Why and where do I use mechanical debulking for the treatment of arterial occlusions?

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Faculty Disclosure

Thomas Zeller, MD

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from:** Abbott Vascular, Bard Peripheral Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme

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“Hostile” Lesions
Where Dubulking Might Improve Outcomes

• Reduce chance of procedural success
• Increase chance of bailout stenting
• Increase rate of complications
• Likely reduce effectiveness of anti-proliferative drugs
• Negatively impact stent expansion
• Increases rate of distal embolization
• Adversely affect long term outcomes
Mechanical Debulking Addresses Clinical Challenges

Lesion characteristics
- Calcium
- In-stent restenosis
- Chronic total occlusions (CTOs)
- Soft plaque
- Thrombus (thrombectomy)

Procedural goals
- Avoid stenting
- Vessel preparation
  - Drug elution
  - Modify vessel compliance
Angiographic Appearance of MMS & Intimal Calcification

- X-ray image of a femoral bifurcation with typical appearance of MMS of the SFA and DFA (native x-ray & angiogram).
- Typical appearance of MMS (“railroad trucks” pattern)


DCB and Calcium (Tepe et al. J Endovasc Ther. 2015)

Not length, nor location but bilateral Calcium distribution observed as strongest predictor of outcome

N=91 (retrospective)
- SFA lesions ~ 5.7 cm
- Restenotic: 45.1%
- CTO: 33.0%
- 6-month LLL (primary endpoint) by Angio Core lab adjudication

Atherectomy and DCB: Clinical Evidence

- **DEFINITIVE AR**: directional atherectomy + DCB vs DCB alone
- Adjunctive atherectomy may improve procedural and clinical outcomes following DCB treatment of the SFA and/or popliteal artery, particularly for longer or severely calcified lesions

### Procedural Results

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>Ath + DCB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success*</td>
<td>64.2%</td>
<td>89.6%</td>
</tr>
<tr>
<td>Bail-out Stent</td>
<td>3.7%</td>
<td>0%</td>
</tr>
<tr>
<td>Flow-limiting Dissection</td>
<td>19%</td>
<td>2%</td>
</tr>
</tbody>
</table>

### Duplex Ultrasound Patency at 12-months

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>DCB + Ather</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions &gt;10 cm</td>
<td>86%</td>
<td>97%</td>
</tr>
<tr>
<td>Severely Calcified</td>
<td>63%</td>
<td>70%</td>
</tr>
<tr>
<td>All patients</td>
<td>90%</td>
<td>93%</td>
</tr>
</tbody>
</table>

*Technical success: Defined as ≤ 30% residual stenosis following the protocol-defined treatment at the target lesion as determined by the Angiographic Core Laboratory. DCB, drug-coated balloon; DUS, duplex ultrasound; SFA, superficial femoral artery*
Optimizing DCB Intervention
Proposed Fem-Pop Treatment Algorithm

Each femoro-popliteal lesion → Pre-Dilatation with 1:1 sized balloon

Flow-limit Dissection or residual stenosis >50%?

Focal Directional Atherectomy

DCB

Stent
Total Occlusions do not predict DCB Failure

Multiple studies consistently indicate total occlusions do not negatively influence DCB outcomes vs. non occlusive lesions


CTOs: Prevalent, Challenges

• ~40% of patients treated for PAD have CTOs

• Complications:
  – Perforation
  – Dissection
  – Embolization
  – Increased radiation and contrast exposure

• Most common reason for open surgical bypass

CTOs Present Many Clinical Challenges

Lesion characteristics

Calcium¹
In-stent restenosis²
Chronic total occlusions (CTOs)³
Thrombus⁴

1. Image Courtesy of Dr. Nick Shammas
2. Image Courtesy of Dr. Thomas Pow
3. Image Courtesy of Dr. Robert Crawford
4. Image Courtesy of Dr. Ali Amim
Thrombus and Drug Elution

- Thrombus is highly prevalent in the periphery and quite often under-diagnosed by angiography.
- Thrombus forms on stents even when not occlusive or angiographically visible.
- A fine layer of thrombus can affect drug elution into the arterial wall.
- Removing thrombus or modifying its presence may be a promising approach in enhancing Drug Eluting Stent / Drug Coated Balloon effectiveness.
Thrombus and Paclitaxel Diffusivity

- Paclitaxel diffusivity is significantly diminished with more RBC cross linked with fibrin in a thrombus.
- Clots with 50% RBC retain 50% more Paclitaxel than pure fibrin clot.

Hwang et al. Circulation 2005;111:1619-1626
Embolic Protection in SFA Interventions?

The Problem

- High-Embolic-Risk Femoropopliteal Interventions
  - Thrombolytic therapy
  - Mechanical thrombectomy
  - Atherectomy
  - Stent graft insertion
  - Unstable plaque

- Devasting sequelae in pts with compromised runoff

<table>
<thead>
<tr>
<th>Author</th>
<th>Patients</th>
<th>Embolized</th>
<th>Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rickard</td>
<td>37</td>
<td>11 (37%)</td>
<td>Failed lysis</td>
</tr>
<tr>
<td>Chalmers</td>
<td>72</td>
<td>6 (8.3%)</td>
<td>Thrombectomy</td>
</tr>
<tr>
<td>Wholey</td>
<td>237</td>
<td>9 (3.8%)</td>
<td>2 amputations</td>
</tr>
</tbody>
</table>

Wholey MH et al Cathet Cardiovasc Diagn 1998;44:159-169
Embolic Protection in SFA Interventions?
The Problem
Distal Embolisation Prevention – Proteus Balloon

Pre-procedure

PROTEUS 6/100

PROTEUS 6/100

Post procedure
Retrieved Material Post PTA
Acute & Subacute SFA-Occlusions
Mechanical Thrombectomy
Distal Embolisation Prevention – Rotarex
Distal Embolisation Prevention – Rotarex
## ECONOMIC BENEFITS

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Authors</strong></td>
<td>Wissgott C, et al</td>
<td>Wissgott C, et al</td>
</tr>
<tr>
<td><strong>Target Vessel</strong></td>
<td>Femoropopliteal arteries</td>
<td>Femoropopliteal arteries</td>
</tr>
<tr>
<td><strong>Number of Patients</strong></td>
<td>256</td>
<td>20</td>
</tr>
<tr>
<td><strong>Hospital Stay</strong></td>
<td>2+1.3 days (1-4)</td>
<td>(1) 2.3 days +-0.67 days (1-3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2) 8.5 days +-13.06 days(1-45)</td>
</tr>
<tr>
<td><strong>Catheter Time / Intervention Time</strong></td>
<td>7+-2.3 min (1-15)</td>
<td>(1) 64.5 min (45-90)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2) 904 min (120-1350)</td>
</tr>
</tbody>
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- no ICU stay
- no lytics required

Potentially:
- less balloons
- less stents
Endovascular Treatment of SFA-ISR

Challenges

Stent-struts

Neo-intimal hyperplasia
Limitations of Treatment of Instant-Restenosis

PTA vs. Cutting Balloon

Dick et al; Radiology 2008,
# Treatment of SFA-ISR

## Drug Coated Balloons

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IN.PACT ISR</strong>&lt;br&gt;(E.Stabile et al. JACC 2012)</td>
<td>39-Patient Registry</td>
<td>92.2% Primary Patency&lt;br&gt;92.2 freedom from TLR&lt;br&gt;ISR length: 8.3 cm&lt;br&gt;12-month freedom from TLR</td>
</tr>
<tr>
<td><strong>DEBATE ISR</strong>&lt;br&gt;(F.Liistro et al. JEVT 2014)</td>
<td>44-Patient Registry vs. historical PTA cohort</td>
<td>Restenosis&lt;br&gt;19.5% (DEB) vs. 71.8% (PTA)&lt;br&gt;(p&lt;0.001)</td>
</tr>
<tr>
<td><strong>FAIR</strong>&lt;br&gt;(H.Krankenberg LINC 2014)</td>
<td>119-Patient RCT</td>
<td>Freedom from TLR:&lt;br&gt;90.8% (DEB) vs. 52.6% (PTA)&lt;br&gt;(p=0.0001)</td>
</tr>
</tbody>
</table>
ISR and DEB

• At 3 year follow-up complete catch-up
• No difference between DEB and POBA
Treatment of SFA-ISR

Drug Coated Balloons

Restenosis Recurrence Rate at two years

Class I

Class II

Class III

Virga V et al. JACC Cardiovasc Int 2014
SFA-ISR and Cool Laser

**EXITE ISR Study**

ELA+PTA: less complications, lower TLR rates, higher Primary Patency rates vs. PTA

- 250 Patients (169 ELA+PTA vs. 81 PTA)
- Mean ISR length: 19.6±12.0 vs. 19.3±11.9 cm
- Occlusive ISR: 30.5% vs. 36.8%

Primary Patency

ELA+PTA vs. PTA @ 6-month: 71.1% vs. 56.4% (p=0.004)

Freedom from TLR

ELA+PTA vs. PTA @ 6-month: 79.8% vs. 63.7% (p=0.003)
SFA-ISR and Cool Laser

**EXITE ISR Study**

ELA+PTA performed proportionally better vs. PTA in longer lesions

<table>
<thead>
<tr>
<th>Lesion Length Estimate</th>
<th>Lower CL</th>
<th>Upper CL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 cm</td>
<td>0.96</td>
<td>4.31</td>
<td>0.002</td>
</tr>
<tr>
<td>15 cm</td>
<td>0.66</td>
<td>1.12</td>
<td>0.003</td>
</tr>
<tr>
<td>25 cm</td>
<td>0.46</td>
<td>0.7</td>
<td>0.006</td>
</tr>
<tr>
<td>35 cm</td>
<td>0.31</td>
<td>0.58</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Dippel E et al. JACC Cardiovasc Int 2015;8:92-101
Rotational Thrombectomy Straub-Rotarex (8F)

1-Year Results

Restenosis rate

- All: 45% (6M), 63% (1Y)
- Native: 33% (6M), 37% (1Y)
- ISR: 54% (6M), 81% (1Y)
- Bypass: 71% (6M), 86% (1Y)
Treatment of SFA-ISR

**ELA/DEB**

100% Occlusive (Tosaka III) ISR with mean ISR treated length: 22.4±9.4 cm vs. 25.9±8.7 cm

12-month Primary Patency: 66.7% vs. 37.5% (p= 0.01)

Gandini R et al, JET 2013;20:805-813
Treatment Algorithm in Thrombotic Femoro-Popliteal Occlusions

1\textsuperscript{st} choice: Mechanical Thrombectomy
2\textsuperscript{nd} choice: Rotational Aspiration Atherectomy

- In case of residual thrombus
  - Local lysis
  - DCB

- Good result
  - DCB according to RVD + 1mm
  - Additional BMS if necessary
Treatment Algorhythm in ISR Femoro-Popliteal Lesions

Occlusion

Mechanical Thrombectomy or Atherectomy

Stenosis

DCB according to stent diameter

Additional BMS if necessary
Why and where do I use mechanical debulking for the treatment of arterial occlusions?