

## CASE REPORT

# Shockwave intravascular lithotripsy in the treatment of under-expanded coronary stent: Case Series

Massimiliano Fedele  | Alessandro Iannone | Davide Bartolini | Paolo Rubartelli

Cardiology Division, Villa Scassi Hospital, Genoa, Italy

**Correspondence**

Massimiliano Fedele, Cardiology Division, Villa Scassi Hospital, Corso Scassi 1, 16149 Genoa, Italy.  
Emails: massimiliano.fedele@asl3.liguria.it; fedelemax@gmail.com

**Funding information**

We would like to thank Innova HTS for unconditional financial support for publication of this article.

**Abstract**

Under-expanded coronary stent related to inadequate preparation of calcified lesion is associated with poor clinical outcomes. Off-label use of S-IVL to correct this clinical issue is effective and safe, probably more than other current techniques. However, this statement needs further evidence.

**KEYWORDS**

calcified coronary lesion, coronary lithotripsy, stent expansion optimization

## 1 | INTRODUCTION

Suboptimal coronary stent expansion due to calcified lesion is one of the strongest predictors of adverse outcomes. Shockwave intravascular lithotripsy (S-IVL) is a new technique used in the treatment of calcified coronary lesions before stenting. We report two cases of use of S-IVL to treat under-expanded coronary stent after implantation. Heavily calcified coronary lesions still represent a challenge for percutaneous coronary intervention, given the difficulty to dilate the stenosis and therefore to obtain the correct delivery and implantation of stents.

Suboptimal stent expansion is in turn associated with poor clinical outcomes in terms of high rate of major adverse cardiac event (MACE), especially stent thrombosis and need for repeated revascularization.<sup>1,2</sup>

Several devices have been shown to be useful for the treatment of heavily calcified coronary lesions, including atherectomy and laser catheters, cutting and scoring

balloons, and very high-pressure noncompliant balloons. However, these devices are generally less effective or even contraindicated, when used to dilate the lesion once the stent has already been implanted.<sup>3-6</sup>

A novel shockwave intravascular lithotripsy (S-IVL; Shockwave Medical, Inc.) technology seems particularly promising to treat calcified lesions for its safety and effectiveness, as shown in DISTRUPT CAD I-II-III study.<sup>7-9</sup>

Clinical registry and case series have recently been published, which showed the effectiveness and safety of S-IVL to improve refractory stent under-expansion.<sup>10-15</sup>

However, no controlled study has tested the use of IVL for the treatment of under-expanded coronary stent, so this usage in this context is currently off-label.

We report two cases:

Patient 1: optimization of under-expanded stent immediately after implantation.

Patient 2: treatment of under-expanded stent 3 years after placement.

## 2 | CASE SERIES

### 2.1 | Patient 1

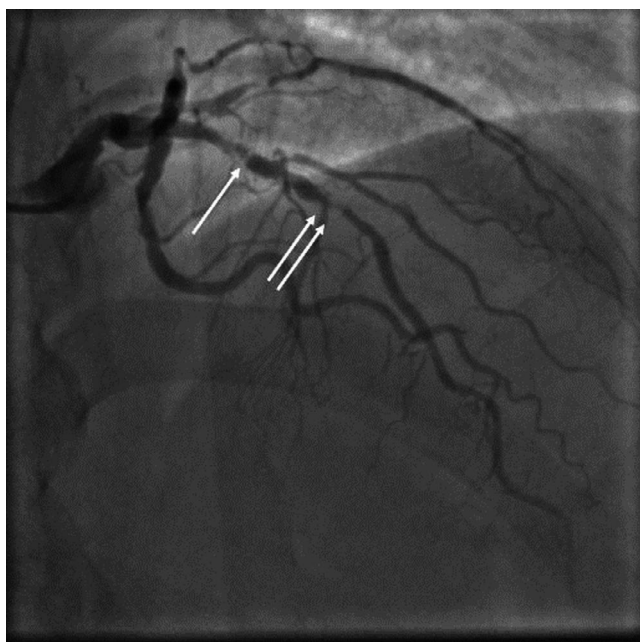
A 59-year-old man, who was a previous smoker with hypertension, dyslipidemia, and diabetes, was admitted to the emergency department for chest pain with mild diffuse ST depression associated with significant rise of hs-Troponin I (peak value 16051 pg/ml, normal value  $\leq 34.2$  pg/ml) and moderate left ventricular dysfunction (EF 45%) with akinesia of the lateral wall and apical hypokinesia.

Seventeen years before, for stable angina, he underwent percutaneous coronary intervention (PCI) and bare metal stent implantation on proximal left anterior descending (LAD) at bifurcation with a diagonal branch.

Immediately after admission, given persistence of symptoms despite initial treatment, we performed coronary angiography by right radial access that demonstrated three-vessel disease. The culprit vessel was deemed to be the LAD, which showed diffuse in-stent restenosis on the proximal segment followed by very tight calcified lesion on the mid-segment with impaired distal flow (Figure 1). In addition, the angiogram displayed a tight stenosis on the Intermediate branch and significant stenoses on proximal Circumflex branch and mid-right coronary artery (RCA).

We planned ad hoc treatment of LAD and Intermediate branch and staged treatment of Circumflex and RCA.

On LAD, we performed predilatation on both lesions with a  $2.5 \times 20$  mm balloon at 20 Atm, obtaining



**FIGURE 1** Basal angiogram. Diffuse in-stent restenosis on the proximal segment of left anterior descending (arrow) and severe very calcified lesion on the mid part of the vessel (double arrow)

an apparently satisfactory dilatation. Then, we placed a  $2.75 \times 40$  mm sirolimus-eluting stent (SES) at 12 Atm, in order to cover both lesions (Figure 2A), and post-dilated it with a  $3.5 \times 20$  mm noncompliant (NC) balloon at 24 Atm, observing an incomplete stent expansion at level of the calcified lesion on mid LAD.

Hence, we attempted to dilate with a  $3.0 \times 8$  mm NC balloon inflated at higher pressure (30 Atm), without any improvement (Figure 2B).

Therefore, we performed S-IVL by using a  $3.5 \times 12$  mm lithotripsy catheter, which was effective just after the second cycle at 6 Atm (Figure 3), obtaining a good angiographic result.

Finally, we completed the treatment by standard PCI and stenting on Intermediate branch. At the staged procedure performed one month later, we observed a persistent good angiographic result on LAD and Intermediate branches: the stent on the proximal and mid LAD was fully patent (Figure 4). The patient had no clinical event at twelve months follow-up.

### 2.2 | Patient 2

A 76-year-old woman with hypertension and dyslipidemia was admitted to the emergency department for persistent chest pain, associated with mild ST depression on lead DII, DIII, AVF, and slight rise of cardiac markers (peak hs-Troponin I 422 pg/ml). The echocardiogram showed normal left ventricular wall motion. Three years before, she had an acute non-ST elevation myocardial infarction and underwent PCI and drug-eluting stenting on mid-proximal and distal right coronary artery (RCA) and PCI and drug-eluting stenting on mid-circumflex, with residual moderate disease on the left anterior descending (LAD).

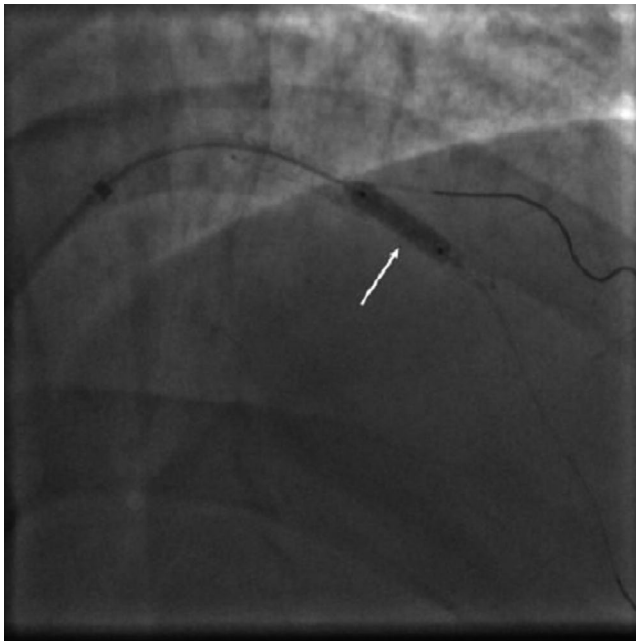
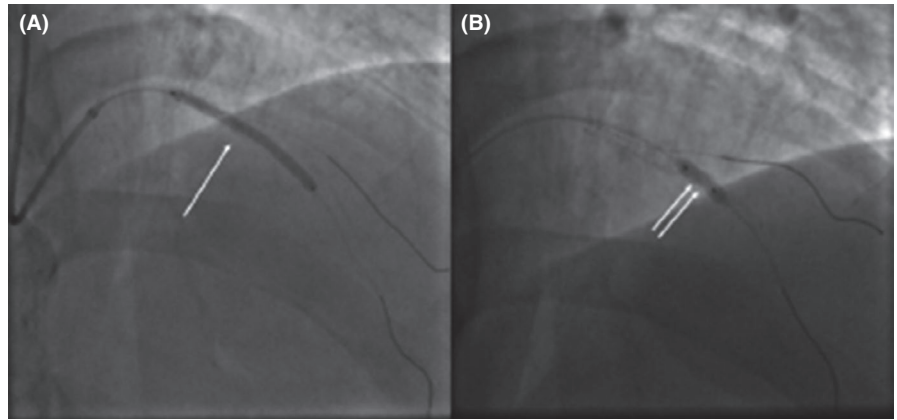
After dual antiplatelet (ticagrelor and aspirin), beta-blockers, statin, and nitrates therapies, the patient was directed to early invasive strategy.

Right coronary angiography showed two critical tandem stenoses on distal part, the proximal one related to an under-expanded previously implanted stent (Figure 5). Left coronary angiography demonstrated noncritical diffuse disease of LAD (proximal and distal), and good patency of the stent on mid-circumflex.

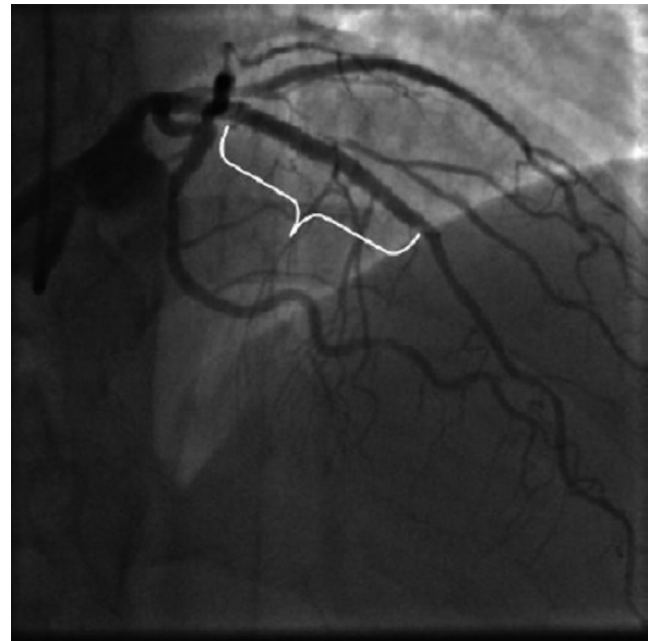
We considered the RCA as the culprit vessel and the two distal tandem stenoses as the target.

We then performed a first attempt of dilatation of the under-expanded stent lesion by using a  $2.5 \times 12$  mm noncompliant (NC) balloon inflated at 30 Atm, without any result (Figure 6). Successively, we performed S-IVL by using a  $3.0 \times 12$  mm lithotripsy catheter that fully expanded just after the second cycle at 6 Atm (Figure 7).

**FIGURE 2** A, Stenting of both lesions with  $2.75 \times 40$  mm SES, at 12 Atm (arrow). B, Incomplete stent expansion at level of the calcified lesion on mid LAD, during dilatation of  $3.0 \times 8$  mm NC balloon inflated at 30 Atm (double arrow)



**FIGURE 3** Complete stent expansion (arrow) during  $3.5 \times 12$  mm Shockwave intravascular lithotripsy catheter dilatation at 6 Atm



**FIGURE 4** Persistent good angiographic result at one-month angiographic check (brackets)

Subsequently, after predilatation of both distal stenoses with a  $3.0 \times 20$  mm NC balloon inflated at 16 Atm, we implanted a  $3.0 \times 26$  mm sirolimus-eluting stent (SES) at 18 Atm and post-dilated it with a  $3.5 \times 15$  mm NC balloon at 20 Atm, obtaining a good angiographic and IVUS result (Figure 8).

The patient was discharged on day 3 in good clinical condition. Twelve-month clinical follow-up was uneventful.

### 3 | DISCUSSION

Coronary stent under-expansion is a recognized risk factor for in-stent restenosis and stent thrombosis.<sup>1,2</sup>

The straightforward way to avoid stent under-expansion is a meticulous preparation of the resistant lesions that

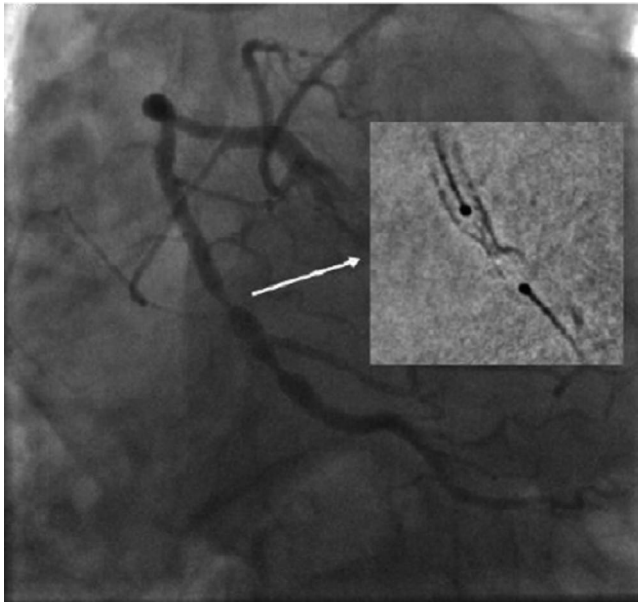
can be accomplished using several devices, including very high-pressure noncompliant balloons, scoring or cutting balloons, lithotripsy balloons, Rotablator device, or excimer laser catheters.

On the other hand, the options for patients with resistant stent under-expansion are limited.

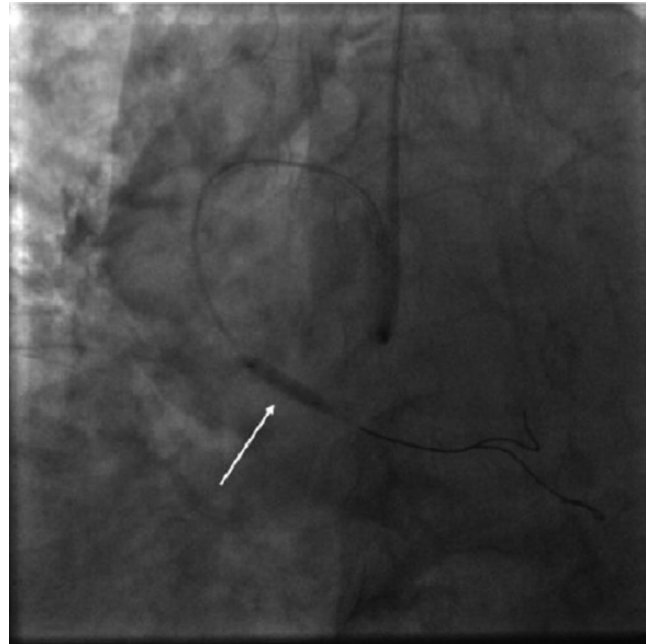
Excimer laser coronary angioplasty, performed during contrast medium injection, has been shown in case series to have a high rate of success and low rate of complications.<sup>3,4</sup>

Rotational atherectomy has been described in case reports to be effective in treating under-expanded stents (so-called stentablation).<sup>5,6</sup>

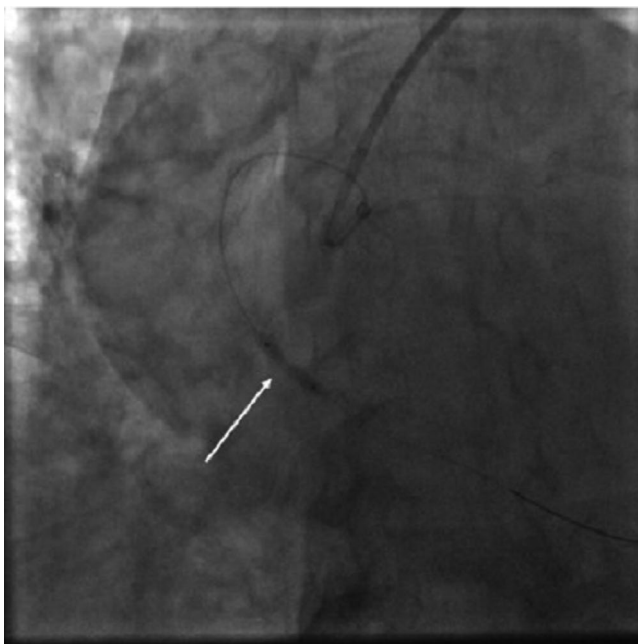
However, concerns about the safety of the procedure is justified, considering the risk of no reflow, strut embolization, vessel dissections, burr entrapment, and stent wrapping around the Rotablator burr.



**FIGURE 5** Basal angiogram showing two critical tandem stenoses on distal right coronary artery; the proximal lesion (arrow) is related to an under-expanded previously implanted stent. (StentViz image in the box)



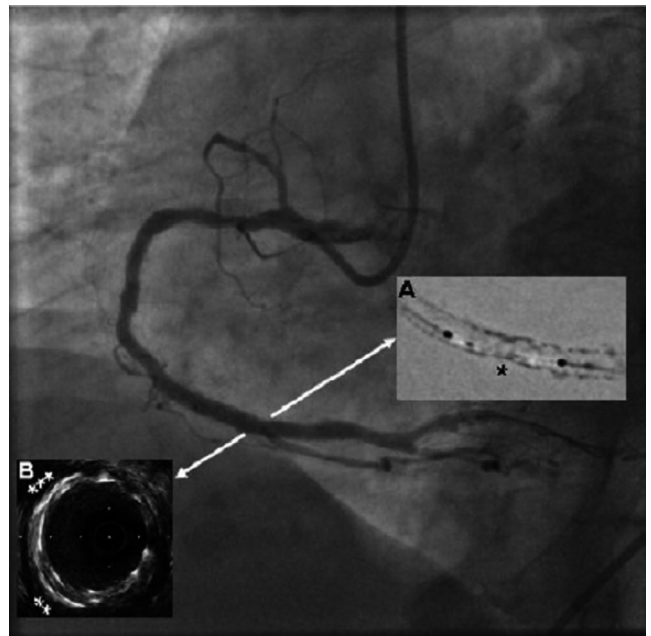
**FIGURE 7** Complete expansion (arrow) of  $3.0 \times 12$  mm shockwave intravascular lithotripsy catheter, after the second cycle at 6 Atm



**FIGURE 6** Attempt of dilatation of the under-expanded stent lesion using a  $2.5 \times 12$  mm NC balloon inflated at 30 Atm, without any result (arrow)

For these reasons, this procedure should be considered with extreme caution in highly experienced hands, preferably with surgical backup.<sup>16,17</sup>

Orbital atherectomy can be effectively performed as an adjunctive tool in the treatment of under-expanded stent, as shown in a retrospective study.<sup>18</sup>



**FIGURE 8** Final angiographic result. box A. StentViz application shows satisfactory stent expansion (asterisk indicate double layer of stent strut). box B. IVUS scan (frame position is pointed by thick arrow) shows complete stent expansion and apposition. Double and triple asterisks indicate double layer of stent strut

Intravascular lithotripsy is a novel technique based on an established treatment strategy for renal calculi. The shockwave medical coronary IVL catheter consists of a

0.014-inch guidewire-compatible, fluid-filled balloon angioplasty catheter with two lithotripsy emitters incorporated into the shaft of the 12-mm-long balloon segment. The coronary IVL system is delivered on a rapid exchange catheter and is available in 2.5-, 3.0-, 3.5-, and 4.0-mm diameters. Each catheter can provide up to 80 total IVL pulses and is intended for single use.

By emitting acoustic pressure waves in a circumferential, transmural fashion, during low-pressure inflation (4 Atm) of the balloon, IVL frequently produces circumferential calcium fractures in multiple planes, minimizing barotrauma of the vessel wall. Calcium fracture is the likely mechanism through which IVL enhances vessel compliance to facilitate optimal stent expansion<sup>7,19,20</sup>.

The critical aspects of these cases were the underuse of coronary intravascular imaging; in particular, IVUS was performed only in second case after angioplasty and restenting to check the final result. As known, intracoronary imaging can provide useful insights for precise lesion assessment including a detailed analysis of the axial, circumferential, and longitudinal distribution of calcium. This is particularly important in order to obtain an effective plaque modification by using the more appropriate device (ie, rotational atherectomy vs orbital atherectomy vs intravascular lithotripsy) before stent implantation.<sup>21</sup>

Anyway in second case, it emphasized the use of StentViz™ application (GE's Innova™ digital X-ray cardiovascular imaging system) as a valid tool to evaluate stent expansion rapidly and directly by angiographic images.

## 4 | CONCLUSION

Our cases demonstrate that IVL may be a promising tool for the treatment of under-expanded coronary stents. IVL was effective in both cases, characterized by very different time elapsed from stent implantation: the stent had been just deployed in case 1 and implanted three years before in case 2.

The main advantages of this technique are the short learning curve and the easiness to use. One drawback of this procedure is that the stenosis has to be crossable by the coronary lithotripsy catheter. In case of lesion uncrossability, rotational or orbital atherectomy or excimer laser angioplasty remains as the only option.

The good angiographic and clinical results observed in these two cases need to be confirmed in larger case series or controlled studies, in order to authorize its use in the treatment of under-expanded coronary stent.

## ACKNOWLEDGEMENTS

In addition, we thank those who were directly involved in the management of these cases.

## CONFLICT OF INTEREST

None of the authors has any conflict of interest in connection with this paper.

## AUTHOR CONTRIBUTIONS

Massimiliano Fedele is the author of the manuscript. Alessandro Iannone was the first operator of case 1 and was involved in data collection. Davide Bartolini was the first operator of case 2 and was involved in picture processing. Paolo Rubartelli is the co-author and supervisor of the manuscript. All the authors have confirmed during submission that patient consent has been signed and collected in accordance with the journal's patient consent policy.

## ETHICAL APPROVAL

Written informed consent was obtained from the patients.

## CONSENT

Published with written consent of the patient.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

## ORCID

Massimiliano Fedele  <https://orcid.org/0000-0002-9234-3806>

## REFERENCES

1. Prati F, Kodama T, Romagnoli E. Suboptimal stent deployment is associated with subacute stent thrombosis: optical coherence tomography insights from a multicenter matched study. From the CLI foundation investigators: the CLI-THRO Study. *Am Heart J*. 2015;169:249-256.
2. Armstrong EJ, Kwa AT, Yeo KK. Angiographically confirmed stent thrombosis in contemporary practice: insights from intravascular ultrasound. *Catheter Cardiovasc Interv*. 2013;81:782-790.
3. Egred M. A novel approach for under-expanded stent: excimer Laser in contrast medium. *J Invasive Cardiol*. 2012;248:E161-E163.
4. Latib A, Takagi K, Chizzola G. Excimer laser lesion modification to expand non dilatatable stents: the ELLEMENT registry. *Cardiovasc Revasc Med*. 2014;15:8-12.
5. Kobayashi Y, Teirsein PS, Linnemeier T. Rotational atherectomy (stentablation) in a lesion with stent underexpansion due to heavily calcified plaque. *Catheter Cardiovasc Interv*. 2001;52:208-211.
6. Kawata M, Kato Y, Takada H. Successfull rotational atherectomy for a repetitive restenosis lesion with underexpansion of double layer drug-eluting stents due to heavily calcified plaque. *Cardiovasc Interv and Ther*. 2016;31:65-69.

7. Brinton TJ, Ali ZA, Hill JM. Feasibility of shockwave coronary intravascular lithotripsy for the treatment of calcified coronary stenoses. *Circulation*. 2019;139:834-836.
8. Ali ZA, Nef H, Escaned J. Safety and effectiveness of coronary intravascular lithotripsy for treatment of severely calcified coronary stenoses: the disrupt CAD II study. *Circ Cardiovasc Interv*. 2019;12(10):e008434.
9. Hill JM, Kereiakes DJ, Shlofmitz RA. Intravascular lithotripsy for treatment of severely calcified coronary artery disease: the disrupt CAD III study. *J Am Coll Cardiol*. 2020;76(22):2635-2646.
10. Watkins S, Good R, Hill J. Intravascular lithotripsy to treat a severely underexpanded coronary stent. *EuroIntervention*. 2019;15(1):124-125.
11. Kassimis G, Didagelos M, Kouparanis A. Intravascular ultrasound-guided coronary intravascular lithotripsy in the treatment of a severely under-expanded stent due to heavy underlying calcification. To re-stent or not? *Kardiol Pol*. 2020;78(4):346-347.
12. Ielasi A, Moscarella E, Testa L. Intravascular lithotripsy for the management of undilatable coronary stent: the SMILE registry. *Cardiovasc Revasc Med*. 2020;1(12):1555-1559.
13. Górny B, Balak W, Bielawski G. Underexpanded stent in left anterior descending coronary artery treated with intravascular lithotripsy. *Postepy Kardiol Interwencyjnej*. 2020;16(2):216-218.
14. Alawami M, Thirunavukarasu S, Ahmed J. Intravascular lithotripsy to treat an underexpanded coronary stent: 4-Month angiographic and OCT follow-up. *Catheter Cardiovasc Interv*. 2020;96(6):1251-1257.
15. Seif S, Kumar A, Arya S. Intravascular lithotripsy to treat an underexpanded coronary stent during index procedure: a case report study. *Avicenna J Med*. 2021;11(1):54-57.
16. Edes IF, Ruzsa Z, Szabo G. Rotational atherectomy of undilatable coronary stents: stentablation, a clinical perspective and recommendation. *EuroIntervention*. 2016;12(5):e632-e635.
17. Barbato E, Carrie D, Dardas P. European expert consensus on rotational atherectomy. *EuroIntervention*. 2015;11:30-36.
18. Neupane S, Basir M, Tan C. Feasibility and safety of orbital atherectomy for the treatment of in-stent restenosis secondary to stent under-expansion. *Catheter Cardiovasc Interv*. 2021;97(1):2-7.
19. Ali ZA, Brinton TJ, Hill JM, et al. Optical coherence tomography characterization of coronary lithoplasty for treatment of calcified lesions: first description. *J Am Coll Cardiol Img*. 2017;10:897-906.
20. Karimi Galougahi K, Patel S, Shlofmitz RA, et al. Calcific plaque modification by acoustic shockwaves: intravascular lithotripsy in coronary interventions. *Circ Cardiovasc Interv*. 2021;14(1):e009354. <https://doi.org/10.1161/CIRCINTERVENTIONS.120.009354>
21. Wang X, Matsumura M, Mintz GS. In vivo calcium detection by comparing optical coherence tomography, intravascular ultrasound, and angiography. *JACC Cardiovasc Imaging*. 2017;10:869-879.

**How to cite this article:** Fedele M, Iannone A, Bartolini D, Rubartelli P. Shockwave intravascular lithotripsy in the treatment of under-expanded coronary stent: Case Series. *Clin Case Rep*. 2021;9:e04961. <https://doi.org/10.1002/ccr3.4961>