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Results of AFX Unibody Stent-Graft Implantation in Patients With TASC D Aortoiliac Lesions and Coexistent Abdominal Aortic Aneurysms

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Abstract

Purpose: To describe results of AFX unibody stent-graft treatment for TransAtlantic Inter-Society Consensus (TASC) D aortoiliac occlusive disease (AIOD) with coexistent abdominal aortic aneurysm (AAA). **Methods:** A retrospective analysis was conducted of 21 consecutive patients (mean age 73.6±6.4 years; 17 men) with TASC D AIOD plus AAA (diameter >3.5 cm) treated electively using the AFX stent-graft. Common iliac artery (CIA) and external iliac artery (EIA) stenosis or occlusion was reported. Outcome measures were technical and clinical success, improvement in ankle-brachial index (ABI), and improvement in Rutherford category. Immediate and midterm patency, AAA exclusion, major adverse events (MAE), and mortality were also evaluated. **Results:** After AFX deployment (100% technical success), 18 EIAs required adjunctive stenting (none required in the CIA). One patient required a reintervention for closure device failure. At 30-day follow-up, no death or MAE was recorded. Improvement in ABI was registered in all patients (mean 0.91±0.11), with 100% primary patency. At a mean follow-up of 25.2±11.1 months, primary patency was maintained in all cases. No death or amputation occurred; 2 patients had a myocardial infarction. Improvement in ABI was maintained (0.88±0.13) as well as Rutherford category. **Conclusion:** This study examined the use of the AFX unibody stent-graft for the treatment of TASC D AIOD with concomitant AAA. The AFX stent-graft appears to be a safe and effective solution for these complex lesions, with low morbidity and mortality.

Keywords

abdominal aortic aneurysm, aortoiliac occlusive disease, common iliac artery, external iliac artery, occlusion, stenosis, TASC D lesion, unibody stent-graft

Introduction

The TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) describes several different presentations of complex type D infrarenal aortoiliac occlusive disease (AIOD) and strongly suggests open surgical treatment with aortobifemoral bypass for all these complex lesions.[1,2] However, in recent years, several authors have proposed an endovascular approach for TASC D lesions despite these recommendations. Consequently, endovascular techniques are becoming a first-line therapy due to the potential to provide a less invasive treatment associated with reduced morbidity and mortality.[3–6]

The most widely investigated procedure for this indication, "kissing stents," demonstrates good results, despite technical challenges and increasing procedure complexity. Moreover, kissing stent patency may be compromised due to radial size mismatch between the stents and the distal aorta.[3] Finally, the covered endovascular reconstruction of the aortic bifurcation (CERAB) technique was developed to overcome the anatomical and physiological disadvantages of kissing stents. The first published results suggest that this

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technique is a safe and feasible alternative to open surgical reconstruction of the aortic bifurcation.[7] Both solutions are limited in cases of concomitant abdominal aortic aneurysms (AAAs).

Recently, Maldonado et al[6] proposed a novel application of the AFX unibody stent-graft (Endologix, Irvine, CA, USA) for AIOD. This low-profile, unibody stent-graft preserves the aortic bifurcation, theoretically offering AAA patients several advantages inherent to endovascular techniques. In the authors' experience, TASC C/D lesions were successfully treated, but patients with concomitant AAA >3.5 cm were excluded from analysis.[6]

Currently, limited data are available regarding the endovascular treatment of complex TASC D AIOD lesions with concomitant AAA, so the aim of this study was to describe the results of AIOD revascularization in patients with coexistent AAA treated using the AFX stent-graft.

Methods

Study Design

A single-center study approved by the institutional review board was conducted to retrospectively evaluate the safety and efficacy of the AFX stent-graft implanted in patients with TASC D AIOD plus AAA between January 2013 and December 2016. The primary indication for treatment was AIOD-related symptoms, but 2 patients had AAAs >5.0 cm. Lesion morphology was assessed from preoperative contrast-enhanced computed tomography (CT) scans performed using a 64-row CT scanner at a slice thickness of 1 mm with and without contrast during the arterial and venous phases. All measurements were performed using a dedicated tool of the Osirix-MD software (Pixmeo, Geneva, Switzerland) and center lumen line reconstruction.[8] Common iliac artery (CIA) and external iliac artery (EIA) stenosis, aortic bifurcation diameter, and narrowest EIA diameters were measured; patency of the internal iliac artery (IIA) and superficial femoral artery (SFA) was recorded.[9]

The choice of endovascular procedure was based on preoperative anatomical and morphological characteristics, operator experience, and patient preferences. Written informed consent was obtained after discussion of all procedure-related risks and benefits, including the off-label use of the AFX device.

Endovascular Technique

Endovascular procedures were performed by vascular surgeons in an operating theatre equipped with a portable fluoroscopy unit (Euroamplin Alien; Eurocolumbus, Milan, Italy). Bilateral surgical cutdowns under general anesthesia were done in 5 patients, while 13 patients had a percutaneous approach under local anesthesia. For the latter cases hemostasis was achieved in a "pre-close" fashion using the Perclose Proglide device (Abbott Vascular, Redwood City, CA, USA). If common femoral artery (CFA) endarterectomy was necessary, a single percutaneous access was obtained, reserving a surgical cutdown for main body access; no iliac conduits were needed for graft insertion.

Subsequent to femoral access, the iliac stenosis was crossed with a 0.035-inch guidewire, followed by predilation with a noncompliant 6- to 8-mm balloon and deployment of the AFX stent-graft for isolated AAA disease.[10] In the setting of total occlusion, accurate AFX placement required that recanalization of the distal aorta occurred close to the aortic bifurcation, as previously described.[6] Total occlusions were managed by intraluminal recanalization whenever possible. For unilateral occlusion, recanalization was achieved from the contralateral femoral artery, without brachial or axillary access or reentry devices. In bilateral CIA occlusions, the shorter lesion was approached first in retrograde fashion then the contralateral, more complex lesion was recanalized via the same access. After recanalization, predilation was performed as described above. Neither fibrinolysis nor debulking techniques were utilized. No reinforcing bare metal stents were implanted in the CIA in this series, while self-expanding stents were implanted in the EIA when needed [Zilver (Cook Medical, Bloomington, IN, USA) or Everflex (Medtronic Inc, Santa Rosa, CA, USA)]. After full AFX deployment, the entire graft was balloon molded with simultaneous balloon dilation of the iliac limbs (Figure 1). Standard endarterectomy, when needed, was routinely performed prior to surgical access closure after endovascular device removal and completed using an interposition Dacron graft.[11]

Follow-up Protocol

The follow-up protocol included a patient interview, physical examination, ABI, duplex ultrasound scan, and CT at 30 days. Duplex was repeated at 3 and 6 months, at 1 year, and yearly thereafter. All patients underwent CT 1 year after the index procedure, without further CT examinations in the absence of complications detected by ultrasound.

Endpoints and Definitions

Outcome measures included primary clinical and technical success, as well as 30-day and midterm patency determined by duplex ultrasound imaging. Loss of patency (>50% stenosis) was indicated by a peak systolic velocity ratio >2.4. Successful AAA exclusion, major adverse events (MAEs), all-cause mortality, and procedure-related mortality were also reported. Clinical success was defined as improvement in ankle-brachial indices (ABI) and of 2 or more Rutherford

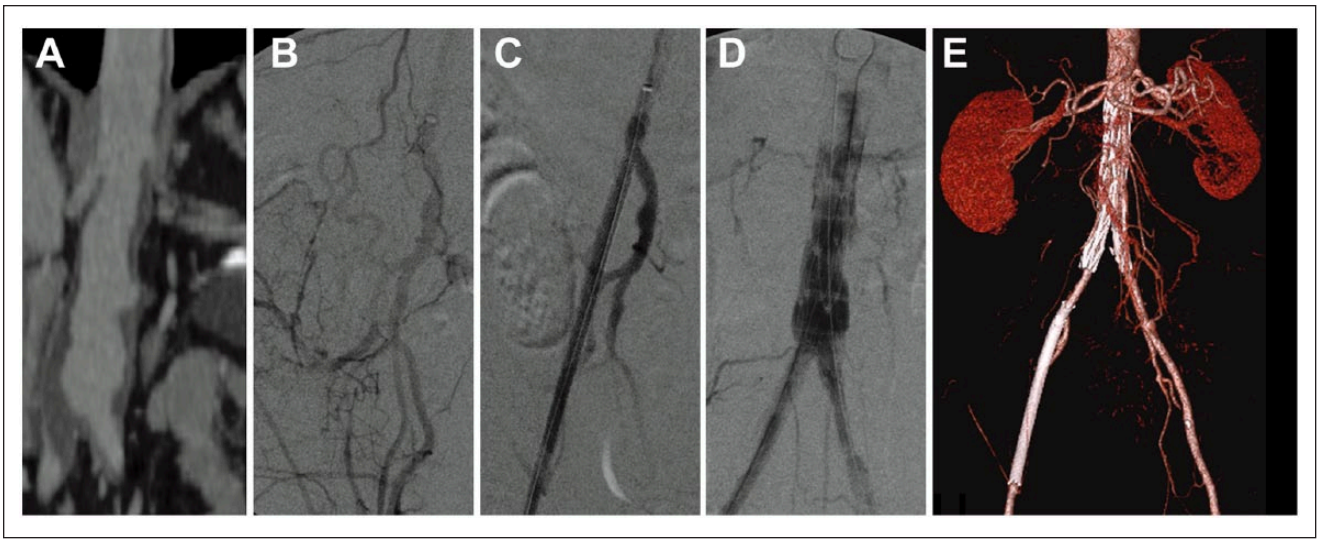

Figure 1. (A) Multiplanar reconstruction of preoperative computed tomography scan showing TransAtlantic Inter-Society Consensus D aortoiliac occlusive disease associated with abdominal aortic aneurysm. (B) Intraoperative angiography showing the long right external iliac artery occlusion (REIA) after ipsilateral common iliac artery (CIA) recanalization. (C) REIA recanalization and stenting, preserving the internal iliac artery. (D) Completion angiography showing AFX unibody stent-graft full expansion and complete AAA exclusion. (E) Volume rendering view from the 30-day computed tomography (CT), confirming complete AAA exclusion and patency of all treated vessels.

categories.[12] Technical success was defined as successful implantation of the AFX stent-graft and iliac vessel revascularization at completion angiography. The AAA was considered successfully excluded in the absence of type I or III endoleaks and type II endoleaks with sac enlargement >5 mm. Patency was defined per the Society for Vascular Surgery standards.[13] Primary patency was defined as uninterrupted flow in the treated aortoiliac segment without occlusion or reintervention. MAE included any death, myocardial infarction (MI), stroke, and adverse limb events [major (above ankle) or minor (below ankle) amputation]. Continuous data are summarized as the means ± standard deviation; categorical data are given as the counts.

Patient Sample

Twenty-one consecutive patients (mean age 73.6±6.4 years, range 57–89; 17 men) with TASC D lesions and concomitant AAA were among 93 patients treated in our university hospital for AIOD during the observation period. Demographic data, risk factors, baseline Rutherford category, and anatomical details are reported in Table 1. Mean AAA diameter was 36.2±4.8 mm (range 35–51), and mean aortic neck length was 12.4±5.5 mm (range 4–20). Four patients had a CIA occlusion, bilateral in one. Mean minimum EIA diameters were 5.7±2.2 mm (range 0–8) on the right and 6.8±1.1 mm (5.5–8.5) on the left side; 2 patients had chronic EIA occlusion. The left IIA was patent in all but 1 patient, while the right IIA was patent in 19 patients. A unilateral SFA occlusion was present in 5 patients and bilateral occlusion in one.

Results

Technical and clinical success was achieved in all cases. No immediate surgical conversion or intraoperative unplanned adjunctive procedures were required, and no adverse events occurred during the endovascular procedures. Intraluminal recanalization was feasible in only 2 CIA occlusions (1 retrograde); the remaining 3 CIA and 2 EIA occlusions were crossed subintimally.

Following recanalization and AFX bifurcated graft implantation, 1 patient required suprarenal active fixation with an Endurant aortic cuff placement (Medtronic Inc) because of a 4-mm angulated aortic neck, while 4 patients required infrarenal proximal extension with a standard AFX proximal cuff. Eighteen EIAs with a stenosis >50% required stenting with 22 nitinol stents (5 Zilver, 17 Everflex; dual stent placement in 4 long lesions). At completion angiography, no type I or III endoleak was detected in our series, but 4 type II endoleaks were evident. Renal artery patency was confirmed in all patients at the end of the procedure; no IIA ostium coverage was observed. CFA patch angioplasty was performed in 4 patients, 1 bilaterally.

Mean operative and mean fluoroscopy times were 130±32 and 24±9 minutes, respectively; mean total contrast volume was 49±13.6 mL. None of the patients required blood transfusions or intensive care unit stay. One patient

Table 1. Characteristics of the 21 Patients in the Present Series.[a]

Age, y	73.6±6.4
Men	17
Hypertension	18
Dyslipidemia	14
Diabetes	13
CAD	9
Smoking	16
COPD	9
CRI	7
Rutherford category	
2	4
3	14
4	3
AAA diameter, mm	36.2±3.8
Aortic neck length, mm	12.4±5.5
Aortic neck diameter, mm	17.8±3.9
Aortic bifurcation diameter, mm	13±2.3
RCIA percent stenosis	
0–49	2
50–69	2
70–99	14
100	3
LCIA percent stenosis	
0–49	1
50–69	5
70–99	
100	2
REIA percent stenosis	
0–49	12
50–69	4
70–99	3
100	2
LEIA percent stenosis	
0–49	12
50–69	6
70–99	3
Occlusion length, mm	
RCIA	30.3±10.8
LCIA	30.5±2.1
REIA	53±2.8
Narrowest REIA diameter, mm	5.7±2.2
Narrowest LEIA diameter, mm	6.8±1.1

Abbreviations: AAA, abdominal aortic aneurysm; CAD, coronary artery disease; CIA, common iliac artery; COPD, chronic obstructive pulmonary disease; CRI, chronic renal insufficiency; EIA, external iliac artery; L, left; R, right.

[a]Continuous data are presented as the means ± standard deviation; categorical data are given as the counts.

underwent a reintervention for acute limb ischemia due to CFA occlusion by the Proglide suture. After stitch removal and endarterectomy, the artery was repaired with a Dacron patch. Mean postoperative hospital stay was 3.75 days. At hospital discharge mean ABI was 0.91±0.11; 17 patients experienced a >80% improvement in the preoperative value.

All patients underwent scheduled duplex and CT at the 30-day follow-up. No high-flow endoleaks were visible on CT, while 3 type II endoleaks were still evident, each without sac enlargement. All AFX devices and iliac vessels were patent, with no suggestion of graft limb compression or infolding. No major adverse events or reinterventions were noted. All patients had improvement in ABI (mean 0.91±0.11; 17/21 >80%) and >2-level increase in the Rutherford category.

Mean follow-up was 25.2±11.1 months (range 5–40); 18 of 21 patients completed 12-month follow-up. All treated aortas and iliac vessels were patent at the latest imaging surveillance without further intervention except for 2 patients who required stenting for disease progression in their untreated EIAs. No AAA-related adverse events were registered, and all type II endoleaks spontaneously resolved based on the CT examination. No deaths or amputations occurred in the present series, while 2 patients suffered a MI. ABI improvement was maintained (0.88±0.13), with a >80% increase compared to baseline in 16 patients. At the last visit, the Rutherford categories were 0 (n=3), 1 (n=17), and 2 (n=1).

Discussion

The current debate on the optimal operative management of complex TASC D AIOD is related to which of the two available techniques, either open or endovascular, is superior in terms of clinical and technical outcomes.[14] The durability offered by open surgery could be balanced by the lower morbidity and mortality provided by endovascular techniques.[15,16] Aortobifemoral bypass is considered the gold standard of repair, with 90% patency at 5 years and 75% at 10 years.[17] Aortobifemoral bypass has a 3% to 8% mortality and 10% morbidity with complications such as graft failure (3%) and graft infection (1%).[18,19] These high complication rates have supported the use of the "kissing stents" technique for AIOD as a safer and effective alternative, even though midterm primary patency ranges from 84% to 92%.[20–22] Moreover, Danczyk et al[23] demonstrated that failed endovascular therapy for AIOD will not result in a worse outcome if secondary open surgery is required. Thus, endovascular treatment of TASC D AIOD lesions in the absence of aortic ectasia or aneurysm is being more widely adopted, including in patients fit for open repair.[4,14,15]

However, a concurrent true AAA (even though small) could influence the clinical and technical aspects related to endovascular therapy. Notably, a recent study showed that aortic outflow occlusion is strictly related to the risk of AAA rupture and recommended early elective AAA repair in patients with AIOD to minimize the rupture risk.[24] That suggestion reinforces the indication used for patients treated in the present series.

Uncovered or covered aortic bifurcation kissing stents intuitively do not represent the procedure of choice in TASC D aortoiliac lesions due the inability to protect infrarenal AAA from further dilatation and risk of rupture. The CERAB technique, theoretically suitable for treating TASC D lesions with concomitant AAAs via covered aortic stent implantation, is no longer a reliable solution. In their recent experience in a large series of 88 TASC D lesions, Grimme et al[7] reported 16 mm as a maximum stent diameter, clearly insufficient for 10- to 23-mm aortic neck diameters in the present series. Bifurcated stent-grafts, indeed, are the currently available option.

To the best of our knowledge, only 2 standard aortic stent-grafts have been used in off-label fashion to treat AIOD. Zander and coworkers[25] adopted the Excluder (W.L. Gore and Associates, Flagstaff, AZ, USA) and 2 investigators employed the AFX unibody stent-graft.[6,26] Unfortunately, data from these series are only partially comparable to ours; all our patients had concomitant AAAs compared to half of the patients in Van Haren's series.[26] AAAs were excluded by protocol in the other reports.[6,25] Notably, despite different indications and procedural choices, a reentry device was never necessary in any series.[6,25,26]

Zander and colleagues[25] described excellent long-term patency after 8 years in TASC C/D AIOD lesions, with a primary patency of 85.7% and 100% secondary patency. This work brought to light important limitations related to using an Excluder device in patients with complex AIOD: the inability to achieve recanalization of the occluded segments and the challenge of a narrow aortic diameter.[25] Neither of these limitations was encountered in the present series because the occluded segment never extended to the infrarenal aorta and the AFX could be deployed in very narrowed aortas (10 mm) without adjunctive technical manipulations, such as repeated progressive dilation or kissing stenting.

Consistent with those results, Maldonado and coworkers[6] reported 100% technical success in 91 TASC A-D lesions treated using the AFX, with an acceptable rate of complications and 30-day mortality. Nine (10%) patients required secondary interventions, with secondary patency of 100%. Notably, in their experience, almost 60% of patients required a kissing stent at the aortic bifurcation, extending into the CIAs. That necessity was not evident in our experience, but once again, this difference could be explained by the absence of occlusion extending to the infrarenal aorta.

Finally, Van Haren et al[26] reported AFX results among 10 high-risk patients treated for TASC D AIOD. Of them, 5 patients presented coexistent AAA (2 were an adjunctive indication for treatment due to diameter). Technical success was 100%, with 2 patients requiring brachial access (not necessary in the present series). In their experience,[26] primary and secondary patency rates were 80% and 100%, respectively.

Consistent with the above-mentioned experiences,[6,25,26] our data showed promising results for this technique in AIOD patients with AAA, achieving 100% primary patency at up to 2 years in our small cohort. Of course, proper device characteristics[13,27] influenced our decision to use the AFX unibody stent-graft. In addition to its well-known anatomical fixation mode, AFX has several unique features. The endograft is constructed of a self-expanding endoskeleton made of Elgiloy (cobalt-chromium alloy), which is notable for its corrosion resistance, high strength, ductility, and good fatigue life.[27] Despite recently reported adverse events, particularly type III endoleaks and consequent suspension of the marketing approval of the AFX in Europe,[28] no case in this series has had device-related failure, even in very narrow and calcified aortic bifurcations.

Limitations

A major shortcoming of this study is the fact that only 4 patients had 5 proximal occlusions, which could represent a selection bias that would partially explain the good results. Also, our data were from a retrospective study without a randomized control group. In addition, the series comprised a relatively small number of patients from a single group.

Conclusion

Our data seem to support the use of the AFX stent-graft in this subgroup of patients with TASC D AIOD and AAA, with satisfactory midterm results and acceptable risk for patients.

Authors' Note

This study was presented as an e-poster at the Vascular Annual Meeting (May 31–June 3, 2017; San Diego, CA, USA).

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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