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Addressing the Limitations of Standard Balloon Angioplasty

By Jun Li, MD, and Mehdi H. Shishehbor, DO, MPH, PhD

Peripheral artery disease (PAD) has been estimated to affect at least 8.5 million Americans over the age of 40 years and affects approximately 202 million people worldwide.¹ Symptoms range widely for patients with PAD. On one extreme are the patients who are either asymptomatic or have sufficiently compensated their activity levels to avert symptom onset. The lack of symptoms may lead to underdiagnosis and underestimated disease prevalence. On the other extreme of the spectrum are the patients with end-stage disease with critical limb ischemia (CLI) in the form of rest pain, tissue loss, and/or gangrene. CLI has an estimated incidence of 500 to 1,000 new cases per 1 million people annually in a North American or European population.²

The quality of life limitations imposed by lifestyle-limiting claudication and CLI have previously been described.^{3,4} The cornerstone of therapy for any patient with PAD is medical optimization to minimize cardiac risk factors. Intermittent claudicants should also undergo guideline-directed structured exercise therapy and consideration of revascularization in patients with ongoing symptoms despite optimized medical therapy.¹ Conversely, patients with CLI are referred for revascularization up front to minimize tissue loss and promote limb salvage.¹ In the last decade, given significant advancements in endovascular techniques and equipment, an endovascular approach has become increasingly favored over open surgery for revascularization in CLI.⁵

Despite innovations in the endovascular space such as drug-coated balloons (DCBs), increasingly flexible self-expanding stents, and drug-eluting stents, there remain significant limitations in long-term primary patency rates.⁶ Patency rates are lower in the peripheral vasculature compared to the coronaries owing to two

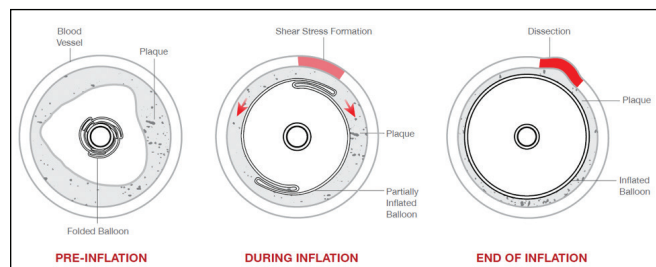


Figure 1. Torsional stress from the unraveling of a folded conventional balloon during inflation, resulting in shear stress formation and vessel dissection. Reprinted with permission from Ward C, Mena-Hurtado C. Novel use of pillows and grooves: the Chocolate® PTA balloon catheter. *Endovasc Today*. 2014;13:24-28.

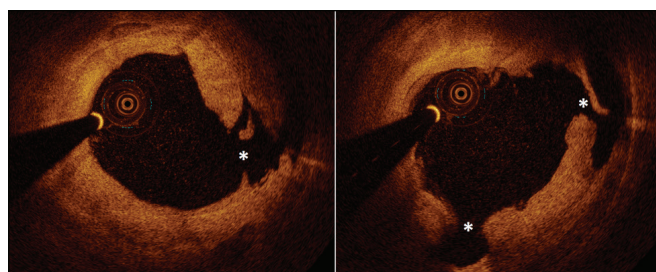


Figure 2. Optical coherence tomography images of a superficial femoral artery following conventional balloon angioplasty. The two panels are different sections of the same artery. The lesion is primarily fibrotic, characterized by high signal (bright) with low attenuation. The asterisks denote areas of vessel dissection secondary to balloon angioplasty.

distinct differences between these vascular beds: (1) the composition of the arterial wall and extracellular matrix is a consequence of each specific vascular bed and the physiological demands affiliated with its location and purpose, and (2) the macroscopic mechanical pressures impressed upon the peripheral vascular bed (torsion, flexion, compression, elongation, and contraction) with activities of daily living.⁷ Given these limitations in the periphery, the primary endovascular revascularization strategy is to perform balloon angioplasty with or without adjunctive DCB depending on lesion location and a primary goal of avoiding stent placement.

However, limitations exist with the mechanism of action in conventional percutaneous transluminal angioplasty (PTA). First, given the nature of a folded balloon, unraveling of the balloon folds during inflation

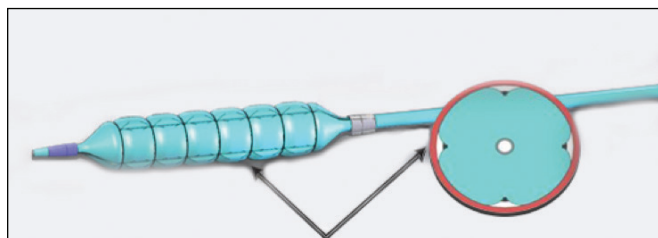


Figure 3. An artist's rendering of the Chocolate™ specialty balloon. The arrows denote the "grooves" created by the nitinol constraints once the balloon is inflated. The presence of multiple grooves create intervening "pillows."

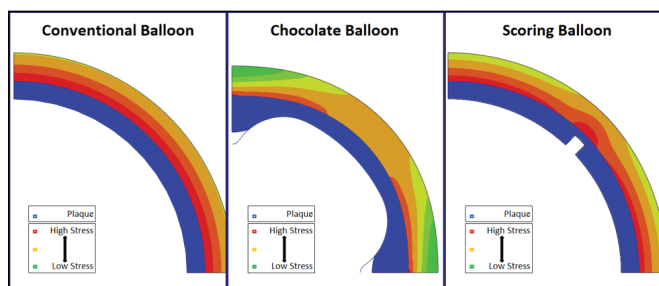


Figure 4. The simulated stress effects of a conventional balloon, the Chocolate™ balloon, and a scoring balloon on a vessel wall. The Chocolate™ balloon pillow creates less stress compared to conventional balloon, with areas of stress relieve in the groove segments. Scoring balloons create more stress than conventional balloons in a focal spot.

results in a shear stress produced upon the overlying plaque (Figure 1).⁸ Furthermore, given that there is no mechanism to control the expansion of a conventional balloon, dilation occurs in the path of least resistance. This renders vessels to be most susceptible to stress deformation and dissection at the ends of the balloon, as it "dog bones" during inflation. The consequence of these mechanisms of injury is vessel trauma (Figure 2) resulting in significant dissections and necessitating bailout stenting.

The mechanism of action in the Chocolate™ PTA balloon catheter is derived from its unique nitinol-constrained structure (Figure 3). The nitinol cage prevents the shear stress caused by unpredictable balloon unfolding, and allows for the uniform distribution of longitudinal and circumferential forces as the balloon is expanded. The "pillows" exert a gentle pressure for vessel dilation while the "grooves" created by the nitinol cage allow for stress relief (Figure 4), ultimately resulting in less wall stress compared to conventional balloon angioplasty (Figure 5). Even in severely calcified lesions, adjunctive atherectomy along with Chocolate™ PTA balloon dilation can yield optimal results without flow-limiting dissection or a need for stenting (Figure 6).

As a proof of concept, the Chocolate™ Balloon Angioplasty Registry (Chocolate BAR) was created as a prospective, core lab–adjudicated registry to analyze

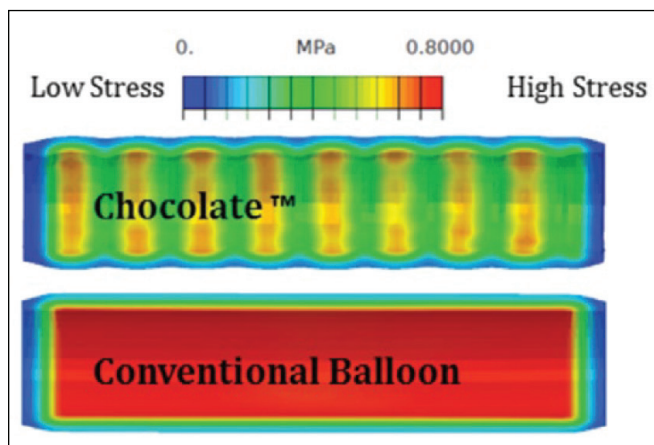


Figure 5. The cumulative vessel wall stress when dilated with a Chocolate™ balloon compared to a conventional balloon. Reprinted with permission from Ward C, Mena-Hurtado C. Novel use of pillows and grooves: the Chocolate® PTA balloon catheter. *Endovasc Today*. 2014;13:24-28.

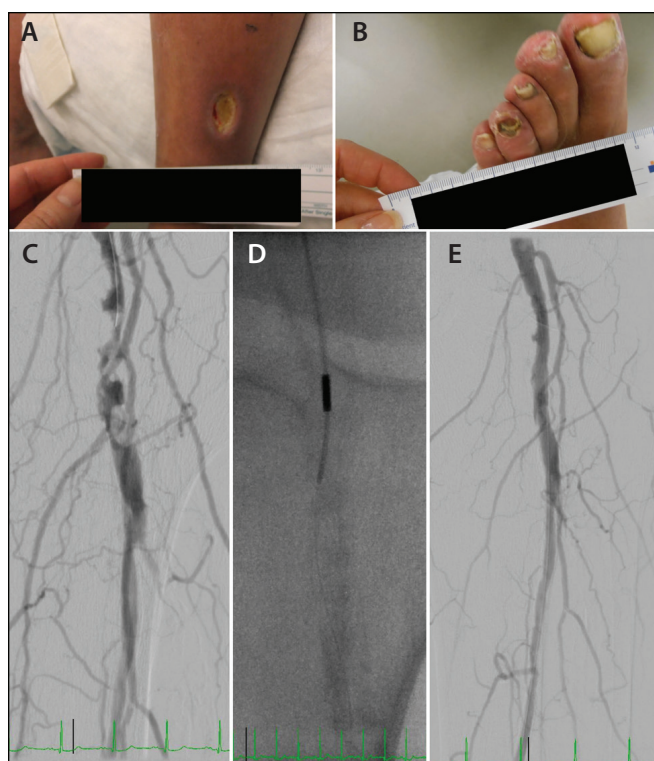


Figure 6. A 72-year-old man with previous coronary artery bypass grafting, hypertension, dyslipidemia, chronic kidney disease status post two prior kidney transplants, and diabetes mellitus. He presented with rest pain and multiple ulcers (A, B) consistent with CLI. Baseline angiographic findings showed severe calcification of the superficial femoral artery, necessitating atherectomy (C). Dilation was then performed with a Chocolate™ balloon (D). Completion angiogram with minimal, non-flow-limiting dissection (E). The patient proceeded to heal his wound in the ensuing weeks.

the effects of Chocolate™ balloon dilation in above- and below-the-knee interventions. The primary endpoint was defined as optimal ($\leq 30\%$ residual stenosis) angiographic outcomes without flow-limiting dissection, and secondary endpoints included the rate of bailout stenting, freedom from target lesion revascularization (TLR), and major amputation-free survival. The interim analysis from 2014 has shown significantly favorable results with a dissection rate of 2%, bailout stenting rate of 3%, 95% freedom from TLR, and 98% amputation-free survival at 3 months in the below-the-knee cohort.⁹

The concomitant use of a Chocolate™ specialty balloon for angioplasty along with DCB to provide adequate lesion preparation while also inhibiting neointimal hyperplasia is attractive. A recently published single-center observational study describes the use of the Chocolate™ balloon followed by DCB in patients with claudication.¹⁰ The rate of chronic total occlusion in this study population was 65.5%, approximately one-third of which was an occlusion > 150 mm in length. The rate of bailout stenting in this study was 9.5%, with an overall primary patency rate of 98.8% and freedom from TLR of 97.6% at 12-month follow-up.¹⁰ This study illustrates the importance of a symbiotic relationship between achieving satisfactory lesion preparation and expansion with antiproliferative drug deposition to improve long-term patency rates. ■

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Chocolate™ PTA Balloon Catheter

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.