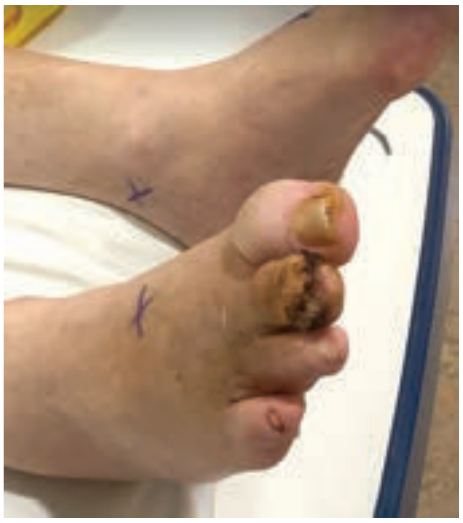
REFLOW MEDICAL
THE PULSE OF MEDICAL INGENUITY

Spur® Stent System Deployed in Tibial and Peroneal Arteries

CASE HISTORY

A 74-year-old male with a history of coronary artery disease, Type II diabetes, chronic kidney disease, hypertension and Rutherford Class 5 peripheral arterial disease (PAD) of the right lower extremity. The patient presented with a non-healing partial amputation surgical wound of the second toe. Pre-procedure Ankle Brachial Index (ABI) 0.84 and 0.61 Tibial Ankle Index (TBI). At enrollment, medications included aspirin, Clopidogrel and a statin.



Pre-procedure

PROCEDURE

Initial angiography (fig. 1) showed patent superficial femoral artery (SFA) and popliteal artery. Below-the-knee (BTK) disease (fig. 2) was noted in the tibial vessels with an occluded segment of the peroneal artery and occluded posterior tibial artery.

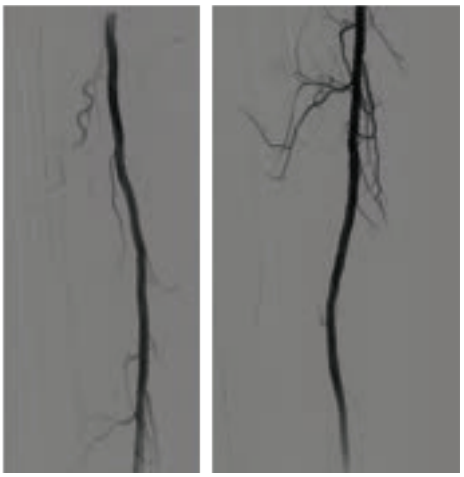


Figure 1. Above-the-knee baseline

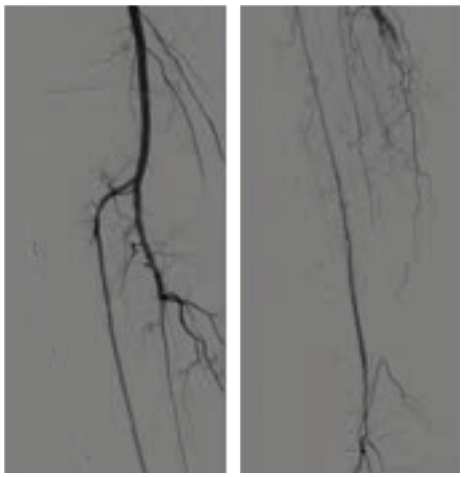


Figure 2. Below-the-knee baseline

PHYSICIAN

Kevin Herman, MD

Vascular and Interventional Radiologist, Premier Endovascular and Holy Name Medical Center

"Successful retrievable stent therapy minus the long-term risk of a stent implant."

Dr. Herman earned his medical degree from Rutgers Medical School; completed his medical internship at Staten Island University Hospital; his diagnostic radiology residency at Saint Barnabas Medical Center, and his interventional radiology fellowship at Montefiore Medical Center, Albert Einstein College of Medicine.

Dr. Herman is board certified in radiology and holds two patents on interventional radiology devices. He is a member of the Society of Interventional Radiology and the CLI Global Society (Communications Committee Chair).

PRODUCTS USED

REFLOW spur®

PERIPHERAL RETRIEVABLE STENT SYSTEM

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The target lesion (fig. 3) in the right peroneal artery was 100 mm in length with 3.0 mm reference vessel diameter (RVD); classification TASC D, and 100% pre-stenosis. Lesion pre-dilatation was performed with a 3 mm x 100 mm balloon with <50% residual stenosis (fig. 4 & 5).

A 3.0 mm x 65 mm Spur Peripheral Retrievable Stent System was used to treat 100 mm length in two cycles: first Spur deployed (fig. 6) followed by integrated balloon inflation (fig. 7) for 2 minutes, deflated and 2 minutes dwell time, and reinflated for 1 minute. Spur deployed (fig. 8) and integrated balloon inflation repeated (fig. 9) for 2 minutes; deflated, 2 minutes dwell time, and reinflated for 1 minute. Inflation/deflation steps per clinical protocol.

Figure 3

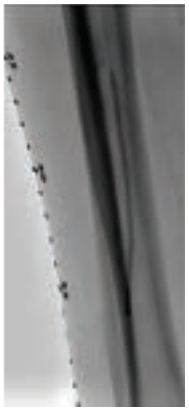


Figure 4

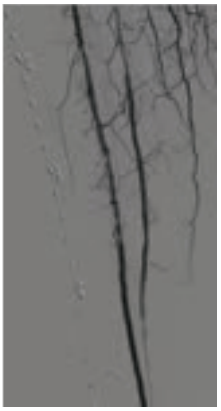


Figure 5

Figure 6

Figure 7

Figure 8

Figure 9

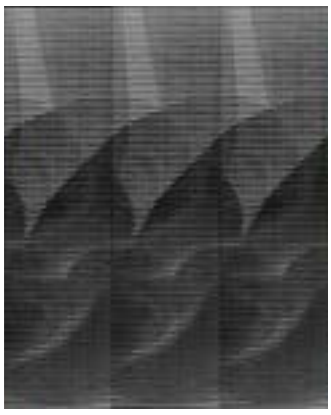
Final results included some spasm in the distal peroneal (fig. 10) and residual stenosis of <30%. No post-dilatation and no post-procedural complications (fig. 11).

CASE CONCLUSION

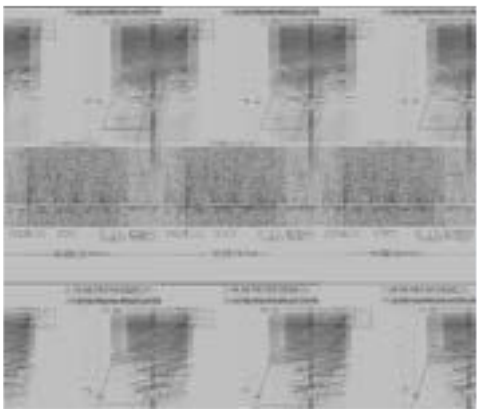
The target lesion remained patent through 12-month follow up on duplex ultrasound with multiphasic flow. ABI improved at one month and remained within normal limits through 12 months. Patient underwent additional partial toe amputation with complete wound healing at 3 months and remained asymptomatic through 12-month follow up.

Figure 10

Figure 11



12 months post-procedure



12 months post-procedure