Initial Experience of "PlasmaWire" for Coronary CTOs:

Results of FIM Study

Etsuo Tsuchikane, MD, PhD

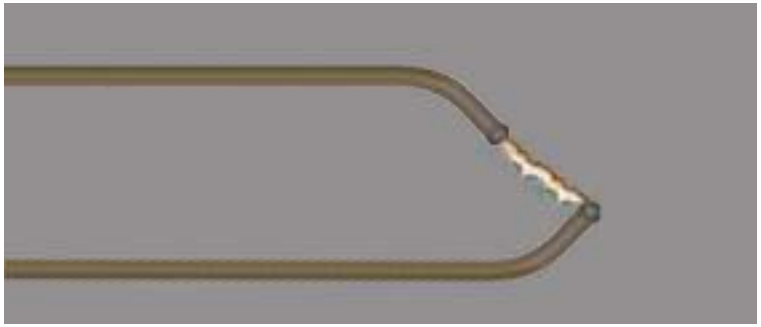
Disclosure

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organizations listed below.

Physician Name	Company/Relationship	
Etsuo Tsuchikane, MD, PhD	Boston Scientific, Japan	Consultant
	Asahi Intecc, Japan	Consultant

FIM of PlasmaWire

PlasmaWire System

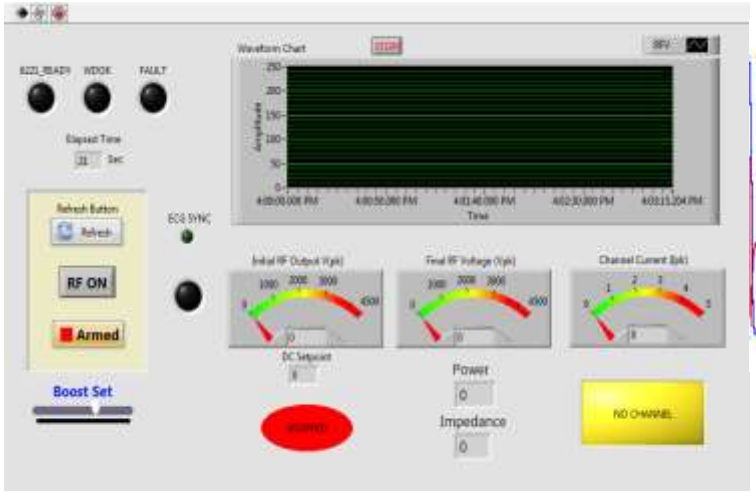


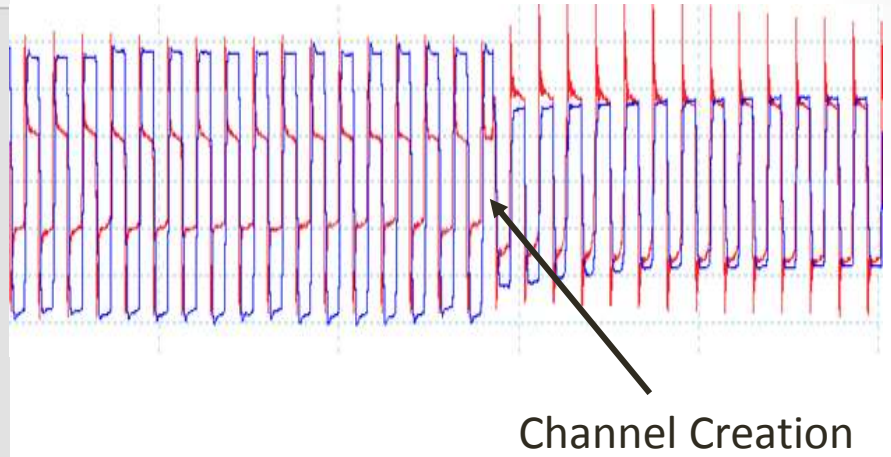
RetroVascular, Inc.

- The PlasmaWire System consists of an RF Generator (RFG), Connector Cable and two 0.014” RF wires (PlasmaWire).
- Two, independently steerable PlasmaWires act as electrodes to form a bipolar arrangement for precise directional ablation.
- RF energy is delivered to the PlasmaWire in “packets” of short pulses to minimize tissue injury while creating plasma to facilitate channel creation between the two wire tips.
- Created channel allows for subsequent CTO crossing and treatment with DES.

FIM of PlasmaWire

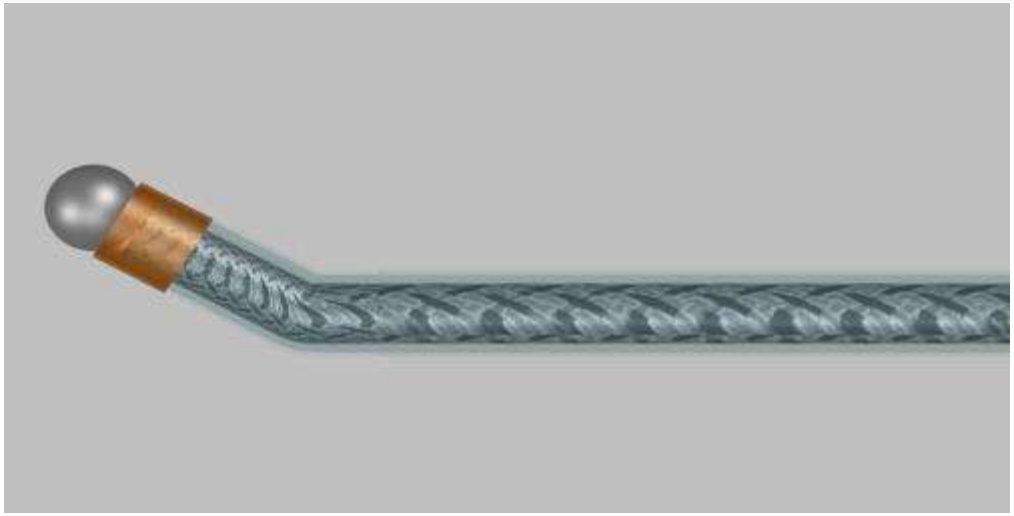
RF Generator (RFG)





- Each “packet” is triggered by an ECG Monitor input based on detection of patient’s ECG R-wave.
- RFG measures and monitors signals in real-time and detects channel creation using a proprietary algorithm and automatically terminates RF cycle to minimize delivered RF energy.
- Maximum RF cycle set at 5 sec.

PlasmaWire

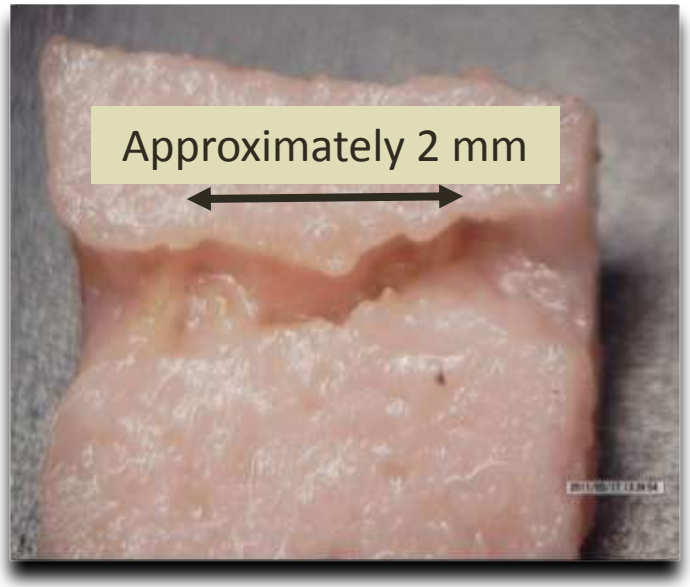


- Next generation Gaia NEXT wire technology offers handling and performance characteristics similar to Gaia 2nd 0.014” diameter guidewires.
- Unique polymer structure provides insulation to ensure safe delivery of RF energy to treatment site for creation of a channel in CTO.

FIM of PlasmaWire

Bench Testing

Plasma ablation in hotdog



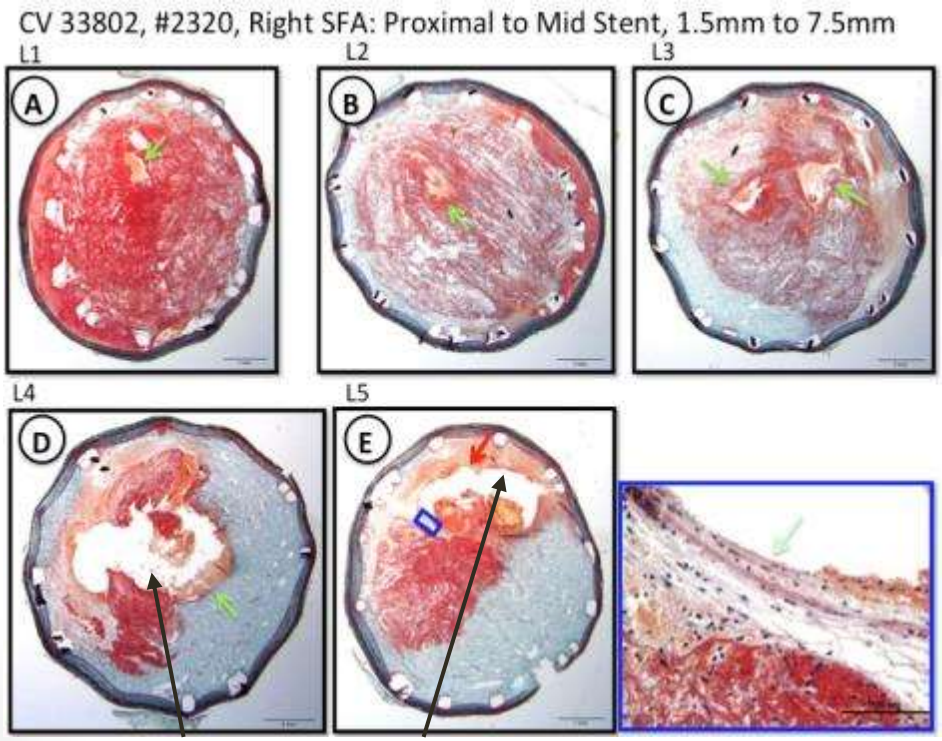
Clear channel created
without charring
(electrodes offset by 2 mm)

Plasma ablation in bone (calcium)

Clear channel created
without charring

Chronic Animal Study

Intimal channel created with minimal RF injury

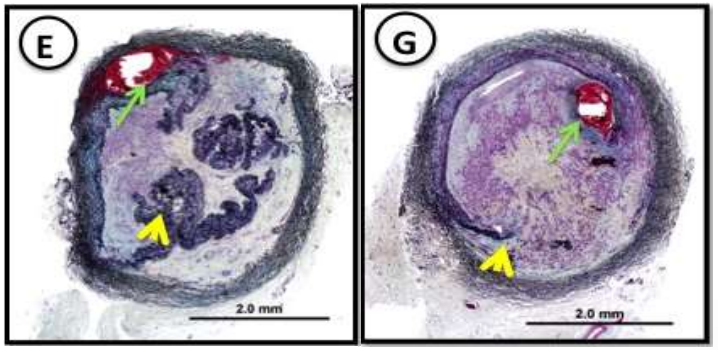


channel by plasma ablation

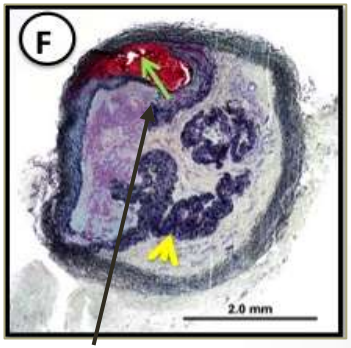
Subintimal sectioning indicated no thermal injury

Antegrade wire in subintima

Retrograde wire in intima



Created channel between antegrade and retrograde wire.



channel by plasma ablation

FIM of PlasmaWire

FIM cases in SCVC, NHC and THC

FIM number	site	date	CASE	Patient ID	age	sex	Targeted CTO (intended ablation site)	Intended use of PlasmaWire
FIM-1	SCVC	Oct. 21	KN	70412581	69	M	mid-RCA (distal)	Ant + Retro
FIM-2	SCVC	Oct. 21	FK	70424407	56	M	mid-RCA (distal bifur.)	Ant + Ant
FIM-3	SCVC	Oct. 22	YS	70459383	68	M	prox-LAD (prox)	Ant + Ant
FIM-4	SCVC	Oct. 22	KB	70453348	69	M	prox-RCA (prox)	Ant + Retro
FIM-5	NHC	Oct. 27	HS	00332239	64	M	mid-RCA (mid)	Ant + Retro
FIM-6	THC	Oct. 28	KY	691291	51	M	distal-RCA (distal)	Ant + Retro
FIM-7	SCVC	Dec. 2	TH	70471802	89	M	mid-RCA (mid)	Ant + Retro

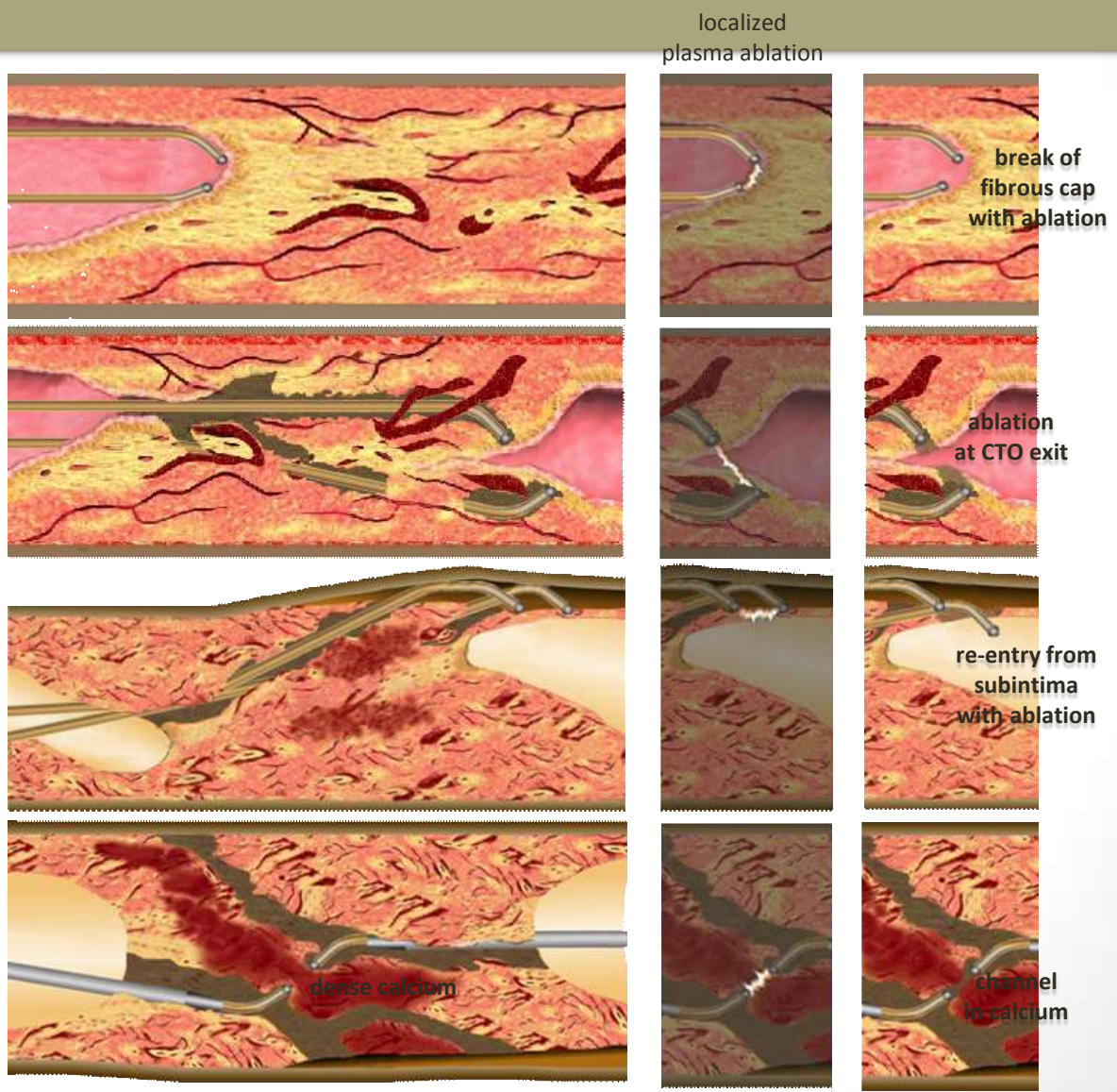
Potential Indications of PlasmaWire System

Ablation of proximal fibrous cap

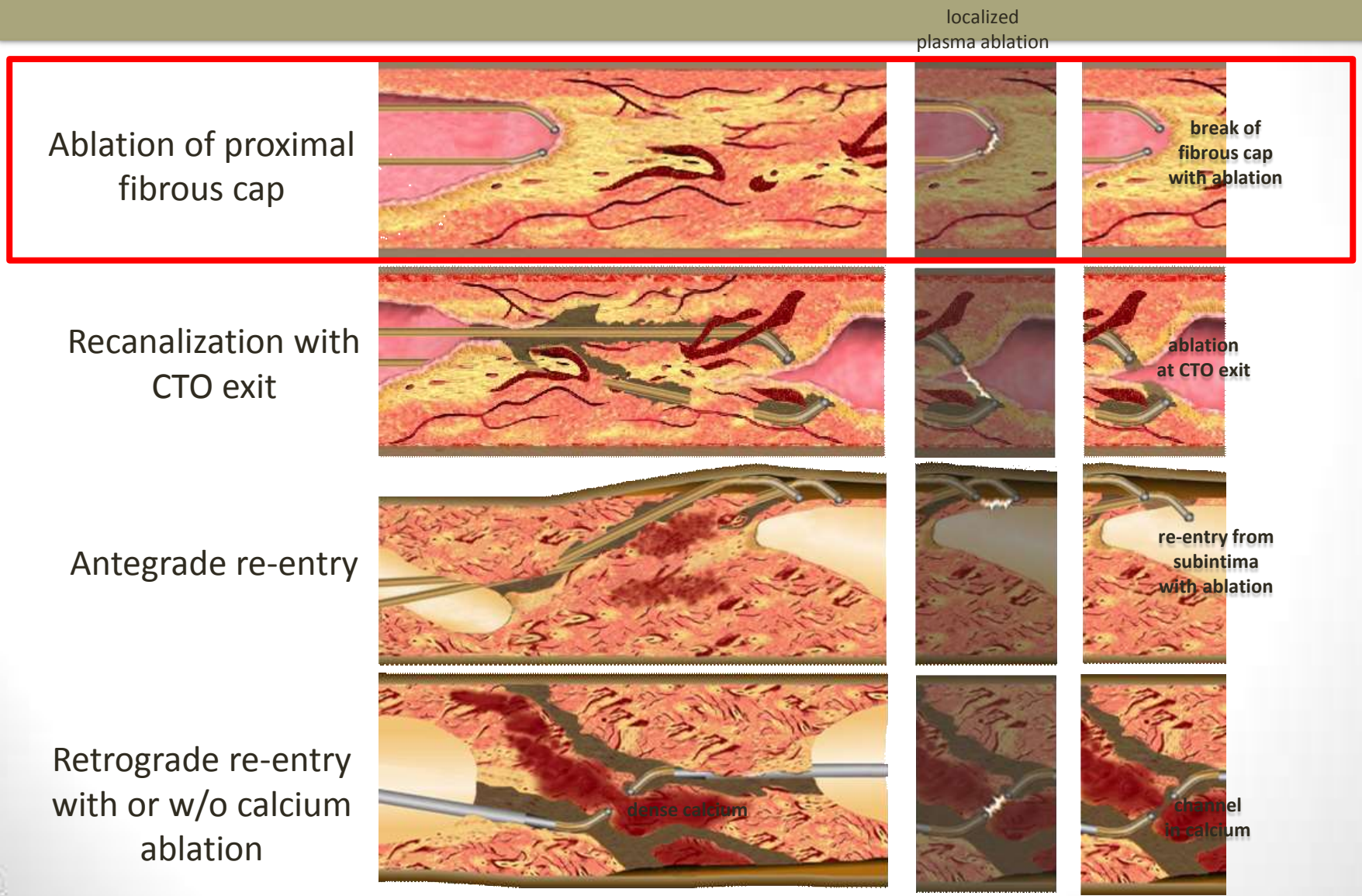
Recanalization with CTO exit

Antegrade re-entry

Retrograde re-entry with or w/o calcium ablation

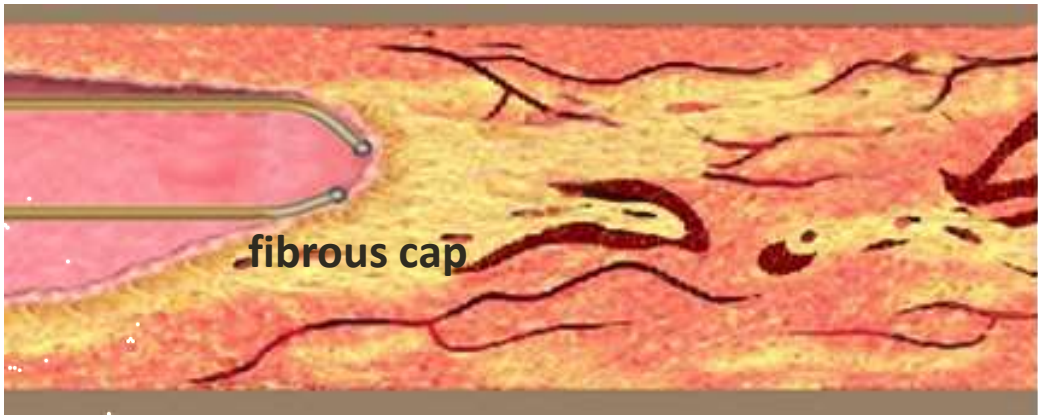


Potential Indications of PlasmaWire System

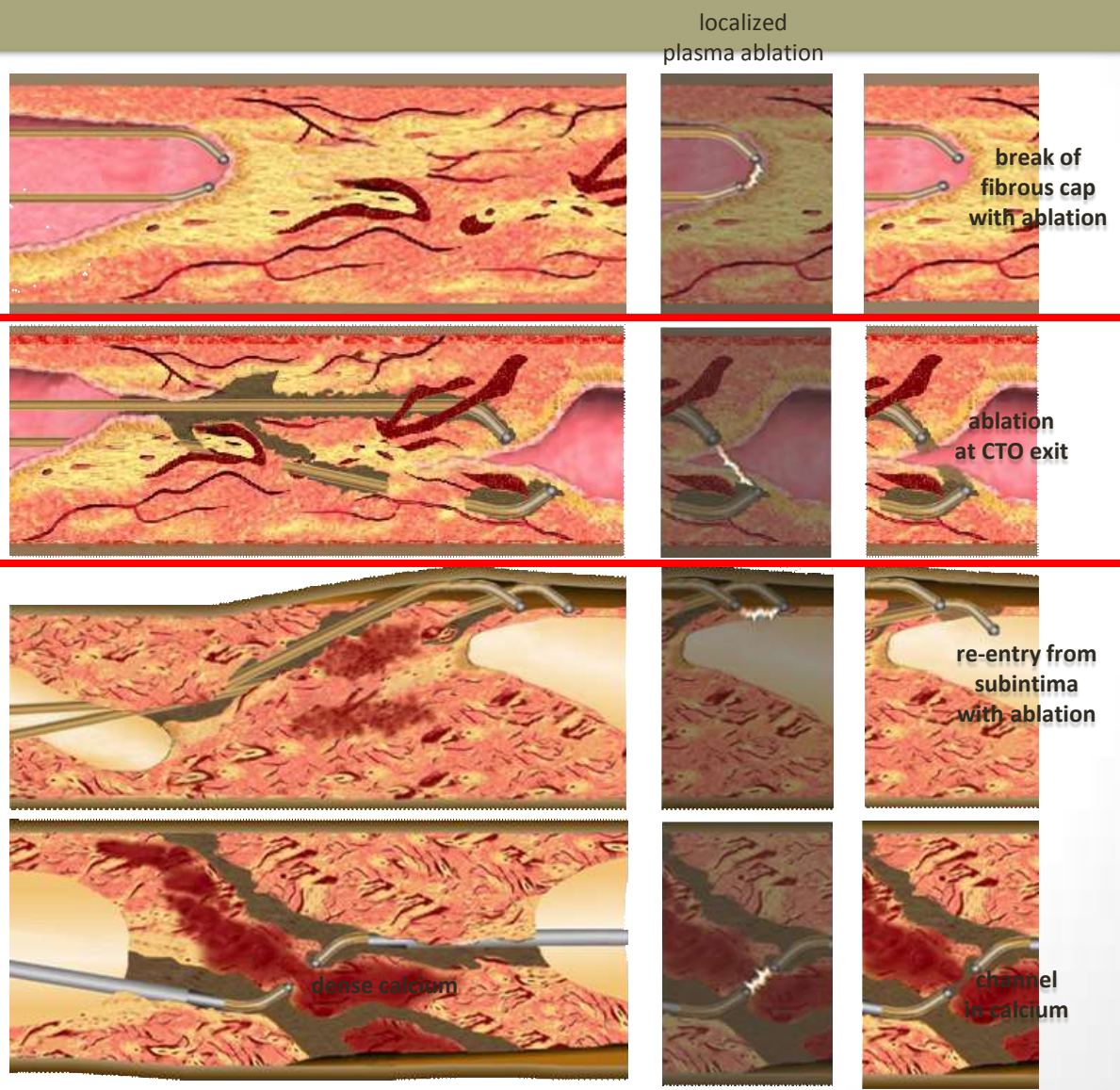


Potential Indications of PlasmaWire System

Ablation of proximal fibrous cap



Potential Indications of PlasmaWire System



Ablation of proximal fibrous cap

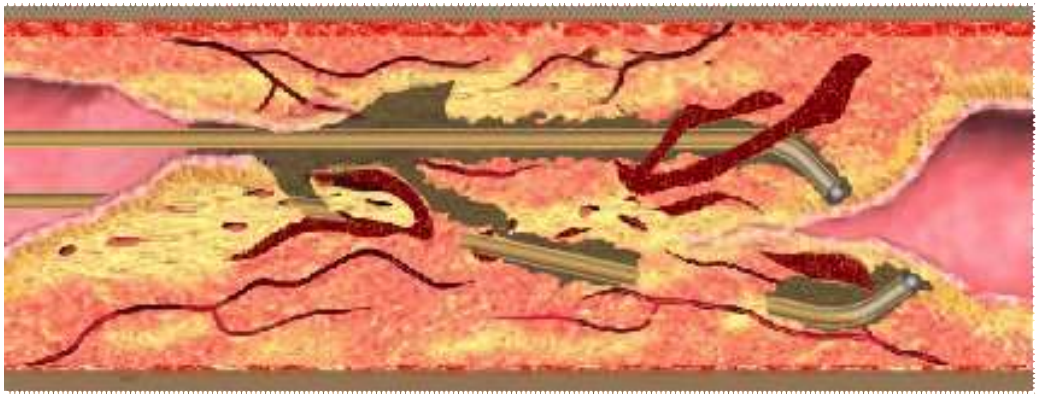
Recanalization with CTO exit

Antegrade re-entry

Retrograde re-entry with or w/o calcium ablation

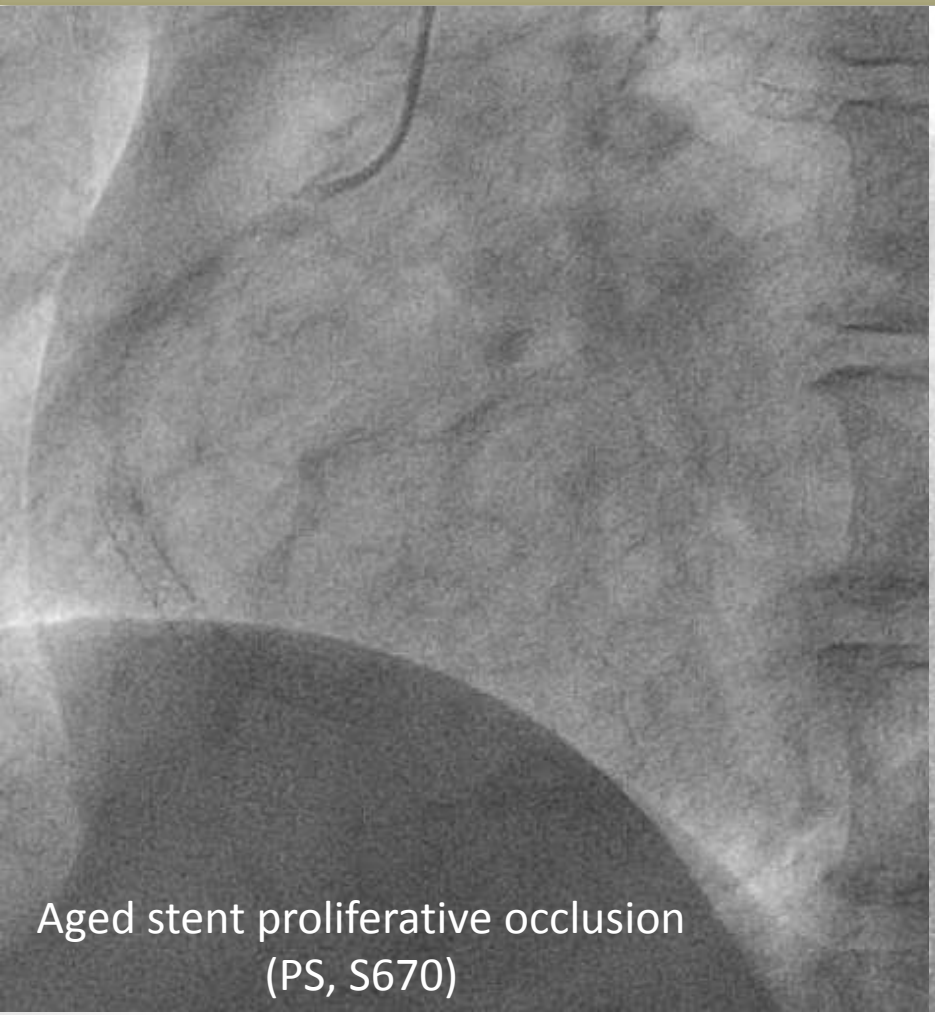
Potential Indications of PlasmaWire System

Recanalization with CTO exit

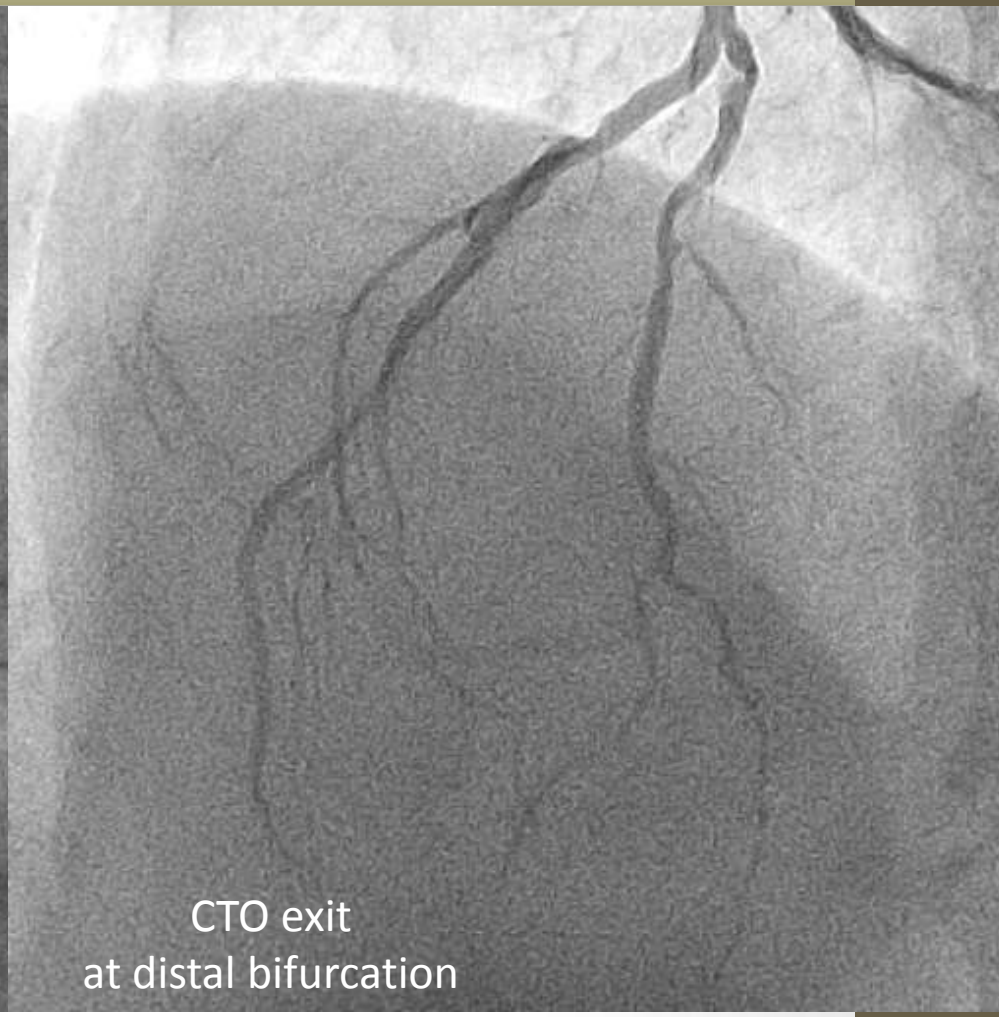


FIM-2

FIM-2



Aged stent proliferative occlusion
(PS, S670)



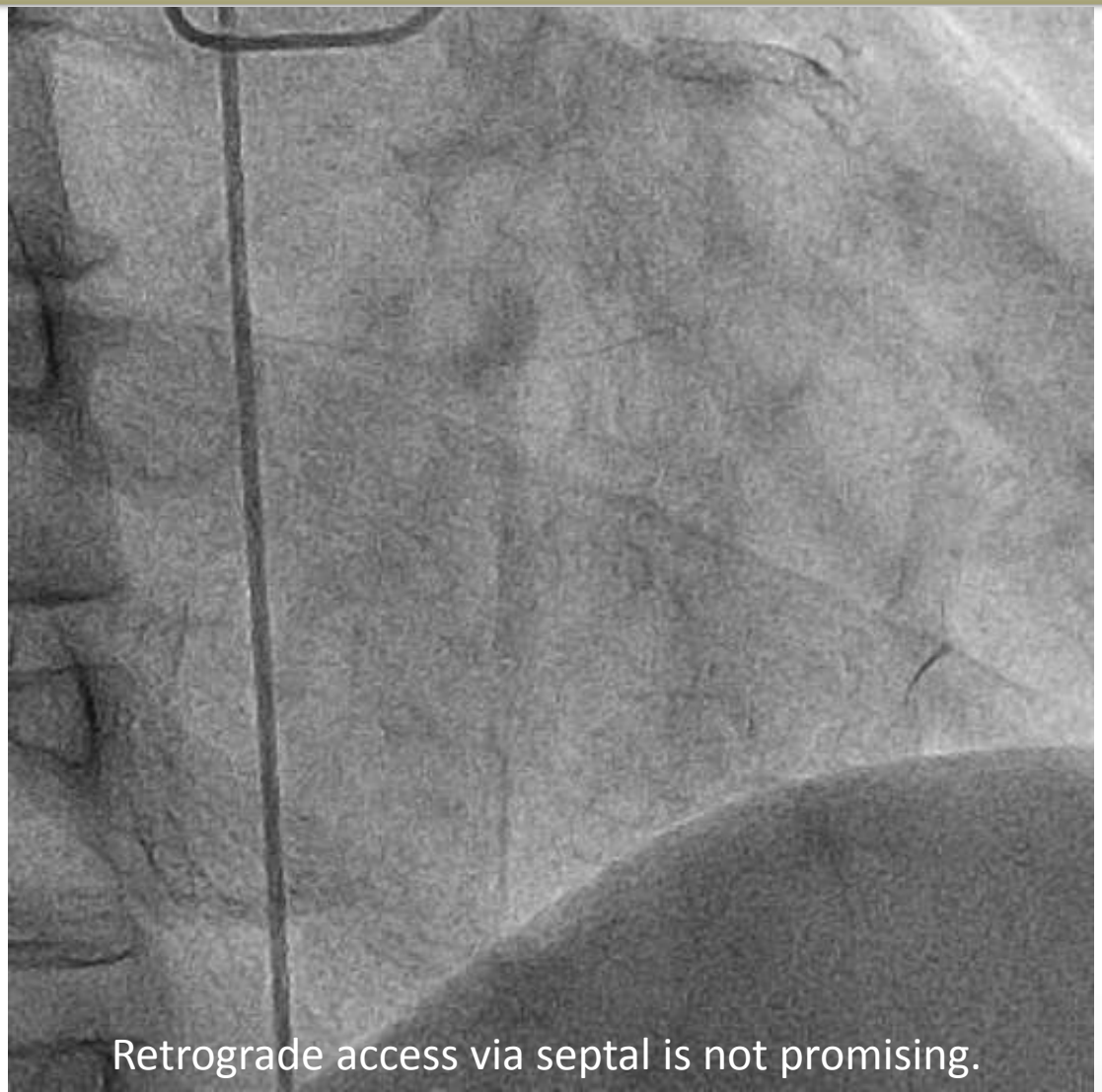
CTO exit
at distal bifurcation

FIM-2

CTO exit is close to stent distal end (< 1 cm)

FIM of PlasmaWire

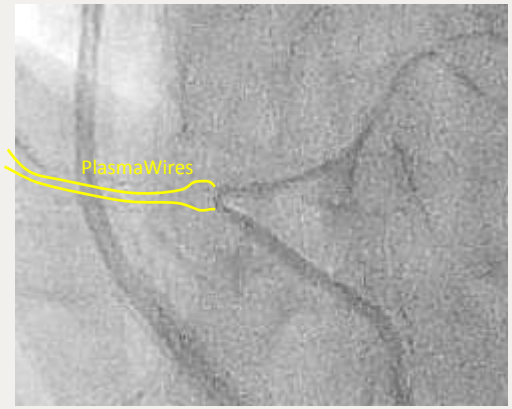
FIM-2



Retrograde access via septal is not promising.

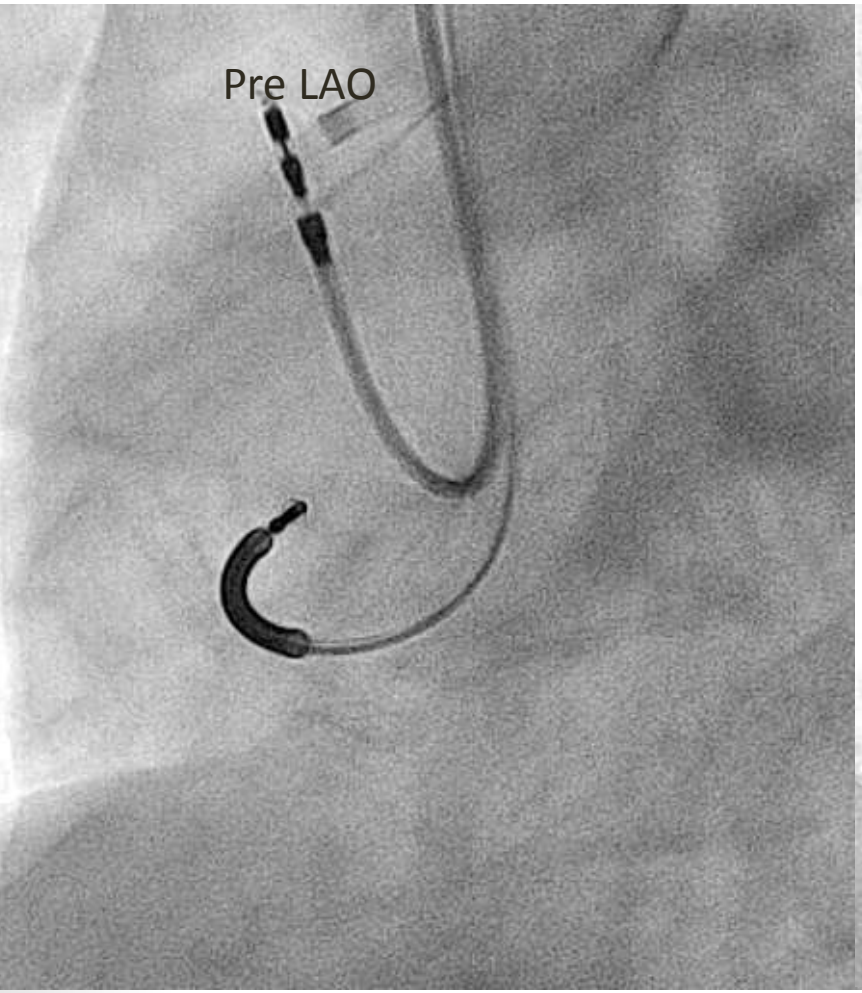
FIM-2 (planning)

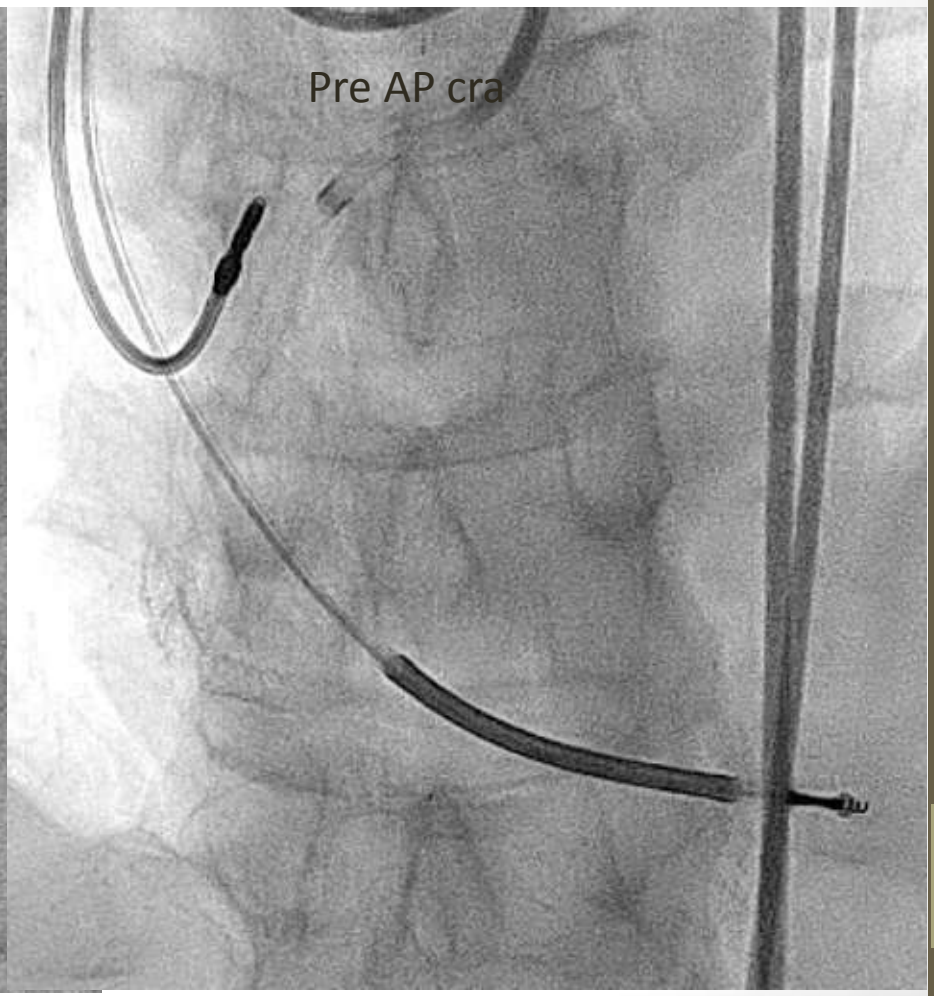
	target vessel	contralateral
Guiding (planned)	Hyperion AL 1 with side hole 8Fr	Hyperion SPB 3.75 no side hole 6 Fr
Access route	Rt femoral	Lt femoral
Planned fashion of Plasma wire use	Antegrade + Antegrade	
Retrograde route	not planned	
CTO wires for preparation	Gaia	not planned



1. After stent crossing, access to CTO exit should be careful to avoid subintimal tracking with Gaia followed by Corsair Pro (beyond stents).
2. Two catheters (Corsair pro + Caravel) are used for exchanging with PlasmaWires.
3. PlasmaWires must be carefully located face-to-face at CTO exit as shown in the left figure.

FIM-2 (results)





FIM of PlasmaWire

FIM-2 (results)

ablation point (AP cra)

ablation point (LAO)

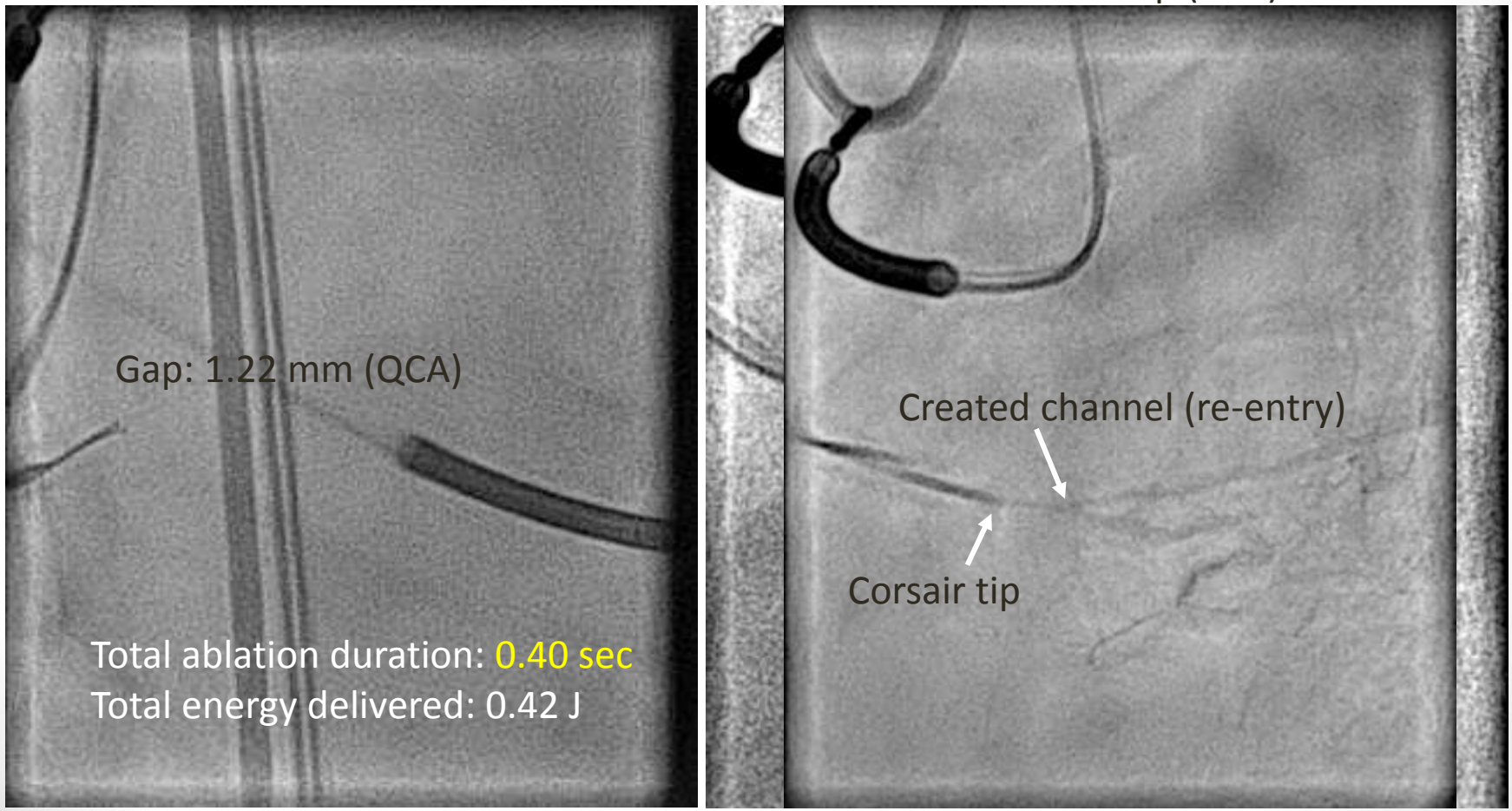
FIM of PlasmaWire

FIM-2 (results)

A First Patient with Electrical Re-entry

During ablation (AP cra)

Contralateral injection+aspiration from Corsair tip (LAO)



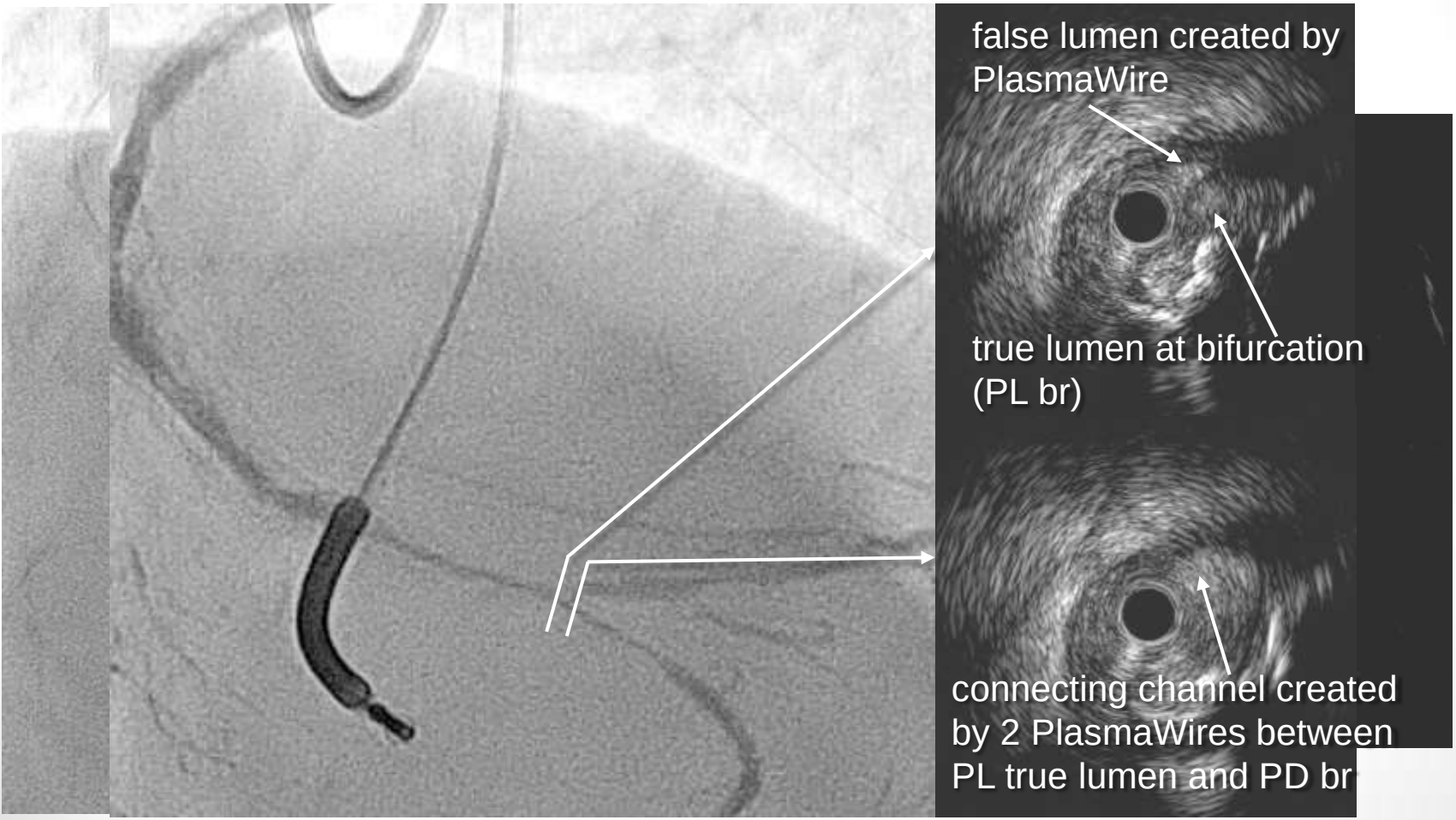
FIM of PlasmaWire

FIM-2 (results)

A First Patient with Electrical Re-entry

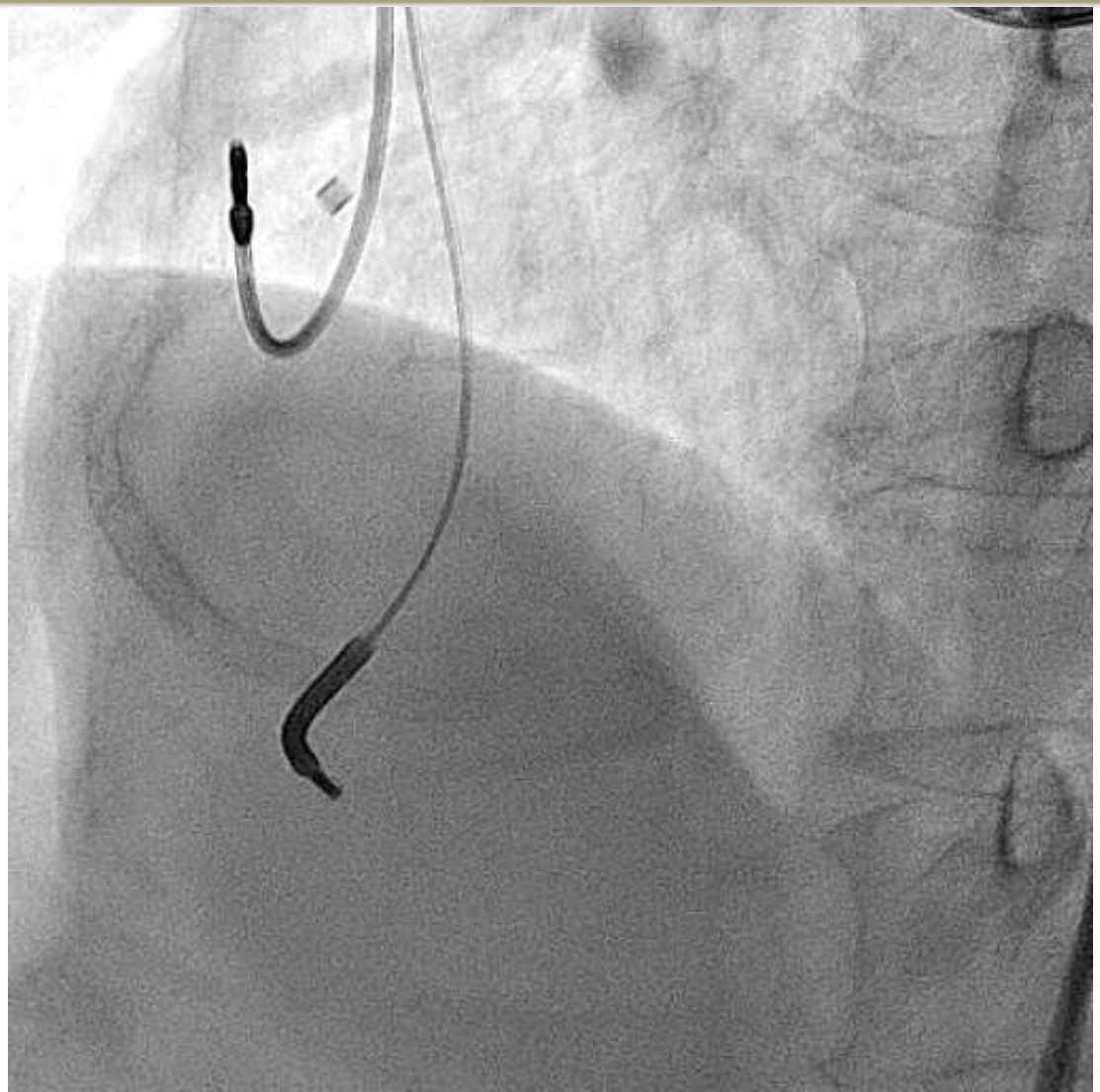
Angiogram just after IVUS (LAO)

IVUS (pull-back image from PD br)



FIM of PlasmaWire

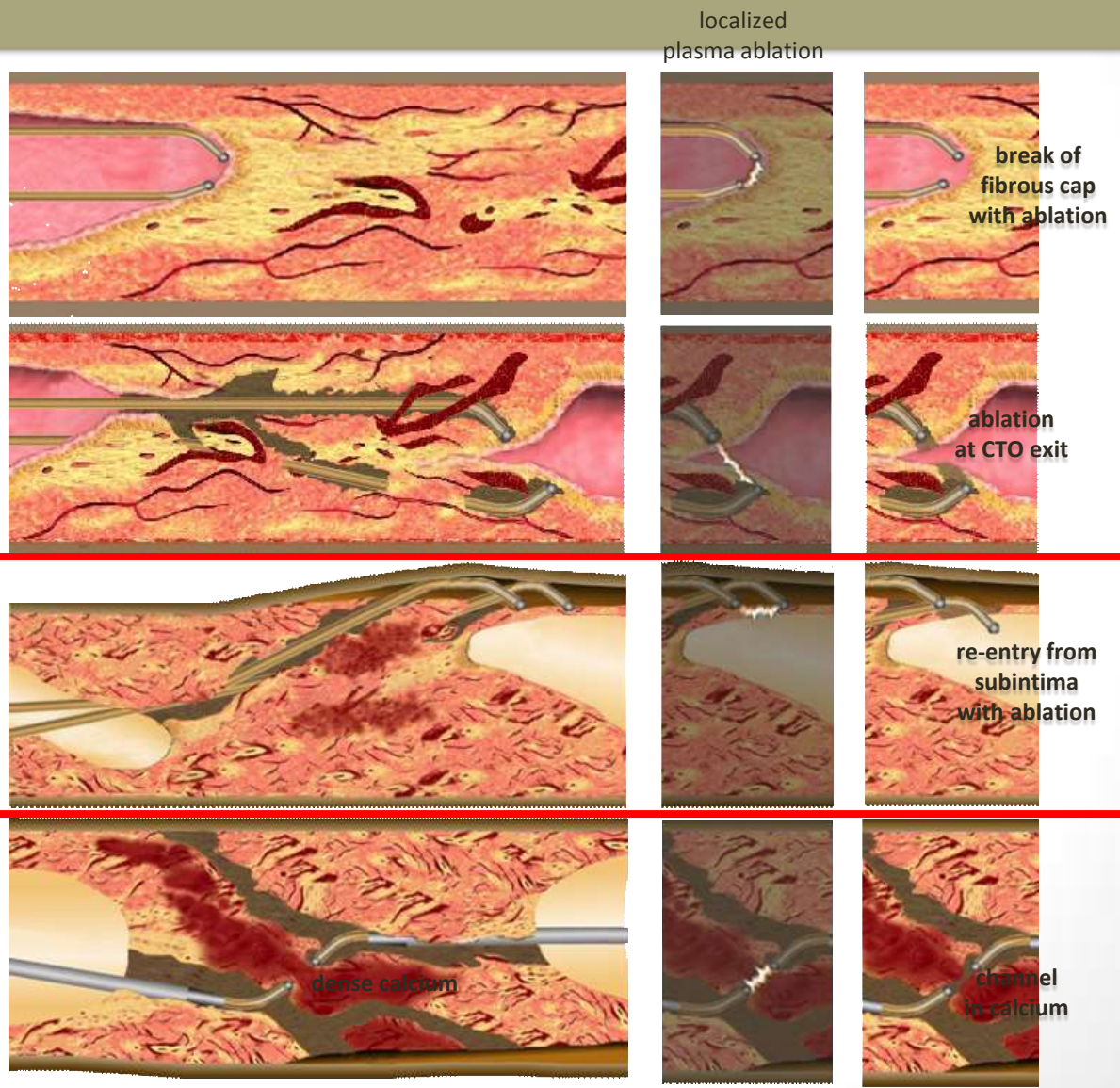
FIM-2 (results)



Summary of FIM-2

- The first case in which electric re-entry was achieved.
- Electrical channeling was successfully performed in antegrade-antegrade fashion at RCA distal bifurcation without PVCs, thrombosis, and vessel injury.
- IVUS clarified how the plasma ablation created the connecting channel (re-entry) at bifurcation. When activated, the walls sandwiched between both PlasmaWires were ablated, and then a channel between the false lumen in PD branch and the true lumen was created as a result.

Potential Indications of PlasmaWire System



Ablation of proximal fibrous cap

Recanalization with CTO exit

Antegrade re-entry

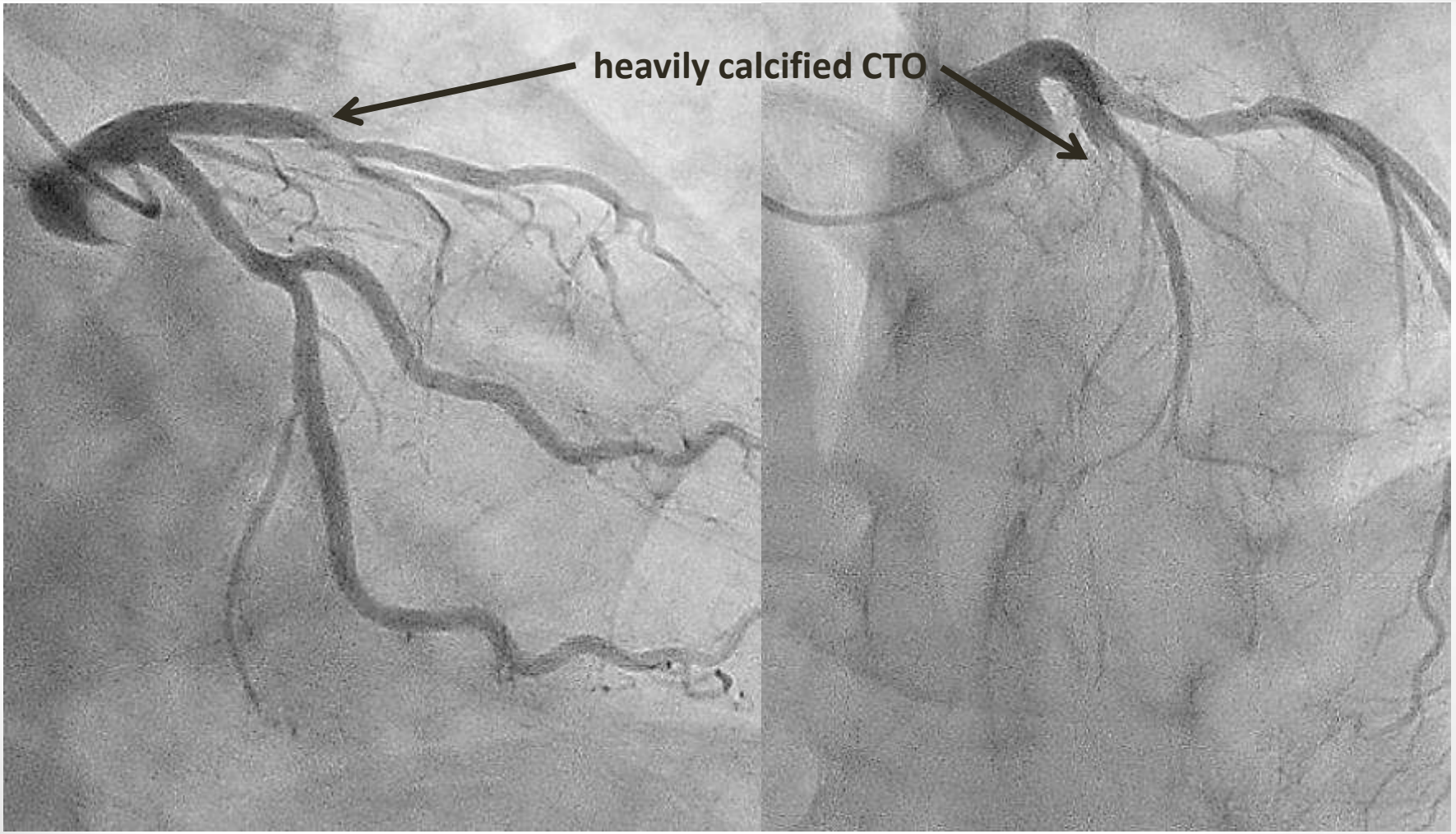
Retrograde re-entry with or w/o calcium ablation

Potential Indications of PlasmaWire System

Antegrade re-entry

FIM-3

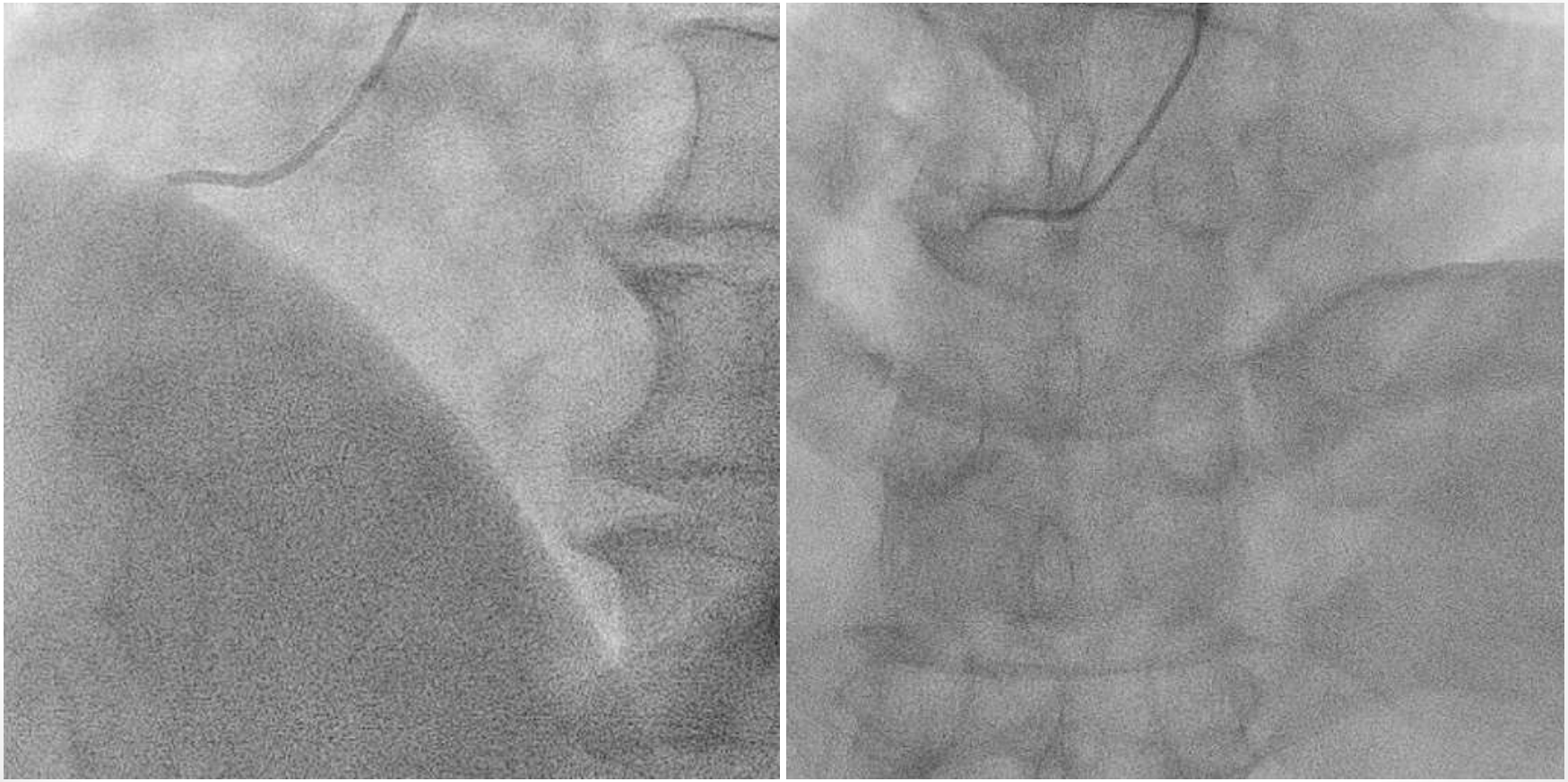
FIM-3



FIM of PlasmaWire

FIM-3

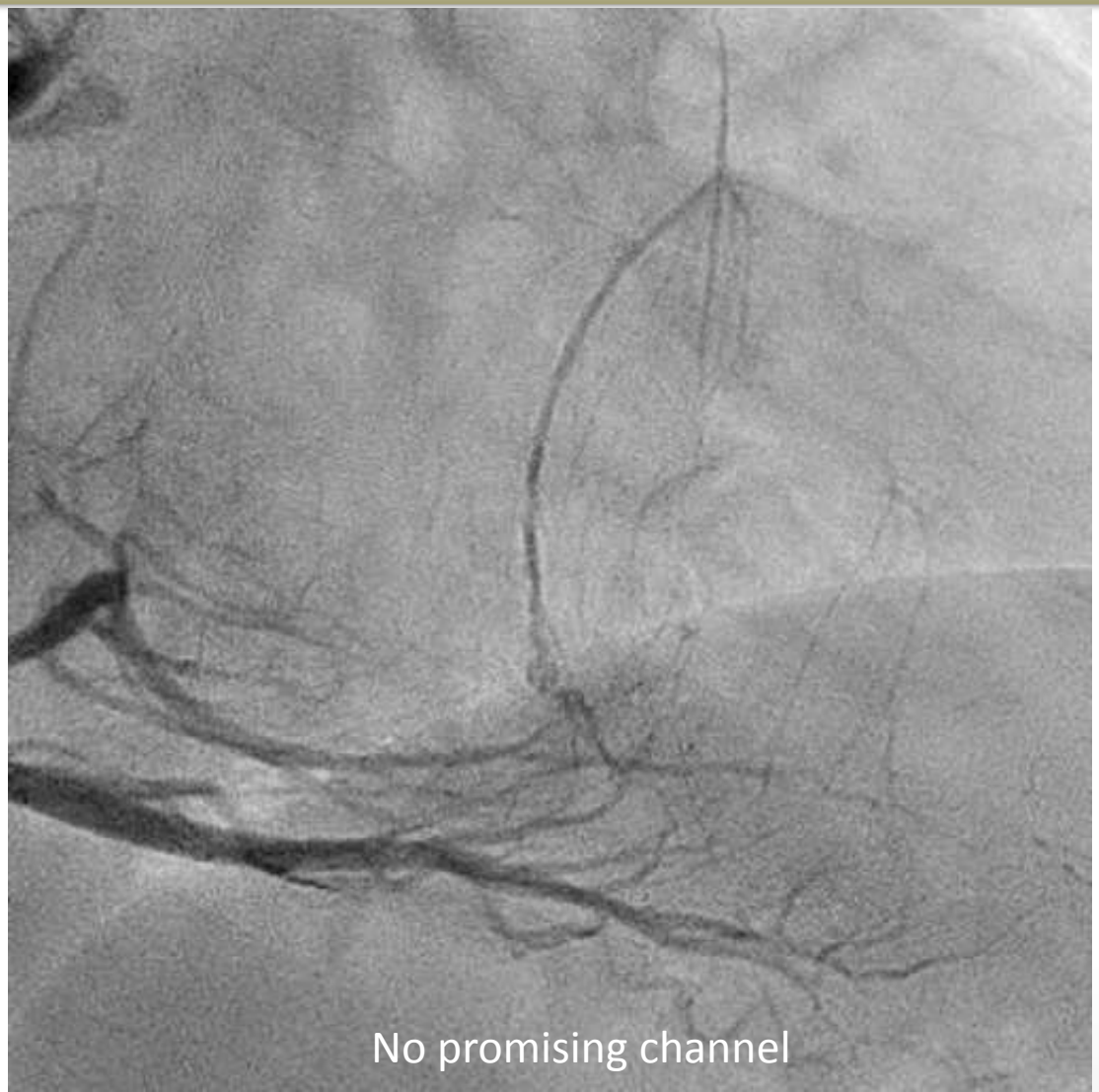
CTO exit is not visualized.



Selective injection in conus br is needed to visualize the CTO exit.

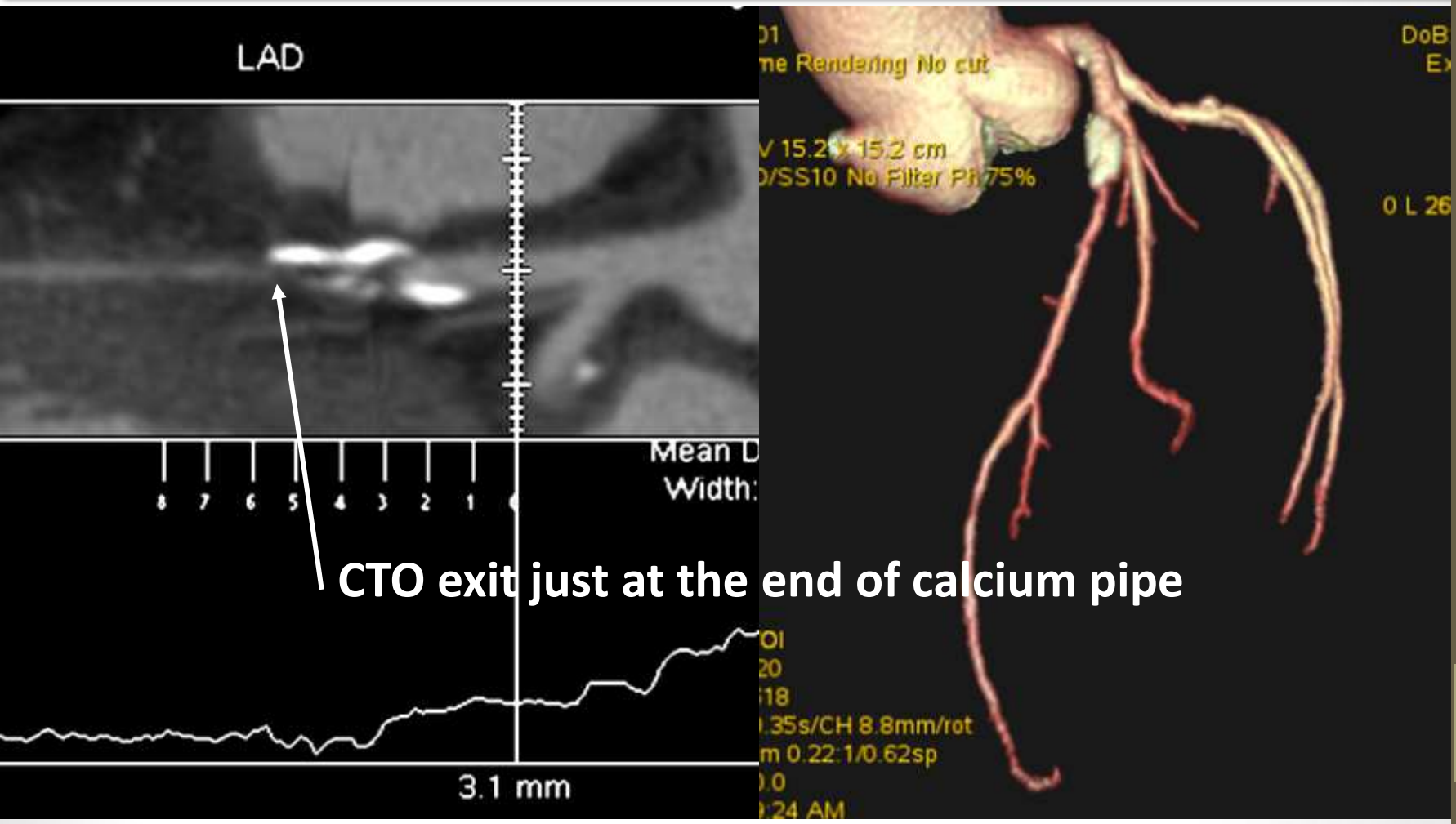
FIM of PlasmaWire

FIM-3



No promising channel

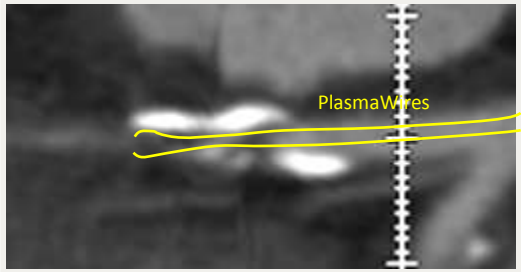
FIM-3



FIM of PlasmaWire

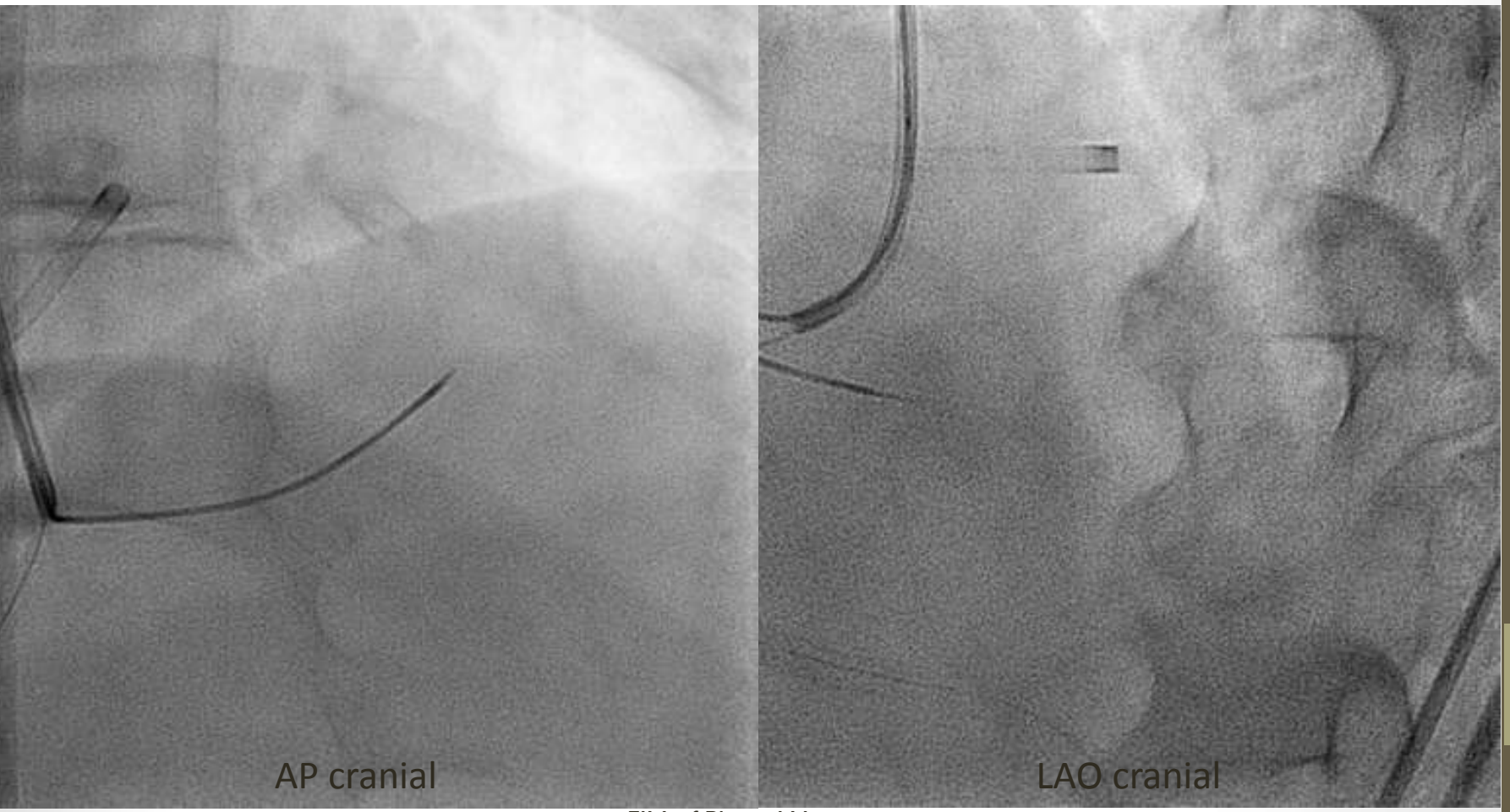
FIM-3 (planning)

	target vessel	contralateral
Guiding (planned)	Hyperion SPB 3.75 with side hole 8Fr	Hyperion JR no side hole 6 Fr
Access route	Rt femoral	Lt femoral
Planned fashion of Plasma wire use	Antegrade + Antegrade	
Retrograde route	not planned (distal PD septal br for backup)	
CTO wires for preparation	Step-up from Gaia	not planned
Procedure for preparation	1. Calcium pipe is negotiated by Gaia. 2. PlasmaWires exchange are done inside calcium pipe. 3. Super-selective injection in conus branch is mandatory. 4. The ablation site is CTO exit at the end of calcium.	



FIM-3 (results)

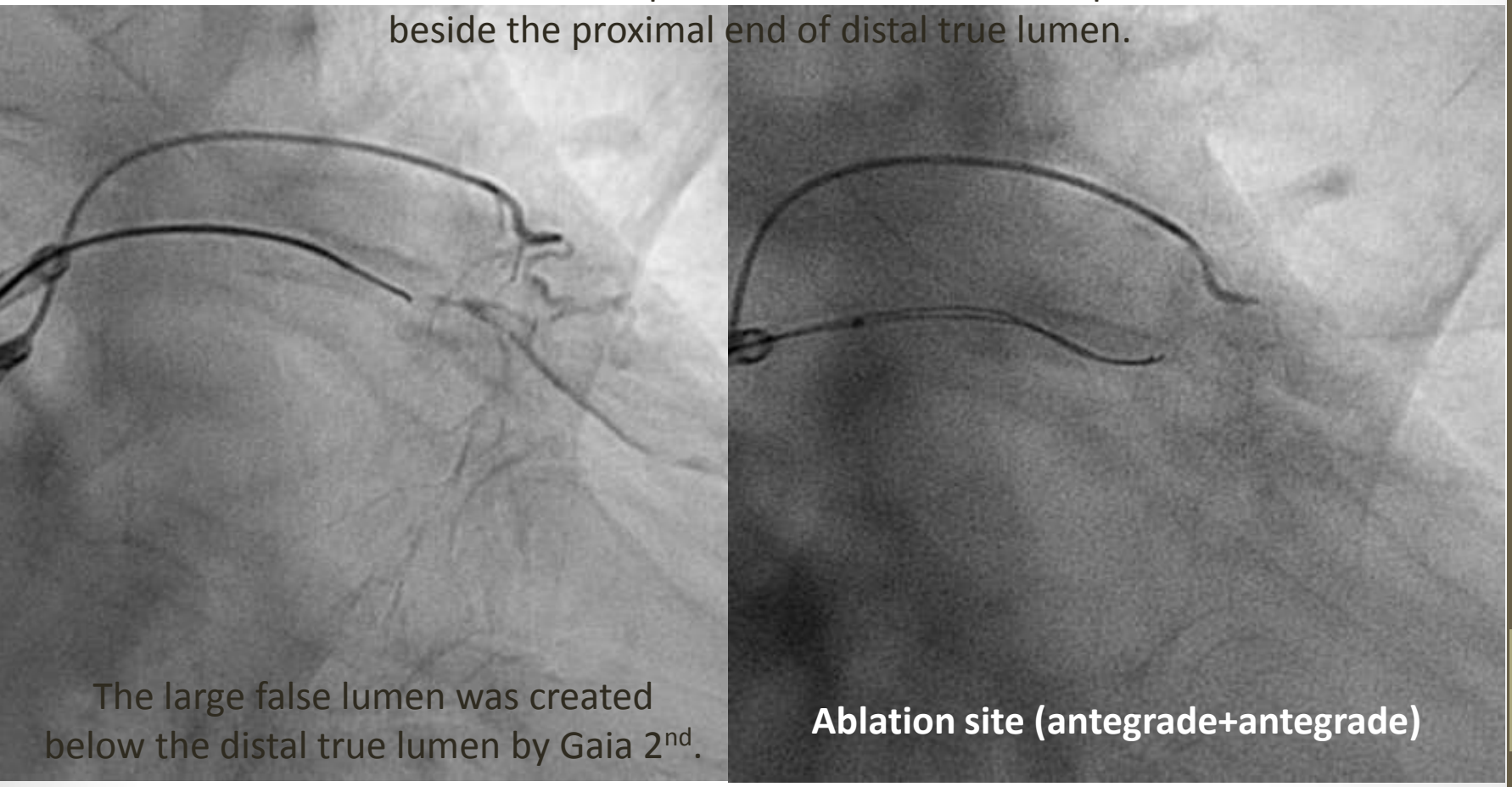
Pre-PCI (simultaneous injection using super-selective injection through the conus br)



FIM of PlasmaWire

FIM-3 (results)

After the false channel was created, plasma ablation was attempted in the false lumen beside the proximal end of distal true lumen.

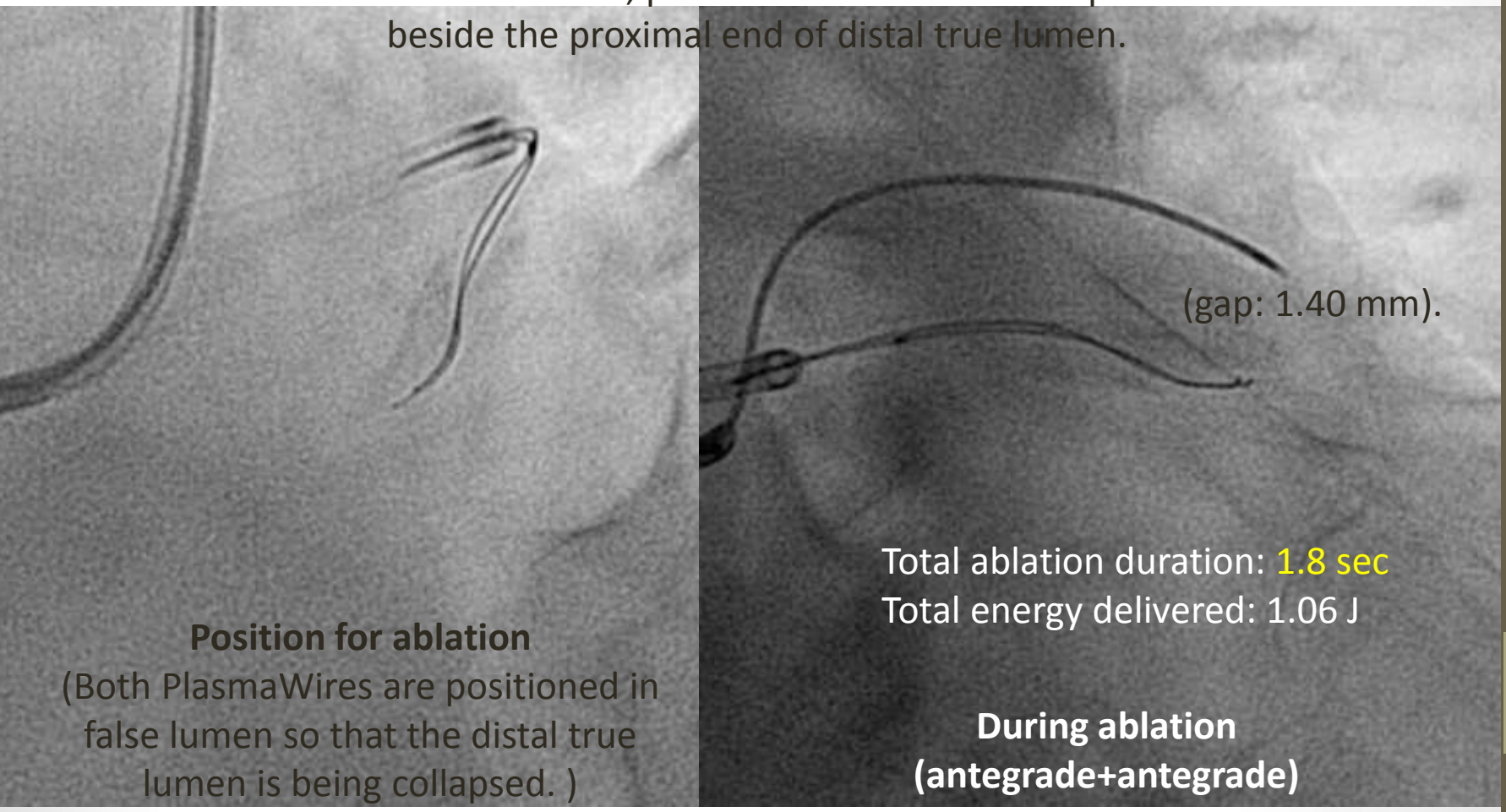


The large false lumen was created below the distal true lumen by Gaia 2nd.

Ablation site (antegrade+antegrade)

FIM-3 (results)

After the false channel was created, plasma ablation was attempted in the false lumen beside the proximal end of distal true lumen.

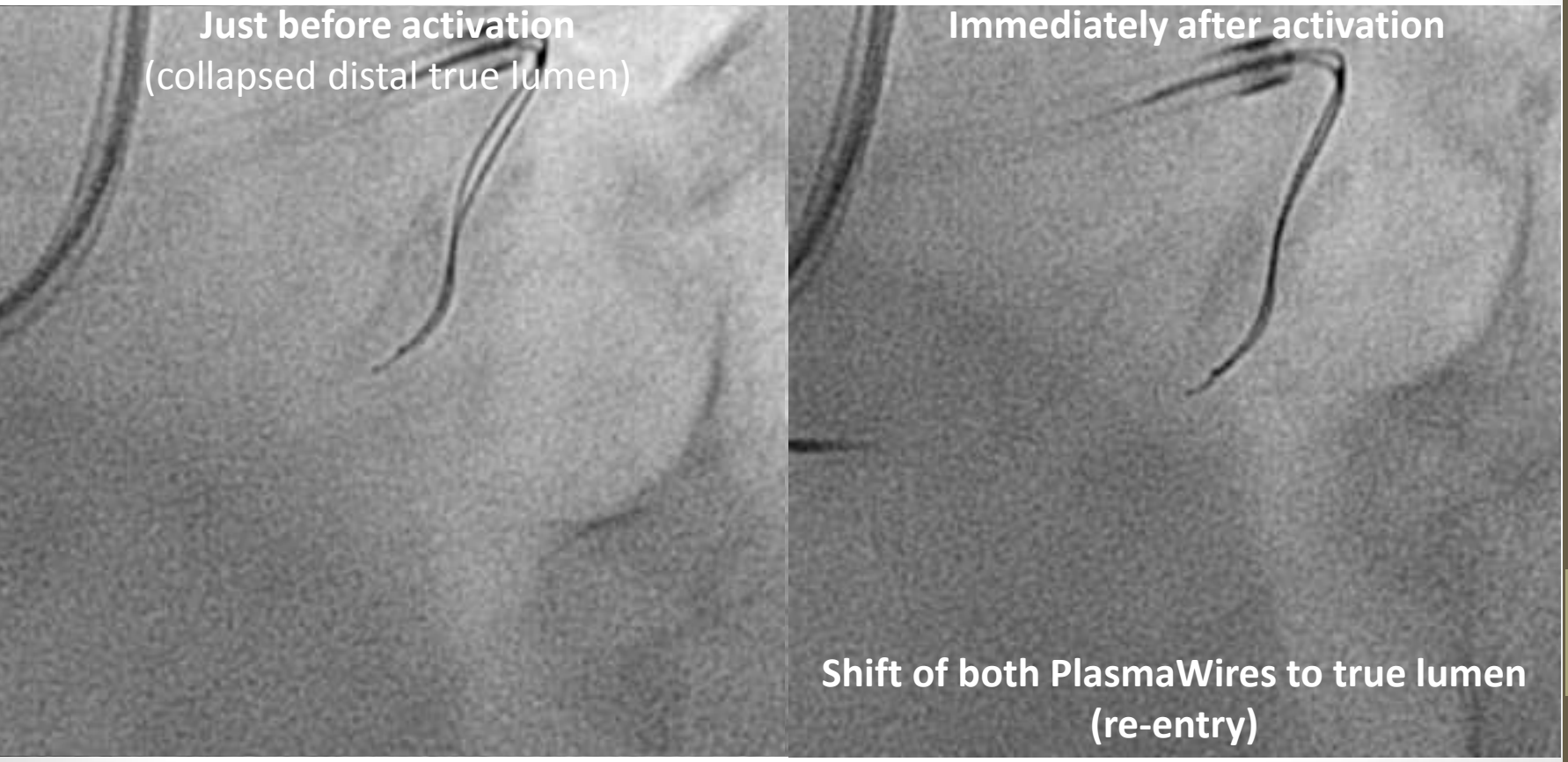


FIM of PlasmaWire

FIM-3 (results)

A Second Patient with Electrical Re-entry

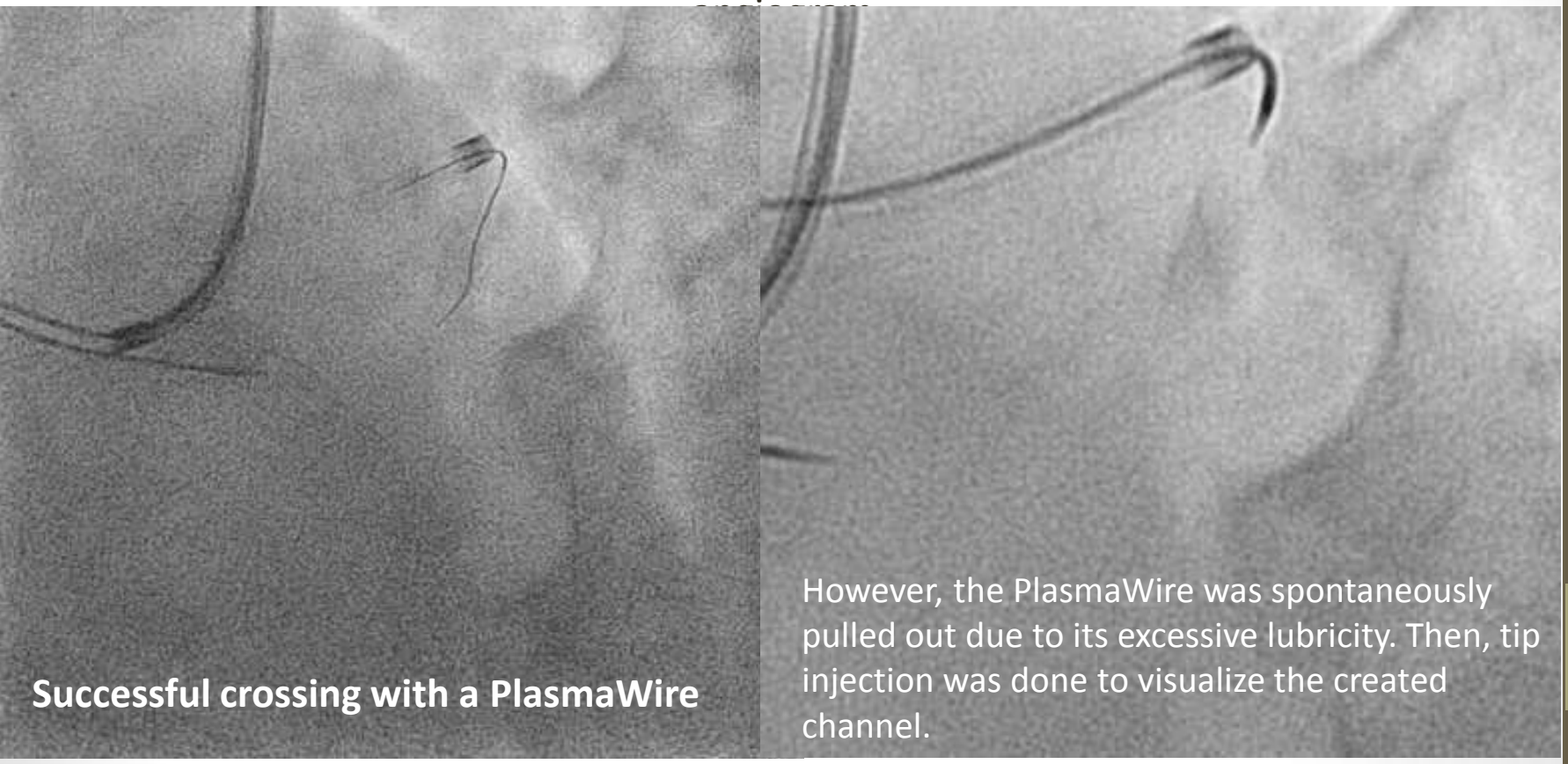
Collateral injection immediately after activation showed the restored true lumen and shift of PlasmaWires from the false lumen to the true lumen.



FIM of PlasmaWire

FIM-3 (results)

After activation, PlasmaWire was directly advanced to the distal true lumen because the tip of wire was confirmed to be automatically shifted to the true lumen by



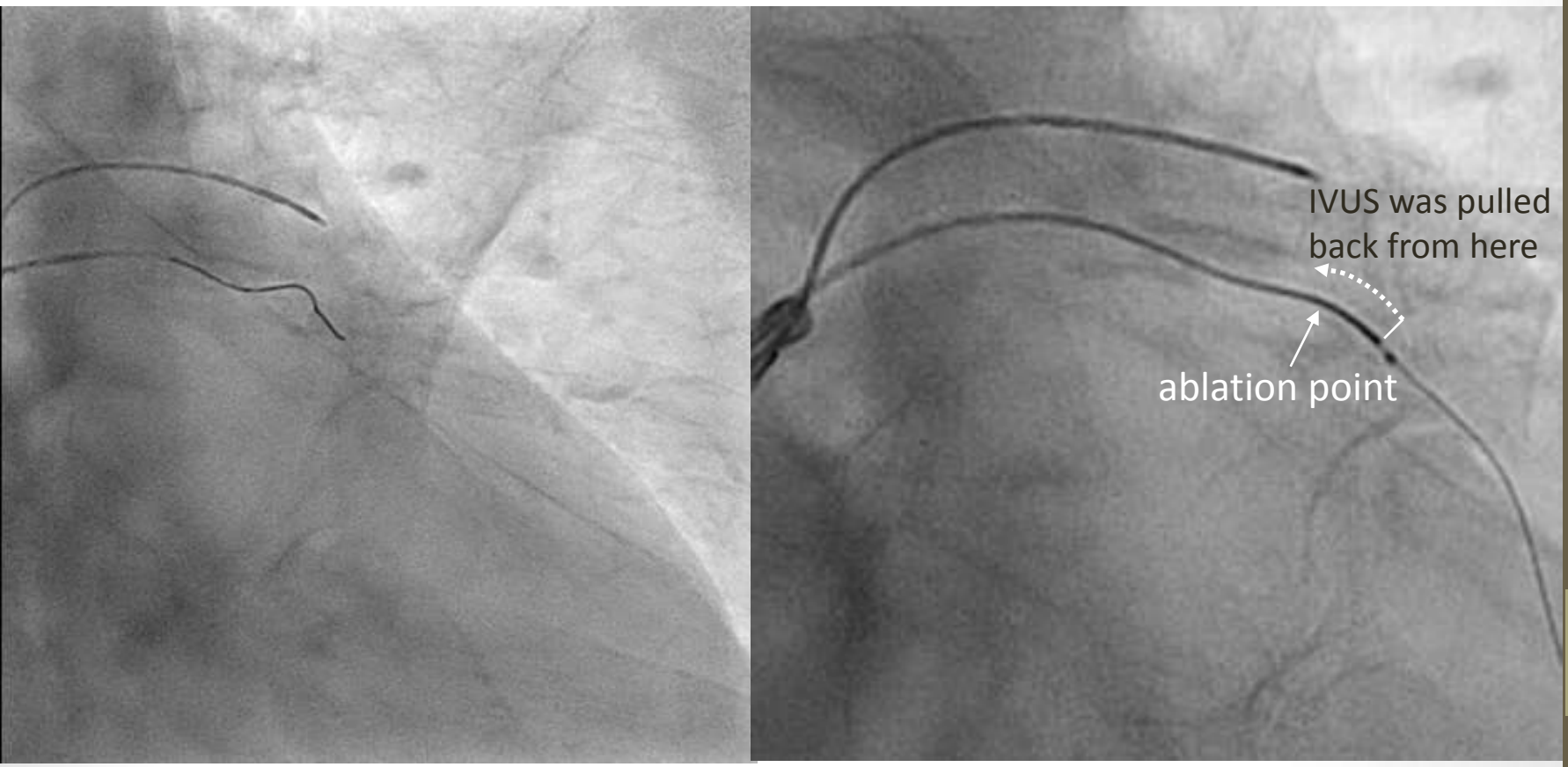
Successful crossing with a PlasmaWire

However, the PlasmaWire was spontaneously pulled out due to its excessive lubricity. Then, tip injection was done to visualize the created channel.

FIM of PlasmaWire

FIM-3 (results)

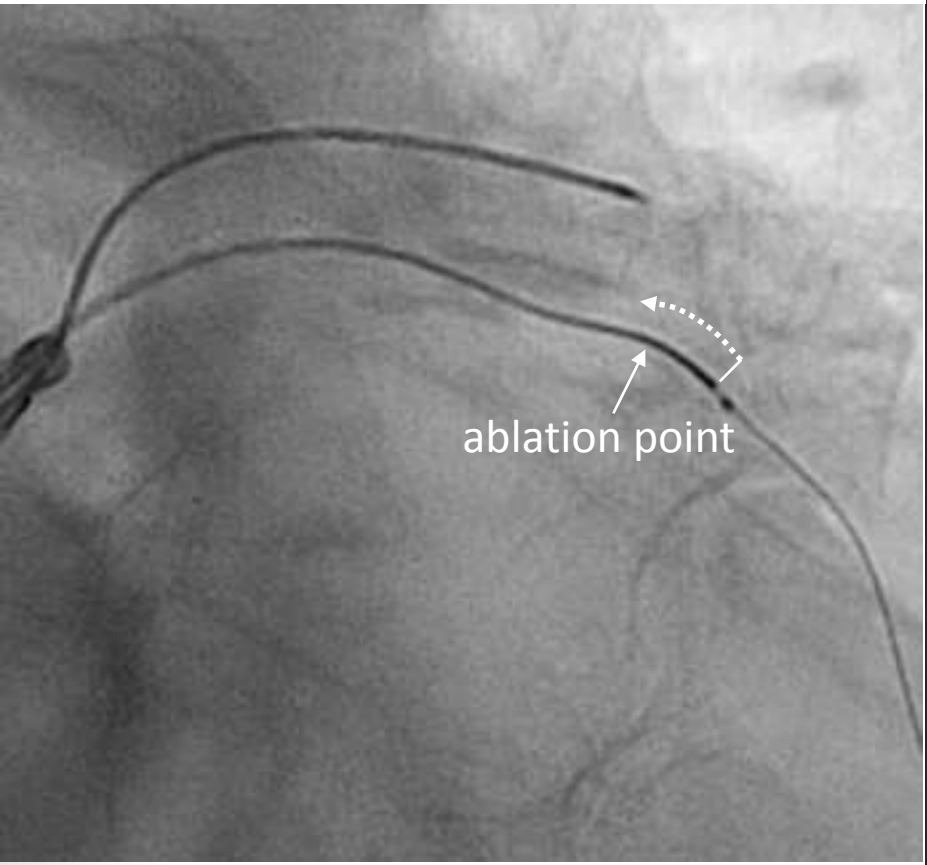
After connecting channel was visualized by tip injection, the channel was recrossed with a very floppy wire (SUOH03). Then IVUS was done to check the channel.

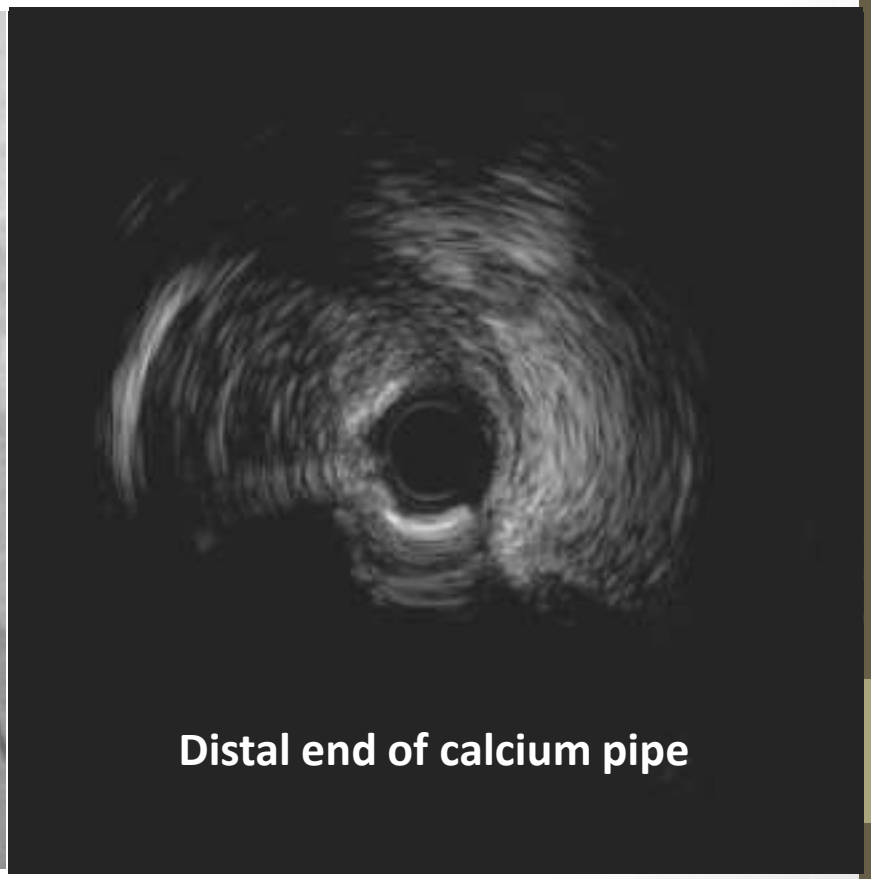


FIM of PlasmaWire

FIM-3 (results)

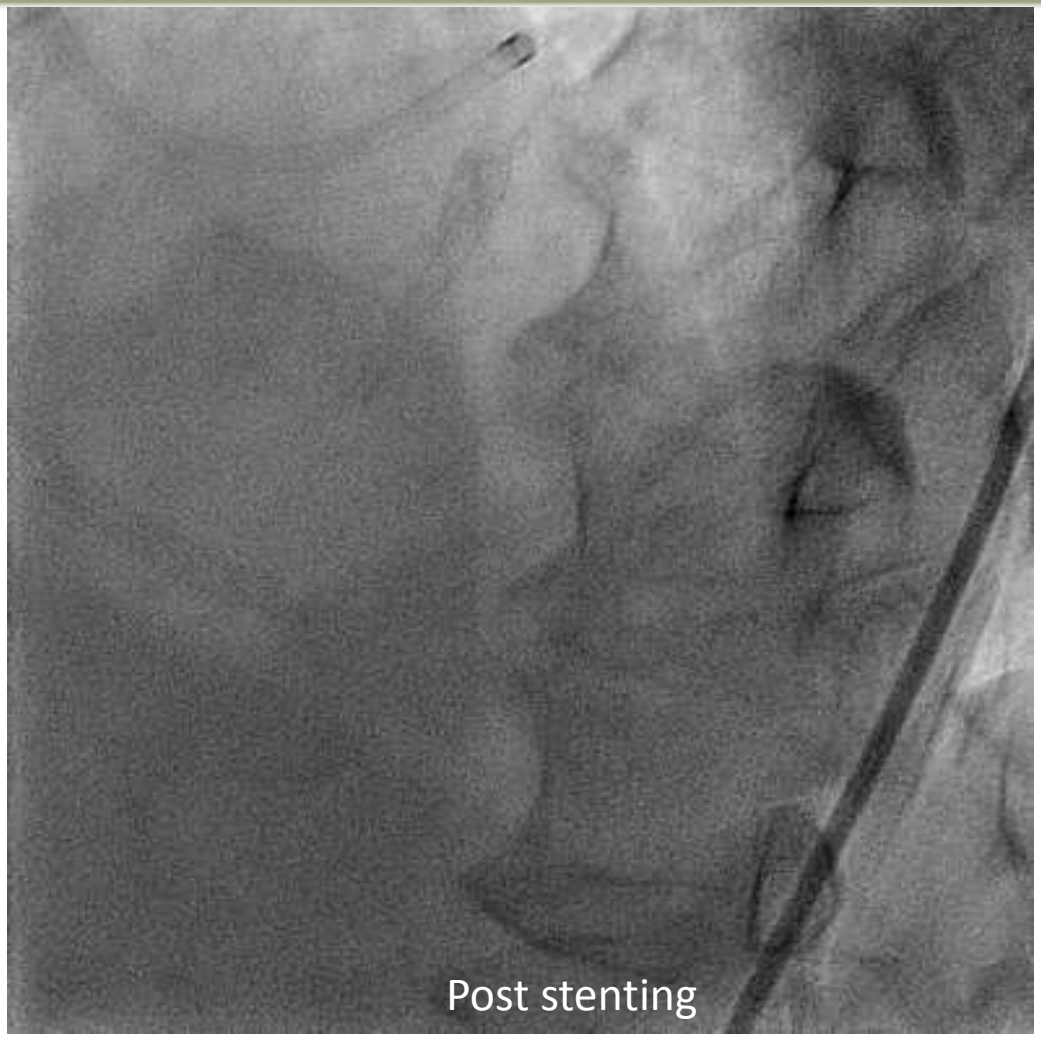
IVUS findings of connecting channel created by plasma ablation





FIM of PlasmaWire

FIM-3 (results)

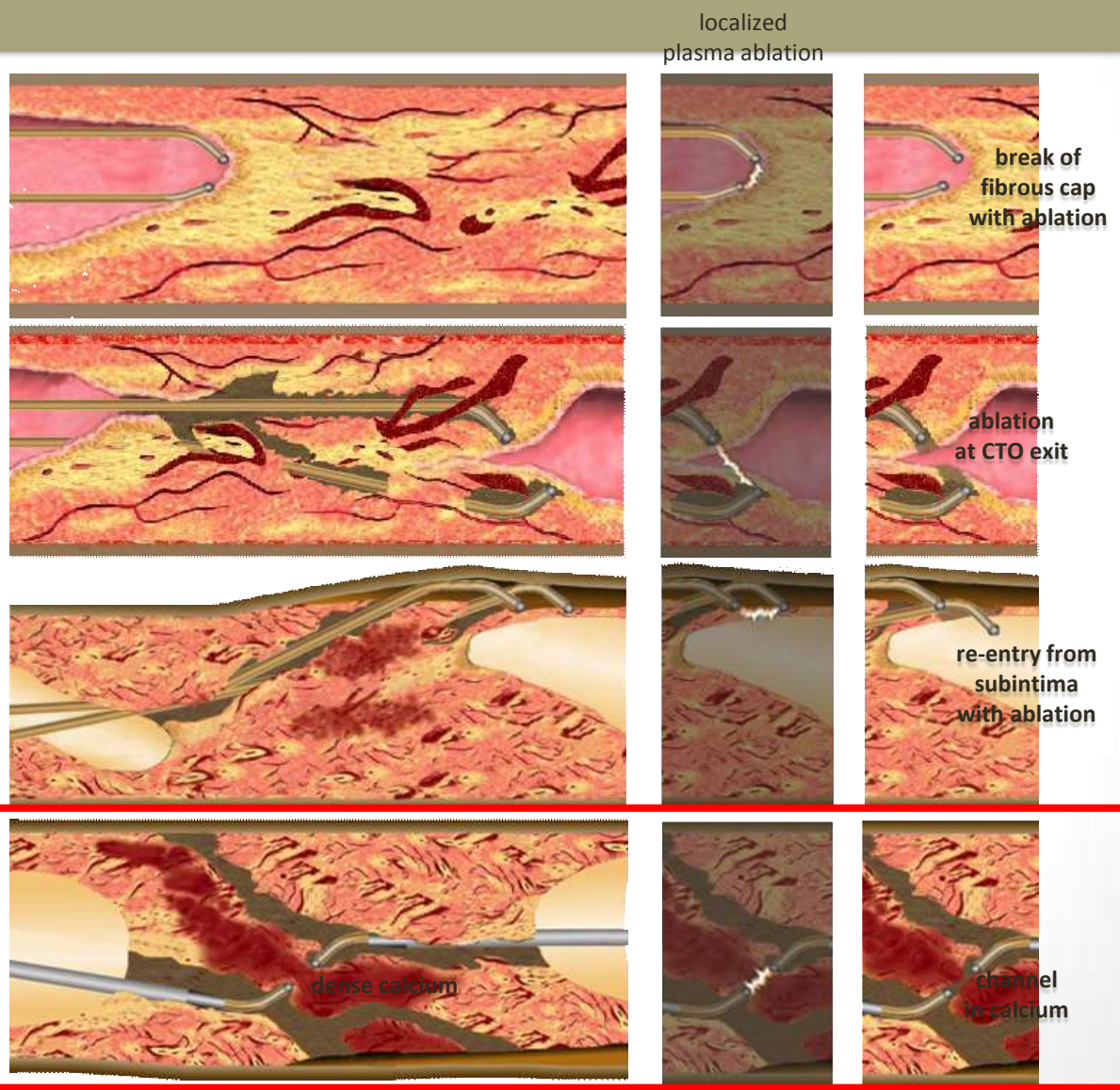


FIM of PlasmaWire

Summary of FIM-3

- The second case in which electrical re-entry was achieved.
- Electrical channeling was successfully done in antegrade-antegrade fashion though both PlasmaWires were positioned parallel to each other beside the distal true lumen.
- Connecting channel (re-entry) between the false and the distal true lumen was created. Subsequently, a PlasmaWire was automatically shifted to the distal true lumen, which confirmed channel creation indirectly.
- Thrombosis and vessel injury was not seen on angiogram and IVUS.

Potential Indications of PlasmaWire System



Ablation of proximal fibrous cap

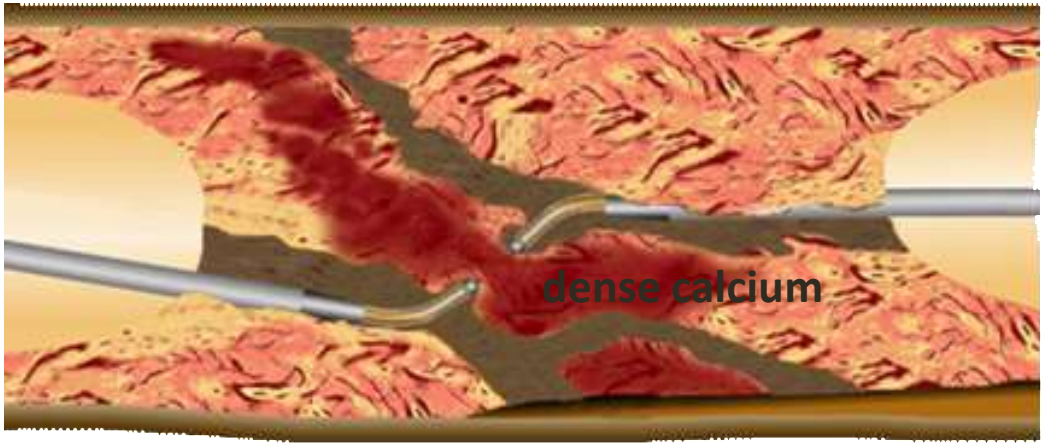
Recanalization with CTO exit

Antegrade re-entry

Retrograde re-entry with or w/o calcium ablation

Potential Indications of PlasmaWire System

Retrograde re-entry
with or w/o calcium ablation

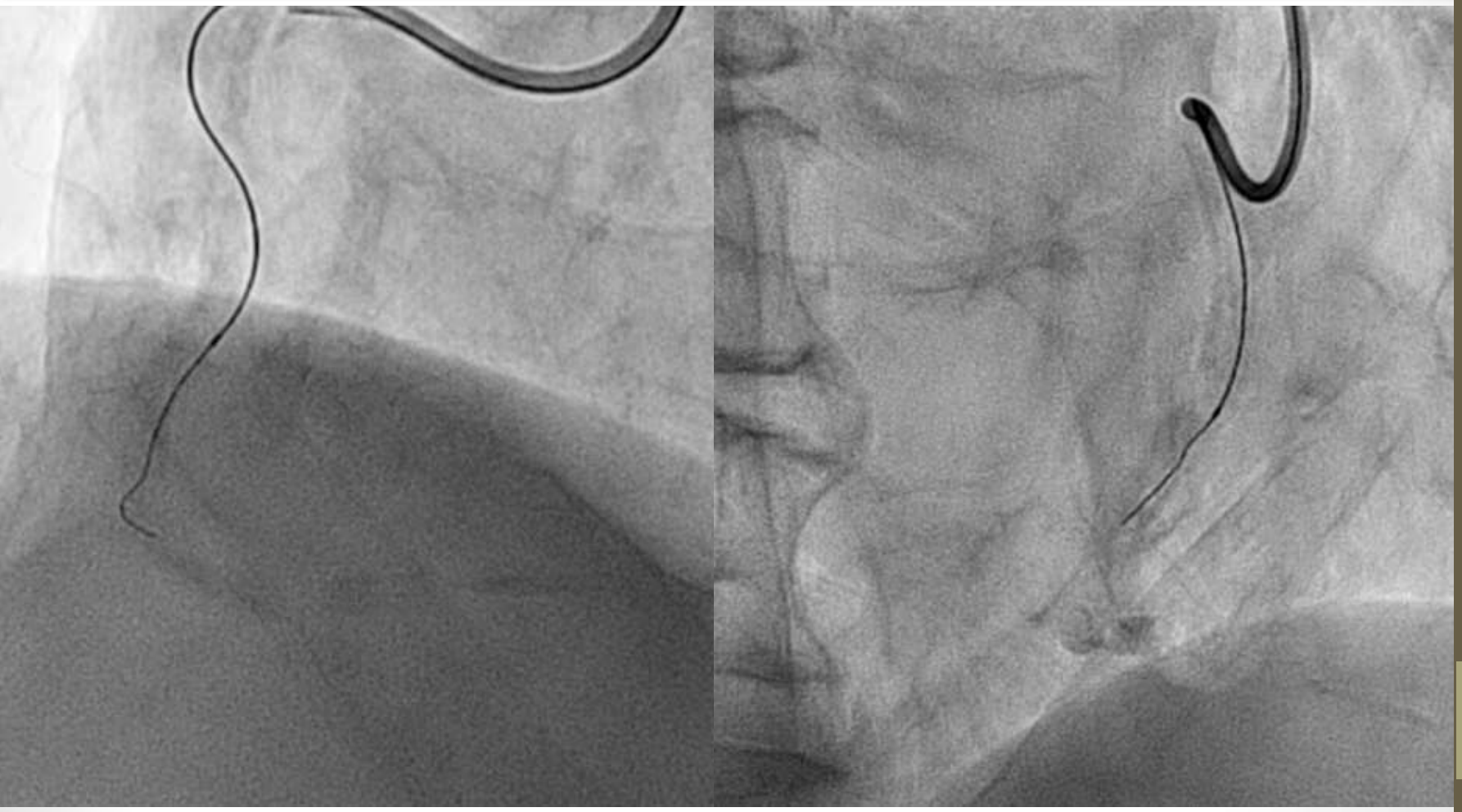


FIM-7

FIM-7 (previous attempt)

FIM of PlasmaWire

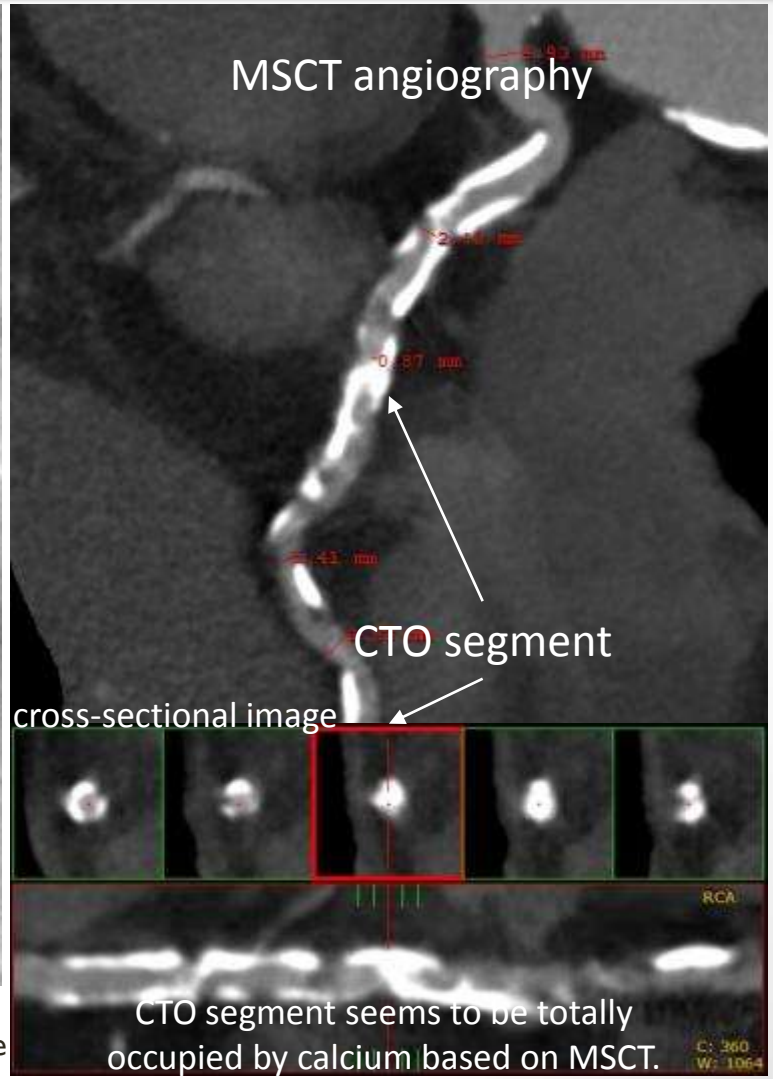
FIM-7 (previous attempt)



FIM of PlasmaWire

FIM-7 (previous attempt)

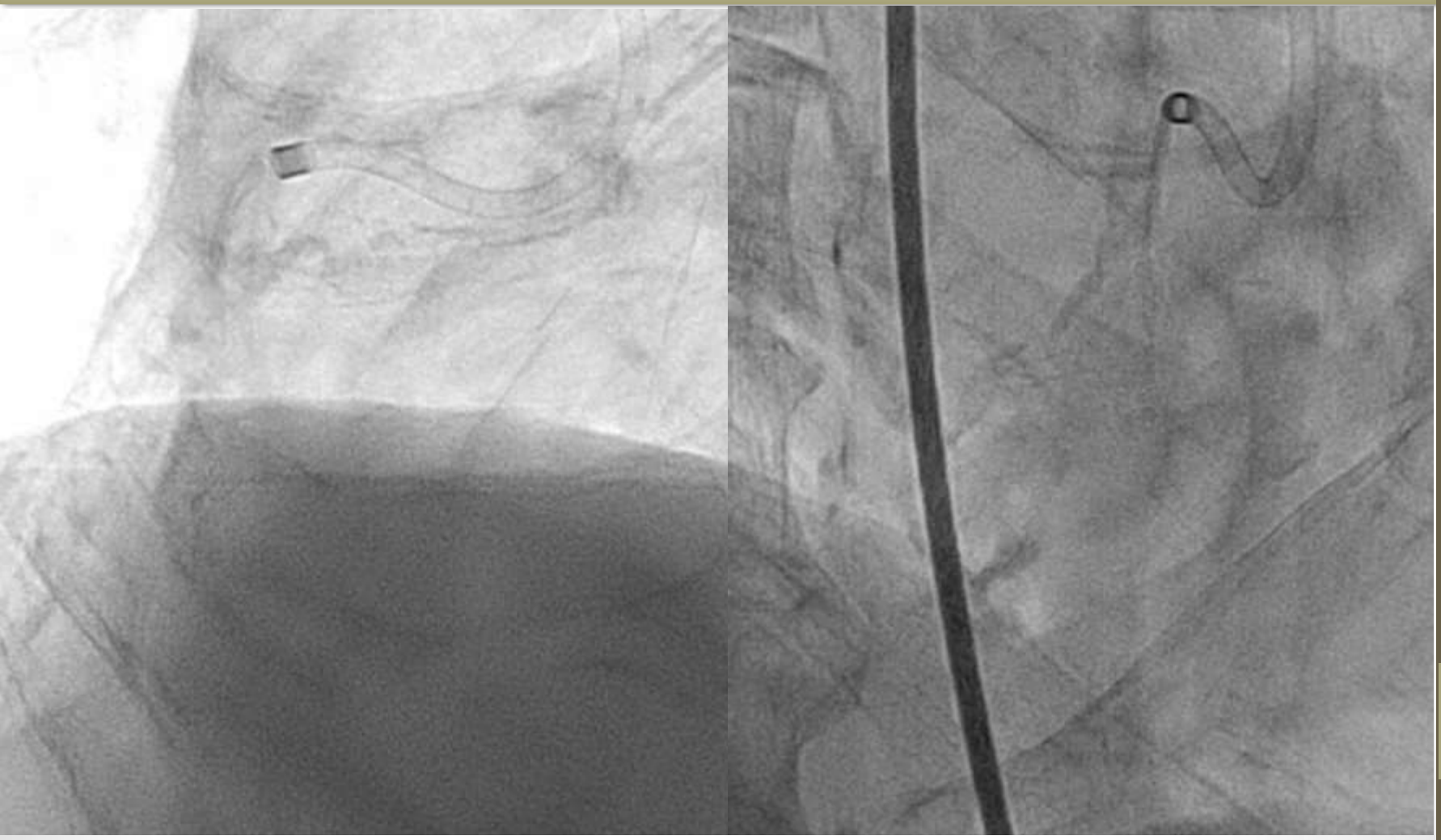
FIM of PlasmaWire



FIM-7 (planning)

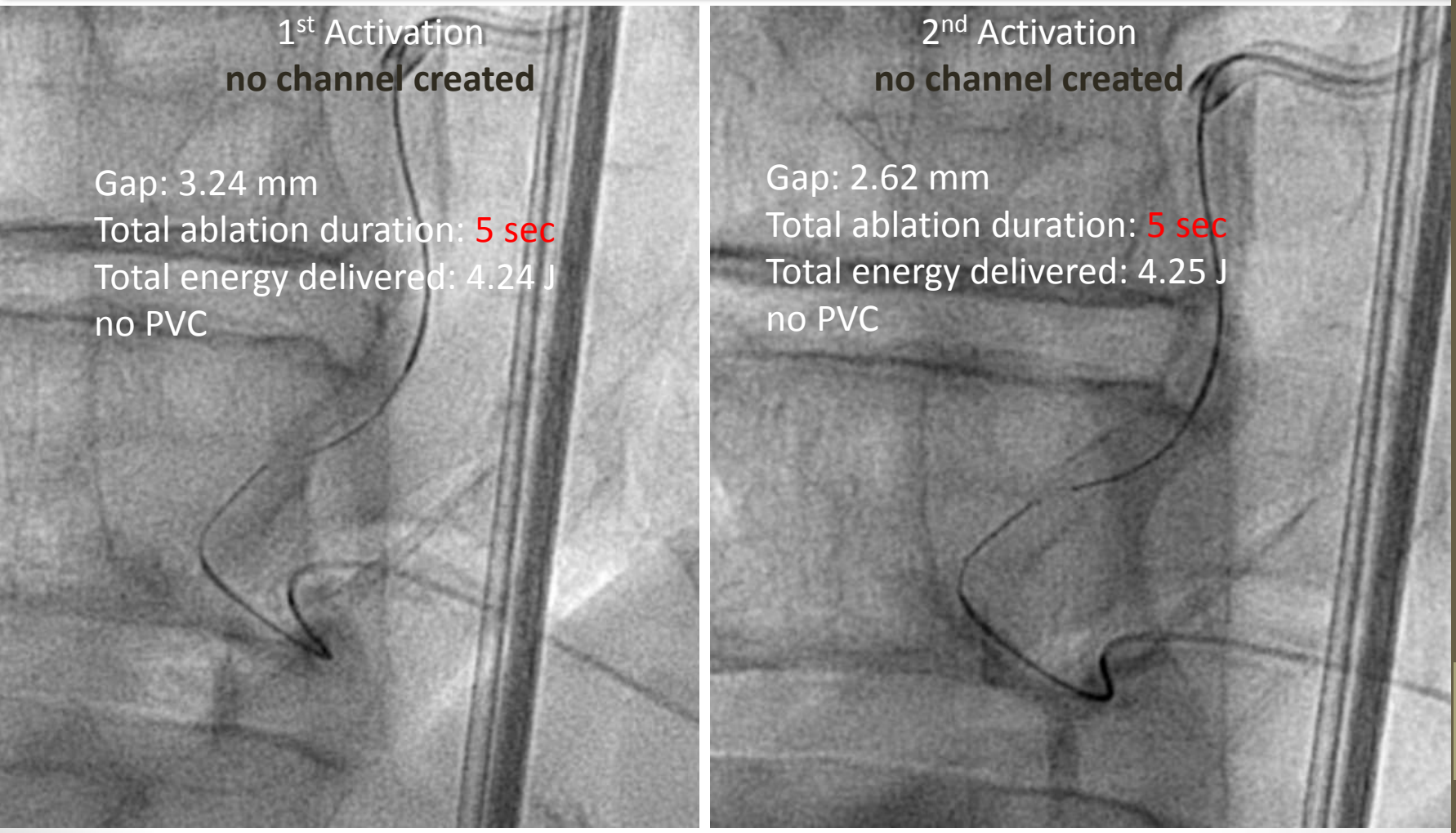
	target vessel	contralateral
Guiding (planned)	Hyperion AL 1 with side hole 8Fr	Hyperion SPB 3.75 with side hole 7 Fr
Access route	Rt femoral	Lt femoral
Planned fashion of PlasmaWire use	Antegrade + Retrograde	
Retrograde route (planned)	septal channel	
CTO wires for preparation	Miracle 3G	Ultimate 3G
Procedure for preparation	1. Antegrade Corsair is advanced to CTO entry and retrograde Caravel is advanced to CTO exit for delivering PlasmaWires.	

FIM-7 (results)



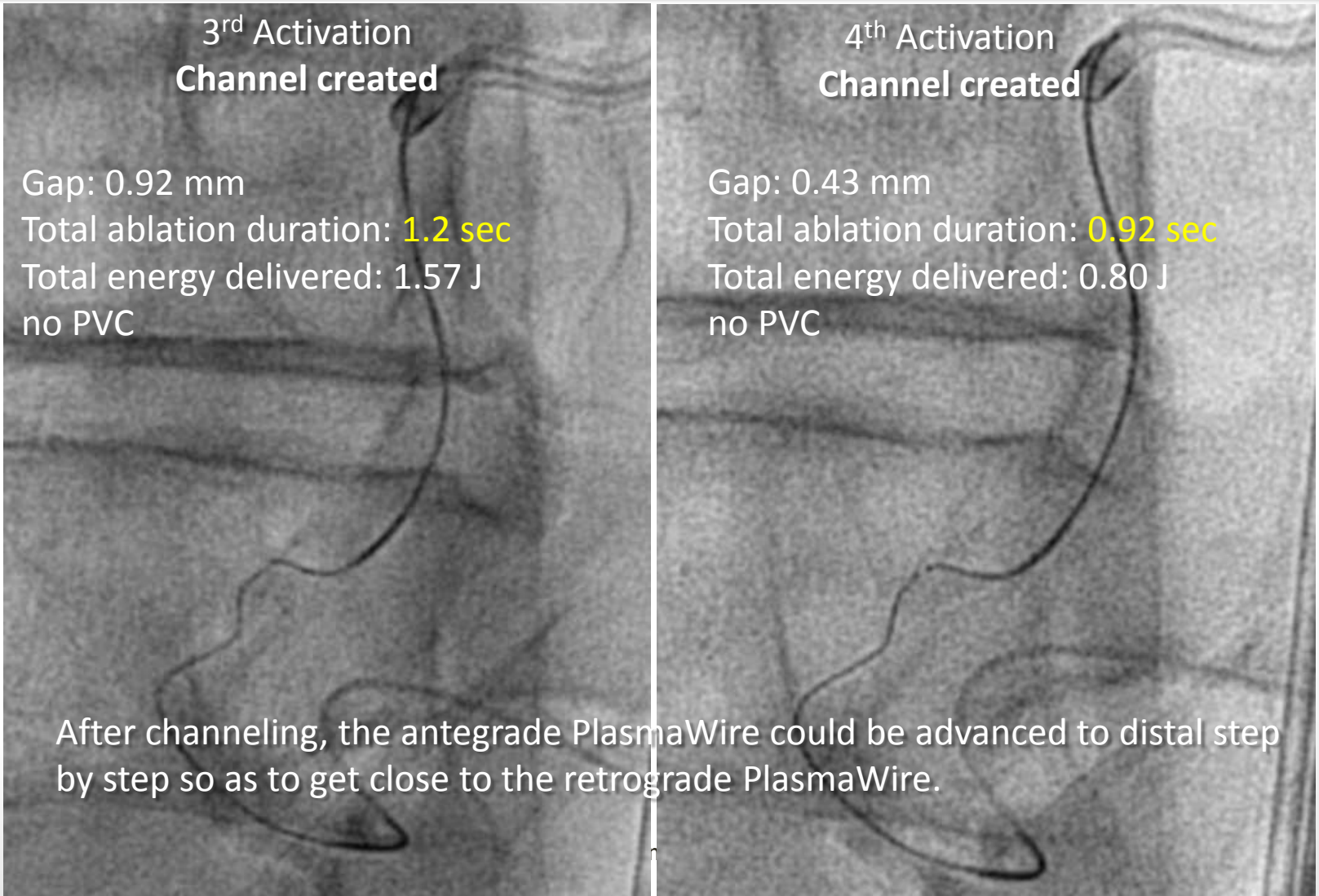
FIM of PlasmaWire

FIM-7 (results)



FIM of PlasmaWire

FIM-7 (results)



After channeling, the antegrade PlasmaWire could be advanced to distal step by step so as to get close to the retrograde PlasmaWire.

FIM-7 (results)

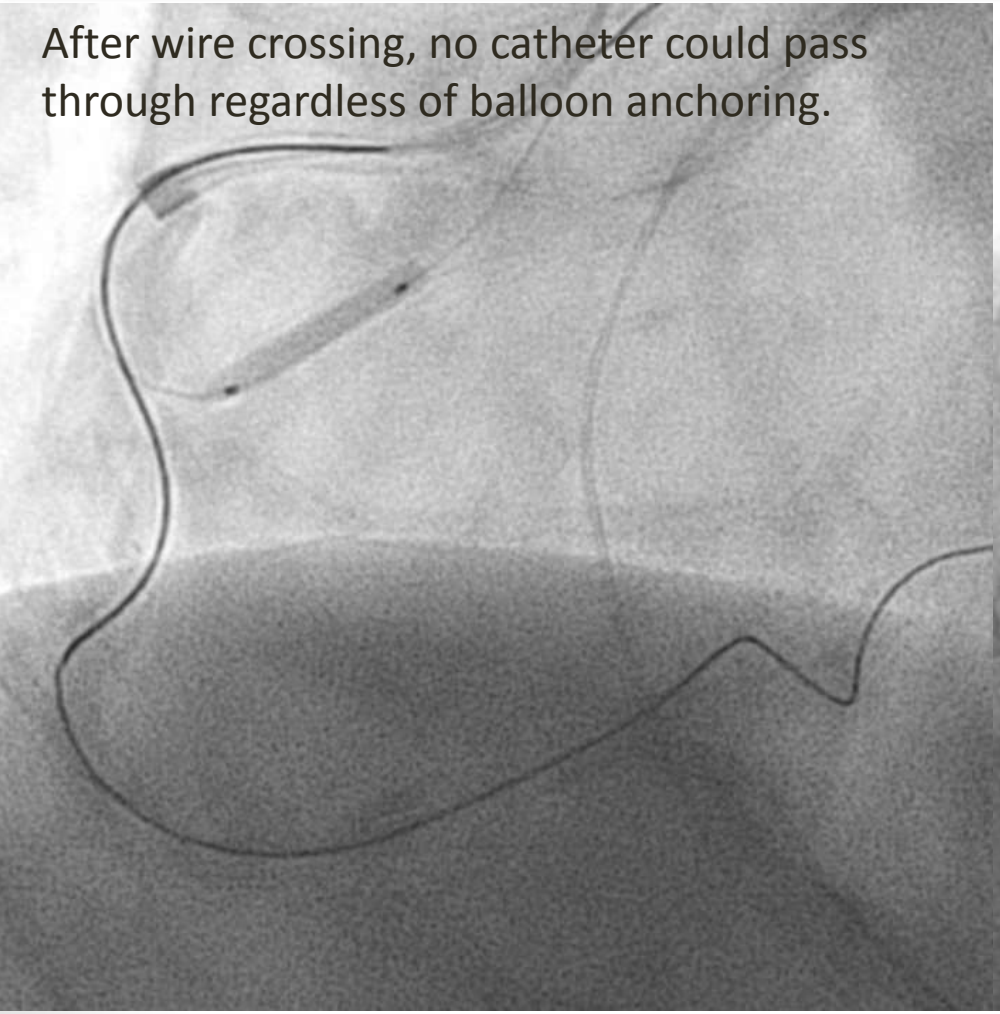
5th Activation
Channel created

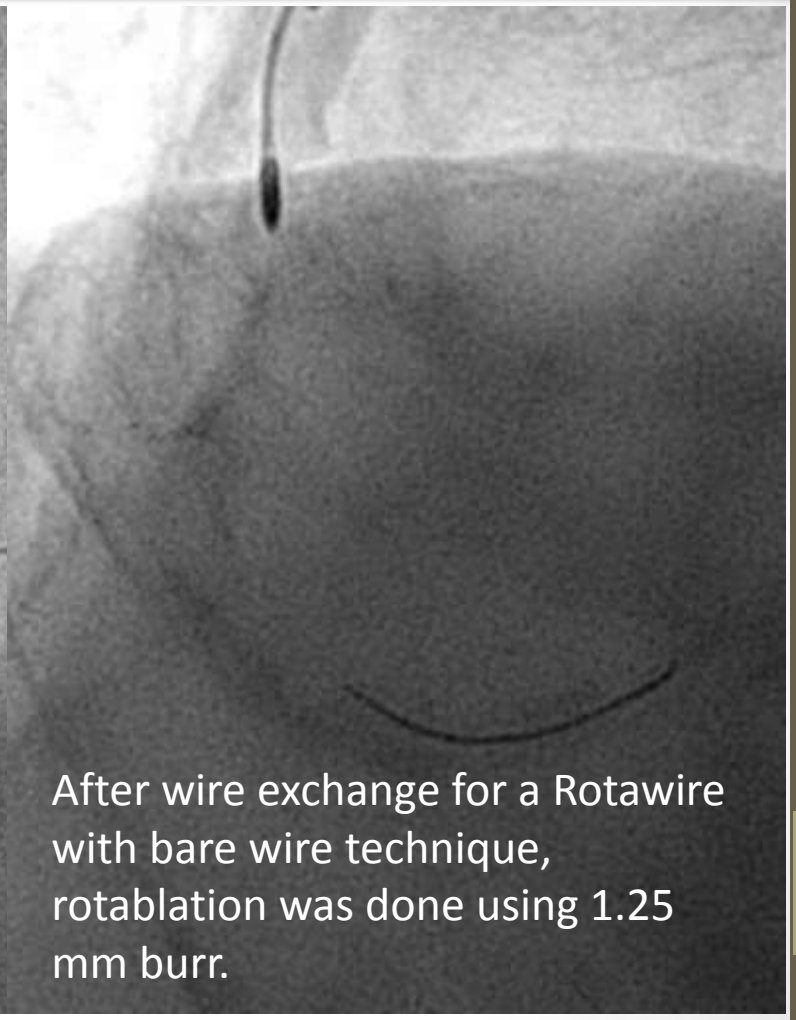
Then, the retrograde PlasmaWire was pulled back 1-2 mm. So, activation was carried out at the distal point.

Gap: 1.75 mm
Total ablation duration: 0.67 sec
Total energy delivered: 1.10 J
no PVC

After 5th activation, the antegrade PlasmaWire was exchanged to XTR. Then, the antegrade XTR wire smoothly passed through the created channel.

FIM-7 (results)

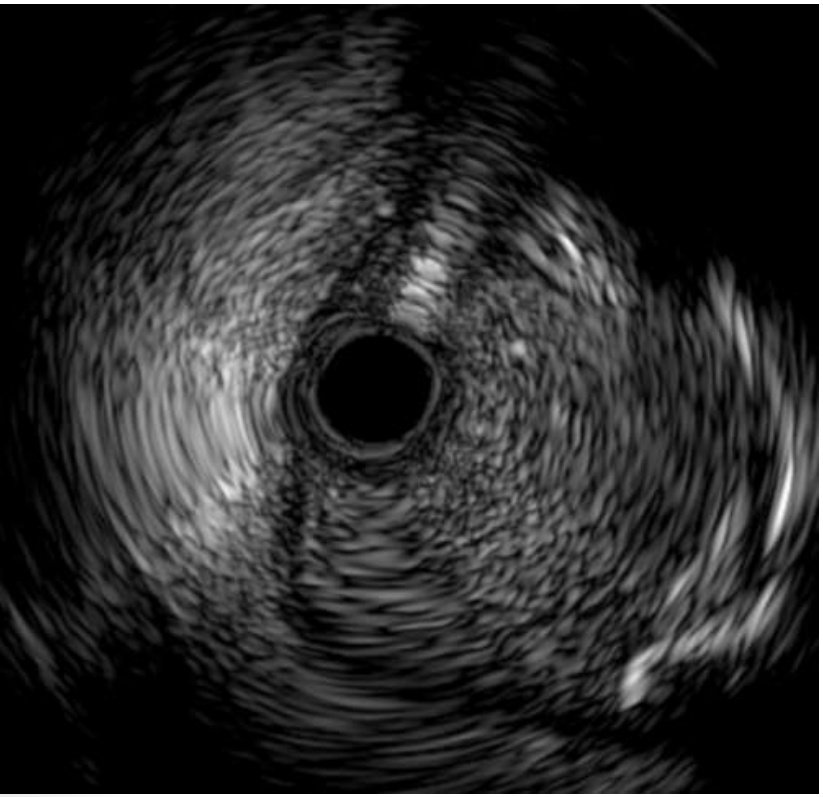


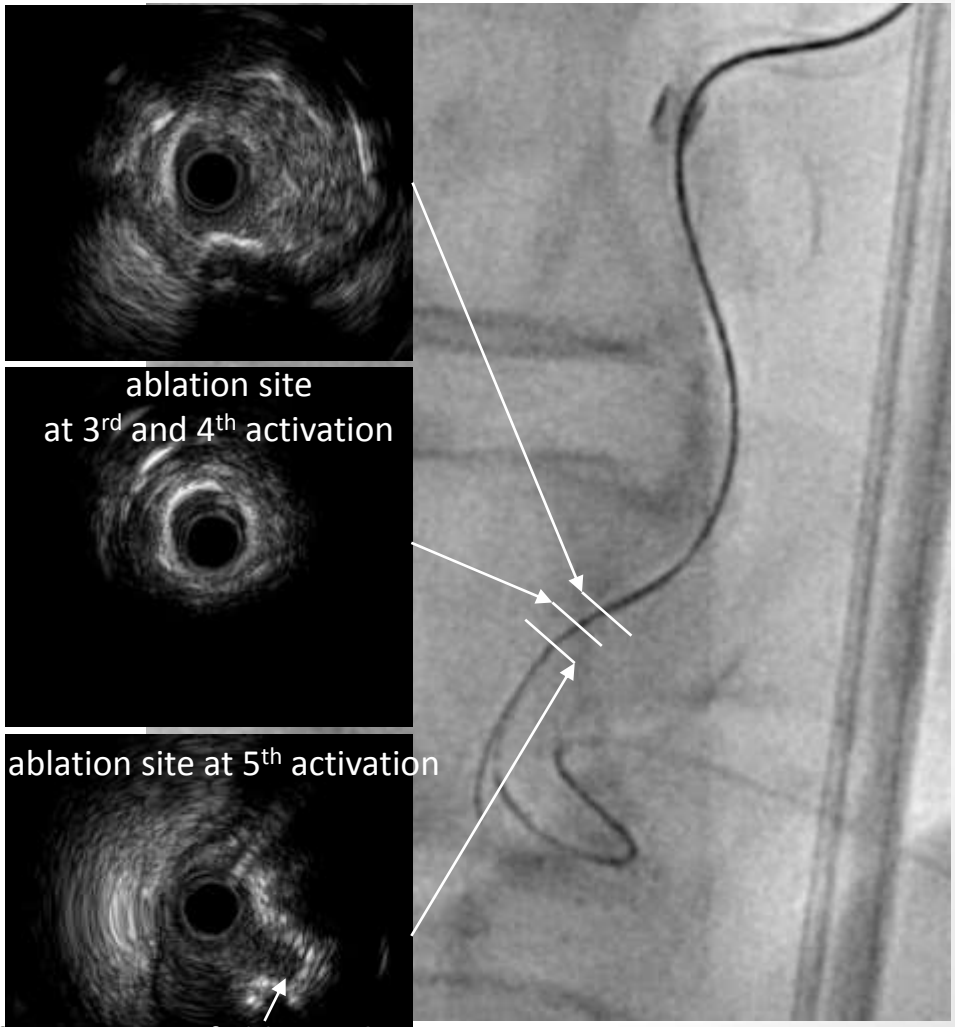


FIM of PlasmaWire

FIM-7 (results)

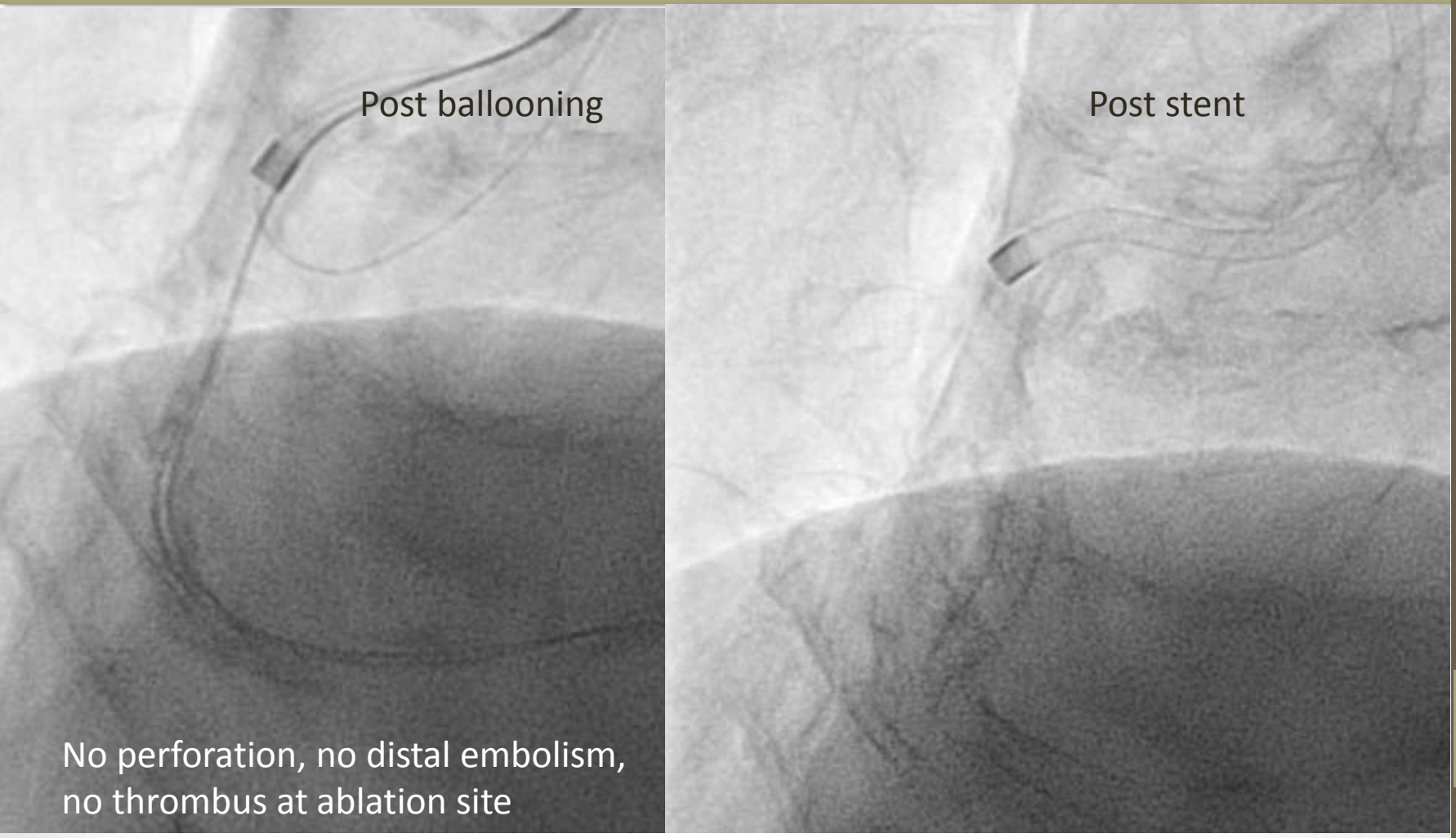
Pullback IVUS image
after rotablation with 1.25 mm burr





FIM of

FIM-7 (results)



Summary of FIM-7

- Historically, this is the first case in which a channel is created in a heavily calcified coronary CTO using a new device in human.
- Channel creation in a dense calcium could be carried out using PlasmaWire without any complications (no PVCs, no thrombosis, no vessel injury).

Conclusions

- PlasmaWire has a potential as a novel recanalization tool of coronary CTOs.
- FIM study results warrant further clinical evaluations.