Spiral Laminar Flow: A Revolution in Understanding?

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Background: Spiral Laminar Flow in Arteries

- Spiral laminar flow (SLF) has been observed in healthy large and medium size arteries.

- SLF is believed to be created because:
  - The heart is twisted on its axis.
  - The aortic arch is curved, twisted and taped.

- SLF has been associated with:
  - Maintenance of wall shear stress.
  - Reduction of near wall turbulent kinetic energy.
  - Enhanced end organ perfusion.
  - Enhanced oxygen flux to the arterial wall.
  - Protection against the development of atherosclerosis in native sections and implanted devices.
Spiral Flow *in vivo*

Cross section view of spiral flow in internal and external carotid arteries.
Technology - Spiral Flow™

Laminar Flow

Healthy Artery

Standard Graft

SLF™ Graft
Prosthetic graft patency: a product of a normal tissue response to a normal flow environment

- Spiral laminar flow grafts produce normal flow patterns at the distal anastomosis
- Endothelial cells are therefore in a normal flow environment
- Flow mediated signals are not switched on and neointimal hyperplasia is lessened
Turbulence = Graft failure

Spiral shows 30 times less “near wall turbulence”
Spiral flow and double spiral flow can be detected in the transverse plane using colour Doppler.

**Figure 3:** Diagram of spiral and double spiral flow in the cross sectional direction.

**Figure 4:** Diagram of spiral flow in the cross sectional direction [3].
Spiral Flow™ Grafts

- PV Grafts for peripheral vascular treatment.
- AV Grafts for arteriovenous connection.

**Figure 7:** 8 mm ID (up) and 6 mm ID (down) PV spiral grafts. The helical ridge at the end of the grafts creates the rotational flow pattern.

Sketch of AV spiral graft and image of its helical ridge from the front.
Materials and Methods: Doppler Flow Experimental Setup

- UHDC flow pump (Shelley Medicals). Constant flow applied for the presented results.
- BMF: 707 Doppler testing fluid (ATS Laboratories).
- VMM: 15% PVA-cryogel (PVA-c) (0.46% wt Benzalkonium Chloride).
- TMM: 9% glycerol solution.
- HDI 5000 (Philips ATL).
- Z.one plus (Zonare).

Flow pump and phantom.
Materials and Methods: Grafts – PVA-c connections

Left: 8mm ID PV spiral graft connection with PVA-c arterial model. Right: 8 mm ID PV plain graft connection with PVA-c arterial model.
Materials and Methods: Arterial Phantoms

Figure 14: 8mm ID PV spiral graft.

Figure 15: 8mm ID PV plain graft.

Figure 16: 6mm ID AV spiral graft.

Figure 17: 8mm ID AV plain graft.
Results:
8mm PV Spiral Graft

Video 1: Spiral flow loop 5 cm downstream the graft outflow. Graft to PVA-c connection angle 35°, velocity approximately 30 cm/s.

(Scanner used: HDI 5000)
Results:
8mm PV Plain Graft

**Video 2:** Cine loop 5 cm downstream the graft outflow. Graft to PVA-c connection angle 35°, velocity 30 cm/s. This flow pattern has been found to imply double helical flow in previous studies [6].

(Machine used: HDI 5000)

**Figure 19:** Flow formation in the graft outflow. Scanning direction follows that of flow. Doppler parameters as in video.

**Figure 20:** Longitudinal imaging. Doppler parameters as in video 2.
Results:

6mm AV Spiral Graft

Helical flow as it was detected in continuous frames 5 cm downstream the graft outflow. Flow velocity approximately 60 cm/s. PRF 3000 Hz, WF Max, Persistence Med, Gain 79% (HDI 5000).
Results:
6mm AV Plain Graft

Figure 22: AV plain graft outflow as it was detected in continuous frames 5 cm downstream the graft outflow. Flow velocity approximately 60 cm/s. PRF 3000 Hz, WF High, Persistence Med, Gain 79% (HDI 5000).
Spiral Flow™ Grafts
Phase 1 Study

Spiral Flow™ Graft
• Induction of spiral flow at distal anastomosis
• 40 Patients
  • 8 centres in Benelux
• Study inclusion period 02/06 - 10/07
• Follow-up till 07/08
• 60% above knee, 40% below knee
• 57% CLI, 43% Claudication
• 73 % male, 27% female

Participating centers
• Ghent University Hospital (B) F. Vermassen, Chief Investigator
• Amphia Hospital Breda (NL)
• Antwerp Hospital (B)
• Catharina Hospital Eindhoven (NL)
• Imelda Hospital Bonheiden (B)
• Blasius Hospital Dendermonde (B)
• Medisch Spectrum Twente
• Zottgem
# Spiral Flow™ Grafts

## Study Results

<table>
<thead>
<tr>
<th>Spiral Flow™ Graft Patency</th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency Above Knee</td>
<td>87%</td>
<td>81%</td>
</tr>
<tr>
<td>Primary patency Below knee</td>
<td>73%</td>
<td>57%</td>
</tr>
<tr>
<td>Secondary patency Above Knee</td>
<td>86%</td>
<td>81%</td>
</tr>
<tr>
<td>Secondary patency Below knee</td>
<td>86%</td>
<td>64%</td>
</tr>
</tbody>
</table>

NO amputations in series to date
• All grafts and stents create turbulent flow
• Turbulent flow damages endothelial cells leading to intimal hyperplasia
• Intimal hyperplasia is the #1 cause of graft failure
• Only Spiral Flow™ Grafts create normal flow
Other Key Papers on Spiral Laminar Flow™

- “Three-dimensional Blood Flow Dynamics: Spiral/Helical Laminar Flow”, Peter A. Stonebridge, Ch.M.
- “Promising Results of a Spiral Flow Synthetic Vascular Graft: Theory and 2-Year Fem-Pop Results” Frank Vermassen, MD
- “Femoropopliteal Bypass with the Spiral Flow™ (SLF™) Graft: Early Results” Uður Çetingök, MD
- “Hemodynamic effects of spiral ePTFE prosthesis compared with standard arteriovenous graft in a carotid to jugular vein porcine model” Ommid Kh. Jahrome
- “Spiral laminar flow in the abdominal aorta: A predictor of renal impairment deterioration in patient’s with renal artery stenosis?” J. Graeme Houston
Conclusion

- SLF is the naturally occurring arterial blood flow pattern
- SLF reduces turbulence
- Standard Grafts destroy SLF
- VFT PV and AV grafts maintain/reintroduce SLF
- Clinical results PV at 24 months encouraging
- Early results AV encouraging