

30-Month Follow-Up Post Spur® RST with DCB in a BTK CLTI Patient

CASE HISTORY

A 74 year-old male, with a past medical history of Type II Diabetes Mellitus, hypertension, and above-the-ankle amputation of the right leg, presented with a non-healing ulcer on the plantar side of the left first toe, (Figure 1) Rutherford class 5. Baseline Ankle Brachial Index (ABI) and Tibial Brachial Index (TBI) were 1.53 and 0.54 respectively. A duplex ultrasound showed absence of inflow disease without significant lesions in the iliac-femoral-popliteal segment, and a high-grade stenosis of the tibioperoneal (TP) trunk of the left leg. An occlusion of the anterior (AT) and posterior tibial (PT) arteries was suspected. The patient provided informed consent to participate in the DEEPER OUS trial.



Figure 1

PROCEDURE

Angiography confirmed that the superficial femoral and popliteal artery were patent. The TP trunk showed mild calcification (PARC grade 1), with a 40 mm high-grade stenosis, TASC D (Figure 2). There was an occlusion of the posterior tibial artery and a

patent peroneal artery with filling of a well-developed collateral network to the foot (Figure 3). The decision was made to recanalize the single vessel to increase flow to the foot. A 0.014" guidewire was used to cross the stenosis in the TP trunk.

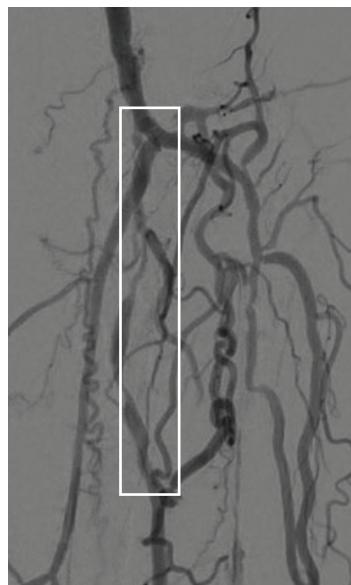


Figure 2

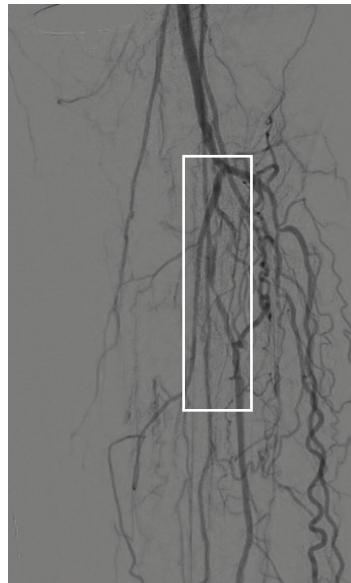


Figure 3

PHYSICIAN



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"The long-term results of Spur with DCB in a complex patient were impressive."

Dr. van den Berg is an internationally respected interventional radiologist and academic leader with over 30 years of clinical and research experience. He currently serves as Associate Professor of Radiology at the University of Bern in Switzerland and is an interventional radiologist at Clinica Luganese Moncucco in Lugano. He is a reviewer and member of the editorial boards of a number of scientific journals; a member of the writing committee of the ESVS guidelines; Vice Chairman for Interdisciplinary Affairs for the Aortic Society, and a CLI Global Society board member, and most recently was named Editor-in-Chief of the official journal of the CLI Global Society, the *Journal of Critical Limb Ischemia*.

PRODUCTS USED



PERIPHERAL RETRIEVABLE SCAFFOLD SYSTEM

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Following successful crossing, predilatation was performed with a 2.0x40 mm balloon (post predilatation Figure 4), followed by treatment with a 3x65 mm Spur Peripheral Retrievable Scaffold System (Figure 5). Result post Spur (Figure 6). Following the Spur, a 3x80 mm Philips Stellarex™ DCB (Figure 7) was deployed across the treated segment, with residual stenosis of <10% and brisk flow to the foot (Figure 8). With no targets for treatment in the anterior or posterior tibial arteries, the procedure was completed without complications.

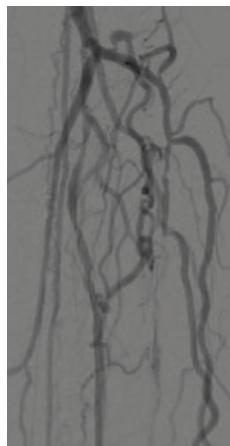


Figure 4



Figure 5

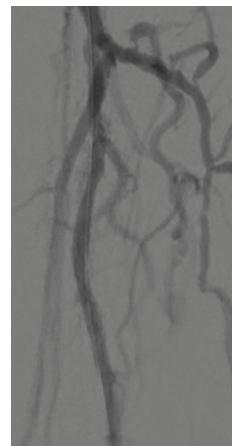


Figure 6



Figure 7

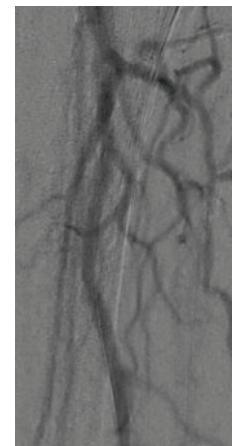


Figure 8

12-MONTH RESULTS

The ulcer healed within 6 months (Figure 9) but recurred after 12 months. Angiography demonstrated patency of the Spur-treated TP trunk (Figure 10), with improved flow through the dorsalis pedis. It was recanalized for treatment (not pictured) with balloon angioplasty (at the time of the procedure the Spur was not yet commercially available) of the anterior tibial artery, with good wound healing.

30-MONTH RESULTS

The ulcer reoccurred at 30 months, likely due in part to continuous pressure with ambulation on the subject's solitary foot. Angiography showed re-occlusion of the AT. However, the Spur-treated TP trunk (Figure 11) remained patent. The AT artery was again recanalized to improve blood flow.



Figure 9



Figure 10

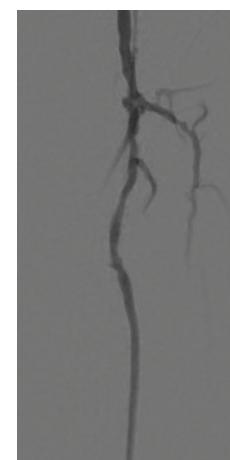


Figure 11

CASE CONCLUSION

The Spur-treated TP trunk remained patent throughout 30 months. The long-term results of treatment with Spur RST in conjunction with a DCB in this complex case were impressive, and instrumental in the preservation of the patient's only limb.