Primary Endovascular Repair of Juxtarenal Aneurysms with Fenestrated Endovascular Grafting


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Purpose. To evaluate outcomes of an endovascular graft incorporating the visceral aortic segment with graft material in the setting of juxtarenal aneurysms.

Materials and methods. A prospective analysis of patients undergoing implantation of an endovascular device with graft material proximal to the renal arteries was conducted. All patients were deemed unacceptable candidates for open surgical repair and had proximal neck length = <10 mm, or = <15 mm with a compromising morphology (funnel or thrombus). Fenestrations were customized to accommodate aortic branch anatomy based upon CT and intravascular ultrasound data. Selective visceral ostia were treated with balloon expandable stents following endograft deployment. All patients were evaluated with CT, duplex ultrasound, and abdominal radiograph at discharge, 1, 6, 12 and 24 months.

Results. A total of 32 patients were enrolled in the trial. Short proximal necks (3–10 mm) were present in 22, and 10 had necks 10–15 mm in length with concomitant angulation or thrombus compromising neck quality. Endograft design included bifurcated (30) and aortic tube (2) systems. A total of 83 visceral vessels were incorporated (mean of 2.6 per patient). These most commonly included both renal arteries and the SMA. All prostheses were implanted successfully without the acute loss of any visceral arteries. The mean follow-up was 9.2 months (range 0–24 months). One patient died within 30 days of device implantation and hypogastric bypass following the development of aspiration pneumonia. Three early (<30 days) and three late secondary interventions were performed. The 30-day endoleak rate was 6.5%. The aneurysm sac decreased greater than 5 mm in 58% of patients at 6 months and in 75% of patients at 12 months. One patient, with a persistent type II endoleak had 5 mm of sac growth over 12 months. Six patients had transient or permanent elevation of serum creatinine (>30% from baseline), with one requiring hemodialysis. Of the 83 vessels incorporated, three late stenoses (all successfully treated with an endovascular approach) and two renal occlusions were detected during follow-up. Three patients died of unrelated causes during the follow-up period.

Conclusions. The placement of endovascular prostheses with graft material incorporating the visceral arteries is technically feasible. The incidence of endoleaks is exceptionally low. It remains critical to follow the status of stented visceral vessels, and establish the long-term efficacy of this type of repair.

Key Words: Aortic aneurysm; Endovascular aneurysm repair; Juxtarenal aneurysm; Pararenal aneurysm; Stentgraft; Renal stent; Fenestrated endografts.

Introduction

Patients presenting with abdominal aortic aneurysms (AAA) are treated with endovascular prosthesis based upon selected anatomical criteria. They include proximal neck diameter, length, angulation and shape.1,2 Compromised proximal neck anatomy is the most frequent rejection criteria for treatment with an endovascular prosthesis. Although more robust proximal fixation systems, such as those with barbs or uncovered suprarenal stents may provide improved device stability, the need for a sealing zone above the aneurysm must be viewed separately. Maximizing the sealing zone with conventional prosthesis requires accurate delivery of the graft material to the immediate infrarenal location. Furthermore, angulation, abnormal morphology (such as thrombus or neck irregularities) may limit the success. These reasons have provided an impetus for the development of devices with extended sealing zones.

The first reports of fenestrated devices were published in 1999,3 and followed by the development of a modular system by John Anderson and Michael Lawrence-Brown. Anderson and Stanley, reported their initial experiences in a combined total of 16
patients, without acute vessel loss or death. Additional case-reports with various designs have been published as well as a subset of patients included in this series. It is the intent of this publication to describe the technical aspects and results using fenestrated endovascular devices in patients with compromised proximal neck anatomy.

**Materials and Methods**

Patients were prospectively enrolled in a physician initiated (not industry sponsored) investigational device exemption protocol beginning in August 2001. The results were analyzed through December 2003. All patients were deemed physiologically high-risk (such as evidence of non-reconstructable cardiac ischemia, ejection fraction <25%, significant chronic obstructive pulmonary disease or chronic renal insufficiency) for open surgical repair, and anatomically unsuitable for traditional infrarenal endovascular grafts. Patients were selected for treatment if the aneurysms were greater than 5.5 cm, grew more than 0.5 cm over 1 year, or were otherwise felt to be at high risk for rupture (morphology, relative diameter with respect to native vasculature). Informed consent, approved by the Institutional Review Board, was obtained for all research subjects.

The preoperative assessment of the aortic morphology centered on high-resolution helical CT-scans incorporating the distal descending thoracic aorta through the profunda femoris. Arteriography was utilized selectively to evaluate concomitant occlusive disease of the visceral or pelvic vasculature. The Zenith device (Cook Inc., Bloomington, Indiana) formed the foundation of the fenestrated graft. The material construct and delivery system are similar to the Zenith described elsewhere. Critical differences include a proximal portion of the device that is customized to match the patient specific orientation of the visceral vessels. Most commonly this involved a proximal tubular component design that was coupled with a separate bifurcate system. The addition of one or two limb extensions completed the implant. Device design required accurate information regarding the ostial diameter of each visceral vessel, their relative distances from a fixed landmark (the superior mesenteric artery), and the orientation from which they arise from an aortic cross-section. Fenestrations were constructed to match the ostial diameter and maximize the sealing zone. Small fenestrations had a diameter between 6 and 8 mm, and were located at a minimum of 15 mm distal to the top of the fabric. The ostia for the small fenestrations were placed between stent struts of the aortic device, to allow unimpeded access into the visceral artery, and intended to be used in conjunction with a balloon expandable stent within the target vessel. Large fenestrations had greater diameters with a strut crossing the fenestration, and thus not intended for use with additional stents. Scallop fenestrations were hemiovals 6–10 mm in height and an 8–12 mm diameter located at the most proximal portion of the fabric. Diagram 1 illustrates the design options for the fenestrated segment.

**Procedure**

Bilateral femoral artery exposure was achieved after the induction of anesthesia (epidural anesthesia in 28 cases, and general anesthesia in four cases). Patients were anticoagulated with heparin such that activated clotting times were maintained greater than 300 s. A stiff wire was placed into the ascending aorta through the side chosen to delivery the main body, while a double puncture was performed in the contralateral femoral vessel to allow the placement of two 8F sheaths. A multi sidehole flush catheter was placed through one of the sheaths to visualize the renal arteries intermittently using small bursts (5–7 cc at 30 cc/s) of non-ionic contrast. The proximal tubular fenestrated endograft component was oriented using gold markers located on the device body and around each fenestration. Partial deployment of this component was followed by minute rotational adjustments to properly orient the fenestrations with their respective ostia (Fig. 1). Access to main body was achieved from both access ports within the contralateral femoral using selective catheterization techniques. Renal artery access was established in a similar manner,

Diagram 1. This illustration depicts the variety of fenestration options. Image 1 shows a small fenestration without struts crossing the orifice. Image 2 shows a large fenestration with at least one strut that crosses the opening, potentially making it difficult to use in conjunction with an additional stent. Image 3 demonstrates a scallop fenestration, located at the proximal aspect of the fabric, not typically used in conjunction with additional stents.
and established prior to release of a tethering wire that provided a means to achieve partial diameter expansion of the fenestrated component, allowing improved rotational ability. The top cap of the device was released following the placement of guiding catheters into the renal arteries. A balloon expandable stent was chosen that was a minimum of 17 mm in length and deployed on a 7 mm × 2 cm balloon such that 2/3 of the stent was within the visceral vessel, and 1/3 extended into the aorta (Fig. 2). The aortic portion of the stent was then flared with a 10 mm balloon and subsequently with a compliant latex balloon. The second (bifurcated) component was implanted allowing at least two stents of overlap. The remainder of the deployment did not differ from previously described publications, and details are available in the device instructions for use.5

**Patient follow-up**

Postoperative evaluations were conducted at hospital discharge, 1, 6, 12 and 24 months. Helical CT scans, duplex ultrasound (with the exception of the discharge timepoint), creatinine assessment, and flat plate radiography were obtained. Secondary interventions were performed in the setting of a suspected type 1 or 3 endoleak, compromised visceral vessel flow, or aneurysmal growth. When appropriate, outcome analyses were conducted in accordance with the reporting standards for endovascular aneurysm repair.8 Elevation of serum creatinine was considered significant if the baseline level increased to greater than 2 mg/dl or a rise of >30% from baseline was noted. Duplex end systolic and diastolic velocities were depicted in each visceral and renal arteries and aortic ratios calculated at each follow-up and compared to baseline.

**Results**

A total of 32 patients were treated. There were 29 men and three women with a mean age of 76 ± 9 years. The pre-operative risk factors are listed in Table 1. The majority of patients had isolated abdominal aortic aneurysms, however, three patients had associated iliac aneurysms, and two patients had thoracic aneurysms. The mean diameter of the proximal neck was 27 ± 4 mm (range 21–32 mm). The proximal neck length was <10 mm in 24 patients, and between 10 and 16 mm in eight patients, all of which had morphologic factors implying compromised sealing or fixation. These included moderate angulation (>40°, <60°) of the proximal neck in 11 patients, and severe angulation (>60°) in seven patients. The presence of thrombus or calcification incorporating 2/3 or more of the proximal neck circumference was noted in 16 patients and 13 patients, respectively. The shape of the pararenal aorta was considered to have an inverted funnel (n = 9), funnel (n = 9), irregular (n = 6), or parallel (n = 8) shape. Mean maximum transverse diameter (MTD) and maximum anteroposterior diameter (MAPD) of the AAA were 63 ± 13 mm
(range 45–100 mm) and 58 ± 12 mm (range 44–90 mm), respectively.

A total of 83 visceral vessels (Fig. 3) were incorporated in the prosthesis design (with a mean of 2.6 per patient). The fenestration was a ‘small’ fenestration in 53 cases, and a ‘scallop’ in 30 cases. Table 2 demonstrates the distribution of renal, superior mesenteric and celiac arteries treated. There was one acute visceral vessel (renal) loss (in addition to a single accessory renal that was intentionally covered).

Procedure

All prostheses were implanted at the intended site. A conduit to the common iliac artery (10 mm diameter Polyester vascular graft) was planned and performed in two patients. The single vessel that was not successfully catheterized and ultimately thrombosed was located in a tortuous portion of a short proximal neck. Procedural time averaged 214 ± 65 min with a

Table 1. Preoperative co-morbidities or risk factors for the 32 patient cohort

<table>
<thead>
<tr>
<th>Co-morbidity</th>
<th>Patients (n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial hypertension</td>
<td>20</td>
<td>63</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>20</td>
<td>63</td>
</tr>
<tr>
<td>Renal insufficiency (creatinemia &gt; 120 µmol/l)</td>
<td>5</td>
<td>16</td>
</tr>
<tr>
<td>COPD</td>
<td>21</td>
<td>66</td>
</tr>
<tr>
<td>Previous laparotomy</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Obesity (weight &gt; 110% ideal body weight)</td>
<td>7</td>
<td>22</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>8</td>
<td>25</td>
</tr>
</tbody>
</table>

Table 2. This table depicts the distribution of vessels incorporated into the fenestrated devices used in this series

<table>
<thead>
<tr>
<th>Fenestration</th>
<th>Patients (n)</th>
<th>Number of vessels</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>3</td>
<td>1 9 3 0</td>
</tr>
<tr>
<td>SMA</td>
<td>0</td>
<td>18 1</td>
</tr>
<tr>
<td>SMA + CELIAC</td>
<td>0</td>
<td>1 0</td>
</tr>
</tbody>
</table>

The vast majority of patients had devices involving two main renal arteries and the SMA. A single patient had a large accessory renal that was preserved with a third renal fenestration, and two patients had renal arteries that were markedly disparate, requiring only single fenestrations. Only one patient required incorporation of all four visceral vessels.

Fig. 2. This image depicts the placement of a balloon-expandable stent into the left renal artery. Following the placement of this stent on a 7 mm × 2 cm balloon, the aortic portion (that is extending about 5 mm into the aorta) is flared with a 10 mm × 2 cm balloon. A compliant latex balloon is then used to complete the flare.

Fig. 3. This completion angiogram demonstrates patency of the three vessels incorporated in this fenestrated endograft (two small fenestrations for the renal arteries and one scallop fenestration for the superior mesenteric artery). The black arrow depicts the SMA.
mean of $56 \pm 23$ min of fluoroscopy time. The mean volume of contrast utilized was $170 \pm 42$ ml.

The use of a large balloon expandable stent immediately below the renal arteries was required in four patients, and at the level of the main body joint in one patient (Fig. 4). Additional self-expanding stents were implanted into 7 iliac limbs to alleviate kinking or unacceptable tortuosity following endograft deployment. Extensions were required in two patients to achieve optimal device overlap. One patient

**Fig. 4.** A joint type three endoleak is depicted on the early post-operative CT-scan (a) and found angiographically to have originated from the modular joint between the fenestrated tubular component and the main body bifurcation (b). After implantation of a complementary balloon-expandable stent (arrow) the leak has resolved (c).
required a femoral endarterectomy and prosthetic patch closure on the side of the main delivery system insertion.

**Early follow-up (<30 days)**

One patient (3%) died 7 days after the initial procedure. This patient had bilateral common iliac aneurysms and an attempted hypogastric bypass which was aborted due to difficult pelvic access (patient weight was 253 lbs.). Although, the patient initially did well, however, he developed an ileus and aspiration pneumonia, further compromising his chronic obstructive pulmonary disease. He ultimately died of multisystem organ failure. The immediate post-procedural CT depicted a type II endoleak in eight patients, of which only two were present at 30 days. One proximal type I endoleak, and a single type III (at a modular joint) endoleak were noted and treated within 30 days of the initial procedure.

**Late follow-up (>30 days)**

The mean follow-up was 9.2 months (range 0–24 months), without any patients lost to follow-up. Three patients expired during the follow-up period, at 2, 6 and 6 months. One death resulted from a hemorrhagic duodenal ulcer resistant to endoscopic cauterization (non-surgical candidate), another expired from severe coronary insufficiency, and the third died of a remotely ruptured aneurysm (aortic arch). Two patients withdrew from the study at the 12-month follow up time point.

The 30-day endoleak rate was 6.5% (two type II endoleaks). Sac shrinkage (>5 mm) was present in 58% (15/26) of patients at six months and in 76% (19/25) at twelve months. Only one patient demonstrated aneurysmal growth of 5 mm, in the setting of a persistent type II endoleak, who has refused further intervention at this time.

**Renal function**

Six patients (18.8%) developed an increase in serum creatinine (>30% over baseline) following treatment. Two patients had a transient rise that later returned to normal levels by the 6-month measurement, attributed to either atheroemboli or contrast nephropathy. All four of the remaining patients with elevated serum creatinine had evidence of renal arterial pathology including three renal occlusions (one accessory renal intentionally covered, one renal artery thrombosis following prolonged hypotension after a ruptured thoracic aneurysm, and one patient with a renal occlusion noted at the 12 month duplex study), and one renal stenosis which was percutaneously treated.

**Visceral vessel patency**

In addition to the aforementioned renal artery issues a single patient, at 12 months, was diagnosed with a renal artery stenosis by duplex ultrasound (without elevation of creatinine or blood pressure), and treated percutaneously. Additionally, one patient was noted to have an SMA stenosis within 30 days of the procedure, which was detected with duplex, but not visualized angiographically. However, an intravascular ultrasound evaluation demonstrated fabric material partially obstructing the SMA origin, which was treated successfully with a self-expanding stent. Overall, impaired blood flow was detected in six of the 83 vessels incorporated within the fenestrated prostheses; successful treatment was undertaken in three patients presenting with stenoses, and no treatment in the other three patients presenting with occluded vessels.

**Lower extremity perfusion**

No patients developed worsening of the measured ankle–brachial indices during the follow-up period. However, a single patient with a baseline ABI of 0.67 suffered an embolic event to her great toe. A superficial femoral artery angioplasty was performed to improve the potential for healing this lesion. She later required repeat angioplasty of the SFA and external iliac artery and underwent a great toe amputation.

**Discussion**

Fenestrated endovascular grafts were designed to extend the proximal sealing zone, accommodate native arterial angulation, and potentially improve proximal fixation. The fenestrations were intended to incorporate any visceral vessels that encroached on the desired sealing zone. Although conceptually a hole placed within the fabric may preclude a seal, the effect of flaring the aortic portion of the renal stent served to rivet the fabric of the prosthesis against the aortic wall, or slightly within the renal artery. Despite this ability, a segment of proximal neck is required and the treatment of true suprarenal aneurysms with an endovascular approach is relegated to branch vessel techniques.9
Successful results with a fenestrated graft required appropriate patient selection, proper device design, and technical expertise with endovascular grafting as well as visceral vessel cannulation and stenting. The absence of any one of these factors will result in visceral vessel loss, unprotected aneurysms, or the need for conversion. For this reason, it is imperative that high-resolution imaging studies be obtained and carefully evaluated for acceptability. Complicating anatomic factors include visceral vessel stenoses, iliac tortuosity or calcifications that diminish the rotational freedom of the device, and proximal neck angulation. In addition to conventional endovascular device sizing requirements, fenestrated device design requires accurate distance calculations to be made between each of the visceral vessels. Furthermore, the location of the visceral vessel ostia from the aortic circumference is important. With these data, one can design a prosthesis that will incorporate the required vessels. Design is limited by the need for unimpeded access through small fenestrations, such that they are created at least 15 mm below the proximal fabric margin. This restriction ensures that the fenestration diameter does not incorporate a strut from the aortic prosthesis and can thus be relatively easily protected with a stent. Disparate renal arteries, or short distances between the renal arteries and superior mesenteric artery were accommodated with either multiple fenestrations or the use of a scallop. Regardless of a given design, multiple alternatives could be constructed and it was ultimately the preference of the treating physician as to the proximal extent of coverage and degree of visceral vessel incorporation.

Despite a proper design, the implantation procedure can be challenging. The delivery system is a modification of the traditional Zenith system. A third trigger wire is used as a tether to allow partial expansion of the fenestrated portion within the proximal neck following sheath retraction. Thus, access to the internal portion of the graft and subsequently the desired visceral vessels, is established while maintaining the ability to rotate and advance the device. However, neck angulation, and tortuous calcific iliac arteries limit this. Furthermore extensive manipulation of the device within the aneurysm and proximal neck has the potential to increase the risk of distal embolization, as was noted in one patient in this study.

The protection of the renal ostia with stents has been the subject of some controversy. Two types of stents were utilized during the course of the study. These included 0.035 and 0.014 systems. The larger system was used in the absence of renal disease (stenosis) and in the setting of single renal arteries, while the presence of significant occlusive disease or the need for kissing stents due to multiple renal ostia in close proximity, or early main renal artery bifurcations, prompted the use of the coronary systems. The 0.035 system incorporated the use of a 17 mm long EV3 double strut balloon-expandable stent (EV3, Plymouth, MN) deployed through an 8F MPB guiding catheter (Cook Inc). The initial deployment of this stent was based upon the diameter of the fenestration rather than renal artery diameter (unless the renal was smaller than the fenestration). This stent was associated with favorable flaring properties. In contrast, a lower profile stent (Herculink, Guidant Inc, Menlo Park, California) was used for more complicated renals. This stent was not flared beyond the desired renal/fenestration diameter. Although, the absence of a flare would likely make later renal access more challenging, the profile of the delivery system, in conjunction with formed 6F guiding catheters and overall stent performance made more palatable.

Despite the technical features allowing the more proximal placement of graft material in the visceral aortic segment, a small number of proximal endoleaks were still noted. This was found to be especially prevalent in the setting of neck angulation. These leaks were all treated during the initial implantation with the superimposition of a Palmaz stent (Cordis Inc., Great Lakes, NJ). This stent was deployed below the renal artery stents and provided additional radial force in that region. It furthermore had the effect of straightening any angulation in that region. However, it is important to note that the preclinical testing for this prosthesis did not incorporate the use of such a stent. The overall low incidence of endoleak, particularly type I leaks, supports the concept that the extended sealing zone adequately excludes the aneurysm, even in the setting of very short proximal necks. This is further reinforced by the sac shrinkage, although with multiple modular components, an emphasis must be placed on ensuring adequate overlap continues to exist between the segments of the device. In the absence of aneurysm exclusion, shrinkage would not likely occur. The fact that it was noted in the majority of our patients at the 6 month follow-up visit gives us optimism that the natural history of the aortic disease has been reversed with the use of this device.

Our results demonstrated that experienced endovascular teams can safely treat patients with challenging neck anatomy. Early post-operative mortality was low, secondary interventions were relatively infrequent, and sac shrinkage was common. Worsening renal function was uncommon, but the presence of restenosis in a single patient was significant and...
demonstrates the importance of duplex follow-up to determine sub-clinical stenoses. Despite these encouraging early results, longer-term data and additional patients will be necessary to determine the safety and efficacy of such a device.

References


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