Abdominal aortic aneurysm repair with the Zenith stent graft: Short to midterm results

Cherrie Z. Abraham, MD, Timothy A. M. Chuter, MD, Linda M. Reilly, MD, Stephen P. Okuhn, MD, Lisa K. Pethan, BSN, Robert B. Kerlan, MD, Rajiv Sawhney, MD, David G. Buck, MD, Roy L. Gordon, MD, and **Louis M. Messina, MD,** *San Francisco, Calif*

Purpose: **The purpose of this study was to assess the short-term and mid-term results of endovascular aneurysm repair with the Zenith stent graft (J Vasc Surg 2002;36:217-25.) in a single-center prospective study.**
Method: **Between October 1998 and July 2001, we used the Zenith stent graft for elective endovascular aneurysm repair in 116 patients, six of whom were women. The mean age was 75 years, and the mean aneurysm diameter was 60.3 ± 8.8 mm. Stent grafts were oversized 10% to 20% relative to computed tomographic (CT) scan–based diameter measurements. All repairs were performed in the operating room through surgically exposed femoral arteries. The results were assessed before discharge with three-phase, contrast-enhanced CT scan and plain abdominal radiograph. These studies were repeated at 1, 6, 12, and 24 months after operation. Follow-up periods ranged from 1 to 34 months.**
Results: **No failed insertions and no conversions to open surgery occurred. The diameter of the main body of the stent graft was 28 mm or more in 73 patients (63%). Additional stents were inserted during surgery to treat kinking in eight patients (6.9%) and renal artery encroachment in two patients (1.7%). Mean fluoroscopy time was 35.1 ± 18.3 minutes, contrast load was 146 ± 53 mL (350 mg/mL), and estimated blood loss was 249 ± 407 mL. The major complication rate was 9.5%, and the minor complication rate was 10.3%. The perioperative complications were myocardial infarction in four patients, arrythmia in four patients, and pulmonary embolism, renal failure, stroke, small bowel obstruction, femoral stenosis, digital embolism, and graft limb thrombosis in one patient each. All 116 patients went home from the hospital, but one patient died 2 weeks later of a combination of pulmonary embolism and myocardial infarction. Endoleak was seen on the first CT scan in 16 patients (15%); 15 were type II, and one was type III. No endoleaks of type I or IV were seen. Additional interventions were performed for each of the following conditions: type II endoleak (n = 4), type III endoleak (n = 1), femoral clamp injury (n = 1), renal artery stenosis (n = 1), and graft limb occlusion (n = 1). One patient had acute aneurysm dilatation and rupture caused by a type II endoleak through the inferior mesenteric artery 6 months after stent graft implantation. No cases were seen of late graft occlusion, stent graft migration, stent fracture, barb fracture, or secondary endoleak.**
Conclusion: **The Zenith device is safe, versatile, and effective in the short to medium term. Most patients need wide stent grafts (≥28 mm proximally and ≥16 mm distally) to achieve 10% to 20% oversizing to prevent type I endoleak. (J Vasc Surg 2002;36:217-25.)**

The Zenith stent graft (Cook, Inc, Bloomington, Ind) was developed in Australia[1] where it has been used in its current form[2] since 1997. This device has also been widely used in Europe, but in the United States, its use has been confined to Food and Drug Administration trials. We have used the Zenith system since 1998, accumulating a total of 116 cases with follow-up beyond a month. This experience is reported here as the basis for an evaluation of the safety, efficacy, and design of the Zenith device.

From the Divisions of Vascular Surgery and Interventional Radiology, University of California–San Francisco.
Sponsored in part by grants from the Pacific Research Foundation.
Competition of interest: Dr Chuter receives income from patent licensing agreements with William Cook, Inc and Guidant Corp. In addition, Dr Chuter served as a paid consultant for Guidant Corp, William Cook, Inc, and WL Gore, Inc.
Presented at the Sixteenth Annual Meeting of the Western Vascular Society, Santa Fe, NM, Sep 23-26, 2001.
Reprint requests: Dr Tim Chuter, UCSF Vascular Surgery, 505 Parnassus Ave, M-488, Box 0222, San Francisco, CA (
e-mail: chutert@surgery.ucsf.edu).
Submitted Oct 4, 2001; accepted Dec 14, 2001.

0741-5214/2002/$35.00 + 0 **24/6/125032**
doi:10.1067/mva.2002.125032

METHODS

This study was performed under two similar protocols: an individual physician-sponsored investigational device exemption with 89 patients and an industry-sponsored (Zenith, Cook, Inc) investigational device exemption with 27 patients divided into one low-risk arm and one high-risk arm. Both protocols were approved by the University's human studies review board.

Device description. The entire system has been described previously in detail.[2-4] We used the Trifab version in this study. The name refers to the routine use of three components—a bifurcated main body and two limbs.

The docking sites of the main body and the limbs all have a diameter of 12 mm, but the other ends vary in diameter according to the diameter of the implantation sites. The proximal end of the main body has a diameter 22 to 32 mm, and the distal ends of the limbs have diameters of 8 to 24 mm. Component lengths are available in increments of 15 mm. One of the most distinctive features of the Zenith device has an uncovered proximal stent, which

Table I. Inclusion criteria for Zenith stent graft

1. Proximal neck
   A. >10 mm in length
   B. ≤28 mm in diameter
   C. Infrarenal neck/AAA angulation ≤80 degrees
2. Iliac diameter >7 mm (after balloon angioplasty if necessary)
3. Dispensable IMA
4. Iliac artery angulation <90 degrees or <60 degrees in presence of severe calcification
5. Both iliac implantation sites >2 cm in length, <16 mm in diameter
6. No pregnancy
7. No anaphylactic reaction to contrast material
8. No allergy to stainless steel or polyester
9. Willingness and ability to comply with follow-up schedule
10. No serious systemic or groin infection
11. No coagulopathy

carries nine caudally oriented barbs at four different levels to enhance suprarenal fixation. The stents at the ends of each component are on the inside of the graft. All other stents are sutured to the outside. The delivery system has a long tapered tip and a valved sheath. The sheath is 18F (inner diameter) for main body grafts measuring 22 to 26 mm and 20F for those measuring 28 to 32 mm.

Patient selection. The basic inclusion criteria were the same for both protocols. These criteria are listed in Table I. The feasibility of endovascular repair was assessed with computed tomographic (CT) scanning and catheter angiography. Suitable patients were enrolled after full informed consent in accordance with the requirements of our institutional committee on human research.

Stent graft sizing. Preoperative measurements of neck diameter, aneurysm diameter, and common iliac diameter were made on the basis of CT scan images. Measurements of neck length, aneurysm length, common iliac artery length, external iliac artery diameter, and neck and length angulation were made on the basis of angiography with calibrated catheters. The proximal stent graft diameter was oversized by 4 to 6 mm relative to the outer diameter of the neck, as measured on the transaxial CT scan. The distal stent graft diameter was oversized by 0 to 2 mm relative to the largest diameter of the iliac implantation site. The main body stent graft was selected from five available lengths to minimize the gap between the contralateral docking site and the contralateral iliac orifice.

Insertion procedure. The steps in this operation have been described in detail elsewhere.[4] One unusual feature of the Zenith system is two-stage deployment of the main body. The central portion of the main body deploys as soon as it is released from the sheath, but the proximal stent is constrained within its own little cap, which is pushed off after contralateral stump catheterization. The stainless steel Z-stents are self-expanding. Nevertheless, a large compliant balloon is used to mold the fully deployed stent graft. Completion angiograms are performed with all guidewires removed so that any potential for kinking manifests itself. If necessary, a variety of adjunctive maneuvers are used to treat type I endoleaks, kinks, or stent graft impingement on the renal arteries.

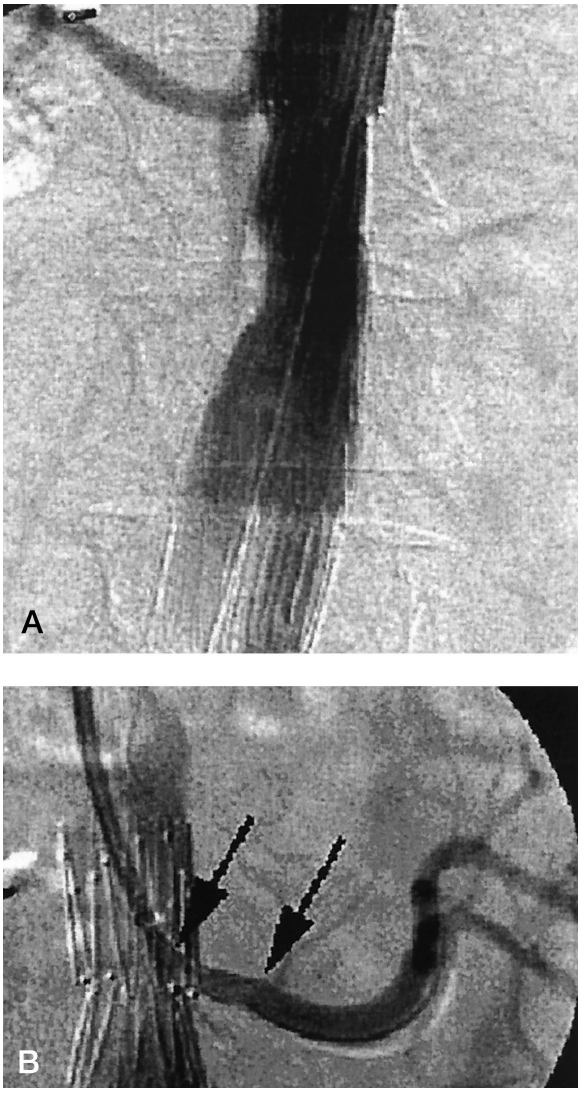

Fig 1. A, Intraoperative angiogram showing occlusion of the left renal artery. **B,** Intraoperative angiogram through a brachial guiding catheter, showing beneficial effect of a Palmaz stent (*arrows*) in the orifice of the left renal artery.

In the case of type I endoleaks, these maneuvers include balloon dilation for reorientation of the proximal stent, additional stent implantation, and additional stent graft implantation. As a result, no patients in this series left the operating room with a type I endoleak.

Palmaz stents (Cordis, Johnson & Johnson, Warren, NJ) were deployed into the renal arteries in two cases to clear a passage for blood around the top on the stent graft. One of these cases had shown impaired renal blood flow (Fig 1, *A* and *B*). In the other case, renal flow was brisk and fabric encroachment was suspected on the basis of the position of the proximal stent and graft markers.

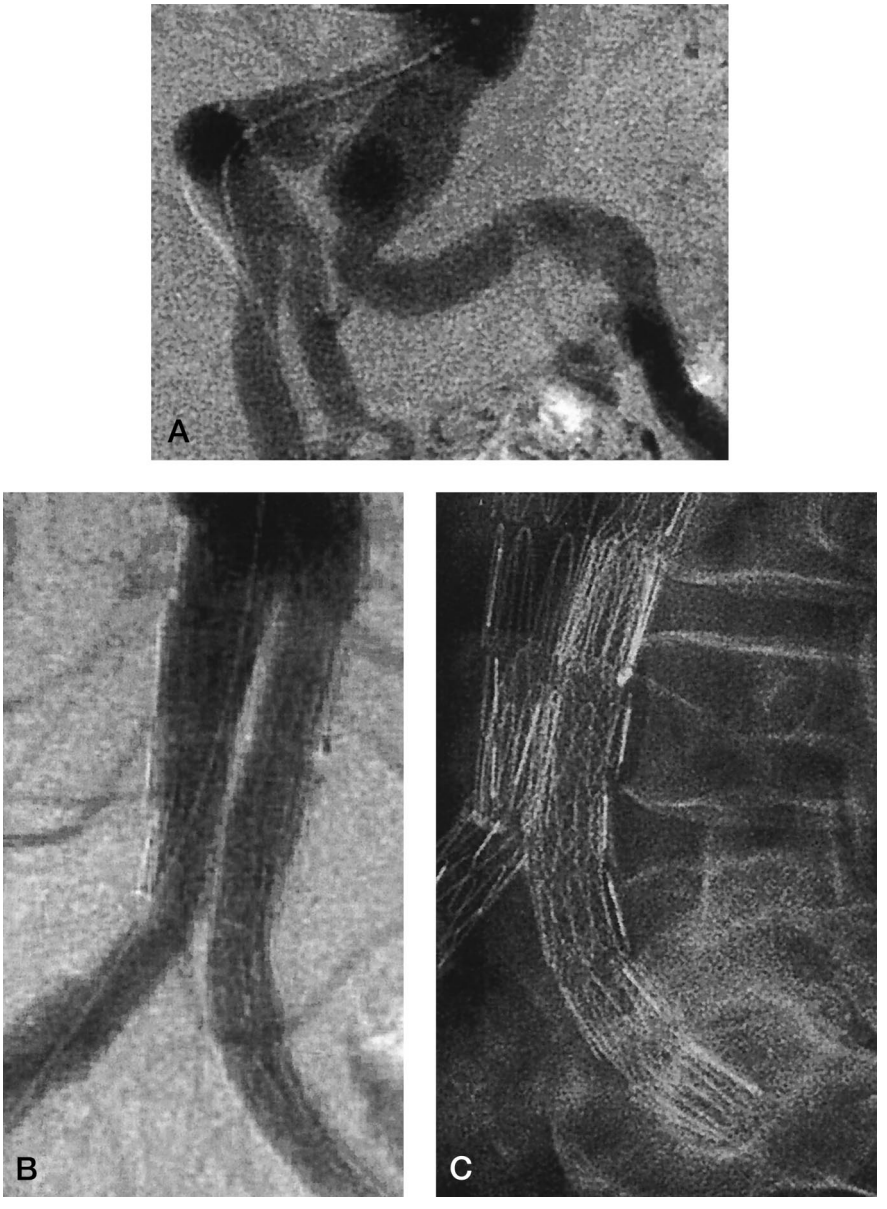

Fig 2. A, Preoperative angiogram showing tortuosity of both common iliac arteries, particularly the left. **B**, Intraoperative angiogram after Wallstent placement, showing the smoothly curved course and wide patency of the left limb. **C**, Postoperative abdominal radiograph showing the Wallstent in the left limb of the graft.

Wallstents (Boston Scientific, Minneapolis, Minn) were used in eight patients to treat kinking or compression or anticipated compression of the graft limbs at points of acute angulation (Fig 2, *A*, *B*, and *C*). Palmaz stents were used in two cases to support the graft limbs where they passed through areas of calcification and narrowing in the distal aorta (Fig 3, *A*, *B*, and *C*).

In two instances, the Zenith bifurcated system was converted to an aortouniiliac graft through the implantation of a tapered stent graft from the main body to the ipsilateral docking site. In one of the cases, uniiliac conversion was used to divert blood away from a heavily calcified fragile external iliac artery as the only way to achieve hemostatic repair. In the other case, the contralateral limb had never been catheterized and the limb had been deployed between the contralateral iliac artery and the aneurysm sac outside the main body of the stent graft. On both occasions, conversion, contralateral iliac occlusion, and femoral-femoral crossover were accomplished without further complications.

Follow-up. Routine follow-up included three-phase contrast-enhanced CT scans before discharge and at 1, 6,

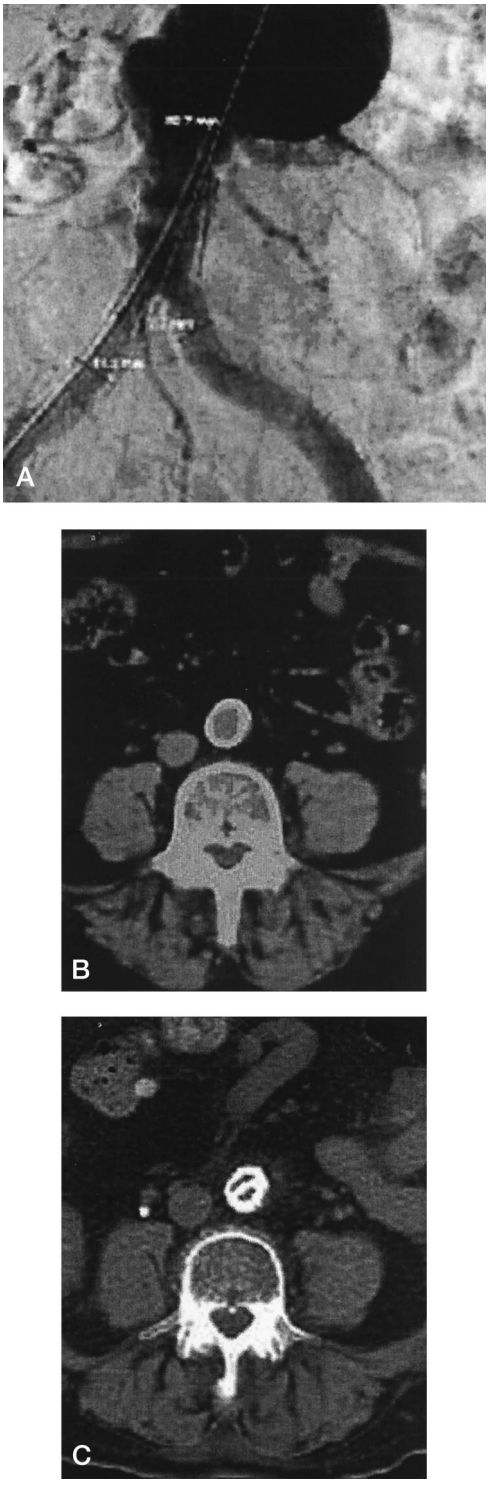

Fig 3. A, Preoperative angiogram showing a narrow, calcified distal aorta. **B,** CT of the distal aorta, showing heavy calcification. **C**, CT 6 months after endovascular repair, showing the two graft limbs within the distal aorta. Both limbs contain Palmaz stents; hence, their D-shaped cross-sectional profile. The graft lumens are actually larger than they appear, due to the stent artifact, and the patient has normal femoral pulses.

Table II. Patient demographics (n = 116) and comorbid conditions

Male/female	110/6
Mean age (y)	75 ± 7
Coronary artery disease	61.2%
Congestive heart failure	15.5%
Arrhythmia	22.4%
Chronic obstructive pulmonary disease	24.1%
Diabetes mellitus	16.4%
Hypertension	60.3%
Chronic renal failure*	12.9%
Smoking history	63.8%
Peripheral vascular disease	11.2%
No. of patients on chronic coumadin therapy	13

*Preoperative creatinine >1.5 mg/dL.

and 12 months and annually thereafter. The details of CT scan data acquisition and processing have been described in a previous report.[2] Posteroanterior and lateral abdominal radiographs were performed on the same schedule as CT scanning to assess stent graft structural integrity, shape, and position. Patients were seen in clinic at 2 weeks after surgery and then at 1, 6, and 12 months and annually.

Treatment of endoleak. Type II endoleaks on completion angiography were observed. Type I and type III endoleaks noted on completion angiography were treated immediately as described previously. Our policy was to investigate proximal type I endoleaks or possible type I endoleaks that were seen on the initial CT scan angiographically, although no such cases were seen in this study. All other endoleaks were observed. Those that persisted to 1 month were managed according to their presumed type, which depended mainly on the size and location of the perfused area. Isolated posterior endoleaks were presumed to be lumbar to lumbar only and were observed. All others were investigated angiographically with a view to coil embolization of inferior mesenteric feeders. According to our policy, aneurysm enlargement of more than 5 mm (not seen in this series) was also an indication for angiography and treatment.

Data collection. Routine prospective data collection included information on patient characteristics, preoperative arterial anatomy, preoperative and postoperative interventions, postoperative changes in aneurysm diameter, and the presence or absence of an endoleak.

RESULTS

Between October 1998 and July 2001, we performed endovascular repair of abdominal aortic aneurysm (AAA) in 116 patients with the Zenith bifurcated stent graft. Of the patients treated, 24.5% were American Society for Anesthesiology (ASA) classification II, 63.4% were ASA classification III, and 11.8% were ASA classification IV. Patient demographics and comorbid conditions are shown in Table II. Follow-up periods ranged from 1 to 34 months, with a mean of 10.3 ± 9.8 months. Fourteen patients were lost to follow-up.

Many patients treated in this study had wide implantation sites. Proximal neck diameter was 26 mm or more in

Table III. Patients with "difficult" anatomic characteristics

	No. of patients
Infrarenal neck/AAA aneurysm angle ≥45 degrees	34
Infrarenal neck length ≤15 mm	15
Infrarenal neck diameter ≥26 mm	30
Circumferential thrombus at neck (partial/complete)	19/3
RCI moderate to severe tortuosity	30
LCI moderate to severe tortuosity	30
RCI moderate to severe calcification	30
LCI moderate to severe calcification	29

RCI, Right common iliac artery; *LCI*, left common iliac artery.

Table IV. Perioperative data

Operating time (min)	175.0 ± 52.7
Fluoroscopy time (min)	35.1 ± 18.3
Contrast (mL)	146.2 ± 53.1
Regional anesthetic (no. of patients)	100
General anesthetic (no. of patients)	16
Estimated blood loss (mL)	249 ± 407
Time to oral intake (days)	0.46 ± 0.50
Time to ambulation (days)	1.07 ± 0.96
Length of stay (postoperative days)	2.9 ± 1.1

30 patients, with a mean of 23.9 ± 2.8 mm for the group as a whole. Consequently, the diameter of the main body of the stent graft was 28 mm or more in 73 patients, with a mean of 28.2 ± 4.2 mm for the group as a whole. Ipsilateral common iliac diameter was 14 mm or more in 46 patients, with a mean of 14.3 ± 5.2 mm for the group as a whole. Consequently, the ipsilateral limb of the stent graft was 16 mm or more in 46 patients, with a mean of 14.9 ± 3.4 mm in the group as a whole. Contralateral common iliac diameter was 14 mm or more in 41 patients, with a mean of 13.3 ± 3.1 mm for the group as a whole. Consequently, the contralateral limb of the graft was 16 mm or more in 42 patients, with a mean of 14.8 ± 3.2 mm for the group as a whole. Many patients also had other forms of challenging arterial anatomy (Table III). Four patients had associated or isolated common iliac aneurysms that necessitated predeployment embolization of the internal iliac artery and implantation of the stent graft limb in the external iliac artery.

All repairs were completed successfully. No failed insertions and no conversions to open surgery were seen. Data on the operation and perioperative recovery are shown in Table IV. Early and late complications are shown in Table V. All patients went home alive, although one died 2 weeks later of a combination of autopsy-proven pulmonary embolus and myocardial infarction. None of the other myocardial infarctions or arrythmias had any serious effects, except one in which myocardial infarction led to cardiac catheterization, which was complicated by contrast-induced renal impairment. One patient suffered a perioperative stroke. This patient's intraoperative course was notable

Table V. Complications

Perioperative complication	*No. of patients*
Arrythmia	4
Myocardial infarction	4
Pulmonary embolus*	1
Stroke	1
Renal failure (dialysis)	1
Wound hematoma	3
Wound lymphocele	4
Wound infection	1
Bowel obstruction	1
Digital embolism	1
Graft limb thrombosis	1
Femoral clamp injury	1
Late complication	
Renal artery occlusion	1
Rupture	1
Endoleak necessitating reintervention	4

*Death.

for intraoperative hypotension, resulting from a combination of severe aortic stenosis and general anesthesia. In the immediate postoperative period, this patient's deficits varied according to blood pressure. Functional recovery was complete within 3 months of operation. One patient had a small bowel obstruction develop on the third postoperative day. The cause was small bowel volvulus around an adhesive band from previous surgery. Two patients had new onset claudication in the postoperative period. In one of these, the cause was recurrent external iliac artery tortuosity, leading to kinking and thrombosis of the graft limb, which was implanted in the external iliac artery (Fig 4, *A*, *B*, and *C*). Femoral-femoral crossover graft successfully restored femoral flow and relieved the symptoms. The other case of new onset claudication was the result of clamp injury with plaque fracture and localized dissection, which necessitated a return to the operating room for endarterectomy. Another patient had self-limited toe pain and discoloration, which we attributed to embolism.

Endoleak was seen on the first postoperative CT scan in 16 patients (14.5%) and was still present at 1 month in 12 (11%). At 1 month, five patients had CT scan findings suggestive of type II endoleak through the inferior mesenteric artery (IMA). Angiography was performed in four cases, of which one proved to be a type III junctional endoleak that necessitated additional stent graft placement. The other three patients underwent successful embolization of the IMA trunk via selective catheterization of the superior mesenteric artery–IMA collateral route in the angiography suite. Two of these patients had no demonstrable endoleak on CT scan performed at 6 months. The other patient continues to show a persistent type II lumbar endoleak at 6 months with no increase in AAA size. The remaining endoleaks were assumed to be type II through the lumbar arteries on the basis of CT scan findings. All these have been observed, and all but four have since resolved. In patients with 1-year follow-up, mean aneurysm size decreased from 60.2 ± 8.8 mm to 51.2 ± 9.4 mm.

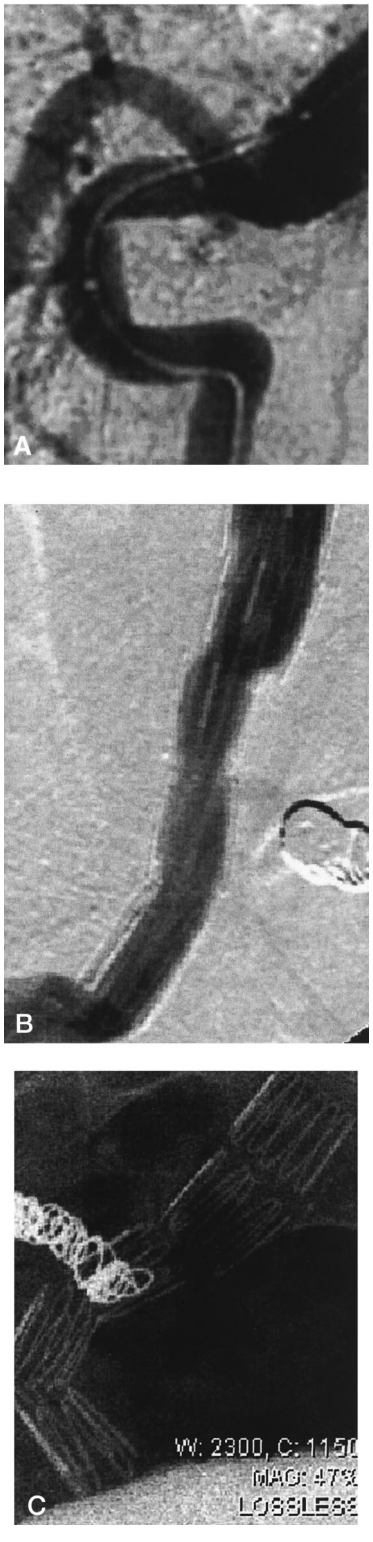

Fig 4. A, Preoperative angiogram showing tortuosity of the right external iliac artery. **B,** Intraoperative angiogram showing straightening of the right iliac artery by the right limb of the stent graft. **C,** Plain radiograph at 1 month after stent-graft insertion, showing recurrent iliac tortuosity and kinking of the stent graft.

The single case of untreated type II inferior mesenteric endoleak deserves a special mention because the management departed from our usual policy and because the patient went on to rupture. This patient (mentioned previously) had contrast-induced renal impairment after cardiac catheterization. We made no attempt to treat the endoleak for fear of inducing further renal damage in the setting of stable aneurysm diameter for the first 6 months of follow-up. At 7 months, the patient suddenly developed abdominal pain with CT scan signs of aneurysm dilatation (1 cm) and rupture. At operation, no arterial clamps were applied before opening of the AAA sac. The only source of bleeding into the aneurysm was the IMA, which was suture ligated. The stent graft was left in place. On the third postoperative day, the patient had a fatal myocardial infarction.

Two additional patients had significant renal complications. One needed dialysis in the postoperative period because of contrast-induced exacerbation of baseline renal dysfunction. The other was found, on CT scan, to have right renal artery thrombosis 6 months after stent graft implantation. On review of angiograms from the initial operation, it was discovered that markers on the proximal edge of the graft were at the same level as the renal arteries, indicating impingement on the renal orifices (Fig 5, *A*). The completion angiogram showed no apparent impairment of renal perfusion, hence the oversight. In addition, the completion angiogram showed a less severe degree of impingement on the left side. Repeat angiography showed right renal occlusion and left renal stenosis (Fig 5, *B*). Because the patient had contraindications to thrombolysis, no attempt was made to treat the occluded renal artery; however, a stent was placed in the left renal artery to push the proximal margin of the graft out of the renal flow channel.

No patients have shown significant aneurysm dilatation (>2 mm from baseline). No cases of stent fracture, barb fracture, stent graft migration, late graft limb occlusion, or secondary endoleak were seen.

DISCUSSION

Endovascular aneurysm repair with the Zenith system appears to be safe. Only one perioperative death and few serious complications occurred. The procedure also appears to be effective, at least in the short to mid term**.** No failed insertions or conversions to open surgery were seen, and all patients were free of direct endoleak (types I and III) within a month of operation. The sole failure of therapy was a case of aneurysm rupture caused by an untreated type II endoleak through the IMA. This case confirms our view that such leaks should be treated aggressively[5] but has no implications for stent graft performance.

By the time we started to use the Zenith device, we already had a large experience with other systems of endovascular aneurysm repair.[4,5] The only learning curve in this series related to specific characteristics of the Zenith device, some of which resulted in complications that we subsequently learned to avoid.

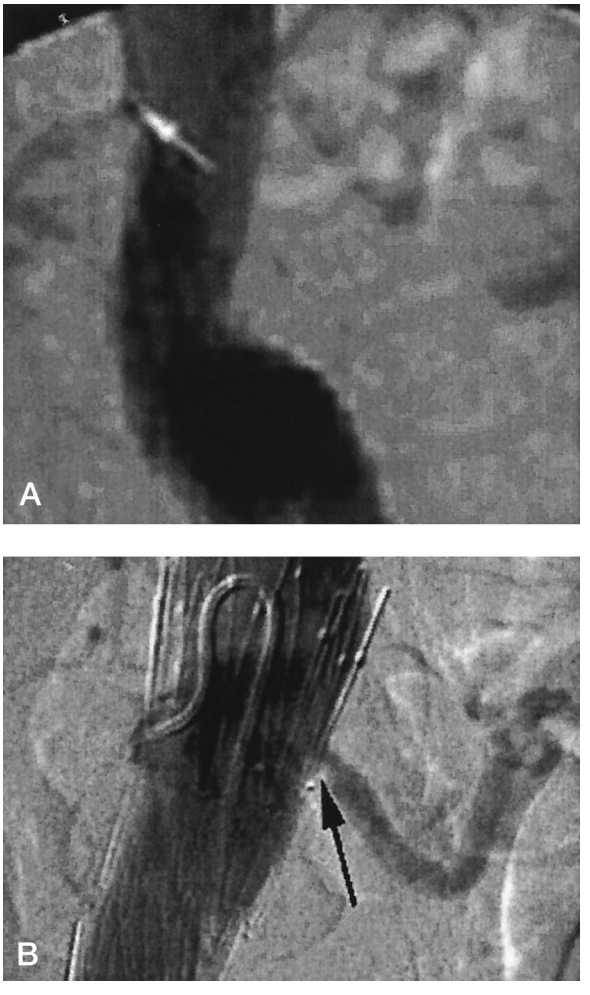

Fig 5. A, Poor-quality intraoperative angiogram, showing both renal arteries with a marker on the stent graft overlying the right renal orifice. There are no apparent abnormalities of renal artery flow or appearance. The stents and markers are barely visible on this subtracted image. **B,** Aortogram 6 months after stent-graft implantation, showing occlusion of the right renal artery and stent-graft impingement on the left renal orifice. The right renal artery was left untreated and the left treated with a balloon-expanded stent.

For example, the case of renal artery occlusion yielded several important lessons regarding the behavior of the Zenith device. Although two-stage deployment of the main body permits accurate deployment, one needs to be aware of the relationship between the relative locations of visible stents or markers and the proximal margin of the graft. Sometimes a look at the angiograms in unsubtracted mode is necessary. One also needs to be aware that covering more than half the renal orifice without any appreciable change in renal flow or profile is possible (Fig 5, *A*). Once deployed, the main body of the stent graft cannot be moved more than 2 to 3 mm. The only way to salvage an inadvertently covered renal artery is renal stent placement (Fig 1).

The case of graft limb occlusion was also instructive. The graft appeared free of kinks on completion angiograms only because of stent graft–induced straightening, which prevented kinking (Fig 4, *A*). The return of iliac coiling was associated with delayed angulation, kinking, and occlusion of the stent graft (Fig 4, *B*). We take from this that native anatomy will reassert itself, intraoperative findings are not permanent, and additional stent support may be warranted in cases of severe tortuosity (Fig 2). We have become fairly liberal with adjunctive stenting, hence the intraoperative insertion of eight Wallstents. This approach was perhaps responsible for the low rate of limb thrombosis (<1%).

Other complications, notable by their absence, included failed insertion, iliac injury, inadvertent internal iliac occlusion, type I endoleak, secondary endoleak, and migration. Many of the patients in this series had severe iliac tortuosity that was often associated with calcification. We found that the combination of a stiff guidewire (Lunderquist) and the external profile of this system (long taper, sheath size <20F) allowed transfemoral insertion in circumstances that would otherwise have necessitated invasive adjunctive maneuvers, such as iliac straightening, iliac conduit, or direct iliac access.

The routine use of three independently deployed components, two limbs and a main body, allowed us to focus on one target at a time and achieve accurate distal placement by varying the overlap between components. In theory, this introduces an additional junction and another potential site for stent graft instability. However, the potential for kinking and component separation is minimized by the use of a long main body. On the contralateral side, the gap between the docking site and the iliac orifice is short and the potential for movement small, and on the ipsilateral side, there is often no gap at all because the docking site is usually inside the ipsilateral iliac artery.

The absence of type I endoleak may be attributable, in part, to the wide range of stent graft diameters. Eurostar data show a decline in the rate of type I endoleak as the degree of oversizing increases to 20%.[6] This degree of oversizing is often difficult to achieve with the current Food and Drug Administration–approved devices,[7,8] for which the largest available diameter (in the United States) is 26 mm. We used a graft smaller than 28 mm in less than half of the cases in this series.

As far as we know, only been one case has been reported of barb fracture with the current Zenith stent design.[9] Perhaps this phenomenon is rare, or perhaps diagnosis is just difficult even with high resolution radiographs in multiple views.

Our follow-up period is too short to draw conclusions regarding the incidence of migration and late rupture, but these also seem to be rare complications, given the paucity of reported cases and the large number of Zenith stent grafts that have been inserted worldwide in the past 4 years. Barb-mediated attachment seems to be important in prevention of migration and late rupture, even when some of the barbs fracture.[10] Both migration and aneurysm rupture are far more common with the AneuRx system (Medtronic, Santa Rosa, Calif), which lacks barbs, than the Ancure system (Guidant, Menlo Park, Calif), which (like the Zenith system) has a self expanding Z-stent and many barbs.

We conclude that the Zenith device is safe, versatile, and effective as a means of excluding AAAs from the circulation. In another 4 years, we will have the data to comment on its stability and its efficacy as a means of preventing AAA rupture.

REFERENCES

1. Lawrence-Brown MM, Hartley D, MacSweeney ST, Kelsey P, Ives FJ, Holden A, et al. The Perth endoluminal bifurcated graft: development and early experience. Cardiovascular Surg 1996;4:706-12.
2. van Schie G, Sieunarine K, Lawrence-Brown M, Hartley D. The Perth bifurcated endovascular graft for infrarenal aortic aneurysms. Semin Intervent Radiol 1998;15:63-9.
3. Greenberg RK, Lawrence-Brown M, Bhandari G, Hartley D, Stelter W, Umscheid T, et al. An update of the Zenith and endovascular graft for abdominal aortic aneurysms: initial implantation and mid-term follow-up data. J Vasc Surg 2001;33:S157-64.
4. Chuter TA, Reilly LM, Faruqi RM, Kerlan RB, Sawhney R, Canto CJ, et al. Endovascular aneurysm repair in high risk patients. J Vasc Surg 2000;31:122-33.
5. Chuter TA, Faruqi RM, Sawhney R, Reilly LM, Kerlan RB, Canto CJ, et al. Endoleak after endovascular repair of abdominal aortic aneurysm. J Vasc Surg 2001;34:98-105.
6. Mohan IV, Laheij RJ, Harris PL. Risk factors for endoleak and the evidence for stent-graft oversizing in patients undergoing endovascular aneurysm repair. Eur J Vasc Endovasc Surg 2001;21:344-9.
7. Makaroun MS. The Ancure endografting system: an update. J Vasc Surg 2001;33:S129-34.
8. Zarins CK, White RA, Moll FL, Crabtree T, Bloch DA, Hodgson KJ, et al. The AneuRx stent graft: four year results and worldwide experience 2000. J Vasc Surg 2001;33:S135-45.
9. Stelter W. Oral presentation at the E2B2: Endograft 2001 and Beyond; 2001 Jul; Dublin, Ireland.
10. Najibi S, Steinberg J, Katzen BT, Zemel G, Lin PH, Weiss VJ, et al. Detection of isolated hook fractures 36 months after implantation of the Ancure endograft: a cautionary note. J Vasc Surg 34:353-6.

DISCUSSION

Dr Wesley S. Moore (Los Angeles, Calif). First of all, I would like to thank Dr Chuter for sending me a copy of his manuscript well in advance of the meeting.

Dr Chuter and his colleagues are to be congratulated for what can only be called a remarkable success story in the management of patients with abdominal aortic aneurysm using a stent graft. They have described their experience during the investigational phase of the Zenith stent graft with implantation in 116 patients. It is particularly noteworthy that they have had a 100% success rate in implantation, and no patient required conversion to open repair in their series. No other series to date of either the approved or the investigational stent grafts has been able to accomplish that record. In my personal experience with nearly 200 implantations using the Ancure device, my overall success rate has been 93%. While the recent success rate is better than the early experience, due primarily to better patient selection, it has still not reached the 100% success level. Dr Chuter's success must be credited to at least two factors: good patient selection due to his extensive experience with stent grafts using other platforms, and the versatility as well as the streamlined delivery system of the Zenith stent graft. It is also noteworthy that 63% of his implants utilized proximal attachment systems that were ≥28 mm. Since the currently approved devices have a limit of 26 mm, it would appear that the Zenith system will expand the utilization of stent grafts in patients who would not have been candidates with other devices. Likewise, more than a third of the patients had iliac arteries that were ≥14 mm in diameter and required distal attachment systems that were ≥16 mm in diameter. In the case of the Ancure system, which is a unibody construction with graft limbs being equal to half the diameter of the proximal attachment system, the maximum diameter of an iliac artery that could be accommodated would be 13 mm. Thus, once again, stent graft utilization has been expanded by the Zenith system. Increased utilization and ability to achieve a 100% success rate for implementation is due in large part to the fact that the delivery sheaths range from 18 to 20 French diameter. In the case of the Ancure system, a 23 French delivery system is required. Thus, the Zenith system is able to pass through smaller diameter arteries. This will also have an effect of increasing utilization. The authors' experience is also remarkable in that they were able to completely avoid Type I endoleaks. Their overall endoleak rate was an acceptably low 14.5%, which dropped to 11% by 1 month. The vast majority of these were Type II with only one Type III endoleak that was treated by secondary intervention. Their 30-day mortality rate included one patient, for a 0.86% overall mortality, and the nonfatal myocardial infarction rate was 3.45%. There were single instances of other complications that were not particularly device-related with the exception of renal artery compromise. Here we do have a problem that is device specific. Since the Zenith system uses a stent that extends above the renal arteries, the placement of the covered portion of the stent in relationship to renal artery orifices can be a problem if there is an attempt to treat patients who have a short proximal neck. The authors report two cases in which the fabric partially covered the renal arteries and required secondary intervention with the placement of a Palmaz stent to push down the fabric and maintain patency of the renal artery. One further patient was found to have a renal artery occlusion on one side and a partial occlusion on the other. A Palmaz stent salvaged the stenotic artery but the renal occlusion resulted in the loss of a kidney. Finally, there was one patient who went on to rupture an aneurysm within 6 months of implantation. This apparently was due to a Type II endoleak secondary to a patent inferior mesenteric artery, which resulted in aneurysm enlargement and rupture. The authors stated that they were reluctant to treat this because of the fact that the patient had contrast-induced compromised renal function, and they were worried about making it worse. Clearly, if they had it to do over again, I suspect that they would have intervened and accepted further compromised renal function rather than accepting what turned out to be a fatal rupture.

I have several questions that I would like to pose to the authors.

First, they mentioned that no patient was allowed to leave the operating room with a Type I endoleak and that there were several options available to manage this intraoperatively. In fact, how many Type I endoleaks did they see on the first arteriogram, or was the 10% to 20% oversizing effective in preventing them in the first place?

Second, were the 116 patients treated with the Zenith stent graft consecutive, or were patients mixed and matched among several stent graft prototypes under investigation? With a 100% implant success rate, the issue is, were there patients who were turned down for the Zenith stent graft who underwent implantation with another device?

Third, there has been considerable concern about stent graft designs that involved placing struts across the renal arteries, including the Zenith device. While it is easy to understand how compromised renal function might occur if the fabric were to partially cover the renal artery, might some of the patients with compro-

mised renal function, attributed to contrast sensitivity, be in fact a consequence of embolization off a strut that crosses a renal artery?

And fourth, the authors have made a very strong case for the utility and versatility of the Zenith system. Can they share with us any information as to how soon this device will be commercially available?

Finally, I very much enjoyed reading the authors' manuscript, and recommend it to you for your consideration at the time of its publication.

Dr Timothy A. M. Chuter. Thank you, Dr Moore, for your insightful comments and questions. If only I had equally insightful answers.

We lack good data on the rate of intraoperative endoleak. The treatment of endoleak was generally regarded as just another stage in the primary procedure. I can tell you that we added proximal extensions in only two cases, both of which had a proximal Type I endoleak on the initial angiogram. I am a firm believer in oversizing as a means of preventing Type I endoleak. As the Eurostar group demonstrated, the lowest endoleak rate occurs with 20% oversizing.

Regarding your second question, no, these were not consecutive cases. Our switch to Zenith took place over a 2-year period, during which we also used a homemade stent-graft. Early in the study, the homemade stent-graft predominated, mainly because there was a long delay in Zenith device manufacture. More recently, we have used the homemade stent-graft only in cases that did not meet the Zenith selection criteria. The availability of a backup device for the very difficult cases was probably a big factor in the high success rate reported here. As Michael Lawrence-Brown has noted, the failure rate with the Zenith device is very low when one sticks to the stated selection criteria, especially those that relate to neck anatomy.

I used to be more concerned about the effects of pararenal stent placement than I am now. It is certainly possible that a transient shower of very small emboli was responsible for some postoperative renal impairment, but I think contrast nephropathy is a more important cause. There were no signs of renal infarction on the postoperative CT and no evidence of continuing deterioration to suggest ongoing embolism. The most likely source for an intraoperative shower of small atheroemboli would be the aorta, but had this occurred, we would have expected to see evidence of embolism elsewhere.

The people at Cook are in the process of submitting the results of their multicenter study to the FDA. If, as they hope, the FDA accepts 5-year data from Australia as evidence of long-term efficacy, the device might be available in the second quarter of next year. On the other hand, if they are required to have 1 year follow-up from the US study, the device will not be available until the fourth quarter.