TASC A/B femoropopliteal lesions treatment
DES should be the first line treatment

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Lugano
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TASC II femoral popliteal lesions

- **Type A lesions**
  - Single stenosis ≤10 cm in length
  - Single occlusion ≤5 cm in length

- **Type B lesions**
  - Multiple lesions (stenoses or occlusions), each ≤5 cm
  - Single stenosis or occlusion ≤15 cm not involving the infra geniculate popliteal artery
  - Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass
  - Heavily calcified occlusion ≤5 cm in length
  - Single popliteal stenosis
TASC II femoral popliteal lesions
Type A and Type B

Type A lesions
- Single stenosis ≤10 cm in length
- Single occlusion ≤5 cm in length

Type B lesions:
- Multiple lesions (stenoses or occlusions), each ≤5 cm
- Single stenosis or occlusion ≤15 cm not involving the infrageniculate popliteal artery
- Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass
- Heavily calcified occlusion ≤5 cm in length
- Single popliteal stenosis
Treatment options

- POBA
- BMS
- DCB
- DES
BMS-RCT’s

- ABSOLUTE
- FAST
- RESILIENT
## BMS-12 months

<table>
<thead>
<tr>
<th></th>
<th>ABSOLUTE</th>
<th>FAST</th>
<th>RESILIENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean lesion length (mm)</td>
<td>101/92</td>
<td>45/44</td>
<td>71/64</td>
</tr>
<tr>
<td>Primary patency (PTA)</td>
<td>50%/37%</td>
<td>66.4%/62.2%</td>
<td>53.8%/36.7%</td>
</tr>
<tr>
<td>Primary patency (stent)</td>
<td>75%/67%</td>
<td>76.2%/67%</td>
<td>84%/81.3%</td>
</tr>
<tr>
<td># stents used</td>
<td>1.7</td>
<td>1</td>
<td>1.6</td>
</tr>
<tr>
<td>Stent fractures</td>
<td>2%</td>
<td>12%</td>
<td>3.1%</td>
</tr>
</tbody>
</table>

### Stent/PTA
- **6 months/12 months**
- Patency per protocol (except 12 month ABSOLUTE)

Schillinger M et al, NEJM 2006;354:1879-1888
ABSOLUTE @ 24 months

• Restenosis rate
  – Intention-to-treat
    • PTA  69.2%
    • Stent  45.7% (p=0.03)
  – Treatment-received analysis
    • PTA  74.3%
    • Stent  49.2%

• Trend toward clinical benefit

Schillinger M et al, Circulation 2007;115:2745-2749
# RESILIENT

## Chronic Effectiveness Measures

<table>
<thead>
<tr>
<th>Time</th>
<th>Measure</th>
<th>Stent (n=134)</th>
<th>Balloon (n=72)</th>
<th>Difference, %</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Months</td>
<td>Freedom from TLR, %</td>
<td>87.3</td>
<td>45.2</td>
<td>42.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Primary patency, %</td>
<td>81.5</td>
<td>36.7</td>
<td>44.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Clinical success, %</td>
<td>72.3</td>
<td>31.8</td>
<td>40.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>24 Months</td>
<td>Freedom from TLR, %</td>
<td>77.8</td>
<td>41.8</td>
<td>36.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Clinical success, %</td>
<td>68.6</td>
<td>25.4</td>
<td>43.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>36 Months</td>
<td>Freedom from TLR, %</td>
<td>75.5</td>
<td>41.8</td>
<td>33.7</td>
<td>&lt;0.0001</td>
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<tr>
<td></td>
<td>Clinical success, %</td>
<td>63.2</td>
<td>17.9</td>
<td>45.3</td>
<td>&lt;0.0001</td>
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Laird JR et al, JET 2012;19:1-9
BMS-RCT’s

- ABSOLUTE
- FAST
- RESILIENT

No Long-term Primary Patency Data
DEB-RCT’s

- LEVANT 2
- INPACT SFA I-II
LEVANT 2

Primary patency 1 yr 73.5%

Freedom TLR 1 yr 89.7%
INPACT SFA I-II

ALL ITT, 12-month Primary Patency [1]

Primary patency 1 yr 89.9%  

ALL ITT, 12-month Clinically-driven TLR

Freedom TLR 1 yr 97.5%

Clinically-driven TLR [1]  
IN.PACT DCB | PTA | p
--- | --- | ---
2.4% | 20.6% | <0.001 [2]
BMS vs. DEB

The graph shows the binary restenosis at 12 months (%) against the length of the lesion (cm). The markers indicate different treatment groups, including PTA plus provisional stent and stent treatments. The graph includes studies such as ASTRON, ABSOLUTE, THUNDER, FAST, FemPac, and SciRocco.
DEB-RCT’s

- LEVANT 2
- INPACT SFA I-II

NO LONG-TERM PRIMARY PATENCY DATA
DES-RCT’s

• ZILVER-PTX
Zilver PTX-12 months

Primary patency primary DES 82.7%

Dake MD et al, Circ Cardiovasc Interv. 2011;4:495-504
### BMS vs. DES - 12 months

<table>
<thead>
<tr>
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<th>Zilver PTX</th>
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<td>1.6</td>
<td>1.5</td>
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**Stent/PTA**  
6months/12 months

Patency per protocol (except 12 month ABSOLUTE)

Schillinger M et al, NEJM 2006;354:1879-1888  
Dake MD et al, Circ Cardiovasc Interv. 2011;4:495-504
DEB vs. DES - 12 months

Primary patency primary DES 82.7%

Primary patency 1 yr 73.5%

Primary patency 1 yr 89.9%
Zilver PTX-24 months

Primary patency primary DES 74.8%

Dake MD et al, JACC 2013;61:2417-2427
Zilver PTX-24 months

Primary patency provisional DES 83.4%

Dake MD et al, JACC 2013;61:2417-2427
BMS vs. DES vs. DEB-24 months

• Primary patency
  – Zilver PTX 83.4%
  – ABSOLUTE 50.8/54.3%
  – RESILIENT/FAST ?
  – LEVANT 2/INPACT SFA I-II ?
Zilver PTX-5 years

Dake MD et al, VIVA2014
Zilver PTX-5 years

5-year Primary Patency (PSVR < 2.0)
Provisional Zilver PTX vs. BMS

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to BMS

Dake MD et al, VIVA2014
At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss.

Dake MD et al, VIVA2014
At 5 years, Zilver PTX demonstrates a 47% reduction in reintervention compared to BMS.
5-year Stent Integrity

<table>
<thead>
<tr>
<th>Study Period</th>
<th>Number of New Events</th>
<th>Fracture Rate&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>1-year</td>
<td>4</td>
<td>0.9%</td>
</tr>
<tr>
<td>3-year</td>
<td>3</td>
<td>1.9%</td>
</tr>
<tr>
<td>5-year</td>
<td>0</td>
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</tr>
</tbody>
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<sup>1</sup> Kaplan-Meier estimates

Zilver PTX has excellent durability in challenging SFA environment

Dake MD et al, VIVA2014
DEB vs. BMS vs. DES

![Graph showing comparison of DEB, BMS, and DES with reference to primary patency and L length (cm).]

**Duplex derived Primary Patency based on PSVR ≤2.4 (†) or PSVR ≤2.0 (‡)**

## Role of PSV

<table>
<thead>
<tr>
<th></th>
<th>Lutonix</th>
<th>Control PTA</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary composite safety endpoint (freedom from perioperative death and 12-month index limb amputation [above and below the ankle], index limb reintervention and index limb-related death)</td>
<td>83.9%</td>
<td>79%</td>
<td>0.005</td>
</tr>
<tr>
<td>12-month primary patency (Kaplan-Meier, PSVR = 2.5)</td>
<td>73.5%</td>
<td>56.8%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>12-month primary patency (PSVR = 2.0)</td>
<td><strong>53.2%</strong></td>
<td><strong>45%</strong></td>
<td>0.13*</td>
</tr>
<tr>
<td>Total TLR at 12 months</td>
<td>12.3%</td>
<td>16.8%</td>
<td>0.208*</td>
</tr>
</tbody>
</table>

*No statistically significant difference.*
Conclusions

• In short term results seem to be equal, in long run differences appear
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• In short term results seem to be equal, in long run differences appear.
• If you want to avoid re-interventions and long-term benefits for your patients.
Conclusions

• In short term results seem to be equal, in long run differences appear
• If you want to avoid re-interventions and long-term benefits for your patients
• The obvious choice is DES