Value of Directional Atherectomy followed by DCBs for Long Calcified Fempop Lesions as Demonstrated by the Results of the REALITY Trial

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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
• Consulting Fees / Honoraria	• Abbott
• Consulting Fees	• Boston Scientific
• Consulting Fees / Honoraria	• Medtronic

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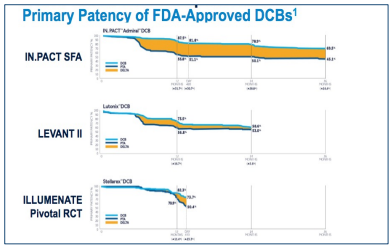
Value of Atherectomy & DCBs: REALITY Trial Results

Drug-Coated Ballons

Primary Patency of FDA-Approved DCBs[1]



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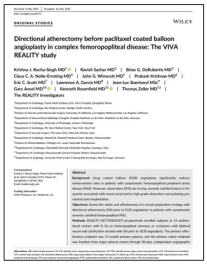

Directional atherectomy before paclitaxel coated balloon angioplasty in complex femoropopliteal disease: The VIVA REALITY study

Study Objective
Evaluate Efficacy of Excisional Atherectomy + INPACT DCB Moderate to severely calcified long femoropopliteal lesions
- Primary Endpoints:
  - **Effectiveness: Primary Patency at 12mo**
  - **Safety: Freedom from Major Adverse Events @ 30days**

Study Design & Oversight
- 102 subjects enrolled at 13 sites in the US & Germany
- Prospective, non-randomized, single-arm study
- Angiographic and duplex ultrasound (DUS) core lab

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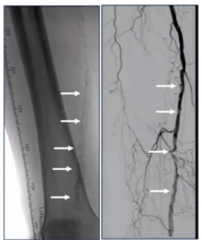
REALITY Inclusion Criteria

- Femoropopliteal lesion lengths: 8-36 cm
- Long chronic total occlusion lengths: >10cm
- Bilateral vessel wall calcification ***required*** in all lesions



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Clinical & Lesion Characteristics

Key Baseline Clinical Characteristics	N = 102
Age (years); ± SD	69.6 ± 9.7
Sex (male)	65.7%
Hypertension	89.2%
Hyperlipidemia	81.4%
Diabetes Mellitus	53.9%
History of Coronary Artery Disease	61.8%
Prior Peripheral Vascular Disease	74.5%

Key Lesion Characteristics	
Lesion Length (mm)	179.36 ± 81.4
Lesion Length ≥ 150 mm	55.6%
MLD (mm) at Baseline	0.57 ± 0.6
Chronic total occlusion length (mm)	226.0 ± 86.0
Diameter Stenosis (%) at Baseline	88.8 ± 11.7
Procedure Metrics:	
Diameter Stenosis (%) Post-DA Treatment	28.1 ± 12.0
Procedural Success*	57.6%

*Procedural success defined as ≤30% post DA+DCB as assessed by the angiographic core lab

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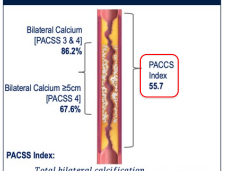
Key Baseline Clinical Characteristics	N = 102
PACSS Score	
Grade 0	1.0%
Grade 1	2.9%
Grade 2	0.0%
Grade 3	18.6%
Grade 4 Bilateral wall Ca++ ≥5cm	67.6%
Not assessable	8.8%
Type of calcification	
Type A: Intimal	0.0%
Type B: Medial	1.0%
Type C: Mixed Intimal + Medial Ca++	86.3%
Not assessable	12.7%

Key Calcium Metrics



Mean lesion length of 17.9cm

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Procedural Characteristics	
Perforations	3.1% (3/98)
Dissection ≥ Grade C	14.3% (14/98)
Distal Embolization	12.8% (11/86)
Provisional Stenting	8.8% (9/102)
Stenting for Perforations (cases)	3
Stenting for Dissection (cases)	5
Stenting for Embolization (cases)	1

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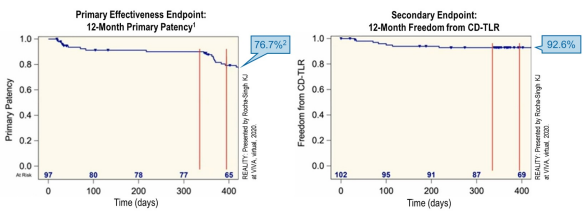

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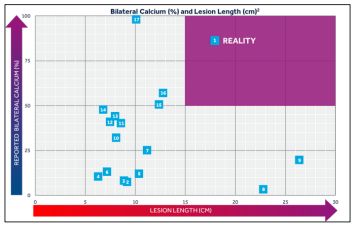

UNMATCHED LESIONS

86.2%	17.9cm	39.0%
Bilateral Calcium	Average Lesion Length	Chronic Total Occlusion

COMPELLING OUTCOMES

92.6%	76.7%
FF-CD TLR	Patency

12-month data include patients beyond the follow-up window.

PRESERVED TREATMENT OPTIONS

8.8%

Bailout stent rate

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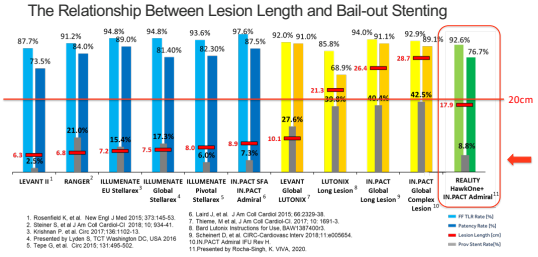
The Relationship Between Lesion Length and Bail-out Stenting



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Total REALITY Analysis

Objective:

- Compare DCB vs DA+DCB using a propensity-matched analysis in patients with femoropopliteal disease and variable calcium burden.
- Independent imaging core laboratory and CEC adjudication

Total IN.PACT
PTA + IN.PACT™ Admiral™ drug-coated balloon

VS

REALITY
HawkOne system + IN.PACT Admiral DCB

Efficacy Endpoints:

Primary Patency - freedom from clinically driven target lesion revascularization and freedom from restenosis (DUS PSVR≤2.4)

Stent-free Patency - as above, and the use of a stent at any time during the index procedure is considered a loss of patency

Presented at VIVA 2024 | Total REALITY | Venita Chandra, MD | 11/2024

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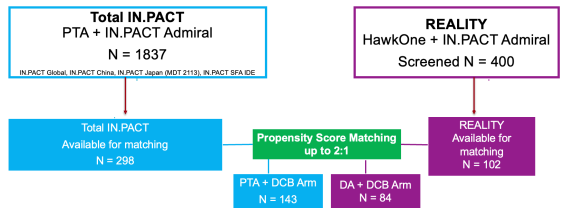

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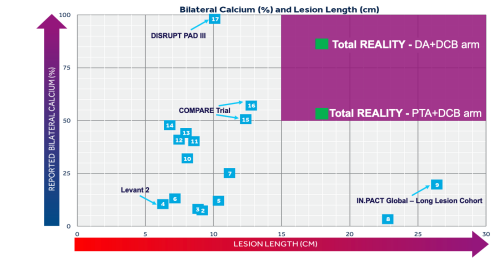

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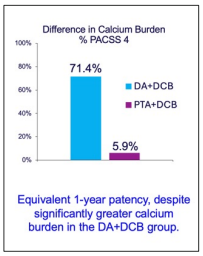
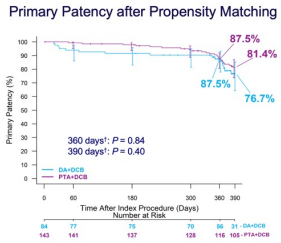


Equivalent 1-year patency, despite significantly greater calcium burden in the DA+DCB group.



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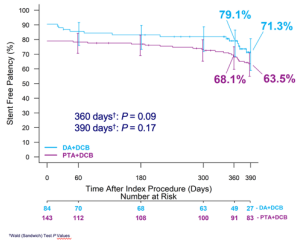
Stent-free Patency after Propensity Matching



Despite the uneven calcium burden between the groups, there was a trend towards higher stent-free patency in the DA+DCB arm

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Conclusions

- The REALITY Study has demonstrated that combination therapy of excisional atherectomy and DCB can result in:
  - Excellent patency rate (76.7%) for this challenging lesion subset
  - Low bail-out stent rate (8.6%) compared to similar patient populations
  - Complication rates (12.8% embolization) that reflect the severity of the disease
- Total REALITY analysis demonstrates:
  - Similar patency rates between DCB alone and DA+DCB
  - Trend toward stent-free patency for DA+DCB despite much more significant calcium burden in these patients

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