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# Vascular Mimetic Implants

A new class of SFA technology.

## PARTICIPANTS



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He has disclosed that he has received consulting fees from Abbott Laboratories and Cordis Corporation, as well as honoraria from Medtronic, Inc., Alpha Medical Products, Inc., and Lutonix, Inc.



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**E**ndovascular Today recently asked a panel of experts in endovascular therapies across specialties to discuss the optimal use of vascular mimetic implants (VMIs) to treat lesions in the superficial femoral (SFA) and proximal popliteal arteries. Their perspectives and recommendations are based upon both the relevant clinical evidence and their own experience.

For important safety information, please see page 33.

**You have been using stents in the SFA for years. Why do you feel there is a need for new treatment options or technology in the SFA?**

**Dr. Montero-Baker:** I think it's no secret that the SFA might be the toughest vessel we treat when dealing with peripheral arterial disease. The complex array of active and passive mechanical stressors to which the SFA is subject are merciless when it comes to a medical implant. Moreover, even now when we have standard laser-cut implants that might be "fracture resistant," the reality is that they have no vasculomimetic properties and hence create a constant inflammatory state in the vessel wall that ultimately leads to intimal hyperplasia. We are still far from finding the ideal solution for treating the SFA.

**Dr. Parikh:** The SFA has proven to be one of the most challenging vascular beds in the human body. As in every other vascular distribution, restenosis is a vexing problem, particularly in the SFA where the stress-strain relationships of flexion, extension, torsion, and compression amplify the vascular response to injury, resulting in very high restenosis rates due to neointimal hyperplasia. In order to offer endovascular therapies that rival autologous venous femoropopliteal bypass surgery, long-term patency rates need to improve beyond those of conventional self-expanding stents.

## CHALLENGES WITH CURRENT TECHNOLOGIES

**What do you see as the primary disadvantages of current technologies (ie, standard nitinol stents) in the SFA and proximal popliteal arteries?**

**Dr. Metzger:** Stents were originally designed to maintain an open vessel after angioplasty. There are several limitations to current stent technologies including suboptimal resistance to compression, limited stent flexibility, recoil or underexpansion, kinking, and fractures (especially in long lesions, which are shown to be associated with reduced patency and poor long-term patency). One observation that has become accepted as a rule in the SFA is that as

lesion lengths increase, patency rates generally decline. Whether treated with bare-metal stents, drug-eluting stents, angioplasty, or atherectomy, long lesions generally equate to poor results and remain a challenge in the SFA.

**Dr. Montero-Baker:** First, one needs to understand how these stents are constructed: You take a rigid metal cylinder and then laser cut specific patterns/designs to get the end product (stent). That end product is constrained into a deployment system. Moving forward in time to implantation, we select the device with a certain degree of oversizing (10%–40%) and create a small channel to implant the device, or on occasions, even consider direct stenting. Once deployed, we postdilate to lessen acute recoiling. After a satisfactory acute result, there are constant temperature-mediated changes that result in persistent outward growth (barotrauma) for up to 120 days—and that's excluding the trauma secondary to the inherited stiffness of the device in a dynamic structure, which ultimately never ends as long as the patient keeps walking. The entire process is conceptually suboptimal.

**Dr. Parikh:** Current self-expanding stents are made from nitinol, a self-expanding alloy of nickel and titanium. The alloy is typically fabricated into a cylinder from which stents are laser cut, heated, and stretched to a desired size. Although these stents are very flexible and elastic, like all metals, they eventually demonstrate fatigue, and stent fracture (particularly in an artery as mobile as the SFA) frequently occurs and often results in restenosis. More importantly, when conventional nitinol self-expanding stents are implanted, the conventional wisdom is to “oversize” the stent to ensure adequate stent apposition and lesion expansion. Although there are improved angiographic results acutely, this practice results in chronic vessel irritation due to the chronic outward force imparted by the stent upon the vessel. This phenomenon can also result in restenosis. Thus, an ideal next-generation device would be fracture resistant and would not impart chronic outward force upon the vessel.

## OPPORTUNITIES WITH VMI TECHNOLOGY

### How are VMIs different than standard nitinol stents?

**Dr. Metzger:** The Supera® VMI (Abbott Vascular) has a design that is different from laser-cut standard nitinol stents, allowing the artery to move naturally without constraining it. Preserving natural movement of the anatomy is critical to ensuring durable clinical outcomes. It also has four to five times the compres-



sion resistance of standard nitinol stents, is highly fracture resistant, and has minimal chronic outward force.

A natural-moving “mimetic” implant such as Supera® can more comprehensively address the common issues that we see with the current modalities of SFA treatment.

**Dr. Montero-Baker:** This is a different class of technology. The woven design allows the wires to move independently, distributing external force across the entire implant. Specifically, regarding the Supera® VMI, you avoid oversizing, as one-to-one sizing is the way to go. The key is to slowly prep the vessel for the implant. One must predilate the vessel to match the outer diameter of the selected implant. This implant has the dual advantage of the lowest chronic outward force plus the highest radial strength as compared to laser-cut nitinol stents.

**Dr. Parikh:** A VMI would emulate an artery's natural flexibility while also resisting flexion, extension, compression, and torsion. The Supera® implant achieves this due to its novel construction with multiple interwoven wires, which not only resists kinking, but also results in a nearly perfectly circular vascular lumen after implantation. Having performed a considerable amount of coronary and peripheral intravascular imaging with both intravascular ultrasound and optical coherence tomography, what I find striking about Supera® is that postimplantation intravascular ultrasound/optical coherence tomography almost always demonstrates a perfectly circular lumen profile, even in eccentric, heavily calcified lesions. This intravascular imaging appearance confirms the radial strength of

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– Dr. Metzger

the Supera® platform, which is paired with the amazing lack of chronic outward force.

#### How has Supera® performed clinically in the SFA and proximal popliteal arteries?

**Dr. Metzger:** The primary patency rate achieved in the SUPERB pivotal trial was 86.3% (Kaplan-Meier) with 1-year freedom from reintervention (target lesion revascularization [TLR]) at 89% and 2-year freedom from reintervention (TLR) at 84%, despite having 45% of patients with severe calcium and 25% with total occlusions.

A subset analysis of the SUPERB trial was conducted to determine the impact of lesion length on restenosis. In both short lesions (3.5 cm) and long lesions (12 cm), the percentage of patients without restenosis was the same at 88%, which was dramatically different than other investigational device exemption trials such as STROLL (S.M.A.R.T.® Control®, Cordis Corporation) or DURABILITY II (EverFlex™, Covidien), which showed a decline in patency as lesion lengths increased. Primary patency was also calculated in lesions where Supera® was deployed at nominal length versus compressed or elongated. In proper deployments of Supera® (nominal deployments), primary patency was 90.5% at 12 months. In addition, 97% and 96% freedom from reintervention rates were achieved at 1 and 2 years, respectively, in nominal deployments.

Lower primary patency and freedom from reintervention rates (TLR) were associated with severely elongated deployments.

**Dr. Montero-Baker:** Although there have been data presented or published on approximately 1,400 worldwide implantations, I can speak more on behalf of our local data. The RESTORE registry (soon to be published) was performed at Tucson Medical Center and consisted of 147 complex patients (67% of patients were Rutherford class 3–4, 35% were Rutherford class 5–6). The Kaplan-Meier 12-month patency rate of 86.2% is similar to those shown in the SUPERB and Leipzig studies.

What are some tips and tricks that relate to achieving “nominal deployments” and excellent clinical outcomes with Supera®?

**Dr. Metzger:** Very importantly, it is imperative that the vessel is appropriately pretreated prior to implantation of Supera®. All areas of the artery that will be treated with Supera® should be predilated at least to the outer diameter of the device that will be implanted. There should be full expansion of the predilatation balloon in all areas where Supera® will be implanted.

Our usual strategy is to use a road map during predilatation; we often use a 6-mm focal-force balloon prior to implantation of a 5.5-mm Supera®. It is important to increase magnification, watch the cell geometry, and use short, even throws of the thumb slide. The geometry will tell you how well the deployment is going. Ideally, Supera® will look like it does on your tabletop—you want the Supera® implant to achieve its nominal length in order to optimize compression resistance and clinical outcomes.

**Dr. Montero-Baker:** I always like first-time users to look at the conformation of an out-of-the-box Supera® implant under fluoroscopy; postimplantation, it should look exactly as the tabletop one does. To avoid elongation, the logical thought process is to create a perfect space for it to effortlessly transition into its nominal length. Achieving this mechanical conformation will optimize compression resistance and clinical outcomes.

**Dr. Parikh:** The most critical aspect of Supera® deployment centers upon lesion preparation. Meticulous predilation with long balloon inflations (2–3 minutes) with appropriately sized balloons (1:1 with the reference vessel diameter) is absolutely critical to achieving nominal deployment. Operators should take their time and watch the geometry of the Supera® with each throw of the thumb slide to ensure adequate deployment. Careful attention to technique will result in optimal results.

#### CONCLUSION

The SUPERB trial demonstrated a 90.5% primary patency rate at 12 months, 97% freedom from reintervention rate (TLR) at 12 months, and a 96% freedom from reintervention rate at 24 months with nominal implant deployments. The Leipzig SFA data also demonstrated similar data to SUPERB in a patient population with longer lesions, more occlusions, and more severe claudication.

The high patency rates with Supera® may be attributed to its low chronic outward force, ability to mimic the natural movement of the anatomy in areas of movement and flexion, and ability to resist recoil in calcified areas while maintaining a round, circular lumen. For more information, please contact your Abbott Vascular representative. ■

## INDICATIONS

The Supera Peripheral Stent System is indicated to improve luminal diameter in the treatment of patients with symptomatic de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters of 4.0 to 6.5 mm, and lesion lengths up to 140 mm.

## CONTRAINDICATIONS

The Supera Peripheral Stent System is contraindicated in:

- patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system
- patients who cannot receive antiplatelet or anticoagulation therapy. Based on in vivo thrombogenicity testing, the device should not be used in patients who cannot be anticoagulated as there may be some thrombus formation in the absence of anticoagulation.

## WARNINGS

• This device is intended for single-use only. Do not reuse. Do not resterilize. Do not use if the package is opened or damaged. • Use this device prior to the "Use By" date as specified on the device package label. Store in a dry, dark, cool place. • DO NOT use if it is suspected that the sterility of the device has been compromised. • Persons with known hypersensitivities to Nitinol and/or its components (e.g. nickel titanium) may suffer an allergic reaction to this implant. • Administer appropriate antiplatelet therapy pre- and post-procedure. • Careful attention should be paid when sizing and deploying the stent to prevent stent elongation. In the SUPERB clinical study, stent elongation was associated with a decrease in patency at 12 months.

## PRECAUTIONS

The Supera Peripheral Stent System should only be used by physicians and medical personnel trained in vascular interventional techniques and trained on the use of this device.

- The long-term safety and effectiveness of the Supera Peripheral Stent System has not been established beyond two years.
- The safety and effectiveness of the Supera Peripheral Stent System has not been established in patients who:

- are less than 18 years old
- are pregnant or lactating
- have in-stent restenosis of the target lesion
- have known hypersensitivity to any component of the stent system (e.g., nickel)
- cannot tolerate contrast media and cannot be pre-treated
- have uncontrolled hypercoagulability and/or other coagulopathy

- This device is not designed for use with contrast media injection systems or power injection systems.
- The flexible design of the Supera stent may result in variation in the deployed stent length.

## Magnetic Resonance Imaging (MRI)

Non-clinical testing has demonstrated the Supera Stents are MR Conditional for lengths up to 250 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 2,500 Gauss/cm or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of

- 2 W/kg for landmarks (i.e. center of RF coil) above the umbilicus
- 1 W/kg for landmarks below the umbilicus and above the mid-thigh
- 0.5 W/kg for landmarks below the mid-thigh for 15 minutes of scanning (per pulse sequence), operating in the Normal Operating Mode (i.e., MR system mode of operation where there is no physiological stress to the patient).

## POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to:

- Abrupt stent closure
- Allergic reaction (contrast medium; drug; stent material)
- Amputation or limb loss
- Aneurysm or pseudoaneurysm in vessel or at vascular access site
- Angina or coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation)
- Arteriovenous fistula
- Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- Death
- Detachment of a system

component or implantation in an unintended site

- Embolization, arterial or other (e.g. air, tissue, plaque, thrombotic material, or stent)
- Fever
- Hematoma or hemorrhagic event, with or without surgical repair
- Hypertension/Hypotension
- Infection, local or systemic, including bacteremia or septicemia
- Ischemia requiring intervention (bypass or amputation of toe, foot, or leg)
- Ischemia or infarction of tissue or organ (e.g., occlusion of SFA/PPA or distal vasculature)
- Myocardial Infarction
- Pain (leg, foot, and/or insertion site)
- Partial stent deployment
- Pulmonary embolism
- Renal failure insufficiency secondary to contrast medium (with or without treatment including dialysis)
- Restenosis of vessel in stented segment
- Shock
- Stent malapposition or migration, which may require emergency surgery to remove stent
- Stent strut fracture
- Stent thrombosis or occlusion
- Stroke
- Thrombosis/occlusion at the puncture site, treatment site or remote site
- Transient ischemic attack
- Venous Thromboembolism
- Vessel dissection, perforation or rupture
- Vessel spasm or recoil
- Worsening claudication or rest pain

Prior to use, please reference the Instructions for Use at [www.abbottvascular.com/ifu](http://www.abbottvascular.com/ifu) for more information on indications, contraindications, warnings, precautions, and adverse events.

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