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Case Report

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Clinical Review of High-Pressure noncompliant balloon, MeCross NC Balloon Dilatation Catheter Balloon and Calcified, Undilatable Coronary Lesions

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Abstract

Optimal stent deployment can become a challenge for the interventional cardiologist, especially when it involves calcified, undilatable lesions. Various technologies have been developed to tackle this scenario and the super high-pressure balloon seems to be a promising adjunct in treating undilatable lesions. Herein, we present our initial experience with a new noncompliant, super high-pressure balloon. The catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion Balloon dilatation of a stent after implantation, where clinical safety and performance is applied based on clinical review done in this study including review of equivalent devices.

Keywords: super high-pressure balloon, catheter, myocardial perfusion, graft stenosis.

Introduction

This study has been applied in order to document clinical review of noncompliant balloon, MeCross NC Balloon Dilatation Catheter. Calcified coronary lesions are common in coronary artery disease. These lesions are resistant and difficult to dilate, and frequently dissect during balloon angioplasty. Optimal stent deployment can become a real challenge. Suboptimal stent expansion can increase the risk of stent thrombosis and restenosis. Different strategies are used to dilate resistant lesions, including the use of a Cutting Balloon (Boston Scientific), non compliant balloons, laser atherectomy, Rotablator (Boston Scientific), Angio Sculpt scoring balloon catheter (Philips), and the buddy wire technique.

Recently, a new noncompliant balloon, MeCross NC Balloon Dilatation Catheter manufactured by Shenzhen Medoo Medical Tech. Co., Ltd. super high-pressure percutaneous transluminal coronary angioplasty balloon, has become available in Europe. MeCross NC Balloon is a double-layered balloon allowing for very high pressure dilation. We report our first experience with this new balloon in the treatment of a calcified lesion resistant to dilation by conventional noncompliant balloons.

Case Report

A 72-year-old male presented to the district hospital with ongoing angina pectoris for thelast 2 hours. His background involved hypertension, diabetes, and a history of coronary artery bypass 10 years prior, followed by percutaneous angioplasty with a drug-elutingstent (DES) of his circumflex coronary artery 3 years later. The result of the angioplastywas not satisfactory, with no expansion of the stent and residual compression in the hour glass, causing a residual stenosis of 50% despite a 26 atmospheres (atm) post dilatation with a 4 mm noncompliant balloon. The patient was hemodynamically stable with clear lungs and no observable cardiac murmurs, S3, or peripheral edema. An initial electrocardiogram (ECG) showed 3 mm of ST segment elevation in the lateral leads and2 mm of ST segment depression in the anterior leads, consistent with an acute lateral wall ST-elevation myocardial infarction (STEMI). He was treated with 5000 units of heparin intravenously, and 300 mg of aspirin and 600 mg clopidogrel. Coronary angiography via right femoral access showed an occlusion of the proximal circumflex by stent thrombosis within the extrinsic compression zone of the stent and a highly calcified lesion (Figure 1).

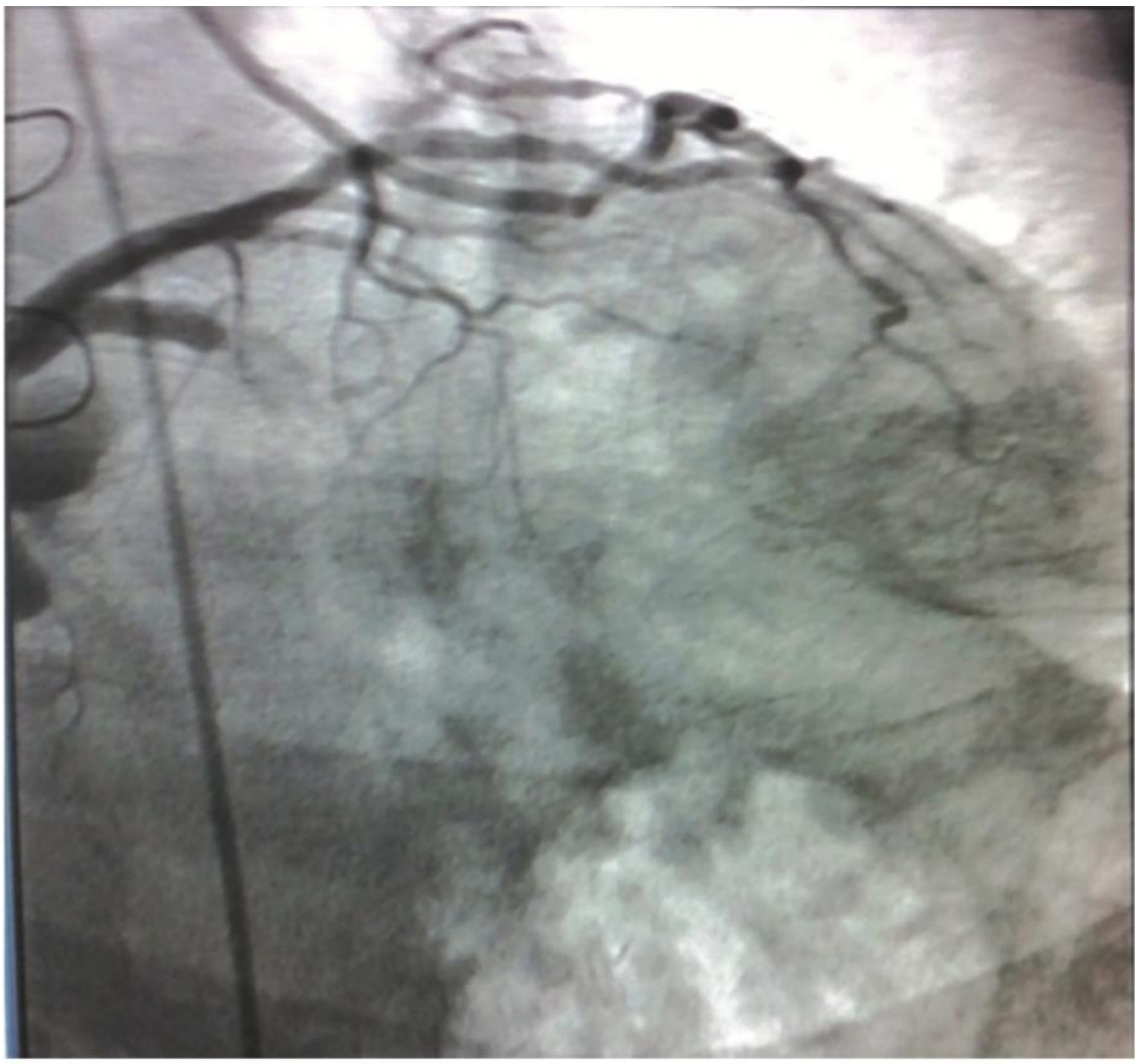

Figure 1. Stent thrombosis in the proximal circumflex artery.

A 6 French (Fr) Extra Backup (EBU) 100 cm MB1 coronary guiding catheter (Medtronic) was positioned at the left main coronary artery ostium. The lesion was crossed with a014-inch x 190 cm straight Hi-Torque Whisper MS guide wire, but TIMI grade 0 flow persisted. It was decided to perform thrombus aspiration and an Eliminate aspiration catheter* (Terumo Europe) was directed to the lesion. The suction of thrombus resulted in the restoration of TIMI grade III flow. The calcified lesion was initially prepared using rotational atherectomy with a 1.75 mm burr. It was pre dilated with a 3.5 mm x 12mm NC Quantum Apex Monorail PTCA balloon (Boston Scientific) and a3.5mm x15mm Cutting Balloon. However, there was still restriction in balloon expansion (Figure2).

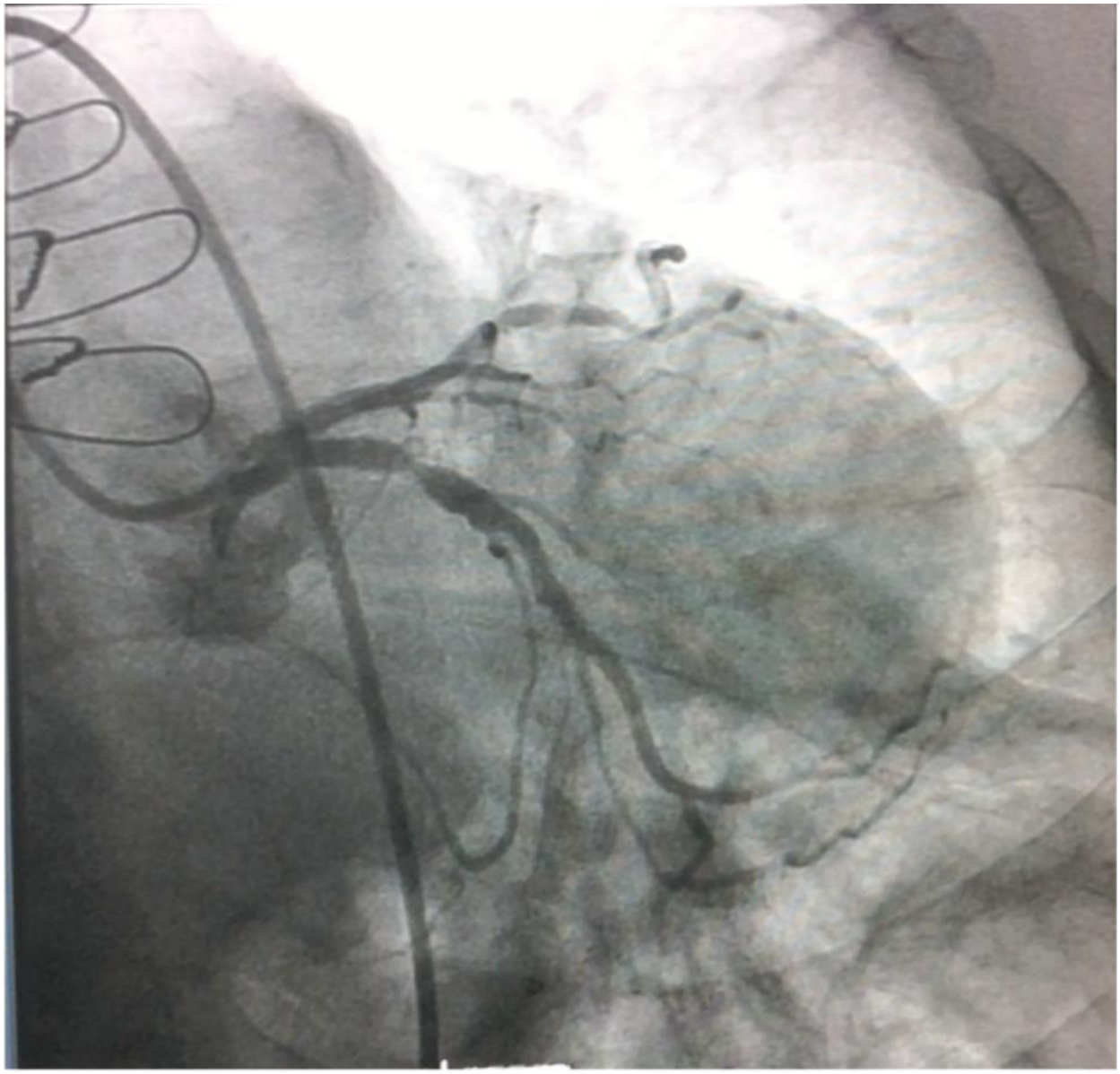

Figure 2. Restriction in balloon expansion remains after pre dilatation.

A3 mm x 10 mm MeCross NC Balloon was used to dilate the residual resistant stenosis and inflated to 40 atm (Figure 3), allowing the rupture of the lesion, followed by prolonged post dilation with a 4.0 mm x 15 mm NC Quantum Apex Monorail balloon.

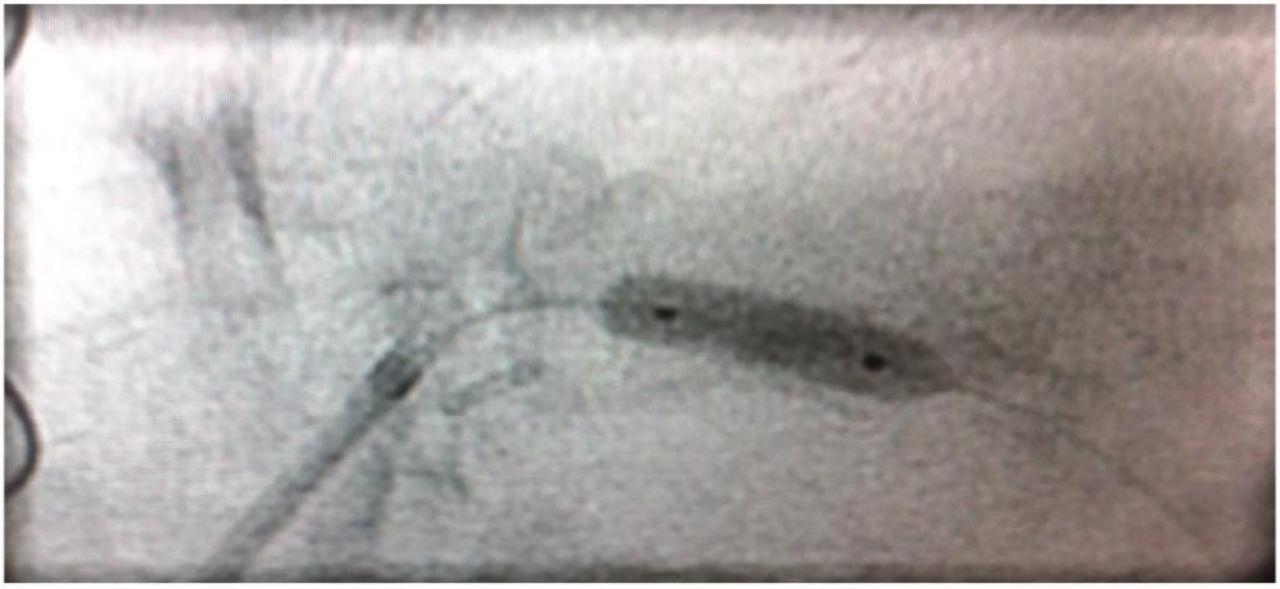

Figure 3. MeCross NC Balloon Dilatation Catheter, inflated to 40 atm.

A drug-elutingstent was deployed, achieving an excellent angiographic result (Figure 4).

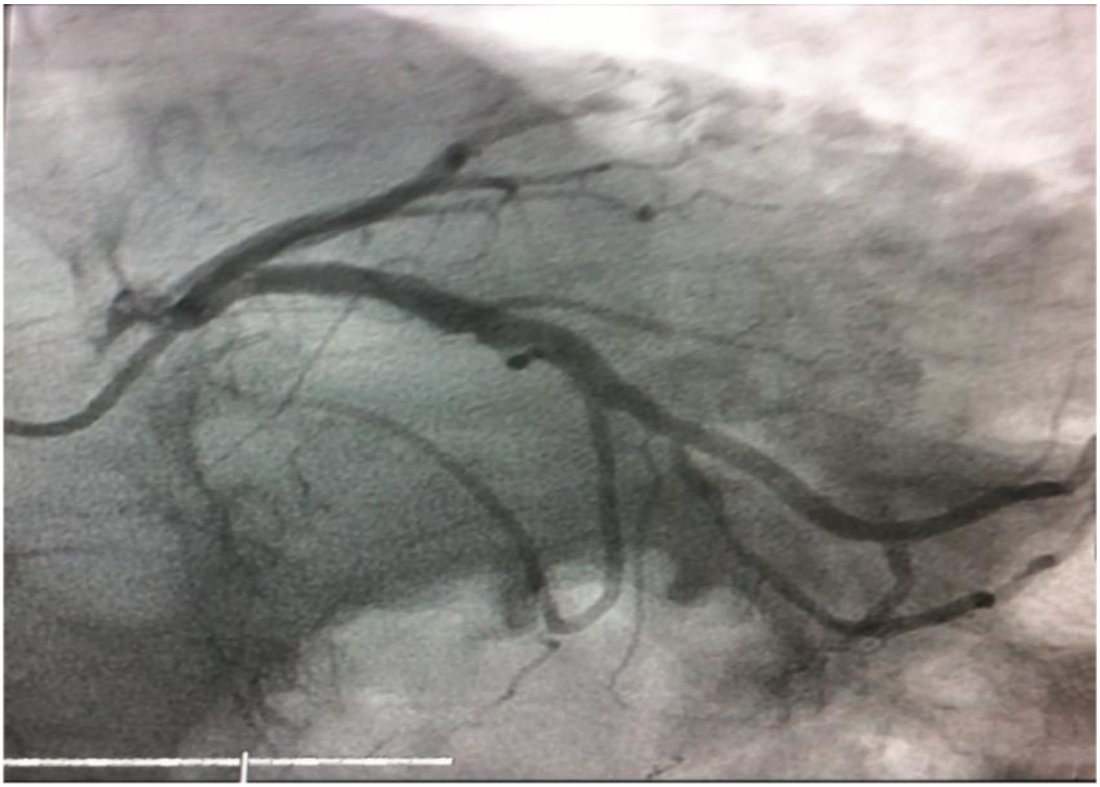

Figure 4. Final result.

Discussion

Fibro calcific plaques reduce vessel distensibility, and impairfull, uniform balloon dilatation and subsequent stent expansion.[1,2] Various technologies have been developed in order to tackle this problem, including the Cutting Balloon[3] and excimer laser[4,5]. Rotational atherectomy has been considered an adequate choice for plaque preparation when dealing with highly calcific lesions or even afterballoonfailure[6-9]; however, in larger vessels and in lesions that are not so tight, burrs might not be able to ablate the plaque[10-12].

The super high-pressure MeCross NC Balloon has been shown to be an effective and safe alternative for optimal lesion preparation and stent deployment even when conventional technologies have failed to achieved equate expansion.[13,14] In our case, dilation of the residual stenosis of the circumflex artery was not possible, despite the use of various techniques in attempts to prepare the calcified lesion, including conventional non compliant balloons at high pressure (24 atm), Cutting Balloon, and rotational atherectomy. This led us to the MeCross NC Balloon, a double-layer balloon with a very low compliance. Its safety seems to be reasonable even at pressures as high as 40atm.[15]The major risk for complication with the MeCross NC Balloon is coronary perforation. However, its particular properties, including an extremely low compliance and resistance to the “dog bone” effect due to its double-layer structure, can reduce the risk of coronaryperforation.[16]TheMeCross NC Balloon has been available in sizes ranging from to 4.0 mm. It is specifically designed for the treatment of resistant, calcified lesions and for the post dilatation of under-deployed stents. It allows for very high pressure inflation and ensures a uniform expansion over a wide range of pressures. MeCross NC Balloon is highly noncompliant, with a nominal pressure of 10 atm and a nominal burst pressure of 35 atm. While more study is necessary, the success of our first experience, as well as those few cases described in the literature thus far, have been favorable for use of this balloon in the treatment of resistant, calcified lesions.[17]

This clinical review and survey were done according to MDD 93/42/EEC and relevant guidelines MEDDEV 2.4/1 where the collected and revised clinical data and clinical review were adequate to demonstrate clinical safety and performance of noncompliant balloon, MeCross NC Balloon Dilatation Catheter Shenzhen Medoo Medical Tech. Co., Ltd; where the review done provide sufficient clinical performance and safety based on equivalent devices with the same clinical performance and clinical safety.

Conclusion

Resistant, calcified coronary lesions are a common challenge in coronary angioplasty. Improper stent deployment increases the risk of thrombosis and in-stent restenosis.

Different techniques and devices are available for the preparation and treatment of calcified lesions. MeCross NC Balloon, with its uniform expansion, offers a new therapeutic option that can be used safely. It provides an effective alternative strategy for the dilatation of resistant coronary lesions when conventional noncompliant balloons fail.

Disclosure: The authors report no conflicts of interest regarding the content

References

1. Nakamura S, Colombo A, Gaglione A, et al. Intracoronary ultrasound observations during stent implantation. *Circulation.*1994 May; 89(5): 2026-2034.
2. Colombo A, Hall P, Nakamura S, et al. Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. *Circulation.*1995 Mar 15; 91(6): 1676-1688.
3. Tang Z, BaiJ, SuS-P, et al.Cutting-balloon angioplasty before drug-eluting stentim plantation for the treatment of severely calcified coronary lesions. *J Geriatr Cardiol JGC.*2014Mar; 11(1):44-49.
4. Reifart N, Vandormael M,Krajcar M, et al. Randomized comparison of angioplasty of complex coronary lesions at a single center. Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison (ERBAC) Study. *Circulation.* 1997 Jul 1; 96(1): 91-98.
5. Fernandez JP, Hobson AR, McKenzie D, et al. Beyond the balloon: excimercoronary laser atherectomy used alone or in combination with rotational atherectomy in the treatment of chronic total occlusions, non-crossable and non-expansible coronary lesions. *Euro Intervention.* 2013 Jun; 9(2): 243-250. doi:10.4244/EIJV9I2A40.

6. Brown DL, George CJ, Steenkiste AR, et al. High-speed rotational atherectomy of human coronary stenoses: acute and one-year outcomes from the New Approachesto Coronary Intervention (NACI) Registry. *Am J Cardiol.* 1997 Nov; 80(10): 60K-67K. doi: https://doi.org/10.1016/S0002-9149(97)00765-0.
7. Couper LT, Loane P, Andrianopoulos N, et al. Utility of rotational atherectomy and outcomes over an eight-year period: RATreats complex lesions with low procedural complications and MACE rates. *Catheter Cardiovasc Interv.* 2015 Oct; 86(4): 626-631. doi: 10.1002/ccd.26077.
8. Dill T. A randomized comparison of balloon angioplasty versus rotational atherectomy in complex coronary lesions (COBRA study). *Eur Heart J*. 2000 Nov 1;21(21):1759-1766.Available onlineathttps://academic.oup.com/eurheartj/article-lookup/doi/10.1053/euhj.2000.2242. Accessed June 20, 2019.
9. Camnitz WM, Keeley EC. Heavily calcified coronary arteries: the bane of an interventionalist's existence. *J Interv Cardiol.* 2010 Jun; 23(3): 254-255. doi:10.1111/j.1540-8183.2010.00553.x.
10. Barbato E, Carrié D, Dardas P, et al. European expert consensus on rotationalatherectomy. *Euro Intervention.*2015May;11(1):30-36.doi:10.4244/EIJV11I1A6.
11. Mauri L, Reisman M, Buchbinder M, et al. Comparison of rotational atherectomy with conventional balloon angioplasty in the prevention of restenosis of small coronary arteries: results of the Dilatation vs Ablation Revascularization Trial Targeting Restenosis (DART). *Am Heart J*. 2003 May; 145(5): 847-854. https://doi.org/10.1016/S0002-8703(03)00080-2.
12. Abdel-Wahab M, Richardt G, Joachim Büttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: the randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease)trial. *JACC Cardiovasc Interv*. 2013 Jan; 6(1): 10-19. doi: 10.1016/j.jcin.2012.07.017.
13. RajaY,RoutledgeHC,DoshiSN.Anoncompliant,high pressureballoontomanageundilatable coronary lesions. *Catheter Cardiovasc Interv*. 2010 Jun 1; 75(7): 1067-1073. doi: 10.1002/ccd.22430.
14. Díaz JF, Gómez-Menchero A, Cardenal R,et al. Extremely high-pressure dilation with a new non compliant balloon.*TexHeartInstJ*.2012;39(5):635-638.
15. Secco GG, Ghione M, Mattesini A, et al. Very high-pressure dilatation for undilatable coronary lesions: indications and results with a new dedicated balloon. *Euro Intervention.* 2016 Jun; 12(3): 359-365. doi: 10.4244/EIJY15M06_04.
16. Fabris E, Caiazzo G, Kilic ID, et al. Is high pressure postdilation safe in bioresorbable vascular scaffolds? Optical coherence tomography observations afternoon compliant balloons inflated at more than 24 atmospheres. *Catheter CardiovascInterv*.2016 Apr;87(5): 839-846. doi:10.1002/ccd.26222.
17. Tanaka A, Jabbour RJ, Kawamoto H, et al. A super high-pressure balloon solution for a non-dilatable in-stent restenosis. *Int J Cardiol.* 2016 Jan; 203: 357-359. doi:10.1016/j.ijcard.2015.10.188.

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