The Montefiore Medical Center Experience with Endovascular Stented Grafts

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The field of vascular surgery is facing an important crossroads. Increasingly, less invasive alternatives are becoming available for the treatment of vascular lesions previously amenable only to conventional operative repair. Endovascular devices and techniques have been developed in experimental and clinical settings in an attempt to reduce the morbidity and mortality seen with conventional treatments and provide for long-term function at reduced costs. One such device is the transluminally placed endovascular graft which has been used at the Montefiore Medical Center in New York to treat patients with a wide variety of vascular pathologies, including abdominal and peripheral aneurysms, aortoiliac and infrainguinal atherosclerotic occlusive lesions, and lesions of traumatic or iatrogenic origin. This work represents our initial results with the endoluminally deployed stented graft in 92 patients with 102 arterial lesions treated over a 30-month period.

MATERIALS AND METHODS

Between November 1992 and April 1995, 96 procedures were performed on 92 patients whose ages ranged from 18 to 89 years (Table 1). Patients with abdominal aortic aneurysms (AAA) were treated with one of two different endovascular graft devices, depending on their medical condition and the anatomy of their aneurysm. Those with significant co-morbid medical conditions who were judged to be at a prohibitive risk for conventional aneurysm repair were treated with a balloon-expandable graft on a compassionate basis under an IRB protocol. This transluminally placed endovascular graft consists of a prosthetic graft, a device such as a stent which can affix the graft to a vessel wall, and a delivery system capable of deploying the device intraluminally at the site of a vascular lesion. If a patient was a good operative risk

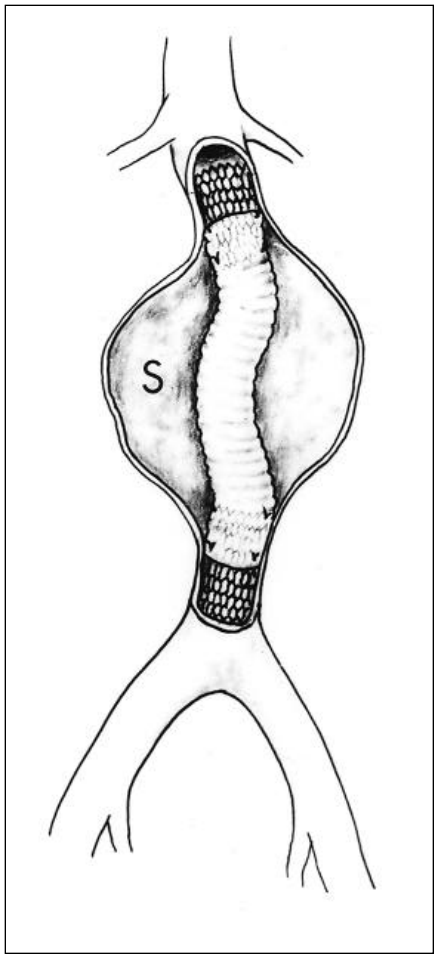

Figure 1. This is an artist's rendition of an aortic reconstruction following transfemoral endoluminal repair of an abdominal aortic aneurysm. Note that the endovascular graft is affixed to the arterial wall via an attachment system which provides a seal excluding the flow of blood through the aneurysmal aortic segment. (Reprinted from Marin ML, Veith FJ, Parodi JC. Stented grafts for the treatment of arterial vascular disease. In: Szabó Z, Kerstein MD, Lewis JE, eds. Surgical technology international III. San Francisco: Universal Medical Pr; 1994. p 421-9.)

and their aortic aneurysm met certain well-defined anatomic criteria, then they were considered for a trial of the Endovascular Technologies' Endograft (EVT) device (Menlo Park, Calif.). The EVT device consists of a woven Dacron graft with a self-expanding, hooked, "Z" stent configuration attachment system and a delivery system capable of deploying the device at the appropriate intra-arterial site. The patients treated for peripheral aneurysms, occlusive lesions, and traumatic or iatrogenic lesions generally had medical or anatomic contraindications to open surgical repair. Limb salvage was the indication for treating occlusive lesions. Those with iatrogenic or traumatic arteriovenous fistulas and pseudoaneurysms would have required an open repair had an endovascular graft not been available.

After appropriate preoperative evaluation, including a combination of computed tomography (CT) scanning, arteriography, and duplex ultrasound, all patients were brought to the operating room where the placement of the graft was performed under fluoroscopic guidance. A completion arteriogram was obtained in all cases and intravascular ultrasound was found to be helpful in select cases. Patient follow-up varied according to the type of endovascular graft that was placed, the initial indication for intervention, and the patient's medical condition (e.g., those with renal insufficiency or contrast hypersensitivity were not subjected to follow-up angiography). Those patients who had repair of an AAA had a CT scan and color duplex ultrasound performed within the first two postoperative days, providing they were medically stable. Evidence of stent migration, change in graft configuration or aneurysm size, and the presence of blood flow outside the graft were noted. In addition, patients underwent a repeat CT scan or duplex study at three months and six months and biannually thereafter. Patients with peripheral aneurysms as well as those treated for traumatic lesions were followed by physical examination and duplex ultrasound studies at similar intervals. Those who underwent stented graft procedures for occlusive disease had a postoperative angiogram in the X-ray department and were then followed with physical examination and ultrasound studies at preset time intervals. Based on the physical exam, CT scan or duplex, any patient who was suspected of having an abnormality related to the graft device underwent a transfemoral arteriogram, unless it was medically contraindicated.

RESULTS

Aneurysmal Disease of the Abdominal Aorta

Eighteen patients were treated for AAA using either the EVT device (4) or the balloon-expandable graft (14). The EVT device employed a tube graft for aneurysm exclusion, whereas 6 of the 14 patients treated with balloon-expandable grafts underwent concurrent aortoiliofemoral reconstructions. General anesthesia was used in all 4 of the patients undergoing treatment with the EVT device and in 1 of the 14 patients receiving balloon-expandable grafts. Local (2) or epidural (11) anesthesia was used in the remaining patients (Figs. 1, 2).

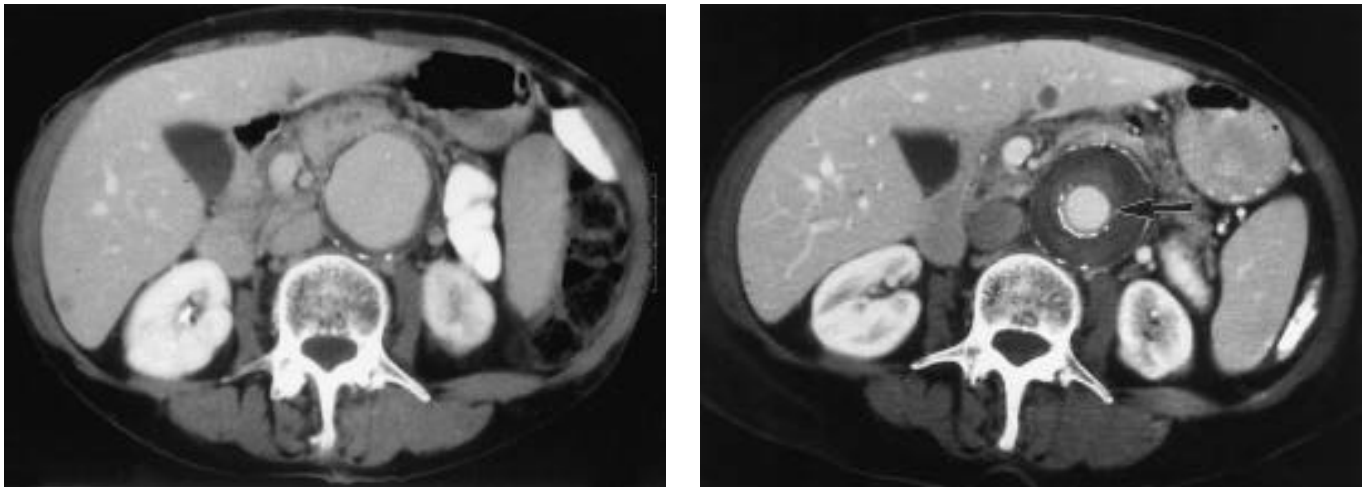

Figure 2 (a, b). Transfemoral, endoluminal repair of an abdominal aortic aneurysm. (a) Preoperative abdominal CT scan reveals a large abdominal aortic aneurysm. (b) Postoperative abdominal CT scan after placement of a stented graft (arrow) demonstrates exclusion of the contrast-enhanced blood flow from the aneurysm wall.

Three of the 18 patients with aneurysmal disease were treated in the presence of a contained rupture, and none of these was repaired using the EVT device. Those treated for a ruptured aorta have been followed for an average of 9 months compared with the remaining patients who were followed just over 13 months. Spanning the entire cohort, grafts were inserted successfully in 16 of the 18 attempts (89%). The mean hospital stay for the patients treated with the EVT device was 3½ days compared with almost 12 days for those treated with balloon-expandable grafts.

Follow-up averaged nine months, during which time three of the aortic aneurysms had slightly increased in size, eight had decreased in size, and no incidences of aortic rupture occurred (Table 2). No graft thromboses or structural failure of either graft device was seen during the study period. One patient with a balloon-expandable graft experienced cephalad migration of the distal end of the graft, and another had a configurational change consistent with extrinsic compression of the graft. One patient with the EVT device also manifested a geometric change in graft configuration. These changes were not judged to be hemodynamically significant, and none of these patients required additional intervention. Five patients with balloon-expandable grafts died within 30 days of the procedure. Three of these had aneurysms greater than 7 cm in association with bilateral iliac disease and died as a result of embolization of intraluminal aneurysm thrombus during the graft insertion procedure; one was suffering from chronic renal insufficiency, severe hepatic disease, and irreparable coronary artery disease and died in the first postoperative week following successful conversion of the procedure to a standard AAA repair; and the last patient died following graft placement in the setting of an acutely ruptured aorta and an evolving myocardial infarction.

Peripheral Aneurysmal Disease

Fifteen patients were treated for aneurysmal disease involving the iliac (11), popliteal (3), or subclavian (1) arteries. Endovascular grafts were successfully deployed in 11 patients (79%) with a total of 14 iliac artery aneurysms (Fig. 3), 2 popliteal artery aneurysms, and 1 aneurysm of the subclavian artery. In this series, there were three instances of graft thrombosis. The first occurred nine months postprocedure in a patient treated for an iliac artery aneurysm. This patient required an axillobifemoral bypass for limb salvage. The second patient underwent a standard vascular reconstruction after the endovascular stented graft that was used to treat his popliteal artery aneurysm thrombosed on the sixth postoperative day. The third instance of thrombosis occurred in a patient whose subclavian artery aneurysm was repaired two years following ipsilateral cervical rib resection for thoracic outlet syndrome. This patient did not require any additional intervention. There were no deaths or reports of aneurysm rupture in this group during the study period.

Aortoiliac and Femoropopliteal Occlusive Disease

Forty-two patients with either gangrene (39 [83%]) or disabling rest pain (8 [17%]) underwent stented endovascular graft procedures to treat 47 aortoiliac occlusive lesions. Thirty-four (72%) had a proximal graft originating in the aorta, and 13 (28%) originated in an external iliac artery. Six patients

Table 1. Patient Demographics and Type of Vascular Lesion Treated

Vascular Lesion	No. of Patients	No. of Lesions	Age Range
Abdominal aortic aneurysm	18	18	66-88
Iliac artery aneurysm	11	14	58-89
Popliteal artery aneurysm	3	3	63-84
Subclavian artery aneurysm	1	1	40
Traumatic arteriovenous fistula	2	2	18-20
Traumatic arterial pseudoaneurysm	11	11	18-78
Aortoiliac occlusive disease	42	47	43-86
Femoropopliteal occlusive disease	6	6	62-82

Table 2. Management of Abdominal Aortic Aneurysms with Endovascular Grafts

	EVT Device	Balloon Expandable Device (no aortic rupture)	Balloon Expandable Device (acutely ruptured aorta)
Number of patients	4	11	3
Type of anesthesia			
General	4 (100%)	1 (9%)	0
Local/regional	0	10 (91%)	3 (100%)
Successful graft insertion	4 (100%)	9 (82%)	3 (100%)
Mean hospital stay (days)	3.5	12	9.5
Mean follow-up (months)	13.7	13.3	9

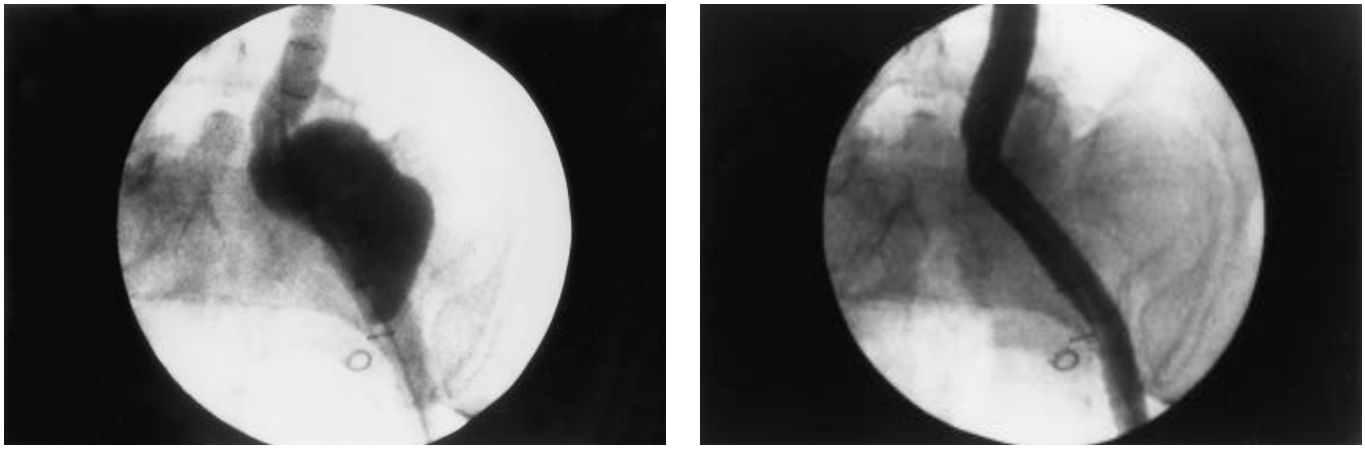

Figure 3 (a, b). Transfemoral endovascular repair of an iliac artery aneurysm. (a) Preoperative angiogram demonstrating the extent of the iliac artery aneurysm. (b) Completion angiogram demonstrating exclusion of the aneurysm following placement of an endovascular stented graft.

were treated with endovascular femoropopliteal stented grafts for gangrene of the distal lower extremities. The patients treated for occlusive atherosclerotic lesions frequently had severe, coexisting medical problems or had undergone previous surgical procedures which would have made conventional aortoiliac or femoropopliteal bypass unusually hazardous (Table 3).

Thirty-nine (92%) of the 42 patients with 47 threatened limbs who underwent endovascular stented graft repair for occlusive lesions had successful graft placement (Fig. 4). Limb salvage in these patients was 98% at 18 months. Primary and secondary graft patency rates, calculated according to the reporting standards of the Society for Vascular Surgery, North American Chapter, International Society for Cardiovascular Surgery,[1] were 77% and 95%, respectively (Fig. 5). It is important to note that 35% of the patients undergoing repair of aortoiliac lesions and 50% of those undergoing treatment for infrainguinal disease had concomitant additional procedures performed. These included lower extremity revascularization in the first group and associated inflow procedures in the latter group (Fig. 6). There were no deaths within the 30-day postoperative period.

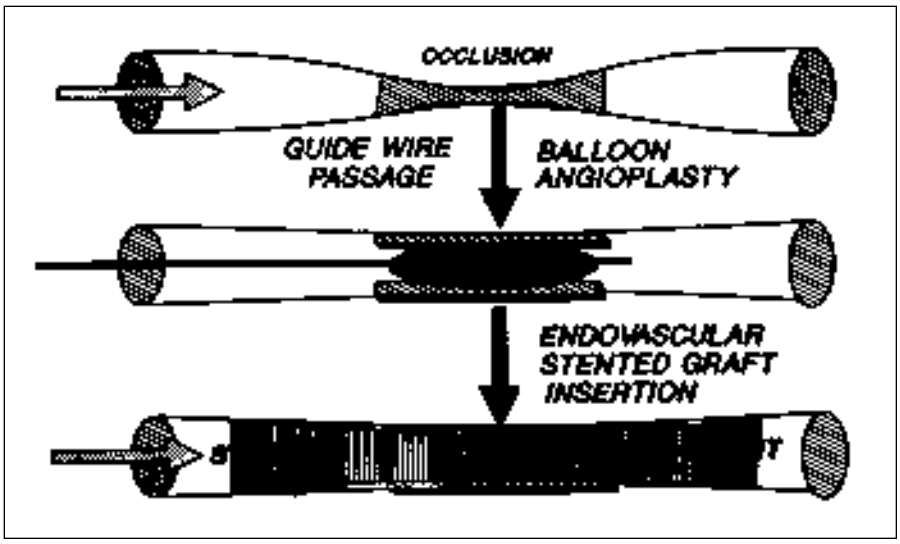

Figure 4. This is an illustration of the use of endovascular stented grafts for the treatment of occlusive disease. An arterial occlusion is first crossed with an angiographic wire. Diffuse balloon dilatation over-the-wire is then performed along the entire length of the diseased vessel. An endovascular stented graft is inserted over-the-wire and secured in position to the normal artery above and below the level of disease. The dilated atherosclerotic plaque is then excluded from the circulation external to the graft. (Reprinted with permission from: Marin ML, Veith FJ. The role of stented grafts in the management of failed arterial reconstructions. Sem Vasc Surg 1994;7:188-94.)

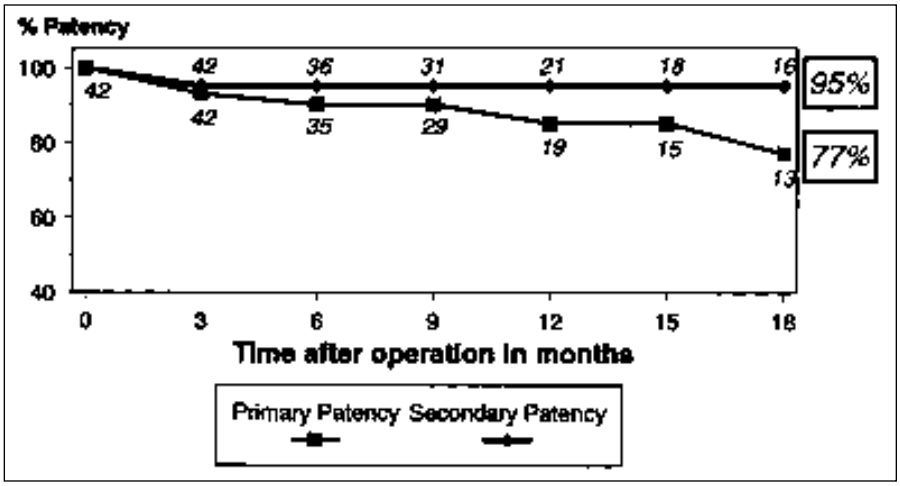

Figure 5. Cumulative 18-month primary and secondary patency rates for patients with aortoiliac occlusive disease who underwent endovascular stented graft treatment. The numbers next to each point indicate the number of grafts observed to be patent for that period. (Reprinted with permission from: Marin ML, Veith FJ, Cynamon J, et al. Initial experience with transluminally placed endovascular grafts for the treatment of complex vascular lesions. Ann Surg 1995. In press.)

Arterial Trauma

Eleven patients were treated for traumatic arterial lesions; 7 were gunshot wounds, 2 were catheterization-related injuries secondary to interventional procedures, 1 was a stab wound, and 1 a pseudoaneurysm at the site of a disruption of an iliac artery graft anastomosis. In all, 11 patients were treated for pseudoaneurysms and 2 for coexistent arteriovenous fistulas (Figs. 7-9). In addition to their arterial

lesions, eight of these patients also had injuries ranging from open femur fractures to a hemopneumothorax and a brachial plexus injury. The interval from time of injury to time of repair ranged from several hours following a gunshot wound to four months in the case of a cardiac catheterization-related injury. There have been no graft thromboses following endovascular stented graft repair of traumatic or iatrogenic lesions with up to 28 months of follow-up in some cases. One patient experienced an injury at the insertion site which was repaired with a vein patch angioplasty at the time of graft placement, and another developed a stenotic lesion within the endovascular graft at eight months which was successfully treated with percutaneous balloon dilatation (Table 4).

DISCUSSION

The concepts central to the development of the endovascular stented graft and the means for its transluminal deployment are the result of work done by both vascular surgeons and radiologists in the 1950s and 1960s. Surgeons introduced prosthetic grafts which could support unimpeded blood flow, making possible bypasses of diseased vessels including the aorta. Radiologists aided in the development of balloon catheters to accomplish percutaneous transluminal angioplasty and later developed metallic intravascular stents to maintain luminal patency following angioplasty. Charles Dotter is credited with originating the field of endovascular therapy after describing the treatment of occlusive arteriosclerotic lesions with serial dilatations by transluminally placed catheters of increasing diameter.[2] The description by Grüntzig and Hopff of a double lumen over a wire balloon catheter was another key step necessary for the development of endovascular stented grafts.[3] The intravascular stent, a metallic device which can be deployed intravascularly and become intimately opposed to the inner circumference of a vessel, was also first described by Dotter.[4] A stent can serve to strengthen the vessel wall and prevent luminal compromise following angioplasty, or it can intimately affix a prosthetic graft to the vascular wall.[5-9] The transluminally placed endovascular graft consists of a prosthetic graft, a device such as a stent which can affix the graft to a vessel wall, and a delivery sys-

Table 3. Coexisting Medical/Surgical Conditions in Patients Treated for Occlusive Disease

	Aortoiliac Occlusive Disease	Femoropopliteal Occlusive Disease
Number of patients/Number of lesions	42/47	6/6
Coronary artery disease*	36 (86%)	6 (100%)
Chronic obstructive pulmonary disease**	9 (21%)	5 (83%)
Diabetes mellitus	22 (52%)	4 (67%)
Renal insufficiency†	7 (17%)	1 (16%)
Difficult surgical field††	13 (31%)	0

*Ejection fraction less than 20% (measured by any modality).

**Room air P_aO_2 <60 mmHg, P_aCO_2 >50 mmHg or FEV^1 <35% of predicted value.

†Serum creatinine ≥ 3.0 mg/dL.

††Presence of previous dissection, scarring or infection at the site of the vascular lesion

Table 4. Endovascular Grafts for Iatrogenic and Traumatic Lesions

Age (years)	Mechanism of Injury*	Type of Injury*	Time from Injury to Repair	Days in Hospital	Graft Patency (months)
20	GSW	PA/AVF	36 hours	5	28
28	GSW	PA	12 hours	9	25
22	GSW	PA	12 hours	6	2**
24	SW	PA	4 hours	7	23
35	GSW	PA	3 weeks	4	19
79	CRI	PA	24 hours	365†	17
78	CRI	PA	4 months	2	16
18	GSW	PA/AVF	1 week	5	11
66	IAGD	PA	2 weeks	4	5
19	GSW	PA	1 day	5	2
27	GSW	PA	4 hours	4	2

*Abbreviations used: GSW, gunshot wound; SW, stab wound; CRI, catheterization related injury; IAGD, iliac artery graft disruption; AVF, arteriovenous fistula; PA, pseudoaneurysm.

**This patient died as a result of a homicide

†Hospitalization was for multiple medical problems unrelated to the vascular procedure

Figure 6 (a, b). Transfemoral iliofemoral bypass for limb-threatening ischemia. (a) Prior to insertion of an endovascular graft, severe aortoiliac disease is demonstrated by this preoperative transfemoral arteriogram. Disease within the right common iliac artery system would preclude effective standard femorofemoral bypass to re-establish circulation to the left lower extremity in this 86-year-old woman. The left iliac artery is completely occluded. (b) Following long segment balloon dilatation of the left iliac artery 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. (Reprinted with permission from: Marin ML, Veith FJ, Cynamon J, et al. Initial experience with transluminally placed endovascular grafts for the treatment of complex vascular lesions. Ann Surg 1995. In press.)

tem capable of deploying the device intraluminally at the site of a vascular lesion. While Volodos is credited with the earliest clinical use of an endovascular graft in treating a thoracic aortic aneurysm and occlusive disease of aortoiliac origin, Parodi's description of the successful treatment of an abdominal aortic aneurysm ignited widespread interest in endovascular graft technologies.[10-12] To date, many small series and case reports have described the successful deployment of stented grafts to treat traumatic,[13-15] occlusive,[16-18] and aneurysmal lesions.[19-22]

The results of our initial experience with the stented graft indicate that technical success in reliably treating a wide range of lesions in a minimally invasive fashion is possible. Furthermore, the procedures seem to be well tolerated by the patients, and early graft patency has been comparable to conventionally inserted grafts. The procedural death of patients whose abdominal aneurysms were treated with balloon-expandable grafts probably reflects the considerable co-morbid medical conditions of these patients as well as early experience with a new technology. The fact that the patients who received the EVT device were healthier, incurred no mortality, and had a hospital length of stay averaging 3.5 days supports the potential safety of this procedure. All the morbidity and mortality statistics must be interpreted by taking into account the fact that some of the patients were treated on a compassionate basis or when conventional repair could not be safely provided.

The acceptance of a new treatment modality is frequently predicated upon how these newer approaches compare with currently accepted treatments. Transluminally deployed stented grafts are generating considerable interest, since they can be placed under minimal anesthesia either percutaneously or by cut-down in patients with profound co-morbid diseases that would preclude conventional open treatment under general anesthesia. In addition, the ability to insert the stent graft device at a site remote from the vascular lesion is frequently advantageous, since it avoids difficult dissections at the sites of previous surgery or in the presence of soft tissue and bony contamination secondary to infection or trauma. The availability of transluminally deployed stented grafts provides an attractive alternative means of therapy for

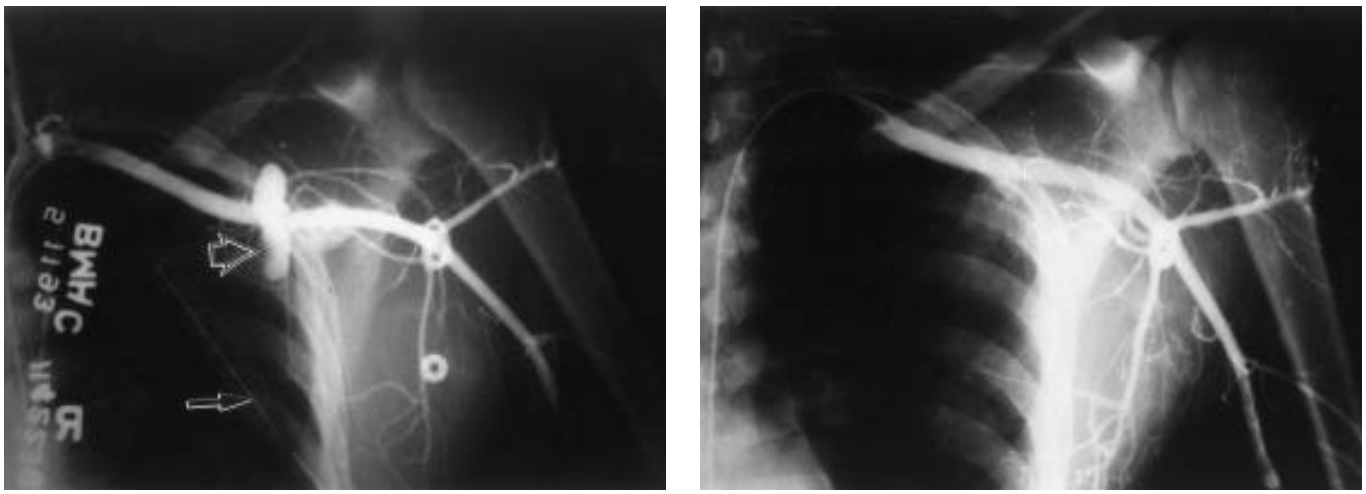

Figure 7 (a, b). (a) Axillary-subclavian artery arteriogram of a patient with a large pseudoaneurysm (open arrow) following a stab wound to the chest which resulted in a hemopneumothorax (closed arrow indicates chest tube). (b) After transluminal insertion of a stented graft, the pseudoaneurysm was repaired and flow was restored. (Reprinted with permission from: Marin ML, Veith FJ, Cynamon J., et al. Transfemoral endovascular stented graft treatment of aortoiliac and femoropopliteal occlusive disease for limb salvage. Am J Surg 1994;168:156-62.)

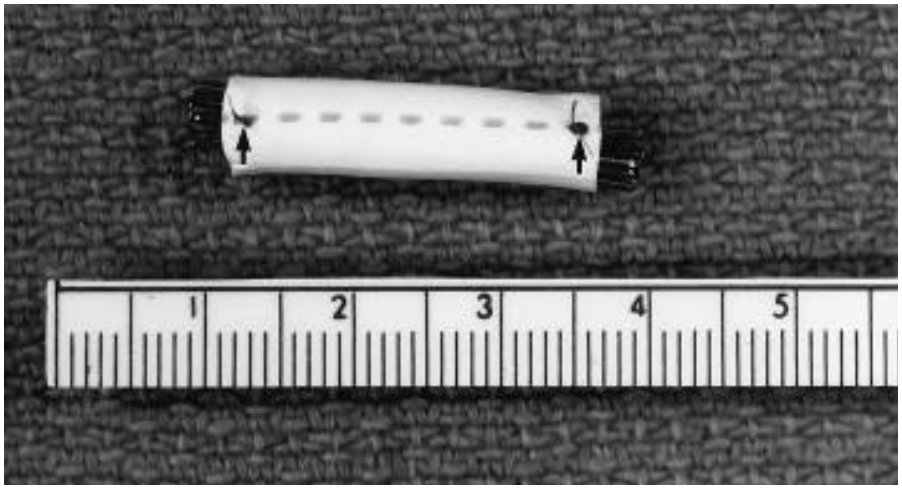

Figure 8. Vascular stented graft. A segment of PTFE is attached to a stainless steel, slotted balloon expandable (Palmaz) stent with two 5-0 Prolene sutures (arrows). The stented graft is then mounted on an angioplasty balloon and placed in a sheath before insertion. (Reprinted from Marin ML, Veith FJ, Parodi JC. Stented grafts for the treatment of arterial vascular disease. In: Szabó Z, Kerstein MD, Lewis JE, eds. Surgical technology international III. San Francisco: Universal Medical Pr; 1994. p 421-9.)

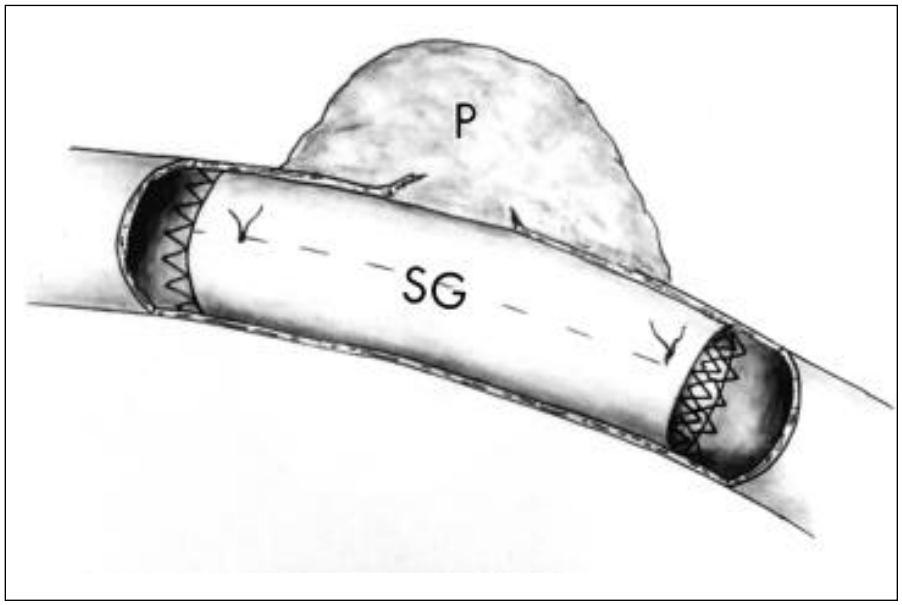

Figure 9. Following placement of a transluminal stented graft (SG), the graft covers the site of the pseudoaneurysm (P) and restores straight line arterial flow. (Reprinted with permission from: Marin ML, Veith FJ, Cynamon J., et al. Transfemoral endovascular stented graft treatment of aortoiliac and femoropopliteal occlusive disease for limb salvage. Am J Surg 1994;168:156-62.)

patients with vascular lesions which in the past would have been repaired by open techniques. Ultimately the results of clinical trials will determine which patients and vascular lesions will be most amenable to the application of these minimally invasive vascular techniques. STI

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