

# Dedicated BTK Balloons

Case reports on a new 0.018-inch platform.

BY MARCO MANZI, MD

Chronic critical limb ischemia (CLI) is a major worldwide cause of morbidity and, especially when threatening the limb, mortality.<sup>1</sup> Major and minor unplanned amputations are associated with significant increases in mortality risk, and every effort should be pursued to minimize amputations and ensure limb salvage.<sup>2</sup> Infragenicular atherosclerotic disease is the most common cause of CLI, and despite the benefits of pharmacologic therapy (eg, angiotensin-converting enzyme inhibitors, antidiabetic drugs, antiplatelet agents, and statins), arterial revascularization remains a mainstay in the management of CLI.<sup>3</sup> Surgical revascularization is recommended in most patients with CLI due to extensive infrapopliteal (ie, below-the-knee [BTK]) atherosclerotic disease,<sup>2</sup> but recent data also support the role of percutaneous transluminal angioplasty (PTA) in this setting,<sup>4</sup> especially when performed with dedicated wires and balloon catheters.

Nonetheless, vascular surgery is not always feasible or recommended because of high surgical risk, lack of venous conduits, or poor vessel runoff, and the procedural success rates of PTA remain suboptimal with current techniques. This is particularly true when atherosclerotic disease also involves the distal tibial arteries or the foot vessels, despite employing aggressive approaches such as subintimal, retrograde, subintimal arterial flossing with antegrade-retrograde intervention, or transcollateral techniques.

The SABER™ PTA dilatation catheter (Cordis Corporation) ranges in diameter from 2 to 10 mm and in length from 20 to 300 mm. It is designed for



Figure 1. The patient's foot at admission.

increased crossability, power, and control. In this article, we report our initial experience with this new balloon now available on the market.

## CASE 1

A 75-year-old man with type 2 diabetes mellitus arrived at our center with a left third toe ulceration that was Texas University class 3C (Figure 1). He had a transcutaneous oxygen tension (TcPO<sub>2</sub>) of 26 mm Hg, and his associated risk factors were dyslipidemia and ischemic heart disease. His serum creatinine was 1.25 mg/dL. According to our protocol, the patient was scheduled for an endovascular recanalization of the left leg before surgical treatment for the foot.



Figure 2. Baseline angiography.

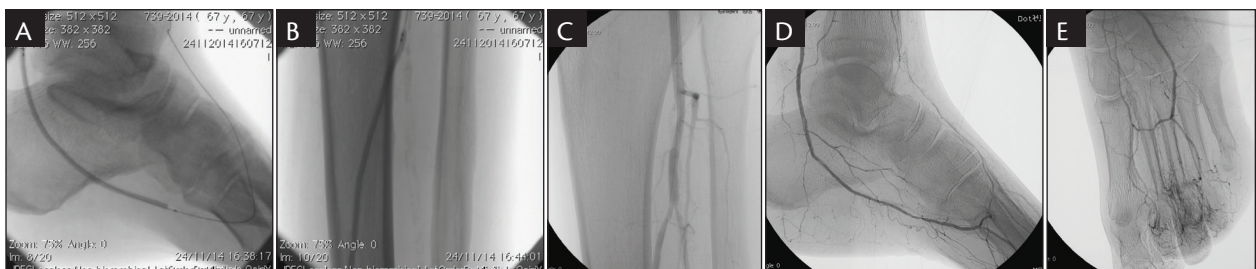


Figure 3. Common plantar, lateral plantar, and PT balloon angioplasty (2.5- X 120-mm SABER™ PTA dilatation catheter) at 8 bar for 2 minutes (A, B). Final acute result (C–E).



Figure 4. The patient's foot after ulcerectomy.



Figure 5. The Case 2 patient's foot at admission.

### Endovascular Treatment

A 6-F, 11-cm Radifocus Introducer II sheath (Terumo Interventional Systems) was deployed in an antegrade fashion under ultrasound (US) guidance in the left common femoral artery, and 5,000 intravenous units of heparin were administered. The baseline angiography (Figure 2) showed a patent superficial femoral-popliteal artery axis while a severe calcified stenosis was represented in the peroneal trunk (PT) and posterior tibial artery ostium. Multiple

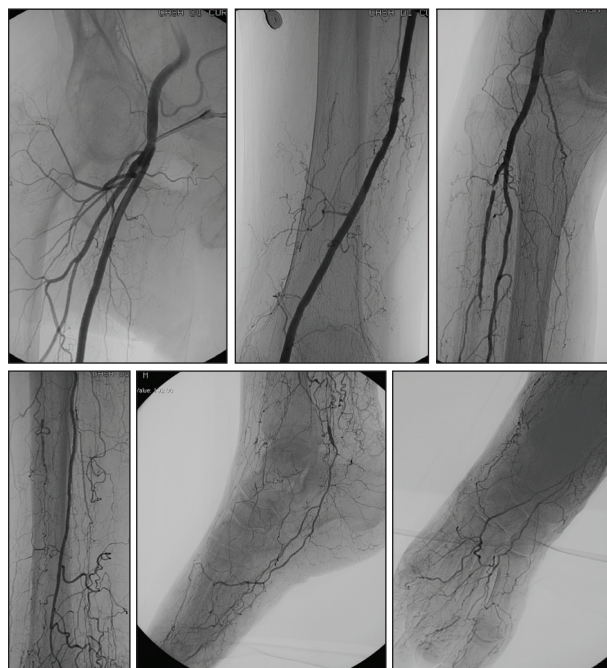


Figure 6. Baseline angiography.

calcified stenoses were recognized in the common plantar and lateral plantar arteries, with a good outflow in the arch and a light "blushing" effect in correspondence with the third toe lesion.

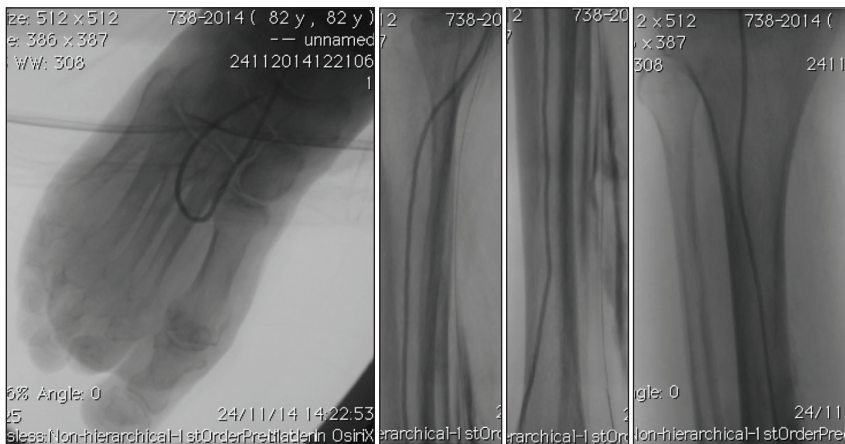
A V-18 ControlWire guidewire (Boston Scientific Corporation) was advanced to the foot and through the arch into the pedal artery to provide improved support, and a 2.5- X 120-mm SABER™ PTA dilatation catheter was directly advanced and inflated in the common and lateral plantar arteries for 2 minutes at 8 bar. After a quick deflation time (5 seconds), the balloon was retrieved and inflated at the PT-posterior tibial ostium level for 2 minutes at 8 bar (Figure 3). Despite the calcification grade, the balloon could be well inflated with a good shape without any residual and persistent indentations due to calcified plaques. The subtracted control angiography showed no dissections, spasms, or distal embolization, with an improved blushing effect in the wounded area.

A 6-F closure device (Angio-Seal, St. Jude Medical, Inc.) was deployed under US guidance, and the next day, an ulcerectomy was performed (Figure 4), and a 3-month regimen of dual-antiplatelet therapy was started (aspirin 125 mg, clopidogrel 75 mg). Clinical control performed on an outpatient basis by podiatric specialists after 10 days was good, with significant TcPO<sub>2</sub> improvement (47 mm Hg).

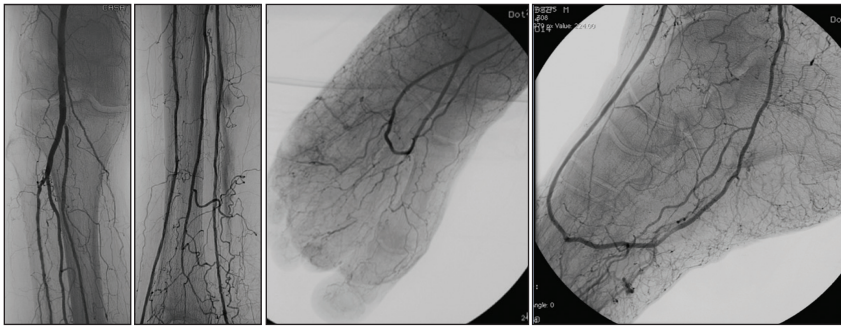
### CASE 2

An 83-year-old man with type 2 diabetes mellitus arrived at our center with right dorsum-lateral fifth toe ulcerations





**Figure 7.** A 2.5- X 300-mm SABER™ PTA dilatation catheter inflated at the arch and tibials level. There was extravasation of the contrast medium due to a fissuration in the posterior tibial artery.



**Figure 8.** Acute angiographic results.



**Figure 9.** The patient's after foot surgery (ulcerectomy and Hyalomatrix grafting)

that were Texas University class 3C. His TcPO<sub>2</sub> measurement was 9 mm Hg (Figure 5), and the associated risk factors were hypertension, dyslipidemia, and previous myocardial infarction. His serum creatinine was 1.31 mg/dL.

## Endovascular Treatment

A 6-F 11-cm Radifocus Introducer II sheath was deployed in an antegrade fashion under US guidance in the left common femoral artery, and 5,000 intravenous units of heparin were administered. Baseline angiography (Figure 6) showed a patent superficial femoral-popliteal artery axis and a severely calcified complete occlusion of high-originating posterior tibial and medium-distal anterior tibial (AT) arteries. Severe stenosis of the proximal AT and occlusion of the pedal artery were represented. A light blushing effect was evidenced in correspondence to the wounded area.

Two V-18 ControlWire guidewires supported by a 40-F Berenstein II Tempo catheter (Cordis Corporation) were subintimally advanced to the foot; proximal arch re-entry was achieved, and the wire was pushed through the arch into the lateral plantar artery to improve support. The purpose of inserting the two wires was to protect the AT and

PT ostiums. A 2.5- X 300-mm SABER™ PTA dilatation catheter was directly advanced and inflated in the arch and AT for 2 minutes at 10 bars first and then in the PT (Figure 7). Despite the calcification grade, the balloon could be well inflated with a good shape, again without any residual indentations due to calcified plaques.

Subtracted control angiography (Figure 8) showed no dissections, spasms, or distal embolization, with an improved blushing effect in the wounded area. A 6-F closure device (Angio-Seal) was deployed under US guidance, and the following day, an ulcerectomy and Hyalomatrix grafting (Anika Therapeutics, Inc.) was performed. A 3-month dual-antiplatelet therapy regimen was started (aspirin 125 mg, clopidogrel 75 mg). The clinical podiatric control after 10 days was good, with a significant improvement in TcPO<sub>2</sub> (51 mm Hg) (Figure 9).

## CONSIDERATIONS

Endovascular treatment is actually considered as the first option at our center.<sup>5</sup> Due to the very frequent multilevel arterial disease and the diffuse calcifications, endovascular procedures in diabetic patients with CLI and wounds are usually very challenging, complex, and long

lasting. During the last 10 years, all of the major medical companies have been investing a lot of effort to develop dedicated devices for CLI endovascular treatment, with a particular attention for BTK and below-the-ankle lesions.

Low-profile over-the-wire long balloons with good pushability and crossability were therefore developed to reduce the number of inflations and shorten the duration of procedures. One of the most frequent problems is the difficulty in crossing a long BTK occlusion directly with a long balloon, especially when the intraluminal technique is used, and there are severe and diffuse calcifications. In our experience, the SABER™ PTA dilatation catheter offers a good compromise between low profile and crossing capability due to its 0.018-inch platform. The balloon is resistant to the calcifications and very fast to be deflated, making it a useful device for everyday practice in BTK procedures. ■

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1. Faglia E, Clerici G, Clerissi J, et al. Early and five-year amputation and survival rate of diabetic patients with critical limb ischemia: data of a cohort study of 564 patients. *Eur J Vasc Endovasc Surg.* 2006;32:484-490.
2. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *Eur J Vasc Endovasc Surg.* 2007;33(suppl 1):S1-75.
3. Hirsch AT, Haskal ZJ, Hertzler NR, et al; American Association for Vascular Surgery/Society for Vascular Surgery; Society for Cardiovascular Angiography and Interventions; Society for Vascular Medicine and Biology; Society of Interventional Radiology; ACC/AHA Task Force on Practice Guidelines. ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Associations for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (writing committee to develop guidelines for the management of patients with peripheral arterial disease) —summary of recommendations. *J Vasc Interv Radiol.* 2006;17:1383-1297.
4. Adam DJ, Beard JD, Cleveland T, et al; BASIL trial participants. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. *Lancet.* 2005;366:1925-1934.
5. Faglia E, Dalla Paola L, et al. Peripheral angioplasty as the first-choice revascularization procedure in diabetic patients with critical limb ischemia: prospective study of 993 consecutive patients hospitalized and followed between 1999 and 2003. *Eur J Vasc Endovasc Surg.* 2005;29:620-627.

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