# Stented Grafts for the Treatment of Arterial Vascular Disease

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**Vascular surgery has evolved considerably over the past 100 years from a specialty that offered patients only palliative procedures to treat significant vascular diseases to a field centered on the diagnosis and correction of vascular disorders. Aortic and peripheral artery aneurysms were once medical problems rarely diagnosed and frequently fatal. Diffuse, occlusive arterial disease secondary to atherosclerosis frequently resulted in limb gangrene or specific end-organ ischemia. Modern vascular therapy has dramatically reduced the incidence of primary limb amputations and significantly decreased the risk of fatal complication of arterial aneurysm rupture.**

Tandem efforts in vascular surgery and interventional radiology have resulted in a series of new developments to treat patients with complications of advanced atherosclerosis. These techniques frequently use minimally invasive approaches in patients who have severe comorbid medical illnesses that would contraindicate alternative open surgeries. This chapter reviews the development and applications of endovascular stented grafts for the treatment of arterial aneurysms, occlusions, and traumatic injuries.

## INTRAVASCULAR STENTS

Intravascular stents are endoluminal support devices that have been used for the treatment of arterial occlusive disease. They were first developed by Charles Dotter in the late 1960s.[1] His early work spawned the development of a variety of intravascular stent designs.

Intravascular stents may be divided into three basic types: balloon-expandable, self-expanding, and thermal-expanding. Each of these designs has unique advantages and limitations that ultimately impact on their deliverability, biocompatibility, and versatility (Figure 1a, 1b).

The Palmaz balloon-expandable stent has gained wide acceptance for the treatment of iliac angioplasty failures and recurrent iliac stenoses where excellent results have been achieved.[2] The Palmaz stent is constructed of stainless steel tubing that contains a variable number of slots arranged in offset rows. Inflation of a coaxially placed balloon results in deformation of the malleable steel stent construction, permitting the slot configuration to change to a diamond-shaped orientation that results in an increase in stent diameter (Figure 1a). The newly formed wire mesh structure embeds into the wall of the artery, fixing the stent in position.

Self-expanding stents include those devices delivered to the site of disease in a collapsed form within a small-diameter introducer sheath. When appropriate positioning has been confirmed by fluoroscopy, the stent is released from the end of the catheter and "springs" to its predetermined size.

The Gianturco wire stent was first used for malignant obstruction of the vena cava.[3] This stent is composed of stainless steel wire (0.45 mm in diameter) bent in a zigzag pattern. Recently, several other stents that appear to have been designed with a construction similar to the Gianturco wire stent have been developed that produce sufficient radial force to secure the stent to the artery wall.[4,5] When compressed, it can be introduced through a Teflon® catheter measuring 8 to 12 Fr. A coaxial pusher device expels the stent out of the catheter at the desired location. Although attempts have been made to use this device in the iliac and femoral arteries, its use has been predominantly limited to larger vessels such as the vena cava. Currently, diameters between 15 and 40 mm are commercially available. Later in the chapter, we review modified versions of this device that have been used to fabricate stent grafts.

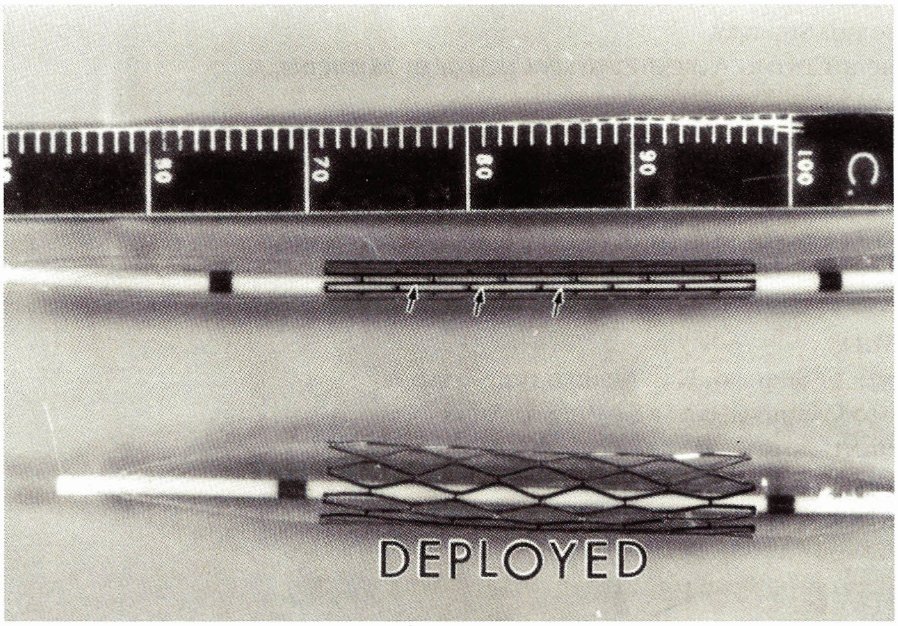


**Figure 1a. The balloon-expandable Palmaz stent is composed of a stainless steel tube that contains multiple rows of offset slots (arrows).**

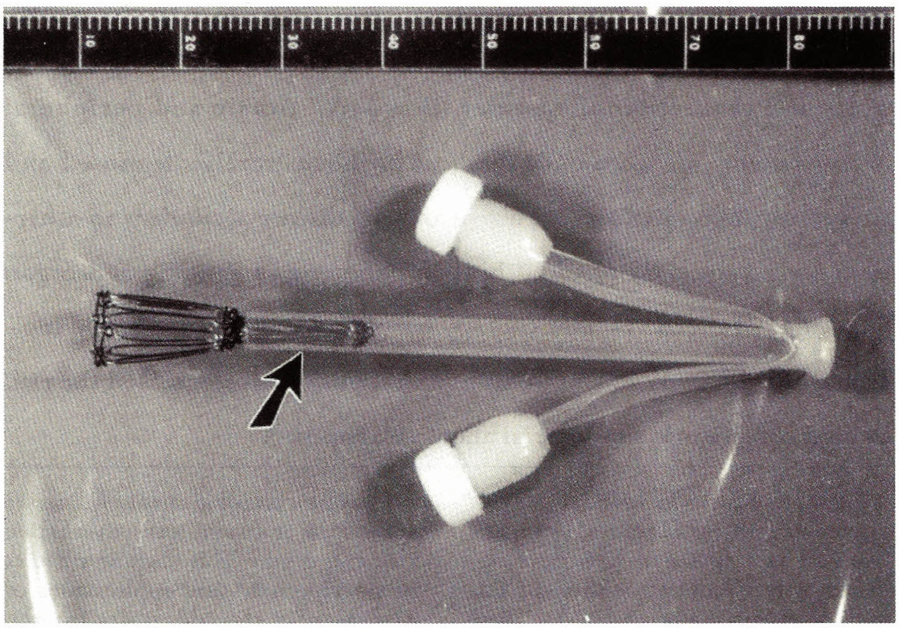

**Figure 1b. The Gianturco wire stent is composed of a "Z"-shaped, bent wire that permits this device to collapse into a small-diameter introducer catheter (arrow). When discharged from the introducer sheath, the stent exerts a considerable amount of radial force.**

## INTRAVASCULAR STENTED GRAFTS

Over the past five years, intravascular stents have gradually obtained acceptance for treating occlusive disease in select arterial systems. Unfortunately, currently available clinical stents are extremely porous and are unsuitable for treating other forms of arterial disease. Arterial aneurysms, pseudoaneurysms, and arteriovenous fistulas require devices with the capacity to form a watertight seal to treat the disorder. An alternative approach blends intravascular stent and prosthetic graft technologies to use the efficient "anchoring" qualities of stents and the flexible hemostatic sealing properties of vascular grafts. Such stent graft devices can be used to treat arterial aneurysms, occlusions, and traumatic vascular injuries.

**Figure 2: Transfemoral endovascular stented graft aortic aneurysm repair.**

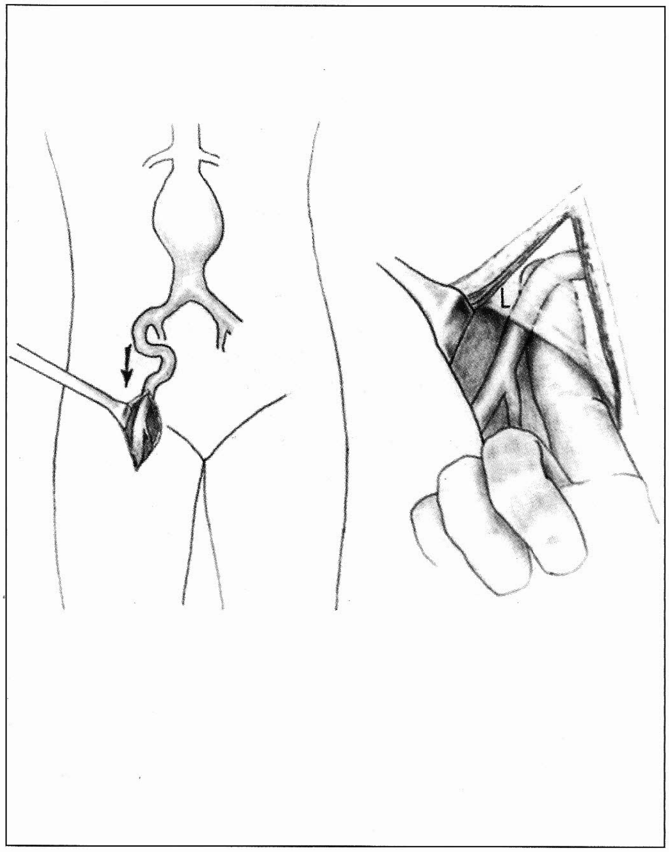


**Figure 2a. An incision is made in the groin to expose the common femoral artery. Blunt finger dissection is used to mobilize the vessel from beneath the inguinal ligament (L). This allows downward traction on the external iliac artery permitting vessel straightening.**

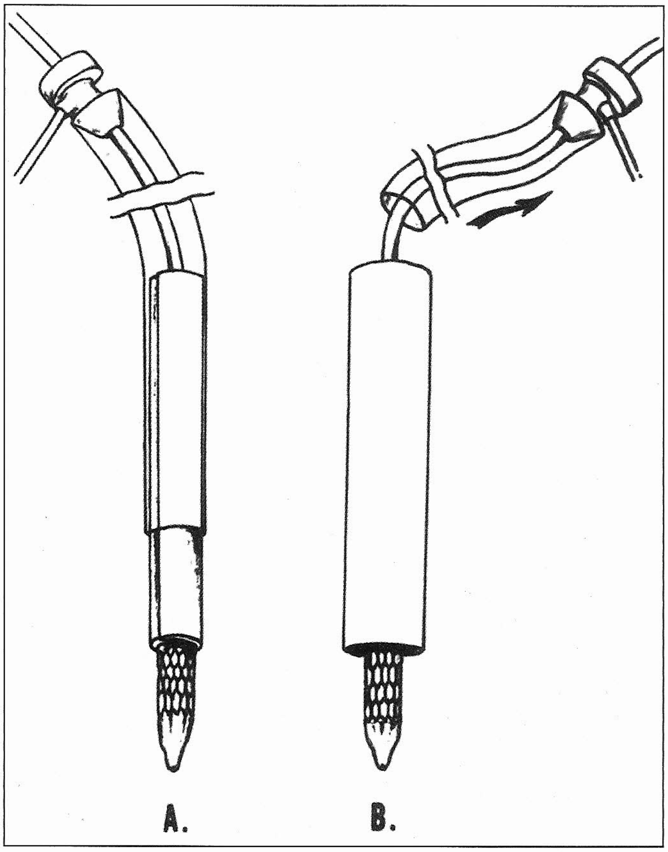


**Figure 2b. A stented graft (A) is folded and placed inside a delivery catheter (B) equipped with a hemostatic valve.**

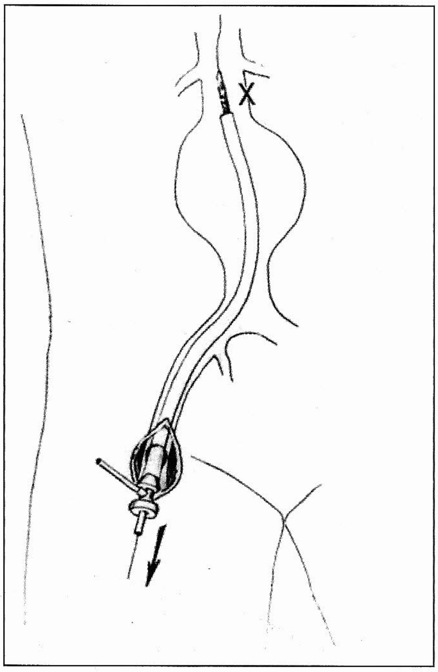


**Figure 2c. The entire system is inserted through an arteriotomy over a wire to a fluoroscopically confirmed proximal attachment site (X).**

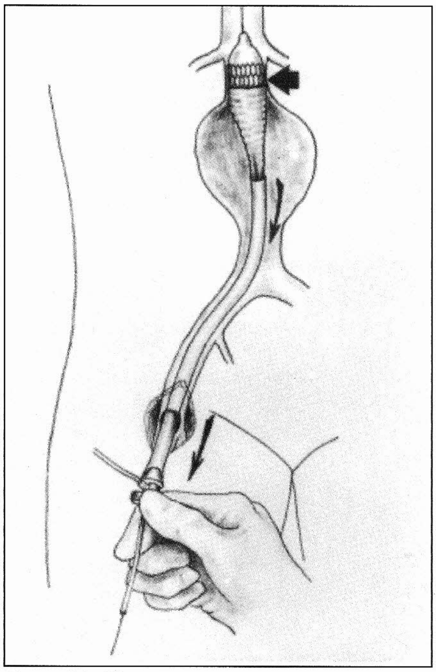

**Figure 2d. After manual withdrawal of the sheath (arrows), a balloon is inflated sealing the stent to the arterial wall (large arrow).**

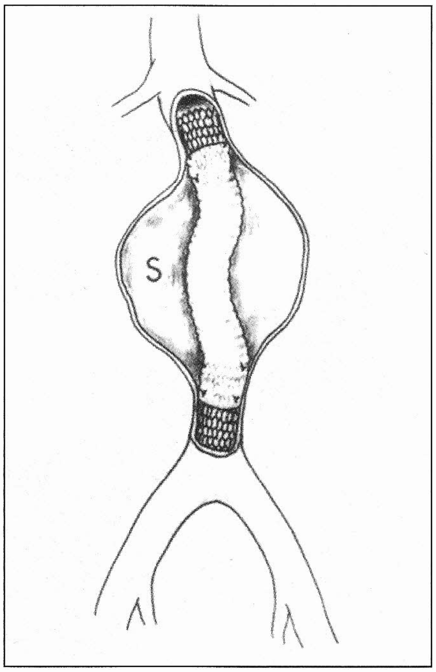


**Figure 2e. A second stent is deployed to seal the lower end of the graft, excluding the aneurysm sac (S).**

### Stented Grafts for Arterial Aneurysms

The clinical significance of arterial aneurysms was recognized over 2000 years ago. However, the advent of modern therapy for the treatment of aortic and peripheral artery aneurysms began as recently as the 1950s. The seminal contributions of Dubost and colleagues who advocated the use of aortic homographs to bridge the defect of aortic aneurysms,[6] followed by the discovery of Voorhees and colleagues of the use of prosthetic vascular grafts marked the beginning of modern aortic surgery.[7] Similar techniques for aneurysm exclusion and endoaneurysmorrhaphy evolved for treating peripheral and aortic aneurysms.

Improvements in surgical technique and pre- and postoperative care of patients with aortic aneurysms were primarily responsible for a marked reduction in the morbidity and mortality from this disease. However, problems in treating patients with large aortic aneurysms and significant comorbid medical illnesses persist. The reintroduction of antiquated techniques such as aneurysmal thrombosis and new approaches to external aortic wrapping were redescribed intermittently in the literature, but it is generally believed that they do not provide significant protection against the complications of aortic rupture.[8-10]

An important potential advance in the management of aneurysmal disease resulted from one of the first clinical applications of endovascular stent grafting to aortic aneurysms by Juan Parodi and his colleagues in 1990.[11] The idea of endovascular grafting was not new and was first conceptualized by Charles Dotter in the late 1960s.[1] Following Dotter's suggestion that such stent grafts could be used for repairing aneurysms and arteriovenous fistulas, a number of experimental studies were performed to evaluate the feasibility of these techniques.[12-14]

A stented graft is usually composed of a device that uses a prosthetic graft inserted through a remote site in the vasculature and fixed to the arterial wall by means of an attachment device such as an intravascular stent (Figure 2). Several different grafts and stent combinations were tested in the experimental setting; however, one of the first clinically used devices was a modified Palmaz stent and Dacron® knitted graft (Figure 3).[11] The stent graft device is packaged inside an introducer sheath equipped with a hemostatic valve. The entire device is inserted through a remote arteriotomy in the femoral artery and advanced in a retrograde fashion to the infrarenal aorta. The location for the proximal and distal portions of the stent graft device is confirmed by fluoroscopy. After fixation of the proximal and distal portions of the prosthetic graft with their respective stents, a completion arteriogram and follow-up computerized tomography scans confirm proper placement and adequate exclusion of the aortic aneurysm.

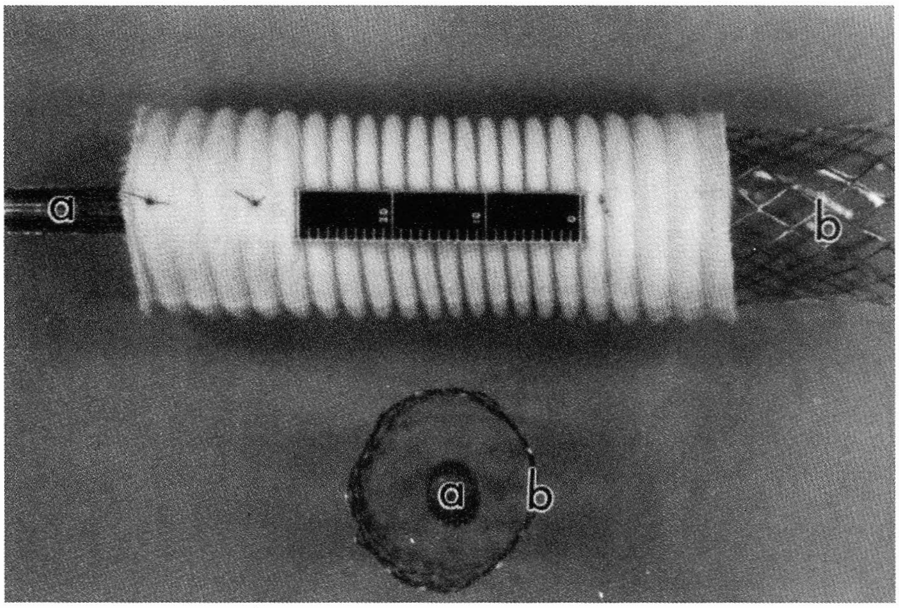


**Figure 3: A Parodi-type stented graft composed of two balloon-expandable Palmaz stents sutured to the ends of a crimped Dacron® vascular graft. The stainless steel tubular stent expands from a relatively compact outer diameter (a) to an expanded form (b) after deployment.**

Using this technique, Dr. Parodi reported his experience with more than 40 patients over a three-year period. A technical success rate of greater than 95% was achieved in his experience. A combined major and minor complication rate of 35% for this early series has been reported, which seems acceptable for the preliminary phases of the development of a new technology.[15]

These stent graft devices are not limited to aneurysms within the aorta. A similar approach can be used for repairing aneurysms in the popliteal and iliac arteries. Successful exclusion of aneurysms in these locations has been demonstrated at the Montefiore Medical Center in New York using polytetrafluoroethylene (PTFE) and Dacron® grafts. In one instance, a large, clot-filled popliteal artery aneurysm was successfully excluded using a 6-mm PTFE graft and two Palmaz stents.[16] The long-term results of endovascular grafting for aortic and peripheral artery aneurysms are as yet unclear. Concern remains as to the fate of the arterial tissue above and below the aneurysm into which the fixation stent has been embedded. Further dilatation of these portions of the artery may result in a dislodgment of the stent graft device and migration. Thus far, this problem has not been seen. In addition, whether endovascular grafting for the treatment of aortic aneurysms will truly eliminate the risk of aneurysmal rupture will require a longer follow-up period in more patients with aneurysms of varying sizes.

### Stented Graft Revascularization for Arterial Occlusive Disease

Standard bypass procedures of the aortoiliac and femoropopliteal arteries have achieved excellent long-term patencies and ultimate limb salvage.[17] Varying approaches to aortoiliac and femoropopliteal arteries, as well as the availability of suitable prosthetic graft materials, have allowed this therapy to become the standard of care for extensive arterial occlusive disease.

As noted earlier in this chapter, the use of intravascular stents has become important in treating aortoiliac occlusive disease. A recent review of the experience with the Palmaz balloon-expandable stent in over 500 patients demonstrated excellent results in select patients.[18] These devices have been used predominantly for treating short-segment stenotic lesions within

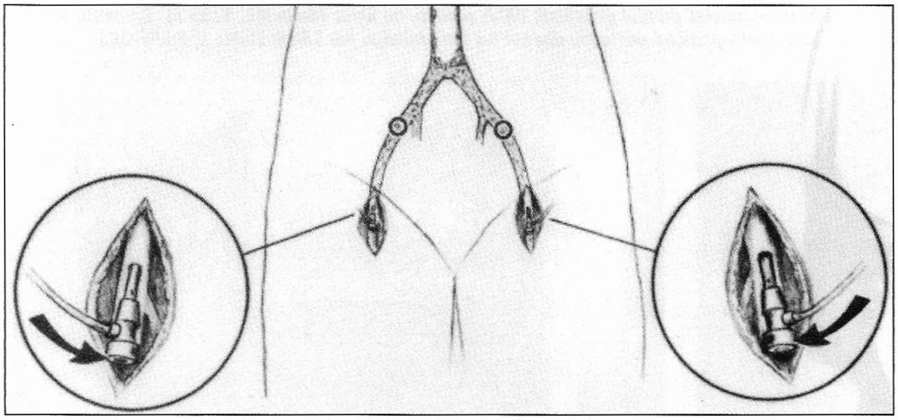

Figure 4a. Guiding catheters (arrows) are inserted directly into the access arteries (o = occluded vessel).

**Figure 4: Schematic drawing of the technique of endovascular stent graft repair for aortoiliac occlusive disease. (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.)**

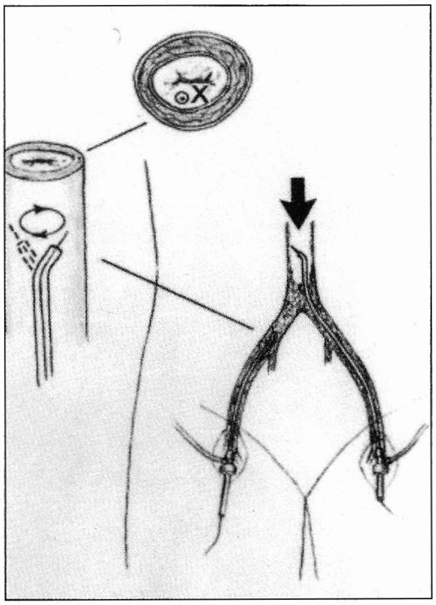

Figure 4b. Angled directional catheters are used to guide a hydrophilic wire through the occluded artery into the patent cephalad vessel (arrow). Ideally, the wire will travel within the residual lumen of a stenotic artery, or within the intra-intimal plane of an occluded vessel (x).

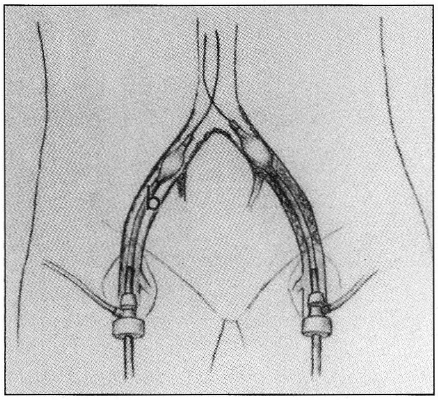

Figure 4c. Diffuse balloon angioplasty (b) using an over-the-wire technique will provide a dilated tract for insertion of the endovascular graft.

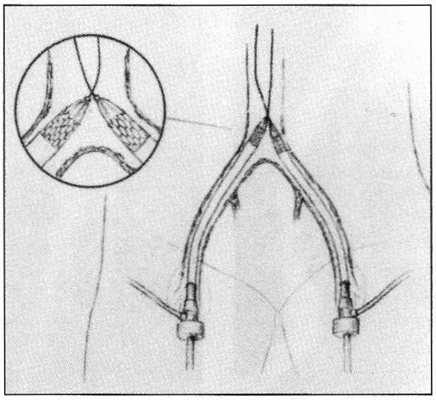

Figure 4d. Stent grafts are inserted and deployed at an appropriate location as determined by fluoroscopic images.

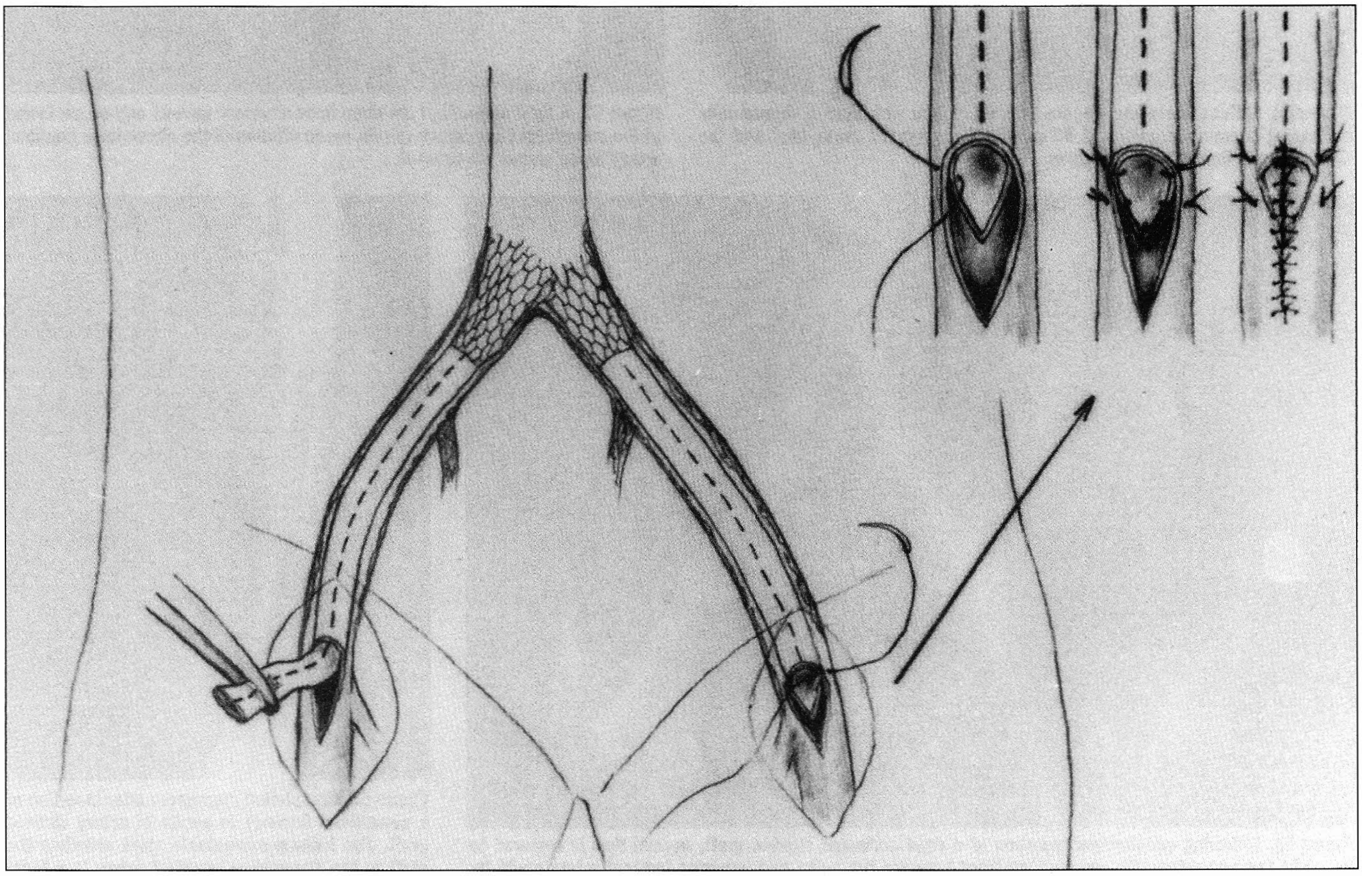

Figure 4e. The caudal end of the graft may then be endoluminally anastomosed to the outflow artery. The artery is then closed over the anastomosis.

**Figure 5: Preoperative femoral arteriograms performed by a left transfemoral arterial puncture. (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.)**

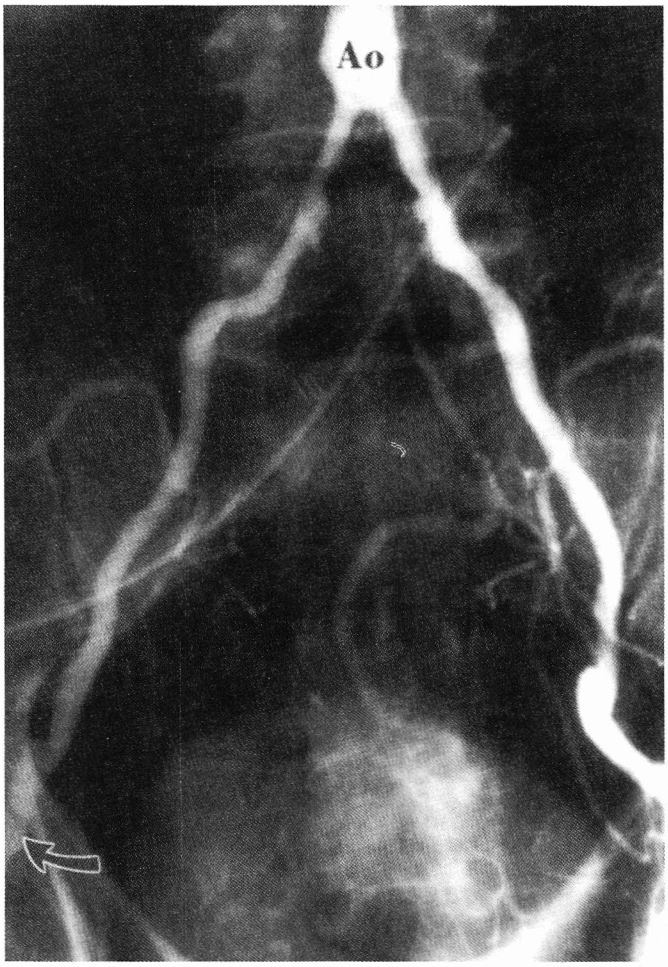


**Figure 5a. Diffuse aortoiliac disease is present that displayed a segmentally increasing pressure gradient of 80 mm Hg between the aorta (Ao) and the right common femoral artery (arrow).**

**Figure 5b. A tight stenosis of the deep femoral artery (arrow) and an occlusion of the superficial femoral artery with reconstitution of the above-knee popliteal artery (open arrow) are present.**

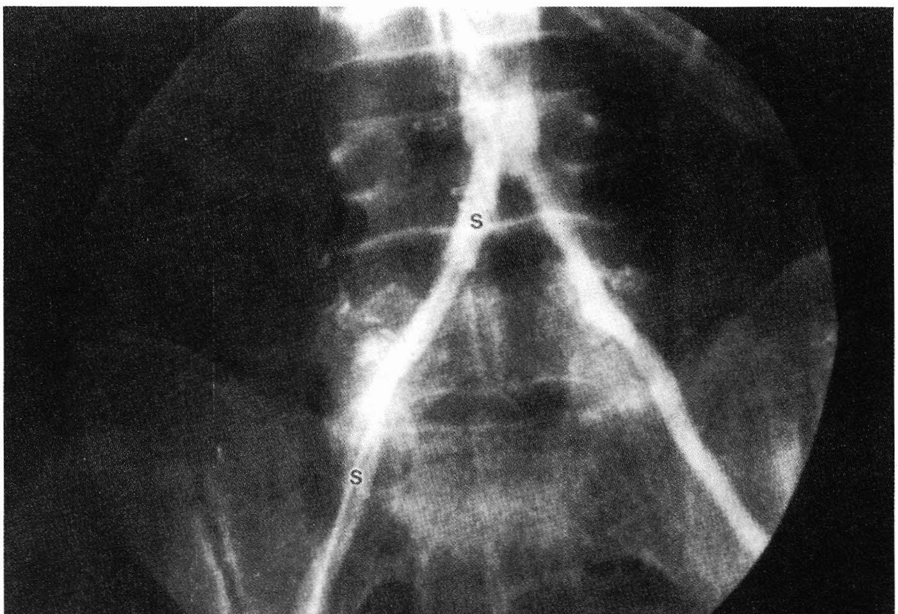


**Figure 5c. Following endoluminal insertion of a right aortoiliac stented graft, normal flow is restored to the right femoral artery. No pressure gradient between the aorta and common femoral artery could be detected after graft insertion (s = location of endovascular stents).**


**Figure 5d. Completion angiogram after insertion of a superficial femoral to popliteal artery stented graft. The balloon-expandable stent attaches the graft to the above-knee popliteal artery (s = location of stent).**

the common iliac artery. When more extensive portions of the aortoiliac or femoropopliteal vasculature are involved, isolated stents have not been effective and stented grafts have the potential to have an important therapeutic role. To date, our experience with stent grafts has concentrated predominantly on those patients who have severe limb-threatening ischemia in the presence of other significant comorbid medical illnesses, making standard surgical bypass procedures risky.

The use of stented grafts for treatment of occlusive disease differs from the techniques used for aneurysms by the addition of an extra step involving diffuse vessel dilation before endovascular grafting. Grafts are created of PTFE material sewn to Palmaz balloon-expandable iliac stents. Occluded vessels are traversed with select recanalization wires, and the diseased segment of the artery is angioplastied. When the vessel has been dilated, a stent graft is inserted from a remote arteriotomy through the newly created tract in the artery into normal proximal vessel. The intravascular stent is used to fix the prosthetic graft to the arterial wall, creating a new lining for the diseased artery (Figures 4 and 5). Early experience with this technique in femoropopliteal arteries has been described, with encouraging results.[19-21] At the Montefiore Medical Center, we have successfully used stented grafts to treat femoropopliteal and aortoiliac occlusive disease. Technical success was achieved in 96% of cases, including endovascular grafts that originated from the aorta or the iliac arteries.[21] Follow up to 16 months showed excellent patency and limb salvage in this preliminary series.

Arterial recoil after dilatation and the possibility for atherosclerotic hyperplastic reaccumulation external to the prosthetic grafts have not been observed. Problems related to these grafts in the follow-up period have been infrequent, with the most common concern related to progression of disease in the outflow vessels. Long-term follow up in a large series of patients will be necessary before the expanded use of this technology. Advances in both graft and stent technologies may be expected to provide more suitable materials for endovascular grafting that will simplify insertion and help ensure durability.

## Stented Graft Treatment of Arterial Trauma

Civilian trauma has been increasing steadily with a dramatic rise in handgun-associated injuries. Penetrating trauma to the vascular system from these high-velocity missiles can lead to the formation of arterial occlusions, pseudoaneurysms, and arteriovenous fistulas. The optimal management of these vascular injuries has been described in both wartime and civilian trauma experiences.[22-27] Significant injuries demonstrating pulse deficits and severe ischemia or expanding hematomas and active hemorrhage require urgent surgical exploration and vascular repair. The direct surgical repair of these injuries may be complicated by several factors, including inaccessibility of the vascular lesion when trauma occurs to central vessels. In addition, false aneurysms and arteriovenous fistulas may distort local anatomy and induce significant venous hypertension, thus increasing the challenge of a standard surgical repair with considerable blood loss. If the patient remains

**Figure 6. Endovascular covered stents for treating traumatic arterial injuries.**

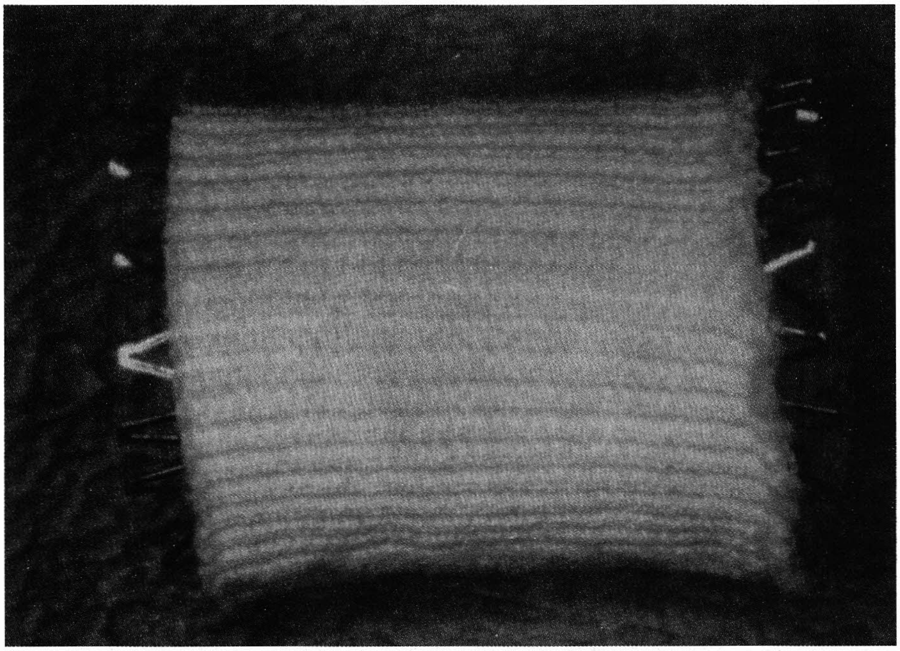

**Figure 6a. Dacron® graft material is used to completely cover a balloon-expandable stent.**

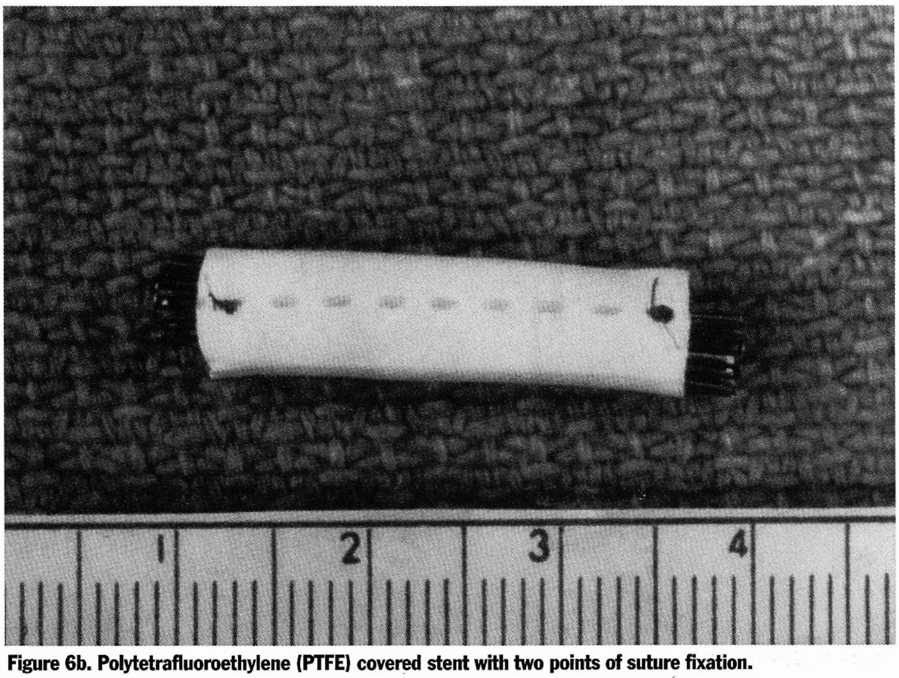


**Figure 6b. Polytetrafluoroethylene (PTFE) covered stent with two points of suture fixation.**

**Figure 7. (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.)**

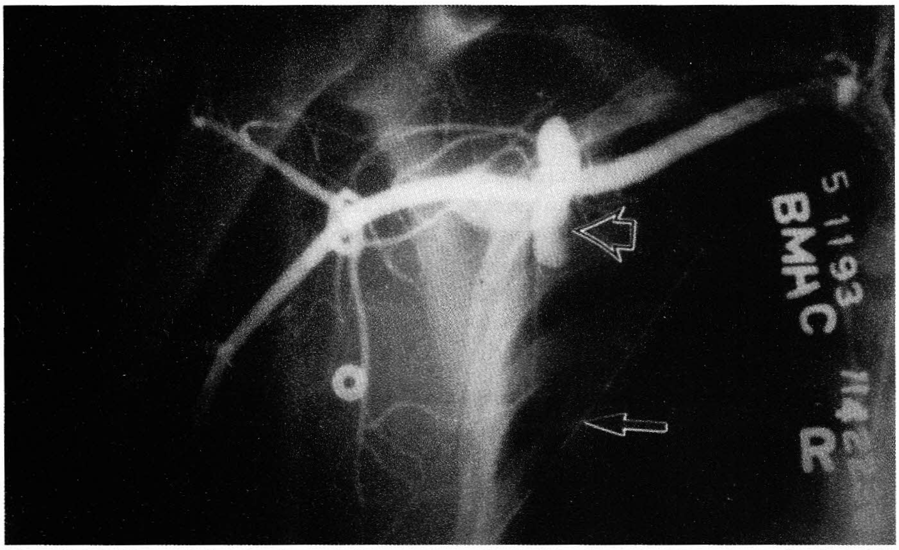

**Figure 7a. Axillary-subclavian artery arteriogram of a patient with a large pseudoaneurysm (open arrow) after a stab wound to the chest, resulting in a hemopneumothorax (arrow - chest tube).**

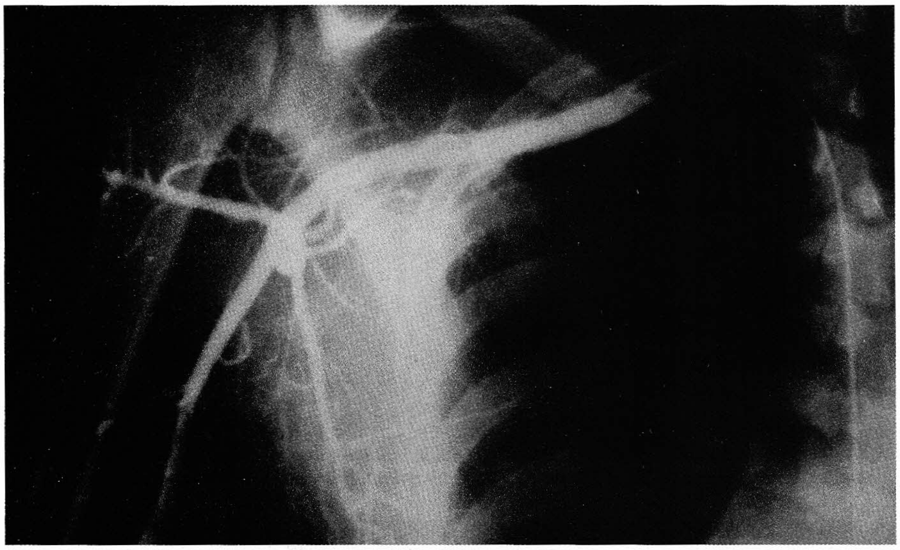

**Figure 7b. Following transluminal insertion of the stent graft device, the pseudoaneurysm was repaired and flow was restored.**

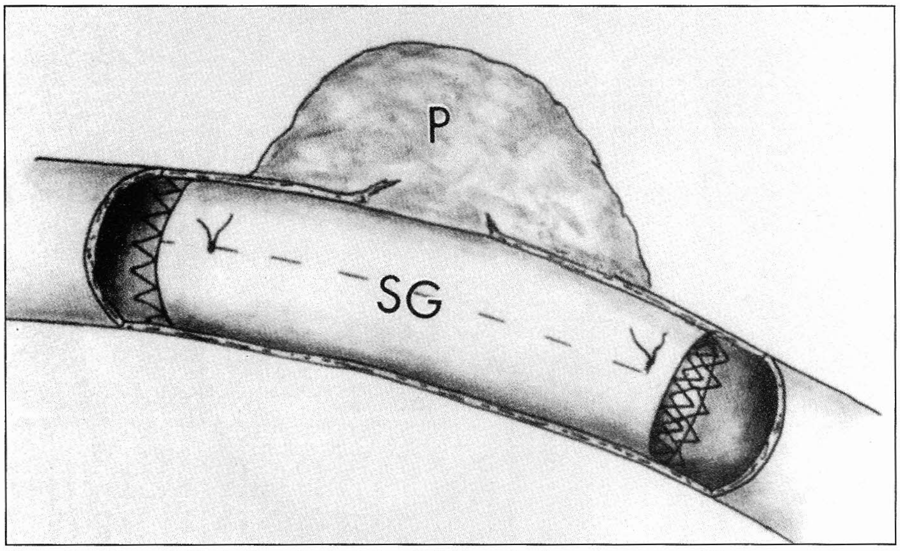


**Figure 7c. Schematic illustration of a stented graft (SG) repair of pseudoaneurysm (P).**

stable after the vascular trauma, an alternative treatment may include endovascular stented grafts to directly repair the injured vessel from the luminal surface.[15,28,29]

Although the use of transluminally placed stented grafts for treating traumatic arterial lesions was conceptualized by Dotter in 1969,[1] the first clinical case was performed by Volodos and colleagues in 1986 using a Dacron® graft and self-expanding stent.[30] Experimental and clinical experience has shown that a wide range of devices may be used for treating traumatic arterial lesions.[15,31] In their current design, stented grafts for treating arterial trauma are composed of a stent that has a total external covering (Figure 6). The composition of the external covering on the stent (ie, PTFE, Dacron®) does not appear to be critical to stent graft function in the treatment of traumatic lesions.

At the Montefiore Medical Center, we have used the Palmaz balloon-expandable stent in conjunction with thin-walled PTFE material to perform arterial repair of pseudoaneurysms and arteriovenous fistulas. The stents varied between 2 to 3 cm in length and were fixed inside 6-mm Gore-Tex® grafts (W.L. Gore and Associates, Flagstaff, AZ) by 2 "U" stitches. The stent grafts were mounted on balloon angioplasty catheters loaded into 12 Fr. delivery systems.

Eight patients received eight stented grafts to treat traumatic arterial lesions.[32] All injuries were associated with a surrounding pseudoaneurysm (Figure 7). In two instances, the arterial injury formed a fistula to an injured adjacent vein. Stented graft patency was 100% with no early or late occlusions. Mean follow up was 12 months, with a range of 4 to 18 months. One patient with an axillary pseudoaneurysm required a vein patch to repair the site of the arteriotomy. No other early or late complications were encountered.

## SUMMARY

The binding of prosthetic graft and intravascular stent technologies is rapidly becoming an important part of vascular intervention for aneurysmal, occlusive, and traumatic vascular injuries. It is conceivable that the use of this technology may not only result in reduced operative morbidity and mortality, but decreased operative blood loss, hospital stay, and cost as well, leading to improved patient care. When additional experience with this important new technique has been obtained, randomized, prospective trials comparing standard therapy to endovascular grafting techniques will be needed to substantiate this form of therapy for the treatment of arterial disease. **STI**

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