Introduction

Since the introduction of endovascular aortic aneurysm repair (EVAR) by Parodi in 1991, the technique has become a validated alternative to open repair (1). Two prospective randomized trials have demonstrated immediate benefits compared to open surgery (2, 3). Mid-term results of these two trials were somewhat disappointing due to a large number of late complications and reinterventions, although most of these complications were treatable again by endovascular means (4, 5).

EVAR is limited by anatomical constraints: the technique is applicable only to infrarenal aneurysms with suitable proximal and distal landing zones for sealing and sufficient caliber access vessels for device insertion. Distally, adverse anatomy can usually be overcome with adjunctive techniques, but a proximal neck is essential to achieve sealing and a long-lasting result. The Eurostar registry has demonstrated that EVAR in short proximal necks (i.e. < 15 mm) is associated with a higher risk of complications (6). Consequently, an important number of aneurysms still have to be classified as unsuitable for standard EVAR. To overcome this issue, we started customizing fenestrated stent-grafts to incorporate renal and mesenteric arteries above such short necks.

This report reviews our experience with fenestrated (and branched) stent-grafts over the last 5 years. It aims at being a comprehensive guide to the technique. First, the indications for fenestrated stent-grafting are reviewed. Then, the principles of the technique and the inherent procedural steps are discussed, including important refinements throughout the years. The gradual evolution towards branched grafts is elaborated. Based on our experience, limitations of the technique are discussed. Finally, clinical results are highlighted.

Indications for fenestrated stent-grafting

From the anatomical point of view, the fenestrated technique aims at treating short-necked aneurysms. As a result of customized fenestrations, patency of vital side branches such as the renal arteries and the superior mesenteric artery can be maintained, whilst positioning the graft over these aortic side branches. Over the years, the technique has been refined. Results in a few experienced centers are good, with excellent patency rates of targeted side branches.

Suprarenal and thoraco-abdominal aneurysms can only be treated by endovascular means with branched grafts. This can be achieved with fenestrated grafts, but with the use of covered stents through the fenestrations, or by fully branched grafts. Both options are feasible and present with specific advantages and disadvantages.

This report gives an overview of our 5-years experience with fenestrated and branched grafts, and discusses the following aspects of the technique: indications, technical principles, results, and limitations.
justy treat with this new and complex technique; we defined this as aneurysms at least 5.5 cm for men and 5.0 cm for women. In cases of smaller aneurysms, we advised conservative treatment (i.e. essentially careful watching).

Principles and technique

The goal of the technique is to achieve sealing in a short neck by positioning the first sealing stent over the renal arteries and routinely even over the superior mesenteric artery. Based on the Zenith(Cook®) stent-graft, a custom made fenestrated graft is built. Fenestrations are designed to be positioned in front of the target vessels in order to maintain patency. The fenestrations allow the positioning of the first sealing stent completely inside the neck, which should provide a more stable and durable solution. The different options for types of fenestrations have been elaborated before (7). A "standard" fenestrated graft involves two small fenestrations for the renal arteries, and a scallop for the superior mesenteric artery, but other configurations are possible to conform to each patient's anatomy (Fig. 1).

The technique involves a few additional steps compared to a standard Zenith Tri-Fab deployment. First the graft is deployed only partly, in terms of diameter. Diameter reducing ties constrain the graft in order to allow final repositioning and catheterization from the contralateral groin (Fig. 2). It is important to realize that catheterization can only be achieved by repositioning the graft until the fenestrations are in front of the target vessels. To achieve correct position, there are orientation markers on the graft and four radio-opaque markers around each small fenestration, and three around the scallop. Both renal arteries are catheterized consecutively through the same large sheath, and three around the scallop. Both renal arteries are catheterized consecutively through the same large sheath. Once perfect position is obtained the graft can be deployed completely by releasing the diameter reducing ties, and subsequently by deploying the top cap. The scallop for the superior mesenteric artery, if present, should automatically fall into position, without necessitating additional catheterization.

A number of technical refinements have taken place and have resulted in an improved technique. First, it was decided to use only three-part composite stent-grafts instead of bifurcated two-part grafts. The composite graft with a tubular body, including the fenestrations, is much easier to reposition and to catheterize. In addition, it has to withstand less downwards forces (Fig. 3).

Second, it became clear that we had to use stents to optimize the appositioning of the fenestrations with regard to the ostia of the target vessels. Indeed, one can not hope for perfect pre-operative measurement and intra-operative position, and the procedural angiogram is unable to demonstrate the degree of appositioning accurately. The purpose of the stents is to adjust the fenestrations slightly if required, and to keep perfect appositioning.

In the early stages, full deployment of the graft was executed with balloons inside the fenestrations and target vessels. Then the balloons were deflated and removed and stents inserted. This carried a risk of loosening access, due to the stiffness of the stents. Now, guiding sheaths are routinely introduced into the renal arteries. The stents can be advanced inside the guiding sheaths before deploying the graft completely (Fig. 4). This guarantees safe deployment of the stents once the graft is fully open. Correct positioning over the ostia needs to be confirmed by final angiography. Usually it is necessary to push up the device slightly during full deployment, to counter the blood pressure. We also like to retrieve the top cap with the guiding sheaths in place, and balloon the first sealing stent immediately after removing the top cap, with the guiding catheters still loaded with the stents. Retrieving the top cap before deployment of the stents eliminates the risk of dislodging a stent.

Evolution

It is clear that the fenestrated stent-graft provided the platform to explore further applications. To treat juxtarenal, suprarenal, and thoraco-abdominal aneurysms, new developments were required. Turning a fenestrated graft into a branched graft by using covered stents instead of uncovered stents was one option; developing truly branched grafts another. Both techniques are feasible, and present with specific advantages and disadvantages.

For juxtarenal aneurysms the fenestrated graft provided with a covered stent seems to be a reasonable option. The covered stent will provide a seal on the fenestration. To achieve a better support for the stents, in particular the covered stents, all fenestrations were reinforced with a nitinol loop (Fig. 5). Scallops were also reinforced, in order to guarantee their complete opening. Indeed, a non-reinforced scallop in the top of an oversized graft proved to be the weakest part in the top stent and tended not to open completely (Fig. 6). By using reinforced small fenestrations and providing each of them with covered stents, it became possible to treat suprarenal and even thoraco-abdominal aneurysms, as demonstrated by Anderson et al. (8). A potential problem with this technique is the durability of the seal between the nitinol ring of the fenestration and the covered stent. Obviously, in suprarenal and thoraco-abdominal aneurysms, a bridge has to be gapped between the fenestration and the target vessel, and the covered stent has to withstand a number of forces and shear stresses. A better option in these cases may there-
fore be a fully branched graft. This approach was initially developed by both WISSELINK and CHUTER (9, 10). The theoretical advantage is that a branch should provide a better seal and fixation for the bridging stent-graft. In addition, because there is a gap to bridge, accuracy in the positioning of a branch is less important compared to a fenestration, as long as the branch is positioned above the target vessel. A disadvantage is that an approach from the arm is required to catheterize the branches and target vessels, and that the available bridging stent-grafts are fairly stiff. Because the initial side branches were all directed straight downwards, the bridging stent-graft had to accommodate an angle of up to 90°. Other disadvantages were that the grafts were more bulky (thus requiring larger introducer systems) and that the aneurysm had to be large enough at the level of the side branches, to provide room for both the main graft with the side branch, and the bridging stent-graft. Catheterization of target vessels and tractability of bridging stent-grafts also proved difficult in most cases.

Many side branches have been designed since then, and some applied in clinical settings. At this moment the most promising is a short 18 to 21 mm long barrel that is positioned half inside and half outside the main stent-graft, in an angle of 30° to 45° (Fig. 7). This barrel can either be pointed downwards or upwards. The oblique orientation helps the bridging stent-graft in reducing the angle towards the target vessel, and leaves both options for catheterization from below or above. Although we have used this type of graft in a few patients already, it needs to be stated that all of this is highly experimental.

**Limitations of the technique**

The limitations of this technique become obvious if one keeps in mind the necessary steps during the deployment process: first the graft needs to be repositioned to its final position during catheterization; second the inser-
tion of stents inside the renal arteries must be achieved correctly. Every anatomical feature rendering these two processes difficult to execute, makes the already complex technique even more tedious.

Following features can render repositioning of the graft difficult: severe angulation of the neck or the iliac arteries, a narrow iliac artery access, previous surgical grafts. Insertion of stents into the renal arteries and renal artery patency are at risk in case of small or diseased renal arteries, short renal arteries with early bifurcations, and a sharp take-off of the renal arteries.

Other anatomical particularities can increase the risk of this procedure: aortic side branches in close proximity to each other render designing the graft more difficult; angulation of the neck makes it difficult to determine correct positioning of the small fenestrations for the renal arteries; thrombus inside the proximal neck is not only a risk for endoleak but also for embolization during repositioning; a small neck diameter can render the catheterization process more difficult because there is not enough room to maneuver with the predesigned catheters.

All these anatomical features have to be taken into account when one considers treating a patient with a fenestrated graft.
Results

Pooled results of current experience with fenestrated stent-grafts demonstrate that this surgery may be accomplished with a 99% (95% Confidence Interval [CI] 92-99%) technical success rate, a 30-day mortality rate of 1.5% (95% CI 0.4 - 8%), and acute loss of visceral arteries in 1.5% (95% CI 0.4 - 8%) of the cases (6, 11-13). At an average follow up of 11 ± 2 months (1 to 24), complications include type I proximal endoleaks in 3% (95% CI 0.4 - 10%), occlusion of renal arteries in 6% (95% CI 1.7 - 15%) but without any of these patients requiring dialysis, and reinterventions in 12% (95% CI 5 - 22%).

Published results of endovascular repair with branched grafts are all anecdotal and should therefore be looked at with some caution (7, 10, 14). Medium and longer term results of fenestrated grafting have to be awaited to demonstrate that these techniques deserve a
place in the treatment of complex aortic aneurysms. A first report showed that these procedures are associated with a significant risk for adverse renal events, demonstrating the need for careful patient selection, patient conditioning (i.e. prehydration) and patient follow-up, particularly in the first month (15). Our personal experience in the mid-term, with regard to renal function, has been somewhat better, but meticulous follow-up is mandatory to detect renal function deterioration and renal artery stenosis at an early stage (16).

In addition to the lack of published reports, the readers have to understand that all publications originate from a few very experienced centers, including people who have cooperated together with William Cook Incorporated, to develop these techniques. New centers attempting the use of fenestrated and branched grafting have to take into account a steep learning curve.

Conclusion

Although these techniques are still to be regarded experimental and in full evolution, there are several reasons to warrant their ongoing development. First, the results seem to be good in the hands of experts. Second, the technique is far less invasive than the open treatment of complex aneurysms. Finally, we will always face patients who are at high surgical risk, due to comorbidity or hostile abdomens, or after previous open surgery (17).

References


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