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Zenith® Fenestrated

The first FDA-approved option for treating ≥ 4mm short-necked infrarenal AAA.

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ZFEN Technology: Why It Works and What's in Its Future

BY GUSTAVO S. ODERICH, MD

The following quote from David Hartley, FIR, remains true today: "It has become clear that not only the technology but also disease progression plays an important role in the durability of endovascular aortic therapy."[1] Endovascular aneurysm repair (EVAR) has changed the way we manage aortic aneurysms. Although the initial focus was on comparisons with open surgical repair, efforts have more recently been on how to expand the indications of EVAR to the 40% of patients who have inadequate landing zones or involvement of the visceral arteries. In these patients, there has been a push for more liberal indications outside the instructions for use and to shorten the minimum neck to 10 mm or less, including the use of parallel grafts or endoluminal stapling. Although some studies have shown favorable early outcomes with short neck indications, others caution higher rates of failure. Moreover, this change in paradigm is coming at a time when long-term results of the EVAR trials indicate a higher risk of aneurysm rupture for patients treated by EVAR compared to open repair.[2,3]

In the last decade, we observed a surge of innovative techniques to extend the indications of EVAR with fenestrations, branches, and parallel stent grafts. Fenestrated endografts have widely been used with increasing clinical experience in the last 2 decades. It is estimated that over 20,000 patients have been treated worldwide (Cook Medical, personal communication). In the United States, the Zenith Fenestrated (ZFEN) stent graft (Cook Medical) was approved by the US Food and Drug Administration for commercial use in April 2012. The device is designed with a maximum of three fenestrations and is indicated for patients who are not candidates for infrarenal EVAR because of short necks between 4 to 14 mm.

WHY IT WORKS

Endovascular sealing is based on the principle that a close interaction between the stent graft and the aortic wall is needed to exclude the aneurysm sac. Thrombus, calcification, short length, and gutters violate this principle. Selection of the landing zone has significant ramifications on endovascular repair, because the aorta continues to enlarge adjacent to aneurysmal segments.

The implications of poor neck selection can be noted intraoperatively but are more often evident 3 to 5 years after the procedure.[2,3] Majewski et al observed that 60% of patients treated by open repair for juxtarenal aneurysms had enlargement of the aorta above the graft anastomosis.[4] Neck dilatation is more prominent with self-expandable stent grafts, which are typically oversized to the normal aortic diameter. Enlargement is > 10 to 15 mm below the renal artery origin and in patients who have proximal necks > 30 mm in diameter.[5-7] Neck enlargement continues to progress even in patients who experience a decreasing aneurysm sac and have no evidence of endoleaks.[8] This process continues beyond 5 years after the initial procedure.[9]

The problem of using short neck indications is that treatment of a failed EVAR remains a challenge with significant morbidity and mortality. Several studies have shown that open surgical explantation for failed EVAR is associated with higher morbidity and mortality.[10] Salvage endovascular procedures (eg, placement of cuff extensions) or chimney grafts are not as effective and may potentially lead to more reinterventions, added cost, and loss of renal function. As for salvage with fenestrated grafts, these are technically more demanding and are associated with lower technical success.[11] For these reasons, the first repair needs to be planned with the goal of long-term durability for the lifespan of the patient.

ZFEN AND FUTURE PERSPECTIVES

The United States Zenith Fenestrated trial has shown that the procedure is safe and effective.[12] Mortality was low (1.5%) with no conversion, aneurysm rupture, and with a low rate of renal artery occlusion (4%). Secondary renal stent patency was high (97%). Type Ia endoleak occurred in only one patient at 3 years due to enlargement of the aortic neck. These results have been replicated by systematic reviews, as well as multicenter and single-center experiences.[13-16]

Two-thirds of patients with complex abdominal aortic aneurysms are not candidates for the ZFEN device due to its design constraints. The maximum of three fenestrations (one nonreinforced) and the use of single-diameter scallops limit the ability to achieve sealing zones above

the superior mesenteric artery or celiac axis, making it impractical to treat suprarenal aneurysms while maintaining the very principle of long, healthy sealing zones.

The next generation of ZFEN devices is being designed to address these limitations and will include features that help to facilitate technical aspects of the procedure. These improvements in device design will also allow for extending the repair to the supraceliac aorta, even for short-necked infrarenal aneurysms, if there is concern with progression of aortic disease. Recent clinical experience with three- or four-vessel fenestrations demonstrates high technical success and low morbidity and mortality, with lower rates of type Ia endoleaks long term as compared to one- or two-vessel fenestrated endografts.[12-16]

SUMMARY

The ZFEN device represents an initial step forward in achieving durable sealing zones in patients with what has been considered "unfavorable" neck anatomy for infrarenal EVAR. The articles in this supplement aim to further illustrate how far the fenestrated EVAR concept has evolved, with excellent and durable outcomes throughout the years of its commercial use. Cook continues to advance this technology forward with improvements in device design, implantation techniques, and adjunctive maneuvers to decrease mortality and morbidity, with the long-term goal of achieving the most durable repair possible.

We greatly appreciate the efforts of the authors who have contributed to this edition, and we hope you will find the following articles to be informative and valuable in your practice. ■

1. Hartley D, Eagleton, M, Roeder B. Proximal abdominal aortic aneurysm necks. Endovasc Today. 2014;13(supp):4-9.
2. Schermerhorn ML, Buck DB, O'Malley AJ, et al. Long-term outcomes of abdominal aortic aneurysm in the Medicare population. N Engl J Med. 2015;373:328-338.
3. Patel R, Sweeting MJ, Powell JT, Greenhalgh RM. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. Lancet. 2016;388:2366-2374.
4. Majewski W, Stanisic M, Pawlaczyk K, et al. Morphological and mechanical changes in juxtarenal aortic segment and aneurysm before and after open surgical repair of abdominal aortic aneurysms. Eur J Vasc Endovasc Surg. 2010;40:202-208.
5. Rodway AD, Powell JT, Brown LC, Greenhalgh RM. Do abdominal aortic aneurysm necks increase in size faster after endovascular than open repair? Eur J Vasc Endovasc Surg. 2008;35:685-693.
6. Oberhuber A, Buecken M, Hoffmann M, et al. Comparison of aortic neck dilatation after open and endovascular repair of abdominal aortic aneurysm. J Vasc Surg. 2012;55:929-934.
7. Arthurs ZM, Lyden SP, Rajani RR, et al. Long-term outcomes of Palmaz stent placement for intraoperative type Ia endoleak during endovascular aneurysm repair. Ann Vasc Surg. 2011;25:120-126.
8. Kaladji A, Cardon A, Laviolle B, et al. Evolution of the upper and lower landing site after endovascular aortic aneurysm repair. J Vasc Surg. 2012;55:24-32.
9. Tsilimparis N, Dayama A, Ricotta JJ. Remodeling of aortic aneurysm and aortic neck on follow-up after endovascular repair with suprarenal fixation. J Vasc Surg. 2015;61:28-34.
10. Turney EJ, Steenberge SP, Lyden SP, et al. Late graft explants in endovascular aneurysm repair. J Vasc Surg. 2014;59:886-892.
11.Katsargyris A, Yazar O, Oikonomou K, et al. Fenestrated stent-grafts for salvage of prior endovascular abdominal aortic aneurysm repair. Eur J Vasc Endovasc Surg. 2013;46:49-56.
12. Oderich GS, Greenberg RK, Farber M, et al; Zenith Fenestrated Study Investigators. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg. 2014;60:1420-1428.
13. Mastracci TM, Eagleton MJ, Kuramochi Y, et al. Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms. J Vasc Surg. 2015;61:355-364.
14. British Society for Endovascular Therapy and the GLOBALSTAR Registry. Early results of fenestrated endovascular repair of juxtarenal aortic aneurysms in the United Kingdom. Circulation. 2012;125:2707-2715.
15. Nordon IM, Hinchliffe RJ, Holt PJ, et al. Modern treatment of juxtarenal abdominal aortic aneurysms with fenestrated endografting and open repair—a systematic review. Eur J Vasc Endovasc Surg, 2009;38:35-41.
16. Oderich GS, Ribeiro M, Hofer J, et al. Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones. J Vasc Surg. 2017;65:1249-1259.

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FEVAR: Long-term Data From the Cleveland Clinic

Continued development and application of fenestrated endovascular technology to treat complex aortic disease and directions for the future.

BY MATTHEW J. EAGLETON, MD

On the 5-year anniversary of commercial approval of the Zenith Fenestrated (ZFEN) system (Cook Medical) in the United States, it is remarkable to note that the first descriptions of use of fenestrated and branched endografts to treat complex aortic aneurysms date back to the mid and late 1990s.[1-4] These early device designs share many similarities with the more sophisticated endografts in use today. The devices were custom made and modular, allowing for the endoluminal assembly of components specifically designed to interact with different sections of the aorta while preserving perfusion to the renal and visceral arteries.

In 2001, the first series of patients from Australia who underwent endovascular aneurysm repair (EVAR) incorporating the renal and superior mesenteric arteries with graft fenestrations was reported.[5] This series included 13 patients treated with devices based on the Zenith EVAR platform (Cook Medical). Similar to current systems, the fenestrated stent graft was placed using a modified delivery system that provided staged deployment of the components that allowed for exact alignment of the fenestrations with their target vessels. Fenestrations were held in alignment with their target vessels using flared bare-metal stents.

However, early experience in the United States was limited primarily to physician-sponsored investigational device exemption (PS-IDE) trials. Despite this, much of our procedural protocols, device enhancements, and understanding of device and repair durability have arisen from these assessments. One of the most prolific contributors to this body of literature was the late Dr. Roy Greenberg, who established an early PS-IDE at the Cleveland Clinic. During and following his tenure, significant contributions based on these studies have helped guide the endovascular care of patients with complex aortic disease. Although the work at the Cleveland Clinic has evolved to primarily focus on the treatment of thoracoabdominal aortic aneurysms (TAAAs), the focus of this article will be on the major contributions and long-term follow-up of patients treated with fenestrated endovascular aneurysm repair (FEVAR).

EARLY EXPERIENCE WITH FEVAR

The first fenestrated endograft placement at the Cleveland Clinic was performed in 2001, and a report in 2004 outlined the outcomes of 22 patients treated in this fashion.[6] This was followed shortly by an update that reported outcomes for a total of 32 patients.[7] These early grafts were more rudimentary than those employed in the United States Zenith Fenestrated AAA Endovascular Graft clinical trial, as they lacked reinforced fenestrations. By 2006, 119 patients had been treated within Dr. Greenberg's program with incorporation of 302 renal and visceral vessels.[8] Outcomes appeared to be excellent with a 30-day endoleak rate of 10% (all type II), aneurysm regression (> 5 mm) occurring in nearly 80% of patients by 2 years, and renal stenosis/occlusion occurring in only 4% of patients. These initial results raised several questions for study.

With excellent early results, it became apparent that more information was needed on long-term follow-up, particularly with regard to aortic stent and branch vessel durability and renal function. In addition, it was clear that device improvements would be necessary to allow for incorporation of more visceral vessels and treatment of more complex aneurysms. Since then, the Cleveland Clinic group has reported outcomes of 607 patients undergoing FEVAR for juxtarenal and type IV TAAA repair with a mean follow-up of 8 years.[9]

RENAL FUNCTION

Given the manipulation and stenting of the renal arteries, as well as the use of iodinated contrast during the procedure and in the repeated follow-up imaging, renal failure following FEVAR has remained one of the greatest concerns. The need for hemodialysis after FEVAR has ranged from 0% to 6% and varies based on the extent and complexity of the aneurysm repaired.[9-12] In fact, the United States Zenith Fenestrated trial boasted a 30-day freedom from acute renal injury rate of 100%, despite nearly 10% of patients having radiographic evidence of renal embolization.[13] Early experience with FEVAR at the Cleveland Clinic demonstrated that acute kidney injury developed in 16% of patients without preoperative renal

insufficiency and in 39% of those with chronic renal disease.[14] The incidence of permanent dialysis was higher in the group with preoperative renal dysfunction, and these patients similarly had a higher mortality. Estimated glomerular filtration rates (eGFRs) stabilized in this population within 6 months of the index surgery. Since then, others have reported that post-FEVAR acute renal failure (assessed with the RIFLE criteria) is as high as 29%, with a 14% decrease in eGFR and renal volume noted at 3 years postoperatively.[15] However, these findings are not unique to FEVAR, as similar rates of acute kidney injury have been observed after open surgery and EVAR, with similar rates of long-term renal decline.

DEVICE DURABILITY

With the evolution of more complex devices, the durability of the repair comes into question, as there are potentially increased modes and locations of failure. In 2008, the Greenberg group reported on the risk of component separation in FEVAR performed at the Cleveland Clinic.[16] Data from 106 patients who underwent cross-sectional imaging follow-up beyond 1 year were analyzed. A total of 14 patients (13%) were identified as having component movement of 10 mm or more, with the range of movement between 11 and 42 mm. This component movement occurred between 2 and 4 years of follow-up. Eight of these patients were noted to have less than two-stent overlap, with one patient presenting with a ruptured aneurysm that resulted in open conversion. The remaining patients had additional stents placed.

An algorithm was developed to assess the risk of potential component separation. It used numerical computing software and predicted the maximum amount of possible intercomponent movement, thereby deriving the minimum overlap required to prevent the risk of complete component separation. This algorithm was based on the distance from the renal artery to the aortic bifurcation (straight line and center line) and maximum aortic diameter. When applying these calculations to the entire cohort of FEVAR patients, it was determined that 38% were at risk for component separation. This meant that if the components had maximum morphologic device changes, they did not have enough component overlap to accommodate the shift. It was determined that a new baseline at attempting to achieve three- to four-stent overlap for components was both possible and would mitigate nearly every risk of aortic component separation. These findings changed device planning parameters for FEVAR!

BRANCH VESSEL DURABILITY

One of the keys to long-term FEVAR success is maintaining branch vessel patency. Midterm branch vessel patency rates have recently been reported by most large series and range from 93% to 98% (at 3–5 years) overall.[10,11,17-19] As with most endovascular procedures, FEVAR requires reintervention to maintain graft and branch vessel patency and ameliorate endoleak development. This requires an active surveillance program in order to identify stented branch vessels at risk for failure. Historically, the Cleveland Clinic program has mandated patient follow-up on an annual basis with contrast-enhanced imaging (provided renal function will allow it) combined with duplex ultrasonography. Early assessment identified that some unique findings have altered both treatment and follow-up protocols.[20] It was determined that revised duplex criteria were necessary in FEVAR given the hemodynamic alterations induced by adding stiff stent systems to both the aorta and the target vessels. Changing a peak systolic velocity criteria to > 280 cm/sec in order to identify 60% to 99% renal artery stenosis improved the sensitivity (93%), specificity (100%), and positive and negative predictive values (99% for both). In addition, it was noted that covered bridging stent use was associated with a lower rate of renal artery stenosis compared to treatment with bare-metal stents. However, there was no difference in branch vessel occlusion rates. This has led to the primary use of covered stents when performing FEVAR, regardless of the need to obtain a seal with the fenestration at that location.

Mastracci et al provided the largest series evaluating the durability of branch vessels after FEVAR.[21] This analysis includes not only patients who underwent FEVAR for short-necked and juxtarenal abdominal aortic aneurysms (AAAs), but also more extensive TAAAs. Given the excellent outcomes in this more complex cohort, extrapolation to standard FEVAR is obvious. Secondary procedures were performed in only 0.6% of celiac arteries, 4% of superior mesenteric arteries, 6% of right renal arteries, and 5% of left renal arteries. Reinterventions are divided equally between restenosis/occlusion and endoleak development. The 5-year freedom from branch vessel reintervention rate was 89%. Unfortunately, there did not appear to be a specific time frame in which the majority of the reinterventions occurred, which again highlights the necessity for lifelong surveillance. As aneurysms become more complex (ie, extensive TAAAs), the rates of reintervention appear to increase over time.[9,10]

AORTIC DURABILITY AND FUTURE NEEDS

Complex aortic endografting is an investment made by the physician and the patient. Proximal endograft failure (ie, type Ia endoleak) is a devastating complication of FEVAR, as further repair becomes even more complicated. This is likely related to either poor judgment of candidates in whom to place an endograft or a failure to recognize the potential for disease progression. This becomes equally important in those who undergo FEVAR. One of the reasons that repairs fail is due to disease progression. The best-designed stent graft in

the world will not survive the continued dilation of the aorta that it relies on for its foundation. FEVAR is not immune to this. Despite the increased ability to land the stent graft in nearly any segment of the aorta, approximately 2% to 3% of FEVAR patients will develop a proximal type I endoleak if given enough time.[22] Some of this may be related to poor patient selection, but the majority is due to disease progression.

In the Cleveland Clinic experience, some of the early failures were due to our lack of appreciation of disease progression, as represented by the higher failure rates observed early in our application of this technology. In those series, we attempted to treat patients with the shortest amount of coverage possible, utilizing only a 15-mm landing zone in the paravisceral segment. Since then, we recognized several aspects particular to FEVAR. Shorter necks are not better, especially in those with potentially other unattractive neck attributes such as the presence of thrombus, a large diameter, or atherosclerosis—all harbingers of potential future degeneration. Currently, we routinely attempt to achieve a 2- to 3-cm landing zone when extending a repair into the visceral aortic segment while balancing the risks of developing other complications such as spinal cord ischemia.

However, commercial FEVAR does not accommodate for this and represents the need for more advanced devices that allow for the incorporation of more visceral vessels and more cephalad extension of these devices for improved durability. Most surgeons with access to devices that can incorporate more fenestrations than the currently approved ZFEN choose to increase the extent of coverage and make the treatment of later disease progression easier. Evolution toward more widespread application of these types of devices has been supported again through the initial evaluations of PS-IDEs (at least in the United States). In the Cleveland Clinic experience, long-term outcomes on 610 patients treated with FEVAR for juxtarenal and type IV TAAAs has been reported.[9] Mean follow-up duration for the cohort was 8 years. The results of this analysis clearly demonstrate successful utilization of this complex treatment option, but more complex device configurations result in higher rates of reintervention. However, these complex designs can be utilized with similar rates of perioperative morbidity and mortality, have lower rates of type I endoleak development, and are associated with nearly 98% freedom from aneurysm-related mortality.

CONCLUSION

As we celebrate the 5-year anniversary of the ZFEN commercialization in the United States, it is still an exciting time to be involved with the development and application of endovascular technology to treat complex aortic disease. Over the next decade, we will certainly attain commercialization of devices that can treat more complex AAA pathology, TAAA disease, and aortic arch aneurysms. Devices will become easier to use, and we will observe lower perioperative morbidity and mortality rates. Failure modes will be better understood, as will the best application of these technologies. All of this, which will be the result of a collaboration between physician- and industry-driven evaluations, will ultimately result in better care for patients with aneurysmal disease. ■

1. Park JH, Chung JW, Choo IW, et al. Fenestrated stent-grafts for preserving visceral arterial branches in the treatment of abdominal aortic aneurysm: preliminary experience. J Vasc Interv Radiol. 1996;7:819-823.
2. Faruqi RM, Chuter TAM, Reilly LM, et al. Endovascular repair of abdominal aortic aneurysm using a pararenal fenestrated stent-graft. J Endovasc Surg. 1999;6:354-358.
3. Kinney EV, Kaebnick HW, Mitchell RA, Jung MT. Repair of mycotic paravisceral aneurysm with a fenestrated stent-graft. J Endovasc Ther. 2000;7:192-197.
4. Browne TF, Hartley D, Purchas S, et al. A fenestrated covered suprarenal aortic stent. Eur J Vasc Endovasc Surg. 1999;18:445-449.
5. Anderson JL, Berce M, Hartley DE. Endoluminal aortic grafting with renal and superior mesenteric artery incorporation by graft fenestrations. J Endovasc Ther. 2001;8:3-15.
6. Greenberg RK, Haulon S, Lyden SP, et al. Endovascular management of juxtarenal aneurysms with fenestrated endovascular grafting. J Vasc Surg. 2004;39:279-287.
7. Greenberg RK, Haulon S, O'Neill S, et al. Primary endovascular repair of juxtarenal aneurysms with fenestrated endovascular grafting. Eur J Vasc Endovasc Surg. 2004;27:484-491.
8. O'Neill S, Greenberg RK, Haddad F, et al. A prospective analysis of fenestrated endovascular grafting: intermediate-term outcomes. Eur J Vasc Endovasc Surg. 2006;32:115-123.
9. Mastracci TM, Eagleton MJ, Kuramochi Y, et al. Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms. J Vasc Surg. 2015;61:355-364.
10. Eagleton MJ, Follansbee M, Wolski K, et al. Fenestrated and branched endovascular aneurysm repair for type II and III thoracoabdominal aortic aneurysms. J Vasc Surg. 2016;63:930-942.
11. Reilly LM, Rapp JH, Grenon SM, et al. Efficacy and durability of endovascular thoracoabdominal aortic aneurysm repair using the caudally directed cuff technique. J Vasc Surg. 2012;56:53-63.
12. Amiot S, Haulon S, Becquemin JP, et al. Fenestrated endovascular grafting: the French multicentre experience. Eur J Vasc Endovasc Surg. 2010;39:537-544.
13. Oderich GS, Greenberg RK, Farber M, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg. 2014;60:1420-1428.
14. Haddad F, Greenberg RK, Walker E, et al. Fenestrated endovascular grafting: the renal side of the story. J Vasc Surg. 2005;41:181-190.
15. Martin-Gonzalez T, Pincon C, Hertault A, et al. Renal outcomes analysis after endovascular and open aortic aneurysm repair. J Vasc Surg. 2015;62:569-577.
16. Dowdall JF, Greenberg RK, West K, et al. Separation of components in fenestrated and branched endovascular grafting—branch protection or a potentially new mode of failure? Eur J Vasc Endovasc Surg. 2008;36:2-9.
17. Verhoeven EL, Katsargyris A, Bekkema F, et al. Editor's Choice—ten-year experience with endovascular repair of thoracoabdominal aortic aneurysms: results from 166 consecutive patients. Eur J Endovasc Surg. 2015;49:524-531.
18. Verhoeven EL, Vourliotakis G, Bos WT, et al. Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single-centre experience. Eur J Vasc Endovasc Surg. 2010;39:529-536.
19. GLOBALSTAR Collaborators. Early results of fenestrated endovascular repair of juxtarenal aortic aneurysms in the United Kingdom. Circulation. 2012;125:2707-2715.
20. Mohabbat W, Greenberg RK, Mastracci TM, et al. Revised duplex criteria and outcomes for renal stents and stent grafts following endovascular repair of juxtarenal and thoracoabdominal aneurysms. J Vasc Surg. 2009;49:827-837.
21. Mastracci TM, Greenberg RK, Eagleton MJ, Hernandez AV. Durability of branches in branched and fenestrated endografts. J Vasc Surg. 2013;57:926-933.
22. O'Callaghan A, Greenberg RK, Eagleton MJ, et al. Type Ia endoleaks after fenestrated and branched endografts may lead to component instability and increased aortic mortality. J Vasc Surg. 2015;61:908-914.

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Ten Steps

A standardized 10-step approach to the planning and sizing of a fenestrated endovascular aortic aneurysm repair.

BY JESSICA P. SIMONS, MD, MPH, AND ANDRES SCHANZER, MD

For patients with short-neck and juxtarenal aortic aneurysms, conventional endovascular aneurysm repair may not provide durable aneurysm exclusion due to a compromised proximal seal zone. In response to this concern, fenestrated endografts were described in the late 1990s that were designed to extend the seal zone above the renal arteries while maintaining flow to critical branch vessels.[1-3] A commercially available option was studied in the United States in 2009,[4] with favorable technical results and patient outcomes.[5] The Zenith Fenestrated (ZFEN) abdominal aortic aneurysm (AAA) endovascular graft (Cook Medical) gained US Food and Drug Administration (FDA) approval for use in the United States in April 2012. At the time of this publication, it remains the only commercially available fenestrated device in the United States for the treatment of short-neck AAAs (necks ≥ 4 mm in length).

There are some notable technical considerations for the planning and execution of fenestrated repair. Although infrarenal endovascular aneurysm repair can often be planned quickly and accurately, the technical success of fenestrated aneurysm repair is contingent upon meticulous preoperative planning. Steps include processing axial CTA images in software capable of generating three-dimensional models and enabling centerline measurements, then carefully measuring the exact locations of the target vessels. There are manufacturing restrictions, based on engineering boundary condition constraints, that must also be considered (please find these listed at fencheck.cookmedical.com). The anatomy must be scrutinized to ensure that a ZFEN device is appropriate, and then the exact configuration must be chosen.

We recently reported on the adoption of ZFEN technology in the United States since FDA approval.[6] A ninefold increase in the number of orders placed per month was seen; however, the vast majority of trained providers ordered fewer than five devices per year. We hypothesized that this skewed adoption pattern may, in part, relate to the perceived complexity of technical planning and sizing. Although previous studies have demonstrated good inter- and intraobserver agreement in fenestrated planning, these studies relied solely upon experienced fenestrated planners,[7,8] leaving the generalizability to less experienced surgeons unknown. Therefore, the following sections describe a standardized 10-step approach to the planning and sizing of fenestrated endovascular aneurysm repair utilizing the ZFEN technology and introduce a simple template (Figure 1) that can be used to record the necessary measurements.

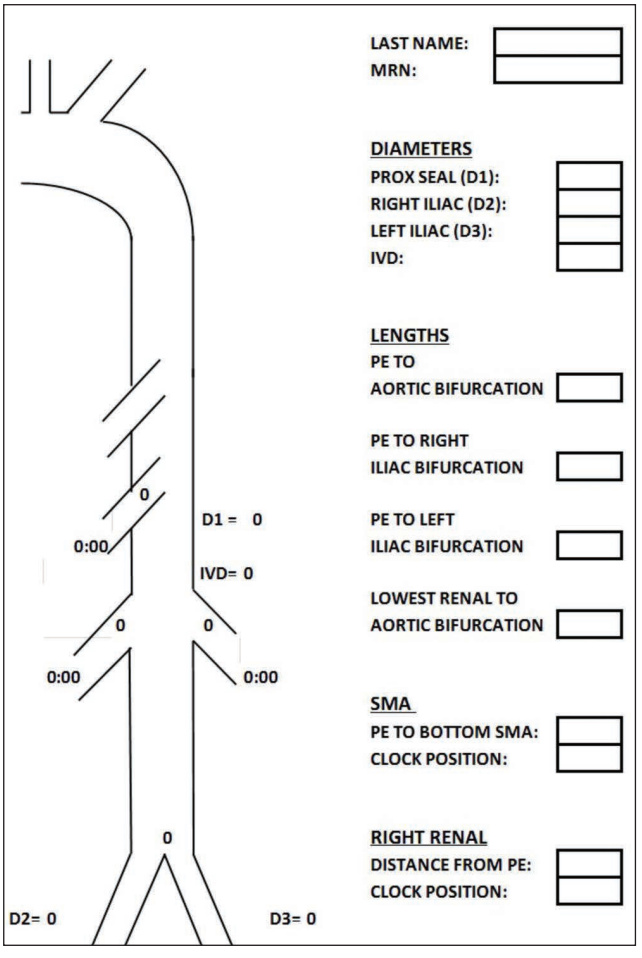

Figure 1. A simple template for recording measurements.

STEP 1: CENTERLINE PLACEMENT

The patient's aortic anatomy is first evaluated by processing a recent CTA of the abdomen and pelvis

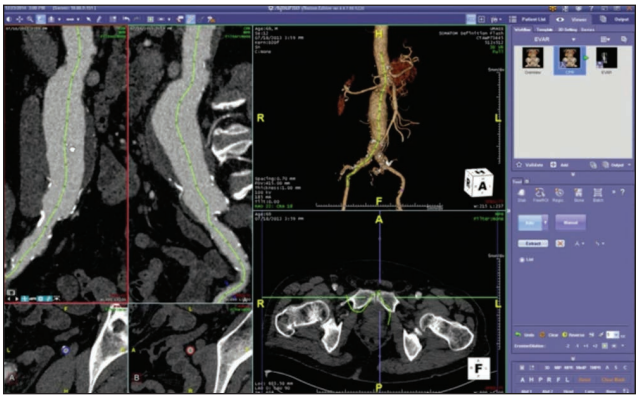

Figure 2. Create and adjust the centerline.

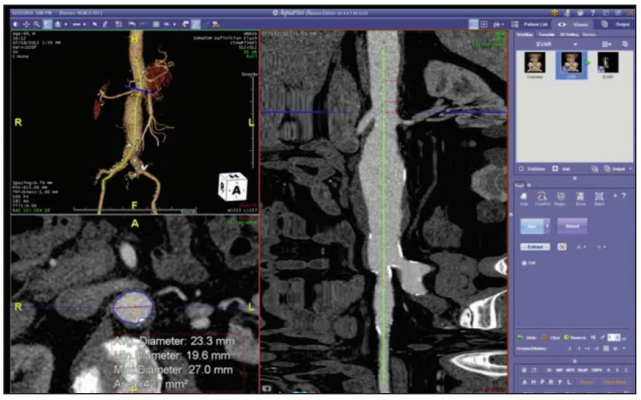

Figure 3. Mark the target vessels.

using three-dimensional reconstruction software. An aortic centerline is made, extending from the suprarenal aorta to each iliac artery. This allows for all subsequent measurements to be made orthogonal to the centerline of flow. The centerline is then manually adjusted to reflect the way in which the stent graft is anticipated to lie within the aorta as a result of any tortuosity (Figure 2).

STEP 2: MARKER PLACEMENT

With the centerline in place, the curved planar reformat (CPR) views, in a "straightened view" of the aorta, are used to place a marker in the center of each of the visceral artery origins. The celiac and superior mesenteric arteries (SMAs) are first marked, and then the CPR view is rotated to identify the origin of the renal arteries (Figure 3). The aortic bifurcation and each iliac artery bifurcation are also marked.

STEP 3: DETERMINE THE PROXIMAL EDGE OF THE ENDOGRAFT

This step is critical, as it determines which branch arteries will need to be incorporated into the repair to ensure a durable proximal seal into healthy aorta. The instructions for use (IFU) specify a minimum acceptable proximal seal zone of 1.5 cm. We are more conservative and use a minimum of 2 cm of healthy parallel walled aorta for the proximal seal zone. The start of the aneurysm is identified on CPR view, then a distance of 2 cm proximal to this is measured (Figure 4); this level of the aorta is assessed to ensure that it is a healthy segment. The one ZFEN graft specification rule that must be followed is that the distance from the top of fabric to the first small fenestration must be 15 mm or greater. In order to comply with this rule, a distance of 15 mm is measured proximally from the highest of the renal arteries within the proximal seal zone. If this brings the measurement above the previously marked 2-cm seal zone, then the proximal edge must be moved to this position. This proximal edge marker serves as the reference from which all

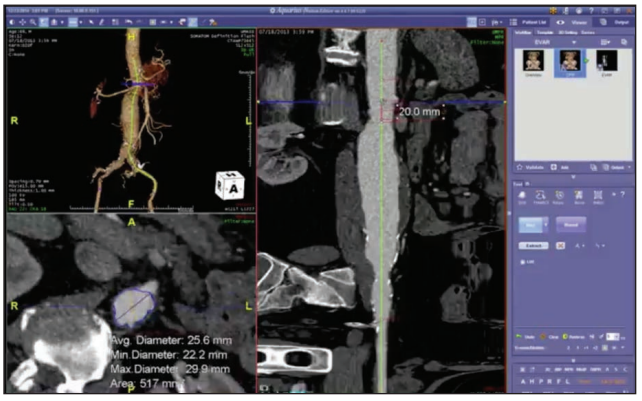

Figure 4. Choose the proximal edge.

subsequent measurements are determined. The proximal edge marker also dictates how the SMA will be incorporated into the repair. If the bottom of the SMA is within 12 mm of the proximal edge, then it can be incorporated with a scallop. If the distance is > 12 mm from the proximal edge, a large fenestration must be used.

STEP 4: MEASURE REQUIRED DIAMETERS

Three measurements are obtained over the length of the seal zone, the largest of which will be used as the diameter measurement to select an appropriately sized proximal seal stent consistent with the diameter sizing guidelines in the IFU (we target 10%–15% oversizing in our practice). The inner aortic diameter is also measured at the level of the renal arteries. Finally, the distal seal zone diameters are measured in each common iliac artery.

STEP 5: MEASURE REQUIRED LENGTHS

Three categories of length measurements are obtained: the length from the proximal graft edge to the center of each visceral branch, from proximal edge to aortic bifurcation, and from proximal edge to each iliac bifurcation.

Figure 5. Mark clock positions of the target vessels.

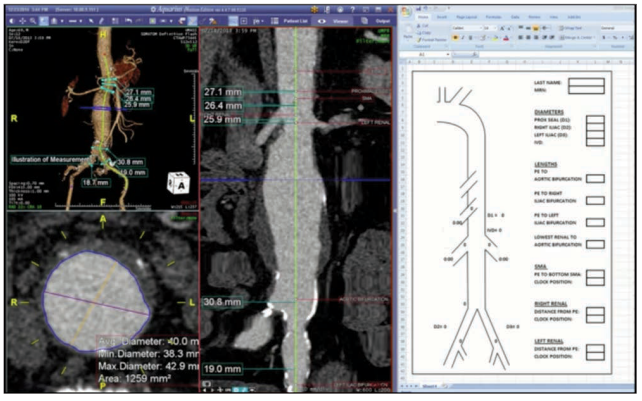

Figure 6. Ensure that all diameters, lengths, and clock positions have been defined.

STEP 6: MEASURE TARGET ARTERY CLOCK POSITIONS

A clock position measurement, rounded to the nearest 15-minute interval, is required for each of the vessels incorporated into the repair (Figure 5).

STEP 7: CHOOSE THE PROXIMAL FENESTRATED COMPONENT

The "two-proximal-seal-stent" design is routinely chosen. The diameter is selected consistent with the diameter sizing guidelines in the IFU (we use 10%–15% oversizing in our practice) for the proximal seal zone diameter. The length is chosen to ensure a minimum of 20 mm of length between the bottom of the fenestrated endograft and the aortic bifurcation to facilitate placement of the bifurcated component (Figure 6).

STEP 8: INDICATE SCALLOP/FENESTRATION DESIGN

For scallops, the depth and clock position are noted. For all fenestrations, the length from the proximal edge to the middle of the target vessel is measured. For the renal arteries, a small fenestration with a height of 8 mm is routinely chosen. The inner aortic diameter is measured at the level of each of the fenestrations.

STEP 9: CHOOSE THE DISTAL BIFURCATED COMPONENT

A range of bifurcated device sizes exists and can be used. The "universal bifurcated" design is routinely used in our practice; this measures 76 mm from the top of the graft to the contralateral gate. The ipsilateral limb extends an additional 28 mm. Both limbs are 12 mm in diameter. The proximal diameter of the bifurcated device is 24 mm to match the distal diameter of the fenestrated component.

STEP 10: CHOOSE THE ILIAC LIMBS

Iliac limbs are chosen with appropriate oversizing to ensure seal in each common iliac artery (we routinely target 10% oversizing).

CONCLUSION

Using a simple template and a standardized 10-step approach, all of the necessary information to successfully plan and order a custom ZFEN device can be obtained. ■

1. Browne TF, Hartley D, Purchas S, et al. A fenestrated covered suprarenal aortic stent. Eur J Vasc Endovasc Surg. 1999;18:445–449.
2. Anderson JL, Berce M, Hartley DE. Endoluminal aortic grafting with renal and superior mesenteric artery incorporation by graft fenestration. J Endovasc Ther. 2001;8:3–15.
3. Faruqi RM, Chuter TA, Reilly LM, et al. Endovascular repair of abdominal aortic aneurysm using a pararenal fenestrated stent-graft. J Endovasc Surg. 1999;6:354–358.
4. Greenberg RK, Sternbergh WC 3rd, Makaroun M, et al. Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms. J Vasc Surg. 2009;50:730–737 e1.
5. Oderich GS, Greenberg RK, Farber M, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg. 2014;60:1420–1428 e1–5.
6. Simons JP, Shue B, Flahive JM, et al. Trends in use of the only Food and Drug Administration–approved commercially available fenestrated endovascular aneurysm repair device in the United States. J Vasc Surg. 2017;65:1260–1269.
7. Oshin OA, England A, McWilliams RG, et al. Intra- and interobserver variability of target vessel measurement for fenestrated endovascular aneurysm repair. J Endovasc Ther. 2010;17:402–407.
8. Malkawi AH, Resch TA, Bown MJ, et al. Sizing fenestrated aortic stent-grafts. Eur J Vasc Endovasc Surg. 2011;41:311–316.

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Use of ZFEN in Community Practice

The current state of treatment for complex abdominal aortic aneurysms in community practice using the Zenith Fenestrated stent graft.

BY JESSE MANUNGA, MD

In 1998, Anderson and colleagues performed the first clinical implant of a Cook Medical fenestrated stent graft to treat a high-risk surgical patient with a juxtarenal aortic aneurysm. Long before the publication of their experience with this novel technique in 2001,[1] the technology was being adopted by others and disseminated through workshops in Australia, Europe, and Southeast Asia. In the United States, it was embraced by Dr. Roy Greenberg, who began implanting fenestrated devices in August 2001 and later reported his experience in a cohort of 22 patients.[2] Over the ensuing decade, only a handful of United States academic centers with US Food and Drug Administration (FDA) approval of an investigational device exemption had access to this device. It was not until April 2012, after a prospective trial at 14 United States academic centers[3] that the FDA approved the commercial use of the Zenith Fenestrated (ZFEN) stent graft (Cook Medical) in the United States, giving community surgeons access to this device for the first time.

THE STATE OF VASCULAR SURGICAL PRACTICE IN THE UNITED STATES

With few exceptions, United States academic institutions continue to be the source of the next generation of physicians. Furthermore, these centers shape the future of medicine by serving as the preeminent engine in charge of evaluating and reporting outcomes of various conditions and procedures, including outcomes of industry-conceived new technologies. This trend will likely continue for the foreseeable future. However, the majority of vascular care in this country is and will continue to be delivered by community vascular surgeons—a group that currently encompasses two-thirds of the entire vascular surgical workforce.[4]

Unfortunately, reports on outcomes of surgical procedures performed by physicians in the community remain scarce, as the majority of vascular publications originate from the very institutions tasked with producing the next generation of vascular specialists. This scarcity is mostly driven by economics of medicine because the majority of community surgeons have productivity-based contracts with few to no incentives to embark on academic endeavors. Recent changes in medical payment are forcing many community physicians to become hospital employed, and thus they can negotiate contracts that are still based on relative value units but also include involvement in hospital leadership committees and, in some instances, reporting of clinical outcomes.

ZFEN EXPERIENCE IN COMMUNITY PRACTICE

A recent report on ordering trends suggests that academic medical centers remain the biggest implanters of ZFEN devices in the United States. However, the number of devices ordered by physicians in community practices nearly doubled from 2013 to 2014.[5] This growth rate was larger than that observed in academic practices during the same period of time. As an increasing number of community vascular surgeons continue to be trained every year, it is assumed that this trend will continue. However, several challenges continue to plague this group of physicians, as highlighted in the following sections.

Patient Selection

Patient selection is one of the most important determinants of clinical outcomes for every surgical procedure. For most physicians in community practice, fenestrated stent grafts continue to be reserved for high-risk surgical patients who are not candidates for open repair. This line of thought originates from the initial uncertainty surrounding the long-term performance of fenestrated devices. However, these devices have been implanted in thousands of patients around the world for the past 20 years, and several studies on their performance have shown that fenestrations have a long-term occlusion rate of < 2%.[6-8] These revelations have led many forward-thinkers in aortic surgery to start offering fenestrated procedures to both high- and low-risk surgical patients as long as the anatomy is suitable for such a repair. It is believed that the vast majority of physicians will come to share this philosophy as reports continue to show the excellent performance of these devices.

Device Design and Sizing

The next challenge after patient selection is device design and planning. Currently, Cook Medical requires a physician to perform a minimum of two cases before

being considered "signed off." Although this decision is left at the discretion of the proctor, most physicians are signed off after these initial two cases. This is largely due to the fact that the first two cases are performed with relative ease, because they are carefully scrutinized by experienced proctoring faculties and fall within the instructions for use (ie, a 4- to 14-mm neck with no thrombus or calcifications, limited neck angulation, and limited iliac artery tortuosity).

However, after implantation of the initial two cases, continued success of the endovascular complex aortic aneurysm program is based on the drive, dedication, vision, and clinical judgment of the lead physician(s) and the support from administration. Obtaining the proper CTA images (2-mm cuts) and meticulous analysis of the scans of every patient undergoing repair using a three-dimensional (3D) reconstruction workstation is paramount. Every CTA scan must be analyzed using centerline-of-flow measurements to determine lengths, angulations, clock positions, and arc lengths.

The challenge is that a large number of community vascular surgeons do not have access to 3D workstations and rely on industry representatives to size cases for them. Although most representatives have been thoroughly trained and can be trusted to perform the job well, it is the physician's responsibility to ascertain the sizing accuracy of devices that are implanted in patients. One way of addressing this challenge is by investing the time required to learn programs such as 3mensio (Pie Medical Imaging), a software available to all of Cook Medical's clinical representatives who are willing to help physicians size cases with them rather than for them. The other option is to take advantage of TeraRecon's complimentary short-term software access. Although this is a short-term fix, we have successfully used it at our institution prior to convincing administration that purchasing the program was a worthwhile investment.

Surgical Team, Ancillary Tools, and Postoperative Care

The impact of surgeon and hospital volume on outcomes has been well documented and should not come as a surprise. Having an experienced team is extremely important for the success of an endovascular complex aortic aneurysm program. This team should not only include a creative and astute lead surgeon(s) with excellent endovascular skills, especially with visceral artery interventions, but also a dedicated support staff. At my institution, we have two techs for these cases, one of which has scrubbed nearly all of our cases and serves as the lead tech for the program. This tech's involvement is invaluable, and the program would not be what it is without him. In addition, a comprehensive inventory of wires, catheters, balloons, sheaths, and stents is key to the successful implantation of fenestrated devices. We have previously reported on a comprehensive list of helpful ancillary tools for endovascular aortic aneurysm repair.[9]

Postoperatively, the majority of patients treated with ZFEN can be admitted to the general floor, provided nurses are trained on how to care for them. This is certainly the case in our practice, where over the last 2 years, the

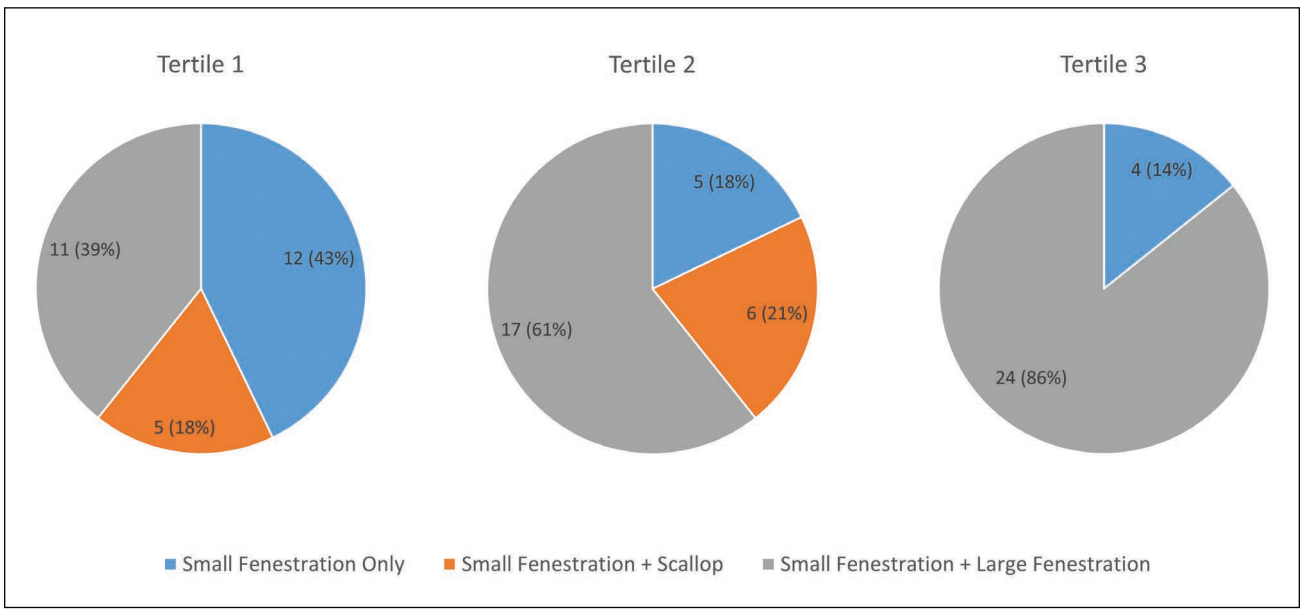

Figure 1. Pie chart showing the trend in device configurations with time in our practice. Note that over time, we have come to favor maximizing the seal zone, with fewer two-vessel fenestrations and more three-vessel fenestration configurations.

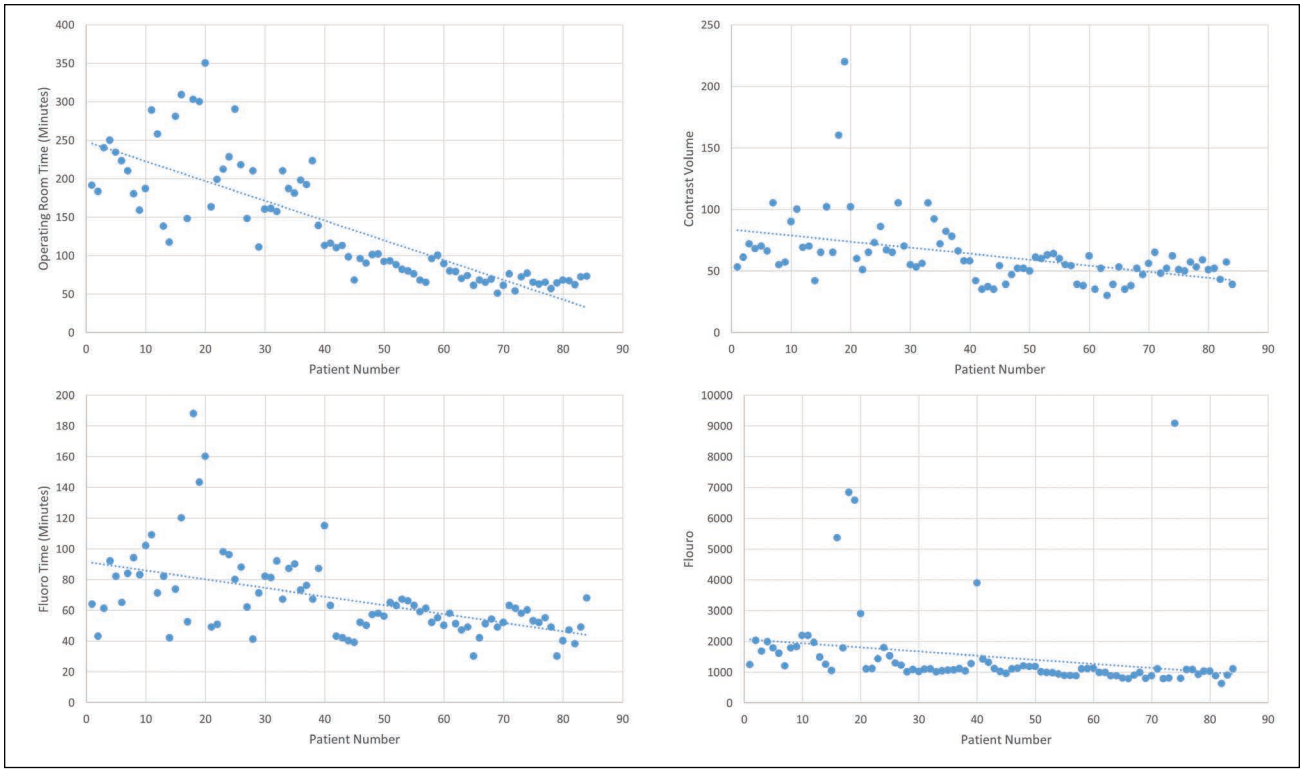

Figure 2. Scatter plots demonstrating a trend in procedure time, contrast volume, fluoroscopy time, and volume as experience was gained.

majority of our patients are admitted directly to the general floor after the repair procedure and discharged home 2 days later. Lactate, complete blood count, and basic metabolic panels are drawn postprocedure and every day that the patient is in the hospital. We prefer to keep the Foley catheter in place the first 24 hours to closely monitor urine output. Postoperative CTA of the abdomen and pelvis is performed prior to discharge in patients with normal renal function, which allows us to address any type I or III endoleaks that might have been missed intraoperatively.

THE MINNEAPOLIS HEART INSTITUTE AT ABBOTT NORTHWESTERN HOSPITAL ENDOVASCULAR PROGRAM

Like many others, we initially struggled to find ideal candidates for fenestrated stent grafts and get buy-in from partners and hospital staff. We had the great fortune of having the trust and support of our chairman who believed in our ability to build this program even though we were fresh out of fellowship. After countless talks to operating room nurses, cath lab techs, anesthesia staff, advanced practice providers, and intensive care unit and surgical floor nursing staff, we implanted the first fenestrated stent graft in Minneapolis/St. Paul, Minnesota, in December 2013—the initiation of our endovascular complex aortic aneurysm repair program.

The majority of low-risk surgical patients with complex abdominal aortic aneurysms (cAAAs) are still treated by open repair in our practice. However, since December 2013, we have endovascularly treated over 84 high-risk surgical patients with cAAAs using the ZFEN stent graft. Five patients underwent repair with local or spinal anesthesia, including one who presented with a ruptured aneurysm.[10] The mean Society for Vascular Surgery/American Association for Vascular Surgeon Comorbidity Severity Score for our cohort was 15 (range, 13–17). Fifty percent of patients were American Society of Anesthesiologists class III or IV. A total of 226 visceral arteries were incorporated in this cohort, with only one renal artery lost as a result of dissection while attempting fenestration cannulation. The majority of patients (97.6%) were discharged directly home 2 days after repair, with only two patients requiring nursing home placement. Further analysis revealed a trend in our practice: there was a move away from offering two-vessel fenestrated devices. This shift resulted in the vast majority of our patients being treated with three-vessel fenestrated devices than any other configuration (Figure 1). With

increasing experience, we noted a decrease in procedure time and radiation dose even as case complexity increased (Figure 2).

Even in this high-risk surgical group, the rate of major adverse events in our cohort was 13.1%, mortality was 2.4%, and all but two patients were discharged directly home 2 days after repair. Our outcomes are in line with contemporary reports from high-volume academic centers that have a reported 30-day mortality of 1% to 5% and a major adverse event rate of 14% in patients treated with fenestrated stent grafts.

CONCLUSION

Advances in medical therapy are enabling people with multiple comorbidities to live longer, and vascular surgeons are being tasked to care for these patients. Because community surgeons deliver the majority of vascular care in the United States, it is imperative that these physicians are equipped with tools needed to effectively care for these patients. Community vascular surgeons are increasingly embracing repair of cAAAs with ZFEN stent grafts. This technology will likely become the treatment modality of choice for all patients with suitable anatomy once it is fully disseminated. ■

1. Anderson JL, Berce M, Hartley DE. Endoluminal aortic grafting with renal and superior mesenteric artery incorporation by graft fenestration. J Endovasc Ther. 2001;8:3-15.
2. Greenberg RK, Haulon S, Lyden SP, et al. Endovascular management of juxtarenal aneurysms with fenestrated endovascular grafting. J Vasc Surg. 2004;39:279-287.
3. Oderich GS, Greenberg RK, Farber M, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg. 2014;60:1420-1428.
4. Perler BA. We care. J Vasc Surg. 2016;64:1197-1211.
5. Simons JP, Shue B, Flahive JM, et al. Trends in use of the only Food and Drug Administration-approved commercially available fenestrated endovascular aneurysm repair device in the United States. J Vasc Surg. 2017;65:1260-1269.
6. Mastracci TM, Greenberg RK, Eagleton MJ, Hernandez AV. Durability of branches in branched and fenestrated endografts. J Vasc Surg. 2013;57:926-933.
7. Martin-Gonzales T, Mastracci T, Carrell T, et al. Mid-term outcomes of renal branches versus renal fenestrations for thoraco-abdominal aneurysm repair. Eur J Vasc Endovasc Surg. 2016;52:141-148.
8. Panuccio G, Bisda T, Berekoven B, et al. Performance of bridging stent grafts in fenestrated and branched aortic endografting. Eur J Vasc Endovasc Surg. 2015;50:60-70.
9. Manunga JM, Oderich GS, Bjellum KE, Bjellum KM. Managing endovascular inventory. In: Oderich GS, ed. Endovascular Aortic Repair: Current Techniques With Fenestrated, Branched and Parallel Stent-Graft. Cham, Switzerland: Springer International Publishing; 2017:215-231.
10. Manunga J, Titus J. Regional anesthesia as the anesthetic of choice for high-risk surgical patients undergoing repair of juxtarenal aortic aneurysms with fenestrated stent grafts. J Vasc Surg. 2017;65:1820-1822.

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Recommendations From a Busy Fenestrated Practice

The top 10 lessons we have learned for optimizing clinical outcomes.

BY GUSTAVO S. ODERICH, MD; EMANUEL TENORIO, MD, PHD; AND GIULIANO SANDRI, MD

Fenestrated endovascular aneurysm repair (FEVAR) has undergone nearly 2 decades of evolution since the pioneering work of Tom Browne, Michael Lawrence-Brown, and David Hartley and the first clinical implantation procedure by John Anderson in 1998. Contemporary reports from large aortic centers worldwide have shown high technical success rates (> 95%), with mortality in the range of 1% to 5% for pararenal and 5% to 10% for thoracoabdominal aortic aneurysms.[1-5] In the United States, the Zenith Fenestrated (ZFEN) stent graft (Cook Medical) is celebrating its 5-year anniversary since commercial approval in 2012. The technique has been widely accepted in many centers, and clinical outcomes continue to improve as a reflection of increasing clinical experience.

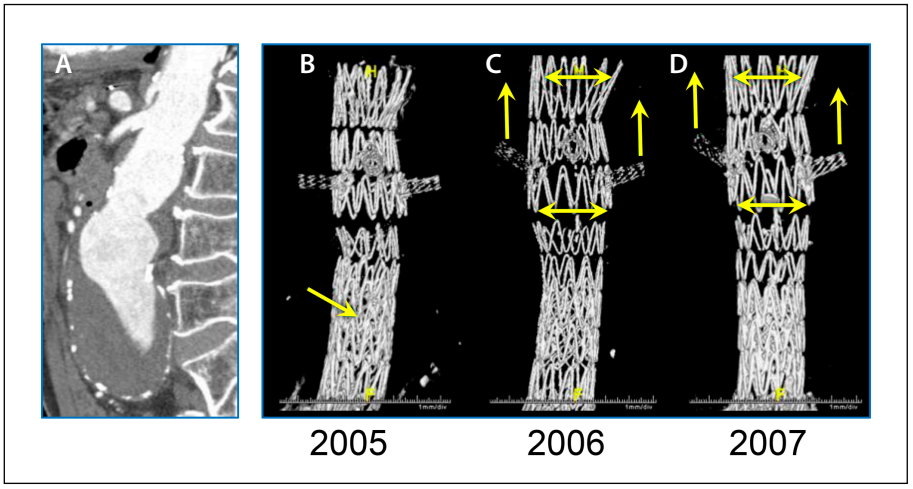

Figure 1. Sagittal view of CTA reveals a slight posterior bulge between the superior mesenteric artery (SMA) and the infrarenal aneurysm sac (A). Note the initial appearance of a three-vessel fenestrated endograft (B) with subsequent progression of aortic disease, causing flaring of the bare-metal stent, neck enlargement, and distal migration (C, D). With permission of Mayo Clinic Foundation.

LESSONS LEARNED

Branch vessel catheterization and incorporation is a critical step when dealing with complex aortic repair, regardless of which technique is used to incorporate the target vessel (ie, fenestrated, branched, or parallel grafts). Adequate planning, technical finesse, and attention to detail are of paramount importance to avoid complications. Excessive catheter and guidewire manipulation can result in a number of complications including atheroembolization, prolonged visceral ischemia, and inadvertent dissection or vessel perforation. The following sections summarize our top 10 tips and tricks for improving FEVAR results.

1. Disease Progression Can Compromise Late Results

It is critical that use of the ZFEN device follows the instructions for use for its intended indication. Although the device was approved for patients with short-necked infrarenal aneurysms (4–14 mm), it can be used more liberally in patients with aneurysms encroaching the renal arteries as long as a minimum sealing zone of 2 cm is achieved in normal aorta, which is defined by parallel aortic wall with no thrombus or calcification.[5] It is important to note that the presence of signs of aortic degeneration, such as ectasia, thoracic disease, thrombus, or posterior bulge (Figure 1), may be an indicator of disease progression. In these patients, the use of two or three fenestrations may be insufficient and lead to late neck dilatation, loss of sealing zone, migration, and displacement of target vessel stents. In most centers with access to more advanced stent graft designs, a minimum of three or four fenestrations is used and the sealing zone is placed in the supraceliac aorta.[1,5]

2. Meticulous Planning

A thorough review of patient anatomy is paramount to anticipate difficulties with side branch placement. The

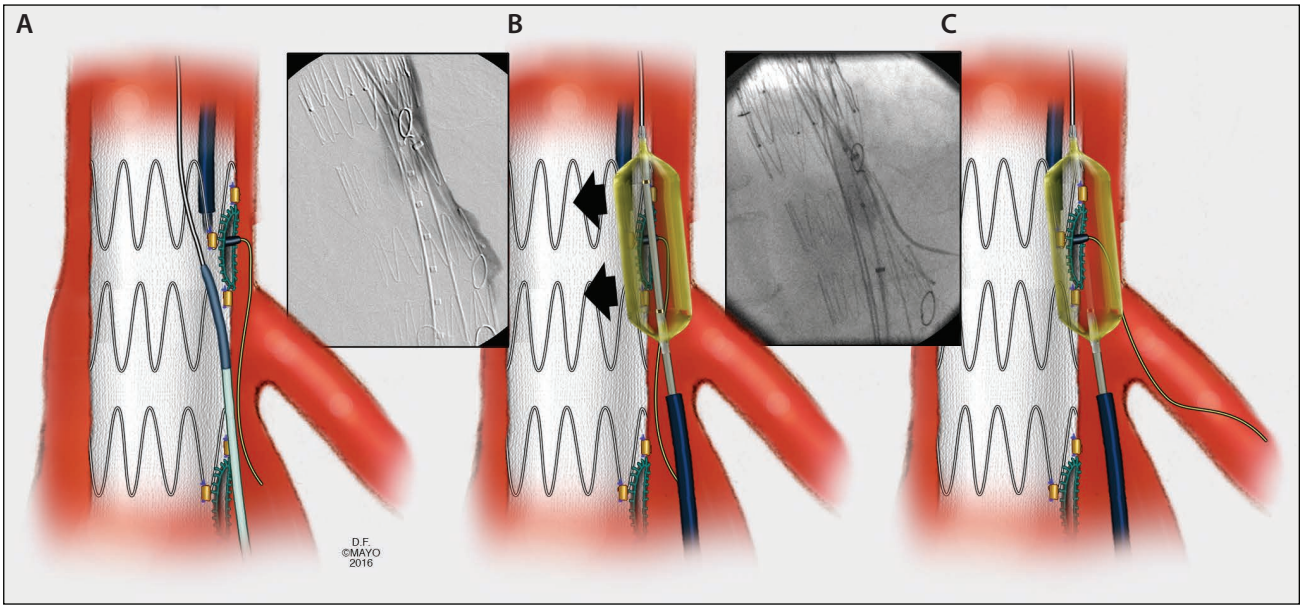

Figure 2. Misalignment between fenestration and target vessel (A) is treated by inflation of a balloon between the aortic endograft and aortic wall (B) to create space for catheter manipulation. The vessel is successfully catheterized using a "buddy" system (C). With permission of Mayo Clinic Foundation.

presence of tortuosity, ostial disease, plaque, debris, small vessel diameter, and early branch bifurcation all increase technical difficulty for placement of bridging stents. Therefore, preoperative case planning remains critical to successful execution of these procedures. Thin-slice CTA of the chest, abdomen, and pelvis determines target vessel orientation, specific stent graft design, and choice of ideal approach. Most complications, as later described, can be anticipated on the basis of careful review of preoperative imaging.

3. Optimize Imaging and Minimize Radiation Exposure

These procedures should ideally be performed in a hybrid operating room that combines optimal imaging with the ideal environment to perform complex open and endovascular operations. Although FEVAR can be performed with portable imaging, modern fixed imaging units have advantages such as stronger x-ray tube power (preventing overheating), flat panel detectors (optimizing imaging quality), and customizable protocols to regulate radiation dose levels. Several features such as CTA fusion, cone-beam CT (CBCT), larger detector panels, digital zoom, and low-dose protocols further reduce the radiation exposure to the patient and operator.

4. Minimize Contrast Use

Fenestrated repair can be technically demanding and require multiple steps. Therefore, large-volume aortography should be avoided during the initial steps of the procedure and reserved for the final assessment. Small hand injections of diluted contrast are used to identify target vessels, and CTA fusion guides device deployment and vessel catheterization. Although precatheterization of vessels is optional, this technique provides excellent means to precisely identify a target without the use of contrast.

5. Dealing With Misalignment Between Fenestration and Vessel

One of the most common difficulties during FEVAR is dealing with misalignment between the fenestration and the target vessel. Although rarely needed, leaving a stiff guidewire between the main aortic stent graft and the aortic wall can serve well in case of severe misalignment when there is not enough space to manipulate catheters. A simple maneuver is to advance and inflate a balloon between the stent graft and aortic wall, creating enough space to cannulate the vessel (Figure 2). If the fenestration can be catheterized and a wire can be advanced between the aortic wall and the stent graft, a 0.018-inch wire system should be used to maintain the tip of the sheath close to the fenestration while a buddy catheter is used to find the target vessel (Figure 3).

Excessive rotation of the device is not recommended and is usually not necessary. However, the constrained fenestrated device with top cap can be rotated to facilitate catheterization. Because the diameter-reducing ties are centered in the posterior aspect of the stent graft, the renal fenestrations are pulled posteriorly (Figure 4).

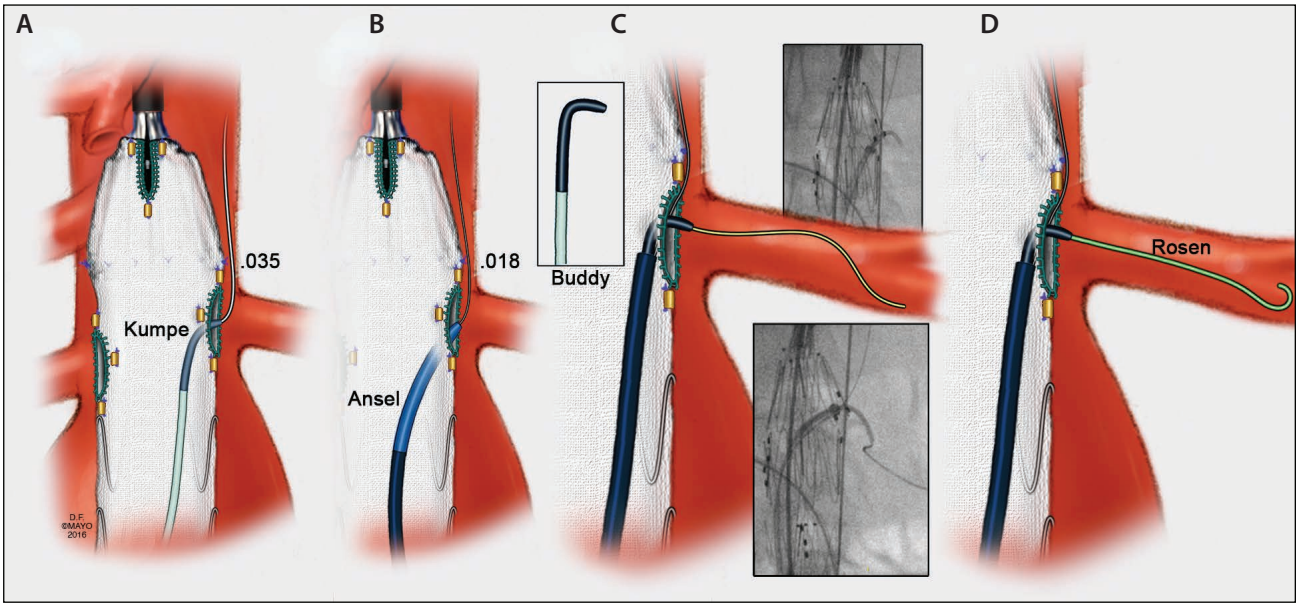

Figure 3. A renal fenestration is accessed and a 0.035-inch guidewire is advanced into the aorta (A), which is exchanged for a 0.018-inch system (B) to allow use of a buddy catheter (C), which is advanced into the target vessel (D). With permission of Mayo Clinic Foundation.

One of the first maneuvers in these cases is to rotate each fenestration more anteriorly. Once the fenestration and vessel are catheterized and a hydrophilic sheath is advanced, the graft is rotated in the opposite direction to allow catheterization of the contralateral renal artery. It is an important caveat to undo any rotation before final release of the top cap and final device deployment to avoid twisting at the distal aspect of the stent graft.

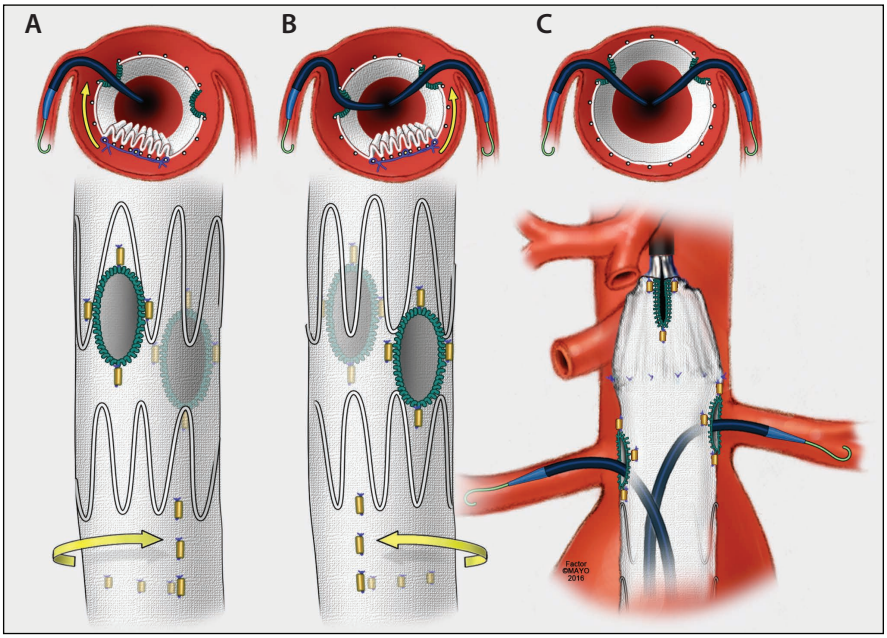

Figure 4. Natural posterior displacement of the fenestrations occurs because of posterior diameter-reducing ties. The device is rotated clockwise for access to the right renal artery (A) and counterclockwise for the left renal artery (B). Hydrophilic sheaths are advanced into both renal arteries over Rosen wires (C). With permission of Mayo Clinic Foundation.

6. Difficult Sheath Advancement

Down-going renal arteries may be difficult to access via the femoral approach. One of the first maneuvers that can be used is advancing the catheter to the top of the device and into the target vessel, allowing guidewire exchange for a Rosen wire (Cook Medical) (Figure 5). If a sheath with soft dilator cannot be advanced into the vessel, a useful maneuver is to inflate a balloon, which is used as a dilator for the sheath. The sheath is advanced into the target vessel while the balloon is deflated.

7. Selection of Bridging Stents

Alignment of fenestrations with balloon-expandable stents is recommended for all reinforced fenestrations, is optional for scallops, and is not recommended for

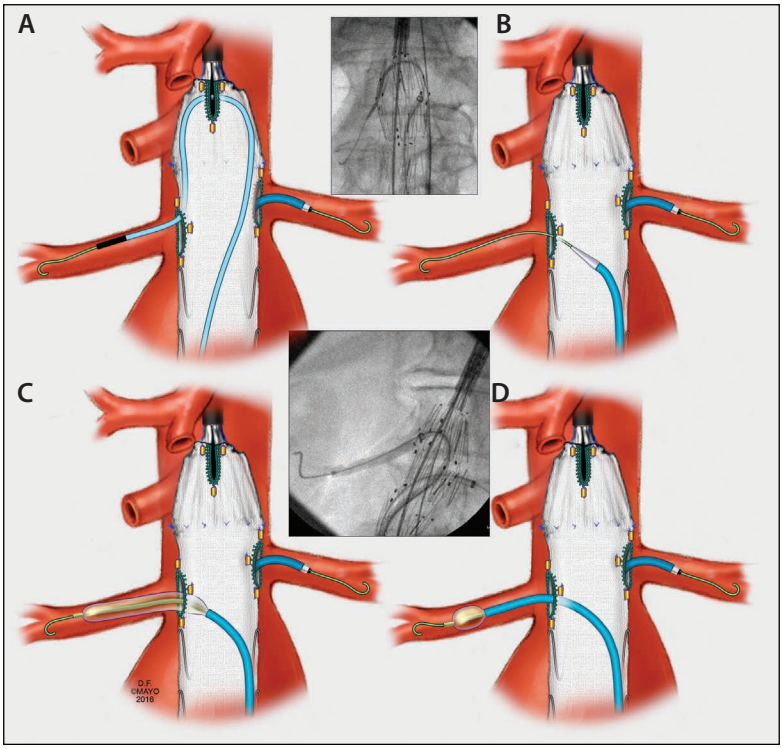

Figure 5. Sheath advancement using the top part of the fenestrated stent (A, B) and a balloon to replace the dilator of the sheath (C, D). With permission of Mayo Clinic Foundation.

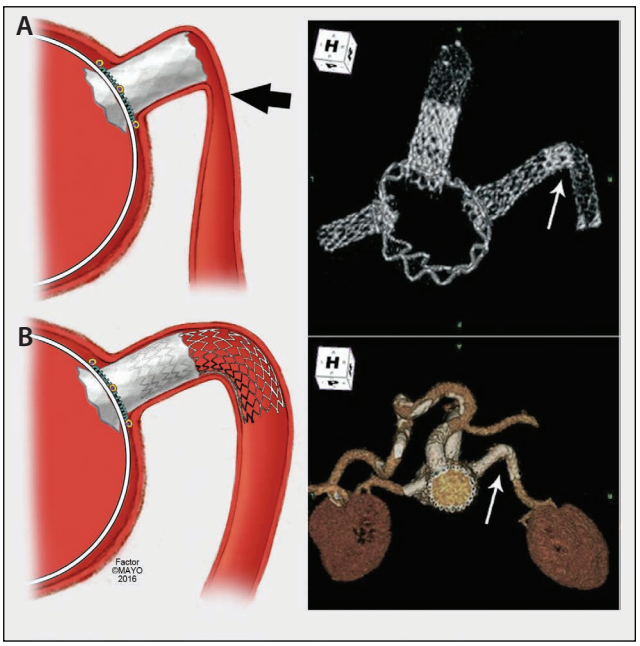

Figure 6. Renal arteries with posterior orientation are prone to kink at the distal edge of the balloon-expandable stents (A), which can be treated by placement of a self-expandable stent (B). With permission of Mayo Clinic Foundation.

large nonreinforced fenestrations. In the United States multicenter prospective study evaluating the ZFEN, a bare-metal balloon-expandable stent was used. However, most experts agree that covered balloon-expandable stents are the standard of care for vessel alignment, offering advantages of improved primary patency, lower rates of neointimal hyperplasia, and improved seal.[1-5] Kinks should immediately be recognized on selective angiography or anticipated based on vessel anatomy (Figure 6). A useful tip is to keep the length of the stents short (< 2 cm), which avoids bends and minimizes the respiratory motion. If flow-limiting kink is noted, a self-expandable stent may be needed to smooth the transition between the alignment stent and the vessel.

8. Technical Finesse

Attention to detail and careful catheter manipulation are critical for avoiding complications. With finesse, proper technique, and good patient selection, vessel perforation or dissections are infrequent. Guidewire selection is the first step. For the renal arteries, we favor using an intermediate-stiffness, J-tip guidewire such as the Rosen wire. Stiff guidewires, such as the Amplatz (Cook Medical), are avoided whenever possible in the renal arteries. It is important not to position the J-tip in small terminal branches, which are prone to perforation or dissection. In addition, the operator should maintain visualization of the tip of the guidewire during manipulations, and the guidewire should be stabilized during exchanges, avoiding forward or retrograde movement. In the unfortunate event of major renal branch perforation, a 0.035-inch balloon should be inflated in the renal stent to minimize bleeding. The 0.035-inch guidewire may be removed with the balloon inflated to allow angiography to be performed via the lumen of the balloon shaft (Figure 7). For more distal branches, access can be obtained with a 3-F microcatheter introduced via the shaft of the 0.035-inch balloon. Coils can then be delivered through the catheter. Dissections within the main renal artery can be treated by placement of an additional self-expandable stent. A devastating complication can occur if there is total disruption of the vessel beyond a short fenestrated stent. It is imperative in these cases that access is not lost. If salvage is not possible, the vessel needs to be sacrificed.

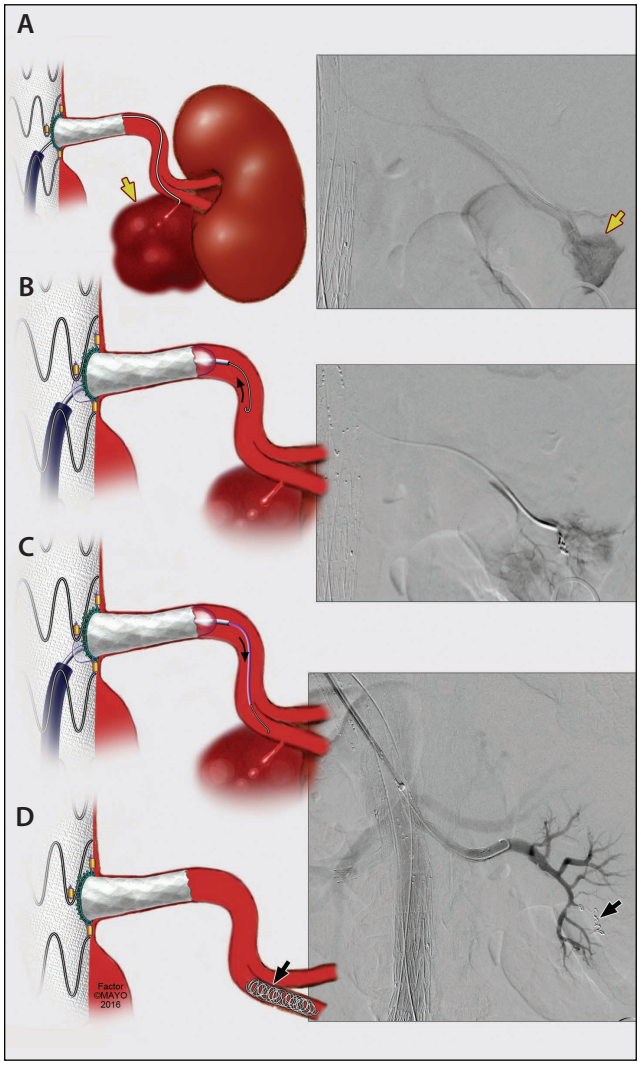

Figure 7. Inadvertent perforation of a side branch (A) should immediately be recognized by completion angiography. The balloon is reinflated in the bridging stent (B), and angiography is performed via the balloon catheter (C). A microcatheter can then be advanced over the inflated balloon, and the perforated distal vessel is coil embolized (D). With permission of Mayo Clinic Foundation.

9. Dealing With Attachment Endoleaks

The addition of more stent graft components increases the potential for failure of one of the attachment sites. The most common endoleaks are type II and IV. Type I endoleaks are uncommon with proper planning and adequately long landing zones. If noted, these should be treated by repeat balloon dilatation of the proximal neck with protection of the side stents using separate balloons. Type III endoleaks may require repeat dilatation or placement of a second covered stent.

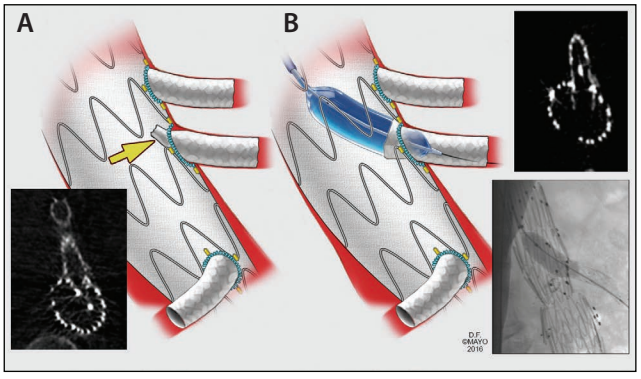

Figure 8. CBCT reveals compression of the SMA stent (A), which tends to occur during advancement of the distal bifurcated device or one of the iliac limbs. This was immediately revised by balloon inflation (B), avoiding the dreaded complication of early SMA thrombosis. With permission of Mayo Clinic Foundation.

10. Technical Assessment

It is important to immediately identify technical problems, such as endoleaks, from sealing zones or compression of side stents (Figure 8). If not recognized, these problems may lead to devastating complications such as stent occlusion or aneurysm rupture. The use of CBCT with or without contrast enhancement using high-definition imaging can be performed through three-dimensional rotation. Multiplanar reconstructions allow immediate assessment of the repair, including the location of stent grafts in relation to target vessels, configuration of side branches, patency of iliac limbs, and presence of endoleaks. These technical complications can be recognized and immediately revised.

CONCLUSION

FEVAR has increasingly been utilized to treat aortic aneurysms involving the aortic arch, thoracoabdominal aorta, and iliac bifurcation. It is important that centers performing these types of procedures are prepared to adapt to the technical demands of newer devices to treat complex anatomy and that physicians are well trained in bailout maneuvers to deal with unanticipated problems. The availability of advanced imaging tools has several advantages, notably the combination of the ideal surgical environment with optimal imaging and advanced applications to minimize radiation exposure, use of contrast media, and need for secondary interventions. ■

1. Greenberg R, Eagleton M, Mastracci T. Branched endografts for thoracoabdominal aneurysms. J Thorac Cardiovasc Surg. 2010;140(6 suppl):S171-178.
2. Haulon S, Amiot S, Magnan PE, et al. An analysis of the French multicentre experience of fenestrated aortic endografts: medium-term outcomes. Ann Surg. 2010;251:357-362.
3. Mastracci TM, Eagleton MJ, Kuramochi Y, et al. Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms. J Vasc Surg. 2015;61:355-364.

4. Oderich GS, Greenberg RK, Farber M, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg. 2014;60:1420-1428.

5. Oderich GS, Ribeiro M, Hofer J, et al. Prospective, nonrandomized study to evaluate endovascular aortic repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones. J Vasc Surg. 2017;65:1249-1259.

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State of the Art in Radiation Safety During Fenestrated EVAR

A discussion of radiation exposure during FEVAR.

BY MELISSA KIRKWOOD, MD; DAVID TIMARAN, MD; AND CARLOS TIMARAN, MD

Fluoroscopically guided interventions (FGIs) are increasing in number and complexity. Vascular surgeons who routinely perform FGIs, as well as their patients, are at risk of significant radiation exposure and the potential associated harmful deterministic and stochastic effects. Deterministic effects result from a predictable dose-related response with a threshold below which the effect is unlikely to occur, such as skin injury and cataract development. Stochastic effects (ie, cancer formation) have a probability of occurrence that increases with dose, but the severity is dose independent.[1]

The Zenith Fenestrated (ZFEN) endovascular graft (Cook Medical) is available for implantation in abdominal aortic aneurysms with short infrarenal necks. This graft can be designed with three fenestrations/scallops at most, each with its own restrictions with respect to location and positioning in the proximal aspect of the graft. There is at least 1 month of manufacturing time required for the device. Multicenter studies have shown that it is a safe and effective tool with low morbidity and mortality in properly selected patients.[2] Because of the increased complexity of fenestrated endovascular aortic aneurysm repair (FEVAR) using the ZFEN device, the purpose of the study described in this article was to assess patient and operating room staff radiation exposure during FEVAR. Device design was also assessed in terms of radiation dose during FEVAR.

METHODS

In our most recent series, we evaluated 79 FEVARs, performed by a single surgeon on the Allura Xper FD20 fluoroscopy system equipped with AlluraClarity technology (Philips Healthcare). Radiation doses to the operating room staff were measured using a personal dosimetry system (DoseAware, Philips Healthcare) worn on the outside of the lead apron at the left upper chest position. Before each procedure, dosimeters were reset and the cumulative reading for each participant was immediately collected following the case from the in-room display monitor. Procedure type, patient body mass index (BMI), reference air kerma (RAK), and kerma area product (KAP) were recorded. RAK and KAP were corrected for BMI based on an exponential fit of fluoroscopy dose rate and the dose per radiographic frame. Operator dose was corrected for BMI by the ratio of normalized to measured KAP. A one-sided Wilcox rank sum test was used to compare personnel radiation doses, RAKs, and KAPs between device design and level of fenestration. The statistical significance was $P \leq .05$.

RESULTS

ZFENs showed relatively low mean RAK (1,800 mGy), KAP (210 Gy·cm^2), primary operator dose (220 µSv), assistant operator dose (60 µSv), circulating nurse dose (10 µSv), and scrub nurse dose (10 µSv). When compared to more complex investigational custom-made devices, ZFENs had significantly lower patient, primary and assistant operator, and operating room personnel dose. Two-vessel fenestration cases tended to have a lower RAK (1,600 mGy vs 2,670 mGy) and KAP (240 mGy·cm^2 vs 320 mGy·cm^2) compared to three-vessel fenestrations, but this trend did not reach significance.

DISCUSSION

The appropriate use of operating factors, as well as the interventionalist's knowledge regarding best practice guidelines during fluoroscopy, greatly contributed to radiation dose. All endovascular surgeons should be properly trained in radiation safety and adhere to using radiation doses that are "as low as reasonably achievable" (ie, the ALARA principle).[3] When these tenets are applied, surgeons are able to lower radiation dose during FGIs.[4] However, even with ALARA compliance, procedure type and case complexity remain major factors in determining dose. We have shown that FEVAR is the highest-dose procedure performed by vascular surgeons in our practice.[4] Furthermore, surgeon and trainee doses are significantly higher with FEVARs compared to other complex FGIs.[5] Additional factors that affect dose during FEVAR include patient BMI, operator position around the angiographic table, the use of dose-lowering software and adjunctive lead shielding, as well as procedure-related factors including level of fenestration and device design.[4-6]

Patient obesity is a risk factor for increased dose because higher radiation doses are needed to penetrate the body in larger patients; therefore, obese patients are exposed to higher levels of radiation for the same procedure compared to thinner patients.[1,7] In terms of surgeon dose, we have found that standing at the left brachial artery position when the C-arm is on the left is the highest-dose position for FEVAR, followed by standing closest to the flat panel detector on the right side of the patient. Both of these positions result in roughly twice as much dose as the assistant operator who stands one position down from the patient on the right side.[5] Routine use of the table-mounted lead skirt also significantly decreases surgeons' lower body dose.[5]

Advances in new image processing and noise-reduction software can also reduce radiation dose during FEVAR. We have shown that the addition of AlluraClarity technology reduces both the fluorography and fluoroscopy dose rates by about 50% for FEVAR.[6] It is essential that endovascular surgeons stay current with new software developments that can minimize dose.

The greatest concern regarding radiation dose during FEVAR is the risk for patient skin injury. A threshold dose of 2 Gy has widely been reported.[8] We have not had any events of skin injury in either our retrospective or prospective FEVAR study with mean RAK doses well above the threshold dose of 2 Gy.[9,10] This demonstrates that FEVAR is safe for patients and operators; nevertheless, the risk of potential harm is real and every attempt must be made to mitigate the risks by limiting exposure. ■

1. Brown KR, Rzucidlo E. Acute and chronic radiation injury. J Vasc Surg. 2011;53(1 suppl):15S-21S.
2. Oderich GS, Greenberg RK, Farber M, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg. 2014;60:1420-1428 e1-5.
3. US Food and Drug Administration. Avoidance of serious x-ray-induced skin injuries to patients during fluoroscopically-guided procedures. https://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm116677.pdf. Published September 9, 1994. Accessed September 8, 2017.
4. Kirkwood ML, Arbique GM, Guild JB, et al. Surgeon education decreases radiation dose in complex endovascular procedures and improves patient safety. J Vasc Surg. 2013;58:715-721.
5. Kirkwood ML, Guild JB, Arbique GM, et al. Surgeon radiation dose during complex endovascular procedures. J Vasc Surg. 2015;62:457-463.
6. Kirkwood ML, Guild JB, Arbique GM, et al. New image-processing and noise-reduction software reduces radiation dose during complex endovascular procedures. J Vasc Surg. 2016;64:1357-1365.
7. Hymes SR, Strom EA, Fife C. Radiation dermatitis: clinical presentation, pathophysiology, and treatment 2006. J Am Acad Dermatol. 2006;54:28-46.
8. Balter S, Hopewell JW, Miller DL, et al. Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair. Radiology. 2010;254:326-341.
9. Kirkwood ML, Arbique GM, Guild JB, et al. Radiation-induced skin injury after complex endovascular procedures. J Vasc Surg. 2014;60:742-748.
10. Kirkwood ML, Arbique GM, Guild JB, et al. Deterministic effects after fenestrated endovascular aortic aneurysm repair. J Vasc Surg. 2015;61:902-906.

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ZENITH® FENESTRATED AAA ENDOVASCULAR GRAFT WITH THE H&L-B ONE-SHOT™ INTRODUCTION SYSTEM

CAUTION: U.S Federal law restricts this device to sale by or on the order of a physician.

INTENDED USE: The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is indicated for the endovascular treatment of patients with abdominal aortic or aorto-iliac aneurysms having morphology suitable for endovascular repair, including: • Adequate iliac/femoral access compatible with the required introduction systems, • Non-aneurysmal infrarenal aortic segment (neck) proximal to the aneurysm: -with a length that is at least 4 mm and unsuitable for a non-fenestrated graft, -with a diameter measured outer wall to outer wall of no greater than 31 mm and no less than 19 mm, -with an angle less than 45 degrees relative to the long axis of the aneurysm, and -with an angle less than 45 degrees relative to the axis of the suprarenal aorta. • Ipsilateral iliac artery distal fixation site greater than 30 mm in length and 9–21 mm in diameter (measured outer wall to outer wall). • Contralateral Iliac artery distal fixation site greater than 30 mm in length and 7–21 mm in diameter (measured outer wall to outer wall).

CONTRAINDICATIONS: The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is contraindicated in the following: • Patients with known sensitivities or allergies to stainless steel, polyester, nitinol, solder (tin, silver), polypropylene or gold • Patients with systemic or local infection that may increase the risk of endovascular graft infection.

WARNINGS AND PRECAUTIONS:

General Use Information Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient. • Fenestrated grafts are made to a customized design to a specification requested by the responsible Physician, and are tailored to a specific patient's anatomy. • The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device, which requires precise planning/sizing as well as accurate longitudinal positioning and rotational orientation during placement. • Lack of non-contrast CT imaging may result in failure to appreciate iliac or aortic calcification, which may preclude access or reliable device fixation and seal. • Preprocedure imaging reconstruction thickness > 3 mm may result in sub-optimal device sizing, or in failure to appreciate focal stenosis from CT. • Implantation of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System requires high quality imaging. Some types of mobile image intensifiers may not provide adequate imaging quality. • **The long-term performance of fenestrated endovascular grafts, including the stents placed in fenestrations/scallops, has not yet been established.** All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, changes in the structure or position of the endovascular graft, or stenosis/occlusion of vessels accommodated by fenestrations) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 12 in the complete INSTRUCTIONS FOR USE.** • After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth, patency of vessels accommodated by a fenestration/scallop, or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is recommended, including: 1) abdominal radiographs to examine device integrity (separation between components, stent fracture or barb separation) and 2) contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information. • The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is not recommended in patients unable to undergo, or who will not be compliant with the necessary preoperative and post-operative imaging and implantation studies as described in **Section 12, Imaging Guidelines and Post-Operative Follow-Up in the complete INSTRUCTIONS FOR USE.** • Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms, unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture. • Patients experiencing reduced blood flow through the graft limb/fenestration and/or leaks may be required to undergo secondary interventions or surgical procedures. • Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary. • Endovascular stent grafting is a surgical procedure, and blood loss from various causes may occur, infrequently requiring intervention (including transfusion) to prevent adverse outcomes. It is important to monitor blood loss from the hemostatic valve throughout the procedure, but is specifically relevant during and after manipulation of the gray positioner. After the gray positioner has been removed, if blood loss is excessive, consider placing an uninflated molding balloon or an introduction system dilator within the valve, restricting flow.

Patient Selection, Treatment and Follow-Up Inappropriate patient selection may result in poor performance of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System. • Access vessel diameter (measured inner wall to inner wall) and morphology (minimal tortuosity, occlusive disease, and/or calcification) should be compatible with vascular access techniques and delivery systems of the profile of a 14 French to 22 French vascular introducer sheath. Iliac conduits may be used to ensure the safe insertion of the introduction system. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the endovascular graft and/or may increase the risk of embolization/trauma. • Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (> 45 degrees for infrarenal neck to axis of AAA or > 45 degrees for suprarenal neck relative to the immediate infrarenal neck); short proximal aortic neck (<4 mm); greater than 10% increase in diameter over 15 mm of proximal aortic neck length; and circumferential thrombus and/or calcification at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites. Necks exhibiting these key anatomic elements may be more conducive to graft migration. • The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging. • The use of this device requires administration of radiographic agents. Patients with pre-existing renal insufficiency may have an increased risk of post-operative renal failure. • The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is not recommended in patients of excessive weight and/or size that would limit, compromise, or prevent the necessary imaging requirements. • Inability to maintain patency of at least one internal iliac artery or occlusion of an indispensable inferior mesenteric artery may increase the risk of pelvic/bowel ischemia. • Multiple large, patent lumbar arteries, mural thrombus and a patent inferior mesenteric artery may all predispose a patient to Type II endoleaks. Patients with uncorrectable coagulopathy may also have an increased risk of Type II endoleak or bleeding complications. • Patients with recurrent aortic aneurysmal disease or with disease above the renal arteries may be prone to further aortic dilation in the renal/visceral segment, which could compromise device integrity/fixation. • The Zenith Fenestrated AAA Endovascular Graft has not been evaluated in the following patient populations: -Less than 18 years of age -Females who are pregnant or breast-feeding -Leaking/ruptured or symptomatic aneurysms -Patients with connective tissue disorders -Patients with previous stent placement in vessels to be accommodated by fenestrations

Implant Procedure Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered. • Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection. • To activate the hydrophilic coating on the outside of the Flexor introducer sheath, the surface must be wiped with 4X4 gauze pads soaked in saline solution. Always keep the sheath hydrated for optimal performance. • Maintain wire guide position during delivery system insertion. • Do not bend or kink the delivery system. Doing so may cause damage to the delivery system and the Zenith Fenestrated AAA Endovascular Graft. • Fluoroscopy should be used during introduction and deployment to confirm proper operation of the delivery system components, proper placement of the graft, and desired procedural outcome. • The use of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively. Care should be taken to limit the amount of contrast media used during the procedure. • To avoid any twist in the endovascular graft, during any rotation of the delivery system, be careful to rotate all of the components of the system together (from outer sheath to inner cannula). • Inaccurate placement and/or incomplete sealing of the Zenith Fenestrated AAA Endovascular Graft within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the renal or internal iliac arteries. Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications. It is recommended that all vessels accommodated by a small fenestration be stented in order to secure positive alignment of the graft fenestration with the vessel origin. • Inadequate fixation of the Zenith Fenestrated AAA Endovascular Graft may result in increased risk of migration of the stent graft. Incorrect deployment or migration of the endoprosthesis may require surgical intervention. • The Zenith Fenestrated AAA Endovascular Graft incorporates a suprarenal stent with fixation barbs. Exercise extreme caution when manipulating interventional devices in the region of the suprarenal stent. • Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the wire guide or delivery system. Stop and assess the cause of resistance. Vessel or catheter damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis or in calcified or tortuous vessels. • Unless medically indicated, do not deploy the Zenith Fenestrated AAA Endovascular Graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Do not cover significant renal or mesenteric arteries (exception is the inferior mesenteric artery) with the endoprosthesis. • Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus, which can cause distal embolization. • Care should be taken not to damage the graft or disturb graft positioning after graft placement in the event reinstrumentation of the graft is necessary.

Molding Balloon Use Prior to molding in the vicinity of any fenestration stent(s) confirm that the aortic section of the stent has been flared. • Confirm complete deflation of balloon prior to repositioning. • Do not inflate balloon in the vessel outside of graft, as doing so could result in damage to the vessel (e.g., rupture).

MRI Safety and Compatibility Non-clinical testing has demonstrated that the Zenith Fenestrated AAA Endovascular Graft is MR Conditional. A patient with this endovascular graft in place for at least 6 months can be scanned safely under the following conditions: • Static magnetic field of 3.0 Tesla or 1.5 Tesla • Maximum spatial magnetic gradient of 720 Gauss/cm or less • Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning or less (i.e., per scanning sequence) • Normal operating mode.

Static Magnetic Field The static magnetic field for comparison to the above limits is the static magnetic field pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

ADVERSE EVENTS

Potential adverse events that may occur and/or require intervention include, but are not limited to: • Amputation • Anesthetic complications and subsequent attendant problems (e.g., aspiration) • Aneurysm enlargement • Aneurysm rupture and death • Aortic damage, including perforation, dissection, bleeding, rupture and death • Arterial or venous thrombosis and/or pseudoaneurysm • Bleeding, hematoma or coagulopathy • Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis) • Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension) • Claudication (e.g. buttock, lower limb) • Death • Edema • Embolization (micro and macro) with transient or permanent ischemia or infarction • Endoleak • Endoprosthesis: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture; perigraft flow; barb separation and corrosion • Fever and localized inflammation • Fistula (e.g., aortoenteric, arteriovenous) • Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection) • Hepatic failure • Impotence • Infection of the aneurysm, device or access site, including abscess formation, transient fever and pain • Lymphatic complications and subsequent attendant problems (e.g., lymph fistula) • Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis) • Occlusion of device or native vessel • Organ impairment/loss due to side-branch vessel occlusion (in particular, renal and/or gastrointestinal impairment/loss) • Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation) • Renal complications and subsequent attendant problems (e.g., artery stenosis or occlusion, contrast toxicity, infarct, insufficiency, failure) • Surgical conversion to open repair • Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection • Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death) • Vessel damage • Wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis).

See instructions for use for full product information.

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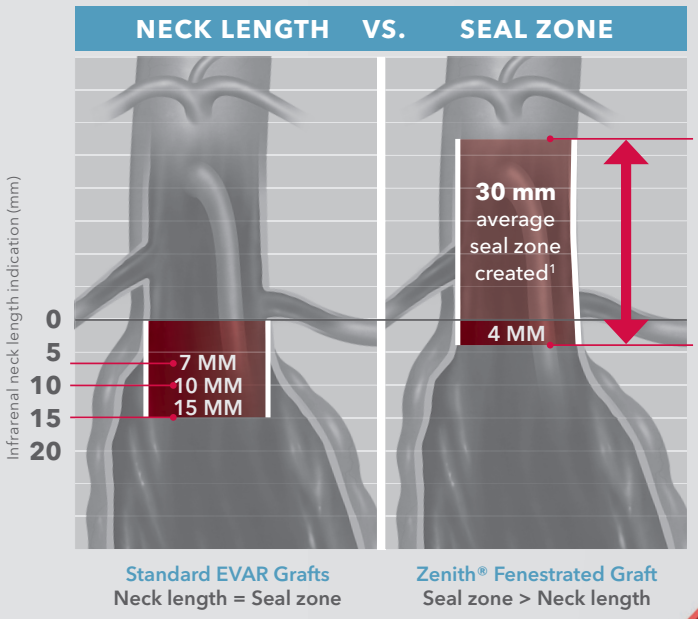

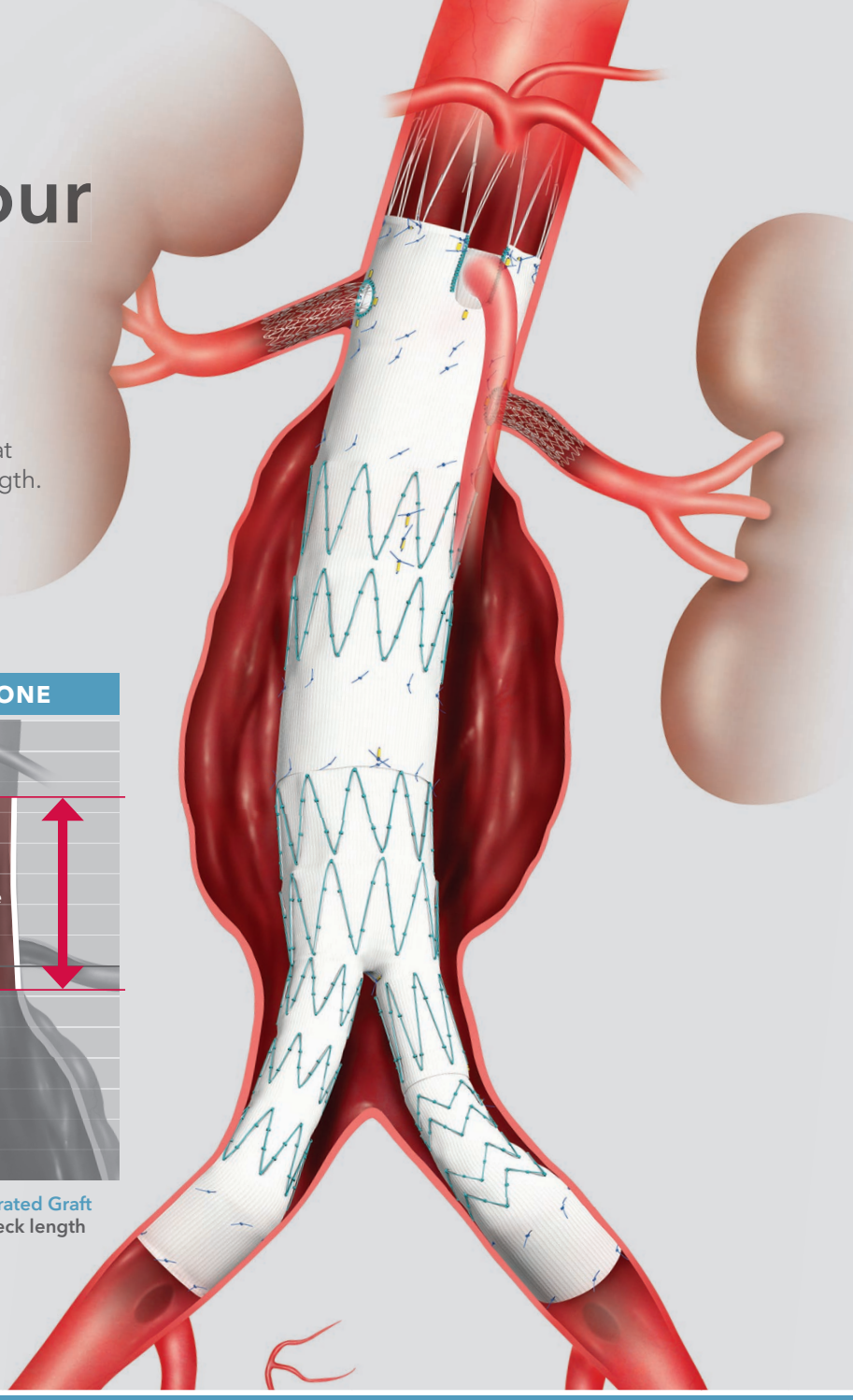

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AAA ENDOVASCULAR GRAFT

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*Based on Cook Research Incorporated internal analysis of patients treated in the Zenith Fenestrated pivotal and continued access studies.

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