

A 2007 Update on Treating Nitinol Stent Restenosis

Using Viabahn covered stents to treat restenosis in the superficial femoral artery.

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With an aging population, symptomatic lower-limb ischemia resulting from atherosclerotic disease of the infrainguinal vascular bed will continue to increase in frequency. The 2- to 5-year primary patency rates with femoropopliteal venous bypass range from 66% to 80%.^{1,2} Recently, with the development of heparin bonding, prosthetic grafts appear to challenge vein-based bypass patency rates at 1 to 2 years and, therefore, potentially establish a new treatment paradigm for surgically based treatment.^{3,4} However, given the significant morbidity and mortality associated with bypass surgery, an endovascular approach still offers a lower-risk, often outpatient, repeatable option.

BIOMECHANICS VERSUS TECHNOLOGY

The initial use of self-expanding stainless steel stents in the infrainguinal location was for the treatment of suboptimal angioplasty with flow-limiting dissection. The long-term patency rates in these clinical series were consistently poor.^{5,6} A subsequent randomized study that compared percutaneous transluminal angioplasty (PTA) to nitinol-coil-based stenting in the superficial femoral artery (SFA) demonstrated that stent usage offered a lower-risk option without a restenosis benefit.⁷ As technically advanced, nitinol, tubular-based stents were introduced, primary stenting increased due to positive anecdotal midterm results.^{8,9} However, after long-term surveillance, the recognition of nitinol stent fractures has emerged and has slowed the overall adoption of this technology. There have been great advances in understanding the biomechanics of the SFA; in particular, the numerous forces that are exerted on stents in this location are now better rec-

ognized. Interestingly, despite these advances in biomechanics, it remains unknown why restenosis is associated with stent strut fractures with some nitinol platforms but not with others. In fact, data have been published from a multicenter registry and a single-center randomized trial that appear to confirm that compared to PTA, restenosis is reduced with certain nitinol stent platforms.¹⁰⁻¹²

With the release of more positive data, the use of nitinol stents may increase. Much of these data, however, are only at the 1- to 2-year time frame. Unlike other vascular beds in which the stent result at approximately 9 months may be maintained, progression of disease and restenosis seems to lead to a continuing decrease in stent patency in the SFA.¹³

Currently, the most effective treatment strategy for in-stent restenosis has not been defined. Although repeat balloon angioplasty may be effective for focal restenosis, in our experience, diffuse, long-segment, nitinol stent restenosis has a high failure rate when treated by angioplasty alone. In our own practice, stand-alone balloon angioplasty of diffuse stent restenosis is associated with dissection and what we believe is a clinically significant pressure gradient (≥ 15 to 20 mm Hg). Because there is still tremendous controversy as to what technology is best suited to treat diffuse SFA stent restenosis, the utilization of newer technology is often touted far before any real clinical data to support its use are available. Early, single-center data on the use of CryoPlasty (Boston Scientific Corporation, Natick, MA) has certainly shown uniformly disappointing results with 100% re-restenosis at 9 months.¹⁴ Results of directional atherectomy with the SilverHawk catheter (FoxHollow Technologies, Redwood City, CA) reported from a single center in short- and mid-

length lesions have also been recently published. In the subset of in-stent restenosis patients ($n=31$; mean length, 13.1 cm), the 12-month restenosis rate (duplex ≥ 2.5) was 54%. Target lesion revascularization occurred in 47%, and 13% went on to surgical bypass.¹⁵ However, use of this device for in-stent disease has been associated with stent entanglement and other complications, necessitating open surgical repair.¹⁶

Utilization of the polytetrafluoroethylene-covered self-expanding Viabahn stents in the SFA appears to offer an alternative treatment. The polytetrafluoroethylene graft material used in this platform incorporates a very small pore size that does not allow for significant tissue ingrowth and may decrease recurrent restenosis. Results from registry data have been overall favorable.¹⁷⁻²⁵ A recent, single-center, randomized trial found no difference between the Viabahn and prosthetic open surgical above-the-knee bypass with 1-year follow-up.²⁶

SINGLE-CENTER STENT GRAFT DATA UPDATE

Our early, single-center experience utilizing Viabahn stent grafts in a small number of patients was favorable. Ten selected patients with diffuse SFA in-stent restenosis and favorable anatomy were treated with an excimer laser, PTA, and then deployment of the Viabahn stent graft. Excimer laser debulking was performed after we realized that stand-alone angioplasty frequently did not result in an acceptable hemodynamic response. At a mean of 1 year, the primary, assisted primary, and secondary patency rates (duplex ratio $>2:1$) were 70%, 80%, and 90%, respectively. Since that time, we have follow-up on 33 patients, with data available on 82%. The lesions were long, with an average length of 26 cm. Twenty-eight percent of the patients were treated for critical limb ischemia, whereas 72% were claudicants. At a mean of 18 months (range, 6 to 41 months), the primary and secondary patency rates were 52% and 82%, respectively. Three of the 27 (11%) patients have gone on to surgical bypass.

LESSONS LEARNED

When using covered stents in the SFA, several variables may affect results, including vessel diameter, inflow, and outflow vessel patency. As in surgical bypass grafting, one should attempt to reach the true vessel diameter and address any significant inflow or outflow



Figure 1. Angiogram demonstrating in-stent restenosis with potential collaterals (A). Angiogram after excimer laser (Spectranetics Corporation, Colorado Springs, CO), PTA, and Viabahn (Gore & Associates, Flagstaff, AZ) stent grafting (B).

obstructive lesions. Because progression of the disease may significantly affect the patency of grafts, the complete length of previously stented SFA plus any area of progressing disease should theoretically be covered. One of the potentially significant drawbacks to the use of stent grafts is the potential exclusion of collaterals. However, we believe an optimal result should not be limited in order to preserve collaterals (Figure 1). As one would expect, the current primary failure mechanism for stent grafting of in-stent restenosis is edge restenosis progressing to thrombosis. We currently practice formal duplex surveillance on these patients, although there are no clinical series to support this approach. It will be of interest to see if the improved patency seen in the thromboresistant heparin-bonded surgical graft can be transferred to a percutaneous stent graft system.

In summary, stent grafting of diffuse nitinol stent restenosis appears to be a promising approach that should be further studied. A multicenter, registry study evaluating the excimer laser, PTA, Viabahn approach is currently planned, and further improvement may be seen when heparin-bonded endovascular stent grafts become available. ■

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