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Preliminary results of Zenith Fenestrated abdominal aortic aneurysm endovascular grafts

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Juxtarenal aortic aneurysm; Fenestrated; Endovascular repair; Scallop

Abstract

BACKGROUND: Patients with juxtarenal aortic aneurysms who are unfit for open repair may be considered for fenestrated endovascular repair (fenEVAR). We report our initial experience with fenEVAR.

METHODS: We reviewed the data on all our patients receiving fenEVAR for juxtarenal aortic aneurysms.

RESULTS: Eight patients, average age 75 years, underwent fenEVAR. Endografts were designed from details obtained from preoperative computed tomography angiography. There were 6 grafts with superior mesenteric scallops and bilateral renal fenestrations, 1 with bilateral renal scallops, and 1 with a single renal fenestration. All patients survived 30 days. There was no renal failure requiring dialysis. At 10 weeks, 1 patient died from acute intestinal ischemia and multisystem organ failure, and another died from respiratory failure.

CONCLUSIONS: It is feasible to offer fenEVAR to patients who are poor candidates for open repair. However, these procedures are technically challenging. Early outcomes are less favorable than other aortic endovascular procedures.

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In the last decade in the United States, there has been a paradigm shift in the management of abdominal aortic aneurysms (AAAs), from open repair to endovascular repair (EVAR). In fact, recent hospital discharge data indicate that nearly 80% of patients have EVAR to treat AAAs. Open AAA repair is still performed because of the patient’s or the surgeon’s preference, or if the AAA is anatomically not suitable for EVAR. Juxtarenal aortic aneurysms (JAAAs) are classified as aneurysms that are close to the origin of the renal arteries but do not involve them. JAAAs account for 15% of all aortic aneurysms, and the traditional open AAA repair usually involves suprarenal clamping with its attendant complications. In patients with JAAAs who are physiologically unfit for open repair, EVAR is feasible with a customized endovascular graft. Most of the commercially available aortic stent grafts are not designed to treat JAAAs with a short neck (proximal seal zone <15 mm). There have been several reports describing modifications to the commercially available stent grafts to accommodate JAAAs.1,2 In mid-2012, the Food and Drug Administration (FDA) approved a customized fenestrated...
aortic graft for commercial use. We began implanting fenestrated endovascular grafts (fenEVAR) for JAAs at our institution in August 2012.

The purpose of this study is to analyze the clinical outcomes of our initial experience using fenestrated aortic grafts.

**Patients and Methods**

**Patient selection**

After the Institutional Review Board approval, the inpatient and outpatient records of all patients undergoing fenEVAR for JAAs between August 2012 and May 2013 were reviewed retrospectively. Prehospital clinical data, intraoperative findings, as well as all imaging studies were obtained.

**Preoperative evaluation**

All consecutive patients selected to undergo fenEVAR underwent preoperative computed tomography angiography (CTA) of the abdomen and pelvis. Images were obtained using a 64-slice multidirectional computed tomography scanner and 80- to 120-mL intravenous contrast. Three-dimensional images were reconstructed using InTuition software (TeraRecon, Foster City, CA). Visceral artery morphology and positions were used to configure custom-made fenestrated endografts. The device used was the Zenith Fenestrated AAA Endovascular Graft (Cook Medical, Bloomington, IN).

**Operative technique**

The procedure was performed in a hybrid operating room with routine intraoperative monitoring under general anesthesia. Anticoagulation (Heparin 80 to 100 U/kg) was administered after femoral or iliac exposure. Angiography was performed to identify the location of the superior mesenteric and renal arteries. The endograft was delivered via the femoral artery or an iliac conduit if the external iliac artery was too small. After proper alignment of the renal fenestrations, the proximal main body segment was deployed. The renal arteries were accessed from within the proximal main body and stented with iCast balloon-expandable covered stents (Atrium, Hudson, NH). The aortic portions of the renal stents were flared with a 10-mm balloon to ensure adequate seal and to prevent migration. The distal bifurcated main body segment and iliac limb extensions were then deployed in a similar fashion to traditional Zenith AAA endografts. Completion angiography was performed to evaluate adequate repair and to rule out type I and type III endoleak.

**Postoperative follow-up**

Postoperatively, patients were monitored in the surgical intensive care unit (ICU) and renal functions were monitored on the first postoperative day. CTA of the abdomen was performed on all patients within the first 30 days postoperatively. Clinical follow-up evaluation was performed in the outpatient setting.

**Results**

**Demographics**

Eight patients (4 men and 4 women) underwent fenEVAR during the study period. The average age was 75 (range, 64 to 85) years. The demographics, major risk factors, device configuration, and procedural data are outlined in Table 1. Prohibitive comorbidities to open repair included oxygen-dependent chronic obstructive pulmonary disease (COPD; 5 patients) and severe coronary artery disease (3 patients). Three patients had abnormal glomerular

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**Table 1** Demographics, device configuration, and procedural data

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age (y)</th>
<th>Comorbidity</th>
<th>AAA diameter (cm)</th>
<th>Infrarenal neck length (cm)</th>
<th>ASA</th>
<th>SMA</th>
<th>LRA</th>
<th>RRA</th>
<th>Diameter (mm)</th>
<th>Contrast (mL)</th>
<th>Fluoroscopy time (min)</th>
<th>LOS (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female 69</td>
<td>COPD</td>
<td>6.3</td>
<td>.8</td>
<td>IV</td>
<td>S</td>
<td>F</td>
<td>F</td>
<td>28</td>
<td>67</td>
<td>52</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Female 80</td>
<td>COPD</td>
<td>5.5</td>
<td>.9</td>
<td>III</td>
<td>S</td>
<td>F</td>
<td>F</td>
<td>28</td>
<td>103</td>
<td>68</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Female 77</td>
<td>CAD</td>
<td>5.6</td>
<td>.4</td>
<td>III</td>
<td>S</td>
<td>S</td>
<td>F</td>
<td>26</td>
<td>89</td>
<td>85</td>
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<td>1</td>
</tr>
<tr>
<td>Male 64</td>
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<td>6.2</td>
<td>1.2*</td>
<td>IV</td>
<td>S</td>
<td>F</td>
<td>F</td>
<td>28</td>
<td>105</td>
<td>32</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Male 80</td>
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<td>.4</td>
<td>IV</td>
<td>–</td>
<td>S</td>
<td>S</td>
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<td>122</td>
<td>81</td>
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<td>2</td>
</tr>
<tr>
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<td>CAD</td>
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<td>.4</td>
<td>IV</td>
<td>S</td>
<td>F</td>
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<td>36</td>
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<td>63</td>
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<tr>
<td>Female 72</td>
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<td>5.2†</td>
<td>.4</td>
<td>III</td>
<td>–</td>
<td>F</td>
<td>–</td>
<td>24</td>
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</tr>
<tr>
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<td>28</td>
<td>83</td>
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</tbody>
</table>

AAA = abdominal aortic aneurysm; ASA = American Society of Anesthesia; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; F = fenestration; LOS = length of stay; LRA = left renal artery; RRA = right renal artery; S = scallop; SMA = superior mesenteric artery.

*This patient had a 1.2-cm infrarenal neck that was funnel shaped.
†This patient had a rapidly enlarging aneurysm.
filtration rate and a baseline serum creatinine >1.5. The average aneurysm size was 5.8 cm (range, 5.2 to 6.3 cm). The average neck length was .6 cm (range, .4 to 1.2 cm).

**Graft configuration**

Endograft configuration and precise location of scallops and fenestrations were determined from preoperative CTA of the abdomen. There were 6 grafts with superior mesenteric scallops and bilateral renal fenestrations/scallops (Fig. 1). One graft had bilateral renal artery scallops. One graft had a single unilateral left renal fenestration in which the right renal artery and superior mesenteric artery were significantly higher on the aorta. Graft delivery was through a femoral cutdown in all but 1 patient who needed an iliac conduit and underwent iliofemoral bypass. All renal fenestrations were stented using balloon-expandable covered stents. The initial technical success rate was 100%.

**Procedural details**

Digital subtraction angiography was performed with Isovue iodinated contrast (Bracco, Monroe Township, NJ). Fluoroscopy time averaged 55 min (range, 17 to 85). The volume of iodinated contrast used was an average of 90 mL (range, 42 to 122).

Perioperative complications after fenEVAR include a right perinephric hematoma found using computed tomography in a patient who developed hematuria and hypotension 10 hours postoperatively. This was most likely due to an unrecognized guide wire perforation of a renal artery branch. He responded to 3 units of packed red blood cells and crystalloid resuscitation. No extravasation was noted on renal angiography on postoperative day 1 and the patient recovered. Another patient developed Clostridium difficile colitis postoperatively and was treated medically. There was no incidence of myocardial infarction, or dialysis-dependent renal failure. The average hospital length of stay was 3 days (range, 1 to 9). The average ICU stay was 1 day (range, 0 to 8).

**Follow-up**

CTA at 30 days showed no evidence of type I or type III endoleak in any patient. There were 2 patients with type II endoleak without sac enlargement. Two other patients had radiographic signs of end-organ damage (small splenic infarcts and decreased renal perfusion). All patients survived 30 days. One patient died 6 weeks postoperatively from respiratory failure after developing worsening COPD and congestive heart failure. Another patient died at 10 weeks because of complications from acute gastroduodenal artery hemorrhage leading to intestinal ischemia and multisystem organ failure. The median follow-up was 6.1 months (range, 2.7 to 8.3).

![Figure 1](image)

**Figure 1** Proximal main body endograft illustrating a scallop for the superior mesenteric artery (top), and 2 fenestrations for the renal arteries. Once the graft is fully deployed, the top of the scallop opens to form a U-shaped gap in the endograft fabric.
Comments

Currently, in the United States, EVAR is the preferred method of treatment for AAAs. Medicare data from 2008 indicated that approximately 70% to 80% of AAAs in the United States were treated with EVAR.1 Traditional stent grafts, however, are not suitable for JAAs because of the lack of an adequate infrarenal neck. Custom-made fenestrated endografts were developed to accommodate visceral branch vessels and achieve an adequate proximal seal.2 The use of fenestrated grafts has been limited to select centers throughout the world, until April 2012 when the FDA approved the device for commercial use in the United States.5 In this study, we offered fenEVAR to our patients who were deemed unfit for open repair.

Population-based studies have provided insight to the natural history of AAAs, which has not changed much over the past few decades. The estimated annual rupture risk for aneurysms 5 to 6 cm in diameter is 3% to 15%, and for 6 to 7 cm is 10% to 20%.6 Overall mortality from rupture is 85%.7 Sixty-six percent of patients die before reaching the hospital or the operating room. Perioperative mortality of open repair in this setting has been reported at approximately 40%.8

Open repair of JAAs with suprarenal aortic cross-clamping remains the gold standard against which fenEVAR will be compared. However, open JAA is technically demanding and is associated with increased morbidity, compared to routine elective infrarenal open AAA repair. In contemporary reports, open JAA repair is associated with pulmonary complications (16%), cardiac complications (13%), and new onset dialysis (up to 3.7%), and a slightly higher perioperative mortality (range, 2.5% to 2.9%).9,10 Renal insufficiency was found in up to 39% (median, 18%) of patients and associated with increased mesenteric ischemia times, supravisceral clamping, and renal artery bypass.11

Cardiac and pulmonary comorbidities increase the risk of open JAA repair and are the main reasons for patients to be considered as unfit for surgery. In these cases, fenEVAR is an alternative. Oxygen-dependent COPD and coronary artery disease were the most prohibitive comorbidities for open repair in our fenEVAR patients. Our frail patients tolerated fenEVAR and we had no deaths in the first month. Most patients were discharged within the first 2 days of admission and spent on average .5 days in the ICU postoperatively. These outcomes compare favorably with other recently published studies.11

As with many surgical problems, proper patient selection determines good outcomes. In this early experience, the ideal patient for fenEVAR has not been completely defined. One of our patients with a 5.5-cm aneurysm, who died in the postoperative period, tolerated the fenEVAR well without immediate complication, but developed worsening respiratory symptoms from severe COPD and congestive heart failure 2 weeks after his 30-day follow-up and decided to go to hospice at 6 weeks. This patient’s mortality risk from his underlying comorbidities likely outweighed his risk from aneurysm rupture. Mastracci et al12 sought to identify “high-risk” endovascular patients and found that preoperative characteristics such as age, history of congestive heart failure, and need for supplemental home oxygen appeared to be significant factors in predicting long-term mortality. More data are needed to identify those patients who would benefit the most from fenEVAR to reduce aneurysm-related death, while considering the mortality risk because of underlying comorbidities.

Finally, mid-term durability data of fenEVAR is unknown. Long-term complications with traditional aortic stent grafts such as endoleak, graft infolding, and proximal migration have been described.13 Continued surveillance with abdominal CTA and possibly ultrasound has been recommended for fenEVAR by some.14 Our surveillance protocol consists of CTA at 30 days, 6 months, and annually to assess graft complications, graft migration, aneurysm size, and renal patency. In our limited follow-up, we observed 2 patients with type II endoleak without aneurysm sac enlargement.

In conclusion, fenEVAR appears to offer an alternative to patients who are poor candidates for open repair. However, these procedures are technically challenging. Early outcomes are less favorable than other aortic endovascular procedures.

References

Discussion

Richard A. Berg (Grosse Pointe Farms, MI): Although, endovascular treatment has become the norm until now for infrarenal aneurysms, we haven’t been able to do this technique for the higher super renal, juxtarenal aneurysms, which required open repair. I have 4 questions. Number 1, ways to do this operation endovascularly also include chimneys and branch grafts. Why did you pick fenestrated? Were there any patients rejected for endo based on anatomic criteria during this time frame that were done open and didn’t make it into this study? As far as the patient with the renal perforation, was this a glide wire, which is known to be notorious for causing this problem? Were these were all juxtarenal aneurysms. Would you consider extending this to perirenal or super renal aneurysms?

And my last question is a philosophical question. Your operative mortality rate was 2 out of 8 patients or 25%. So there’s 2 diametrically opposed ways to look at this. In this high risk patient population with a mortality of 25%, should you have opted for no treatment at all?

Liao: With respect to the first question about the use of chimney grafts and branched grafts with EVAR of these aortic aneurysms, when you have an FDA-approved device, it’s hard to justify the use of these other methods. We had at least 2 patients referred to our center who were rejected for fenEVAR, but after discussions with the surgeon and patient, open repair was done. They were not included in this study.

With respect to the perioperative complications, the perforation in the renal artery was due to glide wire. About our late mortality, 2 out of 8 patients, one of the big questions about our study is who to offer this procedure to, and in looking at these high risk patients it is really important to weigh the risk of aneurysm-related death to their overall expected life expectancy, given their comorbidities. An example of this is the patient who 6 weeks after the procedure decided to enroll into hospice care because of his quality of life, because his quality of life was so poor, given his COPD and congestive heart failure.

Fred A. Weaver (Los Angeles, CA): One of the concerns with fenestrated grafts as well as branched grafts is the patency of the renal conduit. Do you have any information about later renal patency, and just overall renal function beyond 30 days?

Liao: At this point, our mean follow-up is 6 months, and we haven’t seen any renal artery occlusions or renal stenosis, but in the literature, there has been described stenoses as early as 6 months. And so that’s why it is important to have these surveillance protocols.