Vessel Preparation Prior to DCB and Stenting: *How to Do It.*

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Company</th>
<th>Affiliation/Financial Relationship</th>
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</table>
| • Abbott Vascular     | • Scientific Advisory Board  
                          • Consulting agreement  
                          • Speakers fees / Honorarium                                          |
| • Medtronic           | • Scientific Advisory Board  
                          • Consulting agreement  
                          • Speakers fees / Honorarium  
                          • REALITY Trial National Co-PI                                         |
| • Boston Scientific   | • CLI Advisory Board                                                     |
| • Cook Medical        | • Proctoring and Case Review  
                          • Honorarium                                                            |
Percutaneous Lower Extremity Intervention: 
*Evolution in Technique and Treatment Paradigm*

- SFA “Full Metal Jacket” likely not the best treatment strategy anymore
- Diverse range of options for SFA treatment has seen a shift away from balloon/stent
- Increasing number of treatment options have ushered in greater focus on technique
- Technique now individualized to patient or lesion
What Is “Vessel Preparation”?  

- Improving luminal gain to deliver an implant  
- Altering residual mechanical forces in vessel  
- Debulking calcium or barriers to diffusing
Evolving Concept of Vessel Preparation

- Cutting Balloon
- CSI Atherectomy
- TurboHawk
- Chocolate PTA
- Angiosculpt
- Intravascular Lithotripsy
When is Vessel Prep Most Important?

- Drug-coated Balloons in complex lesions
- Interwoven Nitinol Stent implantation
- Bioresorbable Technology
# Vessel Prep in conjunction with DCB

<table>
<thead>
<tr>
<th></th>
<th>LEVANT Global(^1)</th>
<th>IN.PACT Global Full Clinical Cohort(^2)</th>
<th>IN.PACT Global Long Lesion(^3)</th>
<th>IN.PACT Global CTO(^4)</th>
<th>IN.PACT Global ISR(^5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Follow-up</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interim Site-reported</td>
<td>460 subjects</td>
<td>1406 subjects Complete follow-up Core Lab-adjudicated</td>
<td>157 subjects Complete follow-up Core Lab-adjudicated</td>
<td>126 subjects Complete follow-up Core Lab-adjudicated</td>
<td>131 subjects Complete follow-up Core Lab-adjudicated</td>
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<tr>
<td></td>
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<tr>
<td><strong>Key Lesion Characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length (cm)</td>
<td>10.1 cm</td>
<td>12.1 cm</td>
<td>26.4 cm</td>
<td>22.9 cm</td>
<td>17.2 cm</td>
</tr>
<tr>
<td>CTO (%)</td>
<td>30.9%</td>
<td>35.5%</td>
<td>60.4%</td>
<td>100.0%</td>
<td>34.0%</td>
</tr>
<tr>
<td>Ca(^{2+}) (%)</td>
<td>34.2%</td>
<td>68.7%</td>
<td>71.8%</td>
<td>71.2%</td>
<td>59.1%</td>
</tr>
<tr>
<td>Primary Patency</td>
<td>91.0%</td>
<td>-</td>
<td>91.1%</td>
<td>84.4%</td>
<td>88.7%</td>
</tr>
<tr>
<td>FF TLR/CD-TLR</td>
<td>92.0%</td>
<td>92.6%</td>
<td>94.0%</td>
<td>88.2%</td>
<td>92.9%</td>
</tr>
<tr>
<td>Bail-out Stent (%)</td>
<td>27.6%</td>
<td>25.3%</td>
<td>40.4%</td>
<td>46.8%</td>
<td>14.5%</td>
</tr>
</tbody>
</table>

Vessel Prep in conjunction with DCB

Impact of Calcium on Results of DCBs

Atherectomy is associated with extremely low bailout stent rates and may modify plaque surfaces to allow better drug delivery with DCB.
**Vessel Prep in conjunction with DCB**

### DEFINITIVE-AR

<table>
<thead>
<tr>
<th>Design</th>
<th>Randomized; DA+DCB vs DCB alone</th>
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</thead>
<tbody>
<tr>
<td>Patients</td>
<td>121 (98% Claudicant)</td>
</tr>
<tr>
<td>Multicenter</td>
<td>Yes</td>
</tr>
<tr>
<td>Location</td>
<td>SFA</td>
</tr>
<tr>
<td>Lesion Description</td>
<td>Yes (11.2cm, registry arm of severely Ca++)</td>
</tr>
<tr>
<td>Angio Core lab</td>
<td>Yes</td>
</tr>
<tr>
<td>Duplex Core lab</td>
<td>Yes</td>
</tr>
<tr>
<td>12mo Primary Patency</td>
<td>91% (&gt;10cm); 70% (Severe Ca++); 93% all</td>
</tr>
<tr>
<td>12mo Freedom TLR</td>
<td>No</td>
</tr>
<tr>
<td>Bailout Stent Rate</td>
<td>N/A</td>
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</tbody>
</table>

**DEFINITIVE-AR**
Vessel Prep in conjunction with DCB

DEFINITIVE AR: 12-mo Patency by Angio

<table>
<thead>
<tr>
<th>Category</th>
<th>DA+DCB</th>
<th>DCB</th>
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<tbody>
<tr>
<td>All Patients (N=34)</td>
<td>82.4%</td>
<td>71.8%</td>
</tr>
<tr>
<td>Lesions &gt; 10 cm (N=22)</td>
<td>90.9%</td>
<td>68.8%</td>
</tr>
<tr>
<td>All Severe Ca++ (N=24)</td>
<td>58.3%</td>
<td>42.9%</td>
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### Vessel Prep in conjunction with DCB

**REALITY Study**

<table>
<thead>
<tr>
<th></th>
<th>REALITY</th>
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<tbody>
<tr>
<td>Randomized</td>
<td>Prospective registry of atherectomy + DCB</td>
</tr>
<tr>
<td>Patients</td>
<td>150, Rutherford 2-4</td>
</tr>
<tr>
<td>Multicenter</td>
<td>Yes (10 U.S. sites, 3 German sites)</td>
</tr>
<tr>
<td>Location</td>
<td>SFA/pop</td>
</tr>
<tr>
<td>Lesion Description</td>
<td>Yes (&gt;6-25cm US, &gt;6 Germany, PACS 3-4)</td>
</tr>
<tr>
<td>Angio Core lab</td>
<td>Yes</td>
</tr>
<tr>
<td>Duplex Core lab</td>
<td>Yes</td>
</tr>
<tr>
<td>IVUS Core lab</td>
<td>Yes</td>
</tr>
<tr>
<td>Histology Core lab</td>
<td>Yes</td>
</tr>
<tr>
<td>12mo Primary Patency</td>
<td>Yes</td>
</tr>
<tr>
<td>24mo Freedom TLR</td>
<td>Yes</td>
</tr>
<tr>
<td>Bailout Stent Rate</td>
<td>Yes</td>
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</tbody>
</table>
Vessel Prep in conjunction with DCB
Vessel Prep in conjunction with DCB

Goals of Vessel Preparation when treating with DCBs:
1. Debulk residual mechanical forces the lead to need for bailout stenting
2. Improve drug delivery and diffusion into arterial wall
Vessel Prep in conjunction with DCB

- Cadaveric fempop arteries treated with orbital atherectomy under simulated blood flow model
- Pretreatment lesion composition affected paclitaxel absorption (5.5-fold decrease with each calcified quadrant)
- Treated segments revealed thinner intima, 45% less plaque calcification, higher paclitaxel absorption and deeper paclitaxel penetration.
When is Vessel Prep Most Important?

- Drug-coated Balloons in complex lesions
- Interwoven Nitinol Stent implantation
- Bioresorbable Technology
Vessel Prep for Woven Nitinol Stents

**When nominally deployed:**¹
- 91% 12mo Primary Patency
- 94% 36mo Freedom from TLR

¹Data from Superb Trial, Presented at VIVA 2015
Vessel Prep for Woven Nitinol Stents

Vessel prep strategy may be considered much more “aggressive” than DCB prep where focus is on drug delivery and avoiding vessel “injury”
Vessel Prep for Woven Nitinol Stents

Primary Patency (K-M) by Percent Compression/Elongation at 12 months:

- **Moderate (21-40%)**: 83.3% (p=0.480, n=6)
- **Minimal (11-20%)**: 81.8% (p=0.268, n=22)
- **Nominal (± 10%)**: 90.5% (p=0.026, n=74)
- **Minimal (11-20%)**: 73.7% (p=0.029, n=38)
- **Moderate (21-40%)**: 74.4% (p=0.029, n=39)
- **Severe (>40%)**: 57.7% (p=<.001, n=26)

Graph showing comparisons of primary patency for different levels of compression/elongation.
Vessel Prep for Woven Nitinol Stents

CTO
Vessel Prep for Woven Nitinol Stents
Vessel Prep for Woven Nitinol Stents

Predilate with 6x250 Armada35

Residual focal waists

Options:
- Short NC balloon
- Atherectomy
- Scoring balloon
- Cutting balloon
- “Pave & Crack”
Vessel Prep for Woven Nitinol Stents

High-magnification
Slow deployment
5.5x120 Supera (x2)
Emerging Technology for Vessel Preparation

Significant lumen gain while minimizing vessel wall injury

Applicability to DCBs, interwoven stents and scaffolds

Shockwave Intra-vascular Lithotripsy

Significant lumen gain while minimizing vessel wall injury

Applicability to DCBs, interwoven stents and scaffolds
Conclusions

- Increasing number of effective tools for the SFA/pop means that we can optimize and individualize treatment for specific lesion types.
- Vessel preparation is becoming increasingly recognized as important for optimizing outcomes.
- Strategies for vessel prep are especially important for increasing drug delivery in more complex lesions and prior to deployment of certain types of scaffolds.
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