As simple as scoring: Angiosculpt vessel prep and case review (and a few Tips and Tricks)

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Disclosure

Speaker name: Simon Bays, MD

I have the following potential conflicts of interest to report:

- Paid/invited speaker by Spectranetics
- Contributor to SAVER study, using Stellarex DCB (spectranetics)
3 points to remember

• Angiosculpt causes controlled dissection in calcified vessels
• In turn allows better drug delivery
• In turn allows better long term patency
• Greater freedom from repeated intervention
Background: PTA mechanism of action

Dissections

to break circumferential tensions (hoop stress)

PTA = controlled injury through a progressive pressure increase until - suddenly - vessel structure gives up

Early recoil after PTA

Failure to eliminate circumferential tensions may result in higher chances of recoil

Early failures may be the leading cause of late failures

97% of tibial dilatation show early recoil:
~ 29% lumen narrowing @ 15 minutes post intervention

Background

• General rationale for using drug eluting technology
  – Non drug eluting balloon
  – Good result – DCB
  – Bad result – DES
  – Antiplatelet agents
Calcium – the roadblock

• How to get the drug beyond the calcification?

• More and more complex cases – does anyone do bypass surgery any more??!!

• Heavy calcification

• Crossing catheters, atherectomy, weighted wires etc etc

• Luminal/subintimal
Calcium

Calcium makes vessel opening difficult to obtain and to maintain

- Barrier to optimal dilatation
- Barrier to optimal drug absorption
- Underestimated by angiography
- Key cause of severe dissections
- Bilateral / circumferential calcium ranked as most severe by different calcium grading systems
- Highly prevalent in elderlies, diabetics, kidney disease

Dissection

- Random – plain balloon
- Semi-controlled – cutting balloon
- Controlled – angiosculpt concept

- Controlled dissection allows a better drug delivery throughout the vessel with better long term result (TLR etc)
AngioSculpt Device Overview

- Semi-compliant balloon
- Lengths: 10 to 200 mm
- Diameters: 2.0 to 8.0 mm
- Nominal / RBP: 6-8/ 12-20
- Intr. Sheath compatibility: 5 / 6 F
- Guidewire compatibility: 0.014” / 0.018”

3 laser-cut Nitinol scoring elements
- Helical configuration
- Rectangular edges
Plaque Scoring Rationale

Stress concentration and controlled scoring by scoring elements

- Increase vessel compliance and stabilize luminal gain ($\downarrow$ recoil)
- Reduce flow-limiting dissections
- Potentially increase DCB drug uptake
- Confer precision and stability to balloon dilatation

Plaque Scoring reduces flow limiting dissections vs historical PTA benchmarks
Calcification no predictor of 12-month patency loss after lesion preparation with Scoring Balloon

Results from PANTHER Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions
Adjunctive use of BMS or DCB at discretion of interventionalist
124 lesions

Results by Treatment strategy

<table>
<thead>
<tr>
<th></th>
<th>Angiosculpt</th>
<th>Angiosculpt + DEB</th>
<th>Angiosculpt + Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (cm)</td>
<td>0.1</td>
<td>0.9</td>
<td>0.1</td>
</tr>
<tr>
<td>Occlusions (%)</td>
<td>2.2</td>
<td>17.6</td>
<td>31.6</td>
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</tbody>
</table>
Concept of plaque scoring - reminder

Concept of Plaque scoring:

- Can improve acute results
  - No balloon slippage in fibrotic lesions
  - Less residual stenosis/recoil
  - Less intimal flap after balloon dilatation
  - Potential for higher drug tissue uptake

- Potentially improves long term outcomes after DCB in specific settings such as severe calcium - promising PANTHER registry data for scoring balloon in short and moderate calcified fem.-pop- lesions

- **Calcification was no predictor of 12-month loss of patency as long as lesion preparation with Angiosculpt scoring balloon was performed (hypothesis generating)**

- Has to be proven in an RCT comparing scoring balloons plus DCB with POBA plus DCB
Case 1 – Pre – 68m osteomyelitis
occluded calcified AT
Case 2 – claudicant, soft SFA and calcified TPT
Case 3 – how not to use it – it’s not a cutting balloon!! – 74m claudicant
Post high pressure balloon, then angiosculpt then cutting ballon
Case 4 – 70f 20yard claudicant
Case 4 post angiosclupt
Case 4 post sculpt and DCB
Case 5 – 65m, ulcers – calcified prox AT
Case 6 – ulcers, 87m, short SFA occlusion
Post sculpt and DCB
More cases with IVUS – left short distance claudicant

• Mild distal SFA stenosis, but 70% on IVUS, plastied with 6mm angiosculpt, then 6mm stellarex DCB, with excellent effect.
IVUS AK pop to distal SFA
Pre, post sculpt and post DCB
Diabetic (type 2), right heel ulcer

- Peroneal, TPT, and popliteal disease on MRA
- 2.5mm angiosculpt to peroneal, 3mm to TPT, 5mm to popliteal
- Then Stellarex DCB 3mm to peroneal and TPT, 5mm to popliteal
Slow balloon inflation
IVUS pre and post angiosculpt peroneal
IVUS popliteal pre and post sculpt/DCB
CLI – rest pain and bimalleolar ulcers

- MRA showed distal SFA stenosis and TPT near occlusion
- Single vessel run off
- Angio and ivus showed occluded TPT
- TPT plastied with 3.5 angiosculpt and 4mm stellarex DCB – excellent result
- SFA plastied with 6mm angiosculpt and 6mm stellarex – poor result so stented with Zilver DES – excellent result.
83yo recurrent claudication 200yards

- Previous SFA/popliteal plasty March 2013, redo August 2013 with stent, angioplasty Nov 2016 and now recurrent symptoms again (Dec 2017)
- Left CFA puncture, crossover sheath.
- Dense right CFA calcification, diffuse SFA and popliteal calcification with a patent stent
- Angiosculpt and Stellarex DCB to both areas (6/8mm CFA, 5/6mm SFA)
CFA pre and post IVUS
SFA pre, post angiosculpt and post DCB
Conclusions

• In presence of Calcium, successful pre-dilatation can facilitate good drug delivery

• Angiosculpt avoids flow limiting dissection and need for stent, prevents recoil
  • IN THE RIGHT LESION

• Data is beginning to show better results with DCB patency if angiosculpt used in calcified lesions
Thank you – any questions?
Plaque Scoring Proof of Concept
Optical coherence tomography before (B-C) and after (E-F) scoring balloon angioplasty of 2 RCA stenosis

### Insights from the Heidelberg PANTHER Registry

**A Real-world Application of AngioSculpt in Calcification**

- AngioSculpt® PTA in calcified fempop lesions
- Adjunctive use of BMS or DCB at discretion of interventionalist

#### 101 patients

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Age (years)</td>
<td>71.9 ± 9.3</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>76/25</td>
</tr>
<tr>
<td>Arterial Hypertension, n (%)</td>
<td>94 (93.1)</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>45 (44.6)</td>
</tr>
<tr>
<td>Active smoking, n (%)</td>
<td>25 (24.7)</td>
</tr>
<tr>
<td>Hyperlipidemia, n (%)</td>
<td>74 (93.1)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.9 ± 4.5</td>
</tr>
<tr>
<td>Ankle Brachial Index</td>
<td>0.63 ± 0.22</td>
</tr>
<tr>
<td>Claudicants, n (%)</td>
<td>66 (65.3)</td>
</tr>
<tr>
<td>Critical Limb Ischemia, n (%)</td>
<td>35 (34.7)</td>
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#### 124 lesions*

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<tr>
<td>Occlusions (%)</td>
<td>20 (16.1)</td>
</tr>
<tr>
<td>Lesion Length (cm)</td>
<td>7.4 ± 5.9</td>
</tr>
<tr>
<td>Degree of Stenosis (%)</td>
<td>85.5</td>
</tr>
<tr>
<td>Degree of Calcification, n (%)</td>
<td></td>
</tr>
<tr>
<td>1 (mild)</td>
<td>27 (21.8)</td>
</tr>
<tr>
<td>2 (moderate)</td>
<td>43 (34.7)</td>
</tr>
<tr>
<td>3 (severe)</td>
<td>54 (43.5)</td>
</tr>
<tr>
<td>Lesion Localization:</td>
<td></td>
</tr>
<tr>
<td>Iliacal, (%)</td>
<td>2.5</td>
</tr>
<tr>
<td>Femoral (%)</td>
<td>7836</td>
</tr>
<tr>
<td>Popliteal (%)</td>
<td>18.9</td>
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*Non Randomized – by discretion of the interventionalist

Blessing E. The role of vessel preparation – Insights from the Heidelberg PANTHER REGISTRY, presented at LINC Jan 2013
PANTHER Registry Results

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions
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Treatment strategy
124 lesions
PANTHER Registry Results

Results By Calcification

Results By Treatment Strategy

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Ca++: barrier to optimal drug absorption?

- N=60
- De-novo calcified SFA lesions ≥ 6 cm
- CTO: 31.7%
- DCB with standard pre-dilatation

Severe Calcium

- ↓Primary Patency, ↑LLL
- Barrier to optimal drug uptake
- Circumferential Ca++ distribution worst vs. only longitudinal

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