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# An Advanced Solution for SFA Disease: Vascular Mimetic Implants

Perspectives on the use of the Supera® peripheral stent system.

WITH CRAIG WALKER, MD, AND JOSEPH J. RICOTTA II, MD, MS

## PARTICIPANTS



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With this year's US Food and Drug Administration approval of the Supera® peripheral stent system (Abbott Vascular), interventionists across the United States have had the chance to use a truly unique tool for femoropopliteal disease. *Endovascular Today* recently asked two leading endovascular specialists, Craig Walker, MD, and Joseph J. Ricotta II, MD, MS, to discuss how and why they use vascular mimetic implants to treat lesions in the superficial femoral (SFA) and proximal popliteal arteries. Their perspectives and recommendations of this

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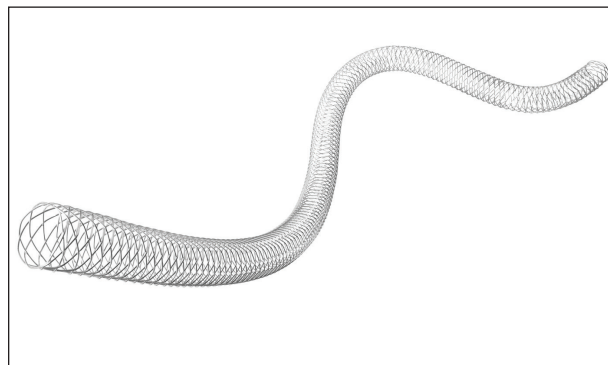


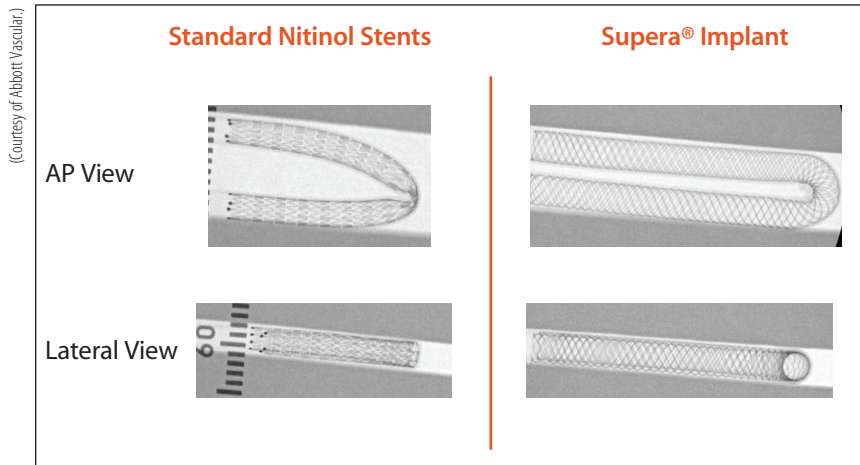
Figure 1. The Supera® peripheral stent system.

unique class of technology are based upon both the relevant clinical evidence and their own experience.

## COMBINING THE IDEAL ATTRIBUTES OF AN SFA TREATMENT

**Dr. Walker:** The first time I felt an early prototype of Supera® (Figure 1) in 2007, I knew it was something special. The design was so simple and yet so robust that I knew immediately it could be a great solution for the SFA, which experiences high stresses and strains from its constant motion.

The Supera® implant has a design that is completely different from laser-cut standard nitinol stents. It has six interwoven nitinol wires in a closed-loop design with ends that are welded; this produces an implant that is incredibly strong, fracture resistant, and yet flexible. This allows the artery to move naturally without being hindered. Because it's so different from standard nitinol stents and because it mimics the movement of the artery so well, I believe a more appropriate term to describe this class of technology is *vascular mimetic implant*.



**Figure 2.** Photos under fluoroscopy taken of Supera® and a standard nitinol stent deployed in a tube and bent. Supera® (right) has the most kink resistance of any stent available.<sup>1</sup> In addition, it maintains its circular lumen even in extreme, bent positions.

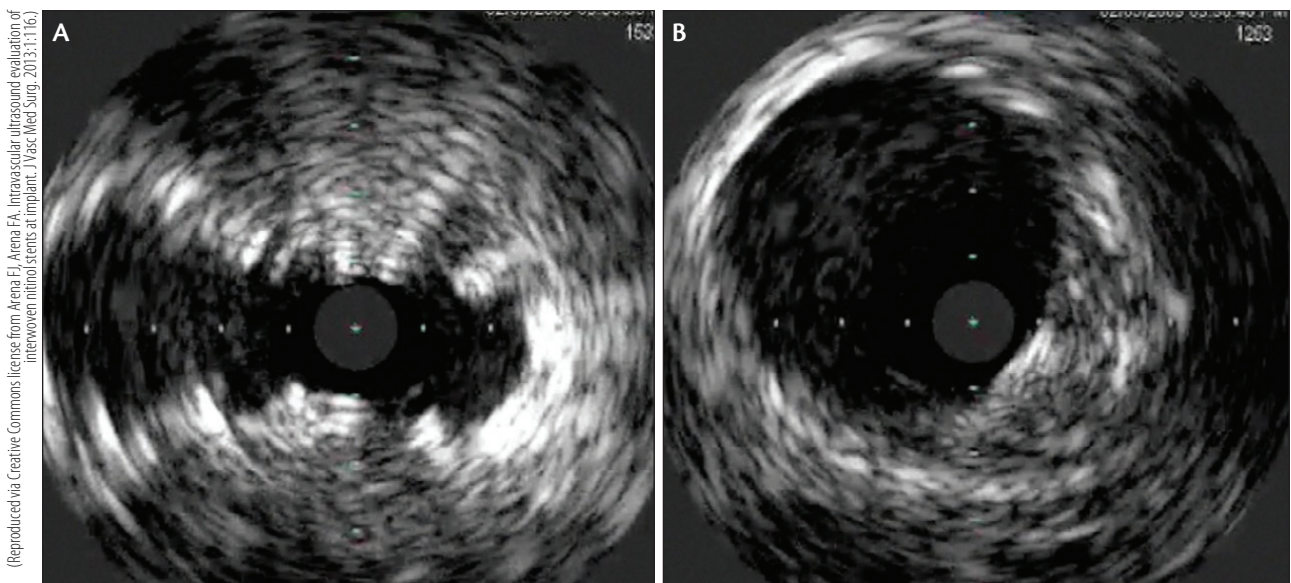
**Dr. Ricotta:** I agree that preserving the natural movement of the anatomy is critical to ensuring durable clinical outcomes. A natural-moving mimetic implant such as Supera® can more comprehensively address the common issues that we see with the current modalities of SFA treatment.

The ideal stent should emulate an artery's natural flexibility while also standing up to the forces of flexion, extension, compression, and torsion. The Supera® implant achieves this due to its novel design, which not only resists kinking and recoil (Figure 2), but also has incredible compression resistance. Testing has shown that Supera® has four to five times the compression resis-

tance of all other standard nitinol stents.<sup>1</sup> The woven design and high compression resistance also result in a very round, open vessel after implantation, preserving a maximization of luminal gain.

**Dr. Walker:** That's one of the biggest surprises to me—the round lumens after deployment. I perform a great deal of imaging with both intravascular ultrasound and optical coherence tomography, and I have been struck with how round the lumens always end up. My neighbor here in Louisiana, Frank Arena, MD, actually published an article analyzing lumen symmetry after stenting with Supera® versus standard nitinol stents last year in the *Journal of Vascular Medicine & Surgery*.<sup>2</sup> He found that with Supera®, the lumens were almost perfectly symmetric (round), even in severe calcification (Figure 3). I believe this is because of the high compression resistance of Supera®.

**Dr. Ricotta:** High degrees of flexibility and strength are important, but we're forgetting one key attribute that helps make this implant different—it has almost no chronic outward force (Figure 4). In recent years, we have become more familiar with this term and the concept of chronic outward force. Chronic outward force occurs because standard nitinol stents are oversized to the vessel diameter by 10% to 40% and subsequently



**Figure 3.** A standard nitinol stent (A) and Supera® (B) implanted in the same artery.<sup>2</sup>

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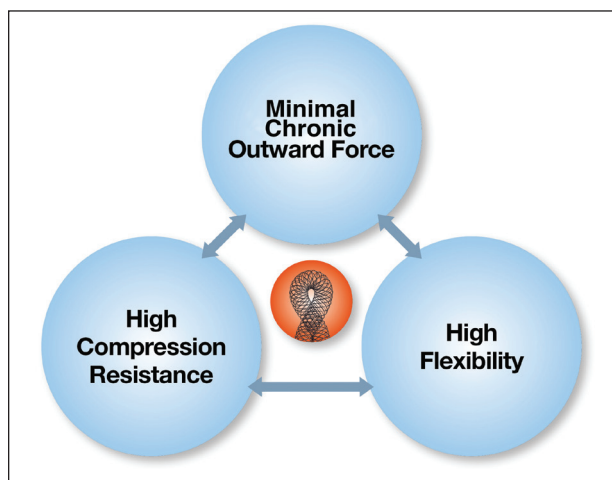


Figure 4. Supera® melds three properties that are often design tradeoffs with standard nitinol stents.

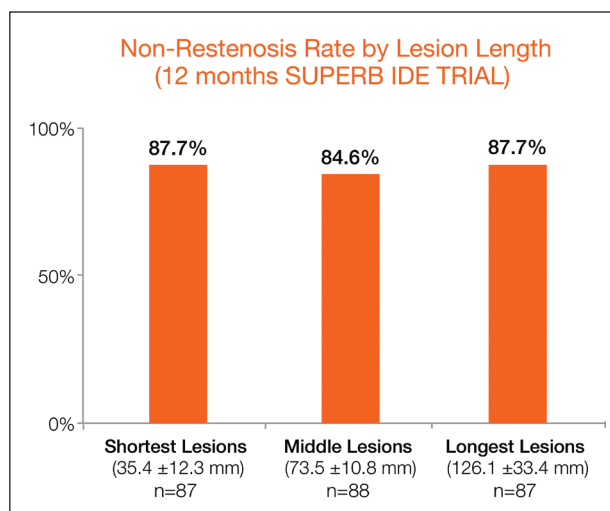


Figure 5. Data from the SUPERB trial show consistent results across lesion lengths.<sup>3</sup>

push outward on the vessel wall with a constant force to try to reach their equilibrium state. This outward force is believed to irritate the vessel and may be a catalyst for accelerated formation of neointimal hyperplasia. We've adjusted down our oversizing with some devices, such as covered self-expanding stents, but Supera® has an innate advantage for two reasons: (1) its woven design has minimal outward force, and (2) it's also sized 1:1 with the vessel.

**Dr. Walker:** That's right, Dr. Ricotta. That's one reason there are limitations with drug-eluting peripheral stents; even if these laser-cut stents were to have a paclitaxel coating, the fundamental mechanical structure is still a standard nitinol stent. Once the drug is gone after 2 or 3 days, a bare-metal standard nitinol

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TABLE 1. SUPERB DATA FOR SEVERE CALCIFICATION (N = 118)\*

Patency (VIVA 12 mo)	89%
Freedom from TLR at 1 y (K-M)	95%
Freedom from TLR at 2 y (K-M)	92%
*Data on file at Abbott Vascular.	

stent remains and imposes a persistent chronic outward force on the vessel.

### CLINICAL DATA

**Dr. Walker:** I had faith that this design would work well in the SFA even before the robust clinical evidence came out. Since the SUPERB trial data<sup>3</sup> have been released, we've learned even more about this device, and they have affirmed our hypotheses. Even before I saw the clinical data, I really believed in the design because I had felt the device and knew it combined the appropriate properties to help revolutionize SFA treatment.

**Dr. Ricotta:** I agree with Dr. Walker. When initial data were released in late 2012 and early 2013,<sup>4</sup> people really took notice of this device. The Leipzig studies<sup>5,6</sup> in particular really caught my eye.

The SUPERB pivotal trial achieved an excellent 12-month primary patency rate of 86.3% (Kaplan-Meier [K-M]). Freedom from reintervention (target lesion revascularization [TLR]) was also excellent at 89% (1 year) and 84% (2 years). This was in a relatively tough patient population that consisted of 45% of patients with severe calcium and 25% with total occlusions.<sup>3</sup>

**Dr. Walker:** SUPERB's subset analyses<sup>3</sup> really impressed me. First was the consistency in outcomes across lesion lengths (Figure 5). Generally, there is a drop in performance as lesions get longer. However, in both the short-lesion tercile and long-lesion tercile of SUPERB, the percentage of patients without restenosis was the same at 88%. I have never seen that before in any SFA device trial, including covered stent trials.

**Dr. Ricotta:** The data that most impressed me were the outcomes when Supera® was deployed nominally, rather than compressed or elongated deployments. In proper deployments of Supera® (where it was deployed to labeled stent length ± 10%), primary patency was 90.5% at 12 months.<sup>3</sup>

In addition, nominal deployment achieved 97% and 96% freedom from reintervention rates at 1 and 2 years,



respectively. However, we found that lower primary patency and freedom from reintervention rates (TLR) were associated with severely elongated deployments. That's why it is important to deploy properly and size appropriately to optimize Supera® nominal deployment.<sup>3</sup>

**Dr. Walker:** I agree. In deploying Supera® nominally, you can really get outstanding results. I was also recently made aware of the SUPERB data in severe calcium (Table 1). Forty-five percent of the patients in the SUPERB trial had severe calcification.<sup>3</sup> In those patients, the 12-month patency was 89% (VIVA [binary] method), and the freedom from reintervention rate was 95%. At 24 months, this number decreased only slightly to 92%.<sup>7</sup> The similarities between 12- and 24-month data show that this is really a durable solution.

This is significant because we know that calcium is one of the environments that standard nitinol stents do not work well in. Furthermore, calcium inhibits drug uptake. I believe that is one reason the recent drug-coated balloon pivotal trials were designed to exclude severe calcification. In my experience with Supera®, I've found it to be the ideal solution for calcified lesions due to its compression resistance and flexibility.

**Dr. Ricotta:** Another reason the outcomes may be so good is because the stent very rarely experiences fracture. In fact, across all 1,400 United States and international patients treated in trials and registries with Supera®, none have had a fracture at 1 year.<sup>8-14</sup> This is a huge benefit, and it gives me great peace of mind when I implant the Supera® in my patients.

### A DIFFERENT CLASS OF IMPLANT, A DIFFERENT DEPLOYMENT MECHANISM

**Dr. Ricotta:** The design of Supera® requires a different type of delivery mechanism. Because the implant is woven and has such high compression resistance, it is not crimped down on the deployment catheter. Instead, it's stretched out within the catheter, and a stent driver within the catheter pushes short segments of the implant out of the delivery system.

**Dr. Walker:** Some physicians have the perception that it's a difficult delivery system. In my opinion, it's not difficult—it's just different. Because it's a two-handed deployment, there is a slight learning curve, but in the end, I strongly believe the clinical results you can achieve with Supera® make it worthwhile.

**Dr. Ricotta:** I believe great outcomes are easily achieved if you follow a few simple guidelines. The most



(Courtesy of Abbott Vascular, from the SUPERB trial.)

**Figure 6.** The Supera® vascular mimetic implant in a calcified SFA lesion.

critical step is lesion preparation. I predilate the vessel carefully by inflating the balloon for a long time: 2 to 3 minutes. When I choose a balloon, I size 1:1 according to the reference vessel diameter. Also, I make sure to predilate 1 cm above and below the lesion.

**Dr. Walker:** That's the algorithm I use, as well. At this point in a procedure, I use road map imaging to help determine the diameter of the predilated lesion and choose the right diameter Supera® to use. It's my goal to use a Supera® that matches the diameter of the predilated vessel 1:1. 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. In essence, thorough lesion preparation and implant sizing are absolutely critical to achieving nominal deployment.

**Dr. Ricotta:** I most often use a 6-mm semicompliant balloon before implanting a 5.5-mm Supera®. During deployment, it is important to increase imaging magnification, watch the cell geometry, and deploy slowly. Short, slow, even pushes of the thumb slide give you

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more control over cell geometry as you pave the vessel with Supera®. A good reference for cell geometry is to compare Supera® in vivo with Supera® on your tabletop (nominal length). As we've discussed, nominal deployment helps to optimize compression resistance, maximize luminal gain, and yield excellent clinical outcomes.

### PRACTICAL APPLICATIONS: WHEN I USE SUPERA®

**Dr. Ricotta:** We are fortunate to have such an array of great tools for the SFA today. Supera® has been a game-changer in my practice. I've found that it's an excellent tool for both routine SFA lesions and extremely challenging, calcified occlusions. If I have a calcified lesion, I use Supera® as a frontline therapy (Figure 6). The only exception is if the lesion is in the proximal SFA, within 2 cm of the ostium.

**Dr. Walker:** It has been an incredibly exciting time to be able to combine the knowledge gained from the SUPERB trial with our clinical experiences. That's why I also use Supera® in a wide variety of SFA and proximal popliteal lesions, from focal to challenging. In particular, Supera® is a great tool for calcified lesions. I have found Supera® to be an effective solution in my practice versus atherectomy, which can cause perforation of the vessel wall and potentially increased radiation exposure due to longer procedure times.

A theme I've heard associated with Supera® is "Change the Rules." I believe this is very appropriate because this implant changes the rules for SFA stenting. It has both the greatest radial strength (ie, compression resistance) and the greatest flexibility of any peripheral stent available today.<sup>1</sup> Strength and flexibility are two properties that are typically design tradeoffs; one must sacrifice one to achieve the other.

**Dr. Ricotta:** Changing the rules also means that with the Supera® vascular mimetic implant, we need to think

about predilatation and sizing a little differently. The key to good deployment is really all about ensuring the vessel is well prepared and 1:1 sizing. Again, once deployment has been initiated, delivering the implant more slowly is the key to success.

**Dr. Walker:** I also think the durable clinical results speak for themselves. Most other stents have steep performance drops after 360 days. With Supera®, the consistent results at 1 and 2 years really make me confident that I am providing my patients with the best solution for treating the SFA. I'm looking forward to helping more physicians gain comfort with the Supera® vascular mimetic implant when they come visit me in Louisiana!

*For more information, please contact your Abbott Vascular representative.* ■

1. Data on file at Abbott Vascular.
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## 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 anti-coagulant 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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