24 Month Follow-Up Data, Interim Analysis, From The Pivotal VISION Study for OCT Guided Directional Atherectomy

Ian Cawich, MD

PML 0496-A

Disclosure

Speaker name:

Dr. Ian Cawich

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☒ I do not have any potential conflict of interest

VISION IDE | VISION Trial for OCT Guided Directional Atherectomy

8Fr/7Fr

130/110 cm working length

.014 guidewire compatible

Cutter rotation = 1000rpm

OCT – frequency domain

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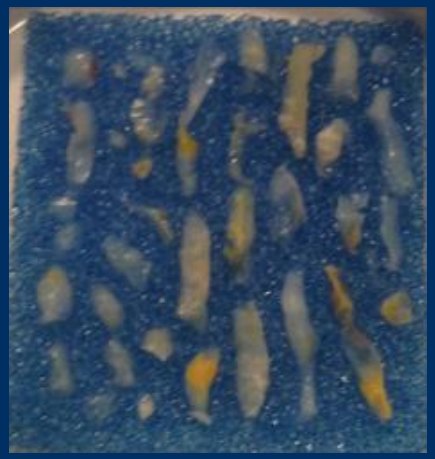
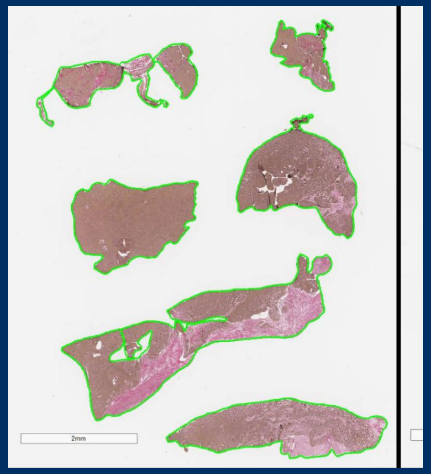
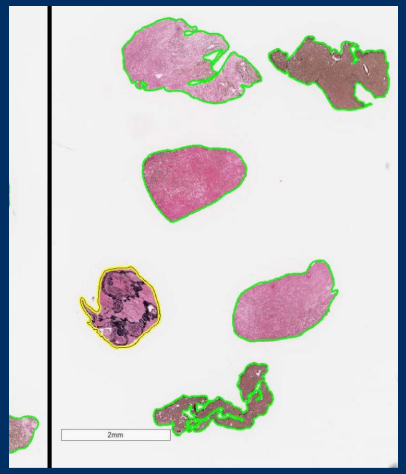
Atherectomy Tissue Gross + Histology







Plaque = 94.43% **Medial Tissue = 5.7%** **Adventitial Tissue = 0%**

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VISION IDE | Inclusion + Exclusion Criteria

MAJOR INCLUSION CRITERIA

- Patient is ≥ 18 years old
- Patient is candidate for percutaneous intervention for PAD
- Rutherford Classification 2-5
- RVD ≥ 3.0mm and ≤7.0mm by visual estimation
- De novo target lesion(s) with stenosis ≥70%. No more than 2 lesions may be treated.
- Target lesions length ≤15cm (may be two tandem lesions that do not exceed 15cm in length)
- At least one patent tibial run-off

MAJOR EXCLUSION CRITERIA

- Moderate to severe calcification
- Target lesion stenosis <70%
- Target lesion within graft or target lesion in the iliac artery
- In-stent restenosis within the target lesion
- Acute ischemia and/or acute thrombosis
- Significant (≥70%) lesions proximal to the TL not successfully treated during the index procedure (i.e., iliac lesion treated prior to target lesion treatment on same day)
- Lesion in the contralateral limb requiring intervention during the index procedure or within 30 days from the index procedure

VISION IDE | Trial Design & Endpoints

ENDPOINTS		BASELINE	30 DAYS	6 MONTHS	24 MONTHS
EFFICACY	PRIMARY	≤ 50% Residual Stenosis post Pantheris*			
	SECONDARY	≤ 30% Post Pantheris* +/- adjunctive treatment	Change from baseline: • Ankle-brachial Index • Rutherford • Quality of Life	Change from baseline: • Ankle-brachial Index • Rutherford • Quality of Life →	
SAFETY	PRIMARY	Device related events (Acute) • Clinically significant perforation • Clinically significant dissection • Clinically significant embolus • Pseudoaneurysm			
		Freedom from MAEs thru 6M (Data collection ongoing) • Cardiovascular Related Death • Unplanned, major index limb amputation • Clinically driven target lesion revascularization (TLR) • Myocardial infarction →			
	SECONDARY	Freedom from procedural emboli			
		Freedom from MAEs			
		Freedom from clinically driven TVR →			

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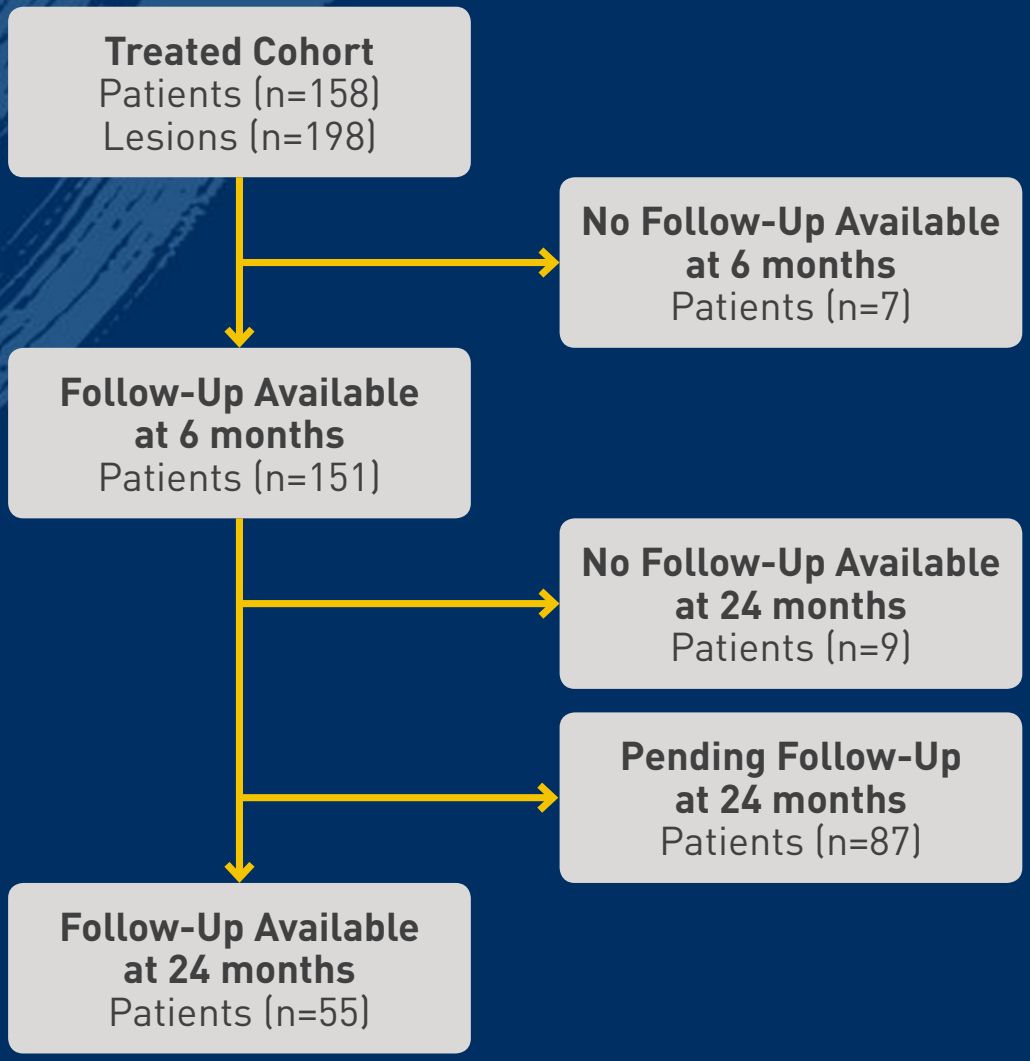
Subject Accountability Through 24 Months
All Treated Cohort – Interim Analysis



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VISION IDE | Baseline Demographics & Co-morbidities

Demographics[1]	All Treated Cohort (N=158 Subjects)
Average Age (yrs)	
Mean ± Stdev (N)	67.2 ± 10.5 (158)
Gender, % (m/N)	
Male	55.1% (87/158)
Female	44.9% (71/158)
Average BMI	
Mean ± Stdev (N)	28.8 ± 6.2 (158)

Co-morbidities[1]	All Treated Cohort (N=158 Subjects)
History of, % (m/N)	
Smoking	84.2% (133/158)
Diabetes requiring therapy	43.7% (69/158)
Hypertension requiring intervention	91.1% (144/158)
Coronary artery disease	60.1% (95/158)
Other vascular disease	85.4% (135/158)

[1] Site reported data

VISION IDE | Baseline Lesion Characteristics

Baseline Lesion Characteristics	All Treated Cohort (N=198 Lesions)[3]
Lesion Location[1], % (m/N)	
SFA	80.8% (160/198)
Proximal	18.2% (36/198)
Mid	38.9% (77/198)
Distal	23.7% (47/198)
SFA/Popliteal	6.1% (12/198)
Popliteal	13.1% (26/198)
TASC[1], % (m/N)	
A	76.5% (150/196)
B	20.4% (40/196)
C	3.1% (6/196)
Califications[2], % (m/N)	
None	21.7% (43/198)
Mild	77.3% (153/198)
Moderate	0.5% (1/198)
Lesions Type[2], % (m/N)	
De Novo	99.5% (197/198)
Restenotic	0.5% (1/198)
Lesion Length[1], (cm)	
Mean ± Stdev (N)	7.2 ± 4.2 (198)
CTO Subgroup, Mean ± Stdev (N)	10.7 ± 4.5 (40)
Mean Reference Vessel Diameter[1], (mm)	
Mean ± Stdev (N)	4.7 ± 0.8 (196)
Percent Pre-Procedure Stenosis[1], (%)	
Mean ± Stdev (N)	78.7 ± 15.1 (196)

[1] Assessed by Imaging Core Lab. [2] Site reported. [3] Denominators < 198 lesions reflect missing data.

VISION IDE | Major Adverse Events through 6 Months

6 Month MAE[1]	All Treated Cohort (N=158 patients[2])	
Overall MAE	**16.6% (25/151)**	
Cardiovascular related death	2.6% (4/151)	
Unplanned, major index limb amputation	0% (0/151)	
Target lesion revascularization (TLR)	**7.9% (12/151)**	
Myocardial infarction	2.0% (3/151)	
Device related events	**4.0% (6/151)**	
	Pantheris Related	**Occlusion Sheath Related**
Clinically significant perforation	**0.0% (0/151)**	**0.0% (0/151)**
Clinically significant dissection	**0.7% (1/151)**	**0.7% (1/151)**
Clinically significant embolus	2.6% (4/151)	0.0% (0/151)
Pseudoaneurysm	0.0% (0/151)	0.7% (1/151)

1. Adjudicated by independent Clinical Events Committee (CEC). 2. Excludes 7 subjects who were not followed through 6 months.

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24 Month Outcomes
Interim Analysis (n=55 patients)

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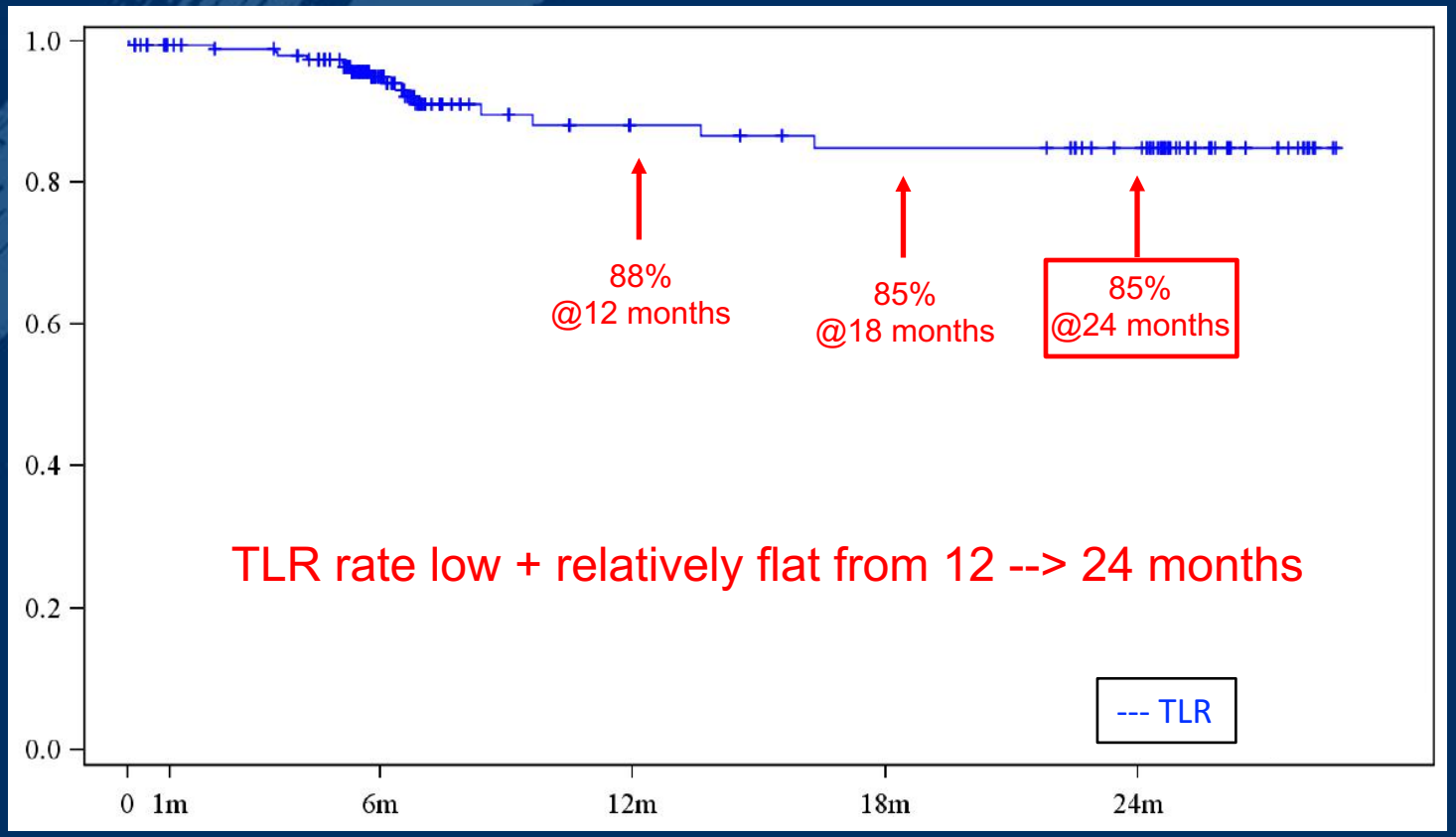
24 Month Outcomes
Freedom from Target Lesion Revascularization (TLR)



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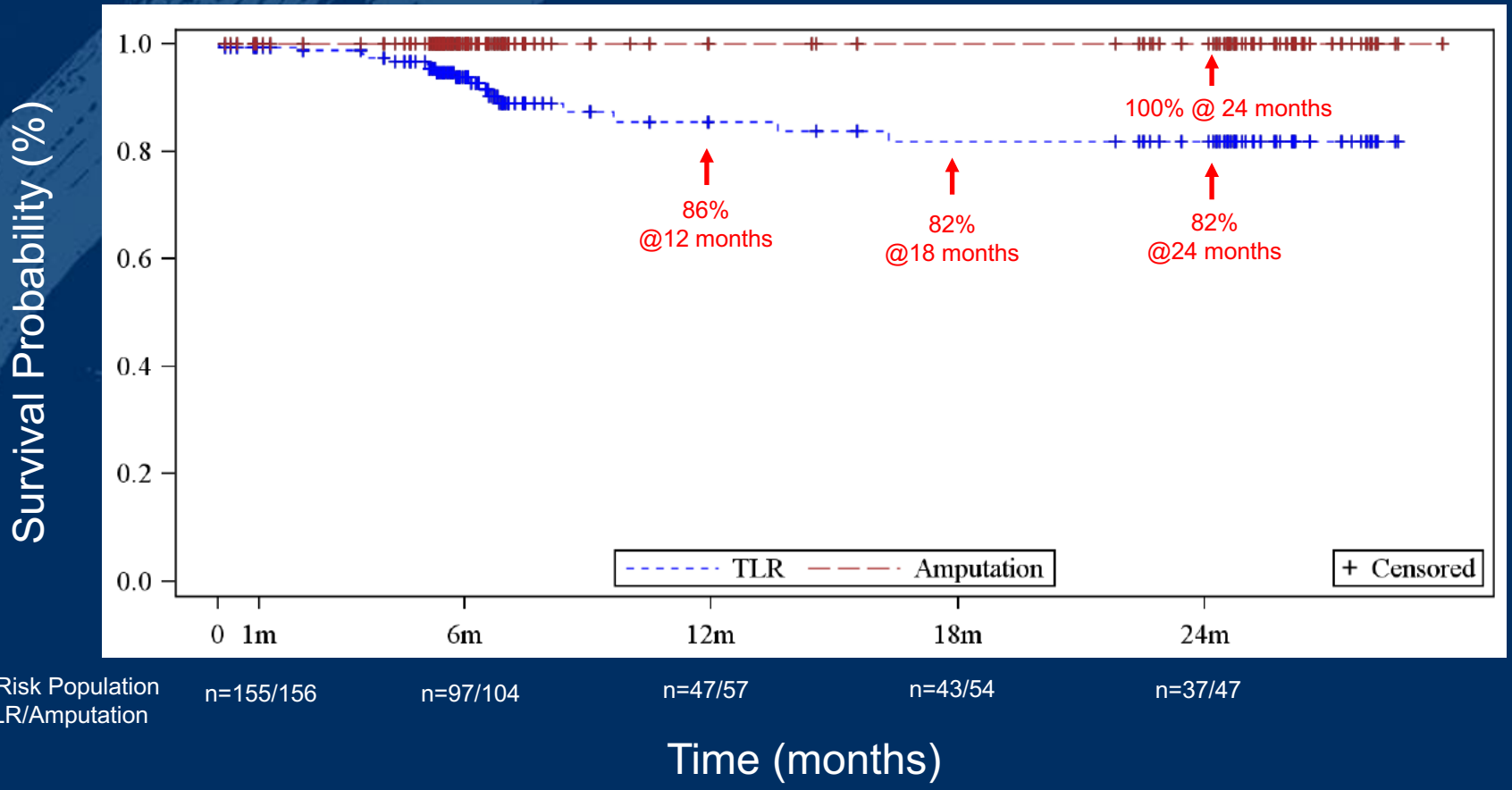
24 Month Outcomes
Freedom from TLR + Amputation by Subject



0% Amputation Rate through 24 months

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24 Month Outcomes
Rutherford Classification

Rutherford Classification	Baseline (n=158)	30 Days (n=144)	6 Months (n=144)	24 Months (n=48)
0 Asymptomatic	0% (0/158)	54.1% (80/148)	41.0% (59/144)	54.2% (26/48)
1 Mild Claudication	0% (0/158)	29.1% (43/148)	30.6% (44/144)	18.8% (9/48)
2 Moderate Claudication	29.1% (46/158)	11.5% (17/148)	13.2% (19/144)	10.4% (5/48)
3 Severe Claudication	54.4% (86/158)	4.7% (7/148)	10.4% (15/144)	8.3% (4/48)
4 Ischemic Rest	13.9% (22/158)	0% (0/148)	2.8% (4/144)	8.3% (4/48)
5 Minor Tissue Loss	2.5% (4/158)	0.7% (1/148)	2.1% (3/144)	0% (0/48)

* P=value is calculated using Bowker's test for matched data.
* Only Rutherford Classification categories that have at least one comparison group with non-zero counts are included in p-value calculation.

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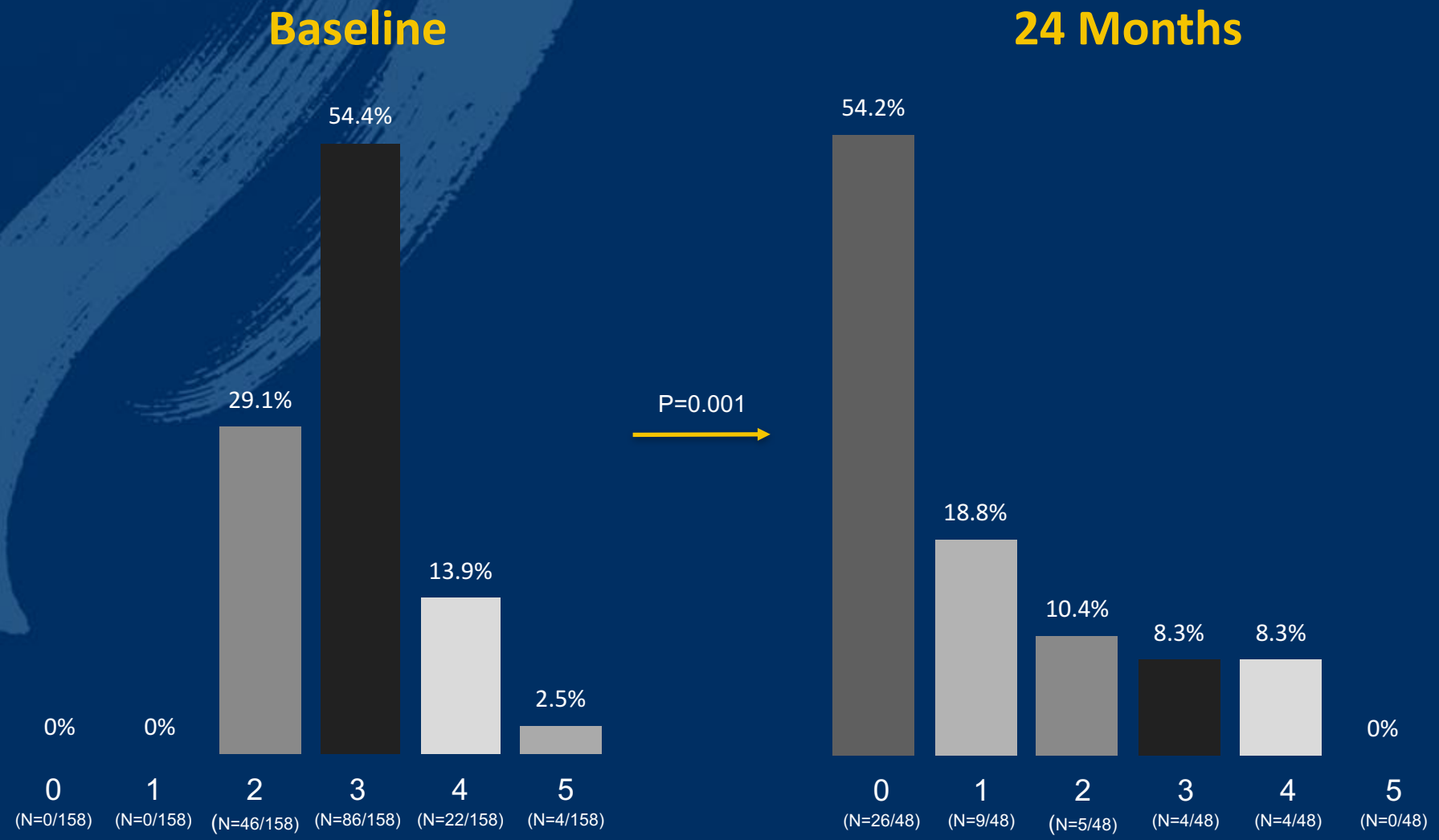
24 Month Outcomes
Rutherford Classification



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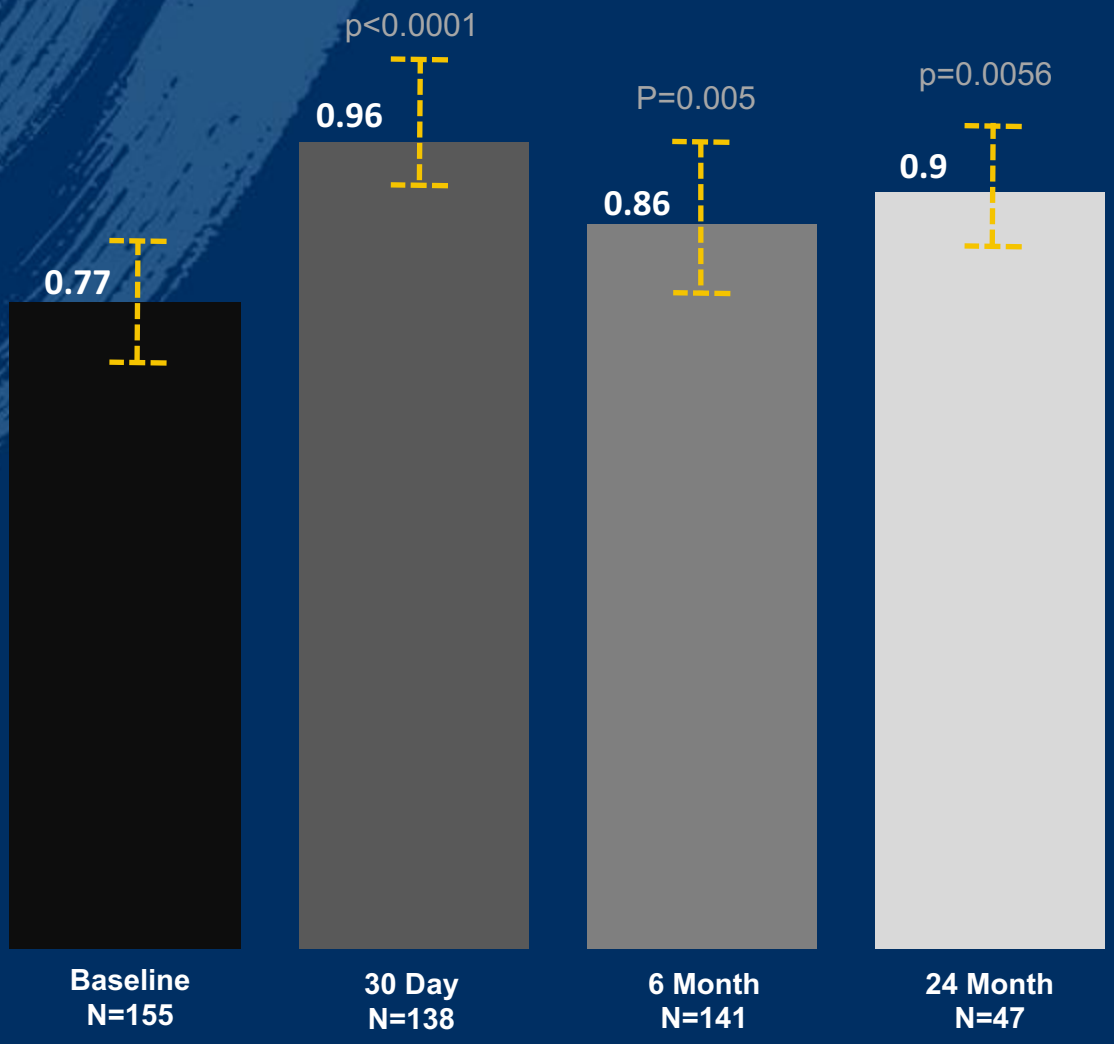
24 Month Outcomes
Ankle Brachial Index (ABI)



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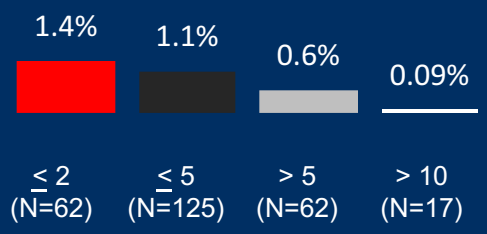
Learning Curve
Outcomes by Physician Case Experience

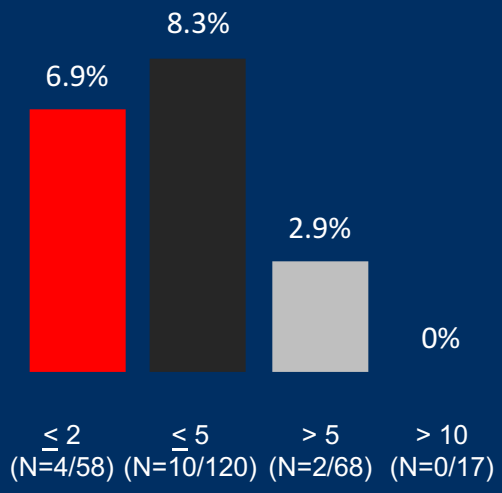
%Adventitia by Area (Atherectomy specimen)

p=0.2397



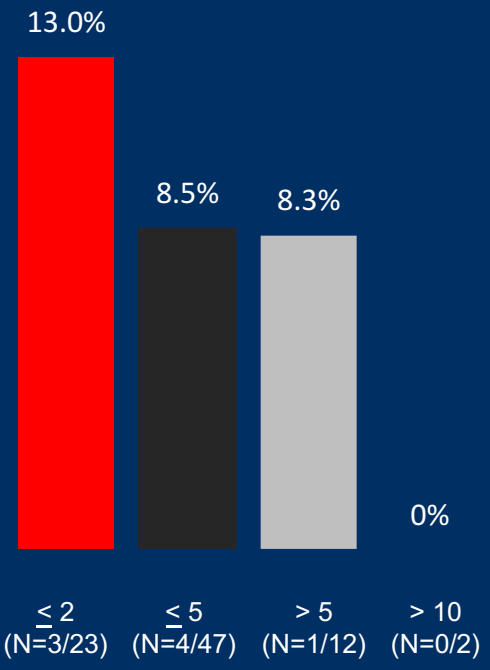
TLR rate @ 6 Months %(m/N)

p=0.2164



TLR rate @ 24 Months %(m/N)

p=1.0000



Physician Cases

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Small learning curve leads to improved patient outcomes

VISION IDE | Conclusion

1) Interim Analysis of VISION Cohort at 24 months

2) TLR rate relatively flat and stable between 12 and 24 months
   - Freedom from TLR: 88% @ 12 months; 85% @ 24 months by lesion at risk
   - Freedom from TLR: 86% @ 12 months; 82% @24 months by subject at risk

3) Zero (0%) amputations through 24 months

4) Statistically significant improvements in ABI and Rutherford at 30 days maintained through 24 months

5) >50% standalone atherectomy rate (n=104/198)
   - Low stent rate: 5.1% (n=10/198)
   - Low adjunctive Drug Coated Balloon (DCB) rate: 9.6% (n=19/198)

6) 5 case learning curve leads to reduction in TLR through 24 months

New Evidence Review for OCT Guided Atherectomy: Long Term Patency, In-Stent Restenosis, and Zero Contrast/Fluoroscopy in CKD Patients

Tom Davis, MD

Presented by: Jihad Mustapha, MD

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Disclosure

Speaker name:

Dr. Tom Davis

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New Evidence Review

- OCT Guided Atherectomy 12 month patency outcomes
- Interim VISION 24 month outcomes data
- ISR Therapy
- Radiation and Contrast Sparing
- OCT Guided Learnings

OCT Guided Directional Atherectomy Case Series (n=30 patients; 35 lesions)

Graz, Austria

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Case Series Breakdown

TOTAL COHORT

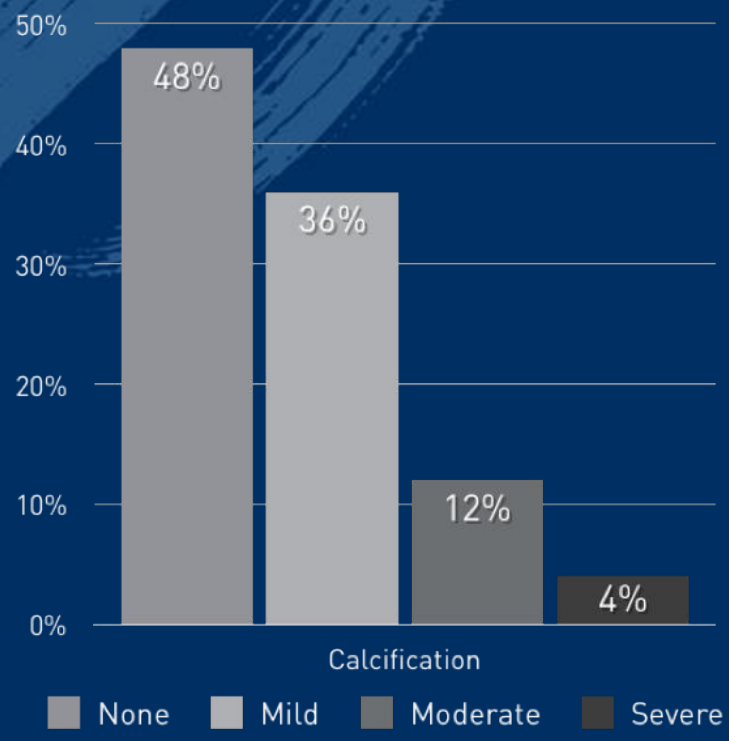
- Patients treated n=30 (35 lesions)
- Treated dates July – December 2015
- Average lesion length 103 mm (20-300mm)

CTO COHORT

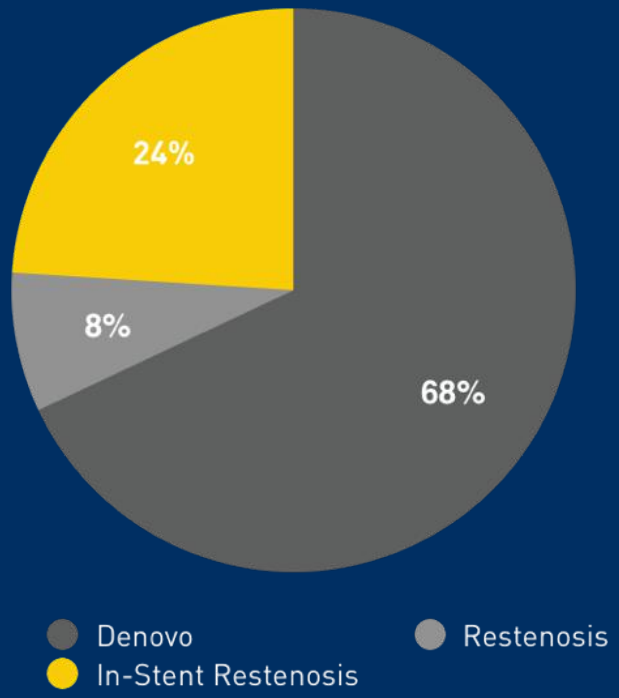
- Patients/lesions treated n=19/21 (63% total patient cohort)
- OCT guided CTO crossing (Ocelot) standalone success (n=20/21 true lumen): 95.2%
- Average CTO lesion length 110mm (40-300mm)

Case Series: Lesion Breakdown

Calcification Grade



Lesion Etiology



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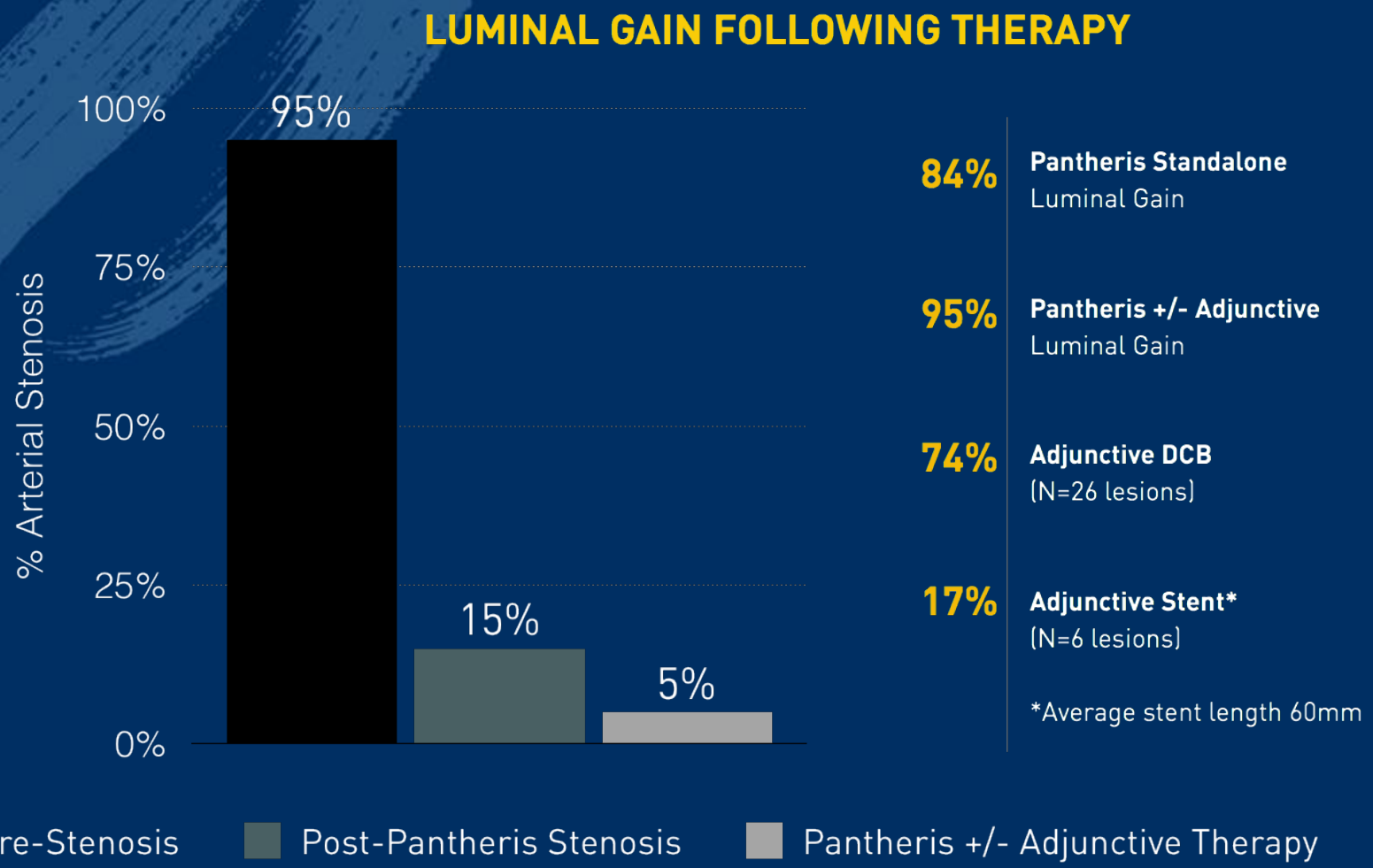
Case Series: Lesion Breakdown
N=30 patients; 35 lesions



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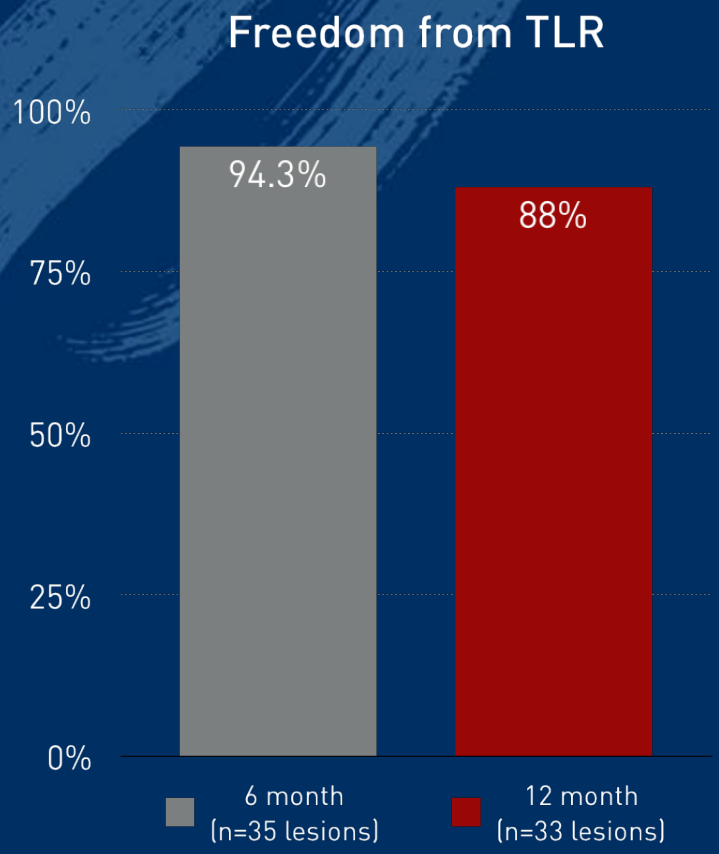
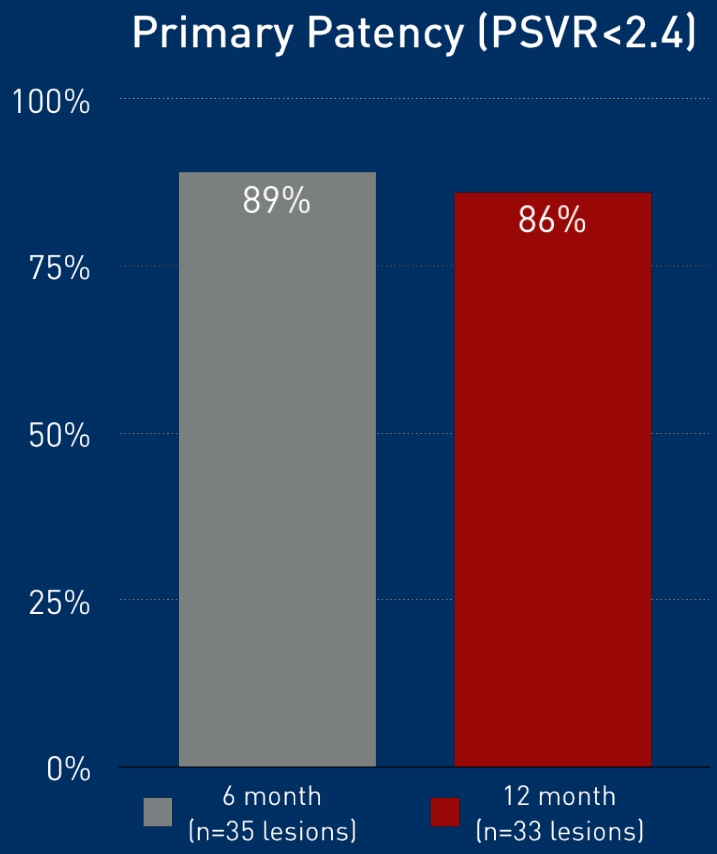
6 vs. 12 Month Outcomes
Duplex PSVR, ABI, TLR





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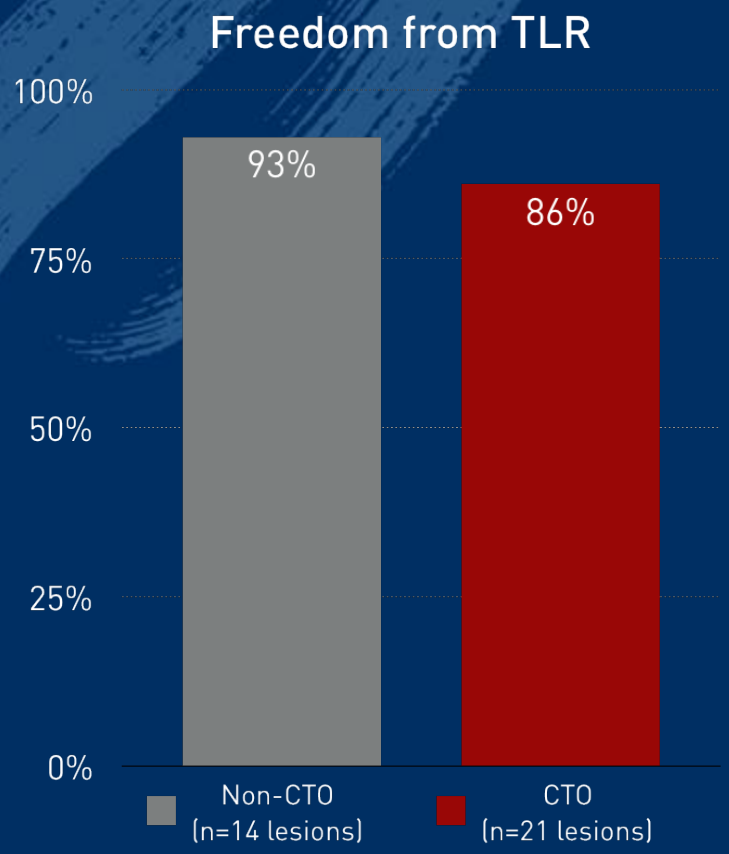
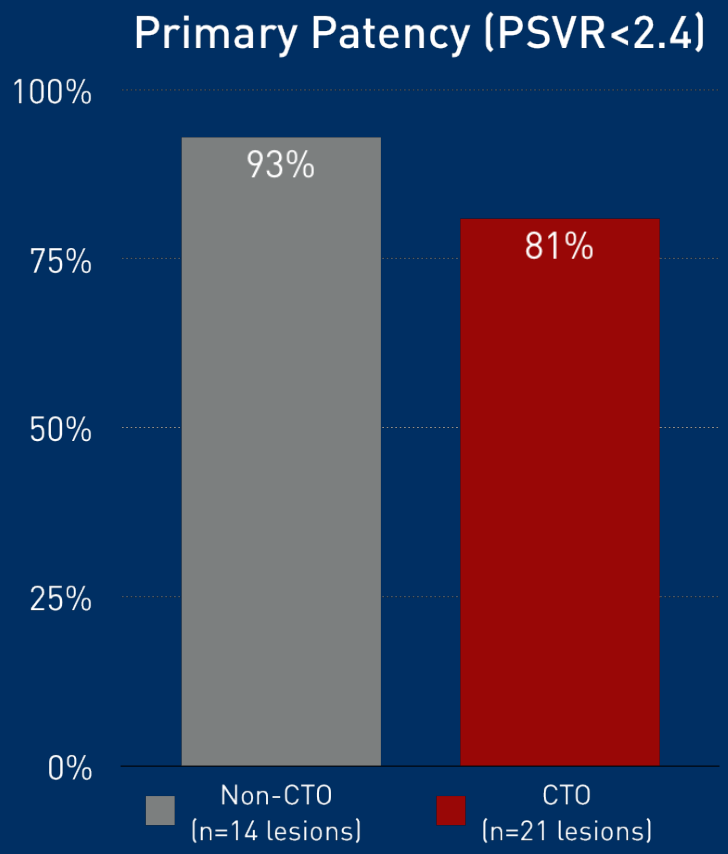
Non-CTO vs. CTO @ 12 Months
TLR, Duplex PSVR





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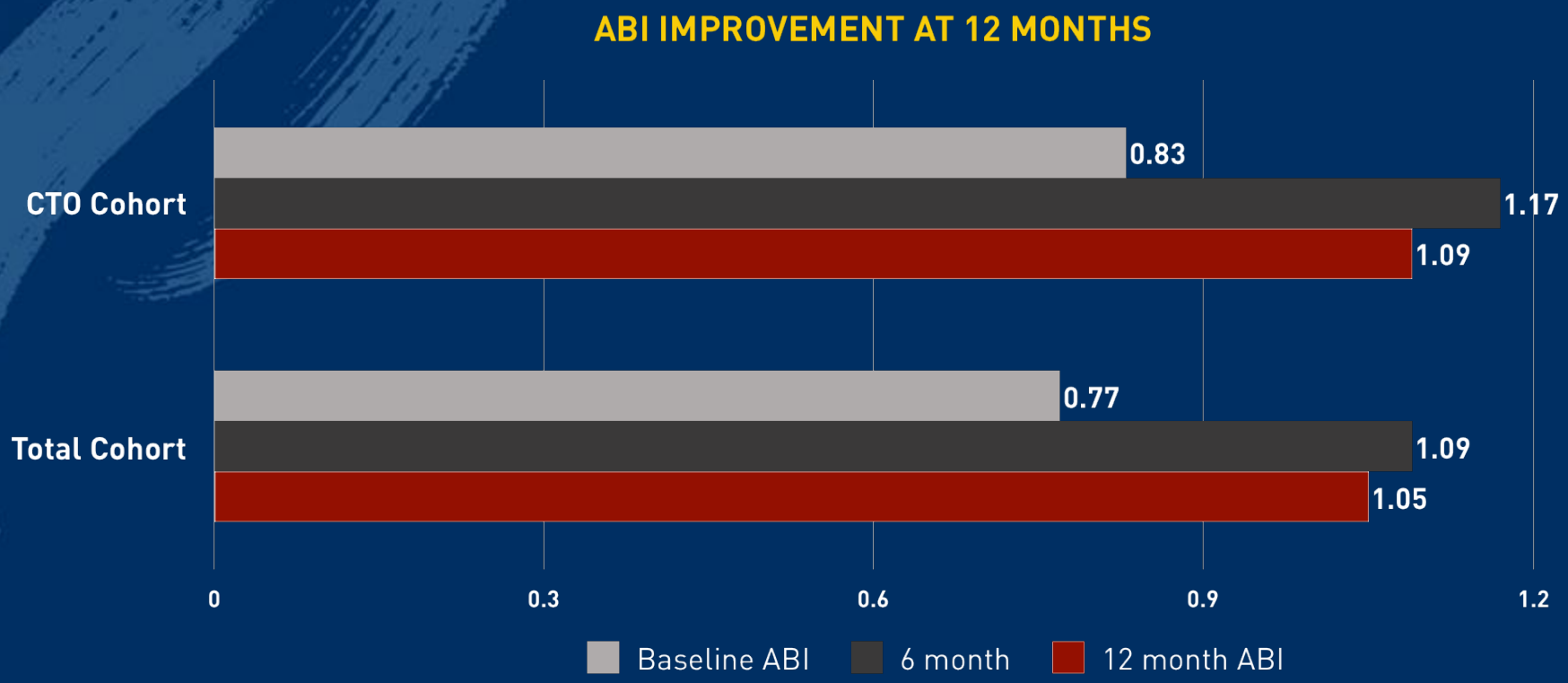
Average Non-CTO lesion length = 72mm
Average CTO lesions length = 110mm

12 Month Outcomes
Duplex PSVR, ABI, TLR



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24 Month Outcomes
Interim Analysis (n=55 patients)

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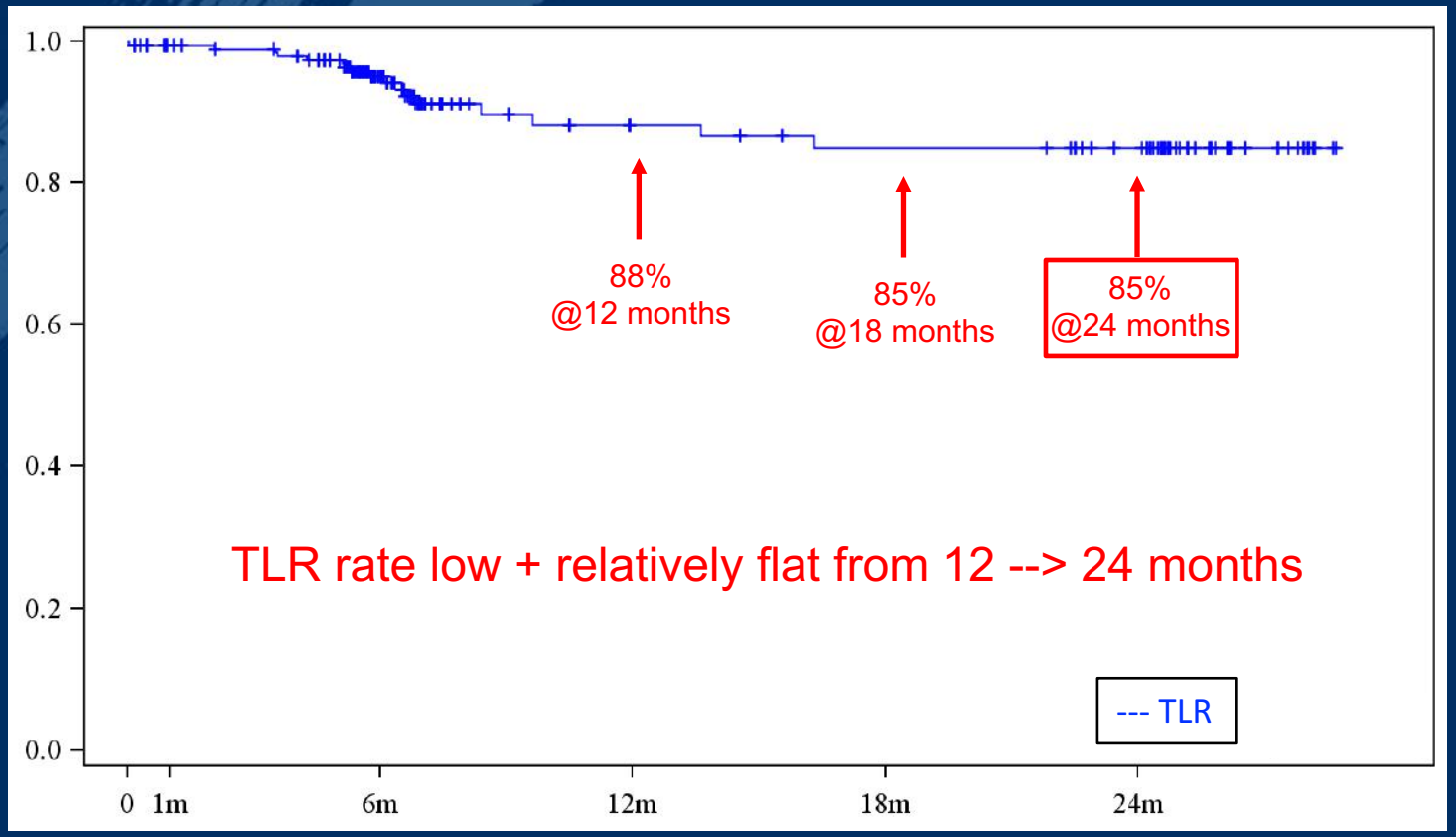
24 Month Outcomes
Freedom from Target Lesion Revascularization (TLR)



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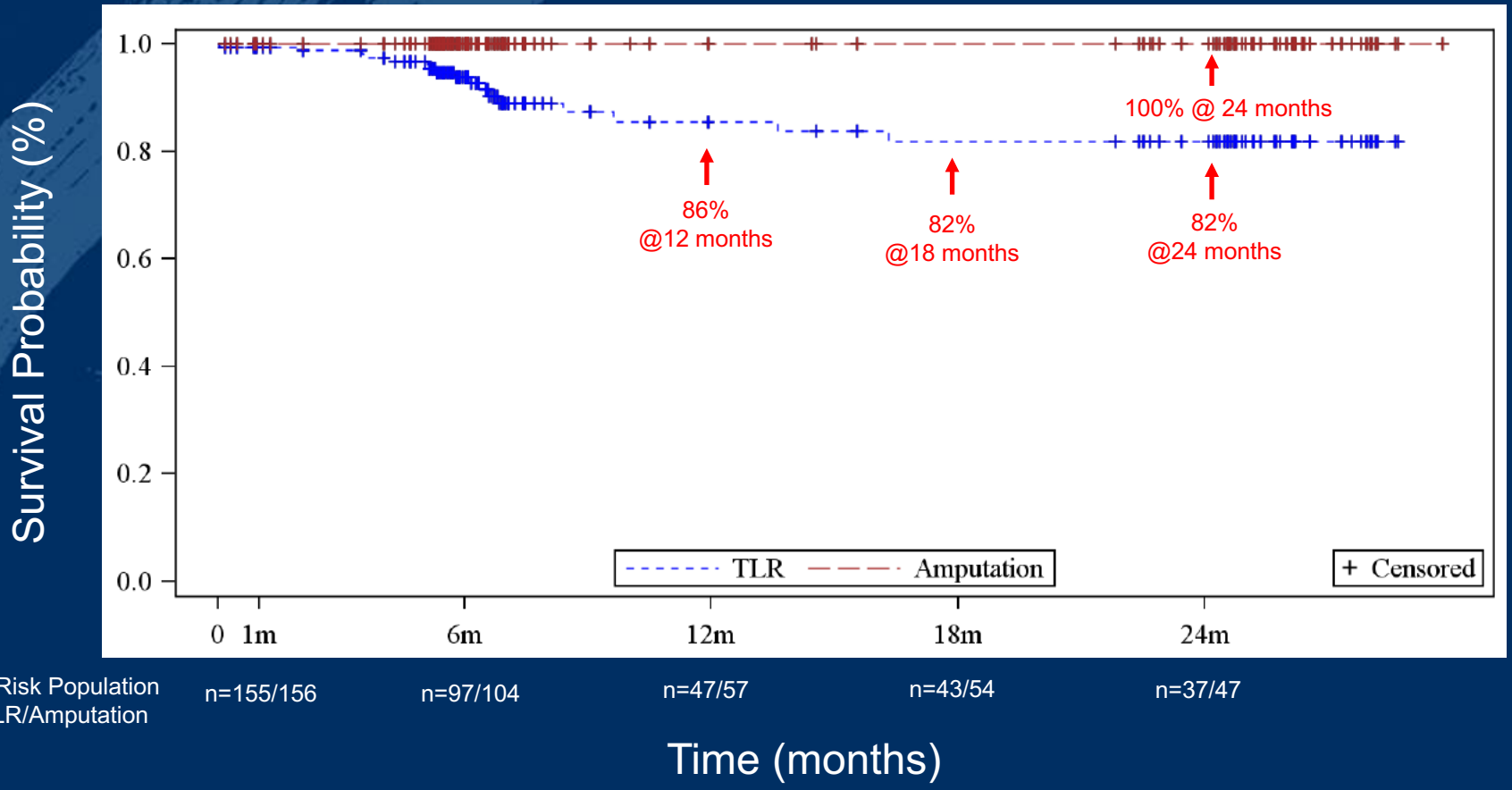
24 Month Outcomes
Freedom from TLR + Amputation by Subject



0% Amputation Rate through 24 months

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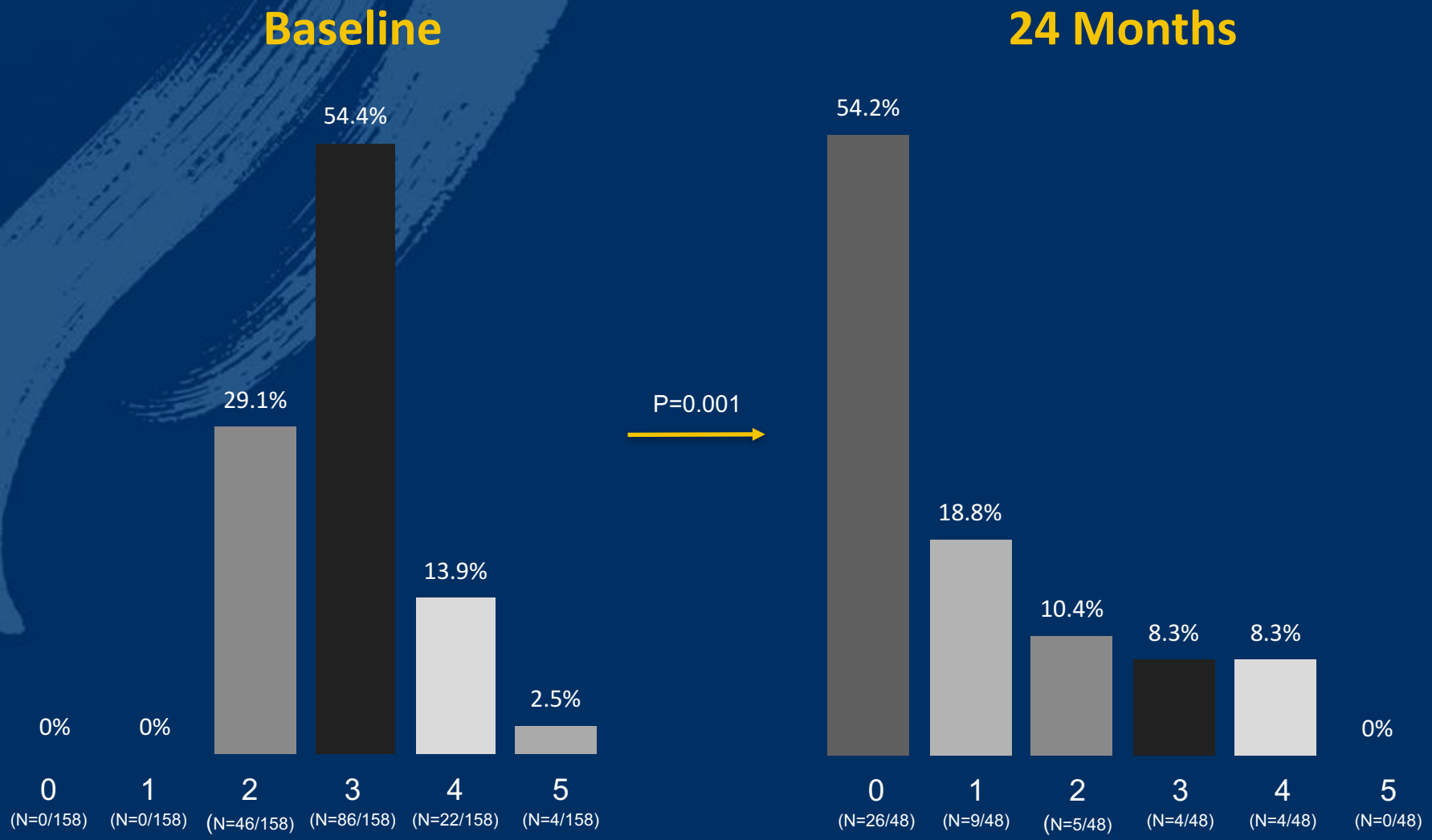
VISION IDE

24 Month Outcomes
Rutherford Classification



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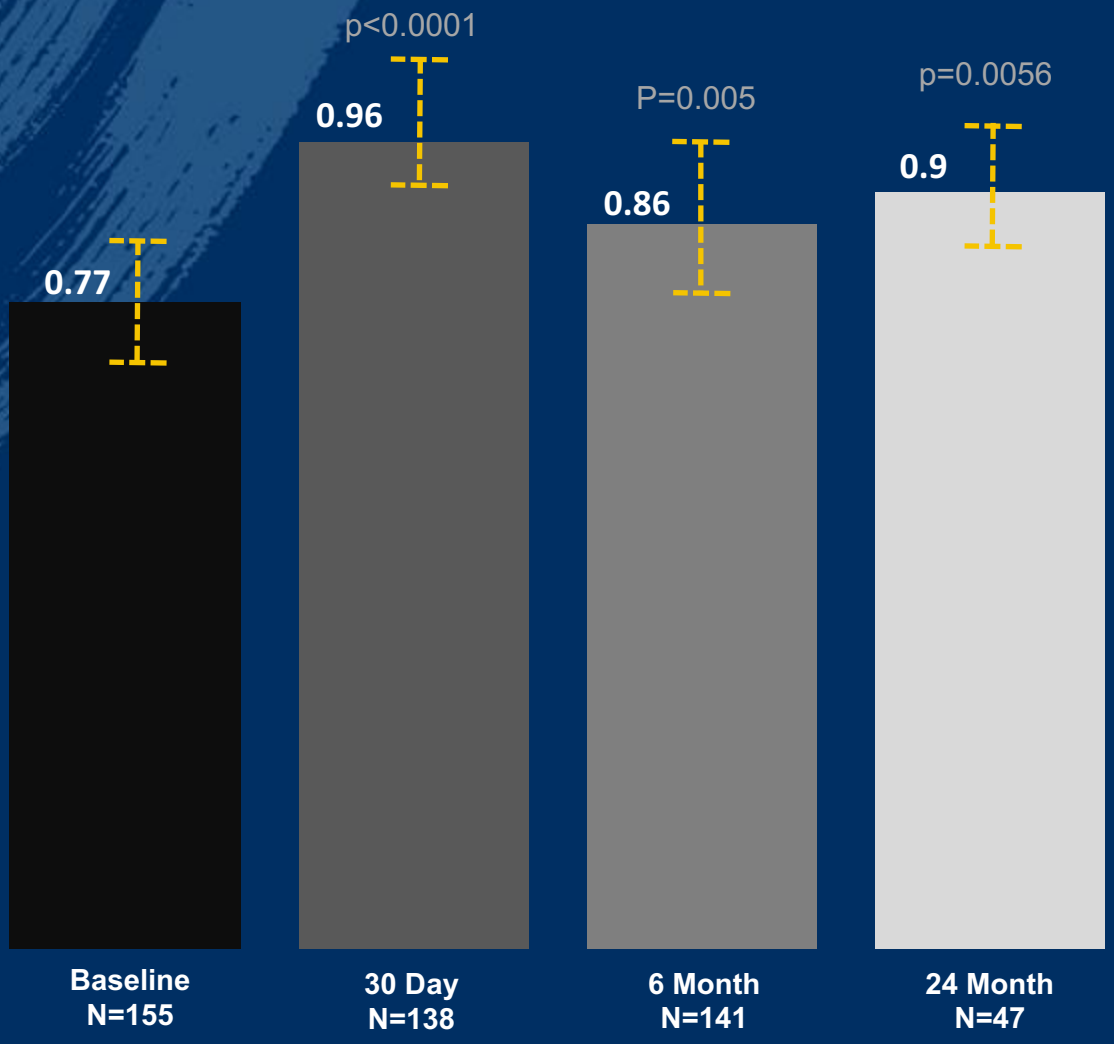
24 Month Outcomes
Ankle Brachial Index (ABI)



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Learning Curve
Outcomes by Physician Case Experience

%Adventitia by Area (Atherectomy specimen)

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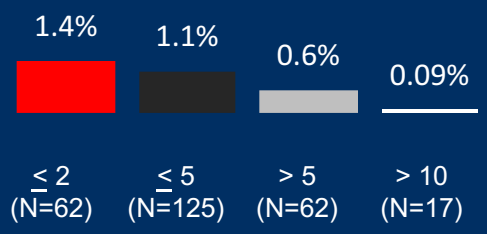
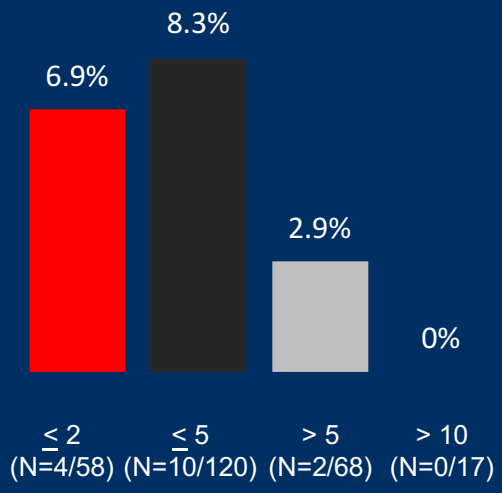


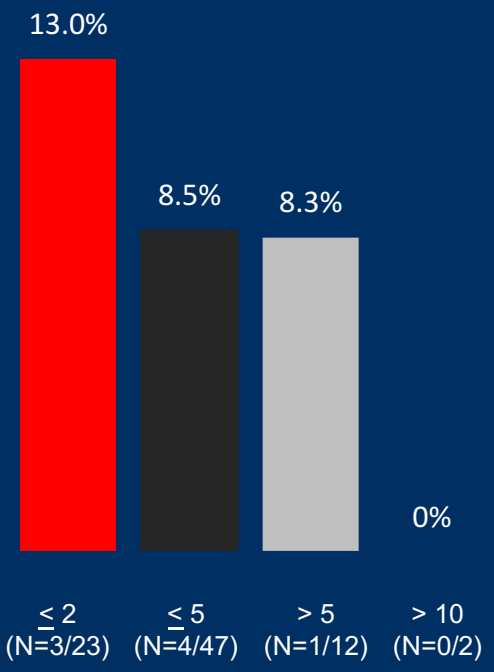
TLR rate @ 6 Months %(m/N)

p=0.2164



TLR rate @ 24 Months %(m/N)

p=1.0000



Physician Cases

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Small learning curve leads to improved patient outcomes

VISION IDE | Conclusion

1) Interim Analysis of VISION Cohort at 24 months

2) TLR rate relatively flat and stable between 12 and 24 months

3) Zero (0%) amputations through 24 months

4) Statistically significant improvements in ABI and Rutherford at 30 days maintained through 24 months

5) >50% standalone atherectomy rate (n=104/198)
   - Low stent rate: 5.1% (n=10/198)
   - Low adjunctive Drug Coated Balloon (DCB) rate: 9.6% (n=19/198)

6) 5 case learning curve leads to reduction in TLR through 24 months

In-Stent Restenosis (ISR)

Design: Retrospective case series

Investigators: 6 institutions US and Europe

Patients: n=21 patients (21 lesions)

Average Lesion Length: 171 mm (20 - 450) (n=18) [1]

Average Stent Length: 148 mm (70 - 200) (n=14) [2]

Acute Primary Efficacy: Post-Pantheris Stenosis < 30% = **100%**

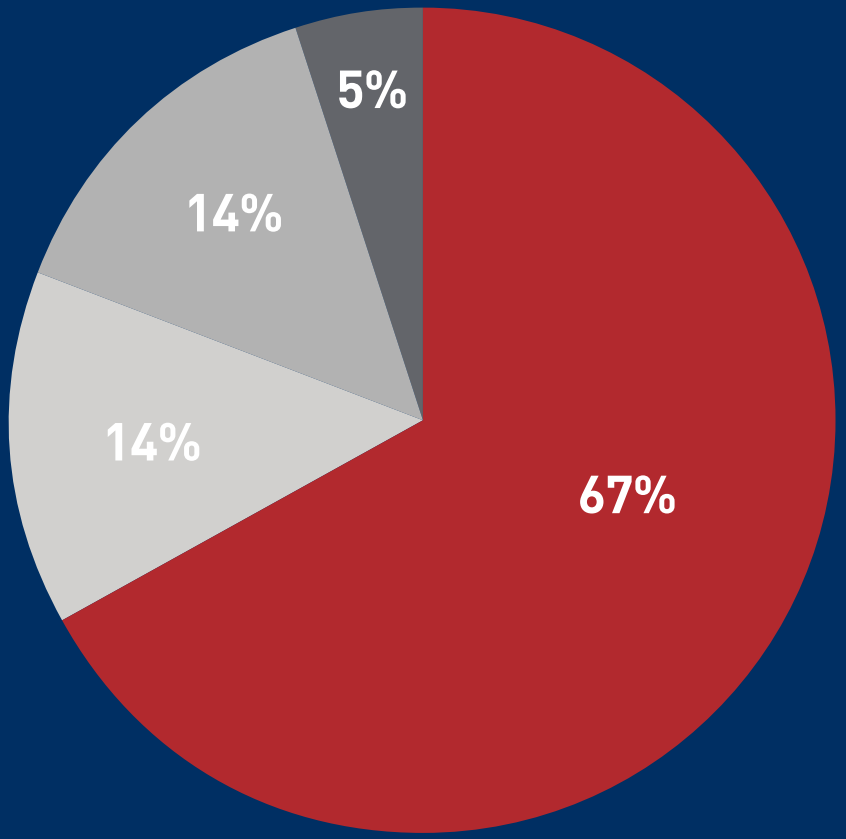
Acute Primary Safety (Emboli, Dissection, Perforation, Device Related events): 0%

1: 3 lesion lengths not measured
2: 7 stent lengths not measured

Lesion Characteristics

LESION LOCATION (N=21)

- SFA
- POPLITEAL
- SFA & POPLITEAL
- SFA & ILLIAC



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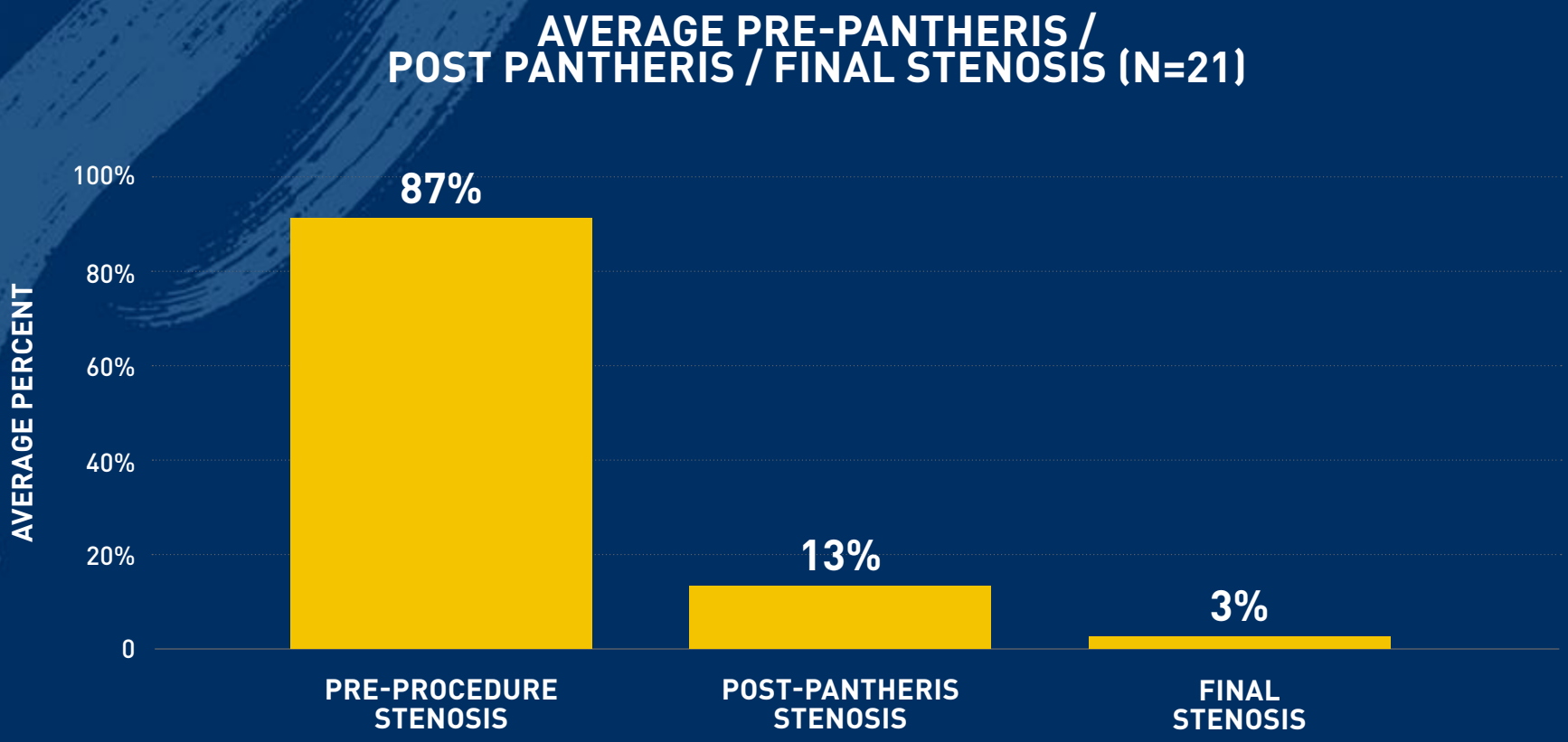
Procedural Characteristics



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Pantheris In-Stent Restenosis (ISR) Global IDE

Catheter

- 9cm nosecone (3cm longer)
- Extended scaffold
- Shaft length markings
- 360 degree nosecone viewing window
- Reinforced proximal catheter and driveshaft

Trial Design

- US + OUS
- 100 patients
- 30 day, 6 month, 12 month ABI, Rutherford, Duplex

Timeline

- Enroll Q2 2017 OUS + US

Radiation & Contrast Sparing

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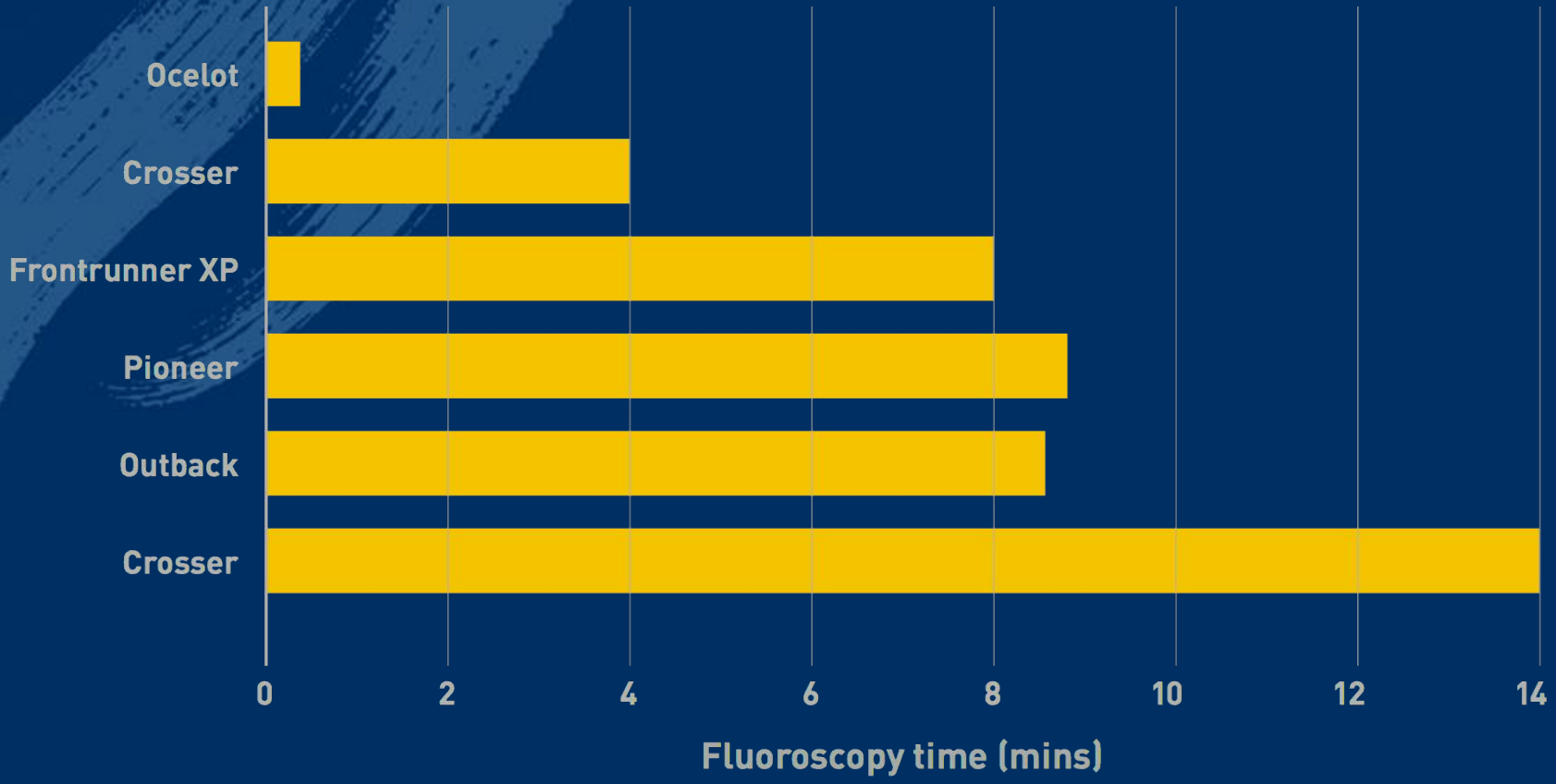
Ocelot Radiation Reduction

≥150mm SFA CTO Peer Reviewed Data

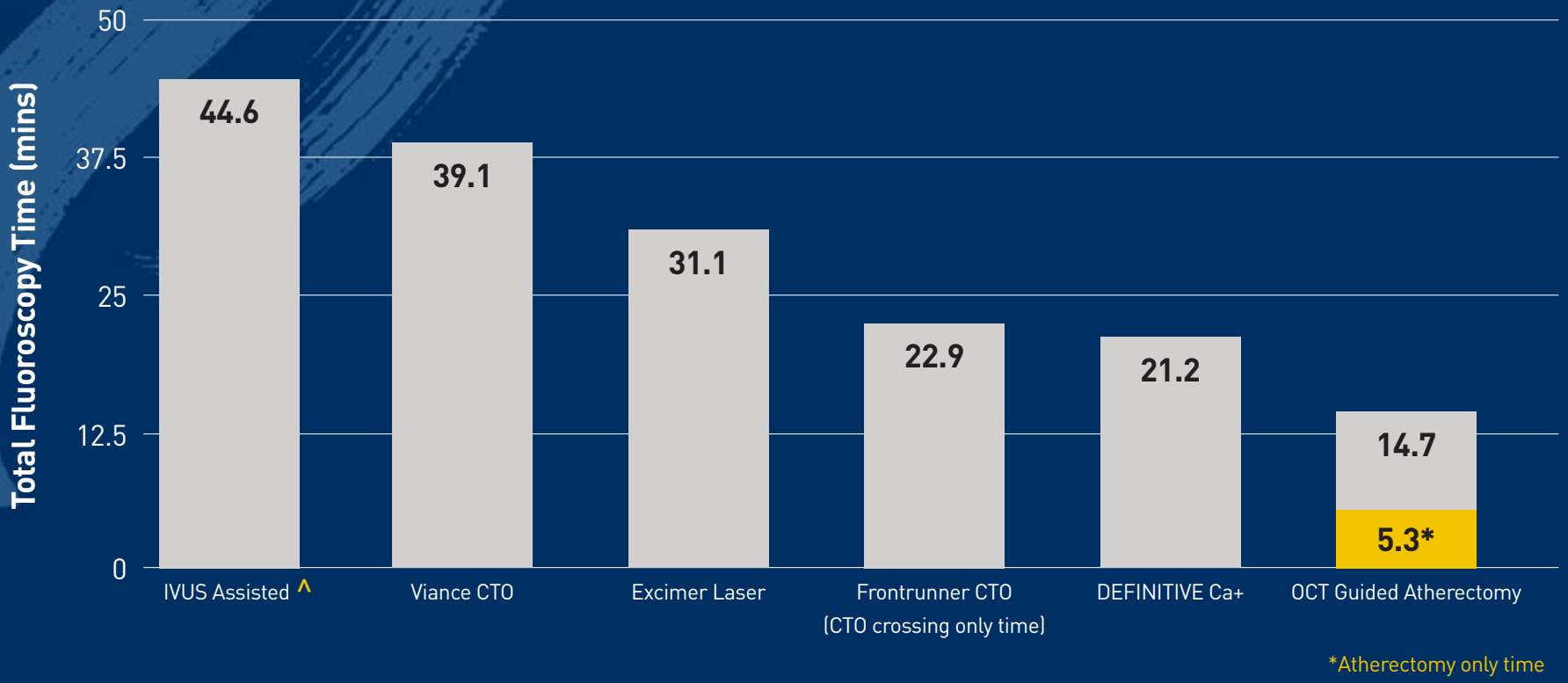


1. Davis, T. Lumivascular approach to crossing chronic total occlusions. JACC. 64:11 Supplement B, pg B157-158
2. D.P. Loomis, D.A. Savitz. Mortality from brain cancer and leukemia among electrical workers. Br J Ind Med, 47 (1990), pp. 633-638
3. J.K. Grayson. Radiation Exposure, socioeconomic status and brain tumor risk in the US Air Force: a nested case-control study. Am J Epidemiol, 143 (1996), pp. 480-486
4. M. Blether, B. Schlehofer, F. Samkange0Zeeb, G. Berg, K. Schaefer, J. Schuz Medical exposure to ionizing radiation and the risk of brain tumours: Interphone study group, Germany Eur J Cancer, 43 (2007), pp. 1990-1998

Pantheris Radiation: LE Revascularization

Total Fluoroscopy Time

(Published Peer Reviewed Data)



*Atherectomy only time

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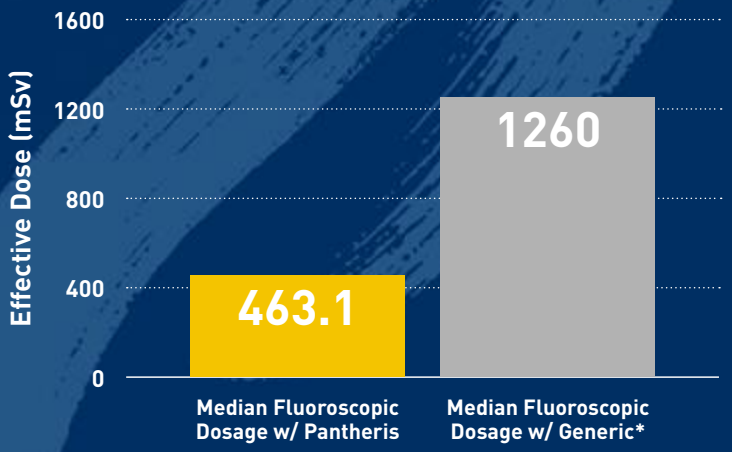
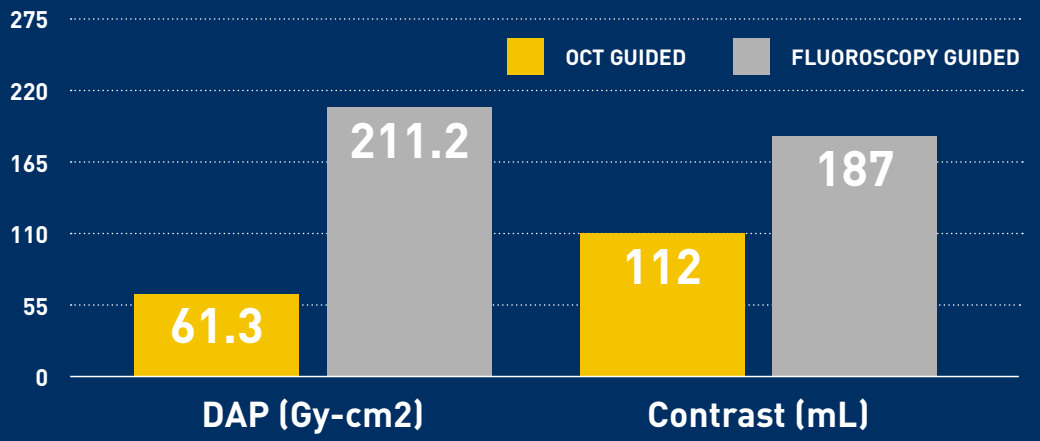
^IVUS creates larger radiation burden secondary to independent catheter placement pre/post therapy

OCT Guided Atherectomy Radiation Reduction

Fluoroscopic Exposure (mSv)



DAP (Gy-cm2) and Contrast



OCT-guided atherectomy:

71% reduction in DAP vs. Fluoroscopy

41% reduction in contrast vs. Fluoroscopy

Summary

- Between March 2016 and June 2016, 38 lesions using OCT-guidance directional atherectomy were treated with the Pantheris Catheter
- Results demonstrated a significant 63% reduction in median fluoroscopic exposure across all procedures completed using OCT guidance ($p<0.05$)

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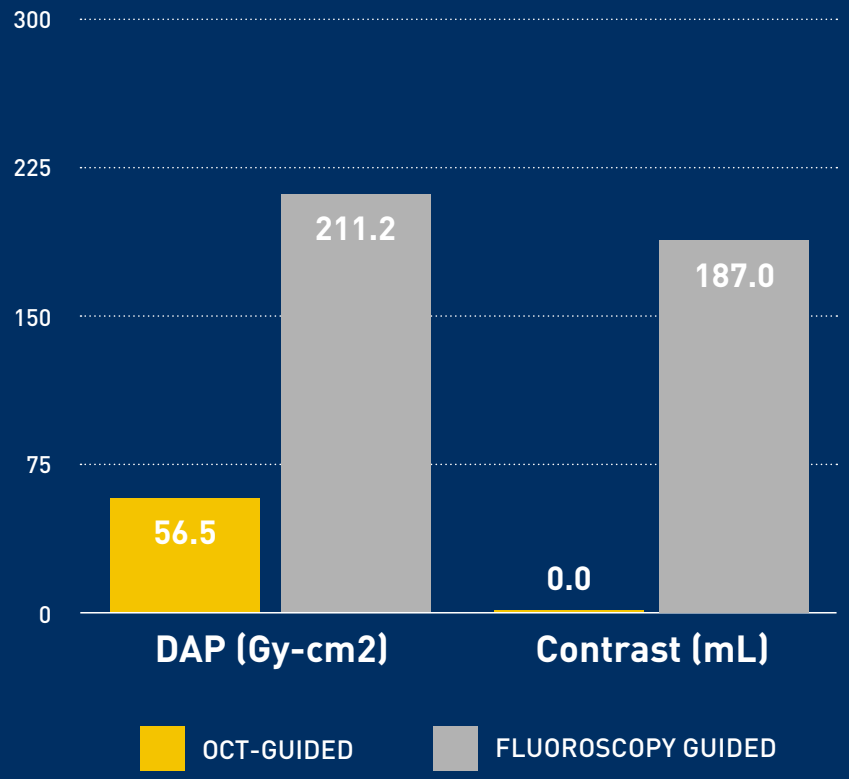
Ocelot + Pantheris with CO2 Angiography for Patients with ESRD

Lumivascular
280mm SFA CTO

1) Constrast = 0mL
2) Total Radiation = 0.3 Gy
2) DAP = 56.5 Gy-cm2

Endovascular[1]
Average 140mm SFA CTO

1) Constrast = 187.8 +/- 72mL
2) Radiation = 39.1 +/- 21.2 min
2) DAP = 210 +/- 212 Gy-cm2



1) J. Invasive Cardiol. 2014 Aug;26(8):363-9

OCT Learnings

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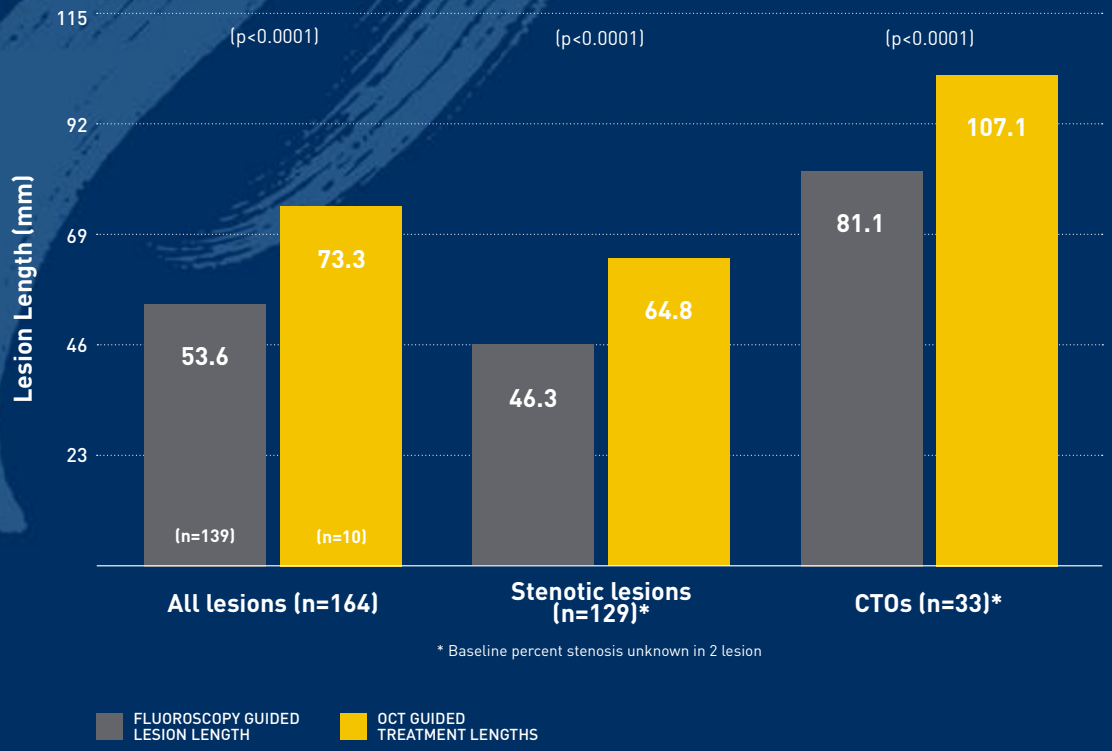
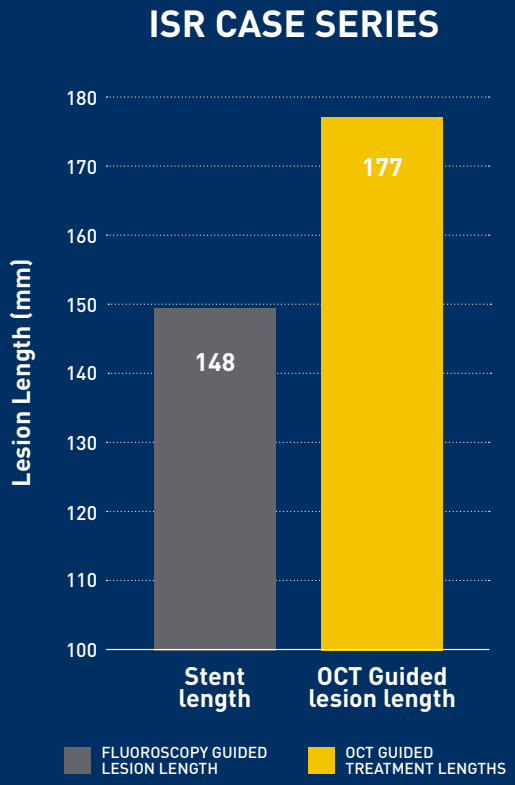
OCT Guided Treatment Length

Longer than Fluoroscopic-Guided Lesion Length (Per Protocol Cohort)





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Conclusion

1) 12 and 24 month outcomes data demonstrate favorable patency and sustained low TLR rates out to 2 years
2) Acute ISR data demonstrates superior efficacy profile – global IDE pending
3) OCT may be used to eliminate or greatly diminish contrast and radiation across all LE revascularizations
4) OCT guided therapy learning curve approx. 5 cases for improved outcomes
5) OCT highlights longer disease burden vs. angiographic interpretation