Supplement to

Sponsored by Cordis Corporation

Endovascular TODAY

October 2015

Over 50 Years Shaping the Future of Health Care

Insights From David J. Wilson, President of Cordis Corporation

As Cordis Corporation joins Cardinal Health, the Cordis President reflects on the company's legacy of innovation and shares goals for the future.

David J. Wilson is the Worldwide President of Cordis Corporation in Fremont, California.

David, you started your career at the Johnson & Johnson Family of Companies with Cordis Corporation, followed by multiple leadership roles within the Johnson & Johnson Family of Companies. Now, you are leading Cordis Corporation, while becoming part of Cardinal Health. What do you think about this move to Cardinal Health?

After 20 years with the Johnson & Johnson Family of Companies, including over 11 years with Cordis Corporation, I'm tremendously excited to be leading Cordis at this moment in time. Cordis is known for delivering meaningful, innovative products to patients and customers, and I am proud to have spent the earlier part of my career in the Cordis Research & Development labs. Cordis is now joining a corporation, Cardinal Health, that deeply values our people and their work, our global capabilities, and our strong customer relationships. The Cordis business is a priority for Cardinal Health. Cardinal Health is looking forward to working with Cordis to continue building on our market reputation and expanding our growth.

Cordis has a long legacy of innovation and of bringing many firsts to the cardiovascular field. How do you envision Cordis innovating in the future?

Today, Cordis is a recognized leader in the development and manufacturing of interventional vascular technology with its more than 50-year history of delivering pioneering products to treat millions of patients worldwide. We will build on this rich history working together with Cardinal Health, utilizing their complementary skills and new expertise. Recognizing the important role we play across the cardiovascular market, Cardinal Health is eager and committed to investing in the Cordis business to drive growth and innovation, and in turn, enhance patient care. Leveraging Cordis' deep experience in product innovation and Cardinal Health's business and operational expertise, we will be uniquely positioned to continue meeting the evolving needs of our customers and their patients.

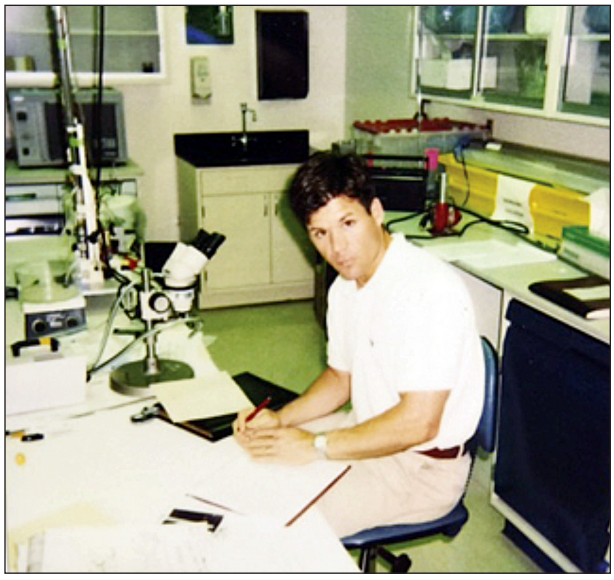
The United States health care industry has been going through significant changes over the past several years. Which of these changes has had the most profound impact on Cordis and its plans for the future?

Health care is changing faster today than at any time in the past. With an aging population and an increase in chronic illnesses, there's greater demand for innovative yet affordable solutions for quality health care. At the same time, in order to deliver better patient care, hospitals today need to provide more access to more patients while being operationally efficient.

For over 50 years, Cordis' mission has been to advance less-invasive therapies, leading to better experiences for patients by innovating across both products and education. This rich legacy of innovation will continue to strengthen the Cordis brand worldwide going forward. Cordis, with Cardinal Health, is committed to doing much more to help health care providers increase access by addressing delivery of care and operational efficiencies that will be critical in this evolving industry. This will also include expanding our high-quality training and service, as well as ensuring our strong clinical acumen.

Physicians are trading private practice for hospital employment, hospitals are becoming larger, and medical device companies and insurance companies are merging at unprecedented levels. What does this significant consolidation mean to the industry and Cordis?

Integrating primary care physicians, specialists, and hospitals into consolidated health care delivery organizations is a strategy intended to help deliver better clinical outcomes at a greater value. Medical device companies are taking a similar approach, by bundling complimentary



David J. Wilson contributing to a specialized catheter design while working in Cordis R&D in 1996.

products and services. There is more we can learn about the effectiveness of integrated health care delivery systems, as well as the consolidation we are seeing in the medical device and insurance companies. At the core of these consolidations is the need for efficiency and coordination of care. It is clear this trend will continue.

Cordis already has a solid reputation in the interventional cardiology and endovascular space, and we plan to continue delivering technology-driven innovation! With Cardinal Health, we also have a significant opportunity to focus on operational efficiencies with information-enabled systems (eg, RFID). Investment in the infrastructure of delivery systems will result in cost savings seen through inventory holding cost reduction, the decrease of inventory levels, and the elimination of costs associated with expired or lost products. This should allow Cordis to drive better patient care, while also helping our customers with efficiencies that support better access for more patients.

With products spanning aortic endografts to chronic total occlusion (CTO) devices, where do you see Cordis' growth opportunities?

While we believe the next phase of health care will focus on innovating *both* technology and services, in the short term we have some promising technological advances for the treatment of both abdominal aortic aneurysms (AAAs) and CTOs resulting from peripheral artery disease.

An estimated 24 million people worldwide are afflicted with AAAs, and millions more suffer from CTOs in peripheral arteries. The INCRAFT® AAA Stent Graft System, which has been cleared for use in Europe and Canada, brings an innovative advancement to the field of endovascular aneurysm repair, entering a growth segment that further diversifies Cordis' strong portfolio of products. The INCRAFT® System is currently approved for investigational device use only in the United States and is being evaluated in a pivotal clinical trial in the United States and Japan (the INSPIRATION Trial), which completed enrollment in 2013.

The latest additions to our CTO Crossing Portfolio underscore Cordis' longstanding commitment to advancing care for the complex critical limb ischemia patient. This began in 2005 with the acquisition of Lumend, Inc. Our workhorse solutions, the FRONTRUNNER® XP CTO Catheter and the AQUATRACK® Nitinol Guidewire, are now supported with our most recent additions, the OUTBACK® Elite Re-Entry Catheter and the soon-to-be launched ELITECROSS™ Support Catheter, which has been cleared for use in the United States. We look forward to continuing the expansion of these new lines and coming up with new complementary products.

Significant technological strides have been made in the treatment of aortic aneurysms and CTOs, and more work needs to be done to provide the most comprehensive offering of products to help treat these conditions.

With Cardinal Health's acquisition of Cordis complete, can you share with us what this means for the entire business?

I truly believe this is a very exciting time for Cordis and Cardinal Health. Cordis is a leader in interventional vascular technology and plans to continue building on our rich history as part of Cardinal Health. This transaction brings together two remarkable players in the health care industry to deliver greater access to quality products, creating an unmatched offering in the cardiovascular space.

From high-quality daily use products to reliable, trackable inventory and logistics with deep analytic capabilities, the Cordis and Cardinal Health venture will result in comprehensive offerings for the entire episode of care. As we move forward, our customers and the patients they serve remain our highest priority. We are excited and look forward to ensuring a continuation of our high-quality, innovative products and exceptional customer service. ■

Covering Every Case: The SABER™ PTA Dilatation Catheter

A discussion with J.A. Mustapha, MD, and Craig Walker, MD, on how the SABER™ Catheter provides an important option for lower extremity endovascular therapy.

Dr. Mustapha is Director of Cardiovascular Catheterization Laboratories, Metro Health Hospital in Wyoming, Michigan. He has disclosed that he is a paid consultant to Cordis, does research with TriReme, and is principal investigator of the Chocolate BAR registry.

Dr. Walker is Founder, President, and Medical Director, Cardiovascular Institute of the South in Houma, Louisiana. He has disclosed that he is a paid consultant/speaker for TriReme and Cordis.

What characteristics of the SABER™ PTA Dilatation Catheter differentiate it from other available balloons?

Dr. Mustapha: The true low profile of the entire balloon and the shaft make the SABER™ Catheter unique. Many balloons are described as being low profile. This is usually referring to the balloon itself. With the SABER™ Catheter, both the balloon and shaft have a low profile.

The second point to emphasize is the tremendous pushability of the shaft of the balloon, which enhances the already low-profile portion. The combination of its low profile and excellent shaft for pushability makes it excellent for trackability. The combination of the balloon's low profile, pushability, and protractability make it an excellent balloon that will add a significant value to the therapy for infrainguinal vessels.

Dr. Walker: We are interested in getting the SABER™ Catheter. It's an 0.018-inch–based wire balloon that comes in diameters from 2 to 10 mm. In particular, the 10-mm diameters are unique in terms of the 0.018-inch–based balloons. That allows us to use a smaller sheath to dilate fairly big vessels. The sizes up to 6 mm in diameter are up to 300-mm long. These longer balloons are important for long-segment disease.

I am interested in this concept of a dual-hydrophilic coating that provides durability and hydrophilicity, and therefore, diminished friction. The fact that the balloon itself is made of DURALYN® and therefore has highly controlled compliance is somewhat of a distinguishing characteristic due to the probability of not overdilating those segments.

How do the inflation times of this balloon compare to others?

Dr. Mustapha: When I compared the deflation and inflation times of this balloon to others, I found that the deflation time of this balloon is significantly faster than other balloons. In my experience, the inflation time is similar.

When would you use the SABER™ Catheter over the Chocolate® PTA Balloon?

Dr. Mustapha: It is well known that low-profile sheaths have a lower access complication rate. A 4-F sheath plays a major role when we access diseased vessels. The SABER™ Catheter allows use of large-diameter balloons, such as 5 or 6 mm, without having to change the sheath. This can mean the difference between failure and success, especially during a TAMI procedure.

The SABER™ Catheter is a phenomenal balloon when doing transtibial intervention because of its ability to track and its pushability. A third attribute that makes the SABER™ Catheter extremely attractive, and a scenario in which I might use it before the Chocolate® PTA Balloon Catheter is when we are doing transpedal loop revascularization. Other than that, if we have a larger-diameter sheath, the Chocolate® PTA Balloon Catheter is phenomenal in the majority of the same

vessels that were mentioned in the earlier discussion. In addition, in vessels where we attempt to open with a traditional balloon and continue to have resistance, the Chocolate® PTA Balloon Catheter can be used to resolve the waist without an undue risk of complication. If there is evidence of moderate to severe calcification, we tend to go straight to the Chocolate® PTA Balloon Catheter, inflate it slowly, and keep it up for 2 minutes to simulate the same results in terms of low dissection and the low perfusion rate that we saw in the Chocolate BAR study.

Would you employ the same technique for the SABER™ Catheter as you would Chocolate®?

Dr. Mustapha: Because we learned from the Chocolate BAR that inflating the balloon for more than 30 seconds and maintaining it for 2 minutes gives us such a good result, we're doing the same now with the SABER™ Catheter. ■

Dedicated BTK Balloons

Case reports on a new 0.018-inch platform.

BY MARCO MANZI, MD

Chronic critical limb ischemia (CLI) is a major worldwide cause of morbidity and, especially when threatening the limb, mortality.[1] Major and minor unplanned amputations are associated with significant increases in mortality risk, and every effort should be pursued to minimize amputations and ensure limb salvage.[2] Infragenicular atherosclerotic disease is the most common cause of CLI, and despite the benefits of pharmacologic therapy (eg, angiotensin-converting enzyme inhibitors, antidiabetic drugs, antiplatelet agents, and statins), arterial revascularization remains a mainstay in the management of CLI.[3] Surgical revascularization is recommended in most patients with CLI due to extensive infrapopliteal (ie, below-the-knee [BTK]) atherosclerotic disease,[2] but recent data also support the role of percutaneous transluminal angioplasty (PTA) in this setting,[4] especially when performed with dedicated wires and balloon catheters.

Nonetheless, vascular surgery is not always feasible or recommended because of high surgical risk, lack of venous conduits, or poor vessel runoff, and the procedural success rates of PTA remain suboptimal with current techniques. This is particularly true when atherosclerotic disease also involves the distal tibial arteries or the foot vessels, despite employing aggressive approaches such as subintimal, retrograde, subintimal arterial flossing with antegrade-retrograde intervention, or transcollateral techniques.

The SABER™ PTA dilatation catheter (Cordis Corporation) ranges in diameter from 2 to 10 mm and in length from 20 to 300 mm. It is designed for increased crossability, power, and control. In this article, we report our initial experience with this new balloon now available on the market.

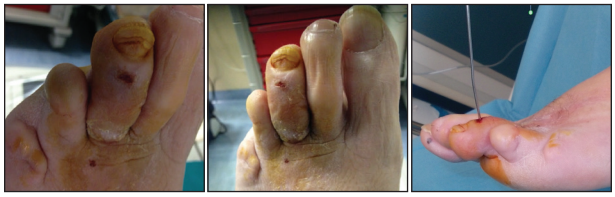


Figure 1. The patient's foot at admission.

CASE 1

A 75-year-old man with type 2 diabetes mellitus arrived at our center with a left third toe ulceration that was Texas University class 3C (Figure 1). He had a transcutaneous oxygen tension ($TcPO_2$) of 26 mm Hg, and his associated risk factors were dyslipidemia and ischemic heart disease. His serum creatinine was 1.25 mg/dL. According to our protocol, the patient was scheduled for an endovascular recanalization of the left leg before surgical treatment for the foot.

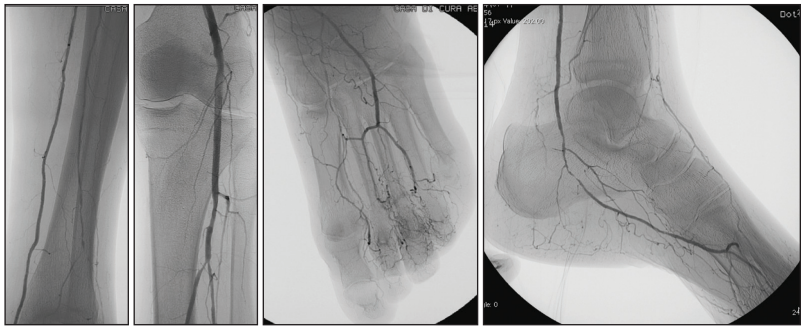


Figure 2. Baseline angiography.

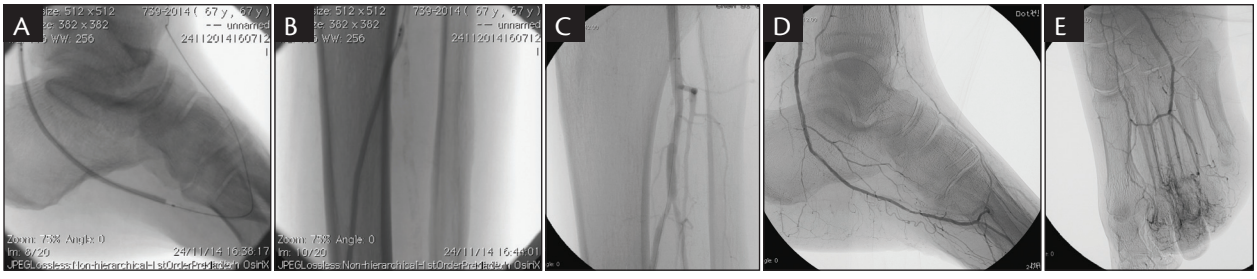
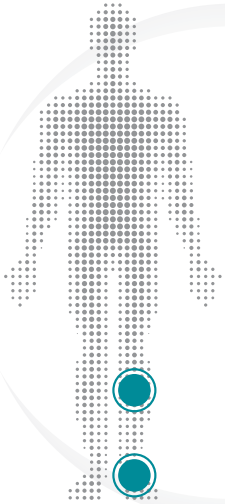


Figure 3. Common plantar, lateral plantar, and PT balloon angioplasty (2.5- X 120-mm SABER™ PTA dilatation catheter) at 8 bar for 2 minutes (A, B). Final acute result (C–E).

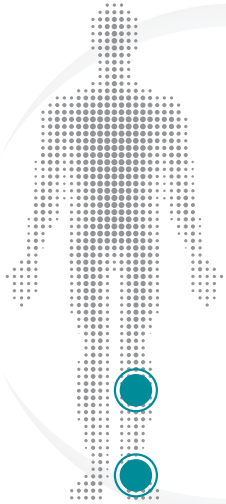
CORDIS® **Complete PTA Balloon Family**



SLEEK® OTW PTA Dilatation Catheter

0.014" OTW PTA Balloon to treat routine and challenging BTK cases

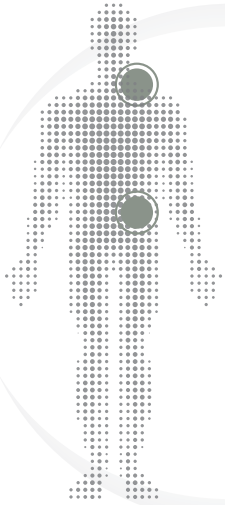
- 0.014'' Over-the-Wire
- Diameter: 1.25-5mm
- Length: 15-280mm



SLEEK® RX PTA Dilatation Catheter

0.014" rapid-exchange balloon fully dedicated to infrapopliteal lesions

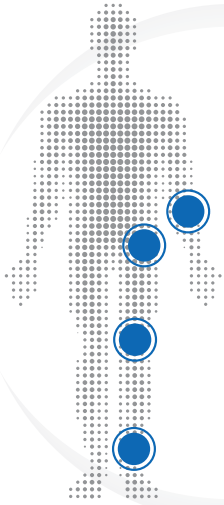
- 0.014'' Rapid-Exchange
- Diameter: 2-4mm
- Length: 40-220mm



AVIATOR® PLUS PTA Dilatation Catheter

PTA Dilatation Catheter for speed and efficiency in carotid and renal peripheral endovascular interventions

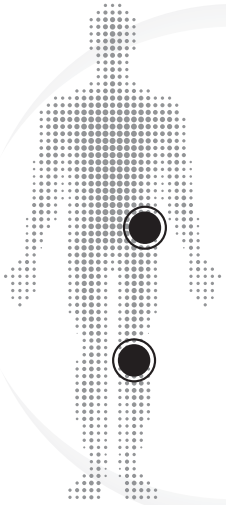
- 0.014'' Rapid-Exchange
- Diameter: 4-7mm
- Length: 15-40mm



SABER™ PTA Dilatation Catheter

The 0.018" OTW next-generation, high performance workhorse balloon designed to treat very tight lesions and a wider range of PAD cases

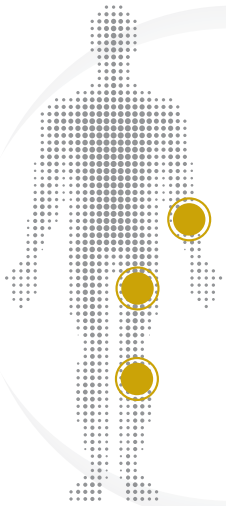
- 0.018'' Over-the-Wire
- Diameter: 2-10mm
- Length: 20-300mm



SLALOM® PTA Dilatation Catheter

The 0.018" over-the-wire system for routine and challenging cases where guidewire choice and sheath fit are key

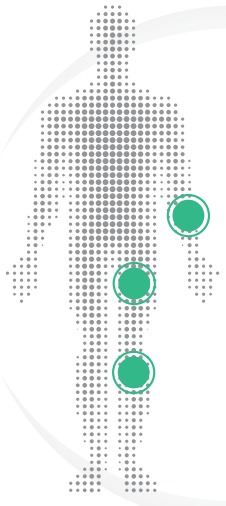
- 0.018'' Over-the-Wire
- Diameter: 3-8mm
- Length: 20-40mm



POWERFLEX® PRO
PTA Dilatation Catheter

Advanced crossing ability and remarkable versatility to treat routine or challenging cases in the lower extremities

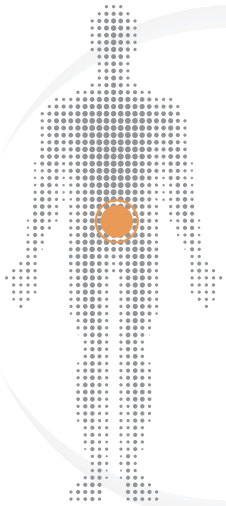
- 0.035'' Over-the-Wire
- Diameter: 3-12mm
- Length: 20-220mm



POWERFLEX® EXTREME
PTA Dilatation Catheter

The high-pressure 0.035" over-the-wire balloon for dialysis fistula and other challenging procedures

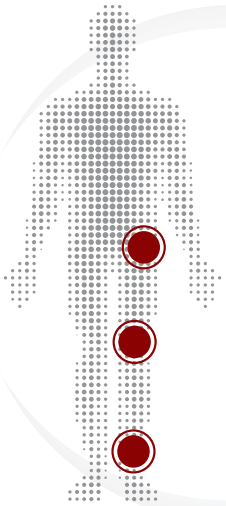
- 0.035'' Over-the-Wire
- Diameter: 4-10mm
- Length: 20-60mm



MAXI LD® PTA
Dilatation Catheter

The 0.035" over-the-wire system of choice for treating large arteries

- 0.035'' Over-the-Wire
- Diameter: 14-25mm
- Length: 20-60mm



CHOCOLATE® PTA
Dilatation Catheter

Features a unique Nitinol Pressure Shield* designed to provide protection form torsional, radial and longitudinal stresses that can lead to vessel trauma

- 0.014/0.018'' Over-the-Wire
- Diameter: 2.5-6mm
- Length: 40-120mm

For More Information Visit www.Cordis.com or Contact Your CORDIS® Representative Today.

*Nitinol Constraining Structure.

**Source: Interim results from the CHOCOLATE® BAR Study

CHOCOLATE® is a trademark of TriReme Medical, LLC.

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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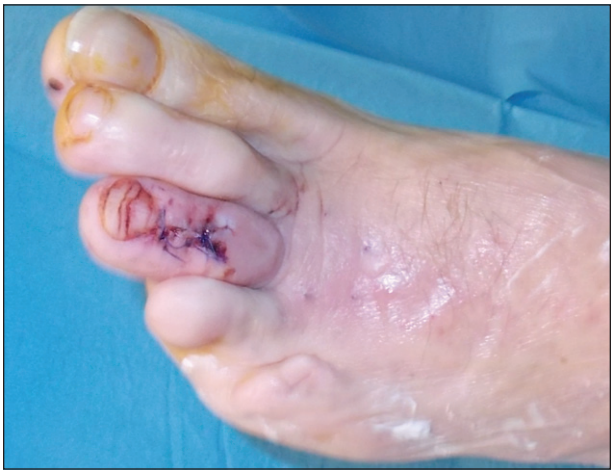

Figure 4. The patient's foot after ulcerectomy.

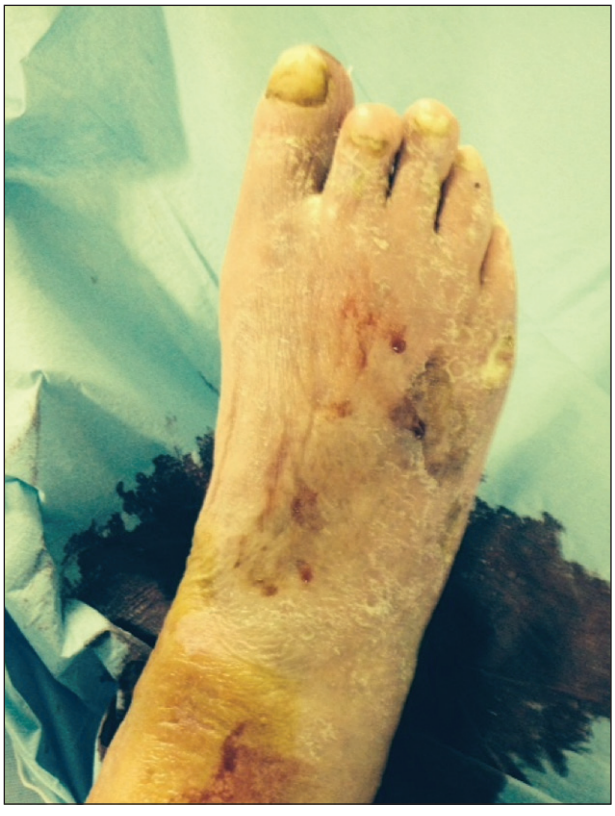

Figure 5. The Case 2 patient's foot at admission.

Endovascular Treatment

A 6-F, 11-cm Radifocus Introducer II sheath (Terumo Interventional Systems) was deployed in an antegrade fashion under ultrasound (US) guidance in the left common femoral artery, and 5,000 intravenous units of heparin were administered. The baseline angiography (Figure 2) showed a patent superficial femoral-popliteal artery axis while a severe calcified stenosis was represented in the peroneal trunk (PT) and posterior tibial artery ostium. Multiple

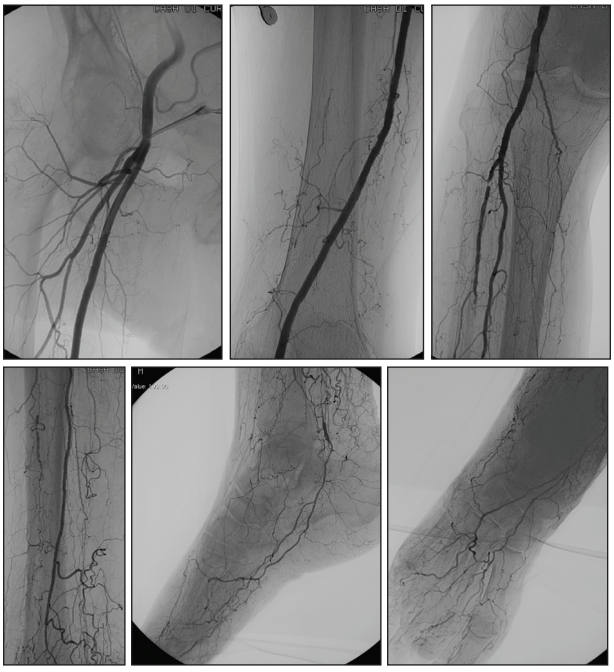

Figure 6. Baseline angiography.

calcified stenoses were recognized in the common plantar and lateral plantar arteries, with a good outflow in the arch and a light "blushing" effect in correspondence with the third toe lesion.

A V-18 ControlWire guidewire (Boston Scientific Corporation) was advanced to the foot and through the arch into the pedal artery to provide improved support, and a 2.5- X 120-mm SABER™ PTA dilatation catheter was directly advanced and inflated in the common and lateral plantar arteries for 2 minutes at 8 bar. After a quick deflation time (5 seconds), the balloon was retrieved and inflated at the PT-posterior tibial ostium level for 2 minutes at 8 bar (Figure 3). Despite the calcification grade, the balloon could be well inflated with a good shape without any residual and persistent indentations due to calcified plaques. The subtracted control angiography showed no dissections, spasms, or distal embolization, with an improved blushing effect in the wounded area.

A 6-F closure device (Angio-Seal, St. Jude Medical, Inc.) was deployed under US guidance, and the next day, an ulcerectomy was performed (Figure 4), and a 3-month regimen of dual-antiplatelet therapy was started (aspirin 125 mg, clopidogrel 75 mg). Clinical control performed on an outpatient basis by podiatric specialists after 10 days was good, with significant $TcPO_2$ improvement (47 mm Hg).

CASE 2

An 83-year-old man with type 2 diabetes mellitus arrived at our center with right dorsum-lateral fifth toe ulcerations

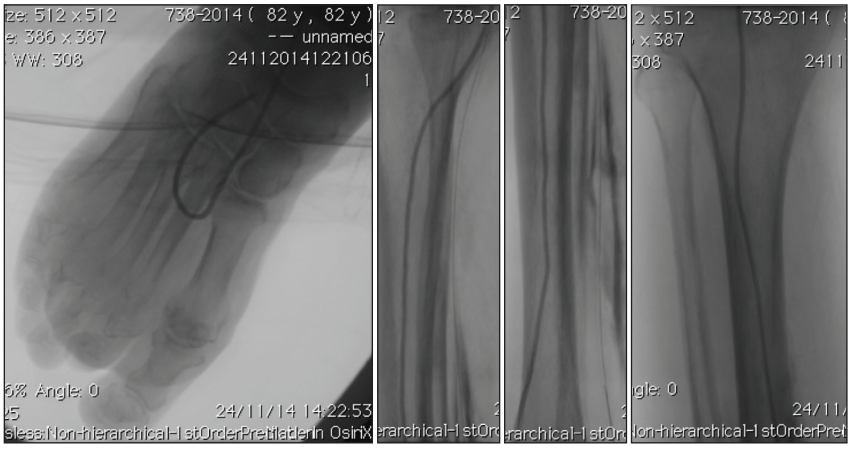

Figure 7. A 2.5- X 300-mm SABER™ PTA dilatation catheter inflated at the arch and tibials level. There was extravasation of the contrast medium due to a fissuration in the posterior tibial artery.

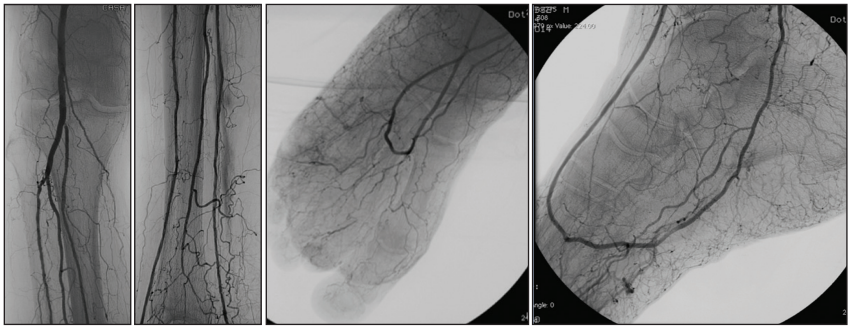

Figure 8. Acute angiographic results.

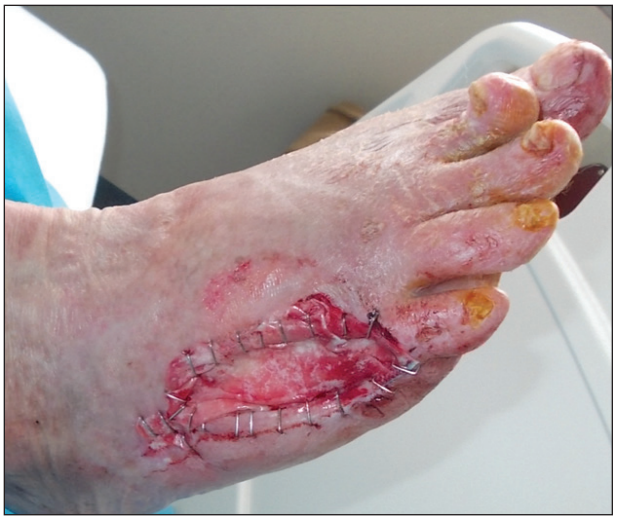

Figure 9. The patient's after foot surgery (ulcerectomy and Hyalomatrix grafting)

that were Texas University class 3C. His $TcPO_2$ measurement was 9 mm Hg (Figure 5), and the associated risk factors were hypertension, dyslipidemia, and previous myocardial infarction. His serum creatinine was 1.31 mg/dL.

Endovascular Treatment

A 6-F 11-cm Radifocus Introducer II sheath was deployed in an antegrade fashion under US guidance in the left common femoral artery, and 5,000 intravenous units of heparin were administered. Baseline angiography (Figure 6) showed a patent superficial femoral-popliteal artery axis and a severely calcified complete occlusion of high-originating posterior tibial and medium-distal anterior tibial (AT) arteries. Severe stenosis of the proximal AT and occlusion of the pedal artery were represented. A light blushing effect was evidenced in correspondence to the wounded area.

Two V-18 ControlWire guidewires supported by a 40-F Berenstein II Tempo catheter (Cordis Corporation) were subintimally advanced to the foot; proximal arch re-entry was achieved, and the wire was pushed through the arch into the lateral plantar artery to improve support. The purpose of inserting the two wires was to protect the AT and PT ostiums. A 2.5- X 300-mm SABER™ PTA dilatation catheter was directly advanced and inflated in the arch and AT for 2 minutes at 10 bars first and then in the PT (Figure 7). Despite the calcification grade, the balloon could be well inflated with a good shape, again without any residual indentations due to calcified plaques.

Subtracted control angiography (Figure 8) showed no dissections, spasms, or distal embolization, with an improved blushing effect in the wounded area. A 6-F closure device (Angio-Seal) was deployed under US guidance, and the following day, an ulcerectomy and Hyalomatrix grafting (Anika Therapeutics, Inc.) was performed. A 3-month dual-antiplatelet therapy regimen was started (aspirin 125 mg, clopidogrel 75 mg). The clinical podiatric control after 10 days was good, with a significant improvement in $TcPO_2$ (51 mm Hg) (Figure 9).

CONSIDERATIONS

Endovascular treatment is actually considered as the first option at our center.[5] Due to the very frequent multilevel arterial disease and the diffuse calcifications, endovascular procedures in diabetic patients with CLI and wounds are usually very challenging, complex, and long

lasting. During the last 10 years, all of the major medical companies have been investing a lot of effort to develop dedicated devices for CLI endovascular treatment, with a particular attention for BTK and below-the-ankle lesions.

Low-profile over-the-wire long balloons with good pushability and crossability were therefore developed to reduce the number of inflations and shorten the duration of procedures. One of the most frequent problems is the difficulty in crossing a long BTK occlusion directly with a long balloon, especially when the intraluminal technique is used, and there are severe and diffuse calcifications. In our experience, the SABER™ PTA dilatation catheter offers a good compromise between low profile and crossing capability due to its 0.018-inch platform. The balloon is resistant to the calcifications and very fast to be deflated, making it a useful device for everyday practice in BTK procedures. ■

Marco Manzi, MD, is with the Interventional Radiology Unit, Foot & Ankle Clinic, Abano Terme Clinic in Abano Terme, Italy. He has disclosed that he is a proctor and consultant for Abbott Vascular, Bard Peripheral Vascular, Boston Scientific Corporation, Cordis Corporation, Cook Medical, and Covidien/Medtronic. Dr. Manzi may be reached at marcodocmanzi@gmail.com.

1. Faglia E, Clerici G, Clerissi J, et al. Early and five-year amputation and survival rate of diabetic patients with critical limb ischemia: data of a cohort study of 564 patients. Eur J Vasc Endovasc Surg. 2006;32:484-490.
2. 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.
3. Hirsch AT, Haskal ZJ, Hertzer NR, et al; American Association for Vascular Surgery/Society for Vascular Surgery; Society for Cardiovascular Angiography and Interventions; Society for Vascular Medicine and Biology; Society of Interventional Radiology; ACC/AHA Task Force on Practice Guidelines. ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Associations for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (writing committee to develop guidelines for the management of patients with peripheral arterial disease)—summary of recommendations. J Vasc Interv Radiol. 2006;17:1383-1297.
4. Adam DJ, Beard JD, Cleveland T, et al; BASIL trial participants. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet. 2005;366:1925–1934.
5. Faglia E, Dalla Paola L, et al. Peripheral angioplasty as the first-choice revascularization procedure in diabetic patients with critical limb ischemia: prospective study of 993 consecutive patients hospitalized and followed between 1999 and 2003. Eur J Vasc Endovasc Surg. 2005;29:620-627.

Critical Design Elements of Self-Expanding Stents

The Cordis S.M.A.R.T.® Vascular Stent System is designed to provide longitudinal stability, scaffolding, and resistance to radial force.

BY CAROLYN RICE, MEM

The Cordis S.M.A.R.T.® Vascular Stent optimizes performance and outcomes through its unique design. In general, a self-expanding stent's performance is determined by its geometrical pattern, in conjunction with stent material properties. The S.M.A.R.T.® Vascular Stent, made of electropolished Nitinol, has a geometry that features 36 struts for each circumferential ring, with six alternating bridges connecting each ring to the next (Figure 1). This unique 36-strut, six-bridge design maximizes the stent's longitudinal stability, scaffolding, and resistance to radial force.

Stent longitudinal stability refers to the ability of the stent to resist stretching during deployment. Stent elongation occurs when the stent geometry distorts and stretches as the outer sheath of the delivery system is retracted. A stent with low longitudinal stability selected to match the length of a lesion may end up stretching past that lesion and providing less structural support than intended. This, in turn, will adversely impact stent performance associated with radial force.

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 2). A low tensile force corresponds with low longitudinal stability and vice versa. Stents with decreased longitudinal stability are more prone to deployment problems, reduced scaffolding, and decreased radial force (Figures 3–10).

The test results indicate that longitudinal stability of the S.M.A.R.T.® Vascular Stent far exceeds other stent platforms (Figure 11). In fact, it demonstrates up to 934% greater longitudinal stability than other stents, as reflected in the chart.

As discussed, stent elongation due to lack of longitudinal stability leads to a reduction in mechanical scaffolding and radial force. One stent manufacturer has demonstrated a correlation between the degree of stent elongation and primary patency. As Figure 12 demonstrates, a decrease in patency was observed when stents were deployed elongated. In a secondary analysis, the manufacturer found a greater amount of elongation correlated to a significant reduction in patency at 12 months. At 12 months, minimal to moderate elongation (11% to 40%) was shown to reduce

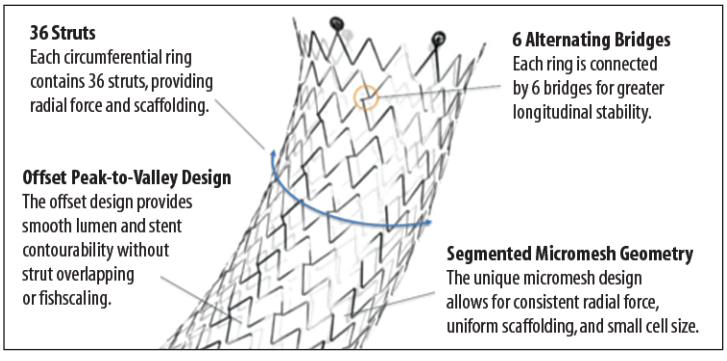

Figure 1. Key features of the S.M.A.R.T.® Vascular Stent design.

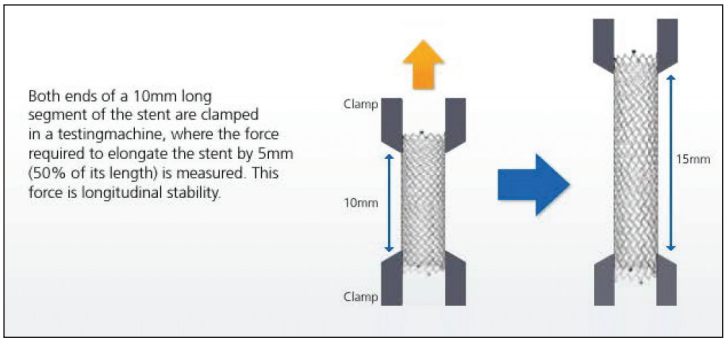

Figure 2. Test for stent longitudinal stability (Longitudinal Stability Test Method, data on file, Cordis Corporation 2013).[1]

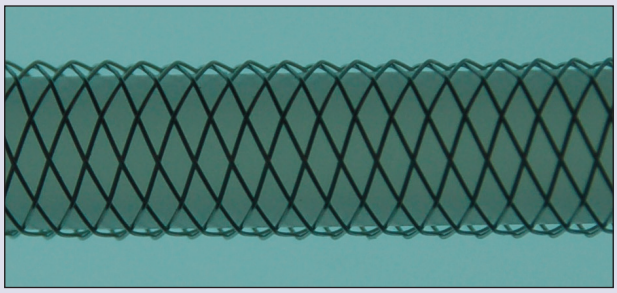

Figure 3. Woven wire stent design, nominal deployment.

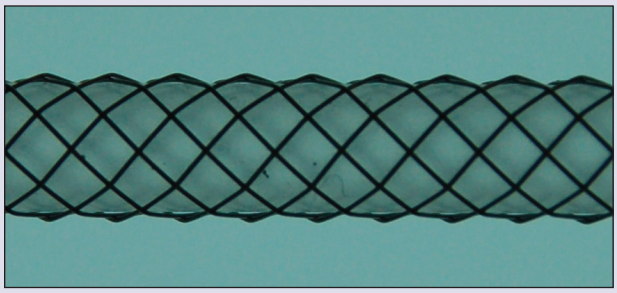

Figure 4. Woven wire stent design, 1 N of force.

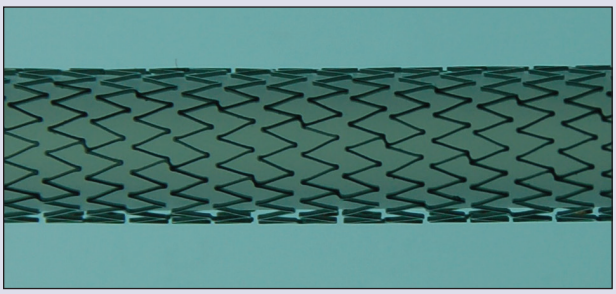

Figure 5. Stent design with fewer connecting bridges, nominal deployment.

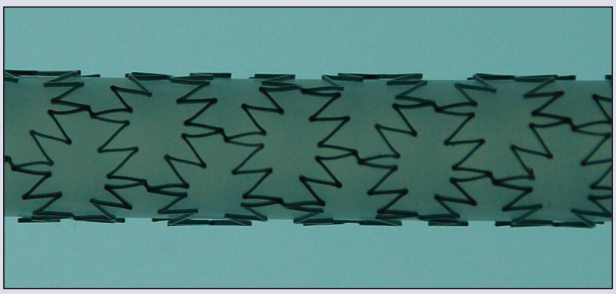

Figure 6. Stent design with fewer connecting bridges, 1 N of force.

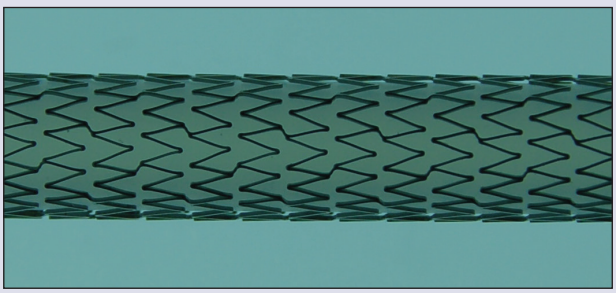

Figure 7. Cordis S.M.A.R.T.® Stent, nominal deployment.

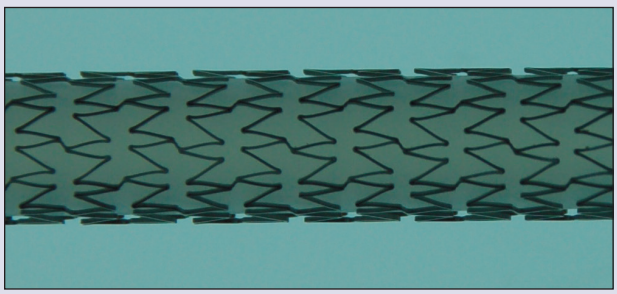

Figure 8. Cordis S.M.A.R.T.® Stent, 1 N of force.

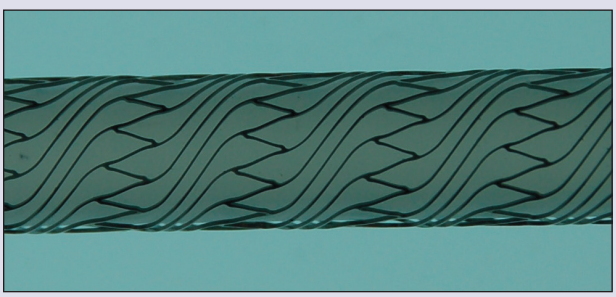

Figure 9. Cordis S.M.A.R.T.® Flex Stent, nominal deployment.

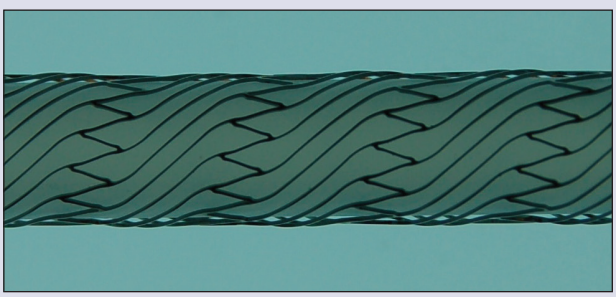

Figure 10. Cordis S.M.A.R.T.® Flex Stent, 1 N of force.

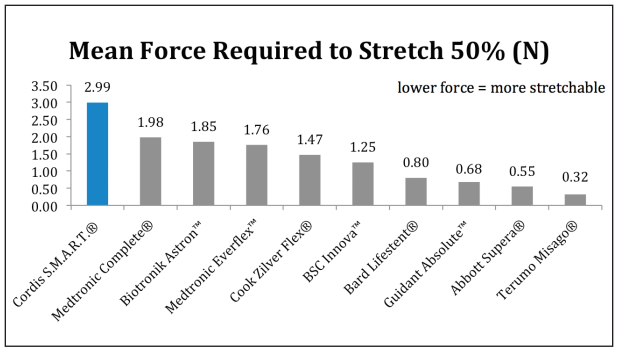

Figure 11. Longitudinal stability of the S.M.A.R.T.® Vascular Stent (S.M.A.R.T. and S.M.A.R.T. Flex Competitive Testing Analysis, data on file, Cordis Corporation 2015).[2]

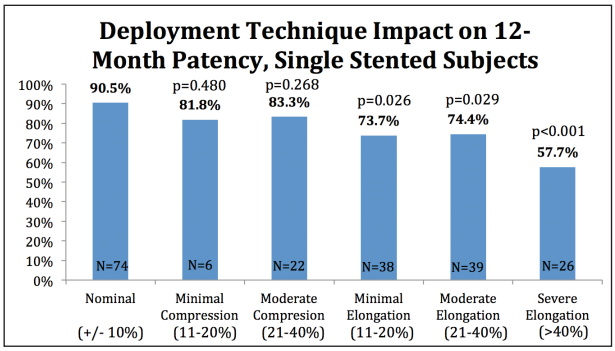

Figure 12. The relationship of stent elongation to primary vessel patency at 12 months (ITT, Single Stented Subjects).[3]

primary patency by 19%. Severe elongation (> 41%) was shown to reduce primary patency by 36%. For this particular stent design, internal bench testing demonstrated an 18% decrease in crush resistance when the stent elongates by 25% and a 31% decrease in crush resistance when elongated by 50%.[3]

Additionally, stent elongation upon deployment has been linked to stent integrity and the occurrence of fractures by another stent manufacturer's investigational device exemption study.[2] Six out of 12 fractures were classified as type IV (complete transverse fracture) at the 18-month analysis. It was observed that in those patients where type IV fractures occurred, all six were elongated at deployment. Nearly 40% of patients with > 10% elongation went on to develop type IV fractures within 1 year.[4]

The S.M.A.R.T.® Vascular Stent offers a unique balance of strut length, number of struts, and bridge connections to maximize longitudinal stability and decrease stretching upon deployment. This results in consistent and predictable scaffolding, as well as resistance to radial force.

The next-generation self-expanding stent platform from Cordis—the S.M.A.R.T.® Flex Self-Expanding Stent System—is currently under clinical investigation in the United States for vascular use. The S.M.A.R.T.® Flex Stent is an evolution of S.M.A.R.T.® Stent technology, building on the performance attributes of the S.M.A.R.T.® Stent design, while adding fully connected helical struts designed to provide longitudinal stability, flexibility, and structural integrity. ■

Carolyn Rice, MEM, is Mechanical Engineer and Group Product Director with Cordis Corporation in Fremont, California. Ms. Rice may be reached at carolyn.rice@cardinalhealth.com.

1. Longitudinal Stability Test Method, data on file, Cordis Corporation 2013.
2. SMART and SMART Flex Competitive Testing Analysis, data on file, Cordis Corporation 2015.
3. SUPERB Study analysis, Abbott Supera® Peripheral Stent System IFU, PPL00038, March 21, 2014.
4. RESILIENT Study Analysis, Bard Lifestent® Solo™ Vascular Stent System IFU, B05692 Vers.4/09-11.

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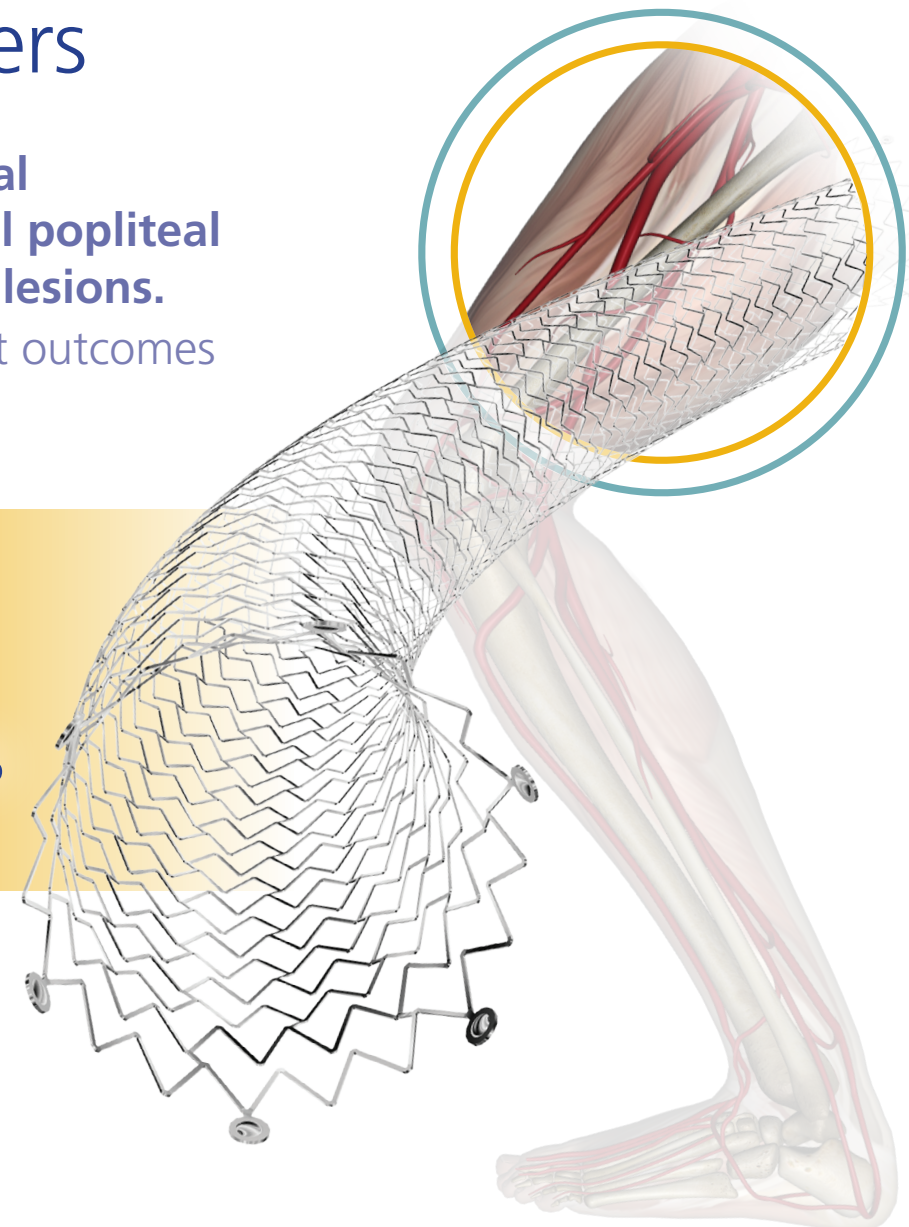


Proven and **durable** results out to **3 years**

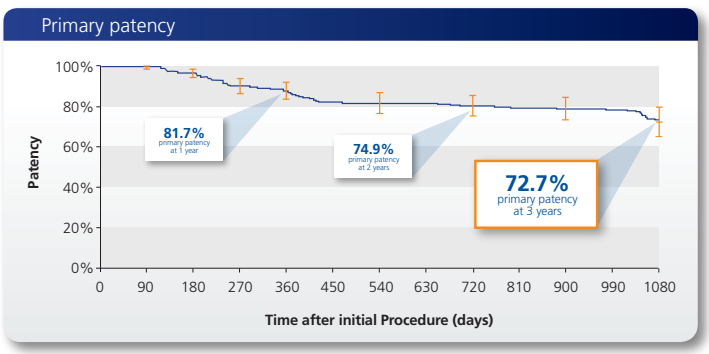
Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. See Instructions for Use for full product information, including indications, contraindication, warnings, precautions and adverse events.

Compelling outcomes in the STROLL* Study

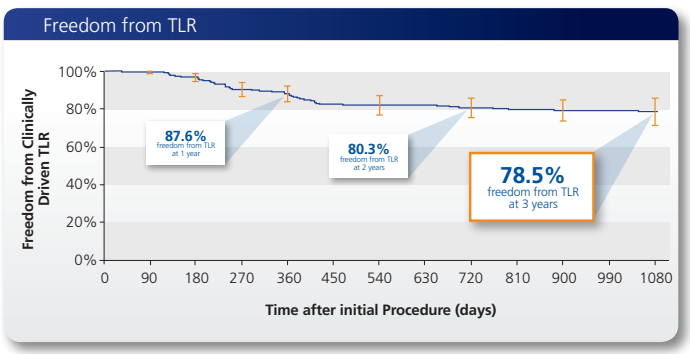
Effective SFA revascularization through 3 years with the S.M.A.R.T.® Vascular Stent Systems[1]

Clinical Outcomes	1 year	2 years	3 years
Primary Patency†	81.7%	74.9%	72.7%
Freedom from TLR	87.6%	80.3%	78.5%
Stent fracture rate	2% (all Type I)	2% (all Type I)	3.6% (all Type I)
Patient Outcomes	**1 year**	**2 years**	**3 years**
Patients with minimal or no PAD symptoms§	76.6%	81.8%	77.8%
Patients with normal ABI (>0.8)	81.0%	80.7%	76.5%

High primary patency rate maintained out to 3 years in the STROLL Study with the S.M.A.R.T.® Vascular Stent Systems[1]



Strong rate of freedom from TLR maintained out to 3 years in the STROLL Study[1]



* The S.M.A.R.T.® Nitinol Self-expanding Stent in the Treatment of Obstructive Superficial Femoral Artery Disease (STROLL) Study.
† 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.

Cordis®
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Case Study: S.M.A.R.T.® Stent System

The Cordis S.M.A.R.T.® Stent is a valuable tool in the management of peripheral artery disease.

BY KOUSTA I. FOTEH, MD

A 70-year-old man with a past medical history of endovascular abdominal aortic aneurysm (AAA) repair, peripheral artery disease (PAD), hyperlipidemia, and hypertension presented with severe lifestyle-limiting claudication of his left lower extremity after walking 25 yards. The patient was an active retiree and a one-pack-per-day smoker. He reported that he was unable to enjoy his activities because of his limited ability to walk. Pain occured in his calf when walking and was described as a cramping pain that relieves with rest. Duplex ultrasound examination revealed an occluded left superficial femoral artery (SFA) with three-vessel runoff. His ankle-brachial index (ABI) of the left leg was 0.6. His right leg showed moderate disease with an ABI of 0.81. We discussed a couple of treatment options for this patient, including best medical therapy versus endovascular intervention. The patient did not want to entertain medical therapy because he refused to quit smoking and therefore elected to proceed with intervention. He was taken to the hybrid operating room for an angiogram with likely intervention.

TREATMENT OPTIONS

Given that the patient had a prior endograft repair of an AAA, intervention via contralateral access was not possible. We did consider an antegrade approach, but in situations such as these, we find ultrasound-guided retrograde popliteal access to be a simple and feasible approach. In the case of ostial lesions, antegrade access can be difficult when trying to guide your sheath into the origin of the SFA. Retrograde popliteal access, in many circumstances, gives you more working room and a "straight shot" to the SFA.

COURSE OF TREATMENT

The patient was placed on the table in a prone position, and his left popliteal fossa was prepped and draped in a sterile fashion. The ultrasound probe was positioned slightly cephalad to the popliteal crease. The skin and soft tissues were anesthetized with 1% lidocaine, and the popliteal artery was accessed with an 18-gauge introducer needle. A 6-F sheath (Terumo Interventional Systems) was placed via the standard Seldinger technique. A retrograde angiogram was obtained, revealing an occluded

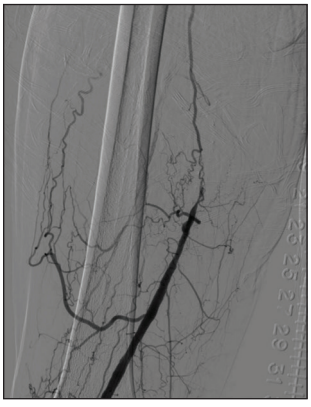

Figure 1. Access via the retrograde popliteal approach revealing an occluded SFA.

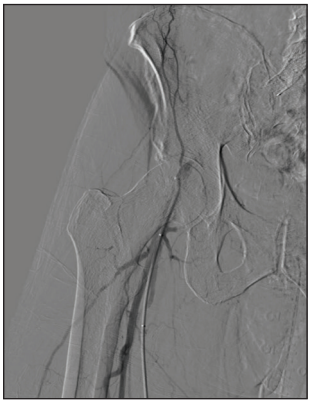

Figure 2. Catheter injection above the CTO to confirm intraluminal access above the occlusion.

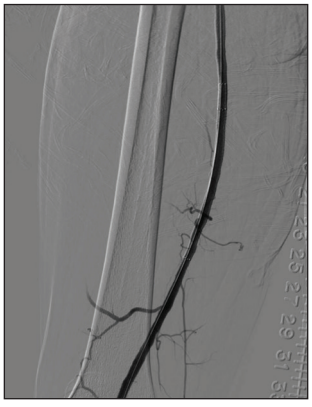

Figure 3. Angiogram after stent deployment and dilation.

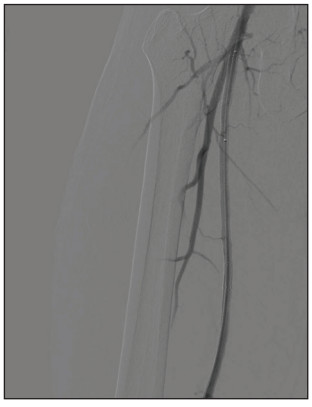

Figure 4. Angiogram after stent deployment and dilation.

SFA (Figure 1). The SFA reconstituted at the adductor canal via the collaterals. Intravenous heparin was administered, and we used a 0.035-inch stiff, angled Glidewire® and 0.035-inch NaviCross® catheter (both from Terumo Interventional Systems) to traverse the occlusion (Figure 2). Once we crossed the lesion, we estimated it to be 22 cm in length (TASC II C). A ViperWire® (Cardiovascular Systems, Inc.) was advanced via the support catheter to perform orbital atherectomy, followed by balloon angioplasty with a 6- X 120-mm Chocolate® Balloon (manufactured by TriReme Medical, LLC, distributed by Cordis Corporation). Two serial inflations of the Chocolate® Balloon were performed for 2 minutes at nominal pressure. For all chronic total occlusions (CTOs) of this caliber, when we anticipate we will be using stents, we prefer to predilate the artery with the Chocolate® Balloon. We find this balloon to be a valuable tool in the management of CTOs, whether in use as a stand-alone therapy or paired with stenting, as the Chocolate® Balloon has shown superior stent-to-artery wall apposition after predilation. At this point, the decision was made to stent the SFA (Figure 3). We used one 6- X 150-mm and one 6- X 120-mm S.M.A.R.T.® Stent (Cordis Corporation) with at least 1 cm of overlap. We postdilated it with a 6- X 220-mm Powerflex® Pro Balloon (Cordis Corporation).

RESULTS

Completion angiogram showed complete resolution of the occlusion with no residual stenosis (Figure 4). The patient tolerated the procedure well, and after his sheath was removed, he had palpable posterior tibial and dorsalis pedis artery pulses. At 1-month follow-up, the patient reported complete resolution of his claudication, and his duplex ultrasound showed a widely patent SFA with an ABI of 1.0. At 3-month follow-up, the patient continued to be free from claudication, with an ABI of 1.0.

DISCUSSION

Although there are many ways to treat CTOs of the SFA, we find the S.M.A.R.T.® Stent to be a valuable tool in the management of PAD. There are many advantages of the S.M.A.R.T.® Stent, including its radial force, that give it the ability to resist compression and maintain luminal gain. Its unique design of 36 struts with six bridges provides uniform scaffolding and small cell size. This design also provides longitudinal stability, which minimizes stretching and enhances placement accuracy. In previous studies, the S.M.A.R.T.® Stent had a primary patency rate of 81.7% at 1 year and 72.7% at 3 years, with 87.4% freedom from target lesion revascularization at 1 year and 75.8% at 3 years, as shown in the STROLL data. Most importantly, we believe it leads to superior patient outcomes. ■

Kousta I. Foteh, MD, is affiliated with Cardiovascular Association P.L.L.C., and is Director of Vascular and Endovascular Surgery at Memorial Hermann Northeast Hospital, in Humble, Texas. He has disclosed that he is a paid consultant to Cordis Corporation. Dr. Foteh may be reached at kfoteh@me.com.

Where Is Carotid Stenting Today?

A discussion with Dr. Christopher Metzger on the available data, reimbursement, and industry efforts surrounding this procedure.

Christopher Metzger, MD, is a practicing interventional cardiologist at the Wellmont CVA Heart Institute in Kingsport, Tennessee. He has disclosed that he is a paid consultant to Cordis Corporation, and he has received speaking and symposium honoraria from Abbott Vascular, Spectranetics, Bard, Boston Scientific Corporation, and TriVascular; and hands-on proctor fees from Abbott Vascular and TriVascular. Dr. Metzger may be reached at cmetzger@mycva.com.

Dr. Metzger, can you please share with us your perspective on the carotid stenting landscape today as opposed to 10 years ago?

There's good news and bad news regarding the landscape for carotid stenting. The good news is results of carotid stenting procedures have improved steadily and dramatically over the last 10 years, as all of the clinical trials I am aware of show. Even in high-risk endarterectomy patients (those patients we know don't do well with carotid endarterectomy), we are now seeing stroke and death rates < 3% for asymptomatic patients and < 6% for symptomatic patients. These results also tend to be better than reported in most trials. Furthermore, proximal protection is now available, which further lowers negative outcomes in high-risk patients, like the elderly and symptomatic patients.

Over the years, these results and subsequent experiences have grown into a large knowledge base of lessons learned. This has led carotid stenting practitioners to a better understanding of who needs to be treated and who should not be treated with this interventional procedure. This, in turn, has continued to lower the complication rates and improve techniques.

So, our technique is better, our judgment is better, our equipment is better, and the results, in multiple real-world trials, clearly show carotid stenting is improving and does at least as well as endarterectomy. We have also demonstrated clinical equipoise with carotid endarterectomy in two randomized published trials (the CREST and SAPPHIRE randomized trials) and a third North American rigorous trial as seen in the roll-in patients studied in ACT I (after preliminary signals). This is the good news.

So, what's the bad news? The bad news is, despite all the clinical and data advances, reimbursement coverage is still restricted.

Aside from the SAPPHIRE randomized study you mentioned, what can you tell us about the SAPPHIRE Worldwide registry?

I was a Co-principal Investigator for the SAPPHIRE Worldwide registry, and it was a privilege to be part of the largest carotid stenting trial with 21,000 patients. The included patients had cardiac enzymes tested after the carotid stent procedure, and they all had independent neurologic assessments at baseline, discharge, and at 30 days. The first 10,000 patients of the registry also had a 1-year follow-up.

Thus, the SAPPHIRE Worldwide registry was a real world study with 21,000 carotid stent patients with careful prospective adjudication. Results for 15,000 patients have already been publicly presented, and the full 21,000 patients' data set is expected to be presented later this year.

How do you feel Cordis Corporation has contributed to providing a treatment option for patients suffering from carotid artery disease?

I think Cordis Corporation has done a tremendous job supporting carotid stenting and education in carotid artery disease. Not only did they sponsor the SAPPHIRE randomized trial, which really launched industry enthusiasm, but Cordis also created and implemented CORDIS CASES® (Carotid Artery Stenting Education System), where they taught people how to do carotid stenting in a highly systematic manner. They followed on to launch SAPPHIRE

Worldwide, the most comprehensive study for carotid artery stenting.

Cordis Corporation also has a fantastic stent, the PRECISE® Nitinol Self-Expanding Stent, which has an autotaper feature that works beautifully. In my opinion, this is by far the best stent to use if you are stenting in tortuous anatomy. In addition, the ANGIOGUARD® Emboli Capture Guidewire System has the shortest basket length of any distal protection system and it comes in multiple sizes.

In your words, why do you feel the current information available on the success of carotid stenting has not led to an expanded reimbursement?

There are several reasons for that. First, there is concern that if you have inexperienced operators performing carotid stenting, the results may not be equivalent to those seen in the various trials.

In addition, I believe there is too much of a turf battle between various subspecialties. In other words, there has not been adequate cooperation between interventional cardiology, interventional radiology, vascular surgery, and neurosurgery.

Finally, some authors have cited controversial nonrandomized, retrospective "studies," which do not have independent neurologic endpoints, and include primarily low-risk patients with moderate disease. These have further muddied the reimbursement waters. For example, most physicians would not and should not stent a carotid patient with only a 50% stenosis. We all need to remember that it's all about the way you're measuring results and who you're measuring.

Unfortunately, all of this has started to form a downward spiral with industry. The medical community is losing their interest for it, industry can't support it, CMS won't reimburse it—it's a somewhat vicious cycle.

Currently, I would like to see the reimbursement decisions change. Carotid stenting has been extensively studied and has been shown to be safe and effective and equivalent to approved carotid endarterectomy in appropriate patients. Nowhere else have we seen a procedure that continues to get better, with results that are equivalent to a procedure with higher morbidity, but cannot get reimbursed until the more invasive procedure is turned down. This is where we are right now.

What would you recommend to industry to continue the fight against carotid artery disease?

In every meaningful manner, the industry should continue ongoing education for carotid stenting. Secondly, I think it's going to take a public awareness campaign as well as collaboration between the subspecialties and industry to petition for the acceptance of carotid stenting at the CMS level. I think we need to set performance standards very high and tie reimbursement to meeting these standards.

If we can't come up with that kind of collaboration between specialties, industry, and our government payers, we risk losing access to an outstanding technology which could be beneficial to a large number of patients who would be best served with this procedure. ■

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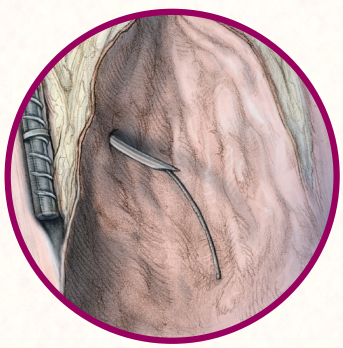

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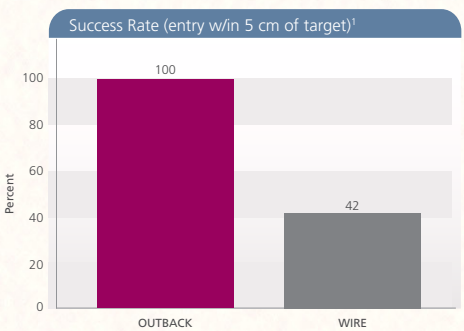

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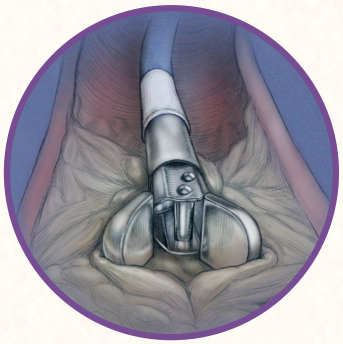


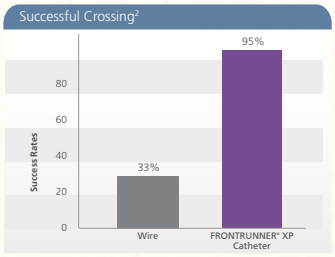
FRONTRUNNER® XP

CTO Catheter

Setting the Standard for Crossing Success.

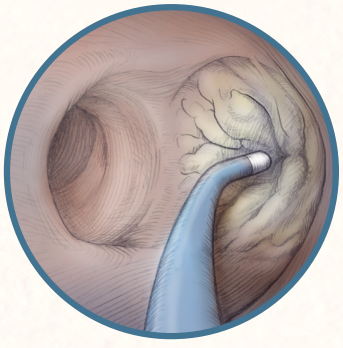
Use **FRONTRUNNER® XP CATHETER** ***first*** to cross with confidence.

- **ENHANCED** pushability when paired with the new ELITECROSS™ Support Catheter
- **HIGH SUCCESS RATES** when conventional guidewire techniques have failed[2]
- **REDUCED EXPOSURE TIME**



High Success Rates

In a recent study by Shetty et al., the **FRONTRUNNER® XP CTO Catheter** had a 95% success rate vs. 33% with wire alone.



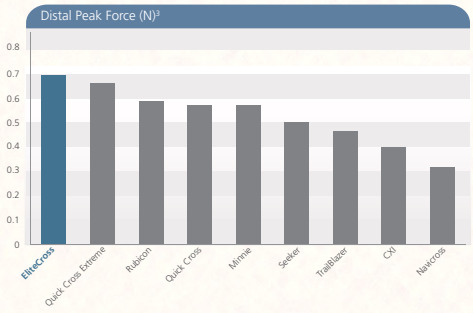
ELITECROSS™

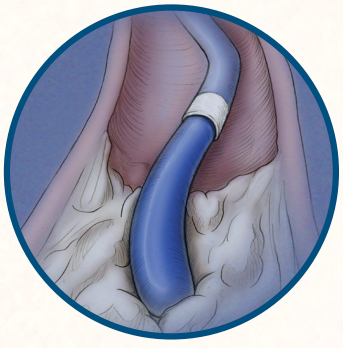
Support Catheter

Power Steering for More Powerful Crossing.

Providing a unique combination of support and shape options to enable a tailored approach to tough lesions.

- UNPARALLELED SUPPORT AND PUSHABILITY
- **EXTRA LARGE INNER LUMEN** can accomodate 0.014" support catheter systems
- Tapered tip and lubricious hydrophilic coating enhance deliverability





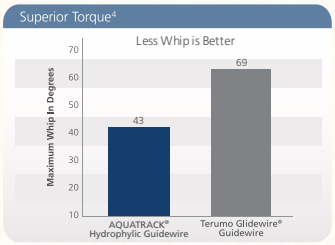
AQUATRACK®

Hydrophilic Nitinol Guidewire

Performance You Can Feel.

Featuring the torque, lubricity and visibility needed to successfully navigate the most tortuous anatomy.

- SUPERIOR TORQUABILITY
- SUPERIOR RADIOPACITY
- LASTING LUBRICITY



[1]Gandini, R., Fabiano, S., Spano, S., Volpi, T., Morosetti, D., Chiaravalloti, A., Nano, G. and Simonetti, G. (2013), Randomized control study of the Outback LTD reentry catheter versus manual reentry for the treatment of chronic total occlusions in the superficial femoral artery. Cathet. Cardiovasc. Intervent., 82: 485–492. doi: 10.1002/ccd.24742

[2] Ranjan Shetty, MD DM, G. Vivek, MD DM, Ashok Thakkar, PhD, Rajaram Prasad, MD, Umesh Pai, MSc, Krishnananda Nayak, MSc. Safety and Efficacy of the Frontrunner XP Catheter for Recanalization of Chronic Total Occlusion of the Femoropoliteal Arteries. J. Invasive Cardiol 2013;25(7):344-347

[3]100242526 Guide Wire Pushability and Support Competitive Testing Report for Micro Guide Catheter Elite, Cordis Corporation 2015, data on file.

[4]11634371 - Competitive Testing Reports of the Aquatrack Hydrophilic Guidewire, Cordis Corporation, 2008, data on file.

Achieving Robust, Durable Angioplasty in the Tibial Arteries by Minimizing Acute Vessel Wall Trauma and Maximizing Luminal Gain

BY ROBERT BEASLEY, MS, MD; ALI MALIK, MD; AMIT BHAKOO, MD; AND BRANDON OLIVIERI, MD

Although percutaneous balloon angioplasty is an established endovascular therapy for tibial revascularization, its mechanism of action involves trauma to the vessel wall due to arterial expansion causing plaque redistribution and rupture.[1-5] This type of injury to the vessel wall, especially with uneven expansion, may lead to an acute flow-limiting dissection, which would necessitate bailout stenting, and neointimal hyperplasia can contribute to late lumen loss.[4,5]

Nevertheless, one of the most important factors in achieving a durable endovascular result in the tibial arteries is to maximize acute luminal gain. The Chocolate® PTA Balloon Catheter (manufactured by TriReme Medical, LLC, distributed by Cordis Corporation) attempts to minimize vessel wall trauma, thereby decreasing both early and late lumen loss.[6] It is composed of a nitinol pressure shield over a semicompliant balloon. Once inflated, it forms multiple alternating grooves and balloon pillows, allowing for a more controlled distribution of shear force despite variability in lesion morphology (Figure 1).[6]

The dynamic shape of this balloon allows the operator to take it up to its rated burst pressure while minimizing the risk of flow-limiting dissections (Figure 2). Unlike cutting or scoring balloons, the pressure shield does not cut into the arterial wall; instead, it constrains the balloon and enables a uniform inflation by creating the mounds or pillows. This provides for the high inflation pressures needed in calcified tibial lesions. The typical outcome is an excellent angioplasty result with no dissection.

By reducing the need for bailout stenting, we have the potential to reduce the overall cost of care for patients with critical limb ischemia and expect improved outcomes. The Chocolate BAR registry demonstrated markedly reduced rates of dissection and bailout stenting compared to trials using normal percutaneous angioplasty alone in both above- and below-the-knee applications.[7-10]

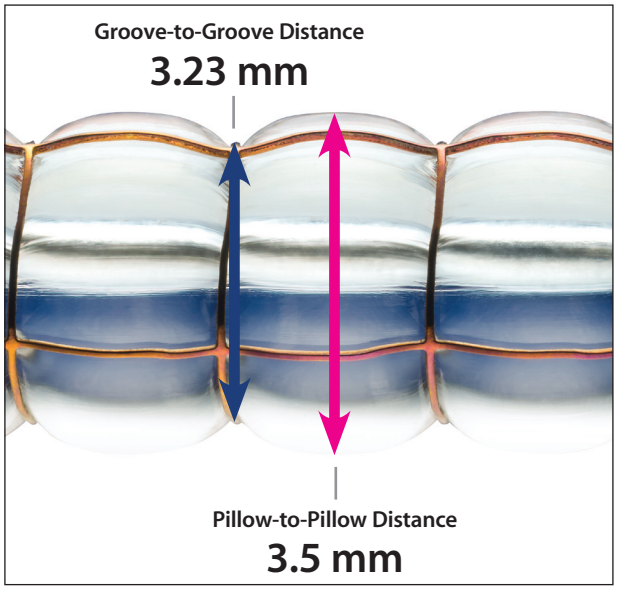


Figure 1. Dimensions for a 3.5-mm balloon at nominal pressure.

We often use Chocolate® PTA Balloon dilatation in conjunction with plaque-debulking atherectomy, especially in calcified vessels, for maximal luminal gain. As for oversizing the balloon, we are quite liberal: For a 5-mm vessel, we typically use a 6-mm balloon. For a 3-mm tibial vessel, we use a 3.5-mm balloon. We also use the 3-mm balloon all the way down to the ankle without issues among any patient population.

CASE STUDY

A 71-year-old man with a history of peripheral vascular disease, coronary artery disease with myocardial infarction (at age 70), hypertension, and chronic obstructive

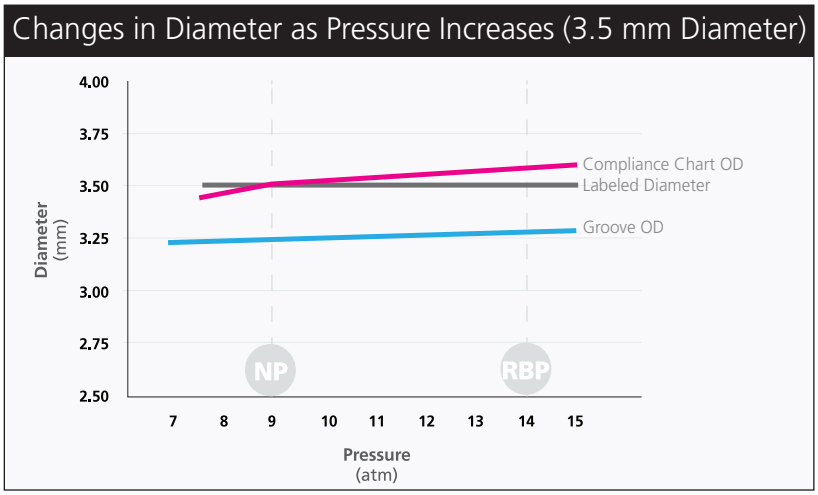


Figure 2. As pressure increases, pillow-to-pillow distance increases. Groove-to-groove distance, however, does not experience the same amount of increase, thus providing stress relief and minimizing the risk of flow-limiting dissection. Abbreviations: NP, nominal pressure; RBP, rated burst pressure. (Data on File. Cordis Corporation.)

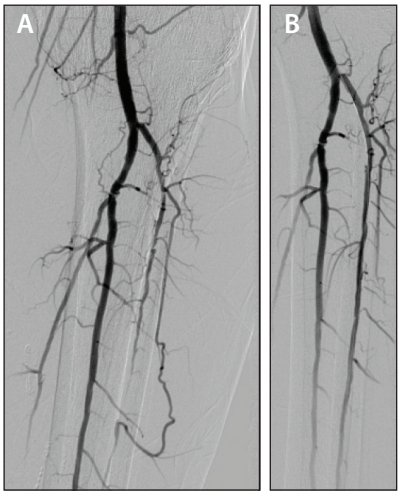


Figure 3. Preprocedural angiogram showing the partially calcified left anterior tibial artery, which was occluded and had minimal distal reconstitution (A). Postprocedural angiogram showing wide patency with excellent flow (B).

pulmonary disease was referred to our vascular clinic with bilateral critical limb ischemia of his lower extremities manifesting as ischemic rest pain. He had good femoral and popliteal pulses bilaterally and Dopplerable dorsalis pedis pulses.

Lower extremity angiography revealed bilateral tibial occlusive disease that was more significant on the left side. The decision was made to intervene on the left side and to address the right tibial occlusion in a subsequent intervention. The partially calcified left anterior tibial artery was occluded, with minimal distal reconstitution (Figure 3A).

Contralateral access was used to place a 6-F sheath over the iliac bifurcation. A microcatheter and hydrophilic guidewire were used to cross the left anterior tibial artery. Atherectomy was then performed using a 1.25-mm Diamondback 360 orbital atherectomy device (Cardiovascular Systems, Inc.).

Angioplasty was performed using a 3-mm outer-diameter Chocolate® PTA Balloon, which was inflated slowly up to half nominal pressure at 30 seconds, then up to nominal pressure by 1 minute, and finally up to its rated burst pressure with deflation at 1 minute, 30 seconds. The results showed wide patency with excellent flow (Figure 3B).

After the intervention and antibiotic therapy, cellulitis and pain resolved. ■

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1. Payne MM. Charles Theodore Dotter: the Father of Intervention. Tex Heart Inst J. 2001;28:28-38.
2. Finet G, Abrysch, F, Rioufol, et al. Qualitative and quantitative descriptions of the mechanisms of action of the angioplasty balloon on coronary stenosis. An endovascular ultrasonic study. Arch Mal Coeur Vaiss. 2000;93:1109-1117.
3. Wilensky RL, March KL, Gradus-Pizlo I, et al. Vascular injury, repair, and restenosis after percutaneous transluminal angioplasty in the atherosclerotic rabbit (in French). Circulation. 1995;92:2995-2300.
4. Bennett MR. In-stent stenosis: pathology and implications for the development of drug-eluting stents. Heart. 2003;89:218-224.
5. Costa MA, Simon DI. Molecular basis of restenosis and drug-eluting stents. Circulation. 2005;111:2257-2273.
6. QTVascular Chocolate PTA Balloon Catheter (2014). http://qtvascular.com/us/products/chocolate. Accessed September 11, 2014.
7. Das T, Mustapha JM (2014). Chocolate BAR: Chocolate PTA in a broad range of patients with PAD, a prospective post-marketing study. Presented at LINC 2014: The Leipzig Interventional Course in Leipzig, Germany.
8. Odink H, van den Berg A, Winkens B. Technical and clinical long-term results of infrapopliteal percutaneous transluminal angioplasty for critical limb ischemia. J Vasc Interv Radiol. 2012;23:461-467.
9. Laird JL. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. Circ: Cardiovasc Interv. 2010;3:267-276.
10. Werk M, Albrecht T, Meyer DR, et al. Paclitaxel-coated balloons reduce restenosis after femoropopliteal angioplasty. Evidence from the randomized PACIFIER trial. Circ: Cardiovasc Interv. 2012;5:831-840.

A Legacy of Providing Best-in-Class Education and Training:

The CORDIS® Cardiac & Vascular Institute℠

A discussion with Tammy Leitsinger, Global Director of Clinical Education & Training, highlighting the legacy of the CORDIS® Cardiac & Vascular Institute℠ educational contributions that are advancing vascular medicine.

Tammy Leitsinger is the Global Director of Clinical Education & Training at Cordis Corporation.

With more than 124 million people suffering from vascular disease, the future of health care is demanding comprehensive solutions. Part of this solution is better accessibility and more content-rich health care provider (HCP) educational programs. In 2006, the CORDIS® Cardiac & Vascular Institute (CCVI) was established, providing physicians and other health care providers with clinical and product educational resources. These training resources are designed to help progress the understanding and treatment of cardiac and vascular conditions, thereby improving patient outcomes. CCVI conducts educational programs for thousands of global health care practitioners annually through both live and web-based education programs. CCVI also operates the largest network of cardiovascular procedural simulators in the world for health care provider training with 150 systems in 10 countries.

What have been the biggest changes over the past 5 years in HCP education?

Over the past 5 years, physicians have less time to leave their practices to attend educational programs. Also, like many other technology or information-centric industries, the global proliferation of new cardiovascular information and interventions is increasing rapidly. Keeping pace with new and innovative devices and clinical breakthroughs is an important part of vascular disease solutions. HCPs want, and arguably need, immediate and convenient access to current evidence-based information regarding therapy options, outcomes, emerging techniques, and virtually every aspect of the procedures they perform. This all needs to be accomplished without taking precious time away from their practices. CCVI online programs were created to bring this type of training to physicians. This training offers easy access to information when it's most convenient for the physician and staff. The programs have been tremendously well-received due to their effectiveness and 24/7 availability. When the need to attend live training is critical, CCVI continues to deliver didactic and observation programs in small group settings to provide the best, most effective training, again limiting the time away from their practices.

What are the CCVI accomplishments that you are most proud of?

From the beginning, CCVI's focus has been on delivering the clinical education and product training needed by physicians around the world. CCVI is recognized globally as an educational leader helping physicians make the most informed choice in patient treatment options. Wherever I travel around the world, health care practitioners are

CCVI LANDMARK EDUCATIONAL INITIATIVES

- **First** stent certification program—PALMAZ-SCHATZ™ Balloon-Expandable Stent
- **First** FDA-approved online training program—Carotid Artery Stent Education System (CASES)
- **Sole** sponsor of the China Ministry of Health Initiative for Cardiology Certification—PROJECT TOUCH
- **First** medical device manufacturer to support the Peripheral Arterial Disease Coalition—an alliance of more than 80 North American health organizations, professional societies, government agencies, and corporations united to improve the health and care of patients with peripheral artery disease

> "Cordis is truly the pioneer in integrated company education with the Macy's approach. Together, we created an accredited CME peripheral vascular training track that included all of the vascular specialties. This groundbreaking training included didactics, live and taped cases, a cadaver lab, and hands-on animal and inanimate labs that allowed for a breadth of various company products. This allows the practicing physician to truly upgrade and expand the treatment for patients with peripheral vascular disease."
>
> *Gary Ansel, MD*

drawn to CCVI educational programs both at the hospital level as well as at major scientific congresses. CCVI is a trusted resource, and I am extremely proud that we are able to provide the best possible educational solutions to help clinicians' advance toward less-invasive therapies.

Just as the understanding and treatment of vascular disease is rapidly evolving, our CCVI team continues to lead educational programs for physicians. This is also especially gratifying and amazing with all the advancements of new products for vascular disease.

What are some of the key lessons you've learned in your role as director of CCVI?

Keeping physicians' goals and objectives at the forefront has been instrumental to CCVI's success. Aligning with physicians' needs drives decisions that deliver the best education, and I am proud that our programs consistently achieve this goal.

There is no single way to provide health care provider training and education. CCVI has learned that supplying multiple educational options can help create and advance solutions. Really listening to physicians' needs and then tailoring a solution organically, or finding an existing program, has been invaluable.

What motivates you as you go to work each day?

Vascular disease is devastating for patients and their families. I have seen and learned this firsthand with my mother who suffered from critical limb ischemia. She was misdiagnosed early on and subsequently passed away from complications after amputation. More needs to be achieved to curb the rate of amputation and mortality associated with critical limb ischemia. Education, awareness, and early detection are at the core of finding a solution to peripheral vascular disease. This is what truly drives me each and every day to do more to educate physicians about treatment options that will aid in the eradication of peripheral artery disease and continue to make a positive difference in the lives of patients. ■

The RFID Revolution

A discussion of how supply chain optimization is changing health care's bottom line.

BY JEAN-CLAUDE SAGHBINI, MS

Jean-Claude Saghbini, MS, is the General Manager of Inventory Management Solutions at Cardinal Health.

The health care supply chain is complex, with many moving parts and multiple obstacles to efficiency. Reductions in reimbursement rates are creating an acute need for providers to reduce their overall costs, and this cost pressure is also being translated to medical device manufacturers. The complex nature of product stocking requires intensive staffing maintenance, and multiple, oftentimes siloed, systems lead to process duplications, a lack of data sharing, and often inadequate or nonexistent analytics. As a result, waste in the medical device and implantables supply chain amounts to an estimated $5 billion in annual losses.[1] At face value, these obstacles seem insurmountable, and the waste appears to be irretrievable. However, a disruptive, technology-based solution is bringing big changes to the health care supply chain as radio frequency identification (RFID) technology enables automated stocking, accurate usage capture, health care ecosystem compatibility, and robust data analytics.

SO WHAT CAN THIS MEAN FOR HEALTH CARE?

A truly networked, end-to-end supply chain solution provides invaluable data assets that deliver insight into many aspects of health care. Usage patterns emerge. Outcomes are linked to products and practices. Waste becomes visible, measured, and reduced. Working capital is reallocated. True product costs are reduced. Even health care industry staffing—from manufacturers' sales teams to caregivers on a hospital floor—is reorganized to reflect insights culled from the supply chain.

The retail industry has been utilizing analytics in the supply chain for quite some time and to great effect. From the point of manufacture, to the distributor, to the store, to the point of sale, items are tracked, and information freely flows both up and down the supply chain.

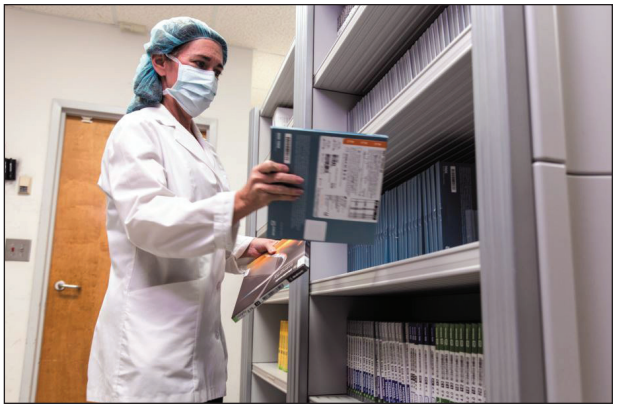
In retail, the benefits of this approach are already clear. Item-level data from manufacture to the point of sale are captured, providing valuable analytic data, which can help reduce stock-outs and lost sales, while at the same time decreasing unnecessary inventory and promoting predictive point-of-sale–based forecasting. In short, retailers and manufacturers have broad visibility throughout the supply chain, and can use historical and predictive data to anticipate the products they need while seamlessly aligning those needs with their current inventory.

The health care supply chain lies in stark contrast with the efficiencies of retailers. More often than not, data are either not captured or not shared, so visibility remains siloed within each separate piece of the supply chain. Furthermore, historical approaches to supply chain management are no longer sustainable, as the current consignment distribution model forces high loss rates to be built into product costs. Data sharing and end-to-end visibility are critically important to recovering this waste and creating a more strategic and efficient supply chain. If we can track a $7 razor from raw materials to a medicine cabinet, imagine the efficiencies that can be gained when we can do the same with high-cost medical devices like pacemakers.

WHEN WILL THE RFID REVOLUTION HIT HEALTH CARE?

The early stages of this disruption—the creation of end-to-end supply chain networks—are already underway. It is easy to underestimate the importance of this development, because on the surface, the supply chain looks much the same. RFID isn't new, nor is inventory control. Even the roles of the players—hospitals, doctors, manufacturers and distributors—are the same. So, what's different?

Reflecting on more than a decade in this business, efficiency gains have been incremental. The next era will be different. The change on the horizon is much greater than what's easily imaginable today. There's an estimated $5 billion in waste in the medical device and implantables supply chain, and stakeholders will go to great lengths to capitalize on this opportunity to reduce costs.



Cardinal Health Smart Cabinets eliminate manual counting and provide real-time visibility.

Manufacturers and health care providers alike have mutually aligned motivations for adopting RFID technologies throughout their supply chains, as their pain points often overlap. Both groups have to reconcile problems with product expiration, product loss, overstocking, and product shortages.

Unfortunately, today the health care supply chain isn't a common-platform network. Rather, it is still heavily fragmented and siloed. Hospitals use RFID, often excelling in its application within their own internal applications like inventory management or patient and capital asset tracking. Similarly, suppliers and manufacturers have excellent management systems that suit their internal needs. But lack of integration between suppliers and purchasers leads to platform incompatibilities, which limit supply chain communication and wastes some of the most important and beneficial applications of an RFID-based tracking platform.

WHAT'S THE ANSWER?

What is needed is an end-to-end networked supply chain: an environment in which all stakeholders—producers, purchasers, and distributors—swim in the same pool of information. End-to-end networked supply chains improve efficiency and coordination for all participants. Hospitals benefit from efficiency improvements, reductions in waste, proactive supply management, enhanced charge capturing, and improvements in patient safety, and clinical satisfaction. Manufacturers share in these benefits, with reduced and optimized inventory and end-to-end inventory visibility, allowing for real-time consignment allocation within the integrated delivery networks (IDNs) and the region.

The health care supply chain is taking notice, and change has begun. For example, Cardinal Health is now working with hospitals and manufacturers to create end-to-end supply chain visibility for high-value products. These items—pacemakers, artificial knees and hips—can cost $200 to $20,000 per box. Ordering and inventory control are done ad hoc, leading to waste that is harmful to everyone's bottom line.

Some of health care's biggest players have already adopted RFID technology into their supply chains, recognizing the enormous value and benefits of end-to-end visibility. RFID technology is one of the most effective ways of ensuring that the communication and data capture required for this visibility is precise, accurate and efficient.

Fueled by the growth of RFID technology, precision inventory management solutions promise dramatically improved efficiency and cost savings, which cascade across entire health care systems. Advances in data capture and analytics have enabled the growth of networked supply chains, which span from the manufacturer line to patient-side point of use.

The use of RFID technology is now linking producers, purchasers, and distributors end-to-end across the entire supply chain. This allows manufacturers to see real-time inventory and consumption data, prompting earlier demand signals and all but eliminating product expiration challenges. Utilizing RFID technology, hospitals are better equipped to manage their high-cost products without burdening clinical staff with tedious supply chain responsibilities. The RFID revolution is increasing efficiency, improving the patient experience, and changing the bottom line for the health care supply chain. ■

1. PNC Healthcare. GHX quantitative research study. August 2011.

More Data, More Visibility, More Insights

The RFID solution from Cardinal Health gave Emory St. Joseph's Hospital what every provider needs in the new health care world: more control over supply costs.

THE CHALLENGE

All over the country, health systems are pledging to cut billions of dollars in unnecessary costs in response to the Affordable Care Act's mandate to eliminate waste. Emory St. Joseph's Hospital in Atlanta, Georgia identified the medical-surgical supply chain as a potential source of savings and turned to Cardinal Health to help the health care provider improve its inventory management through automated tracking and utilization. "We're being careful with supply costs, so we don't have to look at reducing labor to control expenses," said Julie Swann, MBA, MHA, BSN, RN, Specialty Director/eICU for Emory St. Joseph's Hospital. "The Cardinal Health RFID solution is a solid way to help us do that. Now we have an up-to-date and live look at inventory."

> "Before RFID, our inventory visibility was limited to knowing what we had ordered. Now, we're tracking actual usage patterns in real time—and automatically setting accurate par levels."
>
> *Chuck Naylor*
> *Senior Business Manager,*
> *Emory St. Joseph's Hospital*

BACKGROUND

Founded in 1880, Emory St. Joseph's is Atlanta's oldest hospital. The 410-bed, acute-care facility—recognized as one of the top specialty-referral hospitals in the Southeast—offers its patients the latest procedures and treatments by providing its medical staff (comprised of more than 750 physicians) with research services and the most advanced technology available.

SOLUTIONS

When St. Joseph's first decided to update its inventory management and usage tracking system, the plan was to implement barcoding in two high-volume procedure areas—Cardiac Catheterization and Electrophysiology labs. But the hospital switched course after realizing Cardinal Health's RFID solution required minimal investment of time and IT resources and offered an immediate return on investment. "There wouldn't be the year of transition that barcoding would require," said Lisa Stepps, Account Manager for Cardinal Health. St. Joseph's could simply replace the current wire shelving in the procedure areas with Cardinal Health Smart Cabinets.

What's more, RFID would provide St. Joseph with unprecedented visibility, giving the hospital an end-to-end data-driven tool to optimize inventory while also improving patient safety and clinical satisfaction. "The true advantage of the Cardinal Health RFID solution is providing real-time supply chain visibility for the real world," said Carola Endicott, Vice President, Operations and Services for Cardinal Health. "This is the first end-to-end supply chain solution that can give St. Joseph's what every provider needs to succeed in the new healthcare world: more control over supply costs."

RESULTS

The Cardinal Health RFID solution helps St. Joseph's effectively manage more than $2.5 million in inventory, monitoring over 2,000 SKUs in seven Cardiac Catheterization labs and three Electrophysiology labs. In the first 18 to 24 months of the program, St. Joseph's steadily shrunk inventory to match utilization. "The problem in the procedure areas was that there was a lot of product in the storerooms," Swann said. "When we first started using the Cardinal Health RFID solution, we were able to do some 'spring cleaning' right away and save $10,000 in inventory holding costs." With that baseline inventory level established, St. Joseph's was then able to adjust par levels to match utilization.

"Before RFID, our inventory visibility was limited to knowing what we had ordered," said Chuck Naylor, Senior Business Manager at Emory St. Joseph's Hospital. "Now, we're tracking actual usage patterns in real time—and automatically setting accurate par levels."

The solution also improves revenues. "Cardinal Health RFID integrates with our charting and documentation system, which cuts down on manual errors and improves charge capture," said Lisa Newton, Unit Director of the Electrophysiology (EP) Lab.

Other major improvements the hospital experienced from 2012 to 2013:

- Saved 3 hours in labor every day ordering products
- Eliminated 100% of overnight shipping costs due to stockouts
- Improved EP inventory turns by 60%
- Recovered $300,000 in chargeable product costs through active alerts
- Automated 100% of expiration and recall alerts to meet highest patient safety standards

Contact us at GMB-CIMS@cardinalhealth.com for more information. ■

CardinalHealth™ + Cordis®

Powered to transform

United to meet the evolving needs of our cardiovascular customers.

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