FRED Jr stent for acute flow diversion in ruptured cerebral aneurysms arising from small-caliber vessels: a clinical case series

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OBJECTIVE  Treatment of ruptured aneurysms arising from small-caliber (< 2.5 mm) or distal vessels beyond the circle of Willis is considered challenging with all treatment modalities. Recently, the Flow Re-Direction Endoluminal Device Junior (FRED Jr) stent, designed for flow diversion in small arteries, was approved in the United States for the treatment of nonruptured aneurysms. Here, the authors report their experience using this device in the setting of subarachnoid hemorrhage (SAH).

METHODS  Clinical and radiological records of patients sustaining SAH treated with a FRED Jr stent between June 2020 and October 2022 were reviewed. Treatment course, including antiplatelet therapy, external ventricular drain (EVD) management, and vasospasm, and clinical outcomes were analyzed. Angiographic results were assessed according to the O’Kelly-Marotta (OKM) grading scale.

RESULTS  Nine patients at a median age of 62 (range 27–75) years were included. The median Hunt and Hess grade was II (IQR 1) and the median modified Fisher grade was 4 (IQR 1). Aneurysm morphology types included saccular (6 patients), blister (1 patient), and dissecting (2 patients), and the aneurysms were located at the anterior communicating artery complex (n = 3) at the A2/A3 (n = 3), M2/M3 (n = 1), V4 (n = 1), and P2 (n = 1) arterial segments. All stents were deployed successfully with no inprocedural complications. Postoperatively, no rebleeding events were encountered. Vasospasm therapy was initiated in 6 patients, and no symptomatic EVD-related hematomas were observed. Postoperative ischemic events were encountered in 2 patients. The median 3-month modified Rankin Scale score was 2 (IQR 1) for the 7 surviving patients, and 3-month radiographic follow-up revealed OKM grade D in 4 of 7 patients.

CONCLUSIONS  Flow diversion using the FRED Jr stent is feasible as a potential treatment strategy for acutely ruptured aneurysms arising from small-caliber vessels. The complication profile reported in this series is comparable to those of historical microsurgical cohorts, and effective protection was conferred by this treatment modality. Therefore, our small cohort provides a glimpse into a new tool for successfully achieving acute flow diversion for this subset of difficult-to-treat aneurysms.

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KEYWORDS  ruptured aneurysms; small-caliber cerebral vessels; flow diversion; FRED Jr

Ruptured aneurysms arising from cerebral vessels of small caliber (< 2.5 mm) are considered more complex and technically challenging to treat than other aneurysms, resulting in higher rates of patient complications, morbidity, and mortality. In past decades, microsurgical clipping was the treatment of choice for ruptured distal aneurysms owing to their relatively superficial anatomy, paired with technical difficulties from an endovascular standpoint in accessing small and tortuous vessels, as well as the lack of low-profile devices. In recent years, however, there has been a growing body of evidence supporting the off-label use of flow diversion for acutely ruptured intracranial aneurysms. Flow diversion therapy was originally intended for aneurysms at the circle of Willis, however, the recently marketed low-profile devices to treat smaller-caliber vessels has expanded the indications for this treatment.

The Flow Re-Direction Endoluminal Device Junior...
(FRED Jr, MicroVention) is one of the low-profile flow diverters indicated for aneurysms whose parent vessel diameter is less than 3 mm. To date, there are only limited data regarding the use of the FRED Jr stent in the setting of subarachnoid hemorrhage (SAH). In this study, we report our experience with ruptured cerebral aneurysms arising from small-caliber arteries treated in the acute period by use of the FRED Jr stent.

Methods

Patient Selection

This retrospective study was approved by the institution’s local ethics committee. Treatment decisions were made on a case-by-case basis by the neuroendovascular team, which included dual-trained neurosurgeons. Data were included from clinical and radiological records of all consecutive patients with intracranial ruptured aneurysms treated with the FRED Jr stent at our center between June 2020 and October 2022. Patient data included demographic information, clinical presentation, and treatment considerations. Each aneurysm was categorized by type, height, width, neck, parent artery name, parent artery diameter, and presence of branching vessels from the aneurysm or in close proximity to it (distance of ≤ 2 mm to the aneurysm neck). Importantly, data from the postoperative course, including antiplatelet strategy, external ventricular drain (EVD) management, and vasospasm treatment, as well as 3-month clinical outcomes assessed by using the modified Rankin Scale (mRS) and radiographic outcomes, were included.

Device Description

FRED Jr is a self-expandable, double-layer, nitinol braided flow diverter that is used for vessels 2.5–3.0 mm in diameter and can be resheathed as needed. FRED Jr has flow-diverting properties along 90% of its length. The inner flow diverter layer has 36 tightly braided wires, while the outer layer has 16 more widely braided wires. This design is meant to preserve flow to adjacent critical branches, while allowing navigability. Visibility is achieved with four platinum markers on both ends and tantalum spiral wires surrounding the stent. Available stent sizes are 2.5–3 mm in diameter and up to 41 mm in length, with a dual layer coverage of 8–37 mm.

Clinical Presentation, Endovascular Treatment, and Antiplatelet Regimen

All patients presented with acute SAH confirmed by head CT. After initial stabilization, an EVD was placed in patients for whom there was concern for hydrocephalus. Patients were then transported to the endovascular suite/hybrid operating room. All procedures were performed with the patient under general anesthesia while undergoing systemic heparinization (50–70 units/kg bolus followed by 1000 units every hour). First, right common femoral artery access was obtained. A guide catheter was then navigated into the internal carotid or vertebral artery, depending on the aneurysm location. After detailed anatomical evaluation of the parent artery and aneurysm using 2D and 3D rotational angiography, the treatment plan was determined. The following characteristics were recorded: aneurysm type, shape, height, width, neck, parent vessel diameter, and intended stent length (accounting for safety margins of at least 2 mm proximally and distally to the aneurysm). The FRED Jr diameter and length were then decided. In the majority of cases (6 of 9, 66%), FRED Jr stent placement was the primary treatment. In 3 cases stenting was chosen after an initial failed attempt of coil embolization.

Due to the acute setting of ruptured aneurysms, the antiplatelet strategy was determined at the completion of the diagnostic phase. Patients received loading doses of 30 mg prasugrel and 650 mg aspirin through a nasogastric tube, followed by a 30-minute waiting period. In 2 cases, intravenous (IV) antiplatelet treatment was implemented with cangrelor bolused at 30 μg/kg and continued at 2 μg/kg/min. In all cases, patients were transitioned to oral dual antiplatelet therapy (DAPT) the following day.

FRED Jr was deployed using a triaxial system, which included a guide catheter, intermediate catheter, and a Headway 21 microcatheter over a microguidewire (Synchro 0.014, Stryker Neurovascular). Postdeployment angiography was performed in all patients by using high resolution and digital subtraction on magnified views to ensure proper positioning along the aneurysm neck and good wall apposition. Finally, standard view cranial angiography was performed to rule out thromboembolic or hemorrhagic complications. Hemostasis was achieved at the access site using an arterial closure device.

Postoperative Care

All patients were managed postoperatively in a dedicated neurological ICU. Importantly, aneurysms were defined as unsecured for the first 3 days posttreatment, a protocol that included a systolic blood pressure (SBP) goal of under 140 mm Hg, as well as leviteracetam seizure prophylaxis, and a closed EVD (if present) allowing for strict CSF drainage if intracranial pressure exceeded 20 mm Hg. After 3 days, in cases of an uneventful course, SBP goals were liberalized to < 180 mm Hg, seizure prophylaxis was discontinued, and EVDs were open at a height of 20 cm H₂O, allowing more liberal drainage. DAPT with 10 mg prasugrel and 325 mg aspirin was maintained during this period and continued for 6 months.

Transcranial Doppler measurements were routinely obtained at baseline (day 1) and daily thereafter, barring clinical deterioration prompting CTA and angiography. Clinically significant vasospasm was treated with intraarterial verapamil with or without milrinone, as indicated. Routine follow-up DSA was carried out on day 7 (if not indicated prior). EVD weaning was performed based on clinical and imaging assessment of hydrocephalus, and shunts were placed when weaning was not achieved (usually between 2 and 3 weeks after initial placement). These details were documented in the electronic medical records during the ICU and inpatient hospital course and later retrieved. Good clinical outcome at the 3-month follow-up was defined as either an mRS score of 0–2 or a return to the baseline mRS score. Minor stroke was defined by a National Institutes of Health Stroke Scale (NIHSS) score ≤ 3, and major stroke by an NIHSS score > 3.
Angiographic Evaluation

Follow-up imaging was performed with either contrast-enhanced MRA, CTA, or DSA and interpreted by board-certified neuroradiologists. The grade of aneurysm occlusion was rated according to the O’Kelly-Marotta (OKM) grading scale.13 The occlusion grade describes the degree of aneurysm filling after treatment (OKM grade A, total; B, subtotal; C, entry remnant; and D, no filling). Adequate aneurysm occlusion was defined as an OKM grade of C or D.

Results

Patient and Aneurysm Characteristics

Nine patients, 6 men and 3 women, at a median age of 62 (range 27–75) years, harbored 9 aneurysms treated using a FRED Jr flow diverter, either the FRED 21 or FRED X type (see Table 1). The median Hunt and Hess grade was II (IQR 1), and the modified Fisher score was 4 (IQR 1). An EVD was placed in 5 of 9 patients, and in 4 of 5 before treatment with antiplatelet therapy. All treatments were performed during the acute stage. In 1 patient, the aneurysm was not diagnosed on the initial angiogram because it was thrombosed, and therefore treatment took place at postbleed day 14. Most aneurysms were located at either the anterior communicating artery (AComA) complex (3 patients) or the distal anterior cerebral artery (ACA) (3 patients) as noted in Table 1. Heterogenous aneurysm morphologies were observed, including sacular (6 patients), blister (1 patient), and dissecting (3 patients) types.

No technical difficulties were encountered in the process of FRED Jr deployment. In 3 patients previous attempts were made to coil the aneurysm, which were not successful, and it was decided to proceed with a flow diverter. Aneurysm and device characteristics are further detailed in Table 2.

Nine devices were deployed in 9 arteries ranging in caliber from 1.3 to 2.5 mm, and side branches were covered in 8 patients, in whom all remained patent.

Postoperatively, 2 stent-related thrombosis events occurred while using the FRED 21 device during treatment of 2 AComA aneurysms. In the first case, the right A2 arterial segment branch was lost on postoperative day (POD) 2, resulting in transient weakness as the patient was reloaded with DAPT, and this patient eventually suffered a minor stroke. In the second case, reduced filling at the A2 segment across the AComA contralaterally was observed on POD 4, as the patient developed dysphasia. Since the patient had a preexisting critical stenosis in the cervical left internal carotid artery (LICA), it was decided to protect the left hemisphere and the cervical LICA was stented. Other thromboembolic events were related to spasm in distal territories in 2 other patients.

No hemorrhagic complications occurred interprocedurally. Postprocedurally, we encountered 2 groin hematomas (1 of which required thrombin injection to treat a forming pseudoaneurysm), as well as 1 falcial subdural hematoma, managed conservatively. Interval aneurysm growth was seen at a left P2 segment posterior cerebral artery (PCA) aneurysm, necessitating deployment of a second Pipeline flow diverter within the FRED Jr deployed initially, on POD 9. Vasospasm was seen and treated in 6 patients, with 2 patients requiring intra-arterial verapamil. From a CSF management standpoint, EVDs were replaced in 3 patients on DAPT, because prasugrel was stopped perioperatively for 24 hours. In 1 patient a small asymptomatic tract hemorrhage was seen on repeat CT and resolved conservatively. Two patients died later during the hospitalization course. In the first patient, severe systemic complications led to multiorgan failure, and in the second patient severe vasospasm and episodes of hypoperfusion due to hemodynamic instability led to death.

In angiographs performed in the 7 surviving patients, an OKM grade of D was noted at the 3-month follow-up in 4 patients and an OKM grade of C was observed in 3 patients. The median 3-month mRS score was 2 (IQR 1).

Discussion

In this report we summarized the clinical presentation, treatment safety, and efficacy in a series of 9 patients who suffered SAH and were treated by flow diversion using the FRED Jr stent.

In recent years, several studies12,14,15 have supported the utility of flow diversion for ruptured proximal aneurysms. Despite being initially considered inadequate in patients with acute ruptures, growing numbers of centers currently consider flow diversion to be a viable and safe technique with acceptable success rates both angiographically and clinically. In parallel, with the introduction of smaller stents for smaller vessels, several studies have explored the challenges and the unique nature of flow diversion in small arteries.8,16–18 Initially, the small or distal arteries were considered incompatible with the comparatively stiff flow diversion delivery catheters (0.021–0.027 inches), because at that time only proximal segments of the cerebral arteries were considered for safe flow diversion. However, advances in both microcatheter systems and flow diverting stents designed for these smaller vessels allowed the incorporation of flow diversion as an additional tool in the endovascular armamentarium. These two shifting paradigms, flow diversion for acute ruptured aneurysms in conjunction with flow diversion in small-caliber parent vessels, were the focus of this study.

From a technical standpoint, the successful deployment of the FRED Jr stent in all patients (see Fig. 1) supports this approach as it offers a straightforward solution to otherwise difficult-to-treat aneurysms (in 3 of 9 patients flow diversion was utilized as a bailout after failed coiling). Another important consideration is the postoperative safety of the device in the setting of SAH and its associated hypercoagulable state. In this regard, after transitioning to a coated stent (FRED X), which has surface modification, we did not observe any stent-associated thrombosis events.

Postoperatively, vasospasm and hydrocephalus—two main concerns which have traditionally pushed neurosurgeons to clip aneurysms—did not cause significant issues in our cohort. EVDs were replaced or shunts were placed without symptomatic hemorrhagic complications. Furthermore, vasospasm was managed without rebleeding in all patients. As flow-diverted aneurysms were not considered as secured, as in cases of clipped or coiled aneu-
<table>
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<th>Age, yrs/</th>
<th>Sex</th>
<th>H&amp;H Grade</th>
<th>mFS</th>
<th>Aneurysm Location</th>
<th>FRED Jr Tx PBD</th>
<th>Thromboembolic Events</th>
<th>Clinical Mgmt</th>
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<th>Vasospasm</th>
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</table>

Asympt = asymptomatic; Dis = discharge; H&H = Hunt and Hess; IA = intra-arterial; LLE = left lower extremity; MCA = middle cerebral artery; mFS = modified Fisher score; Mgmt = management; NA = not applicable; PBD = postbleed day; PED = Pipeline embolization device; pt = patient; SDH = subdural hematoma; Tx = treatment.

* Intra-arterial verapamil.
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<th>Neck Width</th>
<th>Height</th>
<th>Bifurc (yes/no)</th>
<th>Loading</th>
<th>Maintenance</th>
<th>Device</th>
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AC = anticoagulant; AICA = anterior inferior cerebellar artery; BA = basilar artery; Bifurc = bifurcation; Diam = diameter; inf = inferior; Morph = morphology; prox = proximal; sup = superior; VB = vertebrobasilar.

* Denotes branch fate at the last available radiographic imaging obtained.
rysms, we kept a low threshold for angiography, especially in cases for which vasospasm required the use of pressors, with potential aneurysm growth in mind (in 1 patient interval growth necessitated reintervention).

The results in our present series are corroborated by previously published literature. Sayin et al.\textsuperscript{11} reported 5 cases with acute SAH treated with the FRED Jr stent, which included 2 distal ACA aneurysms, 2 posterior communicating artery wide-necked aneurysms, and 1 fusiform PCA aneurysm. In all of the patients in this series, no residual filling of the neck or part of the aneurysm was observed at follow-up, and no rebleeding events were reported. A Finnish flow diversion study\textsuperscript{12} reported 110 acutely ruptured aneurysms, of which 19 were treated using the FRED Jr stent. Because the reported results of this study did not include a subgroup analysis, it is hard to ascribe the high treatment-related complication rate (45%) to a specific type of stent, approach, vessel size, or aneurysm type. Overall, the reported rebleeding rate was 3%, and 90% of patients who were followed up (mean follow-up duration of 11 months) showed complete occlusion of the aneurysm (OKM scale grade D). In the short follow-up presented here, which by its nature limits the opportunity to fully appreciate the long-term effects seen in flow diversion, OKM grades of D and C were observed in all surviving patients (with the exception of 1 patient in whom aneurysm growth did occur in the acute period). Schüngel et al.\textsuperscript{16} reported on 22 acutely ruptured aneurysms treated with a low-profile flow diverter, Silk Vista Baby (Balt), with approximately 60% of the aneurysms showing occlusion rates with an OKM grade of C and D at an early follow-up period (mean 2.6 months). In our series, although we describe a smaller sample size, an even higher (6 of 7, 83%) adequate occlusion rate was observed in cases with similar baseline characteristics.

The appropriate management of EVD in patients who are undergoing treatment with DAPT is another controversial topic. Although some relatively high rates of hemorrhagic complications (32%) associated with shunting and EVD replacements have been reported for some studies\textsuperscript{19,20} other reported studies have demonstrated extremely low symptomatic intracranial hematomas.\textsuperscript{15} Our overall experience reflects the notion that CSF management in patients on DAPT is feasible with low percentages of adverse events.

Last, although it seems that the data support the idea that flow diversion for ruptured aneurysms in small vessels offers protection from rebleeding, thromboembolic risks associated with stent placement may represent a greater concern, and additional data from larger studies are needed to aid careful patient selection. In our series, 2 of 9 patients (22%) who suffered an AComA aneurysm rupture experienced delayed postoperative thrombosis in an arterial branch related to the stent. Stent coating and surface modification may reduce this risk in the future.

Study Limitations
The main study limitations stemmed from its relatively small sample size. However, this work represents, to our knowledge, the largest reported series with granular detail.

for ruptured aneurysms that includes 3 months of follow-up data. The heterogenous type and location of the aneurysms presented here reflect a real-world experience but do not allow conclusions to be made regarding specific anatomical nuances of stent deployment.

Conclusions

Flow diversion as a treatment strategy for acutely ruptured aneurysms is evolving, with a growing body of literature supporting this approach. The present study adds another layer, focusing on FRED Jr stents, which have shown high rates of successful technical deployment as well as rebleeding protection, while necessitating tailored management of external ventricular drainage and vasospasm. Thus, this device seems to offer a potential therapeutic option in the acute stage for this group of challenging aneurysms.

References


Disclosures

Dr. Regenhardt reported being a Rapid Medical Data and Safety Monitoring Board Member and receiving research grants from NIH, the Heitman Stroke Foundation, and SVIN outside the submitted work. Dr. Patel reported receiving personal fees from Medtronic and MicroVention during the conduct of the study and personal fees from Penumbra and Q’Apel outside the submitted work.

Author Contributions

Conception and design: all authors. Acquisition of data: Doron, McLellan, Vranic, Regenhardt, Patel. Analysis and interpretation of data: Doron, McLellan, Vranic, Regenhardt, Patel. Drafting the article: Doron, Vranic. Critically revising the article: Vranic, Regenhardt. Stapleton, Patel. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Doron. Statistical analysis: Doron. Administrative/technical/material support: Doron, McLellan, Regenhardt. Study supervision: Regenhardt.

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