Rationale and algorithm for below-the-knee acute gain optimization

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Restenosis following PTA of BTK arteries is a multifattorial process which includes:

- Acute recoil
- Late recoil
- Neointimal proliferation
Restenosis following PTA of BTK arteries is a multifactorial process which includes:

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Paclitaxel
Restenosis following PTA of BTK arteries is a multifactorial process which includes:

- Acute recoil
- Late recoil
- Neointimal proliferation
- Paclitaxel
- Less relevant Stents

Rationale
Rationale: early 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

Baumann F, et al.
Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia.
J Endovasc Ther. 2014;21:44-51
Rationale: early recoil

Early failures may be the leading cause of late failures

Algorithm for BTK acute gain optimization

- Correct vessel sizing: IVUS
  1:1 ratio according to IVUS media to media distance

- Scoring balloon
  AngioSculpt, Philips

- Multiple prolonged inflations
  Four 90 sec. inflations
  with 90° rotation of the scoring balloon (total 6 min)
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 Scoring elements
- Nitinol
- helical configuration
- rectangular edges
Plaque Scoring Rationale

Controlled dissections by focal plaque incision, focal stress concentration

- Increase and stabilize luminal gain (↓ recoil)
- Reduce likelihood of flow-limiting dissections
- Confer precision and stability to balloon dilatation
- Potentially increase DCB drug uptake

References:
Algorithm for BTK acute gain optimization

1. Angiogram
2. Standard PTA (*angio based balloon choice*)
3. Angio & IVUS (I)
4. AngioSculpt PTA (*4 inflations, total 6 min.*)
5. Angio & IVUS (II)
6. 15 minutes
7. Angio & IVUS (III)

Study end-point
First end point: minimal lumen diameter MLD (mm)

by automatic quantitative analysis (QCA)
Algorithm for BTK acute gain optimization

Second endpoint: **vessel volume** ($mm^3$) 
*by intravascular ultrasound analysis (IVUS)*
BTK acute gain optimization: angio measurements

<table>
<thead>
<tr>
<th></th>
<th>Post AngioSculpt</th>
<th>15 min post AngioSculpt</th>
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</thead>
<tbody>
<tr>
<td>RVD</td>
<td>2.9 ±0.4</td>
<td>2.9 ±0.4</td>
</tr>
<tr>
<td>MLD</td>
<td>2.7 ±0.5</td>
<td>2.7 ±0.3</td>
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N=5 lesions, 4 patients

Balloon size (mm):
- 3.0 (40%)
- 3.5 (60%)
BTK acute gain optimization: IVUS measurements

**Post AngioSculpt**

Vessel lumen volume

- $623 \pm 34 \text{ mm}^3$

**15 min post AngioSculpt**

Vessel lumen volume

- $614 \pm 42 \text{ mm}^3$

N=5 lesions, 4 patients

Average length 88±24 mm

*I-Lab Boston Sc. IVUS System*
Pre-dilatation 3.0 mm
Standard balloon

Lumen volume  516 mm$^3$

Final dilatation 3.0 mm
AngioSculpt balloon

Lumen volume  631 mm$^3$
Pre-dilatation 3.0 mm
Standard balloon

Plaque rupture
Plaque Scoring Rationale

You can break a glass in different ways
Conclusions

- The results of standard balloon angioplasties of BTK vessels may be jeopardized by acute vessel recoil.

- The combination of correct vessel sizing, scoring balloon angioplasty and multiple prolonged inflations may increase the acute gain and minimize acute vessel recoil.

- The role of these strategy in association with DEB technologies should be explored in future studies.
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Dissections and DCB
Severe, non-flow limiting dissections do not negatively impact DCB outcomes

THUNDER post-hoc analysis
N=86 (43 DCB + 43 PTA)

6-month LLL (mm)
by Angio Core laboratory

24-month TLR (%)

Balloon Angioplasty Mode of Action

Uncontrolled dissections, uncontrolled injury to break circumferential tensions (hoop stress)

The traumatic effect of balloon dilatation: what we did not see before optical coherence tomography

LAD showing the distal (A), mid (B) and proximal (C) segment of the stent after paclitaxel-coated balloon dilatation