A Look at Focused Force in Calcified Lesions

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Disclosure

Speaker name:

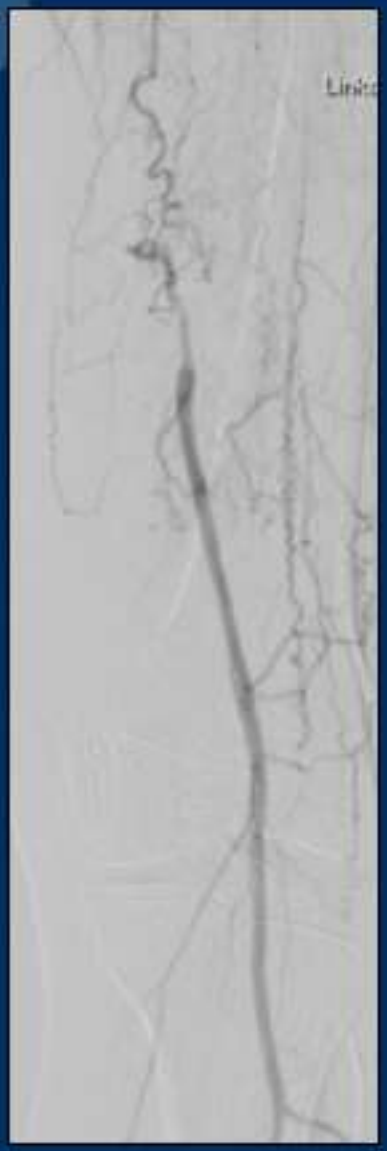
Ralf Langhoff, MD.....

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☒ I do not have any potential conflict of interest

LINC 2016: Live Case (SFA Occlusion DEB with lesion Preparation with Scoring-Balloon VascuTrak)



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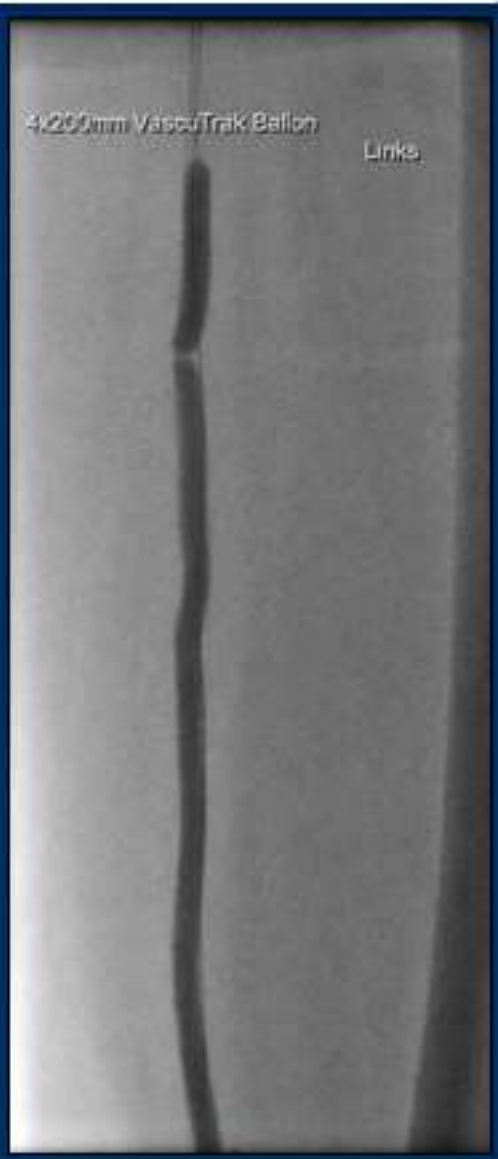

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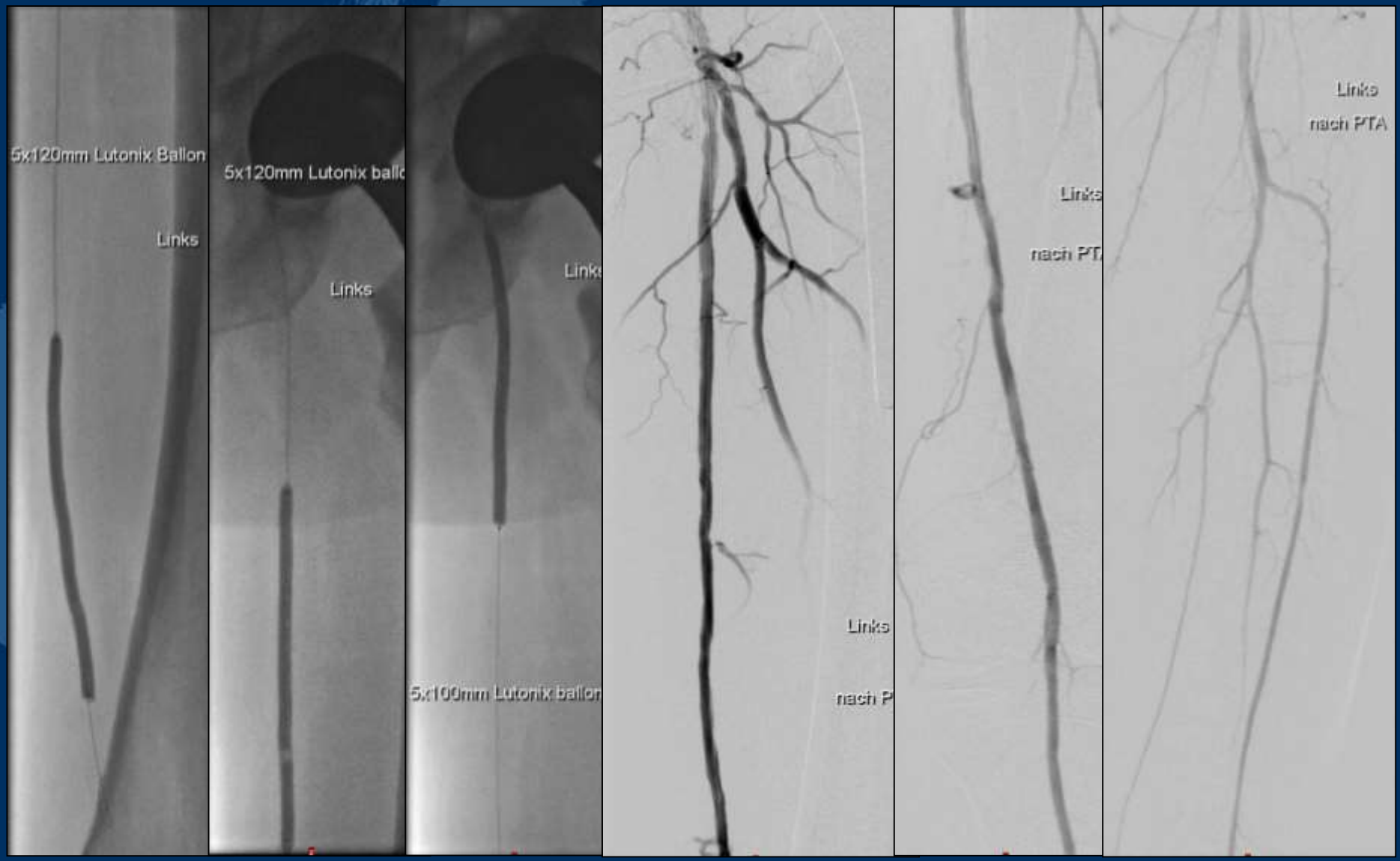


Proper Indications for Scoring Balloons

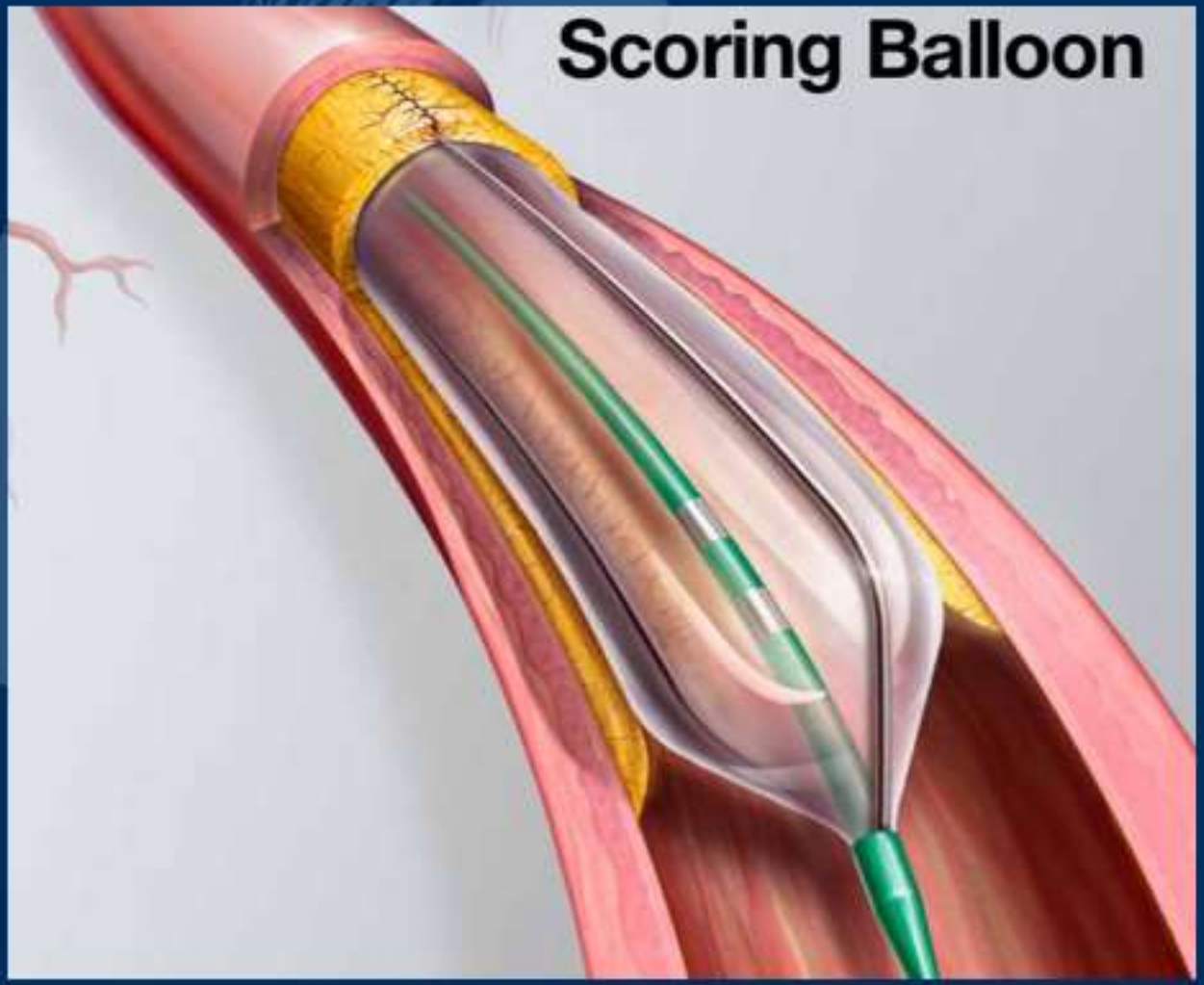
- Calcified Lesions
- Ostial Lesions (to reduce plaques shift)
- In-stent Restenosis
- Bypass Graft stenosis
- Lesion preparation prior to VMI or DEB
- Long Lesions

Challenges with Calcific Lesions in PAD

- Small BTK vessels / long diffuse disease
- No stent zones
- High pressure dilatations
  - Increase arterial trauma
  - May produce major dissections

Walker, Craig: Focal Force Angioplasty for Treatment BTK. *NCVH 2012 Presentation*

UltraScore™ Focused Force PTA Balloon

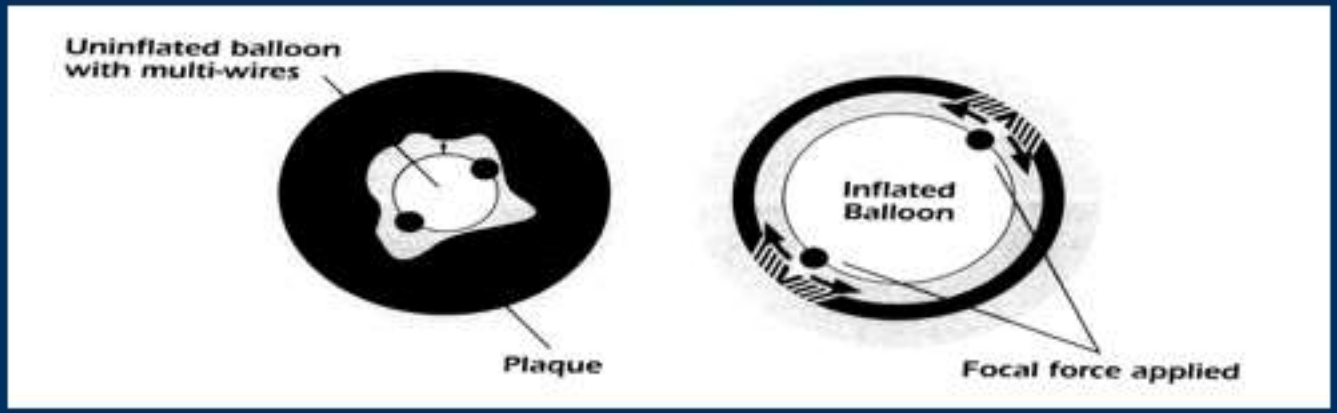


24 x Force

Length up to 300mm

Focused Force Angioplasty

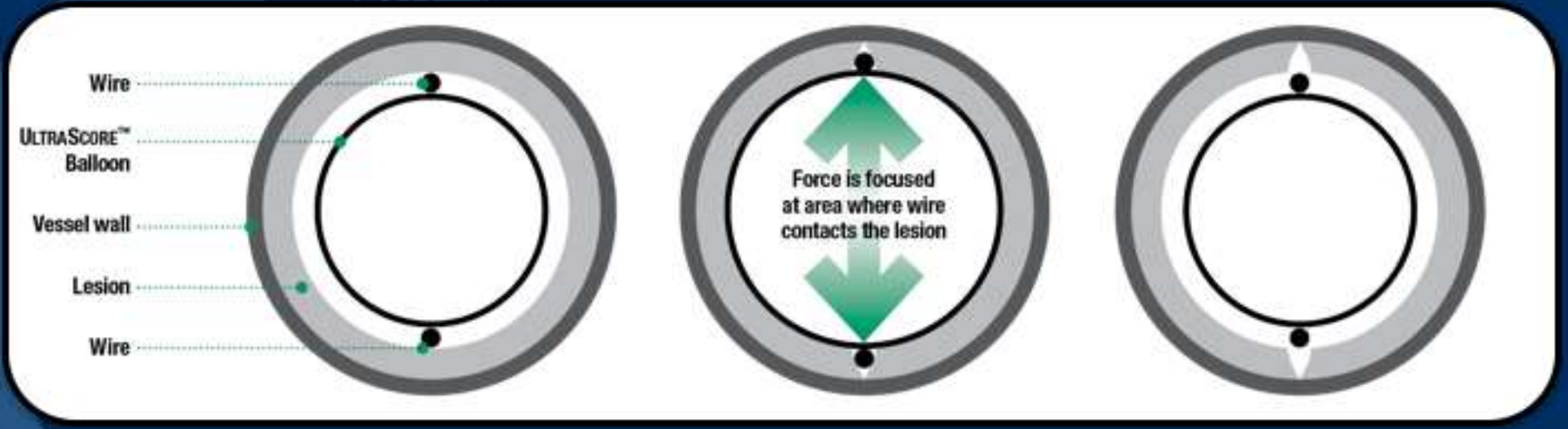
- Incorporates two external focal force wires to introduce high focal stresses longitudinally at low balloon inflation pressures
- This focal force stress concentration can fracture the plaque at low pressure, allowing a slow gradual expansion of the vessel, which can reduce the risk of barotrauma that is associated with use of conventional angioplasty balloons[1]



[1]Solar RJ and Ischinger TA: Focused Force Angioplasty, Theory and Application. *Cardiovasc Radiat Med* 1:47-50. 2003

UltraScore™ Focused Force PTA Balloon

- Mechanism of Action



May allow for a **more controlled plaque fracture** and **less vessel recoil,** even in **calcified lesions**

UltraScore™ Focused Force PTA Balloon

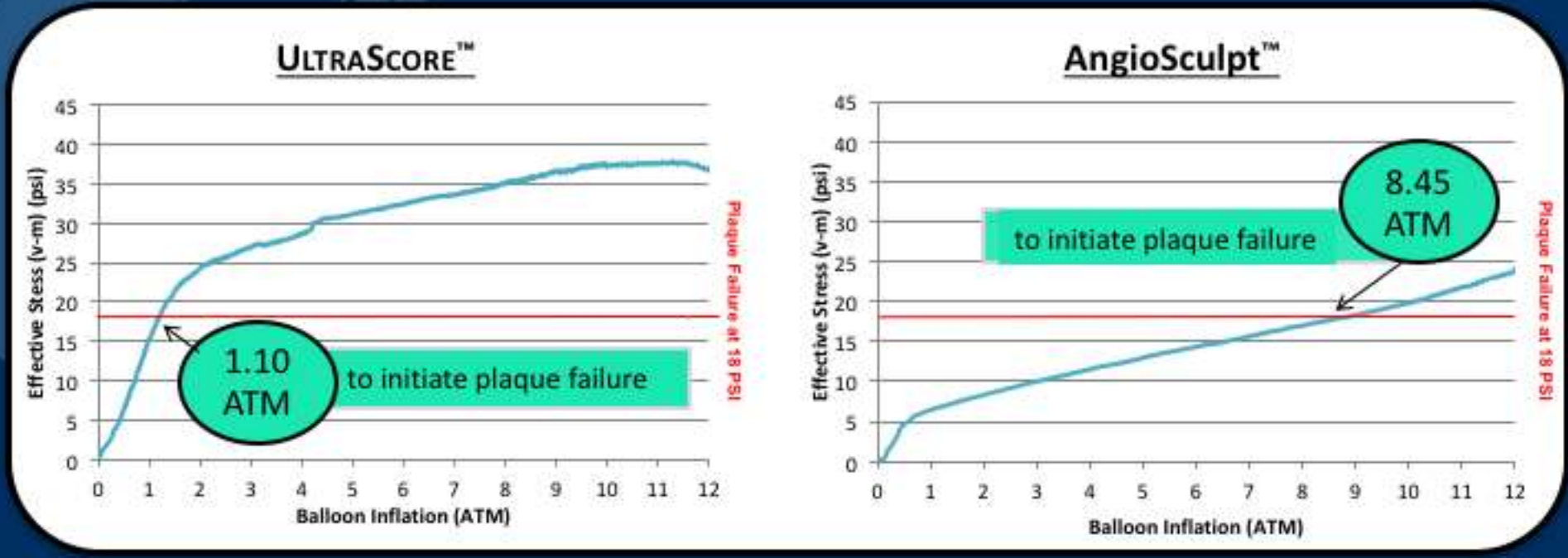
- Product Offering

0.035”	
Shaft Lengths (cm)	130
Balloon Diameters (mm)	4, 5, 6, 7, 8
Balloon Lengths (mm)	20, 40, 80, 100, 120, 150, 200, 300
Sheath Compatibility (Fr)	5F (up to 4X300, 5X150, 6X40), 6F

0.014” – Hydrophilically Coated	
Shaft Lengths (cm)	150
Balloon Diameters (mm)	4, 5, 6, 7, 8
Balloon Lengths (mm)	20, 40, 80, 100, 120, 150, 200, 300
Sheath Compatibility (Fr)	4F (up to 3.5X300), 5F

Testing Results: UltraScore™ to AngioSculpt™

- UltraScore™ causes fracture at **8x lower inflation pressures***

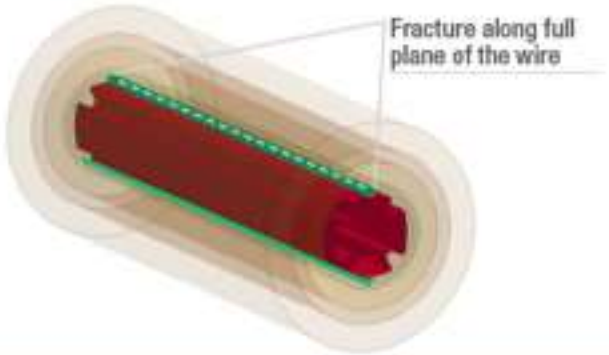


*Based on a simulated finite element analysis. Data on File, Bard Peripheral Vascular, Inc., Tempe, AZ. May not be predictive of clinical performance. Different test methods may yield different results.

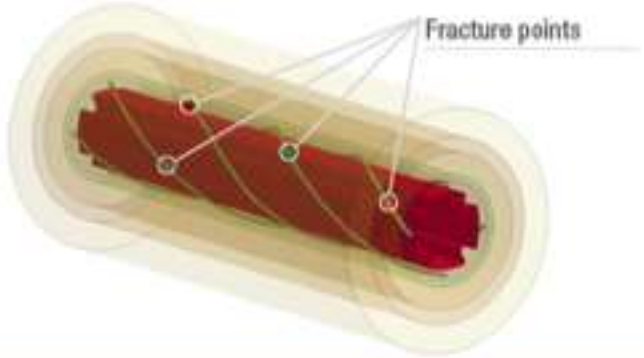
Scoring Mechanism: UltraScore™ to AngioSculpt™

- UltraScore's™ longitudinal scoring wires are **more effective at lower inflation pressure** compared to AngioSculpt's™ wire configuration

UltraScore™
breaks plaque at **1.10atm**
across entire length of lesion



AngioSculpt™
breaks plaque at **8.45atm**
at multiple single points along the lesion



Summary

- Focused force technology is designed for highly calcific PAD
- Focused force technology causes a controlled plaque fracture at lower inflation pressures
- BARD® will be launching ULTRASCORE™ Focused Force PTA Balloon, the next generation scoring balloon technology

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