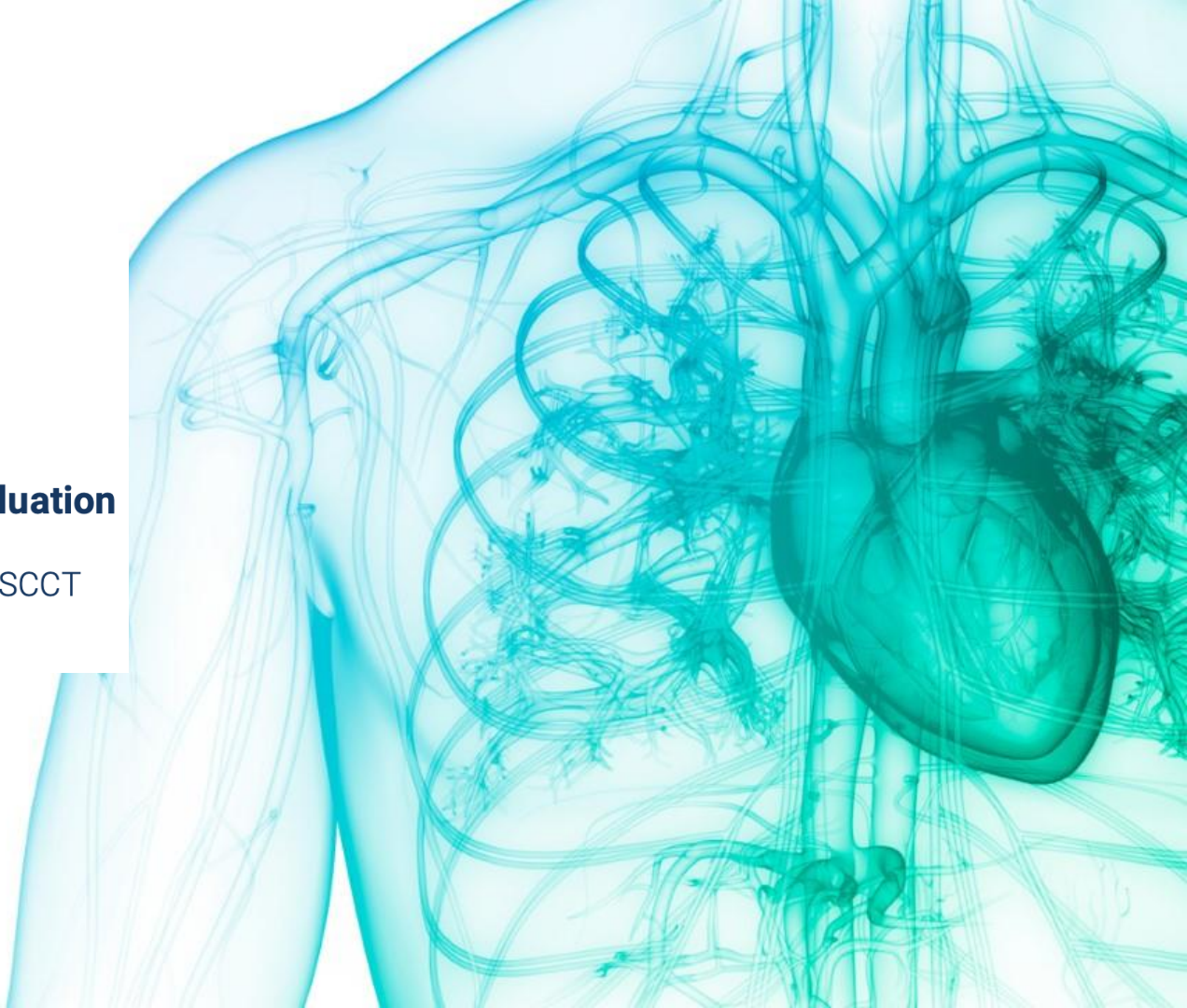




AI-Enabled Whole Heart Evaluation

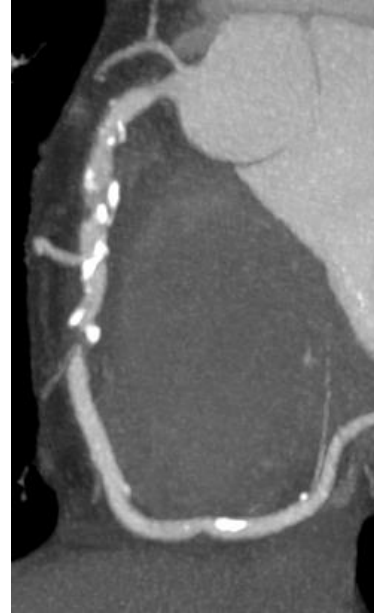
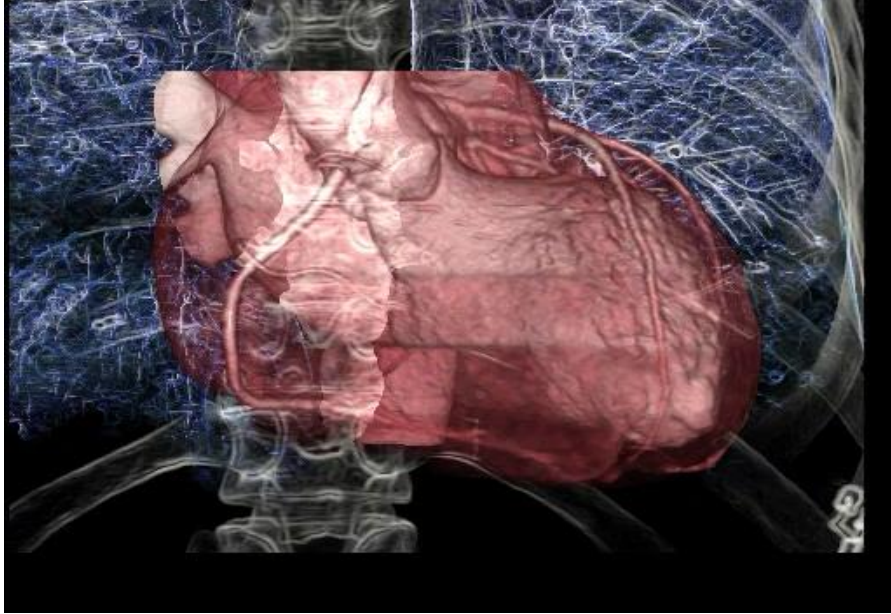
James K. Min, MD FACC FESC MSCCT
Founder & CEO, Cleerly



Outline

- All-in-One CAD Evaluation: Atherosclerosis, Vascular Morphology and Ischemia
- Translating Advanced Image-Based Disease Phenotyping into Actionable Clinical Insights
- Performance Evaluation of AI-Enabled Tools
- Future Directions

Coronary CT Angiography: What can we glean from CT?



Whole heart (<1 second)

Dose (~ screening mammogram)

Cost (~ lab test)

Stenosis (Narrowing)

Ischemia (Blood Flow)

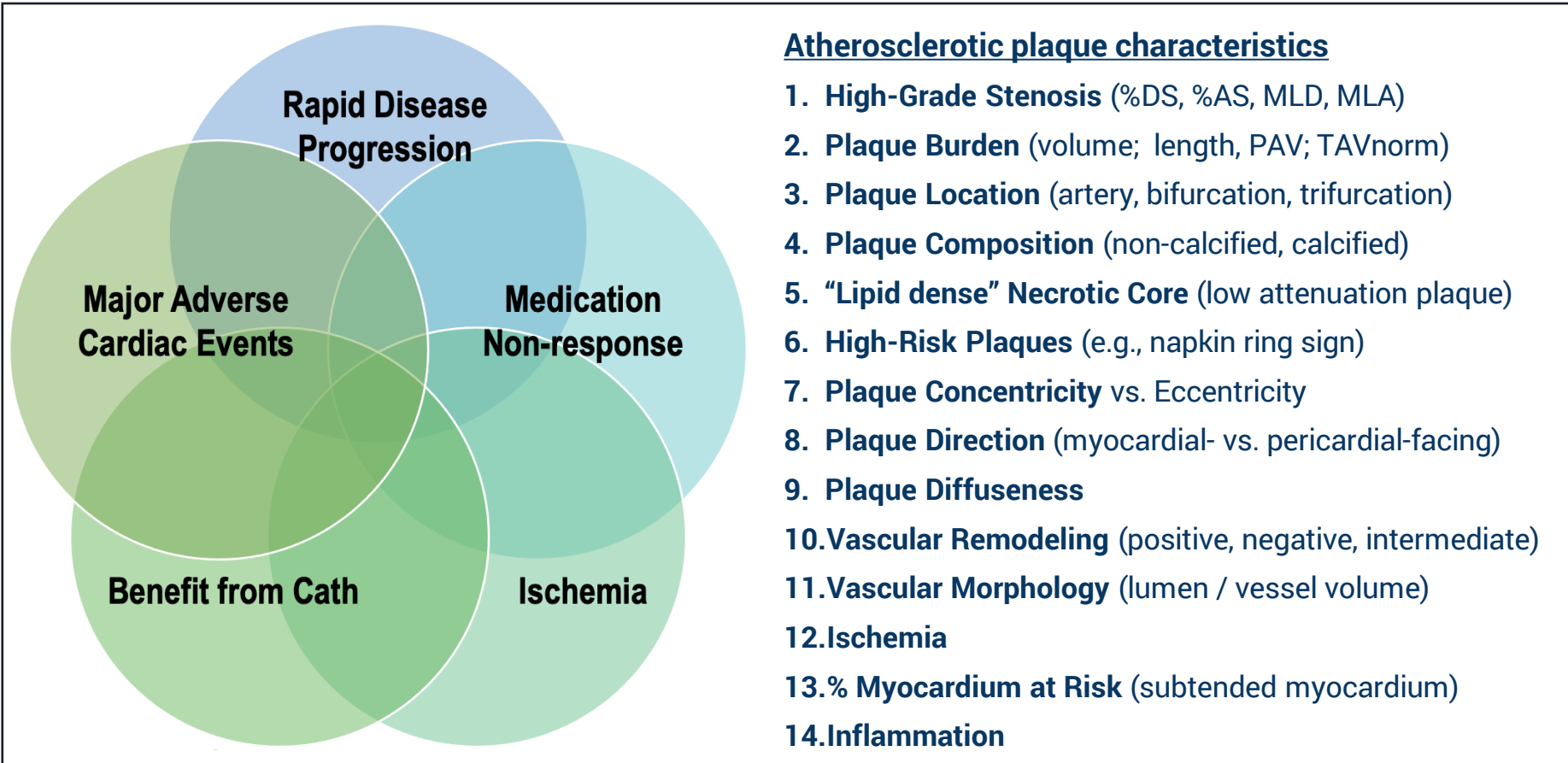
Atherosclerosis (Plaque)

2005-2010

2010-2015

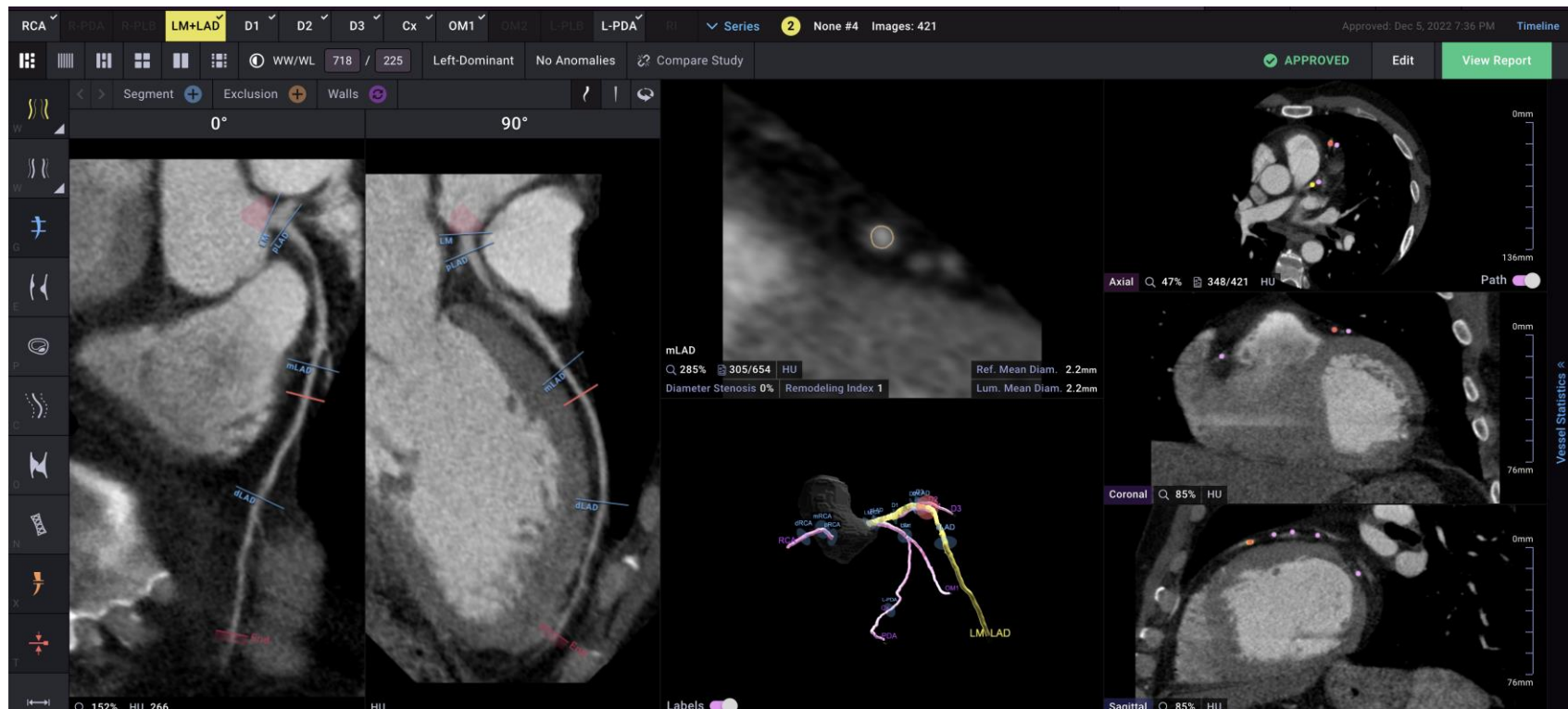
2015+

Comprehensive Coronary CT Evaluation is Limited and Time-Intensive



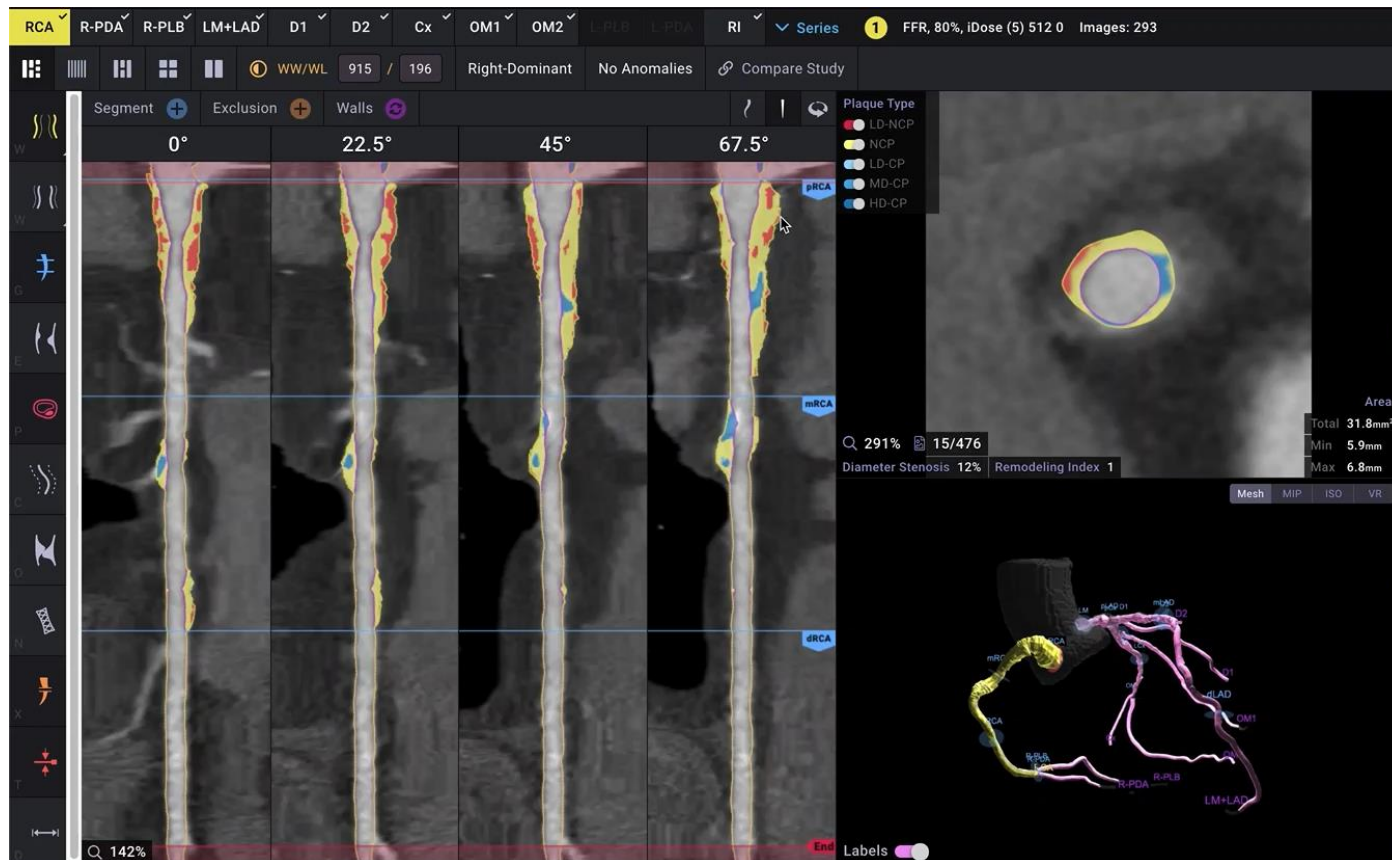
AI-Enabled Whole Heart Evaluation

From Manual and Subjective to Fully Automated

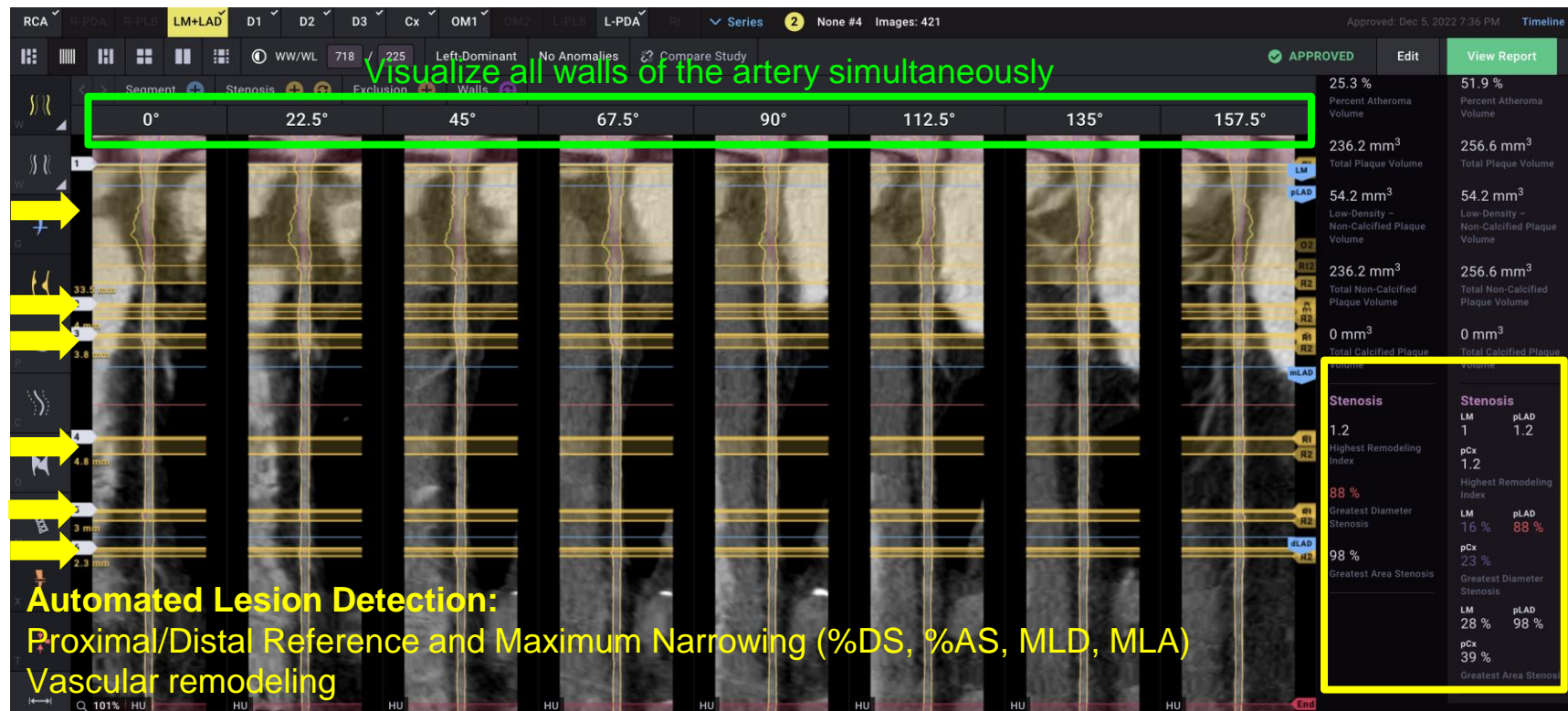


AI-Enabled Tools Now Allow for Comprehensive Whole Heart Evaluation

Atherosclerosis, Vascular Morphology, Ischemia in Minutes-Long Evaluation

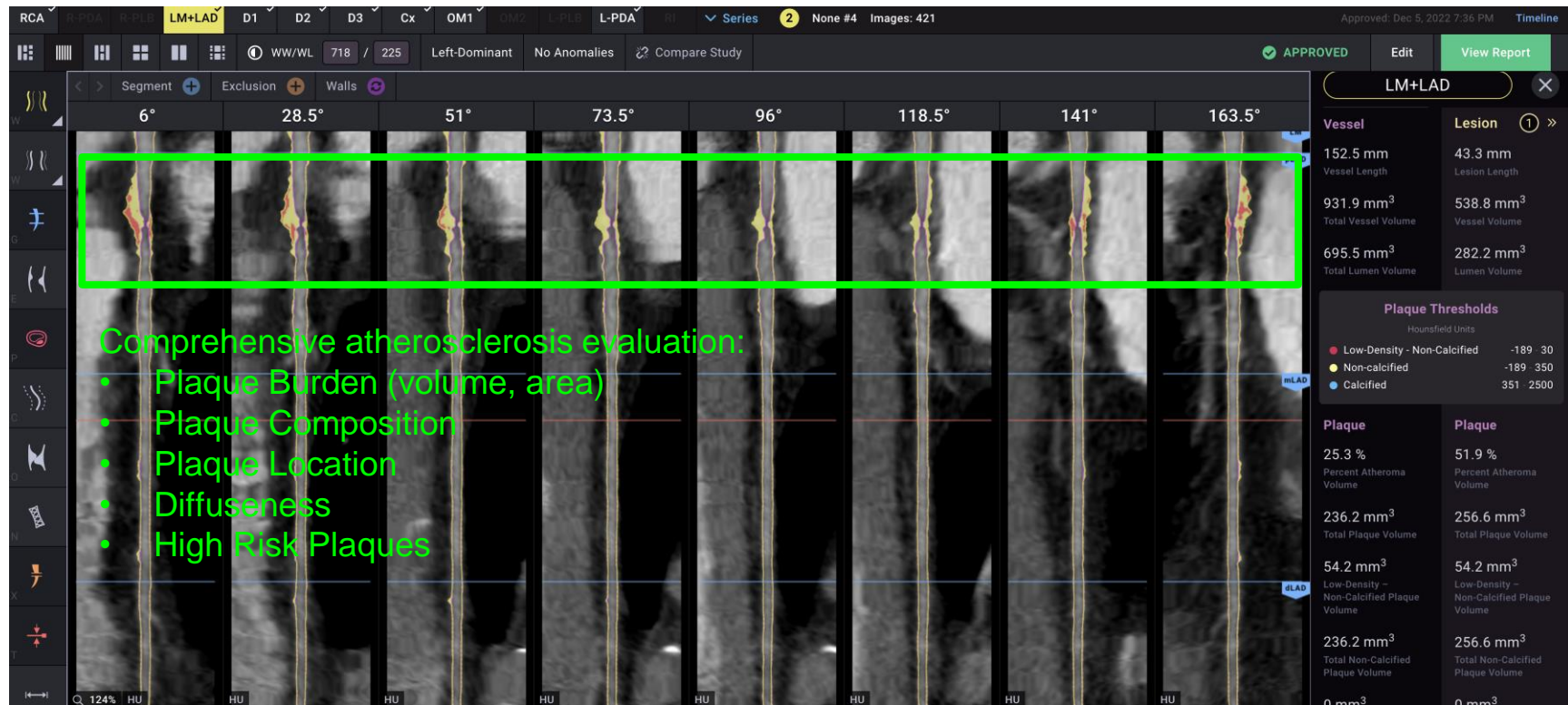


AI-Enabled Whole Heart Evaluation for Vascular Morphology Lesion Detection and Stenosis Quantification



AI-Enabled Whole Heart Evaluation for Atherosclerosis

Comprehensive atherosclerosis evaluation



AI-Enabled Whole Heart Evaluation

Per-Patient, -Vessel, -Segment and -Lesion Quantification

Comprehensive Coronary Artery Evaluation

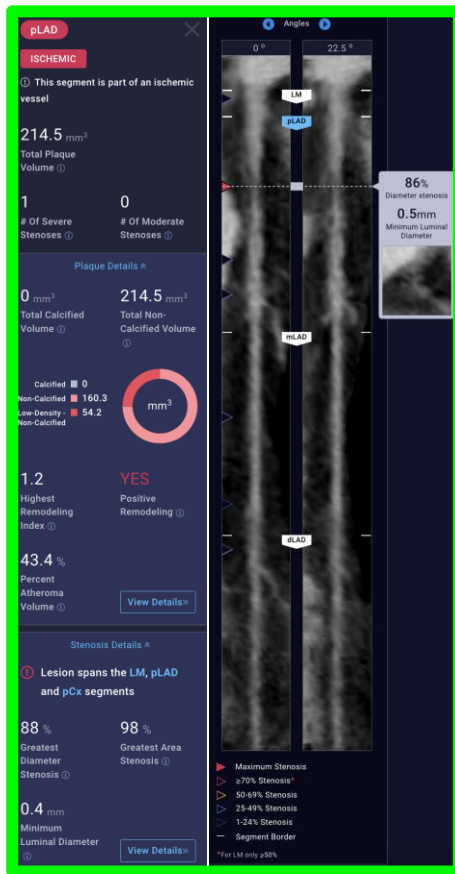
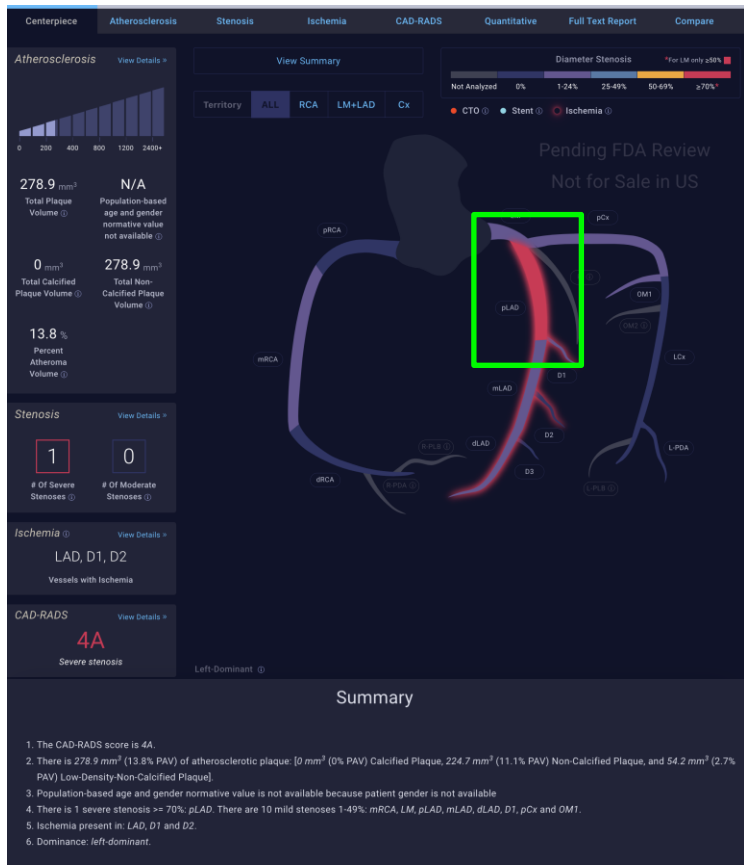
[Download PDF](#)
[Download CSV](#)

Artery	Segment	Length (mm)	Vessel Volume (mm ³)	Lumen Volume (mm ³)	Total Plaque Volume (mm ³)	Greatest Diameter Stenosis (%)	Greatest Area Stenosis (%)	Highest Remodeling Index
LM	LM	6.3	87.2	72.4	14.8	16	28	1
Total		6.3	87.2	72.4	14.8	-	-	-
LAD	pLAD	51	494.3	279.8	214.5	88	98	1.2
	mLAD	48	190.7	184.8	5.8	4	5	1.1
	dLAD	47.3	159.7	158.5	1.1	4	12	1.1
	D1	29.5	75.6	75	0.6	6	13	1.2
	D2	13.3	25.7	25.7	0	N/A	N/A	1
	D3	30	61	61	0	N/A	N/A	1
	RI	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total		219	1007	784.8	222	-	-	-
RCA	pRCA	12.5	55.1	55.1	0	N/A	N/A	1
	mRCA	13.3	45.7	44.5	1.1	5	0	1.1
	dRCA	12	33.9	33.9	0	N/A	N/A	1
	R-PDA	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	R-PLB	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total		37.8	134.7	133.5	1.1	-	-	-
Cx	pCx	26	232.4	195.7	36.6	23	39	1.2
	LCx	63.5	247.8	247.8	0	N/A	N/A	1
	L-PLB	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	L-PDA	49.3	113.1	113.1	0	N/A	N/A	1
	OM1	60.5	200	195.6	4.4	5	3	1.2
	OM2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total		199.3	793.3	752.2	41	-	-	-
Sum Total		462.3	2022.2	1742.9	278.9	-	-	-

Artery	Segment	Total Plaque Volume (mm ³)	Non-Calcified Plaque				Percent Atheroma Volume (%)
			Non-Calcified Plaque Volume (mm ³)	Low-Density - Non-Calcified Plaque Volume (mm ³)	Total Non-Calcified Plaque Volume (mm ³)	Calcified Plaque	
LM	LM	14.8	14.8	0	14.8	0	17
Total		14.8	14.8	0	14.8	0	17
LAD	pLAD	214.5	160.3	54.2	214.5	0	43.4
	mLAD	5.8	5.8	0	5.8	0	3
	dLAD	1.1	1.1	0	1.1	0	0.7
	D1	0.6	0.6	0	0.6	0	0.8
	D2	0	0	0	0	0	0
	D3	0	0	0	0	0	0
	RI	N/A	N/A	N/A	N/A	N/A	N/A
Total		222	167.8	54.2	222	0	22
RCA	pRCA	0	0	0	0	0	0
	mRCA	1.1	1.1	0	1.1	0	2.4
	dRCA	0	0	0	0	0	0
	R-PDA	N/A	N/A	N/A	N/A	N/A	N/A
	R-PLB	N/A	N/A	N/A	N/A	N/A	N/A
Total		1.1	1.1	0	1.1	0	0.8
Cx	pCx	36.6	36.6	0	36.6	0	15.7
	LCx	0	0	0	0	0	0
	L-PLB	N/A	N/A	N/A	N/A	N/A	N/A
	L-PDA	0	0	0	0	0	0
	OM1	4.4	4.4	0	4.4	0	2.2
	OM2	N/A	N/A	N/A	N/A	N/A	N/A
Total		41	41	0	41	0	5.2
Sum Total		278.9	224.7	54.2	278.9	0	13.8

AI-Enabled Tools Now Allow for Effortless Visualization

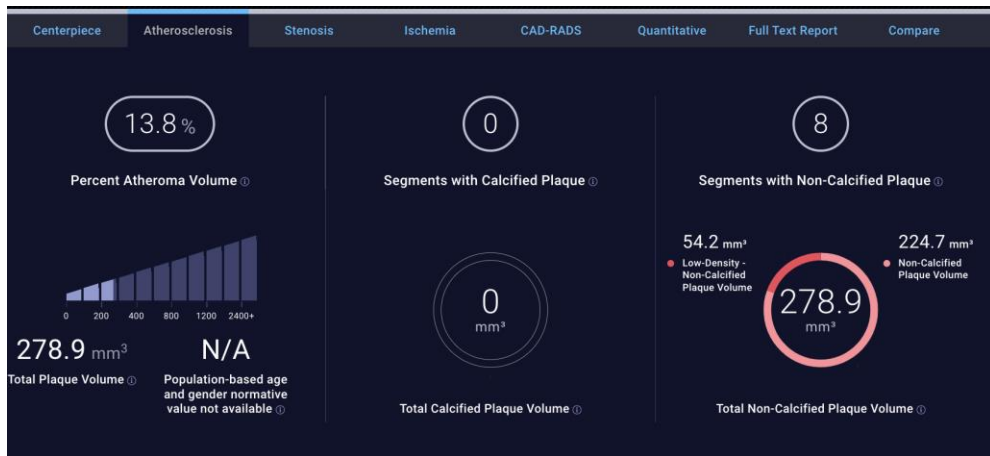
Translating Advanced Image-Based Disease Phenotyping into Actionable Clinical Insights



- Fully Interactive Web-Based Platform
- Deep Dive Visualization
- Patient-, Segment-, Vessel-, Vessel-territory Interrogation
- Automated arrow identification

AI-Enabled Whole Heart Evaluation for Amount and Type of Atherosclerosis

Atherosclerosis Findings for Clinical Action

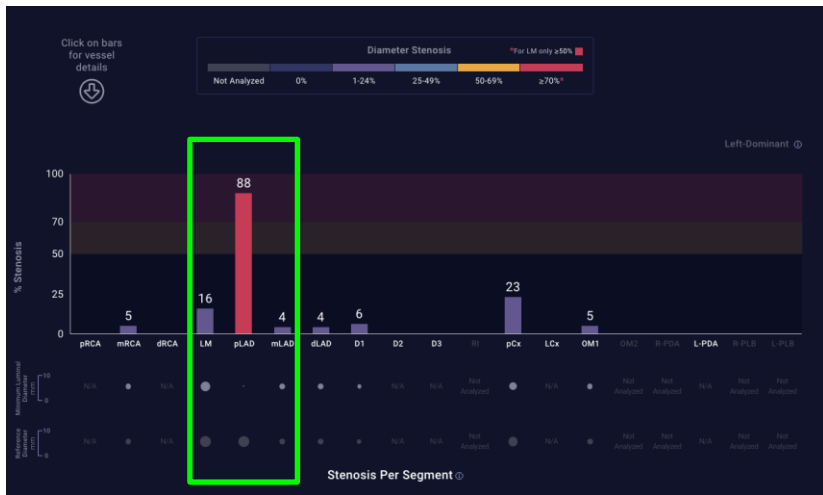


Interactive Emphasis on All Elements of Atherosclerosis



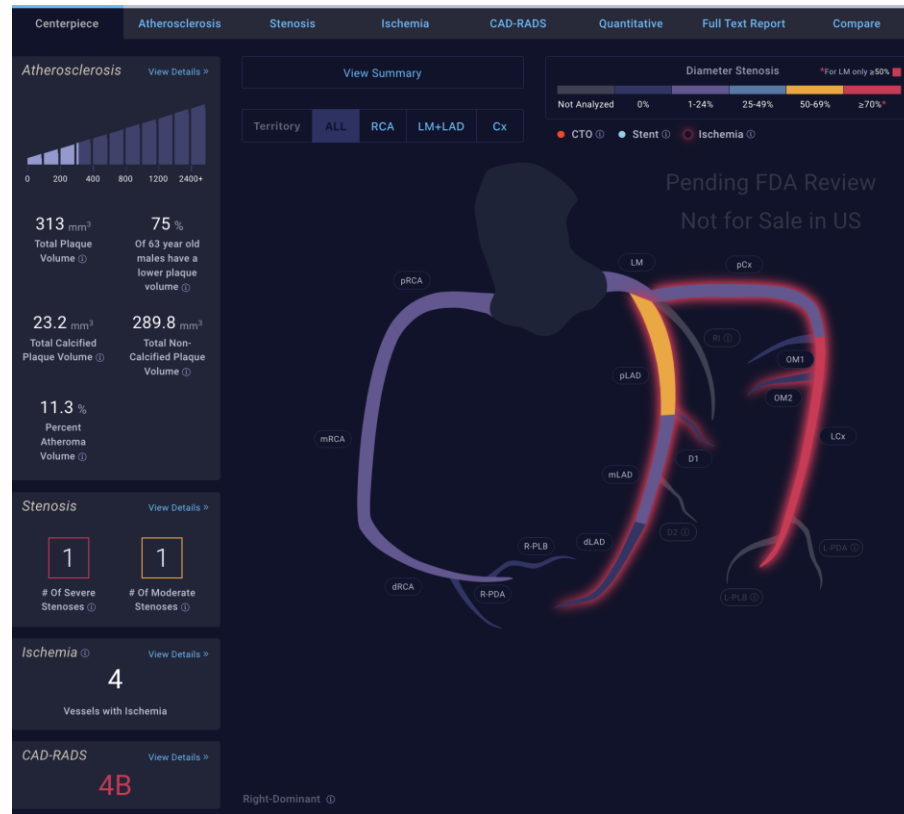
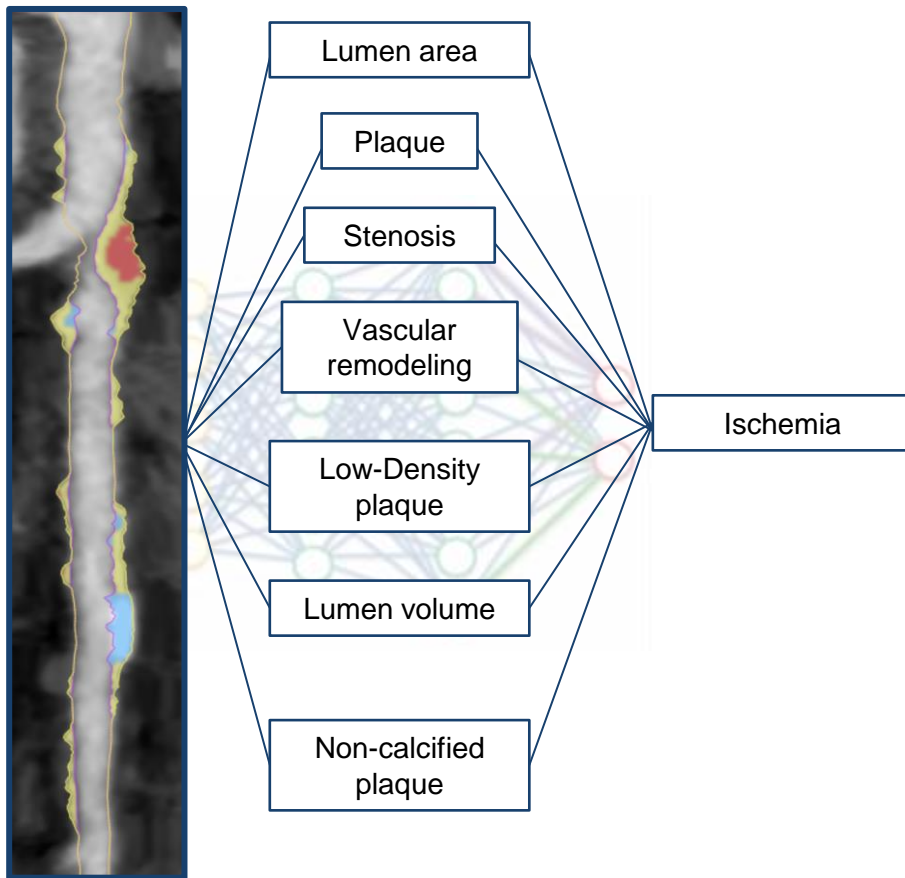
AI-Enabled Whole Heart Evaluation for Comprehensive Stenosis

Whole-Heart Stenosis Evaluation for Pre-Procedural Planning



AI-Enabled Whole Heart Evaluation for Coronary Ischemia

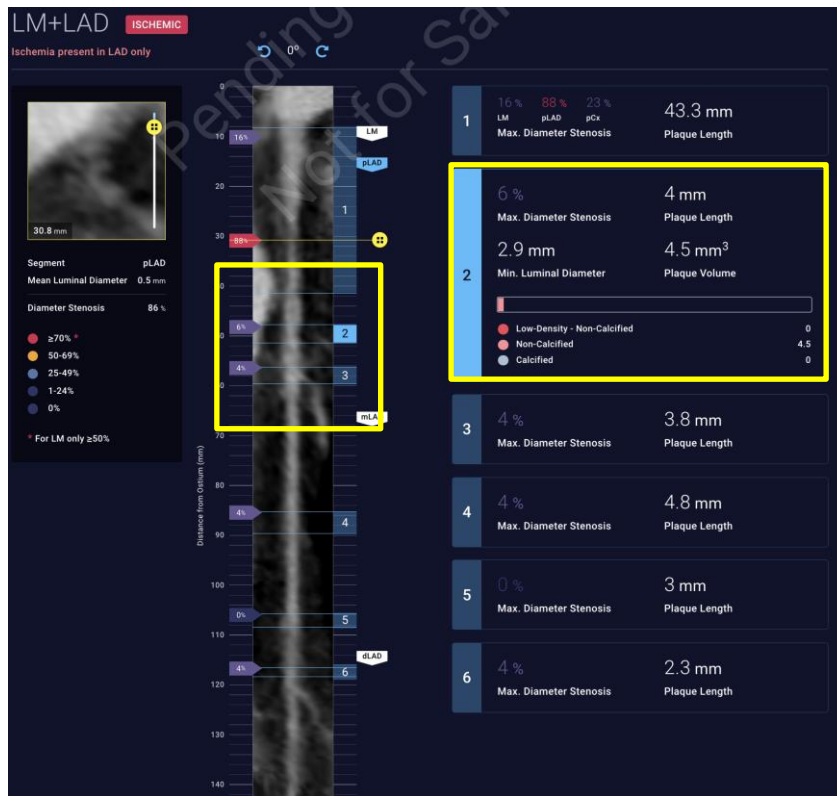
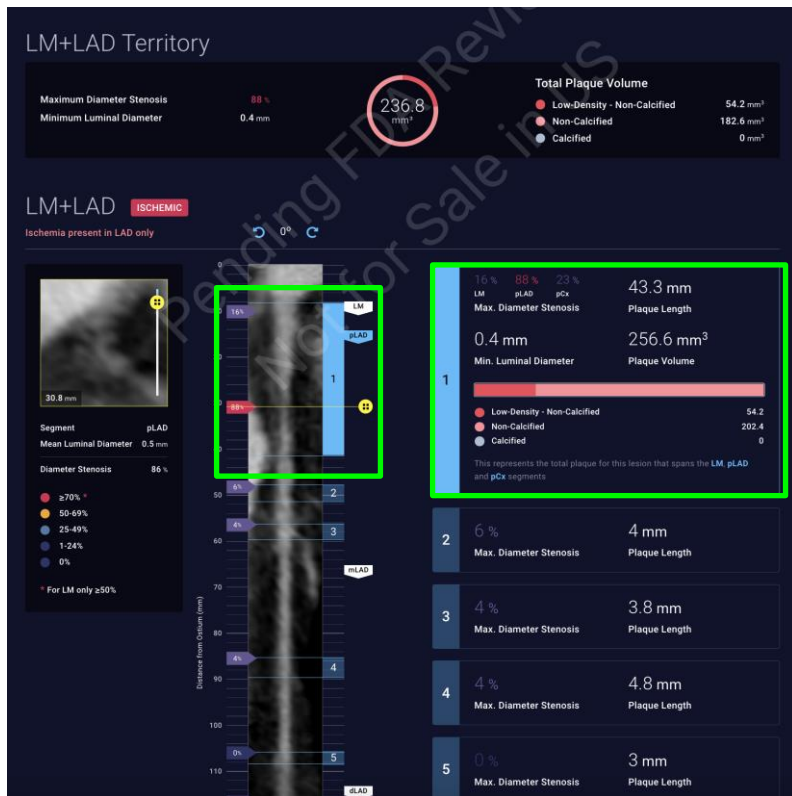
Determination of Ischemia Free of Assumptions



Cleerly ISCHEMIA for investigational use only.

AI-Enabled Whole Heart Evaluation for Coronary Ischemia

Lesion-by-Lesion Interrogation to Determine *Why* a Vessel is Ischemic



AI-Enabled Whole Heart Evaluation for “Risk” Scoring

Automated CAD-RADS Scoring for Stable and Acute Symptoms

CAD-RADS Reporting and Data System Please refer to the Centerpiece in order to determine a CAD-RADS score

Choose a CAD-RADS Score

N	0	1	2	3	4A	4B	5
Non-diagnostic study	No plaque or stenosis	Minimal stenosis or plaque with no stenosis	Mild stenosis	Moderate stenosis	Severe stenosis	Left main >50% or 3-vessel obstructive (≥70%) disease	Total occlusion

Choose Modifiers (optional)

N S G V

Save

Saving the CAD-RADS score will modify the Reports and will send an email to the appropriate users.

Choose Presentation

Stable Symptoms Acute Symptoms

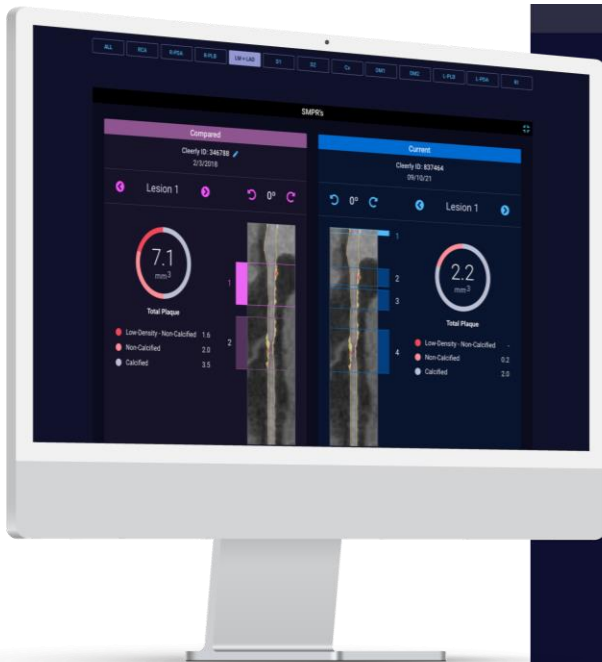
You have chosen CAD-RADS 4A with Stable Symptoms for this patient

CAD-RADS Score	Degree of maximal coronary stenosis	Interpretation	Further Cardiac Investigation	Management
4A	70-99% stenosis	Severe stenosis	Consider ICA or functional assessment	Consider symptom-guided anti-ischemic and preventive pharmacotherapy as well as risk factor modification per guideline-directed care. Other treatments (including options of revascularization) should be considered per guideline-directed care.

Source: CAD-RADS™ Coronary Artery Disease - Reporting and Data System. An expert consensus document.

AI-Enabled Whole Heart Evaluation for Quantitative Disease Tracking

2 Goals: (1) Stop New Disease Progression and (2) Stabilize Pre-Existing Disease (via NCP → CP)



LM+LAD	mm ³	PAV	Compared Cleerly ID: 346788 2/3/2018	Current Cleerly ID: 837464 09/10/21
Total Plaque (mm ³)	220.1	+10.0	220.1	230.1
Total Non-Calcified Plaque (mm ³)	79.9	-20.0	79.9	59.9
Low-Density - Non-Calcified Plaque (mm ³)	25.2	-10.7	25.2	14.5
Non-Calcified Plaque (mm ³)	54.7	-9.3	54.7	45.4
Total Calcified Plaque (mm ³)	140.2	+30.0	140.2	170.2
Low-Density Calcified Plaque (mm ³)	23.1	+7.0	23.1	30.1
Medium-Density Calcified Plaque (mm ³)	37.1	-5.0	37.1	32.1
High-Density Calcified Plaque (mm ³)	80.0	+28.0	80.0	108.0

SMPRs
360°
0°

AI-Enabled Whole Heart Evaluation to Improve Health Literacy

Automated Reporting (1) in Accordance w/ SCCT Guidelines, (2) for Referring Providers, and (3) for Patients

Download Send to PACS

CLINICAL REPORT

Summary

- The CAD-RADS score is 4A.
- There is 278.9 mm³ (13.8% PAV) of atherosclerotic plaque: 0 mm³ (0% PAV) Calcified Plaque, 224.7 mm³ (11.1% PAV) Non-Calcified Plaque, and 54.2 mm³ (2.7% PAV) Low-Density-Non-Calcified Plaque.
- Population-based age and gender normative value is not available because patient gender is not available.
- There is 1 severe stenosis => 70% pLAD. There are 10 mild stenoses 1-49%: mRCA, LM, pLAD, mLAD, dLAD, D1, pCx and OM1.
- Ischemia present in: LAD, D1 and D2.
- Dominance: left-dominant.

Anatomical Findings

This patient is left-dominant.

Coronary Stenosis & Atherosclerosis

The patient's total volume of atherosclerotic plaque is 278.9 mm³ (13.8% PAV), including 278.9 mm³ (13.8% PAV) of Non-Calcified Plaque [54.2 mm³ (2.7% PAV) of Low-Density-Non-Calcified Plaque and 224.7 mm³ (11.1% PAV) of Non-Calcified Plaque] and 0 mm³ (0% PAV) of Calcified Plaque.

Population-based age and gender normative value is not available because patient gender is not available.

Left Main:

A lesion spans the LM, pLAD and pCx with a mild stenosis of 16% in the LM, a severe stenosis of 88% in the pLAD and a mild stenosis of 23% in the pCx. No ischemia present in the Left Main.

Left Main: There is 14.8 mm³ (1.7% PAV) of plaque including 14.8 mm³ (1.7% PAV) of Non-Calcified Plaque [0 mm³ (0% PAV) of Low-Density-Non-Calcified Plaque and 14.8 mm³ (1.7% PAV) of Non-Calcified Plaque] and 0 mm³ (0% PAV) of Calcified Plaque.

Left Anterior Descending Territory:

A lesion spans the LM, pLAD and pCx with a mild stenosis of 16% in the LM, a severe stenosis of 88% in the pLAD and a mild stenosis of 23% in the pCx. There are additional non-obstructive plaques present in the pLAD with a maximum diameter reduction of approximately 6%.

There is a mild stenosis in the mLAD. This reduces the diameter by approximately 4%.

There is a mild stenosis in the D1. This reduces the diameter by approximately 6%.

There is a mild stenosis in the dLAD. This reduces the diameter by approximately 4%.

There is a 0% stenosis in the mLAD. This reduces the diameter by approximately 0%.

Ischemia present in: LAD, D1 and D2.

Left Anterior Descending: There is 222 mm³ (22% PAV) of plaque including 222 mm³ (22% PAV) of Non-Calcified Plaque [54.2 mm³ (5.4% PAV) of Low-Density-

For Medical Record

Left Main and Left Anterior Descending (LM+LAD) **ISCHEMIA** Ischemia present in LAD only

clearly Coronary Imaging Service

Patient: ANONYMOUS MRN: HRP pLAD with STEMI Clearly ID: 1380E65A Study Date: 5/19/2016 03:36 PM Provider: N/A

Summary

Atherosclerosis Stage 2 (278.9 mm³ Total Plaque; 54.2 mm³ Low-Density - Non-Calcified; 224.7 mm³ Non-Calcified; 0 mm³ Calcified) Total Plaque Volume 278.9 mm³

Stenosis 1 Severe (pLAD); 10 Minimal (mRCA, LM, pLAD, mLAD, dLAD, D1, pCx, OM1)

Ischemia Present (LAD, D1, D2)

Dominance Left-Dominant

CAD-RADS 4A

Population-based age and gender normative value is not available because patient gender is not available.

Atherosclerosis | Stage 2

Min. et al. et al. Coronary CT shows atherosclerotic plaques according to invasive coronary angiography and FFR [\(JACC Cardiovasc Imaging. 2016;9\(10\):1143-1151\)](#)

Territory	Plaque Volume (mm ³)				Percent Atherosclerosis Volume	Plaque Stage		
	TOTAL	Low-Density - Non-Calcified	Non-Calcified	Calcified		Stage	mm ³	PAV
RCA	1.1	0	1.1	0	0.8%	0	0	0%
LM+LAD	236.8	54.2	182.6	0	21.6%	1	>0-250	>0-5%
Cx	41	0	41	0	5.2%	2	>250-750	>5-15%
TOTAL	278.9	54.2	224.7	0	13.8%	3	>750	>15%

Stenosis

Severity	% of >50% LM only	Count	Percentage
Severe	>70% of >50% LM only	1	50.00%
Moderate	50-69%	0	0%
Mild	25-49%	0	0%
Minimal	1-24%	10	100%

Territory	Severe	Moderate	Mild	Minimal
mRCA	0%	0%	0%	100%
RCA	0%	0%	0%	100%
R.PDA	0%	0%	0%	100%
R.P.LB	0%	0%	0%	100%
LM	16%	0%	0%	84%
mLAD	4%	0%	0%	96%
dLAD	4%	0%	0%	96%
D1	0%	0%	0%	100%
D2	0%	0%	0%	100%
D3	0%	0%	0%	100%
pCx	0%	0%	0%	100%
Lcx	0%	0%	0%	100%
OM1	0%	0%	0%	100%
OM2	0%	0%	0%	100%
L.PDA	0%	0%	0%	100%
L.P.LB	0%	0%	0%	100%

Ischemia

Present in: **LAD** **D1** **D2**

For Referring Physicians

Know Your Results: Detailed Clearly Analysis Jane Doe

LM + Left Anterior Descending Coronary Artery

Proximal Mid Distal

Know Your Heart: Coronary Artery Disease Jane Doe

clearly

NAME: Jane Doe
MRN: 39459504
Clearly ID Number: 00745232
Date of Examination: 10/03/19
Healthcare Provider: Dr. Jay Earls

Jane Doe,

Let's Examine Your Heart

CHAPTER

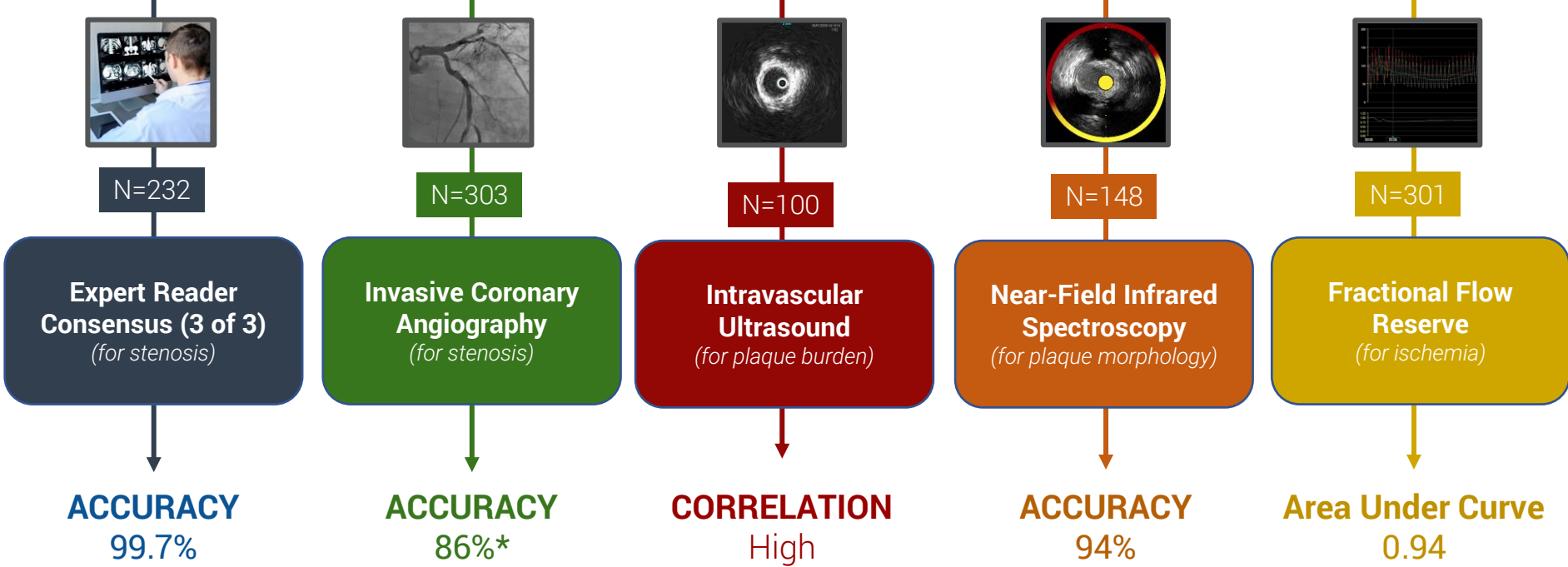
- Know Your Heart: Coronary Artery Disease
- Know Your Risk: Heart Attack Risk Factors
- Know Your Test: Clearly Analysis
- Your Detailed Clearly Analysis

For Patients

Diagnostic Validation of AI-Enabled Evaluation in Multicenter Clinical Trials

MCTs for 'Gold Standard' Validation Determined by Blinded, Expert Core Laboratory Measurements

Proven Accuracy in Multicenter Clinical Trials



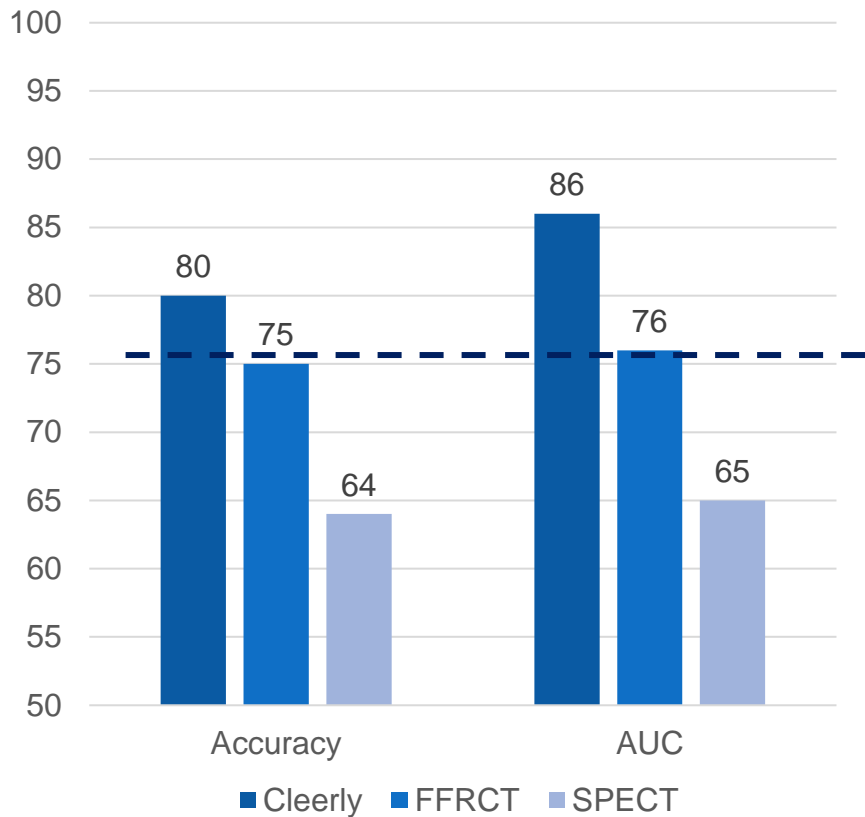
*Clearly demonstrates **higher concordance to invasive FFR (~2 of 3)** than ICA

MCT Comparison to OCT ongoing

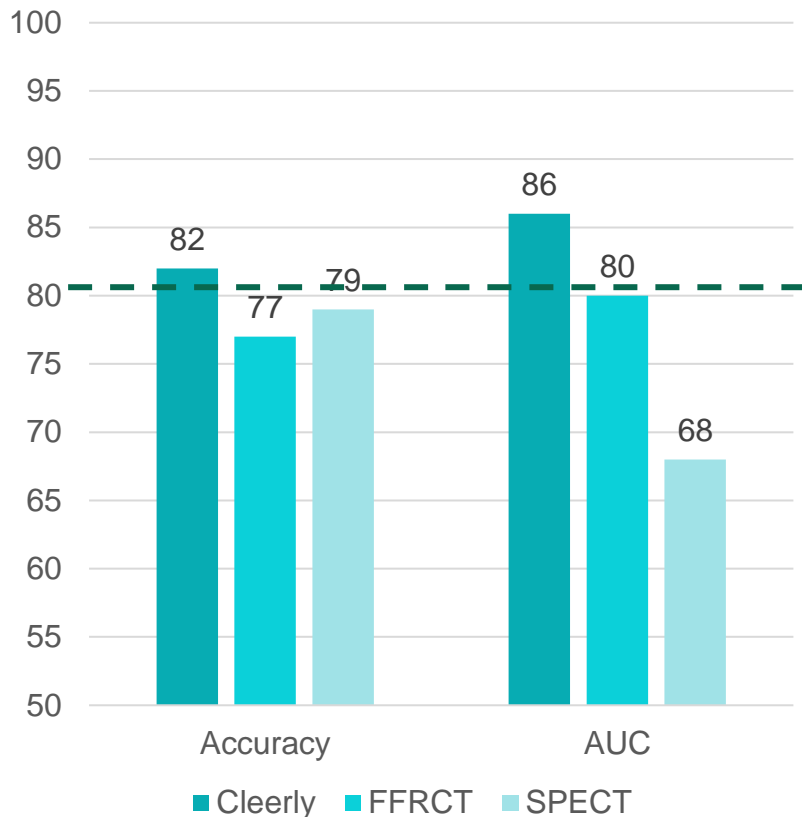
Source: ¹Griffin WF et al. J Am Coll Cardiol 2022 (in press); ²Choi A et al. J Cardiovasc Comput Tomogr 2021; ³Jonas R et al. SCCT Scientific Sessions 2022; ⁴Nakanishi R et al. AHA Scientific Sessions 2022; ⁵Hakim D et al. AHA Scientific Sessions 2021

Diagnostic Validation of AI-Enabled Tools for Ischemia

Comparison to SPECT and FFRCT in CREDESCENCE and PACIFIC Trials with Unbiased 3-vessel Invasive FFR



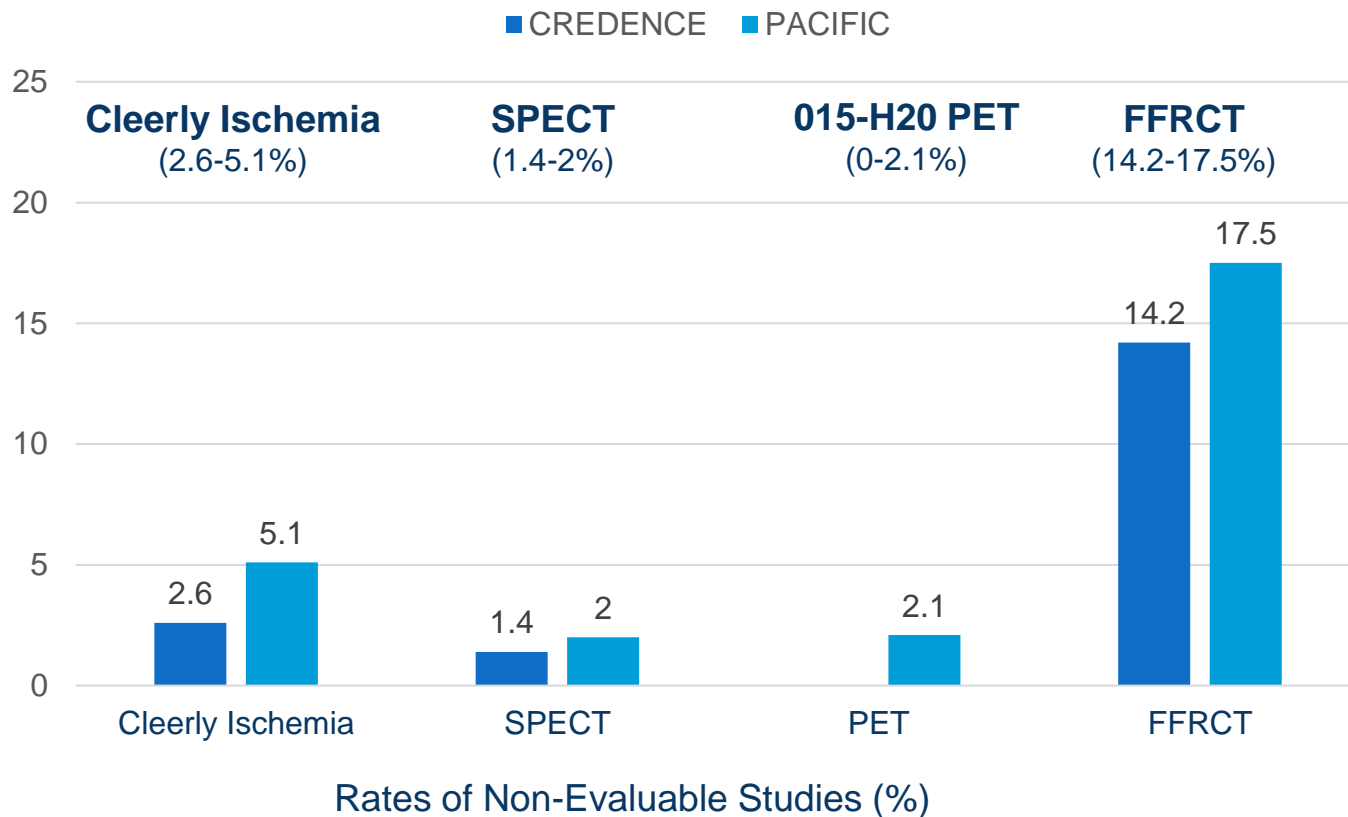
CREDESCENCE Trial (n=868 vessels)



PACIFIC Trial (n=612 vessels)

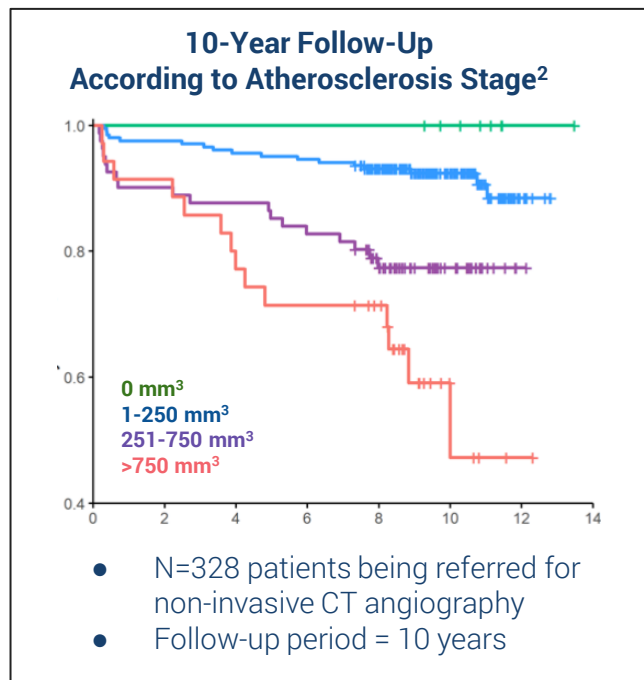
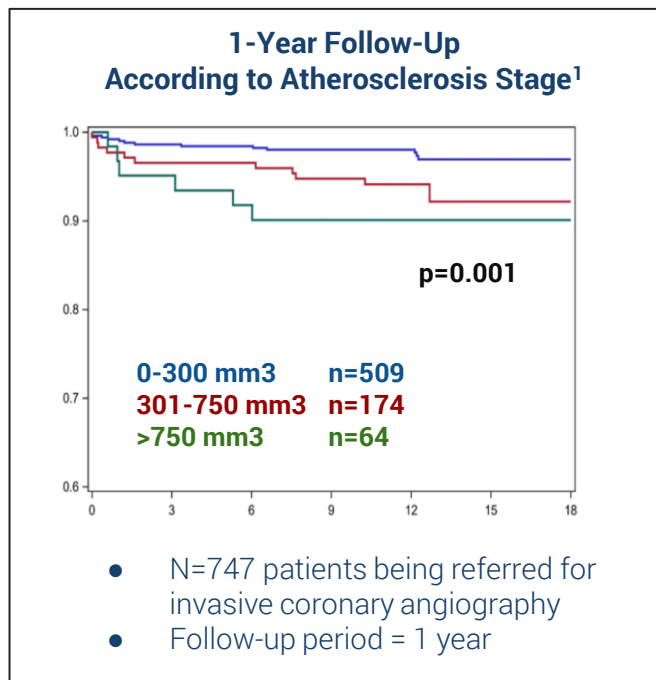
AI-Enabled Whole Heart Evaluation: Rates (%) of Non-Evaluability

AI-Enabled whole heart evaluation allows for assessment of nearly 100% of CCTAs.



Prognostic Validation at 1- and 10-Years for Prediction of MACE

Staging System for Coronary Atherosclerosis Allows for Prediction of MACE with Precision



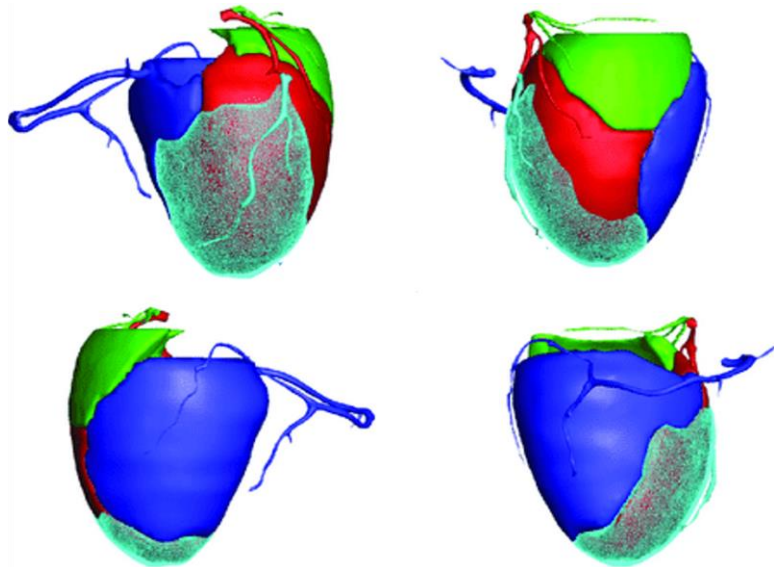
Endpoint: Time to first occurrence of major adverse cardiovascular events (MACE), as defined by death, non-fatal myocardial infarction and late target vessel revascularization

CONFIRM2 ~12,000 patients enrolled to date with 4-year outcomes assessment

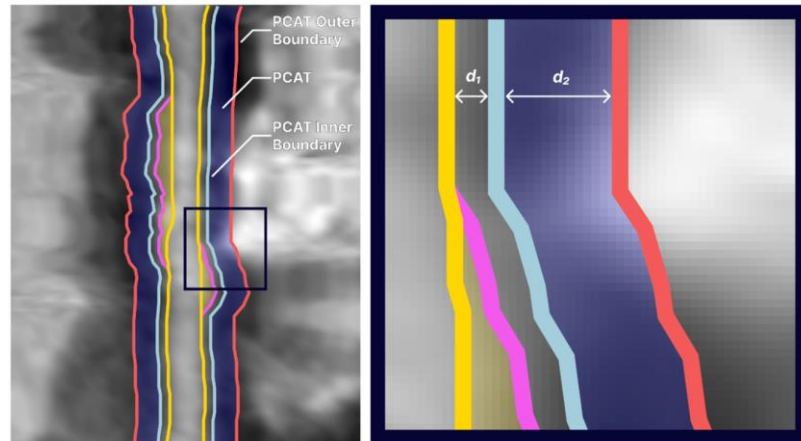
Source: ¹Telluri A et al. Society of Cardiovascular Computed Tomography 2022 Scientific Sessions; ²Nurmohamed NS et al. ACC 2023 Scientific Sessions (In Submission)

AI-Enabled Whole Heart Evaluation

% Subtended Myocardium and Peri-Coronary Adipose Tissue



% Subtended Myocardium
(to guide shared decision making)



Peri-Coronary Adipose Tissue
(Inflammation)

Conclusions

- AI-Enabled Whole Heart Evaluation Now Enables Rapid and Accurate All-in-One CAD Evaluation for Atherosclerosis, Vascular Morphology and Ischemia
- Educational Tools Allow for Translation of Advanced Image-Based Disease Phenotyping into Actionable Clinical Insights
- Patient-, Vessel-, Segment-, Lesion- and Axial-Slice Level Information Can Be Effectively Deployed in Both Clinical Practice and Clinical Trials
- Future Improvements Will Allow for Additional Non-Coronary Features That Will Augment Coronary Artery Disease Assessment