Prolonged Inflation Technique Using a Scoring Balloon for Severe Calcified Lesion Creep Phenomenon

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Summary
Percutaneous coronary intervention for the treatment of a severe calcified lesion is still one of the most technically challenging areas of interventional cardiology. Calcified lesions are a cause of stent underexpansion, which significantly increases the subsequent risks of in-stent restenosis and thrombosis, even when drug-eluting stents are used. In this report, we describe the usefulness of prolonged inflations using a scoring balloon catheter (Scoreflex) for severe calcified lesions. Prolonged inflation using a scoring balloon enables an adequate dilation for treatment of a severe calcified plaque that was unresponsive to conventional technique with or without rotational atherectomy.

Key words: Calcified plaque and indentation, Scoreflex

The use of drug-eluting stents (DESs) reduces the risks of repeat revascularization without an increase in death and myocardial infarction compared with the standard bare-metal stents. However, the risk of in-stent restenosis and stent thrombosis (ST) after DES implantation still remains.

Percutaneous coronary intervention (PCI) for the treatment of a severe calcified lesion is still one of the most technically challenging areas of interventional cardiology.1) Calcified lesions are a cause of stent underexpansion, which significantly increases the subsequent risks of ISR2,3) and ST,4,5) even when DESs are used. In addition, there is occasionally a severe calcified plaque unresponsive to conventional technique with or without rotational atherectomy (RA), and it leads to failure of an adequate dilation. Herein, we describe four cases with usefulness of prolonged inflation using a scoring balloon catheter (Scoreflex) for severe calcified lesions, and we discuss the potential mechanism and optimal management for a calcified lesion that was unresponsive to conventional technique with or without RA.

Case Reports
As a prolonged inflation method, the balloon dilation protocol was performed by doing a 3-minute expansion in 3 cycles for the resistant lesion so as to avoid long-time ischemia during prolonged balloon inflation. If the lesion is not expanded using this protocol, the size of scoring balloon catheter will be adequately increased.

Case 1: Coronary angiography (CAG) showed a severe stenosis of the left circumflex (LCx) artery (Figure 1A) in a 67-year-old male patient with angina pectoris. PCI was performed with a 6-Fr EBU 3.5 Taiga guiding catheter (Medtronic, USA) via the right radial artery. An intravascular ultrasound (IVUS) probe (OptiCross; Boston Scientific, USA) was unable to pass the severe calcified lesion before PCI. A 2.5 × 15 mm Raiden 3 conventional non-compliant balloon (Kaneka, Japan) was placed in the lesion and inflated to 22 atm. However, the calcified lesion could not be dilated (Figure 1B). The buddy wire technique was also unsuccessful (Figure 1C) in dilating the lesion. Subsequently, a 2.5 × 15 mm Scoreflex balloon catheter (OrbusNeich, Hong Kong, China) under the buddy wire technique was used. The Scoreflex balloon catheter was gradually inflated up to 16 atm, but again, it could not fully expand (Figure 1D). Therefore, prolonged inflation was tried to expand this resistant lesion with heavy calcification. We performed a protocol by doing a 3-minute expansion in 3 cycles (16 atm). In this case, the calcified lesion was finally dilated by an expansion of 7.5 minutes in total (Figure 1E). IVUS after Scoreflex balloon angioplasty showed two fissures on a superficial calcified plaque (Figure 1F). A 2.75 × 28 mm Synergy stent (Bos-
Case 2: CAG showed a severe stenosis of the proximal left anterior descending (LAD) artery and a moderate diffuse stenosis of the mid-LAD artery (Figure 2A) in a 63-year-old male patient with silent myocardial ischemia. PCI was performed with a 7-Fr EBU 4.0 Launcher guiding catheter (Medtronic) via the right femoral artery. An IVUS probe (OptiCross; Boston Scientific) was unable to pass the severe calcified lesion before PCI. Therefore, RA was performed in an attempt to partially ablate the underlying calcium to allow subsequent balloon expansion. A 1.5-mm Rotablator burr (Boston Scientific) was first used (Figure 2B). Following RA, IVUS showed a heavy circumferential calcified lesion of the proximal LAD artery. A 2.5 × 10 mm Scoreflex balloon catheter (OrbusNeich) successfully dilated the mid-LAD lesion. Although it was utilized in an attempt to inflate up to 18 atm, it could not fully expand the proximal LAD lesion (Figure 2C). Stepped RA was performed using a 2.0-mm Rotablator burr (Boston Scientific) for the proximal LAD artery (Figure 2D). Following this aggressive rotablation, a 3.0 × 15 mm Scoreflex balloon catheter was used. The Scoreflex balloon catheter was gradually inflated up to 16 atm, but again, it could not fully expand (Figure 2E). Therefore, prolonged inflation (16 atm) was performed, and the calcified lesion was finally dilated by an expansion of 3 minutes in total (Figure 2F) in this case. A 3.0 × 32 mm Promus Element stent (Boston Scientific) at the mid-LAD artery and a 3.5 × 24 mm Nobori stent (Terumo, Japan) from the proximal LAD artery to the left main trunk were successfully implanted (Figure 2G).

Case 3: CAG showed a severe stenosis of the proximal LAD artery and a moderate stenosis of the distal LAD artery (Figure 3A) in a 64-year-old male patient with old myocardial infarction and angina pectoris. PCI was performed with a 7-Fr EBU 3.75 Launcher guiding catheter (Medtronic) via the right femoral artery. An IVUS probe (OptiCross; Boston Scientific) was unable to pass the severe calcified lesion before PCI. Therefore, stepped RA was performed using 1.5- and 2.0-mm Rotablator burrs (Boston Scientific) for the proximal LAD artery (Figure 3B and C). Following RA, IVUS showed a heavy circumferential calcified lesion of the proximal LAD artery (Figure 3B and C). Subsequently, a 2.5 × 10 mm Scoreflex balloon catheter (OrbusNeich) was used. The Scoreflex balloon catheter was dilated for the distal LAD artery, but it could not fully expand for the proximal LAD artery. Then, the size of Scoreflex balloon catheter was increased, and a 3.0 × 15 mm Scoreflex balloon catheter was used for the proximal LAD artery. The Scoreflex balloon catheter was gradually inflated up to 16 atm, but again, it could not fully expand (Figure 3D). Therefore, prolonged inflation (16 atm) was performed, and the calcified lesion was finally dilated by an expansion of 7 minutes in total (Figure 3E) in this case. A 3.0 × 12 mm Promus Element stent (Boston Scientific) at the distal LAD artery and a 3.0 × 38 mm Promus Element stent (Boston Scientific) was successfully implanted at the LCx artery (Figure 1F).
Figure 2. A: CAG showing severe stenoses of the mid and proximal left anterior descending (LAD) artery (white and red arrows). Red arrow indicates a calcified lesion. B: Rotational atherectomy (RA) using a 1.5-mm burr. C: Balloon angioplasty using the Scoreflex balloon catheter. It fully expanded for the mid-LAD artery but not for the proximal LAD artery. D: Stepped RA using a 2.0-mm burr for the proximal LAD artery. E: Balloon angioplasty with the Scoreflex balloon catheter after aggressive RA was performed but could not fully expand (blue arrow). F: It fully expanded by prolonged inflation (blue arrow). G: Final angiography after drug-eluting stent (DES) implantation.

Figure 3. A: CAG showing severe stenoses of the distal and proximal LAD artery (white and red arrows). Red arrow indicates a calcified lesion. B: RA using a 1.5-mm burr. An IVUS image showing a superficial calcified plaque after RA. C: Stepped RA using a 2.0-mm burr. An IVUS image showing a lumen enlargement of a superficial calcified plaque. D: Balloon angioplasty with the Scoreflex balloon catheter after aggressive RA could not fully expand (blue arrow). E: It fully expanded by prolonged inflation (blue arrow). F: Final angiography. An IVUS image showing two fissures (pink arrows) observed on a superficial calcified plaque after Scoreflex balloon angioplasty.
Figure 4. A: CAG showing a chronic total occlusion (CTO) of the LAD artery (white dots). Red arrow indicates a severe stenosis with calcified plaque. Yellow arrows indicates collateral from the isolated conus branch to the distal LAD artery. B: Coronary guidewire crossing CTO lesion. C: Balloon angioplasty with conventional balloon catheter performed but showing existing resistant stenosis revealed by balloon indentation. An IVUS image showing a superficial calcified plaque. D: Balloon angioplasty with the Scoreflex balloon catheter could not yet fully expand (blue arrow). E: It fully expanded by prolonged inflation (blue arrow). F: Final angiography. An IVUS image showing two fissures (pink arrows) observed on a superficial calcified plaque after Scoreflex balloon angioplasty.

Case 4: CAG showed a chronic total occlusion (CTO) of the proximal LAD artery and a good collateral circulation from the isolated conus branch (Figure 4A) in a 62-year-old female patient with angina pectoris. PCI was performed using an antegrade approach with a 7-Fr EBU 3.5 Launcher guiding catheter (Medtronic) via the right femoral artery. Contralateral angiography was performed by a contrast injection from the Mizuki microcatheter (Kaneka) delivered to the isolated conus branch with a 7-Fr JR 3.5 Launcher guiding catheter (Medtronic) via the left femoral artery. An XT-R guidewire (Asahi Intecc, Japan) and a Caravel microcatheter (Asahi Intecc) were used to cross this CTO lesion but were unsuccessful in dilating the lesion. Therefore, we changed the guidewire to a Gaia first guidewire (Asahi Intecc). A Gaia first guidewire was advanced toward the proximal part of the CTO lesion but was advanced to the subintimal space. Then, we changed the guidewire to an XT-R guidewire, and it was finally able to cross this CTO lesion (Figure 4B). A 1.0 mm x 6 mm Ikazuchi Zero balloon catheter (Kaneka) was able to cross and successfully dilate the CTO lesion. However, a conventional balloon was employed in an attempt to inflate up to 18 atm, but it could not fully expand (Figure 4C). An IVUS (OptiCross; Boston Scientific) showed a heavy circumferential calcified lesion of the proximal LAD artery of CTO lesion (Figure 4C). Subsequently, a 2.5 x 10 mm Scoreflex balloon catheter (OrbusNeich) was used. The Scoreflex balloon catheter was gradually inflated up to 16 atm, but again, it could not fully expand (Figure 4D). Therefore, prolonged inflation (16 atm) was performed, and this calcified lesion finally dilated by an expansion of 6.5 minutes in total (Figure 4E) in this case. A 2.5 x 38 mm Promus Premier stent (Boston Scientific) and a 3.0 x 32 mm Promus Premier stent (Boston Scientific) were successfully implanted at the LAD artery (Figure 4F).

Discussion

In the present report, we demonstrated that prolonged inflation using the Scoreflex balloon catheter can safely achieve optimal dilations for severe calcified lesions that were unresponsive to conventional technique with or without RA. It has been reported that stent underexpansion is significantly related to an increased risk of ISR\(^2,3\) and ST,\(^4,5\) even when DES is employed. Calcified lesions are one of the main causes of stent underexpansion.\(^1\) Lesion preparation for enabling optimal stent expansion remains an essential part of current interventional practice and would be particularly beneficial for patients with undilatable calcified lesions prior to DES implantation.\(^1\) Several devices such as those used in directional coronary atherectomy,\(^10\) RA,\(^11,12\) and cutting balloon\(^10,11,12\) for calcified lesions have been proposed to achieve optimal dilation prior to...
tient implantation. However, it is occasionally difficult to achieve dilation because of the presence of a heavy calcified plaque even after RA. Because the maximum size of Rotablator burrs is limited in current procedures, an additional approach should be considered when conventional technique after aggressive RA is ineffective. In addition, the cutting balloon has a poor deliverability because of the bulky device with blades around the surface of the balloon. It is difficult sometimes to cross the cutting balloon in a severe calcified lesion, particularly with bending.

As a first choice for a calcified lesion, we usually use the Scoreflex balloon catheter (the previous name was SafeCut balloon catheter), which is a short monorail-type balloon catheter that has superb passing ability with a lower profile. The Scoreflex balloon catheter is more flexible to deliver than a cutting balloon is. In addition, the Scoreflex balloon catheter is a semicompliant balloon catheter with dual wires that exert focused inflation forces. It can facilitate controlled plaque fractures because the built-in integral wire and the coronary guidewire on the outside of the balloon create a focused force in a localized region of the plaque. Focused-force angioplasty is a technique in which the forces resulting from inflating an angioplasty balloon in a stenotic lesion are concentrated and focused on one or more locations within the stenosis. This technique, including the conventional buddy wire technique and cutting balloon, has been shown to be useful in resolving resistant stenosis. The buddy wire technique is easy and simple and may be an effective technique for dilation of calcified lesions. We have already reported that the Scoreflex balloon was superior to the buddy wire technique for resistant calcified lesions. This suggests that the built-in integral wire of the Scoreflex balloon may play an important role in facilitating fracture of calcified lesions. This device could potentially treat resistant calcified lesions that have failed treatment with other devices. The balloon inflation pressure required for cracking the calcium tubes was lower with the Scoreflex balloon catheter than it was with the conventional balloon catheter in the bench test. In addition, stress of the Scoreflex balloon catheter was concentrated in the outside of the calcified plaque just opposite to the scoring element. It has been known that calcified plaque is weaker in tensile stress than in compressive stress. In short, a tensile stress on the outside of circumferential calcification by the Scoreflex balloon catheter may create the crack of calcified plaque, which was unresponsive to high-pressure inflation using a conventional balloon after aggressive RA.

**Creep phenomenon:** Creep is the deformation that occurs under a prolonged, sustained load and can lead to damage in material. A creep phenomenon curve expresses a relationship between time and strain (elongation due to load) when a constant tensile load during a long time has been added to the material. It is classified into three creep stages (Figure 5). In the primary creep after an instantaneous elongation, the strain rate is relatively high but decreases with time because of work hardening. In the secondary creep, the strain rate eventually reaches a minimum and becomes nearly constant. In the tertiary creep, the strain rate exponentially increases with stress because of microcrack formation and subsequent crack propagation. Fracture and cracking of material occur at the tertiary stage. The expansion of the usual lesion can be dilated in the primary or secondary creep, but a distortion produces a prolonged constant load for the resistant calci-
fied lesion with treatment resistance in the tertiary creep, and it finally induces fracture. We guess that the mechanism of expansion by prolonged inflation is because sustained tensile stress produces a distortion for a resistant heavy calcified lesion by a creep phenomenon.

**Clinical limitation:** This method needs to perform prolonged inflation of balloon, but it may induce long-time ischemia. Therefore, we cannot use this method when long-time ischemia is not tolerable or hemodynamics fails during ischemia in the patients. This method might be unsuitable for treatment of the left main stem artery and the collateral donor artery with a severe calcified plaque. Finally, we believe that this method will lead to the optimal dilation for treatment of unresponsive lesions using conventional technique. However, the number of subjects studied is too small to be able to make any meaningful conclusions. Further study is necessary to verify that this method is the optimal strategy for unresponsive calcified lesion.

**Conclusions**

Prolonged inflation using a scoring balloon enables an adequate dilation for treatment of a severe calcified plaque that was unresponsive to conventional technique with or without RA. Described prolonged inflation is therefore considered to be a worthwhile method for the resistant calcified lesion.

**Disclosures**

**Conflicts of interest:** None.

**References**