Introduction

By Jeffrey W. Chambers, MD

Calcified coronary arteries remain one of the most difficult types of lesions to treat. The disease states that are predictive of coronary artery calcification, including advanced age, diabetes, smoking, chronic kidney disease, hypertension, hyperlipidemia, gender, ethnicity, and body mass index, are on the rise.[1,2] Currently, calcification is found in an estimated 40% to 70% of imaged lesions,[3] and severe calcification is present in 6% to 20% of coronary artery disease patients.[4,5] These rates are expected to increase over the next 10 years.

It is challenging to achieve optimal results in severely calcified lesions with percutaneous coronary intervention, and it is difficult to completely dilate calcified plaques because the process may lead to underexpansion or malapposition.[2,6,7] Calcified occlusions are prone to dissection during balloon angioplasty or predilatation.[8] Delivering a stent to the desired location and calcium may result in stent distortion and insufficient drug penetration.[2,9,10] Patients are often referred to bypass surgery due to the potential for adverse outcomes (both short and long term) related to treating severe coronary calcification.[5,11-13] Fortunately, the availability and optimization of coronary atherectomy has allowed many patients to be treated successfully.

In 2013, the Diamondback 360® Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc.) was approved by the United States Food and Drug Administration for the treatment of de novo, severely calcified coronary artery lesions. In nearly a decade of clinical use, refinements in technique, including integration of imaging strategies along with a growing body of evidence and continuous innovation of the device platform, have enhanced outcomes with orbital atherectomy.[14]

The OAS uses a unique dual mechanism of action that combines differential sanding and pulsatile forces to sand intimal lesions and fracture medial calcium, thereby allowing optimal stent expansion.[11,14] A single Diamondback® device treats vessels from 2.5 to 4.0 mm in diameter. Differential sanding protects soft tissue, while continuous flow of blood and saline during treatment reduces the risk of slow flow and no reflow events. Because of this, a single Diamondback device can safely treat a broad range of lesions with concentric, eccentric, and nodular calcium.

Diamondback utilization and therapy has evolved from early experience and clinical trials. The ORBIT I and ORBIT II clinical trials, as well as 11 major studies, including real-world multicenter studies enrolling approximately 1,000 patients,[15,16] have constantly demonstrated the long-term safety and efficacy of coronary OAS

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for the treatment of severely calcified coronary lesions prior to stent delivery, with low procedural complication rates and low rates of revascularization through 3 years.[11,14,15,17,18]

The evidence supporting orbital atherectomy continues to expand. The prospective, randomized, multicenter ECLIPSE trial (NCT03108456) is currently enrolling. ECLIPSE will evaluate vessel preparation with Diamondback compared to conventional balloon angioplasty technique prior to drug-eluting stent implantation in severely calcified coronary artery lesions. Approximately 2,000 patients with severely calcified coronary lesions will be enrolled at approximately 150 sites in the United States.

This series of articles provides insight into the contemporary practice and use of the Diamondback® system. ■

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Jeffrey W. Chambers, MD
Metropolitan Heart & Vascular Institute
Coon Rapids, Michigan
j.chambers@mhvi.com