

# Early Results of the Aorfix Flexible Bifurcated Endovascular Stent-Graft

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## **Introduction**

First generation stent-grafts were associated with low applicability, high conversion rates due to technical failure and low durability. Second generation stent-grafts need to address these problems in order to secure EVAR as a viable option to open repair in patients with abdominal aortic aneurysms (AAA). The early results of a second-generation stent-graft (Aorfix) for the treatment of AAA are reported.

## **Methods**

A European multi-centre study of the Aorfix bifurcated endovascular stent-graft. The Aorfix stent-grafts were inserted in four centres experienced in EVAR and all data was collected prospectively on a central database.

## **Results**

A total of 24 patients underwent attempted aneurysm repair with the Aorfix stent-graft. There were no conversions to open repair. One technical failure resulted in insertion of another stent-graft. At 30-day follow-up there had been no secondary endovascular or open interventions. There were only two endoleaks, both of which were type II.

## **Conclusions**

The Aorfix currently offers early results, which are at least as good as other second-generation stent-grafts. It has given satisfactory results with highly angulated proximal necks and may improve the treatment outlook for these patients. Whether the unique design features increase durability and reduce long-term complications remains to be seen.

## **Introduction**

Endovascular aneurysm repair (EVAR) is a relatively new technique for the management of abdominal aortic aneurysms. Experiences with first generation stent-grafts in the mid to late 1990s were encouraging. However, a number of important lessons were subsequently learned from these experiences with first generation endovascular stent-grafts.<sup>1</sup>

In some series rates of conversion to open repair reached 20%.<sup>2</sup> The numbers of patients suitable for this method of aneurysm repair were limited. Stent-grafts were subject to significant morphological constraints. Calculations based on early generation stent-grafts suggested in the order of 40% of aneurysms would be unsuitable morphologically due to adverse proximal neck morphology including excessive angulation.<sup>3</sup>

Improved delivery systems associated with second generation devices permitted EVAR through tortuous and calcified iliac vessels previously thought to have been untreatable.

In addition to improved access and applicability stent-grafts required resistance to migration, identified as an important risk factor for aneurysm rupture. (REF) Current designs achieve fixation by either hooks or barbs in combination or singly. Although an alternative solution is to use a balloon expandable stent (e.g. the Palmaz stent in the Montefiore endograft system.)<sup>4</sup>

First generation designs were also prone to kinking, especially those which were not fully stented.<sup>5</sup> Others were associated with late type III endoleak, underscoring the importance of a strong durable graft fabric. In the case of Stentor (Mintec, LaCiotat, France) the problems were due to seam defects and in the case of Vanguard (Boston Scientific, Natick, Mass, USA), metallic wear of the fabric.

The Aorfix stent-graft was conceived by Julian Ellis Associates, Pearsall Sutures and B.R. Hopkinson and was developed with the aid of a Medlink grant from the U.K. government. Anson (now Lombard Medical) took on its later development. Its main design features were that it should be flexible, making it resistant to kinking and twisting and have the ability to shorten without kinking. It also has excellent fixation using very strong proximal hooks. It was hoped that these features would deal with the flaws of many of the first generation stent-grafts. The graft material itself is a polyester PET, which is very strong and puncture resistant.

## **Methods**

The Aorfix stent-graft comprises a polyester (PET) graft to which is embroidered a continuous nitinol wire (the stent). To promote a blood tight seal, the number of turns of the nitinol wire around the graft is increased both proximally and distally (**fig 1**). Fixation in the infra-renal aortic neck is further promoted by hooks, which are sutured to the proximal end of the graft (**fig 2**). There is no supra-renal fixation. All Aorfix stent-grafts reported were of a bifurcated configuration. A uniiliac version has been successfully employed over two years in patients deemed inappropriate for commercially available stent-grafts and has performed well in angulated necks and tortuous iliac arteries.

The stent-graft is available with a diameter of the main component of 24 – 31mm (in 1mm steps) and 10 – 20mm (in 2mm steps) of the iliac component. An oversizing of 2mm is recommended in the aortic neck and 1mm in the iliac component.

The Aorfix stent-graft was inserted in patients at four experienced endovascular centres in Europe (Ippokratio Hospital, University of Thessaloniki, Thessaloniki,

Greece; Medical University of Warsaw, Warsaw, Poland; University Clinics – AKH, University Hospital Vienna, Austria; University School of Medicine, Lublin, Poland).

Pre-operative morphological assessment was made using contrast enhanced spiral computed tomography (spiral CT). Calibration angiography was not required.

Morphological guidelines for inclusion in the study were an AAA >5.0cm (or symptomatic); Minimum neck length of 20mm; maximum neck diameter 29mm or less; neck angulation less than 65 degrees; iliac artery diameter 19mm or less. The overall assessment of suitability was left to the individual centre.

Stent-grafts were deployed in either an operating theatre with a mobile C-arm image intensifier or an interventional radiology suite. All operating interventionalists received pre-operative instruction on deployment of the stent-graft and were familiarised with a non-sterile sample of the implant.

A detailed description of the deployment sequence is given below. The common femoral arteries are exposed bilaterally. The introduction of the stent-graft requires catheterisation of the supra-renal aorta with a stiff guidewire. All patients received systemic anti-coagulation with 5000U of heparin. The delivery system with 22-French outside diameter (maximum external diameter 7.6mm) is then advanced over the guidewire and the stent-graft deployed below the renal arteries using X-ray screening and intermittent angiography. Screening was performed perpendicular to the axis of the aortic neck to avoid parallax errors during deployment. The stent-graft contains radiopaque markers both proximally and distally on the main body of the stent-graft and on the iliac limbs, which facilitate accurate positioning and catheterisation of the contralateral stump. Deployment proceeds on withdrawal of the translucent sheath covering the stent-graft until the 'fishmouth' is exposed. This should commence above the proposed landing point because it is always easier and more reliable to pull

the stent-graft down as it is virtually impossible to push it up. At this point, when the fishmouth is exposed it is quite easy to rotate the device and get the optimum positioning of the backs of the jaws of the fishmouth to lie just below the lowest renal artery. When the orientation of the fishmouth is satisfactory the sheath is withdrawn to just expose the short stump or 'mitt' and at this point the two 'push rods' within the delivery system are pushed up to open out the fishmouth and fix the top end of the graft into its final position. Once the position of the top of the graft is satisfactory, the push rods are released by withdrawing the fixing pins and concentration can now be turned to the lower end of the ipsilateral limb. This is done with the aid of a 4-French catheter previously left lying within the common iliac artery. It may be used for injections to demonstrate the precise position of the iliac bifurcation. At this stage when the top end has been released and the iliac limb is still firmly held within the sheath, it is very easy re-adjust the position of the bottom end of the iliac limb upwards. It is important not to deploy any of the iliac limb within the common iliac artery until the bottom end is placed correctly at the bifurcation of the iliac or just above it. Failing to do so makes re-adjustment of the position of the bottom end very difficult once the limb has been deployed. The push rods are removed with the delivery system following full deployment of the stent-graft. The iliac limb is then introduced through the stump and deployed placing the top end of the contra-lateral limb at the mark for the bifurcation of the stent-graft and again after deploying the stent-graft within the stump it is important to release the top end with the push rod so that we can adjust the position of the bottom end of the graft in relation to the iliac bifurcation. Again it is very easy to adjust the contra-lateral iliac limb bottom end upwards so long as the graft is still sheathed within the iliac limb but it is very difficult to push it upwards once the iliac limb has been released within the common

iliac artery. Again, the position of the iliac bifurcation is identified easily with a 4 French catheter lying within the common iliac artery.”(fig 3) Finally, a low pressure moulding balloon (Cook Europe or Reliant balloon from Medtronic) is inflated at the graft and artery interface and between modular components. Completion angiography is performed in the conventional manner prior to removal of the delivery system. The follow-up schedule comprised clinical review, spiral CT and abdominal X-ray (AXR) on discharge from hospital, at 30-days and six months post-operatively.

## **Results**

A total of 24 patients received the Aorfix stent-graft in the four European centres. (University of Thessaloniki, n=7; Medical University of Warsaw, n=6; University Hospital Vienna, n=1; Lublin, n=10).

The mean age of patients was 67.5 years [95% CI: 64.4, 70.5] and 23 (96%) were male. The ASA distribution was, ASA grade 1 = 1 (4.2%); ASA 2 = 14 (58.3%); ASA 3 = 8 (33.3%); ASA 4 = 1 (4.2%).

There were deviations from the recommended pre-operative aneurysm morphology. (TABLE 1) Three patients had proximal neck lengths of less than the recommended minimum of 20mm (10mm, 16mm and 18mm). One patient had a neck angle in excess of the maximum recommended angle of 65 degrees (80 degrees). Five patients had excessively tortuous and a further five excessively calcified iliac arteries. None of these patients suffered any complication.

<b>Morphological criterion</b>	<b>Mean distance [95% CI] (mm)</b>
Supra-renal diameter	24.9 [26.0, 23.7]
Neck diameter	24.1 [25.4, 22.8]
Maximum aneurysm diameter	55.1 [58.0, 52.2]
Right common iliac diameter	16.7 [19.8, 13.7]
Left common iliac diameter	15.4 [17.9, 12.9]
Neck length	29 [3.5, 2.3]
Renal artery – aortic bifurcation distance	114 [12.4, 10.4]

Seven of the 24 (29%) of patients had significant proximal aortic neck angulation. Of those with a significant neck angulation the mean was 46 degrees [95% CI: 62, 30]. Seven (29.2%) patients had moderate iliac tortuosity and another five (20.8%) with moderate calcification. Four (17%) aortic necks had a moderate amount of thrombus. The mean duration of the operation was 121 minutes [95%CI: 158, 84] with a blood loss of 251ml [95%CI: 359, 144].

In one patient the stent-graft did not deploy successfully. The stent-graft was removed without complication. Conversion to open repair was not necessary and an alternative type of stent-graft (other manufacturer) was inserted. The patient made an uneventful recovery.

There was only one endoleak at completion angiography. This endoleak was not graft related (type II) and had spontaneously sealed by 30-days.

All contralateral iliac limbs were successfully cannulated. Cannulation was achieved in less than 15 minutes in 17 (71%) patients.

In six (25%) patients unplanned iliac occlusion occurred. In four cases this was unilateral and in two bilateral. Therefore a total of eight of 48 (16.7%) internal iliac arteries were occluded. There were no major clinical sequelae resulting from these occlusions, although one case of bilateral internal iliac artery occlusion resulted in mild buttock claudication. There were no episodes of renal artery occlusion.

No patients required monitoring on an intensive care or high-dependency unit for more than one day (mean 0.3 days [95% CI: 0.6, 0.0]). Most patients remained in hospital for one week (mean 6.5 days [95% CI: 7.8, 5.3]) following the procedure and all received a spiral CT and AXR prior to discharge. At discharge there were no graft related endoleaks, however, there was one type II endoleak.

The overall mean follow-up was 60 days. All patients completed 30-day follow-up. At 30-days there were two type II endoleaks and the patient who underwent bilateral internal iliac artery occlusion continued to suffer from mild buttock claudication. All stent grafts were patent with no stent fractures or migrations. No secondary endovascular or open procedures have been required. Maximum aneurysm diameter remained unchanged in all patients.

At the time of writing only three patients have reached six-month review. There have been no adverse events in these patients. Two of three aneurysms have reduced in diameter and one remains unchanged.

## **Discussion**

One technical failure was experienced in this series. A stent-graft did not deploy properly. The stent-graft was immediately retrieved. Another stent-graft (alternative manufacturer) was successfully inserted and the patient made an uneventful recovery. The fault was isolated to an isolated error during manufacture of the delivery system, which was subsequently addressed and rectified.

There are significant problems associated with EVAR in patients with adverse proximal neck anatomy.<sup>6</sup> The accuracy with which grafts can now be deployed and the use of supra-renal fixation have permitted treatment of short necks. Necks as short as 15mm are routinely treated. In some centres there have been successes with even

shorter necks.<sup>7</sup> In this study three patients were successfully treated with necks less than 20mm.

Similarly, the some of the challenges presented by wide necks have been surmounted by the use of large diameter stent-grafts.<sup>8</sup> However, angulation has remained difficult with conventional stent-grafts. In one comprehensive review, morphology was graded according to its likelihood of modifying outcome. Angulation less than 30 degrees was scored zero (the lowest score), whilst an angle greater than 60 degrees scored three, the most severe and likely to adversely affect outcome.

In a publication from Nottingham (using modified Gianturco based stent-grafts), neck angulation was identified as the risk factor most significantly related to proximal endoleak and graft migration.<sup>9</sup> In a report from Australasia, neck angulation was an independent risk factor for the development of endoleak. The risk was multiplied in combination with other adverse morphological factors.<sup>10</sup>

The Aorfix differs from many of the currently available stent-grafts. It does not rely upon stents arranged vertically and therefore may, in theory, conform more closely to the tortuous elements of AAA. In particular it may offer a solution to the difficulties of excluding AAA with angulated necks.

Previously published in vitro experimental studies with a flow model revealed that an angle of 30 degrees or more in Gianturco based stent-grafts resulted in increased risk of proximal perigraft endoleak flow.<sup>11</sup> Our own data (as yet unpublished) suggest the Aorfix is not subject to the same risk of perigraft flow due to its unique stent design. Almost 30% of patients had significant neck angulation in the current study (mean 46 degrees). One aneurysm was successfully excluded with a proximal neck angle of 80 degrees, suggesting the maximum recommended angle of 65 degrees may be conservative. A review of the Australasian experience with the Zenith stent-graft

suggested a neck angle greater than 30 degrees did not increase the risk of proximal endoleak or migration (in contrast to the in vitro experimental model and clinical experience of others with a Gianturco based system ), but may do so if combined with other deviations from the neck parameters. They concluded the Zenith device would be suitable for neck angles up to 60 degrees (If all the other neck criteria were within the guidelines).

Aorfix maybe useful for patients with angulated necks >60 degrees and shorter necks than 20mm but it must not be forgotten that these results are the early ones and the two year results will be much more important.

Another reason for the encouraging results in patients with angulated necks may be the considerable experience of the operating teams (a recognised factor associated with an improvement in EVAR outcome).<sup>12</sup> Particular attention was paid to deployment of the stent-graft as close to the renal artery ostia as possible. In order to achieve this, the image intensifier was orientated at 90 degrees to the axis of the aortic neck.

Other techniques exist, however, both open and endovascular to deal with angulated necks. The giant Palmaz stent has been employed to affect a seal by ‘straightening out’ the aortic neck following deployment of the stent-grafts in angulated necks.<sup>13</sup> An alternative, although more invasive approach is to perform peri-aortic ligature at mini-laparotomy.<sup>14</sup> Both techniques have only been used consequent on failure of seal in the aortic neck (type I endoleak) because they carry significant risk (notably embolisation).<sup>15</sup>

An alternative in patients with difficult proximal neck morphology is the branched or fenestrated graft. Although still in their infancy these devices have been primarily

designed to manage patients with short necks. At present they do not offer any solutions for those with significant neck angulation.

The early results of the Aorfix bifurcated stent-graft are encouraging. To date the only complications have been of one delivery system failure, two persistent non-graft related (type II) endoleaks and six (25%) unplanned internal iliac artery occlusions. The problem with the delivery system has been rectified.

The early results of primary aneurysm exclusion in this study of the Aorfix are comparable with other stent-graft systems. All the Aorfix stent-graft inserted were oversized (2mm proximally and 1mm distally). The degree of oversizing differs according to manufacturer on account of the variety of stent and graft properties. However, the importance in stent-oversizing in reducing the incidence of endoleak was clearly demonstrated in evidence from the EUROSTAR database, which contained a variety of stent-grafts.<sup>16</sup> In a recent series of Talent stent-grafts deployed in the U.K., the immediate exclusion rate was 84% and one month primary exclusion rate was 92.1%.<sup>17</sup> These results are also similar to another second-generation stent-graft, which achieved an exclusion rate of 94.1% on the initial post-operative scan.<sup>18</sup> The cause of the relatively high internal iliac artery occlusion rate (16.7%) in this study is most likely accounted for by the learning curve of the various centres. Firstly, it is difficult to estimate the precise length of a stent-graft in tortuous iliacs and angulated necks and it was only as the trial proceeded that the centres became more confident in the ability to shorten any excessive length of graft that would have covered the internal iliac arteries. By meticulously placing 4 French catheters in both common iliacs and by not starting to deploy the iliac limbs until the bottom end is satisfactorily placed, internal iliac occlusion should become a rare event.

Fortunately, as was demonstrated in this study and by others, the majority of internal iliac arteries can be sacrificed with relative impunity.<sup>19</sup>

Preliminary data from this study suggests the early results of the Aorfix stent-graft are at least comparable to other second-generation devices. Aorfix may offer hope to those patients with angulated necks who were once thought untreatable by conventional aortic stent-grafts. A number of the complications of EVAR do not occur for some time. In particular, migration and graft occlusion may not occur for two years following implantation.<sup>20</sup> Others, such as endoleak and stent fracture may occur at any time.

Naturally, greater follow-up is required to ensure the continuing success of the Aorfix stent-graft in all patients, especially those with adverse anatomical features.

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## **Legends**

Figure 1) Proximal stent-graft demonstrating orientation of nitinol wire on polyester graft

Figure 2) hooks on proximal graft to engage the aortic neck

Figure 3) ‘Mitt’ on the contralateral stump to facilitate catheterisation

Table 1) Pre-operative aneurysm morphology

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- <sup>1</sup> Alric P, Hinchliffe RJ, Chuter TA et al. Lessons learned from the long-term follow-up of a first generation stent-graft. *J Vasc Surg* 2003;37:367-73
- <sup>2</sup> Thompson MM, Sayers RD, Nasim A et al. Aortomonoiliac endovascular grafting: difficult solutions to difficult aneurysms. *J Endovasc Surg* 1997;4:174-81
- <sup>3</sup> Armon MP, Yusuf SW, Latief K et al. Anatomical suitability of abdominal aortic aneurysms for endovascular repair. *Br J Surg* 1997;84:178-80
- <sup>4</sup> Ohki T, Veith FJ, Sanchez LA et al. Endovascular graft repair of ruptured aortoiliac aneurysms. *J Am Coll Surg* 1999;189:102-12
- <sup>5</sup> Parent III FN, Godaziachvili V, Meier GH et al. Endograft limb occlusion and stenosis after ANCURE endovascular abdominal aneurysm repair. *J Vasc Surg* 2002;35:686-90
- <sup>6</sup> Chaikof EL, Fillinger MF, Matsumura JS et al. Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair. *J Vasc Surg* 2002;35:1061-6
- <sup>7</sup> Greenberg R, Fairman R, Srivastava S et al. Endovascular grafting in patients with short proximal necks: an analysis of short-term results. *Cardiovasc Surg* 2000;8:350-4
- <sup>8</sup> Ingle H, Fishwick G, Thompson MM, Bell PR. Endovascular repair of wide neck AAA--preliminary report on feasibility and complications. *Eur J Vasc Endovasc Surg* 2002;24:123-7
- <sup>9</sup> Albertini J, Kalliafas S, Travis S et al. Anatomical risk factors for proximal perigraft endoleak and graft migration following endovascular repair of abdominal aortic aneurysms. *Eur J Vasc Endovasc Surg*. 2000;19:308-12.
- <sup>10</sup> Stanley BM, Semmens JB, Mai Q et al. Evaluation of patient selection guidelines for endoluminal AAA repair with the Zenith Stent-Graft: the Australasian experience. *J Endovasc Ther* 2001;8:457-64
- <sup>11</sup> Albertini JN, Macierewicz JA, Yusuf SW et al. Pathophysiology of proximal perigraft endoleak following endovascular repair of abdominal aortic aneurysms: a study using a flow model. *Eur J Vasc Endovasc Surg*. 2001;22:53-6.
- <sup>12</sup> Lobato AC, Rodriguez-Lopez J, Diethrich EB. Learning curve for endovascular abdominal aortic aneurysm repair: evaluation of a 277 patient single-centre experience. *J Endovasc Ther* 2002;9:262-8
- <sup>13</sup> Dias NV, Resch T, Malina M et al. Intraoperative proximal endoleaks during AAA stent-graft repair: evaluation of risk factors and treatment with Palmaz stents. *J Endovasc Ther* 2001;8:268-73
- <sup>14</sup> Kalliafas S, Albertini JN, Macierewicz J et al. Incidence and treatment of intraoperative technical

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problems during endovascular repair of complex abdominal aortic aneurysms. *J Vasc Surg* 2000;31:1185-92

<sup>15</sup> Tzortzis E, Hinchliffe RJ, Hopkinson BR. Adjunctive Procedures for the Treatment of Proximal Type I Endoleak: The Role of Peri-Aortic Ligatures and Palmaz Stenting. *J Endovasc Ther* 2003;10:

<sup>16</sup> Mohan IV, Laheij RJ, Harris PL; EUROSTAR COLLABORATORS. Risk factors for endoleak and the evidence for stent-graft oversizing in patients undergoing endovascular aneurysm repair. *Eur J Vasc Endovasc Surg* 2001;21:344-9

<sup>17</sup> Cowie AG, Ashleigh RJ, England RE, McCollum CN. Endovascular aneurysm repair with the Talent stent-graft. *J Vasc Interv Radiol.* 2003 Aug;14(8):1011-6.

<sup>18</sup> Hinchliffe RJ, Goldberg J, MacSweeney ST (On Behalf Of The Zenith Users Group.) A U.K. multi-centre experience with a second-generation endovascular stent-graft. *Eur J Vasc Endovasc Surg* 2004;27:51-5

<sup>19</sup> Mehta M, Veith FJ, Ohki T et al. Unilateral and bilateral hypogastric artery interruption during aortoiliac aneurysm repair in 154 patients: a relatively innocuous procedure. *J Vasc Surg.* 2001;33(2 Suppl):S27-32.

<sup>20</sup> Hinchliffe RJ, Alric P, Wenham PW, Hopkinson BR. The Durability of Femoro-Femoral Bypass Grafting Following Aortouniiliac Endovascular Aneurysm Repair. *J Vasc Surg* 2003;38:498-503