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Surgical Neurology International

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SNI: Neurovascular

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Case Report

Localized kinking during deployment of a flow redirection lumen device (FRED) could be due to excessive pushing

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Received : 11 November 2021
Accepted : 01 January 2022
Published : 20 January 2022

DOI
10.25259/SNI_1127_2021

Videos available on:
https://doi.org/10.25259/SNI_1127_2021

Quick Response Code:

ABSTRACT

Background: The safety and efficacy analysis of flow redirection lumen device (FRED) demonstrated the excellent safety profile of FREDs for aneurysm treatment. We describe the first case in which FRED deployment for a paraclinoid aneurysm resulted in in-stent stenosis, necessitating balloon angioplasty, and an additional stent.

Case Description: A 50-year-old woman had a left paraclinoid aneurysm with a maximum diameter of 6.1 mm. We planned FRED deployment. We experienced in-stent stenosis just after the deployment of a FRED. Devices such as guidewires and catheters could not cross the lesion through the FRED because of an obstruction in the FRED. Balloon angioplasty and subsequent stenting resolved thrombosis and kinking. FRED has potential for kinking locally.

Conclusion: Surgeons should consider this possibility when treating cerebral aneurysm using FRED. Cone-beam computed tomography after deployment of FRED may be useful for evaluating the stent shape.

Keywords: Cone-beam computed tomography, Endovascular treatment, Flow diverter, Flow redirection lumen device, Kinking

INTRODUCTION

The safety and efficacy of flow-diverting (FD) therapy using pipeline embolization devices; Medtronic, Irvine, Ca, USA have been proven in a number of studies.[1,2] Flow diverters with various structures have been developed and marketed for this purpose. One such flow diverter, the flow redirection lumen device (FRED; MicroVention, Tustin, California), has an inner low-porosity stent that functions as a flow diverter and an outer portion that functions as a scaffold for the inner stent. It possesses a paired, integrated, and double-layered self-expanding nitinol braided design. This double-layer design is also unique among currently available FD stents.

The safety and efficacy analysis of FRED embolic device in aneurysm treatment (SAFE) study demonstrated the excellent safety profile of FREDs for aneurysm treatment, with low morbidity and mortality rates, and their efficacy.[9]

We describe the first case in which FRED deployment for a paraclinoid aneurysm resulted in in-stent stenosis, necessitating balloon angioplasty, and an additional stent.

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CASE DESCRIPTION

A 50-year-old woman visited another hospital for examination of forgetfulness. She had no relevant medical or family history related to her condition. A paraclinoid aneurysm was identified on magnetic resonance angiography. Therefore, she was referred to our department. Digital subtraction angiography (DSA) demonstrated a left paraclinoid aneurysm with a maximum diameter of 6.1 mm [Figures 1a and b]. She hoped to receive endovascular treatment for this aneurysm; therefore, we planned FRED deployment. This study was approved by relevant ethics committee and the patient provided informed consent for publication.

Under local anesthesia, a 6-Fr shuttle sheath (Cook Medical, Bloomington, IN, USA), was inserted into the right femoral artery. Using a coaxial system consisting of 5-Fr Sofia select (Terumo Corporation, Aliso Viejo, CA, USA), Headway 27 (Terumo Corporation, Aliso Viejo, CA, USA), and ASAHI CHIKAI 18 (ASAHI INTECC CO., LTD. Aichi, Japan), the Sofia select was inserted into the petrous part of the internal carotid artery (ICA), and the Headway 27 was placed to the left middle cerebral artery (MCA). A 4.0 mm × 18 mm FRED was deployed from the orifice of the anterior choroidal artery to the cavernous portion of the ICA, fully covering the aneurysm neck [Figure 1c]. After 5 min, the left ICA angiography showed slow flow and a contrast defect in the FRED [Figure 1d]. A 9-Fr OPTIMO (Tokai Medical Products, Inc. Aichi, Japan) was navigated to the left ICA cervical portion and Ozagrel sodium was injected under balloon inflation. Next, a 4.0 mm × 11 mm Scepter XC (Terumo Corporation, Aliso Viejo, CA, USA) was used to cross the lesion through the FRED, but it was impossible to do so because of some obstruction in the FRED [Figures 2a and b]; [Video 1]. Neurodeo (Medico's Hirata Inc., Osaka, Japan) was navigated to the left MCA through FRED and exchanged for CHIKAI 14 300. Subsequently, transform 4.0 mm × 7.0 mm (Stryker, Fremont, CA, USA) was guided and angioplasty was performed to improve the contrast defect [Figure 2c]. PROWLER SELECT (Cerenovus, Irvine, CA, USA) was exchanged and CERENOVUS ENTERPRISE 2 VRD (Cerenovus, Irvine, CA, USA) 4.0 mm × 16 mm was deployed to improve the defect. Although the defect persisted after the procedure, flow was dramatically improved. The patient had no neurological deficit. Follow-up DSA after 3 days demonstrated that the contrast defect had improved [Figure 2d]. Cone-beam CT showed some space between the FRED and ENTERPRISE 2 VRD [Figure 3a]. Three-dimensional rotational angiography (3DRA) also demonstrated a contrast defect in the same space [Figure 3b]. The patient was discharged after confirmation of no apparent infarction on magnetic resonance imaging. Subsequently, using the aneurysm model, as shown in the figure, we tested whether the FRED would show kinking in such situations.

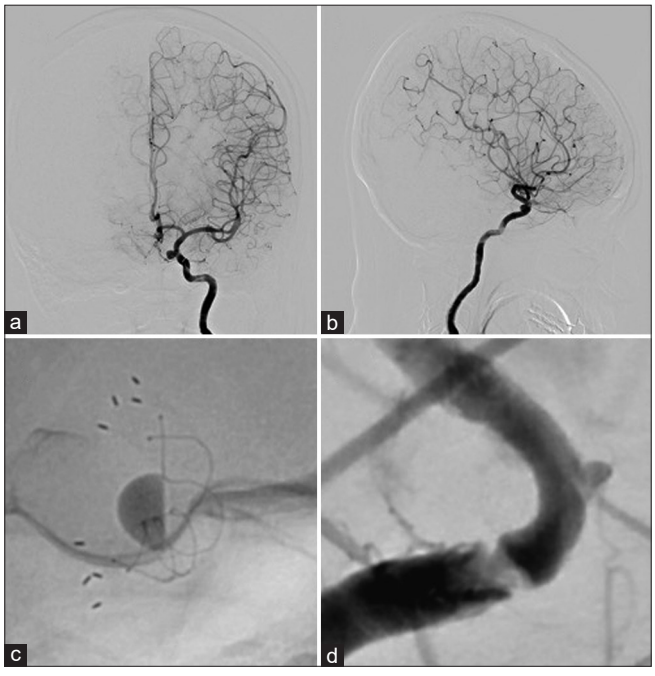

Figure 1: Digital subtraction angiography in the frontal (a) and lateral projections (b) demonstrating an internal carotid artery aneurysm located at the paraclinoid portion. The image shows good dilatation and no twisting of the flow redirection lumen device (FRED) (c). Digital subtraction angiography showing a contrast defect in the FRED (d).

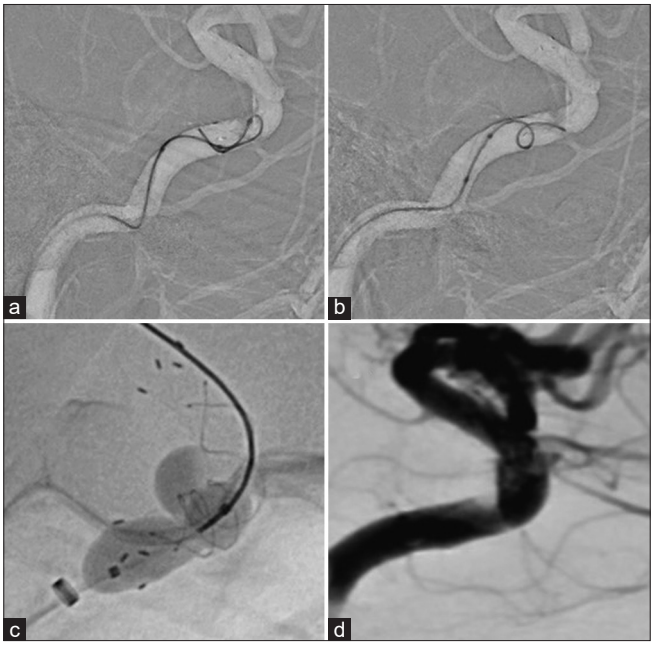

Figure 2: A micro-guidewire could not cross the lesion through the flow redirection lumen device (FRED), indicating an obstruction in the FRED (a and b). The balloon was not fully dilated, consistent with the area of the contrast defect (c). Follow-up DSA after 3 days demonstrated improvement in the contrast defect (d).

A 4.5-mm FRED was deployed with intentional excessive pushing and this shape was verified. The results showed localized kinking of the FRED [Figures 4a-c]. Cone-beam CT demonstrated a folding formation [Figures 4d-f].

DISCUSSION

We present our first experience of in-stent stenosis just after the deployment of a FRED. Devices such as guidewires and catheters could not cross the lesion through the FRED because of an obstruction in the FRED. Cone-beam CT showed some space between the two stents, consistent with the contrast defect on 3DRA. This might have occurred due to kinking of the FRED. We considered that excessive pushing of the system during deployment may have led to kinking.

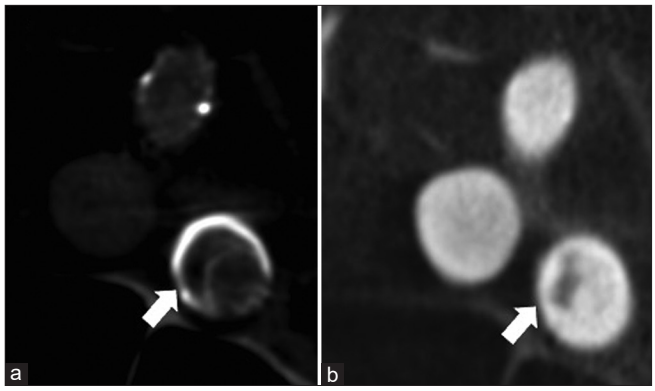

Figure 3: Cone-beam CT showing a marked space (arrows) between the flow redirection lumen device (FRED) and ENTERPRISE 2 VRD (a). This was consistent with the area of the contrast defect (b).

In the FRED Italian registry, follow-up angiography at 3–6 months showed complete or nearly complete occlusion of the aneurysm in 94% of the cases.[8] The 1-year findings of the SAFE trial established the superior safety profile of the FRED for therapeutic aneurysms, with low morbidity and mortality rates of 2.9% and 1.9%, respectively, and proven efficacy (sufficient occlusion was observed in 73/90 cases [81.1%]).[9]

As a complication related to FRED deployment, Guimaraens *et al*. reported that in-stent thrombus or in-stent stenosis was observed in 9 (4.9%) cases.[4] However, they did not mention the cause of these complications. Similarly, the Italian FRED registry, which included 169 aneurysms treated in 30 Italian centers, demonstrated parent artery occlusion in 6 (3.8%) cases.[8] However, they did not mention the cause of these events in detail either. Although Caroff *et al*. reported that the occurrence of in-stent stenosis after flow diverter deployment is associated with cardiovascular risks factors and the stent design, the exact mechanisms underlying in-stent stenosis are still unclear.[3]

In the present case, we confirmed in-stent stenosis just after deployment of FRED. Cone-beam CT showed some space between FRED and CERENOVUS ENTERPRISE 2 VRD [Figure 3a]. Three-dimensional DSA also demonstrated a contrast defect in that space [Figure 3b]. Considering the behavior of the guidewire, catheter, and balloon angioplasty, in-stent stenosis might have been caused by kinking of FRED, not a thrombus [Figure 2a and b].

Murakami *et al*. reported that a carotid open-cell stent could be folded inward under specific circumstances wherein the

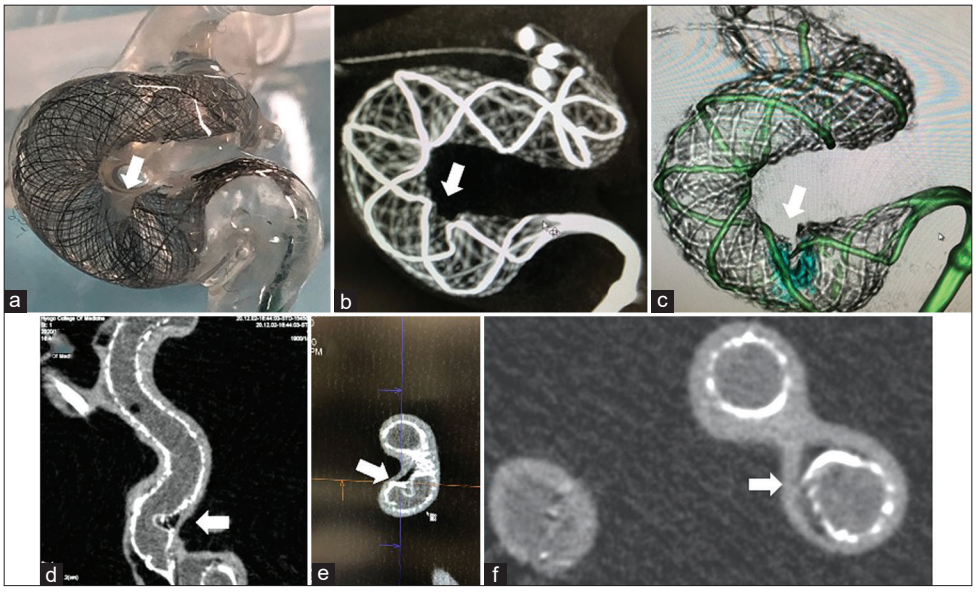

Figure 4: *In vitro* vessel model showing localized kinking of the flow redirection lumen device (FRED) (arrows) (a-c). Cone-beam CT demonstrating the fold formation (arrows) (d-f).

stent does not expand enough to be placed in the stenosis with a device that has a relatively larger diameter outside of the stent.[5] In this case, the patient had no apparent stenotic part and the diameter of proximal part of the ICA was 3.8 mm, suggesting that the stent size was appropriate. We hypothesized that one of the causes of kinking was excessive pushing during the deployment of FRED. A subsequent study with an aneurysm model showed localized kinking of the FRED [Figure 4a-c] and cone-beam CT demonstrated folding formation similar to the present case [Figure 4d-f].

The findings based on the aneurysm model suggested that the localized kinking could have been caused by excessive pushing during FRED deployment. Kinking rates of 15–30% have been reported in stents that are near pulsatile structures such as the myocardium or the great vessels.[6,7] In our case, the kinking of the stent was hypothesized to be partly caused by this pulsatile flow of the artery affecting the stent's structural integrity. Surgeons should guide Sofia select as distally as possible to stabilize the microcatheter.

Since our experience indicated that FRED stent can undergo kinking, surgeons should avoid pushing excessively during FRED deployment. Furthermore, we should confirm the regular shape of tantalum wire of FRED. We also recommend performing cone-beam computed tomography after FRED deployment to evaluate the shape of the stent.

CONCLUSION

We first experienced and treated a case of thrombus formation due to kinking of a FRED. Surgeons should avoid pushing excessively and confirm the regular shape of tantalum wire of FRED.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship

Nil.

Conflicts of interest

Dr. Yoshimura reported research grants from Medtronic, Medicos Hirata, Termo, Bristol-Myers Squibb, and Otsuka; lecturer's fees from Daiichi Sankyo, Pfizer, Boehringer-Ingelheim, Otsuka, Bayer, Pfizer, Bristol-Myers Squibb, Stryker, Medtronic, and Mitsubishi Tanabe. Other authors have no conflicts of interest to declare.

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How to cite this article: Beppu M, Kuramoto Y, Abe S, Namitome S, Yoshimura S. Localized kinking during deployment of a flow redirection lumen device (FRED) could be due to excessive pushing. Surg Neurol Int 2022;13:22.