Failure of endovascular abdominal aortic aneurysm graft limbs

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Objective: **Endovascular abdominal aortic aneurysm (AAA) grafts are subject to subsequent failure of endograft limbs. We sought to determine what device-related factors could be identified that might contribute to limb failure.**
Methods: **We reviewed the records of patients who had undergone endovascular AAA repair and femorofemoral bypass grafting at a single institution.**
Results: **Endovascular AAA repair was performed in 173 patients. There were 137 bifurcated endografts and 36 aortomonoiliac grafts combined with femorofemoral bypass grafts, yielding a total population of 310 aortic graft limbs and 36 femorofemoral grafts. Thirty-nine additional patients underwent femorofemoral bypass grafting for occlusive disease. The cumulative primary patency of all endografts performed for AAA was 92% at 21 months. Secondary patency was achieved for all failed endograft limbs. There were 24 aortic graft limb "failures" that required intervention: seven limbs underwent thrombosis requiring revision; kinked limbs requiring stenting either at the time of graft placement (17) or subsequently (7) were identified. Fully supported endograft limbs had better primary patency (97% at 18 months) than unsupported limbs (69% at 18 months, $P < .001$). The aortomonoiliac grafts with femorofemoral bypass grafts tended to have better patency (97% at 18 months) than bifurcated endografts (90% at 18 months), but this did not reach statistical significance ($P = .28$, not significant). Femorofemoral grafts performed for occlusive disease were found to have somewhat lower patency than those performed for AAA (83% vs 92% at 18 months of follow-up, $P = .37$, not significant).**
Conclusions: **Fully supported AAA endografts provide superior endograft limb patency compared with unsupported designs. Consideration should be given to routine stenting of all unsupported endograft limbs. Aortomonoiliac grafts and bifurcated grafts provide similar results for endograft limb patency. Femorofemoral bypass grafts performed in conjunction with aortomonoiliac grafts for AAA disease provide excellent short-term patency. (J Vasc Surg 2001;33:296-303.)**

Endovascular repair of abdominal aortic aneurysms (AAAs) is becoming increasingly prevalent. The devices available for use are evolving as the technology continues to improve. Various design concepts are currently being tested, and as yet, no consensus has been reached as to which features are optimal for a successful endovascular AAA repair. Currently, designs with bifurcated endografts and aortomonoiliac grafts combined with femorofemoral bypass grafts are used. Fully supported graft limbs with a stented endoskeleton or exoskeleton and unsupported grafts are available. We and others[1-10] have noted failures of endograft limbs in patients after endovascular AAA repair. We sought to investigate which design features could be identified as contributors to patency of endovascular graft limbs.

METHODS

We reviewed the records of patients who had undergone endovascular AAA repair and femorofemoral bypass grafting at a single institution, and the information was entered into a database. Endovascular AAA repair was reviewed over a 2-year interval, beginning in April 1998, at the time of the initiation of our endovascular AAA program in which commercially manufactured devices were used. All patients receiving endovascular AAA repair after this date were included. The records of patients with femorofemoral bypass grafts were reviewed over the interval from September 1994 to July 1999. Only the records of patients receiving femorofemoral bypass grafts for arterial occlusive disease or in conjunction with an aortomonoiliac endograft for aneurysm disease were reviewed. Grafts placed for aortic dissection and trauma, for example, were excluded from the analysis. Statistical analysis was performed with Statview statistical software (Abacus Concepts, Inc, Berkeley, Calif) to perform life-table survival analysis.

RESULTS

Endovascular AAA repair

A total of 173 patients underwent endovascular AAA repair over the 2-year interval. Graft manufacturers included World Medical Talent (111), Ancure (31), Medtronics AneuRx (25), Baxter Lifepath (4), and Cook Zenith (2). Of these, 137 patients received bifurcated grafts (ABG) and 36 underwent aortomonoiliac (AI) grafts (33 World Medical Talent, 3 Ancure EVT) with femorofemoral bypass grafting. All graft designs included a fully stented endoskeleton or exoskeleton with the exception of the Ancure EVT graft, which uses an unsup-

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Table I. Patency of endograft limbs*

Device type (no. of limbs)	*Configuration*	*Primary patency*	*Assisted primary patency*
World Medical Talent (156)	Bifurcated	96%	98%
World Medical Talent (33)	Aortoiliac	97%	100%
Ancure EVT (56)	Bifurcated	69%	91%
Ancure E.T. (3)	Aortoiliac	100%	NA
Medtronix AneuRx (50)	Bifurcated	100%	NA
Baxter Lifepath (8)	Bifurcated	100%	NA
Cook Zenith (4)	Bifurcated	100%	NA

*Secondary patency was achieved for all failed limbs.
NA, Not applicable.

Table II. Endovascular graft limb failure: source and treatment

Device type (no.)	*Configuration*	*Lesion at aortic bifurcation*	*Lesion in iliac*	*Mechanical thrombectomy*	*Thrombolytic therapy*
Ancure E.T. (17)	Bifurcated	8	3	1	2
World Medical Talent (6)	Bifurcated	1	5	1	2
World Medical Talent (1)	Aortoiliac	0	1	0	0

Twenty-four limb failures (17 intraoperative and 7 postoperative) are summarized according to device manufacturer and configuration of failed limbs and the location of the underlying lesion held responsible for the limb failure. All lesions were successfully treated with balloon angioplasty and stenting.

ported graft limb system. The mean length of follow-up was 9.7 months (range, 1-26 months). Overall primary patency of aortic endograft limbs was 92% at 24 months. The patency rate by graft type and configuration is shown in Table I. Secondary patency was achieved for all failed limbs.

During the follow-up interval there were 24 endograft limbs that required intervention (Table II) to maintain or restore patency (17 Ancure EVT, 7 World Medical Talent). Of these, 17 limbs with stenoses or kinks noted on arteriography at the time of graft placement underwent primary stenting to achieve assisted primary patency (Fig 1), resulting in an assisted primary patency rate of 97% at 18 months. The remaining seven limbs thrombosed in later follow-up (4 Ancure EVT, 3 World Medical Talent). Presentation at the time of thrombosis was an acute onset of pain and paresthesias with loss of femoral pulse but intact sensory and motor function (6) or an acute onset of paralysis with loss of sensation (1). All patients presented within 24 hours of their thrombotic event. Of these seven thrombosed endografts, patency was restored with thrombolysis and stenting (4) or surgical thrombectomy followed by stenting (2) (Fig 2). Balloon angioplasty and stenting without the need for thrombolysis or thrombectomy reopened one occluded limb. There were no long-term ischemic sequelae of thrombosed limbs and no amputations. The underlying lesions that narrowed or kinked the graft limbs and that were thought to be responsible for limb failure were located at the aortic bifurcation (9) or in the iliac arteries (9). All grafts treated with thrombolysis cleared thrombus completely within 24 hours of initiation of treatment.

Femorofemoral bypass graft for occlusive disease

Over the interval studied, 39 patients underwent femorofemoral bypass grafting for arterial occlusive disease. The mean patient age was 68 years (range, 42-86 years). There were 30 men and nine women. All grafts were made of externally supported polytetrafluoroethylene. Graft diameters were either 8 mm (32) or 7 mm (7). Inflow was from the native iliofemoral circulation in 34 patients, six of whom had undergone preliminary percutaneous angioplasty with or without stenting of the inflow vessel. For five patients, femorofemoral graft inflow was based on another bypass graft: axillofemoral (1), aortofemoral (2), or thoracofemoral (2). Additional outflow procedures were performed in conjunction with the femorofemoral graft in eight patients (4 femoropopliteal, 4 femorotibial). Graft infections that required graft removal occurred in three patients. Life-table primary graft patency was 83% at 18 months. The primary patency (Fig 3) of femorofemoral bypass graft performed in conjunction with aortomonoiliac endografting for aortic aneurysm disease was better at 18 months follow-up (92%) than for femorofemoral bypass grafts performed for occlusive disease (83%), but this difference was not statistically significant ($P = .37$).

Group comparisons of endograft limbs

Aortomonoiliac versus bifurcated aortic endografts. The primary patency of aortomonoiliac graft limbs was 97% at 18 months, and for bifurcated graft limbs, it was 90% ($P = .28$; Fig 4). If the patency of the femorofemoral graft necessitated by aortomonoiliac graft design was taken into account, then overall patency for patients undergoing this latter procedure was 95% at 18 months,

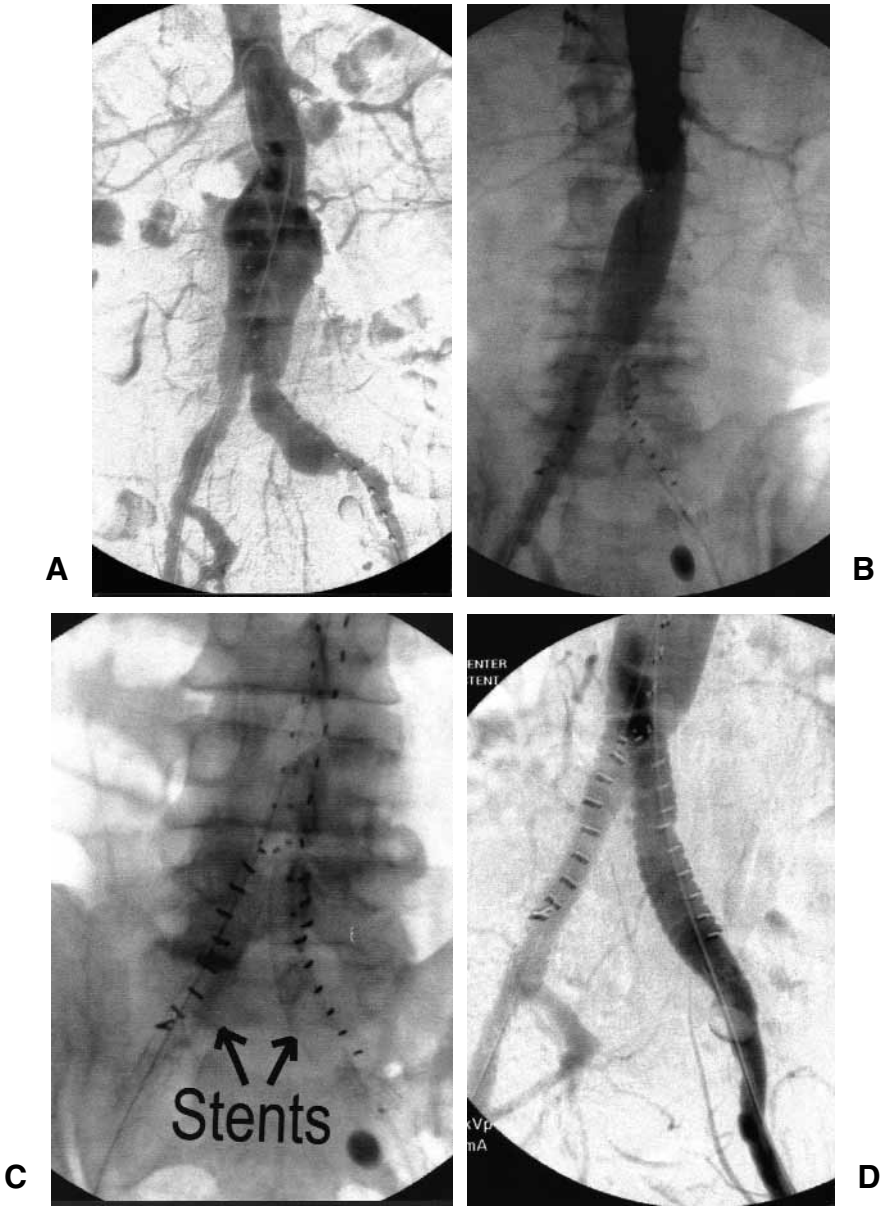

Fig 1. Assisted primary patency with stenting of unsupported graft limbs intraoperatively. **A,** Intraoperative arteriogram performed with a marker catheter (1-cm calibrations) before unsupported graft deployment shows the aortic and left common iliac artery aneurysms. After uneventful graft deployment, a completion arteriogram **(B)** shows no flow into the left limb of the bifurcated graft (note presence of embolization balloon previously placed in left hypogastric artery). Placement of a Wallstent (14 × 40 mm) into left limb restored its patency but caused right limb to fail by compressing it at aortic bifurcation; thus both limbs were fully stented (plain x-ray film showing stents in limbs **[C]**) to obtain assisted primary patency (final arteriogram **[D]**).

which was not significantly different than bifurcated graft patency ($P = .37$).

Supported versus unsupported endograft limbs. The primary patency of supported limbs was 97%, and the assisted primary patency was 99% at 18 months (Fig 5). Unsupported limbs had a primary patency of 69% ($P < .001$) and an assisted primary patency of 91% ($P = .01$) at 18 months.

Supported graft design comparison. No significant difference in patency at 18 months was identified among fully supported graft limbs when compared by the manufacturer (Medtronics/AneuRx vs World Medical/Talent vs Baxter/Lifepath vs Cook/Zenith).

DISCUSSION

The use of endovascular repair of AAAs is rapidly pro-

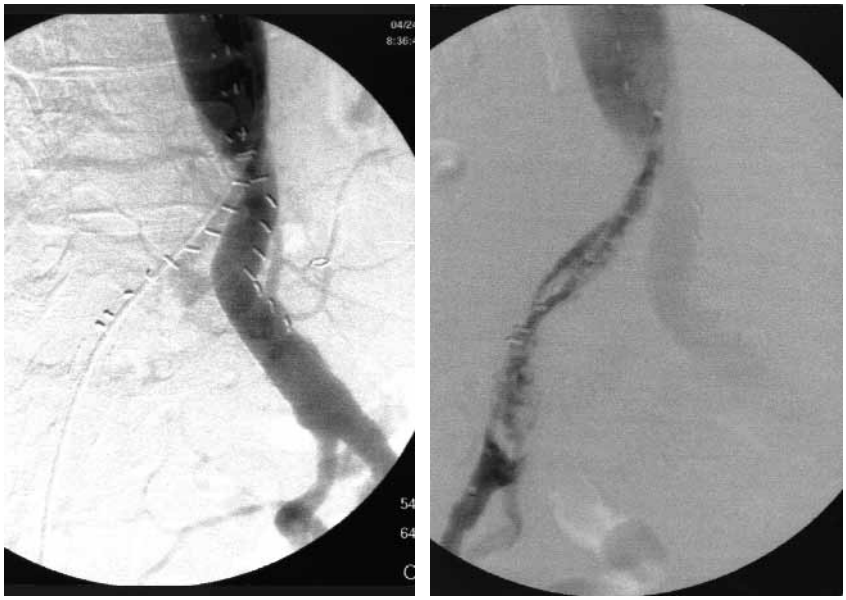

Fig 2. Secondary patency of thrombosed endograft limbs was achieved with mechanical or chemical thrombolysis. The patient shown had received an unsupported bifurcated graft 5 days before readmission for an acutely ischemic right leg. At the initial procedure, a Wallstent was required for left endograft limb to achieve assisted primary patency. Aortography **(A)** revealed a thrombosed right endograft limb. Selective right limb injection showed multiple stenotic regions and thrombus **(B),** which were treated with catheter-directed thrombolytic therapy. The limb was subsequently stented to maintain patency.

liferating. The technology is quickly evolving, but as yet, no clear consensus has emerged with regard to which device design features are optimal. Currently, grafts are of either bifurcated or aortomonoiliac designs, the latter type requiring a femorofemoral bypass graft for contralateral limb and pelvic perfusion. Bifurcated grafts can be in the form of a single body design or a composite of modular components assembled within the patient. The limbs of the endografts can be made of various fabric materials and may or may not be supported by a skeleton of internal or external stents.

We and others have noted the failure of endograft limbs in patients immediately on insertion or at a later time, resulting in limb ischemia.[1-10] Chuter et al[5] noted a 30% incidence of stenoses in their study of bifurcated, unsupported limbs that were readily treated with stents. In the current report, we noted that all limb failures were attributable to mechanical causes. Kinks or stenoses were noted either on completion arteriograms or on arteriograms performed after the removal of thrombus from the failed endograft limb. These stenoses and kinks were treatable with endovascular methods of angioplasty and stenting in all cases and did not require the placement of surgical bypass grafts or conversion of the endovascular AAA repair to an open procedure.

The stenotic areas themselves were located in regions of tortuosity or narrowing in the arteries in which the endografts were constrained. Iliac tortuosity or occlusive disease frequently contributed to limb failure but was easily remedied by balloon angioplasty and stenting. These regions of tortuosity and narrowing can compromise grafts by direct extrinsic compression of the limb or by providing a friction point for introduction of twists, particularly in unsupported graft limbs. Another important site of stenoses we identified was the aortic bifurcation, where several possible mechanical features may contribute to the development of narrowing. First, the angulation of the bifurcation in relation to the course of the iliac artery can introduce kinking. Additionally, the bifurcation, which can be relatively narrowed compared with the large diameter of the aortic aneurysm, can become a friction point or fulcrum for the graft to bend or twist. Also, luminal thrombus within the aneurysm, which jackets the limb, can cause extrinsic limb compression. Finally, in bifurcated systems, two limbs must pass through the aortic bifurcation. If this region is the same (or less) diameter as the sum of the diameters of the individual limbs, there will be compression of one or both limbs. We found that in such situations, the stenting of both limbs with a "kissing" technique was essential. When the kinking is noted to be at the aortic bifurcation level, the treatment of only one limb may result in subsequent failure of the untreated contralateral limb either immediately or subsequently (Fig 1).

Secondary patency of all thrombosed limbs was achieved. We prefer thrombolytic therapy for this situation and have used tissue plasminogen activator infusions, as have others.[3,9] Mechanical thrombolysis with a balloon catheter is hazardous, and there is a high risk of dislodging the endograft limb, which in many cases is held in place only by the radial force of the self-expanding stents.

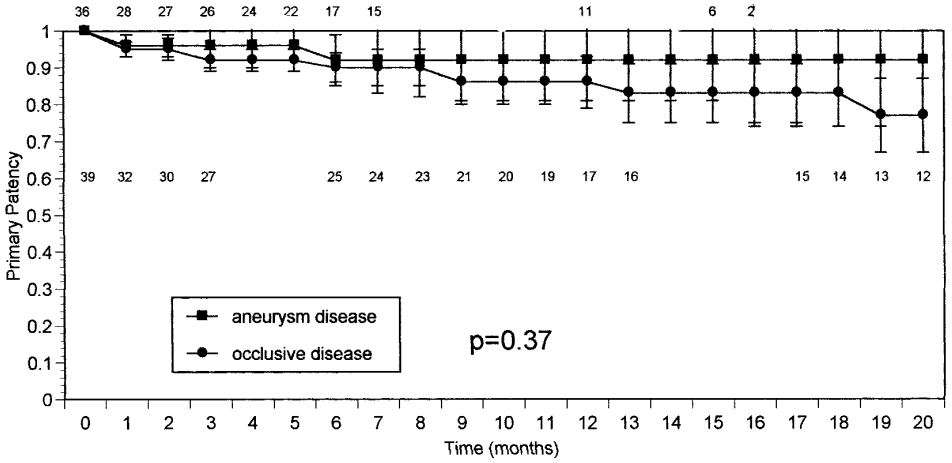

Fig 3. Femorofemoral bypass graft patency comparison for patients with occlusive disease versus patients with aortic aneurysm disease in conjunction with aortomonoiliac endograft. Primary patency at 18 months was 92% for aneurysm patients and 83% for occlusive disease patients ($P = .37$).

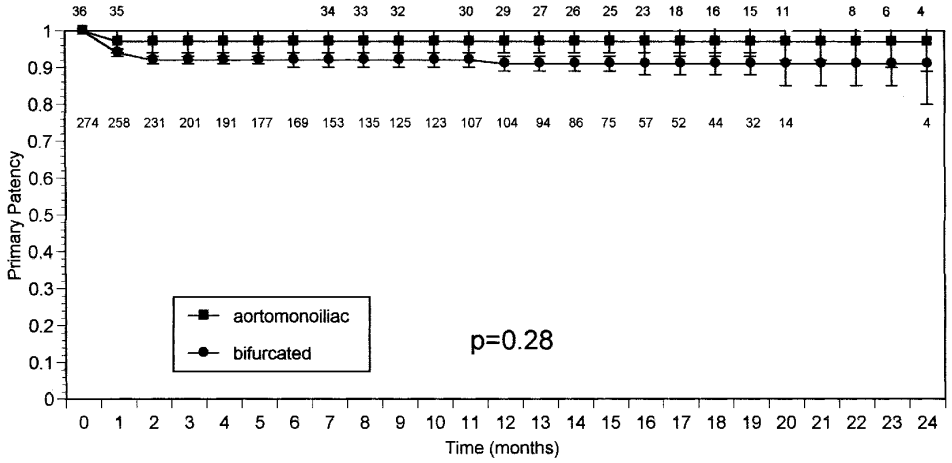

Fig 4. Comparison of patency of endograft limbs: bifurcated versus aortomonoiliac designs. Primary patency of bifurcated graft limbs at 18 months was 90%, and aortomonoiliac limbs was 97% ($P = .28$). Secondary patency was achieved in all cases.

This may be necessary, however, in situations where thrombolytic therapy is contraindicated. We have reserved mechanical thrombolysis for patients who have acute, limb-threatening ischemia as a consequence of their limb thrombosis and for patients who have recent wounds that would not allow safe thrombolysis without the risk of hemorrhage from arteriotomy sites. We have not had to resort to placement of femorofemoral or axillofemoral bypass grafts, but these would remain as reasonable extra-anatomic alternatives to direct treatment of failed limbs.

Our unsupported grafts had significantly lower primary and assisted primary patency rates when compared with their fully supported counterparts. Others have noted this trend as well. In the Ancure data (unsupported limbs) presented to the Food and Drug Administration summarizing results from 242 patients, a 38.4% incidence of decreased limb flow was noted, and in another study of 77 patients with Ancure (unsupported limb) grafts, a 37.7% incidence of decreased limb flow due to stenoses was described.[11] Unsupported limbs are used for traditional open aneurysm surgery, but these limbs are not constrained within a tortuous, diseased, or acutely angulated iliac system. In open procedures, great care is taken, under direct vision, to avoid twists or kinks. This is not possible with the endovascular approach in which a remote delivery system is used. Although arteriography is routinely used at the completion of endovascular aneurysm procedures, others have described the use of intravascular ultra-

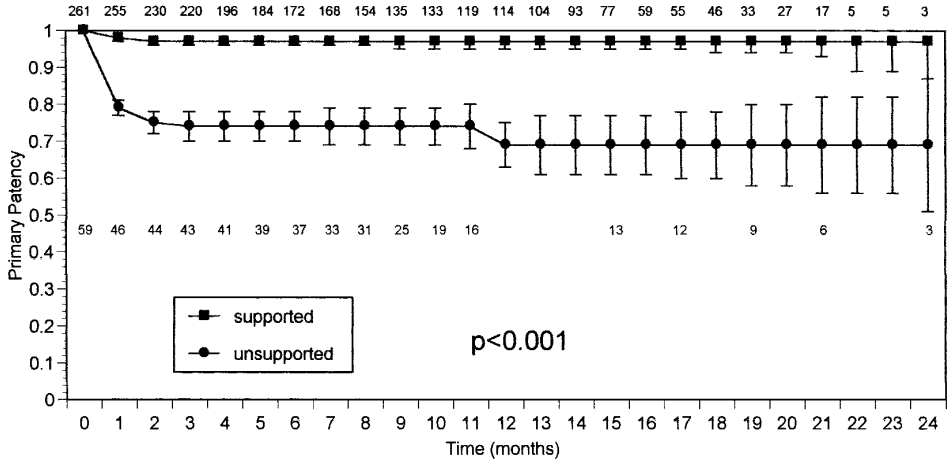

Fig 5. Comparison of patency of endograft limbs: supported (*thick line*) versus unsupported (*thin line*) designs. Primary patency of supported graft limbs at 18 months was 97% and unsupported limbs 69% ($P < .001$). Assisted primary patency (not shown) for supported limbs was 99% and unsupported 91% ($P = .01$). Secondary patency was achieved in all cases.

sound scan, which they believe to be more sensitive for detection of limb narrowing.[12]

The use of fully supported graft limbs provides improved patency compared with the use of unsupported limbs. In a large study of fully supported endografts, no kinks or stenotic lesions were noted in the follow-up interval.[13] We and others currently make liberal use of supplemental stents for unsupported limbs.[5,6,8,9] We have found that a satisfactory arteriographic appearance, free of kinks or stenoses, can still result in a thrombosed limb in longer follow-up because of development of kinks at a later time. Of those patients who presented with late limb thromboses, four were found to have aortic bifurcation kinks, and three had iliac lesions that were not apparent at the time of graft placement. It is suspected that these kinks were induced by changes in configuration subsequent to placement. We have never seen a thrombosed limb that did not prove to have an identifiable kink or stenotic lesion after thrombectomy or thrombolysis. Perhaps these limbs elongate with time, leading to later kinking, or perhaps with subsequent conformational changes in the aneurysm shell (shrinkage), the geometry of the limbs changes, resulting in the development of kinks. It is hoped that supporting the limb with stenting will guard against later problems with limb stenoses. Despite the additional time and cost incurred, consideration should be given to routine prophylactic stenting of all unsupported limbs.

There are advantages to the unibody, unsupported design, when compared with fully stented endograft limbs, which should not be overlooked. Although these grafts are prone to kinking over time, the single-piece configuration guards against separation of modular graft limb components that may occur as the aneurysm shell shrinks. This latter phenomenon has been described and has led to late endoleak and subsequent aneurysm rupture.[14] The stenting of limbs is not without risk, because the friction between the graft limb stents and the fabric of the endograft may lead to erosion of the fabric-producing late endoleaks.[15]

We found no significant difference in the patency of endograft limbs related to the choice of aortomonoiliac versus bifurcated endograft design. This held true even when patency of the femorofemoral bypass graft necessitated by the former choice was taken into account. The choice of configuration is chiefly dictated by the patient's anatomic features. Many patients have only one iliac system that can adequately accommodate passage of the aortic graft delivery system because of occlusive disease or tortuosity. Such patients would not be candidates for bifurcated grafts, and aortomonoiliac grafting with femorofemoral bypass graft is an attractive alternative. Additionally, patients who have short "landing zones" in the common iliac artery may be better served with embolization of the common iliac artery and retrograde perfusion of the hypogastric artery through a femorofemoral bypass graft to avoid pelvic ischemia, rather than with covering the hypogastric artery with a bifurcated graft limb. Also, the previously mentioned situation of a narrow aortic bifurcation that cannot comfortably accommodate the passage of two side-by-side bifurcated limbs is an indication for the use of an aortomonoiliac design. Recently, aortomonoiliac grafts have been suggested as a ready endovascular alternative for patients presenting with ruptured aneurysm.[16] In this emergency situation there is no time for the imaging and measurements required for planning a bifurcated graft design. Our experience suggests that the choice of aortomonoiliac grafting is a reasonable alternative compared with bifurcated designs. The risk of infection of the femorofemoral graft, not patency, seems to be the chief drawback to this approach.

Although we noted slightly higher patency rates in femorofemoral bypass grafts performed in conjunction with aortomonoiliac endografts than in those femoro-

femoral bypass grafts performed for occlusive disease, this finding was not statistically significant. In a larger series, Walker et al[17] have also shown excellent patency rates in femorofemoral bypass grafts performed in conjunction with aortomonoiliac endografts. We had only one thrombosed graft (and one infected graft that was removed), providing a patency rate of 92% at 18 months. We suspect that in the long term, grafts performed for aneurysm disease will prove to have better patency rates than those performed for occlusive disease because of the relative absence of outflow tract occlusive disease in the aneurysm population compared with the occlusive disease population. Infection continues to be the main drawback of the procedure.

The nonrandomized nature and relatively short mean follow-up interval of our study limit its conclusions. Most of our patients were participants in clinical trials of the devices used and subject to the selection criteria unique to each trial. As devices become generally available, direct comparisons of graft designs should be possible, leading to a better understanding of design features that are most likely to result in durable endovascular repairs of AAAs.

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DISCUSSION

Dr James May (Sydney, Australia). This interesting report from the University of Pennsylvania School of Medicine is based on a large experience of endoluminal repair of AAA in 173 patients. The major finding of this study that fully supported AAA endografts provides superior endograft limb patency compared with unsupported designs adds a scientific basis to what has been suspected on an anecdotal basis for some time.

I have some reservations about the study design and analysis. The first concerns the definition of graft limb failure. While there is no problem labeling the seven patients whose limbs thrombosed in later follow-up as graft limb failures, it seems unreasonable to refer to intraoperative blood flow problems in the same way. This seems analogous to counting the successful placement of a cuff or extension to treat extravasation of contrast at the original operation as an endoleak and calling this a failed procedure. The kinks or stenoses that were noted at operation may just as well have been caused by twisting in a unibody prosthesis or a technical error in the deployment process as some intrinsic fault in the design of the graft limbs. In this study the cause of graft limb failure has been attributed to the lack of full metallic support in the limbs. Since the majority of graft limb failures occurred in endografts that were both unibody and lacking in full support, there is no way of apportioning the blame.

The second reservation concerns the validity of analyzing the two groups together since their etiology is quite different. In one group of seven patients the limbs were found to be satisfactory on postprocedure angiography and subsequently occluded in later follow-up. In the other group of 17 patients, the problem was part of the original procedure rather than failure in follow-up. In the first group there were no kinks or stenoses noted, while these were always found in the second group.

I have four questions for the authors.

What was the relative incidence of narrowing of the distal aorta compared with pathology in the iliac arteries as possible etiological factors in graft limb failure?

Secondly, do the authors feel that the use of either on-table biplanar postprocedure angiography or predischarge duplex scanning and plain x-ray would reduce the incidence of graft limb failure?

Thirdly, what technique was used for the thrombolysis of the occluded limbs? Where are the catheters placed, and what was the approximate duration of the treatment?

And finally, will the authors comment on the ethics and cost of using a device that has a predictable requirement of two additional self-expanding stents in a high proportion of cases?

Thank you.

Dr David G. Neschis. Thank you, Dr May.

We agree with you completely with regard to the shortcomings in the evaluation and the definitions, but I think it doesn't

detract from the fact that these grafts do behave differently. A major point of this discussion is that the unibody designs do behave differently and have to be treated differently intraoperatively, although the final outcome can be excellent.

As far as imaging in the OR, in particular with the unibody designs, we've become very meticulous with imaging in multiple planes. And what we've developed is a very low threshold for stenting bilaterally if the views aren't perfect in multiple planes.

As far as lysis, it's performed by our interventional radiologists. They're using t-PA now. The catheter is placed directly in the clot. Usually the first run is for about 6 hours, and then depending on the result, it's continued. But generally, they don't like to go beyond 24 hours.

As far as using a device that we know requires a secondary intervention, we really don't have a problem with that because, as we mentioned in the talk, it's quite possible that the advantages of a unibody design may be sufficient to justify the added expense.

Dr James F. McKinsey (Chicago, Ill). I enjoyed your presentation.

Your follow-up, as best I could tell, was 21 months at maximum length. And I think one question we also have to ask is long term, for these more fully supported grafts. As we have changes in the morphology of the aneurysm sac with exclusion, are they going to be more predisposed to kinking than the unibody construction, not fully supported or augmented with the more flexible Wallstent if that's what you're using? Have you seen this as sequelae in your follow-up, and are you using the Wallstent for your support?

Dr Neschis. To answer your second question, yes, we support the unibody design grafts with the Wallstent.

We haven't seen too many long-term failures, but we have seen limb failures in the fully supported limbs as well. Potentially, we may even bias against the fully supported limbs because some of them, particularly the AneuRx device, come on a smaller introducer. And so in patients with some degree of iliac disease, we may be biasing towards the introducer size as opposed to the device. In otherwise good anatomy but tortuous iliac vessels, if we could, we would use the unibody unsupported.

Dr Evan C. Lipsitz (Bronx, NY). Just a quick question. You've answered it partially with your use of biplane angiography and a low threshold for Wallstenting, but do you also use pressure gradient measurements or any other intraoperative techniques to help you decide whether to stent these unsupported limbs intraoperatively?

Dr Neschis. Absolutely. If there's any question, we do measure pullback pressures. But we've been burned in that situation as well. So it doesn't guarantee success postoperatively.

Dr David C. Brewster (Boston, Mass). I rise to emphasize one mechanism of endograft limb failure as it relates to time. We, as many other groups, have had either periprocedural or early postoperative problems with unsupported graft limbs and flow obstruction. However, all of our late limb failures have in fact been in supported limb grafts that have more difficulty accommodating to morphologic changes of the shrinking AAA sac, what I refer to as the so-called "paradox of success." That is, problems due to kinking of stented graft limbs may occur due to the very same outcome one desires: exclusion and diminishment in AAA size. Therefore, in the long term, unsupported limbs may actually accommodate better to such late morphologic alterations.

Dr Neschis. I agree. In general, even in the later failures, there has been some definable lesion that was able to be addressed; usually in that setting it's kinking.