CARDIOVASCULAR LASER SOCIETY

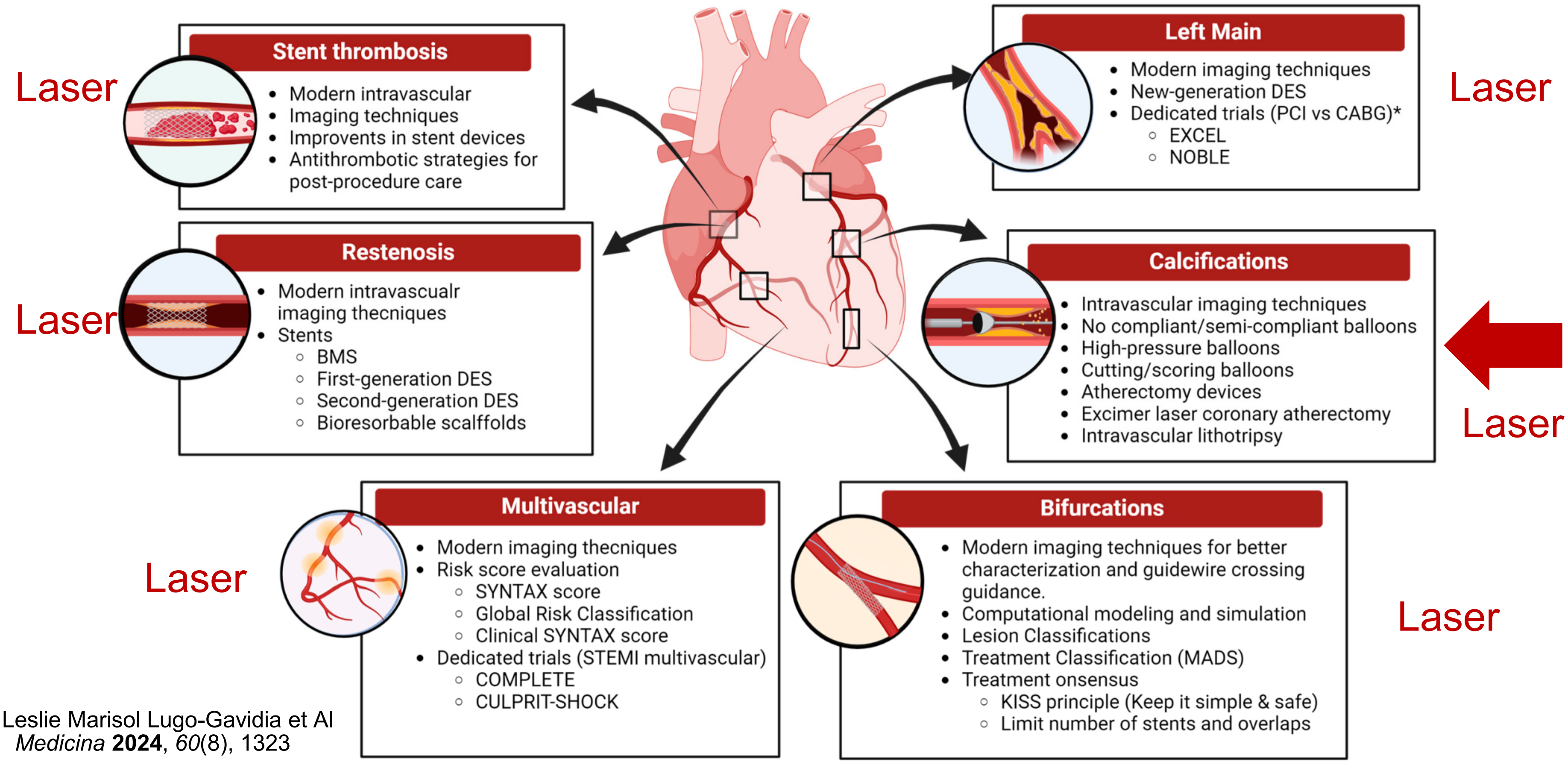
Nuovi avanzamenti tecnologici nel trattamento delle lesioni calcifiche

Pietro Armigliato, MD,PhD, FCLS, FEACTS, FISMCS,FICCS
Cardiovascular Surgeon
Head Micro Cardiac Surgery and Interventional Surgery
Vice President CLS
President CLS FOUNDATION

COLLEGIO
DEI PROFESSORI UNIVERSITARI
DI CARDIOCHIRURGIA
Italian College of Cardiac Surgeons

CLS FOUNDATION

Challenges and Advances in Interventional Cardiology for Coronary Artery Disease Management



Leslie Marisol Lugo-Gavidia et Al
Medicina **2024**, *60*(8), 1323

Lesioni Coronariche Severamente Calcifiche (Severe Coronary Calcific Lesions - SCCL)

Severely calcified coronary lesions (SCCL) represent a huge challenge to perform successful percutaneous coronary interventions (PCI).

Old age, diabetes mellitus, arterial hypertension, chronic kidney disease and smoking are associated **with an increase in coronary calcification.**(1)

Coronary calcium may be underestimated by coronary angiography, and intravascular imaging modalities such as **IVUS** and **OCT**, **CT Angiography should be used for accurate assessment of plaque severity and characterization**.

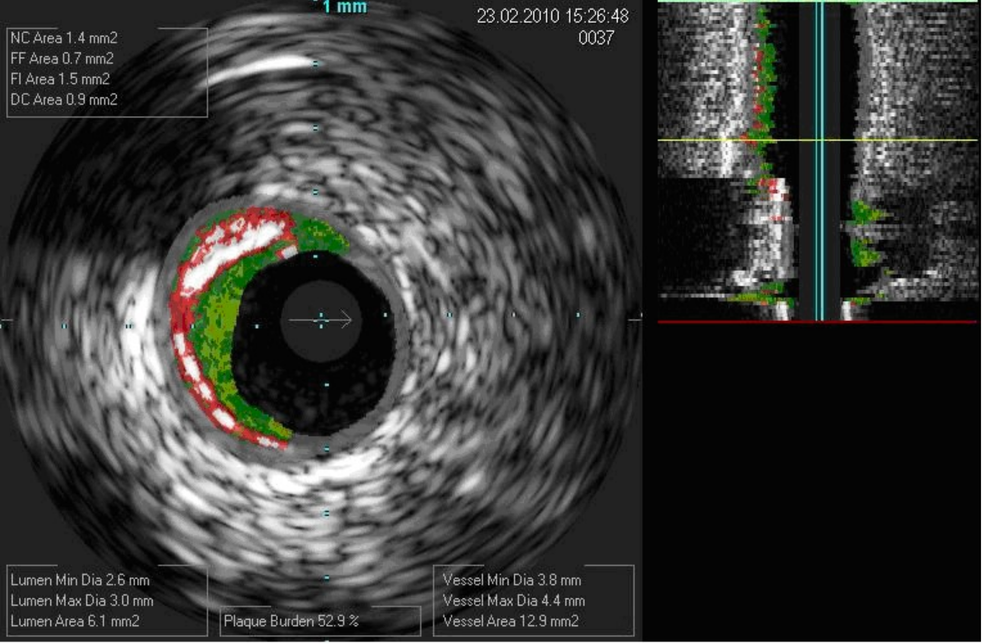
1. Dini CS, Nardi G, Ristalli F, Mattesini A, Hamiti B, Di Mario C. Contemporary approach to heavily
calcified coronary lesions. Interv Cardiol Rev 2019;14:154-63.

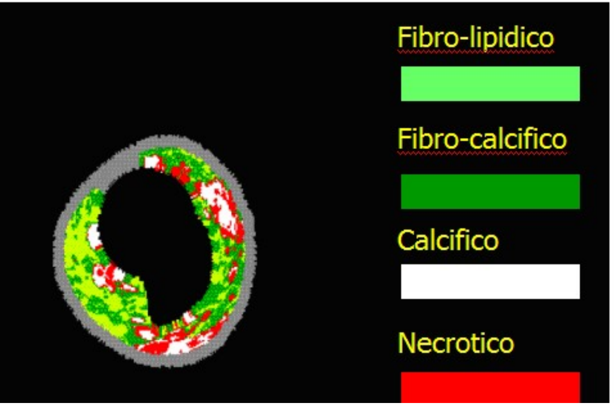
CARDIOVASCULAR
LASER SOCIETY

Severely Calcific Coronary Lesions

- **Coronary calcification** is present in approximately **30% of all lesions using Angiography** alone but this figure increases to **74% when intravascular ultrasound (IVUS)** evaluation is added.(1)
- **Severe coronary calcification increases the complexity of PCI**.(2)
- **It may affect lesion crossing, adequate expansion (underexpansion) and stent apposition (malapposition), directly damage stents, damage drug polymer, increase the risk of stent thrombosis and restenosis, and have a negative impact on outcomes at short and long term**.(3-4)

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
2. Arora S et al. Coronary Atherectomy in the United States (from a Nationwide Inpatient Sample). Am J Cardiol 2016;117:555-562.
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.
4. Riley RF et al. SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions J of the Society for Cardiovascular Angiography & Interventions Volume 3, Issue 2, February 2024





VirtualPlaque Histology with IVUS and OCT

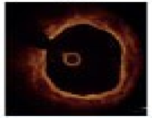
	Angiografia 	IVUS 	OCT 
Distribuzione	+	+ + +	+ + + +
Localizzazione	+	+ + + +	+ + +
Quantificazione	+	+ + +	+ + + +
Arco di calcio	✖	+ + + +	+ + + +
Lunghezza	✖	+	+ + + +
Spessore	✖	✖	+ + + +

Figura 1. Accuratezza nella caratterizzazione del calcio mediante angiografia e imaging coronarico.
IVUS, ecografia intravascolare; OCT, tomografia a coerenza ottica.

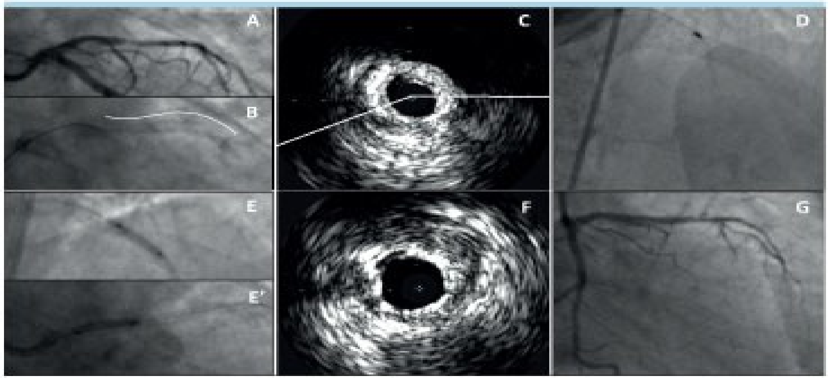


Figura 2. Malattia severamente calcifica dell'arteria interventricolare condizionante stenosi critica al tratto medio (*A,B*); All'ecografia intravascolare conferma dell'elevato grado di calcificazione ed evidenza di arco di calcio >180° (*C*). La terapia con Rotablator (fresa da 1.50 mm) (*D*) risulta efficace come dimostrato dalla piena espansione dei palloni (*E,E'*). Risultato angiografico finale (*G*) con valutazione finale all'ecografia intravascolare (*F*).

Distribution of Calcium in the Plaque

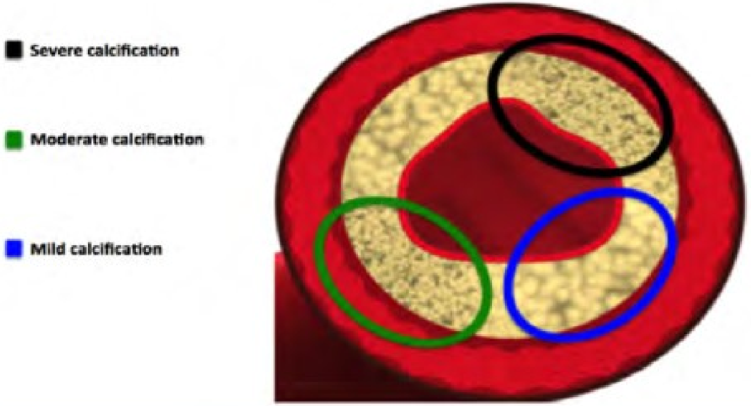
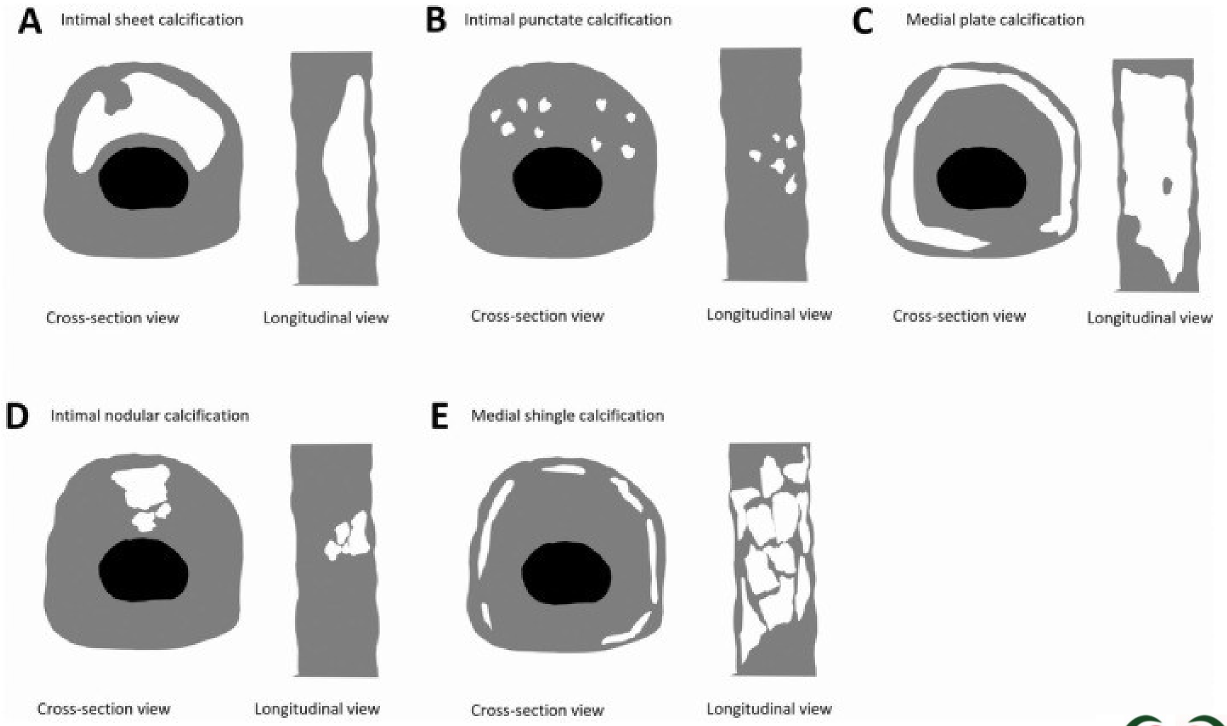


Figure 5. Variable densities of peripheral calcium deposition in the arterial wall. Peripheral plaque is composed of variable layers and islands of different densities that are mildly, moderately, and severely calcified. These densities have a different depth, width, shape, and location. Image courtesy J.A. Mustapha, MD

Densità variabile del deposito di calcio nella parete arteriosa. Il deposito di calcio è composto da strati e isole variabili di densità diverse che sono leggermente, moderatamente e gravemente calcificate. Queste densità hanno profondità, larghezza, forma e posizione diverse.

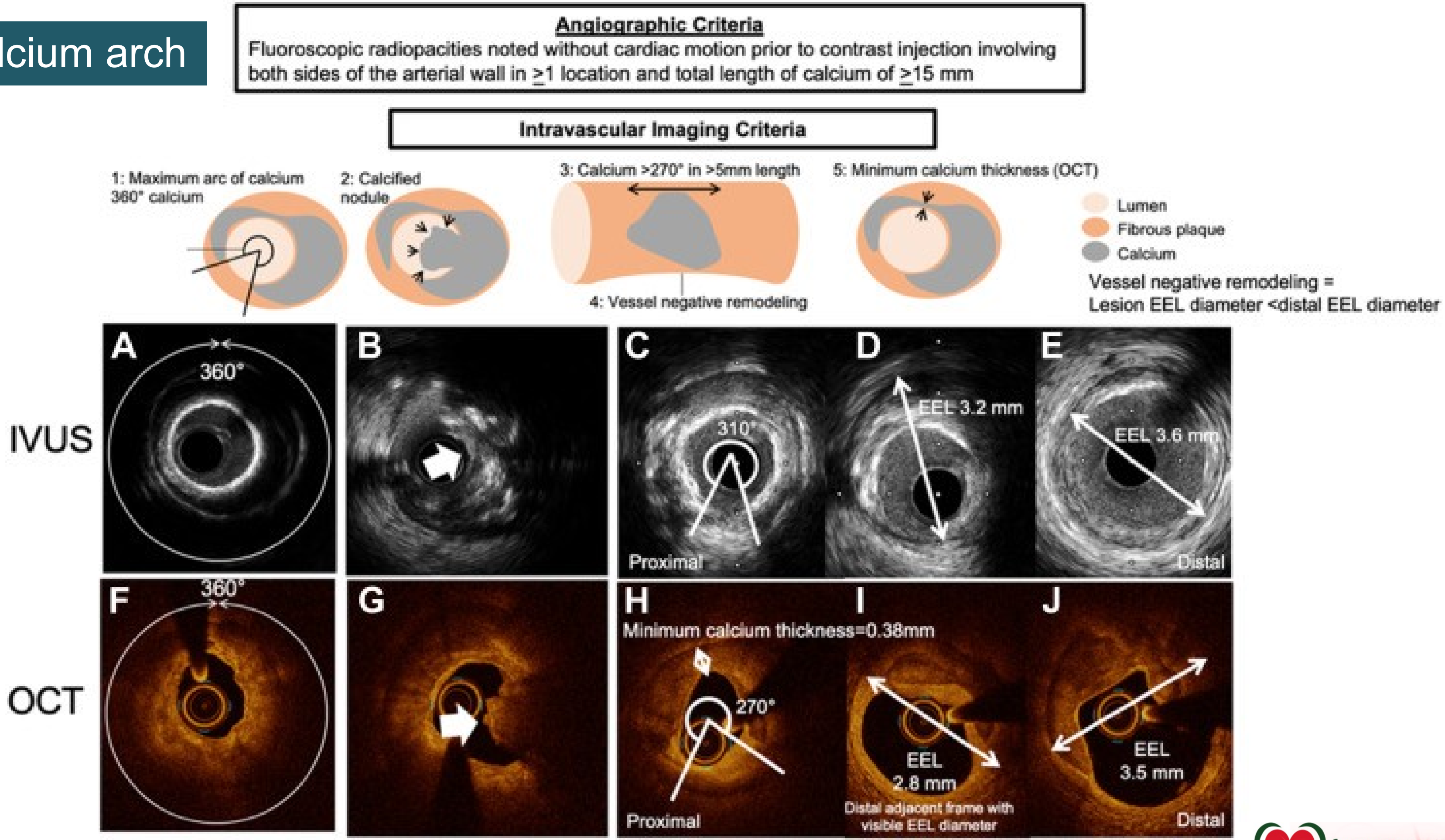
Mustapha J.A. VASCULAR DISEASE MANAGEMENT 2013

Severely Calcific Coronary Lesions
Distribution of Calcium in the Artery



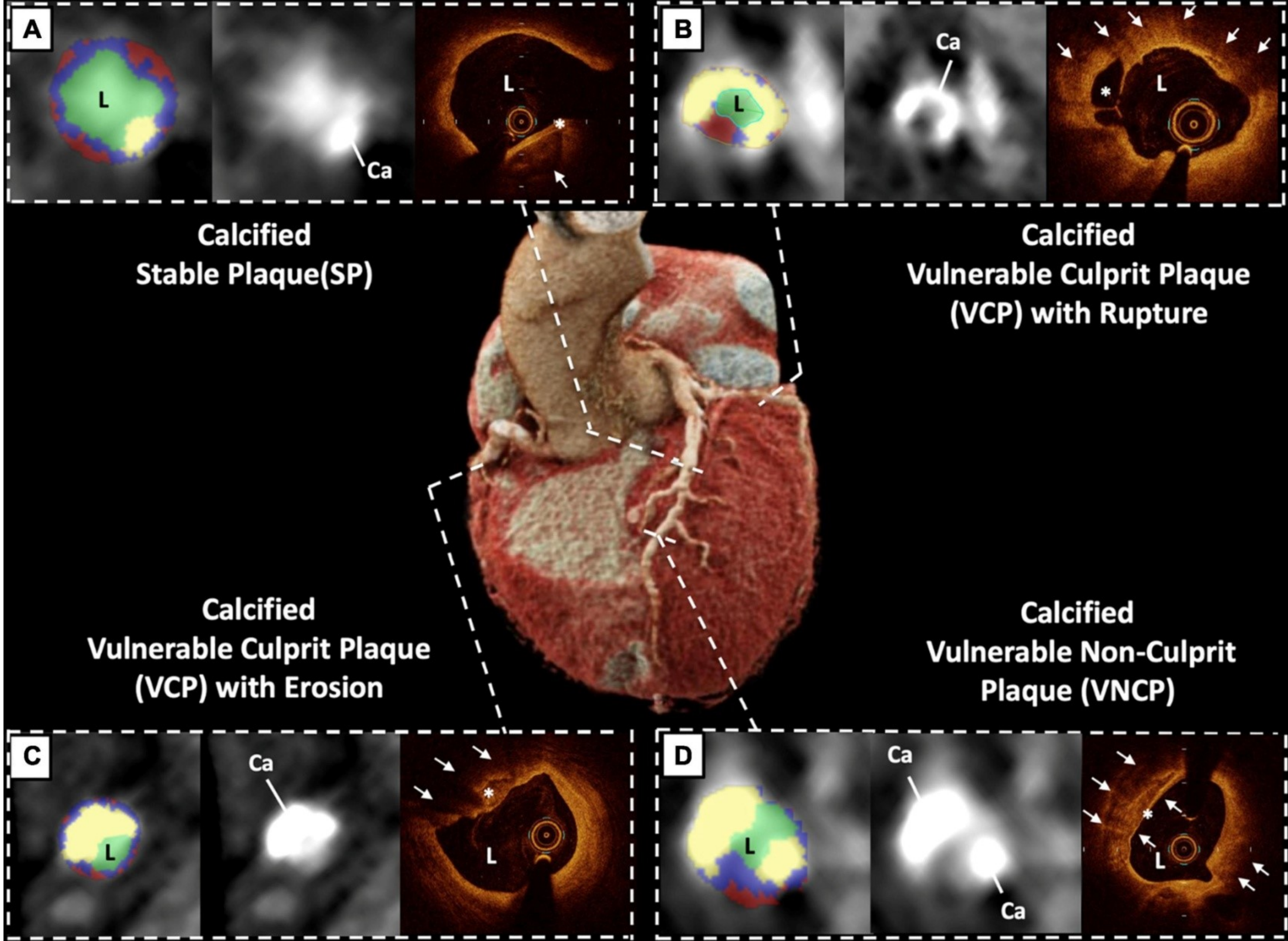
Cardiovascular Laser Society

Calcium arch



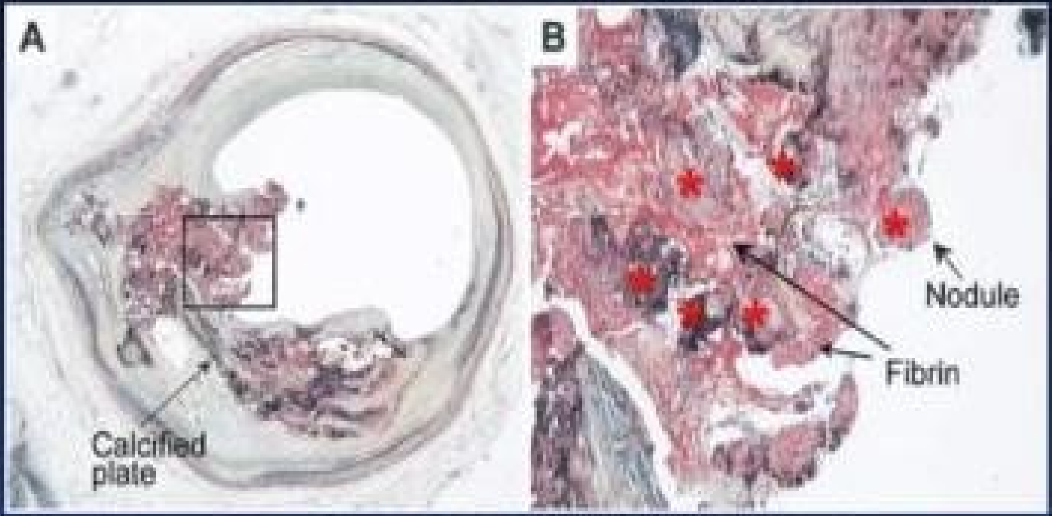
Coronary Computed Tomography Angiography Analysis of Calcium Content in Patients With Acute Coronary Syndrome

T. Pezel et al
Front. Cardiovasc. Med., Vol. 9 2022



Calcified Nodule

Distribution
Localization
Quantification



Virmani R et al. J Am Coll Cardiol 18;47:C13-8.

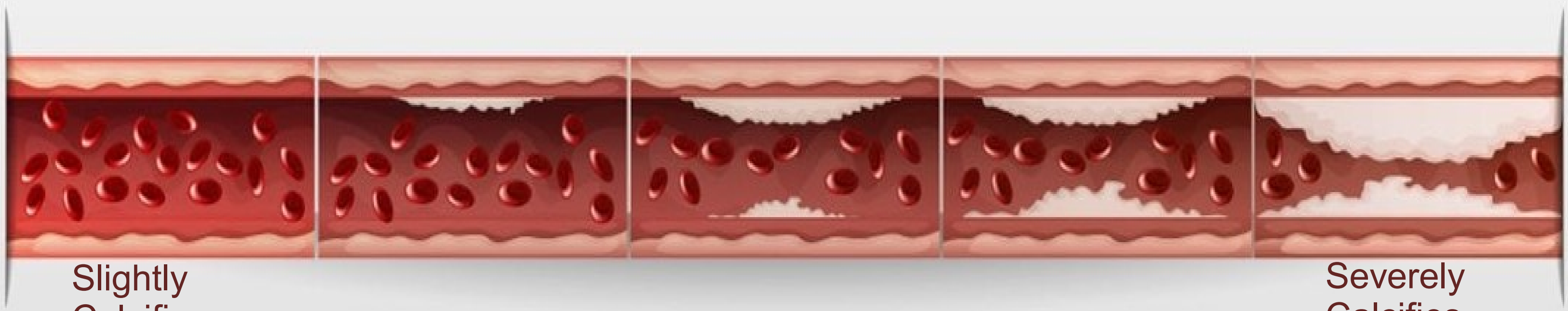
Primary Objective of Plate Preparation

The primary goal of plaque preparation today is to modify the plaque itself to facilitate optimal stent placement and expansion in heavily calcified vessels.

Today, to meet this need, **several dedicated devices are available** for the choice of which an optimal approach to the lesion is essential.

CARDIOVASCULAR LASER SOCIETY

Plaque Morphology and Therapeutic Strategy



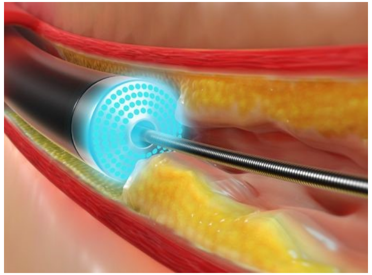
Slightly Calcifies

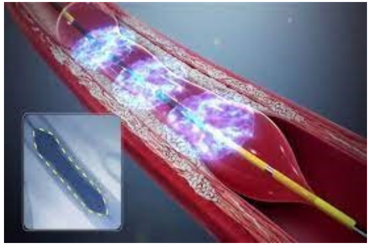
Severely Calcifies

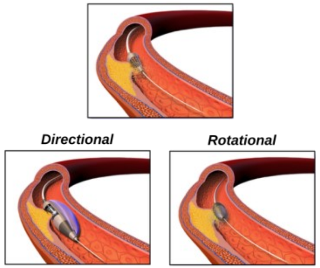
POBA
(Plain Old Balloon Angioplasty)

Cutting Balloon
Scoring Balloon
Chocolate Balloon

LASER
Aterectomia
Litotrissia IV







Types of Atherectomy

CARDIOVASCULAR LASER SOCIETY

Calcific Lesion Preparation Systems

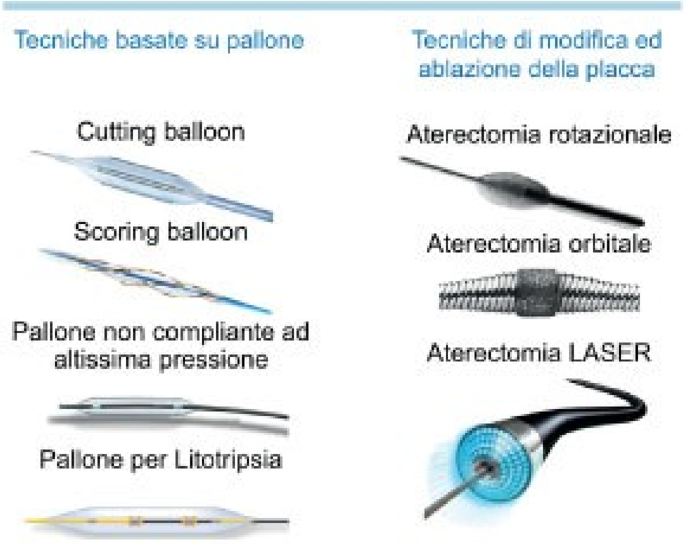


Figura 1 Tecniche di preparazione delle lesioni calcifiche basate su pallone e tecniche di modifica e ablazione della placca calcifica.

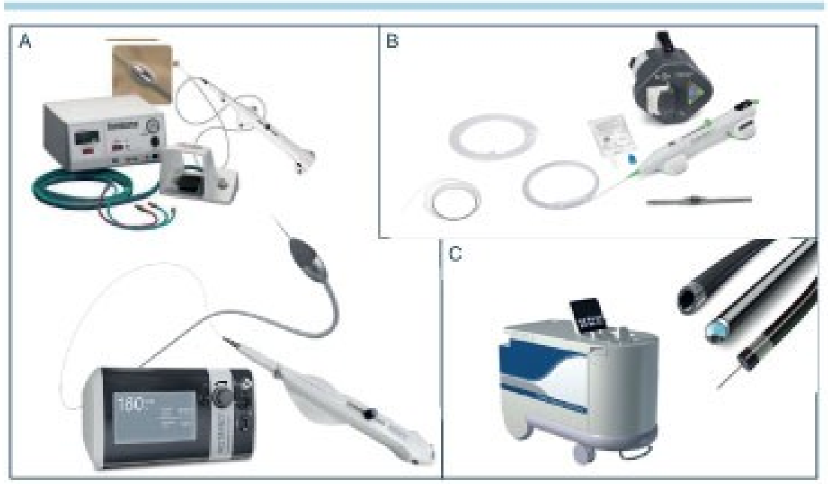


Figura 2 (*A*) Rotablator e Rotapro (Boston Scientific, Natick, MA, USA); (*B*) Diamondback 360® Coronary System (Cardiovascular Systems Inc., St. Paul, MN, USA); (*C*) CVX-300 (Philips, Amsterdam, Olanda) Excimer Laser System.

Cardiovascular Laser Society

Mechanisms of Action

The effectiveness of dedicated balloons, atherectomy and lithotripsy is however limited by:

- **Incrociabilità della lesione**
- **Guide rigide dedicate**
- **Tortuosità anatomiche (curve)**
- **Calcificazioni profonde**
- **Calcificazioni spesse**
- **Distribuzione eccentrica del calcio**

scenarios in which the LASER has proven to be more effective

CARDIOVASCULAR LASER SOCIETY

Cold Laser at 308 (old Laser) and 355 nm (new Laser) Characteristics

308 nm and 355 nm UV lasers have very particular characteristics:

- The energies carried by the photons are high enough to **break molecular bonds**

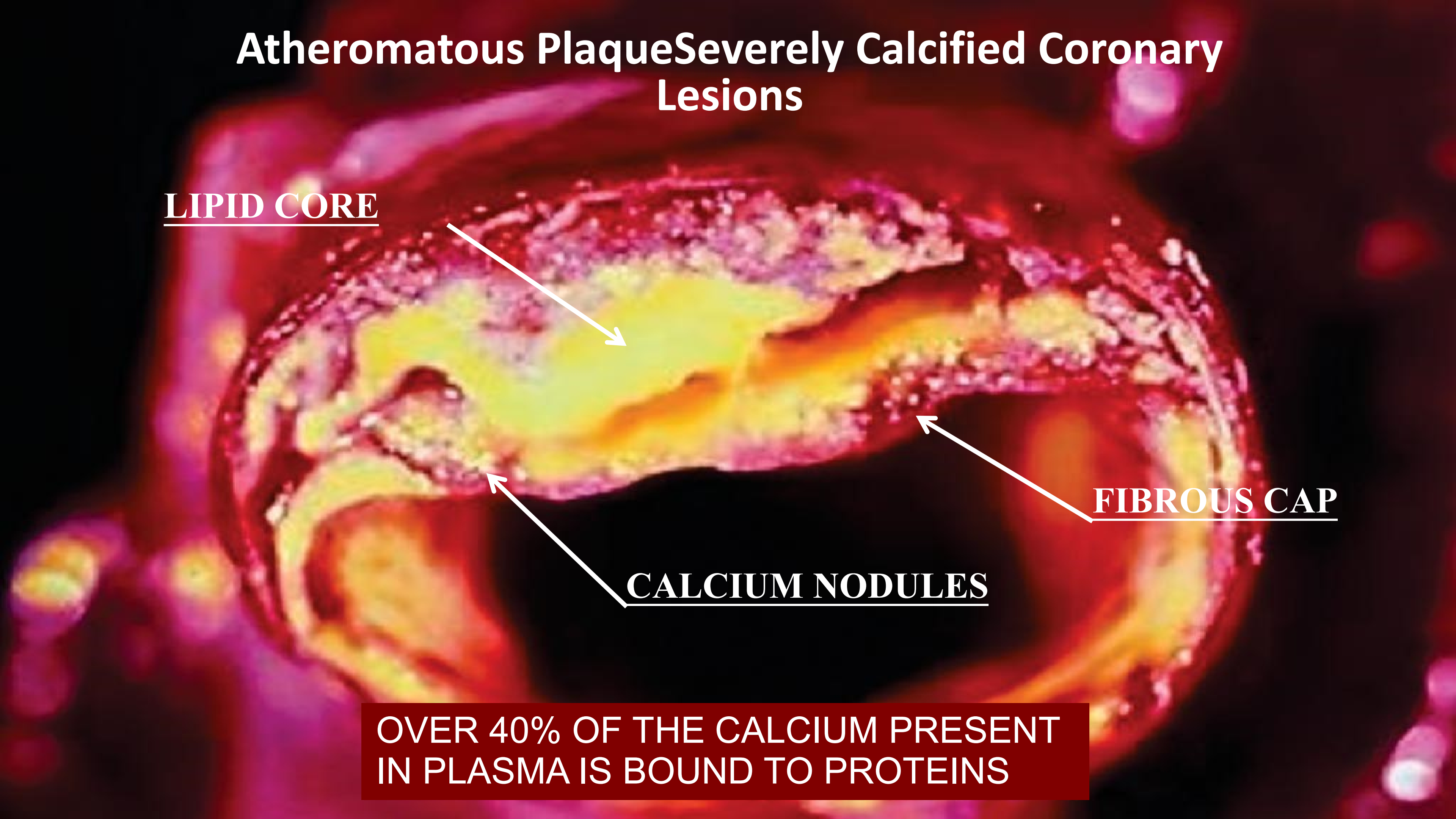
- They have a surface absorption depth of less than 100 microns:
  - with reduction of the energy needed to remove matter (355 nm)
    - with reduction of side effects on biological tissue (355 nm)

- They are pulsed lasers.

ENERGY IS ABSORBED SELECTIVELY (355 nm)

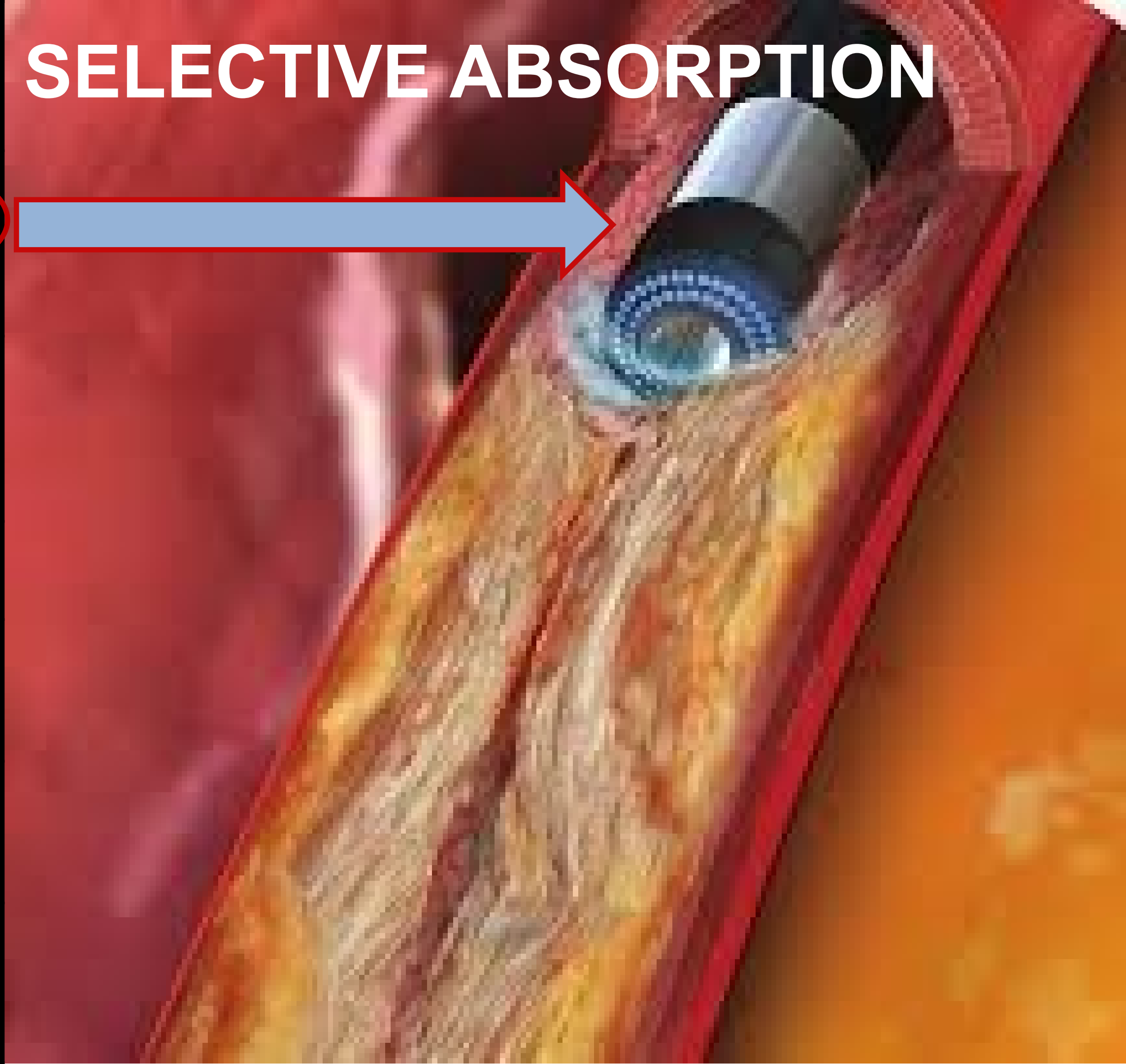
CARDIOVASCULAR LASER SOCIETY

Atheromatous PlaqueSeverely Calcified Coronary Lesions

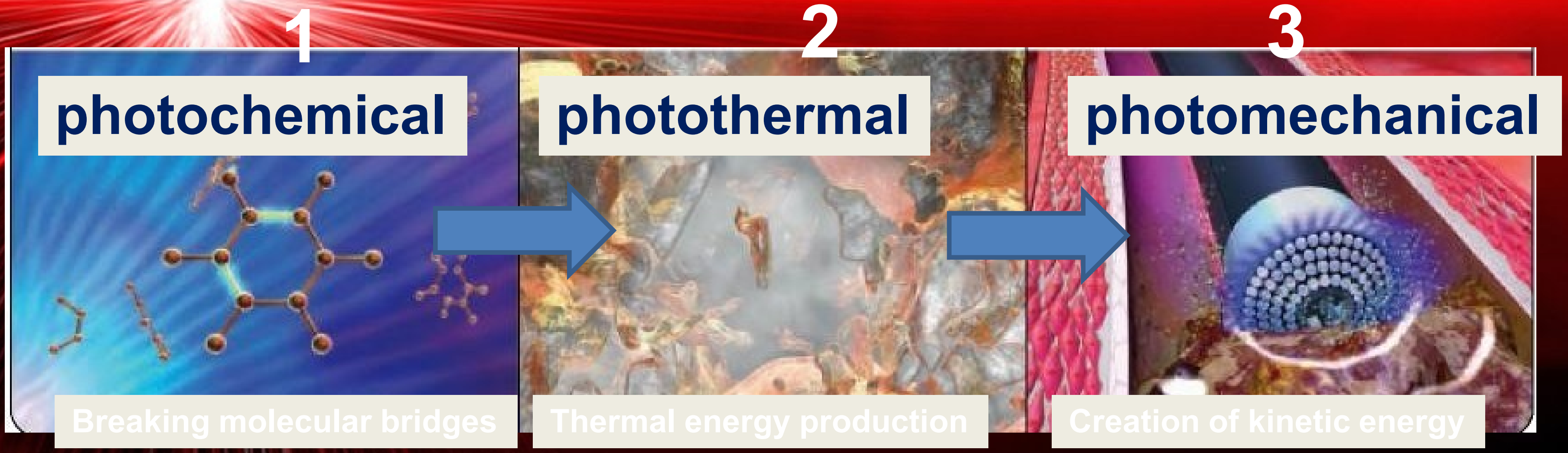


OVER 40% OF THE CALCIUM PRESENT IN PLASMA IS BOUND TO PROTEINS

Laser	Wavelength nm	Absorption Depth (mm)	Absorption Mechanism
XeCl	308	0.05	Protein - Lipids
Nd:YAG	1060	2.0	Protein - Water
Dye	480	0.5	Protein
Argon	488	0.5	Protein
Ho:YAG	2060	0.3	Water
Nd:YAG	1320	1.25	Water

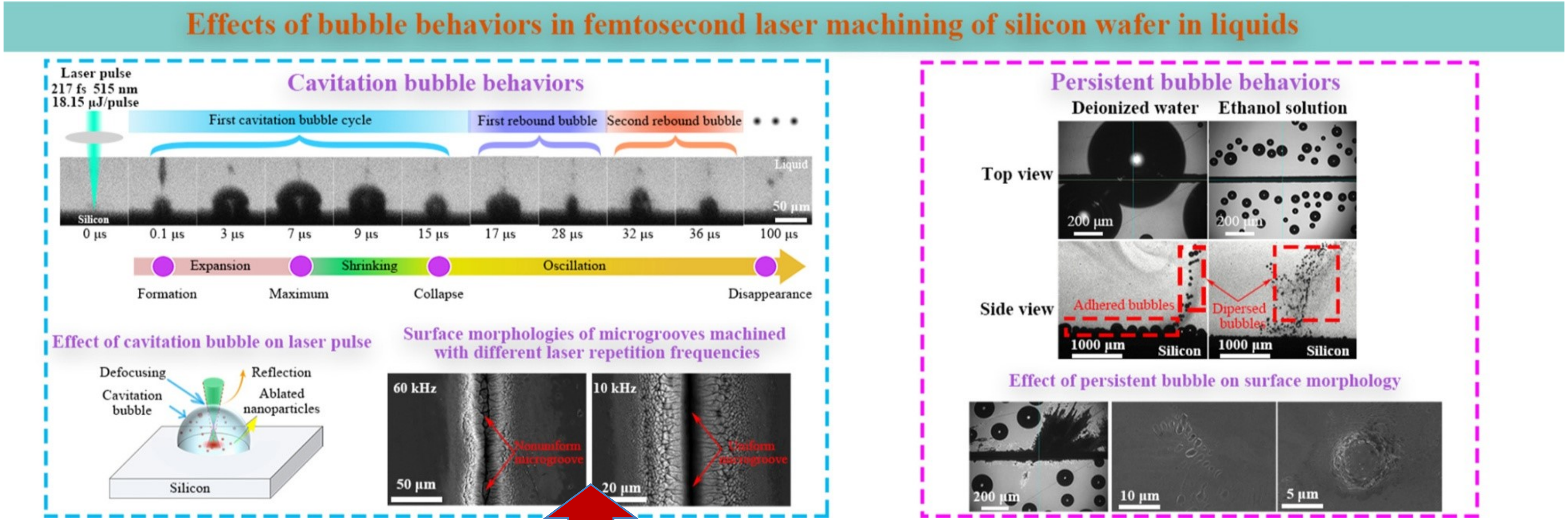


Cascade mechanisms of action of laser photoablation



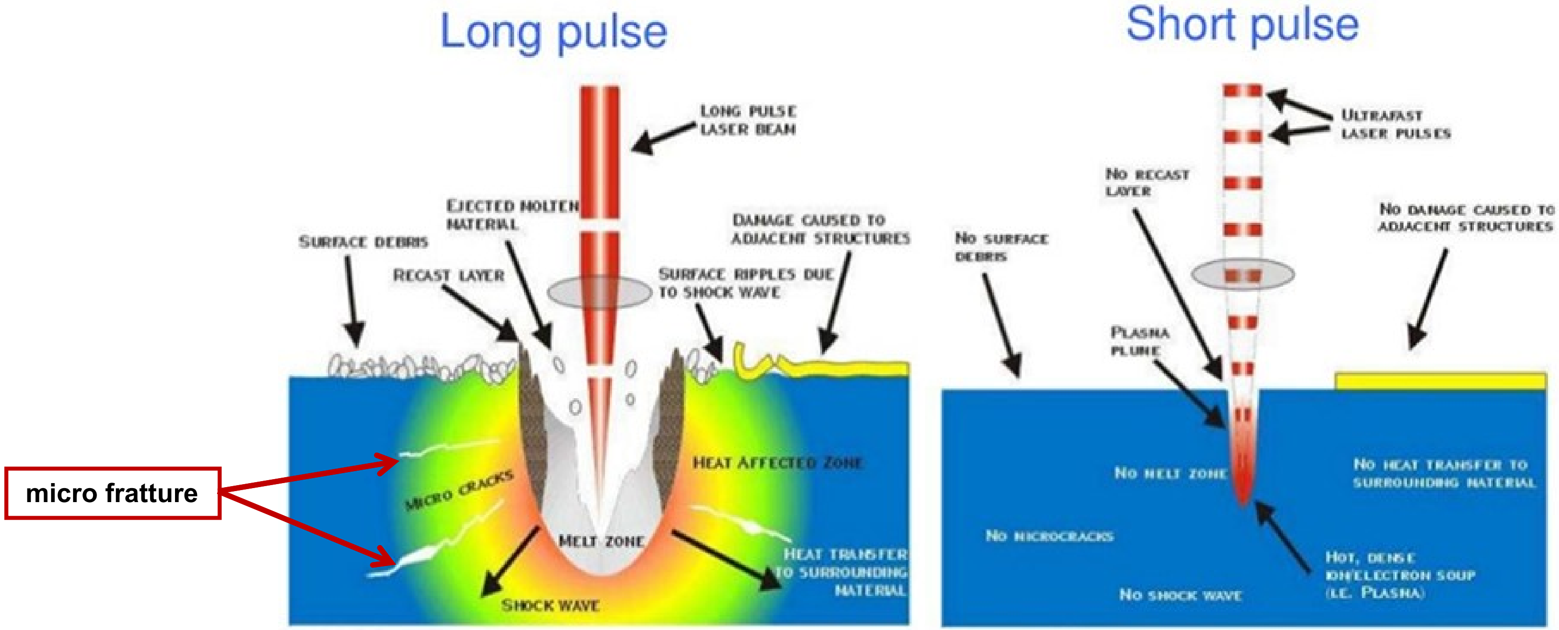
Severely Calcific Coronary Lesions

COMPORTAMENTI DELLE BOLLE DI CAVITAZIONE

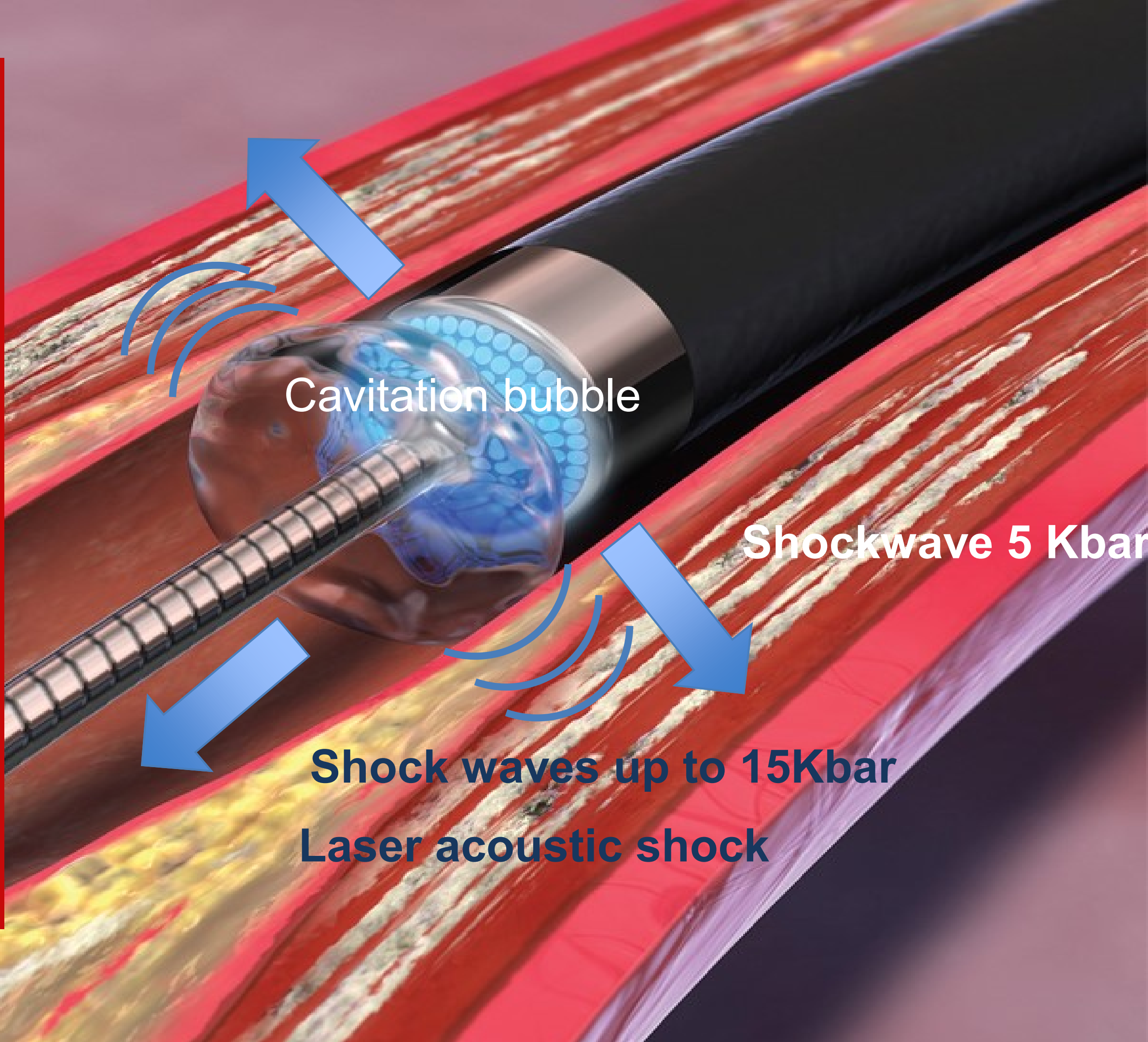


morfologie superficiali delle microfratture
generate con diverse frequenze di ripetizione laser

Severely Calcific Coronary Lesions
COMPORTAMENTI DELLE BOLLE DI CAVITAZIONE

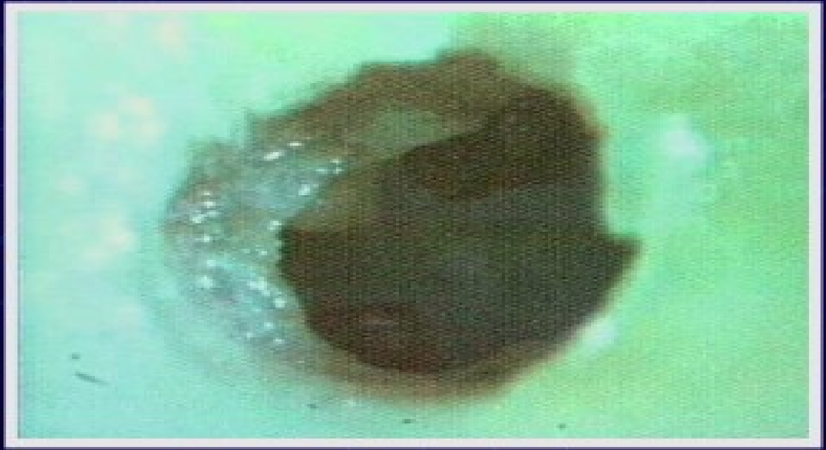


- The vibrations cause the heating of the intracellular water which evaporates and causes the cellular explosion.
- The cellular explosion forms a VAPOR BUBBLE in 100 millionths of a second.
- The expansion and collapse of the vapor bubble causes the disintegration of the plaque in front of the laser probe
- and at the same time causes the emission of ACOUSTIC SHOCK WAVES which propagate radially.
- The by-products of photo-ablation are made up of water, gas, and micro-particulates (<7μ)



Penetration of Calcium

Human cadaver calcified plaque, 1 mm thick



1.4 mm catheter, 60/40, 65 seconds

0.9 mm catheter, 80/80, 33 seconds

Severely Calcific Coronary Lesions

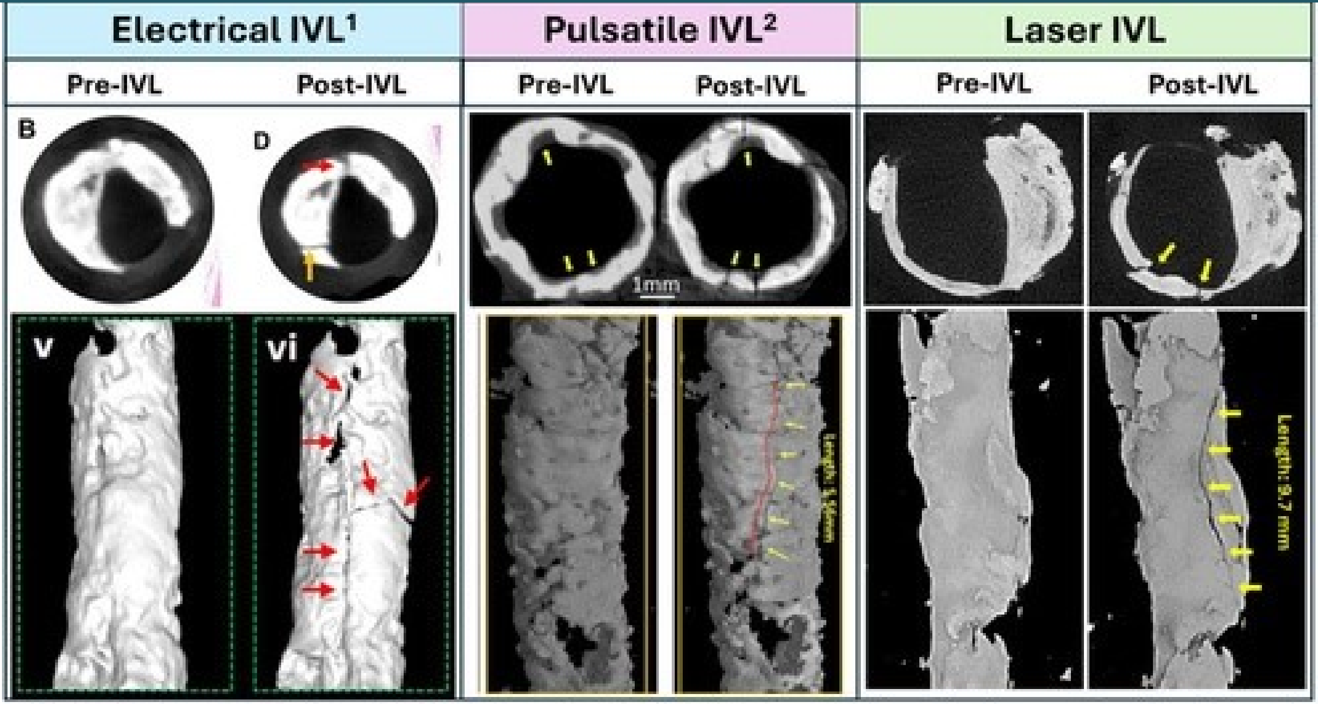
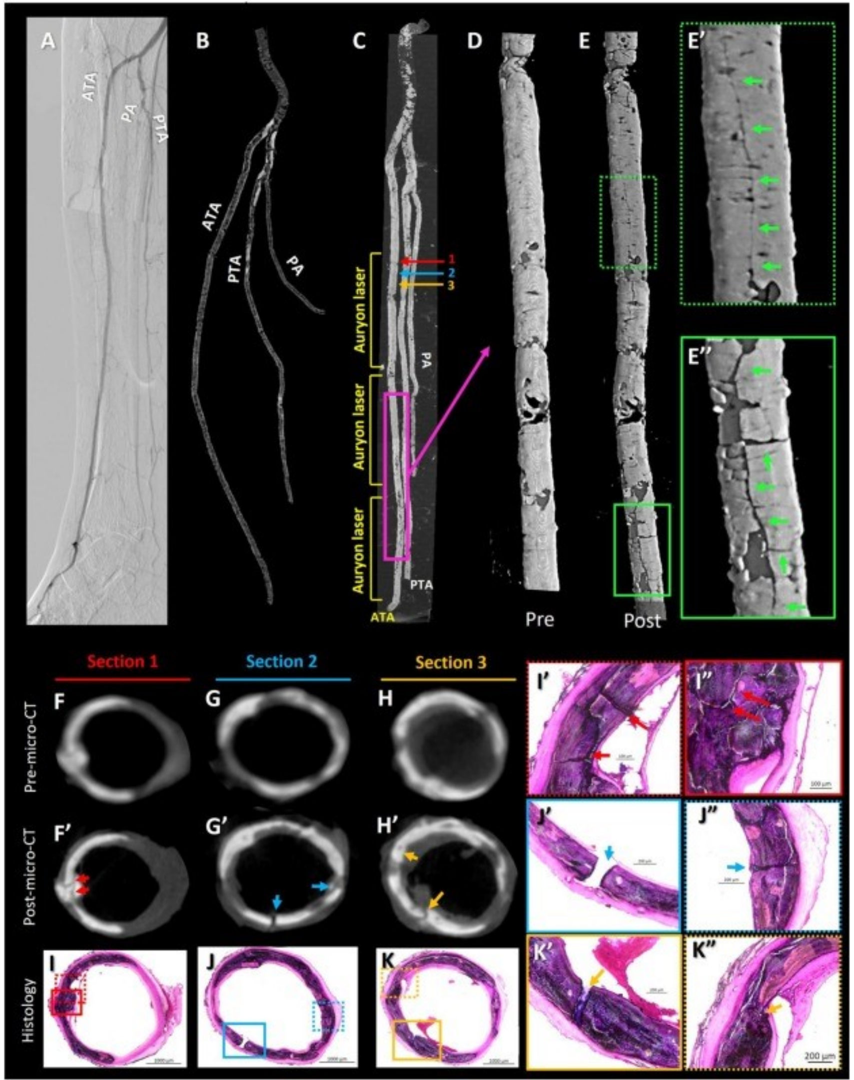


Figure 1. Representative μCT images showing similar longitudinal fractures despite different Intravascular Lithotripsy (IVL) energy sources on calcified human arteries.

(1) K. Kawai et al. JACC: Cardiovascular Intervention. 2023;16(17):2097-2108. (2) R. Virmani et al. Cardiovascular Revascularization Medicine. 2023;50:43-53.

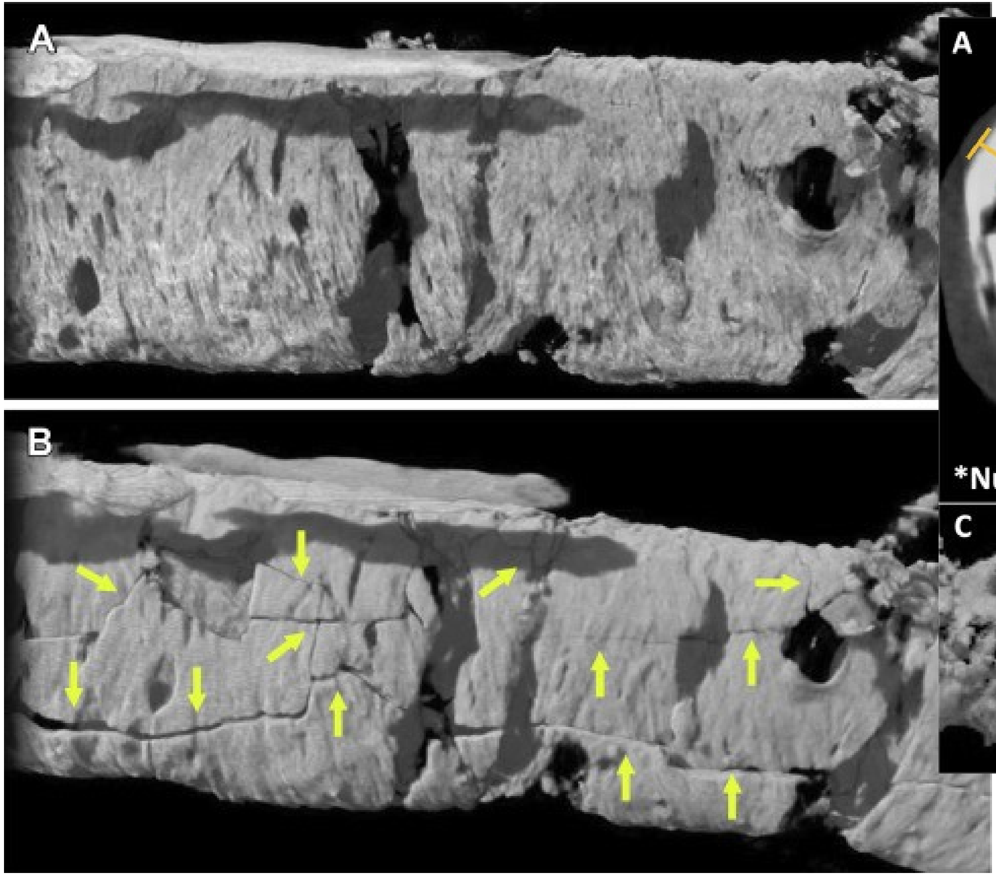
Treatment effect of medial arterial Calcification after Auryon Laser Atherectomy using micro-CT and Histologic evaluation

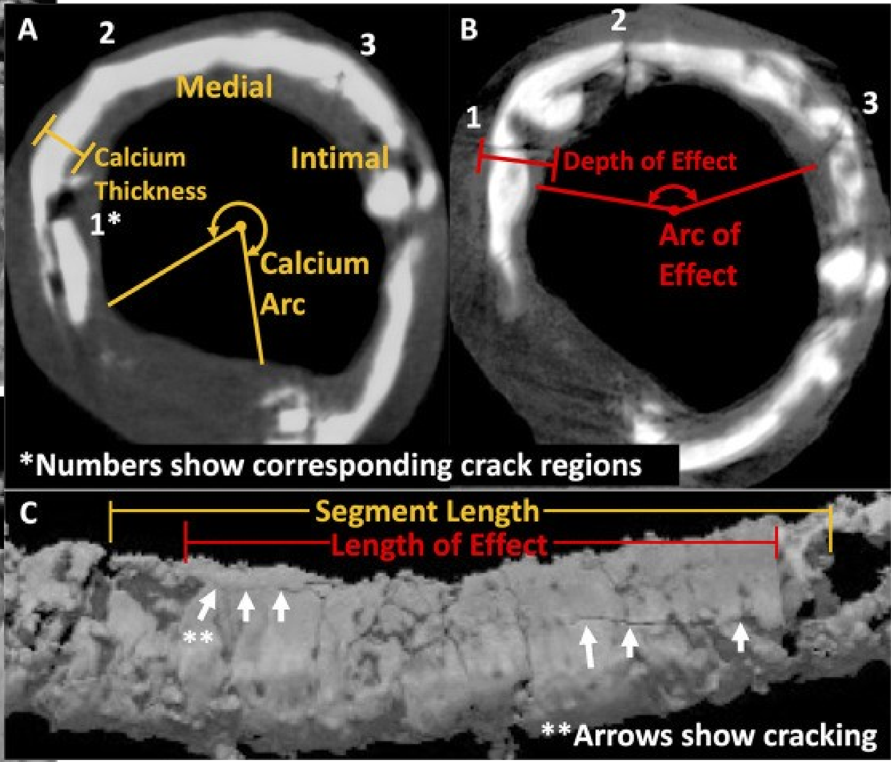


L'aterectomia laser Auryon ha prodotto fratture di calcificazione arteriosa mediale in questo modello di arteria periferica aterosclerotica umana cadaverica. Questo effetto è stato osservato in segmenti arteriosi con un modello di calcificazione circonferenziale ininterrotta (vale a dire arco di calcificazione più ampio) indipendentemente dal carico di calcio. I nostri dati pilota suggeriscono che il laser Auryon potrebbe essere una terapia promettente per le lesioni calcificate.

John Rundback et al
Cardiovascular Revascularization Medicine
Vol 57 Dec 2023

Severely Calcific Coronary Lesions





CARDIOVASCULAR LASER SOCIETY

ELCA TECHNIQUE: THE EXCIMER LASER IN COMPLEX CALCIFIC LESIONS

Contents lists available at ScienceDirect

International Journal of Cardiology

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

ELSEVIER

CARDIOLOGY

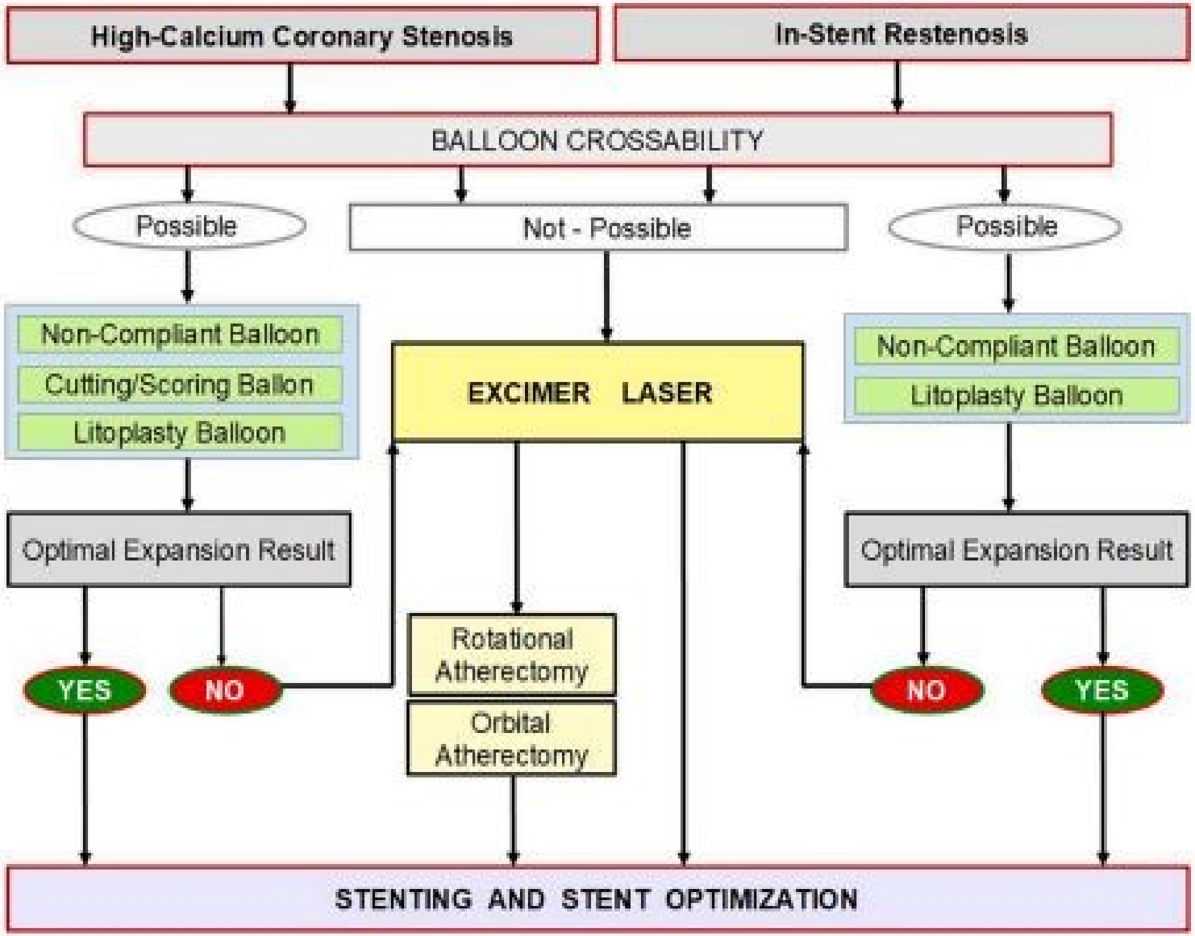
Excimer laser technology in percutaneous coronary interventions: Cardiovascular laser society's position paper

L. Golino [a,*], G. Caiazzo [a], P. Calabrò [b], A. Colombo [c], M. Contarini [d], F. Fedele [e], G. Gabrielli [f], A. R. Galassi [g], P. Golino [h], F. Scotto di Uccio [i], G. Tarantini [j], V. Argentino [m], M. Balbi [n], G. Bernardi [o], M. Boccalatte [p], R. Bonmassari [q], G. Bottiglieri [r], G. Caramanno [s], F. Cesaro [t], E. Cigala [u], G. Chizzola [v], E. Di Lorenzo [l], A. Intorcia [l], L. Fattore [a], S. Galli [w], G. Gerosa [x], D. Giannotta [y], P. Grossi [z], V. Monda [u], A. Mucaj [f], M. Napodano [j], A. Nicosia [aa], R. Perrotta [ab], D. Pieri [ac], F. Prati [ad], V. Ramazzotti [ad], F. Romeo [aj], A. Rubino [ac], E. Russolillo [ae], L. Spedicato [af], B. Tuccillo [i], C. Tumscitz [ag], C. Vigna [ah], L. Bertinato [ai], P. Armigliato [k], V. Ambrosini [l]

Ambrosini V, Armigliato P et Al. Int J Cardiol. 2022 Mar 1;350:19-26.

CARDIOVASCULAR LASER SOCIETY

CLS Position Paper



Ambrosini V, Armigliato P et Al. Int J Cardiol. 2022 Mar 1;350:19-26.

CLS Decision algorithm for heavly calcified coronary lesion treatment

Current laser limits

- **No affinity selective for lesion tissues**
- **Large dispersion of energy (> 40%)**
- **Need for high energy and contrast medium in calcific lesions**
- **Without suction capacity (IMA e BTK)**

CARDIOVASCULAR LASER SOCIETY

TYPES OF LASERS

295 kg	217 kg	119 kg	84 kg
Spectranetics	Philips	Ra Medical	Angiodynamis
CVX 300	LASER SYSTEM	DABRA	AURYON

AURYON CE MARK

- Bsi. By Royal Charter
- EU Quality Management System Certificate
- MDR 778808 R000
- Manufacturer: Eximo Medical LTD
- Single Registration Number: IL-MF-000030615
- EU Authorised Representative: AngioDynamics Netherlands BV
- Device Schedule: Class III and Class Iib devices


AURYON
Suction channel
Recervoir
suction
Control panel

Pulse width and photon energy

WHY PULSE WIDTH MATTERS

Deliver a powerful, efficient pulse

The Auryon System focuses energy where it counts to manage patient risk.

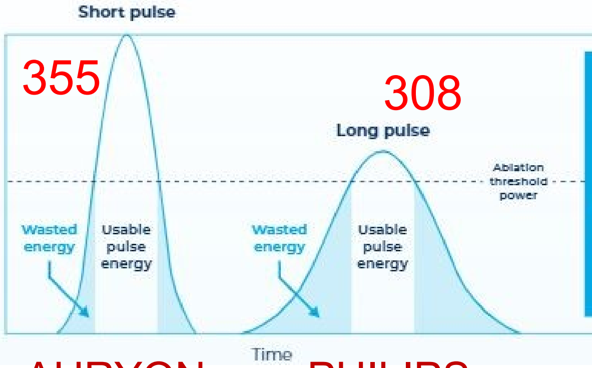
- Pulse widths that are an order of magnitude shorter than the Philips CVX-300, allowing for[11]:
  - Tissue relaxation between bursts, depositing energy before thermal diffusion can occur[6-8]
  - High-power pulsed energy[11]
  - Increased photo-mechanical impact on calcified tissue[12]

Calculating "on" time:
pulse rate x pulse width

The Auryon System
40 Hz x 25 ns = 1000 ns

Philips CVX-300
40 Hz x 200 ns = 8000 ns

8x more efficient

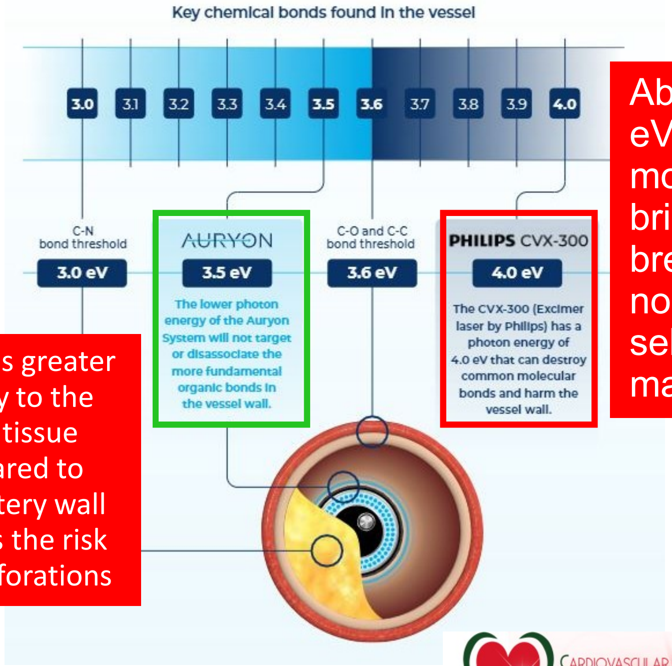


Efficient ablation

A shorter pulse is efficient at material removal by delivering more of the total energy above the biological threshold. With longer pulses, much of the energy contributes only to heating that can spread to surrounding material and cause damage.[6,13]

Targets the lesion and spares the artery wall

The 3.5 eV photon energy of the auryon system saves chemical bonds (C-C and C-O) in the artery wall



3 times greater affinity to the lesion tissue compared to the artery wall lowers the risk of perforations

Above 3.6 eV all molecular bridges break in a non-selective manner

Laser For complex coronary Artery lesion pReparatiOn
FARO STUDY

FARO Study

AURYON LASER: THE FIRST TIME IN THE WORLD IN THE CORONARY SETTING

FINAL RESULTS

- Prospective
- Single arm
- Single center
- Evaluating the safety and procedural effectiveness of the Auryon laser
- The study enrolled 20 patients in CLS Clinical Research Center

Start: October 2022
End: April 2023

CARDIOVASCULAR LASER SOCIETY

FARO PILOT STUDY PAPER

The American Journal of Cardiology
Laser For complex coronary Artery lesion pReparatiOn: the results of the pilot
FARO
study.
--Manuscript Draft--
Manuscript Number: AJC-D-24-00418
Article Type: Full Length Article
Keywords: calcific coronary lesions; complex percutaneous coronary interventions;
excimer laser
coronary atherectomy
Corresponding Author: Luca Golino
Cardiovascular Lser Society (CLS) - Via Camozzini, 24 - Verona (Italy)
ITALY
First Author: Vittorio Ambrosini, MD
Order of Authors: Vittorio Ambrosini, MD
Pietro Armigliato, MD, PhD
Antonio Colombo, MD
Massimo Napodanno, MD
Luca Golino, MD, PhD
Abstract: The Excimer Laser Coronary Artery (ELCA) angioplasty, used by
experienced
operators, has been considered as a well established therapy that can be applied to
treat a wide range of coronary lesions during PCI (in particularly heavily calcified
stenosis). The new Auryon laser System (Angiodynamics Inc©), until now used only
for the treatment of peripheral artery disease (PAD), with its 0.9 mm probe
specifically
designed for percutaneous coronary intervention, has in fact given proof, to
potentially
fill the gap between safety of procedure and effectiveness to treat high calcium and
complex epicardial stenosis. In this study was analyzed the effects and the safe of
Laser angioplasty with the new Auryon Laser in treatment of heavly calcified lesions.

CARDIOVASCULAR
LASER SOCIETY

CLS Faro Team

Dr. Napodano, Prof. Armigliato, Prof. Topaz, Dr.Di Lorenzo, Prof. Colombo, Dr. Ambrosini, Dr. Intorcia

STUDY OBJECTIVES

FARO Study

PREPARE 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

CARDIOVASCULAR LASER SOCIETY

The FARO Pilot study: inclusion/exclusion criteria

FARO Study

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	

CARDIOVASCULAR LASER SOCIETY

CARDIOVASCULAR LASER SOCIETY FOUNDATION

FARO STUDY

(Laser **F**or complex coronary **A**rtery lesion p**R**eparati**O**n)

FARO Study

Demographic and Disease Characteristics	Study Population N=20
Age, years (mean +/- SD)	69.2 +/- 6.8
Hypertension (%)	90
PAS (mean +/- SD)	133 +/- 11
PAD (mean +/- SD)	68 +/- 11
Current smoking (%)	20
Hyperlipidemia (%)	100
Diabetes mellitus (%)	45
Ejection fraction (mean +/- SD)	50.7 +/-12
Heart rate, beats per minute (mean +/- SD)	65 +/- 6
Familiarity (%)	25
Chronic renal failure (%) Creatinine (mean +/- SD)	28.5 2.9 +/- 3.4
Previous PCI (%)	75

AURYON LASER SYSTEM: procedural steps

Table 1. Main characteristics of the B-laser™ system

Active medium	Nd:YAG
Wavelength	355 nm
Catheter output fluence	50-60 mJ/mm2
Pulse repetition rate	40 Hz
Energy at the catheter tip at 60 mJ/mm2	30.6 mJ/Pulse
Averaged power at the catheter tip at 60 mJ/mm2	1.2 Watt
Pulse width (duration)	10-25ns, FWHM
Console	
Weight	85 kg / 187.4 lbs
Main body volume:	
Length	74 cm / 29.13 in
Height	95 cm / 37.4 in
Width	33 cm / 13 in
Blocking volume:	

- A baseline OCT exam will be performed **when possible**
- Laser angioplasty with 0.9 cath. will be performed
- OCT
- Balloon dilatation
- Stent implantation
- Postdilatation as needed
- Repeat final OCT

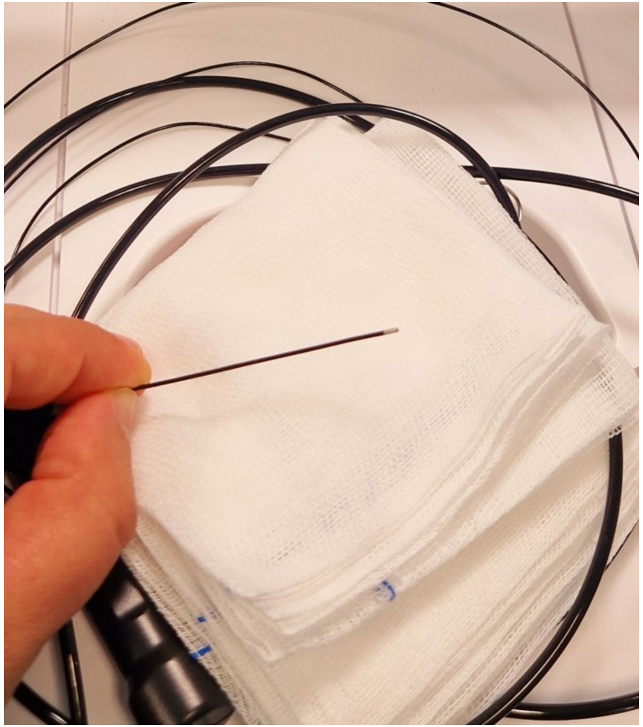
AURYON LASER SYSTEM: technical aspects

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

0.9 mm CATHETER :

1st gen.
-over the wire
-Tip NON radiopaca
-sonda non idrofilica
-primi 5 pazienti
-guida utilizzata 0.014” BMW 300 cm
-lunghezza sonda 150 cm

2nd gen.
-over the wire
-Tip radiopaca
-idrofilica
-15 pazienti
-guida utilizzata: SionBlue 0.014” ES 300 cm
-lunghezza sonda 150 cm



Auryon Laser System Procedure Details

FARO Study

Characteristic	Study Population N=20
Femoral access (%)	75
Radial access (%)	20
CCS (%)	85
NSTE-ACS (%)	15
STE-ACS (%)	0
Balloon uncrossable lesion (%)	35
Balloon undilatable (%)	70
In-stent restenosis (%)	40
Under expansion in-stent restenosis (%)	25
% stenosis pre-PCI (%)	85
Bifurcation (%)	30
TIMI flow pre-PCI (mean +/- SD)	2.5
Lesion length, mm (mean +/- SD)	40.1

CCS = Canadian Cardiovascular Society (Angina Grade); NSTE-ACS = non-ST-elevation acute coronary syndrome; PCI = percutaneous coronary intervention; STE-ACS = ST-elevation acute coronary syndrome; TIMI = Thrombolysis in Myocardial Infarction

- Lesions were de novo (60%),
- In-stent restenosis (ISR) (40 %);
- The patients had under-expanded ISR (25%)

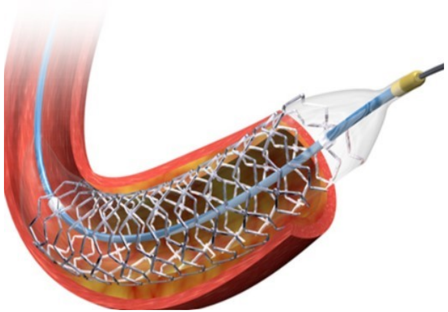
- The mean percent stenosis at the target lesion was 85,5 ± 13,1 %.

Cardiovascular Laser Society

FARO Study

VESSELS TREATED AND STENT IMPLANTATION

LAD (%)	35
CCA (%)	7
RCA (%)	42
TC (%)	14
SVG (%)	14
DRUG ELUTING BALLOON (%)	14.2
DRUG ELUTING STENT (%)	92.8
STENT NUMBER mean, ±SD	1.8
TOTAL STENT LENGHT mean, ±SD	48
MINIMUM STENT DIAMETER (mm) mean, ±SD	3
MAXIMUM STENT DIAMETER (mm) mean, ±SD	3.5
POST-DILATION (%)	64



Cardiovascular Laser Society

CARDIOVASCULAR LASER SOCIETY FOUNDATION

FARO STUDY

(Laser For complex coronary Artery lesion pReparatiOn)

FARO Study

PROCEDURAL FEATURES

- **<u>All the lesions were severely calcified</u>**, as assessed by coronary angiography and intravascular imaging.
- A **<u>successful result</u>**, defined as < 30% residual stenosis and TIMI 3 flow after PCI, was achieved **<u>in 95%</u>** of cases.
- **<u>One case of perforation</u>** of a degenerated saphenous vein graft after high pressure balloon angioplasty dilation, **<u>not related to Auryon laser treatment</u>**, was resolved after covered stent implantation.
- In **<u>one case</u>**, a **<u>very distal embolization</u>** was observed after successful LAD PCI.
- **<u>One case of transient slow-flow</u>** after Auryon laser treatment was observed in a patient with severe left ventricular dysfunction, **<u>with no haemodynamic effect</u>** (**<u>during a LAD PCI performed with Impella support</u>**).

CARDIOVASCULAR LASER SOCIETY FOUNDATION

FARO STUDY

(Laser For complex coronary Artery lesion pReparatiOn)

FARO Study

PROCEDURAL FEATURES

- Only two flow-limiting vessel dissection after Auryon laser treatment were recorded, but resolved after subsequent balloon dilation and/or stent implantation; another distal dissection was related to hydrophilic guidewire manipulation and not accountable to laser device.
- Only one case of clinically relevant periprocedural myocardial infarction (with no significant sequelae) was observed, while a significant periprocedural myocardial injury was observed in 80% of treated patients, with a mean troponin I peak of 3505 pg/ml after procedure, as expectable for very complex PCI.
- There were **no cases of contrast-induced nephropathy**. At a mean **follow-up of 125 ± 63 days** after execution of laser-assisted PCI, **no death or MACE** was assessed in the study cohort.
- Mean procedural time was 37 ± 18 minutes.

SAFETY

• **PERFORATION** (not related to the LASER)	**1 CASO**
• **DISTAL EMBOLIZATION**	**0 %**
• **NO REFLOW/SLOW FLOW** (slow-flow transitorio)	**1 CASO**
• **FLOW LIMITING DISSECTION**	**0 %**

- **NO MAJOR ADVERSE EVENTS AT 30 DAYS**

EFFICACY

POST-PCI TIMI 3	95%
PROCEDURAL SUCCESS	95%

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

QCA > 30%	2% (1 caso)

CARDIOVASCULAR LASER SOCIETY

EFFICACY

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

CONTRAST MEDIUM 2nd 15 CASES: 169 ML ± 175

MEAN PROCEDURE TIME : 37.8 MIN.

CONCLUSIONS

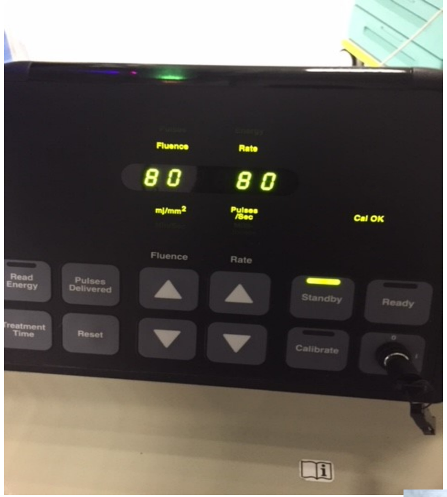
FARO Study

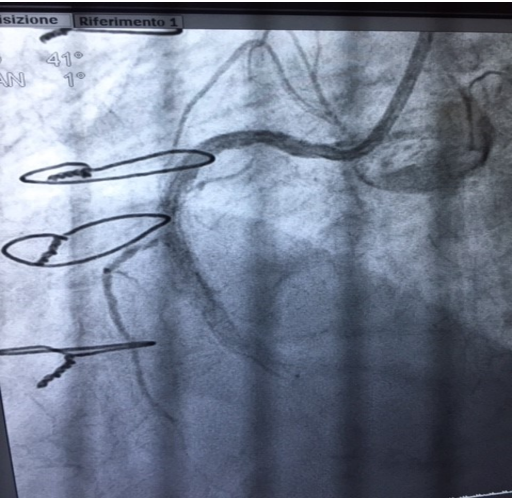
STRENGTHS	ASPECTS TO IMPROVE
EFFICACY and SAFETY	IMPROVING CATHETER TRACKABILITY
EASY TO USE	IMPROVE RADIOPACITY TIP
GENERATOR VERSATILITY	MONORAIL

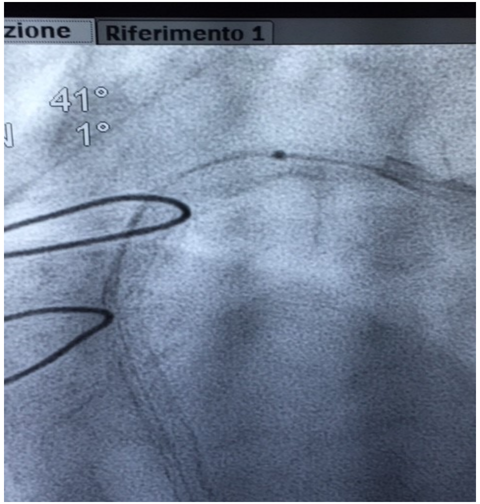
Cardiovascular Laser Society

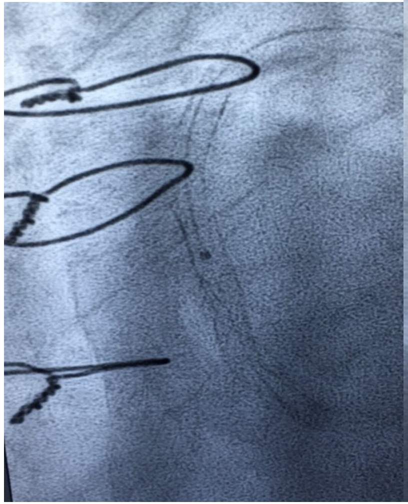

UNIVERSITY
OF PADUA

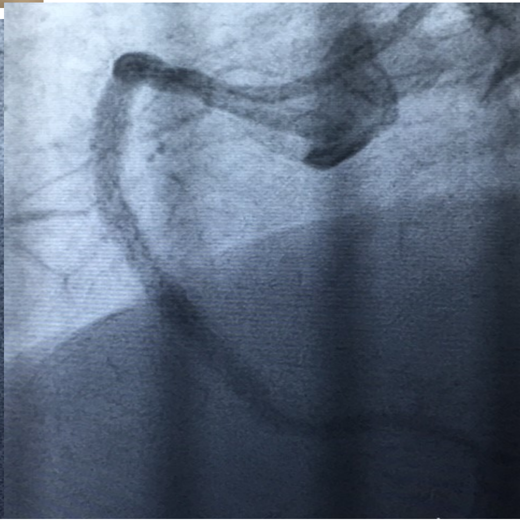

PHILIPS

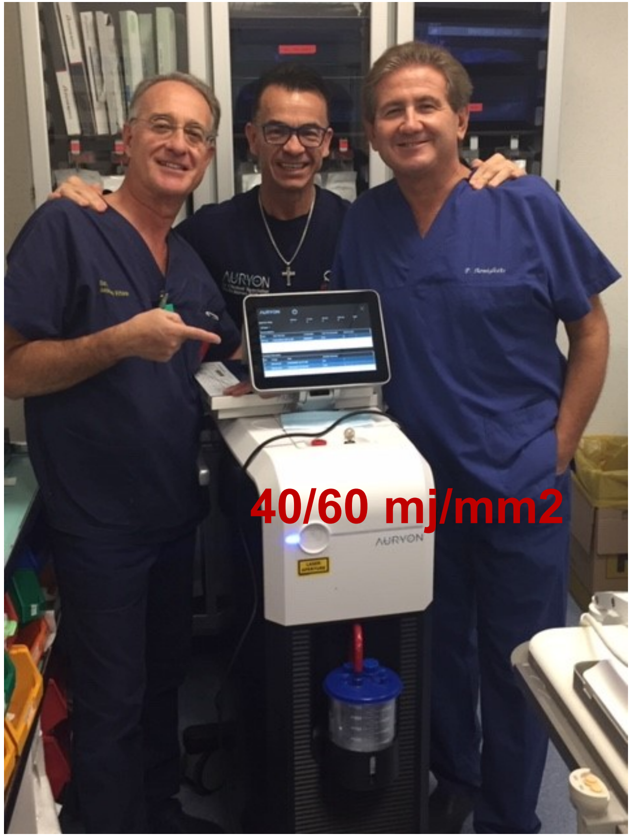

Fluence
Rate
80
80
mJ/mm2
Pulses /Sec
Cal OK
Fluence
Rate
Read Energy
Pulses Delivered
Standby
Ready
reatment Time
Reset
Calibrate

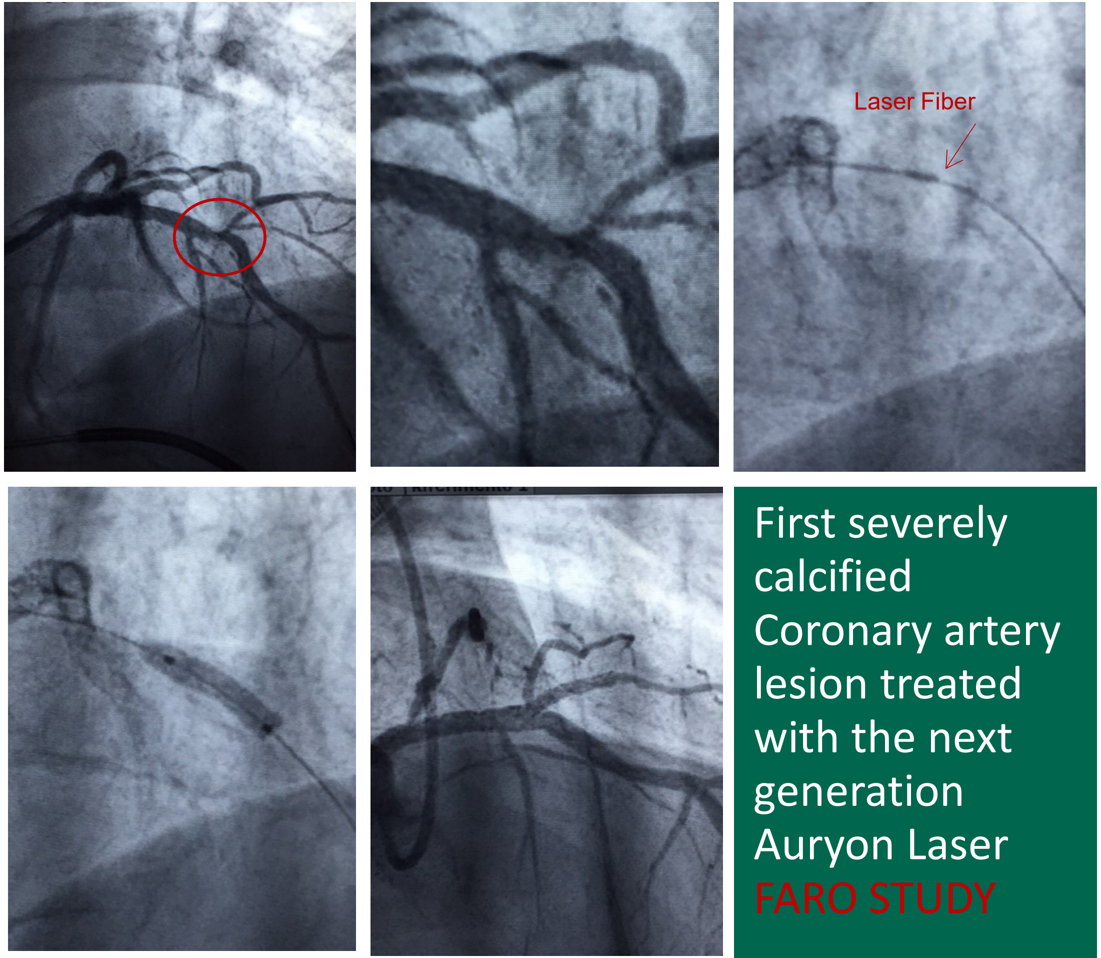

isizione
Riferimento 1
41°
AN 1°


zione
Riferimento 1
41°
1°





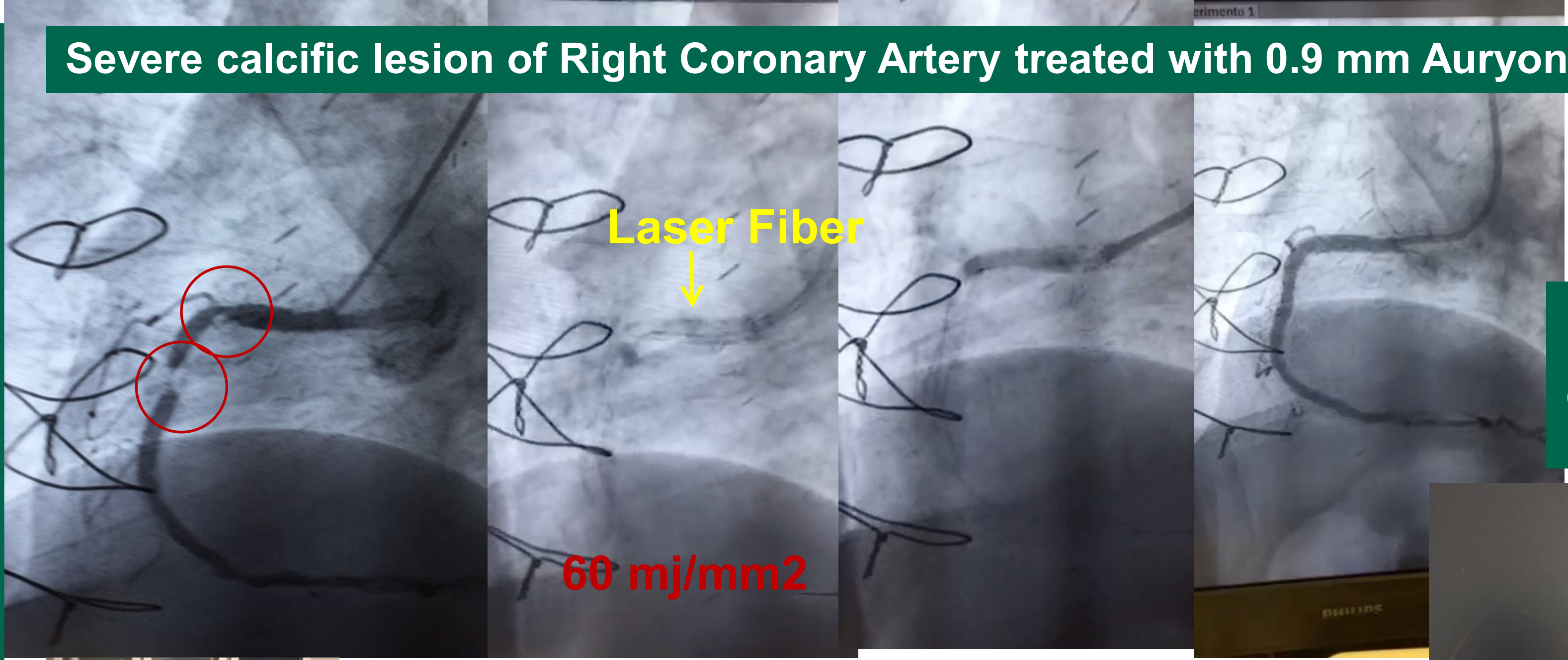




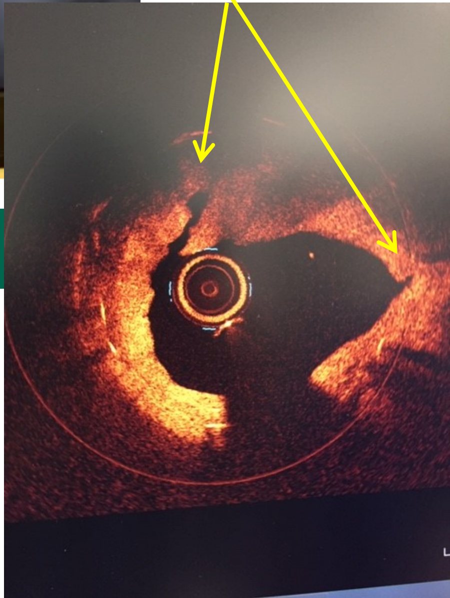
First severely calcified Coronary artery lesion treated with the next generation Auryon Laser FARO STUDY

AURYON LASER FIBER 0.9 mm

Severe calcific lesion of Right Coronary Artery treated with 0.9 mm Auryon Laser Fiber



LASER fracture lines of the calcific plaque



Second case of the FARO Pilot Study

CARDIOVASCULAR LASER SOCIETY

CARDIOVASCULAR LASER SOCIETY FOUNDATION

FARO STUDY

(Laser For complex coronary Artery lesion pReparatiOn)

FARO Study

CONCLUSIONS

- The objective of this study is to suggest that laser angioplasty may produce better preparation of the severely and complex calcified lesion leading to a larger final lumen after stent implantation.
- The first five sample patients undergone to this technique with the first generation 0.9 mm laser-catheters ever built from the Angiodynamics© company while the seconds sample of fifteen patients were treated with a second generation, more efficient, 0.9 mm catheters.
- The second generation 0.9 mm catheters differs from the first one for the idrophilic coating and a more radiopaque tips. The 0.9 mm catheters is an over-the-wire kind compatible with any type of 300 cm 0.014” guide-wire; we expect in the future a more versatile monorail kind of probe.
- The laser system is very compact if we compare with others machine and requires only five seconds to start.

CARDIOVASCULAR LASER SOCIETY FOUNDATION

FARO STUDY

(Laser For complex coronary Artery lesion pReparatiOn)

FARO Study

CONCLUSIONS

- The final results of this pilot study for safety and efficacy are very encouraging.
- These preliminary results suggest very encouraging results with this device; positive impressions are the ease of use and speed of the system, the safety and effectiveness in the treatment of severely calcified lesions even at low energies without the aid of boluses of contrast medium.
- On the other hand, we hope that new, more performing 0.9 catheters will be available (more flexible, with a more radiopaque tip and monorail).
- The Auryon Laser is effective and safe in the ablation of atherosclerotic and restenotic tissue of coronary artery disease. The device has a high safety profile, including a low risk of distal embolization.

FARO Pilot Study Conclusions

The next generation Auryon Laser System (2017) appears to be a major technological advancement over the previous generation Philips/Spectranetics laser (1986).

There has been a **significant mignaturization of the volumetric dimensions** and weight (217 vs 84 Kg)

A marked improvement in ease of use:

NO calibration, machine set-up times (5sec vs 5min) and in storable procedural information (procedure date, fiber used, energies used, fractional delivery times, number of steps of all procedures without limits vs. total delivered pulses and total energy delivered for each non-storable catheter used).

But above all, the technological improvement that leads to having a system that is:

- **more efficient**
- **more effective on calcium**
- **more selective on biological action**
- **safer - faster**
- **independent of the use of the contrast medium**
- **with a suction at the same time as the laser action (BTK and AMI treatment)**

All this allows the system to be used in any type of lesion, of any length and in any district.

CARDIOVASCULAR LASER SOCIETY

Laser For complex coronary Artery lesions pReparatiOn: INTERNATIONAL-FARO study

PROTOCOL

INTERNATIONAL

INTERNATIONAL-FARO INCLUSION CRITERIA

INTER NATIO NAL

- Moderate/severe coronary Calcifications

  (calcium arch >180° -270°) or requiring, according to the judgment of the investigator, rotational atherectomy or IVL.

- Estimated vessel size 2.5 mm or larger.

- **if possible** perform optical coherence (OCT) study prior to the procedure.

CARDIOVASCULAR LASER SOCIETY

INTERNATIONAL-FARO EXCLUSION CRITERIA

INTER
NATIO
NAL

- Age<18 years
- Pregnancy
- Active cancer
- Major bleeding
- STEMI
- Renal Failure (Creatinine < 29)
- Subject is unwilling or unable to sign the Informed Consent Form (ICF).

CARDIOVASCULAR LASER SOCIETY

INTERNATIONAL-FARO PROCEDURE

INTER NATIO NAL

- A **baseline OCT** exam will be performed
- **Laser angioplasty** with 0.9 (or 1.5, 1.7, 2.0) Auryon cath. will be performed with a minimum of 2 passes (at 50 and/or 60 mj/mm2)
- **Repeat OCT**
- High-pressure **balloon dilatation**
- **Stent** or BRS implantation
- **Post-dilatation** as needed
- Repeat **final OCT**

CARDIOVASCULAR LASER SOCIETY

INTERNATIONAL-FARO
STUDY OBJECTIVES

INTER
NATIO
NAL

The **INTERNATIONAL-FARO** (Laser **F**or complex coronary **A**rtery lesion p**R**eparati**O**n) is a prospective, single arm multi-center study and aimed to:

(1) investigate the **primary safety endpoint** defined as **freedom from major adverse events (MAEs) at 30 days** from the procedure with the new Auryon Laser;

(2) the **primary efficacy endpoint** was the average **reduction in residual diameter stenosis of greater than 30% from baseline** prior to any adjunctive therapy achieved by the Auryon -Laser catheter alone ;

(3) investigated the angiographic and intravascular optimal coherence tomography (OCT) results on the calcific plaque burden and evaluation of the optimal positioning of the stent(s).

CARDIOVASCULAR
LASER SOCIETY

INTERNATIONAL-FARO

Ethical Committee, STUDY SAMPLE, OCT Images

INTER
NATIO
NAL

The study must receive approval from the Research **Ethics Committee**.

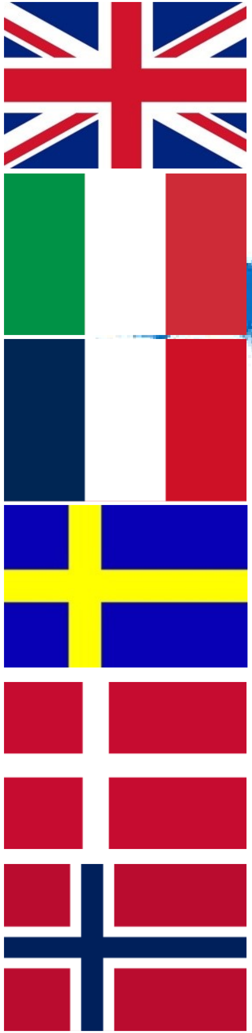
200 patients per center in 13 Centers;

Patient characteristics such as age, cardiovascular risk factors, **angiographic data** (lesion complexity, number of stenoses, chronic total occlusion), **calcium arc**, thrombolysis flow in myocardial infarction (**TIMI) before and after revascularization**, success will be evaluated of percutaneous coronary intervention or stent thrombosis.

Intracoronary images with optimal coherence tomography **(OCT) will be performed at baseline and at the end of the procedure**

CARDIOVASCULAR
LASER SOCIETY

FARO INTERNATIONAL



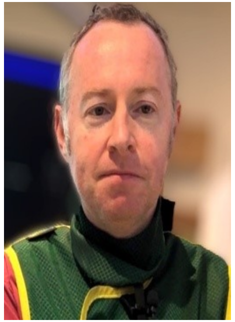
200 patients per center in 13 Centers

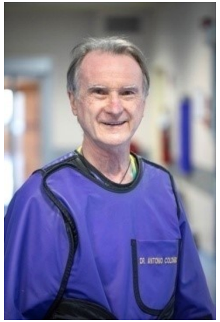
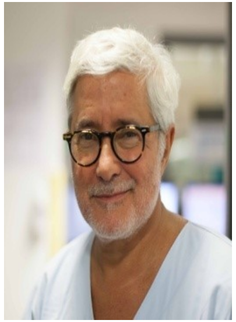
INTERNATIONAL-FARO Investigators

INTER
NATIO
NAL





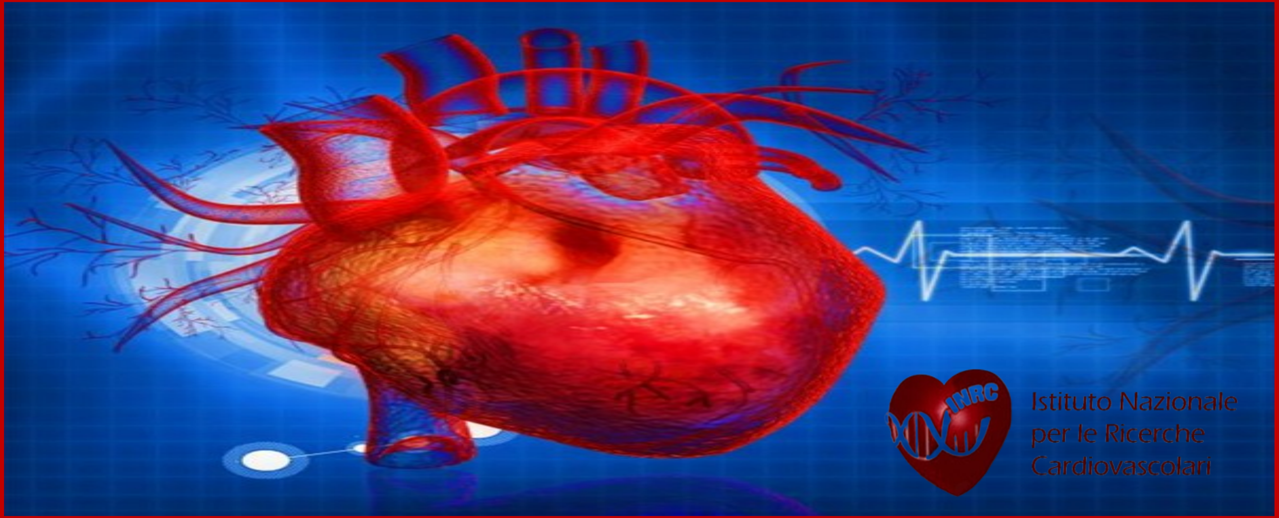
and more........

CARDIOVASCULAR
LASER SOCIETY

CARDIOVASCULAR LASER SOCIETY

ASL AV
AZIENDA SANITARIA LOCALE AVELLINO
REGIONE CAMPANIA

CLS International Symposium on New Generation Laser in Coronary Calcific Lesions



ITALIAN SOCIETY FOR CARDIAC SURGERY

A.N.M.C.O. NEXT GENERATION

ESC European Society of Cardiology

COLLEGIO DEI PROFESSORI UNIVERSITARI DI CARDIOCHIRURGIA
Italian College of Cardiac Surgeons

28 January 2025
Conference Room
S.Ottone Frangipane General Hospital
Ariano Irpino (AV)

CARDIOVASCULAR LASER SOCIETY FOUNDATION

CLS 2025

7th ANNUAL MEETING
2nd ANGIOVAC FORUM

25-26 September 2025 - Congress Center Federico II° University - NAPLES

CLS FOUNDATION

GRAZIE PER L'ATTENZIONE

pietro.armigliato@cardiovascularlasersociety.com