

THE CHOCOLATE® PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER

The following section has been adapted from an article published by Charisse Ward, MD, and Carlos Mena-Hurtado, MD, in the May 2014 issue of Endovascular Today, available online at bit.ly/EVTChocolate.

The technique of balloon inflation during angioplasty is of paramount importance to the end result: underinflation can lead to elastic recoil, whereas over-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.¹

The nitinol-constraining structure of the Chocolate® PTA Balloon cre-

ates balloon segments or “pillows” that make contact with the vessel and functions to minimize local forces. The “grooves” facilitate plaque modification (Figure 4). The distinctive pillows and grooves serve to minimize vessel trauma, reduce the rate of dissection, and lead to a decreased need for bailout stenting.¹ In addition, the Chocolate® PTA Balloon retains a cylindrical shape while deflating and facilitates lesion recrossing after multiple inflations.

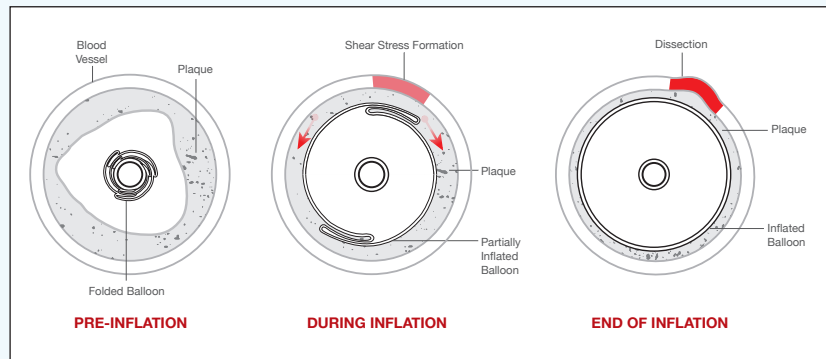


Figure 1. Torsional stress can be imparted on the vessel wall through a twisting motion when a plain balloon unfolds during inflation.

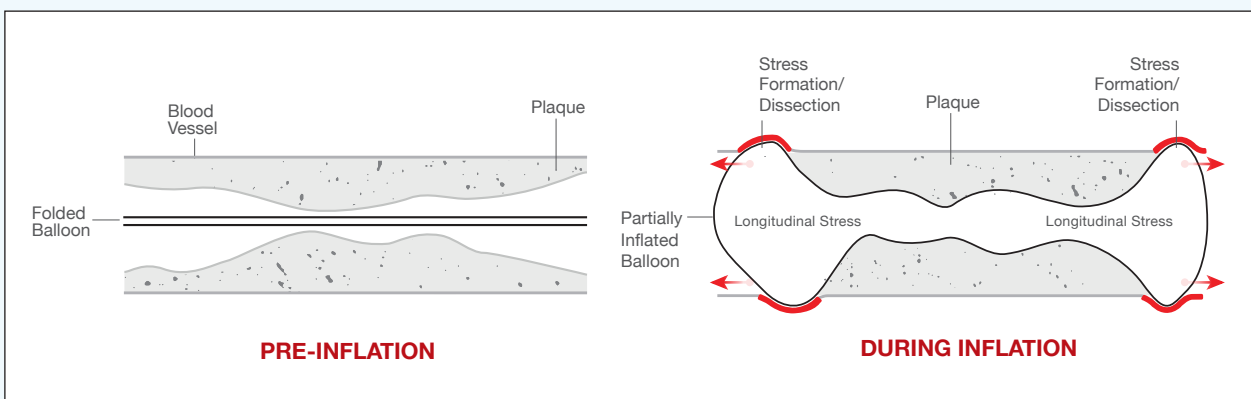


Figure 2. Longitudinal stress elongates the vessel wall when a plain balloon unfolds during inflation.

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 (Figure 5).

CLINICAL RESULTS WITH THE CHOCOLATE® PTA BALLOON CATHETER

The Chocolate® Balloon Angioplasty Registry (BAR, Principal Investigator, J. 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%. ■

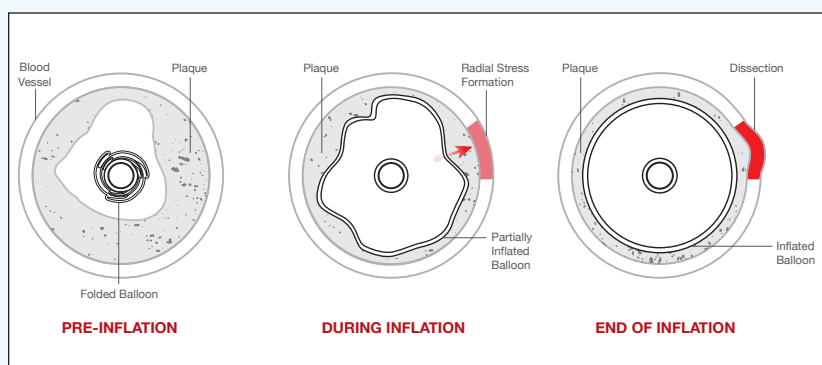


Figure 3. Radial stress outwardly expands the vessel wall when a plain balloon unfolds during inflation.

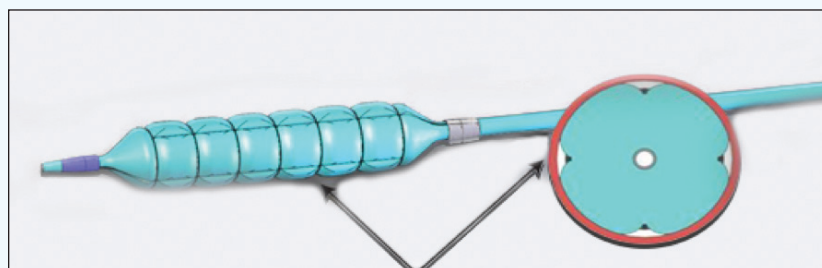


Figure 4. The Chocolate® PTA Balloon Catheter with distinctive “pillows” and “grooves” that serve to reduce vessel wall trauma.

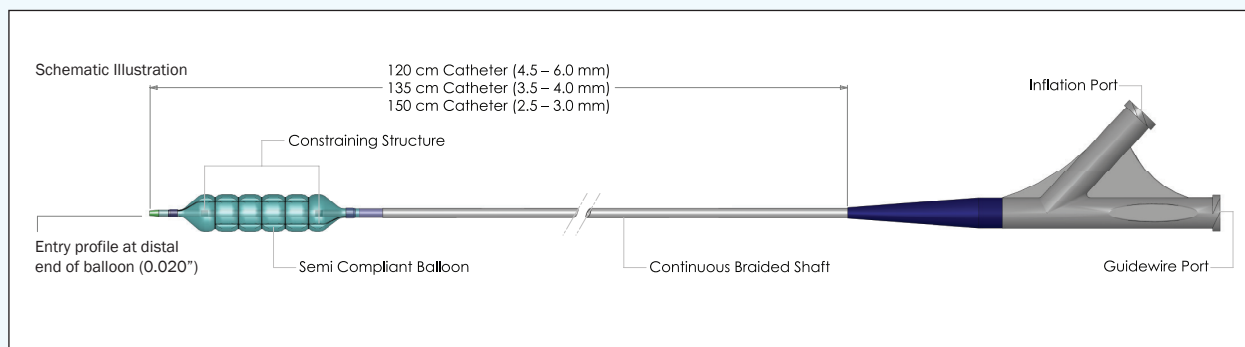


Figure 5. The Chocolate® PTA Balloon Catheter design.

1. Schillinger M, Minar E. Percutaneous treatment of peripheral artery disease: novel techniques. *Circulation*. 2012;126:2433–2440.