Achieving Robust, Durable Angioplasty in the Tibial Arteries by Minimizing Acute Vessel Wall Trauma and Maximizing Luminal Gain

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Although percutaneous balloon angioplasty is an established endovascular therapy for tibial revascularization, its mechanism of action involves trauma to the vessel wall due to arterial expansion causing plaque redistribution and rupture.[1-5] This type of injury to the vessel wall, especially with uneven expansion, may lead to an acute flow-limiting dissection, which would necessitate bailout stenting, and neointimal hyperplasia can contribute to late lumen loss.[4,5]

Nevertheless, one of the most important factors in achieving a durable endovascular result in the tibial arteries is to maximize acute luminal gain. The Chocolate® PTA Balloon Catheter (manufactured by TriReme Medical, LLC, distributed by Cordis Corporation) attempts to minimize vessel wall trauma, thereby decreasing both early and late lumen loss.[6] It is composed of a nitinol pressure shield over a semicompliant balloon. Once inflated, it forms multiple alternating grooves and balloon pillows, allowing for a more controlled distribution of shear force despite variability in lesion morphology (Figure 1).[6]

The dynamic shape of this balloon allows the operator to take it up to its rated burst pressure while minimizing the risk of flow-limiting dissections (Figure 2). Unlike cutting or scoring balloons, the pressure shield does not cut into the arterial wall; instead, it constrains the balloon and enables a uniform inflation by creating the mounds or pillows. This provides for the high inflation pressures needed in calcified tibial lesions. The typical outcome is an excellent angioplasty result with no dissection.

By reducing the need for bailout stenting, we have the potential to reduce the overall cost of care for patients with critical limb ischemia and expect improved outcomes. The Chocolate BAR registry demonstrated markedly reduced rates of dissection and bailout stenting compared to trials using normal percutaneous angioplasty alone in both above- and below-the-knee applications.[7-10]

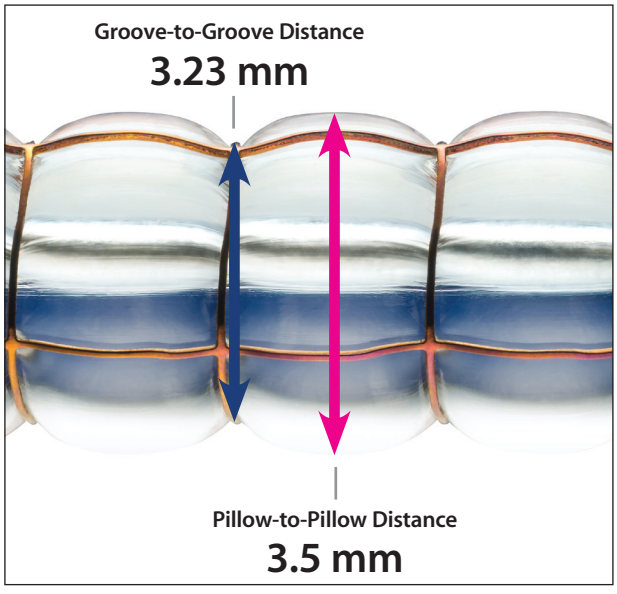

Figure 1. Dimensions for a 3.5-mm balloon at nominal pressure.

We often use Chocolate® PTA Balloon dilatation in conjunction with plaque-debulking atherectomy, especially in calcified vessels, for maximal luminal gain. As for oversizing the balloon, we are quite liberal: For a 5-mm vessel, we typically use a 6-mm balloon. For a 3-mm tibial vessel, we use a 3.5-mm balloon. We also use the 3-mm balloon all the way down to the ankle without issues among any patient population.

CASE STUDY

A 71-year-old man with a history of peripheral vascular disease, coronary artery disease with myocardial infarction (at age 70), hypertension, and chronic obstructive

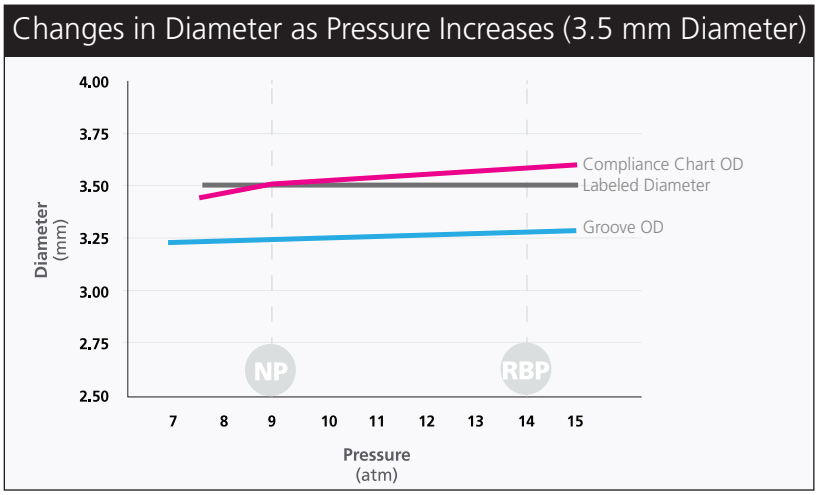

Figure 2. As pressure increases, pillow-to-pillow distance increases. Groove-to-groove distance, however, does not experience the same amount of increase, thus providing stress relief and minimizing the risk of flow-limiting dissection. Abbreviations: NP, nominal pressure; RBP, rated burst pressure. (Data on File. Cordis Corporation.)

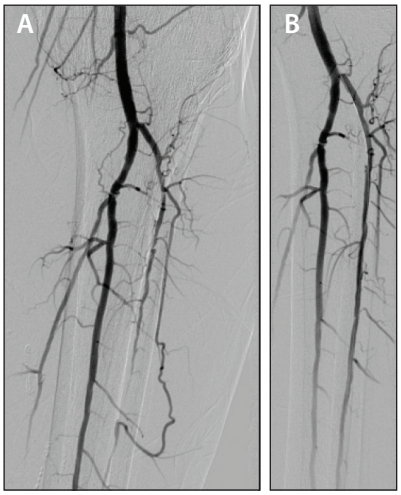

Figure 3. Preprocedural angiogram showing the partially calcified left anterior tibial artery, which was occluded and had minimal distal reconstitution (A). Postprocedural angiogram showing wide patency with excellent flow (B).

pulmonary disease was referred to our vascular clinic with bilateral critical limb ischemia of his lower extremities manifesting as ischemic rest pain. He had good femoral and popliteal pulses bilaterally and Dopplerable dorsalis pedis pulses.

Lower extremity angiography revealed bilateral tibial occlusive disease that was more significant on the left side. The decision was made to intervene on the left side and to address the right tibial occlusion in a subsequent intervention. The partially calcified left anterior tibial artery was occluded, with minimal distal reconstitution (Figure 3A).

Contralateral access was used to place a 6-F sheath over the iliac bifurcation. A microcatheter and hydrophilic guidewire were used to cross the left anterior tibial artery. Atherectomy was then performed using a 1.25-mm Diamondback 360 orbital atherectomy device (Cardiovascular Systems, Inc.).

Angioplasty was performed using a 3-mm outer-diameter Chocolate® PTA Balloon, which was inflated slowly up to half nominal pressure at 30 seconds, then up to nominal pressure by 1 minute, and finally up to its rated burst pressure with deflation at 1 minute, 30 seconds. The results showed wide patency with excellent flow (Figure 3B).

After the intervention and antibiotic therapy, cellulitis and pain resolved. ■

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1. Payne MM. Charles Theodore Dotter: the Father of Intervention. Tex Heart Inst J. 2001;28:28-38.
2. Finet G, Abrysch, F, Rioufol, et al. Qualitative and quantitative descriptions of the mechanisms of action of the angioplasty balloon on coronary stenosis. An endovascular ultrasonic study. Arch Mal Coeur Vaiss. 2000;93:1109-1117.
3. Wilensky RL, March KL, Gradus-Pizlo I, et al. Vascular injury, repair, and restenosis after percutaneous transluminal angioplasty in the atherosclerotic rabbit (in French). Circulation. 1995;92:2995-2300.
4. Bennett MR. In-stent stenosis: pathology and implications for the development of drug-eluting stents. Heart. 2003;89:218-224.
5. Costa MA, Simon DI. Molecular basis of restenosis and drug-eluting stents. Circulation. 2005;111:2257-2273.
6. QTVascular Chocolate PTA Balloon Catheter (2014). http://qtvascular.com/us/products/chocolate. Accessed September 11, 2014.
7. Das T, Mustapha JM (2014). Chocolate BAR: Chocolate PTA in a broad range of patients with PAD, a prospective post-marketing study. Presented at LINC 2014: The Leipzig Interventional Course in Leipzig, Germany.
8. Odink H, van den Berg A, Winkens B. Technical and clinical long-term results of infrapopliteal percutaneous transluminal angioplasty for critical limb ischemia. J Vasc Interv Radiol. 2012;23:461-467.
9. Laird JL. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. Circ: Cardiovasc Interv. 2010;3:267-276.
10. Werk M, Albrecht T, Meyer DR, et al. Paclitaxel-coated balloons reduce restenosis after femoropopliteal angioplasty. Evidence from the randomized PACIFIER trial. Circ: Cardiovasc Interv. 2012;5:831-840.

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