How to reduce dissections in BTK: techniques & devices

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Disclosure

Speaker name:

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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
Clinical problem

- Incidence 5.9%-6.4% (2 meta-analysis, short lesions)
- Probably more frequent in longer lesions
- In long dissections bail-out stenting not feasible

Razavi MK et al JVIR 2014;25:1489-1496
Mustapha JA et al Circ Cardiovasc Interv 2016; 9:e003468
Treatment

- Prolonged balloon inflation
- Bail-out stenting (DES)
Treatment
Treatment
Treatment
Prevention of dissections

- Optimal Balloon sizing
- Balloon inflation rate
- Balloon pressure
- Balloon inflation duration
- Role for specialty balloons
What about data?

- Angiosculpt
- Chocolate
- Cutting balloon (only short lesions, better outcome than PTA)

- No published data on Scoreflex and VascuTrak

Ponylijusz W et al, CVIR 2013;36:1500-1507
Results of the Multicenter First-in-Man Study of a Novel Scoring Balloon Catheter for the Treatment of Infra-Popliteal Peripheral Arterial Disease

Dierk Scheinert, MD, Patrick Peeters, MD, Marc Bosiers, MD, Gerry O’Sullivan, MD, Sherif Sultan, MD, and Gary Gershony, MD

Objective: To evaluate the AngioSculpt® (ASC), a novel scoring balloon catheter designed to treat complex diffuse fibro-calcific atherosclerotic lesions and avoid device slippage during deployment, in patients with infra-popliteal disease. Methods: The ASC incorporates a flexible nitinol scoring element containing three or more spiral struts which encircle a minimally compliant balloon to create focal concentration of the dilating force. Patients scheduled for percutaneous intervention of infra-popliteal arteries or planned amputation and with a reference vessel diameter of 1.5-3.5 mm were included in the study. Results: A total of 42 patients and 56 lesions were treated at five sites. Of these, 38 patients (89.5%) presented with critical limb ischemia (Rutherford Class ≥ 4). The ASC was successfully deployed in 98.2% (55/56) of lesions attempted and was used as primary therapy without stenting in 89.3% (50/56). Lesion morphology was complex, including moderate/severe calcification in 73%, lesion length 33.9 ± 42.2 mm, bifurcation in 26.8%, and ostial in 12.5%. There was no significant device slippage and no perforations. Post-ASC dissections occurred in only six (10.7%) lesions and were minor or resolved with stenting. In 13 patients initially referred for amputation, ASC treatment resulted in limb salvage. Conclusions: The ASC is highly effective in a broad range of complex lesion morphologies, in most cases as stand-alone therapy, is associated with a very low complication rate and avoids device slippage during deployment. Additional studies are planned to assess the long term efficacy of this promising new technology.

Key words: percutaneous transluminal angioplasty; atherotomy; critical limb ischemia; below-the-knee
Angiosculpt (FIM BTK)

- 42 patients, 56 lesions
- Lesion length $33.9 \pm 42.2$ mm
- Dissection rate 10%
- No long-term results

Scheinert D et al, Cath Cardiovasc Interv 2007;70:1034-1039
Angiosculpt (BTK registry)

- 31 patients, 36 BTK lesions (mean lesion length 32.4 mm)
- Low incidence of dissection (9.7%)
- Primary patency rate at 1 yr: 61% (need for improvement)

Bosiers M et al, Vascular 2009;17:29-35
POBA vs. Chocolate

- **PT Prox** POBA 1:1 2 mm apart
- **PT Proximal** POBA 1.2:1 2 mm apart
- **PT Distal** Chocolate™ PTA 1.3:1 2 mm apart
Chocolate Bar Study: Overview

Prospective, multicenter, real-world post market registry evaluating use of Chocolate™ balloon catheter in above and below the knee lesions

- 488 patients enrolled
- 33 sites
- Independent adjudication by independent core labs

### Inclusion Criteria

- Any ATK or BTK lesion with at least 1 vessel runoff successfully crossed with a guidewire
- Use of atherectomy/re-entry devices accepted

### Exclusion Criteria

- Presence of a flow-limiting dissection at the target lesion prior to use of the Chocolate™ PTA balloon (secondary to the use of another device)
- Patients with Rutherford 6
- Chocolate™ PTA balloon not used in accordance with study protocol (2 min inflation to at least nominal pressure)

Data on file with Medtronic — CLR782: Final Study Report The Chocolate BAR by Trireme Medical, LLC

2. Vascure DUS Core Lab, Boston, MA, US
3. Yale University Core, New Haven, CT
# Chocolate Bar Study\textsuperscript{1,2}: Baseline Characteristics

| Patient Characteristics         | ATK**  
|                                | N=262 | BTK  
|                                |       | N=226 |
| Age (yrs)                      | 69.7 ± 10 | 71.5 ± 10.3 |
| Male Gender                    | 61.1% (160) | 65.9% (149) |
| Diabetes                       | 50.4% (132) | 58.8% (133) |
| Hypertension                   | 92.0% (241) | 92.5% (209) |
| Hyperlipidemia                 | 84.7% (222) | 82.3% (186) |
| Current Smoker                 | 29.4% (77) | 11.9% (27) |
| CLI                            | 32.1% (84) | 55.8% (126) |
| RCC 5+                         | 19.1% (50) | 37.6% (85) |

| Lesion Characteristics         | N=265 lesions | N=245 lesions |
| Lesion Length (mm)             | 83.5 ± 59.8 (250) | 66 ± 48.5 (207) |
| Total Occlusion                | 23.0% (60/261) | 41.1% (99/241) |
| Calcification - Moderate       | 43.5% (111/255) | 38.1% (60/229) |
| Calcification - Severe         | 20.0% (51/255) | 2.2% (5/229) |

Calcification: Readily apparent densities noted within the apparent vascular wall at the site of a stenosis.
- none/mild (=0)
- moderate (densities noted only during the cardiac cycle prior to contrast injection =1)
- severe (radiopacities noted without cardiac motion prior to contrast injection generally involving both sides of the arterial wall =2)

\textsuperscript{1} Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC

\textsuperscript{2} Mustapha J, et al. Chocolat BAR registry. CCI 2018;1-5
## Chocolate Bar Study\(^1,\,^2\): Outcomes

<table>
<thead>
<tr>
<th>Procedural Success</th>
<th>ATK** (n = 262)</th>
<th>BTK (n = 226)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Flow Limiting Dissections* (Site Reported)</td>
<td>97.7%</td>
<td>99%</td>
</tr>
<tr>
<td>Freedom from Flow Limiting Dissections* (Adjudicated)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Achieved &lt;30% Diameter Stenosis (Adjudicated)</td>
<td>85.1%</td>
<td>84.6%</td>
</tr>
<tr>
<td>Freedom from Bail-Out Stenting</td>
<td>98.4%</td>
<td>99.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Outcomes (Kaplan Meier)</th>
<th>ATK** (n = 262) 12 months</th>
<th>BTK (n = 226) 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Target Lesion Revascularization</td>
<td>78.5%</td>
<td>88.9%</td>
</tr>
<tr>
<td>Freedom from Major Unplanned Amputation</td>
<td>97.2%</td>
<td>96.7%</td>
</tr>
<tr>
<td>Freedom from All-Cause Mortality</td>
<td>93.3%</td>
<td>97.1%</td>
</tr>
</tbody>
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*Flow Limiting Dissections defined as: Type E - Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen, and Type F - Filling defect accompanied by total occlusion

** many ATK patients had concurrent BTK disease

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1. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
Dissection Rates Across Standard and Specialty PTA

3. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC

Results are from different studies and results may vary in head-to-head study; for illustration purposes only.
Representative case

• 65-year old male
• Risk factors
  – Renal insufficiency (on dialysis)
  – Hypertension
  – IDDM type 2
• Osteomyelitis and amputation of 2\textsuperscript{nd} MT
• Vascular lab
  – Occlusion PTA and ATA
Representative case
Representative case
Representative case
Representative case

Work from distal to proximal
Representative case
Representative case
Representative case
Summary

• Optimal balloon angioplasty can lead to good acute results without the need for stenting

• Chocolate™ balloon catheter is an advanced angioplasty balloon that delivers controlled dilation of the vessel
  • Minimizes the formation of dissections also in the BTK vessels
  • Results from the Chocolate Bar BTK registry show freedom from flow limiting dissection of 99% and very low bailout stent rate
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