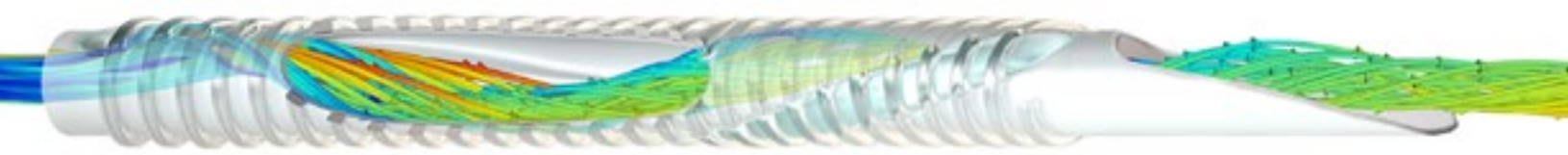
VascularFlow

Spiral Laminar Flow
The Evidence



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VascularFlow

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

PRESENTED AT THE 37TH CHARING CROSS INTERNATIONAL SYMPOSIUM, APRIL 2015, LONDON, UK PRIM. UNIV.-DOZ.
DR. WOLFGANG J. HOFMANN, DEPARTMENT OF VASCULAR SURGERY, LANDESKRANKENHAUS, (LKH) FELDKIRCH, AUSTRIA

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?

IN ABSTRACTS FROM VAS 9TH INTERNATIONAL CONGRESS, APRIL 15-18, 2015 BARCELONA, SPAIN.
J VASC ACCESS 2015; 16(2): 31
HOSAM F. EL SAYED, HOUSTON METHODIST HOSPITAL, HOUSTON, UNITED STATES

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
HOSAM EL SAYED, MD, ASSISTANT PROFESSOR OF CARDIOVASCULAR SURGERY, METHODIST DEBAKEY HEART AND VASCULAR CENTER, HOUSTON, TEXAS, USA.

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 neo-intimal 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.

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.
HOSAM F. EL SAYED, MD, JAVIER E. ANAYA-AYALA, MD, MARK DAVIES, MD. HOUSTON METHODIST DEBAKEY HEART & VASCULAR CENTER, HOUSTON, TEXAS, USA

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.

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

IN ABSTRACTS FROM VAS 8TH INTERNATIONAL CONGRESS, APRIL 25-27, 2013 PRAGUE, CZECH REPUBLIC. J VASC ACCESS 2013; 14(1): 43
INSTON N1, HOFMANN WJ2.
1 DEPARTMENT OF RENAL SURGERY, QUEEN ELIZABETH HOSPITAL, UNIVERSITY HOSPITALS BIRMINGHAM, BIRMINGHAM, UK
2 DEPARTMENT FOR VASCULAR SURGERY, FELDKIRCH GENERAL HOSPITAL, FELDKIRCH, AUSTRIA

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.

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
CETINGOK U, DEPARTMENT OF CARDIOVASCULAR SURGERY, KAVAKLIDERE UMUT HOSPITAL, ANKARA, TURKEY

Background

The most commonly used grafts for vascular access are the polytetraflouroethylene (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
DEPARTMENT OF VASCULAR SURGERY, LANDESKRANKENHAUS (LKH) FELDKIRCH, AUSTRIA

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 tired 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.

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.
HOSAM EL SAYED, MD
ASSISTANT PROFESSOR OF CARDIOVASCULAR SURGERY.
METHODIST DEBAKEY HEART AND VASCULAR CENTER, HOUSTON, TEXAS, USA.

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:

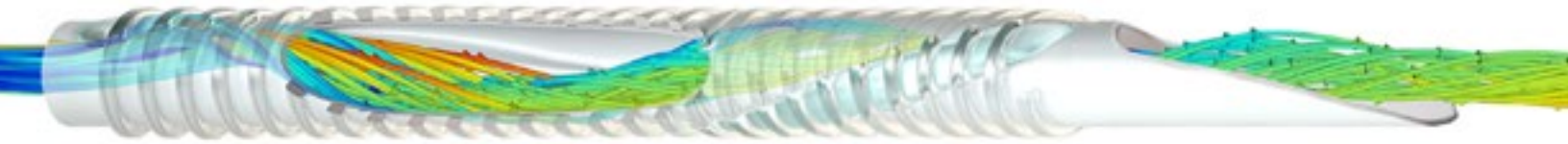
Primary	Primary Assisted	Secondary
90% ± 9%	90% ± 9%	100% ± 0%

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.

VascularFlow

Spiral Laminar Flow
The Evidence



Section B:
Peripheral Bypass Outcome Studies

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

1. **Spiral Flow Prosthetic Grafts In lower extremity bypasses: 1-year results and beyond**
2. **Spiral Laminar Flow and its Influence on Graft Patency: Our Experience with the Spiral Flow Peripheral Bypass Graft in A Multicentre Retrospective Study**
3. **Spiral Laminar Flow grafts show encouraging midterm patency results**
4. **Use of spiral laminar flow technology in peripheral bypass grafts**
5. **Spiral Laminar Flow Prosthetic Bypass Graft: Medium-Term Results From a First-In-Man**
6. **Mid-Term Results of the Spiral Flow PV Grafts**

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

PRESENTED AT VEITH SYMPOSIUM NOVEMBER 2014, NEW YORKMR 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 PFTE 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 VDEPARTMENT OF VASCULAR AND RECONSTRUCTIVE SURGERY. LIBEREC 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 YORKPROF 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 2012MR 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.

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

STRUCTURED REGISTRY STUDY ANN VASC SURG. 2012;26:1093- 1099PETER 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.

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

POSTER AT THE 15TH TURKISH VASCULAR SOCIETY CONGRESS, OCTOBER 2011DR ÇETINGÖK, 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%.

Please reach out with any questions or inquiries to:
inquiries@vascular-flow.com

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Spiral Laminar Flow
The Evidence

Section C:
In Vivo Human Studies

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

1. Patterns of blood flow as a predictor of maturation of arteriovenous fistula for haemodialysis

J VASC ACCESS 2014;15 (3): 169-174YAZIN MARIE1, ALISON GUY1, KAREN TULLETT1, HARI KRISHNAN1, ROBERT G. JONES2, NICHOLAS G. INSTON1
1 DEPARTMENT OF RENAL SURGERY
2 DEPARTMENT OF INTERVENTIONAL RADIOLOGY
QUEEN ELIZABETH HOSPITAL, UNIVERSITY HOSPITALS BIRMINGHAM NHS TRUST, BIRMINGHAM, UK

Purpose

A palpable “thrill” is traditionally associated with success following arteriovenous fistula (AVF) surgery. A thrill typically characterizes turbulent flow and this is a paradox as turbulence is a driver of neointimal hyperplasia. Spiral laminar flow (SLF) has been described as normal and protective pattern of flow in native arteries and is associated with superior patency in bypass grafts that generate it. The aim of this study was to define the pattern of flow within AVFs immediately post-operatively and at follow-up to assess maturation.

Methods

Doppler ultrasound was used immediately post-operatively and at follow-up (6 weeks). Blood flow was assessed as SLF or non-SLF. Two blinded qualified observers analysed the images. Patients were followed up for 6 months. Maturation was statistically analysed against the type of flow.

Results

Sequential patients having AVF surgery (n=56) were assessed: 46 (82%) patients had a thrill, 3 patients had no flow and 7 patients had pulsatile flow without a palpable thrill. SLF was present in 80% of those with a thrill but not in any without a thrill ($p<0.0001$). At follow-up (n=51) 41, patients had a matured AVF (80%), of which 76% had SLF immediately post-operatively. Only one patient with SLF failed to mature. In the non-SLF group 5 of the 15 AVFs failed to mature (66%; $p<0.005$).

Conclusions

SLF was strongly supportive of successful fistula maturation. A “thrill” was characteristic of spiral rather than turbulence. The mechanism of this apparent beneficial effect of this pattern of flow requires further investigation.

2. The characteristic flow pattern of a “thrill” in Autologous AV Fistulae above the swing segment is spiral flow rather than turbulence

PRESENTED AT THE VASCULAR ACCESS FOR HAEMODIALYSIS XIII SYMPOSIUM, MAY 9-11, 2012, ORLANDO, FLORIDA, USANICK G. INSTON, MD, YAZIN MARIE, STEPHEN J. MALLOR, HARI KRISHNAN AND ROBERT JONES

Objectives

In healthy individuals arterial blood flow has been characterized as having a spiral laminar pattern (Stonebridge P et al 1991). A loss of this pattern of flow is associated with pathology (Houston G et al 2004). It can be hypothesized that the effect of the spiral nature of flow is to maintain healthy physiologic levels of shear stress on endothelial cells. Pathological flow patterns and reduction of shear stress result in loss of atheroprotective mechanisms and promote pathology such as neointimal hyperplasia.The desired characteristic of a successful AVF is a thrill typically associated with turbulent flow. The aim of this study was to characterize the nature of flow in autologous AVF and assess spiral flow specifically.

Methods

Using Doppler ultrasound both brachiobasilic and radiocephalic AVF were assessed in the peri-operative period for the characteristic flow patterns. AVFs were assessed immediately post operatively at the swing segment and 5cm above the swing segment in vein that had not been operated on.

Results

In patients with an immediate post-operative thrill (RCF n=10; BCF n=10) spiral flow was demonstrated within all fistulas in the vein above the swing segment. Within the swing segment flow was not spiral and had turbulent characteristics. The inflow artery in all cases demonstrated spiral flow.

Conclusion

The demonstration of spiral flow in the non-operated segment of AVFs has major implications. The low incidence of stenoses within this segment supports the hypothesis that spiral flow is atheroprotective whereas turbulent flow is pathological. In addition the demonstration of flow changing from spiral flow in the artery to turbulent in the swing section and then restoration of spiral flow in the vein supports the vein ultrastructure as the mediator of spiral flow. The impact of spiral flow on AVF maturation and function is currently under investigation.

3. The Presence of Spiral Laminar Flow in Autologous Arterio-venous Fistulae

POSTER AT THE VASCULAR ACCESS SOCIETY OF BRITAIN AND IRELAND SYMPOSIUM, SEPTEMBER 2011, BRIGHTON, UKGUTHRIE, SUTTIE, ROSS, LEVISON & STONEBRIDGE

Purpose

In non-atherosclerotic vessels, flow is predominantly 'spiral laminar' rather than laminar. Spiral Laminar Flow (SLF) stabilises flow patterns at regions of arterial branching. Non SLF at stenotic segments results in poor flow cohesion, increasing turbulence. SLF has been shown to prevent the development of renal and carotid artery stenosis.We aimed to determine if SLF is present in arterio-venous fistulae (AVF) and correlate this with flow limiting stenosis.

Methods

Patients attending routine duplex surveillance of their arterio-venous fistula for haemodialysis (September-November 2010), were assessed for SLF in the venous limb of their AVF. Data collected included: age; sex; type of AVF; primary AVF or not (fistula number); presence of flow limiting stenosis.

Results

We recruited 33 (15 male, 18 female) consecutive patients (mean age of 68 years, range 30-94 years). All AVF were autologous, 10/33 radiocephalic, 15/33 brachiocephalic and 8/33 brachiobasilic with superficialisation and all were being utilised for haemodialysis at time of surveillance. The majority were primary fistulae (24/33), seven being secondary and two being tertiary AVF. SLF was identified in 31 of the AVF, with 10 noted to a have non flow limiting stenosis.
Age, fistula type and fistula number had no significant impact on stenosis formation. Due to only two AVF without SLF, association between stenosis, age, sex, AVF type and number with SLF was not conclusive.

Conclusion

Spiral Laminar Flow is present in autologous arterio-venous fistula with no flow limiting stenosis. We continue to collect data to determine if Spiral Laminar Flow affects patency and flow of arterio-venous fistulae.

4. Three-dimensional blood flow dynamics: spiral/helical laminar flow

METHODIST DEBAKEY CARDIOVASC J. 2011 JAN-MAR;7(1):21-6. STONEBRIDGE P.

Recent work in cardiac and peripheral vascular blood flow has shown evidence for an elegant complexity to flow within the heart and in the large to medium arteries. Blood flow is normally described as laminar in that the blood travels smoothly or in regular paths.
The velocity, pressure, and other flow properties at each point in the fluid remain constant, all parallel to each other. Our understanding has revolved around a two-dimensional representation of flow within three-dimensional blood vessels.
However, MRI and colour Doppler flow imaging techniques have demonstrated that there is a spiral/helical/rotational property to laminar blood flow. The column of blood turns on a central axis as it passes along the major arteries.

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5. Spiral laminar flow in the abdominal aorta: a predictor of renal impairment deterioration in patients with renal artery stenosis?

NEPHROL DIAL TRANSPLANT. 2004 JUL;19(7):1786-91. EPUB 2004 MAY 25
HOUSTON JG, GANDY SJ, MILNE W, DICK JB, BELCH JJ, STONEBRIDGE PA.
TAYSIDE UNIVERSITY HOSPITALS, CLINICAL RADIOLOGY, DUNDEE, UK. GRAEME.HOUSTON@TUHT.SCOT.NHS.UK

Background

Spiral or helical arterial blood flow patterns have been widely observed in both animals and humans. The absence of spiral flow has been associated with carotid arterial disease. The aim of this study was to detect the presence of aortic spiral flow using magnetic resonance imaging (MRI) and to evaluate the relationship of the presence of spiral aortic flow with renal arterial disease and renal function in the follow-up of patients with suspected renal atheromatous disease.

Methods

Prospective study of 100 patients with suspected renal arterial disease and 44 patient controls. Using a 1.5 T MRI unit (Siemens Symphony), phase contrast flow quantification and three-

dimensional contrast enhanced MR angiography of the abdominal aorta were performed. Renal arterial stenoses (RAS) were classified minimal, moderate or severe. Renal function was followed at 3 months before and 6 months after MRI.

RESULTS:

Non-spiral flow was more prevalent in patients with more severe RAS. Renal impairment progressed significantly in severe RAS without spiral flow (P = 0.0065), but did not progress significantly in severe RAS with spiral flow (P = 0.12). In minimal or moderate RAS with or without spiral flow there was no significant progression (P = 0.16, 0.13, 0.47, 0.092, respectively).

Conclusion

Aortic spiral blood flow can be assessed with MRI. Lack of aortic spiral blood flow in patients with severe RAS is associated with significant short-term renal function deterioration. Determination of blood flow patterns may be a useful indicator of renal impairment progression in patients with suspected renal artery stenosis.

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6. Two-dimensional flow quantitative MRI of aortic arch blood flow patterns: Effect of age, sex, and presence of carotid atheromatous disease on prevalence of spiral blood flow

J MAGN RESON IMAGING. 2003 AUG;18(2):169-74.
HOUSTON JG, GANDY SJ, SHEPPARD DG, DICK JB, BELCH JJ, STONEBRIDGE PA.
DEPARTMENT OF CLINICAL RADIOLOGY, NINEWELLS HOSPITAL AND MEDICAL SCHOOL, TAYSIDE UNIVERSITY HOSPITALS NHS TRUST, DUNDEE, SCOTLAND, UK. GRAEMEH@TUHT.SCOT.NHS.UK

Purpose

To determine the effect of age, sex, and presence of carotid atheromatous disease on the presence of aortic spiral blood flow pattern using two-dimensional flow quantitative magnetic resonance imaging (MRI).

Materials & Methods

Sixty subjects (37 women, 23 men) were examined. Prospective phase contrast flow quantitative MRI (1.5 T, Siemens Symphony) sequences in the plane of the aortic arch, and three-dimensional contrast-enhanced MR angiography of the vessels from the aortic arch to the circle of Willis, were performed. Flow quantitative analysis, using circular regions of interest, in the root, apex, and descending aortic arch to determine the presence of a spiral blood flow pattern was undertaken. The results were correlated with the subjects age, sex, and presence of significant carotid arterial disease.

Results

A spiral blood flow pattern was seen during diastole in 43 of 50 (86%), 42 of 48 (88%), and in 26 of 28 (93%) subjects in the root, apex, and descending aortic arch, respectively. Spiral flow was seen during systole in 14 of 35 (40%), 20 of 47 (42%), and 11 of 31 (35%) subjects in the root, apex, and descending aortic arch, respectively. There was no clear effect of age or sex on the presence of spiral flow.
Carotid disease was associated with a significant reduction in the prevalence of systolic spiral flow from 51%-19% subjects ($P < 0.05$).ConclusionSpiral flow pattern can be seen in the arch of the aorta in clinical practice using flow quantitative MRI. The prevalence of spiral flow pattern does not appear affected by subject age or sex. Carotid atheromatous disease is associated with a reduction in prevalence of systolic spiral flow pattern in the aortic arch.

Conclusion

Spiral flow pattern can be seen in the arch of the aorta in clinical practice using flow quantitative MRI. The prevalence of spiral flow pattern does not appear affected by subject age or sex. Carotid atheromatous disease is associated with a reduction in prevalence of systolic spiral flow pattern in the aortic arch.

7. 4D magnetic resonance velocity mapping of blood flow patterns in the aorta in young vs. elderly normal subjects

J MAGN RESON IMAGING. 1999 NOV;10(5):861-9. BOGREN HG, BUONOCORE MH.

Abstract

Four-dimensional magnetic resonance MR velocity mapping was developed to study normal flow patterns in the thoracic aorta using time-resolved cardiac gated three-directional velocity data. Sixteen normal subjects were studied, one young group (average age 31 years) and one group with elderly people (average age 72 years). Blood flowed in a right-handed helix from the ascending aorta to the aortic arch. A straight flow pattern or a left-handed helix was seen in the descending aorta. Blood flow was never parabolic. Blood flowed forward in early systole, retrograde in mid-to-end systole, and forward again in diastole in all subjects as a basic pattern. Continuous retrograde flow over a long distance was not seen, but blood entered a retrograde flow column at various levels.

In young people blood passed from the aortic valve to the mid-descending aorta in less than one heartbeat. In people in their sixties it took two heartbeats and in people older than 78 years, it took three heartbeats.

The maximum systolic forward velocities were higher in young subjects than in elderly while the retrograde velocities were lower.

8. Spiral laminar flow *in vivo*

CLIN SCI (LOND). 1996 JUL;91(1):17-21.
STONEBRIDGE PA, HOSKINS PR, ALLAN PL, BELCH JF.
DEPARTMENT OF SURGERY AND MEDICINE, NINEWELLS HOSPITAL, DUNDEE, U.K.

Blood flow patterns are poorly understood despite their impact on arterial disease. There have been few measurements *in vivo* of the three-dimensional blood flow patterns; we present the results of such studies using a new non-invasive *in vivo* method of examining biplanar arterial blood flow patterns.

Multiple colour Doppler ultrasound directional velocity images were obtained at two different beam target angles from the artery in the plane perpendicular to its axis. Ensemble average images were constructed; the absolute velocity and direction were calculated by compounding the left and right averaged images. Simple directional, non-directional velocity and vector maps were constructed.

Flow patterns were sampled in 11 healthy male volunteers at four points of the pulse cycle; peak systole, systolic downswing, diastolic reverse flow and diastolic forward flow and at three sites; the right common and distal superficial femoral and the left common femoral arteries. Stable rotational flow was observed in all subjects, the direction of rotation varying between sides and individuals.

There are theoretical advantages to spiral laminar blood flow; the forward-directed, rotationally induced stability and reduction of laterally directed forces may reduce turbulence in the tapering branching arterial tree and at stenoses and have a beneficial effect on mechanisms of endothelial damage and repair.

9. Helical and retrograde secondary flow patterns in the aortic arch studied by three-directional magnetic resonance velocity mapping

CIRCULATION. 1993 NOV;88(5 PT 1):2235-47. KILNER PJ, YANG GZ, MOHIADDIN RH, FIRMIN DN, LONGMORE DB.

Background

Helical and retrograde secondary flows have been recorded in the aorta, but their origins and movements in relation to the arch have not been clarified. We set out to do this using magnetic resonance velocity mapping.

Methods & Results

Three-directional phase contrast cine magnetic resonance velocity mapping was used to map multidirectional flow velocities in the aortas of 10 healthy volunteers.
Computer processing was used to visualize flow vector patterns in selected planes.
Right-handed helical flows predominated in the upper aortic arch in late systole, being clearly recognizable in 9 of the 10 subjects.
Non-axial components of velocity in this region reached 0.29 m/s (+/- 0.05 m/s) as axial velocities declined from a peak of 1.0 m/s (+/- 0.1 m/s).
Helical flow patterns in the upper descending aorta varied between subjects, apparently depending on arch curvature. End-systolic retrograde flow originated from regions of blood with low momentum, usually along inner wall curvatures.
Flow studies in a curved tubular phantom showed right-handed helical flow in the upper “arch” when the inflow section was positioned to simulate ascending aortic curvature, and retrograde flow occurred along the inner wall at end systole during pulsatile flow.

Conclusion

Helical and retrograde streams are consistent features of intra-aortic flow in healthy subjects that result, at least in part, from the curvature of the arch and the pulsatility of flow in it.
They may have significance in relation to circulatory dynamics and the pathogenesis of atheroma in the arch.

10. Spiral laminar flow in arteries?

LANCET. 1991 NOV 30;338(8779):1360-1.STONEBRIDGE PA, BROPHY CM.VASCULAR SURGERY UNIT, ROYAL INFIRMARY, EDINBURGH, UK.

Spiral blood-flow patterns in infrainguinal blood-vessels were observed at angioscopy in 54 patients who underwent peripheral vascular reconstruction; the endoluminal surface had spiral folds in 51 of 75 arteries examined.
Spiral flow patterns, congruous with inherent endoluminal anatomical features, might more accurately represent blood-flow in infrainguinal arteries than current models of laminar flow.

Please reach out with any questions or inquiries to:
inquiries@vascular-flow.com

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Spiral Laminar Flow
The Evidence

Section D:
In Vitro, Animal and Scientific Studies

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

1. Computational comparison of spiral and non-spiral peripheral bypass grafts

POSTER AT 7TH WORLD CONGRESS OF BIOMECHANICS, JULY 2014, BOSTON, USA
KOKKALIS E1,2, HOSKINS PR3, VALLURI P4, CORNER GA5, DUCE SL2, HOUSTON JG2
1 INSTITUTE FOR MEDICAL SCIENCE AND TECHNOLOGY,
2 CARDIOVASCULAR AND DIABETES MEDICINE,
3 CENTRE FOR CARDIOVASCULAR SCIENCE,
4 CHEMICAL ENGINEERING, UNIVERSITY OF EDINBURGH, EDINBURGH, UK
5 MEDICAL PHYSICS, UNIVERSITY OF DUNDEE, DUNDEE, UK,

Introduction

A peripheral vascular graft is used for the treatment of peripheral arterial disease. Restenosis in the distal anastomosis is the main reason of occlusion and is related to haemodynamics. Single spiral flow is a normal feature in vessels.
A graft designed to generate a single spiral in its outflow (VFT Ltd, Dundee, UK) has been introduced in clinical practice. This study compared the spiral graft with a control non-spiral using image-guided modelling.

Methods

Both grafts were housed in ultrasound flow phantoms. Anastomotic angle θ was applied at 20°, 40°, 60° and 80°. The phantoms were scanned with CT (Biograph mCT, SIEMENS, Germany) and the graft-vessel mimic lumen geometry was extracted with Amira (FEI Visualization, France). Based on these geometries volume meshes were created (ICEM CFX, ANSYS, Canonsburg, USA), which consisted of tetrahedral cells in the core and prismatic cells in the wall boundary.
Mesh independence tests were applied based on maximum wall shear stress and velocity. The blood was assumed Newtonian, homogeneous and incompressible, the walls rigid and the inflow a steady parabola (Reynolds 620, 935).
The Navier-Stokes governing equations of flow were solved with ANSYS CFX. Fluid dynamic parameters were compared between the spiral and corresponding non-spiral models focusing on the flow downstream of the anastomosis.
The vortical structures at cross-flow patterns 1-4 had previously been studied experimentally with ultrasound vector Doppler imaging, which was used for validation.

Results

The presented results are for θ = 40°. A single spiral was the main characteristic in the outflow of the spiral graft and a double or triple spiral in the outflow of the control.
The maximum in-plane velocity (perpendicular to flow direction) at cross-flow planes 1 – 4 was constantly higher for the spiral graft model.
The total circulation in cross-flow planes 1 – 4 was higher for the spiral graft model particularly for increased Reynolds.
Helicity in the volume between cross-flow plane 1 and 4 was higher for the spiral model. The pressure drop over length from the graft inlet to cross-flow plane 4 was reduced for the non-spiral graft model.
The wall shear stress (WSS) was examined in proximal and distal locations of the floor and toe wall centrelines. The WSS was higher for the spiral graft model in all tested locations. The results from θ = 20°, 60°, 80° were comparable.

Discussion

The flow pattern generated by the spiral graft was related to less flow separation, stagnation and instability than that induced by the control graft.
The increased in-plane velocity, circulation and helicity of the spiral device showed increased in-plane mixing, which has been reported to protect endothelial function.
Pressure drop is not desirable. The detected difference in pressure loss can be assumed negligible because the physiologic pressure is in the range of 1 – 20 × 104 Pa.
Increased WSS is considered atheroprotective, although this may not apply in the proximal floor where the blood impinges abnormally on the wall of the host vessel.

Conclusions

The spiral graft was able to reintroduce a single spiral pattern in its outflow, associated with flow coherence downstream of the host vessel and high intensity cross-flow phenomena. Such local haemodynamics are known to prevent neointimal hyperplasia and thrombosis. These results support the hypothesis that spiral grafts may improve the patency rates in patients.

2. Is the structure of the vessel wall a generator of Spiral Flow? A Cadaveric histological study

IN ABSTRACTS FROM VAS 8TH INTERNATIONAL CONGRESS, APRIL 25-27, 2013 PRAGUE, CZECH REPUBLIC. J VASC ACCESS 2013; 14(1): 5
HEIRE P1, WILTON J1, JACQUES S1,MARIE Y2, JONES R3 INSTON, N2
1 DEPARTMENT OF ANATOMY, SCHOOL OF IMMUNITY AND INFECTION, COLLEGE OF MEDICAL AND DENTAL SCIENCES, UNIVERSITY OF BIRMINGHAM, BIRMINGHAM, UK
2 DEPARTMENT OF RENAL SURGERY, QUEEN ELIZABETH HOSPITAL, UNIVERSITY HOSPITALS BIRMINGHAM, BIRMINGHAM. UK
3 DEPARTMENT OF RADIOLOGY, QUEEN ELIZABETH HOSPITAL, UNIVERSITY HOSPITALS BIRMINGHAM, BIRMINGHAM. UK

Background

In healthy individuals flow patterns in the arterial tree have a spiral vector (Spiral laminar flow, SLF) which is attributed to the eccentric myocardial action and the spiral nature of the aortic arch.

Previous studies have shown that SLF is present within health and also within the arteries of patients with arteriovenous fistulas. This is disrupted through the swing segment yet is regenerated in the venous segment above this.

This pattern is present in AVFs immediately post operatively and is a predictor of superior outcome. This implies that veins are capable of generating spiral flow independently and that SLF may have physiological benefits.

The aims of this study were to assess the anatomical ultra structure of artery and vein with particular reference to muscle fibre orientation as a potential generator of spiral flow.

Materials and Methods

Using preserved cadaveric post-mortem tissue brachial artery and cephalic vein structure was assessed using an established technique to analyse nuclear orientation.

In brief sections were taken from vessels at two different angles allowing nuclear size to be assessed.

By correlating nuclear length and the incident angle of the section the orientation of muscle fibres was determined allowing the 3 dimensional arrangements of muscle fibres to be assessed.

Results

Using sectioning angles of 0˚and 20˚ randomly selected regions of tunica media within vessel sections were analysed. Maximum nuclear length was 18.26μm and 8.29μm at each angle respectively. This estimates an arterial smooth muscle pitch 6.04˚ to 6.28˚ of the muscular fibres using each section respectively.
Within veins the angle estimates are more variable with multidirectional arrangement and the muscle angle pitch estimated at 1.4˚ to 9.3˚.

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.

Discussion

The obliquity of muscle fibres within the vessels is consistent with Doppler ultrasound findings of spiral laminar flow in both artery and vein.
The central generation hypothesis of spiral flow is questioned by the clinical model of an AV fistula and this study supports the vessel wall as an independent peripheral generator of spiral laminar flow.

3. Hemodynamic differences in the outflow of access vascular grafts

IN ABSTRACTS FROM VAS 8TH INTERNATIONAL CONGRESS, APRIL 25-27, 2013 PRAGUE, CZECH REPUBLIC. J VASC ACCESS 2013; 14(1): 47
KOKKALIS E1, HOSKINS PR2, CORNER GA3, DOULL AJ1, STONEBRIDGE PA1, HOUSTON JG1
1 CARDIOVASCULAR AND DIABETES MEDICINE,
2 CENTRE FOR CARDIOVASCULAR SCIENCE, UNIVERSITY OF EDINBURGH, EDINBURGH, UK
3 MEDICAL PHYSICS, NINEWELLS HOSPITAL AND MEDICAL SCHOOL, DUNDEE, UK

Background

Access vascular (AV) prostheses are commonly used for haemodialysis. Their low patency rates remain a challenge with restenosis in the distal anastomosis being the main reason of failure. The blood flow profile affects the wall shear stress which is a crucial factor for the endothelial function.
Single spiral flow has been found to be a normal physiologic characteristic of vascular blood flow. This study compared the Spiral Laminar Flow™ AV graft (Vascular Flow Technologies, UK) which is designed to induce spiral flow against a control AV device.

Materials and Methods

The prostheses were integrated in an in-house ultrasound flow phantom which was consisted of blood, vessel, tissue mimicking materials and a piston pump.
The devices were tested using a curve and straight configuration to mimic vascular surgical implantation geometries. Steady flow rates up to 720 ml/min were applied.
Colour Doppler ultrasound imaging was utilized in a number of cross-sectional planes distally from the grafts outflow.
To visualize and quantify rotational flow patterns, a vector Doppler technique was developed using Matlab (MathWorks, USA).
Two-dimensional velocity magnitude and directional maps were created and an analysis based on the magnitude of the peak radial velocity was performed.

Results

A single spiral flow was detected in the outflow of the spiral graft and two or three spirals in the outflow of the control device, for both types of anastomosis.

Flow separation and areas of stagnation were detected when more than one helix existed.
The radial velocity was consistently higher for the single spiral in comparison to that of the multi-spiral patterns under all the applied conditions.
The flow pattern under high flow rates was stable for the spiral graft and disturbed for the control device.

Conclusions

The single helical pattern created by the spiral graft was associated with increased magnitude of radial velocity. This is an index of increased wall shear stress which is considered atheroprotective.
These results support the hypothesis that spiral graft improves flow stability and coherence which may relate to increased graft patency rates.

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4. Haemodynamic effects of spiral ePTFE prosthesis compared with standard arteriovenous graft in a carotid to jugular vein porcine model

J VASC ACCESS. 2011 JUL-SEP;12(3):224-30. DOI: 10.5301/ JVA.2010.6097
JAHROME OK, HOEFER I, HOUSTON GJ, STONEBRIDGE PA, BLANKESTIJN PJ, MOLL FL, DE BORST GJ.

Introduction

The primary patency rate of arteriovenous (AV) grafts is limited by distal venous anastomosis stenosis or occlusion due to intimal hyperplasia associated with distal graft turbulence. The normal blood flow in native arteries is spiral laminar flow.
Standard vascular grafts do not produce spiral laminar flow at the distal anastomosis. Vascular grafts which induce a spiral laminar flow distally result in lower turbulence, particularly near the vessel wall.
This initial study compares the hemodynamic effects of a spiral flow-inducing graft and a standard graft in a new AV carotid to jugular vein crossover graft porcine model.

Methods

Four spiral flow grafts and 4 control grafts were implanted from the carotid artery to the contralateral jugular vein in 4 pigs.
Two animals were terminated after 48 hours and 2 at 14 days. Graft patency was assessed by selective catheter digital angiography, and the flow pattern was assessed by intraoperative flow probe and colour Doppler ultrasound (CDU) measurements.
The spiral grafts were also assessed at enhanced flow rates using an external roller pump to simulate increased flow rates that may occur during dialysis using a standard dialysis needle cannulation.
The method increased the flow rate through the graft by 660 ml/min. The graft distal anastomotic appearances were evaluated by explant histopathology.

Results

All grafts were patent at explantation with no complications. All anastomoses were found to be wide open and showed no significant angiographic stenosis at the distal anastomosis in both spiral and control grafts.
CDU examinations showed a spiral flow pattern in the spiral graft and double helix pattern in the control graft. No gross histopathological effects were seen in either spiral or control grafts.

Conclusion

This porcine model is robust and allows haemodynamic flow assessment up to 14 days post-implantation. The spiral flow-inducing grafts produced and maintained spiral flow at baseline and enhanced flow rates during dialysis needle cannulation, whereas control grafts did not produce spiral flow through the distal anastomosis. There was no deleterious effect of the spiral flow-inducing graft on macroscopic and histological examination. The reducing effect of spiral flow on intima hyperplasia formation will be the subject of further study using the same AV graft model at a longer period of implantation.

5. Structure/function interface with sequential shortening of basal and apical components of the myocardial band

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY 29S (2006) S75-S97
BUCKBERG GD, CASTELLÁ M, GHARIB M, SALEH S.

Objective

To study the sequential shortening of Torrent-Guasp's 'rope-heart model' of the muscular band, and analyse the structure-function relationship of basal loop wrapping the outer right and left ventricles, around the inner helical apical loop containing reciprocal descending and ascending spiral segments.

Methods

In 24 pigs (27-82 kg), temporal shortening by sonomicrometer crystals was recorded. The ECG evaluated rhythm, and Millar pressure transducers measured intraventricular pressure and dP/dt.

Results

The predominant shortening sequence proceeded from right to left in basal loop, then down the descending and up the ascending apical loop segments. In muscle surrounded by the basal loop, epicardial muscle predominantly shortened before endocardial muscle.
Crystal location defined underlying contractile trajectory; transverse in basal versus oblique in apical loop, subendocardial in descending and subepicardial in ascending segments. Mean shortening fraction average 18 ± 3%, with endocardial exceeding epicardial shortening by 5 ± 1%. Ascending segment crystal displacement followed descending shortening by 82 ± 23ms, and finished 92 ± 33 ms after descending shortening stops, causing active systolic shortening to suction venous return; isovolumetric relaxation was absent.

Conclusion

Shortening sequence followed the rope-like myocardial band model to contradict traditional thinking. Epicardial muscle shortened before endocardial papillary muscle despite early endocardial activation, and suction filling follows active systolic unopposed ascending segment shortening during the 'isovolumetric relaxation' phase.

6. Non spiral and spiral (helical) flow patterns in stenoses. *In Vitro* observations using spin and gradient echo magnetic resonance imaging (MRI) and computational fluid dynamic modelling Int Angiol. 2004 Sep;23(3):276-83.

STONEBRIDGE PA, BUCKLEY C, THOMPSON A, DICK J, HUNTER G, CHUDEK JA, HOUSTON JG, BELCH JJ.
VASCULAR DISEASES RESEARCH UNIT, DEPARTMENT OF SURGERY, THE INSTITUTE OF CARDIOVASCULAR RESEARCH, NINEWELLS HOSPITAL AND MEDICAL SCHOOL, DUNDEE, SCOTLAND, UK.
P.A.STONEBRIDGE@DUNDEE.AC.UK

Aim

Physiological blood flow patterns are themselves poorly understood despite their impact on arterial disease. Stable spiral (helical) laminar flow has been observed in normal subjects. The purpose of the present study is to develop a method of magnetic resonance (MR) flow pattern visualization and to analyse spiral and non-spiral flow patterns with and without luminal narrowing *In Vitro*. The flow conditions were then modelled using computational fluid dynamics (Star-CD).

Methods

Laminar integrity was examined in a flow-rig using spin and gradient echo magnetic resonance imaging (MRI) in non-stenosed and stenosed conduits in the presence of non-spiral and spiral flow.

Results

No difference was observed in a non-stenosed conduit between non-spiral and spiral flow. In the presence of a stenosis spiral flow preserves flow velocity coherence whereas non-spiral flow increasingly lost coherence beginning proximal to the stenosis.
Computational fluid dynamic modelling of the *In Vitro* experiment showed marked differences between the 2 flow patterns. Non-spiral flow produced greater inwardly directed forces just beyond the stenosis and greater outward pressures at more distal sites.
The near wall turbulent energy was up to 700% less with spiral flow over non-spiral flow beyond the stenosis.

Conclusion

Spiral flow appears to offer clear flow profile stabilizing advantages over non-spiral flow, by significantly reducing the turbulence caused by a stenosis.
Spiral flow also produces lower forces acting on the vessel wall.

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7. The heart is not a pump: a refutation of the pressure propulsion premise of heart function

FRONTIER PERSPECTIVES, J CENTRE FRONTIER SCIENCES, TEMPLE UNIVERSITY, PHILADELPHIA, PA. 1995:VOL 5(1)
MARINELLI R, FUERST B, ZEE H, MCGINN A, MARINELLI W

Background

In 1932, Bremer of Harvard filmed the blood in the very early embryo circulating in self-propelled mode in spiralling streams before the heart was functioning. Amazingly, he was so impressed with the spiralling nature of the blood flow pattern that he failed to realize that the phenomena before him had demolished the pressure propulsion principle.
Earlier in 1920, Steiner, of the Goetheanum in Switzerland had pointed out in lectures to medical doctors that the heart was not a pump forcing inert blood to move with pressure but that the blood was propelled with its own biological momentum, as can be seen in the embryo, and boosts itself with “induced” momenta from the heart.
He also stated that the pressure does not cause the blood to circulate but is caused by interrupting the circulation. Experimental corroboration of Steiner’s concepts in the embryo and adult is herein presented.

Please reach out with any questions or inquiries to:
inquiries@vascular-flow.com