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Tackling Below-the-Knee Disease in Critical Limb Ischemia

By S. Hinan Ahmed, MD, FACC, FSCAI, FSVM

Critical limb ischemia (CLI) is a growing problem and challenging to adequately treat due to limited treatment modalities.[1,2] The annual incidence of CLI is estimated at 220 to 1,000 new cases per 1,000,000 people, and the prevalence is estimated to be 1% of adults aged older than 40 years.[3,4] Furthermore, approximately 10% of patients with peripheral artery disease (PAD) are estimated to have CLI,[4] and between 5% and 20% of patients with asymptomatic PAD or intermittent claudication will progress to CLI over a 5-year period.[5] The combination of an aging population burdened by increasing rates of cardiovascular risk factors and diabetes will lead to an increase in PAD and CLI prevalence. Even more concerning, CLI leads to adverse limb-related and systemic outcomes.[2,6] A recent insurance registry of 41,882 patients with PAD in Germany found 4-year amputation rates among those with CLI and tissue loss to be 35% to 67%.[7] The economic impact of PAD in the United States is significant, with annual health care costs estimated to be greater than $4 billion from Medicare data in 2001.[8] The cornerstone of CLI treatment is revascularization to prevent limb loss and dysfunction, although the current paucity in clinical evidence renders the optimal revascularization strategy uncertain.[2] With the advent of new technologies and devices, our options are improving.

The DEFINITIVE LE study demonstrated that directional atherectomy is a safe and effective treatment modality at 12 months in a diverse 800-patient population, including those with claudication or CLI.[9] Furthermore, directional atherectomy was shown to be noninferior for treating PAD in patients with diabetes compared with those without diabetes, with a 1-year primary patency rate of 77% in diabetics compared to 78% in nondiabetics. Particularly in patients with CLI, the rate of freedom from major unplanned amputation of the target limb at 12 months in CLI patients was 95%. The primary patency rate of infrapopliteal vessels (average length, 5.5 cm) was 90% in the claudicant group and 78% in the CLI group (average length, 6 cm). The patency rates were similar in lesions longer than 10 cm. This established the safety and efficacy of directional atherectomy in infrapopliteal vessels. With a bailout stenting rate of < 4%, it also allowed interventionalists to treat with no metal left behind.[9]

Although directional atherectomy can be used as a stand-alone therapy, most often the luminal gain achieved after debulking is further enhanced with percutaneous balloon angioplasty (PTA). However, standard PTA causes

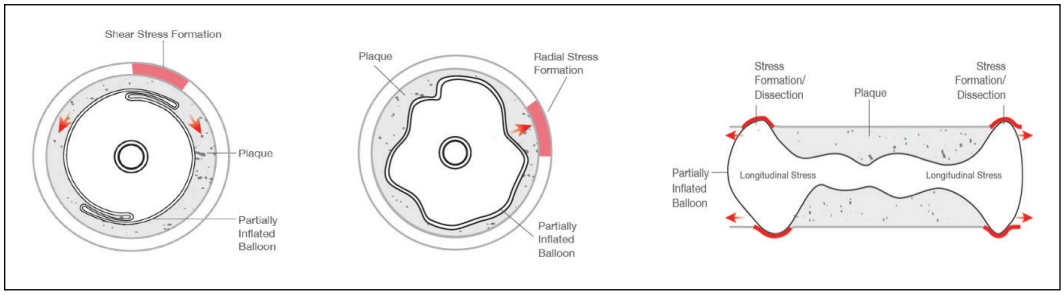

Figure 1. Different types of stresses with PTA: torsional/twisting (A), radial/expanding (B), longitudinal/elongating (C). Reprinted with permission from Ward C, Mena-Hurtado C. Novel use of pillows and grooves: the Chocolate™* PTA balloon catheter. Endovasc Today. 2014;13:24-28.

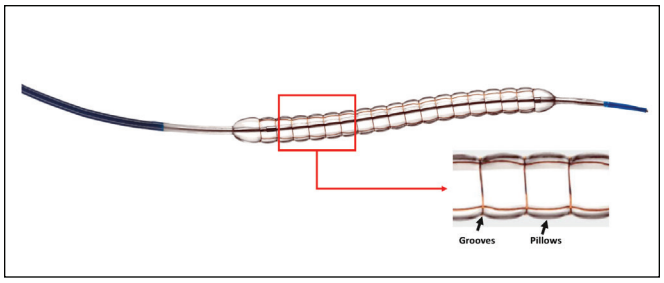

Figure 2. Nitinol-constraining structure creating pillows and grooves.

multidirectional stress and trauma to the vessel wall leading to deformation and possible dissection (Figure 1).

These limitations of standard PTA are reduced with the Chocolate™* PTA balloon catheter (Medtronic), a special balloon design that incorporates a nitinol-constraining structure that creates pillows and grooves in the balloon to provide predictable, uniform, and atraumatic dilation (Figure 2). The pillows allow for vessel dilation without vessel scoring or cutting, while the grooves provide stress relief and plaque modification.

CASE EXAMPLE

A 62-year-old man with a history of coronary artery disease, congestive heart failure, type 2 diabetes mellitus, hypertension, and dyslipidemia presented with a nonhealing ulcer of his left fifth toe (Rutherford class 5). Angiography revealed high-grade distal popliteal stenosis with single-vessel peroneal runoff (Figure 3A). The peroneal artery also had tandem high-grade lesions. We decided to treat these lesions with directional atherectomy with a HawkOne device (Medtronic, Figure 3B), followed by balloon angioplasty with a 2.5- X 100-mm Chocolate balloon (Figure 3C). Completion angiography revealed minimal residual stenosis with brisk flow (Figure 3D). ■

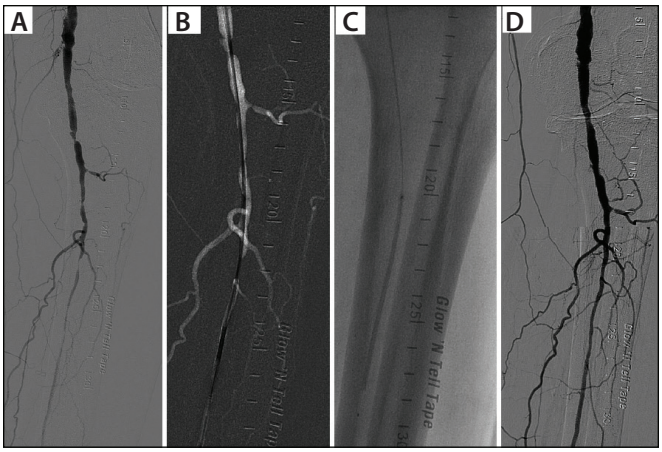

Figure 3. Peripheral angiography in a patient with CLI. Diagnostic angiography showed high-grade popliteal stenosis with single-vessel peroneal runoff with tandem high-grade stenosis (A). Directional atherectomy was performed with the HawkOne directional atherectomy system (B). Balloon angioplasty was performed with a 2.5- X 100-mm Chocolate balloon (C). Final angiogram revealed minimal residual stenosis with brisk flow (D).

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S. Hinan Ahmed, MD, FACC, FSCAI, FSVM
Division of Cardiology
UT Health
San Antonio, Texas
Disclosures: Consultant for Medtronic; speaker's bureau for Medtronic, Amgen Pharmaceuticals, Philips, and AstraZeneca.

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HawkOne™ Directional Atherectomy System
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Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
Indications for Use: The HawkOne™ peripheral directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature. HawkOne is contraindicated in patients with in-stent restenosis.
CAUTION:
Federal (USA) law restricts this product for sale by or on the order of a physician.

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Important Information:
Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device.
Indications for Use:
The Chocolate™* PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.
CAUTION:
Federal (USA) law restricts this product for sale by or on the order of a physician.