



## Shockwave Intravascular Lithotripsy as a “Bail Out” Technique for “Undilatable” In-Stent Restenosis with Two Stent Layers

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### Introduction

Treatment of “undilatable” In Stent Restenosis (ISR) remains a challenge for the interventional cardiologist. Detection of the mechanism of restenosis by Intracoronary Imaging Techniques (IVUS/OCT) is essential in order to choose the appropriate treatment [1]. Restenosis due to stent under expansion in a calcified lesion is hard to treat because calcium deposits do not allow stent expansion. It is important to try all the available techniques in order to achieve the best possible lesion preparation before in stent drug eluting balloon angioplasty or new drug eluting stent implantation. In cases of In Stent Restenosis (ISR) if high pressure non-compliant balloon, scoring and cutting balloon fail to achieve adequate stent expansion, excimer laser coronary angioplasty with contrast injection and Rotational Atherectomy (RA) are the two treatment options that could theoretically lead to fragmentation of calcified tissue surrounding the stent and final good stent expansion [2]. However, excimer laser is not widely used and there are some concerns regarding the risk of no reflow, burr entrapment or coronary perforation with RA. While there are series where RA was used for “undilatable” ISR due to under expanded stents in calcified lesions with favorable procedural outcome, there is also data who demonstrated a high rate of target lesion revascularization within one year [2,3]. RA is less effective in deep and concentric calcium deposits. In contrast with RA, IVL balloon is a new device that breaks both superficial and deep calcium deposits with minimal vessel injury [4]. We describe a case of using IVL balloon in a patient which enabled us to achieve final optimal stent expansion after failure of current techniques.

### Case Presentation

A 71-year-old man with a history of ischemic heart disease, hypertension, dyslipidemia, permanent atrial fibrillation and chronic renal disease (eGFR: 30 ml/min) admitted to our hospital because of decompensated heart failure with reduced left ventricular ejection fraction. His ischemic heart disease included previous Myocardial Infarction (MI) 23 years ago with failed thrombolysis, treated with Bare Metal Stent (BMS) implantation in proximal LAD four days post MI and complementary stenting of middle RCA and distal circumflex few days later. Three months post angioplasty; he presented an ISR at the edge of the previously implanted stent in the RCA that was treated with a new BMS implantation. During the following years he underwent two Coronary Angiograms (CA) the last one in 2003, showing neointimal hyperplasia in LAD and RCA without significant ISR.

During his current hospitalization, he underwent a Coronary Angiogram (CA), which revealed critical left main coronary artery stenosis, critical LAD and RCA in-stent restenosis (in the site of two layers of stent). We performed a PCI with Drug Eluting Balloon (DEB) in LAD restenosis and stent (DES) implantation in left main. Multiple high-pressure inflations with noncompliant balloons, scoring balloon and ultra-high-pressure balloon at 35 atm failed to dilate the RCA lesion (Figure 1A, 1B). We decided to evaluate the lesion with OCT.

OCT imaging (OPTIS™ Integrated Imaging System, Abbott) revealed severe ISR in the two layers of struts due to under expansion of the last stent implanted secondary to circumferential calcification and an estimated minimal lumen area at 1.3 mm<sup>2</sup> (Figure 1C). Considering the reduced efficiency of RA in deep and concentric calcium deposits as well as the risk of peri-procedural complications, we decided to use shockwave balloon.

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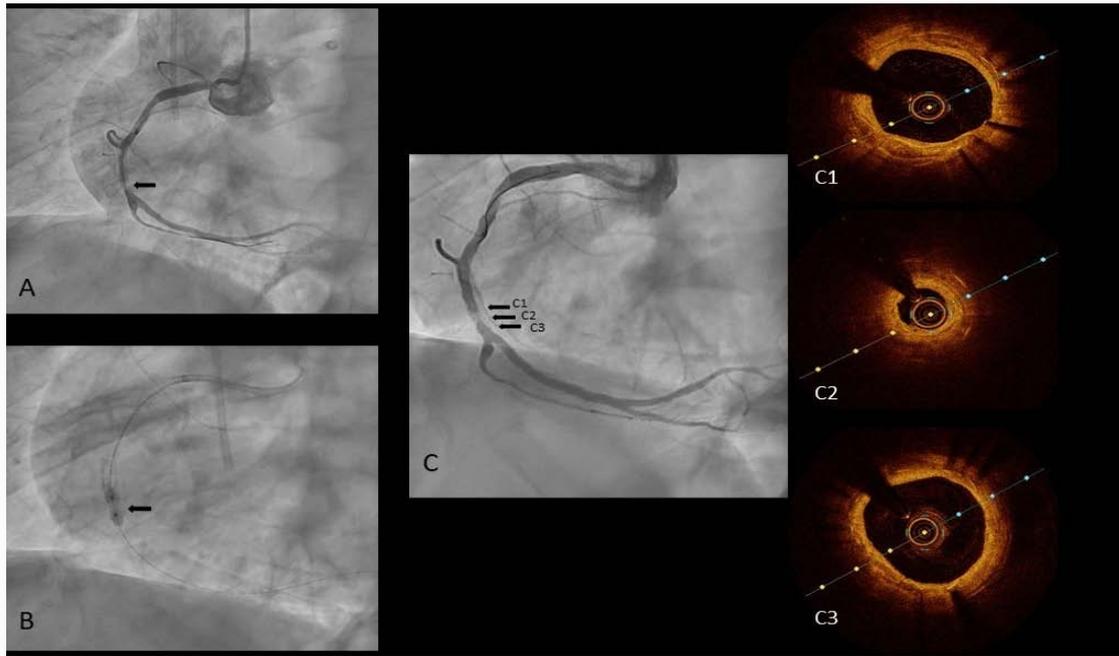
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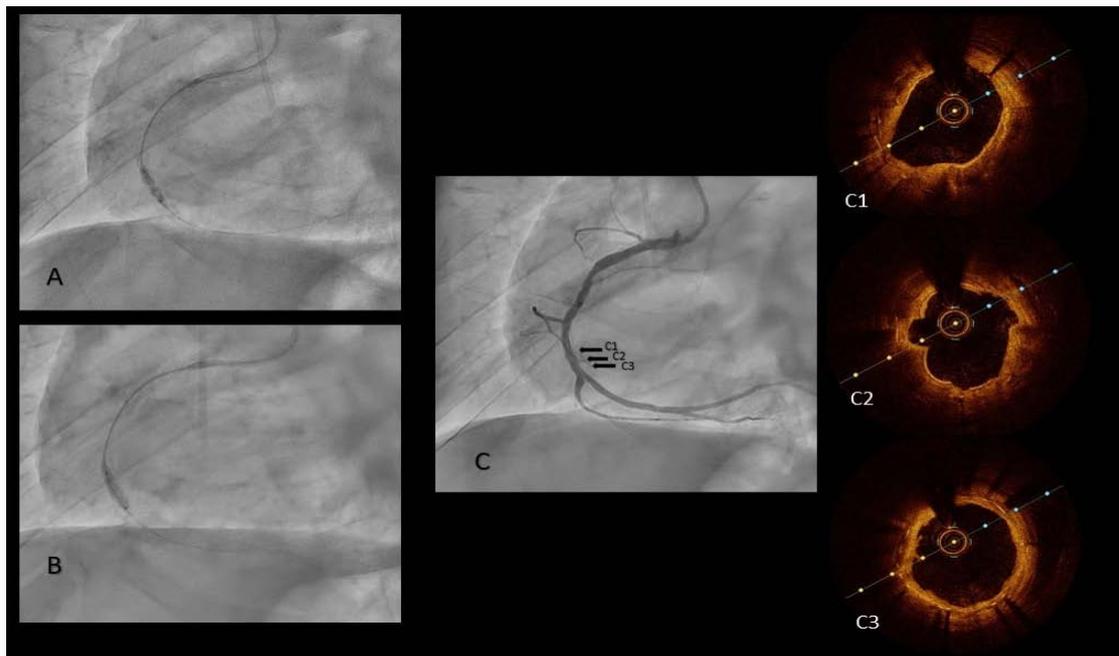
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**Figure 1:** A) Coronary angiography-RCA in stent restenosis. B) Ultra-high-pressure balloon inflation at 35 atm showing “undilatable” segment. C) Coronary angiography and corresponding OCT images before IVL. C1) Circumferential calcification proximal to the “undilatable” lesion C2) under expanded stent (2 stent layers) with MLA at 1.3 mm<sup>2</sup>. C3) Circumferential calcification distal to the “undilatable” lesion.



**Figure 2:** A) First inflation of IVL balloon at 4 atm, 10 pulses delivered. B) Full expansion of IVL balloon inflated at 4 atm after 80 pulses delivered. C) Coronary angiography (resolution of focal stenosis after IVL balloon) and corresponding OCT after IVL. C1) Calcium deposits proximal to the lesion. C2) Calcium fractures post IVL balloon and MLA more than 6 mm<sup>2</sup>. C3) Calcium deposits distal to the lesion.

In detail, AL 0.75 6Fr Launcher (Medtronic) guiding catheter was advanced to RCA and a 0.014 BMW J (Abbott) was passed through the lesion. A 3.0 mm × 12 mm IVL balloon was placed at the level of the lesion and was inflated at 4 atm (Figure 2A, 2B). We applied eight cycles of ultrasound energy, lasting 10 sec each one.

Once finished the IVL balloon dilatation, the angiographic result was optimal and OCT showed optimal expansion of stent with MLA

more than 6 mm<sup>2</sup>. There was no procedural complication such as perforation, edge dissection, slow or no reflow. We completed our angioplasty with a paclitaxel coated balloon SeQuent Please NEO (B. Braun Melsungen AG) 3.5 mm × 10 mm, inflated at 12 atm for 90 sec. At 9-month follow-up, the patient was free of symptoms.

### Discussion

IVL is a new, safe and effective method to treat severely

calcified coronary lesions, as demonstrated in the multinational trial Disrupt CAD III [5]. It is effective with high success rate and low risk of procedural complications [6]. IVL delivers ultrasonic waves to modify calcium, improve plaque compliance and facilitates angioplasty. In contrast to other techniques to disrupt calcium, IVL therapy provokes minimal vessel injury and it is less likely to result in distal embolization because the calcium fragments remain in situ [4]. In 2021, FDA approved the use of IVL for the angioplasty of severely calcified, stenotic arteries when used prior to stenting. In literature there are reports that suggest the use of IVL as a therapeutic option for the treatment of under-expanded stents [7,8].

In our patient, multiple high-pressure inflations with noncompliant balloons, scoring balloon and ultra-high-pressure balloon at 35 atm failed to dilate the lesion. Rotational atherectomy could be an effective treatment, presenting the peri-procedural risk of no reflow, burr entrapment, coronary perforation. We chose to try IVL and it was able to disrupt calcium depots beyond stent struts and obtain complete stent expansion. Similarly, IVL was reported to successfully treat a severe calcific stenosis due to two layers of under-expanded stents treated after failure of only one noncompliant balloon inflated at 20 atm. IVL could be a useful tool for angioplasty of under expanded stent even in lesions with two-layers of stent struts [9].

## Conclusion

We present a case of IVL balloon treatment of ISR due to stent under expansion at the site of two-layers of stent struts secondary to heavy circumferential calcification treated with IVL balloon, after failure of multiple high-pressure inflations with noncompliant balloons, scoring balloon and ultra-high-pressure balloon. OCT allowed us to determine calcium distribution, localization and thickness in order to choose the appropriate therapy. IVL balloon is a promising technique for 'bail out' treating of "undilatable" ISR due to stent under expansion and deep circumferential calcification, even in lesions with two-layers of stent struts when the other techniques fail.

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