Vascular Flow Technology: Another run of the mill graft or a breakthrough Technology? US Experience and Perspective
Spiral Flow
Spiral Flow in Nature

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.
Spiral Flow

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>
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</tr>
<tr>
<td>C</td>
<td>12</td>
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<tr>
<td>D</td>
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<td>E</td>
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<td>F</td>
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<td>11</td>
</tr>
<tr>
<td>G</td>
<td>11</td>
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</table>

ASAIO Journal
1996;42:951-956
Vector Flow Map of the Common Femoral Artery
## Published Features of Spiral Flow

<table>
<thead>
<tr>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laminar stability</td>
</tr>
<tr>
<td>Reduced laterally directed forces</td>
</tr>
<tr>
<td>Reduced near-wall turbulence</td>
</tr>
<tr>
<td>Suppresses acute thrombus formation with no increase in platelet activation</td>
</tr>
<tr>
<td>Enhances oxygen flux to the arterial wall</td>
</tr>
<tr>
<td>Reduces luminal surface LDL concentration</td>
</tr>
<tr>
<td>Dampens wall stress temporal gradients</td>
</tr>
<tr>
<td>Lowers oscillatory shear stress index</td>
</tr>
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</table>
Spiral Laminar Flow Prosthetic Bypass Graft: Medium-Term Results From a First-In-Man Structured Registry Study

Peter A. Stonebridge, Frank Vermassen, John Dick, Jill J.F. Belch, and Graeme Houston, Dundee, Scotland and Ghent, Belgium

Background: A number of surgical strategies and graft enhancements have been trialled to improve the performance of prosthetic grafts. Neointimal hyperplasia may, in part, be a normal cellular response to an abnormal (turbulent) flow environment. This first-in-many study assesses the safety and medium-term patency performance of a new graft designed to induce stable laminar flow through the distal anastomosis.

Method: Forty patients who required an infraringuinal bypass graft were recruited/registered from a number of centers in Belgium and The Netherlands. Thirty-nine received a Spiral Laminar Flow graft as part of a standard treatment protocol (23 above-the-knee and 16 below-the-knee bypasses). Kaplan–Meier analyses were used to calculate primary and secondary patency rates.

Results: The 12-, 24-, and 30-month primary patency rates were 86%, 81%, and 81% for above-the-knee bypasses and 73%, 57%, and 57% for below-the-knee bypasses, respectively. In the case of secondary patency rates, numbers were unchanged for above-the-knee bypasses and were 86%, 64%, and 64%, respectively, for below-the-knee bypasses. There were no amputations in the study population.

Conclusion: This first-in-man series shows potential for the idea of spiral flow–enhanced prosthetic grafts. As always, randomized studies are required to explore the role of different enhanced prosthetic grafts.
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.

In Vitro Evaluation Of Vascular Graft Anastomosis
MRI-Compatible Mock Circulation Schematic

Venous Reservoir

Inflow Valve

Graft Flow Control
Resistance Clamp

Pulsatile Pump

Outflow Valve

Flow Probes

P1 Graft Inlet

X

P2 Graft Outlet

Vein Entry Angle

Vein or Artery Graft

Graft Flow Control

Test

Arterial Compliance Chamber

Gore HVG

Arterial Resistance Clamp

Test
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
Heart Beat Simulator Software

Pumps & Pipes

ExxonMobil

Methodist DeBakey Heart & Vascular Center

Build Heartbeat Simulator Settings

Pump
Stop Run

Actuator?
Computer Online Actuator Enabled
Actuator Message

Print Stop

Thursday, March 18, 2010 3:44:15 PM

Load Heartbeat from file Save Heartbeat to file Clear Heartbeat “Zero” Heartbeat

Ventricular Volume Actuator Position %

Min 0.000
Max 100.000
(100% - 200 cc)

R-R Interval milliseconds
(Time)

100.0
200.0
300.0
400.0
500.0
600.0
700.0
800.0
900.0
1000.0
0.0
10.0
20.0
30.0
40.0
50.0
60.0
70.0
80.0
90.0
100.0

0.000
10.000
20.000
30.000
40.000
50.000
60.000
70.000
80.000
90.000
100.000

msecs

60 BPM
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
End to Side Anastomosis

Hemodynamic Parameters Simulated With CFD

End-To-Side Anastomosis
Disturbed Flow

High Oscillatory Shear Index

End-To-Side Anastomosis
Low WSS

Low Wall Shear Stress
• 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.

AV Access Grafts

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

• There is a huge room for improvement.

• 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.
### PRIMARY PATENCY

![Graph showing primary patency over time for Heparin bonded and Standard grafts.](image)

**Proportion Patent**

**Time (Years)**

- **Heparin bonded**
- **Standard**

**Wilcoxon Test**

<table>
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<tr>
<th>Graft</th>
<th>Year</th>
<th>0</th>
<th>0.5</th>
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<th>1.5</th>
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<td>Patency (%)</td>
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<td>69+6</td>
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<tr>
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<td>Patency (%)</td>
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<td>59+5</td>
<td>41+6</td>
<td>28+6</td>
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<tr>
<td></td>
<td># at Risk</td>
<td>104</td>
<td>41</td>
<td>26</td>
<td>12</td>
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**p=0.034**
ASSISTED PRIMARY PATENCY

Wilcoxon Test

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<th>Year</th>
<th>0</th>
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<tr>
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<tr>
<td>Patency (%)</td>
<td>100</td>
<td>82+5</td>
<td>66+6</td>
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<td># at Risk</td>
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<td>50</td>
<td>29</td>
<td>8</td>
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<tr>
<td>Standard</td>
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<tr>
<td>Patency (%)</td>
<td>100</td>
<td>55+6</td>
<td>36+6</td>
<td>22+6</td>
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<tr>
<td># at Risk</td>
<td>104</td>
<td>44</td>
<td>24</td>
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Heparin bonded

Standard

p=0.002
Spiral Flow 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 Graft

- Retrospective review of all cases that had Spiral Flow graft placement for AV access.
- 19 cases in 18 patients.
- First graft implanted in January, 2012 and the last one in February 2013.
- Mean follow up was 6 months.
Demographics

- Mean Age: 60 (42-84)
- Sex: 7 males (37%)
- Comorbidities:
  - Diabetes: 6 (32%)
  - Hypertension: 17 (90%)
  - CAD: 5 (26%)
  - CHF: 4 (21%)
  - CVA: 5 (26%)
  - PVD: 6 (32%)
Graft Configuration

- Upper arm graft: 11
- Forearm graft: 2
- Femoral graft: 5
- Chest wall graft: 1
Complications

- Graft infection: 3 (15%)
- Severe Steal: 2 (10%)
- Thrombosis: 2 (10%)
- Seroma: 3 (15%)
- Wound complications: 3 (15%)
- Arm swelling: 1 (5%)
- Pseudoaneurysm: 0
Currently in Use

- 11 grafts are currently used (58%).
- 3 grafts were removed for infection.
- 2 grafts were ligated for severe steal.
- 1 graft was ligated for severe arm swelling.
- Two patients are deceased (with their grafts functional).
Patency at 6 months

<table>
<thead>
<tr>
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<th>Primary</th>
<th>Assisted Primary</th>
<th>Secondary</th>
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<tbody>
<tr>
<td>SPIRAL</td>
<td>90±9</td>
<td>90±9</td>
<td>100±0</td>
</tr>
<tr>
<td>Heparin Bonded</td>
<td>65±7</td>
<td>75±7</td>
<td>75±7</td>
</tr>
<tr>
<td>STANDARD</td>
<td>53±10</td>
<td>58±10</td>
<td>78±9</td>
</tr>
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</table>
• No early graft failures.
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 flow study to evaluate the pattern of flow with Spiral flow graft and possible optimization of the anastomosis to achieve the best hemodynamic flow environment