DERIVO® and DERIVO® mini Embolisation Device
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

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

BROADEST RANGE
DERIVO® Embolisation Device
• For vessel diameters from 2.5 mm up to 6 mm
• Device length from 15 mm to 50 mm
• Deliverable through microcatheters with 0.027” ID

DERIVO® mini Embolisation Device
• Miniaturisation of proven and reliable DERIVO® Embolisation Device
• For vessel diameters from 1.5 mm to 3.5 mm
• Device length from 15 to 25 mm
• Deliverable through microcatheters with 0.021” ID

1 results from in-vitro testings
01 | SCIENTIFIC PAPERS

- The DERIVO® Embolisation Device in the treatment of intracranial aneurysms: short-and midterm results
  E. Akgul, H. Onan, S. Akpınar, H. Balli, E. Aksungur  
- Internal Carotid Artery Reconstruction with a "Mega Flow Diverter": First Experience with the 6x50 mm DERIVO® Embolisation Device
- Improved Occlusion Rate of Intracranial Aneurysms Treated with the DERIVO® Embolisation Device: One-Year Clinical and Angiographic Follow-Up in a Multicenter Study
  L. Goertz, F. Dorn, B. Kraus, J. Borggrefe, R. Forbrig, M. Schlamann, T. Liebig, B. Turowski, C. Kabbasch  
- Safety and efficacy of the DERIVO® Embolisation Device for the treatment of ruptured intracranial aneurysms
  L. Goertz, F. Dorn, B. Kraus, J. Borggrefe, M. Schlamann, R. Forbrig, B. Turowski, C. Kabbasch  
- Safety and efficacy of the DERIVO® Embolisation Device for the treatment of unruptured intracranial aneurysms: A Multicentric Study
  B. Kraus, L. Goertz, B. Turowski, J. Borggrefe, M. Schlamann, F. Dorn, C. Kabbasch

02 | CLINICAL STUDIES

- Brazilian Registry
  DERIVO® Embolisation Device for the Treatment of Intracranial Aneurysms: A Multicenter Study of 183 Aneurysms
  Trivelato, Felipe Padovani, et al.  
- Turkish Registry
  The Experience of the DERIVO® Embolisation Device in Intracranial Aneurysms.
  E. Daglioglu, I. Akman, V. Acik, F. Alagoz, B. Sayin, O. Uckun, A. Belen, A. Arat  
- German DERIVO® PMCF Study
  PI: Prof. Dr. Christian Taschner, University Hospital Freiburg, Germany  
- Italian Registro DERIVO®
  PI: Dr. Luca Valvassori, San Gerardo Hospital Monza, Italy

03 | CASE REPORT

- Treatment of an unruptured A1 aneurysm with DERIVO® mini Embolisation Device / First in men
  By Prof. Dr. Marios Psychogios, University Hospital Basel, Switzerland
The DERIVO® Embolisation Device (DED) is a new nitinol flow diverter stent manufactured for the treatment of intracranial aneurysms. In this study, we evaluated the safety and efficacy of the DED in the treatment of intracranial aneurysms and present the short- and midterm results.

Objective

The DERIVO® Embolisation Device (DED) is a new nitinol flow diverter stent manufactured for the treatment of intracranial aneurysms. In this study, we evaluated the safety and efficacy of the DED in the treatment of intracranial aneurysms and present the short- and midterm results.

Methods

We treated 34 aneurysms using 26 devices in 24 patients with wide-necked, mostly medium-sized, and fusiform aneurysms. Fourteen of the patients included in the study were women and the other 10 were men. Headache was the most frequent symptom. Although 31 (91.2 %) aneurysms were in the anterior circulation, 3 (8.8 %) were in the posterior. Intracranial stent medication was accomplished in all patients. All patients were evaluated 1 day later for any ischemic lesion with diffusion-weighted imaging. The first and second follow-up angiograms were planned to be performed after 3 and 9 months.

Results

In all patients, the treatment was successful. No hemorrhagic complication was seen on computed tomography scan performed immediately after the procedure. All patients were discharged without any neurologic deficit. Although 20 (71.4 %) of 28 aneurysms in 20 patients were totally closed on the 3-month follow-up angiogram, 14 (77.8 %) of 18 aneurysms in 9 patients were totally closed on the 9-month follow-up. General morbidity was 8.4 %, and mortality was 4.3 %.

Conclusions

The DED seems effective and safe in the treatment of different kinds of intracranial aneurysms.

Internal Carotid Artery Reconstruction with a ‘Mega Flow Diverter': First Experience with the 6×50 mm DERIVO® Embolisation Device.

Endoluminal reconstruction with a flow diverter device has emerged as a viable and often preferable alternative to traditional techniques for the treatment of intracranial aneurysms. Precise measurement and device selection are mandatory steps when considering flow diverters usage in order to avoid potential complications. In this sense, incomplete wall-apposition has been described as a predictive factor for immediate in-stent and delayed thrombosis after stent use.

One significant usage limitation of flow diverter devices is the parent artery diameter, since the maximum opening of the sizes available are recommended for vessel diameters between 5.2–5.75 mm. Here we present the first clinical use of the largest flow diverter available, the 6×50 mm DERIVO® Embolisation Device (Acandis GmbH & Co. KG, Pforzheim, Germany), into the arterial circulation for a cervical internal carotid artery endovascular reconstruction.

This is a new device for large or fusiform aneurysms requiring flow diversion, especially located in the vertebrobasilar system or extracranial segments.
Improved Occlusion Rate of Intracranial Aneurysms Treated with the DERIVO® Embolisation Device: One-Year Clinical and Angiographic Follow-Up in a Multicenter Study.

L. Goertz, F. Dorn, B. Kraus, J. Borggrefe, R. Forbrig, M. Schlamann, T. Liebig, B. Turowski, C. Kabbasch
In: World Neurosurgery, 2019, 126 (June), pp. 1505-1509

Abstract
Objective
The DERIVO® Embolisation Device (DED) is a novel flow-diverter stent consisting of a flexible structure and a surface modification that aims to reduce thrombogenicity. Here, we report 1-year clinical and angiographic follow-up results of the second-generation DED for the treatment of intracranial aneurysms.

Methods
This is a retrospective study of 59 consecutive patients (mean age: 53 years, 81% women) treated with the DED for 59 aneurysms (mean size: 8.1 mm) between November 2015 and February 2018 at three German tertiary care centers. We evaluated the rate of ischemic stroke, functional outcome, and angiographic results during a 1-year follow-up period.

Results
Deployment of the DED was successful in all cases. Adverse events were observed in 6 procedures (10.2%), of which 2 were symptomatic (3.4%). No delayed ischemic or hemorrhagic events occurred during the 1-year follow-up and there were no deaths. Permanent morbidity due to in-stent thrombosis and consecutive ischemic stroke occurred in 1 patient (1.7%). Complete (O’Kelly-Marotta grading scale D) and favorable (O’Kelly-Marotta grading scale C+D) aneurysm occlusion was obtained in 70.5% (31/44) and 88.7% (39/44) at 6 months and 82.8% (24/29) and 100% (29/29) at 12 months, respectively.

Conclusions
Our results demonstrate that treatment of intracranial aneurysms with the DED is associated with low rates of ischemic complications and adequate aneurysm occlusion at 1-year follow-up.
"Safety and efficacy of the DERIVO® Embolisation Device for the treatment of ruptured intracranial aneurysms."

L. Goertz, F. Dorn, B. Kraus, J. Borggrefe, M. Schlamann, R. Forbrig, B. Turowski, C. Kabbasch

Abstract

Background and Purpose
The DERIVO® Embolisation Device (DED) is a novel flow diverter with advanced X-ray visibility, potentially lower thrombogenicity, and an improved delivery system.

Objective
To evaluate the safety and efficacy of the DED for emergency treatment of ruptured intracranial aneurysms.

Methods
Between February 2016 and March 2018, 10 patients (median age 54.5 years, seven women) with 11 aneurysms were treated with the DED at three neurovascular centers. Procedural details, complications, morbidity, and aneurysm occlusion (O'Kelly-Marotta scale, OKM) were retrospectively reviewed.

Results
Among 11 aneurysms treated, there were nine anterior circulation and two posterior circulation aneurysms. Aneurysm morphology was saccular in four cases, dissecting in three, blister-like in three, and fusiform in one. In each case, a single DED was implanted and deployment was technically successful without exception.

Adjunctive coiling was performed in two aneurysms. We observed one in-stent thrombosis, presumably due to low response to clopidogrel 4 days after the procedure, which remained with a mild hemiparesis after aspiration thrombectomy. No further thromboembolic or hemorrhagic events occurred. Favorable outcome (modified Rankin scale score ≤2) at last follow-up was achieved in all patients. Among 10 aneurysms available for angiographic follow-up, complete aneurysm occlusion (OKM D) was obtained in nine cases (90.0 %).

Conclusions
In this pilot study, endovascular treatment of ruptured intracranial aneurysms with the DED was feasible and not associated with any incidence of rebleeding. Larger series with longer follow-up are warranted to reach a definite conclusion about this device.
Abstract

Background and Purpose
The DERIVO® Embolisation Device (DED) is a novel flow diverter stent that provides increased x-ray visibility, an improved delivery system, and potentially reduced thrombogenicity. The objective of this study was to evaluate the early safety and efficacy of the second-generation DED.

Methods
We retrospectively analyzed all patients with unruptured intracranial aneurysms (UIAs) treated with the DED between November 2015 and December 2017 in three German tertiary care centers. Procedural details, complications, and morbidity within 30 days after treatment, as well as the aneurysm occlusion rates after 6 months (O’Kelly–Marotta scale, OKM), were evaluated.

Results
Implantation of the DED was attempted in 42 patients with 42 aneurysms. All procedures were technically successful. Multiple DEDs were used in three aneurysms (7.2 %) and adjunctive coiling in 11 (26.2 %). Procedure-related complications occurred in four cases (9.5 %) including three thromboembolic events and one aneurysm perforation.

The morbidity rate was 2.4 % and there was no mortality. One patient suffered an ischemic stroke with persistent aphasia at 30-day follow-up due to a thromboembolic infarct (modified Rankin Scale score 1). Among 33 patients (78.6 %) available for angiographic follow-up, complete (OKM D) and favorable (OKM C+D) aneurysm occlusion was obtained in 72.7 % (24/33) and 87.9 % (29/33), respectively.

Conclusions
Endovascular treatment of UIAs with the DED is associated with high procedural safety and adequate occlusion rates. Examinations at 1- and 2-year follow-up will provide data on the long-term safety and angiographic outcomes of this device.
Flow diverter technology improvements are necessary to provide safe and good results and enable the treatment of a larger variety of aneurysms. We report a nationwide experience with the DERIVO® Embolisation Device in the treatment of intracranial aneurysms.

At 6 months, 113 of 140 (80.7 %) aneurysms met the study’s primary end point, and 74 of 83 (89 %) met the study’s primary end point at 12 months. Saccular morphology of the aneurysm (odds ratio, 5.66; 95 % CI, 1.01–31.77) and the presence of a branch arising from the sac (odds ratio, 6.36; 95 % CI, 2.11–22.36) predicted persistence. A long duration of follow-up (odds ratio, 0.86; 95 % CI, 0.78–0.95) predicted total occlusion. Of the 146 enrolled patients, 138 (94.5 %) were treated without serious adverse events during follow-up. In the multivariable analysis, aneurysms located at a sidewall were less likely to experience these events than those located at bifurcations (odds ratio, 0.07; 95 % CI, 0.01–0.51).

Conclusions
The DERIVO® Embolisation Device is a safe and effective treatment for intracranial aneurysms.
Turkish Registry

- **Study Type:** retrospective, multicentric
- **Follow up:** 1-3 and 6 months
- **Enrolment:** 146 patients enrolled, 182 aneurysms treated with DERIVO® Embolisation Device
- **Occlusion:**
  - After 7 months: 78.7%
- **Morbidity:** 3.4%, **Mortality:** 2.7%

The Experience of the DERIVO® Embolisation Device in Intracranial Aneurysms.

**E. Daglioglu, I. Akmangit, V. Acik, F. Alagoz, B. Sayin, O. Uckun, A. Belen, A. Arat**
In: Turkish Neurosurgery, 2019, 27 (March), pp. 1-8

**Objective**
To investigate the safety and efficacy of DERIVO® Embolisation Device (DED), a new-generation flow diverter designed to treat cerebrovascular aneurysms, and its long-term clinical outcomes.

**Material and Methods**
In total, 146 patients with 182 aneurysms were treated with DED. The mean age of the participants was 51.5 years; among them, 46 (31.5 %) presented with acute subarachnoid haemorrhage. The mean aneurysm size was 8.3 mm, and 12 aneurysms were involved the vertebrobasilar system. Ophthalmic aneurysms account for most internal carotid artery (ICA) aneurysms.

**Results**
The Glasgow Coma Scale (GCS) score of 12 patients was <15. DED was associated with a mortality rate of 2.7% and permanent morbidity rate of 3.4%, and a complete aneurysm occlusion rate was achieved in 78.7% of cases after 7.02 months.

**Conclusions**
The DED device is a new-generation flow diverter with excellent opening behaviour and navigational benefits. Our results indicated a safe aneurysm occlusion with optimum morbidity and mortality values despite the fact that almost one-third of the patients presented with subarachnoid haemorrhage.

German DERIVO® PMCF Study

**PI:** Prof. Dr. Christian Taschner, University hospital Freiburg, Germany

- **Study Type:** observational, prospective and multicentric
- **Participants:** 12 participating centres in Germany and Poland
- **PI:** Prof. Taschner, Universitätsklinik Freiburg
- **Estimated Enrolment:** 100 patients, with intracranial aneurysms and treatment with DERIVO® Embolisation Device
- **Follow up:** 12 months
- **Final Assessment:** at the end of 2019

Italian Registro DERIVO®

**PI:** Dr. Luca Valvassori, San Gerardo Hospital Monza, Italy

- **Study Type:** observational, multicentric, independent
- **PI:** Luca Valvassori
- **Patients:** all the cerebral aneurysms treated with DERIVO® during enrolment period
- **Enrolment period:** 14 months (2016-2017)
- **Objective:** Safety and efficacy of DERIVO® Embolisation Device
- **Follow up:** 12 months
- **Results:** expected to be published
Treatment of an unruptured A1 aneurysm with DERIVO® mini Embolisation Device.

First in men

Prof. Dr. Marios Psychogios, University hospital Basel, Switzerland
September/2019

Patient History

> Female, 72 years old
> Unruptured A1 aneurysm right near to the internal carotid artery (ICA), not treated before.
> Aneurysm neck: 6 mm
> Vessel diameter (dist./prox.): 1.8/2.0 mm

Pre Intervenotional Diagnostic

1 Unruptured A1 aneurysm (frontal view) 2 Unruptured A1 aneurysm (lateral view)

Patient with unruptured A1 aneurysm near to the internal carotid artery (ICA), short proximal landing zone

Treatment Information

Before treatment a 3D sizing simulation and training with a patient-specific silicone model were performed in order to support the optimal size selection of DERIVO® mini Embolisation Device for safe and efficient placement as well as best flow diversion properties.

For treatment it was initially planned and tried to pass through the ACOM from contralateral side in order to absolutely control the proximal landing zone but, as the ACOM was very thin it was settled for an ipsilateral navigation.

With the help of the previous 3D sizing simulations and patient-specific silicone model it was able to control the distal and proximal landing zones.

Used Devices

• DERIVO® mini Embolisation Device 2.5 mm x 15 mm
• NeuroSlider® 21 Microcatheter DLC

Patient was released on day two without any symptoms. Looking forward to three months FD CTA.
After Deployment

3 DERIVO® mini Embolisation Device – semi-deployed (frontal view)
4 DERIVO® mini Embolisation Device – semi-deployed (lateral view)

Clear visibility of the three deployed distal radiopaque markers and of contour and shape of the DERIVO® mini Embolisation Device

Post Interventional Diagnostic

5 Fully deployed DERIVO® mini Embolisation Device with transport wire inside (point of no return)
6 3D Sizing simulation with DERIVO® mini Embolisation Device 2.5 mm x 15 mm
7 Fully deployed DERIVO® mini Embolisation Device (Dyna CT)

Evaluation of the Device

• Smooth delivery and easy deployment, re-capture and re-deployment
• Perfect control and visibility
• Excellent performance – comparable to proven DERIVO® Embolisation Device