

Low-Profile and Long Balloons

What is the role of this technology in diabetic macroangiopathy and complex intrapopliteal interventions?

BY LANFROI GRAZIANI, MD

Lower limb peripheral arterial disease (PAD) in diabetic patients is a pathological condition with unique elements that differentiate it from typical atherosclerosis. However, these differences are frequently underappreciated.

Whereas atherosclerosis can be described as asymmetric inflammatory fatty plaque formation, with focal, eccentric subintimal calcification, PAD in below-the-knee (BTK) arteries in diabetes presents a degenerative, circumferential vascular involvement in substantial absence of inflammatory cells. This condition is different from typical atherosclerosis. Specifically, BTK PAD of diabetic patients is characterized by an increased amount of connective tissue, such as fibronectin, collagen, and glycoproteins, as well as an increased amount of calcium in the medial layer. The circumferential Mönckeberg's medial calcification, typically macrophage- and lipid-free, is common in BTK PAD in diabetic patients and occurs independently from atherosclerosis, implying different etiological mechanisms, such as long duration of diabetes.¹⁻⁶ This constellation of findings, known as *diabetic macroangiopathy*, is present in the majority of diabetic subjects with PAD, yet it has been totally ignored by the current official Atherosclerotic Lesions Classification document.⁷ Consequently, the lower limb PAD in patients with diabetes has always been confused with atherosclerosis and treated accordingly.

BACKGROUND OF BTK PTA THERAPY

Due to their anatomical size, analogous with the coronary arteries, the diseased tibial arteries have been

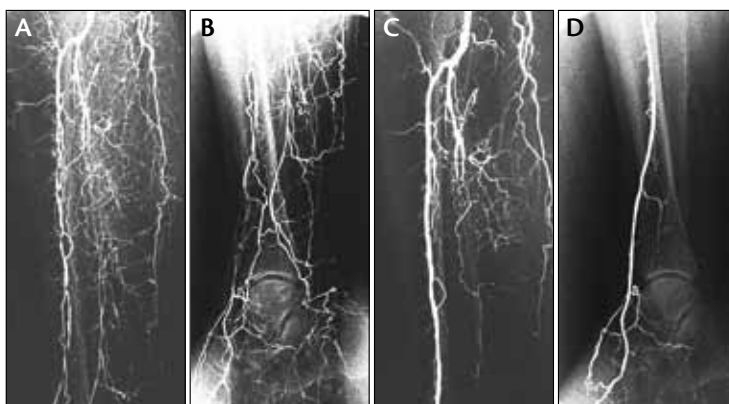


Figure 1. An anterior tibial artery recanalization performed in 1994. Preliminary angiography showing diffuse occlusion of right leg arteries in a diabetic patient with an ischemic foot ulcer (A, B). Result after prolonged balloon angioplasty dilation of the anterior tibial artery showing a very good result in the absence of dissection or recoil (C, D).

approached with coronary-like devices, such as angioplasty balloons, atherectomy devices, cutting balloons, bare-metal or drug-eluting stents, and recently, drug-eluting balloons.

The first devices used were small-vessel balloon catheters that were surprisingly effective and showed a very low incidence of intimal dissection when compared to similar treatment of coronary lesions (Figure 1).

To limit the incidence of intimal dissection and elastic recoil, methods similar to those used during coronary balloon dilation to lower the incidence of dissection or abrupt closure were adopted. In our institution, prolonged balloon dilation of at least 180 seconds and gradual high-pressure balloon dilation using a correct balloon size reduced the risk of dissection. Unfortunately, the use

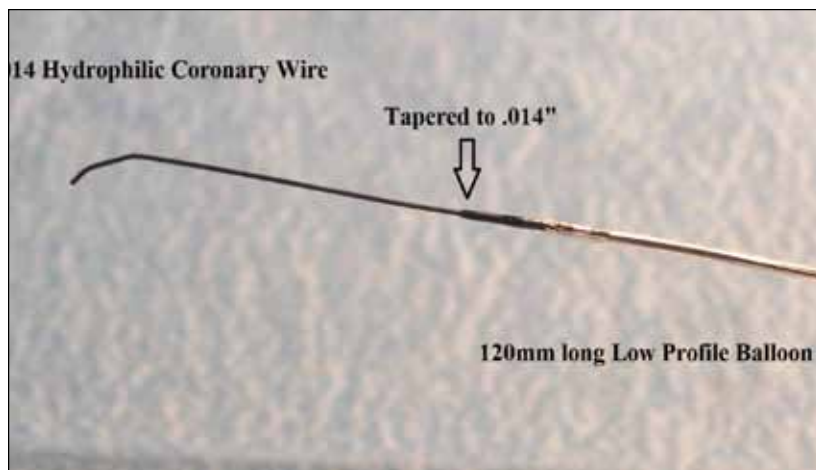


Figure 2. The first prototype of a modern balloon angioplasty catheter from 2003. Innovative 120-mm balloon length, with very low, coronary-style profile and the tip tapered to 0.014 inch.

of multiple, prolonged inflations with short, coronary-type balloons in diffusely diseased tibial arteries dramatically increased the procedure length.⁸⁻¹⁷ After that time, it was clear that there was a need for a significantly longer over-the-wire balloon, tapered to 0.014 inch to fit the same size of the adopted coronary wires.

BALLOON DEVICE TECHNOLOGY

In the early 1990s, 10-cm-long balloons became available from MediTech in either a 5-F shaft tapered to 0.038 inch or small-vessel Ultra-Thin or Symmetry 4-F shaft versions (Boston Scientific Corporation, Natick, MA). The latter were tapered to 0.018 inch, but their tip profile and excessive stiffness limited their use in many BTK arteries. In the late 1990s, the Savvy balloon (Cordis Corporation, Bridgewater, NJ), which was 2 to 4 mm, 10 cm in length, tapered to 0.018 inch, was used at our institution largely due to its superior crossability. Although procedural efficiency improved, no data have demonstrated that balloon length characteristics are associated with a bet-

ter acute or long-term angioplasty result for atherosclerotic lesions. In our experience, however, the benefit of long balloons first became evident in diabetics with PAD, probably due to the disease's pathological characteristics. Long balloons were associated with fewer dissections, better remodeling and uniform lumen gain in patients with diabetic macroangiopathy.

We made a formal request for a 120-mm-long, very low-profile, over-the-wire (OTW) balloon tapered to 0.014 inch in Brescia to the former Invatec company (Roncadelle, Italy, now part of Medtronic, Inc., Minneapolis, MN) in 2000 (Figure 2). Based on my long-term experience

with the antegrade femoral approach, the requested shaft length was 120 cm to allow an easy access to foot arteries in all cases. The request for an unusually long balloon solicited several concerns from the company, which did not find favorable opinions from its consultants at the time. Among the different prototypes submitted, the final selection incorporated the device with the thinnest shaft body. I considered the stiff hydrophilic 0.014-inch wire to be the most important determinant for successful lesion crossing.

The first version (2004–2010) of the Amphirion Deep balloon (Medtronic, Inc.), was characterized by a uniformly thin shaft size and excellent crossing profile, providing an impressive improvement over other PTA balloons of that era. This improvement in BTK balloon technology led to improvement of procedural performance worldwide, promoting large interest in developing similar solutions in other companies (Figure 3).

The first successful BTK recanalization in a large series of diabetic subjects was performed using the ipsilateral



Figure 3. The loop technique dilation for plantar arch reconstruction is a very popular endovascular procedure today.^{19,20} The technique, originally published in 2006, was developed between 2003 to 2005 due to the availability of the new generation of low-profile OTW balloon catheters. These images from September 2005 document one of the first performed cases showing the success of new technologies applied with a new endovascular technique.



Figure 4. A recent loop technique dilation for plantar arch reconstruction. A diabetic foot with small necrotic wounds at the toes and heel level (A, B). Diffuse occlusions of the right popliteal and tibial arteries (C–E). Loop technique dilation using 2.5-, 3-, and 3.5- X 200- to 220-mm RX balloons with complete artery recanalization (F–I). The wounds healed in 1 month (J, K).

antegrade femoral approach and an extensive up-to-the-foot balloon angioplasty dilation strategy.¹⁸ These results were confirmed a few years later in a methodologically identical multicenter experience in a very large population, limiting major amputation rate in this group to 1.8% to 4.0%.¹⁹ Since that time, ipsilateral antegrade femoral balloon angioplasty treatment has remained the only technique with proven efficacy for limb salvage in large series of subjects at risk of limb loss. Despite this evidence, the newly developed OTW long tibial balloons up to about 30 cm in length are unfortunately delivered in 150- and 90-cm shaft length only, with very rare exceptions.

In the author's opinion, these new low-profile OTW balloon catheters are not well suited for the antegrade

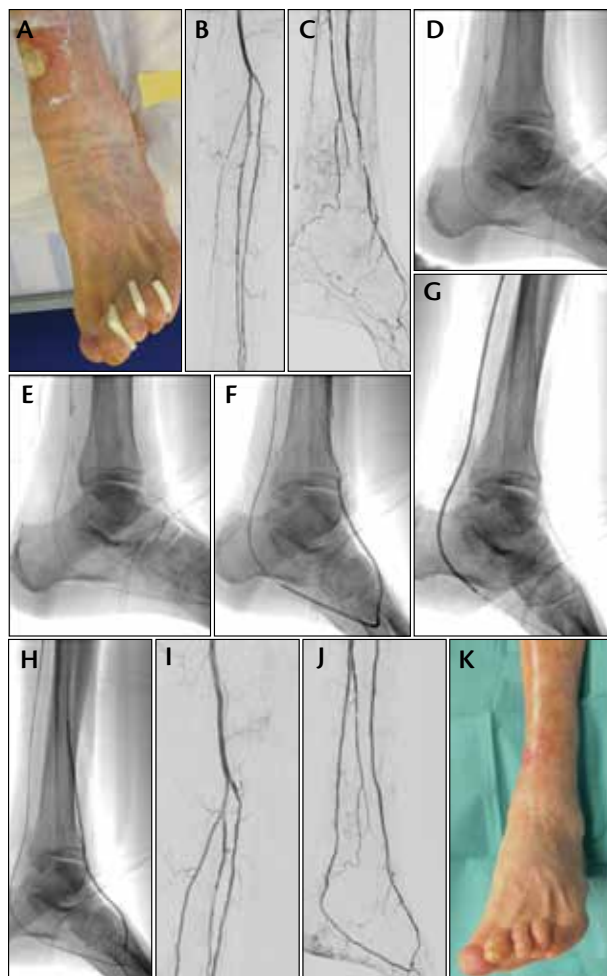


Figure 5. Complex balloon angioplasty dilation with complete leg and foot arterial recanalization. Pretibial and toe ulcerations due to diabetes (A). Left posterior tibial and plantar artery occlusion with severe stenosis of the anterior tibial artery at the pretibial ulcer level (B, C). Loop technique recanalization from the posterior tibial artery using 2.5- and 3- X 200-mm RX balloons at 15 atm (D–H) with both tibial and plantar artery reconstruction (I–J). The wounds healed in 2 months (K).

femoral approach because they are too short to reach the ankle and too long to properly accommodate the commonly available 180-cm-long, 0.014-inch coronary-type guidewires. Paradoxically, one may argue that prejudice against the antegrade femoral approach is responsible for more availability of balloons for contralateral femoral crossover or the ipsilateral pedal approach and the limited availability of balloon lengths that are ideally suited for the antegrade femoral approach (120- to 130-cm catheters). Unfortunately, a catheter's excessive length increases the friction with the guidewire, which

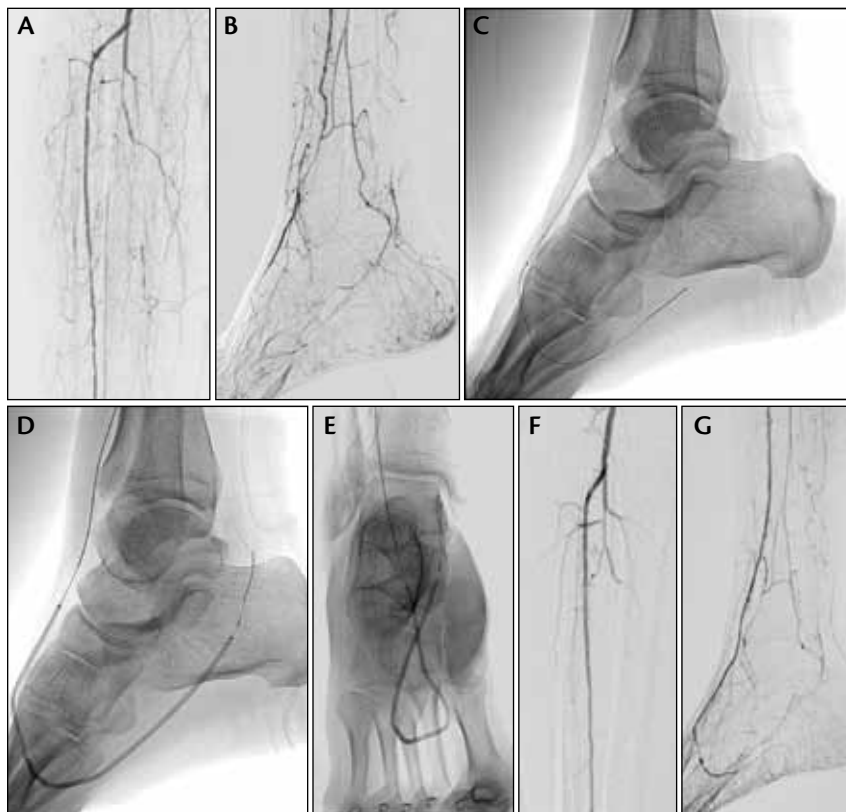


Figure 6. Use of low-profile long balloons in daily practice for an ischemic foot in type 1 diabetes. Diffuse obstruction of right leg and foot arteries (A, B). Loop technique dilation using a 2.5-X 200-mm RX balloon inflated at 14 atm (C–E). Control angiography showing a good result (F, G).

reduces the catheter's pushability and crossability. The rapid exchange (RX) balloon platforms are not similarly affected, but they require the aid of a guiding catheter in many cases, even with the antegrade femoral approach.

CONCLUSION

The technological solutions adopted in the last generation of long infrapopliteal balloons have improved balloon performance dramatically, resulting in increased procedural success rates and reduced procedure length (Figures 4 and 5). With current devices, the rated burst pressure of long balloons has increased to a minimum of 14 atm. Coupled with reduced balloon compliance, these higher-pressure balloons have improved efficacy in heavily calcified arteries. Balloon deflation times continue to shorten over time and can be further improved by the use of additional dilute contrast for balloon inflation without compromising balloon visibility. Particularly impressive is the superior pushability and trackability of newer RX 200-mm-long balloons in comparison to OTW versions. The advantage of newer, low-profile long

balloons is most clearly evident in cases of complex distal revascularization such as those involving the pedal arch (Figure 6). In these cases, the complicated anatomy of the diseased arch can be easily treated with a single balloon covering most of the lesion area, resulting in better arterial remodeling. ■

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