Spiral Flow Technology a Year on: Results of the North American Experience

Hosam F El Sayed, MD, PhD, RVT
CX36 St George Vascular Access Course
04/07/2014
Disclosure

Travel Grant from Vascular Flow Technologies
Causes of Access Failure

Location of Access Failure

• 58% of lesions are within 1 cm of the venous anastomosis.

• 94% are related to the venous end.

Neointimal hyperplasia associated with synthetic hemodialysis grafts
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 Suspended In 3% Gelatin
** Anastomosis Sealed With BioGlue®
End-To-Side Anastomosis Construct
Heart Beat Simulator Flow Loop

Software & Actuator

MRI-Compatible Drive Shaft

Gauss Line

ECG Trigger

MRI-Compatible Flow Loop
Heart Beat Simulator Software
Hemodynamics

Pump Volume (Laser Volts)

Aortic Flow (L/min)

Graft Flow (L/min)

Aortic Pressure (mmHg)

Graft Pressure (mmHg)

Graft Cross-Sectional Velocity (cm/s)

60 B/min
Standard Vascular Graft

End-To-Side Anastomosis
Hemodynamic Parameters Simulated With CFD

- High Oscillatory Shear Index
- Disturbed Flow

End to Side Anastomosis

- Low Wall Shear Stress
- Low WSS
Neointimal hyperplasia associated with synthetic hemodialysis grafts
Li Li et al 2008 Kidney Int ; 74:1247 - 1261
• 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.

Spiral Flow
Spiral flow has been observed in meandering rivers, braided rivers, very shallow sea water, and dust devils.

Rifling is the process of making helical grooves in the barrel of a gun or firearm, which imparts a spin to a projectile around its long axis. This spin serves to stabilize the projectile, improving its aerodynamic stability and accuracy.
How about in Our Vessels
Right-handed helical flow in the ascending aorta and arch during mid and late systole.

# Descending Aortic Helical Flow

<table>
<thead>
<tr>
<th>Position</th>
<th>DOGS (n)</th>
<th>Helical Flow (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>B</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>C</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>D</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>E</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>F</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>G</td>
<td>11</td>
<td>9</td>
</tr>
</tbody>
</table>

ASAIO Journal
1996;42:951-956
Vector Flow Map of the Common Femoral artery
• 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 (Chen, 2002)
  – Inhibition expression of adhesion molecules (Chappelle et al, 1998)

• Improving and stabilizing flow profile through stenoses (Stonebridge et al, 2004)
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.

_Inston et al, presented at the vascular access for hemodialysis XIII Symposium, Orlando, Florida, 2012_
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.
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.
A spiral flow inducer is injected onto the outside of the venous end of the graft.

One size (6 mm diameter, 45 cm length)
Retrospective review of all cases that had Spiral Flow graft placement for AV access in the upper extremities.

- 38 grafts in 37 patients.
Spiral Flow Graft

- Mean follow up of 9 months.
- 15 patients completed 12 months follow up
- One case was lost to follow up
Demographics

- Mean Age: 61 (42-88)
- Sex: 18 males (47%)
- Comorbidities:
  - Diabetes: 25 (66%)
  - Hypertension: 33 (87%)
  - CAD: 8 (21%)
  - CHF: 7 (18%)
  - CVA: 7 (18%)
  - PVD: 8 (21%)
Graft Configuration

- Upper arm graft: 24
- Forearm graft: 11
- Chest wall graft: 3
Complications

- Graft infection: 3 (8%)
- Significant Steal: 3 (8%)
- Thrombosis: 7 (18%)
- Venous stenosis: 3 (8%)
- Seroma: 4 (10%)
- Wound complications: 3 (7%)
- Venous hypertension: 7 (18%)
- Pseudo-aneurysm: 0
• Two early graft thrombosis.
Currently in Use

- 20 grafts are currently used (53%).
- 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.
Secondary Patency

- Heparin Bonded
- Standard PTFE

P = 0.04
### Patencies (%) at 12 months

<table>
<thead>
<tr>
<th></th>
<th>Assisted Primary</th>
<th>Secondary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spiral Flow</strong></td>
<td>81±9</td>
<td>83±9</td>
</tr>
<tr>
<td><strong>Heparin Bonded</strong></td>
<td>60±8</td>
<td>60±8</td>
</tr>
<tr>
<td><strong>Standard ePTFE</strong></td>
<td>47±10</td>
<td>66±9</td>
</tr>
<tr>
<td><strong>P-Value</strong></td>
<td>0.10</td>
<td>0.04</td>
</tr>
</tbody>
</table>
Conclusions

• Spiral flow grafts are a valid and successful option for AV access.
• Early 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

- A formal prospective study of Spiral flow grafts in AV access with larger number of patients with longer follow up and ultrasound examination to evaluate their clinical and hemodynamic behavior in the AV access environment.

- 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.