CASE REPORT

Coroflex® ISAR NEO

Sirolimus Eluting Polymer-Free Coronary Stent System

Conformability

Utilizing the superior conformability of Coroflex® ISAR NEO for complex tortuous lesions

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Background

Selection of appropriate devices that depend upon patient background, lesion morphology and characteristics is important in order to achieve effective outcomes for coronary lesions. For stent treatment too, it is imperative to understand stent functionality and select the appropriate stent that suits the treatment strategy of the particular procedure. Conformability of the stent is considered one of the most important functions for stent treatment. Implantation of a stent in the coronary arteries results in the implantation of a metal device which causes a straightening of naturally curved vessels. Artificially stretching the coronary artery causes a burden to both vessel and stent, resulting in a change to the shear stress or create restenosis or increase the risk of a thrombotic event caused by stent fracture. A drug eluting solution that does not involve a metallic substance such as drug coated balloons is able to alleviate such risk, however, for such cases that require stent treatment, when feasible it is important to undertake stent implantation that minimizes stress to both the vessel and the implanted stent.

CASE

KEY POINT
Conformability

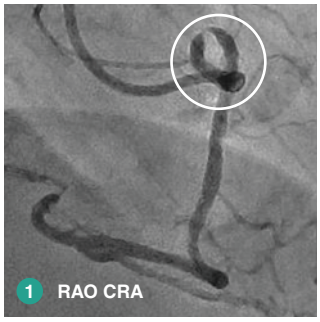
Case 1

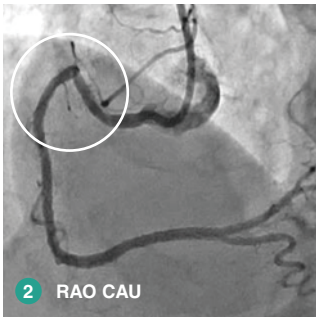
System
- Left Radial
- 6Fr AL1.0
- Glidesheath Slender

Diagnosis
- UAP

Target lesion
- RCA Seg.1 90%

Lesion Characteristics
- De novo
- Short
- Eccentric
- Bend(severe)
- Calcified


1 RAO CRA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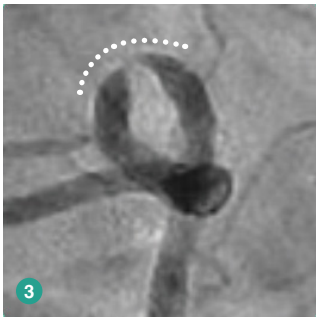
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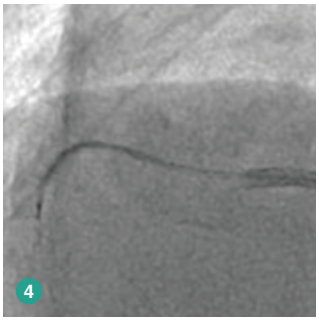
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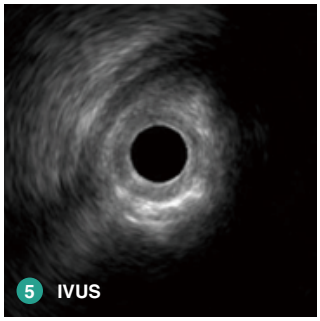
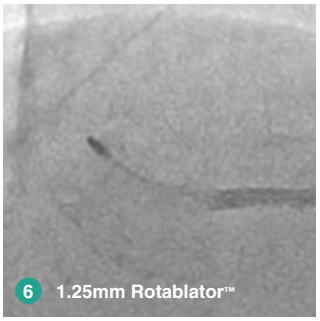
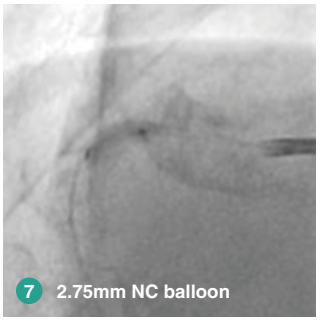
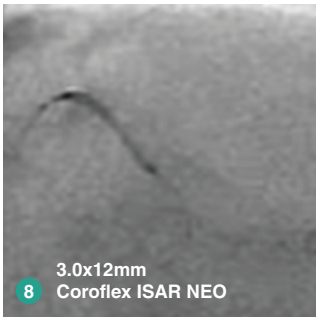
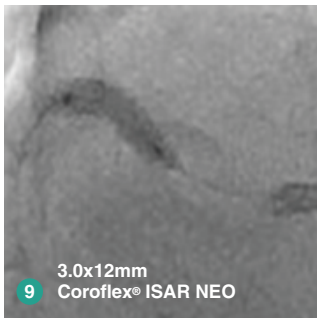
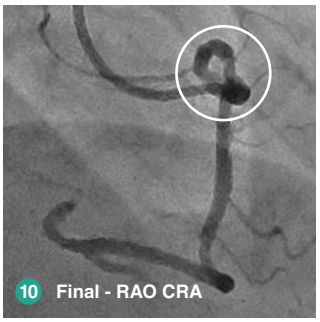

5 IVUS

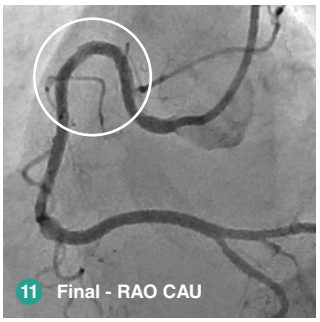

6 1.25mm Rotablator™


7 2.75mm NC balloon


8 3.0x12mm Coroflex ISAR NEO


9 3.0x12mm Coroflex® ISAR NEO


10 Final - RAO CRA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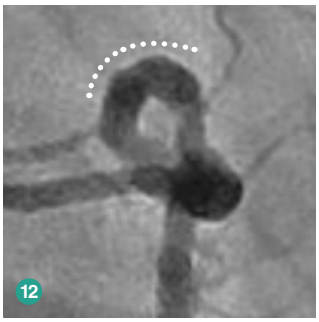
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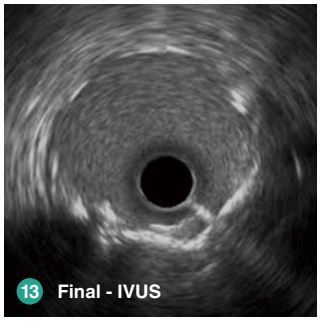

13 Final - IVUS

The culprit lesion is a tortuous, 90% stenosed, severely calcified lesion in the RCA (#1) 1 2 3. Initially the lesion was crossed with a floppy wire under microcatheter support. An ST elevation incurred but was resolved with a predilatation of a 2.0mm semi-compliant balloon (12atm). IVUS was performed, and >270 degrees of calcification was confirmed 4 5. An ablation was performed with a 1.25mm Rotablator™ burr 6. As the lesion was located at a tortuous location in the vessel, it was determined that subsequent further sizing up of the burr would also increase risk. As the lesion was in a looped vessel, an attempt was made to undertake a stentless treatment strategy. A 2.5mm non-compliant balloon (12atm) was dilated, and IVUS confirmed that a portion of the lesion did not achieve effective expansion and further inflation of a sized up 2.75mm non-compliant balloon was undertaken 7. Although a fissure was created, significant calcification remained in some segments and it was determined that a stent implantation was required. A 3.0x12mm Coroflex® ISAR NEO (10atm) was implanted 8 9.
The Coroflex® ISAR NEO was selected due to the superior conformability, and given the selected length was relatively short at 12mm, stent edge apposition was achieved without any accordion phenomena observed, and the stent was implanted conforming to the shape of the vessel 10 11 12 13.

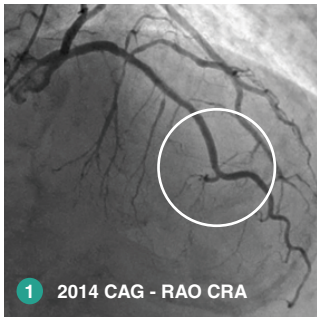
Case 2

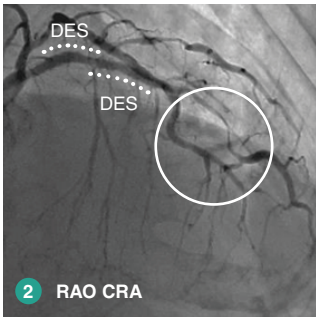
System
- Left Radial
- 6Fr Q3.5

Diagnosis
- UAP
- CKD e-GFR 39.1
  CRE1.63

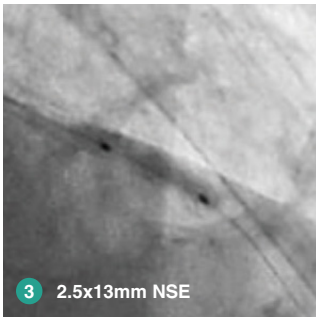
Target lesion
- LAD Seg.7 90%
  Seg.8 90%

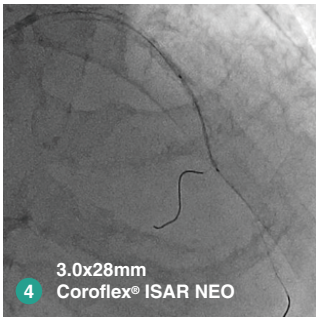
Lesion Characteristics
- De novo
- Long
- Bend(severe)

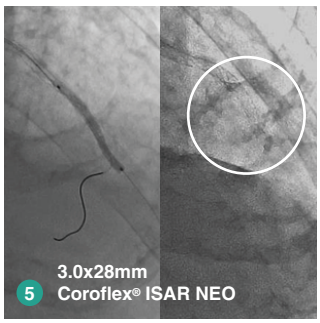

1 2014 CAG - RAO CRA

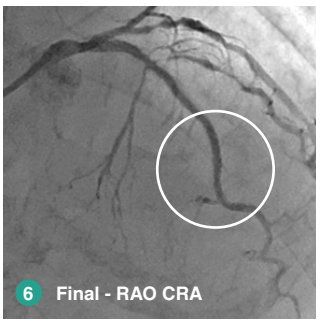


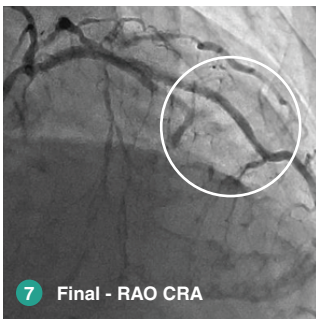
2 RAO CRA

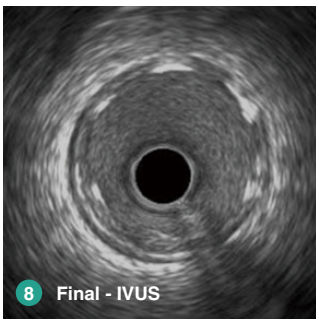

3 2.5x13mm NSE


3.0x28mm
4 Coroflex® ISAR NEO


3.0x28mm
5 Coroflex® ISAR NEO


6 Final - RAO CRA


7 Final - RAO CRA


8 Final - IVUS

There were two previously implanted DES (Seg 6 and 7) in the LAD 1. Treatment was determined for a diffuse 90% stenosed de novo lesion that was located distal to the Seg.7 DES and continuing into Seg.8 2. There was severe tortuosity from the mid to distal portion of the lesion. A 2.5x13mm NSE (8-14atm) was used for pre-dilatation 3, with an ST elevation and slow flow occurring, Nitroprusside was administered and a 3.0x28mm Coroflex® ISAR NEO implanted (6-10atm). The stent was successfully delivered without becoming caught on either of the previously implanted stents 4 5. The stent visibility was sufficient to be observed in normal fluoroscopy mode, allowing for adequate placement 5. IVUS determined mal-apposition at one portion of the stent and subsequent inflations of Seg.7 and 8 were performed (3.0x12mm - 14atm, 2.5x15mm - 12atm, respectively). Final IVUS determined good expansion and apposition, and as with Case 1, CAG showed that the stent greatly conformed to the vessel and the procedure was completed 6 7 8. When compared to the CAG performed in 2014, the vessel structure remained unchanged which indicates the high conformability achieved by the stent. Total contrast media used was 39mL.

Consideration

Both these cases (one of a short lesion and the other of a long lesion) were of lesions that required a high degree of conformability. It is very easy to incur non-conformability of the stent edge when a short stent is implanted in a short lesion located in the middle of a tortuous vessel or when a long lesion in a tortuous segment is stretched. Under these two difficult circumstances, Coroflex® ISAR NEO demonstrated that it achieved a high level of trackability, one of the key concepts of this product. With an aging population, it is expected that lesion morphology will continue to increase in complexity, and that Coroflex® ISAR NEO will continue to meet the high level of conformability needed to complete such cases.
Further, the Coroflex® ISAR NEO strut thickness of the 2.25-3.0mm small vessel design is 55 µm and the 3.5-4.0mm large vessel design is 65µm, both being extremely thin. Additionally, the crossing profile of the small vessel design of <3.0mm is <0.9mm, which is an extremely low profile. This makes it an extremely reliable choice for clinical practice moving forward. In the future it is hoped that polymer-free technology and thin struts will result in favorable long term prognosis.

Technical data

Stent strut thickness	Ø 2.25-3.0mm: 55µm / Ø 3.5-4.0mm: 65µm
Coating drugs	Sirolimus / Probucol
Amount of drug dispersed	1.2µg / mm²
Compatible guidewire	0.014inch / 0.36mm
Compatible guiding catheter (mimimum ID)	5Fr
Nominal pressure	10atm
Rated burst pressure	18 atm (Ø 4.0 mm: 15 atm)
Working length	1,450mm
Shaft OD (Distal / Proximal)	2.5Fr (0.83mm) / 1.9Fr (0.63mm)

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