The Role of Plaque Scoring

DCB therapy in complex settings: how to optimize treatment results

BY PROF. FABRIZIO FANELLI, MD, EBIR

Supported by a growing body of clinical evidence, drug-based endovascular technologies are increasingly adopted within a wide array of clinical and anatomical settings, including a variety of lesion complexities frequently observed in patients with peripheral artery disease. In addition to TASC A and B lesions, much more difficult anatomical challenges are often encountered, such as long lesions and occlusions, frequently with high plaque burden and severe calcium.

Determining how to obtain and maintain vessel patency, as well as the safest, most efficacious, and easiest way to do so is crucial. The achievement of satisfactory and stable lumen gain and flow improvement, while referred to as *acute success*, is likely also instrumental to long-term outcomes, especially in the current era of drug elution and, even more importantly, within these complex lesions.

TREATMENT OF CALCIFIED LESIONS

Calcium is a particularly well-known enemy of endovascular practice. Underdiagnosed and underestimated by angiography, it makes vessels resistant to dilatation, subject to recoil and embolism, and correlates with an increase in the incidence of dissections. Seventy-one percent of flow-limiting dissections occur with calcium. As a result, primary stenting is the preferred strategy in these settings. Nonetheless, once a stent is deployed, calcium continues to bring further challenges with a risk of malapposition, suboptimal expansion, and increased likelihood of stent fractures.[1,2] Moreover, calcium has been indicated as a potential barrier to optimal drug absorption after the use of drug-coated balloons (DCBs). Particularly, circumferential distribution seems to be a strong predictor for loss of patency versus longitudinal extension.[3,4]

Various solutions are being explored to improve the treatment of calcified lesions. Although directional atherectomy has shown promising results, tradeoffs may exist inherent to the length and complexity of the procedure and to the risk of potential complications such as plaque embolization mandating the use of a distal filter; all of which pose a big question concerning cost-effectiveness, especially in the lack of reimbursement.[5,6] Plaque scoring, on the other hand, represents a viable and simple process aimed at improving acute luminal gain while limiting the likelihood of severe dissections. In addition, plaque scoring holds the potential to optimize DCB effectiveness and associated long-term outcomes.

PLAQUE SCORING

The AngioSculpt plaque-scoring angioplasty balloon (Spectranetics Corporation) features three to five (depending on balloon size) rectangular cross-section nitinol wires (the “scoring elements”) wrapped in a spiral fashion around the full length of the balloon. AngioSculpt’s mechanism of action combines balloon dilatation with focal incision of the lesion to aim to break plaque continuity and relieve internal hoop stress (the internal tensions that exert circumferentially within a cylinder). Inducing predictable and controlled dissections that facilitate mechanical dilatation and luminal gain without flow-limiting downsides is the expected outcome.

Plaque scoring has been reported as highly effective in a broad range of complex peripheral and coronary lesions. It confers precision, predictability, and stability during dilatation with significant acute gains and the ability to achieve optimal stent expansion afterward.[7-9]

Tepe et al described the effect of dissections in the context of DCB utilization. They reported that non–flow-limiting dissections cannot only be left unstented while still bringing positive outcomes, but patients with severe dissections (grade C, D, E) seem to benefit the most from DCBs in terms of lower late lumen loss at 6 months and lower target lesion revascularization rates at 2 years (compared to those with less severe dissections [grade A, B]).[10] This observation supports the hypothesis that dissections may create a path for improved drug absorption, which may be beneficial in overcoming plaque burdens and calcium barriers.

Erwin Blessing recently reported the combination of AngioSculpt and DCBs for the treatment of calcified superficial femoral artery (SFA) lesions within a single-center registry.[11] The results supported the notion that plaque scoring can provide a benefit to both procedural and long-term success. Calcification was not a predictor

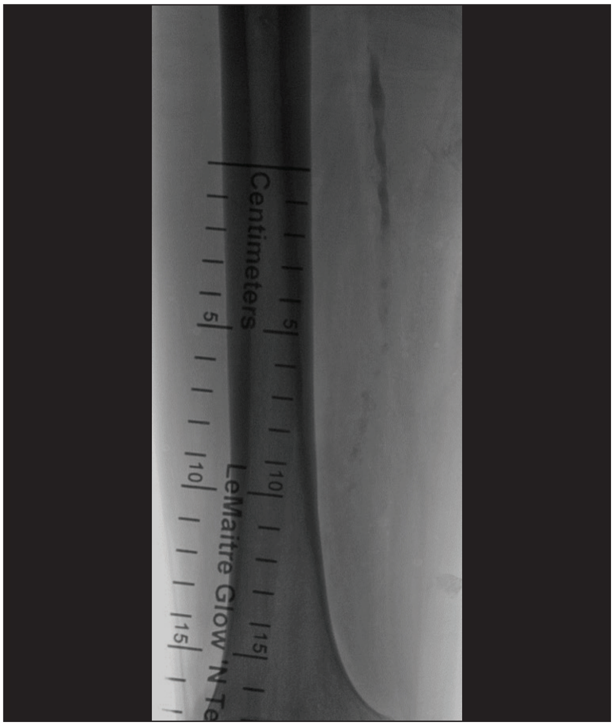

Figure 1. Left SFA with severe calcium.

Figure 2. A 5-mm X 10-cm AngioSculpt in the SFA.

for loss of 12-month patency as long as lesion preparation was performed with AngioSculpt.

CASE STUDY

The following case describes the use and results of AngioSculpt for the treatment of severe calcification.

A 72-year-old man who was a heavy smoker with hypertension and diabetes presented with a small ulcer at the level of the forefoot and rest pain in the right leg. CT angiography showed obstruction of the left SFA with severe calcification (grade 3, according to our classification[3]) (Figure 1). The patient's ankle-brachial index was 0.35 (right) and 0.5 (left).

Retrograde contralateral access was achieved via the left common femoral artery using a 6-F, 45-cm braided introducer (Destination sheath, Terumo Europe). We were unable to cross the SFA occlusion endoluminally using an antegrade approach. Retrograde right popliteal access was then employed. Recanalization of the occluded segment was achieved with a 0.035-inch angled hydrophilic guidewire.

Dilatation of the obstructed segment was performed with a 4-mm X 4-cm AngioSculpt balloon in the P1 segment and a 5-mm X 10-cm balloon in the SFA (Figure 2). The inflation time was 3 minutes each to 10 atm.

Digital subtraction angiography showed recanalization of the vessel with dissection at the level of the distal portion of the SFA (not flow limiting). The P1 segment was dilated with a 4-mm X 8-cm Stellarex DCB (Spectranetics Corporation), and the SFA was dilated with three 5-mm

Figure 3. A 5-mm X 12-cm Stellarex in the SFA.

Figure 4. Left SFA final result. Proximal (A). Distal (B).

balloons (5 mm X 12 cm, 5 mm X 12 cm, 5 mm X 8 cm) up to its origin (Figure 3). The inflation time was 3 minutes for each balloon, overlapping 1 cm, to 10 atm.

Subsequent digital subtraction angiography showed good recanalization with persistence of the dissection flap at the level of the distal portion of the SFA, not limiting the flow. Postdilatation with a 5-mm noncoated Dorado balloon (Bard Peripheral Vascular, Inc.) was performed, with an inflation time of 5 minutes.

The final angiogram showed a complete resolution of the dissection with improvement of the distal flow in the below-the-knee region (Figure 4).

CONCLUSIONS

DCBs are more frequently used for the treatment of increasingly complex lesions. Although further research is warranted, plaque scoring represents a viable, user-friendly, and effective solution to improve acute success by achieving larger luminal gain and decreasing the likelihood of flow-limiting dissections. In addition, plaque scoring holds promise to facilitate optimal drug tissue absorption in settings where calcium may otherwise be a barrier. ■

1. Kashyap VS, Pavkov ML, Bishop PD, et al. Angiography underestimates peripheral atherosclerosis: lumenography revisited. J Endovasc Ther. 2008;15:117-125.
2. Fitzgerald PJ, Ports TA, Yock PG. Contribution of localized calcium deposits to dissection after angioplasty. An observational study using intravascular ultrasound. Circulation. 1992;86:64-70.
3. Fanelli F, Cannavale A, Gazzetti M, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. Cardiovasc Intervent Radiol. 2014;37:898-907.
4. Tepe G, Beschorner U, Ruether C, et al. Drug-eluting balloon therapy for femoropopliteal occlusive disease: predictors of outcome with a special emphasis on calcium. J Endovasc Ther. 2015;22:727-733.
5. Cioppa A, Stabile E, Popusoi G, et al. Combined treatment of heavy calcified femoro-popliteal lesions using directional atherectomy and a paclitaxel coated balloon: one-year single centre clinical results. Cardiovasc Revasc Med. 2012;13:219-223.
6. Roberts D, Niazi K, Miller W, et al. Effective endovascular treatment of calcified femoropopliteal disease with directional atherectomy and distal embolic protection: final results of the DEFINITIVE Ca^{++} trial. Catheter Cardiovasc Interv. 2014;84:236-244.
7. Fonseca A, Costa Jde R Jr, Abizaid A, et al. Intravascular ultrasound assessment of the novel AngioSculpt scoring balloon catheter for the treatment of complex coronary lesions. J Invasive Cardiol. 2008:20:21-27.
8. Costa JR, Mintz GS, Carlier SG, et al. Nonrandomized comparison of coronary stenting under intravascular ultrasound guidance of direct stenting without predilatation versus conventional predilatation with a semi-compliant balloon versus predilatation with a new scoring balloon. Am J Cardiol. 2007;100:812-817.
9. Scheinert D, Peeters P, Bosiers M, et al. Results of the multicenter first-in-man study of a novel scoring balloon catheter for the treatment of infra-popliteal peripheral arterial disease. Catheter Cardiovasc Interv. 2007;70:1034-1039.
10. Tepe G, Zeller T, Schnorr B, et al. High-grade, non-flow-limiting dissections do not negatively impact long-term outcome after paclitaxel-coated balloon angioplasty: an additional analysis from the THUNDER study. J Endovasc Ther. 2013;20:792-800.
11. Blessing E. Advancing DCB therapy in complex SFA lesions: plaque scoring in calcified lesions. Presented at: Leipzig Interventional Course (LINC) 2016; January 28, 2016; Leipzig, Germany.

Prof. Fabrizio Fanelli, MD, EBIR
Vascular and Interventional Radiology Unit
Department of Radiology
"Sapienza" University of Rome
Rome, Italy
fabrizio.fanelli@uniroma1.it
Disclosures: None.