Endovascular Aortic Devices: The Parodi and Palmaz System

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Based on the concept of endoluminal aneurysm exclusion, we began to develop a plan for endovascular treatment for abdominal aortic aneurysm (AAA) in 1976. Two prototypes have been developed and were marked by a high failure rate.[1] The first was a thin fabric graft mounted on a metallic cage-like structure composed by a self-expandable mesh with a zigzag configuration. The apparatus was compressed inside a tubular sheath, which acted as a vessel introducer and carrier. Experiments in normal canine aortas led to the abandonment of this prototype due to an inconsistent deployment of the metallic cage. The radial expansion properties of the cage were difficult to control and predict. Over-expansion resulted in aortic wall injury and subsequent rupture. Controversially, underexpansion led to leakage of blood between the apparatus and the host aorta with subsequent device migrations. The second prototype involved a Dacron graft fitted on a Silastic bag with a cylindrical lumen, which could be distended by injection of silicone into the bag. Unfortunately, this method was associated with prompt graft thrombosis of the aorta in all experimental essays.

Both prototypes were eventually abandoned because of the discouraging results with placement in animals.[2,3] With the stent technology emerging in the field of endovascular treatment, we reinitiated our project in 1988 using balloon-expandable stents.

Our current approach is predicated on the concept that stents may be used in place of sutures to secure the proximal and distal ends of the fabric graft within the lumen of the aortic aneurysm. With the use of a stent graft combination, it is possible to treat patients with AA by transfemoral placement of a prosthetic graft.

This chapter details the endoluminal treatment of 103 patients, of which 88 were affected by an abdominal aortic aneurysm, 2 iliac artery aneurysms (one in association with an AAA), 3 thoracic aneurysms, and 12 vascular injuries in different localizations of the arterial tree.

FEASIBILITY ANIMAL STUDIES

To test the concept of intraluminal graft implantation, a canine aneurysmal model was used. A 6-cm segment of the infrarenal aorta was resected and replaced with a fusiform conduit made of crimped woven Dacron, measuring 8 cm in length.

Histologic studies demonstrated endothelium graft coverage of the experimental aneurysm neck, coupled with mural thrombus formation in the body of

the aneurysm. Both of these changes were regularly encountered within a month after implantation of the aneurysmal graft. Six weeks later the aneurysms were bypassed using endoluminal graft deployment techniques. A noncrimped knitted Dacron tube of an appropriate diameter and length was attached to carefully selected stents (Palmaz, Johnson & Johnson Interventional Systems). Two-thirds of each stent were covered by graft material, but one-third of the stent was left exposed to anchor the graft to the aortic wall. The graft was folded clockwise in two folds, mounted on a balloon catheter, placed over a guidewire, loaded into a 14 Fr. Teflon sheath. The right femoral artery was chosen for vascular access. Under fluoroscopy guidance, the leading stent was advanced over the guidewire into the neck of the aneurysm, below the renal orifices and above the body of the aneurysm. Following the proper positioning of the device, the introducer sheath was withdrawn and balloon inflation used to secure the graft by deploying either one or two stents. In one group of dogs, only a proximal stent was used, but in a second, larger group, a distal stent was added to achieve total aneurysm exclusion. Angiography was then used to confirm correct stent graft deployment and verify that the aneurysm was successfully bypassed (Figs. 1a, 1b).

We operated on a total of 43 dogs, in most cases to evaluate different models for experimental aneurysms or to test a variety of balloons and replacement grafts. In our last group of dogs, we performed 6-month evaluations, obtaining color Doppler ultrasound (duplex) scans in some cases and complete pathologic studies in all animals. Using both optical and electronic micro-scopy, we found that both ends of stented grafts were covered by endothelium, and that the shaft of the graft with the mural thrombus of the experimental AAA was covered by a fibrin platelet barrier.

Once we were satisfied that a Dacron graft could be delivered through a catheter and fixed firmly in place by balloon-expandable stents, we obtained the permission of our institutional ethical committee to perform a pilot clinical study with a small group of patients who were informed fully regarding the nature of our work and subsequently were followed very carefully.

CLINICAL EXPERIENCE

Device Components

The first component of the device is a super stiff guidewire with a diameter of 0.038 inches. It facilitates introduction of the device through tortuous iliac arteries, keeps the axis of our device parallel to that of the aorta, and by minimizing manipulations prevents disruption of laminated thrombus that lines atherosclerotic aneurysms.

The balloon-expandable stent is a cylindrical tube with longitudinal slots that adopt a diamond shape when expanded. This design, initially described by Palmaz,[4,5] permits the stent to expand from a diameter of only 5 mm when collapsed to a diameter of more than 30 mm when expanded. The stent is 3.5 mm in length, and its metallic component represents only 20% of its surface area after deployment.

The knitted Dacron graft has a wall thickness of 0.2 mm and is fabricated using strong yarns with tensile and bursting

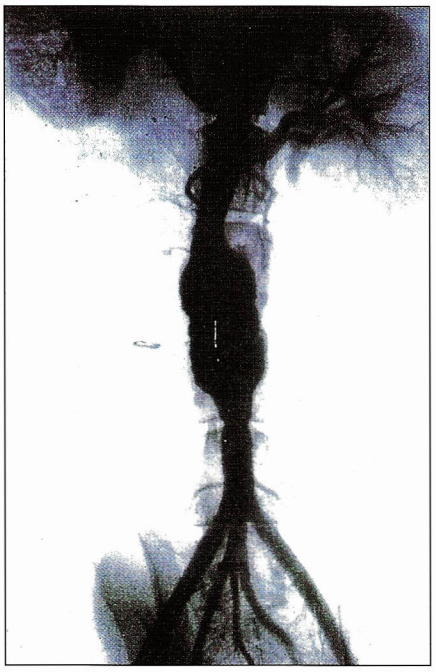

Figure 1a. Aortogram 4 weeks after the construction of an artificial aneurysm in canine aorta. (From: Parodi JC. Endovascular repair of abdominal aortic aneurysm. Adv Vasc Surg 1993;1:89.)

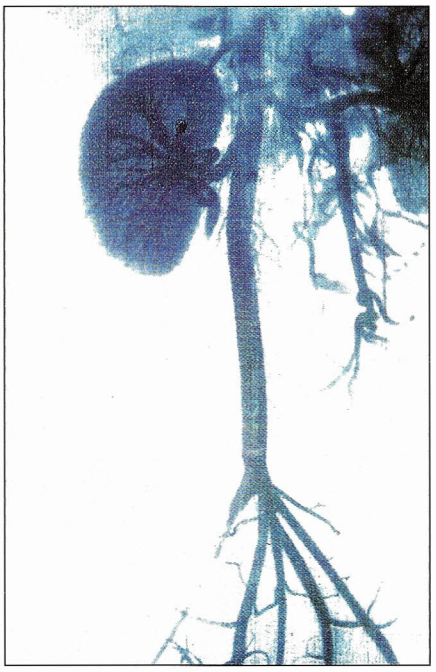

Figure 1b. Aortogram following the implantation of stented graft; a right femoral artery approach in the same dog. (From: Parodi JC. Endovascular repair of abdominal aortic aneurysm. Adv Vasc Surg 1993;1:89.)

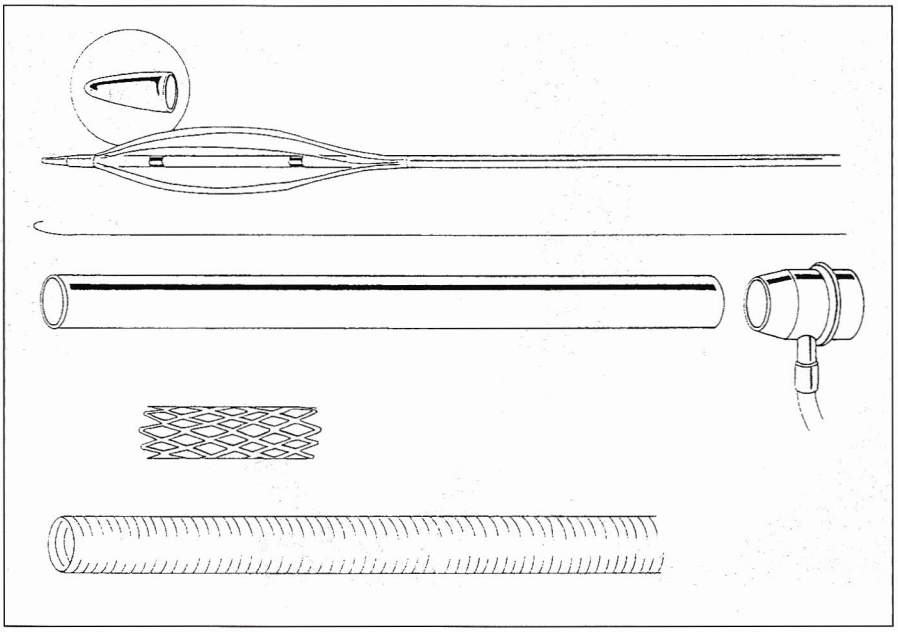

Figure 2. The elements comprising the endovascular device.

strengths comparable to those of commercially available grafts. The compliance of the shaft of the graft (15%) is also similar to standard, knitted Dacron grafts, but the compliance of the segment overlapping the stent is 45% in order to adapt to its expansion. Between these two segments, a transitional zone of intermediate compliance is interposed in an attempt to avoid abrupt changes in the diameter of the graft that eventually could produce deleterious friction between the stent and the shaft of the graft itself. The diameter and length of each graft is tailored to fit the individual patient, but the grafts we have employed most often are 18 to 20 mm in diameter and 8 to 12 mm in length.

Because of its radiopacity, a thin gold wire is knitted to each graft. This permits the radiographic identification of both ends and the sides of the graft in order to allow us to correct torsion during implantation. The balloon catheters have a shaft constructed of polyvinylchloride with a 9 Fr. diameter, and they contain either two or three luminal depending upon the number of low-profile, non-elastomeric polyethylene balloons affixed to them. If two balloons are used, the caudal one has a cylindric configuration leading into a 30-degree angle in the catheter shaft immediately below it in order to accommodate the typical angle of origin taken by the iliac arteries at the level of the aortic bifurcation. We generally use just two balloon diameters that adapt to an inflated diameter of 18 to 30 mm. The last piece of the device is a Teflon sheath that has a diameter of 21 Fr. and a hemostatic valve at the proximal end (Figs. 2, 3).

In cases in which arteriovenous fistulas or false aneurysms were treated, a covered stent was constructed by means of covering the stent with an expandable Dacron graft or pre-expanded polytetrafluorethylene (PTFE) graft. On two occasions the stent was covered with autogenous vein because of the concern for infection.

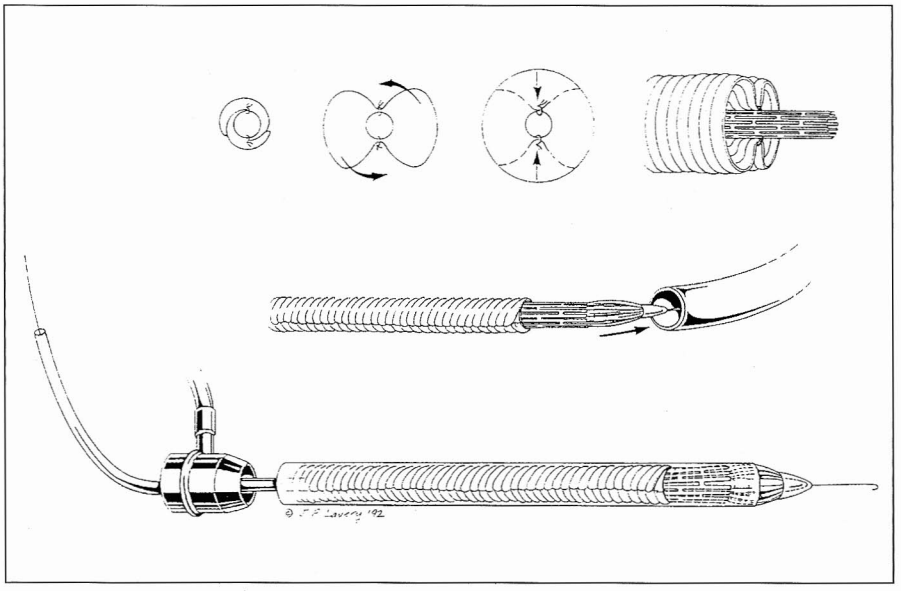

Figure 3. Graft stent combination is mounted on valvuloplasty balloon and placed under fluoroscopy through a sheath introduced through femoral arteriotomy.

Procedure

Details of the procedure have been published before.[3,5] In summary, these are as follows:

Under local or epidural anesthesia, the patient is prepared and draped as for a standard AAA resection. A small incision is developed over the chosen common femoral artery; usually the straighter, wider artery is selected for access.

A soft-tip guidewire is advanced in the aorta up to the level of the diaphragm; over the guidewire a pigtail diagnostic catheter is placed inside the lumen of the aorta with the tip located proximally to the renal arteries. The first injection of 30 mL of contrast medium is performed. The pigtail catheter is coded with radiopaque marker, which is engraved on its surface every 2 cm to facilitate length and diameter measurements using quantitative angiography.

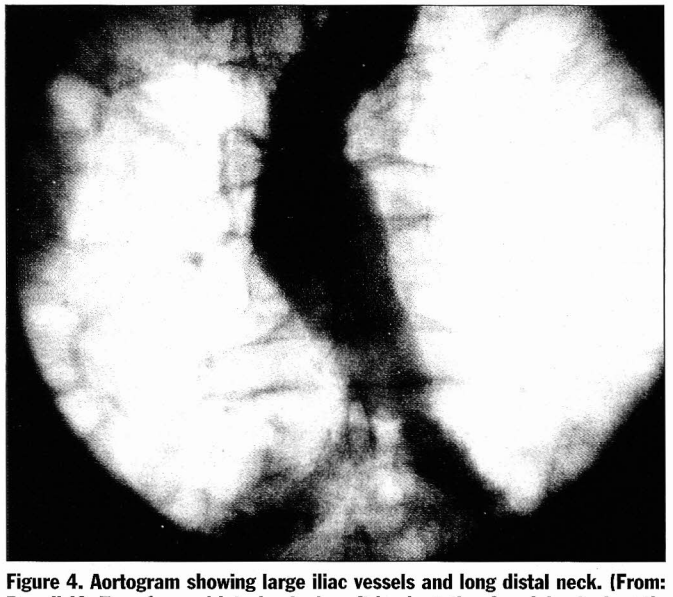

Figure 4. Aortogram showing large iliac vessels and long distal neck. (From: Parodi JC. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:496.)

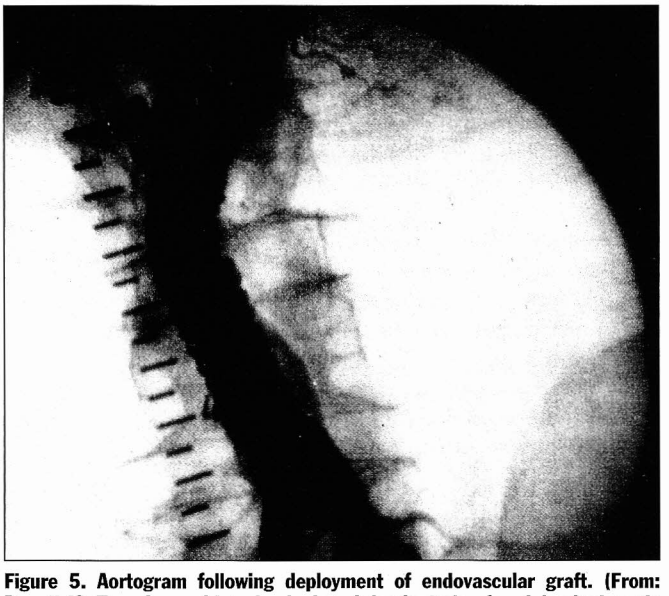

Figure 5. Aortogram following deployment of endovascular graft. (From: Parodi JC. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:496.)

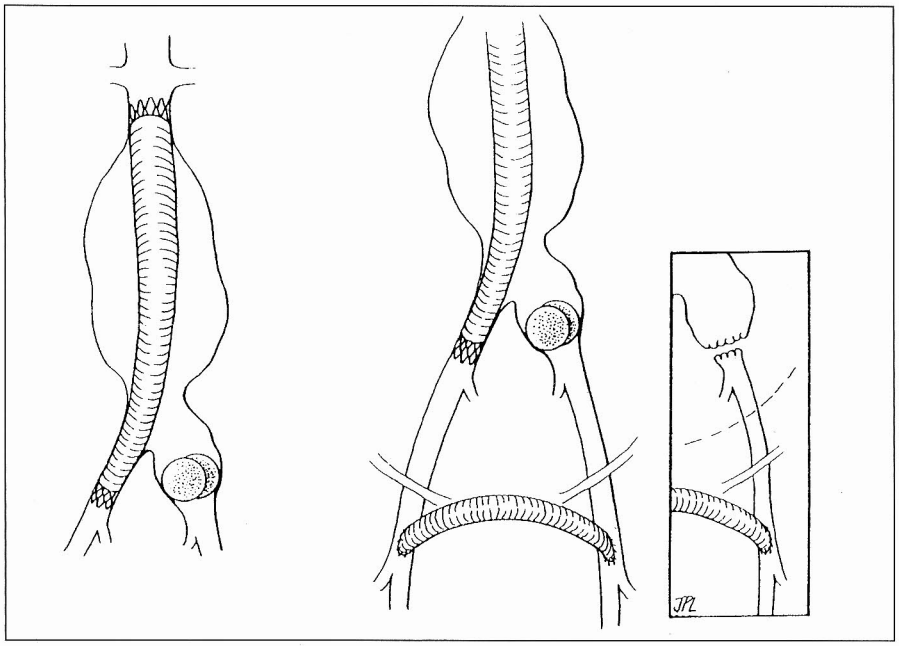

Figure 6. Aortoiliac graft in place, balloon occlusion of the contralateral iliac artery, and femorofemoral bypass.

With previously obtained angiogram and computed tomography (CT) scan, target areas are defined in conjunction with the new angiogram. They could be the proximal neck of the aneurysm and distal cuff in case this latter exists, or the common iliac artery in case of absence of the distal cuff.

The preloaded sheath containing the stent and graft mounted on a balloon is placed inside the lumen of the aneurysm under fluoroscopic guidance.

Once in place, the sheath is removed and the cranial balloon is inflated with a diluted solution of ionic contrast medium and saline. The balloon is kept inflated for 1 minute and then gently deflated. Before proceeding with balloon inflation, the main blood pressure is dropped using nitroglycerin solution. Pressure is kept at 70 mm Hg during balloon inflation. The size of the balloon is selected beforehand to accord with the diameter of the neck of the aneurysm measured in the previous angiogram and CT scan.

After securing the proximal stent, the second stent is placed. In some cases in which a double balloon device was used, the second balloon (either aortic or iliac) is positioned at the appropriate level and inflated deploying the second stent. A final angiogram is obtained (Figs. 4, 5). In cases in which an aortoiliac graft is placed, the procedure is finished by performing a femoro-femoral bypass and balloon occluding or stent occluding the contralateral common iliac artery (Fig. 6).

When a complex procedure was predicted, blood loss from the field was saved and retransfused after being filtered. Blood loss was produced when sheaths of different diameters had to be changed and additional procedures, such as implanting a covered stent, were necessary.

Time of the procedure varied according to the complexity of the case between 25 minutes to 3 hours.

Patient Selection

Patients considered potential candidates for endoluminal aneurysm bypass must be evaluated as if they were going to undergo conventional operative repair. A contrast computed tomography (CT) scan of the abdominal aorta is performed at 1-cm intervals, with added views across the proximal and distal ends of the aneurysm. The CT scan can give an estimate of the proximal neck, the distance between the renal arteries and the beginning of the body of the aneurysm, and the diameter of the aorta at the upper and lower ends of the aortic aneurysm. Also, the distance from the renal arteries to the aortic bifurcation can be calculated and used to predict the graft length that will be needed.

In addition, a biplanar abdominal aortogram is obtained in every patient, since it provides further detail concerning the visceral branches, the patency of the inferior mesenteric and lumbar arteries, and the course and diameter of the iliac arteries. Angiography is performed using a pigtail catheter having gold calibrations at 2-cm intervals and with a radiopaque ruler positioned vertically behind the patient to obtain the most accurate measurements.

Both the angiographic features and the CT data should complement each other. If substantial differences are encountered, the data must be reviewed prior to device assembly. Minor differences are not uncommon with the CT scan, sometimes overestimating the intraluminal diameter of the aorta by a factor of 1 to 4 mm, since coronal views make the aneurysm lumen appear oval rather than circular. Once all dimensions have been determined and agreed on, the implantation device can be designed.

Clinical Findings

As stated before, initially only those patients with serious associated pathologic conditions, implying a high surgical risk with conventional repair, were selected for endoluminal bypass. After initial clinical success, few volunteers considered candidates for standard operative repair have been treated by endoluminal bypass. The following anatomic criteria are desirable for the endoluminal placement of an aorto-aortic tube graft:

1. Both the proximal and distal necks of the aortic aneurysm had to measure at least 2 cm in length.
2. At least one of the iliac arteries had to be patent and sufficiently straight to allow delivery of the device and carrier. An external iliac diameter of at least 7 mm is desirable for a common femoral approach.

Eighty-eight patients harboring abdominal aortic aneurysms were treated from September 1990 to June 1995. Five patients were admitted to the clinic with pain probably related to their aneurysm, but none of them was ruptured. One patient was admitted as an emergency for a rapidly growing aortic dilatation caused by infrarenal aortic dissection. Two patients were admitted with the diagnosis of blue toe syndrome in which the source of the thrombus was an AAA.

The size of the aneurysm at the time of treatment was more than 5 cm in diameter. Two had small aneurysms that caused microembolization, and one patient with an aneurysm of less than 5 cm had bilateral carotid endarterectomy and a coronary bypass surgery the same year and decided to have his 4.5-cm AAA treated by the endoluminal method.

Seventy-five males and 12 females were treated. The average age was 73 years (range: 57–87 years); 10 patients were more than 80 years of age. Forty-five of 88

patients underwent aortic tube graft replacement, with eight patients having only proximal stent placement. Table 1 outlines the procedures performed. All patients had at least one associated morbid condition. Associated pathologic conditions are given in Table 2.

Table 1. Procedures performed

PROCEDURE	No. Performed
Aorto-aortic graft with one stent (proximal)	8 patients
Aorto-aortic graft with two stents (both ends)	37 patients
Aorto-iliac stent graft	38 patients
Aorto-bi-iliac stent graft	2 patients
Thoracic stent graft	3 patients
Total procedures	88 patients.

Table 2. Associated pathologic conditions

Condition	Number of Patients
Severe chronic heart disease	53
Acute myocardial infarction	23
Severe pulmonary insufficiency	26
Renal insufficiency	5
Acute cerebral infarction	1
Two or more previous strokes	10
Hostile abdomen	2
Hepatic failure	2
Mild pulmonary insufficiency	12
Intermitent claudication	33
DIC	1

Results

Of the 88 procedures for AAA exclusion, 75% aortoiliac and 84% aorto-aortic were considered as initial successes. The definition of a successful procedure includes complete exclusion of the aneurysm with restoration of the normal blood flow. The stent graft should be in contact with normal intima, as sealing when the stent graft is deployed in an area covered with laminated thrombus proved to be incomplete and temporary. Patients with successful procedures recovered very rapidly, had breakfast the next morning, and walked within 24 to 48 hours after the procedure. Typically they were discharged from the hospital after 3 or 4 days.

Of the 88 procedures, 18 (20.6%) were considered as initial failures. Four of the 18 failures were correctable using endoluminal treatment, but because of the prohibitive risk of this group of patients, additional treatment was not attempted at that time.

Failures

There was one case of misplacement of the proximal stent, which was treated by standard surgical procedure. The patient survived and did well.

There were three cases of proximal leak. In one patient with minimal leak, the size of the aneurysm decreased in spite of the leak, and the leak disappeared in a few weeks. This patient died from an unrelated cause 6 months after the procedure. The second and third patients had an important leak; one died after 7 months of cardiac insufficiency, and the other died of a ruptured aneurysm 2 months after the procedure. We include every case of leak as a failure.

One case of incomplete deployment of the proximal stent resulted in migration of the graft. Because of the failure, the patient was treated by standard AAA resection. Liver cirrhosis, ascites, and gastrointestinal bleeding was the indication for endoluminal treatment. The patient survived the operation but died of abnormal bleeding the next day.

Two patients had a distal leak. One lasted 3 weeks and subsided; the second persisted with minimal leak but died of pulmonary and cardiac insufficiency 8 months later.

Table 3. Complications

COMPLICATION	No. of Patients
Groin hematoma	2
Proximal leak (treated with a covered stent)	1
Injury to the external iliac artery (sutured)	1
Minimal distal microembolism treated by intra-arterial injection of prostaglandin	1
Distal leak (treated with covered stent)	1

Two patients had massive microembolization after difficult procedures applied in large and tortuous aneurysms. The procedures ended with massive microembolization and the patients died after developing disseminated intravascular coagulation and multiple organ failure.

One other patient died suddenly after 2 days. Postmortem macroscopic examination disclosed findings of intestinal ischemia, which we considered probably related to embolization during the procedure. Microscopic examination, however, failed to find occlusion of the superior mesenteric artery or its branches. Diagnosis of nonocclusive mesenteric ischemia was established. The operative mortality (within 30 days) was 8%.

Complications

In addition to the above-mentioned complications which provoked the procedure to fail, there were others that could be solved at the time of occurrence (see Table 3). In 6 of the 88 aortic procedures, both renal artery ostia were covered with the stent; the graft attached to the stent was placed distally to the renal arteries. None of these patients developed renal insufficiency. Color duplex scans of the renal arteries were normal, and they are repeated every 6 months. Three balloon dilatations of the iliac arteries were performed in the series. Before inserting the stent graft device, two common femoral aneurysms were corrected surgically at the same time as the procedure, and four common iliac temporary conduits with a 10-mm tubular Dacron graft were constructed to permit access to the aorta in the presence of very tortuous and stenotic iliac arteries.

Long-Term Results

All patients were followed by clinical

examination, color duplex studies every 6 months, and CT scans once a year. Angiography was performed in some patients and in every one in whom the color duplex or CT scans indicated or suggested any sign of leak, dilatation, or any change when compared with the study performed immediately after the procedure.

The average follow-up period was 16 months, with a range between 1 and 43 months. One patient developed a distal aortic dilatation 18 months after the initial procedure. The distal stent was placed too distally from the aortic bifurcation and was in contact with mural thrombus and not with normal aortic wall. The complication was corrected by adding a short segment of graft and performing a surgical anastomosis between the old graft and the aortic bifurcation. The patient recovered uneventfully.

Three patients who had only the proximal stent deployed developed a distal reflux with shrinkage of the graft 8, 18, and 24 months after the procedure. These three patients are ready for another procedure to correct this complication (insertion of a covered stent at the distal end). At the time of this writing, two patients had been successfully treated. One patient died 13 months after the procedure from a carcinoma of the colon. Another patient died after being admitted to the clinic because of cardiac failure and respiratory insufficiency 8 months after the initial procedure. Two patients died of cardiac insufficiency 6 and 7 months after the procedure. One patient with proximal leak (failure) died of a ruptured AAA 2 months after the unsuccessful procedure. One patient was readmitted to the clinic 3 months after the initial procedure with pulmonary edema and was discharged after 1 week. Of the patients in the initial group, 70% had good results after the primary procedure until the last clinical visit, or until the moment of death by unrelated cause. Most of the complications were correctable by additional endoluminal procedures.

Discussion

After 88 procedures for treating aneurysms and 12 for other applications (arteriovenous fistulas and false aneurysms), some preliminary conclusions are possible.

1. The procedure is feasible and, when successfully applied, has the great attraction of its simplicity. Second, the application of covered stents in trauma cases appears to be one of the main applications of this method because it transforms a sometimes complicated and potentially dangerous procedure into a simple and safe one. Stenosis can be defined as a potential complication in the long term. In the near future, stent grafts could eventually be used in acute injuries of the vessel, both in civil and military conditions to stop blood loss temporarily or definitively.

This procedure can be combined with endovascular control of bleeding of secondary branches by using detachable balloons, coils, occluding stents, or the injection of fluids that become solid inside the body. This procedure proved to be useful in injuries of vessels such as the subclavian artery that present a real challenge even to the experienced surgeon.

On treating aneurysms, there were, however, more problems than those that initially could be predicted. The procedure is simple in theory, but several details should be attended to before moving ahead with the widespread use of the method. First, measurements of diameters and lengths are crucial. We learned with great effort how to obtain reliable data using enhanced CT scans, quantitative angiography, and three-dimensional reconstruction using magnetic resonance imaging or CT. Scan images, intraluminal measurement, and some geometric calculations helped us to obtain reasonable, reliable data. Understanding that elongation occurs as dilatation of the aorta develops and also that elongation occurs in different planes allowed us to calculate more accurately the actual length of the artery.

2. Access problems accounted for several puzzles we had to work out. Narrow, stenotic, and tortuous iliac arteries were responsible for these difficulties. The rigid stent and the large diameter of the sheath needed for the implantation were drawbacks from the beginning. We overcame some of these problems by modifying the device and using different maneuvers during the procedure. Reducing the diameter of the sheath to 18 Fr. was a remarkable advance toward the ideal device.

The use of an extra-stiff wire, the "pull-down" maneuver, and sometimes implantation of a temporary conduit on the common iliac artery were also useful resources to overcome some of the problems. The "pull-down" maneuver consists of dissecting free the common femoral and external iliac arteries, lifting the inguinal ligament up, and using blunt dissection to reach the iliac bifurcation from the groin. Small branches should be divided between suture ligatures. When the arteries are free, by pulling the artery gently toward the feet of the patient, the tortuous artery becomes straighter, making the introduction of the sheath possible.

Studying morphologic changes in aneurysms over several years revealed that in the initial stages almost all aneurysms have a proximal neck and distal cuff of more than 3 cm; in the second stage, the distal cuff becomes shorter; and in the third stage, the distal cuff tends to disappear, while the proximal neck becomes shorter, but still longer than 2 cm. After this stage we found that elongation takes place, which creates tortuosity.

Usually the distal curve opposes the proximal one. This results in a configuration in which, if the convexity of the proximal neck is to the left, the distal cuff curves to the right, leaving the right iliac artery straight and the left with the tendency of producing a right angle. These findings dictate that in some patients a tubular graft would be applicable. When the distal aortic cuff is not present, an aorto-bi-iliac graft has to be used as advocated by Chuter.[6] In addition, when the angle between the iliac arteries becomes larger than 90 degrees, an aortoiliac graft should be used when placing a femorofemoral bypass.

3. Balloon-expandable stents, because of their high radial force, appear to be anchoring mechanisms. We had one problem when the stent was incompletely deployed (one case of stent migration). Intraluminal ultrasound will be the ideal way to check the completeness of the stent deployment.

4. Microembolization is what we consider to be the main and more dreadful problem with this procedure. We were able to solve almost all the problems we encountered, but microembolization occurred three times in our experience, and two of the three cases resulted in death. In the remaining case discrete microembolization of the right foot was successfully treated with intra-arterial administration of prostaglandin E1. The two cases that resulted in massive microembolization were technically difficult procedures in patients with large aneurysms. In one case visceral ischemia was found in the postmortem examination. In this last case technical problems occurred during the procedure in relation to inappropriate balloon sizing. Microscopic examination, however, disclosed a nonocclusive intestinal infarction, and embolization was ruled out in this case.

A mild, reversible case of microembolization occurred on the side of the implantation of an occluding stent after an

aortoiliac graft implantation with the addition of a femorofemoral bypass and was caused by an incomplete deployment of the stent. Reviewing our cases of embolization, it appears very clear that large and tortuous aneurysms pose an increased potential incidence of embolization. This is probably due to the following: on advancing the guidewire from the femoral artery into the aorta and then into the proximal neck, the operator will negotiate it inside a large and tortuous chamber coated with friable material. Sometimes it is very difficult to get the guidewire inside the proximal neck because, from within the cavity of the aneurysm, the orifice of the proximal neck is very often small. Such maneuvers could eventually cause dislodgment of particles of the laminated thrombus. Thus it is advisable in all cases of large aneurysms with wide lumens to insert the guidewire percutaneously from the brachial artery. Very often miscalculation of the length of the aneurysm created the necessity to change the device or to use complementary procedures such as implanting a third covered stent to increase the length of the device or cover a leak. The more intravascular manipulation we perform, the more the risk of dislodging particles from the aortic wall.

What can we do to prevent microembolization? (1) In cases of large aneurysms with large lumens, the guidewire should be introduced from the brachial artery distalward and recovered in the common femoral artery that has been chosen in advance. (2) Care should be taken to measure precisely the length and diameters of the arteries and perform a simple well-planned procedure. (3) After successfully treating patients who were admitted for spontaneous visceral and distal embolization, allow us to state that even in the presence of friable thrombus in the lumen of the AAA, the endoluminal procedure can be performed safely.

It is clear that this new development presents a new and different challenge for the medical industry. Regarding other applications of the stent graft combination, treatment of arteriovenous fistulas appears to be a simple and effective application of the principle that will save time and prevent bleeding and peripheral nerve injuries. Treatment of false aneurysms in nonaccessible places is also a promising application, as is vascular trauma. The development of an "internal bypass" after balloon dilatation is an appealing idea in view of the failure of balloon dilatation in long lesions. In theory, isolating the inner surface of the treated artery will eventually prevent the interaction between the damaged intima and the circulating elements and substances of the blood. **STI**

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