Effect of a Prescriptive Optical Coherence Tomography Guided Strategy on Treatment of In-Stent Restenosis– Insights from the LightLab Initiative

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On behalf of the LightLab Initiative Investigators

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Affiliation/Financial Relationship	Company
Grant/Research Support	Abbott, Takeda, Teleflex, CSI
Consulting Fees/Honoraria	*Abbott, BSCI, Biotronik, Philips, Abiomed, CSI, Takeda, Cordis*
Major Stock Shareholder/Equity	Dyad Medical

Faculty disclosure information can be found on the app

All content provided by Dr. Croce unless otherwise noted.

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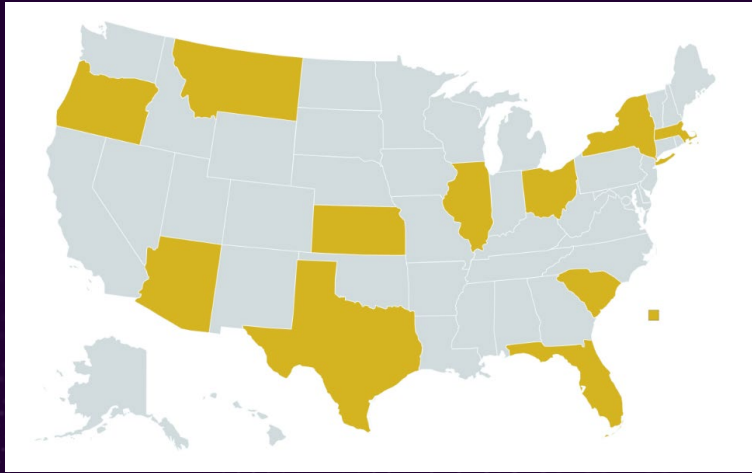
LightLab Clinical Initiative

Vision: To improve cath lab workflow, safety, and efficiency via standardized use of the full range of information derived from OCT



- 12 US centers with ongoing prospective PCI procedural data collection by trained & embedded Field Clinical Engineer
- Multiphase program to examine role & impact of routine use of OCT workflow

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LightLab Program Phases

Baseline Phase	Assessment of current practice and collection of data for comparison to future phases
Clinical Accuracy	Adoption of LightLab OCT-focused workflow and the effect on accuracy/precision
Workflow Utilization	Standardization of LightLab OCT-focused workflow and its effect on efficiency
Workflow Optimization	Optimization of workflow to reduce angiographic pre-diagnosis steps and improve efficiency
Workflow Expansion	Expansion of workflow to increased complexity of procedures and case presentations

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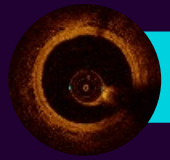
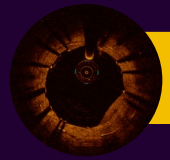
LightLab OCT Workflow

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



Pre-PCI OCT | Strategize



Post-PCI OCT | Optimize

1. Physiological Assessment as appropriate
2. Plaque **M**orphology
3. Lesion **L**ength
4. Vessel **D**iameter
5. Angiographic Co-registration
6. **M**edial Dissection / Stent Edge Assessment
7. Stent **A**pposition
8. Stent E**X**pansion

Learning applied from LightLab program to create simplified workflow for routine use: MLD MAX

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LightLab Study Design

- **DESIGN:** Prospective, multi-center observational study examining the LightLab OCT workflow.
- **OBJECTIVE:** Assess impact of a routine OCT workflow on lesion assessment, treatment strategy, and PCI optimization decisions compared with angiography.
- **INCLUSION/EXCLUSION:** All PCIs performed by participating physicians were eligible; inclusion in LightLab study and suitability for OCT were at physician discretion.
- **STUDY SPONSOR:**
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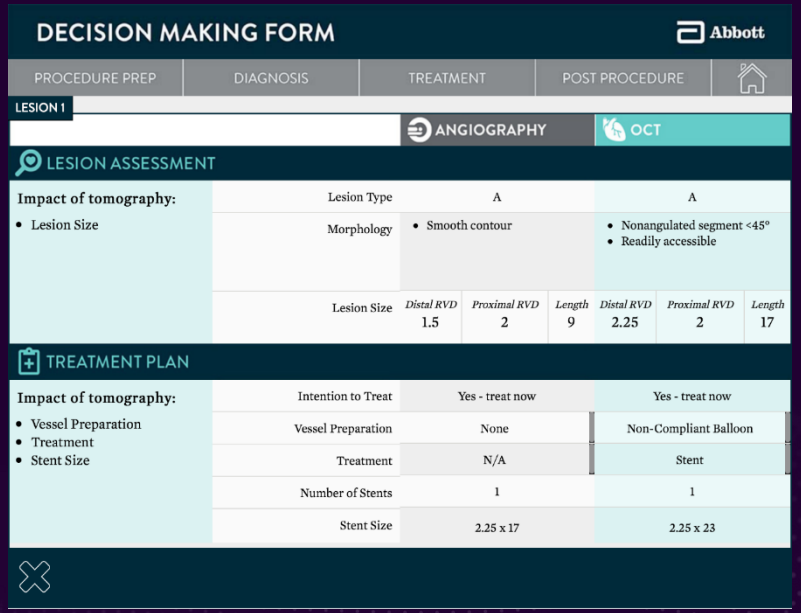
Clinical Accuracy Phase: Overview

- LightLab workflow introduced in the Clinical Accuracy Phase.
- Physician's characterization and treatment plan were recorded after initial angiography and again after pre-PCI OCT:
  - Lesion morphology
  - Vessel preparation strategy
  - Number of stents
  - Stent diameter & length
- Post-PCI OCT was performed and additional optimization recorded.



DECISION MAKING FORM — Abbott

PROCEDURE PREP | DIAGNOSIS | TREATMENT | POST PROCEDURE

LESION 1

		ANGIOGRAPHY			OCT		
LESION ASSESSMENT							
Impact of tomography: • Lesion Size	Lesion Type	A			A		
	Morphology	• Smooth contour			• Nonangulated segment <45° • Readily accessible		
	Lesion Size	*Distal RVD* 1.5	*Proximal RVD* 2	*Length* 9	*Distal RVD* 2.25	*Proximal RVD* 2	*Length* 17
TREATMENT PLAN							
Impact of tomography: • Vessel Preparation • Treatment • Stent Size	Intention to Treat	Yes - treat now			Yes - treat now		
	Vessel Preparation	None			Non-Compliant Balloon		
	Treatment	N/A			Stent		
	Number of Stents	1			1		
	Stent Size	2.25 x 17			2.25 x 23		

Data recorded on custom study proforma

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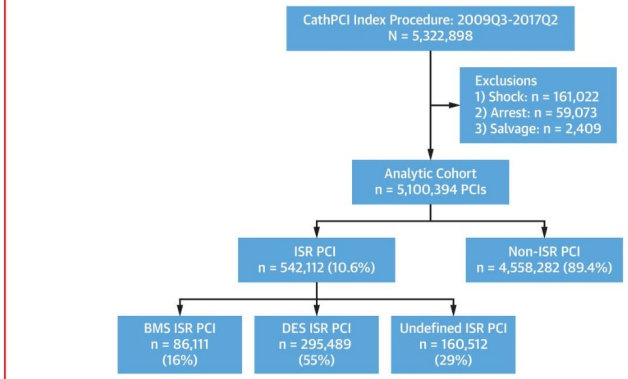
10% of PCIs in US are for ISR

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Trends and Outcomes of Restenosis After Coronary Stent Implantation in the United States

Issam D. Moussa, Divyanshu Mohananey, Jorge Saucedo, Gregg W. Stone, Robert W. Yeh, Kevin F. Kennedy, Ron Waksman, Paul Teirstein, Jeffrey W. Moses and Chuck Simonton

CENTRAL ILLUSTRATION: Flow Chart of the Study Cohort



Moussa, I.D. et al. J Am Coll Cardiol. 2020;76(13):1521-31.

Conclusions ISR represents approximately 10% of all PCI and is treated most commonly with another stent. Approximately 25% of patients present with acute MI. In-hospital outcomes of patients with ISR PCI are comparable with those undergoing non-ISR PCI.

Accurate Diagnosis of ISR Mechanism Can Alter Treatment

Mechanism	*Potential treatments*
Unstented/gap segment	BA, DES
Severe neointimal hyperplasia	BA, laser, DES
Stent fracture	BA, DES, brachytherapy
Undersized	BA high pressure, scoring balloon, larger DES
Underexpansion	BA high pressure inflation, scoring balloon, laser, atherectomy, DES
> 2 layers of stent	Laser, brachytherapy, outside US - DCB

**BA = balloon angioplasty, DES = drug eluting stent, DCB = drug coated balloon*

Kevin Croce MD, PhD

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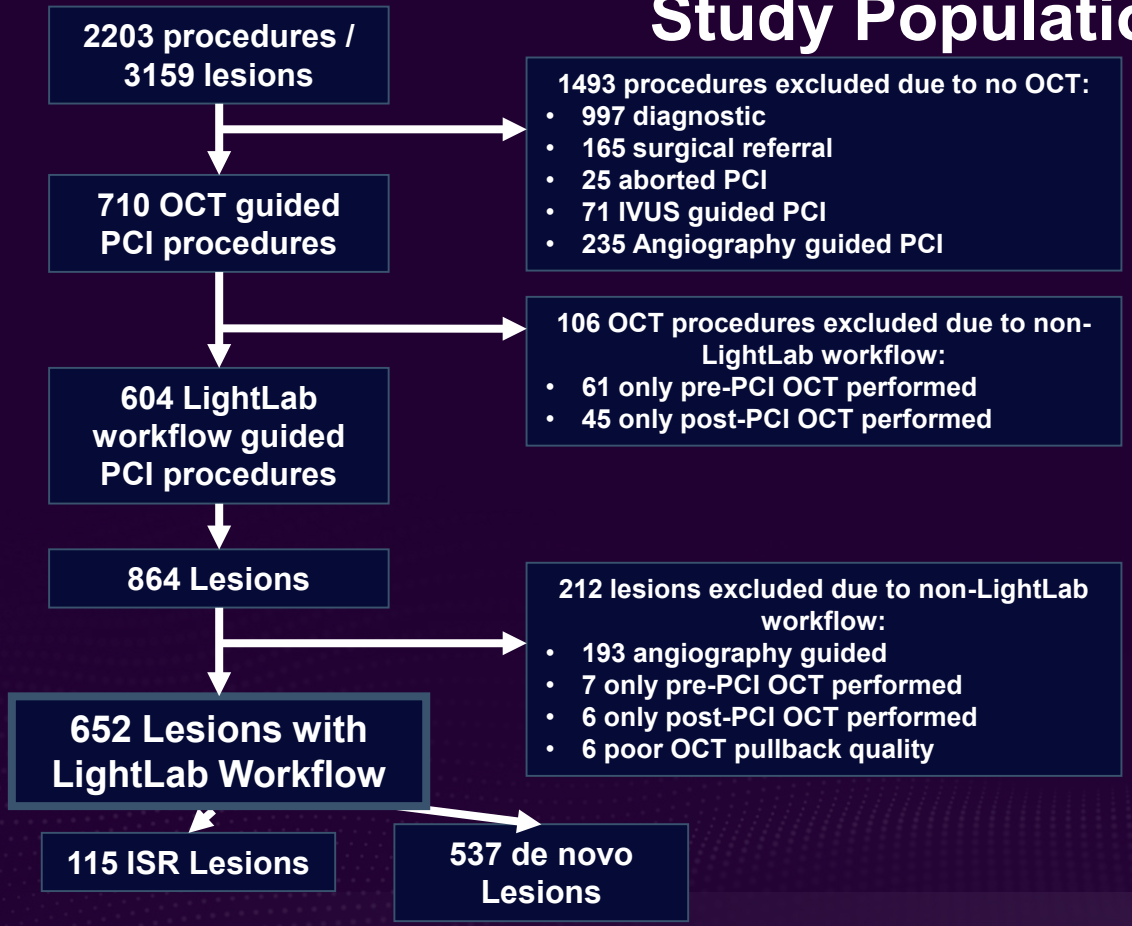
Study Population



- 2203 procedures were assessed in this phase of the LL program (March 6, 2019 – March 12, 2020)
- Lesions that utilized the LightLab workflow were included in the analysis to assess the impact of OCT when the full range of information available from OCT was used for decision-making
- Comparative analysis was conducted to assess the impact of the LL workflow on ISR vs. de novo lesions using Likelihood Ratio Chi-Squared test

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Procedure and Lesion Characteristics

LightLab Workflow Procedures (n=604)

	ISR (n=110)	de novo (n=494)	p value
Planned/staged procedures	32/110 (29%)	149/494 (30%)	0.82
Access Site:			
- Radial	53/105 (50%)	304/468 (65%)	0.02
- Femoral	50/105 (48%)	160/468 (34%)	
- Radial & Femoral	2/105 (1.9%)	4/468 (0.9%)	
Mechanical Support	1/110 (0.9%)	8/494 (1.6%)	0.56
Multivessel	6/110 (5.5%)	57/494 (12%)	0.07
STEMI	3/110 (2.7%)	30/494 (6.1%)	0.13

LightLab Workflow Lesions (n=652)

	ISR (n=115)	de novo (n=537)	p value
Left Main	5/112 (4.5%)	15/529 (2.8%)	0.46
RCA	34/112 (30%)	154/529 (29%)	
LAD	52/112 (46%)	257/529 (49%)	
CX	14/112 (13%)	86/529 (16%)	
Ramus	3/112 (2.7%)	11/529 (2.1%)	
Vein Graft	4/112 (3.6%)	6/529 (1.1%)	
Lesion Type:			
- A	5/115 (4.4%)	28/534 (5.2%)	0.74
- B	43/115 (37%)	215/534 (40%)	
- C	67/115 (58%)	291/534 (54%)	
Long Lesions (OCT Lesion length ≥ 28 mm)	48/113 (42%)	238/533 (45%)	0.67
Chronic Total Occlusions	5/115 (3.2%)	16/536 (3.0%)	0.47
Bifurcations	2/115 (1.7%)	65/536 (12%)	<0.01
Ostial Lesions	4/115 (3.5%)	26/536 (4.9%)	0.51

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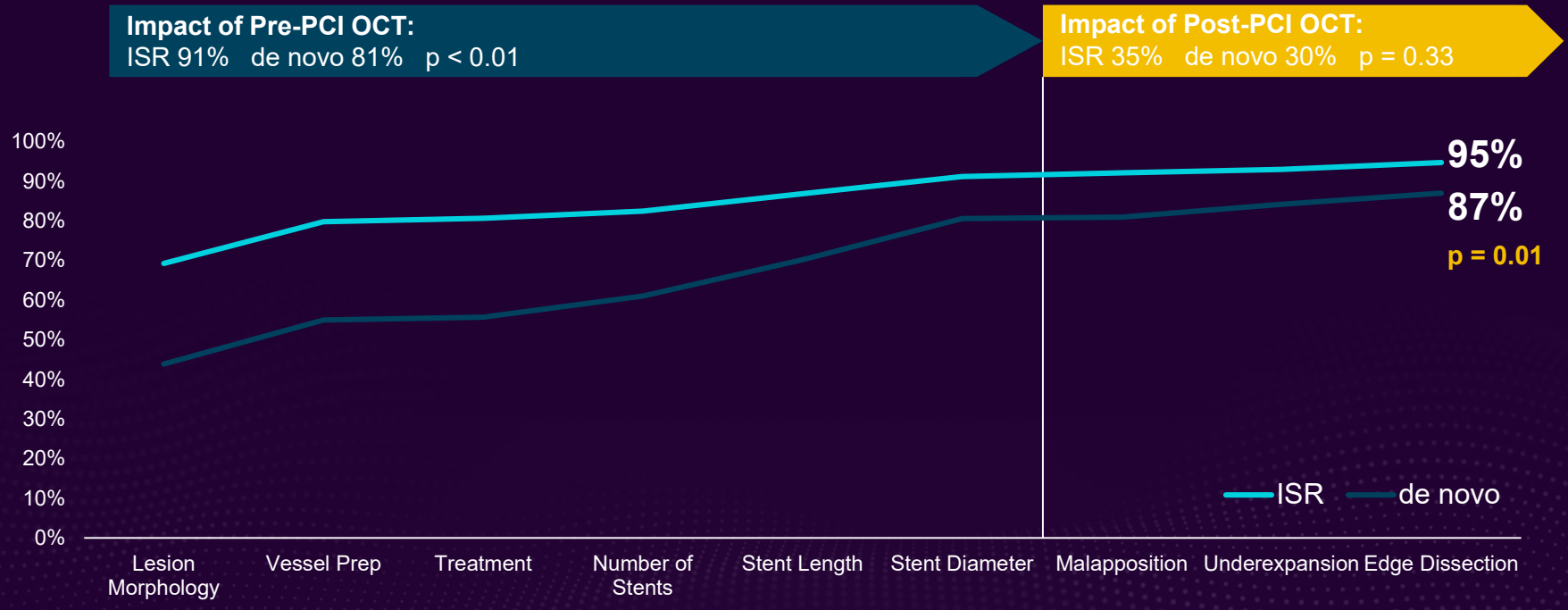
Cumulative impact of OCT-derived information on PCI decision-making



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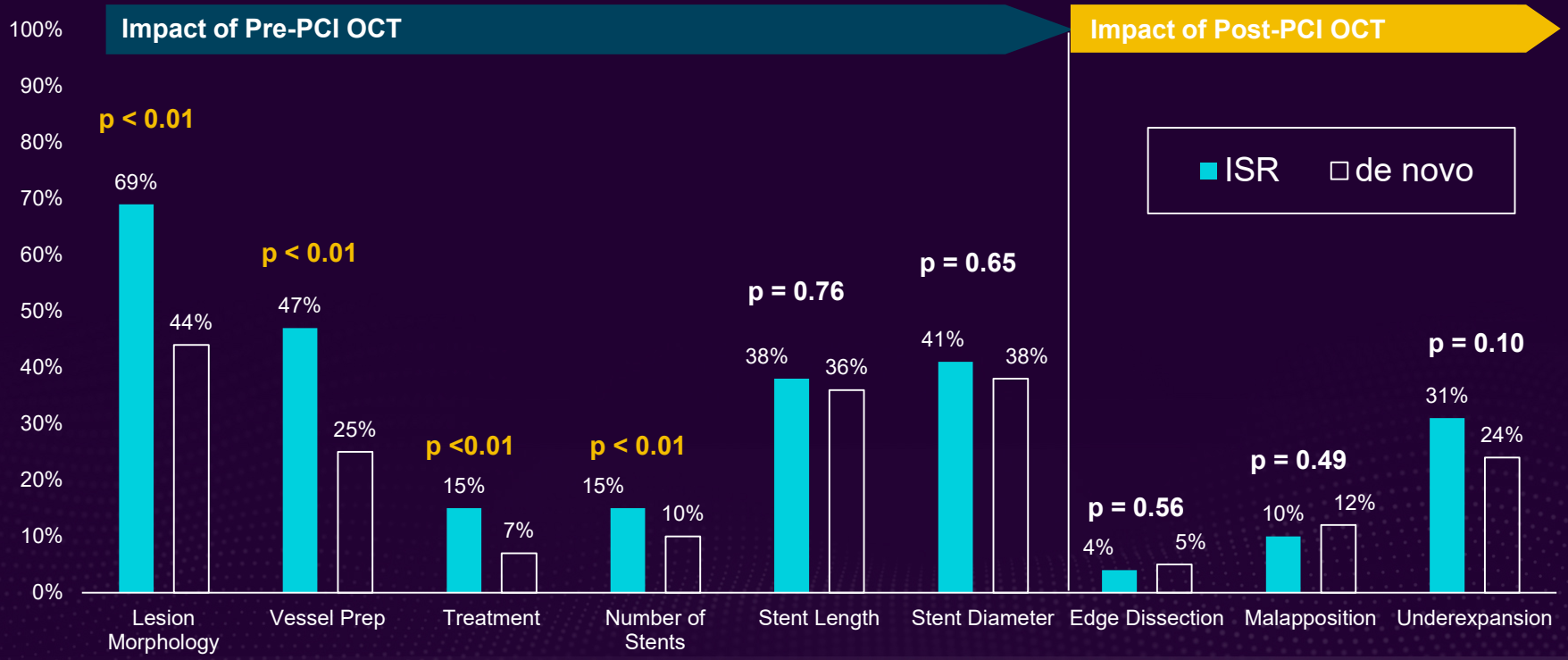
Impact of OCT-derived information on ISR treatment strategy



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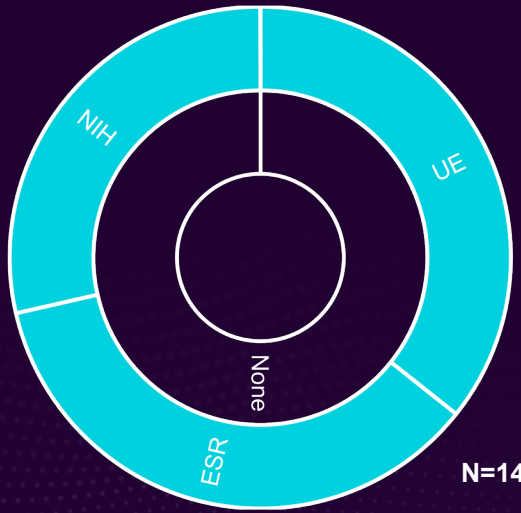
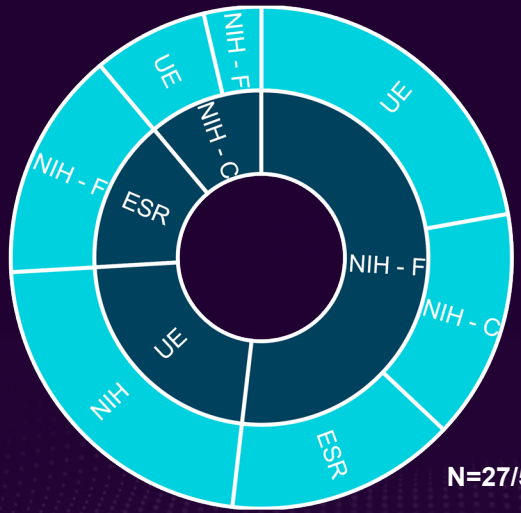
Physician's angiographic assessment of ISR mechanism changed in 48% of ISR lesions

25% ISR was not identified on Angio



N=14/55

50% OCT added ISR mechanism to Angio assessment



N=27/55

Inner ring identifies angiography diagnosis, outer ring identifies OCT diagnosis

- **25% of lesions: OCT completely changed ISR mechanism vs. angio.**
- **Stent underexpansion observed in 34% (39/115) of pre-PCI OCT pullbacks in ISR cases.**

ESR = edge stent restenosis
UE = Underexpansion
NIH = neointimal hyperplasia (c=calcific, f=fibrotic)

Blue = add ISR mechanism by OCT
Purple = no ISR mechanism identified by angio
Dark Blue = ISR mechanism identified by angio confirmed by OCT

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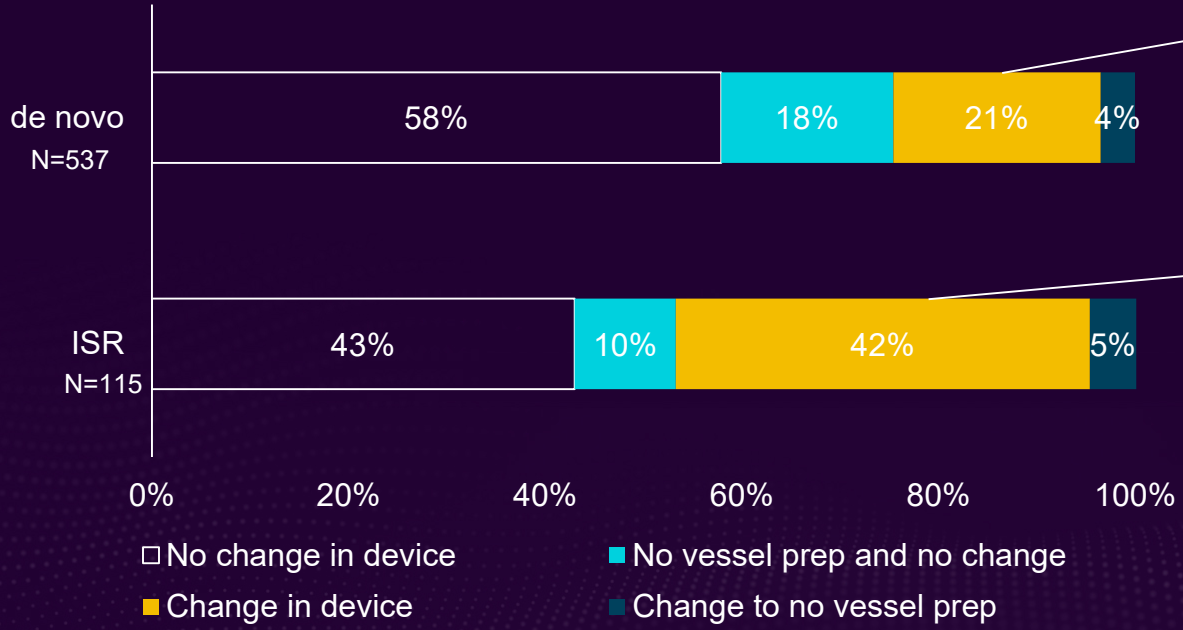
OCT Impact on Vessel Preparation Strategy

OCT changed angiographic vessel preparation treatment decisions in a larger proportion of ISR lesions compared to de novo lesions



When OCT altered vessel preparation strategy for de novo lesions, 41% of vessel preparation performed utilized specialty balloons, atherectomy, or laser

When OCT altered vessel preparation strategy for ISR lesions, 73% of vessel preparation performed utilized specialty balloons, atherectomy, or laser

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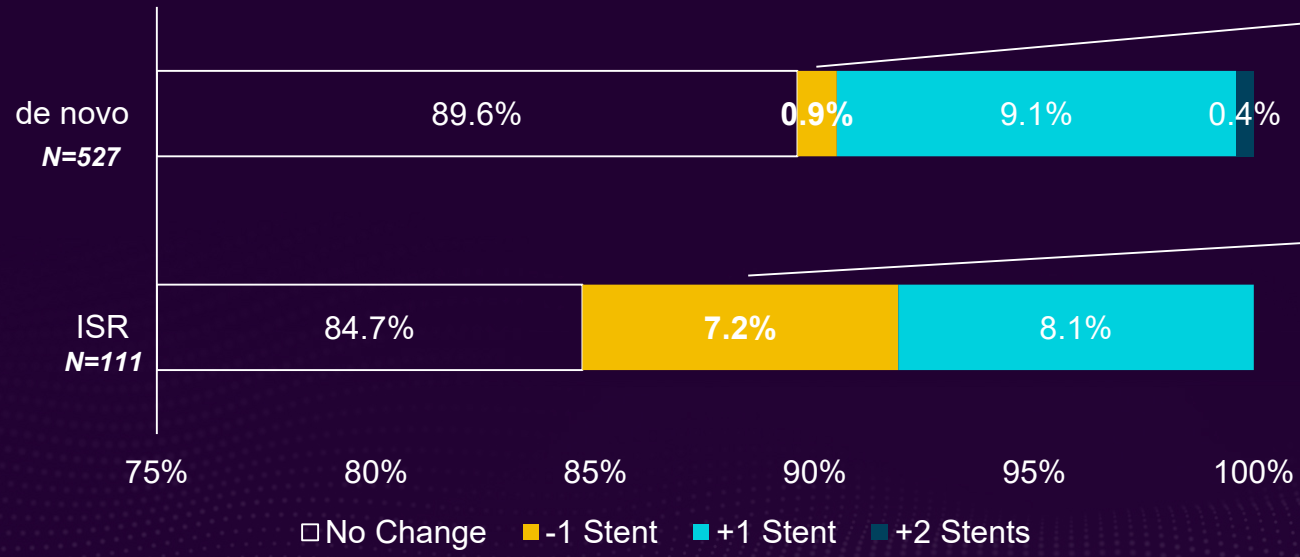
OCT Impact on Number of Stents Planned

OCT influenced change to non-stenting strategy in higher proportion of ISR lesions compared to de novo lesions



Despite reduction in number of planned stents after OCT imaging in de novo lesions, all still received at least 1 stent

For ISR lesions, the reduction in number of stents planned was primarily due to changing to a non-stenting strategy

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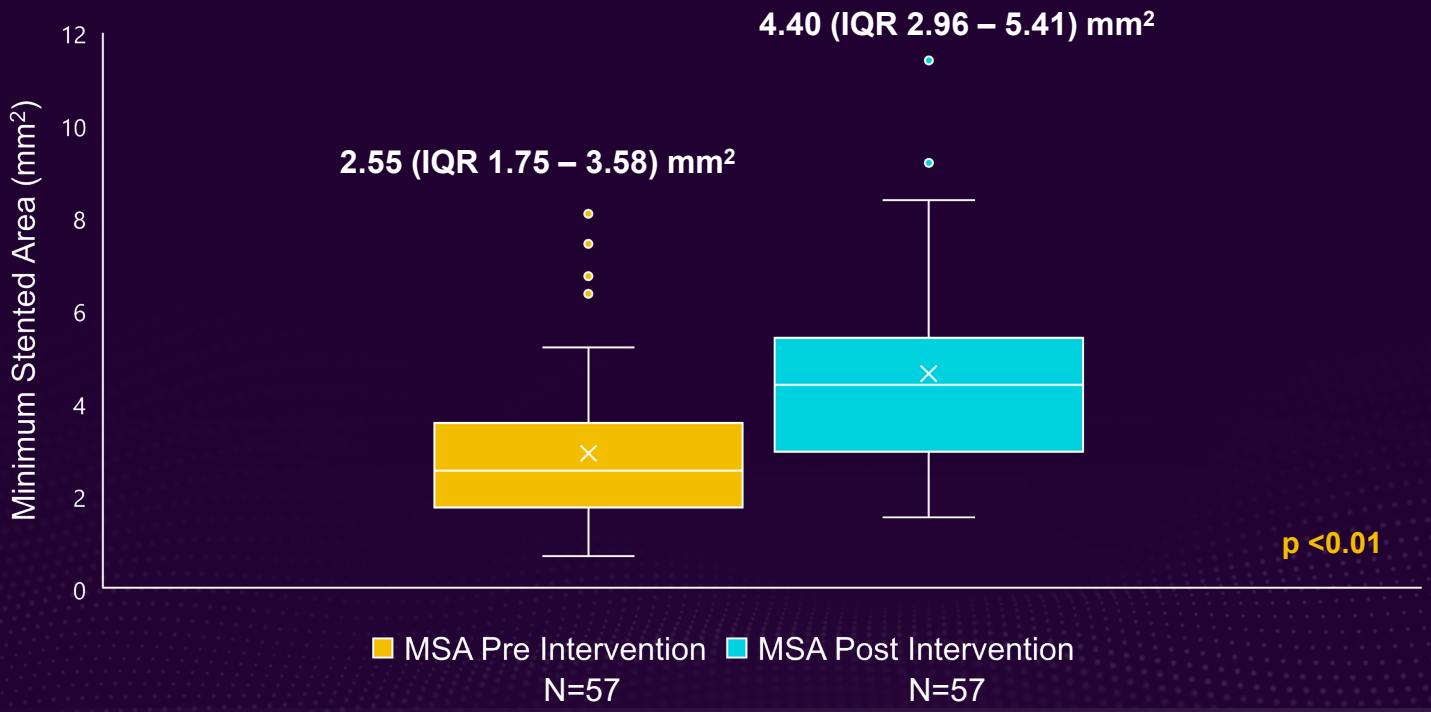
Change in Minimum Stent Area (MSA)

Application of LightLab workflow resulted in an MSA increase of 72% for ISR lesions



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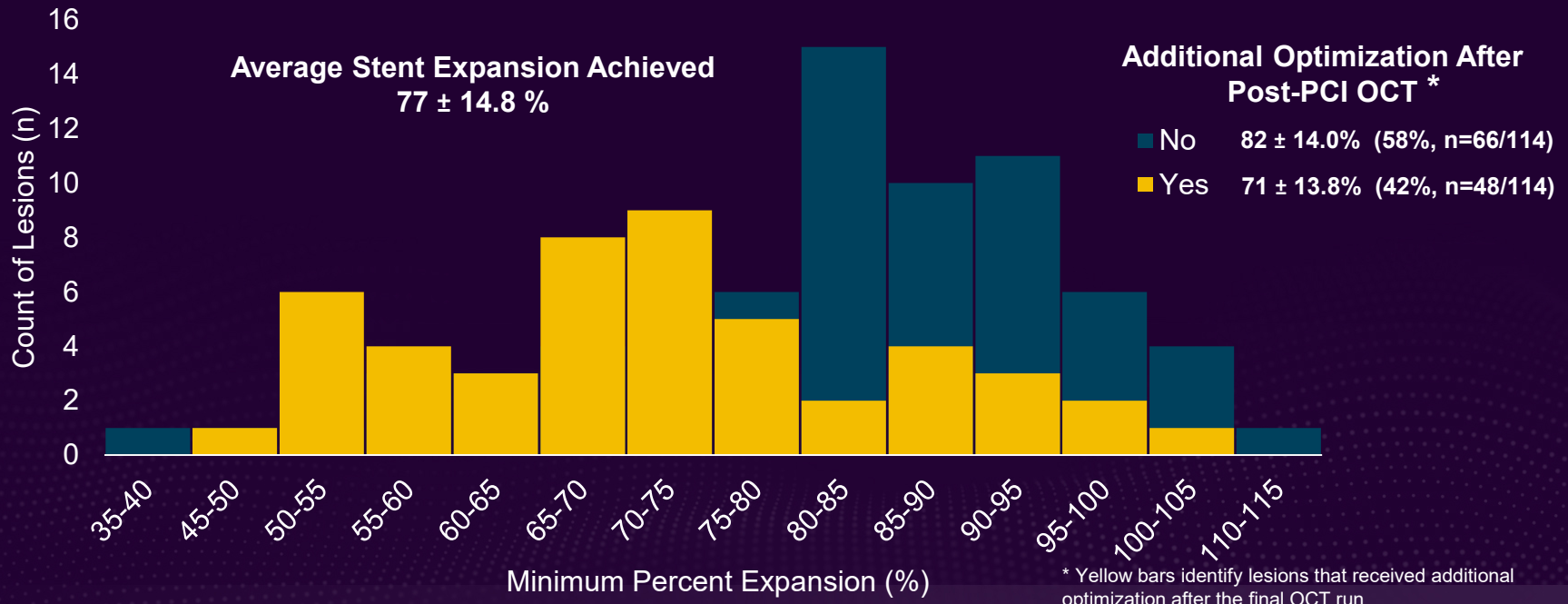
Stent Expansion

LightLab workflow drove ISR treatment strategies that achieved 77% average initial stent expansion



* Yellow bars identify lesions that received additional optimization after the final OCT run

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Conclusion

- ISR treatment constitutes > 10% of US PCIs and represents a significant burden to the healthcare system.
- The OCT MLD MAX PCI workflow impacts PCI decision-making in most lesions, with the highest impact of 91% in changing the diagnosis and treatment of ISR from the pre PCI OCT.
- The OCT MLD MAX workflow drove ISR treatment strategies that achieved 77.4% average initial stent expansion.
- OCT assessment of morphology and stent failure mechanism changes vessel preparation strategy in 47% of ISR lesions.
- OCT dramatically impacts procedural decision-making in ISR treatment.

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OPTIS™
Imaging Systems and Software

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 Catheter 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.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *vascular.eifu.abbott* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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