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ONE LIFE
ONE DESTINATION
CARDIAC SCIENCE
MARENGO CIMS HOSPITAL

Marengo CIMS Hospital
HUMANE BY PRACTICE

HEALTHY HEART

VOLUME-16 | ISSUE-182 | JANUARY 05, 2025

Price : ₹ 5/-

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Honorary Editor :

Dr Tejas V Patel
MD, DM Cardiology (Gold Medalist)
Senior Interventional Cardiologist
Ex. Assist. Prof. CMC Vellore
Fellow in Structural
Heart Intervention (Hungary)

Shattering Barriers: Orbital Atherectomy in Tackling Calcified Coronary Lesions

Plaque modification techniques are crucial for the optimal treatment of calcified coronary lesions. Among these techniques, atherectomy plays an important role by enabling the crossing of very tight stenoses and facilitating stent implantation and optimal expansion. Currently, two atherectomy tools are available in clinical practice: Rotational Atherectomy (RA), which has been extensively investigated for nearly four decades; and Orbital Atherectomy (OA), a more recent addition to the field.

CORONARY ARTERY CALCIFICATION (CAC)

Coronary artery calcification (CAC) is a rising issue among the modern population. The prevalence of this problem is linked to many factors, such as the older age of the patients; increased morbidity of diabetes mellitus, chronic kidney disease, dyslipidemia, and hypertension; cigarette smoking; and others. CAC is a pathological process, associated with the progression of advanced atherosclerosis. The precursory part of CAC is associated with the death of the macrophages and smooth muscle cells, as well as the remaining necrotic debris, serving as nucleating sites for calcium phosphate crystal formation.

Severely calcified coronary arteries are technically challenging. They are difficult to treat and can lead to increased complications.

Calcified lesions:

- Are prone to dissection during balloon angioplasty or pre-dilation,
- Are difficult to completely dilate,
- Can prevent stent delivery to the desired location,
- Can prevent adequate stent expansion, and
- Can preclude drug delivery when using a DES.

Cardiologists

Dr Vipul Kapoor	(M) +91-98240 99848
Dr Tejas V. Patel	(M) +91-89403 05130
Dr Hiren Kevadiya	(M) +91-98254 65205
Dr Gunvant Patel	(M) +91-98240 61266
Dr Keyur Parikh	(M) +91-98250 26999
Dr Milan Chag	(M) +91-98240 22107
Dr Urmil Shah	(M) +91-98250 66939
Dr Hemang Baxi	(M) +91-98250 30111
Dr Anish Chandarana	(M) +91-98250 96922
Dr Ajay Naik	(M) +91-98250 82666
Dr Satya Gupta	(M) +91-99250 45780
Dr Vineet Sankhla	(M) +91-99250 15056

Cardiothoracic & Vascular Surgeons

Dr Dhiren Shah	(M) +91-98255 75933
Dr Dhaval Naik	(M) +91-90991 11133
Dr Amit Chandan	(M) +91-96990 84097
Dr Nikunj Vyas	(M) +91-73531 65955

Congenital & Structural Heart Disease Specialist

Dr Kashyap Sheth	(M) +91-99246 12288
Dr Milan Chag	(M) +91-98240 22107

Paediatric & Structural Heart Surgeon

Dr Shaunak Shah (M) +91-98250 44502

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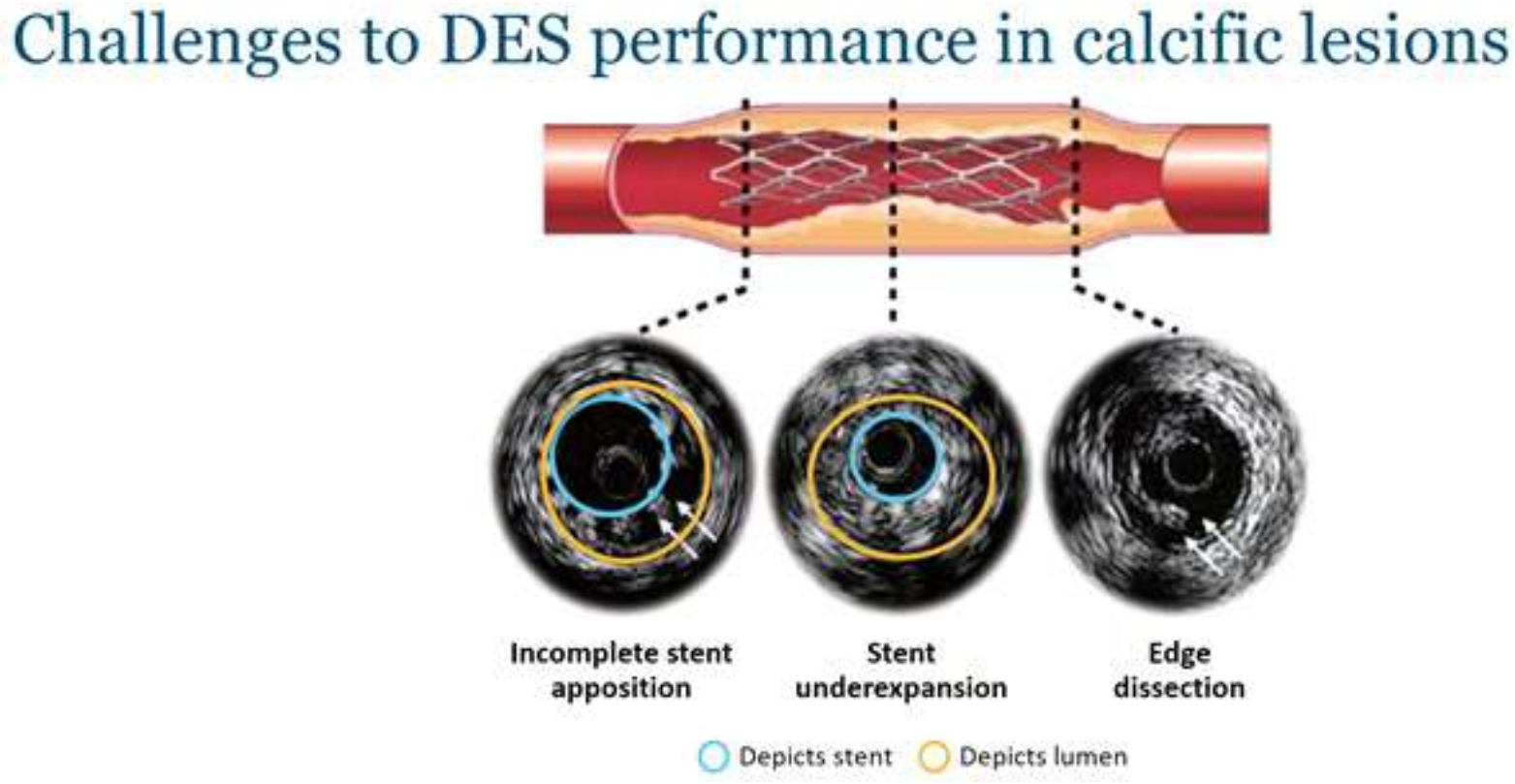
Dr Pranav Modi (M) +91-99240 84700

Cardiac Anaesthetists

Dr Niren Bhavsar	(M) +91-9879571917
Dr Hiren Dholakia	(M) +91-9586375818
Dr Chintan Sheth	(M) +91-9173204454

Cardiac Electrophysiologist

Dr Ajay Naik	(M) +91-98250 82666
Dr Hiren Kevadiya	(M) +91-98254 65205

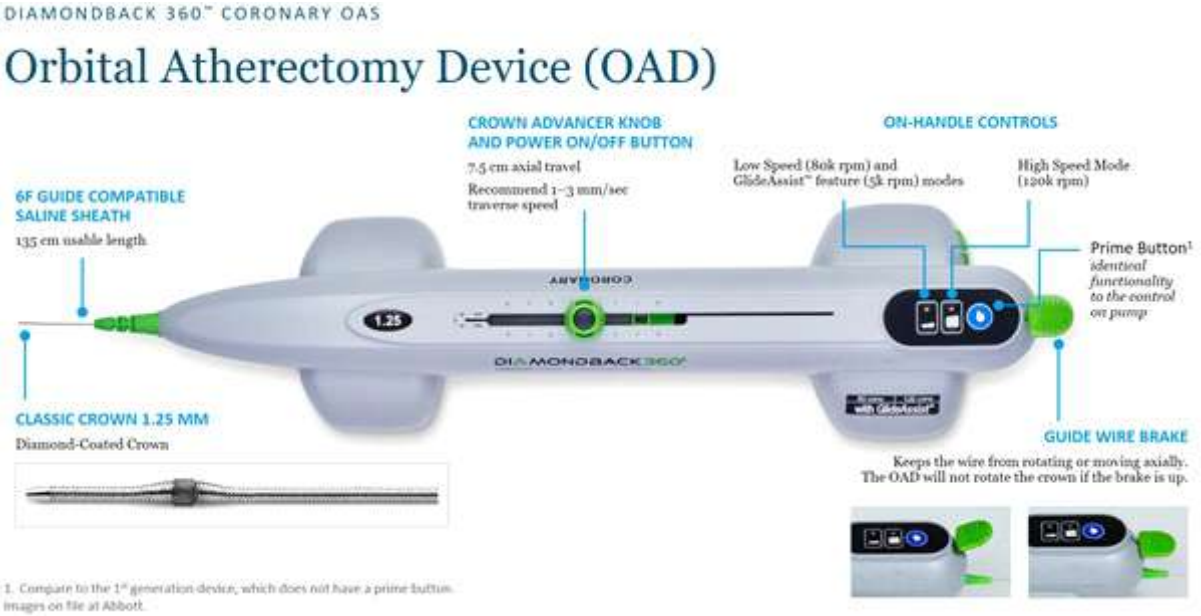


CORONARY ORBITAL ATHERECTOMY (OAS) COMPONENTS

The Diamondback 360™ Coronary Atherectomy System is a percutaneous system indicated to facilitate stent delivery in patients with coronary artery disease who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions.

The system consists of:

- The Orbital Atherectomy Device, which features a 1.25 millimeter classic crown and is compatible with a 6 French guide.
- The Orbital Atherectomy System Pump.
- ViperWire Advance™ or ViperWire Advance™ with Flex Tip coronary guide wire, And ViperSlide™ lubricant.



MECHANISM OF ACTION

Diamondback 360™ is uniquely designed for calcium. It enables simultaneous modification of both intimal and medial calcium for optimal stent delivery, expansion, and apposition in severely calcified lesions.

One device treats eccentric, concentric, and nodular calcium. Through differential sanding, healthy elastic tissue flexes away from the crown, which may minimize damage to the vessel. The crown's orbital motion delivers pulsatile energy at a controllable, predictable rate. Prepping calcified lesions with the Diamondback 360™ Coronary OAS sands superficial calcium and fractures deep calcium.

The crown's movement allows blood and saline to flow continuously during treatment, minimizing risk of thermal injury and slow flow/no reflow events. The diamond-coated crown sands intimal calcium into particulate with an average size of approximately two microns, which is smaller than a capillary vessel.

Calcium modification with OAS optimizes stent delivery, expansion and wall apposition and provides physicians a high rate of procedural results in the most challenging lesions and long-term success.

DUAL ACTION

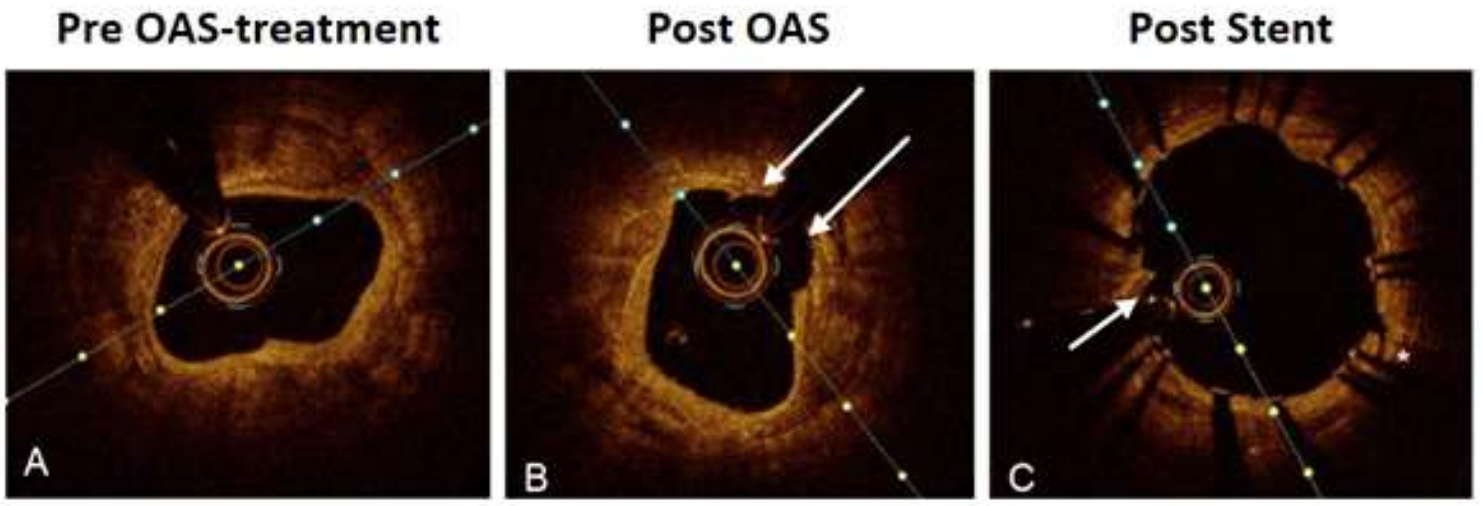
ATHERECTOMY -> Bi-directional Differential Sanding reduces superficial calcium

CALCIUM MODIFICATION -> Pulsatile forces from eccentric-mounted mass may contribute to compliance change

BI-DIRECTIONAL DIFFERENTIAL SANDING[1] REDUCES SUPERFICIAL CALCIUM

- Intimal calcium is sanded by diamond-coated surface[1]
- Differential sanding reduces calcified plaque while potentially minimizing damage to the medial layer of the vessel[1]
- Based on the carbon block model, **98.3% of particles** generated are < **red blood cell with an average particulate size of ~ 2 µm** (microns)[2]

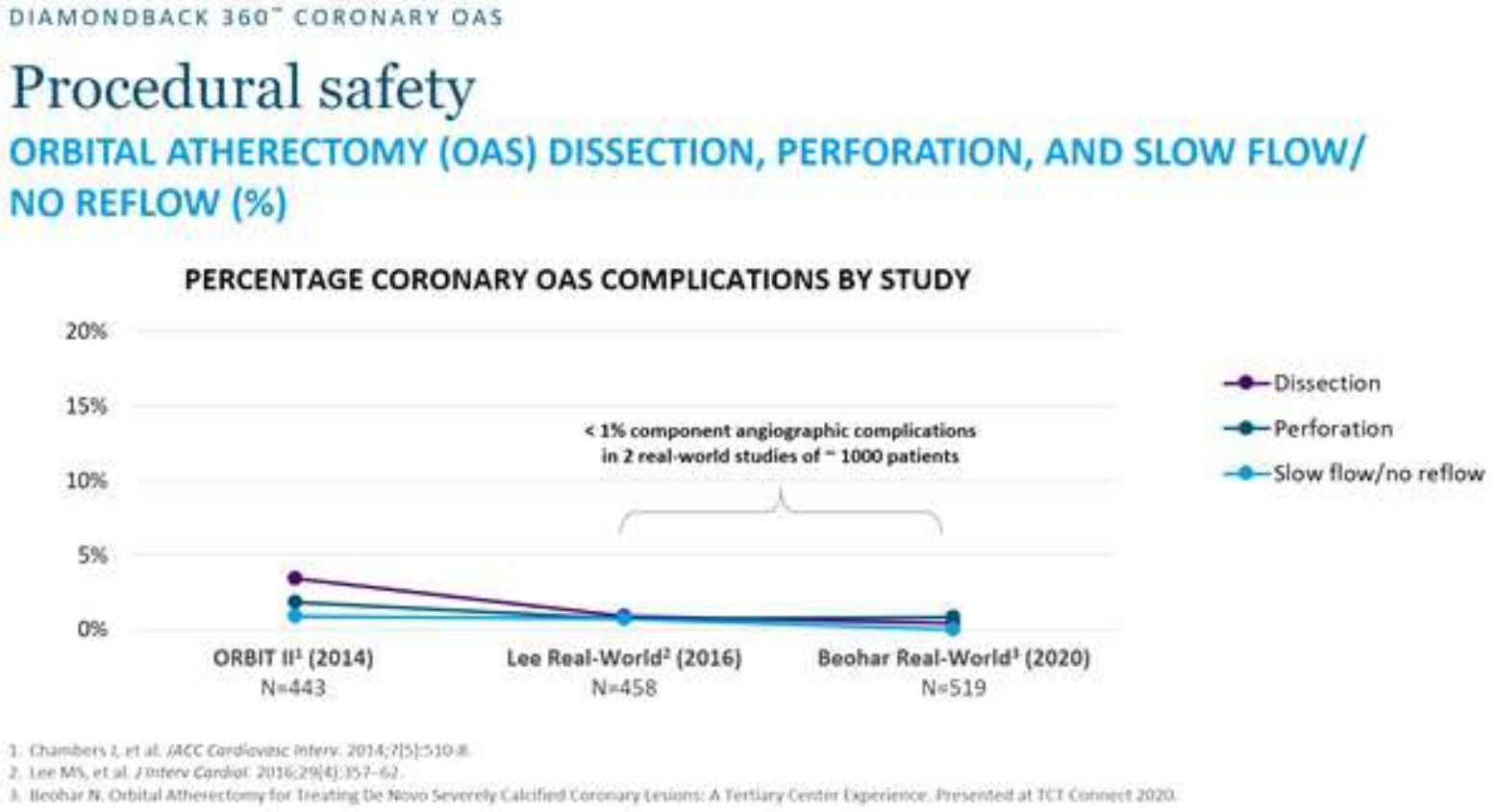
Crown surface:
30-micron diamonds,
10-micron exposed



Example: Pre OAS-treatment (A), post OAS (B), and post stent (C). Post OAS (B) shows characteristic calcium reduction at the white arrows, followed by calcium fracturing observed post stent (C) at the white arrows. Images courtesy of Evan Shlofmitz, MD.

SAFETY

This graph compares the procedural safety results between the ORBIT II study, Lee's Real-World Multicenter Registry study, and Beohar's Real-World Study at Mt. Sinai. As shown, both Lee's and Beohar's studies had less than 1% component angiographic complications of over 1000 patients.



1. Chambers J, et al. *JACC Cardiovasc Interv.* 2014;7(5):510-8.
2. Lee MS, et al. *J Interv Cardiol.* 2016;29(4):357–62.
3. Beohar N. Orbital Atherectomy for Treating De Novo Severely Calcified Coronary Lesions: A Tertiary Center Experience. Presented at TCT Connect 2020.

HOW TO CHOOSE THE RIGHT DEVICE?

		Rotational Atherectomy	Orbital Atherectomy	IVL
Mechanism of Action	Device	Rotating burr (140,000–160,000 rpm)	Rotating crown (80,000–120,000 rpm)	Emits sonic waves (80–120 impulses)
	Temporal vessel occlusion	+	-	++
	Tight stenosis	+	+	-
	Wire bias	+	-	-
	Modifies deep calcium	-	+	+
Periprocedural complications	Wire entrapment	+	+	-
	No-/slow-flow risk	High	Low	No
	Dissection	+	+	Rare
	Perforation	+	+	Rare

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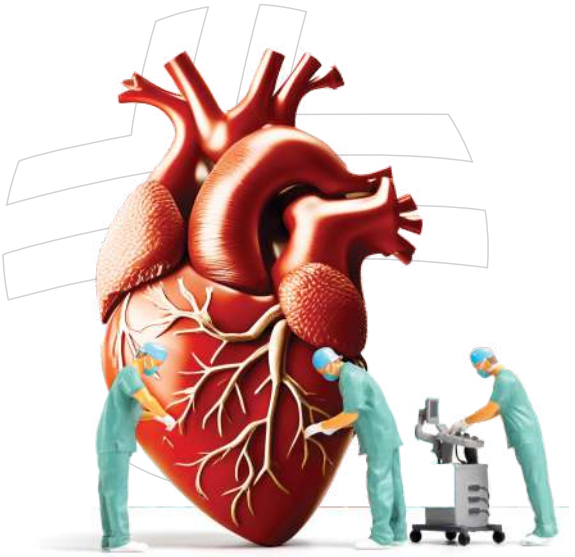

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- Percutaneous Intervention for Structural heart diseases TAVI/TAVR
- Electrophysiology Studies • Left Ventricular Assist Device (LVAD) Implantation
- Balloon Valvuloplasty

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- Minimally Invasive Heart Surgery (MICS) • Bypass Surgery (CABG) • Aortic Surgery
- Heart Valve Surgery • Heart Failure Surgery • Robotic Bypass Surgery
- Paediatric Cardiac Surgery

Disease-Specific Clinics

- Heart Transplant Clinic
- STEMI initiative
- Structural and Valvular Clinic & STROKE Centre
- Heart Failure Clinic
- Arrhythmia Clinic
- Cardio-Oncology Clinic

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Welcomes

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Consultant Liver Transplant Programme

Dr Keval Patel
MBBS, MS, DNB (Urology)
Consultant Robotic Uro-Onco Surgeon

Dr Mansi Shah
MBBS, MD DVL (Dermatology, Venereology and Leprology)
Consultant Dermatologist

Dr Krunal Solanki
MS, FMAS, FIAGES, FALS
Consultant Laparoscopic and Robotic General and AWR Surgeon

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THE PIONEER AND LEADER IN LAUNCHING
THE TAVI PROGRAM IN GUJARAT SINCE 2015

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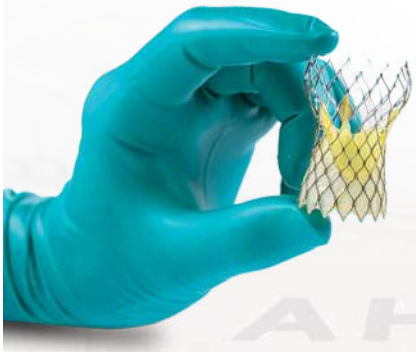
56 TAVI
Transcatheter Aortic Valve Implantation (TAVI)
7 TMVR
Transcatheter Mitral Valve Replacement (TMVR)



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