A multicenter experience with the Talent endovascular graft for the treatment of abdominal aortic aneurysms

Peter L. Faries, MD,[a] Bruce J. Brener, MD,[b] Timothy L. Connelly, MD,[c] Barry T. Katzen, MD,[d] Vania L. Briggs, BA,[a] James A. Burks, Jr, MD,[a] Edwin C. Gravereaux, MD,[a] Alfio Carroccio, MD,[a] Nicholas J. Morrissey, MD,[a] Victoria Teodorescu, MD,[a] Jamie Won, BA,[a] Salvatore Sparacino, BA,[a] Kristina S. Chae, BA,[a] Larry H. Hollier, MD,[a] and **Michael L. Marin, MD,[a]** *New York, NY; Newark, NJ; Urbana, Ill; and Miami, Fla*

Objective: **The Talent endovascular graft has been used in the treatment of abdominal aortic aneurysms (AAAs) in more than 13,000 patients worldwide. However, information regarding the results of its use has been limited. This report describes the experience with 368 patients with AAAs who underwent treatment at four medical centers as part of an investigator-sponsored investigational device exemption trial.**

Methods: **Patients with AAAs were enrolled at four sites during a 32-month period from January 1999 to July 2001. All patients underwent treatment for infrarenal AAA with the Talent endovascular graft. Repair was performed with transrenal stent fixation under epidural (362/368 patients; 98.3%), local (4/368 patients; 1.1%), or general (2/368 patients; 0.5%) anesthesia. The average diameters were: maximum aortic aneurysm, 6.2 ± 1.2 cm; proximal aortic fixation site, 2.6 ± 0.4 cm; and distal iliac fixation site, 1.4 ± 0.6 cm. Bifurcated grafts were used in 276 of 366 patients (75%), aortouniiliac in 57 of 366 patients (16%), and tube aortoaortic in 33 of 366 patients (9%). Multiple comorbid medical conditions were present in all patients (average, 4.7 conditions/patient). The mean age was 75.8 years, and 85% of the patients were male. Follow-up period ranged from 2 to 33 months (mean, 7.3 months).**

Results: **Endovascular graft deployment was accomplished in 366 of 368 patients. In the 263 patients followed for at least 6 months after endovascular repair, AAA diameter decreased by 5 mm or more in 83 patients (32%); diameter remained unchanged (change < 5 mm) in 157 patients (60%) and increased by 5 mm or more in 23 patients (8.7%). Major morbidity occurred in 46 of 368 patients (12.5%), and minor morbidity occurred in 31 of 368 (8.4%). The 30-day mortality rate was 1.9%. Secondary procedures were performed in 32 patients (8.7%). Late rupture occurred in two patients, and late deaths unrelated to AAA occurred in 32 patients (8.7%) during the follow-up period. The primary technical success rate for all patients was 93.4%. The 30-day primary procedural success rate was 73.3%. The 30-day secondary procedural success rate was significantly higher at 85.8%. Computed tomographic scan was performed within 1 month after surgery in 349 patients. An endoleak was present in 43 of 349 patients (12.3%). These endoleaks were comprised of 10 attachment site (type I; 2.9%), 31 retrograde side-branch (type II; 8.9%), and two transgraft (type III; 0.6%).**

Conclusion: **These midterm findings show a high degree of technical and procedural success achieved in a patient population with extensive comorbid medical illnesses with low perioperative morbidity and mortality rates. Further follow-up study will be necessary to determine the effectiveness of the Talent endograft for the long-term treatment of AAA. (J Vasc Surg 2002;35:1123-8.)**

In the 10 years since the first published report of endovascular repair of abdominal aortic aneurysms (AAA),[1] the devices used for endovascular repair have gone through several phases of evolution. Physician-fabricated stent grafts have been largely replaced with commercially produced endovascular grafts.[2-6] Extensive data have been published on the results of AAA repair with the first generation of commercially produced devices, including the EVT/Guidant Ancure (Menlo Park, Calif)[7,8] and the Medtronic AneuRx (Minneapolis, Minn) grafts.[9] Modifications to the original design concepts of these devices have resulted in subsequent generations of additional endovascular grafts that are undergoing clinical evaluation.[10,11] The Talent endovascular device (Medtronic/AVE-Worldmedical, Sunrise, Fla) is currently being evaluated in a phase II Food and Drug Administration trial to determine its efficacy in the treatment of AAA.[12] The device, with both the original and the modified low-profile delivery systems, has been used in AAA repair in more than 13,000 patients worldwide, making it one of the most widely used endovascular grafts to date. Despite this extensive clinical experience, limited data regarding the results of AAA treatment with the Talent low-profile system (Talent-LPS) graft have been

From the Division of Vascular Surgery, Department of Surgery, Mount Sinai School of Medicine[a]; Newark Beth Israel Medical Center[b]; Carle Heart Center[c]; and Miami Cardiac and Vascular Institute.[d]

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Reprint requests: Peter L. Faries, MD, Division of Vascular Surgery, Department of Surgery, Mount Sinai Medical Center, 5 E 98th St, Box 1259, New York, NY 10029 (e-mail: peter.faries@mssm.edu).

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Table I. Patient demographics and comorbid illnesses

Characteristic	*No.*
Male gender	313 (85%)
Hypertension	254 (69%)
Coronary artery disease	217 (59%)
Previous CABG or PTCA	88 (24%)
COPD	92 (25%)
Hypercholesterolemia	66 (18%)
Renal insufficiency	48 (13%)
End stage renal disease	7 (2%)
Peripheral vascular disease	48 (13%)
Diabetes	37 (10%)
Stroke or TIA	18 (5%)
History of recent smoking	309 (84%)
Average age (years)	75.8

CABG, Coronary artery bypass grafting; *PTCA*, percutaneous transluminal angioplasty; *COPD*, chronic obstructive pulmonary disease; *TIA*, transient ischemic attack.

published.[13-17] This report details the results of a multicenter investigational device exemption trial in which 368 patients with AAA underwent treatment with the Talent-LPS endovascular graft system.

PATIENTS AND METHODS

Database and patient demographics. From January 1999 to July 2001, a consecutive series of 368 patients with AAA were enrolled in a multicenter investigational device exemption trial with the Talent-LPS endovascular grafting system. All data regarding each patient, procedure, and follow-up study were entered prospectively in a computerized vascular registry. All procedures were performed with protocol approved by the Institutional Review Board of the Mount Sinai School of Medicine and approved for an investigational device exemption by the Food and Drug Administration. The responsible authors had access to the raw data, which was reviewed to confirm the statistical analysis before writing the manuscript. All patients had extensive concomitant medical conditions that rendered conventional open surgical repair high risk (average, 4.7 comorbid conditions/patient; Table I).

Endovascular device description. The Talent-LPS endovascular grafting system has been described in detail previously.[12] Briefly, the endoprosthesis is comprised of woven polyester fabric, which is supported along its entire length with self-expanding nitinol stents joined by a nitinol spine (Fig 1). A 15-mm uncovered proximal stent allows for transrenal fixation (Fig 2). The endoprosthesis is modular and is custom fabricated to the specifications of each individual patient anatomy. The endoprosthesis may be made in a bifurcated aortobiiliac, a tapered aortouniiliac, or a tube aortoaortic configuration. The diameters available for the aortic body of the device range between 16 and 36 mm. The iliac limbs range from 8 to 22 mm in diameter. The delivery system used to deploy the Talent endoprosthesis contains an internal push rod placed coaxially within a tapered-tipped delivery sheath. The outer diameter of the delivery system ranges between 18F and 24F. Exchange of the delivery sheath over the push rod exposes the endoprosthesis, allowing self-expansion and deployment. A compliant polyurethane balloon is used to ensure complete apposition of the endoprosthesis to the artery wall.

Preoperative management. Preoperative assessment included standard contrast arteriography and helical computed tomographic (CT) scan, with intravenous contrast and images acquired at 3-mm intervals. These studies were used to determine suitability for endovascular repair and to prepare the specifications of the endovascular graft. Maximum aortic diameter ranged from 5.1 cm to 10.2 cm (mean, 6.2 ± 1.2 cm). The average maximum common iliac artery diameter was 15.1 ± 4.5 (range, 0.8 to 6.0 cm). The average diameter of the aorta at the proximal implantation site was 2.6 ± 0.4 cm (range, 1.8 to 3.4 cm). The diameter of the iliac arteries at the distal implantation site ranged from 0.6 to 2.2 cm (mean, 1.4 ± 0.6 cm).

Surgical procedure. All procedures were carried out in the operating room with a radiolucent table under fluoroscopic guidance. Epidural or spinal anesthesia was used in 362 of 368 patients (98.3%). General anesthesia was used in four cases (1.1%), and local anesthesia in two cases (0.5%). Exposure of the common femoral and distal external iliac arteries was performed with an oblique groin incision.[18] Bifurcated aortobiiliac endoprostheses were used in 276 of 366 patients (75.4%) (Fig 3); tapered aortouniiliac endoprostheses were placed in conjunction with concomitant femorofemoral bypass and contralateral common iliac artery occlusion in 57 patients (15.6%), and tube aortoaortic endoprostheses were used in 33 patients (9.0%). All patients were admitted to the hospital after surgery for observation, and 87% were discharged to home on the 1st postoperative day.

Postoperative monitoring and follow-up examination. All patients were entered into a standard follow-up protocol that included office visits within 1 month of surgery, at 6 and 12 months after surgery, and annually thereafter. During the visit, a detailed history and physical examination were performed. Plane radiographs of the abdomen and a contrast enhanced helical CT scan also were obtained at these intervals. Angiography was performed selectively on the basis of persistent endoleak or aneurysm expansion or for evidence of graft limb compromise. Follow-up periods ranged from 2 to 33 months (mean, 7.3 months).

Definitions and statistical analysis. Definitions used are those outlined by the Ad Hoc Committee on Reporting Standards, Society for Vascular Surgery/North American Chapter of the International Society of Cardiovascular Surgery.[19] In addition, the definition of *primary technical success* is survival of the procedure with an excluded aneurysm (no endoleak) and a patent graft without need for a second intervention as described by Zarins et al.[20] *Primary procedural success* was defined as survival at 30 days with a patent graft, an excluded aneurysm, no need for reoperation or secondary procedures, and no major complication. *Secondary procedural success* included survival at 30 days with a patent graft and an excluded aneurysm.[20] All figures are represented as the mean ± the standard deviation. A

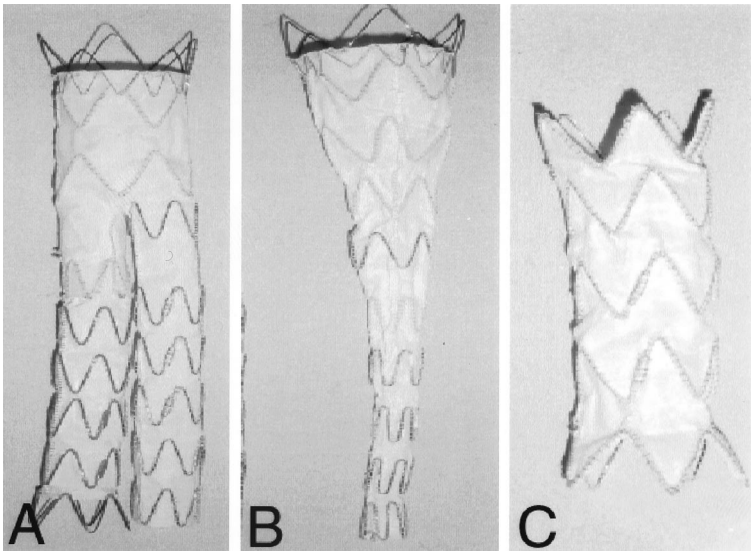

Fig 1. Talent endovascular prostheses. **A,** Modular bifurcated prosthesis is comprised of aortic body and ipsilateral iliac limb and separate contralateral iliac limb. **B,** Aortouniiliac prosthesis is gradually tapered from aortic attachment site to iliac attachment site and is used in conjunction with femorofemoral crossover graft and occlusion of contralateral common iliac artery. **C,** Aortoaortic tube prosthesis.

Student *t* test was used to compare continuous variables. Significance was assumed at a *P* value of less than .05.

RESULTS

Procedural and technical success. The Talent endovascular graft was deployed in 366 of the 368 patients enrolled in the study. The primary technical success rate for all patients was 93.4%. The 30-day primary procedural success rate was 73.3%. The 30-day secondary procedural success rate was significantly higher as expected and was 85.8%.

Aneurysm size. Aneurysm size was calculated for patients with 6 months or more of follow-up examination. Maximum aortic diameter decreased by 5 mm or more in 83 of 263 patients (32%). Maximum aortic diameter remained unchanged (change < 5 mm) in 157 of 263 patients (60%). Maximum aneurysm size increased by 5 mm or more in 23 of 263 patients (8.7%). Twenty-three patients with an increase in aneurysm size had a demonstrable endoleak on CT scan results. However, no endoleak was shown in the remaining 10 patients. For the study group overall, the average maximum aortic diameter consistently decreased during the follow-up period. A statistically significant reduction in average maximum aneurysm size was shown for the 165 patients who were followed for at least 12 months (mean preoperative aneurysm diameter, 59.7 ± 8.9, versus mean 12-month aneurysm diameter, 55.4 ± 11.2; $P = .014$).

Endoleaks. Endoleaks were present in a total of 43 of 349 cases (12.3%) on CT scan results obtained within 30 days after surgery. These endoleaks were comprised of 10 attachment site (type I; 2.9%), 31 retrograde side-branch (type II; 8.9%), and two transgraft (type III; 0.6%). All transgraft endoleaks were successfully treated with second-

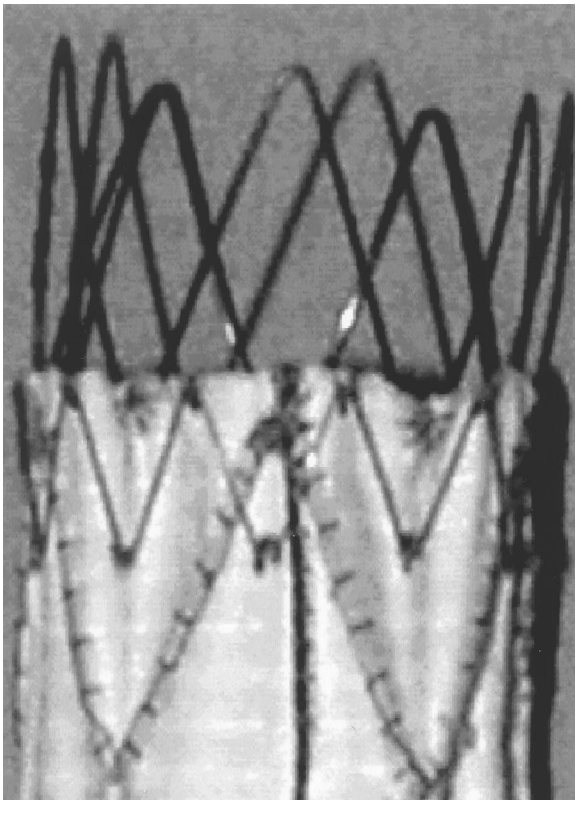

Fig 2. Uncovered proximal stent (15 mm) allows for transrenal device fixation.

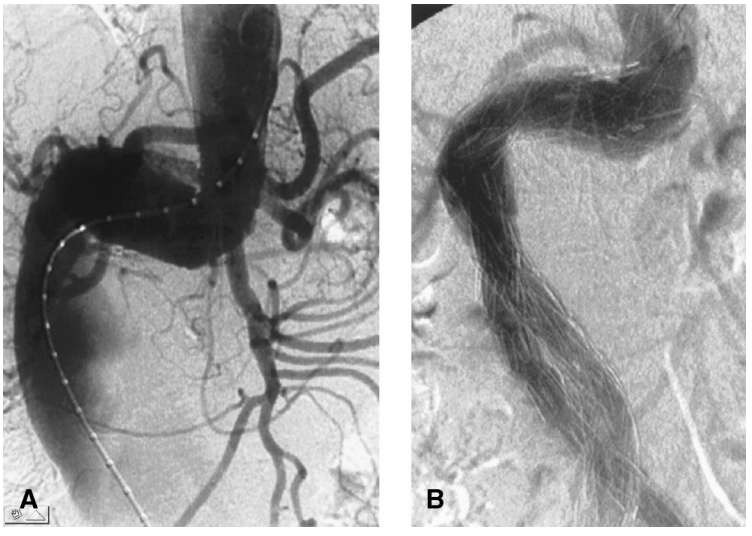

Fig 3. Treatment of AAA with Talent-LPS device. **A,** Marked tortuosity of proximal aortic neck presented significant challenge to endovascular treatment. **B,** Use of proximal extension prosthesis permitted device to conform to aortic neck and prevent endoleak at proximal fixation site.

ary endovascular interventions. At 12 months, only eight of 165 patients (4.8%) showed retrograde side-branch endoleaks. Attachment site endoleaks persisted in all patients who were unable to undergo secondary endovascular procedures or conversion to conventional open surgical repair (three patients at 12 months after surgery). Secondary procedures could not be performed because of inadequate proximal implantation length distal to the renal ostia. Two patients with persistent attachment site endoleaks that could not be treated with endovascular means and who were unable to undergo conventional open repair died of subsequent aneurysm rupture at 18 and 23 months, respectively, after surgery.

Secondary procedures. Conversion to open surgical repair was necessary in four patients with attachment site endoleaks not amenable to treatment with endovascular means. One of these four patients died of multisystem organ failure in the 30-day postoperative period. During the initial 30-day follow-up period, 10 patients (2.7%) had iliac limb occlusion. An additional eight patients (2.2%) had iliac limb occlusion develop during the subsequent follow-up period. Limb occlusion was treated with thrombectomy, angioplasty, and stent placement in six of 18 cases (33%), with femorofemoral or axillofemoral bypass in 11 of 18 cases (61%), and with no intervention in one patient (6%). Coil embolization of retrograde side-branch endoleaks that persisted for more than 6 months and were associated with an increase in aneurysm size was performed in five patients (16% of type II endoleaks).

Morbidity and mortality. The 30-day perioperative mortality rate was 1.9%(7/368). Causes of death included myocardial infarction (n = 3), arrhythmia (n = 1), and multisystem organ failure (n = 3). The total 30-day major morbidity rate was 12.5% (46/368; Table II), and the total 30-day minor morbidity rate was 8.4% (31/368; Table III). Late death unrelated to the aneurysm or its repair occurred in 32 patients (8.7%) during the follow-up period.

Table II. Major morbidity and mortality

	Characteristic	*No.*
Systemic	Myocardial infarction	11 (3.0%)
	Cardiac arrhythmia	1 (0.3%)
	Pulmonary failure	4 (1.1%)
	Renal failure	3 (0.8%)
	Congestive heart failure	3 (0.8%)
Technical	Iliac graft limb occlusion	10 (2.7%)
	Conversion to open repair	4 (1.1%)
	Graft migration	6 (1.6%)
	Renal artery occlusion	3 (0.9%)
	Graft infection	1 (0.3%)
	Total	46 (12.5%)
	30-day mortality	7 (1.9%)

Table III. Minor morbidity

Characteristic	*No.*
Hematoma	21 (5.7%)
Lymphocele	8 (2.2%)
Superficial wound infection	2 (0.5%)
Total	31 (8.4%)

DISCUSSION

Endovascular treatments for AAA have undergone considerable evolution with a succession of modifications and improvements since the earliest physician-made devices were used.[1-13] These changes have allowed a greater number of patients with a greater range of anatomic variability to undergo endovascular treatment.[13] Results with advanced generation devices have been reported to be superior to those achieved with first generation grafts.[9,11,21,22]

The Talent-LPS endovascular grafting system uses several features that may contribute to successful treatment outcomes for endovascular AAA repair. Custom fabrication of devices allowed a greater range of anatomic configurations to be treated in this study. The wide array of proximal neck (1.8 to 3.4 cm) and iliac (0.6 to 2.2 cm) implantation sizes treated in this study are an indication of the anatomic flexibility that can be achieved with custom fabrication. The patient with the 3.4-cm proximal neck had Ehlers-Danlos syndrome and was at high risk for standard arterial surgery. The endovascular device can be used in patients not anatomically suitable for treatment with the currently approved devices. In addition, the use of a 15-mm uncovered proximal stent allowed for transrenal fixation of the endoprosthesis in the patients treated in this study. Transrenal fixation may allow successful exclusion of a greater proportion of AAAs with short proximal implantation sites as compared with proximal fixation that is limited to the infrarenal aorta.[23]

All patients who underwent treatment in this multicenter study were at high risk for conventional open surgical repair on the basis of the number and nature of their comorbid medical conditions. Population-based studies have consistently indicated that although mortality rates less than 5% can be achieved in patients at good risk in centers of excellence in vascular surgery, mortality rates increase dramatically when AAA repair is undertaken in patients with significant concomitant medical diseases.[24,25] These patients at high risk were able to undergo endovascular AAA repair with acceptable morbidity and mortality rates. In addition, the primary goals of treatment, prevention of aneurysm rupture and aneurysm-related death,[26] were successfully achieved in more than 98% of patients during short-term and intermediate-term follow-up periods.

A number of questions regarding the durability of endovascular repair of AAA remain to be answered. Previous studies have indicated that endovascular repair is associated with an increased incidence of subsequent need for intervention to preserve aneurysm exclusion as compared with conventional open repair.[20,27] Although some problems related to device fatigue and failure have been successfully addressed with technical improvements,[20] the development of late complications, such as new endoleaks or graft limb occlusions, has not been eliminated. Development of distal attachment site endoleak may be observed in aortoaortic tube prostheses, and their use has been abandoned for fusiform AAA in the participating centers. The development of late endoleaks originating from the distal aortic implantation site in aortoaortic tube grafts can be eliminated with the preferential use of bifurcated or aortouniiliac devices.

Continued radiologic follow-up examination of all patients with AAA treated with endovascular means remains mandatory. In addition to assessment of the repair with regard to endoleaks, aneurysm size determination may be performed to assess the adequacy of treatment. In this study, successful treatment was suggested with stabilization or reduction in AAA size in 91.3% of patients. Aneurysm diameter increase was most frequently associated with a new or persistent endoleak and was considered an indication for further therapy in all cases where such intervention was possible. Both instances of aneurysm rupture after endovascular treatment occurred in association with endoleaks originating from the proximal implantation site that could not be treated with endovascular techniques. The risk of mortality associated with conventional open repair was considered to be prohibitive in both of these patients.

In conclusion, the Talent endovascular grafting system has been used as an effective means for the prevention of aneurysm rupture in a large number of patients with considerable comorbid medical illnesses. Aneurysm exclusion was achieved with low perioperative morbidity and mortality rates. The degree of technical and procedural success achieved in this difficult-to-treat patient population is comparable with that reported for the phase I and II trials of other endovascular devices. Although the short-term and intermediate-term results with the Talent endovascular graft are encouraging, careful continued follow-up study will be necessary to determine the long-term effectiveness of this system for the treatment of AAA.

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DISCUSSION

Dr Frank LoGerfo (Boston, Mass). Peter, maybe you could explain the process here in terms of an investigational device and where this device is in that evolution. I assume your mortality rate here was zero.

Dr Peter Faries. Actually, 1.9% was the 30-day mortality rate. The Talent device had been used extensively in Europe, and the majority of their experience has taken place in those centers. It has only more recently begun the Food and Drug Administration phase 1 and 2 trials for approval for use in the United States. This trial was conducted as part of an investigational device exemption for high-risk patients who were considered to be at prohibitive risk or increased risk for standard aneurysm surgery and as such is an investigator-sponsored trial, distinct from the phase 2 trial.

Dr Gregorio Sicard (St Louis, Mo). In your review, did you see any problem with proximal endograft migration?

Dr Faries. We have only seen migration in 1% of patients, and that seems to be related to either inappropriate selection of a too short proximal neck or inaccurate placement of the proximal fixation site. In patients who have had an adequate length 1.5 cm of proximal aortic neck and in whom the graft is deployed in an accurate position, we have not seen significant problems with migration.

Dr David Brewster (Boston, Mass). Peter, you had nice early results, which as you indicated are similar to the short-term results of many other series. What was your mean duration of follow-up? You seem to be implying midterm results, but are you in fact at midterm in terms of follow-up? And secondly, the Talent device has often been used by investigators for challenging anatomy that falls outside of the boundaries of other clinical trial protocols. What were your selection criteria? Were you in fact treating big necks over 28 mm, etc?

Dr Faries. With regard to the second question, a number of these patients did have what you describe as challenging anatomy, certainly anatomy that could not be treated with the commercially available devices currently. We did have a significant proportion of patients whose necks were over 28 mm, and the graft itself is produced up to 36 mm in its proximal diameter. We oversize by about 4 mm typically, so we have treated patients up to 32 mm with the device itself.

The average follow-up was 7.3 months for these patients. The longest follow-up in this group was 33 months. Whether that constitutes midterm or not is difficult to say. We felt that it did and described it as that, but I am not sure that what actually defines a midterm follow-up is well-defined.

Dr Joseph Meyer (Concord, NH). I enjoyed your paper very much. I am wondering how you excluded a graft complication as a cause of death in the 10% of people that died after follow-up, particularly if postmortem examination was not performed.

Dr Faries. Typically all patients have been followed carefully, and those who have died in follow-up have had their complete medical record acquired from the institution where they were treated. Those determinations were made by autopsy when possible, and when not possible, it is typically apparent what the cause of death was.

Dr Robert Zwolak (Lebanon, NH). Peter, very nice paper. I was curious about the 4% 30-day and the 1% 12-month type 1 endoleak. Does that imply a more permissive approach towards type 1 endoleaks, or are these simply patients that are too sick or refusing subsequent intervention?

Dr Faries. If I understand your question correctly, you are asking why was there still 1% endoleak at 12 months? Typically, those are patients in whom the anatomy simply does not permit placement of an extension proximal cuff. They have a very short neck and were not considered to be candidates for open surgical repair. These patients were particularly poorly off physiologically and were thought to be prohibitively risky to convert to open repair. So that explains the persistence of type 1 endoleaks at 12 months.