Insights from LightLab Clinical Initiative: OCT MLD MAX Workflow Improves PCI Decision Making and Efficiency

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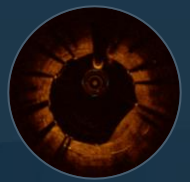


CRF TCT

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
Grant/Research Support	Takeda, Abbott, Teleflex, Boston Scientific
Consulting Fees/Honoraria	Abbott, Boston Scientific, Philips, Abiomed, Cordis, Biotronik, CSI, Takeda.
Major Stock Shareholder/Equity	Dyad, Impact Medical
Royalty Income	None
Ownership/Founder	None
Intellectual Property Rights	None
Other Financial Benefit	None

Faculty disclosure information can be found on the TCT app

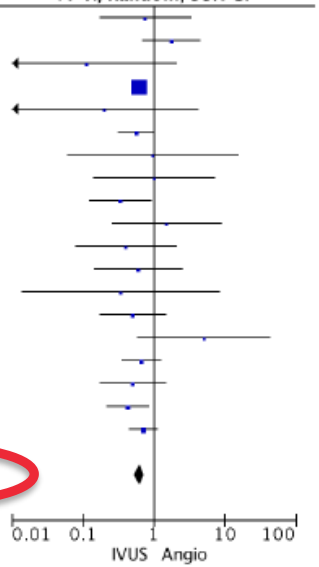
Intravascular Imaging Improves PCI Outcomes

Cardiovascular Death

Study or Subgroup	IVUS Events	IVUS Total	Angio Events	Angio Total	Weight	Risk Ratio M-H, Random, 95% CI
AIR-CTO 2015	3	115	4	115	1.1%	0.75 [0.17, 3.28]
AVID 2009	12	395	7	406	2.9%	1.76 [0.70, 4.43]
CHEN et al 2012	0	123	4	123	0.3%	0.11 [0.01, 2.04]
Choi et al	98	1647	416	4331	53.6%	0.62 [0.50, 0.77]
CTO-IVUS 2015	0	201	2	201	0.3%	0.20 [0.01, 4.14]
De la Torre Hernandez 2014	17	505	30	505	7.2%	0.57 [0.32, 1.01]
DIPOL 2007	1	83	1	80	0.3%	0.96 [0.06, 15.15]
EXELLENT 2013	2	463	2	463	0.6%	1.00 [0.14, 7.07]
Gao et al 2014	5	291	15	291	2.4%	0.33 [0.12, 0.91]
HOME DES IVUS 2010	3	105	2	105	0.8%	1.50 [0.26, 8.79]
Hong et al 2014	2	201	5	201	0.9%	0.40 [0.08, 2.04]
IVUS-XPL 2015	3	700	5	700	1.2%	0.60 [0.14, 2.50]
Kim et al 2013	0	269	1	274	0.2%	0.34 [0.01, 8.30]
MATRIX 2011	5	548	10	548	2.1%	0.50 [0.17, 1.45]
OPTICUS 2001	5	273	1	275	0.5%	5.04 [0.59, 42.83]
Roy et al 2008	16	884	24	884	6.2%	0.67 [0.36, 1.25]
Ultimate 2018	5	724	10	724	2.1%	0.50 [0.17, 1.46]
Wakabayashi et al 2012	12	637	28	637	5.4%	0.43 [0.22, 0.84]
Witzenbichler et al 2014	27	3349	60	5234	11.9%	0.70 [0.45, 1.11]
Total (95% CI)		**11513**		**16097**	**100.0%**	**0.63 [0.54, 0.73]**
Total events	216		627			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 15.65$, df = 18 (P = 0.62); $I^2 = 0\%$

Test for overall effect: Z = 5.91 (P < 0.00001)

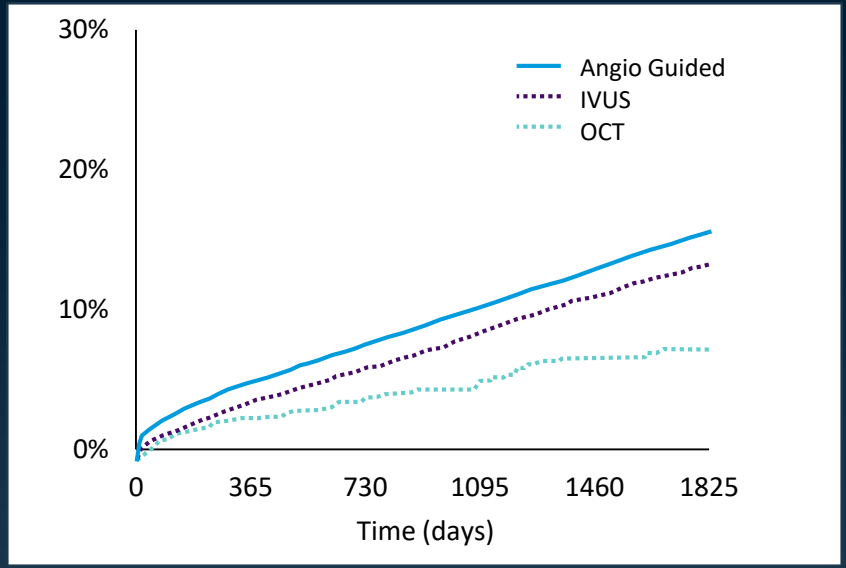


Fahed Darmoch, J Am Heart Assoc. 2020;9:e013678.

Emerging Evidence of Clinical Benefits of OCT

- Significant difference in mortality was observed between OCT-guided PCI compared with IVUS- or angiography-guided PCI ($p < 0.0001$)
- OCT-guided PCI was associated with significantly reduced rates of in-hospital MACE compared with angiography alone (0.80% vs. 2.00%; $p = 0.01$)

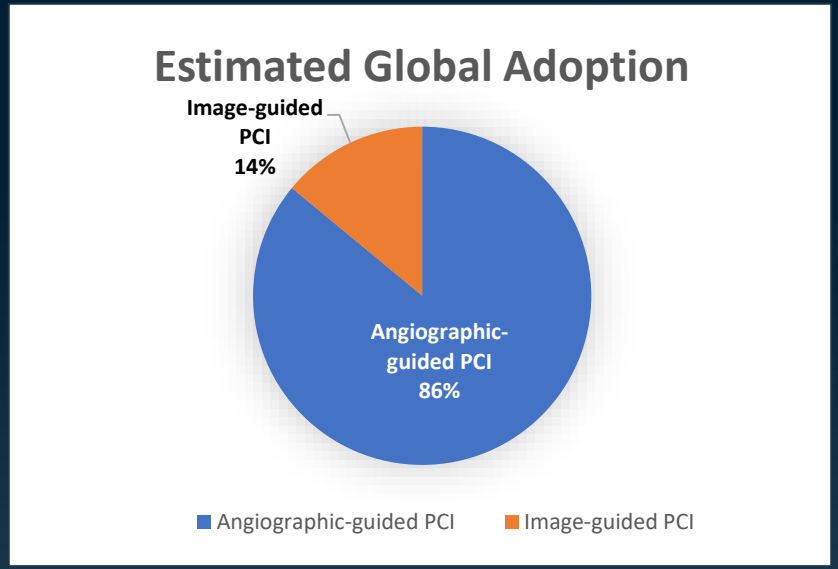
Cumulative Incidence of All-cause Mortality

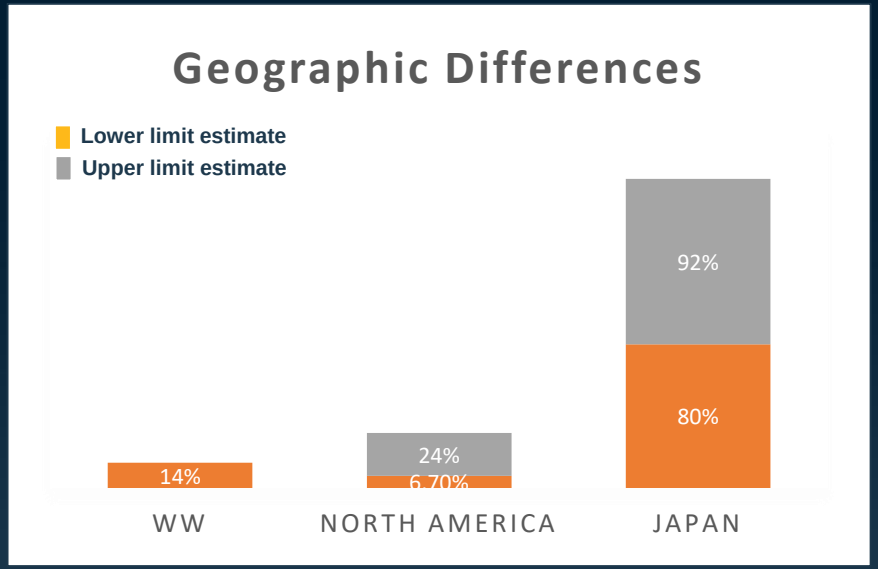


Numbers at Risk						
Angio only	75046	66033	56182	51030	40053	28765
MUS	10971	8954	7838	6632	5431	4242
OCT	1149	901	789	654	561	410

Jones, Daniel A. et al "Angiography Alone Versus Angiography Plus Optical Coherence Tomography to Guide Percutaneous Coronary Intervention." JACC: Cardiovascular Interventions 11.14 (2018): 1313-1321. Web. 23 Aug. 2018.

Adoption of Image Guided PCI



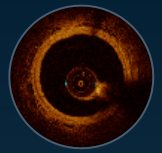


Compiled by Dr. Kevin Croce:
Koskinas, KC, et al. EuroInterventions 2018;14:e475-e484.
Hibi, K, et al. Circ J. 2015;79(1):24-33. doi: 10.1253/circj.CJ-14-1044.
Lemor, A., et al. Critical Pathways in Cardiology 2020:19(2):69-74.
Buccheri, S, et al. JACC Cariovasc Interv 2017;10:2488-2498.

Modern Image Guided PCI Workflow | MLD MAX

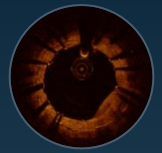
Designed to make OCT Guided PCI Easy, Teachable, and Consistent

Prescriptive utilization of the full range of information from OCT pre-PCI and post-PCI to guide treatment decisions



Pre-PCI OCT | Strategize

- **M**ORPHOLOGY
- **L**ENGTH
- **D**IAMETER

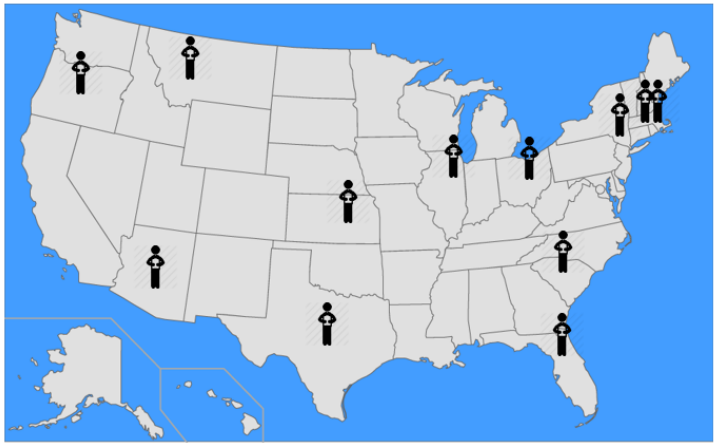


Post-PCI OCT | Optimize

- **M**EDIAL DISSECTION
- **A**PPOSITION
- E**X**PANSION

LightLab Clinical Initiative

Assess the Impact of a Prescriptive OCT MLD MAX PCI Workflow



- Ongoing Multiphase program 12 US centers to examine impact of prescriptive MLDMAX OCT use.

LightLab Workflow Procedures (n=604)	
Planned/staged procedures	181/604 (30%)
Access Site:	
Radial	357/573 (62%)
Femoral	210/573 (37%)
Radial & Femoral	6/573 (1%)
Mechanical Support	9/604 (2%)
Multivessel	63/604 (10%)
STEMI	33/604 (6%)
LightLab Workflow Lesions (n=652)	
Left Main	20/642 (3%)
RCA	188/642 (29%)
LAD	310/642 (48%)
CX	100/642 (16%)
Ramus	14/642 (2%)
Vein Graft	10/642 (2%)
Lesion Type: **Real world**	
A	34/650 (5%)
B	258/650 (40%)
C	358/650 (55%)
In-stent Restenosis	115/651 (18%)
Long Lesions (OCT Lesion length ≥ 28 mm)	286/652 (44%)
Chronic Total Occlusions	21/652 (3%)
Bifurcations	66/648 (10%)
Ostial Lesions	30/652 (5%)

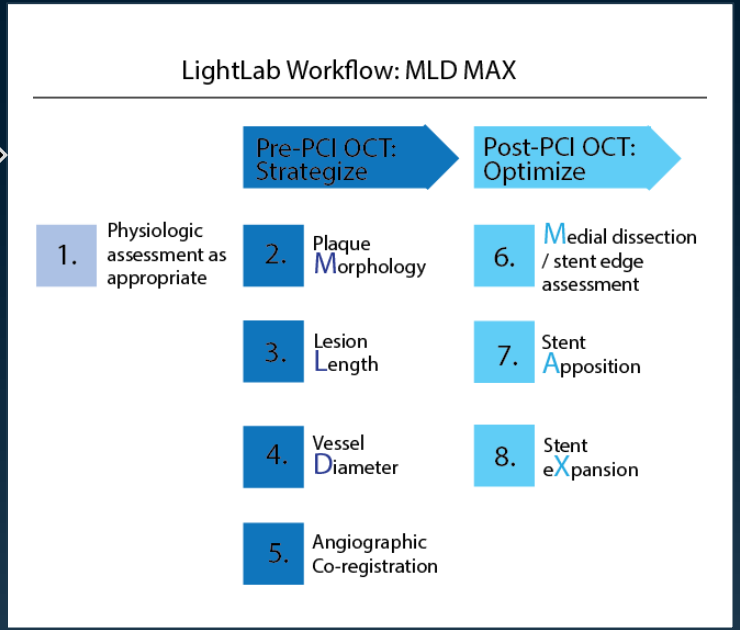
Bezerra, Hiram et al. Analysis of changes in decision-making process during OCT-guided PCI: New Insights from the LightLab Initiative. EuroPCR 2020.

LightLab Clinical Initiative Phases

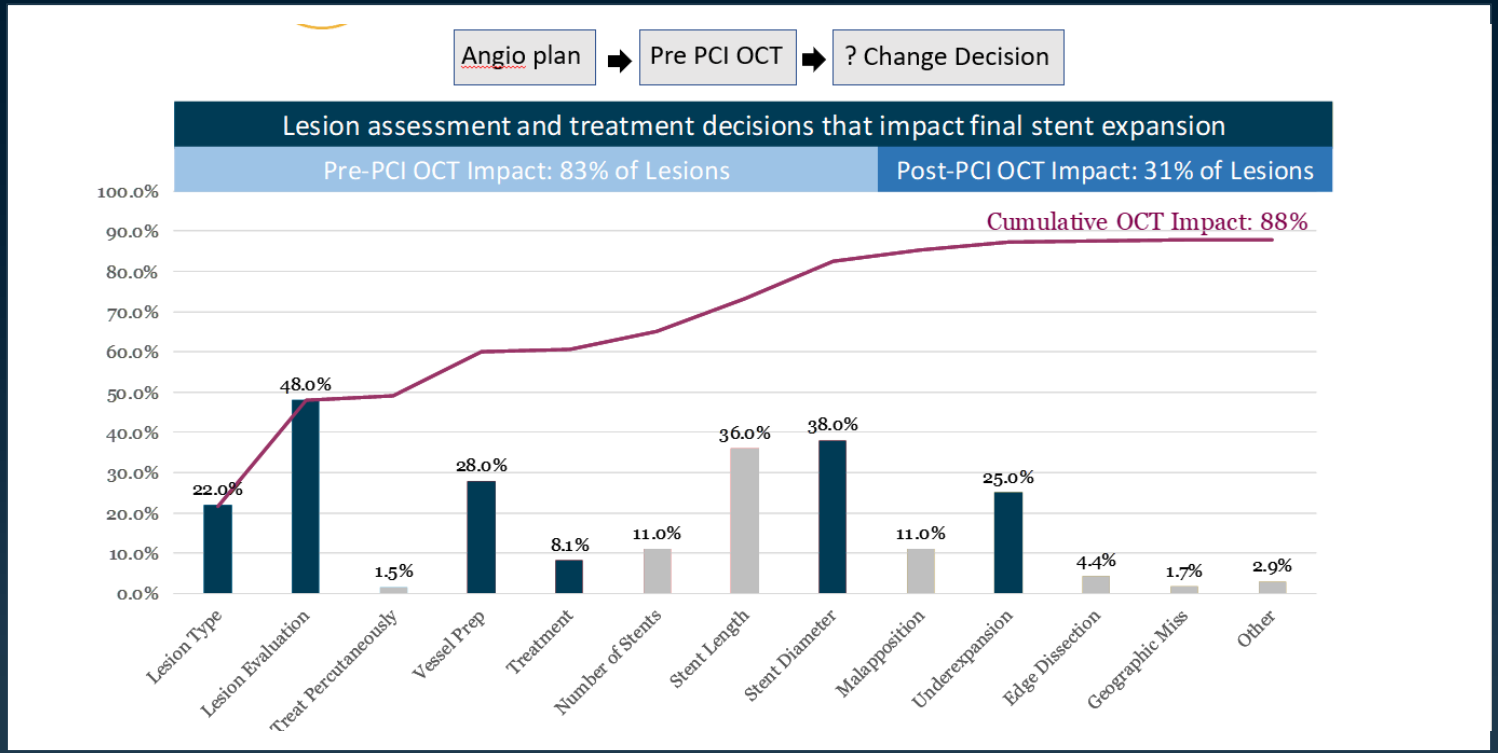
Baseline Phase	Data on baseline practice

Investigator training on LightLab OCT MLD MAX workflow

Clinical Accuracy	OCT workflow — impact on PCI accuracy and decision making
Workflow Utilization	OCT workflow standardization — effect on PCI proficiency
Workflow Optimization	OCT workflow optimization — effect on procedural steps, safety, and efficiency
Workflow Expansion	OCT workflow expansion to complex bifurcation, CTO, MVD procedures

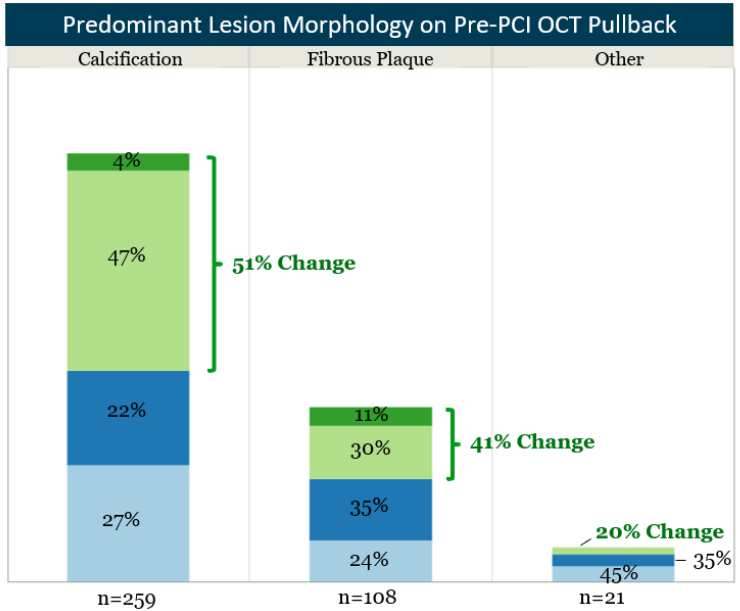


OCT MLD MAX Impacts PCI Decision Making



Bezerra, Hiram et al. Analysis of changes in decision-making process during OCT-guided PCI: New Insights from the LightLab Initiative. EuroPCR 2020.

OCT Identified Calcium Impacts Vessel Preparation Strategy



*Excludes n=257 lesions where vessel prep was performed before pre-PCI OCT

Vessel Prep Change Type
- No Change in Device
- No vessel prep and no change
- Change in Device
- Change to no vessel prep

Calcified Lesions

Vessel preparation methods performed in 47% with device change:

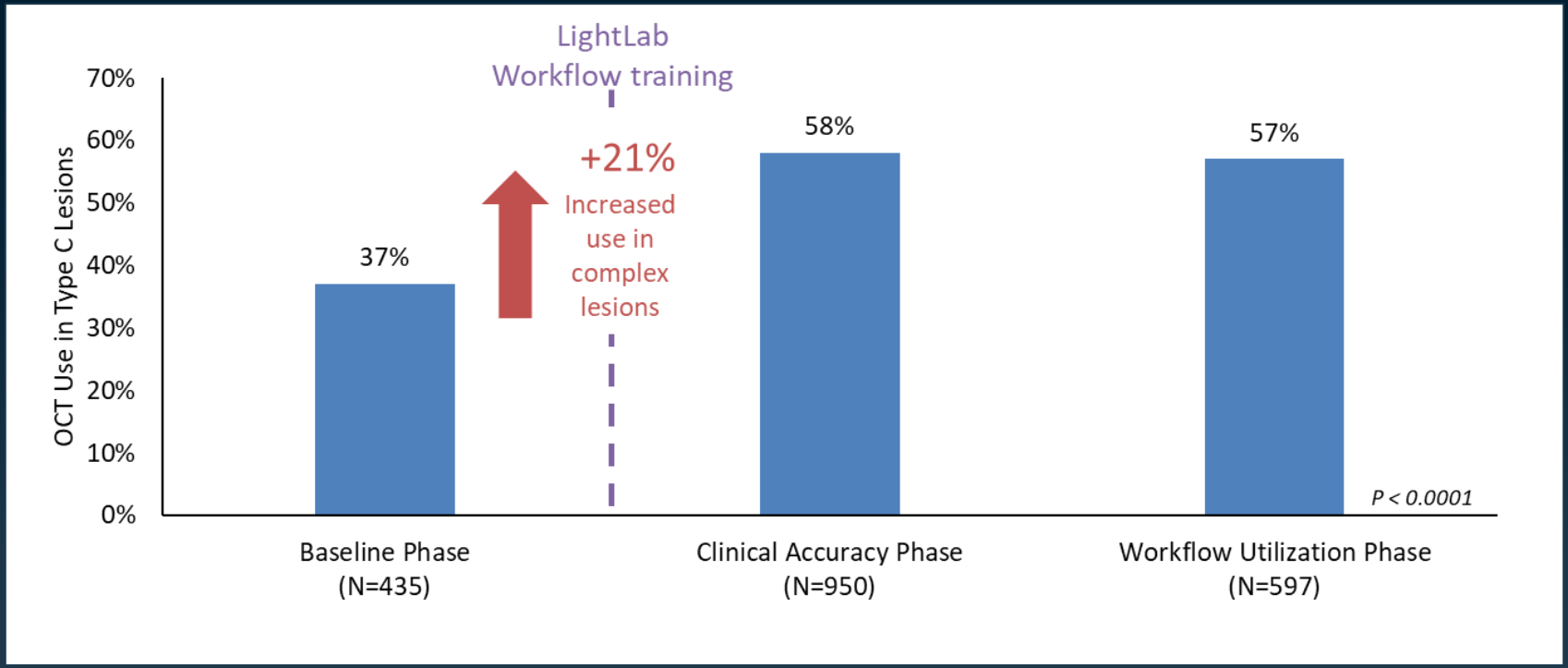
- 49% Pre-dilatation with compliant or non-compliant balloons
- 26% Pre-dilatation with cutting or scoring balloons
- 25% Atherectomy or laser

Vessel preparation methods performed in 27% without device change:

- 88% Pre-dilatation with compliant or non-compliant balloons
- 2% Pre-dilatation with cutting or scoring balloons
- 10% Atherectomy or laser

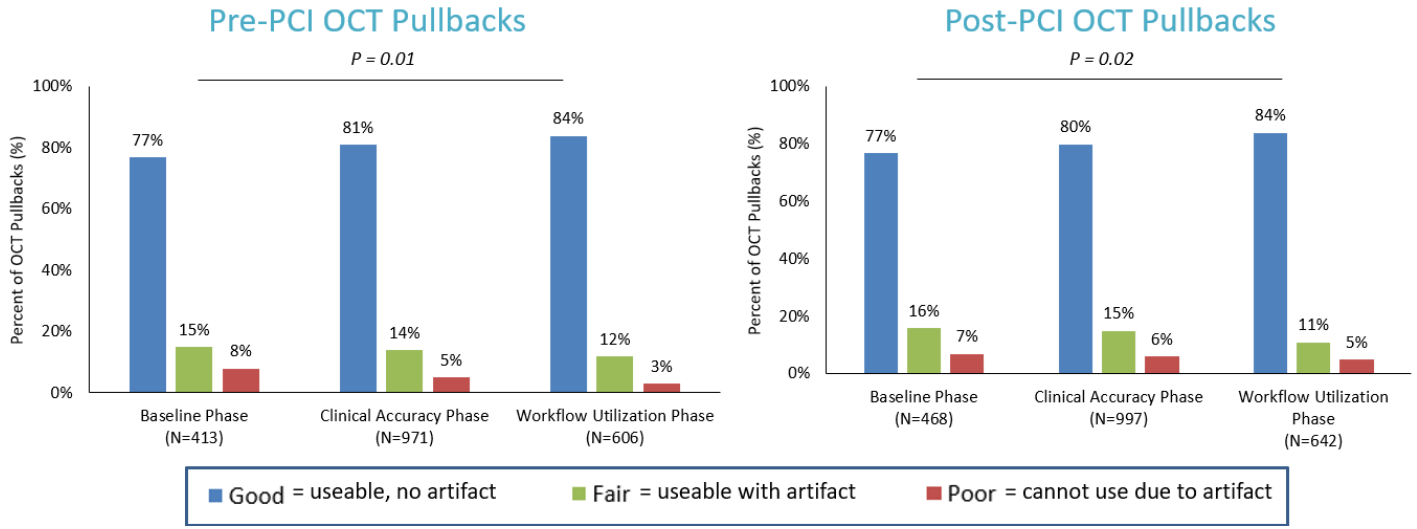
Bezerra, Hiram et al. Analysis of changes in decision-making process during OCT-guided PCI: New Insights from the LightLab Initiative. EuroPCR 2020.

OCT Use in Type C Lesions Increased After LightLab Workflow Training



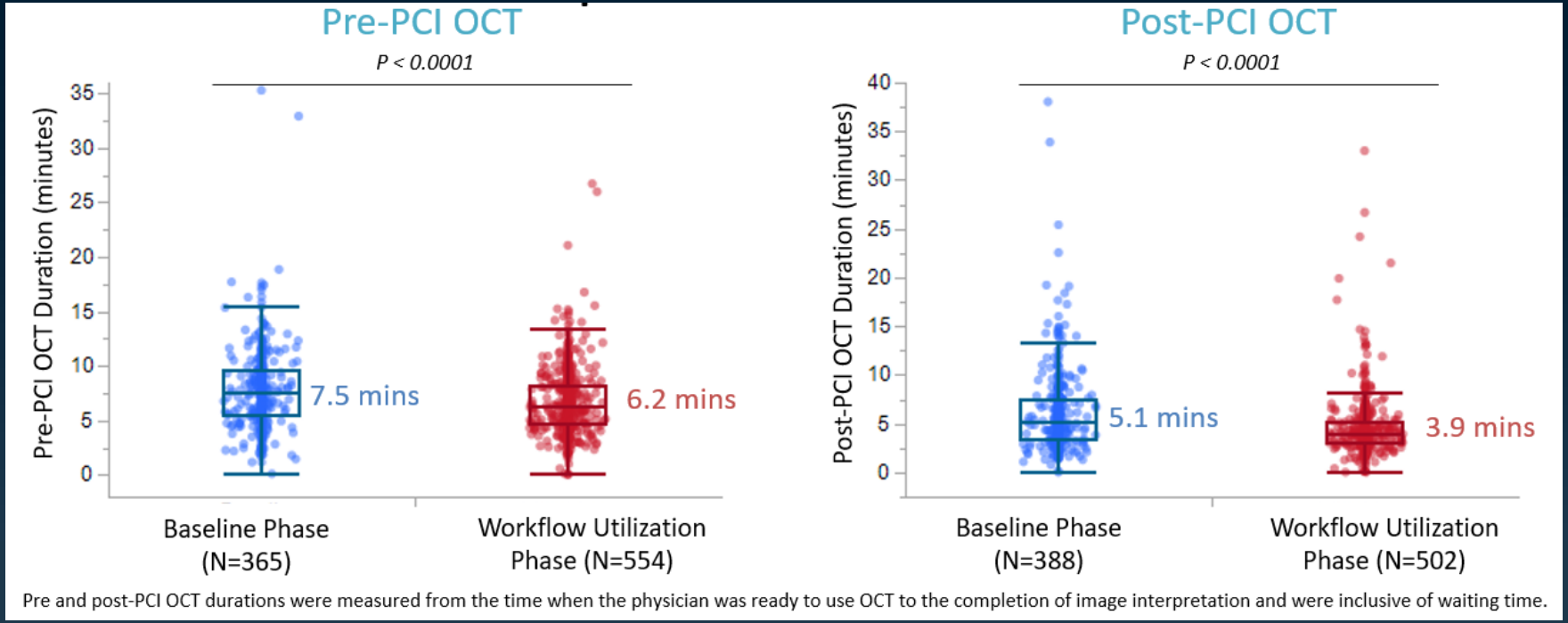
Khuddus, Matheen et al. Effect of Workflow Training and a Standardized OCT Workflow on Imaging Proficiency and Treatment Decisions During PCI in a Real-World Setting: Results from the LightLab Initiative. CRT 2021.

OCT Pullback Quality Improves with Increased Use and Training



Khuddus, Matheen et al. Effect of Workflow Training and a Standardized OCT Workflow on Imaging Proficiency and Treatment Decisions During PCI in a Real-World Setting: Results from the LightLab Initiative. CRT 2021.

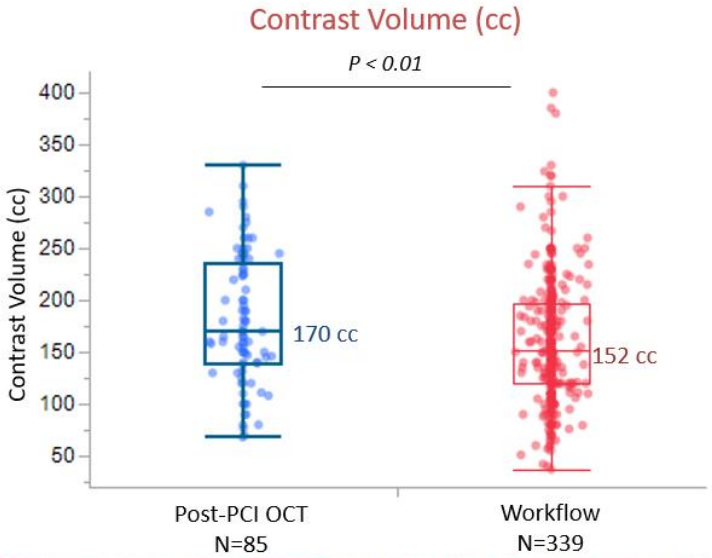
Time Spent on OCT Decreases with Increased Experience and Use



Pre and post-PCI OCT durations were measured from the time when the physician was ready to use OCT to the completion of image interpretation and were inclusive of waiting time.

Khuddus, Matheen et al. Effect of Workflow Training and a Standardized OCT Workflow on Imaging Proficiency and Treatment Decisions During PCI in a Real-World Setting: Results from the LightLab Initiative. CRT 2021.

Contrast Volume Reduced Through Use of LightLab Workflow



Subset of single lesion procedures to ensure comparison of post-PCI OCT only versus LightLab Workflow procedures.

Khuddus, Matheen et al.Cardiac Cahterization Laboratory Efficiency and Quality Improvement during PCI Utilizing a Standardized OCT Workflow in a Real-World Setting: Results from the LightLab Initiative. CRT 2021.

Angiography vs. OCT Optimized MLD MAX Workflow

Baseline Phase	Data on baseline practice
Clinical Accuracy	OCT workflow — impact on PCI accuracy and decision making
Workflow Utilization	OCT workflow standardization — effect on PCI proficiency
Workflow Optimization	OCT workflow optimization — effect on procedural steps, safety and efficiency
Workflow Expansion	OCT workflow expansion to complex bifurcation, CTO, MVD procedures

Propensity-score Matched Analysis

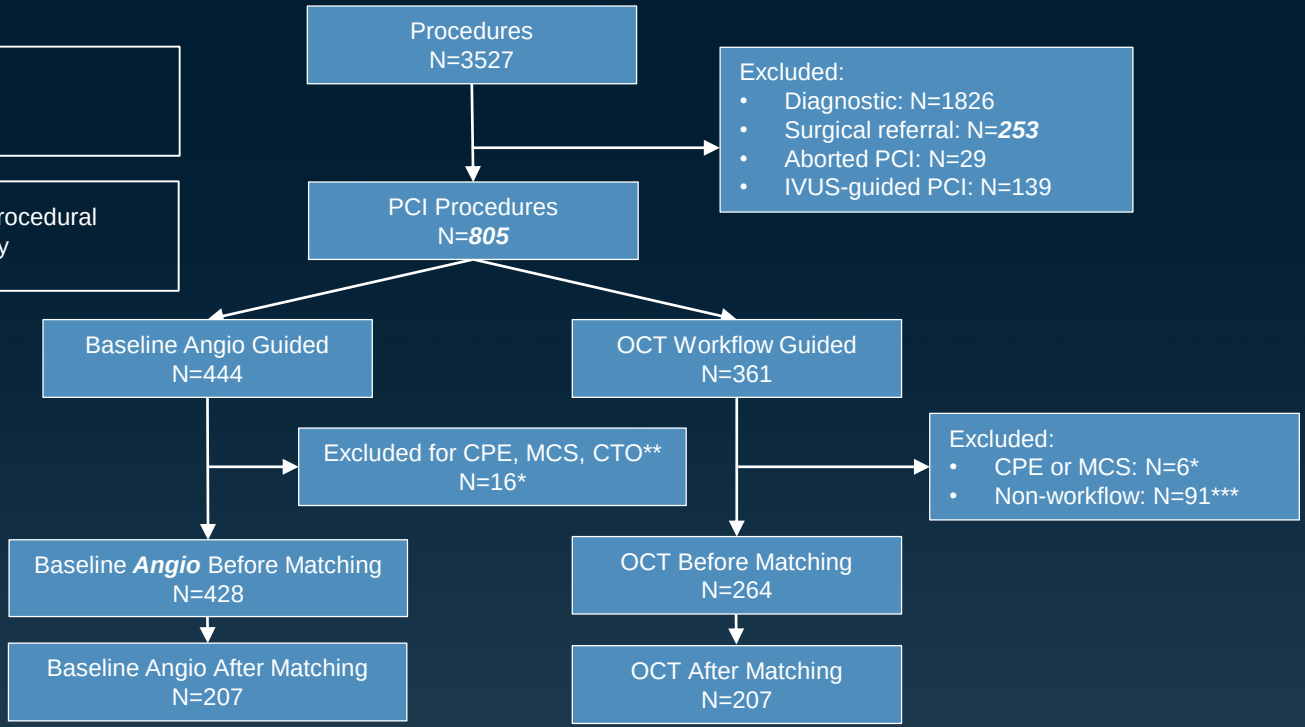
Angio Guided PCI

vs.

MLD MAX Workflow Optimized PCI

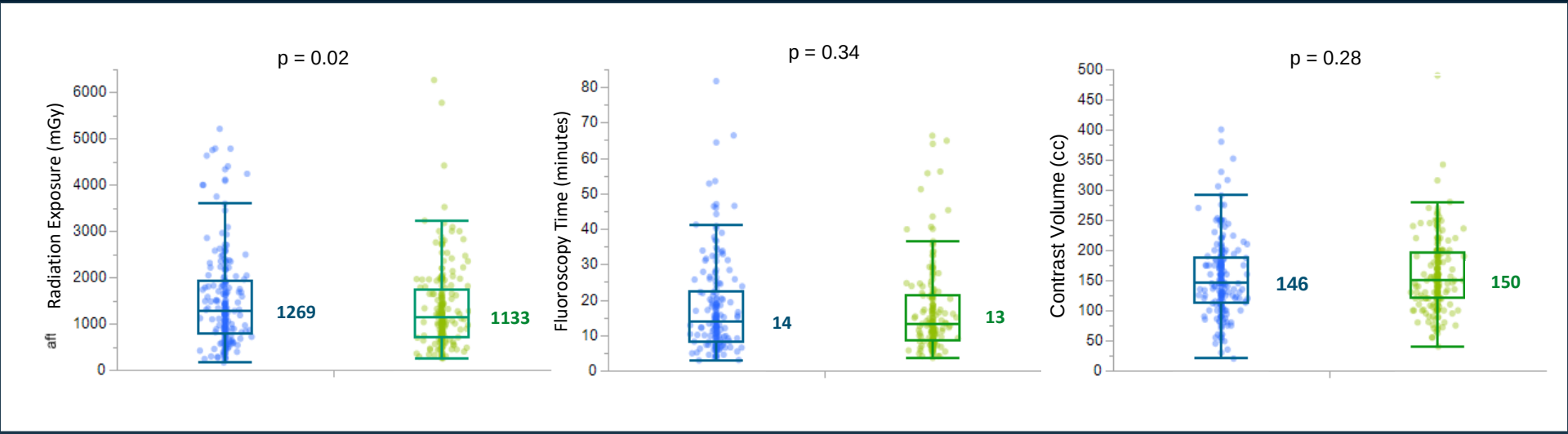
Propensity-Score Matched Analysis

Baseline Phase	Data on baseline practice
Workflow Optimization	OCT workflow effect on procedural steps, safety and efficiency



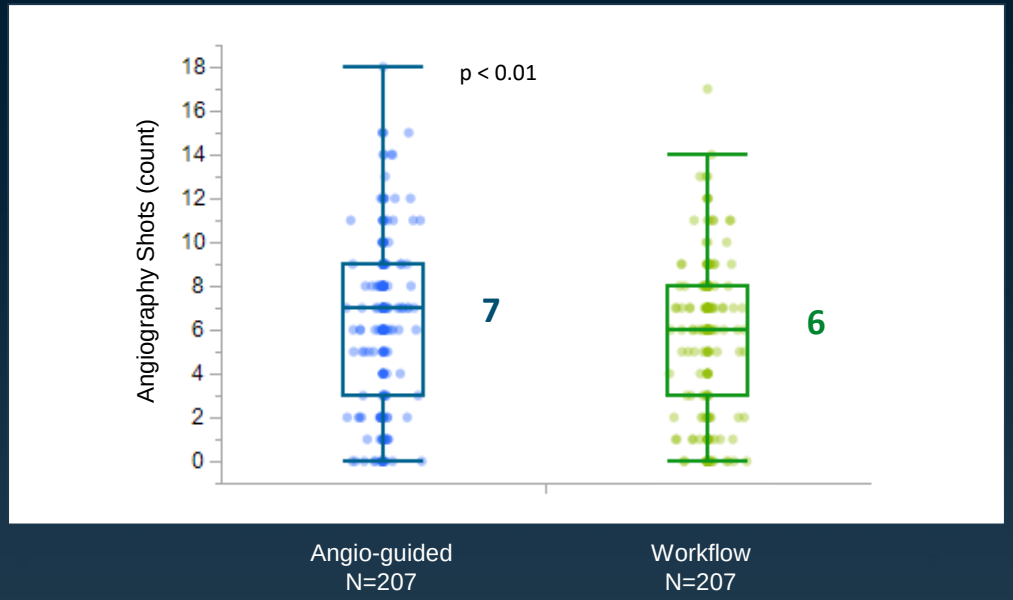
*Excluded PCIs for critical patient event (CPE) or use of mechanical circulatory support (MCS).
**CTOs with retrograde and/or dissection reentry are excluded in Angio arm because they are not represented in OCT arm.
***Inclusion in Phase 2 requires use of workflow in every treated lesion within the procedure.

OCT MLD MAX Decreases Radiation Exposure with No Change in Contrast Utilization



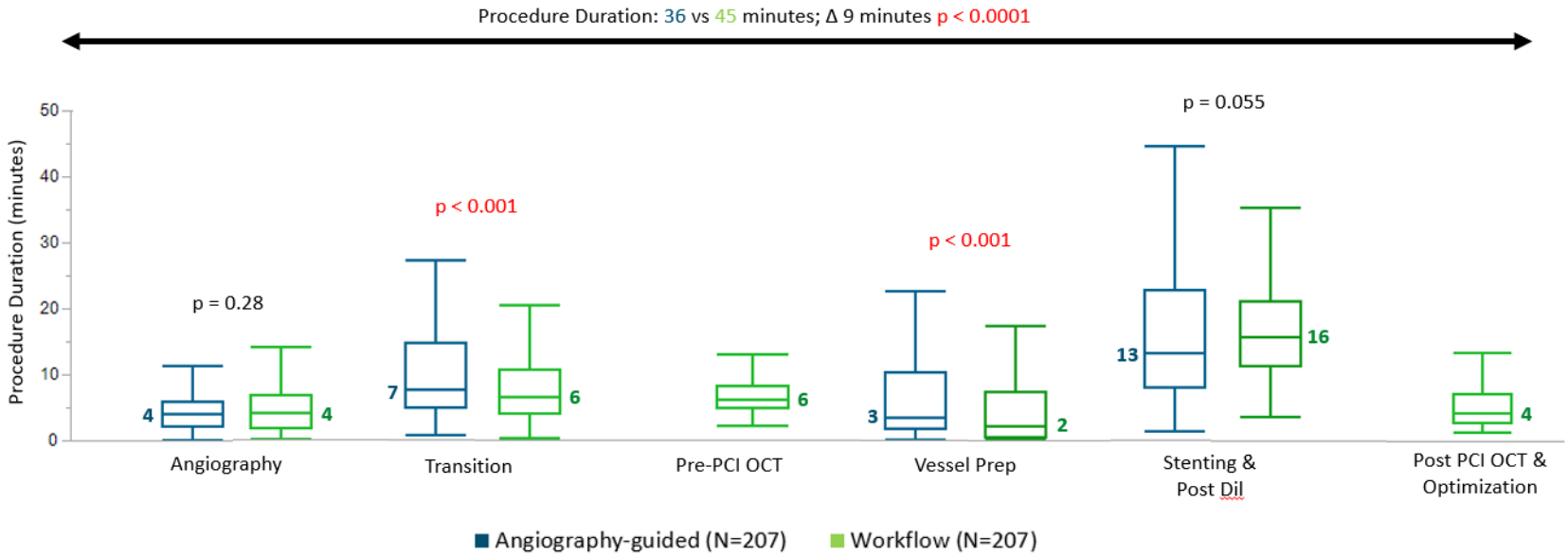
Angio-guided N=205	Workflow N=205	Angio-guided N=182	Workflow N=182	Angio-guided N=205	Workflow N=205

OCT MLD MAX Decreases Pre-PCI Angiogram Imaging

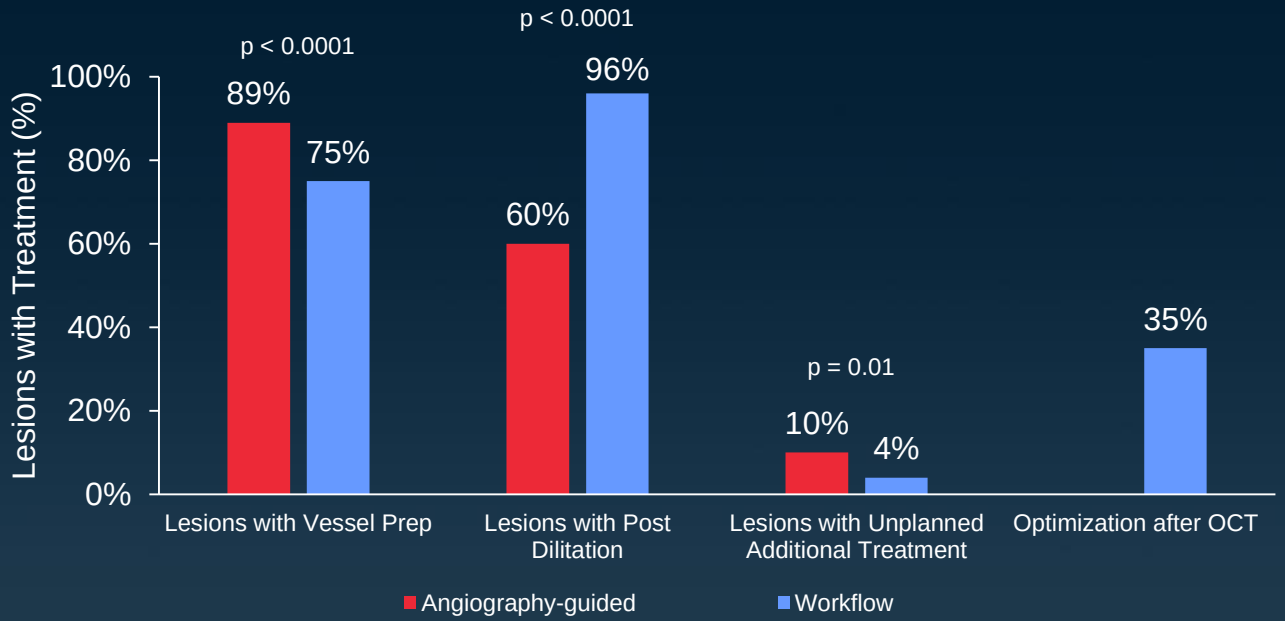


Increased reliance on accurate OCT information

OCT MLD MAX: Improved Accuracy with Minimal Increase in Procedure Time

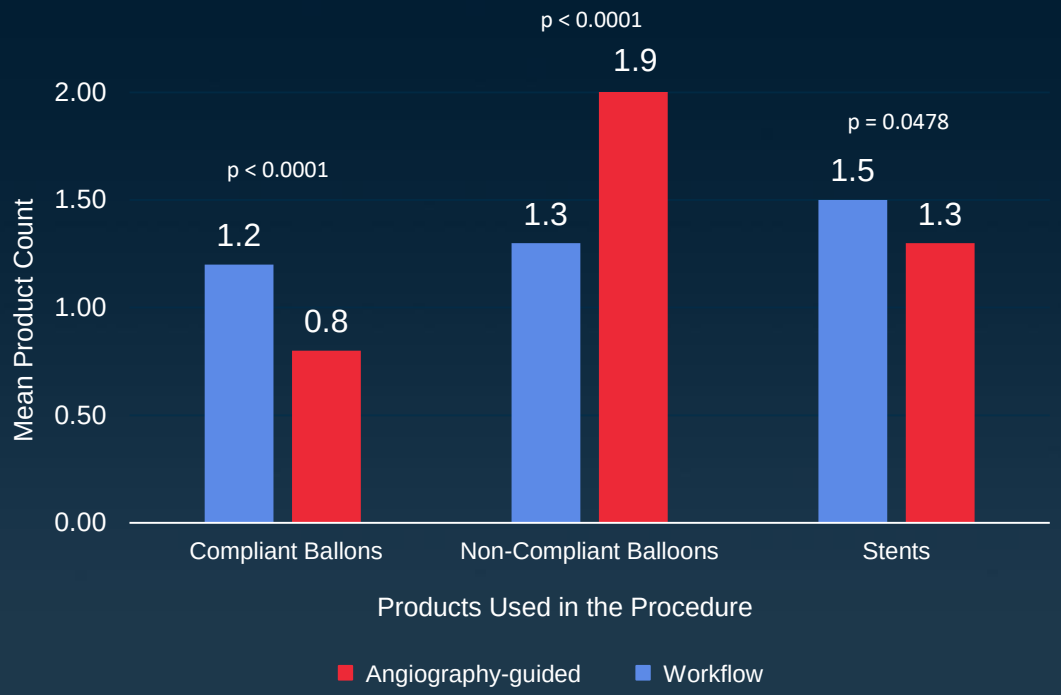


OCT MLD MAX: Morphology Based Vessel Prep and Optimization with Less Unplanned Treatment



*Post-dilation performed before post-PCI OCT in 90% of workflow-guided lesions

OCT MLD MAX: Impacts Device and Stent Utilization



LightLab Clinical Initiative Phases

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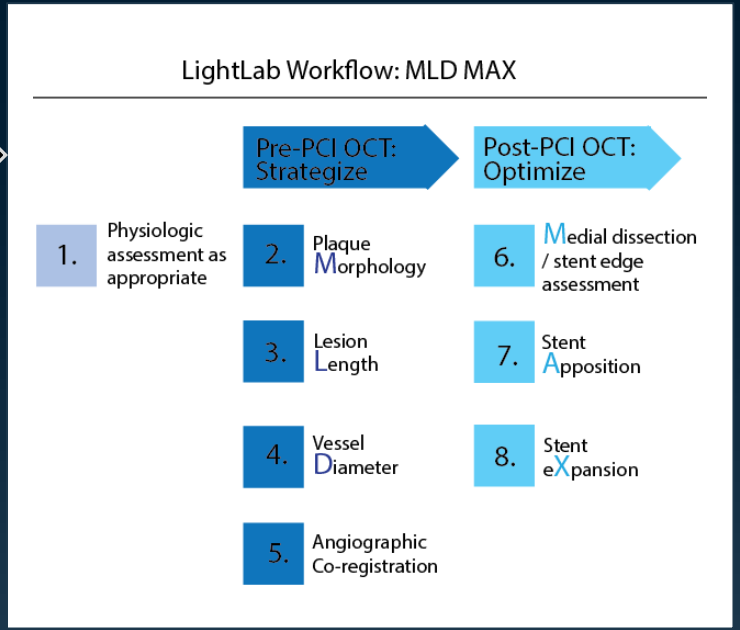
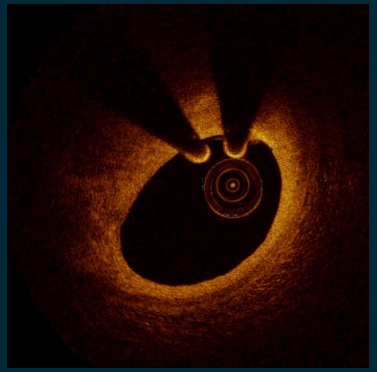
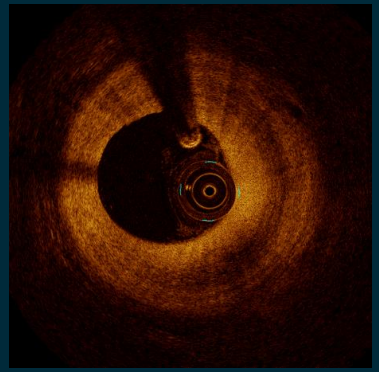


OCT MLD MAX in Complex PCI

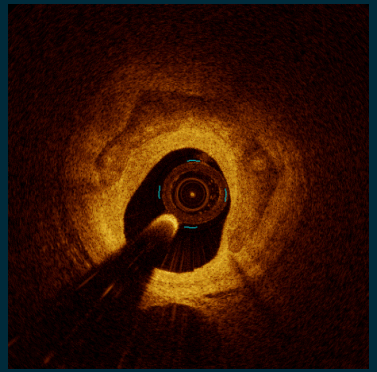
Morphology Guided Lesion Preparation



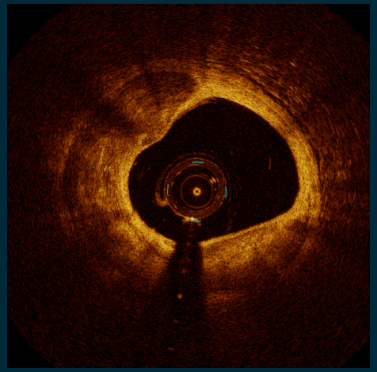
Lipidic



Fibrotic



Mild/Moderate Ca^{2+}



Severe Ca^{2+}

DIRECT STENTING[1]

COMPLIANT BALLOON[2]

NON-COMPLIANT BALLOON[3]

ATHERECTOMY OR IVL[4]

1. Taylor, A., et al. Efficacy and Safety of Direct Stenting in Coronary Angioplasty, J. Invasive Cardiology, 2000; 12(11); 2. Romagnoli, E., et al. Drug Eluting Stenting, JACC Cardiovascular Interventions, 2008; 1(1): 21-31; 3. Seyithanoglu, B., Compliant vs Non-compliant balloons. A Prospective Randomised Study, 1998; 39(1): 45-54; 4. Tomey, M., Current Status of Rotational Atherectomy, JACC Cardiovascular Interventions, 2014; 7(4): 345-354.

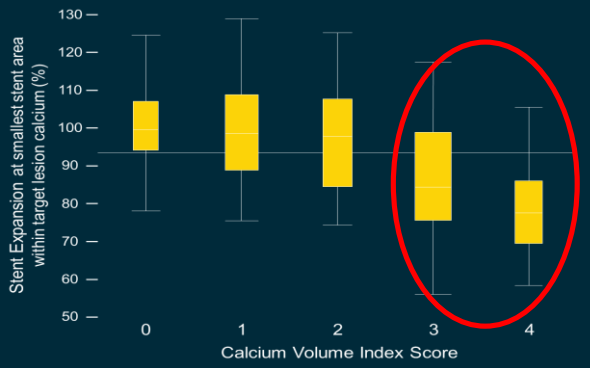
Influence of Calcium on Stent Expansion

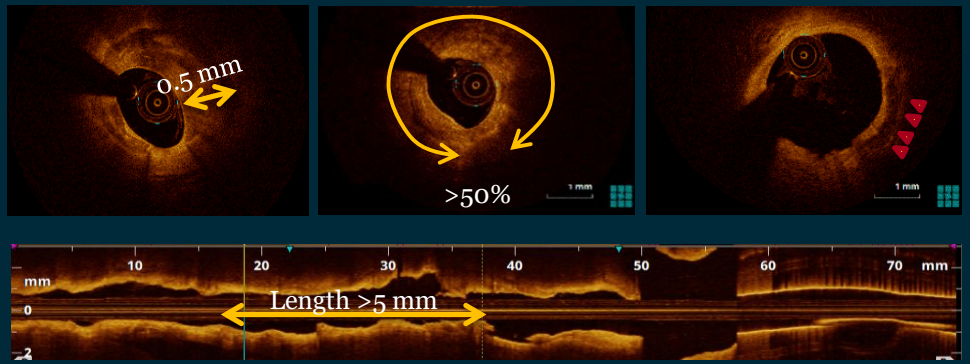
OCT-Based Calcium Volume Index Score[1]

1. Maximum Calcium Angle (°)	≤ 90°	▶ 0 point
	90° < Angle ≤ 180°	▶ 1 point
	> 180°	▶ 2 points
2. Maximum Calcium Thickness (mm)	≤ 0.5 mm	▶ 0 point
	> 0.5 mm	▶ 1 point
3. Calcium Length (mm)	≤ 5.0 mm	▶ 0 point
	> 5.0 mm	▶ 1 point
Total score	**0 to 4 points**	

Rule of 5's

- 0.5 mm thickness
- 5.0 mm long
- 50% vessel arc





1. Fujino, A. et al. A new optical coherence tomography-based calcium scoring system to predict stent under expansion. *EuroIntervention*, April 2018; 13(18):e2182-e2189.

Summary: LightLab OCT MLD MAX Guided PCI

OCT MLD MAX Guided vs. Angiography Guided PCI:

- Dramatic impact on PCI diagnosis and decision making
- Escalation in Ca+ based vessel preparation
- Similar contrast utilization and fluoroscopy time
- Decreased radiation exposure
- Optimized product utilization
  - Less complaint balloons, more noncompliant balloons
  - Fewer stents that were longer in length
- Precise case planning and decision making with only 9 min added to procedure time
- Future LightLab Clinical Initiative updates on OCT in complex PCI

A Standardized Optical Coherence Tomography Workflow Improves Procedural Efficiency and Safety During Percutaneous Coronary Intervention: Insights from the LightLab Clinical Initiative

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[a]Montefiore Einstein Center for Heart and Cardiovascular Care, Bronx, NY; [b]Cardiovascular Research Institute of Kansas, Wichita, KS; [c]Kansas Heart Hospital, Wichita, KS; [d]International Heart Institute of Montana, Missoula, MT; [e]Austin Heart, Austin, TX; [f]Providence Heart Institute, Portland, OR; [g]Abbott Vascular, Santa Clara, CA; [h]Cardiology Division, Beth Israel Deaconess Medical Center, Boston, MA

BACKGROUND

- Percutaneous coronary intervention (PCI) guided by intravascular imaging improves clinical outcomes and is endorsed by society guidelines.
- Nonetheless, routine intravascular imaging use remains low, partly owing to a perceived lack of efficiency.
- The LightLab (LL) Program was designed to evaluate the impact of a standardized workflow (LL workflow) using optical coherence tomography (OCT) on PCI procedural efficiency.

OBJECTIVES

- To compare procedural efficiency and quality metrics between PCI procedures guided by angiography only versus the LL workflow.

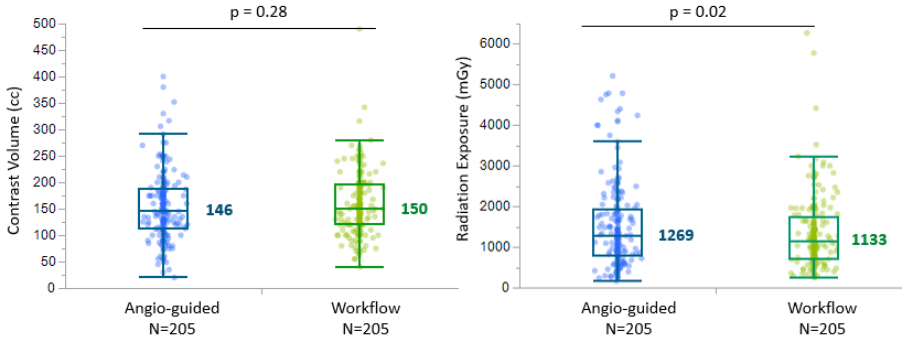
METHODS

- Detailed PCI procedural data were collected over 2 years from 41 physicians at 16 US centers.
- OCT-guided PCIs incorporating the LL workflow (routine pre- and post-PCI OCT; N= 264) were compared with baseline angiography-guided PCI (N = 428).
- Propensity-score analysis was used to control for differences between the groups, resulting in 207 matched subject pairs.
- Outcomes included procedure time, radiation exposure, contrast volume, device utilization, and treatment strategy.
- Continuous and categorical variables were assessed using the Wilcoxon (Rank Sum) test and Likelihood Ratio Chi-Squared test, respectively. A p value of <0.05 was considered statistically significant.

AUTHOR DISCLOSURES

J.R. is on the speaker's bureau for Abbott Vascular.
All other coauthor disclosures are available online.

Principal Finding: A standardized OCT workflow reduces radiation exposure with no difference in contrast usage compared to angiography alone



Incorporation of a standardized OCT workflow to guide PCI improves multiple efficiency and safety metrics. As intravascular imaging improves PCI outcomes, these data support greater adoption of routine OCT use in clinical practice.

TABLES

Metrics	Angiography Guided PCI (N=207)	LL Workflow Guided PCI (N=207)	P Value
PRODUCT UTILIZATION	**Mean ± SD**		
Stents	1.5 ± 0.86	1.3 ± 0.67	0.0478
Non-compliant Balloons	1.3 ± 1.13	1.9 ± 1.19	< 0.0001
Compliant Balloons	1.2 ± 0.87	0.8 ± 0.74	< 0.0001
LESION TREATMENT	**% (n/N)**		
Lesions with Unplanned Additional Treatment	10% (24/231)	4% (10/235)	0.01
Lesions with Vessel Prep	89% (212/238)	75% (179/239)	< 0.0001
Lesions with Post-Dilation	60% (138/231)	96% (218/227)	< 0.0001
PROCEDURE METRICS	**Median (IQR)**		
Procedure Duration (minutes)	36 (24 – 55)	45 (34 – 64)	< 0.0001
Cineangiography runs (# diagnostic views)	7 (3 – 9)	6 (3 – 8)	< 0.01

Acknowledgements

LightLab Initiative Investigators & Affiliated Hospitals

Austin Heart	Frank Zidar Thomas McMinn
Beth Israel Deaconess	Eric Osborn Eric Secemsky Marie-France Poulin Hector Tamez
Brigham and Women's Hospital	Kevin Croce Brian Bergmark Ajar Kochar
Greenville Memorial Hospital	Zach George Jesse Jorgensen Josh Doll Joseph Henderson Chetan Patel Dominic Johnson
HonorHealth Shea & Deer Valley	David Rizik Bimal Padaliya Kethes Waram Alok Sharma Mayurkumar Bhakta
Loyola University Hospital	John Lopez Amir Darki Lowell Steen
Montefiore Medical Center	Judah Rauch Michael Johnson Mark Greenberg
North Florida Regional Medical	Matheen Khuddus Jay Koons Mark Tulli Steven Roark Chris Caputo
Providence St. Vincent & Providence Portland	Ethan Korngold Jason Wollmuth Rick Sohn Charles Cannan
St. Patrick's Hospital	Daniel Spoon James "Tod" Maddux Michael Reed
University Hospitals Cleveland Medical Center & UH Ahuja	Hiram Bezerra William Wolf
Via Christi St. Francis & Kansas Heart Hospital	Bassem Chehab Aziz Maksoud

Abbott

Veda Inamdar
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Sydney Green
Savni Kulkarni
Chiedza Chauruka
Haley Mitchell
Morgan Prince
Karl Engel
Aimee Gerold
Amir Dolaty
Jossel Disengi
Raymond Dong
Michael Hammerstone
Gregory Amis
Jana Buccola
Joia Spinelli
Jennifer Meinen
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Supplemental Methods and Data

Propensity Score Generation — Covariates

25 Procedures & Lesion Characteristics Used to Match Populations

Procedure Level:

- Access Site
- Number of Lesions Assessed
- Number of Lesions Treated
- Number of Lesions Treated without a stent
- STEMI
- Multivessel Disease
- LV-Gram
- Right Heart Cath
- Guest Present
- Tortuosity
- Planned/staged procedure
- Complex
- Method of Closure

Lesion Level → Lesions Treated:

- Number of each Lesion Type (A, B, C)
- Number of CTO Lesions
- Number of In-stent Restenosis
- Number of Long Lesions
  - *Defined by total stented length ≥ 28 mm*
- Number of Calcified Lesions
  - *Defined by moderate to severely calcified*
- Number of lesions with Physiology
- Number of lesions in Vein Grafts
- Number of Ostial lesions
- Left Main
- Number of Bifurcation Lesions

Table 1

Before Matching

Covariate Median(IQR); % (n/N)	Angiography (N=428)	LL Workflow (N=264)	P Value
Lesions Assessed: 1 Lesions Assessed: ≥ 2	59% (251/428) 41% (177/428)	77% (203/264) 23% (61/264)	< 0.0001
Lesions Treated: 1 Lesions Treated: ≥ 2	72% (306/428) 29% (122/428)	89% (234/264) 11% (30/264)	< 0.0001
Any Lesions Treated w/o a Stent	9% (38/428)	5% (12/264)	0.03
STEMI	6% (27/428)	5% (14/264)	0.58
Multivessel Disease	12% (50/428)	6% (16/264)	0.01
Complex	58% (249/428)	78% (205/264)	< 0.0001
Tortuosity	5% (21/428)	3% (8/264)	0.22
Planned/staged	28% (118/428)	33% (88/264)	0.11
Fellow Present	26% (113/428)	34% (89/264)	0.04
LV-Gram	32% (138/428)	25% (66/264)	0.04
Right Heath Cath	5% (20/428)	4% (10/264)	0.58
Access Site: Radial Femoral	 45% (193/428) 45% (192/428)	 50% (132/264) 48% (127/264)	 < 0.0001
Closure Method: Device Manual	 84% (361/426) 7% (29/428)	 93% (246/264) 5% (13/264)	 < 0.001

After Matching

Covariate Median(IQR); % (n/N)	Angiography (N=207)	LL Workflow (N=207)	P Value
Lesions Assessed: 1 Lesions Assessed: ≥ 2	74% (154/207) 26% (53/207)	72% (150/207) 28% (57/207)	0.66
Lesions Treated: 1 Lesions Treated: ≥ 2	86% (177/207) 14% (30/207)	86% (178/207) 14% (29/207)	0.89
Any Lesions Treated w/o a Stent	5% (10/207)	4% (9/207)	0.81
STEMI	8% (16/207)	7% (14/207)	0.70
Multivessel Disease	7% (15/207)	7% (15/207)	1.0
Complex	66% (136/207)	72% (148/207)	0.20
Tortuosity	4% (9/207)	4% (8/207)	0.80
Planned/staged	29% (59/207)	30% (63/207)	0.67
Fellow Present	28% (58/207)	29% (61/207)	0.74
LV-Gram	28% (57/207)	26% (54/207)	0.74
Right Heath Cath	4% (9/207)	3% (6/207)	0.43
Access Site: Radial Femoral	 53% (110/207) 44% (91/207)	 52% (108/207) 45% (94/207)	0.98
Closure Method: Device Manual	 92% (191/207) 6% (13/207)	 93% (193/207) 5% (11/207)	0.92

Table 1 *(cont.)*

Before Matching

Covariate Median(IQR); % (n/N)	Angiography (N=428)	LL Workflow (N=264)	P Value
Type A	18% (75/428)	6% (17/264)	< 0.0001
Type B	40% (171/428)	36% (96/264)	0.35
Type C	39% (168/428)	64% (168/264)	< 0.0001
CTO	11% (46/428)	5% (13/264)	< 0.01
ISR	13% (57/428)	20% (52/264)	0.03
Long Lesion	44% (189/428)	57% (151/264)	< 0.001
Calcified	22% (92/428)	25% (65/264)	0.34
Vein Grafts	7% (28/428)	2% (4/264)	< 0.001
Ostial Lesions	9% (37/428)	4% (10/264	0.01
Left Main	4% (15/428)	2% (6/264)	0.35
Bifurcation (any treated)	3% (12/428)	0% (1/264)	0.01
# Lesions w/Physiology	9% (37/428)	12% (31/264)	0.19

After Matching

Covariate Median(IQR); % (n/N)	Angiography (N=428)	LL Workflow (N=264)	P Value
Type A	12% (24/207)	8% (17/207)	0.25
Type B	43% (88/207)	42% (86/207)	0.84
Type C	54% (112/207)	58% (121/207)	0.37
CTO	9% (19/207)	6% (13/207)	0.27
ISR	16% (33/207)	17% (35/207)	0.79
Long Lesion	50% (103/207)	52% (108/207)	0.62
Calcified	24% (50/207)	28% (58/207)	0.37
Vein Grafts	2% (4/207)	2% (4/207)	1.0
Ostial Lesions	4% (8/207)	5% (10/207)	0.63
Left Main	2% (5/207)	2% (5/207)	1.0
Bifurcation (any treated)	0% (0/207)	0% (1/207)	0.24
# Lesions w/Physiology	10% (21/207)	12% (25/207)	0.53

Table 2

Procedural Outputs *% (n/N)*	**Angiography-guided**	**Workflow**	**P Value** *Likelihood Ratio Chi-Squared*
Lesions with Unplanned Additional Treatment (Stent)	10% (24/231)	4% (10/235)	0.01
Lesions with Post Dil	60% (138/231)	96% (218/227)	< 0.0001
Post Dil performed before post-PCI OCT	--	90% (206/228)	--
Optimization after post-PCI OCT	--	35% (72/206)	--
Lesions with Vessel Prep	89% (212/238)	75% (179/239)	< 0.0001
Optimization when no vessel prep*	--	32% (19/60)	--

*Post dil performed before post-PCI OCT in n=56 of 60.

Table 3

Procedural Outputs *Mean ± Stdev Provided*	**Angiography-guided (N=207)**	**Workflow (N=207)**	**P Value** *Wilcoxon Rank Sums*
Stents Used	1.5 ± 0.86	1.3 ± 0.67	0.0478
Non-compliant Balloons Used	1.3 ± 1.13	1.9 ± 1.19	< 0.0001
Compliant Balloons Used	1.2 ± 0.87	0.8 ± 0.74	< 0.0001
Guidewires Used	1.6 ± 1.12	1.4 ± 0.72	< 0.01

IMPORTANT SAFETY INFORMATION

℞ OPTIS™ Imaging Systems and Software

ONLY

INDICATIONS

The OPTIS™ Software and AptiVue™ E Series Software are intended to be used only with compatible OPTIS™ Imaging Systems.

The OPTIS™ Imaging System with a compatible Dragonfly™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The compatible Dragonfly™ Imaging Catheters are intended for use in vessels 2.0 to 3.5 mm in diameter. The compatible Dragonfly™ Imaging Catheters are not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The OPTIS™ Imaging System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

CONTRAINDICATIONS

The OPTIS™ Integrated System and Mobile System with Software are contraindicated where introduction of any catheter would constitute a threat to patient safety. Contraindications include:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for CABG surgery
- Patients disqualified for PTCA
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure

NOTE: The systems have no patient alarm functions. Do not use for cardiac monitoring.

WARNINGS

- Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.
- Observe all advancement and movement of the Dragonfly™ Imaging Catheter under fluoroscopy. Always advance and withdraw the catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage.
- Leave the guidewire engaged with the catheter at all times during use. Do not withdraw or advance the guidewire prior to withdrawing the catheter.
- If resistance is encountered during advancement or withdrawal of the Dragonfly™ Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire together.
- The Dragonfly™ Imaging Catheter should never be forced into lumens that are narrower than the catheter body or forced through a tight or heavily calcified lesion.
- The Dragonfly™ Imaging Catheter should not be advanced through abnormally tortuous anatomy.
- When advancing or retracting a catheter with a monorail tip through a stented vessel, the catheter may engage the stent between the junction of the Dragonfly™ Imaging Catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- Refer to the contrast media's instructions-for-use for general warnings and precautions relating to use of the contrast media.
- To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), and to protect the integrity of the system itself, the system should be located in a physically secure, access controlled environment.
- Do not use the OPTIS™ Imaging System if there is reason to believe the system's security has been compromised or if the system was unaccounted for a period of time (i.e. misappropriated, modified or tampered with).

PRECAUTIONS

- Safety and effectiveness have been established for the following patient population: adult patients undergoing non emergent percutaneous coronary interventions in lesions with reference vessel diameters between 2.0 to 3.5 mm, which were not located in the left main coronary artery or in a target vessel which has undergone previous bypass procedures.
- For optimal imaging, only use 100% contrast media.
- Store the Dragonfly™ Imaging Catheter at ambient temperature in a dry location out of direct sunlight.
- Never attempt to attach or detach a Dragonfly™ Imaging Catheter to the DOC while the "lock" LED is lit.
- Do not kink, sharply bend, pinch, or crush the Dragonfly™ Imaging Catheter at any time.
- The Dragonfly™ Imaging Catheter is for single use only. Do not reuse, re-sterilize, or reprocess.
- The Dragonfly™ Imaging is sterilized by ethylene oxide and is intended for one time use only. Non-pyrogenic. Do not use if the package is opened or damaged.
- After use, the Dragonfly™ Imaging Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
- The Dragonfly™ Imaging Catheter has no user serviceable parts. Do not attempt to repair or alter any part of the catheter assembly as provided.

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IMPORTANT SAFETY INFORMATION

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OPTIS™ Next Imaging Systems and Software

INDICATIONS

The Ultreon™ 1.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems. The OPTIS™ Next Imaging System with a compatible Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The OPTIS™ Next Imaging System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise, and clinical judgment to determine if therapeutic intervention is indicated.

CONTRAINDICATIONS

Use of the Ultreon™ 1.0 Software is contraindicated where introduction of any catheter would constitute a threat to patient safety.

Contraindications include:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for coronary artery bypass graft (CABG) surgery
- Patients disqualified for percutaneous transluminal coronary angioplasty (PTCA)
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure
- Inability to tolerate systemic anticoagulation is a contraindication to use of OCT for coronary imaging.
- PressureWire™ Guidewire is contraindicated for use in the cerebral vasculature.
- The system has no patient alarm functions. Do not use for cardiac monitoring.

COMPLICATIONS

The risks involved in vascular imaging include those associated with all catheterization procedures. The following complications may occur as a consequence of intravascular imaging and may necessitate additional medical treatment including surgical intervention.

- Abnormal heart rhythm or arrhythmias
- Acute myocardial infarction
- Allergic reaction to the contrast media or drug administered for the procedure
- Arterial dissection, injury, or perforation
- Bleeding
- Catheter access site reactions: sterile inflammation or granuloma
- Coronary artery spasm
- Death
- Embolism
- Myocardial ischemia
- Renal insufficiency or failure from contrast media use
- Repeat revascularization
- Thrombus formation, abrupt closure, or total occlusion
- Tissue necrosis
- Unstable angina
- Hypotension

WARNINGS

- Refer to the contrast media Instructions for Use for general warnings and precautions relating to use of contrast media.
- The heart rate and mean pressure values shown on the OPTIS™ Next Imaging System are for reference only and are not intended to be used as the primary display.
- The system may place the point of index value at the wrong location due to pressure artifacts, for example: abnormal heartbeats, artifacts in AO (Pa) caused by flushing of guiding catheter, or valve opening / closing. The physician should always confirm that the point selected by the system is a valid point for the calculation of index value.
- Inside the catheterization laboratory, only port-powered USB drives may be connected to the USB port. Connecting externally powered devices to the USB port in the patient vicinity may compromise electrical isolation and cause patient injury.
- To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), and to protect the integrity of the system itself, the system should be located in a physically secure, access-controlled environment. Do not use the OPTIS™ Next Imaging System if there is reason to believe the system's security has been compromised or if the system was unaccounted for during a period of time (i.e., misappropriated, modified, or tampered with).

PRECAUTIONS

- Safety and effectiveness have been established for the following patient population: adult patients undergoing non-emergent percutaneous coronary interventions in lesions with reference vessel diameters between 2.0 to 3.5 mm, which were not located in the left main coronary artery or in a target vessel which has undergone previous bypass procedures.
- Monitor the OCT image for indications of Dragonfly™ Imaging Catheter optical failure. If optical failure is suspected, remove the Dragonfly™ Imaging Catheter from the patient, press "Unload" on the drive motor and optical controller (DOC), detach the catheter, and replace it with a new one.
- If the pullback triggers before contrast is injected, repeat the pullback.
- For optimal imaging, only use 100% contrast media.

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