

CASE REPORT

Vessel Preparation and Drug-Eluting Balloon in a Complex Multilevel CLTI Patient

Treatment of recurrent CLTI using atherectomy and the SELUTION SLR™ PTA Drug-Eluting Balloon.

By Bruno Migliara, MD, PhD

CASE PRESENTATION

A woman in her early 60s presented with a recurrence of chronic limb-threatening ischemia (CLTI) 8 months after she had been previously treated for CLTI in the left limb with percutaneous transluminal angioplasty (PTA) alone of the superficial femoral artery (SFA), popliteal artery, and tibial/foot arteries, followed by amputation of the first ray. She had a history of arterial hypertension, diabetes, severe heart disease, and stage 3B chronic kidney disease.

A duplex ultrasound scan showed nearly complete reocclusion of the SFA, popliteal, and below-the-knee (BTK) arteries. The patient's transcutaneous oximetry (TcPO₂) was measured at 15 mm Hg, the Wifl (wound, ischemia, and foot infection) classification was 2-3-2, and the pedal acceleration time (PAT) on the dorsalis pedis was 220 msec (stage 4). Clinically, there was new necrosis in the site of the previous first ray amputation, with severe pain and no infection.

Carbon dioxide (CO₂) angiography was performed and confirmed a nearly complete reocclusion of the SFA and popliteal arteries, with diffuse calcifications and poor distal flow (Figure 1).

TREATMENT

Due to this quick reocclusion, the first question we asked was: how can we treat this patient to improve the mid- and long-term outcomes? We decided to do an effective vessel preparation (VP). In this case, due to the presence of a long (> 30 cm), mixed lesion (with

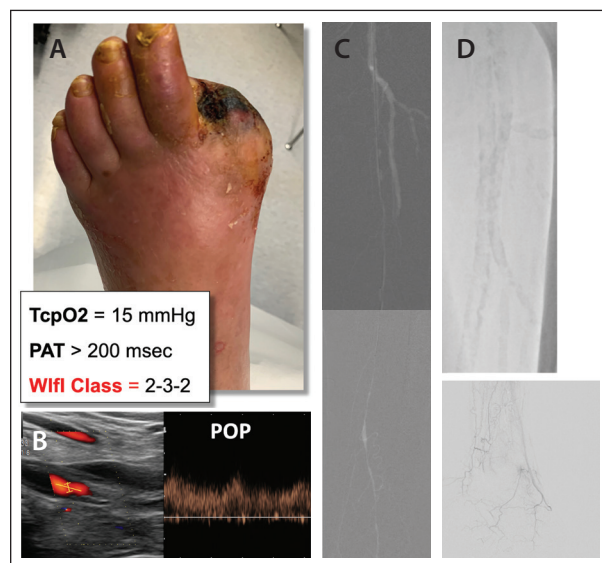


Figure 1. Image of the foot at presentation (A) and initial diagnostic testing (B). Preprocedural imaging showing nearly complete reocclusion of the SFA and popliteal arteries with diffuse calcifications and poor distal flow (C, D). POP, popliteal artery.

intimal hyperplasia and diffuse calcifications), we used rotational atherectomy (Jetstream 2.4-3.4 mm, Boston Scientific Corporation). We treated also the BTK/below-the-ankle (BTA) arteries with PTA to obtain a direct flow into the forefoot (Figure 2).



Figure 2. Vessel preparation using rotational atherectomy in the SFA and popliteal artery, and noncompliant balloons in BTK/BTA arteries.

With complete resolution of the reocclusion of the SFA and popliteal arteries without residual stenosis, plaque recoil, and flow-limiting dissection, the second question was around whether we should use antiproliferative therapy to reduce inflammation after this quite aggressive VP and improve long-term patency or not, and if so, what type.

Recently, drug-coated balloons with sirolimus for peripheral artery disease (PAD) have appeared on the market. In the coronary area, sirolimus has been proven to be an effective antirestenotic agent^{1,2}; furthermore, initial studies in PAD confirmed the superiority of sirolimus compared with PTA alone.³

The biggest limitation of using sirolimus-coated balloons in PAD is the lower bioavailability compared to paclitaxel, resulting in a rapid dilution of sirolimus and subtherapeutic dose. The unique technology of the SELUTION SLR™ Drug-Eluting Balloon (DEB; Cordis Corporation), designed with CELL ADHERENT TECHNOLOGY (CAT)™ and MicroReservoirs, overcomes this problem. CAT™ is a mix of phospholipids containing and protecting MicroReservoirs which facilitates drug uptake and retention in the tissue with a

minimal drug loss during the procedure while providing excellent deliverability.

In patients like this, we prefer to use sirolimus as antiproliferative drug for a few reasons. First, in experimental models, paclitaxel caused dose-dependent tissue necrosis and vascular wall hemorrhage, so in case of an aggressive and extensive VP, there is a risk of arterial wall damage.⁴ Second, in about 8% of cases, the use of paclitaxel is related to the risk of “slow-flow phenomena,” and this is particularly evident in cases with poor tibial vessels runoff.⁵

After two passes of rotational atherectomy, first with blades down and second with blades up, three SELUTION SLR™ PTA DEBs (5 X 150, 5 X 150, and 6 X 120 mm) were used to cover all the damaged endothelium and avoid the “geographic miss” that is one of the major reasons of late reocclusions (Figure 3).⁶

At the end of the procedure, CO₂ angiography showed an effective recanalization of the SFA and popliteal artery, with a direct flow into the BTA arteries. The PAT on the dorsalis pedis was < 90 msec.

POSTTREATMENT COURSE

Twenty days after revascularization, when the TcPO₂

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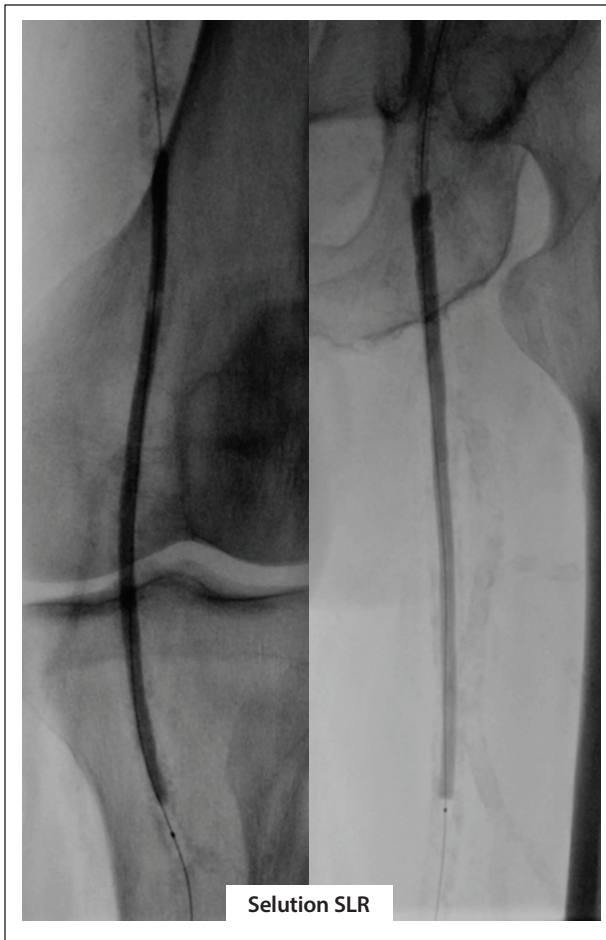


Figure 3. Antiproliferative therapy with Selution SLR DEBs.

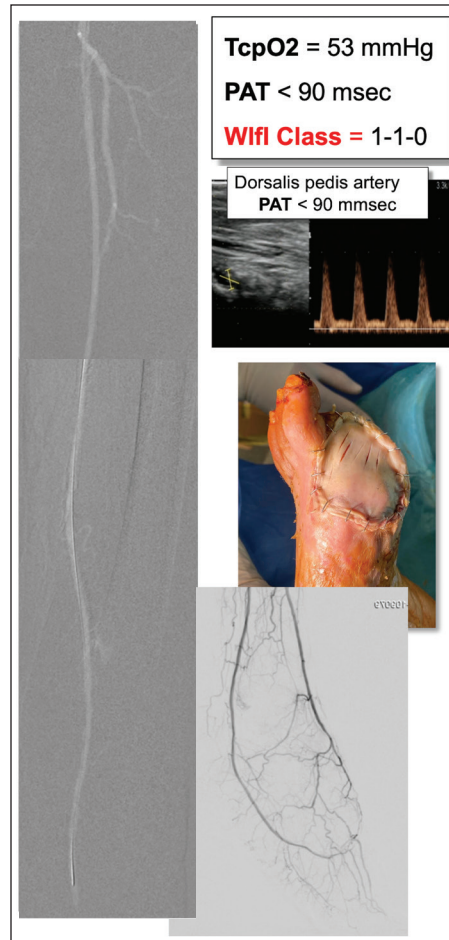


Figure 4. Final angiogram and foot healing progression.

reached > 50 mm Hg, the foot surgeon carried out an adequate foot surgery, achieving complete healing in a few weeks. The endovascular and foot surgical treatment are shown in Figure 4. ■

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