

Intravascular Lithotripsy is Effective in the Treatment of Calcified Nodules

Patient-level Pooled Analysis of the Disrupt CAD OCT Sub-studies

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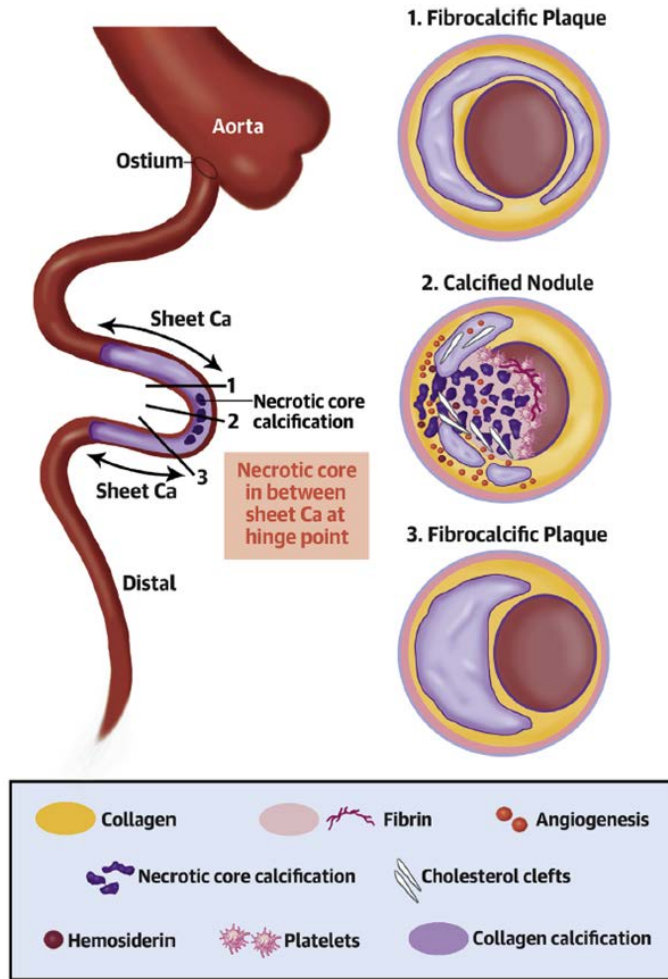
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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Consulting Fees	Boston Scientific, Philips
Research Grant	Boston Scientific, Abbott Vascular
Advisory Board	SpectraWave

Background

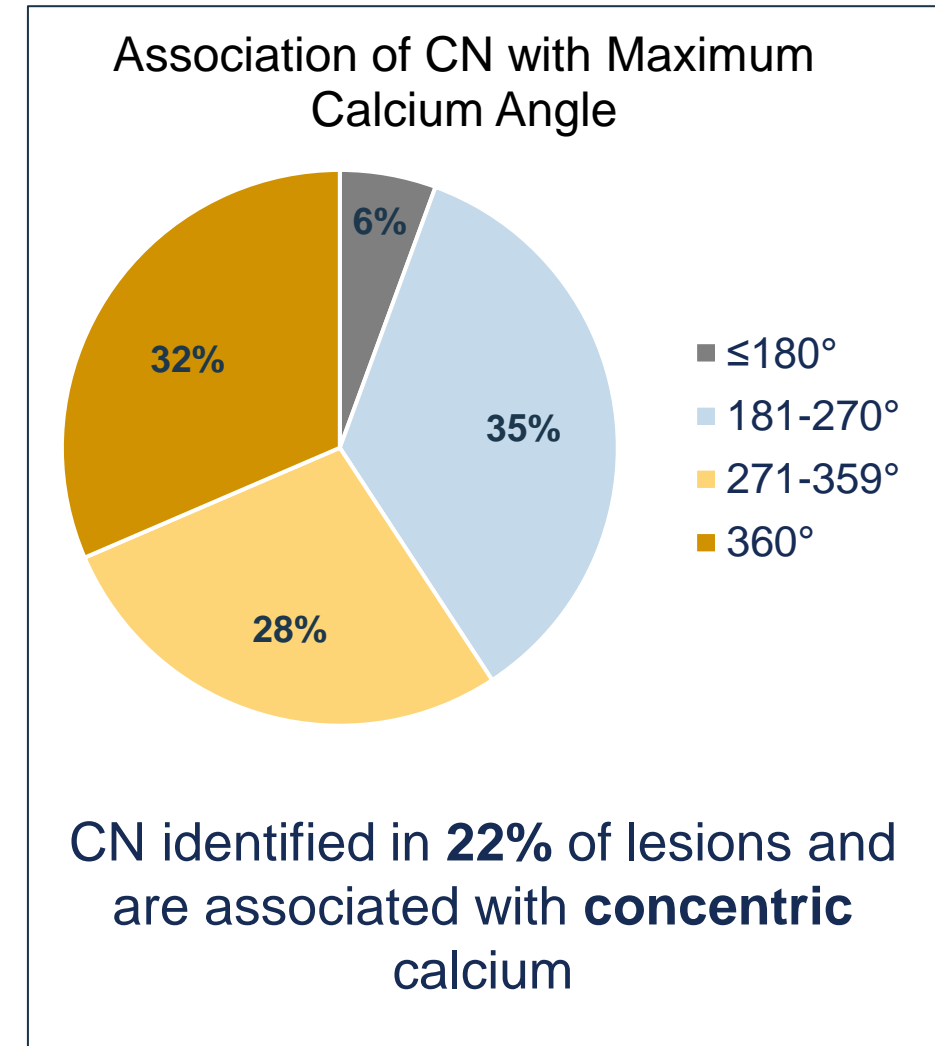


Calcium nodule (CN)

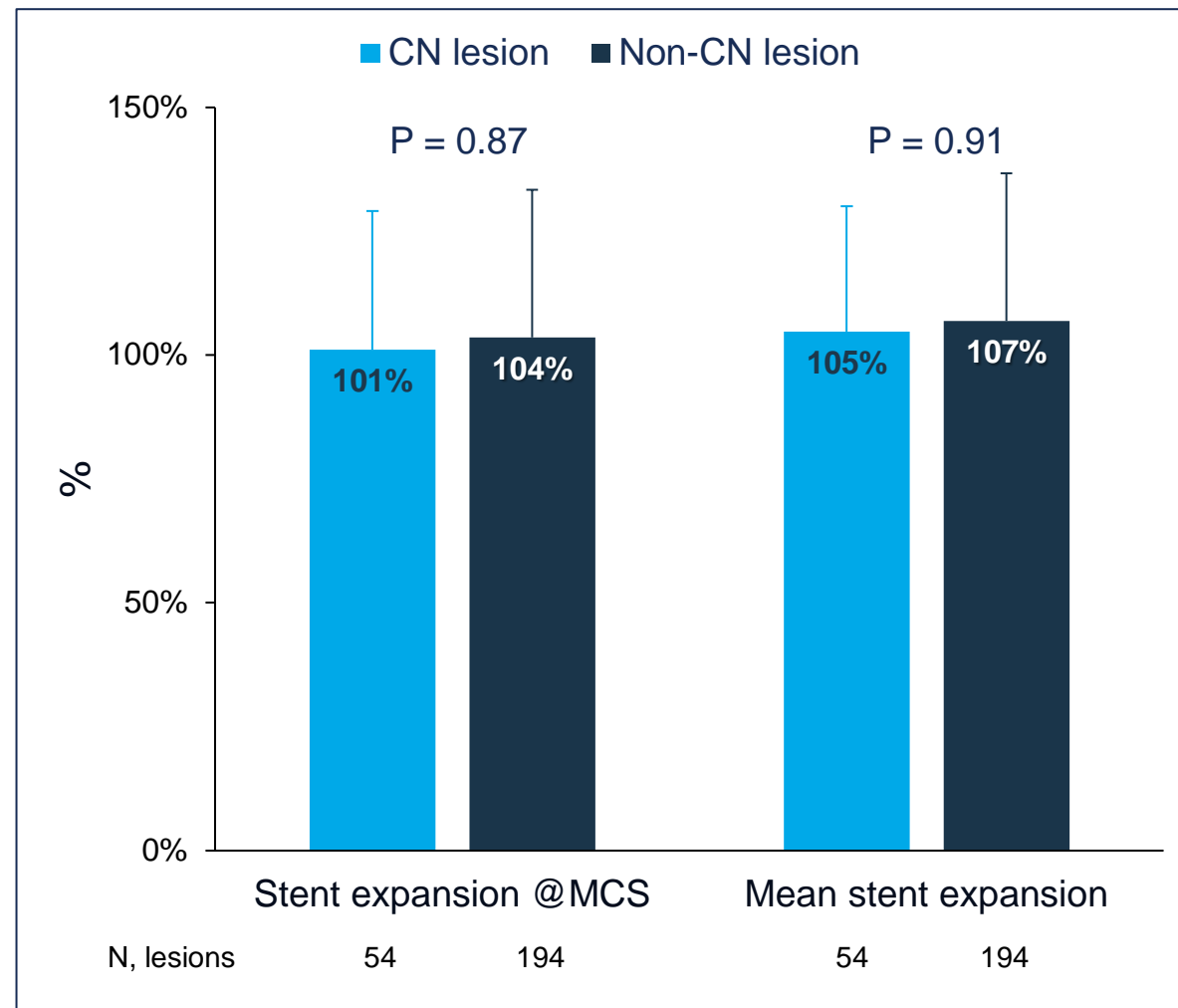
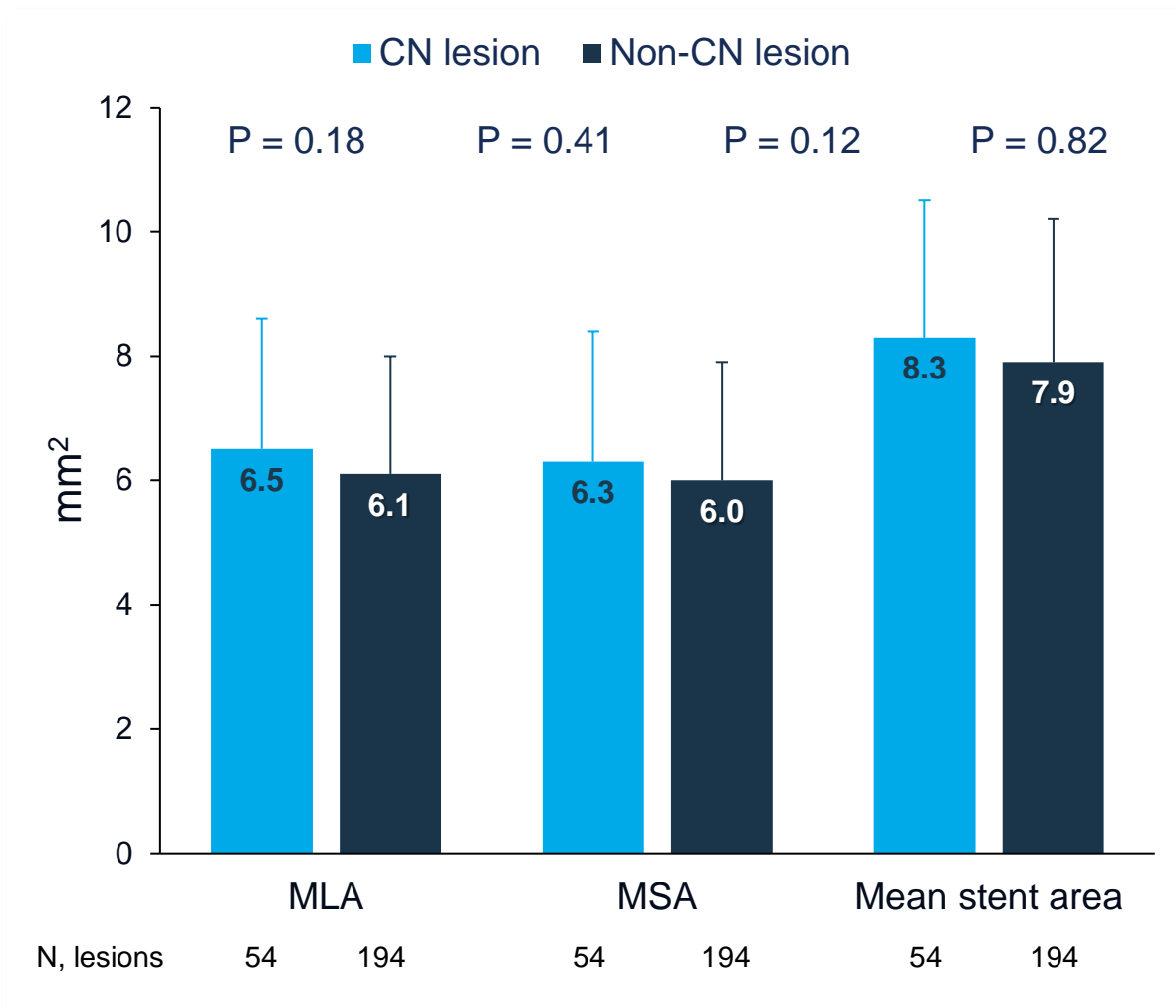
- **Eruptive CN:** Accumulation of small calcium fragments with irregular surface and adjacent proximal or distal deep sheet calcification
- **Nodular calcification (healed calcified nodule):** Accumulation of small calcium fragments with smooth thick fibrous cap with adjacent proximal or distal deep sheet calcification

Lesion Characteristics

	CN lesion N=54	Non-CN lesion N=194	P value
ACL			
Target vessel			
Left main	3.7%	0%	0.05
LAD	29.6%	77.8%	<0.0001
Circumflex	14.8%	5.7%	0.04
RCA	51.9%	16.5%	<0.0001
Lesion length, mm	24.8 ± 12.3	26.1 ± 11.1	0.44
Calcification length, mm	43.5 ± 22.9	42.6 ± 20.7	0.78
Diameter stenosis, %	66.5 ± 14.4	61.3 ± 10.4	0.02
OCT			
MLA, mm ²	2.3 ± 1.3	2.0 ± 0.8	0.19
Area stenosis @MLA, %	71.0 ± 13.4	72.1 ± 11.0	0.92
Max Ca angle @MCS	287.9 ± 70.9	264.8 ± 83.4	0.10
Ca thickness @MCS	1.00 ± 0.24	0.95 ± 0.25	0.10

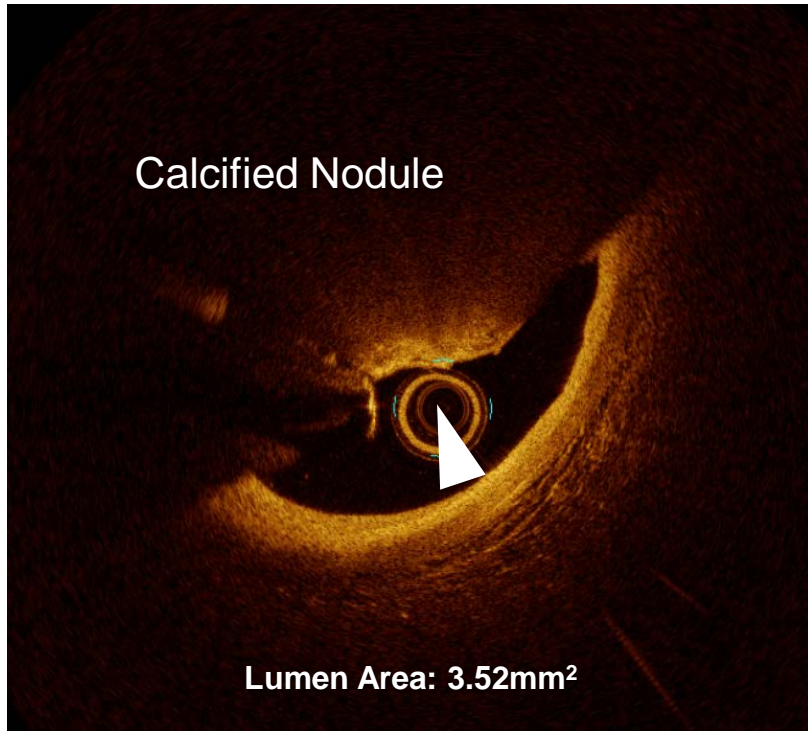


Post-stent Outcomes

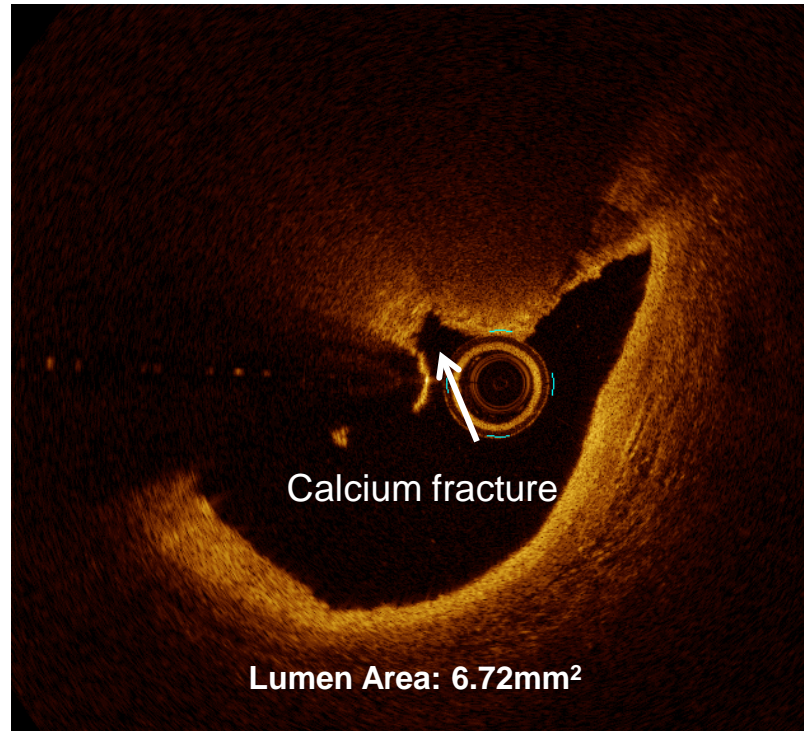


Calcium Nodule Visualization by OCT

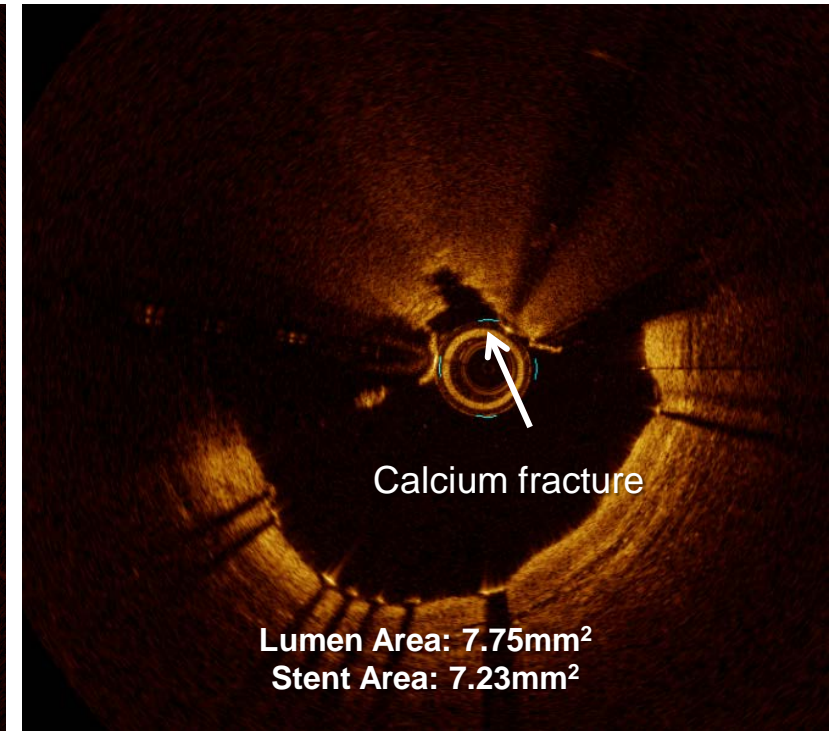
Pre-IVL



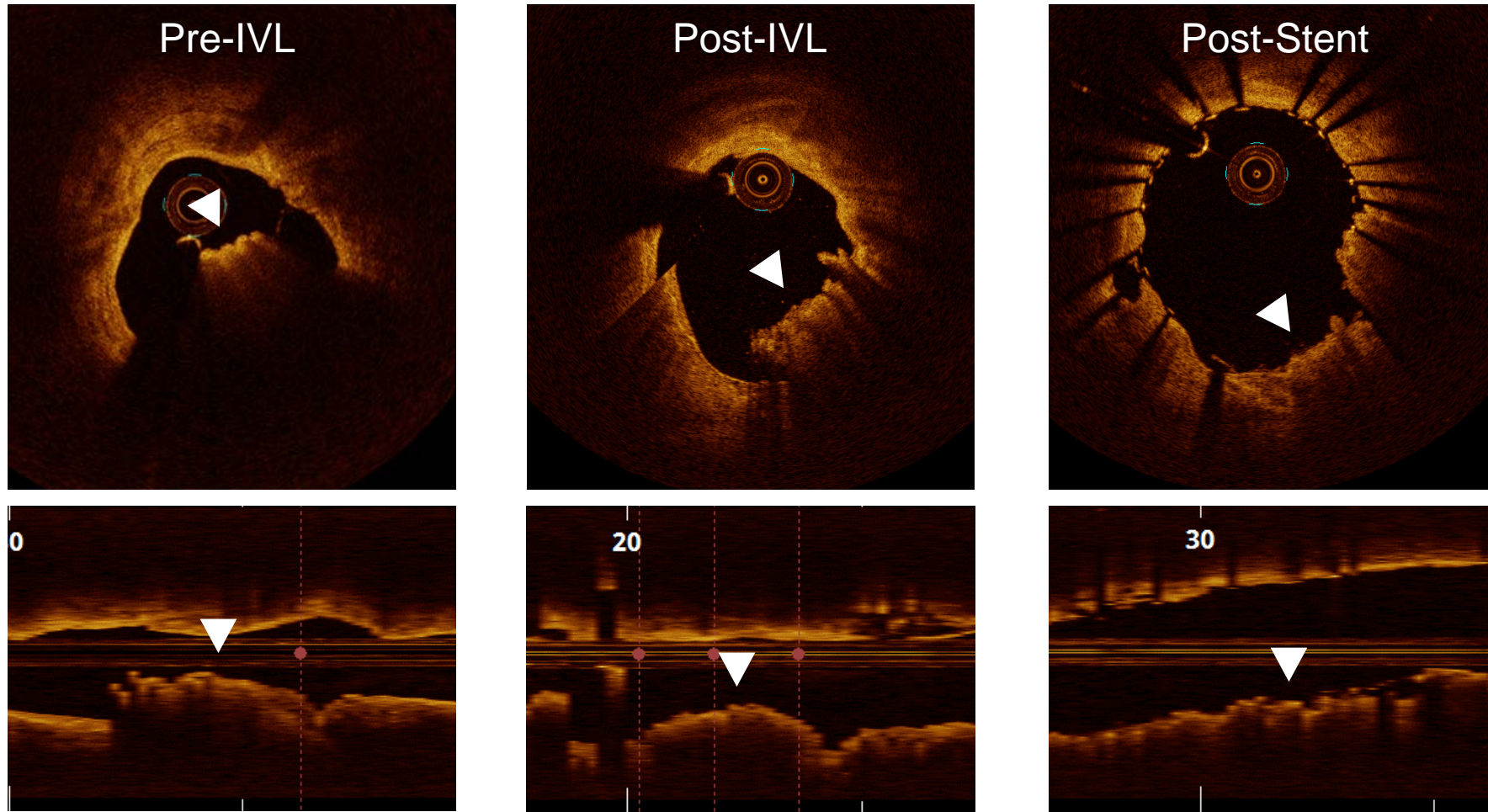
Post-IVL



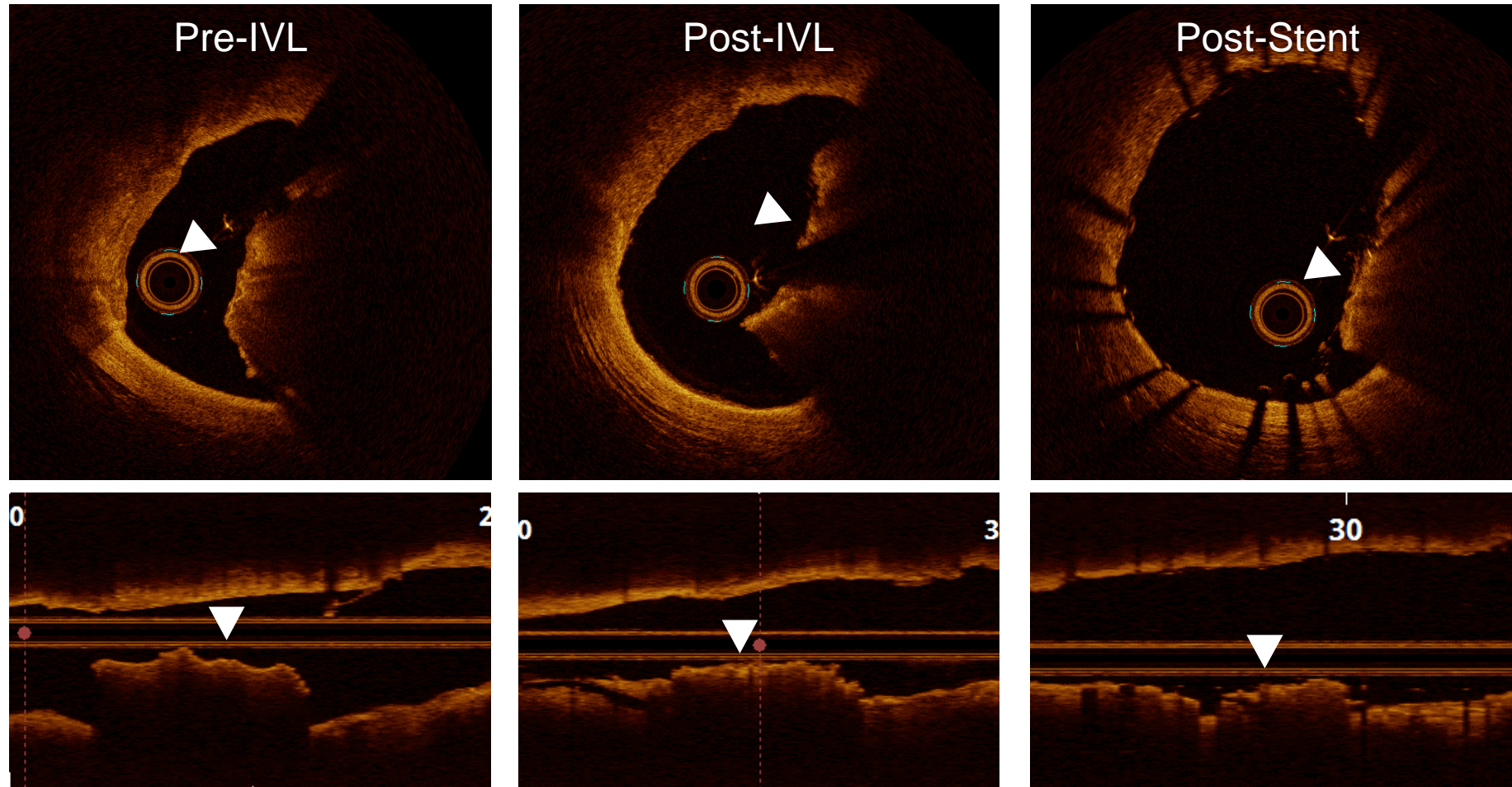
Post-Stent



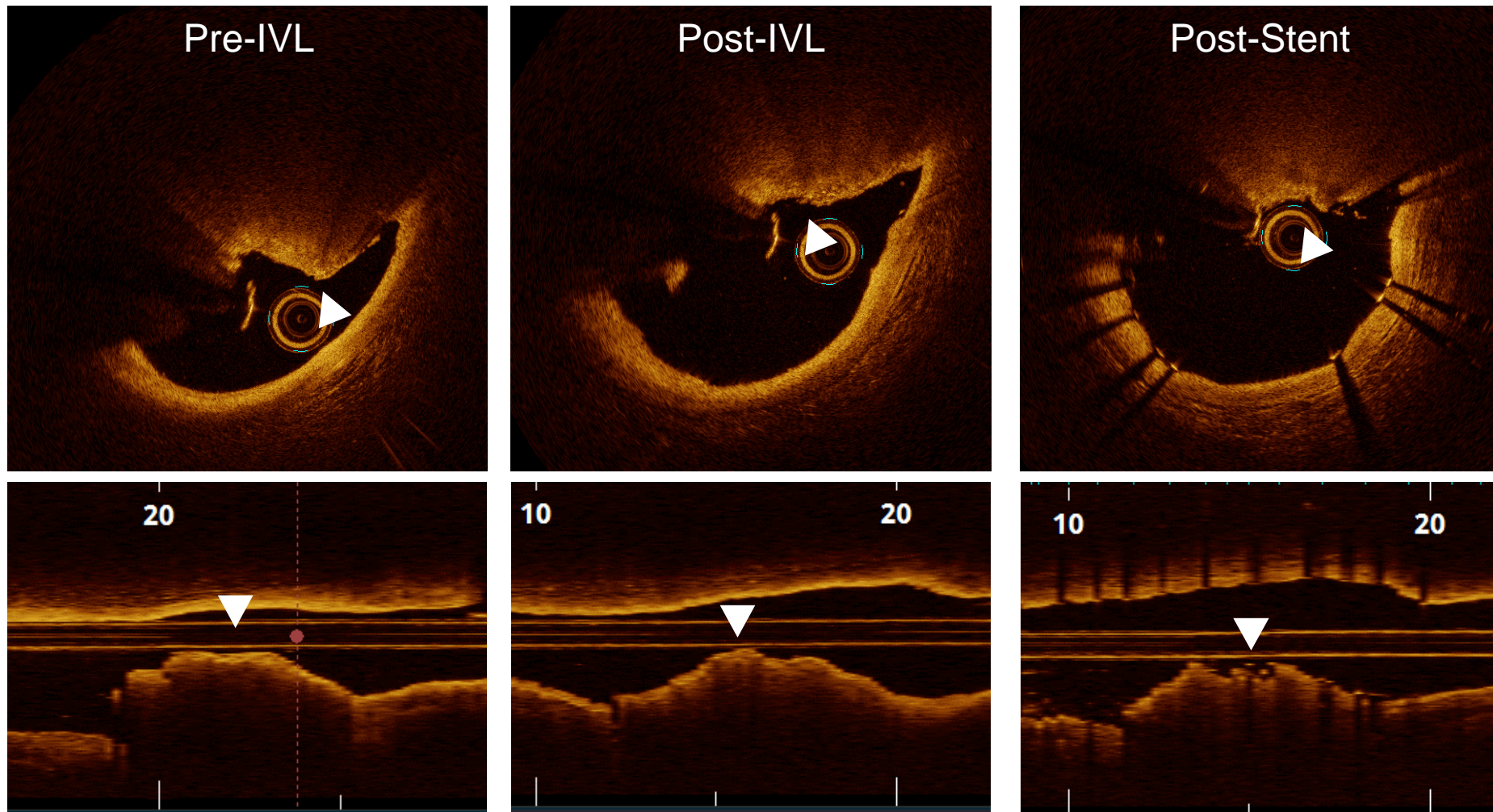
Concentric Stent Expansion: Deformed Eruptive CN



Concentric Stent Expansion: Deformed Nodular Calcification



Eccentric Stent Expansion: Non-Deformed Nodular Calcification

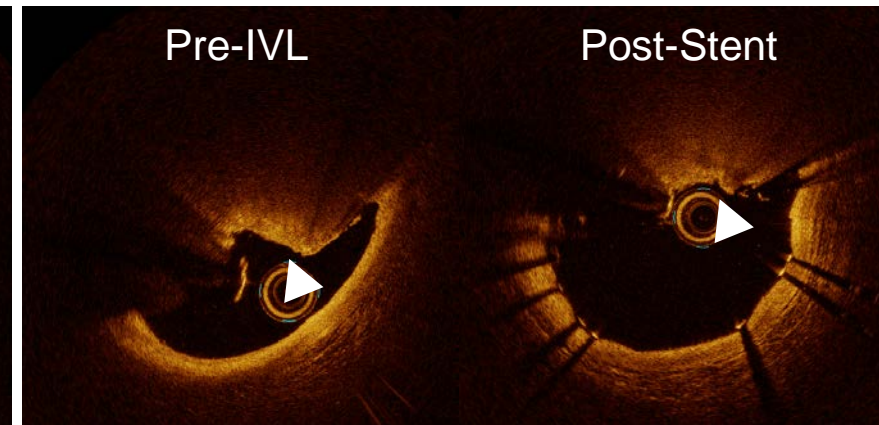
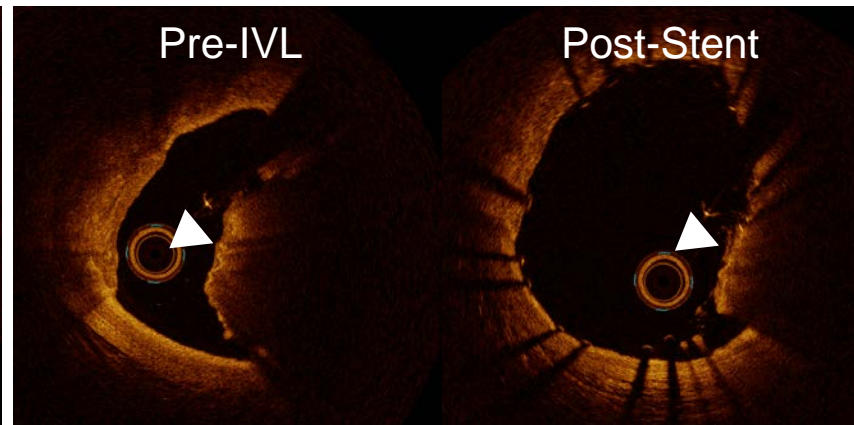
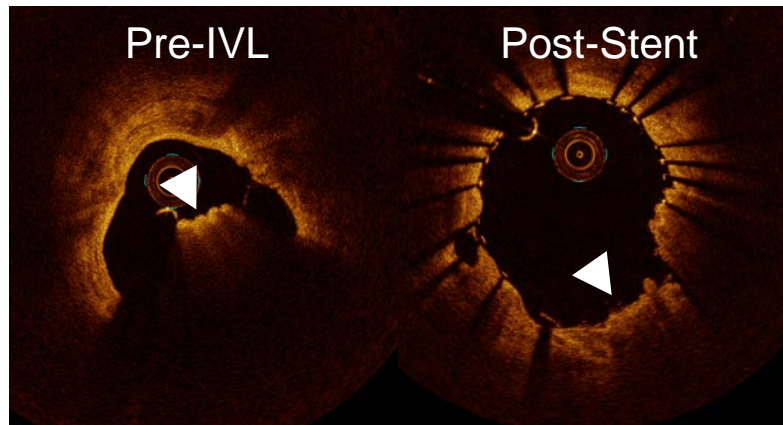


Patterns of Stent Expansion

Concentric expansion
Deformed Eruptive Nodule
34%

Concentric expansion
Deformed Nodular Calcification
43%

Eccentric expansion
Non-deformed Nodular Calcification
23%



Post-stent Outcomes

Core Lab Analysis	CN lesion N=54	Non-CN lesion N=194	P value
Visible calcium fracture	79%	65%	0.07
Visible fractures/lesion	4.1 ± 3.6	2.9 ± 2.5	0.04
Acute lumen gain at MLA site, mm ²	2.6 ± 2.1	2.6 ± 1.8	0.83
Mean lumen area, mm ²	8.8 ± 2.4	8.1 ± 2.2	0.05
Mean stent area, mm ²	8.3 ± 2.2	7.9 ± 2.3	0.12
Mean stent expansion, mm ²	104.7 ± 25.3	106.9 ± 29.8	0.91
Any malapposition strut, %	5.8 ± 5.8	3.4 ± 4.2	0.0003

Greater number of visible calcium fractures in CN lesions
Concentric stent expansion in CN lesions in majority of cases

Conclusions

- OCT demonstrated consistent MSA and stent expansion outcomes regardless of the presence of calcified nodules
- Deformation of calcified nodules was observed following treatment with IVL
 - IVL acoustic shockwaves may affect calcium deep to the CN allowing for concentric stent expansion
- Increased visible calcium fracture was observed in CN lesions likely due to increased calcium concentricity