Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

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This study reports on animal experimentation and initial clinical trials exploring the feasibility of exclusion of an abdominal aortic aneurysm by placement of an intraluminal, stent-anchored, Dacron prosthetic graft using retrograde cannulation of the common femoral artery under local or regional anesthesia. Experiments showed that when a balloon-expandable stent was sutured to the partially overlapping ends of a tubular, knitted Dacron graft, friction seals were created which fixed the ends of the graft to the vessel wall. This excludes the aneurysm from circulation and allows normal flow through the graft lumen. Initial treatment in five patients with serious co-morbidities is described. Each patient had an individually tailored balloon diameter and diameter and length of their Dacron graft. Standard stents were used and the diameter of the stent-graft was determined by sonography, computed tomography, and arteriography. In three of them a cephalic stent was used without a distal stent. In two other patients both ends of the Dacron tubular stent were attached to stents using a one-third stent overlap. In these latter two, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a saline/contrast solution. The catheter was gently removed caudally towards the arterial entry site in the groin to keep tension on the graft, and the second balloon inflated so as to deploy the second stent. Four of the five patients had heparin reversal at the end of the procedure. We are encouraged by this early experience, but believe that further developments and more clinical trials are needed before this technique becomes widely used. (*Ann Vasc Surg* 1991;*5*:491–499).

KEY WORDS: Graft-stent exclusions; grafts; abdominal aortic aneurysm; transfemoral intraluminal grafts.

Abdominal aortic aneurysm (AAA) has been recognized since antiquity as a lethal pathologic process. As a result, the last 50 years of vascular surgery have seen a variety of attempts at cure of the condition. Intraluminal wiring [1], external wrapping [2], and exclusion of the aneurysm by ligation have been tried and discarded in the past [3]. Experience with those showed that they did not offer durable protection from aneurysm rupture [4]. Neither wrapping nor thrombosis of the aneurysm protected the patient from fatal rupture [5–7].

Today, vascular surgeons are dealing with an increasingly aged population. These are persons in whom abdominal aortic aneurysms occur. Autopsy studies have placed the overall incidence of AAA disease between 1.8 and 6.6% [8–10]. Actual incidence of AAA is increasing with the aging of the

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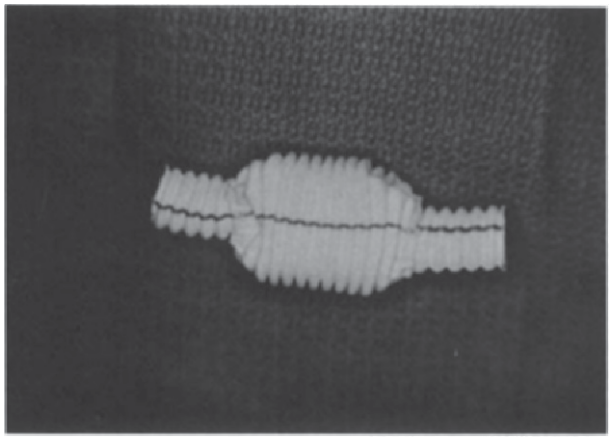

Fig. 1. Artificial abdominal aortic aneurysm created by fusiform-shaped Dacron conduit.

population [11]. In the 30-year period of study, the incidence of AAA was seen to rise threefold. Furthermore, aneurysm screening in select populations such as first-order relatives of patients with AAA or patients in cardiovascular clinics has shown that in select populations, the incidence of aneurysms may vary from 5% to 20% [12–14].

Durable protection from aneurysm rupture began with DuBost [15] who demonstrated that aortic replacement was an effective method of treatment. Prosthetic graft replacement is the treatment of choice for aortic aneurysms today. Elective repair is regularly performed with an operative mortality of under 5% with the expectation that long-term survival is markedly extended [16,17].

Increasingly, vascular surgeons are encountering older patients with severe co-morbid conditions. These can increase operative morbidity and may even elevate mortality of aortic surgery to a figure in excess of 60% [18]. With this in mind, new methods of aortic aneurysm exclusion deserve exploration. The following study reports on animal experimentation and initial clinical trials which explored the feasibility of exclusion of AAA by placement of an intraluminal, stent-anchored, Dacron prosthetic graft using retrograde cannulation of the common femoral artery under local or regional anesthesia.

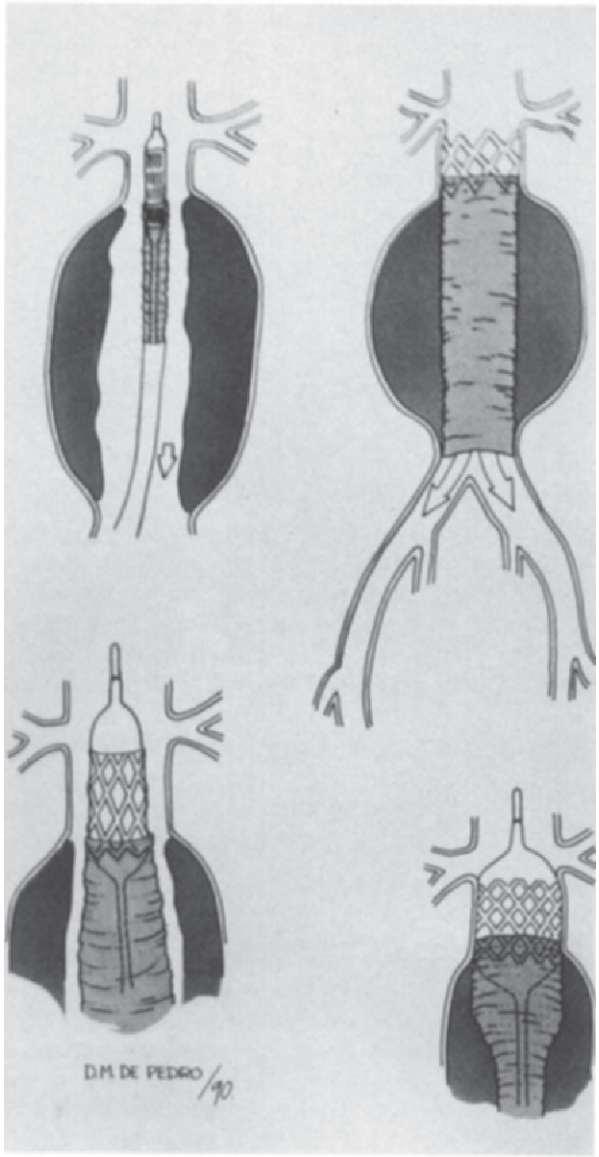

Fig. 2. Intraluminal exclusion of artificial aneurysm by implanting Dacron tubular grafts by transfemoral route. Balloon expandable tents anchor graft to aortic wall.

ANIMAL STUDIES

Initial exploration of a solution to the problem involved in intraluminal graft placement was begun in 1976. Simultaneously, experiments progressed towards debulking the Dacron prosthesis so that it could be implanted through a miniaturized sheath, and modification of stents so that they could anchor the Dacron prosthetic material to aortic wall. Finally, artificial AAAs were created in experimental animals by replacing a segment of the infrarenal aorta with a fusiform-shaped, Dacron conduit (Fig. 1). After creation of the artificial AAA in the experimental animal, experiments were completed by successfully excluding the aneurysm by implanting Dacron tubular grafts through the transfemoral route (Fig. 2) [19–21].

Experimental study had shown that stents could replace surgical suture and could act as friction seals to fix ends of the graft to vessel wall. These friction seals were developed by creating a transluminal graft-stent combination by suturing a Pal-

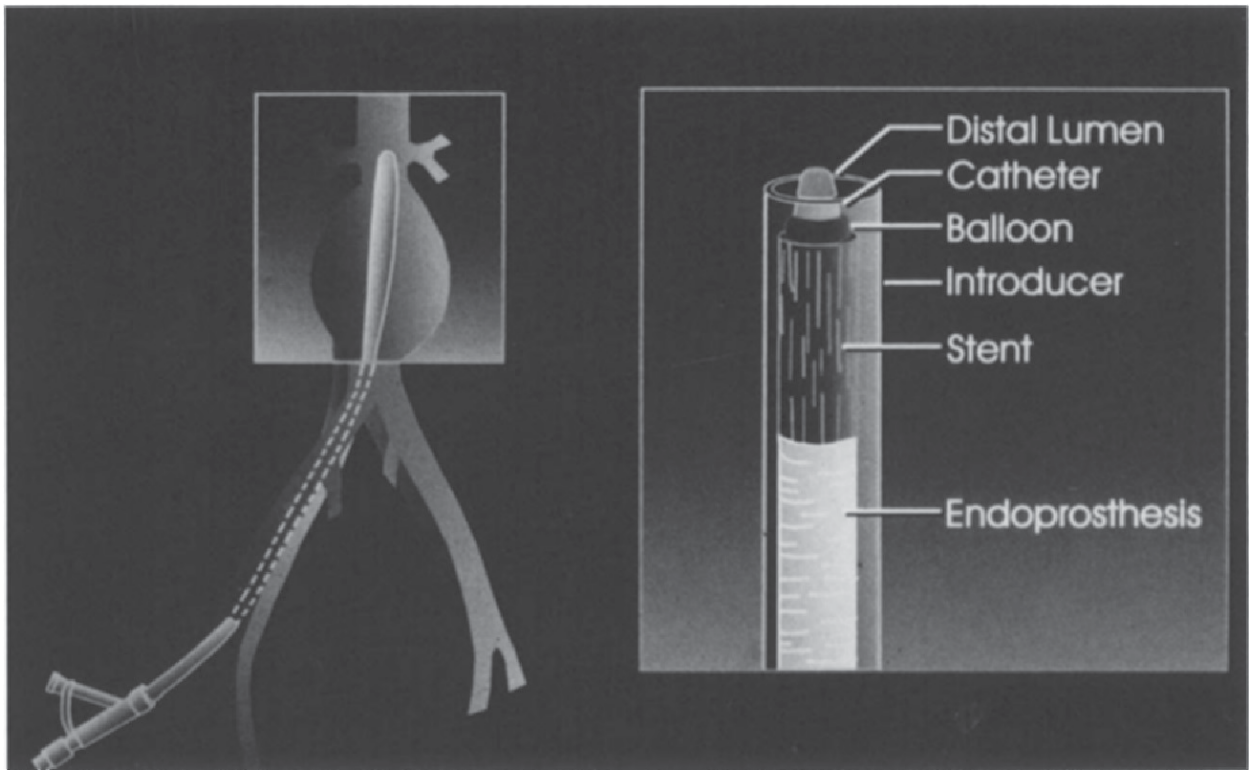

Fig. 3. Graft-stent combination is mounted on valvuloplasty balloon and placed under fluoroscopy through sheath introduced through femoral arteriotomy.

maz, balloon-expandable stent* to the partially overlapping ends of a tubular, knitted Dacron graft. This was done so that the stent expansion would press the graft against the aortic wall, creating a watertight seal. Placement of the stent-graft assembly was planned to be done by actually mounting the assembly on a balloon angioplasty catheter. This would then be placed under fluoroscopy through a #14 French sheath introduced through a femoral arteriotomy (Fig. 3).

Figures 4 and 5 show that the concept is correct. The graft-stent combination, when expanded by the balloon, can exclude the aneurysm from the circulation and allow normal flow through the graft lumen. Once the concept was proven that a Dacron graft could be delivered through a catheter and be firmly fixed in place by balloon-expandable stents, attention turned to human studies.

This report details the initial treatment in five patients. A sixth patient treated by J.C. Palmaz is not reported here.

GRAFT-STENT COMBINATION

A Teflon, #22 French sheath, 45 cm in length with a hemostatic valve closure in the operator end contains the balloon catheter consisting of a #9 French, polyethylene (PE) shaft and one or two PE valvuloplasty balloons, 3.5 cm in length, and either 23 or 25 mm in diameter†. The assembly contains either one or two aortic balloon-expandable stents, 6 mm in diameter and 3.5 cm in length. These are stainless steel, modified Palmaz stents. A specially created, thin-walled, crimped, knitted, Dacron graft§ was sutured to the stents, overlapping one-third of the length of the stent**.

In three patients, a cephalic stent was used without a distal stent (Fig. 2). In the two other patients, both ends of the Dacron tubular stent were attached to stents using one-third stent overlap. In these two cases, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a solution containing 50% saline and 50% nonionic contrast material. The balloon was kept inflated under low pressure to expand the folded graft. Finally, in those two cases with a double balloon, the catheter was gently moved caudally toward the arterial entry site in the groin to keep tension on the graft, and the second balloon was inflated so as to deploy the second

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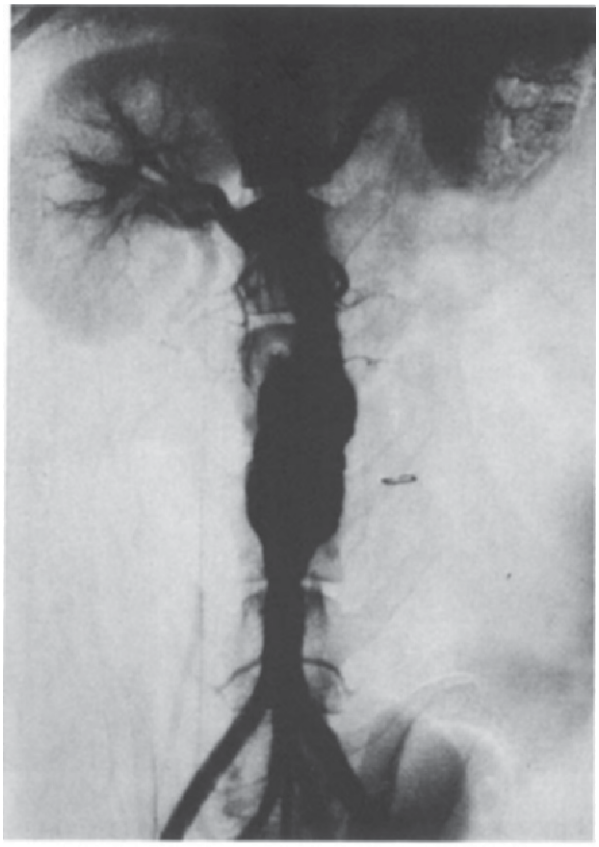

Fig. 4. Arteriogram of aorta four weeks after replacing segment with artificial aortic aneurysm in dogs.

stent. Thus, the prosthetic graft was anchored in place both proximally and distally.

The procedure was terminated by performing an arteriogram after introducing an arteriographic catheter over the guidewire. After removal of the guidewire and overlying catheter, the arteriotomy in the femoral vessels was closed with 6–0 polypropylene suture. Because 10,000 units of heparin solution was given intravenously before graft placement, the heparin was reversed with the appropriate dose of Protamine sulfate at the conclusion of the procedure. Patients were routinely monitored in the coronary care unit, postoperatively.

In the following cases, each patient had an individually tailored device. Both the diameter of the balloon and diameter and length of the Dacron graft were individualized. The stents themselves were standard and the diameter of the stent and graft combination was determined by data obtained from sonograms, computed tomographic (CT) scans, and arteriograms. Stent size determined diameter of the balloon used to deploy the stent. Cardiopulmonary monitoring was done under cover of an antibiotic umbrella (1 gm Keflin, given intravenously).

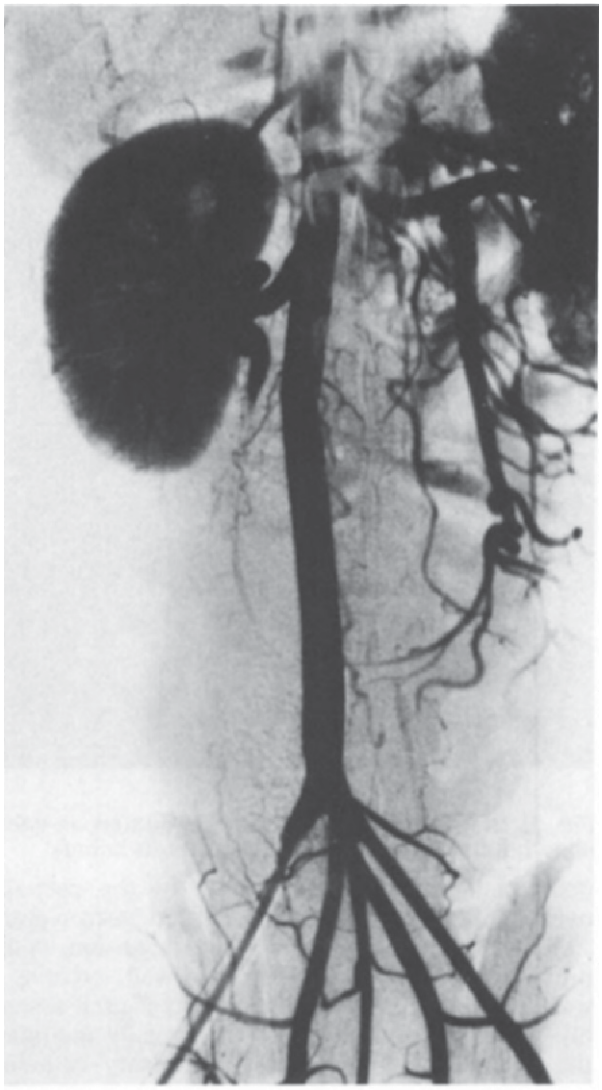

Fig. 5. Arteriogram of same dog after implanting graft-stent combination through right femoral artery.

CASE HISTORIES

Patient No. 1

A 70-year-old man with severe chronic obstructive pulmonary disease complained of severe back pain caused by a 6 cm AAA (Fig. 6). Incidental note was made of bilateral lower extremity intermittent claudication. The patient refused a surgical procedure but did agree to enter the clinical trial. After explanation of the alternatives and expected complications, informed consent for the experimental procedure was obtained.

The patient was prepared as if for standard surgical AAA resection. Under epidural anesthesia, the common femoral artery was freely dissected and mobilized. Arteriography was then performed under fluoroscopy (Fig.7) and an Amplatz wire was placed in the descending thoracic aorta. An intraluminal graft was implanted on

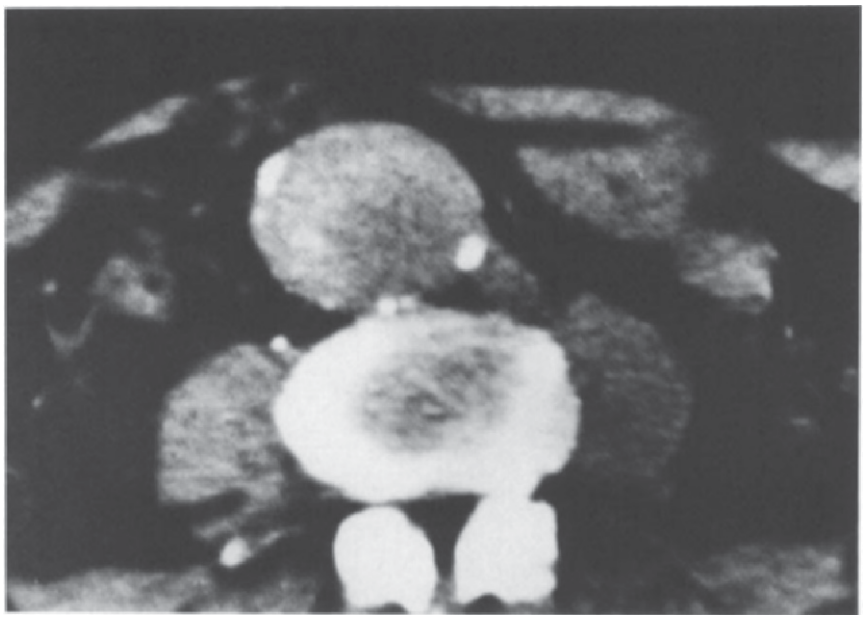

Fig. 6. Computed tomographic scan of Patient Number 1.

September 6, 1990. This patient had a hematoma in the right groin containing approximately 100 cc of blood. This was evacuated on the day of operation. In this instance, the initial heparin dose was not reversed following placement of the stent-graft combination.

Note: Heparin anticoagulation was reversed in the following four cases and care was given not to administer antiplatelet agents or Dextran to these patients.

Patient No. 2

A 68-year-old man was admitted because of a 6 cm, pulsatile abdominal mass, confirmed to be an AAA. He volunteered to enter the clinical trial, and after information was given regarding alternative treatments and description of complications, he gave written consent for the procedure. A single stent-graft combination was implanted on September 6, 1990. During the procedure, there was an accidental displacement of the marking ruler. This reference, therefore, failed to identify the exact target area in which the stent would be placed. As a consequence, the stent was deployed 3 cm distal to the selected site. Therefore, the Dacron graft was overly long and the caudal end of the prosthesis lay within the right common iliac artery. This effectively excluded the contralateral iliac artery from the circulation. This was a patently unsatisfactory situation and the patient was taken to the operating room where a standard AAA resection was performed. Fortunately, he recovered from this procedure uneventfully. In surgery, it was found that the stent was firmly attached to the wall of the aorta which required resection.

Patient No. 3

A 63-year-old man was referred from the French Hospital in Buenos Aires where he had been admitted because of an acute stroke. Computed tomographic scans had shown a massive, right hemispheric, hemorrhagic infarction. Two weeks following admission for treatment of this event while the patient was recovering satisfactorily, he experienced acute abdominal discomfort and increasing pain. A large, pulsatile mass in his abdomen enlarged rapidly, and he was transferred with the diagnosis of AAA dissection. Because of his severe neurologic injury, a decision was made to use the transfemoral prosthetic graft implantation technique, and the procedure was done on November 11, 1990 after informed consent.

Because only a proximal stent was used in this case, reflux was noted at the distal end of the prosthetic graft. The stent effectively closed the proximal intimal disruption, the patient's pain subsided, and the diameter of the aorta dramatically diminished. Follow-up at seven months has been completed, and reflux at the distal end of the graft is still noted. The reflux does not fill the false lumen of the dissection. Presumably, the intimal rent which initiated the dissection has been sealed (Figs. 6, 7).

Patient No. 4

A 61-year-old man was asymptomatic but was afflicted with a 6.5 cm AAA. He was a severe asthmatic with profound chronic obstructive pulmonary disease. He volunteered for the graft trial and the stent-graft combination was implanted on January 3, 1991. Following placement of the prosthetic graft and proximal stent, reflux was noted at the distal end of the graft and a second stent was placed. Six months of follow-up have been completed. The aneurysm has not increased in size and is effectively excluded from the circulation with arterial continuity being established through the prosthetic graft and its double stent fixation.

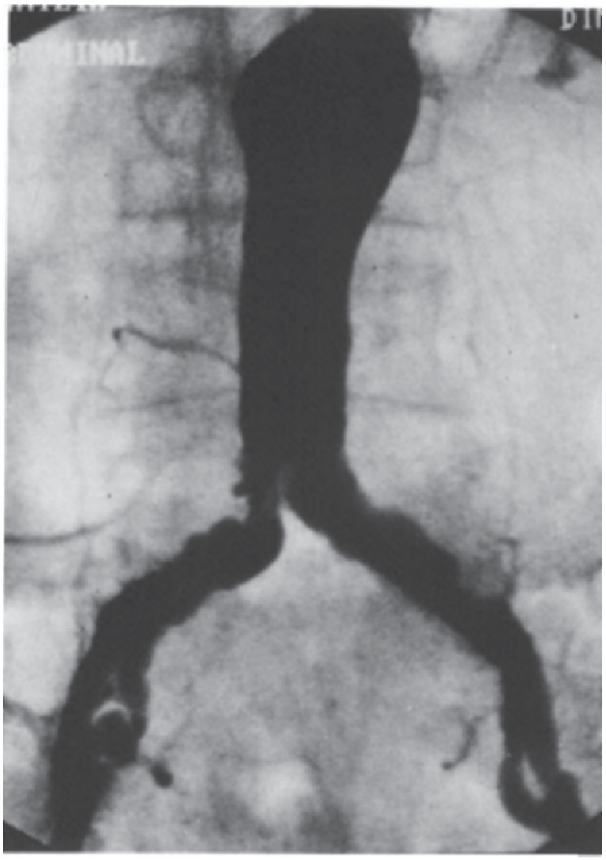

Fig. 7. Aortography of Patient Number 1 depicting an infrarenal aneurysm.

Patient No. 5

A 62-year-old man was referred from the Argentinian province of Santa Fe. He had experienced multiple, recurrent episodes of atheromatous embolization to the lower extremities. In addition, he had severe and noncorrectable coronary artery occlusive disease with a cardiac ejection fraction of less than 20%. Recent pulmonary edema had been treated successfully. A small, 3.8 cm AAA was discovered and this was found to have an irregular luminal surface, suggesting mural thrombosis. Cardiac echocardiography demonstrated an enlarged left ventricle without thrombus formation. No arrhythmias were found on Holter monitoring.

The distal atheromatous embolization was treated with intraarterial infusion of prostaglandin E_1 (Prostin)[‡]. After four days of arterial infusion, a marked improvement in the perfusion of the distal lower extremity was achieved. Therefore, on May 26, 1991, the graft-stent combination was implanted. In this case, a double stent was placed initially, thus sealing the proximal and distal ends of the prosthetic graft to aortic wall. There has been no recurrence of distal embolization since implantation of the device (Fig. 10).

At this time, all five patients are doing well. The follow-up time has been 12 months in two patients, and nine, eight, and three months in the other three. All

[‡]Upjohn Company, Kalamazoo, Michigan.

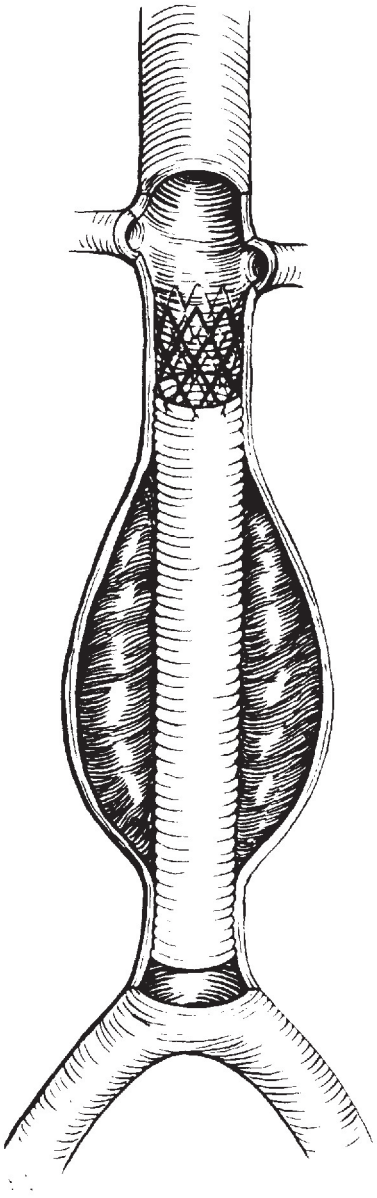

Fig. 8. Graft-stent combination with cephalic stent.

patients have been studied by duplex Doppler color ultrasound and CT scans. Late arteriograms have been performed in two patients (Cases 1 and 3) (Fig. 9). As noted above in Case 3, persistent distal reflux has been noted at the distal end of the prosthetic graft. However, the dissection itself has been controlled and no attempt has been made to attach the distal end of the prosthesis. The size of the excluded AAA is considered to have decreased in three patients.

DISCUSSION

The study in experimental animals and in the five human subjects cited above suggests that transfem-

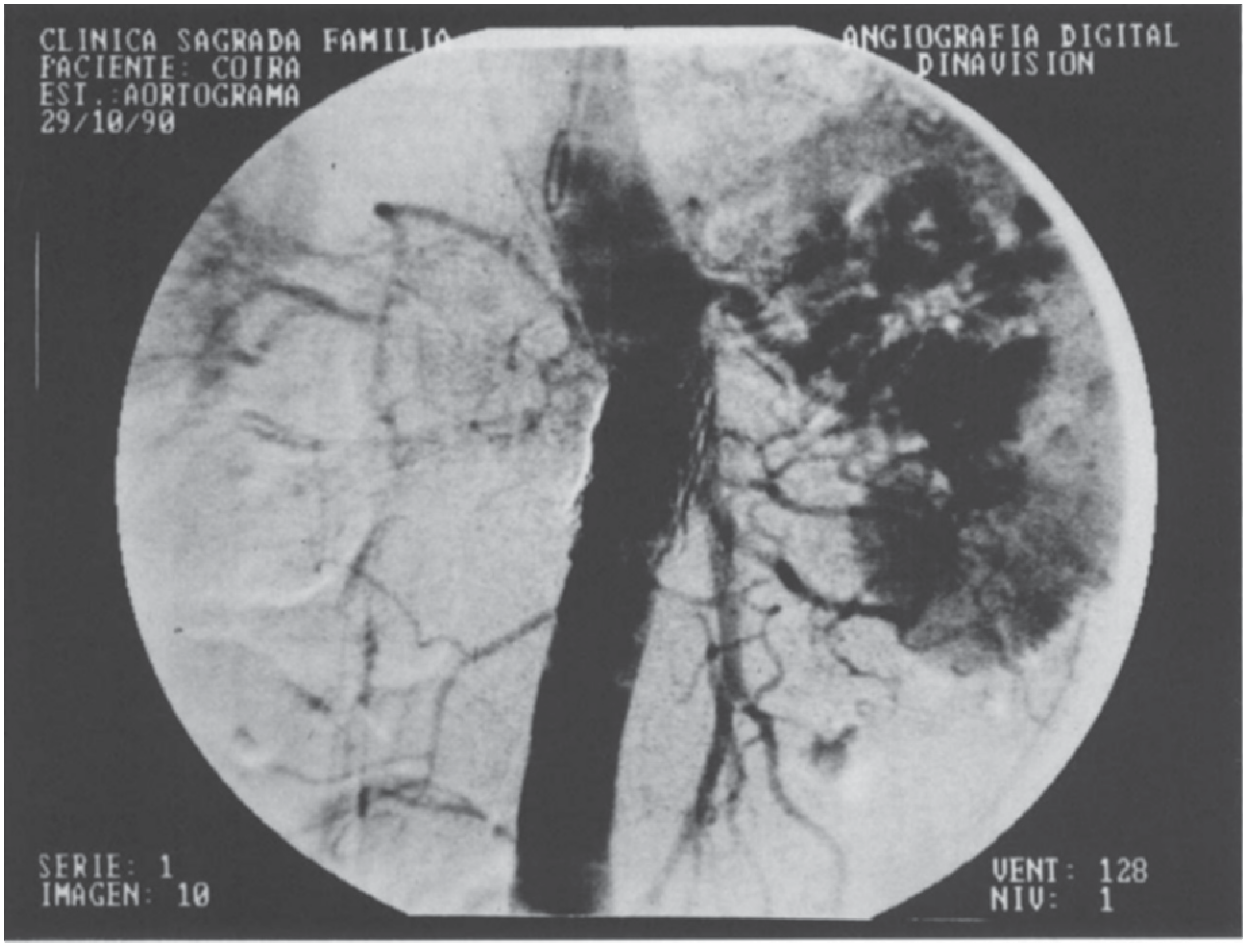

Fig. 9. Aortography of Patient Number 1, 53 days after implantation of graft-stent combination.

oral, intraluminal prosthetic graft placement can be achieved using balloon-expandable stent fixation of the prosthetic graft. The transfemoral approach allows placement of the prosthesis and exclusion of the AAA from the circulation under local or limited epidural anesthesia without the morbidity of a high, regional block, or general inhalation anesthetic. Lack of aortic cross-clamping and brief total aortic occlusion time allows graft exclusion of the aneurysm without cardiac compromise.

Justification for the procedure is found in the fact that AAAs must be excluded from the circulation in order to prevent aneurysm rupture. In Szilagyi's classic study [22], small, surgically untreated aneurysms were the cause of death in 29.5% of patients. Treatment of small AAAs has been shown to improve late survival [22]. Furthermore, in Darling's much quoted study [23], 18.1% of 182 ruptured aneurysms were less than 5 cm in diameter. A more modern report by Cronenwett [24] suggests that AAAs as small as 4 cm in diameter can be associated with a rate of rupture as high as 20% per year if hypertension is present. These facts have suggested to some that the presence, and not the size, of an AAA should be the indication for exclusion from the circulation. It is the smaller aortic aneurysm that lends itself to correction by this technique.

The larger the aneurysm, the greater the risk of rupture, so resection and graft replacement have emerged as the treatment of choice for these lesions. This is true even in high-risk patients with associated co-morbidity. Even non-correctable myocardial ischemia, cardiomyopathy, and pulmonary and renal insufficiency do not entirely contraindicate graft replacement of the aortic aneurysms. They do, however, increase operative mortality. Other factors, when present, may increase the difficulty and therefore the morbidity and mortality of the procedure. These include the hostile abdomen with impenetrable peritoneal adhesions, multiple prior arterial reconstructive procedures, or abdominal wall stomas. Patients with such medical co-morbidities or with technical factors

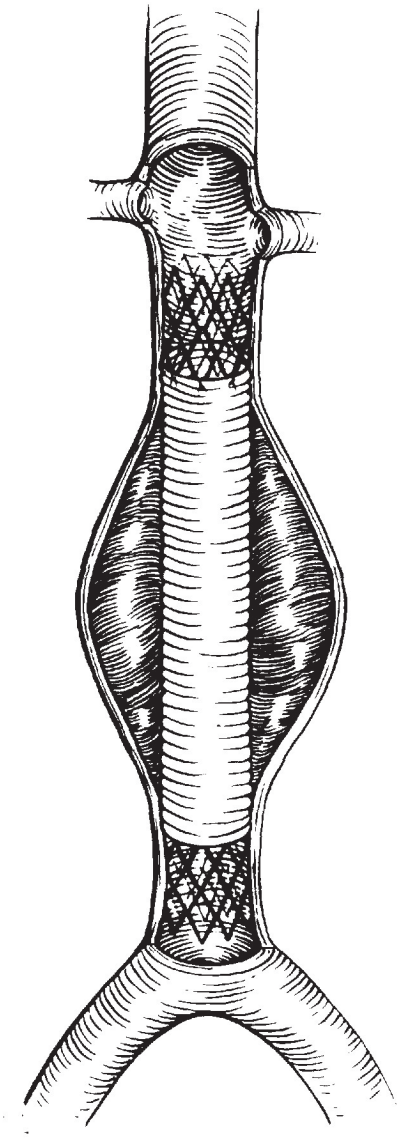

Fig. 10. Graft-stent combination with both cephalic and caudal stent.

increasing operative risk have, over the years, stimulated continuation of this study.

As in all studies, experience with this small group of patients turns up questions as well as answers. Fortunately, an extensive follow-up of Palmaz stent placement has proven that no migration of the stent occurs [25,26].

Transfemoral graft placement requires that the prosthetic material be a compliant, knitted graft which is thin-walled. The tendency of such graft materials to dilate in the arterial stream is well known. However, in transfemoral graft placement, this material is placed within an intact, though dilated, aorta. Whether or not this graft inclusion technique will allow graft expansion remains to be shown. More important is the fact that graft dilation is more a postoperative finding than a clinical problem. In two patients in this study, follow-up has suggested that the excluded aneurysm and intraluminal thrombus exterior to the prosthetic graft appear to fibrose and diminish in diameter. Such retraction is noted, and to date, no graft dilation has been seen.

The question of patent lumbar arteries contributing to continuing aneurysm expansion has not been solved by the present study. Admittedly, many lumbar arteries may have been occluded by the atherosclerotic aortic aneurysm wall or intraluminal thrombus. However, in some patients it is predictable that lumbar arteries will remain patent and, in fact, the inferior mesenteric artery may also remain patent. Whether or not these patent vessels will contribute to continuing aneurysm expansion is unknown. Theoretically, occlusion of the lumbar arteries and mesenteric artery could be expected to follow intraluminal graft placement.

Because AAAs frequently contain intraluminal thrombus, the possibility of distal embolization of such thrombus by intraluminal manipulation remains a threat. The fact that no apparent intraluminal thrombus embolized distally in the initial five cases does not exclude this complication as a possibility. As the Amplatz guidewire is relatively stiff, the graft-stent sheath is maintained in an access parallel to the aortic wall, and this may minimize dislodgement of thrombus from the wall of the aneurysm.

The Palmaz stent has been shown to become covered with endothelium relatively rapidly. Thus, it becomes included in the wall of the artery in which it is placed. The natural history of the aortic wall proximal and distal to the aneurysm remains to be seen. Whether or not it will be the site of intimal hyperplasia is unknown [25,26].

Certain anatomic characteristics of the aortic aneurysm must be present for the graft-stent device to be utilized. The aortic aneurysm should be associated with normal aortic wall proximally and distally. Such normal aorta should be at least 3 cm in length proximally and at least 2 cm in length distally near the bifurcation. The iliac arteries should be patent or be suitable for balloon angioplasty. The #22 French sheath is large and the iliac arteries should be straight or nearly straight and not elongated or tortuous. Should such anatomic features be present, the potential advantages of transfemoral intraluminal graft placement are obvious. A lower cardiovascular, respiratory, and renal morbidity should decrease mortality. Furthermore, blood transfusions can be obviated and trauma to the periaortic and periiliac autonomic plexes will be avoided by the procedure.

We are encouraged by the early experience but acknowledge that further developments are to be expected and more experience must be acquired

before the procedure can be safely included in the armamentarium of vascular surgeons. Once the procedure reaches a greater degree of perfection, there is no doubt that patients who present a prohibitive risk of operation can be treated and their life expectancy extended.

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Commentary

It has been said that the essence of great art is simplification. In working out the details of transfemoral exclusion of abdominal aneurysms from the aortic stream, Dr. Juan Parodi and his colleagues have simplified aortic surgery. Thus, their work is truly artistic as well as scientific.

There is no doubt that the procedure achieves its purpose. Predictably, it will be offered at first to patients who are at prohibitive risk for conventional aortic surgery. As experience grows, it will be offered to patients who are good surgical risks, even those with aneurysms smaller than the ones conventionally requiring surgical repair. During this time, complications will occur, some of which are cited in this initial clinical experience. As every interventional procedure has its own complications, new problems will arise. Opposition to the procedure will be mounted. In vascular surgery no change for the better has occurred that wise and good men have not opposed. Now that this initial barrier is broached, new applications, including transluminal distal bypass are predictable. Such change is inevitable. It is, as Thoreau said, " . . . a miracle to contemplate; but it is a miracle which is taking place every minute."

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