Surgeon-Modified Fenestrated and Branched Stent Grafts

An alternative method for treating complex aortic emergencies in patients who are unfit for surgery.

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Open surgery for complex aneurysms of the abdominal aorta (AAAs), including thoracoabdominal aortic aneurysms (TAAAs), has greatly developed during the past decades to provide patients adequate management with good functional results and reduced perioperative morbidity and mortality.[1] However, despite many advances in preoperative evaluation and perioperative care of patients with TAAAs, open surgical repair of TAAAs remains a formidable challenge for the vascular surgeon.

In a recent meta-analysis from Emory University of 7,833 patients who underwent open surgical repair of TAAAs between 2000 and 2010, the overall risk of death within 30 days was 7%, and in-hospital mortality was 10%.[2] The 30-day mortality rate was 5% for elective cases, with significant associated morbidity, including a 7.5% incidence of spinal cord ischemia, a 19% rate of renal failure, and a 36% rate of pulmonary dysfunction. The 30-day mortality rate for open repair of ruptured TAAAs has been reported to be as high as 40%, with an average of 19% in this meta-analysis.

These data clearly demonstrate the high morbidity and mortality associated with the open procedure, particularly in the urgent or emergent setting, even in patients who are considered to be at low or moderate risk for surgery. As a consequence, many high-risk patients with significant comorbidities will be denied elective open surgery. Nevertheless, even these high-risk patients may present acutely with symptomatic or ruptured TAAAs or complex AAAs that require urgent repair.

Endovascular aneurysm repair (EVAR) has been shown to be effective in treating uncomplicated infrarenal and thoracic aneurysms in both the elective[3,4] and urgent setting,[5,6] yet there is limited experience with this technology in complex conditions.

Fenestrated and branched endografts have been developed as a minimally invasive, totally endovascular alternative for the treatment of complex aortic aneurysms in high-risk patients. However, construction of these devices requires that they be custom made to fit the specific anatomical requirements of each patient. As a result, it can take as long as 6 to 12 weeks to manufacture these devices. Restricted access to investigational devices and delays for device customization limit treatment with these endografts to a small group of patients with relatively stable aneurysms. Patients who present emergently with ruptured or symptomatic TAAAs cannot be treated with the current fenestrated/branched endograft technology because of the degree of customization required to treat each individual patient.

The question often arises, "How can we treat patients who are unfit for open repair or aortic debranching procedures but who present with symptomatic or ruptured complex aortic aneurysms and cannot wait for a custom fenestrated/branched endograft to be created?" In these circumstances, we have modified commercially available aortic endovascular stent grafts with reinforced fenestrations, as well as cuffed branches. In our opinion, surgeon-modified endografts with branches for the visceral vessels represent the best option for high-risk patients who are unfit for open surgery and require urgent treatment.

EMERGENCY TREATMENT OPTIONS

Patients who are at high risk for open surgery and present with complex aortic aneurysms requiring urgent or emergent treatment could be considered candidates for the following treatment options.

Parallel Graft Endovascular Repair (Snorkel/Chimney Technique)

As endovascular techniques have become a routine in the daily practice of vascular surgeons and interventionists, many are confident using these techniques as a quick bailout procedure when they believe that the life of their patient may be at risk. Recently, several reports have been published describing the repair of TAAAs or juxtarenal aneurysms with visceral vessel revascularization in patients with acute pathologies (mostly contained aortic ruptures).[7-10] Most of the authors concluded that this treatment option is technically feasible and useful in settings requiring emergent repair but, unfortunately, do not report any mid- or long-term results.

A report from Sweden of 25 patients undergoing the parallel graft technique for aneurysmal disease of the visceral aorta and aortic arch demonstrated feasibility of the technique.[11] However, the authors emphasize the importance of distinguishing the difference in complexity of repair between juxtarenal aneurysms and TAAAs. They also acknowledge a lack of mid- and long-term follow-up and the issue of unknown durability with these repairs. The issue of endoleak with these parallel grafts, as well as the durability of the branches, remains unresolved, and their mid- and long-term outcomes are unknown.

Conventional EVAR for Short-Neck AAAs

Short-neck AAAs and juxtarenal aneurysms represent the simplest form of complex aortic aneurysms. The feasibility of EVAR in these cases has been described along with worse long-term outcomes in terms of endoleaks and reintervention rates when compared with normal-neck AAAs.[12] On the other hand, Verhoeven et al[13] reviewed their series of 100 fenestrated grafts for short-neck and juxtarenal aneurysms and were able to demonstrate acceptable long-term outcomes. The role of standard EVAR in patients with short-neck or juxtarenal aneurysms should be approached with caution in an era of good results with open repair for low- to medium-risk patients[14] and excellent results for total endovascular repair with fenestrated grafts.[13]

Customized Fenestrated Endografts

While the custom-made fenestrated graft by Cook Medical (Bloomington, IN) awaits US Food and Drug Administration approval in the United States, substantial experience with treatment of elective cases in high-risk patients has been acquired worldwide with excellent results.[15-17] Custom-made fenestrated and branched grafts are patient-tailored, and an interval of 4 to 12 weeks is required between measurement and delivery of the graft from the producing company. This is acceptable in high-risk patients who do not have the alternative of open surgery but cannot be implemented in patients requiring urgent repair.[18]

The concept of a standardized, off-the-shelf, multibranched stent graft is exciting. However, use of a standardized graft could compromise the principle of perfect alignment to the target vessels, with unknown results in long-term branch patency. The routine use of plugs to occlude unused branches could potentially lead to a higher risk of endoleaks, and the efficacy of these grafts in the emergent setting is unknown.

Surgeon-Modified Fenestrated and Branched Stent Grafts

The value of fenestrated and branched stent grafts in the management of high-risk patients with TAAA and who are unfit for open surgery is indisputable. Lower perioperative morbidity and mortality rates with good mid- and long-term results have been demonstrated.[15,16,19] Both standardized and surgeon-modified grafts offer patients similar results in terms of technical success.[20] Nevertheless, until industry develops a multiple standardized, off-the-shelf, multibranched stent graft that can be used in urgent and emergent situations, surgeon-modified grafts remain the best option for these high-risk patients in the emergent setting.

The technique we use has been previously published.[21,22] Modification of a stent graft to produce one to four fenestrations, constrain the device, and resheath it varies in our experience from 32 to 140 minutes, with a mean device modification time of 90 minutes. This represents the major drawback of this technique for managing aortic emergencies in hemodynamically unstable patients in that a window of 1 to 2 hours has to be available to enable safe patient management. Nevertheless, considering that the preparation of the graft can begin independently of the procedure (as soon as the computed tomographic [CT] scan is available) and the measurements are made, this time often coincides with the preparation of the patient from the anesthesiology team and bilateral femoral artery exposure and access. In cases of high-risk contained ruptures, an aortic occlusion balloon is ready for deployment while waiting for completion of the modified graft.

The use of surgeon-modified grafts is an alternative that is more complicated than use of the parallel graft technique, but it is validated with good long-term results. The experience required to modify these grafts will likely be an obsta-

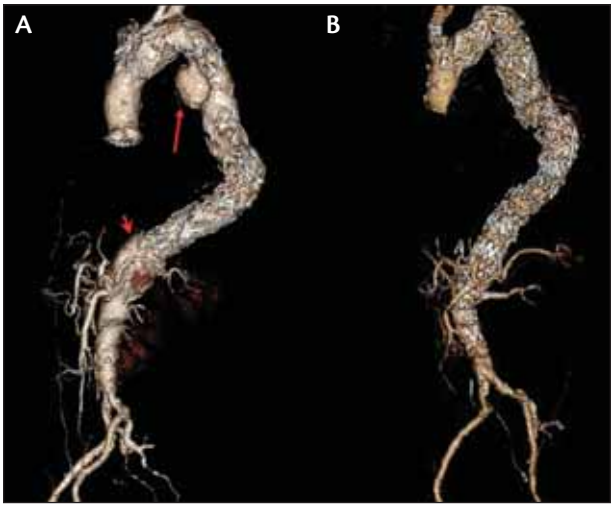

Figure 1. Aneurysm of the visceral aorta, prior stent graft in the thoracic aorta with type III endoleak at the junction of the thoracic stent grafts (long arrow), and distal type I endoleak (short arrow) (A). CT angiogram (CTA) at 6-month follow-up showing no endoleaks and patency of all visceral vessels (B).

cle in achieving widespread application of this technique in vascular practice, but with the significant advance of endovascular experience during the past decade, this is an option that best serves the short-term goal of rescuing the patient, as well as the long-term goal of providing durable exclusion of the aneurysm.

From our experience with endovascular treatment of complex aortic aneurysms in the emergent setting using surgeon-modified fenestrated and branched endografts, we present the following three case reports.

CASE 1: SYMPTOMATIC, ENLARGING TAAA

A 67-year-old man, who had previously undergone endovascular repair of a proximal thoracic aortic aneurysm with placement of thoracic endografts in his descending thoracic aorta and distal aortic arch and concomitant carotid-subclavian artery bypass, presented to the emergency department with acute back and flank pain. The patient had no history of disease of the spinal column or kidneys but had known coronary artery disease with congestive heart failure and an ejection fraction of 20%. The total Society for Vascular Surgery (SVS) risk score was significantly elevated at 18, and the American Society of Anesthesiologists (ASA) classification was IV. On physical examination, the patient had left flank tenderness. A CT scan showed a type III TAAA involving the visceral aorta that had grown to 8.7 cm in diameter from 4.3 cm, as shown by a CT scan obtained 12 months earlier (Figure 1A), as well as a type III and distal type I endoleak from the previously placed thoracic endograft components.

Based on the patient's acute symptomatic presentation, pain on physical examination, and substantial aneurysm growth, an urgent repair was planned. A 34- X 30- X 157-mm thoracic Zenith TX2 stent graft (Cook Medical) was modified to include fenestrations for the superior mesenteric artery (SMA) and both renal arteries. The celiac axis was chronically occluded, as shown by CT scan. Bilateral femoral artery exposure was achieved, and fenestrations and branches to both renal arteries and the SMA were successfully performed by placing iCast stent grafts (Atrium Medical Corporation, Hudson, NH) through the fenestrations and into the target vessels. The endoleak of the thoracic stent graft was sealed with placement of an additional

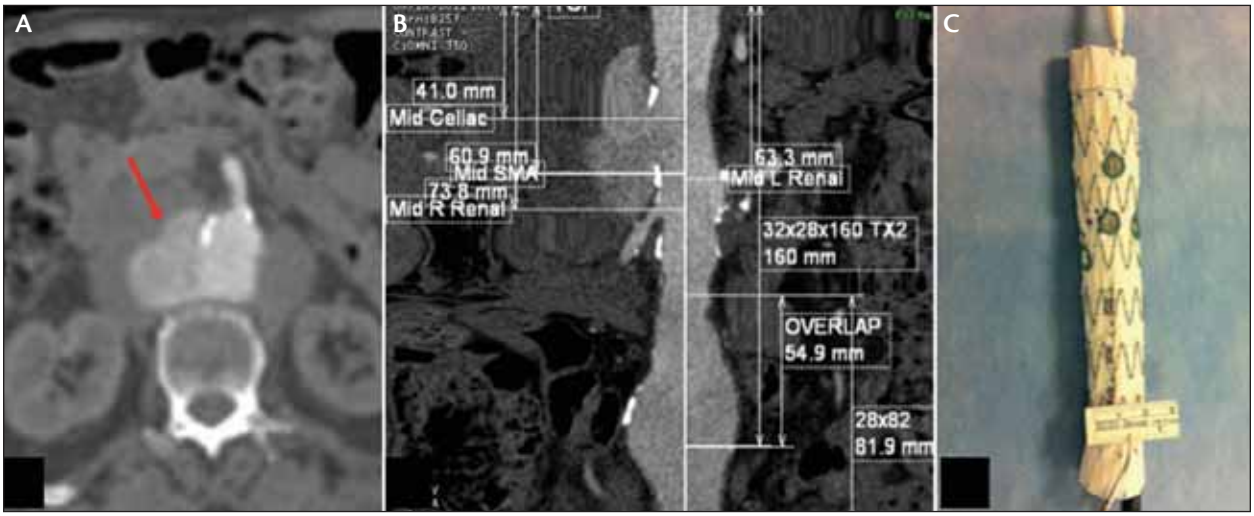

Figure 2. Contained rupture of a type IV TAAA (arrow) (A). CT reconstruction and center-line measurement showed the rupture and the preoperative measurements (B). Surgeon-modified Zenith TX2 stent graft with four reinforced fenestrations for the visceral vessels (C).

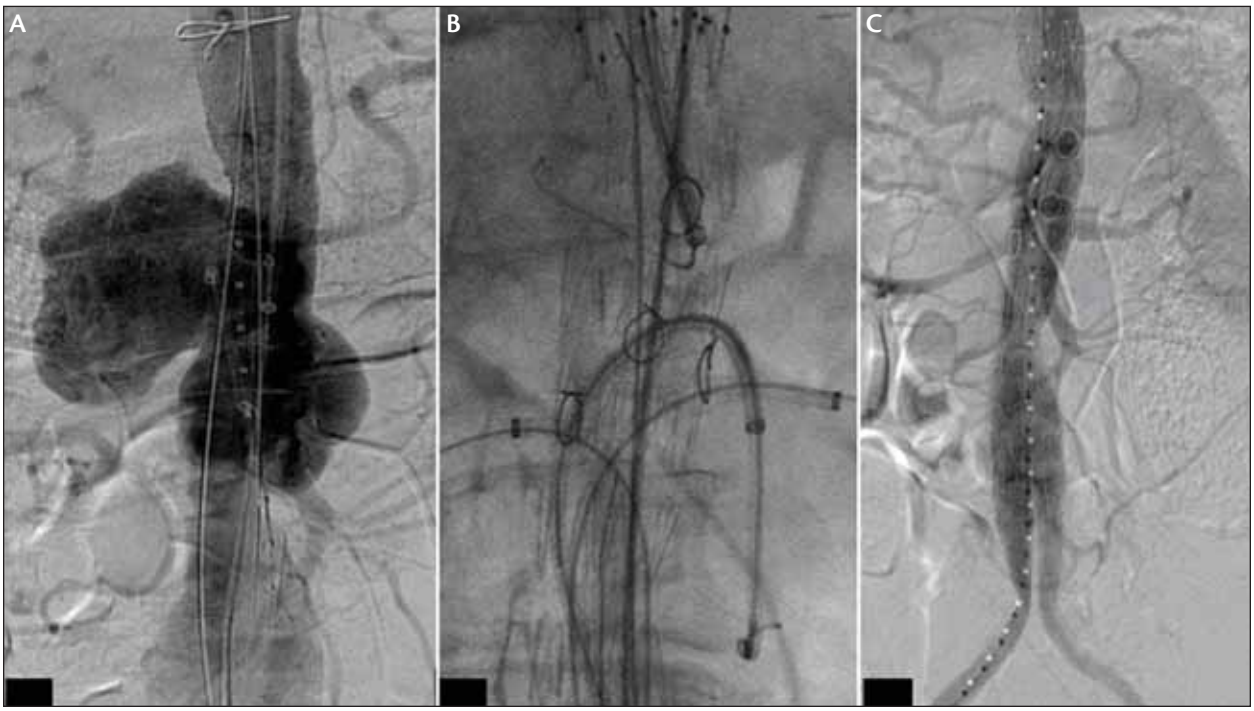

Figure 3. Angiogram showing rupture of the thoracoabdominal aorta (A). Intraoperative fluoroscopy with all visceral vessels cannulated before complete deployment of the endograft (B). Completion angiogram after successful exclusion of the aneurysm with patent visceral vessels and lack of endoleak (C).

thoracic Zenith TX2 stent graft.

Final angiography showed exclusion of the TAAA, with patency of all three branch stents and no endoleak. The patient did well postoperatively and was discharged from the hospital on postoperative day 5. He was seen for follow-up at 6 months. The patient had resumed his normal lifestyle, his groin incisions were well healed, and CT scan and duplex ultrasound showed shrinkage of the aneurysm sac to 7 cm, patency of all branch stents, and no endoleak with preserved device integrity (Figure 1B).

CASE 2: RUPTURED TYPE IV TAAA

An 80-year-old man was referred to our institution for acute management of a 7.6-cm-diameter type IV TAAA (Figure 2A). The patient was at high risk for open repair because he was classified as an ASA III patient with an SVS risk score of 16, and 2 months earlier, he underwent an attempt at open repair of his TAAA and suffered a cardiac arrest on the operating table upon induction of general anesthesia. He presented to an outside facility with acute onset of chest and abdominal pain. A CT scan showed a contained rupture of his 7.6-cm type IV TAAA. He was transferred to our institution and taken emergently to the operating room.

Following center line of flow analysis and measurement of the CT scan (Figure 2B) (and while undergoing fluid resuscitation, venous and arterial line placement, and bilateral femoral artery and left brachial artery exposure), a Zenith TX2 was modified on the back table to create four fenestrations for the right and left renal arteries, SMA, and the celiac artery (Figure 2C). Modification took approximately 60 minutes, and modification completion coincided with anesthesia induction and exposure of the femoral and left brachial arteries. After successful implantation of the modified fenestrated graft, with placement of iCast branched stents in all

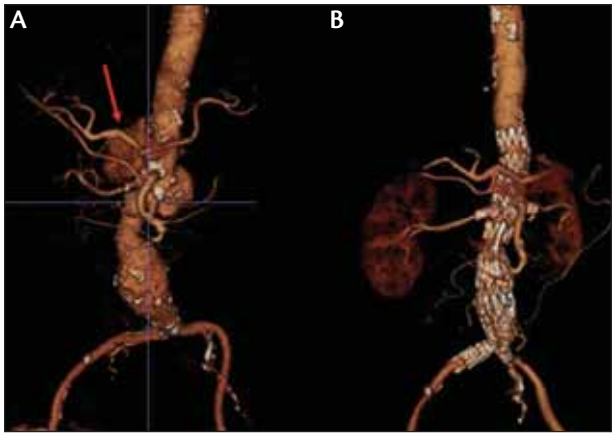

Figure 4. Preoperative CTA showing rupture of the visceral aorta (arrow) (A). CTA at 1-month follow-up showing no endoleaks and good perfusion of all visceral vessels (B).

four visceral branches, the repair was extended to both common iliac arteries using a standard Zenith bifurcated device (Cook Medical), which was placed within the modified TX2 graft after removal of the Zenith suprarenal stent (Figure 3A and 3B).

Final angiography showed no endoleaks and patent visceral vessels (Figure 3C). The patient had an uneventful postoperative course, with a 2-day stay in the intensive care unit and discharge home on the fourth postoperative day. A CT scan that was performed at 1-month follow-up showed patency of the aortic grafts and all four visceral vessel branch stents without endoleak (Figure 4).

CASE 3: RAPIDLY ENLARGING, SYMPTOMATIC PARARENAL AORTIC ANEURYSM

A 57-year-old man presented to our institution with back pain. The patient was in poor general health with congestive heart failure and ischemic cardiomyopathy resulting in an ejection fraction of 15% to 20%. In addition, he underwent a cardiac stress test in the recent past that was notable for myocardial ischemia. His SVS cardiac risk score was 12, and his SVS total score was 27. He had a known aortic aneurysm that measured 4.6 cm on a CT scan obtained 6 months earlier. Upon presentation at our institution, he underwent an urgent CT scan, which showed rapid enlargement of his aortic aneurysm to a maximal diameter of 5.8 cm and proximal extension of the aneurysm to involve the right renal artery (Figure 5A). The patient was considered to be unfit for open repair and, because of the rapid growth and new-onset back pain, emergent endovascular treatment was performed with a surgeon-modified fenestrated and branched endograft using an Endurant AAA stent graft (Medtronic, Inc., Minneapolis, MN) with a single reinforced fenestration to the right renal artery through which an iCast stent graft was placed (Figure 5B and 5C).

The patient remained hemodynamically stable postoperatively and was transferred from the intensive care unit to the ward the day after the procedure. The patient was discharged home 3 days postoperatively and returned at 1 month and then at 6 months, with CT scans showing no endoleaks, a patent right renal stent, and continued exclusion of the aneurysm (Figure 5D).

CONCLUSION

Surgeon-modified fenestrated and branched devices may play an important role in the treatment of selected

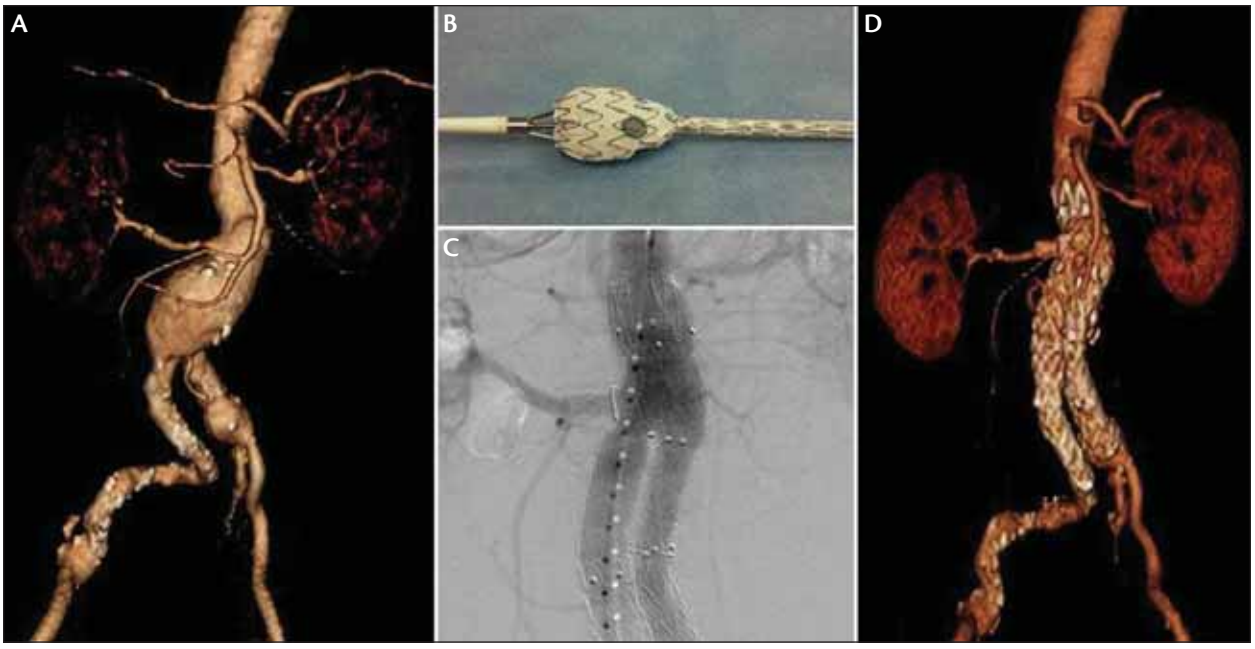

Figure 5. Preoperative CTA showing a 5.8-cm pararenal aortic aneurysm with involvement of the right renal artery (A). Surgeon-modified stent graft with a fenestration to the right renal artery (B). Final intraoperative angiogram (C) and postoperative CTA at 6-month follow-up showing no endoleaks and good perfusion of the renal artery (D).

high-risk patients with symptomatic or ruptured aneurysms that cannot be repaired with open surgery because of comorbidities and cannot wait the time required for device customization. Until the commercially made fenestrated and branched devices become more widely disseminated and/or an off-the-shelf device is created that does not require a prolonged waiting period, this may be the best option we have to treat these patients with symptomatic or ruptured complex aneurysms and who are at excessively high surgical risk. ■

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