Endovascular Repair of Aortic Aneurysms, Arteriovenous Fistulas, and False Aneurysms

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The diagnosis of abdominal aortic aneurysms (AAA) has been established with increasing frequency during the past two decades.[1] This is probably due to the aging of the population as well as to the extensive use of ultrasonography and computerized tomography (CT) scanning for different pathologies. Although AAA may occasionally cause distal embolization, rupture remains the most common and deadly complication. Elective replacement with a synthetic graft has proved to be the most appropriate method to prevent AAA rupture for nearly 40 years, and at respected medical centers, it has been associated with a postoperative mortality of less than 5%.[2] Non-fatal complications occur with some regularity irrespective of the setting in which the operation is performed. Increasingly, vascular surgeons are encountering older patients with severe co-morbid conditions. This can increase operative morbidity and may even elevate mortality of aortic surgery to a figure in excess of 60%.[3] It seems inevitable that every vascular surgeon will, with some frequency, encounter patients who represent a prohibitive risk for conventional graft replacement, yet alternative forms of treatment (such as axillofemoral bypass in conjunction with induced AAA thrombosis) generally have been abandoned despite preliminary reports of their initial success.[4]

In 1976, we began to develop a plan for endovascular treatment of AAA which was based upon the fundamental principles of aortic replacement. We developed two prototypes. The first was a self-expandable metal cage with a zig-zag configuration covered by a nylon fabric, and the second a silastic bag with a cylindrical lumen. We eventually abandoned both of these prototypes because of the discouraging results we had in animal models, but we reinitiated our project in 1988 using balloon-expandable stents.

Our current approach is predicated upon the concept that stents may be used in place of sutures to secure the proximal and distal ends of a fabric graft extending the length of the AAA. In arteriovenous fistulas and false aneurysms, a covered balloon-expandable stent has been used. A tubular Dacron or polytetrafluoroethylene (PTFE) graft or a segment of autologous deep vein has been used to cover stents.

Experimental studies had shown that stents could replace surgical suture and

could act as friction seals to fix the ends of the graft to the vessel wall. These friction seals were developed by a transluminal stent-graft combination, suturing a modified Palmaz 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. Placing of the stent-graft assembly was to be accomplished by mounting the assembly on a large balloon catheter. This would be placed under fluoroscopy through a 18 Fr. sheath (inner diameter [i.d.]), introduced through a femoral arteriotomy.

This report details the endoluminal treatment of 92 patients: 78 abdominal aortic aneurysms (in one patient, an AAA and a common iliac aneurysm were treated simultaneously; an infrarenal dissection with aneurysmal dilatation is also included in this group); 1 thoraco-abdominal aneurysm; 1 ascending aortic dissection; 7 posttraumatic arteriovenous fistulas (AVF); 1 infected false aneurysm of the common femoral artery; and 4 false aneurysms (axillary artery, common carotid artery, internal carotid artery, and subclavian artery).

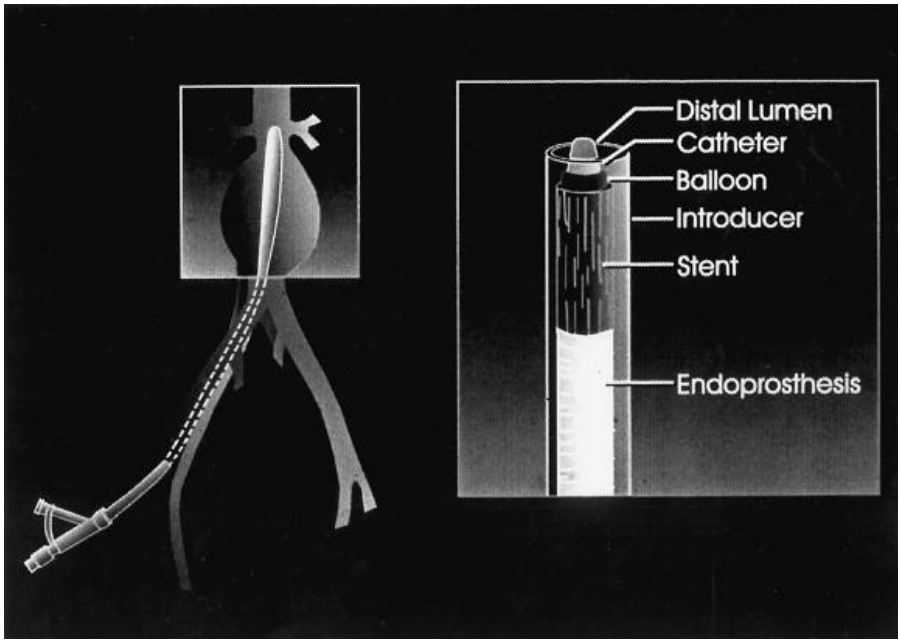

Figure 1. Stent-graft combination is mounted on a valvuloplasty balloon and placed under fluoroscopy through a sheath introduced through femoral arteriotomy.

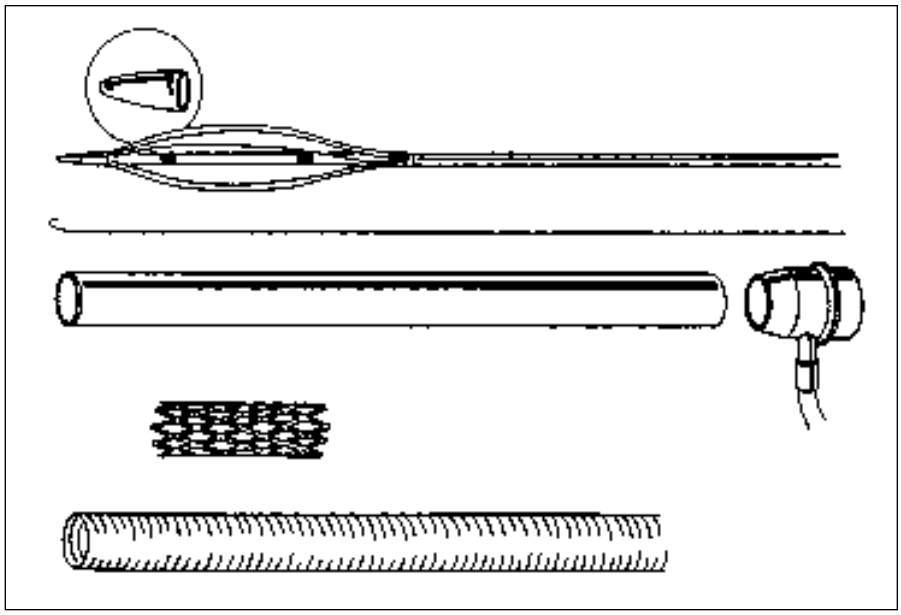

Figure 2. The elements comprising the endovascular device. (Reprinted with permission from Parodi JC. Endovascular repair of abdominal aortic aneurysms and other arterial lesions. In: Szabó Z, Kerstein MD, Lewis JE, eds. Surgical technology international III. San Francisco: Universal Medical Pr; 1994. p 431-436.)

MATERIALS AND METHODS

Stent-Graft Device

We used a Teflon 18 Fr. sheath, 45 cm in length with a hemostatic valve closure in the operator end containing the balloon catheter, consisting of a 9 Fr. polyethylene shaft and one or two nylon balloons (3.5 cm in length and either 30, 25, or 16 mm in diameter). The assembly contains one or two balloon-expandable stents (in case of two balloons, either two aortic stents or an aortic and an iliac stent). A thin-walled, crimped, knitted Dacron graft was sutured to the stents, overlapping one-half of the length of the stent.

The stent is made of annealed stainless steel (316L), as this alloy has been widely used in a variety of prosthetic applications. Corrosion of implanted metal pieces usually occurs at sites of cracks and crevices on the metal surface. Therefore, the surface of metal stents must be uniform. The balloon-expandable stent is made as a single piece to avoid motion between parts. Micromotion between metal surfaces disrupts protective oxide films, allowing the area to corrode rapidly.

The graft is a thin-walled (0.2 mm) weft-knitted graft with compliant ends (45%) to allow expansion of the stent. The diameters of the grafts are 18 and 20 mm when tubular grafts are applied and 18 and 8 mm when tapered grafts for the aortoiliac position are needed. For thoracic aortic application, a 25-mm diameter graft was utilized.

The balloon catheter we currently use (Balt Company, Paris, France) is constructed of nylon material and has some degree of compliance. This compliance allows us to use only two balloon sizes (25 and 30 mm in diameter). For aortoiliac grafting, either a double balloon (25 and 12 mm in diameter) or two independent balloons are used.

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 a pre-expanded PTFE graft. In two occasions the stent was covered with autogenous vein because of the concern of infection. The only case of false aneurysm of the internal carotid was treated by a vein-covered stent in order to provide a less thrombogenic surface.

Procedure

The procedure[5] is executed as follows. Under local or epidural anesthesia, the patient is prepared and draped as for a standard AAA resection. In the two cases in which the thoracic aneurysm was treated, general anesthesia was utilized. A small incision is made over the chosen common femoral artery (usually the straighter and wider artery is selected for access). A soft-tip guidewire is advanced in the aorta up to the level of the diaphragm. Over the wire, a pigtail diagnostic catheter is placed inside the lumen of the aorta with the tip located proximal to the renal arteries. The first 30 cc of contrast media is injected. The pigtail catheter has radiopaque marks engraved on its surface every 2 cm to facilitate length and diameter measurements using quantitative angiography.

With the previously obtained images (angiogram and CT scan) and the new angiogram, target areas are defined. These could be the proximal neck of the aneurysm and distal cuff, or, in the absence of the distal cuff, the common iliac artery. 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 media and saline. We discarded the non-ionic contrast media because of the potential problem of crystallization. The balloon is kept inflated for one minute and then gently deflated.

Before proceeding with balloon inflation, the main blood pressure is dropped using nitroglycerin solution. Pressure is kept within 70 mm of mercury during balloon inflation. The size of the balloon is selected beforehand according to the diameter of the neck of the aneurysm measured in the previous angiogram and CT scan. The second stent is placed after securing the proximal stent, and when a double balloon device is used, the second balloon (either aortic or iliac) is positioned at the appropriate level and inflated to deploy the second stent. A final angiogram is then performed. If an aortoiliac graft is placed, the procedure concludes with a femorofemoral bypass, and the contralateral common iliac artery is occluded with a detachable balloon and/or stent (Fig. 3).

When a complex procedure was predicted, blood loss from the field was saved and re-transfused after filtering it. Blood loss was reduced when sheaths of different diameters had to be changed and additional procedures (e.g., implanting a covered stent) were necessary.

The duration of the procedure varied according to the complexity of the case. When an aorto-aortic procedure in a rather small aneurysm with non-tortuous and wide lumen iliac arteries was performed, the procedure lasted 20 to 45 minutes. When an aortoiliac graft plus a femorofemoral bypass and occlusion of the contralateral iliac were needed, the time spent in the operating room on occasion exceeded three hours.

Abdominal Aortic Aneurysm

Seventy-eight patients harboring abdominal aortic aneurysms were treated from September 1990 to May 1995. Two patients were treated for common iliac aneurysms; one patient had an AAA treated simultaneously. Both procedures were successful in the short and long term. Five patients were admitted to the clinic with pain probably related to their

Table 1. Associated pathologic conditions

Conditions	Number of patients
Severe chronic heart disease	25
Acute myocardial infarction	23
Severe pulmonary insufficiency	26 (three oxygen-dependent)
Renal insufficiency	5 (one on dialysis)
Acute hemorrhagic cerebral infarction	1
Two previous strokes	10
Hostile abdomen	2
Cirrhosis ascitis G.I. Bleeding	1
Mild pulmonary insufficiency	12

Table 2. Procedures performed

Procedures	Number
Aorto-aortic graft with one stent (proximal)	8
Aorto-aortic graft with two stents (both ends)	37
Aorto-iliac graft	32 *
Ileo-iliac graft	2 **
Total procedures Total of patients	79

* *One secondary procedure was performed after a late failure of and aorto-aortic graft.*

** *In one patient a simultaneous aorto-aortic and ileo-iliac grafts were used to treat an AAA and a common iliac aneurysm.*

aneurysm, but no aneurysm was ruptured. One patient was admitted as an emergency for a rapidly expanding aortic dilatation caused by an infra-renal aortic dissection. Two patients were admitted with the diagnosis of blue toe syndrome; the source of the thrombus was believed to be an AAA.

In 69 patients, the size of the aneurysm at the time of treatment was more than 5 cm in diameter. Two patients had small aneurysms that caused microembolization. The third patient with an aneurysm of less than 5 cm had bilateral carotid endarterectomies and a coronary bypass surgery the same year and decided to have his 4.5 cm AAA treated by the endoluminal method. Sizes ranged from 3.8 cm to 12 cm. The last 6 cases included in a clinical trial in Europe had AAA of diameters ranging from 3.8 to 5 cm.

One patient had a type of dissecting aneurysm treated surgically by replacing a segment of the ascending aorta with a Dacron graft. A few days after the procedure, he developed a new flap of dissection starting from the distal aortic suture and developed a rupture of the descending aorta. A covered stent (Dacron) was implanted at the suture line, effectively closing the false lumen.

A 68-year-old female had treatment of her thoraco-abdominal aneurysm with a stent graft; the aneurysm did not compromise the visceral branches.

Every patient and a close relative gave their written informed consent.

Patients treated for other conditions (AV fistulas and false aneurysms) will be described below.

Demographics (Patients with Aneurysms)

Seventy-one males and nine females were treated. The average age was 72 years (range: 57 to 89 years), and eight patients were more than 80 years of age.

Associated Pathologic Conditions

All patients had at least one associated morbid condition (Table 1). Eight patients were considered to be in the group of acceptable risk to be treated with the standard surgical operation and were included as volunteers. Twenty-five were clearly included in the high-risk group, and 17 were considered inoperable by at least two well-recognized vascular surgeons (For the procedures performed, see Table 2).

RESULTS

Sixty-two of the 80 (75%) procedures for AAA exclusion were considered successful. The definition of a successful procedure includes complete exclusion of the aneurysm with restoration of normal blood flow. In addition, the stent-graft should be in contact with normal intima since sealing proved to be incomplete and temporary when the stent graft was deployed in an area covered with laminated thrombus.

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 three or four days.

Eighteen of the 80 (25%) procedures were considered as initial failures. Five of the 10 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

1. One case of misplacement of the proximal stent was treated by standard surgical procedure. The patient survived and did well.
2. There were three cases of proximal leak. In one patient with minimal leakage, the size of the aneurysm decreased in spite of the leakage, and the leakage ceased in a few weeks. This patient died six months postoperatively of an unrelated cause. The second and third patients had an important leak; one died after seven months of cardiac insufficiency, and the second died of a ruptured aneurysm after two months of the procedure. (We included every case of leakage as a failure.)
3. 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. Cirrhosis of the liver, ascites, and gastrointestinal bleeding were the indications for endoluminal treatment. The patient survived the operation but died of abnormal bleeding the next day.
4. Two patients had distal leakage. One lasted three weeks and subsided; the second, on the other hand, persisted with minimal leakage and died of pulmonary and cardiac insufficiency eight months later.
5. 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 D.I.C. and multiple organ failure. One additional patient died suddenly after two days, the postmortem examination disclosing intestinal ischemia and renal infarcts probably related to embolization during the procedure.
6. Incomplete deployment of the distal stent occurred in one patient. Attempts to open the stent with different balloons failed, and the procedure was converted to an open procedure.

Operative mortality (within 30 days) was 8.7%. Causes of death were as follows: massive microembolization (2), visceral embolization (1), pulmonary embolism (1), pulmonary insufficiency (1), myocardial infarction (1), and coagulopathy (1).

Table 3. Complications (failures treated separately)

Complications	Number
Groin hematoma	2 patients
Proximal leak (treated with a covered stent)	2 patients
Injury to the external iliac artery (sutured)	2 patients
Minimal distal microembolization treated by intra-arterial injection of prostaglandin	3 patients
Distal leak (treated with covered stent)	2 patients

Complications

In addition to the above-mentioned complications that caused the procedure to fail, we had some others that could be solved at the time of occurrence (Table 3).

In 8 of the 56 aortic procedures, both renal artery ostia were covered

Figure 3. Aorto-iliac graft in place, balloon occlusion of the contralateral iliac artery, and femorofemoral bypass.

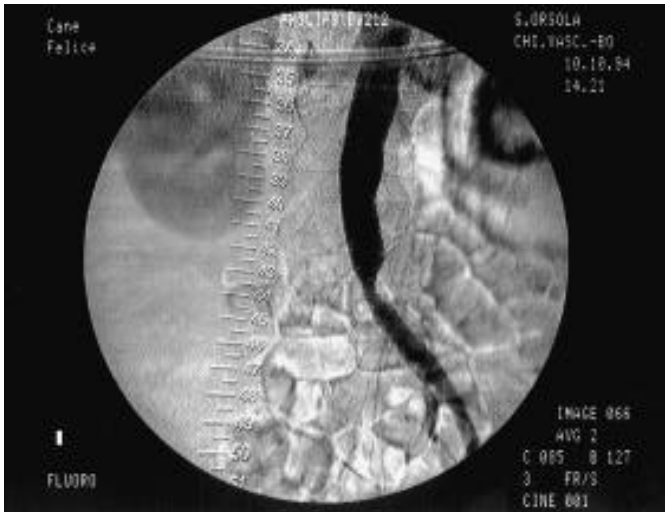

Figure 3a.

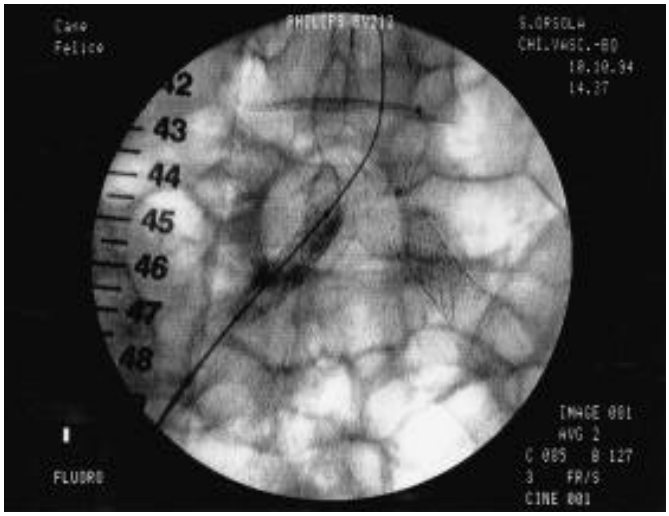

Figure 3b.

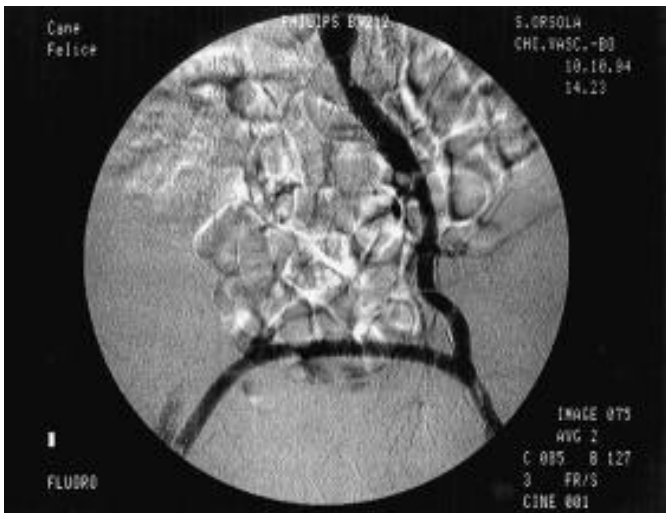

Figure 3c.

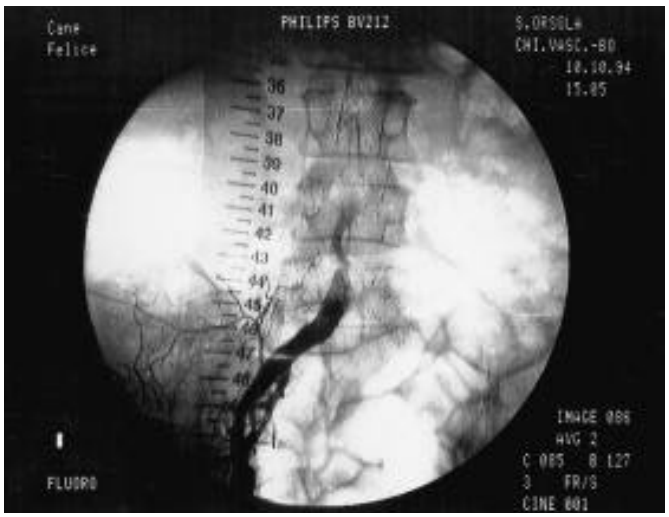

Figure 3d.

with the stent, and the graft attached to the stent was placed distally to the renal arteries. None of these patients developed renal insufficiency. The results of the color duplex studies of the renal arteries were normal; studies are repeated every six 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 of 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 up by clinical examination, color duplex studies every six months, and CT scans once a year. Angiograms were performed in some patients and in each one in whom the color duplex and/or CT scan indicated or suggested any sign of leakage into the aneurysmal sac (incomplete sealing), 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 56 months.

One patient developed a distal aortic dilatation after 18 months of the initial procedure. The distal stent was placed too distally to the aortic bifurcation and in contact with a mural thrombus and not with the 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.

Four patients who had only the proximal stent deployed developed a distal reflux with shrinkage of the graft 8, 18, 24, and 29 months after the procedure. Two had an additional procedure to correct this complication (insertion of an additional covered stent at the distal end). The second case was left with a minimal leak, as it was impossible to obtain the expected result with our current resources. One patient is ready to have additional treatment, and the fourth declined the possibility to undergo further procedures.

One patient, who had an aortoiliac graft implanted two years earlier, developed a distal leak. The iliac artery in which the distal stent was implanted was aneurysmal, and the stent was anchored at the point of a ring of normal caliber in the middle of the common iliac artery. The aneurysm

increased in size and the leak was created. An attempt to seal the leak failed.

Two patients with aorto-aortic graft with two stents developed a distal leak after 12 and 16 months. The reason for this change could not be explained.

Two patients died 13 and 24 months respectively after the procedure, due to carcinoma of the colon. An additional patient died after being admitted to the clinic because of cardiac failure and respiratory insufficiency eight months after the initial procedure. Two patients died of cardiac insufficiency six and seven months after the procedure. One patient with proximal leakage (failure) died of a ruptured AAA two months after the unsuccessful procedure. One patient who had a late failure after 16 months of the procedure (distal leak after an aorto-aortic graft) sustained a ruptured aneurysm and died.

One patient was re-admitted to the clinic after three months of the initial procedure with a pulmonary edema and was discharged after one week.

One patient developed a subdural hematoma three months after the initial treatment. He did well after draining the hematoma surgically. The hematoma was probably caused by a small trauma since our patients did not receive any specific medication after the treatment, not even antiplatelet drugs.

Sixty-two percent of the patients of the initial group and 80% of the initially successful group of patients had good results after the primary procedure until the last clinical visit, or until the moment of their death caused by an unrelated cause.

Only one patient with an aortoiliac procedure had a late failure (distal reflux into the aneurysmal sac). Initial results of aortoiliac procedures were inferior when compared with aorto-aortic procedures because of the larger profile of the introducer needed for its deployment that generated inconveniences with access; however, late results were more favorable with the aortoiliac procedure.

Most of the complications were correctable by additional endoluminal procedures.

Arteriovenous Fistulas

Six patients were treated using this procedure. The first patient had a subclavian arteriovenous fistula developed after a gunshot wound sustained two years prior to consultation. The patient developed congestive heart failure as a consequence of a high-output arteriovenous fistula. This patient was treated under local anesthesia by inserting a covered Palmaz iliac stent closing the abnormal communication. The stent was covered with a knitted Dacron graft. A 12-mm-diameter balloon was used to deploy the stent-graft device. The patient had a favorable outcome.

The second patient had a common iliac–inferior vena cava fistula caused by an accident during laparoscopic surgery. A percutaneous stent-graft was applied from the ipsilateral common femoral artery.

The third patient was referred to us for treatment of an AV fistula between the abdominal aorta and the inferior vena cava. The patient sustained a gunshot wound several months before and had had four surgical attempts to treat multiple lesions in the abdomen including the AV fistula. The last attempt to do so was unsuccessful and ended with a cardiac arrest after an exsanguination episode while trying to close the communication. The inferior vena cava was ligated and the procedure concluded after resuscitation of the patient with large volumes of whole blood. The patient was transferred to our clinic and treated a few days later with an endoluminal procedure performed under local anesthesia. A 3.5-cm covered stent was deployed covering the communication, interrupting effectively the flow through the fistula. The patient was discharged the next day. An additional patient who was admitted because of an aortocaval fistula was treated successfully in the same way.

The sixth patient treated for an AV fistula was a young female who was attacked in her store and sustained a gunshot wound in her right thigh. An arteriovenous fistula between the superficial femoral artery and vein was diagnosed, a covered stent was applied at the site of the fistula percutaneously using a 14 Fr. sheath applied in anterograde fashion through the common femoral artery.

Another patient was admitted with an infected false aneurysm of the common femoral artery caused by a coronary stenting procedure performed 10 days earlier. The patient suffered renal insufficiency and unstable angina. A stent covered with autologous vein was deployed through the superficial femoral artery. Expansion of the false aneurysm subsided, and the cavity was debrided and drained.

A 30-year-old male who sustained a gunshot wound in the right supraclavicular region developed an AV fistula between the subclavian artery and vein and a false aneurysm of the thyrocervical branch of the subclavian artery. A detachable balloon occluded the false aneurysm of the branch and a Dacron-covered stent occluded the abnormal communication between the artery and vein.

A 20-year-old HIV-positive male was admitted to the clinic with a false aneurysm of the common carotid artery near its takeoff from the innominate trunk. A covered stent using autologous vein was deployed covering the orifice of the carotid artery.

The last vascular trauma case we treated was a 38-year-old patient who sustained neck trauma in the past and developed a false aneurysm at the level of the base of the skull probably related to a carotid dissection. The patient had five episodes of cerebral ischemia with resulting cerebral infarcts depicted in the CT scan. The last two episodes of cerebral ischemia occurred during oral anticoagulation treatment. The patient was treated using a vein-covered Palmaz stent. He did not have further episodes of cerebral ischemia, and the false aneurysm was effectively excluded.

All the procedures employed to treat trauma cases were successful.

Secondary Procedures

When the endoluminal treatment failed either initially or after variable periods of time after an initially successful procedure (usually signs of incomplete sealing of the graft were the indicators of failure), attention was directed at performing secondary procedures to solve the problem. Needless to say that in many cases because of the prohibitive risk to the patient submitting to a standard surgical treatment, if the initial endoluminal treatment could not be completed, the procedure was abandoned leaving the patient in the initial condition. Exceptions to this approach consisted of one patient in whom the stent-graft was mispositioned, resulting in occlusion of both iliac arteries, and a second patient in whom the device migrated caudally due to incomplete deployment of the stent. Both patients were operated upon immediately.

An additional patient, who had a distal reflux a few months after the primary procedure, required surgical insertion of a graft which was anastomosed to the initial one placed endoluminally and then sutured to the distal aorta.

One patient had an unsuccessful endoluminal procedure: proximal leakage could not be fixed endoluminally. Because of the prohibitive risk, the patient was not operated upon. He sustained a ruptured aneurysm two months later and was submitted to surgery. During surgery he sustained a cardiac arrest shortly after laparotomy was performed. It is important to note that the area in which the stent was placed could not be clamped. As the proximal stent was deployed flush to the renal ostia, clamping was performed at the supra-celiac level and then a balloon inflated at the level of the neck releasing the supra-celiac clamp.

Another comment should be made regarding sutures in the presence of metal stents. Suture in contact with metal can rupture immediately or as a result of friction over time. It is not advisable, then, to suture a graft at the level of the stent. There are two ways to overcome this problem. One is to remove the stent, if it was deployed recently (less than two weeks). It is possible to compress the stent, reducing its diameter, and remove it. If the stent was inserted weeks or months before, it is not recommended to try to remove the stent since the wall of the artery will be severely damaged. Facing this dilemma, we believe that it is advisable to place a second stent graft inside the first.

All other secondary procedures were endoluminal treatments and not surgical procedures.

DISCUSSION

After 80 procedures for treating aneurysms and 12 for other applications (AV fistulas and false aneurysms), some preliminary conclusions are discussed.

1. The procedure is feasible and, when successfully applied, has the great attraction of its simplicity.
2. The application of covered stents in trauma cases appears as one of the main applications of this method, since it transforms a complicated and potentially dangerous procedure into a simple and safe one. Stenosis can be defined as the only potential complication in the long term. In the near future, stent-grafts could eventually be used in acute injuries of the vessel in both civil and war conditions to stop blood loss temporarily or definitively. This procedure can be combined with endovascular control of bleeding of secondary branches using detachable balloons, coils, occluding stents, or the injection of fluids that become solid inside the body when the body temperature is reached. This procedure proved to be useful in injuries of vessels such as the subclavian artery that represent a real challenge even to the experienced surgeon. On treating aortic aneurysms, there were, however, more problems than those that initially could be predicted. The procedure is simple in theory, but there are several details that should be taken care of before moving ahead with the widespread use of the method.
3. Measurement of diameters and lengths is crucial. We learned with great effort how to obtain reliable data. Enhanced CT scan, quantitative angiography, three-dimensional reconstruction using MR or CT-scan images, intraluminal measurement, and some geometric calculations helped us to obtain reasonably 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.

Using a diagnostic catheter with radiopaque marks helps to obtain measurement of the length and diameters. However, one factor that should be considered to prevent misinterpretation of the data obtained is parallax, which is a result of the dispersion of the X-ray beams. As soon as the beams are released from the source of radiation, they are not completely parallel, and that makes measurements performed at the periphery of the X-ray screen distorted. Error in measuring of aneurysmal length caused by parallax can be in excess of 3 cm. Another cause of error in measuring length using a catheter is that the location of the catheter inside the lumen depends on the morphology of the lumen, and the catheter does not always occupy the center of the lumen; as a matter of fact, the catheter will situate itself in the shortest path inside the lumen. The graft to be used is not linear as the catheter is, since it has some volume and a diameter not less than 18 mm. The location of the catheter inside the lumen of the aneurysm is also influenced by the presence of angles. The catheter is semi-rigid; thus it does not duplicate the shape of the curves. As a result of this, in very tortuous aneurysms, the axial length is underestimated when measured using a catheter with radiopaque marks.

One simple maneuver to prevent or diminish error from parallax is to use only the center of the screen for measurements, either using a radiopaque ruler or a diagnostic catheter with marks.

We developed a simple software program based on the Pythagorean theorem to overcome the problem of measuring lengths in tortuous aneurysms, since the unknown side of the triangle is the hypotenuse. The triangle is formed as follows. One side is the distance between slices of the CT scan (usually 0.5 to 1 cm). The second, forming a 90° angle with the former, is the distance between the center of the lumen of the two adjacent slices. The third is the actual axis of the lumen, lies opposite the right angle, and is thus considered the hypotenuse.

Vertical measurement in the presence of elongation is incorrect, since it does not count the extra length provoked by elongation. Making CT scan studies with slices every 5 mm and measuring displacement of the axis of the lumen is all that is needed. As it was described before, two of the three sides of a triangle are known; one side is the distance between slices (5 or 10 mm) and the second is the distance between two consecutive center points of the aneurysmal lumen. When no change in the vertical axis occurs, this side is equivalent to 0. Then the distance between two consecutive slices is simply the interval between slices (5 mm or 1 cm). On the other hand, when the axis varies, the second side has a value. This figure should be included in the Pythagorean equation, and its square is added to the square of the slice length. The square root of the sum is the actual distance between two center points of the lumen of the aneurysm. Adding the distances between consecutive slices results in the length of the selected section of the axis.

At this point we know that we need a hologram rather than a three-dimensional reconstruction shown on a two-dimensional screen.

Measurement is accomplished between the lower renal artery and the aortic bifurcation. As in surgery, we prefer to cover the whole length between these two sites with a stent graft.

There is a problem, however, when the cut is made oblique to the axis of the AAA, since tortuosity makes the axis of the aneurysm not parallel to the axis of the body. When the artery bends and the slice is taken perpendicular to the body axis, the shape of the slice is not circular but oval; therefore, the actual diameter is smaller. When this oval figure is obtained, it is not possible, just using this method, to determine which is the center of the slice. Additional data is necessary.

There is a simpler method of measurement using the spiral CT scan. The 3-D image is developed and the segment between the more distal renal artery and the aortic bifurcation is divided in 10 equal segments. The image is rotated 360 degrees and the maximum length of each segment measured in any of the images of rotation is considered the actual length. The sum of the maximum length of all 10 segments is equivalent to the actual length of the artery.

It appears that the final answer regarding measurements will come from computer image processing using 3-D reconstruction of spiral CT or MRI scans and probably a simulation program demonstrating the insertion of a stent-graft device. Meanwhile, we prefer to overestimate the length, since grafts in excess can be accommodated by the "accordion mechanism" allowed by crimping of the graft. If kinking results, it could be solved by inserting an inner stent at that level, as we have done.

4. Access problems accounted for several problems that had to be solved.

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 represented a drawback from the beginning. We overcame some of these problems, modifying the device and using different maneuvers during the procedure.

Reducing the diameter of the sheath to 18 Fr. was an important advance towards 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 the common femoral and external iliac arteries free, just 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, the artery should be pulled gently towards the feet of the patient. The tortuous artery then 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 2 cm respectively. In the second stage, the distal cuff becomes shorter. In the third stage the distal cuff tends to disappear, while the proximal neck becomes shorter (yet still longer than 2 cm). After this stage, we found that elongation takes place, creating 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 right, the distal cuff curves to the left, leaving the left iliac artery straight and the left with the tendency of producing a right angle.

These findings dictate that in some group of 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] Additionally, when the angle between the iliac arteries becomes larger than 90 degrees, an aorto-iliac graft should be used, along with creation of a femorofemoral bypass.

We foresee that the three systems available will be applicable in patients harboring AAA. Small and medium-size AAA will benefit with aorto-aortic systems, large aneurysms with aorto-bi-iliac or aorto-iliac systems, with the addition of a femorofemoral bypass and exclusion of the contralateral common iliac artery.

We believe, at this stage, that endoluminal treatment of AAA will be applicable in patients with large or symptomatic aneurysms in whom the standard surgical graft replacement represents a prohibitive operative risk. For those patients the best solution will be the aorto-iliac procedure, since most of them have tortuous and often aneurysmatic iliac arteries. Frequently the axis of both common iliac arteries defines an angle in excess of 100 degrees, making the placement of a bifurcated graft impossible.

The issue of arterial dilatation should be addressed. We still do not know what is going to be the impact of a stent embedded in the vessel wall in terms of prevention of future dilatation; meanwhile, we elected to treat high-risk patients with large or symptomatic aneurysms. We believe that only well-controlled limited trials involving young patients with small aneurysms should be conducted due to the uncertain long-term results of the endoluminal treatment of AAA.

5. Anchoring mechanism. The balloon-expandable stent because of its high radial force appears as the ideal device for this purpose. This is probably true for the time of implant and shortly afterward. Diameter of arteries increases with time; in addition, the effect of a stent producing an internal radial force would produce further dilatation.

We have 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. In this regard, the pioneer work of White[7] indicates that intraluminal ultrasound should be almost mandatory as a completion study after finishing a stent-graft implantation. In our modest experience with this method, abnormalities were found with intraluminal ultrasound that were not detected with digital angiography. As predicated by White, ultrasound real-time imaging during stent deployment will probably be a requirement in the future to obtain reliable results. An ultrasound probe can be placed in one of the lumens of the balloon catheter and positioned at the level of the balloon. In our opinion, having had many inconveniences in our experience, this will be one of the most striking developments to improve the endoluminal technique to treat AAA.

In regard to the use of a modification of the J & J stent as an anchoring system, it should be said that clinical results utilizing the J & J stent in occlusive disease cannot be compared with the reaction of the arterial tissue in this new application. Arteries in patients with AAA are usually dilated and not

stenotic, and their walls are very often thinner than those of normal arteries and much thinner than the atherosclerotic artery. We do not know the reaction of the thin-walled artery, and it also should be emphasized that this segment of the artery with normal or near-normal diameter has some biochemical changes such as enhanced activity of elastase and collagenase that make the situation more unpredictable.

Most probably, our next generation of stents will have an intermediate radial force which will be enough to anchor the graft properly but, on the other hand, will not produce dilatation of the artery.

We performed experiments in pigs using an extraperitoneal laparoscopic approach, placing a tape around the aorta close to the renal arteries in order to create an external banding and to prevent dilatation of the artery. The tape is a polyethylene mesh with wide open interstices to avoid decubitus when compressing the arterial wall with the stent inside.

The extraperitoneal laparoscopic approach seems not to be very difficult and perhaps will represent a step forward eventually to treat young patients harboring AAA with a long life expectancy, without the compromise of the stent-graft attachment due to arterial dilatation.

6. Microembolization. This is what we consider the main and more severe problem with this procedure.

We were able to solve almost all the problems we had, but microembolization as a complication happened four times in our experience, and three of the four cases ended in death. In the remaining case, discrete microembolization of the right foot was successfully treated with intra-arterial administration of prostaglandin E_1.

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 case technical problems occurred during the procedure in relation to inappropriate balloon sizing.

A third case of embolization occurred again after a complex situation created by a technical failure of the balloons used in the procedure. The patient died suddenly 48 hours after the procedure. Postmortem examination disclosed visceral embolization.

The mild, reversible case of microembolization occurred on the side of implantation of an occluding stent after an aorto-iliac 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 clearly that large and tortuous aneurysms pose an increased potential risk of embolization probably due to the following conditions. 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, since 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 cases of large aneurysms with wide lumens to insert the guidewire percutaneously from the brachial artery.

In addition, 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 manipulations we perform, the more the risk for the dislodging of particles from the aortic wall.

Several measures can be tried in order to minimize the occurrence of microembolization. In cases of large aneurysms with large lumens, the soft-tip guidewire should be introduced distally from the brachial artery and recovered from the common femoral artery that has been chosen in advance. Care should be taken to measure precisely the length and diameters of the arteries and perform a simple well-planned procedure. After successfully treating patients who were admitted because of spontaneous visceral and distal embolization, we concluded that, even in the presence of friable thrombus in the lumen of the AAA, endoluminal treatment can be performed safely.

FUTURE DIRECTIONS

It is clear that this new development represented a different and new challenge for the medical industry.

What do we foresee as constitutive of the ideal device to be utilized in endoluminal treatment of aneurysms?

Anchoring mechanism. The balloon-expandable stent we are using seems to be the ideal way to obtain a dependable fixation of the graft.

A computer projection study of the stress load to the stent struts during the foreseeable life span of an average patient suggested that the fatigue limit of the stent will not be approached.

A flexible stent will be needed to be able to negotiate tortuous iliac arteries.

Hooks are dangerous and probably not needed.

Self-expandable, spring-loaded stents are generally weaker in radial force and also would not accommodate irregular lumens. Besides, if made of multiple parts, micromotion between metal surfaces disrupts protective oxide films, allowing the area to corrode rapidly, leading to mechanical failure. One should keep in mind that this device should remain intact for the life span of the patient.

Self-expandable, spring-loaded stents made of nitinol with thermal memory, deserve an independent comment. In these stents there is a combination of two forces that when interacting create a stronger force. Radial force in self-expandable stents depend on the strength and diameter of the wire among other characteristics; if in addition to this mechanism a second force generated by thermal memory of the metal produces a secondary expansion of the stent as soon as the given temperature is reached, final hoop stress will be almost comparable to a strong, one-piece, balloon-expandable stent.

Graft Material. Either Dacron or PTFE could be used. A thin wall is needed, as is the crimping in the case of Dacron; or the ability to stretch, if PTFE is used. Crimping is needed to obtain a kink-resistant graft.

Balloons. These devices should be partially compliant, scratch-resistant, reinforced to prevent rupture, and wrapped in such a way that rotation will not take place or at least should not be significant. A rigid, noncompliant balloon could be an inconvenience in dealing with patients with irregular lumens; in these cases gaps between the stent and arterial wall could generate thrombus and leaks between the graft and arterial lumen.

CT Scans. Preprocedure studies should include CT scans (slices every 5 mm or less and 3-D reconstruction) and angiography. Spiral CT scan, when available, would represent a significant advantage. MR angiography with additional software can be the procedure of choice in the future.

High-Resolution Fluoroscopy. During the procedure, high-resolution fluoroscopy is needed. Road-mapping seems advantageous. Intravascular ultrasound (IVUS) proved to be very useful to assess completeness of stent deployment. We have used IVUS in two instances. For the second time, the IVUS allowed us to detect and solve a graft fold in the iliac artery that was missed in the arteriogram.

Speculation could be made regarding imaging in endovascular stent-graft treatment of AAA and occlusive disease in the near future. It will be possible to complete the procedure without using any X-ray method. Provided that new developments now in research are completed, MR imaging and ultrasound could eventually cover all needs, without irradiating the patient and the attending staff.

We still have some basic doubts about the procedure we are proposing. Long-term stent-graft interaction is one of our main concerns. Stent edges could cause damage to the graft through direct mechanical action or through material fatigue mechanism. As the stent and graft are covered by tissue in a few weeks, the potential impact of this possible damage will be probably without clinical importance. What is unquestionable is that the device should be designed to last, accomplishing the aneurysm exclusion and keeping the flow through it for a lifetime.

A second main concern is the tissue reaction after the endovascular treatment of AAA. It is known[8] that both the composition and mechanical properties of AAA are different from those of nonaneurysmal aortas. The aneurysms are stiffer, and the volume fractions of collagen and ground substance are increased, whereas the volume fractions of elastin and muscle are decreased in aneurysms.

Whether or not changes occur in the diameter of the neck of the aneurysm after stent implantation is not known. Intimal hyperplasia develops regularly over the stent. Some atrophy of the media and reaction of the adventitia are expected after stent implantation. These changes and also the presence of the stent itself forming part of the architecture of the arterial wall will probably prevent dilatation of the tension of the wall.

It should be emphasized that watertight sealing between the arterial wall and the stent-graft unit should be obtained from the first moment.

Lack of leakage into the aneurysmal sac, upon injection of contrast media, should not be considered a primary success. A graft and stent in contact with the thrombus can temporarily seal but not for an extended time. The thrombus dissolves and a leak may appear in a few weeks or months. Endovascular ultrasound and or CT scanning with contrast media can tell with certainty the completeness of stent deployment. Both ends of the graft should be in contact and sealed with arterial wall and not with the thrombus to consider the result acceptable. X-ray images during procedures should be interpreted through a reconstruction of the actual aneurysm based upon CT scan images taken in small slices (5 mm or less). A clear identification of the locations where the thrombus starts and finishes will allow the surgeon to place stents in the appropriate site.

Spontaneous embolization is the second complication of AAA in number and importance. Embolization takes place when the thrombus becomes friable and the mural thrombus suffers a dissection. Usually microthombi migrate to the extremities and also, in a retrograde fashion, to the visceral arteries (mainly the renal arteries). In our experience these very sick patients can be treated endoluminally. Providing that great care is taken to prevent rupture and damage of this friable material while the procedure is performed, the thrombus can be effectively excluded, interrupting the shower of microemboli. We treated three patients affected by spontaneous microembolization with this method, administering an intra-arterial prostaglandin E_1 injection to control distal tissue damage.[9]

The relationship between the stented graft and microembolization deserves a special comment. Microembolization is the most severe complication of the use of stented grafts for endoluminal treatment of AAA. On the other hand, endoluminal exclusion of AAA is an emerging tool to treat microembolization resulting from aneurysms.

At first glance, it seems unreasonable to use a therapy for a condition that can be caused by the proposed technique. The explanation for this dispute is that aneurysms that embolize spontaneously are usually small. Small aneurysms have straight iliac arteries, and aneurysms are usually nontortuous. Conversely, aneurysms that caused microembolization during endoluminal treatment were, in our experience, very large and tortuous. Iliac arteries were elongated. All of these characteristics created technical difficulties when performing the endoluminal exclusion of the aneurysm. Out of 50 procedures of the endoluminal treatment of AAA, massive microembolization occurred in three patients (3.7%) and mild unilateral microembolization in one (1.2%).

In spite of the encouraging results we have had, we are aware of the necessity of performing controlled trials with a sufficient number of patients followed for a long period of time before introducing the endoluminal treatment in clinical practice. Meanwhile, experience should be concentrated in a few centers with appropriate equipment, a skilled group of surgeons, and interventional radiologists or a cardiologist with experience in interventional vascular procedures.

A word of caution should be issued before definitive conclusions are made, since we are finding new abnormalities among the group of patients we treated as far as three years after performing what we considered a successful procedure. Before this procedure can be offered to the community as an alternative treatment for AAA, a clear, unremarkable long-term experience should be available to be presented to the medical community.

Regarding other applications of the stent-graft combination, treatment of arteriovenous fistulas appears as a simple and effective application of the concept. It will save time and prevent bleeding and peripheral nerve injuries. Treatment of false aneurysms in nonaccessible places also is a very promising application, as it is a form of vascular trauma. Arterial dissections (mostly aortic dissections) will probably be efficiently treated endoluminally, interrupting the flow through intimal tearing. One of our cases showed how promising this approach could be.

The development of an "internal

bypass" after balloon dilatation is an appealing idea in view of the failure of balloon dilatation in long stenosis or occlusions. 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.

Our initial experience on treating thoracic aneurysms (one resulting from aortic dissection, and the second a thoraco-abdominal aneurysm with no compromise of the visceral arteries) indicates that the procedure is simpler than treating AAA and very promising. STI

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