The FlexStent Femoropopliteal Self-Expanding Stent

Shortly after the release of preliminary data in New Zealand and Germany, evaluation of the FlexStent system in the United States will begin later this year.

BY WILLIAM A. GRAY, MD

When lifestyle changes and/or medication alone are not an effective treatment for peripheral artery disease (PAD), endovascular or surgical procedures become an option. Endovascular devices and surgical treatment for PAD represent a major challenge for physicians treating superficial femoral (SFA) and popliteal arteries. PAD is characterized by long areas of stenosis and occlusion with relatively low flow and vessels exposed to enormous stresses. During flexion of the knee, the SFA and popliteal artery can bend, rotate, elongate, and compress dramatically. An ideal stent design would be fatigue resistant and offer a great range of movement and strength while adequately supporting the arteries and providing high patency rates.

The FlexStent femoropopliteal self-expanding stent system (Flexible Stenting Solutions, Inc., Eatontown, NJ) is a third-generation stent used for treating PAD in the SFA and proximal popliteal arteries. With the US Food and Drug Administration's conditional investigational device exemption approval for the FlexStent, Flexible Stenting Solutions will be conducting a clinical trial in the United States to evaluate the safety and efficacy of the FlexStent femoropopliteal self-expanding stent system (Figure 1).

Fracture susceptibility and resistance is largely a function of stent design, and previous studies have suggested that both for performance and durability, not all laser-cut self-expanding stents are alike. The FlexStent is a uniquely constructed, fully connected self-expanding stent made from laser-cut superelastic nitinol tubing.

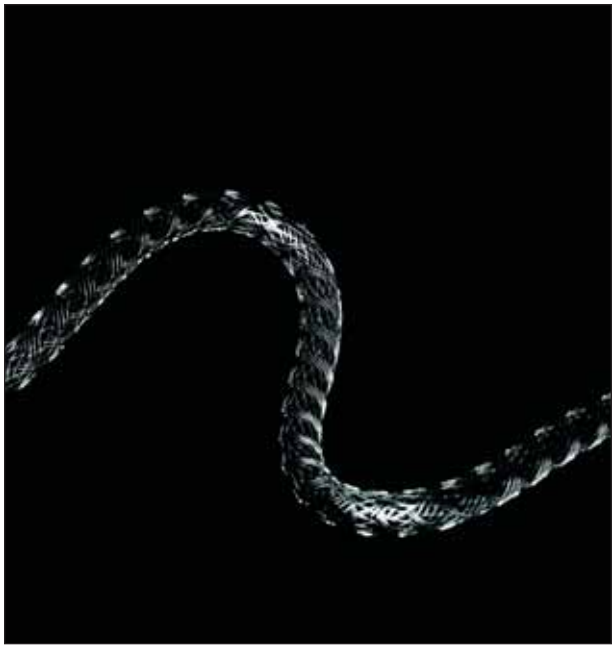

Figure 1. FlexStent is designed for challenges of the SFA and popliteal arteries.

The integration of helically oriented struts and coils provides strength, flexibility, and durability. The fully connected structure is meant to facilitate a continuous but atraumatic synergy between stent and vessel (Figure 2). This structure further enables biased axial compliance, so unlike other femoropopliteal stent designs, the fully

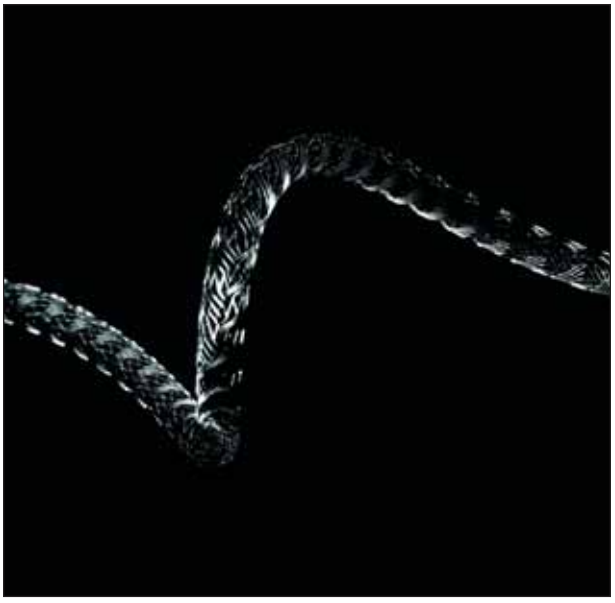

Figure 2. Shortening and bending of the femoral-popliteal segments may impose considerable stresses on a stented segment.

connected structure provides enhanced durability and redundancy with more than 12 connections around the circumference compared to that of three or four connections in most competitive stents. The FlexStent has successfully undergone numerous and vigorous fatigue tests to well over 10 million cycles.

In designing the stent, Flexible Stenting Solutions recognized that durability is not simply reflected in high-cycle fatigue resistance but in the system's ability to deliver the stent uniformly and as intended. With a biased axial compliance, the FlexStent does not significantly elongate on delivery. The unique marking mechanism, the uniform and fully connected stent design, and the simple push and pull mechanism provide quick and accurate placement from the 6-F compatible over-the-wire (0.035-inch) system. During and after deployment, the stent is intended to readily conform to the vessel wall in the configuration designed for optimum performance.

Flexible Stenting Solutions currently has completed full enrollment of 35 patients at two sites outside of the United States. In May 2008, Professor Andrew Holden, MD, began enrollment of 15 patients for the first-in-man FlexStent safety and efficacy study at Auckland City Hospital in Auckland, New Zealand. In December 2008, Professor Dierk Scheinert, MD, began enrollment of 20 patients for the second FlexStent safety and efficacy study at the Heart Centre in Leipzig, Germany. The lesion length and stenosis severity for both sites averages 8.7 cm and 92%, respectively. After stent placement, the in-stent mean lumen diameter is 5.1 ± 0.7 mm. The residual stenosis or recoil is 2%, demonstrating the strength and scaffolding ability of the FlexStent. Freedom from major adverse cardiac events is 100% at 30 days. At 6 months, no fractures have been reported, and both sites report a pooled duplex patency rate of 91%. As of early February 2010, patients that have had either 9- or 12-month visits have not reported any additional stenosis or fractures than those reported at 6 months.

The FlexStent femoropopliteal self-expanding stent system has received CE Mark approval in the European Union for peripheral vascular indications. Commercialization in certain European countries has begun. The FlexStent stent design provides a great range of motion for highly flexi-

US TRIAL SECONDARY ENDPOINTS (PROPOSED)

Safety Endpoints

- Periprocedural (within 30 days of procedure) complications and device malfunction
- Adverse events throughout the 12 months

Efficacy Endpoints

- Device success (successful vascular access and deployment)
- Procedure success (deployment of FlexStent and ≤ 30% residual stenosis)
- Freedom from target lesion revascularization at 6 and 12 months
- Freedom from target vessel revascularization at 6 and 12 months
- Change in Rutherford classification at 1, 6, and 12 months compared to preprocedure
- Change in ankle-brachial index at 1, 6, and 12 months compared to preprocedure
- Initial and absolute claudication distance via standard treadmill test at 1 and 12 months

> "At 6 months, no fractures have been reported, and both sites report a pooled Duplex patency rate of 91%."

ble femoropopliteal arteries while safely supporting the vessel to maintain patency.

CLINICAL INVESTIGATION IN THE UNITED STATES

Evaluation of the safety and efficacy of the FlexStent femoropopliteal self-expanding stent system is a prospective, single-arm, multicenter clinical trial. Subjects targeted for enrollment must have a single de novo lesion located in the femoropopliteal artery, which includes the entire extent of the SFA and the proximal portion of the popliteal artery with > 70% stenosis. The lesion treated must be < 150 mm in length, and the reference vessel diameter must be 3.5 to 7.5 mm. The proposed primary safety endpoint for the study is defined as freedom from all-cause death, index limb amputation, and target lesion revascularization through 30 days. The proposed primary efficacy endpoint is vessel patency at 12 months. Vessel patency is defined as freedom from > 50% stenosis in the stented segment as determined by Doppler ultrasound peak systolic velocity ratio. A core lab will evaluate all Doppler ultrasounds. For secondary safety and efficacy endpoints, see *US Trial Secondary Endpoints (Proposed)*. Primary and secondary endpoints will be assessed at 1, 6, and 12 months, with postmarket surveillance follow-up for long-term safety and stent integrity at 24 and 36 months. Further details of the study will be published at a later date. Commencement of The Evaluation of the Safety and Efficacy of the FlexStent Femoropopliteal Self-Expanding Stent System clinical study is targeted for the third quarter of 2010. ■

William A. Gray, MD, is Associate Professor of Clinical Medicine and Director of Endovascular Services, Center for Interventional Vascular Therapy, New York-Presbyterian Hospital/Columbia University Medical Center in New York. Dr. Gray is slated to be the principal investigator for the Flexible Stenting Solutions trial. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Gray may be reached at wg2131@columbia.edu.

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Texas. He has disclosed that he is a paid consultant to and receives grant/research funding from Boston Scientific Corporation and that he receives grant/research funding from Cordis Corporation. Dr. Das may be reached at tdas@civadallas.com.

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