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# Treatment of Aortoiliac Occlusive Disease with the Endologix AFX Unibody Endograft

**T.S. Maldonado [a,*], G.G. Westin [a], O. Jazaeri [b], M. Mewissen [c], M.M.P.J. Reijnen [d], A.J. Dwivedi [e], H.E. Garrett, Jr. [f], A. Dias Perera [g], T. Shimshak [h], V. Mantese [i], C.J. Smolock [j], Z.M. Arthurs [k]**

[a] New York University Langone Medical Center, New York, NY, USA
[b] University of Colorado Denver, Denver, CO, USA
[c] Vascular Center at St. Luke's Medical Center, Milwaukee, WI, USA
[d] Rijnstate Hospital, Arnhem, The Netherlands
[e] University of Louisville, Louisville, KY, USA
[f] University of Tennessee, Baptist Memorial Hospital Memphis, Memphis, TN, USA
[g] University of Tennessee, Cardiovascular Surgery Clinic, PLLC, Memphis, TN, USA
[h] Wheaton Franciscan Healthcare, Milwaukee, WI, USA
[i] Mercy Clinic Vascular Specialists, St. Louis, MO, USA
[j] Cleveland Clinic, Cleveland, OH, USA
[k] San Antonio Military Medical Center, Uniformed Services University of the Health Sciences, San Antonio, TX, USA

**WHAT THIS PAPER ADDS**

Treatment of aortoiliac occlusive lesions with a unibody stent-graft positioned at the aortic bifurcation has several potential advantages for the treatment of aortoiliac occlusive disease (AIOD): it can preserve the aortic bifurcation, avoid limb competition in the distal aorta, allow for future endovascular interventions, and protect against potentially fatal aortoiliac rupture in heavily calcified lesions. The current study examines the safety, efficacy, and early patency rates of the Endologix AFX unibody stent-graft for treatment of AIOD. This is the largest study examining the use of the Endologix AFX unibody stent-graft for the treatment of AIOD. The results of this study offer a significant contribution to the treatment of AIOD.

**Objective/Background:** Aorto-bifemoral bypass remains the gold standard for treatment of aortoiliac occlusive disease (AIOD) in patients with advanced (TASC D) lesions, but has significant associated morbidity and mortality. Treatment with a unibody stent-graft positioned at the aortic bifurcation is a potential endovascular option for the treatment of AIOD. The current study examines the safety, efficacy, and early patency rates of the Endologix AFX unibody stent-graft for treatment of AIOD.

**Methods:** A multicenter retrospective review was conducted of patients treated exclusively for AIOD with the AFX device. Primary, assisted primary, and secondary patency rates were noted. Clinical improvement was assessed using Rutherford classification and ankle brachial index. Mean duration of follow-up was 22.2 $\pm$ 11.2 months. Ninety-one patients (56 males [62%]) were studied.

**Results:** Sixty-seven patients (74%) presented with lifestyle-limiting intermittent claudication and the remaining 24 (26%) had critical limb ischemia. Technical success was 100%. Complications included groin infection ($n = 4$ [4%]), groin hematoma ($n = 4$ [4%]), common iliac rupture ($n = 4$ [4%]), iliac dissection ($n = 4$ [4%]), and thromboembolic event ($n = 3$ [3%]; one femoral, one internal iliac artery, and one internal iliac with bilateral popliteal/tibial thromboemboli). Thirty-day mortality was 1% (1/91) resulting from a case of extensive pelvic thromboembolism. At 1 year, 73% of patients experienced improvement in Rutherford stage of $-3$ or greater compared with baseline. Nine patients (10%) required 16 secondary interventions. At all time points, primary patency rates were $>$ 90%, assisted patency rates were $>$ 98%, and secondary patency rates were 100%.

**Conclusion:** This is the largest study to examine the use of the Endologix AFX unibody stent-graft for the treatment of AIOD. Use of the AFX stent-graft appears to be a safe and effective endovascular treatment for complex AIOD.



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* Corresponding author.
*E-mail address:* thomas.maldonado@nyumc.org (T.S. Maldonado).



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## INTRODUCTION

In recent years, the shift in vascular surgery from open surgical intervention to endovascular therapy has been particularly pronounced in patients with atherosclerotic occlusive disease of the aorta and iliac arteries (aortoiliac occlusive disease [AIOD]), with an 8.5-fold increase (from 0.4 to 3.4 per 100,000 adults) in iliac artery angioplasty and stenting between 1996 and 2000 alone, while aorto-bifemoral bypass rates fell by only 15% (from 5.8 to 4.9 per 100,000 adults).[1] However, for those lesions most difficult to treat with endovascular techniques (Trans-Atlantic Inter-Society Consensus [TASC II] type D lesions), aorto-bifemoral bypass (AFB) is the preferred revascularization strategy. Traditional endovascular interventions for complex AIOD, such as "kissing" stents, pose technical challenges and increase procedural complexity and risk in patients with heavily calcified aortic bifurcations or aortic thrombus. Moreover, patency may be compromised in more complex lesions owing to radial size mismatch between stents and certain stent configurations within the distal aorta.[2]

However, despite these technical limitations, endovascular therapy has the potential to reduce significantly the morbidity and mortality associated with the treatment of complex AIOD. Indeed, endovascular therapy as a first-line treatment is becoming more commonplace, with open surgery reserved as a secondary option.[3] One alternative to treat disease of both the distal aorta and the iliac arteries is the use of stent-grafts. The Endologix AFX stent-graft is a unibody, low-profile stent-graft that preserves the aortic bifurcation and has a number of the advantages inherent to endovascular techniques. The current study examines the safety, efficacy, and early patency rates of the AFX unibody stent-graft for the treatment of AIOD.

## METHODS

### *Design and data collection*

An institutional review board-approved retrospective review of patients treated exclusively for AIOD with the Endologix AFX unibody stent-graft was conducted at nine centers in the USA and one in the Netherlands. This device is approved for the treatment of abdominal aortic aneurysms (AAAs) and holds unique advantages for use in patients with aortoiliac occlusive disease, owing to its low-profile delivery system. All risks and benefits to using this device, including its off-label indication, as well as all alternatives (endovascular and open) were discussed with the patients in detail prior to surgery. Any patient with a concomitant aortic aneurysm (defined as an aortic diameter $>$ 3.5 cm) was excluded so as to assure that intention to treat was for AIOD and not for aneurysmal disease. Trained chart abstractors reviewed medical records, including operative notes, to record patient demographics, presenting symptoms, anatomic and procedural details (including need for adjunctive procedures), secondary interventions after the initial intervention, and complications.

### *Technique*

Techniques for delivery and deployment of the AFX device have been well described when treating AAAs.[4] The AFX system consists of bifurcated unibodies with short, integrated iliac limbs. All AFX endografts feature a cobalt chromium stent frame with a multilayer expanded polytetrafluoroethylene material external to the stent. The implant is delivered using a dedicated 17-Fr introducer sheath on the ipsilateral side and an auxiliary 9-Fr introducer sheath on the contralateral side. The unibody design avoids the need to cannulate the contralateral gate and allows for placement of the flow divider of the bifurcated component of the AFX system directly on the native aortic bifurcation.

Choice of anesthesia is physician- and patient-dependent, and may depend on the decision to perform adjunctive surgical interventions such as femoral endarterectomy. In this study, 41.4% of patients were treated percutaneously. Hemostasis was achieved using the Proglide (Abbott Vascular, Abbott Park, IL, USA). Intraoperative heparin dosing varied by center. However, generally, heparin was administered so as to maintain an activated clotting time $>$ 250 seconds, when possible.

There are some important nuances in technique that are unique when using the AFX device to treat occlusive disease. Most centers represented in this study used exclusively femoral access, although a brachial approach can be useful for crossing total occlusions. Generally, even for TASC B and C lesions, predilation of the iliac lesions is advisable, to minimize resistance as the AFX is delivered into the aorta and to allow for easier rotation of the device as needed. For TASC D lesions, the procedure demands that recanalization of the distal aorta occurs as close as possible to the aortic bifurcation. This will ensure that the AFX device sits directly on the aortic bifurcation and that it is not wedged on aortic debris. For these reasons, a key technique is to recanalize from one common iliac artery into the opposing common iliac artery, and then snare the wire to create a femoral-femoral wire (see Fig. 2). In this experience, the use of reentry devices was not necessary, although this may be useful to help achieve through and through femoral-femoral wire access in some cases. The aortic occlusion is then recanalized from one of the common iliac arteries. The femoral-femoral wire is then replaced with a Kumpe catheter; the SurePass wire attached to the contralateral limb is then passed through the Kumpe. This step avoids trying to snare the wire within the distal aortic occlusion. In addition, it is not necessary to place the 17-Fr sheath up to the aortic bifurcation. The sheath can be placed within 5 cm of the aortic bifurcation, and the AFX can be delivered through the common iliac and aortic occlusion. It is imperative that the chronic occlusions are predilated, preferably with bilateral 6—8 mm $\times$ 150 mm balloons. Without predilatation, there is severe resistance as the device is placed into position, and it is very difficult to rotate the device to ensure the limbs seat appropriately. Most centers represented in this study recommend that all common iliac arteries be treated with