CASE REPORT

IKAZUCHI ZERO™

Semi-Compliant PTCA Balloon

RAIDEN3™

Non-Compliant PTCA Balloon



Left main stenosis behind bars addressed with Kaneka RAIDEN3™ NC PTCA Balloon

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CAG findings:

Case outline

Patient: 78 yr. old male

Clinical presentation: Acute NSTEMI

Clinical history: The patient presented with a coronary 2-VD and severe aortic valve stenosis. 4 months before the acute admission, a TAVI had been implanted and a DES had been placed into the ostial LCX.

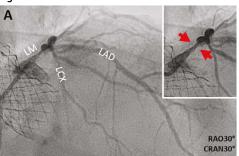
Risk factors:

Obesity, arterial hypertension, smoking.

Due to the TAVI cage, access to the LCA and RCA ostia was anticipated to be difficult, therefore a femoral access was used. Our diagnostic angiogram showed a distal left main stenosis (**Fig. 1A**), furthermore an ostial stenosis of the LCX (**Fig. 1B**). During the TAVI procedure 4 months prior to admission, a DES had been implanted into the ostial LCX, obviously not completely covering the ostium, which now showed a subtotal restenosis. Furthermore, the RM1, over stented by the LCX stent, showed a significant stenosis (**Fig. 1B**).

Fig 1B

Fig 1A



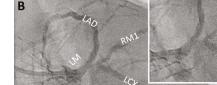


Figure 1A and B: Diagnostic angiography of the NSTEMI patient: (A) RAO30°CRAN30° angulation showing the left coronary pocket obstructed by the TAVI cage and the distal LM stenosis. (B) LAO40°CAUD30° showing the full extent with additional ostial LCX stenosis proximal to the stent in the prox. LCX and the ostial RM1 stenosis. Inserts on the upper right are enlarged views.

Treatment approach

Access site: Right femoral artery, Medtronic Launcher[™] Coronary Guide Catheter EBU 4.0.

Lesion: Distal LM, ostial LCX, ostial RM1.

Strategy: The diagnostic angiogram showed a rapid deterioration of the severity of coronary artery disease within only 4

months post TAVI implant and ostial LCX repair. Due to the poor result of the previous LCX repair with DES our goal was (1) not to implant too much new stent material and (2) provide an optimal repair of the transition from

LM to LCX.

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We considered two strategies as shown in **Fig. 2A and 2B**. Considering the robust data in clinical trials DK-crush might have been performed. However, the bulk of struts (red) which are dilated back into the LCX might have made repair of the RM1 ostium difficult. Therefore, we favored Culotte with four steps: (1) Strut opening of the previously implanted LCX stent into the RM1 to avoid double layers of struts. (2) DES from LM to LAD to treat the distal LM stenosis. (3) DES stenting from LM to LCX to facilitate a gapless transition with high radial force from LM to LCX, followed by kissing-balloon inflation and POT. (4) Finally opening of the second strut layer from LCX into the RM1 to facilitate further access to this large vessel.

Fig 2A and B

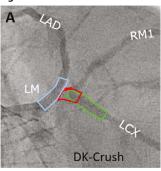
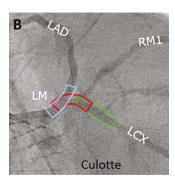


Figure 2A and B: Potential stenting strategies for the acute NSTEMI patient with LM bifurcation stenosis post TAVI (LAO40°CAUD30°): (A) DK-Crush would have the benefit of avoiding double layer semgents in the LM, the bulky carina adjacent to the RM1 ostium might, however, make future access difficult. (B) Culotte would provide a robust diameter transition from LM to LAD and from LM to LCX. As a tradeoff, this would involve a short double-layer segment in the LM (blue/red overlap).



Treatment progress

The guiding catheter could only be advanced through a TAVI cage cell lateral and slightly cranial of the LM ostium, giving our intervention a somewhat unfavorable angle with the LM stem. Therefore, we targeted LM-LAD repair first and then in the direct line of the catheter LM-LCX as the second major Culotte step.

Three ASAHI SION wires were passed from LM to distal LAD, LM to distal LCX and LM to RM1 through the struts of the previously implanted LCX stent. After that we could dilate a strut opening from LCX to RM1 with a Kaneka RAIDEN3 $^{\text{m}}$ NC PTCA Balloon 2.5 x 10 mm at 16 ATM (**Fig. 3A**). The result showed a significant diameter gain without additional stenting (**Fig. 3B**).

Fig 3A and B

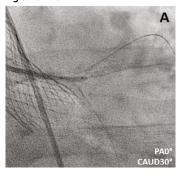
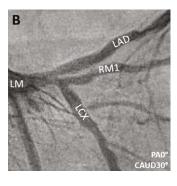


Figure 3A and B: PA caudal views of the prox. LCA with TAVI cage on the left. (A) LCX cell opening and ostial RM1 dilatation with Kaneka RAIDEN3™ NC PTCA Balloon 2.5 x 10 mm, inflation to 16 ATM. (B) Favorable result without further Stent-Implantation



We proceeded with the Culotte technique as intended and pre-dilatated from LM to LCX (**Fig. 4A**) and from LM to LAD (**Fig. 4B**), both with a Kaneka RAIDEN3^m NC PTCA Balloon 3.5 x 13 mm at 16 ATM. After predilatation the angiogram showed a significant gain in diameter at the ostial LCX (**Fig. 4C**) and the distal LM (**Fig. 4D**).

Fig 4A, B, C and D

A

LAO40°
CAUD30°



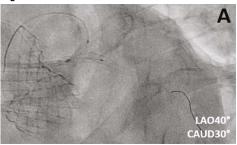
Figure 4 A, B, C and D
Predilatation of (A) LM to LCX
and (B) LM to LAD with Kaneka
RAIDEN3™ NC PTCA Balloon 3.5 x
13 mm at 16 ATM. The lower part
shows the dilatation result with
significant lumen gain in the
ostial LCX (C) and distal LM (D).





After that we proceeded with sequential DES implantation from LM to LAD, wire-exchange and strut opening to LCX and subsequent DES implant LM to LCX (both stents Biotronik Orsiro® Mission DES 3.5 x 15 mm, inflation to 16 ATM). After POT, struts were opened from LM to LAD and LCX to RM1. Subsequently, kissing-balloon-inflation was performed with two Kaneka RAIDEN3 $^{\text{TM}}$ NC PTCA Balloon 3.5 x 15 mm, inflation to 12 ATM (**Fig. 5A and 5B**).

Fig 5A and B



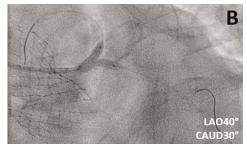


Figure 5A and B: Kissing-balloon inflation with two Kaneka RAIDEN3™ NC PTCA Balloon 3.5 x 15 mm NC balloons. (A) Positioning from LM to prox. LAD and LM to prox. RCX. (B) Sequential inflation to 12 ATM.

As a final step a POT maneuver was performed with a Kaneka RAIDEN3 TM NC PTCA Balloon 4.5 x 10 mm inflated to 16 ATM (**Fig. 6A and 6B**).

Fig 6A and B

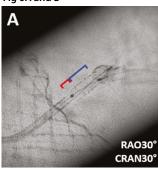
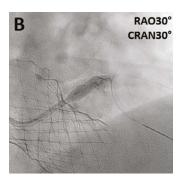


Figure 6 A and B: Final POT maneuver with a Kaneka RAIDEN3™ NC PTCA Balloon 4.5 x 10 mm NC balloon. (A) Positioning with StentBoost Live imaging showing the ostial DES single-layer segment (red) and the double-layer segment (blue) further distally. (B) Inflation to 16 ATM.



The final result showed a smooth diameter transition from LM to LAD and LM into the previously implanted LCX stent while maintaining a satisfactory diameter at the ostial RM1 (Fig. 7A and 7B).

Fig 7A and B

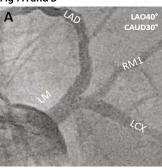
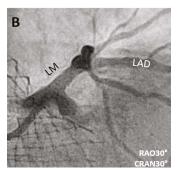


Figure 7: Postinterventional result with restitution of the transition from LM to LAD and LM to LCX overlapping into the previous LCX stent. Angiographic image from (A) LAO40°CAUD30° and (B) RAO30°CRAN30°.



Key points on the treatment strategy

From difficult access to the coronary ostia to low backup, PCI in TAVI patients can be very challenging. In the current case left main bifurcation repair had to be achieved from an unfavorable angle with poor maneuverability of the guiding catheter. Taking into consideration the LCX stent already in place we chose a 2-stent Culotte strategy (Fig. 2B). This intervention depends on spotless performance of the balloons used for re-crossing and strut opening, which is an essential point-of-no-return during the Culotte sequence. The final kissing-balloon inflation (Fig. 5) and POT maneuver is obligatory in LM Culotte interventions and could swiftly be achieved (Fig. 6). During these crucial steps the Kaneka RAIDEN3™ NC PTCA balloons performed very reliably even when used for repetitive dilatations.





Reference: Burzotta F, et al., Stankovic G. European Bifurcation Club white paper on stenting techniques for patients with bifurcated coronary artery lesions. Cath Cardiovasc Interv 2020; 96(5): 1067-1079.

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