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Role of Stent Grafts and Helical-Woven Bare-Metal Stents in the Superficial Femoral and Popliteal Arteries

Sreekumar Madassery, MD, Ulku C. Turba, MD, and Bulent Arslan, MD

Peripheral vascular disease (PVD) is a devastating medical problem that may lead to significant life alterations for patients, from simply limiting their daily activities to potential loss of limbs and eventual demise. Superficial femoral and popliteal arteries are significantly common locations for PVD sequelae to present itself, and owing to their length and mobile nature, treatment of these segments are quite challenging. Indications for PVD treatment include lifestyle-limiting claudication that is not responding to medical management, ischemic rest pain, nonhealing ulcers, and lower extremity gangrene. There is a wide variety of treatment options that include medical management, interventional, and surgical techniques. Interventional techniques include plain old balloon angioplasty, cryoplasty, drug-coated balloon angioplasty, self-expanding bare-nitinol stents, self-expanding covered stents, self-expanding drug-eluding stents, and a number of atherectomy devices (ie, laser, rotational, orbital, and excisional). The scope of this article is to review indications, patient selection, and deployment techniques of Viabahn and Supera self-expanding stents.

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Introduction

Over the recent years, there have been significant shifts in the paradigm of treating peripheral arterial disease, particularly in the territory of the superficial femoral and popliteal arteries. Medical management, endovascular interventions, and surgical bypasses (prosthetic or native) with or without femoral endarterectomy are currently offered to most patients. Medical management, including smoking cessation, control of blood sugar and blood pressure, cholesterol levels, and exercise when feasible should be offered to every patient with any degree of disease. Surgical bypass used to be the main treatment option in patients not responding to medical therapy, but during the past 10-15 years, there has been a shift to endovascular interventions from surgical bypasses.

The femoropopliteal segment has certain challenges in achieving a successful technical result as well as long-term patency. Long lesion lengths and the mobile nature of the artery results in high rates of intimal hyperplasia or thrombosis after endovascular interventions. Endovascular treatment options for femoropopliteal lesions are numerous. One can speculate that there is no single perfect tool. Many new options have been regularly introduced for the interventionalists' use, including plain old balloon angioplasty, cryoplasty, scoring balloons, multiple forms of atherectomy, self-expanding bare-metal stents, self-expanding covered stents, and lately drug-coated balloons and drug-eluting stents. This ongoing evolution of endovascular treatment modalities is of vital importance as there is an increasing population of patients presenting with and needing treatment for critical limb ischemia (CLI), with studies showing that only an estimated 40% of patients with CLI survive more than 5 years.[1] A thorough description and evaluation of all modalities currently in use are out of the scope of this article. Rather, we aim to provide an update on femoropopliteal revascularization using self-expanding covered stents (Viabahn W.L. Gore & Associates, Flagstaff, AZ) and a novel self-expanding bare-metal stent with kink resistance (Supera

Rush University Medical Center, Chicago, IL.
Address reprint requests to Bulent Arslan, MD, Rush University Medical Center, 1725 W Harrison St, Suite 450, Chicago, IL 60523. E-mail: Bulent_arslan@rush.edu

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Abbott Vascular, Santa Clara, CA). The information provided here would be primarily based on authors' experience complemented by literature.

Indications for Treatment of Superficial Femoral and Popliteal Arteries

Lifestyle-limiting claudication, not responding to medical management, rest pain, nonhealing ulcers, and gangrene are indications for endovascular interventions of the superficial femoral artery (SFA) and popliteal artery. Device and technique selection should depend on the indication, patient's age, arterial anatomy, and disease extent.

Self-Expanding Stent Grafts

The Viabahn is the only Food and Drug Administration-approved self-expanding covered stent for use in the femoropopliteal territory. It has evolved over many iterations, the most recent of which is a Heparin-bonded expanded polytetrafluoroethylene (ePTFE) inner liner, supported with a nitinol external scaffold. The instructions for use (IFU) provided by the manufacturer states that the Viabahn stent is intended to be used in de novo, and restenotic lesions of the SFA, for lesions up to 270 mm in length, with a reference vessel diameter between 4.0 and 7.5 mm, and for SFA in-stent restenosis up to 270 mm in length, with vessel diameter between 4.0 and 6.5 mm. This stent is contraindicated in patients with a history of heparin-induced thrombocytopenia type II. The manufacturer recommends 5%-20% oversizing in choosing the stent compared to native vessel diameter and 1 cm overlap with the proximal and distal extents of the lesion being treated. If overlapping stents are being placed, 1 cm overlap is recommended. Overlapping stents of differing diameters are to be placed with the larger diameter stent deployed inside the smaller caliber stent (IFU Documents). Both 5 and 6 mm diameter stents require a 6 French sheath with the 0.018 guidewire system and 7 French sheath with the 0.035 guidewire system. For the 7 and 8 mm diameter stents, the sheath sizes would be 7 and 8 French, respectively.

Patient Selection

Before utilization of a Viabahn stent, authors of this article consider several criteria. The ePTFE covering acts as a mechanical barrier preventing intimal hyperplasia throughout the length of the stent graft; however, it is still prone to stenosis at the proximal and distal edges. When that happens, the risk of in-situ thrombosis increases, which is the most common failure mode for the stent. This is akin to prosthetic bypass grafts failing due to an anastomotic stenosis. In patients with poor inflow or outflow, even away from the edges of the stent, this would be a risk for failure. For these reasons, our tendency to use Viabahn in femoropopliteal segments depends on the quality and diameter of the artery above and below the diseased segments, as well as the location of the diseased segments.

Another criterion is the presence of any large collaterals in the treatment zone. If edge stenosis or occlusion of the Viabahn were to occur, the covered collaterals would not be able to provide supply to the leg distally. Additionally, proximity of the lesion to the deep femoral origin is a consideration, as it is considered a critical source of collateral vascular supply for patients with CLI. For this reason, inadvertent coverage of the deep femoral artery should be avoided. The authors feel, although in-line arterial flow would be established at the completion of revascularization, coverage of any large collaterals that are otherwise providing flow to the distal leg may become problematic and should be avoided.

Viabahn is also a salvage option in cases of unexpected perforation due to aggressive angioplasty of a circumferentially calcific lesions, or arteriovenous fistula formation because of an excisional atherectomy.

Additionally, if the indication for treatment requires longer-term patency, such as a relatively younger patient with lifestyle-limiting claudication or rest pain, and if the proximal and distal landing zones are suitable, we believe Viabahn would provide a longer-term patency in long lesions of the femoropopliteal segment than most other methods available. Another scenario where Viabahn stening is indicated is in the treatment of in-stent restenosis in previously placed bare self-expanding stents.

Anticoagulation

There is no scientifically established anticoagulation protocol for Viabahn stents. The authors prefer at least 2 agents that may be Aspirin 81 mg qd or Clopidogrel 75 mg qd or both after a loading dose of 300 mg indefinitely. If there is high risk for thrombosis, or if the patient already had an episode of thrombosis, Warfarin plus Aspirin or Clopidogrel can be used. If patients are not candidates for long-term anticoagulation for any reason, Viabahn should not be the first choice for treatment. Although anectodal, most failures seen by the authors after technically successful placement of the stents are due to interruption of the anticoagulation.

Current Literature

Studies involving use of the Viabahn stent compared to prosthetic bypass surgery demonstrated no statistical significance in patency, followed to 4 years in a total of 100 limbs treated, with total patency reported at 59%.[2] Additionally, the 2-year follow-up report of the VIASTAR study, which followed 141 patients with either Viabahn vs bare-metal stenting for femoropopliteal disease, showed that particularly in long lesions (greater than or equal to 20 cm), the Viabahn endoprosthesis was superior to bare-metal stenting.[3] These findings were noted despite the concerns that covered stenting increases the risk for thrombosis, which many consider to be due to edge