original article

Viabahn for femoropopliteal in-stent restenosis

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Ann Saudi Med 2012; 32(6): 575-582

DOI: 10.5144/0256-4947.2012.575

BACKGROUND AND OBJECTIVES: In-stent restenosis in the femoropopliteal artery is common (20%-40%). Treatment of in-stent restenosis is challenged by poor patency rate. An ePTFE-covered stent-graft (Viabahn) is inert with a very small pore size that does not allow for significant tissue in-growth. Use of a Viabahn stent-graft may improve the patency rate in the treatment of in-stent restenosis.

DESIGN AND SETTING: A retrospective chart review of the use of Viabahn stent grafts implanted in patients with symptomatic femoropopliteal artery in-stent restenosis performed from January 2004 to December 2008.

PATIENTS AND METHODS: We measured the primary patency rate using duplex ultrasound at 1 year and 3 years. We also examined the rate of secondary patency, acute limb ischemia and amputation.

RESULTS: Twenty-seven cases with in-stent restenosis of the femoropopliteal artery treated by Viabahn stent-graft were identified. The average lesion length was 24.5 cm; 52% of the lesions were total occlusion and 37% had critical limb ischemia. The 1- and 3-year primary patency rates were 85.1% and 81.4%, respectively. The secondary patency rate was 96%. All recurrent in-stent restenoses were focal at the proximal and distal edges and none had stent fracture.

CONCLUSION: Our single center experience in a small number of patients showed a favorable patency of ePTFE-covered stent-graft for treatment of patients with in-stent restenosis in the femoropopliteal artery.

In-stent restenosis (ISR) in the femoropopliteal artery (FPA) is common with 20% to 40% rate in the recent trials.[1,2] Restenosis tends to be diffuse and correlate with the length of stented segment, vessel diameter and the presence of stent fracture. Patients with ISR carry the highest risk of recurrent ISR. The results of percutaneous balloon angioplasty (PTA) alone for ISR are dismal.[3] Other modalities include bypass surgery, repeat balloon angioplasty with or without repeat stenting, use of a debulking device such as laser, directional, or orbital atherectomy with or without adjunctive angioplasty, cryoplasty, a drug-eluting balloon, brachytherapy, or use of stent-grafts. Stent-graft may prevent the tissue infiltration and intimal hyperplasia that can lead to ISR. Use of a polyester-covered stent-graft in the FPA was disappointing, with low patency, significant thrombosis rates, and significant inflammatory response.[4-6] The use of ePTFE (expanded polytetrafluorethylene)-covered stent-graft is growing and well documented.

In June 2005, the FDA approved Viabahn (formerly Hemobahn) endoprosthesis (WL Gore and Associates, Flagstaff, Arizona, United States; www.goremedical.com) for superficial femoral artery (SFA) implantation. The stent is a flexible, self-expanding endoluminal graft consisting of an ePTFE lining with an external nitinol support extending along its entire length. There is scarce data evaluating the role of the Viabahn stent-graft for ISR. The Salvage trial (a proSpective, multicenter triAL to eValuate the safety and performance of Spectranetics' laser with adjunct PTA and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface for the treatment of SFA in-stent restenosis) enrolled 27 patients for SFA ISR, which was terminated prematurely by FDA for further evaluation. We assessed the primary patency rate of Viabahn stent graft when used for bare metal ISR in the FPA.

PATIENTS AND METHODS

The peripheral vascular lab registry database at Saint Elizabeth Medical Center in Boston, Massachusetts, was interrogated to identify patients who had the Viabahn stent graft implantation for ISR in the FPA from January 2004 until December 2008. A retrospec-

tive chart review study was then conducted using the electronic medical record database, ultrasound report and images, angiographic reports and images as well as the vascular clinic medical record. The only FDA approved strategy to treat ISR is balloon angioplasty. The use of the Viabahn stent graft is an off-label use for in-stent restenosis. The initial two cases received the first verision of Viabahn and the rest received the newer generation, heparin-coated with contoured edges. Our study protocol was approved by the local review board according to our institutional guidelines.

Patient demographics including age, gender, atherosclerosis risk factors and detailed present history (whether severe claudication or critical limb ischemia) at the time of intervention and details of previous interventions were obtained from the electronic medical record. The baseline ankle-brachial index as well as arterial duplex ultrasonographic data (stenosis or total occlusion) was collected from the ultrasound database in the same institution. Angiographic data were studied from the angiographic films and further procedural details were obtained from notes, including any procedural complications owing to large sheath use. Clinical follow up was traced from the vascular clinic visit medical records. Follow-up arterial duplex ultrasound report and images were studied from a different electronic database.

During the Viabahn stent-graft procedure, all the patients received either heparin (60 U/kg) or bivalirudin. Activated clotting time (ACT) was measured 5 minutes after administration of anticoagulation; the average maximum ACT was 289 seconds. If the ACT was less than 250 seconds, an additional heparin dose (1000-2000 units) was given to target ACT >250 seconds, if the patient was already on heparin. The vessel was prepared before implantation of the Viabahn stent-graft to have a ratio of 1:1. The cutting balloon was used for ostial SFA lesions as well as for suboptimal results (undilatable lesions) after plain PTA to ensure optimal vessel preparation. Three stents were needed in the majority of patients to cover from the angiographically healthy segment to the healthy segment with at least 1 cm of stent overlap. The average Viabahn stent-graft diameter was 5.6 cm and average total length was 26.7 cm. Postdilatation was performed in all patients with extra caution to avoid dilatation outside the Viabahn stent graft margins. The average diameter, length and number of stent-graft implanated in each procedure was 5.6 mm, 274 mm, and 2.6 stent-grafts, respectively (stent-graft number ranged between 1-4 stent-grafts in each procedure). The procedural technical success rate was 100% (defined as <10% residual stenosis by visual estimation). There was only one complication, a distal embolization treated successfully by suction thrombectomy. There was no documented local complications of large sheath use, such as hematoma or pseudoaneurysm; however, arterial punctures were done under fluoroscopic guidance. Adjunctive interventions were performed in 37% of patients to insure at least one vessel runoff, but it was preferable to have two-vessel runoff as well as good inflow. At the end of the Viabahn stent-graft implantation angiogram, 21% of patients had one vessel runoff (53% at baseline), 51% had two vessels run off (21.5% at baseline), and 28% had three-vessel runoff (25% at baseline).

All the patients received clopidogrel (75 mg per day after a loading dose of 600 mg if the patient was not on clopidogrel) in addition to aspirin 81 mg daily. Clopidogrel was used for a minimum duration of 6 months and aspirin indefinitely. We also found that all patients were taking statins, β blockers and angiotensin converting enzyme inhibitors and angiotensin II receptor blockers except one, four and four patients, respectively.

We looked at the primary patency rate using duplex ultrasound at 1 year and 3 years. The definition of significant stenosis (>50%) in our laboratory is when the peak systolic velocity ratio (peak systolic velocity of the arterial segment pre-stenosis to the peak systolic velocity at the stenosis) is more than two. We also looked at the secondary patency rate in a similar manner after target lesion revascularization. We checked for any evidence of stent fracture in patients who had had recurrent ISR. Detailed clinical follow up was recorded including acute limb ischemia, amputation, stroke, myocardial infarction, and surgical revascularization. The ankle-brachial index (ABI) was not done as a surveillance tool, but arterial duplex ultrasound was performed 6 months after the procedure, then annually unless clinically indicated. The surveillance was made to rule out edge restenosis or progression of preexistent inflow or outflow disease. The Rutherford Category was not documented during clinical follow up if the patient remained asymptomatic. In addition, the Rutherford category was also affected by the presence of contralateral disease.

RESULTS

From January 2004 to December 2008, 28 limbs in 26 patients with ISR in the FPA treated by Viabahn stent graft were identified. The demographic data indicated a high-risk population with a mean age of 73 years with more than half diabetic, with chronic kidney disease or coronary artery disease (**Table 1**). The majority

Table 1. Demographic data for 26 patients and 28 limbs.

Mean age (years)	73
Female gender, %	57
Clinical presentation	
Initial bare metal stent procedure	
Intermittent claudication, n (%)	16 (57)
Critical limb ischemia, n (%)	12 (43)
Index Viabahn stent graft procedure	
Intermittent claudication, n (%)	18 (63)
Critical limb ischemia, n (%)	10 (37)
Rutherford Category, n	
3	18
4	7
5	2
6	1
Mean duration from the initial bare metal stent procedure to the index VIABAHN procedure, months (standard deviation)	29.6 (29.5)
Diabetes, n (%)	15 (55)
Hypertension, n (%)	26 (100)
Hyperlipiemia, n (%)	26 (100)
Smoking, n (%)	25 (96)
Coronary artery disease, n (%)	20 (77)
Congestive heart failure, n (%)	6 (22)
Chronic kidney disease, n (%)	14 (53)
Cerebrovascular disease, n (%)	10 (40)
Baseline ankle-brachial index	0.59
Medications, %	
Aspirin	100
Angiotensin converting enzyme Inhibitors	77
Beta blocker	85
Statin	96
Coumadin	0
Cilostazol	8

Table 2. Angiographic data.

Total occlusion, n (%)	
Initial bare metal stent procedure	23 (82)
Index Viabahn procedure	14 (50)
Stenosis, n (%)	
Initial bare metal stent procedure	5 (18)
Index Viabahn procedure	14 (50)
Average bare metal stent length, cm (standard deviation, cm)	18.5 (10.6)
Average bare metal stent diameter, mm (range)	6.4 (5-9)
Average ISR lesion length, cm (range)	24.5 (4-38)
Average vessel diameter, cm (range)	5.52 (5-8)
ISR location, n (%)	
Femoral	6 (21)
Femoropopliteal	18 (64)
Popliteal	2 (7)
Iliac	2 (7)
Previous ISR interventions before Viabahn, n (%)	
Single	4 (14)
Multiple	9 (32)
Baseline number of vessels runoff, n (%)	
One	15 (53)
Two	6 (21)
Three	7 (25)

of patients had severe intermittent claudication (63% Rutherford Category 3), but 37% had critical limb ischemia. Only one patient was taking cilostazol and no patient was taking coumadin. The average baseline and postprocedure ABIs were 0.59 (range 0.25-0.89) and 1.02 (range 0.7-1.4), respectively. In addition, the average lesion length was 24.5 cm and 52% of the lesions were total occlusions (**Table 2**). Not surprisingly, the lesion length had been lengthened from the initial bare metal stent procedure where the total average bare metal stent length was 18.2 cm. Forty-five percent of patients had prior angioplasty to treat ISR with or without laser atherectomy after the initial bare metal stenting and prior to the index Viabahn procedure. All the patients had at least one vessel runoff, and 81% had two or more vessel runoff.

The interventions data are summarized in **Table 3**; laser atherectomy was used in a third of patients followed by balloon angioplasty. **Table 4** shows a subgroup analysis comparing the lesion characteristics pretreated with laser atherectomy versus no laser atherectomy. Most of the laser atherectomy lesions were more likely to be a total occlusion and longer. There were favorable outcomes in the treatment of long ISR of the FPA disease. The one-year and three-year primary patency rates were 85.1% and 81.4%, respectively (**Table 5**). **Figure 1** shows the Kaplan-Meier curve of the re-intervention events after implantation of Viabahn stent-graft for ISR in the FPA. Five patients had recurrent ISR after Viabahn implantation, but focal ISR in both proximal and distal edges and none had stent fracture. Most of the recurrent (4/5) ISR occurred within the first year of follow up. All recurrent ISR patients had stent thromboses due to impaired inflow and outflow of the stent graft. However, only two patients presented with acute limb ischemia and three patients presented as recurrent severe intermittent claudication. Of the acute limb ischemia patients, one prematurely stopped dual antiplatelet therapy and one had prolonged knee-bending posture. Only one patient, who had 2 other recurrences

Table 3. Procedural treatments.

Laser atherectomy, n (%)	10 (35.7)
Predilatation	
Cutting balloon, n (%)	18 (64)
Balloon diameter, average; mm	5.25
Balloon pressure, average; atmospheres	14
Viabahn stent graft	
Diameter, average (range); mm	5.6 (5-8)
Total number implanted, average (range)	2.5 (1-4)
Total length, cm (standard deviation); cm	26.7 (12)
Post dilatation	
Balloon diameter, average; mm	5.5
Balloon pressure, average; atmospheres	15.6
Adjunctive Intervention	
Inflow, n (%)	7 (25)
Iliac PTA and stenting, n	5
Common femoral artery atherectomy,[a] n	2
Outflow and runoff vessels, n (%)	11 (39)
Atherectomy,[b] n	2
PTA, n	2
Stenting,[c] n	7
Profunda femoris artery PTA, n	1
Runoff vessels post-intervention, n (%)	
One	21
Two	51
Three	28

[a]One orbital atherectomy and one rotational atherectomy [b]One laser atherecomy and one orbital atherectomy [c]Two patients received Supera nitinol bare metal stents extended to the below knee popliteal artery and five patients had a drug-eluting stent at one or two of the tibial arteries.

Table 4. Subgroup analysis of laser debulking vs. no laser debulking.

	Laser Debulking (n=10)	No laser Debulking (n=18)
Clinical presentation, n		
Rutherford Category 3	4	14
Rutherford Category 4	3	4
Rutherford Category 5	2	0
Rutherford Category 6	1	0
Total occlusion, n	6	8
Lesion length, average (range), cm	25.5 (10-35)	23.2 (4-38)
Vessel diameter, average (range), cm	5.6 (5-6)	5.6 (5-6)
Average bare metal stent diameter, mm	6.4 (5-9)	
Average ISR lesion length, cm	24.5 (4-38)	
Average vessel diameter, cm	5.52 (5-8)	
Previous ISR interventions before Viabahn, %		
Single	0	4
Multiple	2	7
No. of vessels runoff,[a] n		
One	2	4
Two	6	8
Three	2	6
Viabahn stent graft		
Diameter, average	5.6	5.6
Number, n	2.8	2.5
Cutting balloon use, n	6	12
Adjunctive intervention, n		
Inflow (Iliac/Common femoral)	3[b]	3
Outflow (popliteal/crural vessels)	5	7
Target lesion revascularization, n		
Duration from index Viabahn procedure; days, average (range)	1 173	4 576 (241-1164)
Amputation		
Minor, n (time from Viabahn procedure, days)	1 (81)	0
Major, n (time from Viabahn procedure, days)	1 (182)	0

[a]No. of vessels run off before Viabahn stent graft Intervention

[b]Two out of three patients had combined inflow and outflow intervention during the index viabahn procedure

leading to a secondary patency rate of 96%, had a second recurrent Viabahn in-stent restenosis . However, the duration was relatively short (8-18 months) for the rest of the other target lesion revascularization patients. There were two patients with amputations (one minor and one major); both had a patent Viabahn stent graft by ultrasound one month after the amputation. The cause for the major amputation was extensive osteomyelitis for which the patient had a below knee amputation; the patient died a year later due to cancer.

DISCUSSION

To our knowledge this is the first reported study of the 3-year patency of Viabahn stent-graft for treatment of ISR in FPA disease. We found very favorable outcomes in the treatment of complex long FPA ISR using Viabahn stent-graft with three-year primary patency rates of 81%. Our data support the use of Viabahn stent-graft for complex long FPA ISR in a carefully selected patient population by the operator. A suggested guideline or opinion for use of Viabahn is summarized in **Table 6**. This complete guideline is formulated after the completion of the study based on the operator's experience. **Figure 2** shows one example of 54-year-old male known to have coronary artery disease and lifestyle disabling intermittent claudication (Rutherford category 3). He had had multiple interventions due to in-stent restenoses and finally became asymptomatic

Table 5. Clinical outcomes in 28 limbs of 26 patients.

Primary patency rate	
One year, %	85.1
Three year, %	81.4
Post-Procedure ABI, average	1.01
Amputation	
Major, n	1
Minor, n	1
Long term follow-up	
Stroke, n	1
Myocardial infarction, n	1
Stent fracture rate, n	0

ABI: Ankle Brachial Index

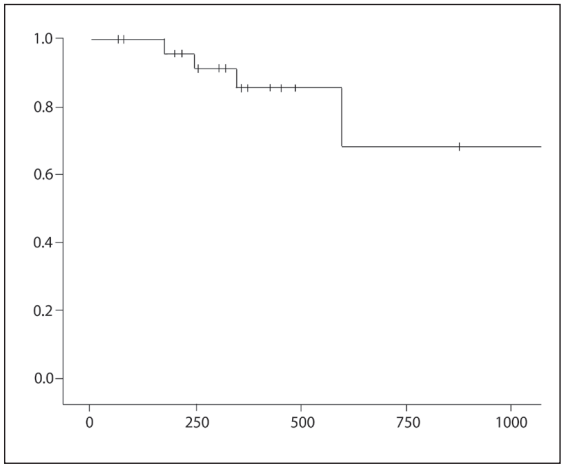


Figure 1. Kaplan-Meier curve of re-intervention events after implantation of Viabahn stent.

since the implantation of Vibahn stent grafts 4 years previously.

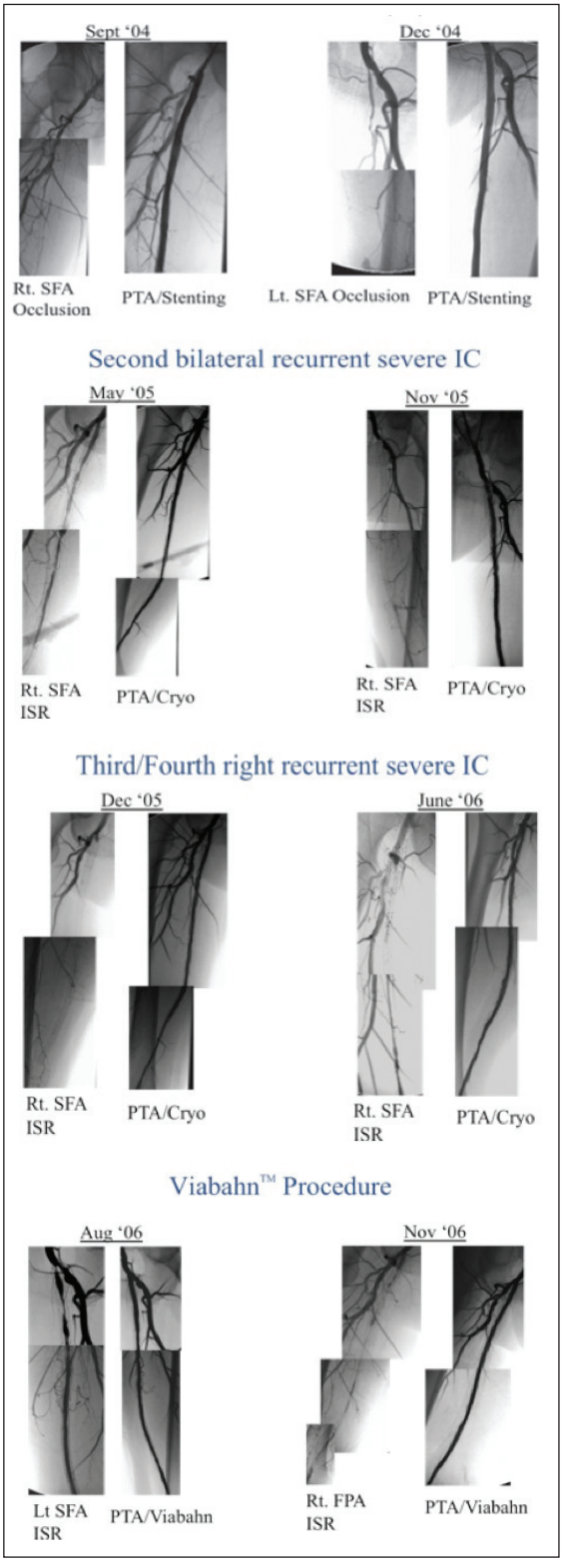
Three out of the five recurrent ISR cases presented as severe intermittent claudication, Rutherford category 3. Despite two patients who presented with acute limb ischemia (7%), Rutherford category 4, they were potentially preventable by means of dual antiplatelet therapy, especially in the first six months postimplantation as well as avoidance of prolonged knee bending postures. The rate of stent graft endothelialization was studied by Marin et al[7,8] who showed that endothelialization can cover up to 8 cm of the stent-graft at 5 months postimplantation. Therefore, we generally recommend continuing dual antiplatelet therapy beyond six months if there is no high bleeding risk or cost concerns because recurrent ISR occur at the stent's edges. It is also well documented in bypass graft reports that bending of the affected limb will kink the endovascular graft leading to cessation of the blood flow leading to graft thrombosis.

Table 6. Suggested guidelines for use of Viabahn.

Preimplantation
• Good Inflow • Acceptable outflow with at least one patent vessel runoff • Vessel diameter at least 4.8 mm • Avoid in heavily calcified arteries • Prepare the lesion to have artery: stent graft ratio of 1:1 • No planned surgery for the next 6 months • Caution in patients at high risk of bleeding
Implantation
• Avoid stent graft oversizing to prevent enfolding which can be a nidus for stent thrombosis • Optimal and cautious post dilatation to avoid dilating stent edges which can be a nidus for edge in-stent restenosis • Cover the lesion completely from healthy angiographic segment to another healthy angiographic segment • At least 1 cm of stent graft overlap if more than one Viabahn stent graft were needed • Cautious implantation in ostial SFA to avoid jailing deep profunda artery
Postimplantation
• Dual antiplatelet therapy for at least 6 month followed by lifelong aspirin • Avoid prolonged knee bending positions • Ultrasound surveillance particularly in the first year postimplantation

Treatment of ISR in the lower extremities is one of the most challenging pathologies. There are more than 150 000 FPA stent procedures per year in United States.[9] In the most recent trials, the rate of ISR is as common as 40%. Thus, the burden of FPA ISR may reach up to 60 000 cases per year in this country. The only FDA-approved treatment of ISR is PTA. However, Rocha-Singh et al showed in a survey of randomized control trials that the PTA control–arm data have estimated a 12-month primary patency (by duplex ultrasound) of only 33% for lesions 4 to 15 cm long.[10] Not surprisingly, the patency of PTA for ISR was even worse. Dick P et al[3] randomized 40 patients to conventional balloon angioplasty versus cutting balloon for ISR with a mean lesion length of 8 cm. They found that primary patency rates were only 27% to 35% at 6 months. Use of atherectomy devices was also disappointing. Treatment using excisional atherectomy on 43 limbs with in-stent restenoses and a mean lesion length of 13.1 cm showed a one-year primary patency rate of 54%.[11] Anecdotally, repeat stenting will invariably increase the risk of ISR as well as risk of stent fracture since the lesion will be longer and less flexible. Scheinert et al[12] showed the risk of stent fracture in non ISR lesions is as high as 52% if the lesion length was more than 16 cm and the stent fracture would lower the patency rate by half compared to a non-fractured stent

Figure 2. Case illustration.



particularly in the first two years postimplantation as seen in a different study.[13]

While there were multiple small studies for Viabahn stent-graft to treat de novo FPA lesions, there are minimal data using Viabahn stent-graft for ISR.[14] Recurrent ISR of Viabahn stent graft is almost always at the edges and subsequently its patency is independent to the lesion length but dependent on the Viabahn stent diameter.[15] **Table 7** summarizes the published Viabahn patency data with relation to the lesion length. Viabahn stent graft is more flexible (but not kink-free stent) than a bare metal stent, which would reduce the risk of stent fracture and its consequences. In this study, no stent fracture was noted in patients who came for recurrent intervention or as a control when a procedure elsewhere was performed; only 10 patients were specifically examined for fracture. The Viabahn stent-graft has a low tendency to jump during delivery. This makes it reliable for implantation, though carefully, up to the ostium of the SFA. Two orthogonal views are needed before implantation to insure coverage of the ostium of the SFA and so as to not inadvertently cover the ostium of the deep profunda femoris artery. According to the operator experience, the Viabahn stent-graft should be avoided in heavily calcified lesions or if the vessel diameter is less than 5 mm to avoid enfolding of the Viabahn stent graft. Enfolding of stent-graft may function like a nidus for stent thrombosis. Like in prosthetic bypass graft surgery, an endovascular stent-graft also requires adequate inflow and outflow as well as avoidance of prolonged knee bending postures to prevent kinking of the stent graft which would lead to cessation of the blood flow and stent thrombosis.

Ansel G et al[15] showed a similar favorable outcome in ten patients with diffuse nitinol stent restenosis in the femoropopliteal artery treated with Viabahn stent-graft. The primary, assisted primary and secondary patency rates were 70%, 80%, and 90%, respectively after at least one year of follow up. The Salvage trial, which is the only randomized control trial to date using the Viabahn stent graft for ISR in the SFA, was suspended after the enrollment of 27 patients due to FDA concerns about the interaction between laser therapy and the nitinol stent. The results of the enrolled 27 patients are still pending.

The limitations of Viabahn stent graft include coverage of collaterals, which would put the patient at risk of acute limb ischemia if the stent graft is thrombosed. However, in our study the two patients who presented with acute limb ischemia may have had explainable causes (one prematurely stopped dual antiplatelet therapy and one had prolonged knee bending posture). It is

Table 7. Viabahn Stent Graft for de novo femoropopliteal disease.

Study	No. of limbs	Lesion length, cm	1-yr patency rate, %	Comments
Farraj et al[13]	32	15.4	94	Chronic total occlusion study
Saxon et al[14]	87	14.2	76	4-yr patency, 55%
Kedora et al[15]	50	25.6	73.5	Similar to prosthetic bypass surgery
Fischer et al[16]	48	10.7	80	6-yr patency, 57%
Hartung et al[17]	34	10.8	85	2-yr patency, 85%, TASC D excluded
Bleyn et al[18]	67	14.3	82	5-yr patency, 47%
Jahnke et al[19]	52	8.5	74	2-yr patency, 62%
Lammer et al[20]	80	13.8	78.7	No thienopyridine, high thrombosis rate

TASC: TransAtlantic InterSociety Consensus Classification, D indicating chronic total occlusion of the popliteal artery and proximal trifurcation vessels.

unwise to intentionally keep gaps in between multiple stent grafts to preserve collaterals since it would be a source for restenosis. The concern of using catheter-directed thrombolysis in all the patients in this study with recurrent ISR of Viabahn stent-graft is well taken, but may be closer follow up (particularly in the first year postprocedure) can select those patients with edge ISR for further short touch angioplasty, preferably using a drug-eluting balloon. The data for drug-eluting balloons in peripheral vessel showed favorable late lumen loss.[16,17] The Viabahn stent graft is easily detected by duplex ultrasound making the diagnosis of edge restenosis easy and accurate. In addition, it is crucial to assess for any inflow and particularly outflow disease during ultrasound follow up which also can jeopardize the patency of Viabahn stent-graft without having edge ISR, eg, popliteal artery stenosis may lead to stagnation of blood flow in the Viabahn endoprosthesis, which will lead to stent thrombosis despite the absence of edge ISR. The secondary patency rate in our study is limited by the paucity of days of follow up. It ranged between 3 months to 2 years for the five patients who had re-interventions after Viabahn stent-graft implantation.

In summary, our experience in a small number of patients showed a very favorable result with an ePTFE covered stent-graft (Viabahn) for patients with in-stent restenosis in the femoropopliteal artery with a 3-year primary patency rate of 81%.

All authors declared no conflict of interest or relationship with the manufacturer.

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