BRILLIANT HIGH-FLYER

ACCERO® Stent

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

acandis®

ENGINEERING STROKE SOLUTIONS

ACCERO® Stent

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

ADAPTIVE

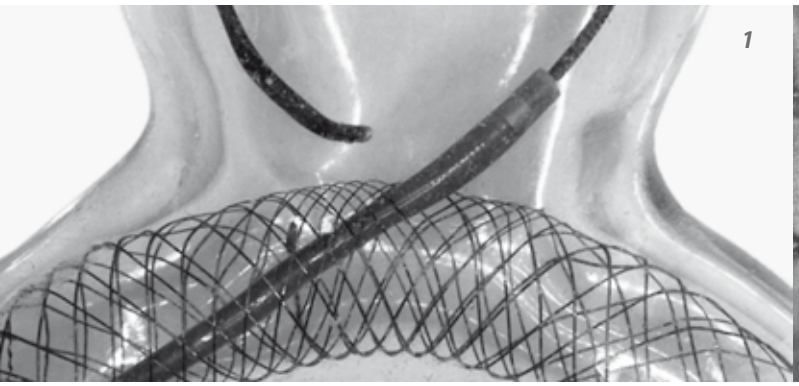
The stent has an excellent opening behaviour and an advanced wall apposition at the ends. Our engineers designed a high radial resistive force to ensure reliable coil retention.

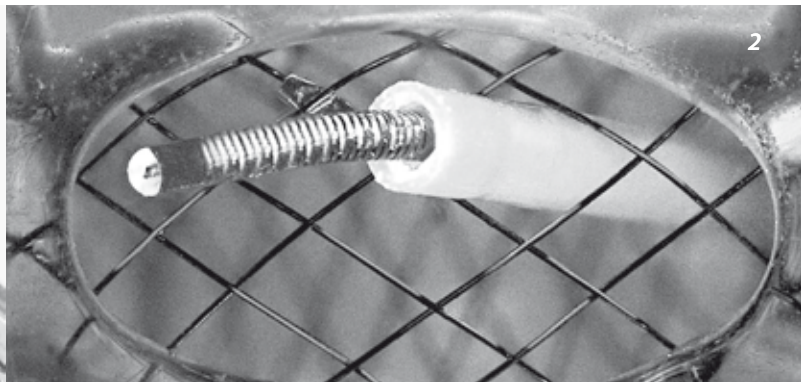
EASY TO USE

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

** contact Acandis for detailled microcatheter compatibility information*

Captions:
1,2 Stent assisted coiling with ACCERO® Stent

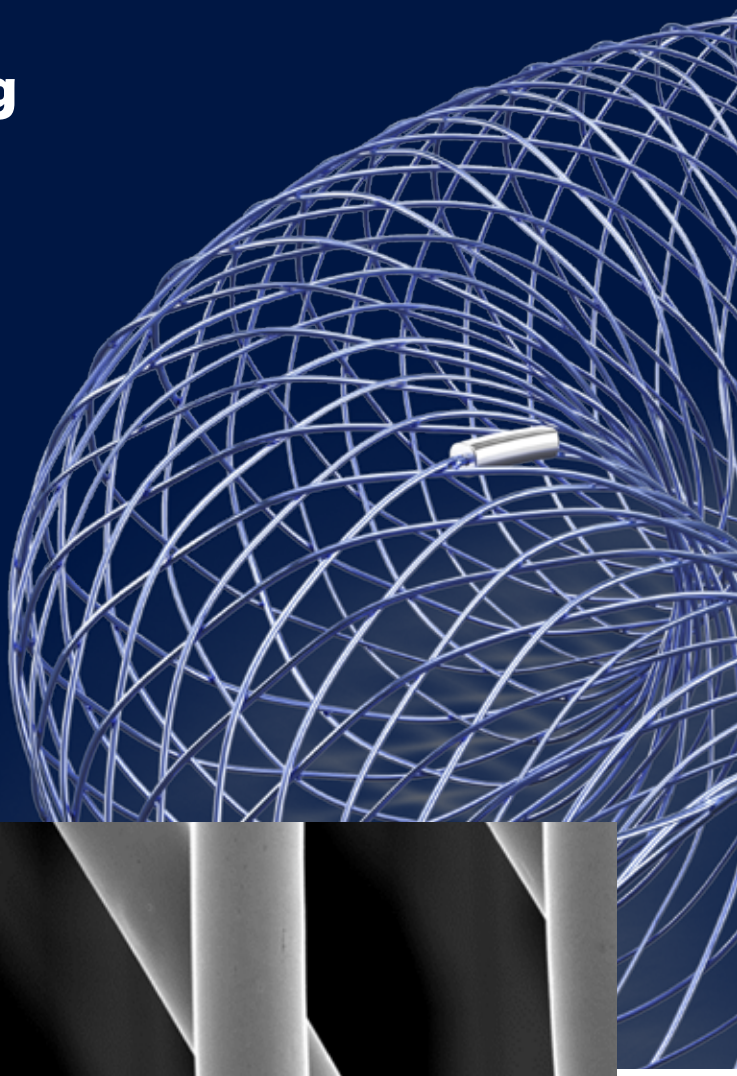


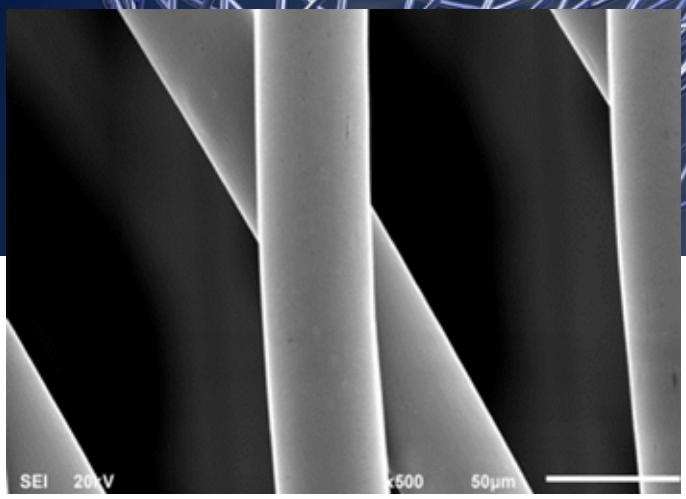


BlueXide® Surface Finishing

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**.



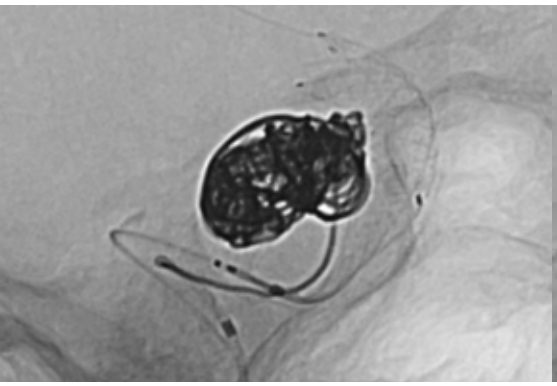


SEM (scanning electron microscope) image of the surface

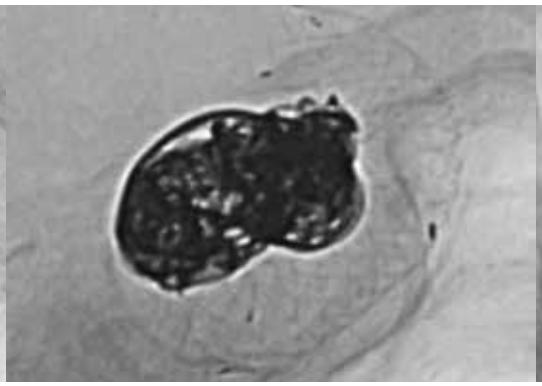
VISIBLE

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.

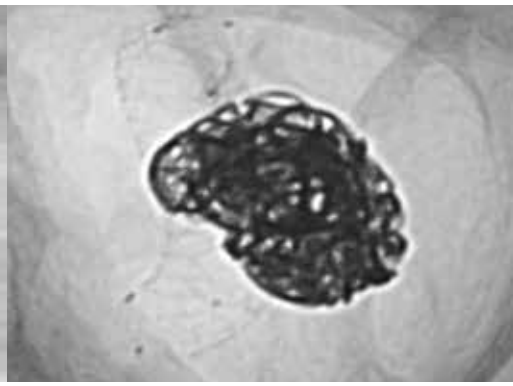
STENT ASSISTED COILING WITH ACCERO®



Initial Deployment of ACCERO® 4.5 x 20 mm



ACCERO® fully deployed



Final Angio

Images are Courtesy of Dr. P. Stracke, Alfried Krupp Hospital, Essen

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®.

All changes or modifications, may they be technical or other, or changes in the availability of products are expressively reserved.

Distributed by:

ENGINEERING STROKE SOLUTIONS

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

09-000095 EN 11/2018

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	

CE 0297

www.3we.de 2107

09-000093 EN 06/2021

Acandis GmbH | Theodor-Fahrner-Str. 6 | 75177 Pforzheim | Germany
Phone: +49 7231 155 00 0 | info@acandis.com | **www.acandis.com**

acandis®
ENGINEERING STROKE SOLUTIONS

UNIQUE FLEXIBILITY

ACCLINO® flex plus Stent

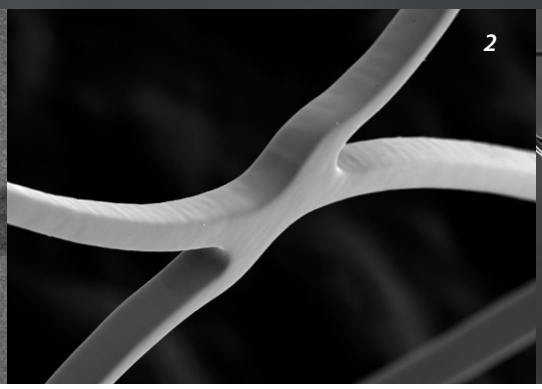
- Improved visibility
- New range for more treatment options
- For microcatheters with 0.0165 – 0.021“ ID

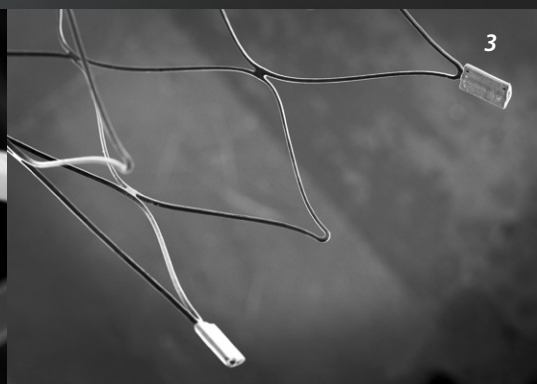
acandis®

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.



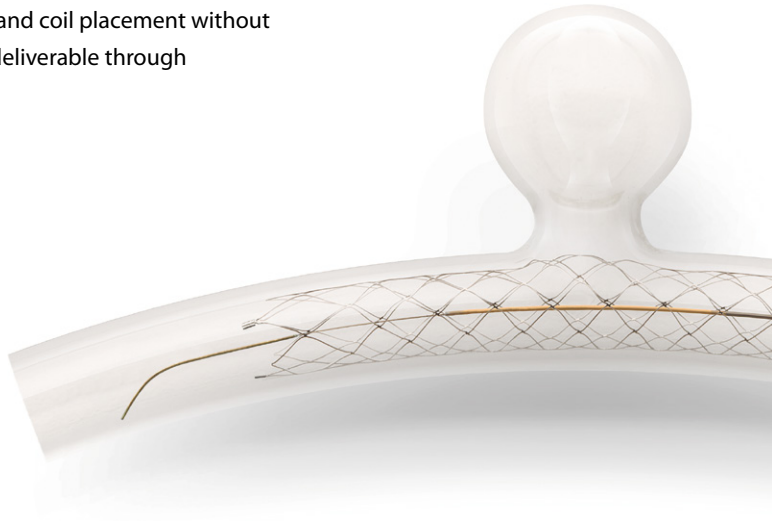


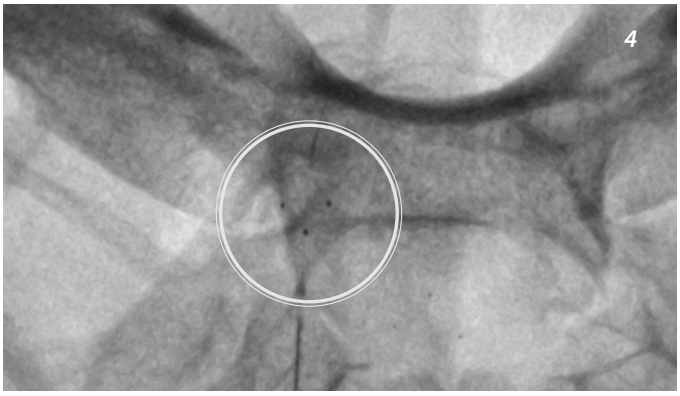
MORE TREATMENT OPTIONS

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

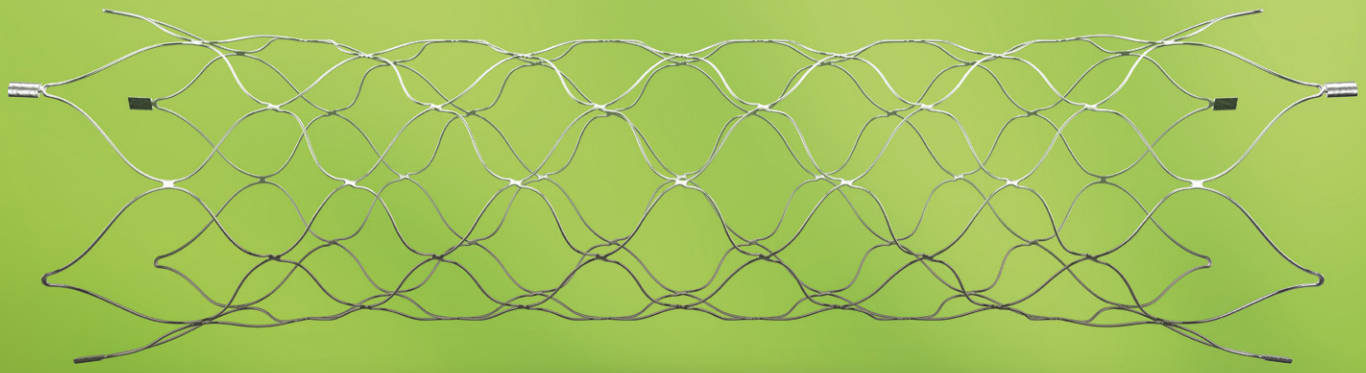
Visibility leads to maximum safety. The three flat Platinum-Iridium X-ray markers on each end of the ACCLINO® flex plus Stent and the two golden transport wire markers support a safe and precise placement under fluoroscopy.





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 resheated 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 thrombogenicity[1].

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

EASY GRIP

The sleek surface of the transport wire changes into a unique griped 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	01-001122	3.0	15	1.5 – 2.5	0.0165 – 0.017 NeuroSlider® 17 NeuroSlider® 17 DLC
HRF	3.0 × 20	01-001123	3.0	20	1.5 – 2.5	
HRF	3.0 × 25	01-001124	3.0	25	1.5 – 2.5	
HRF	3.0 × 30	01-001125	3.0	30	1.5 – 2.5	
HRF	3.0 × 35	01-001126	3.0	35	1.5 – 2.5	
	3.5 × 15	01-001132	3.5	15	1.5 – 3.0	
	3.5 × 20	01-001133	3.5	20	1.5 – 3.0	
	3.5 × 25	01-001134	3.5	25	1.5 – 3.0	
	3.5 × 30	01-001135	3.5	30	1.5 – 3.0	
	3.5 × 35	01-001136	3.5	35	1.5 – 3.0	
HRF	4.0 × 15	01-001142	4.0	15	2.5 – 3.5	
HRF	4.0 × 20	01-001143	4.0	20	2.5 – 3.5	
HRF	4.0 × 25	01-001144	4.0	25	2.5 – 3.5	
HRF	4.0 × 30	01-001145	4.0	30	2.5 – 3.5	
HRF	4.0 × 35	01-001146	4.0	35	2.5 – 3.5	
	4.5 × 15	01-001152	4.5	15	2.5 – 4.0	
	4.5 × 20	01-001153	4.5	20	2.5 – 4.0	
	4.5 × 25	01-001154	4.5	25	2.5 – 4.0	
	4.5 × 30	01-001155	4.5	30	2.5 – 4.0	
	4.5 × 35	01-001156	4.5	35	2.5 – 4.0	
HRF	5.0 × 15	01-001162	5.0	15	3.0 – 4.5	
HRF	5.0 × 20	01-001163	5.0	20	3.0 – 4.5	
HRF	5.0 × 25	01-001164	5.0	25	3.0 – 4.5	
HRF	5.0 × 30	01-001165	5.0	30	3.0 – 4.5	
HRF	5.0 × 35	01-001166	5.0	35	3.0 – 4.5	
	5.5 × 20	01-001173	5.5	20	3.5 – 5.0	
	5.5 × 25	01-001174	5.5	25	3.5 – 5.0	
	5.5 × 30	01-001175	5.5	30	3.5 – 5.0	
	5.5 × 35	01-001176	5.5	35	3.5 – 5.0	
	6.5 × 20	01-001193	6.5	20	4.0 – 6.0	0.021 NeuroSlider® 21 NeuroSlider® 21 DLC
	6.5 × 25	01-001194	6.5	25	4.0 – 6.0	
	6.5 × 30	01-001195	6.5	30	4.0 – 6.0	
	6.5 × 35	01-001196	6.5	35	4.0 – 6.0	
HRF	8.0 × 20*	01-001213	8.0	20	6.0 – 7.0	0.027 NeuroSlider® 27 (DLC)
HRF	8.0 × 30*	01-001215	8.0	30	6.0 – 7.0	
HRF	8.0 × 40*	01-001217	8.0	40	6.0 – 7.0	
HRF	8.0 × 60*	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®

All changes or modifications, may they be technical or other, or changes in the availability of products are expressively reserved.

CE 0297

www.3we.de 2107

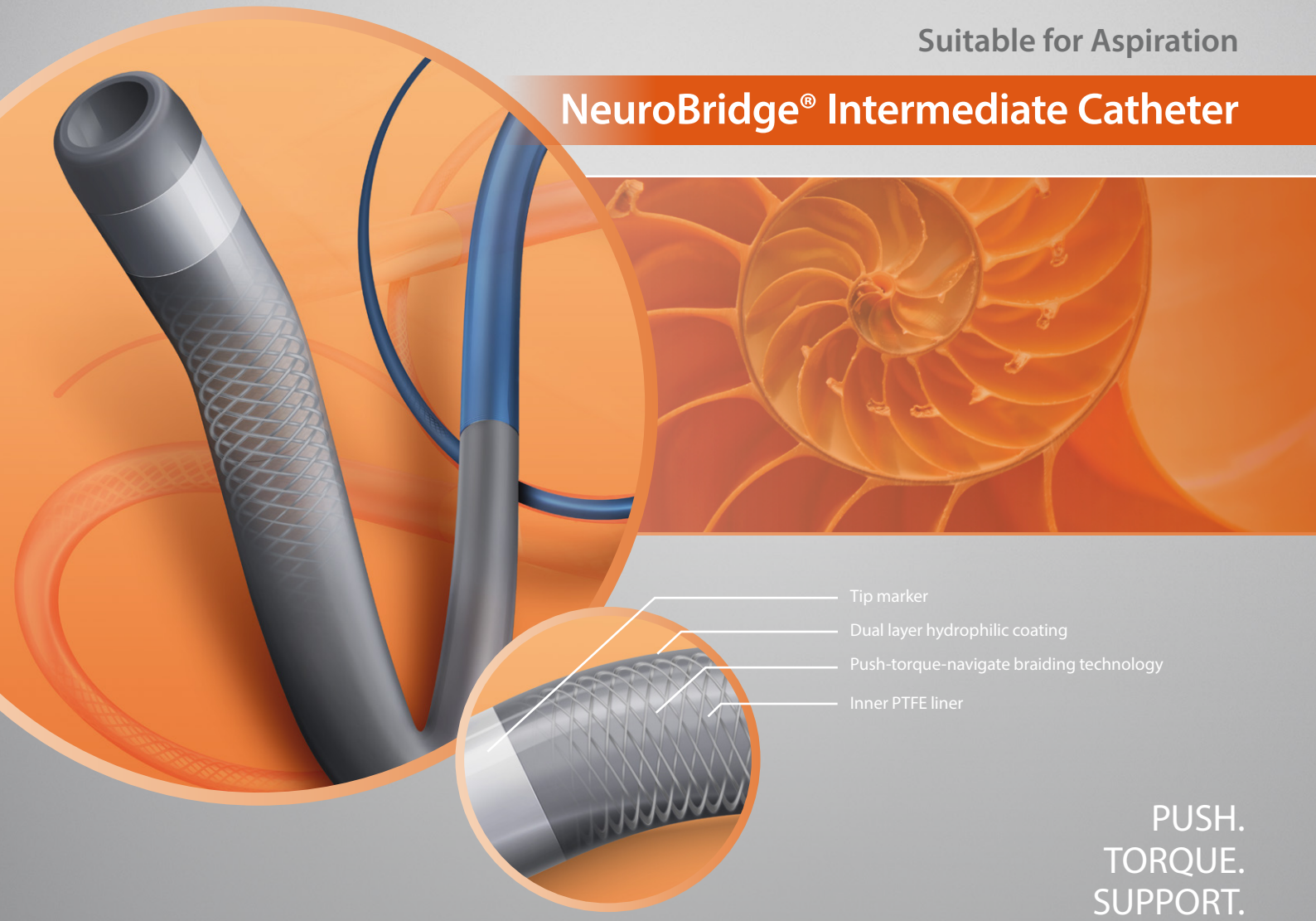
09-000081 EN 06/2021

Acandis GmbH | Theodor-Fahrner-Str. 6 | 75177 Pforzheim | Germany
Phone: +49 7231 155 00 0 | info@acandis.com | **www.acandis.com**

acandis®
ENGINEERING STROKE SOLUTIONS

Suitable for Aspiration

NeuroBridge® Intermediate Catheter



PUSH.
TORQUE.
SUPPORT.

αcandis®

ENGINEERING STROKE SOLUTIONS

FEATURES AND BENEFITS OF THE NeuroBridge®

PUSH.

- Proximal shaft stiffness leads to superior pushability
- Dual layer hydrophilic coating ensures enhanced lubricity and durability

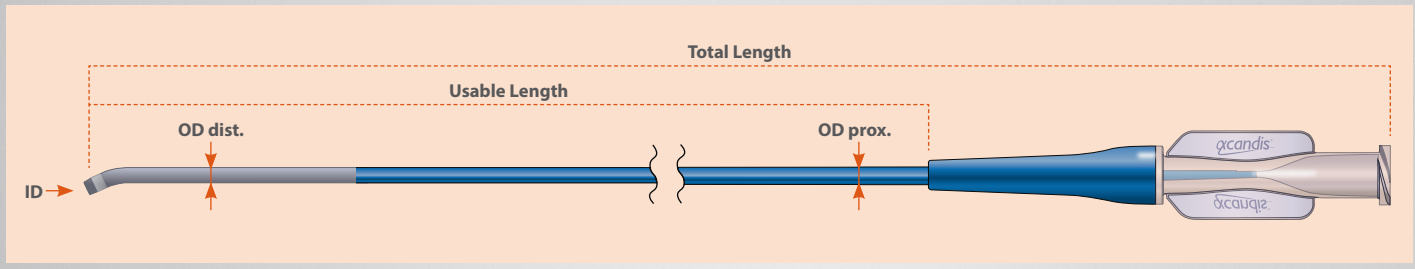
TORQUE.

- 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°

Distributed by:

acandis®
ENGINEERING STROKE SOLUTIONS

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

09-000061 EN 09/2017

SIMPLY UNIQUE

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

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

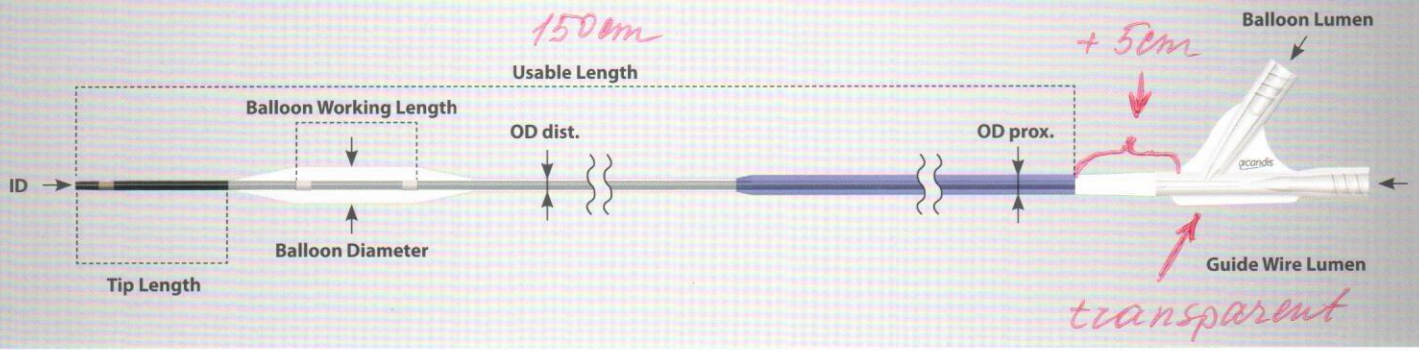
* ICAD Intracranial Atherosclerotic Disease

acandis®

ENGINEERING STROKE SOLUTIONS

NeuroSpeed® PTA Balloon Catheter

FEW SIZES – BIG IMPACT



FLEXIBLE

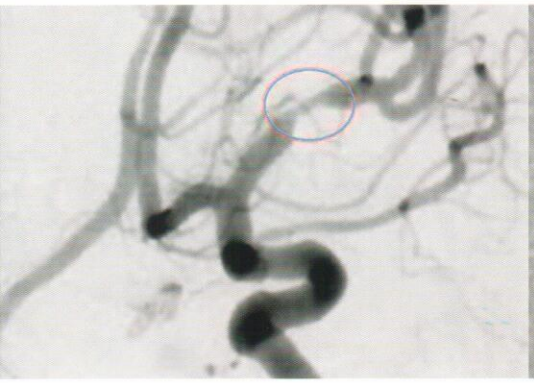
The NeuroSpeed® PTA Balloon Catheter is ideal for gentle and controllable PTA of intracranial stenosis.
If stent placement is required for stabilitation of the stenotic leason, the CREDO® Stent can be delivered through the low-profile NeuroSpeed® PTA Balloon Catheter without exchange manoeuvre.

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 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

Images by courtesy of Dr. Christian Löhr, Klinikum Vest, Recklinghausen, Germany

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

dimensioni

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

All changes or modifications, may they be technical or other, or changes in the availability of products are expressively reserved.

Distributed by:

acandis®
ENGINEERING STROKE SOLUTIONS

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

09-000092 EN 10/2020

MOVING ELEGANCE

NeuroSlider® Microcatheter DLC

- Superior torqueability and pushability
- Smooth and safe device delivery
- Longlasting tip shape retention

ENGINEERING STROKE SOLUTIONS

ADVANCE.

- Dual layer hydrophilic coating ensures outstanding lubricity and durability.
- Braiding / coiling reinforcement induces superior torqueability and significant reduction of ovalisation and elongation.

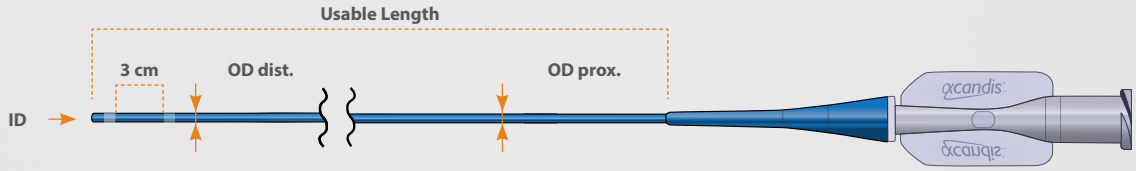
NAVIGATE.

- 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

Distributed by:

acandis®
ENGINEERING STROKE SOLUTIONS

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

09-000060 EN 08/2019

VISIBLE ADAPTABILITY

DERIVO® Embolisation Device

- Unique visibility
- 2.5 mm to 6.0 mm vessel diameter
- True self-expansion

αcandis®

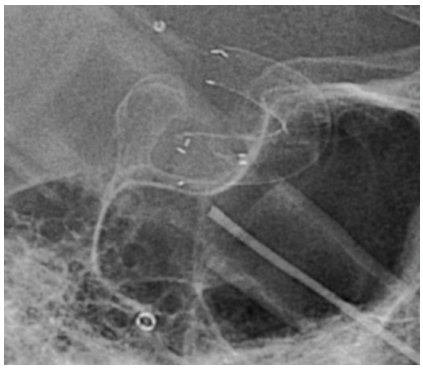
ENGINEERING STROKE SOLUTIONS

Proven Technology – Safe and Efficient

New composite wire concept for outstanding visibility of the DERIVO® contour

Treatment of left saccular ICA aneurysm with DERIVO® 5.0 mm x 20 mm

Excellent visibility of DERIVO® contour even in front of dense bone structures. View inside the lumen is possible.

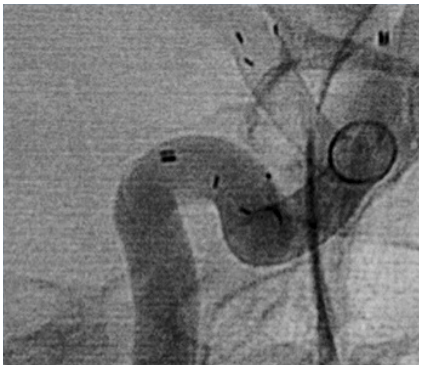


Opening of DERIVO® in tight curve is clearly visible.

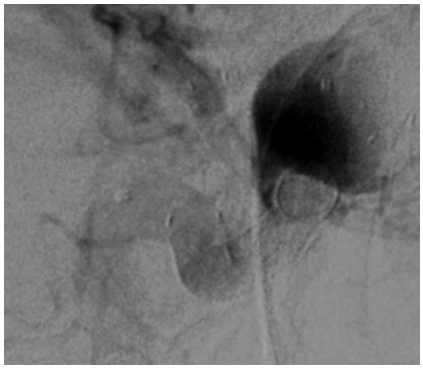
Images by courtesy of: Prof. Reith, Department of Neuroradiology, Saarland University Hospital, Homburg, Germany

Balanced mechanical properties for excellent clinical performance

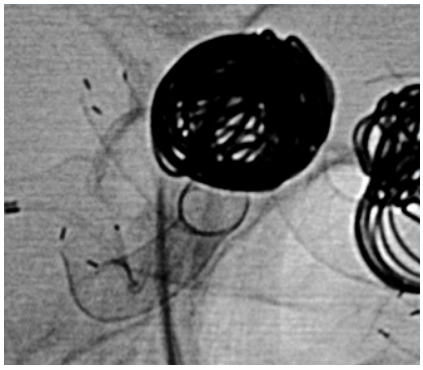
Treatment of large right ICA aneurysm with DERIVO® 4.0 mm x 30 mm



Perfect wall apposition: DERIVO® contour follows exactly the tortuous shape of the vessel.

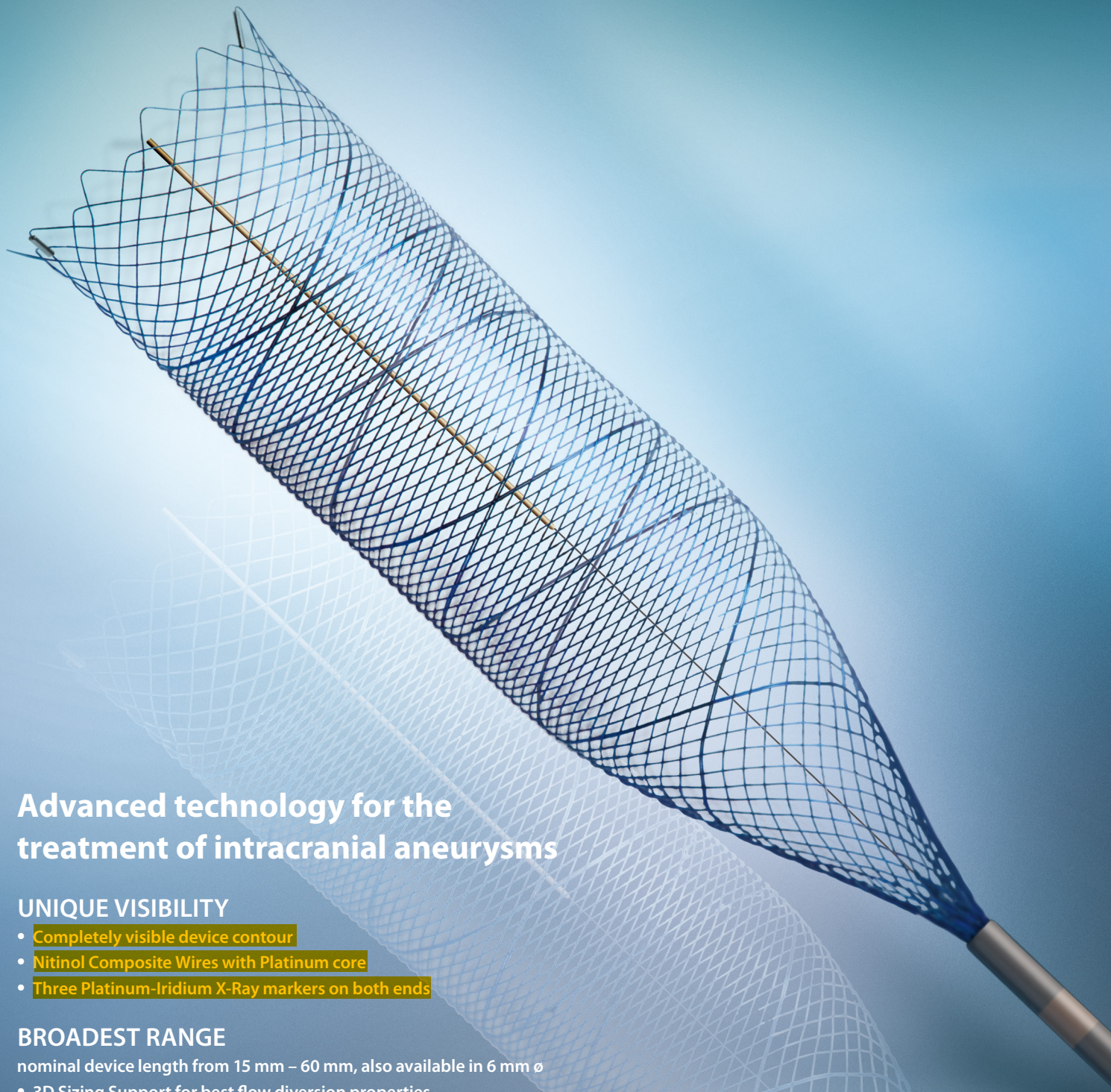


Immediate flow diversion effect after DERIVO® placement.



Excellent visibility of fully released DERIVO®.

Images by courtesy of: Dr. Prothmann, Klinikum rechts der Isar, Department of Diagnostic and Interventional Neuroradiology, Technical University Munich, Germany



Advanced technology for the treatment of intracranial aneurysms

UNIQUE VISIBILITY

- Completely visible device contour
- Nitinol Composite Wires with Platinum core
- Three Platinum-Iridium X-Ray markers on both ends

BROADEST RANGE

nominal device length from 15 mm – 60 mm, also available in 6 mm ø

- 3D Sizing Support for best flow diversion properties
- Long lengths to avoid telescoping
- Intended vessel diameters from 2.5 mm up to 6 mm

EXCEPTIONAL RELIABILITY

- Secure wall apposition because of flared ends & closed distal ends
- Better corrosion resistance and lower thrombogenicity[1] due to BlueXide® Surface Finishing
- Outstanding flexibility combined with well-balanced radial force

[1] results from in-vitro testings

FLOW – WHERE IT SHOULD BE

Acandis® is using the latest technological developments to ensure a smooth, reliable and precise treatment of intracranial aneurysms with the DERIVO® Embolisation Device.

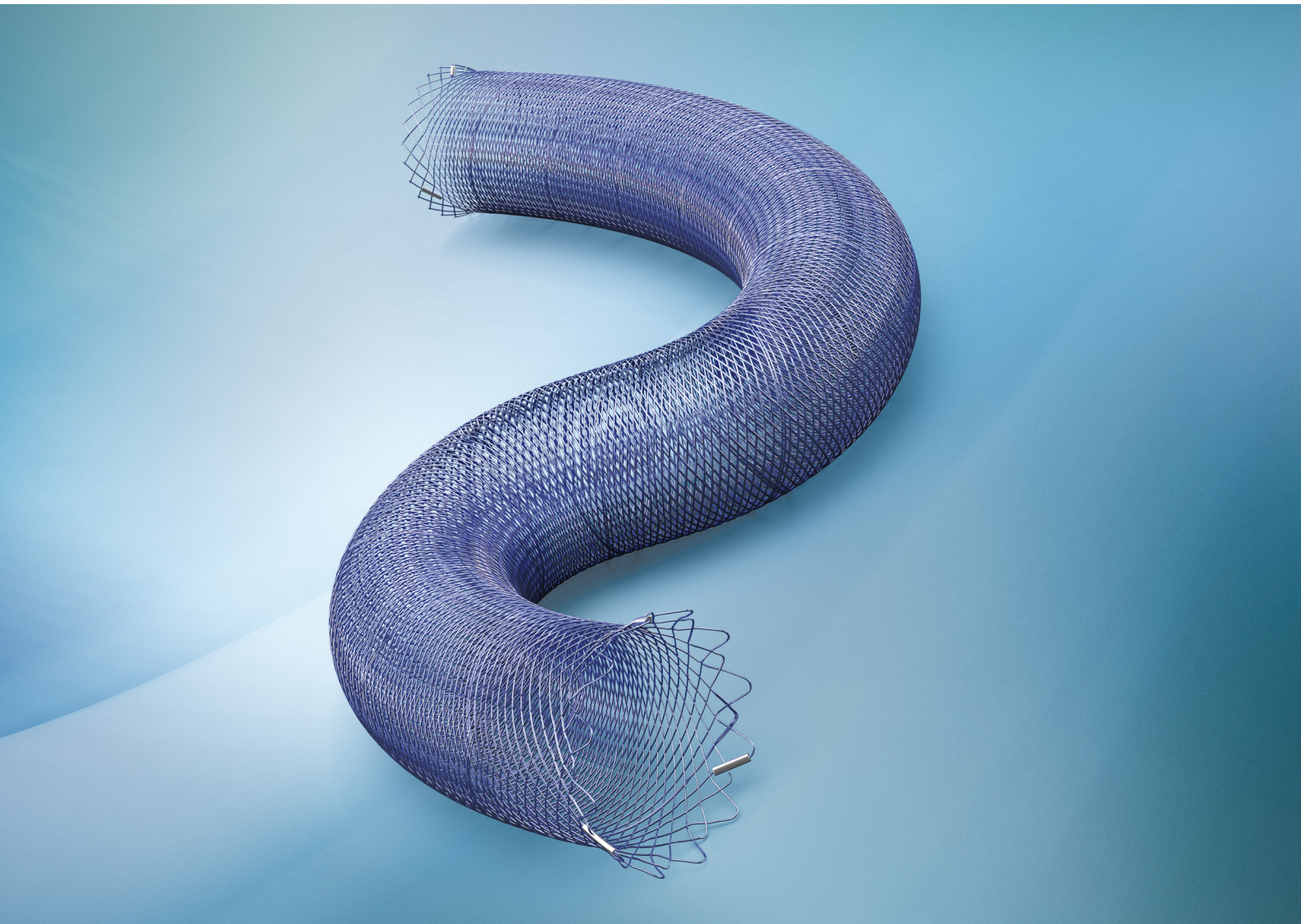
BlueXide® Surface Finishing
The Acandis® proprietary BlueXide® Surface Finishing Technology ensures less friction during delivery through the microcatheter as well as during expansion, making the opening of the device smooth and reliable. This finishing contributes to better corrosion resistance which might lead to lower thrombogenicity.

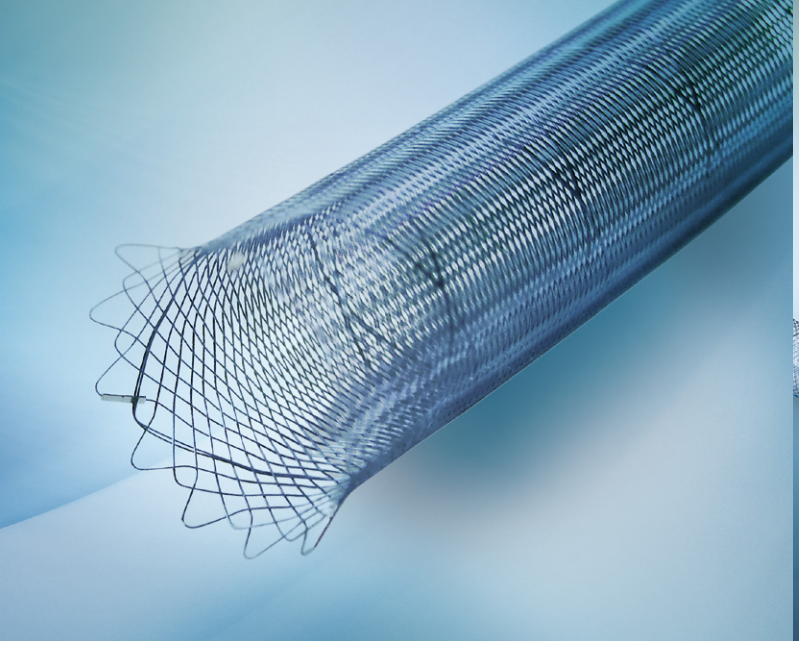
Nitinol Composite Wires
The entire device consists of Nitinol Composite Wires with Platinum core leading to an outstanding visualisation of the contour and shape of the device under fluoroscopy.

X-Ray Markers
Three Platinum-Iridium X-Ray markers are positioned on each end of the DERIVO® Embolisation Device for an accurate placement.

Closed Distal Ends
The closed distal ends of the DERIVO® Embolisation Device help in delivering the device smoothly and releasing it simply, as they create less friction during the delivery through the microcatheter. Additionally these ends are less traumatic, even if the implant is oversized in the distal part of the vessel.

Flared Ends
The DERIVO® Embolisation Device has flared ends for a secure wall apposition immediately after the initial distal opening, while the foreshortening on the proximal end is reduced.





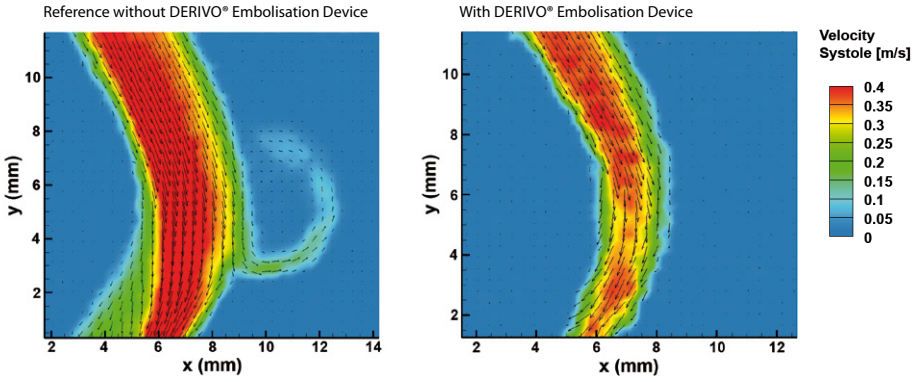
Flow Diversion

The mesh density enables flow diversion away from the aneurysm while maintaining the flow into the side branches. Particle Image Velocimetry (PIV) proves the effectiveness of the DERIVO® Embolisation Device flow diversion properties.

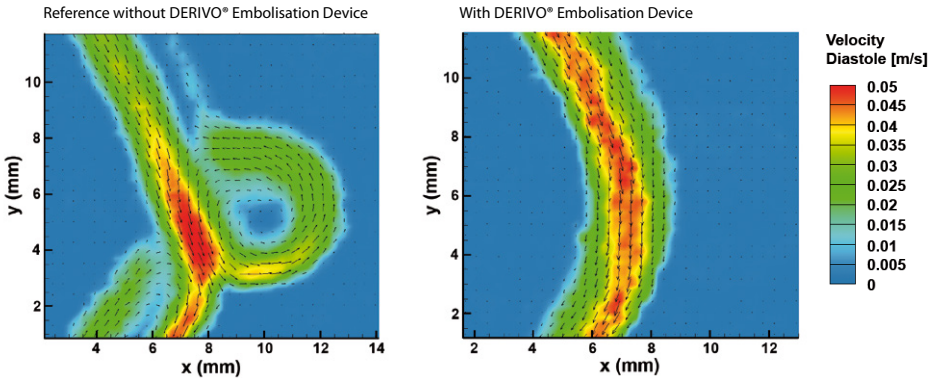
Vessel Wall Conformability

The braiding design ensures a good vessel wall conformability, even in highly variable vessel diameters and in tortuous anatomies.

Velocity during Systole



Velocity during Diastole



Particle Image Velocimetry (PIV) by courtesy of: Dept. of Cardiovascular Engineering RWTH Aachen (CVE/AME)

PROCEDURE – RELIABLE AND EFFECTIVE

s.e.c.u.r.e. GP Technology

The DERIVO® Embolisation Device is equipped with a Nitinol transport wire using the s.e.c.u.r.e. GP Technology engineered to meet the demands of a reliable and effective procedure.

S- safe

E- enhanced

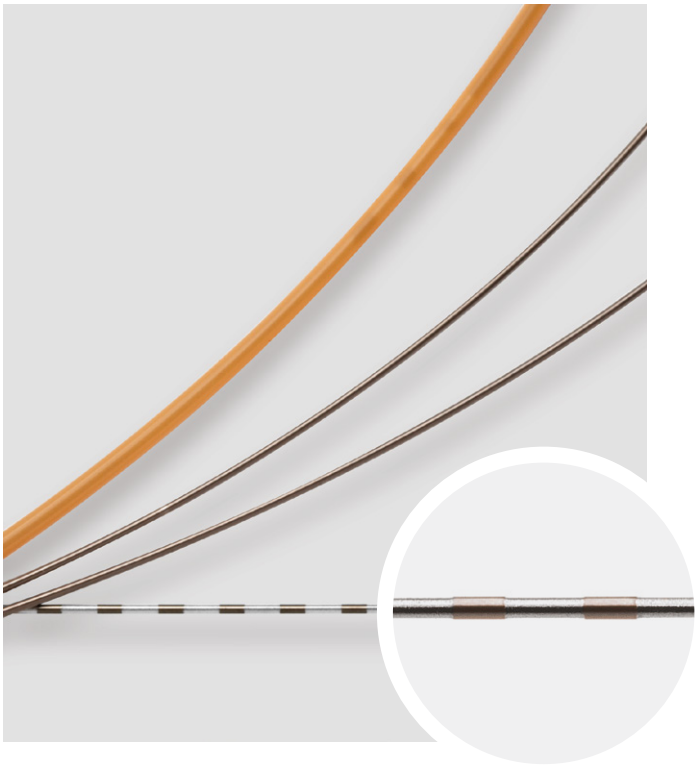
C- controlled

U- unique

R- reliable

E- effective

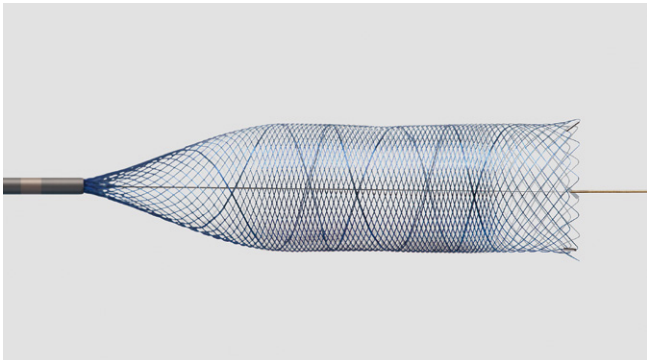
The sleek surface of the transport wire changes into a unique – optically and tactile perceptible – checkered surface at the fluoroscopy marker point, to enhance the grip and push for a controlled and safe placement of the DERIVO® Embolisation Device.



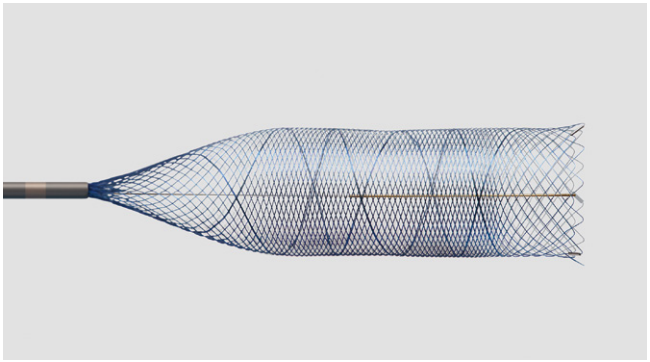
Resheathability

The device can be safely recaptured and repositioned if an adjustment and superior placement is needed.

Tip Design



With tip – for additional distal support and retention of device access after release.



Without tip (only applicable for 40 mm and 50 mm device lengths) – for more flexibility and tip control in the treatment of long lesions.

SIZING SUPPORT CHART – DERIVO® EMBOLISATION DEVICE

Labelled DERIVO® Dimensions (mm)	Reference Number		Unconstrained DERIVO® Dimensions (mm)	DERIVO® Lengths in corresponding Intended Use Diameters (mm)		
		Ø	3.7	3.5	3.0	2.5
3.5 × 15	01-000408	Device Length	10	15	20	25
3.5 × 20	01-000409		13	20	27	32
3.5 × 25	01-000410		16	25	35	41
3.5 × 30	01-000411		19	30	41	48
3.5 × 40	01-000415		25	40	53	66
		Ø	4.2	4.0	3.5	3.0
4.0 × 15	01-000381	Device Length	11	15	20	25
4.0 × 20	01-000330		14	20	27	32
4.0 × 25	01-000335		17	25	35	41
4.0 × 30	01-000340		20	30	41	48
4.0 × 40	01-000360		26	40	53	66
		Ø	4.7	4.5	4.0	3.5
4.5 × 15	01-000382	Device Length	11	15	20	25
4.5 × 20	01-000331		14	20	27	32
4.5 × 25	01-000336		17	25	35	41
4.5 × 30	01-000341		20	30	41	48
4.5 × 40	01-000361		26	40	53	66
		Ø	5.2	5.0	4.5	4.0
5.0 × 15	01-000383	Device Length	11	15	20	23
5.0 × 20	01-000332		14	20	27	32
5.0 × 25	01-000337		17	25	35	41
5.0 × 30	01-000342		20	30	41	48
5.0 × 40	01-000362		26	40	53	62
5.0 × 50	01-000363		34	50	68	82
		Ø	5.7	5.5	5.0	4.5
5.5 × 15	01-000384	Device Length	11	15	20	23
5.5 × 20	01-000333		14	20	27	32
5.5 × 25	01-000338		17	25	35	41
5.5 × 30	01-000343		20	30	41	48
5.5 × 40	01-000364		26	40	53	62
5.5 × 50	01-000365		34	50	68	82
		Ø	6.2	6.0	5.5	5.0
6.0 × 15	01-000385	Device Length	11	15	20	23
6.0 × 20	01-000334		14	20	27	32
6.0 × 25	01-000339		17	25	35	41
6.0 × 30	01-000344		20	30	41	48
6.0 × 40	01-000366		26	40	53	62
6.0 × 50	01-000367		34	50	68	82

Note: all indicated lengths can vary within a tolerance range of +/- 1mm

For optimal case preparation, Acandis also offers software-based 3D Sizing Support.

For further information please contact the Clinical Support Team: **clinical-support@acandis.com**

ORDERING INFORMATION

Labelled DERIVO® Diameter (mm)	Labelled DERIVO® Length (mm)	Reference Number	Recommended Vessel Diameter (mm)	Required Microcatheter for Delivery ** (inch)
3.5	15	01-000408	2.5 – 3.5	0.027
	20	01-000409		
	25	01-000410		
	30	01-000411		
	40	01-000415*		
4.0	15	01-000381	3.0 – 4.0	
	20	01-000330		
	25	01-000335		
	30	01-000340		
	40	01-000360*		
4.5	15	01-000382	3.5 – 4.5	
	20	01-000331		
	25	01-000336		
	30	01-000341		
	40	01-000361*		
5.0	15	01-000383	4.0 – 5.0	
	20	01-000332		
	25	01-000337		
	30	01-000342		
	40	01-000362*		
	50	01-000363*		
5.5	15	01-000384	4.5 – 5.5	
	20	01-000333		
	25	01-000338		
	30	01-000343		
	40	01-000364*		
	50	01-000365*		
6.0	15	01-000385	5.0 – 6.0	
	20	01-000334		
	25	01-000339		
	30	01-000344		
	40	01-000366*		
	50	01-000367*		

All changes or modifications, may they be technical or other, or changes in the availability of products are expressively reserved.

* Indicated on package as „without Tip" as the tip always stays inside the stent for the 40 mm and 50 mm length
** Please contact your local Acandis® representative for information on compatible microcatheters

Distributed by:

acandis®
ENGINEERING STROKE SOLUTIONS

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

09-000052 EN 09/2017

ORDERING INFORMATION

Labelled DERIVO® 2 Dimensions (mm)	Reference Number	Device Diameter (mm)	Device Length (mm)	Recommended Vessel Diameter (mm)	Required / Recommended (Micro)Catheters for Delivery (Inch)
2.5 x 10	01-107001	2.5	10	1.5 – 2.5	0.0165" - 0.017" NeuroSlider® 17 DLC
2.5 x 15	01-107002	2.5	15	1.5 – 2.5	
2.5 x 20	01-107003	2.5	20	1.5 – 2.5	
3.0 x 10	01-107005	3.0	10	2.0 – 3.0	
3.0 x 15	01-107006	3.0	15	2.0 – 3.0	
3.0 x 20	01-107007	3.0	20	2.0 – 3.0	
3.0 x 25	01-107008	3.0	25	2.0 – 3.0	
3.5 x 10	01-107009	3.5	10	2.5 – 3.5	
3.5 x 15	01-107010	3.5	15	2.5 – 3.5	
3.5 x 20	01-107011	3.5	20	2.5 – 3.5	
3.5 x 25	01-107012	3.5	25	2.5 – 3.5	
3.5 x 30	01-107013	3.5	30	2.5 – 3.5	0.027" NeuroSlider® 27 (DLC)
3.5 x 40	01-107035	3.5	40	2.5 – 3.5	
4.0 x 15	01-107014	4.0	15	3.0 – 4.0	
4.0 x 20	01-107015	4.0	20	3.0 – 4.0	
4.0 x 25	01-107016	4.0	25	3.0 – 4.0	
4.0 x 30	01-107017	4.0	30	3.0 – 4.0	
4.0 x 40	01-107039	4.0	40	3.0 – 4.0	
4.5 x 15	01-107018	4.5	15	3.5 – 4.5	
4.5 x 20	01-107019	4.5	20	3.5 – 4.5	
4.5 x 25	01-107020	4.5	25	3.5 – 4.5	
4.5 x 30	01-107021	4.5	30	3.5 – 4.5	
4.5 x 40	01-107043	4.5	40	3.5 – 4.5	
5.0 x 15	01-107022	5.0	15	4.0 – 5.0	
5.0 x 20	01-107023	5.0	20	4.0 – 5.0	
5.0 x 25	01-107024	5.0	25	4.0 – 5.0	
5.0 x 30	01-107025	5.0	30	4.0 – 5.0	
5.0 x 40	01-107047	5.0	40	4.0 – 5.0	
5.0 x 50	01-107048	5.0	50	4.0 – 5.0	
5.5 x 15	01-107026	5.5	15	4.5 – 5.5	
5.5 x 20	01-107027	5.5	20	4.5 – 5.5	
5.5 x 25	01-107028	5.5	25	4.5 – 5.5	
5.5 x 30	01-107029	5.5	30	4.5 – 5.5	
5.5 x 40	01-107052	5.5	40	4.5 – 5.5	
5.5 x 50	01-107053	5.5	50	4.5 – 5.5	
6.0 x 15	01-107030	6.0	15	5.0 – 6.0	
6.0 x 20	01-107031	6.0	20	5.0 – 6.0	
6.0 x 25	01-107032	6.0	25	5.0 – 6.0	
6.0 x 30	01-107033	6.0	30	5.0 – 6.0	
6.0 x 40	01-107057	6.0	40	5.0 – 6.0	
6.0 x 50	01-107058	6.0	50	5.0 – 6.0	
7.0 x 20	01-107059	7.0	20	6.0 – 7.0	0.039" NeuroBridge® 39
7.0 x 25	01-107060	7.0	25	6.0 – 7.0	
7.0 x 30	01-107061	7.0	30	6.0 – 7.0	
7.0 x 40	01-107068	7.0	40	6.0 – 7.0	
7.0 x 50	01-107069	7.0	50	6.0 – 7.0	
8.0 x 20	01-107062	8.0	20	7.0 – 8.0	
8.0 x 25	01-107063	8.0	25	7.0 – 8.0	
8.0 x 30	01-107064	8.0	30	7.0 – 8.0	
8.0 x 40	01-107073	8.0	40	7.0 – 8.0	
8.0 x 50	01-107074	8.0	50	7.0 – 8.0	

All changes or modifications, may they be technical or other, or changes in the availability of products are expressively reserved.
Please contact your local Acandis® representative for information on compatible (micro)catheters.

09-000108 EN 10/2020

acandis®
ENGINEERING STROKE SOLUTIONS

CE 0297

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

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

Clin Neuroradiol
https://doi.org/10.1007/s00062-021-01086-2

ORIGINAL ARTICLE

Implantation of Large Diameter (5.5–6 mm) Derivo Embolization Devices for the Treatment of Cerebral Aneurysms

Waleed Butt[1,2] · Cha-ney Kim[1] · Rajesh Ramaswamy[1] · Aubrey Smith[1] · Paul Maliakal[1]

Received: 25 April 2021 / Accepted: 7 August 2021

Abstract

Background The efficacy of flow diverters is dependent upon robust wall apposition in the parent artery. Usage in large caliber cerebral vessels has therefore been limited as few implants with diameters >5 mm exist. We present our initial experience in treating cerebral aneurysms using the 5.5 mm and 6 mm diameter implants of the Derivo embolization device (DED).

Methods Our prospectively maintained institutional database was reviewed to identify patients in whom a >5 mm DED was implanted between November 2016 and February 2021. The primary efficacy outcome was complete or near-complete aneurysm occlusion at 6 months (O'Kelly-Marotta, OKM, C–D, adapted for magnetic resonance angiography). Safety outcomes included 30-day major morbidity defined as modified Rankin Score (mRS) 3–5, mortality, serious adverse events and procedural complications.

Results A total of 21 large diameter DEDs were deployed in 18 patients (age 59.5 ± 14.1 years), harboring 19 unruptured aneurysms. Of the aneurysms 14 (73.7%) were saccular in morphology (sac diameter 10.9 ± 5.5 mm, neck diameter 6.8 ± 3.1 mm), 3 (15.8%) aneurysms were dissecting, 1 (5.3%) iatrogenic pseudoaneurysm and 1 (5.3%) fusiform. Aneurysm locations were: ICA (internal carotid artery) (n = 17); (7 cavernous, 4 paraophthalmic, 2 paraclinoid, 1 petrous, 2 communicating, 1 cervical); vertebrobasilar (n = 2). Adjunct stenting to optimize proximal wall apposition was undertaken in 5 (27.8%) patients. At 6 months 75% of patients followed-up met the primary efficacy endpoint (OKM C–D). There were no serious adverse events, 30-day major morbidity (mRS 3–5) or mortality.

Conclusion Implantation of large diameter (5.5 mm and 6 mm) DEDs into capacious cerebral vessels to treat a range of complex aneurysms is safe and technically feasible but may require adjunct stenting to optimize proximal wall apposition. Short-term efficacy of this device subset is comparable to previous DED and other flow diverter studies. Long-term follow-up and comparative studies are required for further assessment.

Keywords Flow diverter · Stent · Intracranial aneurysm · Embolization · Endovascular

Abbreviations

CTA Computed tomography angiography,
DED Derivo embolization device,
DSA Digital subtraction angiography,
EVT Endovascular treatment,
ICA Internal carotid artery,
MRA Magnetic resonance angiography,
OKM O'Kelly-Marotta,
PED Pipeline embolization device,
SAH Subarachnoid hemorrhage

All authors approved the final version of the manuscript for submission.

✉ Waleed Butt
mohammad.butt2@nuh.nhs.uk

[1] Interventional Neuroradiology, Hull Royal Infirmary, Hull University Teaching Hospitals NHS Trust, Hull, UK

[2] Interventional Neuroradiology, Queens Medical Centre, Nottingham University Hospitals NHS Trust, Nottingham, UK

Introduction

Since the introduction of flow diverters into the neurointerventional armamentarium there has been a paradigm shift in the treatment of large, giant, wide-necked, dissecting and fusiform aneurysms [1]. The principle mechanism is aneurysm exclusion from the circulation by creating

Published online: 08 September 2021

impedance to blood flow at the vessel wall defect with subsequent hemodynamic decoupling between the normal vessel and aneurysm lumen [2]. Robust wall apposition in the parent artery promotes endothelialization, prevents endoleaks and is a key determinant of aneurysm obliteration [3, 4].

Although there has been continued expansion in the number of available devices, only a few implants with diameters greater than 5 mm are available [5]. This has limited the use of flow diverters in anatomies where the maximum unconstrained opening diameter of the stent is less than that of the parent artery. The Derivo embolization device (DED) (Acandis, Pforzheim, Germany) is a second-generation flow diverter braided from 48 nitinol wires with an inner platinum core to improve visibility and a further 3 radiopaque markers at the distal and proximal ends. It is available in lengths between 15 and 50 mm, diameters between 3.5 and 6 mm, and can be resheathed to its point of no-return if repositioning is required.

Recently published DED multicentric series and single-arm trials have yielded promising short-term clinical and angiographic outcomes; however, data pertaining to device and parent vessel diameter and device size cannot be gleaned from these studies [6–8]. Furthermore, reports on the usage of large diameter flow diverter stents are scarce [9]. Therefore, we sought to present our experience and evaluate short-term efficacy and feasibility with 5.5 and 6 mm DEDs for the treatment of cerebral aneurysms.

Methods

Study Design

The prospectively maintained electronic database at a regional neurosciences center (Hull Royal Infirmary, Hull, UK) was reviewed to identify patients treated with 5.5 and 6 mm DEDs between November 2016 and February 2021. In accordance with our institutional and Health Research Authority (United Kingdom) guidelines, ethical approval was not required given the retrospective observational nature of the study and non-personally identifiable data. The study was performed in accordance with the 1964 Declaration of Helsinki and its later amendments.

Primary Efficacy End-point

The primary efficacy outcome was near-complete or complete aneurysm occlusion at 6 months. Evaluation was performed by time-of-flight MRA and contrast-enhanced MRA which are noninvasive and have sensitivities and specificities comparable with DSA [10, 11]. The degree of aneurysm filling was graded using the O'Kelly-Marotta (OKM) scale (A = total, B = subtotal, C = entry remnant, D = no filling) [12]. The OKM grades C and D were considered to meet the primary efficacy end-point.

Safety Outcomes

The primary end-point for clinical safety was the absence of 30-day major morbidity defined as modified Rankin Score (mRS) 3–5 and mortality. Serious adverse events were screened using the electronic patient records, which included any new neurological deficit and stroke. Periprocedural complications were additionally recorded irrespective of clinical effect. The DSA images were evaluated by the operating neurointerventionalist. Difficulties in device delivery, the use of adjunct devices including coils, thromboembolic and access site complications were assessed. Follow-up MRI scans were also evaluated for evidence of new ischemic lesions as reported by the consultant neuroradiologist in comparison to prior preprocedure baseline MRI.

Procedural Details

The decision for endovascular treatment of aneurysms was achieved by consensus between neurointerventionalists and vascular neurosurgeons taking into consideration the estimated lifetime rupture risk, clinical symptoms and patient wishes after informed consultation on the risk and benefits of treatment. The choice of technique, implant and the use of adjunctive devices was left to the operator's discretion. The diameter and length of the stent was based on 3D-DSA volume rendered images, considering the size and morphology of the aneurysm and parent vessel.

Patients were premedicated with dual antiplatelets (aspirin 300 mg and either ticagrelor 180 mg or clopidogrel 600 mg), usually the day prior to the procedure. Dual antiplatelets were maintained for 3 months (aspirin 75 mg once a day and either ticagrelor 90 mg twice a day or clopidogrel 75 mg once a day), with aspirin 75 mg once a day being administered life-long. Antiplatelet testing was not routinely performed. Systematic intravenous heparin was administered (typically 5000 IU), adjusted to body weight. Procedures were performed withe patient under general anesthesia utilizing a dedicated neurointerventional bi-plane angiography system (Allura Xper FD, Philips Healthcare, Amsterdam, The Netherlands).

A standardised triaxial, transfemoral approach was utilized. A 0.088″ Asahi Fubuki (Asahi Intecc, Tokyo, Japan) guide-catheter was positioned in the ipsilateral cervical internal carotid artery (ICA). The 5 Fr or 6 Fr intermediate (distal access/intracranial support) catheter used in both anterior and posterior circulations was either a CAT5 or CAT6 (Stryker Neurovascular, Fremont, CA, USA)

or Navien 0.058″/0.072″ (Navien, Covidien, Irvine, CA, USA). We endeavored to place the intermediate catheter as close to the intended landing zone to optimize stability during stent delivery.

The DED was deployed through a 0.027″ microcatheter: Via27 (Sequent Medical/MicroVention Terumo, Tustin, CA, USA) or Phenom 027 (Medtronic, Dublin, Ireland). In cases requiring adjunctive coiling, this was performed through either an Excelsior SL10 (Stryker, Kalamazoo, MI, USA) or Echelon (Covidien/Medtronic). The decision to perform adjunct coiling at the discretion of the operator, taking into consideration aneurysm size, location, morphology and the requirement for scaffolding support during stent delivery to reduce the risk of device foreshortening or prolapse. In select cases requiring adjunct stenting to correct suboptimal wall apposition of the DED proximal end, this was done using a second DED or a Solitaire AB stent (eV3, Irvine, CA, USA).

Statistical Analysis

Descriptive and comparative statistical analyses were performed using SPSS (Version 23.0; IBM, Armonk, NY, USA). Categorical variables were presented as numbers and percentages. Continuous variables were presented as means ± SD.

Results

Baseline Patient and Aneurysm Characteristics

A total of 18 patients (14 females, 4 males; age 59.5 ± 14.1 years) harboring 19 aneurysms were included. Of the aneurysms 14 (73.7%) were saccular in morphology (sac diameter 10.9 ± 5.5 mm, neck diameter 6.8 ± 3.1 mm), 3 (15.8%) aneurysms were dissecting (2 of which were iatrogenic), 1 (5.3%) iatrogenic pseudoaneurysm and 1 (5.3%) was fusiform. Aneurysm locations were: cavernous ICA ($n=7$), paraophthalmic ICA ($n=4$), paraclinoid ICA ($n=2$), petrous ICA ($n=1$), communicating ICA ($n=2$), cervical ICA ($n=1$), vertebral ($n=1$) and basilar ($n=1$). All aneurysms were considered unruptured with the exception of one iatrogenic pseudoaneurysm that presented with hemorrhagic otorrhea (patient 17). Baseline aneurysm characteristics and clinical presentation are presented in Table 1.

Procedural Results and Efficacy Outcomes

In total, 21 DEDs were deployed, 16 (76.2%) of which were 5.5 mm diameter implants and 5 (23.8%) being 6 mm diameter implants: 19 devices were deployed in 16 patients in the internal carotid artery (ICA) and 2 devices were deployed in 2 patients in the vertebrobasilar system. The mean number

Table 1 Baseline aneurysm characteristics and clinical presentation

Patient No	Aneurysm type	Clinical presentation and symptoms	Location	Aneurysm, max. diameter, mm	Aneurysm neck size, mm
1	Saccular	Headache/diplopia	Left cavernous ICA	10	5.3
2	Fusiform	Asymptomatic/Incidental	Right paraclinoid ICA	6.2	–
3	Saccular	Otalgia	Right cavernous ICA	9	7
4	Saccular	Asymptomatic/Incidental	Left PCOM	10	8
5	Saccular	Asymptomatic/Incidental	Left paraclinoid ICA	9	5
6	Saccular	3rd cranial nerve palsy	Right cavernous ICA	25	14
7	Dissecting	Infarct of left upper pons	Basilar	6.3	–
8	Saccular	3rd Cranial nerve palsy	Left PCOM (recurrence, previously coiled)	6	5
9	Saccular (partially thrombosed)	Headache, 3rd cranial nerve palsy	Right cavernous ICA	19	–
10	Saccular	Headache	Left paraophthalmic ICA	7.5	6
11	Saccular	Headache, 3rd cranial nerve palsy	1) Left cavernous ICA	14	13
			2) Left para-ophthalmic	4	3
12	Dissecting (iatrogenic)	Iatrogenic	Right cervical ICA	6.5	–
13	Saccular	Asymptomatic/Incidental	Left paraophthalmic ICA	9	7
14	Saccular	Diplopia, headache	Left cavernous ICA	16	6
15	Dissecting (iatrogenic)	Iatrogenic	Left cavernous ICA	5.3	–
16	Saccular	Asymptomatic/Incidental	Left paraophthalmic ICA	7.5	4.5
17	Iatrogenic pseudoaneurysm	Iatrogenic Hemorrhagic otorrhea	Left petrous ICA	5.7	–
18	Saccular	Asymptomatic/Incidental	Left VA	7	5

ICA Internal carotid artery, *PCOM* Posterior communicating artery, *VA* Vertebral artery

of devices deployed per patient and per aneurysm were 1.2 and 1.1, respectively. The cohort parent vessel distal landing zone was 4.5 mm ± 0.6 mm and the proximal landing zone 5.4 mm ± 0.5 mm. Adjunct intrasaccular coiling was undertaken for 6 (out of 14) saccular aneurysms (42.9%). Adjunct stenting to optimize proximal wall apposition was undertaken in 5 (27.8%) patients. In 2 (11.1%) patients with iatrogenic dissecting aneurysms a second DED was telescoped to achieve double mesh density.

The 6-month follow-up MRAs were available for 16 out of 19 (84.2%) aneurysms. Of these, 12 (75%) demonstrated near-complete or complete occlusion. One aneurysm (patient 3) which initially demonstrated subtotal filling (OKM-B) was retreated with a third stent (PED) and completely occluded on follow-up at 24 months. The sole fusiform aneurysm (patient 2) remodeled and remained stable at the 24-month follow-up. There were no cases of in-stent stenosis or occlusion Representative cases are illustrated in Figs. 1 and 2. Parent vessel size, device dimensions and efficacy outcomes are summarized in Table 2.

Safety Outcomes

There was no major 30-day morbidity (mRS 3-5) or morality in this patient cohort. There was one pseudoaneurysm at the femoral arterial access site which was repaired surgically. No other serious adverse events, including new neurological deficits and stroke, were identified in the patient records. Procedural DSA images did not reveal evidence of a thromboembolic event nor did any of the 6-month follow-up MRI scans demonstrate evidence of an interval ischemic lesion/infarct when compared to preprocedure baseline MRI. In 5 (27.8%) patients there was suboptimal opening of the proximal end of the DED and/or "fish mouthing" which was corrected using adjunct stenting. Periprocedural complications and safety outcomes are listed in Table 2.

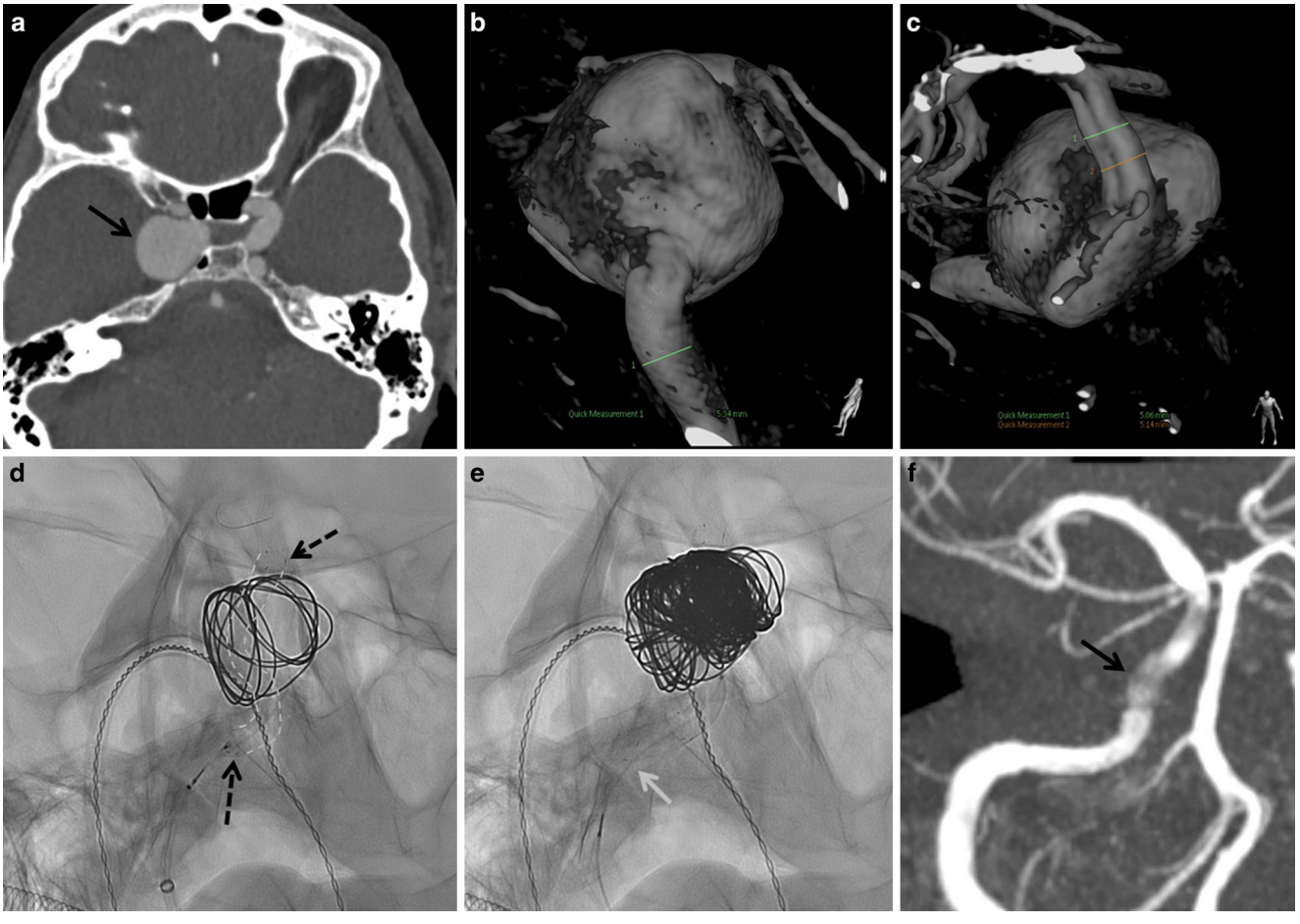


Fig. 1 Patient 6 presented with 3rd cranial nerve palsy. **a** CTA revealed a right cavernous ICA aneurysm measuring 25 mm in maximum diameter. Volume rendered 3D-DSA images illustrating the proximal (**b**) and distal (**c**) parent vessel artery diameters. **d** Initial 5.5 × 30 DED delivered (*dashed white lines* identify position, *dashed black arrows* identify markers) with adjunct coiling of the sac performed through a jailed SL-10 microcatheter to provide structural support for the stent. Mild proximal "fish mouthing" was corrected with a second 6 × 20 mm DED (*solid white arrow* in **e** indicates proximal markers). **f** Follow-up MRA demonstrates complete aneurysm occlusion at the cavernous ICA (*solid black arrow*)

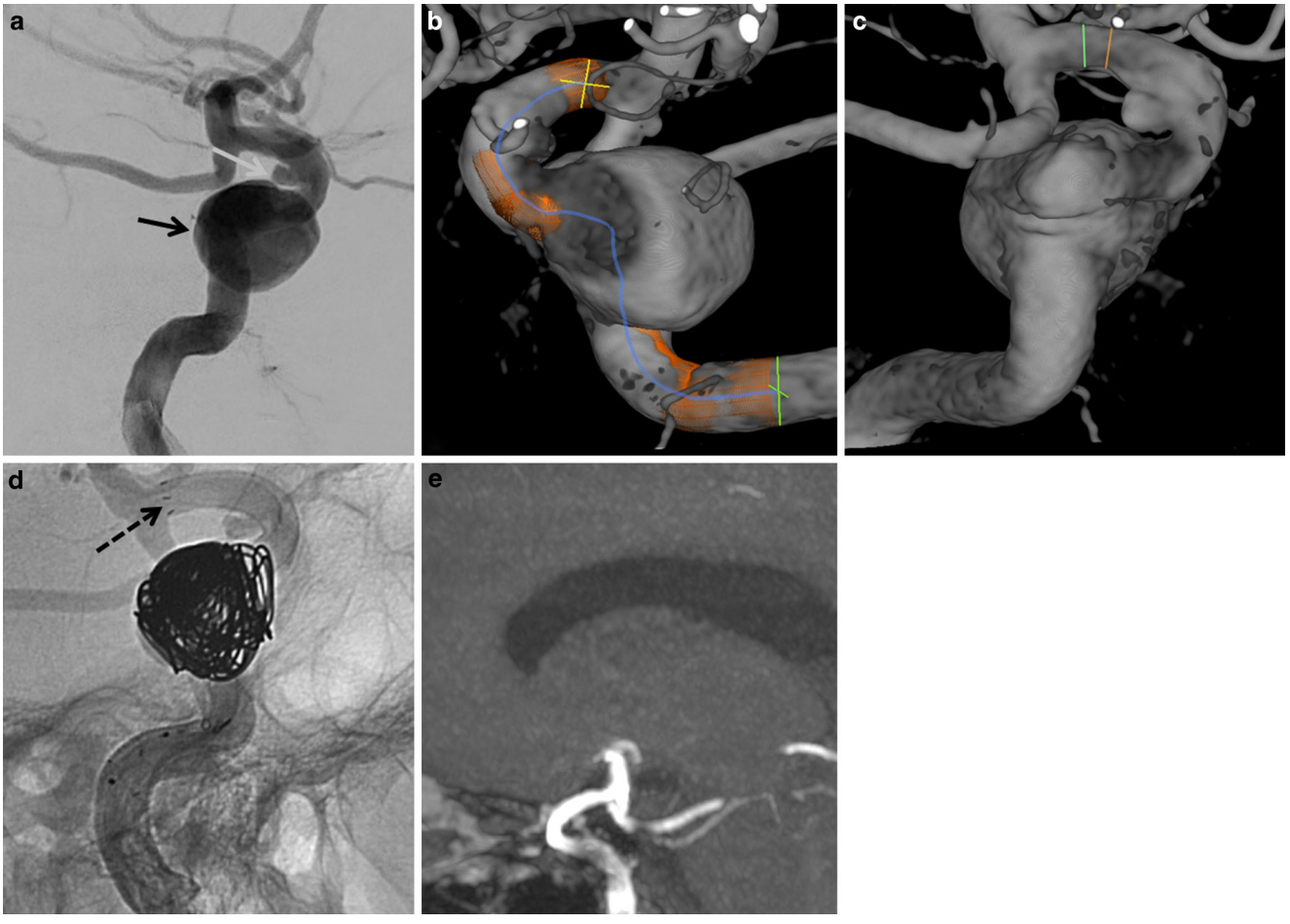


Fig. 2 Patient 11 presented with right 3rd cranial nerve palsy and worsening headaches. **a** Initial DSA reveals a 14 mm left cavernous ICA aneurysm (*solid black arrow*) and a smaller 4 mm left paraophthalmic ICA aneurysm (*solid white arrow*). **b** and **c** 3D-DSA volume rendered images illustrating aneurysm and parent vessel size/morphology. **d** A 6 × 50 mm DED was deployed covering both aneurysms with good wall apposition. Adjunct coiling of the cavernous ICA aneurysm was performed through to provide architectural support during stent delivery. **e** Follow-up MRA demonstrating complete occlusions of both aneurysms

Discussion

In this single center observational study, we assessed the feasibility and short-term efficacy of 5.5 and 6 mm implants of the DED in the treatment of a range of cerebral aneurysms. Whilst there exist a number of studies reporting on angiographic and clinical outcomes of the DED, to our knowledge none have specifically reported outcomes for large diameter devices [6–8, 13]. In recent series where the DED was used to treat ruptured and dissecting aneurysms all devices implanted were ≤ 5 mm [14, 15]. Furthermore, DED is one of the few flow diverters currently used with diameters in 5.5 and 6 mm. From the commonly available flow diverters, the Flow-Redirection Endoluminal Device (FRED; Microvention) and the SILK stent (Balt Extrusion, Montmorency, France) are also available in a 5.5 mm diameter however similar to the DED, studies reporting on outcomes have not specifically assessed this size of implant precluding cross-manufacturer comparisons [16–20].

Procedural Outcomes

In our complied experience, 21 large diameter DEDs were implanted into 18 patients to treat 19 cerebral aneurysms. A variety of aneurysm subtypes (saccular, fusiform and dissecting) were represented in the cohort reflecting the expanding utilization of flow diverters [21]. The saccular aneurysms included were on average large (10.9 ± 5.5 mm) and wide-necked (6.8 ± 3.1), which is an established indication for flow diversion [22, 23]. Although their use in posterior circulation, fusiform and dissecting aneurysms may carry increased treatment-related complications they offer an effective treatment option when conventional methods are unfeasible [24–26]. Out of 17 anterior circulation aneurysms in this cohort 7 (41.2%) arose from the cavernous ICA which represents a higher proportion than the 9.8% presented in the Brazilian DED registry [7]. This is not unsurprising given the relatively capacious geometry

Table 2 Parent vessel and device size, procedural complications and follow-up efficacy outcomes

Patient No	Distal landing zone max. diameter, mm	Proximal landing zone max. diameter, mm	DED size, mm (DxL)	Adjunct devices	Anti-platelet regime	Periprocedural complications/difficulties	Occlusion OKM grade (A–D) at 6-month follow-up	Occlusion OKM grade (A–D) at 24-month follow-up
1	4.3	5.5	5.5 × 20	Coils (to provide scaffold for stent)	Aspirin Clopidogrel	Angioseal-related femoral occlusion, surgically repaired	D	D
2	3.8	5.3	5.5 × 25	–	Aspirin Clopidogrel	–	C	C
3	5.5	6.0	5.5 × 25	Coils (to provide scaffold for stent) Solitaire 6 × 20 Pipeline 5 × 18	Aspirin Clopidogrel	Small endoleak of the proximal end of the flow diverter, treated with 6 × 20 mm Solitaire 2nd flow diverter treatment at 9 months, initially attempted using DED 6 × 30 (proximal segment failed to open). Pipeline 5 × 18 eventually deployed	B	D
4	5.3	5.6	5.5 × 20	–	Aspirin Clopidogrel	–	A 8 mm residuum	A 9 mm residuum
5	4.5	5.4	5.5 × 25	Coils (to provide scaffold for stent and view to reduce risk of delayed SAH)	Aspirin Clopidogrel	–	D	D
6	5.1	5.4	5.5 × 30 6 × 20	Coils (to provide scaffold for stent)	Aspirin Ticagrelor	Proximal fish mouthing of initial 5.5 × 30 stent, 2nd DED 6 × 20 telescoped	D	–
7	4.4	4.9	6 × 50	Right VA PVO (coils)	Aspirin Ticagrelor	–	D	–
8	4.6	5.5	5.5 × 25	–	Aspirin Ticagrelor	–	B (4 mm remnant)	B Stable
9	4.7	5.1	5.5 × 25	Solitaire 5.5 × 20	Aspirin Ticagrelor	Sub-optimal proximal apposition, re-inforced with Solitaire 5 × 20 stent	D	D
10	4.3	5.5	5.5 × 25	Coils (to provide scaffold for stent and view to reduce risk of delayed SAH) Solitaire 6 × 20	Aspirin Ticagrelor	Sub-optimal proximal apposition, endoleak, re-enforced with Solitaire 6 × 20 stent	D	D
11	3.5	6.1	6 × 50	Coils (to provide scaffold for stent)	Aspirin Ticagrelor	–	D	–
12	5.1	5.3	6 × 30	–	Aspirin Ticagrelor	–	–	–
13	3.9	5.3	5.5 × 25	Solitaire 6 × 20	Aspirin Ticagrelor	Sub-optimal proximal apposition, re-enforced with Solitaire 6 × 20	B	–
14	5.3	5.4	5.5 × 25	–	Aspirin Ticagrelor	6 × 30 initially attempted but proximal fish-mouthing/ribboning	–	–

Table 2 (Continued)

Patient No	Distal landing zone max. diameter, mm	Proximal landing zone max. diameter, mm	DED size, mm (DxL)	Adjunct devices	Anti-platelet regime	Periprocedural complications/difficulties	Occlusion OKM grade (A–D) at 6-month follow-up	Occlusion OKM grade (A–D) at 24-month follow-up
15	3.9	4.0	5.5 × 25 5.5 × 30	–	Aspirin Ticagrelor	Initial attempts with pipeline and Evolve failed. 2nd DED telescoped to achieve double mesh density across dissected segment	D	–
16	3.5	5.3	5.5 × 25	–	Aspirin Ticagrelor	–	D	–
17	4.6	4.6	5.5 × 30 5.5 × 30	–	Aspirin Ticagrelor	2nd DED telescoped to achieve double mesh density across dissected segment	D	–
18	3.9	6.1	6 × 30	–	Aspirin Ticagrelor	–	–	–

DED Derivo embolization device, *DxL* Diameter × Length, *OKM* O'Kelly-Marotta, *PVO* Parent vessel occlusion, *SAH* Subarachnoid hemorrhage, *VA* Vertebral artery

of the cavernous segment [27] and the selection for large diameter implants in our study.

Although final device size was left to the discretion of the individual operator, the maximum diameters of the parent vessel proximal and distal landing zones were key determinants of implant selection. Undersized devices carry the potential risk of an endoleak whereas substantially oversized devices may reduce flow-diversion efficacy [28, 29]. In 3 (out of 18) patients the proximal and distal landing zone measurements on 3D-DSA volume rendered images were < 5.0 mm; however, a larger device was used to account for the maximum diameter of the dilated diseased parent vessel (patients 7 and 15) and size underestimation due to vasospasm (patient 17).

Adjunct intrasaccular coiling was undertaken in 6 aneurysms in this series. In 4 (out of 6) of these cases the aneurysm was located was at the cavernous ICA and the primary reason to use adjunct coils was to provide a scaffold for the stent and to reduce the risk of the device foreshortening or prolapse. There is also some evidence that adjunct coiling may expedite and improve occlusion outcomes; however, whether this reduces delayed subarachnoid hemorrhage is undetermined [30]. Adjunct stenting was undertaken in 5 cases to optimize wall apposition which may also improve occlusion rates [31]. Similar to Taschner et al. [8] we found the proximal part of the device particularly prone to fish mouthing/suboptimal expansion; however, it is not possible to draw conclusions from our study whether the rates are significantly higher with the use of the 5.5 and 6 mm devices.

Efficacy Outcomes

Of the 16 aneurysms with follow-up MRA at 6 months, 12 (75%) demonstrated near-complete or complete occlusion (OKM-C or D). These results are similar to flow diverter studies in general with a meta-analysis by Brinjikji et al. reporting a 6-month complete occlusion rate of 76% [32]. Our findings are also comparable with the Brazilian DED registry which reported a 6-month occlusion rate of 80.7% (113 of 140 aneurysms) with the smaller sac size in their cohort (6.7 ± 5.1 mm) potentially accounting for some of the difference [7]. Direct comparison with the higher rates of near-complete or complete occlusion rate of 89% (79/89) reported by Taschner et al. is difficult due to the longer follow-up time point (median 12.4 ± 5.84 months) [8]. Furthermore, given that we specifically assessed large diameter stents which arguably have their own unique deployment challenges to achieve satisfactory wall apposition and therefore aneurysm healing, the results from our preliminary experience are promising.

Whilst DSA remains the gold standard for the detection of aneurysm recurrence it carries the risk of ionising radia-

tion and stroke which accumulates over time with sequential DSA follow-up. A recent cross-modality meta-analysis concluded that MRA can reliably be used to follow up aneurysms treated with flow diverters with 86% sensitivity and 95% specificity for time-of-flight MRA, and 90% sensitivity and 92% specificity for contrast-enhanced MRA [33]. Although potentially cumbersome, we employ both techniques at our institution as they provide complementary information and the addition of contrast may mitigate potential false positive results on time-of-flight MRA of in-stent thrombosis due to stent-induced signal loss and false positive intra-aneurysmal flow due to T1-weighted hyperintensity of thrombus [11].

Limitations

The study presented is limited by its single-center retrospective design but provides a real-world sense of efficacy, limitations and associated technical challenges when using select 5.5 and 6 mm diameter DED implants. Secondly, the overall sample size was small but is comparable to previous series assessing the feasibility of the device for specific indications [14]. Furthermore, to the best of our knowledge this is the first study specifically reporting on the use of flow diverters >5 mm in diameter. Thirdly, only short-term 6-month MRA follow-up was available for most patients which precludes assessment of medium and long-term efficacy. Fourth, procedural DSA and follow-up MRA data were self-assessed thereby introducing potential bias. Lastly, the absence of follow-up DSA may impair the reliability of comparison with previous studies.

Conclusion

Implantation of large diameter (5.5 and 6 mm) DEDs into capacious cerebral vessels to treat a range of complex aneurysms is safe and technically feasible but may require adjunct stenting to optimize proximal wall apposition. Short-term efficacy of this device subset is comparable to previous DED and other flow diverter studies. Long-term follow-up and comparative studies are required for further assessment.

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Conflict of interest W. Butt, C.-N. Kim, R. Ramaswamy, A. Smith and P. Maliakal declare that they have no competing interests.

References

1. Wakhloo AK, Gounis MJ. Revolution in aneurysm treatment: flow diversion to cure aneurysms: a paradigm shift. Neurosurgery. 2014;61 Suppl 1:111–20.
2. Lieber BB, Gounis MJ. The physics of endoluminal stenting in the treatment of cerebrovascular aneurysms. Neurol Res. 2002;24 Suppl 1:S33–42.
3. Rouchaud A, Ramana C, Brinjikji W, Ding YH, Dai D, Gunderson T, Cebral J, Kallmes DF, Kadirvel R. Wall Apposition Is a Key Factor for Aneurysm Occlusion after Flow Diversion: A Histologic Evaluation in 41 Rabbits. AJNR Am J Neuroradiol. 2016;37:2087–91.
4. Aquarius R, de Korte A, Smits D, Gounis M, Verrijp K, Driessen L, Leenders W, de Vries J. The Importance of Wall Apposition in Flow Diverters. Neurosurgery. 2019;84:804–10.
5. Dandapat S, Mendez-Ruiz A, Martínez-Galdámez M, Macho J, Derakhshani S, Foa Torres G, Pereira VM, Arat A, Wakhloo AK, Ortega-Gutierrez S. Review of current intracranial aneurysm flow diversion technology and clinical use. J Neurointerv Surg. 2021;13:54–62.
6. Kraus B, Goertz L, Turowski B, Borggrefe J, Schlamann M, Dorn F, Kabbasch C. Safety and efficacy of the Derivo Embolization Device for the treatment of unruptured intracranial aneurysms: a multicentric study. J Neurointerv Surg. 2019;11:68–73.
7. Trivelato FP, Abud DG, Ulhôa AC, Waihrich ES, Abud TG, Castro Afonso LH, Nakiri GS, de Castro GD, Parente BSM, Dos Santos Silva R, Manzato LB, Bonadio LE, Viana DC, Vanzin JR, Baccin CE, Rezende MTS. Derivo Embolization Device for the Treatment of Intracranial Aneurysms. Stroke. 2019;50:2351–8.
8. Taschner CA, Stracke CP, Dorn F, Kadziolka KB, Kreiser K, Solymosi L, Pham M, Buhk JH, Turowski B, Reith W, Elsheikh S, Meckel S, Janssen H, Hammer A, Beuing O, Jansen O, Urbach H, Knauth M, Jenkner C, Chapot R. Derivo embolization device in the treatment of unruptured intracranial aneurysms: a prospective multicenter study. J Neurointerv Surg. 2021;13:541–6.
9. Martínez-Galdámez M, Rodríguez C, Hermosín A, Crespo-Vallejo E, Monedero G, Chaviano J, Zheng B. Internal Carotid Artery Reconstruction with a "Mega Flow Diverter": First Experience with the 6×50 mm DERIVO Embolization Device. Neurointervention. 2018;13:133–7.
10. Xiang S, Fan F, Hu P, Yang K, Zhai X, Geng J, Ji Z, Lu J, Zhang H. The sensitivity and specificity of TOF-MRA compared with DSA in the follow-up of treated intracranial aneurysms. J Neurointerv Surg. 2021. https://doi.org/10.1136/neurintsurg-2020-016788.
11. Boddu SR, Tong FC, Dehkharghani S, Dion JE, Saindane AM. Contrast-enhanced time-resolved MRA for follow-up of intracranial aneurysms treated with the pipeline embolization device. AJNR Am J Neuroradiol. 2014;35:2112–8.
12. O'kelly CJ, Krings T, Fiorella D, Marotta TR. A novel grading scale for the angiographic assessment of intracranial aneurysms treated using flow diverting stents. Interv Neuroradiol. 2010;16:133–7.
13. Akgul E, Onan HB, Akpinar S, Balli HT, Aksungur EH. The DERIVO Embolization Device in the Treatment of Intracranial Aneurysms: Short- and Midterm Results. World Neurosurg. 2016;95:229–40.
14. Goertz L, Dorn F, Kraus B, Borggrefe J, Schlamann M, Forbrig R, Turowski B, Kabbasch C. Safety and efficacy of the Derivo Embolization Device for the treatment of ruptured intracranial aneurysms. J Neurointerv Surg. 2019;11:290–5.
15. Kaschner MG, Petridis A, Turowski B. Single-center experience with the new generation Derivo Embolization Device in ruptured dissecting and blister aneurysms. Acta Radiol. 2020;61:37–46.
16. Killer-Oberpfalzer M, Kocer N, Griessenauer CJ, Janssen H, Engelhorn T, Holtmannspötter M, Buhk JH, Finkenzeller T, Fesl G, Tren-

kler J, Reith W, Berlis A, Hausegger K, Augustin M, Islak C, Minnich B, Möhlenbruch M. European Multicenter Study for the Evaluation of a Dual-Layer Flow-Diverting Stent for Treatment of Wide-Neck Intracranial Aneurysms: The European Flow-Redirection Intraluminal Device Study. AJNR Am J Neuroradiol. 2018;39:841–7.
17. Guimaraens L, Vivas E, Saldaña J, Llibre JC, Gil A, Balaguer E, Rodríguez-Campello A, Cuadrado-Godia E, Ois A. Efficacy and safety of the dual-layer flow-diverting stent (FRED) for the treatment of intracranial aneurysms. J Neurointerv Surg. 2020;12:521–5.
18. Pierot L, Spelle L, Berge J, Januel AC, Herbreteau D, Aggour M, Piotin M, Biondi A, Barreau X, Mounayer C, Papagiannaki C, Lejeune JP, Gauvrit JY, Derelle AL, Chabert E, Costalat V. SAFE study (Safety and efficacy Analysis of FRED Embolic device in aneurysm treatment): 1-year clinical and anatomical results. J Neurointerv Surg. 2019;11:184–9.
19. Shankar JJ, Tampieri D, Iancu D, Cortes M, Agid R, Krings T, Wong J, Lavoie P, Ghostine J, Shettar B, Ritchie K, Weill A. SILK flow diverter for complex intracranial aneurysms: a Canadian registry. J Neurointerv Surg. 2016;8:273–8.
20. Berge J, Biondi A, Machi P, Brunel H, Pierot L, Gabrillargues J, Kadziolka K, Barreau X, Dousset V, Bonafé A. Flow-diverter silk stent for the treatment of intracranial aneurysms: 1-year follow-up in a multicenter study. AJNR Am J Neuroradiol. 2012;33:1150–5.
21. Kan P, Sweid A, Srivatsan A, Jabbour P. Expanding Indications for Flow Diverters: Ruptured Aneurysms, Blister Aneurysms, and Dissecting Aneurysms. Neurosurgery. 2020;86(Suppl 1):S96–103.
22. Kallmes DF, Brinjikji W, Cekirge S, Fiorella D, Hanel RA, Jabbour P, Lopes D, Lylyk P, McDougall CG, Siddiqui A. Safety and efficacy of the Pipeline embolization device for treatment of intracranial aneurysms: a pooled analysis of 3 large studies. J Neurosurg. 2017;127:775–80.
23. Chalouhi N, Starke RM, Yang S, Bovenzi CD, Tjoumakaris S, Hasan D, Gonzalez LF, Rosenwasser R, Jabbour P. Extending the indications of flow diversion to small, unruptured, saccular aneurysms of the anterior circulation. Stroke. 2014;45:54–8.
24. Cagnazzo F, Lefevre PH, Derraz I, Dargazanli C, Gascou G, di Carlo DT, Perrini P, Ahmed R, Hak JF, Riquelme C, Bonafe A, Costalat V. Flow-Diversion Treatment for Unruptured Nonsaccular Intracranial Aneurysms of the Posterior and Distal Anterior Circulation: A Meta-Analysis. AJNR Am J Neuroradiol. 2020;41:134–9.
25. Toth G, Bain M, Hussain MS, Moskowitz S, Masaryk T, Rasmussen P, Hui F. Posterior circulation flow diversion: a single-center experience and literature review. J Neurointerv Surg. 2015;7:574–83.
26. Wang CB, Shi WW, Zhang GX, Lu HC, Ma J. Flow diverter treatment of posterior circulation aneurysms. A meta-analysis. Neuroradiology. 2016;58:391–400.
27. Rai AT, Hogg JP, Cline B, Hobbs G. Cerebrovascular geometry in the anterior circulation: an analysis of diameter, length and the vessel taper. J Neurointerv Surg. 2013;5:371–5.
28. Mut F, Cebral JR. Effects of flow-diverting device oversizing on hemodynamics alteration in cerebral aneurysms. AJNR Am J Neuroradiol. 2012;33:2010-6.
29. Zhou G, Su M, Yin YL, Li MH. Complications associated with the use of flow-diverting devices for cerebral aneurysms: a systematic review and meta-analysis. Neurosurg Focus. 2017;42:E17.
30. Bender MT, Jiang B, Campos JK, Lin LM, Beaty N, Vo CD, Zarrin DA, Caplan JM, Huang J, Tamargo RJ, Colby GP, Coon AL. Single-stage flow diversion with adjunctive coiling for cerebral aneurysm: outcomes and technical considerations in 72 cases. J Neurointerv Surg. 2018;10:843–50.
31. Ocal O, Peker A, Balci S, Arat A. Placement of a Stent within a Flow Diverter Improves Aneurysm Occlusion Rates. AJNR Am J Neuroradiol. 2019;40:1932–8.
32. Brinjikji W, Murad MH, Lanzino G, Cloft HJ, Kallmes DF. Endovascular treatment of intracranial aneurysms with flow diverters: a meta-analysis. Stroke. 2013;44:442–7.
33. Ahmed SU, Mocco J, Zhang X, Kelly M, Doshi A, Nael K, De Leacy R. MRA versus DSA for the follow-up imaging of intracranial aneurysms treated using endovascular techniques: a meta-analysis. J Neurointerv Surg. 2019;11:1009–14.

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

αcandis®

ENGINEERING STROKE SOLUTIONS

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.

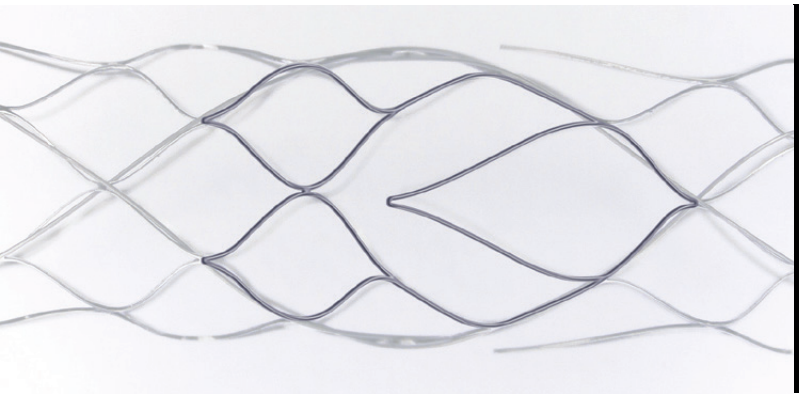
Small closed cells ensure a perfect vessel wall apposition and expansion into the clot. Large open cells with integrated anchoring elements assure efficient clot retention for reliable and atraumatic retrieval even in tortuous vessel anatomies. In combination, these two cell designs build up a functional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

VARIABLE

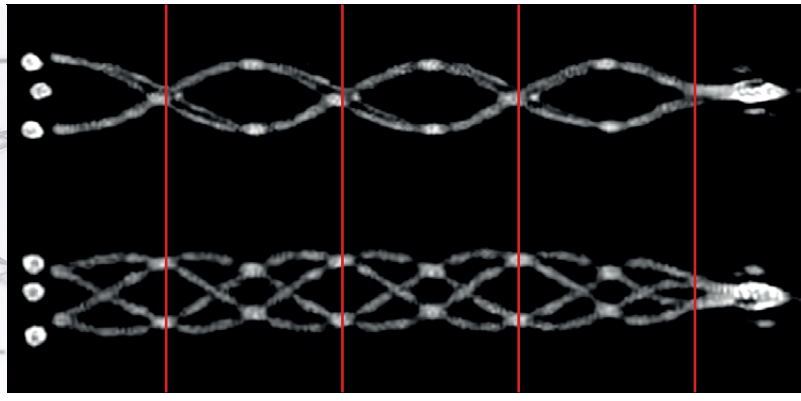
The broad range of sizes enables the treatment of vessel diameters from 1.5 mm up to 5.5 mm.

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



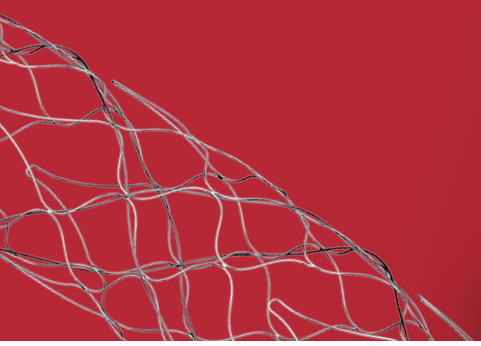
APERIO® Hybrid Thrombectomy Device (6.0 x 50 mm) – functional segments

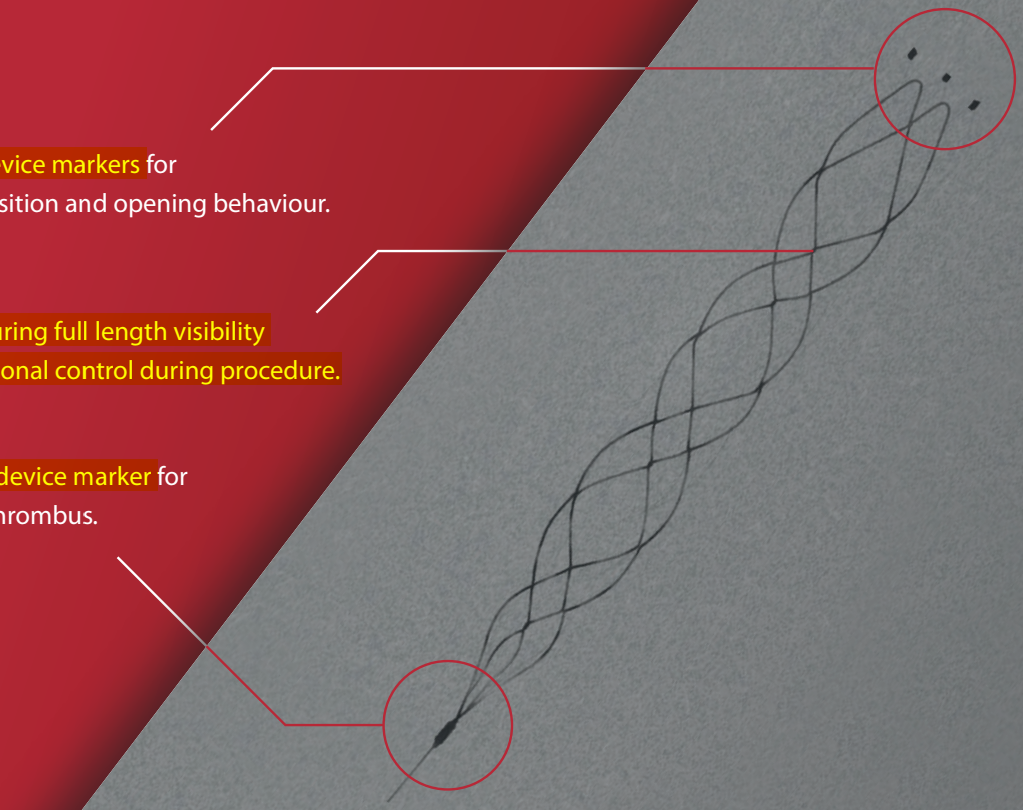
Simple and clear visibility concept for maximum control and assurance

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.





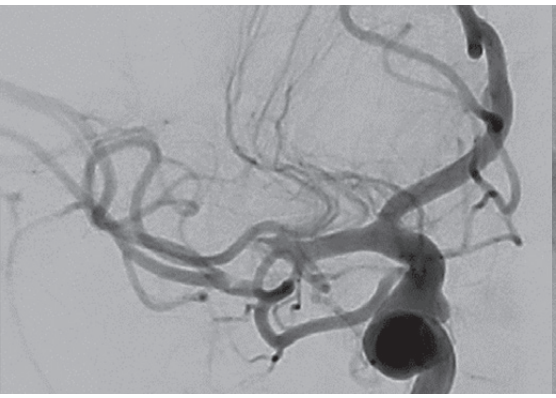
SAFE

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 reliablitity during the procedure.

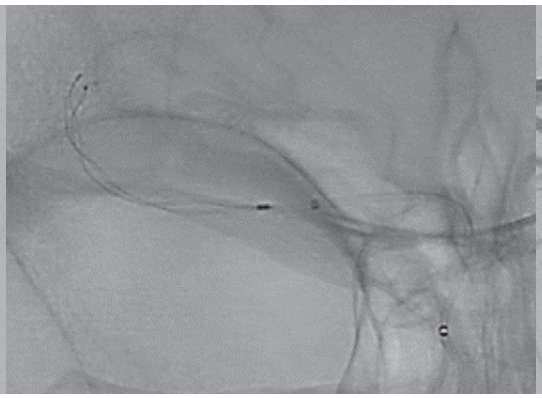
EFFICIENT

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

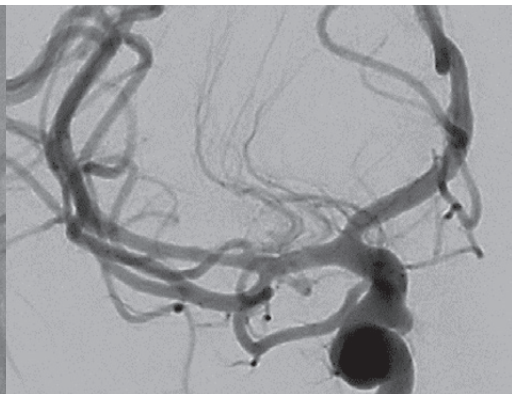
[1] Machi P, Jourdan F, Ambard D, et al Experimental evaluation of stent retrievers' mechanical properties and effectiveness, Journal of NeuroInterventional Surgery 2017;9:257-263.



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

Images are courtesy of Dr. Christoph Kabbasch, University Hospital, Cologne

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°

Distributed by:

acandis®
ENGINEERING STROKE SOLUTIONS

CE 0297

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

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

09-000100 EN 10/2019

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

CE 0297

www.3we.de 2107

09-000114 EN 06/2021

Acandis GmbH | Theodor-Fahrner-Str. 6 | 75177 Pforzheim | Germany
Phone: +49 7231 155 00 0 | info@acandis.com | **www.acandis.com**

acandis®
ENGINEERING STROKE SOLUTIONS

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

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

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

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

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

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

INTRODUCTION

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

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

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

From the [1]Medical Faculty, Department of Diagnostic and Interventional Radiology, University Duesseldorf, Duesseldorf; [2]Institute for Diagnostic and Interventional Radiology, and [3]Center for Neurosurgery, Faculty of Medicine and University Hospital Cologne, University of Cologne, Cologne; [4]Institute of Radiology and Neuroradiology, Evangelisches Krankenhaus, University of Oldenburg; and [5]Research 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.

Citation: World Neurosurg. (2020). https://doi.org/10.1016/j.wneu.2020.05.104

*Journal homepage: **www.journals.elsevier.com/world-neurosurgery***

*Available online: **www.sciencedirect.com***

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.

REFERENCES

1. Turc G, Bhogal P, Fischer U, et al. European Stroke Organisation (ESO)—European Society for Minimally Invasive Neurological Therapy (ESMINT) guidelines on mechanical thrombectomy in acute ischemic stroke [e-pub ahead of print]. *J Neurointerv Surg* https://doi.org/10.1136/neurintsurg-2018-014569, accessed February 16, 2020.

2. Powers WJ, Rabinstein AA, Ackerson T, et al. 2018 Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2018;49:E46-E110.

3. Berkhemer OA, Fransen PSS, Beumer D, et al. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med*. 2015;372:11-20.

4. Campbell BCV, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med*. 2015;372:1009-1018.

5. Goyal M, Demchuk AM, Menon BK, et al. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med*. 2015;372:1019-1030.

6. Saver JL, Goyal M, Bonafe A, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. *N Engl J Med*. 2015;372:2285-2295.

7. Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med*. 2015;372:2296-2306.

8. Riedel CH, Zimmermann P, Jensen-Kondering U, Stingele R, Deuschl G, Jansen O. The importance of size. *Stroke*. 2011;42:1775-1777.

9. Nogueira RG, Jadhav AP, Haussen DC, et al. Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. *N Engl J Med*. 2018;378:11-21.

10. Albers GW, Marks MP, Kemp S, et al. Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. *N Engl J Med*. 2018;378:708-718.

11. Pfaff J, Rohde S, Engelhorn T, Doerfler A, Bendszus M, Möhlenbruch MA. Mechanical thrombectomy using the new Solitaire™ Platinum stent-retriever: reperfusion results, complication rates and early neurological outcome. *Clin Neuroradiol*. 2019;29:311-319.

12. Kabbasch C, Mpotsaris A, Chang D-H, et al. Mechanical thrombectomy with the Trevo ProVue device in ischemic stroke patients: does improved visibility translate into a clinical benefit? *J Neurointerv Surg*. 2016;8:778-782.

13. Kaschner MG, Weiss D, Rubbert C, et al. One-year single-center experience with the Aperio thrombectomy device in large vessel occlusion in the anterior circulation: safety, efficacy, and clinical outcome. *Neurol Sci*. 2019;40:1443-1451.

14. Humphries W, Hoit D, Doss VT, et al. Distal aspiration with retrievable stent assisted thrombectomy for the treatment of acute ischemic stroke. *J Neurointerv Surg*. 2015;7:90-94.

15. Zaidat OO, Castonguay AC, Nogueira RG, et al. TREVO stent-retriever mechanical thrombectomy for acute ischemic stroke secondary to large vessel occlusion registry. *J Neurointerv Surg*. 2018;10:516.

16. Brouwer PA, Yeo LLL, Holmberg A, et al. Thrombectomy using the EmboTrap device: core laboratory-assessed results in 201 consecutive patients in a real-world setting. *J Neurointerv Surg*. 2018;10:964.

17. Kabbasch C, Mpotsaris A, Liebig T, et al. First-in-man procedural experience with the novel EmboTrap® revascularization device for the treatment of ischemic stroke—a European multicenter series. *Clin Neuroradiol*. 2016;26:221-228.

18. Zaidat OO, Bozorgchami H, Ribó M, et al. Primary results of the multicenter ARISE II study (Analysis

of Revascularization in Ischemic Stroke with EmboTrap). *Stroke*. 2018;49:1107-1115.

19. Yi HJ, Lee DH, Kim SU. Effectiveness of Trevo stent retriever in acute ischemic stroke. *Medicine*. 2018;97:e10747.

20. Zaidat OO, Castonguay AC, Gupta R, et al. North American Solitaire Stent Retriever Acute Stroke registry: post-marketing revascularization and clinical outcome results. *J Neurointerv Surg*. 2014;6:584.

21. Singer OC, Haring H-P, Trenkler J, et al. Age dependency of successful recanalization in anterior circulation stroke: the ENDOSTROKE study. *Cerebrovasc Dis*. 2013;36:437-445.

22. Kallenberg K, Solymosi L, Taschner CA, et al. Endovascular stroke therapy with the Aperio thrombectomy device. *J Neurointerv Surg*. 2016;8:834.

23. Berg R van den, Mayer TE. International survey on neuroradiological interventional and therapeutic devices and materials. *Interv Neuroradiol*. 2015;21:646-652.

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.

Received 24 March 2020; accepted 12 May 2020

Citation: World Neurosurg. (2020). https://doi.org/10.1016/j.wneu.2020.05.104

*Journal homepage: **www.journals.elsevier.com/world-neurosurgery***

*Available online: **www.sciencedirect.com***

1878-8750/$ - see front matter

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

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

CE 0297

9-000092 EN 06/2022

Acandis GmbH | Theodor-Fahrner-Str. 6 | 75177 Pforzheim | Germany
Phone: +49 7231 155 00 0 | info@acandis.com | **www.acandis.com**

acandis®
ENGINEERING STROKE SOLUTIONS

www.3we.de 2206

CREDO® Stent | **NeuroSpeed®** 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)

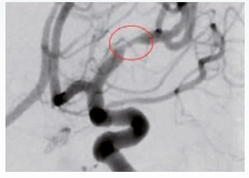
acandis®
ENGINEERING STROKE SOLUTIONS

CREDO® Stent | NeuroSpeed® PTA Balloon Catheter

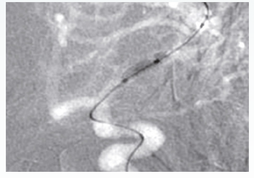
Simply unique

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.

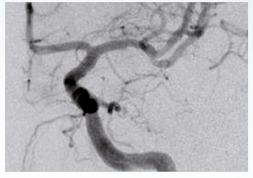
Treatment with NeuroSpeed® PTA Balloon Catheter[1]



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

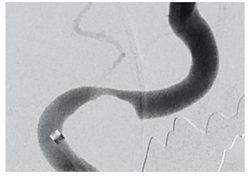


Inflation
NeuroSpeed® PTA Balloon Catheter 2.0 x 8 mm Inflation

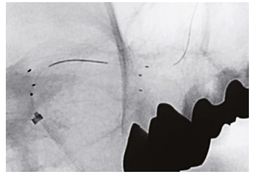


Post-dilation
Final degree of stenosis ~ 10 % post-dilation

Treatment with CREDO® Stent[2]



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.

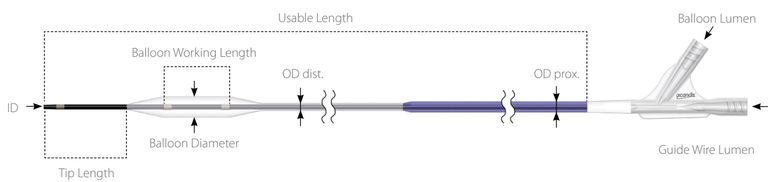
The flexible 10 mm tip, with distal tip X-ray marker, ensures atraumatic access and easy navigation. With a usable length of 150 cm it is possible to reach more distal vessels.

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.

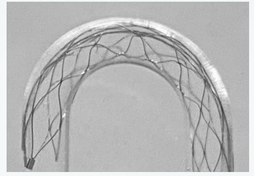
Compared to the ACCLINO® flex plus Stent (for aneurysm bridging) the CREDO® Stent features a higher radial force, which is well-balanced and adjusted for stenosis treatment.

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

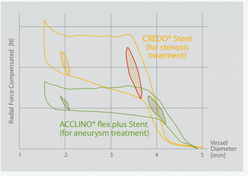
Unique

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

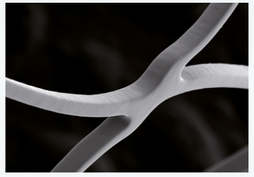
Due to its low profile, the stent can be delivered through the 0.0165" NeuroSpeed® PTA Balloon Catheter.
No exchange of the PTA balloon catheter by a microcatheter is required – minimising treatment time and procedural risks.



Stent flexibility



Radial force comparison



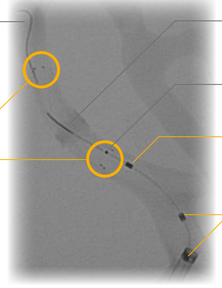
SEM of stent surface

Radiopaque Marker Concept

Distal transport wire marker

Three distal / proximal device markers

for additional control of stent position and opening behaviour



Central transport wire marker

Proximal transport wire marker

Distal tip marker

indicating the distal tip of the NeuroSpeed® PTA Balloon Catheter

Two balloon markers

indicating the nominal length of the balloon

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 Hanning[2]

[1]Department of Intracranial Endovascular Therapy, Alfried Krupp Klinikum Essen, Essen, Germany
[2]Department of Diagnostic and Interventional Neuroradiology, University Medical Center Hamburg-Eppendorf, Hamburg, Germany
[3]Department of Neurology, University Hospital Hamburg-Eppendorf, Hamburg, Germany
[4]Department of Neurology, Klinikum Osnabrück GmbH, Osnabruck, Germany
[5]Department of Radiology, Klinikum Osnabrück GmbH, Osnabruck, 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.

Received 25 March 2019
Revised 23 May 2019
Accepted 27 May 2019
Published Online First 25 June 2019

To cite: Stracke CP, Meyer L, Fiehler J, *et al*. *J NeuroIntervent Surg* 2020;**12**:43–47.

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

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 ≥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 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.

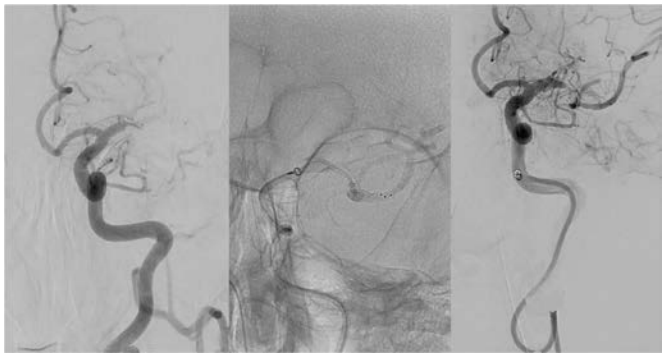


Figure 2 Thrombectomy of M1 occlusion. Stent retriever configuration with proximal narrowing and post-retrieval images indicate a stenosis as the underlying pathology.

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). Th 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

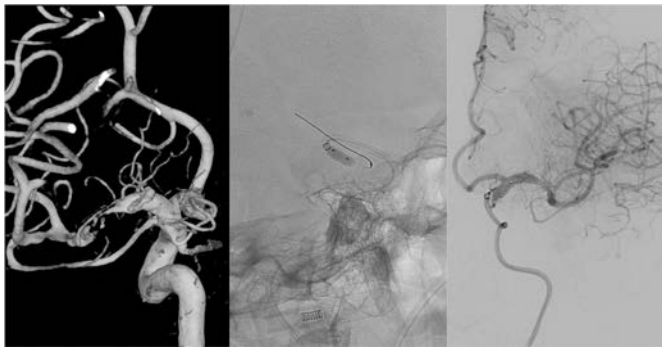


Figure 3 Three-dimensional angiographic reconstruction of the M1 stenosis, percutaneous transluminal angioplasty with the NeuroSpeed catheter, and angiographic result after stent placement.

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 100 mg 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 ≥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 ≤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 ≤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 ≥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

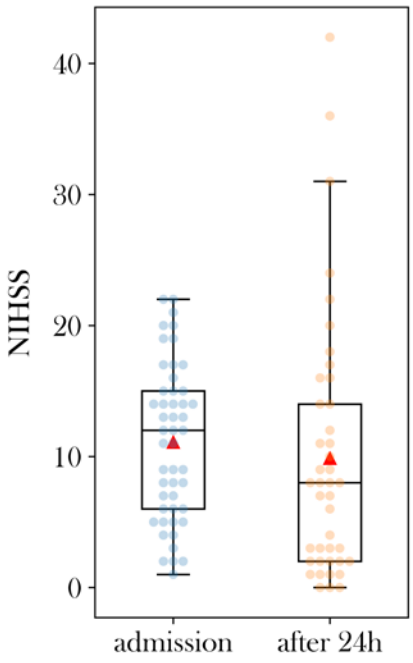


Figure 4 Boxplot of median National Institutes of Health Stroke Scale (NIHSS) score at 24 hours post-intervention compared with admission.

can be mimicked by residual adherent or calcified clots and dissections that are also know 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 ≥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 antithrombotic 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 peri-interventional 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.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests CPS: Consultant and/or proctor for Acandis, Balt, and Rapid Medical. JF: Consultant for Acandis, Boehringer Ingelheim, Codman, Microvention, Sequent, Stryker. Speaker for Bayer Healthcare, Bracco, Covidien/ev3, Penumbra, Philips, Siemens. Grants from Bundesministeriums für Wirtschaft und Energie (BMWi), Bundesministerium für Bildung und Forschung (BMBF), Deutsche Forschungsgemeinschaft (DFG), European Union (EU), Covidien, Stryker (THRILL study), Microvention (ERASER study), Philips. JHB: Received consultancy fees from Acandis, Cerenovus, MicroVention, Stryker. MB: Consultant for Acandis. RC: Consultant and/or proctor for BALT, Stryker, Microvention, Rapid Medical, Siemens Medical Systems. GT: Received personal fees as consultant/lecturer from Acandis, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb/Pfizer, Daichi Sankyo, Stryker, and research grants from Bayer, Federal Ministry for Economic Affairs and Energy (BMWi), Corona-Foundation, German Research Foundation (DFG), Else Kröner-Fresenius Foundation, European Union (Horizon 2020), German Innovation Fund. JR: Consultant for Acandis and Phenox. LUK: Received speaker honoraria from Boehringer Ingelheim, Medtronic and Stryker.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

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

REFERENCES

1 Albers GW, Lansberg MG, Kemp S, *et al*. A multicenter randomized controlled trial of endovascular therapy following imaging evaluation for ischemic stroke (DEFUSE 3). *Int J Stroke* 2017;12:896–905.
2 Goyal M, Menon BK, van Zwam WH, *et al*. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *Lancet* 2016;387:1723–31.
3 Nogueira RG, Jadhav AP, Haussen DC, *et al*. Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. *N Engl J Med* 2018;378:11–21.
4 Al Kasab S, Almadidy Z, Spiotta AM, *et al*. Endovascular treatment for AIS with underlying ICAD. *J Neurointerv Surg* 2017;9:948–51.
5 Jia B, Feng L, Liebeskind DS, *et al*. Mechanical thrombectomy and rescue therapy for intracranial large artery occlusion with underlying atherosclerosis. *J Neurointerv Surg* 2018;10:746–50.
6 Behme D, Weber W, Mpotsaris A. Acute basilar artery occlusion with underlying high-grade basilar artery stenosis: multimodal endovascular therapy in a series of seven patients. *Clin Neuroradiol* 2015;25:267–74.
7 Gao F, Lo WT, Sun X, *et al*. Combined use of mechanical thrombectomy with angioplasty and stenting for acute basilar occlusions with underlying severe intracranial vertebrobasilar stenosis: preliminary experience from a single Chinese center. *AJNR Am J Neuroradiol* 2015;36:1947–52.
8 Dobrocky T, Piechowiak E, Cianfoni A, *et al*. Thrombectomy of calcified emboli in stroke. Does histology of thrombi influence the effectiveness of thrombectomy? *J Neurointerv Surg* 2018;10:345–50.
9 Chang Y, Kim BM, Bang OY, *et al*. Rescue stenting for failed mechanical thrombectomy in acute ischemic stroke: a multicenter experience. *Stroke* 2018;49:958–64.
10 Gruber P, Garcia-Esperon C, Berberat J, *et al*. Neuro Elutax SV drug-eluting balloon versus Wingspan stent system in symptomatic intracranial high-grade stenosis: a single-center experience. *J Neurointerv Surg* 2018;10:e32.
11 Kim GE, Yoon W, Kim SK, *et al*. Incidence and clinical significance of acute reocclusion after emergent angioplasty or stenting for underlying intracranial stenosis in patients with acute stroke. *AJNR Am J Neuroradiol* 2016;37:1690–5.
12 Yoon W, Kim SK, Park MS, *et al*. Endovascular treatment and the outcomes of atherosclerotic intracranial stenosis in patients with hyperacute stroke. *Neurosurgery* 2015;76:680–6.
13 Lee HK, Kwak HS, Chung GH, *et al*. Balloon-expandable stent placement in patients with immediate reocclusion after initial successful thrombolysis of acute middle cerebral arterial obstruction. *Interv Neuroradiol* 2012;18:80–8.
14 Wareham J, Flood R, Phan K, *et al*. A systematic review and meta-analysis of observational evidence for the use of bailout self-expandable stents following failed anterior circulation stroke thrombectomy. *J Neurointerv Surg* 2018:neurintsurg-2018-014459.
15 Chimowitz MI, Lynn MJ, Derdeyn CP, *et al*. Stenting versus aggressive medical therapy for intracranial arterial stenosis. *N Engl J Med* 2011;365:993–1003.
16 Brekenfeld C, Schroth G, Mattle HP, *et al*. Stent placement in acute cerebral artery occlusion: use of a self-expandable intracranial stent for acute stroke treatment. *Stroke* 2009;40:847–52.
17 Zaidat OO, Fitzsimmons B-F, Woodward BK, *et al*. Effect of a balloon-expandable intracranial stent vs medical therapy on risk of stroke in patients with symptomatic intracranial stenosis: the VISSIT randomized clinical trial. *JAMA* 2015;313:1240–8.
18 Mocco J, Hanel RA, Sharma J, *et al*. Use of a vascular reconstruction device to salvage acute ischemic occlusions refractory to traditional endovascular recanalization methods. *J Neurosurg* 2010;112:557–62.
19 Chang Y, Kim BM, Bang OY, *et al*. Rescue stenting for failed mechanical thrombectomy in acute ischemic stroke. *Stroke* 2018;49:958–64.
20 Sato S, Toyoda K, Uehara T, *et al*. Baseline NIH Stroke Scale Score predicting outcome in anterior and posterior circulation strokes. *Neurology* 2008;70(24 Pt 2):2371–7.

21 Schlegel D, Kolb SJ, Luciano JM, *et al*. Utility of the NIH Stroke Scale as a predictor of hospital disposition. *Stroke* 2003;34:134–7.
22 Wouters A, Nysten C, Thijs V, *et al*. Prediction of outcome in patients with acute ischemic stroke based on initial severity and improvement in the first 24 h. *Front Neurol* 2018;9:308.
23 Zinkstok SM, Roos YB, ARTIS investigators. Early administration of aspirin in patients treated with alteplase for acute ischaemic stroke: a randomised controlled trial. *Lancet* 2012;380:731–7.
24 Papanagiotou P, Haussen DC, Turjman F, *et al*. Carotid stenting with antithrombotic agents and intracranial thrombectomy leads to the highest recanalization rate in patients with acute stroke with tandem lesions. *JACC Cardiovasc Interv* 2018;11:1290–9.
25 Thel MC, Califf RM, Tardiff BE, *et al*. Timing of and risk factors for myocardial ischemic events after percutaneous coronary intervention (IMPACT-II). *Am J Cardiol* 2000;85:427–34.
26 Cortese B, Sebik R, Valgimigli M. The conundrum of antithrombotic drugs before, during and after primary PCI. *EuroIntervention* 2014;10:T64–T73.

ORIGINAL RESEARCH

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 outcomewere 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 occured 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 trails.[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 Osnabruck, Osnabruck, 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

Received April 1, 2019; accepted October 29, 2019.

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 (Aerztekammer 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 $\geq$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 Abxicimab (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 noticeablely 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 (19.4)	

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=3.496[29]; 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: 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; $P<0.00$; 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-analysis[32] 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 CLEAN[1] (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 al[33] 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.

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.

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 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

Stracke is a consultant and/or proctor for Acandis, Balt, and Rapid Medical. Fiehler received research support from German Ministry of Science and Education (BMBF), German Ministry of Economy and Innovation (BMWi), German Research Foundation (DFG), European Union (EU), Hamburgische Investitions- und Förderbank (IFB), Medtronic, Microvention, Philips, and Stryker and is a consultant for Acandis, Boehringer Ingelheim, Cerenovus, Covidien, Evasc Neurovascular, MD Clinicals, Medtronic, Medina, Microvention, Penumbra, Route92, Stryker, and Transverse Medical. Götz Thomalla received consulting fees from Acandis, grant support and lecture fees from Bayer, lecture fees from Boehringer Ingelheim, Bristol-Myers Squibb/Pfizer, and Daiichi Sankyo, and consulting fees and lecture fees from Stryker. Krause received speaker honoraria from Boehringer Ingelheim, Medtronic, and Stryker. Rothaupt is a consultant for Acandis and Phenox. Andersson is a consultant for Ablynx, Amnis Therapeutics, Medtronic, Cerenovus/J&J, Rapid Medical, and Anaconda. Yeo has received substantial grant funding from the National Medical Research Council (NMRC), Singapore and substantial support from the ministry of health (MOH), Singapore. Christoph Kabbasch is a proctor for Acandis. Dorn is a consultant for Acandis. Rene Chapot is a consultant and/or proctor for BALT, Stryker, Microvention, Rapid Medical, and Siemens Medical Systems. The remaining authors have no disclosures to report.

References

1. Berkhemer OA, Fransen PS, Beumer D, van den Berg LA, Lingsma HF, Yoo AJ, Schonewille WJ, Vos JA, Nederkoorn PJ, Wermer MJ, van Walderveen MA, Staals J, Hofmeijer J, van Oostayen JA, Lycklama à Nijeholt GJ, Boiten J, Brouwer PA, Emmer BJ, de Bruijn SF, van Dijk LC, Kappelle LJ, Lo RH, van Dijk EJ, de Vries J, de Kort PL, van Rooij WJ, van den Berg JS, van Hasselt BA, Aerden LA, Dallinga RJ, Visser MC, Bot JC, Vroomen PC, Eshghi O, Schreuder TH, Heijboer RJ, Keizer K, Tielbeek AV, den Hertog HM, Gerrits DG, van den Berg-Vos RM, Karas GB, Steyerberg EW, Flach HZ, Marquering HA, Sprengers ME, Jenniskens SF, Beenen LF, van den Berg R, Koudstaal PJ, van Zwam WH, Roos YB, van der Lugt A, van Oostenbrugge RJ, Majoie CB, Dippel DW; MR CLEAN Investigators. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med*. 2015;372:11–20.
2. Dávalos A, Cobo E, Molina CA, Chamorro A, de Miquel MA, Román LS, Serena J, López-Cancio E, Ribó M, Millán M, Urra X, Cardona P, Tomasello A, Castaño C, Blasco J, Aja L, Rubiera M, Gomis M, Renú A, Lara B, Martí-Fàbregas J, Jankowitz B, Cerdà N, Jovin TG; REVASCAT Trial Investigators. Safety and efficacy of thrombectomy in acute ischaemic stroke (REVASCAT): 1-year follow-up of a randomised open-label trial. *Lancet Neurol*. 2017;16:369–376.
3. De Meyer SF, Andersson T, Baxter B, Bendszus M, Brouwer P, Brinjikji W, Campbell BC, Costalat V, Davalos A, Demchuk A, Dippel D, Fiehler J, Fischer U, Gilvarry M, Gounis MJ, Gralla J, Jansen O, Jovin T, Kallmes D, Khatri P, Lees KR, López-Cancio E, Majoie C, Marquering H, Narata AP, Nogueira R, Ringleb P, Siddiqui A, Szikora I, Vale D, von Kummer R, Yoo AJ, Hacke W, Liebeskind DS; Clot Summit Group. Analyses of thrombi in acute ischemic stroke: a consensus statement on current knowledge and future directions. *Int J Stroke*. 2017;12:606–614.
4. Goyal M, Demchuk AM, Menon BK, Eesa M, Rempel JL, Thornton J, Roy D, Jovin TG, Willinsky RA, Sapkota BL, Dowlatshahi D, Frei DF, Kamal NR, Montanera WJ, Poppe AY, Ryckborst KJ, Silver FL, Shuaib A, Tampieri D, Williams D, Bang OY, Baxter BW, Burns PA, Choe H, Heo JH, Holmstedt CA, Jankowitz B, Kelly M, Linares G, Mandzia JL, Shankar J, Sohn SI, Swartz RH, Barber PA, Coutts SB, Smith EE, Morrish WF, Weill A, Subramaniam S, Mitha AP, Wong JH, Lowerison MW, Sajobi TT, Hill MD; ESCAPE Trial Investigators. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med*. 2015;372:1019–1030.
5. Jovin TG, Chamorro A, Cobo E, de Miquel MA, Molina CA, Rovira A, San Roman L, Serena J, Abilleira S, Ribo M, Millan M, Urra X, Cardona P, Lopez-Cancio E, Tomasello A, Castano C, Blasco J, Aja L, Dorado L, Quesada H, Rubiera M, Hernandez-Perez M, Goyal M, Demchuk AM, von Kummer R, Gallofre M, Davalos A; REVASCAT Trial Investigators. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med*. 2015;372:2296–2306.
6. Albers GW, Lansberg MG, Kemp S, Tsai JP, Lavori P, Christensen S, Mlynash M, Kim S, Hamilton S, Yeatts SD, Palesch Y, Bammer R, Broderick J, Marks MP. A multicenter randomized controlled trial of endovascular therapy following imaging evaluation for ischemic stroke (DEFUSE 3). *Int J Stroke*. 2017;12:896–905.
7. Goyal M, Menon BK, van Zwam WH, Dippel DW, Mitchell PJ, Demchuk AM, Davalos A, Majoie CB, van der Lugt A, de Miquel MA, Donnan GA, Roos YB, Bonafe A, Jahan R, Diener HC, van den Berg LA, Levy EI, Berkhemer OA, Pereira VM, Rempel J, Millán M, Davis SM, Roy D, Thornton J, Román LS, Ribó M, Beumer D, Stouch B, Brown S, Campbell BC, van Oostenbrugge RJ, Saver JL, Hill MD, Jovin TG; HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *Lancet*. 2016;387:1723–1731.
8. Nogueira RG, Jadhav AP, Haussen DC, Bonafe A, Budzik RF, Bhuva P, Yavagal DR, Ribo M, Cognard C, Hanel RA, Sila CA, Hassan AE, Millan M, Levy EI, Mitchell P, Chen M, English JD, Shah QA, Silver FL, Pereira VM, Mehta BP, Baxter BW, Abraham MG, Cardona P, Veznedaroglu E, Hellinger FR, Feng L, Kirmani JF, Lopes DK, Jankowitz BT, Frankel MR, Costalat V, Vora NA, Yoo AJ, Malik AM, Furlan AJ, Rubiera M, Aghaebrahim A, Olivot JM, Tekle WG, Shields R, Graves T, Lewis RJ, Smith WS, Liebeskind DS, Saver JL, Jovin TG; DAWN Trial Investigators. Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. *N Engl J Med*. 2018;378:11–21.
9. Saver JL, Goyal M, Bonafe A, Diener HC, Levy EI, Pereira VM, Albers GW, Cognard C, Cohen DJ, Hacke W, Jansen O, Jovin TG, Mattle HP, Nogueira RG, Siddiqui AH, Yavagal DR, Baxter BW, Devlin TG, Lopes DK, Reddy VK, du Mesnil de Rochemont R, Singer OC, Jahan R; SWIFT PRIME Investigators. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. *N Engl J Med*. 2015;372:2285–2295.
10. Behme D, Weber W, Mpotsaris A. Acute basilar artery occlusion with underlying high-grade basilar artery stenosis: multimodal endovascular therapy in a series of seven patients. *Clin Neuroradiol*. 2015;25:267–274.
11. Gao F, Lo WT, Sun X, Mo DP, Ma N, Miao ZR. Combined use of mechanical thrombectomy with angioplasty and stenting for acute basilar occlusions with underlying severe intracranial vertebrobasilar stenosis: preliminary experience from a single Chinese center. *AJNR Am J Neuroradiol*. 2015;36:1947–1952.
12. Wong LK. Global burden of intracranial atherosclerosis. *Int J Stroke*. 2006;1:158–159.
13. Kim GE, Yoon W, Kim SK, Kim BC, Heo TW, Baek BH, Lee YY, Yim NY. Incidence and clinical significance of acute reocclusion after emergent angioplasty or stenting for underlying intracranial stenosis in patients with acute stroke. *AJNR Am J Neuroradiol*. 2016;37:1690–1695.
14. Gruber P, Garcia-Esperon C, Berberat J, Kahles T, Hlavica M, Anon J, Diepers M, Nedeltchev K, Remonda L. Neuro Elutax SV drug-eluting balloon versus

Wingspan stent system in symptomatic intracranial high-grade stenosis: a single-center experience. *J Neurointerv Surg*. 2018;10:e32.

15. Chang Y, Kim BM, Bang OY, Baek JH, Heo JH, Nam HS, Kim YD, Yoo J, Kim DJ, Jeon P, Baik SK, Suh SH, Lee KY, Kwak HS, Roh HG, Lee YJ, Kim SH, Ryu CW, Ihn YK, Kim B, Jeon HJ, Kim JW, Byun JS, Suh S, Park JJ, Lee WJ, Roh J, Shin BS, Kim JM. Rescue stenting for failed mechanical thrombectomy in acute ischemic stroke: a multicenter experience. *Stroke*. 2018;49:958–964.
16. Yoon W, Kim SK, Park MS, Kim BC, Kang HK. Endovascular treatment and the outcomes of atherosclerotic intracranial stenosis in patients with hyperacute stroke. *Neurosurgery*. 2015;76:680–686; discussion, 686.
17. Lee HK, Kwak HS, Chung GH, Hwang SB. Balloon-expandable stent placement in patients with immediate reocclusion after initial successful thrombolysis of acute middle cerebral arterial obstruction. *Interv Neuroradiol*. 2012;18:80–88.
18. Chimowitz MI, Lynn MJ, Derdeyn CP, Turan TN, Fiorella D, Lane BF, Janis LS, Lutsep HL, Barnwell SL, Waters MF, Hoh BL, Hourihane JM, Levy EI, Alexandrov AV, Harrigan MR, Chiu D, Klucznik RP, Clark JM, McDougall CG, Johnson MD, Pride GL Jr, Torbey MT, Zaidat OO, Rumboldt Z, Cloft HJ; SAMMPRIS Trial Investigators. Stenting versus aggressive medical therapy for intracranial arterial stenosis. *N Engl J Med*. 2011;365:993–1003.
19. Zaidat OO, Fitzsimmons BF, Woodward BK, Wang Z, Killer-Oberpfalzer M, Wakhloo A, Gupta R, Kirshner H, Megerian JT, Lesko J, Pitzer P, Ramos J, Castonguay AC, Barnwell S, Smith WS, Gress DR; VISSIT Trial Investigators. Effect of a balloon-expandable intracranial stent vs medical therapy on risk of stroke in patients with symptomatic intracranial stenosis: the VISSIT randomized clinical trial. *JAMA*. 2015;313:1240–1248.
20. Forbrig R, Lockau H, Flottmann F, Boeckh-Behrens T, Kabbasch C, Patzig M, Mpotsaris A, Fiehler J, Liebig T, Thomalla G, Onur OA, Wunderlich S, Kreiser K, Herzberg M, Wollenweber FA, Prothmann S, Dorn F. Intracranial rescue stent angioplasty after stent-retriever thrombectomy: multicenter experience. *Clin Neuroradiol*. 2019;29:445–457.
21. Woo HG, Sunwoo L, Jung C, Kim BJ, Han MK, Bae HJ, Bae YJ, Choi BS, Kim JH. Feasibility of permanent stenting with solitaire FR as a rescue treatment for the reperfusion of acute intracranial artery occlusion. *AJNR Am J Neuroradiol*. 2018;39:331–336.
22. Baek JH, Kim BM, Kim DJ, Heo JH, Nam HS, Yoo J. Stenting as a rescue treatment after failure of mechanical thrombectomy for anterior circulation large artery occlusion. *Stroke*. 2016;47:2360–2363.
23. Cornelissen SA, Andersson T, Holmberg A, Brouwer PA, Soderman M, Bhogal P, Yeo LLL. Intracranial stenting after failure of thrombectomy with the emboTrap((r)) device. *Clin Neuroradiol*. 2019;29:677–683.
24. Jia B, Feng L, Liebeskind DS, Huo X, Gao F, Ma N, Mo D, Liao X, Wang C, Zhao X, Pan Y, Li H, Liu L, Wang Y, Wang Y, Miao ZR; EAST Study Group. Mechanical thrombectomy and rescue therapy for intracranial large artery occlusion with underlying atherosclerosis. *J Neurointerv Surg*. 2018;10:746–750.
25. Zhou T, Li T, Zhu L, Wang M, He Y, Shao Q, Wang Z, Bai W, Liang X. Intracranial stenting as a rescue therapy for acute ischemic stroke after stentriever thrombectomy failure. *World Neurosurg*. 2018;120:e181–e187.
26. Nappini S, Limbucci N, Leone G, Rosi A, Renieri L, Consoli A, Laiso A, Valente I, Rosella F, Rosati R, Mangiafico S. Bail-out intracranial stenting with Solitaire AB device after unsuccessful thrombectomy in acute ischemic stroke of anterior circulation. *J Neuroradiol*. 2019;46:141–147.
27. Fiehler J. Failed thrombectomy in acute ischemic stroke: return of the stent? *Stroke*. 2018;49:811–812.
28. Zaidat OO, Yoo AJ, Khatri P, Tomsick TA, von Kummer R, Saver JL, Marks MP, Prabhakaran S, Kallmes DF, Fitzsimmons BF, Mocco J, Wardlaw JM, Barnwell SL, Jovin TG, Linfante I, Siddiqui AH, Alexander MJ, Hirsch JA, Wintermark M, Albers G, Woo HH, Heck DV, Lev M, Aviv R, Hacke W, Warach S, Broderick J, Derdeyn CP, Furlan A, Nogueira RG, Yavagal DR, Goyal M, Demchuk AM, Bendszus M, Liebeskind DS; Cerebral Angiographic Revascularization Grading (CARG) Collaborators; STIR Revascularization working group; STIR Thrombolysis in Cerebral Infarction (TICI) Task Force. Recommendations on angiographic revascularization grading standards for acute ischemic stroke: a consensus statement. *Stroke*. 2013;44:2650–2663.
29. VanderWeele TJ, Ding P. Sensitivity analysis in observational research: introducing the E-value. *Ann Intern Med*. 2017;167:268–274.
30. Baracchini C, Farina F, Soso M, Viaro F, Favaretto S, Palmieri A, Kulyk C, Ballotta E, Nico L, Cester G, Causin F. Stentriever thrombectomy failure: a challenge in stroke management. *World Neurosurg*. 2017;103:57–64.
31. Liebeskind DS, Bracard S, Guillemin F, Jahan R, Jovin TG, Majoie CB, Mitchell PJ, van der Lugt A, Menon BK, San Román L, Campbell BC, Muir KW, Hill MD, Dippel DW, Saver JL, Demchuk AM, Davalos A, White P, Brown S, Goyal M; HERMES Collaborators. eTICI reperfusion: defining success in endovascular stroke therapy. *J Neurointerv Surg*. 2019;11:433–438.
32. Wareham J, Flood R, Phan K, Crossley R, Mortimer A. A systematic review and meta-analysis of observational evidence for the use of bailout self-expandable stents following failed anterior circulation stroke thrombectomy. *J Neurointerv Surg*. 2019;11:675–682.
33. Behme D, Mpotsaris A, Zeyen P, Psychogios MN, Kowoll A, Maurer CJ, Joachimski F, Liman J, Wasser K, Kabbasch C, Berlis A, Knauth M, Liebig T, Weber W. Emergency stenting of the extracranial internal carotid artery in combination with anterior circulation thrombectomy in acute ischemic stroke: a retrospective multicenter study. *AJNR Am J Neuroradiol*. 2015;36:2340–2345.
34. Fiehler J, Cognard C, Gallitelli M, Jansen O, Kobayashi A, Mattle HP, Muir KW, Mazighi M, Schaller K, Schellinger PD. European recommendations on organisation of interventional care in acute stroke (EROICAS). *Int J Stroke*. 2016;11:701–716.
35. Gory B, Mazighi M, Blanc R, Labreuche J, Piotin M, Turjman F, Lapergue B. Mechanical thrombectomy in basilar artery occlusion: influence of reperfusion on clinical outcome and impact of the first-line strategy (ADAPT vs stent retriever). *J Neurosurg*. 2018;129:1482–1491.
36. Rentzos A, Karlsson JE, Lundqvist C, Rosengren L, Hellstrom M, Wikholm G. Endovascular treatment of acute ischemic stroke in the posterior circulation. *Interv Neuroradiol*. 2018;24:405–411.
37. Flottmann F, Leischner H, Broocks G, Nawabi J, Bernhardt M, Faizy TD, Deb-Chatterji M, Thomalla G, Fiehler J, Brekenfeld C. Recanalization rate per retrieval attempt in mechanical thrombectomy for acute ischemic stroke. *Stroke*. 2018;49:2523–2525.
38. Zaidat OO, Castonguay AC, Linfante I, Gupta R, Martin CO, Holloway WE, Mueller-Kronast N, English JD, Dabus G, Malisch TW, Marden FA, Bozorgchami H, Xavier A, Rai AT, Froehler MT, Badruddin A, Nguyen TN, Taqi MA, Abraham MG, Yoo AJ, Janardhan V, Shaltoni H, Novakovic R, Abou-Chebl A, Chen PR, Britz GW, Sun CJ, Bansal V, Kaushal R, Nanda A, Nogueira RG. First pass effect: a new measure for stroke thrombectomy devices. *Stroke*. 2018;49:660–666.