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.
The SFA and Proximal Popliteal Environment is Complex and Challenging

Image courtesy of Dr. Chris Metzger.


3. Maximum compression from muscular contraction; based on arterial pressure of 160 mmHg for a 6 x 100 mm vessel under 1 mm compression. Supinski GS, et al., Effect of diaphragmatic contraction on intramuscular pressure and vascular impedance, Journal of Applied Physiology, 1990, 68(4): 1486-1493.

The SFA and Proximal Popliteal Environment is Complex and Challenging

25% shortening

3 lbs compression

60° twisting

8° bending

These issues are under-appreciated with AP angiograms!


3. Maximum compression from muscular contraction; based on arterial pressure of 160 mmHg for a 6 x 100 mm vessel under 1 mm compression. Supinski GS, et al., Effect of diaphragmatic contraction on intramuscular pressure and vascular impedance, Journal of Applied Physiology, 1990, 68(4): 1486-1493.

Limitations of Standard Nitinol Stents
Oversizing Can Lead to In-Stent Restenosis

Example: 8 mm stent

Optimal Oversizing
1.1 – 1.3 : 1

Medium Oversizing
1.3 – 1.6 : 1

High Oversizing
1.6 – 1.9 : 1

Oversized stent to vessel ratio:

Preclinical animal model at 180 days

A link between stent radial forces and vascular wall remodeling: The discovery of an optimal stent radial force for minimal vessel restenosis

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ABSTRACT

Coronary and peripheral artery disease (PAD) continue to be primary causes of morbidity and mortality in western nations; percutaneous transluminal angioplasty (PTA) with stenting has become a popular treatment. Unfortunately, restenosis is a significant problem following intravascular stent placement. This study considers the contribution of stent forces in vascular stenosis and remodeling to develop an equation for identifying the optimal stent force. Z-Type stents of three radial forces [low (3.4 N), high (16.4 N), and ultrahigh (19.4 N)] were deployed into the iliac arteries of a juvenile porcine model. Vessel diameters were measured before, after deployment, and again at 30 days. At 30 days animals were killed and the vessels fixed in situ. After implantation, there was a significant increase in total thickness and neointimal hyperplasia with increasing stent force. The model for vessel radius and experimental data was in agreement. The model shows that maximum late-term radius is achieved with a stent deployment stress of 480 kPa, which occurs at the end of the stress-strain curve nonlinear domain and beginning of the high-strain collagen domain. The results and calculations suggest that an optimal stent force exists that is subject to the geometry, structure, and mechanics of the target vessel. To achieve maximum late-term dilatation, stents should not produce stress in the vessel wall greater than the end of the transitional domain of the vessel's stress-strain curve. This finding is extremely important for vascular stent development and will be expanded to preliminary vessel wall injury and atherosclerotic models.

KEYWORDS: restenosis; blood vessel; artery; neointimal hyperplasia; mechanics
Effect of endovascular stent strut geometry on vascular injury, myointimal hyperplasia, and restenosis

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Purpose: Early restenosis and the development of myointimal hyperplasia in stented blood vessels have been attributed to deep vascular injury with fracture of the internal elastic lamina (IEL). The purpose of this study was the evaluation of the vascular wall response to superficial injury (without IEL rupture) after balloon angioplasty and intravascular stent placement in porcine arteries and the determination of the effect of stent strut geometry on the degree of vessel injury and early restenosis.

Methods: Balloon-expandable stainless-steel stents were placed into the iliac arteries of 10 Sinclair miniature swine that had been fed an atherogenic diet. A Palmaz stent, with rectangular struts and smooth corners, was randomly assigned to one iliac artery (group 1), and a novel stent, which was designed and manufactured in the laboratory with thicker struts and sharper corners specifically to induce large wall stress concentrations, was placed in the contralateral iliac artery (group 2). Intravascular ultrasound scan was used in all deployments to ensure accurate balloon sizing and to avoid stent overexpansion and deep vascular injury. At 90 days after implantation, the animals were killed, the stented vessels harvested, and histomorphometric analysis performed.

Results: Deployment of novel stents in group 2 resulted in a statistically higher incidence rate of deep vascular injury (fracture of the IEL) compared with group 1, despite identical balloon size used for deployment (with Student t test, P < .05). Vessels with deep injury showed a 10-fold increase in myointimal thickening compared with those vessels in which the IEL remained intact. A statistically higher restenosis rate was observed for group 2 (33.5% ± 19.90%) compared with group 1 (20.39% ± 14.70%). For both stent designs, there was a trend toward lower degrees of restenosis within the mid-portion of the stent. For superficially injured arteries in both groups, no correlation was observed between the amount of vessel wall/medial layer compression and the development of restenosis from myointimal hyperplasia.

Conclusion: Maintenance of an intact IEL is an important factor in the prevention of myointimal hyperplasia and restenosis in stented porcine iliac arteries. The alteration of stent strut height and geometry does not significantly affect restenosis and the development of myointimal hyperplasia in vessels with superficial injury. Superficial injury elicits a response that is independent of stent strut geometry and vessel wall compression. Stent strut profile may, however, increase local vessel wall stress concentrations, leading to IEL rupture and an exaggerated response to injury. (J Vasc Surg 2002;36:143-9.)
Limitations of Standard Nitinol Stents (SNS)
Fractures – especially in Proximal Popliteal Artery

In a single center study evaluating stent fracture in 93 patients, Scheinert et al. found that stent fracture was associated with reduced patency with the following stents: S.M.A.R.T.®, SelfX and Luminexx™.

Images courtesy of Prof. Dr. Dierk Scheinert.
- **Lumen**
  - Basement membranes: type IV collagen, laminin, heparan sulphate proteoglycans
  - Endothelial cells

- **Intima**
  - Proteoglycan rich matrix

- **Media**
  - Interstitial matrix: type I, III collagen, fibronectin, dermatan/ chondroitin sulphate proteoglycans
  - Elastic laminae
LUMEN

Basement membranes: type IV collagen, laminin, heparan sulphate proteoglycans

INTIMA

Proteoglycan rich matrix

MEDIA

Interstitial matrix: type I, III collagen, fibronectin, dermatan/ chondroitin sulphate proteoglycans

Endothelial cells

Smooth muscle cells (SMC)

elastic laminae
Migration + proliferation is a multistep process
Quiescent
“contractile”

TRAUMA / INFLAMMATION

Active
“synthetic”

Growth Factors (PDGF)

The extracellular matrix

Proteinases

Integrins

Intracellular Signal Transduction
The Supera® implant mimics the natural structure and movement of the anatomy\textsuperscript{1,2}

- An innovative, interwoven nitinol design creates an implant that supports rather than resists the vessel
- Resists kinking and fracture with minimal chronic outward force\textsuperscript{3}
- Supports the natural movement of the vessel for high patency rates\textsuperscript{1}

Angio image courtesy of Dr. Hans Biemans, Rivas Hospital Gorinchem, the Netherlands.

\textsuperscript{1} Scheinert, et al., Real world perspectives of treating complex SFA-Pop lesions, Results from the SUPERA-500 Registry, LINC 2013.
\textsuperscript{3} Data on file at Abbott Vascular.
Supera® is a New Class of SFA Technology

Unlike Standard Nitinol Stents (SNS), Supera’s Vascular Mimetic Technology offers unparalleled strength and flexibility.

1. Flexibility is defined as kink resistance. Supera® implant demonstrated lowest kink resistance for 5.5 and 6.5 x 100 mm implants as compared to 6 x 100 mm standard nitinol stents in a tube. Data on file at Abbott Vascular.

Angio photos courtesy of Dr. Dierk Schienert (top row) and SUPERB study (bottom row). IVUS images courtesy of Dr. Dierk Scheinert and Dr. Frank Arena. Kink photos on file at Abbott Vascular.
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Chronic Outward Force (CoF) is exerted on vessel by self-expanding stents due to inherent oversizing.


SNS Oversizing 1.1-1.3 : 1
SNS Oversizing 1.6-1.9 : 1

Stent Struts (initially deployed)
Stent Struts (nominal diameter)
Stent Chronic Outward Force* (CoF)
Recoil Force (vessel wall)
Vessel Wall

COF, chronic outward force; SES, self-expanding stent. Illustrations are artist’s renditions. Not drawn to scale.
Chronic Outward Force (CoF) is exerted on vessel by self-expanding stents due to inherent oversizing


**COF, chronic outward force; SES, self-expanding stent. Illustrations are artist’s renditions. Not drawn to scale.**

COF, chronic outward force; SES, self-expanding stent.
PSVR 2.0
PSVR 2.5
PSVR 3.5

Treat

Obs

See Important Safety Information Referenced Within.
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### 12-Month Primary Patency (K-M) for SFA Endovascular Therapies

The image displays a bar chart comparing the 12-month primary patency rates (Kaplan-Meier method) for different stent and intervention therapies used in various clinical trials. The therapies listed include Supera®, Zilver® PTX®, Standard Nitinol Stents, Viabahn®, Atherectomy, and others. The bars represent the proportion of patients remaining free from target lesion revascularization (TLR) at 12 months.

#### Key Details:
- **Supera®**: 0.86
- **Zilver® PTX®**: 0.83
- **Standard Nitinol Stents**: 0.82
- **Viabahn®**: 0.77
- **Atherectomy**: 0.66
- **DCB (Drug-Eluting Balloon)**: 0.54

The chart also shows the number of patients (n) and the mean lesion length (cm) across different studies. The PSVR (Proximal Stenosis Severity Rate) values are listed for various studies.

Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.

See appendix for sources.

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**Important Safety Information**
- Referenced within: [Abbott Vascular]
Preliminary results of the initial United States experience with the Supera woven nitinol stent in the popliteal artery.


Abstract

BACKGROUND: Popliteal artery stenting is not routinely performed due to concerns related to the high mobility of the knee joint and the potential for external stent compression, fractures, and occlusion. Open bypass is traditionally considered the gold standard for popliteal artery atherosclerotic lesions. The Supera stent (IDEV Technologies Inc, Webster, Tex) was developed to provide superior radial strength, fracture resistance, and flexibility compared with laser-cut nitinol stents. This study represents the initial United States experience in the management of popliteal artery atherosclerotic disease with the Supera interwoven wire stent.

METHODS: Patients undergoing stent implantation in the 20-month period after the 2008 Food and Drug Administration clearance were included. Medical records, radiographic imaging, and procedural data were examined. Procedural angiograms were classified according to Trans-Atlantic Inter-Society Consensus criteria. Patency and limb loss rates were calculated using Kaplan-Meier analysis.

RESULTS: A total of 39 stents were placed in 34 patients due to isolated popliteal artery occlusive disease. Clinical follow-up was a mean of 12.7 months (range, 0.2-33.7 months), and radiologic follow-up was a mean of 8.4 months (range, 0-26.8 months). Most patients had critical limb ischemia (CLI), with tissue loss (38.2%) or rest pain (35.3%) as the indication for intervention. In 20 patients (58.8%), the most distal end of the stent(s) landed in the below-the-knee popliteal segment, 12 (35.3%) landed in the above-the-knee segment, and two (5.9%) landed precisely at the knee. Other than angioplasty and stenting, 47% of patients did not receive any adjuvant concomitant therapy in the treated leg. Two patients underwent concomitant atherectomy of the popliteal segment. Primary, primary assisted, and secondary patency rates by duplex ultrasound imaging were 79.2%, 88.1% and 93%, respectively, by Kaplan-Meier estimates, with a mean stented length of 12 cm. Six instances of stent occlusion were noted, and six patients were identified with hemodynamically significant in-stent stenosis. Three patients sustained limb loss (8.8%), two related to uncontrolled infections, and one due to periprocedural ischemic complications (both with patent stents at the time of limb loss). The overall mortality was 8.8% during the study period. Knee roentgenography was performed in all but one patient, and no stent fractures were identified.

CONCLUSIONS: Stenting of the popliteal artery using the Supera stent system appears to be safe and effective. The interwoven stent design may better serve areas under extreme mechanical stress. Our results with this highly diseased patient population justify a prospective trial in this subject.

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