Supplement to

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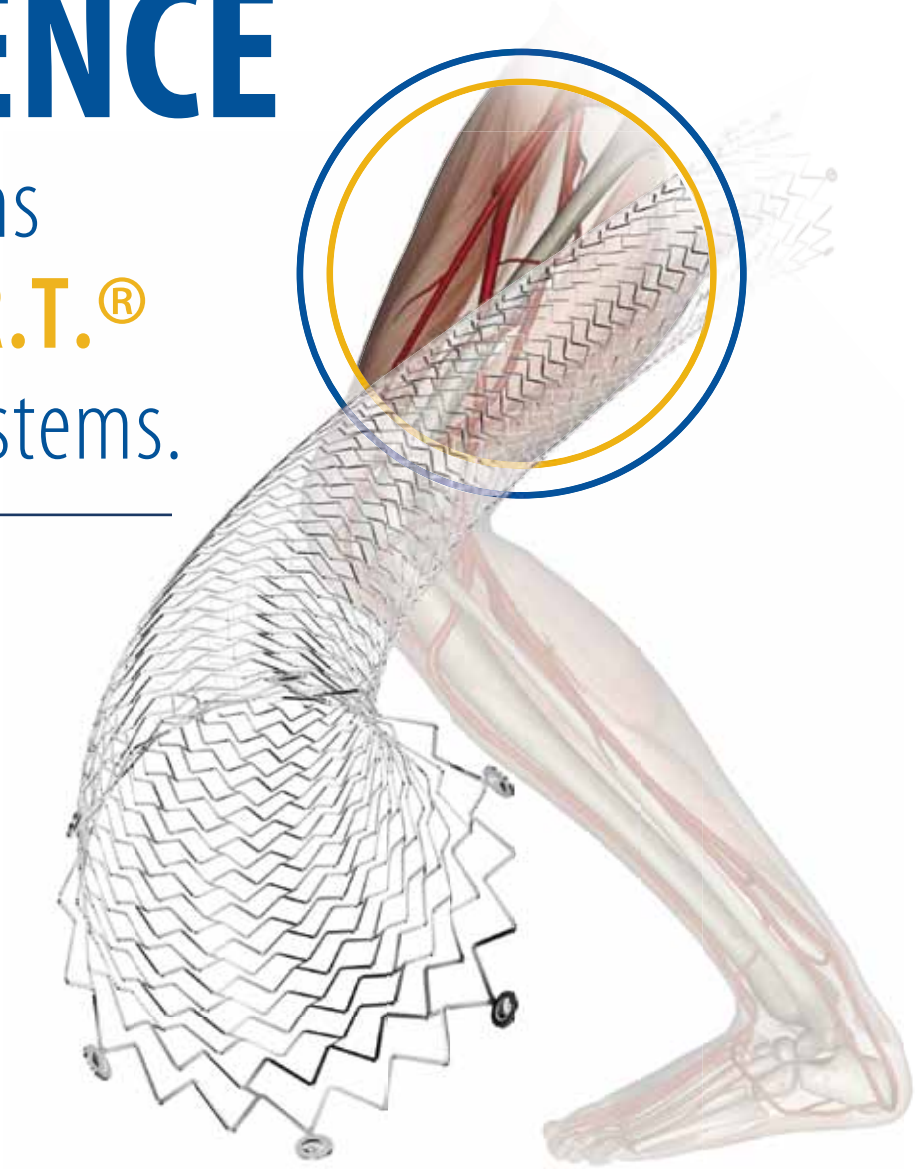
Endovascular TODAY

August 2013

# THE DESIGN DIFFERENCE

## Optimum solutions with the S.M.A.R.T.® Vascular Stent Systems.



# Contents

# THE **DESIGN DIFFERENCE**

## Optimum solutions with the **S.M.A.R.T.®** Vascular Stent Systems.

The S.M.A.R.T.® Stent System (Cordis Corporation) has been a workhorse endovascular self-expanding nitinol stent since its approval for the iliac bed in August 2003. In November 2012, the Food and Drug Administration (FDA) granted approval for the S.M.A.R.T.® Vascular Stent for the superficial femoral and proximal popliteal arteries. This approval was earned based on the strength of the compelling data presented from the STROLL study.[1] Taken together, the S.M.A.R.T.® Vascular Stent is the only stent available in the United States that carries dual approval for iliac and femoropopliteal arterial indications.

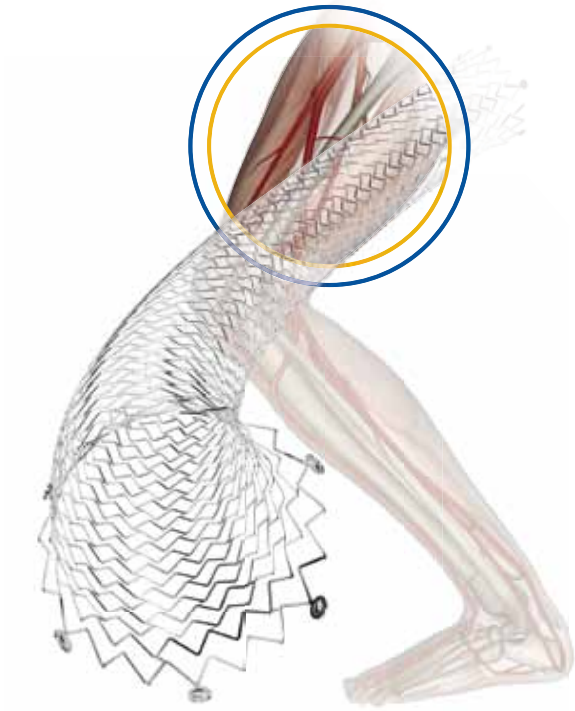
This supplement to *Endovascular Today*, which focuses on the S.M.A.R.T.® Vascular Stent System, has four sections: (1) the design behind the S.M.A.R.T.® Vascular Stent System, (2) the data supporting the S.M.A.R.T.® Vascular Stent System in various clinical investigations, (3) a case example highlighting the use of the S.M.A.R.T.® Vascular Stent, and (4) a discussion about health economics regarding the use of stents in the femoral artery segment.

### DESIGN CONSIDERATIONS

The forces exerted on the femoral artery are unique in the human body and include compression, flexion, extension, torsion, and fixation. Any stent or endoprosthetic implanted in this segment faces substantial demands to maintain resilience and integrity in the face of these forces. The design of the S.M.A.R.T.® Vascular Stent incorporates these factors to provide the optimal combination of radial strength, flexibility, longitudinal stability, and crush and fracture resistance, thereby maximizing performance and vessel patency.

### STRENGTH OF DATA

The S.M.A.R.T.® Vascular Stent has been evaluated in numerous investigations ranging from retrospective analyses, to prospective registries, to single- and double-arm randomized clinical trials. Long-term efficacy has been carefully reported with follow-up out to 5 years, as discussed later. Multiple clinical performance measures, including clinical, noninvasive, and invasive imaging, have been employed to meticulously follow study patients. Protocol-driven assessments of fracture rates and type have been reported, as well as their effect on restenosis.



### CASE REPORT

While angioplasty alone is considered the primary therapy of choice according to published guidelines, stenting has been shown to have superior long-term patency when compared with angioplasty in moderate and long lesions. The case example in this supplement highlights the application of the S.M.A.R.T.® Vascular Stent in a complex but frequently encountered clinical scenario.

### HEALTH ECONOMICS

The rate of endovascular procedures has increased over recent years, and there are obvious associated economic considerations for patients and health care systems. Relative to surgical procedures, endovascular care is less invasive, less expensive, and may offer substantial quality-of-life improvements for patients with peripheral artery disease, especially those facing amputation and the attendant loss of function.

—Kanwar Singh, MD, FACC, FSCAI, RPVI

1. Gray WA. S.M.A.R.T. Vascular Stent Systems in the Treatment of Obstructive Superficial Femoral Artery Disease: 2-Year Results. Presented at ISET 2013; January 20-24, 2013; Miami Beach, Florida.

# The Evolution of Stent Design

A look at S.M.A.R.T.® Vascular Stent design specifics for a new generation of durable performance.

**BY RAMESH MARREY, PHD**

The Cordis S.M.A.R.T.® Vascular Stent System (Cordis Corporation, Bridgewater, NJ) optimizes performance and outcomes through its unique design and associated characteristics. In general, a self-expanding stent's performance is determined by its geometrical pattern in conjunction with stent material (nitinol) parameters. Specifically, the construction of the circumferential rings comprising the stent struts, as well as the manner in which the bridges connect the longitudinally adjacent struts, fundamentally govern stent performance. The S.M.A.R.T.® Vascular Stent features 36 struts for each circumferential ring, with six alternating bridges connecting each ring to the next (Figure 1); through the 36-strut, six-bridge design, the stent's longitudinal stability, scaffolding, and resistance to radial force are maximized.

## STENT DESIGN CHARACTERISTICS

The stent's response to a uniform radial force, the scaffolding it offers to the arterial wall as well as the stent expansion range, heavily depends on strut length, the axial spacing of strut rings along the length of the stent, and the number of struts within a given ring. For instance, if the number of struts were decreased across a ring while maintaining strut length, the radial stiffness of the stent would increase—however, this would result in a wider strut angle at the deployed state, thereby compromising scaffolding, as well as directly impacting stent expansion capability.

On the other hand, a stent with a greater number of struts may result in a more acute angle between the struts at the deployed state and could increase scaffolding while trading off radial stiffness. This decrease in radial stiffness may in turn be compensated by shortening the length of the struts, thereby stiffening the radial response. The short struts and 36-strut pattern inherent in the S.M.A.R.T.® Vascular Stent offer a balance of strut length and number of struts to maximize the aforementioned stent performance attributes.

Another important characteristic is the alignment of strut rings to the rings immediately (longitudinally) adjacent to it. The S.M.A.R.T.® Vascular Stent utilizes a peak-to-valley design (Figure 2), in which the peak of one strut is aligned with the valley in the next ring of struts, but with a slight circumferential offset to that alignment. This offset peak-to-valley design allows for each ring of struts to actually sit just slightly inside the adjacent

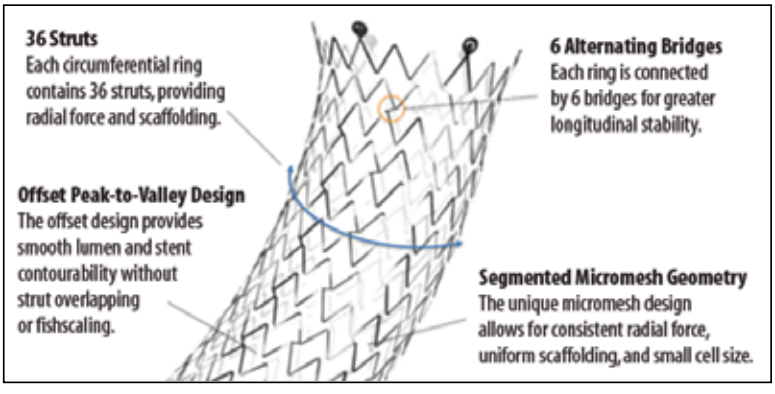



**Figure 1. Key features of S.M.A.R.T.® Vascular Stent design.**

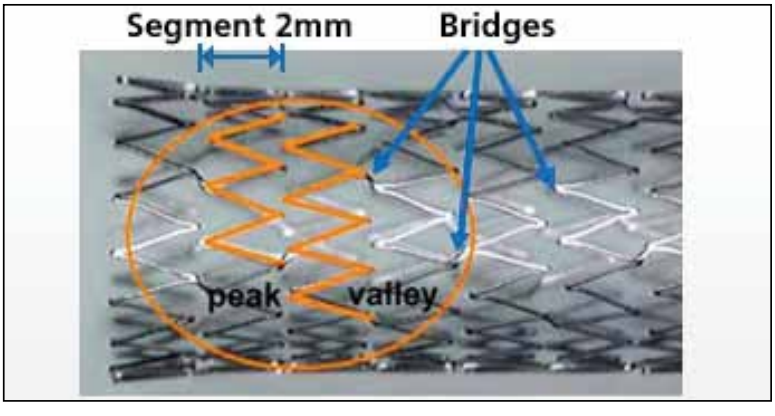



**Figure 2. Offset peak-to-valley design.**

ring. This has an impact on several performance characteristics:

(1) The number of strut rings per unit stent length plays an important role in the radial stiffness of the device. The peak-to-valley design allows for strut rings to be densely packed along the stent length, resulting in an increased number of strut rings per unit length and thus more resistance to radial loading.

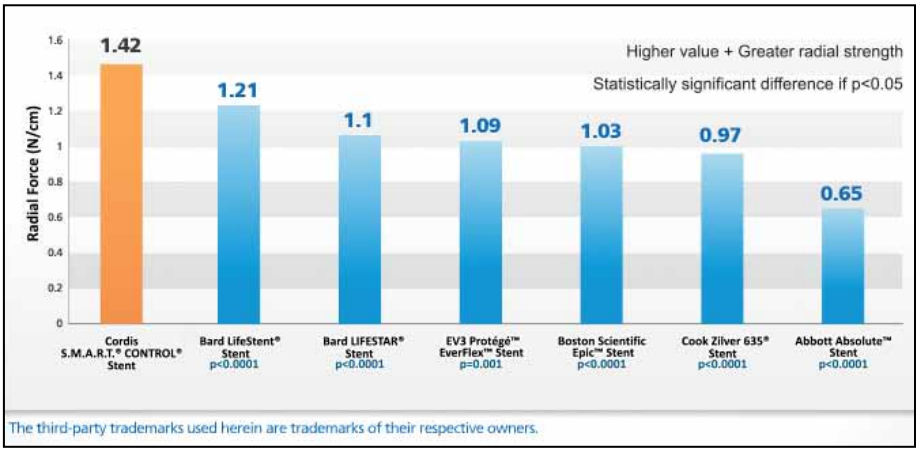



**Figure 3. S.M.A.R.T.® Vascular Stent's resistance to radial force.**

(2) With peak-to-peak designs, a sharp arterial bend would cause struts at the outside of the bend to lift up or "fish scale" while also causing strut "collisions" along the inner radius of the bend. The peak-to-valley configuration in the S.M.A.R.T.® Vascular Stent helps to mitigate both fish-scaling and strut collisions at tight arterial bends, resulting in a smooth vessel lumen and enhanced stent contourability.

(3) Stent scaffolding is further improved with the offset peak-to-valley configuration in conjunction with the earlier-mentioned short stent struts. This configuration results in a smaller cell size (Table 1), thereby helping to mitigate plaque prolapse while continuing to provide high and consistent radial stiffness.

**TABLE 1. COMPARISON OF S.M.A.R.T.® VASCULAR STENT GEOMETRY WITH COMPETITIVE STENT PLATFORMS**

| Company Name | Product Name | No. of Struts | No. of Bridges | Cells |
|---|---|---|---|---|
| Abbott Vascular (Santa Clara, CA) | Absolute® Stent | 12 | 3 |  |
| Bard Peripheral Vascular (Tempe, AZ) | LifeStent® Stent | 36 | 4 |  |
| | LifeStar™ Stent | 24 | 4 |  |
| Boston Scientific Corporation (Natick, MA) | Epic™ Stent | 30 | 5 |  |
| Cook Medical (Bloomington, IN) | Zilver 635® Stent | 24 | 4 |  |
| Cordis Corporation | S.M.A.R.T.® Vascular Stent | 36 | 6 |  |
| Covidien (Mansfield, MA) | Protégé™ Stent | 32 | 4 |  |

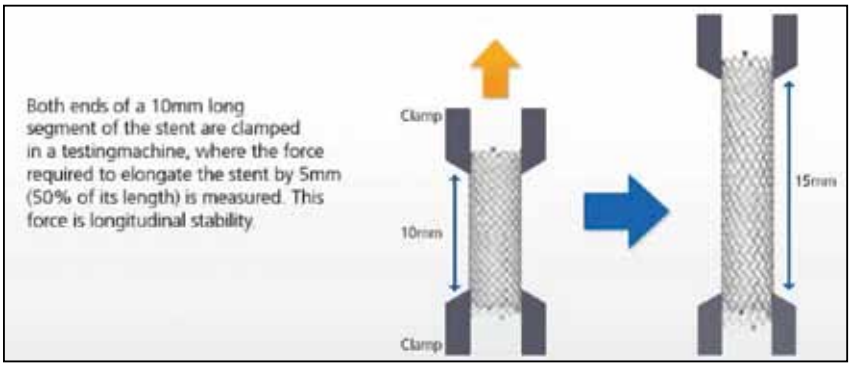



**Figure 4. Longitudinal stability of the S.M.A.R.T.® Vascular Stent.**

The six bridges per ring that connect those struts to the next ring are also designed to maximize performance characteristics. A reduced number of bridges compromise stent longitudinal stability and may lead to potential stent elongation during deployment. Stent elongation implies stent stretching during deployment, meaning that a device optimized to match the length of a lesion may end up stretching past that lesion and providing less structural support than is necessary. This in turn may affect placement accuracy, as well as radial performance (due to increased strut spacing). On the other hand, an increased number of bridge connections could make a stent too stiff, especially in tortuous anatomies in which sharp arterial bends are present.

The bridge geometry and the number of bridge connections are also crucial with regard to the propensity of stent fracture and subsequent fracture propagation. In stents with fewer bridges—for example, three to four bridges per ring—a fracture of a single bridge (type I fracture) can lead to complete transverse fractures (type III–V fractures) due to a decreased axial load-carrying capability of the remaining bridges. The six-bridge design of the S.M.A.R.T.® Vascular Stent helps prevent this fracture propagation, as is evident from the STROLL (S.M.A.R.T.® Vascular Stent Systems in the Treatment of Obstructive Superficial Femoral Artery Disease) clinical study. Specifically, the STROLL study determined a low (2%) fracture rate at 12 months, with no additional fractures at 24 months. Additionally, all fractures observed were type I fractures. The results from this clinical study are described in detail by William A. Gray, MD, in this supplement.

## STENT PERFORMANCE METRICS

The various design characteristics of the S.M.A.R.T.® Vascular Stent, as previously discussed, have a profound impact on performance. From a vessel patency standpoint, a small gain in the poststented vessel radius can dramatically increase the flow rate of blood. For example, a 1-mm gain in radius from 4 to 5 mm, or a 25% radius gain, translates to a 56% increase in the cross-sectional area and eventual flow rate. A 2-mm gain in vessel radius would yield a huge (125%) increase in resulting flow rate. Maximizing the vessel radius gain in turn relates to three key stent performance metrics—specifically, stent radial force, longitudinal stability, and scaffolding.

### Radial Force

The excellent resistance to radial force demonstrated by the S.M.A.R.T.® Vascular Stent due to its short struts and offset peak-to-valley design support significant long-term luminal gain. Bench tests have shown the S.M.A.R.T.® Vascular Stent to be superior in radial stiffness (resistance to radial force) compared to the majority of competitive stent designs, as evidenced by the results presented in Figure 3.

### Longitudinal Stability

Stent longitudinal stability refers to the ability of the stent to resist stretching during deployment. Longitudinal stability was measured for various stent platforms by performing a tensile test along the stent axis and measuring the force required to stretch the stent by 50% (Figure 4). A lower force response would imply decreased longitudinal stability, indicating that the stent is more stretchable and thus more prone to deployment problems, resulting in reduced scaffolding and radial force.

The test results indicate that the longitudinal stability of the S.M.A.R.T.® Vascular Stent far exceeds competi-

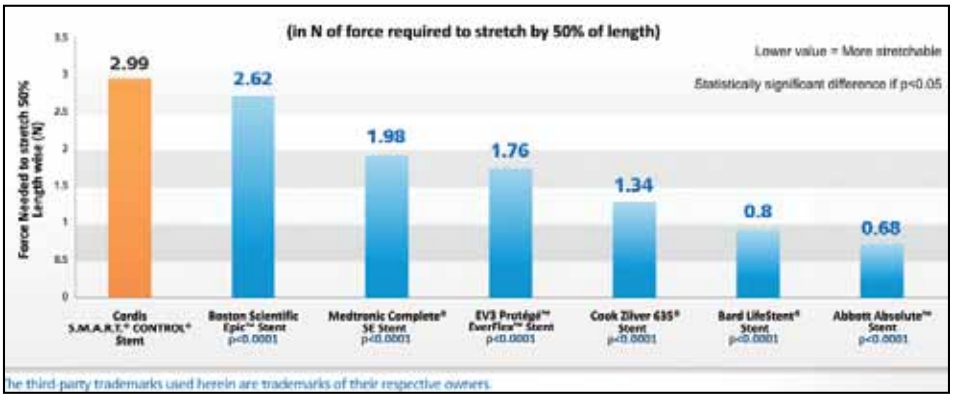



**Figure 5. Stent longitudinal stability testing.**

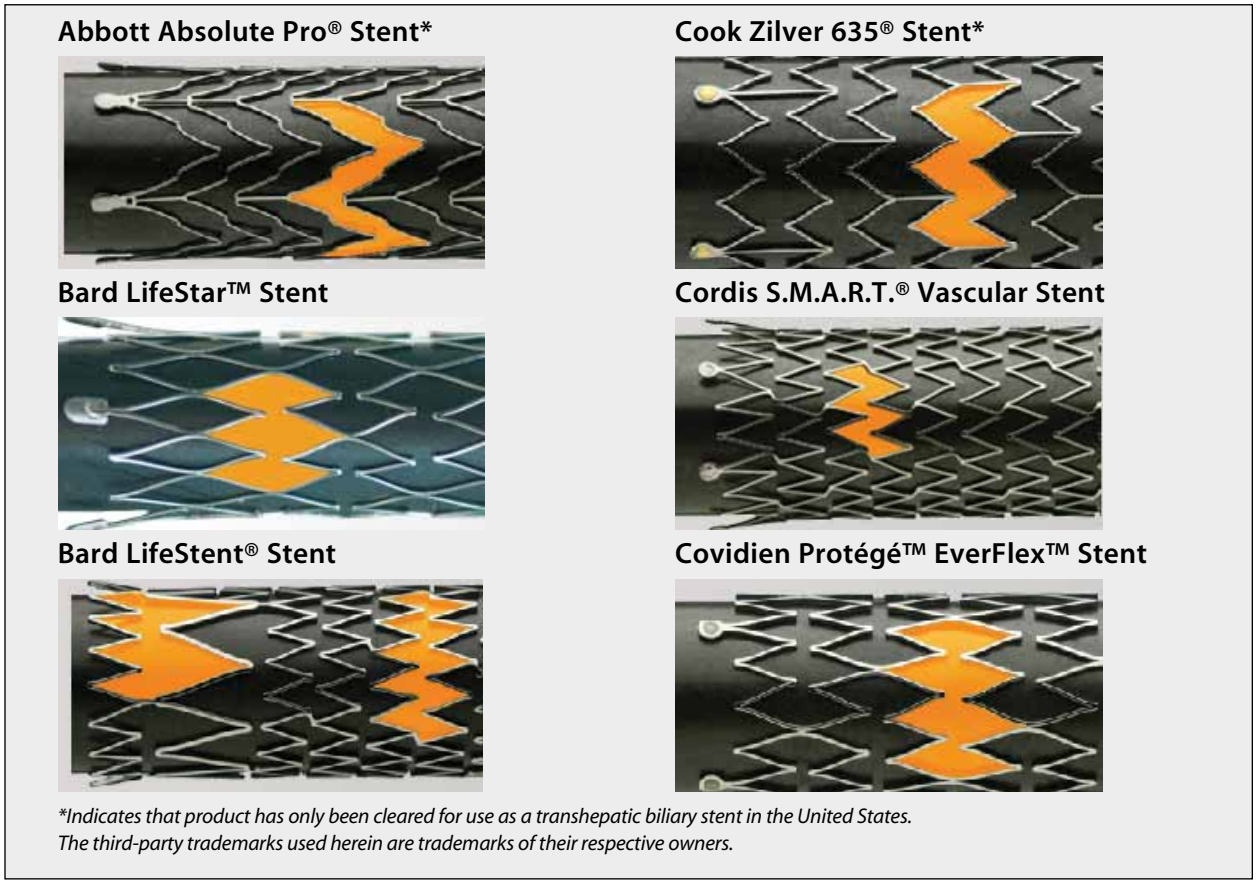



**Figure 6. Cell size of the S.M.A.R.T.® Vascular Stent.**

tive stent platforms (Figure 5). In fact, it demonstrates up to 349% greater longitudinal stability than competitive stents, as reflected in the chart.

### Scaffolding

The effect of the close-packed stent struts and offset peak-to-valley design on stent scaffolding was previously described. The resulting small cell size and uniform coverage inherent in the S.M.A.R.T.® Vascular Stent is evident from the comparison presented in Figure 6.

The fatigue resistance of the S.M.A.R.T.® Vascular Stent has been characterized via rigorous chronic bench top tests and computational (FEA) models utilizing loading conditions relevant for the proximal, mid, and distal SFA, as well as the proximal popliteal artery. The cyclic loads incorporated for these studies include (1) radial pulsatile loading, (2) axial compression, (3) arterial bend, (4) arterial twist, (5) stent crush, (6) combined axial compression and bend, and (7) combined axial compression and twist. These chronic durability studies and low STROLL fracture rates at 12 and 24 months corroborate the structural fatigue robustness of the S.M.A.R.T.® Vascular Stent.

These excellent stent performance results will be further substantiated with clinical outcomes from the STROLL clinical study within this supplement.

## CONCLUSION AND FUTURE STUDY

The next-generation, self-expanding stent platform from Cordis Corporation—the S.M.A.R.T.® Flex Vascular Stent—is currently under clinical investigation in the United States. The S.M.A.R.T.® Flex Vascular Stent is an evolution of S.M.A.R.T.® Stent technology, building on the radial strength, longitudinal stability, and scaffolding attributes of the S.M.A.R.T.® Stent design while adding fully connected helical struts to accommodate torsional, compressive, and bending loads and enabling reconstrainability during stent deployment. ■

*Ramesh Marrey, PhD, is an Engineering Fellow at Cordis Corporation. He may be reached at rmarrey@its.jnj.com.*

The S.M.A.R.T.® Vascular Stent demonstrates up to 349% greater longitudinal stability than competitive stents.

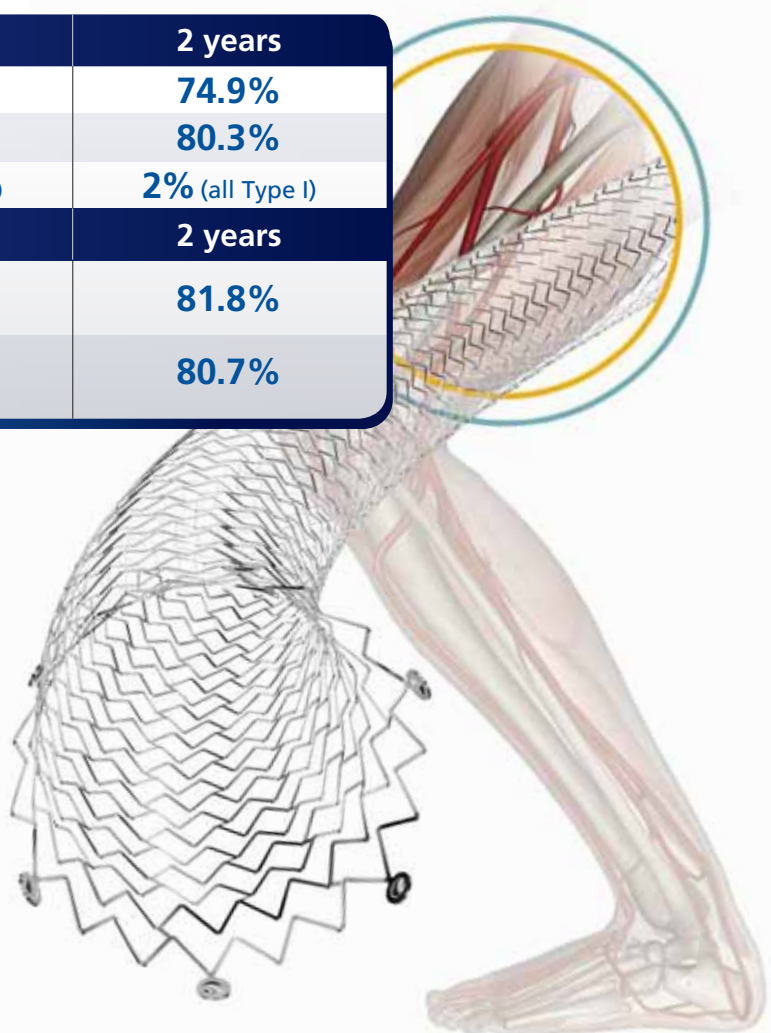
# Now with FDA Approval for SFA INDICATION!

# Cordis **S.M.A.R.T.®**
## Vascular Stent Systems

## Effective SFA revascularization through 2 years with the S.M.A.R.T.® Vascular Stent Systems[1]

## STROLL Outcomes

| Clinical Outcomes | 1 year | 2 years |
|---|---|---|
| Primary Patency† | 81.7% | 74.9% |
| Freedom from TLR | 87.6% | 80.3% |
| Stent fracture rate | 2% (all Type I) | 2% (all Type I) |
| **Patient Outcomes** | **1 year** | **2 years** |
| Patients with minimal or no PAD symptoms§ | 76.6% | 81.8% |
| Patients with normal ABI (>0.8) | 81.0% | 80.7% |



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*Defined as no significant reduction in flow detectable by duplex ultrasound and no further clinically driven target lesion revascularization.

**Defined as Rutherford-Becker classification 0 or 1.

**Reference: 1.** Data on file, Cordis Corporation.

**IMPORTANT INFORMATION:** Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.

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# Smart Utility, Smart Outcomes

What do the data tell us about the role of the S.M.A.R.T.® Vascular Stent for treating SFA disease?

**BY WILLIAM A. GRAY, MD**

Since its introduction more than a decade ago, there has been a great deal of high-quality data generated for the use of the S.M.A.R.T.® Stent (Cordis Corporation, Bridgewater, NJ) in the superficial femoral/popliteal artery (SFA) circulations. From the more than 2,000 patient outcomes published or presented using the S.M.A.R.T.® Stent, it becomes possible to characterize this device with regard to its clinical utility and durability in a variety of lesion subsets, both in isolation and compared to other self-expanding nitinol stents, in some of the longest follow-up available for any SFA stent. This article reviews these data as a prelude to a discussion regarding the pivotal STROLL trial outcomes and draws conclusions regarding the place of the S.M.A.R.T.® Stent in the management of patients with occlusive SFA disease.

## CLINICAL TRIALS AND REGISTRIES

The earliest controlled data on the S.M.A.R.T.® Stent come from the prospective SIROCCO study,[1] which randomized the bare S.M.A.R.T.® Stent to a drug-eluting sirolimus (DES) version. Although the DES version did not demonstrate a differential improvement in efficacy, the results of the study were nevertheless impressive, showing an 18-month primary patency rate for the bare S.M.A.R.T.® Stent of 87% for lesions of approximately 8 cm in length. The next set of data came from the BLASTER study,[2] which randomized patients receiving the S.M.A.R.T.® Stent for treatment with and without abciximab. Although there were no differences in outcomes as a result of the adjunctive pharmacology, in a population in which the mean length was approximately 12 cm, the clinical patency at 12 months was 83%, confirming the earlier SIROCCO results.

Early comparative data on the S.M.A.R.T.® Stent come, albeit retrospectively, from the FESTO study,[3] which reviewed the SFA outcomes of S.M.A.R.T.®, SelfX (Abbott Vascular, Santa Clara, CA), and Luminexx® (Bard Peripheral Vascular, Tempe, AZ) stents. In this analysis, the S.M.A.R.T.® Stent outperformed the other stents on 12-month patency as well as fracture resistance. In that study, fractures were associated with a loss of patency.

Some of the longest-term data on SFA stenting exists with the S.M.A.R.T.® Stent. The SIROCCO II trial[4] (a second-phase randomized DES study meant to assess changes in elution rates) enrolled 57 patients who were followed to 4 years. Both the DES and bare-metal S.M.A.R.T.® Stents demonstrated durable results, with a freedom from reintervention rate of approximately 74% at 4 years. In the retrospective J-SMART study[5] of 432 patients with lesion lengths of approximately 16 cm (approximately twice that of SIROCCO II), 5-year primary patency was a remarkable 66%. In fact, combined with other S.M.A.R.T.® Stent data, there appears to be an inverse relationship between lesion length and patency, not previously well demonstrated with a single-stent system.

## THE STROLL TRIAL

It is on this background of a robust experience with the S.M.A.R.T.® Stent in the SFA that the pivotal STROLL trial[6] was conceived and executed in 250 patients at 39 sites in the United States. The STROLL trial was a multicenter, prospective, single-arm study of the S.M.A.R.T.® Stent in SFA/popliteal lesions, designed to gain an FDA vascular indication for the S.M.A.R.T.® Stent, which was achieved in November 2012 based on the strength of the STROLL data.

It becomes possible to characterize the S.M.A.R.T.® Stent with regard to its clinical utility and durability in a variety of lesion subsets … in some of the longest follow-up available for any SFA stent.

STROLL demonstrated an excellent safety and efficacy profile when patients were treated for SFA/popliteal disease with the S.M.A.R.T.® Stent, with additional measures of long-term clinical efficacy tracking the sustained and durable patency results.

Patients eligible for the S.M.A.R.T.® Stent had to be Rutherford classification 2 through 4 with SFA/popliteal lesions between 4 and 15 cm in length and diameters between 4 and 6 cm. The primary efficacy endpoint of the study was patency (defined as the composite of the absence of both target lesion revascularization [TLR] and Doppler ultrasound-detected stenosis < 50%) at 12 months. There were important secondary endpoints that included 3-year clinical follow-up, functional and hemodynamic outcome measures, and protocol-driven core-lab radiographic evaluation of stent fracture. Follow-up is quite complete, with evaluable data on 234 subjects available at 1 year and on 224 subjects at 2 years.

Baseline patient characteristics are in keeping with other SFA trials, with a mean age of 68 years, two-thirds being men, and nearly 50% with diabetes. The average lesion length was approximately 8 cm, and one-quarter of the lesions were chronic total occlusions (CTOs).

Procedural results were excellent, with a technical success rate of 100% in relieving the stenosis, and no safety events (death, amputation, and TLR) within the first 30 days. Long-term follow-up of these acute results demonstrate primary patency, by Kaplan-Meier estimate, was 81.7% at 1 year and 74.9% at 2 years. Doppler ultrasound determination of patency was > 80% for both time intervals, as was the freedom from clinically driven TLR.

The careful radiographic assessment and core lab adjudication of stent strut fractures demonstrated that, of the five possible grades of fracture, S.M.A.R.T.® Stent usage in STROLL only resulted in fractures in four of 197 stents at 1 year, and no further fractures were noted at 2 years. Furthermore, only the simplest and most "benign" type of fracture was seen (type I, single-connector fracture), and no more complex fractures were noted. Last, there was no association with fracture and loss of patency in STROLL. These data were in contradistinction to previous data suggesting both higher rates of fracture with the S.M.A.R.T.® Stent, as well as an association with restenosis when fracture occurs.

Two populations within STROLL who are thought to be particularly at risk for device failure—patients with CTO or diabetes—had a prespecified analysis of efficacy outcomes. Interestingly, the presence of diabetes or CTO did not lead to any worse outcomes in patency after treatment with the S.M.A.R.T.® Stent when compared to patients without those conditions.

Increasingly, it is no longer adequate to simply demonstrate patency outcomes when treating claudicants. Specifically, patients must show benefit in hemodynamic and functional outcomes. Accordingly, these endpoints were built into the STROLL study. Mean ankle-brachial indices demonstrated marked and significant improvement from baseline (0.66 ± 0.15) to postprocedure (0.98 ± 0.14), and these improvements were durable to 2 years (0.93 ± 0.18). Similarly, > 80% of all patients were Rutherford-Becker class 0 or 1 at 2 years, whereas preprocedure, almost all patients were class 2 through 4.

## SUMMARY

STROLL demonstrated an excellent safety and efficacy profile when patients were treated for SFA/popliteal disease with the S.M.A.R.T.® Stent, with additional measures of long-term clinical efficacy tracking the sustained and durable patency results. There were satisfying data on the at-risk populations with diabetes and CTOs that assured no difference in safety, efficacy, or durability of results.

These outcomes compare favorably with those obtained with other FDA-approved bare-metal and DES self-expanding nitinol stents, and place the S.M.A.R.T.® Stent results squarely among the treatment options available to physicians for the treatment of patients with SFA/popliteal disease. ■

*William A. Gray, MD, is Associate Professor of Medicine at Columbia University Medical Center in New York, New York. He has disclosed that he is a consultant for Abbott Vascular, Cordis, Medtronic, Inc., and Gore & Associates, and holds stock in Contego Medical. Dr. Gray may be reached at wg2131@cumc.columbia.edu.*

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# Lower Extremity Solutions

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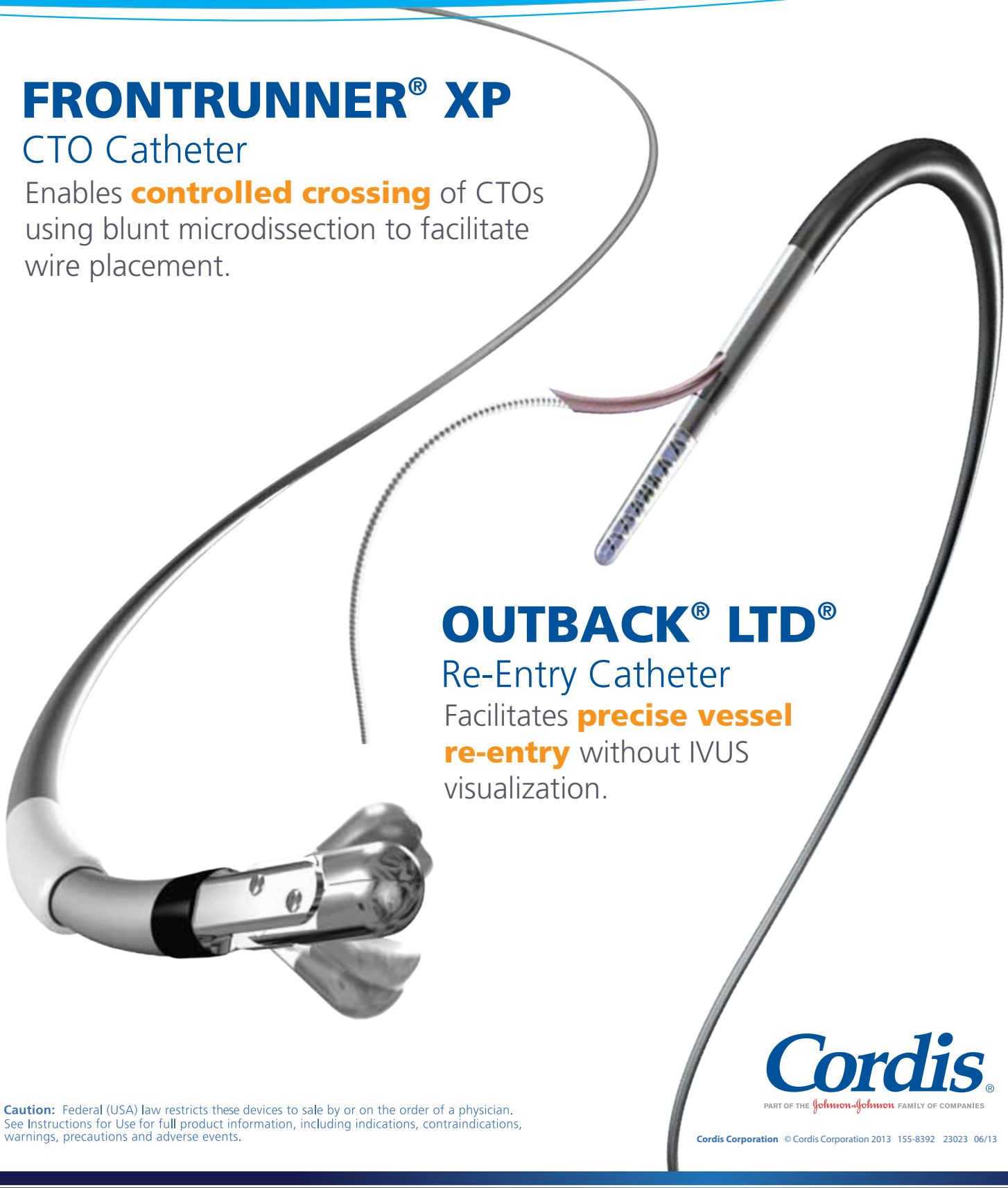

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# Case Report: Managing Multilevel Occlusions

Successful crossing and revascularization of the femoral, popliteal, and tibial arteries in a patient with critical limb ischemia.

**BY KANWAR SINGH, MD, FACC, FSCAI, RPVI**

An 80-year-old man presented to his primary care physician with complaints of nonhealing ulceration of the dorsal surface of the left great toe for 1 year and the development of a new blackened third toe on both the dorsal and plantar surfaces. The recent lesions were associated with severe rest pain, and there was a long-standing history of bilateral calf claudication.

The patient's past medical history was notable for type II diabetes mellitus, coronary artery disease with previous acute myocardial infarction and coronary stenting, hypertension, and chronic renal replacement therapy with hemodialysis. A reformed tobacco user, he had a 70-pack/year history of smoking. His medications included aspirin, clopidogrel, Lopressor®, lisinopril, and calcium acetate. He had no drug allergies and no history of illicit substance use.

A physical exam showed a heart rate of 106 bpm, blood pressure of 154/90 mm Hg (right side), 5/10 on the pain scale, respiratory rate of 18, and temperature of 99º F. The left arm blood pressure was not interrogated due to dialysis access in the left brachial position. His weight was 155 pounds, and his height was 5' 8".

The patient's neck was supple but featured a soft right carotid bruit. His lungs were clear, and a cardiac exam revealed a 2/6 systolic ejection murmur. The left arm access had an excellent thrill. Abdominal pulsation was not apparently increased. Femoral pulses were readily appreciable and were without bruits. The right leg had a reduced pulse amplitude in the popliteal position, and pedal pulses were not palpable. The left side (the affected side) had pulse in neither the popliteal nor pedal positions, and the left foot was cool. The skin was shiny and hairless on both sides, and a dark skin tone complicated the assessment of elevation pallor, dependent rubor, and mottling. Neurologically, the patient was cognitively intact, alert, oriented, and in obvious discomfort. He had stocking-glove sensory neuropathy and no gross motor deficits. The lesion on the third toe extended to the midmetatarsal and was dry, whereas the more chronic wound on the first toe had some purulent discharge and surrounding edema without fluctuance.

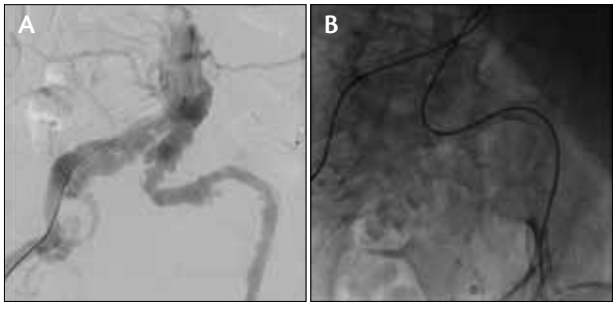


**Figure 1. Cobblestone aorta with severe tortuosity (A). Difficulty delivering the catheter to the contralateral limb (B).**

Bedside ankle-brachial index testing showed the right side to be 0.52 and the left side to be 0.1 by Doppler evaluation.

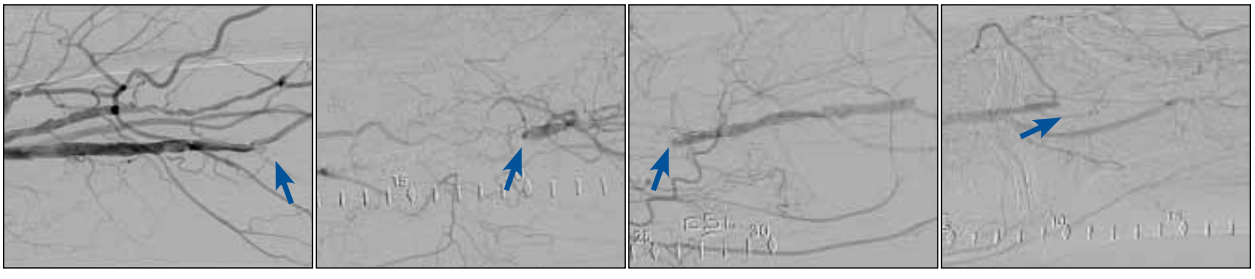

**Figure 2. Left leg runoff. Arrows indicate multisegment occlusions and no runoff at the foot.**

**Figure 3. Popliteal occlusion.**

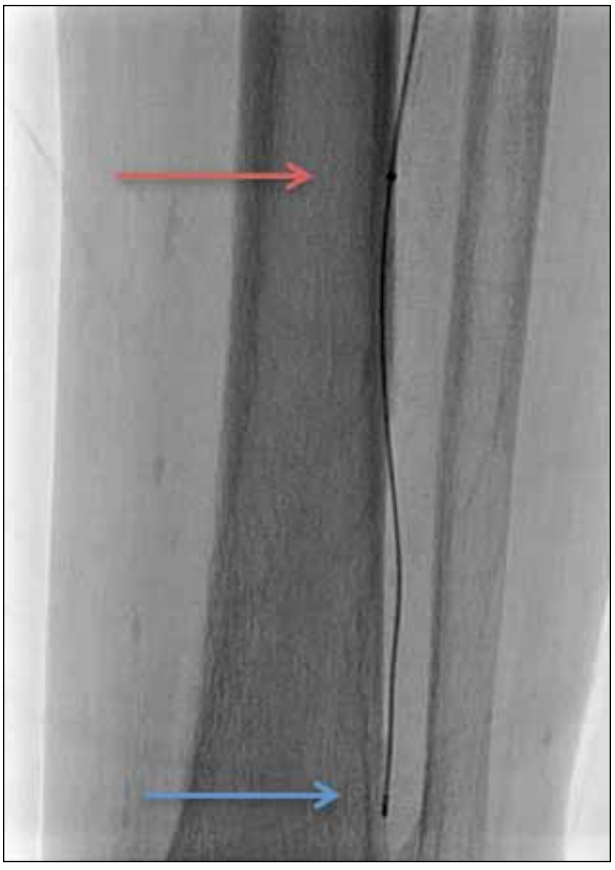

**Figure 4. Micro-Guide Catheter position (red arrow) and FRONTRUNNER® XP CTO Catheter position (blue arrow).**

The patient was diagnosed with critical limb ischemia with probable cellulitis. He was admitted and started on intravenous heparin and broad-spectrum antibiotics.

Abdominal aortography was notable for cobblestone aorta with severe tortuosity (Figure 1A). An Aquatrack® Hydrophilic Guidewire (Cordis Corporation, Bridgewater, NJ) and diagnostic catheter were introduced via the right common femoral artery. Crossover was difficult (Figure 1B) but did permit runoff diagnostic angiography.

Runoff digital subtraction angiography revealed severe calcification and multilevel chronic total occlusion within the superficial femoral artery (SFA), as well as total occlusion of the popliteal artery with a lack of evident nameable distal runoff (Figure 2).

With this clinical scenario and angiographic picture in mind (Figure 3), it was evident that without revascularization, amputation would be required to the above-knee level, which, with his comorbidities, would be severely debilitating. It was clear that an aggressive effort to reconstruct flow to the foot would be required to attempt to salvage the foot and heal an amputation of the third toe.

## REVASCULARIZATION STRATEGY

Ipsilateral access was achieved with antegrade access using a combination of fluoroscopic localization and ultrasound guidance. A 6-F short sheath was introduced, and the patient was systemically anticoagulated with unfractionated heparin to a target activated clotting time of 250 seconds. A FRONTRUNNER® XP

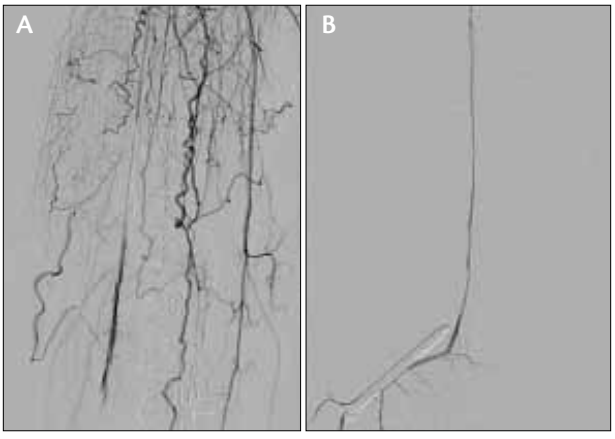


**Figure 5. Injection via Micro-Guide Catheter at the popliteal artery showed hints of tibial branches (A). Final crossing with 0.014-inch wire and support catheter; flow was restored to foot (B).**

CTO Catheter (140-cm length) (Cordis Corporation) with support from a Micro-Guide Catheter (Cordis Corporation) was chosen to optimize crossing in the SFA. The FRONTRUNNER® XP CTO Catheter was able to cross luminally throughout the totally occluded segment beyond the popliteal artery. The presumed course of the FRONTRUNNER® XP CTO Catheter was into the peroneal artery due to the straight, inline direction of progress (Figure 4).

However, the Micro-Guide Catheter would not advance beyond the midtibial artery due to profound calcification, hence the FRONTRUNNER® XP Catheter was removed, and careful injection was performed (Figure 5), which showed hints of hibernating tibial vasculature. At this point, we exchanged to a

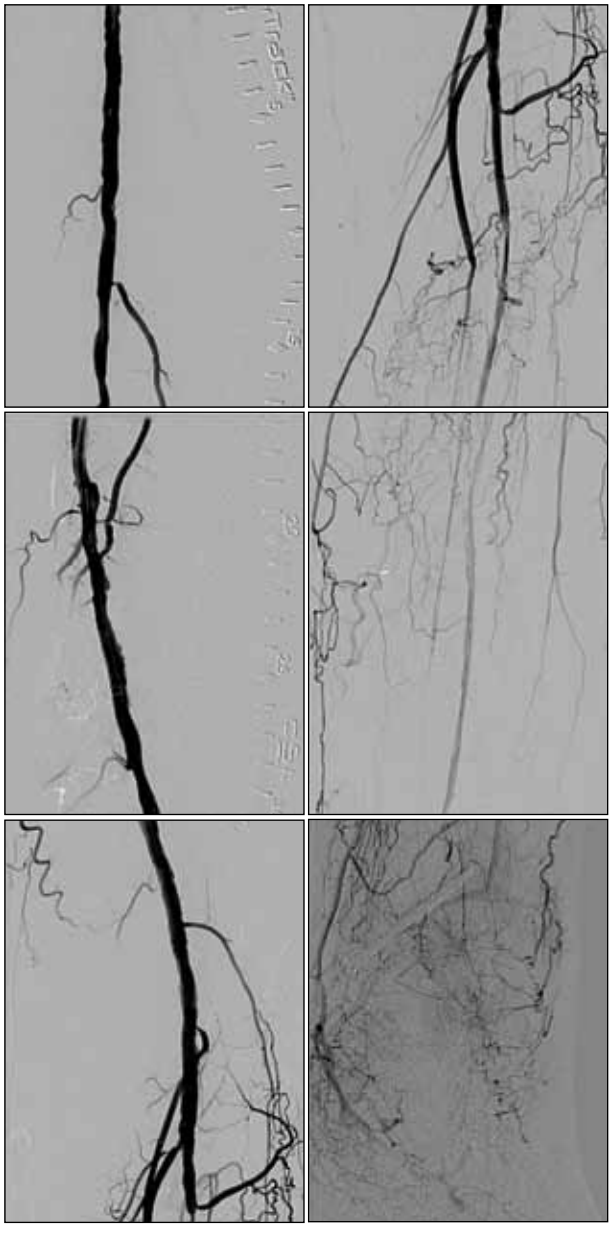

**Figure 6. Flow reestablished to the foot with blush.**

The FRONTRUNNER® XP CTO Catheter was able to cross luminally throughout the totally occluded segment beyond the popliteal artery.

0.014-inch wire system (Hi-Torque Pilot 200 [Abbott Vascular, Santa Clara, CA], 300-cm length), and an 0.014-inch support catheter (0.014-inch Quick-Cross® [Spectranetics Corporation, Colorado Springs, CO]). The wire was readily passed into calcaneal branches off the peroneal artery.

Angioplasty was performed across the occluded peroneal artery using a 2.5- X 220-mm SLEEK® OTW PTA Dilatation Catheter (Cordis Corporation), and the popliteal and SFA were treated with a 5- X 150-mm POWERFLEX® Pro PTA Dilatation Catheter (Cordis Corporation), restoring inline flow from the aorta to the foot. Stenting was performed in the SFA and proximal popliteal arteries using two overlapping 6- X 150-mm S.M.A.R.T.® Vascular Stent Systems. Spot-stenting was also performed in an off-label fashion in the proximal cap of the occluded segment of the peroneal artery using a 3.5- X 33-mm sirolimus-eluting coronary stent (Figure 6).

## FOLLOW-UP

The patient remained hospitalized for 48 hours for pain control medication and renal replacement therapy. He was discharged on oral antibiotics and underwent distal amputation for the necrotic third digit. He has remained ambulatory and independent at 24-month follow-up to date.

## SUMMARY AND CONCLUSION

This patient presented with critical limb ischemia and had multilevel occlusions, as is common for such patients. A combination of careful crossing with aggressive revascularization of the femoral, popliteal, and tibial arteries resulted in the re-establishment of inline flow from aorta to ankle. Robust collateralization of the dorsal and plantar surfaces of the foot were seen to arise from communicating arteries from peroneal to dorsalis pedis and posterior tibial arteries. Clinically, the patient was definitively treated with a functional, limited amputation of nonviable tissue and remained independent at long-term follow-up. ■

*Kanwar Singh, MD, FACC, FSCAI, RPVI, is an interventional cardiologist and currently an Associate Professor of Medicine and Co-Director of the Cardiovascular Catheterization Laboratory at the University of Virginia Health System. He has disclosed that he is a paid consultant and moderator for Cordis Corporation. Dr. Singh may be reached at kps2u@virginia.edu.*

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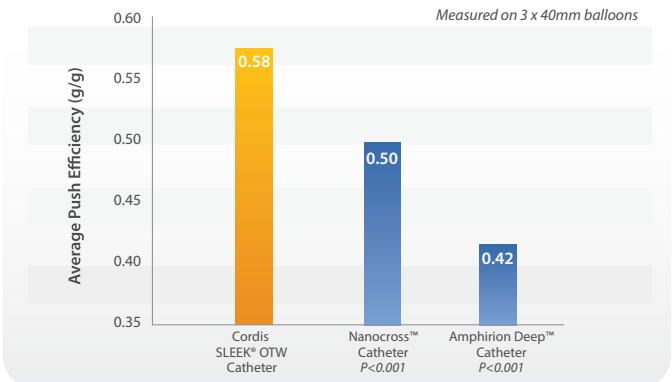
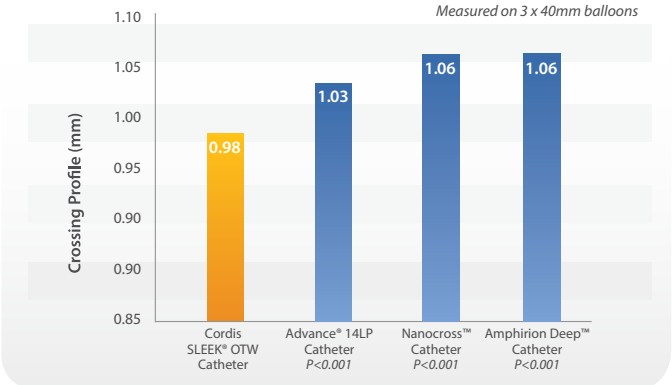



### Small Crossing Profile *for tighter lesions*[1]




## Product Benefits:

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# Value of Endovascular Interventions

When released, will the TASC III guidelines eliminate the discord with current clinical practice?

**BY DAVID E. BANKO, CPA, MS**

The growth of endovascular interventions is linked to the positive outcomes and value these procedures provide to patients. Physicians are increasingly recommending an endovascular-first revascularization strategy when combined medical treatment and exercise fails in achieving the desired outcome. The publication of consensus guidelines advocating the use of endovascular interventions in treating peripheral arterial disease (PAD) has accelerated the adoption of this less invasive treatment alternative.[1] This article highlights the value drivers for endovascular interventions and discusses a potential shift in future volumes.

## INCREASING TECHNOLOGY ADOPTION

In the March 2013 edition of *Endovascular Today*, Brian Contos of The Advisory Board Company authored an informative article on the growth of endovascular services and specifically detailed the 67% increase in lower extremity arterial angioplasty procedures between 2005 and 2011.[2] The article identified select technologies that were enablers of the procedural growth and the resulting outcomes that truly drive increased utilization of endovascular interventions. When innovative medical devices fail to produce the desired and anticipated outcome, physicians will swiftly evolve their practice pattern away from the technology. The key to increased adoption of next-generation technologies is the development of a comprehensive evidence base during both product development and the initial launch phase. Comparative effectiveness research of competing interventions or technologies is very influential with physicians, payers, and hospital providers. A positive recommendation in a consensus guidance document leads to broad market access.

## FORMATION OF TASC

More than a decade ago, the predominant treatment for symptomatic PAD involving lesions in the femoropopliteal region was bypass surgery and, if symptoms were severe enough, amputation. Endovascular treatment options were not available. The Transatlantic Intersociety Consensus (TASC) was established soon after and provided the first consensus guideline on PAD, focusing on symptomatic rather than asymptomatic patients.[3] With the advancement of endovascular techniques, the Intersociety Consensus for the Management of Peripheral Artery Disease (TASC II) consensus process started in 2004, aiming to reach vascular specialists and primary care physicians globally.[4] The goal of these guidelines was to provide a truly international consensus on the diagnosis and management of PAD. The fact that endovascular revascularization is increasingly recommended and used for treatment of lower extremity lesions in patients with PAD is primary evidence that the targeted outcomes are being achieved (Table 1).

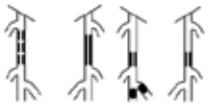
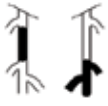
## ENDOVASCULAR ADVANTAGES

The use of these minimally invasive devices and procedures is attractive to patients when compared to surgical interventions, which are accompanied by increased risk and need for recovery time. This is especially true for patients with critical limb ischemia (CLI), for whom in the past the only option was to undergo surgery or amputation. When considered in combination, the advancements in endovascular techniques have coincided with an increase in the use of endovascular approaches over time, as evidenced through observational data.[1] In this 12-year retrospective single-center study, the percentage of revascularization procedures being performed using the endovascular method ranged from 0% in 1999 to 89% in 2010. In 2005, the split between open surgical and endovascular revascularization was essentially equivalent.

Lower extremity bypass surgery, compared with endovascular interventions, may pose an increased procedural risk due to the invasiveness involved. This may be evident in older patients with more advanced disease and comorbid conditions. This population is also more likely to have severe PAD and complex lesions for which guidelines may recommend surgery.

**TABLE 1. CURRENT TASC II GUIDELINES AND TREATMENT OF FEMOROPOPLITEAL LESIONS**

A technical update known as TASC IIb was presented based upon newer clinical data but never published, as physician consensus was not achieved. Discussions are ongoing for the creation of TASC III, but a definitive publication date is not currently available.[5] One of the central questions anticipated to be answered with TASC III is whether the available evidence base supports creating a formal recommendation for endovascular interventions on type C and D lesions.

| Femoropopliteal Lesions | | |
|---|---|---|
| **Lesion Type** | **Lesion Characteristics** | **TASC II Guidelines Recommendation** |
| Type A Lesion  | Single occlusion ≤ 5 cm in length | Endovascular |
| | Single stenosis ≤ 10 cm in length | |
| Type B Lesion  | Multiple lesions (stenosis or occlusions), each ≤ 5 cm | Endovascular[a] |
| | Single stenosis or occlusion ≤ 15 cm not involving the infrageniculate popliteal artery | |
| | Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass | |
| | Heavy calcified occlusion ≤ 5 cm in length | |
| | Single popliteal occlusion | |
| Type C Lesion  | Multiple stenosis or occlusion totalling > 15 cm with or without heavy calcification | Bypass surgery[a] |
| | Recurrent stenosis or occlusion that needs treatment after two endovascular interventions | |
| Type D Lesion  | CTO of CFA or SFA (> 20 cm, involving the popliteal artery) | Bypass surgery |
| | CTO of popliteal artery and proximal trifurcation vessels | |

*Adapted from Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33(suppl 1):S1-75.*[4]

*[a]Patient comorbidity, fully informed patient preference, and local operator long-term success rates must be considered when making recommendations.*

Compared to endovascular management, several studies show a greater complication risk with bypass surgery in those with lower extremity lesions. Complications may extend the patient's length of stay, increasing the consumption of hospital resources. Nonfatal complications can often reduce patient quality of life. Certain procedure-related complications (eg, myocardial infarction) may reduce life expectancy considerably.

Hospital providers and physicians seeking to demonstrate the value of endovascular techniques will require a current comparison of total costs versus surgery, paying particular attention to the initial procedure-related costs and tracking the potentially lower risk of complication-associated costs such as surgical site infections. These lower costs may more than offset reintervention costs to maintain patency. The likelihood of total costs being lower for endovascular procedures increases in populations where primary patency is expected to be similar for both the minimally invasive and open surgical modalities. Studies focusing on the initial episode of care related to the hospitalization fail to track the downstream costs associated with each revascularization option.

## CONCLUSION

In the recommended treatment populations, endovascular interventions provide a practical treatment alternative for patients failing to respond to medical treatment and exercise. The utilization of a minimally invasive procedure to alleviate symptoms as compared to surgical bypass creates value by reducing the complication risks such as surgical site infections. As newer clinical study data become available, the recommendations for the types of lesions that should be managed with endovascular techniques may be expanded to include type C and D lesions. ■

*David E. Banko, CPA, MS, is Director, Health Economics, Reimbursement and Strategic Pricing at Cordis Corporation, a Johnson & Johnson company. He may be reached at (908) 541-4107; dbanko@its.jnj.com.*

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4. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33 Suppl 1:S1-75.
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