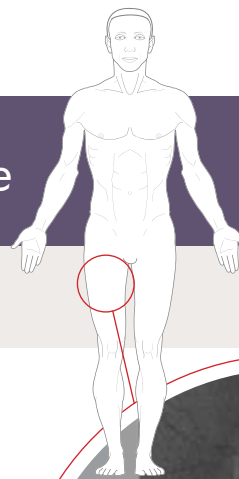


SUPERA® SFA Treatment in Limb Salvage

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Patient Overview

68 year old man ex-smoker with IDDM, diabetic neuropathy, hypertension and hypercholesterolemia, kidney transplant 5 years ago, coronary heart disease, and severe PAD of the lower extremities. Thrombendarterectomy of the right CFA with patch profundaplasty and intraoperative balloon angioplasty of stenosis of the SFA and popliteal artery occlusion 6 years ago. Developed heavy calcified restenosis of the SFA and popliteal artery 4 years ago, treated by balloon angioplasty and standard nitinol stents (SNS).

Presents with resting ischemic pain and non-healing ulcer of DIG II of the right foot. Angiography reveals a severely diseased SFA with stent thrombosis and SNS fracture due to compression of highly calcified plaque.

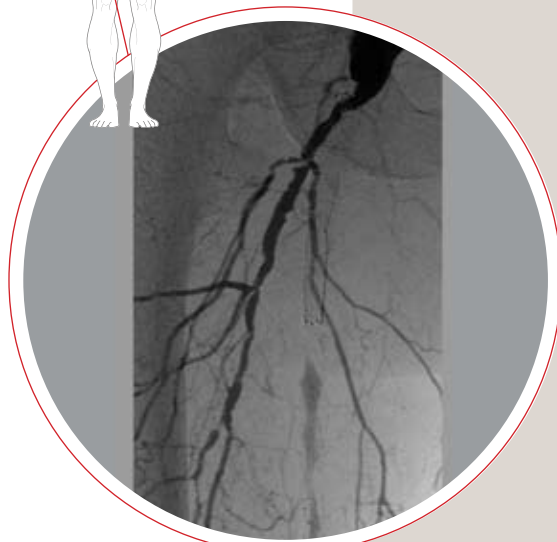
Keys to Success

- The SUPERA stent is best deployed in a fully expanded artery.
- This applies also for treatment of a SNS fracture by the SUPERA stent.
- Pre-dilate the fractured stent to nominal size, for example with a focal force angioplasty balloon.
- Avoid stent stretching during deployment and try to tighten the struts in the fractured area to increase radial strength.
- It is imperative to use 1:1 sizing of the OD of the SUPERA stent to the ID of the fractured stent.

Potential Treatment Strategy

Treatment of the SFA was indicated for limb salvage.

Therapeutic options were to implant an iliaco-popliteal cross-over bypass (to not threaten the ipsilateral kidney transplant and avoid surgical access in the pre-operated area after common femoral thrombendarterectomy) in a patient at higher risk for perioperative mortality OR proceed to balloon angioplasty and stent-in-stent implantation under local anesthesia.



Pre



Pre

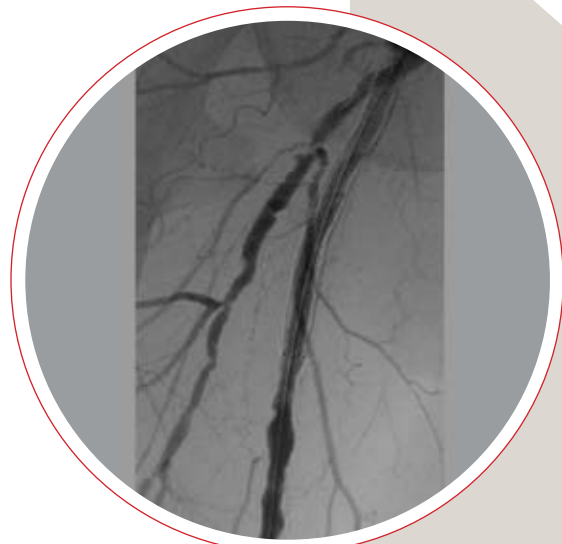


SUPERA
stent in a
fractured
SNS

Post

Procedural Steps

- Retrograde ipsilateral popliteal cut down, ready for access via arteriotomy to place the stent exactly at the SFA origin, ready for end-to-side anastomosis in case of endovascular failure.
- This hybrid intervention allows the possibility to perform a bypass operation in the same session if the endovascular procedure failed.
- Introduction of 7 Fr sheath in the popliteal artery.
- SFA occlusion and stent fracture crossed using a hydrophilic 0.035" guidewire in wire loop technique, keeping the wire inside the lumen and avoiding the wire passing through the ruptured SNS struts.
- 4 Fr support catheter was advanced and the hydrophilic wire exchanged for a stiff 0.035" wire.
- Occluded stent dilated with a 6 mm x 60 mm high pressure balloon.
- Exchanged to a 0.018" guidewire and deployed a 5 mm x 40 mm SUPERA stent in the fractured SNS, keeping the proximal stent edge just above the CFA.
- Post-dilated the stent with a 5 mm balloon.
- SFA was dilated with a 5 mm x 120 mm balloon.



Post

Discussion of Results

Stent fracture is an occasional complication of SNS, especially in highly calcified vessels, sometimes causing stent thrombosis and reocclusion of treated vessels. Stent fracture is usually an indication for a bypass operation. This patient was a poor bypass candidate due to a highly calcified popliteal artery with hostile anatomy, single vessel run-off, and multiple co-morbidities.

Endovascular treatment of stent fracture is challenging. Atherectomy devices involve the danger of further stent destruction, and our experience with stent-in-stent implantation with SNS is not good. Treating stent fracture combined with highly calcified plaque requires a stent with high radial strength.

The interwoven design of the SUPERA stent makes stent fracture unlikely. Its radial strength is unique and it provides unmatched flexibility in the presence of physical deformation.

The successful treatment of stent fracture using the SUPERA stent avoided a cross-over bypass with potentially poor outcome or major amputation. At follow-up the patient had immediate relief of foot pain and a healed ulcer.



Post

Conclusion

The SUPERA stent opens new possibilities in the treatment of heavily calcified or very tortuous vessels and in the treatment of standard nitinol stent fractures. The interwoven design offers unrivaled tolerance to extreme distortions or compression and the radial strength of the SUPERA is unmatched. Since SUPERA is highly resistant to fractures it has been used successfully behind the knee.



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INDICATIONS FOR USE: The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent System is indicated for palliative treatment of biliary strictures produced by malignant neoplasms and peripheral vascular use following failed percutaneous transluminal angioplasty (PTA). **WARNINGS:** DO NOT resterilize or reuse this device. For single use only. Sterilized with ethylene oxide gas. DO NOT use the device if the device or the device package is open or damaged. Use this device prior to the "use-before" ("expiration") date as specified on the device package label. DO NOT expose the device to organic solvents. DO NOT use with Ethiodol or Lipiodol contrast media. This device is not designed for use with contrast media or power injection systems. DO NOT oversize stent. Size stent to vessel reference diameter. Refer to Section 3b under Preparation Procedures of the "Instructions for Use". Flush the device prior to use. Never advance the device without the guidewire extending from the tip. The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent System is not designed for repositioning or recapturing. Implantation of the SUPERA® Interwoven Self-Expanding Nitinol Stent should be performed only under fluoroscopic observation with radiographic equipment providing high-resolution images. This device is intended for use by physicians that have received appropriate training. Use caution when crossing a partially or fully deployed stent with adjunct devices. When multiple stents are used, they should be of similar composition. Long term outcomes following repeat dilatation of endothelialized stents are unknown. **CAUTION:** This device is not yet approved by the FDA for distribution in the United States for peripheral vascular disease. ©IDEV Technologies, Inc. All rights reserved. MKT00104 (03/30/11)

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