Can adjunctive operative techniques improve vascular access outcomes

Richard F. Neville, M.D.
Professor of Surgery
Sara P. Friedman and Carol A. Ludwig Chief of Vascular Surgery
George Washington University

Disclosures

- WL Gore
- Vascular Flow Technologies
- Cormatrix
- Graftworxx

Dialysis access graft failure

- Myointimal hyperplasia
- Stenosis at the venous anastomosis

“Hyperplasia is a normal response to an abnormal flow environment”

The Role of Hemodynamics

Hyperplasia at the anastomosis

- Flow separation
- Recirculation/Stagnation
- High Velocity impact

The Role of Hemodynamics

Hyperplasia at the anastomosis

- Flow separation
- Recirculation/Stagnation
- High Velocity impact
Turbulent flow = suboptimal hemodynamics
MRV flow model

Spiral laminar flow
Pattern noted in normal arterial tree

Spiral laminar flow
Common femoral artery duplex US

Proposed benefits of spiral laminar flow

- May reduce incidence of stenosis due to neointimal hyperplasia:
  - Reducing laterally directed forces on the vessel wall and
    stabilizing flow improving shearing forces (Snowbridge et al. 2004)
  - Inhibiting expression of genes involved in neointimal hyperplasia (Chen, 2002)
  - Inhibition expression of adhesion molecules (Ouyang et al. 1998)
- Improving and stabilizing flow profile through stenoses (Snowbridge et al. 2004)

Recreate spiral laminar flow pattern
Improve graft performance

Spiral Flow Graft
Dialysis access
Clinical Results:
Spiral Flow AV Grafts

<table>
<thead>
<tr>
<th>Product</th>
<th>Size</th>
<th>Num</th>
<th>Mean Duration</th>
<th>Primary patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiral Flow Graft</td>
<td>El Sayed, USA</td>
<td>48</td>
<td>14 months</td>
<td>70%*</td>
</tr>
<tr>
<td>Spiral Flow Graft</td>
<td>Hoffmann, Austria</td>
<td>16</td>
<td>24 months</td>
<td>72%</td>
</tr>
<tr>
<td>Spiral Flow Graft</td>
<td>Cetingök, Turkey</td>
<td>16</td>
<td>26 months</td>
<td>72%</td>
</tr>
<tr>
<td>Standard PTFE</td>
<td>Pisoni et al</td>
<td>251</td>
<td>12 months</td>
<td>49%</td>
</tr>
</tbody>
</table>

Spiral Flow AVG for dialysis access
Dr. Hosam El Sayed

- 12 months Kaplan-Meier analysis

<table>
<thead>
<tr>
<th>Assisted Primary</th>
<th>Secondary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiral Flow</td>
<td>70±8</td>
</tr>
<tr>
<td>Heparin Bonded</td>
<td>54±9</td>
</tr>
<tr>
<td>Standard ePTFE</td>
<td>43±6</td>
</tr>
</tbody>
</table>

P-Value: 0.01 0.0005

Spiral Flow graft; 2 year follow up
Wolfgang Hofmann, Feldkirch Austria

- 16 dialysis access AVG
  - 11 forearm (all loop)
  - 4 upper arm (2 loop, 2 straight)
  - 1 thigh (loop)
- Median follow-up 24 months
- Duplex US every 3 months
- 4 Graft occlusions
  - 2 successful thrombectomies
- 4 Graft explants
  - 2 for steal
  - 2 for infection

Spiral Flow graft; 2 year follow up
Cetingök U., Kavakkale University Hospital, Turkey

- July 2010 until January 2013
- Implanted in 16 patients for dialysis access
- Mean follow-up 26 months
- No graft infection or pseudoaneurysm
- Primary patency 88%
- Secondary patency 100%
STAAR trial
Spiral Flow Technology Arteriovenous Access Registry

- Device performance in “real world practice”
- Comparison with other grafts
- Vascular Flow Technologies sponsorship
- 75 patient cohort
- Follow up 1 month, 6 months, 1 year
- SVS PSO – does not require IRB approval
- VQU Dialysis Access participant

---

STAAR trial
Current enrollment

- Sites
  - 4 contracted
  - 2 entering
- Patients enrolled: 18
- Follow-up
  - 12 at two weeks
  - 2 at 6 months

To participate, email: STAAR@m2s.com

---

---