

INDICATIONS AND LESION SELECTION FOR FEMORAL- POPLITEAL ATHERECTOMY

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I have the following potential conflicts of interest to report:

Compensated Board Member – VIVA Physicians Inc.

Compensated Consultant – Medtronic, Abbott Vascular, Boston Scientific, Phillips, CSI, Cook, Intact Vascular, Angiodynamics, Vesper

Non-compensated Investigator – Pluristem, Intact, Bard, Medtronic, Boston Scientific, Surmodics, Micromedical

Equity – Eximo

- **Changing treatment landscape**
 - Desire to avoid slotted nitinol stents
 - Theoretical rationale of debulking
 - Facilitate intervention
 - Reduce dissections
 - “Vessel prep” to optimize drug delivery
- **Challenging lesions**
 - Long calcified stenoses/occlusions
 - Restenosis
- **Favorable reimbursement**

DEVICE	TRIAL
Turbo Elite Laser (Spectranetics)	LACI, EXCITE ISR
Auryon Laser (Angiodynamics)	Eximo B-Laser IDE
Turbohawk (Medtronic/Covidien)	DEFINITIVE
Diamondback 360 (CSI)	COMPLIANCE/CALCIUM/ CONFIRM/LIBERTY
Pathway (Boston Scientific)	PATHWAY PVD
Phoenix (Phillips)	NA (IDE Registry)
Pantheris (Avinger)	Vision



40%
One yr
patency

54%
One yr
patency

EXCITE ISR

PATENT

CELLO

All FP
5.6m

- 90 ISR patients
- 12 cm lesions
- 87.8% freedom from TLR at 6m

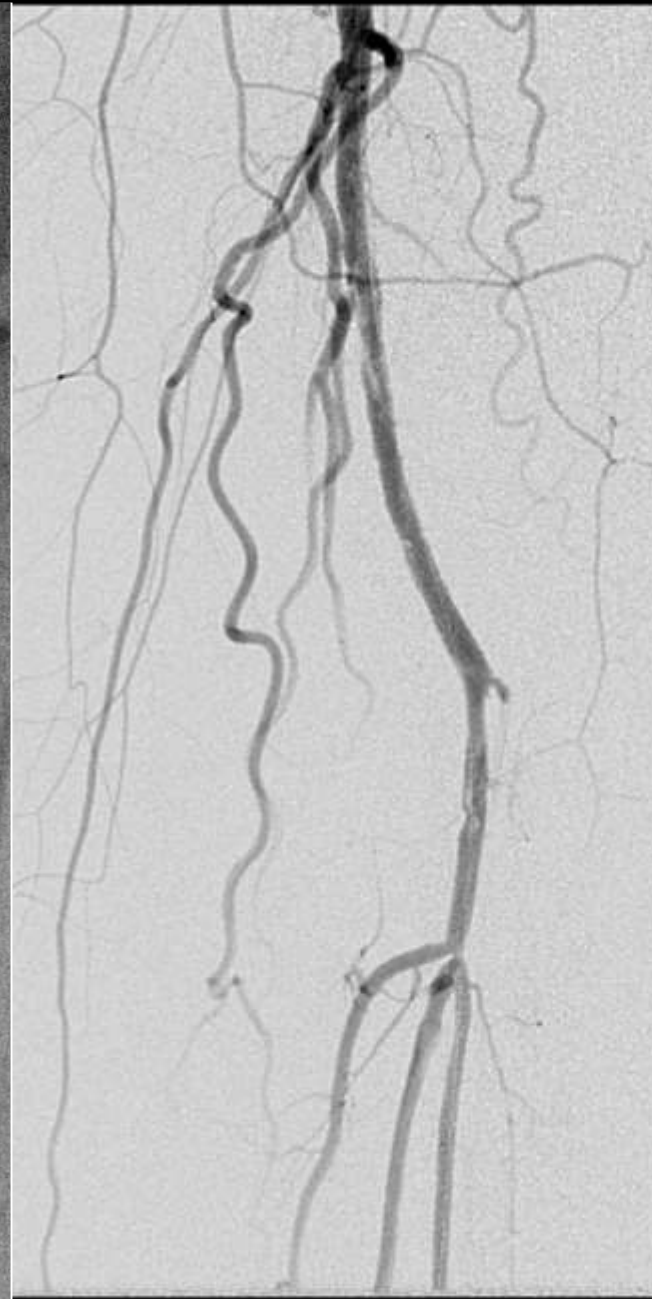
- Randomized 250 patients
- 19 cm lesions
- Significant advantage of laser vs. PTA

LACI

- 3 prospective/ retrospective international studies
- 229 CLI patients w/ multi level disease
- 90.5%-93% limb salvage at 6 months

- DSMB and independent data review
- 98.5% procedural success
- 77% freedom from TLR at 6m

23.1%
one yr
TLR



Non-calcified fibrotic lesions
Long lesions

Embolic concern

Restenosis + adjunctive therapy

Acute on chronic presentation

- 355 nm 20 nsec pulsed laser
- Small footprint, easy to use
- Indifferent to calcium
- Indifferent to tissue type
- Indifferent to adjunctive Rx ?



Below the Ankle/Tibials



Tibials/Popliteal/SFA



ASPIRATING
Tibials/Popliteal/SFA



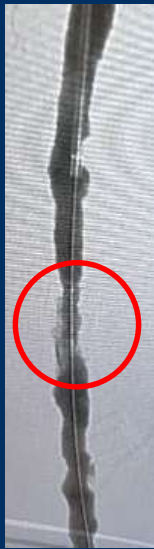
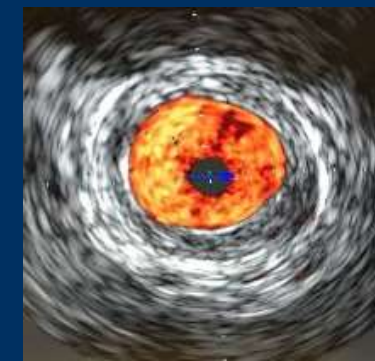
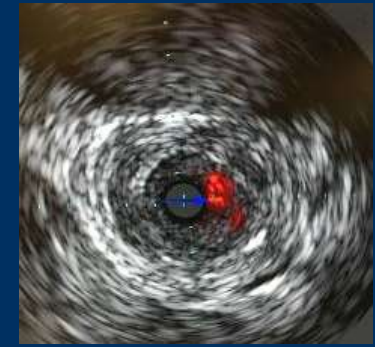
ASPIRATING
Off-centering
Popliteal/SFA

Case Examples

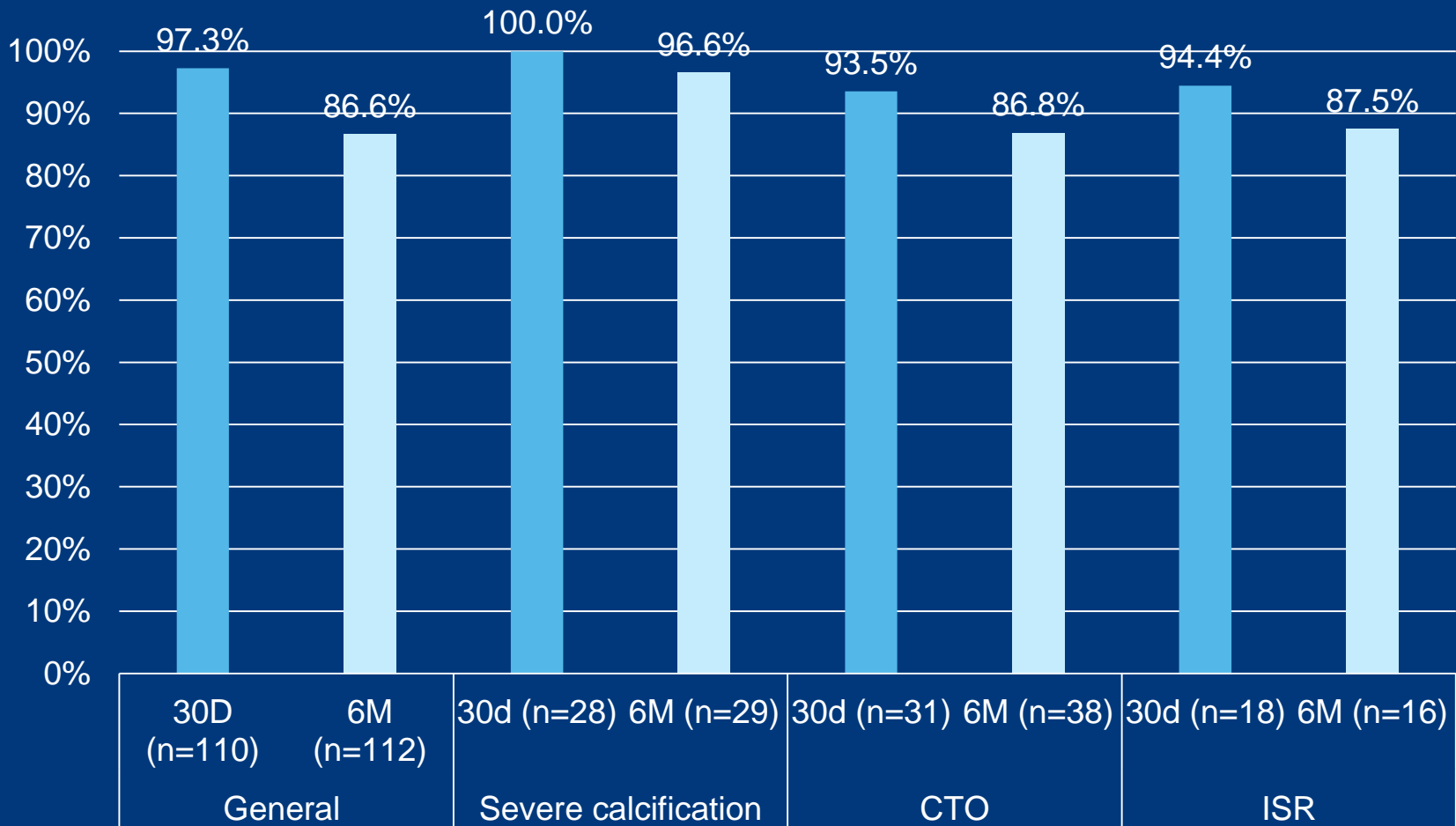
Before

After B-Laser™

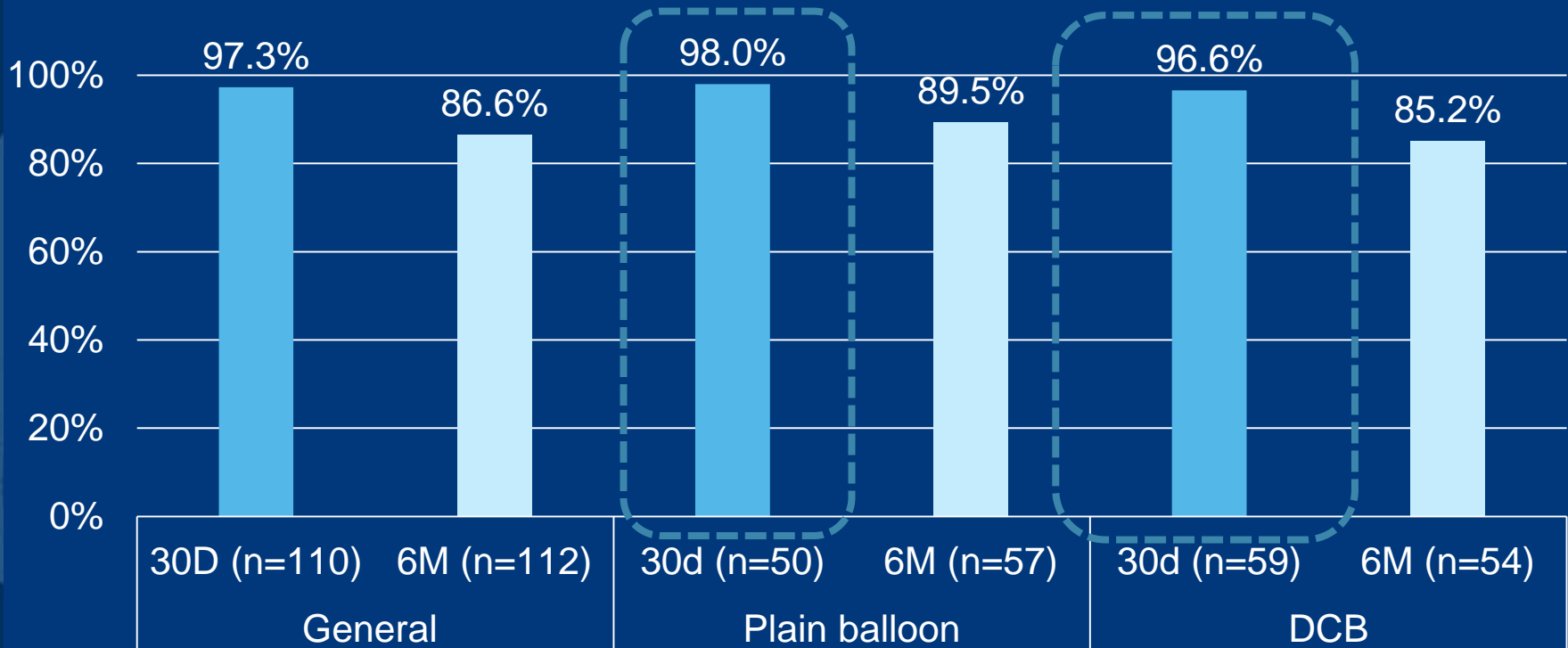
After B-Laser™ + Balloon



Patency rate by lesion type (both studies)



Patency rate by balloon type (both studies)



- With or without stenting
- Lesions treated with both POBA and DCB, were counted as DCB, were compared to lesions treated with POBA alone.
- One patient did not receive balloon angioplasty

Mild-moderate Ca⁺⁺

Unable to use protection
Acute presentation

Restenosis

WANT TO AVOID PTX 1st LINE?

ASPIRATION
FEATURE

Definitive LE

Claudicant Cohort 12-mth results

SILVERHAWK

(severe calcification excluded)

743

Lesions

87% femoropopliteal

7.5 cm

Mean lesion length

72.7%

Mean baseline stenosis

Bail-out
stent 3%

PSVR \leq 3.5



82%

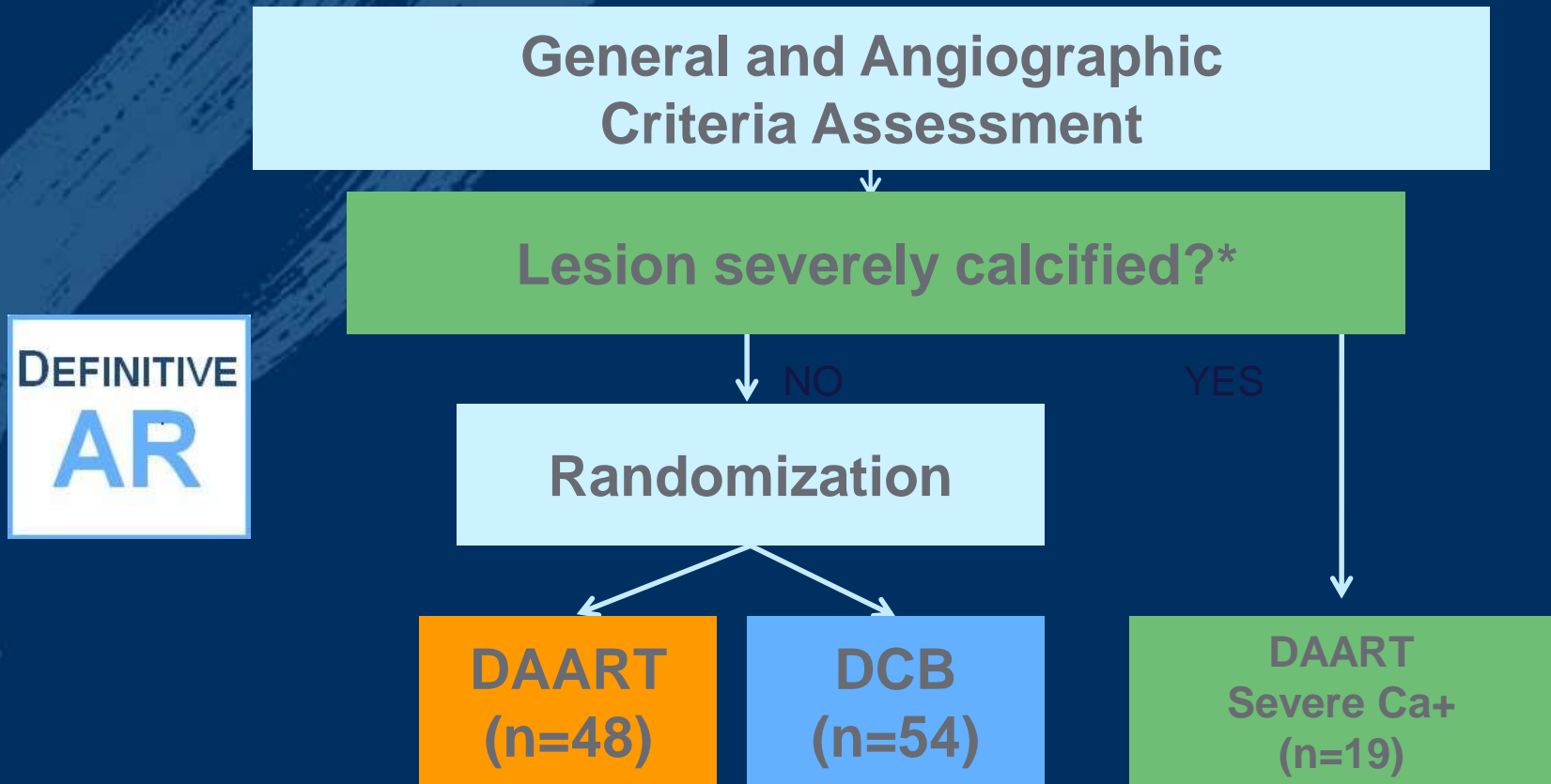
PSVR \leq 2.4



78%

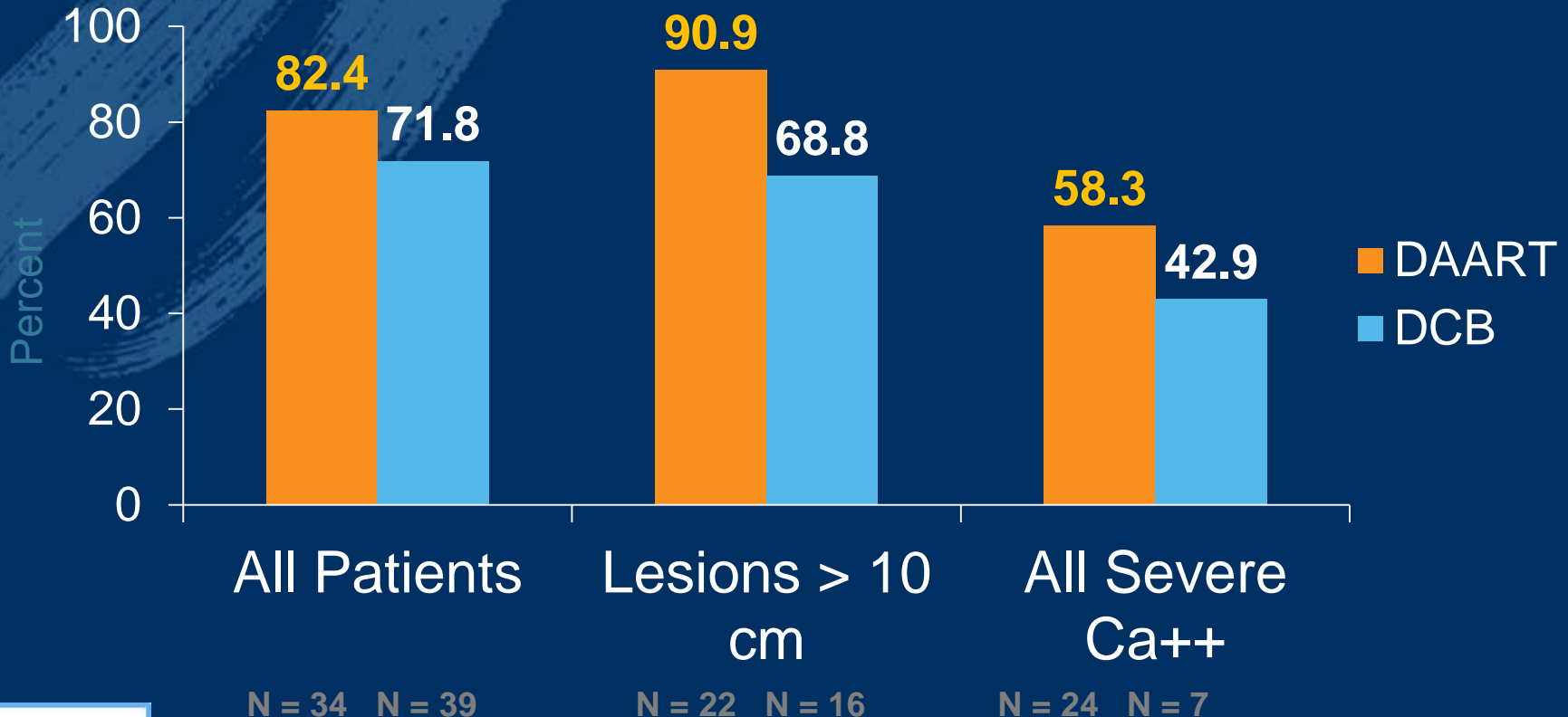


	Patency (PSVR \leq 2.4)	Lesion Length (cm)
All Claudicants (n= 743)	78%	7.5
Lesion type		
Stenoses (n=611 lesions)	81%	6.7
Occlusions (n=128 lesions)	64%	11.1
<10 cm	82%	
\geq 10cm	67%	(14.4 cm)
Embolization		3.8%
Flow limiting dissection		2.3%
Perforation		5.3%



*Defined as: dense circumferential calcification extending > 5 cm

ANGIOGRAPHIC DATA SHOWS SIMILAR PATTERN



DEFINITIVE
AR

Mild-no Ca⁺⁺

WANT MAXIMAL DEBULKING

WITH DCB ON CALCIFIED
OCCLUSIONS

Eccentric lesions

JETSTREAM / PATHWAY



Pathway
PVD trial

n=172

Calcium
included

ATK 64%
POP 28%
BTK 9%;
Mean LL: 27.4±23.9

99% device success
99% freedom from MAE at 30 days

**TLR rates 15% (6mo)
26% (12mo)
38.2% 1-year restenosis**

Procedure related AEs in 22% of patients [1% abrupt closures, 9% dissections, 10% embolizations, 2% perforations]

Mild-moderate Ca^{++}

Possible acute on chronic

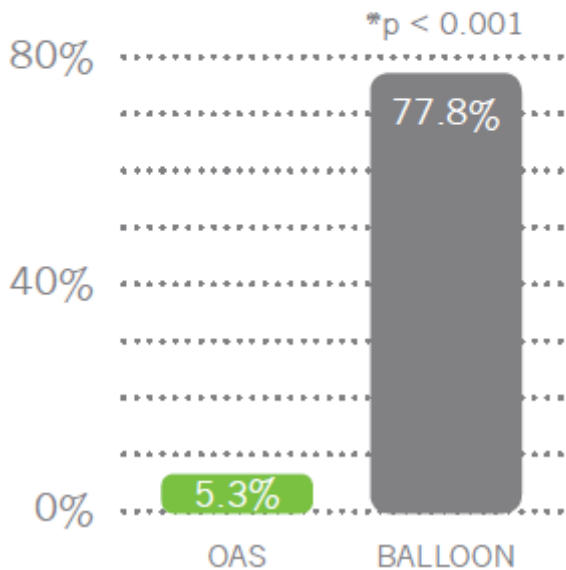
Want aspiration feature

Compliance 360

DIAMONDBACK

Bail-out Stenting

% Lesions Requiring Bail-out Stents*



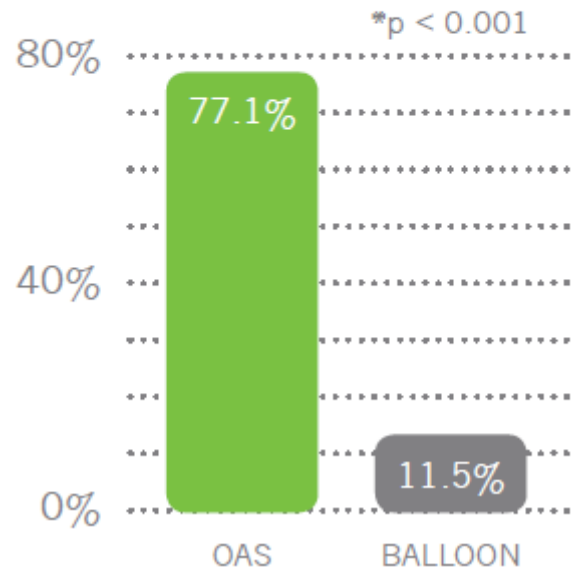
- 50 pts, 65 lesions
- 72% diabetic
- 77% mod-severe Ca++

12 mth freedom from TLR or restenosis:

OA – 81.2%
PTA – 78.3%

Primary Endpoint Met at 6 months

Freedom From Bail-out Stent Placement, TLR or Restenosis*





CONFIRM 360° Study



Catheterization and Cardiovascular Interventions

Short Title: Orbital Atherectomy in the CONFIRM Series

Technique Optimization of Orbital Atherectomy in Calcified Peripheral Lesions of the Lower Extremities: The CONFIRM Series, A Prospective Multicenter Registry

Tony Das, M.D.^{1*}, Jihad Mustapha, M.D.², Jeffrey Indes, M.D.³, Robert Vorhies, M.D.⁴, Robert Beasley, M.D.⁵, Nilesh Doshi, M.D.⁶, and George L. Adams, M.D., MHS⁷

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Tony Das, M.D.

Lesion Location

84% of lesions BTK with moderate/severe calcium

85% utilized smallest crown sizes (1.25 mm, 1.50 mm)

- Post OAS residual stenosis $33 \pm 20\%$
- Final residual stenosis $10 \pm 11\%$

ORBITAL



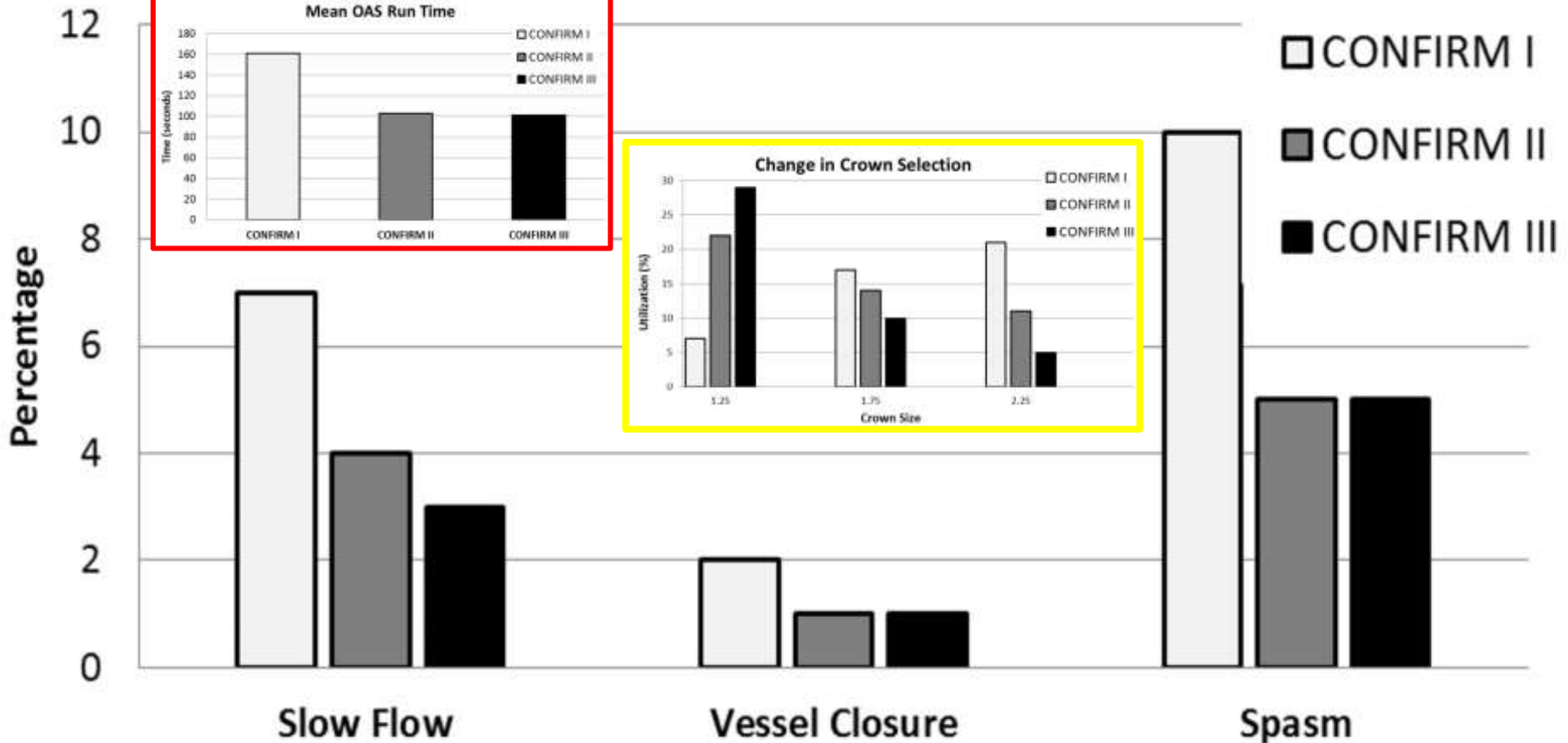
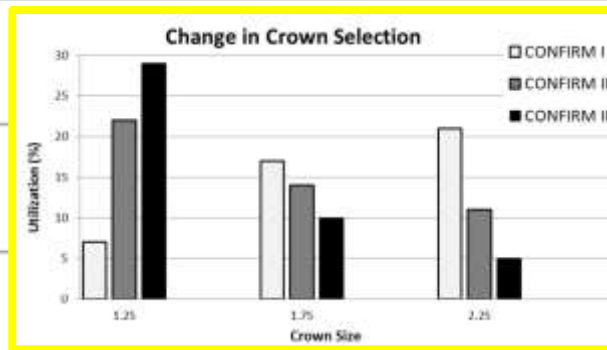
	Lesion Characteristics			P-value		
	ATK(n=2213)	BTK(n=1708)	POP (n=786)	A vs B	A vs P	B vs P
Moderate/Severe Ca ²⁺ (%)	82	84	83	0.24	0.42	0.92
Mean Lesion Length (mm)	77.1 ± 77.3	74.3 ± 72.0	53.6 ± 47.8	0.24	<0.001	<0.001
% Stenosis (Pre-)	87 ± 12	90 ± 12	87 ± 13	< 0.001	0.43	< 0.001
% Stenosis (Post-)	37 ± 19	33 ± 20	36 ± 19	< 0.001	0.29	< 0.001
% Stenosis (Final)	11 ± 11	10 ± 11	11 ± 11	< 0.001	0.61	0.04
Max. Balloon Pressure (atm)	5.8 ± 3.0	5.5 ± 2.8	5.5 ± 2.9	< 0.001	0.04	0.55

Reduction in plaque burden:

Plaque Morphology	N	Mean	SD	P-value
Severe Calcium	1966	54%	21%	<0.001
Moderate Calcium	1690	52%	20%	
Mild Calcium	430	50%	21%	
Minimal Calcium	121	45%	20%	
Fibrotic	167	45%	20%	
Soft	30	41%	22%	

	OASIS n = 201	CONFIRM I Diamondback n = 1146	CONFIRM II Predator n = 1734	CONFIRM III Outflow n = 1886	CALCIUM n = 29	COMPLIANCE n = 38
Dissections (minor and major)	3.5%	11.7%	12.3%	9.9%	3.4%	13.2%
Bail-out Stent (due to complication)	0.5%	4.6%	6.3%	6.0%	6.9%	2.6%
Perforation	1.0%	0.9%	0.6%	0.7%	0.0%	0.0%
Embolization	0.5%	0.0%	2.2%	2.2%	0.0%	2.6%
Re-interventions (TLR/TVR) @ 6mo	2.0%	n/a	n/a	n/a	0.0%	15.8%

Procedural Complications by Lesion (%)



MODERATE-SEVERE Ca⁺⁺

ONLY WIRE WILL CROSS
LESION

TIBIAL INTERVENTION

TRANSPEDAL

➤ **There are advantages to atherectomy**

➤ Facility

➤ Optimal

➤ Improves

➤ **Risks**

➤ **General**

➤ **Choice of**

20% of FP cases
50 of tibial cases

specific,

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