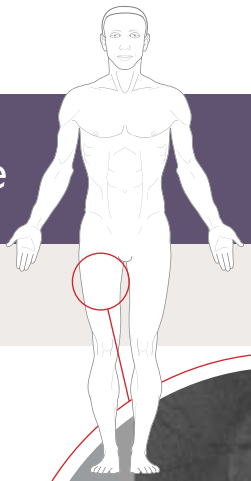
SUPERA® SFA Treatment in Limb Salvage



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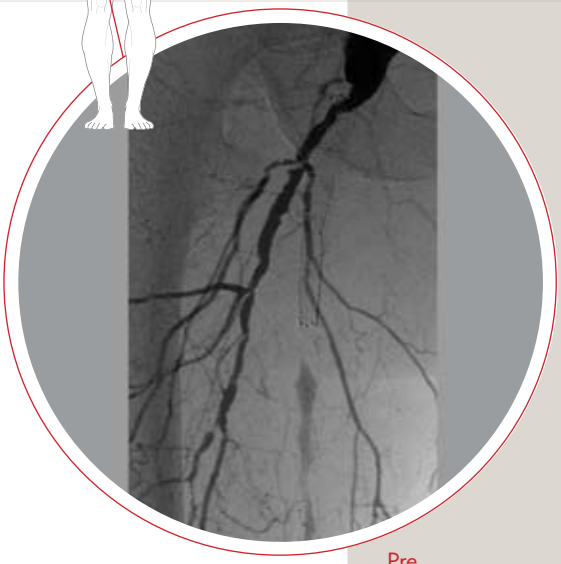
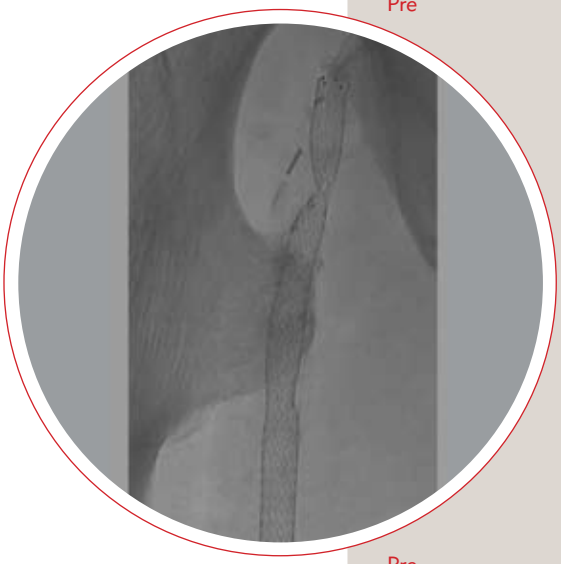
Patient Overview

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.



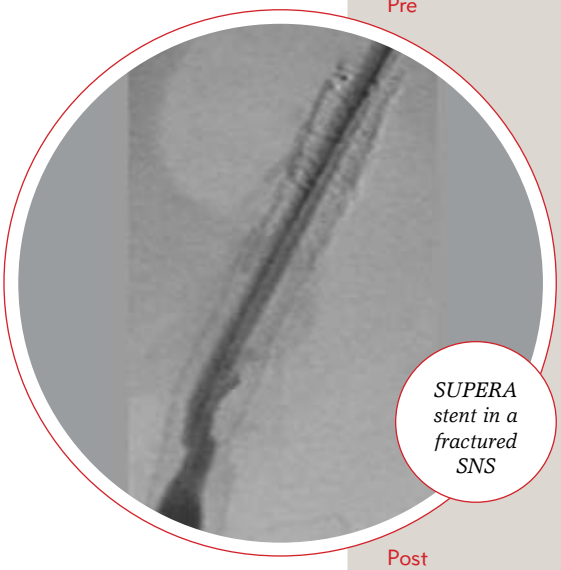
Pre



Pre

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 use1:1 sizing of the OD of the SUPERA stent to the ID of the fractured stent.*



SUPERA stent in a fractured SNS

Post

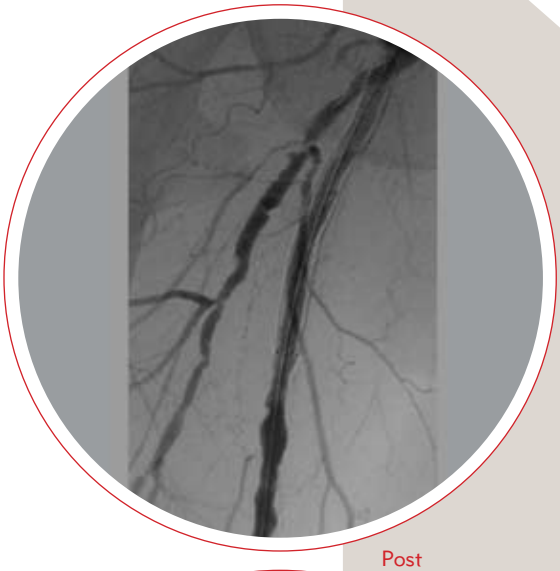
Potential Treatment Strategy

Treatment of the SFA was indicated for limb salvage.

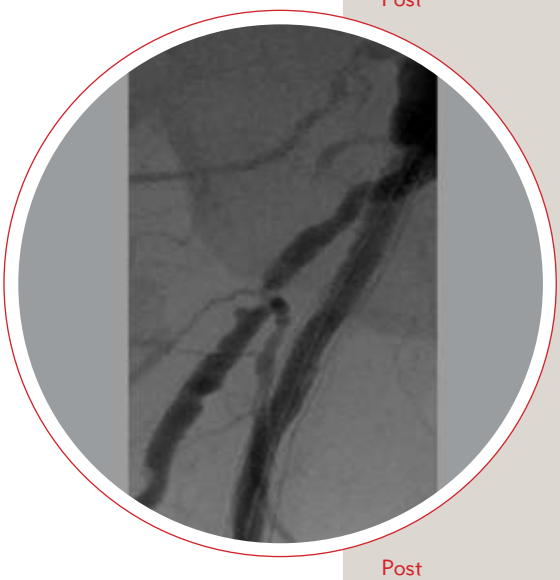
Therapeutic options were to implant an iliaco-popliteal cross-over bypass (to not threaten the ipsilateral kidney transplant and avoid surgical access in the pre-operated area after common femoral thrombendarterectomy) in a patient at higher risk for perioperative mortality OR proceed to balloon angioplasty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

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



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.

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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