

# Causes and Management of Failing Unibody EVAR Grafts

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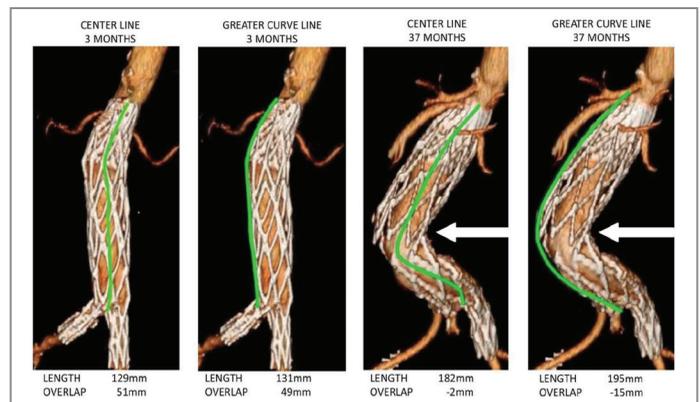
**Abstract: Objectives.** To describe the incidence of type III endoleak observed in our experience with the AFX Strata and Duraply materials (Endologix) as well as to describe endovascular management techniques to treat these graft failures. **Methods.** A total of 83 patients underwent elective endovascular aneurysm repair (EVAR) with the AFX stent-graft at a single center between 2010 and 2017. The AFX with Strata was used in 49 patients from 2010 to 2013 and the AFX with Duraply was used in 34 patients from 2014 to 2017. Main outcomes of this study were incidence of type III endoleak and associated secondary interventions. **Results.** During follow-up, serious type III endoleaks were observed in 6 patients (including 1 that resulted in rupture), all initially treated with the older AFX Strata. Overall, the type III endoleak rate was 12% with AFX Strata and 0% with AFX Duraply. All type III endoleaks were electively treated with modular bifurcated endografts with a single contralateral gate-docking limb. All repairs were technically successful and no complications have been observed during follow-up. **Conclusion.** Patients treated with AFX Strata have an elevated risk of type III endoleak, which may be treated with relining. Liberal and aggressive imaging surveillance may be warranted in these patients to aid with early detection of type III endoleak.

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**Key words:** abdominal aortic aneurysm, endoleak, endovascular aneurysm repair

Unibody endovascular aortic stent grafts have been commercially available for infrarenal abdominal aortic aneurysm repair since 2003 following United States Food and Drug Administration approval of the Powerlink system (Endologix). The device is a unibody, bifurcated, self-expanding, fully stented endovascular graft with an endoskeleton constructed as a single-wire cobalt-chromium alloy body with a double spine covered with expanded polytetrafluoroethylene (ePTFE) graft material. The graft material is sutured to the endoskeleton only at the ends of the device.

In 2011, the lower-profile AFX system was introduced that utilized a thin, conformable, ePTFE graft fabric material (Strata). However, this device was associated with numerous reports of late type III endoleak,<sup>1-3</sup> which is a separation of overlapping stent-graft components that allows blood flow to repressurize the aneurysm sac. The suspected failure mode of these type III endoleaks was progressive uncoupling of the main unibody endograft from the proximal endoprosthesis extension, particularly in cases with progressive aortic tortuosity (**Figure 1**). Furthermore, explanted unibody endografts revealed graft erosions in the region of the bifurcation, which were referred to as type IIIb endoleaks (**Figure 2**). In 2013, Endologix conducted an investigation into reports of type IIIa endoleaks (separation of bifurcated and extension stent-grafts at the point of overlap), which was followed by an investigation into type IIIb endoleaks (disruption of the stent graft material).<sup>4</sup> Endologix ultimately revised the instructions for use to recommend maximizing overlap between the main unibody and proximal endoprosthesis component.<sup>4</sup>



**Figure 1.** AFX Strata endograft with 5 cm overlap at 3-month follow-up, but uncoupling of the main unibody endograft from its proximal endoprosthesis extension due to progressive aortic tortuosity at 3-year follow-up, resulting in type IIIa endoleak.

Additionally, modifications to the endograft were implemented, with the Strata material replaced with a new graft material (Duraply). Our group has extensive experience with the AFX stent-graft in elective and urgent treatment of abdominal aortic aneurysms. The purpose of this report is to describe the incidence of type III endoleak observed in our AFX experience with the Strata and Duraply materials as well as to describe endovascular management techniques to treat these graft failures.



**Figure 2.** Explanted unibody AFX Strata endografts with graft material erosion at the bifurcation resulting in large type IIIb endoleaks requiring emergent endovascular treatment.

**METHODS**

A total of 83 abdominal aortic aneurysm patients were electively treated with the AFX stent-graft at a single center (Vascular Group of Naples, Naples, Florida) between 2010 and 2017. The AFX with Strata was used in 49 patients from 2010 to 2013 and the AFX with Duraply was used in 34 patients from 2014 to 2017. Main

outcomes of this study were incidence of type III endoleak and associated secondary interventions.

**RESULTS**

During follow-up, serious type III endoleaks (one resulting in rupture) were observed in 6 patients treated with the older AFX Strata. Overall, the type III endoleak rate in our experience was 12% with AFX Strata and 0% with AFX Duraply. All 6 failing unibody EVARs were successfully salvaged with elective endovascular repair utilizing modular bifurcated endografts with a single contralateral gate-docking limb. The choice of endograft device was based on the need to allow for repositionability of the contralateral gate limb to ease cannulation, given the technical challenge posed by the unibody endoskeleton. In addition, a preference for durable ePTFE fabric over Dacron was made to reduce the risk of recurrent type IIIb endoleaks produced by friction and/or tears with the existing unibody endoskeleton. Consequently, we selected the Gore C3 modular bifurcated stent-graft to treat all failing AFX grafts. All repairs were technically successful and no complications have been observed during follow-up.

**DISCUSSION**

Overall, EVAR with a unibody stent-graft has historically been associated with a higher incidence of type III endoleaks, which appears to be related to inadequate overlap between the main unibody device and the proximal endoprosthesis extension during

**Table 1.** Type III endoleak rates reported in studies with Powerlink and AFX stent-grafts.

Study	Device	Treatment Period	Sample Size	Follow-up	Type III Endoleak
Albertini, 2005 <sup>5</sup>	Powerlink	2000-2001	64	41 months	0%
Carpenter, 2010 <sup>6</sup>	Powerlink	2000-2008	157	12 months	0%
Coppi, 2008 <sup>7</sup>	Powerlink	1999-2007	205	42 months	0%
Helo, 2017 <sup>8</sup>	Powerlink (84%) AFX (16%) <sup>a</sup>	2002-2013	100	20 months	0%
Kouvelos, 2017 <sup>9</sup>	AFX	2014	10	23 months	0%
Lemmon, 2016 <sup>2</sup>	Powerlink, AFX <sup>b</sup>	2011-2014	83	24 months	14.4% <sup>c</sup>
Melas, 2015 <sup>10</sup>	AFX	2013-2014	21	10 months	0%
Qu, 2009 <sup>11</sup>	Powerlink	1998-2008	612	62 months	0%
Skibba, 2015 <sup>1</sup>	Powerlink (50%) AFX (50%)	2006-2014	701	–	2.4% <sup>d</sup>
Wang, 2008 <sup>12</sup>	Powerlink	2000-2003	192	49 months	0%

<sup>a</sup>Estimated values.

<sup>b</sup>Percentage of Powerlink and AFX usage not reported.

<sup>c</sup>Includes 6 with type IIIa and 8 with type IIIb endoleak.

<sup>d</sup>Includes 17 with type IIIa and 2 with type IIIb endoleak.

primary implantation. Other groups have reported similarly high rates of type III endoleak with the Powerlink or AFX stent-grafts. We systematically reviewed the literature and identified 10 clinical studies with 2145 patients who underwent elective treatment with a Powerlink or AFX stent-graft with Strata.<sup>1,2,5-12</sup> Over a median follow-up of 24 months (range, 10 to 62 months), the type III endoleak incidence ranged from 0%–14% (**Table 1**). Mimicking our experience, all type III endoleaks reported in the literature required reintervention. To our knowledge, there are no published series with the AFX Duraply stent-graft. However, Endologix states that the incidence of type IIIB endoleaks occurring after implementation of the Duraply graft process decreased by approximately 80%.<sup>4</sup>

Based on our 9-year experience using the AFX stent-graft with the older Strata material and subsequently the newer Duraply material, increased type III endoleak risk appears to be limited to the earlier-generation AFX Strata platform. We continue to use the AFX Duraply by maximizing overlap between the main body and proximal endoprosthesis extension. The AFX Strata utilized a comparatively thinner PTFE fabric and incorporated shorter overlap between the main body and proximal component, which together conferred the higher type III endoleak risk. Repair may be successfully undertaken by endovascular means. We have had great success in treating failed unibody grafts with modular bifurcated PTFE endografts that employ repositionability to overcome technical challenges posed by the unibody skeleton. Based on our experience, we recommend liberal and aggressive use of computed tomography imaging surveillance of post-unibody endograft EVARs, particularly in patients who have had AFX Strata or device implantation prior to 2014, to aid with early detection of type III endoleak.

## CONCLUSION

Patients treated with the AFX Strata have an elevated risk of type III endoleak, which may be treated with relining. Liberal and aggressive imaging surveillance may be warranted in these patients to aid with the early detection of type III endoleak. ■

*Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Miller reports consultant income from Endologix. The remaining authors report no conflicts of interest regarding the content herein.*

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