The Takeru™ PTCA Balloon Dilatation Catheter for Pre Intravascular Lithotripsy (IVL)

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The presence of heavily calcified lesions increases the complexity of percutaneous coronary intervention (PCI) and is associated with adverse outcomes[1] such as increased risk of death, myocardial infarction, target vessel revascularization, and stent thrombosis. Challenges associated with the treatment of these lesions include difficulties in pre-dilation, an increased risk of dissection, and difficult stent delivery and expansion. To increase the success of PCI, atheroablative techniques have traditionally been used. The use of intravascular lithotripsy (IVL) is a recent addition to the available resources for treatment of complex calcified disease. Intravascular lithotripsy has been associated[2] with decreased rates of target vessel revascularization and stent thrombosis. However, deliverability of IVL devices can be challenging. Thankfully, the low-profile design coupled with increased pushability of Terumo's Takeru™ PTCA Balloon Dilatation Catheter facilitates the use of IVL in heavily calcified lesions.

Clinical Case

An 81-year-old male with hypertension, diabetes, and hyperlipidemia was referred for evaluation of an abnormal stress test. He originally complained of shortness of breath with exertion. A pharmacologic stress test was performed at an outside facility and showed inferior wall ischemia with a normal ejection fraction. He underwent coronary angiography via a right radial approach that revealed a heavily calcified, eccentric lesion in the large, codominant circumflex artery with TIMI-3 flow (Figure 1). Due to a small ulnar artery, the decision was made to access the right femoral artery in preparation for complex intervention. Utilizing a 6 French Judkins Left 4 guide catheter, the left system was engaged. The lesion was wired with a Runthrough® Izanai™ wire (Terumo Interventional Systems) and pretreated with balloon angioplasty using a 2.0 mm x 15 mm Takeru™ RX balloon (Terumo Interventional Systems) (Figure 2). A 2.5 mm x 15 mm Takeru™ RX noncompliant (NC) balloon was then advanced to perform further pre-dilation balloon angioplasty (Figure 3). Despite this, access past the mid-portion of the lesion continued to prove difficult due to the significant angulation of the lesion. Utilizing a 6 French GuideLiner catheter (Teleflex), the 2.0 mm x 15 mm Takeru™ RX balloon was able to be advanced past the mid-portion of the circumflex lesion for additional angioplasty. Following this, IVL was performed using 60 shocks (6 inflations) of a 3.0 mm x 12 mm Shockwave lithotripsy balloon (Shockwave Medical) (Figure 4). IVL allowed for delivery of a 3.0 mm x 22 mm Onyx Frontier drug-eluting stent (Medtronic) and a 3.5 mm x 26 mm Onyx drug-eluting stent, deployed in an overlapping fashion from the distal to mid left circumflex artery, respectively (Figures 5-6). Finally, the stents were

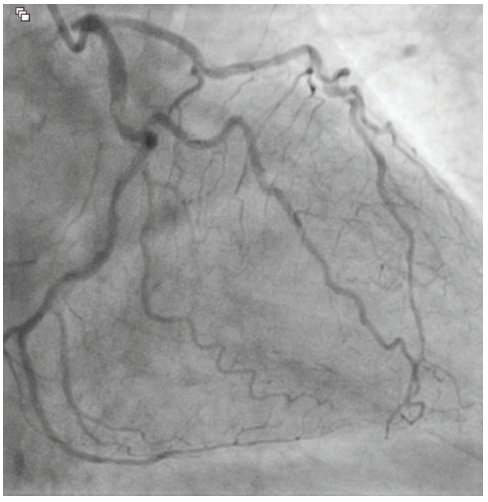

Figure 1. Heavily calcified eccentric lesion in the large codominant circumflex artery (initial angiogram).

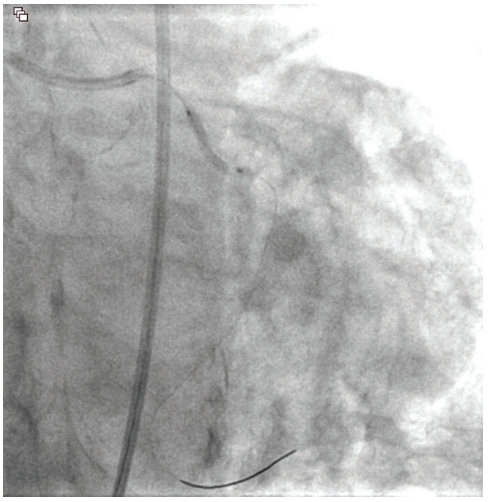

Figure 2. Wired with Runthrough® Izanai™ and PTCA with 2.0 Takeru™ RX balloon.

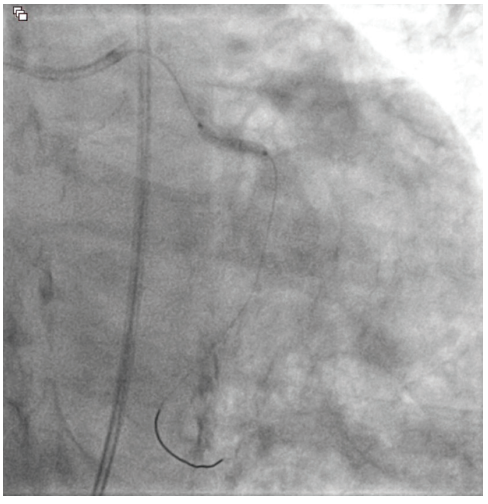

Figure 3. 2.5 mm Takeru™ RX balloon.

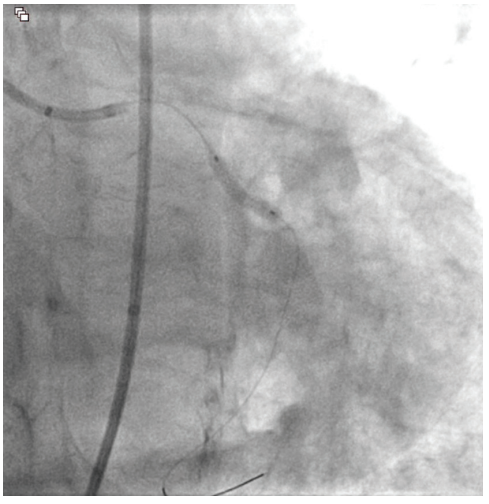

Figure 4. 3.0 mm Shockwave lithotripsy balloon.

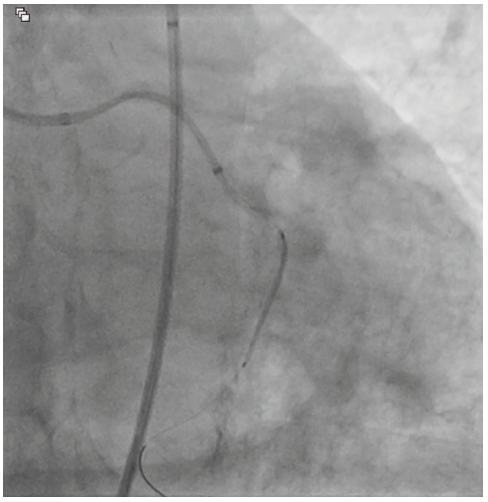

Figure 5. 3.0 mm x 22 mm Onyx Frontier drug-eluting stent.

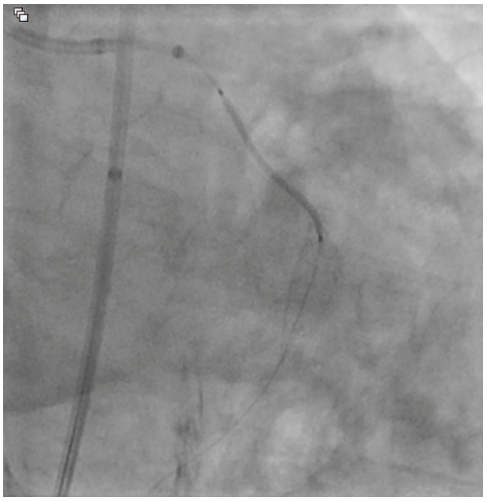

Figure 6. 3.5 mm x 26 mm Onyx stent.

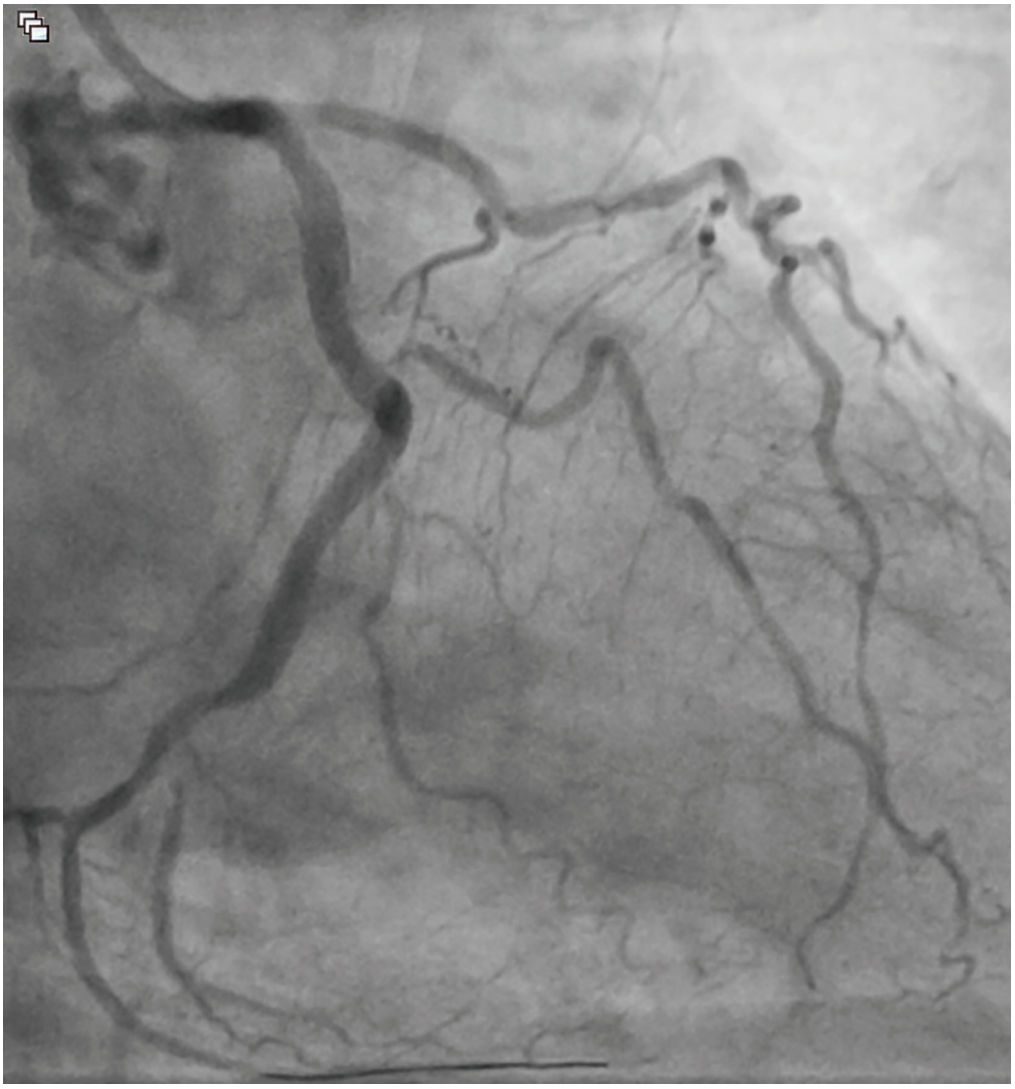

Figure 7. Final angiogram with 0% stenosis and TIMI-3 flow.

Using the Takeru™ RX NC balloon to perform pre-dilation in heavily calcified lesions aids in the delivery of an IVL catheter to further treat nodular, concentric, and even eccentric calcified lesions, as in the case herein.

post-dilated with a 4.0 mm x 12 mm Takeru™ RX NC balloon. The result demonstrated 0% residual stenosis with TIMI-3 flow, free from dissection or perforation (Figure 7).

Conclusion

Integrating a multifaceted approach to complex PCI has improved the ability to manage heavily calcified lesions that may have previously been too difficult to treat. Using the Takeru™ RX NC balloon to perform pre-dilation in heavily calcified lesions aids in the delivery of an IVL catheter to further treat nodular, concentric, and even eccentric calcified lesions, as in the case herein.

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