Use of the Aorfix™ stent graft in patients with tortuous iliac anatomy

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Aim. Iliac limb occlusion following endovascular repair (EVAR) may result in limb threatening acute ischemia. The incidence is reported at up to 10% and is known to be influenced by iliac angulation and kinking of the stent graft. The aim of this study was to evaluate the performance of the Aorfix™ graft in tortuous iliac anatomy and examine the impact of the graft on the rate of iliac limb thrombosis following EVAR in a single UK centre.

Methods. We performed a retrospective review of all EVAR performed from May 1998 to May 2010. From November 2007, patients with highly angulated iliac anatomy were treated with the Aorfix™ (Lombard) stent graft, or when a Zenith™ (Cook) main body was chosen, the Aorfix™ iliac limbs were used with the Zenith™ (Cook) device. We compared the rate of iliac limb occlusions before (group 1) and after (group 2) the adoption of this policy.

Results. Two hundred twenty-seven patients underwent EVAR (group 1 N=128; group 2 N=139). In group 1, eight patients had a unilateral iliac limb occlusion (6.2%). Six of the patients had ≥90° iliac angulation, one had an unrecognised limb stenosis, and one patient had the stent landed in the external iliac. In group 2 there were no limb occlusions. Of the 139 patients, 25 had iliac angulation of >90°. Of these 25, eighteen were treated with the Aorfix™ stent graft system because of iliac angulation, and 7 were treated with Aorfix™ legs and Zenith™ bodies.

Conclusion. The rate of early iliac limb occlusion following EVAR in patients with angulated iliac anatomy can be substantially reduced by using the flexible Aorfix® stent graft system.

Key words: Aortic aneurysm, abdominal - Iliac artery - Ischemia.

The suitability of endovascular repair (EVAR) for a patient with an abdominal aortic aneurysm is dependent on aorto-iliac morphology. Indeed complications following EVAR are strongly associated to non-adherence to the manufacturer’s instructions for use (IFU). Iliac limb thrombosis following bifurcated device insertion may occur in up to 10% of patients, although rates vary widely between series. Graft thrombosis is associated with iliac angulation and the resulting kinking of z-stent graft systems, small graft limb diameters and extension in to the external iliac artery.

The Aorfix™ aortic stent-graft is a modular device composed of a circular Nitinol frame covered by a woven polyester fabric, which in contrast to the rigid z-stent designs, is extremely flexible and compliant with tortuous vessels. The device is therefore well suited to highly angulated anatomy. This has been demonstrated in studies examining the graft in patients with high angled aneurysm necks. The aim of this study was to evaluate the performance of the Aorfix™ graft in tortuous iliac anatomy and examine the impact of the graft on the rate of iliac limb thrombosis following EVAR in a single UK centre.

Materials and methods

Study design

This was a retrospective analysis of a prospective-ly collected database of endovascular aneurysm repairs.
performed in a single UK centre (Royal United Hospital, Bath, UK) between May 1998 and May 2010. Following successful use of the Aorfix™ stent graft device in patients with high angled necks we adopted a policy of selectively using the Aorfix™ stent graft device in all patients with severe iliac angulation (>90°); this was from November 2007 onwards. In patients with highly angulated anatomy in whom a Zenith™ (Cook) body was chosen, the Aorfix™ iliac limbs were still used with Zenith™ main body. Prior to using a combination of stent grafts in the clinical setting we performed bench testing and gained local hospital approval. All patients were informed that combining stent grafts was outside the manufacturer's instructions for use.

The other indication for using the Aorfix™ device in this series was high neck angulation (>60°).

We compared patients treated prior to November 2007 (Group 1 – historical control) with patients treated following the adoption of the policy (Group 2). The primary outcome was iliac limb thrombosis. All

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<th>Table I.— Patient demographics.</th>
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<td>Male sex (N. of males)</td>
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<td>Age (yrs)</td>
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<td>(Standard deviation)</td>
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<tr>
<td>Severe iliac angulation in 12%</td>
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<td>patients undergoing repair</td>
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<tr>
<td>Aorfix™ iliac limbs</td>
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<td>Zenith</td>
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*Includes 7 patients in whom a Zenith body was used in conjunction with Aorfix legs.

Figure 1.—A patient with highly angulated iliac anatomy, treated with the Aorfix™ device.
patients were followed up using a protocol of CT at 1 month post op and then annually. In this study all patients had undergone at least one CT scan (minimum follow-up 28 days).

Aorfix™ stent graft system

The device and technique has been described in detail previously. It is commercially available in a range of sizes to accommodate aorto-iliac anatomy (main body 24-31mm proximal diameter; iliac limb diameters 10-20 mm). The device is suitable for patients with an external iliac diameter of at least 7 mm.

Statistical analysis

The two groups were compared using chi squared test for categorical values and Student t test for continuous variables. Statistical analysis was performed with the Software Package for the Social Sciences (version 16.0 for Windows, SPSS Inc, Chicago, Ill, USA). A P value of <0.05 was considered statistically significant.

Results

Patient population

Two hundred and sixty seven patients underwent EVAR between May 1998 and May 2010. Patient demographics for each group are shown in Table I.

Outcomes

There were eight iliac limb occlusions in the historical control group (6.2%). Six of the eight patients had iliac angulation of >90°, one patient had an in stent stenosis that was unrecognised per-procedure, and the final patient had the graft limb landed in the external iliac (late occlusion). All the early occlusions occurred using the Cook Zenith™ device. This was used to treat the vast majority of patients in this group (N=106). The patient with a late limb occlusion was treated with a Vanguard (Boston Scientific Ltd) stent. Eight patients were treated with the Aorfix graft (prior to formally adopting a policy of use for highly angulated iliac anatomy) – the primary indication in
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WEALE

this group of patients was high angulation of the infra-
renal aortic neck.

Fourteen patients (10.9%) in Group 1 had severe ili-
ac angulation or required on table adjunctive stenting
due to limb kinking. Seven occlusions occurred in
the first 14 postoperative days (range 1-14); the one
late occlusion occurred at 5 years. Five patients
required femoro-femoral cross over grafting. No
patient underwent lower limb amputation.

In Group 2, twenty five patients had severe iliac
angulation (18.2%). In eighteen of these patients the
Aorfix™ stent graft system was used - an example of
which is shown in Figure 1. In the other seven patients
with severe iliac angulation, Aorfix limbs were com-
bined with various Z-stent devices. Two patients had
Aorfix™ iliac limbs used in conjunction with fenes-
trated devices (Cook). In four patients a
Zenith™(Cook) main body was deployed with uni-
lateral Aorfix™ iliac limbs, due to adverse neck mor-
phology (large diameter required). In the final patient
an Aorfix™ iliac limb was used to extend into a high-
ly tortuous external iliac following deployment of an
iliac bifurcation device (Cook). Following the adop-
tion of the policy of using the Aorfix™ device there
have been no iliac limb occlusions (P=0.003). The
device and delivery system were delivered to the
intended position in all patients and withdrawn with-
out complication. There has been no stent fracture,
device migration/dislocation or aneurysm rupture.

These results are summarized in Figure 2.

Discussion

This study has demonstrated that the Aorfix™ device
can be successfully used to treat abdominal aortic
aneurysms in patients with high angled iliac anato-
my, without the associated risk of graft kinking and
limb thrombosis.

In the historical control group of this series 6.2% of
patients had iliac limb thrombosis and in the major-
ty of these patients this was due to severe iliac an-
gulation. This rate is similar to other contemporary
single centre series – for example Cochennecc reports a
rate limb occlusion of 7.2% for patients treated
between 1995 and 2005 with a similar pattern of device
use.3 However the rates are generally lower in the
large randomized trials (EVAR 1,10 EVAR 2,11 DREAM,12
PIVOTAL 13), with the rate of graft thrombosis fol-
lowing EVAR ranging from 1.4% 14 to 6.4%.12 The vast
majority of limb thromboses observed in this series
occurred very early (less than 2 weeks). This is in
keeping with the literature, where most occlusions
occur in the first few months following grafting.3, 5, 6

In the DREAM and EVAR 1 trials, 3.5% 12 and 10%
patients respectively, were treated using aorto-unii-
iliac grafts; whilst in Group 1 in our study 3.8% patients
had uni-iliac systems deployed. Aorto-uni-iliac (AUI)
stenting with cross-over femoro-femoral bypass (CFFB)
is indicated in patients with adverse iliac anatomy
(occlusive or angulated) or narrow aortic bifurcations.
However it is associated with a significantly higher rate
of peri-operative morbidity,10 than bifurcated devices.
In one recently reported study, AUI stenting and CFFB
was performed in over a quarter of patients treated in
the centre.16 The authors do not explicitly state the pro-
portion of patients where the indication for AUI/CFFB
was iliac tortuosity or narrow bifurcations, but do
state that only 25% of the AUI/CFFB group patients
had TASC C or D iliac occlusive disease; therefore it
is possible that up to three quarters of the patients in
this series were excluded from receiving a bifurcated
device due to iliac tortuosity. The authors argue that
it is aorto-iliac occlusive disease rather than AUI/CFFB
itself which is associated with clinical failure of endo-
grafting (re-intervention/thrombosis).15 However the
addition of a prosthetic bypass brings with it the
potential issues of loss of patency and infection. The
large AUI series from Nottingham (UK) reported CFFB
patency at 5 years of 83%.17 Given such problems we
have avoided AUI/CFFB in our centre where possible
and we no longer consider iliac tortuosity a contra-
indication to the use of a bifurcated device.

The conventional rigid z-stent design of commer-
cially available grafts requires that angulation in the
patient’s aorto-iliac anatomy is to some extent straight-
ened out. Where this does not occur successfully,
kinking of the graft occurs. Chuter et al. have observed
that during the deployment of a Zenith™ endograft
when narrowing of a graft limb occurred in associa-
tion with kinking, that the use of adjunctive primary
stenting (Wallstent™ [Boston Scientific Ltd]) reduced
the rate of graft thrombosis from 5.2% to 0%.5 However
the use of bare metal stents increases the length, com-
plexity and cost of the procedure. In our series, limb
thrombosis occurred despite the use of adjunctive
stenting.

In our study we observed all the early limb occlu-
sions in patients treated with Zenith™ (Cook) devices
- it is likely that this was simply because this was the

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device that the vast majority of patients were treated with - there is no evidence that this device has a higher rate of occlusion than other commercially available z-stent devices. Since 2008, the Zenith™ AAA Iliac Flex Legs (Cook) have been available in Europe - this device has shorter Z-stents and greater gaps between the stents to improve flexibility and reduce the risk of kinking in tortuous anatomy. Nevertheless the IFU still warn that “vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the endovascular graft”.

The continuous circular Nitinol frame of the Aorfix™ device gives the endograft support without compromise on flexibility. There is accumulating evidence that the device performs well in highly angulated anatomy. Albertini reported the high technical success (96%) of the device in severe angulation in the proximal neck. More recently Perdikides reported a single centre experience of 20 patients with severe neck angulation (60-90°) and/or severe iliac angulation (present in 40% of the study group). Technical success was 95% and freedom from intervention was 89% at 1 year and 79% at 2 years. Such rates of re-intervention are lower than those reported in the EVAR 1 trial, and similar to those in the DREAM trial - trials in which patients with far more favourable anatomy were treated.

In our total series of 267 patients, we have used the Aorfix stent graft system as a whole or in part to treat 50 patients. In half of these aneurysms repairs, the indication to choose this graft was primarily the high degree of angulation within the iliacs, rather than angulation of the neck for which the graft is best known. It was our initial use of the graft in the latter context which led us to hypothesise that Aorfix™ graft would perform well in tortuous iliacs and resulted in our explicit shift in stent choice in that scenario. Like all stent graft systems there is an operator learning curve which is particular pertinent when applying a graft to challenging anatomy. The Aorfix™ graft requires accurate antero-posterior alignment of the two peaks of the graft main body during deployment; this requires some rotation of the graft which can be difficult in highly angulated iliac anatomy. Furthermore catheter control during cannulation of the contralateral limb is complicated by a tortuous iliac artery because the ability to torque the catheter is lost. We have found the use of a long guiding sheath into the aorta a particularly useful adjunct in this scenario.

Although the series we have presented may be criticised for the use of a historical control group and all its associated problems, there is no doubt that we have demonstrated that the device performs extremely well in such highly challenging iliac anatomy. We believe that use of the Aorfix™ device can increase the number of patients considered suitable for EVAR with a bifurcated device who were previously excluded from this type of treatment due to iliac tortuosity.

**Conclusions**

The rate of early iliac limb occlusion following EVAR in patients with angulated iliac anatomy can be substantially reduced by using the flexible Aorfix® stent graft system.

**References**