

BTK PAD Treatment with the Spur[®] Stent System

CASE HISTORY

A man in his early 80s with a history of congestive heart failure, type 2 diabetes, hypertension, and high cholesterol presented for evaluation of rest pain in the left lower extremity. There were no wounds present. His initial ankle brachial index (ABI) was abnormal at 1.73; toe brachial index (TBI) was 0.19. He was classified as Rutherford class 4 and enrolled in the DEEPER REVEAL trial.

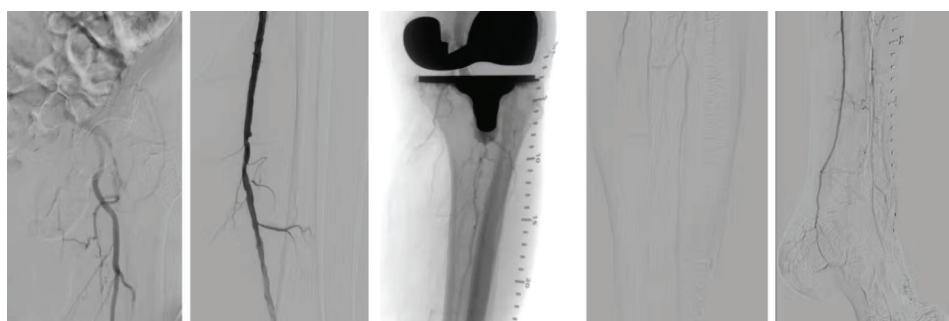


Figure 1

Baseline imaging of the affected lower extremity showed mild-to-moderate disease in the superficial femoral artery (SFA) and popliteal region. Runoff to the foot was supplied by a patent anterior tibial (AT) and posterior tibial artery. Severe disease was observed in the tibioperoneal trunk (TPT) and peroneal artery (Figure 1). The lesion in the TPT and peroneal artery measured 4 mm in diameter and 60 mm in length. Visual estimate by the physician suggested an initial stenosis of 91% to 99%. The core lab adjudicated the stenosis as 80% (Figure 2).

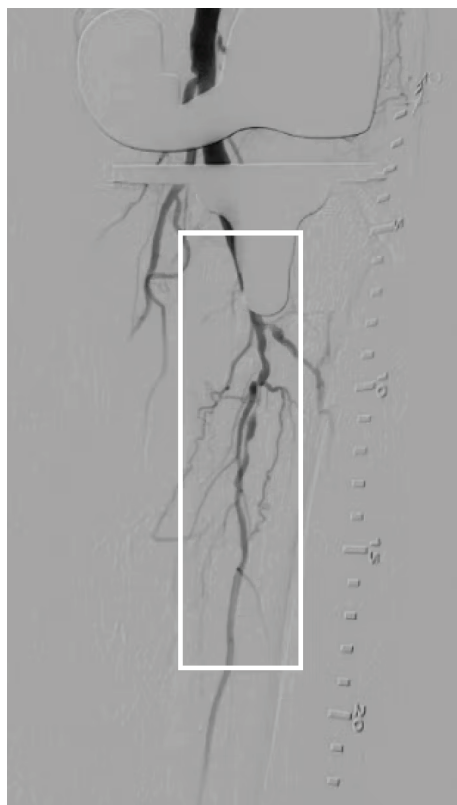


Figure 2

PHYSICIAN



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"I've used Spur RST in challenging real-world lesions with great early outcomes, and I'm excited to see how these patients fare in longer-term follow-up."

Michael Siah, MD earned his medical degree at the John A. Burns School of Medicine, University of Hawai'i, and completed a residency in vascular surgery at MedStar Georgetown University Hospital in Washington, DC. He joined the UT Southwestern Medical Center faculty in 2019.

Dr. Siah is a member of the Eastern Vascular Society, the Society for Vascular Surgery, and the American College of Surgeons. He has delivered a number of presentations and published several academic articles and book chapters.

PRODUCTS USED



PERIPHERAL RETRIEVABLE STENT SYSTEM

BTK PAD Treatment with the Spur Stent System

PROCEDURE

Per the DEEPER REVEAL trial protocol, all inflow lesions were treated prior to treatment of the target lesion. A significant lesion in the proximal SFA was successfully treated with the Shockwave IVL balloon (Shockwave Medical) and balloon angioplasty.

Over a 0.014 inch Spartacore™ wire (Abbott), predilatation of the 60 mm lesion was performed with a 2.5 × 40 mm Coyote™ balloon (Boston Scientific Corporation) from ruler markers 14 distal to 8 proximal. Figure 3 shows the index lesion and Figure 4 the angiographic result after predilatation.

Using the 2-3-1 deployment protocol* for the DEEPER REVEAL trial, a 4.0 × 60 mm Spur Stent was deployed from 14 distal to 7 proximal on the radiographic ruler (Figure 5).

Only one deployment cycle was needed to cover the 60 mm lesion in the TPT and peroneal artery.

Final imaging showed improved flow to the distal extremity (Figure 6). No complications were noted during the procedure.

CASE CONCLUSION

At 12-month follow-up, the lesion remained patent by duplex ultrasound.

Although the ABI was unattainable at the time, the TBI value increased from 0.19 at baseline to 0.7. The patient improved from severe PAD to mild PAD based on this metric.

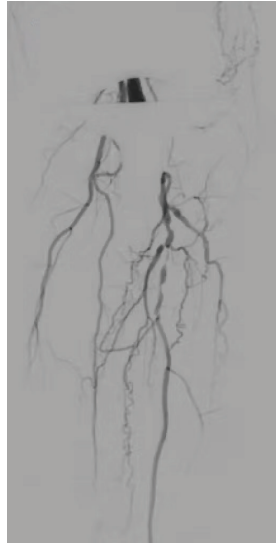


Figure 3

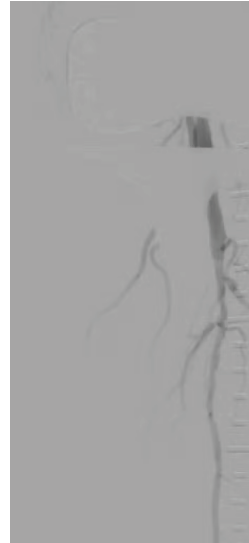


Figure 4



Figure 5

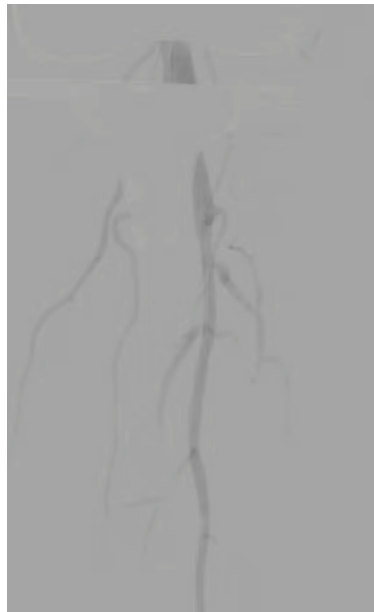


Figure 6

*After deploying the Spur Stent, inflate integrated balloon for 2 minutes, deflate and hold 3 minutes, inflate for 1 minute.