Vessel prep is the key...
to extending the role of DCBs to more challenging lesions and to optimize the outcome of stenting

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Disclosure

Peter A. Schneider

I have the following potential conflicts of interest to report:

Scientific Advisory Board (non-paid): Cardinal, Abbott, Medtronic

Royalty (modest): Cook

Co-founder and Chief Medical Officer: Intact, Cagent

Enter patients into studies: NIH, Bard, Gore, Medtronic, BSI, Silk Road (no financial relationship).

VIVA Board member (nonprofit)
Vessel Preparation

Technologies that Benefit
• Drug coated balloon
• Woven nitinol stent
• Bioabsorbable vasc scaffold
• Stent-graft
• Self expanding nitinol stent

Tools for Vessel Preparation
• PTA
• Modified angioplasty balloons
• Atherectomy
• Lithoplasty

Sustained lumen gain that permits definitive treatment.

Finished result must be without surface irregularities.
Vessel Prep=Drug Uptake

- Calcium limits drug uptake
- 5-20% of Paclitaxel taken up by artery wall.
- Uneven distribution of drug
- More drug into the artery wall is key, but must be done in a uniform manner, both longitudinally and circumferentially
- Better delivery=lower dose on the balloon?

Presentation Charing Cross Meeting 2016
“Drug needs to enter the medial layer within the first 3 days”, R. Virmani, MD
IN.PACT DCB vs PTA Trial Design

Study Designed to Reduce Bias Against Control Group

PTA Pre-Dilatation
With 1mm undersized Uncoated Balloon

Successful Pre-Dilation
Randomize 2:1

Test Arm:
Dilatation with Drug Coated Balloon

Control Arm:
Dilatation with Uncoated Balloon

Treat per standard practice
30 day follow-up for safety

PTA Pre-Dilatation
With 1mm undersized Uncoated Balloon

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Treat per standard practice
30 day follow-up for safety
Post-PTA Dissection

Ballooon angioplasty causes too much acute injury

Why do we think that balloon angioplasty will be the best way to prepare the lesion, deliver the medication and treat the lesion, all at the same time?
Overexpansion Results in Improved 1-year Patency

LEVANT 2 Clinical Trial
Average 0.9:1
Balloon to Artery Ratio

LEVANT 2 Full Wall Apposition Sub Group
≥1 .04: 1 Balloon to Artery Ratio
Clinical Limitations & Unmet Needs

**Calcium as a Barrier**

Calcium Limits Vessel Expansion

Significant difference in vessel compliance leads to overstretch in non-diseased tissue causing dissections, recoil, excessive injury, and poor outcomes.

![Fully inflated balloon](image1)

Calcium May Limit Drug Effect

Increased lesion length is an independent predictor of decreased patency.

**Longer Lesion Length**

Increased lesion length is an independent predictor of decreased patency.

![Graph showing lesion length vs primary patency](image2)

References:


Courtesy: L Garcia
Challenges with DCB and Long Lesions
Need for Dissection Repair

Provisional Stenting in Randomized Controlled Trials may not be representative of actual stenting in studies due to study design
Full wall to wall balloon inflation: no waist

Inadequate stent expansion due to calcium-mediated recoil

Limeted flow through stent

Pre-dilatation

Supera Stent 6.5mm

Stent Deployment

Final Result

SFA
Chronic Total Occlusion
220mm lesion length
POBA 6mm X 120mm balloon

Compliments M Razavi
Superb Trial
Deployment Technique and 12-Month Patency

<table>
<thead>
<tr>
<th>Compression Type</th>
<th>Patency (%)</th>
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<tbody>
<tr>
<td>Nominal (±10%)</td>
<td>90.5</td>
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<tr>
<td>Minimal Compression (11-20%)</td>
<td>83.3</td>
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<tr>
<td>Moderate Compression (21-40%)</td>
<td>81.8</td>
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<tr>
<td>Minimal Elongation (11-20%)</td>
<td>73.7</td>
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<tr>
<td>Moderate Elongation (21-40%)</td>
<td>74.4</td>
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<tr>
<td>Severe Elongation (&gt;40%)</td>
<td>57.7</td>
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L Garcia VIVA 2016
# Atherectomy Devices

<table>
<thead>
<tr>
<th>Feature</th>
<th>Jetstream™ Atherectomy System (Boston Scientific)</th>
<th>Peripheral Rotablator™ Rotational Atherectomy System (Boston Scientific)</th>
<th>Diamondback 360™, Stealth 360™ Atherectomy System (Cardiovascular Systems, Inc)</th>
<th>SilverHawk™, TurboHawk™ Plaque Excision System (Covidien)</th>
<th>Turbo-Elite™ Laser Atherectomy Catheter (Spectranetics)</th>
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<tbody>
<tr>
<td>Front-Cutting</td>
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<td>✓</td>
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<tr>
<td>Differential Cutting</td>
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<tr>
<td>Active Aspiration</td>
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<td>Concentric Lumens</td>
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<td>Lesion Morphology:</td>
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<tr>
<td>Calcium</td>
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<tr>
<td>Soft/Fibrotic Plaque</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
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<tr>
<td>Thrombus</td>
<td>✓ (indicated for thrombectomy and atherectomy)</td>
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<td></td>
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</tr>
</tbody>
</table>


Courtesy: L Garcia
DEFINITIVE AR at 12 Months

**Angiographic Patency**

Results for all patients who returned for angiographic follow-up

Up next: REALITY Trial
Lithoplasty

- Shockwave technology (Shockwave Medical)
- 35 patients Europe 30 day safety
- 87% achieved <50% stenosis with lithotripsy alone
- Average stenosis 23% post ShockWave

- Familiar Balloon-based endovascular technique
- “Front-line” balloon strategy (.014”compatible)
- Disrupts both deep & superficial calcium predilation
- Normalizes vessel wall compliance
- Ultra-low pressure
- Minimized effect on healthy tissue
Micro-Serration Scoring Technology: simple easy to use angioplasty balloon designed to provide controlled, predictable results in lumen gain.
Pre-Clinical: SEM Porcine Model*

Documented Linear Interrupted Scoring

Acute Animal Study: SEM

Chronic Animal Study

“From an aspect of safety the device shows evidence of early intimal healing.”

Michael Joner, MD/CVPath Institute

Disclosure: Co-Founder
How do you know vessel is adequately prepared?
Conclusion

• Evidence of need for and results of vessel prep are all indirect at present.

• Vessel prep will likely be the key to optimizing the use of drug coated balloons
  – Deliver more medication
  – Avoid stenting
Vessel prep is the key...
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