Atherectomy: Data and current developments

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Disclosure

Speaker name: .................................................................

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Atherectomy: Is there a role?

Restenosis after PTA or stenting + the need for re-interventions are the main limitations in the femoropoliteal segment.

Contemporary strategies to overcome these limitations:

- Antiproliferative drugs
- Debulking
Atherectomy: Is there a role?

Principle: Removing plaque without outward stretching or causing barotrauma to the target vessel wall.

Different debulking mechanisms:

directional, orbital, and rotational
Atherectomy: Is there a role?

Rationale:

- less barotrauma
- less dissections
- less bailout stenting
- potentially less intimahyperplasia
- vessel compliance is reserved
- "leaving nothing behind" concept
Atherectomy: Is there a role?

Cons:

- Potential for embolization
- Need for embolic protection devices
  - high costs
  - higher radiation exposure
  - time consuming
Atherectomy: Is it more effective than BMS/DCBs

**Definitive LE:**
SilverHawk Device
800 patients
mean LL 8cm
PP 1y: 78%

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**Definitive LE**

- **FAST**
- **FACT**
- **Astron**
- **Absolute**
- **Levant I**
- **Durability**
- **Definitive LE**
- **Resolute**
- **Impact SFA**
- **SUPERA (Superb)**
- **ZILVER PTX**

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**12 months binary restenosis rate (%)**

- **Durability II**

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**Lesion length**
# Atherectomy: Is it more effective than BMS/DCBs

<table>
<thead>
<tr>
<th>Study</th>
<th>Device</th>
<th>Design</th>
<th>Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITIVE LE (2014)</td>
<td>Silverhawk (Medtronic)</td>
<td>Single-arm, prospective, 800 pat.</td>
<td>PP 12Mo: 78%</td>
</tr>
<tr>
<td>COMPLIANCE 360° (2014)</td>
<td>Diamondback 360° (CSI)</td>
<td>Randomized to PTA, 50 pat.</td>
<td>PP 6Mo: 77%</td>
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<tr>
<td>CELLO (2009)</td>
<td>Excimer Laser (Spectranetics)</td>
<td>Single arm, prospective, 56 pat.</td>
<td>PP 12Mo: 56%</td>
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<tr>
<td>Jetstream RCT (2011)</td>
<td>Jetstream (Pathway)</td>
<td>Single arm, prospective, 172 pat.</td>
<td>PP 12 Mo 61.8%</td>
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Atherectomy: Is it more effective than BMS/DCBs

*Not enough evidence to support this theory*

*Need for RCTs with clinical endpoints*
Atherectomy: Combination with DCBs

- high acute *procedural success* with atherectomy (low bail-out stenting rates)
- effective *antiproliferative therapy* using DCBs

could be an important strategy in treating femoropopliteal disease.
Atherectomy: Combination with DCBs - Data

Cioppa et al. (2009)
Silverhawk + Impact DCB
30 patients
12 months TLR rate: 10%

Scheer et al. (2014)
Rotarex (Straub) + Impact DCB
29 patients
6 months restenosis rate: 6.9%
Atherectomy: Combination with DCBs - Data

Definitive AR study
Silverhawk + Impact DCB vs. DCB alone

Primary endpoint: 1y angiogr. restenosis
33.6% vs. 36.4% (control arm, n.s.)

Better results in patients with more plaque removal
DCBs: Limitations: Calcification

DEFINITIVE AR 12m results
Atherectomy+DCB vs. DCB+PTA

Zeller, VIVA 2014
Atherectomy ±DCBs

Evidence does not support routine use

Potential in severely calcified lesions

Randomized data are mandatory

Theoretical potential has – until now – not been translated into clinical benefit

Cost-effectiveness!