Good Treatment for ISR:  
What is the Pattern of Failure  
What can be done for Treatment

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Disclosures

• None

Pattern of Failure

• Acute stent trauma: Intimal hyperplasia due to trauma of stent placement.
• Chronic stent trauma: Intimal hyperplasia due to wall shear stress, chronic outward force.
• Edge stenosis due to compliance mismatch.

Patterns of in-stent restenosis (ISR)
— Bare Metal Stents: >90% diffuse ISR, edge stenosis  
— Stentgraft: >90% edge stenosis

Wall shear stress due to flexion, torsion, compression, and chronic outward force (COF)

Oversizing Leads to In-Stent Restenosis

5-Month Restenosis in Porcine Iliofemoral Arteries

DEB - DEBATE-ISR Study

Single arm, 44 patients, mean lesion length 13.2 cm

At 1-year:
- Primary patency rate: 80.5%
- Freedom from TLR: 86.4%

PACUBA Trial - Freedom from TLR

RCT (DEB vs. PTA in ISR): 74 patients, mean lesion length 17 cm

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>DEB (34)</th>
<th>PTA (40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>88.2%</td>
<td>49.0%</td>
</tr>
<tr>
<td>6</td>
<td>83.8%</td>
<td>22.0%</td>
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<tr>
<td>12</td>
<td>49.0%</td>
<td>25.0%</td>
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</tbody>
</table>

P = 0.11

PACUBA Trial

12-month Primary Patency TASC A and B lesions

RCT (DEB vs. PTA in ISR): 74 patients

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>DEB (34)</th>
<th>PTA (40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>55.0%</td>
<td>9.5%</td>
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<tr>
<td>6</td>
<td>46.4%</td>
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<td>12</td>
<td>17.0%</td>
<td>3.7%</td>
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P = 0.008

Laser Atherectomy – EXCITE ISR

RCT: ELA (n=169) vs PTA (n=81), mean lesion length 19 cm

12m 34%
12m 13%


VIABAHN® vs PTA in ISR – RELINE study

83 patients with SFA ISR: VIABAHN® (n = 39) vs PTA (n = 44)

Technical success:
- VIABAHN®: 100%
- PTA: 81.8% (p = 0.002)

12-month primary patency rate:
- VIABAHN®: 74.8%
- PTA: 28.0% (p < 0.001)


CONCLUSION

- In short lesions (TASC A-B) DEB – angioplasty may be first choice.
- In long lesions (TASC C-D) VIABAHN endoprosthesis is recommended.