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Original Article

Comparison of mechanical thrombectomy techniques in an in vitro stroke model: How to obtain a first pass recanalization?

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ABSTRACT

Background: Since mechanical thrombectomy (MT) has proven to be effective in the treatment of acute ischemic stroke (AIS), significant research has been dedicated to establishing procedural techniques offering best rate of first pass effect (FPE). In this study, we compared the efficacy of different techniques in vitro to achieve the first pass recanalisation (FPR).
Methods: In vitro MT procedures were performed using a realistic silicone model of the human cerebral vasculature. The MT with stent retriever (SR) were performed with manual co-aspiration through the respective access catheter and intermediate catheter (IC), with Solumbra or partial retrieval techniques into the IC. Two SRs (Solitaire and EmboTrap) were selected to retrieve both red blood cells (RBC) rich and fibrin-rich clots. FPR rates were recorded for each case.
Results: Overall, 144 MT were performed. FPR rates using the partial retrieval and Solumbra technique were of 100% and 87%, respectively ($p = 0.01$). The rate of FPR was of 92% using the balloon-guide catheter (BGC) compared to 64% with the guide catheter (GC) ($p = 0.0001$). With an IC, no differences were found between using a BGC or a GC (87.9% vs 89,6%, $p = 0.75$). No significant difference was observed between the Embotrap and the Solitaire device for the rate of FPR (82% and 74%, respectively; $p = 0.23$).
Conclusions: In this study, FPR rates were higher with the use of an IC associated with the partial retrieval technique, regardless the guide catheter, the SR, or the clot composition. The less effective technique was the association of GC and SR, without an IC.

Introduction

Mechanical thrombectomy (MT), either alone or in combination with intravenous thrombolysis, has become the standard of care for acute ischemic stroke (AIS) secondary to an acute large vessel occlusion (LVO).[1] The introduction of stent retrievers (SR) has significantly increased the speed and efficacy of reperfusion and markedly improved clinical outcomes.[1,2] Recent analyses have shown the significant benefit of a first pass effect (FPE),[3,4] resulting in a growing interest to identify technique factors that could promote complete recanalization after one pass (i.e., first pass recanalisation, FPR).[5,8] In this context, the use of balloon guiding catheter (BGC) for aspiration and proximal occlusion, the use of intermediate catheter (IC) for distal aspiration, the use of SR optimized for first pass recanalization, as well as different techniques of retrieving (Solumbra or partial retrieval techniques) were proposed: The Solumbra technique was described as a complete withdrawal of a SR into an intracranial IC, converted to a partial retrieval when the SR could not be withdrawn into the IC completely[9,10] while the partial retrieval techniques such as the ARTS,[6] SAVE,[7] Protect[5] or BADDAS[11] consisted in a partial withdrawal of the SR within the IC (i.e., non-Solumbra technique) that may prevent thrombus migration.[7,8] However, there is limited angiographic and clinical evidence to inform comparative assessments of the various MT techniques with stent retrievers and their combination with aspiration catheters and guide catheters. In addition, in vitro studies evaluating clot–device interactions have shown that device performance and procedural efficacy can be influenced by clot composition.[12,13]

The aim of the present study was to compare in an in vitro model of AIS the FPR rates obtained with different MT techniques according to several variables, such as: the use of a BGC versus a GC, the Solumbra technique versus partial retrieval techniques, the use of a Solitaire FR (Medtronic, Irvine, CA) versus a EmboTrap (Cerenovus, Galway,

Abbreviations: MT, Mechanical Thrombectomy; AIS, Acute ischemic Stroke; LVO, Large Vessel Occlusion; SR, Stent retriever; BGC, Balloon guide catheter; GC, Guide Catheter; IC, Intermediate Catheter; FPE, First Pass Effect; FPR, First Pass Recanalization; RBC, Red Blood Cells

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Ireland) stent retrievers, and two histologically distinct experimental clot analogues.

Materials and methods

Thrombi preparation

Ovine blood was selected for clot analogue production in this study as it has been shown to be the most suitable for coagulation studies.[14] Both RBC and fibrin-rich clot analogue types were produced for analysis using the methodology outlined previously by Duffy *et al.*[15] The two clot types selected for this study consist of 80% and 5% RBC content by volume to represent a soft and friable RBC rich clot versus a tough clot, respectively. These two clot analogue types represent the two extremes of composition reported in the literature of human thrombi[16-19] to allow 'worst-case-scenario' testing. Each clot sample was cut to an approximate size of 4 mm x 8 mm (diameter x length), which is within the reported range of thrombi retrieved from patients with acute ischemic stroke.[20]

Silicone vascular in vitro model

Simulated in vitro MT procedures were performed using a realistic soft 3-D silicone model (Elastrat Sarl, Geneva, Switzerland) of the human cerebral vasculature with complete circle of Willis (Fig. 1). An isotonic saline solution, heated to 38 °C to simulate human body temperature, circulated within the model using a continuous flow pump at a flow rate of 900 ml/min. This flow rate was selected to simulate severe flow conditions to test the most challenging patient conditions. The model allowed a direct access to the carotid artery through an access tubing located on the external carotid artery for thrombus injection.

In vitro procedural technique

Before all simulated endovascular procedure, the clot was inserted inside the anterior circulation through the previously mentioned carotid access by injection with a 20cc syringe of an isotonic saline solution containing the clot. It allowed the migration of the clot with the circulating flow into M1 segment of the middle cerebral artery (MCA). The clots that failed to reach M1 segment or migrated distal to M1 were discarded. Each clot sample was tested only once.

Through several different experiments, different techniques of MT with two different SR, the Solitaire FR (Medtronic, Irvine, CA) versus the EmboTrap (Cerenovus, Galway, Ireland), and two histologically distinct experimental clot analogues, red blood cell (RBC) rich and fibrin rich clots, were compared as follows:

1) The use of a GC with a SR alone.
2) The use of BGC with a SR alone.
3) The use of a GC with the Solumbra technique.
4) The use of a BGC with the Solumbra technique.
5) The use of a GC with a partial retrieval technique.
6) The use of a BGC with a partial retrieval technique.

The CELLO 9F catheter (Medtronic, Irvine, CA) was used as GC (with no inflation of the balloon) and as BGC (with an inflation of the balloon). It was positioned into the ICA. The clot was reached and crossed with a 0.021-inch HEADWAY microcatheter (Microvention, AlisoViejo, California, USA) which allowed to deploy the SR. According to their respective instructions for use, the Solitaire was positioned such the clot was located at the mid third of the device, whereas the Embotrap was positioned such the proximal end of the clot was located at proximal marker of the device. SR were left in place 3 min before retrieval. The ARC 6F (Medtronic, Irvine, CA) with a usable length of 132 cm and inner diameter of 0.061 inches, was used as IC. It was positioned proximal and in front of the proximal end of the clot. The Solumbra technique consisted of a complete withdrawal of the SR and clot into the IC under manual aspiration as previously described in the literature.[9,10] In the partial retrieval technique, the SR and clot were partially retrieved into the IC under distal aspiration, then the SR/clot/IC system was removed as one unit, as described in the literature.[5-7] For all procedures, the aspiration was performed manually using a 60cc syringe from the aspiration catheter (either through the GC, BGC or IC). All experiments were performed with both Solitaire FR 4 × 20 mm and Embotrap 5 × 21 mm, and with both a fibrin-rich clot and a RBC-rich clot, resulting in a total of 24 batch of experiments. Each experiment was repeated three times by two different interventional neuroradiologists experienced in MT (GG and OFE). Thrombectomy technics were performed in a precise pre-established order to facilitate their implementation and their sequence between the two operators. For each technic, both the stent used, and the clot type were known by the operator. When a thrombectomy technic was tested, it was performed 3 times by one operator then 3 times by the other one, changing the clot between each removal. Then, another thrombectomy technic was tested according to the same protocol. During the clot retrieval, alternately, one physician performed the MT under fluoroscopic guidance while the other physician noticed any clot fragmentation or migration into the model. Both direct visual control and high-definition video were performed to document any clot fragmentation. If clot fragmentation or clot migration was observed, the result was noted as recanalization failure. Each operator was blind to the result of the other one. Primary outcome was the FPR defined as a complete recanalization after one pass of SR.

Statistical analysis

The number of FPR were summarized as counts and percentages. Differences of FPR between each subgroup were tested with the Fisher's exact. The Fisher exact test was used to compare the numbers of FPR between the following subgroups:

1- The Solitaire FR versus the EmboTrap SRs subgroups,
2- The GC versus the BGC subgroups,
3- The RBC-rich versus fibrin-rich clots,
4- The IC versus no-IC subgroups,
5- The no-IC versus Solumbra technique versus partial retrieval technique subgroups,
6- The no-IC and GC versus no-IC and BGC subgroups,
7- The IC and GC versus IC and BGC subgroups,
8- The Solitaire FR with Solumbra technique versus the EmboTrap with Solumbra technique subgroups,
9- The Solitaire FR with partial retrieval technique versus the EmboTrap with partial retrieval technique subgroups,
10- The RBC-rich clots with Solumbra technique versus Fibrin-rich clots with Solumbra technique subgroups,
11- The RBC-rich clots with partial retrieval technique versus Fibrin-rich clots with partial retrieval technique subgroups,

A Bonferroni correction was applied to correct the results of the comparison tests by dividing the alpha level of 0.05 by the number of tests (n = 11). The Bonferroni-corrected p-value was of 0.005 which was new threshold that needed to be reached for a single test to be considered as significant. The statistical analyses were performed with the R software, version 3.2.1 (R foundation for Statistical Computing, Vienna, Austria).

Results

In total, 144 experiments were performed without any technical difficulty with RBC rich (n = 72) and fibrin-rich clot analogues

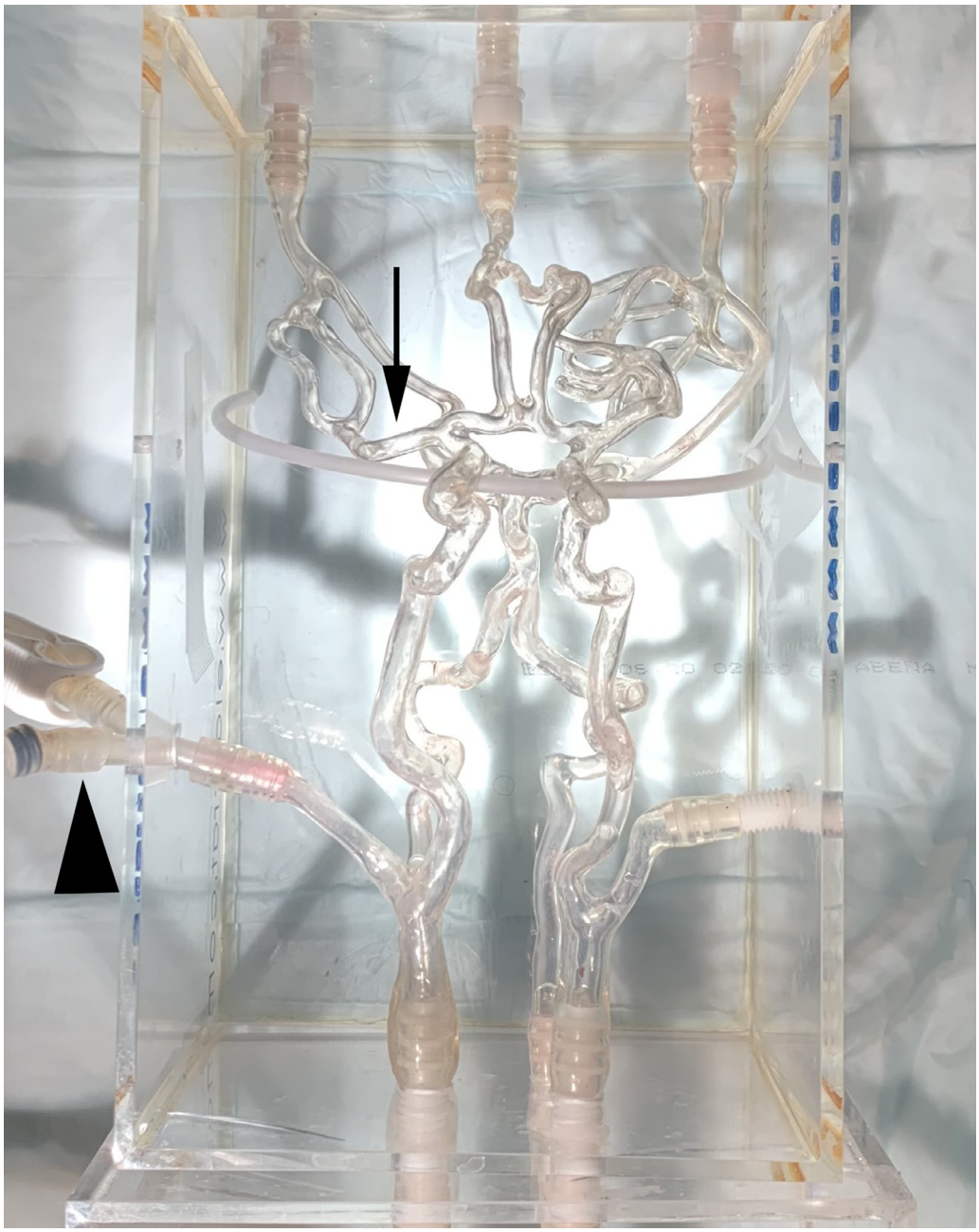

Fig. 1. Silicone vascular flow model used in this study to complete the in vitro mechanical thrombectomy procedures; highlighting the side port into which clot was introduced (arrow head) and M1 where occlusion occurred (arrow).

(n = 72). The rates of FPR according to MT technique, stent retriever device, and clot composition are listed in Table 1 and summarized in Fig. 2. The overall FPR rate with the SR was 74.3%. The highest rates were observed with the partial retrieval technique, with 100% of full recanalization in all cases, regardless of clot composition, the use of BGC or different types of stents.

Mechanical thrombectomy technique

- Guide Catheter vs. Balloon Guide Catheter

The overall rate of FPR was 87.5% for procedures employing a BGC compared with 61.1% for those in which a GC alone was used (p < 0.001). In the absence of an IC, the recanalization rate was 87.5% with the BGC compared with 4.2% with GC (p < 0.001). When an IC was employed, inflation of the balloon conferred no additional benefit; FPR was achieved in 89.6% of procedures performed with GC compared with 87.9% procedures with BGC (p = 0.75).

- Intermediate Catheter Technique

The overall rate of recanalization was 89.6% for procedures using an IC versus 45.8% in procedures in which an IC was not used. Solumbra technique resulted in FPR in 77.1% of procedures versus 100% with the partial retrieval technique (p < 0.001). Recanalization failures with Solumbra techniques were always due to migration of a fragmented RBC clot during the stent withdrawal within the IC.

- Stent Retriever Device

The overall rate of FPR was 80.6% for procedures performed using the EmboTrap device compared with 68.1% for procedures performed

Table 1
Breakdown of results based on access catheter (GC vs BGC), clot analogue type (RBC or fibrin-rich), SR device (EmboTrap 5 × 21 mm vs Solitaire 4 × 20 mm), IC and retrieval technique (Solumbra or partial retrieval) used for each in vitro MT procedure of this study.

Access Catheter	Retrieval Technique	Clot Tested	Device	FPR (%)
GC	n/a	RBC	EmboTrap	1/6 (17)
			Solitaire	0/6 (0)
		Fibrin	EmboTrap	0/6 (0)
			Solitaire	0/6 (0)
BGC	n/a	RBC	EmboTrap	6/6 (100)
			Solitaire	6/6 (100)
		Fibrin	EmboTrap	5/6 (83)
			Solitaire	4/6 (67)
GC	Solumbra	RBC	EmboTrap	5/6 (83)
			Solitaire	3/6 (50)
		Fibrin	EmboTrap	6/6 (100)
			Solitaire	5/6 (83)
BGC	Solumbra	RBC	EmboTrap	5/6 (83)
			Solitaire	1/6 (17)
		Fibrin	EmboTrap	6/6 (100)
			Solitaire	6/6 (100)
GC	Partial Retrieval	RBC	EmboTrap	6/6 (100)
			Solitaire	6/6 (100)
		Fibrin	EmboTrap	6/6 (100)
			Solitaire	6/6 (100)
BGC	Partial Retrieval	RBC	EmboTrap	6/6 (100)
			Solitaire	6/6 (100)
		Fibrin	EmboTrap	6/6 (100)
			Solitaire	6/6 (100)

GC: Guide Catheter, BGC: Balloon Guide catheter, FPR: First Pass Recanalization, RBC: Red Blood Cells.

using the Solitaire device (p = 0.09). Clot composition did not significantly affect the performance of the SR. There was no difference in recanalization rates between the EmboTrap and Solitaire devices when the partial retrieval technique was employed. A higher recanalization rate was observed with the EmboTrap device compared with the Solitaire device when the Solumbra technique was used but without any significant difference (91.7% vs. 62.5%, p = 0.02).

Clot histology

FPR was achieved in 70.8% of procedures performed using an RBC clot compared with 77.8% of procedures performed using a fibrin-rich analogue (p = 0.3). Solumbra technique was associated with higher FPR rates for fibrin-rich clots compared with RBC clots (95.8% vs. 58.3%; p = 0.002). However, 62.5% of these Solumbra retrievals were converted to partial retrieval (as part of the technique) due to significantly high force of retrieval of the SR into the IC, another 8% of Solumbra retrievals damaged the IC, and another 17% blocked the access catheter with the clot after IC withdrawal. For RBC rich clots retrieved with the Solumbra technique, all recanalization failures were due to clot fragmentation upon entry into the IC and distal clot migration responsible for M1 occlusion. When the partial retrieval technique was employed, FPR was observed in 100% of procedures for both types of clot analogue (p = 1).

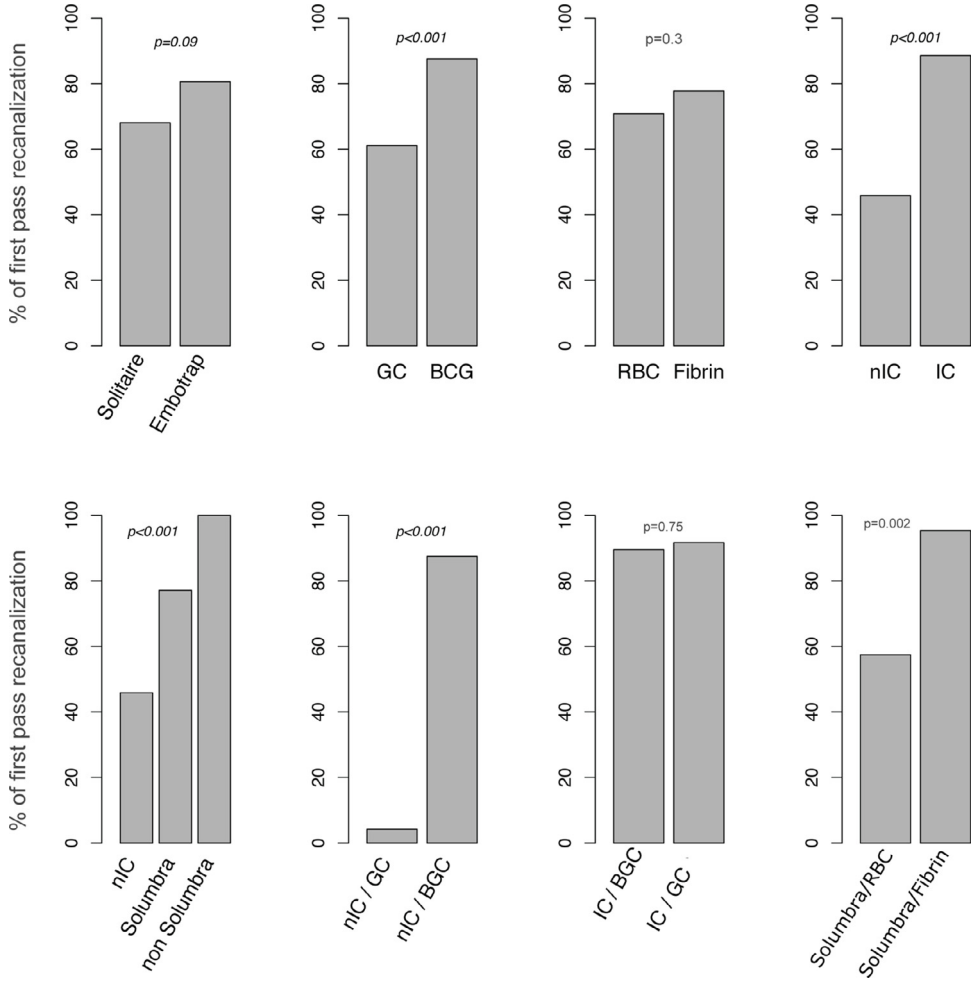

Fig. 2. Summary of results based on access catheter (GC vs BGC), clot analogue type (RBC or fibrin-rich), stentriever device (EmboTrap vs Solitaire), IC and retrieval technique (solumbra or non solumbra) used for each in vitro MT procedure of this study.

Discussion

Nowadays, achieving complete revascularization with a single pass should be the primary angiographic goal of MT in patients with acute ischemic stroke secondary to LVO.[2-4] The FPR is a strong predictor of good outcome.[4] In our work, we explored different factors that are known to potentially impact the FPR in MT for AIS related to LVO. To our knowledge, this is the first study comparing the recanalization rate of different techniques with two different types of clots on such a large number of thrombectomies.

In this study, we found that BGC significantly improved FPR, regardless of the clot histology or the stent retriever used. The lowest rate of recanalization was obtained with the GC alone. The use of a GC alone seems a less effective method for FPR compared to flow arrest with a BGC. The antegrade flow may put greater force on the clot that makes it more challenging to retrieve and increased risk of distal embolization.[21] This was possibly attributable in part to the high circulatory flow in the model and the complete circle of Willis, which was selected to simulate the most challenging flow conditions. These results highlight the benefit of the BGC in thrombectomy procedures and are consistent with the literature data.[22-25] Clinical trials are ongoing and should address this point with clinical evidence.[26] Interestingly, in agreement with prior studies,[27] we observed that the BGC yielded no incremental benefit compared with GC alone when the MT was performed with an IC. This was probably due to a lower efficiency of cervical ICA proximal aspiration via the BGC when IC was used. In addition, stopping the flow in the ICA causes a reversion of the flow in the posterior communicating artery and A1 responsible for an anterograde flow in M1.[7] However, the use of a BGC may still be beneficial in patients without a complete Circle of Willis where this flow arrest and reversal may be further exaggerated.

In the present study, compared to Solumbra technique, the partial retrieval was more effective resulting in complete revascularization with a single pass in all simulated procedures, regardless of clot histology, SR type or support catheter. This result is consistent with the clinical literature.[7] In our knowledge there is no in vitro study comparing the efficacy of Solumbra technique versus other IC techniques. Mokin et al.[28] compared the efficacy of a combined SR-IC approach versus SR alone and found better recanalization rates in the combined group. Maus et al.[7] reported that the partial retrieval techniques like ARTS and SAVE were superior to the Solumbra technique regarding the FPR due to less clot fragments in the partial retrieval approach, especially in friable RBC rich clots.[29]

Overall recanalization rates were similar for RBC clots and fibrin-rich clots. In the partial retrieval technique, successful retrieval occurred more frequently with fibrin rich clot. The use of an IC yielded a greater benefit in retrieving fibrin-rich clots compared with RBC clots, as RBC clots were more prone to fragmentation upon retrieval into the IC as described in previous in vitro study.[29] This highlights the role of pre-procedural imaging which may influence the choice of thrombectomy technique if the nature of the clot can be assessed.[30]

Limitations

Our findings should be interpreted in the context of certain limitations. While the model used in the study replicates the size and the morphology of the human arterial tree, it does not reproduce anatomical variations and MCA angulation that can affect MT effect. In addition, the silicone material has a higher tensile strength and a higher coefficient of friction than human intracranial arteries.[31] These physical properties of the material do not reproduce exactly the interaction between the clot with the arterial wall that might affect the clot retrieval. However, in the present study we compared the current MT techniques and devices in a standardized and reproducible manner with a large sample size. This should have mitigated the previous limitations by strengthening our results. We compared only two SR devices; therefore, our result cannot be generalized to all. Finally, the clot analogues used in the study were homogenous and uniform in size. Even though this was necessary to facilitate standardized comparisons of MT techniques and SR devices, this is unlikely in clinical practice. Another limitation is the number of variables explored in this study that can reduce the strength of the study. To mitigate this limitation, we performed multiple MT for each experimental conditions and we applied a multiple testing correction. To confirm our results, larger scale in vitro studies on fewer variables are mandatory.

Conclusion

Comparison of MT techniques in an in vitro model of acute ischemic stroke demonstrated that procedural efficacy was influenced by thrombectomy technique, clot composition, and SR device. The highest rates of FPR were observed with the partial retrieval technique regardless of clot histology, SR generation or support catheter. Mechanical thrombectomies using SR and GC, without IC, provided the worse rates of recanalization. BGC increased the probability of FPR compared to GC only in cases of procedure performed without an IC. Fibrin-rich clots were associated with higher overall recanalization rates and a lower risk of fragmentation compared with friable RBC clots.

All authors have made substantial contributions to all of the following

The conception and design of the study: GG, OFE,
Acquisition of data: GG, OFE, CD
Analysis and interpretation of data: GG, OFE, LPH
Drafting the article or revising it critically for important intellectual content: GG, OFE, FC, VC

Author contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship

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Declaration of Competing Interest

The authors declare that they have no known competing financial or personal relationships that could be viewed as influencing the work reported in this paper

Human and animal rights

The authors declare that the work described has not involved experimentation on humans or animals.

Informed consent and patient details

The authors declare that the work described does not involve patients or volunteers

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