Limb interventions in patients undergoing treatment with an unsupported bifurcated aortic endograft system: A review of the Phase II EVT Trial

Ronald M. Fairman, MD, Richard A. Baum, MD, Jeffrey P. Carpenter, MD, David H. Deaton, MD, Michel S. Makaroun, MD, and **Omaida C. Velazquez, MD, for the Phase II EVT Investigators,** *Philadelphia, Pa*

Introduction: **Both supported and unsupported bifurcated endograft limbs develop flow-restricting lesions, including kinks, stenoses, and occlusions, which can be identified during or after surgery. Recognition and intervention are essential to achieve long-term graft patency and a satisfactory functional result. This report represents a comprehensive retrospective review of graft limb interventions from the Phase II EVT Trial with the Endovascular Grafting System unsupported bifurcated endograft (Guidant/EVT, Menlo Park, Calif).**

Methods: **The study population consists of 242 patients who underwent treatment with bifurcated endografts implanted during the EVT Phase II Trial. Graft limb interventions have been divided into two groups: those in whom the intervention occurred during surgery versus those in whom the intervention occurred after surgery. Parameters studied included type, incidence, and timing of graft limb intervention, indications for intervention, procedures performed, and overall patient outcome.**

Results: **The mean follow-up period was 31 months. Primary, primary assisted, and secondary limb patency rates were 61.6%, 93.7%, and 97.1%, respectively. Technical success rate at case completion was 97.5%. In 68 of the 242 cases, limb interventions were performed during surgery to assure patency (28.1%). In 28 cases, interventions were performed after surgery (11.6%). Of these postoperative limb problems, 82% occurred during the first 6 months. Repeat limb interventions were necessitated in three patients (1.2%). Within the intraoperative intervention group, perceived indications included kinks (15%), stenosis (57%), dissection (6%), graft redundancy (12%), and instances of twists, thrombosis, and pressure gradients (10%). These findings were successfully managed with percutaneous transluminal angioplasty only (41%), percutaneous transluminal angioplasty and stent (50%), and various combined interventions. Within the postoperative intervention group, symptomatic indications included stenosis (46%) and thrombosis/occlusion (54%). These postoperative limb events were successfully managed with stent (64%), thrombolysis (32%), and femoral-femoral bypass (21%). When limb dysfunction developed in the postoperative setting, it most often occurred within the first 6 months of implantation. Only one patient in this Phase II cohort had a lower extremity amputation unrelated to a graft limb abnormality.**

Conclusion: **The unsupported bifurcated limbs of this endograft necessitated primary adjunctive intervention in 40% of cases. Primary intervention was two times more likely to be performed at the time of the implant rather than after surgery. Repeat limb interventions were not common. Endograft limb flow problems were successfully treated with standard endovascular or surgical interventions or both. These data may support prophylactic stenting of unsupported Ancure graft limbs. A strategy that includes both intraoperative and early postoperative graft limb surveillance is essential to detect reduced limb flow. (J Vasc Surg 2002;36:118-26.)**

The design of the Endovascular Grafting System bifurcated endograft (Guidant/EVT, Menlo Park, Calif) includes proximal and distal hook fixation and no stent support within its limbs. The resulting design features have potential unique strengths and problems. With the sharp elgiloy hooks at each end, fixation at the proximal and distal attachment sites is enhanced, potentially decreasing migration problems. The unsupported endograft body and legs made of polyester fabric theoretically may respond favorably to morphologic changes occurring within the aneurysm sac after implantation. However, although endograft migration has not been an issue with this particular endograft, the unsupported endograft limbs are vulnerable and can develop flow-restricting lesions in association with heavily calcified aortic bifurcations, stenotic, tortuous or angulated common iliac arteries, and graft oversizing. Not only narrow calcified rigid aortic bifurcations but also small angulated origins of the common iliac arteries may result in kinking problems. In the presence of such anatomy, implantation of an aortouniiliac graft may be indicated rather

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Reprint requests: Ronald M. Fairman, MD, University of Pennsylvania Medical Center, 3400 Spruce St, 4 Silverstein, Philadelphia, PA 19104 (e-mail: ron.fairman@uphs.upenn.edu).
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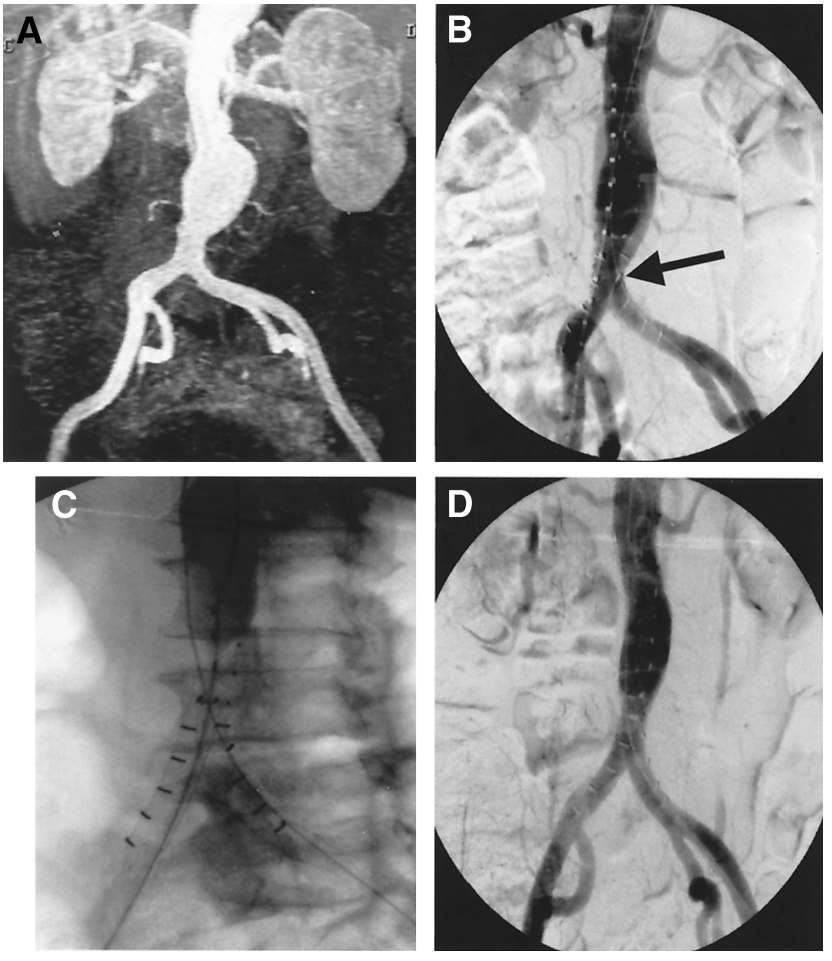

Fig 1. A, Preoperative arteriogram. **B,** Intraoperative arteriogram after deployment. *Arrow* points to compression of left limb by aortic bifurcation. **C,** Placement of bilateral Wallstents. **D,** Completion arteriogram.

than an attempt to accommodate two limbs through a narrow calcified angulated orifice. This endograft has a short body, such that after deployment, the endograft bifurcation resides high above the native aortic bifurcation, resulting in the potential for compression and kinking of the limbs, particularly in the presence of a small rigid aortic bifurcation. These resulting limb kinks, twists, and redundant fabric pleats can produce stenoses and occlusions that may be perceived during surgery but that may also present in a delayed fashion after surgery (Figs 1 to 3).[1-6]

The Endovascular Grafting System endograft underwent design modifications to the delivery/deployment system without changing the endograft itself in 1998 and was renamed the Ancure endograft system. The US Food and Drug Administration approved the Ancure endograft on September 28, 1999, and since then, more than 2000 physicians have been trained in the United States to implant the device.

Recognition of the potential for limb dysfunction both during and after surgery and prompt intervention by physicians implanting the Ancure endograft is essential to achieve long-term graft limb patency and a satisfactory functional result. This report represents the first comprehensive retrospective review of graft limb interventions from the Phase II EVT Trial. On the basis of the data presented in this work, the authors intend to develop a set of recommendations relevant to graft limb deployment and follow-up.

METHODS

We reviewed the records of 242 patients who underwent treatment at 18 centers during the US Food and Drug Administration-approved Phase II Trial from December 20, 1995, to February 15, 1998. This report only includes patients who received bifurcated endografts and excludes patients treated with tube or aortouniiliac endografts. The mean follow-up period was 31 months. Preoperative assessment included marker catheter arteriograms and unenhanced and 3-mm cut enhanced computerized tomographic scans of the abdomen and pelvis. Patient enrollment into the trial was on the basis of an intent-to-treat design analysis. Criteria for patient selection were

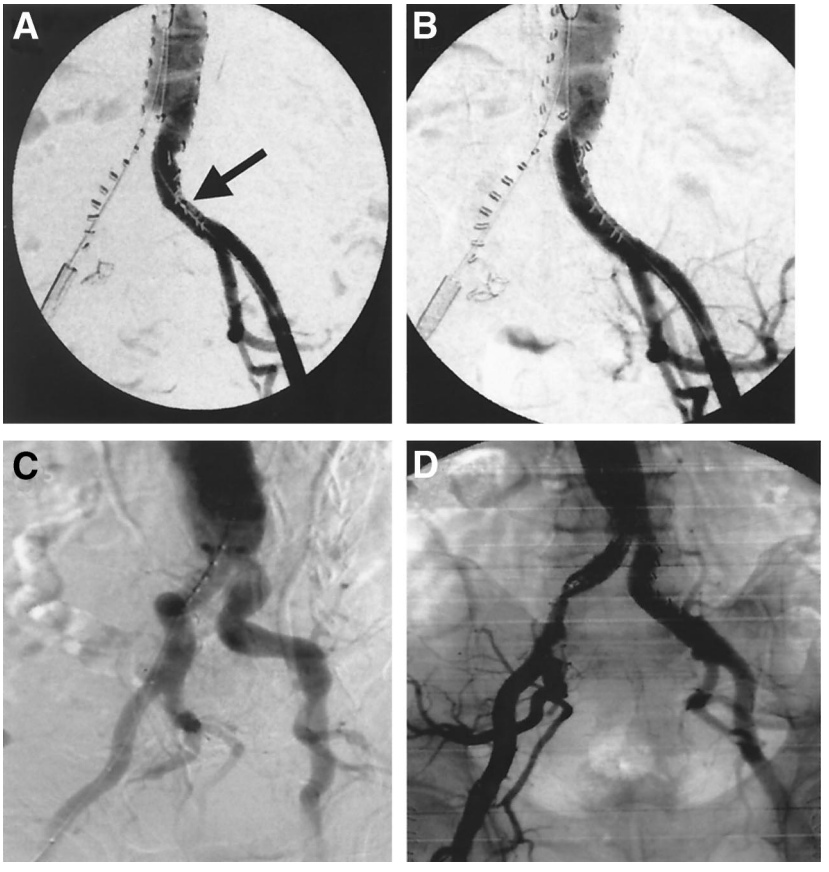

Fig 2. A, *Arrow* points to redundant fabric pleats in left limb after deployment. Right limb still has delivery system in place, so blood flow is obstructed. **B,** Resolution after placement of Wallstent. **C,** Another patient with tortuous angulated right common iliac artery on preoperative arteriogram. **D,** Right limb twist after deployment and removal of stiff wires.

largely on the basis of anatomic issues, but subjects also were required to provide informed consent and have anesthesia clearance and a 2-year life expectancy. The anatomic parameters are summarized in Table I. The primary investigators decided on individual patient enrollment, although film reading and sizing were done in Menlo Park. Interventions for graft limb dysfunction have been divided into two groups: those in whom the intervention occurred during surgery versus those in whom the intervention occurred after surgery. Repeated interventions were performed for recurrent episodes of reduced limb flow. In addition, we calculated the primary, primary assisted, and secondary patency rates. However, that primary intraoperative interventions for perceived reduced graft limb flow represent a phenomenon that is not strictly comparable with the primary assisted patency of other arterial bypass grafts must be kept in mind. In addition to the timing and incidence of graft limb dysfunction, the other focused outcome parameters examined included specification of each type of limb abnormality, type and frequency of interventions, overall patient outcome, and identification of variables predictive of graft limb dysfunction.

RESULTS

At a mean follow-up period of 31 months, overall primary patency was obtained in 149 of 242 cases (61.6%). Of all cases, 76 of 242 (31.4%) had either perceived or objectively measured reduced limb flow that prompted an intervention, either during or after surgery. Thus, a primary assisted patency rate of 93.7% was achieved at 31 months of follow-up. Seventeen of 242 cases (7%) had a thrombosed limb either during or after surgery. Flow was successfully restored after secondary intervention in 10 of those 17 cases, thus yielding an overall secondary limb patency rate of 97.1%. In 68 of the 242 cases (28.1%), limb interventions were performed during surgery to assure patency at the completion of the case. *Technical success* was defined as adequate bilateral limb patency without conversion to open techniques, such as thrombectomy, retroperitoneal limb exposure/suture, or femorofemoral bypass. Within the in-

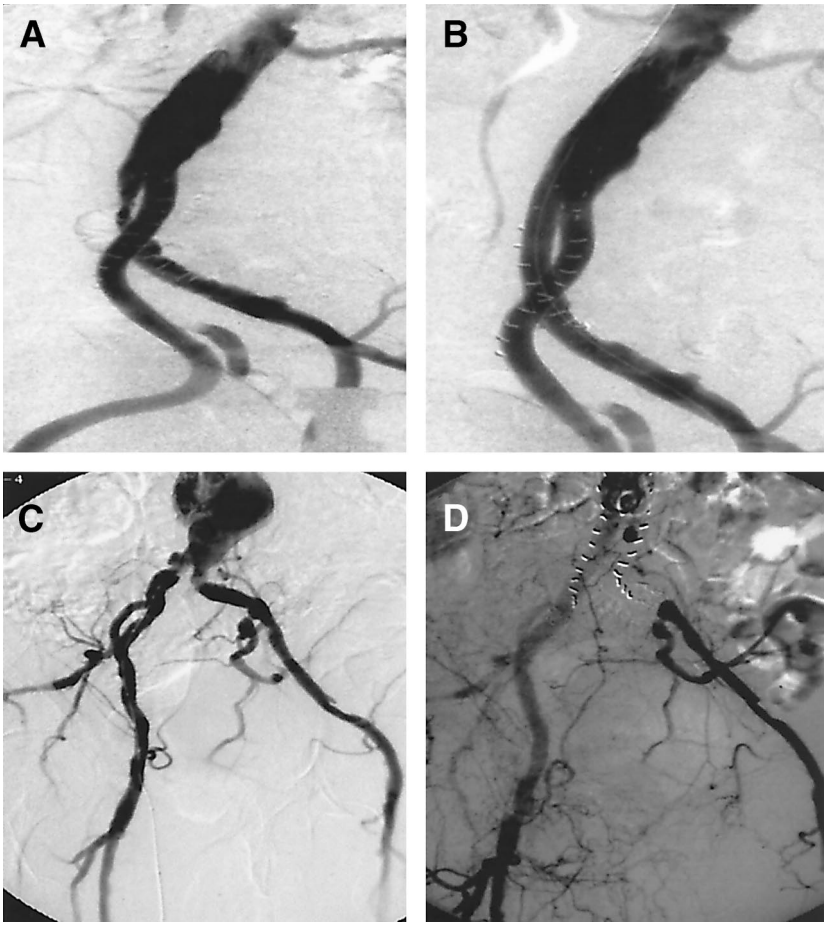

Fig 3. A, Right limb stenosis 3 weeks after implantation in patient with claudication. **B,** Resolution with Wallstent placement. **C,** Another patient with angulated left common iliac artery on preoperative arteriogram. **D,** Patient was seen with claudication and left limb occlusion 4 weeks after implantation.

Table I. Anatomic considerations for endovascular abdominal aortic aneurysm repair

Anatomy	*Graft type*	*Requirement*
Superior neck	All	Aortic superior neck ≤26 mm in diameter and ≥15 mm in length, with ≤45-degree angulation and without circumferential calcification or circumferential atheroma
Inferior neck	Tube	Aortic inferior neck ≤26 mm in diameter and ≥12 mm in length
Access vessels	All	At least one femoral or iliac artery permitting access with 23.5F (7.9-mm) device, with ≤60-degree iliac angulation and without circumferential iliac calcification or atheroma
Iliac attachment sites	Bifurcated	Both iliac vessels having healthy segments ≥20 mm in length and ≤13.4 mm in diameter; contralateral femoral artery or iliac artery permitting access with 12F (4.0-mm) device

traoperative intervention group, perceived indications included kinks (15%), stenosis (57%), and dissection (6%) and graft redundancy (12%). In addition, obvious instances of twists, thrombosis, and pressure gradients occurred in 10%. Intraoperative findings were successfully managed with percutaneous transluminal angioplasty only (41%), percutaneous transluminal angioplasty/stent (50%), and various open/endovascular combined interventions (Fig 4). At the completion of the case including any needed intraoperative endovascular interventions, technical success was achieved in 236 of 242 cases (97.5%). Four patients needed open retroperitoneal suture repair of one of the endograft limbs, one patient needed thrombectomy of one of the limbs, and one patient needed a femorofemoral bypass after failed endovascular attempts at obtaining adequate limb patency (Fig 4).

In 28 cases (11.6%), interventions were performed after surgery to treat symptoms, measured flow problems, or

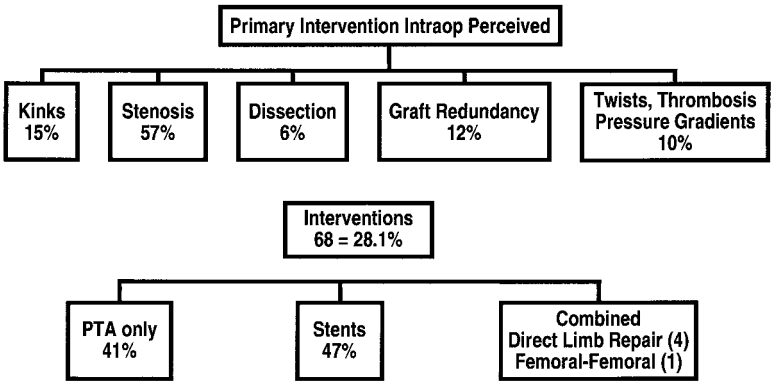

Fig 4. Interventions performed during surgery: indications and techniques.

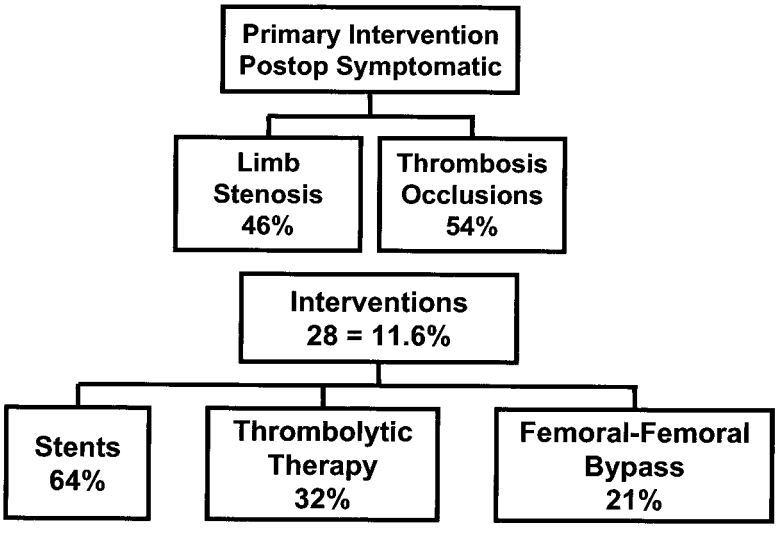

Fig 5. Interventions performed after surgery: indications and techniques.

limb thromboses. Of these postoperative limb problems, 82% occurred during the first 6 months. Repeated limb interventions were necessitated in only three patients (1.2%). Postoperative interventions were performed for symptoms that included stenosis (46%) and thrombosis/occlusion (54%). These 28 postoperative limb events were successfully managed with stent (64%), thrombolysis (32%), and femorofemoral bypass (21%). Several patients underwent more than one approach in the management of limb flow problems (Fig 5). Thus, only seven patients in the entire series (2.9%) needed a femorofemoral bypass graft (one during and six after surgery). Three patients underwent primary femorofemoral bypass for limb occlusion without an initial endovascular approach. When limb dysfunction developed in the postoperative setting, it most often occurred within the first 6 months of implantation. Only one patient in this Phase II cohort had a lower extremity amputation, and this patient did not have an endograft limb abnormality. Repeated limb interventions were necessary in three patients (1.2%). One patient in this Phase II cohort had a lower extremity amputation that occurred in the early postimplantation period but was not associated with graft limb dysfunction. Table II provides the results of a multivariate logistic regression analysis performed to identify variables predictive of reduced graft limb flow and dysfunction. Two variables showed a significant statistical correlation predictive of graft limb dysfunction: female gender ($P = .002$) and graft limb diameter oversizing by 3.5 to 4.4 mm relative to the common iliac artery attachment site. This degree of graft diameter oversizing increased the risk of limb dysfunction necessitating intervention by 12 fold ($P = .011$; Table III). The presence of coexistent infrainguinal arterial occlusive disease showed a trend toward increased risk for graft limb dysfunction ($P = .080$). A statistically significant correlation was seen between the number of implants performed at a center (case volume) and the percentage of intraoperative interventions (Spearman rank correlation coefficient, $r = 0.606$;

Table II. Variables predictive of reduced limb flow

Variable	P *value*
Age	.67
Anticoagulants	.46
Antiplatelet agents	.89
Coronary artery disease	.41
Current smoking	.87
Diabetes	.83
Gender	.002
Graft limb diameter	.98
Hypertension	.78
Investigator experience	.15
Limb diameter oversize	.09
Common iliac diameters	.36
Arterial occlusive disease	.08
Procedural antiplatelet use	.64
Superior neck diameter	.50

Table III. Effect of limb oversizing relative to ipsilateral common iliac artery attachment site

	No. of patients in whom limb intervention was necessitated		
Iliac diameter oversized by:	*No*	*Yes*	*Total*
3.5 to 4.4 mm	1	12	13
2.5 to 3.4 mm	19	19	38
1.5 to 2.4 mm	56	20	76
0.5 to 1.4 mm	57	32	89
0 to 0.4 mm	15	10	25
Total	148	93	241*

Size 4, $P = .011$.
*One patient excluded because iliac sizing data were incomplete.

$P = .008$; Fig 6). Other potential correlations, including case volume versus the percentage of postoperative interventions and percentage of intraoperative interventions versus postoperative interventions per center, were not statistically significant (Figs 7 and 8).

DISCUSSION

This review of endograft limb problems during Phase II EVT clinical trials shows that unsupported bifurcated limbs received primary adjunctive interventions in approximately 40% of cases. Primary intervention was two times more likely to be performed at the time of implant for perceived limb dysfunction rather than after surgery for symptomatic limb dysfunction. Standard endovascular approaches were frequently successful in the intraoperative setting and took the form of supplemental angioplasty and stents in 90% of cases. When limb dysfunction developed in the postoperative setting, it most often occurred within the first 6 months after implantation. Although postoperative instances of limb dysfunction were similarly managed with endovascular approaches (stents) in 60% of cases, both thrombolytic therapy and surgical revision with femorofemoral bypass were used in cases of limb occlusions. Furthermore, postoperative instances of reduced limb flow typically were managed with combined interventions. Mechanical thrombectomy with balloon-tipped catheters was not commonly used in either the intraoperative or postoperative setting and may be relatively contraindicated because of the risk of precipitating endograft migration. Of the 28 postoperative interventions, femorofemoral bypass was necessitated in six cases (21%). One additional femorofemoral bypass was necessitated during. Thus, of a total of 17 patients with limb thromboses, limb patency was achieved in 10 patients (59%) with endovascular techniques. In the remaining seven cases (41% of all limb thromboses), a femorofemoral bypass was necessitated after failed endovascular interventions (four patients) or was done as the primary procedure without an initial endovascular approach (three patients).

Repeated interventions were rarely necessitated (1%). In spite of the incidence of limb dysfunction reported in this Phase II cohort, only one patient had an amputation, and this could be attributed to local femoral artery issues, not a technical or patency problem with the graft limb.

The results of analysis for identification of variables predictive of reduced graft limb flow revealed a statistical association with increased risk for limb problems in female patients, most likely related to access and oversizing issues. Velazquez et al[7] showed that there are gender-related differences in infrarenal aortic aneurysm morphologic features, including (but not limited to) significantly reduced iliac artery size in women. In this work, we show that when graft limb diameters were oversized by approximately 4 mm compared with the ipsilateral common iliac artery, the incidence rate of limb dysfunction was increased 12 fold. Presumably, the mechanism of reduced limb flow in oversized graft limbs is a consequence of fabric pleats and compliance mismatch. The trend toward reduced limb flow in the presence of coexistent infrainguinal arterial occlusive disease (poor runoff) may be attributable to high resistance outflow. This trend also may potentially be attributed to an association between infrainguinal disease and suprainguinal disease. That is, patients with large calcified plaques in the femoral arteries may often have a similar degree of calcified occlusive disease within the common iliac arteries.

The assessment of a potential intraoperative limb dysfunction was often made on the basis of a perceived problem. However, on the basis of the data, the need for intraoperative intervention could be interpreted as probably underestimated, given that the rate of limb problems in the absence of any intraoperative treatment was as high as 16%. The rate of postoperative intervention in patients treated during surgery was 4%, whereas the rate in those not treated during surgery was 16%, suggesting that the intraoperative assessment of the operating team was likely on target and thus indirectly suggesting a beneficial affect for preventative intraoperative interventions. Clearly, the centers performing more implants were more likely to perform a greater percentage of intraoperative interventions. This suggests that as investigators gained more experience, they were more likely to support the limbs at the time of implantation in an educated effort to avoid postoperative limb problems. Interestingly, centers that performed less intra-

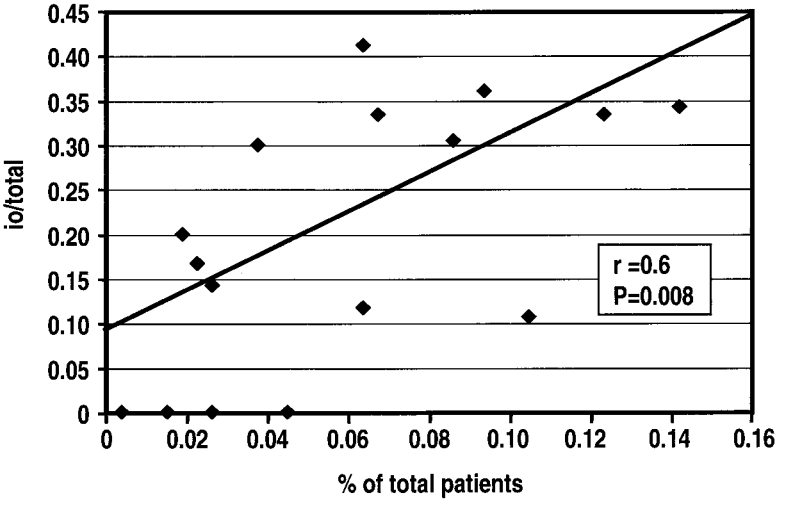

Fig 6. Case volume versus percentage of intraoperative interventions per center. Depicted is number of implants performed at center expressed as percent of total patients on X-axis versus intraoperative *(io)* interventions as ratio of all interventions on Y-axis.

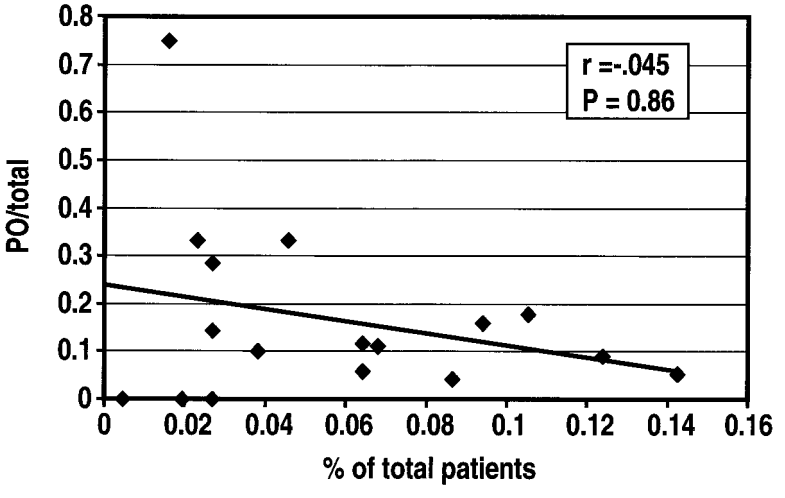

Fig 7. Case volume versus percentage of postoperative interventions per center. Depicted is case volume performed at center expressed as percent of total cases on X-axis versus postoperative *(PO)* interventions as ratio of all interventions on Y-axis.

operative interventions did not observe significantly higher postoperative adverse limb events.

We believe recommendation of the practice of routinely supporting (stenting) Ancure graft limbs is premature, although the data presented in this work may be used to support such a recommendation. One should keep in mind, however, that 60% of the patients maintained limb patency without adjunctive intervention. Longer term results are needed to truly determine the need for limb support. Placing a stent to support an Ancure limb effectively creates an endoskeleton, and although no instances of Ancure type III endoleaks have been identified to date (2-year to 4-year follow-up), other endografts with an endoskeletal design with sutures and thinner fabric have proven vulnerable to friction and fabric erosion, over time producing late endoleaks.[8,9] Whether the mechanism of failure is the result of the endoskeletal design model itself or the suturing of stents to fabric remains to be determined. However, the Ancure device is unlikely to be negatively impacted by Wallstents placed within its limbs. At this time, placing an unsutured stent inside an Ancure limb appears to be a safe practice but may not be necessitated routinely. Routinely placing bilateral stents within the Ancure limbs significantly inflates the cost of this technology and would not be necessary on the basis of these data in most patients (60%) in the given follow-up interval. Calculation of the

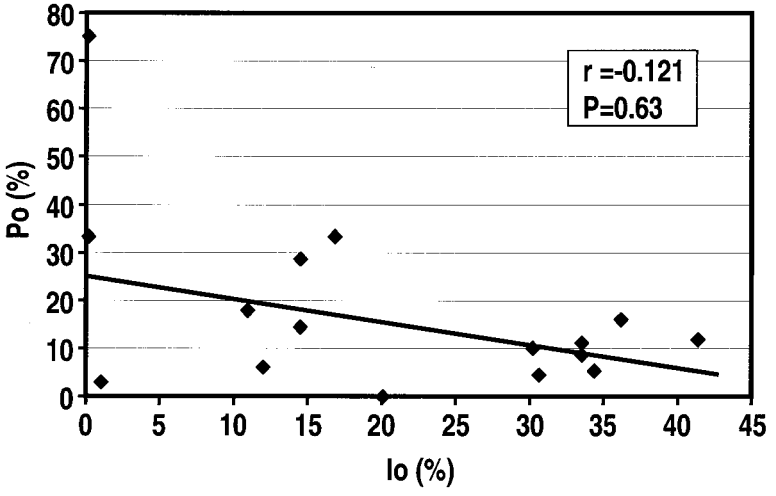

Fig 8. Percentage of intraoperative versus postoperative interventions per center. Depicted is number of intraoperative interventions *(Io)* at center expressed as percent of total interventions on X-axis versus postoperative *(Po)* interventions as percent of all interventions on Y-axis.

added expense of supporting all endolegs at the time of initial deployment compared with the anticipated expense of delayed primary interventions necessary in potentially as many as 40% of patients would be noteworthy, however. The cost of prophylactic stent placement is approximately $11,000 per patient. However, one could easily offset this cost against the cost of readmission for a potentially occluded limb. Beyond cost, however, presumably real issues of morbidity, which are less predictive and difficult to quantify, are associated with delayed intervention other than amputation. Clearly, a subset of patients appears to benefit from prophylactic stent placement. This subset includes women with small iliac arteries, instances of graft limb oversizing (compared with the ipsilateral iliac artery attachment site), and patients with coexistent infrainguinal arterial occlusive disease. In addition, any case in which the operating team believes that technical success has not been satisfactorily achieved should likely not leave the operating room until any real or perceived limb flow problem is completely resolved. We would advocate a methodic intraoperative assessment of the graft limbs. After endograft deployment and routine ballooning, the completion arteriogram should be performed after all stiff wires have been removed. Although stiff wires are essential for device access and deployment because they straighten the iliac arteries, removing them before the final arteriogram occasionally uncovers instances of kinks, twists, pleats, and compression resulting in stenoses. In addition to the standard anteroposterior projections, bilateral oblique imaging may be a useful adjunct. When the threat of reduced limb flow remains unresolved, intraoperative pullout pressure measurements or intravascular ultrasound scan may detect limb dysfunction.[2,10] We would certainly endorse supporting graft limbs when arteriographic/intravascular ultrasound scan or physiologic documentation of limb dysfunction has been found.

Unresolved technical points include the routine use of bilateral stents to avoid compression of an unsupported limb and the need to support an entire limb, as opposed to the portion of the limb where the problem exists. The authors favor supporting only the portion of the limb where an identifiable problem exists and placement of bilateral stents only when bilateral limb problems arise. Furthermore, because this report is an analysis of limb interventions associated with the use of the first generation deployment system, current results with the Ancure deployment system may not be strictly comparable. The lessons learned from Phase II and more aggressive intraoperative stenting may have significantly reduced the incidence of postoperative intervention with the newer Ancure system.

Furthermore, recognition that supported and unsupported stent grafts are associated with limb kinking is important, although direct comparison suggests than an unsupported limb may be more than 15 times more likely to need intervention because of kinking than a supported one in short-term follow-up.[1] That unsupported endograft limbs are susceptible to reduced flow and dysfunction early has been suggested and that supported limbs are in fact also vulnerable, but perhaps later on.[11,12]

Lastly, because most postoperative limb problems (80%) occurred during the first 6 months after implantation, the early follow-up surveillance should not only concentrate on endoleak detection and aneurysm sac size but may justifiably include focused questions regarding claudication and a noninvasive assessment of graft limb flow with duplex scanning, segmental pressures, ankle-brachial indices, and pulse volume recordings. The determination of the most ideal technique to identify a vulnerable or failing endograft limb is not addressed with these data and is beyond the scope of this report. However, physicians should remain sensitized to the potential for reduced limb

flow occurring both during and after surgery and necessitating adjunctive interventions.

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