Peripheral Vascular Disease

Wire-Interwoven Nitinol Stent Outcome in the Superficial Femoral and Proximal Popliteal Arteries

Twelve-Month Results of the SUPERB Trial

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Background—Stent-based therapy in the superficial femoral and popliteal arteries in patients with peripheral artery disease is compromised by restenosis and risk of stent fracture or distortion. A novel self-expanding nitinol stent was developed that incorporates an interwoven-wire design (Supera stent, IDEV Technologies, Inc, Webster, TX) to confer greater radial strength, flexibility, and fracture resistance.

Methods and Results—This prospective, multicenter, investigational device exemption, single-arm trial enrolled 264 patients with symptomatic peripheral artery disease undergoing percutaneous treatment of de novo or restenotic lesions of the superficial femoral or proximal popliteal (femoropopliteal) artery. Freedom from death, target lesion revascularization, or any amputation of the index limb at 30 days (+7 days) postprocedure was achieved in 99.2% (258/260) of patients (P<0.001). Primary patency at 12 months (360±30 days) was achieved in 78.9% (180/228) of the population (P<0.001). Primary patency by Kaplan–Meier analysis at 12 months (360 days) was 86.3%. No stent fracture was observed by independent core laboratory analysis in the 243 stents (228 patients) evaluated at 12 months. Clinical assessment at 12 months demonstrated improvement by at least 1 Rutherford–Becker category in 88.7% of patients.

Conclusions—The SUPERB Trial, an investigational device exemption study using an interwoven nitinol wire stent in the femoropopliteal artery, achieved the efficacy and safety performance goals predesignated by the Food and Drug Administration. On the basis of the high primary patency rate, absence of stent fracture, and significant improvements in functional and quality-of-life measures, the Supera stent provides safe and effective treatment of femoropopliteal lesions in symptomatic patients with peripheral artery disease.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00933270.

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Key Words: biological mimetic • femoral artery • peripheral artery disease • stent

Peripheral artery disease (PAD) is common, affecting between 8 and 12 million US residents. Treatment strategies are well defined for aortoiliac vessels, yet the initial success and durability of endovascular therapy in the femoropopliteal artery is limited by the diffuse nature of the disease, presence of calcification, heavy plaque burden, and high prevalence of total occlusion. Furthermore, dynamic forces (compression, torsion, bending, lengthening,
WHAT IS KNOWN

• In patients with peripheral artery disease, the superficial femoral and popliteal (femoropopliteal) arteries are challenging vessels in which to achieve both initial success and durable patency.
• Nitinol stents of the slotted tube configuration have demonstrated enhanced outcome over balloon angioplasty alone, but may be prone to distortion, fracture, and restenosis because of the unique forces in the femoropopliteal arteries.

WHAT THE STUDY ADDS

• The Supera stent, a novel stent designed with interwoven braided nitinol wires, demonstrates excellent initial outcomes and durable patency in the femoropopliteal arteries, with no fractures seen at follow-up.
• The Supera stent has biomimetic properties that confer higher radial strength, while enabling the stent to flex, bend, and otherwise move with the vessel so as to distribute the stress more evenly.
• The Supera stent requires careful preparation of the target vessel and proper selection of stent size, and must be deployed correctly to optimize outcome.

In patients with peripheral artery disease, the superficial femoral and popliteal (femoropopliteal) arteries are challenging vessels in which to achieve both initial success and durable patency. Nitinol has superelasticity and thermal shape memory, making nitinol stents preferred for use in flexible sites where the stent forces are greatest. Stress is not effectively dissipated within the stent mesh network. Native arteries contain (within the vessel wall) a reticular network of interconnected collagen and elastin fibers that dissipates radial, axial, and torsional forces and prevents the creation of focal areas of high wall stress. The Supera bio-mimetic vascular stent incorporates a wire-interwoven design that partially mimics the reticular structure of native collagen and elastin within vessels, emphasizing radial strength, flexibility, and kink resistance.

We prospectively compared the performance of the Supera stent to a previously reported objective performance goal (OPG) of percutaneous transluminal angioplasty, to establish superiority for treatment of the femoropopliteal artery. This trial was conducted under a Food and Drug Administration-approved investigational device exemption clinical protocol in support of a premarket approval.

Methods

Trial Design, End Points, and Sample Size

The SUPERB trial was a multicenter, prospective, single-arm, pivotal investigational device exemption trial of symptomatic patients with de novo or restenotic lesions in the superficial femoral artery (SFA) or proximal popliteal artery. Patients were scheduled to receive the Supera stent (IDEV Technologies, Inc) and undergo evaluation at 1, 6, and 12 months after the implant procedure. The trial protocol was approved by the Institutional Review Board associated with each participating center. All patients provided written informed consent. This trial was registered with clinicaltrials.gov.

The primary safety end point was the composite rate of freedom from death from any cause, target lesion revascularization (TLR), or any amputation of the index limb within 30 days (+7 days) after stent implantation. The primary efficacy end point was patency of the stent at 12 months, defined as freedom from restenosis (diameter stenosis >50%, as identified by a peak systolic velocity ratio >2.0 measured by duplex ultrasonography) and freedom from TLR.

The primary safety objective was to establish superiority of Supera compared with an OPG of 88% that was established by VIVA Physicians (VPI). On the basis of the meta-analysis of 116 premarket approval subjects performed by VPI, the estimated proportion of the composite rate was 0.94, with lower 95% confidence limit (CL): 0.88 (as defined by the Agresti and Coull method). To demonstrate superiority with the Supera stent, the 1-sided lower 95% CL of the primary safety end point had to be >88%.

The primary effectiveness objective was to establish superiority of the Supera to an OPG of 66% established by VPI. This performance goal was based on an analysis performed by VPI demonstrating 12-month SFA patency of 33% after percutaneous transluminal angioplasty alone. The Food and Drug Administration–approved performance goal for nitinol stents was to be twice that of the percutaneous transluminal angioplasty patency rate, or 66%. To demonstrate superiority with the Supera stent, the 1-sided lower 95% CL of the patency rate at 12 months after Supera implantation had to be >66%.

All other protocol-defined end points are listed in the results section and included the rate of device success, defined as achievement of a residual diameter stenosis of <50% by postprocedure quantitative angiography after treatment using the trial stent. The secondary safety end point of major adverse vascular events within 30 days postprocedure was defined as a composite of stent thrombosis, target limb amputation, clinically apparent distal embolization, procedure-related arterial rupture, acute limb ischemia, or bleeding event requiring transfusion.

On the basis of an expected incidence of 94% for the primary safety end point and 76% for the primary efficacy end point, a sample size of 232 patients provided 93% power (safety end point) and 96% power (efficacy end point) in the 1-sided $\chi^2$ test (5% significance
and 150 mm) and diameters (4.0, 5.0, and 6.0 mm) were available.

The Supera stent is comprised of 6 closed-end interwoven nitinol wires.

**Device Description**

The Supera stent is comprised of 6 closed-end interwoven nitinol wires.

**Patient Selection**

Eligible participants had lifestyle limiting intermittent claudication or ischemic rest pain (Rutherford–Becker scale 2–4) and a resting ankle-brachial index (ABI) ≤0.9 (or resting toe-brachial index ≤0.7 if the ABI could not be reliably assessed). A single de novo or restenotic native SFA lesion was required with >60% stenosis or total occlusion and reference vessel diameter of 4.0 to 6.0 mm by visual assessment. Lesion lengths of 40 to 140 mm within the same vessel (1 long steno-segment or multiple serial stenoses contained within a total span of <140 mm), with the intention of using a single stent, were included. All treated lesions were >2 cm distal to the origin of the profunda artery and >3 cm proximal to the knee joint (distal end of the femur). Patent distal popliteal and infrapopliteal arteries were required, with at least 1 tibial vessel patent continuously to the ankle.

Patients were excluded if they had aneurysm of the ipsilateral common femoral, SFA, or popliteal artery; or tissue loss (Rutherford–Becker classification category 5 or 6). The complete list of inclusion/exclusion criteria may be found in the Appendix in the Data Supplement.

**Core Laboratory Oversight and Adverse Event Evaluation**

All angiographic images were independently reviewed and reported by the Angiographic Core Laboratory, (Beth Israel Deaconess Medical Center, Boston, MA). Duplex ultrasonography and radiographic

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>68.7±10.0 (264)</td>
</tr>
<tr>
<td>Sex, Male</td>
<td>63.6% (168/264)</td>
</tr>
<tr>
<td>Race</td>
<td>Asian 8.4% (2/264), Black 13.3% (35/264), White 83.7% (221/264), Other 2.3% (6/264)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>93.9% (248/264)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>86.7% (229/264)</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>43.5% (114/262)</td>
</tr>
<tr>
<td>Renal Insufficiency</td>
<td>9.1% (24/264)</td>
</tr>
<tr>
<td>History of Coronary Artery Disease</td>
<td>66.9% (176/263)</td>
</tr>
<tr>
<td>Previous Peripheral Artery Revascularization or Surgery</td>
<td>38.0% (100/263)</td>
</tr>
<tr>
<td>Previous Amputation</td>
<td>1.1% (3/264)</td>
</tr>
<tr>
<td>Cigarette Smoking</td>
<td>Current 31.8% (84/264), Former 48.1% (127/264), Nonsmoker 20.1% (53/264)</td>
</tr>
<tr>
<td>Rutherford–Becker Category</td>
<td>2 37.5% (99/264), 3 57.2% (151/264), 4 5.3% (14/264)</td>
</tr>
<tr>
<td>Lesion Length, mm</td>
<td>78.1±42.8 (264)</td>
</tr>
<tr>
<td>Lesion Location</td>
<td>Proximal SFA 12.1% (32/265), Middle SFA 54.3% (144/265), Distal SFA* 31.7% (84/265), Popliteal, Above Knee 1.9% (5/265)</td>
</tr>
<tr>
<td>Lesion Type</td>
<td>A 55.5% (147/265), B 38.9% (103/265), C 5.7% (15/265), D 0.0% (0/265)</td>
</tr>
<tr>
<td>Lesion Diameter</td>
<td>9.10±0.88 (265)</td>
</tr>
<tr>
<td>Lesion Stenosis</td>
<td>78.0±16.8 (265)</td>
</tr>
<tr>
<td>Total Occlusion</td>
<td>25.0% (69/264)</td>
</tr>
</tbody>
</table>

Continuous variables are reported as mean±SD (n). Categorical variables are reported as % (proportion).

Continuous variables are reported as mean±SD (n). Categorical variables are reported as % (proportion). CI indicates confidence interval; SFA, superficial femoral artery; and TASC, Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease.

Twentynine of these 84 lesions extended into the popliteal artery.
images were independently reviewed by VasCore (Massachusetts General Hospital, Boston, MA). Core laboratory assessment of vessel patency, residual stenosis, and stent fracture status superseded site investigator measurement for data analysis purposes. All technologists performing duplex ultrasonograms were qualified by VasCore before their participation in the trial.

An independent Clinical Events Committee (Harvard Clinical Research Institute, Boston, MA) adjudicated all serious adverse events (deaths, clinical trial endpoints, and reports of device failure). Safety data and risks to patients were monitored by an independent data safety monitoring board at prespecified enrollment targets.

Data Analysis and Statistical Methods
The trial results were analyzed by an independent data coordinating and analysis center (Harvard Clinical Research Institute), which had access to the primary data. As prespecified in the study protocol, the primary and safety end points were based on the intent-to-treat patient population and were compared with the VPI OPG's.21 Primary patency, defined as freedom from restenosis and TLR, is reported using 2 distinct methodologies: a Kaplan–Meier survival analysis at 12 months (360 days) and the VPI OPG at 12 months (360±30 days). Restenosis was defined as diameter stenosis >50% with a peak systolic velocity ratio ≥2.0 as measured by duplex ultrasonography.

Protocol-defined secondary event-driven end points are presented in the results section with mean, SD, and 95% confidence interval, computed using the normal approximation. Additional statistical inference tests were performed on the primary safety end point and the primary efficacy end point using the \( \chi^2 \) comparing the 95% 1-sided Wilson confidence interval to the respective performance goal. For continuous efficacy variables, changes from baseline were tested using the nonparametric Friedman test.

Results
Patient and Lesion Characteristics at Baseline
Between July 30, 2009 and May 20, 2011, a total of 325 patients were enrolled at 46 trial centers in the United States. Investigators who were less familiar with the novel stent and delivery system and stent were required to enroll ≤2 roll-in patients. Data obtained from the 61 roll-in subjects were analyzed independently of the main cohort for both safety and efficacy; the remaining 264 patients formed the basis of the primary intent-to-treat analysis. Of the 264 patients, 260 had valid information at day 30 (+7 days) to evaluate the primary safety end point. By day 360 (visit window±30 days), 243 patients (92.0%) remained in the trial, while 21 exited prematurely (7 died, 3 lost to follow-up, 10 withdrew consent, and 1 withdrew because of metastatic cancer).

Mean (±SD) age was 68.7 (±10.0) years; 63.6% were males. Clinical characteristics of the cohort were typical of symptomatic patients with PAD (Table 1). The majority of patients (57.2%) were Rutherford–Becker category 3. Two hundred sixty-five target segments were treated. Mean (±SD) target lesion length measurements preprocedure by site and angiographic core laboratory were 82.8 (±33.0) and 78.1 (±42.8) mm, respectively. Reported baseline angiographic mean preprocedure percent diameter stenosis was 78.0% (±16.8%; Table 2). Total occlusions were present in 25.0% (66/264) of patients.

Stent Implantation Procedure
Stent diameter was selected to match the nominal vessel diameter in a 1:1 fashion. Stent placement was preceded by predilation of the target site, with a balloon sized to approximate the outer diameter of the selected stent. Postdeployment balloon dilation was recommended at sites of incomplete stent expansion.

Device implantation was graded as successful by the Clinical Events Committee in 257 of 261 patients (98.5%). Of the 4 patients in whom implantation was deemed unsuccessful, 3 received a different stent after the failed attempt to deliver the Supera stent, and 1 patient had an additional stent implanted during the index procedure to treat a flow-limiting dissection at the distal end of the lesion. In addition, 18 subjects had >1 stent implanted to cover the length of the target lesion.
Of 280 stents implanted, the majority (69.3%) had a diameter of 5 mm. Angiographic core laboratory analysis demonstrated mean-delivered stent length of 115.3 (±48.07) mm; no spasm, abrupt vessel closure, or no-reflow was noted.

### Event-Driven Safety and Efficacy End Points

**Freedom from death, TLR or any amputation of index limb 30 days (±7 days) after stent implantation** was achieved in 99.2% (258/260) of patients (1-sided lower 95% CL of 97.7%), significantly greater than the safety performance goal of 88% ($P<0.001$).

Stent patency, calculated as a simple fraction at 390 days, was achieved in 78.9% (180/228) of the cohort (1-sided lower 95% Wilson Score CL of 74.2%), also significantly higher than the efficacy performance goal of 66% ($P<0.001$). Using Kaplan–Meier survival estimates, the more traditional method of calculating patency rate, 86.3% (±2.3 SE) of patients were free from loss of patency at 365 days (Figure). Other protocol-defined secondary safety and efficacy end points are summarized in Table 3.

### Table 3. Event-Driven Safety, Efficacy, and Device-Performance End Points

<table>
<thead>
<tr>
<th>End point</th>
<th>Rate (n/N)</th>
<th>95% CI Using Normal Approximation</th>
<th>Lower Bound of 95% 1-Sided Wilson CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety end points</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-Day freedom from death, TLR or any amputation of index limb</td>
<td>99.2% (258/260)</td>
<td>97.2%, 99.9%</td>
<td>97.7%*</td>
</tr>
<tr>
<td>Inclusive of 4 pts with unsuccessful device implantation</td>
<td>97.7% (254/260)</td>
<td>97.2%, 99.9%</td>
<td>95.1%*</td>
</tr>
<tr>
<td>30-Day freedom from all cause death</td>
<td>99.6% (259/260)</td>
<td>97.9%, 100.0%</td>
<td></td>
</tr>
<tr>
<td>30-Day freedom from TLR</td>
<td>99.6% (259/260)</td>
<td>97.9%, 100.0%</td>
<td></td>
</tr>
<tr>
<td>30-Day freedom from amputation of index limb</td>
<td>100.0% (260/260)</td>
<td>98.6%, 100.0%</td>
<td></td>
</tr>
<tr>
<td>30-Day major adverse vascular events</td>
<td>1.2% (3/260)</td>
<td>0.2%, 3.3%</td>
<td></td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>0.4% (1/260)</td>
<td>0.0%, 2.1%</td>
<td></td>
</tr>
<tr>
<td>Clinically apparent distal embolization</td>
<td>0.4% (1/260)</td>
<td>0.0%, 2.1%</td>
<td></td>
</tr>
<tr>
<td>Procedure-related arterial rupture</td>
<td>0.0% (0/260)</td>
<td>0.0%, 1.4%</td>
<td></td>
</tr>
<tr>
<td>Acute limb ischemia</td>
<td>0.4% (1/260)</td>
<td>0.0%, 2.1%</td>
<td></td>
</tr>
<tr>
<td>Target limb amputation</td>
<td>0.0% (0/260)</td>
<td>0.0%, 1.4%</td>
<td></td>
</tr>
<tr>
<td>Procedure-related bleeding requiring transfusion</td>
<td>0.4% (1/260)</td>
<td>0.0%, 2.1%</td>
<td></td>
</tr>
<tr>
<td>6-Month index limb amputations</td>
<td>0.0% (0/240)</td>
<td>0.0%, 1.4%</td>
<td></td>
</tr>
<tr>
<td>12-Month index limb amputations</td>
<td>0.4% (1/233)</td>
<td>0.0%, 2.2%</td>
<td></td>
</tr>
<tr>
<td><strong>Efficacy end points</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-Month primary patency rate</td>
<td>78.9% (180/228)</td>
<td>73.1%, 84.1%</td>
<td>74.2%*</td>
</tr>
<tr>
<td>6-Month primary patency</td>
<td>84.9% (191/225)</td>
<td>79.5%, 89.3%</td>
<td></td>
</tr>
<tr>
<td>12-Month freedom from restenosis</td>
<td>86.7% (196/226)</td>
<td>81.6%, 90.9%</td>
<td></td>
</tr>
<tr>
<td>12-Month freedom from TLR</td>
<td>88.9% (209/235)</td>
<td>84.2%, 92.6%</td>
<td></td>
</tr>
<tr>
<td>6-Month TLR</td>
<td>1.7% (4/241)</td>
<td>0.5%, 4.2%</td>
<td></td>
</tr>
<tr>
<td>12-Month TLR</td>
<td>11.1% (26/235)</td>
<td>7.4%, 15.8%</td>
<td></td>
</tr>
<tr>
<td>6-Month target vessel revascularization</td>
<td>2.5% (6/241)</td>
<td>0.9%, 5.3%</td>
<td></td>
</tr>
<tr>
<td>12-Month target vessel revascularization</td>
<td>13.2% (31/235)</td>
<td>9.1%, 18.2%</td>
<td></td>
</tr>
<tr>
<td><strong>Device performance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical success (per segment)</td>
<td>100.0% (262/262)</td>
<td>98.6%, 100.0%</td>
<td></td>
</tr>
<tr>
<td>Procedural success (per patient)</td>
<td>100.0% (261/261)†</td>
<td>98.6%, 100.0%</td>
<td></td>
</tr>
<tr>
<td>Device success (per patient)</td>
<td>98.5% (257/261)†</td>
<td>96.1%, 99.6%</td>
<td></td>
</tr>
<tr>
<td>12-Month stent fracture</td>
<td>0.0% (0/243)</td>
<td>0.0%, 1.6%</td>
<td></td>
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</tbody>
</table>

All events defined for the period of 30 days postprocedure are reported for patients with at least 23 days of follow-up or with event before 37 days. All events defined for the period of 12 mo postprocedure are reported for patients with at least 330 days of follow-up or with event to 390 days. Superficial femoral artery patency rate at 6 mo and 12 mo defined as freedom from restenosis (diameter stenosis >50% with a peak systolic velocity ratio >2.0 as measured by duplex ultrasound) and TLR. Technical (segment) success was defined as the attainment of <50% residual stenosis (in postprocedure QA) by any percutaneous method. Procedural success was defined as the achievement of a diameter stenosis of <50% (by postprocedure QA) using any percutaneous method, without the occurrence of death, target limb amputation or clinically driven repeat revascularization of the target lesion during the hospital stay. Device success was defined as achievement of a residual diameter stenosis of <50% (by postprocedure QA) using the assigned trial stent. CI indicates confidence interval; QA, quantitative angiography; and TLR, target lesion revascularization.

*P<0.001 comparing the 95% 1-sided Wilson CI to the performance goal of 88% for the primary safety end point and to 66% for the primary efficacy end point, using the binomial exact test.

†Three patients are not included because they did not have an evaluable postprocedure QA assessment.
Three of 260 patients (1.2%) suffered major adverse vascular events within 30 days of the procedure. Two occurred on the day of the procedure and were successfully treated. One patient developed acute limb ischemia poststent placement in the distal SFA. Subsequent angiography revealed distal embolization of atherothrombotic material with occlusion of the tibial peroneal trunk. Another patient developed a hemorrhagic complication after accidentally sitting up with the contralateral sheath still in place. Subsequent angiography demonstrated acute thrombotic occlusion of the severely diseased contralateral SFA. The third patient developed subacute stent thrombosis 27 days postprocedure, requiring balloon angioplasty.

Rutherford Category and ABI
Rutherford–Becker category improved by >1 level over baseline in 88.7% of patients and by 3 levels in 53.5% of patients at 12 months (Tables 4–6). Mean (±SD) ABI in the target limb rose from 0.73 (±0.18) at baseline to 0.92 (±0.22) at 12 months (P<0.001; Tables 4–6).

Quality of Life
Baseline quality-of-life measures related to physical health, PAD symptoms, and PAD-related physical limitation were all below the US population average23 (Tables 4–6). At 6 and 12 months, SF-12 physical score and Peripheral Artery Questionnaire scales improved significantly (P<0.001 for all comparisons except treatment satisfaction, which received a high rating initially and throughout). Mean SF-12 physical score at 12 months increased from baseline by =8 points, >3× the minimum threshold considered to be clinically meaningful.24,25 Evaluation at 12 months demonstrated 13 to 35 point improvement in all Peripheral Artery Questionnaire scales; overall summary score increased 32 points, 4× the threshold considered to be clinically important.26

Discussion
In this trial of 264 symptomatic patients with PAD treated prospectively with the Supera stent, both the safety and efficacy end points exceeded the OPGs, as assessed by independent core laboratories. This was corroborated by clinically significant improvements in Rutherford–Becker category, ABI, and quality-of-life domains related to symptoms and physical function. Of 243 stents in 228 patients evaluated with rigorous radiographic follow-up, none (0/243) had evidence of fracture. These results are consistent with those reported in 2 published registry analyses of the Supera stent in the SFA27 and popliteal artery,28 which demonstrated 12-month patency rates of 85% and 88%, respectively, and no stent fractures identified.

Supera demonstrated a 12-month primary patency rate of 86.3% by Kaplan–Meier survival analysis in this femoropopliteal investigational device exemption trial. This study does not allow for direct comparison with other stents; however, primary patency reported in the present trial is similar or superior to that reported in other trials in the femoropopliteal artery. The Zilver PTX drug-coated nitinol stent reported 12-month primary patency rate (Kaplan–Meier estimates) of 83.1% in 241 patients, with 31% shorter lesion length (5.4 cm compared with 7.8 cm for SUPERB).14 In 3 other clinical trials of self-expanding nitinol slotted-tube stents, reported primary patency rates (Kaplan–Meier estimates) were: 81.7% (S.M.A.R.T. Nitinol Self-Expandable Stent in the Treatment of Obstructive Superficial Femoral Artery Disease [STROLL] trial)29; 81.3% (LifeStent FlexStar and FlexStar XL RESILIENT trial)15; and 77.2% (Safety and Effectiveness Study of EverFlex Stent to Treat Symptomatic Femoral-Popliteal Atherosclerosis [DURABILITY II] trial).30 The reported 12-month fracture rates were 0.9% for the drug-coated Zilver PTX stent trial, and 1.8%, 3.1%, and 0.4% in the 3 nitinol stent studies, respectively. The Supera stent is constructed differently than slotted-tube stents; it contains nitinol wires that are interwoven to confer additional radial strength, flexibility, and fracture-resistance. Its design also differs from previous interwoven-wire stents: Supera’s 6 wires form a closed loop at both ends of the stent;

Table 4. Change in Rutherford Classification

<table>
<thead>
<tr>
<th>Rutherford Becker Category</th>
<th>Baseline</th>
<th>1 Mo</th>
<th>12 Mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>+3 Grades, markedly improved</td>
<td>NA</td>
<td>68.0% (176/259)</td>
<td>53.5% (123/230)</td>
</tr>
<tr>
<td>+2 Grades, moderately improved</td>
<td>NA</td>
<td>23.2% (60/259)</td>
<td>24.3% (56/230)</td>
</tr>
<tr>
<td>+1 Grade, minimally improved</td>
<td>NA</td>
<td>6.2% (16/259)</td>
<td>10.9% (25/230)</td>
</tr>
<tr>
<td>0 No change</td>
<td>NA</td>
<td>2.7% (7/259)</td>
<td>8.7% (20/230)</td>
</tr>
<tr>
<td>−1 Grade, mildly worse</td>
<td>NA</td>
<td>0.0% (0/259)</td>
<td>1.3% (3/230)</td>
</tr>
<tr>
<td>−2 Grades, moderately worse</td>
<td>NA</td>
<td>0.0% (0/259)</td>
<td>0.9% (2/230)</td>
</tr>
<tr>
<td>−3 Grades, markedly worse</td>
<td>NA</td>
<td>0.0% (0/259)</td>
<td>0.4% (1/230)</td>
</tr>
<tr>
<td>Limb ischemia improvement &gt;1 grade</td>
<td>NA</td>
<td>97.3% (252/259)</td>
<td>88.7% (204/230)</td>
</tr>
</tbody>
</table>

Continuous variables are reported as mean±SD (n). Ordinal variables are reported as % (proportion).

Table 5. Change in ABI

<table>
<thead>
<tr>
<th>ABI/TBI</th>
<th>Measurements</th>
<th>Baseline</th>
<th>6 Mo</th>
<th>12 Mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI on target limb</td>
<td>0.73±0.18 (257)</td>
<td>0.92±0.22 (226)*</td>
<td>0.92±0.22 (227)*</td>
<td></td>
</tr>
<tr>
<td>TBI on target limb</td>
<td>0.38±0.32 (60)</td>
<td>0.48±0.29 (56)*</td>
<td>0.44±0.31 (60)*</td>
<td></td>
</tr>
</tbody>
</table>

Continuous variables are reported as mean±SD (n). ABI indicates ankle-brachial index; and TBI, toe-brachial index.

*P<0.001 for difference from baseline to month 1, 6, or 12 using the nonparametric Friedman test.
it has a different braiding design (number of wire crossings per inch, braiding angle); and it is nitinol rather than stainless steel. The biomimetic design, which allows the stent to flex, twist, and otherwise mimic the motion of the vessel in which it is placed, make it particularly well-suited for the femoropopliteal artery.

Limitations

The biomimetic design of the Supera stent, while conferring certain advantages in terms of flexibility, conformability, and radial strength, is also associated with certain liabilities if the stent is not deployed properly. Optimal deployment of the Supera stent is critically dependent on accurate assessment of vessel diameter and vessel preparation. If the vessel is smaller in caliber than the selected stent size, or not adequately prepared with predilation to the same diameter as the outer dimension of the stent, the Supera may elongate during deployment. Such elongation may be associated with loss of both radial strength and precision in placement. For this reason, precise localization of the stent at the ostium of the SFA is not reliable in this study and this site was excluded. Proper stent sizing and predilation allow the stent to assume its nominal diameter and length, thus enabling more precise positioning even at bifurcations. There is an operator learning curve associated with use of Supera. Both the learning curve and precision in placement will be enhanced with newer iterations of Supera.

Another limitation of the present trial is the single-arm nonrandomized design, making it more susceptible to bias than a randomized controlled trial. However, single-arm trial designs are considered acceptable for new device evaluation when the expected outcomes are well-understood based on patient characteristics, similar inclusion characteristics of the trial population, and minimal difference between-trial variation. The SUPERB trial was conducted using an US Food and Drug Administration–sanctioned OPG, based on published data from previous trials. Patient characteristics in the current trial were consistent with those used to create this OPG.

Summary

The SUPERB trial evaluated the primary treatment of the SFA and proximal popliteal artery with a flexible, self-expanding interwoven nitinol wire stent for moderate-length lesions. The primary efficacy end point was achieved, with a primary patency rate of 86.3% at 360 days through Kaplan–Meier analysis. Secondary end points also demonstrated significant improvement. The rate of stent fracture was zero. The Supera stent provides excellent stent integrity and efficacy when compared with other nitinol stents currently available. Long-term efficacy and safety will continue to be assessed through 3 years follow-up.

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Disclosures

M.R. Jaff is a Board Member, VIVA Physicians (a 501 (c) 3 not-for-profit education and research organization), Intersocietal Accreditation Commission, and CBSET. He is also an equity shareholder for PQ Bypass, and a compensated Scientific Advisory Board Member for Abbott Vascular and Cardinal Health; and a noncompensated advisor for Abbott Vascular, Boston Scientific, Cordis, and Medtronic Vascular. Dr Mauri is an employee of Harvard Clinical Research Institute, Boston, MA, a 501 (c) 3 not-for-profit research organization. C.C. Base is a full-time employee of IDEV Technologies, Inc, VIVA Physicians, a 501 (c) 3 not-for-profit education and research organization; is a paid Scientific Advisory Board member for Abbott Vascular and Cardinal Health; receives grant support from National Institutes of Health as Co-Principal Investigator for Best Endovascular versus Surgical Treatment for Critical Limb Ischemia Trial (BEST-CLI); received honorarium for an educational lecture from Cook; and his institution (Massachusetts General Hospital) has received research support from IDEV Technologies and Abbott Vascular, Lutonix-Bard, Cordis, Cook, Medtronic, and Atrium. Drs Garcia, Metzger, Sedillo, Patiño, Wilkins, Espinoza, Khatib, Makam, Kovach, Kamat, Leon Jr, Eaves, Popma, and Rosenfield were research consultants for IDEV Technologies. The other authors report no conflicts.

References

8. Garcia et al. Wire-Interwoven Nitinol Stent in Peripheral Artery


Wire-Interwoven Nitinol Stent Outcome in the Superficial Femoral and Proximal Popliteal Arteries: Twelve-Month Results of the SUPERB Trial

for the SUPERB Trial Investigators*

*C. Base and Kenneth Rosenfield
for the SUPERB Trial Investigators*

On page 7, in the Disclosures section, “M.R. Jaff is a Board Member, VIVA Physicians, a 501 (c) 3 not-for-profit education and research organization,” has been changed to read, “M.R. Jaff is a Board Member, VIVA Physicians (a 501 (c) 3 not-for-profit education and research organization), Intersocietal Accreditation Commission, and CBSET. He is also an equity shareholder for PQ Bypass, and a compensated Scientific Advisory Board Member for Cardinal Health; and a noncompensated advisor for Abbott Vascular, Boston Scientific, Cordis, and Medtronic Vascular.”

The authors regret the error.

This correction has been made to the online version of the article, which is available at http://circinterventions.ahajournals.org/content/8/5/e000937.
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