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Case Report

Leopard crawl technique using a tapping motion delivery method for Aperta NSE in severely calcified coronary lesions

Kazuhiro Ashida, Takayuki Shinmura, Keisuke Nakashima, Kei Kawai, Takayuki Senba, Kazuki Hasegawa, Togo Norimatsu

Seirei Yokohama Hospital, Yokohama-shi, Kanagawa, Japan

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Abstract: Calcified coronary lesions are a significant factor contributing to both problematic stent delivery and/or inadequate stent expansion. Creating multiple cracks in calcified lesions is essential in order to facilitate ease of stent delivery and sufficient non-eccentric stent expansion. The correct selection of a scoring or cutting balloon is paramount to creating reproducible results in terms of forming multiple cracks within a calcified lesion. The conventional Lacrosse NSE is a scoring balloon catheter that is considered capable of achieving a high scoring effect. An improved scoring balloon, Aperta NSE PTCA (Aperta NSE), has recently become commercially available in Japan. The Aperta NSE uses a non-compliant balloon platform with three nylon elements integrated longitudinally on the balloon and positioned 120 degrees apart. The expansion force of the entire balloon is concentrated at these three elements, resulting in a superior dilative effect during balloon dilatation. Compared to the conventional Lacrosse NSE, the Aperta NSE incorporates several modifications: 1) it utilizes a non-compliant balloon delivery platform, 2) the elements are integrated with the balloon, and 3) it features a shortened, lower-profile tip. Various techniques, such as the 'leopard crawl' method, have been employed to enhance the deployment of the conventional Lacrosse NSE for calcified lesions. This same "leopard crawl" method was tested on the new Aperta NSE to assess the efficacy and to evaluate if this technique does in fact bolster delivery efficiency. Based on in-vitro clinical test results, a modified leopard crawl technique was proved to be effective. In light of the structural improvements to the Aperta NSE, we present our findings on a modified leopard crawl technique that employs a tapping method to enhance delivery functionality.

Keywords: Percutaneous coronary intervention, scoring balloon, coronary calcification, 'leopard crawl' technique, intravascular ultrasonic imaging, computed tomography angiography

Introduction

Pre-dilatation is a preparatory medical procedure conducted before the main intervention, in which a balloon catheter is employed to dilate a narrowed or obstructed blood vessel. This step is typically undertaken to ready the vessel for stent placement, ensuring adequate expansion of the target area and facilitating the successful delivery and deployment of the primary therapeutic device. Stent delivery in the context of severely calcified coronary lesions often leads to inadequate or eccentric dilatation, even if clinically successful [1-3]. Therefore, a controlled pre-dilatation is essential prior to stent deployment [4, 5].

Devices such as the Rotablator and RotaPro (RA) (Boston Scientific, Marlborough, MA, USA) and the Diamondback 360 (OA) (Cardiovascular Systems Inc., St. Paul, MN, USA) primarily function to reduce the thickness of calcified plaque. In contrast, scoring and cutting balloons are designed to facilitate reproducible outcomes by creating multiple cracks within calcified lesions, thereby enhancing the effectiveness of subsequent stent deployment. However, many commercially available scoring balloons have been reported to be less effective compared to the conventional Lacrosse NSE (NIPRO Corporation, Osaka, Japan), which offers improved deliverability and successful stenting [6, 7].

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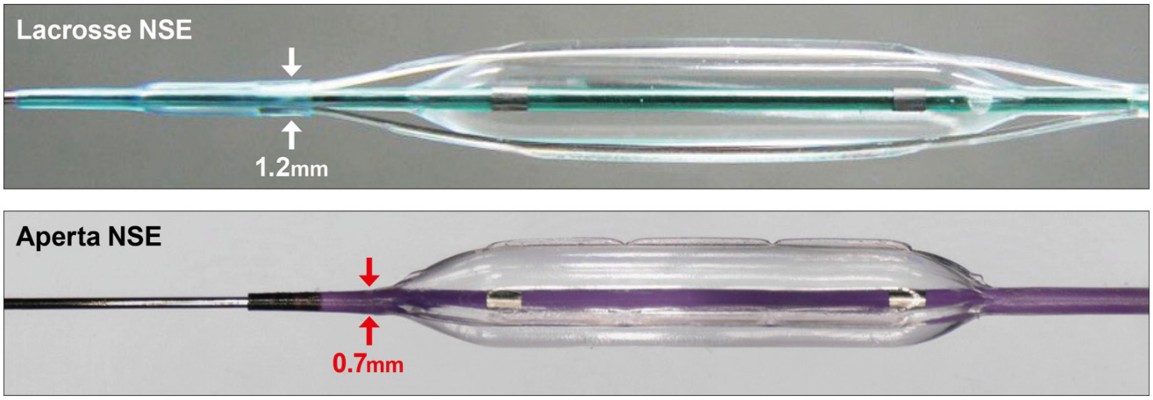

Figure 1. The difference between Lacrosse NSE and Aperta NSE. Compared to Lacrosse NSE, Aperta NSE utilizes 1) a non-compliant balloon delivery platform, 2) elements that are integrated with the balloon, and 3) a shortened, lower profile tip.

Most recently, the Aperta NSE, an improved version of the Lacrosse NSE, has become commercially available for use in Japan. Compared to the conventional Lacrosse NSE, the Aperta NSE incorporates several modifications: 1) it utilizes a non-compliant balloon delivery platform, 2) the elements are integrated with the balloon, and 3) it features a shortened, lower-profile tip as seen in **Figure 1**. The Aperta NSE is also configured as a non-compliant balloon catheter with three nylon elements integrated longitudinally with the balloon which are positioned 120 degrees apart (**Figure 1**). During balloon dilatation, the expansion force of the entire balloon is concentrated at the three elements, which provides for a superior dilative effect. When the distal tip of the Aperta NSE is positioned within the calcified lesion, the expansion force of the non-compliant balloon, combined with the highly concentrated transmission force from the three elements in contact with the lesion, facilitates a multiple cracking effect on the plaque.

Conventionally, the "leopard crawl" technique is employed for such procedures. However, due to changes in the catheter construction and underlying mechanics of the Aperta NSE, the effectiveness of this method may be compromised. The leopard crawl technique traditionally relies on the portion of the catheter where the elements are attached distally to the balloon. In the Aperta NSE, these elements are integrated with the balloon itself (**Figure 1**), potentially diminishing the technique's efficacy.

This paper investigates the effectiveness of the leopard crawl technique with the Aperta NSE, necessitating rigorous testing to validate its performance and preparing modifications to the existing technique.

Test

Test 1

In order to evaluate the effectiveness of the leopard crawl technique for Aperta NSE, a paraffin model (Sakura Color Products Corporation) with an inner diameter (ID) of 1.2±0.1 mm was utilized (**Figure 2A**). With the tip of distal marker of Aperta NSE inserted into the model, the chronological change of the inner diameter was measured using micro-computed tomography (Micro CT).

Method

A 3.0×13 mm Aperta NSE was inserted up to the distal marker in the paraffin model (ID: 1.2 mm), and was dilated to control, 8 atmosphere (atm), 14 atm (nominal pressure (NP)), and 24 atm (rated burst pressure (RBP)) (**Figure 2B**). Micro CT images were obtained, and the cardinal point was set at the position in which no change in diameter was observed during balloon dilatation. Diameter measurement was obtained at the position where luminal expansion from the cardinal point was observed by Micro CT (measurement point; mean of 1.24 mm from the cardinal point) (**Figure 2C**). The maximum inner diameter (long axis × short axis

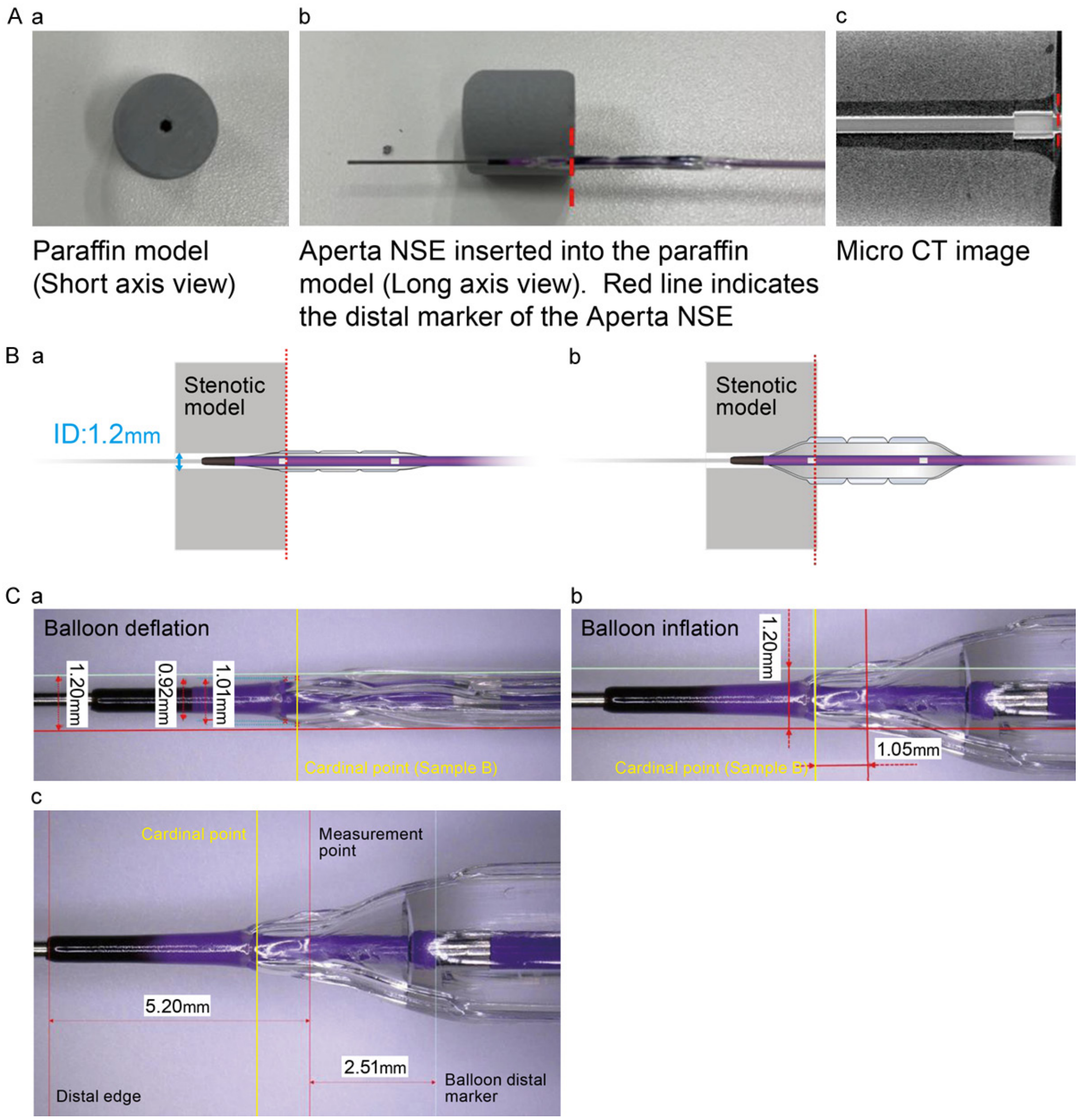

Figure 2. Circumferential stenotic model. A: A paraffin model (Sakura Color Products Corporation) with an inner diameter (ID) of 1.2±0.1 mm. a; Short axis view, b; Long axis view (red arrow is the distal marker of the Aperta NSE), c; Micro computed tomography (Micro CT). B: A 3.0×13 mm Aperta NSE was inserted up to the distal marker in the paraffin stenotic model. C: a; Balloon deflation, b; Balloon inflation (red arrow is cardinal point; the position whereby no change in diameter was observed during balloon dilatation), c; The measurement point was the location where the lumen opening was confirmed from the cardinal point observed by Micro CT (measurement point; average 1.24 mm from the base point, 5.2 mm from the balloon distal edge and 2.51 mm from the balloon distal marker).

= mean) was measured within a 1.5 mm range from the cardinal point.

The same test was conducted using five samples.

Results

The mean maximum inner diameters of the five samples were 1.26 mm at 8 atm, 1.27 mm at 14 atm (NP), and all models were destroyed by balloon pressure at 24 atm (RBP) (**Figure 3A**).

This result suggests that even when the balloon working length is unable to contact the culprit lesion, if the distal tip is advanced 5.2 mm into the lesion (the balloon shoulder is inserted by 1.05 mm) the inner lumen can incur expansion, which would facilitate the effective use of the leopard crawl technique (**Figure 3B**).

A

Long axis x short axis = mean	A	B	C	D	E	Avg. of 5 samples
Control	1.20mm	1.21mm	1.21mm	1.20mm	1.20mm	**1.20mm**
8atm	1.26mm	1.29mm	1.25mm	1.26mm	1.24mm	**1.26mm**
14atm	1.26mm	1.30mm	1.27mm	1.26mm	1.27mm	**1.27mm**
24atm	Collapse	Collapse	Collapse	Collapse	Collapse	-

B

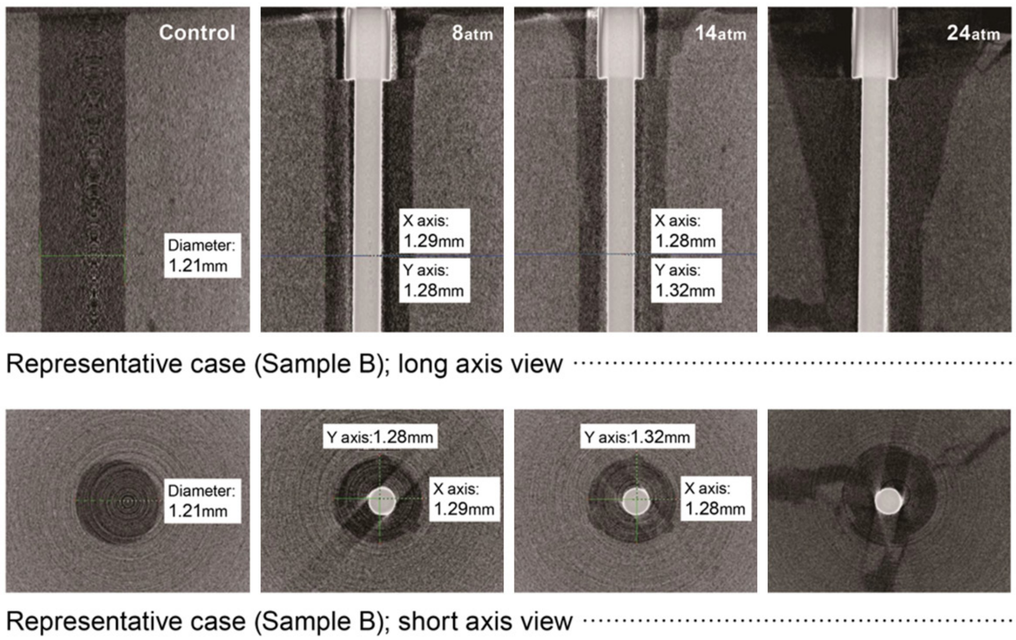

Figure 3. The effectiveness of leopard crawl technique for Aperta NSE (bench test 1). A: The mean maximum inner diameters of the five samples were 1.26 mm at 8 atm, 1.27 mm at 14 atm (NP), and all models were destroyed by balloon pressure at 24 atm (RBP). B: Representative case; The blue line indicates the measurement point. 1.28×1.29 mm was obtained at 8 atm, and 1.28×1.32 mm was obtained at 14 atm, with the model destroyed at an inflation of 24 atm.

Test 2

The dilative effect of the balloon shoulder was tested in order to evaluate the efficacy of the balloon shoulder of Aperta NSE for the leopard crawl technique.

Method

A model was used for evaluating the dilative effect of the balloon shoulder of Aperta NSE. The Aperta NSE was dilated while a load burden of 500 g was applied to the balloon shoulder (**Figure 4A**). Chronological change from 8 atm (1 atm increment) was observed.

Results

The Aperta NSE was dilated by 1 atm increments, and expansion of the balloon shoulder was observed under a load burden of 500 g which was applied from 8 atm. Balloon shoulder expansion was confirmed as the inflation pressure was increased (**Figure 4B**). This result demonstrated that the balloon shoulder contributes to the mechanism of the leopard crawl technique.

Modified leopard crawl technique

The conventional leopard crawl technique is used for cases whereby crossing of the balloon is problematic due to calcification/plaque proximal to the lesion. A low inflation pressure of the balloon proximal to the lesion creates a wedge into the calcified lesion. During subsequent balloon deflation, the catheter is further advanced. This process of dilatation/catheter advancement is then repeated (**Figure 5A**).

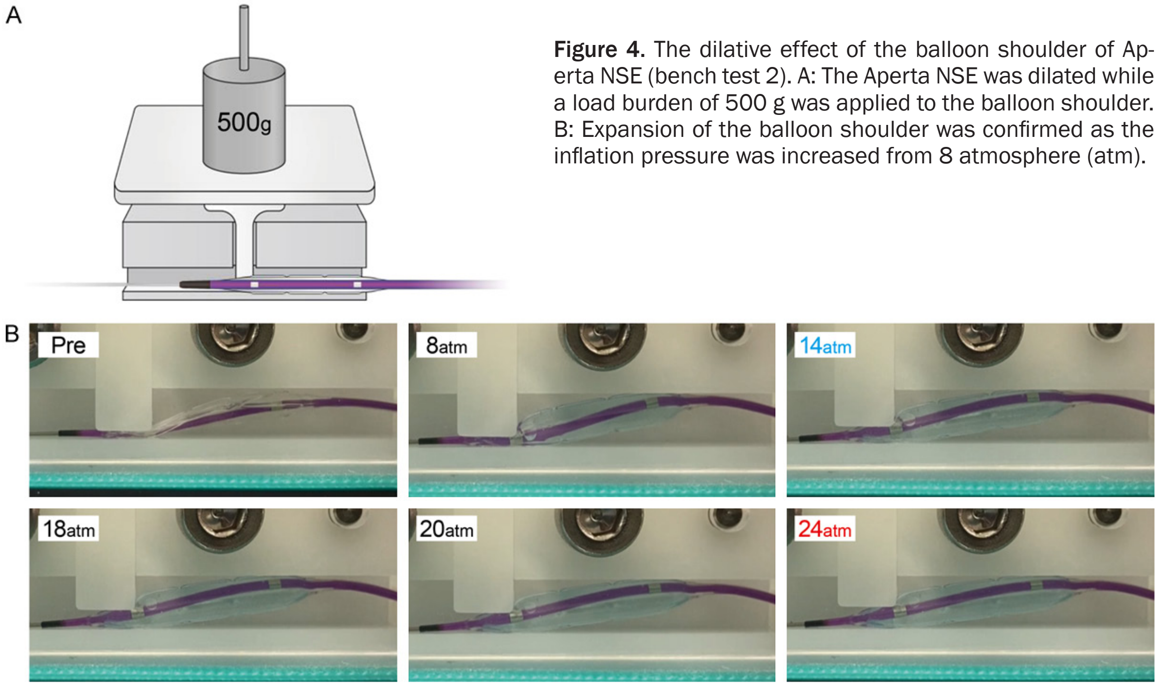

Figure 4. The dilative effect of the balloon shoulder of Aperta NSE (bench test 2). A: The Aperta NSE was dilated while a load burden of 500 g was applied to the balloon shoulder. B: Expansion of the balloon shoulder was confirmed as the inflation pressure was increased from 8 atmosphere (atm).

While the balloon is inflated, the guiding catheter is deeply engaged in a coaxial position (in line with the anchor balloon technique), which improves back-up force and is important for creating an environment favorable for undertaking the leopard crawl technique.

In comparison to the conventional Lacrosse NSE, the tip of Aperta NSE is shorter and has a lower profile. The elements are integrated with the balloon, and under magnification shows that the elements are attached slightly more distal and proximal to the working length of the balloon (**Figure 1**). The fact that the elements are attached slightly distally to the balloon and are located outside of the balloon suggests the potential to maintain a lower profile post dilatation (**Figure 5B**). As previously mentioned during testing, the leopard crawl technique becomes feasible if the distal end of the balloon can be delivered to the lesion. Therefore, in order to facilitate entry of the catheter tip into the lesion (utilizing the characteristics of the catheter and tip), a tapping motion method was utilized (**Figure 6**). The tapping motion is a method whereby the operator applies a tapping motion to the proximal segment of the catheter, resulting in a transmission of rectilinear force to the distal segment of the balloon, which facilitates delivery of the tip into the lesion.

Simply maintaining a continuous push force towards the difficult to cross section does not maximize push transmission. Tapping of the proximal segment while pushing instantly maximizes the rectilinear force without incurring slacking of the balloon catheter, with the tip gradually entering the lesion. The delivery strategy is commenced utilizing the conventional leopard crawl technique, and when the catheter no longer advances, a tapping motion is added. The catheter tip gradually enters the lesion, with subsequent inflation performed. Upon deflation, the tapping motion is repeated, followed by further inflation and deflation, which allows for the catheter to advance. This defines the premise of the modified leopard crawl technique with a tapping motion strategy.

Case

Case 1

The patient was an 80-year-old female hospitalized for acute heart failure (heart failure reduced ejection fraction; HFrEF). Coronary computed tomography (CT) testing and angiography post-improvement of pulmonary congestion confirmed three vessel disease with a long diffuse, severely calcified lesion of the left anterior descending artery (LAD) (**Figure 7A**,

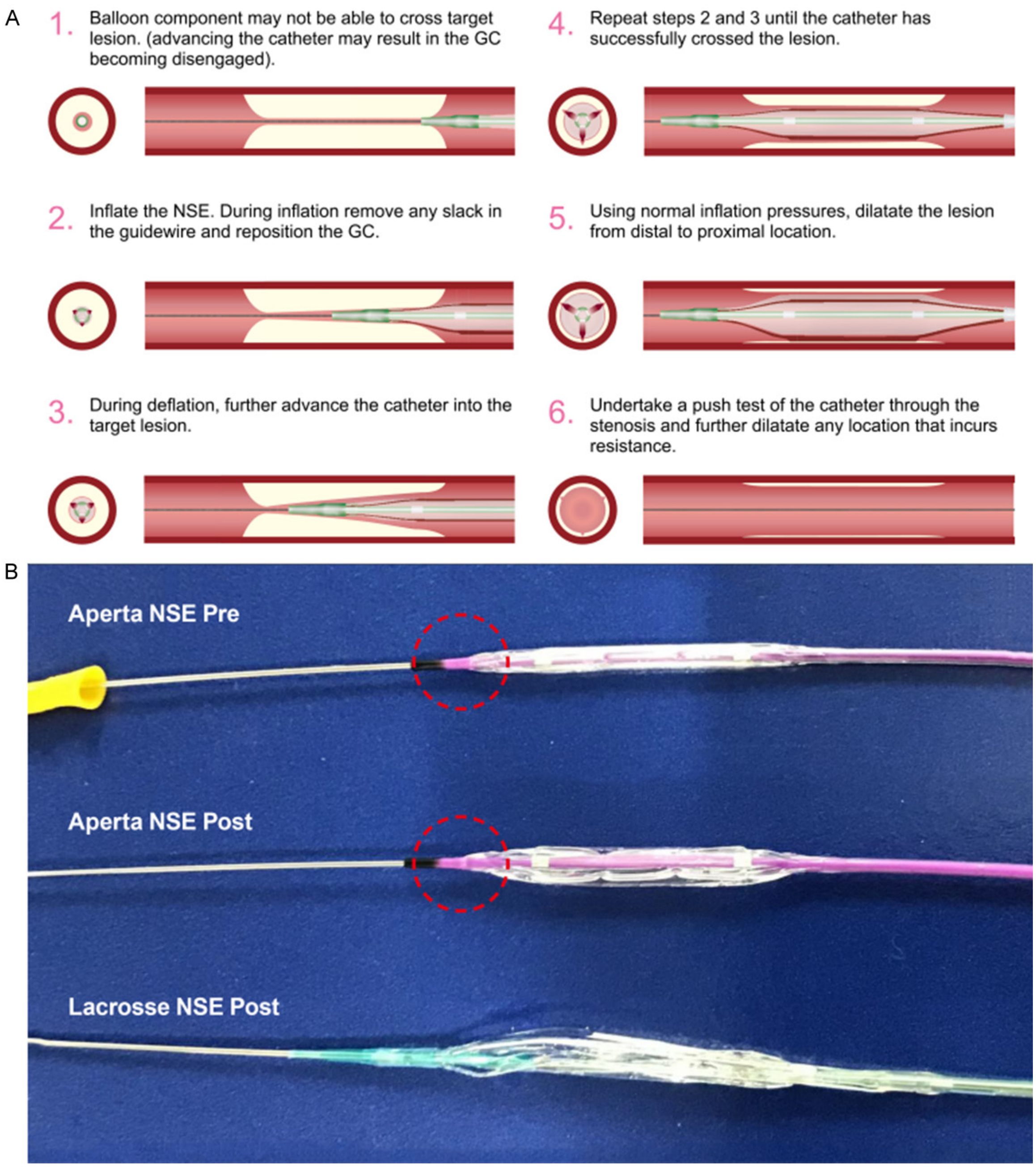

Figure 5. Leopard crawl technique and the balloon shapes (before Aperta NSE, after Aperta NSE, and after Lacrosse NSE). A: Efficacy of Lacrosse NSE using the "Leopard-Crawl" technique on severely calcified lesions. B: The elements of Aperta NSE protrude slightly distally to the balloon and are located outside of the balloon, providing for a lower profile post dilatation. The red circle indicates the shoulder portion of the element.

7B). Treatment of the calcified lesion of the LAD was proposed following treatment of the right coronary artery (RCA) and left circumflex artery (LCX). Due to a lowered left ventricular function and mid-level renal dysfunction, the use of RA was determined inappropriate. Pre-dilatation with an Aperta NSE to create cracking of the calcification was selected. A 7F ASAHI Hyperion SPB3.5SH guiding catheter (Asahi Intec Co., Ltd., Aichi, Japan) was inserted to the left coronary artery (LCA) via a right femoral approach (**Figure 7C**).

An intravascular ultrasound (IVUS) catheter (TERUMO Corporation, Tokyo, Japan) was unable to cross due to the severe calcification. A

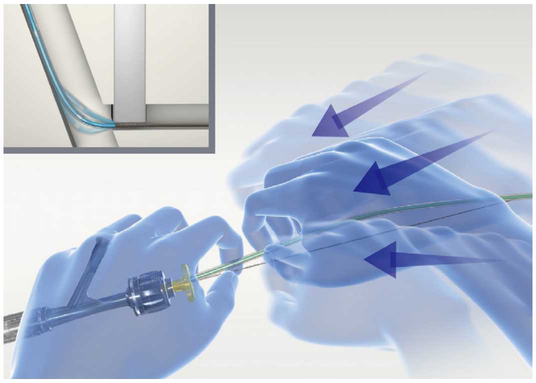

Figure 6. Tapping motion method. The tapping motion is a method whereby the operator applies a tapping motion to the proximal segment of the catheter, resulting in a transmission of rectilinear force to the distal segment of the balloon, which facilitates delivery of the tip into the lesion.

2.5 mm Aperta NSE was selected in order to perform pre-dilatation, however it also experienced difficulty in crossing the same location of severe calcification proximal to the lesion (**Figure 7D**). The Aperta NSE was inflated at a low pressure of 10 atm at the non-crossed segment and pushing of the catheter following deflation advanced the balloon slightly (**Figure 7E**). However, subsequent repeated inflations at 20 atm did not facilitate further advancement of the catheter (**Figure 7F**).

The catheter tip was positioned proximal to the lesion. Therefore, in addition to the previously mentioned leopard crawl technique, a tapping motion was applied (whereby the operator manipulates the catheter by forcibly tapping back and forth while deflating the Aperta NSE). Gradually, the catheter tip successfully entered the lesion (**Figure 8A**). At this point, the Aperta NSE was inflated again at 10 atm. Following deflation, a tapping motion was re-performed, and it facilitated further catheter advancement. Consequently, the Aperta NSE catheter was able to cross the lesion and the lesion was dilated at 22 atm (**Figure 8B**). Adequate expansion was achieved without any balloon indentation.

Following pre-dilatation, a push test with the Aperta NSE catheter used earlier was performed to confirm the crossing condition of the lesion, and the catheter was able to cross without incurring any resistance. IVUS observed 2 locations of cracking in the nearly fully circumferential calcification (**Figure 8C**). A 2.25×32 mm Coroflex ISAR NEO stent (NIPRO Corporation, Osaka, Japan) was implanted at 12 atm in the mid-LAD (**Figure 8D**), and the proximal LAD was stented with a 3.0×38 mm Ultimaster Tansei stent (TERUMO Corporation, Tokyo, Japan) (**Figure 8E**). Final angiography and IVUS confirmed adequate stent expansion (**Figure 8F**).

Case 2

The patient was a 61-year-old male who presented to our facility for exertional chest pain. Coronary CT (**Figure 9A**, **9B**) and angiography confirmed a tortuous lesion with severe calcification of the LCX. A 7F Mach1 CLS4.0 guiding catheter (Boston Scientific Corporation, Marlborough, MA, USA) was inserted to the LCA via a right femoral approach (**Figure 9C**). An ASAHI SION Blue guidewire (Asahi Intecc Co., Ltd., Aichi, Japan) crossed the lesion, however IVUS (TERUMO Corporation, Tokyo, Japan) and optical coherence tomography (OCT) (Abbott Vascular, Santa Clara, CA, USA) catheters were unable to cross. In order to create cracking of the calcification, pre-dilatation by a 2.5 mm Aperta NSE was selected, however, the catheter was unable to cross at the calcified portion (**Figure 9D**). Application of the conventional leopard crawl technique still encountered difficulty in crossing the lesion and a combined tapping motion method was applied. The Aperta NSE was inserted to the non-culprit section and was inflated at 12 atm. Following deflation, a tapping motion whereby the proximal segment of the catheter was tapped back and forth was performed, and the catheter tip was able to enter the lesion (**Figure 9E**). The Aperta NSE was reinflated at this position to 16 atm. Another tapping motion post deflation facilitated further catheter advancement (**Figure 9F**).

Consequently, the Aperta NSE catheter was able to cross, and the lesion was dilated at a 22 atm. A push test of the Aperta NSE catheter was performed to confirm the crossing condition of the lesion, however strong resistance might exist proximal to the lesion, and another inflation of 22 atm was performed. A push test was reattempted, and the balloon catheter was crossed smoothly without resistance. IVUS and OCT were used to observe the lesion, and two cracks of the fully circumferential calcification were confirmed (**Figure 10A**, **10B**).

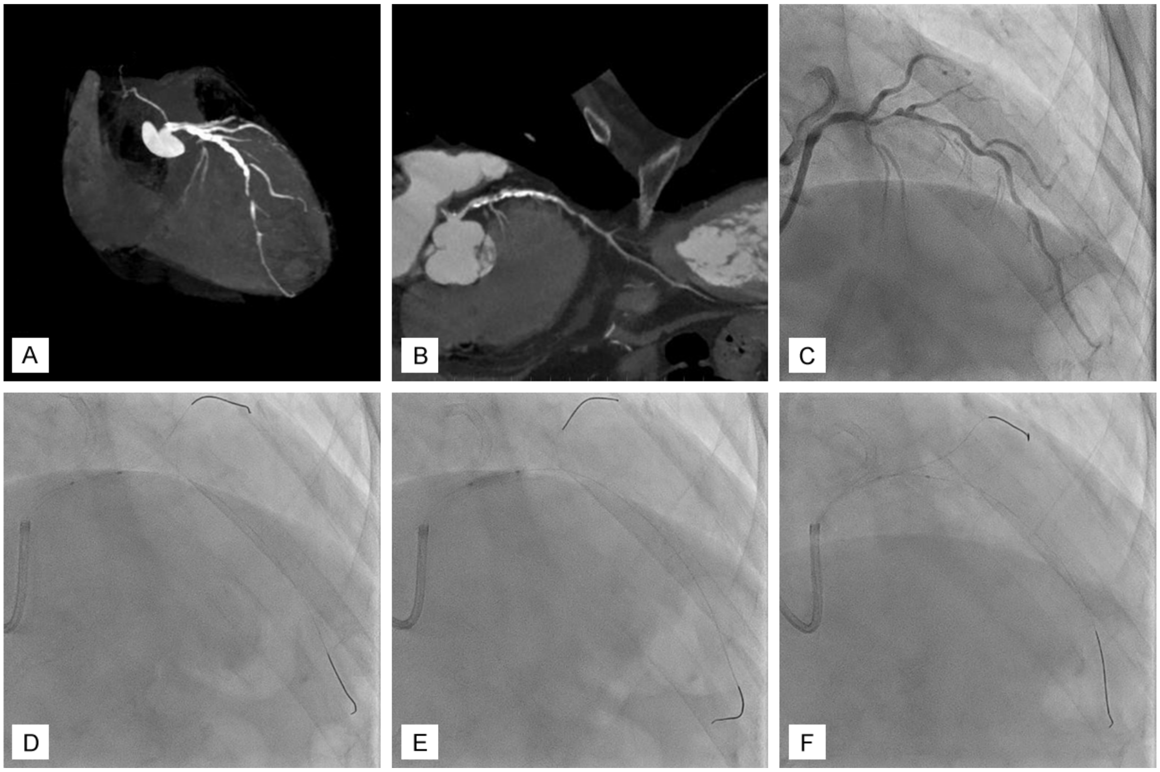

Figure 7. Representative case (1). A: Coronary computed tomography (CT) image; 3 vessel disease with a long diffuse, severely calcified lesion of the left anterior descending artery (LAD). B: Curved multi-planar reconstruction (curved CPR) view for LAD. C: Angiography; 7F ASAHI Hyperion SPB3.5SH guiding catheter was inserted to the left coronary artery (LCA) via a right femoral approach. D: A 2.5 mm Aperta NSE was unable to cross the severe calcification proximal to the culprit lesion. E: A low inflation of 10 atm followed by inserting the catheter during deflation advanced the catheter slightly. F: Subsequent repeated inflations at 20 atm did not facilitate further advancement of the catheter.

Due to the severe tortuosity of the lesion, stent delivery was problematic. Therefore, a 3.5×34 mm Resolute Onyx (Medtronic Vascular, Santa Rosa, CA, USA) was delivered under GUIDEPLUS II ST (NIPRO Corporation, Osaka, Japan) support (**Figure 10C**). The proximal location was post-dilated with a 3.5×15 mm Sapphire NC24 (Orbus Neich Medical, Hong Kong, China). The procedure was completed given adequate expansion confirmed by final angiography and IVUS (**Figure 10D**).

Discussion

Even in the drug-eluting stent (DES) era, percutaneous coronary intervention (PCI) for severely calcified lesions is yet to achieve desirable long-term prognosis. Problematic stent delivery is often encountered [8-10]. The use of an RA (Rotablator) or an OA (Diamondback 360) to perform debulking of the calcification is an effective treatment strategy for plaque modification of severely calcified lesions [11-14]. However, the nature of these devices lies in reducing the thickness of the calcification and creating cracks in multiple locations of calcification is required in order to facilitate adequate stent expansion. There are number of cases in a clinical setting whereby utilization of an RA and OA is difficult due to various factors including lower left ventricular function, severe renal dysfunction, etc. [15, 16].

Conventionally, a scoring balloon or cutting balloon was used for creating multiple cracks with reproducible results [17, 18]. Recently, the modified Aperta NSE has become commercially available. In comparison to the conventional Lacrosse NSE, the delivery platform of the modified Aperta NSE utilizes a non-compliant balloon platform, and the elements are now integrated with the balloon. This design maintains the same working height as the conventional Lacrosse NSE (0.0155”), which is the

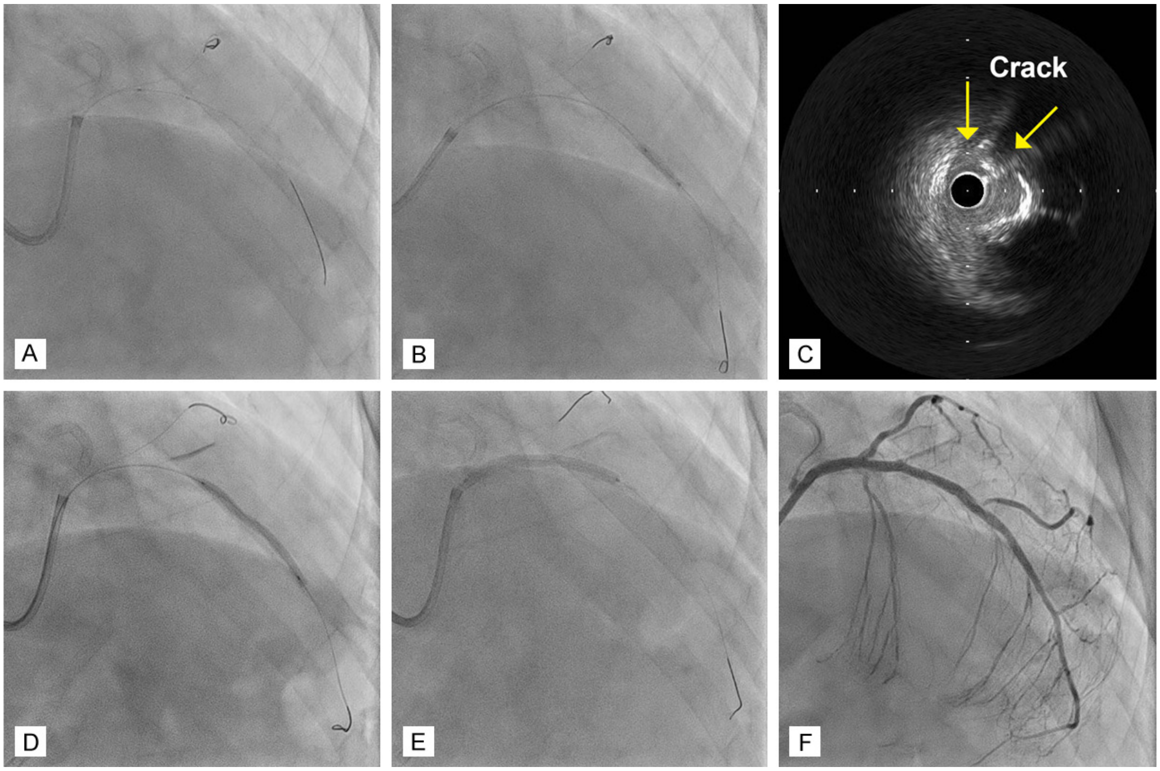

Figure 8. Representative case (1). A: A tapping motion was applied (whereby the operator manipulates the catheter by forcibly tapping back and forth while deflating the Aperta NSE). Gradually, the catheter tip successfully entered the lesion. B: After repeated tapping motion with leopard crawl technique, the Aperta NSE catheter was able to cross the lesion and the lesion was dilated at a high pressure of 22 atm. C: An intravascular ultrasound (IVUS) observed 2 locations of cracking in the nearly fully circumferential calcification. The yellow line indicates cracking of the calcified lesions. D: A 2.25×32 mm Coroflex ISAR NEO stent was implanted at 12 atm in the mid-LAD. E: The proximal LAD was stented with a 3.0×38 mm Ultimaster Tansei stent. F: Final angiography confirmed adequate stent expansion.

highest among the scoring balloons. Consequently, this integration provides for high expansion force and high plaque modification functionality. Scoring balloons are inferior in lesion cross-ability compared to conventional balloon catheters [19], and it is necessary to utilize techniques to enhance the cross-ability of Aperta NSE. Therefore, the leopard crawl technique utilized with Lacrosse NSE was modified, and taking the constructional characteristics of Aperta NSE into consideration, the leopard crawl technique with tapping motion was developed. The cases reported illustrate the efficacy of the modified technique in a clinical setting to improve cross-ability, with reproducible results.

Techniques for situations where a when a therapeutic device (balloon or stent) cannot be delivered to the lesion alone after without the aid of the guidewire has being passed through the lesion include the anchor technique, buddy wire technique, and mother-in-child technique (**Table 1**) [20].

These techniques are utilized when backup support of the guide catheter is insufficient for passing a therapeutic device (balloon or stent) alone, or when the therapeutic device cannot be delivered to the lesion due to severe tortuosity of vessels, etc. The leopard crawl technique is used for passing an Aperta NSE through a complex lesion where the lumen is narrowed and other interventional devices cannot pass through, by creating a gap into the lesion be utilized.

Using the original leopard crawl technique, the Aperta NSE is delivered to the coronary artery and inflated at the non-crossed segment. Further insertion of the Aperta NSE during deflation produces gives a slight advancement of the catheter. The balloon is further inflated (while adjustments to the guide wire slack and

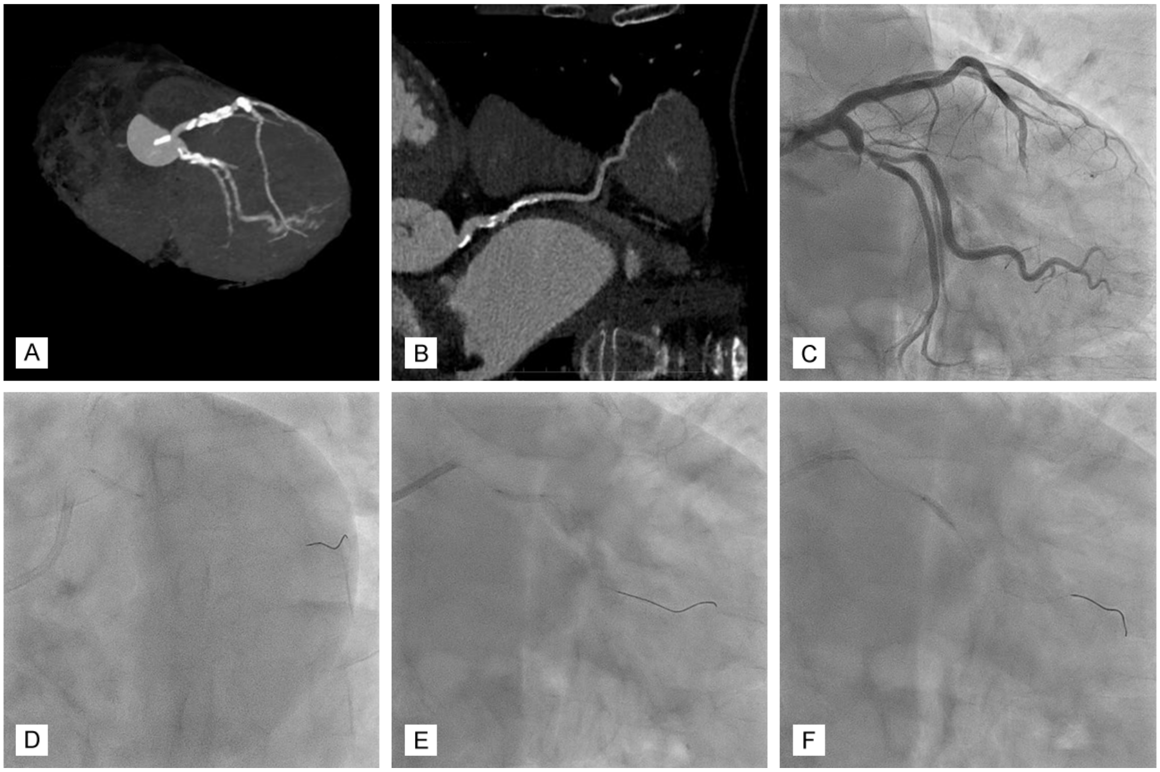

Figure 9. Representative case (2). A: Coronary CT image; tortuous lesion with severe calcification of the LCx. B: Curved CPR view of LCx. C: Angiography; A 7F Mach1 CLS4.0 guiding catheter was inserted into the LCA via a right femoral approach. D: A 2.5 mm Aperta NSE was selected, however the catheter was unable to cross at the calcified component. E: The Aperta NSE was inserted to the non-culprit section and was inflated at 12 atm. Following deflation, a tapping motion whereby the proximal segment of the balloon was intensely tapped back and forth was performed, and the catheter tip was able to enter the lesion. F: Another tapping motion with the leopard crawl technique post deflation facilitated further catheter advancement. Consequently, the Aperta NSE catheter was able to cross, and the lesion was dilated at a high pressure of 22 atm.

repositioning of the guiding catheter are performed) and is inserted following deflation. This process is then repeated. Due to the position of the radiopaque marker of Aperta NSE, it is difficult to visually confirm the entry of the catheter tip into the lesion. If an IVUS catheter has previously been crossed, the exact location of Aperta NSE can be confirmed using the IVUS images.

Even in cases whereby an IVUS catheter cannot be crossed, by determining the location of where Aperta NSE was unable to advance and given the visual location of the calcification on the angiogram, it is feasible to gradually enter the lesion safely if the balloon is inflated from a low pressure. Selection of a smaller sized balloon and a low-pressure inflation minimizes the risk of causing injury proximal to the target lesion. The primary purpose of utilizing an Aperta NSE for a calcified coronary lesion is not to dilate the vasculature, but to create multiple cracks within the calcification. Hence, the selection of the balloon size which equates to the minimum lumen diameter (MLD) or a quarter size larger is sufficient, and an Aperta NSE which is smaller in size than the reference vessel diameter is typically selected.

The mechanism of the leopard crawl technique relies on the positioning of elements. Even if the entire balloon cannot be delivered to the lesion, the elements attached distally to the balloon create gaps during inflation which facilitate advancing of the balloon during deflation.

Unlike the conventional NSE catheter, the elements of Aperta NSE are integrated with the balloon, and therefore if the balloon itself cannot be delivered to the lesion, it is considered that the conventional leopard crawl technique may not be as effective.

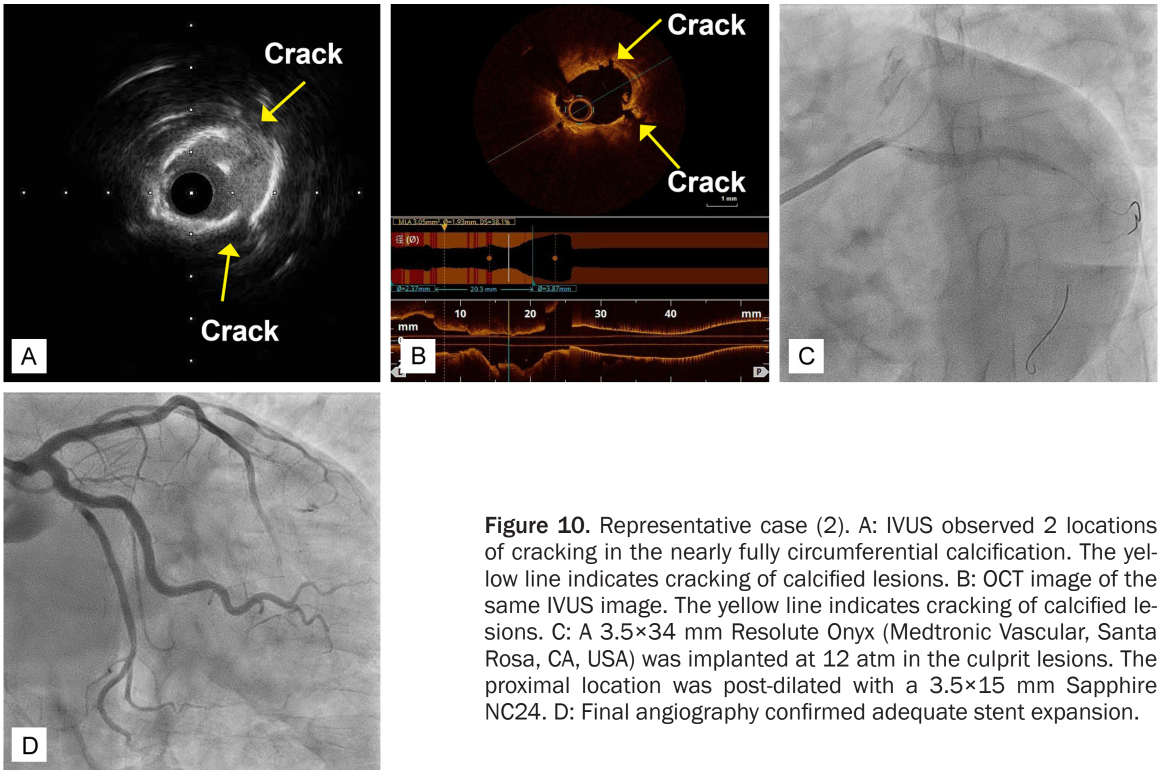

Figure 10. Representative case (2). A: IVUS observed 2 locations of cracking in the nearly fully circumferential calcification. The yellow line indicates cracking of calcified lesions. B: OCT image of the same IVUS image. The yellow line indicates cracking of calcified lesions. C: A 3.5×34 mm Resolute Onyx (Medtronic Vascular, Santa Rosa, CA, USA) was implanted at 12 atm in the culprit lesions. The proximal location was post-dilated with a 3.5×15 mm Sapphire NC24. D: Final angiography confirmed adequate stent expansion.

Table 1. Device delivery techniques

Device Deliverability Techniques	
Anchor Balloon Technique	This technique requires the use of an extra balloon for anchorage. The extra balloon is dilatated in a non-target vessel to increase the backup force of the guiding catheter.
Buddy Wire Technique	The technique involves placing a second guide wire parallel to an already in-place guide wire. The buddy wire is especially useful in tortuous vessels whereby it straightens the vessel tortuosity and facilitates delivery by modifying guide wire bias and changing the position of the stent during delivery.
Mother in Child Technique	A child catheter (small size guiding catheter or guide extension catheter) is introduced into the large size guiding catheter over the wire, and the small-diameter catheter is placed near the lesion. The child catheter is positioned close to the lesion, making it easier to pass the therapeutic device (balloon or stent) to the lesion.

As previously mentioned, the elements of the balloon are integrated outside of the balloon on the long axis (along with on the short axis). Therefore, as suggested by the test results, if the distal portion of the balloon can be delivered to the lesion, the leopard crawl technique becomes feasible. As is observed in the enlarged images, there is a wing-like construction of the elements close to the balloon edge (**Figure 11**).

This construction may contribute to creating gaps when the Aperta NSE is inflated while in contact with the proximal part of the lesion.

Due to Aperta NSE having a shorter tip than the conventional product, the leopard crawl technique potentially produces gaps, which facilitates catheter advancement, given the tip can be successfully delivered to the lesion. Therefore, the leopard crawl technique with tapping motion was conceived. Testing and cases hereby reported suggests that the tapping motion helps facilitate the catheter tip to advance into the lesion.

By performing the tapping motion, the kinetic energy towards the non-culprit segment of the lesion is increased (compared to a continuous pushing motion, tapping by the operator increases the instant kinetic energy). Typically, the balloon shaft comes into direct contact with the inside of the guiding catheter and the coronary artery. Specifically, when the balloon is

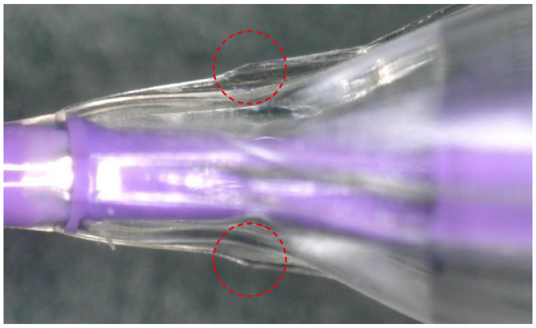

Figure 11. Magnified view of the distal portion of Aperta NSE. A wing-like construction of the elements close to the balloon edge (area circled in red) may contribute to create gaps when the Aperta NSE is inflated while in contact with the proximal part of the lesion.

pushed and moved towards the outer bend of the coronary artery, the portion contacting the vasculature increases. Performing the tapping motion reduces the static friction to dynamic friction, thereby allowing the tip and the balloon to be advanced into the lesion, particularly when the contact area is increased. For this reason, it is suggested that the tapping motion is preferable to a continuous pushing motion in order to cross the tip of Aperta NSE.

Taking constructional characteristics into consideration, another method which should be considered is to apply a shaping of the balloon in order to change the location where the tip comes into contact (**Figure 12**). This can be efficacious for hard-to-cross lesions such as tortuous lesions. However, in most cases, increasing the rectilinear force is preferable, and attempting the tapping motion first is recommended.

In cases where the catheter tip can be advanced into the lesion but the balloon component of the Aperta NSE is unable to advance following dilatation, it is necessary to increase the expansion force of the distal segment of the balloon. In such cases, either attempting to increase the transmitted force to the lesion by utilizing two wires, or pre-dilatation by a small size balloon (providing for a sufficient size of the Aperta NSE tip) needs to be performed prior to reattempting the leopard crawl technique by an Aperta NSE.

As previously mentioned, RA and OA cannot be used for all calcified lesions due to efficacy and safety reasons, and Lithotripsy (Shockwave

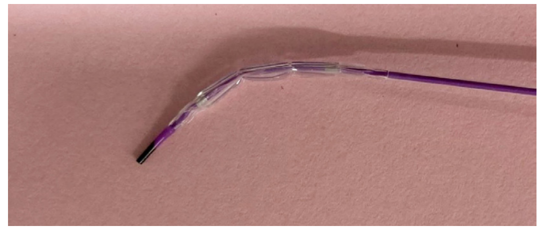

Figure 12. Balloon shaping. Applying shaping of Aperta NSE to change the location of where the tip comes into contact.

Medical, CA, USA) alone is not superior in crossability either [21, 22]. Utilizing various techniques to deliver the Aperta NSE balloon (which is superior in expansion force and ability to create plaque modification) is necessary in a clinical setting. The leopard crawl technique with tapping motion does not require other devices, and thus has the potential to become an imperative cost-effective technique.

Conclusion

In the context of a modified crossing technique utilizing the Aperta NSE, based on both test results and clinical observations, the conventional Lacrosse NSE has been commonly employed for addressing severely calcified coronary lesions. Given the structural attributes, it is imperative to advance the catheter tip of the Aperta NSE, benefiting from enhanced expansion force, toward the lesion. Employing the leopard crawl technique with tapping motion has proven effective in facilitating delivery.

In instances of targeting highly calcified lesions, where traversing a device post-wire crossing poses challenges, the deliverability of the Aperta assumes significance. Its capability to facilitate cracks within calcified lesions and the reproducibility of such delivery without necessitating supplementary devices are pivotal considerations, particularly in the context of minimizing medical expenses.

The outcomes of this experimental technique underscore its potential to enhance cross-ability with commendable reproducibility. Furthermore, the clinical cases presented would lend support to its utility within a clinical environment.

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Kazuhiro Ashida, Cardiovascular Center, Seirei Yokohama Hospital, 215 Iwai-cho, Hodogaya-ku, Yokohama-shi, Kanagawa, Japan. Tel: +81-45-715-3111; Fax: +81-45-715-3387; E-mail: kazuhiro_ashida@yahoo.co.jp

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