Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

J.C. Parodi, MD*, J.C. Palmaz, MD†, H.D. Barone, PhD, *Buenos Aires, Argentina, and San Antonio, Texas*

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 In these latter two, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a saline/contrast solution.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

From the Department of Vascular Surgery, Instituto Cardiovascular de Buenos Aires, Buenos Aires, Argentina, and the Department of Radiology, University of Texas†, San Antonio, Texas.*

Reprint requests: Dr. J.C. Parodi, Mercedes 4255, Cap. Fed. Buenos Aires, Argentina (1419).

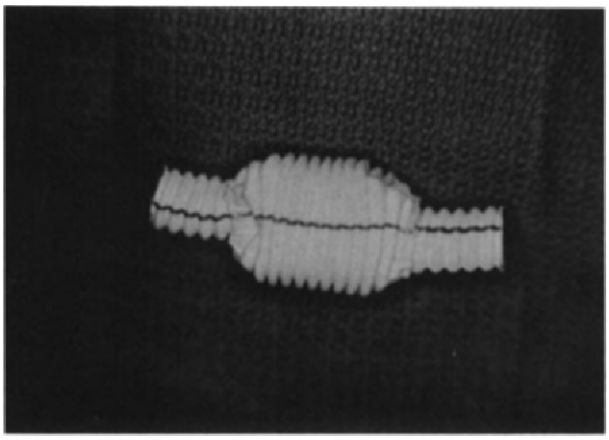

Fig. 1. Artificial abdominal aortic aneurysm created by fusiform-shaped Dacron conduit.

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.

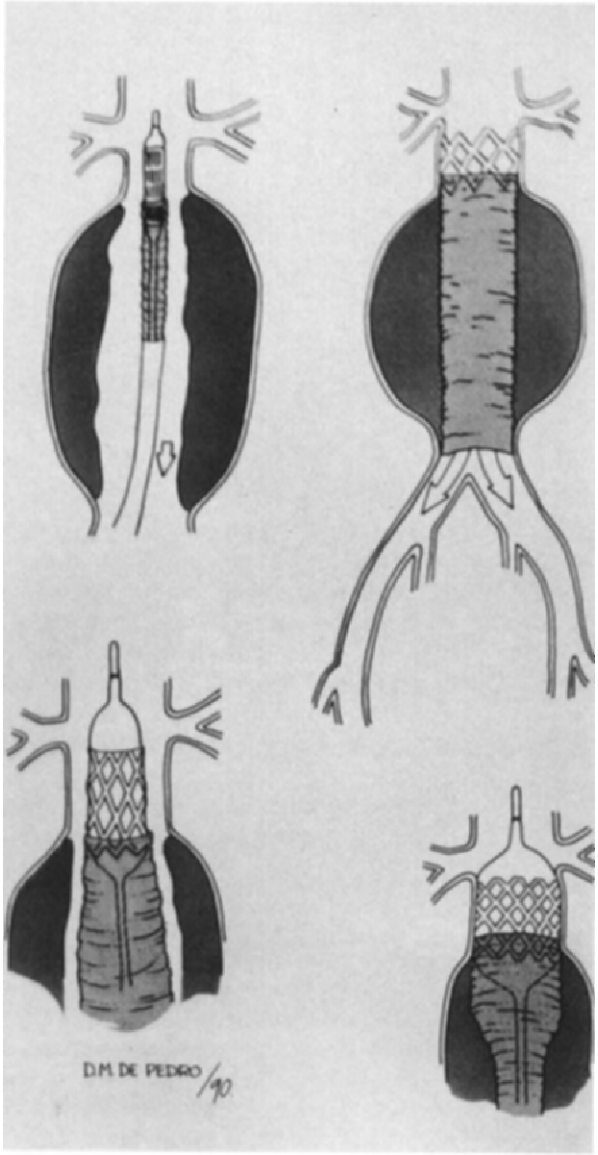

Fig. 2. Intraluminal exclusion of artificial aneurysm by implanting Dacron tubular grafts by transfemoral route. Balloon expandable tents anchor graft to aortic wall.

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-

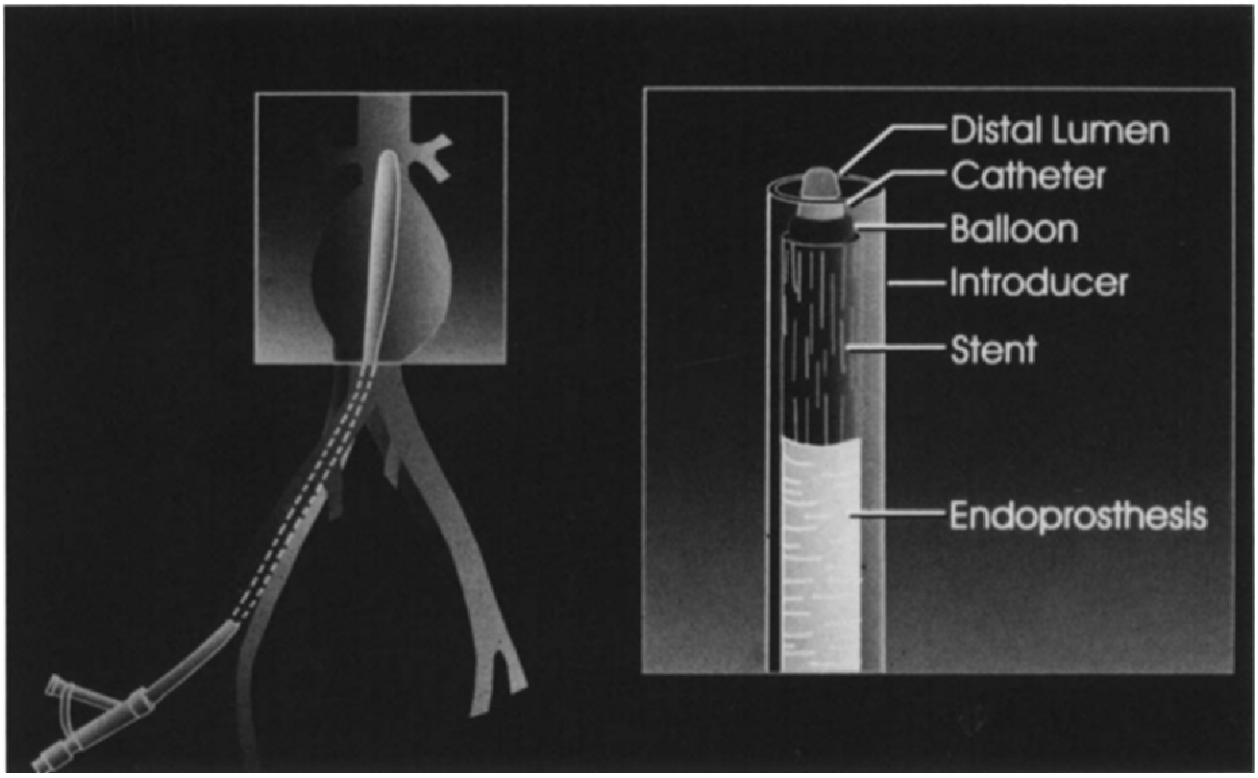

Fig. 3. Graft-stent combination is mounted on valvuloplasty balloon and placed under fluoroscopy through sheath introduced through femoral arteriotomy.

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

*Johnson & Johnson Interventional Systems, Warren, N. J.

†Mansfield Corporation, Boston, Massachusetts.
§Barone Manufacturers, Buenos Aires, Argentina.
**Barone Manufacturers, Buenos Aires, Argentina.

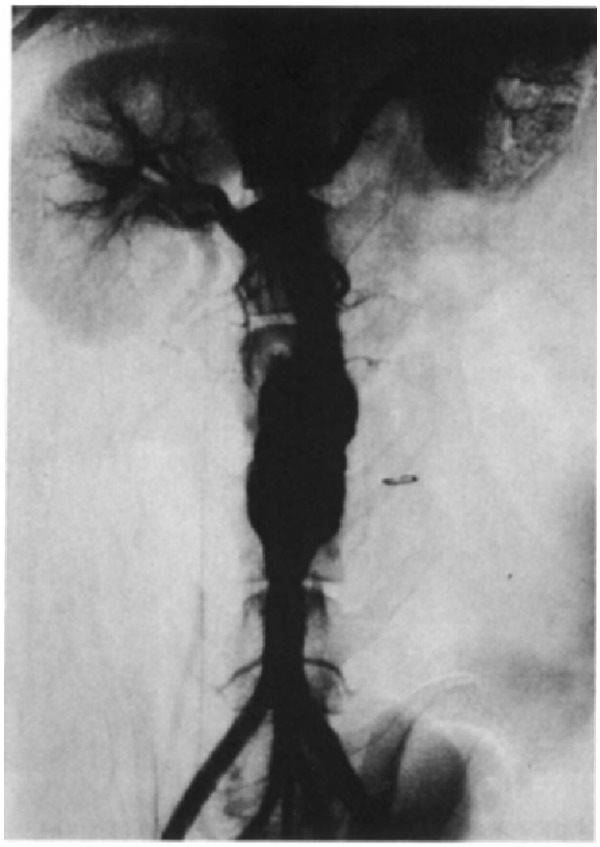

Fig. 4. Arteriogram of aorta four weeks after replacing segment with artificial aortic aneurysm in dogs.

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).

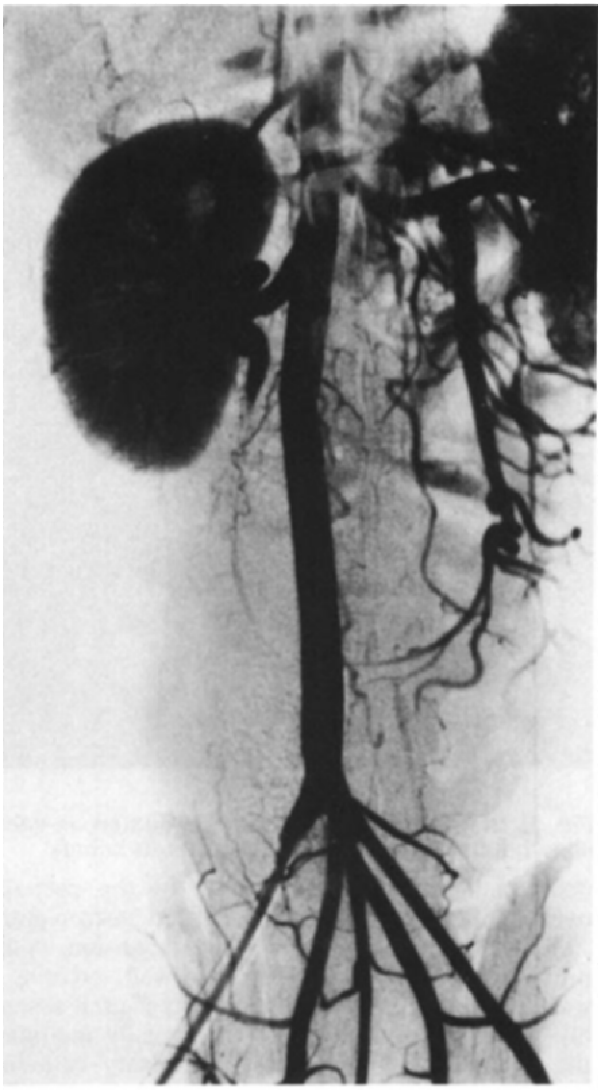

Fig. 5. Arteriogram of same dog after implanting graft-stent combination through right femoral artery.

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

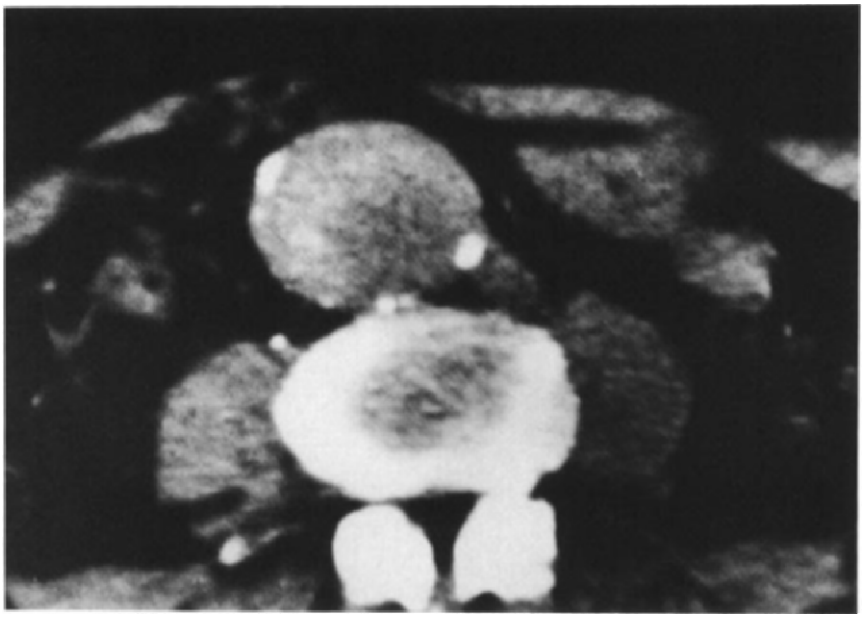

Fig. 6. Computed tomographic scan of Patient Number 1.

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.

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