Atherectomy (Silverhawk) plus DEB is the best treatment for ISR and is cost effective: Based on 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, Angioslide, Bard Peripheral Vascular, Venix, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Covidien, Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme, Viva Physicians
- **Consulted for**: Abbott Vascular, Bard Peripheral Vascular, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, ReCar
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DEFINITIVE AR: Study Design

- **Key Exclusion Criteria**
  - In-stent restenosis
  - Anomalous target vessel
  - 2 or more lesions that require treatment in the target limb
- Silverhawk and Turbohawk are not approved for ISR

Silverhawk Atherectomy

*Kaplan-Meier event-free survival without TLR*

ISR and laser ELA

ELA+PTA: less complications, lower TLR rates, higher
Primary Patency rates vs. PTA

- **250 Patients (169 ELA+PTA vs. 81 PTA)**
- **Mean ISR length**: 19.6±12.0 vs. 19.3±11.9 cm
- **Occlusive ISR**: 30.5% vs. 36.8%

ISR and ELA

ELA+PTA vs. PTA @ 6-month:
- **71.1% vs. 56.4% (p=0.064)**
- **79.8% vs. 63.7% (p=0.003)**

Zeller T et al. JACC 2006

Dippel E et al JACC Cardiovasc Int 2015;8:92-101

Schmidt A et al, JET 2014;21:52-60

Zeller T et al. JACC 2006
ISR and ELA/DEB

100% Occlusive (Tosaka III) ISR with mean ISR treated length: 22.4±9.4 cm vs. 25.9±8.7 cm.
12-month Primary Patency: 66.7% vs. 37.5% (p= 0.01)

ISR and ELA/DEB

Patency translated into significant TLR reduction, lower overall MAE and higher 12-month healing rates.

Gandini R et al, JET 2013;20:805-813

Economic Value can be Provided in a Number of Different Ways in the Interventional Space

- Procedural Efficiencies:
  - Faster procedure times
  - Fewer complications
  - Reduction in needed materials
  - Reduced procedure costs
  - Faster recovery times
  - Shorter hospital stays

- Long-term, Durable Clinical Outcomes:
  - Reduced disease recurrence
  - Delay in progression of disease
  - Improved clinical & functional outcomes (fewer CV events, mortality, morbidity)

Economic value of Stellarex DCB vs. PTA analyzed from a German HC system Payer’s perspective

- Key cost economic driver: Target Lesion Revascularization rate through 2 years
- Stellarex DCB source: ILLUMENATE FIH (pre-dil cohort)
- PTA Source: pooled TLR rates derived from published clinical studies, weighted by sample size


24 Month Budget Impact:

- Cost Neutral

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24 Month Budget Impact – One DEB Only:

- 741€ Per Patient Savings

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24 Month Budget Impact

Savings to health care system over 24 months using Stellarex™ DCB vs. POBA.
Per Patient: € 741
Per 25,000 pts = €18,500,000
Summary

Atherectomy & DEB in ISR is cost-effective?

- DEB angioplasty represents the first line strategy for TASC A & B de novo lesions with device depending 2-year freedom from TLR rates up to 91% (Level 1 of evidence)
- DEB ± DA should be considered as first line strategy in the complex lesions (TASC C & D femoro-popliteal lesions or calcified lesions)
- Cost-effectiveness of the combined treatment approach (DAART) is not yet proven and might be reserved to complex lesions