**Value of Lesion Preparation with DA in Improving Outcomes of DCB Treatment: From the DEFINITIVE AR Trial**

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**Faculty Disclosure**

**Thomas Zeller, MD**

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from:** Abbott Vascular, Bard Peripheral Vascular, Viva, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme, VIVA Physicians
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**Background**

- Treatment of SFA disease remains challenging
- Debubbling with directional atherectomy (DA) has resulted in lumen gain and improved patency\(^1\)
- Anti-restenotic therapy with drug-coated balloons (DCB) have shown superior patency and lower re-intervention rates versus PTA\(^2,3,4\)
- Early results from the DEFINITIVE AR study with combination therapy suggest trends favoring DA and DCB treatment over DCB alone in long and severely calcified lesions\(^5\)
- Longer term benefits of DA and DCB are not well-defined

**DEFINITIVE AR Study**

**Primary Outcome:** Target Lesion Percent Stenosis at 1 year (Angiographic Core Lab)

<table>
<thead>
<tr>
<th>DA+DCB (n=48)</th>
<th>DCB (n=54)</th>
<th>NR DA+DCB (n=14)</th>
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<td>33.6%</td>
<td>36.4%</td>
<td>55%</td>
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**General and Angiographic Criteria Assessment**

Lesion severely calcified\(^6\)

1. Defined as dense circumferential calcification extending > 5 cm

**References**

DEFINITIVE AR Study

Angiographic patency at 12 months shows a trend in favor of combination therapy

Zeller T et al. Circ Cardiovasc Interv 2017

Increased lumen gain with DA before DCB resulted in improved patency at 12 months¹

Zeller T et al. Circ Cardiovasc Interv 2017

DEFINITIVE AR Study

Assess longer-term effects of treating a lesion with directional atherectomy followed by drug-coated balloon vs. drug-coated balloon alone

- Major Adverse Event Rate at 2 Years
- Defined as major unplanned amputation of the treated limb, all-cause mortality or clinically-driven target lesion revascularization.
- Change in WQoL/SD Score at 2 Years
- Target Lesion Revascularization (TLR) at 2 Years

121 Patients

1 year

53 Patients

2 years

DEFINITIVE AR Study

Freedom from Major Adverse Events at 2 years

Freedom from TLR at 2 years

Impact of lumen gain at 2 years: trend towards lower TLR with ≤30% residual stenosis after DA
## DEFINITIVE AR Study
### 2-Year Results

- DEFINITIVE AR was a pilot study to detect trends in treatment differences between therapy with DA + DCB versus DCB alone, to aid in the development of further research.

- Results suggest that achieving ≤30% residual stenosis following DA leads to better outcomes, which were sustained through 2 years.

- Outcomes from the larger, statistically powered REALITY study will evaluate this concept.