Flow Re-Direction Endoluminal Device

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Kocer and colleagues present their early experience using the Flow Re-direction Endoluminal Device (FRED; MicroVention Inc.) in 33 patients with 37 cerebral aneurysms. This paper provides the largest series of patients treated with the FRED to date, with the only other patient series being the recently published series of 13 patients with 14 aneurysms by Diaz et al.6 Kocer’s 33 patient series, although retrospective and unblinded, indicates excellent angiographic occlusion following treatment. Similar to other flow diversion technologies, angiographic occlusion improved with time such that 8 of 8 patients evaluated with angiographic imaging between 7 and 12 months from device deployment demonstrated complete angiographic aneurysm obliteration.

While flow diversion technologies have improved the ability to treat difficult or wide-necked aneurysms, 2 devices, the Pipeline Embolization Device (PED; Cividien) and the SILK device (Balt Extrusion), have shed light on important limitations of these technologies. Our group reviewed the largest initial series of PED and found a major complication rate (ischemic or hemorrhagic events) and mortality of 5.3% and 1.3% of treated patients, respectively.5 Alarming, delayed parenchymal hemorrhages, occurring downstream in the territory supplied by the treated vessel, were noted to occur in about 4% of PED-treated patients.16 Furthermore, delayed aneurysmal rupture, or re-rupture, and progressive enlargement secondary to thrombosis have also been noted.5,12 Embolic events are also common after PED deployment and have been identified in up to 52% of patients after MRI evaluation.8 Similar rates of thromboembolic and hemorrhagic complications have been noted with the SILK stent, although there has been less of a reported association with delayed parenchymal hemorrhages. In addition, difficulties with device deployment, stent foreshortening, the need for multiple devices, stenosis after deployment requiring angioplasty, and other technical challenges have been noted with both the PED and SILK.1,5,9 Finally, there has been concern over stent coverage of perforator or major branching vessels resulting in their occlusion, although most reports to date have fortunately suggested that the majority of ophthalmic artery occlusions seen after flow diversion are asymptomatic.11,13

The FRED, already in its second generation, has a novel design that attempts to improve upon some of the limitations of the older flow diverter devices. This design includes a stent-in-stent design with a high-porosity outer stent and an inner, low-porosity mesh. As the authors note, the second-generation FRED attempted to improve on the initial design by including a distal support wire, both proximal and distal attachment zones between the inner and outer stents, and a wider outer stent diameter. The authors argue that the stent-in-stent design provides less friction while passing the stent through the microcatheter than previous flow diversion devices due to fewer contact points, making it more navigable. Furthermore, additional zones of high-porosity stent without overlapping low-porosity mesh on both the proximal and distal margins allow for less coverage of perforator or branching vessels away from the aneurysm neck. In their study, Kocer and colleagues reported that all covered ophthalmic and anterior choroidal arteries remained patent, although an ophthalmic transient ischemic attack (TIA) did occur in one of these patients.10 Furthermore, the authors argue that the design allows for full expansion of the distal stent and is fully retrievable until approximately 80% of the stent has been deployed. This is in contrast to the PED, which is not retrievable.

While the data from both FRED series represent fewer than 50 total patients with brief follow-up, both have indicated technical ease with FRED deployment and a low periprocedural complication rate. No technical, ischemic, or hemorrhagic complications were noted in the 13 patients treated by Diaz.4 In the series by Kocer et al., only 2 procedural complications occurred (dissection leading to cerebral TIA with multiple emboli seen on MRI, and ophthalmic artery TIA with preserved patency), representing a 6% thromboembolic complication rate with 0% permanent morbidity and mortality.10 However, delayed “fish mouthing” or foreshortening of the stent after deployment was noted in approximately 15% of patients, although none of these stent morphological complications had clinical sequelae.

As our experience with flow diversion technologies grows, our understanding of stent porosity, parent artery and perforator hemodynamic changes, hemorrhagic and ischemic sequelae, and technical considerations of successful deployment of these devices will expand. The FRED represents a novel innovation from the single, low-porosity flow diversion stents by using a stent-in-stent design. Early studies suggest that the FRED is safe. Further
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studies will bear out whether these device innovations will have actual clinical or technical benefits over older flow diverter designs.

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Disclosure

Dr. Hoh serves as a consultant for Edge Therapeutics. Dr. Fargen has no disclosures to report.

References


Response

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Firstly, we would like to thank Drs. Fargen and Hoh for their meticulous evaluation of our paper and valuable comments. It is obvious that evolving endovascular device technology has a potential to widen our indication spectrum for the treatment of intracranial aneurysms that are very complex and difficult in terms of morphological features. As we reported, flow diverter (FD) devices are recent examples of these technological improvements for certain indications. Although our neurointerventional society has obtained very satisfying results with FD treatment, there are also some potential complications that have come to light with our increasing practice that cannot be ignored. However, we are not able to understand the pathophysiological mechanisms behind some of the complications with our current knowledge. We hope that ongoing and future studies on vascular hemodynamics (intraarterial and intrasaccular), pathophysiology of healing reactions of intracerebral arteries, and antithrombotic-anticoagulation regimens will help us better understand these complications and in turn provide opportunities to prevent them in the future. Meanwhile, we should not overlook the natural history, regrowth, and retreatment rates of complex aneurysms treated with techniques other than FDs. From this perspective, new devices such as the FRED may be promising for those cases. To enhance our vision on endoluminal treatment strategies of intracerebral aneurysms, there is an obvious need for more cases, longer follow-up times, and scientific comparisons with other devices and techniques.

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