

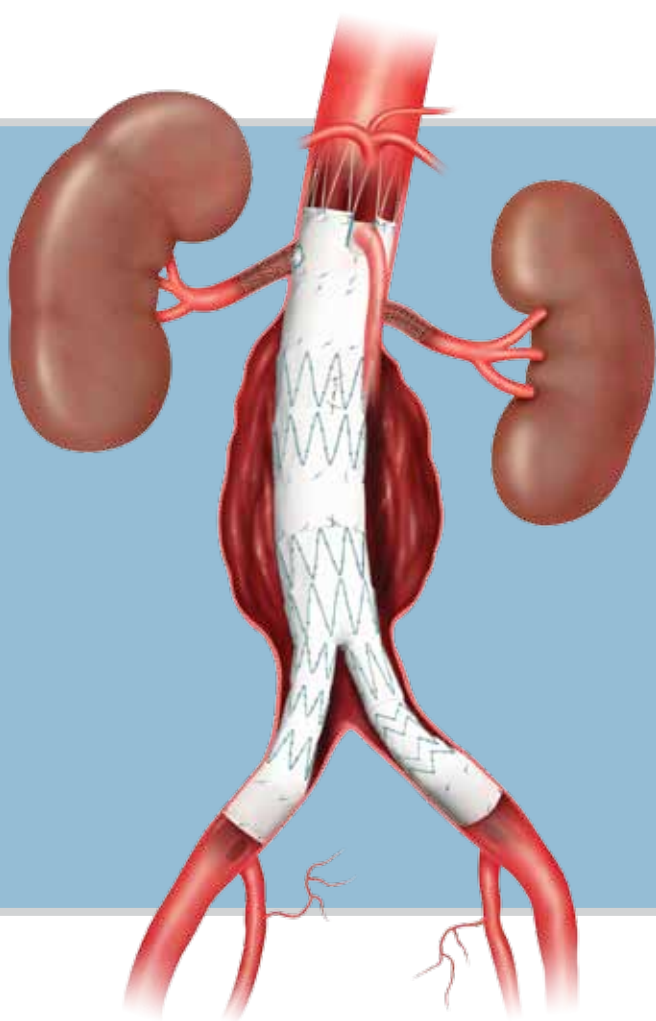
Endovascular TODAY

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MOVING EVAR FORWARD



Physicians' experiences and opinions
of the Zenith Fenestrated AAA endovascular graft.



Equipping Physicians With Cutting-Edge Technology... Responsibly

Endovascular aneurysm repair (EVAR) as an approach to the treatment of aortic disease is reaching a more mature stage in its history. It is now more than 20 years since the first EVAR was performed. During this time, the most significant debate has been the comparison of EVAR to open surgical repair. As we go forward, the debate needs to evolve.

We at Cook Medical believe that the most central question today is whether the placement of a stent endograft resolves the pathological process causing the aneurysm or dissection. The answer is a resounding no—aortic disease is progressive, and the disease process will continue. However, it is also true that EVAR prevents aneurysm rupture and death, provided the patient selection and device selection are appropriate.

To this end, the relevant debate going forward should be: how does the progressive nature of aortic disease affect patient and device selection to ensure a durable repair?

There are two considerations in approaching this challenge: how does the patient present clinically and anatomically, and how might that change post-EVAR? Effective device selection to ensure a durable repair

requires careful scrutiny with both critical considerations. We already know that the most important decision is choosing a seal zone within healthy tissue. With abdominal aortic aneurysm (AAA), this probably means selecting a more proximal seal zone.

At Cook Medical, we believe that the risks of failure and reintervention due to the effects of the progressive disease process are minimized when a standard AAA stent endograft is used with an infrarenal seal zone of at least 15 mm. As the infrarenal neck (and therefore the seal zone) becomes smaller and the aortic diameter gets larger, the risk increases for aortic disease progression, causing failure of the seal at the landing zone and resulting in type IA endoleak and subsequent reintervention or rupture.

That's where the Zenith Fenestrated graft fits into this picture. It offers the opportunity to choose a suprarenal seal zone that lands in healthy aortic tissue above the renals.

This is also the foundation of the Zenith product line. Zenith products have indications that accommodate a durable endovascular repair in the presence of progressive aortic disease. To treat AAA, we designed the Zenith Flex device for infrarenal necks of 15 mm or greater. For

infrarenal necks of 4 to 14 mm, in which the risks of type IA endoleak, reintervention, or rupture increase as the disease progresses, we designed the Zenith Fenestrated graft.

This introduces a second and equally important debate topic: how should technology be made available to a physician after regulatory approval?

This contentious issue faces all medical device companies today. There are many stakeholders to consider: the patient and their families, the doctor, the regulator, the payer, the company and its people. A medical device company must balance all stakeholders' interests, many of which are potentially competing interests, when a plan to launch a new technology is developed and executed.

We at Cook Medical believe physicians should expect medical device companies to be responsible in how they act and to demonstrate appropriate rigor and discipline. It is ultimately the patient who carries the risk, and we take that responsibility very seriously. This is particularly important with the launch of new devices, especially when utilizing the new technology involves ample consideration of patient selection criteria and specific planning guidelines.

All of this is true with the Zenith Fenestrated device. Per specific requirements included in the terms of US

Food and Drug Administration approval, Cook Medical has instituted a prescribed Zenith Fenestrated training program, recognized the need for a certain number of cases to be proctored by suitably experienced physicians, and developed both a postmarket study and training-effectiveness analysis. Although the Zenith Fenestrated device has been available in other markets for quite some time, it is totally new to the US. Therefore, we sought to bring about a slow launch, which was driven by the desire to provide the best training and support possible with a limited number of physicians who are suitably experienced with the technology and were ready, willing, and able to proctor.

Today, we are ready to accelerate access to the Zenith Fenestrated graft. Cook Medical will always strive to ensure that we show the necessary rigor and discipline to be the responsible partner you expect. I believe we are demonstrating this commitment in our approach to providing broad access to the Zenith Fenestrated graft across the US and over time. ■

—Philip B. Nowell

Vice President, Cook Medical
Global Business Unit Leader, Aortic Intervention

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The European Zenith Fenestrated Experience

Indications, outcomes, and tips for successful execution.

**BY ATHANASIOS KATSARGYRIS, MD; BALASZ BOTOS, MD;
AND ERIC L. G. VERHOEVEN, MD, PhD**

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

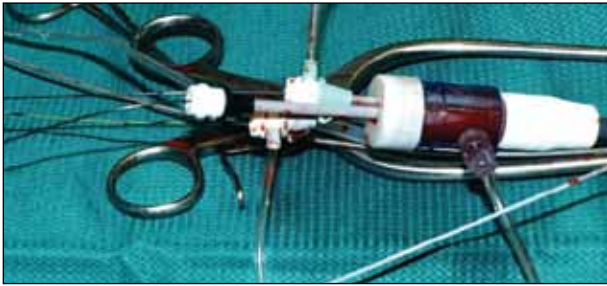


Figure 2. Separate 5-F sheaths for each target vessel catheterization inserted in the valve leaflets of a large 20-F sheath via contralateral femoral access.

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

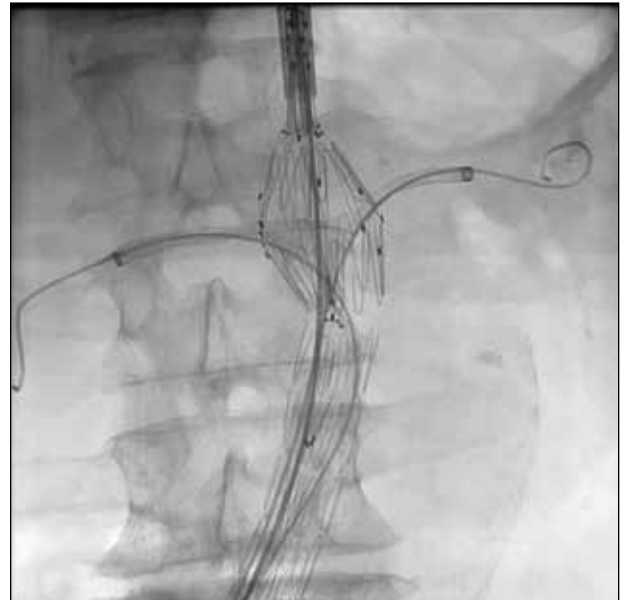


Figure 3. Guiding sheaths (7 F) advanced into the renal arteries before complete opening of the main tube graft.

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

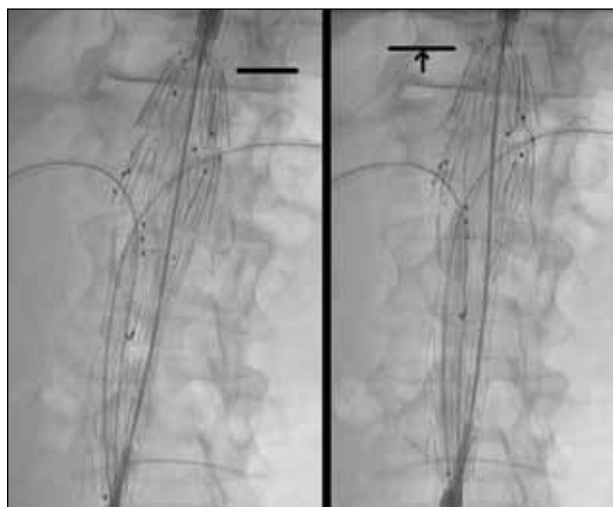


Figure 4. Pushing up of the entire stent graft in order to position the fenestrations as high as possible before removal of the diameter-reducing ties and release of the top cap. This maneuver compensates for a 1- to 2-mm downward migration after opening of the graft due to encroachment of the hooks 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

^aOn behalf of the British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry.

^bThree thoracic aortic aneurysms were excluded.

^cIncludes both intraoperative and early postoperative endoleak (1 month).

^dMean or median value depending on the reporting method of each article.

^eRepresents 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 studies¹⁵⁻¹⁷ 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 hematoma 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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Physician Training and Outcomes With the Zenith Fenestrated Graft

Appropriate physician training and selective application of this technology are critical in achieving the best possible outcomes for a complex patient population.

BY LUIS A. SANCHEZ, MD, FACS

The use of endovascular grafts for the treatment of infrarenal aneurysms was initially approved in the US in 1999. At that time, extensive physician training (2-day courses), live case observation, and physician proctoring by experienced users were required as part of the rollout process. Inexperienced physicians learned appropriate patient selection as well as basic and critical endovascular techniques for the safe and effective use of these early endovascular devices. To date, eight devices have been approved in the US for endovascular aneurysm repair (EVAR). Physician training for each one of these devices has been simplified as the expertise of endovascular specialists has increased, and many of these devices have similar technical requirements and deployment techniques.

BACKGROUND

The Zenith Fenestrated graft (Cook Medical, Bloomington, IN) was approved in the US in April 2012. This graft is the first fenestrated graft approved in the US, and its application is significantly different from currently available EVAR devices. These devices are custom-made based on the specific anatomy of the patient and require careful patient selection and detailed device planning by the treating physician. Additionally, the technical endovascular skills necessary for the safe and effective performance of these procedures (ie, fenestrated EVAR [FEVAR]) is significantly more extensive than for standard EVAR. Appropriate physician training and selective application of the technology will be critical in achieving the best possible outcomes for a complex patient population. A rigorous training program for physicians with extensive expertise in EVAR and other complex endovascular procedures was started in June 2012.

TRAINING SESSIONS

The in-depth, 2-day training sessions for the physi-

cians include multiplanar reconstructions for planning the Zenith Fenestrated graft procedure, detailed graft planning and sizing, extensive review of the device and its deployment, a taped case observation, discussions on tips and tricks for successful FEVAR, and hands-on deployment of the fenestrated devices under fluoroscopy. A small group of physicians (five to eight) is being trained in every course to achieve one-on-one training in the critical aspects of image evaluation, case selection, and device planning, which are essential for the successful application of this advanced technology. Additionally, every trained physician will be proctored for a minimum of two cases (usually two to five cases) by an experienced endovascular specialist with expertise in performing FEVAR.

To evaluate the postapproval FEVAR results, as well as the training program, a ZFEN Post-Approval Study and ZFEN Training Registry are being conducted. The ZFEN Post-Approval Study will enroll 21 new patients who will be followed for 5 years (data from these patients will be combined with those from the patients in the initial ZFEN study). The patients in this postapproval study will come from centers that did not participate in the initial study and that have completed the commercial training program.

To further assess the success of the training program, the ZFEN Training Registry will include 82 patients. No more than two patients will be entered at any one site, providing for at least 41 participating sites in the registry. The aim of the registry is to assess whether the commercial training program is adequate to enable physicians who did not enroll patients in the initial study to achieve operative results comparable to those achieved by experienced users based on technical success. The ZFEN Training Registry will only collect procedural data. The primary endpoint is technical

success, which is defined as successful completion of the procedure with endograft patency, preservation of all vessels targeted by a fenestration, and no type I or type III endoleaks at completion of the procedure. Importantly, as the training program and its results are being evaluated, the endovascular expertise of the physicians trained over time and their commitment to this advanced technology will advance the training program. The training programs will have to evolve over time to accommodate the knowledge base of the physicians being trained to ultimately achieve the best possible results.

RESULTS

To date, 17 training sessions have been conducted since June 2012. During those sessions, 114 physicians from 76 facilities were trained. Of this group of physicians, 24 of them have successfully completed both the workshop and the required proctored cases. Additionally, our institution has been involved in data collection of early postapproval experience with FEVAR from selected sites that have either completed the commercial training program or have access to the device due to prior experience with it. Early clinical data have been collected on 57 consecutive patients treated with the commercial Zenith Fenestrated graft

at seven US institutions from June 2012 to December 2012. Seventy-four percent of the patients were from five original trial sites, whereas 26% of the patients were from two postapproval trained sites. The technical success rate was 100%, and only one patient had a kinked renal stent that was successfully restented. In this group, the 30-day outcomes of FEVAR for juxtarenal aneurysms compares well with the results of the US fenestrated trial.

CONCLUSION

In summary, the training and early outcomes of FEVAR with commercially available devices will be carefully scrutinized over the next few years. The results of the ZFEN Post-Approval Study and the Training Program Registry will be very helpful in assessing the treatment results of FEVAR and improving the training programs available for current and future fenestrated and branched devices. ■

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Getting Started With the Zenith Fenestrated Graft

The long-term success of this exciting new technology relies on proper patient selection, physician training, accurate sizing and assessment of anatomy, and delivering excellent patient outcomes.

BY JASON T. LEE, MD

The US Food and Drug Administration (FDA) approval of the custom Zenith Fenestrated graft (Cook Medical, Bloomington, IN) in the United States during the spring of 2012 was a significant step and evolution in the endovascular treatment of complex abdominal aortic aneurysms (AAAs) (Figure 1). Many centers had the capability of treating patients with various iterations of this device in their practice through the initial clinical trial,¹ physician-sponsored investigational device exemptions,^{2,3} or with physician-modified endografts,⁴ but widespread US experience with this particular device was limited. Although snorkel or chimney approaches have been increasing in popularity and reporting early success,^{5,6} long-term durability and patency data are still lacking. Because the Zenith Fenestrated graft gained significant utilization throughout Europe and Australia with excellent midterm outcomes⁷ in the treatment of short-neck juxtarenal aneurysms, there currently is great interest and early demand among US endovascular surgeons to have access to this newly approved endograft.

Our center had been a clinical trial site for the Zenith Fenestrated graft, but relatively strict anatomic inclusion criteria led to several patient exclusions, and we did not implant a device in the trial. When FDA approval was announced last spring, I was fortunate to be asked to participate in the first US training program as the technology was disseminated, giving our program the unique perspective as the first physician team to complete the FDA-mandated training and proctoring on the device, which we completed in the summer of 2012. The purpose of this article is to discuss the process our center went through in order to have full access to the device postapproval, how we prepared the operating room and angiography suite team to incorporate the technology into our practice, and some early lessons learned in setting up our fenestrated endovascular aneurysm repair (EVAR) program.

PHYSICIAN TRAINING

Training began even before participating in the 2-day mandated course in the form of reviewing the instructions for use (IFU) of the device and considering several patients for implantation. The IFU for this device requires an infrarenal neck of 4 mm or greater and those unsuitable for a nonfenestrated graft, which allows treatment of the short-necked aneurysms that are not treatable under the IFU for the standard Zenith Flex device (Cook Medical). Identifying several patients prior to attending the training course and bringing the DICOM CT data to analyze on the AquariusNet Intuition software package (TeraRecon, San Mateo, CA) was key to getting the most out of the training course. Much emphasis during the course was on the proper sizing and ordering of the custom Zenith Fenestrated device. I identified nine patients with aneurysms who had not yet been offered an endovascular solution to treat their AAAs at our institution due to various neck morphologic criteria.

Armed with these CDs, the course began with an introductory lecture about indications, instructions, and deployment sequences of the Zenith Fenestrated device. The bulk of the training course centered around working on computer workstations and performing three-dimensional (3D) analysis of the CT angiography (CTA) images we brought to the course of our own patients. If course participants did not have enough CTAs of their own patients, model patients were provided as standard training cases. Although I had already extensively used AquariusNet 3D software, as we routinely evaluate EVAR cases at our institution with it, the sequence and types of measurements necessary for the custom Zenith Fenestrated device were different and quite substantial.

As described throughout this supplement, understanding arc lengths, clock positions, and curved and multiplanar reformats are vital to accurately building the custom device. Because millimeters can make the difference between easy and challenging catheterization of

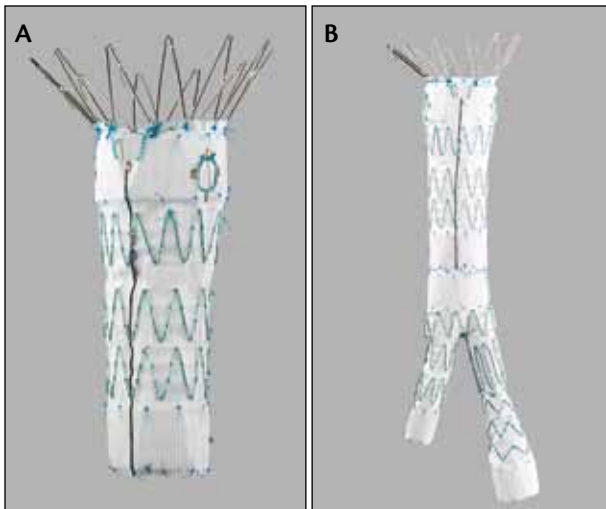


Figure 1. The proximal component of the Zenith Fenestrated graft (A). The distal component in place with an extension spiral Z limb to the left iliac (B).

renal arteries through fenestrations, as well as adequate perfusion through scallops, accurate sizing is paramount to optimal outcomes. I would estimate that even a relatively intermediate user of TeraRecon software initially requires 45 to 60 minutes per patient to make all the necessary measurements to order the device.

Regional clinical specialists, as well as core faculty, who are experienced with the Zenith Fenestrated device are obviously part of the training course and provide invaluable tips and tricks to successful analysis of CTA data and ordering of the appropriate endograft components (see the *Tips and Tricks for Getting Started With the Zenith Fenestrated Graft* sidebar). Based on my experience at the training course and performing 21 cases in the first 6 months after approval, measuring and sizing at least six cases and discussing them with the faculty at the course is a reasonable goal for understanding the process. As previously indicated, prior experience with TeraRecon software potentially shortens the learning curve. Not having access to TeraRecon software at one's institution puts the surgeon at a particular disadvantage for this device, as the clinical specialists, support from Cook Medical, and the server to share in creating 3D measurements are all based on this software platform.

The final part of the physician training course involved hands-on device deployment under fluoroscopy on a tabletop model to understand the general steps in completing a case with the Zenith Fenestrated device. Again, faculty course leaders and clinical specialists who are well versed in these cases provided key pearls as to the most efficient sequence of steps, types of catheters and equipment necessary, and the general nuances of visualizing the device markers during the case. This hands-on demonstration was one of the key components of the training, and even watching your other training course

colleagues perform their own hands-on deployment was extremely informative.

From that point on during the training, the physician should have developed a list of catheters, balloons, sheaths, and ancillary endovascular equipment to successfully plan out their required two proctored cases. Participants at the training course should try to plan and size and get signed off on by the faculty course leader for one, if not both, of their required proctored cases. This process involves uploading the CTA data to the central server, sizing and measuring the case, reviewing the case with your local clinical specialist, and then having a faculty proctor independently review the case to provide advice and confirmation of the device order. The training course is an ideal environment to speed up this process should you have an anxious patient anticipating repair with the Zenith Fenestrated device.

SETTING UP YOUR TEAM

Most, if not all, surgeons going through the Zenith Fenestrated graft training process will already have extensive experience with routine EVAR and perhaps even more complex EVAR. The planning and orchestration of a "fenestrated EVAR" case requires adequately trained staff, slightly more patience on the surgeon's side, and some additional time. One of the helpful tips I learned from the training program was to discuss some of the upcoming changes with the operating room and angiography suite staff. The list I created of additional catheters, wires, balloons, and sheaths was printed, laminated, and attached to our hybrid operating room wall. We changed our scheduling system so we could book a fenestrated EVAR case, and the staff would know to pull the additional ancillary equipment.

We met with our key nursing personnel to discuss the additional time and extra equipment that was to be expected during the learning phase with the Zenith Fenestrated graft. I met with our purchasing managers in the angiography suite to ensure that they understood that these were custom-ordered devices to be charged to a particular patient. Although all hospital policies are different, understanding this process might be new to many surgeons. Because the devices are manufactured in Australia and then shipped locally, a purchase order must be set up ahead of time. Making sure your hospital staff understands this process will make the ordering and delivery of devices more streamlined. Speaking with your billing and finance officers is recommended, as there are new "G-codes" as of April 2013 for billing of fenestrated cases. Ensuring that the program is financially viable is obviously a local issue, but this can cause problems if it is not acknowledged early on.

My own personal bias for performing these cases is that they should be done in a hybrid endovascular suite with fixed imaging. Being acquainted with the visualiza-

TIPS AND TRICKS FOR GETTING STARTED WITH THE ZENITH FENESTRATED GRAFT

- Identify several patients who might be candidates and bring their DICOM data to the training course.
- Familiarize yourself with 3D workstation software for imaging manipulation and discuss the feasibility of purchasing/leasing TeraRecon software with the hospital or radiology department.
- Meet with your operating room and angiography suite staff, nurses, technologists, and inventory purchasers to prepare them for this new technology.
- Choose routine cases for your first several Zenith Fenestrated graft cases that include good iliac access, minimal tortuosity and angulation, and straightforward renal anatomy.
- Consider prewiring the renal arteries to mark the positions of the ostia or use imaging overlays.
- Anticipate difficult renal cannulations and have backup plans of how to advance devices through the fenestrations and into target vessels.
- Do not hesitate to create better iliac access via open or endovascular conduits.

tion of the markers on the device for accurate placement, as well as the potential amount of fluoroscopy time needed to perform the case, makes using a portable C-arm potentially unsafe and inefficient. Preliminary data are accumulating that use of a hybrid room is safer, even for routine EVAR.⁸

For surgeons who perform EVAR with an assistant, surgical partner, or trainee, familiarizing the group with this procedure is also important. Several additional steps and attention to detail so that sheaths do not slip, wires stay in place, and devices deploy accurately are key changes compared to more routine EVAR. Debriefing with your assistants and empowering your partners to size up their own cases allows further education in the rollout of this exciting new technology.

THE FIRST TWO CASES

To be “signed off” for Zenith Fenestrated graft use after completing the physician training course, you must complete two observed cases with a faculty proctor. Choosing these first two cases can be a source of some difficulty for many, but some relatively simple rules apply. First and foremost, the case must fit within the IFU, meaning a modest neck of 4 to 14 mm should be present to ensure that the device behaves and acts the way it was meant to be utilized. Challenging anatomy that would cause early cases to be more complicated with longer operative times includes severely angulated necks, neck thrombus,

downward-angulated renal arteries, narrow distal aortas, iliac tortuosity, and poor external iliac access.

There will be enough challenges during Zenith Fenestrated graft training involved with using a new device, achieving familiarity with the steps, and ancillary help, so choosing an anatomically challenging case can potentially lead to compromised results. Active discussion prior to your first case with the faculty proctor provides invaluable insight into completing the case safely and effectively. Newer imaging technology that can be extremely helpful includes fusion software to provide overlays of the anatomy on the screen while trying to cannulate. When still in the learning curve, I prefer the technique of prewiring both renal arteries with 0.018-inch wires through multiple punctures in the contralateral sheath to mark the renal ostia. This allows clear visualization of the target renal arteries when catheterizing through the small fenestrations. An added benefit of the prewired renal arteries is the occasional misaligned proximal body and the ability to inflate a balloon at the renal ostium to deflect away the fabric to allow successful catheterization.

THE NEXT SEVERAL CASES AND HOW TO PREPARE YOUR PRACTICE

After two successful cases and being signed off by the proctor, there remains much potential to expand your practice and referral network. Our team developed a streamlined process for evaluation and local recruitment of these patients with challenging EVAR anatomy. Personal calls to local surgeons and primary care physicians informing them of our new access to the Zenith Fenestrated device immediately generated several referrals, and the word spread relatively quickly. This not only garnered referrals for more Zenith Fenestrated graft cases, but even for more routine cases that were treated with standard EVAR. Certainly, an unintended consequence is now the referral of cases that are clearly not suitable for the Zenith Fenestrated device, which includes “no-neck” aneurysms, thoracoabdominal aneurysms, and reintervention for previously placed endografts.

Perhaps the most challenging part of the next several cases after one has been “signed off” is that planning and sizing has to be done independently from that point on. Anticipating every angle, curve, or challenge is difficult at best and, to reiterate an earlier point, requires full access, comfort, and experience with the TeraRecon software. Now, we can complete the usual measurements for routine Zenith Fenestrated graft cases in under 20 minutes, but some uncertainty remains in how the renal angulations can affect cannulations and how iliac tortuosity can misalign or twist a proximal piece when inserted. Although the Zenith Fenestrated graft is a dramatic improvement in the current endograft technology

and allows for the treatment of more challenging neck anatomy, further refinements are already underway, and next-generation fenestrated and branch technology is in the pipeline. The rollout and dissemination of the Zenith Fenestrated device has helped with the process of physician training, emphasizing reliance on imaging and sizing, and stressing the technical skill set necessary to successfully treat these patients.

SUMMARY

Like all new devices, the long-term success of this exciting new technology will be predicated on careful patient selection, adequate physician training, expert sizing and assessment of anatomy, and delivering excellent patient outcomes. The endovascular surgeon remains the key stakeholder and provider of this care and should remain at the forefront of the learning, teaching, and development of future fenestrated technology. Attention to detail and the precision in planning and sizing cannot be overemphasized. The process of training was purposefully developed to be comprehensive with several checks and balances and perhaps should serve as a model as EVAR technology continues to be refined.

The early experience with the Zenith Fenestrated graft has been very successful from a patient treatment standpoint, yet challenging in that multiple resources

were necessary for programs to be launched. The expertise of several colleagues and proctors nationally to share in their experience, as well as my local partners and ancillary staff, has been extraordinary as we shepherd in this next wave of advanced EVAR treatments. ■

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Fenestrated Stent Graft Repair for Complex Aneurysms

How to improve outcomes with optimal device design, planning, and techniques using the Zenith Fenestrated stent graft system.

BY GUSTAVO S. ODERICH, MD

Endovascular aortic aneurysm repair has been shown to reduce blood loss, operative time, hospital stay, mortality, and morbidity compared to open surgical repair of infrarenal abdominal aortic aneurysms.¹⁻³ Inadequate proximal necks limit the use of endovascular approaches in up to 40% of patients because of short length, angulation, or involvement of the visceral arteries.⁴ In these patients, stent grafts designed with fenestrations and/or scallops provide a means to incorporate segments of the visceral arteries into the proximal sealing zone.⁵⁻⁷ Single-center reports, multicenter registries, and systematic reviews indicate that the technique is reproducible, with rates of high technical success, low morbidity, and low mortality.^{5,8-13}

The Zenith Fenestrated stent graft system (Cook Medical, Bloomington, IN) has been implanted in more than 5,500 patients worldwide to treat complex aortic aneurysms (A. Smith, personal communication, April 2013). The preliminary results of the United States prospective multicenter trial have shown no aneurysm-related mortalities, low morbidity, and no ruptures, conversions, or type I or III endoleaks at the attachment sites, although there has been one case of device migration.¹⁴ The device was approved by the US Food and Drug Administration for commercial use in April 2012. This article summarizes concepts of device design, case planning, and techniques of implantation using the Zenith Fenestrated stent graft system.

DEVICE DESCRIPTION

The Zenith Fenestrated stent graft has been approved to treat patients with short-necked abdominal aortic aneurysms that are ≥ 4 mm in length and those who do not meet the proposed anatomical criteria for the use of infrarenal stent grafts. The device consists of a proximal fenestrated component, a distal bifurcated component,

and a contralateral iliac limb extension (Figure 1). The fenestrated tubular component is custom-made to fit the patient's anatomy with up to three fenestrations, of which, two can be of the same type. There are three types of fenestrations that can be manufactured in the fenestrated component, including small, large, and scallop fenestrations (Figure 1). Small fenestrations have dimensions of 6 X 6 mm or 6 X 8 mm, do not have struts crossing the middle of the fenestration, and are reinforced by a nitinol ring. Small fenestrations can be fashioned > 15 mm and < 36 mm (for 24- to 32-mm devices) or < 46 mm (for 34- to 36-mm devices) from the edge of the fabric. Large fenestrations are not reinforced by a nitinol ring, measure 8 to 12 mm in diameter, and can be fashioned > 10 mm from the edge of the fabric. Large

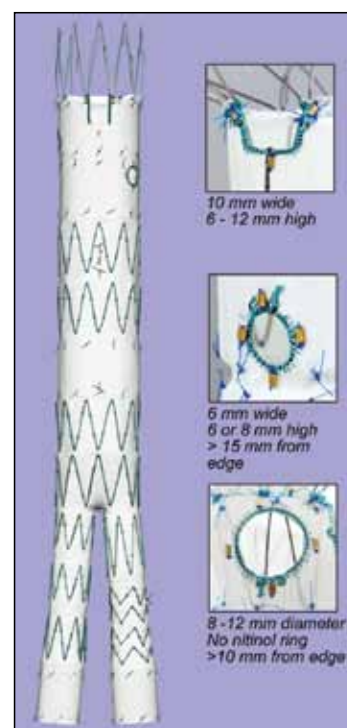


Figure 1. Configuration of the Zenith Fenestrated stent graft system with a proximal fenestrated component, distal bifurcated universal component, and contralateral iliac limb extension. The fenestrated component is custom-made with a maximum of three fenestrations, including scallop, large, or small fenestrations.

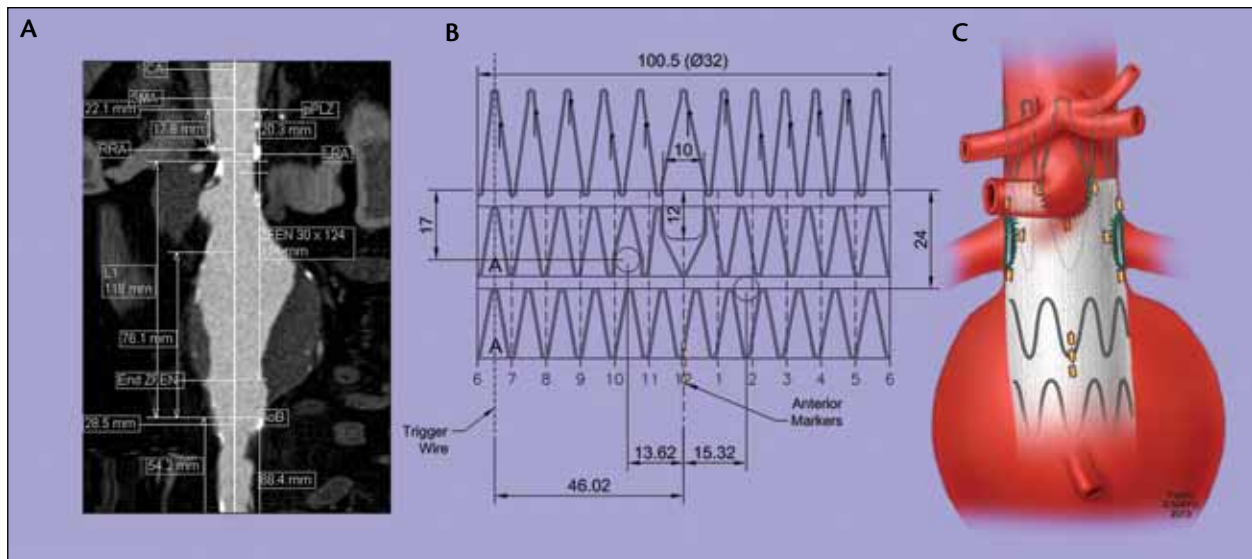


Figure 2. Digital computed tomography angiography with centerline-of-flow analysis (A) is used for measurements. The most common device design in 70% of patients includes two small fenestrations and a scallop (as depicted in B and C).

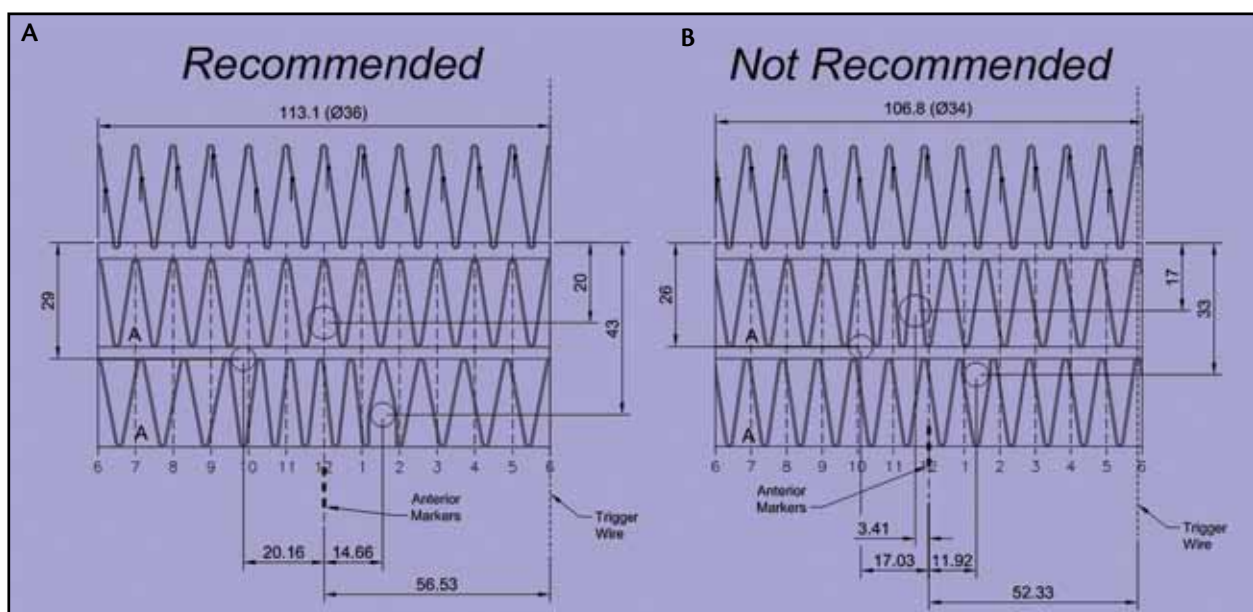


Figure 3. Large fenestrations have struts at the edge (A) or middle of the fenestrations (B). A design with struts at the middle of the fenestration (B) is not recommended, whereas large fenestrations with no struts or minimal struts at the edge of the fenestration are preferable by allowing placement of alignment stents.

fenestrations have struts crossing at the edge or middle of the fenestration, which limit the ability to place alignment stents. Scallops are openings in the upper edge of the fabric that are 10 X 6 to 12 mm.

DESIGN AND PLANNING

Device design and planning are based on careful analysis of aneurysm morphology using high-resolution CT angiography (CTA) datasets. CTA with small (1–3 mm) cuts is recommended for optimal imaging, allowing review with three-dimensional reformatting techniques,

maximum-intensity projection, and volume rendering. The design is based on analysis of centerline-of-flow measurements to determine accurate estimates of lengths, axial clock position, arc lengths and angles (Figure 2).

Device planning starts with selection of the proximal landing zone based on “healthy” aortic anatomy. A normal aorta should have parallel walls with an outer-to-outer diameter of ≥ 19 and ≤ 31 mm and no calcium or thrombus. The portion of the aorta selected as a landing zone should not be larger than the aorta proximal to the fixation site. Although a proximal landing zone > 15 mm is

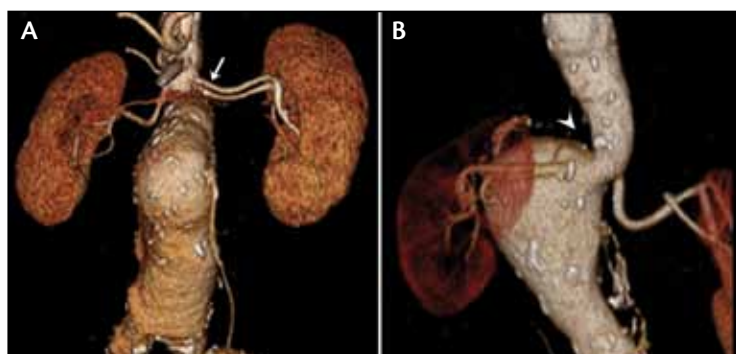


Figure 4. Common anatomical reasons limiting the application of fenestrated endografts include inadequate renal anatomy from early bifurcation or multiple, small accessory renal arteries (A) and severe angulation in the visceral segment of the aorta (B).

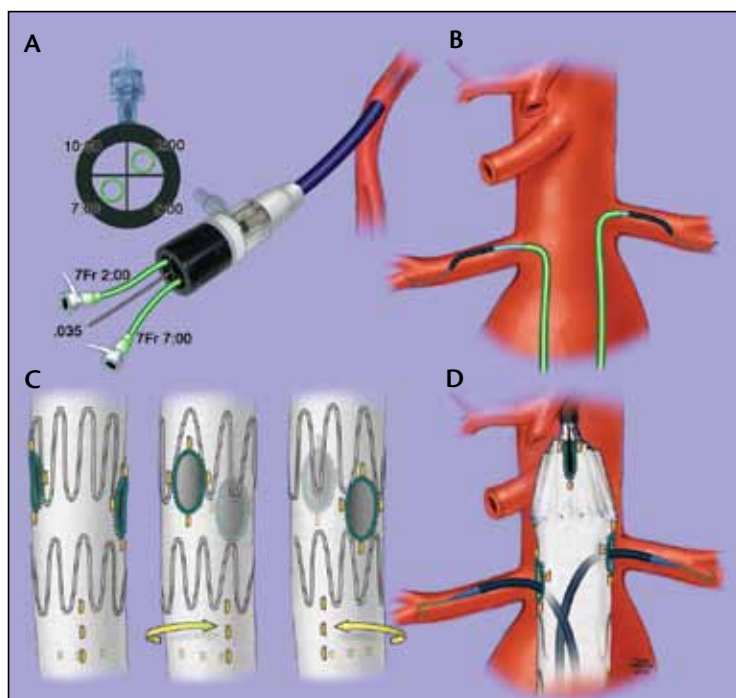


Figure 5. Multisheath femoral access is achieved using a 20- to 22-F CheckFlo sheath (Cook Medical). The sheath valve is punctured to allow placement of multiple small (5–7 F) sheaths (A). Catheters and guide catheters are used for selective catheterization of the target arteries before deployment of the device (B). The device is oriented extracorporeally by fluoroscopic visualization of the anterior and posterior radiopaque markers (C). After the device is oriented and deployed, the catheters are sequentially removed from each vessel and used to regain access into the main fenestrated component, fenestration, and target artery (D).

considered acceptable according to the instructions for use, I recommend a minimal length of 20 mm, similar to what is needed in the thoracic aorta. The most common design used in 66.7% of patients in the US multicenter pivotal trial includes two small fenestrations for the renal arteries and a scallop for the superior mesenteric artery.¹⁴ Scallop fenestrations are rarely utilized for renal arteries.

When selecting large fenestrations, it is useful to review the design outline provided by the manufacturer (Figure 3). I recommend using large fenestrations only if the stent struts are located at the edge of the fenestration; fenestrations with struts crossing in the middle cannot be aligned by a stent, and higher rates of vessel occlusion have been reported in these cases.¹⁵ Anatomical factors limiting the use of the Zenith Fenestrated stent graft system include proximal aneurysm extension requiring more than three fenestrations, excessive angulation at the visceral segment, or inadequate renal artery anatomy due to multiple small accessory renal arteries or early renal artery bifurcation (Figure 4).

ANCILLARY TOOLS

The implantation of fenestrated stent grafts requires advanced endovascular skills and a comprehensive inventory with a wide range of catheters, balloons, and stents (Table 1). These procedures should be performed by physicians with extensive experience with endovascular treatment of complex aortic anatomy and visceral artery disease. Most importantly, dedicated training in fenestrated and branched techniques is highly recommended, even for physicians who are already very experienced with other types of endovascular procedures. One of the basic tenets of the technique, which cannot be overemphasized, is a clear understanding of proximal neck selection combined with the techniques of branch catheterization and “bailout” maneuvers to deal with intraoperative complications, if they occur.

PERIOPERATIVE MEASURES

Some of the perioperative measures, as later proposed in this article, should be considered during the learning phase and may not be necessary once an operator gains more experience with these procedures. Preadmission for bowel preparation and intravenous hydration with bicarbonate infusion and oral acetylcysteine minimizes the risk of renal function deterioration. These

procedures should be performed in a hybrid endovascular suite with a fixed imaging unit. The type of anesthesia used varies with the institution, but our preference has been general endotracheal anesthesia. Intraoperative blood salvage is highly recommended at the beginning of one’s experience for difficult cases and thoracoabdominal repair (more than three vessels); a useful tip is

TABLE 1. LIST OF ANCILLARY TOOLS RECOMMENDED FOR PHYSICIANS PERFORMING FENESTRATED STENT GRAFT PROCEDURES

Category	Manufacturer	Application
Sheaths		
Check-Flo sheath 20–24 F (30 cm)	Cook Medical	Femoral access for multivessel catheterization
Ansel sheath 7 F (55 cm, flexible dilator)	Cook Medical	Femoral access for branch artery stenting
Raabe sheath 7 or 8 F (90 cm long)	Cook Medical	Brachial access for branch artery stenting
Ansel sheath 12 F (55 cm, flexible dilator)	Cook Medical	Brachial access for tortuous aortic arch to facilitate branch artery stenting
Shuttle 5 F (90 cm)	Cook Medical	Branch artery access during difficult arch
Catheters		
Kumpe catheter 5 F (65 cm)	Multiple	Selective vessel catheterization
Kumpe catheter 5 F (100 cm)	Multiple	Selective vessel catheterization
C1 catheter 5 F (100 cm)	Multiple	Selective vessel catheterization
MPA catheter 5 F (125 cm)	Multiple	Selective vessel catheterization
MPB catheter 5 F (100 cm)	Multiple	Selective vessel catheterization
Van Schie 3 catheter 5 F (65 cm)	Cook Medical	Selective vessel catheterization
Vertebral catheter 4 F (125 cm)	Multiple	Selective vessel catheterization
VS1 catheter 5 F (80 cm)	Multiple	Selective vessel catheterization
Simmons I catheter 5 F (100 cm)	Multiple	Selective vessel catheterization
Diagnostic flush catheter 5 F (100 cm)	Multiple	Diagnostic angiography
Diagnostic pigtail catheter 5 F (100 cm)	Multiple	Diagnostic angiography, selective vessel catheterization
Quick-Cross catheter 0.014–0.035 inch (150 cm)	Spectranetics Corporation	Selective vessel catheterization
Renegade catheter (150 cm)	Boston Scientific Corporation	Selective vessel catheterization
Guide Catheters		
LIMA guide 7 F (55 cm)	Cordis Corporation	Precatheterization
Internal mammary guide 7 F (100 cm)	Multiple	Selective vessel catheterization
MPA guide 7 F (100 cm)	Multiple	Selective vessel catheterization
Balloons		
10-mm X 2-cm angioplasty balloon	Multiple	Proximal stent flare
12-mm X 2-cm angioplasty balloon	Multiple	Proximal stent flare
5-mm X 2-cm angioplasty balloon	Multiple	Advance sheath over balloon
Wires		
Benson wire 0.035 inch (150 cm)	Multiple	Initial access
Soft Glidewire 0.035 inch (260 cm)	Terumo Interventional Systems	Target vessel catheterization
Stiff Glidewire 0.035 inch (260 cm)	Terumo Interventional Systems	Target vessel catheterization
Rosen wire 0.035 inch (260 cm)	Multiple	Branch artery stenting
1-cm tip Amplatz wire 0.035 inch (260 cm)	Multiple	Branch artery stenting
Lunderquist wire 0.035 inch (260 cm)	Multiple	Aortic stent graft
Glidewire Gold 0.018 inch (180 cm)	Terumo Interventional Systems	Target vessel catheterization
Stents		
iCast stent grafts 5–10 mm	Atrium Medical Corporation	Branch artery stenting
Balloon-expandable stents 0.035 inch	Multiple	Branch artery stenting or reinforcement
Self-expandable stents 0.035 inch	Multiple	Distal branch artery stenting
Self-expandable stents 0.014 inch	Multiple	Distal branch artery stenting

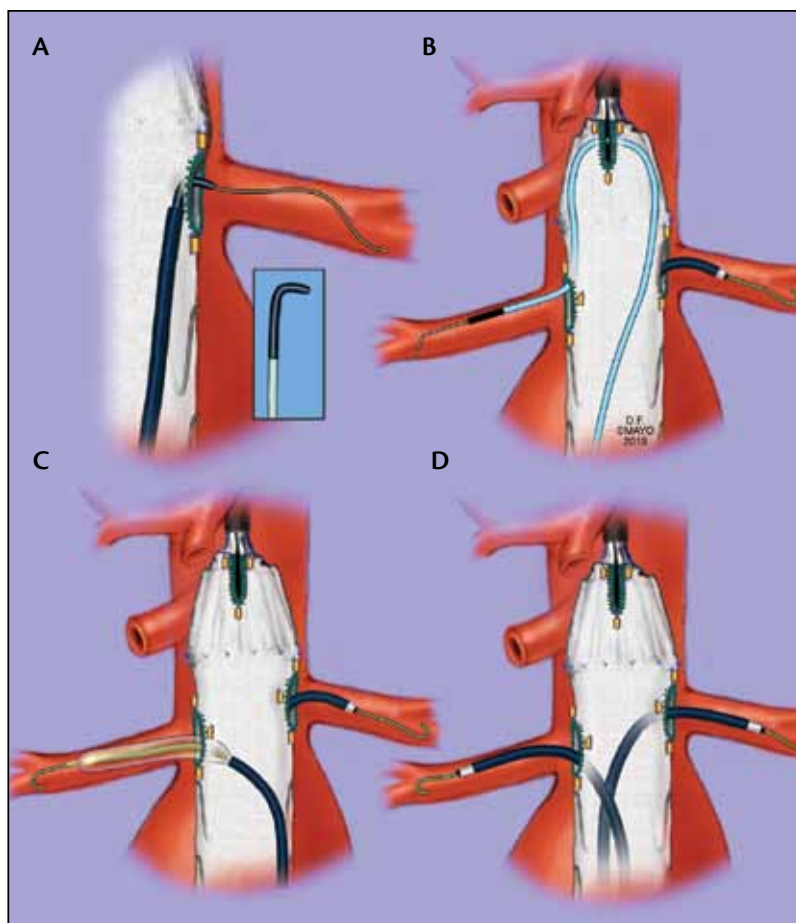


Figure 6. Selective catheterization of the target vessels is the most critical step of the procedure. In most cases, this is done without difficulty. If there is misalignment, occlusive disease or tortuous vessels, several maneuvers can be used to secure access and to advance the sheath. Placement of a 7-F sheath with a 0.018-inch guidewire (A) through the fenestration allows use of a 5-F “buddy catheter” (A, inset) for manipulations to locate the renal artery while the guidewire maintains the sheath in close proximity to the fenestration. For down-going renal arteries, the catheter and Glidewire are allowed to bounce up toward the top cap (B), providing enough support for the catheter to be advanced into the renal artery. If the sheath and dilator cannot be advanced over the guidewire, a useful maneuver is to use an undersized angioplasty balloon as a dilator (C), while the sheath is advanced over the inflated balloon. Finally, once the sheath is advanced, the alignment stents are positioned under protection of the sheath (D).

to create large pockets in the surgical drape, allowing the blood to be collected with cell saver. The use of iodinated contrast should be minimized during all steps of the procedure. Conventional angiography using the power injector should be avoided during the implantation phase, and completion angiography should be performed using a diluted contrast agent (iodixanol with normal saline in a 50:50 ratio). For selective angiography, hand injections of a small volume of diluted contrast (3 mL of contrast with 7 mL of saline) are sufficient to visualize the anatomy. I use precatheterization and/or on-lay CTA prior to deployment of the fenestrated com-

ponent; in experienced hands, this step requires minimal manipulation and can be accomplished in a short time. Most recently, this has been replaced by fusion imaging using on-lay CTA. Iliac conduits are recommended in patients with small or narrowed iliac arteries.

My preference is to use a totally percutaneous technique with a double Perclose device (Abbott Vascular, Santa Clara, CA) whenever possible, provided that the patient has suitable femoral arteries and no excessive calcification. Intravenous heparinization is administered immediately after femoral access. A target activated clotting time > 300 seconds should be maintained throughout the procedure, with frequent rechecks every 30 minutes and repeated doses of heparin as needed. Diuresis is induced prior to deployment of the fenestrated component with mannitol and/or furosemide.

DEVICE IMPLANTATION

The procedure is performed using a bilateral femoral approach. The left brachial approach is typically not needed for juxtarenal aortic aneurysms unless there is difficulty with catheterization. For right-handed operators, the branches and fenestrations are accessed using the right femoral approach, whereas the fenestrated and bifurcated components are introduced via the left side. The procedure can be summarized in 10 critical steps:

Step 1: Multisheath Femoral Access

Bilateral percutaneous femoral access is established under ultrasound guidance. Each femoral puncture is preclosed using two Perclose devices

oriented medially and laterally. Next, 8-F sheaths are introduced to the external iliac arteries over Benson guidewires (Cook Medical). These are exchanged to 0.035-inch soft Glidewires and Kumpe catheters, which are advanced to the ascending aorta. The Glidewires are exchanged for 0.035-inch (260 cm in length) Lunderquist guidewires (Cook Medical). Multisheath access is achieved in the right femoral artery using a 20- or 22-F Check-Flo sheath for two or three fenestrations, respectively. The valve of the Check-Flo sheath has four leaflets, which are accessed by two short 7-F sheaths at 2- and 7-o'clock positions (Figure 5A).

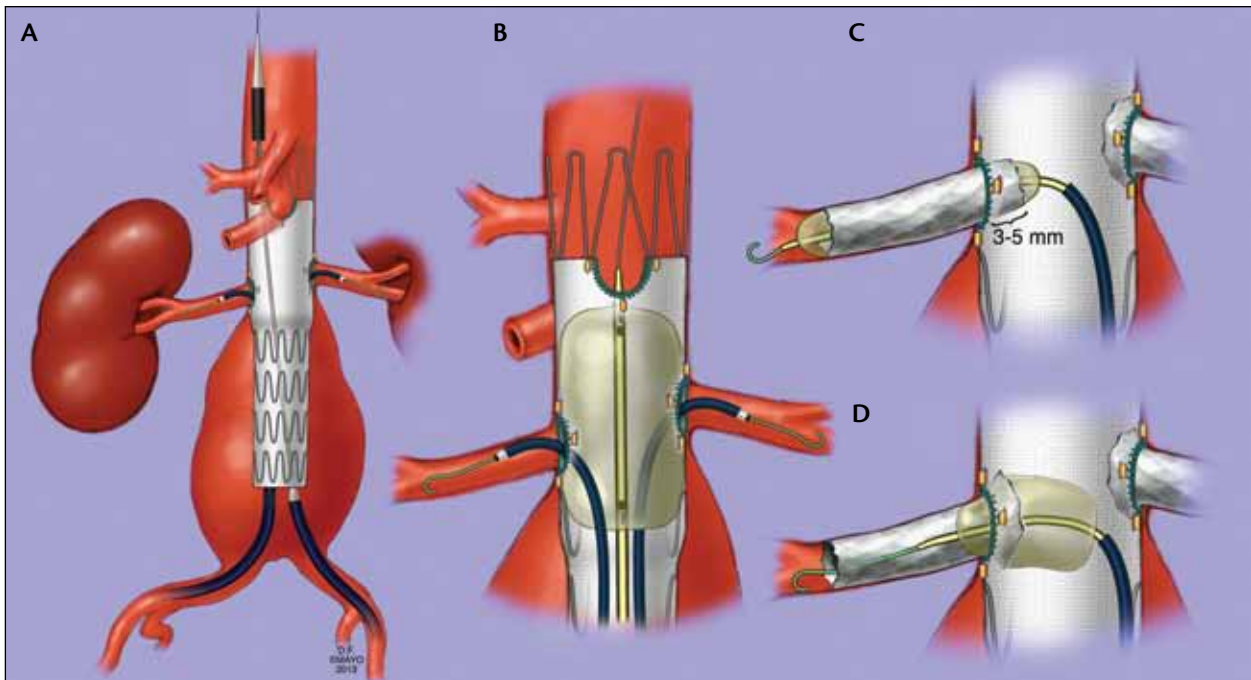


Figure 7. The diameter-reducing tie is removed after all sheaths and side stents are positioned, allowing deployment of the top cap and device (A). After the top cap is retrieved, the proximal sealing stents are gently dilated (B). Sequential stenting is performed by deployment of the alignment stents with 3 to 5 mm into the aortic lumen (C) followed by flaring of the proximal portion of the stent using a 10-mm angioplasty balloon (D).

Step 2: Precatheterization of Target Vessels

Precatheterization or use of on-lay CTA is recommended. This step avoids multiple angiographies during deployment of the device. Typically, a 5-F Kumpe or C1 catheter (Cook Medical), supported by a 7-F LIMA guide catheter, is advanced over 0.035-inch, soft, angled Glidewires (Terumo Interventional Systems, Inc., Somerset, NJ) into the renal arteries (Figure 5B). Access into the renal arteries is confirmed by hand injection. It is useful to acquire anterolateral and oblique views of the catheters (without contrast injection), which can later be “faded” to facilitate branch catheterization.

Step 3: Device Orientation and Deployment

Once the target vessels are catheterized, the fenestrated component is oriented extracorporeally (Figure 5C), introduced via the left femoral approach, and deployed with perfect apposition between the fenestrations and the target catheters. Prior to deployment, it is critical to ensure proper orientation of the device using the anterior and posterior gold markers. Typically, the first two or three stents are deployed, confirming alignment between the catheters and each respective fenestration. The device should be deployed slightly higher than what is anticipated, with the catheters matching the lowest of the four radiopaque markers in the fenestration. The diameter-reducing tie constricts the expansion of the fenestrated component and allows some rotational and craniocaudal movement of the main stent graft to optimize alignment.

Step 4: Fenestration and Target Vessel Catheterization and Sheath Advancement

This is the most critical step of the procedure. Each selective catheter is sequentially removed from the target artery and used to regain access into the fenestrated component, fenestration, and target vessel. Some advocate advancing the Check-Flo sheath into the fenestrated component, but my preference is to avoid this maneuver and instead use sequential catheterization (Figure 5D). The renal arteries are typically catheterized using the same catheter or guide catheter that was used for precatheterization. Although in most cases the target vessel is accessed without difficulty, several maneuvers can be used if there is misalignment. Initially, the catheter and guidewire are rotated to “probe” the aortic wall in search of the vessel. To avoid losing access into the fenestration during this maneuver, it is useful to secure access into the fenestration by advancing the 0.035-inch guidewire and catheter out of the fenestration and into the thoracic aorta followed by a 7-F Ansel sheath (Cook Medical) through the fenestration (Figure 6).

The guidewire is then exchanged for a 0.018-inch guidewire, and the sheath is repositioned at the level of the fenestration; the 0.018-inch guidewire allows the sheath to stay close to the fenestration while a 5-F “buddy” catheter (eg, Van Schie 3 [Cook Medical]) is used to locate the renal artery (Figure 6A). It may be difficult to advance the catheter over a soft Glidewire if

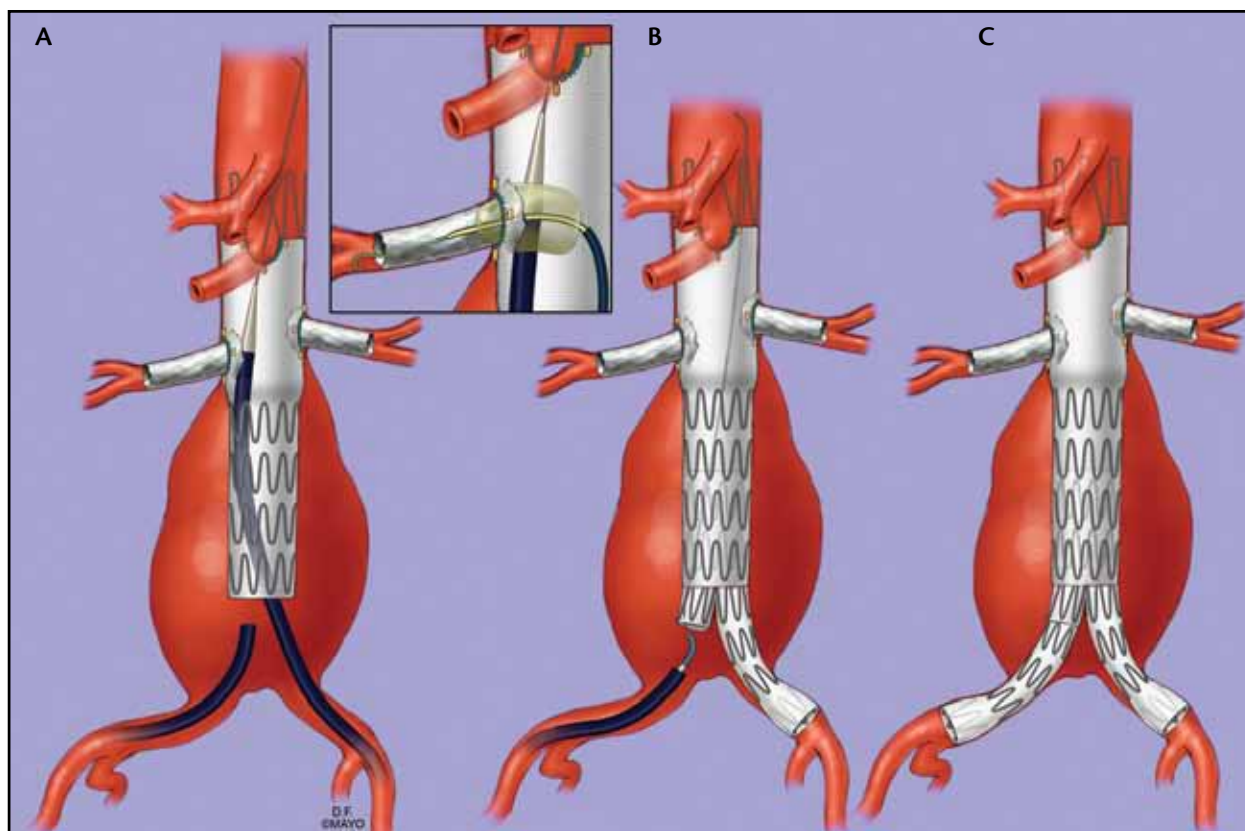


Figure 8. The universal bifurcated component is deployed after placement of the alignment stents. In some cases, the dilator of the bifurcated component encroaches one of the renal stents, usually the contralateral side (A). It is useful to leave a balloon positioned in the renal stent. This can be inflated during movement of the dilator across the renal stent (A, inset). The bifurcated component is deployed with at least two stents overlapped to minimize the risk of component separation (B). Access to the contralateral gate is established followed by placement of the iliac limb extension (C).

the artery is down-going, tortuous, or diseased. In these cases, the catheter and Glidewire bounce up into the top cap (Figure 6B), allowing a Kumpe or Quick-Cross catheter (Spectranetics Corporation, Colorado Springs, CO) to be advanced deep into the renal artery.

After the renal artery is catheterized, the soft Glidewire is removed, and hand injection is used to confirm that the renal artery branch is of adequate diameter to accept a 0.035-inch Rosen wire (Cook Medical). The choice of the interventional guidewire varies, but my preference is for a Rosen wire, which is less traumatic and has a J tip. If more support is needed, an Amplatz guidewire (Cook Medical) with a 1-cm soft tip can be used, but this guidewire is more prone to cause dissections and perforations. After a stiff guidewire is positioned, a 7-F Ansel sheath with flexible dilator is advanced into the renal artery. If the sheath cannot be advanced, an undersized balloon may be used as a dilator to facilitate advancement (Figure 6C). The alignment stent is advanced under protection of the sheath, with the tip of the stent just beyond the tip of the sheath to serve as a dilator during the next step of the procedure (Figure 6D).

Step 5: Deployment and Retrieval of the Top Cap

The diameter-reducing tie is removed after the target arteries are accessed by 7-F hydrophilic sheaths and the alignment stents are in position. The top cap is advanced forward, allowing deployment of the uncovered fixation stent (Figure 7A). This is followed by retrieval of the top cap, which should be done before placing the renal alignment stents to prevent damage during retrieval of the top cap. One should note that the dilator of the device often encroaches the contralateral renal stent.

Step 6: Proximal Neck Balloon Dilatation

After the top cap and dilator are retrieved, the proximal neck is gently dilated using a compliant balloon such as the Coda balloon (Cook Medical). It is critical that this is performed prior to placement of the alignment stents, or alternatively, each stent has to be protected by separate balloons (Figure 7B).

Step 7: Target Vessel Stenting

Target vessel stenting is only performed after removal of the diameter-reducing tie and retrieval of the top cap and neck dilatation balloon. All small fenestrations should

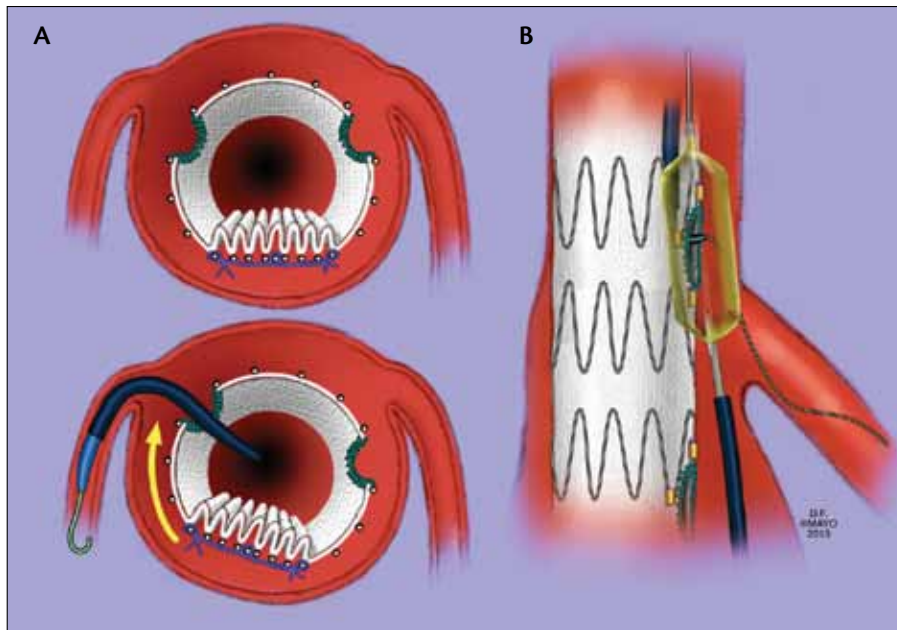


Figure 9. Misaligned fenestrations are infrequent but can increase technical difficulty. Because the device is constrained in the posterior aspect, the fenestrations may be facing posterior (A). Gentle rotation of the device and fenestration anterior may be sufficient to allow catheterization of the target vessel. Less frequently, in cases of severe misalignment, a balloon can be inflated between the aorta and stent graft to create space for catheter manipulations (B).

be aligned by stents, starting with the renal arteries. Prior to stent deployment, positioning is confirmed by hand injection. The stent should be deployed 3 to 5 mm into the aorta (Figure 7C) and flared using a 10-mm X 2-cm balloon (Figure 7D). Selective hand-injection angiography is performed after administration of 100 to 200 µg of nitroglycerin to minimize spasm. In general, short stents (15–22 mm) are preferred to minimize kinks. A short, self-expandable stent may be needed distal to the alignment stent if there is kinking on angiography. A kink can often be anticipated based on review of preoperative CTA.

The approval for the Zenith Fenestrated device also included approval for the Zenith Alignment stent, a bare-metal balloon-expandable stent. However, superior patency has been reported with the use of covered stents compared to bare-metal stents.¹⁶ This is likely due to the polytetrafluoroethylene coverage, which prevents intimal growth through the struts of the stent. With bare-metal stents, intimal hyperplasia occurs predominantly in the proximal portion of the stent, likely from damage to the intima and media due to flaring of the proximal aspect of the stent.¹⁷ Therefore, for alignment of fenestrations, my preference is to use a covered stent (iCast, Atrium Medical Corporation, Hudson, NH).

The use of alignment stents for large fenestrations and scallops remains controversial among clinicians. I favor stenting all large fenestrations, when possible, and most 10-mm scallops. For large fenestrations, I only

accept the design if the stent struts are minimally present at the edge of the fenestration (Figure 3). Large fenestrations are aligned by a covered stent and reinforced by another bare-metal stent to improve radial force and prevent lateral compression of the alignment stent. For scallop fenestrations, I recommend a low threshold for using alignment stents.

Step 8: The Distal Bifurcated Component

Limited iliac angiography demonstrates the location of the internal iliac artery. The bifurcated component is advanced, positioned, and deployed with preservation of the ipsilateral internal iliac artery. If the dilator of the bifurcated device encroaches on the contralateral renal stent, it is useful to have a

10-mm balloon ready to be inflated in the renal stent to protect it from any damage (Figure 8A and inset). The recommended overlap between the bifurcated and the fenestrated component is more than two full-length stents in order to minimize the risk of component separation (Figure 8B).¹⁷ After deployment of the bifurcated device, the dilator is removed with attention to avoid damage to the renal stents.

Step 9: Gate Catheterization and Contralateral Iliac Extension

The contralateral gate is catheterized, and access to the main bifurcated and fenestrated component is confirmed by a 360° catheter rotation (Figure 8B). A 0.035-inch Lunderquist guidewire is advanced, followed by oblique iliac angiography using hand injection of a small volume of contrast via one of the renal sheaths to determine the location of the internal iliac artery. The contralateral limb extension is deployed with preservation of the internal iliac artery (Figure 8C).

Step 10: Balloon Dilatation of Attachment Sites and Distal Landing Zones

The procedure is completed by balloon dilatation of the attachment sites between the fenestrated and bifurcated components and the iliac limb extensions. Completion angiography (typically the only power injection performed during the case) should demonstrate

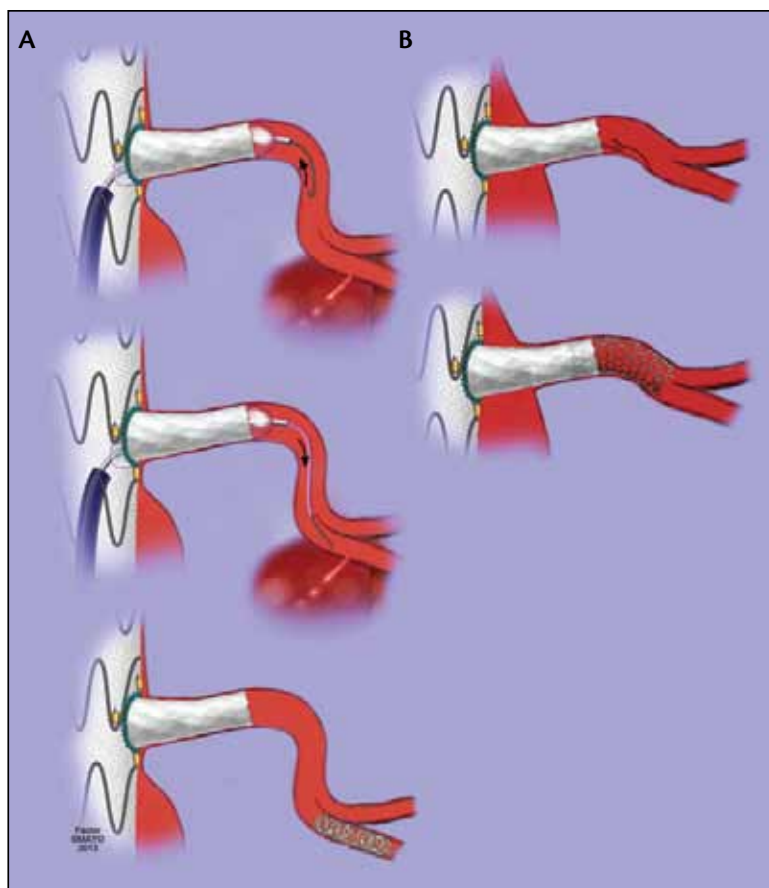


Figure 10. Branch perforations are infrequent and should be avoided by meticulous technique, attention to detail and visualization of the tip of the guidewire. In the unfortunate event of a perforation (A), the balloon can be inflated in the stent while the guidewire is removed, and angiography is performed through the shaft of the balloon. A 3-F microcatheter can be introduced via the inflated balloon and advanced into the perforated branch, which should be immediately embolized. A dissection (B) may be treated by placement of a short-length self-expandable stent.

patency of the visceral arteries, main body, iliac limbs, and iliac arteries.

DEALING WITH INTRAPROCEDURAL COMPLICATIONS

Misalignment of Fenestrations

The Zenith Fenestrated stent graft undergoes extensive quality control and is precisely designed to fit the patient's anatomy. Planning and sizing by experienced physicians or by the Cook sizing team allow little room for errors of design. Nonetheless, neck angulation, tortuosity, and errors of design can lead to misalignment between the fenestration and the target vessel. Diameter-reducing ties are located posteriorly, which may result in the fenestrations being pulled slightly more posterior than its intended location (Figure 9A). A useful maneuver is to gently rotate each fenestration, usually anteriorly. Other maneuvers are rarely needed but include the use of curved

catheters (eg, VS1 [Cook Medical] or SOS [AngioDynamics, Queensbury, NY]) for downward-facing vessels or vessels that are originating from the lower part of the fenestration, microcatheters, and balloon displacement of the main stent graft. The latter is rarely needed but may provide more room for catheter manipulations (Figure 9B).

Branch Perforation or Dissection

Branch vessel perforation and/or dissection can be prevented by meticulous technique, visualization of the tip of the guidewire, and avoiding excessive manipulations. The guidewire should not be positioned in small terminal branches, which are prone to perforate or dissect. It should be visualized and stabilized during exchange manipulations, avoiding forward or retrograde movement. If perforation occurs, it should be immediately recognized and treated. Renal artery perforations rarely seal off and may lead to large parenchymal or subcapsular hematomas with loss of the kidney.

In the unfortunate event of a perforation, the balloon should be reintroduced and inflated in the renal stent to minimize bleeding. The 0.035-inch guidewire is removed, and angiography is performed via the shaft of the balloon (Figure 10A). Using a microcatheter and Glidewire Gold (Terumo Interventional Systems, Inc.), the perforated branch is accessed and coiled with 0.018-inch coils (Figure 10B).

Dissections within the main renal artery can be treated by placing a self-expandable stent (Figure 10C).

Endoleaks

Type II and type IV endoleaks may occur and should be left untreated. Type I and type III endoleaks are infrequent (< 3%) with proper selection of a healthy landing zone and adequate planning.^{5,18,19} In the event of a type IA endoleak, the proximal neck may be redilated (Figure 11), but all of the alignment stents need to be protected by separate balloons. Type III endoleaks may result from inadequate flare, lack of apposition, use of a bare-metal stent, or inadequate length into the aorta. Fortunately, these rarely occur, but in such cases, I redilate or restent the stent and reflare.

Stent Kinking or Narrowing

Kinks are highly preventable and can be anticipated from review of vessel anatomy on CTA. These remain a

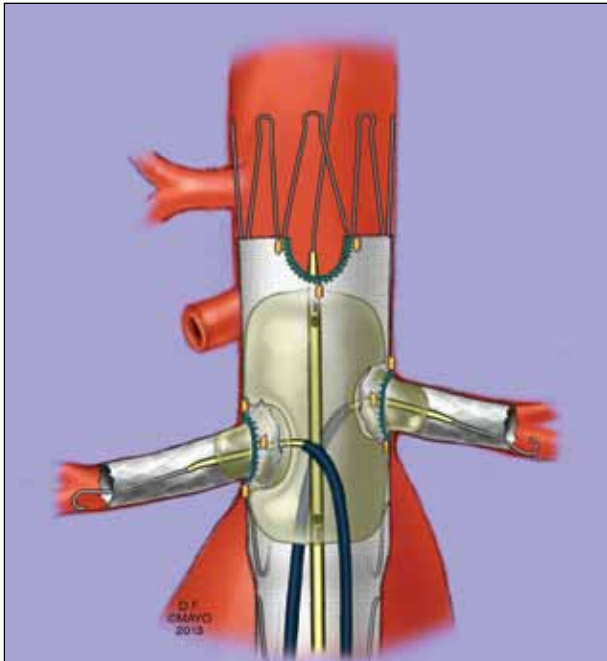


Figure 11. Type I endoleaks are infrequent with proper patient selection and adequate design. In the event redilatation of the neck is needed for treatment of a type I endoleak after the renal stents are deployed, each stent needs to be protected by a separate balloon while the aortic balloon is inflated.

cause for reintervention or branch vessel loss if not recognized. The use of short stents (< 2 cm) avoids landing the stent in the mid or distal portion of the renal artery, which have greater respiratory motion. The right renal artery may have a posterior orientation from its course behind the inferior vena cava. If a kink is anticipated by review of the anatomy on CTA or is evident on completion angiography, a self-expandable stent should be

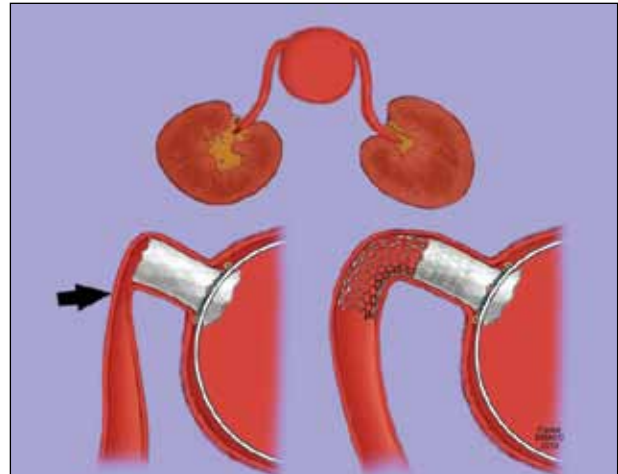


Figure 12. If a kink is anticipated based on the trajectory of the renal artery or it is noted on completion angiography, a self-expandable stent should be placed at the distal aspect of the stent for better transition.

placed (Figure 12). Further, kinks or narrowing may result from inadequate flare, strut compression, and/or ostial disease. In these cases, angioplasty or stenting with a second balloon-expandable stent may be considered.

POSTOPERATIVE MEASURES

The length of hospital stay averages from 2 to 3 days for uncomplicated cases. Oral diet is resumed the day after the operation. I perform CTA and baseline duplex ultrasound prior to patient discharge (Figure 13). Follow-up includes clinical examination and imaging (CTA and ultrasound) at 6 to 8 weeks, every 6 months for a year, and yearly thereafter. All patients are on aspirin. Clopidogrel is not prescribed unless there are concerns of branch vessel disease, small branch vessel size (< 4 mm) or dissection.

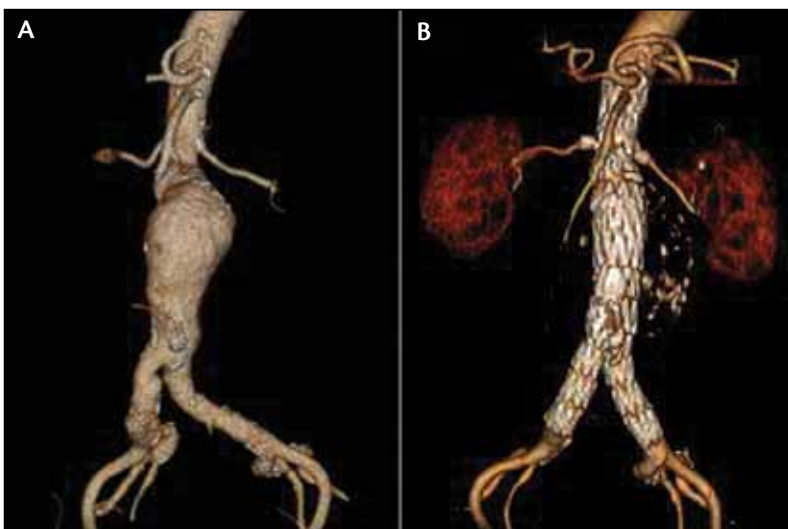


Figure 13. Preoperative CTA of a patient treated for juxtarenal aortic aneurysm (A) with a Zenith Fenestrated stent graft (B).

SUMMARY

Endovascular repair of complex aneurysms involving the visceral arteries has become a reality. Fenestrated stent grafts have been increasingly utilized to treat pararenal and thoracoabdominal aneurysms. The technique is safe, effective, and can be performed with high technical success and low risk of complications in the hands of experienced physicians.⁵ More than 5,500 patients have been treated with Zenith Fenestrated endografts (more than 5,500 with the iliac branch devices and more than 1,500 with the thoracoabdominal branch devices worldwide).

The Zenith Fenestrated stent graft system is the first fenestrated device

approved for commercial use in the US. Based on the results of the US prospective trial and large single-center experiences, rates of type I and III endoleak, migration, aneurysm rupture, and conversion to open repair are exceptionally low.¹⁴ Branch patency averages > 95% with covered stents.^{16,20} These results should serve as benchmarks for comparison with alternative endovascular techniques of branch vessel incorporation, including debranching, snorkel, and physician-modified grafts. ■

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Current State and Future of Fenestrated Technology

The appropriate patient selection, imaging, device design, and technical expertise needed for this technology to continue evolving.

BY MARK FARBER, MD

Pararenal, paravisceral, and thoracoabdominal aortic aneurysms pose complex problems for the vascular surgeons who manage them. Endovascular repair of aortic aneurysms (EVAR) has been associated with low perioperative morbidity and mortality, even in high-risk patients. Recent publications reveal that almost half of these aneurysms are not amenable to treatment with endovascular techniques based on the instructions for use for infrarenal aortic devices.¹ Until recently, EVAR has not been available for these patients in the United States, unless they were participating in investigational device exemption studies.

In general, exclusion from EVAR is due to adverse proximal neck anatomy including short, nonexistent, or angulated necks, which preclude an adequate, durable proximal seal. Good surgical candidates may tolerate the complex open procedures necessary to exclude these aneurysms, but many patients possess serious cardiac, pulmonary, or renal comorbidities, predisposing them to the significant risk for perioperative morbidity and mortality that is associated with an extensive open procedure. These patients may be best served by a minimally invasive approach to aneurysm exclusion, with the most appropriate treatment determined by an experienced surgeon after consideration of each patient's risk profile.

AN APPROVED FENESTRATED DEVICE

In April 2012, the Cook Zenith Fenestrated device (Cook Medical, Bloomington, IN) received approval from the US Food and Drug Administration (FDA) for implantation in patients with short infrarenal necks (4–14 mm in length). During this past year, numerous physicians have undertaken extensive training so that these procedures can be conducted safely at more centers across the United States. To date, more than 100 procedures have been performed since FDA approval in the US. Currently, physicians without experience with the fenestrated technology are required to submit data on their first few cases to a registry so that the FDA can confirm the safety of this device outside the centers of excellence that

helped advance the technology over the past decade.

It should be noted that there are limitations to the current device. At most, three fenestrations/scallops can be utilized, each with their own restrictions with respect to location and positioning in the proximal aspect of the graft. Furthermore, the instructions for use restricts implantation to suprarenal neck and aortic neck angulations within 45° each. Neck angulation poses a particularly difficult problem, as device orientation and positioning of the fenestration can become extremely difficult in these situations, resulting in either severe stenosis or occlusion of the target vessels due to malalignment with the fenestrations.

CLINICAL RESULTS IN THE LITERATURE

Clinical results supporting the use of fenestrated endovascular aortic repair (FEVAR) in complex cases are mainly derived from approval in 2005. Since that time, there have been three reviews published regarding its use.

In 2009, Nordon et al² analyzed eight reports involving 368 patients who underwent FEVAR and compared them to 12 open surgical cohort studies involving 1,164 patients. They determined that there was an increased risk of 30-day mortality associated with open repair between the homogenous groups (increased absolute risk, 2%; relative risk, 1.03). Although there was no increase in the incidence of permanent dialysis, transient renal failure occurred more commonly after open repair. As with most comparative studies involving endovascular techniques, reinterventions occurred more commonly with endovascular repair.

Two additional reviews^{3,4} have also been published, each involving more than 600 patients in the FEVAR cohort and containing many of the same patients in their analysis. In an article by Linsen et al,³ nine studies were evaluated, with a total of 629 patients and 1,622 target vessels. The combined estimate of technical success and 30-day mortality was 90.4% and 2.1%, respectively. Branch vessel patency was 93.2% during follow-up.

Renal impairment was reported in 22.2% of patients, with only 2.1% requiring dialysis. They concluded that the immediate and midterm outcomes were very promising, but the long-term durability is yet to be determined.

Recently, there has been a GLOBALSTAR publication⁵ involving 314 patients who were treated by FEVAR at experienced institutions (> 10 procedures) between January 2007 and December 2010 in the United Kingdom. Technical success was 99%, with a 30-day mortality rate of 4.1%. Kaplan-Meier survival at 1, 2, and 3 years was 94%, 91%, and 89%, respectively. Target vessel patency was 85% at 3 years, with a reintervention rate of 30% at 3 years. These outcomes demonstrated high technical and clinical success in regard to satisfactory target vessel patency and reintervention rates.

The final results of the US multicenter fenestrated trial have not been published yet, but the intermediate results from the first 30 patients have been reported.⁶ In an article by Greenberg et al,⁶ there was no loss of visceral target vessels during the initial procedure and no aneurysm-related deaths, ruptures, or conversions to open repair through 2 years. No type I or III endoleaks were detected; however, there were eight renal events that occurred during follow-up. Five of the eight renal events required secondary interventions, but no patient progressed to dialysis.

Because all of these reports are based upon the Cook Zenith Fenestrated graft, the conclusion can be made that fenestrated repair with this device provides a viable alternative to open repair with favorable midterm results supporting its use.

CHALLENGES OF THIS TECHNIQUE

Fenestrated device development is still in its early phases. The current FDA-approved device does not treat all patients due to limitations in location, number, and type of fenestrations that can be manufactured. Combined with the anatomic applicability criteria, many patients still cannot be treated at this time. Implantation of the fenestrated device in specific patient populations, as described later, can also pose a significant problem as target vessel patency and durability will most likely be compromised.

Patient selection has always been critically important in achieving excellent results with vascular procedures. Recognition of these limitations and their impact on outcomes is important in counseling patients appropriately and achieving outcomes that are comparable to published clinical trial results.

Target Vessel Stenosis

The presence of target vessel stenosis > 50% creates potential problems for FEVAR. Its presence can increase the difficulty and duration of the procedure, resulting in

increased perioperative morbidity. Lower extremity ischemic complications have been noted when the total procedure time exceeds 3 to 4 hours. Successful target vessel cannulation and revascularization may also be affected, resulting in a higher incidence of renal and mesenteric complications.

Angulation

Aortic angulation in the visceral and iliac regions is often overlooked as a contraindication for FEVAR. Severe vessel tortuosity creates alignment issues with respect to the position of the endoprosthesis to the native target vessel origins. Failure to correct for even mild neck tortuosity by manually adjusting the centerline analysis tools can result in misalignment of the fenestrations and target vessel occlusion. Even when appropriate accommodation for tortuosity is undertaken, severe angulation can result in difficult target vessel cannulation strategies that increase the risks of complications associated with the procedure.

Aortic Neck Diameter/Contour

Special attention should be focused on the aortic neck contour when performing all EVAR procedures in order to detect early aneurysmal disease. Although large devices may create a seal in a region based on size measurements, aortic diameters that are larger than their more proximal segment indicate early aneurysmal disease and should not be used as a sealing region. Placing infrarenal EVAR devices in dilated necks can result in early device failures, which often require secondary procedures for aneurysm exclusion that are difficult but feasible. Placing fenestrated devices in regions that are prone to failure is extremely dangerous, as techniques for repair other than device removal do not currently exist.

Renal Issues

Attention must also be given to renal artery diameters and orientation relative to the aorta. Small renal arteries (< 5 mm) have a higher incidence of failure with renal artery stenting as compared to larger renal arteries. The orientation of the artery must also be inspected. Severely ptotic renal arteries may be difficult to cannulate, and in some cases, early bifurcations or severe renal artery tortuosity precludes successful FEVAR. Important determinates of success after FEVAR are not only aneurysmal exclusion but also renal function. Deterioration of renal function during complex aortic repair may depend on numerous factors (nephrotoxic contrast, wire manipulation, microembolization, etc.). After FEVAR, as many as one-third of patients may experience deterioration in their renal function.⁷ This is especially true if they possess preexisting renal insufficiency. Nordon et al² reported that 14.9% of patients experienced an increase of their serum creatinine of > 30%. This was significantly lower

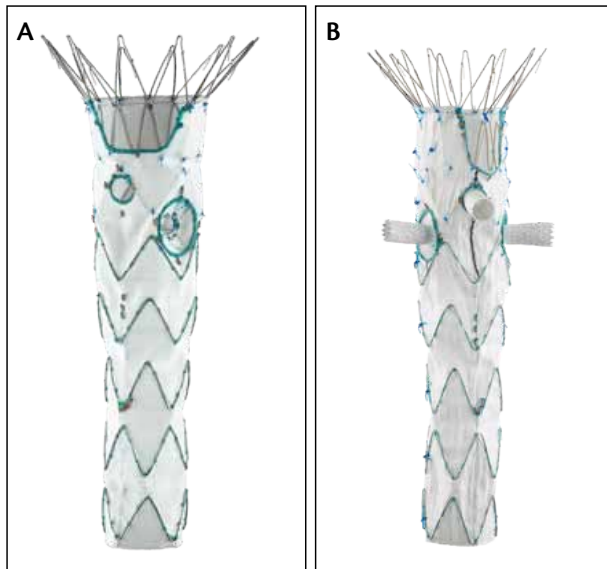


Figure 1. The Zenith p-Branch device with pivot fenestrations (A). The Zenith p-Branch device with stent inserted (B).

than the 20% incidence in the surgical cohort (relative risk, 1.06). Haddad et al from the Cleveland Clinic reported⁸ a 16% incidence of perioperative renal insufficiency in patients with a normal glomerular filtration rate (> 60 mL/min/1.73 m²) and 39% in those with preoperative chronic renal insufficiency. Baseline renal insufficiency was also a good predictor of mortality ($P = .02$) with a relative risk of 8.52. The majority of the changes observed in the Cleveland Clinic cohort⁸ occurred during the first month after repair, with a return to their mean estimated glomerular filtration rate within 6 months.

Long-term patency of renal artery fenestrated vessels has also been a concern. Early experience with bare stents revealed a low incidence of in-stent stenosis. This complication appears to have been rectified with the routine use of covered stents. Currently, renal artery complications are most likely related to the native renal artery kinking as a result of compliance mismatch induced by the balloon-expandable renal artery stent. Careful attention must be paid to the native vessel contour, and often, a self-expanding stent is implanted distally in order to provide a transition region and avoid renal artery occlusion due to kinking.

Production Time

The current production time involved in creating these devices can pose a problem for patients requiring urgent or emergent repair. Device manufacturing, including sterilization, takes approximately 3 weeks, with an additional week required for shipping, as devices are not currently manufactured in Europe or the United States. As a result, efforts are underway to develop an “off-the-shelf” alternative to enable treatment with minimum delay.

DEVICES IN DEVELOPMENT

Two devices are currently undergoing investigation as off-the-shelf designs in order to help reduce treatment delay in patients. The first is the Cook Zenith p-Branch device (Cook Medical) (Figure 1). This device design is centered around a fixed fenestration for the superior mesenteric artery (SMA). A double- or triple-wide scallop is used to incorporate the celiac artery, and two pivot fenestrations provide flexibility in the treatment locations of the renal arteries. There are currently two different configurations of the device to accommodate a larger proportion of patients. The extent of aneurysmal disease can extend up to the level of the base of the SMA. The renal fenestrations are also precannulated, making it easier to catheterize the target vessels. There are several centers with early access to this device, and the US trial has started patient enrollment. The only published report of its use is from Resch et al,⁹ which details the initial seven patients with 100% target vessel catheterization and 0% 30-day mortality. During follow-up, there was one renal artery stent occlusion. The only other report was presented in an abstract format during the recent Society of Clinical Vascular Surgery, detailing successful implantation in seven additional patients. All procedures were technically successful (no type I or III endoleaks) with 0% 30-day mortality. One patient experienced renal insufficiency, which resolved within 30 days.

The other device undergoing evaluation is the Ventana fenestrated device (Endologix, Inc., Irvine, CA). It incorporates a large scallop for the SMA and celiac artery, with two fenestrations for the renal arteries. Flexibility in the location of the renal artery fenestration is accomplished by having fabric redundancy in the mid-section without attaching it to the stent frame. A nonaneurysmal neck length of 15 mm must exist below the SMA in order to achieve aneurysmal exclusion. The report of the first 15 implants was recently published.¹⁰ Among these patients, there was no perioperative mortality, and all vessels were successfully treated. With 11 of the 15 patients having reached their 6-month follow-up visit, there have been no type I or III endoleaks and only one patient experiencing bilateral renal artery stenosis. Early reports of these devices are encouraging; however, approval will require more extensive clinical trial enrollment and follow-up.

Applicability of New Designs

As future designs are developed, mesenteric and renal vessel variability must be taken into account so that a larger proportion of patients can be treated without individual customization. Sobocinski et al¹¹ evaluated a total of 100 patients with juxtarenal and/or pararenal aortic aneurysms who had undergone treatment with custom-manufactured fenestrated designs to determine their applicability for off-the-shelf options. Surprisingly, 72% of patients had anatomy amenable to a standard

fenestrated approach, with the right renal artery location causing exclusion in most cases. This percentage seems slightly high and may be the result of prior exclusion of some patients based upon their initial CT scan results. Other limitations may also exist, such as the relative location of each branched vessel and early bifurcation vessels. As previously mentioned, neck characteristics including angulation, shape, and quality play a critical role in treatment success. In some cases, aortic narrowing in the visceral region can create challenging anatomy for standardized treatment designs.

Alternative device designs also merit mention. Most renal arteries are transversely or cranially oriented with respect to the aorta and lend themselves to fenestrated repair. The mesenteric vessels are often longitudinally oriented, and thus may be better treated with branched graft designs. Chuter¹² has advocated branched designs for treatment of most complex aortic aneurysms, with good results. However, difficulties exist when the renal arteries are cranially oriented and severe angulation exists. Combining these two approaches may also allow for a larger portion of patients to be treated with off-the-shelf designs.

CONCLUSION

Endovascular repair of aneurysms involving the visceral aorta has become a reality with the approval of the Zenith Fenestrated device. It is estimated that more than 5,000 cases have been performed worldwide, with promising midterm results with respect to safety and success. Appropriate patient selection, high-resolution imaging, proper device design, and technical expertise will be required for this therapy to continue. As technology and techniques evolve, the endovascular treatment of thoracoabdominal aortic aneurysms and

juxtarenal aneurysms is certain to become more commonplace. The continued efforts to make safe, prefabricated devices available to more patients will certainly allow the dissemination of the technology. In the future, the number of devices and the percentage of patients amenable to this therapy will gradually increase until it becomes the procedure of choice in appropriately selected patients. ■

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