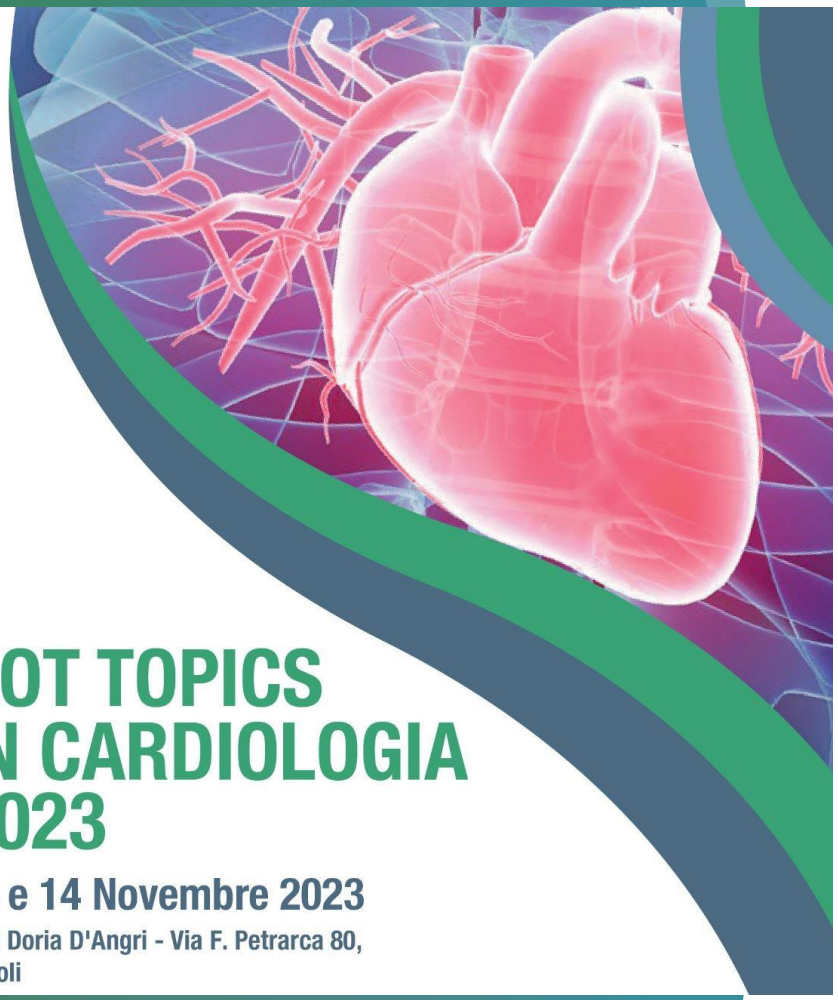


HOT TOPICS IN CARDIOLOGIA 2023

13 e 14 Novembre 2023

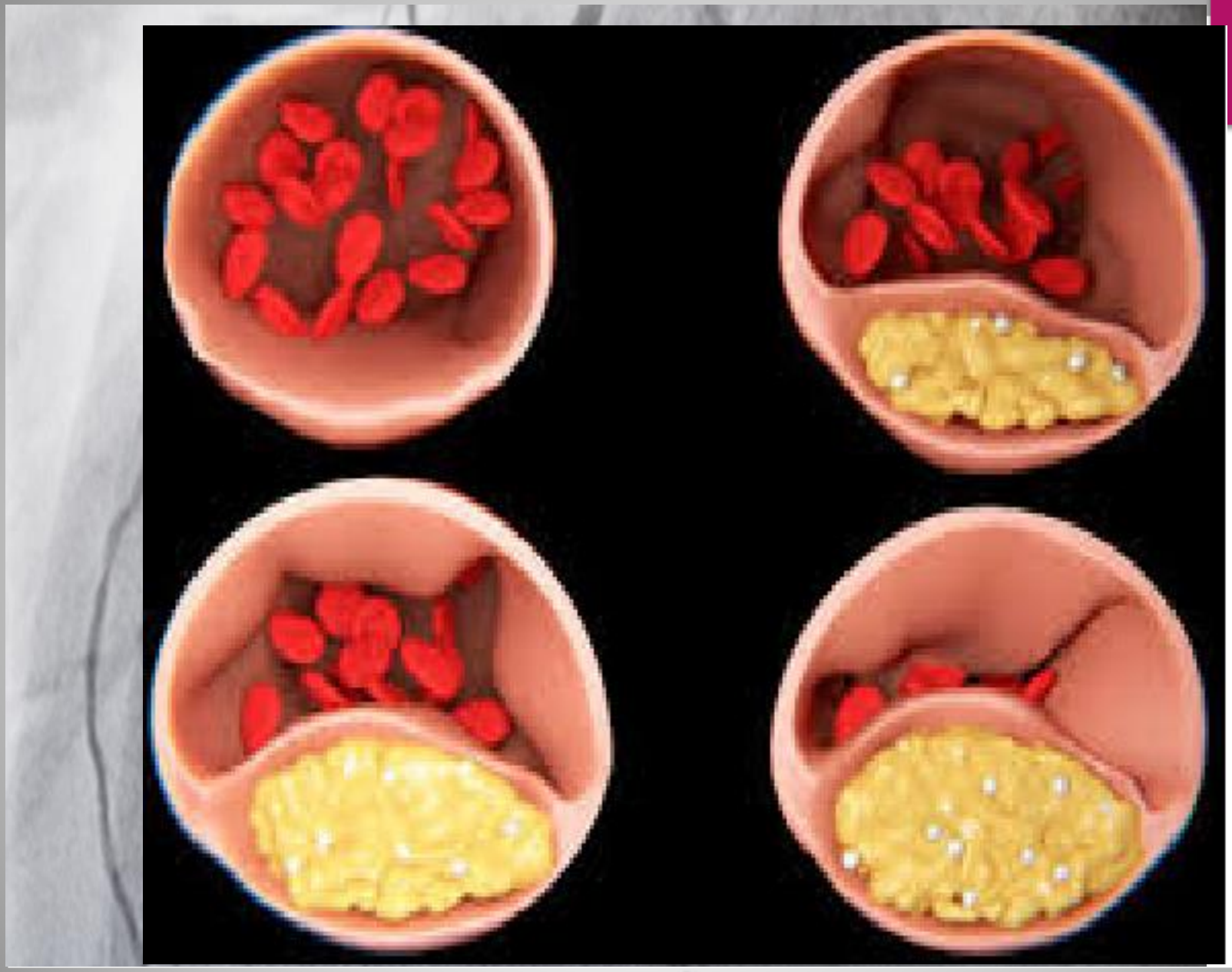
Villa Doria D'Angri - Via F. Petrarca 80,
Napoli

Prevenzione e Trattamento delle complicanze nelle lesioni calcifiche complesse.

VITTORIO AMBROSINI M.D.

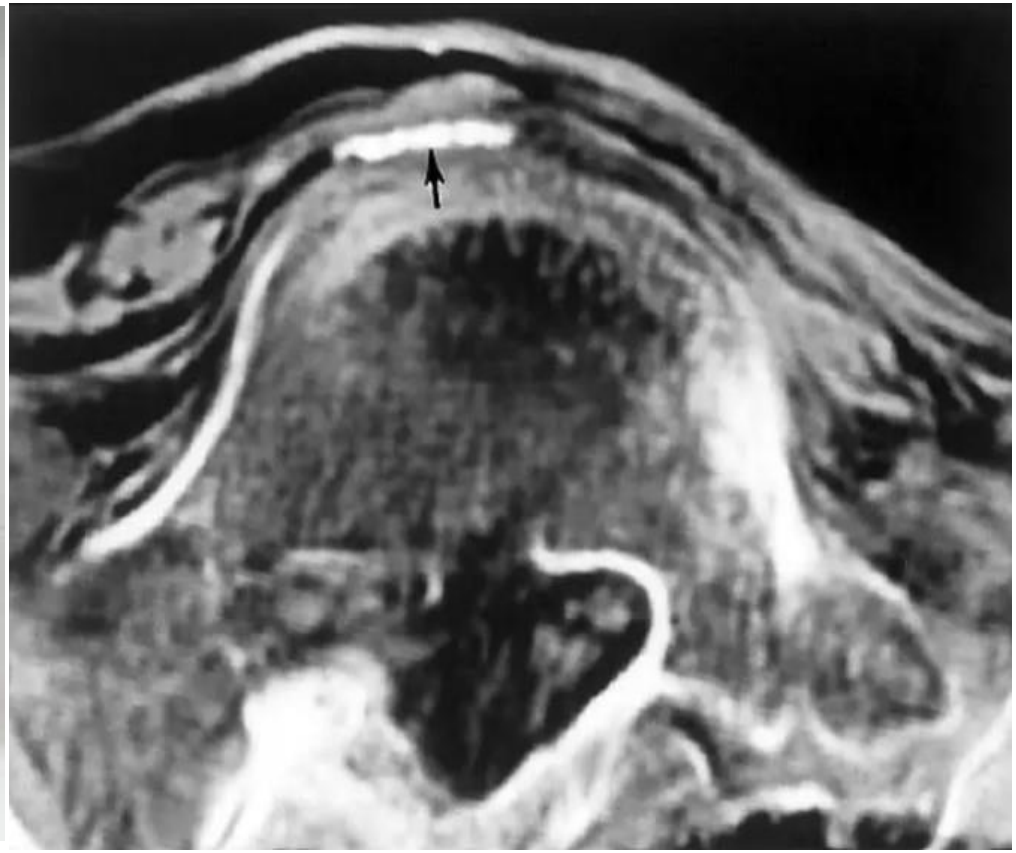
PRESIDENT OF CLS

OSPEDALE FRANGIPANE ARIANO IRPINO



THE CALCIUM: A 5000 YEAR OLD PROBLEM and at the same time:

A CURRENT PROBLEM!!!



- Severe Coronary Calcific Lesions (SCCLs) pose a **huge challenge** to performing successful percutaneous coronary interventions (PCI).
- **Old age**, **diabetes mellitus**, **arterial hypertension**, **chronic kidney disease and smoking** are associated with increased coronary calcification.(1)
- Coronary calcium can be underestimated by coronary angiography, and intravascular imaging modalities such as IVUS and OCT should be used for accurate assessment of plaque severity and characterization.

1. Dini CS, Nardi G, Ristalli F, Mattesini A, Hamiti B, Di Mario C. Contemporary approach to heavily calcified coronary lesions. Interv Cardiol Rev 2019;14:154-63.

Radiology 2003; 226:614–629

- Coronary calcification is present in approximately 30% of all lesions using Angiography alone but this datum increases to 74% when intravascular ultrasound (IVUS) assessment is added.(1)
- Severe coronary calcification increases the complexity of PCI.(2)
- It can affect lesion crossing, proper stent expansion and deposition, damage the drug polymer, increase the risk of stent thrombosis and restenosis, and negatively impact short- and long-term outcomes.(3)

1. Mintz GS et al. Patterns of calcification in coronary artery disease. A statistical analysis of intravascular ultrasound and coronary angiography in 1155 lesions. Circulation 1995;91:1959-65.

3. Abdel-Wahab M, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: the randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. J Am Coll Cardiol Intv 2013;6:10-19.

Radiology 2003; 226:614–629

FUNDAMENTAL POINTS:

Coronary calcification is an important predictor of the non-possibility of DES[1] implantation

- The lack of flexibility in a calcified coronary artery makes it difficult to advance the Stent in tortuous anatomies.
- Difficulties in navigating the Stent could damage the polymer and/or the coating, making the action of the drug ineffective[2]

1 Ferrer Gracia MC, et al. Failure in the implantation of drug eluting stents. Frequency and related factors. Med Intensiva. 2007.

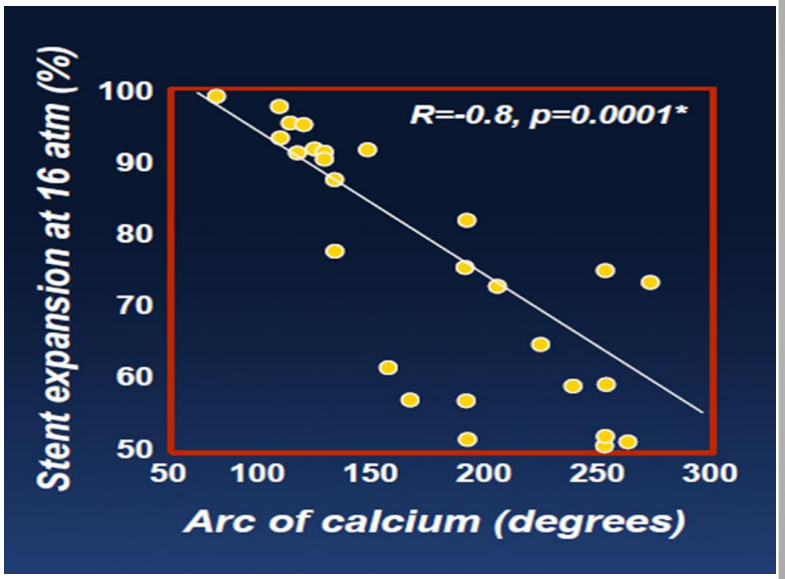
2 Grech ED. Percutaneous coronary intervention. I: History and development. BMJ. 2003; 326:1080-1082

CALCIFICATION INHIBITS THE OPTIMAL CIRCUMFERENTIAL EXPANSION OF THE STENT

The greater the arch, length or thickness of the butt, the greater the likelihood of under-expansion of the Stent[1]

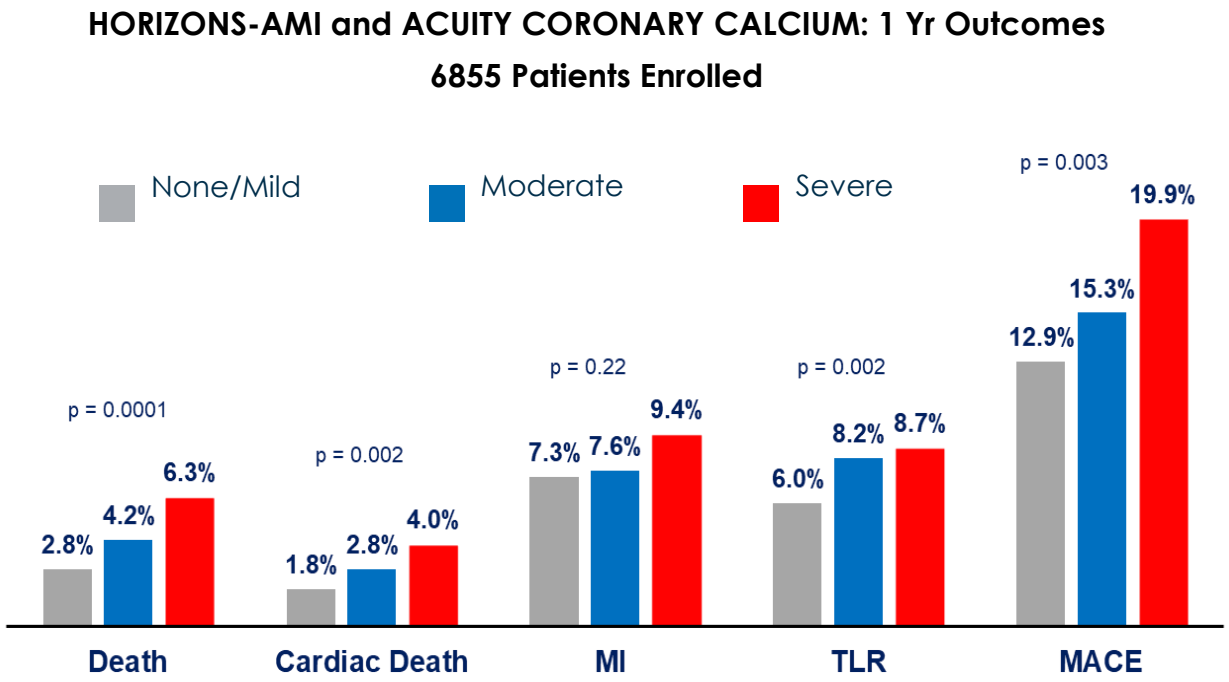
Asymmetric expansion of the Stent is present in more than 50% of stents positioned on calcific lesions[2]

Stent under-expansion is associated with an increase in ischemic events after 1 year[3]



1. Mintz, G; I. J Am Coll Cardiol Imaging 2015;8(4): 461-71.
2. Chambers JW, et al. J Am Coll Cardiol Intv 2014; 7:510–8.
3. Généreux P, et al. JACC 2014; 63(18);1845-54

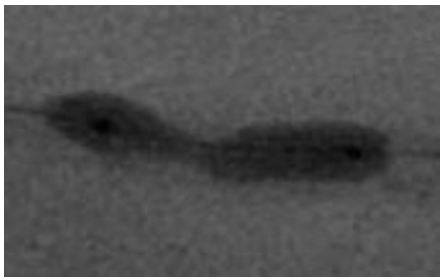
More calcification, worse results



Généreux P; Ischemic outcomes after coronary intervention of calcified vessels. J Am Coll Cardiol 2014;63:1845–54

TREATMENT OPTIONS: MAJOR LIMITATIONS

HIGH PRESSURE BALLOON

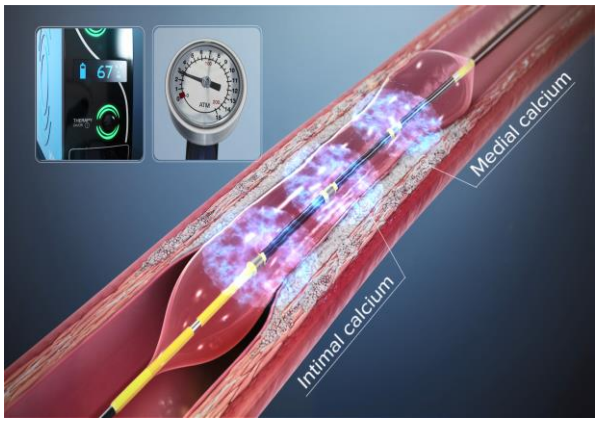


-Constant high pressure damages the intima, causing inflammation, risk of major restenosis and scarring
-Increases risk of dissection

ROTATIONAL ATHETRECTOMY

-Superficial calcium ablation
-Complexity of the device
-Dedicated guides

INTRACORONARY LITHOTRIPSY

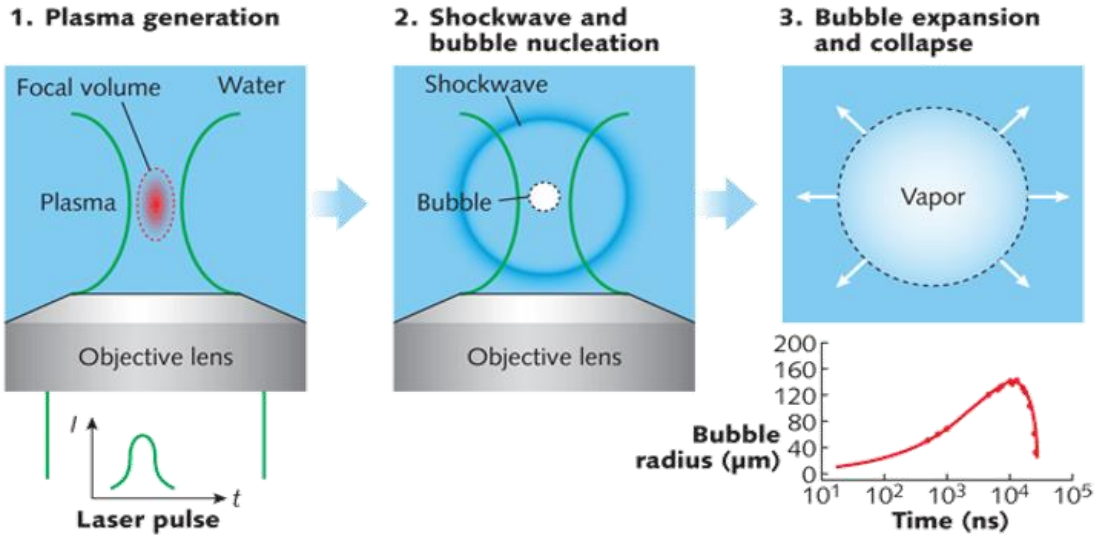


Main limitation: not usable in “uncrossable” lesions”

Selective Absorption:

Cool Laser	308 355	0.05	Protein - Lipids

CAVITATION BUBBLES



- When a laser pulse is highly focused in a liquid medium such as BLOOD and/or contrast medium, the **laser energy generates sound waves** which break down molecules in the liquid and generate hot ionized plasma (6000-15,000 K) near the point focal. On nanosecond timescales, the hot plasma recombines, instantly heats the liquid, and **creates an explosive vapor bubble** that expands at speeds exceeding 100 m/s. The **pressure inside the bubble** can be up to **tens of megapascals**.

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Excimer laser technology in percutaneous coronary interventions: Cardiovascular laser society's position paper

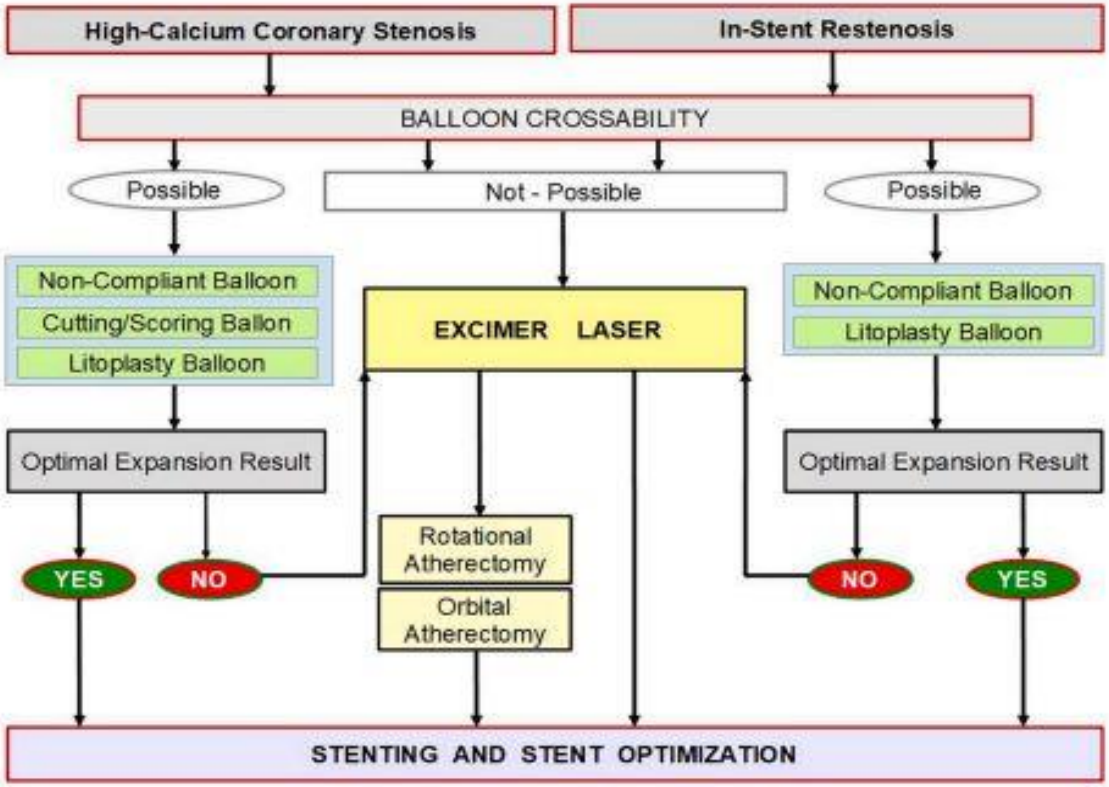
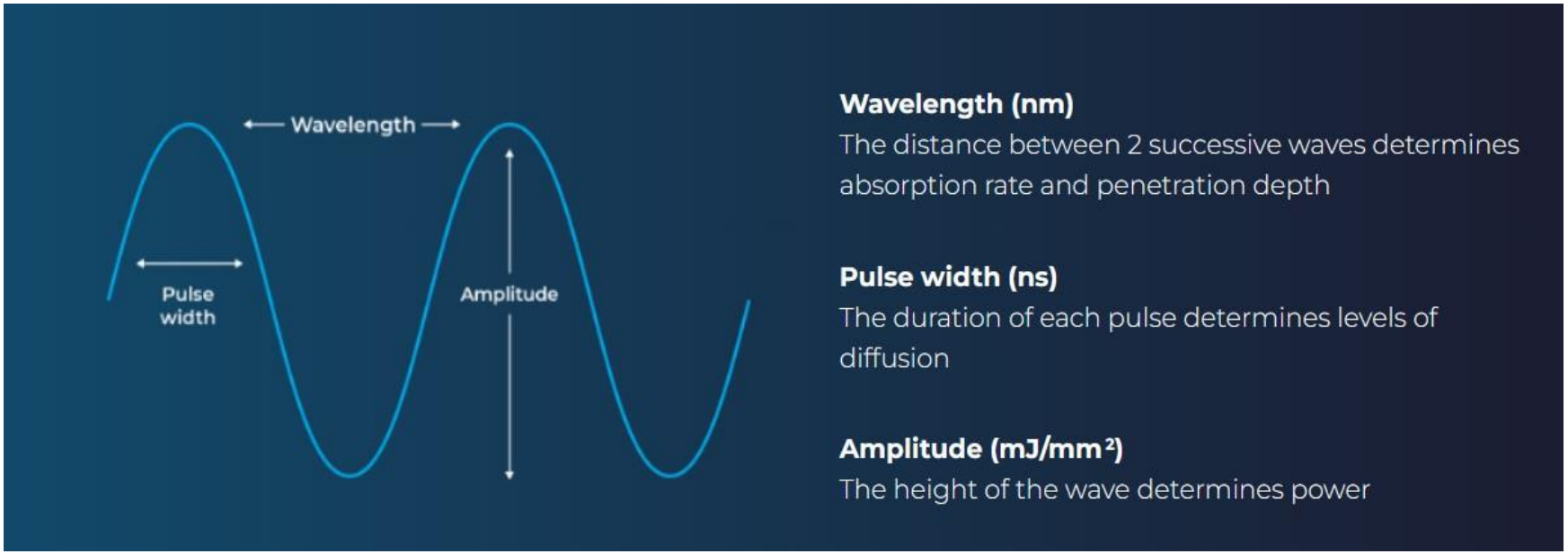


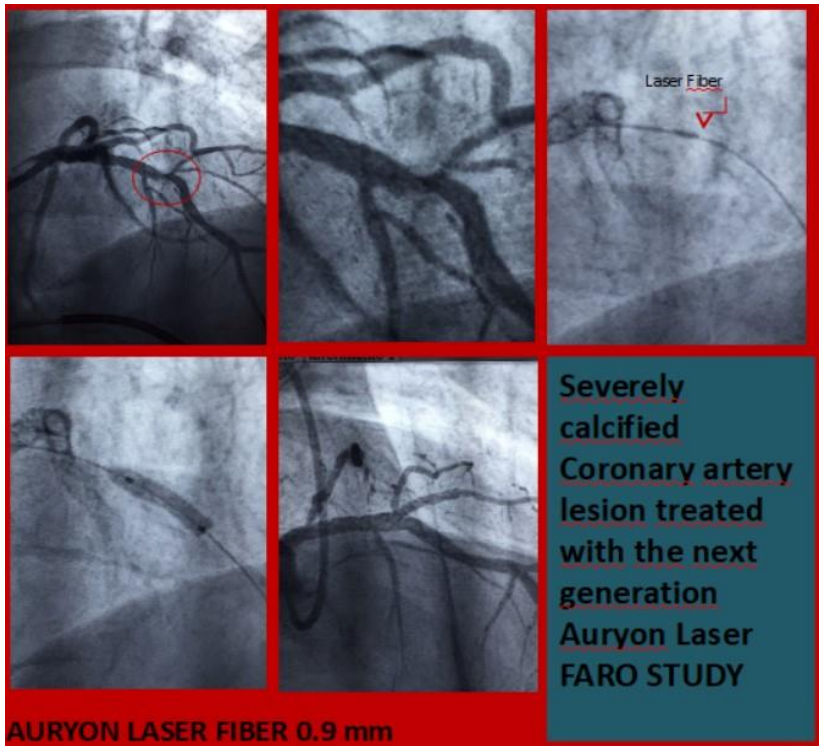
Fig. 3. A step-by-step decision algorithm for the treatment of heavly-calcified coronary lesion and In-Stent restenosis proposed by Cardiovascular Laser Society. It includes the different available techniques to modify the lesion.

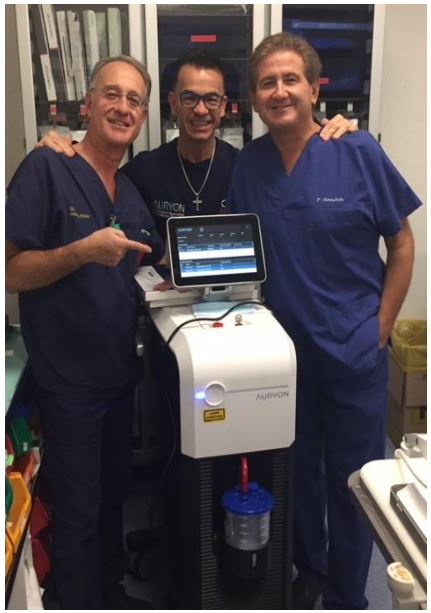
AURYON LASER: NEW HORIZONS IN LASER-ASSISTED ANGIOPLASTY

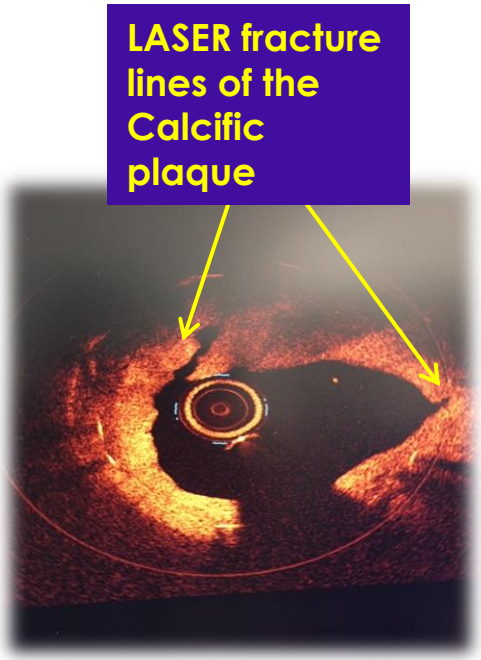


LESS ENERGY DISPERSION, MORE FOCUSED LASER BEAM

Laser For complex coronary Artery lesion pReparatiOn : Faro Pilot Study







PREPARING THE COMPLEX CALCIFIC CORONARY LESION

1. **SAFETY**: investigate the safety of the procedure with the new Auryon Laser and the freedom from major adverse events (**MACE**) at 30 days from the procedure.

2.**EFFICACY**: The primary efficacy endpoint was the average reduction in residual diameter stenosis greater than 50% from baseline achieved by the Auryon -Laser catheter alone

3.Investigated the angiographic and intravascular optimal coherence tomography (OCT) results on the calcific plaque burden

The FARO Pilot Study: inclusion/exclusion criteria

INCLUSION CRITERIA	EXCLUSION CRITERIA
AGE > 18 YR	ACTIVE CANCER
ESTIMATED VESSELS SIZE > 2.5 MM	PREGNANCY
MODERATE/SEVERE CORONARY CALCIFICATION (CALCIUM ARCH > 180 ° REQUIRING DEBULKING SYSTEM (according to the judgement of investigator).	MAJOR BLEEDING
POSSIBILITY TO PERFORM OCT PRIOR TO THE PROCEDURE	

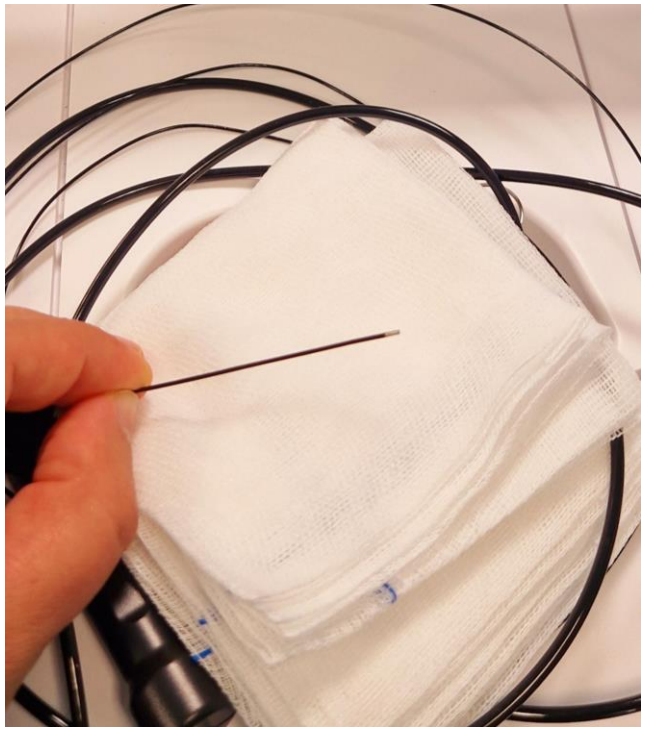
AURYON LASER SYSTEM : technical aspects.

FLUENCY**60 mJ/mm2**
REPETITION RATE: **40 Hz**

0.9 mm CATHETER :

1st gen.
-Over the wire
-Non-radiopaque tip
-Non-hydrophilic catheter
-First 5 patients
-Wire used 0.014” BMW 300 cm
-Catheter lenght 150 cm

2nd gen.
-over the wire
-Radiopaque Tip
-Hydrophilic
-15 patients
-Wire used: SionBlue 0.014” ES 300 cm
-Catheter lenght 150 cm



SAFETY

- **PERFORATION 1**
  CASE (not related to the LASER)
- **DISTAL EMBOLIZATION 0 %**

- **NO REFLOW/SLOW FLOW 1**
  CASE (transitory slow-flow)
- **FLOW LIMITING DISSECTION 0 %**

- **<u>NO MAJOR ADVERSE EVENTS AT 30 DAYS</u>**

EFFICACY

POST-PCI TIMI 3	98%
PROCEDURAL SUCCESS	98%

MEAN STENOSIS IMPROVED FROM 85.5% TO 12% (98%)

QCA > 30%	2% (1 caso)

EFFICACY

CONTRAST MEDIUM (MEAN, ± SD) : 313 ML ± 155

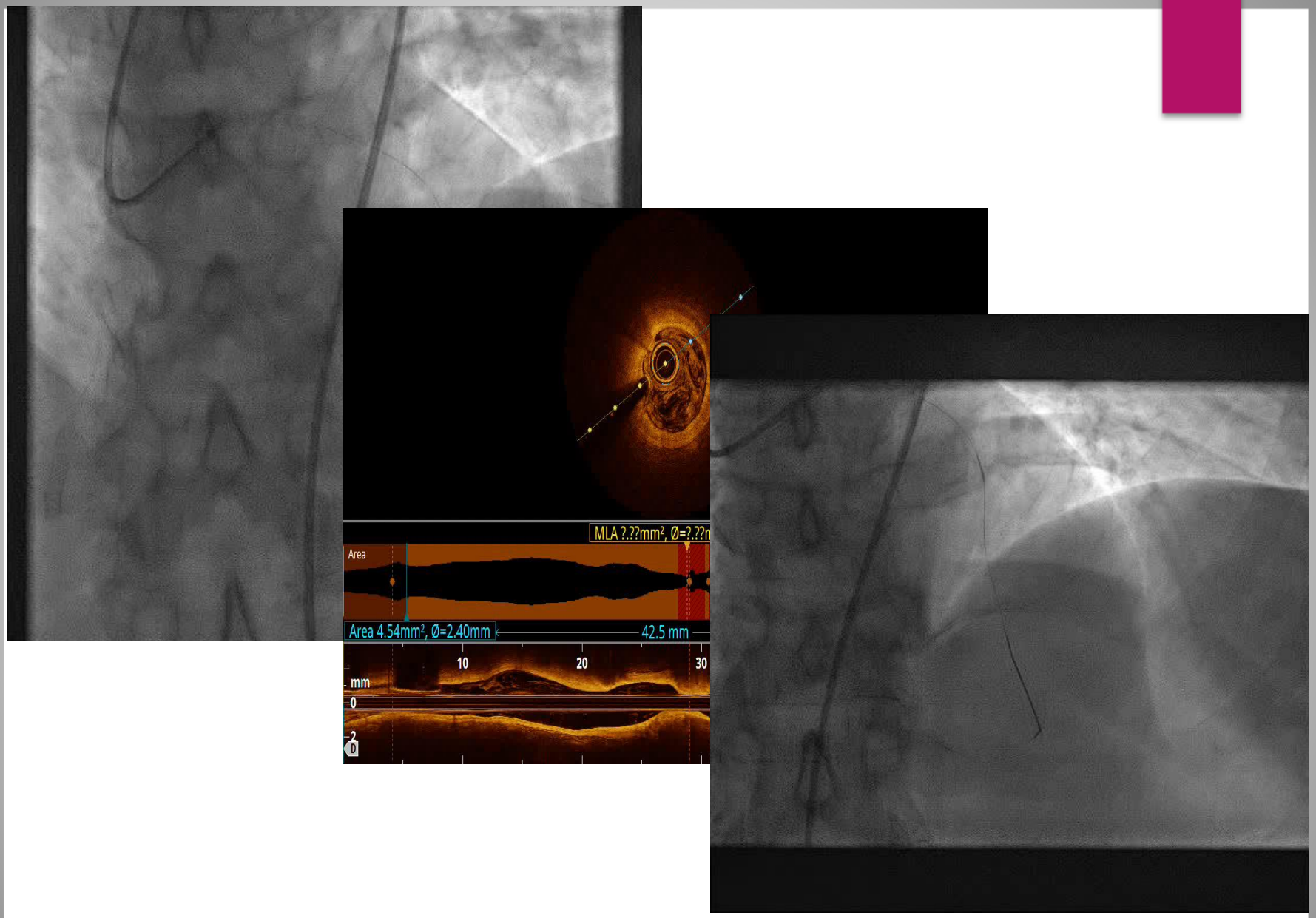
CONTRAST MEDIUM 2nd 15 CASES: 169 ML ± 175

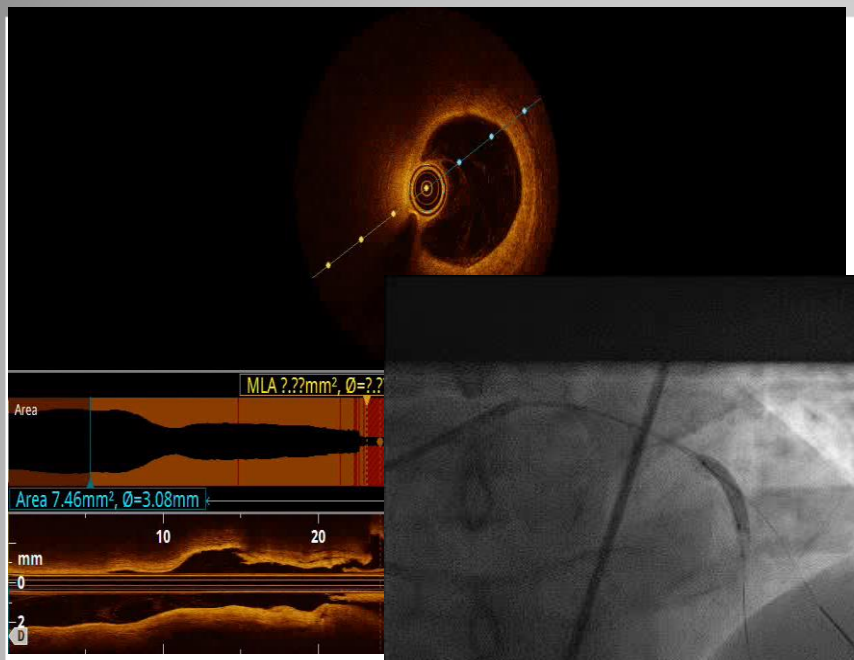
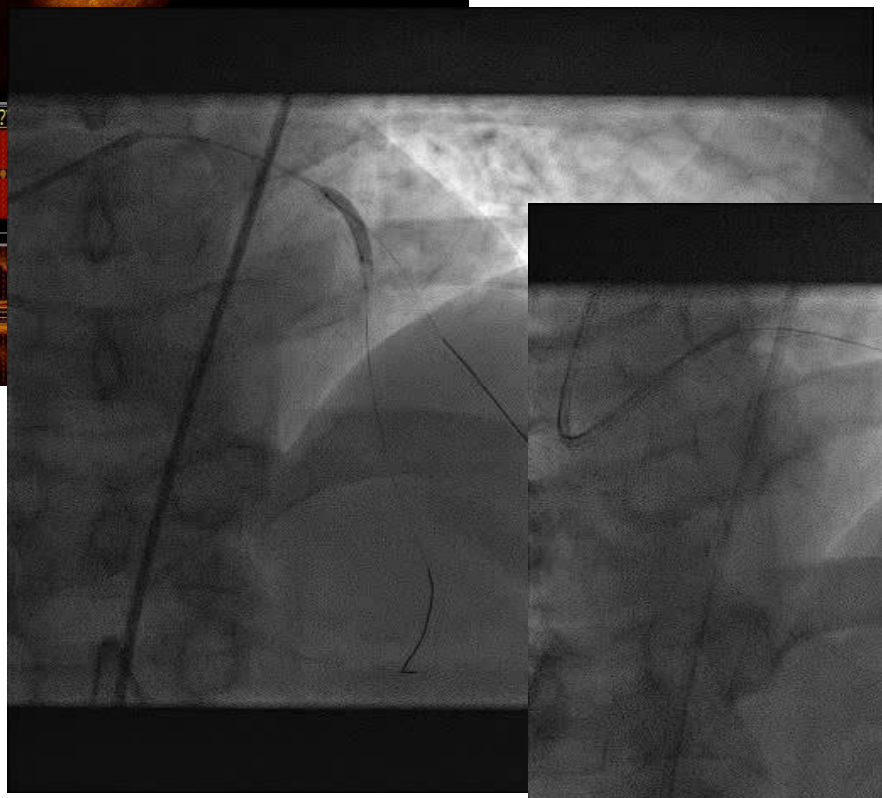
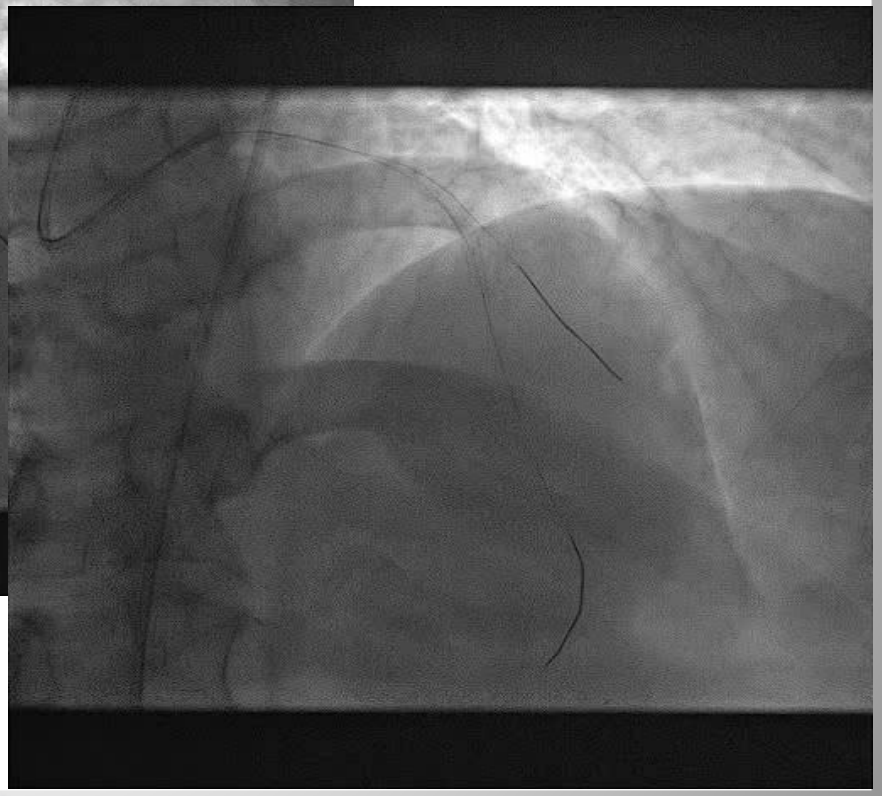
MEAN PROCEDURE TIME : 37.8 MIN.

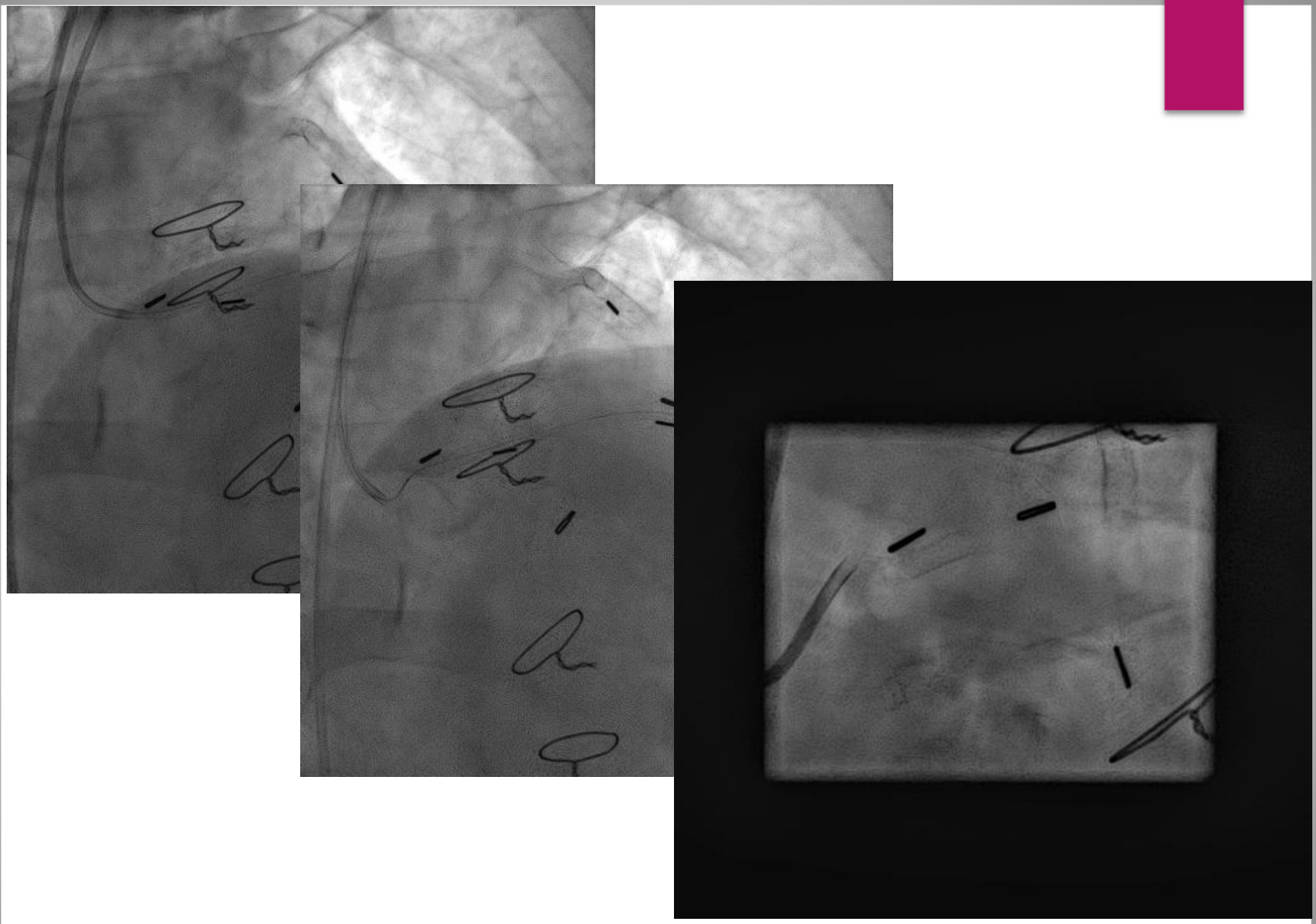
CONCLUSIONS:

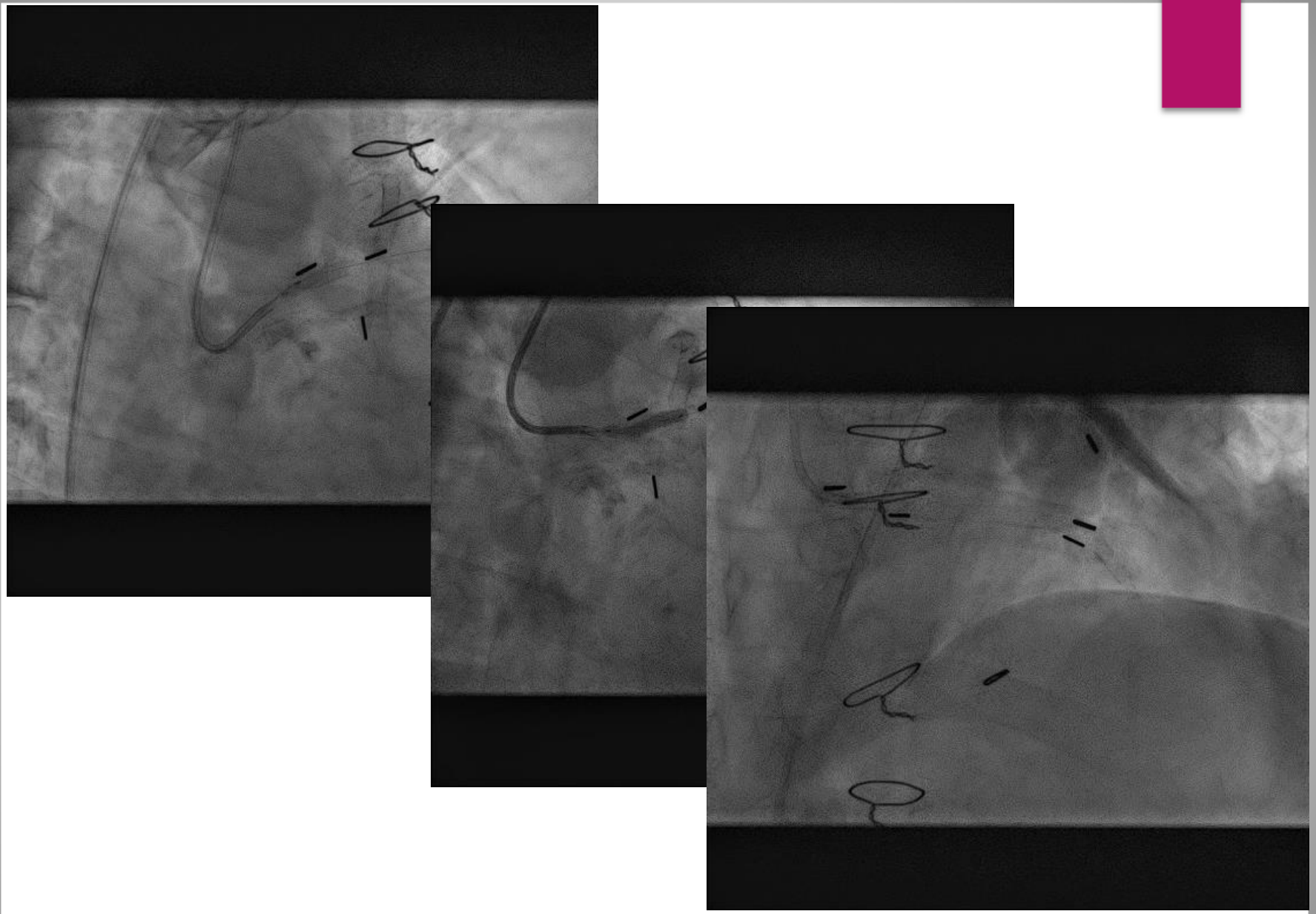
TECHNICAL FEATURES	
Positive	**NEGATIVE**

SAFETY and EFFICACY	IMPROVE THE TRACKABILITY OF THE CATETHER 0,9 mm
EASY TO USE	BEST RADiOPAQUE TIP
VERSATILITY OF THE GENERATOR	MONORAIL


MLA ?.??mm², Ø=?.??m
Area
Area 4.54mm², Ø=2.40mm
42.5 mm
10
20
30
mm
0
2
D


MLA ?.??mm², Ø=?.?
Area
Area 7.46mm², Ø=3.08mm
10
20
mm
0
2
D







AURYON LASER: NEW HORIZONS IN LASER-ASSISTED ANGIOPLASTY

Laser allows you to easily pre-treat severely calcified lesions to allow for successful PCI and prevent the need to consider surgical coronary revascularization such as CABG.

If the strategy is anticipated at the beginning of the case, it allows us to reduce:

- Radiation exposure
- The duration of the procedure
- The contrast load
- The procedural costs
- No need to dedicated guideline
- Useful in crossable or uncrossable stenosis


THANK
YOU