ENDOLUMINAL STENT–GRAFTS FOR INFRARENAL ABDOMINAL AORTIC ANEURYSMS

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ABSTRACT

Background The treatment of aortic aneurysms with endovascular stents or stent–graft prostheses is receiving increasing attention as an alternative to major abdominal surgery. To define the clinical value of this technique, we prospectively studied the use of stent–graft endoprostheses made of nitinol and covered with polyester fabric for the treatment of infrarenal abdominal aortic aneurysms.

Methods We treated a total of 154 patients at three academic hospitals. Twenty-one patients with aortic aneurysms not involving the aortic bifurcation received straight stent–grafts, and 133 patients with aortic aneurysms involving the bifurcation and the common iliac arteries received bifurcated stent–grafts. After a unilateral surgical arteriotomy, the endoprostheses were advanced through the femoral arteries and placed under fluoroscopic guidance. Computed tomography and intraarterial angiography were performed during an average follow-up of 12.5 months.

Results The primary success rate, defined as complete exclusion of the abdominal aortic aneurysm from the circulation, was 86 percent in the group receiving straight grafts and 87 percent in the group receiving bifurcated grafts. In three patients the procedure had to be converted to an open surgical operation. Minor (n = 13) or major (n = 3) complications associated with the procedure (including 1 death) occurred in 10 percent of the patients. All patients had a postimplantation syndrome, with leukocytosis and elevated C-reactive protein levels.

Conclusions Our results suggest that endovascular treatment of infrarenal abdominal aortic aneurysms is technically feasible and can effectively exclude abdominal aortic aneurysms from the circulation. With further refinement, endoluminal repair may emerge as an interventional strategy to treat infrarenal aortic aneurysms, especially in patients at high surgical risk. (N Engl J Med 1997;336:13-20.)

THE routine management of aortic aneurysms is surgical, with placement of a graft in the involved segment.[1,2] Surgical treatment of nonruptured abdominal aortic aneurysms is associated with an overall mortality rate of 1.4 to 7.6 percent,[3-5] and the rate is as high as 10 percent in patients with symptomatic aneurysms.[6] With the percutaneous placement of endoluminal stent–grafts, major abdominal surgery and the related morbidity and mortality can be avoided. This is particularly important because of the high incidence of coexisting morbid conditions[7,8] in unselected patients between 65 and 80 years of age, in whom the prevalence of abdominal aortic aneurysm is rather high (3 percent).[9,10]

The use of endoprostheses was first proposed by Dotter in 1969.[11] In 1986 Balko et al. reported the repair of artificially induced aneurysms with polyurethane prostheses in animals.[12] This was followed by several reports of experimental endoluminal grafting in animal models.[13-22] The use of straight grafts in patients with aortic dissection or abdominal aortic aneurysms was first described in 1991 by Parodi et al.[23] Since then, endoluminal treatment of aneurysms of the thoracic and infrarenal abdominal aorta with different types of endoprostheses has been used in a number of centers.[24-36]

We report the short-term and midterm results of stent–grafting for infrarenal abdominal aortic aneurysms with polyester-covered nitinol endoprostheses in 154 patients who would have otherwise required surgical repair. The aim of this study was to assess the feasibility, rate of complications, and clinical effectiveness of endoluminal treatment of infrarenal abdominal aortic aneurysms.

METHODS

Selection of Patients

Among 331 patients with infrarenal abdominal aortic aneurysms who were referred to the three study hospitals between August 1994 and April 1996 for evaluation, a total of 154 patients (47 percent) were treated by transfemoral placement of straight or bifurcated stent–grafts for aneurysms with maximal diameters of 3.7 to 9.7 cm (mean, 5.4). Seventy-four patients were treated at University Hospital, Freiburg, Germany; 47 at Henriettenstiftung, Hannover, Germany; and 33 at University Hospital, Vienna, Austria. The base-line clinical characteristics of the patients and the types of abdominal aneurysms present are listed in Table 1.

The patients were selected on the basis of the anatomy of the

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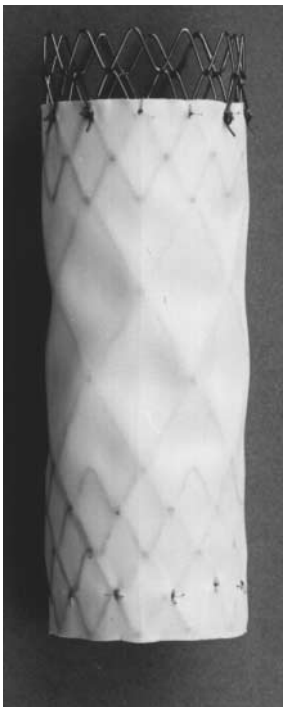
TABLE 1. CLINICAL CHARACTERISTICS OF 154 PATIENTS WITH ABDOMINAL AORTIC ANEURYSMS WHO WERE TREATED WITH ENDOLUMINAL STENT–GRAFTS.

CHARACTERISTIC	VALUE	%
Age (yr)		
Mean ±SD	68±8.7	
Range	41–90	
Sex		
Male	150	97
Female	4	3
Coexisting conditions (no. of patients)		
Cigarette smoking	82	53
Hypertension	115	75
Hypercholesterolemia	38	25
Obesity	47	31
Renal failure*		
Mild	23	15
Severe	4	3
Diabetes mellitus	28	18
Coronary artery disease	87	56
Peripheral vascular disease	59	38
Cerebrovascular disease†	16	10
Previous laparotomy	73	47
American Society of Anesthesiologists class (no. of patients)		
II	28	18
III	76	49
IV	50	32
Type of aneurysm (no. of patients)‡		
A	21	14
B	91	59
C	42	27

*Mild renal failure was defined as a creatinine concentration of 1.3 to 2.3 mg per deciliter (115 to 203 μmol per liter), and severe renal failure as a creatinine concentration ≥2.4 mg per deciliter (212 μmol per liter).

†Cerebrovascular disease was defined as a transient ischemic attack or stroke.

‡A type A aneurysm had proximal and distal aortic necks that were more than 10 mm in length and less than 25 mm in diameter without iliac involvement. A type B aneurysm involved the aortic bifurcation and had a proximal aortic neck that was more than 10 mm in length and less than 25 mm in diameter, with a common iliac artery that was less than 12 mm in diameter. A type C aneurysm had a proximal aortic neck that was more than 10 mm in length and less than 25 mm in diameter and involved the common iliac arteries and the iliac bifurcation (diameter, <12 mm).



A

B

Figure 1. Stent–Grafts Used for the Endoluminal Treatment of Infrarenal Abdominal Aortic Aneurysms.

The grafts are composed of a nitinol frame covered with a thin woven-polyester fabric. Panel A shows the straight stent–graft in which the top of the graft is not covered by fabric and has a row of barbs for anchoring into the proximal neck of the aneurysm. Panel B shows the bifurcated graft. The graft has two components that are inserted separately and then joined: the primary component consists of an aortic and iliac stent–graft with an attachment site for the secondary component, which is placed in the contralateral iliac artery.

aneurysm and the classification of the infrarenal abdominal aortic aneurysm. Patients selected for endoluminal therapy were eligible for the study irrespective of their eligibility for surgery.

To be included in the study the patients had to have an aneurysm classified as type A, B, or C. A type A aneurysm had proximal and distal aortic necks that were more than 10 mm in length and less than 25 mm in diameter without involvement of the iliac arteries. A type B aneurysm involved the aortic bifurcation and had a proximal aortic neck that was more than 10 mm in length and less than 25 mm in diameter, with a common iliac artery that was less than 12 mm in diameter. A type C aneurysm had a proximal aortic neck that was more than 10 mm in length and less than 25 mm in diameter and involved the common iliac arteries and the iliac bifurcation (diameter, <12 mm).

Patients were excluded from the study if they had type D aneurysms (involvement of both internal iliac arteries), type E aneurysms (proximal aortic neck of <10 mm in length or >25 mm in diameter), or stenosis or occlusion of the superior mesenteric artery, or if they were not available for follow-up.

The patients were divided into two groups according to the type of the abdominal aortic aneurysm. In one group, only the abdominal aorta was involved (type A aneurysm), requiring the implantation of a straight stent–graft. In the second group, the aortic bifurcation or the bifurcation and the common iliac arteries were involved (type B or C aneurysm), requiring the implantation of a bifurcated stent–graft.

All patients were informed about the procedure in detail and gave their written consent. The study protocol was approved by the ethics committees of the three centers.

Endoprostheses

The stent–graft (Mialhe Stentor, MinTec, Freeport, Bahamas, and Vanguard, Boston Scientific, Oakland, N.J.) is a self-expanding endoprosthesis composed of a nitinol frame annealed into a tubular zigzag configuration by a 7-0 polypropylene thread[37] and covered with a 0.1-mm woven-polyester fabric. The stent–grafts are straight (Fig. 1A) or bifurcated (Fig. 1B), depending on the anatomy of the aneurysm.[34] The bifurcated device has two components that are introduced separately and then joined intraluminally: the larger component consists of an aortic and iliac graft with a short branch 10 mm in diameter into which the smaller component, which is placed in the contralateral iliac artery, is inserted. The devices are commercially available in standard sizes (total length, 153 or 165 mm; diameter of the aortic section, 22, 24, or 26 mm; diameter of the iliac section, 10 or 12 mm), or they can be custom-made.

Preprocedural Evaluation and Implantation Technique

To determine the length and diameter of the aneurysms, we performed multiplane angiography using a graduated catheter and spiral computed tomography with three-dimensional vascular reconstructions at least one week before the procedure in all patients considered for stent–graft implantation.[34]

The implantations were performed with the patients under general anesthesia (n = 151) or local anesthesia (n = 3) in the angiography suite (in the German hospitals) or in the operating room (in the Austrian hospital) by teams of interventional radiologists and vascular surgeons. The vascular surgeon performed the arteriotomy, and the radiologist placed the stent–graft. The patients were prepared for surgery in case serious complications occurred or the endoluminal technique failed. The technique of placing the stent–graft — illustrated in Figure 2 — and the peri-interventional and postinterventional management have been described previously.[34]

Follow-up Protocol

The follow-up protocol included intraarterial angiography and spiral computed tomography. The first follow-up study was performed in all patients before discharge, within seven days after the initial procedure. Thereafter, all follow-up examinations were performed on an outpatient basis: the second examination was conducted 3 months after the procedure (computed tomography), the third examination 6 months later (intraarterial angiography and computed tomography), and the fourth and fifth examinations after 12 and 24 months, respectively (computed tomography).

Statistical Analysis

Continuous variables are expressed as means ±SD. The laboratory measurements made before and after stent–graft implantation were compared by Student's t-test. A P value below 0.05 was considered to indicate statistical significance.

RESULTS

Primary Technical Results

Primary technical success, defined as the complete exclusion of the abdominal aortic aneurysm from the circulation, with restoration of normal blood flow, was achieved in 134 of the 154 patients (87 percent).

Type A Aneurysms

Transfemoral treatment with straight grafts was technically successful in 18 of 21 patients with type A abdominal aortic aneurysms (86 percent). Imme-

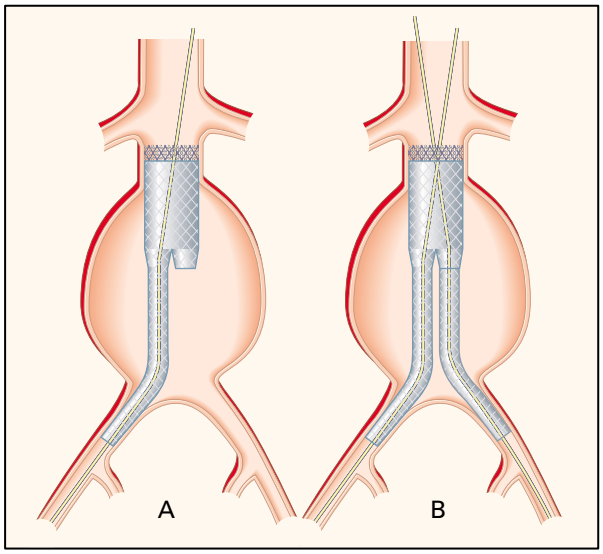


Figure 2. Placement of the Bifurcated Stent–Graft.
In Panel A, the aortic section with the attached iliac limb is implanted with use of a delivery system inserted through a surgical cutdown below the renal arteries. In Panel B, the contralateral iliac limb is inserted percutaneously.

TABLE 2. CAUSES OF PRIMARY OR SECONDARY FAILURE OF ENDOLUMINAL TREATMENT OF ABDOMINAL AORTIC ANEURYSM.

CAUSE	NO. OF PATIENTS (%)
Primary failure	20 (13)
Problems with access	3
Leaks	17
Proximal*	5
Spontaneous thrombosis	1
Repaired†	4
Distal	4
Repaired†	4
Tear in polyester fabric	8
Spontaneous thrombosis	2
Repaired†	4
Persistent	2
Secondary failure‡	7 (5)
Tear in polyester fabric†	4
Reperfusion of aneurysm through lumbar arteries§	3

*Proximal leaks were due to marked angulation of the proximal aneurysmal neck followed by dislodgment of the stent.

†The defect was repaired during a second intervention with use of an additional stent–graft to seal the leak or cover the tear.

‡These problems occurred more than seven days after implantation and were successfully treated by means of endovascular techniques.

§Backbleeding was successfully embolized with use of platinum coils.

diately after the procedure, angiography revealed proximal leaks in two patients due to short proximal necks, which led to dislodgment of the stents, and a distal leak in one patient due to a short distal neck (<10 mm) (Table 2).

The average length of time needed to implant the stent–graft was 43±21 minutes in the first 6 patients and 30±5 minutes in the last 15 patients. The total length of the procedure (including arteriotomy and closure) was 88±24 minutes (range, 50 to 220). The average hospital stay was 6.75±2.5 days.

Type B and C Aneurysms

Endovascular repair with a bifurcated stent–graft was technically successful in 116 of 133 patients with type B or C aneurysms (87 percent) (Fig. 3A and 3B). In three patients the procedure had to be converted to surgical repair. In one patient a coiled external iliac artery ruptured during the insertion of the delivery system, requiring emergency surgery. In the two other patients the 18-French introducer system could not be advanced to the abdominal aorta because of marked tortuosity of the iliac arteries and inadequate diameter of the external iliac artery (<7 mm), requiring elective open surgical repair.

Technical failure due to marked angulation of the proximal aneurysmal neck (>80 degrees) followed by dislodgment of the stent–graft and a proximal leak occurred in three patients. Because of the large diameter of the common iliac artery, three patients had distal leaks from the lower end of the iliac limbs. Minor or major leaks related to tears in the polyester fabric occurred in the right or left iliac limb in eight patients immediately after the procedure (Table 2).

In 17 patients, the iliac bifurcation had to be covered unilaterally with an additional stent–graft to seal a distal leak. In one other patient we had to extend both iliac limbs with covered nitinol stents. This resulted in obstruction of both internal iliac arteries without clinically affecting the pelvic or intestinal blood supply, and the aortic aneurysm thrombosed completely with no evidence of retrograde flow to the aneurysm through the internal iliac arteries.

The average length of time needed to implant the stent–graft was 67±26 minutes in this group, with the entire procedure taking an average of 105±31 minutes (range, 45 to 270). The average hospital stay was 11.5±13.1 days (range, 4 to 83). As we gained more experience with the technique, the average hospital stay decreased to six days for the last 45 patients.

Complications and Management

There were 13 minor and 3 major complications, including 1 perioperative death related to the intervention, in 16 patients (10 percent) (Table 3).

Minor Complications

Clinically and angiographically evident macroembolization into peripheral vessels was detected in three patients and successfully managed by local thrombolysis in one, aspiration thrombectomy in one, and Fogarty catheterization in one. Peripheral microembolization of cholesterol to a toe was observed in one patient and treated by intraarterial infusion of prostaglandin.

In two patients serum creatinine concentrations rose from 1.8 and 2.1 mg per deciliter (160 and 185 μmol per liter) to 4.0 and 3.8 mg per deciliter (355 and 336 μmol per liter), respectively, requiring temporary hemodialysis.

Femoral-artery damage at the access site occurred in two patients. In both, the common femoral artery was heavily calcified and was injured during advancement of the delivery system. Surgical patching of the artery was needed in both. Arteriovenous fistula developed in one patient at the site of the percutaneous puncture and was surgically repaired. In one other patient who was receiving anticoagulation therapy a local hematoma developed at the puncture site, requiring surgical intervention. Lymph fistulas were observed in two obese patients after surgical arteriotomy.

In one patient with occlusion of the left iliac limb within 24 hours after the stent–graft procedure, local thrombolysis with a total dose of 15 mg of recombinant tissue plasminogen activator was successful.

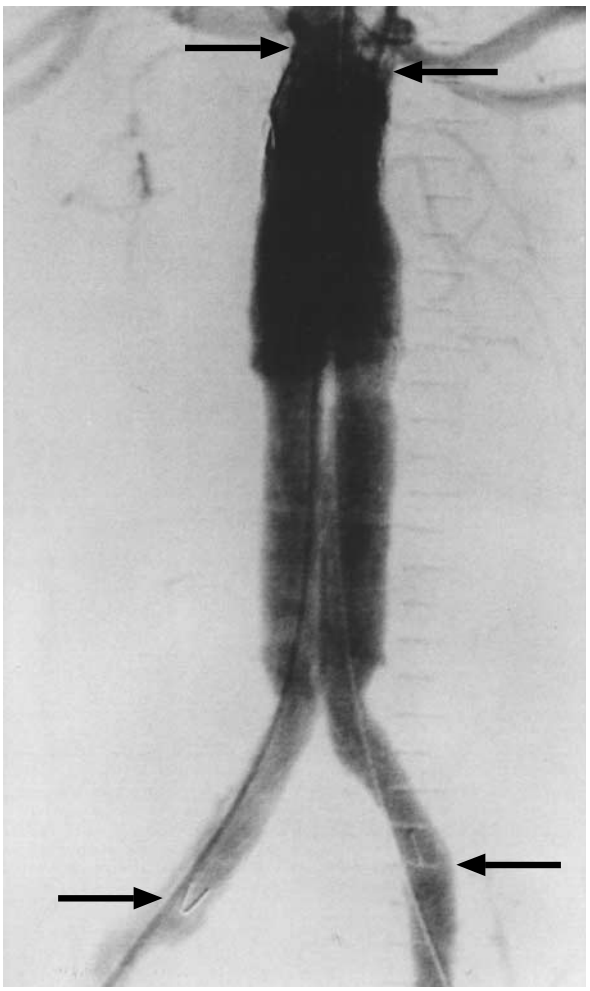
Major Complications

In addition to the patient with rupture of the coiled external iliac artery during the introduction of the delivery system, a patient with atrial fibrillation had embolic occlusion of the left limb of the graft four days after the procedure and complete occlusion of the aortic section two days later. Local

Figure 3. Implantation of a Bifurcated Graft in a 73-Year-Old Patient with an Infrarenal Abdominal Aortic Aneurysm.

In Panel A, an arteriogram with a calibrated catheter obtained before the procedure shows an infrarenal abdominal aortic aneurysm with involvement of the aortic bifurcation (type B aneurysm). In Panel B, an angiogram taken after the procedure shows the restored aortic lumen with complete exclusion of the aneurysmal sac. There is no leak at either end of the bifurcated endoprosthesis (arrows). In Panel C, follow-up computed tomography 12 months later confirms the exclusion of the aortic aneurysm by the absence of contrast enhancement within the aneurysmal sac. The diameter of the aneurysmal sac is virtually the same as it was before treatment. In Panel D, computed tomography at 24 months demonstrates that blood flow into the endoprosthesis remains good, with no evidence of a leak. The maximal diameter of the aneurysmal sac is now 5 mm smaller than it was at 12 months. In addition, the iliac limbs of the graft have shifted after thrombosis of the aneurysm.

A



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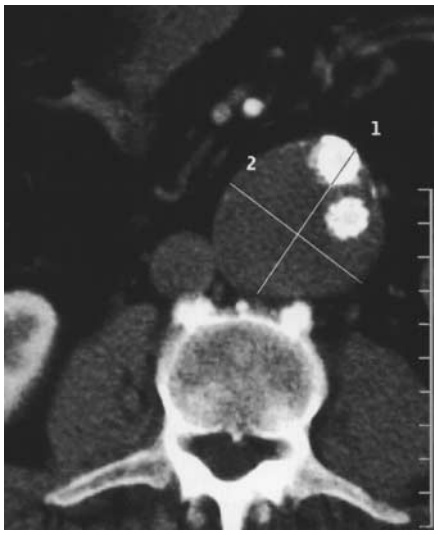

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TABLE 3. COMPLICATIONS OF ENDOLUMINAL REPAIR OF INFRARENAL ABDOMINAL AORTIC ANEURYSMS IN 154 PATIENTS.

CHARACTERISTIC	NO. OF PATIENTS (%)
Minor complication	13 (8)
Peripheral macroembolization	3
Peripheral microembolization	1
Femoral-artery damage	2
Arteriovenous fistula	1
Groin hematoma requiring surgery	1
Lymph fistula	2
Graft occlusion	1
Renal insufficiency requiring dialysis	2
Major complication	3 (2)
Rupture of iliac artery requiring surgery	1
Embolic graft occlusion requiring amputation of foot	1
Acute hepatic failure and death	1

thrombolysis resulted in complete resolution of the thrombus. This process was complicated, however, by microembolization to the left foot, which ultimately required amputation.

One patient with cirrhosis of the liver (Child–Pugh class C) and a transjugular intrahepatic portosystemic stent–shunt placed two years previously died of acute hepatic failure eight days after the intervention because of massive bleeding from a gastric ulcer and hepatorenal syndrome.

Postimplantation Syndrome

Fever (temperature, 38.0 to 39.7°C) developed in 87 of the 154 patients (56 percent) after treatment and lasted for 4 to 10 days, without evidence of bacteremia or graft infection. In all patients, laboratory tests showed leukocytosis (range, 9800 to 29,500 cells per cubic millimeter) and a mild or marked elevation of C-reactive protein concentrations (range, 4 to 34.1 mg per deciliter).

Follow-up

As of this writing, the average length of follow-up is 13 months (range, 8 days to 26 months). Five of 154 patients were followed for 24 months, 66 for 12 months, 89 for 6 months, and 123 for 3 months. There was only one death during the entire study period.

Patients with Straight Grafts

Two patients with minor persistent proximal leaks after dislodgment of the stent and one patient with a major distal leak were successfully treated 4 and 12 months, respectively, after the initial procedure by the placement of an additional straight graft (for the proximal leaks) or an overlapping bifurcated graft (for the distal leak).

Patients with Bifurcated Grafts

Follow-up studies in patients with bifurcated grafts revealed no migration of stent–grafts but a total of 11 persistent leaks. Three patients had a leak at the upper end of the graft; the leak thrombosed spontaneously in one patient and was corrected by the implantation of an additional short straight stent–graft in the other two patients. The three persistent leaks at the lower end of the stent–graft were successfully sealed by the implantation of an additional covered nitinol stent. Leaks related to tears in the polyester fabric thrombosed spontaneously in two of eight patients within seven days after the intervention. In four patients the tear was treated by placing a second covered stent, resulting in complete thrombosis. The remaining two patients declined further intervention.

Angiography at six months did not demonstrate any long-term occlusive disease of the external iliac arteries attributable to the placement of the delivery system.

Once the abdominal aortic aneurysm was excluded from the circulation, no further expansion of the aneurysmal sac was observed. Computed tomography of the infrarenal aorta demonstrated a reduction of 2 to 4 mm in the diameter of the aneurysmal sac at 12 months (Fig. 3C), and a substantial shrinkage of 5 to 15 mm at 24 months (Fig. 3D). Circumscribed spontaneous reperfusion of the aneurysm from the right or left iliac limb was detected in four patients at three and six months of follow-up. In addition, follow-up studies demonstrated minor late reperfusion of the aortic aneurysm with evidence of retrograde blood flow through the hypogastric and lumbar arteries in three patients. These leaks were successfully embolized with platinum coils.

DISCUSSION

Elective surgical repair with synthetic grafts is the standard approach to the treatment of abdominal aortic aneurysms and is associated with a perioperative mortality rate of 4 percent.[4] We evaluated stent–grafts placed percutaneously for the treatment of abdominal aortic aneurysms as an alternative to major abdominal surgery. Becker et al. were the first to implant a covered stent into a subclavian aneurysm in humans.[38] The use of a nonbifurcated stent–graft in patients with infrarenal aortic aneurysm was first reported by Parodi et al. in 1991.[23] The use of various stented or nonstented grafts for the endoluminal repair of abdominal aortic aneurysm has been reported subsequently.[24-27,29,31-36]

Currently, there are five types of stent–grafts under clinical investigation. Parodi[31] treated 50 patients with abdominal aortic aneurysms with non-

bifurcated Dacron grafts sutured to stents with an expandable balloon, with a primary success rate of 80 percent and a 30-day mortality rate of 8 percent. White et al.[27] and May et al.[28,32] used a nonstented balloon-expandable graft consisting of a conventional Dacron graft with metallic implants (Sydney endograft). They treated 53 patients with aortic aneurysms with straight grafts and a limited number of patients with bifurcated grafts, with an initial success rate of 81 percent. The intervention was associated, however, with frequent local (32 percent) or systemic (17 percent) complications and a perioperative mortality rate of 3.7 percent.

The third type of stent–graft, designed by Chuter et al.,[18] consists of a Dacron sleeve anchored by stents at each end. It was implanted in 22 patients, with an initial success rate of 55 percent and a complication rate of 45 percent, including one perioperative death.[33]

The only type of stent–graft approved by the Food and Drug Administration is the EVT device (Endovascular Technologies, Menlo Park, Calif.), composed of a Dacron tube with self-expanding crowns at both ends for anchoring. Moore and Vescera[29] and Balm et al.[35] respectively treated 10 and 31 patients with infrarenal abdominal aortic aneurysms using straight grafts, with primary success rates of 80 percent and 77 percent. The rate of local and systemic adverse effects was considerable, with one perioperative death and a total morbidity rate of 74 percent.[35]

In our study we implanted a fifth type of nonbifurcated or bifurcated stent–graft based on a self-expandable nitinol framework covered with a thin polyester fabric for the endovascular repair of abdominal aortic aneurysms. Our initial technical success rate in patients with type A, B, or C aneurysms was 87 percent. The rate of minor complications was 8 percent, the rate of major complications was 2 percent, and the perioperative mortality rate was 0.6 percent.

Incomplete sealing between the stent–graft and the aorta, defined as technical failure, was a major problem in our study group. Primary failure, which occurred in 13 percent of the patients, was due to problems with access, to dislodgment of the stent–graft resulting in proximal leaks, to distal leaks from the lower end of the iliac limbs because the diameter of the common iliac artery was too large, or to leaks from the right or left iliac limb related to tears in the polyester fabric. Secondary failure with minor spontaneous reperfusion was observed in seven patients at three and six months and was due either to a tear in the polyester along the iliac limb or to reperfusion through the lumbar arteries. Technical failure was successfully treated in all patients who agreed to the intervention, resulting in complete exclusion of the aortic aneurysm and restoration of normal blood flow and a secondary success rate of 97 percent.

In the series studied by Parodi,[31] aneurysms generally decreased in size by 10 to 20 percent during a mean follow-up of 17 months after stent–graft implantation. In our study detailed computed tomographic measurements of the infrarenal aorta after 6 and 12 months showed only slight reductions in the diameter of the aneurysmal sac, whereas in patients followed for 24 months, successful endoluminal treatment resulted in a substantial shrinkage of the aneurysm. In no case was an increase in the diameter of the aneurysmal sac observed during follow-up in patients with initially successful exclusion of the abdominal aortic aneurysm.

At present, our main concern is the durability of stent–graft material and the fixation system, which is crucial to the success of this endoluminal technique. Refinements of the stent framework and, particularly, its polyester fabric are now in progress. The enlargement of the diameter of the aortic section and the iliac limbs will potentially increase the number of patients in whom this technique is appropriate.

In conclusion, on the basis of our initial results and a limited follow-up of an average of 13 months, endoluminal repair of infrarenal abdominal aortic aneurysms with the use of straight or bifurcated grafts is a feasible, safe, and effective alternative to conventional surgery. Although we do not yet have extended follow-up data on the durability, safety, efficacy, and costs of stent–grafts, the approach may be a viable therapeutic option, especially in patients at high surgical risk, and should be evaluated in a prospective, randomized study comparing endoluminal and surgical repair to determine the clinical benefits of this new technique.[39,40]

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