Size Matters?
The Role of Lumen Gain in BTK and How to Achieve it

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Disclosure

• Equity – LimFlow SA
• Consultant/Advisory Board
  • Medtronic
  • BSC
  • Abbott Vascular
  • BD
  • LimFlow SA
  • Philips
  • Orbus Niech
  • PEDRA
  • Bypass Solutions
  • 3M / Acelity
Agenda

• Pathology
• Size of a normal Tibial vessel
• Why is lumen gain /bigger better important?
• Improving Assessment of Lumen Gain
  – Anatomical imaging
  – Functional assessment
• How do we achieve lumen gain
**Intimal Calcium**

- Associated with advanced atherosclerotic plaques \(^{1,2}\)
- In larger arteries including coronaries
- Associated with interventional consequences eg dissection post PTA \(^{3}\)

**Medial Calcium (Monckeberg)**

- Independent of atherosclerosis \(^{1,2}\)
- Separate development pathway from intimal calcium \(^{1,2,4}\)
- Located in muscular arteries of extremeties \(^{2}\) and in concentric rings
- Leads to vessel wall stiffening and increased pulse pressure \(^{1}\)
- Common in diabetics and renal disease

What is the correct size of a tibial vessel? - **ATA vs PTA**

<table>
<thead>
<tr>
<th></th>
<th>ATA</th>
<th>PTA</th>
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<tbody>
<tr>
<td>Prox</td>
<td>3.3 ± 0.71</td>
<td>2.9 ± 0.54</td>
</tr>
<tr>
<td>Dist</td>
<td>2.3 ± 0.61</td>
<td>2.3 ± 0.52</td>
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- Echo measure in 124 legs
- Mean diameter ± 50 mm

Courtesy Ferraresi
Elastic Recoil following POBA

97% Recoil ( >10% recoil 15m after POBA)

29% Mean MLD lumen reduction (15 min)

MLD = 1.47mm

Medial calcification produces vessel recoil and restenosis$^{2,3,4}$

1) Baumann et al, Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia, J Endovasc Ther 2014
2) Guzman et al, Tibial artery calcification as a marker of amputation risk in patients with PAD, JACC 2008
3) Zettervall et al, Association of arterial calcification with CLI in patients with PAD, J Vasc Surg 2017
4) Mustapha et al, One-Month Duplex Ultrasound Evaluation of Vessel Recoil After Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12m TLR, AMP 2017
Why is Lumen Gain important?

• Lumen gain is necessary for *wound healing/limb salvage*

• Lumen gain affects *vessel patency*
Diameter of Bypass Conduits affects *Patency* and *Limb Outcomes*

- 239 infrapopliteal reversed greater saphenous vein graft bypasses for CLI 7 year period,
- 4 grps: <3.0 mm, 3.0 mm, 3.5 mm, > = 4.0 mm measured with caliper
- A pattern of increasing *graft patency* and *limb salvage* as diameter increased
- long 3.0 mm and all <3.0 mm high risk for failure


$$Q = \frac{\Delta P \pi r^4}{8 L \eta}$$

Q = Flow, r = radius, L = length, P = pressure
Lumen Gain for better Patency
Tibial US after 1 month ➔ predictive of reintervention at 12 months

Recoil and vessel diameter were significant predictors of re-intervention within 12 months
every 10% recoil, odds ratio 12.76
IMPROVING ASSESSMENT OF LUMEN GAIN?
**Anatomical Imaging** of lumen gain

- **Angiography:**
  - Undersizing may be up to 1mm

- **IVUS**
  - Plaque morphology
  - Lumen gain

- **OCT**
  - Short lesions only, cumbersome in long lesions


Anatomical ways to measure effects of Lumen Gain - IVUS
**Functional** ways to measure effects of Lumen Gain – **PEDRA**

- Based on scatter of Coherent Laser Photons
- Measurement of **Deep Tissue perfusion** (8mm)
- Radiolucent probes attached before, during and after Angio
HOW DO WE ACHIEVE LUMEN GAIN?
**Aim** of Interventions for BTK Lumen Gain

Lumen gain without:
- Excessive dissection
- Excessive vessel injury
- No complications of rupture
- No excessive size mismatch
- No distal embolism
- No permanent implant if possible

**Solutions** for *Acute* and *Sustained* lumen Gain

- Optimal POBA
- HP NC POBA
- Plaque modifying balloons
- Atherectomy
- DCBs
- Tacks/DES/Bioabsorbable scaffolds
Optimising POBA – *Prolonged POBA*

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<tr>
<th></th>
<th>30</th>
<th>180</th>
<th>P Value</th>
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<tbody>
<tr>
<td>Major dissection (grades 3 and 4)</td>
<td>16</td>
<td>5</td>
<td>.010</td>
</tr>
<tr>
<td>Minor or no dissection (grades 1 and 2)</td>
<td>21</td>
<td>32</td>
<td>.010</td>
</tr>
<tr>
<td>Further interventions</td>
<td>20</td>
<td>9</td>
<td>.017</td>
</tr>
<tr>
<td>Stent</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Further dilation (Prolonged dilation, dilation with larger diameter)</td>
<td>16</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Residual stenosis (&gt;30%)</td>
<td>12</td>
<td>5</td>
<td>.097</td>
</tr>
<tr>
<td>Complication (embolization, thrombosis)</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mean ankle-brachial index (before, after intervention)</td>
<td>0.66, 0.87</td>
<td>0.65, 0.84</td>
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*Prolonged inflation (180 sec)* improves the immediate result of BTK angioplasty compared to short dilation times (30 sec).

Significantly fewer major dissections and a modest reduction of residual stenoses are observed.

High-pressure, non-compliant balloon angioplasty for long and calcified infrapopliteal and inframalleolar lesions is feasible.

Plaque Modifying Balloons

Vasctrak-Balloon Dilatation
Atherectomy

STEALTH 360® Peripheral Orbital Atherectomy System
Streamlined Setup and Treatment

Circumferential Cuts
• Protects the adjacent tissue
• Minimizes the risk of complications

Crews
Micro Crown
Classic Crown
Solid Crown

OAS Pump
• Mounts directly to an I.V. pole
• Bathes shaft and crown with Viper/Slide
• Lubricant to facilitate smooth device operation

Crews shown are the 1.25 mm Micro Crown, 1.56 mm Classic Crown, and 2.60 mm Solid Crown. Photographs are not to scale and for illustrative purposes only.
Lithotripsy
Tack® Implant
- Unique anchoring minimizes migration
- Nitinol with gold radiopaque markers
- Designed for high-accuracy deployment

4 Fr Delivery System
- Pin-and-pull delivery technique
- 150 cm length 0.014” guidewire
- Over-the-wire system
The SAVAL™ Drug Eluting Vascular Stent System

- Nitinol self-expanding stent
- Flexible, crush-resistant scaffold
- Diameter compliant
- Polymer-drug coating (PBMA/PVDF:HFP-paclitaxel)
- Provides sustained release of paclitaxel

CAUTION: Investigational device and not available for sale in the U.S.
Bioabsorbable Scaffolds

2 Year Pooled Analysis of a Infra-popliteal BVS
A Multi Centre Study

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Ramon Varcoe MD
Prince of Wales Hospital
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WORD OF CAUTION
Oversizing and “slow flow”

Size of run-off vessels will also dictate size of balloon
Summary

• Lumen gain is important for
  – Perfusion ➔ wound healing
  – Patency
• We need better tools to evaluate success of our procedures and observe lumen gain
• A multitude of endovascular tools will help us push the envelope