Lesion Modification with Turbohawk is Better

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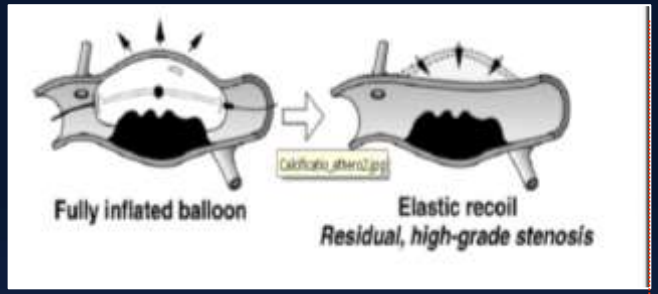
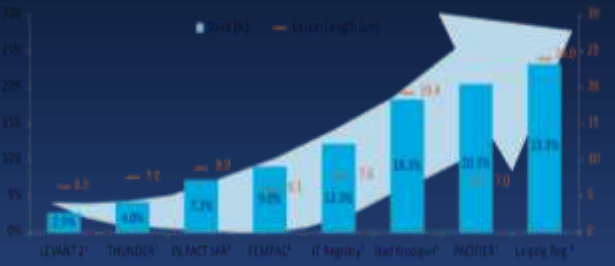
Area of Concerns for DCBs

Limitations of DCB

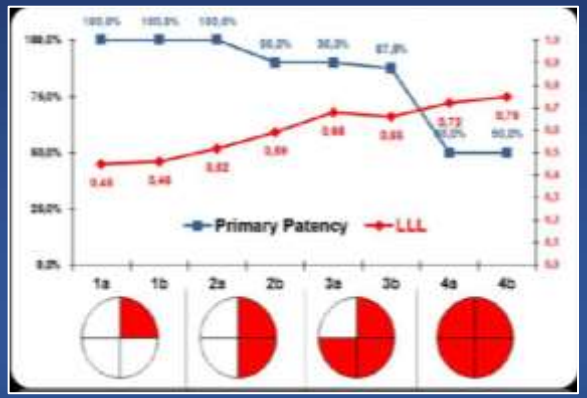
DCB is based on Angioplasty



Provisional Stent Rate increases with Lesion Length



Calcium May Limit Drug Effect



Addressed by atherectomy

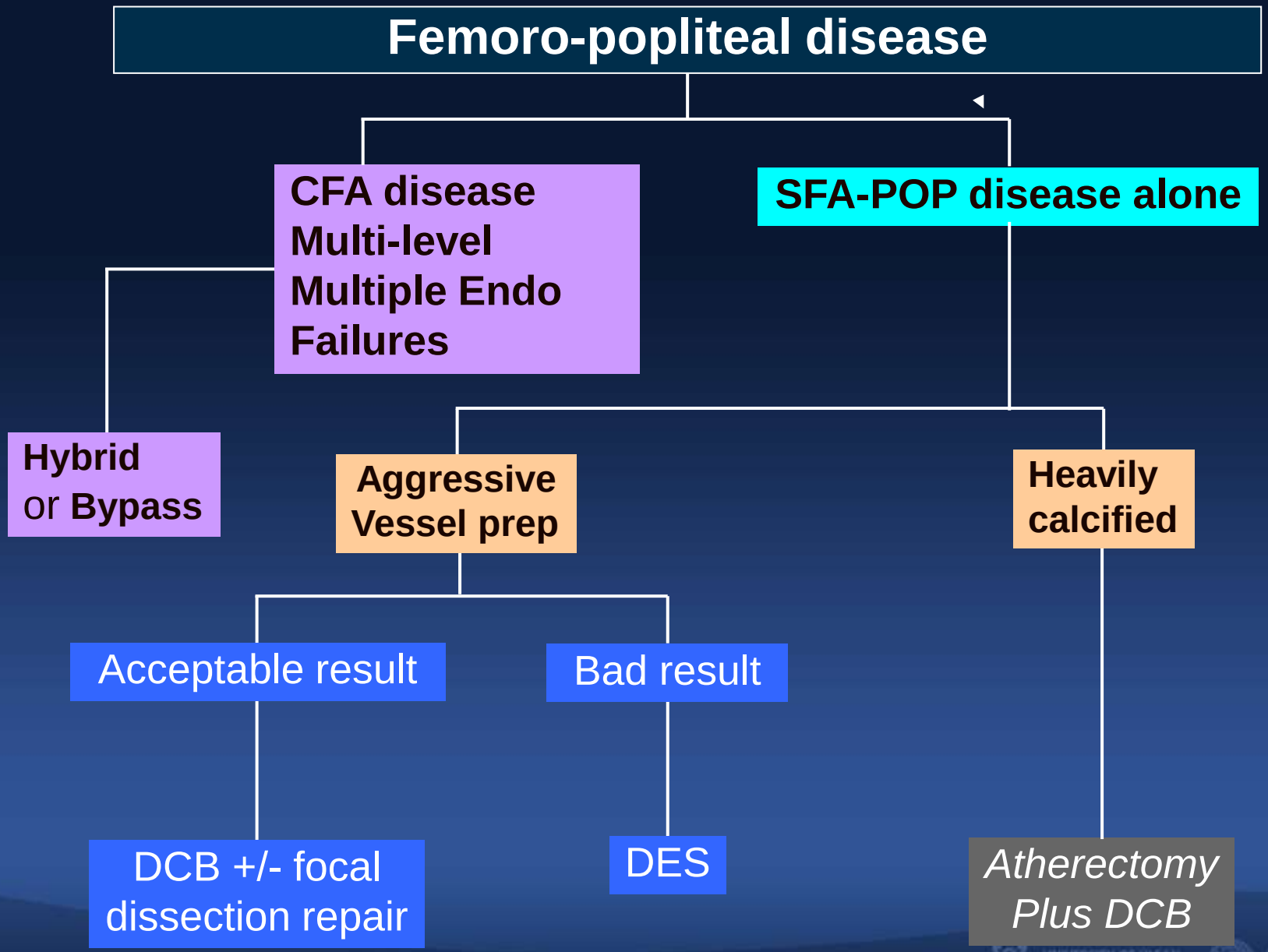
Mechanically recanalize the vessel without overstretch

Reduce the likelihood of b ail-out stenting and prese rve the native vessel - *% S tent Rate in DEFINITIVE se ries was <=3%*

Removes potential barriers for drug uptake

Atherectomy enables us to shift from treating dissections and recoil to preventing it

Treatment Algorithm



Available Devices

Directional Atherectomy

- Hawk portfolio: Silver Hawk, Turbo Hawk, & HawkOne (Medtronic)
- Pantheris (Avinger)

Orbital Atherectomy

- Diamondback 360 (CSI)

Rotational Atherectomy

- JetStream (Boston Scientific)
- Phoenix (Volcano)

Photoablation Atherectomy

- Turbo-Elite & Turbo-Tandem (Spectranetics)

Directional Atherectomy

DEFINITIVE LE and Ca^{2+}: Baseline Lesion Characteristics

SilverHawk, TurboHawk

	DEFINITIVE LE [1]		DEFINITIVE Ca^{2+} [2]
Lesion #	743 (RCC 1-3)	279 (RCC 4-6)	168
Location SFA	72.1% (536)	48.4% (135)	89.3% (150)
PA	15.3% (114)	17.2% (48)	10.7% (18)
Infrapop	12.5% (93)	34.4% (96)	
RVD (mm)	4.3 ± 1.1	3.7 ± 1.3	4.9 ± 0.9
% Stenosis	72.7% ± 18.1	75.9% ± 20.0	76.5% ± 15.4
Length (cm)	7.5 ± 5.3	7.2 ± 5.5	3.9 ± 2.7
Occlusion	17.4% (129/741)	29.9% (83/278)	17.9% (30)
Ca^{2+}	37.1% (275/742)	37.1% (103/278)	
None-Mild			6.0% (10)
Mod-Severe			94.1% (158)

Boldfaced values indicate statistical significance ($p < 0.05$). Definitions, e.g. Ca^{2+}, may differ between studies.

1. McKinsey J, et al. JACC Cardiovasc Interv 7(8):923-33:2014.
2. Roberts D, et al. Catheter Cardiovasc Interv 84(2):236-44:2014.

Directional Atherectomy

DEFINITIVE LE and Ca^{2+}: Outcomes

SilverHawk, TurboHawk

	DEFINITIVE LE [1]		DEFINITIVE Ca^{2+} [2]	
Patient #	598 (RCC 1-3)	201 (RCC 4-6)	133	
Lesion #	743	279	168	
Bail-out Stent	3.2%	(33/1022)	4.1%	(7/169)[1]
MAE (30d)	1.0% (6/598)	3.5% (7/201)	6.9%	(9/131)
1° Patency (1y)	78.0%	71.0%	NR[2]	
1° Patency Def	PSVR ≤ 2.4 by DUS		NR[2]	
TLR	NR	NR	NR	

NR = Not Reported. Boldfaced values indicate statistical significance ($p < 0.05$).

1. Site-reported lesions totaled 169 while Core Lab evaluated lesions totaled 168 (two site-reported lesions were considered one diffuse lesion by the Core Lab). Provisional stent rate was reported by Roberts, et al., with respect to the site-reported lesion number, i.e. 169 not 168.
2. Primary endpoint for DEFINITIVE Ca^{2+} was safety; patency was not evaluated.

1. McKinsey J, et al. JACC Cardiovasc Interv 7(8):923-33:2014.
2. Roberts D, et al. Catheter Cardiovasc Interv 84(2):236-44:2014.

DEFINITIVE AR

Pilot study to detect trends in treatment differences between groups and designe d to assess the effect of treating lesions with DA followed by DCB (DAART)

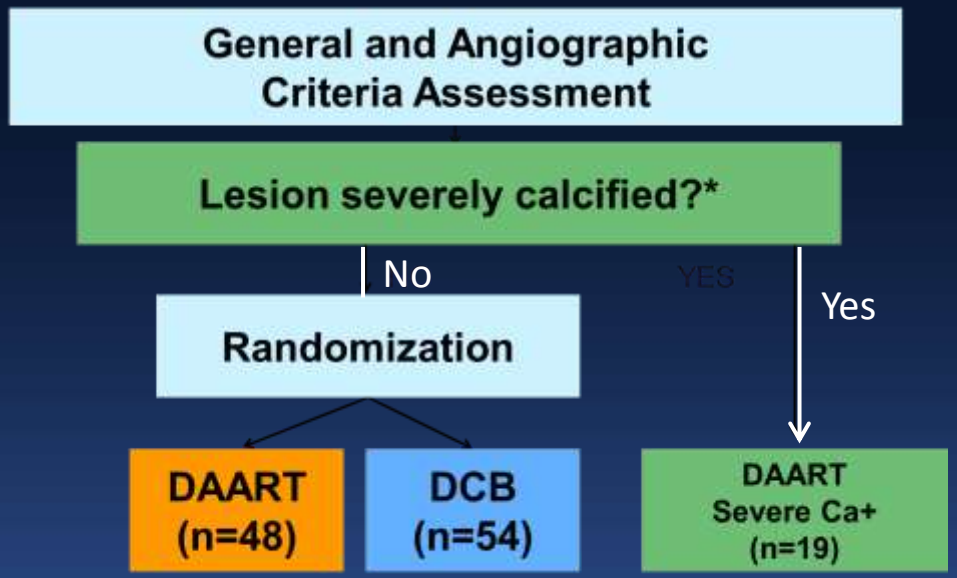
DAART: Directional Atherectomy + Anti-Restenotic Therapy

Inclusion Criteria

- RCC 2-4
- ≥ 70% stenosis of SFA and/or popliteal artery
- Lesion Length 7-15cm
- Reference Vessel ≥ 4mm and ≤ 7mm

Exclusion Criteria

- In-stent restenosis
- Aneurysmal target vessel
- Multiple lesions in target limb that require treatment



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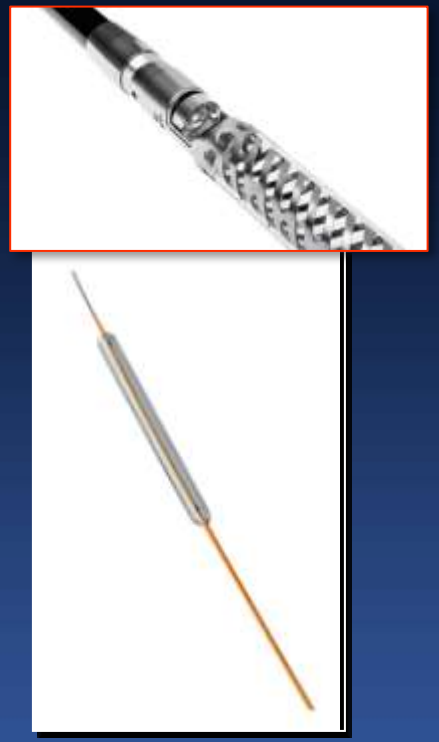
DEFINITIVE AR

Baseline Lesion Characteristics

SilverHawk and TurboHawk Directional Atherectomy plus Paccocath DCB

	DEFINITIVE AR		
	Random DAART	Random DCB	Ca^{2+}-DAART
Lesion #	48	54	19
Lesion Length (cm)	11.2	9.7	11.9
Diameter Stenosis (%)	82%	85%	88%
RVD (mm)	4.9	4.9	5.1
Calcification	70.8%	74.1%	94.7%
Severe calcification	25.0%	18.5%	89.8%

Reported values per Core Lab. Bold-faced values indicate statistical significance ($p < 0.05$).



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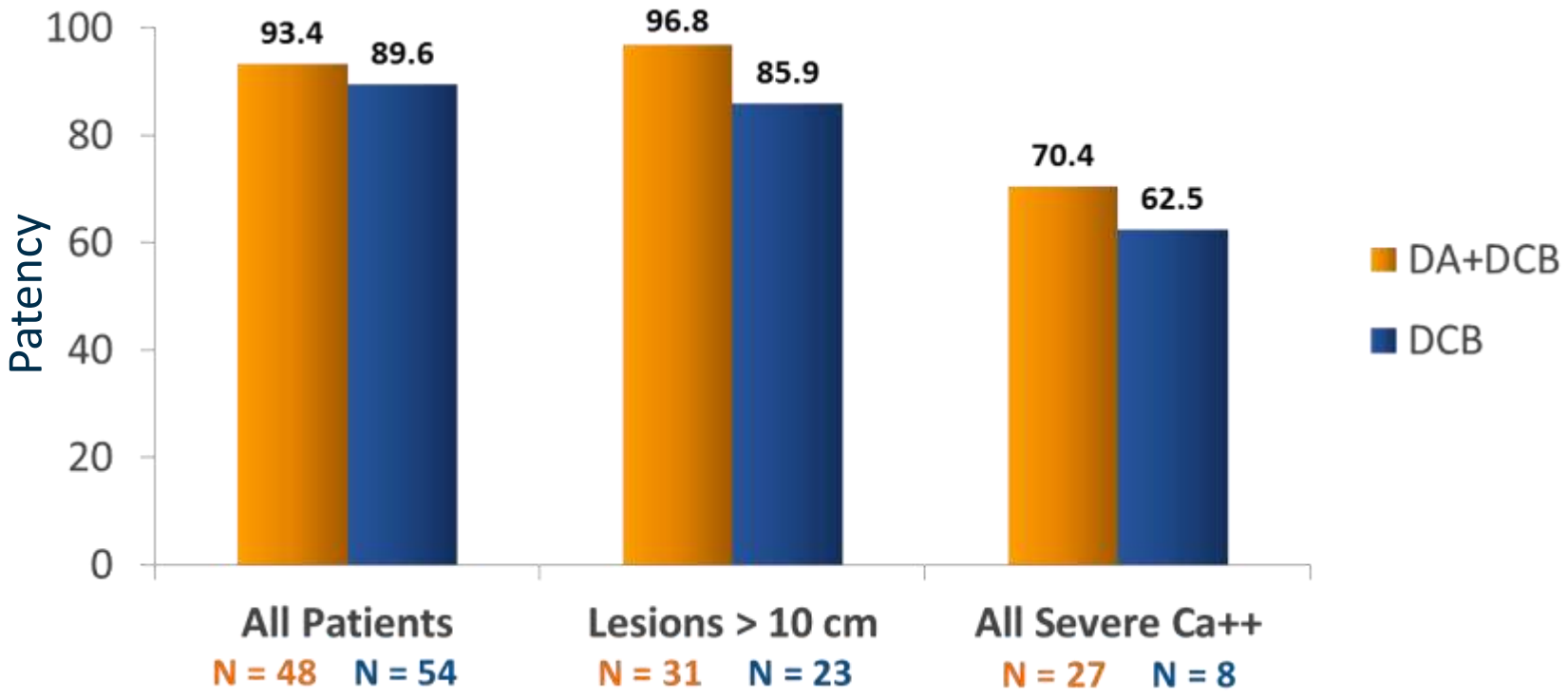
DEFINITIVE AR: 12-mo Patency via DUS

Potential Advantage Emerging in Long and Severely Calcified Lesions



Per Core Lab Assessment. “All Severe Ca++ “ group includes all patients treated with DA+DCB ther apy including randomized and non-randomized patients with severe calcium.

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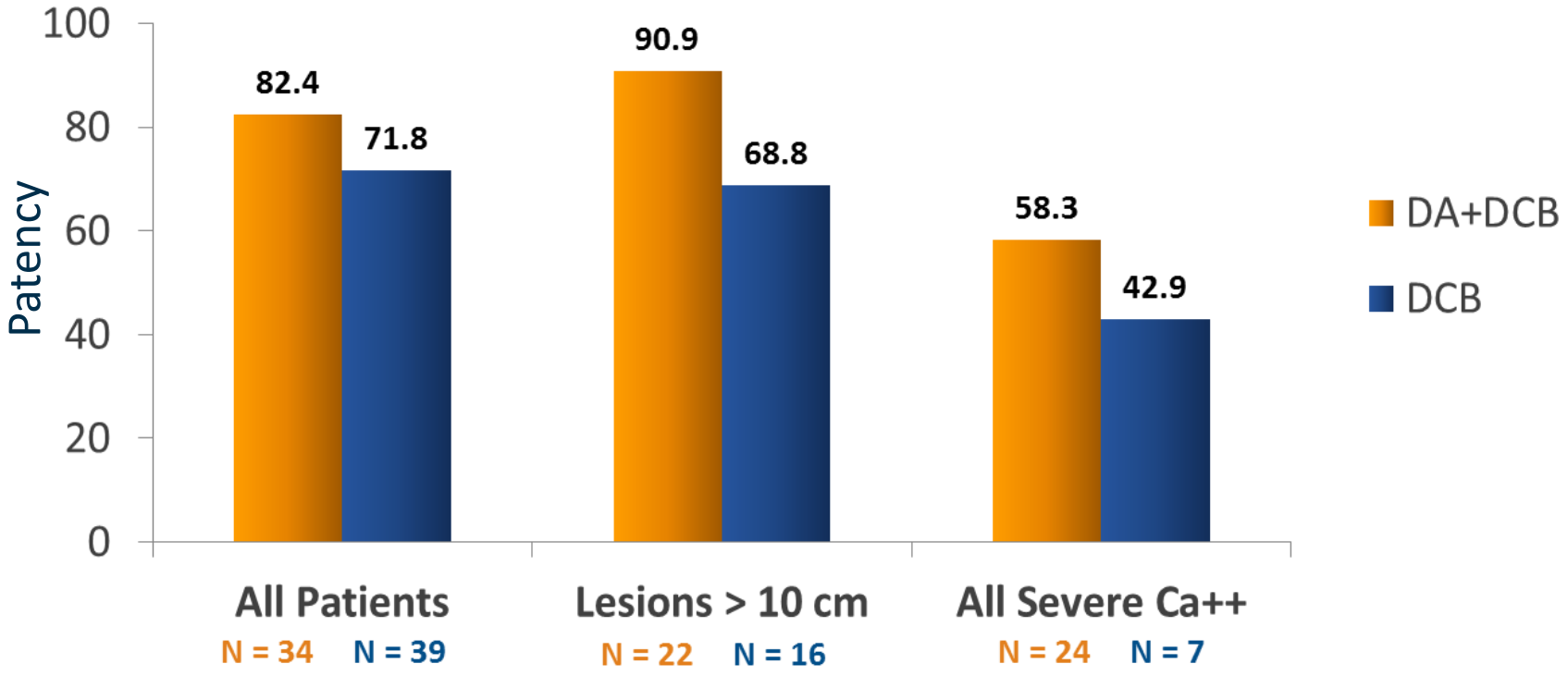
DEFINITIVE AR: 12-mo Patency via Angio

Same trend:
Potential Advantage Emerging in Long and Severely Calcified Lesions



Results for all patients who returned for angiographic follow-up.

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Cioppa, et al., DAART Study

Prospective, single-center study to c haracterize conjunctive DA + DCB us e in severely calcified lesions


Cardiovascular Revascularization Medicine

Combined treatment of heavy calcified femoro-popliteal lesions using directional atherectomy and a paclitaxel coated balloon: One-year single centre clinical results☆

Angelo Cioppa*, Eugenio Stabile, Grigore Popusoi, Luigi Salemme, Linda Cota, Armando Pucciarelli, Vittorio Ambrosini, Giovanni Sorropago, Tullio Tesorio, Alessia Agresta, Giancarlo Biamino, Paolo Rubino

Procedural Characteristics (n=30)

- Mean lesion length: 115mm
- Total occlusion: 13.3% (4)
- < 30% residual stenosis achieved i n all cases
- No procedure-related AEs
- Provisional stenting rate: 6.7% (2) [due to flow limiting dissections]

12-mo Results (n=30)

- 1° patency (PSVR<2.5): 90% (27)
- TLR: 10% (3)
- Limb salvage: 100% (12 CLI Pts)

Authors note DA+DCB may be a strategy for treating severely calcified lesions of the femoropopliteal artery

Cioppa A, et al. Cardiovasc Revasc Med 13:219-23 (2012).

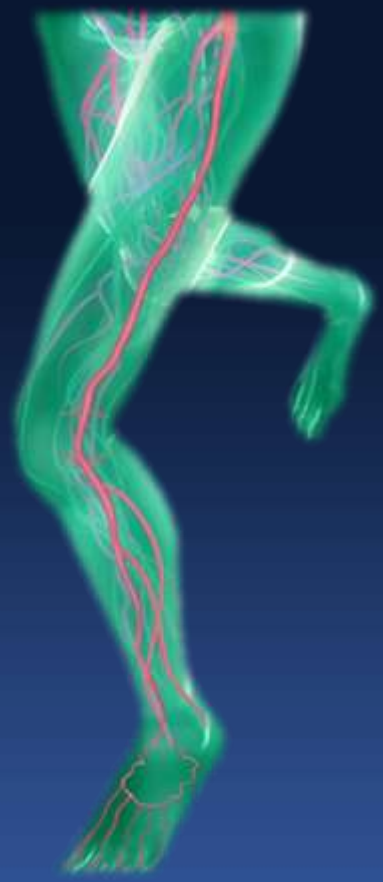
When and Where?
Devices are not Equal for Vessel Prep

Anatomical Location

DA	RA	OA	Laser	Location
X	X	X	X	Above-knee
X	X	X	X	Below-knee

Plaque Composition

DA	RA	OA	Laser	Composition
X	X	X		Ca^{2+}
X	X		X	Soft
	X		X	Thrombus



Lesion Morphology

Morphology	DA	RA	OA	Laser
Focal	X			
CTO	X	X		X
Eccentric	X			
Long Ca^{2++}	?	X	X	

In-Stent Restenosis

ISR	DA	RA	OA	Laser
Indication				X

Individual operator experience and preference are likely the primary influencers in device selection.

Long Heavily Calcific F-P Lesion

Problems

- Not front cutting
- Nosecone has to pass through the lesion, sometime needs ballooning, rarely doesn't work
- Have to repeat the cutting process

HAWKONE™ SYSTEM

Improved Crossing and Deliverability

- Reduction overall tip diameter
- Long, tapered distal tip provides enhanced deliverability

TurboHawk 7F High Efficiency Cutter – 2.7 mm

HawkOne System 7F – 2.6 mm

HawkOne™ Device Technology Spotlight

Three enhancements lead to superior performance in calcium

1) Rotational Speed

50% increase in rotational speed

HawkOne Cutter Driver: 12,000 RPMs

TurboHawk Cutter Driver: 8,000 RPMs

2) Robust Drive Shaft

25% improvement in tor sional performance

Slightly larger OD (0.05 mm)

3) Blade Design

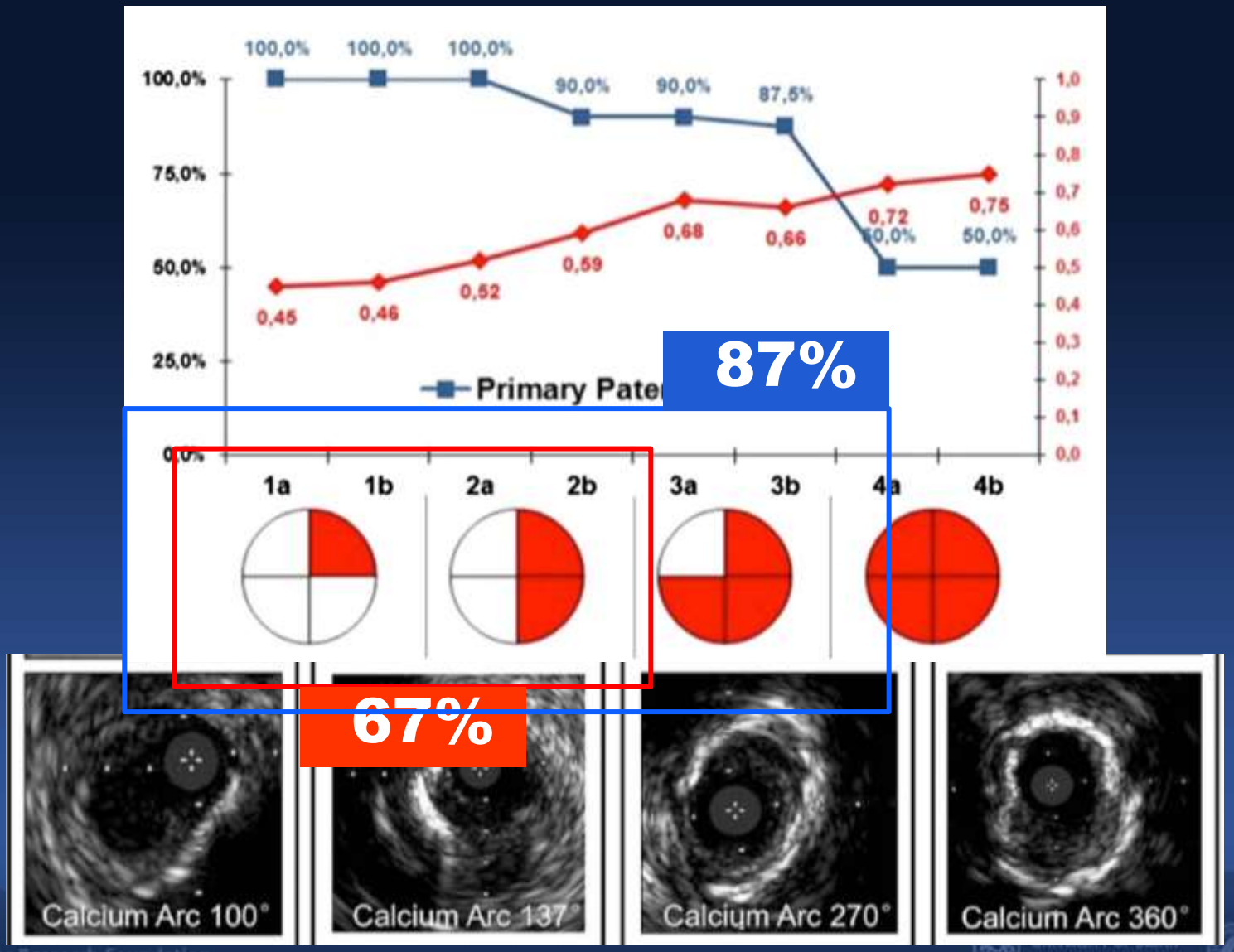
HawkOne™ Cutter

4 contoured blades

Calcified Long F-P Lesion

In Reality

Circumferential Distribution of Calcium is Mostly Eccentric



Fanelli et al. Cardiovasc Intervent Radiol (2014) 37:898-907)

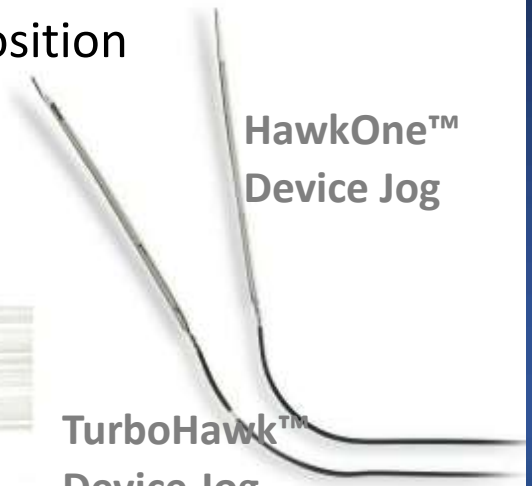
Greater Directional Control

Device	Jetstream (Boston Scientific Corporation)	Phoenix (Philips Volcano)	HawkOne (Medtronic)	Pantheris (Avinger, Inc.)	Turbo-Elite Laser (Spectranetics Corporation)
Atherectomy Type	Rotational	Rotational	Directional	Directional	Photoablative
Eccentric lesion	X	X	XX	XX	
Soft/fibrotic plaque	XX	XX	XX	XX	XX

- Consistent contact with the lesion, with improved wall apposition
- **Cutter angle is comparable** for all 7F devices

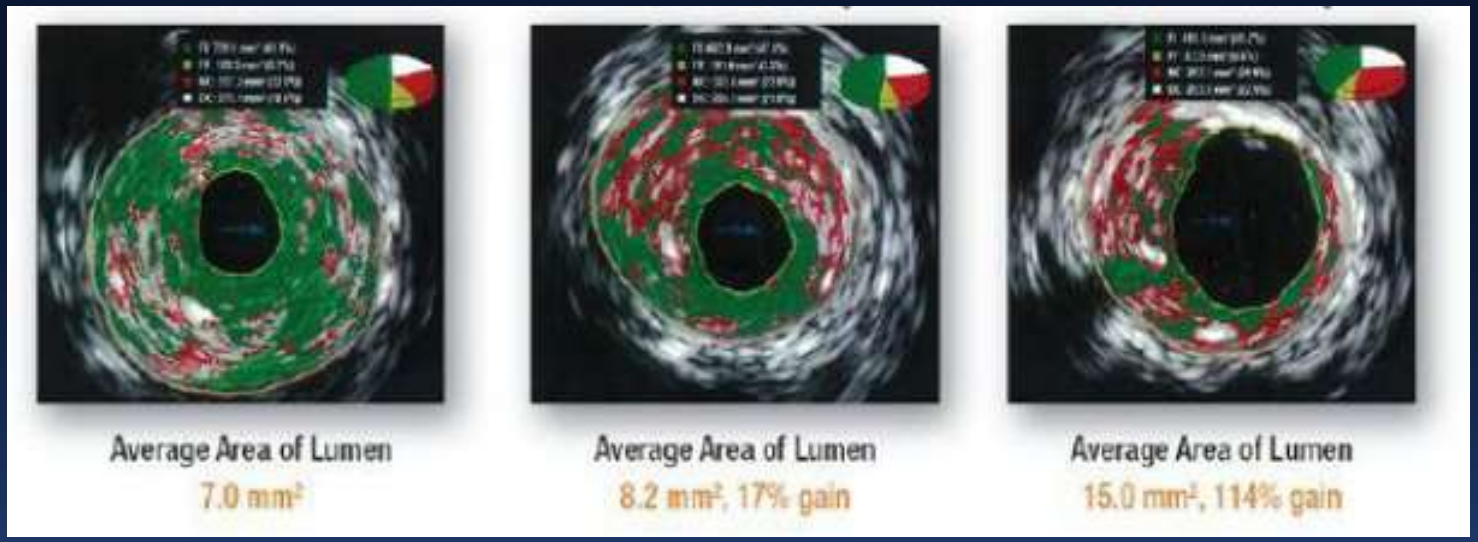
Cutter Angle Comparison: Simulated 7 mm Vessel

Top: H1-LX Bottom: TH LX-C

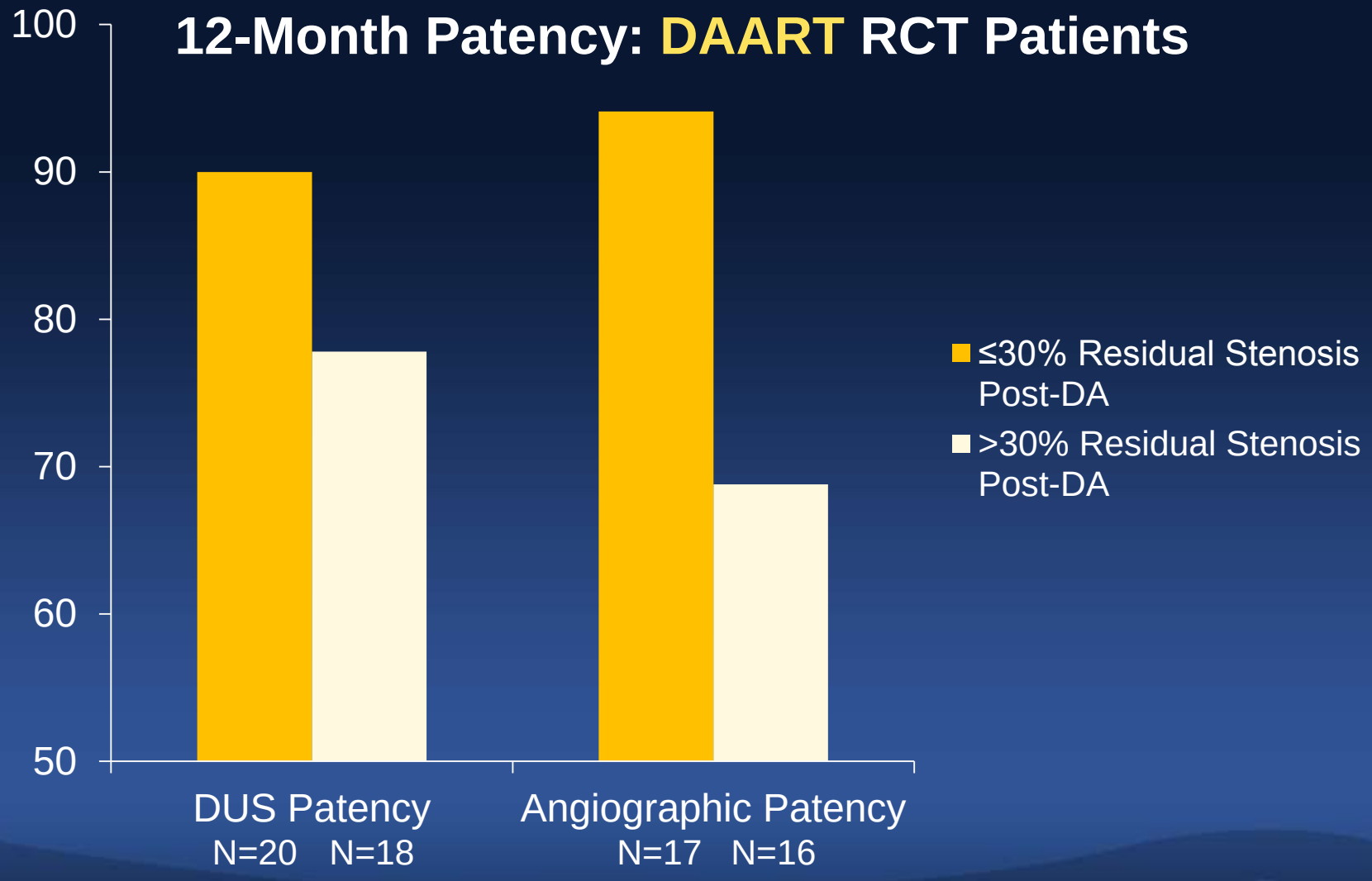


Achieve Maximal Lumen gain

De Novo Lesion | **After Initial OA** | **After Subsequent DA**



More Lumen Gain After Atherectomy Higher Patency Rate



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REALITY
Sponsored by VIVA

Co-Principal Investigators

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Chief Scientific Officer
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Brian DeRubertis MD, FACS
Associate Professor of Surgery
UCLA Division of Vascular Surgery

Primary Effectiveness Endpoint:

Primary patency (PSVR ≤ 2.4) and freedom from CD-TLR at one-year in subjects with long, moderate and severely calcified symptomatic femoropopliteal lesions and/or occlusions after treatment with DA + DCB

Primary Safety Endpoint:

Freedom from (MAEs) defined as freedom from flow-limiting dissections (D-F), vessel perforations requiring stenting or stent-grafts, unplanned amputation, intra-procedure distal athero-embolization and clinically-driven TVR in subjects with long, moderate and severely calcified FP lesions and/or occlusions through 30-day follow-up visit.

- Consent 250 subjects
- Goal Enrollment 150 subjects
- 10 U.S. Sites
  - Lesion length 8-18cm
  - Occlusion length 6-10cm
- 3 German Sites
  - Lesion length up to 25cm

REALITY Update (9/11/17)

- Eight U.S. sites/ 3 German Sites activated
- All sites have begun enrollment
- 39 patients enrolled

CardioVascular Research Foundation

COLLEGE MEDICINE

Medical Center

ClinicalTrials.gov Identifier: NCT02850107

A Real Efficient Device

Atherectomy device	Capital equipment required?	Capital equipment	Disposables
Diamondback	Yes		
Excimer Laser	Yes		
Jetstream	Yes		
Crosser	Yes		

Battery driven motor unit within the handle

Thank you