The STROLL Study

Nitinol self-expandable stent placement for the treatment of obstructive SFA disease.

BY ANDREW J. FEIRING, MD, FACC, FSCAI

The STROLL study (SMART Nitinol Self-Expandable Stent in the Treatment of Obstructive Superficial Femoral Artery Disease) is a multicenter, nonrandomized, single-arm, prospective trial that is designed to evaluate the safety and effectiveness of the SMART nitinol stent system (Cordis Corporation, Bridgewater, NJ) in treating patients with obstructive superficial femoral artery disease.

The STROLL trial is currently enrolling at 46 sites across the United States. It is slated to enroll 250 patients with either de novo or restenotic native SFA lesions and abnormal ankle-brachial indices. Treated lesion lengths range from 4 to 15 cm for patients with reference vessel diameters between 4 and 6 mm. Stent diameters are 6, 7, and 8 mm, and the longest single stent allowable is 15 cm. All patients will be followed for 3 years after the procedure, with the primary endpoint assessed at 12 months.

STROLL's primary endpoint is 12-month stent patency defined as ≤ 50% in-stent diameter stenosis determined by duplex ultrasonography (peak systolic velocity of ≤ 2:1). The primary safety endpoint includes 30-day freedom from death, index limb amputation, and clinically driven target lesion revascularization. Secondary endpoints will address improvement in clinical status, ankle-brachial indices, and freedom from late target vessel revascularization. At 1 year, clinically driven target vessel revascularization, changes in Rutherford-Becker classification, improvement in ankle-brachial index, and quality-of-life information will be assessed.

All imaging studies will be independently reviewed and analyzed at the angiographic and ultrasound core labs. All stents placed will undergo evaluation for stent fracture at 6 months, 1, 2, and 3 years after implantation.

Restenosis will be assessed using continuous variables from the angiographic images should patients require any postinterventional procedures. The core laboratory will conduct independent, quantitative, angiographic measurements for the purpose of clinical study reporting.

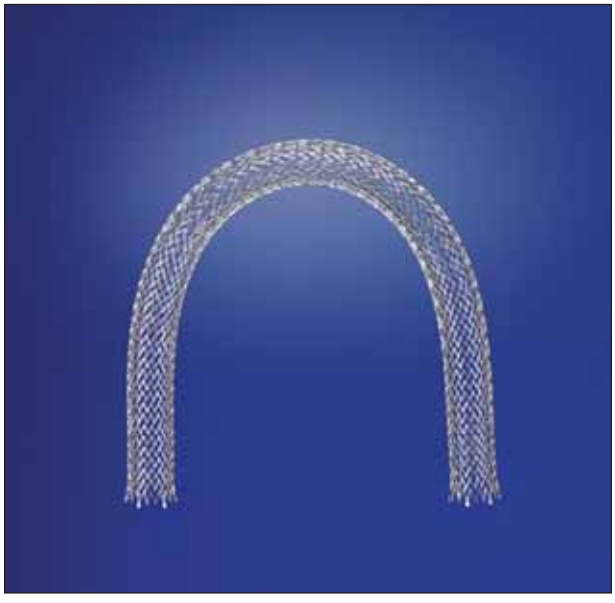

Figure 1. The SMART nitinol stent.

The STROLL study is currently enrolling and anticipates completion of enrollment in 2010. The SMART nitinol stent system is not currently Food and Drug Administration approved for the treatment of superficial artery lesions. ■

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