Bioresorbable Scaffolds in BTK Arteries

24-month results from The ABSORB BTK Study

Ramon L. Varcoe, MBBS, MS, FRACS, PhD
Associate Professor of Vascular Surgery
University of New South Wales
Sydney, Australia
Disclosure

Speaker name:

.........Ramon L. Varcoe...........................................................

I have the following potential conflicts of interest to report:

- Consulting: Medtronic, Abbott Vascular, Boston
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
WHY DO WE STENT?
WHY DO WE STENT?

- TO IMPROVE PATENCY
- MECHANICAL SUPPORT
  - Scaffolding
  - Elastic Recoil
  - Flow Limiting Dissection
- DRUG DELIVERY
WHY DO WE TRY TO AVOID THE STENT?
WHY DO WE STENT?

• VESSEL WALL EFFECTS
  • Vasomotion
  • Autoregulation
  • Adaptive Remodelling
• LATE FAILURE
  • Incomplete endothelialisation
  • Fracture
  • Malapposition
• IMPEDIMENT TO FUTURE REVASCULARISATION
THE BIORESORBABLE SCAFFOLD MAY BE THE BEST OF BOTH WORLDS?
• Poly-L-Lactic Acid structure
• Poly-D,L-Lactic Acid polymer
• Everolimus (100µg/cm²)
• 80% (±10%) elutes 28d
- Multilink design
- Circumferential hoops
- Straight connection bridges
- Radio-opaque platinum markers
- 150 µm strut thickness

![Diagram of scaffold design](image)

<table>
<thead>
<tr>
<th>Scaffold Diameter (mm)</th>
<th>2.5</th>
<th>3.0</th>
<th>3.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scaffold Length (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>1012462-08</td>
<td>1012463-08</td>
<td>---</td>
</tr>
<tr>
<td>12</td>
<td>1012462-12</td>
<td>1012463-12</td>
<td>1012464-12</td>
</tr>
<tr>
<td>18</td>
<td>1012462-18</td>
<td>1012463-18</td>
<td>1012464-18</td>
</tr>
<tr>
<td>23</td>
<td>1012462-23</td>
<td>1012463-23</td>
<td>1012464-23</td>
</tr>
<tr>
<td>28</td>
<td>1012462-28</td>
<td>1012463-28</td>
<td>1012464-28</td>
</tr>
</tbody>
</table>
Single centre
3 Implanters under special access conditions

**Inclusion Criteria**
- Chronic lower limb ischemia: RC 3-6
- Life expectancy >1yr
- De novo lesions; >60%
- Tibial arteries (distal P3)
- Length ≤5cm,
- Diameters 2.5-4.0mm
- Treated inflow lesion were accepted
• Safety: Major adverse events @ 30d
  • Death, target limb loss, major morbidity
• Feasibility: Technical success

• Clinical Improvement: Rutherford-Becker Class

• Duplex FU; 1, 3, 6 & 12mo (PSVR > 2.0)
  • Binary restenosis
  • Primary patency
  • TVR, TLR
PERIPHERAL

Experience With the Absorb Everolimus-Eluting Bioresorbable Vascular Scaffold in Arteries Below the Knee

12-Month Clinical and Imaging Outcomes

Ramon L. Varcoe, MBBS, MS, PhD, a,b,c Olaf Schouten, MD, PhD,a,d Shannon D. Thomas, BSc Med Hons, MBBS, a,b,c
Andrew F. Lennox, MBBS, MSc a,c

38 limbs & 50 Bioresorbable Scaffolds
• 49 Limbs (CLI 69%:IC 31%)
  – 44 patients
  – Age range 65-97yo
  – M:F 55:45

• 65 Scaffolds
  – Vessels treated
    • ATA 15
    • PTA 9
    • PA 12
    • TPT 25
    • P3 2

• Mean lesion length **19.7 ±10.4mm** (5-50mm)
• 100% Procedural success
• 1 Acute occlusion (day 1: no DAPT)
• 7 death (15.9%): Outside 30d

Sustained Clinical Improvement
Primary patency
Assisted primary/secondary patency
Limb salvage

82%
58/65 (89.2%)
100%
100%
Sustained Clinical Improvement in 82%

Change in Rutherford Category

-6 -5 -3 -1 0 1

-20 -15 -10 -5 0 5 10 15 20 25
• 100% Procedural success
• 1 Acute occlusion (day 1: no DAPT)
• 7 death (15.9%): Outside 30d

Sustained Clinical Improvement 82%
Primary patency 58/65 (89.2%)
Assisted primary/secondary patency 100%
Limb salvage 100%
Primary Patency: 92.3%

CD-TLR: 97.1%
**Primary Patency**

- CD-TLR 97.1%
- Primary Patency 92.3%

**CD-TLR & PP-censored**

- CD-TLR 97.1%
- Primary Patency 84.9%
• Vascular restorative therapy with BVS offers several advantages over metal stents
• Safety using ABSORB BVS within the tibias has been demonstrated, now at longer timepoints
• Excellent 12-month patency has been maintained to “best-in-class” 24-month results
Bioresorbable Scaffolds in BTK Arteries

24-month results from The ABSORB BTK Study

Ramon L. Varcoe, MBBS, MS, FRACS, PhD
Associate Professor of Vascular Surgery
University of New South Wales
Sydney, Australia
Bioresorbable Scaffolds in BTK Arteries

24-month results from The ABSORB BTK Study

Ramon L. Varcoe, MBBS, MS, FRACS, PhD
Associate Professor of Vascular Surgery
University of New South Wales
Sydney, Australia