Endovascular treatment of complex aortic aneurysms

Endovascular aortic aneurysm repair has been established as an alternative to open surgical repair. One of the main limitations of endovascular aortic aneurysm repair is the need for a sufficient sealing zone below or above vital aortic branches. During the last 10 years, efforts have been made to overcome these limitations by incorporating fenestrations or branches into customized stent grafts. First, short-necked infrarenal aneurysms were addressed. Later, juxtarenal and suprarenal aneurysms were treated with the same technique. Last, it became possible to treat thoracoabdominal aneurysms by endovascular means. This article reviews the technical and clinical possibilities, as well as the published results of endovascular aortic aneurysm repair with fenestrated and branched stent grafts. The current status and future considerations are discussed.

KEYWORDS: aortic aneurysm ▪ branched ▪ endovascular ▪ fenestrated ▪ juxtarenal ▪ stent graft ▪ thoracoabdominal

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Since the first publications of endovascular aortic aneurysm repair (EVAR) by Volodos' and Parodi almost 20 years ago [1,2], the technique has matured into a viable alternative to open repair. Two prospective randomized trials have demonstrated the immediate benefits with EVAR compared with open surgery [3,4], but no difference in medium-term overall survival (EVAR 1) and a higher incidence of late graft-related complications, the majority of which can be treated using endovascular techniques [5,6]. Standard endovascular repair has continued to evolve after the trials; stent grafts, endovascular techniques and patient selection have improved. Many patients are now treated using locoregional anesthesia with only a short postoperative hospital stay [7,8]. Another milestone was achieved with the introduction of emergency EVAR for acute and ruptured infrarenal aneurysms [9].

The principle limitation of standard EVAR is the requirement of a suitable proximal and distal portion of the normal aortoiliac segment to serve as a sealing zone for the stent graft. Vital branches, such as the celiac axis, superior mesenteric artery and renal arteries, cannot be sacrificed without a significant risk of end-organ ischemia. The proposed solution to this problem came with the customization of fenestrated stent grafts to incorporate these vital branches. First, short-necked infrarenal abdominal aortic aneurysms were addressed, followed by juxtarenal aneurysms and even selected suprarenal and thoracoabdominal aneurysms. The further development of stent grafts with incorporated branches has opened the way to the treatment of more complex thoracoabdominal aneurysms (TAAAs).

For completeness, we report that hybrid methods have been explored to treat these complex aneurysms: these include chimney or snorkel techniques for juxtarenal aneurysms [10] and surgical debranching techniques followed by endovascular repair for TAAAs [11–13].

This article discusses the endovascular repair of complex aortic aneurysms. In open surgery, a complex aortic aneurysm involves the visceral branches of the aorta and requires, at the very least, clamping above the renal arteries to allow a secure proximal anastomosis. Therefore, this surgical definition includes juxtarenal, suprarenal and TAAAs. Short-necked infrarenal aneurysms (i.e., neck length between 4 and 10 mm) are not generally regarded as suitable for standard EVAR, but they do not fit the surgical definition of complex aortic aneurysms since most surgeons would still consider infrarenal aortic clamping. Publications of fenestrated EVAR invariably include both juxtarenal and short-necked infrarenal aneurysms because the endovascular technique is the same for both types of aneurysm. Similarly, the surgical classification for TAAA is not tailored to endovascular techniques with fenestrated and branched grafts. The main determinant of the complexity of endovascular treatment is the number of visceral branches incorporated in the repair. Unlike open surgery, the length of aorta to be treated does not add much to the technical difficulty of

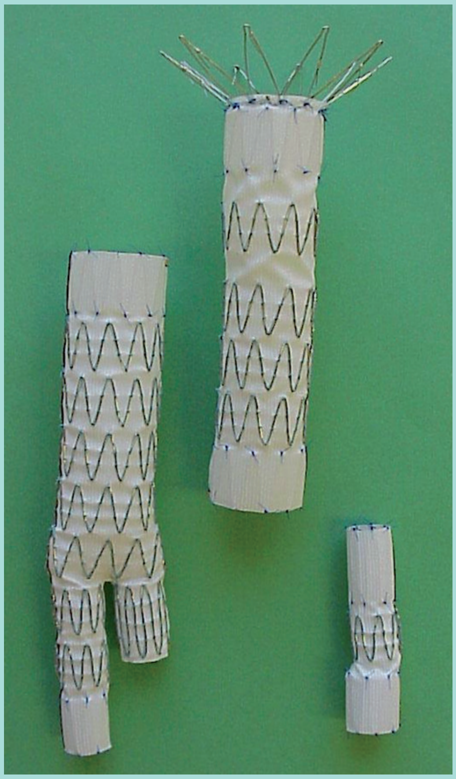

Figure 1. Composite three-part Zenith® stent graft. To make a fenestrated graft, the first tubular part can be customized with fenestrations and scallops.

the procedure, although it does have a bearing on the risk of spinal cord ischemia. This article discusses the following:

- Endovascular repair of complex abdominal aneurysms (short-necked infrarenal, juxtarenal and suprarenal) with fenestrated grafts;
- Endovascular repair of TAAA with fenestrated and branched stent grafts.

Complex abdominal aneurysms and TAAA differ not only in the extent of the aneurysm requiring treatment, but also in the complexity of the endovascular repair and the risks to the patient from intervention. In addition, the fenestrated technique for complex abdominal aneurysms is mature, has been disseminated widely and there are now several large series reporting midterm results. By contrast, thoracoabdominal branched techniques are still evolving, they are performed only in a small number of specialist centers and only a few literature reports exist, usually of small series with short-term results. Readers should understand that all these techniques must be regarded as highly specialized. Endovascular teams who want to introduce these techniques should be trained in patient selection, planning of the graft and execution of the procedure. Although such training is provided by the manufacturer in cooperation with expert centers, it is difficult to gauge when a team is ready to apply the technique without support. It is even more difficult to determine who should be allowed to give the 'green light' to new users.

Endovascular repair of complex abdominal aneurysms with fenestrated grafts

■ Literature review

In 1996, Park *et al.* reported the first two cases of fenestrated EVAR [14]. The first patient had an anastomotic aneurysm with an occluded celiac trunk and superior mesenteric artery; a tube graft was fashioned with a fenestration to preserve the inferior mesenteric artery. In the second patient with an abdominal aneurysm, the graft had a single fenestration for a low right renal artery. In 1999, Browne *et al.* published the use of a Dacron® (Invista, Inc.)-covered stent with one fenestration to preserve flow to the renal artery in a canine model [15]. Faruqi *et al.* then published the use of a fenestrated graft to preserve a single renal artery [16], and Kinney *et al.* successfully implanted a tube graft with a large diamond-shaped fenestration for the celiac trunk and superior mesenteric artery in a patient with a mycotic paravisceral aneurysm [17]. In 2001, Anderson *et al.* published the first cohort study comprising 13 patients in which 33 renal and superior mesenteric arteries were targeted [18]. This study had 100% procedural success, no 30-day mortality and only one renal artery occlusion at follow-up between 3 and 24 months. In 2004, Greenberg *et al.* reported on 22 patients with 58 targeted visceral vessels [19]. There was no mortality and only one occlusion and two stenoses in target vessels at 6-month follow-up. The same group published an extended series of 32 patients with one death (3%) and two late renal artery occlusions [20]. The first author of the present review reported a series of 18 patients with a procedural success of 45 out of 46 targeted vessels with the loss of only one accessory renal artery [21]. During mean follow-up of 9.4 months, one additional renal artery occluded. No proximal type I endoleak was detected during follow-up. A report from the Cleveland Clinic (OH, USA), undoubtedly the most experienced center, discussed the risks of renal impairment associated with the technique and provided important guidance on patient selection and follow-up [22]. In recent years, there have been larger series reporting excellent early- and medium-term outcomes, with perioperative mortality rates of approximately 1%

and midterm target vessel patency rates approximately of 95% [23–25]. Several authors have also demonstrated the fenestrated technique to be a viable alternative to open surgery in patients with secondary aneurysms (either para-anastomotic aneurysms or new aneurysmal progression after previous open surgery) or type 1 endoleak after previous EVAR [26–30].

A recently published review comparing fenestrated EVAR with open surgery for juxtarenal abdominal aortic aneurysm has confirmed the lower perioperative mortality with endovascular approach, but acknowledges the lack of longer-term data [31]. In the USA, a small multicenter trial was conducted in order to obtain graft approval from the US FDA; the outcomes confirmed the results of previous reports [32]. The largest European experiences from The Netherlands and France have confirmed that fenestrated EVAR is associated with low perioperative mortality, excellent target vessel patency, low reintervention rate and excellent protection from aneurysm rupture. The estimated 5-year survival rate is approximately 50–60%, reflecting the high-risk population treated [33,34].

Technique

Fenestrated stent grafting requires access via two femoral arteries. The procedure can be performed under general or regional anesthesia using cutdown femoral artery exposure or a percutaneous approach. At present, the stent graft is a composite prosthesis based on the Zenith® system (William A Cook Australia Pty Ltd, Australia), which has a self-expanding modular design with an uncovered Gianturco Z-stent (William Cook Europe, Denmark) for proximal fixation in the standard configuration (Figure 1). The proximal part of the graft is fitted with single or double diameter reducing ties to allow only partial deployment prior to catheterization of the branches and final orientation of the stent graft (Figure 2). Customization of the stent grafts is based on each individual anatomical configuration. Three types of fenestration are possible: scallops and large and small fenestrations (Figure 3). Each fenestration is marked by three (scallop) or four (small or large fenestration) radiopaque markers to enable accurate alignment. Each tube graft is fitted with anterior and posterior markers to facilitate orientation during insertion and deployment. Complete deployment of the stent graft has to be carried out after catheterization of the branches and secure positioning of a guiding sheath inside them. Stenting of small fenestrations has been applied in most cases (Figure 4). The purpose of stenting the fenestrations is to match and secure the fenestration with the ostium of each branch. Moore *et al.* have published a comprehensive step-by-step technical approach [35].

Evolution

A major advance was the decision to move towards a composite three-part system instead of a bifurcated system. The reason behind this was to make catheterization of the fenestrated tube and the side branches easier and to position the second bifurcated part as close as possible to the aortic bifurcation. Another improvement included the stenting of small fenestrations for the renal arteries to ensure full apposition of the

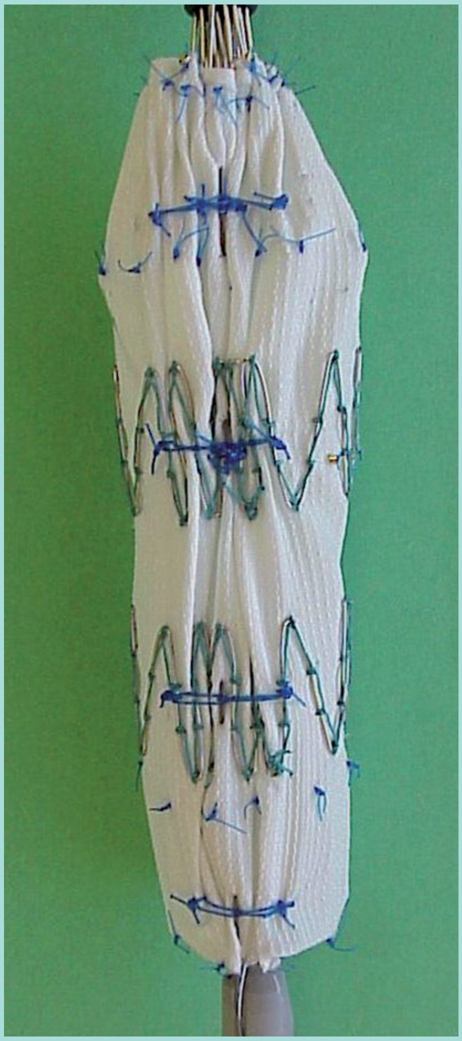

Figure 2. Diameter reducing ties on the back side of the fenestrated tube, which constrain the graft to 60–70% of its intended diameter, and allows for repositioning and final orientation during catheterization.

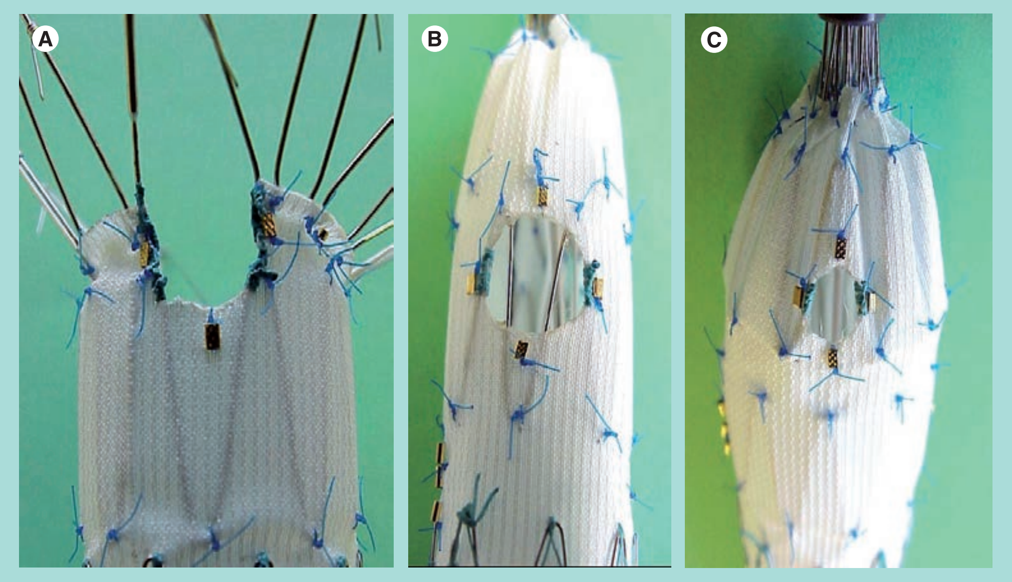

Figure 3. Types of fenestrations. (A) A scallop in the top of the stent graft. **(B)** A large fenestration (metal struts crossing). **(C)** A small fenestration (no metal struts across).

fenestrations to the targeted vessel. This policy was introduced because most of the target vessel occlusions in the early years occurred in non-stented small fenestrations. A third improvement to the device was the reinforcement of both fenestrations and scallops with a double nitinol wire ring (Figure 5). This reinforcement holds the fenestration/scallop open for catheterization in the middle stages of deployment when the body of the stent graft is still in a partially compressed state. For scallops that are not stented, the reinforcement takes care of keeping the scallop open to the nominal 10 mm of width, thus avoiding narrowing down due to the planned oversizing of the graft.

Figure 4. Stents in small fenestrations to maintain fixation and apposition.

The use of a preloaded fenestrated device has recently been explored, which allows for device deployment and target vessel catheterization in patients who have only one good femoral artery access vessel. This device features preloaded catheters that are fixed to a fenestration with an in-dwelling wire, thus allowing the wire to pass directly outside the fenestration.

Ancillary products have also contributed to technical success. Most important were the use of guiding sheaths with soft dilators (ANL1 7-Fr yellow dilator, Cook Inc., IN, USA) to ensure access to the target vessels during full deployment. These guiding sheaths allow for safe introduction of the bridging stents. Covered stents have been used for aneurysms with no neck, but are increasingly used in short-necked aneurysms as they seem to perform better than uncovered stents [36]. The covered stents are usually flaired with a 12 × 2 cm percutaneous transluminal angioplasty balloon to ensure encroachment on the reinforced fenestration, both for fixation and for sealing, and to facilitate recatheterization if needed at a later stage (Figure 6).

Future perspective for complex abdominal aneurysms with fenestrated grafts

A randomized trial comparing fenestrated with open repair for juxtarenal aneurysm has not been performed. Such a trial would probably only give answers in a very select group of patients. Indeed, a large proportion of patients will not be anatomically (or physiologically) suitable for either technique. For those patients who are candidates for both techniques, it may prove difficult to randomize for a number of reasons. Patient compliance might be low and clinical equipoise for those clinicians who have sufficient experience to participate in the trial may be absent. Despite these potential problems with trial design and execution, issues with reimbursement and lack of level I evidence may ultimately make a trial necessary. In patients with juxta- and supra-renal aneurysms, the advantages of fenestrated EVAR may be more pronounced than in infrarenal aneurysms suitable for open repair or standard EVAR. However, one concern is the risk of renal dysfunction during follow-up [22], although this risk is also present with open surgery including suprarenal clamping. In view of its minimally invasive nature and proven efficacy and durability, fenestrated EVAR has become a valid alternative to open repair in selected patients. More studies including longer-term data will be needed to confirm these results and to determine the patient subgroups who will benefit from fenestrated EVAR.

Figure 5. New-generation nitinol-ring-reinforced small fenestration.

Endovascular repair of thoracoabdominal aneurysms with fenestrated & branched grafts

■ Literature review

In 2001, Chuter *et al.* published the first case of a patient with a thoracoabdominal aneurysm treated with a multibranched stent graft [37,38]. A 76-year-old man with a contained ruptured type III TAAA was successfully treated with a custom-made four-branch device, but developed paraplegia on the second postoperative day. In 2005, Anderson *et al.* described four patients with TAAA treated by fenestrated and branched endografts, including the first totally percutaneous procedure [39]. The Cleveland Clinic group have published the largest experience to date [40–42]. In their series of 73 patients, there were 28 type I, II or III TAAAs and 45 type IV TAAAs. The mean aneurysm size was 7.1 cm (range: 4.5–11.3 cm). Regional anesthesia was used in a little over half of the cases. The technical success was achieved in 93% of patients (68/73) and the 30-day mortality was 5.5% (4/73). Major perioperative complications occurred in 11 patients (14%) and included paraplegia (2.7%; 2/73), new onset of dialysis (1.4%, 1/73), prolonged ventilator support (6.8%, 5/73), myocardial infarction (5.5%, 4/73) and minor hemorrhagic stroke (1.4%; 1/72). The mean length of stay was 8.6 days. At follow-up, six deaths had occurred and there were no cases of stent migration or aneurysm growth. The same authors have published an overview of late complications after endovascular repair of TAAA [43]. Renal failure may be a technical issue or may be due to multiple contrast-enhanced follow-up investigations. Haddad *et al.* reported a glomerular filtration rate increase of more than 30% in 24 of 72 (33%) patients [22,43]. Spinal cord ischemia is less common than after open surgery (4.3 vs 7.5%, respectively; p = 0.08) and

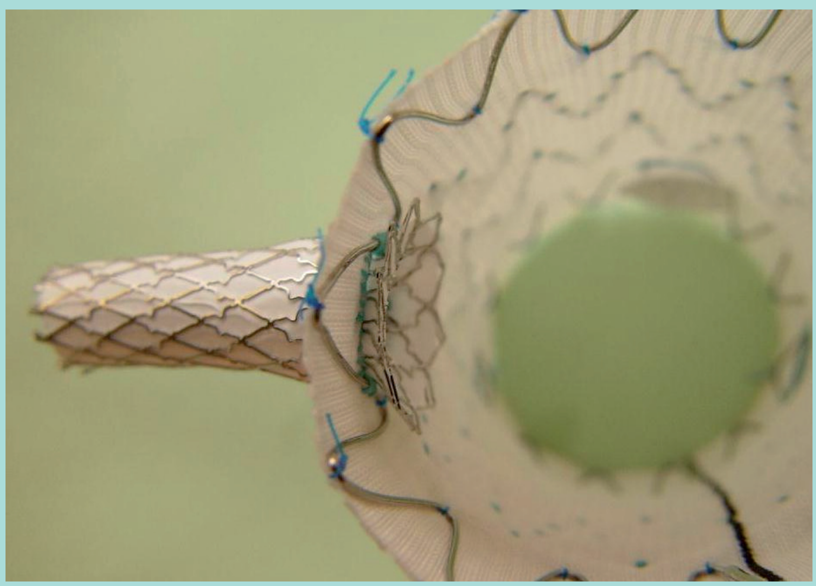

Figure 6. Stents are flaired on the inside of the main stent graft to create a tied fixation and seal (in case of a covered stent).

Table 1. Reported results with branched and fenestrated endovascular thoracoabdominal aneurysms repair.

Study (year)	Number	Technical success (%)	30-day mortality (%)	1-year survival (%)	Ref.
Chuter *et al.* (2001)	1	100	–	–	[37,38]
Anderson *et al.* (2005)	4	75	25	75	[39]
Greenberg *et al.* (2006)†	9	89	0	78	[45]
Simi *et al.* (2007)	1	100	–	–	[46]
Roselli *et al.* (2007)†	73	93	5.5	81	[40]
Chuter *et al.* (2008)	22	100	9.1	77	[47]
Gilling-Smith *et al.* (2008)	6	100	0	100	[48]
Ferreira *et al.* (2008)	11	–	23.7	76.3	[49]
Bicknell *et al.* (2009)	8	100	0	–	[50]
Verhoeven *et al.* (2009)	30	93	6.7	76	[51]
Haulon *et al.* (2010)	33	94	9	82	[52]

†*Same series.*

the risk can be reduced by maintaining adequate systolic blood pressure and cerebrospinal fluid drainage intraoperatively and for 48–72 h postoperatively [43].

Recently, Haulon and colleagues published the first literature review of TAAA-branched stent grafting, which demonstrated encouraging outcomes, especially as most patients were high-risk for open surgery [44]. Results of published case series of endovascular TAAA repair are summarized in Table 1 [37–40,45–52]. Longer-term reports are awaited, but both graft and target vessel stability appear to be good and type 1 endoleak is very uncommon. However, a comparison with open repair is unrealistic; on the one hand, most of the patients treated by endovascular means were deemed unsuitable for open repair, and on the other hand, one must acknowledge that anatomical suitability for endovascular repair represents a selection bias.

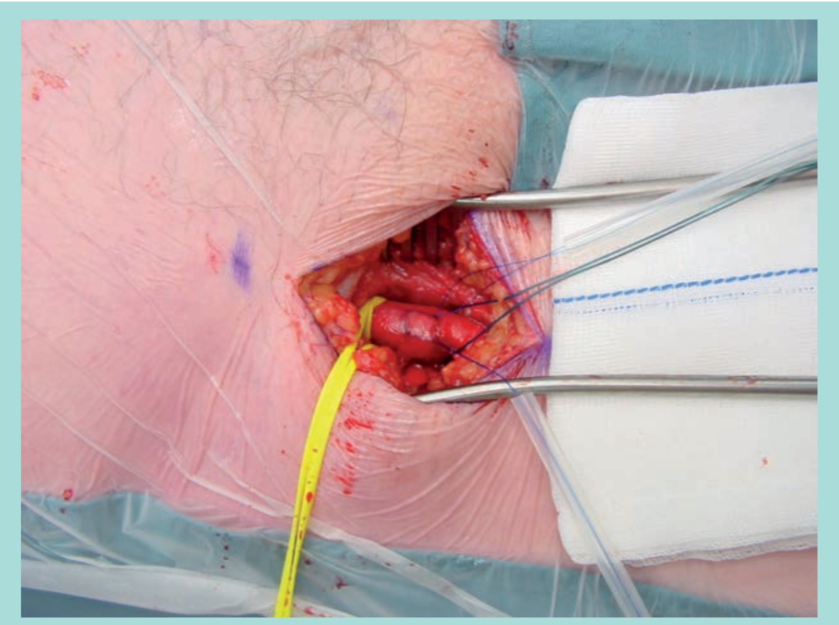

Figure 7. Purse-string sutures in a femoral artery.

Chuter *et al.* recently focused on device options with regard to fenestrations and different types of branches (e.g., type of orientation, internal or external, caudally directed, axial and helical), as well as the potential standardization of branched grafts, in an attempt to make them available over-the-counter [53–55]. A certain degree of misalignment and distance between graft branch and target vessel has been shown to have no detrimental effect on the feasibility of multibranched stent graft insertion. Interestingly, it may be possible to treat almost 90% of TAAA cases with a standard over-the-counter multibranched stent graft [55], thereby eliminating long manufacturing delays and expanding the scope of endovascular repair to the treatment of symptomatic or even ruptured TAAAs.

■ Technique

Endovascular branched techniques for TAAAs usually require access via one or sometimes two femoral arteries and one brachial access. The procedure can be performed under general or regional anesthesia, using open arterial exposure or using a percutaneous approach. The individual anatomy of a visceral artery and the aorta (including the diameter and quality of the aorta in the proximity of the visceral artery and the take-off angle of the visceral artery) dictates the choice between a fenestration or a branch. Grafts for complex TAAAs may only have fenestrations or only have branches, or may have a combination of both. The TAAA branched-stent graft is based on the Zenith system and is broadly

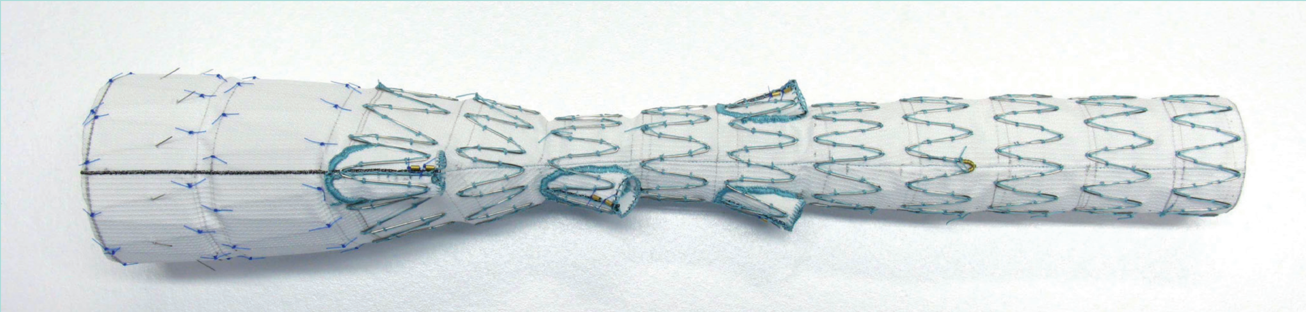

Figure 8. Down tapering of the main graft body diameter to allow room for the branches.

similar to the fenestrated abdominal graft, with single or double diameter reducing ties, markers on the fenestrations or branches and anterior and posterior markers. It may have an uncovered Gianturco Z-stent with hooks for proximal fixation if the graft has fenestrations and a covered proximal stent with hooks (as for the Zenith TX2 proximal component) if the graft only has branches. There is usually at least one preloaded catheter, most often placed in the branch for the superior mesenteric artery. A 300-cm wire can be passed through this catheter and snared from the brachial artery to allow an 80-cm, 10–12-Fr flexor sheath to pass into the body of the main graft. Where a graft has only downward facing branches, each target vessel is cannulated and the bridging stent graft deployed before moving to the next target vessel. For grafts that also have fenestrations, catheterization of these fenestrations is mandatory before complete deployment of the stent graft (as in the previously described fenestrated technique). Early removal of the large diameter introduction systems may reduce lower limb ischemia–reperfusion injury. This is facilitated by using purse-string sutures for the access vessels (Figure 7) before introducing the device. When removing an introduction system, these purse-string sutures can be snugged around the wire to achieve hemostasis but also allow for flow into the limb and, importantly, the internal iliac artery, which provides the collateral circulation to the spine.

■ Evolution

The technique of endovascular TAAA repair has evolved at an altogether slower pace compared with the fenestrated technique for complex abdominal aortic aneurysms, probably due to the smaller proportion of thoracoabdominal aneurysms. Two important improvements to the graft have been made. First, tapering the main graft down at the level of the branches creates room for the branches to open fully within the lumen of the aneurysm and greatly facilitates the catheterization process and the introduction of the bridging of covered stents (Figure 8). The second improvement is the deliberate off-set positioning of branches in terms of their orientation, which again creates room for catheterization and avoids jamming of lower target vessels by a branch (Figure 9). This is often important for the celiac trunk and superior mesenteric artery.

Correct orientation of the graft is mandatory during deployment. This is not always easy because the grafts are usually long and are not always perfectly aligned (degree of torque) inside the introduction system. A new spiral wire should take care of this problem and stabilize the graft,

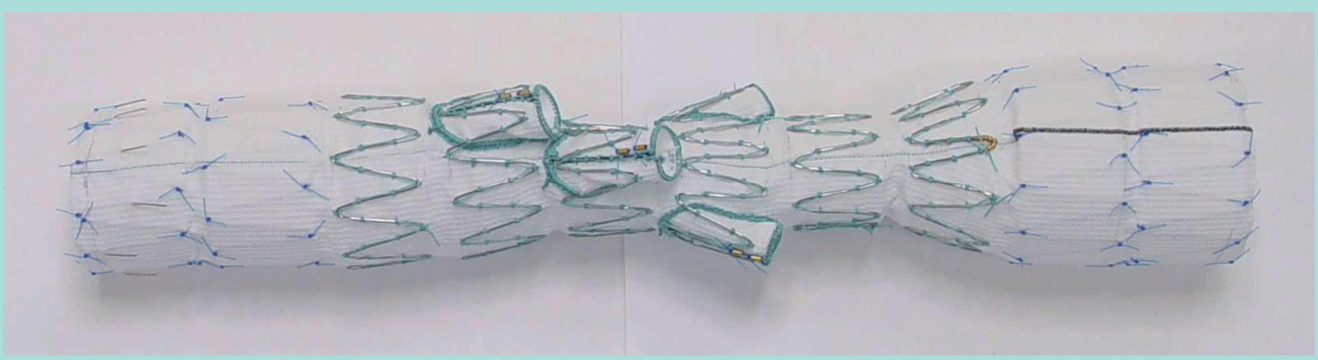

Figure 9. Deliberate off-set positioning of branches for the celiac artery and the superior mesenteric artery.

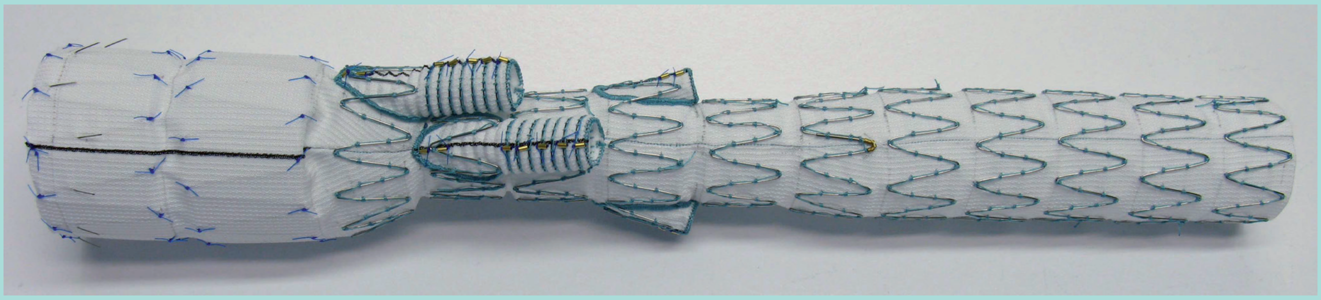

Figure 10. Flexible branches (for celiac and superior mesenteric arteries).

making orientation during deployment easier. New branch types have been designed with greater flexibility, but need further testing (Figure 10). The use of both indwelling wires and additional through-and-through wires to stabilize the upper introduction sheath can be helpful. Finally, modern hydrophilic-coated guiding sheaths facilitate access, even in smaller or tortuous vessels.

Future perspective

The results of endovascular repair of TAAAs are excellent in the short term, with operative mortality rates of approximately 10%. This is probably due to the reduced physiological insult compared with open surgery in the high-risk patients currently being offered treatment. Endovascular-specific issues include renal failure, which is multifactorial due to intraprocedural technical complications, late occlusions of renal artery stent grafts and multiple contrast-enhanced CT scans; iatrogenic retroperitoneal hematoma owing to wire perforations of small branch vessels and stiff, covered stents used to bridge the gap between branches and target vessels; and lower limb compartment syndrome if the large diameter introduction systems have to remain in place for prolonged periods.

Despite the fact that there are only limited short-term data and no long-term data, one can see that there are obvious clinical benefits associated with an endovascular approach compared with open surgery. As expertise and knowledge disseminate among specialist centers and devices become available over-the-counter, it is likely that endovascular repair will become the procedure of choice for the majority of patients with TAAAs.

Financial & competing interests disclosure

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Executive summary

Epidemiology

- If left untreated, complex abdominal and thoracoabdominal aortic aneurysms will eventually rupture, causing death of the patient.
- Open repair for complex aortic aneurysms, especially thoracoabdominal aortic aneurysms, is associated with high mortality and morbidity.
- A substantial number of patients with thoracoabdominal aortic aneurysms are still not offered treatment owing to age and comorbidity.

Treatment of complex abdominal aortic aneurysms

- Complex abdominal aortic aneurysms can now be treated by endovascular means with fenestrated grafts.
- The fenestrated technique has matured and is now widely available in Europe.
- Results in the short- and mid-term are good and consistent.
- Postoperative renal function impairment is a concern.

Treatment of thoracoabdominal aortic aneurysms

- Branched endovascular repair for thoracoabdominal aortic aneurysms is still undergoing full evolution.
- Mortality and morbidity of the technique applied in high-risk surgical patients is approximately 10%.
- The lack of longer-term data prevents widespread use at present.

Future perspective

- Fenestrated stent grafting will become a valid alternative to open surgery in selected patients.
- In view of the much higher impact on the patient with open surgical techniques for thoracoabdominal aortic aneurysms, branched endovascular techniques are likely to become a first choice treatment option in many patients.
- More studies including mid- and long-term data are needed to determine the value of these techniques and the targeted patient categories.

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