Long-term Patency and Clinical Outcome of the Viabahn Stent-Graft for Femoropopliteal Artery Obstructions

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PURPOSE: To assess the long-term patency of the Viabahn stent-graft after placement for the treatment of occlusive disease of the femoropopliteal artery (FPA).

MATERIALS AND METHODS: Viabahn stent-grafts were placed into 87 limbs in 76 patients for the treatment of atherosclerotic occlusive disease of the FPA. Mean lesion length was 14.2 cm (range, 2.8–40 cm), with 80 of 87 lesions (92%) at least 7 cm in length. Patients were followed by duplex ultrasound (US), resting ankle brachial index (ABI) measurement, and clinical status at 6 months, 1 year, and yearly thereafter for a maximum of 8.5 years. A systolic velocity ratio greater than 2.0 on duplex US anywhere in the FPA was defined as a loss of primary vessel patency.

RESULTS: Primary, primary assisted, and secondary vessel patency rates were 76%, 87%, and 93%, respectively, at 1 year and 55%, 67%, and 79%, respectively, at 4 years. Mean resting ABI improved from 0.70 before the procedure to 0.90 as of the most recent follow-up ($P < .001$). Mean Rutherford-Becker classification improved from 3.4 before the procedure to 0.68 as of the most recent follow-up ($P < .001$). Eighty-eight percent of limbs showed a maintained improvement in clinical status. Primary patency was independent of lesion length and type but dependent on device diameter ($P = .001$). The primary vessel patency rate in devices of at least 7 mm ($n = 21$) was 82% at 4 years. No stent fractures were observed despite the use of multiple overlapping stent-grafts in 36.8% of limbs ($n = 32$).

CONCLUSIONS: This study demonstrates durable vessel patency to 4 years for long Transatlantic Inter-Society Consensus class C and D lesions treated with the Viabahn stent-graft. Results were independent of lesion length and type but dependent on device diameter. This study helps confirm the durability and clinical utility of this device in the treatment of FPA occlusive disease.

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Abbreviations: ABI = ankle brachial index, FPA = femoropopliteal artery, PAD = peripheral arterial disease, PTA = percutaneous transluminal angioplasty, SFA = superficial femoral artery, TASC = Transatlantic Inter-Society Consensus

THE treatment of atherosclerotic occlusive disease of the femoropopliteal artery (FPA) is complex and rapidly evolving. Although techniques designed to improve technical outcome and patency have been developed, there are few data to support significant improvements in long-term patency. Patency results for PTA and stent placement in the FPA vary widely depending on lesion length, whether a stenosis or occlusion is being treated, and the quality of the distal runoff (1). When objective follow-up techniques are used, the primary patency associated with endovascular techniques has been poor for longer lesions (2–4). Consequently, the Transatlantic Inter-Society Consensus (TASC) I and II consensus statements (5,6) advise against endovascular intervention for longer FPA lesions, with the treatment of these patients limited to an exercise program and medications when possible or bypass when symptoms are severe.

Initial reports of the use of stent-grafts for the treatment of peripheral arterial disease (PAD) of the FPA were less than encouraging, with primary patency rates ranging from 20% to 50% at 1 year (7–10). However, results have been far better with second-generation devices such as the expanded polytetrafluoroethylene–covered Viabahn endoprosthesis (formerly Hemobahn; W.L. Gore, Flagstaff, Ariz) (11,12). The results of a multicenter, prospective, randomized trial of the Viabahn endoprosthesis versus percutaneous transluminal angioplasty (PTA)

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have not yet been published, but have been presented and demonstrate a 25% improvement in target vessel primary patency and a 15% improvement in limb ischemia score (13). These multicenter data led to Food and Drug Administration approval of the Viabahn device for use in the SFA in June 2005. The Viabahn endoprosthesis is only the second implantable device approved for use in the SFA for the treatment of PAD, the first being the IntraCoil device (ev3, Plymouth, MN), which was approved for cases of failed PTA (14). Additional data are required to confirm long-term durability of the Viabahn device and to assess which patient population would best benefit from the use of the Viabahn device for the treatment of FPA disease.

We previously reported the results of our single-center experience with the Viabahn as part of the aforementioned multicenter trial (15). Our results showed statistically significant improvements in clinical outcome and patency at the 2-year endpoint: primary patency rates were 87% in the Viabahn group ($n = 15$) and 25% in the PTA group ($n = 13$; $P = .002$). In 2002, we began to use the Viabahn device in a nonrandomized fashion to treat patients with long SFA stenoses (>5 cm) and occlusions (>3 cm). Patients have been enrolled in an institutional review board–approved duplex and radiographic follow-up protocol that was designed to gather long-term clinical outcome and patency data on the use of this endovascular stent-graft. The purpose of this article is to describe the results of this follow-up study.

MATERIALS AND METHODS

Patient Population

The study design was approved by the institutional review board, and all data were collected after written informed consent was obtained. Viabahn stent-grafts were placed into 87 limbs in 76 patients (49 men, 27 women) with a mean age of 72 years (range, 45–88 y) between June 1998 and September 2006 for the treatment of atherosclerotic occlusive disease of the SFA and popliteal arteries. Between 1998 and 1999, 15 limbs were treated as part of the prospective multicenter approval trial for the Viabahn device (known as the Hemobahn device at that time) in 6- and 7-mm sizes. Starting in 2002, an additional 72 limbs were treated in an off-label fashion (until the device was approved in 2005). Eleven patients received bilateral devices and therefore a total of 87 limbs were treated. Seventy-five percent of treated limbs were causing Rutherford-Becker grade 3 or greater claudication, including chronic limb ischemia, nonhealing ulcers, or acute critical limb ischemia with underlying PAD identified after thrombolytic therapy.

This study was designed to capture long-term patency and durability data. Detailed demographic characteristics of the patient population, including risk factors for PAD, were not recorded. However, patients were not excluded for any risk factors that are known to adversely affect patency; patients with diabetes or renal failure and active smokers were all enrolled. No patients were excluded from follow-up. Patients were enrolled in the study after receiving a Viabahn stent-graft for the treatment of PAD. This study collected only long-term patency and clinical outcomes data and did not assess periprocedural and 30-day adverse event rates, as patients were enrolled after their procedures had already been completed.

Study Endpoints and Definitions

Technical success was defined by the successful placement of a Viabahn stent-graft with less than 30% residual stenosis anywhere in the FPA seen on angiography after the procedure. Primary patency was defined as no evidence of restenosis or occlusion within the treated FPA on duplex sonography (ie, no evidence of a systolic velocity ratio >2.0 anywhere in the FPA) or angiography (ie, <50% diameter narrowing). Primary assisted patency was defined by patency of the treated FPA maintained by repeat intervention with no arterial or stent-graft occlusion. Secondary patency was defined as patency of the treated FPA and stent-graft maintained by repeat intervention after occlusion of the treated vessel. Clinical improvement was defined as maintenance of at least a one-grade improvement in Rutherford-Becker ischemia score after treatment.

Lesion Characteristics

Fifty stenoses (58%) and 37 occlusions (42%) were treated, with a mean lesion length of 14.2 cm (range, 2.8–40 cm). Lesions were categorized according to the original TASC working group definitions (5). There were no TASC class A lesions and six grade B lesions (7.4%), and the remainder were TASC class C or D lesions ($n = 81$, 93.1%). Only seven lesions 7 cm or shorter in length were treated (five as part of the initial multicenter trial).

Technique

The Viabahn stent-graft is made of a nitinol exoskeleton and thin-walled 100-μm expanded polytetrafluoroethylene lining. The technical aspects of the device and our approach to its use have been described in detail elsewhere (16,17). Patients in the multicenter trial were treated with oral ticlopidine HCl 250 mg twice daily in addition to aspirin 81–325 mg orally once daily. Beginning in 2002, most patients were prescribed oral clopidogrel 75 mg daily for at least 2 months after the procedure. If possible, patients were administered oral clopidogrel 75 mg/d and aspirin 81 mg/d for 3 days before the procedure. Patients who did not receive clopidogrel before the procedure received a loading dose of 150–300 mg clopidogrel orally immediately after the procedure.

The stent-grafts were placed percutaneously in all cases from an antegrade or retrograde over-the-bifurcation approach. An antegrade approach was preferred in distal occlusions for recanalization, whereas a contralateral approach was used for proximal superficial femoral artery (SFA) lesions and in obese patients. An over-the-bifurcation approach was used preferentially when either seemed acceptable.

All lesions were assessed with quantitative angiography for proper PTA balloon and device sizing. Great attention was paid to vessel size in the proximal and distal landing zones. The goal was to oversize the device by approximately 10%–15%. Five-millimeter devices were not available as part of the multicenter trial. Patients with vessels larger than 4.8 mm were treated with 6-mm devices initially. When 5-mm devices became available,