Present And Future Status Of DCBs: Successes, Failures, Adjuncts Needed, Problems And Solutions - Will They Have A Role In All Vascular Beds Including BTK Arteries?

2018 Annual VEITH Symposium
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New York, NY

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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.

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<thead>
<tr>
<th>Company</th>
<th>Affiliation/Financial Relationship</th>
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<tbody>
<tr>
<td>Abbott Vascular</td>
<td>Scientific Advisory Board</td>
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<td>Consulting agreement</td>
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<td>Speakers fees / Honorarium</td>
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<td>Research support / REALITY Trial Co-PI</td>
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<td>Boston Scientific</td>
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Present and Future Status of DCBs: Current Successes on the DCB Landscape

**Mechanical Forces**
- Lesion Length
- Calcification

**Biological Factors**
- Patient’s vascular biology
- Intimal hyperplasia

Original RCT trials: <10cm lesions, little calcium, 30% occlusions

<table>
<thead>
<tr>
<th>Key Lesion Characteristics</th>
<th>LEVANT Global</th>
<th>IN.PACT Global (Full Global Cohort)</th>
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<td>Length (cm)</td>
<td>10.1</td>
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<td>17.2</td>
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<tr>
<td>CTO (%)</td>
<td>36.0%</td>
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**2nd Success:** Real-world registries have demonstrated applicability to more complex disease and longer lesions

Present and Future Status of DCBs: Current Successes on the DCB Landscape

**1st Success:** They Work!!! We finally have a solution to biologic restenosis that does not add to the problem with an implant

Present and Future Status of DCBs: Failures and Limitations of DCBs

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<td></td>
</tr>
<tr>
<td>Bail-out Stent (%)</td>
<td>27.6%</td>
<td>20.3%</td>
<td>10.4%</td>
<td>48.8%</td>
<td>14.5%</td>
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**1st Limitation:** Longer and more complex lesions appear to be associated with higher bail-out stent rates requiring implants
Present and Future Status of DCBs: Failures and Limitations of DCBs

1st Limitation: Longer and more complex lesions appear to be associated with higher bail-out stent rates requiring implants.

Primary patency negatively impacted by increasing degree of calcification.

2nd Limitation: Efficacy limited by increasing degrees of calcification (structural vs drug barrier vs both?)

Present and Future Status of DCBs: Adjuncts to DCB for Improved Results

Adjuncts: Likely continued reliance on implants like woven nitinol stents that can manage most difficult and calcified lesions.

Present and Future Status of DCBs: Adjuncts to DCB for Improved Results

Adjuncts: Vessel preparation with atherectomy is most logical strategy as an adjunct to manage these DCB limitations.

Present and Future Status of DCBs: Adjuncts to DCB for Improved Results

Adjuncts: Vessel preparation with atherectomy is most logical strategy as an adjunct to manage these DCB limitations.
Present and Future Status of DCBs: DCBs for the BTK Space – Will It Succeed?

Amphirion DEEP: failed to meet primary endpoint; amputat safety trend
Biolux P-II: failed to meet primary endpoint; no safety concerns

Primary Safety Endpoint:
• No difference between DCB/PTA at 30 days (p=0.001)

Primary Efficacy Endpoint (patency + limb salvage) @ 6m:
• DCB 73.7%, PTA 63.5% (p=0.0273, NS)

Kaplan Meier efficacy estimate @6m:
• DCB 85.3%, PTA 70.7% (p=0.001)

Current DCBs have proven to be successful stand alone therapy for femoropopliteal occlusive disease
While they have been shown to handle even complex disease, long lesions and heavy calcification often requires adjunctive measures including spot stenting or atherectomy
The applicability of DCB technology in the below knee space is yet to be determined, and may not be as effective as it is against femoropopliteal disease

Conclusions
• Current DCBs have proven to be successful stand alone therapy for femoropopliteal occlusive disease
• While they have been shown to handle even complex disease, long lesions and heavy calcification often requires adjunctive measures including spot stenting or atherectomy
• The applicability of DCB technology in the below knee space is yet to be determined, and may not be as effective as it is against femoropopliteal disease

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