Endovascular technology has evolved considerably over the past several years. Since the first description of endovascular repair of an abdominal aortic aneurysm (EVAR),1 multiple alterations have been made to the technology, providing significant improvements in its performance and resulting in its application to increasingly challenging anatomy—despite being outside of the indications for use. To help accommodate more challenging anatomy, the technology has advanced to allow us to treat longer, more complex segments of the aorta; in particular, those regions that span the visceral segment, including the treatment of juxtarenal abdominal aortic aneurysms (AAAs) and thoracoabdominal aortic aneurysms (TAAAs). One approach has been to use off-the-shelf tools applied in a parallel fashion to allow for the exclusion of aneurysms while continuing to perfuse the visceral vessels. Alternatively, purpose-built devices have been developed utilizing fenestrations or directional branches in order to include these important vessels in the repair.

Since the first description of these custom tools to treat a short-necked aneurysm, there has been further development of the technology in order to allow for the exclusion of extensive TAAAs.2-6 With more than a decade of experience in using fenestrated and branched endografts (F/B-EVAR) to treat complex aortic disease, much data have been collected, and outcomes have been assessed. During the past decade, especially with dissemination of these techniques, many lessons have been learned. Outlined in this article are, in my opinion, 10 of the top lessons learned.

F/B-EVAR CAN BE DONE

So, you are thinking to yourself, of course it can; however, at its inception, this was not so obvious. The original device designs encompassed a nonsupported fenestration that was mated with the target vessel (typically the renal artery) utilizing a bare-metal stent. This design would not allow for the exclusion of aneurysms spanning the visceral segment. Enhancements such as the use of reinforced fenestrations, directional branches, and the use of covered bridging stents allowed for the exclusion of more extensive aneurysms. Again, this seems rather intuitive, but despite the first description of their use in 1999,7 fenestrated endografts were not approved for commercial use in the United States until just a few years ago.

Given its relative newness and potential unpredictable results, most of the initial evaluations were performed in patients who were considered to be at high risk for conventional (open) surgery. This is detailed in many of the large databases that have, over the recent years, reported their outcomes.8-17 Thousands of “high-risk” patients have been treated with F/B-EVAR for complex aortic aneurysms worldwide; most of these are included in investigational trials in which enrollment criteria and follow-up are monitored as part of a protocol. Although we can debate what defines “high risk,”18,19 and whether all patients with complex aneurysms are really “high risk,” the fact remains that most of the reports encompass patients who have American Society of Anesthesiologists classifications of 3 and 4 or who were turned down for conventional surgery secondary to physiologic or anatomic complexity.

Despite this, we have demonstrated the capability to successfully exclude complex aortic aneurysms in this population, with perioperative mortality rates of 0.5% to 9%.8-17,20 These rates vary based on the complexity of the aneurysm, with more complex TAAAs having higher mortality rates than those reported for juxtarenal AAAs. These outcomes challenge the results of open surgery, which report higher or equivalent mortality rates for repair of similar aneurysm extents, even in high-volume centers.5,21-26 Factors influencing the development of in-hospital mortality and severe complications appear to be directly related to the extent of the aneurysm repaired.9,14 Not only is it possible to operate on these patients with complex aneurysms, and have them survive, but most larger series boast technical success rates > 95%.

PLANNING IS KEY

Although planning is the key to all successful endografting, even straightforward EVAR, it is even more imperative for the endovascular treatment of complex aortic disease.
In order for device construction and implantation to be performed, appropriate case planning requires expert knowledge of device construction, the properties of ancillary tools (such as covered bridging stent grafts), the interaction of the devices with each other, and what imaging protocols are necessary to obtain correct anatomic information. It is during this stage that intraoperative problems can be anticipated with the development of a “plan B” and “plan C,” in order to be prepared (both mentally and with the correct equipment) to expediously treat the patient, as most errors are made during the planning phase of the procedure.

Comprehensive aortic assessment is mandatory for procedural planning when using devices that incorporate branched vessels. This is accomplished with the use of high-quality image acquisition and the ability to manipulate the data at three-dimensional workstations. Longitudinal and/or rotational misalignment can result in critical end-organ loss, with potentially disastrous consequences. Currently available spiral CT technology renders images of excellent quality that can be used to design devices that incorporate the visceral, renal, iliac, internal, and arch vessel. The use of a 0.75- to 1-mm slice image acquisition is frequently employed. After acquisition, image reconstruction is performed with multiplanar techniques to allow for the accurate measurement of a variety of arterial anatomic criteria, such as the accurate assessment of the proximal aortic neck, as well as the location, distance, and rotational alignment of target branches. The use of three-dimensional workstations to plan for EVAR has been shown to reduce rates of perioperative complications, including the development of type I endoleaks and the need for secondary interventions.28

Several anatomic structures must be considered when planning an F/B-EVAR and multiple, different anatomic structures and their locations must be considered when planning a branched endograft. Initial planning revolves around placement of the stent graft in a location that will allow for adequate proximal fixation and seal. Standard commercial EVAR allows for a proximal landing zone of 10 to 15 mm by most graft indications for use. With branched aortic endograft placement, we prefer to follow guidelines more akin to those for placement of a thoracic endograft and extend the proximal landing zone to 25 mm. The proximal and distal landing/seal zones should be free of significant atheroma and thrombus, and the aortic walls should be parallel. This can be overcome in more proximal aortic disease through the utilization of elephant trunk grafts and/or debranching procedures, in which a hybrid procedure is performed utilizing both open and endovascular surgery. In addition, the linear and axial location of the target branched vessels must be noted. This will dictate where on the graft the location of the fenestrations or branches will be constructed, and what branch morphology is most appropriate for that patient. Also, access must be considered—can you get the graft and branches where they need to be? Newer low-profile systems allow for an 18-F delivery sheath, although other designs still require 20- to 22-F sizes. The ability to deliver the endograft is not only affected by the size, narrowing, and tortuosity of the iliac artery system, but many designs also require antegrade delivery of components, requiring knowledge of similar information about the axillosubclavian artery system and the aortic arch.

**TECHNICAL SKILLS ARE NECESSARY, AND THERE IS A LEARNING CURVE THAT AFFECTS OUTCOMES**

The reported technical success rates for F/B-EVAR are quite high, ranging from 96% to 99% at high-volume centers. With increasingly complex procedures comes the need for a higher skill set to perform these procedures in an expeditious fashion with limited complications. To achieve this, surgeons need to be adept with skills in renal and visceral intervention, as well as routine aortic endografting. If a surgeon lacks experience in these areas, “jumping right in” to perform F/B-EVAR is foolhardy. You can learn from others’ experiences and take advantage of the proctoring of initial case performances. The right tools and maneuvers that are frequently needed in F/B-EVAR have been discussed in the literature and are beyond the scope of this article.28 It is worth knowing how to perform these maneuvers, what tools are necessary to perform them, and (most importantly) anticipating when they will need to be applied.

Several reports have demonstrated that with increasing experience, most surgeons become more aggressive at aortic coverage and incorporate a larger number of visceral vessels.10,29,30 However, the increase of case complexity does not correspond with an increase in perioperative morbidity. Several series have demonstrated that with increased experience, there is a decrease in fluoroscopy time and radiation dose time, even for these more complex cases.30,31 The Cleveland Clinic demonstrated that over time, operative times significantly decrease for individual surgeons performing an endograft for some of the most complex TAAAs.9 This becomes important when it is observed that shorter operative times are directly associated with improved outcomes and lower incidence rates of severe complications, such as spinal cord ischemia (SCI) and renal failure. This learning curve has made a direct effect on patient outcomes.

**SPINAL CORD ISCHEMIA IS A CHALLENGE**

SCI remains a challenge after TAAA, regardless of the surgical approach to this disease. Only one direct comparison of F/B-EVAR to conventional surgery exists for these
patients, and it demonstrated no significant difference in rates of SCI. The open and endovascular groups, however, were not equivalent with regard to patient demographics, but the consistent finding was that higher rates of SCI were associated with more extensive aneurysms. Our ability to overcome this complication is somewhat limited in endovascular repair, and it is imperative that we identify factors that can help to prevent this devastating complication. The Cleveland Clinic group identified that patients who developed SCI, especially those who developed permanent lower extremity motor dysfunction, had accelerated mortality rates, with only 36% survival at 3 months in this group.32

One of the important concepts in preservation of spinal cord blood flow is the collateral network pathway.33 In F/B-EVAR, it is evident that patients with occluded alternate collateral routes (such as hypogastric or subclavian artery occlusion) have higher rates of SCI, more severe symptoms, and are less likely to recover. Multiple evaluations have been conducted investigating methods of augmenting the collateral flow in the perioperative period. Animal studies have suggested that a staged exclusion of the aorta may be protective of SCI through the recruitment of collateral network pathways.34 The Cleveland Clinic experience demonstrated that patients who had intentionally staged approaches to extensive (type II) TAAA repair benefited with lower rates of motor dysfunction and higher rates of recovery.35 This further translated into higher long-term survival rates. The pathophysiology behind spinal cord protection with this method is not entirely clear, but it may relate to shorter operative times and early reperfusion of the lower extremities and pelvis. The benefit of this approach has been demonstrated by others, such as by Maurel et al who demonstrated that changing their operative paradigm to one that involved early removal of large occlusive sheaths resulted in a significant reduction of SCI development.36

**RENAL FUNCTION REMAINS A CONCERN**

Renal failure is one of the most frequent complications after surgery involving the paravisceral aorta; F/B-EVAR has the potential to exacerbate or alleviate that risk. The upside of endovascular therapy is that there should be more limited renal ischemic time due to the lack of an aortic clamp and time for renal revascularization. In some instances, however, the sheaths used for cannulation of the renal arteries can be occlusive, and renal ischemia may exist without the operating surgeon being completely aware of the situation. In addition, manipulation of the renal arteries themselves, with catheter and guidewire manipulation into the renal vessel followed by stent placement, may result in atheroembolization and the development of postoperative acute renal injury. In fact, in the United States Zenith fenestrated trial (Cook Medical), up to 10% of patients had evidence of renal infarct within 30 days of the index procedure.30

Despite this, renal function after F/B-EVAR appears to be preserved in most patients. Even with the apparent high rate of renal infarction associated with fenestrated endovascular aortic repair (FEVAR), the United States Zenith fenestrated trial still boasted a 100% 30-day freedom from acute renal injury.30 Others, however, have reported the incidence of acute kidney injury to be higher. The need for hemodialysis after F/B-EVAR has varied from 0% to 6% and varied based on the extent and complexity of the aneurysm repaired.9,10,15,17 Early experience with FEVAR demonstrated that acute kidney injury developed in 16% of patients without preoperative renal insufficiency and in 39% of those with chronic renal disease.37 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 stabilized in this population within 6 months of the index surgery.

In a more contemporary series, Martin-Gonzalez et al reported that postoperative acute renal failure (assessed with the RIFLE criteria) is as high as 29% after F/B-EVAR.38 At 3-year follow-up, a 14% decrease in estimated glomerular filtration rates and renal volume were observed in these patients. The cause and correlation of the change in renal volume is not clear. These findings, however, are not unique to F/B-EVAR, as higher rates of acute kidney injury are observed after open surgery with similar rates of long-term renal decline39 and are observed after open surgery and EVAR for conventional AAAs.40

**THE SUCCESS OF THE BRANCHES IS THE KEYSTONE**

Certainly, one of the contributors to long-term renal function success is continued branch patency. The difficulty with F/B-EVAR is incorporating the visceral and renal vessels into the repair. Once this is achieved (with a high rate of technical success), the key to long-term success is maintaining branch patency along with aneurysm exclusion. Midterm branch patency rates have recently been reported by most large series and range from 93% to 98% (3–5 years) overall.9,12,13,16,17 There are a number of factors that may affect long-term branch patency, including the implantation angles of the visceral vessels onto the aorta, the diameter of the target vessel, the length and curvature of the branch component, and the stent graft utilized for bridging.41-44 In addition, the ideal postoperative pharmacologic adjuncts are not currently known.

As with most endovascular procedures, F/B-EVAR requires reintervention to maintain graft branch patency and ameliorate endoleak development. This requires an active surveillance program to identify branches at risk for...
failure. At the Cleveland Clinic, we routinely follow our patients on an annual basis with contrast-enhanced imaging (provided that renal function will allow us to do so) combined with duplex ultrasonography. Care must be taken, however, in interpreting the results of the imaging because revised duplex criteria is necessary when assessing for stenosis after F/B-EVAR.55,46

The largest series evaluating the durability of branches after F/B-EVAR is from Mastracci et al.47 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 reintervention 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 of lifelong surveillance. As aneurysms become more complex (ie, extensive TAAA), the rates of reintervention appear to increase over time.9,10 Although no branch patency advantage has been clearly identified based on whether fenestrations or directional branches are used overall, there is potentially a slight advantage for the use of fenestrations for the renal arteries. The trade off is the potentially higher rates of reintervention for endoleak development in the reinforced fenestration. These issues may be overcome with the development of purpose-built devices that are targeted for use in reinforced fenestrations, or devices that can handle the inherent tortuosity that occurs in using a caudally directed branch when incorporating an upward pointing renal artery.

BE AWARE (BEWARE) OF DISEASE PROGRESSION

Complex aortic endografting is an investment made by the physician and the patient. Once the endograft is placed, there is a need for continued follow-up. We stress the importance of this with standard EVAR, and a variety of follow-up paradigms have been recommended. Despite evaluations of the best approach, failure rates of endografting are extraordinarily high. This is likely related to either poor judgment within whom to place an endograft, or failure to recognize the potential for disease progression. This becomes equally important in patients who undergo F/B-EVAR. In addition to the follow-up associated with ensuring branch patency and lack of branch-associated endoleaks (as previously discussed), there is a continued need to survey the aortic components, as well as the untreated portions of the aorta. One of the most beneficial aspects of all of the endovascular applications is that it has sparked a renewed interest in evaluating the biology and natural history of aortic disease. Devices fail, and one of the reasons that they fail is due to disease progression. The best designed stent graft in the world will not survive the continued dilation of the aorta it relies upon for its foundation.

F/B-EVAR is not immune to this. Despite the increased ability to land the stent graft in nearly any segment of the aorta, nearly 2% to 3% of F/B-EVAR will develop a proximal type I endoleak, given enough time,50 due to disease progression. Some of our early failures are due to our lack of appreciation for disease progression. This is highlighted by the fact that the majority of our failures, due to disease progression, occurred in patients treated early in our experience. 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 have recognized several aspects relevant to the F/B-EVAR. Shorter necks are not better, and now the attempt is made to achieve a 2- to 3-cm landing zone, balancing the risks of developing other complications such as SCI. It appears that this risk, however, may not become relevant in most patients until we cover nearly 4 to 5 cm above the level of the celiac artery.10 In addition, the failure of an endograft becomes more difficult to treat. If an F/B-EVAR or an open AAA repair had been performed as the primary procedure, the patient would have lower mortality and morbidity rates than if an F/B-EVAR or explantation of the EVAR were performed once it failed.48,49 The complexity of the repair, and the associated morbidity and mortality, are expected to increase even more significantly when we begin repairing failed complex endograft repairs, which is beginning to happen, as there is a more widespread application of the parallel grafting technique and the commercialization of FEVAR in the United States. Given this, most surgeons with access to devices that can incorporate more branches choose to increase the extent of coverage and make the treatment of later disease progression easier.10

It may be, however, that we do not need to apply this approach to everyone who requires an F/B-EVAR. There is some increase in morbidity once all four visceral vessels are incorporated into a repair.10 Given the increase in morbidity, it demands that we better evaluate our outcomes to identify patients at risk for disease progression that may occur in patients with a familial or genetic predisposition to aneurysm formation.50 Certainly, a young patient with a longer life expectancy will have a higher chance of late failure, and the initial repair should be planned accordingly.51 In older individuals, complex endovascular repair may not need to be as aggressive, but we should not underestimate their life expectancy and appropriately limit the repair. These patients tend to fail earlier when shorter landing zones, or “unhealthy” aorta, are used, often leaving them potentially unreconstructable at that point.
PROTECT YOURSELF (AND THOSE AROUND YOU)!

Increasing complexity of aortic endografting correlates with longer procedure times and the corresponding radiation exposure. Surgeons performing these procedures must be cognizant of the risks of radiation exposure and be fluent in the methods that can be used to decrease exposure. The deterministic effects are predictable, dose-related, and easier to manage. The stochastic effects, however, are the cumulative long-term exposure that causes these untoward effects—one of the most feared being the development of cancer. Surgeons must understand these mechanisms and the methods with which to reduce exposure risk in order to protect the patient, as well as the treatment team.

In an early evaluation of the radiation exposure during F/B-EVAR, Panuccio et al calculated that the effective radiation dose of an endovascular TAAA repair was equivalent to preoperative CT scans. Using correct protective measures, they estimated that an operator could potentially perform nearly 300 procedures per year before reaching the recommended maximum operator dose. Certainly, intraoperative maneuvers can be performed to limit radiation exposure, including minimizing the use of digital subtraction acquisitions, avoiding lateral angulation, and being diligent about the use of shielding during fluoroscopy.

There are a number of adjuncts that have more recently become available that can assist in limiting the amount of fluoroscopy time necessary to perform cases. One such adjunct is the use of image fusion to help guide the intervention. The use of this technology has been associated with a reduction in procedure times and the reduction of radiation to patients and operator exposure during both standard EVAR and complex aneurysm repair. If you are not familiar with the mechanisms of fluoroscopy, the risk of radiation exposure, and the methods you can employ to reduce everyone’s exposure, take the time to learn. It is a small effort that can save lives—and not just the patient’s.

ENDOVASCULAR SURGERY IS NOT ALWAYS THE BEST ANSWER

Not everyone is a candidate for F/B-EVAR, and not every patient requires an operation. One of the seemingly pressing issues related to F/B-EVAR is the delay until custom-made grafts are available. However, an evaluation of off-the-shelf versions has demonstrated the potential lack of widespread applicability of these grafts to patients. Up to 70% of patients who are already candidates for FEVAR may be candidates for an off-the-shelf device, although the number of eligible patients decreases considerably when “all-comers” are evaluated. Even with customization, not all patients are candidates. In the Windows trial, up to 40% of patients were not candidates for F/B-EVAR. So what do we offer these patients? Certainly, other complex endovascular alternatives such as parallel endografting may provide an option for some percentage, but not all. In some instances, open surgery may still be the answer! In addition, whether this is a practical long-term answer to patients with connective tissue disorders is unknown. It may be that, with our current knowledge of this technology, the best approaches are limited applications of open surgery combined with endovascular bridging.

Furthermore, while we can attempt to apply endovascular technology to these high-risk patients, what needs much more careful attention is the question of whether we should. Evaluation of the Cleveland Clinic experience demonstrates that in these high-risk patients, 40% die by 3 years, despite exclusion of their aneurysms. The majority of these deaths are not aortic- or surgery-related. Clearly, there is a subset of these patients that benefited greatly from exclusion of their aneurysm, but what about the set that died from other causes? What was the risk of them dying from their aneurysm during that period of time, and were they really provided with an improved, extended life due to this surgery? In addition to the question of quality and quantity of life improvement, what is the cost benefit from a societal perspective? In-depth analyses of these issues is paramount and pending.

TEAM APPROACH

The widespread application of this technology has been somewhat limited by the availability of the tools. Although commercially available in many countries, most of the advanced technology is only available through physician-sponsored investigational device exemption trials within the United States. As availability becomes more global, it is unlikely that the application of F/B-EVAR, particularly for more complex TAAAs, will occur at institutions that do not currently support, or have the ability to develop, an aortic program. These programs are labor intensive and involve a team of caregivers, including physicians (surgeons, intensivists, radiologists, to name a few), nurses, and radiologic technologists, at a minimum. It is easier to approach these patients with the ability to maintain a stock of ancillary devices. Outcomes are improved with the use of specialized imaging equipment, which is frequently a capital investment, and in many institutions, the cost to run one of these programs may be prohibitive. Much like open aortic surgery, volume will affect outcomes. It has been demonstrated that centers performing high volumes of open aortic surgery and standard EVAR have teams in place that improve outcomes. Similar to open TAAA repair, it is likely that given the need for a dedicated team to care for these patients, much of the work will be relegated to centers that have developed
such a team and have invested in an aortic center, which will improve patient outcomes.

CONCLUSION

This is an exciting time in the treatment of aortic disease, and in particular, the treatment of complex aortic disease. A large number of advances have been made during the past decade, and a number of problems have been overcome. This, however, brings more challenges for study, allowing the opportunity for continuous improvement in device, patient selection, and procedure performance.