Endovascular management of juxtarenal aneurysms with fenestrated endovascular grafting

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**Purpose:** To evaluate the technical feasibility and short-term results of juxtarenal aneurysm repair with an endovascular graft that incorporated the visceral aortic segment with graft material.

**Methods:** Patients were studied prospectively after the implantation of an endovascular device with graft material extending proximal to the renal arteries, variably incorporating the superior mesenteric and celiac arteries. All patients were deemed to be high risk with respect to open surgical repair and had compromised proximal neck anatomy. Proximal neck lengths were ≤10 mm, or ≤15 mm with a challenging morphology (funnel shape or extensive thrombus). Fenestrations within the graft material were customized to accommodate visceral and renal vessels on the basis of computerized tomography (CT), angiography, or intravascular ultrasound data. Selected visceral ostia were protected with balloon-expandable stents after partial endograft deployment. All patients were evaluated with CT and kidney, ureters, and bladder x-ray at discharge and at 1, 6, and 12 months. Visceral duplex scan studies were performed at 1, 6, and 12 months.

**Results:** A total of 22 patients were enrolled in the study. Sixteen patients had short proximal necks (3-10 mm), and six had compromised necks of 10 to 15 mm in length. Endograft design included bifurcated (20) and tube (2) systems. All prostheses were implanted successfully without the acute loss of any visceral arteries. A total of 58 visceral vessels were incorporated (mean, 2.6 per patient) and most commonly included both renal arteries and the superior mesenteric artery. The mean follow-up was 6 months. There were no deaths within 30 days and no aneurysm-related deaths during the follow-up period. Two early (<30 days) and two late secondary interventions were performed, inclusive of two visceral artery stenoses detected with duplex scanning. The 30-day endoleak rate was 4.5%. The aneurysm sac decreased greater than 5 mm in 53% of patients at 6 months and three of four patients at 12 months. Three patients developed renal insufficiency, only one of which required temporary hemodialysis.

**Conclusions:** The placement of an endovascular prosthesis with graft material that incorporates the visceral arteries is technically feasible. The occurrence of endoleaks appears to be relatively low. The increased sealing and fixation zones in this patient population should limit the late development of proximal endoleak or migration; however, this situation will require more patients and extended follow-up. *(J Vasc Surg 2004;39:279-87.)*

Estimates suggest that approximately 50% of patients with abdominal aortic aneurysms will be candidates for endovascular repair on the basis of anatomic exclusion criteria. The recent approval of the Excluder (W.L. Gore, Flagstaff, Ariz) and the Zenith (Cook Inc, Bloomington, Ind) by the Food and Drug Administration (FDA) increase the versatility of endovascular repair allowing for treatment for patients with smaller, more complex iliac anatomy, and larger diameter proximal necks. Several reports of undesirable late sequelae associated with venous devices, such as migration, and rupture have caused concern among clinicians performing these procedures. Despite the incorporation of improved proximal fixation mechanisms with the Zenith device (suprarenal stent with barbs), the inclusion criteria for participation in the phase II U.S. trial and, consequently, the commercial instructions for use require an adequate proximal neck length of 15 mm. The treatment of shorter necks with alternative devices has been described; however, the margin for technical error, limited sealing stent to aortic wall apposition, and a decreased sealing region have swayed most interventionalists from treating this patient population. However, for the patient without an open surgical option who is still considered to have a reasonable life expectancy, aneurysm repair might be warranted. Surgical repair, in this setting, is more challenging than infrarenal aneurysms, as many will require suprarenal or supraceliac clamping, which has been associated with a greater blood loss and potentially worse outcomes. Consequently, the advent of endovascular devices capable of incorporating the renal and visceral arteries that provide equivalent durability to open repair would be a valuable tool to improve patient outcomes. The development and initial clinical implants with this fenestrated device, manufactured by Cook Inc, were carried out by Anderson, Stanley, and Lawrence-Brown and have been previously reported.
MATERIAL AND METHODS

From August 2001 to December 2002, 22 patients were treated electively for juxtarenal abdominal aortic aneurysm with a fenestrated endovascular Zenith device. All patients were considered to be at high risk for complications if they were to undergo an open surgical repair. Most commonly this risk related to uncorrectable coronary disease, severe pulmonary dysfunction, or multiple prior abdominal surgeries. Informed consent, approved by the Institutional Review Board, was obtained for all research subjects.

Endograft design. Preoperative assessment of patients included high-resolution helical computerized tomography (CT) scans that incorporated the distal descending thoracic aorta to the profunda femoris. Selectively, angiography, magnetic resonance imaging, and intravascular ultrasound scanning were used. Traditional measurements were obtained (proximal and distal neck lengths and diameters, angulation, and aneurysm morphology). Additional attention was given to the visceral aortic segment. The ostial diameters of each vessel, their relative distances from the superior mesenteric artery, and orientations from which they arise from an aortic cross-section were recorded. Device design was intended to maximize the proximal sealing zone, accommodate native arterial angulation, and provide durable fixation. The initial device used was a two-piece modular bifurcated system. This system evolved into a tubular proximal component that incorporated the desired visceral segment, which was then coupled with a separate bifurcate system, in conjunction with one or two limb extensions (Fig 1), similar to the standard Zenith previously described. The areas of overlap for the tubular and bifurcate sections were intentionally long, preferably greater than 4 cm.

Three types of fenestrations were available to accommodate the visceral vessels. A small fenestration, with dimensions ranging from 4 to 6 mm in width and 4 to 8 mm in height, could be created a minimum of 15 mm inferior to the proximal aspect of the graft. This type of fenestration had no crossing struts from the sealing stent and was intended to be used in conjunction with an additional balloon-expandable stent. Alternatively, a larger fenestration with a diameter between 9 and 12 mm could be created at least 10 mm below the top of the fabric. A portion of the large fenestration was traversed by one of the struts of the proximal sealing Z-stent and, thus, was not typically used with an additional visceral vessel stent. Finally, a scallop, allowing the incorporation of one or more vessels, could be carved out of the proximal end of the fabric with a nominal width of 10 mm and a height ranging from 6 to 12 mm. The location of the fenestrations and scallops were customized to fit individual patient anatomy.

Procedure. After femoral artery exposure, patients were heparinized to maintain activated clotting times greater than 300 seconds for the duration of the procedure. A stiff wire was advanced into the aortic arch through the femoral artery on the intended side of delivery. Two sheaths were inserted through separate puncture sites into the contralateral femoral artery. A flush catheter was positioned immediately above the celiac artery through the contralateral femoral artery. An angled catheter was placed through the second sheath on the contralateral side and left at the level of the aortic bifurcation. The first component was
oriented, using radio-opaque markers, to accommodate the incorporated renal and visceral ostia and inserted over the stiff wire. Partial expansion of the device was then accomplished by sheath withdrawal that occurs amid several small contrast injections (7 cc injected at 30 cc/second) through the flush catheter. Posterior tethering (Fig 2) prevents complete expansion of the prostheses after sheath withdrawal, allowing additional adjustment of the fenestrations position (rotational and longitudinal movement). Access to the partially expanded endograft was achieved through both of the contralateral femoral sheaths with the use of steerable catheter-guidewire systems. A minimum of two visceral vessels were then cannulated through the respective fenestrations from within the prosthesis. Guiding catheters (8F Multipurpose B Lumex Guiding Catheter; Cook Inc) were inserted over Rosen wires into both of the accessed fenestrations (Fig 3). In the setting of significant ostial stenosis, microcatheter systems (Renegade, Boston Scientific, Boston, Mass) were used in conjunction with Balanced Middle Weight wires (Guidant Inc, Menlo Park, Calif) and 6F guides that were shape matched to accommodate the visceral vessel. The graft material was then fully expanded by removing the wire tethering the posterior aspect of the prosthesis. The top cap was then deployed,

Fig 2. A, The posterior sutures tether the graft, providing the ability to partially expand the prosthesis to allow for cannulation of fenestrated vessels, which serves to ensure proper rotation of the device as it fully expands. B, Renal fenestrations with four gold markers oriented in a circular manner 90 degrees apart. These markers, in conjunction with a set of anterior vertically oriented linear markers that are oblique to the set of posterior horizontal markers, are used to help orient the device prior to deployment (C).
Fig 3. The standard technique for ensuring the proper orientation of the device after deployment consists of the placement of guiding catheters or balloons into two vessels (A) prior to removal of the wire maintaining the posterior tethering sutures. Alternatively, in the setting of an early renal branch or two adjacent renal arteries, the use of kissing stents can be accomplished with 0.014-inch systems in conjunction with 6F guiding catheters (B-C). Simultaneous stent (Herculink plus 6.5 × 18 mm; Guidant, Menlo Park, Calif) inflation and caution when manipulating device or ballooning the proximal neck will help to ensure preservation of renal blood flow.
and relatively long (17-mm) balloon-expandable stents (Double Strut, EV3) were deployed, such that approximately 12 mm were lodged within the visceral vessel and 5 mm extended into the aorta. The visceral and renal stenting technique was modified to account for early bifurcations, ostial stenoses, and severe angulation. The aortic component of the balloon-expanded visceral stents were further dilated to 10 mm and then selectively flared with a compliant latex balloon. The top cap was retrieved while access to both stented vessels was maintained with the guiding catheters. The guiding catheters were removed after renal angiography. The second component of the system was then inserted through the ipsilateral femoral artery, oriented, and deployed such that the contralateral limb expanded immediately above the aortic bifurcation. Contralateral access was then obtained through the most proximal of the contralateral sheaths, and the remainder of the deployment sequence is similar to the Zenith system. Compliant balloon inflation at all joints and distal sealing zones preceeded completion angiography (Fig 4).

Follow-up Imaging. Postoperative evaluation consisted of helical CT studies, duplex ultrasound scan, creatinine assessment, and flat plate radiography prior to hospital discharge (except duplex scan) and at 1, 6, and 12 months. Secondary interventions were indicated in the setting of a suspected type I or 3 endoleak or compromised visceral or renal flow. The status of each visceral and renal artery was recorded in addition to the flow velocities measured. Aneurysm size change, endoleak classification, and outcome analyses were conducted in accordance with the reporting standards for endovascular aneurysm repair.

RESULTS

Patients. A total of 22 patients underwent endovascular grafting with a fenestrated device. There were 20 men and 2 women with a mean age of 76 ± 8 years (range, 62-92 years). Preoperative risk factors are listed in Table I. The abdominal aortic aneurysm (AAA) was associated with a common iliac aneurysm in two patients, and a thoracic aneurysm in one patient, all of which were ultimately repaired with an endovascular approach. The mean proximal neck diameter was 26 ± 3 mm (range, 21-30 mm) and proximal neck length 8 ± 5 mm (range, 3-16 mm), respectively. Moderate angulation (40° < 60°) of the proximal neck was noted in 10 patients and severe angulation (>60°) in 3 patients. Thrombus incorporating greater than two thirds of the proximal neck circumference was noted in 10 patients. Overall, 16 patients were treated with fenestrated grafts because of short proximal necks (3-10 mm), and 6 patients had compromised quality of necks with lengths ranging from 10 to 16 mm. Mean maximum transverse aneurysm diameter was 62 ± 14 mm. Prosthesis designs incorporated a total of 58 visceral vessels, with a mean number of fenestrations per patient of 2.6. Table II shows the distribution of renal, superior mesenteric, and celiac arteries treated. All prostheses were implanted successfully without any acute loss of branches (with the exception of a single accessory renal that...
Table I. Preoperative comorbidities or risk factors for the 22 patient cohort

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>No. of patients</th>
<th>%</th>
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<tbody>
<tr>
<td>Arterial hypertension</td>
<td>14</td>
<td>64</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>14</td>
<td>64</td>
</tr>
<tr>
<td>Renal insufficiency (serum creatinine &gt;120 μmol/L)</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td>COPD</td>
<td>16</td>
<td>73</td>
</tr>
<tr>
<td>Previous laparotomy</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td>Obesity (weight &gt;110% ideal body weight)</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>6</td>
<td>27</td>
</tr>
</tbody>
</table>

The predominance of hypertension, severe chronic obstructive pulmonary disease (COPD), and coronary artery disease (all patients were treated either medically or surgically for these conditions) characterized most of the population treated.

Table II. Distribution of vessels incorporated into the fenestrated devices

<table>
<thead>
<tr>
<th>Mesenteric fenestrations</th>
<th>No. of renal fenestrations</th>
</tr>
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<tbody>
<tr>
<td>None</td>
<td>2 5 0</td>
</tr>
<tr>
<td>SMA</td>
<td>0 13 1</td>
</tr>
<tr>
<td>SMA + CELIAC</td>
<td>0 1 0</td>
</tr>
</tbody>
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Most of the patients had devices involving two main renal arteries and the SMA. A single patient had a large accessory renal artery 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 5 demonstrates the patency of the visceral vessels incorporated into the repair. The 12-month primary patency was 94%, with an assisted primary patency of 98%.

was intentionally covered in one patient). Procedural time averaged 211 ± 55 minutes with a mean of 55 ± 20 minutes of fluoroscopy time. The mean volume of contrast used was 169 ± 43 mL.

Complementary endovascular procedures were performed with the initial procedure in 11 (50%) patients. The procedures included the placement of a balloon-expandable stent immediately below the renal arteries in three patients to seal a proximal leak and at the level of the aortic bifurcation in one patient to seal a distal leak in an aortoartery device. Wallstents (Boston Scientific, Natick, Mass) were implanted into five iliac limbs to alleviate kinking or unacceptable tortuosity after endograft deployment. Endograft extensions were required in two patients to achieve appropriate coverage of the iliac vasculature and adequate device overlap. Completion angiography demonstrated type 2 endoleaks in five patients. One patient required a femoral endarterectomy and prosthetic patch closure on the side of the main delivery system insertion.

Follow-up. There were no acute mortalities or aneurysm related deaths. The postprocedural CT depicted a type II endoleak in 4 patients, a proximal type I endoleak in 1 patient, and a type III (component-sealing defect) endoleak in 1 patient. The later two patients underwent an early secondary intervention. A balloon-expandable stainless steel stent was implanted at the proximal neck in the first patient, and a complementary extension piece was implanted increasing the overlap between modular components in the second patient, resolving both endoleaks. The mean follow-up was 6 months (range, 1-12 months). One patient died 6 months after the initial procedure from severe coronary insufficiency. There were no aneurysm-related deaths, and no patients were lost to follow-up.

The 30-day endoleak rate was 9% (2 type II endoleaks). Sac shrinkage (>5 mm) was noted in 53% (9 of 17) of patients at 6 months and 75% (3 of 4) of patients imaged at 12 months. The remaining patient had an increasing aneurysm size that was attributed to a patent inferior mesenteric artery. This was treated with transarterial glue embolization (TrueFill Glue; Cordis Endovascular, Great Lakes, NJ) after the 12-month CT scan.

Three patients (14%) developed an increase in serum creatinine (>30% over baseline value) during the course of the follow-up period. One patient had a transient rise from 1.3 mg/dL to 2.7 mg/dL that later diminished to 2.0 mg/dL by the 6-month measurement. A second patient suffered a ruptured thoracic aortic aneurysm with prolonged severe hypotension, incipient renal failure, and right renal artery occlusion. The rupture was treated with an endovascular graft, and the patient required hemodialysis for a period of 2 months before recovering his renal function. A right renal artery stenosis was diagnosed in a third patient from the 6-month duplex ultrasound scan. This stenosis was associated with a significant serum creatinine rise, which decreased to baseline levels after successful treatment of the stenosis with angioplasty and stenting. An additional branch vessel stenosis was detected in one patient that presented with abdominal pain approximately 30 days after the procedure. Duplex ultrasound scanning demonstrated elevated velocities at the origin of the superior mesenteric artery (SMA); however, the stenosis was not visualized angiographically. Intravascular ultrasound scanning demonstrated fabric material partially obstructing the SMA origin, which was treated successfully with a self-expanding stent. The primary patency and assisted primary patency rate of the 58 vessels incorporated in the fenestrated endografts, assessed by Kaplan-Meier analysis, were respectively 97% and 98% at 1 month, and 94% and 98% at 12 months (Fig 5).

DISCUSSION

A great deal of progress has been made since the inception of endovascular grafting in 1991. Complex anatomies that were previously considered untreatable with such an approach are now commonly addressed. The progression from an aortic tube graft to a modular bifurcated design greatly improved the versatility of this procedure. Large diameter iliac limbs and combined surgical and endovascular procedures have provided a means to address most complex iliac anatomy. However, the proximity of the aneurysm to the visceral vessels has limited the fixation and sealing potential for most grafts and poses the
outcomes. However, follow-up paradigms and outcome
various designs have been published, all with successful
without vessel loss or death. A number of case reports with
sealing and in infrarenal position. The addition of
proximal sealing is still required and must occur in the
effect on renal function. However, an adequate region of
Stanley et al reported a series of three patients also
vessels, and periprocedural mortality at 30 days was nil.
an implant design is potentially bene
proach in our institution. Incorporation of such vessels into
most frequent contraindication to an endovascular ap-
approach in an extremely morbid population that is associated with a
related deaths. However, the relatively high anesthetic risk
management. The expanded versatility of endovascular
aneurysms heretofore untreatable with an endovascular
questions as to the durability of such a repair remain.
There exists a substantial population of patients with
aneurysms heretofore untreatable with an endovascular
approach, unfit for open repair, and relegated to medical
management. The expanded versatility of endovascular
grafting has the potential to further diminish aneurysm-
related deaths. However, the relatively high anesthetic risk
in an extremely morbid population that is associated with a
decreased life expectancy and, thus, reduced benefit from
prophylactic treatment, must be considered during the
treatment selection process. Additional concerns with the
durability of such repairs have also resulted in considerable
speculation. The use of suprarenal stenting has been advo-
cated to enhance proximal fixation, particularly when cou-
pled with barbs, and was shown to have no detrimental
effect on renal function. However, an adequate region of
proximal sealing is still required and must occur in the
infrarenal position. The addition of fixed diameter fenestra-
tion provides the ability to maintain branch vessel patency.
It also has the potential to ensure a sealing zone that
incorporates the entire infrarenal neck and can extend
proximal to the renal arteries when the graft fabric is
anchored directly to the renal ostium. This technique has
allowed the successful exclusion of aneurysms that, strictly
speaking, may be defined as pararenal aneurysms (as de-
picted in Fig 4) under favorable anatomic conditions.

Despite the extended versatility of this type of prosthe-
sis, anatomic factors can seriously complicate the design
and delivery of the device. After initial graft positioning it is
critical to maintain rotational movement to properly orient
the fenestrations. Significant angulation within the proxi-
mal neck or small diameter, calcific, or overly tortuous iliac
anatomy will hamper this and increase the risk of acute
branch vessel loss. Furthermore, a proximal renal artery
bifurcation, as is frequently seen, undermines the ability to
properly stent the renal artery with a flarable stent. In these
circumstances we have used a kissing stent technique, (Fig
3, B); however, one cannot flare the stents properly, and
this adds a level of complexity to the procedure and might
increase the risk of loss of renal parenchyma. The fenes-
trated procedures take longer on average than conventional
infrarenal endografts and require more fluoroscopy time
and contrast media as well. Thus, in a neck that is felt to be
of good quality, a traditional prosthesis with secure fixation
should be used rather than a fenestrated device.

Renal function remained stable in all but three patients,
two of which were attributable to the procedure. Evalua-
tion techniques for renal artery stenosis and patency were
limited in this study to CT, angiography, and duplex ultra-
sound scanning. However, the significant amount of metal
artifact generated by the renal stents and stent graft pre-
cluded accurate calculations of renal stenosis from cross-
sectional imaging studies. One patient developed a renal
artery stenosis of a previously nonstenosed renal vessel
associated with an elevated serum creatinine 6 months after
implantation of the fenestrated device with a renal stent.
The stenosis and renal insufficiency were remedied by re-
peat angioplasty and stenting; however, the potential for in-
stant stenosis mandates careful assessment of the renal and
visceral vessels after device placement. A second patient was
noted to have a periprocedural rise in serum creatine that
was attributed to atheroemboli. Theoretically, the potential
for embolic problems could be greater with this procedure,
owing to the increased amount of manipulation required
within the proximal neck. A third patient was treated with a
fenestrated device for a 9-cm AAA in the setting of a
remote7-cm aneurysm of the mid descending thoracic
aorta. Although an endovascular repair of the thoracic
aneurysm was planned, the patient suffered a thoracic aortic
rupture. A period of prolonged (48 hours) hypotension was
associated with worsening renal function. He underwent an
urgent thoracic aortic endovascular repair, and, at that
time, he was noted to have occlusion of his right renal
artery. He required initial treatment with dialysis but ulti-
ately recovered his renal function.

The definitive nature of the proximal seal is manifest by
the relatively rapid size reduction noted in this small series.
Within 6 months, more than 50% of patients had aneurysms
decreasing >5mm. By 12 months, three of four patients

Fig 5. This expanded axis view demonstrates the primary and
assisted patency of any visceral vessels incorporated into a fenes-
trated repair, as calculated with the Kaplan-Meier method.
had decreasing aneurysm size, and the remaining patient was noted to have a type II endoleak. No patients experienced aneurysmal growth. The incidence of endoleaks is quite low (<10%) despite a rigorous high-resolution (1.5 mm reconstruction) CT follow-up protocol. Although the rate of decrease appears to be faster than nonfenestrated counterparts, the number of patients treated and follow-up duration is too short to provide a proper comparison.

Despite the complexity of the planning and intraoperative steps, the use of fenestrated devices has the potential to become widespread. Fixed imaging systems, well-stocked procedure rooms (with a variety of guiding catheters, balloons, stents, microcatheter, and other low-profile systems) and experienced interventionists are likely to achieve success. The backbone of the fenestrated technology is derived from the Zenith device, and consequently a solid understanding of the Zenith delivery system, in conjunction with significant experience in problem-solving techniques, will be helpful.

This series demonstrates favorable outcomes of juxtarenal aneurysm repair with a fenestrated endovascular graft that incorporates the renal and/or visceral aortic segment with graft material. The short-term absence of branch vessel loss, low endoleak incidence, rapid contraction of the aneurysm sac, and limited need for secondary interventions support further development and distribution of this device. However, the procedure remains challenging, the patient population is relatively unforgiving, and technical precision is mandatory to achieve a successful outcome.

REFERENCES


DISCUSSION

Dr Roy K. Greenberg. Well, at the time of abstract submission we had completed the procedure on 22 patients. We have now performed a total of 44 procedures and have 30 or more planned for the future. I truly believe that this is a technology that needs to be more widespread. How to enact this dissemination remains to be determined.

Dr. Charles Sternbergh (New Orleans, La). I very much enjoyed that presentation. I agree with you that this technology is going to be key in increasing the applicability of endovascular repair for our patients. There is an incorrect but pervasive impression that suprarenal devices are going to allow treatment of very adverse anatomy. I think we both know that attitude is going to be problematic. We need these fenestrated devices to offer a durable endovascular treatment option.
lar specialist needs to be quite familiar with the Zenith system for the procedure to work.

But at the same time, I think that we are on the tip of an iceberg in terms of training endovascular specialists to do these procedures. In my opinion the training can be widely disseminated.

Dr Piergiorgio Cao (Perugia, Italy). I enjoyed very much your presentation. I have a short technical question.

The Cook company tends to exclude patients with a neck less than 5 mm. You projected the slide in which the left renal artery arises below the neck Because you need to have at least a few millimeters below the lowest renal artery, how could you reach the sealing? How do you handle this problem? Do you put the Palmaz stent on that area?

Dr Greenberg. That is a good question. I think the use of fenestrated devices has caused me to reconsider what defines a sealing zone. Our protocol calls for a 3-mm proximal sealing zone. But how we define a proximal neck depends on the specific aortic morphology in the region of the renal arteries.

It is possible with this device to use the renal stent as a rivet and actually drag the fabric into the renal artery itself. Thus, when a stent is flared, the stent functions like a rivet that holds the fabric up against the wall. If it is functioning like a rivet, it extends the seal into the renal artery. So, an aneurysm opposite a renal artery, or abutting a renal artery, might be successfully treated with this device. However, this is not truly a branch vessel device. I would not try to use this device in a large aneurysm that incorporated the renal arteries. But if you can get the fabric into the renal artery itself, it does seal. Two other patients in our series are similar and have had successful sealing in the setting of disparate arteries. We have seen aneurysm shrinkage in all of those cases.

Dr Patrick Clagett (Dallas, Tex). I may have missed it, but with a lot of these aneurysms there is a considerable amount of laminated thrombus in the area. Was that the case with these patients? Do laminated thrombi contraindicate this approach?

Dr Greenberg. It was variable. I think that there is more manipulation in the proximal neck than with conventional devices. If there is a lot of thrombus, we may be subjecting patients to a higher incidence of atheroemboli, which we saw in one patient with adverse renal function. However, if the device is put in and oriented properly before being deployed, the amount of rotational motion is limited, thus reducing the risk of emboli. We continue to evaluate this risk in the ongoing trails.