Hertz Contact Intravascular Lithotripsy for Calcified Coronary Lesions in Complex and High-Risk PCI populations

Primary Outcomes from Real-World Practice: The MY-IVL Study

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Consultant Fees/Honoraria	AstraZeneca, Elixir Medical, Novartis AG, Boston Scientific

MY-IVL Study Organization



Cardiac Vascular Sentral Kuala Lumpur Hospital (CVSKL) Wilayah Persekutuan, Malaysia

A top referral center in Kuala Lumpur for complex CV cases across Malaysia

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Imaging Core Laboratory QCA and OCT/IVUS

MedStar Cardiovascular Research Network Core Laboratory

MedStar Cardiovascular Research Network

MedStar Washington Hospital Center

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- Gebremedhin D Melaku, MD
- Solomon S Beyene, MD

Lithotripsy

From Greek "Breaking (or pulverizing) Stones" (litho- + τρίψω [tripso])

Lithotripsy

1832- first kidney stone removal procedure by Jean Civiale

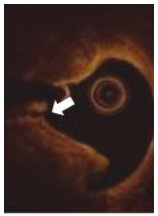
- Mechanical
- Extracorporeal
- Laser





Acoustic Energy Intravascular Lithotripsy

Pressure waves generated inside the balloon to create pulsing forces to fracture adjacent calcium

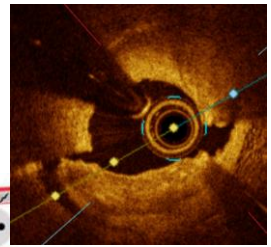


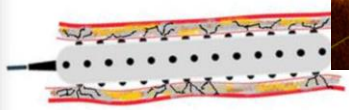


Hertz Contact Intravascular Lithotripsy

Hertz Contact Stress principle: Discrete amplification of force creates focal stresses at the point of contact with hard calcium to create fractures







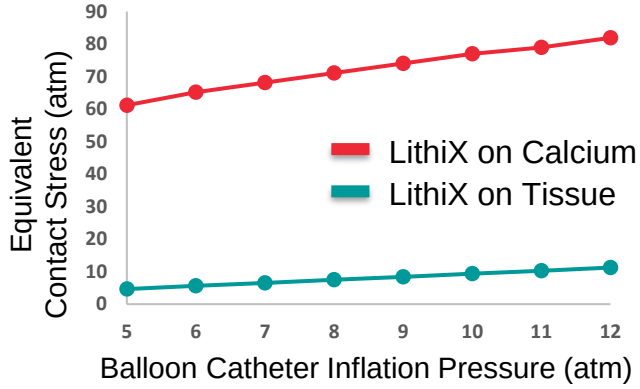
Hertz Contact Stress Mechanism

- ***Focal localized stresses develop*** when a curved sphere contacts a plane and deforms it under the imposed loads

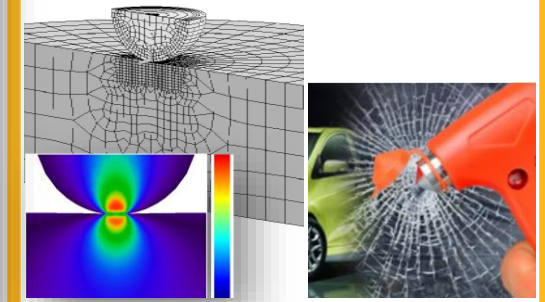
Parameters

- Contact force
- Modulus of elasticity
- Discrete area of contact

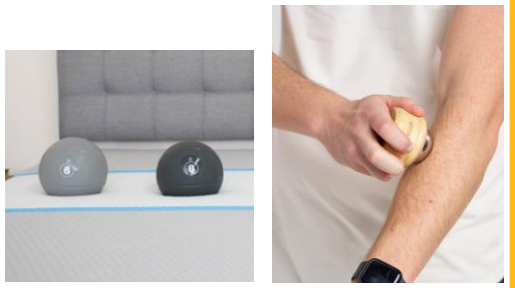
Discrete and High Stress for Calcium Fragmentation



Hard on Calcium



Soft on Tissue



Data on file.

MY-IVL Study Design

Study Objective

To assess the safety and performance of Hertz Contact Intravascular Lithotripsy (HC-IVL) to treat calcified, stenotic, coronary lesions prior to PCI in real-world practice.

***Performance Goal (PG)** was derived from the average MSA (5.65 mm²) reported in prior IVL and RA studies[1-3] with a statistical margin of 0.75 mm²

102 consecutive patients treated with HC-IVL

Enrolled at CVSKL Hospital between April and September 2025

Native CAD requiring PCI: full spectrum of ischemic heart disease, including stable or unstable angina, silent ischemia, ACS (NSTEMI/STEMI), concomitant cardiogenic shock

↓

Angiography and 100% Intravascular Imaging (IVUS/OCT)

Per standard of care pre- and post-PCI

All images adjudicated by the Core Laboratory (MedStar Health)

↓

Primary Safety Endpoint: Freedom from MACE within 30 days of the index procedure

Co-Primary Effectiveness Endpoint-1: The proportion of subjects with residual stenosis <30%, including both stenting and DCB treatment, and without intra-procedural MACE

Powered Co-Primary Effectiveness Endpoint-2: Minimum Stent Area (MSA) (compared to ≥ 4.9 mm² PG*), as assessed by intravascular imaging, stenting cohort only

↓

30-Day Clinical Follow-up

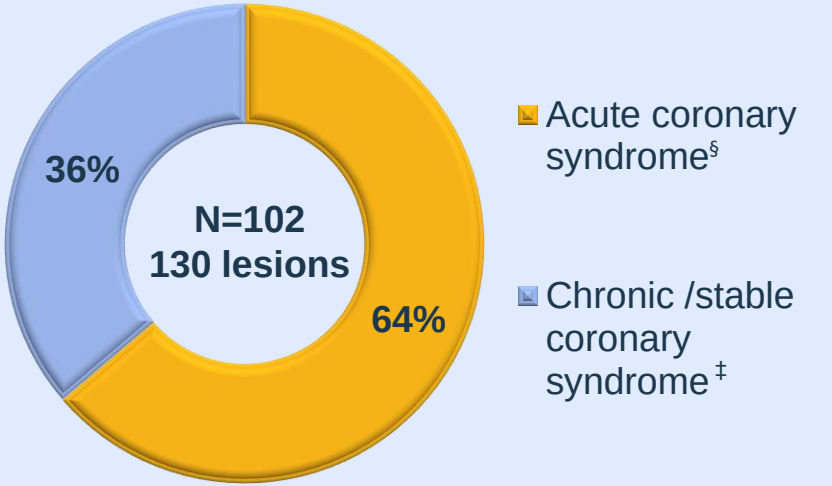
*MACE defined as a composite of cardiovascular death, myocardial infarction and target vessel revascularization

[1]Honton B, et al. ICARE trial, EuroPCR 2025
[2]Abdelhakim A, et al. CCI. 2022 Nov;100(6):979-989
[3]Ziad A, et al. Circ Interv. 2023, 16(10): e012898

Baseline Characteristics

Demographics	N=102
Age, years	65.3 ± 11.0
Male	83 (81.4%)
Hypertension	77 (75.5%)
Hyperlipidemia	87 (85.3%)
Diabetes mellitus	68 (66.7%)
Prior MI	14 (13.7%)
Prior PCI	35 (34.3%)
Prior CABG	4 (3.9%)
Prior stroke	2 (2.0%)
Current or former smoker	15 (14.7%)
Renal failure	12 (11.8%)

Clinical presentation

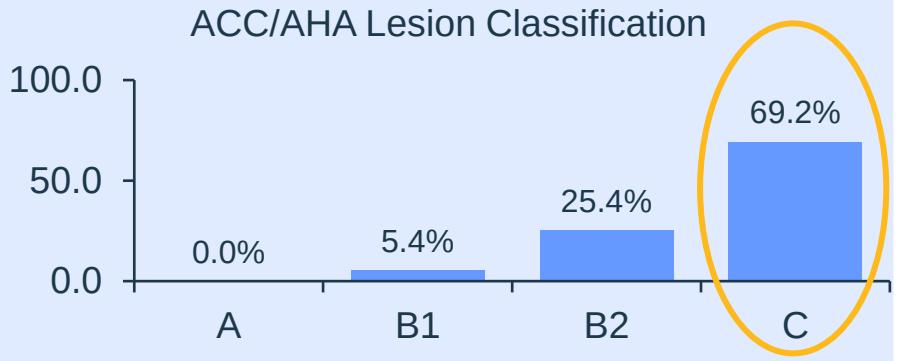


§, Unstable angina, STEMI or NSTEMI.
‡, Stable angina or silent ischemia.

Baseline Lesion Characteristics

Angiographic measurements	L=117
Target vessel	
LAD	77 (65.8%)
LM-LAD: 11/77 (14.3%)	
LCx	17 (14.5%)
LM-LCx: 4/17 (23.5%)	
RCA	23 (19.7%)
Reference Vessel Diameter, mm	2.64 ± 0.57
Minimum Lumen Diameter, mm	0.90 ± 0.38
Diameter Stenosis, %	61.40 ± 14.65
Lesion length, mm	19.72 ± 14.09
>20 mm (L=39)	35.70 ± 12.94

Lesion characteristics	L=130
Calcification	
Severe	115 (88%)
Moderate	15 (12%)
In-stent restenosis lesion	7 (5.4%)



Procedure Characteristics

Procedure details	L=130
Pre-dilatation (to confirm undilatable lesion)	117 (90.0%)
Number of LithiX HC-IVL used per procedure	1.0 (1.0, 1.0)
Post-stent dilatation*	95 (93.1%)

Values are n (%) or median (interquartile range). *, Post dilatation applicable only to stented target lesions (L=102).

Procedural Safety Outcomes

Angiographic complication	N=96
Any severe dissection (Type D-F)	0
Any perforation*	1 (1.0%)
Any abrupt closure	0
Any no-reflow	0
Any thrombus	0
Any spasm	0
Any distal embolism	0

*, One subject had perforation occurred during stent deployment (not HC-IVL related).

Angiographic Outcomes

Final Post-PCI	L=116
Acute gain, mm	1.75 ± 0.58
Minimum lumen diameter, mm	2.65 ± 0.56
In-lesion DS, %	10.71 ± 11.49
In-lesion DS <50%	116 (100.0%)
In-lesion DS <30%	109 (94.0%)

Imaging Core Lab adjudicated.

Primary Safety Endpoint

30-Day freedom from MACE indicates an early procedural safety profile of HC-IVL

Primary Safety Endpoint	
Freedom from MACE (30 days)	**98 (96.1%)**
MI	0
TVR	0
CVD*	4 (3.92%)

No device related events were reported
****, Three CVDs were assessed by the site as not related to the HC-IVL procedure; one death had an unknown cause***

1. 75 year-old subject with acute aortic dissection two days after TAVR for severe bicuspid type 0 aortic valve stenosis; family declined active treatment
2. 63 year-old subject was in cardiogenic shock with intractable angina and NSTEMI prior to procedure; underwent CHIP PCI with Impella support; pre-existing shock subsequently complicated by sepsis/disseminated intravascular coagulation (DIC)
3. 74 year-old subject with diffuse disease in 31.3 mm long tapered lesion; developed cardiogenic shock following left main–LAD thrombotic occlusion post-PCI after perforation that occurred during overlapping stent deployment (accounted for as an intra-procedural MACE)
4. 78 year-old subject with renal failure, hypertension and hyperlipidemia; death at home within one month; cause unknown, no post-mortem performed

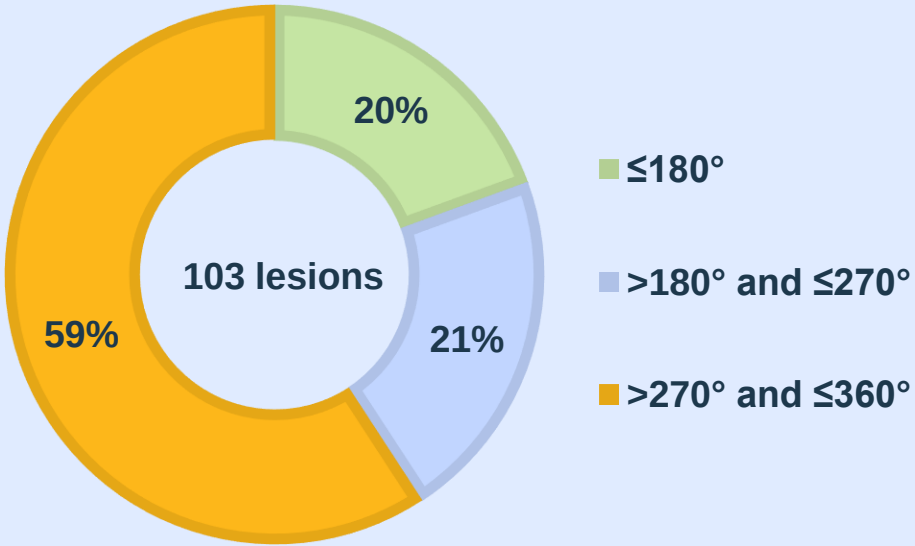
Co-Primary Effectiveness Endpoint - 1

Proportion of subjects with residual stenosis < 30%, and without intra-procedural MACE

Co-Primary Effectiveness Endpoint - 1	
Patients received DES treatment post HC-IVL	**79/82 (96.3%)**
All patients (DES, DCB)	88/96 (91.7%)

Angiographic measurements available in 96 subjects

Intravascular Imaging Analysis
Calcified Lesions Characteristics



- 25 lesions characterized by OCT
- 78 lesions characterized by IVUS
- Maximum continuous calcium arc: 276.05 ± 85.29°

Calcified Lesions Characteristics

Consistent with IVL Mechanism of Action

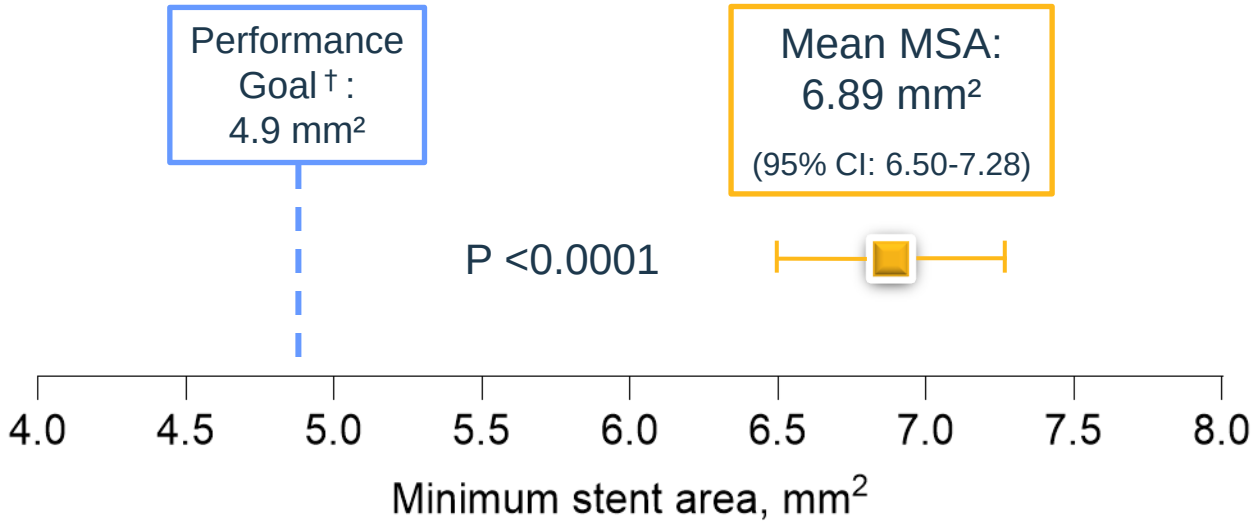
Calcium Eccentricity	Eccentric Calcium		Concentric Calcium	Overall
Maximum continuous calcium arc, °	**≤180°**	**>180° and ≤270°**	**>270° and ≤360°**	
Pre-PCI	L=20	L=22	L=61	L=105
Minimum lumen area*, mm^2	2.45 ± 1.02	3.03 ± 1.44	2.58 ± 1.00	2.71 ± 1.30
Post-PCI	L=18	L=19	L=47	L=94
Minimum stent area†, mm^2	6.52 ± 1.77	6.86 ± 1.91	7.08 ± 1.82	6.89 ± 1.88
Mean stent expansion‡, %	123.15 ± 13.81	106.77 ± 18.30	110.96 ± 17.97	113.71 ± 17.80§

Imaging Core Lab adjudicated.

Maximum continuous calcium arc measurements available in *103, †84, and ‡53 lesions. §L=58

Met Co-Primary Effectiveness Endpoint – 2

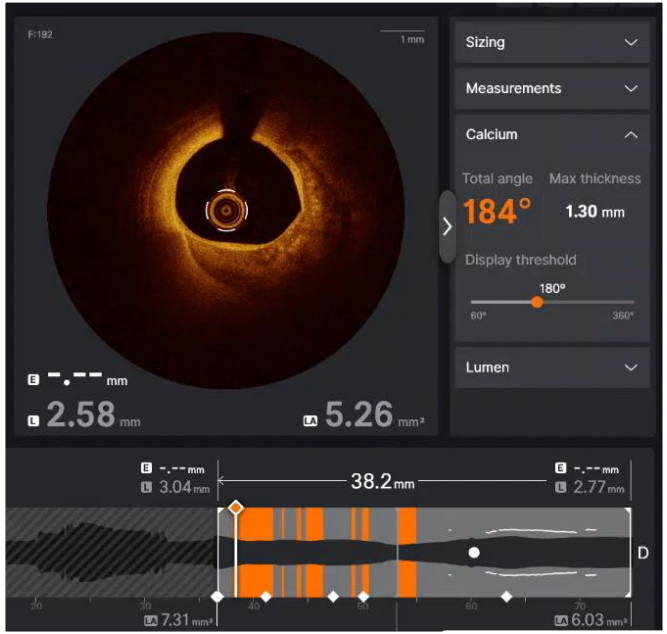
Minimum Stent Area‡ (MSA) for stented lesion after HCI-IVL (Powered)



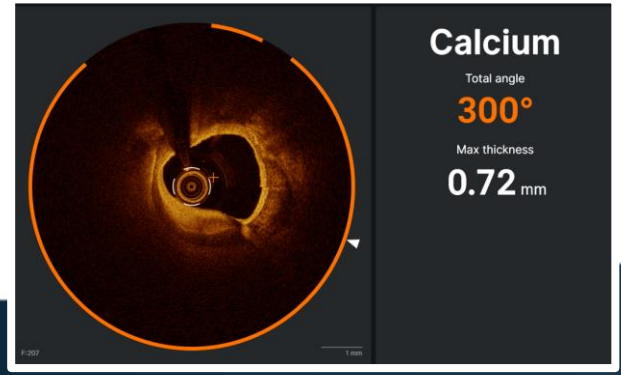
***, Imaging Core Lab adjudicated.** †, PG derived from the average MSA 5.65 ± 0.75 mm². ‡, OCT/IVUS measurements available: 94 lesions

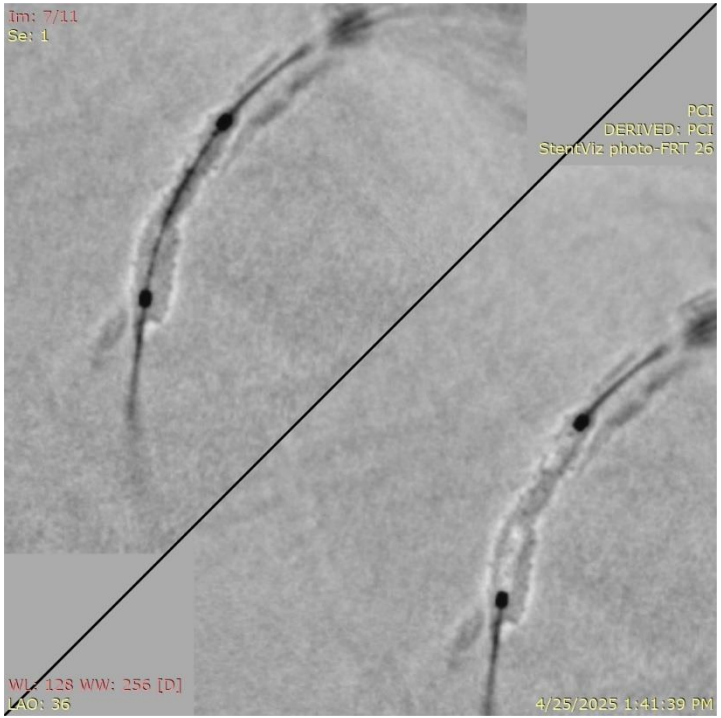


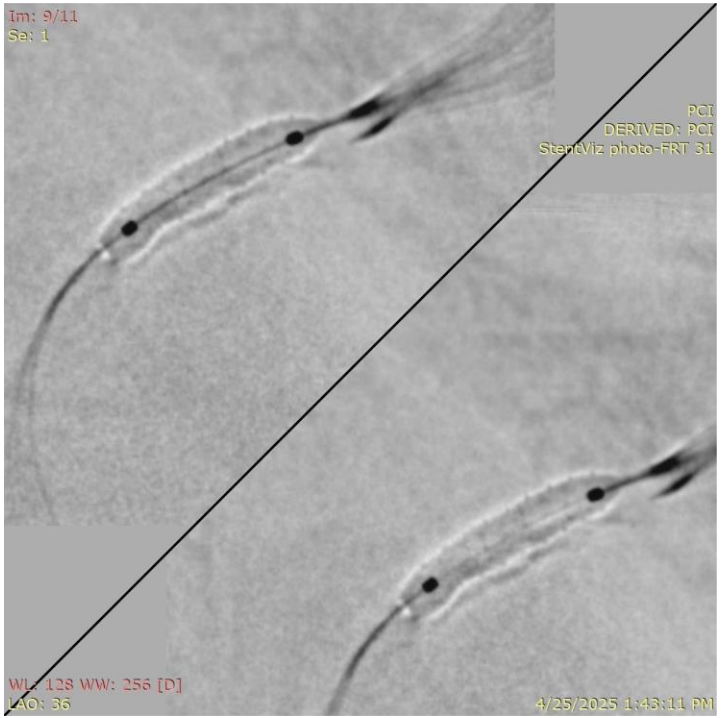
Baseline RCA Angiography



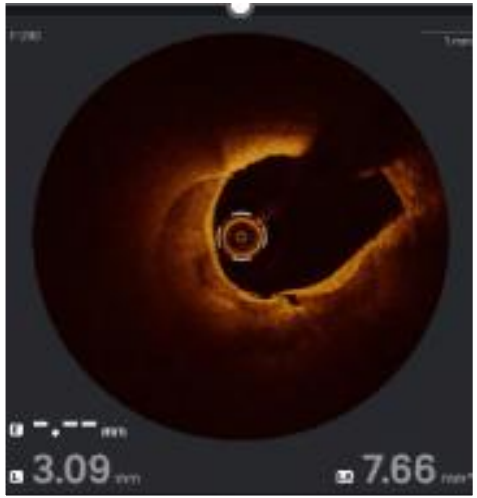
Pre-RCA OCT Imaging



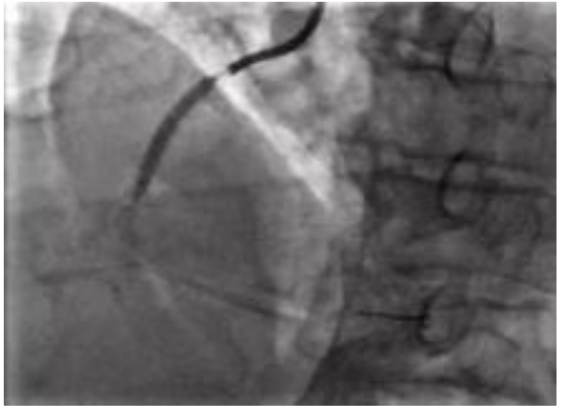




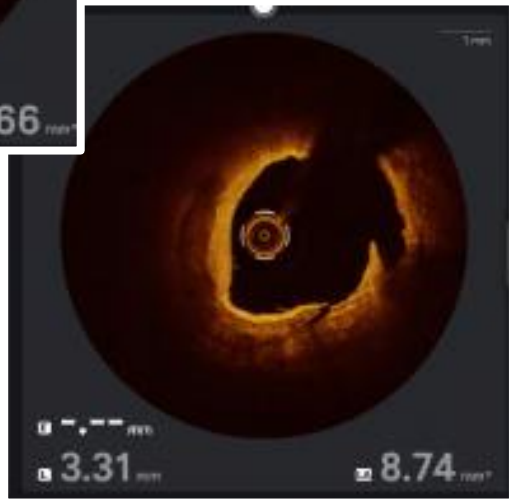
HC-IVL under stent boost showing the lesion yield

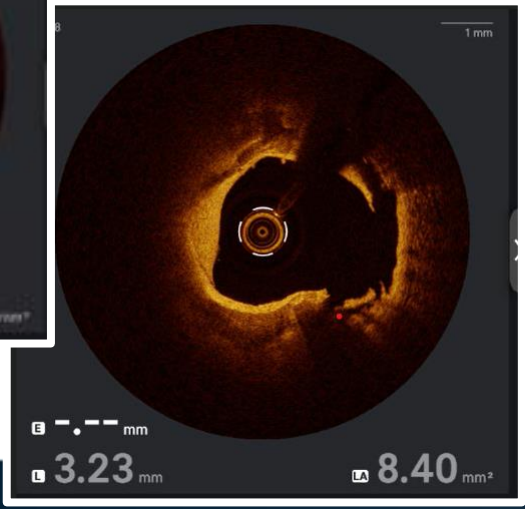


Post HC-IVL
OCT images



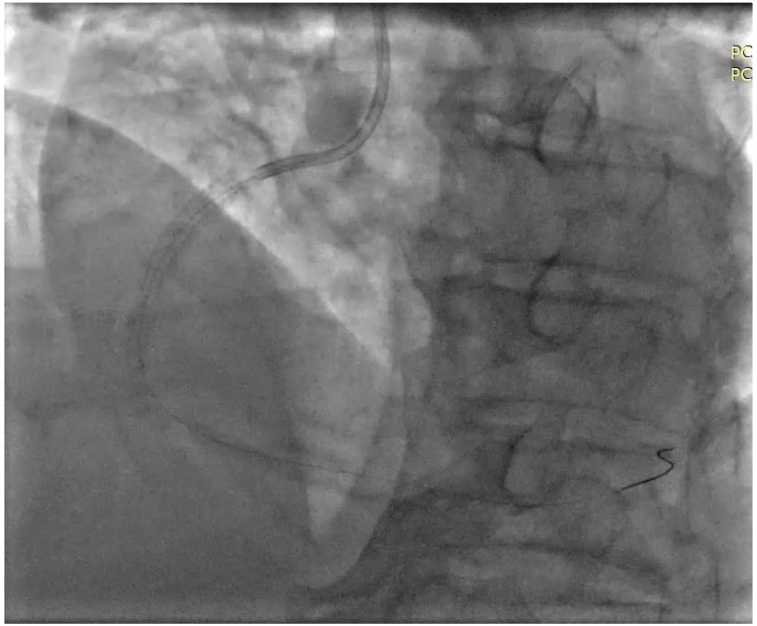
Post NC
4.0 x 30 mm







Implanted Bioadaptor
4.0 x 38 mm

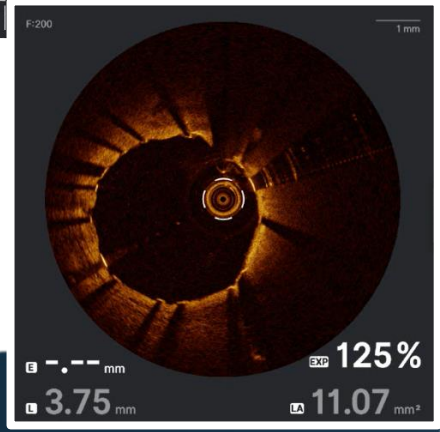


Final Angiogram



Final OCT

Excellent Bioadaptor Expansion



Conclusion

- MY-IVL Study demonstrated the safety and effectiveness of HC-IVL and its mechanism of action for calcium fragmentation in complex and high-risk PCI populations.

- Core Lab adjudicated results showed
  - **96.1% achieved 30-day freedom from MACE**
  - **96.3% with stenting achieved residual stenosis <30% and no intra-procedural MACE**
  - **Powered endpoint of MSA was met (mean MSA 6.89 mm²) per OCT/IVUS analysis**
  - Optimal stent expansion achieved in all eccentric and concentric calcified lesions
  - Single HC-IVL device effectively fragmented calcium in long, diffused and multi-vessel lesions

- LithiX HC-IVL offers a safe, effective approach for calcium fragmentation to optimize stent expansion, with no external energy source and a simple streamlined IVL workflow for real-world PCI.