Endovascular Repair of Complex Aortic Aneurysms

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ABSTRACT: **Background:** Surgery for complex aortic aneurysms (thoracoabdominal, juxtarenal and pseudoaneurysms) is associated with a high morbidity and mortality rate. Branched and fenestrated stent grafts constitute a new technology intended as an alternative treatment for this disease.

Objectives: To describe a single-center experience with fenestrated and branched endografts for the treatment of complex aortic aneurysms.

Methods: We reviewed all cases of complex aortic aneurysms treated with branched or fenestrated devices in our center. Data collected included device specifics, perioperative morbidity and mortality, re-intervention rates and mid-term results.

Results: Between 2007 and 2012 nine patients were treated with branched and fenestrated stent grafts. Mean age was 73 years. Mean aneurysm size was 63 mm. Perioperative mortality was 22% (2/9). During the follow-up, re-interventions were required in 3 patients (33%). Of 34 visceral artery branches 33 remained patent, resulting in a patency rate of 97%. Sac expansion was seen in a single patient due to a large endoleak. No late aneurysm-related deaths occurred.

Conclusions: Branched and fenestrated stent grafts are feasible and relatively safe alternatives for the treatment of complex aortic aneurysms involving the visceral segment. Further research is needed to determine the long-term durability of this new technology.

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KEY WORDS: fenestrated stent graft, branched stent graft, complex aortic aneurysm

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Large diameter thoracoabdominal aortic aneurysms are at significant risk for rupture and death. Prospectively gathered natural history data for patients with untreated TAAA suggest an overall rupture rate of 26% [1,2]. The conventional approach to treating these aneurysms requires large surgical exposures and interruption of flow to vital organs during the operation. These procedures are associated with high morbidity and mortality, even in high volume experienced centers. This is attributed to several factors: the complex nature of the surgical repair, the extent of the aortic disease, the patient's comorbidities, the experience of the performing surgeon, and the quality of the perioperative care. Surgical morbidity, including cardiac and respiratory complications, renal failure, and bowel and spinal cord ischemia are not uncommon, and 30 day mortality has been reported to reach 20% [3].

Endovascular repair of aortic aneurysmal disease has revolutionized the management of aortic aneurysms over the past two decades. This is generally true regarding the treatment of infrarenal abdominal aortic aneurysms and descending thoracic aortic aneurysms. The short and mid-term results of these repairs compare favorably with those of open repair. The 30 day mortality rate following endovascular repair of abdominal aortic aneurysms in the EVAR-1 trial was 1.7% compared to 4.7% following conventional open repair. The DREAM trial was a randomized controlled study that compared perioperative morbidity and mortality rates following EVAR and open AAA repair. Combined operative mortality and severe complication rates were 4.7% in the EVAR arm vs. 9.8% in the open-repair arm [4,5].

EVAR offers several benefits. It does not require large surgical exposure or cross-clamping of the aorta, thus avoiding the associated potentially hazardous hemodynamic consequences. No surgical vascular anastomoses are undertaken. The repair can be performed under regional or local anesthesia and the hospital stay is not long. It is estimated, however, that up to 50% of all patients with AAA are not candidates for conventional endovascular repair [6]. This is due to an unfavorable aortic and iliac artery anatomy that precludes endovascular surgery with standard devices. Patients with juxtarenal, pararenal or thoracoabdominal aortic aneurysms are not candidates for standard EVAR using the current commercially available devices.

FENESTRATED AND BRANCHED ENDOGRAFTS

The development of fenestrated and branched endografts has widened the therapeutic options for complex aortic aneurysms. These stent grafts are modifications of existing endografts that

TAAA = thoracoabdominal aortic aneurysms

EVAR = endovascular aneurysm repair
AAA = abdominal aortic aneurysms

have been developed for the treatment of AAA. Side branches are added to the main tubular component providing critical end-organ blood supply to the abdominal viscera (kidneys, bowel, liver) during and after the procedure. This modification allows covering of the visceral segment of the aorta with the main body, thereby providing a good seal zone proximally and distally to the aneurysm. The flow to the visceral segment is uninterrupted during the procedure and thus avoids harmful ischemic time.

Two types of endografts have been developed for the treatment of complex aortic aneurysms:

- **Fenestrated stent grafts:** circular fenestrations or scalloped fenestrations are created in the main module, accurately positioned across from the orifice of the relevant artery. After cannulation of the visceral artery through the fenestration, a balloon-expandable stent graft is placed, bridging between the visceral artery and the main module. The segment of the balloon-expandable stent graft located at the fenestration is flared in order to create an adequate seal. Scalloped fenestrations, as opposed to circular fenestrations, are typically not stented. Fenestrated stent grafts are used to treat aneurysms with visceral vessels that abut, but are not involved with, the aneurysmal disease, such as juxtarenal AAA and pseudoaneurysms [Figure 1].

- **Side branches:** these consist of grafts sewn to the aortic prosthesis in the direction of the relevant visceral ostia [Figure 2]. The orifices of the visceral arteries (renal arteries, superior mesenteric artery and/or celiac artery) are selectively cannulated through the side branches. The gap between the side branches and the target vessels is then bridged with self-expandable stent grafts. Branched endografts are largely used in cases where the entire visceral segment is involved in the aneurysm, such as in TAAA [Figure 3].

The first case of a fenestrated aortic graft was described in 1996 by Park and colleagues [7] who implanted fenestrated stent devices to treat two patients with infrarenal AAA. Since then several series using branched and fenestrated technology have been published, with encouraging results of a relatively low acute mortality rate and lack of short-term branch vessel loss [8,9].

We report a single-center experience with fenestrated/branched endografts for the treatment of complex aortic aneurysmal disease. The aim of the study was to evaluate the feasibility of the procedure and report the early and mid-term outcome.

PATIENTS AND METHODS

We reviewed a prospectively maintained database of all patients who underwent endovascular repair of complex aortic aneurysms with fenestrated or branched endografts at our institution during the period 2007–2012. The data collected included patient demographics, anatomic morphology of the aneurysm, anesthetic specifics, stent graft configuration, and perioperative morbidity and mortality. Follow-up data included evidence of sac expansion or endoleaks, preservation of target vessels, need for re-intervention, and survival rates.

Figure 1. Three-dimensional reconstructions show a juxtarenal AAA before **[A]** and after **[B]** treatment with a fenestrated stent graft with branches for the celiac trunk, superior mesenteric artery and both renal arteries

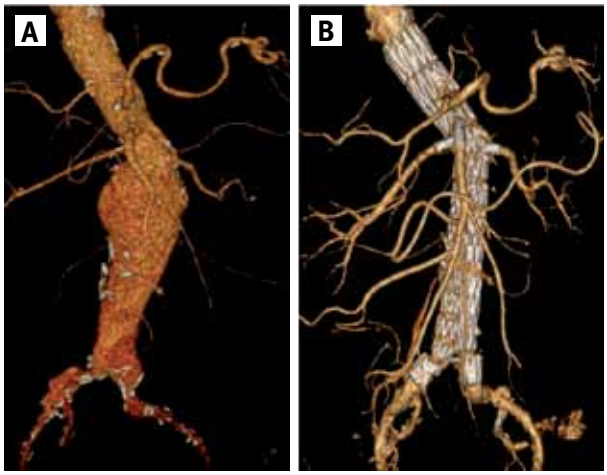
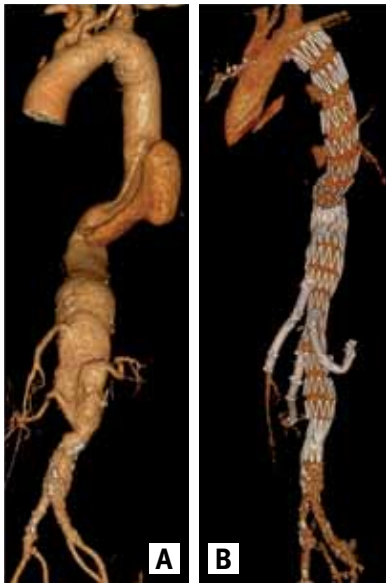


Figure 2. Branched endograft with multiple side branches attached to main aortic module

Figure 3. Three-dimensional reconstructions of a thoracoabdominal aortic aneurysm before **[A]** and after **[B]** treatment with a branched endograft with branches in the superior mesenteric artery and both renal arteries



DEVICE DESIGN

Currently these devices are custom made and are not manufactured commercially. All our branched/fenestrated stent graft designs are based on a conventional Zenith platform (Zenith, COOK Inc., Bloomington, IN, USA) used for AAA and are customized to fit specific patient anatomy. The time needed to prepare such a device is 6–8 weeks and the cost ranges from $20,000 to $30,000.

PREOPERATIVE PLANNING

All patients underwent computed tomography angiography center-line length measurements with three-dimensional reconstructions and precise positioning of the target vessel origins relative to the graft fenestrations or branches. Additional aortic modules were planned based on the length of aorta that had to be covered in order to obtain a sufficient seal.

SURGICAL PROCEDURE

All procedures were performed under general anesthesia. Spinal drainage was used for spinal cord protection in all patients with TAAA and in the setting of prior aortic surgery. The drain was removed 72 hours after the procedure.

Similar to standard EVAR procedures, these procedures were performed under fluoroscopy in a hybrid operating suite. Bilateral femoral cut-downs were performed in all cases. The left brachial artery was exposed and accessed in those cases where branched endografts were used. Following delivery and positioning of the main body in the aorta, the main body was partially deployed. The target visceral vessels were cannulated through the dedicated fenestrations/branches with wires and catheters. The main body was then fully deployed and the gaps between the main aortic module and the target vessels were bridged with covered stents, as described in the previous section. Care was taken to minimize contrast in order to avoid nephrotoxicity. A completion angiogram was performed to confirm adequate seal of the aneurysm and patency of the side branches. Patients spent the first postoperative 24 hours in an intensive care unit setting and were transferred to a step-down unit the next day.

FOLLOW-UP PROTOCOL

Following the surgery patients were monitored every 3 months in the first year and every 6 months thereafter, with physical examination and abdominal ultrasound for aneurysm sac expansion and the presence of endoleaks. Routine CTA was performed 3 months post-surgery and every 6 months thereafter for the first 2 years. Urgent CTA was performed in cases where an endoleak or evidence of sac expansion was noticed on ultrasound or if the loss of a target vessel was suspected. Re-interventions were performed in cases where sac enlargement > 0.5 cm in diameter was noted during follow-up or if a gross abnormality was seen on the CTA such as large endoleaks (type 1 or 3), component separation, or stenosis in a branch.

CTA = computed tomography angiography

RESULTS

During the period 2007–2012 we performed endovascular treatment of complex aortic aneurysms in nine patients. All patients were evaluated preoperatively by the surgical and anesthesiology team and were deemed high risk for open repair. This was determined by a variety of parameters, including the existence of debilitating comorbidities, a high ASA score, the risk of reoperative surgery in scarred surgical fields, and lack of acceptable surgical options.

The patients' mean age was 73 years (range 62–82 years). Mean aneurysm size was 63 mm (range 52–78 mm). The patients' demographics are presented in Table 1. Indications for treatment included TAAA (n=5), pseudoaneurysms at prior anastamotic sites involving the visceral segment (n=2), and juxtarenal AAA abutting the renal arteries (n=2).

Table 1. Patient demographics and operative data

	No. (%)	Range
Age (yr)	73	62–82
Gender		
Male	8	
Female	1	
Comorbidities		
Coronary artery disease	6 (66)	
Congestive heart failure	2 (22)	
Hypertension	8 (89)	
Diabetes mellitus	1 (11)	
Hypercholesterolemia	4 (44)	
Chronic obstructive pulmonary disease	4 (44)	
Active smoker	5 (55)	
Past smoker	2 (22)	
Renal insufficiency	5 (55)	
Baseline creatinine (mg/dl)	1.2	1–1.8
ASA (mean)	3.5	
Prior aortic surgery	5	
Aneurysm information		
Diameter (mm)	63	52–78
Juxtarenal aneurysm	2	
Pseudoaneurysm	2	
Thoracoabdominal aneurysm	5	
Operative data		
Spinal drain	5	
Contrast (mean) (ml)	618	150–2500
Mean operative time (hr)	9	4–13
Mean blood loss (ml)	1732	200–2800
Device data		
Fenestrated endografts	4	
Average no. of fenestrations per case	3	
Branched endografts	5	
Average no. of branches per case	4	
Mean no. of aortic modules	2	
Mean hospital stay (days)	19	9–37

ASA = American Society of Anesthesiologists

Technical success, defined as the ability to deploy the main body and successfully cannulate and stent all the target visceral vessels, was achieved in 8 of the 9 patients (88%). One renal artery was successfully cannulated and stented. However, it occluded during the course of the procedure and could not be recanalized.

A total of 34 target vessels were treated. The average number of fenestrations and branches in each case was 3.7. Completion angiogram showed adequate seal of the aneurysm in eight of the nine cases. In one case a small endoleak was seen from around the attachment site of the superior mesenteric artery stent, presumably a type 2 endoleak. The mean operative time was 9 hours (range 4–13 hours) and mean intraoperative blood loss was 1732 ml (range 200–2800 ml).

PERIOPERATIVE MORTALITY

Two perioperative deaths occurred. One intraoperative death occurred due to a ruptured iliac artery after successfully implanting the stent graft, most probably the result of iatrogenic injury from a dilatation balloon. The second patient experienced excessive blood loss from an access site and thrombosis of the left renal artery during the procedure. Postoperatively his condition gradually deteriorated. He went on to develop multi-organ failure and expired on postoperative day 4.

THIRTY DAY MORBIDITY

Morbidity at 30 days included acute renal failure (n=1) that resolved, unilateral lower extremity compartment syndrome that required fasciotomies (n=1), respiratory failure that required re-intubation (n=1), and an iliac artery occlusion requiring a cross-over femoro-femoral bypass (n=1). No cases of spinal cord or bowel ischemia were observed.

FOLLOW-UP

Mean follow-up time was 16 months (range 6–36 months). Follow-up information was complete in all patients. Endoleaks requiring intervention were seen in three patients, resulting in a re-intervention rate of 33%. In one patient separation of an SMA stent graft from the aortic module occurred and was treated successfully with a bridging stent graft. The second was an endoleak at the attachment site of a celiac artery stent to the main module. Despite attempts to manage the endoleak with additional stent grafts and balloon dilatation of the attachment site, the endoleak remained visible. Since there was no sac expansion, the residual endoleak was managed conservatively. A third endoleak was due to separation of components within a renal artery, resulting in a large type 3 endoleak and sac expansion of 15 mm. The patient underwent an unsuccessful endovascular attempt to bridge the two disconnected stents. Ultimately he underwent deliberate occlusion of the renal branch with subsequent loss of the target kidney. No other sac expansion occurred during the period of follow-up. Four of the nine patients experienced shrinkage of the sac. These findings suggest adequate exclusion of the sac in eight of the nine cases.

Four patients experienced deterioration in their renal function (mean preoperative creatinine 1.2 mg/dl, postoperative 1.8 mg/dl), but none required dialysis. Of the 34 visceral artery branches, 33 remained patent, resulting in a patency rate of 97%. A single target vessel was lost during the follow-up, observed in a patient who experienced asymptomatic occlusion of a renal artery found incidentally on a routine CTA. No graft migration, kink or stent fracture was seen during the follow-up. No late aneurysm-related deaths occurred. One patient expired 36 months following the repair from a non-aneurysm-related cause.

DISCUSSION

The surgical management of juxtarenal AAA and TAAA aneurysms is a challenging and technically demanding task for vascular surgeons. The reported operative mortality and morbidity following open repair is substantial. Studies of open TAAA repair have reported perioperative and 30 day death rates of 5.5%–19% [8,10]. Hybrid procedures involving a combination of visceral artery bypasses with endovascular exclusion of the aortic aneurysm were reported previously [11]. These procedures, in theory, are less morbid than open TAAA repair; however, the results have been disappointing and these operations are not suitable for high risk patients.

The introduction of fenestrated and branched stent graft technology has expanded the options to treat patients with complex aortic aneurysmal disease, and to date, these procedures are performed only in selected centers of excellence. This technology seems particularly attractive in high risk patients who are not candidates for standard open or hybrid repairs. It offers several potential advantages: namely, no laparotomy or thoracotomy is required, cross-clamping of the aorta is unnecessary, and no visceral organs are rendered ischemic. Although there are limited published reports of endovascular repair of these complex aneurysms, the procedure appears technically feasible, and favorable short and mid-term outcomes have been reported [8,9,12-14]. In the study by Chuter et al. [8] of 22 patients treated with multibranched stent grafts, the procedural success rate was 100%. Two patients (9.1%) died perioperatively. Renal failure, myocardial infarction, stroke and paraplegia did not occur in any of the surviving patients. During the follow-up, 2 patients (9.1%) required re-interventions, both of which were performed by endovascular methods. Of the 81 branches 98% remained patent. No aneurysm-related deaths were reported.

SMA = superior mesenteric artery

Roselli et al. [13] used custom-made branched endovascular devices to treat 73 patients with TAAA. Technical success was achieved in 93% of patients. The 30 day mortality was 5.5%. Major perioperative complications (renal failure, myocardial infarction, stroke, among others) occurred in 14%. Freedom from aneurysm-related mortality was 89% at 12 months. There were no cases of aneurysm ruptures or sac enlargement during the follow-up period. Technical success in our series was achieved in 88% of the cases, which correlates well with other reported series [8,13,15].

Our operative time, amount of contrast delivered, and blood loss all exceeded those in other reported series [8]. This can be explained in part by the learning curve that we experienced during the earlier cases. Procedures performed in the latter half of this study required less operative time and considerably less contrast.

We had two perioperative deaths (22%). The first was due to iliac artery rupture, an uncommon but well-described cause of death in patients undergoing EVAR [16]. These arteries, which serve as the access vessels for the introduction of large-bore sheaths and delivery systems, are frequently damaged during their introduction into or removal from the body. The arteries are commonly tortuous and calcified and are prone to damage even if sized appropriately prior to surgery. Rupture due to aggressive dilatation may also occur. The second perioperative death was due to multi-organ failure that probably resulted from gradual underestimated blood loss from the sheaths during the procedure. Since then, we have improved our hemostatic techniques and avert excessive blood loss from the delivery systems, using improved equipment such as dry seal sheaths and removing access sheaths earlier when possible.

During the follow-up 32 of the 34 branches (94%) remained patent. Although one patient experienced loss of a kidney, he did not require dialysis. No patient suffered a branch occlusion resulting in bowel ischemia. No patients required conversion to open surgery and only one patient developed enlargement of the excluded aneurysm sac. One patient expired from non-aneurysm-related disease during the follow-up. In contrast, 33% required additional endovascular interventions. These findings parallel other reported series and reflect the known benefits of endovascular treatment previously reported for infrarenal aneurysm disease [4,5].

Although we have succeeded in avoiding the significant morbidity associated with open repair, this comes at a cost – namely, the need for secondary interventions, additional hospitalizations, exposure to contrast material, and radiation.

There are several disadvantages to this new technology. Currently there are no over-the-counter devices available. All the devices are custom made and require 6–8 weeks to be manufactured. As such, they obviously cannot be used in an emergency setting. Over-the-counter fenestrated stent grafts are being developed and are expected to be available in the near future. Accurate preoperative planning is essential since a slight inaccuracy in the placement of a fenestration or branch may have detrimental consequences and may result in target organ loss as it may not be possible to cannulate the target vessel. The procedure is time consuming and requires exposure to prolonged periods of radiation. The dye load administered during these cases is not negligible and may be taxing to the patient. In addition, these cases require a large inventory of endovascular equipment such as wires, sheaths, catheters, stents, etc., which increase the cost and complexity of these procedures.

CONCLUSIONS

Branched and fenestrated stent grafts are feasible alternatives for the treatment of complex aortic aneurysms involving the visceral segment. The technology offers several advantages over conventional open repair and appears to offer a durable solution to the aneurysmal disease. Further improvements in operative technique and device design are needed to simplify the planning and operative procedure, and additional investigations are needed to ensure the long-term durability of these stent grafts.

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