

Combined AFX2 with thoracic stent graft: A different endovascular approach of an abdominal aorta aneurysm

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Abstract

The AFX2 endovascular repair system is a unibody, bifurcated stent graft that can be used in an abdominal aortic aneurysm associated with anatomical challenges, especially if it is combined with different aortic cuffs. The use of an AFX2 main body combined with a thoracic stent graft as a proximal aortic cuff was selected to treat a 77-year-old male patient with abdominal aortic aneurysm. The AFX2 endograft combined with a proximal thoracic aortic cuff plays a safe and effective role in treating complex infrarenal abdominal aortic aneurysm that may otherwise be technically more challenging with the open technique and inaccessible with the traditional endovascular technique.

Keywords

Infrarenal abdominal aortic aneurysm, EVAR, AFX2, endograft system, thoracic stent

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Introduction

The first endovascular aneurysm repair (EVAR) procedure was performed by Nicolai Volodos 37 years ago.¹

Since then, several anatomical criteria have required consideration during planning for EVAR, which play a decisive role in the formation of endograft in some patients with anatomical restrictions. The different combinations of endograft have been proposed and are a challenge in their application, promoting new ideas for the evolution of the endovascular technique.^{2,3} Herein, we describe a patient, who finally underwent an endovascular elective repair of his abdominal aortic aneurysm (AAA), using an Anatomically fixated endograft (AFX)-bifurcated body combined with a thoracic aortic cuff, because of complex aortic anatomical challenges in the aortic neck, achieving an optimal outcome. Additionally, a literature report on the combinations of different endograft is described.

Case report

We describe a 77-year-old patient with an infrarenal AAA found on ultrasound and CT angiography, with a diameter of approximately 70 mm. The patient's medical history includes hypertension, diabetes mellitus type 2, hyperlipidemia,

chronic kidney disease with creatinine 1.6 as a baseline, under follow-up by a nephrologist, current smoker, mild lung disease, social alcohol drinker, mild aortic stenosis, and left ventricular hypertrophy with Ejection fraction (EF) 45%. According to the patient's age, medical characteristics, and risk factors the endovascular approach would be the most appropriate method of treating AAA. However, the preoperative Computed Tomography Angiography (CTA) scan revealed greater stenosis of the left renal artery and a 72 mm infrarenal AAA with an enlarged aortic neck diameter (Figure 1); the suprarenal aorta measured 33.0 mm, while the infrarenal aorta was 31.9 mm just below the renal arteries with an enlargement of aortic neck to 37.4 mm. These aortic neck measurements were not compatible with conventional commercially available endovascular grafts. Therefore, the choice of open repair of the AAA seemed to be the only option for the patient, even if the patient was characterized as a very high-risk patient and unfit for the operation. But a more careful

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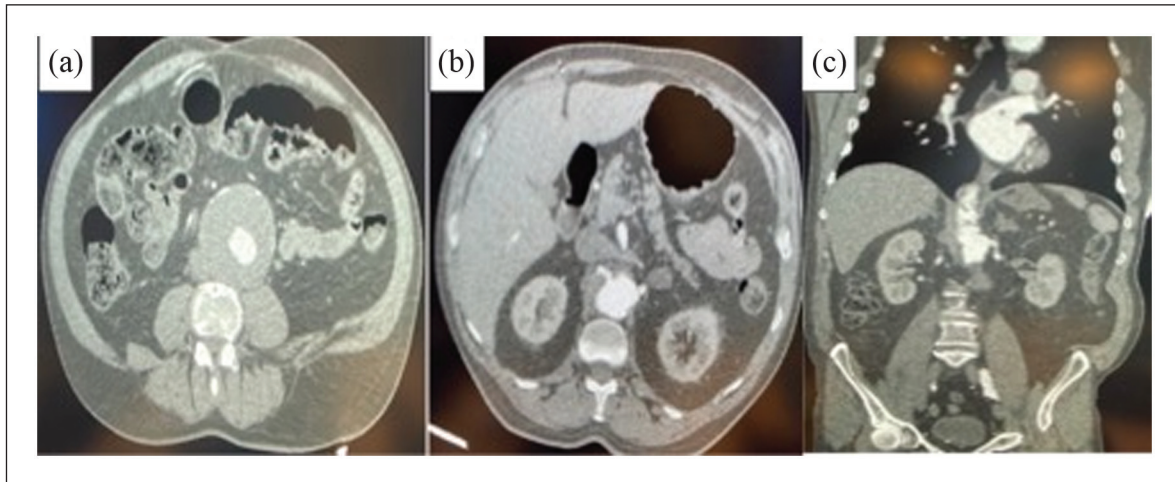


Figure 1. CTA. (a) Infrarenal abdominal aortic aneurysm (AAA) with a diameter of 71.8 mm and suprarenal diameter aorta of 33.0 mm, (b) axial, and (c) coronal view showing the great stenosis of the left renal artery and the infrarenal aneurysm with an enlarged aortic neck diameter.

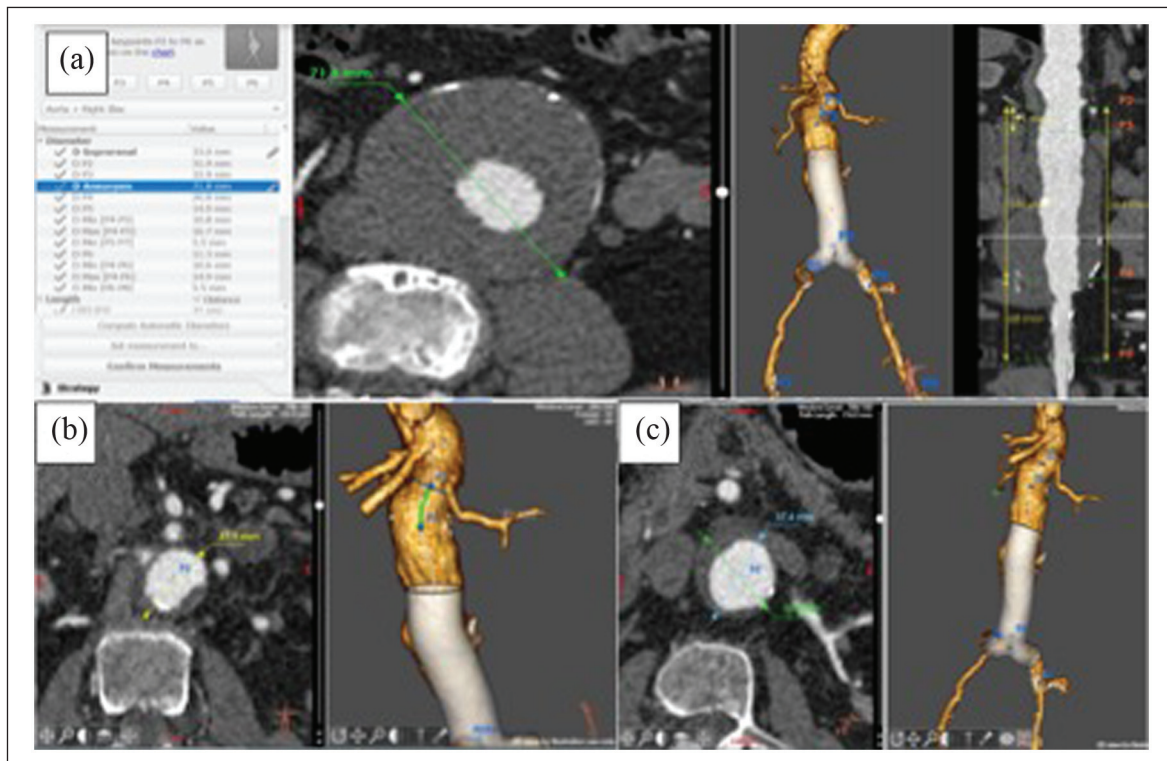


Figure 2. 3D computed tomographic reconstruction of an infrarenal abdominal aortic aneurysm. (a) Maximum diameter of the aneurysm, (b) P2: infrarenal aortic neck diameter, and (c) P3: distal diameter aortic neck.

study brought an EVAR idea, which was successfully applied. The sizing before EVAR was performed using EndoSize Case Planning Software—Version 3.1.47 (EndoSize® is registered trademarks of Therenva SAS) (Figure 2). Due to the impaired renal function of the patient and the extensive stenosis of the left renal artery, it was deemed necessary to place a renal artery stent of Abbott Vascular RX Herculink Elite of 5.5×15 mm, before the EVAR is carried out. The stent was

fully placed inside the renal artery via brachial access. The patient finally underwent an endovascular repair of AAA, using an AFX2® of 28×100 /I 20×40 bifurcated body and a Lifetech Ankura of $38 \times 38 \times 100$ thoracic stent graft as a proximal cuff. All procedures were performed in an adequately equipped operating room with the patient under general anesthesia and a surgical cut down of both femoral arteries. First, the AFX2 unibody was deployed in the distal aorta and the

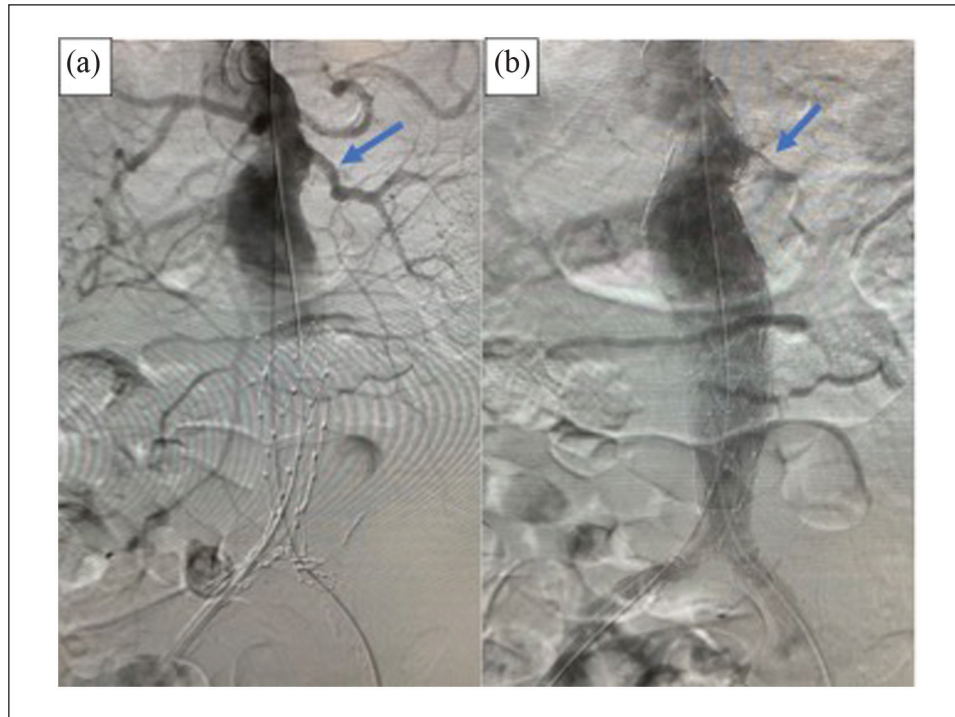


Figure 3. Endovascular aneurysm repair. (a) AFX2 endograft and (b) AFX2 endograft placement with a thoracic stent as a proximal cuff, normal renal perfusion—renal artery stent (arrows).

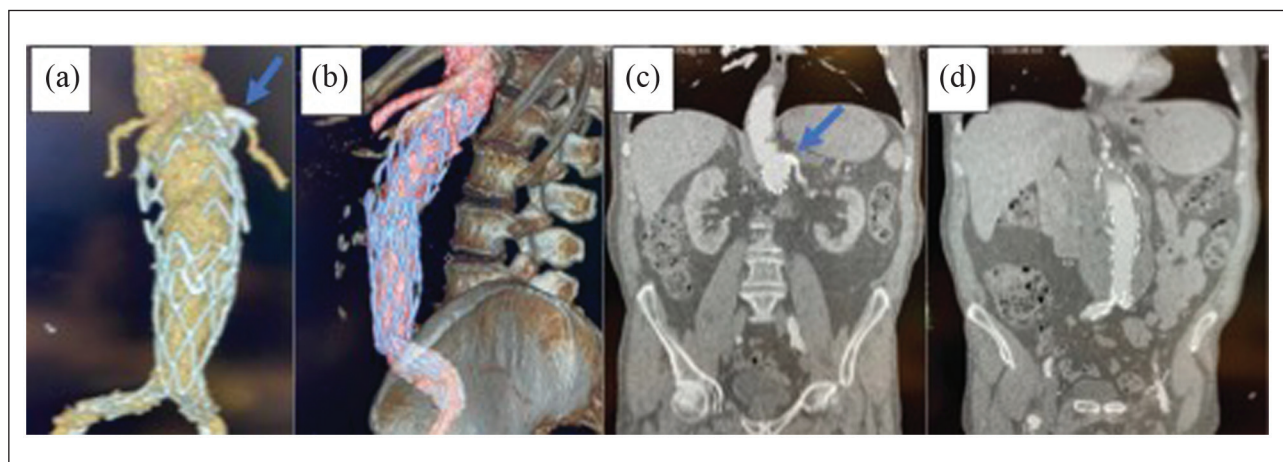


Figure 4. Follow-up CTA after 1 month. (a, b) Three-dimensional reconstruction of an adequate aneurysm sealing with no sign of endoleak or migration, (c, d) coronal view demonstrating the combined AFX2 with a thoracic stent graft, and (a, c) patent left renal artery with a stent (blue arrow).

common iliac arteries, followed by the thoracic proximal aortic cuff (length of 70 mm in all cases). The proximal sealing zone of the thoracic stent graft was the infrarenal aorta, while the two grafts had at least a 4 cm overlap to minimize the risk of a type III endoleak (TIIIEL; Figure 3). Due to impaired renal function, endovascular revascularization was performed mainly with the use of 460 ml carbon dioxide (CO₂) and 62 ml of iodinated contrast medium (ICM). The operative time was 123 min, and the fluoroscopy time was 19 min. The procedure

was completed successfully, without any type of endoleak. Therefore, immediately postoperatively, the laboratory indicators of renal function were not affected and the patient was under close monitoring by a nephrologist. The patient was discharged on the second postoperative day, fully ambulatory and in good general condition, and he was discharged with lower creatinine levels than on admission. Repeat CTA, 3 months postoperatively, showed no evidence of endoleak or migration and an adequate aneurysm sealing (Figure 4). Reevaluation of

the patient after 6 months with ultrasound examination did not reveal any pathological findings of an aneurysmal sac diameter increase or endoleak.

Discussion

The anatomical limitations in patients undergoing EVAR are a challenge for vascular surgeons and graft suppliers. A large percentage of patients do not meet the indications and are out of instructions for use (IFU) for endovascular restoration with the commercially available endograft, even if some of them are indicated for anatomical configurations.³ Perhaps the suitability of IFU grafts is fictitious, given that off-label device, users may still be appropriate if vascular surgeons decide that the patient's anatomy is suitable,⁴ but undoubtedly the current guidelines suggest avoiding EVAR outside IFU. To avoid all these limitations and to approach the patient with the most appropriate endovascular method, combinations of endograft have been proposed. Herein, we describe a patient with an infrarenal AAA, where a different enlarged aortic neck with a diameter of 31.9 mm and enlargement to 37.4 mm below the renal arteries did not allow the conventional use of an endograft, because according to the IFU of AFX2, the deployment of endograft requires non-aneurysmal aortic neck between the renal arteries and the aneurysm: with a length of ≥ 15 mm, with a diameter of ≥ 18 mm and ≤ 32 mm, and with a neck angle of $\leq 60^\circ$ to the body of the aneurysm (<https://eifu.endologix.com/hcp/endologix/all?keycode=ELX10050>). According to these limitations, the patient was a candidate for open surgery to restore AAA, but the patient's risk factors were prohibitive and dangerous for open AAA reconstruction. On the other hand, the Ankura™ TAA Stent Graft System (Lamed GmbH; Gleißentalstraße 5a, Oberhaching, Germany) is indicated for endovascular repair of patients with thoracic aortic aneurysms requiring morphology suitable for endovascular repair, an aortic inner diameter in the range of 18–44 mm, and ≥ 15 mm non-aneurysmal aorta proximal and distal to the lesion (<http://www.lifetechmed.com/upload/20220923/17140f82.pdf>). However, the combination of the AFX2 endovascular AAA system and Ankura™ TAA Stent Graft System specifications allowed the application of an endovascular approach with a satisfactory result. The Endologix AFX2 AAA endograft system differs from the other approved EVAR systems because it is the only unibody main body component deployed directly to the aortic bifurcation and is then complemented by an aortic infrarenal or suprarenal extension cuff. It was considered ideal for many reasons, including reverse tapered or bulging necks, just like our patient's case.⁵ Due to the large neck of the AAA and the possible type of intraoperative Ia endoleak,^{6–9} the AFX2 endograft was combined with a thoracic stent, which sealed the neck, without a final angiographic image of the endoleak.

A problem that cannot be ignored is the risk of accelerated erosion and hydrolysis, resulting from the combination of

two different components of the two grafts, resulting in a fracture or endoleak of the graft. AFX2 consists of polytetrafluoroethylene (PTFE) and a cobalt-chromium-nickel mixture, while the thoracic stent is made of PTFE and nitinol. According to a study, nitinol stents have the lowest susceptibility to corrosion and the longest period without damage than the cobalt-chromium-nickel alloy, which is the worst-performing material of which the AFX is composed.¹⁰ Regarding the combination of endografts we used for our patient, the Ankura™ TAA Stent Graft is made of nitinol, which is the most corrosion resistant of these materials and is in direct contact with the aortic wall, while the AFX2 is anchored to the bifurcation of the aorta.

According to recent studies, another problem arising from AFX2 is TIIIEL, which has been recorded at high rates.^{8,11–13} Hoshina et al.⁸ reported a series of 175 patients repaired with AFX2 endograft in combination with aortic cuffs, recording low rates of types IIIa and IIIb endoleaks and higher rates of sideways displacement and migration in the midterm (3.1%), which could cause future type IIIa endoleaks.⁸ On the other hand, Ankura is a suprarenal nitinol stent graft that fixes inside the aorta at the level of the renal arteries, where proportions of endoleaks and repeat interventions were 11.4% and 7.6%, respectively, which is consistent with literature data on elective EVARs.¹¹ According to early- and mid-term complication rates, these rates are comparable to those of other stent grafts with suprarenal fixation.^{14–16}

Recently, Gennai et al. reported their experience on outcomes, and risk factors of TIIIELs after EVAR. They analyzed 2565 EVAR cases over 26 years and 95 (3.7%) TIIIELs were diagnosed at a median interval of 49.5 months. Moreover, they highlight that the combination of different endograft is a risk factor for TIIIEL, concluding that old endograft, the implantation of nonproprietary extensions, large AAAs, and angulated and calcified necks are risk factors for TIIIEL that require careful follow-up due to the high rate of recurrence.¹⁷

According to Chang et al.,¹¹ of 33 patients treated with AFX2, over 2 years, 14.1% developed type 1 and type 3 endoleaks.¹¹ In a 5-year cohort study, 460 patients were treated with AFX2, and the type Ia and type III endoleaks rates at 4 years appear to be within acceptable limits.¹³ The first reports of graft combination a decade ago referred to treating endoleaks,^{18,19} while recent ones mainly refer to complex aortoiliac anatomy.²⁰ de Bruijn et al.²⁰ combined the AFX and Valiant Captiva endograft for the treatment of large-diameter aortic necks and small aortic bifurcations. One patient to five suffered type 1a and 1b endoleaks at 1.5 years of follow-up.²⁰

Matsagkas et al.²¹ combined the AFX main body with a different proximal aortic cuff to treat 14 patients with an AAA. No re-intervention was needed during a median follow-up period of 13 months (range 6–28 months).²¹ All studies conclude that the AFX2 endograft in combination with aortic cuffs is not suitable for all patients and is individualized

according to the patient's anatomy. Also, patients should be monitored closely, due to the possibility of adverse events of type III endoleak or any other devices.²² No endoleak was noticed perioperatively, at the reevaluation examination and the follow-up CTA 1 month later, and at the follow-up ultrasound examination, which was performed 6 months after the endovascular procedure, with the planning of a next follow-up in 6 months as a preventive check to avoid a possible endoleak.

ICM is considered the gold standard in patients undergoing EVAR but is related to nephrotoxicity and allergic reactions. Carbon dioxide (CO₂) has been suggested as an alternative non-nephrotoxic contrast media agent, especially for patients with chronic kidney disease and impaired renal function.²³ Bussutti et al., showed that the administration of either CO₂ alone or along with low-dose ICM is safer than full-dose ICM alone, lowering the incidence of post-contrast acute kidney injury.²⁴ Moreover, a significant worsening of renal function in patients treated with a standard dose of ICM in 1-year follow-up was observed, which can lead to chronic kidney damage that affects long-term renal outcomes.

In our patient, the endovascular procedure was performed in an adequately equipped operating room mainly using CO₂ and ICM as a diagnostic angiography material, because of the patient's impaired renal function. The creatinine levels of the patient were better than the admission and is under nephrology evaluation.

Undoubtedly, in difficult anatomies of large vessels and mainly of the aorta, there is always a dilemma and concern for the choice of the correct surgical direction. In patients with anatomic challenges precluding EVAR use in IFU, open repair or Branched Endovascular Aneurysm Repair (BEVAR)/Fenestrated endovascular repair (FEVAR) remains an important choice. Therefore, the combination of different grafts is an off-label procedure to use in very selected cases, unfit for OR or complex endovascular aortic procedures, and is a feasible solution after careful preoperative study and planning of the operation.

Conclusion

The AFX2 endograft can be combined with other types of endograft cuffs in complex anatomies as an off-label procedure for a safe and effective result in treating AAA disease. The close short-term and long-term monitoring of the patient is considered necessary and important, due to the increased possibility of type III endoleak.

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Patient's consent

The authors declare that there is a patient's consent regarding the publication of this article.

Ethics approval

Our institution does not require ethical approval for reporting individual cases or case series.

Informed consent

Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

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