were completely retrieved together, while the vacuum system was connected to the guide catheter without an intermediate aspiration catheter. In the case of DTA, the aspiration catheter tip was placed in contact with the proximal edge of the clot and the vacuum system was connected to the catheter by the aspiration tubing. When the maximum suction force was reached (−87 kPa), the aspiration tubing was unclamped. Hence the aspiration was continued for at least 20 s and if the CA was not ingested, the aspiration catheter was retrieved gently out of the vascular model.

The model was continuously flushed with water heated at 37°C and the anterograde flow was interrupted during the MTB attempts. Five experiments were performed for each technique and each CA consistency. The success was determined by the complete ingestion of the clot by DTA or the retrieval of the clot

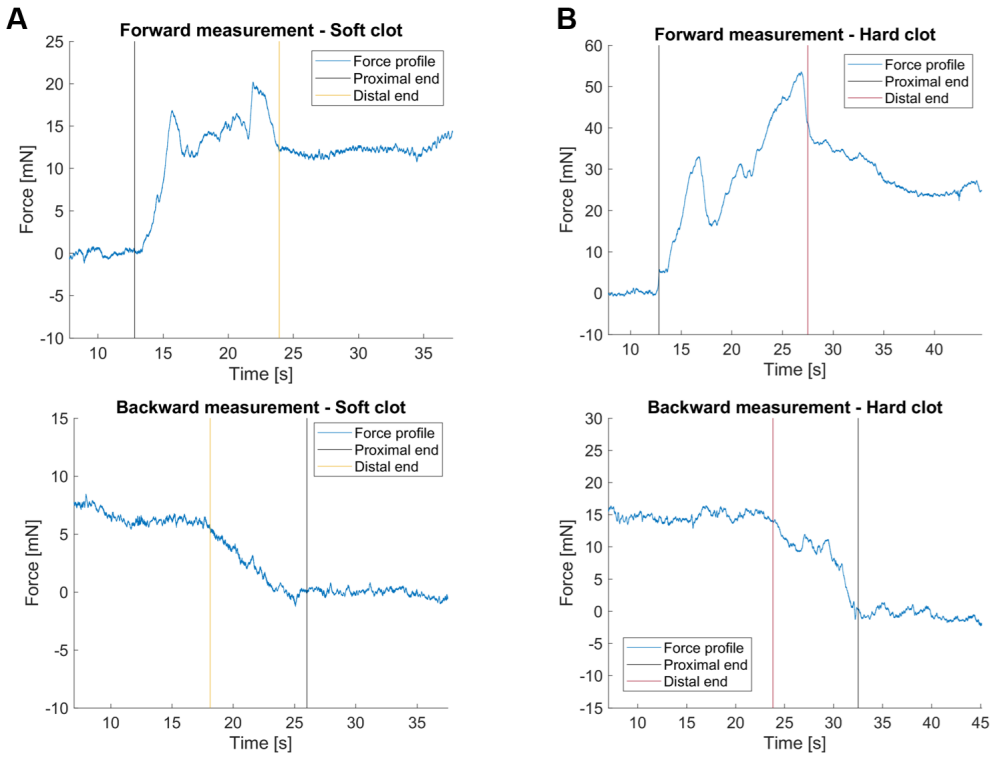

Figure 3 Examples of individual curves for clot penetration (forward measurement) and guidewire retrieval (backward measurement). (A) Forward and backward curves of one of the soft clots. (B) Forward and backward curves of one of the hard clots.

inside the guide catheter either by the STR or by the aspiration catheter. These experiments were aimed to evaluate the interaction of the MTB devices with clots of different stiffness. The study was not powered to evaluate difference in terms of the best technique.

Analysis

Videos of the experiments were retrospectively analyzed to identify the distal and proximal edges of the CAs over the force curves. In order to evaluate the force needed to penetrate the CA during advancement of the guidewire, we defined two metrics: the maximum slope of the curve over the first 3 s of penetration (*S*-max) and the maximal force within the clot (*F*-max). In addition, in order to evaluate the force needed to retrieve the guidewire after penetration of the CA, we considered a single metric as the average slope of the force curves within the clot recorded during guidewire retrieval. The rationale for the first metric (*S*-max) was to check if there was a significant difference between the different types of clots early on in the penetration. The other two metrics considered a full penetration of the clot. The signal processing steps were as follows. The raw voltage signal of the force sensor, acquired at 1 kHz, was filtered with a moving average filter with a window of 100 ms and then converted to a force signal through the calibration curve of the sensor. For the calculation of *S*-max, the force signal was additionally filtered with a third order low pass Butterworth filter with a cut-off frequency of 5 Hz before calculating the slope and taking the maximum value in a window of 3 s after the proximal edge was touched. For the calculation of the average slope between the distal and proximal end of the clot during guidewire retrieval, the additional third order low pass Butterworth filter was with a cut-off frequency of 0.5 Hz, after which the mean value was calculated.

Due to the relatively small sample size of each compared group, the statistical analysis between the two groups (eg, 'soft clots vs hard clots' or 'soft clots vs without clot') was done with the Wilcoxon rank-sum test. Statistical significance was set at $P<0.05$. All statistical analyses were performed with SAS software, version 9.2 (SAS Institute).

RESULTS

Clot consistency analysis

For each parameter (ie, two CA consistencies), 15 experiments were performed. This included a total of 30 measurements of the force needed to advance the guidewire through the CA and 30 measurements of the force needed to retrieve the guidewire from it. The median values of *S*-max during the advancement of the guidewire (first 3 s) through the CAs were 23.9 mN/s (Interquartile range (IQR) 8.5 mN/s) and 7.6 mN/s (IQR 8.9 mN/s) for hard and soft CAs, respectively. Thus, *S*-max significantly differentiates soft from hard CAs ($P<0.0001$) (figure 2B). In addition, hard CA penetration generated a higher *F*-max (maximum force within the clot) than soft CAs (median 55.6 mN (IQR 6.1 mN) vs 15.4 mN (IQR 4.7 mN); $P<0.0001$) (figure 2C). The average slope of the force curves within the clot during retrieval was −2.2 mN/s (IQR 0.56 mN/s) and −0.46 mN/s (IQR 0.33 mN/s) for hard and soft CAs, respectively, also allowing to differentiate between soft and hard CAs ($P<0.0001$) (figure 2E). As for the experimental condition without clot, the maximum forces were significantly lower than experimental runs with clots. The average slopes during guidewire retrieval were also significantly different. Interestingly, the maximum force slope during the first 3 s of penetration was significantly lower without clot than with hard clots, but was not significantly lower than with soft clots. We found that this was primarily due to interaction with the vessel wall.

Table 1 Results of mechanical thrombectomy

Measurement	Clot	Clot size (mm)	Clot location	Direct thromboaspiration
1	Stiff	5×5	ICA T	Clot not ingested but retrieved
2	Stiff	4×10	M1	Clot not ingested, not retrieved
3	Stiff	4×10	M1	Clot not ingested but retrieved
4	Stiff	4×10	M1	Clot not ingested but retrieved
5	Stiff	4×10	M1	Clot not ingested but retrieved
1	Soft	4×10	M2	Clot not ingested but retrieved
2	Soft	4×10	M1-2	Clot ingested
3	Soft	4×10	M1-2	Clot ingested
4	Soft	4×10	M1	Clot ingested
5	Soft	4×10	M1	Clot ingested
Measurement	**Clot**	**Clot size**	**Clot location**	**STR thrombectomy**
1	Stiff	4×10	M1-2	Clot not penetrated and lost during retrieval
2	Stiff	4×10	M1	Clot not penetrated and lost during retrieval
3	Stiff	4×10	M1	Clot not penetrated and lost during retrieval
4	Stiff	4×10	M1-2	Clot not penetrated and lost during retrieval
5	Stiff	4×10	M1	Clot not penetrated and lost during retrieval
1	Soft	4×10	M1-2	Clot successfully retrieved
2	Soft	4×10	M1-2	Clot successfully retrieved
3	Soft	4×10	M1-2	Clot successfully retrieved
4	Soft	4×10	M1	Clot successfully retrieved
5	Soft	4×10	M1	Clot successfully retrieved

ICA, internal carotid artery; STR, stent retriever.

The shapes of the force curves obtained during the advancement and retrieval of the guidewire were qualitatively analyzed in order to evaluate the potential for the identification of the proximal and distal edges of the CA. Four individual curves are shown in figure 3: two showing a forward (clot penetration) measurement, and two showing a backward (guidewire retrieval) measurement, one set being from a soft clot (panel A) and one set from a hard clot (panel B). In the forward curves, one can observe that the force increases rapidly at the beginning of penetration. It then reaches a maximum value and converges to a stable level after the distal end. The backward curve presents fewer variations because there are no effects linked to frontal contact with the clot or with the arterial wall, bending, buckling, etc. Beyond the clot, we can observe a relatively constant force level or a force with a slightly decreasing slope. The slope changes once the guidewire starts being retrieved within the clot and, finally, the force level becomes constant after the proximal edge of the clot. Thus, qualitatively, we see that the force could give important information about the location of the clot extremities.

In vitro thrombectomies

Results of MTB are reported in table 1. Overall, soft CAs were retrieved by both the STR and DTA techniques at the first attempt. Soft CAs allowed the expansion of the STR that penetrated and captured the CA. For DTA, most soft CAs were completely ingested by the aspiration catheter immediately after turning on the vacuum system. Hard CAs were not captured by STR, which did not expand over the clot, but remained constrained between the clot and the vessel wall. Subsequently, during retrieval, the STR slid beside the clot without any removal effect. DTA was more effective in retrieving hard CAs. In such instances, the removal was not related to the direct ingestion of the CA, but after the actioning of the vacuum system, that is, the proximal edge of the CA was aspirated and remained stuck at the distal tip of the catheter. Hence, the catheter and the CA were retrieved and extracted from the vascular model.

DISCUSSION

Our experiments showed that the analysis of the forces exerted on the proximal extremity of a guidewire during an MTB procedure was able to differentiate between soft and hard CAs in a statistically significant manner. In addition, our study showed the potential to identify the proximal and distal edges of the clot through the force curves that must be further investigated. In this study, we did not have enough samples to build a robust algorithm for the quantitative detection of the extremities.

Previous studies have evaluated the implementation of different device-integrating systems able to provide force feedback to their proximal extremities, including either piezoresistive force or fiber optic sensors integrated into a guidewire device.[9] In an experimental animal study, Skyrman *et al*[10] evaluated the use of diffuse reflectance spectroscopy applied to a custom guidewire to differentiate clot composition, which allowed the identification of red cell-rich soft clots, fibrin-rich stiff clots, and mixed clots. Messina *et al*[11] conducted an experimental study conceived to evaluate a guidewire device that used an impedance-based microsensor placed at its tip, coupled with a machine learning algorithm, to identify different types of clot composition by contact. However, contrary to our approach, none of these technologies provide information on the mechanical properties of the clot or have been currently implemented in clinical practice.

A few specific imaging biomarkers, such as the HDVS on CT and the SVS on MRI, are associated with a specific clot histological pattern, such as red blood cell-rich clot. They are correlated with a higher success of MTB first pass in general and are more prone to be retrieved with STR devices.[2–4] However, pre-interventional imaging biomarkers have several limitations, as fibrin-rich, platelet-rich, and mixed clots are not (or only roughly) identifiable on CT and MRI imaging. In addition, the detection of red cell-rich clots is variable and quite dependent on the percentage of red cells,[12] the specific accuracy of the imaging system, and the technique parameters used.[13] Consequently, in certain cases, even red cell-rich clots are only poorly identified. In addition, it is difficult to assess other clot characteristics using these imaging biomarkers, such as its precise location and limits (ie, the location of the clot proximal and distal extremities).

In comparison to HDVS and SVS, our approach focuses on the in situ identification of mechanical parameters that allowed the identification of different types of clots (CAs) and not only the detection of the red blood cell-rich type. Moreover, our approach made it possible to qualitatively identify the proximal and distal margins of the clot.

DTA appeared to be more effective in retrieving stiff CAs compared with the STR-based MTB technique, while both DTA and STR techniques were effective in capturing soft CAs. In the presence of stiff CAs, STR remained constrained between the vessel wall and the clot and slid during the retrieval without capturing the clot, as demonstrated by previous studies.[14] When DTA was used to retrieve stiff CAs, the CA was not ingested by the catheter, but remained stuck at its distal tip. Nevertheless, the retrieval of the catheter allowed the extraction of the CA from the vascular model. The results of thrombectomy experiments were likely related to the geometry of our vascular model, which may have favored the DTA. The higher efficacy of the DTA for stiff CA was probably also related to the favorable angle of interaction (AOI)[15] between the aspiration catheter and the CA, which was due to the specific geometry of the model used. Such an angle was open and favorable for M1 occlusions (around 165°) and more acute, but also favorable for carotid terminus occlusions (around 125°).

The potential use of the reported approach in clinical practice could allow the identification of the clot consistency and extension and, consequently, its location, together with a prediction of the potential AOI between the catheter and the proximal edge of the clot. Indeed, such an AOI could be inferred by analyzing the orientation that the guidewire assumed after penetrating the clot and the potential position assumed by the aspiration catheter. Thus, in the presence of a stiff clot and a favorable AOI, the DTA could be prospectively selected as the front-line approach. However, in the presence of a soft red blood-rich clot, in concordance with some evidence from clinical and experimental studies, an STR-based MTB could be performed in order to reduce the risk of fragmentation of the clot during retrieval.[2 14 16] Moreover, in the presence of a stiff white clot and a predictable, unfavorable AOI between the clot and the aspiration catheter, a combined technique could be performed. With such an approach, the STR could be used to bring the clot close to the aspiration catheter, improving the AOI with the clot and thus potentially improving the efficacy of the clot removal.

The forces measured in our study to penetrate and withdraw the guidewire from the clot by the robotic system are not perceptible to the human hand (eg, 1.6 g median maximum force value for the soft CAs). In addition to these forces, those required to navigate the catheter and the guidewire from the femoral artery to the intracranial vessels are likely to exceed the forces generated at the level of the clot. From a clinical perspective, this proof-of-concept study provides insights on the potential application of a robotic device used during neurointerventional procedures to provide quantitative information to the operator in real-time in order to improve the technical outcome of the procedure.

Limitations

This study was intended to be a proof of concept of a novel approach and presents several limitations. First, the guidewires used for the experiments were straight and not formed. The use of such straight guidewires does not seem to be applicable in current clinical practice. The reason for this choice was that the analysis of penetration forces was simplified compared with the analysis of forces related to interactions with a guidewire having a shape at its distal end. Further investigations using a guidewire with a shaped distal tip need to be conducted. Second, the analysis of clot consistency and extension involves maneuvers of advancing and retracting the guidewire through the clot, which are not currently performed in the clinical setting, particularly when DTA is selected as the first-line technique. Third, a further reason why this approach is not immediately transposable to the clinic is that a controlled linear displacement system was used and such a system is not currently usable to treat real patients. We hypothesized that such an approach could potentially be integrated in a cutting-edge set-up where the MTB procedure will be performed under the guidance of a robotic system. At the present time, only one robotic system is approved for neurointerventions, the CorPath GRX (Corindus, A Siemens Healthineers Company, Waltham, MA), but it was designed to treat brain aneurysm with stent-assisted coiling.[17] The system has only a force alarm on extreme push forces and does not provide any force feedback to the operator.[18] Fourth, the set-up did not include aortic arch and cervical carotid arteries, which could influence the force measurements. However, we subtracted the friction force between the micro-guidewire and the microcatheter, measured in the few millimeters before the guidewire exits the catheter. In a more anatomic situation where the friction forces increase, this should not impact the measurement at the clot level. However, this should be further investigated. Finally, we did not measure the adhesion properties of the clot analogs.[19] We assumed that, given the similar chemical composition of the hard and soft clot analogs, adhesion and friction properties should not be too different. This is to some extent confirmed by the force profiles, as the forces resulting from an interaction with the soft clots are significantly lower than those with hard clots.

CONCLUSION

Our findings demonstrated that it was feasible to differentiate between soft and hard CAs and showed promise regarding the identification of their proximal and distal edges by measuring the forces exerted on the proximal extremity of the guidewire during the advancement and retrieval through the CAs. Such an approach would potentially allow the selection of the first-line MTB technique. Further investigations are needed to translate such an approach to clinical practice.

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Contributors PR: study design, data acquisition, data analysis, data interpretation, manuscript preparation, revised the draft manuscript. ER: study design, data acquisition, data analysis, data interpretation, manuscript preparation, revised the draft manuscript. OB: data acquisition, data analysis, data interpretation, manuscript preparation, revised the draft manuscript. JH: manuscript preparation. GB: manuscript preparation. AR: manuscript preparation. WG: data acquisition, data analysis. K-OL: manuscript preparation. VMP: manuscript preparation. MB: study design, data analysis, data interpretation, manuscript preparation, revised the

draft manuscript. PM: study design, data analysis, data interpretation, manuscript preparation, revised the draft manuscript and guarantor.

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