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Initial Experience with Transluminally Placed Endovascular Grafts for the Treatment of Complex Vascular Lesions

Michael L. Marin, M.D., Frank J. Veith, M.D., Jacob Cynamon, M.D., Luis A. Sanchez, M.D., Ross T. Lyon, M.D., Barry A. Levine, M.D., Curtis W. Bakal, M.D., William D. Suggs, M.D., Kurt R. Wengerter, M.D., Steven P. Rivers, M.D., Richard E. Parsons, M.D., John G. Yuan, M.D., Reese A. Wain, M.D., Takao Ohki, M.D., Alla Rozenblit, M.D., and Juan C. Parodi, M.D.

From the Departments of Surgery and Radiology, Montefiore Medical Center/Albert Einstein College of Medicine, New York, New York

Objectives

Complex arterial occlusive, traumatic, and aneurysmal lesions may be difficult or impossible to treat successfully by standard surgical techniques when severe medical or surgical comorbidities exist. The authors describe a single center's experience over a 2½-year period with 96 endovascular graft procedures performed to treat 100 arterial lesions in 92 patients.

Patients and Methods

Thirty-three patients had 36 large aortic and/or peripheral artery aneurysms, 48 had 53 multilevel limb-threatening aortoiliac and/or femoropopliteal occlusive lesions, and 11 had traumatic arterial injuries (false aneurysms and arteriovenous fistulas). Endovascular grafts were placed through remote arteriotomies under local (16 [17%]), epidural (42 [43%]), or general (38 [40%]) anesthesia.

Results

Technical and clinical successes were achieved in 91% of the patients with aneurysms, 91% with occlusive lesions, and 100% with traumatic arterial lesions. These patients and grafts have been followed from 1 to 30 months (mean, 13 months). The primary and secondary patency rates at 18 months for aortoiliac occlusions were 77% and 95%, respectively. The 18-month limb salvage rate was 98%. Immediately after aortic aneurysm exclusion, a total of 6 (33%) perigraft channels were detected; 3 of these closed within 8 weeks. Endovascular stented graft procedures were associated with a 10% major and a 14% minor complication rate. The overall 30-day mortality rate for this entire series was 6%.

Conclusions

This initial experience with endovascular graft repair of complex arterial lesions justifies further use and careful evaluation of this technique for major arterial reconstruction.

Surgical therapy for complex vascular diseases has advanced greatly over the past 40 years, shifting from the use of palliative measures to treat lethal or limb-threatening disease to therapy focused on the precise diagnosis and open surgical correction of arterial disorders. The operative mortality rate for elective aortic aneurysm repair has since decreased markedly, from 21% in the 1950s to below 5% currently.[1-5] Multilevel lower extremity occlusive disease with gangrene, which once mandated amputation, can be treated with interventional techniques or bypass surgery, resulting in favorable limb salvage rates.[6] Finally, despite advances in resuscitation, anesthesia, and intensive care, complex acute arterial injury from penetrating or blunt vascular trauma has remained a challenging problem with substantial morbidity and mortality, particularly when central vascular injuries occur with other severe injuries.[7-9] Despite important improvements in the management of all of these vascular lesions, significant perioperative morbidity and mortality still occur, particularly in those patients who have severe comorbid medical illnesses, who require a second operation at a particular surgical site, or who have had multiple traumatic injuries.[10-16]

A trend in surgery over the past decade has been to develop less invasive procedures to accomplish treatment goals with reduced operative risks and complications, thus allowing therapy to be extended to high-risk patients with severe comorbid medical illnesses. One such evolving technique for less invasive vascular surgery involves the use of endovascular grafts that combine intravascular stent and prosthetic graft technologies.[17-38] These devices may be inserted through remote arterial access sites to treat vascular lesions without the need to directly expose the diseased artery through an extensive incision or dissection. Endovascular grafts have been used successfully to treat aortic and peripheral artery aneurysms, long-segment arterial occlusive disease, and vascular trauma. Despite the potential advantages of these new techniques, the devices are primitive and require further development before they can be widely applied for the treatment of vascular disease. In this report we describe our initial experience over a 2½-year period with the use of 96 endovascular grafts for the treatment of arterial aneurysms, occlusions, and traumatic or iatrogenic vascular injuries.

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Address reprint requests to Michael L. Marin, M.D., Division of Vascular Surgery, Montefiore Medical Center, 111 East 210th Street, New York, NY 10467.

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MATERIALS AND METHODS

Patient Selection

The criteria for patient selection were based on the type of vascular disease being treated (Table 1). For patients with aortic aneurysms, two protocols were followed. Those patients with severe comorbid medical and surgical illnesses in association with large, threatening abdominal aortic aneurysms (AAAs) were treated with a balloon expandable device on a compassionate basis (*i.e.*, no other corrective treatment is feasible or the risk of such other treatment is excessively great) in accordance with a protocol approved by our hospital's institutional review board. Patients with suitable aortic anatomy (long proximal and distal aortic necks [≥2 cm and ≥1.5 cm, respectively]) who were not at increased risk for complications from standard AAA repair were entered into a Food and Drug Administration phase I feasibility trial of endoluminal AAA repair with the Endovascular Technologies' (EVT) Endograft device (Menlo Park, CA).

Patients with peripheral artery aneurysms, chronic arterial occlusive disease, or penetrating or iatrogenic vascular injuries usually coexisting with a serious comorbid medical illness or with contraindications for standard treatment underwent endovascular graft procedures that involved use of standard polytetrafluoroethylene grafts (W.L. Gore and Associates, Flagstaff, AZ) and commercially available intravascular stents. All patients provided informed consent. Patients with occlusive lesions were treated for limb salvage only. All traumatic lesions were associated with large pseudoaneurysms or arteriovenous fistulas that would have mandated open surgical repair.

Endovascular Stented Graft Devices

The endovascular stented graft devices were chosen based on the type of vascular lesion being excluded (Table 2, Fig. 1). With the exception of the aortic devices, all endovascular grafts were composed of commercially available materials. The balloon expandable aortic device and EVT device have been described in detail elsewhere.[39,40]

Techniques for Endovascular Stented Graft Insertion

The principles of endovascular stented graft insertion and deployment are similar for treatment of all vascular diseases. Specific procedural modifications were made in accordance with the anatomic locations of the lesions as well as the presence or absence of arterial occlusive dis-

Table 1. PATIENT SELECTION CRITERIA

Vascular Pathology	Severe Underlying Medical/Surgical Comorbidity or Immediate Life-Threatening Lesion	Characteristics or Limitation of Vascular Lesion
Aortic aneurysms		
Balloon expandable device	Yes	≥6 cm AAA with rupture or impending rupture
EVT device	No	Suitable proximal/distal neck, ≥5 cm AAA
Peripheral artery aneurysms	No*	≥3 times normal vessel diameter
Chronic arterial occlusions	No*	Multilevel occlusive disease with critical ischemia and a threatened limb
Arterial trauma	Yes	Pseudoaneurysm; arteriovenous fistula

AAA = abdominal aortic aneurysm; EVT = Endovascular Technologies' Endograft.
* Most of these patients had severe coexisting medical problems or a surgical contraindication to standard treatment.

ease. Target lesions were generally approached through the largest available access vessel (i.e., common femoral or brachial arteries). After insertion of a guide wire through the access vessel and the interpretation of preinsertion arteriograms, endovascular stented grafts contained in delivery catheters were advanced to the desired location by coaxial movement of the device over the guide wire under fluoroscopic control. If stenotic or occluded arteries were being treated, the diseased vessel was first balloon dilated diffusely, creating a widened tract before insertion of the device (Fig. 2). Once proper positioning of the endovascular graft was confirmed, the delivery catheter was withdrawn, permitting deployment of the graft-to-artery attachment system (stent).[25,41] Each procedure was followed immediately by an intraoperative completion arteriogram and, in selected cases, intravascular ultrasound examination to evaluate the adequacy of the technique. All procedures were performed in the operating room with use of a portable C-arm fluoroscope.

Patient Follow-up

The method of follow-up for each patient who received an endovascular graft was dependent on the type of endoluminal reconstruction and, occasionally, the presence of significant comorbid medical illnesses (e.g., renal insufficiency precluding contrast injection). When medically feasible, each patient who underwent an AAA repair had a contrast-enhanced computed tomography (CT) scan and a color duplex ultrasound performed 1 to 2 days after the procedure. Serial contrast-enhanced CT and/or color duplex analyses were performed at 3-month intervals for 6 months and at 6-month intervals thereafter. Each scan was analyzed for perigraft channels (flow outside the endovascular graft but within the aneurysmal sac), alteration in the geometric configuration of the graft, device migration, and any change in the aneurysm size. Similar analyses were performed during the follow-up of patients who had undergone endovascular graft repairs of iliac artery aneurysms. The protocol for follow-

Table 2. CHARACTERISTICS OF ENDOVASCULAR GRAFTS

Vascular Pathology	Graft Material	Attachment System	Introducer System
Aortic aneurysm			
Balloon expandable device	Thin walled knitted, crimped Dacron*	Balloon expandable stent*	Teflon, double sheath (24 Fr)*
EVT device	Woven Dacron†	Self-expanding, hooked, "Z" stent configuration†	Endovascular deployment assembly (26 Fr)†
Peripheral artery aneurysm	PTFE‡	Palmaz balloon expandable stent§	Teflon, single sheath (12–14 Fr)
Chronic arterial occlusion	PTFE‡	Palmaz balloon expandable stent§	Teflon, single sheath (14 Fr)
Arterial trauma	PTFE‡	Palmaz balloon expendable stent§	Teflon, single sheath (12 Fr)

EVT = Endovascular Technologies' Endograft; PTFE = polytetrafluoroethylene.
* Barone, Inc., Buenos Aires, Argentina.
† Endovascular Technologies Corporation, Menlo Park, California.
‡ W.L. Gore and Associates, Flagstaff, Arizona.
§ Johnson and Johnson Interventional Systems, Warren, New Jersey.

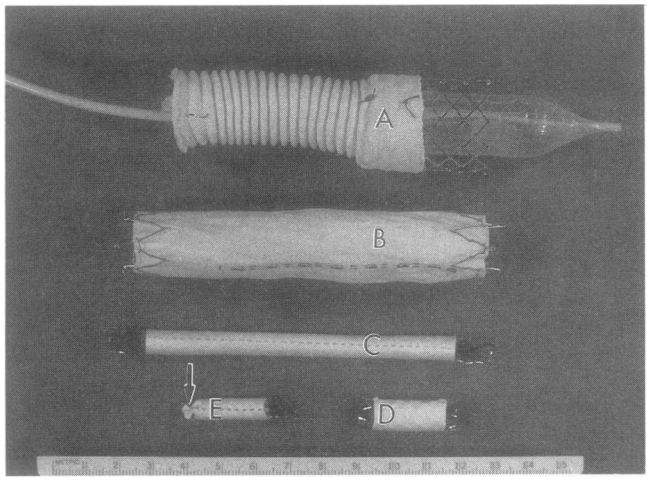

Figure 1. Endovascular grafts used for the repair of aortic and peripheral artery aneurysms, arterial occlusions, and traumatic vascular injuries. (A) Balloon expandable (Parodi) endovascular aortic device; (B) EVT Endograft; (C) polytetrafluoroethylene (PTFE) endovascular graft used for the treatment of peripheral artery aneurysms and arterial occlusive disease; (D) PTFE-covered Palmaz balloon expandable stent used for the treatment of traumatic arterial injuries; (E) an occluding PTFE-covered Palmaz stent (one end of this device is closed with a purse-string suture) (arrow).

up of aneurysms in the popliteal or subclavian arteries involved a physical examination supplemented by color duplex ultrasonography, ankle-brachial indices, and pulse volume recordings at 3-month intervals for 6 months and at 6-month intervals thereafter.

After endovascular stented graft repair of multilevel occlusive disease, patients who did not have an absolute contraindication to arteriography underwent a postoperative arteriogram in an angiography suite so that their grafts could be evaluated further before discharge from the hospital. In addition, each patient was followed with a physical examination and color duplex ultrasonography at 3-month intervals for 6 months and every 6 months thereafter. Patients treated for traumatic vascular injuries were similarly followed with physical examination and serial color duplex ultrasonograms.

Any patient with an endovascular graft who had an abnormality detected by physical examination, CT scan, or color duplex ultrasonography was further evaluated with a transfemoral or transbrachial arteriogram, unless the patient was medically unfit to undergo an arterial contrast study.

Data Analysis

The patency data for patients treated for aortoiliofemoral occlusive disease were analyzed by the cumulative life-table method. The primary and secondary patencies were calculated according to the reporting standards of the Society for Vascular Surgery/North American Chapter, International Society for Cardiovascular Surgery.[42]

RESULTS

We performed 96 endovascular stented graft procedures in 92 patients with 100 arterial lesions between November 1992 and April 1995 at our institution, Montefiore Medical Center (New York) (Table 3). These grafts were used to treat 36 arterial aneurysms, 11 lesions secondary to penetrating vascular trauma, and 53 long-segment arterial stenotic or occlusive lesions. Endovascular grafts were inserted under local (16 [17%]), epidural (42 [43%]), or general anesthesia (38 [40%]). The mean age of patients with aneurysmal and occlusive lesions was 69 years, whereas the mean age of patients treated for penetrating traumatic vascular injuries was 38 years. Most of the patients treated for aneurysmal or occlusive arterial disease also had significant comorbid medical illnesses or a major surgical contraindication to standard treatment.

Abdominal Aortic Aneurysms

Eighteen patients with AAAs were treated with two different endovascular graft devices. An EVT device was implanted in four low-risk patients with suitable arterial anatomy[28] (Figs. 3 and 4). The remaining 14 high-risk patients received balloon expandable endovascular grafts (Table 4, Fig. 5). All EVT procedures involved use of tubular, aorto-aortic grafts, whereas 6 of the 14 balloon expandable device procedures involved use of aortoiliofemoral reconstructions with the addition of femorofemoral bypass and occlusion of the common iliac arteries contralateral to the main endovascular graft. Blood loss for repair of aortic aneurysms ranged from 100 to 4000 cc (mean, 1970 cc). Blood loss for the four EVT low-risk patients ranged from 100 to 250 cc (mean, 162 cc). There were no thromboses of the aortic grafts and no postimplantation structural device failures. One patient with a balloon expandable device demonstrated apparent cephalad migration of the distal stent seen on a CT scan at 13 months. One EVT graft and one balloon expandable graft showed geometric configuration changes, which were consistent with either a kink or an extrinsic graft compression. Neither of these lesions were flow restricting, and no intervention was required. During a mean follow-up period of 8 months, two of the four aneurysms treated with the EVT device became smaller. Six of the 14 aneurysms repaired with the balloon expandable device became smaller (1–3 mm), and 3 showed evidence of minimal enlargement (0.5–1 mm). No new aortic aneurysm ruptures occurred in this series after graft placement.

Three patients in this series had presented with severe medical comorbidities in association with contained aortic ruptures. The first patient had a ruptured 6-cm AAA

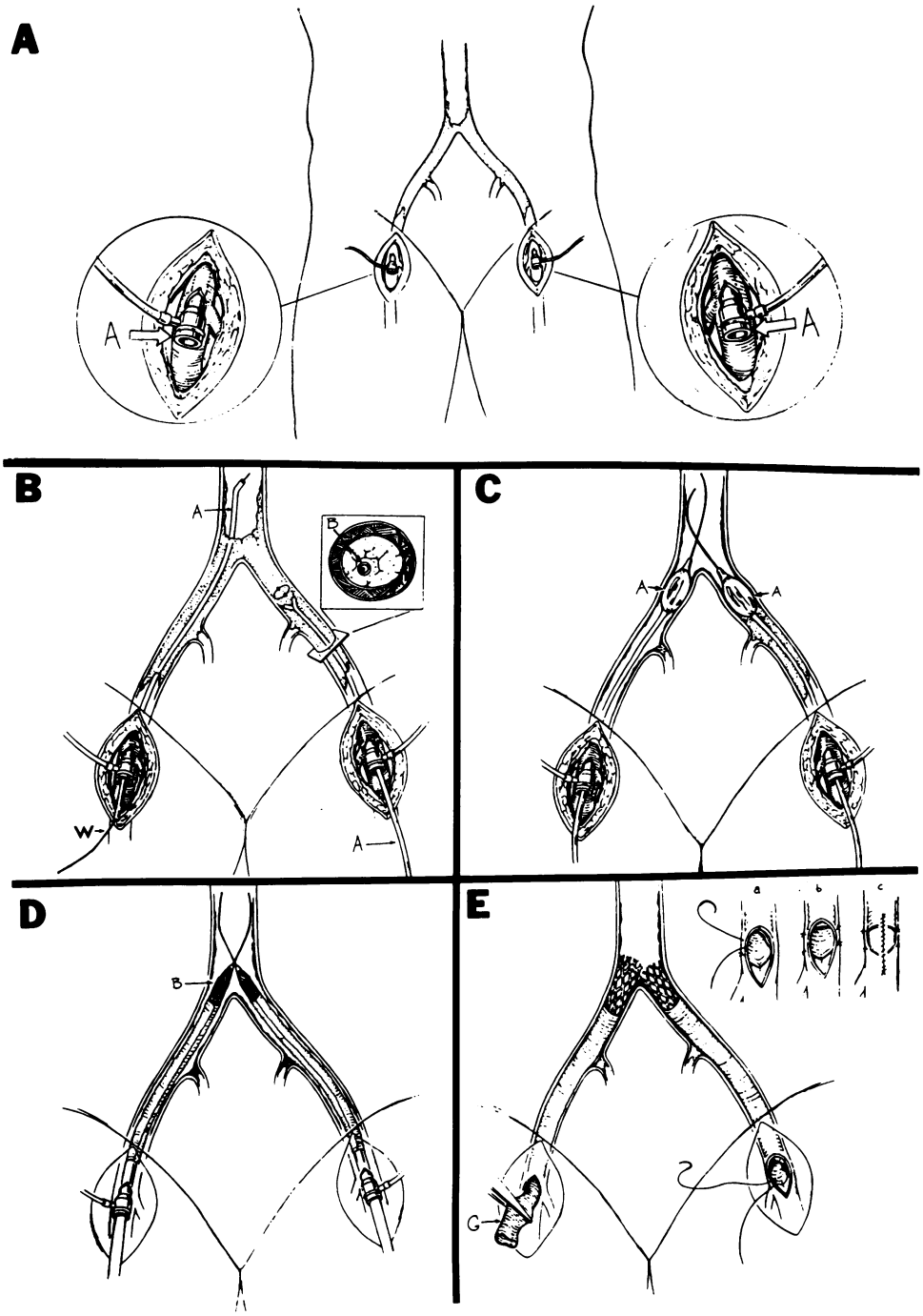

Figure 2. Techniques for endoluminal aortoiliac bypass for occlusive disease. (A) Bilateral inguinal incisions are performed to expose the common femoral arteries. An introducer catheter, equipped with a hemostatic valve (A), is inserted retrograde into the common femoral artery in each groin. It is through these introducer catheters that all subsequent catheter manipulations on the occluded or diseased arterial system are carried out. (B) A hydrophilic guide wire (w) is then inserted through each introducer catheter and guided through the occluded or stenotic segment of an artery by means of directional catheters (A). (Inset) An effort is made to guide the recanalization process within the native lumen of diffusely stenotic arteries. In situations in which the entire vessel is chronically occluded, the recanalization process occurs relatively randomly following the planes of least resistance within the subintimal plane (B). (C) After successful recanalization of an artery, long-segment diffuse balloon dilatation is performed (A). Balloon catheters are inserted over the previously placed guide wires. Balloon dilatation creates a new tract within the diseased artery that must communicate with the lumen of a patent proximal vessel. (D) An endovascular graft is inserted through an arteriotomy in the common femoral artery. Endovascular grafts, contained within introducer catheters, are advanced over the previously placed guide wires and into the patent proximal vessels. The delivery sheath is then withdrawn, exposing the anchoring stent (B). (E) After inflation of the coaxially loaded angioplasty balloon, the Palmaz balloon expandable stent expands, creating a friction seal between the stent and attached graft, and the underlying arterial wall. The introducer catheters on each side are then withdrawn, permitting the free end of the prosthetic endovascular graft (G) to be withdrawn from the common femoral arteriotomy and clamped. Vascular clamps are then positioned across the native proximal common femoral artery, which will, in turn, compress its enclosed endovascular graft. An endoluminal anastomosis is then created between the endovascular graft and the internal surface of the common femoral artery with a series of interrupted U stitches (insets a, b). This anastomotic technique can be tailored to each individual vessel, depending on the extent of local disease. The endoluminal anastomosis can be completed with a running monofilament suture across the linear arteriotomy (inset c). Under some circumstances, a common femoral endarterectomy or a patch angioplasty of the arteriotomy site may be required to establish unobstructed flow through the endovascular graft and into the distal circulation.

Table 3. DISTRIBUTION OF PATIENT CHARACTERISTICS AND LESIONS TREATED WITH ENDOVASCULAR GRAFTS

Vascular Pathology	No. of Patients	No. of Lesions	Sex (male/female)	Age Range (mean)	Coexisting Coronary Artery Disease* [no. (%)]	Coexisting Chronic Obstructive Pulmonary Disease† [no. (%)]	Diabetes Mellitus [no. (%)]	Renal Insufficiency‡ [no. (%)]	Hostile Surgical Field§ [no. (%)]
Abdominal aortic aneurysm	18	18	15 M; 3 F	66–88 (76)	17 (94)	11 (61)	5 (28)	6 (33)	3 (17)
Iliac artery aneurysm	11	14	11 M	58–89 (72)	11 (100)	5 (45)	5 (45)	3 (27)	5 (45)
Popliteal artery aneurysm	3	3	2 M; 1F	63–84 (74)	2 (67)	1 (33)	1 (33)	0	0
Subclavian artery aneurysm	1	1	1 F	40	0	0	0	0	1 (100)
Traumatic arterial pseudoaneurysm	9	9	8 M; 1 F	18–78 (44)	1 (11)	1 (11)	1 (11)	0	0
Traumatic arteriovenous fistula	2	2	2 M	18–20 (19)	0	0	0	0	0
Aortoiliac occlusive disease	42	47	23 M; 19 F	43–86 (65)	36 (86)	9 (21)	22 (52)	7 (17)	13 (31)
Femoropopliteal occlusive disease	6	6	4 M; 2F	62–82 (68)	6 (100)	5 (83)	4 (67)	1 (17)	0

* Ejection fraction less than 20% on echocardiography, thallium or MUGA scans.
† FEV_1 < 35% of predicted, room air Pa_aO_2 < 60 mmHg or P_aCO_2 > 50 mmHg.
‡ Creatinine ≥ 3.0 mg/dL.
§ Hostile surgical field implies at least one previous dissection, scarring, or infection in the region of the vascular lesion treated by the endovascular graft.

and an acute anterior wall myocardial infarction. The second patient, who experienced renal failure and severe congestive heart failure, had complete anastomotic disruption (proximal and distal) of an infrarenal aortic graft and two contained pseudoaneurysms. The third patient, who had congestive heart failure and pulmonary insufficiency, had a distal aortic disruption and a pseudoaneurysm secondary to the extension of a Pott's abscess of the lumbar spine to the wall of the infrarenal aorta (Fig. 6).

The complications encountered in this series are outlined in Table 5. Of the five deaths that occurred, three resulted from complications of diffuse aneurysmal thrombus embolization during device insertion. These three patients had large (≥7 cm) AAAs in association with bilateral iliac disease. The fourth patient, who experienced preoperative chronic renal failure, hepatic insufficiency, and severe coronary artery disease, developed multiorgan failure after successful aortic grafting and died 1 week after surgery. The fifth death in this series occurred in a patient with a ruptured AAA in association with acute myocardial infarction. This patient died of a ventricular arrhythmia after successful insertion of an endovascular graft.

Peripheral Artery Aneurysms

Fifteen patients had aneurysms involving the popliteal, iliac, or subclavian arteries (Table 3, Figs. 7 and 8). Endovascular stented grafts were successfully placed in 11 patients who had a total of 14 iliac artery aneurysms, in 2 patients with popliteal artery aneurysms, and in 1 patient with a subclavian artery aneurysm. One endovascular graft inserted to treat a complex iliac artery aneurysm thrombosed at 9 months, and limb salvage was achieved with an axillobifemoral bypass. One patient with a popliteal artery aneurysm underwent standard vascular reconstruction when the endovascular graft device could not be inserted successfully. A second patient had thrombosis in a popliteal endovascular graft on the 6th postoperative day without apparent cause, and this endovascular graft procedure was converted to a standard vascular reconstruction. A third patient with a popliteal artery aneurysm was treated with an endovascular stented graft, which has maintained graft patency free of any hemodynamically significant lesions for 26 months.

An endovascular graft was inserted successfully in a patient with a subclavian artery aneurysm with distal embolization who, 2 years earlier, had undergone cervi-

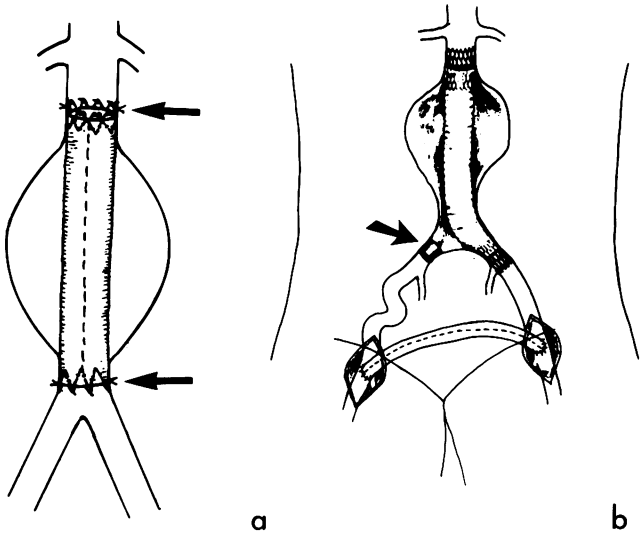

Figure 3. Aortic reconstruction after transfemoral, endoluminal repair of an abdominal aortic aneurysm. (a) After transfemoral insertion of the EVT self-expanding, hooked prosthesis (Endograft), sealing of the graft to the underlying arterial wall is accomplished by implantation of the self-expanding, hooked attachment system into the arterial wall (arrows). The current configuration of this device is useful only for those aneurysms that have a suitable segment of normal aorta both proximal and distal to the lesion. (b) For those aneurysms that extend to the aortic bifurcation, an aortoiliac reconstruction (after Parodi) may be performed. Flow through the contralateral common iliac artery is occluded by an endoluminal occlusion device (arrow) similar to that shown in Figure 1e. A femorofemoral extraanatomic bypass is performed to restore arterial flow to the contralateral limb. Right hypogastric artery flow was preserved.

cal rib resection for thoracic outlet syndrome. This graft thrombosed abruptly 6 weeks after insertion without upper extremity symptoms or limb-threatening consequences. No further interventions were performed in this patient. No deaths occurred during or after endovascular graft repair of peripheral artery aneurysms (Table 5).

Aortoiliac Occlusive Disease

Forty-two patients received 47 aortoiliofemoral endovascular grafts to treat 47 extremities at risk for limb loss (Table 6, Fig. 9). Most of these patients had significant comorbid medical illnesses or conditions that precluded standard aortoiliac reconstructions, extraanatomic bypasses, or treatment by balloon angioplasty and stent placement (Table 3). Technical success of graft insertion was achieved in 43 procedures (91%). Primary and secondary graft patency rates at 18 months were 77% and 95%, respectively (Tables 7 and 8, Fig. 10). Limb salvage at 18 months was 98% (Table 9). A 7% major and a 17% minor complication rate resulted from these procedures (Table 5).

Femoropopliteal Occlusive Disease

Six patients with severe comorbid medical problems received endovascular femoropopliteal grafts to treat pedal gangrene. Two grafts were performed in association with an endovascular aortoiliofemoral graft. One endovascular femoropopliteal graft was performed in conjunction with an axillofemoral bypass after an unsuccessful attempt to perform an endovascular iliofemoral reconstruction. Three patients with patent grafts died of acute myocardial infarctions at 2, 7, and 15 months after endovascular graft insertion. One graft to an isolated popliteal segment thrombosed at 1 week, and this patient maintained stable pedal gangrene until he died 2 months later of cardiac disease. Another endovascular femoropopliteal graft closed at 14 months after complete healing of a previously gangrenous foot. This limb has continued to remain healed with the graft closed. This patient has a patent endovascular aortofemoral graft with runoff only to the deep femoral artery. One endovascular femoropopliteal graft remains patent at 22 months.

Penetrating and Iatrogenic Arterial Trauma

Eleven patients sustained vascular trauma resulting in nine isolated pseudoaneurysms and two arteriovenous fistulas (Table 10, Fig. 11). Seven of these injuries were the result of gunshot wounds and two were secondary to iatrogenic needle injuries. Eight patients had sustained other injuries in conjunction with their vascular trauma. All penetrating and iatrogenic traumatic vascular injuries were repaired from 4 hours to 4 months after the

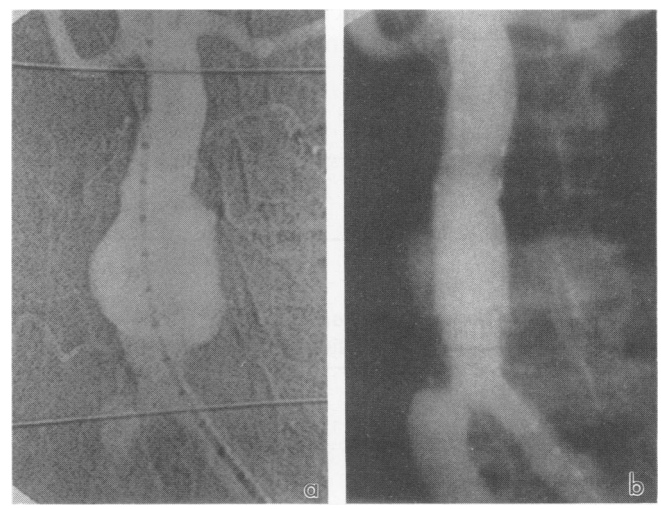

Figure 4. Transfemoral, endoluminal repair of an abdominal aortic aneurysm with the EVT Endograft. (a) Preoperative arteriogram demonstrates a suitable proximal and distal segment of normal aorta above and below the aneurysm. (b) After transfemoral insertion of the Endograft, the aneurysm lumen is excluded from the circulation.

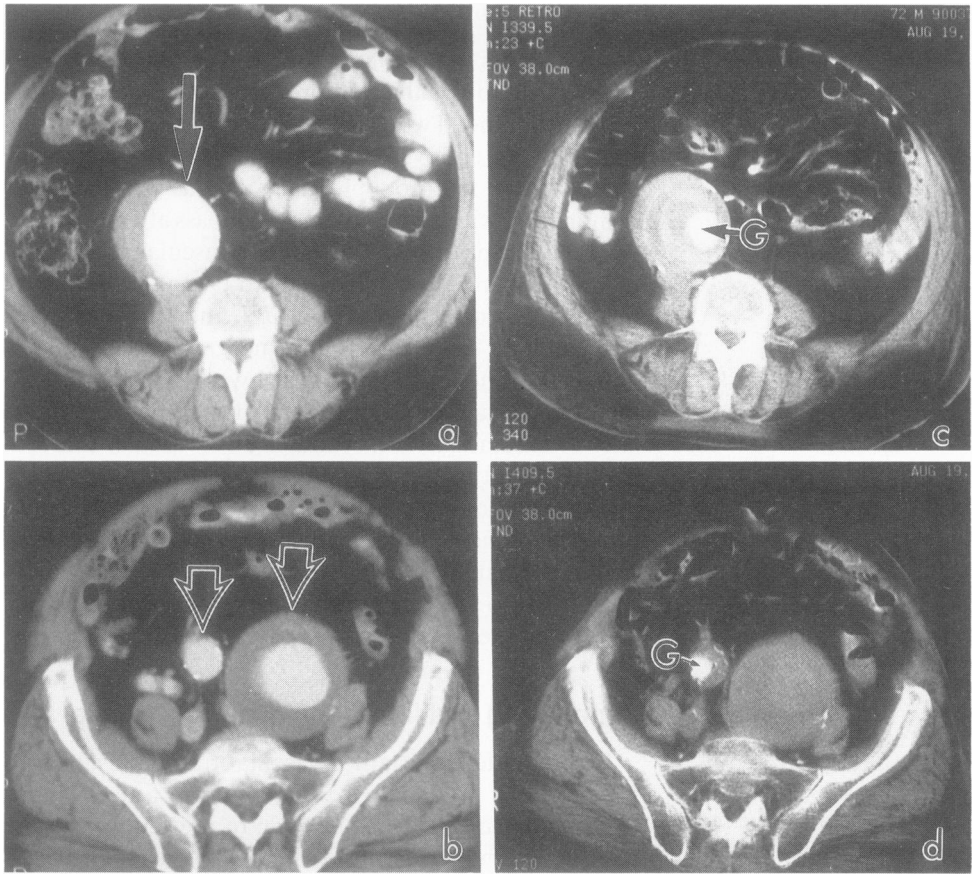

Figure 5. (a,b) Transfemoral, endoluminal repair of a complex abdominal aortic aneurysm (arrow) and bilateral common iliac artery aneurysms (open arrows). (c,d) After insertion of an endovascular graft (G), the aortic aneurysm and the bilateral common iliac artery aneurysms have thrombosed. (e) (next page) This transbrachial arteriogram demonstrates the completed reconstruction. Note the presence of embolization coils within the origin of the left hypogastric artery (arrow), which prevent backflow from this vessel into the left common iliac artery aneurysm. Ligation of the proximal left common femoral artery at point X followed by the creation of a femorofemoral bypass (FF) restores circulation to the lower extremities. s: proximal stent fixation site.

primary injury. No endovascular grafts inserted for penetrating trauma have thrombosed during the follow-up period, which ranges from 2 to 28 months (mean, 15 months). Complications encountered with the use of endovascular grafts for traumatic vascular injuries included one immediate insertion site stenosis that was successfully treated with a vein patch angioplasty (Table 5). A single stent graft stenosis, which occurred at 8 months' follow-up, responded to percutaneous balloon angioplasty and remained patent for 23 months.

Table 4. ENDOVASCULAR GRAFTS FOR THE TREATMENT OF ABDOMINAL AORTIC ANEURYSMS

Endovascular Device	No. of Patients	Type of Anesthesia [no. (%)]			Successful Graft Insertion [no. (%)]	Hospital Stay‡ [days (mean)]	Perigraft Channel§ [no. (%)]	Follow-up [mo (mean)]
		General	Epidural	Local				
EVT	4	4 (100)	0	0	4 (100)	2–7 (3.5)	2 (50)	4–22 (13.7)
Balloon expandable device*	11	1 (9)	8 (73)	2 (18)	9 (82)‖	6–21 (12)	4 (36)	4–25 (13.3)
Balloon expandable device†	3	0	3 (100)	0	3 (100)	4–15 (9.5)	0	6–12 (9)

EVT = Endovascular Technologies' Endograft.

* Includes both aorto-aortic (8 patients) and aortoiliac with femorofemoral bypasses (3 patients).

† Endovascular graft for contained aortic rupture. All had aortoiliac grafts, contralateral iliac occlusion, and femorofemoral bypasses.

‡ Mean hospital length of stay is calculated exclusive of early postoperative deaths.

§ Perigraft channel describes any contrast flow seen outside the lumen of the graft and into the aneurysmal sac on the initial follow-up computed tomograph with contrast.

‖ One procedure was converted to a standard repair, and one procedure was aborted without grafting.

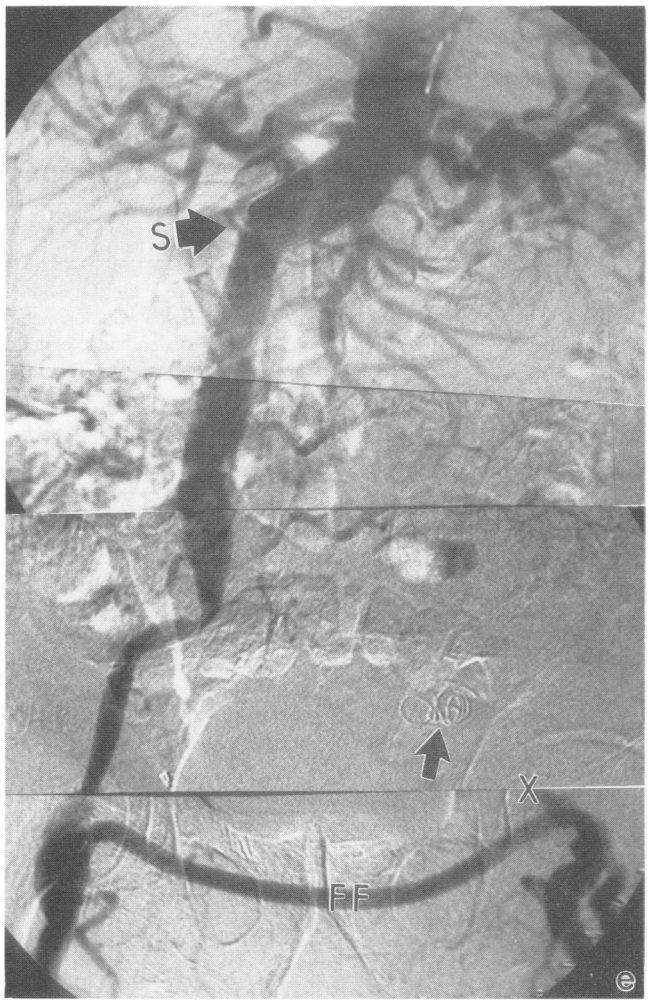

Figure 5. *continued*

DISCUSSION

Transluminally placed endovascular grafting procedures are part of a growing trend to provide improved patient care in association with reduced cost by means of carefully planned, less invasive therapies. Such concepts have resulted in the successful development of important techniques, such as transurethral prostatectomy, laparoscopic cholecystectomy, and a variety of other endoscopic procedures.

Less invasive endovascular therapies were conceptualized by Dotter, who first described catheter-based angioplasty and conceived of devices for intravascular stenting.[43,44] The use of balloon angioplasty procedures for the treatment of short-segment arterial occlusive disease has become relatively well established in a variety of vascular systems.[45–47] The supplemental use of arterial stents for more complex lesions has also proved beneficial.[48] The logical extension of transluminally placed endovascular grafting using covered stents and stent-fixed prosthetic conduits to treat more complex arterial lesions has followed a relatively ordered course with the development of new devices and animal models in which to test these devices.[49–55]

The earliest clinical experience with endovascular grafts is attributed to Volodos in Russia, who described his experience with self-expanding endovascular grafts for the treatment of a thoracic aortic aneurysm and aortoiliac occlusive disease.[17,19] However, the true potential of this technology was realized only after Parodi et al. successfully treated a patient with an abdominal aortic aneurysm in Argentina in 1990.[18] This and subsequent efforts by Parodi have sparked worldwide efforts to find new applications and improved devices for endovascular graft treatment of various vascular lesions.[20–38,56–58]

In the current report, we described our institution's initial experience with this new technology for the treatment of abdominal and peripheral artery aneurysms, arterial occlusions, and traumatic vascular injuries. Although the pathologic lesions for each of these entities are markedly different, the technical concepts for endovascular graft treatment are surprisingly constant. They include remote arterial access, limited operative incisions, and a dependence on catheter-based instruments that are guided by indirect imaging systems, which chiefly use digital fluoroscopy.

The decision regarding which patients should initially be treated by this new technology has provoked controversy among vascular specialists.[18,25,28,59] Should low-risk patients without coexisting medical or surgical problems be used in the early trials of this new technology, so as to permit rapid and safe conversion to standard techniques if the endovascular graft procedure is unsuccessful? Until such devices are proven effective, this philosophy would deny all patients with life-threatening aortic aneurysms, limb-threatening ischemia, or central vascular injuries in the face of prohibitive cardiac, pulmonary, and other medical comorbidities possible benefit from receiving this treatment.

We have chosen the alternative approach of largely using these endovascular grafts in patients for whom standard surgical operations would be difficult or impossible to perform because of major medical or surgical comorbidities that precluded general or other major anesthesia and/or easy direct surgical access to the lesion. Although this approach offers the hope of great benefit to the patients if the new devices are effective, it largely denies them the possibility of a surgical "rescue" procedure should the device fail or cause a complication. Such a surgical rescue would be associated with a very high risk. These concerns have prompted us to treat with these endovascular graft devices those patients who were facing immediate loss of life or limb. Moreover, in our initial

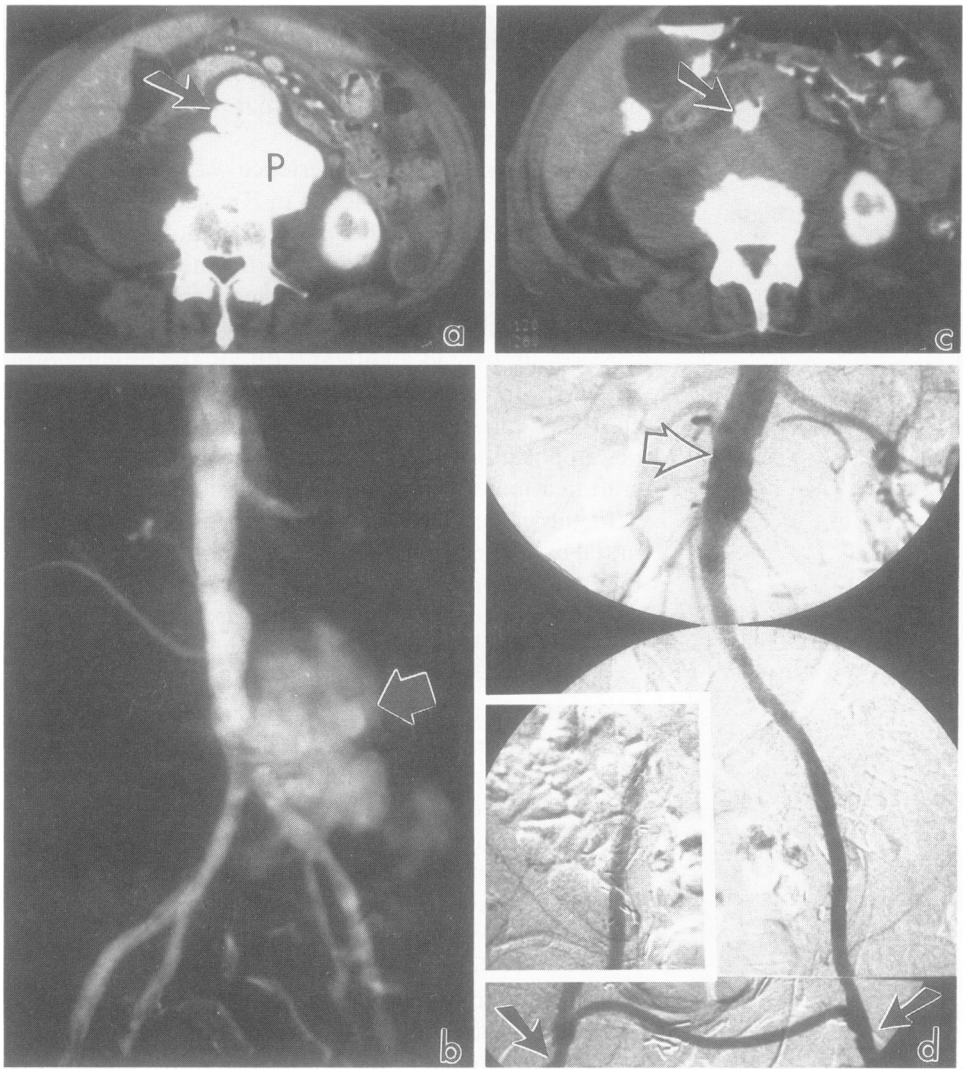

Figure 6. Transfemoral repair of a contained rupture of the distal aorta. (a) A spiral CT scan demonstrates extravasation of contrast material from the aorta (arrow) into a large, partially clot-filled pseudoaneurysm (P). (b) A transfemoral arteriogram confirms the presence of the large aortic pseudoaneurysm (arrow). (c) A spiral CT scan performed after transfemoral insertion of an endovascular graft demonstrates that the pseudoaneurysm is thrombosed, and vascular continuity within the lumen of the aorta (arrow) is preserved. (d) A postoperative transfemoral arteriogram at 1 week demonstrates vascular continuity between the aorta (open arrow) and the common femoral arteries (arrows).

Table 5. COMPLICATIONS AND DEATHS FROM ENDOVASCULAR GRAFT PROCEDURES

Procedure	No. of Patients	Major† [no. (%)]	Minor‡ [no. (%)]	Acute Graft Thrombosis§ [no. (%)]	30 Day Mortality ([no. (%)]
EVT aneurysm repair	4	0	1 (25)	0	0
Balloon expandable aneurysm repair	11	4 (36)	2 (18)	0	4 (36)
Balloon expandable aneurysm repair (for contained rupture)	3	1 (33)	0	0	1 (33)
Peripheral artery aneurysms*	15	2 (13)	2 (13)	1 (17)	0
Femoropopliteal occlusive disease	6	0	1 (17)	1 (17)	0
Aortoiliac occlusive disease	42	3 (7)	7 (17)	‖	0
Arterial trauma	11	0	0	0	0

EVT = Endovascular Technologies' Endograft.
* Includes iliac, popliteal, and subclavian aneurysms.
† Includes pulmonary failure, renal insufficiency, intestinal ischemia, multiorgan failure, myocardial infarction, congestive heart failure, and stroke (excluding death).
‡ Includes wound complications, urinary tract infection, and uncomplicated pneumonia.
§ Thrombosis within 30 days of graft insertion.
‖ Refer to Tables 7 and 8 regarding early and late patency data.

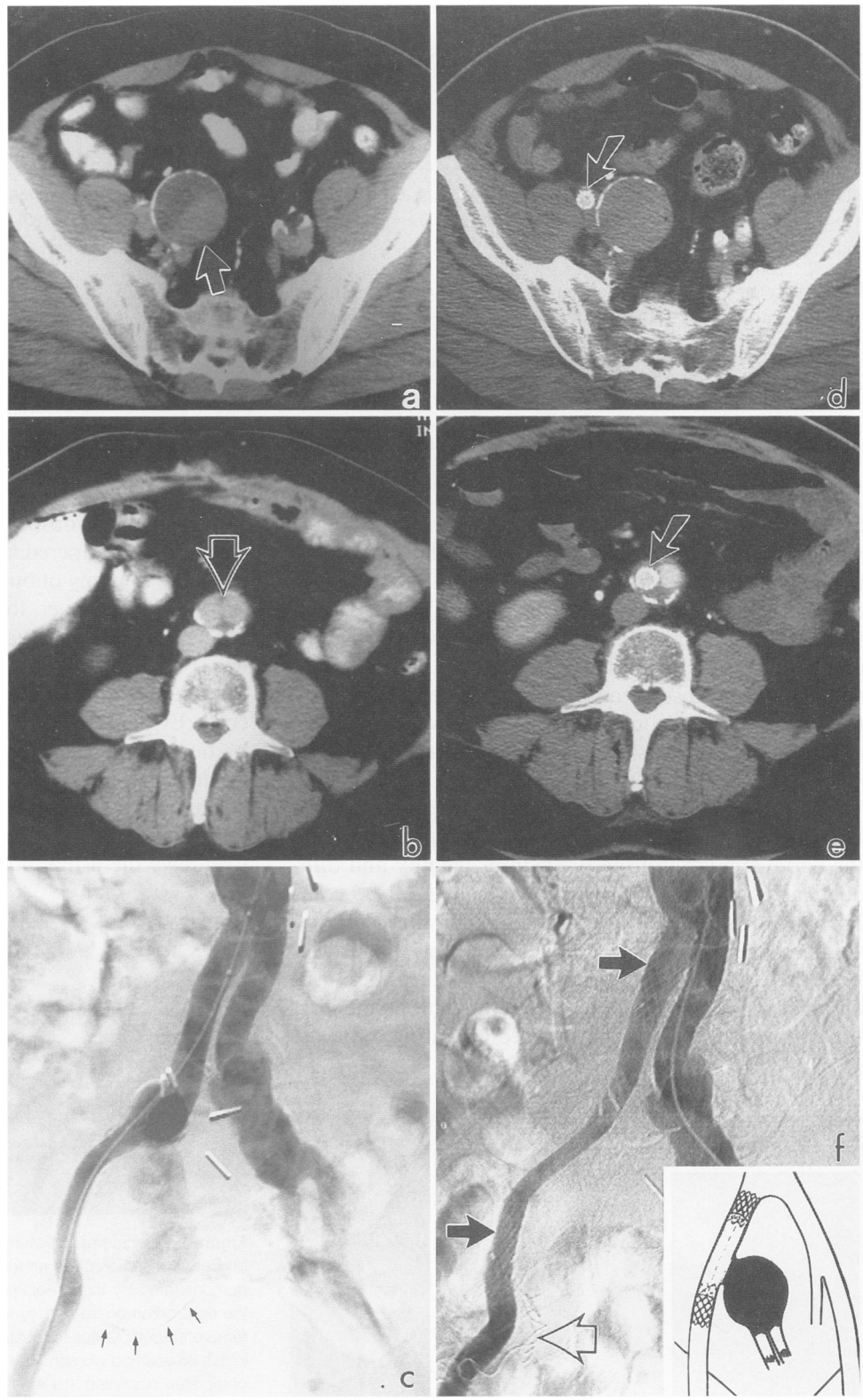

Figure 7. Transfemoral repair of a right internal iliac artery aneurysm 5 years after a bifurcated graft repair of aortic and common iliac artery aneurysms. (a) CT scan documents the presence of the right internal iliac artery aneurysm (arrow). (b) The two limbs of the bifurcated graft can be identified (arrow). (c) Transfemoral arteriography documents filling of the aneurysm before coil embolization of the anterior and posterior divisions of the vessel. (Note aneurysmal wall calcification [small arrows].) (d) After endovascular graft repair, the aneurysm has thrombosed. Contrast can be identified within the endovascular graft (arrow). (e) This CT scan documents fixation of the proximal Palmaz stent (arrow) within the old bifurcated graft. (f) Postoperative digital arteriogram shows the anchoring stents (arrows) and coils in the posterior and anterior divisions of the right internal iliac artery for prevention of retrograde flow (open arrow). (Inset) Diagram of a completed repair.

Table 6. ENDOVASCULAR GRAFTS FOR THE TREATMENT OF OCCLUSIVE DISEASE

Disease Location	No. of Grafts	Indication for Surgery [no. (%)]	Proximal Graft Origin [no. (%)]	Distal Graft Insertion [no. (%)]	Graft Length [m (mean)]	Associated Procedures [No. (%)]	Ankle/Brachial Indices (mean)	
							Pre	Post
Aortoiliac	47	Gangrene = 39 (83) Rest pain = 8 (17)	Aorta or CIA = 34 (72) EIA = 13 (28)	CFA = 29 (62) SFA = 4 (8.5) DFA = 11 (23) AKP = 3 (6)	15–46 (20)	35 (74)*	0.32	0.78
Femoropopliteal	6	Gangrene = 6 (100)	CFA = 3 (50) SFA = 3 (50)	AKP = 6 (100)	24–37 (29)	3 (50)†	0.30	0.71

CIA = common iliac artery; EIA = external iliac artery; CFA = common femoral artery; SFA = superficial femoral artery; DFA = deep femoral artery; AKP = above-knee popliteal artery.

* Associated procedures include standard femoropopliteal, femorocrural, femorofemoral, and endoluminal femoropopliteal bypasses.

† Associated inflow procedure (axillofemoral or femorofemoral bypass or endoluminal aortoiliofemoral bypass).

experience, these high medical risks in patients with advanced vascular disease contributed significantly to the relatively high mortality and complication rates that occurred in our aortic aneurysm patients (Table 4). Considering that our patients with occlusions were similar in regard to risk status and the presence of complex, advanced arterial disease and ischemia, it is encouraging that mortality and morbidity were so low and patency and limb salvage rates were acceptable (Tables 7–9, Fig. 10).

The advanced nature of the arterial disease in most of our patients with aneurysms and occlusions often made the endovascular grafting procedures lengthy and difficult and required that the endovascular graft be combined with a relatively simple, open, standard arterial surgical operation (e.g., a distal arterial reconstruction).[38] Although these combined procedures were usually successful, they made it difficult to demonstrate that the endovascular approach reduced operating room usage or length of hospitalization. Such a demonstration was further hampered by the presence of advanced foot gangrene in many of our patients with occlusive disease. We believe, however, that the use of endovascular grafting techniques, when applied to lower-risk patients with less complex and less advanced arterial disease, will lead to a reduced requirement for hospitalization and lower costs. Evidence of this has been documented with traumatic lesions and anatomically simple aortic aneurysms treated with endovascular grafts.[26,28]

This raises the question of whether it is justified to use these new grafts to replace standard treatment in patients who have the usual indications for surgery and who do

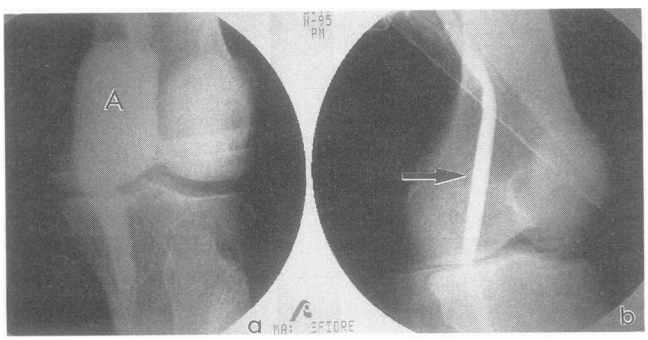

Figure 8. Transluminal repair of a popliteal artery aneurysm. (a) A transfemoral digital arteriogram demonstrates a large popliteal artery aneurysm (A). (b) After insertion of an endovascular graft (arrow) affixed to the below-knee popliteal artery with a 1-cm Palmaz stent, the popliteal artery aneurysm is excluded.

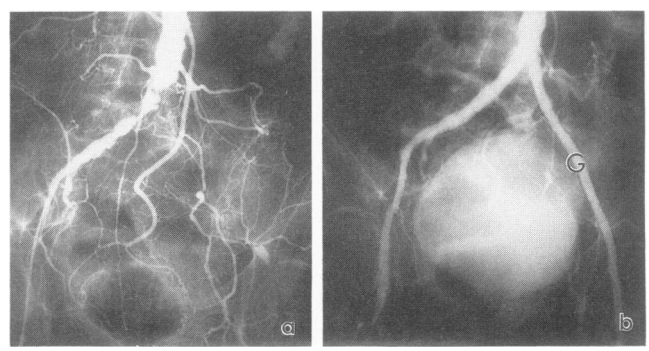

Figure 9. Transfemoral iliofemoral bypass for limb-threatening ischemia. (a) Before insertion of an endovascular graft, severe aortoiliac disease is demonstrated by this preoperative transfemoral arteriogram. Disease in the right common iliac artery system would preclude effective standard femorofemoral bypass to reestablish circulation to the left lower extremity in this 86-year-old woman. The left common and external iliac arteries are completely occluded. (b) After long-segment balloon dilatation of the left common and external iliac arteries and insertion of an endovascular graft (G), vascular continuity is established to the left lower extremity. A percutaneous balloon expandable stent has also been inserted into the right common iliac artery to treat the symptomatic high-grade common iliac artery stenosis and to protect the origin of the right common iliac artery during endovascular graft insertion.

Table 7. PRIMARY PATENCY OF ENDOVASCULAR GRAFT PROCEDURES TO TREAT AORTOILIAC OCCLUSIVE DISEASE

Month	No. of Limbs at Risk	Closed	Dead	Duration	Interval Patency (%)	Cumulative Patency (%)	Standard Error
0-1	42	0	0	0	100	100	0
1-3	42	3	0	4	93	93	3.9
3-6	35	1	0	5	97	90	4.8
6-9	29	0	0	10	100	90	5.3
9-12	19	1	0	3	94	85	7.6
12-15	15	0	0	2	100	85	8.5
15-18	13	1	0	2	92	77	10.0

Table 8. SECONDARY PATENCY OF ENDOVASCULAR GRAFT PROCEDURES TO TREAT AORTOILIAC OCCLUSIVE DISEASE

Month	No. of Limbs at Risk	Closed	Dead	Duration	Interval Patency (%)	Cumulative Patency (%)	Standard Error
0-1	42	0	0	0	100	100	0
1-3	42	2	0	4	95	95	3.27
3-6	36	0	0	5	100	95	3.54
6-9	31	0	0	10	100	95	3.81
9-12	21	0	0	3	100	95	4.63
12-15	18	0	0	2	100	95	5.00
15-18	16	0	0	2	100	95	5.31

Table 9. LIMB SALVAGE FOR PATIENTS WITH ENDOVASCULAR GRAFTS FOR THE TREATMENT OF AORTOILIAC OCCLUSIVE DISEASE

Month	No. of Limbs at Risk	Closed	Dead	Duration	Interval Patency (%)	Cumulative Patency (%)	Standard Error
0-1	42	0	0	0	100	100	0
1-3	42	1	0	4	98	98	2.3
3-6	37	0	0	5	100	98	2.5
6-9	32	0	0	10	100	98	2.7
9-12	22	0	0	3	100	98	3.2
12-15	19	0	0	2	100	98	3.5
15-18	17	0	0	2	100	98	3.7

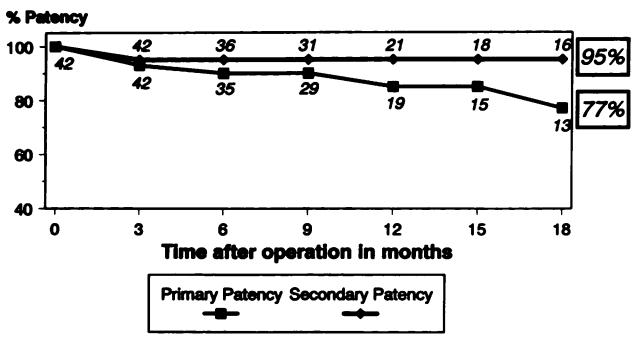

Figure 10. Cumulative 18-month primary and secondary patency rates for endovascular grafts. The numbers next to each point indicate the number of grafts observed to be patent for that length of time.

not have major systemic or local factors that increase risk and contraindicate standard therapy. The less invasive nature of endovascular grafts makes them intrinsically attractive to patients and physicians. One would think that endovascular grafting procedures should lower morbidity and cost. However, their safety, efficacy, and effectiveness in treating and curing various pathologic lesions must be proven by appropriately controlled scientific studies showing that these endovascular grafts are as good or better than standard grafts or other treatments. Only then can they be recommended for widespread use and their exact role in treating vascular disease be defined. Reasonable guidelines have been created to direct

Table 10. ENDOVASCULAR GRAFTS FOR PENETRATING OR IATROGENIC ARTERIAL TRAUMA

Sex/ Age (yr)	Mechanism of Injury	Vessel(s) Involved	Pseudoaneurysm	Arteriovenous Fistula	Associated injuries	Injury to Repair Time Interval	Endovascular Graft Length (cm)	Access Site	Hospital Stay (days)	Patency (mo)
M/20	Bullet	LSFA LSFV	Yes	Yes	Soft tissue buttock	36 hr	3	LSFA percutaneous	5	28
M/28	Bullet	RSFA	Yes	No	Left open femur fracture	12 hr	3	RSFA arteriotomy	9	25
M/22	Bullet	LSFA	Yes	No	Soft tissue right thigh, left DVT	12 hr	3	LSFA arteriotomy	6	2*
M/24	Knife	LASA	Yes	No	Pneumothorax Hemothorax	4 hr	3	Left brachial arteriotomy	7	23
M/35	Bullet	RASA	Yes	No	Brachial plexus	3 wk	3	Right brachial arteriotomy	4	19
F/78	Catheterization	RSA	Yes	No	Hemothorax	24 hr	3	Right brachial arteriotomy	56 wk†	17
M/78	Catheterization	LCIA	Yes	No	None	4 mo	2	LCFA arteriotomy	2	16
M/18	Bullet	RSA RSV	Yes	Yes	Rib fracture	1 wk	3	LCFA arteriotomy	5	11
M/66	Iliac graft disruption	RCIA	Yes	No	None	2 wk	12	LCFA arteriotomy	4	6
M/19	Bullet	RSA	Yes	No	Rib fracture	1 day	3	Right brachial arteriotomy	5	2
M/27	Bullet	RSA	Yes	No	None	4 hr	3	Right brachial arteriotomy	4	2

LSFV = left superficial femoral vein; RSA = right subclavian artery; RSV = right subclavian vein; LCIA = left common iliac artery; RASA = right axillary-subclavian artery; LSFA = left superficial femoral artery; LASA = left axillary-subclavian artery; RSFA = right superficial femoral artery; RCA = right carotid artery; LCFA = left common femoral artery; RCIA = right common iliac artery; DVT = deep vein thrombosis.

* Died 2 months postprocedure (homicide).

† Hospitalized for multiple acute medical problems not directly related to the vascular trauma.

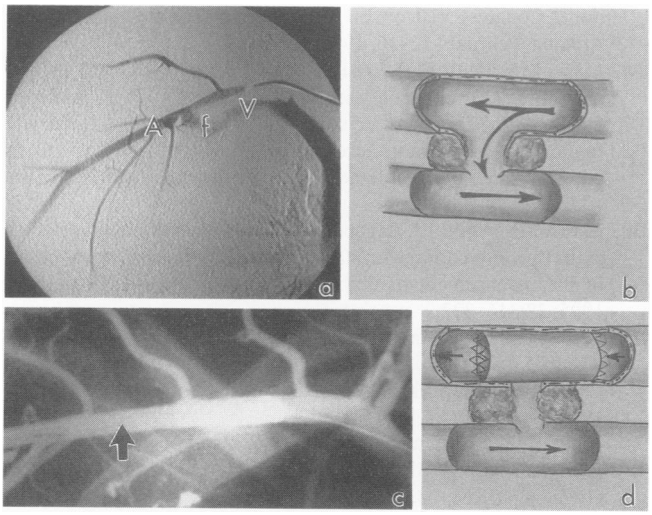

Figure 11. Transluminal treatment of a traumatic arteriovenous fistula. A 20-year-old man sustained a gunshot wound to the right upper chest. (a) A transfemoral arteriogram demonstrated a fistula between the distal subclavian artery and vein. (b) Schematic illustration of the fistula. (c) With the patient under local anesthesia, an endovascular graft was inserted through a brachial artery cut-down. After deployment of the device (arrow), a prograde arteriogram demonstrated occlusion of the arteriovenous fistula with preservation of the distal circulation. (d) Endovascular graft occlusion of a fistula. f: fistula; v: vein; a: artery.

the development of this field and to help prevent early uncontrolled and unjustified overuse.[59]

Before endovascular grafts can be accepted for widespread use to treat aneurysms, they must be shown to effectively and permanently exclude the aneurysm from the arterial circulation and to prevent aneurysm expansion and rupture. The high rate of perigraft channels into the aneurysm sac and the associated reports of aneurysm expansion and rupture after endovascular graft treatment mandate caution before these techniques are used widely or without appropriately controlled studies (Table 4).[60] Sealing of these channels by thrombosis may not prevent transmission of arterial pressure to the aneurysm wall. We are encouraged, however, by our observation of aneurysm shrinkage in some of our cases and in those of others.[32]

The devices and techniques for inserting endovascular grafts are primitive. We believe that they will be improved and that these improvements will lead to higher success rates and fewer complications with wider applicability. However, such extensions of use must be founded on carefully controlled clinical trials and proven effectiveness.

Endovascular stented grafts have a combined origin in the disciplines of vascular surgery and interventional radiology. This and the fact that vascular surgeons and interventional radiologists have been involved in developing and pioneering clinical use of these devices raise the question of who should use them and who should control them. Both specialties have legitimate claims. The procedures described in this report have often been complex and difficult and have challenged the surgical and catheter-guide wire skills of a combined group of surgeons and radiologists. Surgical and endovascular rescue techniques have often been required. We therefore believe that these devices should be used initially by a health care team that combines the highest levels of skill in vascular surgery and interventional radiology.[61,62] This has been effective in the developmental phase of these devices at our institution and at others as well. Ultimate development of a single, combined specialty or a group of specialists with dual skills working together will likely lead to the most rapid, effective advancement not only in the evolution of transluminally placed endovascular grafts, but also in the treatment of patients with vascular disease in general.

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Discussion

DR. CLYDE F. BARKER (Philadelphia, Pennsylvania): This is an important paper. As those who attend vascular meetings are well aware, endovascular techniques appear to be sweeping the country. This report by a pioneering group describes one of the largest experiences with these methods.

The appeal of this approach for treatment of aortic aneurysms, particularly in high-risk patients, is obvious. The manuscript details the technical challenges and the immediate and early complications and the remarkable success which is sometimes achieved. It will be equally important to define the possible late complications.

Will the neck of the aneurysm continue to dilate, resulting in aneurysm formation proximal to the endovascular device or distal migration of the prosthesis? How important are perigraft channels? Will they all thrombose in time? Or will they allow continued enlargement of the aneurysm? The authors' manuscript contains the first systemic attempt I have seen at serial observations of the size of endovascular-treated aneurysms in which a perigraft channel remains open.

The place of this endovascular approach for arterial occlusive disease is even less clear than it is for aneurysms. The authors are the real pioneers in endovascular procedures for arterial occlusion, a setting in which the appeal and possible advantage of this method over conventional reconstructive surgery is less obvious. In high-risk patients with occlusive disease, extra-anatomic bypasses would be another method to avoid the risk of conventional surgery, such as aortofemoral bypass. Comparison of endovascular with standard bypass procedures will have to await determination of long-term patency of the grafts as well as immediate outcome.

I am convinced by the results presented here and in the manuscript that endovascular techniques will sometimes result in long-term patency, but definitive comparisons to conventional bypass surgery must still await randomized trials. I wonder if the authors feel that randomized comparisons of endovascular treatment *versus* conventional surgery for occlusive disease are warranted at this stage.

Is there a role for this technique in more distal arterial occlusion? It seems as though it might be especially suitable for popliteal aneurysms because for these, only a short stent would be required. For distal bypasses in the leg. It might be more difficult to see an advantage. Does Dr. Veith, whose interest and success with distal bypasses performed with prostheses are well known, have optimism for an endovascular approach for femoral-popliteal or femoral-tibial bypasses? Or will surgical placement with autogenous veins remain the optimal procedure for distal occlusions?

There are several important nonmedical issues on which I would like to have the authors' views. First, will the scrutiny of the Food and Drug Administration and other accrediting bodies seriously delay the broad application of endovascular procedures? In view of the current Medicare audits that many university hospitals are undergoing with regard to the use of experimental devices, can either the surgeons or the hospitals bill patients for such treatment?

Finally, there is a turf issue here. The authors seem to have achieved an admirable collaborative arrangement with their radiology colleagues. But this has not been true everywhere. What is their advice on this? Endovascular techniques will clearly have a place in treatment of vascular disease and the authors are among those who are defining it. There will be a tendency for these procedures to proliferate because of the appeal of minimally invasive procedures to patients. This is perfectly understandable and proper, but there is a danger that this, along with turf and marketing issues, may prevail, rather than sound judgment, based on clinical experience and appropriately constructed comparative studies.

Surgeons need to remain involved and in appropriate control of the patient care, decision making, and in reporting of the outcome and complications of these procedures. The authors are to be congratulated on a good beginning in all three of these areas.

DR. LAZAR J. GREENFIELD (Ann Arbor, Michigan): My compliments to Dr. Marin for an excellent presentation. I also appreciate the opportunity to review the manuscript and comment on this impressive initial experience with endovascular grafts. The concept is certainly an attractive one, but has been limited by current technology, which was developed to deliver stents rather than the combination of graft and stent.

Dr. Veith has also pioneered in extending the application from the high-risk aneurysm patient to the patient with limb-threatening occlusive disease. This latter group raises some questions in my mind.

First, were pressure gradients measured before and after vessel dilation and graft placement? It seems that adequate dilation with or without stent placement has a respectable record and adding a graft could compromise the lumen for only a marginal improvement in the surface of the vessel.