Uncrossable and undilatable lesions—A practical approach to optimizing outcomes in PCI

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Abstract
Uncrossable lesions are those that cannot be crossed with a balloon after successful guidewire crossing. These lesions are challenging and are commonly encountered in tortuous and calcified arteries as well as chronic total occlusions. They are the second most common barrier to successful PCI in CTO intervention after inability to cross the CTO segment with a guidewire. Procedures involving balloon uncrossable lesions during routine and CTO PCI utilize longer procedural times, radiation dose and contrast volumes with a lower likelihood of procedural success. In this article, we describe a pragmatic approach of managing balloon uncrossable lesions utilising the most contemporary equipment available in an algorithmic fashion beginning with simple, cost-effective techniques right up to complex strategies for advanced operators. In addition, some of these lesions, even when crossed by any technique, they may remain difficult to dilate and prepare for stent insertion. We describe an approach of how to manage these undilatable lesions.

KEYWORDS
atherectomy, directional/rotational, coronary artery disease, laser, percutaneous coronary intervention, percutaneous coronary intervention, complex PCI, CHIP PCI, Resistant lesions

INTRODUCTION
Uncrossable lesions are those that cannot be crossed with a balloon after successful guidewire crossing. These lesions are challenging and are commonly encountered in day-to-day PCI particularly in tortuous and calcified arteries as well as chronic total occlusions (CTO). Uncrossable lesions are encountered in up to 9% of all CTO interventions and are the second most common barrier to successful PCI in CTO intervention after inability to cross the CTO segment with a guidewire.\(^1,2\) Balloon uncrossable lesions encountered during CTO PCI are more likely to be heavily calcified, tortuous and have higher J-CTO scores.\(^2\) Procedures involving balloon uncrossable lesions during routine and CTO PCI utilize longer procedural times, radiation dose and contrast volumes with a lower likelihood of procedural success.\(^1\)

In this article, we describe a pragmatic approach of managing balloon uncrossable lesions utilizing the most contemporary equipment available in an algorithmic fashion beginning with simple, cost-effective techniques right up to complex strategies for advanced operators.

In addition, some of these lesions, even when crossed by any technique, they may remain difficult to dilate and prepare for stent insertion. We describe an approach of how to manage these undilatable lesions.
2 | BALLOON UNCROSSABLE LESIONS

2.1 | First line strategies

2.1.1 | Guide catheter support

The use of a supportive guide catheter can be the difference between success and failure. Active and passive support can be increased by selecting different shaped guides or those with larger diameters (7Fr or 8Fr). Supportive guiding catheters utilize back up support from the contralateral wall of the aorta and help with coaxial alignment to the coronary arteries. Deep engagement of the guide catheter into the coronary artery helps to provide active support, although as catheter size increases there is potential for complications from dissection and pressure damping.

In the senior author’s practice and in cases of CTO or calcified and tortuous arteries, it is the norm to use 7Fr or 8Fr (for CTO cases) right from the start. The senior author’s moto for trainees is “you want to be fighting with one thing and one thing only and that is the lesion, guide support is paramount.”

2.1.2 | Balloon selection

Adequate lesion preparation requires an expanded noncompliant (NC) balloon sized 1:1 with the arterial diameter. Low-profile semi-compliant (0.85–1.5 mm in diameter) balloons with lubricious coatings and low crossing profiles should first be utilized before a lesion is deemed uncrossable. Examples include the 1.0 mm Sapphire Pro (Orbus Neisch), 1.2 mm Mini-Trek (Abbott Vascular), 0.85 mm Nano (Vascular Perspectives), Sprinter Legend (Medtronic), Across CTO (Acrostak), Apex Push (Boston Scientific), and Chocolate (Teleflex) balloons. Oscillating the balloon in a forward and backward motion is a technique based upon the physical principle that dynamic friction is less than static friction and may help with crossing resistant lesions.

A new ultralow profile balloon for resistant uncrossable lesions particularly in CTO PCI has been introduced, the Blimp balloon (Abbott Vascular). However, limited experience exists so far.

2.1.3 | Guide catheter extensions

Guide catheter extensions permit deep intubation and reach into the coronary artery and facilitate a smooth pathway to the lesion, traversing calcification and tortuosity in the proximal artery. This increases support and push at highly resistant lesions increasing the chances of crossing and successful lesion preparation. Many devices with subtle design enhancements are available including the Heartrail II (Terumo) which is an over the wire (OTW) catheter, Guideliner (Vascular Solutions), Guidezella (Boston Scientific), and the Telescope (Medtronic).

Previous publications have supported the use of guide catheter extensions to enhance lesion crossability with two case series using the Guideliner device reporting 93% device success rate when used in cases with tortuous and calcified anatomy.

In cases of difficult delivery of the guide extension catheters, a method called “inchworm technique” can be used. It works by inflating the balloon immediately distal to the guide extender than pulling the extender over as the balloon is deflated. This is usually the most efficient way to advance the guide extender. Alternatively, a balloon can be inflated distally and the Guide Extender advanced with the balloon inflated (anchor technique).

2.1.4 | Wire-based support techniques

The use of an extra supportive wire is important when dealing with these cases and can help overcome the problem. A specialty wire, the Wiggle wire (Abbott Vascular) that has several bends in its body proximal to the tip can be an option. It works by shifting the direction of the pushing forces thus “stepping over” the obstacle and pushing the balloon or stent away from the arterial wall and facilitating delivery.

The Buddy wire technique involves passing a second wire through the lesion in order to enhance support. This can help to straighten tortuous bends and reduce friction from wire bias. An extension of this technique is the use of a second wire to modify resistant lesions in the so-called wire cutting technique as described by Hu et al. In this process, two coronary guidewires are passed into the distal vessel and a balloon advanced to the site of the lesion abutting the uncrossable segment. The balloon is then inflated, jailing the second guidewire between the balloon and the lesion; this guidewire is then rapidly withdrawn producing a cutting effect and modifying the lesion to facilitate balloon crossing.

2.1.5 | Anchoring techniques

Anchor balloon support techniques offer additional support by inflating a balloon in a proximal side branch to enhance guide catheter stability and alignment. Appropriate sizing of the anchor balloon is crucial to prevent side-branch dissection or perforation. An optimal anchor balloon needs to be large enough not to slip.

Similarly, a wire can be used as an anchor by positioning it in a side branch which helps to stabilize the guide catheter and offer some support albeit not as efficient as an anchor balloon. An extra supportive wire is always advisable whenever an anchor wire or balloon is used alone. A guide catheter extension and an anchor balloon can also be used with two French discrepancies (i.e., 8Fr with 6Fr or less).

2.1.6 | Microcatheters

Microcatheters offer a tapered pushable device with the ability to transmit torque into and beyond resistant lesions. This can create a small channel through which small, and subsequently larger, balloons can be passed. Coiled microcatheters in particular need to be spun quickly in order to reduce friction in the proximal vessel and to build up torque helping to cross-resistant lesions. Depending on task at
hand, a range of microcatheters with differing design properties are available including Tornus (Asahi Intecc), Corsair (Asahi Intecc), Finncross (Terumo), Turnpike, Turnpike LP, Turnpike Spiral, Turnpike Gold (Teleflex), and Mamba (Boston Scientific). The Tornus catheter is a metal exchange penetration catheter comprising eight individual larger wires stranded together to form a spiral (0.12 mm in Tornus (2.1F) and 0.18 mm in Tornus 88Flex (2.6F)). This results in a highly pushable device making it useful in calcified lesions, while the thicker wires, higher tip stiffness and screw pitch design of the Tornus 88Flex makes it a more forceful, penetrating microcatheter. Its contribution to case completion by enhancing lesion crossing has been established in multiple small case series. The Corsair and Caravel microcatheters (Asahi Intecc) are hybrid microcatheter/septal dilators useful for antegrade and retrograde CTO PCI. The "Shinka" shaft of the Corsair microcatheter is made of 2 larger (0.12 mm) stainless steel wires wrapped around eight smaller (0.07 mm) wires allowing pushability and transmission of force, along with flexibility. The braided spiral structure allows bidirectional rotation while advancing this tapered, low profile microcatheter.

The Turnpike family of microcatheters (Turnpike, Turnpike Spiral, Turnpike LP, Turnpike Gold) use a unique multilayered shaft to enhance torque, flexibility and tracking whilst the hydrophilic coating over the distal 60 cm enhances lubricity. The Turnpike Spiral has a soft nylon outer coil on the distal 2 cm of shaft which provides rotational assistance for forward progression through lesions when rotated clockwise. The Turnpike Gold has a threaded metal tip enhancing penetrative capability by screwing through resistant lesions.

2.2 Second line strategies

2.2.1 Balloon-assisted microdissection

If the proximal cap is "uncrossable" with low-profile balloons despite the use of enhanced guide catheter and wire support, balloon-assisted microdissection can allow devices to penetrate the cap or facilitate subintimal access. This technique involves advancing the balloon tightly against the lesion and intentionally rupturing it adjacent to the lesion, which can create microdissections around or into lesion. This can modify the morphology of the lesion or create microdissections, which in turn can allow another balloon to pass or makes subintimal entry possible, thus bypassing the resistant lesion in the subintimal space and allowing reentry distal to the lesion. This technique is easy to perform and low in cost with a small case series suggesting up to 50% success rate. There is a small risk of staining or perforation with this technique.

2.2.2 Excimer laser coronary atherectomy

Excimer laser coronary atherectomy (ELCA) utilizes a directional beam of monochromatic (single wavelength) light and heat energy to modify plaque by photochemical (fracture of molecular bonds), photothermal (tissue vaporization), and photokinetic (clearance of by-products) mechanisms. The prominent mechanism that affects calcium is mainly the photoacoustic which creates fractures in the calcium and facilitate lesion preparation. The laser machine emits energy with a fluence between 30 and 80 mJ/mm² and a repetition rate of 25–80 pulses/s through a multitude of catheters ranging in size from 0.9 to 2.0 mm in diameter. ELCA is performed under continuous saline infusion. In highly resistant lesions, activation in contrast potentiates the formation of larger bubbles to modify plaque but is associated with increased risk of perforation.

2.2.3 High-speed rotational atherectomy and orbital atherectomy

High-speed rotational atherectomy (HSRA) is fundamental to facilitate lesion debulking and crossing where balloons will not track. Thinning of the calcium with HSRA that allows its fracture with dilatation is thought to be the mechanism of action. The ROTABLATOR system and ROTAPRO (Boston Scientific) offer burr sizes from 1.25 to 2.50 mm for calcium modification on a 0.009” stainless steel wire. Utilizing HSRA to modify calcific plaque and incite fractures within the calcium to enable lesion expansion is the preferred strategy prior to stent implantation. It does, however, require the 0.009” wire to be passed distally which on occasion can be challenging in uncrossable lesions.

Orbital atherectomy (OA), where available, is another way of overcoming this type of lesions once crossed by a wire. In Europe OA is not currently in clinical use while it is available in North America and other countries.

Combining ELCA and HRSA (also known as RASER angioplasty) has also been reported for use in lesions where ELCA cannot fully debulk in isolation but creates a "pilot hole" that facilitates passage of RotaWire either independently or via microcatheter exchange to permit subsequent HRSA and procedural success.

2.3 Third line strategies

2.3.1 Dissection reentry: The subintimal approach

If a lesion remains truly uncrossable then the final option would be to go around it. This means entry to the subintimal space and modification of the lesion from the outside.

A wire is left in the true lumen to help minimize the risk of vessel occlusion and ischemia and it can be used as a landmark for reentry. Access to the subintimal space can be gained by a "scratch and go" technique where a stiff wire is used to penetrate into the subintimal space followed by a softer wire which can knuckle or track around the lesion. Access to the subintimal space can also come from balloon-assisted subintimal entry procedure where a balloon sized 1:1 with the reference diameter of the vessel is inflated proximal to the
lesion. This balloon incites dissections which act as an entry point to the subintimal space. From here wires, and subsequently balloons, can be passed around the lesion and reenter the distal true lumen. This allows modification of the uncrossable lesion from a different perspective, often crushing and distorting it from the outside. Once modified, access to the distal true lumen can be regained with a stiff wire or the dedicated stingray reentry balloon and the lesion stented in the usual fashion.

This approach should be a last resort and only performed by experienced CTO operators.

3 | THE UNDILATABLE LESIONS

Once the lesion has been crossed, it is essential to get adequate lesion preparation prior to stent implantation. Stent deployment prior to effective lesion preparation leaves limited and challenging therapeutic interventions to achieve a good final result if the stent remains under expanded. Luminal dimensions and minimal stent area are important factors in determining long-term incidence of in-stent restenosis (ISR) and stent thrombosis. In a similar approach to crossing uncrossable lesions, a step-wise approach to lesion modification should be utilized beginning with the least invasive strategy.

3.1 | NC balloons

NC balloons allow transmission of high pressures to resistant lesions without change in volume, therefore focusing the pressure within the lesion rather than transmitting it to other parts of the artery as can happen with semicompliant balloons. Balloon dilatation is limited in eccentric calcific plaque as guidewire bias may direct transmission of force away from the calcified segment or due to eccentric dilatation due to segmental compliance. Despite this transmission of high pressure, many lesions fail to dilate and require more aggressive strategies.

On occasions, inflating two smaller size balloons in the lesion simultaneously can produce a positive outcome or inflating a 1/1 size balloon to high pressure then reducing and then inflating it again in an oscillating manner can work too (personal experience).

We recommend the use of shorter NC balloons which help to focus the applied pressure.

3.2 | Ultrahigh-pressure NC balloons

Ultrahigh-pressure balloons can deliver pressures of up to 40 atm. The OPN balloon (SIS Medical, Switzerland) has a unique twin layer balloon construction allowing transmission of super high pressure with a low incidence of balloon rupture (factory tested rated burst pressure 42 atm). Although seemingly aggressive and intuitively may increase the risk of perforation, their safety and efficacy have been established with a low incidence of complications. Deliverability of the bulky twin layer balloon means that its utility in crossing resistant lesions is limited.

3.3 | Cutting/scoring balloons

Cutting balloons consist of OTW or monorail NC balloons with atherotomes (microsurgical blades) mounted longitudinally along the surface. The Wolverine coronary cutting balloon (Boston Scientific, Marlborough, MA) is available in size 2.00–3.25 mm (balloon diameter models with three atherotomes) or 3.5–4.0 mm (balloon with four atherotomes) which cut into plaque creating initiation sites for crack propagation. The atherotomes have the advantage of anchoring into the intima, preventing slippage frequently seen with focal short lesions and ISR.

Scoring balloons consist of balloon mounted spiral scoring wires designed to anchor into fibrocalcific plaque. The AngioSculpt RX (Spectranetics, Colorado Springs, CO) is composed of a semicompliant balloon surrounded by three nitinol spiral scoring wires. It has a lower crossing profile than OPN ultra high-pressure balloons or cutting balloons and is associated with an increased luminal gain compared to lesion preparation with NC balloons alone.

While cutting balloons and scoring balloons should preferentially be used in plaque modification pretreatment implantation, they can also be used to improve stent expansion post stent deployment, and are a useful adjunct in treating ISR.

3.4 | Excimer laser coronary atherectomy

Similar to enhancing lesion crossing, excimer laser can be used to modify undilatable lesions through photothermal, photochemical and photomechanical disruption of resistant plaque. After modification of the underlying plaque with ELCA, balloon dilatation with a NC balloon sized 1:1 with the lumen diameter should be used to ensure adequate lesion expansions. Excimer laser with and without contrast for the management of under expanded stents is a safe and viable method to achieve adequate stent expansion in underexpanded stents that are usually the result of deploying a stent in an undilatable and poorly prepared lesion.

3.5 | Rotational atherectomy

HSRA is a fundamental technique to enhance lesion crossing as a debulking device. Debunking and fracturing heavy calcification enhances lesion crossing and expansion. Balloon dilatation with a NC balloon sized 1:1 with the artery is essential following HSRA to ensure effective calcium modification, fracture and lesion expansion prior to stent implantation.

3.6 | Intravascular lithotripsy

Intravascular lithotripsy (IVL) uses a series of electrohydraulic lithotripsy emitters housed within a balloon to create ultrasonic pressure waves which dissipate through calcific plaque causing fractures.
shockwave IVL system (Shockwave Medical Inc., Fremont, CA) is available in balloon sized 2.5–4.0 mm and 12 mm length and balloons should be sized 1:1 with the vessel reference diameter. The balloon catheter is then connected to a generator which delivers 10 pulses of ultrasonic energy over 10 s, up to a maximum of eight cycles per balloon. IVL works best with a circumferential arc of calcium (>270°) as the ultrasonic waves reverberate to cause fractures in calcium. After delivering the IVL and if the balloon has fully expanded, then it is not uniformly recommended to follow on with a predilatation balloon. However, many operators use an NC balloon for optimal lesion expansion. In the DISRUPT CAD I trial (ClinicalTrials.gov, number NCT02650128) calcified lesions pretreated with IVL had reduced residual stenosis and multiple fracture lines in calcific plaque on OCT without any MACE. It is easy to use, has a low crossing profile especially in comparison to OPN and cutting balloons and has very few side effects.

Figure 1 demonstrates an algorithm of the techniques that can be used in resistant lesions.

4 | CONCLUSION

Balloon uncrossable lesions are commonly encountered during routine and CTO PCI and are a potential barrier to successful revascularization. Employing basic principles in guide catheter support and adjunctive techniques for crossing resistant lesions increases the likelihood of successful lesion crossing. Once a balloon can cross a lesion, the lesion must be adequately prepared and expanded prior to stent implantation.

Undilatable lesions pose a further challenge to obtaining optimal stent expansion which can result in ISR and stent thrombosis. Utilizing advanced techniques and embracing new technological advances is key to adequately preparing and debulking lesions in order to get the best stent results and outcomes for patients.

It is important to emphasize that these techniques are interchangeable and can be used in any order depending on availability and operator experience to help achieve a successful PCI outcome.
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