A Novel Thrombectomy Device: An In Vitro Evaluation of a Prototype Catheter

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A novel thrombectomy device: an in vitro evaluation of a prototype catheter

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Abstract

Purpose: This prototype catheter is a newly-developed distal access catheter featuring a self-expanding, flexible, funnel-shaped tip. The purpose of its design is to reduce the risk of thrombus fragmentation during mechanical thrombectomy and improve first-pass recanalization (TICI 3). In this experimental setup, we preclinically evaluated the effectiveness and navigability of the new catheter.

Methods: A vessel model was filled with a blood-like-viscous medium, and the image was projected with the corresponding vessel area by camera transmission to correspond to the conditions in an angiography. Thrombi from porcine blood were placed into the Arteria Carotis interna of the vascular model and subsequently mechanically thrombectomized with a stent retriever. In the first part, the prototype was compared to a standard distal-access-catheter without using an external catheter. (N = 20 for each catheter). In the second part the prototype was inserted through a guiding catheter (n=11) to determine the navigability performance.

Results: In the first experimental series, mechanical thrombectomy was successful 19 out of 20 times (95% success rate) for the prototype catheter versus 15 out of 20 times (75% success rate) for the standard distal-access-catheter. In the second experimental series, the prototype catheter achieved first-pass recanalization 10 out of 11 times (91% success rate) and 1 out of 11 times at second pass (9%).

Conclusion: This series of experiments demonstrated higher first-pass recanalization rates for the newly-developed funnel-shaped prototype featuring a self-expanding tip in comparison to a cylindrical standard distal-access-catheter.
Introduction

Mechanical thrombectomy (MT) has become the standard treatment for acute ischemic stroke (AIS) in large vessel occlusions (LVO) of the anterior circulation[1]. Several studies have demonstrated the benefits using MT in combination with IV rt-PA lysis. By combining these two procedures significantly higher recanalization rates, ranging from 55 to 89% (TICI ≥ 2b) were achieved, compared to using IV lysis alone[2-6]. However, improved long-term functional outcome, defined as modified Ranking Scale (mRS) < 2, was registered in only 33-60% of cases. This could be caused by clot fragmentation during MT resulting in embolization of peripheral vessels in up to 17% of cases and embolization in new territories (ENT) in 2 to 11% of cases.

Clot fragmentation during MT may occur at different times, during stent retriever retraction before reaching the catheter tip or at the wall of the catheter. To the best of our knowledge, this problem still remains unresolved. Parts of the thrombus can be carried to the periphery during MT, thereby occluding collateral vessels. This can often cause irreversible damage to the brain parenchyma. This is associated with worsening neurological outcome and increased mortality rates[7-9]. The rate of TICI 3 recanalizations can be considered as a suitable and clinically relevant safety measure for studies evaluating MT devices and techniques[10].

Thrombus loss or fragmentation of the thrombus at the catheter wall could be caused by the cylindrical shape of a standard distal-access-catheter (DAC) which does not expand across the entire vessel lumen. The disproportionally larger size of the self-expanding stent retriever in relation to the smaller opening of a standard DAC during retraction may lead to clot abruption at the wall of the tip. Currently, only cylindrically shaped catheters are available, which cannot be adjusted flexibly to the inner diameter of the distal end.
Therefore, the Department of Neuroradiology at the University Hospital Mainz, Germany, developed a novel catheter designed to prevent thrombus loss and fragmentation at the catheter wall during stent retriever retraction. A recent proof-of-principle-study showed a better recanalization rate for the funnel-shaped tip compared to a standard cylindrical tip\cite{11}. Our prototype catheter (PC) was developed on this basis. In the first part of the present study, this prototype was tested for functionality and effectiveness of the funnel-shaped extension. The second part of the trial, focused on determining the handling and navigability performance of the new catheter. We used the ACI because the funnel-shaped tip of our PC occludes this lumen of about 0.25-0.35 cm\cite{12} totally occludes. In this segment, too, endovascular treatment has become the standard of care for acute ACI occlusions\cite{13}.

**Materials and Methods**

**Experimental setup**

An anatomical vascular model (Neuro System Trainer with 6 Aneurysms NST00V02 #5117, United Biologics, California, USA) was used to perform the experiments. The structure of the transparent silicone model includes an aortic arch with bilateral branches of the common carotid arteries, vertebral arteries, and intracranial arterial supply (Figure 1). A solution mimicking blood-like viscosity was used as a substitute for human blood. Distilled Water containing 40 % glycerol (Glycerin 85%; Caesar & Lorenz GmbH, Hilden, Germany) was freshly mixed prior to each experiment and used at body temperature.

In the first part of the experiment, thrombectomy was performed in the vessel model and in a small number of cases under fluoroscopy in angiography.
In the second part of the experiment, the model was projected onto a screen with the aid of a video camera to realistically simulate working with the catheter and to better assess its handling.

The experimental setup is shown schematically in the figure above (Figure 2).

**Processing of thrombi**

A Chandler Loop System, which mechanically simulates extracorporeal blood circulation was used to generate the required thrombi. Venous blood was taken from live pigs (German Landrace) prior to being sacrificed in other approved and unrelated final animal experiments.

Immediately after taking blood, polyvinyl chloride (PVC) laboratory tubes (clear PVC tubing, inner diameter 8.0 mm, outer diameter 12.0 mm; Thermo Scientific Fischer, Waltham, Massachusetts, USA) were half-filled with the freshly-extracted blood. Then the tubes were closed and transferred to the rotation unit of the Chandler Loop System which was set to 15 rotations per minute. The temperature-controlled water basin was preheated to 38.5°C in advance. After the blood had clotted (approximately after 20 minutes), the tubes were removed, the thrombi captured in Iodine (Solutrast) and stored in a refrigerator for a maximum of two days until used in the experiment.

For the MT experiments with the prototype catheter, only mechanically-prepared clots were used within 0-24 hours after preparation. This was based on the results obtained from previous experiments. Thrombi prepared by a Chandler loop and used within 0-24h showed a tendency towards improved recanalization compared to thrombi prepared under static conditions.
Ethics approval: Animal experiments were carried out after receiving approval by the local governmental committee (Landesuntersuchungsamt Rheinland-Pfalz, Germany) under the reference numbers AZ G 14-1-093 and AZ 23177 – 07 A16 -1-001 AFW and in accordance with the German Animal Welfare Act (Tierschutzgesetz). All applicable international, national and/or institutional guidelines for the care and use of animals were adhered to. We confirm that the study was carried out in compliance with the ARRIVE guidelines.

The Prototype

The Prototype Catheter (PC) has a modified, funnel-shaped flared distal end made of a vessel-protecting, flexible Nitinol stent mesh. The PC is a modified DAC. It runs inside a Guiding Catheter (GC).

The inner and outer diameters of the PC enable the catheter to fit into a GC and is also large enough to accommodate a microcatheter with stent retriever (SR).

In addition to its guiding function, the GC acts as a shell to prevent the self-expanding tip of the prototype from erecting.

The funnel-shaped end of the new catheter has been designed so that the maximum diameter of the opening extension continues cylindrically over a length of approximately 2-3 cm (Figure 3). This cylindrical lumen has the same flexibility and erectile force as the proximal funnel-shaped portion. The design was chosen to allow the lumen of the prototype to adapt to the vessel diameter over a longer distance and to provide a protective sheath around the retrievable stent. To ensure visibility under fluoroscopy, the funnel-shaped tip is radiopaque marked.

Thrombectomy procedure
For each thrombectomy procedure, the thrombi were cut in 10 mm pieces and flushed into the arteria carotis interna (ACI) of the vascular model, which was then sealed.

In the first part of the experiment, the PC was introduced into the silicone system in the expanded form, without a guide catheter. First, a microcatheter (Trevo® Pro 14 microcatheter, Stryker) with an outer diameter of 2.4 F (0.8 mm) and a microwire (Traxcess®, MicroVention GmbH, Düsseldorf, Germany) were advanced into the respective catheter and probed past the thrombus. After removal of the wire, the stent retriever (Trevo® XP ProVue 3/20 mm; Stryker, Kalamazoo, Michigan, USA) was released over the thrombus. Subsequently, the stent-retriever was deployed for three minutes and then pulled back into the funnel-shaped tip of the PC in the cylindrical shaped Tip of the DAC (Figure 4).

During the second part of the experiment, the PC was introduced inside a guiding catheter (GC) (AXS 7 DAC, Catalyst from Stryker). The GC serves as a shell for the funnel-shaped, not yet expanded catheter tip. The microcatheter and a microwire were probed past the thrombus. After removal of the microwire wire, the stent retriever was also released over the thrombus and the funnel-shaped tip was expanded by pulling back the GC. Subsequently, the stent-retriever was deployed for three minutes and then pulled back into the funnel-shaped tip of the PC.

Statistical Analyses

Statistical analyses were performed using SPSS Software (23.0) (IBM, New York, USA). Usually, the chi-squared test is suited for significance tests of independence in contingency tables. However, a prerequisite is that the number of observations in all groups must exceed five, which is not the case for this dataset. Alternatives to the chi-squared test include the Fisher’s exact test and the Barnard test, which both do not require five observations per group.
Generally, the amount of observations in this dataset is very low (n=20), accordingly, all statistical calculations should be considered carefully.

The level of significance was set at $\alpha = 0.05$.

**Results**

**First experiment**

MT was performed 20 times for each catheter system.

The prototype catheter and stent retriever achieved successful MT in 19 out of 20 cases (95% success rate). In comparison, successful MT for the DAC and stent retriever occurred in only 15 cases (75% success rate). (Figure 5)

Results of thrombectomy with the PC compared with the DAC (AXS 7 Catalyst from Stryker) (Table 1):

| Stent-Retriever Type                              | Prototype Catheter | DAC Catalyst (7F Stryker) | P-value |
|--------------------------------------------------|--------------------|---------------------------|---------|
| Trevo® XP ProVue 3/20 mm (n =20) positive MT     | 19                 | 15                        | 0.053   |
Fisher’s exact test and Barnard's exact test were used to analyse the test data for the two different tested catheters, with dichotomous results (successful thrombectomy, unsuccessful thrombectomy).

The Null hypothesis (catheter type has no effect on the outcome) cannot be rejected on a 5 % significance niveau (p>0.05). Accordingly, there is no statistically significant improvement in using the new prototype catheter over the old DAC catheter.

The odds ratio provides a measurement of how the odds for successful thrombectomies compare for the two catheters. The results of the Fisher’s exact test show an odd’s ratio of 6.1, which means that it is 6.1 times more likely to have a successful thrombectomy using the prototype compared to the DAC. Unfortunately the result is not significant. This is primarily an effect from the small sample size. Repeating the calculations with n = 100 and equal success rates reveals a significantly higher success rate for the prototype catheter.

**Second experiment**

In 10 of 11 cases, MT was successful in the first pass (Figure 6). In 1 of 11 cases, MT was only successful in the second pass (Table 2).

|Prototype Catheter with FlowGate Trevo® XP ProVue 3/20 mm (n =11) positive MT| TICI 3 First Pass| TICI 3 Second Pass|
|---|---|---|
|Prototype Catheter with FlowGate Trevo® XP ProVue 3/20 mm (n =11) positive MT| 10 | 1 |
Discussion

The aim of the present study is to reduce the risk of thrombus fragmentation during mechanical thrombectomy. For this purpose, a novel catheter was developed and manufactured. In an in vitro setup the prototype was tested for effectiveness and handling. In two different experimental approaches, the performance of the newly-developed prototype was tested and compared with a standard DAC.

In the first part of the experiments, successful first-pass recanalization was achieved in 19 out of 20 (95%) cases for the prototype catheter (Figure 7). The thrombus was lost once during retraction before reaching the catheter tip. This was caused by insufficient interaction between the stent retriever and the thrombus. In contrast, MT using the cylindrically shaped commercially available DAC, was successful in 15 of 20 (75%) cases after the first maneuver. The main failure cause was clot abruption and fragmentation at the catheter wall during stent retriever retraction (Figure 8).

Since the thrombus is disproportionally larger than the diameter of common cylindrical catheters, there is a risk that it will be abraded against the catheter wall. We have now been able to confirm the superiority of the funnel-shaped extension from previously published preliminary tests with the new prototype catheter[11].

In the last 20 years, thrombectomy devices and techniques have evolved significantly with results improving gradually over time[14]. Local antegrade/proximal flow arrest can be achieved by using a BGC (balloon-guided-catheter) to prevent thrombus fragments from being dissipated. As a result, significantly higher recanalization rates, 78.9% using a BCG vs. 67.0% for non-BCG MT (TICI $\leq 2b$); and lower mortality rates were achieved[1]. However, local clot fragmentation and dissipation still remains unresolved.

Another concept known as Larzarus Cover and first described in the scientific literature in 2016, involves covering the stent retriever to reduce embolism in new territories [15]. The Lazarus Cover consists of a conically-shaped wire mesh sheath that completely
encases the stent retriever. It is inserted into the vascular system after placement of
the stent retriever and removal of the microcatheter. Using this technique, a
recanalization rate of TICI 2b/3 has been achieved in 95% of cases. Evidence of
occlusion in new territories could not be observed.[16,17]

The Advanced Thrombectomy System (ANCD) is another novel stroke thrombectomy
device featuring a self-expanding funnel-shaped opening, reaching recanalization
rates up to 94%. The results of the underlying study stand in accordance with the
results achieved by the ANCD (94%)[18]. This emphasizes the possibility of increasing
first-pass recanalization rates by using a funnel-shaped distal catheter end.

The main advantages of the newly-developed catheter tested in this study are 1) the
prevention of clot abruption and fragmentation at the catheter wall enabled by the
flexible and funnel-shaped tip, 2) inducing local flow arrest by “sealing” the vessel
lumen after deployment of the dilated end, and 3) ensuring safe retraction by encasing.

The second part of the experiments registered a first-pass recanalization rate of 91%.
A fragment of the thrombus was lost before reaching the prototype in 1 out of 11 passes
due to insufficient interaction between the thrombus and the stent retriever. The
navigability of the new prototype was assessed in an in vitro vessel model by using a
video camera, and a monitor to simulate an angiography setting. MT were performed
by an experienced interventionalist, and both procedure and materials were consistent
with routine practice. Handling and navigability of the prototype were not impaired.

Thus, the present study confirms the results of previous in vitro studies published by
our research group. Moreover, the prototype catheter with its flexible and self-erecting
end successfully demonstrated improved recanalization rates compared with
conventional standard DACs. The new prototype has the potential to improve first-pass
recanalization rates and to reduce clot migration into distal territories.
A major limitation of this research development is that in vivo animal experiments are still pending. The inner diameter of the prototype catheter is another limitation. Due to the PC’s inner diameter, only microcatheters with an inner diameter of 2.4 F (0.08 mm) can be inserted into it. Consequently, only a few stent retriever sizes can be used. Also, the lumen of the prototype catheter is small and already almost completely obstructed by the microcatheter and stent retriever. Because of this limitation, aspiration can only be applied across a small contact area.

The number of MT experiments was limited by the small amount of porcine blood for clot preparation. Furthermore, the effect of IV lysis with rt-PA could not be determined in an in vitro setting. In this study, only one MT technique was used (primary combined approach) although the technical features of the prototype catheter would allow a wider range of techniques to be used in future studies.

**Conclusion**

The experimental series demonstrated that the newly-developed prototype catheter featuring a funnel-shaped and self-expanding tip achieved a higher first pass recanalization rate than a cylindrical standard DAC.
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**Author contributions**

All authors reviewed the manuscript and have approved the submitted version.

Design and conception of the study: Y.T.; S.K.-R.; M.A.B.; A.H.; Data acquisition: Y.T.; S.K.-R.; M.A.B.; A.H.; O.K.; E.S.P.; Analysis and interpretation of data: Y.T.; E.S.P.; M.A.B.; O.K.; Wrote the manuscript: Y.T.; S.K.-R.; Prepared Figures 1-4: N.K.; J.M.-
Legends

Figures

**Figure 1.** The vascular model showing the anatomical vessels.

**Figure 2.** Setup for the second part of the experiment.

**Figure 3.** The flexible tip of the prototype catheter is 2.4 cm long and consists of a flexible nitinol mesh.

**Figure 4.** Porcine blood thrombus (from left to right): a) before MT; b) trapped in the funnel of the PC after MT; and c) after removal from the PC.

**Figure 5.** The prototype catheter achieved a success rate of 95%. The DAC achieves a success rate of 75%.

**Figure 6.** Success of mechanical thrombectomy with the prototype catheter in the first pass

**Figure 7.** Thrombectomy under fluoroscopy with the prototype catheter (arrow) and stent retriever. The funnel-shaped expanded tip of the prototype fills the vessel lumen, enabling the thrombus to be completely retracted into the DAC.

A and B show retraction of the stent retriever toward the prototype catheter.

C and E show retraction of the stent retriever into the prototype catheter.
F shows retraction of the prototype catheter with trapped stent retriever and thrombus, with no evidence of thrombus fragmentation and migration.

**Figure 8.** A normal DAC does not fill the lumen of the vessel. When the trapped thrombus is retracted (E-C), it is abraded against the wall of the DAC (D-F).

### Tables

**Table 1.** Mechanical thrombectomy results for the Prototype Catheter compared with the DAC (AXS 7 Catalyst from Stryker)

| Stent-Retriever Type                                      | Prototype Catheter | DAC Catalyst (7F Stryker) | P-value |
|-----------------------------------------------------------|--------------------|---------------------------|---------|
| Trevo® XP ProVue 3/20 mm (n = 20), positive MT           | 19                 | 15                        | 0.053   |

**Table 2.** Success of mechanical thrombectomy with the prototype catheter in the first and second pass

| Prototype Catheter with FlowGate Trevo® XP ProVue 3/20 mm (n = 11), positive MT | TICI 3 First Pass | TICI 3 Second Pass |
|---------------------------------------------------------------------------------|-------------------|--------------------|
|                                                                                 | 10                | 1                  |
Supplements

Video Clip:

Successful thrombectomy with the new prototype catheter
Figures

Figure 1

The vascular model showing the anatomical vessels.

Figure 2

Setup for the second part of the experiment.
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**Figure 4**

Porcine blood thrombus (from left to right): a) before MT; b) trapped in the funnel of the PC after MT; and c) after removal from the PC.
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Figure 8

A normal DAC does not fill the lumen of the vessel. When the trapped thrombus is retracted (E-C), it is abraded against the wall of the DAC (D-F).

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