FRED™ X™

Flow Diverter

CASE REPORT

WITH TWO YEAR FOLLOW UP IMAGING

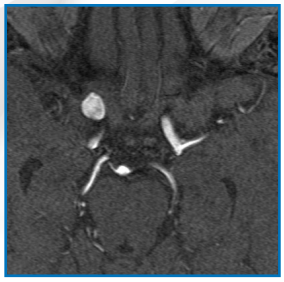
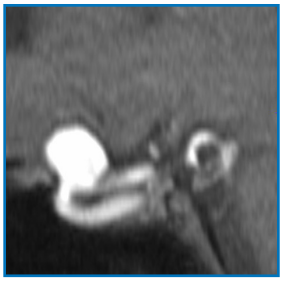
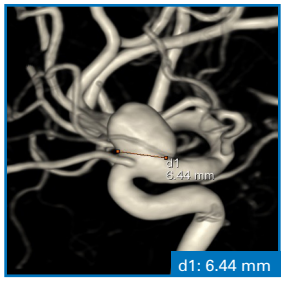
University Hospital Heidelberg | Dr. Markus Möhlenbruch

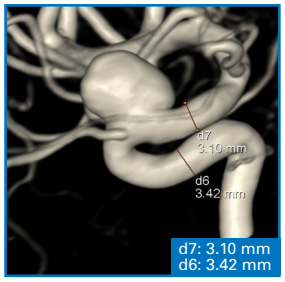
Case Overview

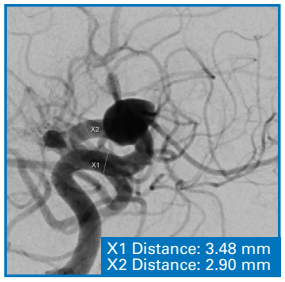
The case details below are courtesy of Dr. Markus Möhlenbruch and his team at University Hospital Heidelberg in Germany*

OPHTHALMIC ICA ANEURYSM

A 63-year-old female presented with a right ophthalmic ICA aneurysm.



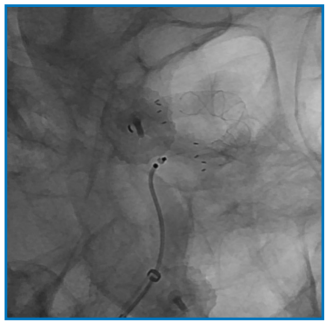
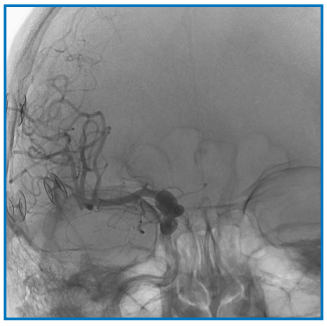
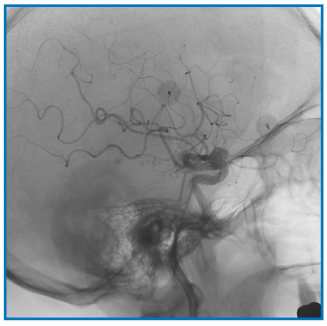


Pre-procedural images and measurements are shown above. A FRED X 4 x 18/12mm device was chosen to ensure ample wall apposition (~0.5mm greater than the largest vessel segment).

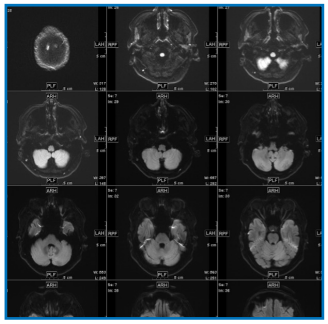
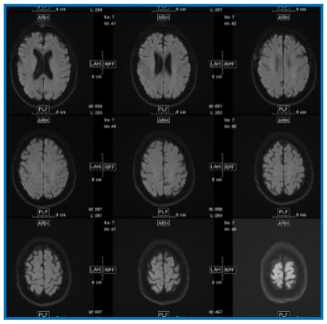
INTRA-PROCEDURAL DETAILS

Dr. Möhlenbruch used an access setup of Sofia 6F and Headway 27 catheters.

The images below show the FRED X device immediately post deployment. Dr. Möhlenbruch used a two-handed deployment technique where he predominantly unsheathed the microcatheter while holding steady forward pressure on the device delivery wire. Dr. Möhlenbruch was careful to keep the system centered in the vessel throughout the deployment.

Immediately post deployment, the device looked completely open and well apposed to the vessel wall. Dr. Möhlenbruch removed the delivery wire slowly and carefully to ensure that the proximal finished ends did not get caught on the distal tip of the delivery wire.

There were no DWI lesions present immediately post deployment.

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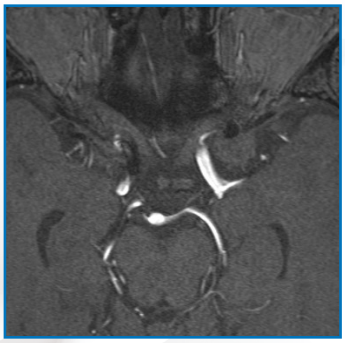
*THIS IS A CASE STUDY EXAMPLE. INDIVIDUAL PATIENT RESULTS MAY VARY.

DUAL ANTIPLATELET (DAPT) REGIMEN

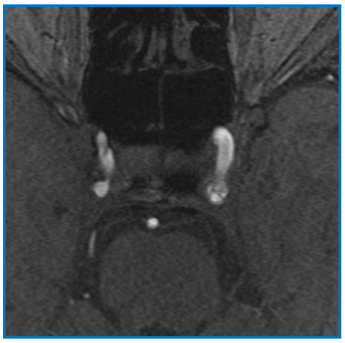
Dr. Möhlenbruch prescribed a DAPT regimen of Aspirin (on-going) and Clopidogrel (for 3 months).

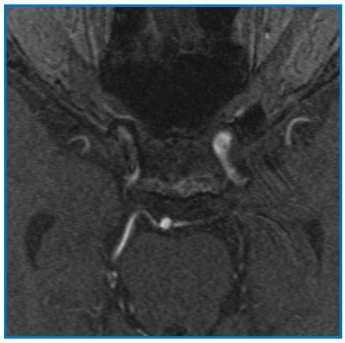
3 MONTH FOLLOW-UP



At three-month follow-up, the aneurysm is partially occluded and the device remains fully open, with no complications.

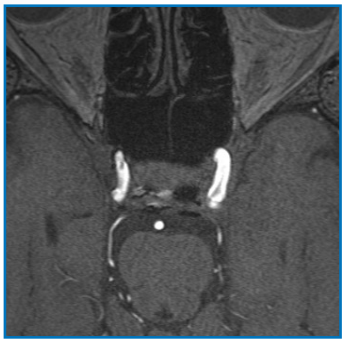
6 MONTH FOLLOW-UP

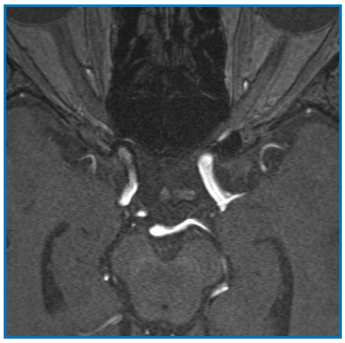




At six-month follow-up, there is complete aneurysm occlusion.

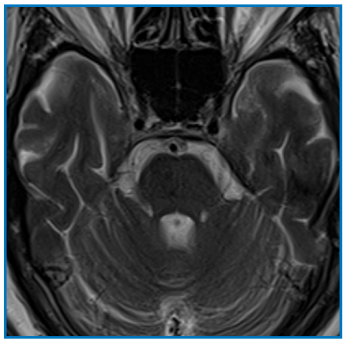
12 MONTH FOLLOW-UP





Twelve-month follow-up continues to show complete aneurysm occlusion.

24 MONTH FOLLOW-UP



At twenty-four-month follow-up, results are consistent and the anuerysm continues to be completely occluded.

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For more information, contact your local MicroVention sales representative or visit our website. **www.fred-x.com**

FRED™ X System Product Indications, U.S.: The Flow Re-Direction Endoluminal Device (FRED) System is indicated for use in the internal carotid artery from the petrous segment to the terminus for the endovascular treatment of adult patients (22 years of age or older) with wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm.

FRED™ X System Product Indications, EMEA: The FRED system is intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED system may also be used with embolic coils for the treatment of intracranial neurovascular lesions.

HEADWAY™ Microcatheter Indications for Use: The HEADWAY Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

SOFIA™ EX Catheter Indications for Use: The SOFIA EX Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA EX Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA EX Catheter is not intended for use in coronary arteries.

SOFIA™ Catheter Indications for Use: The SOFIA Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA Catheter can be used to facilitate introduction of diagnostic or therapeutic agents. The SOFIA Catheter is not intended for use in coronary arteries. Moreover, the SOFIA Catheter is intended for use in removal/aspiration of emboli and thrombi from selected blood vessels in the arterial system, including the peripheral and neuro vasculatures.

For Healthcare Professional Use Only

RX Only: Federal (FDA) law restricts this device to sale by or on the order of a physician.

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