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Novel Use of Pillows and Grooves: The Chocolate® PTA Balloon Catheter

Reducing trauma and improving outcomes in complex lower extremity interventions.

BY CHARISSE WARD, MD, MPH, AND CARLOS MENA-HURTADO, MD, FACC, FSCAI

Lower extremity peripheral artery disease (PAD) affects more than 8 million people in the United States and in excess of 202 million people globally. PAD is associated with a high prevalence of coincident coronary artery disease and cerebrovascular disease, which serves to increase morbidity and mortality in this population.[1-5] For patients with symptomatic lower extremity PAD, assuagement of pain, prevention of amputation, preservation of ambulatory/functional status, cardiovascular protection, and containment of health care cost are important.[6] The safety, efficacy, and lower cost of endovascular interventions compared to surgical revascularization for the treatment of PAD have been previously demonstrated.[7,8]

Balloon angioplasty, either as primary or adjunctive therapy for stents and other devices, remains the core of lower extremity endovascular intervention. The ongoing improvements in angioplasty balloon design, catheters, and stents serve to further increase acute technical success, primary patency, and long-term viability of lower extremity endovascular interventions; however, flow-limiting dissection, the need for bailout stenting, and the need for target lesion revascularization (TLR) remain frustrating concerns for the endovascular specialist.[9,10]

THE CHOCOLATE® PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER

The technique of balloon inflation during angioplasty is of paramount importance to the end result: underinflation can lead to elastic recoil, whereas over-

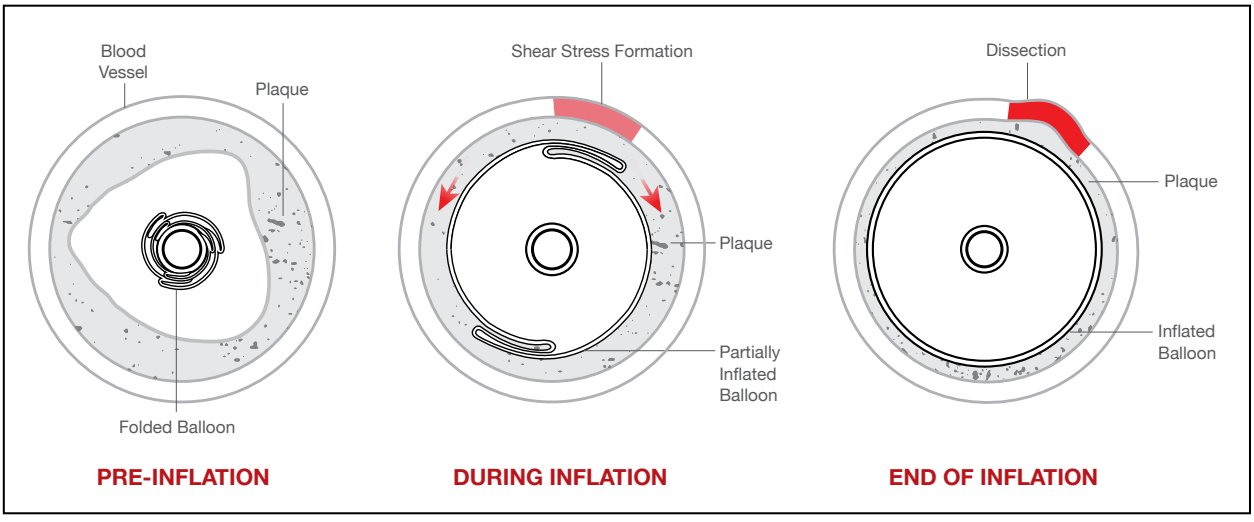

Figure 1. Torsional stress can be imparted on the vessel wall through a twisting motion when a plain balloon unfolds during inflation.

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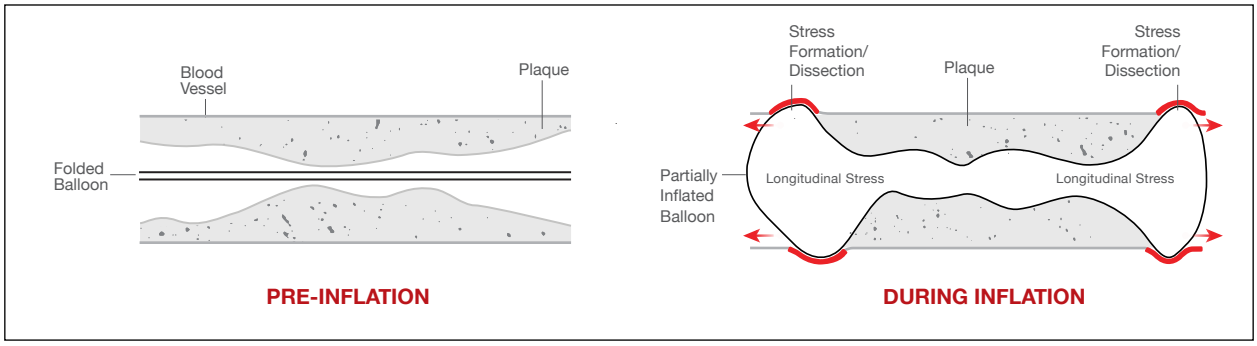

Figure 2. Longitudinal stress elongates the vessel wall when a plain balloon unfolds during inflation.

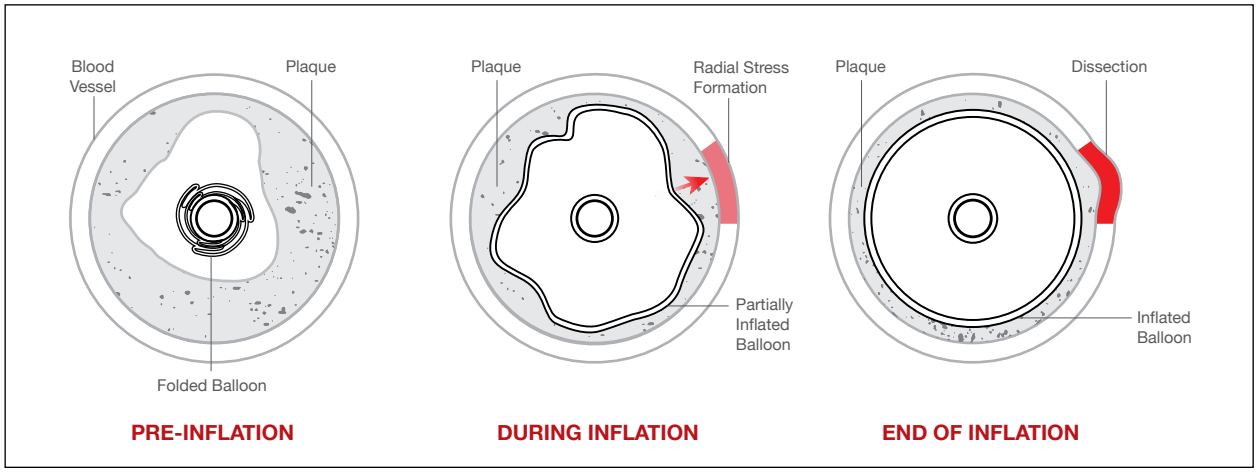

Figure 3. Radial stress outwardly expands the vessel wall when a plain balloon unfolds during inflation.

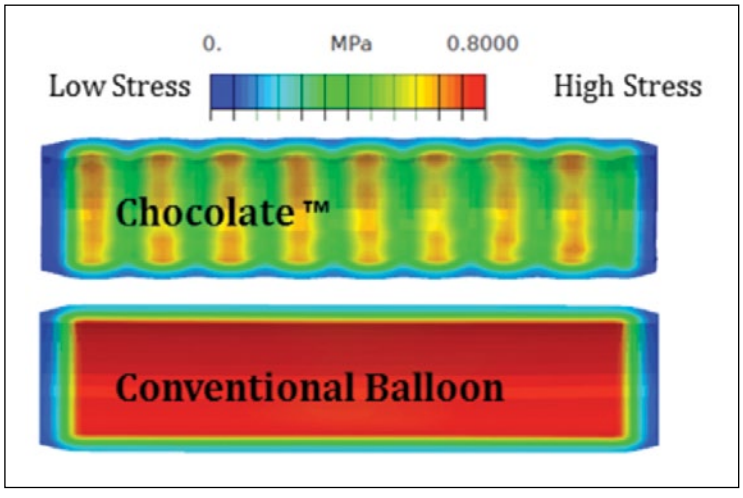

Figure 4. Finite Element Analysis of vessel wall stress of the Chocolate® PTA Balloon Catheter compared to a conventional PTA balloon catheter.

inflation can lead to neointimal hyperplasia, either of which could result in restenosis. Achieving the best possible result with angioplasty entails minimizing strain on the vessel wall. The standard angioplasty balloon unfolds with inflation, resulting in the application of force in a nonuniform manner to the stenotic lesion. Uncontrolled expansion with the standard angioplasty balloon results in increased torsional (Figure 1), longitudinal (Figure 2), and radial (Figure 3) stresses that can strain the vessel wall and lead to increased incidence of dissection, elastic recoil, and abrupt vessel closure. However, a controlled dilatation technique can help to mitigate these challenges and ultimately achieve much better flow.

The Chocolate® Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (manufactured by TriReme Medical, LLC, distributed by Cordis Corporation) is a novel balloon catheter with a mounted nitinol constraining structure specifically designed for uniform, controlled inflation and rapid deflation resulting in atraumatic dilatation without the need for cutting or scoring (Figure 4).[11]

The nitinol-constraining structure of the Chocolate® PTA Balloon creates balloon segments or "pillows" that make contact with the vessel and functions to mini-

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TABLE 1. RECENT STUDIES EVALUATING ATK ENDOVASCULAR INTERVENTIONS

Trial	Device	Average Lesion Length	Number of Patients	Flow-Limiting Dissection, n (%)	Bailout Stenting, n (%)	Target Lesion Revascularization
Chocolate® BAR, as of 2014	Chocolate PTA Balloon Catheter (Cordis)	93 mm	180	3 (< 2%)	10 (5.6%)	11% at 6 months
Bare-Metal Stents						
ABSOLUTE Schillinger et al[13]	Dynalink or Absolute (Guidant) vs PTA	132 ± 71 BMS; 127 ± 55 PTA	104	PTA group, 9 (16%)	PTA group, 17 (32%)	Binary restenosis (> 50%) at 6 months was 25% for the BMS group and 45% for PTA group
ASTRON Dick et al[14]	Astron (Biotronik GmbH) vs PTA	98 ± 54 BMS; 71 ± 43 PTA	73	PTA group, 6 (15%)	PTA group, 10 (26%)	Binary restenosis (> 50%) at 6 months was 21% for the BMS group and 50% for PTA group
RESILIENT Laird et al[15]	Lifestent (Bard Peripheral Vascular) vs PTA	71 ± 44 BMS; 64 ± 41 PTA	206	PTA group, 11 (15%)	PTA group, 29 (40.3%)	BMS group, 1.5%; PTA group, 47.4%
Drug-Eluting Stents						
SIROCCO long term Duda et al[16]	Sirolimus-coated S.M.A.R.T.® stents (Cordis) vs Uncoated S.M.A.R.T.® Stents (Cordis)	85 ± 44 DES; 81 ± 52 BMS	93	Not reported	Not reported	Binary in-stent restenosis (> 50%) at 24 months was 22% for the Sirolimus stent group and 21% for BMS group
Zilver® PTX Dake et al[17]	Zilver PTX (Cook Medical) vs PTA	66.4 ± 38.9 DES; 63.2 ± 40.5 BMS	479	Not reported	Not reported	Patency at 12 months 83% in the Zilver PTX group and 33% in the PTA group
Drug-Coated Balloons						
PACIFIER Werk et al[18]	Paclitaxel-coated In.Pact Pacific (Medtronic, Inc.) vs Uncoated Pacific Xtreme balloons (Medtronic, Inc.)	70 ± 5.3 DCB; 66 ± 5.5 uncoated balloon	85	Uncoated balloon, 25/34 (74%); DCB, 18/38 (47.4%)	Uncoated balloon, 16/47 (34%); DCB, 9/44 (20.5%)	Uncoated balloon, 21%; DCB, 7%
LEVANT Scheinert et al[19]	Lutonix DCB (Lutonix, Inc., a subsidiary of C. R. Bard) vs uncoated balloons	80.8 ± 37 DCB; 80.2 ± 37.8 uncoated balloon	101	Uncoated balloon, 10/52 (19%); DCB, 9/49 (18%)	Uncoated balloon, 6/38 (16%); DCB, 1/37 (3%)	Uncoated balloon, 10/45 (22%); DCB, 6/47 (13%)

Abbreviations: ATK, above-the-knee; BMS, bare-metal stent; DCB, drug-coated balloon; DES, drug-eluting stent; PTA, percutaneous transluminal angioplasty.

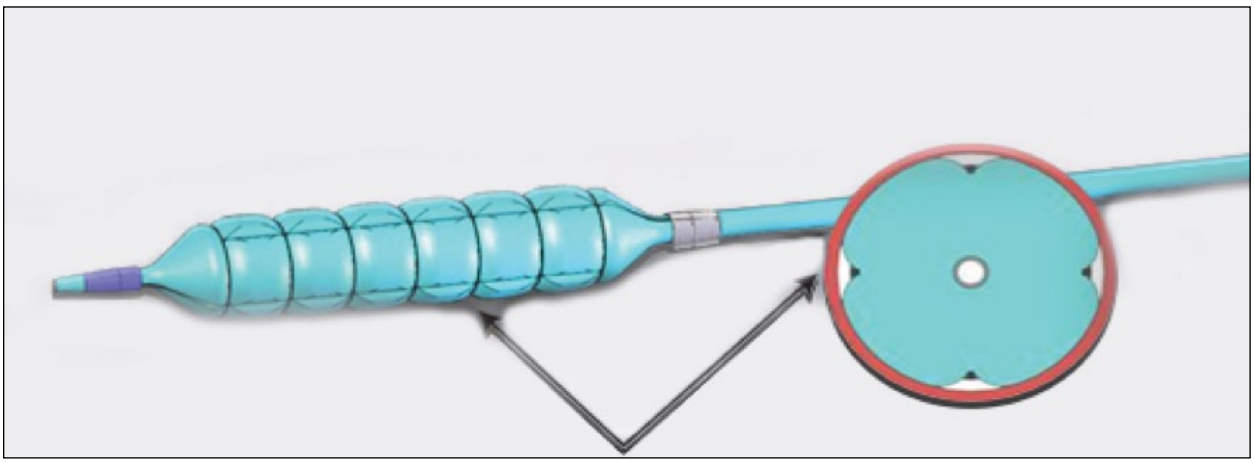

Figure 5. The Chocolate® PTA Balloon Catheter with distinctive "pillows" and "grooves" that serve to reduce vessel wall trauma.

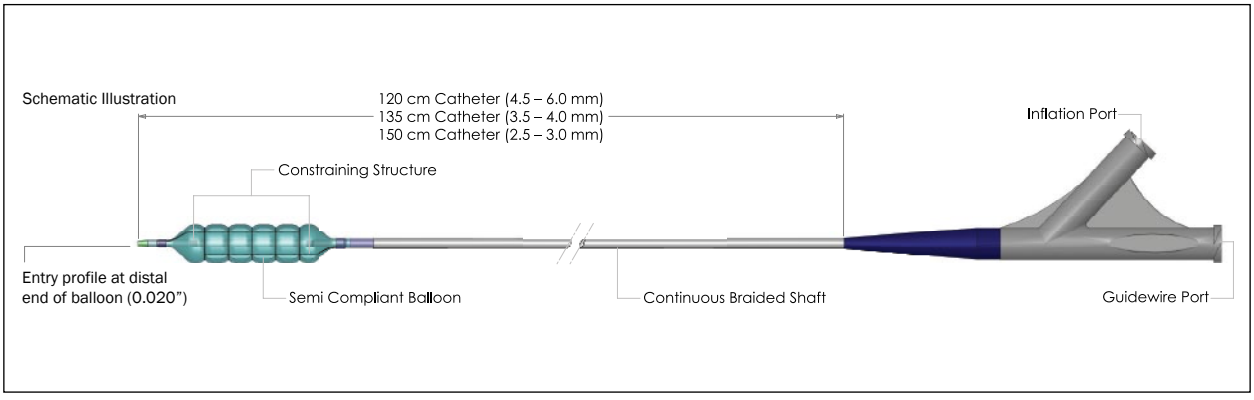

Figure 6. The Chocolate® PTA Balloon Catheter design.

mize local forces. The "grooves" facilitate plaque modification (Figure 5). The distinctive pillows and grooves serve to minimize vessel trauma, reduce the rate of dissection, and lead to a decreased need for bailout stenting.[11] In addition, the Chocolate® PTA Balloon retains a cylindrical shape while deflating and facilitates lesion recrossing after multiple inflations.

The Chocolate® PTA Balloon Catheter is an over-the-wire balloon dilatation catheter that is compatible with 0.014- and 0.018-inch guidewires. It is available in sizes to treat both above- (ATK) and below-the-knee (BTK) lesions with balloon diameters of 2.5 to 6 mm, balloon lengths of 40 to 120 mm, and catheter lengths that range from 120 to 150 cm.

CLINICAL RESULTS WITH THE CHOCOLATE® PTA BALLOON CATHETER

The Chocolate® Balloon Angioplasty Registry (BAR, Principal Investigator, Jihad A. Mustapha, MD) is a core-lab adjudicated registry with up to 500 patients from up to 40 centers. The interim data from the first 354 patients in the registry were presented at LINC 2014 by Tony Das, MD, and include 174 patients in the ATK cohort and 180 patients in the BTK cohort.

Only 2% of patients who underwent ATK interventions with the Chocolate® PTA Balloon Catheter had evidence of a flow-limiting dissection; 90% achieved < 30% diameter stenosis, and 94% achieved freedom from bailout stenting. At 6 months postintervention, 11% required TLR, 96% of patients had amputation-free survival, and 89% of patients were free of major adverse events.

The success rate for BTK interventions was similarly impressive: 99% of patients treated with the Chocolate® PTA Balloon Catheter had no flow-limiting dissections, 94% achieved < 30% diameter stenosis, and 3% required bailout stenting. At 3 months, 7% of patients required TLR, the amputation-free survival rate was 97%, and freedom from major adverse events was 90%.

CHOCOLATE® CATHETER VERSUS OTHER SPECIALTY BALLOONS AND STENTS

Over the past decade, several specialty balloons and stents have been developed to address the limitations

of conventional balloon angioplasty. To date—while there are no published randomized controlled trials comparing the Chocolate® PTA Balloon Catheter to other specialty balloons or stents, and caution must be used in cross-study comparison—the Chocolate® BAR Registry revealed that the Chocolate® PTA Balloon Catheter is safe and efficacious for long, complex, ATK and BTK lesions without the need for cutting, scoring, or stenting. The Flextome™ Cutting Balloon (Boston Scientific Corporation) has been shown to achieve better midterm patency compared to conventional PTA for focal (< 30 mm) lesions.[12] In contrast, the Chocolate® PTA Balloon Catheter has been successfully used for much longer lesions ATK and BTK. In fact, the average lesion length in the Chocolate® BAR registry was 93 mm.

For the treatment of patients with intermittent claudication or critical limb ischemia, the Chocolate® PTA Balloon Catheter is associated with 11% TLR at 6 months. The initial bare-nitinol stents were associated with significant rates of in-stent restenosis, low patency rates, and stent fractures, which may further increase the risk of in-stent restenosis.[11] The ABSOLUTE and ASTRON trials reveal a binary restenosis rate of > 20% for the bare-metal stent (BMS) group and > 45% for the PTA group at 6 months (Table 1).[13,14] The newer generation of BMS and drug-eluting stents (DES) has greater flexibility and are more fracture resistant, but in-stent restenosis and the problem of stent fracture continues to have important clinical consequences.[15-17]

Drug-coated balloons (DCBs) are designed to increase long-term patency while avoiding stent placement. The PACIFIER trial compared paclitaxel-coated In.Pact Pacific DCB (Medtronic, Inc.) versus the uncoated Pacific Xtreme™ balloons (Medtronic, Inc.). The need for TLR was 21% for the uncoated balloon and 7% for the DCB, but the rate of flow-limiting dissections and the need for bailout stenting was notable.[18] The LEVANT trial compared the Lutonix® DCB to uncoated balloons.[19] The 6-month target lesion revascularization was 22% in the uncoated balloon group and 13% for the Lutonix® DCB. The results, however, were also tempered by the rate of flow-limiting dissection and the need for bailout stenting.[19]

CONCLUSION

Balloon angioplasty, either as primary therapy in regions where stenting is avoided (eg, popliteal and infrapopliteal arteries) or as adjunctive therapy for stents and other devices, remains the mainstay of lower extremity endovascular intervention. The Chocolate® PTA Balloon Catheter has proven to be safe, highly deliverable, and efficacious in ATK and complex BTK interventions with a low rate of dissections and low need for bailout stenting or TLR at 3- and 6-month follow-up. The Chocolate® PTA Balloon Catheter is indicated for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries. It is not indicated for use in the coronary or cerebral vasculature. ■

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