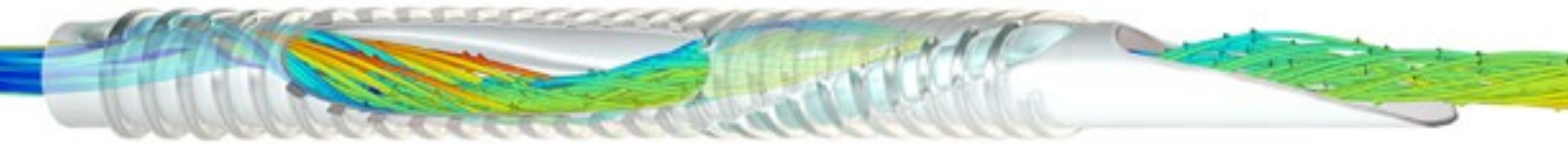


## Spiral Laminar Flow The Evidence



### Section B: Peripheral Bypass Outcome Studies

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# 1. Spiral Flow Prosthetic Grafts In lower extremity bypasses: 1-year results and beyond

PRESENTED AT VEITH SYMPOSIUM NOVEMBER 2014, NEW YORK MR N SHAPER, BRADFORD ROYAL INFIRMARY, UK

## Purpose

The aim of this single centre study was to compare the primary and secondary patency rates at one year of conventional PTFE infrainguinal bypass grafts with a new Spiral Laminar Flow ePTFE graft.

## Methods

Prospective data on primary and secondary patency rates and interventions/complications was gathered on 68 infrainguinal bypasses using Spiral Flow Grafts from February 2011 to October 2014. The data on 136 standard grafts was gathered retrospectively on all infrainguinal PTFE grafts over a six year period from Jan 2003 to Dec 2008. Data was obtained from case notes and surveillance scans. There were no changes in case mix or operative/interventional procedures between the two groups/time periods. Data was also obtained on type of operation, mortality and amputation rates. At one year, data for 54 Spiral Flow Grafts and 124 standard grafts was available for review.

### Patient Demographics

	Spiral Flow™	Conventional ePTFE
Age	69.6 mean (47- 92)	70.3 (45-93)
Sex	78% male	48% male
Critical ischaemia	53%	55%

### Level of Implantation

	Spiral Flow™	Conventional ePTFE
Above Knee	48%	13%
Below Knee/Tibia/Complex	52%	87%

Vein cuffs were added to all BK/distal anastomoses.

Spiral Flow was seen on post-operative imaging at all distal anastomoses and run-off vessels.

## Results

### Primary patency (Actuarial %)

	Spiral Flow™	Conventional ePTFE
Overall	76%	48%
Above Knee	77%	50%
Below Knee/Tibia/Complex	61%	48%

### Secondary patency

	Spiral Flow™	Conventional ePTFE
Overall	87%	55%
Above Knee	88%	71%
Below Knee/Tibia/Complex	79%	53%
Amputation Rate	2%	10%

## Conclusion

Benchmarked against conventional grafts highlights a 30% actuarial improvement in primary and secondary patency. Results out to 3 years, particularly of more complex grafts, would appear to indicate a sustained patency advantage over conventional grafts. Significantly encouraging initial results to warrant continued usage and further long term data acquisition.

## 2. Spiral Laminar Flow and its Influence on Graft Patency: Our Experience with the Spiral Flow Peripheral Bypass Graft in A Multicentre Retrospective Study

PRESENTED AT THE ASSOCIATION OF INTERNATIONAL VASCULAR SURGEONS (AIVS) CONGRESS MARCH 2014, KITZBUHEL, AUSTRIA.

MARUSIAK J, SHIHATA K, ZAJIC J, STRINCL J, RAMBOUSEK Z, SKARYD A, KAVALKOVA V DEPARTMENT OF VASCULAR AND RECONSTRUCTIVE SURGERY. LIBREC GENERAL TEACHING HOSPITAL, DEPARTMENT OF VASCULAR SURGERY, RYCHNOV, DEPARTMENT OF SURGERY, CESKA LIPA, CZECH REPUBLIC

### Objective

Spiral Laminar Flow, SLF, is the natural flow pattern found in healthy arteries. Blood leaves the left ventricle of the heart with a distinctive single spiral flow pattern and is propagated within the arterial system by the spiral configuration of the arterial luminal layers. SLF reduces static wall pressures at the intimal layer and, if destroyed, the severity of arterial disease and the tendency towards myointimal hyperplasia is greater. The Spiral Flow Peripheral Bypass Graft (Vascular Flow Technologies) reintroduces SLF at the distal anastomosis by a novel design at the distal end. To verify the advantages of this design, a series of peripheral bypass procedures using the graft were reviewed.

### Method

A retrospective multicentred, structured study of 72 patients who received the Spiral Flow Graft for peripheral bypass between February 2010 and February 2013 was performed. There were 61 males and 11 females, in which 75 bypasses were constructed; 68% were above knee and 32% were below knee. In all cases, the Fontaine Classification was 2b (severe claudication) or higher. Using duplex ultrasound and Computed Tomographic Angiography (CTA), all patients were scored as level C or D suitable for surgical revascularization according to the TASC IIb morphological stratification guidelines. In all cases the patients received general or epidural anaesthesia and antibiotic prophylaxis. Low molecular heparin was administered postoperatively out to 12 weeks.

### Results

Technical success at implantation was achieved in all 75 cases. The maximum and minimum follow-up was 38 months and 2 months respectively. There were no amputations in the limbs implanted with the Spiral Flow Graft and no cases of peri-operative bleeding or infection. There

were 2 deaths due to serious comorbidities in this high-risk group of patients. Risk factors for vascular disease and indications for surgery were similarly distributed in the above knee and below knee bypasses. Primary patency rate was 85% and secondary patency 96%. 8 of 11 occlusions were successfully reopened with the use of thrombolysis, percutaneous angioplasty or open surgical revision. There were 3 permanent graft occlusions.

## Conclusions

We implanted the Spiral Flow Peripheral Vascular Graft in 72 patients with peripheral occlusive arterial disease. The unique SLF™ technology is based on a renewed understanding of blood flow patterns in the healthy arterial system, the evidence of which is well documented. The mid-term results from this multicentre series of femoro-popliteal bypass procedures using the Spiral Flow Bypass Graft are encouraging.

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## 3. Spiral Laminar Flow grafts show encouraging midterm patency results

PRESENTED AT VEITH SYMPOSIUM NOVEMBER 2013, NEW YORK PROF FRANK VERMASSEN, UNIVERSITY OF GHENT HOSPITAL, BELGIUM.

### Introduction

Advantages of spiral flow laminar flow stability

- Spiral flow preserves laminar flow through a stenosis better reducing turbulent kinetic energy

### Why a Spiral Flow™ graft?

Hypothesis:

- Intimal hyperplasia at the distal anastomosis is a frequent reason for graft failure.
- Development of intimal hyperplasia is a reaction of the blood vessel to abnormal flow patterns
- By inducing normal, spiral flow the development of intimal hyperplasia can be prevented

### Patients and methods

Phase 1 Study using 6 mm ringed ePTFE SLF graft (Vascular Flow Technologies Ltd). Spiral inducer at distal end to induce spiral flow at distal anastomosis

39 Patients from 8 centres in Benelux

Study inclusion 02/06- 10/07; 5 year follow-up till 07/2013

- 73% male, 27% female
- 59% above knee, 41% below knee
- 57% CLI, 43% Claudication
- 3% diabetics
- 43% current smokers

## Results

In 10 random patients the presence of spiral laminar flow at 3-6 months was assessed. All showed the distinctive flow pattern. The five year cumulative patency rates were 62% above knee and 52% below knee.

## Conclusions

- The phase 1 study showed that implantation of the Spiral Flow graft is feasible and safe
  - The Spiral Flow graft induces Spiral Laminar Flow at the distal anastomosis
  - The 5 year results are encouraging compared to published literature
  - Other products incorporating Spiral Laminar Flow technology are in development
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## 4. Use of spiral laminar flow technology in peripheral bypass grafts

PRESENTED AT THE 34TH CHARING CROSS INTERNATIONAL SYMPOSIUM. APRIL 2012 MR N SHAPER, BRADFORD GENERAL HOSPITAL

### Summary of presentation

Spiral Laminar Flow (SLF) exhibits biological advantages:

- Holds cellular components in the centre of the flow
- Reduces near wall kinetic energy turbulence
- Reduces pressure drops across arterial branch points
- Should result in reduced downstream disease progression

A registry series experience using the Spiral Flow PV Graft between Feb 2011 and April 2012

## Demographics

- 17 implanted
- 73% male / 27% female
- Mean age at operation 67.7 (47.6 to 91.3) years
- 47% diabetic
- 30% right leg / 70% left leg
- 47% severe claudication / 53% critical ischemia

## Operative details

- 65% above knee popliteal
- 18% below knee popliteal with vein cuff
- 17% tibial vessels with vein cuff

## Challenging cases

- 1 x 'Y' graft onto distal limb of posterior tibial artery
- 1 x common femoral artery to contralateral distal anterior tibial artery
- 2 x common iliac transobturator to the above knee popliteal artery

## Doppler ultrasound review

SLF observed at distal anastomosis and all run-off vessels in all cases in all post-op and subsequent scans.

## Results at April 2012

- Primary patency rate: 93% at mean follow-up 4.47 (0 to 12.2) months
- Secondary patency rate: 100%, single graft, occluded 5.5 months post-op was successfully thrombolysed; re-occluded three months later, thrombolysed and angioplasty to the tibia-peroneal trunk, patient warfarenised and still patent.

Early results are encouraging with SLF PV grafts showing good primary patency rates.

## Future work

More data required on the performance of the Spiral Flow PV Graft bench marked against conventional grafts.

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## 5. Spiral Laminar Flow Prosthetic Bypass Graft: Medium-Term Results From a First-In-Man

STRUCTURED REGISTRY STUDY ANN VASC SURG. 2012;26:1093- 1099 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-man 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 infrainguinal bypass graft were recruited / registered from a number of centres 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, randomised studies are required to explore the role of different enhanced prosthetic grafts.

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## 6. Mid-Term Results of the Spiral Flow PV Grafts

POSTER AT THE 15TH TURKISH VASCULAR SOCIETY CONGRESS, OCTOBER 2011 DR ÇETİNGÖK, CORUM HOSPITAL, CORUM, TURKEY

### Patients and Methods

47 patients implanted from June 2009 to August 2011 with a mean follow-up period of 14 months. Mean age at operation was 67 (41 to 89) years and 6% were female. 77% were stage IIb and 23% stage III Fontaine Classification.

73 implantations were performed (a number of patients received more than one graft), 45% of patients received above knee (AK) procedures and 55% received a below knee (BK) procedure.

### Results

Five grafts thrombosed (7%) and were all successfully thrombolysed to fully restore patency. There was one patient death unrelated to the graft.

At 14 months mean follow-up primary patency is 93% and secondary is 98%.

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