

Objective

To assess the dual mechanism of action with Diamondback 360 Coronary Orbital Atherectomy System (OAS) on both superficial and deep severe calcium in coronary artery lesions assessed with Optical Coherence Tomography (OCT).

Background

- Treatment of calcified coronary lesions can be very challenging and without proper lesion preparation achieving optimal results post stent implantation can be difficult.
- To this end we want to evaluate the efficacy of the Diamondback 360 Coronary Orbital Atherectomy System (OAS) with a prespecified treatment algorithm. (Mandatory 3 runs of OAS at 80,000rpm, pre and post OAS imaging with OCT (Optical Coherence Tomography) system prior to stenting in coronary vessels more than 2.5 mm.

Images



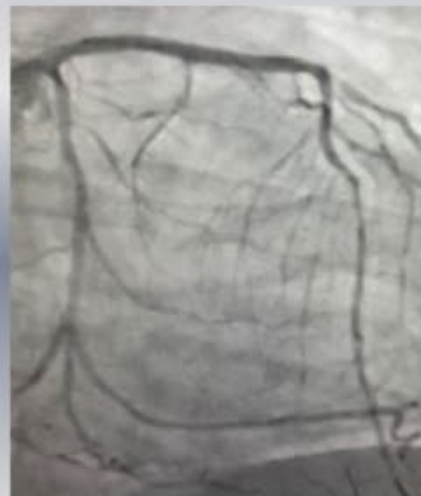
Pre OA-OCT



Post OA-OCT



Pre OA



Post OA

Methods

20 consecutive patients with calcific lesions identified on coronary angiogram (STEMI excluded) were evaluated in this prospective observational single operator study. The calcific lesions in all patients were further evaluated with OCT prior to atherectomy. Patients with vessel diameters of larger than 2.5 mm and ≥ 180 degrees of calcium via OCT were included for the study. After OCT confirmed the severity of calcium, orbital atherectomy was utilized. Three runs were performed for an average of 25 seconds per run. After atherectomy with OAS, reimaging with OCT was performed to assess the lesion modification by dual mechanism of action with OAS system.

Results

In 100 % of patients post atherectomy, OCT confirmed that calcium fracture effecting both superficial and deep calcium (defined as fissures, craters, and in some typical smooth concave ablation). Stent Delivery and subsequently stent expansion occurred in all patients successfully without any complications.

Conclusion

Using intravascular imaging such as OCT to identify lesions that would benefit from vessel preparation, as done here, is a key factor in ensuring procedural success. In these lesions, the use of OAS helped to facilitate stent delivery and appropriate stent expansion through its dual mechanism of action that sands intimal calcium and fractures deep calcium.

Coronary Brief Statement

Indications: The DIAMONDBACK 360[®] Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions.

Contraindications: The OAS is contraindicated when the VIPERWIRE[®] guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children.

Warnings/Precautions: Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS was only evaluated in severely calcified lesions, A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25% has not been evaluated.

See the instructions for use before performing DIAMONDBACK 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

CSI, Diamondback, Diamondback 360, ViperWire, ViperWire Advance, and Be Calculated are registered trademarks of Cardiovascular Systems.