Original Paper

Novel Distal Emboli Protection Technology: The EmboTrap

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Abstract
Background: Over the course of the thrombectomy procedure, clot fragments may become dislodged and lead to downstream emboli due to manipulation of an endovascular device. The EmboTrap thrombectomy system features an inner stent channel with an outer stent trap design that may potentially reduce the risk of distal clot fragmentation during clot removal. We tested the hypothesis that distal emboli to both the same and new territory generated during mechanical thrombectomy are a function of device design. ***Methods:*** EmboTrap and Solitaire thrombectomy were conducted in an in vitro model system that mimicked a middle-cerebral artery (MCA) occlusion within a complete circle of Willis vascular replica and a contrast-enhanced clot analog. Emboli generated during the procedure with a size >1,000 μm were collected and measured with calipers. The Coulter principle was used to characterize emboli with a size between 200 and 1,000 μm. ***Results:*** EmboTrap thrombectomy resulted in a significant reduction in the risk of large emboli (>1,000 μm) formation as compared to first-generation stent retriever thrombectomy (p = 0.031, Fisher exact test). The majority of emboli >1,000 μm (~80%) were found in the MCA, regardless of device type. There was no significant difference between the EmboTrap and Solitaire in 200 to 1,000 μm emboli formation (p = 0.89, Mann-Whitney test). When combining all emboli in the most dangerous range (>200 μm), EmboTrap offered a size reduction of emboli (p = 0.022). ***Conclusion:*** The risk of distal embolization can be altered with improved stent retriever design. When encountering fragment-prone clots, EmboTrap thrombectomy may lower the risk of distal embolization.

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Introduction

The findings of recent randomized controlled trials have shown a large benefit from stent retriever-mediated endovascular thrombectomy for selected acute ischemic stroke patients with large-vessel occlusion in the anterior circulation [1–5]. Recanalization rates have improved significantly with stent retriever thrombectomy with meta-analyses of the randomized trials yielding mTICI (modified treatment in cerebral infarction) 2b–3 reperfusion of 70–80% and 90-day modified Rankin Scale 0–2 outcomes of 46–54% [6, 7]. Some of the areas under investigation to further improve outcomes include improving the rates of full TICI 3 perfusion, minimizing the number of thrombectomy passes required to achieve full reperfusion, and reducing the rates of distal and new territory embolization.

Different thrombectomy techniques and different device designs may influence the rate of embolic events. Studies have suggested that protective effects may be achieved using proximal flow control with a balloon guide catheter [8–11]. The ability of the stent retriever to retain the clot in the stent struts during clot retrieval is an important predictor of successful recanalization and may in part be affected by the device design. Loss of interaction between clot and stent retriever when passing the tortuous cerebral arteries can result in partial or failed thrombectomy, which increases the need for multiple passes and additional rescue therapy. Multiple passes may be associated with poorer clinical outcomes due to delay of recanalization [12] or injury to the vessel [13–16].

The Conformité Européenne (CE)-approved EmboTrap® Revascularization Device (Neuravi Ltd., Galway, Ireland) has a dual-layer structure. The outer open structure of the device is designed to engage the clot with minimal maceration and pin it to the inner stent-like channel [17]. The EmboTrap device also features a distal emboli protection zone to catch possible clot fragments generated during mechanical thrombectomy. The objective of this study is the characterization of distal emboli generated during EmboTrap thrombectomy as compared with existing, first-generation stent retriever technology for the treatment of acute ischemic stroke. It is our hypothesis that the efficacy of thrombectomy devices as indicated by the risk of embolic shower may potentially be altered by stent retriever design alone.

Methods

Creation of Middle-Cerebral Artery Occlusion

Mechanical thrombectomy was performed in a patient-specific circle of Willis model which was connected to a circulation flow loop in preparation for simulation of cerebrovascular occlusion. The circle of Willis model was selected based on data from magnetic resonance angiograms of 20 patients and had a representative internal carotid artery (ICA) siphon in terms of curvature (0.36 mm^{-1}), diameter (4.21 mm), and length (20.62 mm). During the image post-processing, the 3-D reconstruction of the vasculature was modified to rejoin the M2 and A2 divisions, resulting in a single output from each vascular territory. The virtual design was finally transformed into a physical silicone model using a 3-D printing-assisted manufacturing process [18].

The circle of Willis model was connected to a flow loop which contained a peristaltic roller pump used to deliver an oscillatory flow of saline solution and adjustable clamps to allow the tuning of the peripheral resistance [19]. Real-time flow distribution was monitored using flow sensors (Transonic Systems Inc., Ithaca, NY, USA). Pressure transducers (Validyne Engineering, Northridge, CA, USA) recorded the ICA and distal middle-cerebral artery (MCA) pressure. The model was calibrated to maintain physiologically representative flow in each branch of the model.

An inelastic clot model was generated by thrombin-induced clotting of bovine blood (2.5 NIH-U thrombin/mL blood) with addition of barium sulfate (1 g/10 mL blood). This type of clot was prone to fragmentation during mechanical thrombectomy and was chosen to mimic the worst-case scenario with respect to clot fragmentation. A segment of clot (4 mm in diameter and 8 mm in length) was introduced into the ICA and was carried to the MCA bifurcation by the fluid flow. Details regarding the composition and mechanical behavior of the aforementioned clot model are described elsewhere [20].

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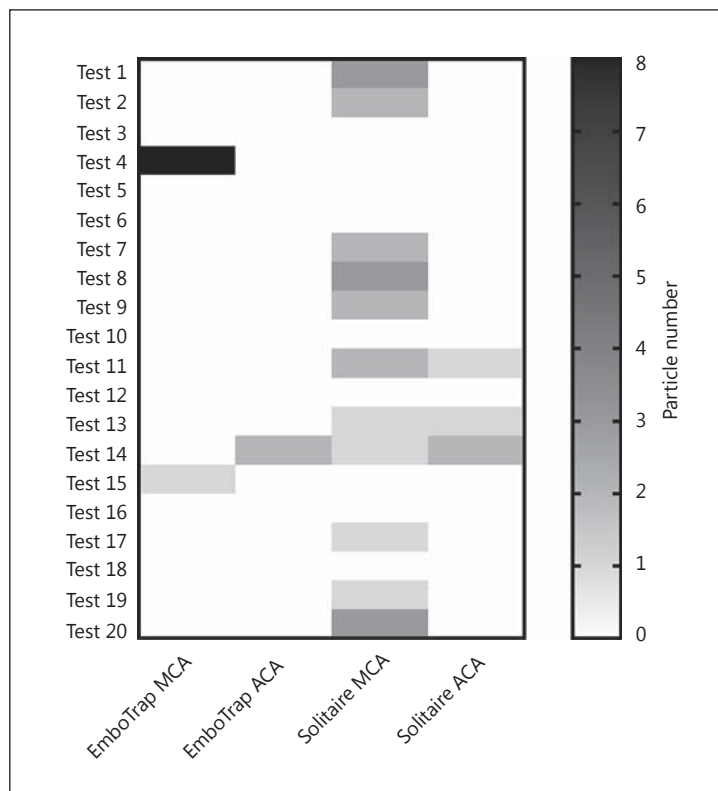
Fig. 1. Frequency of emboli formation of >1,000 μm. MCA, middle-cerebral artery; ACA, anterior cerebral artery.

Flow Restoration Procedure

A Neuron Max 088 guide catheter (Penumbra, Oakland, CA, USA) was placed in the cervical ICA and delivered the 0.014-inch microwire which was then softly advanced through the clot. A Headway 021 microcatheter (MicroVention, Tustin, CA, USA) was navigated over the wire across the occlusive clot. The microwire was withdrawn followed by device (EmboTrap® or Solitaire™ FR) deployment for mechanical thrombectomy. The commercially available Solitaire device served as the control device in this study, and active push deployment technique was used to improve the interaction between stent retriever and clot [21]. The device size was 4 mm × 20 mm for the Solitaire device and 5 mm × 21 mm for EmboTrap. During retriever retraction, continuous aspiration was applied during retrieval with the assistance of an aspiration pump. Twenty experiments were carried out for each device. The maximum number of thrombectomy attempts was limited to 3.

Particulate Analysis for Distal Emboli

Collection of clot fragments started immediately prior to device deployment and ended after clot removal. Clot fragments generated during thrombectomy washed into 2 collection reservoirs, one for emboli to the MCA distribution and the other for emboli to the anterior cerebral artery (ACA) distribution, where they were collected and analyzed. First, clot fragments >1,000 μm were manually separated from the collection chamber and measured with calipers, while those with a size between 200 and 1,000 μm were measured with a Coulter counter.

The primary endpoint was the number and size of distal clot fragments generated during the procedure. The secondary endpoint was the rate and number of passes to achieve full flow restoration.

Statistical Analysis

Statistical analyses were performed with Prism software (GraphPad, San Diego, CA, USA). Results were shown as means ± standard deviations. The medians of 2 independent groups, if non-normal distributions, were analyzed using the Mann-Whitney test. Categorical comparisons were made using the Fisher exact test. Significance was concluded when $p < 0.05$.
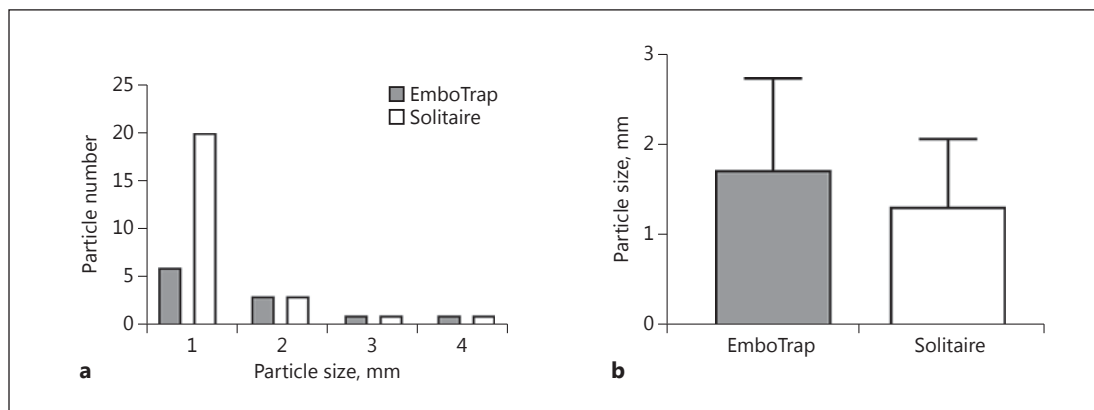
Fig. 2. a Size distribution of clot fragments. The majority of the fragments have a size of 1 mm. **b** Average size of clot fragments (>1,000 μm) produced during mechanical thrombectomy.

Results

Number of Clot Fragments with a Size >1,000 μm

Formation of clot fragments with a size >1,000 μm was observed in 15% of cases in the EmboTrap group versus 55% of cases in the Solitaire control group (Fig. 1). The risk of embolic events in the EmboTrap and Solitaire groups was 10 and 45%, respectively, when using only first-pass data.

EmboTrap thrombectomy reduced the generation of hard clot fragments with a size >1,000 μm by >50%, as compared to Solitaire thrombectomy ($p = 0.0096$, Mann-Whitney test). The clot fragments had a size ranging from 1,000 to 4,000 μm (Fig. 2a). There was no significant difference in average clot size between EmboTrap and control groups (EmboTrap: 1,727 ± 1,009 μm, Solitaire: 1,320 ± 748.3 μm; Fig. 2b). Importantly, there was a significant reduction in the frequency of large clot fragmentation (>1,000 μm) dislodgement ($p = 0.031$, Fisher exact test).

Number of Clot Fragments with a Size between 200 and 1,000 μm

There was no significant difference between the EmboTrap and Solitaire devices in clot fragment creation within the 200 to 1,000 μm size range ($p = 0.8953$, Mann-Whitney test). A broader size distribution of clot fragments was observed with the Solitaire device (200–770 μm) compared to the EmboTrap device (200–325 μm). Formation of 200 to 1,000 μm clot fragments was observed in >50% cases regardless of thrombectomy devices (Fig. 3). Excluding those trials where more than one thrombectomy attempt was required, the same results were observed. When combining all particles >200 μm, EmboTrap offered a size reduction of clot fragments (545 vs. 650 μm, $p = 0.0222$; 314 vs. 685 μm, $p = 0.008$ when using only first-pass data).

Distribution of Clot Fragments

The majority of the disrupted clots with a size >1,000 μm were found in the MCA (approximately 80%) in both the EmboTrap and Solitaire groups. On average, 25 and 46% of the clot fragments with a size between 200 and 1,000 μm travelled through the ACA (unaffected area) with the use of EmboTrap and control devices, respectively. Although the distribution difference did not meet statistical significance ($p = 0.0656$, Fisher exact test), there is a trend of nearly doubling the percentage of emboli that flow to the ACA in the control group.
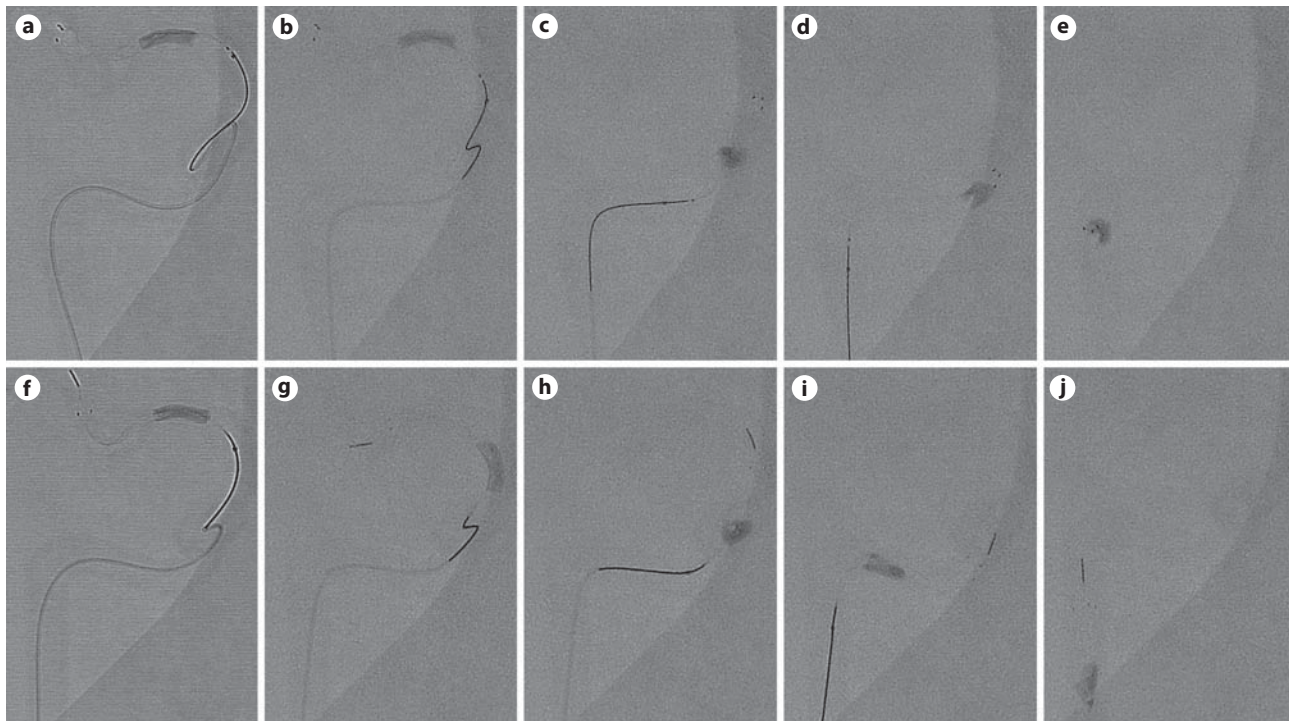
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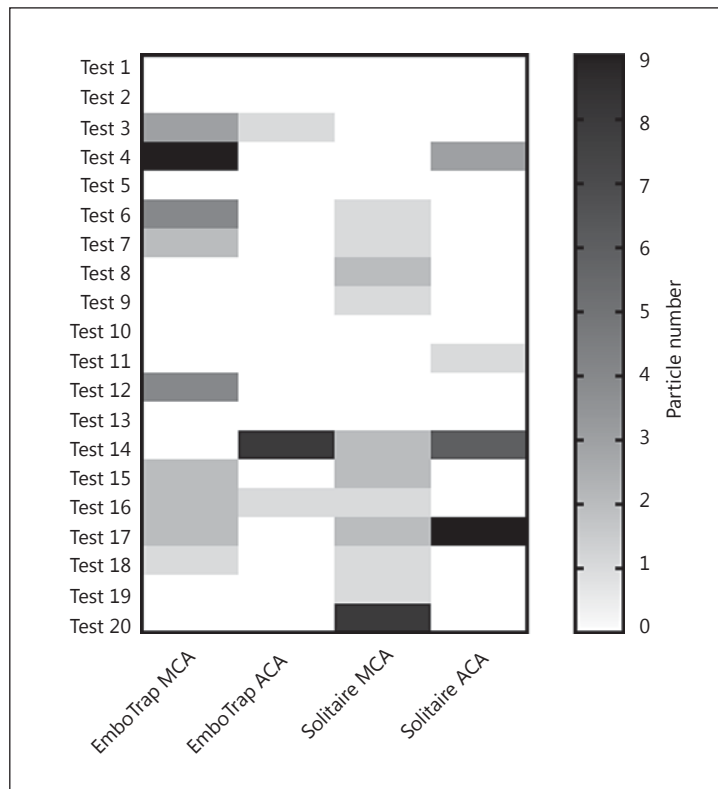
Fig. 3. Frequency of emboli formation of 200–1,000 μm. MCA, middle-cerebral artery; ACA, anterior cerebral artery.

Recanalization Rate and Flow Restoration

The efficacy of removing the occlusion was very high (>90% first-pass success) in both arms. The EmboTrap devices achieved a 100% flow restoration in all cases, whereas a 95% recanalization rate was observed with the control devices. Successful clot removal was achieved at the first attempt in 19 out of 20 cases in the EmboTrap group and in 18 out of 20 cases in the Solitaire group. Although there was no statistical difference in the mean number of pass attempts in the EmboTrap and control groups (1.1 and 1.2, respectively), the number of attempts was, in general, one of the determinants of embolic shower produced during mechanical thrombectomy.

Clot Engagement and Removal through Thrombectomy Devices

Clot disruption during device retraction was observed to a lesser degree with the EmboTrap device as compared to thrombectomy with Solitaire. Figure 4a–e shows that despite the clot appearing to be integrated with the control device at the beginning of retraction, during passage of each ICA turn (entering the ICA terminus from M1, siphon, and petrosal cervical transition), the clot was progressively disrupted and unstable, thus increasing the potential risk for multiple distal emboli. On the other hand, examples of clot engagement through the EmboTrap stent struts are demonstrated in Figure 4f–j, which enabled successful clot retrieval. Co-aspiration with a pump was used during this bench test to ensure consistency of aspiration across each thrombectomy run and was helpful in mitigating the embolization risk for fragments forming while entering the receiving catheter.

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Fig. 4. Still images captured during a single pull of the Solitaire stent (top panels) and of the EmboTrap device (bottom panels) to extract a radiopaque clot. The clot is engaged into the proximal part of the Solitaire stent (**a**), the pass is initiated (**b**), and as it navigates through the siphon (**c**, **d**), the clot slips along the surface of the device and is only held by the distal end of the Solitaire stent (**e**). The same procedural steps are illustrated for the EmboTrap device (**f–j**), showing clot retention at the same location of the device through all aspects of the thrombectomy.

Discussion

The efficacy profile of the EmboTrap device was examined in a reproducible experimental setup. The high rate of MCA recanalization observed in this in vitro study is in line with a previous multicenter study in 40 patients [17]. The extent of clot integration into the EmboTrap device was assessed by taking the advantage of the transparent vascular model and radiopaque clot. Furthermore, the open flow loop allowed us to record the risk of distal embolization during EmboTrap thrombectomy in a manner that facilitated comparisons with the gold-standard first-generation stent retriever for clearing large-vessel occlusions.

There have been continuous advances in endovascular techniques for acute ischemic stroke over the past decade, from intra-arterial thrombolysis, Merci Retrievers, and Penumbra aspiration to recent stent retrievers [22, 23]. Compared to the first-generation Merci and Penumbra thrombectomy devices, technical improvements in design of stent retriever-based technology have resulted in higher rates of successful recanalization and improved functional outcome [24, 25].

The EmboTrap is composed of a 2-layer Nitinol structure with a closed tip to facilitate capture of clot debris. Use of the EmboTrap revascularization device was not only associated with a statistically lower number of distal emboli with a size >1,000 μm, but also with a less frequent occurrence of embolic events. In addition, when combining all particles >200 μm, EmboTrap offered a size reduction of clot fragments. Although only marginally significant, the

Table 1. Reported clinical rates range from 0 to 12.5% embolization to new territory

Study	Subjects, n	New territory embolization	Distal embolization	Ref.
Gascou et al., 2014	144	18 (12.5%)		26
Kurre et al., 2013	105	12 (11.4%)		31
NASA, 2013	338	18 (5.3%)	55 (16.3%)	11
Gratz et al., 2014	227		15 (6.6%)	27
MR CLEAN, 2015	233	20 (8.6%)		1
EXTEND-IA, 2015	35	2 (5.7%)		2
Klinger-Gratz et al., 2015	57		13 (22.8%)	28
McTaggart et al. (traditional group), 2016	53	6 (11.3%)		32
McTaggart et al. (CAPTIVE group), 2016	39	2 (5.1%)		32

distribution of disrupted emboli to the ACA territory was almost doubled with Solitaire ($p = 0.0656$). This likely points to a mechanism where the clot is plowed against the wall by the device and fragments are dislodged into the ACA with the first-generation stent retrievers, whereas the EmboTrap reduces emboli to the ACA by capturing the clot between the inner and outer stent features.

The presence of embolic complications has been associated with poorer outcomes [26, 27]. Reported clinical rates range from 0 to 12.5% embolization to new territory (Table 1). Assessment of distal embolization with angiography can be difficult, and a recent study using susceptibility-weighted imaging indicated that rates may be in the range of 23% [28]. Susceptibility-weighted imaging seems to be more sensitive to detect emboli than digital subtraction angiography.

In this study, we only characterized clot fragments with a size >200 μm. This is due to the limited amount of samples collected during device deployment and retrieval. It should be taken into consideration that the clot fragments generated during the EmboTrap procedure are potentially smaller, since the clot fragments associated with Solitaire thrombectomy could dislodge and further fragment while traveling downstream. Prior quantitative studies have shown the enormous advantage of balloon guide catheter-assisted stent retriever thrombectomy [29, 30]; however, we chose to use a long sheath, since this is clinically representative and enables testing the hypothesis that stent retriever design alone can alter rates of distal emboli. Subsequent studies should assess adjunctive techniques, such as proximal flow control with and without distal access catheter thromboaspiration.

Conclusions

Our preliminary data confirm the hypothesis that stent retriever design can be optimized to alter the particle size distribution of distal emboli. When encountering friable hard clots, the use of the EmboTrap device may provide an additional reduction in distal emboli to both affected and unaffected territories.

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Statement of Ethics

This is an in vitro study. No human or animal subjects were involved in this study.

Disclosure Statement

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