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Experience in crossing previously failed Chronic Total Occlusions using an innovative guidewire support catheter

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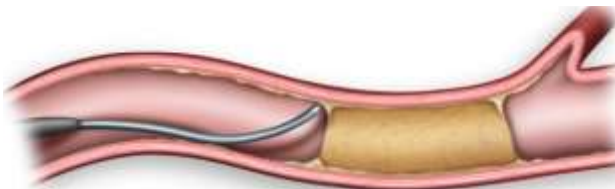
The technology

- Nhancer ProTM guidewire support catheter (IMDS BV, Netherlands)
 - Extruded catheter using compressible polymer technology (Body OD 2,3 F)
 - Radiopaque, tapered soft, flexible tip (Tip ID 0,016")
 - Braided technology
- Unique ability to lock the catheter shaft on the PCI guidewire, creating a hybrid system
- Benefits:
 - Improving guidewire body and guidewire tip column strength
 - Improved torque control
 - Active guidewire tip shaping & centering

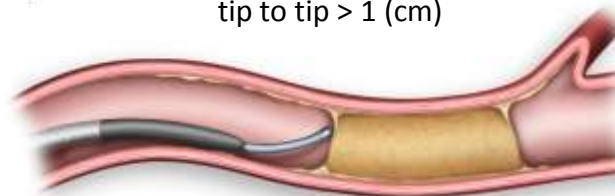




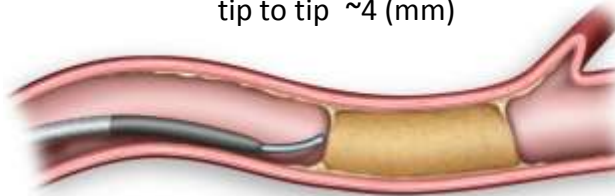
Device Specs



tip to tip > 1 (cm)



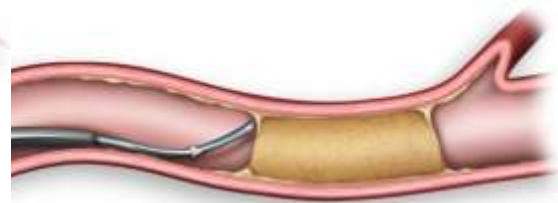
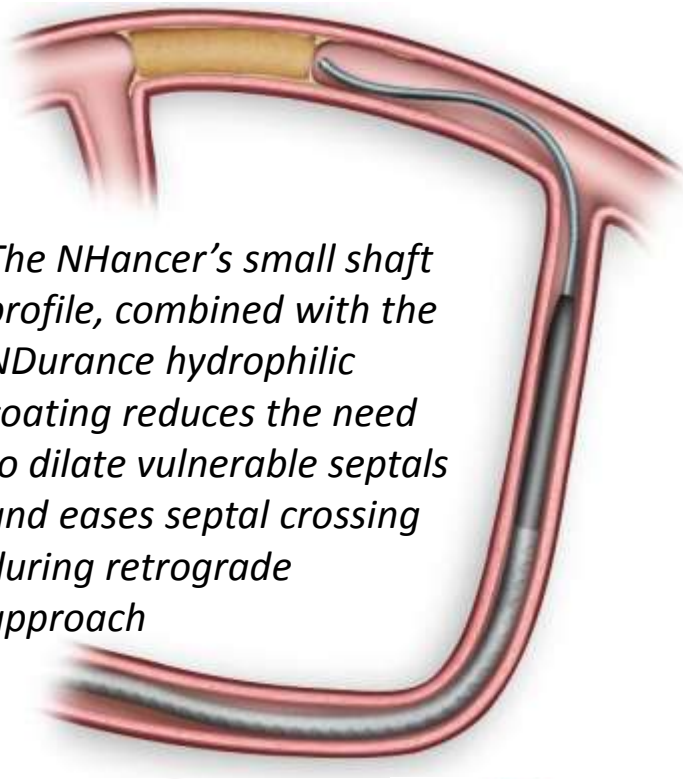
tip to tip ~4 (mm)



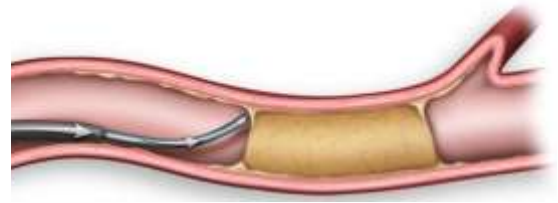
tip to tip ~2 (mm)

NHancer enables on angio tip shapin which increase the ability to seek CTO entry more to the center of the CTO

The NHancer's small shaft profile, combined with the NDurance hydrophilic coating reduces the need to dilate vulnerable septals and eases septal crossing during retrograde approach

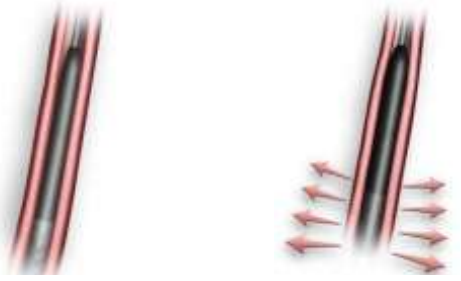


traditional support catheters back-out backup support is needed



to the unique locking feature the ncer cannot back out and provides support to the guidewire tip.

Improved force transmission ases the capability of the wire to trate and cross the CTO.





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FIRST CLINICAL EXPERIENCE

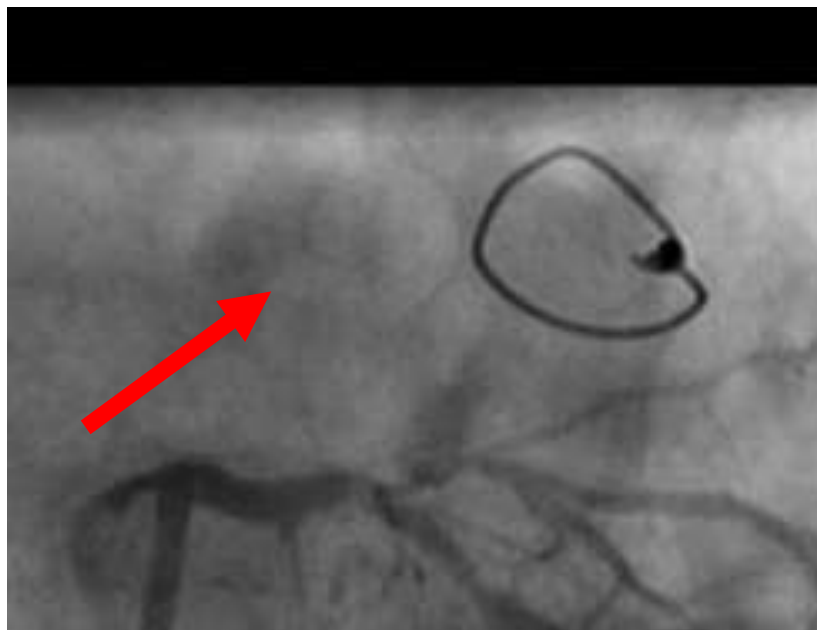


Case Review 1

- Patient Information
 - Male 70y
 - CTO located in prox LCX
 - Failed attempt 2 weeks before (aborted procedure after small perforation after 15 minutes)
 - Material used during failed procedure:
 - Guidings: Medtronic EBU 3.5 Zuma, EBU 4.0 Launcher
 - Guidewires: Asahi ULTIMATEbros3, Asahi Fielder XT
 - Balloons: Boston Scientific 1.5/15 mm Apex push
 - Radiation dose: 119187 mGy
 - Contrast used: 170 ml



Guidewire Tip Performance

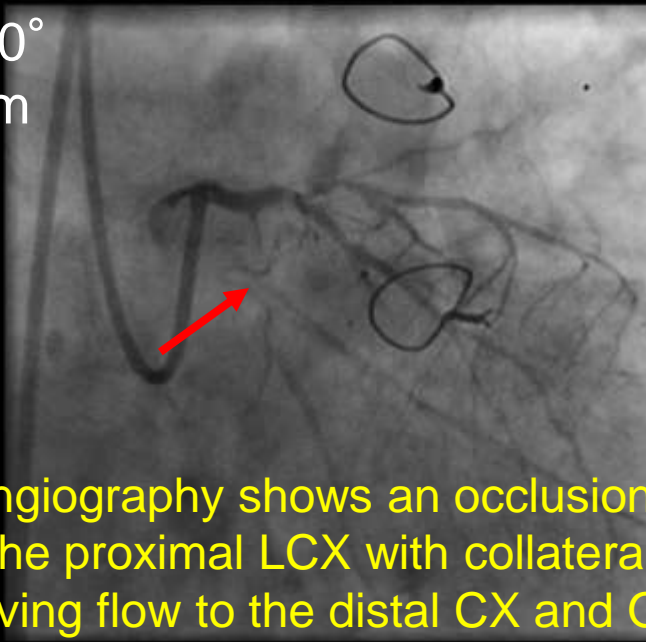


NHancer Tip Flexibility

The NHancer catheter tip flexibility and conformability helps in addressing tight stenoses and occlusions that are located after acute take offs. The catheter locking feature helps in providing continuous push transfer to the guidewire tip towards the lesion, instead of the applied push making the wire tip prolapsing in the main branch.

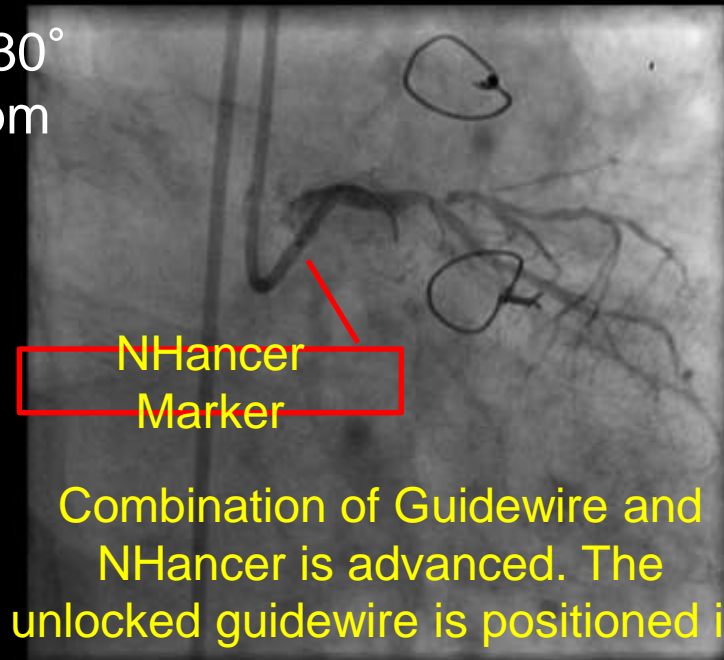


RAO 30°
1u38pm



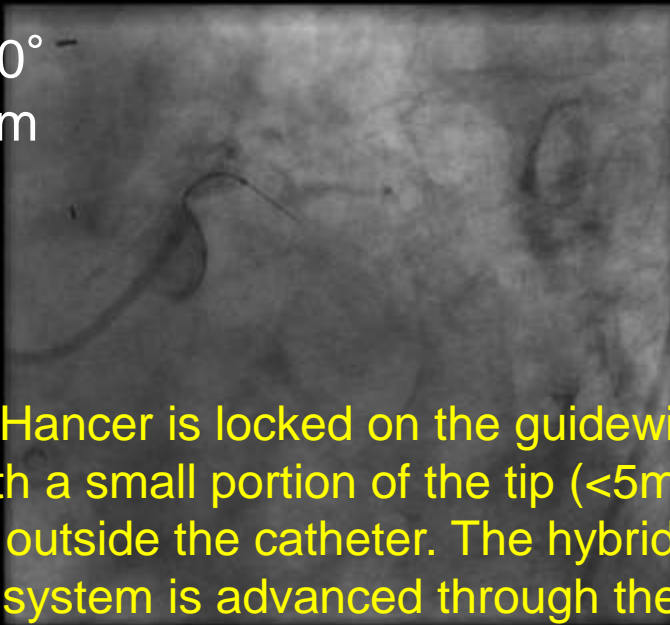
Angiography shows an occlusion at the proximal LCX with collaterals giving flow to the distal CX and OM

RAO 30°
1u43pm



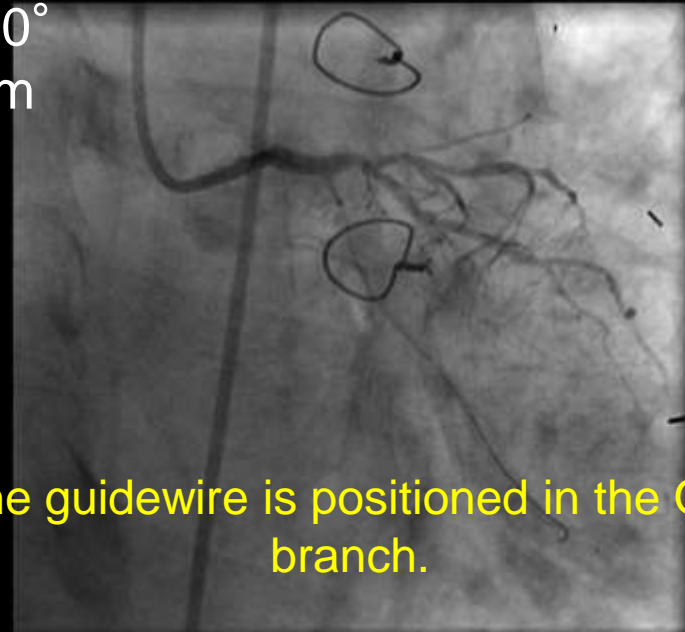
Combination of Guidewire and NHancer is advanced. The unlocked guidewire is positioned in front of occlusion.

LAO 50°
1u47pm



NHancer is locked on the guidewire with a small portion of the tip (<5mm) outside the catheter. The hybrid system is advanced through the occlusion

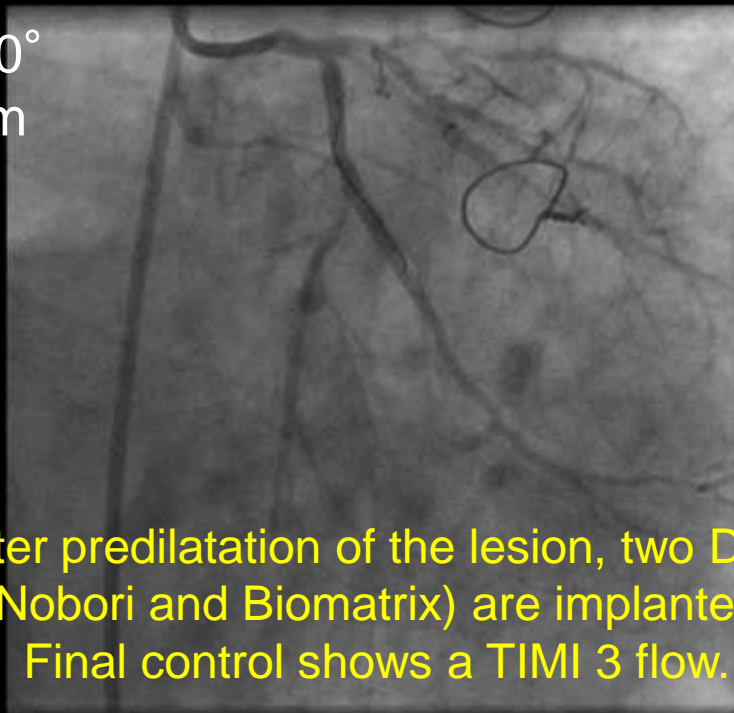
RAO 20°
1u51pm



The guidewire is positioned in the OM branch.



RAO 30°
2u15pm



After predilatation of the lesion, two DES
(Nobori and Biomatrix) are implanted.
Final control shows a TIMI 3 flow.

Procedure Findings

Crossing time <10 mins

Total procedure time 1h03'

Radiation Dose: 224626 mGy

Contrast used: 290 ml

Used Material

Guidings: AL 2.0 Launcher; EBU
4.0 Launcher

Wires: PT2 Moderate, PT Graphix
Guidewire support catheter:
NHancer

Balloons: Maverick

Stents: Nobori, Biomatrix



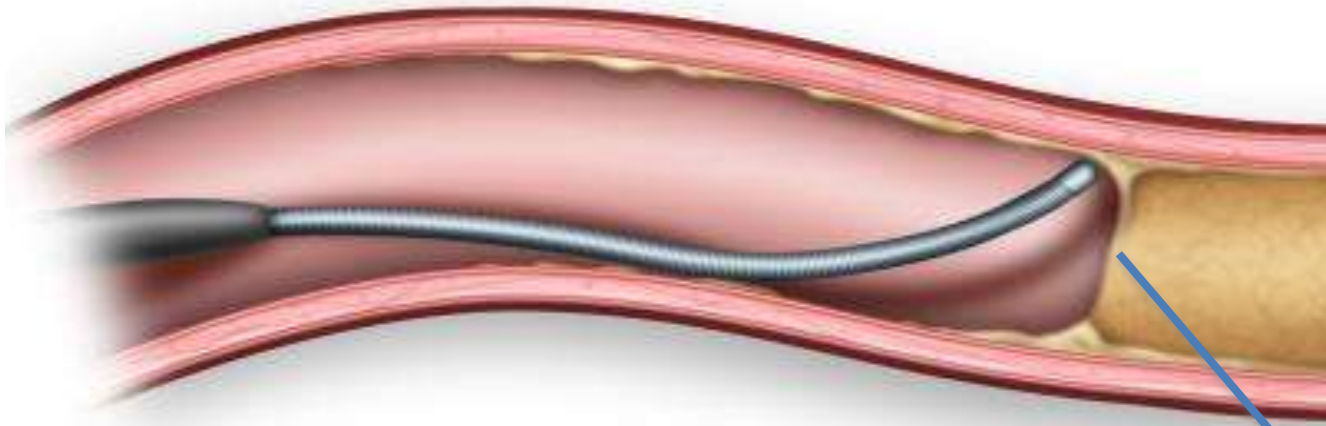
Case Review 2

- Patient Information

- Male 67y
- Stable Angina Pectoris
- Lesion 1: Right Coronary Artery (Culprit - Diffuse disease)
- Lesion 2: 1st Diagonal CTO (Optional)
 - Failed attempt 10 months before (November 2011)
 - Material used during failed attempt
 - » Guidings: JL4 Launcher
 - » Wires: PT Graphix (2), Galeo M
 - » Balloons: Tazuna, Fluydo
 - Duration: 2h10'
 - Radiation dose: 256202 mGy
 - Contrast used: 500 ml

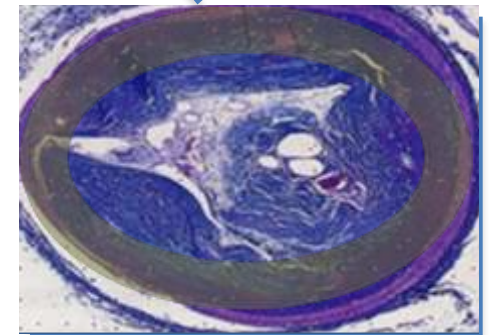


Active tip shaping and centering

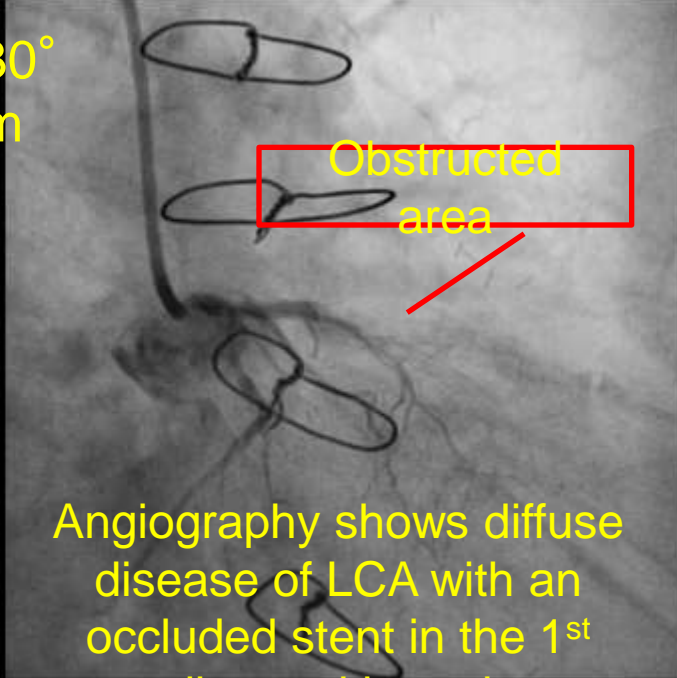


NHancer active wire shaping

A small distal tip bend (take off 1-1.5 (mm) in combination with a very distal NHancer tip positioning in relation to the guidewire tip results into an increased possibility to center guidewire tip towards the true lumen.

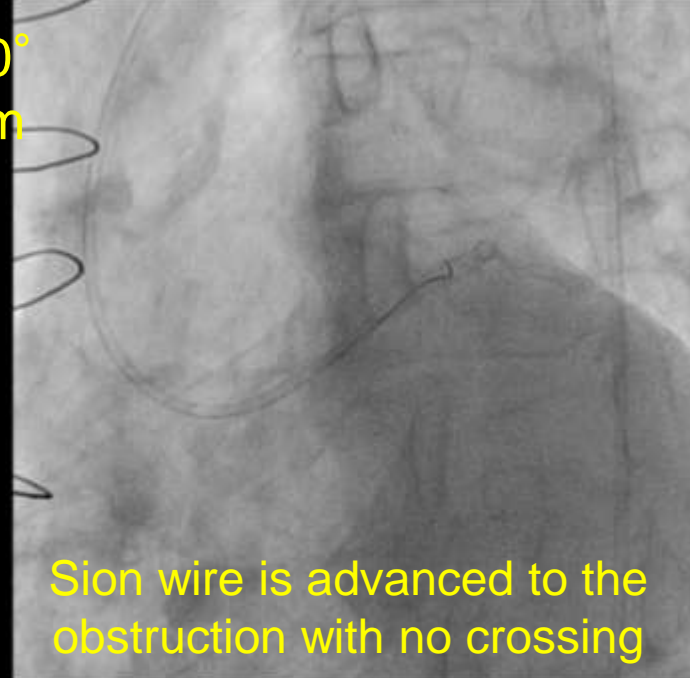


RAO -30°
3u02pm



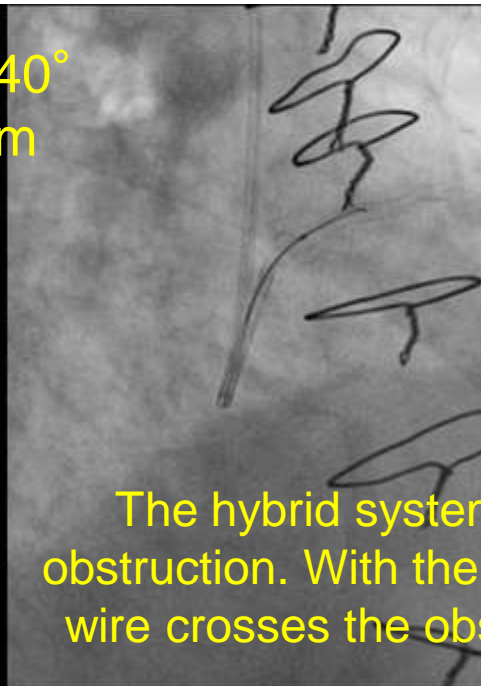
Angiography shows diffuse disease of LCA with an occluded stent in the 1st diagonal branch

LAO 40°
3u21pm



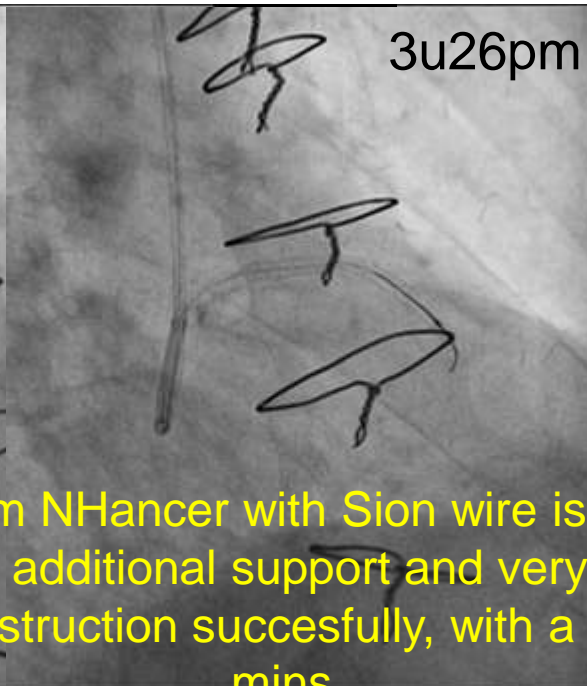
Sion wire is advanced to the obstruction with no crossing success.

RAO -40°
3u25pm

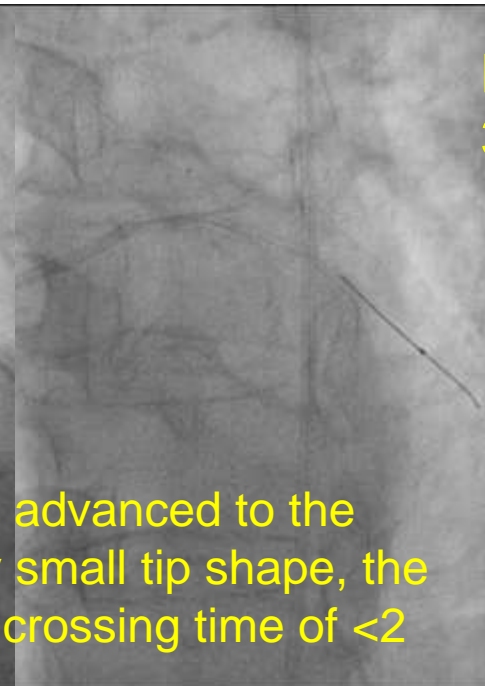


The hybrid system NHancer with Sion wire is advanced to the obstruction. With the additional support and very small tip shape, the wire crosses the obstruction successfully, with a crossing time of <2 mins

3u26pm

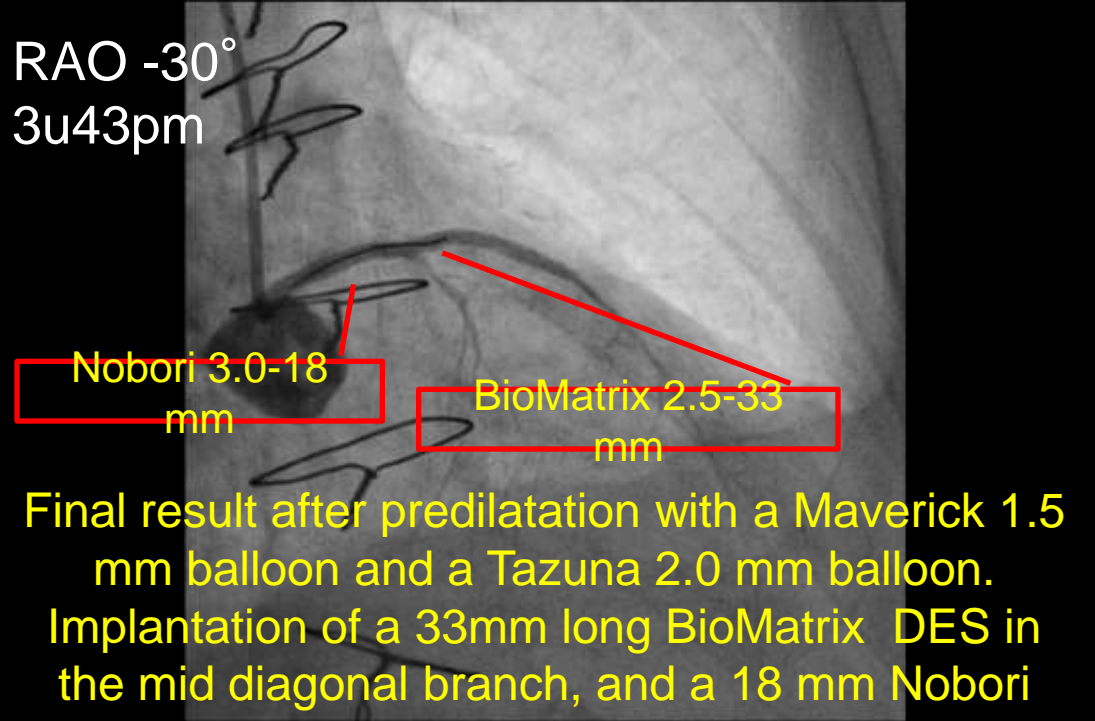


LAO 35°
3u26pm





RAO -30°
3u43pm



Nobori 3.0-18
mm

BioMatrix 2.5-33
mm

Final result after predilatation with a Maverick 1.5 mm balloon and a Tazuna 2.0 mm balloon. Implantation of a 33mm long BioMatrix DES in the mid diagonal branch, and a 18 mm Nobori DES in the proximal LCA.

Procedure Findings

Crossing time <10 mins

Crossing time NHancer <2 mins

Total procedure time: 1h45' (*)

Procedure time for Diagonal branch: 45'

Radiation Dose: 188381 mGy (*)

Contrast used: 300 ml (*)

Used Material

Guiding: Medtronic EBU 4.0 Launcher

Wires: Asahi Sion, Biotronik Galeo

Guidewire support catheter: NHancer

Balloons: Boston Scientific Maverick,

Terumo Tazuna

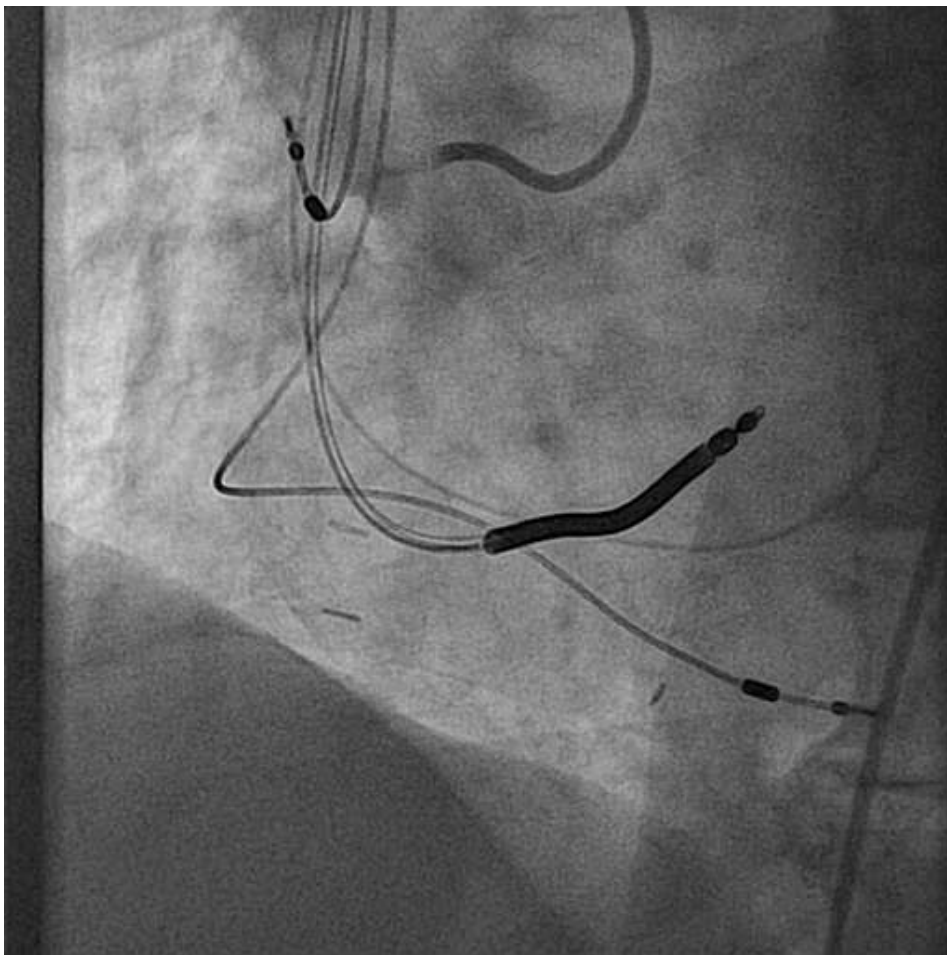
Stents: Terumo Nobori,

Biosensors Biomatrix

* (incl double stenting in Right Coronary Artery)

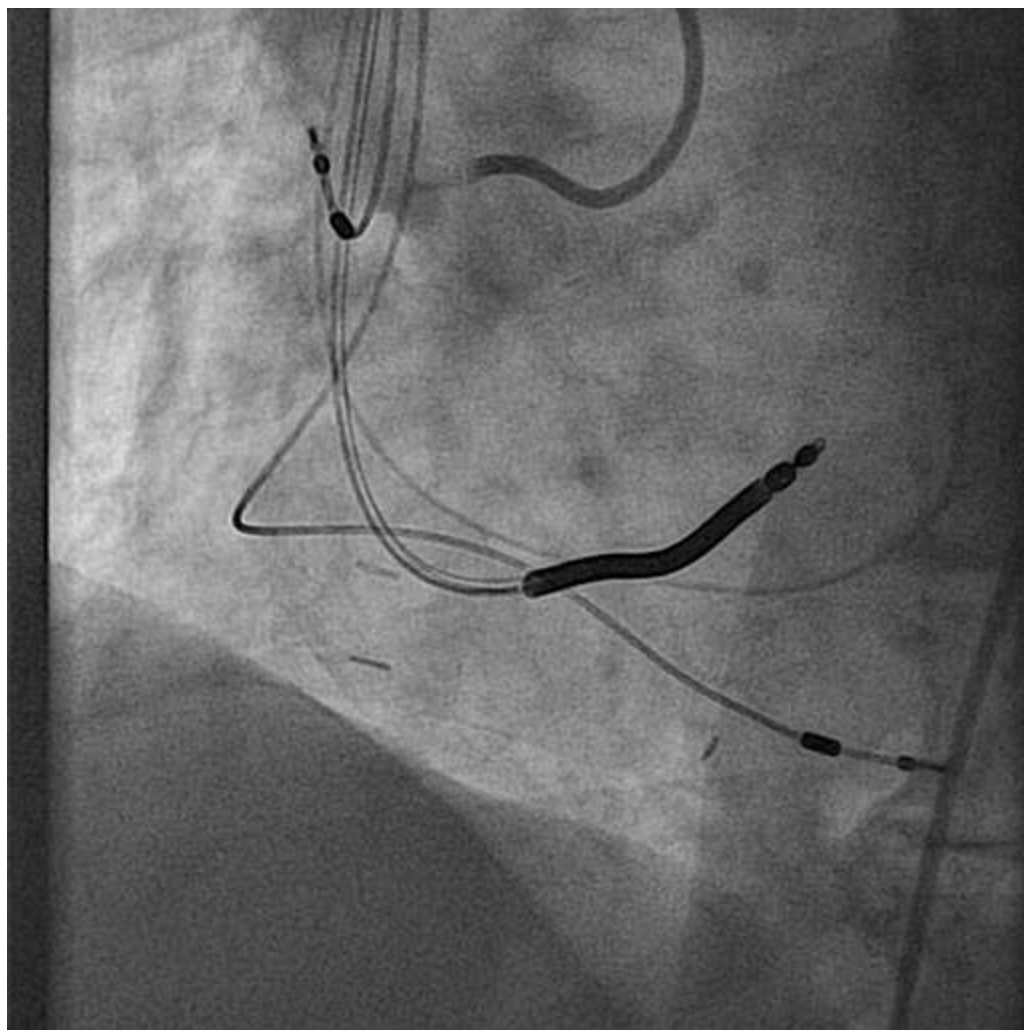


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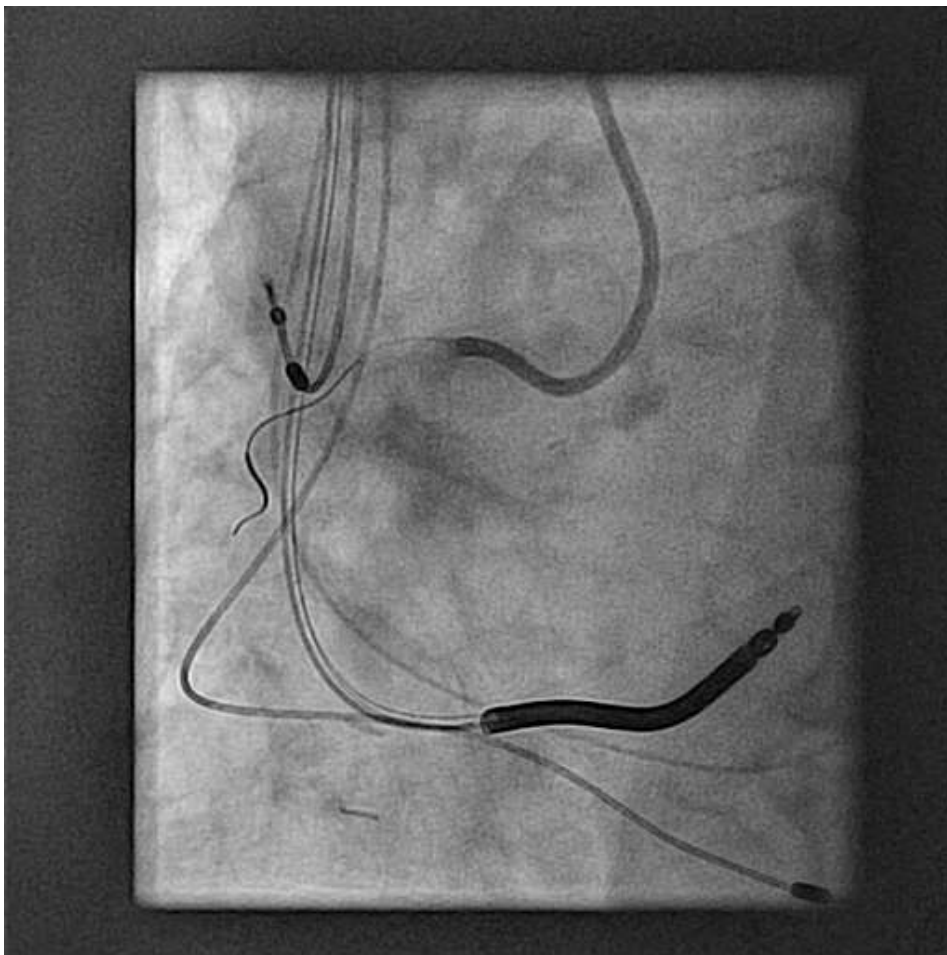


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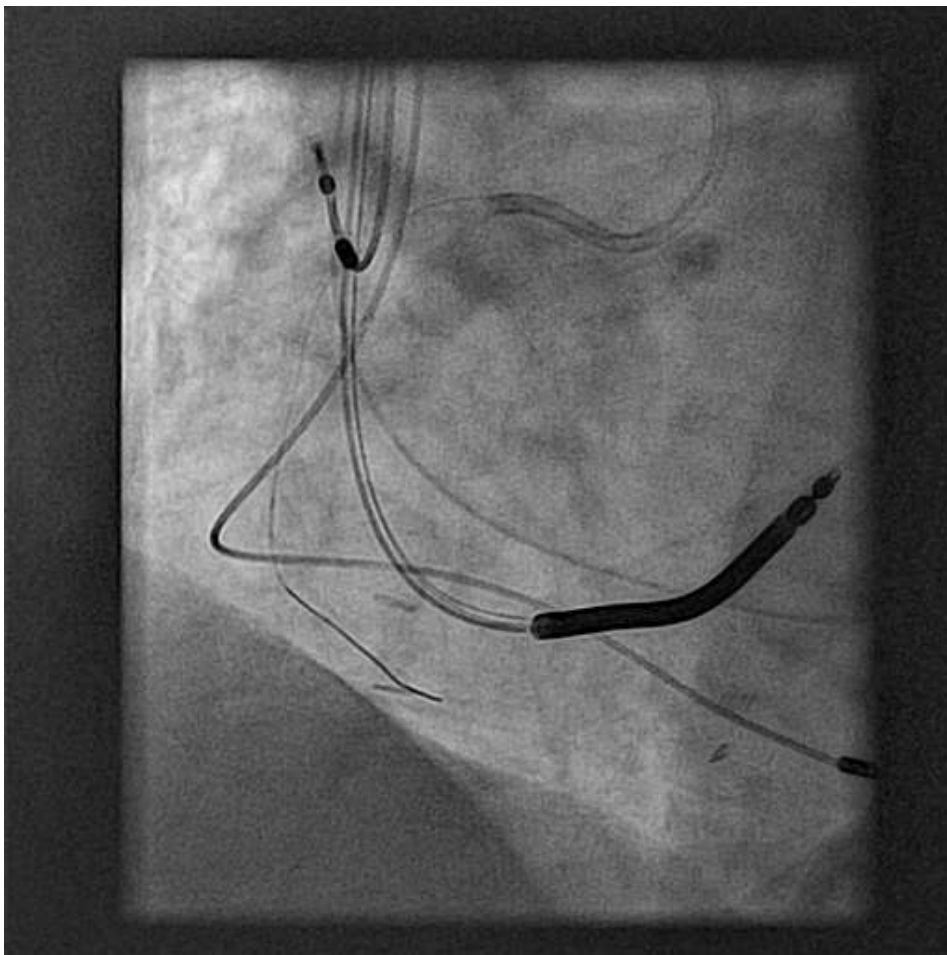


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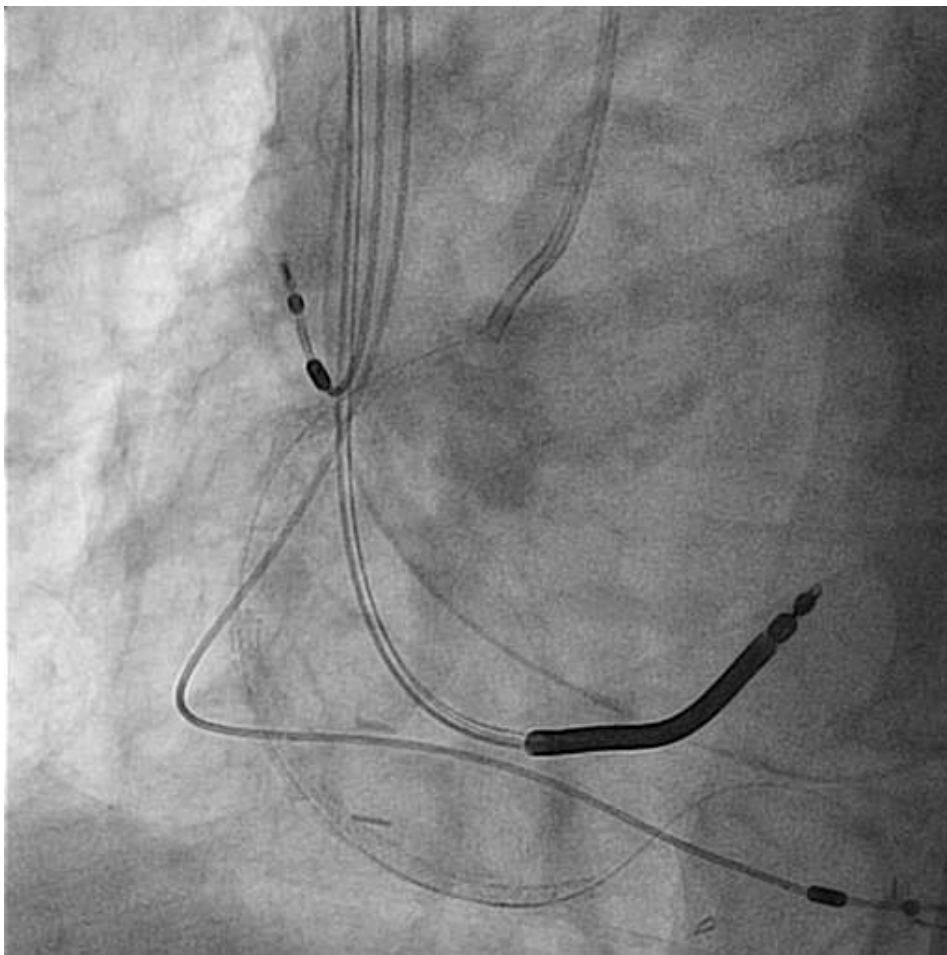


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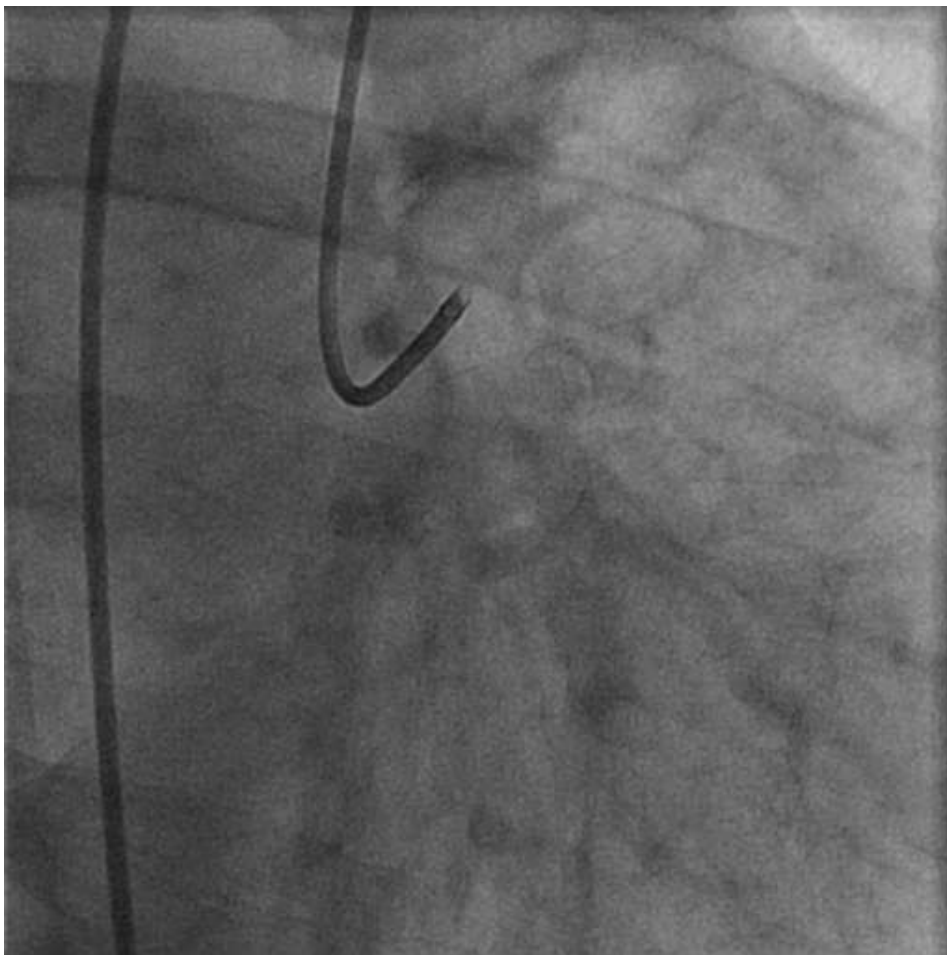


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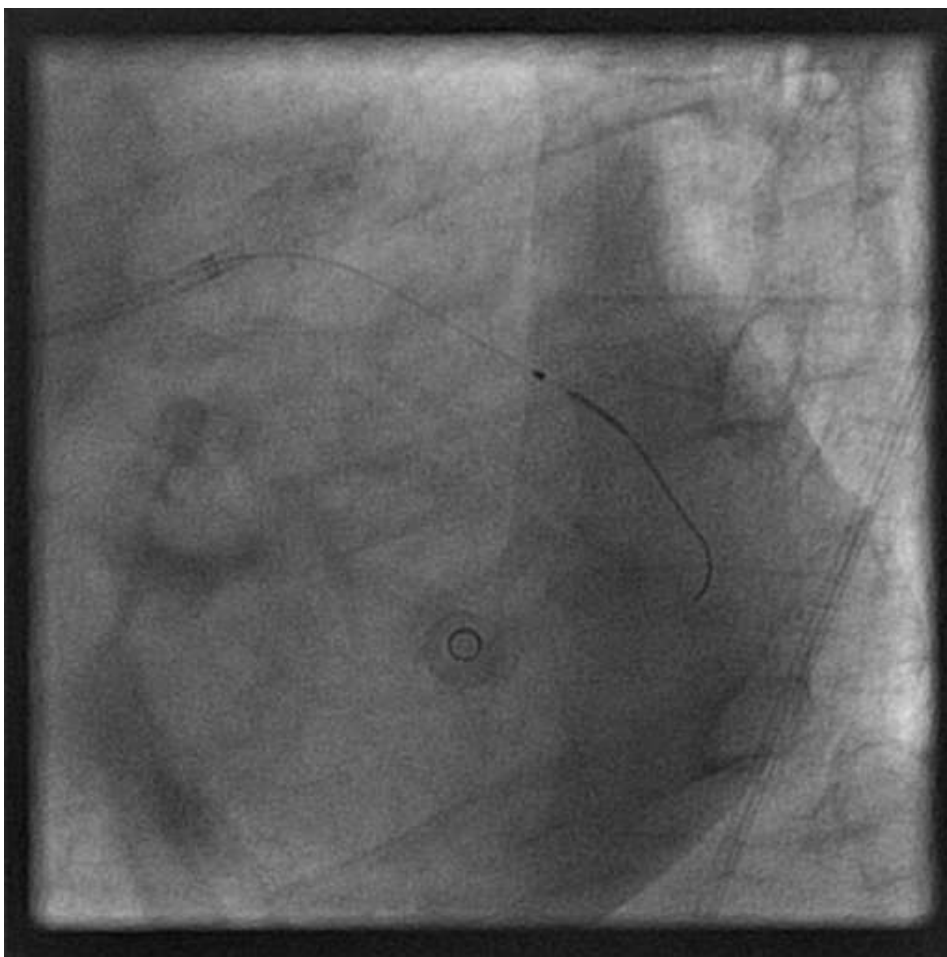


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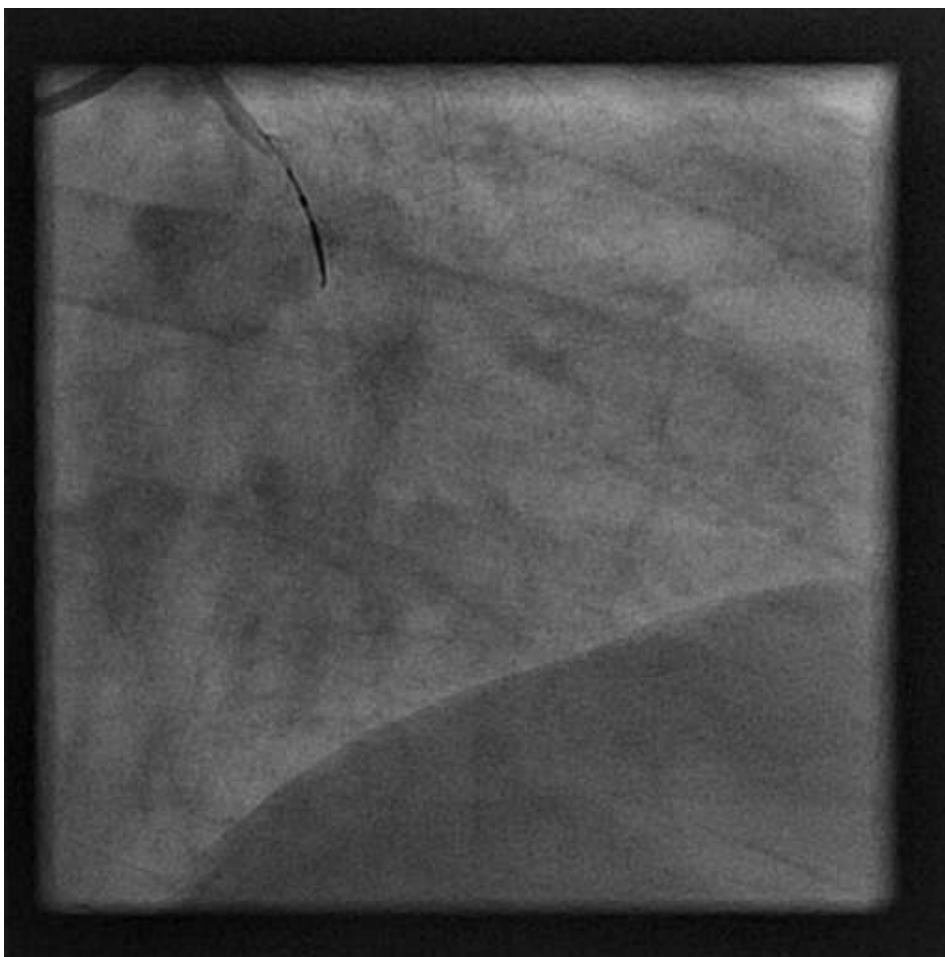


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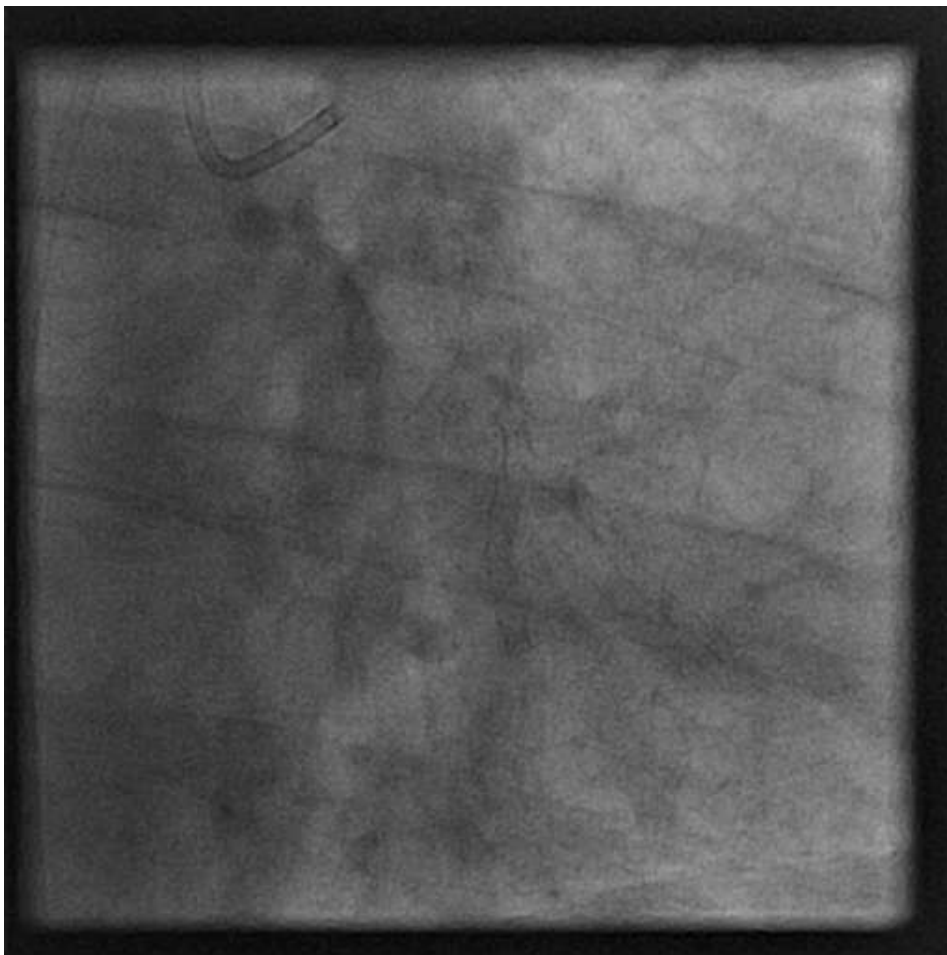


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Conclusions

- The NHancer™ guidewire support catheter was essential in the success of crossing Chronic Total Occlusions that previously failed to be crossed
- The NHancer™ provides a higher guidewire steerability and helps in altering the characteristics of the guidewire tip
- Important procedural benefits were observed including:
 - Shortened procedure time
 - Low radiation and contrast use
 - Potential cost savings in the use of interventional devices