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ABSTRACT

BACKGROUND AND PURPOSE: Mechanical thrombectomy has become a first-line treatment for acute ischemic stroke. Several techniques combining stent retrievers and distal aspiration catheters have been described. We aimed to characterize the efficacy of 2 commonly used techniques according to clot characteristics.

MATERIALS AND METHODS: Soft (mean stiffness = 95.77 [SD, 5.80] kPa) or stiff (mean stiffness = 205.63 [SD, 6.70] kPa) clots (3 × 10 mm and 2 × 10 mm, respectively) were embolized to the distal M1 segment of the MCA in an in vitro model. The technique was randomly allocated (1:1): stent retriever assisted vacuum-locked extraction (SAVE) versus complete retraction (Solumbra). The primary end point was the percentage of first-pass recanalization. Secondary end points were periprocedural distal embolization measures.

RESULTS: A total of 130 mechanical thrombectomies were performed (50 for soft clots and 15 for stiff clots per arm). Overall, the rate of first-pass recanalizaton was 35% with Solumbra and 15% with SAVE ($P < .01$). For stiff clots, the first-pass recanalizaton was equal for both methods (27%; $P = 1.00$). With soft clots, the first-pass recanalizaton was higher with Solumbra (38%) than with SAVE (12%; $P < .01$). When we used soft clots, the maximum embolus size (mean, 1.19 [SD, 0.9] mm versus 2.16 [SD, 1.48] mm; $P < .01$) and total area of emboli (mean, 1.82 [SD, 2.73] versus 3.34 [SD, 3.2]; $P = .01$) were also lower with Solumbra than with SAVE.

CONCLUSIONS: Clot characteristics may influence the efficacy of the thrombectomy technique. In occlusions caused by soft clots, complete retrieval into the distal aspiration catheters achieved higher rates of first-pass recanalizaton and lower embolization.

ABBREVIATIONS: DAC = distal aspiration catheter; %FPR = percentage of first-pass recanalization; MT = mechanical thrombectomy; SAVE = stent retriever assisted vacuum-locked extraction; Solumbra = total retraction; SR = stent retriever

Stroke is the second leading global cause of mortality, with an annual fatality rate of approximately 3.3 million worldwide.[1] Endovascular treatment has proved its efficacy in patients with acute ischemic stroke due to large-vessel occlusion.[2-4] First-pass recanalization (FPR), defined as a single pass of the device to achieve complete or successful recanalization without the use of rescue therapy,[5] has been related to improved functional outcomes and identified as an independent predictor of no disability at 90 days.[6]

A better understanding of the device-clot interactions during all steps of mechanical thrombectomy (MT) is needed to optimize the technique to achieve the highest rates of FPR. In vitro studies have demonstrated that clot composition and biomechanical characteristics may impact device performance and the outcome of a procedure.[7,8]

Stent retrievers (SRs) have undoubtedly shown their safety and efficacy in the endovascular treatment of stroke.[9] Moreover, different treatment strategies combining a SR with aspiration through a distal access catheter (DAC) have been proposed to increase recanalization rates. Strategies commonly referred to as stent retriever assisted vacuum-locked extraction (SAVE) and complete retraction (Solumbra) are probably the most frequently used by neurointerventionalists.

The Solumbra technique consists of fully retracting the entire SR inside the DAC under continuous aspiration at the level of the occlusion site before retracting the DAC.[10] Full ingestion of the clot at the occlusion site potentially avoids embolization of the whole clot or fragments to uninvolved arterial territories such as the anterior cerebral artery during retrieval.

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From the 2nd Department of Radiology (M.J.), Medical University of Gdansk, Gdansk, Poland; Stroke Unit (M.J., J.L., R.T., P.C., M.R.), Stroke Research (J.L., R.T., P.C., A.T., M.R.), and Neurointerventional Radiology Department (A.T.), Vall d'Hebron University Hospital, Barcelona, Spain; and Department of Neurology (S.O.), The University of Iowa Hospitals and Clinics, Iowa City, Iowa.

Please address correspondence to Marc Ribo, MD, Stroke Unit, Vall d'Hebron University Hospital, Barcelona, Spain, Hospital Vall d'Hebron, Passeig de la Vall d'Hebron, Barcelona 119-129, Spain; e-mail: marcriboj@hotmail.com

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Indicates article with supplemental online videos.

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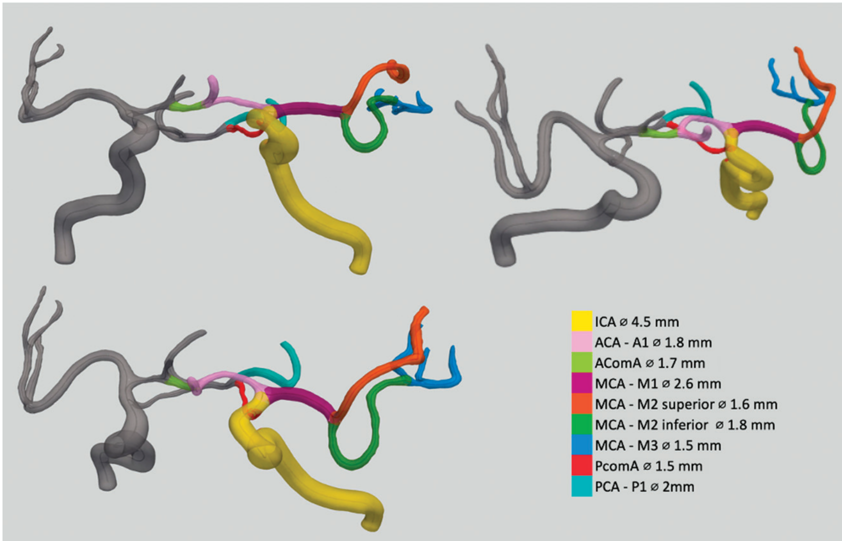

FIG 1. Virtual model of the circle of Willis segmented vessels. ACA indicates anterior cerebral artery; AcomA, anterior communicating artery; PcomA, posterior communicating artery; PCA, posterior cerebral artery.

In contrast, with the SAVE technique, the SR is only partially retracted inside the DAC, with the intention of pinching the clot between the SR and the tip of the DAC; continuous aspiration is also applied to this area to increase clot entrapment.[11] Then the whole system is retracted into the guiding catheter under this configuration. The main potential advantage is the reduction of the probability of stripping the clot at the time of the ingestion into the exiting catheter. The clot is never fully retracted into the DAC and is only ingested into the guiding catheter, which has a larger inner diameter at the level of the ICA. Therefore, the probability of clot shaving during this critical step with embolization of the resulting fragments is theoretically reduced.

To date, there is no clear evidence supporting an increased efficacy of one technique over the other, and both are routinely used in clinical practice according to the neurointerventionalist's preferences. We hypothesized that the efficacy of each technique might be related to the mechanical characteristics of the clot.

This randomized, in vitro study aimed to compare 2 MT techniques, SAVE versus Solumbra, in terms of FPR and periprocedural distal embolization.

MATERIALS AND METHODS

Clot Analogs

Two types of clot analogs, namely soft and stiff, were embolized to create an occlusion within the distal M1 segment of the MCA in a 3D-printed neurovascular model. Clot analogs used in the experiments were within the comparable stiffness range of aged thrombus retrieved from patients with stroke (elasticity $[E]_{0\%-45\%} = 170$ [SD, 39] kPa).[12] The Secant modulus of elasticity at 0%–45% strain ($E_{0\%-45\%}$) was a mean of 95.77 [SD, 5.80] kPa and 205.63 [SD, 6.70] kPa for soft and stiff clots, respectively. Three replicates of the Unconfined Compression Test were performed per clot type, as previously described.[13]

The production of the clots comprises the preparation of 2 solutions: for stiff clots, 3% sodium alginate and 40% calcium chloride, and for soft clots, 1% sodium alginate and 2% calcium chloride. The alginate solution was stained using red food coloring to increase the visibility of the clot within the model. Such a prepared alginate solution was subsequently drawn into prepared silicone tubes with a fixed diameter of 3 mm for soft clots and 2 mm for stiff clots. The next step involved casting the alginate solution into the solution with calcium ions and waiting 5 minutes to let the reaction occur. The obtained material was then cut into equal 10-mm-long fragments to create ready-to-use clot analogs.

Neurovascular Model

Experiments were conducted using a 3D-printed neurovascular model (FlowCAT, Barcelona, Spain), realistically reflecting human neurovascular anatomy obtained from anonymized CT scans (Fig 1). The model included a fragment of the descending aorta, aortic arch, bilateral carotid arteries, and a complete circle of Willis. The manufacturing procedure has been previously described.[14] The model functions in a closed circulatory system with the mean water temperature maintained at 36.6 [SD, 1]°C and the continuous flow rate fixed at 800 mL/min (Fig 2).

In Vitro MT Technique

Before each experiment, preprocedural data were recorded, consisting of clot dimensions before embolization, clot length, and location after the initial embolization inside the model.

The clot was inserted into the model through an access port at the proximal portion of the ICA. Flow was subsequently activated in the model, resulting in an embolization of the clot to the distal M1 segment of the MCA. After primary embolization, the experiments were randomized to 1 of the 2 study arms: complete (Solumbra) versus partial (SAVE) stent retrieval into the DAC (1:1). The type of clot was known to the operator.

Initially, 30 in vitro MTs were performed using stiff clots, followed by 30 MTs with soft clots. After a preplanned interim analysis, further experiments with stiff clots were abandoned for futility reasons, and 60 additional experiments with soft clots were performed.

The same MT setup was used for conducting every experiment.

The 8F sheath was plugged into a silicone tube that acts as an extension of the descending aorta to mimic femoral access. A long sheath (Cerebase DA 8F; Cerenovus) was placed in the distal C3 ICA segment. A triaxial system composed of a DAC (React 71; Medtronic), a microcatheter (Phenom 21; Medtronic), and a microguidewire (Synchro 14; Stryker) was advanced. Permanent saline flush lines were connected to the long sheath, DAC, and microcatheter, simulating the clinical setting. After we crossed the clot with the microguidewire and microcatheter into 1 of the

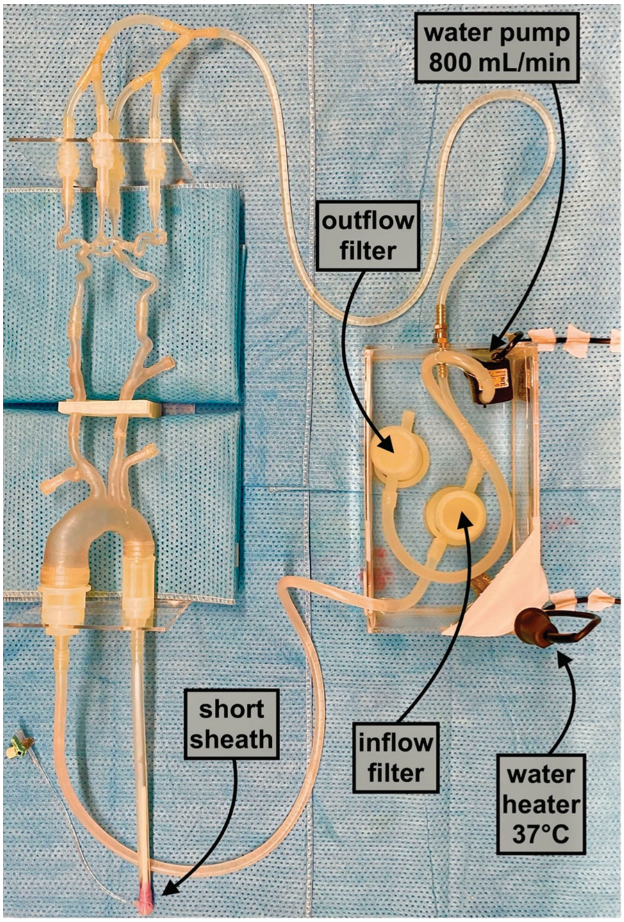

FIG 2. Flow loop setup including the neurovascular model, continuous pump, temperature regulator, and inflow and outflow filters.

M2 MCA branches, the microguidewire was exchanged for an SR (Solitaire 4 × 40; Medtronic). SR deployment was performed using the push-and-fluff technique[15] from the M2 to the M1 MCA segment, aligning the proximal ends of the clot and the stent. The SR (Medtronic, MN) was replaced after every 10 experiments.

After SR deployment, the DAC was advanced up to the proximity of the clot. Manual aspiration with a 60-mL syringe (VacLok; Merit Medical) was initiated through the DAC, and the MT technique was performed according to the study arm allocation. Each experiment was video recorded. Only 1 MT attempt was performed per clot. FPR was defined as no remnant clot fragments of >1 mm either in the model (partial recanalization) or in the filter (distal embolization). Partial recanalization (TICI 2b50) was defined as the presence of particles of >1 mm in the filter but no remnant in the model. After the experiment, the number, size, and location of distal emboli were registered. The primary end point was the percentage of first-pass recanalization (%FPR). Secondary end points were periprocedural distal embolization measures. After each experiment, the entire model and equipment were flushed to ensure no residual contaminants were left.

Filter Analysis

The model included an outflow filter designed to trap particles of >100 μm to precisely evaluate the periprocedural distal embolization of small particles. Before each experiment, a new filter was installed in the model. After each experiment, the filter was removed, and the contents were stained with Congo red dye to increase the visibility and accurate assessment of the smallest particles. A photograph of each filter was obtained using a high-resolution camera (VZ-R; IPEVO). An independent researcher, who was blinded to all experimental data, analyzed the images by processing an algorithm developed in Matlab R2020a (MathWorks) as previously described.[14] The algorithm automatically provided the following data about emboli collected in the filter: Feret diameter of the largest embolus (maximum [max]-E), total count of emboli (count-E), total count of emboli larger than 1 mm (count-E > 1mm), and total area of emboli (area-E), thus providing a detailed characterization and quantification of distal emboli generated at each pass.

Statistical Analysis

Statistical analyses were performed using SPSS, Version 23.0 software (IBM).

Emboli variables were expressed as mean (SD). The χ^2 test was used to compare both techniques regarding the %FPR. *A t* test was used to analyze the distal emboli parameters. The statistical significance was defined as $P < .05$.

RESULTS

We performed a total of 130 MTs at the level of the left distal M1 MCA segment: 50 cases per arm for soft clots and 15 cases per arm for stiff clots. Overall, FPR was achieved in 25% (33/130) of the cases: 35% (23/65) for Solumbra and 15% (10/65) for SAVE ($P < .01$). Partial recanalization (TICI 2b50) was achieved in 73% (48/65) for Solumbra and 63% (41/65) for SAVE ($P = .186$). Analyses of emboli showed better results with Solumbra technique: Lower maximal embolus diameter (mean, 1.24 [SD, 1] mm versus 2.03 [SD, 1.43] mm; $P < .01$), lower total area of emboli (mean, 1.98 [SD, 3] versus 3.36 [SD, 3.38]; $P = .01$), and lower count E > 1 mm (mean, 1.12 [SD, 1.71] mm versus 1.71 [SD, 1.85] mm; $P = .06$) compared with SAVE (Online Supplemental Data).

Stiff Clots

There was no statistical difference between the 2 techniques in FPR: Solumbra 27% (4/15) versus SAVE 27% (4/15) and partial recanalization (TICI 2b50) (47% [7/15] versus 47% [7/15]; $P = 1$). No significant differences were identified in distal emboli analyses (Online Supplemental Data and Fig 3).

Soft Clots

With soft clots, the Solumbra technique achieved higher rates of FPR (38% [19/50] versus 12% [6/50]; $P < .01$) and partial recanalization (TICI 2b50) (82% [41/50] versus 68% [34/50]; $P = 106$).

The Solumbra technique also showed a lower maximal embolus size (mean, 1.19 [SD, 0.9] mm versus 2.16 [SD, 1.48] mm; $P < .01$) and a lower total area of emboli (mean, 1.82 [SD, 2.73] versus 3.34 [SD, 3.18]; $P = .01$). Additional emboli measures are shown in Fig 3.

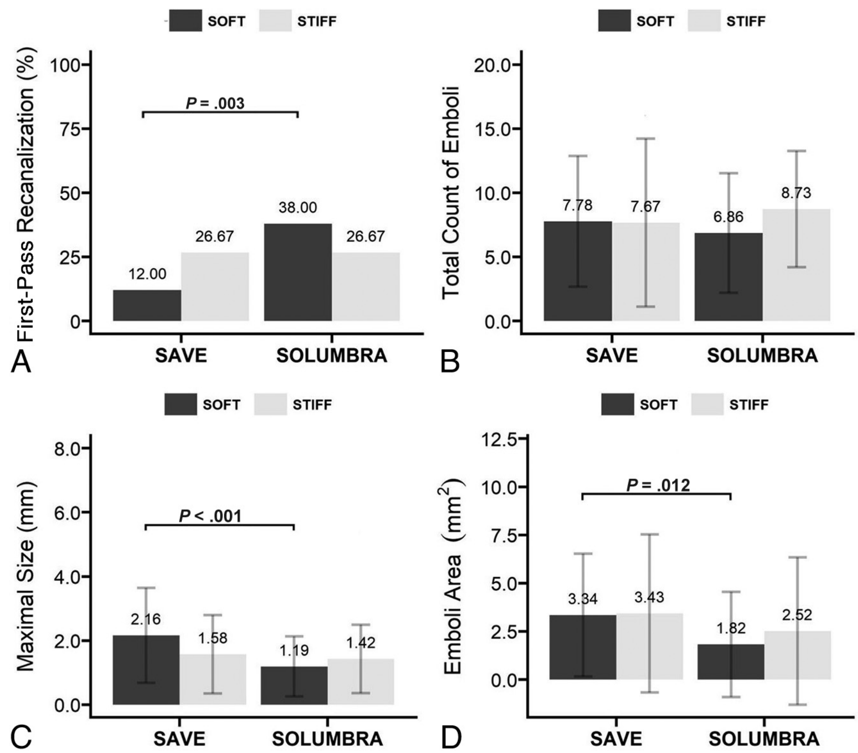

FIG 3. Recanalization rate and distal emboli parameters according to the treatment arm and the type of clot. *A*, %FPR. *B*, Total count of emboli (count-E). *C*, Feret diameter of the largest embolus (max-E). *D*, Total area of emboli (area-E).

DISCUSSION

This randomized in vitro thrombectomy study assessing 2 different DAC + SR combination techniques demonstrates that clot characteristics influence angiographic outcomes according to the technique used. While complete and partial retrieval of the SR into the DAC have similar efficacy with stiff clots, complete retrieval showed superior outcomes with soft clots.

Several studies indicated that MT outcome and device performance may be influenced by clot composition and its biomechanical characteristics.[16] While soft clots are prone to fragmentation[17] but are more easily ingested into smaller-diameter catheters, stiff clots are characterized by high rigidity, probably less friability, increased resistance to be ingested into the catheters, and higher friction against the vessel wall.[13] The physical characteristics of the synthetic clot analogs used in the present experiments mimic these features and remain within the reported biomechanical ranges of human clots obtained from thrombectomies.[12] The adjunctive effect of aspiration, generating a protective flow reversal, might also be modified by clot characteristics: Soft clots, easily ingested into the DAC, allow continuous transmission of the negative pressure to the tip of the catheter, generating a sustained local flow reversal. On the other hand, stiff clots that remain stuck or pinched at the tip of the catheter interfere with the transmission of the negative pressure and interrupt the local flow reversal. Thus, small clot fragments generated by the tip of the catheter during ingestion (clot-shaving effect) or while dragging the clot with the SR through the vessel tortuosities (roll-out effect) have higher probabilities of embolizing to distal or new vascular territories. Our hypotheses are confirmed by the frequencies of occurrence of the aforementioned phenomena for individual MT techniques. Clot shaving was observed more frequently while performing the Solumbra technique than with SAVE (17% versus 13%) (Online Supplemental Data), and the roll-out effect was more common in the SAVE group than in the Solumbra group (20% versus 2%) (Online Supplemental Data).

Given these characteristics, total retrieval of the SR and the clot (Solumbra) at the initial clot location (ie, M1 MCA segment) should theoretically be favored in occlusions caused by soft clots for different reasons. First, a softer clot will still be ingested into the DAC (even with the DAC being smaller than the base catheter), and second, eventual shaved clot fragments will be locally aspirated by the uninterrupted flow reversal (Online Supplemental Data). On the other hand, a partial retrieval of the SR into the DAC (SAVE) seems apparently more adequate for stiff clots because the ingestion of a less deformable clot will be finally made into a larger catheter (the base catheter positioned in the ICA) and the local flow reversal being interrupted by the clot itself seems less relevant in clots that, by nature, are predominantly nonfriable (Online Supplemental Data).

This hypothesis is mainly supported by the present findings, in which the total retrieval of the SR at the level of the occlusion led to improved FPR rates and a lower distal emboli count, mainly with soft clots. In contrast, when retrieving stiff clots, the efficacy was overall significantly lower than with soft clots, but the 2 studied methods had very similar results. It is possible that if even stiffer clots were to be used, the results might have shown a complete shift, indicating a higher efficacy of the partial SR retrieval technique.

The results of our study may not have a direct impact on clinical practice until the nature and characteristics of the clot cannot be definitively predicted before retrieval. However, indirect recommendations can still be made. Our preferred protocol would be to perform a total retrieval of the SR in the first attempt, considering that softer clots are more prevalent and that in the event that the clot is of stiff, it will remain unfragmented in the original location. If the initial technique fails, the neurointerventionalist could assume that the clot is of a stiffer nature, and a second attempt, partially retrieving the SR, could increase the probability of success. Proceeding inversely with frontline partial retrieval of the SR technique may result in clot fragmentation and embolization of softer clots outside of the DAC during retrieval and before final ingestion into the sheath (Online Supplemental Data).

Additionally, the skills of the interventionalist could be another factor that influences the efficacy, especially when adopting the SAVE technique. The SAVE technique requires that the SR remain partially retracted into the DAC during the whole maneuver until the system is totally retracted into the base catheter. However, it is frequently observed that due to the elongation of the DAC, which is not paralleled by the SR wire, the SR is progressively (on occasions totally) retracted into the DAC during the operation, increasing the chances of clot shaving and rolling before ingestion into the base catheter (Online Supplemental Data). The frequency of elongation of the DAC during the SAVE technique leading to premature clot ingestion was found to be 22%, being more common for stiff clots compared with soft clots (53% versus 12%). To minimize this phenomenon, the interventionalist should release the tension of the DAC as much as possible before initiating the SAVE technique and control the relative position of the SR and the DAC during the whole procedure, steps that require substantial skills and expertise of the interventionalist. In our study, there were also unsuccessful attempts for each technique, in which the clot remained in its original location (Solumbra 9%, SAVE 5%; $P = .289$). We provide supplemental videos that demonstrate the mechanisms of MT failure for both techniques (Online Supplemental Data).

Our results are in contrast to those of a recently published in vitro study comparing multiple MT methods in terms of FPR, which demonstrated the superiority of the SAVE technique regarding the %FPR.[18] The differences may be due to the lower number of experiments performed using the present techniques with the same thrombectomy setup (SAVE $n = 6$; Solumbra $n = 6$), a different method of assessing distal emboli, and, especially, the use of a smaller DAC size (0.061 versus 0.071 in the present study), which directly affects aspiration efficacy and clot ingestion.[19] Using a larger-bore DAC predominantly favors the Solumbra technique because the clot is ingested by the DAC only with this technique. Under the SAVE technique, the diameter of the DAC may have a limited impact because clot ingestion occurs at the base catheter. In any case, the contradictory results suggest that further research to define the optimal device combination for each clot type is still required.

Limitations

As in every in vitro study, our experiments have some limitations. Although the anatomy in the neuroanatomic model is reproduced very realistically, the material from which the model is made cannot fully reflect the plasticity of the human vasculature and mimic the interactions among the vessel wall, devices, and the clot. In addition, clot analogs were used in the study, which do not fully reflect the heterogeneous structure and wide range of characteristics of human thrombus.

In our study, we used only 1 type of SR and DAC; thus, the results should not be applied universally and may be different with other device combinations.

Another limitation of our study arises from the use of a single clot size. This choice was motivated by the desire to minimize the accumulation of confounding variables and maintain consistency in our experimental conditions. Nevertheless, we are well-aware that the diverse sizes of clots could substantially impact the effectiveness of the different MT techniques. Thus, we advocate further research in this sense to enrich our understanding and optimize treatment outcomes.

Despite these limitations, given the randomized design, the rates of FPR comparable with the rates achieved in clinical practice, and the large quantity of experiments, it is reasonable to assume that the conditions of our experiment replicated real clinical settings to a high degree.

CONCLUSIONS

Clot characteristics may influence the efficacy of the thrombectomy technique. In occlusions caused by soft clots, complete retrieval of the SR into the DAC achieved higher rates of FPR and lower distal embolization.

Disclosure forms provided by the authors are available with the full text and PDF of this article at www.ajnr.org.

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In the article “Partial (SAVE) versus Complete (Solumbra) Stent Retriever Retraction Technique for Mechanical Thrombectomy: A Randomized In Vitro Study” published in the October 2023 issue of *AJNR* (44:1165–70; 10.3174/ajnr.A7996), the authors regret that Santiago Ortega-Guiterrez’s name was published as Santiago Ortega.

In the December 2024 issue, credit for the cover art was omitted. The original art was created by Ann Mary John. Also in this issue, the credit line for the art on the third cover should read, “*A Look Within, The Brain of a Radiologist*” by Bar Neeman, and the credit line on the back cover should read, “*Yestermorrow*” by Andria M. Powers. The journal regrets these errors.

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