

The advantages of Aorfix™ for endovascular repair of abdominal aortic aneurysm

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Aim. The aim of this paper was to review the use of the Aorfix™ stent-graft in the endovascular repair of abdominal aortic aneurysms and to report the early results of a multicenter study conducted on patients receiving this endograft.

Methods. A retrospective review of 40 patients having the Aorfix™ stent-grafts for their aneurysm repair was undertaken at two centers. Patient notes and imaging findings were used to identify technical success, 30 day mortality, rupture rates during follow-up, postoperative complications including endoleaks, graft migration and any secondary interventions.

Results. All patients were treated successfully. Four patients required the use of proximal extensions due to severe neck angulation. There were neither deaths nor secondary interventions in the follow-up period. No incidence of graft migration or endoleaks was identified at 12 months after the procedure.

Conclusion. Early data with the Aorfix™ stent-graft shows favorable results. The device's flexible design allows safe and accurate aneurysm sac exclusion in patients with highly challenging anatomy. This is likely to increase the number of patients considered suitable for endovascular aneurysm repair, who were previously excluded from this type of treatment and also reduce the levels of endoleaks.

KEY WORDS: Aortic aneurysm, abdominal - Cardiovascular surgical procedures - Stents.

Endovascular aneurysm repair (EVAR) is a well-established treatment option for the management of infrarenal abdominal aortic aneurysms. Whilst open surgical repair of abdominal aortic aneurysms is an effective and durable treatment, it is associated with

significant peri- and postoperative morbidity and mortality, and the latter may be as high as 8% within 30 days of surgery. EVAR is a less invasive treatment and is associated with a significant reduction in aneurysm related mortality¹ in short and medium term follow-up and the proportion of aneurysms treated by EVAR has risen dramatically in the last decade. However, a significant minority of patients with abdominal aortic aneurysms are unsuitable for EVAR, due to adverse aneurysm morphology.

Factors that are unfavorable in graft deployment include aneurysm necks that are angulated, short or conical and tortuous, calcified, stenotic iliac vessels. Severe angulation at the proximal aneurysm neck is a well recognised risk factor contributing to the failure of EVAR.² A study carried out by Albertini *et al.*³ using a flow model confirmed the hypothesis that neck angulation increased the risk of type I endoleak and identified stent-graft stiffness as a cause of failure of the seal. Angulation also poses greater challenges to the delivery and deployment of standard stent-graft systems. This is especially true in tortuous iliac vessels, where rigid stent-grafts may kink and occlude,⁴ and often necessitate adjunctive stenting. These factors led to a program designed to manufacture a flexible stent-graft capable of overcoming such adverse conditions. The result of this program is the Aorfix™ stent-graft.

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This review considers the design and configuration of the Aorfix™ stent-graft including its delivery and deployment in the treatment of elective abdominal aortic aneurysms. The authors present their own experience in using this device in challenging patients together with a discussion on the advantages of this graft.

Aorfix™

Aorfix™ is a two-part modular implant comprising a bifurcated main body section and a straight contralateral limb section (the “plug in”). This device comprises a Nitinol (alloy of nickel and titanium) circular frame covered by a woven polyester fabric, resulting in an extremely compliant graft. The main body section bifurcates into a full length ipsilateral iliac section and a contralateral short leg section (the “socket”). The contralateral limb is mated during the procedure to the socket to form the complete bifurcated system.

Once implanted, the proximal end of the graft is fish mouth shaped. This, together with the four pairs of hooks at the proximal end of the graft, made of nitinol, provides resistance to graft migration.

Each of the two components of the graft is supplied preloaded into a delivery system comprising a catheter with built in deployment handle. The delivery system also includes a pair of longitudinal push rods within the graft. The push rods allow the proximal part of the graft to stay in place during deployment by retracting the outer sheath. Once the proximal part of the graft is in a good position, the push rods can be used to dilate the proximal part of the graft and then release it in that position. The contralateral socket is cannulated in a standard way and the contralateral limb placed. The ipsilateral leg is then deployed. The delivery systems are then removed and 16-French sheaths are placed. The whole graft is dilated with a moulding balloon. Radio-opaque markers made of tantalum are also available on the device to facilitate accurate deployment. The graft is shown in Figure 1.

Device fixation

Exclusion of the aneurysm is achieved mainly thanks to the radial expansion force of the stent frame

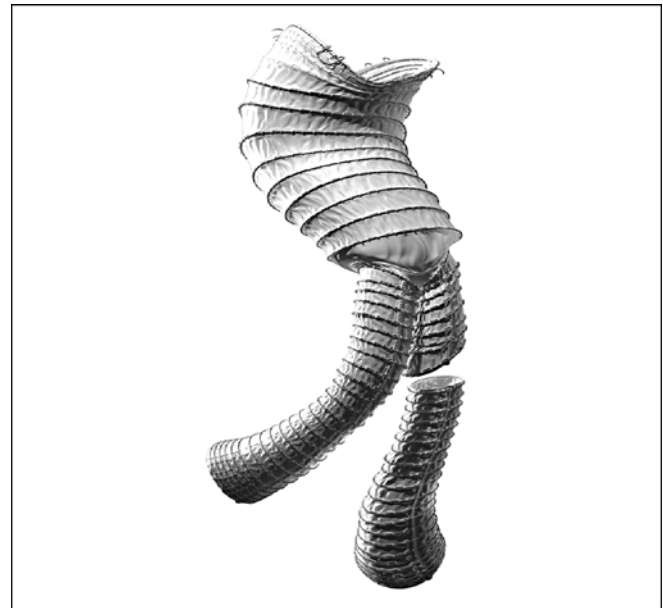


Figure 1.—Configuration of the Aorfix™ stent-graft.

in the sealing zones. Consequently, a 10-15% oversizing of the aneurysm neck and of the iliac graft by at least 1 mm but no more than 20% is critical to the success of aneurysm exclusion. Care needs to be taken when sizing the proximal fish-mouth section of the graft, as gross oversizing may cause luminal distortion.

In addition to oversizing, proximal fixation is also provided by the nitinol hooks.

Patient suitability

The device is available in a range of diameters, as illustrated in Table I, making it suitable for aneurysms with necks measuring from 21 to 29 mm in diameter. The size range available for the main body and iliac limbs are due to be expanded in the future. The unique design and the construction described above offer this stent-graft greater flexibility, facilitating its use in aneurysms with neck angulation up to 90°.

The device delivery system is also able to negotiate markedly tortuous iliac arteries, once again making endovascular repair possible in a greater number of patients. The outer diameter of the main body delivery system is approximately 7.6 mm and the plug-in

TABLE I.—*Currently available devices and their characteristics.*

Device	Material	Configuration	Deployment	Fixation	Aortic graft diameters	Iliac graft diameters	Suprarenal stent
Aorfix	Polyester	Modular	Self-expanding	Compression fit and hooks	24-31	10-20	No
Zenith (Cook)	Polyester	Modular	Self-expanding	Compression fit and barbs	22-36	8-24	Yes
Excluder (Gore)	PTFE	Modular	Self-expanding	Compression fit and anchors	23, 26, 28.5	12-14.5	No
Anaconda (Terumo)	Twillweave	Modular	Self-expanding	Compression fit and hooks	19.5-34	9-18	No

leg delivery system is 6.6 mm. In those patients with iliac diameters less than 7 mm, the use of this device is not recommended by the manufacturers, due to increased risk of device complications.

Additional complementary devices are also available to fit individual patient anatomy, including proximal extenders, distal extenders and converters. The latter device is used after implantation of the bifurcated body, if implantation of the contralateral limb proves impossible. The device converts the bifurcated main body into an aorto-uni-iliac stent-graft.

Ease of use

The deployment and delivery sequences of this graft differ from most other grafts. Some familiarity with the orientation of the proximal fish-mouth configuration of the graft is essential for a successful deployment. Once this process is mastered, the subsequent steps can be implemented with minimal difficulty.

Personal experience

Study design and method

A retrospective review of all patients having the Aorfix™ stent-grafts for their aneurysm repair was undertaken at two centers (Royal United Hospital, Bath and Freeman Hospital, Newcastle, UK). Patient notes and imaging findings were used to identify technical success, 30-day mortality, rupture rates during follow-up, postoperative complications including endoleaks, graft migration and any secondary interventions.

Neck angulation was defined as the angle between the longitudinal axis of the proximal aneurysm neck and the longitudinal axis of the aneurysm lumen.

Results

Study population

Forty (39 males, 1 female) patients underwent EVAR using the Aorfix™ stent-graft between November 2006 and January 2009. All were elective repairs. Mean age was 77.5 years (range 70-88). Mean aneurysm sac diameter was 73 mm (standard deviation 17, range 53-105). Proximal neck length mean was 24 mm (range 15-35) and proximal neck diameter mean was 24 mm (range 21-28).

Neck angulation ranged from 0 to 90°, with a median of 47.5°. Sixteen out of the 40 (40%) patients had a neck angulation greater than 60°. Iliac angulation ranged from 0 to 120°, with a median of 50°. Thirty-eight percent of patients had iliac angulation greater than 90°.

Device deployment

All procedures were performed in interventional suites, within Radiology Departments. Table II outlines the key intraoperative variables. All devices were deployed with total exclusion of aneurysm sac. Proximal extensions were required in four patients with severe neck angulation. Inadvertent internal iliac occlusion occurred in two patients. Type IV, self-limiting endoleaks were identified in four patients.

TABLE II.—*Intraoperative data - mean values with range expressed in brackets.*

Blood loss	125 mL (100-1 500)
Contrast volume	205 mL (110-580)
Fluoroscopic time	38 minutes (25-70)
Operating time	172.5 minutes (120-280)
Duration of hospital stay	4 days (2-10)



Figure 2.—A) Coronal CT reconstruction in a patient with markedly tortuous iliac arteries; B) coronal CT reconstruction in the same patient shown in figure IIA, following Aorfix™ stent-grafting.

Postprocedure results

THIRTY-DAY MORTALITY

No deaths were observed within 30 days of the procedure.

ENDOLEAKS

Computed tomography (CT) angiograms performed at 2 and 12 months postprocedure revealed no evidence of endoleaks. In all patients the aneurysm sac remained unchanged or decreased following the procedure.

GRAFT MIGRATION

No evidence of graft migration could be seen on postprocedure imaging. All grafts were patent and remained free of kinks.

SECONDARY PROCEDURES OR CONVERSIONS

None were required.

Discussion

Present data demonstrate favorable results in patients with challenging anatomy. Highly angulated proximal necks increase the likelihood of technical fail-

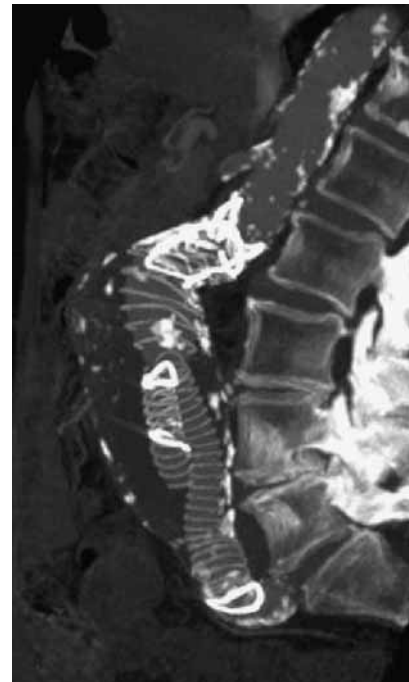


Figure 3.—Sagittal CT reconstruction in a patient with a severely angulated aneurysm neck, following Aorfix™ stent-graft repair

ure of EVAR. A number of studies^{5,6} have reported higher frequency of adverse events with increasing neck angulation.

The positive results attained so far can be attributed to appropriate patient selection, careful planning using multiplanar CT imaging, accurate selection of appropriate graft dimensions and the high degree of flexibility and conformability of the graft.

In patients with highly tortuous iliac arteries, meticulous assessment of anatomy prior to the procedure, in all three planes can help choose the side with the least angulation for the introduction of the delivery system. The use of a very stiff guide wire, such as Lundquist (Cook), is also invaluable. Caution with using push rods at proximal end in angulated necks is needed as well. In such angulated necks, the push rods may be distorted and then asymmetrically dilate and distort the graft. In these circumstances we do not use the push rods and prefer to dilate the proximal end with a moulding balloon immediately after the rods are released.

The proximal fish-mouth needs careful orientation, so that the renal vessels are placed at the troughs of the graft. Care is also needed with a low-lying supe-

rior mesenteric artery, in order to avoid the anterior peak of the fish mouth compromising its lumen. Figures 2 and 3 illustrate some patients with challenging anatomy encountered in the two centers.

The characteristics of the Aorfix™ graft, namely flexibility and trackability, allow its delivery into patients with challenging anatomy. In angulated necks, rigid grafts find it difficult to conform to the anatomy, increasing the risk of technical failure. The concentric nitinol ring structure of the Aorfix™ graft offers it greater flexibility, thereby allowing it to conform to the vessel, thus reducing the likelihood of endoleaks. This has been proven by Albertini *et al.*⁷ in a bench test study.

The ability to offer EVAR using Aorfix™ stent-grafts in patients with angulated necks and tortuous iliac arteries is more than likely to increase the proportion of patients who are deemed suitable, who otherwise would not have been considered for EVAR previously. This stent-graft can also be used in patients with standard anatomy where its use can increase operator familiarity with the device. On certain occasions, namely in patients with tortuous iliac vessels and wide proximal aneurysm necks, main bodies made by other manufacturers in conjunction with the Aorfix™ iliac limbs have been used.

Conclusions

Currently, there is no ideal graft available for the treatment of highly angulated aneurysms. Early data with the Aorfix™ stent-graft show favorable results. The results of the Aorfix™ bifurcated safety and performance trial (ARBITER-2), which has recruited

patients with marked aneurysm neck angulations between 60 and 90° is due to be published shortly. Additionally more than 70 patients with neck angles >60° have been recruited into Pythagoras in the United States. The device's flexible design allows safe and accurate aneurysm sac exclusion in patients with highly challenging anatomy. This is likely to increase the number of patients considered suitable for EVAR, who were previously excluded from this type of treatment and also reduce the levels of endoleaks.

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