

## Spiral Laminar Flow The Evidence



### Section A: AV Access Outcome Studies

Click on one of the topics below to jump to that section.

1. [Two year follow-up results for Spiral Flow Grafts in AV Access](#)
2. [Intermediate results of using spiral flow av graft: is it a breakthrough solution to a difficult problem?](#)
3. [Spiral Flow Technology a year on: Results of the North American experience](#)
4. [Early results of using Spiral Flow AV Graft: Is it a breakthrough solution to a difficult problem?](#)
5. [Early experience with the SLF \(Spiral Laminar Flow\) AV Access Graft](#)
6. [A new choice for vascular access: Spiral Flow AV Graft](#)
7. [Vascular Flow Technology: Another run of the mill graft or a breakthrough technology?](#)
8. [Vascular Flow Technology: Another run-of-the-mill graft or a breakthrough technology? Experience and perspective from a US centre](#)

# 1. Two year follow-up results for Spiral Flow Grafts in AV Access

PRESENTED AT THE 37TH CHARING CROSS INTERNATIONAL SYMPOSIUM, APRIL 2015, LONDON, UK PRIM. UNIV.-DOZ.

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## Introduction

The AV access strategy at LKH Feldkirch focusses primarily on utilising native fistula and Duplex mapping of the upper extremity is undertaken to identify the most appropriate approach.

AV grafts are only used in patients not suitable for a native fistula.

Conventional AV grafts typically require one to two revisions per year.

## Methods

Since September 2010, a series of 16 grafts have been implanted in 15 patients. All patients have had previous surgery (mean of 4.3 previous procedures (0-24)).

Mostly loop grafts in the forearm are utilised.

- 11 loop forearm
- 2 loop upper arm
- 2 straight upper arm
- 1 loop thigh
- 4 graft occlusions / two successful thrombectomies
- 4 graft explants (2 due to steal, 2 due to infection)

## Results

The results from 16 Spiral Flow™ AV Grafts, implanted between September 2010 and August 2013 were reviewed. Median follow up was 22 months and all grafts were Duplex scanned every three months to confirm the presence of Spiral Flow. Additional scans were performed if there was any suspicion of graft failure.

At 22 months, the primary rate was 72%; secondary patency was 85.5%

The results were compared to a series of 79 conventional PTFE grafts implanted by Dr Hofmann between January 2005 and December 2009. A Kaplan-Meier analysis highlighted primary patency rates at 18 months of 72% for Spiral Flow™ and 36.7% for conventional PTFE grafts. (P=0.01)

## Conclusion

Changing the flow pattern at the venous anastomosis of AV grafts using the Spiral Flow Technology seems to be a simple but valuable tool in order to improve patency rates of PTFE AV grafts.

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## 2. Intermediate results of using spiral flow av graft: is it a breakthrough solution to a difficult problem?

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J VASC ACCESS 2015; 16(2): 31  
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## Introduction

AV access grafts are used in those patients where there are no available superficial veins for native AV fistula creation.

Their usable life and patency rates are far from being ideal requiring frequent interventions to maintain their use for dialysis. Their failure is usually related to neointimal hyperplasia leading to stenosis of the venous outflow near the venous anastomosis. Studies have shown that, Spiral laminar flow is the normal pattern of flow in most of the large and medium sized vessels *in vivo* as well as many functioning native AV fistulas. The Spiral flow graft has a design that creates a spiral laminar flow at the venous end that is a hypothetically reduces intimal hyperplasia and graft failure. We here report the midterm results of the largest reported series of using the graft in AV access.

## Material & Methods

After IRB approval, a prospective study of using Spiral Flow graft for AV access in our institution between Jan 2012 to Dec 2014 was performed. Enrolled patients had no suitable superficial veins for native AV fistula creation. Patient demographics and comorbidities were recorded. Kaplan Meier curve analysis was used to calculate patency rates compared to historic controls of straight ePTFE and heparin bonded grafts in our institution. Complications were also recorded.

## Results

48 cases were included. The access site was the upper arm (32), the forearm (13), and chest wall (3). Mean age of 61 and mean follow up of 14 months. At 12 month, the assisted primary and secondary patency rates were 70% and 82%, respectively that was significantly better than historic controls using straight ePTFE and heparin bonded grafts in our own institution. Complications included 4 graft infections; 3 severe steal syndrome, 4 seromas and 3 arm swelling. There were only 2 early graft failures.

## Conclusions

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

One year results are superior to using straight ePTFE and heparin bonded grafts. This may be explained on the basis of the hemodynamic environment created by the spiral laminar flow and may be a significant contribution to preventing neointimal hyperplasia and hence AV access graft failure.

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## 3. Spiral Flow Technology a year on: Results of the North American experience

PRESENTED AT THE 36TH CHARING CROSS INTERNATIONAL SYMPOSIUM APRIL 2014, LONDON, UK  
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## Introduction

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 signalling neointimal hyperplasia thus promoting failure. Results with prosthetic AV access grafts are far from ideal. We decided to use the Spiral flow graft for AV access based on early encouraging reports.

## Patients and methods

This is a retrospective review of all cases that had Spiral Flow graft placement for AV access in the upper extremities.

From January, 2012 – January, 2014, 38 Spiral Flow™ AV Access Grafts (Vascular Flow Technologies Ltd) were placed in 37 patients.

The mean age was 61 years (range 42-88 years); 47% (18) were male. Patients presented with the following comorbidities: Diabetes: 25 (66%); Hypertension: 33 (87%); CAD: 8 (21%); CHF: 7 (18%); CVA: 7 (18%); PVD: 8 (21%).

Grafts were implanted as: Upper arm: 24; Forearm: 11; Chest wall: 3

## Results

The mean follow-up was nine months. 15 patients completed 12 months follow up. There are 20 grafts (53%) currently in use. Three grafts were removed for infection, 3 grafts were ligated for severe steal and 1 graft was ligated for severe arm swelling. Seven patients are deceased, all with their grafts patent.

Complications were as follows:

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) and Pseudo-aneurysm: 0

Overall patency (%) results at 12 months are as follows:

Primary Assisted	Secondary
81% ± 9	83% ± 9

## 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.

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## 4. Early results of using Spiral Flow AV Graft: Is it a breakthrough solution to a difficult problem?

POSTER AT SOCIETY FOR CLINICAL VASCULAR SURGERY (SCVS) SYMPOSIUM MARCH 2014, CARLSBAD, CALIFORNIA, USA.

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### Objective

Although, the preferred method to create an access is native AV fistula, there is still a significant number of patients where this is not feasible. AV access grafts are used in those patients and their patency rates are far from being ideal requiring frequent interventions to maintain their use. Their failure is usually related to stenosis of the venous outflow due to intimal hyperplasia, near the venous anastomosis of the graft. Neo-intimal hyperplasia may, in part, be a normal cellular response to an abnormal (turbulent) flow environment created by the AV access. Studies have shown that, Spiral laminar flow is the normal pattern of flow in most of the large and medium sized vessels *in vivo*. The Spiral flow graft has a design that creates a more natural spiral laminar flow at the venous end that is a hypothetically a more friendly hemodynamic environment thus reducing intimal hyperplasia and graft failure. We here report the early results of the largest available series of using the graft in AV access.

### Method

Retrospective review of all cases using the Spiral Flow graft for AV access in our institution, Jan 2012 to Jan 2014. Patients selected had no suitable superficial veins for native AV fistula. Patient demographics and comorbidities were recorded. Kaplan Meier curve analysis was used to calculate primary, assisted primary and secondary patency rates in comparison to historic controls of straight ePTFE and heparin bonded grafts for the same indication in our institution. Complications were also recorded.

### Results

A total of 38 cases were included. The access site was the arm (24), the forearm (11), and chest wall (3). Two thirds were females, mean age of 60 years and mean follow up of 8 months. At 12 month, the primary, assisted primary and secondary patency rates were 73%, 73% and 79%, respectively. Complications included 4 graft infections; 3 severe steal syndrome, 4 seromas

and 2 arm swelling. There was only 1 early graft failure. There was only one early graft failure in less than 30 days in a patient with known hypercoagulable state who was not therapeutic on anticoagulation.

	Primary	Primary Assisted	Secondary
Spiral AVG	73 ± 8	73 ± 8	79 ± 8
Heparin bonded	56 ± 8	60 ± 8	59 ± 8
Standard ePTFE	38 ± 10	47 ± 10	66 ± 11
P-Value	0.055	0.16	0.042

*12 month patency rates*

## Conclusion

Spiral flow grafts are a valid and successful option for AV access. One year results tend to be significantly superior to using straight ePTFE and heparin bonded grafts. This may be explained on the basis of the hemodynamic environment created by the spiral laminar flow and may be a significant contribution to preventing neointimal hyperplasia and hence AV access graft failure.

## 5. Early experience with the SLF (Spiral Laminar Flow) AV Access Graft

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## Background

Arteriovenous grafts for dialysis are associated with a high incidence of outflow stenosis requiring re-intervention and increased risk of failure. Pathological flow patterns promote neointimal hyperplasia in the outflow vein and attempts to improve graft outcomes have resulted in innovative graft technologies. One such strategy involves the generation of spiral laminar outflow from the graft and the SLF AV graft (Vascular Flow Technologies, Dundee) is

designed to recreate normal patterns of blood flow to reduce outflow stenosis. The aims of this study were to audit the early clinical outcomes of SLF grafts in a patient series from two European units.

## Materials & Methods

A prospective series of implants was been collated from two surgeons series. The decision to use an SLF was based on surgeon preference and the site of implant based on clinical parameters. Flow was determined using Doppler ultrasound. For clinical outcomes data was collected prospectively with a standardized data collection tool at set time points post surgery.

## Results

Since September 2010 twelve SLF-AV Access grafts were implanted. All grafts were used in patients with complex access histories (median of 6 previous AV access procedures). One graft failed immediately, the cause attributed to poor inflow (small diseased high bifurcation brachial artery and hypotension). Of the eleven with immediate function two failed (56 days and 58 days). Thrombectomy was performed and no outflow stenosis was demonstrated in either. Despite this both grafts re-clotted within 24 hours. Primary patency in the series is 75% at a mean time point of 188 days (range 0 to 448). One superficial wound infection occurred which required surgical intervention. No graft infections occurred requiring graft intervention.

## Conclusions

Whilst this represents a small series with limited follow up this early experience of the SLF AV is encouraging. Doppler studies support the SLF generating spiral flow at the distal (graft to vein) outflow and the short term data herein supports a low incidence of outflow stenosis with excellent primary patency to date.

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## 6. A new choice for vascular access: Spiral Flow AV Graft

IN ABSTRACTS FROM VAS 8TH INTERNATIONAL CONGRESS, APRIL 25-27, 2013 PRAGUE, CZECH REPUBLIC. J VASC ACCESS 2013; 14(1): 36-37

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### Background

The most commonly used grafts for vascular access are the polytetrafluoroethylene (PTFE) grafts. Different types of PTFE grafts are used in the vascular access applications for a long time. Neointimal hyperplasia at the distal anastomosis is one of the primary failure modes for prosthetic grafts resulting in occlusion and loss of function. The Spiral Flow Vascular Access Graft is a wrapped, expanded polytetrafluoroethylene (ePTFE) graft with custom features injection moulded of Chronoflex polyurethane. The distal portion of the graft contains the patented Spiral Flow™ Inducer, the Inducer Indicator Ring and pre-cut distal anastomotic cuff. The injection moulded components of the graft are non-removable.

### Materials & Methods

From July 2010 until January 2013, Spiral Laminar Flow PTFE Graft (Vascular Flow Technologies Ltd., UK) was implanted in 16 patients for vascular access. Primary graft implantation was performed in 2 patients.

### Results

Mean follow-up was 26 months. The complications as graft infection, pseudoaneurysm, venous hypertension was not seen and thrombectomy was performed two patients due to graft thrombosis. Primary patency rate was 88% and secondary patency rate was 100% during follow-up.

### Conclusions

The process of blockage caused by neointimal hyperplasia in and near the graft-vein anastomosis is driven to a large part by disturbed or turbulent flow. The Spiral Flow™ Vascular Access Graft delivering less turbulent energy by utilizing Spiral Laminar Flow™ delivering blood flow into the venous system like a native AV fistula should: Improve device patency, prolong the effective life of devices, reduce downstream disease progression, improve patient quality of life. This flow pattern can be determined with color doppler ultrasound study using a transverse interrogation of the vessel at low velocity settings. The “red/blue split” seen in transverse color

doppler ultrasound study is characteristic of spiral laminar flow and is usually seen in healthy arteries. The goal of this study is to determine if the SLF™ Graft creates spiral laminar flow and if that might contribute to improved patency.

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## 7. Vascular Flow Technology: Another run of the mill graft or a breakthrough technology?

EXPERIENCE AND PERSPECTIVE FROM A EUROPEAN CENTRE.

PRESENTED AT THE 35TH CHARING CROSS INTERNATIONAL SYMPOSIUM, 7TH APRIL, 2013, LONDON, UK

PRIM. UNIV.-DOZ. DR. WOLFGANG J. HOFMANN

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### Background

The AV access strategy at LKH Feldkirch focusses primarily on utilising native fistula and Duplex mapping of the upper extremity is undertaken to identify the most appropriate of the following approaches:

- Cimino Brescia Fistula
- Cubital Fistula
- Ulnar Artery – Basilic Vein Shunt
- Transposition and Shunting of the Basilic Vein

AV prosthetic grafts are only used in patients if using a native fistula is not possible. So these are negatively selected. Conventional AV grafts typically require one to two revisions per year. There is neointimal hyperplasia at the heel, toe and bed of the anastomosis. This is due to turbulence at the venous anastomosis.

In order to prevent stenosis and occlusion a number of tactics were tried unsuccessfully in the last 10 years, including:

- Configuration of the Anastomosis (Venaflo®)
- External beam radiation
- Patchplasty
- PTA (repetitive)

On introduction to the Spiral Flow graft in 2010, a Duplex scan confirmed that this spiral movement in a normal healthy artery is real and if you can see it. The first Spiral Flow graft implantation was undertaken in September 2010.

More than 26 months after implantation, that graft is working well and we have spiral flow at the venous anastomosis.

## Method

Since September 2010, a series of 10 cases have been completed so far. All patients have had previous surgery (mean of 3.8 previous procedures; median of 3) Only three patients were diabetic, which is less than our average. Mostly loop grafts in the forearm are utilised.

## Results

Only one problem was observed. One patient had an early occlusion of graft only two months after implantation. A revision was undertaken thinking that the venous anastomosis could be slightly better in a more proximal position. Another spiral graft was implanted but it thrombosed also. As it was discovered that this patient is an alcoholic, who is said to sleep with his head on his arm (directly over the graft), it was decided to abandon further graft therapy (the patient is now on a dialysis cannula).

Currently, 10 grafts have been implanted in nine patients with a mean follow-up of six months. Only two failures were observed, both in the same patient. All other grafts are patent and on haemodialysis with no evidence of neointimal hyperplasia (NIH) under Duplex review.

- 10 grafts in nine patients
- Mean follow up 6.1 months (range: 31 – 1 months)
- Two early failures in one patient (patient deemed not suitable for treatment)
- All other grafts patent (80%) without evidence of NIH in Duplex control

## Conclusion

From our European perspective, this Spiral Flow Graft, which restores the natural blood flow pattern, seems to be a strong tool to prevent stenosis at the AV graft venous anastomosis.

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## 8. Vascular Flow Technology: Another run-of-the-mill graft or a breakthrough technology? Experience and perspective from a US centre

PRESENTED AT THE 35TH CHARING CROSS INTERNATIONAL SYMPOSIUM, LONDON, UK 7 APRIL 2013.

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### Patients and methods

From January, 2012 – February, 2013, 19 Spiral Flow™ AV Access Grafts (Vascular Flow Technologies Ltd) were placed in 18 patients. The mean age was 60 years (range 42-84 years); 37% (7) were male. Patients presented with the following comorbidities: six diabetes (32%); 17 hypertension (90%); five CAD (26%); four CHF (21%); five CVA (26%); six PVD (32%). Grafts were implanted as: 11 upper arm; two forearm; five femoral; and one chest wall.

### Results

The mean follow-up was six months. There are 11 grafts (58%) still in use. Three grafts (15%) were removed for infection; two grafts thrombosed (10%); two grafts were ligated for severe steal (10%). There were two grafts with seroma (10%), but they remained functional. There were three wound complications (15%) and three arm swelling (15%). One graft was ligated (5%). There were no pseudoaneurysms. Two patients died with functioning grafts.

Overall patency results are as follows:

Primary	Primary Assisted	Secondary
90% ± 9%	90% ± 9%	100% ± 0%

### Conclusion

The early results are encouraging and tend to be better compared to standard straight ePTFE and heparin bonded grafts. This might be explained on the basis of improved haemodynamics created by the spiral laminar flow.