

# The VIPER Trial

With heparin bonded to the surface and a contoured edge, how will stent grafts perform in SFA revascularization?

BY RICHARD R. SAXON, MD, FSIR

Investigators have shown a patency benefit to both stents and stent grafts for treating longer superficial femoral artery (SFA) stenoses when compared to percutaneous transluminal angioplasty alone.<sup>1-3</sup> Some studies show stent graft patency to be less dependent on lesion length.<sup>4,5</sup> However, stent graft patency has been limited by the development of intimal hyperplastic edge stenosis in more than 20% to 25% of patients. When edge stenosis occurs, it is at the proximal edge of the device in 60% to 70% of cases.<sup>5,6</sup> Theoretically, turbulent flow due to infolding of the graft material at the proximal interface with the SFA may contribute to focal edge stenosis development. Moreover, some series have shown diminished patency rates when small vessels are treated with the original 5-mm devices due to edge stenosis and stent graft occlusion.<sup>5</sup>

The VIPER (Gore Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) study is a prospective, nonrandomized, single-arm, multicenter, postmarket evaluation of the Gore Viabahn endoprosthesis (5–8 mm) (W. L. Gore & Associates, Flagstaff, AZ) with the Carmeda BioActive Surface (CBAS) coating (Upplands Väsby, Sweden [a subsidiary of W. L. Gore & Associates]). The CBAS coating uses the company's proprietary End-point attachment method, which permits heparin molecules to be covalently bound to a surface without impeding the heparin's biological properties to create a more thromboresistant surface. Unlike

drug-eluting stents, which deliver drugs to a target over time, CBAS is a surface modification technology that does not appreciably release heparin. The VIPER study aims to collect important performance data on the use of the next-generation Viabahn self-expanding stent graft in the SFA, evaluating whether the heparin bioactive surface and the proximal contoured edge have the potential to mitigate both graft occlusion in smaller device diameters and the development of edge stenosis.

The current-generation Viabahn endoprosthesis combines the benefits of an endovascular device with the heparin bioactive surface (based on the CBAS technology). The Gore Viabahn endoprosthesis with heparin bioactive surface is a flexible, self-expanding, endoluminal endoprosthesis consisting of an expanded polytetrafluoroethylene lining with an external nitinol support extending along its entire length. The surface of the endoprosthesis is modified with covalently bound bioactive heparin, which uses the same bioactive heparin surface technology that is present on Gore's Propaten vascular graft. The Propaten vascular graft has been sold in Europe since 2002, and several studies have shown that it has high patency rates and low thrombosis rates and have identified no additional



Figure 1. The new, contoured-edge Viabahn endoprosthesis demonstrating the laser-cut proximal edge.

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safety or performance concerns as a result of the CBAS.<sup>7-10</sup>

Previous studies have demonstrated the utility of the Gore Viabahn endoprosthesis in the percutaneous treatment of chronic superficial artery disease.<sup>2-6,11-16</sup> One failure mechanism seen with the Gore Viabahn endoprosthesis is device thrombosis. Early thrombosis ( $\leq 30$  days postprocedure) for the device has been reported to be between 0% and 5%.<sup>5,4-11</sup> These events may be attributed to inadequate distal runoff, patient-specific prothrombotic complications, poor patient selection, or technical failure. Late thrombotic events ( $> 30$  days postprocedure) usually result from compromised flow through the stent graft secondary to edge stenosis or disease progression. In either case, a thromboresistant surface on the expanded polytetrafluoroethylene lining of the Viabahn endoprosthesis may provide a benefit to clinical performance.

VIPER is the first clinical trial to evaluate the performance of the heparin bioactive surface in the Viabahn device. It is also the first clinical trial to evaluate the effects of a new laser-contoured proximal edge on flow dynamics within the device. In 2009, Gore modified the manufacturing process for the Viabahn endoprosthesis to include a laser-cut, contoured proximal edge. Previously, the proximal edge of the device was a straight cut. This improves device apposition to the vessel wall, especially in oversizing conditions, and it may also improve flow dynamics.

A total of 120 patients (40 patients with the straight-cut proximal edge, 80 patients with the proximal contoured edge) will be enrolled in the VIPER study. Clinical follow-up will occur at 30 days, 6 months, and 12 months; patency will be compared at 1 year in both groups. Patients enrolled in the VIPER study have lifestyle-limiting claudication, resting pain, or minor tissue loss affecting a lower extremity (Rutherford categories 1–5), and de novo stenosis or postangioplasty restenosis ( $> 50\%$ ) or occlusion of native SFA  $\geq 5$  cm located in the region beginning 1 cm below the SFA origin and ending within 1 cm of the proximal margin of the intercondylar fossa of the femur.

The primary safety endpoint is the proportion of subjects who have experienced major procedural ( $\leq 30$  days postprocedure) adverse events, including death, myocardial infarction, acute renal insufficiency, study limb amputation, and access site and treatment site complications requiring surgery or blood transfusion. The primary efficacy endpoint for the study is primary patency measured at 12 months postprocedure, with primary patency defined as no evidence of

restenosis or occlusion within the originally treated lesion based on color-coded duplex sonography (peak systolic velocity ratio  $< 2.5$ ) or no angiographic evidence of stenosis  $> 50\%$  if color-coded duplex sonography is uninterpretable or unavailable. The study is currently enrolling, with anticipated completion by June 2010. ■

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