Bioresorbable Stent Implantation for Tibial Disease

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Disclosure

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I have the following potential conflicts of interest to report:

☒ Consulting: Abbott Vascular
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
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Current Limitations of Endovascular Tibial Interventions

- Diffuse nature of disease in CLI patients
- Heavy calcium burden and propensity for persistent mechanical forces
- High rate of restenosis after successful intervention
- Importance of reconstituted tibial vessels as bypass targets for limb-salvage
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*Best in Class Devices and Strategies for Tibial Disease*

**Excisional Atherectomy**

- DEFINITIVE LE: 90% Primary patency (5.5cm)
- Limitation in severe calcification and small vessels
- Operator dependent device

**Orbital, Rotational, and Laser Atherectomy**

- Absence of core-lab adjudicated data with relevant clinical endpoints (primary & secondary patency)
- Small sample size
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Best in Class Devices and Strategies for Tibial Disease

**DES vs PTA/BMS/DCB**

- Several European RCTs have demonstrated the superiority of DES vs other modalities

<table>
<thead>
<tr>
<th>Study</th>
<th>Drug</th>
<th>N</th>
<th>Control Arm</th>
<th>Follow Up</th>
<th>Patency</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACHILLES</td>
<td>Sirolimus</td>
<td>200</td>
<td>PTA</td>
<td>12 mo</td>
<td>75% vs 57%</td>
<td>0.025</td>
</tr>
<tr>
<td>DESTINY</td>
<td>Everolimus</td>
<td>140</td>
<td>BMS</td>
<td>12 mo</td>
<td>85% vs 54%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>YUKON-BTX</td>
<td>Sirolimus</td>
<td>161</td>
<td>BMS</td>
<td>12 mo</td>
<td>81% vs 56%</td>
<td>0.004</td>
</tr>
<tr>
<td>IDEAS</td>
<td>Drug</td>
<td>50</td>
<td>DCB</td>
<td>6 mo</td>
<td>72% vs 42%</td>
<td>0.046</td>
</tr>
</tbody>
</table>

DES provides:

- **SCAFFOLD** - mechanical forces
- **DRUG** - biologic forces
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Limitations of DES in the Infra-geniculate Circulation

- Need for prolonged antiplatelet therapy
- Stent properties may contribute to late failure (chronic vessel inflammation)
- Stent failure can have implications for re-intervention
- Potential change in surgical options / affect on bypass target
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Alternative to Permanent Implant: Bioresorbable Scaffold

- Ideal Platform: drug delivery in a temporary scaffold
- Would allow anti-restenotic therapy and scaffolding for mechanical sources of failure
- Resorption of the scaffold would prevent chronic vessel irritation and promote vascular remodelling
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Alternative to Permanent Implant: Bioresorbable Scaffold

ABSORB GT1 BVS (Abbott)

PLLA Scaffold
- Semi-crystalline poly-L-lactide backbone
- Provides device structure
- Developed to optimize radial strength
- 150μm strut thickness

Everolimus / PDLLA Matrix Coating
- 2-4μm amorphous (non-crystalline) coating
- Poly-L,D-lactide matrix/Everlimus at 1:1 ratio
- Provides controlled drug release
- Same dose concentration as Xience DES
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Alternative to Permanent Implant: Bioresorbable Scaffold

Controlled drug delivery and scaffold support with endothelialization, followed by gradual loss of mechanical support and finally bioresorption of scaffold mass.
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Alternative to Permanent Implant: Bioresorbable Scaffold
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Alternative to Permanent Implant: Bioresorbable Scaffold

74 yo woman with ESRD and forefoot gangrene who suffered repeated restenosis of TPT (feeding dominant peroneal runoff)

OCT for size assessment of reference vessel diameter

Focal predilatation with non-compliant 3.0x20 balloon
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*Alternative to Permanent Implant: Bioresorbable Scaffold*

- 3.0x28mm ABSORB GT1

- Balloon marker
- Platinum Scaffold markers
- Balloon marker
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Alternative to Permanent Implant: Bioresorbable Scaffold
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*Alternative to Permanent Implant: Bioresorbable Scaffold*

- Slow, controlled deployment to nominal diameter
- 2ATM increase every 5 sec
- Post-dilate with 3.5x20 non-compliant balloon
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Alternative to Permanent Implant: Bioresorbable Scaffold

Completion imaging to ensure <10% residual stenosis
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Alternative to Permanent Implant: Bioresorbable Scaffold

Completion OCT to ensure strut apposition to vessel wall
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**Alternative to Permanent Implant: Bioresorbable Scaffold**

Predilate with 2.75x20 NC Trek

ABSORB GT1 3.0x28 Scaffold

Post-dilate with NC 3.5x20 balloon
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*Alternative to Permanent Implant: Bioresorbable Scaffold*
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Keys to Successful Implantation of Bioresorbable Scaffolds

ABSORB II Lessons: Optimal Results Require Proper Deployment Technique

- Predilate lesion 1:1 with non-compliant balloon or plaque modification device
- OCT/IVUS for accurate vessel sizing (2.5-3.75mm)
- Slow deployment (2ATM / 5 sec) to allow expansion of scaffold without fractures
- Post-dilate with non-compliant balloon not to exceed 0.5mm beyond nominal diameter
- OCT to ensure strut apposition to vessel wall
- Attention to distal disease (affect on patency)

Not just another balloon expandable stent!
Experience With the Absorb Everolimus-Eluting Bioresorbable Vascular Scaffold in Arteries Below the Knee

12-Month Clinical and Imaging Results

- 38 limbs in 33 patients
- 50 scaffolds implanted
- 43 infrageniculate lesions
- Mean lesion length 1.9 cm
- 68% CLI, 32% Claudication

Primary Patency (KM)
- 12 mo 96%
- 24 mo 85%

Freedom from CD-TLR
- 12 mo 96%
- 24 mo 96%

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Alternative to Permanent Implant: Bioresorbable Scaffold

R. Varcoe: 24 month update
- 64 scaffolds in 49 limbs
- Primary patency 89.2% at 24 mo (84.9% by KM)
- Secondary patency and limb salvage of 100%
- Freedom from CD-TLR 97.1% at 24 mo
- Sustained clinical improvement of 82%

S. Kum: 12 month Results
- 28 pts, 22% obclusions, 28mm mean lesion length
- 97% Freedom from CD-TLR at 6 mo

LINC 2017 (Wednesday CLI Session)
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Conclusions

- Biologic and mechanical forces continue to limit the durability of currently available options for BTK disease

- Permanent implants in the infrapopliteal location may limit future interventional and surgical therapies

- Bioresorbable technology with drug elution may be an important answer to some of these challenging lesions as early results appear quite promising
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