The European Zenith Fenestrated Experience

Indications, outcomes, and tips for successful execution.

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When treating aneurysmal disease, it is important to realize that only longer-term durability will be of benefit to our patients. Experience has taught us that aortic disease is a progressive disease. Cook acknowledges this in their research and efforts to give physicians the tools to achieve durability with their devices. The Zenith Fenestrated device in particular acknowledges the fact that aortic disease is a progressive disease and allows operators to move the landing zones/seal zones into healthier tissue and to create a long neck.

Fenestrated endovascular aortic aneurysm repair (FEVAR) has gained increasing interest throughout Europe in the last decade, as well as lately in the United States. Fenestrated customized stent grafts based on the Cook Zenith system (Cook Medical, Bloomington, IN) have made it possible to treat aneurysms with adverse proximal anatomy, including short-necked abdominal aortic aneurysms (AAAs), juxtarenal aortic aneurysms (JAAs), and even suprarenal aortic aneurysms. This article provides a brief historical overview of FEVAR in Europe and discusses its indications and contraindications, the alternative treatment options, and outcomes from expert European centers. Useful tips and tricks for FEVAR planning and execution are also described.

HISTORICAL OVERVIEW AND DIFFUSION OF FEVAR IN EUROPE

The initial experiences with fenestrated stent grafting originate from Australia and go back to 1997. Anderson et al published their experience with 13 patients who were treated with customized fenestrated stent grafts between 1998 and 2000 in Adelaide and Perth in Southern and Western Australia.[1] Semmens et al also reported early data of FEVAR from the period of 1997 to 2004 at seven centers in Perth, Western Australia.[2] In Europe, FEVAR made its entry in a few selected centers around the year 2000. Frankfurt, Germany; Groningen, The Netherlands; and Malmö, Sweden were among the first centers to start FEVAR programs. The first FEVAR series from Groningen was published almost 10 years ago, with a total of 18 patients with short-necked AAAs.[3] All patients had significant contraindications for open repair, making FEVAR a viable alternative.
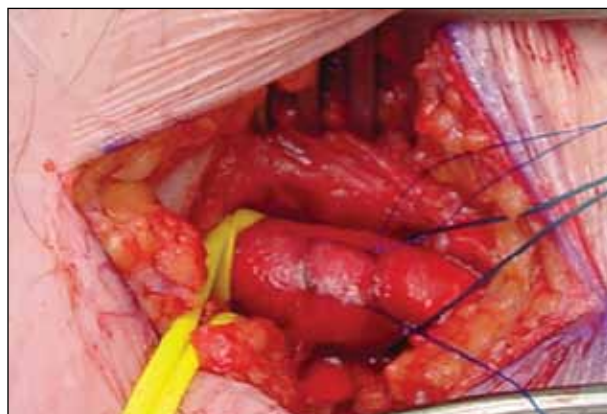
Figure 1. Double purse-string sutures at the common femoral artery before puncture. These contribute to minimal blood loss during sheath exchange and enable complete removal of the delivery system of the proximal body while stenting the target vessels, restoring blood flow to the ipsilateral lower limb.

This approach was initially considered as a last option in high-risk patients who were unfit for open surgery and anatomically unsuitable for standard EVAR. In the last decade, FEVAR has evolved in terms of technical refinements and application. Improvements in device technology and design, quicker and more efficient customization, advanced imaging equipment, and physicians' and manufacturers' cumulative experience have all led to continued widespread use of FEVAR in Europe. In addition, FEVAR increasingly came to be viewed as a "standard" procedure, one that was considered for normal-surgical-risk patients with JAAs with more frequency. At our institution, FEVAR is now considered and discussed

Figure 2. Separate 5-F sheaths for each target vessel catheterization inserted in the valve leaflets of a large 20-F sheath via contralateral femoral access.

in all anatomically suitable patients with JAAs as an alternative treatment option to open repair.

ALTERNATIVE ENDOVASCULAR TREATMENT OPTIONS FOR JAA

An adequate length of healthy, nonaneurysmal aorta is essential for proximal landing of the stent graft in order to provide good sealing and minimize the risk of type I endoleak and migration.[4] This is reflected in the manufacturers' instructions for use for all commercially available stent grafts. A minimum proximal neck length of 15 mm is commonly suggested, although a ≥ 10-mm proximal neck length is proposed by one manufacturer (Endurant, Medtronic, Inc., Minneapolis, MN). Despite these instructions for use, standard EVAR has been used in treating many AAAs with shorter proximal necks. Although initial technical success is frequently achieved, long-term durability has never been demonstrated. Increased rates of type I endoleak, migration, and perioperative mortality and morbidity have to be expected.[5-8]

New devices with novel design concepts are being considered for treating 7-mm aneurysms (Ovation, TriVascular, Santa Rosa, CA) and even those with virtually no necks (Nellix, Endologix, Irvine, CA). It is too premature to discuss results with these stent grafts, as only longer-term clinical evaluation will inform us about their durable efficacy. In our opinion, standard EVAR in short-necked AAAs is not recommended, especially if other treatment options (ie, open repair or FEVAR) are applicable.[9]

The chimney graft (CG) or "snorkel" technique (Ch-EVAR), referring to a stent implanted parallel to the aortic stent graft to preserve flow in a visceral aortic branch, has been also reported in the treatment of short-necked AAAs and JAAs. This technique, although initially introduced as a "bailout" procedure in cases of unintentionally overstented renal arteries, has gained interest for the elective treatment of short-necked AAAs and JAAs, particularly in centers where FEVAR is not available or reimbursed.[10,11] Comparison of Ch-EVAR with FEVAR is not straightforward due to inherent biases of the available literature, including different patient cohorts, anatomical
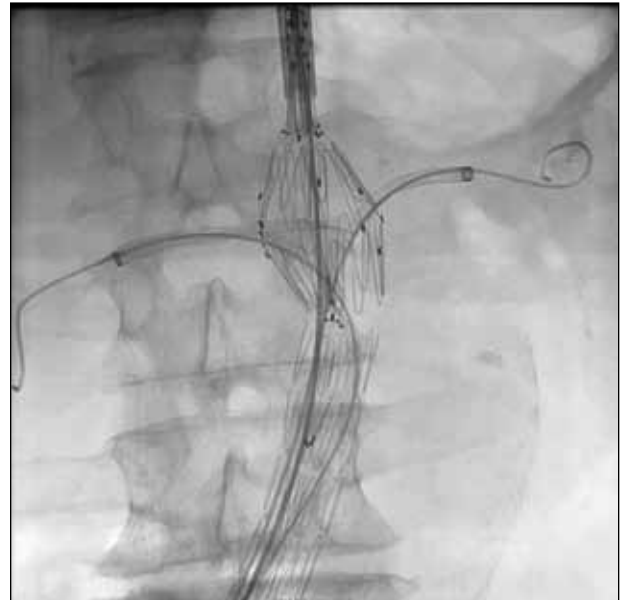

Figure 3. Guiding sheaths (7 F) advanced into the renal arteries before complete opening of the main tube graft.

configurations, and indications. Potential advantages of Ch-EVAR over FEVAR include wider availability in smaller centers and an immediate treatment option in the acute setting. On the other hand, Ch-EVAR is associated with a higher rate of proximal type I endoleak due to the gutters between the CG and the main stent graft. Ch-EVAR is also associated with an increased ischemic stroke rate of up to 6%, which is probably due to wire manipulation from upper access.[10] Ch-EVAR seems to work better when only one or two target vessels need to be treated, whereas FEVAR routinely handles three or four target vessels.

Long-term durability of Ch-EVAR has yet to be proven. Much longer follow-up is needed to assess the long-term risks of the unavoidable gutters between the CG and main stent graft. Long-term patency of the CG also remains a potential concern. In view of the previous, Ch-EVAR is currently justified in acute patients who are unfit for surgery, as a bailout treatment in case of unintentional renal artery coverage, or in elective patients who are poor candidates for open surgery and FEVAR.

INDICATIONS AND CONTRAINDICATIONS FOR FEVAR

The FEVAR technique aims to achieve sealing in aneurysms with a short or absent proximal neck below the renal arteries. With the ability to customize two to four fenestrations, the graft can be positioned higher in the aorta, over the renal arteries, and if needed, over the superior mesenteric artery (SMA) and the celiac artery. This customization needs to be individually tailored to make sure that the first sealing stent (containing the fenestrations) is completely inside the "neo" neck in a stable position. Clinical and anatomical indications for
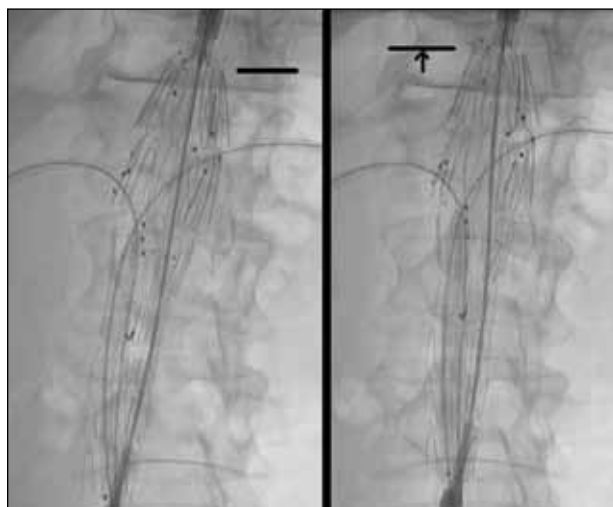
Figure 4. Pushing up of the entire stent graft in order to position the fenestrations as high as possible before removal of the diameter-reducing ties and release of the top cap. This maneuver compensates for a 1- to 2-mm downward migration after opening of the graft due to encroachment of the hooks and barbs.

FEVAR mainly include short-necked AAAs or JAAs and some suprarenal and thoracoabdominal aortic aneurysms. Furthermore, FEVAR can also be used to treat type I proximal endoleaks after previous EVAR and proximal anastomotic aneurysms or juxta/suprarenal AAAs after previous open aortic surgery, as well as in cases of aborted open surgery due to technical difficulties (ie, inflammatory AAAs, etc.). In terms of patient indications, FEVAR has been shown to be effective and safe in high-risk surgical patients (ie, patients with cardiopulmonary comorbidities, previous aortic surgery [open or EVAR], and hostile abdomen), but nowadays is also a valid alternative treatment option in normal-surgical-risk patients.[12]

Relative contraindications for FEVAR include narrow or severely angulated access vessels, adverse proximal landing zone characteristics other than length (such as circular calcification or thrombus, small diameter, or angulation), and narrow, short, or early bifurcated target vessels with a sharp downward takeoff. Acute cases are also usually not amenable to FEVAR due to the required 4 to 6 weeks for device customization. The development of "off-the-shelf" fenestrated stent grafts is expected to improve the availability of FEVAR in the acute setting.[13]

TIPS AND TRICKS FOR FEVAR PLANNING AND EXECUTION
Planning
The choice of one or two internal sealing stents is the first step in planning a fenestrated stent graft procedure. Choosing two internal sealing stents, whenever possible,

Figure 5. Balloon molding of the completely opened main stent graft with a compliant balloon before insertion of the renal covered stents in order to improve apposition to the wall. This is not performed routinely, but it should be considered in angulated necks.

is advantageous for two reasons. First, it increases fixation of the stent graft in the available neck. Second, it allows positioning of the fenestrations in the second sealing stent with better apposition to the aortic wall.

The second step is the proper selection of small fenestration types. A small fenestration can be either 6 X 6 mm or 6 X 8 mm. The second option is preferred because it provides additional room for catheterization and positioning of the stent graft. To avoid endoleaks, it is advisable to use covered, balloon-expandable stents that can be flared with a larger balloon on the inside of the main stent graft (eg, Advanta V12, Atrium Medical Corporation, Hudson, NH). Covered stents have also been shown to perform better than noncovered stents.[14]

A maximum overlap between the first fenestrated tube part and the second bifurcated graft is mandatory. Two overlapping stents, especially in an angulated aorta, have been shown to be insufficient and have resulted in some disconnections. Therefore, the longest possible tube should be planned to land 2 to 3 cm above the aortic bifurcation. To create a long overlap, the longest

TABLE 1. SUMMARY OF EUROPEAN SERIES REPORTING FEVAR FOR JAAs							
First Author (year)	N =	Fenestrations	Target Vessel Stents	Operative Target Vessel Preservation (%)	Proximal Early Type I Endoleak (%)[c]	30-Day Mortality (%)	Follow-Up (Months)[d]	Vessel Patency (%)[e]
Ziegler,[15] 2007	60[b]	41 S/78 F	56 C, 2 B	96.7	6.7	1.7	23	95.7
Scurr,[16] 2008	45	39 S/76 F	21 C, 61 B	98.3	0	2.2	24	98.2
Kristmundsson,[17] 2009	54	43 S/91 F	27 C, 69 B	98	5.6	3.7	25	98.5
Amiot,[18] 2010	134	133 S/269 F/1 BR	NR	99	2	2	15	99
Verhoeven,[19] 2010	100	106 S/169 F	93 C, 76 B	98.9	2	1	24	96.7
GLOBALSTAR,[20] 2012[a]	318	201 S/688 F	529 C, 63 B	99.4	4.4	3.5	6	98.4

[a]On behalf of the British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry.
[b]Three thoracic aortic aneurysms were excluded.
[c]Includes both intraoperative and early postoperative endoleak (1 month).
[d]Mean or median value depending on the reporting method of each article.
[e]Represents the ratio of patent target vessels at latest follow-up to successfully initially preserved target vessels.
Abbreviations: B, bare stents; BR, branch; C, covered stents; F, fenestration; N, number of patients; NR, data not retrievable; S, scallop.

possible bifurcation should be used, as this will result in a three-to-four-stent overlap.

Procedure

Femoral access. In our institution, the routine use of purse-string sutures in the common femoral artery is advocated (Figure 1). This contributes to minimal blood loss during large sheath exchange and allows for complete removal of the delivery system of the proximal body while stenting the target vessels, restoring blood flow to the ipsilateral lower limb.

Target vessel cannulation and stenting. Target vessel cannulation is performed through separate 5-F sheaths inserted in the valve leaflets of a large 20-F sheath via contralateral femoral access (Figure 2). The use of the 20-F sheath avoids repeated cannulation of the fenestrated body for each target vessel and provides better stability for the wires and catheters when addressing the target arteries. Catheterization of target vessels is a two-operator job: one operator positions the catheter in the fenestration, and the second operator aims to "open the door" via slight repositioning of the stent graft to optimize apposition of the fenestration and the target vessel.

Upon catheterization, it is advisable to select the longest main branch of the target vessel to position the stiff wire. This will provide the support needed for insertion of a guiding sheath and, later, the bridging covered stent. Also, it is necessary to always check the correct position of the catheter via angiography. We routinely use either a heavy-duty, 1.5-mm "J" Rosen wire (Cook Medical) or an Amplatz super stiff 1-cm floppy-tip wire (Boston Scientific Corporation, Natick, MA), especially for the SMA and difficult anatomies (eg, stenosis, severe angulation, short length) in the renal arteries. After adequate wire advancement into the target artery, the guiding sheaths are advanced, avoiding pushing the dilator too far inside the renal artery (Figure 3). To advance the sheath far enough into the renal artery, it is possible to slide the sheath forward over the dilator.

After positioning the guiding sheaths into the target vessels, the proximal tube is completely opened. The guiding sheaths tend to pull down the fenestrations a bit. Therefore, the removal of the diameter-reducing ties and the release of the top cap should be done while the second operator is firmly pushing up the entire stent graft in order to position the fenestrations as high as possible (even a bit higher than the target vessel) (Figure 4). After opening of the graft, encroachment of the hooks and barbs may result in an initial 1- to 2-mm downward migration before reaching the final position. With the fenestrations in an ideal position, the stents will have less stress to withstand. In angulated necks, balloon molding of the main stent graft with a compliant balloon should be considered before insertion of the covered stents to improve apposition to the wall (Figure 5).

It is advisable to start target vessel stenting with the

highest renal artery to prevent damage to the contralateral renal stent during deployment. When inflating the delivery balloon, its catheter needs to be tilted upward to position the stent in a natural position. To flare the stent, a 12-mm X 2-cm noncompliant balloon is used, as this can also be tilted upward to achieve circumferential flaring.

Bifurcated component deployment. While advancing the bifurcated component, care must be taken not to disrupt the renal stents. Before deployment, the following positions need to be carefully checked: (1) the bifurcated stent is positioned below the lowest renal artery stent; (2) the overlap between the bifurcated graft and tube graft is done with at least three stents; (3) the position and orientation of the contralateral limb is adequate; and (4) the ipsilateral limb is well-positioned inside the ipsilateral common iliac artery above the iliac bifurcation. It is better to perform balloon dilatation before insertion and deployment of the contralateral limb, as this one is usually deployed slightly above the flow divider. Correct catheterization of the contralateral gate is the last important step and should be carefully verified in order to avoid inaccurate positioning of the contralateral limb (ie, between bifurcated and tube part but outside the gate).

OUTCOMES WITH FEVAR IN EUROPEAN CENTERS

Outcomes with FEVAR in Europe are reflected in three relatively small studies[15-17] and three larger studies with 100 patients or more each, originating in France, the UK, and the Netherlands (Table 1).[18-20] These six European studies (four single- and two multicenter) include a total of 711 patients (89% men). The mean patient age was 72 years. The maximum AAA diameter ranged from 5.5 to 6.8 cm. In 666 patients (93.7%), FEVAR was performed to treat a primary short-necked AAA or JAA. In 28 cases (4%), the indication for treatment was a para-anastomotic pseudoaneurysm or proximal extension of disease after prior conventional open AAA repair, and in 12 patients (1.7%), a proximal endoleak after prior EVAR. In the remaining five patients (0.7%), the indication for FEVAR was an aortic ulcer (n = 3) or an aortic aneurysm secondary to aortic dissection (n = 2). All procedures were performed on an elective basis.

A total of 1,934 fenestrations (mean, 2.7 fenestrations per patient) were incorporated in the implanted stent grafts. Of those, 1,371 were small/large fenestrations, and 563 were scallops. A total of 1,286 fenestrations (71.6%) targeted the renal arteries; 420, the SMA (23.4%); and 91, the celiac axis (5.1%); whereas the target vessels for the remaining 137 fenestrations were not reported. The cumulative operative target vessel preservation success was 1,915 of 1,934 (99%). Most vessels lost were renal arteries, with only one SMA and one celiac axis reported.

Intraoperative open conversion was required in two of 711 cases (0.3%) due to an inability to remove the introduction system in one case and one case of distal aorta occlusion. Two procedures (0.3%) were aborted, one due to failure to achieve the desired orientation and one due to access-related problems. Early proximal type I endoleak was detected in 29 of 711 patients (4.1%), 22 of which were diagnosed intraoperatively. Eleven were successfully treated with repeated ballooning or cuffs, either during the primary FEVAR procedure or during a secondary intervention. One patient required conversion to open surgery 9 months after the initial FEVAR procedure. The remaining 17 proximal type I endoleaks resolved spontaneously during follow-up.

The 30-day in-hospital mortality rate was 2.7%, with acute myocardial infarction being the most common cause of postoperative death. Postoperative impairment of renal function, defined as a postoperative rise in serum creatinine level > 30% over baseline, was noticed in 52 of 711 patients (7.3%). Additional postoperative complications included cardiac complications (acute myocardial infarction or arrhythmias) in 30 (4.2%), pulmonary complications (pneumonia, acute respiratory distress syndrome, respiratory insufficiency) in 17 (2.4%), segmental renal infarcts in seven (1%), spinal cord ischemia in six (0.8%), sepsis in five (0.7%), external iliac artery rupture in six (0.8%), access site complications in three (0.4%), ischemic stroke in three (0.4%), and retroperitoneal hematomas in three (0.4%) patients.

The median follow-up duration was 25 months. During follow-up, 37 target vessel occlusions were reported, accounting for a late cumulative target vessel patency rate of 98.1%. Patient survival was not widely reported. In our 8 years of experience, with a 1% surgical mortality rate, the estimated survival rate was 90.3%, 84.4%, and 58.5% at 1, 2, and 5 years, respectively.[15] Most recently, the UK GLOBALSTAR registry reported survival rates of 94%, 91%, and 89% at 1, 2, and 3 years, respectively.[17]

CONCLUSION

Fenestrated stent grafting is now a well-validated technique in Europe, demonstrating excellent short- and midterm results for the treatment of short-necked, juxtarenal, and selected cases of suprarenal and thoracoabdominal aneurysms. Cumulative outcomes from European centers illustrate the safety and efficacy of the technique for the prevention of aneurysm rupture, along with significantly reduced mortality and morbidity rates compared to conventional surgery. Alternative endovascular options such as standard EVAR and Ch-EVAR have been far less reported in the literature; there are no longer-term data available to prove their durability. In view of this, it is worthwhile to focus on the recruitment of new FEVAR centers. Patient selection, device planning, and correct execution of the technique are required for successful outcomes. ■

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