Advantages Of Spiral Flow Grafts In Reducing Intimal Hyperplasia

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Disclosures

• Research support Vascular Flow Technologies

Location of Access Failure

• 58% of lesions are within 1 cm of the venous anastomosis.
• 94% are related to the venous end.

Pattern of Access Failure


Li Li et al 2008 Kidney Int ; 74:1247 - 1261

In Vitro Evaluation of Vascular Graft Anastomosis
MRI-Compatible Mock Circulation Schematic
ePTFE Vascular Graft
End-To-Side Anastomosis Construct

Graft Inflow

Vessel Outflow

Graft Suspended In 3% Gelatin

** Anastomosis Sealed With BioGlue®

End-To-Side Anastomosis Construct

Heart Beat Simulator Flow Loop
Software & Actuator

MRI-Compatible Drive Shaft

MRI-Compatible Flow Loop

Heart Beat Simulator Software

End-To-Side Anastomosis

Pump Volume (Laser Volts)
Aortic Flow (L/min)
Graft Flow (L/min)
Aortic Pressure (mmHg)
Graft Pressure (mmHg)
Graft Cross-Sectional Velocity (cm/s)
Hemodynamic Parameters Simulated with CFD

- End to Side Anastomosis

High Oscillatory Shear Index  Low Wall Shear Stress

Pattern of Access Failure

- Prosthetic graft failure is a normal tissue response to an abnormal flow environment
- Endothelial cells at the anastomosis are sensitive to non laminar flow environment (turbulence, stagnation, low shear stress, increased oscillatory index)
- These cells respond by signaling neo-intimal hyperplasia thus promoting failure.

How about in Our Native Vessels

- Right-handed helical flow in the ascending aorta and arch during mid and late systole.

- Descending Aortic Helical Flow
  ASAIO Journal 1996;42:381-956
Vector Flow Map of the Common Femoral artery

Spiral Flow AV Fistulae

- Spiral flow is present in the inflow artery and the outflow vein above the swing segment and not present in the juxta-anastomotic zone.

- This might be an explanation to the high rate of stenosis in the juxta-anastomotic zone of autologous fistulae.

Published Benefits of Spiral Flow

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

Our AVG Experience

- We perform 100-120 AVG cases per year.
- Grafts include
  - Standard ePTFE grafts.
  - Heparin bonded ePTFE grafts.
  - Biologic grafts.
  - Early access grafts.
  - Hybrid grafts.
  - Hero devices.

AV Access Grafts

- Results with prosthetic AV access grafts are far from ideal.

- Benefits of Spiral Flow.

- We decided to use the Spiral flow graft to the AV access field based on early encouraging reports.

Spiral Flow™ AV Graft

- A spiral flow inducer is injected onto the outside of the venous end of the graft.

- One size (6 mm diameter, 45 cm length)
Spiral Flow™ AV Graft

- Prospective study of all cases that had Spiral Flow graft placement for AV access in the upper extremities.
- 48 grafts in 48 patients.
- First graft implanted in January 2012 and the last one in September 2014.

Mean follow up of 10 months.
17 patients completed 12 months follow up
One case was lost to follow up

Demographics

- Mean Age: 59 (20-88)
- Sex: 22 males (46%)
- Comorbidities:
  - Diabetes: 35 (73%)
  - Hypertension: 43 (90%)
  - CAD: 13 (27%)
  - CHF: 13 (27%)
  - CVA: 9 (19%)
  - PVD: 10 (21%)

Upper arm graft: 33
Forearm graft: 12
Chest wall graft: 3

Complications

- Graft infection: 3 (6%)
- Significant Steal: 3 (6%)
- Thrombosis: 6 (13%)
- Venous stenosis: 3 (8%)
- Seroma: 5 (10%)
- Wound complications: 3 (7%)
- Venous hypertension: 8 (17%)
- Pseudo-aneurysm: 0
Spiral Flow™ AV Graft

- Two early graft thrombosis.

Currently in Use

- 31 grafts are currently used (65%).
- 3 grafts were removed for infection.
- 3 grafts were ligated for severe steal.
- 1 graft was ligated for severe arm swelling.
- Seven patients are deceased all with their grafts patent.

Primary Patency at 12 Months

Assisted Primary Patency at 12 Months

Secondary Patency at 12 Months

Patencies (%) at 12 months

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<th>Assisted Primary</th>
<th>Secondary</th>
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<td>Spiral Flow</td>
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<tr>
<td>Heparin Bonded</td>
<td>54±9</td>
<td>71±9</td>
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<tr>
<td>Standard ePTFE</td>
<td>43±6</td>
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<tr>
<td>P-Value</td>
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<td>0.005</td>
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Patencies at 12 Months

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<td>Spiral AVG</td>
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<tr>
<td>Standard ePTFE</td>
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<td>P-Value</td>
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Conclusions

- Spiral flow grafts are a valid and successful option for AV access.
- One year results are encouraging and tend to be better compared to standard straight ePTFE and heparin bonded grafts.
- This may be explained on the basis of improved hemodynamics created by the spiral laminar flow.

Future Plans

- Formalize a prospective trial of Spiral flow grafts in AV access head to head to standard ePTFE and heparin bonded grafts for clinical evidence of their superiority.
- An in vitro and in vivo flow study using MRI to evaluate the pattern of flow with Spiral flow graft and possible optimization of the anastomosis to achieve the best hemodynamic flow environment.