



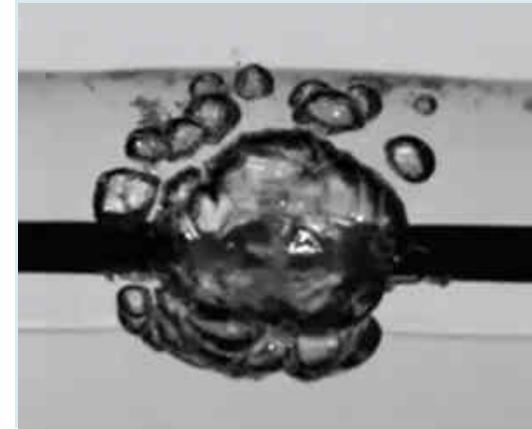
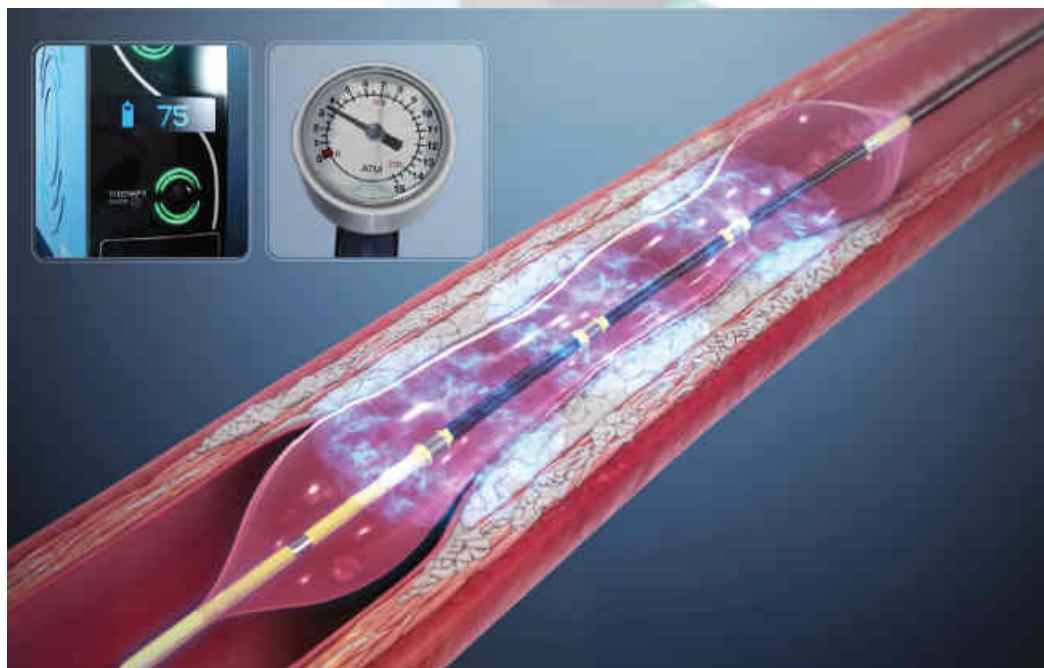
AORN “S.Pio” di Benevento
Azienda Ospedaliera di Rilievo Nazionale e di Alta Specializzazione
Unità Operativa Complessa
Cardiologia Interventistica e UTIC
Direttore : Dr Marino Scherillo



PCI Complessa: Strategie Alternative Shockwave Litotrissia

Dario Formigli

Napoli, 1 ottobre 2021



After inflating the integrated balloon to 4-atm, a small spark at the emitters vaporizes the saline-contrast solution and creates a bubble which rapidly expands and collapses within the balloon; this expanding and collapsing bubble creates a **short burst of sonic pressure waves**.

The sonic pressure waves travel through the coronary tissue, while reflecting off and cracking calcium with an effective pressure of **~50 atm**. The emitters along the length of the device create a **localized field effect** within the vessel to fracture both **intimal and medial** calcium.

The integrated balloon plays a unique role; its apposition to the vessel wall **facilitates efficient energy transfer** during IVL, after which, it is used to dilate the lesion to maximize lumen gain.

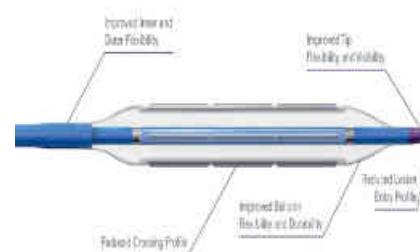
**CE Mark 17 May 2017
Marketing in Italy 2018
FDA Approval 16 Feb 2021**

Technical Features of Dedicated Devices for the Treatment of Coronary Calcified Lesions

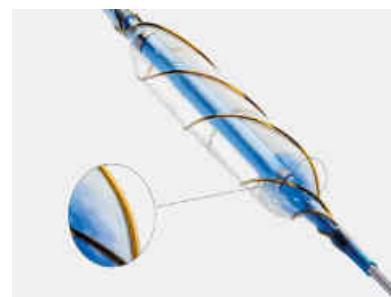
**Very High-pressure
Balloon**



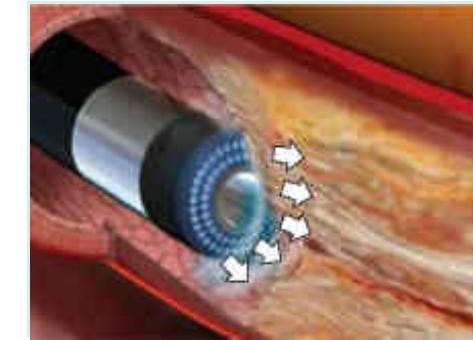
Cutting Balloon



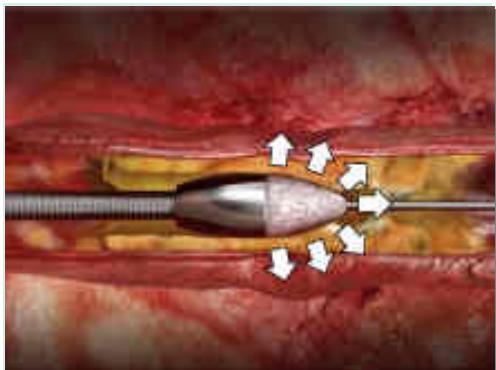
Scoring Balloon



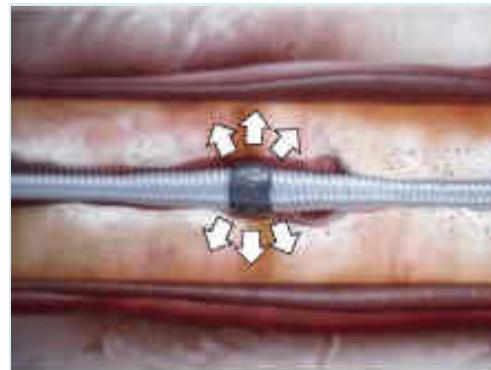
**Excimer Laser
Coronary
Atherectomy**



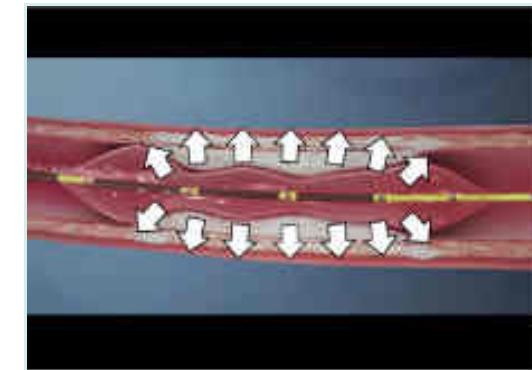
**Rotational
Atherectomy**



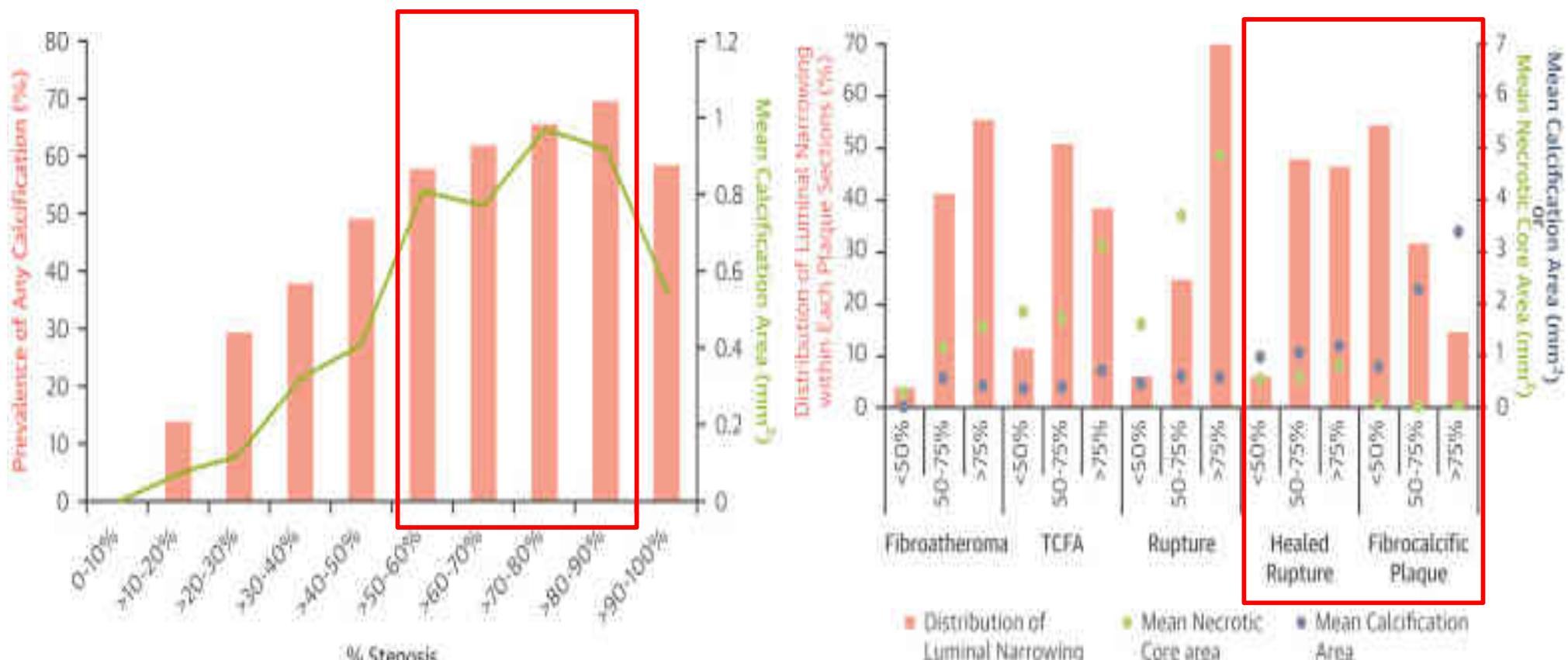
**Orbital
Atherectomy**



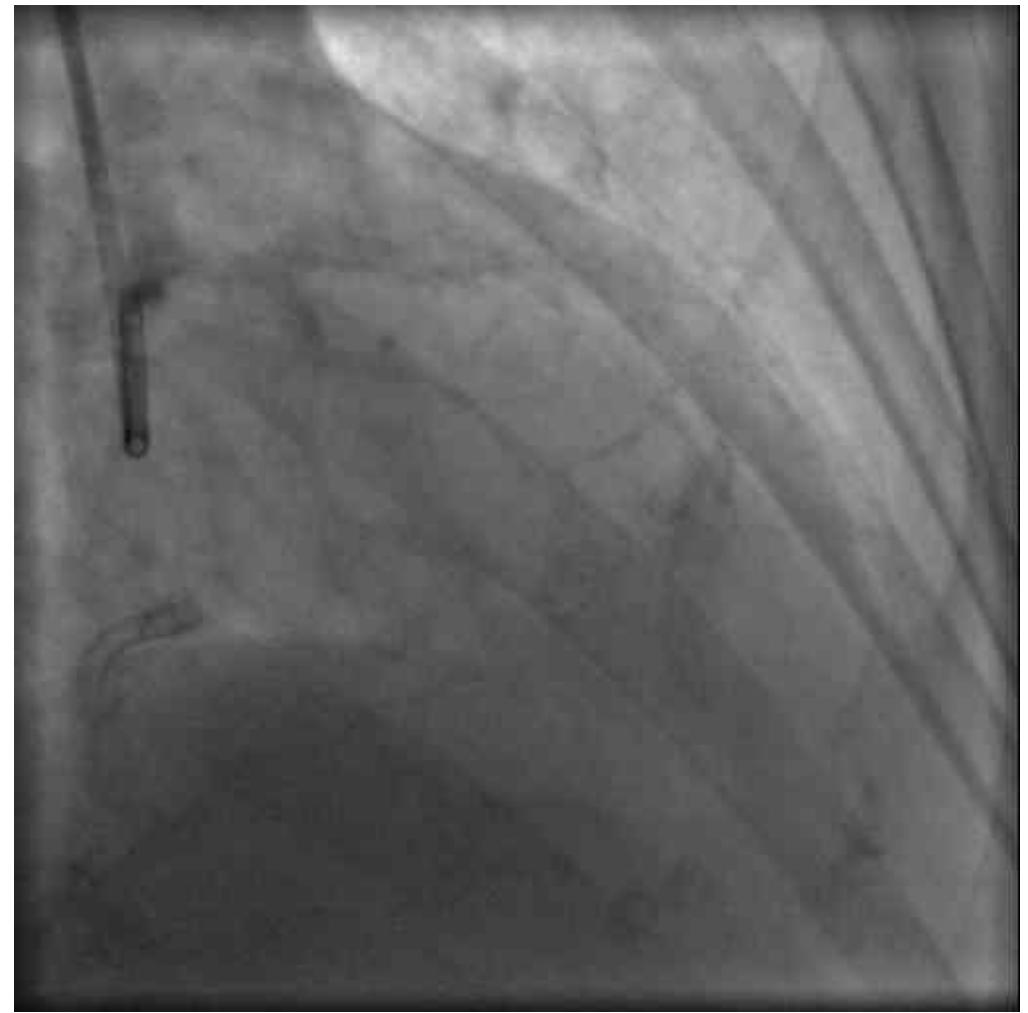
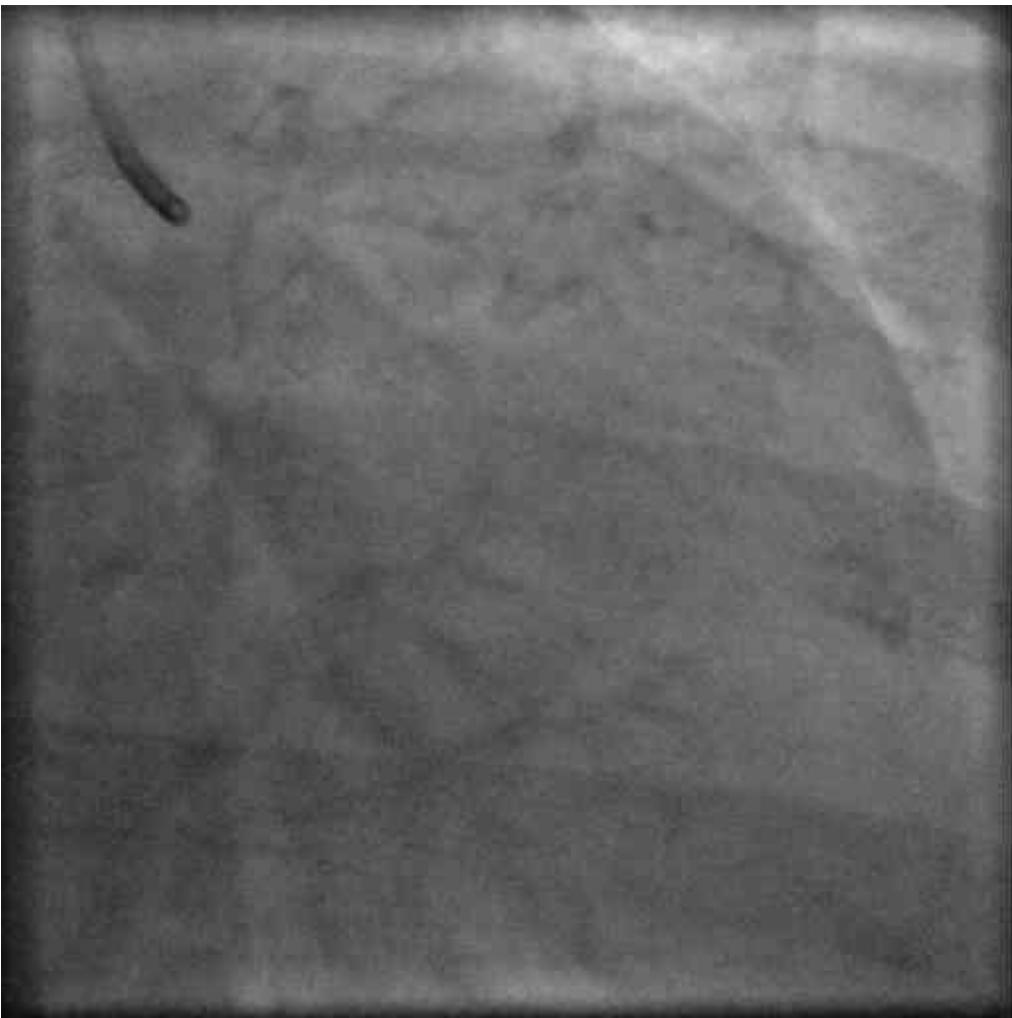
**Intravascular
Lithotripsy**



Relationship of Calcification, Plaque Type, and Percent Stenosis



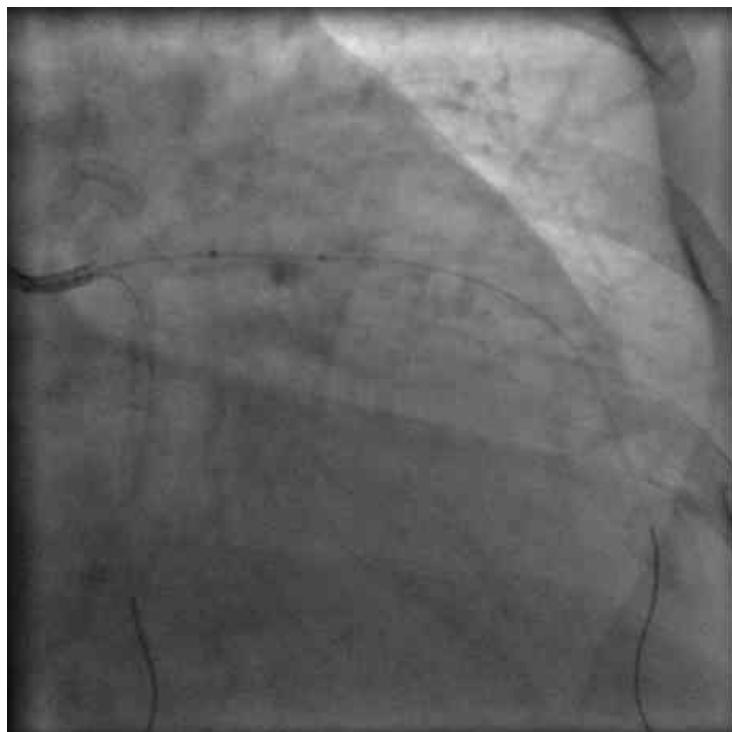
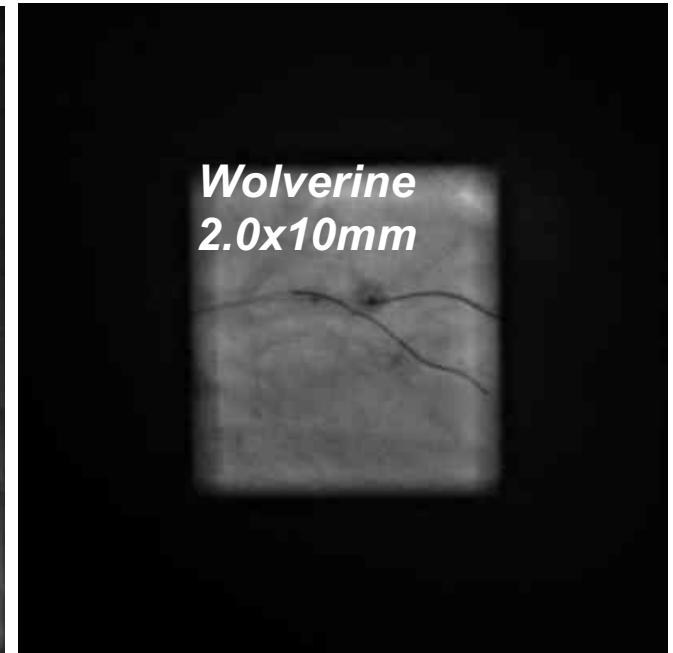
Lesioni Calcifiche = SCC



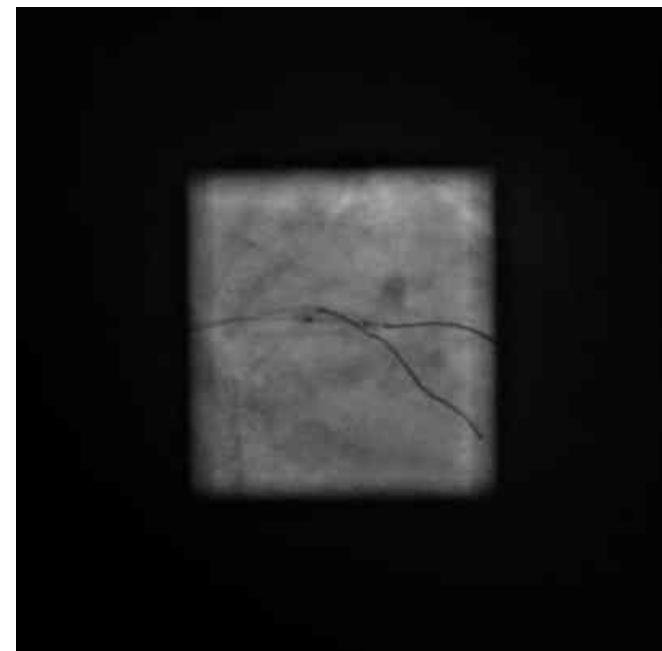
F, 75 anni
2-11-2020



Unità Operativa Complessa Cardiologia Interventistica e UTIC AORN "S.Pio" di Benevento



**Shockwave
3.0x12mm**



**F, 75 anni
2-11-2020**



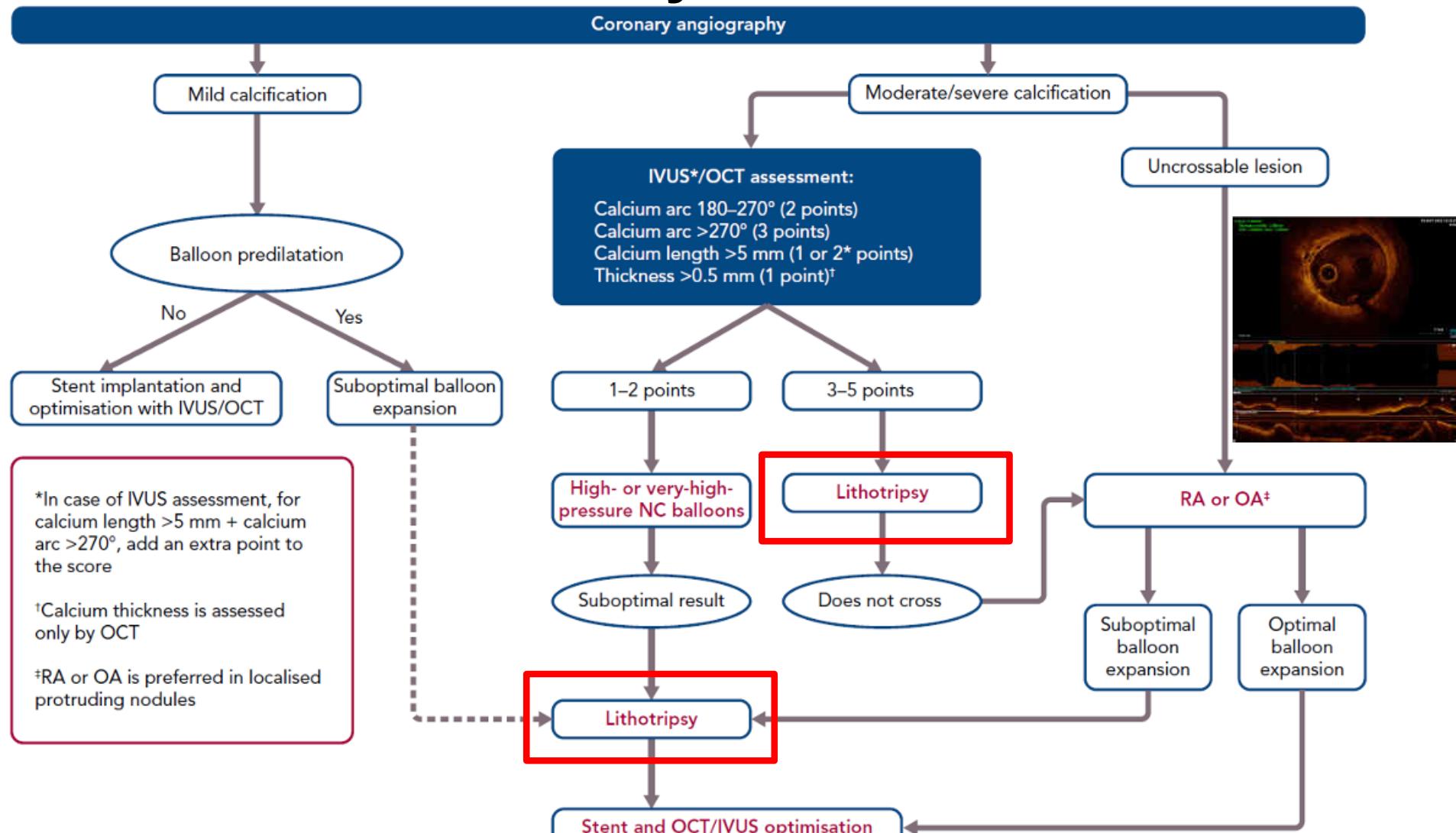
4 DES su IVA max 3.0 mm



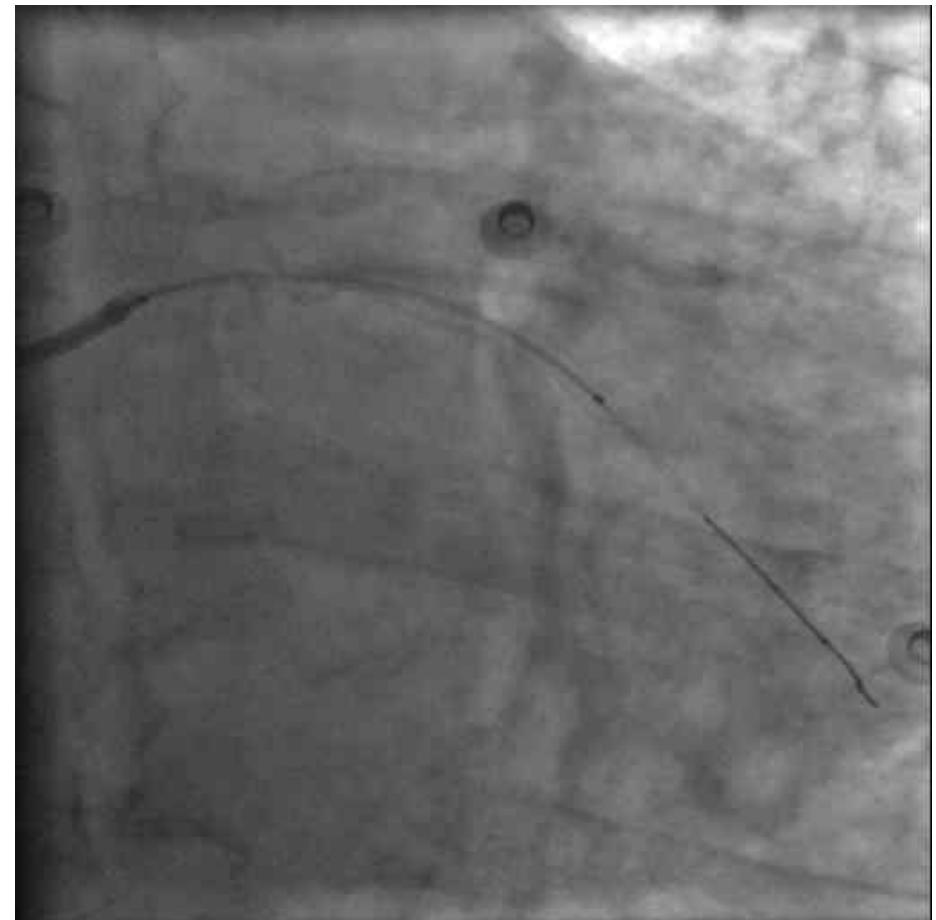
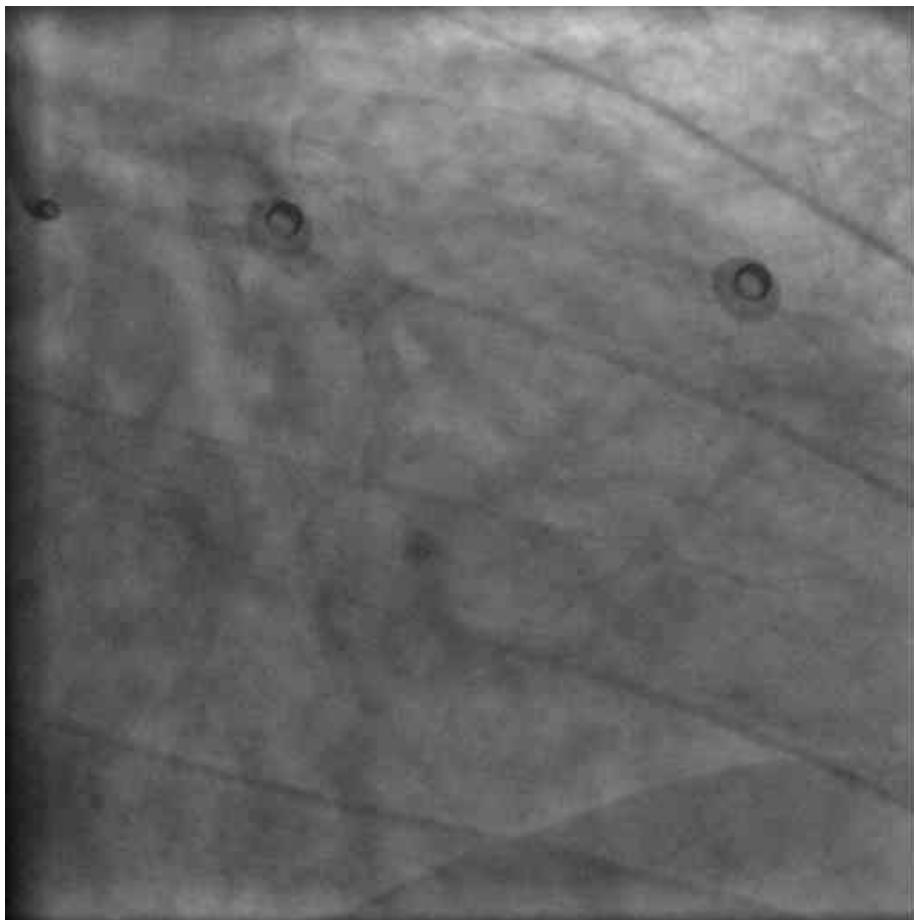
F, 75 anni
2-11-2020

Unità Operativa Complessa Cardiologia Interventistica e UTIC AORN "S.Pio" di Benevento

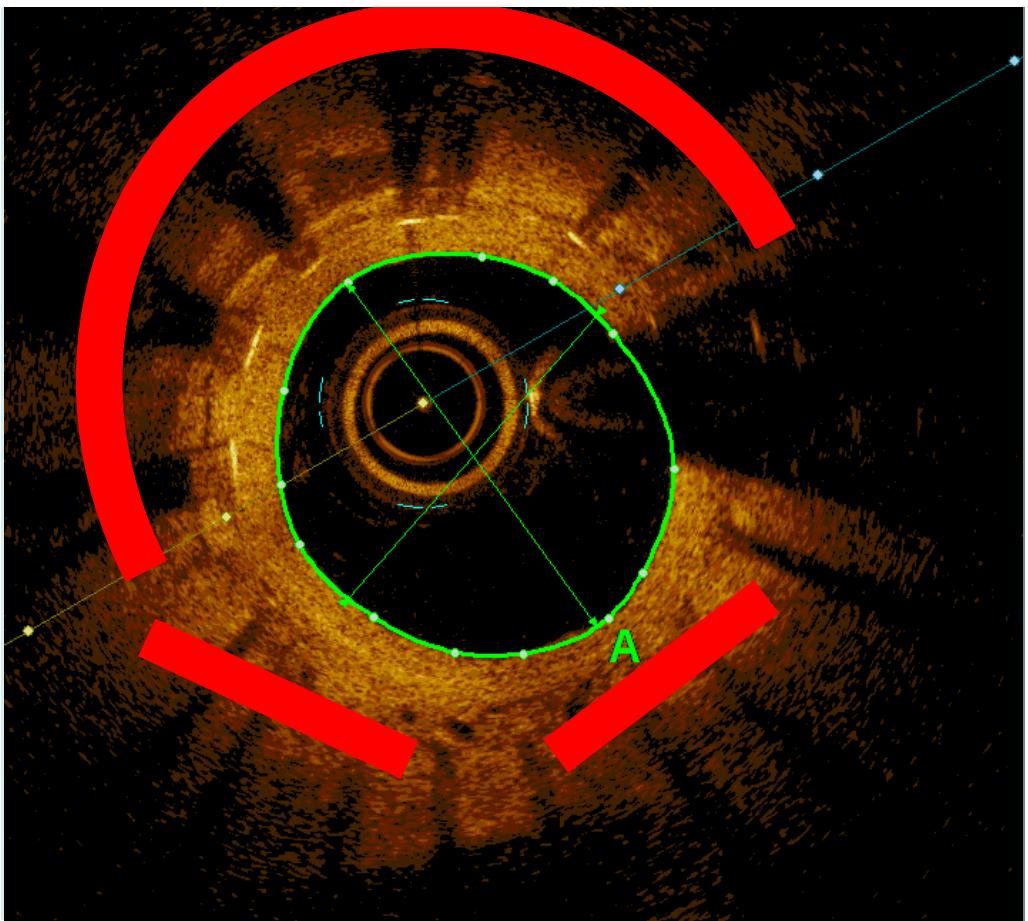
Decision Algorithm for the Treatment of Calcified Coronary Lesions



IVUS = intravascular ultrasound; NC, non-compliant; OA = orbital atherectomy; OCT = optical coherence tomography; RA = rotational atherectomy.

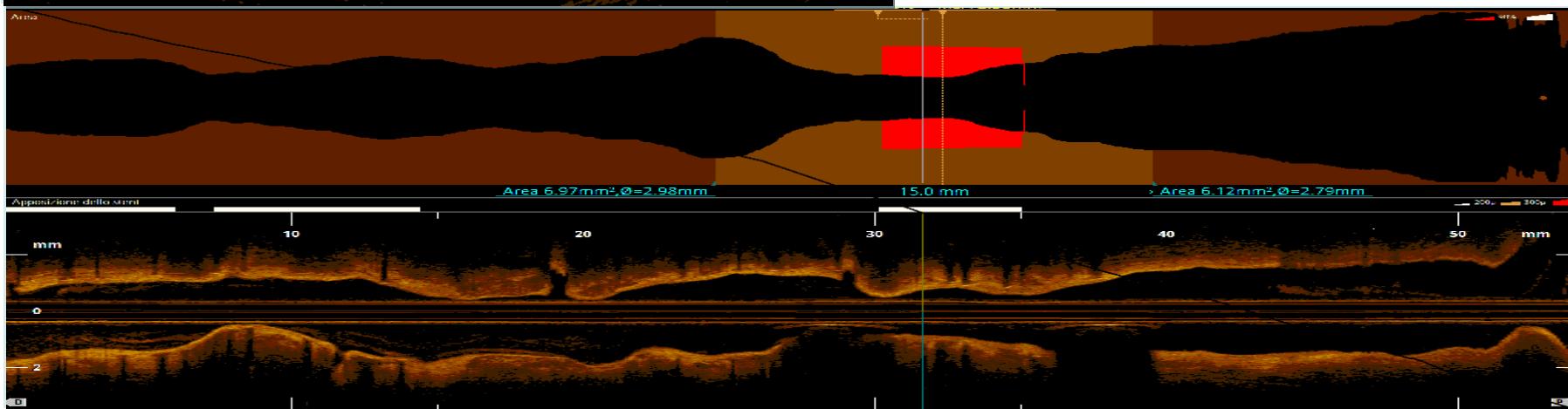


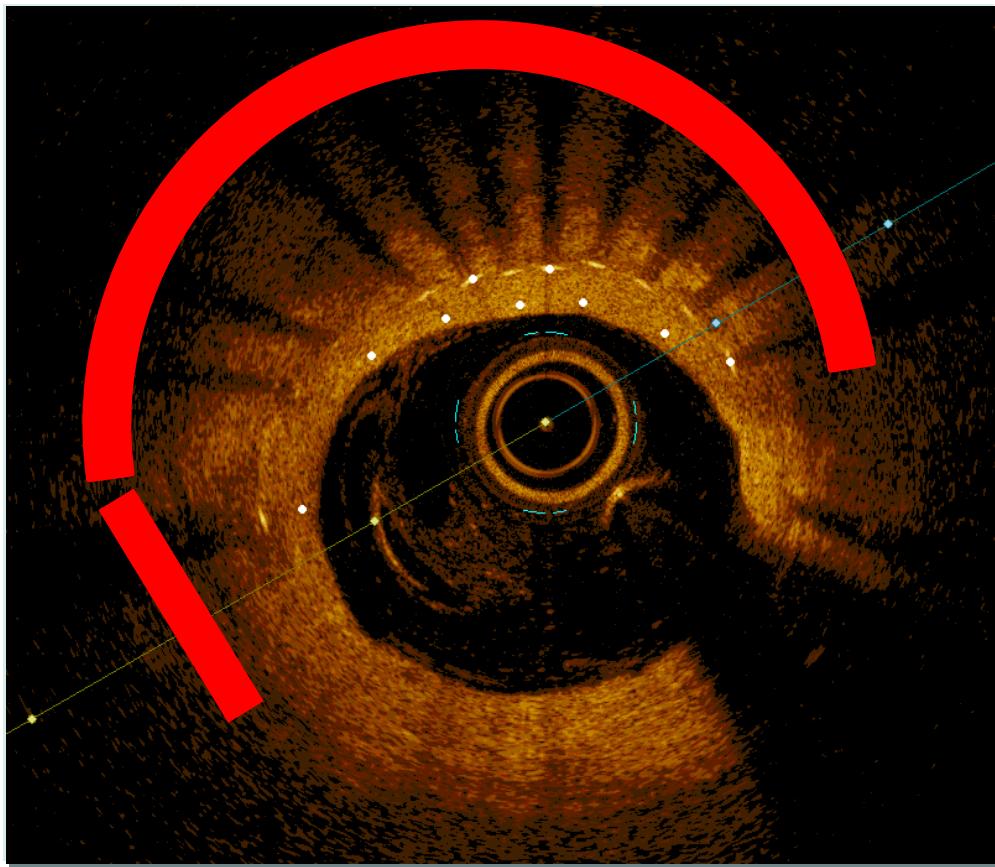
Pregressa PCI nel 2008 su Cx. Scintigrafia POS posteriore



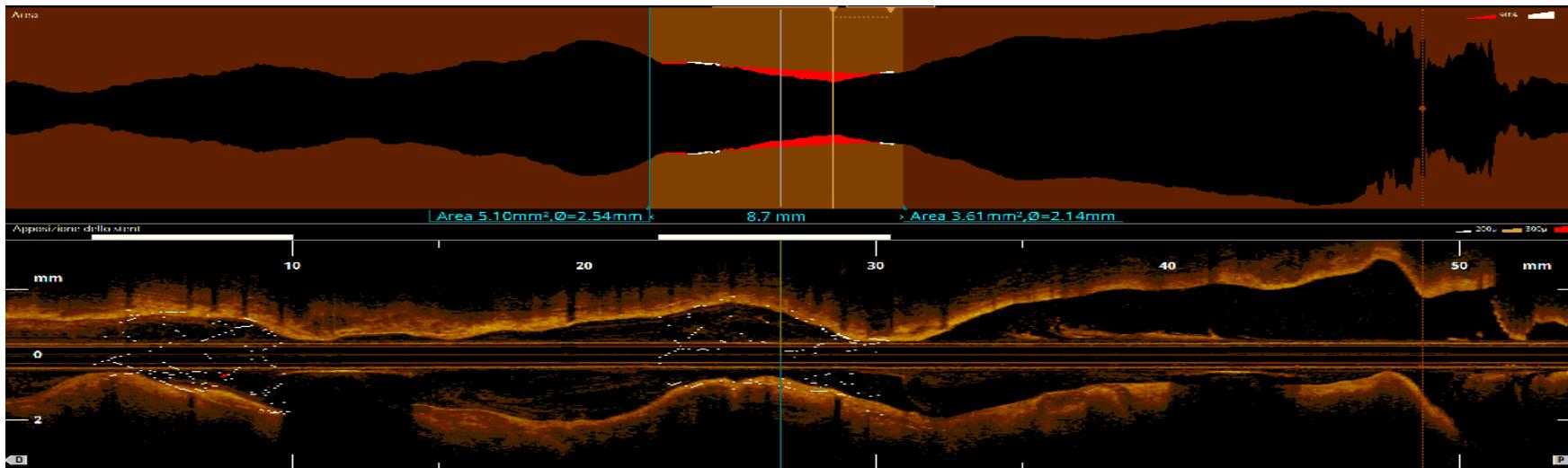
**Arco di calcio 270° MSA 2.3 mm²
Espansione Stent 37%
Lunghezza Calcio 10 mm**

5 PUNTI



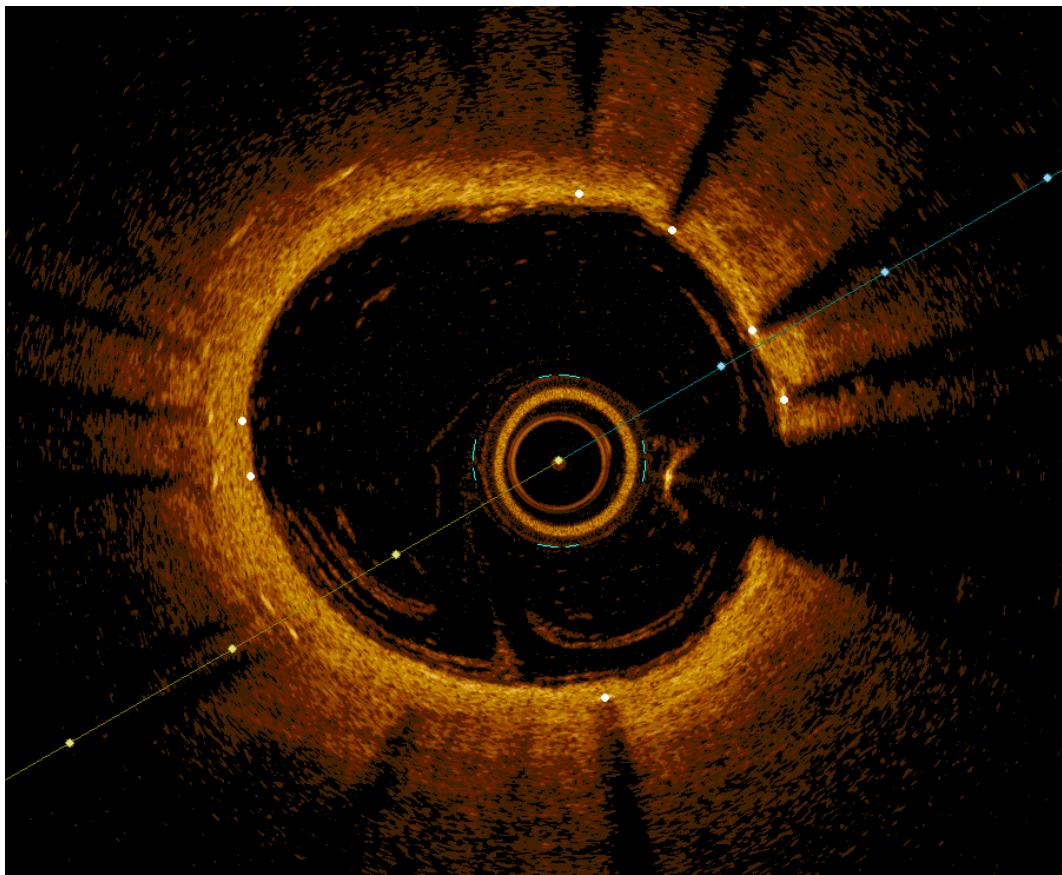


**Dopo POBA NC 3.0x10mm
Arco di calcio 200° MSA 2.4 mm²
Espansione Stent 75%
Lunghezza Calcio 10 mm**

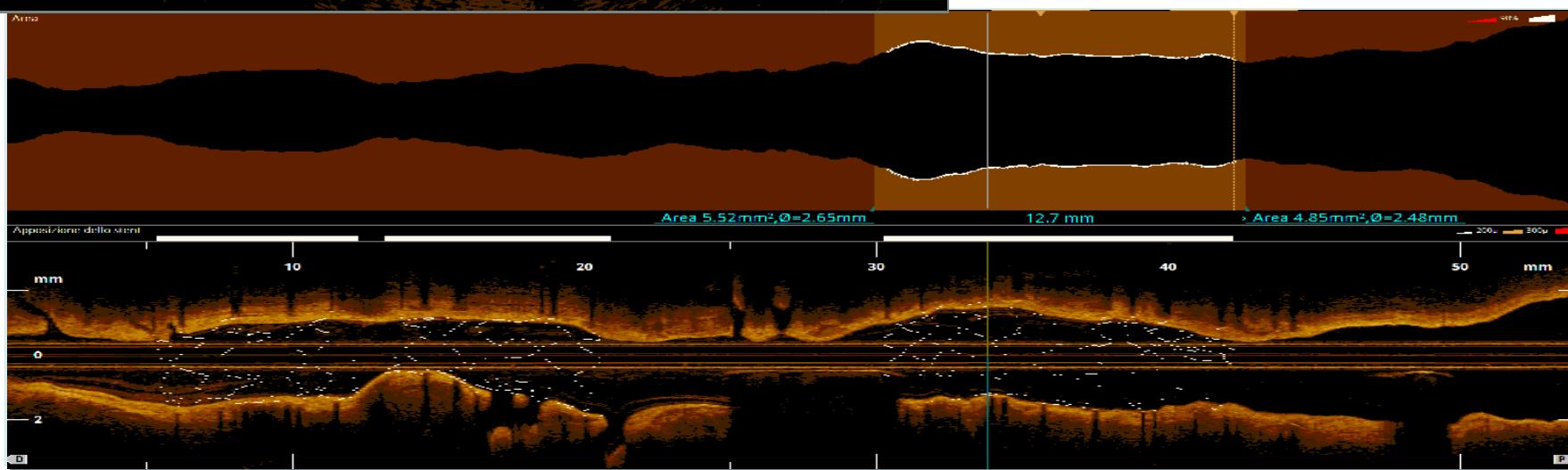


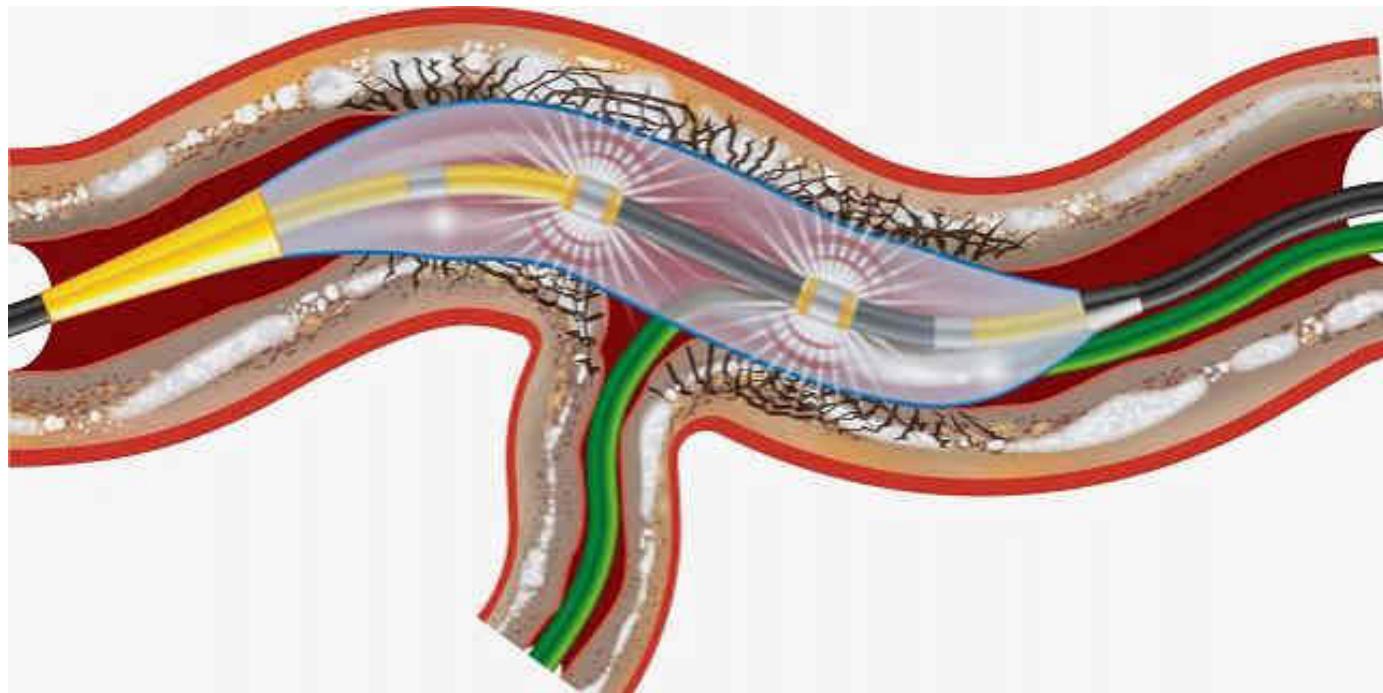
**M, 69 anni
1-09-2021**





**Dopo Shockwave 3.0x12mm +
NC Balloon + DEB Dior 3.0x15mm
Espansione Stent 107%**





Complicanze dell' IVL

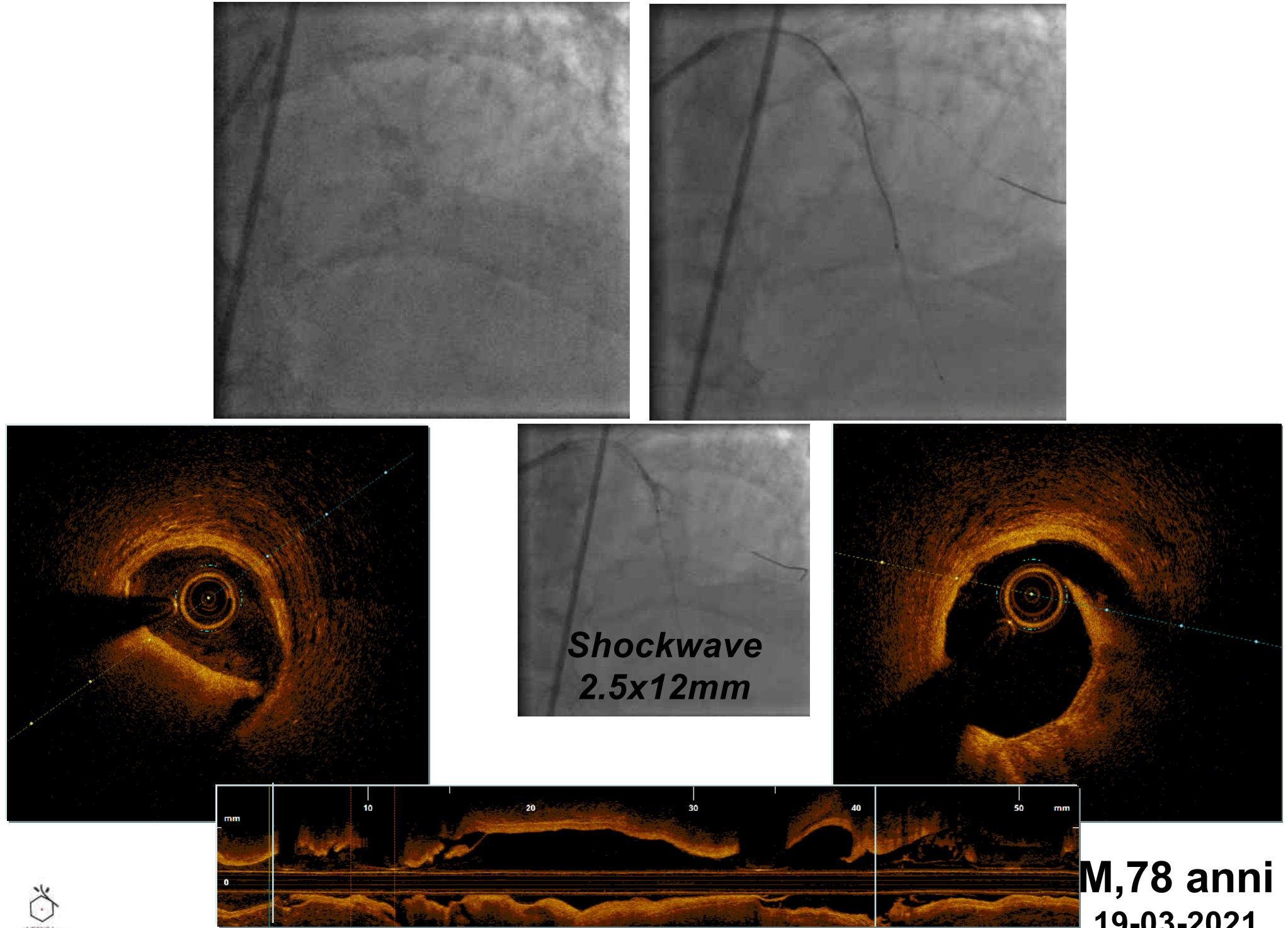
Study Flow and Follow-up

Patients enrolled from January 2019 to March 2020
Safety Population
N=431

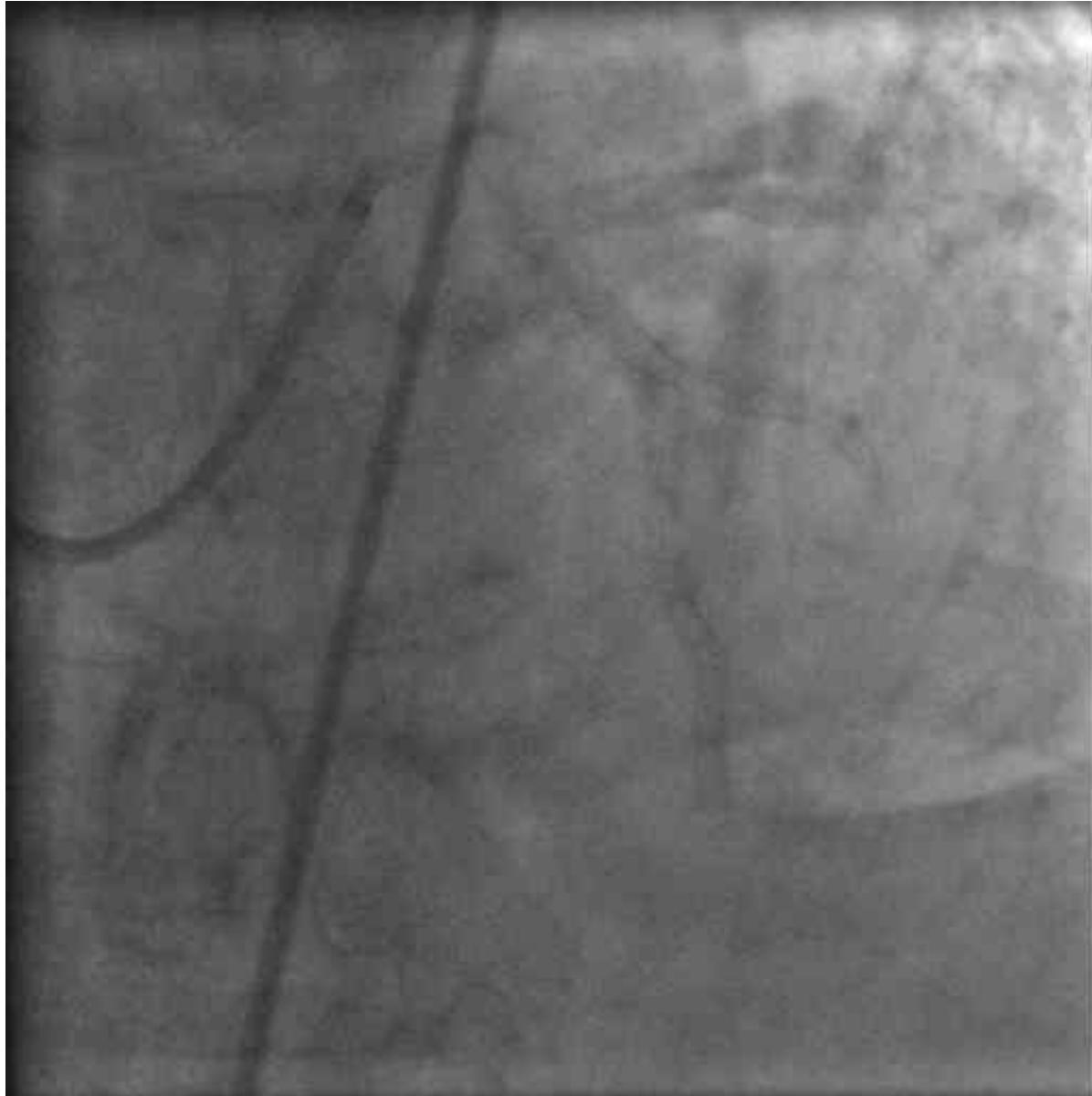
Angiographic Complications

**DISRUPT
CAD III**

Core Lab Analysis	Immediately Post-IVL	Final Post-stent
Any serious angiographic complication	2.6%	0.5%
Severe dissection (Type D-F)	2.1%	0.3%
Perforation	0.0%	0.3%
Abrupt closure	0.0%	0.3%
Slow flow	0.6%	0.0%
No-reflow	0.0%	0.0%



M,78 anni
19-03-2021



Triplice DES su IVA e duplice DES su D1 tecnica «Culottes»

Evidence From the Serial Disrupt CAD Trials

TABLE 6 | Angiographic outcomes.

	Disrupt CAD I (N = 60)	Disrupt CAD II (N = 120)	Disrupt CAD III (N = 384)	Disrupt CAD IV (N = 64)	Total (N = 628)
Final in-segment angiographic outcomes					
Minimum lumen diameter (mm)	NA	2.83 ± 0.48	2.47 ± 0.45	2.42 ± 0.40	2.5 ± 0.5 [568]
Acute gain, mm	NA	1.63 ± 0.49	1.41 ± 0.48	1.42 ± 0.42	1.5 ± 0.5 [568]
Residual diameter stenosis (%)	NA	9.4 ± 7.5	17.8 ± 8.8	15.9 ± 7.9	15.8 ± 9.1 [568]
Residual diameter stenosis <50%	NA	120 (100.0%)	381 (99.5%) [383]	63 (98.4%)	564 (99.5%) [567]
Residual diameter stenosis <30%	NA	119 (99.2%)	363 (94.8%) [383]	63 (98.4%)	545 (96.1%) [567]
Final in-stent angiographic outcomes					
Minimum lumen diameter (mm)	2.6 (2.3–2.9)	2.88 ± 0.47	2.74 ± 0.43	2.67 ± 0.36	2.7 ± 0.4
Acute gain (mm)	1.7 (1.3–2.1)	1.67 ± 0.49	1.68 ± 0.46	1.67 ± 0.37	1.7 ± 0.5
Residual diameter stenosis (%)	12 (7–21)	7.8 ± 7.1	11.9 ± 7.1	9.9 ± 5.7	11.1 ± 7.6
Residual diameter stenosis <50%	60 (100.0%)	120 (100.0%)	381 (100.0%) [381]	64 (100.0%)	625 (100.0%) [625]
Residual diameter stenosis <30%	55 (91.7%)	120 (100.0%)	379 (99.5%) [381]	64 (100.0%)	585 (93.6%) [625]
Residual diameter stenosis <20%	44 (73.3%)	NA	NA	NA	44 (73.3%) [60]
Final angiographic complications					
Residual dissections	0 (0.0%)	2 (1.7%)	1 (0.3%)	0 (0.0%)	3 (0.5%)
Perforations	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)
Abrupt closure	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)
Slow flow	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
No reflow	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Values are n (%) [N], or median with interquartile range (25%–75%), or mean ± standard deviation. NA, not applicable.

Conclusioni

Device Sicuro ed Efficace

Procedure Più Rapide

Coprire Sempre con Stent

Associare ad Imaging

