ORDERING INFORMATION | APERIO® Hybrid[17|21]

Labelled:
APERIO® Hybrid[17|21]

Dimensions (mm)	Reference Number	Device Diameter (mm)	Device Length* (mm)	Recommended Vessel Diameter (mm)	Required / Recommended Microcatheters for Delivery (Inch)
2.5 × 16	01-000713	2.5	16	1.0 – 2.0	0.0165 – 0.021 NeuroSlider® 17 DLC NeuroSlider® 21 DLC
2.5 × 28	01-000710	2.5	28	1.0 – 2.0	
3.5 × 28	01-000711	3.5	28	1.5 – 3.0	
4.5 × 30	01-000712	4.5	30	2.0 – 4.0	
4.5 × 40	01-000715	4.5	40	2.0 – 4.0	0.021 – 0.027 NeuroSlider® 21 DLC NeuroSlider® 27 (DLC)
4.5 × 50	01-000716	4.5	50	2.0 – 4.0	
6.0 × 40	01-000717	6.0	40	3.5 – 5.5	
6.0 × 50	01-000718	6.0	50	3.5 – 5.5	

* Average length within intended vessel diameter

All changes or modifications, may they be technical or other, or changes in the availability of products are expressively reserved.
Not available for sale in the United States.

CE 0297

09-000109 EN 04/2022

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ENGINEERING STROKE SOLUTIONS

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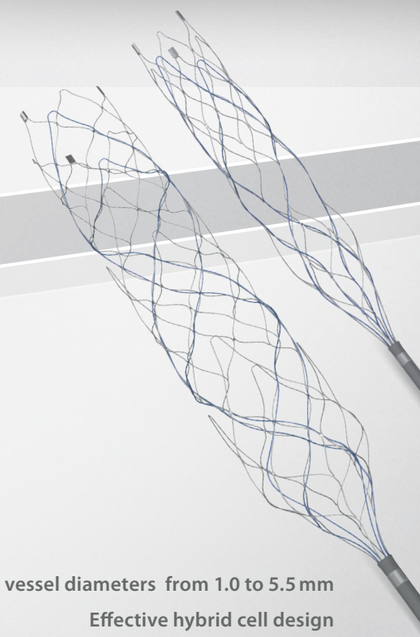
APERIO® Hybrid[17|21]
Thrombectomy Device



For vessel diameters from 1.0 to 5.5 mm
Effective hybrid cell design
Full length visibility

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ENGINEERING STROKE SOLUTIONS

APERIO® Hybrid[17|21]
Thrombectomy Device

Perfect Interplay – Safe and efficient

Next generation of the reliable and safe APERIO® Hybrid Thrombectomy Device dedicated to further improve fast and efficient flow restoration – even for distal thrombectomy.

Various combination possibilities to find the optimal setting depending on the anatomy and treatment strategy.

"Treatment of occlusions in distal branches of eloquent brain areas such as the ACA territory is a promising extension of mechanical thrombectomy. The APERIO® Hybrid[17] enables safe treatment of small vessels down to a diameter of 1 mm and its 2.5 mm version easily navigates through a 0.0165" ID microcatheter."

Dr. Hannes Nordmeyer, radprax at St. Lukas Hospital, Solingen, Germany

Improved

The APERIO® Hybrid[17] Thrombectomy Device is improved for distal thrombectomy and treatment of vessel diameters from 1.0 mm to 4.0 mm with 0.0165" ID microcatheters.

The APERIO® Hybrid[21] Thrombectomy Device is the portfolio unification enabling the treatment of vessel diameters from 2.0 – 5.5 mm with 0.021" ID microcatheters.

Efficient

Proven and effective hybrid cell design: Smaller closed cells ensure perfect vessel wall apposition and expansion into the clot.

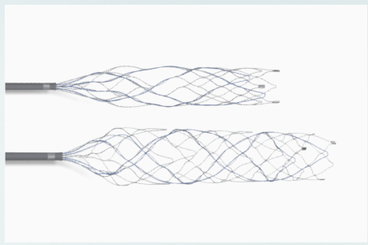
Larger clot catching cells assure good integration of the thrombus.

Integrated anchoring elements (except for device with Ø 2,5 mm) offer additional support for efficient clot retention enabling confident and atraumatic retrieval even in challenging anatomies.

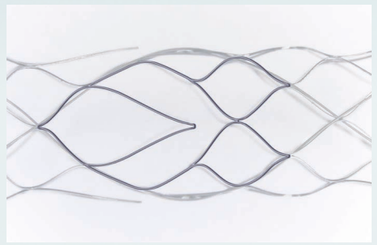
Safe

The sleek electropolished surface in combination with smooth atraumatic design elements enable a gentle and safe retrieval.

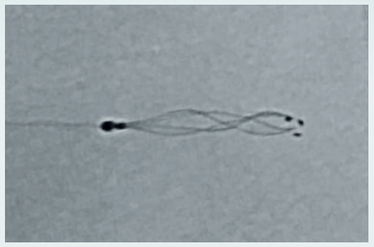
The full length visibility of the device leads to maximum control and assurance during procedure.



Improved portfolio

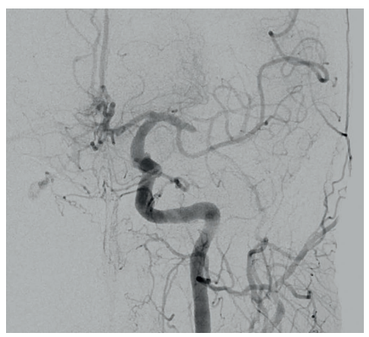


Hybrid cell design

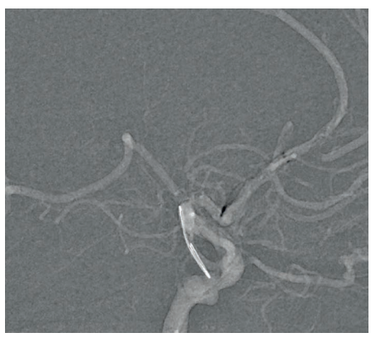


Full length visibility[1]

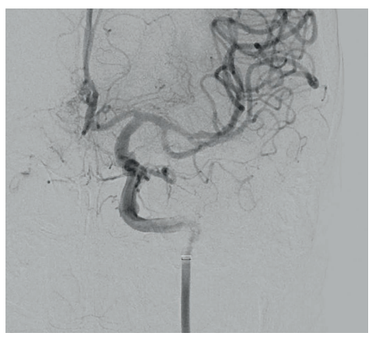
Treatment with APERIO® Hybrid[17] Thrombectomy Device[1]



Pre-treatment
M1, A2-A3, A4 occlusion

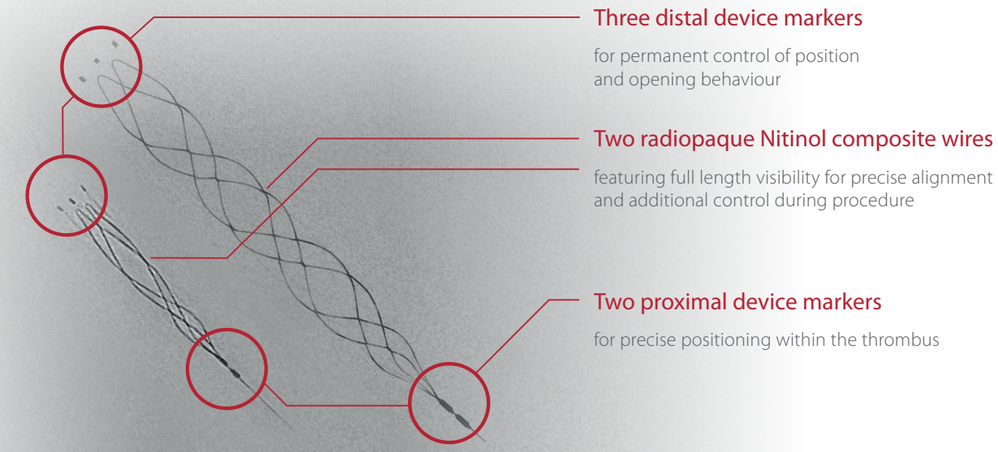


***Recanalisation** of A2-A3*
with APERIO® Hybrid[17] 2.5 x 16 mm



Post-treatment
Final result (first pass, TICI 3)

Radiopaque Marker Concept



1 Images are courtesy of Dr. Hannes Nordmeyer, radprax at St. Lukas Hospital, Solingen, Germany
2 Machi P., et al. (2017): Experimental evaluation of stent retrievers' mechanical properties and effectiveness. Journal of NeuroInterventional Surgery, 2017; Mar; 9(3):257-263

ORDERING INFORMATION

Labelled APERIO® Hybrid Dimensions (mm)	Reference Number	Device Diameter (mm)	Device Length* (mm)	Recommended Vessel Diameter (mm)	Required Microcatheters for Delivery (Inch)
3.5 x 28	01-000704	3.5	28	1.5 – 3.0	0.021
4.5 x 30	01-000705	4.5	30	2.0 – 4.0	0.021
4.5 x 40	01-000706	4.5	40	2.0 – 4.0	0.021
4.5 x 50	01-000707	4.5	50	2.0 – 4.0	0.021
6.0 x 40	01-000708	6.0	40	3.5 – 5.5	0.021 – 0.027
6.0 x 50	01-000709	6.0	50	3.5 – 5.5	0.021 – 0.027

* Average length within intended vessel diameter

Recommended Microcatheters

Product Name	Reference Number	ID (Inch)	OD dist. / prox. (French)	Usable Length (cm)	Tip Shape
NeuroSlider® 21	01-000273	0.021	2.4 / 2.5	155	Straight
NeuroSlider® 27	01-000274	0.027	3.0 / 3.1	155	Straight

Recommended Intermediate Catheters

Product Name	Reference Number	ID (Inch)	OD dist. OD prox. (French / Inch)	Usable / Total Length (cm)	Tip Shape
NeuroBridge® 52	01-000518	0.052	5.0 / 0.066 5.3 / 0.070	105 / 111	Multi-Purpose 25°
	01-000511	0.052	5.0 / 0.066 5.3 / 0.070	115 / 121	Multi-Purpose 25°
	01-000512	0.052	5.0 / 0.066 5.3 / 0.070	125 / 131	Multi-Purpose 25°
	01-000513	0.052	5.0 / 0.066 5.3 / 0.070	135 / 141	Multi-Purpose 25°
NeuroBridge® 65	01-000519	0.065	6.1 / 0.080 6.3 / 0.083	105 / 111	Multi-Purpose 25°
	01-000514	0.065	6.1 / 0.080 6.3 / 0.083	115 / 121	Multi-Purpose 25°
	01-000515	0.065	6.1 / 0.080 6.3 / 0.083	125 / 131	Multi-Purpose 25°

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The New Fully Radiopaque Aperio Hybrid Stent Retriever: Efficient and Safe? An Early Multicenter Experience

Marius Kaschner[1], Thorsten Lichtenstein[2], Daniel Weiss[1], Bernd Turowski[1], Lukas Goertz[2,3], Claudia Kluner[4], Marc Schlamann[2], Christian Mathys[1,4,5], Christoph Kabbasch[2]

■ OBJECTIVE: **To investigate the visibility, safety, and efficacy of the full-length radiopaque Aperio Hybrid stent retriever (APH) in mechanical thrombectomy of large vessel occlusions.**

■ METHODS: **Multicentric retrospective analysis of patients with stroke, treated with the APH due to an acute ischemic stroke by large vessel occlusions in the anterior or posterior circulation, was performed. We focused on technical and angiographic parameters including device visibility, perfusion results (modified thrombolysis in cerebral infarction scale [mTICI]), procedural times, periprocedural complications, and favorable clinical outcome (modified Rankin Scale, 0–2) at discharge and after 90 days.**

■ RESULTS: **A total of 48 patients (male: n = 22, 45.8%, mean age 73 years [standard deviation (SD), ±15], median baseline National Institutes of Health Stroke Scale: 15 [2–36], n = 25, 52.1% received additional intravenous thrombolytics) were treated with the APH with a mean number of 2 device passes (SD, +3) in APH-only cases (n = 41). The median time from groin puncture to the final mTICI was 54 minutes (SD, +33). In 46 patients (95.8%), mTICI 2b–3 was achieved (mTICI 2c, 12.5%; mTICI 3, 47.9%). Favorable outcome (modified Rankin Scale <2) was achieved in 15 (32.6%) patients at discharge and in 11 of the 30 (36.7%) patients available for 90-day follow-up. Symptomatic intracranial hemorrhage was recorded in 3 of 48 cases (6.3%). Difficulties during device delivery and/or deployment occurred in 6.3% (3 of 48). APH-related adverse events did not occur. APH radiopacity was rated as good and very good in 97.9% (47 of 48).**

■ CONCLUSIONS: **Mechanical thrombectomy with the APH appeared feasible, efficient, and safe. Full-length device radiopacity may facilitate thrombectomy or support to adapt the course of action during retrieval, if required.**

INTRODUCTION

Mechanical thrombectomy (MT) in acute ischemic stroke treatment caused by large vascular occlusions (LVO) has evolved into the gold standard of care.[1,2] Mechanical retrieval of the vessel occluding clot may lead to reliable and fast vessel recanalization. The superiority of stent-retriever–based thrombectomy over intravenous thrombolysis (IVT) alone was demonstrated in numerous large, randomized,

Key words
- Aperio Hybrid
- Ischemic stroke
- Mechanical thrombectomy
- Recanalization
- Stent retriever

Abbreviations and Acronyms
APH: Aperio Hybrid stent retriever
ARISE II: Analysis of Revascularization in Ischemic Stroke with EmboTrap
ASPECTS: Alberta Stroke Program Early CT Score
CT: Computed tomography
DFT: Drawn filled tubing
IVT: Intravenous thrombolysis
LVO: Large vascular occlusions
mRS: Modified Rankin Scale
MT: Mechanical thrombectomy
mTICI: Modified thrombolysis in cerebral infarction
NIHSS: National Institutes of Health Stroke Scale
RCT: Randomized controlled trial
SAH: Subarachnoid hemorrhage
sICH: Symptomatic intracranial hemorrhage

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All listed authors contributed to the work. M. Kaschner and T. Lichtenstein contributed equally and share first authorship. C. Mathys and C. Kabbasch contributed equally and share the last authorship.

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multicenter studies,[3-7] in particular when a certain clot length is exceeded.[8] Furthermore, recent studies have shown that, in specific circumstances, even in an extended time window of up to 16 or 24 hours after symptom onset, mechanical recanalization may lead to an improved outcome compared with sole conservative care.[9,10]

In addition, stent retrievers with enhanced radiopacity characteristics as the Trevo ProVue (Stryker Neurovascular, Fremont, California, USA) and the Solitaire Platinum (Medtronic, Minneapolis, Minnesota, USA) could demonstrate a positive influence on the intervention procedure.[11,12]

The first-generation Aperio stent retriever (Acandis, Pforzheim, Germany) has been available since 2011 and proved to be efficient and safe.[13] A successor version, the Aperio Hybrid stent retriever (APH), recently obtained European CE mark approval. The APH offers full-length visibility through embedded radiopaque drawn filled tubing (DFT) wires that aim to achieve better assessment of stent-retriever positioning and interaction with the clot and vessel wall under fluoroscopy.

In this multicenter study, we report on our early experience with the full-length radiopaque APH and focus on its safety and efficacy.

MATERIALS AND METHODS

In this observational study, the data of the first 48 consecutive patients with stroke from 3 university neurovascular centers treated with the APH due to an acute stroke by LVO in the anterior (carotid-T, M1, M2) or posterior circulation (basilar artery) were evaluated. Anonymized data were retrospectively evaluated; patient files and radiological imaging from the acute phase until hospital discharge were analyzed.

Primary endpoints were first-pass excellent and first-pass favorable recanalization rate, defined as the modified thrombolysis in cerebral infarction (mTICI) scale score of $\geq$2c and $\geq$2b, respectively. The secondary outcome parameters contained final excellent and favorable reperfusion rate, favorable clinical outcome (modified Rankin Scale [mRS], 0–2) at discharge and at 90 days, symptomatic intracranial hemorrhage (sICH) with neurological deterioration (National Institutes of Health Stroke Scale [NIHSS] worsening >4) within 24 hours after intervention, periprocedural subarachnoid hemorrhage (SAH), embolisms into new territories, dissections, and material defects as well as evaluation of technical practicability, for example, pushability and deployment.

Aperio Hybrid Stent Retriever

The APH is a further development of its predecessor, the Aperio stent retriever. Like its predecessor, the APH is self-expanding and made of nitinol. Furthermore, it exhibits a hybrid cell design that should allow effective interaction with the clot, reliable clot recovery, and good vessel wall apposition (Figure 1). The APH is designed in repetitive functional segments, to enable adaptation of the working length to the thrombus length even in tortuous vessels, while maintaining the functionality. In addition, the APH offers improved full-length visibility under fluoroscopy due to embedded radiopaque DFT made of a nitinol tube and a highly radiopaque platinum core. The APH is delivered through a 0.021″ microcatheter and is available in working lengths from 30 to 50 mm and diameters from 3.5 to 6 mm.

Competing stent retrievers have also been developed with the intention to improve radiopaque visibility. By integration of

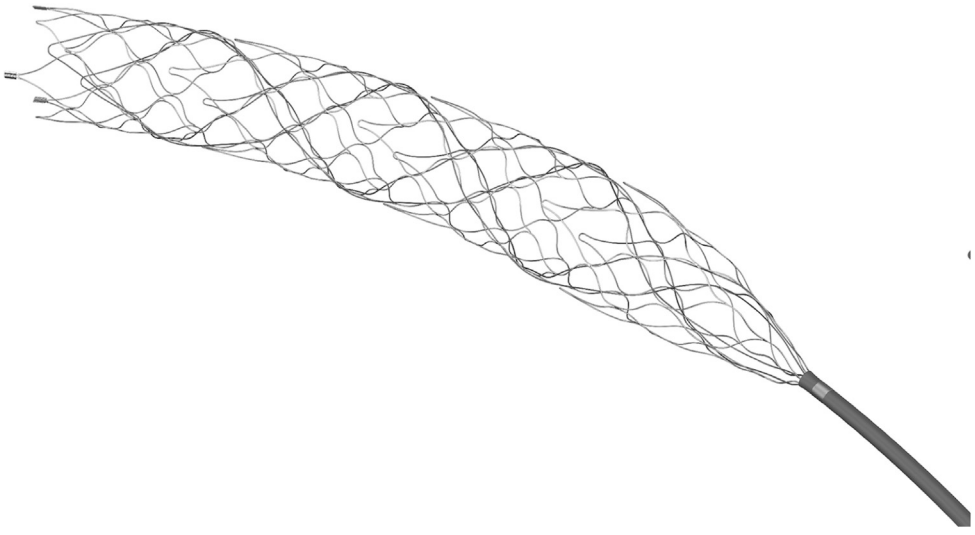

Figure 1. The Aperio Hybrid device (photograph provided by Acandis). Functional segment: small closed cells, large open cells; repeating functional segments allowing adaption of working length to thrombus length. (The small closed cells may attain a good vessel wall apposition and expansion into the clot, and large open cells with integrated anchoring elements aim to assure efficient clot retention and are supposed to result in favorable recanalization rates.)

platinum wires into the existing nitinol stent struts, the Trevo ProVue aims to visualize the complete working length, whereas the Solitaire Platinum only exhibits evenly spaced single platinum markers added every 10 mm (Figure 2).

Procedure Description

Thrombectomies were performed either under general anesthesia or conscious sedation at the discretion of the neurointerventionalist operator. As standard, a triaxial system was used via a femoral access. At first, a short 8F sheath was inserted to place an 8F guide catheter (e.g., Vista brite tip; Johnson & Johnson, New Brunswick, New Jersey, USA) into the internal carotid artery or a short 6F sheath to navigate a 6F catheter (e.g., Envoy MPC; Codman Neurovascular, Raynham, Massachusetts, USA) into the vertebral artery, respectively. Afterward, the occluded intracranial artery was visualized by contrast injection. The large majority of procedures were performed on a biplanar angiography suite using the "Solumbra technique," in which the stent retriever is usually retracted into an aspiration catheter placed proximal to the clot.[14] Under the guidance of a standard 0.014″ microguidewire, a microcatheter (Neuroslider 21, Acandis [n = 33]; Rebar 18, Medtronic [n = 15]) was placed distal to the clot and a large bore aspiration catheter (e.g., 6F Sofia Plus aspiration catheter in the anterior, or Sofia 5F in the posterior circulation; Microvention, Tustin, California, USA) was placed as proximal as possible to the thrombus. Afterward, the microguidewire was replaced by the APH. The size of the APH was determined considering the length and the cross-section of the thrombus and vessel, respectively. After deployment of the APH, the microcatheter was removed to maximize suction lumen inside the aspiration catheter. Correct deployment was confirmed under fluoroscopy until the APH was fully expanded. A 60 mL vacuum pressure syringe (VacLok; Merit Medical, South Jordan, Utah, USA) was attached to the aspiration catheter. Under continuous fluoroscopy and manual suction, the APH and thrombus were withdrawn into the large bore catheter. An example case is shown in Figure 3. Afterward, a control angiography was performed, and if necessary, the thrombectomy maneuver was repeated. If the recanalization attempts remained insufficient (<mTICI2b), a rescue device was used at the discretion of the treating physician.

Patient Selection

An ethical approval and patient consent were waived by the local ethics committees of the respective Faculties of Medicine for this retrospective observational study.

Inclusion criteria were as follows: the APH as the first-line device, LVO, and no evidence of intracranial bleeding in the initial magnetic resonance imaging or computed tomography (CT) examination. Furthermore, only patients with an Alberta Stroke Program Early CT Score (ASPECTS) ≥5 and an NIHSS ≥5 (unless they suffered from aphasia) were included. There was no age limit and no upper time limit between onset and expected groin puncture as long as the above criteria were met. No other

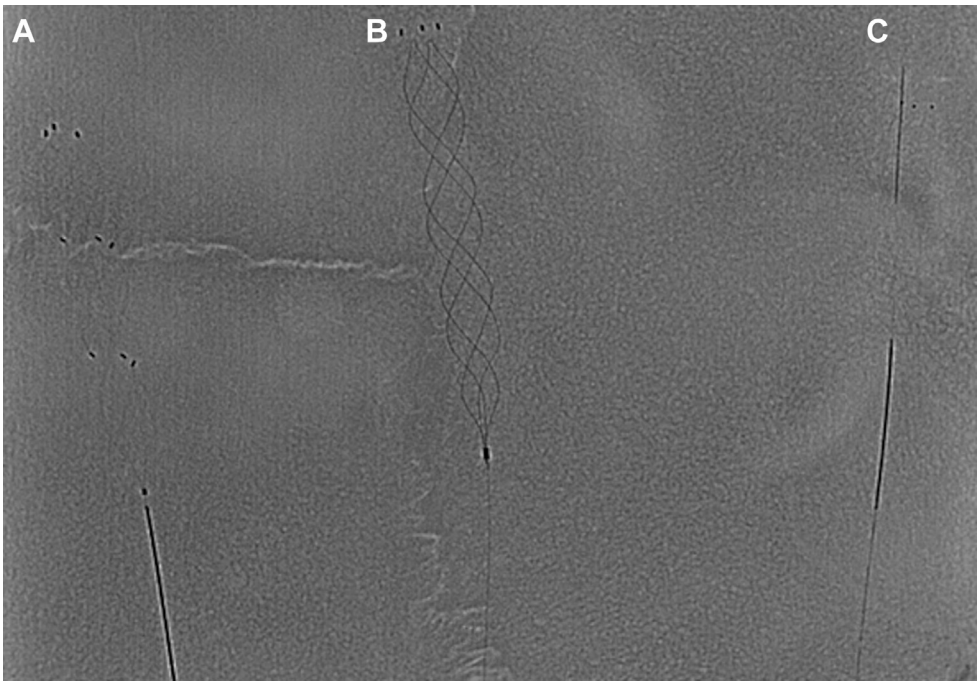

Figure 2. Image (provided by Acandis) demonstrating enhanced visibility of the Aperio Hybrid stent retriever (**B**) under fluoroscopy compared with the precursor device Aperio (**C**) and the Solitaire Platinum (**A**) stent retriever.

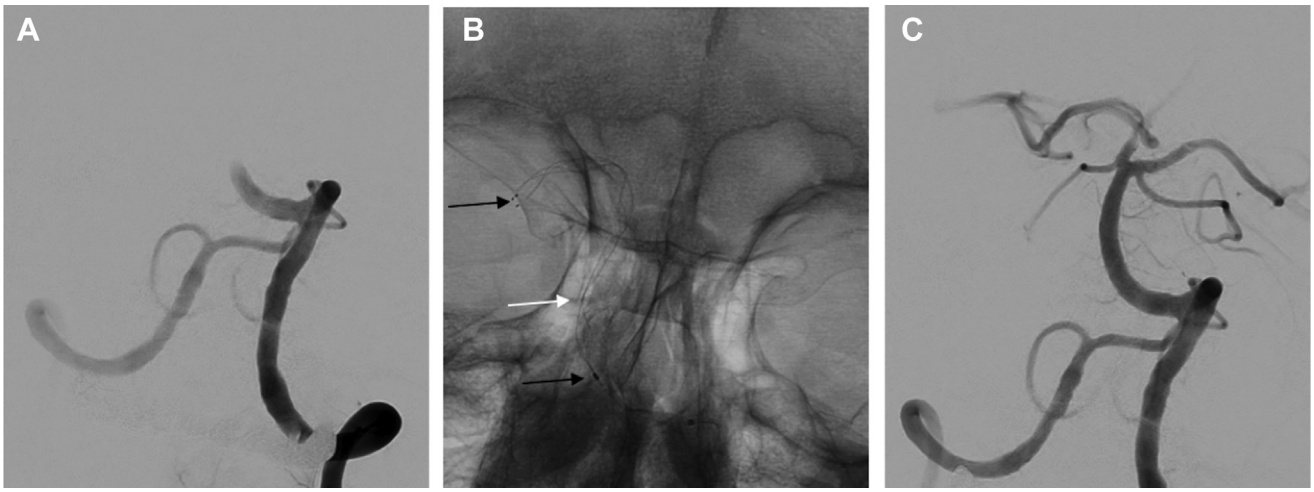

Figure 3. Images illustrate the case of a patient with a basilar artery occlusion. (**A**) Digital subtraction angiography shows the initial finding of a proximal basilar artery occlusion (mTICI 0). CTA (not shown) reveals long-sectioned thrombus load within the BA. (**B**) A nonsubtracted angiography shows the completely released 4.5 × 50 mm Aperio Hybrid stent retriever from the right posterior cerebral artery to the basilar artery origin. The Aperio Hybrid exhibits superior radiopacity; visibility is ensured not only at the proximal tip of the retriever and the 3 distal device markers (*black arrows*), but also within full length of the device due to integrated radiopaque drawn filled tubing wires. The tapering of the stent retriever at the level of the thrombus is clearly visible (*white arrow*). (**C**) Complete recanalization of the occlusion after first pass (mTICI 3). BA, basilar artery; CTA, computed tomography angiography; mTICI, modified thrombolysis in cerebral infarction.

exclusion criteria existed. IVT was administered according to the guidelines of the German Neurological Society.

Clinical and Radiological Data

Basic demographics (age and sex) and pre-existing conditions (e.g., previous strokes, high blood pressure, atrial fibrillation, diabetes) as well as premedications were derived from the routinely collected patient data. In addition, specific data on the acute stroke event itself were extracted: NIHSS and mRS at admission and discharge, 90-day mRS (which was available for 2 of the 3 participating centers), time of stroke or in case of unknown onset, the time when the patient was last well seen, the time of admission to hospital, and the time of initial imaging. In addition, it was documented if and when IVT was administered. Clinical data and scores were evaluated by a consultant neurologist.

From the radiological image documentation, the affected side, the affected vessel, the ASPECTS before and after intervention, the diameter of the affected vessel, the time of the inguinal puncture, the first and last attempt of recanalization, the number of thrombectomy maneuvers, and final perfusion result (mTICI) were evaluated. It was documented whether a rescue stent retriever was used, if supplementary intra-arterial lysis was administered and if any complications occurred during angiography or further clinical course. In particular, the number and severity of subarachnoid and intraparenchymal hemorrhages, and the number of embolisms into new territories, of periprocedural dissections, and of material defects (e.g., stent retriever fails to open, breaks, tears) were evaluated. The type (diameter and length) of the APH used was also documented. All image-based outcome was collected by blinded review of images by board-certified neuroradiologists at each site.

Questionnaire

A questionnaire about the technical performance of the APH, which was routinely issued by the manufacturer as part of the product launch, was completed by the operators for all cases. The following aspects were evaluated: transfer of the APH into the microcatheter, pushability into the microcatheter, positioning, device deployment, resheathing into the microcatheter and introducer, and visibility of the markers and the device itself. Therefore, a 5-point Likert scale from − (poor) to ++ (very good) was used. In addition, the operators had the opportunity to make individual comments. In particular, they were asked to comment if they had replaced the stent retriever due to the improved visibility, whether the improved visibility helped to evaluate the interaction of the device with the clot, and whether they could observe a deformation of the stent during the retraction of the stent retriever. Devices were compared with the ones routinely used at each institution (Solitaire Platinum and Aperio, respectively). The MT procedures were conducted by board-certified neuroradiologists with an experience ranging between 2 and 15 years in endovascular stroke treatment.

RESULTS

Patients

A total of 48 patients with acute stroke (26 women, 22 men, mean age: 73 ± 2 years) were treated by MT in 3 university neurovascular centers, between May 2019 and July 2019 with the following occlusion patterns: carotid-T in 8 (16.7%), M1-segment in 31 (64.6%), M2-segment in 4 (8.3%), and basilar artery in 5 (10.4%) cases. The incidence of carotid-T occlusion was significantly higher ($P = 0.03$) in the rescue group (3 of 7; 42.9%)

compared with the APH-only group (5 of 41; 12.2%) (Table 1). The mean diameter of the occluded vessels was 2.8 ± 0.1 mm. Before thrombectomy, 25 of 48 patients (52.1%) received IVT according to the guidelines of the German Neurological Society (Table 1).

Operator Evaluation of Aperio Hybrid Performance

In an ordinal rating scale, the device was rated "good" and "very good" in terms of transfer into a required 0.021″ microcatheter in all cases (100%), pushability in a microcatheter (93.8%), positioning of a stent retriever (98.0%), device deployment (97.9%), marker visibility (100%), and device contour visibility (97.9%). If necessarily performed, all procedures of resheathing into the microcatheter as well as resheathing into the introducer sheath were effortless and rated as good or very good.

In 2 of 48 (4.2%) cases, pushability of the device was rated as "poor" or "very poor" and positioning of the APH was rated "poor" in 1 of 48 cases (2.1%) due to increased force to advance the device within the microcatheter.

Technical Success

Overall favorable revascularization (mTICI ≥ 2b) was achieved in 95.8% (46 of 48) including a first-pass recanalization rate (mTICI > 2b) of 60.4% (29 of 48). Final mTICI ≥ 2c was achieved in 29 of 48 procedures (60.4%). Regarding the total number of 48 procedures, a recanalization rate of mTICI ≥ 2b was achieved in 83.4% (40 of 48), final mTICI ≥ 2c in 52.1% (25 of 48), first-pass recanalization mTICI ≥ 2b in 52.1% (25 of 48), and first-pass mTICI ≥ 2c in 31.3% (15 of 48) when the APH was used as an exclusive device (Table 1). The overall mean number of stent-retriever passes was 3 ± 3. The mean number of passages for additional devices was 1 ± 0 after a mean of 3 ± 1 passes with the APH before switching. Whenever the APH was used exclusively, the mean number of maneuvers accounted to 2 ± 3.

The overall mean time to final recanalization from femoral access to final revascularization was 54 ± 5 minutes. Intra-arterial recombinant tissue plasminogen activator was administered in a single case (2.1%). The post-treatment median ASPECTS in follow-up CT after 16–24 hours was 6 (0–10) (Table 1).

In all 48 cases, the APH was the first-line stent-retriever device using sizes of 4.5 × 50 mm in 7 patients, 4.5 × 40 mm in 32 patients, and 4.5 × 30 mm in 9 patients. In 7 procedures (14.6%), a rescue stent retriever was used at the discretion of the individual neurointerventionalist due to primary insufficient results with the APH. In 5 cases, stent retrievers from other manufacturers (NeVa Mi 4 × 30 mm [n = 1], Vesalio, Lake Forest, California, USA; pREset LITE 3 × 20 mm [n = 1], Phenox, Bochum, Germany; Solitaire Platinum 4 × 40 mm [n = 2], Medtronic, Dublin, Ireland; Trevo XP ProVue 4 × 30 mm [n = 1], Stryker Neurovascular) were applied. In 2 procedures, the operator switched from the APH to a conventional predecessor Aperio 4.5 × 40 and 3.5 × 28 mm (Acandis) due to anticipated increased pushability. In case of rescue maneuver, final mTICI ≥ 2b could be achieved in 85.7% (6 of 7) of the patients. In one case of basilar artery occlusion, PTA and stent implantation after MT were necessary due to a high-grade atheriosclerotic stenosis.

Safety, Complications, and Clinical Outcome

No clinically relevant device-related procedural complications were encountered (Table 1). Angiographically apparent SAH did not occur. Periprocedural embolization into previously unaffected territories by fragmented or lost clots did not appear. In follow-up CT or magnetic resonance imaging 16–24 hours after MT, asymptomatic hemorrhagic transformation or parenchymal hematoma (HI-1, HI-2, PH-1) was observed in 6 patients (12.5%) and asymptomatic, mild SAH, Fisher 1, in 3 patients (6.3%). Three (6.3%) parenchymal hematomas (PH-2), as a result of a reperfusion injury, were symptomatic, and conductance of a craniectomy was required in 1 case. There were no device-related adverse events. Forty-six patients (95.8%) were available for follow-up at discharge; 2 were lost to follow-up (4.3%). A favorable clinical outcome at discharge according to the mRS (0–2) was achieved in 32.6% (15 of 46) and in 36.7% (11 of 30) of the patients available for 90-day follow-up (Table 1). Overall mortality during hospital stay was 21.7% (10 of 46). Procedure-related deaths did not occur.

DISCUSSION

The aim of this multicentric trial was to evaluate the efficacy, safety, and clinical outcome of the APH for the treatment of LVO in the anterior and posterior circulation in patients with acute ischemic stroke. The device was designed to achieve improvements in visibility by implementing radiopaque DFT wires that allow full-length visibility of the device. This quality may increase control during the procedure and reflect thrombus position within the stent frame itself during the retrieval. This new visibility concept was combined with the proven hybrid design[13] of the established predecessor Aperio. In this retrospective, multicentric trial, an overall mTICI 2b–3 revascularization rate was achieved in 95.8%. The rate of final favorable reperfusion (mTICI ≥ 2b) accounted already for 83.4% (40 of 48) when the APH was used exclusively. These results compare favorably with data from the TRACK registry in which Trevo devices were used with reported mTICI ≥ 2b recanalization in 68.8% of patients for the only use of the Trevo device[15] and with the reported rates of 71.1% for the sole use of EmboTrap in a recent core laboratory-audited single-center experience or a previous EmboTrap multicenter series with 73% recanalization rate.[16,17]

The rate of excellent final reperfusion (mTICI ≥ 2c) by the exclusive use of the APH was 52.1% in the present study and is slightly inferior to the outcome data of excellent reperfusion (mTICI ≥ 2c) in the Analysis of Revascularization in Ischemic Stroke with EmboTrap (ARISE II) study (64.7%) where EmboTrap was used.[18] First-pass recanalization rate mTICI ≥ 2b for procedures in which the APH was used solely was achieved in 52.1% and was comparable with EmboTrap in the recently published ARISE II trial (51.5%) and was higher compared with Trevo (40.8%) and Solitaire (32%) in a non–randomized controlled trial (RCT), whereas the rate of excellent first-pass recanalization (mTICI ≥ 2c) was slightly lower in our study compared with EmboTrap in ARISE II (33.4% vs. 40.1%).[18,19]

The mean number of passes (mean, 3.0 ± 3) with the APH was in line with results from a recent nonrandomized comparative trial for Trevo (mean, 2.1; interquartile range, 1–6) and Solitaire

Table 1. Baseline Data, Angiographic Results, Clinical Outcome, and Complications

	Overall Patients	Aperio Hybrid Only	Patients with Rescue
Sample Size	N = 48 Patients	N = 41 Patients	N = 7 Patients
Age, mean (±SD)	73 (±15)	74 (±16)	72 (±8)
Sex, n (%)	f = 26 (54.2), m = 22 (45.8)	f = 21 (51.2), m = 20 (48.8)	f = 5 (71.4), m = 2 (28.6)
Medical history			
Hypertension, n (%)	40 (87.0)	31 (84.6)	7 (100.0)
Diabetes mellitus, n (%)	6 (13.0)	4 (10.3)	2 (28.6)
Atrial fibrillation, n (%)	23 (47.9)	18 (46.2)	5 (71.4)
Previous stroke, n (%)	11 (23.9)	10 (25.6)	1 (14.3)
ASA, n (%)	10 (23.3)	8 (22.2)	2 (28.6)
Clopidogrel, n (%)	1 (2.3)	1 (2.8)	0 (0.0)
Phenprocoumon, n (%)	4 (9.3)	4 (11.1)	0 (0.0)
DOAC, n (%)	7 (16.3)	6 (16.7)	1 (14.3)
IVT, n (%)	25 (52.1)	21 (51.2)	4 (57.1)
NIHSS pre, median, n (%)	15 (2–36)	14 (2–36)	18 (16–20)
mRS pre, median, n (%)	5 (2–5)	5 (2–5)	5 (5–5)
Prestroke imaging			
Hemisphere, n (%)	r = 24 (50.0), l = 19 (39.6), v = 5 (10.4)	r = 21 (51.2), l = 15 (36.6), v = 5 (12.2)	r = 3 (42.9), l = 4 (57.1), v = 0 (0.0)
T-type occlusion, n (%)	8 (16.7)	5 (12.2)	3 (42.9)
M1 occlusion, n (%)	31 (64.6)	27 (65.9)	4 (57.1)
M2 occlusion, n (%)	4 (8.3)	4 (9.8)	0 (0.0)
Basilary occlusion, n (%)	5 (10.4)	5 (12.2)	0 (0.0)
Vessel diameter, mean (±SD)	2.8 (±0.8)	2.8 (±0.8)	3.1 (±0.9)
ASPECTS, median	9 (2–10)	9 (2–10)	8 (5–10)
Procedural data			
Onset-to-needle time (minutes), mean (±SD)	124 (±90)	132 (±94)	72 (±28)
Door-to-needle (minutes), mean (±SD)	70 (±175)	74 (±188)	46 (±33)
Onset-to-groin puncture (minutes), mean (±SD)	221 (±112)	224 (±117)	200 (±72)
Door-to-groin puncture (minutes), mean (±SD)	99 (±151)	99 (±154)	96 (±112)
Onset-to-recanalization (minutes), mean (±SD)	273 (±119)	275 (±127)	256 (±54)
Door-to-recanalization (minutes), mean (±SD)	149 (±163)	148 (±167)	159 (±128)
Groin-to-recanalization (minutes), mean (±SD)	54 (±33)	51 (±33)	69 (±31)
Number of passes, mean (±SD)	3 (±3)	2 (±3)	3 (±2)
Number of device passes to TICI2b/3 recanalization, mean (±SD)	3 (±3)	2 (±3)	3 (±2)

Continues

Table 1. Continued

	Overall Patients		Aperio Hybrid Only	Patients with Rescue
IA tPA, n (%)	1 (2.1)		1 (2.8)	0 (0.0)
Rate of Recanalization After Stent-retriever First Pass				
TICI 0, n (%)	8 (16.7)	7 (17.1)		1 (14.3)
TICI 1, n (%)	3 (6.3)	3 (7.3)		0 (0)
TICI 2a, n (%)	8 (16.7)	6 (14.6)		2 (28.6)
TICI 2b, n (%)	13 (27.1)	10 (24.4)		3 (42.9)
TICI 2c, n (%)	4 (8.3)	3 (7.3)		1 (14.3)
TICI 3, n (%)	12 (25.0)	12 (29.3)		0 (0)
Final Angiographic and Postprocedural Imaging Outcomes			Percentage on Overall Sample (N = 48)	
TICI 0, n (%)	0 (0)	0 (0)	0 (0)	0 (0)
TICI 1, n (%)	0 (0)	0 (0)	0 (0)	0 (0)
TICI 2a, n (%)	2 (4.2)	1 (2.4)	1 (2.1)	1 (14.3)
TICI 2b, n (%)	17 (35.4)	15 (36.6)	15 (31.3)	2 (28.6)
TICI 2c, n (%)	6 (12.5)	4 (9.8)	4 (8.3)	2 (28.6)
TICI 3, n (%)	23 (47.9)	21 (51.2)	21 (43.8)	2 (28.6)
ASPECTS, median	6 (0–10)	7 (0–10)		6 (1–8)
Clinical outcome	(N = 46)		(N = 39)	(N = 7)
Number of patients (%) of mRS ≤2 (at discharge)	15 (32.6)		15 (38.5)	0 (0)
mRS 0, n (%)	3 (6.5)		3 (7.7)	0 (0)
mRS 1, n (%)	9 (19.6)		9 (23.1)	0 (0)
mRS 2, n (%)	3 (6.5)		3 (7.7)	0 (0)
mRS 3, n (%)	3 (6.5)		3 (7.7)	0 (0)
mRS 4, n (%)	8 (17.4)		5 (12.8)	3 (42.9)
mRS 5, n (%)	10 (21.7)		8 (20.5)	2 (28.6)
Mortality (discharge), mRS 6, n (%)	10 (21.7)		8 (20.5)	2 (28.6)
NIHSS discharge	7 (0–42)		5 (0–42)	16 (7–42)
Number of patients (%) of mRS ≤2 (at 90-day FU)	11 (36.7)		10 (41.7)	1 (16.7)
mRS 0, n (%)	4 (13.3)		3 (12.5)	1 (16.7)
mRS 1, n (%)	6 (20.0)		6 (25.0)	0 (0)
mRS 2, n (%)	1 (3.3)		1 (4.2)	0 (0)
mRS 3, n (%)	1 (3.3)		1 (4.2)	0 (0)
mRS 4, n (%)	3 (10.0)		1 (4.2)	2 (33.3)
mRS 5, n (%)	6 (20.0)		4 (16.7)	2 (33.3)
Mortality (90-day FU), mRS 6, n (%)	9 (30.0)		8 (33.3)	1 (16.7)

SD, standard deviation; ASA, acetylsalicylic acid; DOAC, new oral anticoagulants; IVT, intravenous thrombolysis; NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin Scale; ASPECTS, Alberta Stroke Program Early Computed Tomography Score; IA tPA, intra-arterial tissue plasminogen activator; TICI, thrombolysis in cerebral infarction; FU, follow-up; SAH, subarachnoid hemorrhage; sICH, symptomatic intracranial hemorrhage.

Continues

Table 1. Continued

	Overall Patients	Aperio Hybrid Only	Patients with Rescue
Complications			
None, n (%)	36 (75.0)	29 (70.7)	7 (100.0)
SAH, n (%)	3 (6.3)	3 (7.3)	0 (0)
HI-1, n (%)	3 (6.3)	3 (7.3)	0 (0)
HI-2, n (%)	2 (4.2)	2 (4.9)	0 (0)
PH-1, n (%)	1 (2.1)	1 (2.4)	0 (0)
PH-2, n (%)	3 (6.3)	3 (7.3)	0 (0)
sICH, n (%)	3 (6.3)	3 (7.3)	0 (0)

SD, standard deviation; ASA, acetylsalicylic acid; DOAC, new oral anticoagulants; IVT, intravenous thrombolysis; NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin Scale; ASPECTS, Alberta Stroke Program Early Computed Tomography Score; IA tPA, intra-arterial tissue plasminogen activator; TICI, thrombolysis in cerebral infarction; FU, follow-up; SAH, subarachnoid hemorrhage; sICH, symptomatic intracranial hemorrhage.

(mean, 2.9; interquartile range, 1–8),[19] with Trevo from the TRACK registry (mean, 1.9 ± 1.2) or EmboTrap from ARISE II (average, 2.6; range, 1–10).[15,18,19]

If MT with the APH was regarded as unsuccessful and aborted, another competing stent retriever was chosen. The rate of 14.6% for rescue maneuvers was consistent with results reported from other non-RCT stent-retriever studies ranging between 15% and 28%.[15-18,20]

An early favorable clinical outcome (mRS, 0–2) at discharge was achieved in 32.6% of our patient sample and is superior to the discharge mRS of the TRACK study (mean [standard deviation], 17.4% [6.7%]).[15]

Being well aware of limited outcome follow-up data in the present study, a 3-month mRS rate of 36.7% seems to be in line with self-reported rates for EmboTrap (35%)[17] and with non-RCT trials for the Aperio (41.2%)[13] and Solitaire (42.1%)[19] as well as rates in the NASA (42%)[20] and Endostroke registry (41%).[21] Better 3-month follow-up rates in further non-RCT trials are reported for EmboTrap[16] and Trevo[15,19] (**Table 2**).

The safety of the APH in the current study is within the range of recent stent-retriever trials (**Table 2**). The rate of 6.3% for sICH is comparable with 5% in the ARISE II trial[18] and 7.1% and 9.9% sICH rates in TRACK[15] and NASA,[20] respectively. Clot fragment embolization into previously unaffected territories did not occur. The all-cause mortality rate at 30 days was 21.7%, which is comparable with TRACK data (19.8%)[15] and NASA,[20] and is higher compared with ARISE II (9%)[18] and in non-RCT trials for EmboTrap (12.9%)[16] and Solitaire and Trevo (6.8% and 4%).[19] No case of death in our patients was procedural related. These safety results support an acceptable benefit-risk profile for the device.

The preceding model of the APH, the Aperio, was evaluated in 2 trials with patients with stroke with LVO of the cerebral circulation. In the first trial, 119 patients from 9 centers, where 42% had the occlusion in the M1 segment, were treated by MT.[22] Rate of mTICI ≥ 2b–3 was 71% at a median of device passes of 2.[22] The handling and effectiveness of the predecessor APH was evaluated regarding trackability, visualization, positioning, and deployment. Trackability was rated as very good and good in 82%, visualization in 91%, deployment in 91%, and positioning in 89%. In the present study, we assessed an improvement in the rating of the new APH in device deployment, positioning of a stent retriever, and visibility.

In 2 cases of the current study, impeded device pushability was observed, but no correlation with a particular microcatheter was ascertainable. In both cases, a tortuous vessel anatomy of the cavernous or terminal internal carotid artery segment, or curved vessels of the M1 segment and its division were assumed as likely causes for increased resistance. In addition, another explanation might be increased friction inside the microcatheter during stent-retriever advancement due higher volume of material evoked by the new embedded DFT wires into the APH. This extra material may become noticeable in the aforementioned challenging anatomic conditions with elongated and curved extra- and intracranial vessels.

These challenges might be overcome by using the new generation of the dedicated neuroslider microcatheter (NeuroSlider DLC; Acandis) for delivery that is expected to offer more stability. In the aforementioned cases, the predecessor Aperio as a rescue device was used assuming a smoother pushability due to less friction within the microcatheter.

The second single-center study evaluated the safety and efficacy of the first-generation Aperio in 82 patients with stroke with LVO of the anterior circulation.[13] mTICI ≥ 2b rate was achieved in 85.3% and first-pass mTICI ≥ 2b in 43.9% at a mean of device passes of 2.6 ± 1.7. Compared with the present study an increase in recanalization rates by the use of the APH with mTICI ≥ 2b in 95.8% and first-pass mTICI ≥ 2b in 52.1% at a mean of 3 ± 3 passes could be assessed.[13] Complication rates were reported with rates of 10% including embolization in new territory in 1.2% (vs. 0% in the present study) and 7.3% sICH (vs. 6.3% in the present study).[13,22] As in the present APH study, serious device-related complications did not occur with the precursor Aperio. Hence, the performance and safety of the APH compares favorably with the predecessor model. Although both stent retrievers have the same hybrid cell design, higher

Table 2. Clinical and Angiographic Outcome of Selected Stent-Retriever Trials

Study	Endovascular Treatment (n)	Device	Baseline NIHSS (Median)	Overall TICI 2b–3 (%)	First Pass TICI (%)	Postinterventional NIHSS (Median)	mRS 0–2 at 90 Days (%)	Mortality (%)	sICH (%)
Singer et al. 2013[21]	309*	Various	16	77	N.A.	N.A.	41	27	15
Kallenberg et al. 2016[22]	119	Aperio	N.A.	71	N.A.	N.A.	N.A.	0	0
Kabbasch et al. 2016[17]	40	EmboTrap	16	95	TICI 3: 38	N.A.	35	17	15
Zaidat et al. 2018[15]	634	Trevo	17	80	TICI 3: 54.3	Mean (SD) Discharge: 17.4 (6.7); 90 day: 18.1 (18.7)	47.9	19.8	7.1
Kaschner et al. 2019[13]	82	Aperio	14	85.3	TICI 2b–3: 43.9	N.A.	41.2	17.1	7.3
Zaidat et al. 2018[18]	227	EmboTrap	Mean (SD) 15.8 (5)	92.5	TICI 2b–3: 51.5 TICI ≥2c: 40.1	N.A.	67	9	5.3
Zaidat et al. 2014[20]	354	Solitaire	17	73	N.A.	N.A.	42	30.2	9.9
Brouwer et al. 2018[16]	201	EmboTrap	15	84.6	N.A.	N.A.	52.8	12.9	N.A.
Yi et al. 2018[19]	102	Solitaire	11.3	82.3	TICI 2b–3: 32	At 30 days: 6.2	42.1	6.8	N.A.
	98	Trevo	11.7	89.7	TICI 2b–3: 40.8	At 30 days: 5.4	48.9	4	N.A.
This study	48	Aperio Hybrid	15	96	TICI 2b–3: 60.4 TICI ≥2c: 33.4 TICI 3: 25	At discharge: 7	36.7	22	6

NIHSS, National Institutes of Health Stroke Scale; N.A., not available; SD, standard deviation; TICI, thrombolysis in cerebral infarction; mRS, modified Rankin Scale; sICH, symptomatic intracranial hemorrhage.

*Number of patients with available TICI scoring.

recanalization rates of the APH were achieved in the current study compared with the Aperio. An explanation might be higher expansion forces of the APH due to the additional DFT wires that may improve clot incorporation. This hypothesis is currently under investigation by the manufacturer, but data from laboratory experiments are still pending.

The major limitations of this study are the nonrandomized retrospective nature, a missing reference group, and the relatively small sample particularly for the posterior circulation.

In addition, angiographic images were evaluated by blinded neurointerventionalists at their own center and not core laboratory adjudicated that can potentially bias the interpretation results. In this study, it was up to the individual operator's discretion when to abstain from the APH and switch to another rescue device. Therefore, it is not known whether a continuation with the APH would have still led to a success in the 7 cases in which rescue devices have been chosen. A further consideration in the present study is the primary use of a concomitant lesional local aspiration technique during stent-retriever retrieval, termed the Solumbra technique.[14] It is important to note that the overall endovasular treatment techniques have evolved. Particularly in Solumbra the aspiration component is very important and effective and might be at least in part an explanation for the good revascularization results that are superior to some of the prementioned RCTs. In this context, it is conceivable that different thrombectomy techniques for different circumstances may impact the rate of excellent reperfusion and first-past complete revascularization, for example, using a balloon guide–assisted proximal aspiration under flow reversal. Further RCTs may help define subgroups of patients, in which the APH, in combination with a specific thrombectomy method, based on the occlusion pattern, would yield the most effective recanalization results.

Follow-up clinical outcome after 90 days is limited to 30 of 48 (63%) patients and therefore has to be interpreted with caution. However, a German multicentric registry is being initiated by our group and will provide more extensive data.

In this initial evaluation, there was no major criticism toward the overall handling of the device. The improved visibility concept of the APH was rated to be “good” or “very good” in 100% of its first clinical trial. Technically, its use seems feasible and safe, and the high rates of successful

recanalization appear to be in the range of comparable stent-retriever publications.

Full structural radiopacity would allow a more targeted deployment of the APH and delineation of the stent retriever. From a procedural point of view, visualization of just the distal markers would be sufficient but a reliable detection of clot integration and clot displacement requires full-length visibility of the stent structures. Moreover, during retrieval there is no visual control of the clot-stent interaction in conventional nitinol retrievers as the predecessor Aperio. Compared with the Aperio, the APH is one of few stent retrievers that allow visualization of the clot-strut interaction during both deployment and retrieval.[11,12] As a result of full-length visibility, a potential failure of the thrombectomy maneuver might be detected at an early stage and enables us to adapt or modify the procedure, for example, obvious nonintegration of the clot within the stent retriever just sliding past it or visible straightening of the target vessel without relative movement of the stent retriever that may indicate increased force transmitted to the vessel, with the risk of structural damage. In our cases in which pushability of the device was rated as "poor" and "very poor" (4.2%, 2 of 48) and positioning of the APH as "poor" (2.1%, 1 of 48), the added DFT wires were supposed to increase the resistance during the delivery and deployment of the APH stent retriever via the microcatheter. This assumption is in accord with reports of an international survey performed among the members of the World Federation of Interventional and Therapeutic.[23] In this context, a final assessment of friction or resistance during delivery and deployment of the device, and evaluation of the used material in combination with the APH (e.g., microcatheters, aspiration catheters), should be subject to a prospective evaluation.

CONCLUSIONS

This early multicenter experience demonstrated that the recently introduced APH yielded high rates of favorable and excellent reperfusion in cerebral LVO in conjunction with lesional aspiration in the setting of acute stroke. Clinical outcome after 90 days seems to be in line with published literature. The absence of device-related procedural complications reflects a high safety profile. Full-length visibility of the APH may allow the detection of the alignment of the device with the clot and may guide procedural adaptation by control of the actual stent-clot or stent-vessel interaction. These promising initial results will be further evaluated in a German multicentric registry.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Marius Kaschner: Writing - original draft, Data curation, Investigation. **Thorsten Lichtenstein:** Writing - original draft, Data curation, Investigation. **Daniel Weiss:** Data curation, Formal analysis. **Bernd Turowski:** Data curation, Formal analysis. **Lukas Goertz:** Data curation, Formal analysis. **Claudia Kluner:** Data curation, Formal analysis. **Marc Schlamann:** Data curation, Formal analysis. **Christian Mathys:** Writing - review & editing, Data curation, Project administration, Investigation, Validation, Supervision. **Christoph Kabbasch:** Conceptualization, Writing - review & editing, Data curation, Project administration, Investigation, Validation, Supervision.

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All data will be made available on request in an anonymized manner.

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