

The logo for LINIC, featuring the letters 'L', 'I', 'N', and 'C' in a white, sans-serif font. The letters are arranged in a slightly curved line. Behind the letters are three overlapping, brush-stroke-like shapes in dark blue, red, and yellow, suggesting a stylized flame or a dynamic motion.

What Have We Learned (or Will We Learn) from the REALITY Study

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Krishna Rocha-Singh, MD

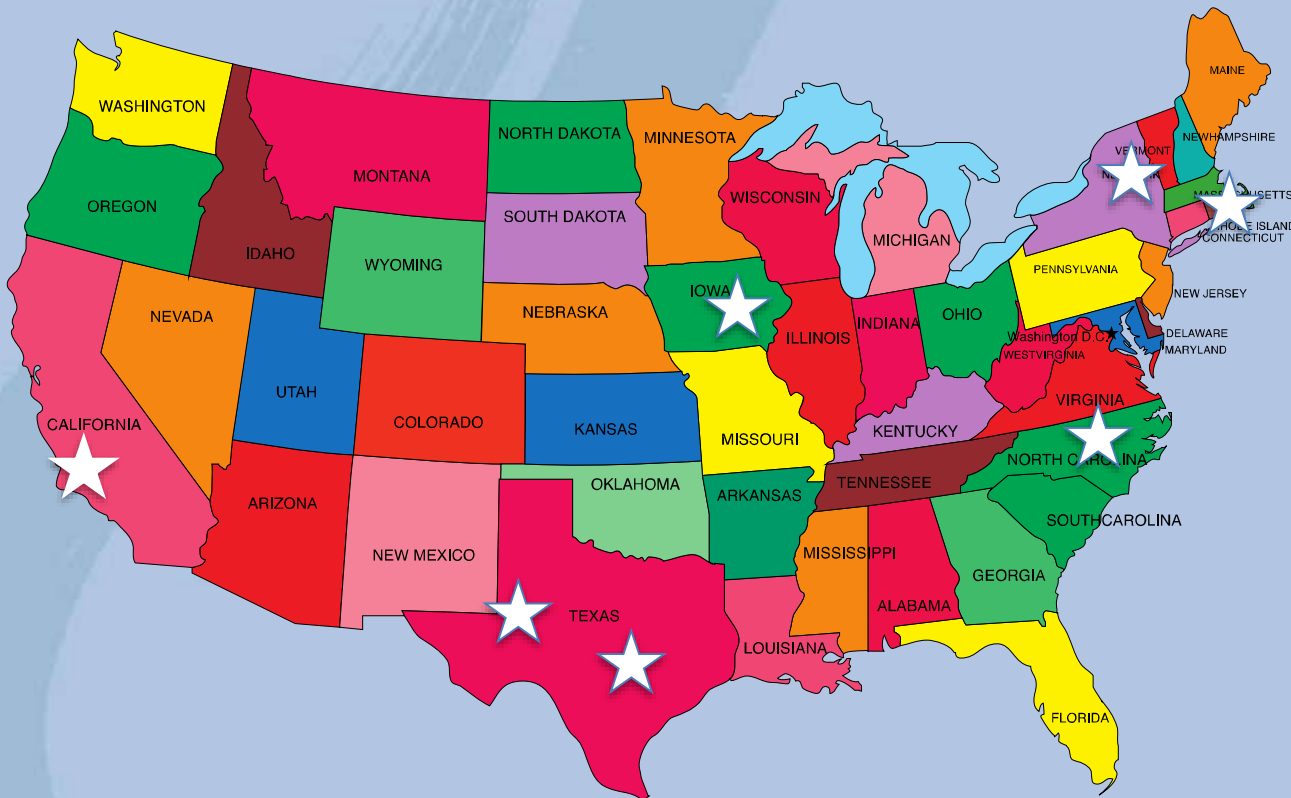
- Research Grants
 - MDT
- Consultant/Advisory Board
 - Medtronic
 - Alucent Medical
 - SoundBite Medical
 - ROX Medical
 - Abbott Medical
- Royalties/Financial Interest
 - None
- Speaker's Bureau
 - None
- VIVA Board Member
- I will discuss 'off-label' DCB use (outside the US IFU).

What REALITY Will Tell Us:

Validating the “Vessel Preparation” Hypothesis

- DCBs is superior to PTA in TASC II A-B lesions
- Large adjudicated registries report DCB use in complex lesions (long lesions, CTOs and ‘severe’ Ca++) are associated with high rates of provisional stent use
- DCB as a ‘stand alone, leave nothing behind’ technology in ‘real world’ patients is questionable
- REALITY: Is DA “vessel preparation” prior to IN.PACT Admiral DCB use in long, calcified FP lesions safe and effective?

REALITY US/EU Clinical Sites



- Dr. Ravish Sachar – Raleigh, NC
- Dr. Prakash Krishnan – Mt. Sinai, NYC, NY
- Dr. Brian DeRubertis, UCLA
- Dr. Lawrence Garcia, Boston, MA
- Dr. Roger Gammon, Austin, TX
- Dr. Michael Scott, Iowa Methodist, IA
- Dr. Samir Germanwalla, Longview, TX

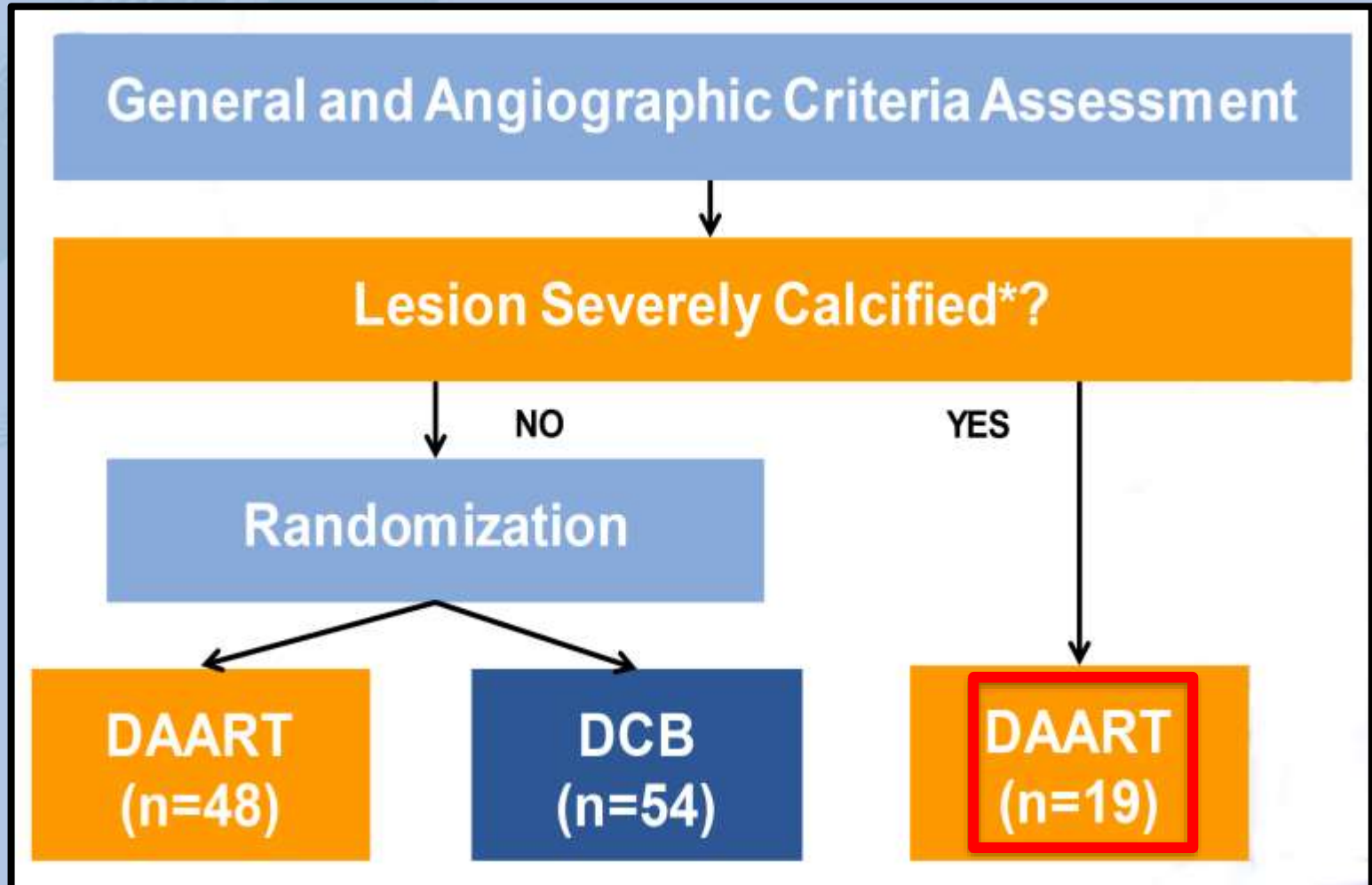
- Dr. Thomas Zeller, Bad Krozingen
- Dr. Giovanni Torsello, Munster
- Dr. Nolte-Esring, Muhlheim

REALITY: The Follow-Up to DEF AR

A Hypotheses Generating Trial

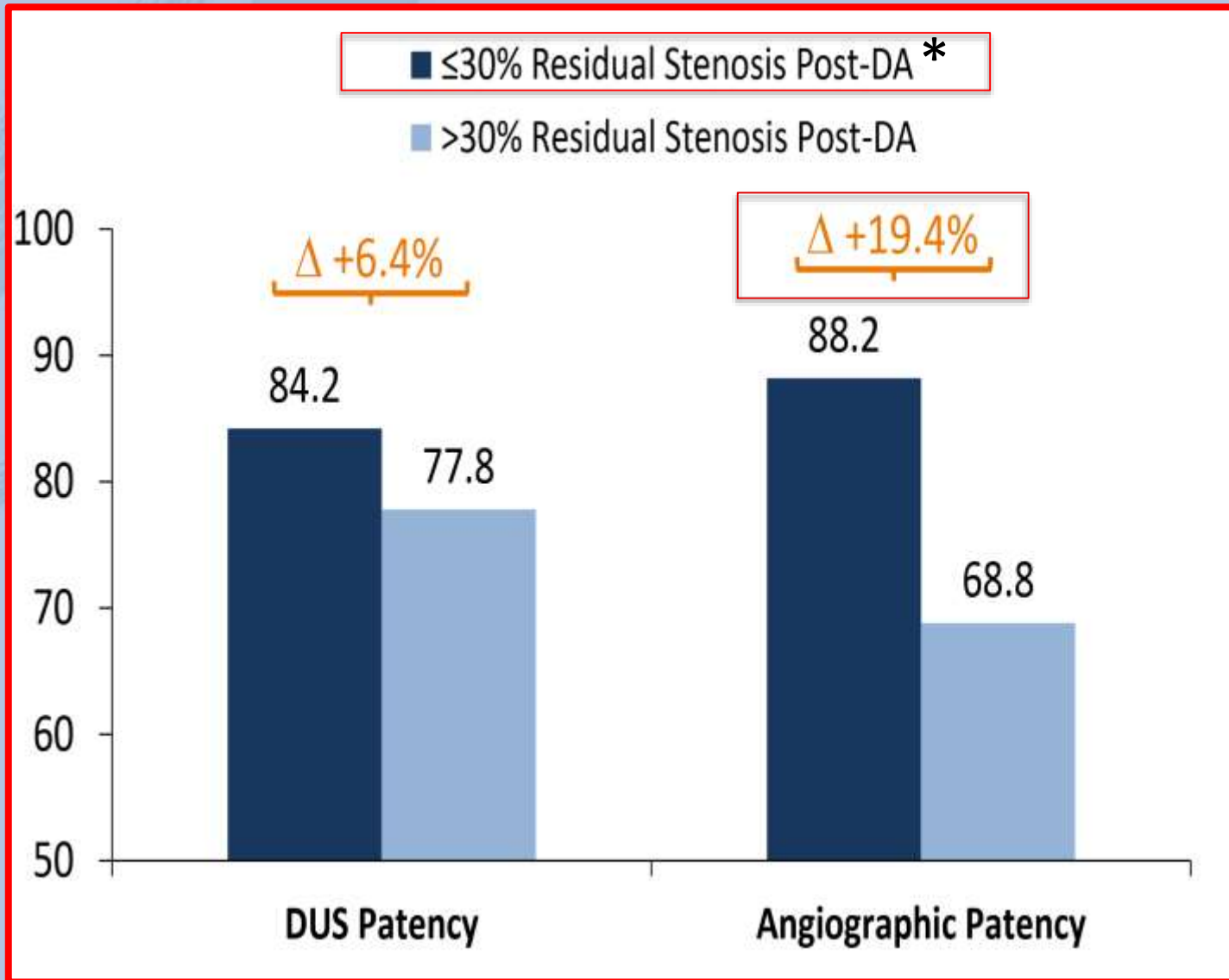
- ***Pilot RCT*** designed to assess the safety/effectiveness of DA followed by a paclitaxel-coated balloon (DA-ART) vs. a DCB alone
 - Small study to detect ***trends*** in treatment differences between groups
 - Observational investigation of outcomes; not-powered primary one-year outcomes
- ***Evaluate the DA-ART hypotheses*** to develop further investigational research of this device combination

DEF AR Study Design



*Defined as: dense circumferential calcification extending > 5 cm

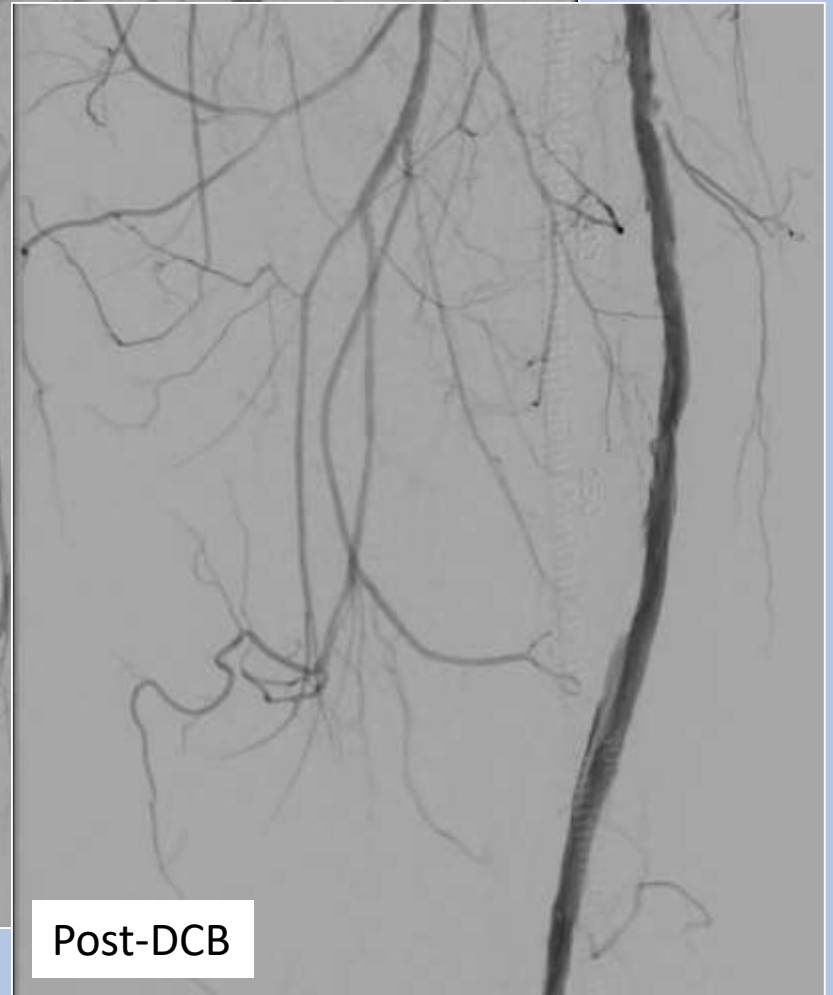
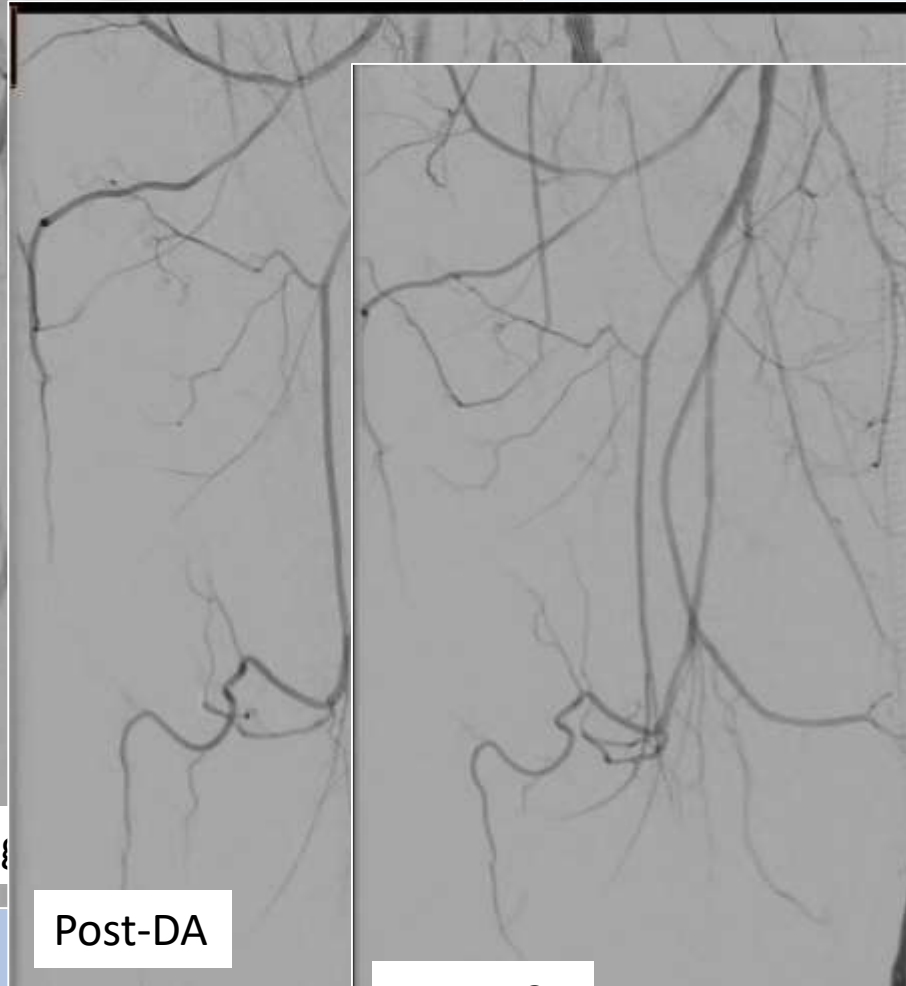
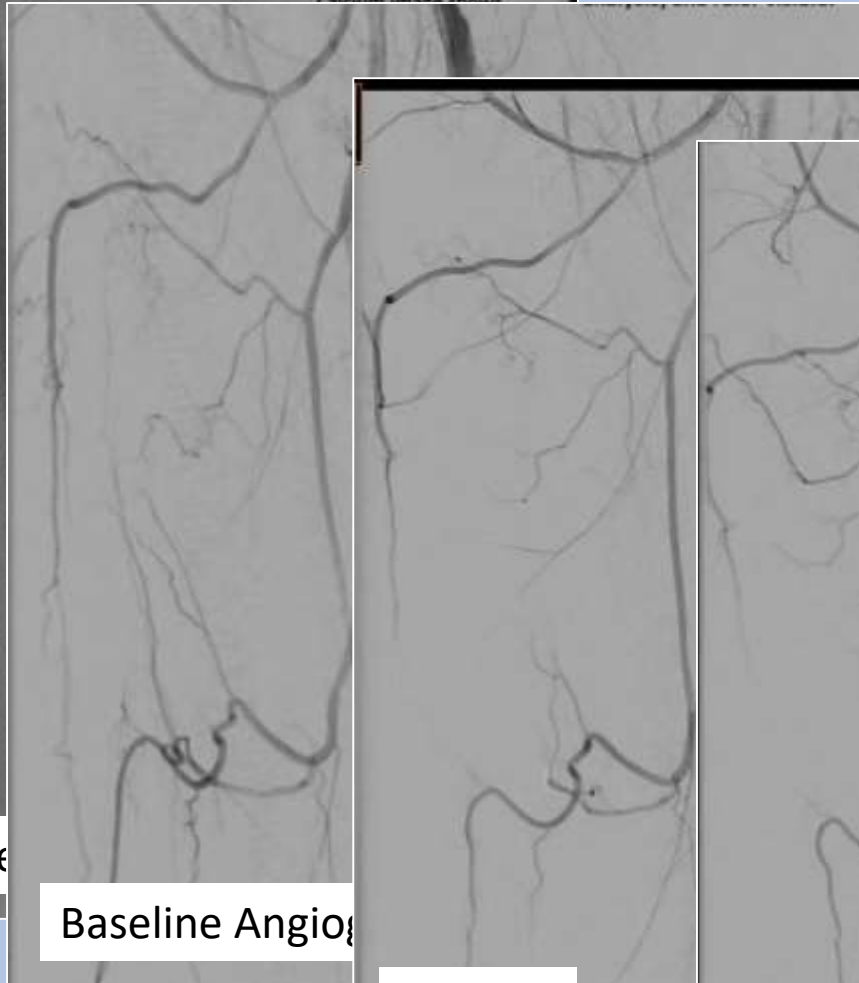
DEFINITIVE AR at One-Year



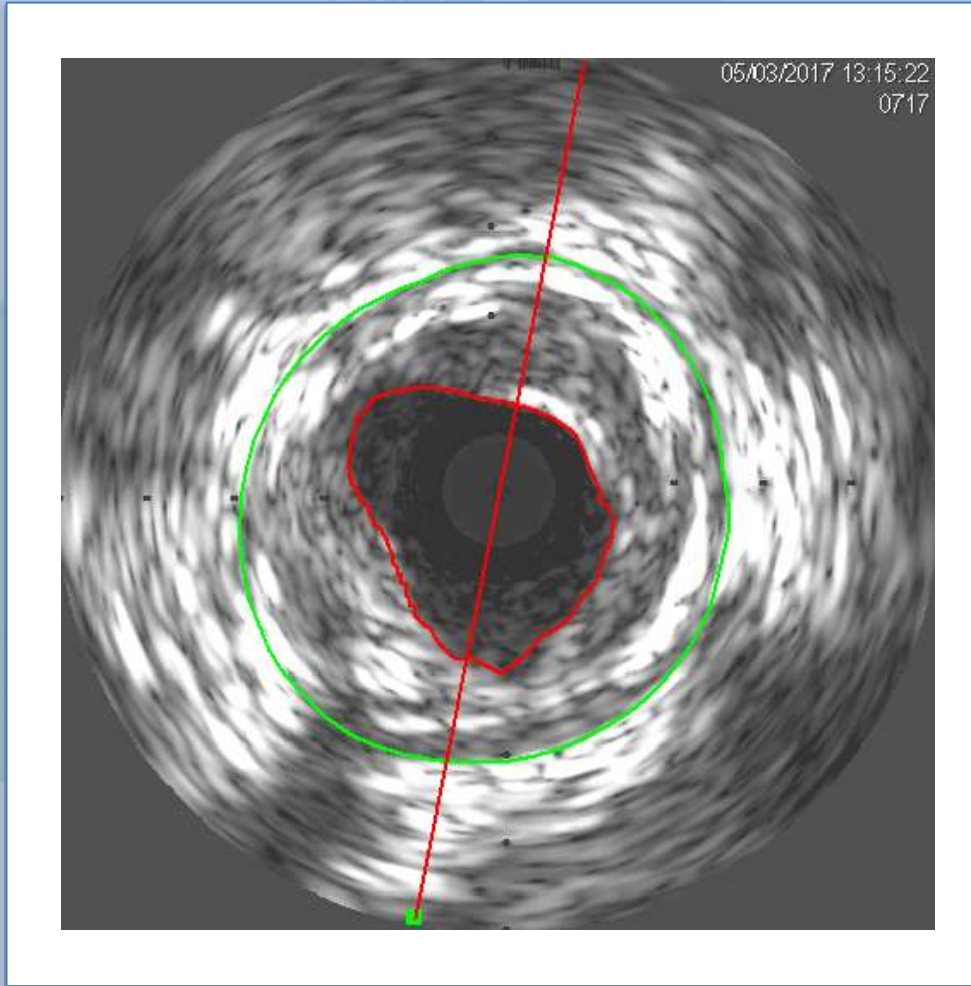
Three Primary Hypotheses of REALITY

- DA + DCB use in long (8-25 cm lesions) moderate-to-severely calcified lesions is safe and effective, reducing the need for provisional stenting, and promoting 12-mo. primary patency.
- A <30% post-DA residual %DS is associated with superior 12-mo primary patency
- The IVUS metric of 'plaque burden' post-DA is more sensitive than angiography in predicting 12-mo primary patency

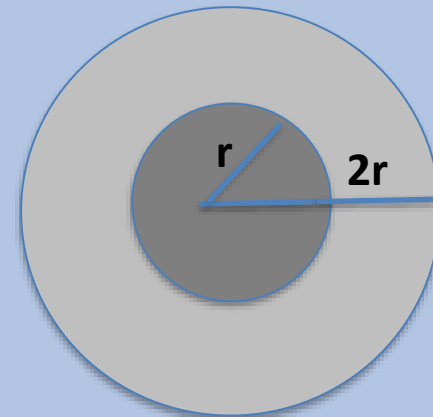
What Angiographic Metrics Are Adjudicated?



REALITY Study: IVUS Sub-Study



Plaque Burden:
An area-based calculation and percentage



Vessel Area: $4\pi r^2$

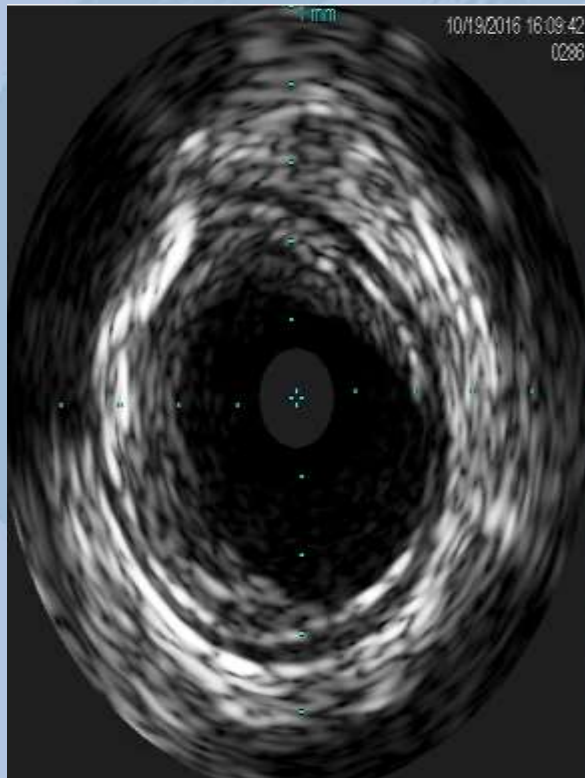
Lumen Area: πr^2

Plaque Burden (Area) = $3\pi r^2$

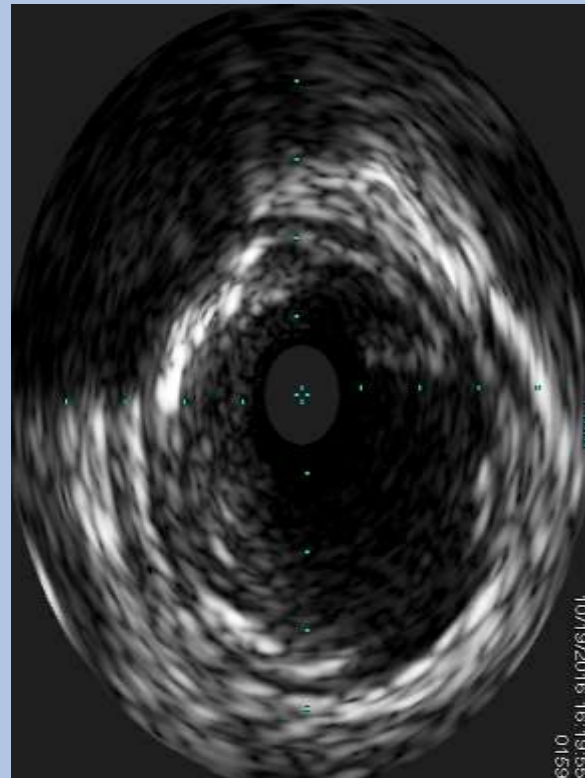
Percent: 75

REALITY: IVUS Plaque Burden Analysis

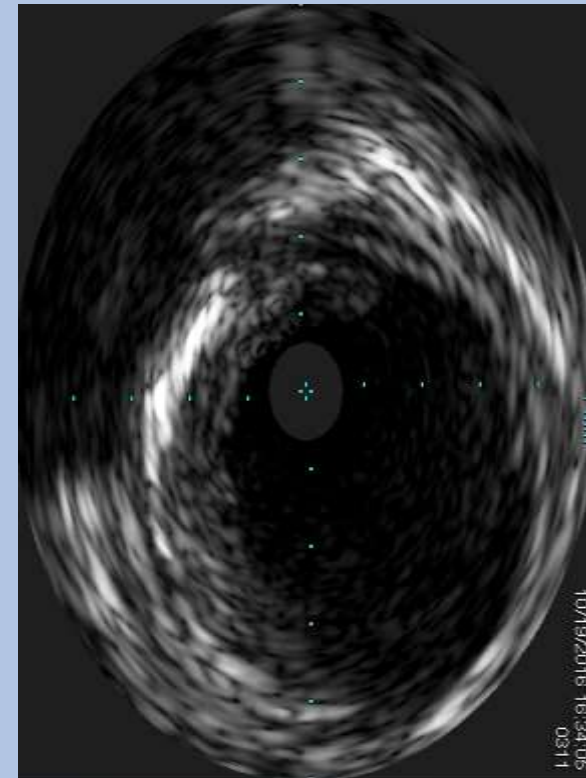
Baseline IVUS



Post-DA

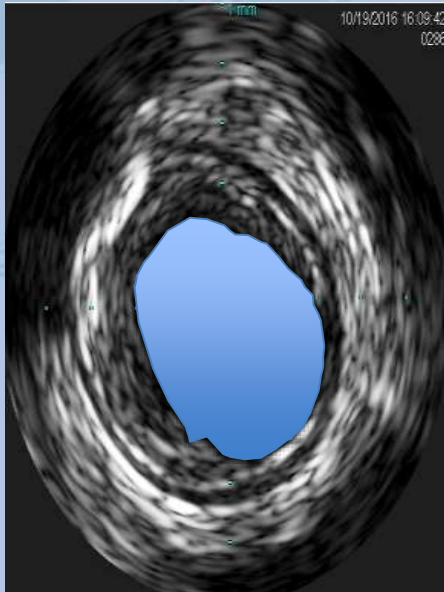


Post-DCB

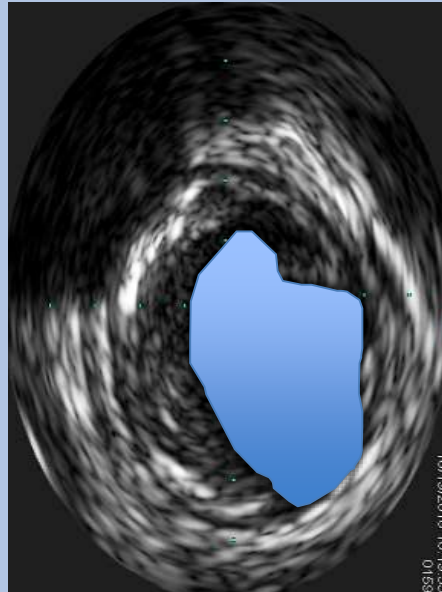


REALITY: IVUS Plaque Burden Analysis

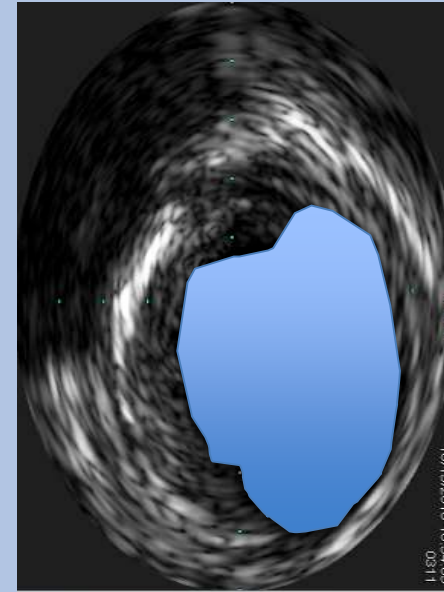
Baseline IVUS



Post-DA



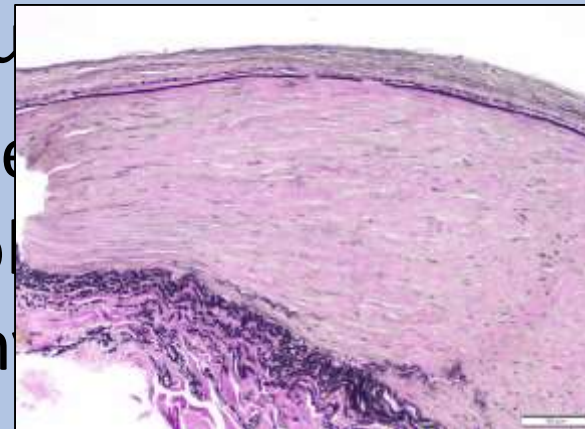
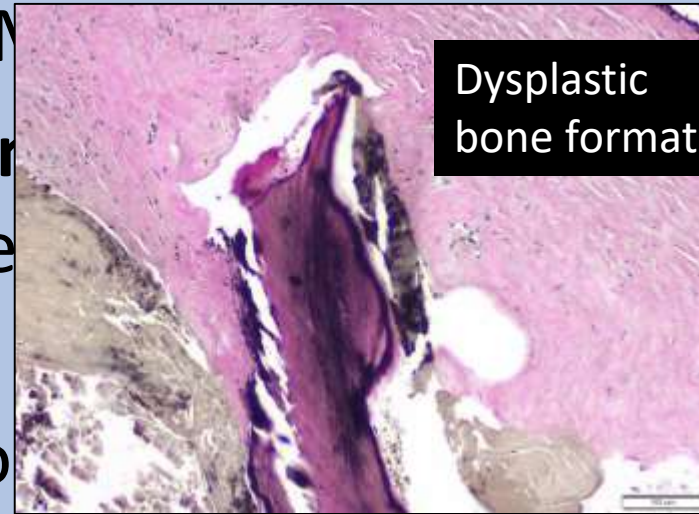
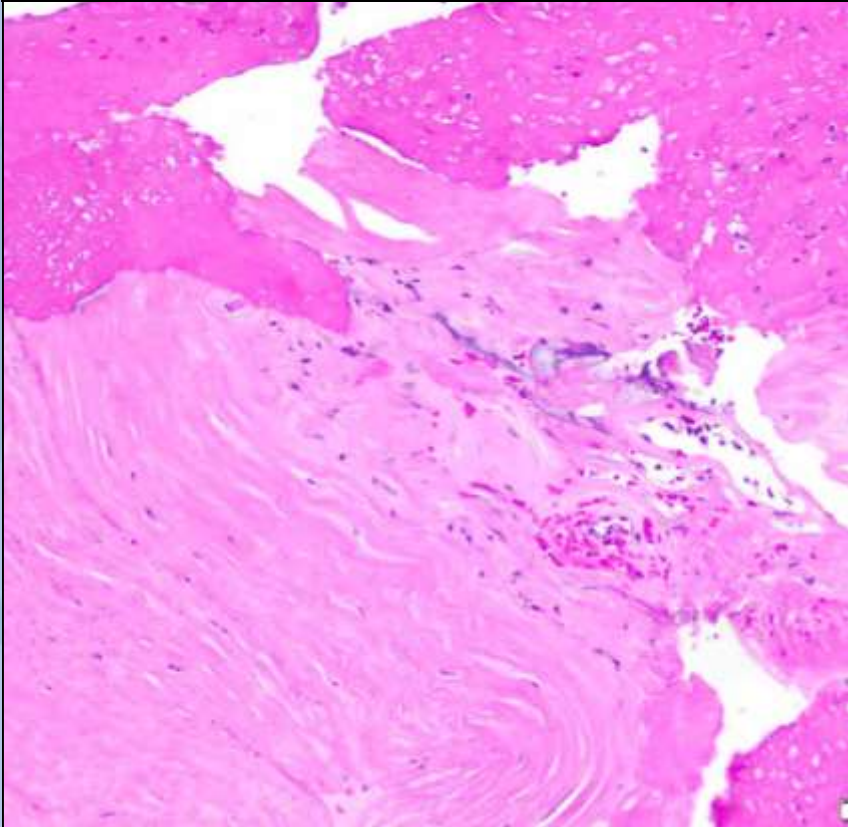
Post-DCB



**The Lumen Eccentricity Index:
The Directional Atherectomy 'Foot Print'**

Histomorphologic Assessment of Extracted Tissue

- Histology Core Lab analysis of all tissues extracted



Questions in Need of Answers:

- Is the directional atherectomy + DCB paradigm safe in long moderate-severely calcified lesions?
- How effective is DA in removing calcified atheroma prior to DCB and what can IVUS teach us regarding optimal technique?
- Does a $\leq 30\%$ %DS post-DA portend a favorable one-year clinical outcome? How is this best assessed?
- What is the appropriate metric to assess ideal vessel prep (residual %DS by angio or luminal gain, residual plaque burden by IVUS)?



THANK-YOU

The logo for LINC (Lung Cancer Intervention and Prevention Cooperative Group) features a stylized flame or brushstroke in shades of blue, red, and yellow, with the letters "LINC" in white to its left.

LINC

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