

The logo for LINC (Lung and Intestine Network for Clinical Research) features the letters 'LINC' in a white, sans-serif font. The letters are positioned over a stylized graphic of three curved, overlapping brushstrokes in dark blue, red, and yellow. The background of the slide is a light blue gradient with large, abstract, light blue brushstrokes.

LINC

Patterns of Vessel Calcification and Clinical Relevance

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Conflicts of Interest

- **Consultant**

- Abbott Vascular (non-compensated)
- AOPA
- Boston Scientific (non-compensated)
- Cardinal Health
- Cordis Corporation (non-compensated)
- Janacare, Inc
- Medtronic (non-compensated)
- Micell, Inc
- Novella (DSMB)
- Primacea
- Valiant
- Volcano

- **Board Member**

- VIVA Physicians (Not For Profit
501(c) 3 Organization)
 - www.vivapvd.com
- Intersocietal Accreditation Commission
- 2 -CBSET

- **Equity**

- Access Closure, Inc
- Embolitech
- I.C.Sciences, Inc
- Janacare, Inc
- MC10
- Northwind Medical, Inc.
- PQ Bypass, Inc
- Primacea
- Sano V, Inc.
- Vascular Therapies, Inc

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Vascular Calcium in PAD

- Difficult to manage with any revascularization strategy
- Acute *and* long-term endovascular outcomes inferior when *severe* calcium is present
- Grading the severity of vascular calcium in peripheral arteries is subjective with no uniform grading scale...an art.

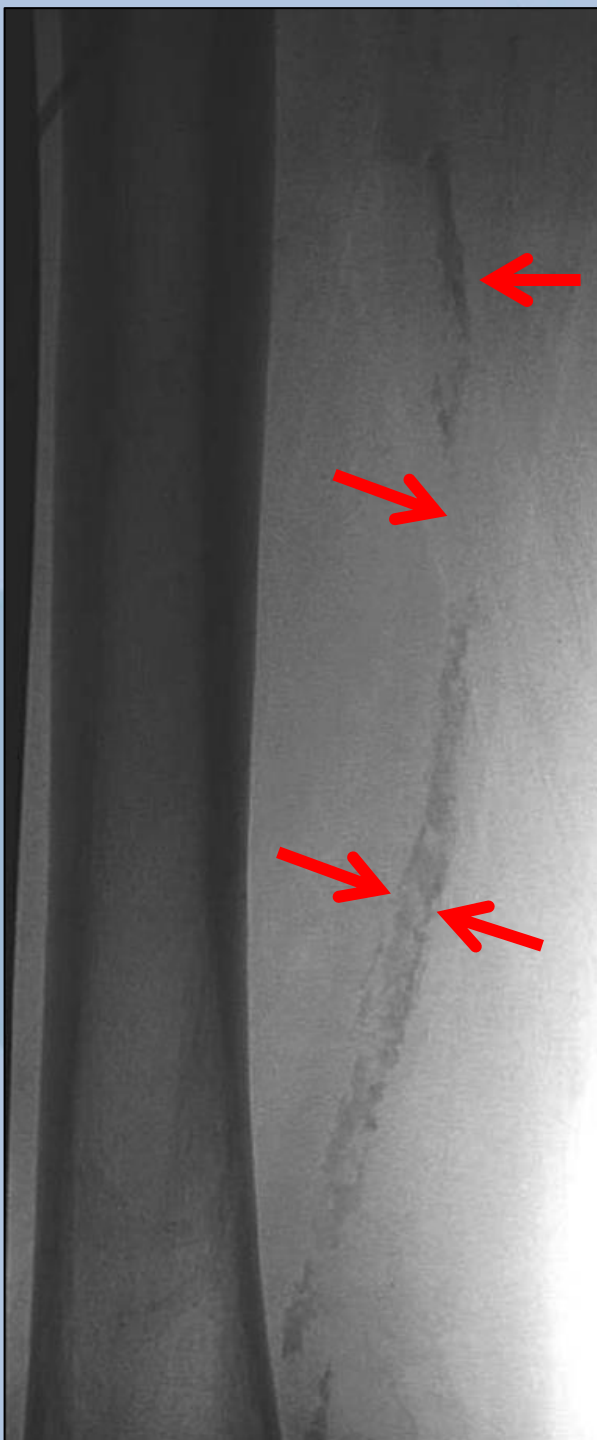
IN.PACT Global Long Lesion Imaging Cohort: Lesion/Procedural Characteristics

Lesions (N)	164
Lesion Type:	
de novo	83.2% (134/161)
restenotic (no ISR)	16.8% (27/161)
ISR	0.0% (0/161)
Lesion Length	26.40 ± 8.61 cm
Total Occlusions	60.4% (99/164)
Calcification	71.8% (117/163)
Severe	19.6% (32/163)
RVD (mm)	4.594 ± 0.819
Diameter Stenosis (pre-treatment)	90.9% ± 14.2
Dissections: 0	37.9% (61/161)
A-C	47.2% (76/161)
D-F	14.9% (24/161)

Device Success ^[1]	99.5% (442/444)
Procedure Success ^[2]	99.4% (155/156)
Clinical Success ^[3]	99.4% (155/156)
Pre-dilatation	89.8% (141/157)
Post-dilatation	39.1% (61/156)
Provisional Stent	40.4% (63/156)
- LL 15-25 cm:	33.3% (33/99)
- LL > 25 cm:	52.6% (30/57)

1. Device success: successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP
2. Procedure success: residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site reported estimate was used)
3. Clinical success: procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge

How Should this Lesion Be Uniformly Graded?



- Assessment method should be widely available (i.e., fluoroscopy)
- Important features of vascular Ca⁺⁺ should be assessed: intimal v. medial v. mixed (combination of fluoroscopy and DSA)
- Ratio of Ca⁺⁺ grade length as a % of total lesion length should be assessed:
SEVERE CA⁺⁺ INDEX

No Consistent and Validated Calcium Scoring System has been established

Physician reported based on arbitrary scale (biased and not specific)

DEFINITIVE Ca++ Trial¹

Definition of moderate and severe calcification was agreed upon by the study's national principal investigators and the FDA

DEFINITIVE AR²

Determination of severe calcification made by site at time of enrollment [severe calcification was defined as dense circumferential calcification extending >5 cm]

Bard Lutonix DCB

Any "undilatable" lesion

MDT Admiral DCB³

Definition of moderate and severe calcification was defined as dense circumferential calcification extending >5 cm

1. Roberts D, et al. *Catheter Cardiovasc Interv.* 2014;84:236-244.
2. Zeller T. *VIVA* 2014.
3. Tepe G. et al. *Circulation* Jan 2015

Published (Proposed) Ca++ Grading Scales

Degree of Lesion Calcification – PARC	
Focal	<180° (one side of vessel) and less than half the total lesion length
Mild	<180° and greater than half the total lesion length
Moderate	≥ 180° (both sides of vessel at same location) and less than half the total lesion length
Severe	>180° (both sides of the vessel at the same location) and greater than half the total lesion length

This proposed scale does not account for intimal vs. medial calcification patterns

Proposed Vascular Ca++ Grading Scale: PACSS

Catheterization and Cardiovascular Interventions 83:E212–E220 (2014)

PERIPHERAL VASCULAR DISEASE

Core Curriculum

Peripheral Arterial Calcification: Prevalence, Mechanism, Detection, and Clinical Implications

**Krishna J. Rocha-Singh,^{1*} MD, FACC, FAHA, Thomas Zeller,² MD, and
Michael R. Jaff,³ DO, FACC, FAHA**

Proposed PACSS Scoring System

Proposed Fluoroscopy/DSA based Peripheral Arterial Calcification Scoring Systems (**PACSS**): Intimal and medial vessel wall calcification at the target lesion site as assessed by high intensity fluoroscopy and digital subtraction angiography (DSA) assessed in the AP projection.

Grade 0: No visible calcium at the target lesion site

Grade 1: unilateral calcification $< 5\text{cm}$; a) intimal calcification;
b) medial calcification; c) mixed type

Grade 2: unilateral calcification $\geq 5\text{cm}$; a) intimal calcification;
b) medial calcification; c) mixed type

Grade 3: bilateral calcification $< 5\text{cm}$; a) intimal calcification;
b) medial calcification; c) mixed type

Grade 4: bilateral calcification $\geq 5\text{cm}$; a) intimal calcification;
b) medial calcification; c) mixed type

Tips to Assessing Peripheral Artery Calcium

- Assessment best performed at the time of diagnostic arteriography
- *Medial* calcification best assessed using fluoroscopy with a contrast-filled artery
- *Intimal* calcification best assessed using a dynamic DSA/cine run
- ***The majority of moderate/severely calcified SFA lesions have mixed components***

The REALITY Study

- Multi-center, prospective assessment of the safety and effectiveness of combined “vessel preparation” with directional atherectomy (HawkOne[®] /TurboHawk[®]) + IN.PACT Admiral[®] DCB in LONG and SEVERELY calcified FP lesions in 250 patients with RC 2-4 claudication.
- Angiographic & Doppler core labs will independently adjudicate PP through 12 mos. and freedom from CD-TLR through 24 mos.
- IVUS, **peripheral Ca++ grading scale validation** sub-studies, WIQ, QoL and health economic assessments.

Vascular Calcification in PAD

- A uniform grading scale is needed
 - ✓ PACSS is currently being prospectively evaluated
- A validated peripheral Ca++ scoring system will allow the comparison of technologies designed to manage vascular calcium:
 - ✓ Atherectomy
 - ✓ Atherectomy + DCB
 - ✓ BMS
 - ✓ DES

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