Bioresorbable Everolimus-Eluting Vascular Scaffold for Patients With Peripheral Artery Disease (ESPRIT I): 2-Year Clinical and Imaging Results

Prof. PD Dr. Florian Wolf, MBA, EBIR, EBCR
Division of Cardiovascular and Interventional Radiology
Department of Biomedical Imaging and Image-Guided Therapy
Medical University of Vienna

www.florianwolf.at
Bioabsorbable Stents/Scaffolds

- Therapy of PAOD – endovascular methods in most patients first line treatment
- Multiple different methods and available techniques
  - PTA with POBA
  - PTA with DEB +/- lesion preparation
  - PTA with Scoring Balloon +/- Drug (e.g. chocolate touch)
  - Bare metal stent +/- PTA with DEB (before or after?)
  - Covered stent
  - Drug eluting stent
  - Bioabsorbable Stent +/- drug → Best of all worlds? Leave nothing behind?
**Bioabsorbable Stents/Scaffolds**

**Bioresorbable stent**
A.R.T's stent supports the artery wall long enough for it to remodel itself, and is then simply absorbed by the body.

**Pure polylactic acid**
The polymer that forms the stent mesh is derived from lactic acid, a naturally-occurring substance found in the human body.

**The right mix**
A specific ratio of L- to D-isomers gives the stent the appropriate stiffness and rate of degradation compatible with the artery healing process and ensures absence of recoil.

**Biocompatible**
Water from blood enters the polymer and gradually breaks apart the chains.

Because the stent is made only from polylactic acid, it is resorbed by the body after it breaks down, using natural biochemical pathways.

---

**Poly(D,L-lactide)**

![Chemical Structure](image)
Bioabsorbable Stents in the coronaries

Initial and 6-month results of biodegradable poly-l-lactic acid coronary stents in humans.
• 19 lesions in 15 patients with CHD
• 6-months restenosis rate 10.5%.
Bioabsorbable Stents in the coronaries

Long-Term (>10 Years) clinical outcomes of first-in-human biodegradable poly-l-lactic acid coronary stents: Igaki-Tamai stents.


Figure 2. Kaplan-Meier curves showing survival rates free of (A) cardiac death, (B) death, and (C) major cardiac adverse events.
Bioabsorbable DES Stents vs. DES/BMS

Clinical outcomes with bioabsorbable polymer- versus durable polymer-based drug-eluting and bare-metal stents: evidence from a comprehensive network meta-analysis.

Palmerini T¹, Biondi-Zoccai G², Della Riva D¹, Mariani A¹, Sabaté M³, Smits PC⁴, Kaiser C⁵, D'Ascenzo F⁶, Frati G⁷, Mancone M², Genereux P⁸, Stone GW⁹.

• 89 Trials with 85,490 patients – meta analysis
• Bioabsorbable DES Stents
  • Superior clinical outcomes compared with BMS and first-generation DES
  • Similar rates of cardiac death, MI and TVR compared to 2nd generation DES
  • Higher Rates of definite stent thrombosis compared to CoCr-EES

→ Present latest generation DES work excellent → Bioabsorbable Stents still not used in clinical cardiological routine → no need
AMS Stent (Magnesium Stent; Biotronic AG, Swiss)

IGAKI-TAMAI Stent Trial - REMEDY Trial.

- Goverde P et al. EuroPCR 2013
- Igaki-Tamai poly-L-lactide acid (PLLA) Stent
- 95 patients, SFA lesions mean length 35mm
- technical success in 95%
- 6-month primary patency rate 71%

- 30 patients, SFA mean lesion length 5.9 cm.
- Binary restenosis rate was 39.3% and 67.9% at 6 and 12 months follow-up, respectively.
- TLR rate was 25.0% and 57.1% after 6 and 12 months.
Esprit BVS (Bioresorbable Vascular Scaffold) (Abbott Vascular)

**Bioresorbable Scaffold**
- Poly(L-lactide) (PLLA)
- Naturally resorbed, fully metabolized
- Designed for SFA and Iliac Arteries

**Bioresorbable Coating**
- Poly(D,L-lactide) (PDLLA) coating
- Naturally resorbed, fully metabolized

**Everolimus**
- 100 μg/cm²
ESPRIT I Trial - Pharmacokinetic Study

![Graph showing everolimus concentrations (ng/mL) in human whole blood](image-url)
### ESPRIT I BVS Trial – Lesions and Results

<table>
<thead>
<tr>
<th></th>
<th>Esprit BVS (N=35)</th>
<th>Esprit BVS (N=34) 6-Month</th>
<th>Esprit BVS (N=34) 12-Month</th>
<th>Esprit BVS (N=34) 24-Month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion length</strong></td>
<td>35.7±16.0mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>External Iliac (%)</strong></td>
<td>11.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SFA (%)</strong></td>
<td>88.6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Proximal</strong></td>
<td>14.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mid</strong></td>
<td>31.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Distal</strong></td>
<td>54.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Binary restenosis</strong></td>
<td>0%</td>
<td>12.9% (4/31)</td>
<td>16.1% (5/31)</td>
<td></td>
</tr>
<tr>
<td><strong>Scaffold thrombosis (%)</strong></td>
<td>0.0</td>
<td>2.9% (1/34)</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td><strong>Target lesion revascularization (TLR) (%)</strong></td>
<td>0.0</td>
<td>8.8% (3/34)</td>
<td>11.8% (4/34)</td>
<td></td>
</tr>
</tbody>
</table>
ESPRIT I BVS Trial – Freedom from TLR

Days Post Index Procedure | 0 | (0, 30] | (30, 180] | (180, 365] | (365, 730] |
---|---|---|---|---|---|
Number at Risk | 35 | 35 | 34 | 34 | 31 |
Number Censored | 0 | 1 | 0 | 0 | 3 |
Number of Events | 0 | 0 | 0 | 3 | 1 |
Event Free (%) | 100.0% | 100.0% | 100.0% | 91.2% | 88.2% |
Standard Error (%) | 0.0% | 0.0% | 0.0% | 4.9% | 5.5% |
ESPRIT I BVS Trial – Rutherford Becker Becker
clinical improvement
## ESPRIT I Angiographic Results (CorLab)

<table>
<thead>
<tr>
<th></th>
<th>Pre-Procedural (N=35)</th>
<th>Post-Procedural (N=35)</th>
<th>1 Year (N=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-segment RVD (mm)</td>
<td>4.9</td>
<td></td>
<td>4.9</td>
</tr>
<tr>
<td>In-segment MLD (mm)</td>
<td>1.0</td>
<td>4.5</td>
<td>3.2</td>
</tr>
<tr>
<td>In-segment stenosis (%)</td>
<td>80.0</td>
<td>9.2</td>
<td>31.8</td>
</tr>
</tbody>
</table>

MLD = minimum lumen diameter, RVD = reference vessel diameter

## ESPRIT I Duplex Ultrasound Results (CorLab)

<table>
<thead>
<tr>
<th></th>
<th>Post-Procedural (N=30)</th>
<th>6-Month (N=29)</th>
<th>12-Month (N=24)</th>
<th>24-Month (N=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSVR</td>
<td>1.27</td>
<td>1.35</td>
<td>1.66</td>
<td>1.56</td>
</tr>
</tbody>
</table>
K. W., 56y, male, intermittent claudication (RB 3)
K. W., 56y, male, 6 months CTA/CDUS, 12 months angio
L.J., 55y, male, intermittent claudication (RB 3)
L.J., 55y, male, 6-month (CTA, CDUS), 12-month angio
ESPRIT I Angiographic Results  
Impact of vessel size on outcomes

<table>
<thead>
<tr>
<th></th>
<th>All 1-year F/U (N=27)</th>
<th>$D_{\text{max}}^*$ ≤ median (N=14)</th>
<th>$D_{\text{max}}^*$ &gt; median (N=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-scaffold %DS post-procedure</td>
<td>8.7%</td>
<td>8.9%</td>
<td>8.5%</td>
</tr>
<tr>
<td>In-scaffold %DS 1 year</td>
<td>31.8%</td>
<td>20.1%</td>
<td>44.4%</td>
</tr>
</tbody>
</table>

* $D_{\text{max}}$ = largest diameter within the treated segment by core lab assessment

Outcomes are better in smaller arteries where BVS is well imbedded in vessel wall
Conclusion

✓ In coronary arteries bioabsorbable vascular stents are safe but show no benefit compared to last generation DES → still not used in daily clinical routine

✓ In peripheral arteries BVS made from magnesium and PLLA without drug-elution have shown high restenosis rate (AMS-Stent, Igaki-Tamai stent).

✓ The ESPRIT everolimus-eluting BVS has shown a low binary restenosis rate (16.1%) and TLR rate (11.8%) at 2-year follow-up.

✓ Multiple other promising techniques available – next years and possible upcoming RCTs will show if this technology will be used in daily routine
Bioresorbable Everolimus-Eluting Vascular Scaffold for Patients With Peripheral Artery Disease (ESPRIT I): 2-Year Clinical and Imaging Results

Prof. PD Dr. Florian Wolf, MBA, EBIR, EBCR

Division of Cardiovascular and Interventional Radiology
Department of Biomedical Imaging and Image-Guided Therapy
Medical University of Vienna

www.florianwolf.at