Peripheral Interventions

Comparison of WALLGRAFT™ and WALLSTENT® for Treatment of Complex Iliac Artery Stenosis and Occlusion

Preliminary Results of a Prospective Randomized Study

Zvonimir Krajcer, MD
Geraldo Sioco, MD
Tim Reynolds, MD

We performed a prospective randomized study to compare the use of a bare metal stent (WALLSTENT® Endoprosthesis) with use of a covered stent (WALLGRAFT™ Endoprosthesis)—both made by Schneider, Inc.; Minneapolis, Minn—for the treatment of complex iliac artery stenosis and occlusion. We report the preliminary results of a study performed at our institution from 1 February 1997 through 31 April 1997.

The patient group was composed of 6 women and 4 men, with a mean age of 61.8 years (range, 47 to 73 years). Six WALLGRAFT endoprostheses (4 in the left iliac artery and 2 in the right) and 9 WALLSTENT endoprostheses (5 in the left iliac artery and 4 in the right) were implanted. The mean percent stenosis before treatment was similar in both groups (84.17% in the WALLGRAFT group and 82.14% in the WALLSTENT group). The post-treatment stenosis and peak systolic gradients were negligible or zero in both groups. The devices were safely deployed and technical success (<30% residual stenosis) was achieved in both groups. The mean thigh-brachial index was similar in the 2 groups, both before treatment (0.65 in the WALLGRAFT group and 0.64 in the WALLSTENT group) and after treatment (1.12 in the WALLGRAFT group and 1.12 in the WALLSTENT group). Evaluation of clinical success revealed that symptoms of intermittent claudication improved markedly in 4 of 5 patients who received the WALLGRAFT Endoprosthesis. In the WALLSTENT group, 1 patient had symptomatic improvement, another had 1 limb improve and the other worsen, and the rest had no improvement. Clinical complications were observed in only 1 patient in the WALLGRAFT group and in 2 patients in the WALLSTENT group.

These preliminary results indicate very good technical and early success at the 1-month follow-up with the use of the WALLGRAFT Endoprosthesis in complex iliac artery stenosis and occlusion. Despite these promising preliminary results, a longer follow-up study with a larger number of patients is needed to determine the benefits of the WALLGRAFT Endoprosthesis in patients with complex iliac artery stenosis or occlusion. ***(Tex Heart Inst J 1997;24:193-9)***

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From: *The Department of Cardiology, Texas Heart Institute and St. Luke's Episcopal Hospital, Houston, Texas 77030*

Address for reprints: *Zvonimir Krajcer, MD, Suite 2780, 6624 Fannin, Houston, TX 77030*

Restenosis rates with the use of percutaneous transluminal angioplasty (PTA) and bare metal stents are significantly higher in vessels with complex iliac artery stenosis and occlusions than in short lesions and in vessels that are not totally occluded.[1] Balloon angioplasty in the iliac and femoropopliteal arteries is generally most successful when applied to short, concentric stenoses, and less successful with complex lesions that are long, eccentric, calcified, or occluded. The most common mechanism of restenosis is the development of fibrointimal hyperplasia after PTA and stenting.[2] During the past 2 decades, bypass grafting has been the standard method of aortoiliac repair.[3] Arterial bypasses with prosthetic grafts made of materials such as polyester are associated with a patency rate of greater than 95% at 1 year.[4] In this study, we report the use of a covered stent and a bare stent for treatment of complex iliac artery lesions and occlusions. We hypothesized that the use of a covered endoprosthesis might improve the restenosis rate by preventing fibrointimal hyperplasia and tissue growth within the stent.

Methods

This prospective randomized study was undertaken at our institution from 1 February 1997 through 31 April 1997 in order to compare the efficacy of the covered metal stent (WALLGRAFT™ Endoprosthesis) with that of the bare metal stent (WALLSTENT®) in the treatment of complex iliac artery lesions. Both products are made by Schneider, Inc. (Minneapolis, Minn). Another objective was to determine if the WALLGRAFT could be accurately and safely deployed in the iliac arteries.

The study was approved by our institutional review board under the investigational drug exempt protocol. The participating patients were judged eligible for the study in accordance with the inclusion criteria, and they gave their informed consent. They were then randomized to treatment with the WALLGRAFT or WALLSTENT endoprosthesis. Pre-treatment and post-treatment clinical and angiographic data were collected.

Inclusion Criteria. Patients were considered eligible for the study if their test results showed angiographic evidence of a lesion located in the common or external iliac artery with a stenosis of 50% or greater, or with a total occlusion. In addition, the iliac artery stenosis had to be 1) more than 3 cm in length, 2) calcified or eccentric and less than 3 cm in length, or 3) totally occluded.

Exclusion Criteria. Patients were excluded from the study if their clinical evaluations or medical history revealed any of the following:

- A thigh-brachial index (TBI) greater than 0.90 (normal);
- A Society for Vascular Surgery (SVS)[5] clinical category of zero (asymptomatic);
- A contraindication for antiplatelet, anticoagulant, or thrombolytic agents;
- The presence of a profunda femoris and superficial femoral artery occlusion within the limb supplied by the iliac artery to be treated;
- Unsuccessful passage of the guidewire and the accessories used for access;
- Perforation at the angioplasty site;
- A persistent acute intraluminal thrombus at the proposed lesion site;
- Previous treatment of lesions with the use of bare metal stents;
- Previous ipsilateral bypass of the iliac artery under consideration;
- An abdominal aortic aneurysm greater than 5 cm in diameter;
- An iliac artery aneurysm;
- An anticipated life expectancy of less than 1 year; or
- Previous randomization of the opposite iliac artery in this study during an earlier hospital stay.

Clinical and Angiographic Data. Clinical data included segmental pressure measurements, Doppler wave recordings, determination of SVS clinical category, and completion of a walking impairment questionnaire. Angiographic data included lesion length, percent stenosis, lesion characteristics, systolic gradients, and residual stenosis. Technical success was defined as less than 30% stenosis in the treated lesion immediately after the procedure. Deployment difficulties such as device misplacement and delivery system failure were recorded in order evaluate the ease of use of the WALLGRAFT Endoprosthesis. The safety profile included variables such as: device migration; bleeding requiring transfusion; complications requiring a surgical procedure; stroke; and death.

After diagnostic peripheral angiography was completed and the patient was randomized, stenting was performed during the same time period or within the same hospital stay. If the patient had bilateral limbs to be treated in the study, both limbs received the identical randomized treatment.

Materials and Techniques

The target lesion was dilated prior to deployment of the endoprosthesis. A 9-F Unistep™ LS Delivery System (Schneider) was used with the WALLGRAFT Endoprosthesis (Fig. 1). The procedure was performed in a cardiac catheterization laboratory, with the use of local anesthesia for access via the ipsilateral or contralateral groin. An appropriately sized hemostatic introducing sheath was used (1 F larger than the delivery system, approximately 10 to 12 cm long). The lesion length was calculated and the nominal implanted diameter considered. After allowing for possible shortening of the endoprosthesis consequent to continued expansion after implantation, we selected an endoprosthesis that was longer than the minimum length needed for adequate coverage.

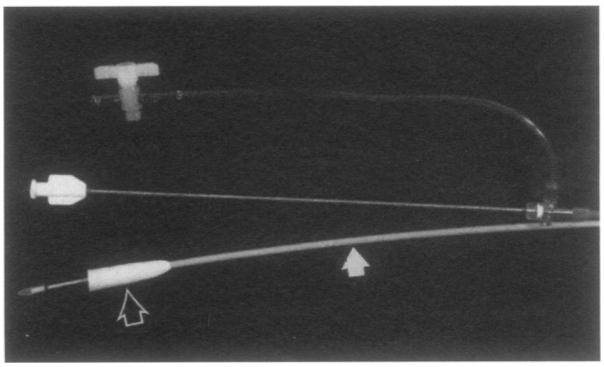

Fig. 1 *A partially exposed WALLGRAFT Endoprosthesis (open arrow) mounted on a Unistep LS Delivery System (solid arrow).*

The WALLGRAFT Endoprosthesis was mounted on the delivery device. The delivery system was primed with sterile saline, mounted on the guidewire, and inserted into the introducer sheath. The endoprosthesis was then advanced across the site of the previously dilated lesion. The leading and trailing marker bands (which define the constrained length of the endoprosthesis) were aligned with the target vessel segment. With the stainless steel tube immobilized, the valve body was gently pulled along the stainless steel tube to deploy the endoprosthesis. After the endoprosthesis was correctly positioned and fully deployed, the delivery system was withdrawn.

An angiogram was obtained after implantation to confirm the proper location of the endoprosthesis. Balloon dilation was performed to achieve maximal lumen diameter and to ensure good apposition of the endoprosthesis to the vessel wall (Fig. 2). The vessel diameter and peak systolic gradient were then measured.

A follow-up duplex scan was performed for verification of lesion patency if any of the following conditions occurred: loss of the femoral pulse, a greater than 0.15 decrease in the TBI, or a change in the SVS clinical category. In patients with non-compressible arteries, a duplex scan was performed if there was a decrease in the pulse volume recordings (PVR) or in the Doppler wave recording. If the duplex scan could not be performed or there was doubling of the peak systolic velocity within the stent (indicating ≥25% stenosis), angiography was used to evaluate patency.

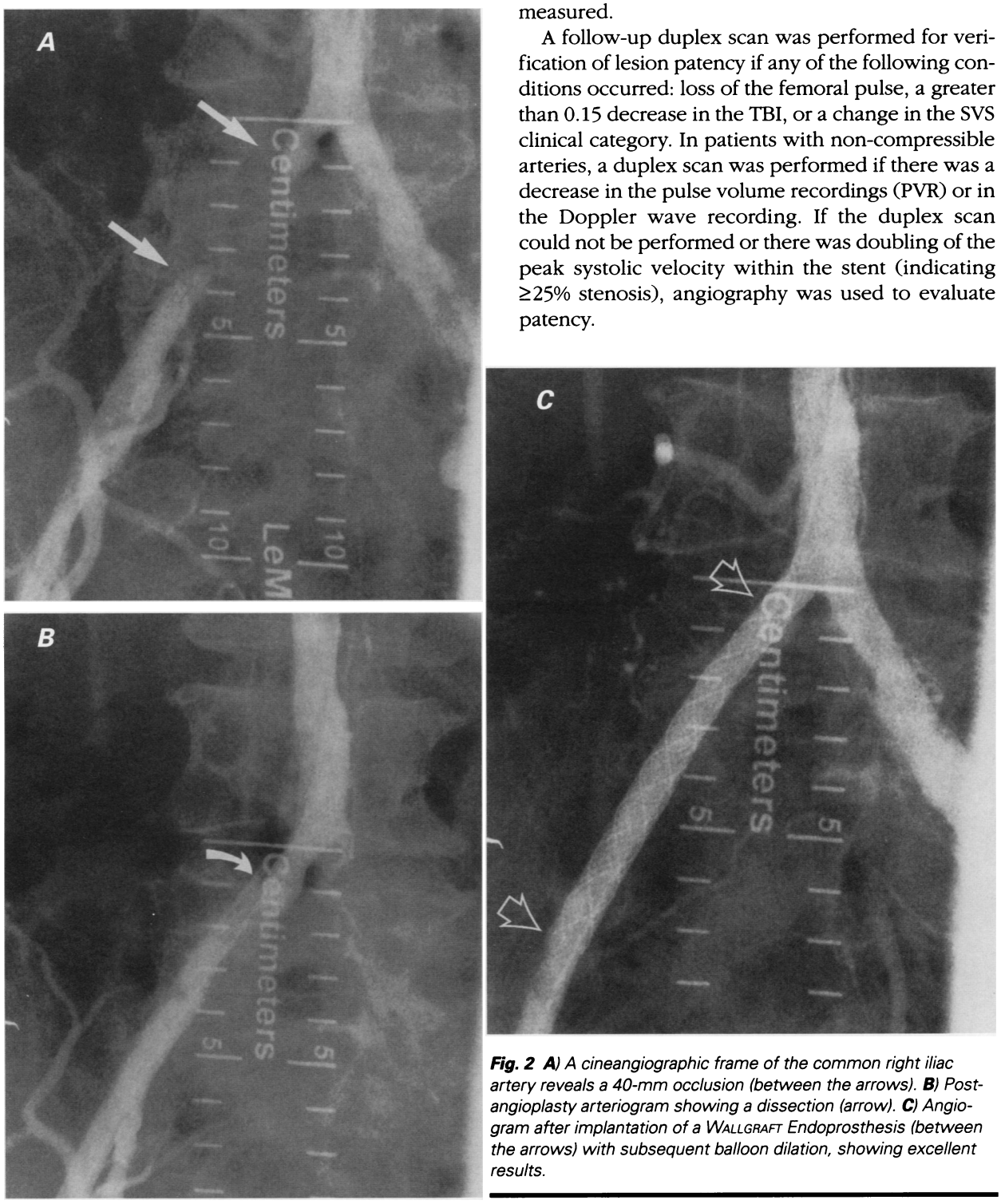

Fig. 2 ***A****) A cineangiographic frame of the common right iliac artery reveals a 40-mm occlusion (between the arrows).* ***B****) Post-angioplasty arteriogram showing a dissection (arrow).* ***C****) Angiogram after implantation of a WALLGRAFT Endoprosthesis (between the arrows) with subsequent balloon dilation, showing excellent results.*

The anticoagulation regimen called for all patients to receive intravenous heparin (5,000 units) during the procedure. They were also given aspirin (325 mg) at least 1 day before the procedure and then daily throughout the follow-up period. Additional anticoagulation treatment was administered at the discretion of the investigator.

Results

Ten patients (6 women and 4 men) were enrolled in this study. Their ages ranged from 47 to 73 years (mean age, 61.8 years). Six WALLGRAFT endoprostheses were deployed (4 in the left iliac artery and 2 in the right). Nine WALLSTENT endoprostheses were deployed (5 in the left iliac artery and 4 in the right). The mean percent stenosis of the target lesion was similar in the 2 groups. The mean peak systolic gradient was slightly greater in the WALLGRAFT group. The post-treatment stenosis and peak systolic gradients were negligible or zero in both groups. In the WALLGRAFT group, the mean TBI before treatment was 0.65, which improved to 1.12 at the 1-month follow-up (Table I).

WALLGRAFT Group. Data analysis of clinical success parameters revealed that patients 1, 2, 3, and 5 who received the WALLGRAFT Endoprosthesis experienced major improvement in their symptoms of intermittent claudication (Table I). In this group, baseline claudication symptoms had been moderate or severe in all 5 patients before treatment. None of the patients showed signs of claudication at the 1-month follow-up evaluation, as indicated by the SVS clinical category, distance to claudication, or the walking impairment questionnaire.

There were no complications related to the technical aspects of the delivery and deployment of the WALLGRAFT Endoprosthesis with the Unistep LS Delivery System. The device was safely deployed and technical success (<30% residual stenosis) was achieved in all patients. Only patient number 2 in this group had a clinical complication, which was angina, experienced the day after the procedure. This patient had a history of angina and her angina was thought to be unrelated to the use of the endoprosthesis. The patient was discharged but was later readmitted with abdominal pain, diarrhea, and tachycardia. This episode was thought to be caused by ticlopidine, which was discontinued. The patient's diarrhea was treated empirically with metronidazole, and her symptoms were alleviated.

WALLSTENT Group. Technical success (<30% residual stenosis immediately after treatment) was achieved in all the patients in this group. However, 4 of 5 patients still had moderate or severe claudication at follow-up.

Patient number 6 showed no improvement of claudication after treatment. This lack of improvement was attributed to the presence of more distal disease, as evidenced by the ankle–brachial indices. Patient number 7 continued to have a severe SVS clinical score secondary to pre-existing gangrene of the toes; subsequently they had to be amputated. This patient later underwent a left femoropopliteal bypass for ischemic changes in the left foot and a left superficial artery occlusion. This surgery had been planned before the patient's enrollment in the study.

In patient number 8, claudication of the right lower extremity worsened after treatment due to an occlusion in the treated segment. Because of a right external iliac artery stenosis and dissection that was not originally stented, the patient was given another WALLSTENT endoprosthesis at this site via a left brachial approach. The stented site in the left iliac artery was patent. Thirty-one days after the initial treatment, the right iliac artery became reoccluded (possibly because of a residual dissection) and the patient received a 3rd WALLSTENT. Intra-arterial urokinase (500,000 units) was administered during this procedure at the site of the WALLSTENT thrombosis. This patient's procedural angiogram of the 1st WALLSTENT implantation, analyzed retrospectively, revealed a 50% stenosis in the external iliac artery that was not stented. The patient remained asymptomatic after the 3rd intervention.

Three of the 10 patients in this study have undergone repeat angiography, as described here. Patient 4 had ulcerative and gangrenous right toes. Angioplasty of the right posterior tibial artery was performed during the WALLGRAFT implantation. Approximately 3 weeks later, the patient presented with a severe ischemic right leg and subsequently underwent a right femorotibial bypass. The bypass was occluded a week later and the patient required amputation of the right leg below the knee. A month later, the patient presented with pain and gangrene of the left 3rd and 4th toes, necessitating a femoropopliteal bypass in the left lower leg. Patient 9 had peripheral angiograms performed when he returned for angioplasty of a right renal artery in-stent restenosis. The angiogram showed the WALLSTENT in the right iliac artery to be patent. Patient 8 had repeat angiograms because of recurrent claudication of the right leg; these showed the left iliac artery to be patent and the right iliac artery to be occluded.

Discussion

Atherosclerotic occlusive disease commonly occurs in the aortoiliac segments. Prosthetic arterial bypasses have constituted the standard treatment for lower extremity ischemia due to extensive aortoiliac

TABLE I. Clinical Characteristics and Results in 10 Patients Receiving Endoprostheses

				Lesion Characteristics				Thigh-Brachial Index (TBI)		SVS/Fontaine/WI		
				Pre-Treatment		Post-Treatment		Pre-Treatment	Post-Treatment	Pre-Treatment	Post-Treatment	
Pt. No.	Sex	Prosthesis	Limb	% Stenosis	Sys Grad	% Stenosis	Sys Grad		(1-mo. follow-up)		(1-mo. follow-up)	Complications
1	F	WALLGRAFT	L	90	NA	20	NA	0.67	1.34	Severe	None	No
2	F	WALLGRAFT	L	70	40	0	0	0.76	1.10	Severe	None	Yes
			R	85	60	0	0	0.73	1.15	Severe	None	Yes
3	F	WALLGRAFT	L	90	NA	0	0	0.83	1.21	Moderate	None	No
4	F	WALLGRAFT	L	70	10	0	0	0.49	1.00	Rest pain	NA	No
5	F	WALLGRAFT	R	100	60	0	0	0.44	0.92	Moderate	None	No
6	M	WALLSTENT	L	70	30	0	0	0.65	1.02	Moderate	Moderate	No
7	M	WALLSTENT	L	80	40	10	0	NA	NA	Tissue loss	Severe	Yes
8	F	WALLSTENT	L(x2)	85	50	0	0	0.71	1.00	Mild	None	No
			R	90	60	0	0	0.17	0.69	Mild	Severe	Yes
9	M	WALLSTENT	R(x2)	80	24	0	0	0.84	0.73	Severe	Severe	No
10	M	WALLSTENT	L	75	10	0	0	NA	1.33	None	None	No
			R	95	40	0	0	0.85	1.93	Moderate	None	No
Mean		WALLGRAFT		84.17	42.50	3.33	0	0.65	1.12			
Mean		WALLSTENT		82.14	36.29	1.43	0	0.64	1.12			

NA = not available; SVS = Society for Vascular Surgery clinical category; sys grad = systolic gradient; WIQ = walking impairment questionnaire

occlusive disease.[6] In 1 study,[7] reconstructive surgery in the aortofemoral and iliofemoral arteries resulted in patency rates exceeding 80% at 5 years and 70% at 10 years.

In the early days of percutaneous management of peripheral vascular disease, balloon angioplasty was the primary method used. The patency rates after angioplasty are somewhat lower than those of arterial bypass surgery: iliac angioplasty has an average success rate of approximately 75% at 1 year, 60% at 3 years, and 53% at 5 years.[3] Percutaneous transluminal angioplasty (PTA) is the treatment of choice for iliac artery stenoses that are short, concentric, and focal; the 1-year patency is 90% or greater in this subgroup.[1,5]

More recently, the treatment of peripheral vascular disease with intravascular stents via a percutaneous approach has gradually gained acceptance.[8] Initially, the peripheral stent was used in order to solve acute problems associated with balloon angioplasty, such as dissection, recoil, and residual stenosis. In the iliac arteries, the rate of restenosis is lower with use of angioplasty and the stent than it is with angioplasty alone. With or without a stent, the results have been less satisfactory when angioplasty has been applied to long, eccentric, calcified iliac arteries and long segments of arterial occlusive disease.[2] These results are presumably due to the combination of a highly thrombogenic flow surface and the extensive intimal damage resulting from the angioplasty procedure.[5]

The endovascular stented graft offers a theoretical advantage in that it presents a relatively nonthrombogenic surface to completely reline the endothelial vessel wall, which is dilated and frequently disrupted and dissected. Because prosthetic vascular grafts in the aortoiliac segment have traditionally yielded excellent long-term patency rates, it might be anticipated that comparable patency rates could be achieved with the use of similar grafts in the endoluminal position.[5] Different graft materials have been used in the treatment of severe peripheral vascular disease, each with advantages and disadvantages. Dacron, polyurethane, and polyesters (PET) are some examples of graft materials that have been used. Fabrics for use in endoprostheses must match the performance characteristics of those used in conventional operations. The fabric must be as thin as possible to allow for a low-profile device, yet it must have long-term stability. The most durable thin-walled fabrics are woven, not knitted. Although conventional knitted fabrics are an advantage because of better tissue incorporation, this property may not be important for an endoprosthesis. Crimped fabrics are less likely to kink. Therefore, a crimped, woven graft with a very low profile appears to be the best option.[9]

There is some concern about an acute inflammatory reaction that can occur after the use of polyester-covered stents. This reaction occasionally results in cell proliferation and potential occlusion of the stented segment. It is postulated that the local inflammatory reaction may be related to the physical properties of polyester fibers.[10] Dacron is a knitted fabric and lacks the radial expansion characteristics of polytetrafluoroethylene (PTFE). There is some evidence that Dacron is more thrombogenic than PTFE, especially in small vessels.[11] Nonetheless, Dacron is preferable for a large conduit bypass because of its ease of handling and its saturability. The lower thrombogenicity of PTFE has made it the preferred material in small-caliber vessels. Synthetic elastomers constitute another class of possible graft materials; among these, polyurethane is the most durable and elastic.[12]

Stented grafts are being used for exclusion of arterial aneurysms involving the iliac and popliteal arteries and the abdominal aorta.[8,12] In this study we used the WALLSTENT Endoprosthesis and the WALLGRAFT Endoprosthesis, which is a WALLSTENT covered with a polyester graft material. Arterial bypasses using prosthetic grafts made of polyester are associated with patency rates exceeding 95% at 1 year.[13]

We have presented preliminary results achieved with our 1st 10 patients enrolled in a prospective randomized trial comparing a covered stent (WALLGRAFT) to a bare metal stent (WALLSTENT) for treatment of complex iliac artery lesions and occlusions. Our preliminary data from the 1-month follow-up indicate very good technical and early clinical success with use of the WALLGRAFT. We anticipate that the use of a covered endoprosthesis, such as the WALLGRAFT, might improve the restenosis rate in comparison with percutaneous transluminal angioplasty and bare stents, by preventing fibrointimal hyperplasia and tissue growth within the stent. WALLGRAFT insertion is less invasive than arterial bypass and may yield a shorter hospital stay and recovery period. When compared to the patency rates of angioplasty, with or without a bare stent, the potentially improved patency rates with the WALLGRAFT could decrease the need for reintervention. Although these preliminary results appear promising, a longer follow-up study with a larger number of patients is needed to document the benefits of the WALLGRAFT Endoprosthesis.

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