

# Intravascular imaging-guided treatment of severe coronary artery calcification with orbital atherectomy: A prospective single-centre registry

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## ABSTRACT

**Introduction:** Coronary artery calcification can lead to suboptimal results when performing coronary angioplasty with conventional techniques. The presence of severe coronary artery calcium increases the complications of percutaneous coronary intervention as it may impede stent delivery and optimal stent expansion. The purpose of this study was to determine the procedural success and safety of orbital atherectomy (OA) in calcified lesions.

**Materials and Methods:** This was a prospective single-centre study regarding the utility of OA in the treatment of calcified coronaries. Intravascular ultrasound (IVUS) or optical coherence tomography (OCT) was used in all cases to characterise the severity of calcium pre-procedure, guide vessel sizing and assess procedural success. The primary endpoint was procedural success, defined by successful stent implantation following OA treatment. The secondary endpoint was in-hospital and 30-day major adverse cardiovascular event (MACE).

**Results:** Ten patients with severely calcified lesions were successfully treated with OA. The primary endpoint was achieved in all patients. All of the lesions were severely calcified with concentric calcium. None of the patients suffered in-hospital or 30-day MACE. The average minimal luminal diameter at baseline was  $1.7 \pm 0.3$  mm and the post-PCI luminal diameter was  $3.0 \pm 0.3$  mm, with a significant luminal gain of  $1.3 \pm 0.3$  mm ( $p < 0.01$ ). Slow flow during procedure occurred in 2 (20%) cases and dissection occurred in 1 (10%) case during procedure. These were successfully treated with stent delivery to achieve TIMI III flow. There were no cases of stent thrombosis or vessel perforation.

**Conclusion:** Our experience demonstrates the feasibility and safety of OA in the management of calcified coronary stenosis. Intravascular imaging is an important adjunct to the use of OA to assess the severity of calcified coronary lesions, success of OA treatment and to aid sizing of the vessel for stent implantation. OA is an effective treatment approach to disrupt coronary calcification, facilitating stent implantation with optimal results. It is a safe procedure with good success rate and low rate of complications.

## KEYWORDS:

*Orbital Atherectomy; Intravascular Imaging; Intravascular Ultrasound; Optical Coherence Tomography; Coronary artery calcification*

## INTRODUCTION

Coronary artery calcification occurs due to the deposition of calcium in the arterial wall and is associated with increasing age and co-morbidities.<sup>1,2</sup> Severe calcification occurs in 10–20% of cases of ischaemic heart disease.<sup>3</sup> Severe coronary artery calcification is associated with an increased risk of major adverse cardiac events (MACE), including death and myocardial infarction.<sup>4,5</sup> Calcification poses difficult challenges to coronary angioplasty since plaques are difficult to cross and pre-dilate with conventional devices.<sup>6</sup> Severe calcification may also limit optimal stent expansion thus leading to increased risk of restenosis and stent thrombosis. The difficulty in dilating a calcified lesion may require the use of high-pressure non-compliant (NC) balloons and cutting balloons which pose risks of dissection or arterial perforation.<sup>7,8</sup> Additionally, inadequate stent expansion may lead to malapposition of stent struts<sup>9</sup> and subsequent stent thrombosis and early stent restenosis.<sup>10</sup> There has thus been a need for alternative calcium modification techniques, including rotational atherectomy, orbital atherectomy (OA) and intravascular lithotripsy.<sup>11</sup>

The Diamondback 360 Coronary orbital atherectomy system (Cardiovascular Systems, Inc., Saint Paul, MN, USA) consists of a diamond-coated crown which spins (orbits) and removes a thin layer of plaque as it comes into contact with a lesion. OA is designed to selectively ablate calcium while minimising treatment of soft non-calcified plaque.<sup>12</sup> Preparation prior to percutaneous coronary intervention (PCI) of calcified lesions with OA can improve changes of optimal stent delivery and stent expansion. Although atherectomy devices have classically been used for calcified lesions which are difficult to cross, the focus has more recently shifted to lesion preparation in order to optimise results in PCI. The aim of lesion preparation is to modify the plaque and change its morphology with the aim of achieving good stent expansion. Intravascular imaging techniques such as intravascular ultrasound (IVUS) or optical coherent tomography (OCT) are often performed alongside OA treatment to evaluate the

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extent of calcification and post-procedure as well as to demonstrate calcium fractures and evaluate procedural success.<sup>13</sup>

The use of OA is gradually increasing but currently there is limited real-world data published in Asia. In this study, we describe the data of a prospective registry in a single centre for the use of OA to treat severely calcified coronary artery lesions.

## MATERIALS AND METHODS

### *Patients and Study Design*

The Prospective Registry of Calcified Coronary Artery Lesions undergoing Atherectomy is a single-centre registry. Approval for the study was granted by Independent Ethics Committee of Ramsay Sime Darby Healthcare. Anonymised data between Mar 2021 and Mar 2022 was collected by medical record review and all patients gave written informed consent for inclusion into the registry. Baseline characteristics of patients including age, cardiac risk factors, clinical presentation, left ventricular ejection fraction (EF) and baseline renal function were documented.

### *Intravascular Imaging*

Intravascular imaging with either OCT or IVUS was used in all OA cases. Calcium on OCT was defined as a signal-poor region with sharply delineated borders.<sup>14</sup> Calcium on IVUS was defined as a (hyperechoic) lesion with brighter shadow than reference adventitia.<sup>15</sup> Measurements of pre and post-PCI minimal luminal diameter (MLD), minimal luminal area (MLA) and stent cross-sectional area (CSA) were recorded. Calcium scoring systems were used in both intravascular imaging modalities to ascertain the severity of calcium to determine the need for OA treatment.

The OCT-based calcium scoring system (Fig. 1, Table I) is calculated with the following criteria (also known as Rule of 5s): 2 points for maximum calcium angle  $> 180^\circ$  (i.e.  $>50\%$  vessel arc), 1 point for maximum calcium thickness  $> 0.5$  mm, and 1 point for calcium length  $> 5$  mm, for a total calcium score of 0–4 points.<sup>16</sup> Severe calcium with an OCT score of 3 and above predicts an 80% chance of stent underexpansion.

The IVUS-based scoring system (Fig. 1, Table I) is calculated with the following: 1 point for circumferential calcium =  $360^\circ$ , 1 point for calcium arc  $> 270^\circ$  that is  $> 5$  mm in length, 1 point for vessel size (media-to-media)  $\leq 3.5$  mm adjacent to the maximum calcium, and 1 point for a calcific nodule (convex shape on luminal side of calcium).<sup>17</sup> Severe calcium with an IVUS score of 3 and above predicts a significant risk of stent underexpansion.

A score of  $\geq 3$  for both OCT and IVUS scoring systems is regarded as an indication for OA.

IVUS or OCT were also used to assess the effect of atherectomy. Effective post-OA calcium modification is identified on IVUS or OCT as the presence of a new disruption or discontinuity in the calcium arc (fractures).

### *Percutaneous Coronary Intervention*

All patients were given dual-antiplatelet therapy and received intra-arterial heparin for anticoagulation during the PCI procedure. The coronary OA device (Cardiovascular Systems, Inc. [CSI], St Paul, MN) is advanced over a 0.014 guidewire (ViperWire, CSI) with the concomitant use of a lubricant, ViperSlide (CSI). OA was commenced with low speed (80,000 rpm) in all cases with some cases requiring subsequent high-speed (120,000 rpm) atherectomy. The recommended duration of each OA pass was 20 seconds or less. After atherectomy, predilatation angioplasty and PCI were performed with stent implantation. Following PCI, all patients were given dual antiplatelet therapy with either aspirin 100 mg, clopidogrel 75mg or ticagrelor 180 mg/day for 12 months.

### *Endpoints*

The primary end point was procedural success, defined as successful OA treatment and stent implantation with  $<30\%$  residual stenosis. The secondary endpoint was in-hospital MACE, including cardiac death, myocardial infarction (MI), or target-vessel revascularisation (TVR) and 30-day MACE.<sup>18</sup> Safety outcome was procedural complication, defined as coronary dissection, slow or no reflow, stent thrombus or vessel perforation.

### *Statistical Analysis*

Descriptive statistics including mean and percentages were used. Categorical variables are presented as counts (%) and continuous variables are presented as mean  $\pm$  standard deviation (SD). The paired t-test was used for the comparison of MLD at baseline and after PCI. A *p* value of  $\leq 0.05$  was considered significant.

## RESULTS

### *Baseline Characteristics*

Between March 2021 and March 2022, 10 patients with severely calcified lesions were treated with OA. The baseline characteristics of the patients are shown in Table II. Mean age was  $57 \pm 11$  years, with a high prevalence of risk factors of hypertension and hypercholesterolaemia. The mean ejection fraction on echocardiogram was  $60.4 \pm 4.9\%$ .

### *Procedural Characteristics*

The procedural characteristics are shown in Table III. Femoral vascular access was preferred in majority of cases. The target artery was the left anterior descending coronary artery in all patients and the left main was treated in two patients. All of the lesions were severely calcified with a calculated OCT or IVUS score of 3 and above. 6 (60%) cases had one stent used, while two stents were used in 4 (40%) of cases. The median number of OA passes was 4 per case. OCT and IVUS cases pre- and post-OA showing effective atherectomy are shown in Figure 2. The angiogram images for a case of heavily calcified LAD artery effectively treated with OA are shown in Figure 2.

### *Clinical Outcomes*

The primary endpoint of procedural success was achieved in all patients. There were no in-hospital MACE and 30-day

**Table I: Intravascular imaging: determination of severity of coronary artery calcium with OCT and IVUS scoring systems (corresponding to images in Figure 1)**

OCT score	OCT Characteristic	Score
Calcium depth	≤ 0.5 mm	0
	> 0.5 mm	1
Calcium arc	≤ 90 °	0
	90-180 °	1
	> 180 °	2
Calcium length	≤ 5 mm	0
	> 5 mm	1

IVUS score	IVUS Characteristic	Score
Calcium arc	< 360 °	0
	360 °	1
Length of calcium > 270	≤ 5 mm	0
	> 5 mm	1
Diameter	> 3.5 mm	0
	≤ 3.5 mm	1
Calcified nodule	Absent	0
	Present	1

**Table II: Baseline characteristics (n=?)**

Characteristic	Number
Male, n (%)	5 (50)
Age (mean ± SD)	57 ± 11
Hypertension, n (%)	5 (50)
Hypercholesterolemia, n (%)	7 (70)
Smoking, n (%)	3 (30)
Family history of cardiac disease, n (%)	4 (40)
Diabetes mellitus, n (%)	6 (40)
LVEF (mean ± SD)	60.4 ± 4.9
eGFR (ml/min/1.73 m <sup>2</sup> )	83 ± 21
Stable angina/positive stress test	5 (50)
Unstable angina	5 (50)

LVEF - Left ventricular ejection fraction

eGFR - Estimated glomerular filtration rate

MACE events (Table III). The average stenosis diameter at baseline was  $1.7 \pm 0.3$  mm and the post-PCI diameter was  $3.0 \pm 0.3$  mm, with a significant acute luminal gain of  $1.3 \pm 0.3$  mm ( $p < 0.01$ ). Slow flow during the procedure occurred in 2 (20%) cases and dissection occurred in 1 (10%) case during the procedure. These were successfully treated with stent delivery to achieve TIMI III flow. There were no cases of stent thrombosis or vessel perforation.

## DISCUSSION

OA is a relative new technology for calcium modification in complex angioplasty. We sought to prospectively assess the in-hospital safety and efficacy of treatment using intravascular imaging guidance and OA in a real-world population. The main finding of this study was that OA could be performed safely and relatively easily with successful stent delivery in all cases. In our patient cohort, there were no major angiographic complications with OA and none of the patients had in-hospital and 30-day follow-up MACE.

### Orbital Atherectomy

The Diamondback 360 Coronary OA System (Cardiovascular Systems, Inc., St. Paul, Minnesota) is a device that modifies calcific lesions by a sanding mechanism.<sup>19</sup> The system uses a 1.25-mm diamond-coated crown which can be advanced bidirectionally over a 0.014" ViperWire coronary guidewire.<sup>20,21</sup> The continuous flow of lubricant, combined

with small particle size of 2 µm, leads to low incidence of thermal injury, heart block, and no reflow.<sup>22</sup> In our study, there was a low rate of complications with the OA device, with slow flow during the procedure in 2 (20%) cases during procedure. Additionally, this improved following stent delivery to achieve TIMI III flow.

The OA crown is moved by the operator in both directions a slow movement at a speed of 1 to 3 mm/s for ablation.<sup>23</sup> During atherectomy, softer tissue flexes away from the crown while superficial and deep calcium is treated.<sup>24</sup> The OA console has speed selection options for low speed (80,000 rpm) and high speed (120,000 rpm). The small amount of luminal gain from debulking is not the main objective of OA treatment. Treatment with OA can hence increase the vessel diameter and reduce the risk of stent underexpansion, stent thrombosis, and stent restenosis.<sup>25</sup> Among our study patients, it was found that OA improved the vessel diameter from baseline of 1.7 mm to a post-PCI diameter of 3.0 mm, with a significant luminal gain of  $1.3 \pm 0.3$  mm.

### Safety of OA

Infrequent complications of OA may include slow coronary blood flow or no flow, distal embolisation, coronary artery perforation, and vessel dissection. Coronary vessel perforation is a serious complication that can occur 0.7% to 2% of OA cases.<sup>20</sup> Avoiding highly tortuous vessels can help to reduce the risk of coronary vessel perforation. OA should

Table III : Procedural characteristics and clinical outcomes (n=?)

Characteristic	Number
<b>Vessel treated</b>	
LMS, n (%)	2 (20)
LAD, n (%)	10 (100)
LCX, n (%)	0 (0)
RCA, n (%)	0 (0)
<b>Lesion characteristics</b>	
Proximal, n (%)	8 (80)
Mid, n (%)	5 (50)
Length (mean ± SD), mm	34.7 ± 11.1
Severe calcification, n (%)	10 (100)
<b>Procedural characteristics</b>	
Procedural time (min ± SD)	125.2 ± 34.4
Fluroscopy time (min ± SD)	27 ± 10.5
Femoral vascular access, n (%)	9 (90)
Number of orbital atherectomy runs (median)	4
Largest diameter of predilatation balloon, mm (mean ± SD)	2.6 ± 0.2
Mean pressure of predilatation, atm (mean ± SD)	14.6 ± 2.5
Largest diameter of postdilatation balloon, mm (mean ± SD)	3.4 ± 0.4
Mean pressure, of postdilatation, atm (mean ± SD)	14.2 ± 1.7
2 stents/lesion, n (%)	4 (40)
1 stent /lesion, n (%)	6 (60)
<b>IVUS or OCT characteristics</b>	
IVUS or OCT score ≥ 3	10 (100)
Baseline MLD (mm ± SD)	1.7 ± 0.3
Post-PCI MLD (mm ± SD)	3.0 ± 0.3
Baseline MLA (mm <sup>2</sup> ± SD)	3.5 ± 0.8
Post-PCI-stent CSA (mm <sup>2</sup> ± SD)	7.5 ± 1.3
Post-PCI-luminal gain (mm ± SD )	1.3 ± 0.3
<b>Angiographic and clinical outcomes</b>	
Procedure success with facilitated stent delivery	10 (100)
Slow flow during procedure	2 (20)
Coronary dissection during procedure	1 (10)
Stent thrombosis	0 (0)
Vessel perforation	0 (0)
In-hospital MACE (MI/TVR/death)	0 (0)
30-day MACE (MI/TVR/death)	0 (0)

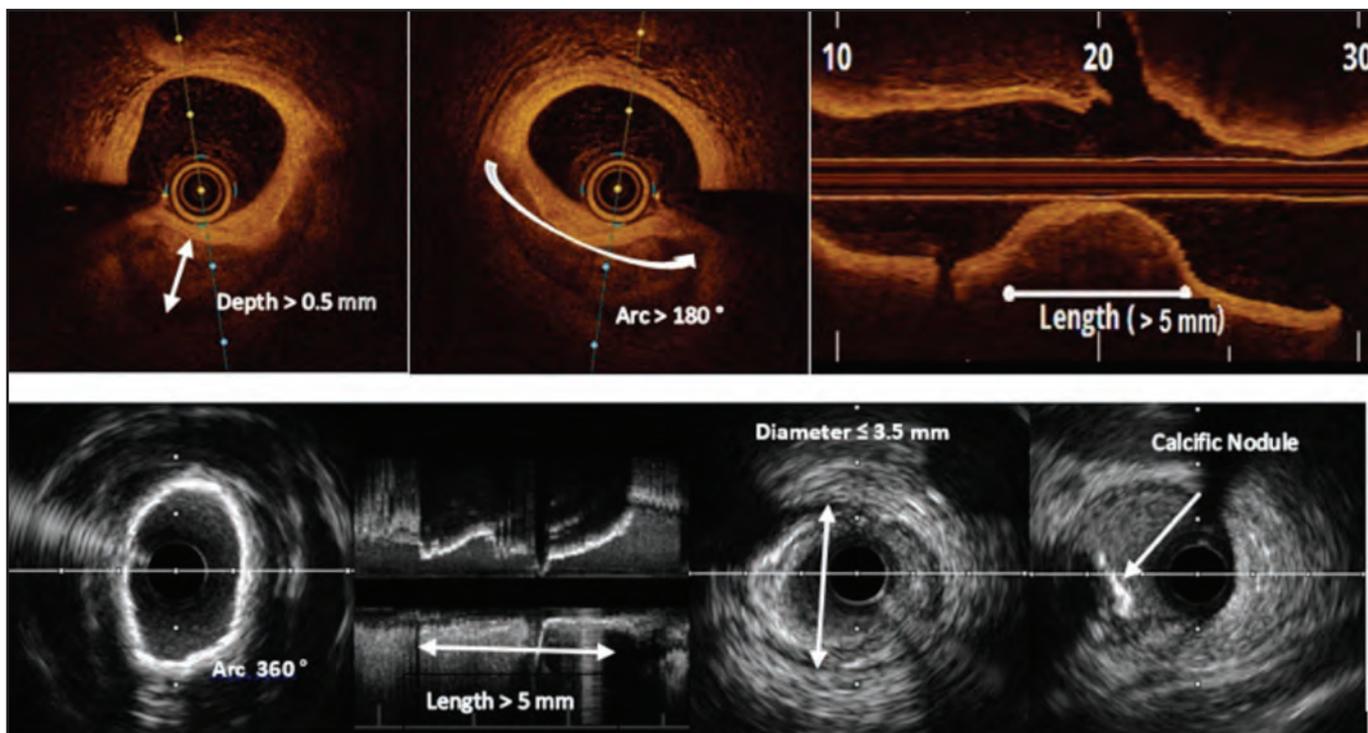
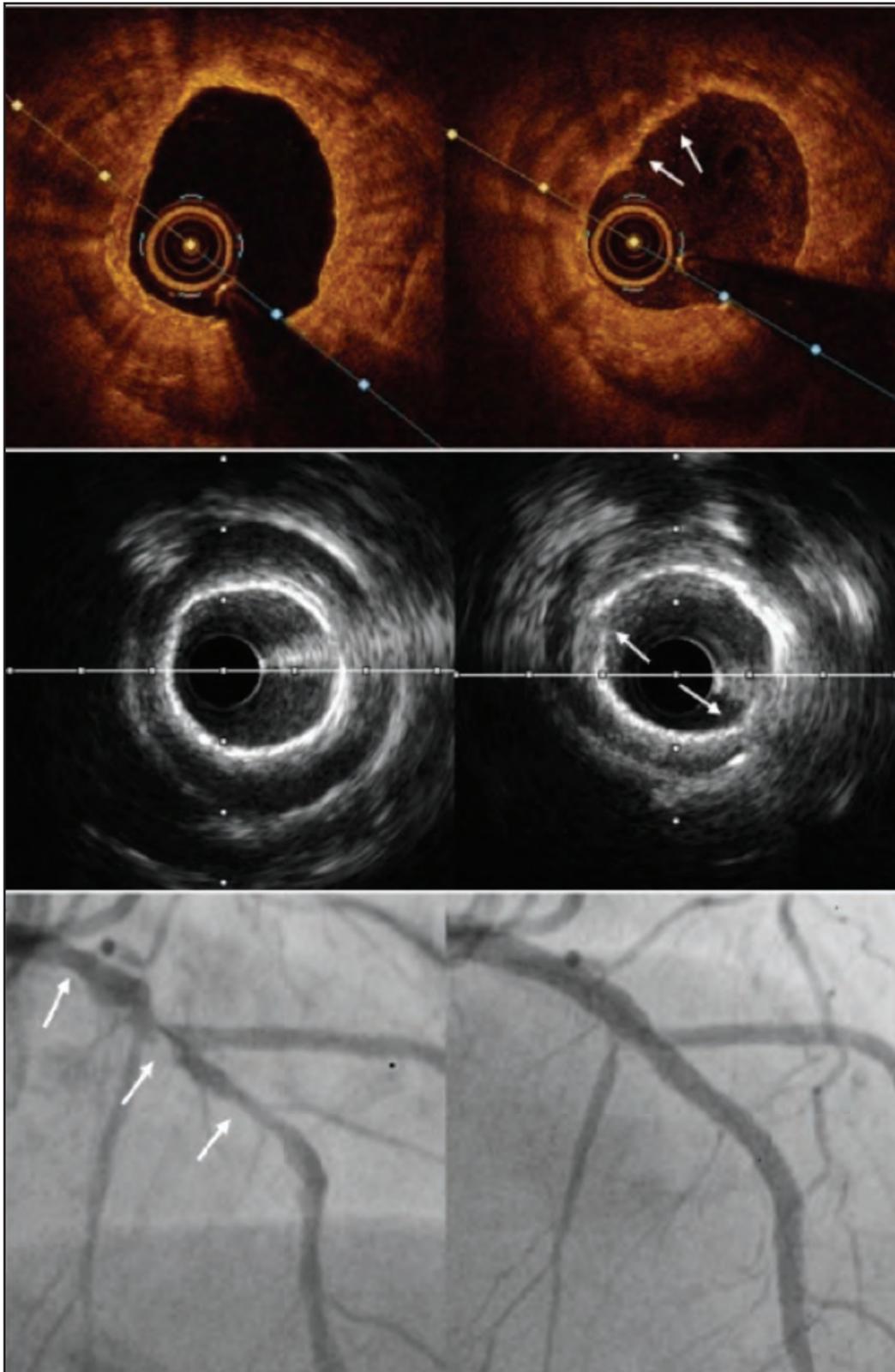


Fig. 1: OCT Images (row above) demonstrating measurements of depth, arc and length. IVUS images (row below) demonstrating measurements of arc, length, vessel diameter and calcific nodule



**Fig. 2:** OCT cross-section images (above left) demonstrating severe concentric calcification. Post-OA images (above right) demonstrating the mechanism of action of OA - polishing of the calcified surface, with characteristic smooth, concave ablation (arrows). IVUS cross-section images (middle left) demonstrating concentric arc of calcium and post-OA images on the (middle right) showing plaque modification with thinning and disruption of calcium ring (arrow). Coronary angiogram showing heavy calcification (arrows) at the proximal to mid LAD (below left). Post-treatment with OA and successful PCI of the LAD with stent implantation (below right)

be avoided in vessel anatomy with greater than 2 bends exceeding 90° angulation. We found that using OCT or IVUS guidance for careful patient selection and also monitoring of complications intraprocedure helped to minimise complications from OA. There was a low rate of acute complications in our study cohort with dissection occurring in 1 (10%) case during the procedure.

#### *Trial Evidence for OA*

The early clinical trial assessing OA in coronary arteries was the ORBIT I study. The study examined the safety and feasibility in 50 patients, demonstrating procedural success in 94% of patients.<sup>26</sup> Complications included six cases of coronary artery dissection and one case of perforation. The MACE rate was 6% at 30 days.

Following this, the ORBIT II trial, a multicenter, prospective trial studied 443 patients from 49 sites with severely calcified coronary disease.<sup>27</sup> The primary endpoint of 30-day MACE and cerebrovascular events was 1.7%. Angiographic complication rates were low: perforation was 0.7%, dissection 0.9%, and no-reflow 0.7%; emergency coronary artery bypass graft surgery was performed in 0.2% of patients. There was a low rate of 1-year target vessel revascularisation (5.9%), cardiac death (3.0%), and peri-procedural MI (2%). The trial demonstrated that OA was safe and effective for the treatment of severely calcified coronary lesions.

Our study findings are comparable to such larger trials, with a low rate of MACE events post-OA in our study (0%) at 30 days as compared to 1.7% at 30 days with the ORBIT II trial.

#### *Intravascular Imaging*

Both IVUS and OCT provide good resolution for severity assessment of coronary calcification compared with visualisation during coronary angiography. The calcium arc on IVUS<sup>28</sup> and OCT<sup>29</sup>, which indicates severity of calcification, is a measure of risk of stent under expansion. With IVUS, ultrasound waves reflect off calcium instead of penetrating calcium, making it difficult to assess calcium depth.<sup>30</sup> The thickness of calcium can influence the likelihood of calcium fracture during balloon angioplasty.<sup>31</sup> Lesions with calcium thickness exceeding a depth of 0.24 mm can benefit from atherectomy-induced calcium modification to avoid stent underexpansion.<sup>32</sup> Treatment of calcified lesions with OA leads to ablation of calcified plaque which may be seen on intravascular imaging.<sup>33</sup>

Calcium scoring algorithms with intravascular imaging allow a structured approach in routine practice to help minimise the likelihood of stent restenosis and stent thrombosis.<sup>34</sup> We found that OCT and IVUS scoring algorithms to assess for severity of calcium have been important for judicious selection of appropriate cases for the use of OA in angioplasty. Additionally, it has been essential to perform intravascular imaging post-OA treatment to aid in accurate stent diameter sizing and to demonstrate success with documentation of MLD, luminal gain, post-stent CSA with the use of either OCT or IVUS.

#### **LIMITATIONS**

This was a prospective, single-arm registry with short-term follow-up period of 30 days. Larger randomised studies or clinical registries of OA with long-term follow-up will be of significant clinical value.

#### **CONCLUSION**

Calcified coronary lesions are challenging to treat and are associated with an increased risk of acute complications and poor long-term outcomes. Our experience demonstrates the feasibility and safety of OA in the management of calcified coronary stenosis. Intravascular imaging is an important adjunct to the use of OA to assess the severity of calcified coronary lesions, success of OA treatment, and aid in sizing the vessel for stent implantation. OA has an important role in lesion preparation of calcified lesions before stent implantation to best ensure optimal results for adequate stent expansion. OA is a safe procedure with good success rate and low rate of complications.

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