AI-Enabled Whole Heart Evaluation

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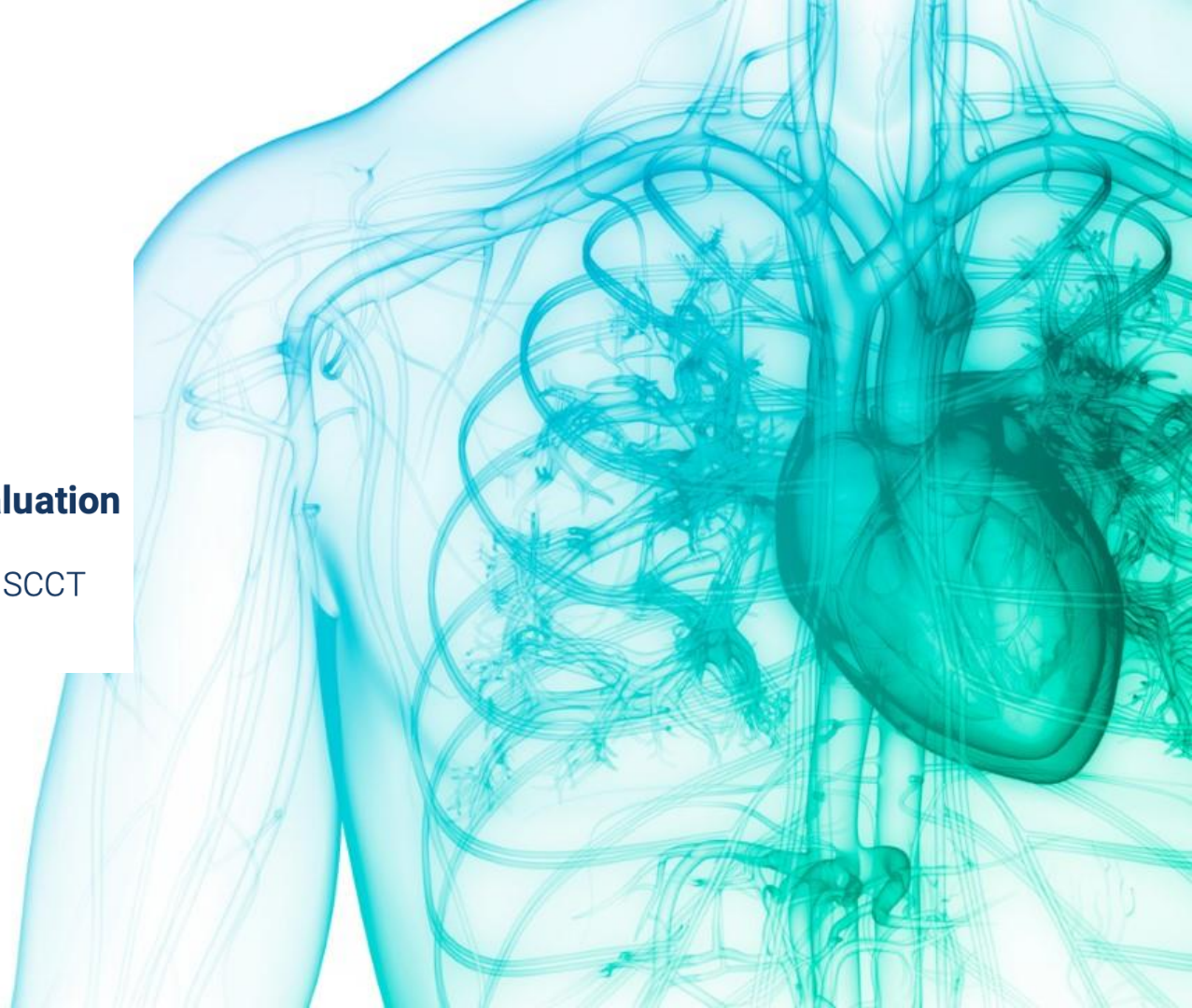

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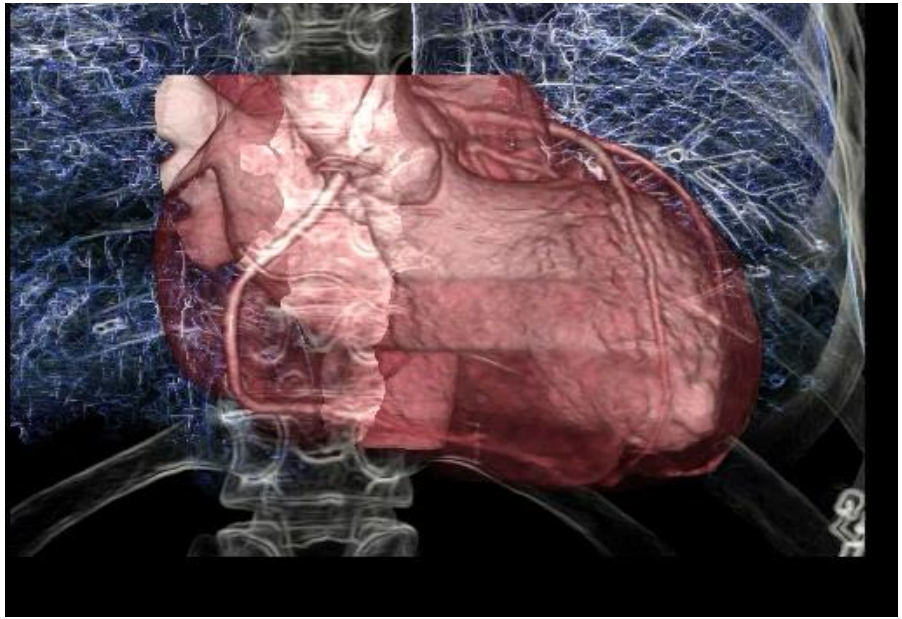
Outline

- 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

cleerly
seeing more of what matters

Coronary CT Angiography: What can we glean from CT?



Whole heart (<1 second)

Dose (~ screening mammogram)

Cost (~ lab test)

Stenosis (Narrowing)

2005-2010

Ischemia (Blood Flow)

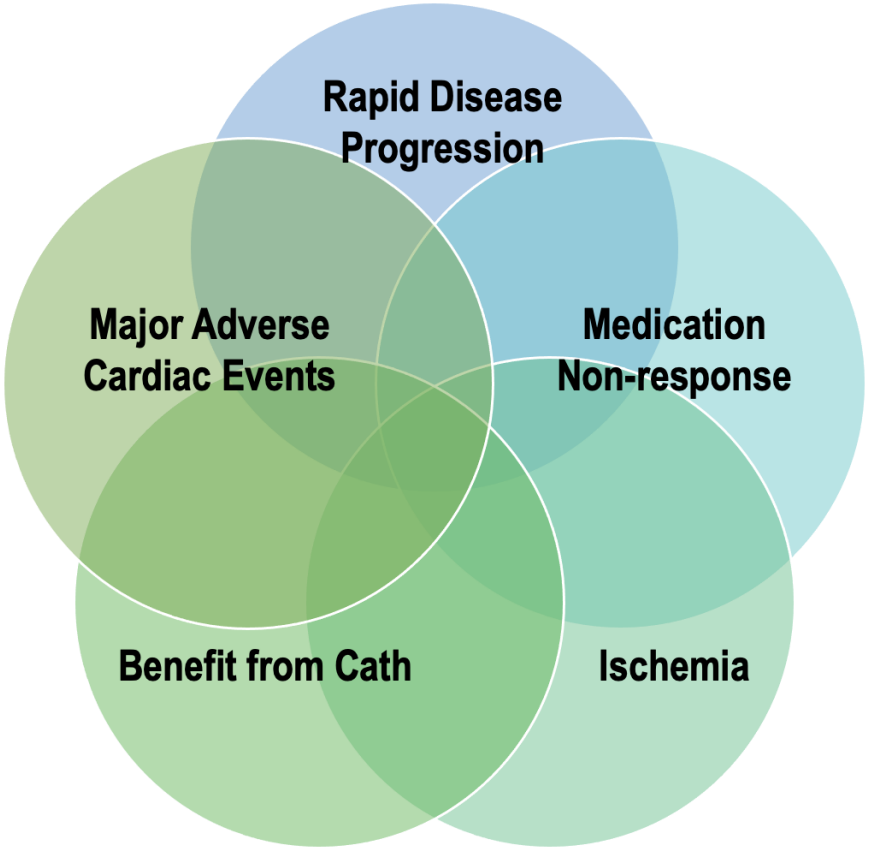
2010-2015

Atherosclerosis (Plaque)

2015+

Source: Marwick TH et al. J Am Coll Cardiol 2015

Comprehensive Coronary CT Evaluation is Limited and Time-Intensive



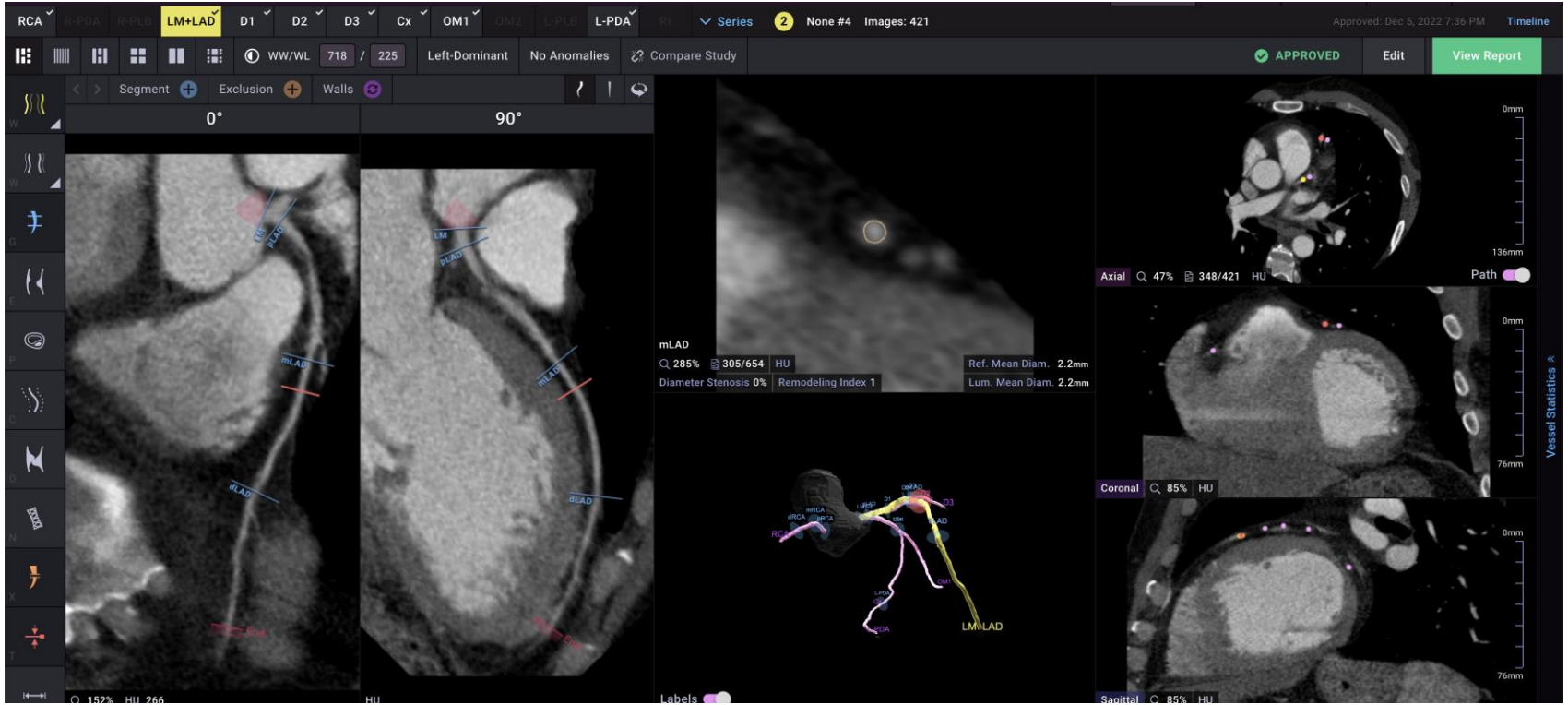
Atherosclerotic plaque characteristics

1. **High-Grade Stenosis** (%DS, %AS, MLD, MLA)
2. **Plaque Burden** (volume; length, PAV; TAVnorm)
3. **Plaque Location** (artery, bifurcation, trifurcation)
4. **Plaque Composition** (non-calcified, calcified)
5. **"Lipid dense" Necrotic Core** (low attenuation plaque)
6. **High-Risk Plaques** (e.g., napkin ring sign)
7. **Plaque Concentricity** vs. Eccentricity
8. **Plaque Direction** (myocardial- vs. pericardial-facing)
9. **Plaque Diffuseness**
10. **Vascular Remodeling** (positive, negative, intermediate)
11. **Vascular Morphology** (lumen / vessel volume)
12. **Ischemia**
13. **% Myocardium at Risk** (subtended myocardium)
14. **Inflammation**

Source: Thomsen C and Abdulla J, Eur Heart J Cardiovasc Imaging 2016; Rodriguez-Granillo GA et al. Eur Heart J Cardiovasc Imaging 2016; Danad I et al. JACC Cardiovasc Imaging 2015

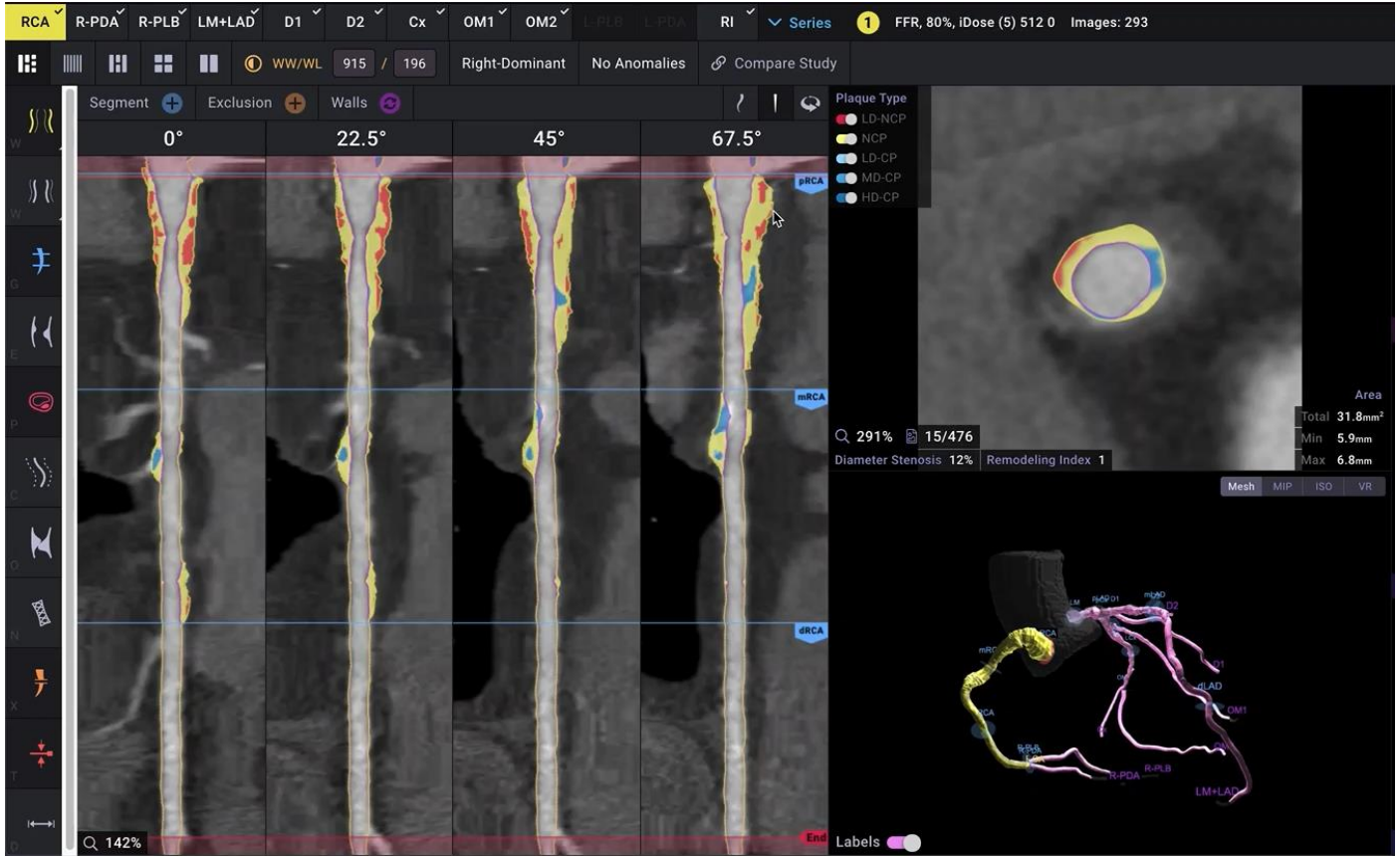
AI-Enabled Whole Heart Evaluation

From Manual and Subjective to Fully Automated



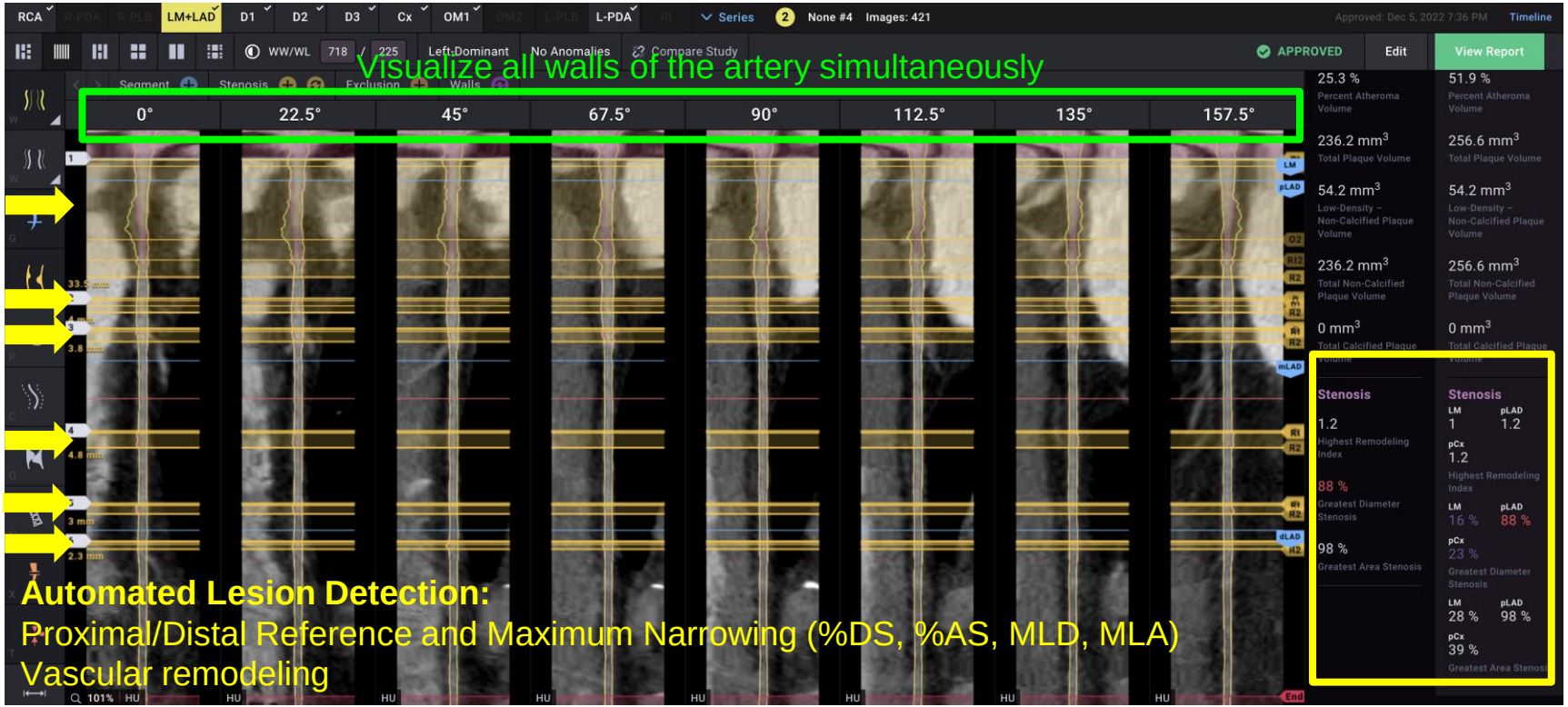
AI-Enabled Tools Now Allow for Comprehensive Whole Heart Evaluation

Atherosclerosis, Vascular Morphology, Ischemia in Minutes-Long Evaluation



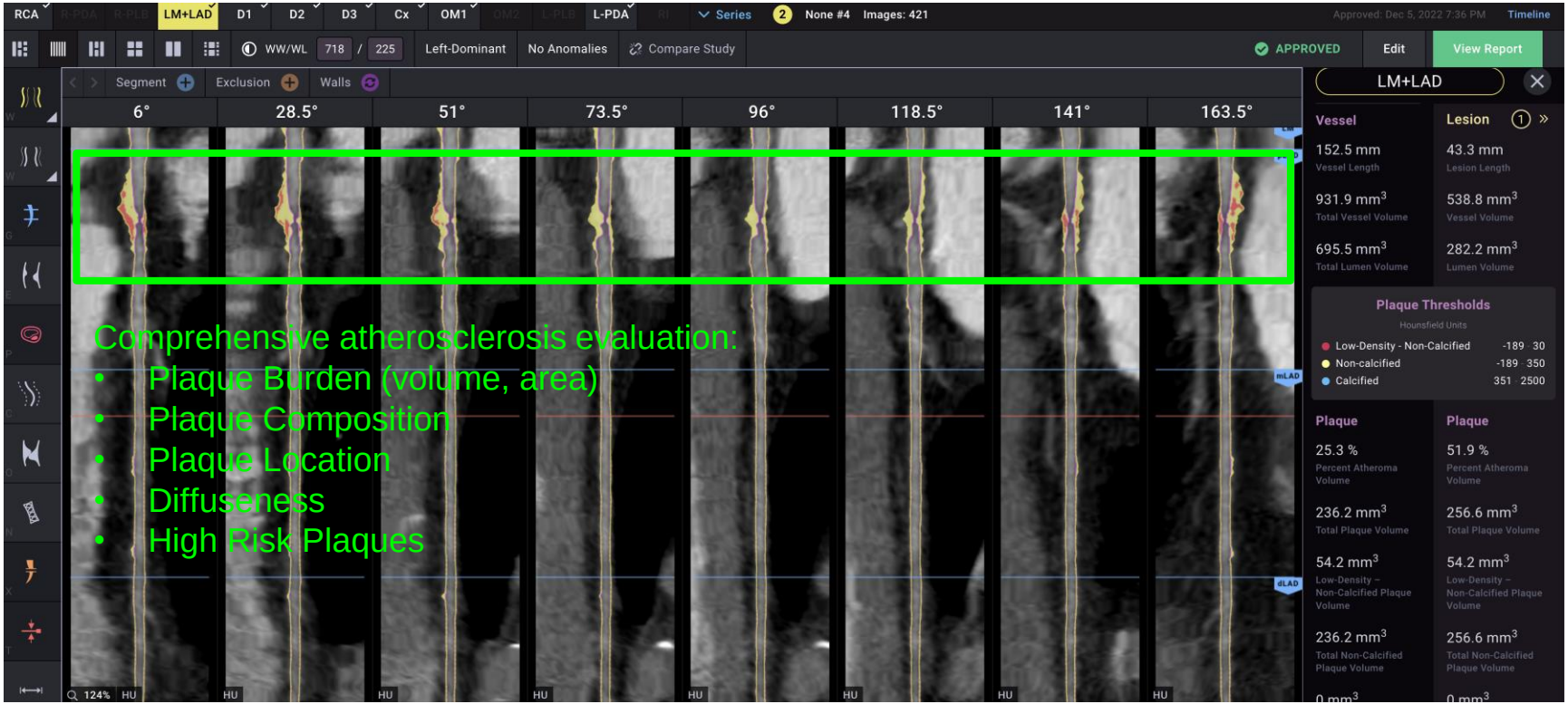
AI-Enabled Whole Heart Evaluation for Vascular Morphology

Lesion Detection and Stenosis Quantification



AI-Enabled Whole Heart Evaluation for Atherosclerosis

Comprehensive atherosclerosis evaluation



Comprehensive atherosclerosis evaluation:

- Plaque Burden (volume, area)
- Plaque Composition
- Plaque Location
- Diffuseness
- High Risk Plaques

AI-Enabled Whole Heart Evaluation

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

Comprehensive Coronary Artery Evaluation

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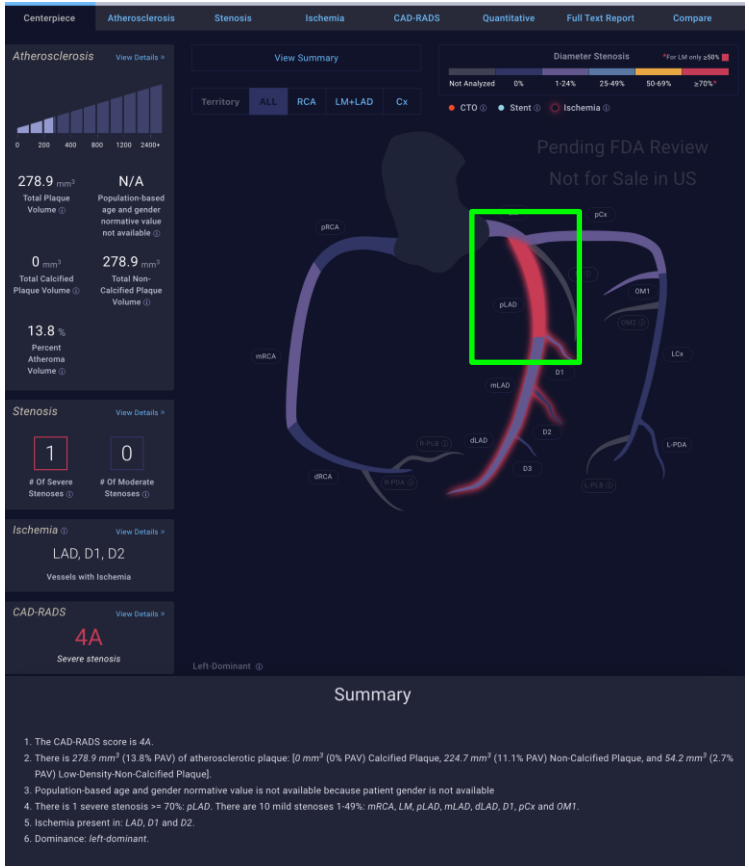
Artery	Segment	Length (mm)	Vessel Volume (mm^3)	Lumen Volume (mm^3)	Total Plaque Volume (mm^3)	Greatest Diameter Stenosis (%)	Greatest Area Stenosis (%)	Highest Remodeling Index
LM	LM	6.3	87.2	72.4	14.8	16	28	1
Total		6.3	87.2	72.4	14.8	-	-	-
LAD	pLAD	51	494.3	279.8	214.5	88	98	1.2
	mLAD	48	190.7	184.8	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			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)		
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

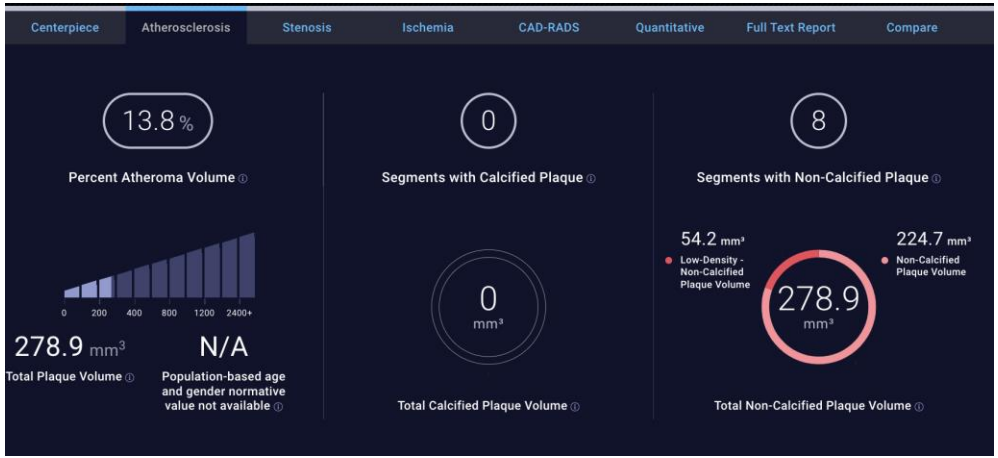
Translating Advanced Image-Based Disease Phenotyping into Actionable Clinical Insights



- 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

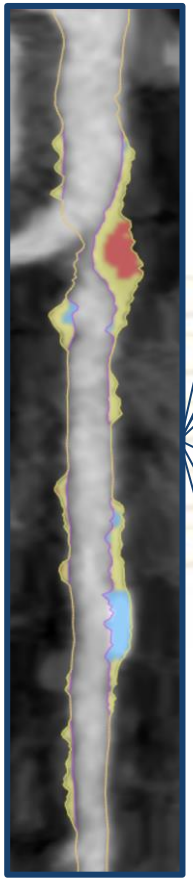
AI-Enabled Whole Heart Evaluation for Comprehensive Stenosis

Whole-Heart Stenosis Evaluation for Pre-Procedural Planning

- Luminal narrowing (%DS, %AS, MLD)
- Lesion Length
- Normal Reference Diameter
- Fully Interactive, w/ sub-mm coronary mapping
- Automated arrow identification

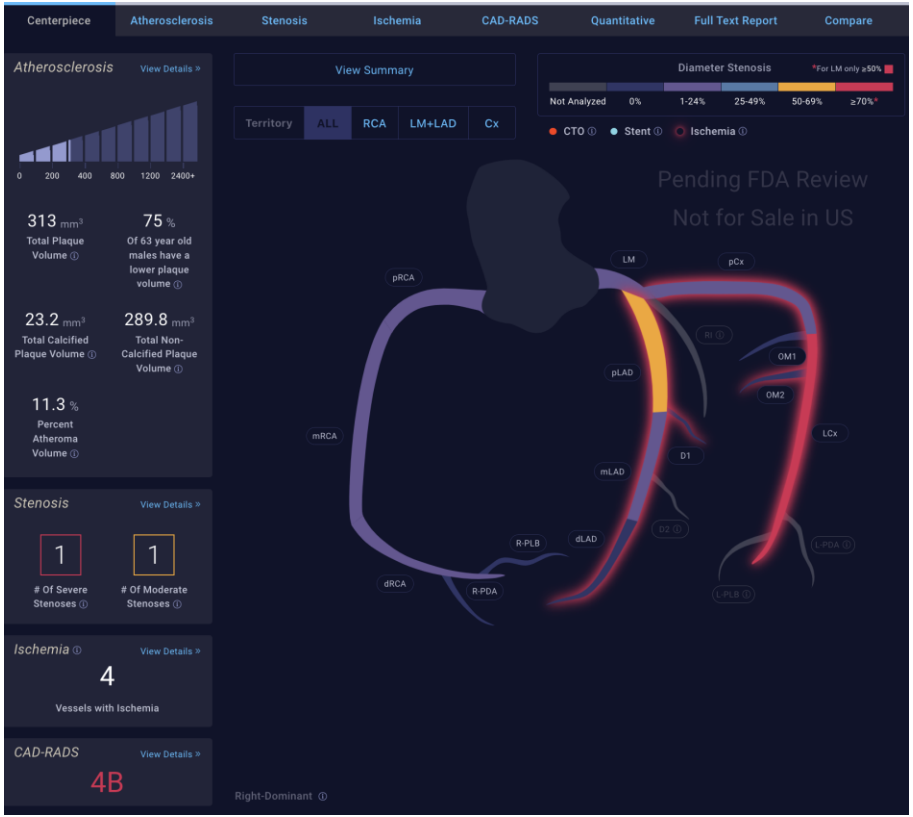
AI-Enabled Whole Heart Evaluation for Coronary Ischemia

Determination of Ischemia Free of Assumptions



- Lumen area
- Plaque
- Stenosis
- Vascular remodeling
- Low-Density plaque
- Lumen volume
- Non-calcified plaque

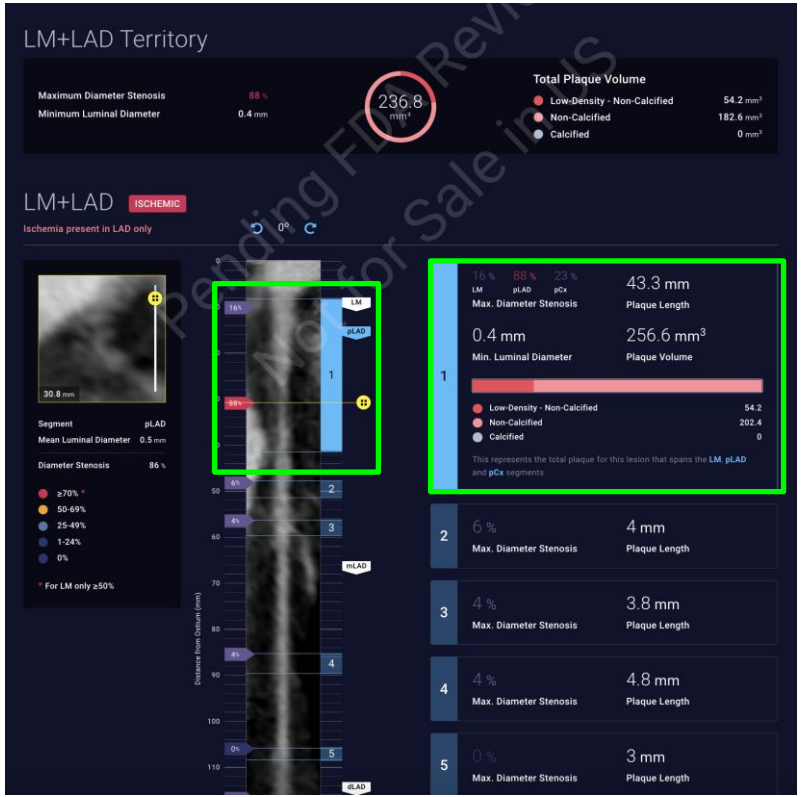
→ Ischemia

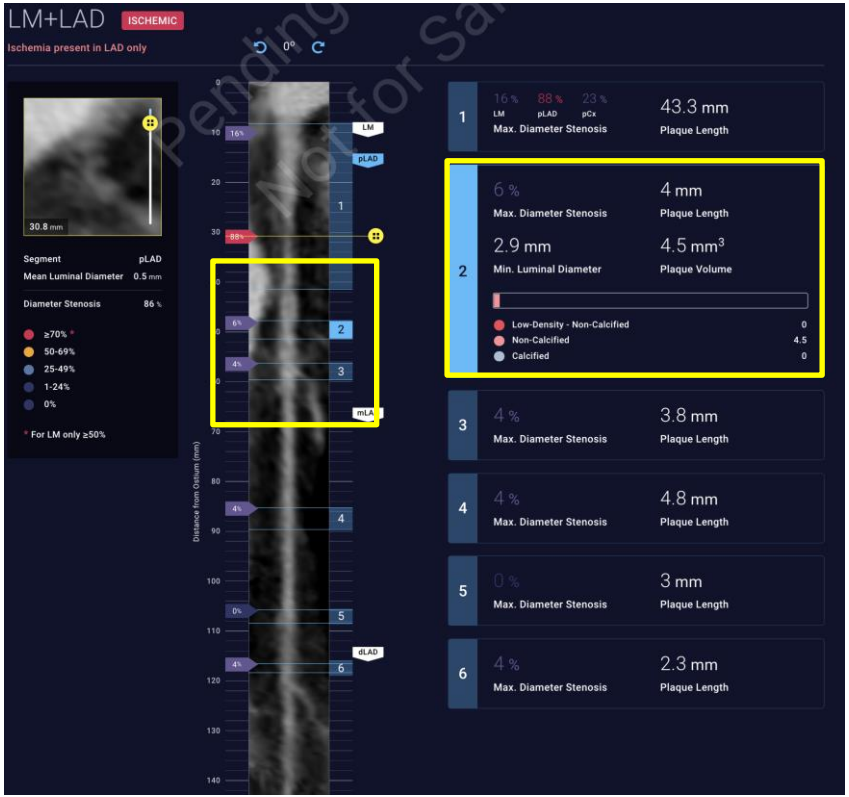


Cleerly ISCHEMIA for investigational use only.

AI-Enabled Whole Heart Evaluation for Coronary Ischemia

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





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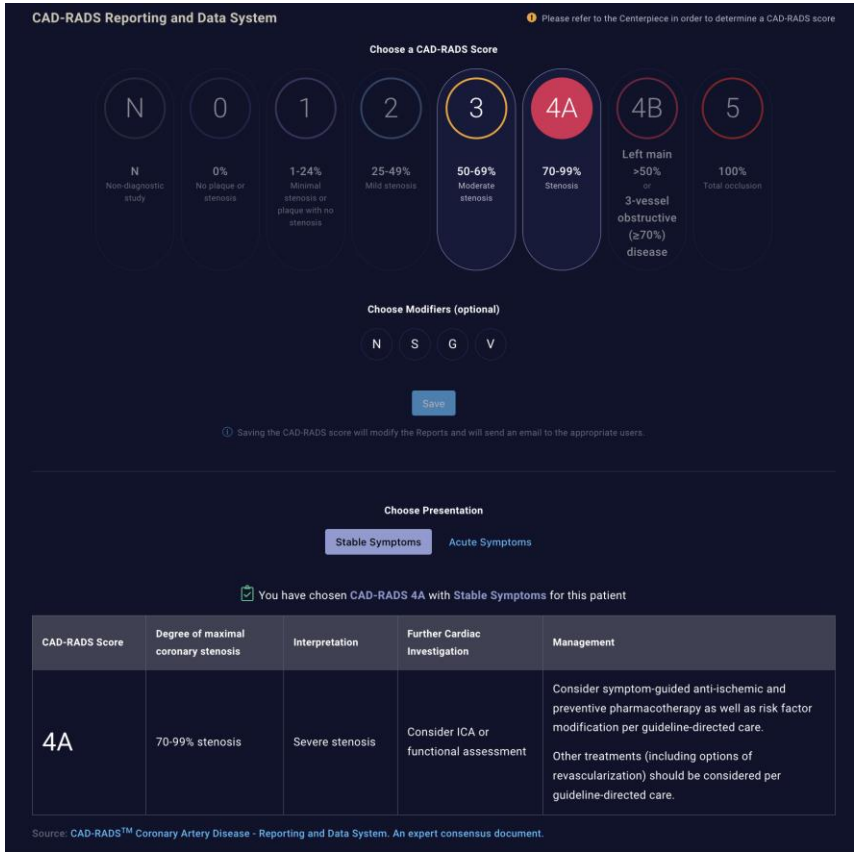
AI-Enabled Whole Heart Evaluation for “Risk” Scoring

Automated CADRADS Scoring for Stable and Acute Symptoms

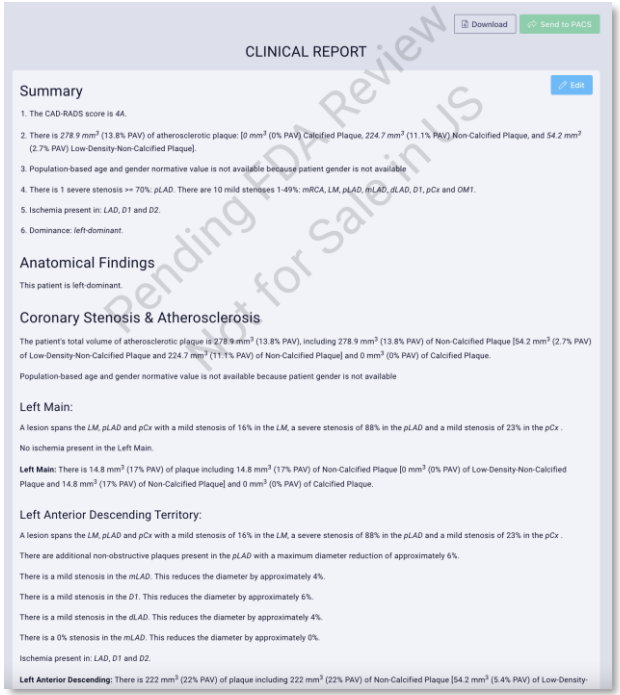


AI-Enabled Whole Heart Evaluation for Quantitative Disease Tracking

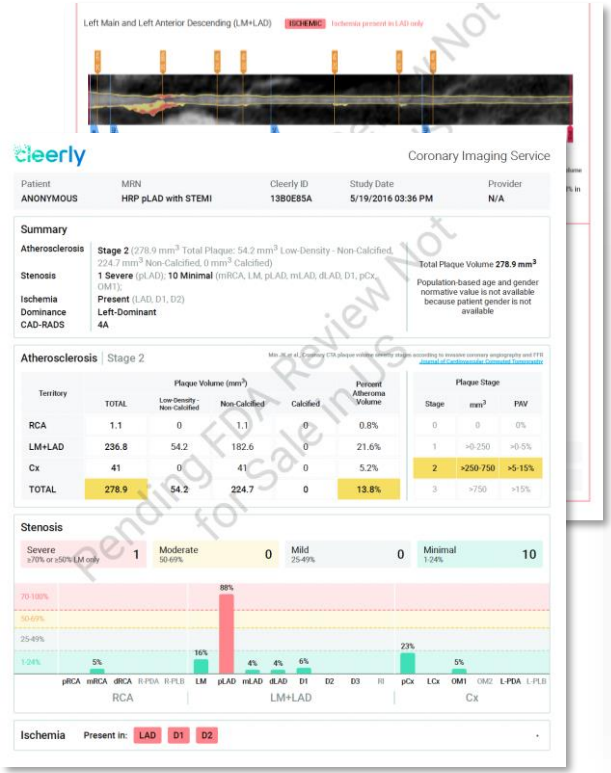
2 Goals: (1) Stop New Disease Progression and (2) Stabilize Pre-Existing Disease (via NCP → CP)

AI-Enabled Whole Heart Evaluation to Improve Health Literacy

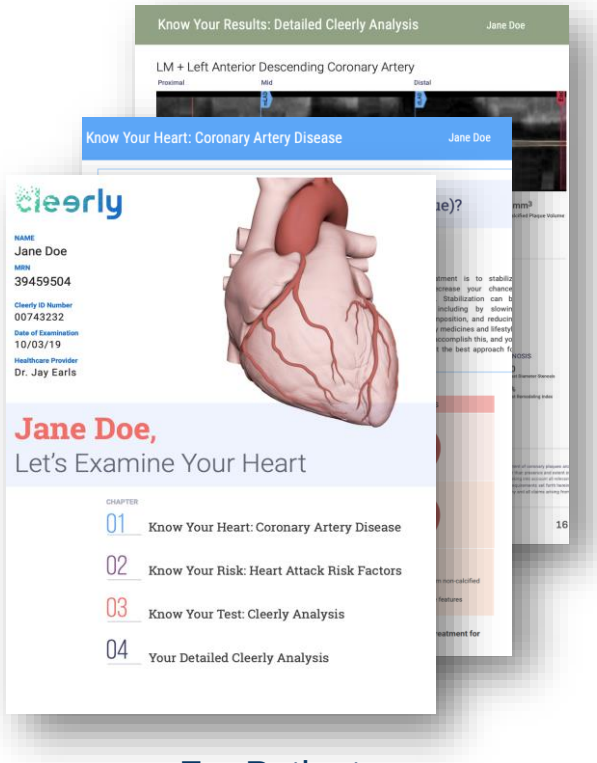
Automated Reporting (1) in Accordance w/ SCCT Guidelines, (2) for Referring Providers, and (3) for Patients



For Medical Record



For Referring Physicians



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

N=232

Expert Reader Consensus (3 of 3)
(for stenosis)

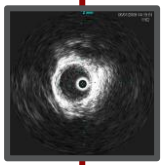
ACCURACY
99.7%

N=303

Invasive Coronary Angiography
(for stenosis)

ACCURACY
86%*

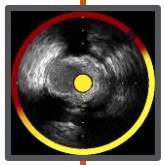
*Cleerly demonstrates ***higher concordance to invasive FFR (~2 of 3)*** *than ICA*



N=100

Intravascular Ultrasound
(for plaque burden)

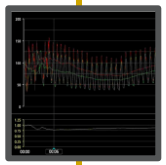
CORRELATION
High



N=148

Near-Field Infrared Spectroscopy
(for plaque morphology)

ACCURACY
94%



N=301

Fractional Flow Reserve
(for ischemia)

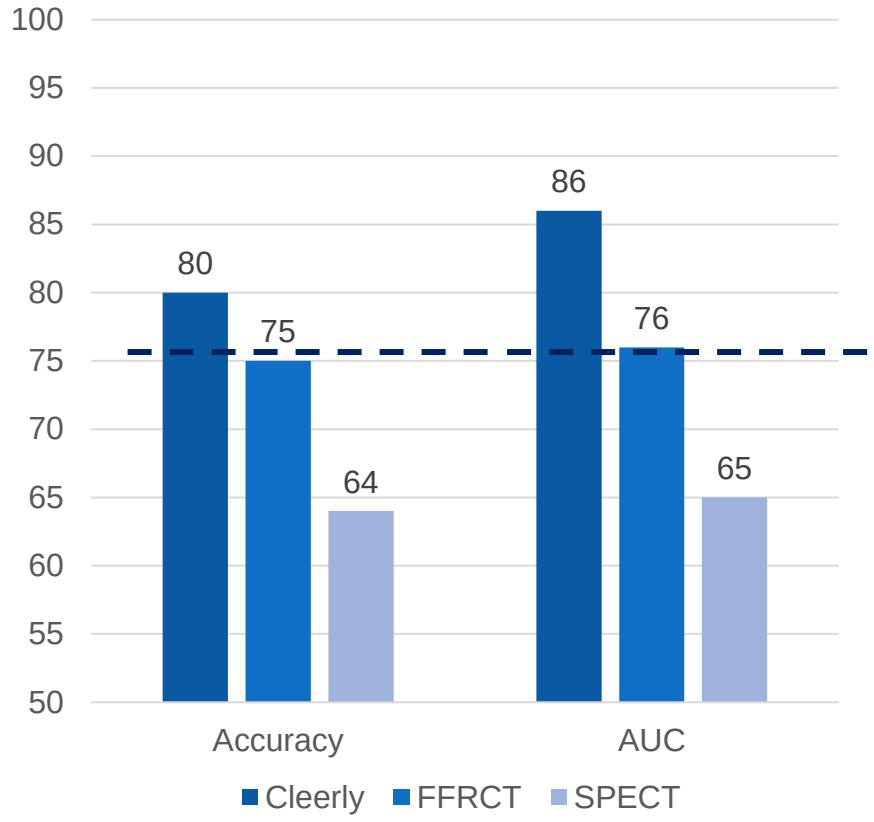
Area Under Curve
0.94

MCT Comparison to OCT ongoing

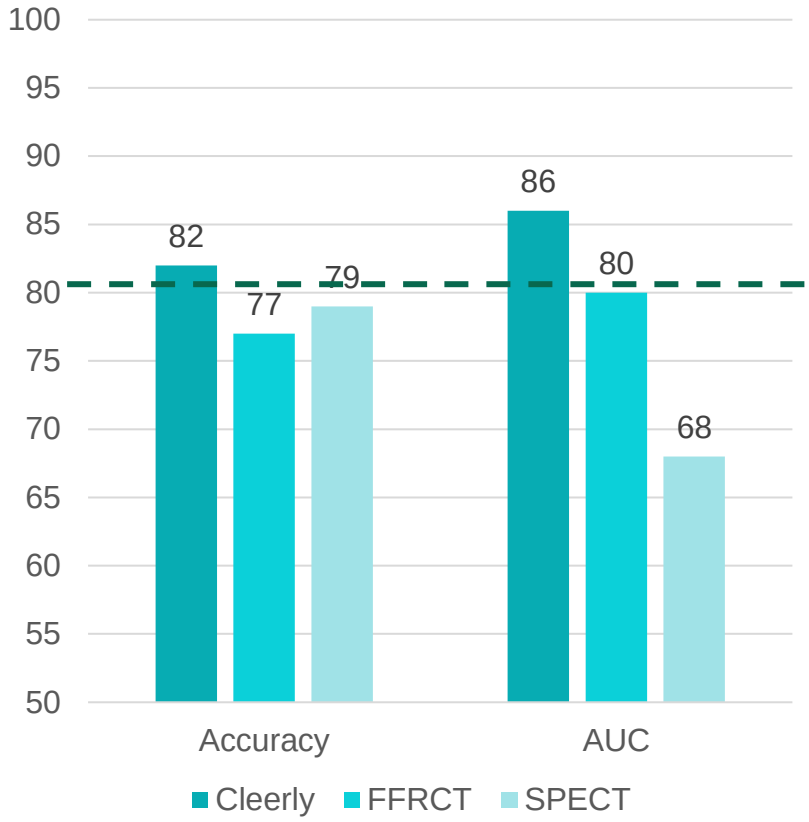
Source: [1]Griffin WF et al. J Am Coll Cardiol 2022 (in press); [2]Choi A et al. J Cardiovasc Comput Tomogr 2021; [3]Jonas R et al. SCCT Scientific Sessions 2022; [4]Nakanishi R et al. AHA Scientific Sessions 2022; [5]Hakim D et al. AHA Scientific Sessions 2021

Diagnostic Validation of AI-Enabled Tools for Ischemia

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



CREDENCE Trial (n=868 vessels)



PACIFIC Trial (n=612 vessels)

Source: Preliminary data on file at Cleerly

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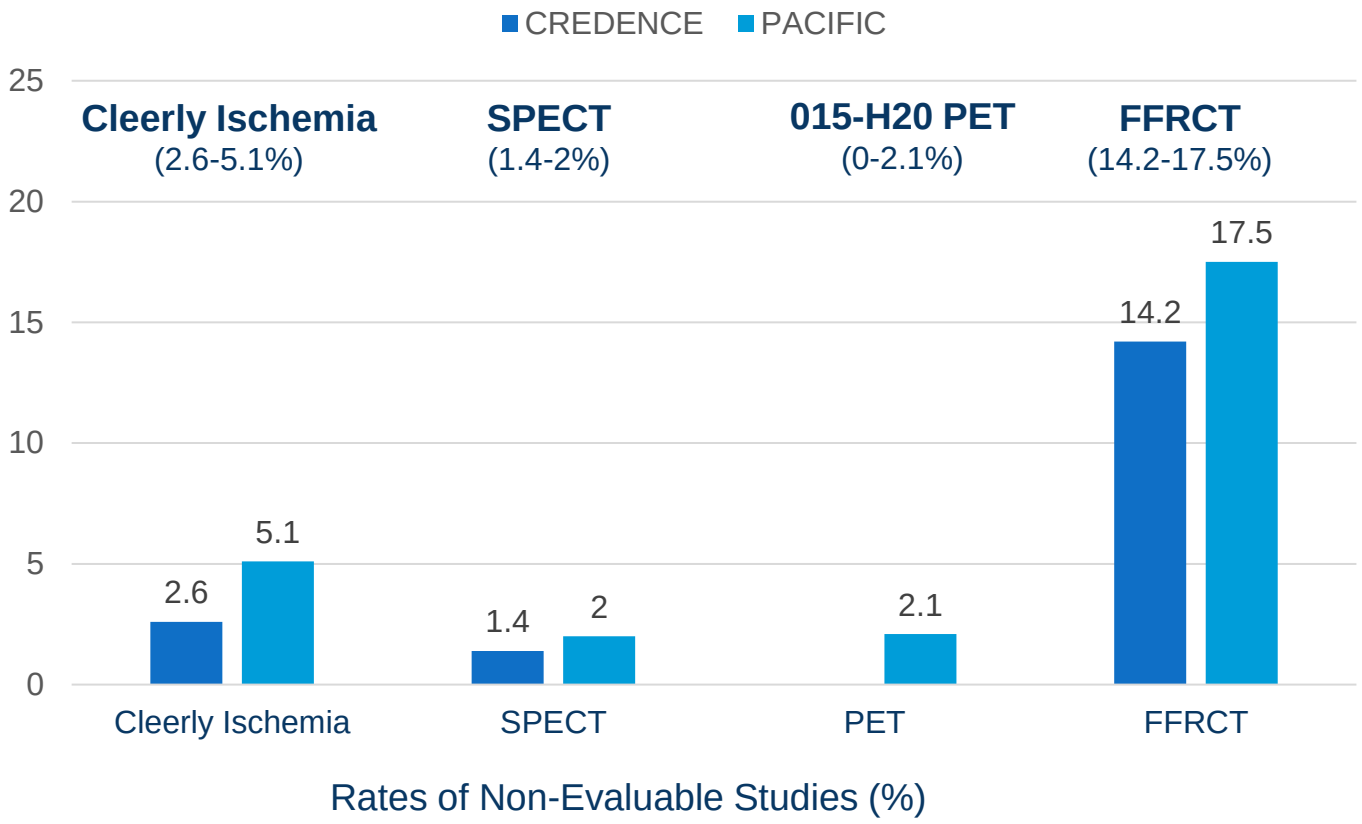
AI-Enabled Whole Heart Evaluation: Rates (%) of Non-Evaluability

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



Source: Preliminary data on file at Cleerly

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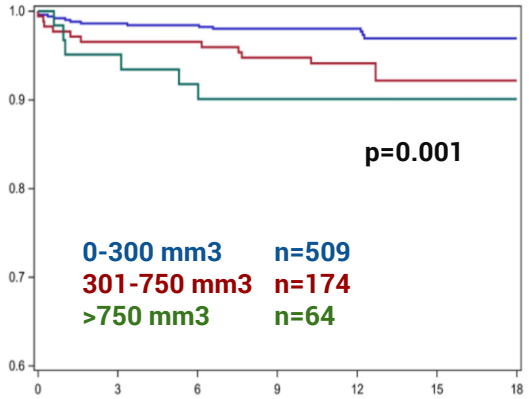
Prognostic Validation at 1- and 10-Years for Prediction of MACE

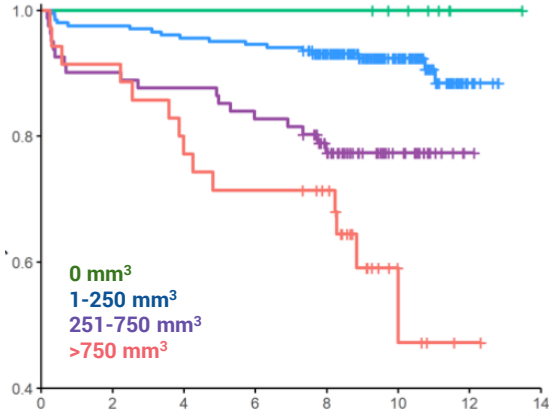
Staging System for Coronary Atherosclerosis Allows for Prediction of MACE with Precision

1-Year Follow-Up According to Atherosclerosis Stage[1]



- N=747 patients being referred for invasive coronary angiography
- Follow-up period = 1 year

10-Year Follow-Up According to Atherosclerosis Stage[2]



- N=328 patients being referred for non-invasive CT angiography
- Follow-up period = 10 years

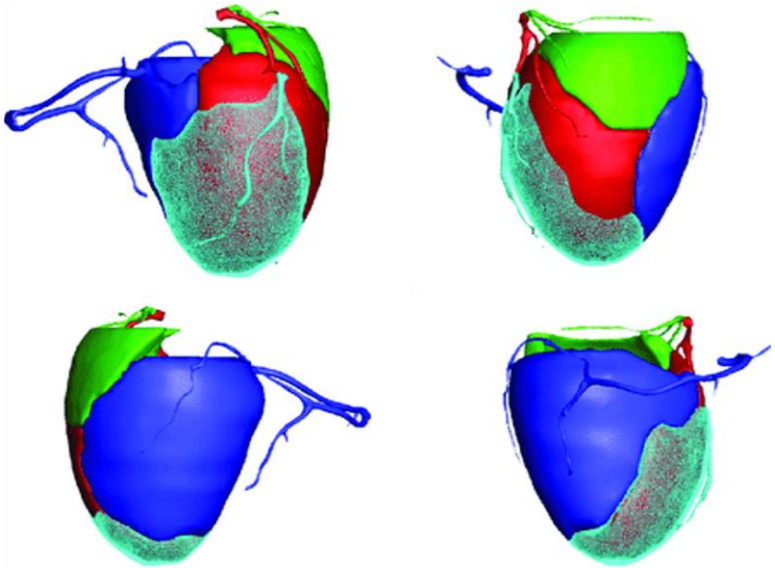
Endpoint: Time to first occurrence of major adverse cardiovascular events (MACE), as defined by death, non-fatal myocardial infarction and late target vessel revascularization

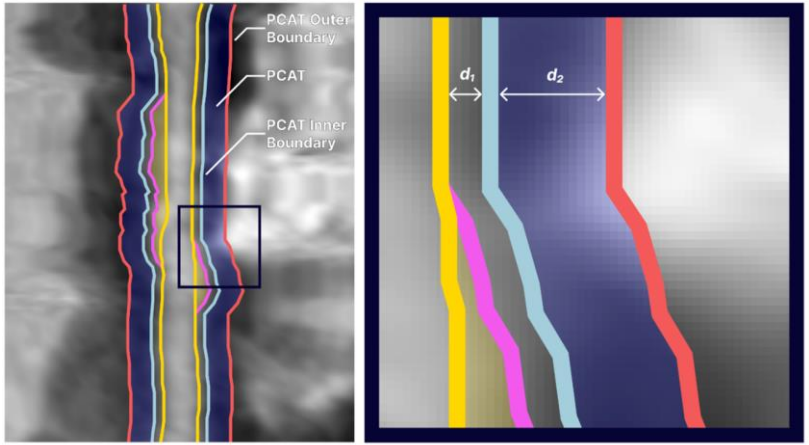
CONFIRM2 ~12,000 patients enrolled to date with 4-year outcomes assessment

Source: [1]Telluri A et al. Society of Cardiovascular Computed Tomography 2022 Scientific Sessions; [2]Nurmohamed 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

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seeing more of what matters