

A Case Study in CLTI with Spur™ RST (Retrievable Scaffold Therapy)

CASE HISTORY

A man in his late 70s presented to our institution with a nonhealing wound after undergoing amputation of the right big toe months previously (fig. 1). In addition to peripheral artery disease, the patient's history was significant for diabetes mellitus; diabetic foot ulcers; a previous amputation of the first, second, and third right toes; chronic atrial flutter; and arterial hypertension. His ankle-brachial index (ABI) at initial presentation was 0.72, and initial duplex ultrasound revealed a suspected crosssectional occlusion of the BTK vessels.



Figure 1. Baseline image of the nonhealing wound on the right foot.

PHYSICIAN



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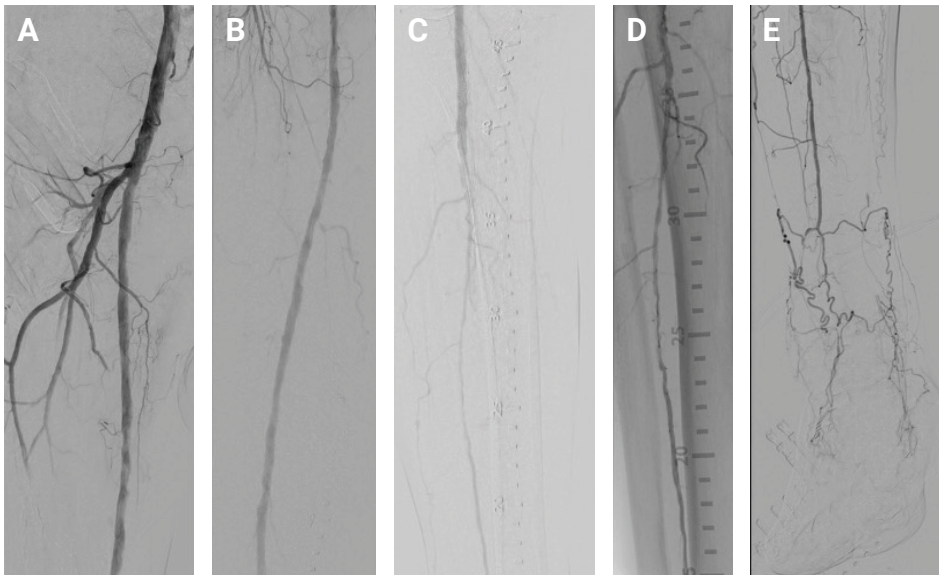


Figure 2. Angiograms of the femoropopliteal vessels (A, B) and PT and proximal peroneal arteries (C, D). Good collateral supply to the foot in the peroneal artery (E).

PROCEDURAL OVERVIEW

Angiographic imaging showed patent femoropopliteal vessels (fig. 2A and 2B). The anterior tibial (AT) and posterior tibial (PT) arteries were completely occluded, and the proximal peroneal artery was highly stenosed over a distance of almost 12cm (fig. 2C and 2D). The peroneal artery showed a very good collateral supply to the foot (fig. 2E), so the decision was made to recanalize this artery. After crossing the lesion with a 0.014" guidewire, predilation was performed with a 2.5 X 120mm balloon (fig. 3A). The lesion was then treated twice with the same 3 X 60mm Spur™ device (fig. 3B-3E). After subsequent dilatation with a 3- X 150-mm Luminor® paclitaxel-coated balloon (iVascular), the result was very satisfactory (fig. 4A and 4B), with good outflow into the foot (fig. 4C).

PRODUCTS USED



REFLOW
spur™

PERIPHERAL RETRIEVABLE SCAFFOLD SYSTEM

Successful CLTI treatment result with Spur RST

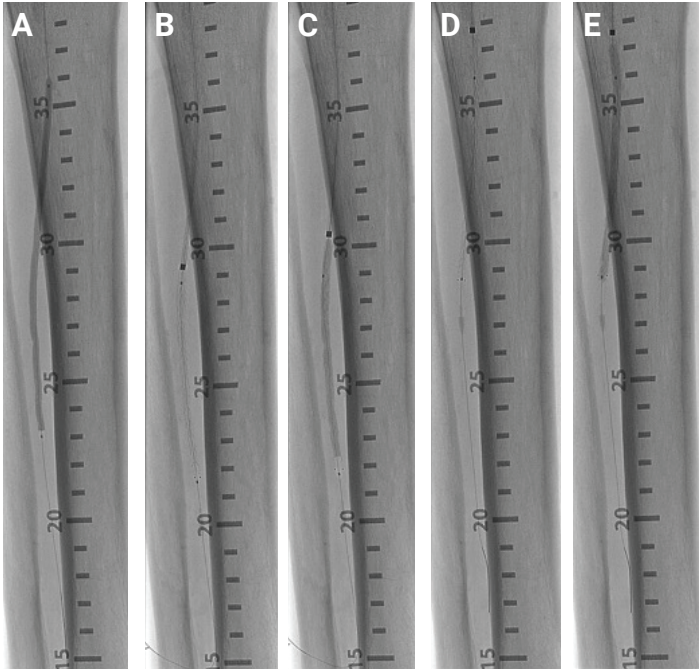


Figure 3. Angiograms showing predilation of the peroneal artery lesion (A), as well as the lesion with the native Spur RST (B, D) and with the inflated balloon (C, E).

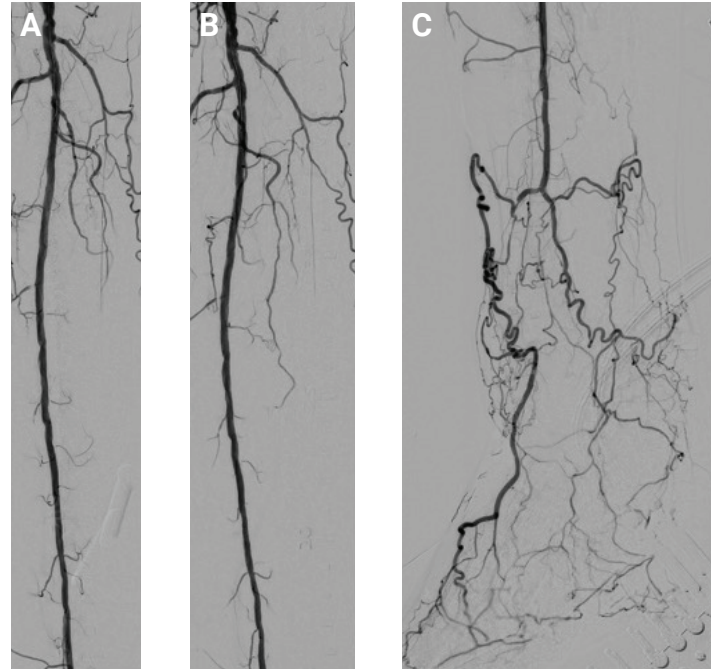


Figure 4. Angiograms after Spur RST (A) and after paclitaxel balloon (B), showing good outflow into the foot (C).

DISCUSSION

Alternatively, treatment with plain old balloon angioplasty (POBA) could have been considered in this case; however, high restenosis rates are associated with this therapy. The lesion length was slightly too long for implantation of DES, and there is still limited evidence for use of DCBs in BTK vessels. In our view, because the patient was included in the DEEPER OUS (NCT NCT03807531) study, we were able to offer a treatment strategy of optimal lesion preparation with Spur prior to DCB application. Good wound healing was already evident at 1-month follow-up (fig.5), and the wound was classified as healed at 6-month follow-up. Postintervention, the ABI had improved to 0.92, and this was maintained at subsequent follow-up visits. Duplex ultrasound showed the vessel to be patent at 12-month followup. To date, no further interventions on the right leg have been necessary, and the patient is independent of external help.



Figure 5. Wound healing progress seen at 1-month follow-up.