



# What is vessel preparation and why is it important?

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# Disclosures



Speaker name: Fabrizio Fanelli, MD

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## Consultant / Speaker / Proctor / Advisory Board

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# Vessel Preparation.....

Vessel prep is improving the local environment of the vessel prior to leaving something behind, whether that something is a stent or an anti-proliferative agent



Vessel Compliance  
Lumen Gain  
Lumen size stability  
Vessel scaffolding  
Drug transfer and uptake



Early recoil  
Flow limiting dissections  
Bail-out stent

# Vessel Preparation.....

Lesion preparation may serve notoriously complex settings such as:

- de-novo
- ISR
- CTO
- severe calcium

# Vessel Preparation Tools



## Balloons

- Standard Balloons
- Chocolate Balloon
- Cutting Balloons
- Scoring Balloons

## Atherectomy

- Directional
- Orbital
- Rotational
- Hybrid
- Laser

## Others

- Lythoplasty

# Plaque Scoring in Calcified SFA

## Insights form the PANTHER Registry



Original communication



### Treatment of femoropopliteal lesions with the AngioSculpt scoring balloon – results from the Heidelberg PANTHER registry

Ira Lugenbiel<sup>1</sup>, Michaela Grebner<sup>2</sup>, Qianxing Zhou<sup>3</sup>, Anna Strothmeyer<sup>4</sup>, Britta Vogel<sup>2</sup>, Rita Cebola<sup>2</sup>, Oliver Müller<sup>2</sup>, Bernadett Brado<sup>5</sup>, Marc Mittnacht<sup>6</sup>, Benedikt Kohler<sup>7</sup>, Hugo Katus<sup>2</sup>, and Erwin Blessing<sup>8</sup>

Single center, retrospective registry

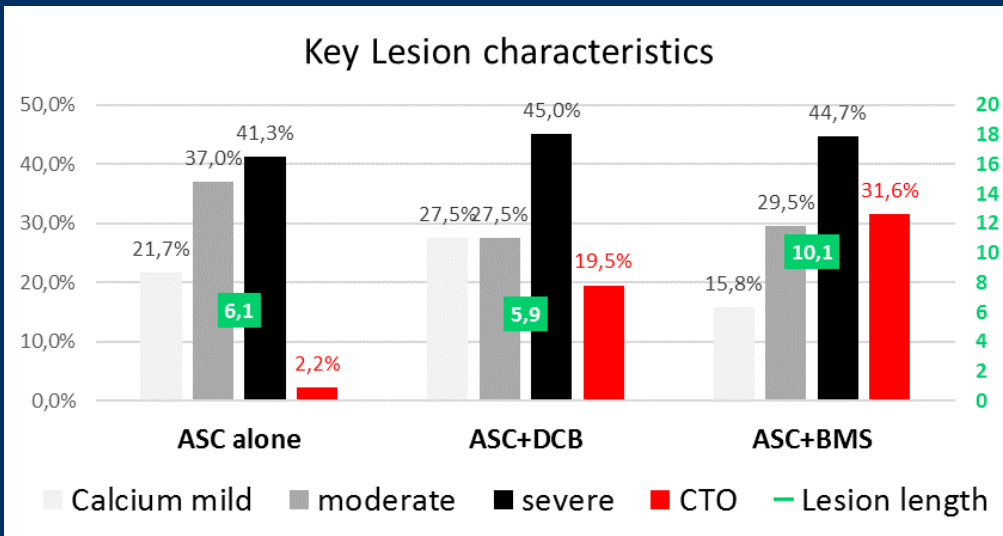
**N= 124** calcified fem-pop Lesions treated with Angiosculpt™\* scoring balloon (ASC)

- 37.1% ASC alone
- 32.3% prep before DCB
- 30.6% prep before BMS

### Overall Calcium rates and definition

- 21.8% mild (unilateral < 3 cm)
- 34.7% moderate (unilateral, > 3 cm)
- 43.5% severe (bilateral, any length)

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Lugenbiel I, Grebner M, Zhou Q, Strothmeyer A, Vogel B, Cebola R, Müller O, Brado B, Mittnacht M, Kohler B, Katus H, Blessing E. Treatment of femoropopliteal lesions with the AngioSculpt scoring balloon - results from the Heidelberg PANTHER registry. Vasa. 2017 Nov 8:1-7

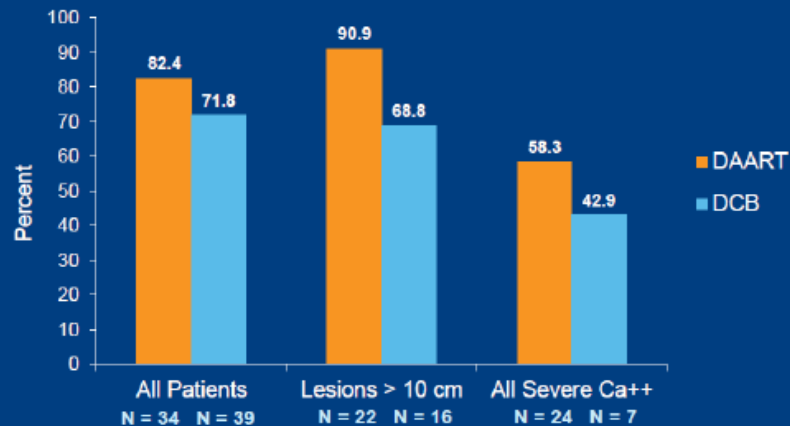
# Debulking + DCB in Ca++



Highest benefit suggested in presence of long and/or calcified arteries and following highest plaque debulking ( $\leq 30\%$  DS post-atherectomy)

## Angiographic Patency at 12 Months

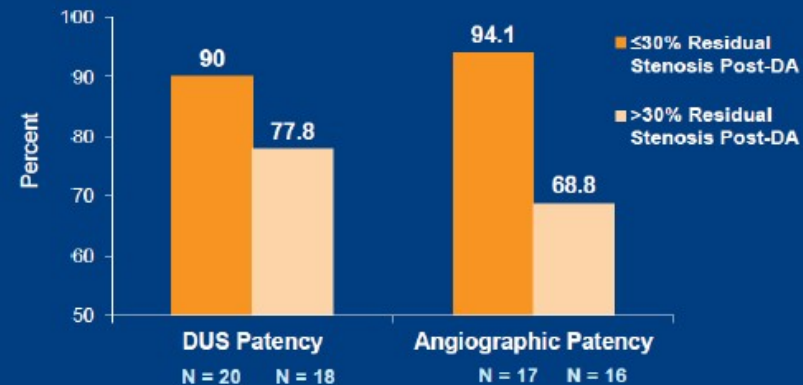
Angiographic Patency shows similar pattern



Per Core Lab Assessment. "All Severe Ca++" group includes all patients with severe calcium (including randomized and non-randomized). Results for all patients who returned for angiographic follow-up.

## 12-Month Patency: DAART RCT Patients

Increased lumen gain with DA before DCB may result in improved 12-month patency



- Zeller T, Langhoff R, Rocha-Singh KJ, Jaff MR, Blessing E, Amann-Vesti B, Krzanowski M, Peeters P, Scheinert D, Torsello G, Sixt S, Tepe G; DEFINITIVE AR Investigators. Directional Atherectomy Followed by a Paclitaxel-Coated Balloon to Inhibit Restenosis and Maintain Vessel Patency: Twelve-Month Results of the DEFINITIVE AR Study. *Circ Cardiovasc Interv.* 2017 Sep;10(9)
- T.Zeller - When DCB is not enough: Is there a need for a new DAART study? – LINC 2016, oral presentation

# DCB and Calcium



Evidence (in-vivo and ex-vivo) indicates Calcium as potential barrier to optimal drug absorption. Circumferential Calcium strongest contributor

**N=5** human cadaveric lower limbs with observed arterial calcification

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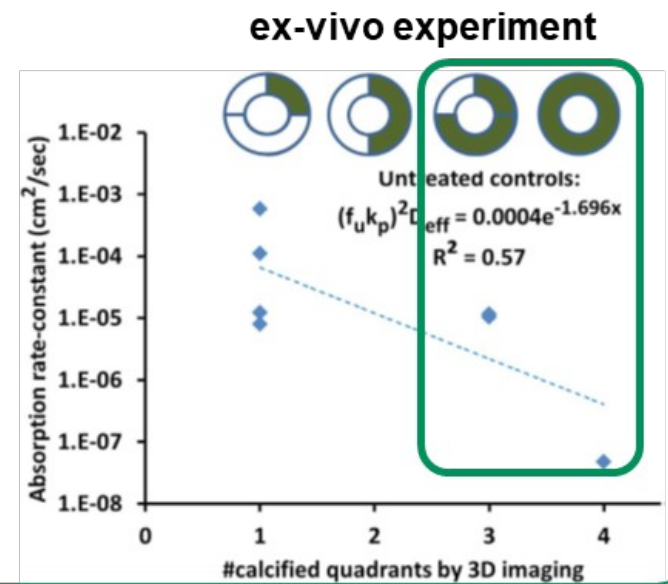
ELSEVIER

Calcified plaque modification alters local drug delivery in the treatment of peripheral atherosclerosis

Abraham R. Tzafriri<sup>a,b,\*</sup>, Fernando Garcia-Polite<sup>a,b</sup>, Brett Zani<sup>a</sup>, James Stanley<sup>a</sup>, Benny Muraj<sup>a</sup>, Jennifer Knutson<sup>a,c</sup>, Robert Kohler<sup>c</sup>, Peter Markham<sup>a</sup>, Alexander Nikanorov<sup>c</sup>, Elazer R. Edelman<sup>b,d</sup>

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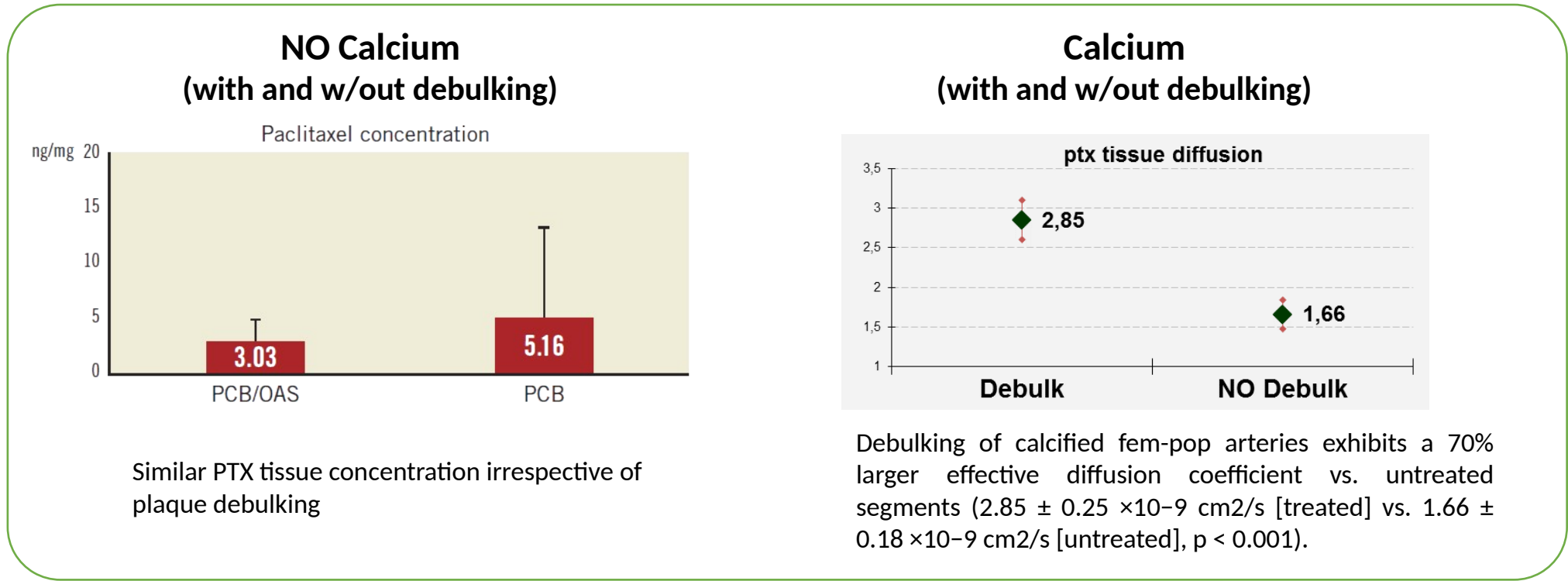
Tzafriri AR, Garcia-Polite F, Zani B, Stanley J, Muraj B, Knutson J, Kohler R, Markham P, Nikanorov A, Edelman ER. Calcified plaque modification alters local drug delivery in the treatment of peripheral atherosclerosis. J Control Release. 2017 Sep 1;264:203-210



# DCB and Calcium



Ex-vivo and pre-clinical experiments confirm Calcium, not plaque burden, remains the real barrier for DCB drug uptake

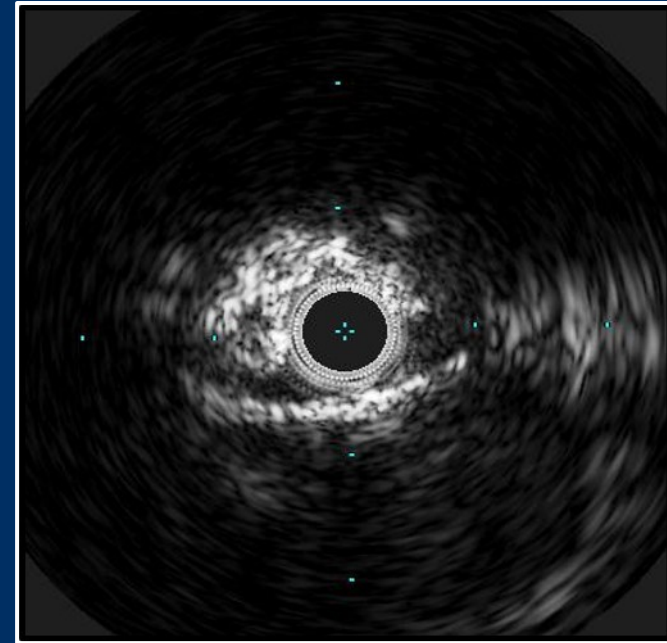


1. Tzafirri AR, Garcia-Polite F, Zani B, Stanley J, Muraj B, Knutson J, Kohler R, Markham P, Nikanorov A, Edelman ER. Calcified plaque modification alters local drug delivery in the treatment of peripheral atherosclerosis. J Control Release. 2017 Sep 1;264:203-210
2. Tellez A, Dattilo R, Mustapha JA, Gongora CA, Hyon CM, Palmieri T, Rousselle S, Kaluza GL, Granada JF. Biological effect of orbital atherectomy and adjunctive paclitaxel-coated balloon therapy on vascular healing and drug retention: early experimental insights into the familial hypercholesterolaemic swine model of femoral artery stenosis. EuroIntervention. 2014 Dec;10(8):1002-8

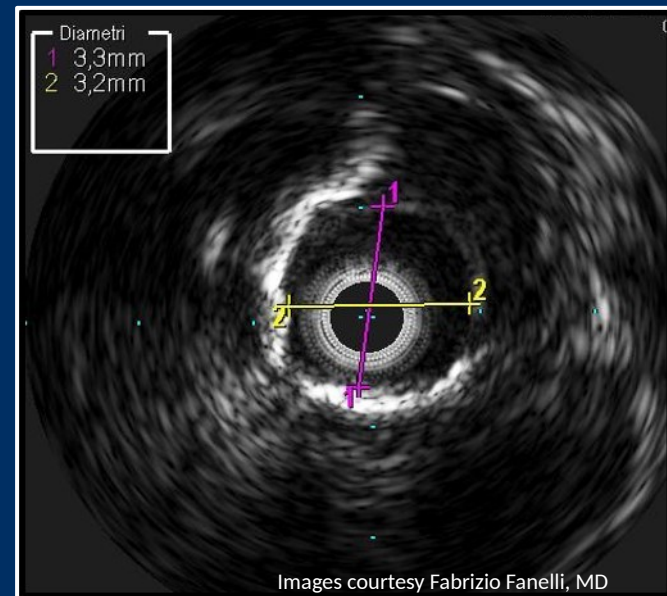
# Debulking + DCB in Ca++



HawkOne™ directional atherectomy system



Pre



Post

# Conclusions



- Vessel preparation remains a must in total occlusions and severely calcified lesions
- Multiple technologies are nowadays available but ..... “the ideal” isn’t available yet
- Atherectomy devices increase the luminal gain and may also improve drug uptake
- Vessel preparation with plaque scoring and lithoplasty do not debulk calcium but are able to increase vessel permeability, drug absorption, and patency rate
- Lesion preparation with plaque modification methods (non-conventional balloon) may further improve technical success and long-term outcomes in complex settings

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