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'Pre-crack the plaque technique' using OPN super high-pressure balloons in tight, calcified stenoses: A case series

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ABSTRACT

The OPN super high-pressure balloon is a safe and effective up-front plaque modification tool that facilitates lesion expansion and optimal stent deployment in tight, calcified coronary stenoses. Here we describe a case series of OPN use with very small diameter balloons (1.5–2.5 mm) in tight stenoses and subsequent larger non-compliant (NC) balloon inflation that expands existing calcium fractures. It is best guided by intracoronary imaging, but may have acceptable safety profile even when imaging catheters will not initially cross. This technique may be efficient and cost-effective in applicable cases, relative to other modification options. It is. This technique appears to be a safe, effective, and technically straightforward method for modifying some tight, reasonably calcified coronary lesions.

1. Introduction

Tight, calcified coronary stenoses may require calcium modification to facilitate adequate lesion expansion and optimal stent deployment. Many approaches to this task require the setup and use of dedicated devices, which can be both time-consuming and costly. The risk/patient tolerance profile of available device options also varies with clinical scenarios, such as those where patients have clinical features like reduced LV systolic function or high-risk anatomy. The OPN super high-pressure balloon (OPN ®; SIS Medical AG, Winterthur, Switzerland) has perhaps traditionally been used more often for expanding under-expanded prior stents, but it is gaining increasing interest as an up-front plaque modification tool. Despite the existence of largely reassuring safety data [1–3], clinicians may be hesitant to inflate a larger-sized OPN to high pressures within a vessel for fear of perforation. Furthermore, at times, larger-sized OPN may not readily cross in tighter initial stenoses. We describe a modified use of the OPN here (Fig. 1), with the use of at times, very small diameter balloons (1.5–2.5 mm) or those sized according to the initial lumen diameter in tight stenoses, crossing either up front, or after the use of low-profile semi-compliant balloons. These smaller double-wall OPN balloons are inflated to very high pressure, delivering a potent initial force to the lesion/vessel wall and initiating early small calcium fractures and plaque modification. Subsequently, larger non-compliant (NC) balloons are inflated and expand the existing fractures or further modify the lesion segments, allowing for adequate plaque modification and successful stenting. The technique is optimally performed under intracoronary imaging guidance, but if imaging catheters do not cross the initial tight lesion or imaging quality is poor up front, then the use of the very small balloon also appears to have a good safety profile even when initial imaging cannot be completed.

1.1. Case 1

A 51-year-old woman with a history of type 2 diabetes, dyslipidemia, smoking and obesity was admitted to hospital with unstable angina. Prior to admission, she had an attempt at a coronary CT angiogram that had noted marked calcification within the left anterior descending (LAD), left circumflex (LCx) and right coronary artery (RCA) and the full CT imaging was therefore not completed (Fig. 2 panels A-B). After admission, she was taken to the cardiac cath lab, where a coronary angiogram revealed significant tandem stenoses in the LAD (Fig. 2 panel C). Fig. 3 (panels A-C) shows initial lesion findings by intracoronary Optical Coherence Tomography imaging (OCT). Fig. 3 (panels *E*-H) shows OCT initial calcium fractures and plaque modification induced by inflation of an OPN 2.0 × 10 mm balloon to 40 atm. Fig. 3 (panels I-L) shows OCT progressive plaque modification with the use of larger NC balloons. Fig. 3 (panels M-P), after stent deployment and post-dilation, shows successful expansion by OCT at the lesion sites. Fig. 4 shows co-registered and pre and post-OCT and angiographic appearances of the

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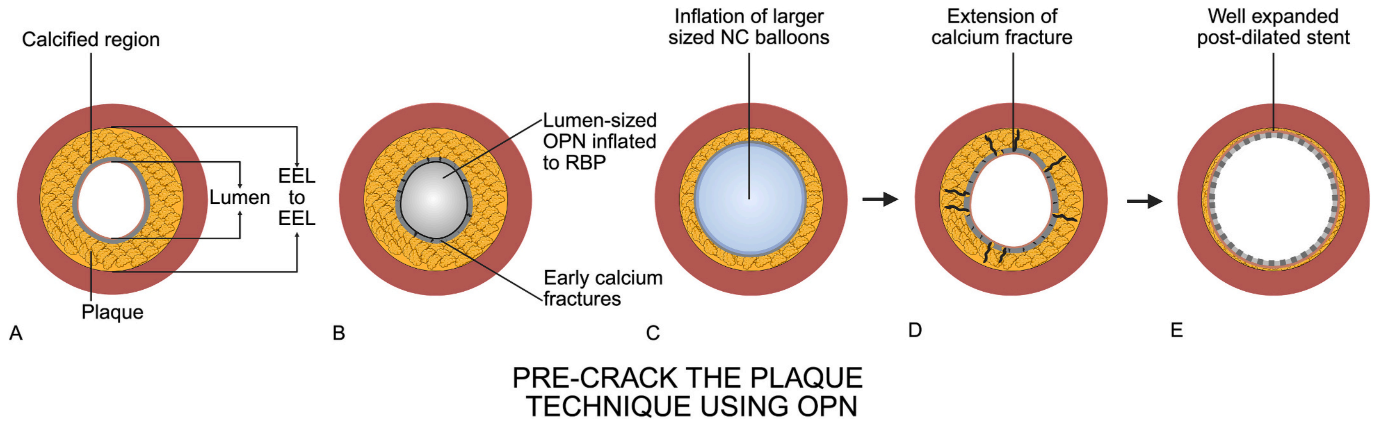

Fig. 1. Panel A shows a coronary artery with plaque and a calcified region of subluminal intra-plaque calcification; in this example the calcification is concentric. EEL = external elastic lamima. Panel B shows an OPN Super High Pressure non-compliant (NC) balloon sized to the lumen diameter and inflated to high pressures. The inflation results in early small calcium fractures and plaque modification. Panel C shows subsequent inflation of a larger NC balloon sized closer to the EEL-EEL diameter. This extends the initial calcium fractures and further modifies the plaque (Panel D). Panel F shows the stent deployed and post-dilated with good expansion.

Fig. 2. Panels A and B show marked calcification with the LAD (arrow) noted on attempted outpatient coronary CT angiogram which was abandoned due to heavy calcification burden. Panel C shows the LAD appearance at coronary angiogram with a region of disease in the mid LAD (bracket) with tandem lesions (p = more proximal lesion, d = more distal lesion).

lesion sites, as well as the final coronary angiogram appearance.

1.2. Case 2

A 79-year-old man with multiple medical co-morbidities was admitted with a non-ST elevation myocardial infarction. Due to his significant renal impairment, he had initial attempts at optimal medical therapy and a MyoView done to help identify the burden of ischemia/risk. This study indicated significant inferior ischemia. Due to ongoing symptoms, he was referred for a coronary angiogram, which revealed multivessel CAD with a functional CTO or subtotal occlusion of the RCA, which was collateralized from the left system. After discussion at multidisciplinary rounds, he was turned down for coronary artery bypass grafting and referred for PCI to his RCA with a plan for initial medical therapy for his other residual CAD. Fig. 5 panel A shows the target tight stenoses in the distal RCA, the right posterolateral branch and the right posterior descending branch. The distal lesion was crossed with use of a microcatheter and a Sion wire. Initial IVUS findings at the distal tight stenotic region are shown in Fig. 5 panel B. Fig. 4 Panel C shows IVUS findings after inflation of an OPN 1.5 × 10mmn balloon to 35 atm with subtle calcium fractures. Fig. 4 Panel D—F shows IVUS findings after inflation of 3.0 mm and 4.0 mm NC balloons, with further resulting plaque modification. The vessel was then stented and post-dilated through the proximal to distal segments (Fig. 5 panel G). After this, an imaging catheter could not pass all the way down to the distal branches. However, the same 1.5 × 10 mm OPN balloon was taken to the tight distal lesion sites in the RPL and RPDA and inflated in each to 35 atm followed by further dilation with larger NC balloons (Fig. 5 panels H-L). The RPL and RPDA were both stented and post-dilated with good final angiographic and IVUS results throughout the vessel (Fig. 6, panels A-G; Supplemental Video 1).

1.3. Case 3

A 73-year-old man presented with NSTEMI. He was noted to have multivessel disease at cardiac cath, but was turned down for surgical revascularization due to his co-morbid status. He had successful PCI to his calcified LAD and was now planned for PCI to calcified disease in his OM (Fig. 7, panel A). An imaging catheter would not pass through his tight stenosis, also due to proximal vessel tortuosity. At this time, a low-profile 1 mm diameter semi-compliant balloon was able to pass, followed by a 2.0 mm semi-compliant balloon. After this, an OPN 2.5 × 10 mm balloon was inflated multiple times to 35 atm throughout the diseased segment. After this, a 3.0 mm NC balloon was advanced to the lesion site with use of a guide extension and the vessel was then stented and post-dilated with acceptable angiographic appearance (Fig. 7, panel B).

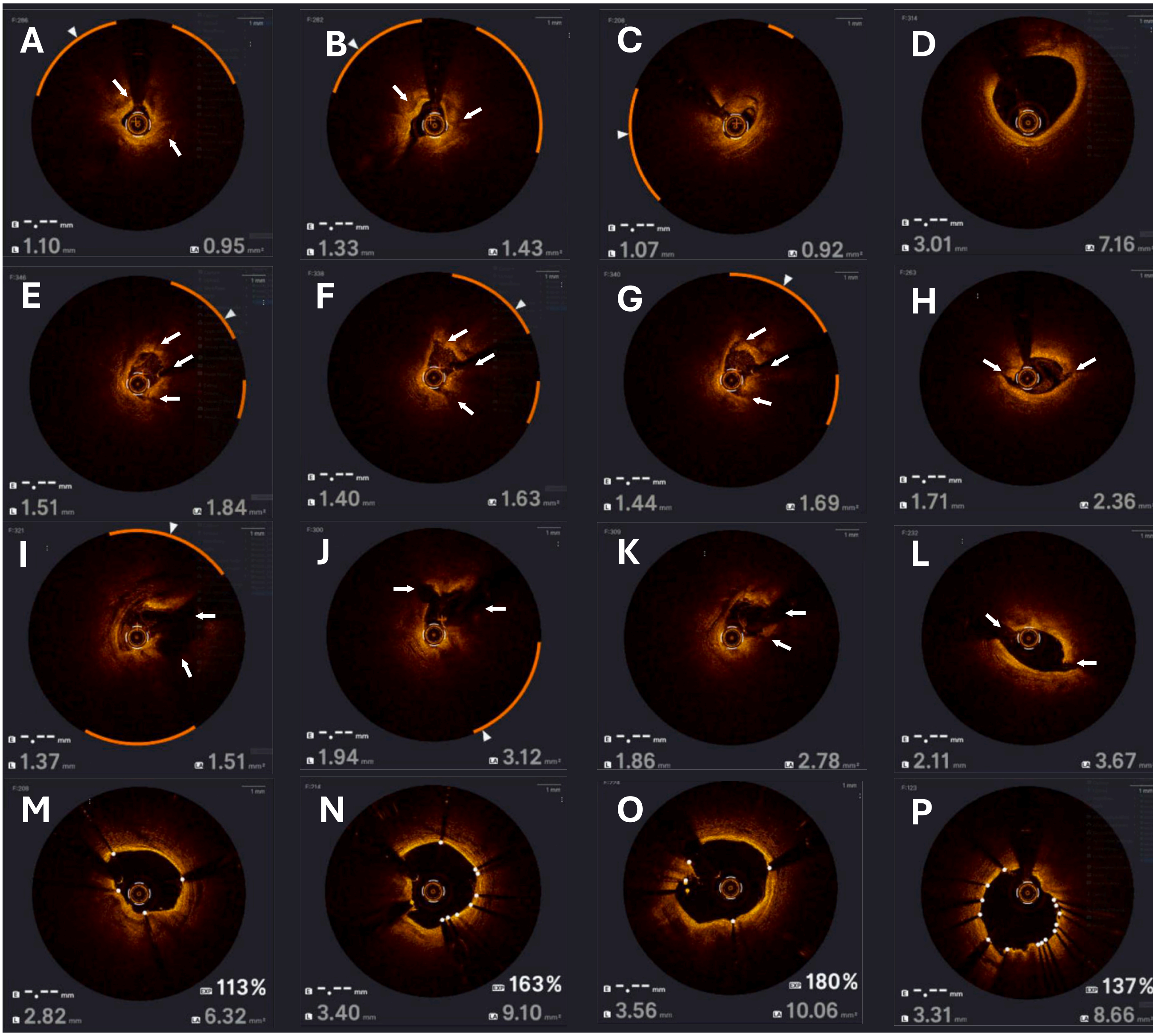

Fig. 3. Panels A and B show the initial Optical Coherence Tomography (OCT) appearance of the distal lesion with regions of calcification (arrows) and lumen size about 1.4 mm diameter. Panel C shows the initial appearance of the proximal lesion with poor visualization and blood swirl in the tight region. Panel D shows the distal reference vessel. Panels E, F and G show the distal lesion appearance after inflation of an OPN balloon 2.0 × 10 mm to 40 atm with evidence of early calcium fractures and plaque modification (arrows). Panel H shows the proximal lesion appearance. Panels I, J and K show expansion of calcium fractures/modified regions (arrows) after inflation of a 3.0 mm NC balloon. Panel L shows proximal lesion appearance after 3.0 mm and 3.5 mm NC balloon inflations. Panels M, N, O and P show well expanded stent through the target diseased region (dots). Distal lesion after 3.0 × 38 mm drug-eluting stent (DES) & 3.75 mm and 4.0 mm NC balloons and proximal lesion after 3.5 × 15 mm DES and 4.0 mm NC balloon.

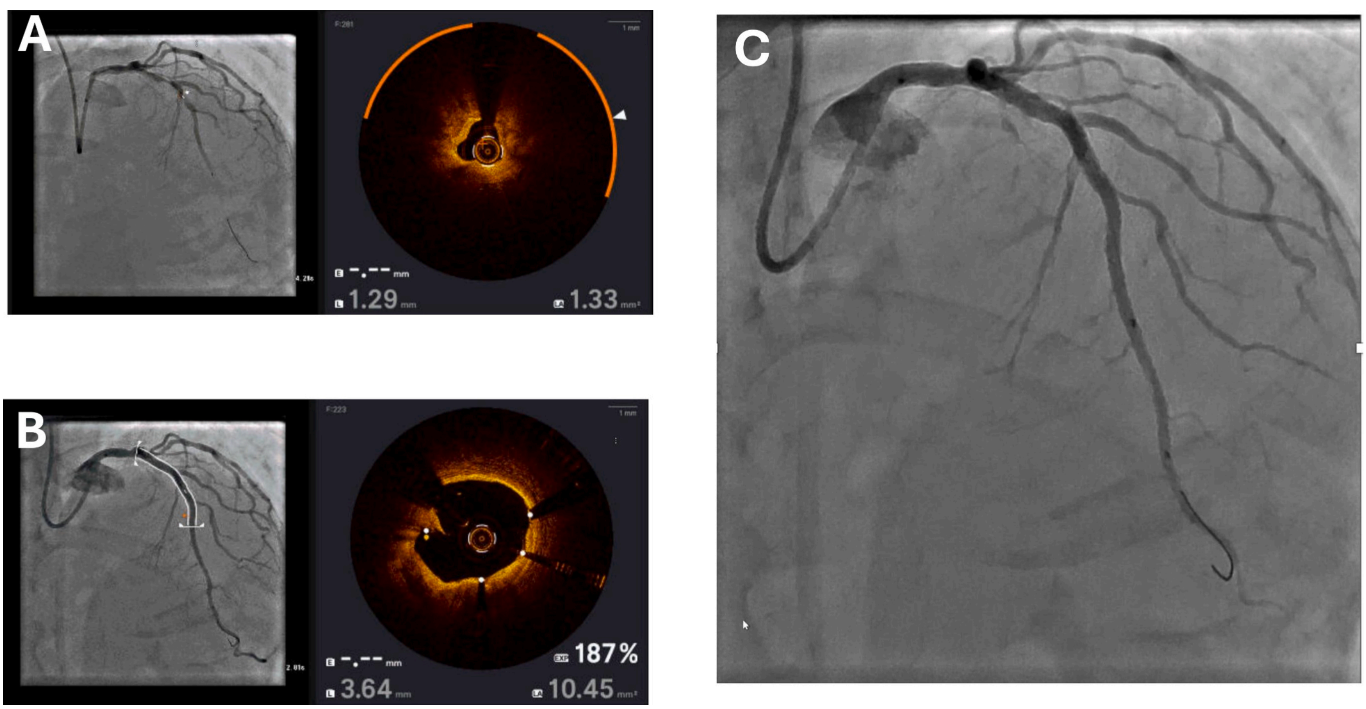

Fig. 4. Panel A shows the initial angiographic co-registered OCT image at the distal lesion site and Panel B shows the final angiographic co-registered OCT image at the stented region. Panel C shows the final angiographic image taken with the OCT catheter still in the vessel.

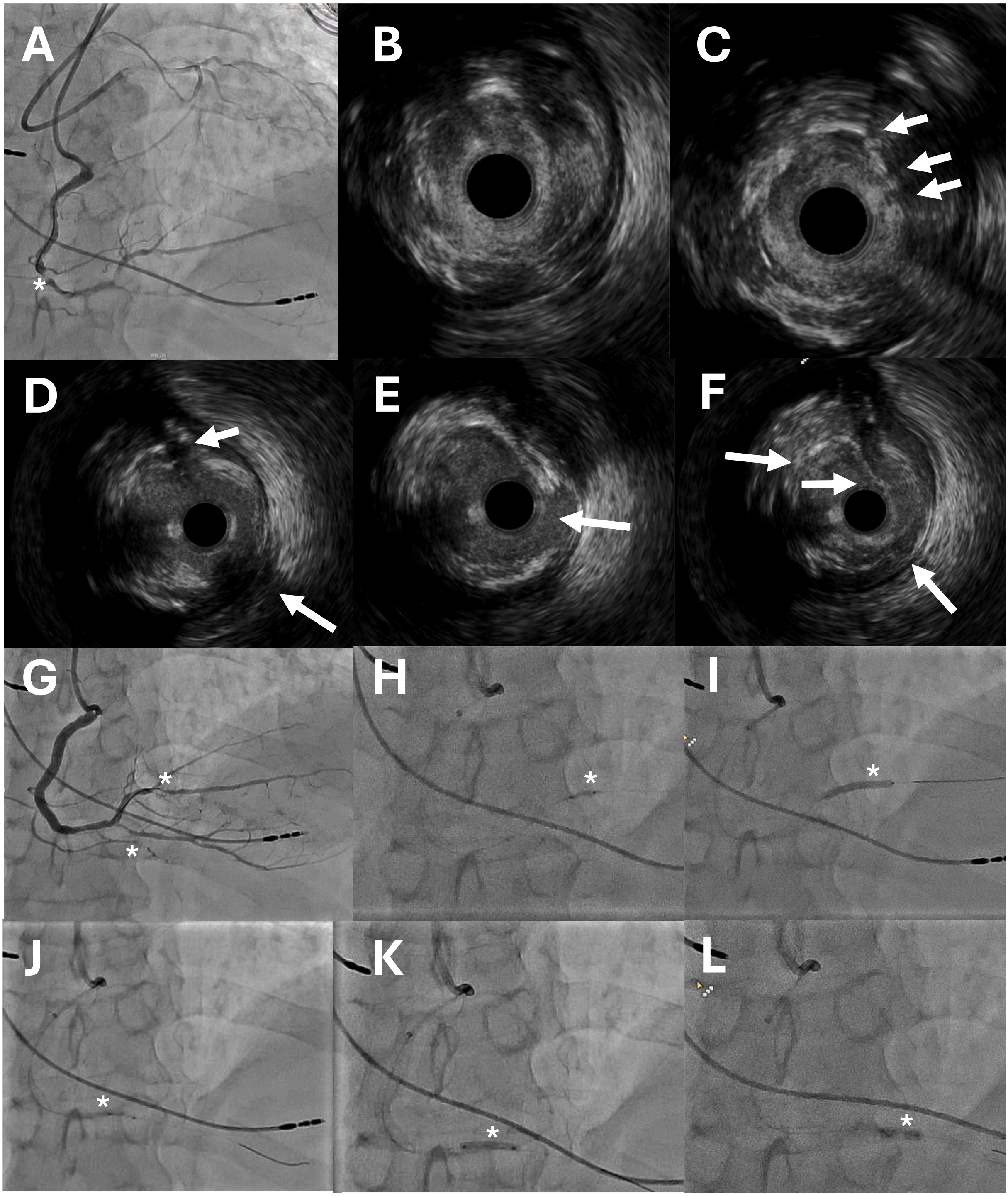

Fig. 5. Panel A shows the angiographic findings on dual injection within the right coronary artery including a tight mid vessel stenosis (*) with angiographic calcification. Panel B shows the initial IVUS image at the mid vessel stenosis. Panel C shows early calcium fractures and plaque modification (arrows) following inflation of an OPN 1.5 × 10 mm balloon to 35 atm. Panels D, E and F show further expansion of calcium fractures and plaque modification (arrows) following inflation of 3.0 mm and 4.0 mm NC balloons. Panel G shows the remaining lesions in the right posterolateral (RPL) and posterior descending (RPDA) branches after main vessel stenting (*). Panel H shows inflation of a 1.5 × 10 mm OPN to 35 atm at the RPL followed by 2.5 mm NC and 2.5 mm drug-eluting stent (panel I) which was further post-dilated with a 2.75 mm NC. Panel J (*) shows inflation of a 1.5 × 10 mm OPN to 35 atm at the RPDA which was then dilated further with a 2.5 mm NC followed by deployment of a 2.5 mm drug-eluting stent (panel K *) and post-dilation with a 3.0 mm NC balloon (panel L *).

2. Conclusions

Use of small OPN balloons, sized approximately to stenosis lumen diameter and inflated to 35–40 atm (high pressures) at the site of tight, calcified stenoses, can successfully initiate lesion modification that can then be further expanded upon with use of regular NC balloons. This technique appears to have a good safety profile, though further clinical experience and study would be needed to confirm this. The lesion must be balloon-crossable to use this technique. It is best guided by intracoronary imaging, but may have acceptable safety profile even when imaging catheters will not initially cross, if the OPN is adequately undersized relative to the true vessel diameter. This technique may be

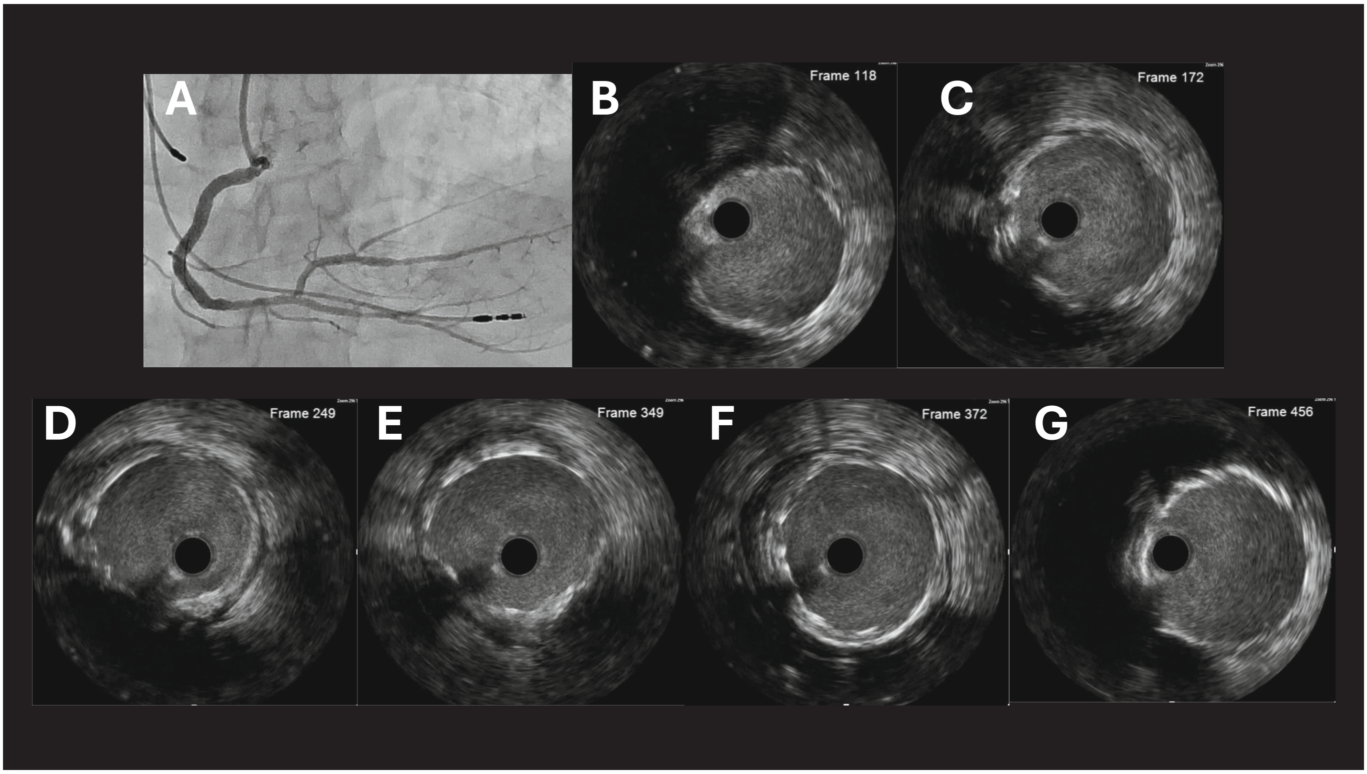

Fig. 6. Panel A shows the final angiographic result. Panels B-G show the final IVUS images from distal RCA (Fig. B) to ostium (Fig. G), with acceptable stent expansion throughout.

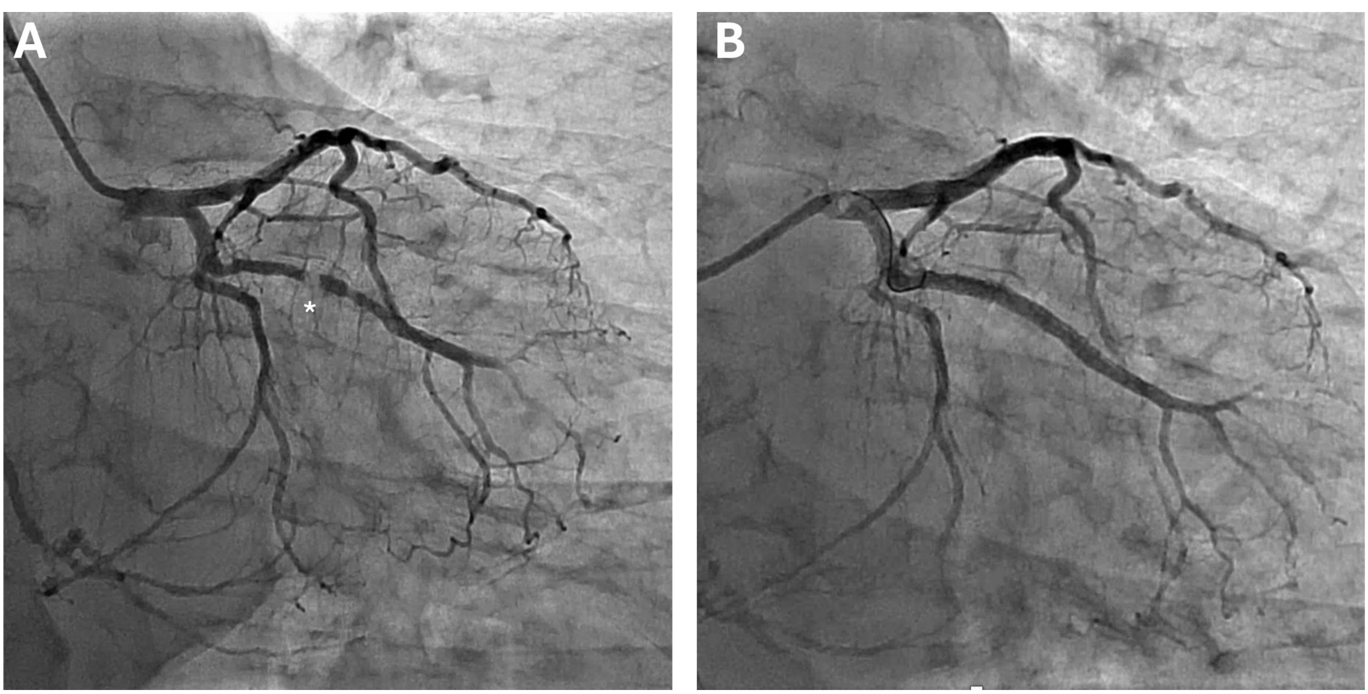

Fig. 7. Panel A shows a calcified tight obtuse marginal stenosis (*). Panel B shows the final angiographic result after an imaging catheter would not pass, but the lesion was dilated with 1.0 mm and 2.0 mm semi-compliant balloons which allowed passage and inflation of an OPN 2.5 × 10 mm balloon to 35 atm several times followed by inflation with a 3.0 mm NC balloon and guide-extension facilitated placement of a 3.0 × 38 mm drug-eluting stent and post-dilation with a 3.5 mm NC balloon.

efficient and cost-effective in applicable cases, relative to other modification options. It is technically simple to perform. The efficacy of the technique in extremely calcified/eccentric/nodular calcium may be more limited. The initial balloon size may be safest when quite small, but there will be some cases where it may then be undersized and requiring sizing up to a second OPN; the exact range of sizing on the initial balloon choice requires more case experience to best delineate. This case series does not provide a direct efficacy comparison to attempting initial dilation in these lesions with regular NC balloons to higher pressure. This technique, when feasible, appears to be a safe, simple and effective means of modifying some tight, reasonably calcified coronary lesions.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.crmic.2025.100114.

CRediT authorship contribution statement

Michael S. Connolly: Data curation, Software, Visualization, Writing – original draft, Writing – review & editing. **Allison B. Hall:** Conceptualization, Data curation, Investigation, Methodology, Supervision.

Declaration of competing interest

A. Hall has received speaker fees/honoraria from Ates Medical, Teleflex, Shockwave Medical, SIS Medical. No other interests to declare.

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Some images created in BioRender. Connolly, M. (2025) https://BioRender.com/f9v6226

Data availability

Data will be made available on request.

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