Flow Re-Direction Endoluminal Device

What is it? The FRED® System MicroVention double-layered flow diverter uses a permanent metal wire stent to provide support for a weakened area in a blood vessel in the brain that has bulged or ballooned into a brain aneurysm. The FRED® System blocks off blood flow to the aneurysm.

<html><iframe width="560" height="315" src="https://www.youtube.com/embed/LKEDhIp1sNg" title="YouTube video player" frameborder="0" allow="accelerometer; autoplay; clipboard-write; encrypted-media; gyroscope; picture-in-picture; web-share" allowfullscreen></iframe></html>

How does it work? The tight wire mesh stent of the FRED® device is intended to reduce or stop blood flow into the aneurysm by diverting blood to flow past the aneurysm site. The stent is delivered to the target area using minimally invasive surgery through the femoral artery in the groin, and then is threaded via guidewires through blood vessels until it reaches the target artery.

When is it used? The FRED® System is indicated for the treatment of brain aneurysms in patients 22 years of age and older when the aneurysm is bulging on one side (saccular) or both sides of the vessel wall (fusiform). The device can be used when there is a wide entry point to the aneurysm area (a "neck" width 4 mm or wider or dome-to-neck ratio less than 2 mm) in certain regions of the internal carotid artery, which supplies blood to the brain, when the carotid artery's diameter is between 2 mm and 5 mm.

What will it accomplish? The FRED® System is designed to prevent an existing aneurysm from getting bigger by stopping blood flow into the aneurysm. It also relieves the pressure that blood flow puts on the weakened blood vessel wall. The support of the FRED® stent in the blood vessel gives the damaged vessel the opportunity to repair itself around the stent and across the neck of the aneurysm (endothelialization) over time. Sometimes, the stent allows for closing off the aneurysm from blood flow (occlusion).

In a clinical study, 76 out of 135 (56.7%) patients within the FDA-approved indicated use population who were treated with the device had complete occlusion of the aneurysm within one year of the procedure.

When should it not be used? The FRED® System should not be used in patients who:

Are unable to take blood thinners (anti-coagulants or anti-platelet therapies) or who cannot take clot-busting (thrombolytic) drugs. Have a known metal hypersensitivity to metal jewelry or metals such as nickel-titanium. Have blood vessels or other anatomy that prevent the device system from passing through. Have an active bacterial infection. Already have a stent in place for the brain aneurysm. Have blood vessels that are larger or smaller than the size indicated for using the system. Have not received drugs that prevent clotting before the procedure (anti-platelet agents).

The purpose of this study was to report the author's experiences in treating large (10-25 mm) and giant (>25 mm) intracranial aneurysms (IAs) using a single Flow Re-direction Endoluminal Device (FRED) without assistant coiling, with a focus on procedure-related complications.

Materials and methods: A total of 33 patients who were treated with FRED between January 2018 and July 2020 were retrospectively reviewed. The timing of procedure-related complications was chronologically categorized as acute (within 7 days), subacute (8 to 21 days), and delayed (after 21 days) periods. Follow-up angiography was performed at 2 to 27 months (mean 9.7 months), and clinical follow-up was performed at 1 to 31 months (mean 14.1 months) in all patients.

Results: Six (18.2%) patients experienced procedure-related complications, including 2 (6.1%) in acute period, 1 (3.0%) in subacute period, and 3 (9.1%) in delayed period. Thromboembolic complications occurred in 5 (15.2%) patients and hemorrhagic complications in 1 (3.0%). Permanent morbidity and mortality rates were 3.0% each. Non-internal carotid artery (ICA) location of IAs (odds ratio 6.532; 95% confidence interval, 1.335-17.816; p=0.034) was the only independent risk factor for procedure-related complications on multivariate logistic regression analysis.

Conclusion: The procedure-related complication rate was 18.2% in this study. Procedure-related complications might increase when treating large and giant IAs located on a non-ICA, especially on the middle cerebral artery. Therefore, it may be suggested that neurointerventionists and endovascular neurosurgeons should pay attention to the location of IAs when treating large and giant IAs with a single FRED [1)].

The intracranial aneurysm treatment has significantly evolved over the last decade with the advancement in endovascular techniques and devices. Flow diverters are the latest in the armamentarium for vascular reconstruction, aneurysm exclusion, and preservation of branch vessels. The possibility of treating various types of intracranial aneurysms, including those previously considered untreatable, has represented a new paradigm in the neurovascular era.

Areas covered: This paper describes in detail the current status in the use of new generation double-layered Flow Redirection Endoluminal Device (FRED; MicroVention Terumo, Tustin, California). For this report, we reviewed the published literature for properties of the currently available FRED devices regarding safety, efficacy, and potential risks and complications associated with their use.

Expert opinion: FRED and FRED Jr are the new flow diverter devices for which the existing data suggest that they are safe and efficient in addressing the treatment issues with giant, wide-necked saccular and fusiform aneurysms and those with perforators and branch vessels at high risk of occlusion with surgical clipping. Evidence is mounting on their long-term durability which increases the confidence of both the endovascular surgeon in prescribing and the patient side in accepting these FDs as treatment option for intracranial aneurysms [2)].

Between February 2012 and May 2013, 33 patients with 37 aneurysms (35 unruptured and 2 previously ruptured aneurysms) were treated with the FRED. Clinical and radiological data of the patients were retrospectively reviewed.

Results: In all patients only 1 device was used without any additional device or material, such as a stent or coil. All procedures were successfully performed. The procedural complication rate was 3% (1 of 33). Thirty patients underwent clinical and radiological follow-up. During the follow-up period, changes in stent morphology, such as “fish mouth” and “foreshortening” phenomena, occurred in 5 patients. The mortality and permanent morbidity rates were 0%. The complete occlusion rates were 32% (6 of 19) at 0-1 month, 67% (8 of 12) at 2-3 months, 80% (4 of 5) at 4-6 months, and 100% (8 of

8) at 7-12 months. The rates for some aneurysms were assessed at more than one time point.

Conclusions: The FRED has an ability to serve neurointerventionalists in the treatment of cerebral aneurysms with its different technical advantages. The occlusion rates with FRED are similar to those with other FD devices. However, these short-term results need to be confirmed with mid- and long-term follow-up results of multicenter large series [3].

1)
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2)
Pavlov O, Shrivastava A, Moscote-Salazar LR, Mishra R, Gupta A, Agrawal A. The new generation double layered flow diverters for endovascular treatment of intracranial aneurysms: current status of ongoing clinical uses. Expert Rev Med Devices. 2021 Jan 27:1-6. doi: 10.1080/17434440.2021.1879636. Epub ahead of print. PMID: 33476247.
3)
Kocer N, Islak C, Kizilkilic O, Kocak B, Saglam M, Tureci E. Flow Re-direction Endoluminal Device in treatment of cerebral aneurysms: initial experience with short-term follow-up results. J Neurosurg. 2014 May;120(5):1158-71. doi: 10.3171/2014.1.JNS131442. Epub 2014 Mar 14. PMID: 24628615.