Thieme

Comparison of Efficacy, Embolism Rate and Safety of Thrombectomy with Stent Retrievers in an Anterior Circulation Stroke Model

Vergleich von Effektivität, Embolisationsrate und Sicherheit der Thrombektomie mit Stentretrievern bei ischämischem Schlaganfall: eine Studie am Flussmodell

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Key words
thrombectomy, stroke, stent retriever

received 18.11.2017
accepted 04.05.2018

Bibliography
DOI https://doi.org/10.1055/a-0631-4118
Published online: 18.6.2018
Fortschr Röntgenstr 2018; 190: 1053–1058

ISSN 1438-9029

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ZUSAMMENFASSUNG

Ziel In der Therapie des ischämischen Schlaganfalles kommen verschiedene Stentretriever zum Einsatz, die sich in Stentdesign und mechanischen Eigenschaften unterscheiden. Wir führten diese in vitro-Studie durch, um Effektivität, Embolisationsrate und notwendige Retraktionskraft von kommerziell erhältlichen Stentretrievern und zwei Prototypen zu vergleichen.

Material und Methoden In einem Chandler loop generierte Vollblutthromben wurden in das bogig verlaufende M1-Segment eines Silikonmodells der vorderen intrakraniellen Zirkulation eingebracht. Thrombektomiemanöver wurden mit 6 kommerziell erhältlichen Stentretrievern und 2 Prototypen, die sich in der Stärke der Stentstreben unterschieden, durchgeführt. Die Adaptation des Stentretrievers an die Gefäßwand, first pass-Rekanalisierungsrate, Retraktionskraft und Embolisationsrate wurden verglichen.

Ergebnisse Die Stentretriever, die eine vollständige Adaptation an die Gefäßwand zeigten, wiesen eine höhere first pass-Rekanalisierungsrate und geringere Embolisationsrate auf als Stentretriever, die sich nicht in voller Länge an die Gefäßwand anlegten. Andererseits war bei ersteren eine höhere Retraktionskraft notwendig. Der Prototyp mit dünneren Stentstreben erreichte eine vergleichbare Rekanalisations- und Emboliерate bei geringerer aufzuwendender Retraktionskraft im Vergleich zum Prototypen mit stärkeren Stentstreben.

Schlussfolgerung Eine vollständige Adaptation des Stentretrievers an die Gefäßwand ermöglicht eine effektive Thrombektomie mit geringer Emboliерate, ist jedoch mit einer höheren notwendigen Retraktionskraft und damit potentiell höheren Gefahr einer Endothelverletzung verbunden. Veränderungen des Stentdesigns in den Prototypen mit Verminderung der Stärke der Stentstreben führen zu einer geringeren Retraktionskraft, beeinträchtigten jedoch nicht die Rekanalisierungs- und Emboliерate.

Kernaussagen:
- Die vollständige Adaptation des Stentretrievers an die Gefäßwand ermöglicht eine effektive Thrombektomie
- Diese ist mit einer höheren Retraktionskraft und möglicherweise Gefahr der Endothelverletzung verbunden
- Durch Verringerung der Strebendicke wird die Rekanalisations- und Emboliерate nicht beeinträchtigt
- Die Retraktionskraft kann hierdurch vermindert werden

ABSTRACT

Purpose Various stent retrievers differing in stent design and mechanical properties are currently available for the treatment of ischemic stroke. We conducted this in vitro study to compare the efficacy, embolism rate, and safety of commercially available stent retrievers and prototypes.

Materials and Methods Whole blood thrombi were produced in a Chandler loop. The thrombi were inserted into the curved M1 segment of a silicone model of the anterior cerebral circulation. Thrombectomy maneuvers were performed

with six commercially available stent retrievers and 2 prototypes with different strut thickness. Wall-stent apposition, first pass recanalization rate, retraction force, and embolism rate were compared.

Results Devices with complete wall-stent apposition had the highest first pass recanalization rate and lowest embolism rate, but showed the highest retraction force. The prototype with thinner struts had a comparable recanalization and embolism rate, while a lower retraction force had to be applied compared to the prototype with thicker struts.

Conclusion Complete wall-stent apposition facilitates a higher recanalization rate and lower embolism rate but also correlates to a higher necessary retraction force and thus possibly higher risk of endothelium damage. Stent modifications leading to a reduced retraction force do not compromise efficacy and embolism rate.

Key Points:

- Complete wall-stent apposition facilitates an effective thrombectomy
- Complete wall-stent apposition leads to higher retraction force and possibly greater endothelium damage
- Modifications of strut thickness do not compromise recanalization and embolism rate
- Thinner struts correlate with a lower retraction force

Citation Format

- Larsen N, Oberbeck K, Lima de Miranda R et al. Comparison of Efficacy, Embolism Rate and Safety of Thrombectomy with Stent Retrievers in an Anterior Circulation Stroke Model. Fortschr Röntgenstr 2018; 190: 1053–1058

Introduction

Mechanical thrombectomy with stent retrievers has emerged as an effective and safe therapy in acute ischemic anterior circulation stroke with thromboembolic proximal vessel occlusion [1 – 5]. Various stent retrievers are in use, differing in stent design and mechanical properties [6 – 13]. The exact mechanisms of device-vessel wall and device-thrombus interaction are not fully understood yet and probably depend on stent design and behavior during retraction, vessel anatomy, histological and mechanical properties of the thrombus [14 – 17]. However, it is necessary to understand which stent retriever is most efficient in a given clinical situation. It has to be taken into account that the average age of patients with ischemic stroke is older than 70 years [18, 19]. During thrombectomy, the neurointerventionalist often encounters tortuous intra- and extracranial vessels, which are atherosclerotically altered and probably more vulnerable. The goal of this study was to compare the behavior, efficacy and safety of commercially available stent retrievers and 2 prototypes using an in vitro-flow model with a curved M1 segment.

Materials and Methods

Flow model

The stent retrievers were evaluated in a self-constructed closed-circuit silicone model. It comprises a tube with a 4 mm diameter to simulate the terminal carotid segment, a carotid T with an angle of 150°, a tapered tube with a proximal diameter of 2.5 mm and a distal diameter of 2 mm to simulate the M1 segment. The M1 segment was arranged in a c-shape simulating a curved vessel anatomy. The system was filled with saline at body temperature. Blood circulation was simulated by a pump producing a pulsatile flow at a frequency of 70 pulses per minute maintaining a pressure of 70 mmHg. A filter was placed in the distal outflow tract to retain thrombus fragments.

Thrombi

Standardized whole blood thrombi with a diameter of 3 mm were generated in a Chandler Loop from human blood as described before [20, 21] and cut into fragments with a length of 15 mm. The thrombi were aspirated together with saline into a 20 ml syringe and injected into the internal carotid artery segment of the silicone model. After that, the A1 segment was clamped and the pump engaged until the thrombus had migrated into the M1 segment. The clamp was removed and the thrombectomy maneuver started.

Stent retrievers

Six commercially available stent retrievers were compared:

Aperio (Acandis, Pforzheim, Germany) 4.5 × 40 mm, Separator 3 D (Penumbra, Almeda, USA) 4.5 × 26 mm, pREset (Phenox, Bochum, Germany) 4 × 20 mm, Revive SE (Codman Neuro, Raynham, USA), 4.5 × 22 mm, Solitaire FR (ev3, Irvine, USA), 4 × 20 mm and Trevo (Concentric Medical, Mountain View, USA) 4 × 20 mm.

Prototypes

We tested two NiTinol stent retriever prototypes (Acquandas GmbH, Kiel, Germany) with a generic cell design, which were manufactured using a unique fabrication based on UV lithography, sacrificial layer and wet etching technology [22]. These devices were designed with special features: 1) tapered (2.0 – 3.5 × 35 mm); 2) thin struts (Prototype I – 40 µm, Prototype II – 30 µm) (▶ **Fig. 1**).

Thrombectomy maneuver

A distal access catheter (DAC 057, Concentric Medical, Mountain View, USA) was advanced through an introducer sheath (6F Radiofocus Introducer 2, Terumo, USA) to a position 3 cm proximal to the thrombus. A microcatheter containing the stent retriever was navigated through the thrombus to a position with the tip 0.5 cm distal to the thrombus and the stent retriever was deployed. After

▶ **Fig. 1** Prototype I (40 µm stent struts, tapered design, 2.0 – 3.5 × 35 mm) with thrombus.

▶ **Abb. 1** Prototyp I (40 µm Streben, konisches Design, 2,0 – 3,5 × 35 mm) mit Thrombus.

3 minutes, the stent retriever and microcatheter were retracted while applying negative flow through aspiration at the distal access catheter.

Six thrombi were extracted with each stent retriever. If the thrombus was not removed on the first attempt, two more attempts were allowed.

Contact of the stent struts with the wall of the curved M1 segment was observed during retraction.

Retraction force measurements

The force that had to be applied to retract the stent retriever was measured with a spring scale (Micro Line 20 001, Pesola, Schindellegi, Switzerland) in a separate experiment using the same flow model without aspiration. The spring scale was connected to the microcatheter via a crocodile clamp. The maximum force that was necessary to retract the microcatheter and stent retriever through the M1 segment was documented.

Thrombus fragmentation and embolism

After each retraction maneuver, the filter was checked for embolized thrombus fragments. Fragments >= 1 mm (macroemboli) and < 1 mm (microemboli) were separately counted.

Statistics

Results of retraction force measurements were tested for normal distribution with the Shapiro-Wilk test, followed by an analysis of variance. Significance levels were determined using the Scheffé procedure and significance was set at $p < 0.05$.

Results

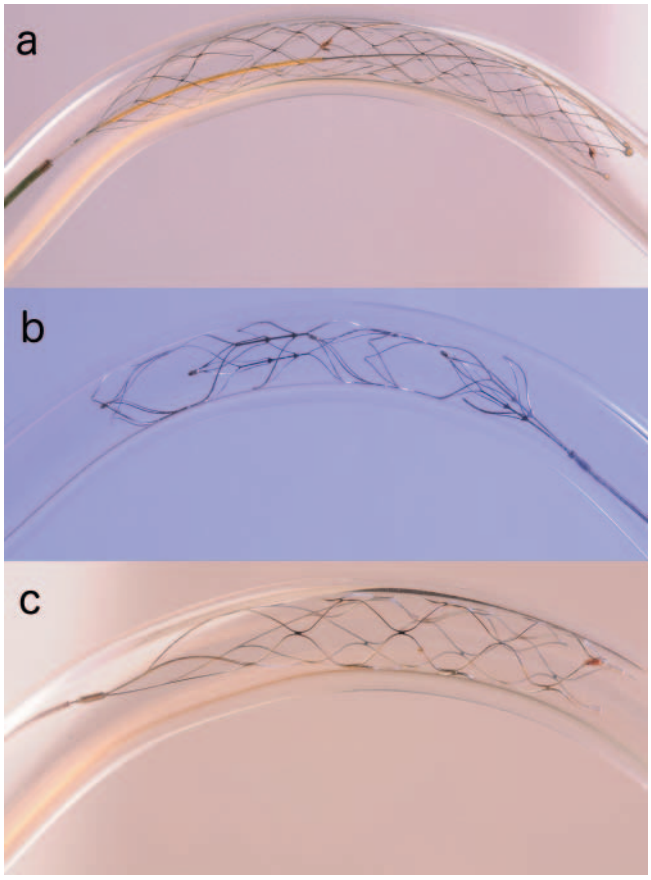
Aperio, Separator and pREset lined up with the wall of the curved M1 segment along their entire length (▶ **Fig. 2**).

In contrast, the inner stent struts of the bent Revive were not in contact with the wall at the concave aspect of the tube curvature.

Solitaire and Trevo both showed malapposition at the convex aspect of the vessel (▶ **Fig. 3**).

The prototypes apposed the wall only with the broader proximal part.

All stent retrievers including the prototypes were able to remove the clot after a maximum of 2 attempts. Aperio, Separator and pREset always removed the thrombus in the first pass.



▶ **Fig. 2** Wall-stent apposition in the **a** Aperio, **b** Separator and **c** pREset. Complete contact of the stent retrievers with the tube wall is noted.

▶ **Abb. 2** Wand-Stent-Apposition beim **a** Aperio, **b** Separator und **c** pREset. Es besteht ein vollständiger Kontakt des Stentes mit der Schlauchwand.

Macroemboli did not occur with the Aperio and Separator stent retrievers. Most macroemboli were observed using the Trevo. Revive (n = 1), Solitaire (n = 1) and Trevo (n = 2) lost the complete thrombus without fragmentation during retraction resulting in embolization to the original occlusion site.

The 2 prototypes did not differ in number of macroemboli (n = 1).

Microembolism occurred in all stent retrievers including the prototypes (▶ **Table 1**).

A significantly higher retraction force was necessary for pREset and Separator compared to the other commercial stent retrievers. However, the highest retraction force was observed with the 40 µm prototype. The 30 µm prototype ranked second compared to the commercial stent retrievers (▶ **Fig. 4**).

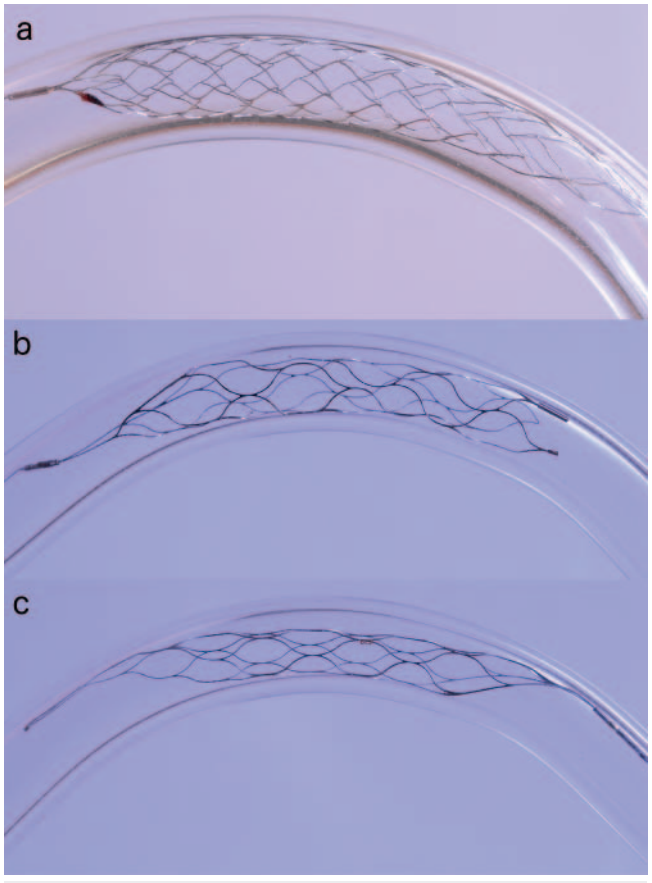
Discussion

Thrombectomy with NiTinol stent retrievers has undoubtedly brought about a significant improvement in anterior circulation stroke therapy. Various stent retrievers are available differing in

▶ **Table 1** First pass recanalization rate, number of macro- and microemboli in commercial stent retrievers and prototypes.

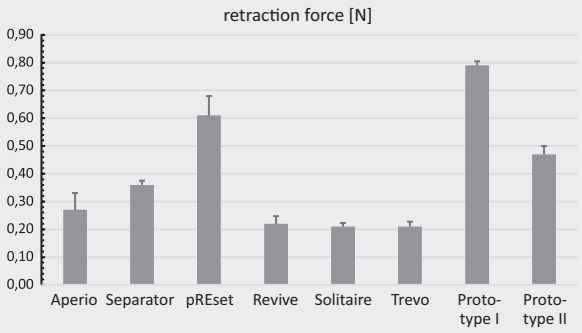
▶ **Tab. 1** First pass-Rekanalisierungsrate, Anzahl der Makro- und Mikroemboli bei kommerziellen Stentretrievern und Prototypen.

	first pass recanalization (%)	macroemboli (n)	microemboli (n)
Aperio	100	0	2
Separator	100	0	1
pREset	100	1	4
Revive	83	1	3
Solitaire	83	1	2
Trevo	67	3	2
Prototype I	83	1	4
Prototype II	83	1	4



▶ **Fig. 3** Wall-stent apposition in the **a** Revive, **b** Solitaire and **c** Trevo. There is incomplete apposition of the inner struts in the Revive **a**. Solitaire **b** and Trevo **c** show a gap between struts and the wall at the outer aspect of the tube curvature.

▶ **Abb. 3** Wand-Stent-Apposition beim **a** Revive, **b** Solitaire und **c** Trevo. Es besteht lediglich ein partieller Kontakt der inneren Streben beim Revive **a**. Solitaire **b** und Trevo **c** zeigen eine Lücke zwischen Streben und äußerer Kurvatur der Schlauchwand.



▶ **Fig. 4** Retraction force of the commercially available stent retrievers and prototypes. Retraction force of the pREset and Separator was significantly higher than retraction force of the Revive, Solitaire and Trevo stent retrievers ($p < 0.05$). Prototype II with thinner struts had a lower retraction force than Prototype I.

▶ **Abb. 4** Retraktionskraft bei den kommerziellen Stentretrievern und Prototypen. Die aufzubringende Retraktionskraft bei pREset und Separator war signifikant höher als bei Revive, Solitaire and Trevo ($p < 0,05$). Bei Prototyp II mit dünneren Stentstreben war eine geringere Retraktionskraft notwendig als bei Prototyp I.

strut arrangement, strut thickness and radial force. Moreover, recanalization rates most probably not only depend on stent retriever design but on mechanical and histologic properties of the thrombus, possibly altered by thrombolytic agents or platelet inhibitors, thrombus interaction with the vessel wall, relapsed time since occlusion onset, thrombus length, occlusion site and vessel anatomy. This leads to a complex clinical situation and the demand for an individually adjusted therapy.

Few in vivo studies examining the mechanical properties, recanalization, and embolization rate of stent retrievers have been conducted in the recent past [9, 23, 24].

However, these studies focused on clot-stent interaction, in contrast to our study, where stent-vessel wall alignment was evaluated.

Machi et al. [25] conducted a comprehensive evaluation comprising mechanical and functional tests of all available stent retrie-

vers. They performed a visual assessment of strut alignment with the vessel wall with the results differing slightly from the results of our study. The authors described full adaptation of the stent to the vessel wall with the pREset 4 × 20 mm in accordance with our results. In contrast to that, they also described full apposition of the Solitaire 4 × 20 mm, which our observations did not confirm. The group used a rigid vascular model with a straight M1 segment and described stent adaptation throughout the entire retraction maneuver covering also more proximal vessel segments with larger diameters. In our model, however, we simulated a curved M1 segment in a non-rigid vascular model and focused our observations of stent apposition solely on the clot-bearing segment.

To our knowledge, there are no previous studies evaluating stent retriever prototypes. Since they are generic designs, it is possible to fabricate stent retrievers with any geometry and surface patterning. Using our own prototypes enabled us to study the influence of strut thickness on the mechanical behavior of a thrombectomy device.

In this in vitro study, we isolated the effect of stent retriever design on efficacy and safety in a curved M1 segment with a minimum diameter of 2 mm. The retrievers with complete stent apposition had the highest first pass recanalization success rate (Aperio, Separator and pREset) and did not cause macroemboli (Aperio and Separator). Close contact of the entire stent structure to the vessel wall seems to be an important factor to ensure complete thrombus retraction and prevent thrombus fragmentation. On the other hand, the highest retraction force had to be applied using these stent retrievers. The higher force needed for retraction relates to the higher radial force of the stent and possibly the higher risk of wall damage. It has been suggested that vessel wall damage occurs during thrombectomy with stent retrievers, which possibly results in secondary stenosis [26 – 30]. However, another study could not find any evidence of significant wall trauma [31]. Still, the question of whether vessel wall injury leads to clinically significant complications has not been fully explored yet [32, 33]. A reduction of strut thickness in our prototype led to a significantly reduced retraction force while maintaining an excellent recanalization and low embolization rate, indicating the fact that modifications of the stent design resulting in reduced radial force do not necessarily negatively affect recanalization efficiency.

A major drawback of this study is the in vitro nature. The flow model closely simulates in vivo conditions but does not incorporate the possible influence of the endothelium on stent-thrombus interaction. Furthermore, it remains uncertain whether the results can be transferred to the occlusion of M2 or more distal segments with a smaller diameter.

Rapid development in the field of mechanical thrombectomy continuously provides newer generation stent retrievers, and the results may not be applicable to these devices.

Various thrombectomy techniques are in clinical use today. In our study, we performed thrombectomy with simultaneous aspiration through a distal access catheter. This technique has been proven effective in in vitro and clinical studies [24, 34]. We did not consider other techniques such as proximal flow arrest using a balloon guide catheter.

In conclusion, the results show that choosing a stent retriever with complete vessel wall-stent apposition even in a curved vessel segment maximizes the success rate and minimizes the embolization rate, but correlates with a higher retraction force and thus possibly a higher risk of endothelium damage. Modifications in stent retriever prototype design leading to a reduced retraction force did not compromise efficacy and embolism rate.

CLINICAL RELEVANCE OF THIS STUDY

- Understanding the behavior of a stent retriever during deployment and retraction is crucial for the choice of the appropriate device in a given clinical situation.
- It is pivotal to elucidate the properties of different stent retrievers to assess the risk of thrombectomy therapy.
- Understanding the impact of changes to stent retriever design aids in the development of new devices.

Conflict of Interest

The authors declare that they have no conflict of interest.

Acknowledgments

The study was conducted in collaboration with the Research Study Group 2154 “Materials for Brain” at Christian-Albrechts-University Kiel.

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