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Early results of a flexible bifurcated endovascular stent-graft (Aorfix)

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Aim. **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 endovascular aneurysm repair (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 was performed. The Aorfix stent-grafts were inserted according to a predefined clinical protocol in 4 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 2 endoleaks, both of which were type II.**

Conclusion. **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.**

Key words: Aortic aneurysm, abdominal, surgery - Aorfix endovascular stent-graft - Blood vessel prosthesis implantation.

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Endovascular aneurysm repair (EVAR) is a relatively new technique for the management of abdominal aortic aneurysms (AAA). 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.[1]

In some series, rates of conversion to open repair reached 20%.[2] The numbers of patients suitable for this method of aneurysm repair were limited. Stent-grafts were subject to significant morphological con-

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

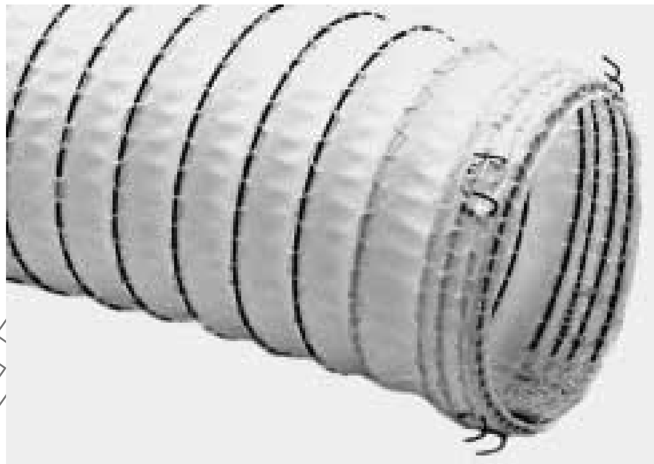

Figure 2.—Hooks on proximal graft to engage the aortic neck.

straints. Calculations based on early generation stent-grafts suggested in the order of 40% of aneurysms would be morphologically unsuitable due to adverse proximal neck morphology including excessive angulation.[3]

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.[4] 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).[5]

First generation designs were also prone to kinking, especially those which were not fully stented.[6] 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, MA, 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 UK 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. Strong proximal hooks were added to resist migration and the graft material is a polyester PET which is strong and puncture resistant. It was hoped that these features would deal with the flaws of many of the first generation stent-grafts.

Materials and 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 (Figure 1). Fixation in the infra-renal aortic neck is further promoted by hooks, which are sutured to the proximal end of the graft (Figure 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 2 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 24-31 mm (in 1 mm increments) and 10-20 mm (in 2 mm increments) of the iliac component. An oversizing of between 10% and 20% proximally in the aortic neck and 1 mm in the iliac component is recommended.

The Aorfix stent-graft was inserted in patients at 4 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).

Preoperative 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 cm (or symptomatic); minimum neck length of 20 mm; maximum neck diameter 29 mm or less; neck angulation less than 65°; iliac artery diameter 19 mm 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 preoperative 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 anticoagulation with 5 000 U of heparin. The delivery system with 22-French outside diameter (maximum external diameter 7.6 mm) 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 a “fishmouth” shape of stent-graft is exposed. This should commence above the proposed landing point because it is always easier and more reliable to pull the stent-graft down whereas it is virtually impossible to push it up. At this point, when the fishmouth is exposed it is quite easy to rotate the

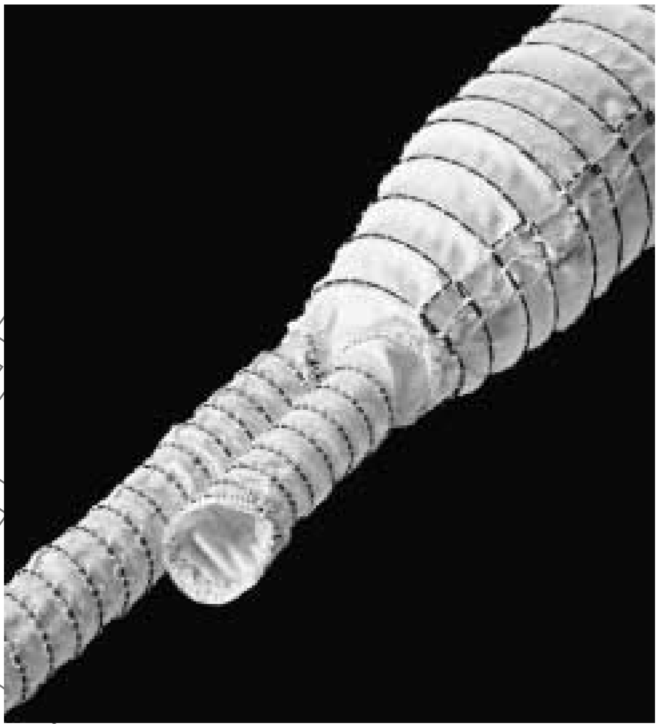

Figure 3.—“Mitt” on the contralateral stump to facilitate catheterisation.

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 2 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 common iliac artery or just above it. Failing to do so makes re-adjustment of the position of the bottom

TABLE I.—*Preoperative aneurysm morphology.*

Morphological criterion	Mean distance (95% CI) (mm)
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)

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 (Figure 3) and deployed placing the top end of the contra-lateral limb at the mark for the bifurcation of the stent-graft. After deploying the stent-graft within the stump it is important to release the top end with the push rod so that the position of the bottom end of the graft in relation to the iliac bifurcation can be adjusted. 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 relased within the common iliac artery. The position of the iliac bifurcation is identified easily with a 4 French catheter lying within the common iliac artery. 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 6 months postoperatively.

Results

A total of 24 patients received the Aorfix stent-graft in the 4 European centres (University of Thessaloniki, n=7; Medical University of Warsaw, n=6; University Hospital Vienna, n=1; University School of Medicine, 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 preoperative aneurysm morphology (Table I). Three patients had proximal neck lengths of less than the recommended minimum of 20 mm (10 mm, 16 mm and 18 mm). One patient had a neck angle in excess of the maximum recommended angle of 65° (80°). Five patients had excessively tortuous and a further 5 excessively calcified iliac arteries. None of these patients suffered any complication.

Seven of the 24 (29%) patients had significant proximal aortic neck angulation. Of those with a significant neck angulation the mean was 46° [95% CI: 62, 30]. Seven (29.2%) patients had moderate iliac tortuosity and another 5 (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 251 ml [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 occurred in a patient with 4 paired lumbar arteries. It 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 6 (25%) patients unplanned iliac occlusion occurred. In 4 cases this was unilateral and in 2 bilateral. Therefore a total of 8 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 1 day (mean 0.3 days [95% CI: 0.6, 0]). Most patients remained in hospital for 1 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 1 type II endoleak.

The overall mean follow-up was 60 days. All patients completed 30-day follow-up. At 30-days there were 2 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 3 patients have reached 6-month review. There have been no adverse events in these patients. Two of 3 aneurysms have reduced in diameter and 1 remains unchanged.

Discussion and conclusions

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 manufactuer) was successfully inserted and the patient made an uneventful recovery. The fault was traced 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.[7] However, the accuracy with which second generation stent-grafts can now be deployed and the use of supra-renal fixation have permitted treatment of shorter necks. Necks as shorter as 15 mm are routinely treated. In some centres there have been successes with even shorter necks.[8] In this study 3 patients were successfully treated with necks less than 20 mm.

Similarly, some of the challenges presented by wide necks have been surmounted by the use of large diameter stent-grafts.[9] 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° was scored 0 (the lowest score), whilst an angle greater than 60° scored 3, the most severe and likely to adversely affect outcome.[7] 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.[10] 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.[11]

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° or more in Gianturco based stent-grafts resulted in increased risk of proximal perigraft endoleak flow.[12] 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°). One aneurysm was successfully excluded with a proximal neck angle of 80°, suggesting the maximum recommended angle of 65° may be conservative. A review of the Australasian experience with the Zenith stent-graft suggested a neck angle greater than 30° 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,[12-13] 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° (if all the other neck criteria were within the guidelines).[11]

Aorfix maybe useful for patients with angulated necks >60° and shorter necks than 20 mm but it must not be forgotten that these results are the early ones and the 2 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 in improvement in EVAR outcome).[14] 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° to the axis of the aortic neck.

Other techniques, both open and endovascular, exist 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.[15] An alternative, although more invasive approach is to perform periaortic ligature at mini-laparotomy.[13] Both techniques have only been used consequent to failure of seal in the aortic neck (type I endoleak) because they carry significant risk (notably embolisation).[16]

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, 2 persistent non-graft related (type II) endoleaks and 6 (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. In a recent series of Talent stent-grafts deployed in the UK, the immediate exclusion rate was 84% and 1 month primary exclusion rate was 92.1%.[17] These results are also similar to another second-generation stent-graft, which achieved an exclusion rate of 94.1% on the initial postoperative scan.[18]

All the Aorfix stent-graft inserted were oversized (>10% and <20% proximal and 1 mm distal oversize). 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.[19]

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 as was demonstrated in this study and by others, the majority of internal iliac arteries can be sacrificed with relative impunity.[20]

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 2 years following implantation.[1, 21] 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. Aorfix may be useful for patients with angulated necks >60° and shorter necks than 20 mm. To address this last point, a further study examining neck angles up to 90° is planned.

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