Nitinol-Constrained Balloon Dilatation to Minimize Vessel Trauma and Dissections in Peripheral Arterial Interventions

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ABSTRACT: Balloon angioplasty of severely calcified peripheral arterial lesions often results in vessel trauma and dissection. We present a case of right superficial femoral artery calcified stenosis treated using rotational atherectomy with aspiration thrombectomy complicated by a small non-flow-limiting dissection of the treated segment. Subsequent nitinol-constrained balloon angioplasty significantly improved the angiographic result with intravascular ultrasound-confirmed resolution of dissection and improved luminal gain.

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CASE REPORT

A 61-year-old female with history of coronary artery disease (CAD) and extensive peripheral arterial disease (PAD) presented to the endovascular clinic for significant lower extremity pain with ambulation. On history, she had Rutherford Class III claudication symptoms in the right lower extremity without rest pain. Her PAD history included stenting of the left internal carotid artery, right brachiocephalic artery, abdominal aorta, right common iliac artery, left superficial femoral artery (SFA), and cutting balloon angioplasty to the left tibioperoneal trunk. Her atherosclerotic medication regimen included aspirin, clopidogrel, and atorvastatin. Clinical examination revealed no signs of ulceration, skin breakdown, or edema. Ankle Brachial Index was abnormal at 0.65 in the right lower extremity, and arterial Doppler ultrasound displayed elevated velocities of 252 cm per second in the mid to distal SFA segment. Based on these findings, an angiogram of the right lower extremity was recommended.

Access was obtained in the left common femoral artery (CFA) and a 7 Fr Pinnacle Destination sheath (Terumo) was positioned across the aortic bifurcation in the right CFA. Selective angiogram of the right lower extremity confirmed mid to distal 80% calcified stenosis of the right SFA (Figure 1), mild popliteal artery disease, and 2-vessel run-off into the right foot. A Grand Slam Wire (Abbott Vascular) was advanced across the right SFA lesion into the distal peroneal artery after anticoagulation with intravenous heparin. Intravascular ultrasound (IVUS) imaging (Volcano) was performed to determine the burden and character of the plaque, which confirmed a severe calcific and eccentric stenosis in the mid SFA (Figure 2). Rotational...
Atherectomy with aspiration thrombectomy was performed using a Jetstream 2.1/3.0 atherectomy catheter (Bayer Healthcare) with four passes across the lesion, two with blades down and two with blades up (Figure 3). Follow-up angiography displayed improved flow but with a non-flow-limiting dissection within the treated segment of the right SFA (Figure 4). Repeat IVUS imaging confirmed an intimal flap consistent with post-atherectomy dissection (Figure 5). Nitinol-constrained balloon angioplasty was performed using a 5 mm x 80 mm over-the-wire Chocolate PTA balloon catheter (TriReme Medical) with a prolonged expansion over 2 minutes (Figure 6). Final angiogram demonstrated excellent angiographic result with brisk flow through the treated segment (Figure 7) and preserved run-off into the foot. Final IVUS imaging confirmed no residual dissection flap and improved luminal gain (Figure 8).

The patient was discharged home the following day with significant improvement in symptoms.

**DISCUSSION**

Angioplasty for PAD using a standard balloon catheter is often associated with acute complications related to vessel trauma, including dissection and recoil. These limitations have spurred the development of newer designs of angioplasty catheters.

Cutting and scoring balloons focus the force of dilation at the tips of the atheromes bonded to the balloon, resulting in gentle dilatation of the vessel with less vessel wall disruption. However, the need for bailout stenting due to dissection or suboptimal result has been reported to be as high as 20%.

Cryoplasty is a technique that combines balloon angioplasty and cooling therapy using liquid nitrous oxide, hypothesized to favorably modify plaque and reduce elastic recoil. However, bailout stenting in a registry of cryoplasty was required in 9% of cases, and significant dissection in 7% of cases.

The Chocolate PTA balloon catheter is a novel balloon catheter with a mounted nitinol-constraining structure (CS) to allow for uniform inflation and rapid deflation. The unique design of the CS allows uniform expansion of the balloon while creating “pillows” and “valleys” from balloon expansion beyond the diameter of the CS to facilitate plaque modification and vessel stress relief, clinically translated to minimizing vessel damage.

The Chocolate first-in-man study confirmed the safety and efficacy of the device in below-the-knee (BTK) atherosclerotic lesions. The first 22 patients (58% critical limb ischemia and 42% claudication) had BTK target lesions with an average length of 11 cm that were treated using the
Chocolate device. Technical success was achieved in 100% of cases including successful delivery, inflation, deflation, and fluoroscopic expansion. There were no flow-limiting dissections noted and there were no bailout stents used. There were also no in-hospital or 30-day major adverse events reported.

**CONCLUSION**

Intimal dissection during peripheral intervention is often treated successfully with prolonged balloon inflation or stenting. The case presented herein highlights the use of a nitinol-constrained balloon for successful treatment of an intimal dissection post atherectomy.

**Figure 5.** Intravascular ultrasound imaging confirming intimal dissection flap post atherectomy.

**Figure 6.** Nitinol-constrained balloon angioplasty (arrow) using a Chocolate PTA balloon catheter (TriReme Medical).

**Figure 7.** Final angiogram demonstrating excellent angiographic result with brisk flow through the treated segment (arrow).

**Figure 8.** Intravascular ultrasound imaging confirming no residual dissection flap and improved luminal gain.

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