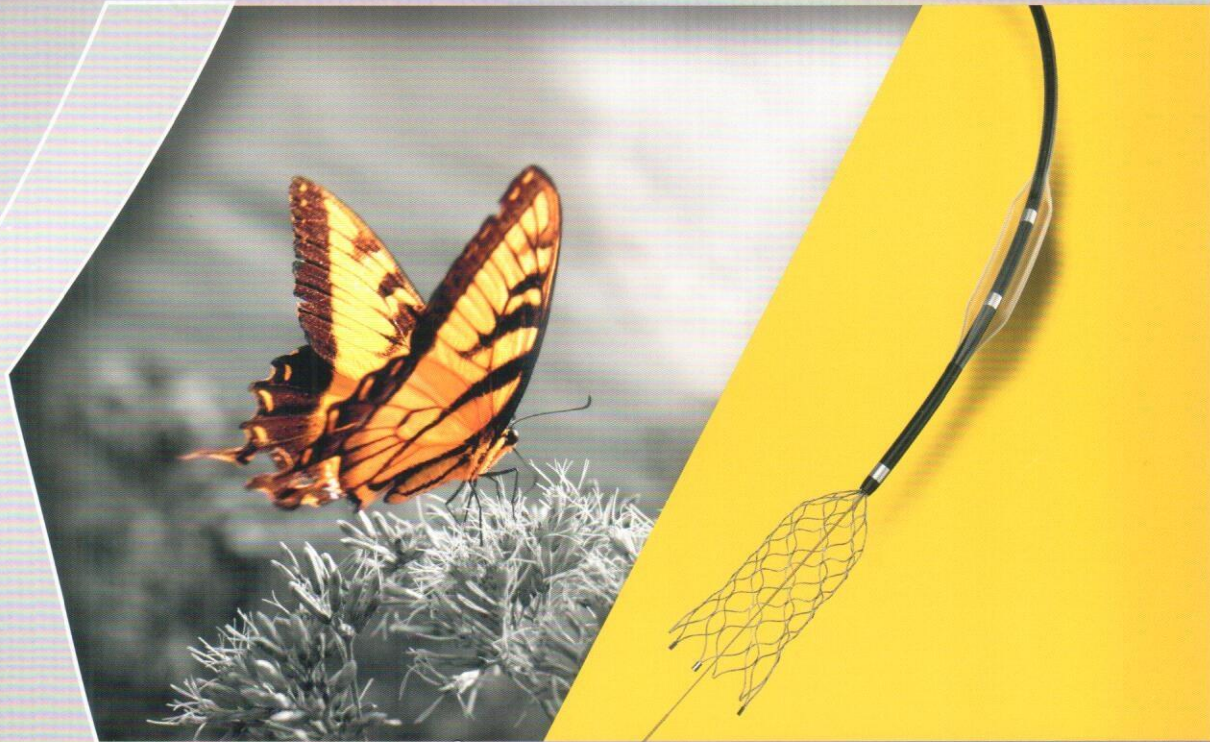


SIMPLY UNIQUE

ICAD* Treatment with
NeuroSpeed® PTA Balloon Catheter and CREDO® Stent



- Over-the-wire system — 8.184m OTW (over-the-wire)
- Flexible self-expanding highly visible stent
- Deliverable through 0.0165" NeuroSpeed® PTA Balloon Catheter

* ICAD Intracranial Atherosclerotic Disease

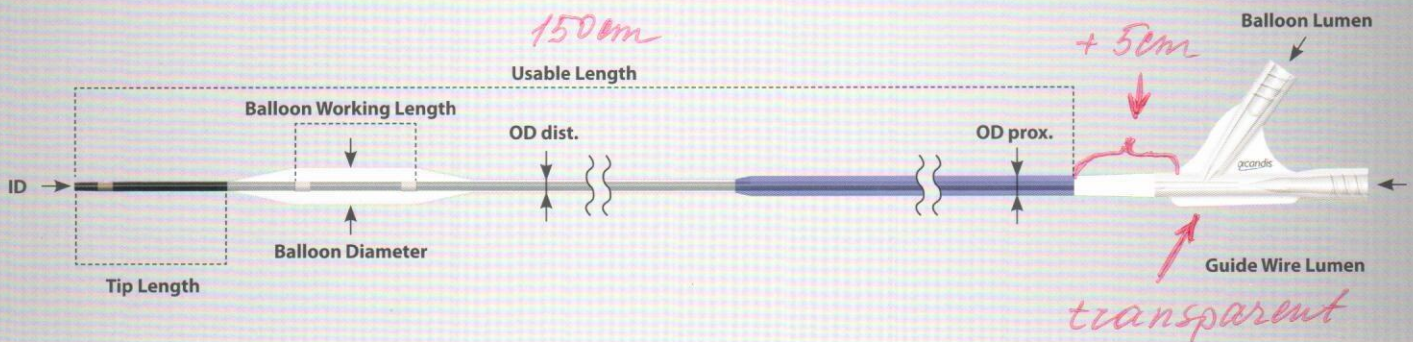
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NeuroSpeed® PTA Balloon Catheter



FEW SIZES – BIG IMPACT



FLEXIBLE

The NeuroSpeed® PTA Balloon Catheter is ideal for gentle and controllable PTA of intracranial stenosis. If stent placement is required for stabilisation of the stenotic lesion, the CREDO® Stent can be delivered through the low-profile NeuroSpeed® PTA Balloon Catheter without exchange manoeuvre.

SMOOTH

The NeuroSpeed® PTA Balloon Catheter features a slim entrance profile and double hydrophilic coating. The flexible 10 mm tip, with distal tip X-ray marker, ensures atraumatic access and easy navigation. With a usable length of 150 cm, it is possible to reach more distal vessels.

*dist maleabil
double stratificat*

EFFECTIVE

The semi-compliant balloon material of the NeuroSpeed® PTA Balloon Catheter enables a precise and controllable inflation behaviour for gentle and effective dilation. The portfolio consist of only 6 sizes with nominal balloon diameters ranging from 1.5 to 4.0 mm.



Initial degree of stenosis 80 %
Pre Dilatation

NeuroSpeed® PTA Balloon Catheter 2.0 x 8 mm
Inflation

Final degree of stenosis ~ 10 %
Post Dilatation

ORDERING INFORMATION

Labelled Credo® Dimensions (mm)	Reference Number	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Diameter (mm)	Required Catheter for Delivery
3.0 × 15	01-000930	3.0	15	2.0–2.5	NeuroSpeed® PTA Balloon Catheter
3.0 × 20	01-000931	3.0	20	2.0–2.5	NeuroSpeed® PTA Balloon Catheter
4.0 × 15	01-000940	4.0	15	2.5–3.5	NeuroSpeed® PTA Balloon Catheter
4.0 × 20	01-000941	4.0	20	2.5–3.5	NeuroSpeed® PTA Balloon Catheter
5.0 × 15	01-000950	5.0	15	3.5–4.5	NeuroSpeed® PTA Balloon Catheter
5.0 × 20	01-000951	5.0	20	3.5–4.5	NeuroSpeed® PTA Balloon Catheter

Labelled NeuroSpeed® Dimensions (mm)	Reference Number	Balloon Diameter (mm)	Balloon Working Length (mm)	ID (Inch)	OD dist. / prox. (French)	Usable Length (cm)
1.5 × 8	01-000605	1.5	8	0.0165	2.7 / 3.7	150
2.0 × 8	01-000600	2.0	8	0.0165	2.7 / 3.7	150
2.5 × 8	01-000601	2.5	8	0.0165	2.7 / 3.7	150
3.0 × 8	01-000602	3.0	8	0.0165	2.7 / 3.7	150
3.5 × 8	01-000603	3.5	8	0.0165	2.7 / 3.7	150
4.0 × 8	01-000604	4.0	8	0.0165	2.7 / 3.7	150

dimensions

Inflation Pressure (bar)	NeuroSpeed® Diameter (mm)					
	1.5	2.0	2.5	3.0	3.5	4.0
2.0	1.21	1.72	2.09	2.42	3.06	3.26
4.0	1.37	1.84	2.33	2.78	3.25	3.72
6.0	1.50*	2.00*	2.50*	3.00*	3.50*	4.00*
8.0	1.67	2.16	2.65	3.22	3.69	4.23
10.0	1.85	2.27	2.75	3.38	3.83	4.37
12.0	2.02	2.39	2.87	3.54	3.97**	4.53**
14.0	2.20**	2.52**	2.98**	3.73**	–	–

* Nominal pressure ** Rated burst pressure

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ACANDIS GmbH
Theodor-Fahrner-Str. 6
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PERFECT INTERPLAY

APERIO® Hybrid Thrombectomy Device



- Effective hybrid-cell design for fast flow restoration
- Outstanding visibility for maximum control and safety
- Broad range of sizes for tailored treatment options

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APERIO® Hybrid Thrombectomy Device

The hybrid cell design combined with perfect visibility lead to utmost safety and reliability during procedure – for fast flow restoration.

PERFECT INTERPLAY.

RELIABLE

The APERIO® Hybrid Thrombectomy Device is the third generation of Acandis® stent retriever featuring the proven **hybrid cell design**.

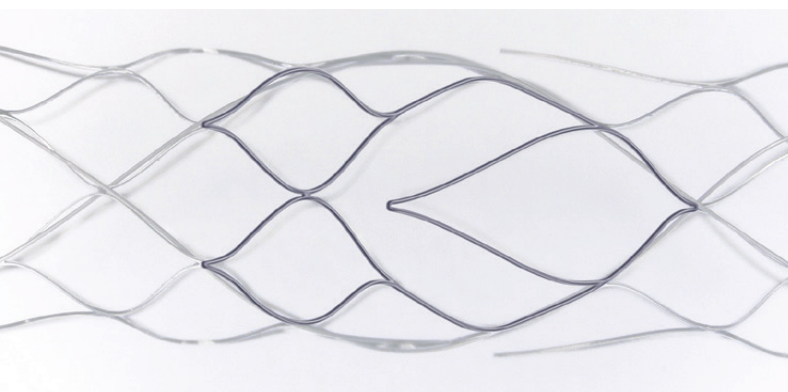
Small closed cells ensure a perfect vessel wall apposition and expansion into the clot. Large open cells with integrated anchoring elements assure efficient clot retention for reliable and atraumatic retrieval even in tortuous vessel anatomies. In combination, these two cell designs build up a functional segment.

VARIABLE

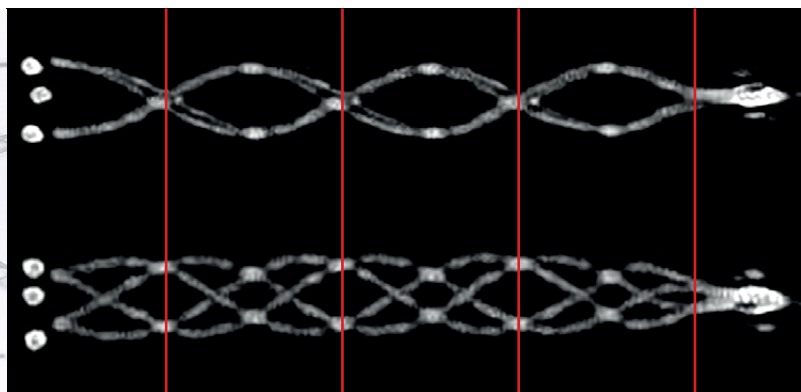
The broad range of sizes enables the treatment of vessel diameters from 1.5 mm up to 5.5 mm.

All sizes are suitable with 0.021" microcatheter.

Due to repeating functional segments the device working length can be adapted.



Functional segment of the APERIO® Hybrid Thrombectomy Device



APERIO® Hybrid Thrombectomy Device (6.0 x 50 mm) – functional segments

Simple and clear visibility concept for maximum control and assurance

Three distal platinum iridium device markers for permanent control of device position and opening behaviour.

Two radiopaque DFT wires featuring full length visibility for precise alignment and additional control during procedure.

One proximal platinum iridium device marker for precise positioning within the thrombus.

SAFE

Thanks to the proven hybrid cell design and the excellent full length visibility, the APERIO® Hybrid Thrombectomy Device leads to a maximum in safety and reliability during the procedure.

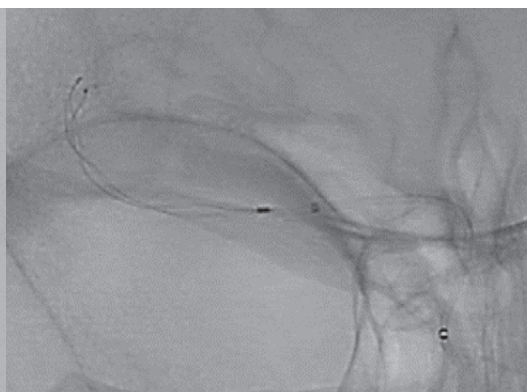
EFFICIENT

The constant and balanced radial force over the intended vessel diameter allows a gentle and highly efficient clot removal.¹

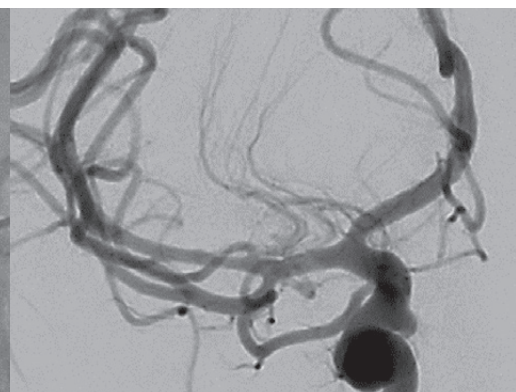
¹ Machi P, Jourdan F, Ambard D, et al Experimental evaluation of stent retrievers' mechanical properties and effectiveness, Journal of NeuroInterventional Surgery 2017;9:257-263.



Pre treatment
Total occlusion of middle cerebral artery



Treatment
with APERIO® Hybrid Thrombectomy Device 4.5 x 30 mm



Post treatment
Final result after first pass

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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ACANDIS GmbH
Theodor-Fahrner-Str. 8
75177 Pforzheim
Deutschland

Tel: +49 7231 155 00 0
Fax: +49 7231 155 00 129
E-Mail: info@acandis.com
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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

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

Marius Kaschner¹, Thorsten Lichtenstein², Daniel Weiss¹, Bernd Turowski¹, Lukas Goertz^{2,3}, Claudia Kluner⁴, Marc Schlamann², Christian Mathys^{1,4,5}, Christoph Kabbasch²

■ **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

From the ¹Medical Faculty, Department of Diagnostic and Interventional Radiology, University Duesseldorf, Duesseldorf; ²Institute for Diagnostic and Interventional Radiology, and ³Center for Neurosurgery, Faculty of Medicine and University Hospital Cologne, University of Cologne, Cologne; ⁴Institute of Radiology and Neuroradiology, Evangelisches Krankenhaus, University of Oldenburg; and ⁵Research Center Neurosensory Science, Carl von Ossietzky Universität Oldenburg, Oldenburg, Germany

To whom correspondence should be addressed: Christoph Kabbasch, M.D.
[E-mail: christoph.kabbasch@uk-koeln.de]

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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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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Conflict of interest statement: C. Kabbasch reports personal fees from Acandis and personal fees from Microvention,

outside the submitted work. The remaining authors have no conflicts to report.

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

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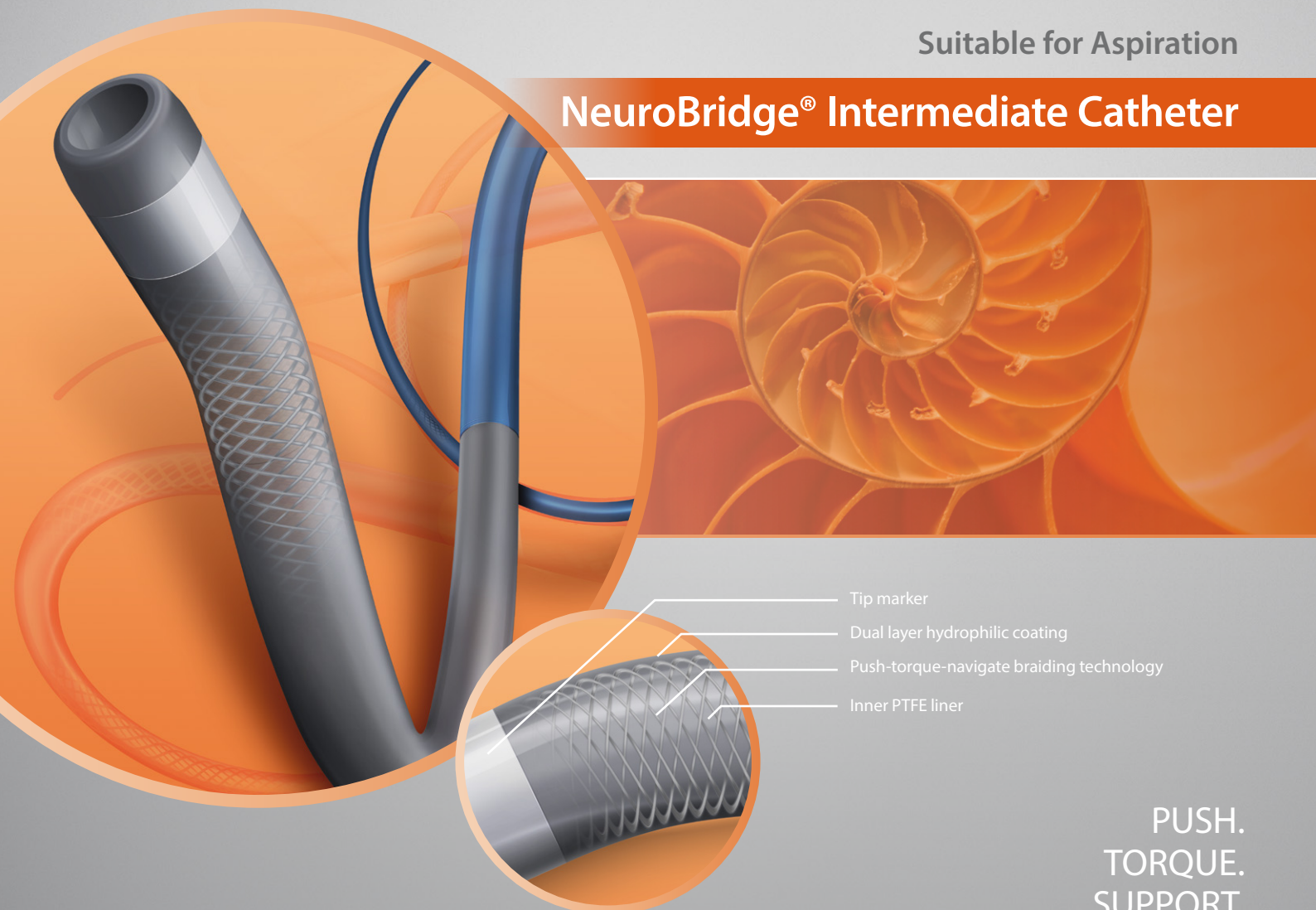
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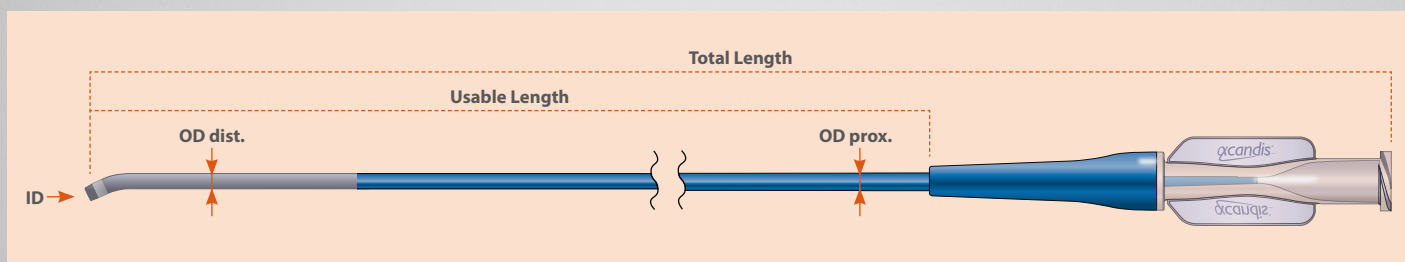
TORQUE.

- Push-torque-navigate braiding technology induces excellent torquability
- Multi polymer shaft construction consisting of 5 different zones with smooth transition from hub to tip ensures precise navigation and optimized torque control
- 25° multi-purpose tip shape enables an easy and safe vessel targeting

SUPPORT.

- Robust inner lumen leads to enhanced stability and safety for strong and powerful aspiration
- Special braiding construction ensures overall increased kink and ovalization resistance
- Soft, rounded and flexible tip allows atraumatic access even through tortuous anatomies
- Low friction inner PTFE liner assures smooth passage and safe delivery of microcatheters

SPECIFICATIONS



ORDERING INFORMATION

Product Name	Reference Number	ID (Inch)	OD dist. (French / Inch)	OD prox. (French / Inch)	Usable Length (cm)	Total Length (cm)	Tip Shape
NeuroBridge® 39	01-000508	0.039	3.9 / 0.051	4.2 / 0.055	125	131	Multi-Purpose 25°
NeuroBridge® 39	01-000509	0.039	3.9 / 0.051	4.2 / 0.055	135	141	Multi-Purpose 25°
NeuroBridge® 39	01-000510	0.039	3.9 / 0.051	4.2 / 0.055	145	151	Multi-Purpose 25°
NeuroBridge® 52	01-000518	0.052	5.0 / 0.066	5.3 / 0.070	105	111	Multi-Purpose 25°
NeuroBridge® 52	01-000511	0.052	5.0 / 0.066	5.3 / 0.070	115	121	Multi-Purpose 25°
NeuroBridge® 52	01-000512	0.052	5.0 / 0.066	5.3 / 0.070	125	131	Multi-Purpose 25°
NeuroBridge® 52	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°
NeuroBridge® 65	01-000514	0.065	6.1 / 0.080	6.3 / 0.083	115	121	Multi-Purpose 25°
NeuroBridge® 65	01-000515	0.065	6.1 / 0.080	6.3 / 0.083	125	131	Multi-Purpose 25°

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ACANDIS GmbH
Theodor-Fahrner-Str. 6
75177 Pforzheim
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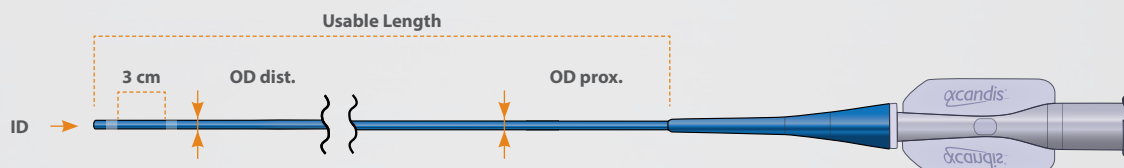
NAVIGATE.

- Shapeable tip with lasting shape retention allows excellent distal navigation even in tortuous anatomies.
- Multi polymer construction consisting of different flexibility zones with smooth transitions from maximum stability at the hub to maximum flexibility at the tip permits precise and effective navigation.

DELIVER.

- Inner PTFE liner minimises friction and allows a controlled and safe delivery of therapeutic and diagnostic agents.
- Advanced hub design with a transparent window results in a precise device transfer into the hub.

NeuroSlider® Microcatheter DLC



ORDERING INFORMATION

Product Name	Reference Number	ID (Inch)	OD dist. / prox. (French)	Usable Length (cm)	Tip Shape	Tip Marker
NeuroSlider® 17	01-000272	0.0165	1.9 / 2.1	155	Straight (shapeable)	2
NeuroSlider® 17 DLC	01-000282	0.0165	1.9 / 2.3	155	Straight (shapeable)	2
	01-000283	0.0165	1.9 / 2.3	160	Straight (shapeable)	2
	01-000284	0.0165	1.9 / 2.3	167	Straight (shapeable)	2
NeuroSlider® 21	01-000273	0.021	2.4 / 2.5	155	Straight (shapeable)	2
NeuroSlider® 21 DLC	01-000292	0.021	2.2 / 2.6	155	Straight (shapeable)	2
	01-000293	0.021	2.2 / 2.6	160	Straight (shapeable)	2
	01-000294	0.021	2.2 / 2.6	167	Straight (shapeable)	2
NeuroSlider® 27 (DLC)	01-000274	0.027	3.0 / 3.6	155	Straight (shapeable)	1

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ACANDIS GmbH
Theodor-Fahrner-Str. 6
75177 Pforzheim
Germany

Tel: +49 7231 155 00 0
Fax: +49 7231 155 00 129
E-Mail: info@acandis.com
www.acandis.com

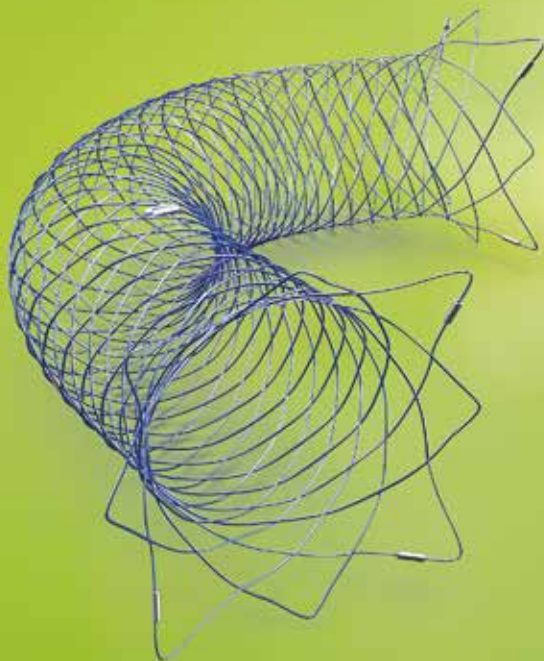
BRILLIANT HIGH-FLYER

ACCERO® Stent



- Self-expanding braided stent
- BlueXide® surface finishing
- Excellent opening behaviour & adaptability
- Brilliant visibility

ACCERO® Stent



ACCERO® Stent is a highly visible, braided self-expanding stent with BlueXide® surface technology.

ADAPTIVE

The stent has an excellent opening behaviour and an advanced wall apposition at the ends. Our engineers designed a high radial resistive force to ensure reliable coil retention.

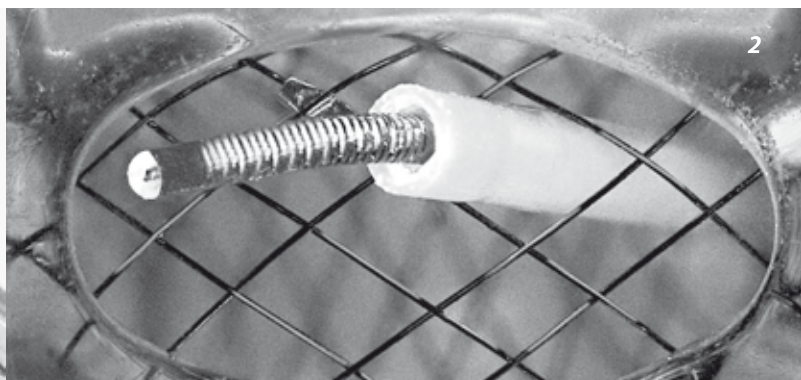
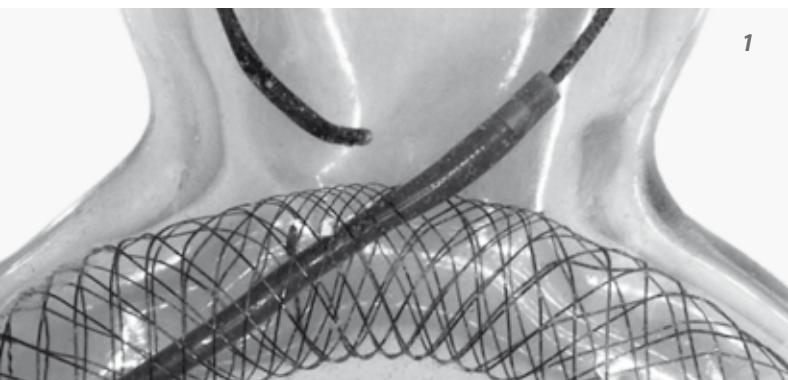
EASY TO USE

The ACCERO® can be delivered through 0.0165"-0.0170" microcatheters and double lumen balloon guidecatheters* and can be resheathed more than 95% of its length.

* contact Acandis for detailed microcatheter compatibility information

Captions:

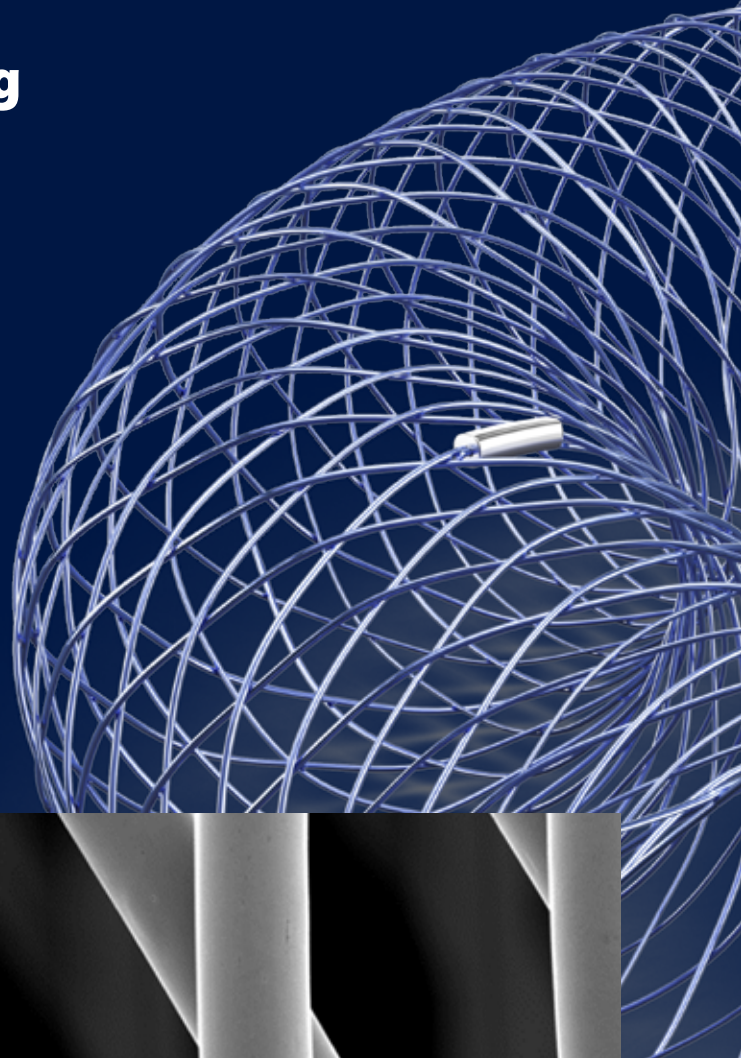
1,2 Stent assisted coiling with ACCERO® Stent



BlueXide® Surface Finishing

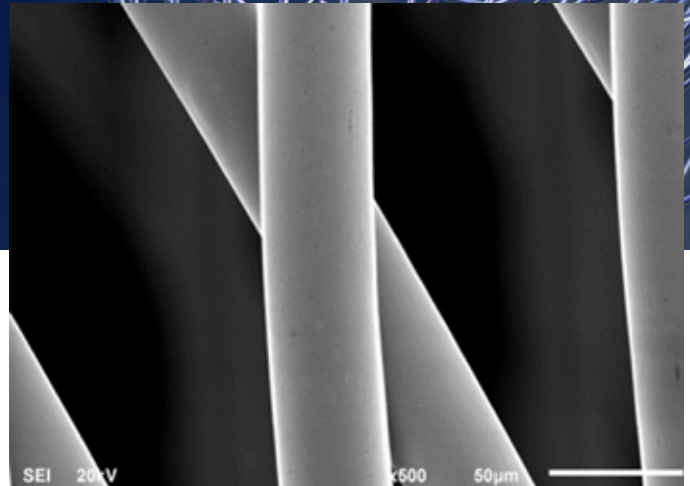
The Acandis® proprietary BlueXide® surface finishing aims to optimize hemocompatibility and facilitates stent delivery by:

- Corrosion protective BlueXide® surface ensures an extremely **low Nickel ion release**.
- High Oxygen and Nitrogen intensity of the protective Titanium Oxide/Oxynitride film **reduces platelet adhesion and favours endothelialization** compared to native oxide and therefore results in improved vessel healing.
- **Smooth surface of Nitinol wires favours excellent opening behaviour and low delivery force.**



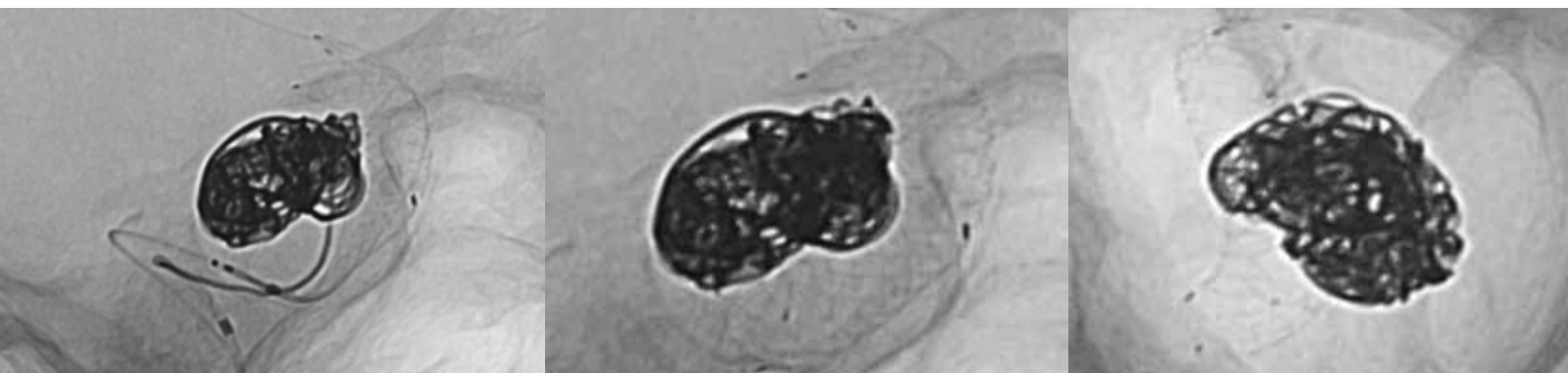
VISIBLE

Enhanced radiopacity of the Platinum-Nitinol composite wire allow the visibility of the entire contour of the stent. Three additional Platinum markers at each end plus the middle marker allow an accurate placement.



SEM (scanning electron microscope) image of the surface

STENT ASSISTED COILING WITH ACCERO®



Initial Deployment of ACCERO® 4.5 x 20 mm

ACCERO® fully deployed

Final Angio

ORDERING INFORMATION

Labelled ACCERO® Stent Ø (mm)	Labelled ACCERO® Stent Length (mm)	Reference Number	Recommended Vessel Ø (mm)	Recommended MC for Delivery (inch)
2.5	10	01-000800	1.5 – 2.5	0.0165-0.017
	15	01-000801		
	20	01-000802		
3.5	10	01-000806	2.5 – 3.5	
	15	01-000807		
	20	01-000808		
	25	01-000841		
4.5	15	01-000813	3.5 – 4.5	
	20	01-000814		
	25	01-000842		

Product Name	Reference Number*	ID (inch)	OD dist. / prox. (French)	Usable Length (cm)
NeuroSlider® 17	01-000272	0.0165	1.9 / 2.1	155

* For availability please contact your local representative from Acandis®.

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CE 0297

ACANDIS GmbH
Theodor-Fahrner-Str. 6
75177 Pforzheim
Germany

Tel: +49 7231 155 00 0
Fax: +49 7231 155 00 129
E-Mail: info@acandis.com
www.acandis.com

ORDERING INFORMATION | ACCERO®

Labelled ACCERO® Dimensions (mm)	Reference Number	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Diameter (mm)	Required / Recommended Microcatheters for Delivery (Inch)
2.5 × 10	01-000800	2.5	10	1.5 – 2.5	0.0165 – 0.017 NeuroSlider® 17 DLC
2.5 × 15	01-000801	2.5	15	1.5 – 2.5	
2.5 × 20	01-000802	2.5	20	1.5 – 2.5	
3.0 × 10	01-000803	3.0	10	2.0 – 3.0	
3.0 × 15	01-000804	3.0	15	2.0 – 3.0	
3.0 × 20	01-000805	3.0	20	2.0 – 3.0	
3.5 × 10	01-000806	3.5	10	2.5 – 3.5	
3.5 × 15	01-000807	3.5	15	2.5 – 3.5	
3.5 × 20	01-000808	3.5	20	2.5 – 3.5	
3.5 × 25	01-000841	3.5	25	2.5 – 3.5	
4.0 × 15	01-000810	4.0	15	3.0 – 4.0	
4.0 × 20	01-000811	4.0	20	3.0 – 4.0	
4.0 × 25	01-000845	4.0	25	3.0 – 4.0	

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Unique
ICAD treatment

NeuroSpeed®
PTA Balloon Catheter

CREDO®
Stent

indicated for
ACUTE (LVO) & ELECTIVE stenting

ORDERING INFORMATION | CREDO® with NeuroSpeed®

Labelled CREDO® Dimensions (mm)	Reference Number	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Diameter (mm)	Required Catheters for Delivery
3.0 × 15	01-000930	3.0	15	2.0 – 2.5	NeuroSpeed® PTA Balloon Catheter
3.0 × 20	01-000931	3.0	20	2.0 – 2.5	
3.0 × 25	01-000932	3.0	25	2.0 – 2.5	
3.0 × 30	01-000933	3.0	30	2.0 – 2.5	
4.0 × 15	01-000940	4.0	15	2.5 – 3.5	
4.0 × 20	01-000941	4.0	20	2.5 – 3.5	
4.0 × 25	01-000942	4.0	25	2.5 – 3.5	
4.0 × 30	01-000943	4.0	30	2.5 – 3.5	
5.0 × 15	01-000950	5.0	15	3.5 – 4.5	
5.0 × 20	01-000951	5.0	20	3.5 – 4.5	
5.0 × 25	01-000952	5.0	25	3.5 – 4.5	
5.0 × 30	01-000953	5.0	30	3.5 – 4.5	

All sizes feature HRF (High Radial Force)

Labelled NeuroSpeed® Dimensions (mm)	Reference Number	Balloon Diameter (mm)	Balloon Working Length (mm)	ID (Inch)	OD dist. / prox. (French)	Usable Length (cm)
1.5 × 8	01-000605	1.5	8	0.0165	2.7 / 3.7	150
2.0 × 8	01-000600	2.0	8	0.0165	2.7 / 3.7	150
2.5 × 8	01-000601	2.5	8	0.0165	2.7 / 3.7	150
3.0 × 8	01-000602	3.0	8	0.0165	2.7 / 3.7	150
3.5 × 8	01-000603	3.5	8	0.0165	2.7 / 3.7	150
4.0 × 8	01-000604	4.0	8	0.0165	2.7 / 3.7	150

Inflation Pressure (bar)	NeuroSpeed® Diameter (mm)					
	1.5	2.0	2.5	3.0	3.5	4.0
2.0	1.21	1.72	2.09	2.42	3.06	3.26
4.0	1.37	1.84	2.33	2.78	3.25	3.72
6.0	1.50*	2.00*	2.50*	3.00*	3.50*	4.00*
8.0	1.67	2.16	2.65	3.22	3.69	4.23
10.0	1.85	2.27	2.75	3.38	3.83	4.37
12.0	2.02	2.39	2.87	3.54	3.97**	4.53**
14.0	2.20**	2.52**	2.98**	3.73**	–	–

* Nominal pressure ** Rated burst pressure

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Not available for sale in the United States.

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CREDO® | NeuroSpeed®
Stent | PTA Balloon Catheter

Approved for acute (LVO) and elective stenting
Repositionable up to 90% deployment
New diameter (5.0 mm) and longer lengths (25 mm, 30 mm)

CREDO®
Stent

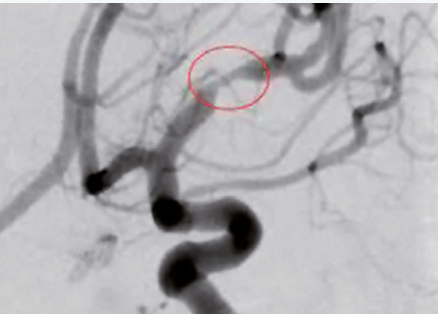
NeuroSpeed®
PTA Balloon Catheter

Simply unique

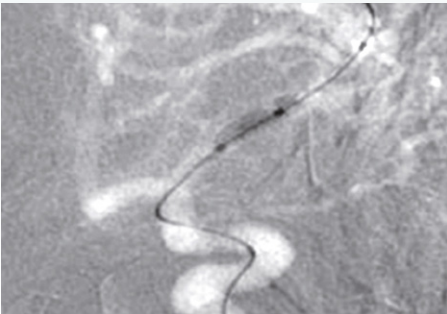
The unique combination possibility of the low-profile NeuroSpeed® PTA Balloon Catheter with the self-expanding laser-cut CREDO® Stent enables a gentle and effective stenosis treatment.



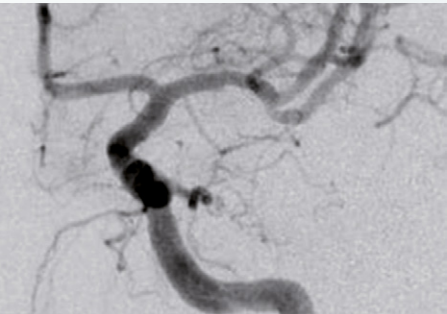
Treatment with NeuroSpeed® PTA Balloon Catheter¹



Pre-dilation
Initial degree of stenosis 80 % pre-dilation



Inflation
NeuroSpeed® PTA Balloon Catheter 2.0 x 8 mm Inflation

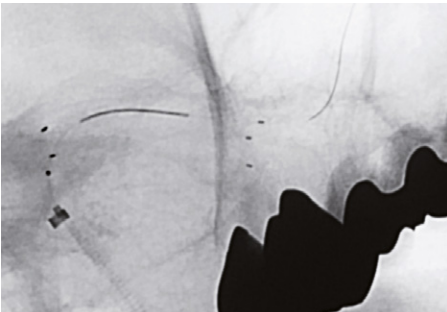


Post-dilation
Final degree of stenosis ~ 10 % post-dilation

Treatment with CREDO® Stent²



Pre-interventional diagnostic stenosis grade 80 %



Deployment of CREDO® Stent after pre dilatation with NeuroSpeed® PTA Balloon Catheter



Final control after stent placement stenosis grade 30 %

1 Images are courtesy of Dr. Christian Löhr, Klinikum Vest, Recklinghausen, Germany
2 Images are courtesy of Dr. Hannes Nordmeyer, radprax MVZ GmbH, Solingen, Germany

NeuroSpeed®
PTA Balloon Catheter

Flexible

The NeuroSpeed® PTA Balloon Catheter is ideal for gentle and controllable PTA of intracranial stenosis.

If stent placement is required for stabilisation of the stenotic lesion, the CREDO® Stent can be delivered through the low-profile NeuroSpeed® PTA Balloon Catheter without exchange manoeuvre.

Smooth

The NeuroSpeed® PTA Balloon Catheter features a slim entrance profile and double hydrophilic coating.

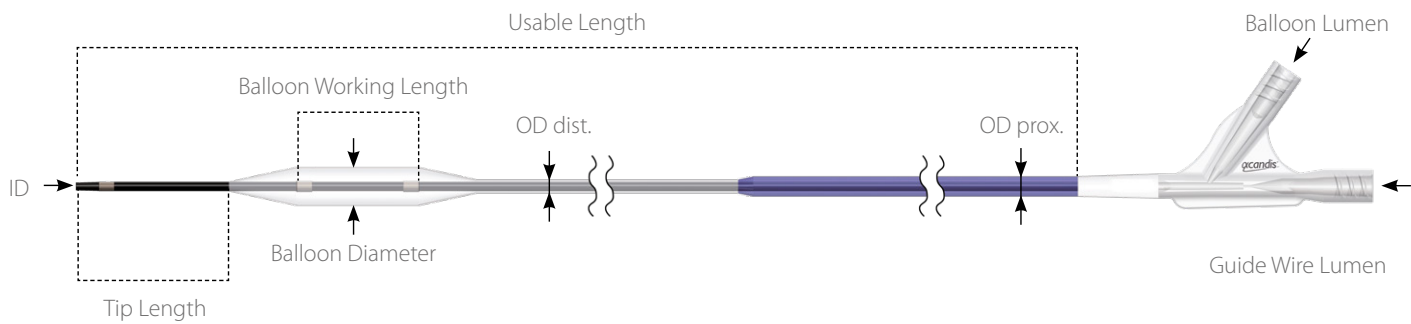
The flexible 10 mm tip, with distal tip X-ray marker, ensures atraumatic access and easy navigation. With a usable length of 150 cm it is possible to reach more distal vessels.

Effective

The semi-compliant balloon material of the NeuroSpeed® PTA Balloon Catheter enables a precise and controllable inflation behaviour for gentle and effective dilation.

The portfolio consists of only 6 sizes with nominal balloon diameters ranging from 1.5 to 4.0 mm.

Technical Specification



CREDO®
Stent

Reliable

The CREDO® Stent is based on Acandis' reliable and proven laser-cut stent platform with asymmetric cell geometry, enabling excellent adaptability even in tortuous anatomies.

Thanks to the well-established radiopaque marker concept and the resheathability up to 90 % of its length, the CREDO® Stent provides maximum safety and comfort during procedure.

Gentle

The CREDO® Stent gives additional stabilisation and support to dilated stenosis.

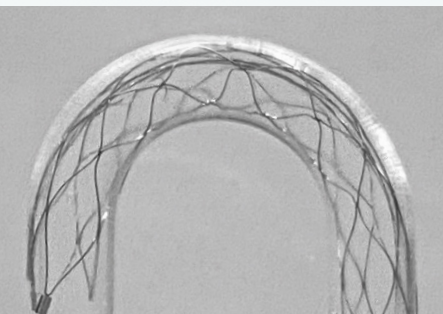
Compared to the ACCLINO® flex plus Stent (for aneurysm bridging) the CREDO® Stent features a higher radial force, which is well-balanced and adjusted for stenosis treatment.

The CREDO® Stent exerts an outward force optimised for perfect vessel wall apposition and a high resistive force against compression.

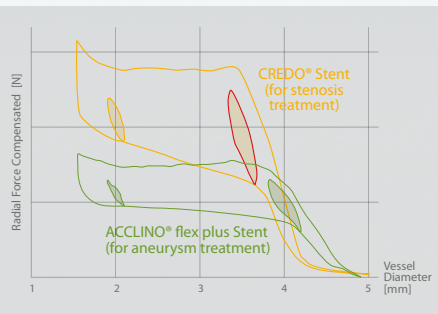
Unique

The CREDO® Stent is a self-expanding stent for treatment of intracranial stenosis.

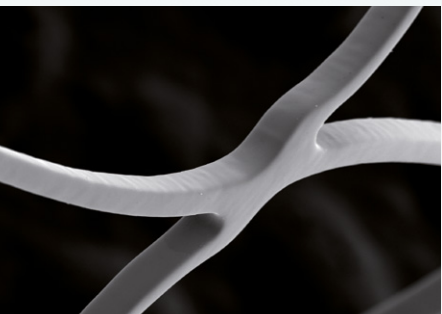
Due to its low profile, the stent can be delivered through the 0.0165" NeuroSpeed® PTA Balloon Catheter. No exchange of the PTA balloon catheter by a microcatheter is required – minimising treatment time and procedural risks.



Stent flexibility



Radial force comparison



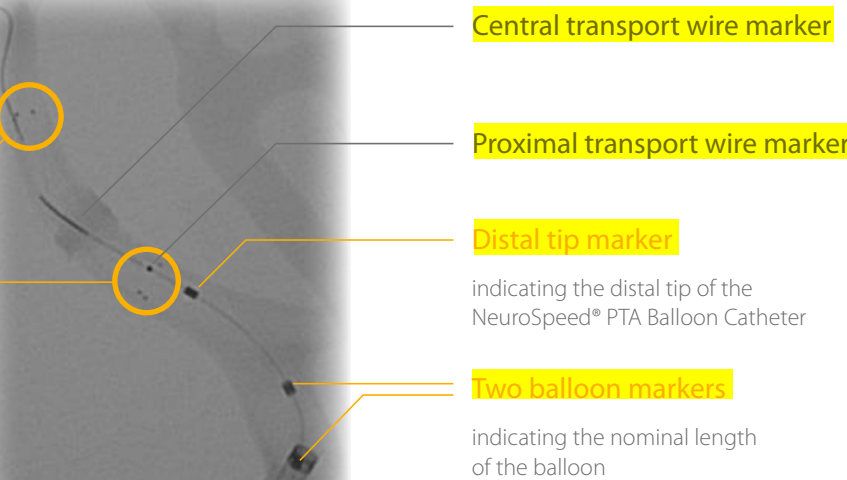
SEM of stent surface

Radiopaque Marker Concept

Distal transport wire marker

Three distal / proximal device markers

for additional control of stent position and opening behaviour



ORIGINAL RESEARCH

Intracranial bailout stenting with the Acclino (Flex) Stent/NeuroSpeed Balloon Catheter after failed thrombectomy in acute ischemic stroke: a multicenter experience

Christian Paul Stracke,^{1,2} Lukas Meyer ,² Jens Fiehler,² Hannes Leischner,² Maxim Bester,² Jan Hendrik Buhk,² Goetz Thomalla,³ Lars Udo Krause,⁴ Stephan Lowens,⁵ Jan Rothaupt,⁵ René Chapot,¹ Uta Hanning²

¹Department of Intracranial Endovascular Therapy, Alfried Krupp Klinikum Essen, Essen, Germany

²Department of Diagnostic and Interventional Neuroradiology, University Medical Center Hamburg-Eppendorf, Hamburg, Germany

³Department of Neurology, University Hospital Hamburg-Eppendorf, Hamburg, Germany

⁴Department of Neurology, Klinikum Osnabrück GmbH, Osnabrück, Germany

⁵Department of Radiology, Klinikum Osnabrück GmbH, Osnabrück, Germany

Correspondence to

PD Dr Uta Hanning, Department of Diagnostic and Interventional Neuroradiology, University Medical Center Hamburg-Eppendorf, Hamburg, Germany; u.hanning@uke.de

CPS and LM contributed equally.

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ABSTRACTS

Background and purpose To report on the feasibility, safety, and outcome of acute intracranial stenting (ICS) with the Acclino (Flex) Stent and NeuroSpeed Balloon Catheter in cases of failed mechanical thrombectomy (MT) for acute ischemic stroke (AIS).

Methods We retrospectively reviewed the data of patients treated with acute bailout stenting after failed MT in three large neurointerventional centers using exclusively the Acclino (Flex) Stent and the NeuroSpeed Balloon Catheter. Functional outcome was assessed by the rate of major early neurological recovery (mENR) at 24 hours and at 90 days with the modified Rankin Scale (mRS). Safety evaluation included symptomatic intracranial hemorrhage (sICH), mortality, and intervention-related serious adverse events (SAEs).

Results 50 patients with a median age of 71 years met the inclusion criteria and 52% (26/50) of the occluded vessels were located within the anterior circulation. mENR was observed in 38.8% and 90-day favorable outcome (mRS ≤ 2) was 40.6% (13/32). Higher NIH Stroke Scale scores on admission were significantly associated with poor functional outcome (mRS ≥ 3) at 90 days (adjusted OR 1.28; 95% CI 1.07 to 1.53; $p=0.007$). sICH occurred in two cases of the study population. There were no intervention-related SAEs.

Conclusion Intracranial bailout stenting with the Acclino (Flex) Stent and the NeuroSpeed Balloon Catheter after failed MT is a feasible and effective recanalization method for atherosclerotic stenosis-based stroke that is associated especially with low rates of sICH.

INTRODUCTION

Mechanical thrombectomy (MT) for patients with large vessel occlusion (LVO) has proved its superiority as best medical treatment in several randomized clinical trials and is now the first-line therapy for these patients.^{1–3} In these studies, successful recanalization rates of Thrombolysis in Cerebral Infarction (TICI) 2b and 3 were achieved in up to 71% of cases.² However, in a certain number of cases MT does result in recanalization of the target vessel but, instead, acute or prolonged reocclusion occurs due to suspected intracranial atherosclerotic

disease (ICAD)^{4–5} or other possible causes such as dissection or adherent calcified thrombi.^{6–8}

Acute reocclusion or high-grade stenosis after unsuccessful MT is associated with poor functional outcome. Potential rescue strategies have recently been described including percutaneous transluminal angioplasty (PTA) with or without drug-eluting balloons and intracranial stenting (ICS) with self-expandable or balloon-mounted stents.^{9–13}

Recently, a meta-analysis demonstrated that acute ICS after failed thrombectomy can lead to good functional outcomes with relatively high symptomatic bleeding rates.¹⁴ However, since the included patients and devices were from the early years of endovascular stroke treatment, the heterogeneity of these reports is generally high. In the past years, new technical devices have been introduced potentially leading to more promising therapeutic results.

This study provides the first report on experiences in three high-volume stroke centers with ICS for ICAD stroke after failed MT using the Acclino (Flex) Stent and the NeuroSpeed Balloon Catheter (Acandis GmbH, Pforzheim, Germany). These devices allow PTA with a double-lumen catheter followed by implantation of a new generation self-expanding stent without wire exchange maneuvers.

MATERIALS AND METHODS

Patient selection and baseline characteristics

Patients treated with acute bailout stenting after failed MT between January 2014 and October 2018 were identified from the databases of three tertiary stroke centers. Inclusion criteria were (1) evidence of intracranial LVO; (2) absence of intracranial hemorrhage; (3) acute reocclusion or persistent high-grade stenosis after MT; and (4) pre-stroke modified Rankin Scale (mRS) score of 0–2. All patients were treated exclusively with the Acclino (Flex) Stent and the NeuroSpeed Balloon Catheter for delivery. Prior to stenting, thrombectomy was performed with the latest stent retriever devices. LVOs of both the anterior and poster circulation were included. If eligible, patients received intravenous lysis (IVT) additionally to MT. Baseline characteristics and outcome parameters were analyzed



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Figure 1 Schematics of NeuroSpeed-based Acclino delivery (with permission from Acandis GmbH, Pforzheim, Germany).

and compared by the rate of major early neurological recovery (mENR). Stroke severity based on initial imaging was assessed with the Alberta Stroke Program Early CT Score (ASPECTS) for anterior circulation stroke. Experienced neurologists examined all patients applying the National Institutes of Health Stroke Scale (NIHSS) and mRS on admission, at discharge, and at 90-day follow-up for neurological evaluation. All anonymized data were recorded with approval of the local ethics committees and no informed consent was necessary after review (Chamber of Physicians, Hamburg, Germany).

Outcome and procedural parameters

Functional outcome was evaluated by the rate of mENR, defined as a decrease in NIHSS score from baseline of at least eight points or reaching 0–1 according to HERMES classification. The rate of favorable outcome was assessed as mRS score ≤ 2 at 90 days. Due to the retrospective approach, mENR data for one patient and 90-day mRS data for 18 patients were missing. Successful angiographic recanalization was assessed by the rate of TICI $\geq 2b$. Further procedural parameters were the time from CT scan to groin puncture and number of retrieval passes. For safety and complication assessment, cases with symptomatic intracranial hemorrhage (sICH), defined according to ECASS-II, mortality, and intervention-related serious adverse events (SAEs) such as iatrogenic dissection and distal emboli were evaluated.

Interventional procedure

Endovascular treatment was performed as a state-of-the-art stent retriever-based procedure using common guiding and balloon guiding catheters. The number of retrieval maneuvers as well as PTA and ICS after unsuccessful thrombectomy was left to the interventionalist's decision.

Acclino (Flex) Stent and NeuroSpeed Balloon Catheter

The NeuroSpeed catheter is an over-the-wire double-lumen PTA balloon ranging from 1.5 to 4.5 mm in size (figure 1). The balloon is semicompliant and allows PTA to the nominal size with standard pressure and modification of the diameter plus or minus 0.3 mm according to the inflation pressure. The central 0.165 inch lumen allows navigation with standard wires and the application of the Acclino Flex or Acclino Flex HRF stent. This stent is a self-expanding laser-cut nitinol stent available in sizes between 3 and 4.5 mm, passing through a 0.0165 inch lumen. The Acclino HRF stent has a higher radial force than the regular Acclino Flex stent (see illustrative case in figures 2 and 3).

Statistical analysis

Standard descriptive statistics were employed for all data. Univariable distribution of metric variables was described by median and IQR. The Mann–Whitney U test or χ^2 test was performed for two independent samples on a metric or categorical outcome. The Wilcoxon signed-rank test was used to compare related samples for outcome pre- and post-intervention. The association

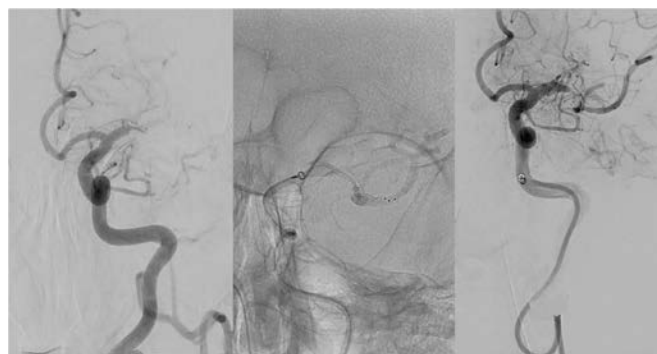


Figure 2 Thrombectomy of M1 occlusion. Stent retriever configuration with proximal narrowing and post-retrieval images indicate a stenosis as the underlying pathology.

between clinical, radiological, and interventional parameters and functional clinical outcome (good: mRS 0–2 or poor: mRS 3–6) was assessed by logistic regression analysis.

For multivariable model building, stepwise forward selection was used (inclusion criterion, p value of the score test ≤ 0.05 and exclusion criterion, p value of the likelihood ratio test > 0.1). The factors of the model from step 1 were then fitted together with all pairwise interactions in a second block using stepwise forward selection (inclusion, p value of the score test ≤ 0.05 and exclusion, p value of the likelihood ratio test > 0.1). Selected variables were presented as odds ratios with 95% CI and p value of likelihood ratio test. For non-selected variables, the p value of the score test is shown. Odds were calculated as the ratio of the probability for a poor outcome to the probability of a good outcome. Due to partially missing data of ASPECTS and mTICI at the end of the procedure, these variables were not included in the logistic regression models. P values ≤ 0.05 were considered significant. Analyses were performed using SPSS Version 25 (IBM Corporation, Armonk, New York, USA).

RESULTS

Baseline characteristics

Between January 2014 and October 2018, 50 patients met the inclusion criteria and were treated with ICS for AIS after failed MT. The overall number of MTs performed in the three centers during this period was 3110, resulting in a percentage of 1.6% for intracranial rescue stenting with the Acclino/NeuroSpeed device combination. The median age of the patients was 71 years (IQR 61–79) and 28% (14/50) were women. Median NIHSS on admission was 12 (IQR 6–15). Initial CT showed a median

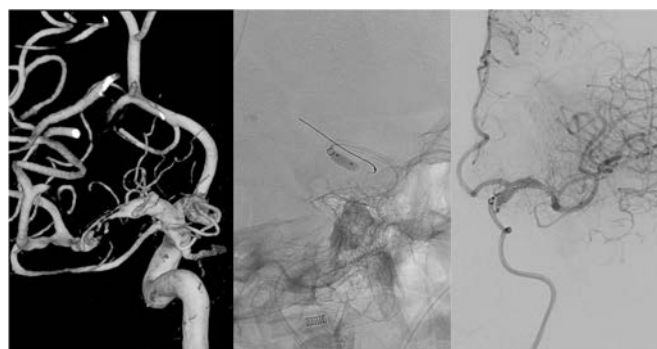


Figure 3 Three-dimensional angiographic reconstruction of the M1 stenosis, percutaneous transluminal angioplasty with the NeuroSpeed catheter, and angiographic result after stent placement.

Table 1 Baseline demographic, clinical, radiological characteristics, and outcomes

Baseline characteristics	NeuroSpeed and Acclino (Flex) Stent (n=50)	Major early neurological recovery (n=19)	No major early neurological recovery (n=30)	P value
Age (years), median (IQR)	71 (61–79)	68 (60–77)	71 (62–79)	0.417
Female, n (%)	14 (28)	5 (26.3)	8 (26.7)	0.978
CT parameters, median (IQR)				
ASPECTS (13 missing)	9 (7–10)	8 (8–10)	9 (7–10)	0.800
Clinical parameters				
NIHSS on admission, median (IQR)	12 (6–15)	7 (5–15)	13 (8–15)	0.221
Premorbid mRS, median (IQR)	0 (0–1)	0 (0–1)	1 (0–2)	0.269
NIHSS at discharge, median (IQR)	8 (2–16)	2 (1–5)	13 (8–20)	<0.001
mRS 90 days (18 missing)	4 (0–6)	1 (0–2)	5 (4–6)	<0.001
mRS 0–2 (n (%), 18 missing)	13 (40.6)	11 (84.6)	2 (10.5)	<0.001
sICH, n (%)	2 (4.0)	1 (5.3)	1 (3.3)	0.739
Occlusion type, n (%)				
ICA	7 (14.0)	3 (15.8)	4 (13.3)	0.798
ACA	1 (2.0)	1 (5.3)	0 (0.0)	
M1	17 (34.0)	6 (31.6)	11 (36.7)	
M2	1 (2.0)	0 (0.0)	1 (3.3)	
VA	10 (20.0)	4 (21.1)	6 (20.0)	
BA	14 (28.0)	5 (26.3)	8 (26.7)	
Anterior circulation	26 (52.0)	10 (52.6)	16 (53.5)	0.962
Procedure process and results				
Intravenous thrombolysis, n (%)	11 (22.0)	4 (21.1)	7 (23.3)	0.852
CT to groin puncture (min), median (IQR)	90.0 (45.0–131.5)	90.0 (45.0–130.0)	90.0 (50.3–137.0)	0.891
Passes of retriever, median (IQR)	2 (1–3)	1 (1–2)	2 (1–3)	0.233
mTICI 2b or 3, n (%)	8 (29.6)	3 (33.3)	4 (23.5)	0.592

ACA, anterior cerebral artery; ASPECTS, Alberta Stroke Program Early CT Score; BA, basilar artery; ICA, internal carotid artery; M1, M2, M1 and M2 segments of middle cerebral artery; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; sICH, symptomatic intracranial hemorrhage; VA, vertebral artery.

ASPECTS of 9 (IQR 7–10). 52% (26/50) of the occluded vessels were located within the anterior circulation and 48% (24/50) in the posterior circulation. The most frequent site of occlusion was the M1 segment of the middle cerebral artery (MCA; 34%, 17/50). Other locations within the anterior circulation included the MCA M2 segment (2%, (1/50). Posterior circulation stroke involved the vertebral artery (VA; 20.0%, 10/50) and the basilar artery (BA; 28%, 14/50).

Eleven of the 50 patients (22%) received IVT prior to MT and no heparinization. All patients received antiplatelet medication during the procedure; 8% (4/50) received IV aspirin only and the remaining 92% (46/50) received glycoprotein IIb/IIIa antagonists (4 (8%), abciximab; 6 (12%) tirofiban; 36 (72%) eptifibatide). After the hyperacute phase, patients were treated with oral double antiplatelets aspirin 100mg and clopidogrel 75mg for 3 months. sICH occurred in two cases, both in the anterior circulation after administration of eptifibatide.

Procedural and functional outcome

The median time from CT to groin puncture was 90 min (IQR 45–131.5). Successful recanalization of TICI \geq 2b before ICS was achieved in 29.6% (8/50) of the cases with a median of 2 (IQR 1–3) retrieval maneuvers (table 1).

mENR was observed in 38.8% (19/49) of the cases and the median NIHSS score at 24 hours post-intervention improved non-significantly ($p=0.098$) from 12 (IQR 6–15) on admission

to 8 (IQR 2–14) at 24 hours (figure 4). mENR was significantly associated with lower NIHSS scores on discharge and a favorable functional outcome (mRS \leq 2) at 90 days. Table 1 presents an overview of baseline characteristics and outcome parameters for all patients. Logistic regression analysis did not confirm any independent predictor for mENR at 24 hours. A favorable functional outcome (mRS \leq 2) at 90 days was observed in 40.6% (13/32) of the cases. In univariable analysis, higher NIHSS scores on admission were significantly associated with poor functional outcome (mRS \geq 3) at 90-day follow-up (OR 1.27; 95% CI 1.07 to 1.51; $p=0.008$). This finding was confirmed in multivariable logistic regression analysis as an independent predictor for poor functional outcome (table 2). Ninety-day mortality was 17.1% (6/32). sICH occurred in 4% (2/50) of the cases. No intervention-related SAEs were observed.

DISCUSSION

The results show that intracranial bailout stenting with a novel technique using the Acclino (Flex) Stent and the NeuroSpeed Balloon Catheter is a feasible and effective recanalization method in cases of failed MT with outstandingly low rates of sICH. This rescue approach was applied in certain cases based on the interventionalist's decision after the primary MT had failed. In these particular cases it is often not possible to clearly classify the underlying pathology. ICAD seems to have the highest prevalence for cases with unsuccessful MT, but

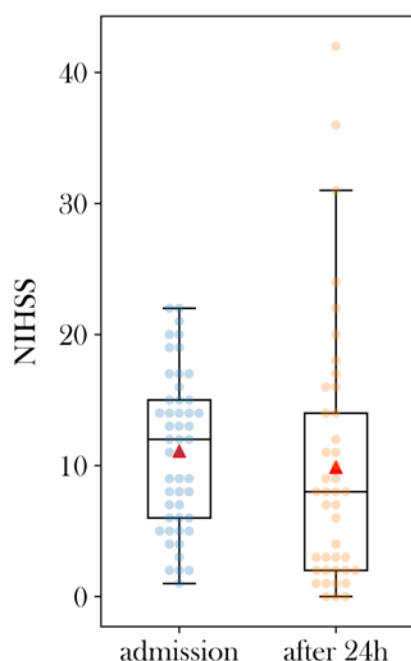


Figure 4 Boxplot of median National Institutes of Health Stroke Scale (NIHSS) score at 24 hours post-intervention compared with admission.

can be mimicked by residual adherent or calcified clots and dissections that are also known to be associated with failure of thrombectomy.⁸ There are no criteria to distinguish between an adherent clot, local dissection, or arteriosclerotic stenosis. However, in our study all cases were performed in tertiary stroke centers by experienced neurointerventionalists. With regard to the total number of thrombectomy procedures in the study period, the rate of bailout stenting was low, indicating that ICS was only performed in cases where MT truly failed.

Permanent ICS was an earlier approach for the treatment of endovascular stroke based on LVO. Although first reports on experiences with ICS were promising, permanent ICS was

never implemented as a primary endovascular therapy option for AIS.^{15 16} Instead, several large controlled randomized trials demonstrated the efficacy of MT.² Recently, the SAMMPRIS and VISSIT trials represented the best available evidence of endovascular treatment for ICAD. Both studies found no benefit of elective endovascular stenting for ICAD stenosis compared with best medical treatment as secondary stroke prevention. Instead, stroke or death rate at 30 days was significantly higher in the stenting group than in the medical treatment group (14.7% vs 5.8%).^{15 17} A major disadvantage shown in these trials was the high rate of periprocedural bleeding, which might be associated with the devices. Even though ICS after failed endovascular recanalization was an early rescue approach, it needed time to regain the reputation as a promising therapy option in endovascular stroke treatment.¹⁸

In 2018 Chang *et al* presented a multicenter cases series of 48 consecutively treated patients between 2010 and 2015 with ICS for AIS after failed MT. Favorable outcome at 90 days was 39.5% and mortality was 12.5%.¹⁹ A currently published meta-analysis on ICS, including early cases from 2003, also reported promising results with favorable outcomes (mRS ≤ 2) of 43% (95% CI 34% to 53%) and mortality rates of 21% (95% CI 13% to 33%).¹⁴ Further recent studies confirmed these results with favorable outcomes of 42.4% (14/33) and 63.8% (30/47) and an in-hospital mortality rate of 13–22%.^{4 5} With a favorable outcome rate at 90 days of 40.6% and a mortality rate of 17.1%, our results were comparably good. In addition, our analysis showed a median improvement in the NIHSS score from 12 to 8 ($p=0.098$) and mENR was reached in 38.8%. This is a remarkable result in comparison to the HERMES meta-analysis with 50.2% mENR and 46% mRS ≤ 2 , considering that these patients represent a negative selection of predictors for both successful recanalization and long-term favorable outcome.

Unsurprisingly, the rate of successful recanalization pre-ICS was low with 29.6% TICI $\geq 2b$ and time from groin puncture to recanalization was long, taking into account that these are complex cases and MT as well as ICS were performed. As in most stroke studies, we found higher NIHSS scores to be an independent predictor for poor clinical outcome, suggesting that it is always necessary to consider the individual patient's stroke severity.^{20–22} Even though case numbers are small, the clinical outcomes of the present study, along with latest published results on ICS, are very encouraging considering that these patients are the most challenging to treat.

The need for antiplatelet therapy after stenting has always been a major concern in AIS due to its potentially increased risk for intracerebral bleeding.²³ In our study two of the 50 patients had sICH. This result is comparable to those of past stroke studies focusing on thrombectomy alone with 4.4%, and unexpectedly low compared with latest ICS studies, which range from 8% to 17%.^{2 14} All patients received anti-thrombotic agents peri-interventionally, some in combination with IV tissue plasminogen activator (tPA). Recently, we have learnt from the TITAN Investigator Group that the combination of acute stenting for extracranial internal carotid artery stenosis with antithrombotic agents and intracranial thrombectomy in so-called tandem occlusions did not increase the rate of sICH, even with additional IV tPA.²⁴ Thus, it seems that premedication antithrombotic therapy can be considered a justifiable risk factor in AIS which should not deter performing ICS. The possibility of in-stent thrombosis cannot be ruled out in our study due to missing follow-up imaging that could prove

Table 2 Univariable and multivariable analysis of predictors of poor clinical outcome (mRS 3–6 at 90 days) after acute stenting (n=32)*

Univariable analysis	OR	95% CI	P value
Age (years)	1.07	0.98 to 1.16	0.124
Gender (ref: male)	2.54	0.42 to 15.21	0.308
NIHSS on admission	1.27	1.07 to 1.51	0.008
Premorbid mRS	1.31	0.65 to 2.63	0.448
Target vessel (ref: posterior circulation)	2.20	0.57 to 8.82	0.284
Intravenous thrombolysis (ref: no)	0.80	0.17 to 3.82	0.783
Passes of retriever	1.28	0.72 to 2.27	0.398
Multivariable analysis			
Age (years)	–	–	0.100 (NS)
Gender (ref: male)	–	–	0.329 (NS)
NIHSS on admission	1.28	1.07 to 1.53	0.007
Premorbid mRS	–	–	0.405 (NS)
Target vessel (ref: posterior circulation)	–	–	0.600 (NS)
Intravenous thrombolysis, (ref: no)	–	–	0.726 (NS)
Passes of retriever	–	–	0.541 (NS)

*Eighteen missing mRS values.

mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale.

stent patency. Nevertheless, the study by Chang *et al* showed that a favorable 90-day outcome (mRS ≤ 2) is significantly associated with stent patency.¹⁹ Valid information also comes from cardiointerventional studies demonstrating that most in-stent thrombosis occurs during the first hours after stent placement.²⁵ However, there is still no consensus on periprocedural antithrombotic management for prevention of in-stent thrombosis after endovascular stenting in neurovascular and even cardiovascular interventions.^{24 26}

The Acclino (Flex) Stent is part of a new generation of self-expanding stents which have been available since 2014. A special feature of this stent is that it can be delivered directly without exchange maneuvers through the suitable NeuroSpeed Balloon Catheter. Logically, this technical feature eases the workflow by simplifying stent placement and might therefore increase the safety of the procedure. In our cohort of 50 patients treated in three different tertiary stroke centers with this particular stent/catheter combination, we did not observe any intervention- or device-related complications and, surprisingly, found only two cases of sICH. Both findings could be related to the reduced number of exchange maneuvers using the NeuroSpeed Balloon Catheter. Since there is currently no multicenter study on ICS for AIS using exclusively one device (combination) of the latest generation, our study gives important insights into new technical developments and raises future expectations for the treatment of ICAD stroke. However, to prove the safety of this particular stent/catheter combination, further studies are needed for comparison.

Limitation of study

Besides all the disadvantages of a retrospective approach, the major limitation of this study is the missing data, especially ASPECTS, follow-up imaging, and mRS outcome data of 18 patients at 90-day follow-up. However, the case series of Chang *et al* with 48 patients still represents the largest ICS cohort that has been published so far, hence our cohort can be considered as relatively large and could provide valid information on latest devices for possible future randomized ICS trials.

CONCLUSION

Our multicenter study suggests the feasibility and safety of bailout stenting after failed MT with latest generation devices. It supports previous findings that indicated ICS as a valuable therapeutic option after unsuccessful thrombectomy. With a reduced number of catheter exchange maneuvers and therefore less iatrogenic vessel manipulation, the combination of the Acclino (Flex) Stent and NeuroSpeed Balloon Catheter was associated with low rates of sICH. Further studies are needed to establish if new devices might improve the latest promising results of ICS and guarantee greater safety.

Contributors LM, UH, and CPS made substantial contributions to the conception and design of the work. Data acquisition was performed by CPS, LM, HL, LUK, SL, and JR. UH and LM performed the data analysis. Interpretation of the data was done by JF, GT, CPS, UH, LM. LM, CPS, and UH drafted the manuscript and all of the other authors revised it critically for important intellectual content. All authors approved the final version to be published. They agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the manuscript are appropriately investigated and resolved.

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ORCID iD

Lukas Meyer <http://orcid.org/0000-0002-3776-638X>

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Emergency Intracranial Stenting in Acute Stroke: Predictors for Poor Outcome and for Complications

Christian Paul Stracke, MD; Jens Fiehler, MD; Lukas Meyer, MD; Götz Thomalla, MD; Lars Udo Krause, MD; Stephan Lowens, MD; Jan Rothaupt, MD; Byung Moon Kim, MD; Ji Hoe Heo, MD; Leonard L.L. Yeo, MBBS; Tommy Andersson, MD, PhD; Christoph Kabbasch, MD; Franziska Dorn, MD; Rene Chapot, MD; Uta Hanning, MD, MHBA

Background—Stent-retriever thrombectomy is the first-line therapy in acute stroke with intracranial large vessel occlusion. In case of failure of stent-retriever thrombectomy, rescue stent angioplasty might be the only treatment option to achieve permanent recanalization. This study aims at identifying predictors for poor outcome and complications in a large, multicenter cohort receiving rescue stent angioplasty.

Methods and Results—We performed a retrospective analysis of patients with large vessel occlusion who were treated with rescue stent angioplasty after stent-retriever thrombectomy between 2012 and 2018 in 7 neurovascular centers. We defined 2 binary outcomes: (1) functional clinical outcome (good modified Rankin Scale, 0–2; and poor modified Rankin Scale, 4–6) and (2) early symptomatic intracerebral hemorrhage. Impacts of clinical, radiological, and interventional parameters on outcome were assessed in uni- and multivariable logistic regression models. Two hundred ten patients were included with target vessels located within the anterior circulation (136 of 210; 64.8%) and posterior circulation (74 of 210; 35.2%). Symptomatic intracerebral hemorrhage occurred in 22 patients, 86.4% (19 of 22) after anterior and 13.6% (3 of 22) after posterior circulation large vessel occlusion. Good functional outcome was observed in 44.8% (73 of 163). A higher National Institutes of Health Stroke Scale on admission (adjusted odds ratio, 1.10; $P=0.002$), a higher premorbid modified Rankin Scale (adjusted odds ratio, 2.02; $P=0.049$), and a modified Thrombolysis in Cerebral Infarction score of 0 to 2a after stenting (adjusted odds ratio, 23.24; $P<0.001$) were independent predictors of poor functional outcome.

Conclusions—Use of rescue stent angioplasty can be considered for acute intracranial large vessel occlusion in cases after unsuccessful stent-retriever thrombectomy. Likelihood of symptomatic intracerebral hemorrhage is higher in anterior circulation stroke. (*J Am Heart Assoc.* 2020;9:e012795. DOI: 10.1161/JAHA.119.012795.)

Key Words: intracranial stenosis • retriever • stenting • thrombectomy • thrombus

Stent-retriever thrombectomy (SRT) is the first-line therapy in acute stroke with intracranial large artery vessel occlusion (LVO) of the anterior circulation.^{1–5} The superiority of SRT compared with best medical treatment has been proven in several randomized, multicenter trials.^{6–8} In these studies, patients treated with SRT achieved high rates of recanalization with modified Thrombolysis in Cerebral Infarction (mTICI) grades 2b or 3 up to 88%.⁹ Despite an initially

successful recanalization, patients may develop immediate reocclusion of the target vessel. In the majority of these cases, the underlying pathology is intracranial atherosclerotic disease,^{10,11} which is much more prevalent in Asian populations.^{11,12}

Acute reocclusion or high-grade stenosis after unsuccessful SRT is associated with poor functional outcome.¹³ Potential rescue strategies include angioplasty (PTA), PTA with drug

From the Department of Intracranial Endovascular Therapy, Alfried-Krupp Krankenhaus Hospital, Essen, Germany (C.P.S., R.C.); Departments of Diagnostic and Interventional Neuroradiology (C.P.S., J.F., L.M., U.H.) and Neurology (G.T.), University Medical Center Hamburg-Eppendorf, Hamburg, Germany; Departments of Neurology (L.U.K.) and Radiology (S.L., J.R.), Klinikum Osnabrück, Osnabrück, Germany; Department of Radiology, Interventional Neuroradiology (B.M.K.) and Department of Neurology (J.H.H.), Severance Stroke Center, Severance Hospital, Yonsei University College of Medicine, Seoul, South Korea; Department of Neuroradiology, Karolinska University Hospital, Stockholm, Sweden (L.L.L.Y., T.A.); Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden (L.L.L.Y., T.A.); Division of Neurology, Department of Medicine, National University Health System, Singapore (L.L.L.Y.); Department Medical Imaging, AZ Groeninge, Kortrijk, Belgium (T.A.); Department of Neuroradiology, University of Cologne, Germany (C.K.); Department of Neuroradiology, University Hospital of Munich, Germany (F.D.).

Correspondence to: Christian Paul Stracke, MD, Department of Intracranial Endovascular Therapy, Alfried-Krupp Krankenhaus Hospital, Alfried-Krupp Strasse 21, 45131 Essen, Germany. E-mail: c.stracke@uke.de

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Clinical Perspective

What Is New?

- In case of unsuccessful recanalization of intracranial vessels in acute stroke, rescue stenting using self-expandable stents can achieve permanent recanalization.

What Are the Clinical Implications?

- Rate of good functional clinical outcome is high, and rate of symptomatic intracerebral hemorrhage is acceptable; therefore, rescue stenting should be considered rather than leaving the patient with a nonrecanalized vessel.

eluting balloon,¹⁴ and rescue stent angioplasty (RSA)^{13–16} with self-expandable stents or balloon-mounted stents.¹⁷

The best currently available evidence for endovascular treatment of intracranial atherosclerotic disease is based on the SAMMPRIS (Stenting and Aggressive Medical Management for Preventing Recurrent stroke in Intracranial Stenosis) study and the VISSIT (Vitesse Intracranial Stent Study for Ischemic Stroke Therapy) study,^{18,19} showing the superiority of best medical treatment over elective intracranial stenting. Lately, mostly small retrospective studies reported consistently on improved functional outcomes after RSA for cases where initial thrombectomy attempts fail or high-grade stenosis increases the risk for acute reocclusion.^{15,20–26} Accordingly, Chang et al reported significantly better outcomes after RSA versus medical treatment representing the largest study (n=50) on RSA.^{15,27}

We analyzed patient data from 7 neurovascular centers to identify predictors of poor outcome after RSA in the largest patient-level pooled analysis to date. We hypothesized that we would be able to identify predictors, both for poor outcome and hemorrhage, in the postinterventional phase after RSA that would help in selecting patients and informing future trial design.

Methods

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Study Population

Patients with acute ischemic stroke caused by intracranial LVO of the anterior and posterior circulation, who received RSA between February 2012 and October 2018, were identified from the databases of 7 tertiary stroke centers. The study was approved by the responsible ethics committee (Aerzteammer Nordrhein, Duesseldorf, Germany), and therefore no informed consent from every individual could be waived. As inclusion criteria, we defined (1) evidence of intracranial large vessel occlusion, (2) absence of intracranial hemorrhage, and (3) acute

reocclusion or persistent high-grade stenosis after SRT. Patients with missing recanalization at any time during the procedure were excluded. Differentiation between high-grade stenosis, residual clot, or dissection as the cause for high-grade stenosis or reocclusion was not made. Patients with extra-/intracranial tandem lesions were excluded.

All anonymized patient data were entered in the databases of the participating centers. Data from 41 of 210 patients have been published already.^{13,23}

Baseline Characteristics

Patient data were evaluated regarding demographics, premorbid disability (modified Rankin Scale [mRS] score), and stroke severity on admission using the National Institute of Health Stroke Scale (NIHSS). NIHSS scoring was performed exclusively by experienced neurologists, both on admission and on the following days on the stroke unit.

Administration of intravenous recombinant tissue plasminogen activator was recorded. If available, time intervals between onset and imaging time to groin puncture, as well as procedural data, such as final endovascular revascularization, were documented.

Intracranial anterior circulation LVO was defined as occlusion of: (1) internal carotid artery (carotid T), (2) anterior cerebral artery, (3) the first segment of the middle cerebral artery (M1), and (4) the second segment of the middle cerebral artery (M2). Intracranial posterior circulation LVO was defined as occlusion of the: (1) basilar artery and (2) intracranial segment of the vertebral arteries.

Interventional and Postprocedural Parameters

Interventional data, including type of stent-retriever, number of thrombectomy maneuvers, as well as the stent design (balloon or self-expanding), were evaluated. The recanalization result was graded by the mTICI (modified Thrombolysis in Cerebral Infarction) score.²⁸ Time to first PTA of the intracranial target vessel as well as the antiplatelet regimes were recorded.

Complications, including the occurrence of symptomatic intracranial hemorrhage (sICH) resulting in a deterioration of ≥ 4 NIHSS points and postinterventional stent occlusion and restenosis, were recorded. NIHSS score on admission and at discharge from the hospital as well as the mRS after 90 days were documented. A final mRS score of 0 to 2 was defined as “good functional clinical outcome.”

Endovascular Revascularization

Endovascular treatment was performed as a state-of-the-art stent-retriever-based procedure using common guiding and

balloon guiding catheters. Numbers of retrieval maneuvers as well as the PTA and intracranial stenting after unsuccessful thrombectomy were left to the interventionalist's decision.

Statistical Analysis

Univariable distribution of metric variables is described by median and interquartile range (IQR). For categorical data, absolute and relative frequencies are given. The Mann–Whitney U test or χ^2 test was used to compare 2 independent samples on a metric or categorical outcome, respectively. We defined 2 binary outcomes: (1) sICH occurrence in the immediate postinterventional phase (yes/no) and (2) functional clinical outcome (good [mRS 0–2] and poor [mRS 4–6]). Impacts of clinical, radiological, and interventional parameters on outcome were assessed in uni- and multivariable logistic regression models.

Multivariable model building was performed using a step-wise variable selection procedure: In a first step, all factors were fitted together by a step-wise forward selection (inclusion: P value of the score test ≤ 0.05 and exclusion: P value of the likelihood ratio test > 0.1). Then, the factors of the model from step 1 were fitted together with all pair-wise interactions in a second block using step-wise forward selection (inclusion: P value of the score test ≤ 0.05 and exclusion: P value of the likelihood ratio test > 0.1). Given for selected variables are odds ratios (ORs) with 95% CI and P value of a likelihood ratio test. For nonselected variables, the P value of score test is displayed. Odds were calculated as ratio of the probability for poor outcome to the probability of good outcome. Because of partially missing data of Alberta Stroke Program Early CT Score at the end of the procedure, these variables were not included into logistic regression models. No adjustment for multiple testing was performed, and analyses are regarded as explorative. Local, unadjusted $P < 0.05$ was considered as statistically noticeable.

Statistical analyses were performed in SPSS (version 24; IBM Corporation, Armonk, NY) and in SAS software (version 9.4; SAS Institute Inc, Cary, NC).

Results

Baseline Characteristics

A total of 210 patients fulfilled the inclusion criteria and were included for further analysis. The total amount of thrombectomies performed in the participating centers in this time period was 4751, resulting in a percentage for RSA of 4.4%.

In the stenting group, median age of patients was 67 years (IQR, 59–75), and 84 (40%) patients were female. Median NIHSS score on admission was 13 (IQR, 3–14) and the premorbid mRS 0 (IQR 0–1). Detailed baseline characteristics are listed in Table 1. The M1 segment of the middle cerebral artery was occluded in 85 patients (40.5%) and the basilar artery in 46 (21.9%). Median time between computed

tomography to groin puncture was 99 minutes (IQR, 60–137). Intravenous recombinant tissue plasminogen activator was administered in 66 of 210 patients (31.4%) before the recanalization procedure.

Interventional Data

In 201 of 210 patients (95.7%), a self-expanding stent was implanted and in 9 (4.3%) a balloon-expanding stent. The most commonly used clot-retrieving device was the Solitaire FR Stent (80 of 210 patients [40%]). The numbers of SRT maneuvers before stenting ranged from 1 to 17, with a median of 2 (IQR, 1–3). The final run after PTA/stenting confirmed a successful recanalization (mTICI 2b/3) in 174 (82.9%); thereof, a successful recanalization was observed in 106 (77.9%) of the anterior circulation LVO and in 68 (97.1%) of the posterior circulation LVO.

For RSA, the Acclino/Acclino flex/**Credo stent** (Acandis GmbH, Pforzheim, Germany) was placed in 61 of 201 (29%), the Solitaire AB Stent (ev3/Medtronic, Irvine, CA) in 45 of 201 (31%) patients, the Wingspan Stent (Stryker) in 8 of 201 (3.8%), the Neuroform (Stryker) in 65 of 201 patients (20.0%), and others (eg Leo Stent [Balt, Montmorency, France], Coroflex Blue Ultra Stent [B. Braun, Berlin, Germany], the Enterprise Stent [Codman Neuro, Raynham, MA], and Pharos[®] Stent [Codman]) in 31 of 201 patients (14.8%).

There was not a standard protocol for antiplatelet therapy regime. All patients received at least monoantiaggregation or a GpIIb/IIIa antagonist in the acute setting. Detailed data for antiaggregation were available in 150 patients. In this group, 124 patients (82%) received a GpIIb/IIIa antagonist, mainly eptifibatide (109 cases), Tirofiban (12 cases), and Abxiximab (3 cases). GpIIb/IIIa antagonists were continued until the control computed tomography scan 24 hours after the procedure. After that, mono- or double antiaggregation was continued depending on each center's decision.

Symptomatic Intracerebral Hemorrhage

Of the 210 patients, 22 (10.5%) experienced an sICH in the immediate postinterventional phase. Median age differed statistically noticeably between patients with sICH (median, 74 [IQR, 65–88]) and no sICH (median, 66 [IQR 58–74]; $P < 0.004$). Nineteen of 22 patients with sICH (86.4%) were treated for anterior circulation LVO whereas there were 3 patients with posterior circulation LVO ($P < 0.025$; Table 1). A successful recanalization after RSA (mTICI 2b–3) was significantly more often observed in patients without sICH compared with patients with sICH (all $P = 0.004$; Table 1). Logistic regression analysis was performed to assess the association between various clinical and interventional parameters and sICH in the postinterventional phase.

Table 1. Comparison of Baseline Demographic, Clinical, and Radiological Characteristics Between Patients With sICH and Without Intracranial Hemorrhage After Acute Stenting

Baseline Characteristics	All (n=210)	Without sICH (n=188)	With sICH (n=22)	P Value
Age (y), median (IQR)	67 (59; 75)	66 (58; 74)	74 (65; 88)	0.004
Female, n (%)	84 (40.0)	70 (37.2)	14 (63.6)	0.017
CT parameters, median (IQR)				
ASPECTS	9 (8; 10)	9 (8; 10)	8 (7; 9)	0.209
Clinical parameters, median (IQR)				
NIHSS on admission	13 (8;18)	12 (7; 18)	14 (12; 21)	0.032
Premorbid mRS	0 (0;1)	0 (0; 1)	0 (0; 2)	0.249
NIHSS at discharge	6 (3;14)	5 (2; 12)	20 (11; 32)	<0.001
mRS, 90 days	3 (1; 5)	2 (1; 5)	6 (5; 6)	<0.001
Occlusion type, n (%)				0.186
ICA	41 (19.5)	35 (18.6)	6 (27.3)	
ACA	1 (0.5)	1 (0.5)	0 (0)	
M1	85 (40.5)	73 (38.8)	12 (54.5)	
M2	8 (3.8)	7 (3.7)	1 (4.5)	
VA	29 (13.8)	26 (13.8)	3 (13.6)	
BA	46 (21.9)	46 (24.5)	0 (0)	
Anterior circulation (vs posterior circulation)	136 (64.8)	117 (62.2)	19 (86.4)	0.025
Procedure process and results				
Intravenous thrombolysis, n (%)	66 (31.4)	57 (30.3)	9 (40.9)	0.311
CT to groin puncture (min), median (IQR)	99 (60.0; 137.0)	98 (60.0; 135.8)	106.5 (75.3; 146.8)	0.629
Passes of retriever	2 (1;3)	2 (1;3)	2 (1;4)	0.829
mTICI after last stent-retriever/aspiration (TICI 2b/3), n (%)	68 (32.4)	65 (34.6)	3 (13.6)	0.285
mTICI in final run after RSA (TICI 2b/3), n (%)	174 (82.9)	160 (85.1)	14 (63.6)	0.004
Stent category, n (%)				
Self-expandable stents	201 (95.7)	179 (89.1)	22 (10.9)	
Balloon-expandable stents	9 (4.3)	9 (4.8)	0 (0)	
Stent type, n (%)				
Acclino flex	61 (29.0)	59 (31.4)	2 (9.1)	
Solitaire	45 (31.0)	37 (19.7)	8 (36.4)	
Neuroform	65 (29.0)	56 (29.8)	9 (40.9)	
Wingspan	8 (3.8)	7 (3.7)	1 (4.5)	
Others (Leo, Enterprise, coroflex, Pharos)	31 (14.8)	29 (15.4)	2 (9.4)	

ACA indicates anterior cerebral artery; ASPECTS, Alberta Stroke Program Early CT Score; BA, basilar artery; CT, computed tomography; ICA, internal carotid artery; INR, international normalized ratio; IQR, interquartile range; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; RSA, rescue stent angioplasty; sICH, symptomatic intracranial hemorrhage, hemorrhagic transformation; TICI, thrombolysis in cerebral infarction; VA, vertebral artery.

In univariable logistic regression, higher age ($P=0.007$), female sex ($P=0.021$), and anterior circulation LVO ($P=0.035$) and an unsuccessful recanalization (mTICI of 0–2a) after RSA ($P=0.007$) were associated with presence of sICH after acute stenting (Table 2). Multivariable logistic regression analysis confirmed an unsuccessful recanalization (mTICI of 0–2a) after RSA as an independent predictor of sICH (adjusted OR, 4.16; $P=0.007$; e-value=3.496²⁹; Table 3). Intravenous

thrombolysis, premorbid mRS, NIHSS on admission, and number of SRT attempts were not independent predictors of sICH in the logistic regression analysis.

Functional Clinical Outcome After Acute Intracranial Stenting in Stroke Patients

Functional clinical outcome (mRS) after 90 days was only available in 163 of the patients (median, 3 [IQR, 1–5]).

Table 2. Univariable Analysis of Predictors of sICH in the Immediate Postinterventional Phase After Acute Stenting

	OR	95% CI	P Value
Age, y	1.06	0.02–1.10	0.007
Sex (ref: male)	0.34	0.35–0.85	0.021
NIHSS on admission	1.05	0.99–1.11	0.090
Premorbid mRS	1.37	0.93–2.02	0.109
Target vessel (ref: posterior circulation)	3.84	1.10–13.45	0.035
Intravenous thrombolysis (ref: no)	0.63	0.25–1.55	0.315
Passes of retriever	1.06	0.89–1.27	0.488
mTICI in final run after RSA	3.81	1.45–10.04	0.007

Given for selected variables are odds ratios (OR) with 95% CI and *P* value of likelihood ratio test. mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; RSA, rescue stent angioplasty; sICH, symptomatic intracranial hemorrhage, hemorrhagic transformation.

Seventy-three of 163 (44.8%) patients had a good functional clinical outcome (mRS 0–2) after 3 months. In-house mortality was 25 of 210 (11.9%); overall mortality after 3 months was 39 of 210 (18.5%). A higher NIHSS on admission, premorbid mRS, and NIHSS at discharge were significantly more often observed in patients with a poor outcome compared with patients with a good outcome (all $P<0.001$; Table 4). The number of retrieval maneuvers as an indirect parameter for procedure duration and complexity differed noticeably between patients with good (median, 2 [IQR, 1–3]) and poor functional outcome (median, 3 [IQR, 1–4]; $P<0.035$). A successful recanalization after RSA (mTICI 2b–3) was significantly more often observed in patients with good outcome compared with patients with poor outcome ($P<0.001$; Table 4).

Table 3. Multivariable Analysis of Predictors of sICH in the Immediate Postinterventional Phase After Acute Stenting

	OR	95% CI	P Value
Age, y	1.06	1.02–1.11	0.008
Sex (ref: male)	2.11	0.73–6.12	NS: 0.071
NIHSS on admission	1.04	0.96–1.12	NS: 0.288
Premorbid mRS	1.44	0.90–2.31	NS: 0.227
Target vessel (ref: posterior circulation)	3.31	0.66–16.58	NS: 0.71
Intravenous thrombolysis	1.55	0.53–4.56	NS: 0.482
Passes of retriever	1.00	0.79–1.26	NS: 0.662
mTICI in final run after RSA	4.16	1.49–11.06	0.007

Given for selected variables are odds ratios (OR) with 95% CI and *P* value of likelihood ratio test. mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; RSA, rescue stent angioplasty; sICH, symptomatic intracranial hemorrhage, hemorrhagic transformation.

In univariable logistic regression, higher age ($P=0.002$), higher NIHSS on admission ($P=0.001$), higher premorbid mRS ($P=0.001$), higher number of retrievals ($P=0.029$), and an unsuccessful recanalization (mTICI of 0–2a) after RSA ($P<0.001$) were associated with a poor functional outcome in the postinterventional phase after acute stenting (Table 5). Multivariable logistic regression analysis identified higher NIHSS at admission (adjusted OR, 1.10; $P=0.002$; e-value=1.275), higher premorbid mRS (adjusted OR, 2.02; $P=0.002$; e-value=2.195), and an unsuccessful recanalization (mTICI of 0–2a) after RSA (adjusted OR, 23.24; $P<0.001$; e-value=9.113) as independent predictors of poor functional outcome after acute stenting (Table 6).

Discussion

This analysis of data from 7 centers worldwide is the largest published series for acute RSA so far, allowing, for the first time, the identification of predictive factors for functional clinical outcome. The study population was broad and representative of daily clinical practice, including patients with anterior and posterior circulation, low NIHSS, and long duration from symptom onset to presentation at the hospital.

In our study, good outcome was observed in 73 of 163 (44.8%) patients with recorded outcomes at 90 days. Even if all patients without recorded outcomes were defined as poor outcome, the rate of good outcome would still be 35%. This is considerably better than the rates of 7% to 22% in cohorts with reocclusion or persistent occlusion reports without RSA.^{15,22,23,30} The rate of good functional clinical outcome in our analysis is also substantially better than in patients without recanalization (Thrombolysis in Cerebral Infarction 0/1) in the meta-analysis of the large thrombectomy randomized controlled trials.³¹ These results are comparable with the data of a recent meta-analysis³² of 160 patients treated with RSA, which showed 43% good functional outcome.

Placement of an intracranial stent requires antiplatelet therapy, which might increase the risk of intracranial bleeding in acute stroke. The rate of sICH in our analysis (11%) was somewhat higher than in the aggregated thrombectomy studies without intracranial stenting of 4.4%,⁷ but comparable with the 12% in the meta-analysis of Wareham et al.³² In the MR CLEAN¹ (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands) trial, the rate of sICH was 7.7% in the interventional group. Behme et al³³ reported a hemorrhage rate of 9% in emergency stenting of the internal carotid artery in tandem lesions, where an antiplatelet therapy was also administered.

A standard of antiplatelet therapy for acute intracranial stenting does not exist.³⁴ In our study, GpIIb/IIIa antagonists were used in most of the cases. The minority of cases were

Table 4. Comparison of Baseline Demographic, Clinical, and Radiological Characteristics Between Patients With Good (mRS 1–2) and Poor (mRS 3–6) Functional Clinical Outcome After Acute Stenting

Baseline Characteristics	Functional Independent (mRS 1–2; n=73)	Poor Outcome (mRS 3–6; n=90)	P Value
Age (y), median (IQR)	63 (54; 72)	69 (62; 77)	0.001
Female, n (%)	28 (38.4)	39 (43.3)	0.521
CT parameters, median (IQR)			
ASPECTS	9 (8; 10)	8 (7; 9)	0.072
Clinical parameters, median (IQR)			
NIHSS on admission	11 (6; 16)	15 (11; 20)	<0.001
Premorbid mRS	0 (0; 0)	0 (0; 2)	<0.001
NIHSS at discharge	2 (0; 5)	14 (10; 23)	<0.001
Occlusion type, n (%)			0.314
ICA	17 (23.3)	16 (17.8)	
M1	29 (39.7)	39 (43.3)	
M2	1 (1.4)	4 (4.4)	
VA	7 (9.6)	15 (16.7)	
BA	19 (26.0)	16 (17.8)	
Anterior circulation (vs posterior circulation)	47 (64.4)	60 (66.7)	0.760
Procedure process and results			
Intravenous thrombolysis, n (%)	26 (35.6)	29 (32.2)	0.649
CT-to-groin puncture (min), median (IQR)	103 (66.3; 166.0)	92.5 (53.0; 132.5)	0.273
Passes of retriever	2 (1;3)	3 (1;4)	0.035
mTICI after last stent-retriever/aspiration (TICI 2b/3), n (%), 63 missings	26 (35.6)	19 (21.1)	0.119
mTICI in final run after RSA, n (%)	70 (95.9)	63 (70.0)	<0.001
Stent category, n (%)			
Self-expandable stents	68 (93.2)	88 (97.8)	0.147
Balloon-expandable stents	5 (6.8)	2 (2.2)	
Stent type, n (%)			
Acclino flex	15 (20.5)	20 (22.2)	
Solitaire	15 (20.5)	12 (13.3)	
Neuroform	21 (28.8)	27 (30.0)	
Wingspan	2 (2.7)	6 (6.7)	
Others (Leo, Enterprise, coroflex, Pharos)	15 (20.5)	12 (13.3)	

ASPECTS indicates Alberta Stroke Program Early CT Score; BA, basilar artery; CT, computed tomography; ICA, internal carotid artery; IQR, interquartile range; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; RSA, rescue stent angioplasty; TICI, thrombolysis in cerebral infarction; VA, vertebral artery.

treated with antiplatelet drugs acetylsalicylic acid, dipyridamol, or clopidogrel as sole or combined therapy. For intracranial stenting, the decision for double antiplatelet therapy or GpIIb/IIIa antagonist administration is based on experience with acute stenting not only in stenosis treatment, but also on aneurysm treatment, including implantation of braided stents and flow diverters. For the acute stroke setting, it is unclear which antiplatelet therapy offers the best balance between bleeding and stent occlusion risk. A main finding of

this study is the significant difference in hemorrhage rate between anterior (N=19; 11%) and posterior circulation (N=3; 4.1%).

We did not observe any technical complications explaining the higher rate of sICH in the anterior circulation. Data in the literature for sICH in posterior circulation stroke thrombectomy without stenting vary between 4% and 9%.^{35,36} There are no larger series of posterior circulation RSA to compare with our study.

Table 5. Univariable Analysis of Predictors of Poor Clinical Outcome (mRS 3–6 at 90 Days) After Acute Stenting (n=151)*

	OR	95% CI	P Value
Age, y	1.04	1.02–1.07	0.002
Sex (ref: male)	1.22	0.65–2.30	0.521
NIHSS on admission	1.08	1.04–1.14	0.001
Premorbid mRS	2.14	1.35–3.34	0.001
Target vessel (ref: posterior circulation)	1.10	0.58–2.12	0.760
Intravenous thrombolysis	1.16	0.61–2.23	0.649
Passes of retriever	1.22	1.02–1.46	0.029
mTICI in final run after RSA	15.0	3.42–65.64	<0.001

Given for selected variables are odds ratios (OR) with 95% CI and *P* value of likelihood ratio test. mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; RSA, rescue stent angioplasty.

*Forty-seven missing mRS values.

A possible consequence of our finding could be that postinterventional management, and especially management of blood pressure, should be paid even more attention in anterior circulation stroke.

There was also a predominance of sICH in female patients, which did not reach significance in the multivariate analysis. Intravenous thrombolysis with PTA had no influence on the bleeding rate. Therefore, the decision for a stent should not be influenced by the administration of intravenous tissue plasminogen activator.

The more retriever passes performed, the worse the outcome. The number of retriever maneuvers reflects the overall procedure time and complexity. This might indicate that in cases of unsuccessful thrombectomy, the decision toward stenting should not be made too late. On the other hand, not every sticky clot should be stented, given that we have to consider the significant hemorrhage risk, especially in the anterior circulation. Recent research suggests that recanalization improves clinical outcome only if achieved with not more than 3 attempts.^{22,37,38}

Concerning the interventional method used, there was 1 statistically significant finding. The use of the Acclino/Acclino flex stent (Acandis GmbH) was associated with a significantly lower rate of sICH (3.3% versus 14.3%; $P<0.01$). This stent is a new-generation self-expanding stent, which requires no exchange maneuver and can be delivered through a standard 0.017 microcatheter or the **NeuroSpeed** balloon directly. These features of easier delivery might increase the safety of the procedure. Moreover, other factors, from stent design such as the radial force, metal surface, and release mechanism, might play a role here. On the other hand, the stent has been available since 2014, and therefore the learning curve of the endovascular sites might

Table 6. Multivariate Analysis of Predictors of Poor Clinical Outcome (mRS 3–6 at 90 Days) After Acute Stenting (n=151)*

	OR	95% CI	P Value
Age, y	1.04	1.00–1.06	0.016
Sex (ref: male)	0.79	0.34–1.84	NS: 0.661
NIHSS on admission	1.10	1.03–1.16	0.002
Premorbid mRS	2.02	1.32–3.36	0.002
Target vessel (ref: posterior circulation)	0.59	0.23–1.49	NS: 0.375
Intravenous thrombolysis	0.54	0.22–1.32	NS: 0.199
Passes of retriever	1.23	0.96–1.67	NS: 0.269
mTICI in final run after RSA	23.24	4.65–116.06	<0.001

Given for selected variables are odds ratios (OR) with 95% CI and *P* value of likelihood ratio test. mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; NS, not significant; RSA, rescue stent angioplasty.

*Forty-seven missing mRS values.

be more advanced. However, the included sites were all very experienced in neurointerventions and acute stroke therapy.

Higher age, low Alberta Stroke Program Early CT Score, high NIHSS, and higher premorbid mRS were predictors for a poor outcome. These findings correlate with findings in other stroke treatment studies. Also, imaging to groin time plays a significant role for the outcome, as proven in other thrombectomy trials. From other studies, it is known that a longer procedural time decreases the chance for a good outcome.

Limitations

In our retrospective, multicenter analysis, a high number of data are missing such as Alberta Stroke Program Early CT Score and mRS outcome data of 47 patients at 90-days' follow-up. This drawback is attributable to the retrospective nature of our study. Several centers anonymized their results, and analyzing these variables to complete a full data set was not possible. We presumed a poor outcome for the 46 patients with missing follow-up mRS data. This might be too pessimistic given that of the 46 patients lost for 90-days' mRS follow-up (32%), 18 had had an NIHSS score at discharge of ≤ 4 points. It is unlikely that all of these patients had a poor neurological outcome.

The criteria for stenting were up to the interventionalist's decision, which could have caused a selection bias.

The antiplatelet regime in this study was not homogenous and partially unknown. Thus, we cannot conclude whether the preferred administration of GpIIb/IIIa antagonists is superior to other antiplatelet drugs (acetylsalicylic acid, dipyridamole, and clopidogrel) or newer, fast deliverable drugs like Ticagrelor. However, despite these limitations, we believe

that this analysis allows us to draw valid and novel conclusions.

Conclusions

The rate of good outcome after intracranial rescue stenting after mechanical thrombectomy failure is considerably higher than reported for patients with persistent occlusions and comparable with that of patients treated with thrombectomy alone. A main predictor for good outcome was a low number of thrombectomy maneuvers before stenting. The observed hemorrhage rate is higher than that in regular thrombectomy procedures, but seems acceptable. Hemorrhage is more likely in the anterior circulation. Acute intracranial rescue stenting is a valid treatment option that deserves further study in prospective trials.

Disclosures

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UNIQUE FLEXIBILITY

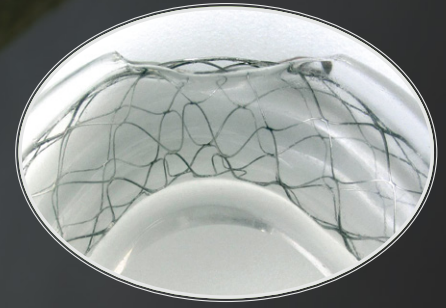
ACCLINO® flex plus Stent



- Improved visibility
- New range for more treatment options
- For microcatheters with 0.0165 – 0.021" ID

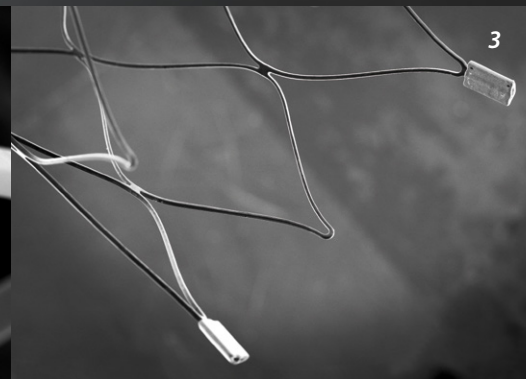
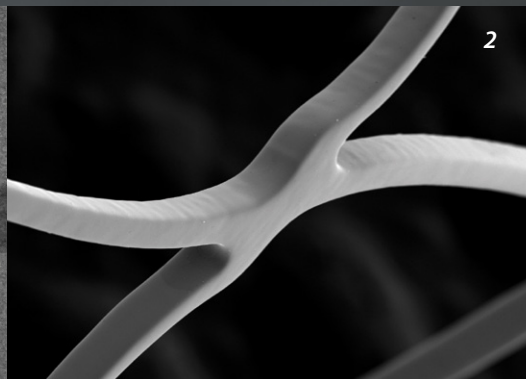
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ENGINEERING STROKE SOLUTIONS



UNIQUE FLEXIBILITY

The optimised asymmetric cell design of the closed cell laser-cut Stent ensures the highest flexibility in its class. The Stent displays enhanced expansion behaviour, excellent vessel wall apposition and optimal conformability even in tortuous vessel anatomies.

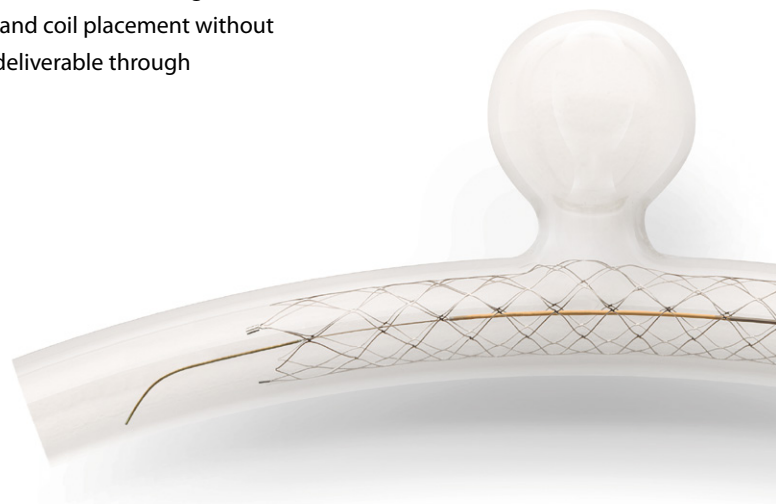
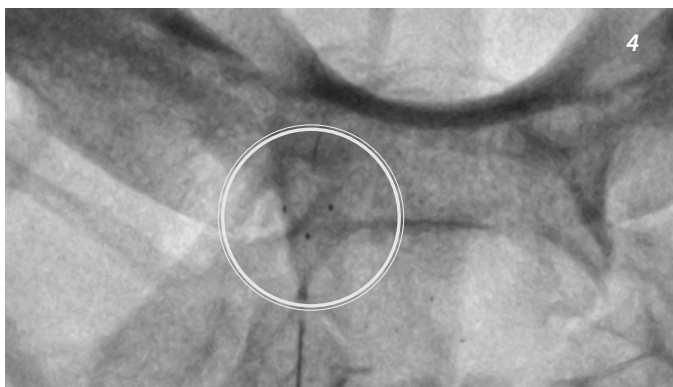


MORE TREATMENT OPTIONS

The new ACCLINO® flex plus Stent provides an increased range and is suitable for vessel diameters from 1.5 to 6.0 mm. For an easy handling all sizes from 3.0 – 5.5 mm are deliverable through microcatheters with 0.0165" – 0.017" ID. This allows a sequential stent and coil placement without the changing of the microcatheter. The 6.5 mm diameter devices are deliverable through microcatheters with 0.021" ID.

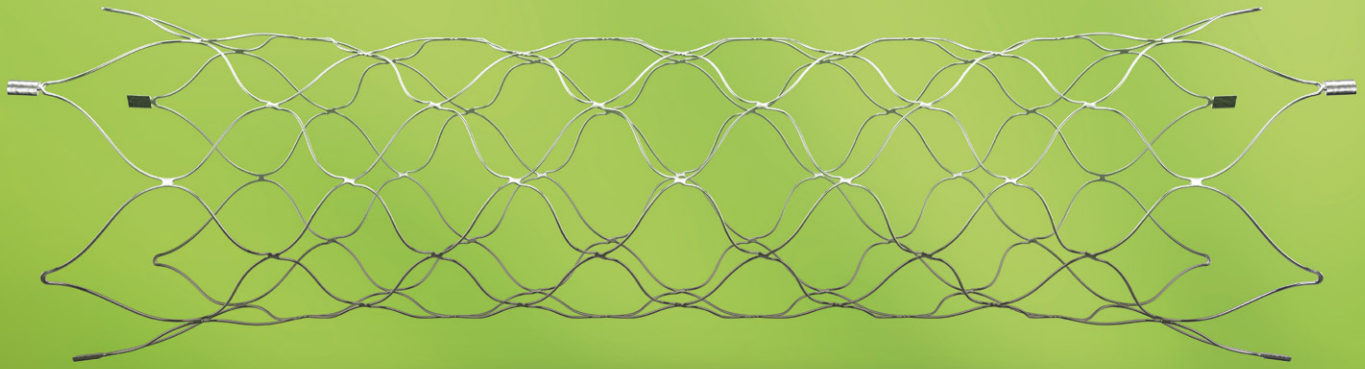
NEW X-RAY MARKER

Visibility leads to maximum safety. The three flat Platinum-Iridium X-ray markers on each end of the ACCLINO® flex plus Stent and the two golden transport wire markers support a safe and precise placement under fluoroscopy.



Captions:

- 1 Improved visibility
- 2 SEM (scanning electron microscope) image of the surface
- 3 Three low profile Platinum-Iridium X-ray markers
- 4 Good visibility even behind solid bone structures



Highly flexible self-expanding nitinol Stent for the treatment of intracranial aneurysms

FLEXIBLE

- Excellent vessel wall apposition and exceptional conformability
- Enhanced expansion behaviour due to balanced radial force and adaptive cell geometry

SECURE & VISIBLE

- Improved X-ray marker concept
- Maximum vessel lumen patency
- Low thrombogenicity

RELIABLE

- Enhanced delivery and accurate placement
- Resheathability

REPOSITIONABLE

The proximal transport wire markers indicate the "point of no return" up to where the Stent can be resheathed securely.

The ACCLINO® flex plus Stent can be recaptured and repositioned up to 90% of its length – if needed.

REDUCED THROMBOGENICITY

The perfectly electropolished stent cell connectors, only between 50 to 70 µm thin, occupy minimal space in the vessel lumen and lead to a low thrombogenicity¹.

¹ (Brassel et. Al, j Neurointervent Surg 2016. 0:1-6)



EASY GRIP

The sleek surface of the transport wire changes into a unique gripped surface, perceptible visually and by touch at the fluoroscopy marker point, to enhance the grip and push for a controlled and safe placement.

ORDERING INFORMATION | ACCLINO® flex plus

Labelled ACCLINO® flex plus Dimensions (mm)	Reference Number	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Diameter (mm)	Required / Recommended Microcatheters for Delivery (Inch)
[HRF] 3.0 × 15 3.0 × 20 3.0 × 25 3.0 × 30 3.0 × 35	01-001122	3.0	15	1.5 – 2.5	0.0165 – 0.017 NeuroSlider® 17 NeuroSlider® 17 DLC
	01-001123	3.0	20	1.5 – 2.5	
	01-001124	3.0	25	1.5 – 2.5	
	01-001125	3.0	30	1.5 – 2.5	
	01-001126	3.0	35	1.5 – 2.5	
[HRF] 3.5 × 15 3.5 × 20 3.5 × 25 3.5 × 30 3.5 × 35	01-001132	3.5	15	1.5 – 3.0	
	01-001133	3.5	20	1.5 – 3.0	
	01-001134	3.5	25	1.5 – 3.0	
	01-001135	3.5	30	1.5 – 3.0	
	01-001136	3.5	35	1.5 – 3.0	
[HRF] 4.0 × 15 4.0 × 20 4.0 × 25 4.0 × 30 4.0 × 35	01-001142	4.0	15	2.5 – 3.5	
	01-001143	4.0	20	2.5 – 3.5	
	01-001144	4.0	25	2.5 – 3.5	
	01-001145	4.0	30	2.5 – 3.5	
	01-001146	4.0	35	2.5 – 3.5	
[HRF] 4.5 × 15 4.5 × 20 4.5 × 25 4.5 × 30 4.5 × 35	01-001152	4.5	15	2.5 – 4.0	
	01-001153	4.5	20	2.5 – 4.0	
	01-001154	4.5	25	2.5 – 4.0	
	01-001155	4.5	30	2.5 – 4.0	
	01-001156	4.5	35	2.5 – 4.0	
[HRF] 5.0 × 15 5.0 × 20 5.0 × 25 5.0 × 30 5.0 × 35	01-001162	5.0	15	3.0 – 4.5	
	01-001163	5.0	20	3.0 – 4.5	
	01-001164	5.0	25	3.0 – 4.5	
	01-001165	5.0	30	3.0 – 4.5	
	01-001166	5.0	35	3.0 – 4.5	
[HRF] 5.5 × 20 5.5 × 25 5.5 × 30 5.5 × 35	01-001173	5.5	20	3.5 – 5.0	
	01-001174	5.5	25	3.5 – 5.0	
	01-001175	5.5	30	3.5 – 5.0	
	01-001176	5.5	35	3.5 – 5.0	
[HRF] 6.5 × 20 6.5 × 25 6.5 × 30 6.5 × 35	01-001193	6.5	20	4.0 – 6.0	0.021 NeuroSlider® 21 NeuroSlider® 21 DLC
	01-001194	6.5	25	4.0 – 6.0	
	01-001195	6.5	30	4.0 – 6.0	
	01-001196	6.5	35	4.0 – 6.0	
[HRF] 8.0 × 20* 8.0 × 30* 8.0 × 40* 8.0 × 60*	01-001213	8.0	20	6.0 – 7.0	0.027 NeuroSlider® 27 (DLC)
	01-001215	8.0	30	6.0 – 7.0	
	01-001217	8.0	40	6.0 – 7.0	
	01-001221	8.0	60	6.0 – 7.0	

HRF: High Radial Force – compared to ACCLINO® flex plus Stents within the same recommended vessel diameter.

* For availability please contact your local representative from Acandis®

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