◆ CLINICAL INVESTIGATION ◆

Wallgraft Endoprosthesis for the Percutaneous Treatment of Femoral and Popliteal Artery Aneurysms

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Purpose: To evaluate the safety and efficacy of the Wallgraft Endoprosthesis for the treatment of femoropopliteal artery aneurysms.
Methods: From October 1997 to April 2000, 17 patients (13 men; mean age 73.5 ± 7.1 years) with 7 femoral and 13 popliteal artery aneurysms underwent percutaneous aneurysm exclusion using the Wallgraft Endoprosthesis as part of a larger clinical trial. The mean aneurysm diameters were 37.6 ± 12.9 mm and 22.3 ± 8.7 mm, respectively.
Results: Acute procedural success was 100% for femoral aneurysms and 92.3% (12/13) in the popliteal artery owing to one endoleak that resolved after 1 month. There were no complications, and the mean length of stay was 2.2 ± 3.8 days. Six-month and 1-year aneurysm exclusion rates were 100% for both locations, but 4 (31%) popliteal stent-grafts thrombosed in follow-up. Three were recanalized, but the fourth underwent bypass grafting after 3 thrombotic episodes. The 1-year primary and secondary patency rates were both 100% for the femoral aneurysms and 69% and 92%, respectively, for popliteal repairs. No procedure or device-related deaths occurred.
Conclusions: Treatment of aneurysms in the femoropopliteal segment appears to be safe and effective with the Wallgraft Endoprosthesis, although longer follow-up in a larger patient group will be needed to determine this technique's potential versus surgical repair.
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Key words: stent-graft, aneurysm exclusion, self-expanding stents, thrombosis

Significant progress has occurred in the endovascular treatment of arterial aneurysms, especially those of the abdominal aorta. Femoral and popliteal artery aneurysms, although less potentially lethal, can cause limb-threatening complications, such as nerve or venous compression in 18% to 35% of patients who are not treated.[1–3] The amputation rate is as high as 40% in patients who experience a thromboembolic event.[3]

Once rather rarely encountered, femoropopliteal segment aneurysms appear to be increasing in frequency, as are all peripheral aneurysms in our aging population.[1] As documentation of this trend, Graham[1] compared a study from 1972, in which the ratio of pe-

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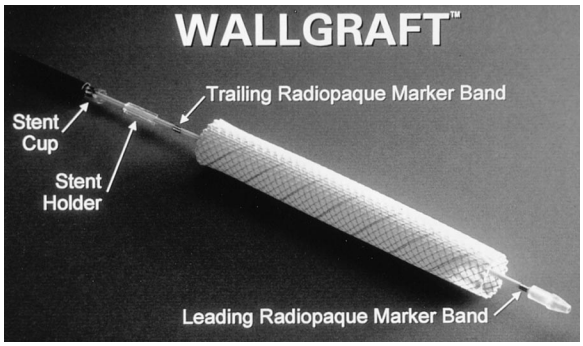

Figure 1 ◆ The Wallgraft Endoprosthesis is a polyester-covered Wallstent mounted on the Unistep Plus delivery system. Image courtesy of Boston Scientific/Medi-tech.

ripheral atherosclerotic aneurysms to abdominal aortic aneurysms was 1:23, to more recent studies that reported ratios of 1:8 and 1:15.

The treatment for femoropopliteal aneurysms has historically been open surgical repair with bypass or resection and interposition of a tube graft.[1] Although stent-graft treatment of arterial aneurysmal[4–6] and occlusive[7–8] disease has shown satisfactory results above the inguinal ligament, endografts have traditionally performed less well in the superficial femoral and popliteal arteries.[9–14] To determine if a new polyester covered self-expanding stent can improve upon these early results, we evaluated the safety and efficacy of the Wallgraft Endoprosthesis (Fig. 1) for the treatment of femoral and proximal popliteal artery aneurysms.

METHODS

Study Design

This study was part of a prospective, multicenter cohort trial that featured consecutive enrollment of all qualified patients having atherosclerotic arterial aneurysms in peripheral arteries with reference diameters of between 5 and 11 mm; aneurysms in the carotid arteries and the aorta were not eligible. Other inclusion and exclusion criteria are given in Table 1.

Eligible patients underwent an initial evaluation that included a history and physical examination, computed tomography (CT), duplex ultrasound, and angiography. Each eligible patient was required to sign an informed consent document before enrollment into the study.

TABLE 1
Inclusion and Exclusion Criteria of Multicenter Wallgraft Trial in Peripheral Aneurysms

Inclusion
♦ Aneurysmal lesion in the femoral artery or proximal popliteal artery (above the knee) at least 1.5 times larger in diameter than the normal reference vessel
♦ Aneurysms must be atherosclerotic in etiology
♦ Reference vessel diameter between 5 and 11 mm
♦ The artery proximal and distal to the aneurysm must be able to accommodate fixation of the stent-graft with a minimum 1 cm of normal vessel from an essential branch vessel or bifurcation
Exclusion
♦ Age <50 years
♦ A lesion in which the stent-graft would cross a joint
♦ Connective tissue disease or mycotic aneurysm
♦ Contraindication to antiplatelet, anticoagulant, or thrombolytic medications
♦ Anticipated life expectancy <1 year
♦ Not a surgical candidate

Patient Characteristics

From October 1, 1997 to April 1, 2000, 17 patients (13 men; mean age 73.5 ± 7.1 years) with 7 femoral artery and 13 popliteal artery aneurysms gave written informed consent to be treated with the Wallgraft Endoprosthesis (Boston Scientific/Medi-tech, Natick, MA, USA). Patient characteristics are listed in Table 2. The mean aneurysm diameters were 37.6 ± 12.9 mm in the femoral artery (reference vessel diameter 8.4 ± 2.0 mm) and 22.3 ± 8.7 mm in the popliteal artery (reference diameter 7.6 ± 1.8 mm).

Stent-Graft Design

The original Wallgraft Endoprosthesis was a self-expanding cobalt superalloy Wallstent to which polyethylene terephthalate graft material was bonded with a thin layer of siliconate. The first-generation device, which had to be manually mounted on the delivery device, was used in the first 9 patients (2 femoral and 7 popliteal aneurysms).

The second-generation Wallgraft, which is

TABLE 2
Demographics of 17 Patients Undergoing Wallgraft Implantation in the Femoropopliteal Segment

Men	13 (76.4%)
Mean age, y	72.4 ± 9.2
Angina	6 (35.2%)
Prior myocardial infarction	6 (35.2%)
Congestive heart failure	1 (5.8%)
Hypertension	12 (70.5%)
Diabetes mellitus	4 (23.5%)
Hyperlipidemia	5 (29.4%)
Chronic obstructive pulmonary disease	4 (23.5%)
Chronic renal failure	3 (17.6%)
Cerebrovascular accident	1 (5.8%)
Current tobacco use	4 (23.5%)

composed of a braided polyester graft bonded to the outside of a Wallstent with a thin layer of polycarbonate urethane, is premounted on the Unistep Plus (Boston Scientific/Medi-tech) delivery system, making delivery and placement significantly faster, easier, and more accurate. The prosthesis is radiopaque and has tracer wires braided with the stent to distinguish it from a Wallstent under fluoroscopy. The Wallgraft is available in diameters of 6 to 12 mm and lengths of 20, 30, 50, and 70 mm with a delivery system that is ≤11 F and has a 90-cm working length. The central lumen accommodates a 0.035-inch guidewire.

Implantation Technique

After giving informed consent, the patient was taken to the angiography suite, where a subcutaneous injection of lidocaine was used for local anesthesia of the femoral access site if general anesthesia was not used. A 13-cm, 9- to 11-F valved sheath was introduced percutaneously and advanced over a 0.035-inch guidewire into the femoral artery. Heparin was administered intravenously as needed to maintain an activated coagulation time (ACT) between 200 and 250 seconds. Based on lesion characteristics documented by on-table angiography of the lower limb, a Wallgraft was sized 1 to 2 mm larger than the proximal reference vessel diameter and at least 2 cm longer than the aneurysm for adequate fixation to normal vessel wall.

The endoprosthesis was positioned under fluoroscopic guidance and deployed by retracting the valve body, which allowed the self-expanding stent-graft to enlarge until equilibrium was attained between the elastic resistance of the vessel wall and the dilating force of the prosthesis. The endograft was then dilated to ensure optimal apposition to the vessel wall. Multiple stent-grafts were overlapped by at least 1 cm. A final angiogram was performed to verify exclusion of the aneurysm, and the femoral sheath was removed when the ACT was ≤150 seconds. All patients were discharged on aspirin (325 mg/d).

Patients were examined at 1, 3, and 6 months and yearly thereafter using duplex ultrasound to evaluate arterial patency and aneurysm exclusion. If the duplex findings did not adequately visualize the aneurysm, a CT scan was performed.

Definitions and Statistical Analysis

Acute procedural success was defined as complete exclusion of the aneurysm immediately after implantation of the endograft. Device failure was the inability to deliver or deploy the device, while procedural failure resulted from conversion to surgery or an endoleak that did not resolve by the initial follow-up visit. The exclusion rate was the percent of patients with an excluded aneurysm at follow-up without perioperative death, limb loss, or surgical crossover. Composite success was freedom of death, bypass, or reintervention due to the device or procedure. Cumulative patency rates were calculated by the Kaplan-Meier life-table method.

RESULTS

Acute procedural success was 100% for the femoral artery aneurysms and 92% for those in the popliteal artery; this single procedural failure was due to a small endoleak that resolved after the 1-month follow-up. No device failures occurred at the time of the procedure, and no blood transfusions were necessary. The mean length of stay for the entire cohort was 2.2 ± 3.8 days.

Eleven prostheses were placed in the 7 femoral arteries: 3 aneurysms required 1 stent-

graft and 4 needed tandem devices to successfully complete the procedure. Four of the 11 stent-grafts were 8 mm, 2 were 10 mm, and 5 were 12 mm in diameter. The mean length of the implanted femoral prostheses was 82.4 ± 35.2 mm.

In the popliteal artery, 19 stent-grafts were placed in 13 lesions: single devices were used in 8 aneurysms, while 4 aneurysms required 2 stent-grafts and 1 needed 3. Three of the stent-grafts were 6 mm, 7 were 8 mm, 2 were 10 mm, and 7 were 12 mm in diameter. The mean length of the implanted prostheses was 97.0 ± 37.4 mm.

Seventeen patients were available for the 6-month follow-up, after which 3 patients died of unrelated causes, leaving 14 patients for examination at 1 year. At both time intervals, the exclusion rates were 100% for both the femoral and popliteal aneurysms, as was the 1-year primary patency rate for the femoral aneurysms. Primary patency in the popliteal aneurysms (Fig. 2) was 77% at 6 months and 69% at 1 year. The secondary patency rate was 100% for the femoral and 92.3% for the popliteal artery aneurysms.

Stent-graft thrombosis was not seen in any of the femoral arteries, but 4 (31%) popliteal endografts thrombosed. Three occlusions occurred in 6-mm-diameter grafts, and the other in a 12-mm graft; 2 cases were in first-generation (unmounted) devices. In the patient with the 12-mm graft, proximal shortening or migration of the stent-graft at the 6-month follow-up prompted placement of an additional Wallgraft following locally infused, intra-arterial thrombolytic therapy. Two other patients were treated with lytic therapy and dilation of the stent-graft; in one, the thrombotic occlusion was diagnosed 7 months following the procedure, but there was no evidence of restenosis or stent-graft deformity. The patient had only 2-vessel runoff.

The fourth patient had 3 thrombotic episodes at 12, 40, and 90 days in a femoral–posterior tibial venous bypass graft that had Wallgrafts deployed to cover proximal and distal anastomotic aneurysms. Although the thromboses were successfully recanalized, the patient underwent a redo bypass procedure after the third episode; fortunately, no lower extremity embolic or ischemic complications resulted from the thrombotic episodes.

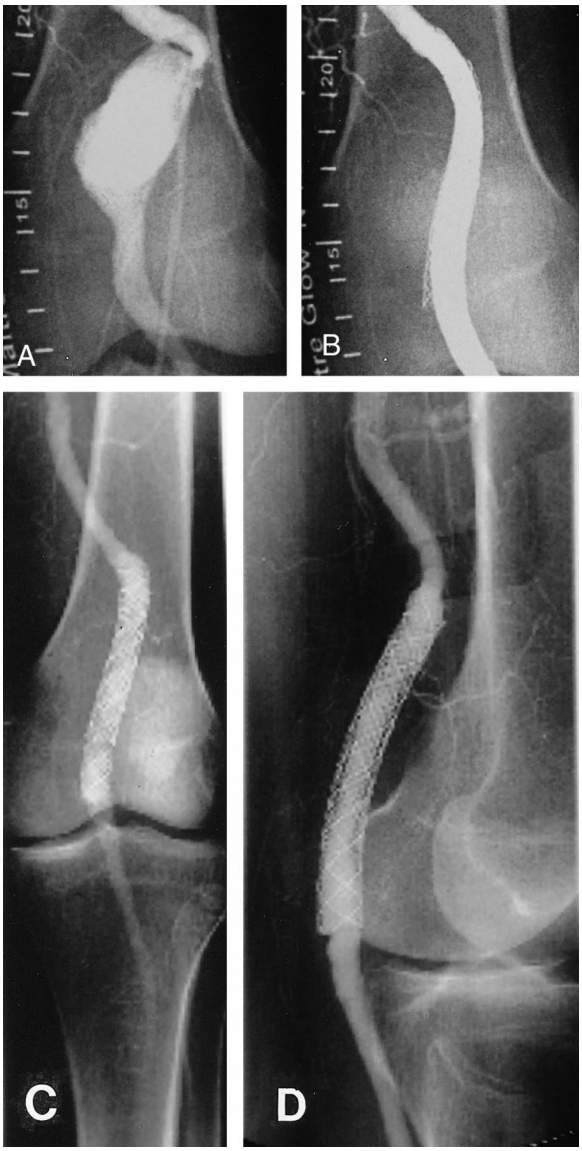

Figure 2 ◆ Angiograms before **(A)** and immediately after **(B)** placement of a Wallgraft Endoprosthesis in a patient with a popliteal artery aneurysm. A 1-year follow-up angiographic study in both anteroposterior **(C)** and oblique **(D)** views shows continued successful exclusion of the popliteal aneurysm.

These reinterventions and single failure resulted in a 92% secondary patency rate at 1 year for the popliteal aneurysms, while there were no failures of the femoral endoprostheses. No clinical restenosis was observed in

any of the stent-grafts. One-year composite success was 100% for femoral aneurysms and 69% for popliteal aneurysms.

DISCUSSION

Isolated femoral aneurysms account for approximately one third of peripheral aneurysms and have a much more benign natural history than do the more common popliteal artery aneurysms.[1] Complication rates between 18% to 35% have been reported for patients who are not treated,[1–3] and the limb loss rate is high following a thromboembolic event.[3] Thus, treatment strives to prevent lower extremity embolism and limb loss.

Surgical management is currently the treatment of choice for these aneurysms, especially if the patients are symptomatic. Five-year patency rates after surgical repair are 91% for asymptomatic aneurysms, but only 54% in patients with symptoms. Surgical mortality is low, ranging from 0% to $<$1% in asymptomatic patients and 2.1% in acute patients.[1] However, morbidity rates as high as 30% to 40% have been reported, usually associated with wound complications.[15,16]

Compared with conventional surgical treatment, percutaneous endoluminal exclusion of lower extremity aneurysms is a minimally invasive procedure that can result in less blood loss, quicker recovery, and shorter hospital stay.[4–6,8] However, given the currently available stent-graft designs, a percentage of aneurysms are not amenable to percutaneous exclusion because of their position at the hip or knee joint or the branching of major vessels.

Owing to these limitations and the low incidence of femoropopliteal aneurysms, the experience with endoluminal grafting for aneurysm disease in this vessel segment has been limited and largely ancedotal.[9,10,17–26] In these reports, a variety of stents (Palmaz, Cragg, Wallstent, or Gianturco) covered with polytetrafluoroethylene (PTFE), polyester, polyurethane, or autologous vein were used. The early models, polyester and PTFE grafts supported by stents, were only marginally successful,[17] but more recently, encouraging preliminary results were achieved with Wallstent-PTFE and the Wallgraft (Wallstent covered by a polyester graft) for endoluminal treatment of popliteal aneurysms.[23,24] Burger et al.[26] have also observed good early outcomes with the Hemobahn stent-graft, which consists of a flexible nitinol framework to which thin-walled PTFE graft material has been affixed internally.

Because the popliteal artery is in a very dynamic anatomical segment, rigid stents such as the Palmaz model have demonstrated compression and deformity in this area.[9,18] Self-expanding stent-grafts, however, are more flexible and resist external deformation.[23,24,26] Nonetheless, the manufacturers recommend that these devices not be placed across joints because of potential problems of metal fatigue over long periods of time. Although we observed no deformity of the Wallgraft, we did encounter 4 episodes of thrombotic occlusion, 3 of which occurred in the smallest diameter graft and 2 in the first-generation devices. All of these episodes were successfully treated with local thrombolysis, and only 1 patient required surgery due to recurrent thrombosis.

There were some limitations to the investigation, however. This was not a randomized trial or a direct comparison to surgical treatment, and the stent-graft design was changed in the middle of the study. Not all patients underwent CT scans during follow-up, and duplex ultrasound is not sufficiently sensitive to give precise aneurysm diameters, so we were unable to document the exact change in size of the aneurysm after exclusion.

In summary, treatment of isolated femoral and proximal popliteal artery aneurysms is safe and effective with the Wallgraft Endoprosthesis at up to 1 year, particularly in the femoral artery. Even though the early results show a disconcerting incidence of endograft thrombosis in the popliteal artery, the secondary patency rates and lack of distal embolism and amputation are encouraging. Longer follow-up will be needed to determine if this device offers comparable results to surgical repair of aneurysms in the femoropopliteal segment.

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REFERENCES

1. Graham LM. Femoral and popliteal aneurysms. In: Rutherford RB, ed. *Vascular Surgery.* 5th ed. Philadelphia: WB Saunders Co.; 2000:1345–1356.
2. Vermilion BD, Kimmins SA, Pace WG, et al. A review of 147 popliteal artery aneurysms with long-term follow-up. *Surgery.* 1981;90:1009–1014.
3. Rosenthal D, Atkins CP, Shuler FW, et al. Popliteal artery aneurysm treated with a minimally invasive endovascular approach: an initial report. *J Endovasc Surg.* 1998;5:60–63.
4. Curti T, Stella A, Rossi C, et al. Endovascular repair as first-choice treatment for anastomotic and true iliac aneurysms. *J Endovasc Ther.* 2001;8:139–143.
5. Henry M, Amor M, Henry I, et al. Endovascular treatment of internal iliac artery aneurysms. *J Endovasc Surg.* 1998;5:345–348.
6. Nagarajan M, Chandrasekar P, Krishnan E, et al. Repair of iliac artery aneurysms by endoluminal grafting. *Tex Heart Inst J.* 2000;27:250–252.
7. Lacroix H, Stockx L, Wilms G, et al. Transfemoral treatment for iliac occlusive disease with endoluminal stent-grafts. *Eur J Vasc Endovasc Surg.* 1997;14:204–207.
8. Diethrich EB. Endoluminal grafting in the treatment of iliac and superficial femoral artery disease. *Tex Heart Inst J.* 1997;24:185–192.
9. Diethrich EB, Papazoglou K. Endoluminal grafting for aneurysmal and occlusive disease in the femoropopliteal arteries: early experience. *J Endovasc Surg.* 1995;2:225–239.
10. Rodriguez-Lopez JA, Soler L, Werner A, et al. Long-term follow-up of endoluminal grafting for aneurysmal and occlusive disease in the superficial femoral artery. *J Endovasc Surg.* 1999;6:270–277.
11. Lundquist PB, Kalin B, Olofsson P, et al. Endovascular treatment of atherosclerotic lower limb lesions using a PTFE-collared stent-graft. *J Endovasc Ther.* 2000;7:221–226.
12. Bauermeister G. Endovascular stent-grafting in the treatment of superficial femoral artery occlusive disease. *J Endovasc Ther.* 2001;8:315–320.
13. Brodmann M, Stark G, Pabst E, et al. Osteomyelitis of the spine and abscess formation in the left thigh after stent-graft implantation in the superficial femoral artery. *J Endovasc Ther.* 2000;7:150–154.
14. Kessel DO, Wijesinghe LD, Robertson I, et al. Endovascular stent-grafts for superficial femoral artery disease: results of 1-year follow-up. *J Vasc Interv Radiol.* 1999;10:289–296.
15. Wengrovitz M, Atnip RG, Gifford RM, et al. Wound complications of autogenous subcutaneous infrainguinal arterial bypass surgery: predisposing factors and management. *J Vasc Surg.* 1990;11:156–163.
16. Schwartz ME, Harrington EB, Schanzer H. Wound complications after in situ bypass. *J Vasc Surg.* 1988;7:802–807.
17. Rousseau H, Gieskes L, Joffre F, et al. Percutaneous treatment of peripheral aneurysms with the Cragg Endopro System. *J Vasc Interv Radiol.* 1996;7:35–39.
18. Marin ML, Veith FJ, Panetta TF, et al. Transfemoral endoluminal stented graft repair of a popliteal artery aneurysm. *J Vasc Surg.* 1994;19:754–757.
19. Muller-Julsbeck S, Link J, Scharzenberg H, et al. Percutaneous endoluminal stent and stent-graft placement for the treatment of femoropopliteal aneurysms: early experience. *Cardiovasc Intervent Radiol.* 1999;22:96–102.
20. Puech-Leão P, Kauffman P, Wolosker N, et al. Endovascular grafting of a popliteal aneurysm using the saphenous vein. *J Endovasc Surg.* 1998;5:64–70.
21. van Sambeek MRHM, Gussenhoven EJ, van der Lugt A, et al. Endovascular stent-grafts for aneurysms of the femoral and popliteal arteries. *Ann Vasc Surg.* 1999;13:247–253.
22. Henry M, Amor M, Cragg A, et al. Occlusive and aneurysmal peripheral arterial disease: assessment of a stent-graft system. *Radiology.* 1996;201:717–724.
23. Krajcer Z, Diethrich EB. Successful endoluminal repair of arterial aneurysms by Wallstent prosthesis and PTFE graft: preliminary results with a new technique. *J Endovasc Surg.* 1997;4:80–87.
24. Kudelkoll PE, Alfaro-Franco C, Diethrich EB, et al. Successful endoluminal repair of a popliteal artery aneurysm using the Wallgraft endoprosthesis. *J Endovasc Surg.* 1998;5:373–377.
25. Dorros G, Joseph G. Closure of a popliteal arteriovenous fistula using an autogenous vein covered Palmaz stent. *J Endovasc Surg.* 1995;2:177–181.
26. Bürger T, Meyer F, Tautenhahn J, et al. Initial experiences with percutaneous endovascular repair of popliteal artery lesions using a new PTFE stent-graft. *J Endovasc Surg.* 1998;5:365–372.