Endoluminal Aortic Aneurysm Repair Using a Balloon-Expandable Stent-Graft Device: A Progress Report

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We describe our experience with endoluminal repair of abdominal aortic aneurysms using the stent-graft device. Twenty-four patients underwent 25 procedures in the 27-month period ending December 31, 1992. Twenty-one of the patients were considered high-risk candidates for conventional surgical repair. The endoluminal stented grafts were aortoaortic in 16 procedures and unilateral aortoiliac in eight. One patient underwent a second procedure consisting of an ilioiliac graft to repair a separate common iliac artery aneurysm. Technical problems were primarily related to retrograde transluminal access across the iliac arteries, tortuous aneurysms, and misjudgments as to measurement of length. One patient died and another required secondary deployment of a distal stent at 4 months; subsequent aneurysm expansion mandated surgical replacement at 18 months. It is clear that this device and methodology will have to undergo further refinement before the technique is acceptable for wider clinical application. Current experience, however, is encouraging. Aneurysm exclusion with an endoluminal prosthesis is likely to become an important therapeutic alternative over the next several years. (Ann Vasc Surg 1994;8:523-529.)

The graft inclusion technique for intra-aneurysmal prosthetic replacement, first described in 1962,[1,2] has justifiably become the surgical method of choice over the past 25 years. Its simplicity and safety have contributed significantly to the excellent results currently attained with surgical treatment of aortic aneurysms.[3] Although operative mortality rates are quite low in good-risk candidates, there remains a subset of patients with serious multiple comorbid conditions for whom aneurysm surgery remains a formidable undertaking. Additionally, overall perioperative morbidity and costs continue to be major concerns for aneurysm patients facing surgical repair.

Aneurysm exclusion by a graft implanted transluminally would achieve the same therapeutic goal as the inclusion technique but would avoid the risks and costs of conventional surgery. It would also permit treatment of high-risk patients who might not tolerate a major abdominal operation and aortic cross-clamping. Conceived with this purpose in mind, the device consists of a stent-graft combination deployed within the aneurysm via retrograde transluminal introduction.[4] Clinical application began in 1990, following preliminary bench testing and animal experimentation.[4] This report focuses on the techniques used and results obtained with endoluminal treatment of abdominal aortic aneurysms.

MATERIAL AND METHODS

In the period beginning September 1, 1990 (first clinical case), and ending December 31, 1992, 24

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patients were treated with the endoluminal method. Patient ages ranged from 66 to 83 years. There were 23 males and one female. At the time of intervention, two patients had a symptomatic aneurysm and 22 were asymptomatic. No ruptured aneurysm was treated during the study period. Twenty-one patients were considered high risk by currently accepted criteria.[3,5] Aneurysm size ranged from 5.1 to 14.0 cm in greatest transverse diameter. Aneurysms were all infrarenal. Preoperative evaluation included CT and aortography in all cases.

Treatment consisted of transluminal retrograde insertion of a thin-walled Dacron graft sutured to a balloon-expandable stent. The stent-graft combination was mounted on a balloon catheter of appropriate size and assembled into an introducer sheath for transluminal delivery within the aneurysm (Fig. 1). The device, in terms of balloon diameter and graft length, was tailored to the characteristics and size of the lesion in each individual patient. Cranial and caudal balloon-expandable stainless steel stents were deployed to attach the prosthesis in its intra-aortic position. A distal stent was not used in the first four procedures of this series. Access was by femoral cutdown and arteriotomy in the common femoral artery (Fig. 2). Aneurysms involving the aortic bifurcation and common iliac arteries were treated by insertion of a tapered aortoiliac unilateral graft and contralateral iliac exclusion using a transcatheter technique or surgical ligation. Revascularization of the opposite lower extremity required a crossover femorofemoral bypass. A total of 16 procedures involved a straight aortoaortic graft (Fig. 3); in eight cases an aortoiliac (unilateral) prosthesis was inserted, seven of which required a concomitant femorofemoral bypass (Fig. 4). Chronic iliac occlusion in one case obviated the need for crossover grafting. One patient underwent aortoaortic grafting first, and then a similar ilioiliac graft was placed 2 days later for a separate common iliac artery aneurysm, making a total of 25 endoluminal grafting procedures in 24 patients.

The procedures were all performed under fluoroscopic, arteriographic guidance. Intraoperative measurements of aortic and aneurysm diameter and length were aided by the use of a specially designed arteriographic catheter containing radiopaque markings at known intervals. Computer

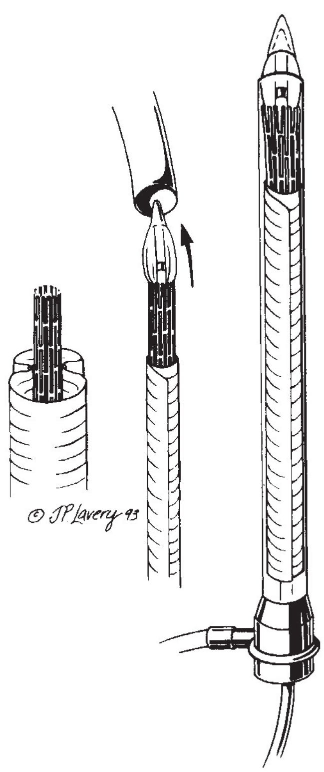

Fig. 1. The thin-walled Dacron graft is sutured to the stent as shown. The stent-graft combination is then mounted on a balloon catheter and the graft folded around the stent and the catheter. Introduction into the delivery sheath completes preparation of the device for endoluminal deployment.

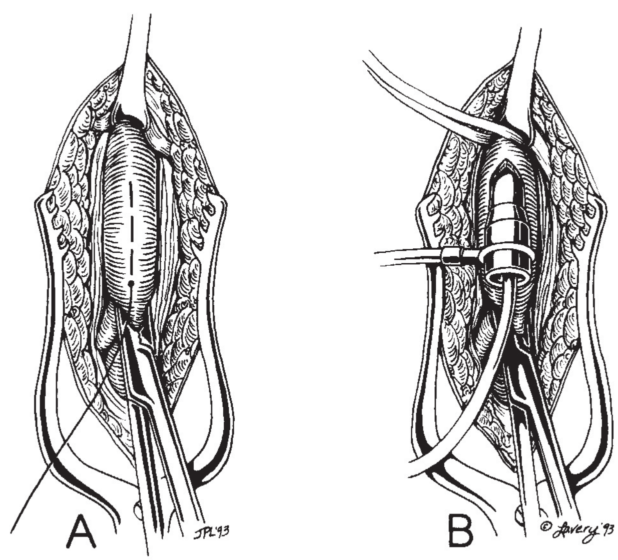

Fig. 2. Exposure of the common femoral artery by surgical cutdown. A guidewire is introduced transluminally across the aneurysm. The arteriotomy begins at the wire introduction point **(A).** The ensheathed assembled device is inserted over the wire **(B).**

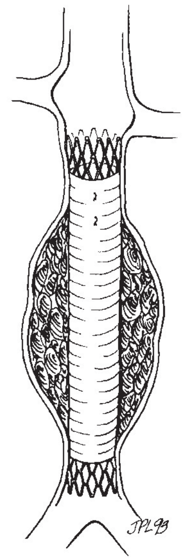

Fig. 3. Completed aortoaortic endoluminal graft.

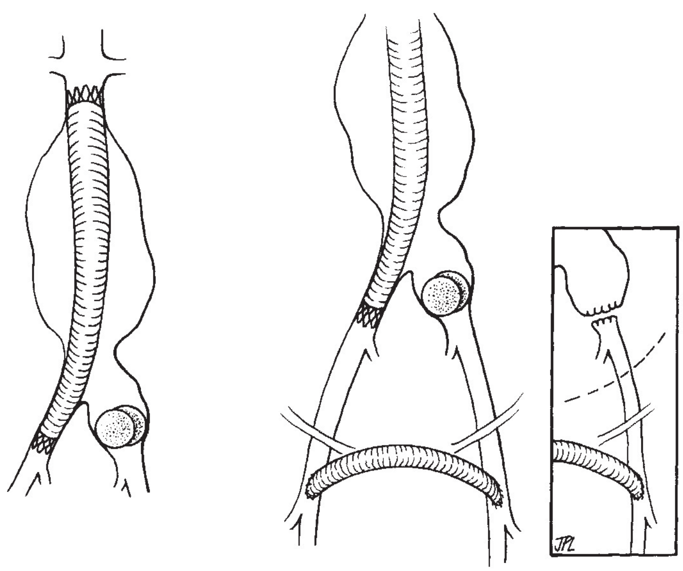

Fig. 4. Tapered endoluminal aortoiliac unilateral graft. Crossover grafting and contralateral iliac exclusion, either transluminally or by surgical ligation (inset), complete the procedure.

assistance was utilized in these calculations. Epidural anesthesia supplemented with intravenous sedation was employed in 23 procedures, and local anesthesia in two. Average length of hospital stay was 3 days. Linear follow-up in each patient included clinical reassessment, color-flow duplex, and CT scanning at 6-month intervals. Aortography was performed at least once during the follow-up period.

RESULTS

One death occurred in the series; this was in a 72-year-old man with an 8 cm abdominal aortic aneurysm that was very tortuous. Technical difficulties with proper positioning and deployment of the cranial stent led to multiple transluminal reentries that caused distal embolization of aneurysm contents, leading ultimately to severe disseminated intravascular coagulation and fatal intracerebral hemorrhage.

Intraprocedural complications have generally involved misjudgments as to the length and three-dimensional configuration of the aneurysm and its upper neck. In two operations there was inadequate proximal bloodtight sealing because of incomplete or improper deployment of the upper stent, resulting in an antegrade "leak" into the aneurysm sac. This required insertion of a second graft-covered stent within the proximal stent in one case; in the other, luminal reentry proved impossible and the patient was left with a pulsatile aneurysm. Conventional surgical repair has not been undertaken because of prohibitive associated medical risks. As of the time of this writing (August 1993), the aneurysm remains pulsatile but has not enlarged appreciably. The other type of intraoperative complication involved one patient with a retrograde "leak" at the distal end caused by failure of the stent to completely seal the graft-aorta interface. Correction was also by deployment of a second cloth-covered stent.

Postoperative complications have occurred in two patients. Secondary reflux from the distal, unstented end of the graft with recurrent, palpable pulsatility of the aneurysm was discovered in one patient 4 months following the initial intervention. Secondary deployment of a distal stent seemed to correct the situation. However, the patient presented again at 18 months with an expanding pulsatile aneurysm that required conventional surgical repair. The cause of the problem had been the insertion of a graft that was too short to begin with and secondary deployment of a distal stent that did not attain complete exclusion of the aneurysm with consequent continued expansion in its distal portion. In one other patient a large groin wound hematoma developed that resolved with conservative management. All of the patients continue to be followed serially, primarily as to the signs of pulsatility or aneurysm expansion, endoluminal graft dilatation, and signs of intra-aneurysm "leaks."

DISCUSSION

Endovascular grafting for aneurysmal exclusion would have the potential of avoiding a major abdominal operation involving significant blood loss and aortic cross-clamping. Furthermore, the risks of nerve injury causing sexual dysfunction and the occurrence of graft-enteric complications would be obviated altogether. It was first envisioned by one of us (J.C.P.) in 1977; various attachment methods and devices were conceived but none proved satisfactory. It was the development of balloon-expandable metallic stents that provided the critical component for the endovascular repair technique.

Several designs and inventions have been patented.[4,6-8] The first in vivo demonstration of the endoluminal methodology was reported by Balko et al.[9] who excluded experimental aneurysms in sheep using a polyurethane graft with a Nitinol or stainless steel frame. These acute experiments proved the feasibility and soundness of the concept. More recent experiments in dogs by Mirich et al.[10] involved the implantation of wire stents covered by a porous nylon graft.

The design of an endoluminal repair device and technique must take into consideration the unique anatomic and pathologic characteristics of abdominal aortic aneurysms. More to the point, the presence of intraluminal thrombus and at times marked tortuosity and elongation of the aorta may pose difficulties and risks when using an intraluminal method. Precise three-dimensional sizing of the aneurysm and its neck is paramount in tailoring the appropriate device and implantation technique in a given case. This point was emphatically underlined in our experience by the one fatality resulting from misjudging the length of the aneurysm and its neck, which led to multiple reentries and exchanges that dislodged the thrombus and caused downstream embolization. Current and future advances in CT and MR arteriography are likely to become critical components for proper and safe execution of endoluminal repair techniques. Intravascular ultrasound imaging may also play a role in the future.

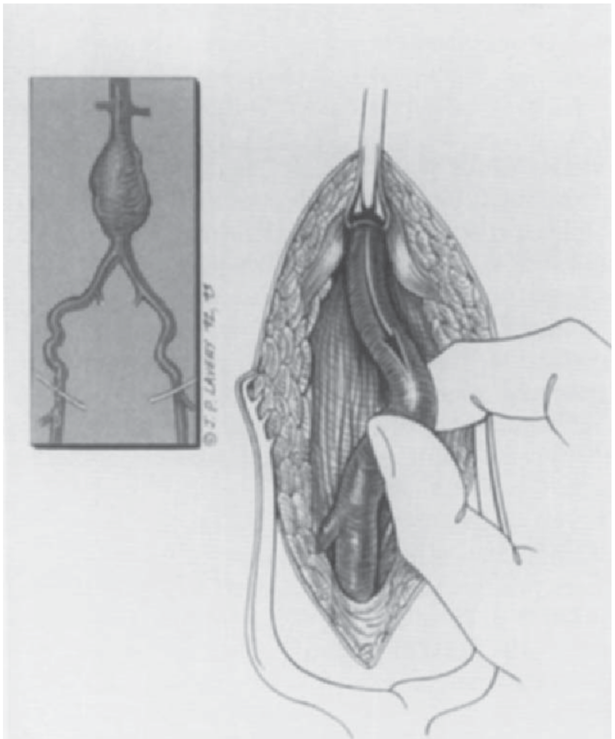

Fig. 5. Iliac pull-down maneuver by extensive circumferential dissection of common femoral and external iliac arteries.

Retrograde transluminal access through the femoral-iliac arterial system is a critical step and a frequent limitation. Current technology has permitted reduction of the entire ensheathed stent-graft device to a minimum diameter of 18 F. This still requires iliac arteries of considerable caliber and free of significant atherosclerosis. Focal stenotic lesions, when present, should undergo angioplasty in preparation for the performance of the procedure, ideally in such a way as to allow enough time (2 weeks or more) for healing of the angioplasty site. The rigidity of the current device represents a problem when dealing with tortuous iliac arteries. It has been found that iliac tortuosity can be overcome and the artery straightened, provided it is essentially free of atherosclerosis. The "iliac pull-down maneuver" (Fig. 5) has been a simple and effective aid in several cases. In other situations involving more severe angulations and iliac arterial disease, we have resorted to another solution consisting of the attachment of a temporary prosthetic graft to the common iliac artery exposed through a limited retroperitoneal incision. This graft is then passed down under the inguinal ligament and used as the conduit for introduction and deployment of the endoluminal device (Fig. 6). Percu-

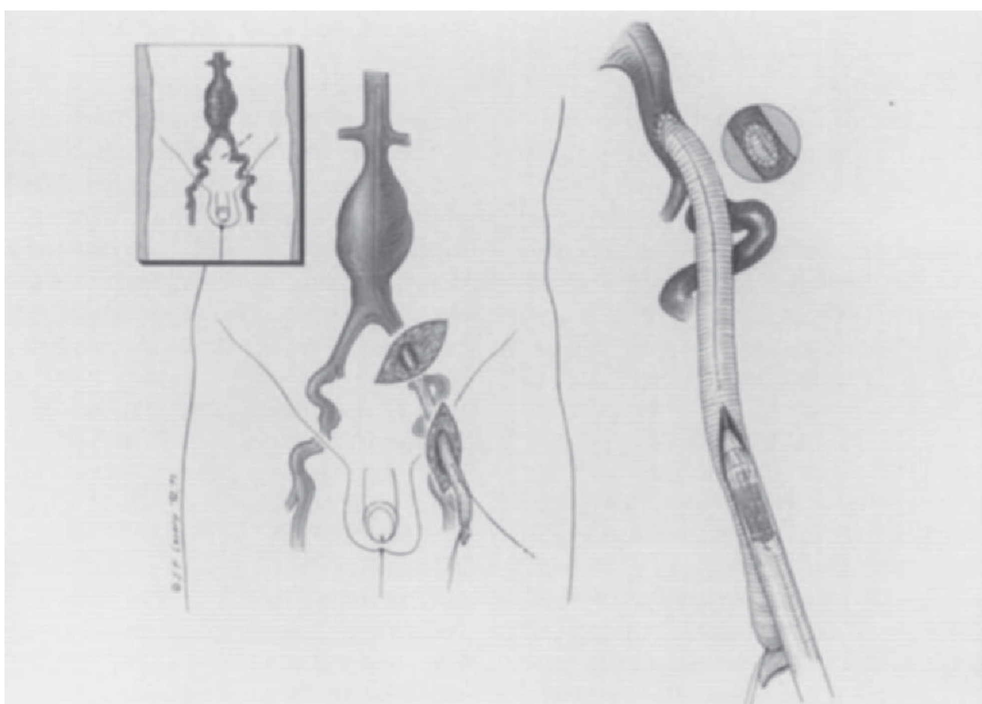

Fig. 6. Retroperitoneal exposure of the common iliac artery and anastomosis of a 10 mm Dacron tube used for transluminal delivery of the device. Following implantation the Dacron iliac graft is cut and oversewn almost flush with the iliac artery.

taneous access is not likely in the near future with a balloon-expandable device of this type. Spring-loaded prostheses would have an advantage in this regard. In any case, it is our view that percutaneous insertion per se does not constitute a critically important goal of these developments. The focus, by definition, is the avoidance of a major transabdominal operation and aortic cross-clamping.

One other critical aspect of the technique relates to the nature of the graft required and its attachment to the aortic wall. Knitted thin-walled Dacron tubes were used exclusively in this experience. Although bench testing and tensile strength measurements have been reassuring, it remains to be seen whether progressive graft dilatation will be a concern. In theory, such would be unlikely and probably inconsequential because of the intra-aortic endoluminal position of the prosthesis.

The integrity of the graft attachment with properly placed stents has not been a problem, either acutely or during the follow-up period. We remain confident that long-term graft anchoring afforded by this technique is adequate. Migrations have been related to improper positioning and deployment of the stents, highlighting again the importance of pre- and intraoperative imaging and measurements of the aneurysm and its neck. A minimum length of upper neck is required for proper stenting and anchoring; this is probably in the range of 2.5 to 3.0 cm.

Precise visualization of the renal arteries during implantation is paramount. More often than not the cranial stent is deployed immediately below the renal artery ostia. In three patients the superior, uncovered portion of the stent was implanted across one or both renal artery ostia without any apparent compromise of renal blood flow either acutely or during the follow-up period. This is certainly in keeping with experience in other arterial segments where the Palmaz stent can be expanded across an important branch orifice (internal iliac) without occluding flow.

Unlike the proximal "anchoring" stent, the distal stent is designed to achieve a bloodtight seal of the space between the (inner) graft and the (outer) aortic wall, thus preventing retrograde flow outside the graft and continued aneurysm expansion. A minimum length of nonaneurysmal aorta of approximately 2 cm is required to safely "seat" the stent. Unlike the surgical scenario, where one can suture the tube graft to the bifurcation itself or even the iliac artery ostia, the endoluminal method requires clear-cut sparing of the bifurcation and distalmost aorta from aneurysmal involvement. If this is not the case, and when the aneurysm is frankly aortoiliac, we have resorted to direct deployment distally into one iliac artery using a tapered prosthesis and a smaller distal sealing stent. The contralateral iliac artery must be excluded via transcatheter balloon deployment or surgical ligation of the external and internal iliac arteries. Crossover femorofemoral grafting completes the procedure. A bifurcated endoluminal graft would be the best approach, but the technique is currently in an early developmental stage.

The fate of the inferior mesenteric and lumbar arteries following endoluminal graft implantation is not clear at this time. Continued patency of these vessels might prevent complete thrombosis of the periprosthetic intra-aneurysmal lumen and result in blood flow to some degree. This is unlikely to be of sufficient magnitude as to cause aneurysm pulsatility and further expansion, but the issue may require specific clarification in the future.

Several other methods of endoluminal aneurysm repair are being developed throughout the world. Variations of the stent-graft concept include self-expanding (spring-loaded) devices and the use of alternate attachment methods with and without stents. Stents to encompass the length of the aneurysm (cloth-covered, tightly knit, and other modifications) are also being tried. It is clear that further development of the device itself and the techniques of deployment will be required before widespread clinical application is warranted. Specifically, miniaturization, improved trackability and flexibility, as well as better methods of bipolar stent deployment will be forthcoming and contribute to simplification, increased safety, and wider applicability of the technique. Precise anatomic characterization of the aneurysm and nonaneurysmal aorta, especially at the upper neck, will also be required and contribute enormously to further refinements of this methodology. Endovascular grafting with this type of stent-graft combination has also been used successfully to obliterate arteriovenous fistulas and acute dissections through a transluminal approach (Fig. 7).

Although it is still too early to predict what role these techniques will have in the management of aneurysm patients in the future and what number of patients will be suitable candidates, it appears safe to state that this and other endoluminal methods will likely prove useful in some cases. "Opposition will be mounted"[11] but as in

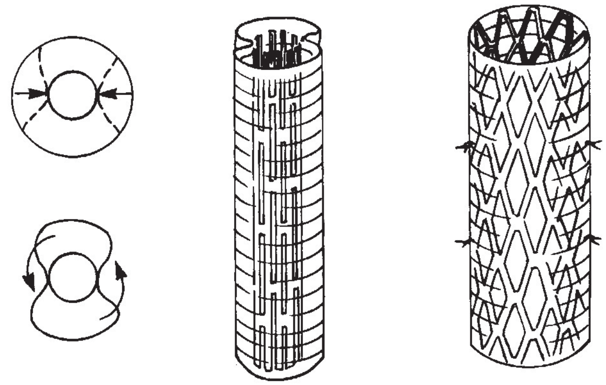

Fig. 7. Cloth-covered stent used to obliterate arteriovenous fistulas and other lesions.

other areas of surgery, the march toward less invasive techniques is inevitable. Vascular surgeons would be ill advised not to follow these developments with curiosity and receptivity, for they have the potential to change the treatment of aneurysms and other vascular lesions dramatically in the twenty-first century.

CONCLUSION

Aneurysm repair by endoaortic transluminal grafting is clearly feasible. Potentially it is a promising alternative for high-risk patients who would experience significant morbidity and mortality with conventional surgical repair. Further developments are needed with the device itself and the techniques of deployment. In particular, trackability and miniaturization of the device, transluminal access through the iliac arteries, intra-aortic attachment, and precise sizing and anatomic characterization of aneurysms are areas that should be the focus of current and future research. These techniques are likely to have a major impact on the way we manage aneurysm patients.

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