

Stent underexpansion in the CRUNCH registry: worth cracking?

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Stent failure represents an unwanted, yet common¹ cause of repeat coronary revascularisation of which underexpansion remains the leading cause. As might be expected, this unscheduled stop on the “revascularisation journey” predicts adverse clinical outcomes and is challenging to treat.

Stent underexpansion frequently relates to failure to modify the lesion sufficiently prior to stent deployment but may also be due to stent undersizing. Whilst coronary arterial calcium represents the plaque subtype with the lowest compliance and thus the most resistance to expansion, incomplete preparation of fibrous plaque may also lead to underexpansion, either through “primary” underexpansion or due to recoil.

Critically, without intravascular imaging (IVI) it remains nearly impossible to differentiate between these mechanisms, which have very different treatments. A “catch-22” scenario exists where the absence of prospective IVI makes the need for lesion preparation difficult to assess, stent sizing challenging and the mechanism of stent failure guesswork.

In the presence of established stent underexpansion, treatment is challenging and mechanism dependant. If due to calcium, the mechanistic goal is to fracture the calcium sufficiently to modify vascular compliance to allow stent expansion. It is probable that

fracturing this “retro-stent” calcium is more difficult than prospective lesion modification, and until recently the available options were limited.

These include high-pressure balloon dilatation, atherectomy, excimer laser catheter atherectomy (ELCA) and now, intravascular lithotripsy (IVL)

Of these, high-pressure balloon dilatation is the most frequently employed, but (especially in the absence of imaging) is not without risks and has questionable efficacy. The other available techniques (rotational atherectomy and ELCA) remain niche without convincing data on safety and with inherent technical challenges. As such, a genuine step forward in this challenging area is urgently needed but will require both safety and efficacy data.

Since its proven efficacy in native coronary lesions, IVL has been used off-label in stent underexpansion despite a lack of randomised data². In this issue of EuroIntervention, in the CRUNCH registry, Tovar Forero et al³ present outcomes in 70 patients undergoing IVL for underexpanded stents. Patients were included from 7 sites across Europe and Canada if they'd undergone IVL for significant stent underexpansion in previously deployed stents, or as a bailout strategy in immediately implanted stents. No formal angiographic or IVI criteria were used, and the use of adjunct

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treatments and decisions made were according to operator preference. Vessel measurements were performed by quantitative coronary angiography (QCA) or intracoronary imaging pre- and post-treatment. Device success was achieved in 92% of cases, meaning safe delivery of the device and energy ($\times 80$ pulses), residual stenosis $< 50\%$ and no predischARGE major adverse cardiovascular events (MACE). Importantly, there were no procedural complications, and only one case when the device was not deliverable. As per previous data, IVL was demonstrably safe and easy to use⁴.

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In this retrospective and uncontrolled analysis, it is not possible to confidently attribute all luminal gains to IVL; however, a significant increase in minimum stent area (MSA; 4.3 mm^2 to 6.5 mm^2) is statistically, and likely clinically, significant. Data such as previous non-compliant (NC) balloon size and inflation pressures are not available to compare, but it can be inferred that IVL has utility in the treatment of stent underexpansion due to calcification, consistent with its effect in *de novo* native lesions.

Does this then reduce the need for lesion preparation prior to stent deployment? Certainly not. It should be emphasised that the best way to prevent stent underexpansion and indeed stent failure is imaging-guided lesion preparation prior to stent deployment.

Intravascular imaging is underused

Intravascular imaging has become an indispensable tool in complex coronary intervention and is central to understanding how both to prevent and treat stent underexpansion.

Unfortunately, its adoption remains poor with a global penetration of 12% ⁵. Even in this contemporary cohort of underexpansion cases, only 63% were managed with the benefit of intravascular imaging, and fewer than $2/3$ of those had available MSA data. This is entirely consistent with the findings that IVL was in fact deployed as a bailout strategy during the index case in 43% of those included. Education in this area is clearly needed.

Mechanism of stent failure

Although it's reasonable to assume that coronary calcium is the predominant mechanism of underexpansion, other causes do exist.

Fibrotic lesions for example can be equally challenging but are morphologically and mechanically quite different. Unlike calcium, they are not visible on plain angiography, and are usually identified due to poor or differential expansion of predilatation balloons. Restrictive and prone to recoil, these lesions are not well modified by NC balloons, nor IVL, and ablative approaches such as cutting balloons, ELCA or brachytherapy are emerging as preferred techniques^{6,7}.

Stent underexpansion can also be a consequence of underdeployment and undersizing, where proper expansion with NC balloons is all that may be required.

When the mechanism is calcium, there is still nuance as to which strategy to adopt dependent on lesion morphology. Here, the balance of risk versus benefits needs to be carefully assessed.

Indeed, there is some suggestion that perforation risk is higher in eccentric or nodular calcium, which in turn might favour the greater safety profile of IVL.

Finally, other mechanisms of stent failure in addition to underexpansion are likely to co-exist and are equally important to identify. Stent fractures, geographic miss, and multiple layers of stent will all affect downstream decision-making once adequate expansion has been achieved. Multiple stent layers, as seen in 21% of this cohort, are a strong predictor of target lesion failure. Here there is a strong mandate to avoid further stenting and instead to aim for optimal expansion⁸.

Without intracoronary imaging to understand these mechanisms, the choice of treatment to remedy the problem is no more than guesswork.

In conclusion, stent underexpansion is avoidable with effective, imaging-guided lesion preparation. Although IVL, along with other calcium modification techniques, appears to be effective in the rescue of underexpanded stents, prevention is always better than cure. Intracoronary imaging use in percutaneous coronary interventions must increase to secure the best possible outcomes for patients. This data, whilst encouraging, should serve as a driver for further, much needed research within this challenging cohort.

Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Yin D, Mintz GS, Song L, Chen Z, Lee T, Kirtane AJ, Parikh MA, Moses JM, Fall KN, Jeremias A, Ali ZA, Shlofmitz RA, Maehara A; Collaborators. In-stent restenosis characteristics and repeat stenting underexpansion: insights from optical coherence tomography. *EuroIntervention*. 2020;16:e335-43.
2. Yeoh J, Cottens D, Cosgrove C, Mallek K, Strange J, Anderson R, Wilson S, Hanratty C, Walsh S, McEntegart M, Hill J, Spratt JC. Management of stent underexpansion using intravascular lithotripsy-Defining the utility of a novel device. *Catheter Cardiovasc Interv*. 2021;97:22-9.
3. Tovar Forero MN, Sardella G, Salvi N, Cortese B, di Palma G, Werner N, Aksoy A, Escaned J, Salazar CH, Gonzalo N, Ugo F, Cavallino C, Sheth TN, Kardys I, Van Mieghem NM, Daemen J. Coronary lithotripsy for the treatment of underexpanded stents; the international multicentre CRUNCH registry. *EuroIntervention*. 2022;18:574-81.
4. Hill JM, Kereiakes DJ, Shlofmitz RA, Klein AJ, Riley RF, Price MJ, Herrmann HC, Bachinsky W, Waksman R, Stone GW; Disrupt CAD III Investigators. Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease. *J Am Coll Cardiol*. 2020;76:2635-46.
5. Fearon WF, Zimmermann FM, De Bruyne B, Piroth Z, van Straten AHM, Szekely L, Davidavičius G, Kalinauskas G, Mansour S, Kharbada R, Östlund-Papadogeorgos N, Aminian A, Oldroyd KG, Al-Attar N, Jagic N, Dambrink JE, Kala P, Angerås O, MacCarthy P, Wendler O, Casselman F, Witt N, Mavromatis K, Miner SES, Sarma J, Engström T, Christiansen EH, Tonino PAL, Reardon MJ, Lu D, Ding VY, Kobayashi Y, Hlatky MA, Mahaffey KW, Desai M, Woo YJ, Yeung AC, Pijls NHJ; FAME 3 Investigators. Fractional Flow Reserve-Guided PCI as Compared with Coronary Bypass Surgery. *N Engl J Med*. 2022;386:128-37.
6. Latib A, Takagi K, Chizzola G, Tobis J, Ambrosini V, Niccoli G, Sardella G, DiSalvo M, Armigliato P, Valgimigli M, Tarsia G, Gabrielli G, Lazar L, Maffeo D, Colombo A. Excimer Laser LEsion modification to expand non-dilatable stents: the ELLEMENT registry. *Cardiovasc Revasc Med*. 2014;15:8-12.
7. Mangione FM, Jatene T, Badr Eslam R, Bergmark BA, Gallagher JR, Shah PB, Mauri L, Leopold JA, Sobieszczyk PS, Faxon DP, Croce KJ, Bhatt DL, Devlin PM. Usefulness of Intracoronary Brachytherapy for Patients With Resistant Drug-Eluting Stent Restenosis. *Am J Cardiol*. 2017;120:369-73.
8. Pal N, Din J, O'Kane P. Contemporary Management of Stent Failure: Part One. *Interv Cardiol*. 2019;14:10-6.