

Surgery for late type Ia/IIIb endoleak from a fabric tear and stent fracture of AFX2 stent graft

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ABSTRACT

Technical improvements and labeling updates of the AFX2 stent graft (Endologix Inc, Irvine, CA) seemed to have solved the known issues of its previous generation (AFX Strata). Although most endograft failures after endovascular abdominal aortic aneurysm repair will be managed endovascularly, a small subset of patients will still require secondary open conversion. Partial or complete endograft removal can be required, mainly dependent on the characteristics of the stent graft previously placed. We have report a case of secondary open conversion for late type Ia/IIIb endoleak due to stent fracture and fabric tear of the AFX2 stent graft 3 years after endovascular abdominal aortic aneurysm repair. (*J Vasc Surg Cases Innov Tech* 2022;8:458-61.)

Keywords: Abdominal aortic aneurysms; AFX2 stent graft; EVAR complications; Type Ia/IIIb endoleak

CASE REPORT

A 79-year-old man was admitted to our Unit of Vascular Surgery for treatment of a type Ia/IIIb endoleak with sac enlargement detected by computed tomography angiography (CTA) performed as a part of a bladder cancer follow-up protocol. His previous endovascular abdominal aortic aneurysm (AAA) repair (EVAR) had been performed with an AFX2 stent graft (28-110/I20-30; Endologix Inc, Irvine, CA) and a suprarenal aortic cuff (34-34/C100-O20V) at another hospital in 2018.

The patient's medical history included a lifelong smoking habit, chronic obstructive pulmonary disease, hypercholesterolemia, arterial hypertension, atrial fibrillation, obesity (class I; body mass index, 34.9 kg/m²), previous bladder cancer in complete remission, and recent SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) pneumonia. No previous open abdominal surgery had been performed. Thus, the patient was considered at high risk for open surgery (American Society of Anesthesiologists class IV).

CTA revealed distal migration (≥ 10 mm) and crumpling of the suprarenal aortic cuff that had resulted in a type Ia endoleak and sac enlargement, with a maximum transversal diameter of 10.4 cm (Fig 1).¹ The severe stent kinking of the unibody stent graft without a residual lumen, the crumpling of the suprarenal aortic cuff, and the characteristics of the device itself

(endoskeleton attached only at the proximal and distal ends of the inner surface of the fabric), meant that additional bailout endovascular procedures would not be suitable. Thus, open conversion was chosen.

After the midline incision, a large and pulsatile mass was observed. The short and angulated infrarenal neck was dissected after mobilization of the left renal vein. An aortic clamp was placed immediately below the lowest renal artery and in the distal part of the common iliac artery bilaterally. The aneurysmal sac was opened and the endograft exposed. The crumpled suprarenal aortic cuff had become incorporated into the thrombus of the aneurysmal sac, which had also extended inside the device. A posterior longitudinal tear of fabric 2.7 cm long and fracture or disconnection of the stent were observed (Fig 2). After manual removal of the aortic cuff, the unibody stent graft was found, correctly in place at the aortic bifurcation (Fig 3). The device's configuration and design allowed for easy removal of the endograft without causing any intimal lesions of the surface of the common iliac arteries. The procedure was completed by performing aortic-aortic reconstruction with a Dacron prosthesis. No intraoperative complications occurred. His postoperative course was uneventful, and he was discharged home on postoperative day 6. The patient completed our standard 6-month follow-up protocol with duplex ultrasound examinations. Any major or minor adverse events were recorded during follow-up. The patient provided written informed consent for the report of his case details and imaging studies.

DISCUSSION

The AFX platform (Endologix Inc) is a unibody endograft for the treatment of AAAs. Its design is based on the concept of anatomic fixation to counteract the potential for distal migration.²⁻⁴ In contrast, its proximal extension relies on radial force to provide a seal into the proximal aorta.

In the present case, EVAR had failed, although it had been performed within the instructions for use, for both

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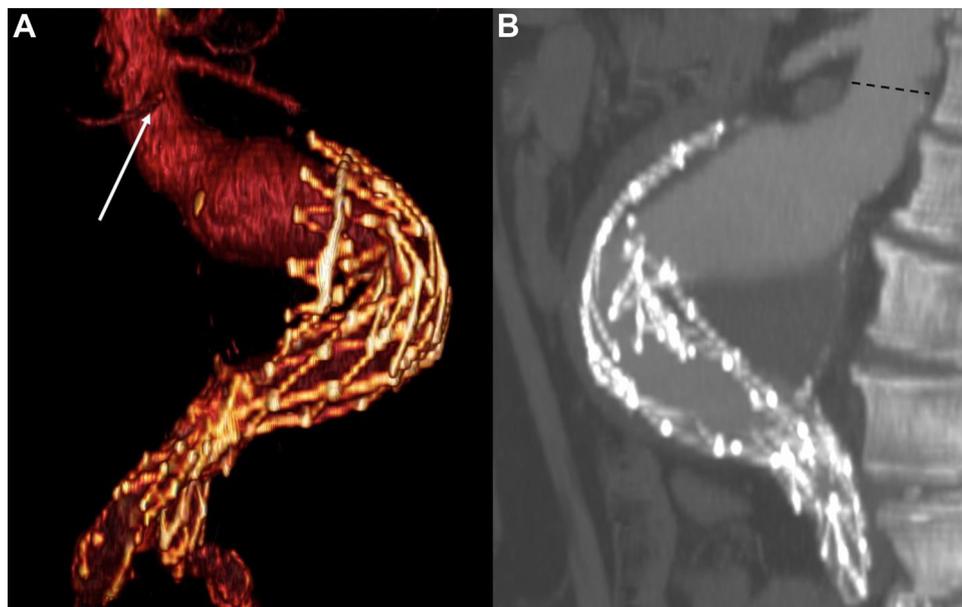


Fig 1. Three-dimensional volume rendering (A) and three-dimensional multiplanar reconstruction (B) showing distal migration and crumpling of the suprarenal aortic cuff. Arrow (A) and dashed line (B) indicate the level of the lowest renal artery.

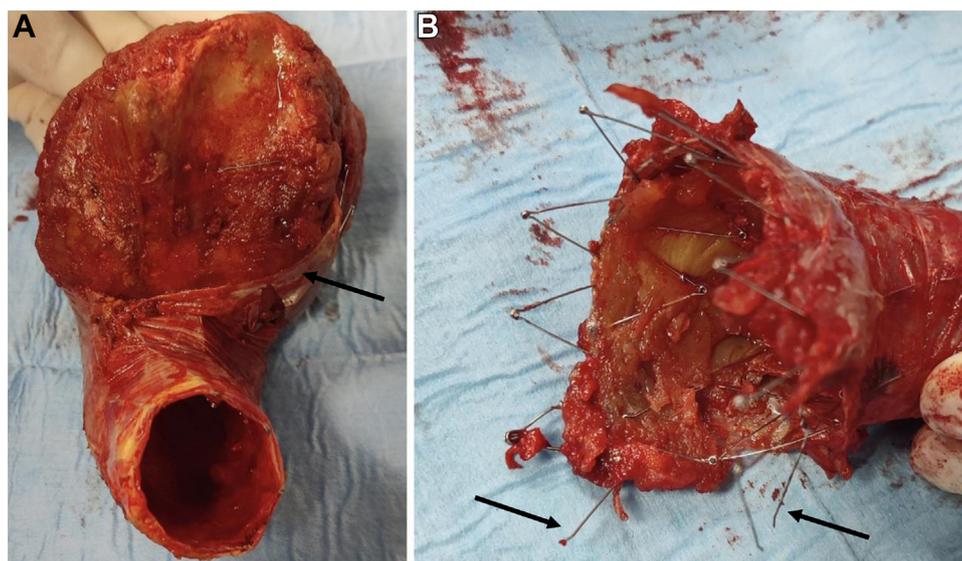


Fig 2. Longitudinal tear of graft fabric seen in anteroposterior (A) and lateral (B) views. The tear caused collapse of the suprarenal proximal aortic cuff. Arrows mark the fabric tear (A) and fracture or disconnection of the stent (B).

the aortic neck anatomy and the component overlap recommendations. CTA revealed distal migration and crumpling of the suprarenal aortic cuff that had resulted in a type Ia endoleak. At first, the aortic neck anatomy (Table) and lack of a high radial force of the aortic extension seemed the cause of the migration. Although a type Ia endoleak after AFX implantation is rare, our case has confirmed the critical importance of the aortic neck anatomy in the outcomes after EVAR.⁵⁻⁷ The sealing mechanism of the AFX platform allows for flexibility

and optimal apposition of the expanded polytetrafluoroethylene (ePTFE) graft into the irregularities, including in hostile anatomies. However, different studies have confirmed that hostile anatomy at the proximal aortic neck has been the main cause of EVAR failure.^{8,9} Comparing the pre-endovascular procedure CTA with the last CTA, no significant changes in the aortic neck anatomy were detected. Thus, the causes of EVAR failure were not related to disease progression but, rather, to failure of the device itself.

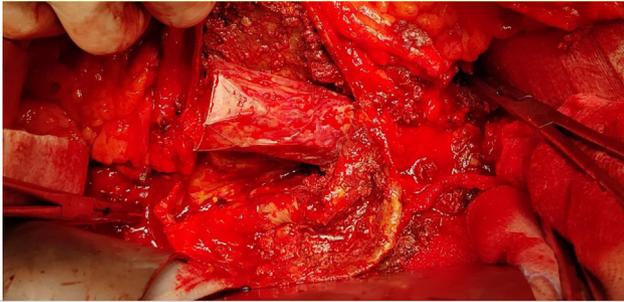


Fig 3. AFX unibody stent graft in place at the aortic bifurcation. The proximal edge of the unibody stent graft was immediately below the aortic angulation.

Table. Proximal aortic neck anatomy and planned technical aspects

Diameter at level of lowest renal artery, 24.74 mm
Diameter 10 mm below lowest renal artery, 26.61 mm
Diameter 15 mm below lowest renal artery, 28.79 mm
Percentage of enlargement of neck at 10 mm, 7.5%
Percentage of enlargement of neck at 15 mm, 16.4%
Conical shape of proximal aortic neck
β -Angle, 57.2°
Planned oversizing, 20%
Planned overlap, 80 mm

During surgery, fracture or disconnection of the stent and a posterior longitudinal tear of the fabric were observed (Fig 2). Studies have reported that tears occur near the saddle of the endograft and have been more commonly attributed to use of the bifurcated unibody device.¹⁰ In the present case, the tear was 2.7 cm long, which extended caudocranially from the beginning of the overlap up to the proximal edge of the aortic extension. The proximal edge of the unibody stent graft was immediately below the aortic angulation (Fig 3).

The explanted stent graft was sent to the manufacturer for analysis to detect any structural defects and to understand the mechanism that had led to failure, if possible. Although a stent fracture could be a reasonable failure mechanism, a second hypothesis for EVAR failure was postulated. As is known, the AFX stent graft is prone to lateral- and anterolateral forces that can lead to a reduction or loss of the components overlap, especially in angulated anatomies and large AAAs (≥ 65 mm).¹¹⁻¹⁴ Several studies have investigated the outcomes associated with the first generation of the AFX (Strata) and reported a high rate of type IIIa/IIIb endoleaks at 3 years after treatment.^{15,16} Following these investigations, multiple product design, manufacturing, and labeling updates were implemented, which led to significant improvement in the outcomes by a reduction

in the incidence of aneurysm-related complications and a lower incidence of type III endoleaks using the DuraPly AFX stent compared with the Strata stent.^{17,18}

The AFX instructions for use have recommended an aortic neck angulation of $\leq 60^\circ$, and labeling updates have stated that care should be taken to maximize the overlap, especially for large AAAs. Concerning our patient, the β -angle was 57.2°, and the overlap between the AFX components was 8 cm, larger than the sizing recommendation (6.15 cm). We postulated that the angulation of the aortic cuff with respect to the unibody stent graft could have resulted in the stent cage of the bifurcated component damaging the ePTFE of the cuff. Disruption of the graft fabric resulting from graft interaction has led to the occurrence of a type IIIb endoleak. Subsequently, the loss of device integrity, with the adjunct of the arterial impulse, resulted in the collapse of the stent graft, leading to the development of a type Ia endoleak.

If the manufacturer's analysis confirms the second hypothesis, the selection of a unibody stent graft, 110 mm long, placed just below the aortic angulation and the resulting excessive maximization of the overlap could have been the cause of the failure. Nevertheless, we could not definitively determine the mechanism that had led to failure. Both conditions, a fabric tear due to graft interaction or a primary stent fracture, are rare but require particular attention. Technical improvements of the DuraPly/AFX2 platform, including improved suture retention strength and tear propagation resistance, seem to have solved the issue of type IIIb endoleak formation. Longer and tighter follow-up are mandatory to confirm the safety and efficacy and whether ours was an isolated case or could be a recurrent problem.

No conclusive evidence could be determined from our single isolated case. A large AAA with a wide and angulated neck remains the critical indication for the use of AFX stent grafts. The reported data have suggested the need to preoperatively evaluate the relationship between grafts and the aortic anatomy and, in determining the target, to consider, not only the maximization of the overlap, but also where it can be achieved safely and where it cannot. Moreover, only the use of open conversion can determine the actual incidence of this complication. If any endovascular bailout procedure had been performed, the present case would have been addressed as type Ia endoleak due to distal migration, without further investigation.

CONCLUSIONS

AFX technical and labeling updates have resulted in improvements in the outcomes to those comparable with all other contemporary EVAR devices. The AFX2 system remains safe and effective but should not be considered as a first choice for AAA repair in patients with a challenging anatomy and a large AAA. Further studies

are mandatory to evaluate the long-term durability of the ePTFE material and the stent structure.

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