NICE advice

Spiral Flow peripheral vascular graft for treating peripheral arterial disease

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Summary

The Spiral Flow peripheral vascular (PV) graft is used for peripheral arterial disease to bypass or reconstruct damaged blood vessels. Of 5 studies (2 published and 3 abstracts), 1 of the published studies compared the Spiral Flow graft to other artificial grafts and reported similar or worse primary patency. The second comparative study, available as an abstract only, reported better patency rates for the Spiral Flow graft than for PTFE grafts. The other studies investigated primary and secondary patency rates for the Spiral Flow graft. The cost of a Spiral Flow PV graft is £952 to £1520, excluding VAT, depending on size.

Likely place in therapy

- The Spiral Flow peripheral vascular (PV) graft is a synthetic graft used to treat peripheral arterial disease.
- It would be used as an alternative to current peripheral vascular grafts to maintain effective blood flow to the lower limbs. Current practice varies in the choice of artificial grafts, which are used only when an autologous graft is unavailable.

Effectiveness and safety

- The currently available evidence for the clinical effectiveness of the Spiral Flow PV graft is limited in both quantity and quality.
- In the only fully-published comparative study, patency rates for the Spiral Flow PV graft were the same or worse compared with another expanded polytetrafluoroethylene graft.
- In 4 other studies, of which 3 were available only as abstracts, primary patency rates varied from 57% to 93%.
- The exact number of patients included in all 5 studies is not clearly reported, but it is estimated to be around 230. Three studies (1 fully-published) reported adverse effects, including 4 deaths. Two deaths were unrelated to the graft and 2 were in patients with serious comorbidities.

Technical factors

- The Spiral Flow PV graft incorporates a helical interior that is designed to promote a natural spiral pattern of blood flow, which is claimed to reduce the risk of neointimal hyperplasia that can arise from unnatural turbulence in the blood flow.
- The Spiral Flow PV graft is available in a range of lengths and diameters.
- The Spiral Flow PV graft would be used in secondary care by suitably qualified clinicians, experienced in carrying out peripheral vascular bypass graft procedures.

Cost and resource use

- The Spiral Flow PV graft costs between £952 and £1520, depending on size.
- There was no published evidence on cost and resource use for the Spiral Flow PV graft.
- Any graft reducing the need for repeated interventional procedures could reduce long-term treatment costs.

Introduction

Peripheral arterial disease (PAD) is a form of cardiovascular disease caused by a build-up of fatty deposits in the arterial walls of the leg. These fatty deposits, called atheroma, narrow the arteries in a process known as atherosclerosis. PAD is estimated to affect 1 in 5 people aged over 60 years in the UK and its incidence increases with age, according to NICE's quality standard on peripheral arterial disease. It is more common in people with type-I and type-II diabetes, those with high blood pressure or high cholesterol and in those who smoke. PAD is more common in men, with an overall incidence of 8.2% compared with 5.5% in women (Kroger et al. 2006).

Although some people with PAD may have no symptoms, it often causes muscle pain and aching (known as claudication) in the affected leg. PAD can cause severe claudication, making walking painful and reducing quality of life. In approximately 1 in 5 people with PAD, the narrowing of the arteries leads to increasingly severe symptoms with the development of critical limb ischaemia (CLI). Symptoms of CLI include gangrene and ulcers (NHS Choices 2014) and it is the most common cause of leg amputation in the UK (NICE quality standard 52).

PAD is also a risk factor for other cardiovascular events, such as heart attack and ischaemic stroke; people with PAD have a 3–4 fold increased risk of one of these events (NICE quality standard 52).

Peripheral vascular (PV) grafts are used during vascular bypass procedures carried out to restore blood flow to the lower limbs. This is achieved through bypass of the diseased (blocked) portion of the blood vessel with a portion of healthy vessel (first-line choice) or, if no healthy vessels are available, with an artificial graft.

During bypass surgery, a healthy vein is taken from another part of the leg and joined, or grafted, above and below the blocked artery. This procedure, referred to as an autologous graft, allows the flow of blood to be rerouted to avoid the blockage and maintain an efficient blood supply. A vascular surgeon assesses whether a vein is available and suitable for the procedure. Autologous grafts have a lower failure rate than prosthetic grafts and are used wherever possible. When it is not feasible to use a healthy vein, an artificial graft may be used.

Blood naturally flows through the arteries in a spiral pattern, which has been reported in an in vitro model to increase the pressure and velocity of the blood flow (Paul et al. 2009). Standard artificial PV grafts can interrupt this spiral flow, causing turbulence in the flow of the blood. Over time, this turbulence can lead to neointimal hyperplasia (NIH), an accumulation of vascular smooth muscle cells at the furthest attachment of the graft (the distal anastomosis). NIH causes thickening of the graft walls and restenosis or narrowing of the vessel, which reduces blood flow and can lead to graft

failure. Further surgery may be needed to salvage or re-open the graft using techniques such as endovascular thrombolysis, angioplasty, stent placement or mechanical thrombectomy to restore blood flow. If this is unsuccessful, and if all other revascularisation options have been exhausted, the affected limb may have to be amputated. Artificial grafts that are designed to mimic a more natural blood flow may be less prone to failure than standard prosthetic grafts.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

Vascular Flow Technologies was awarded a Class IIb CE mark for the Spiral Flow peripheral vascular graft in August 2007. The CE mark covers the different sized grafts from 50–80-cm lengths and 6 and 8-mm diameters.

Description

The Spiral Flow peripheral vascular (PV) graft is made from expanded polytetrafluoroethylene (ePTFE), for treating peripheral arterial disease. In the distal portion of the graft there is a 'spiral flow inducer' in the form of a ridge that creates a helix on the lumen of the graft. This helix causes blood passing through the graft to move in a spiral flow. The manufacturer claims that this spiral flow ensures natural blood-flow patterns and normal pressure in the artery to reduce the risk of neointimal hyperplasia (NIH). The graft is available in 50, 60, 70 and 80-cm lengths, and in diameters of 6 or 8 mm.

The Spiral Flow PV graft contains a distal cuff that is separated from the spiral flow inducer segment by a 3–5-mm area called the 'trim gap'. The distal end of the graft can be cut up to the trim gap to modify the graft's toe in preparation for suturing to the heel of the target vessel. This trim gap ensures that the spiral flow inducer segment is not inadvertently cut, thereby disrupting the graft's ability to generate spiral flow. However, the manufacturer recommends that a portion of the trim gap be left in place to allow for clamping of the graft to achieve haemostatic control. The graft can also be reduced in length by cutting its proximal (nearest) end.

The manufacturer recommends that the distal end of the graft should be connected to the artery first. The heel of the artery should be aligned to the end of the spiral inducer segment to provide the correct geometry for spiral laminar flow. To hold the graft in place, a tunnel must be made through the tissue surrounding the damaged vessel. The graft is fed through this tunnel before the proximal end of the graft is connected to the artery, bypassing the damaged section.

Intended use

The Spiral Flow PV graft is intended for use in patients with symptomatic peripheral arterial disease (PAD) in whom a peripheral vascular bypass procedure using a prosthetic graft is clinically indicated. The Spiral Flow PV graft is also indicated for use in intravascular access for haemodialysis. This indication is beyond the scope of this briefing.

Setting and intended user

The device is designed to be used in the secondary-care inpatient setting. It is intended only to be used by suitably qualified clinicians who are experienced in carrying out peripheral vascular bypass procedures.

Current NHS options

Currently there is no cure for peripheral arterial disease (PAD) and initial management places a focus on lifestyle changes to reduce symptoms. These changes include:

- exercising
- giving up smoking
- eating a healthy diet
- cutting down on alcohol.

Medications such as statins, antihypertensives and antiplatelets can also be prescribed to treat the underlying cause of PAD and help reduce the risk of developing other types of cardiovascular disease (NHS Choices). Additionally, NICE technology appraisal guidance on cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate for the treatment of intermittent claudication in people with peripheral arterial disease has previously recommended naftidrofuryl oxalate for treating intermittent claudication in people with PAD.

Surgical procedures, including angioplasty and bypass grafts, are additional treatment options for PAD. These aim to restore the flow of blood through the arteries of the legs, known as revascularisation. Angioplasty is a method where the narrowed area of the artery is widened by a small balloon, which is inflated inside the vessel. Sometimes a 'stent' or small mesh tube may be left in place to keep the artery open.

Bypass surgery may be offered to people with severe lifestyle-limiting intermittent claudication when angioplasty has been unsuccessful or is unsuitable, and where imaging has confirmed that it is appropriate. It may also be used in people with critical limb ischaemia needing revascularisation. NICE's guideline on lower limb peripheral arterial disease recommends that an autologous vein should be used whenever possible. A range of synthetic grafts is currently available to the NHS and current practice varies in the choice of graft.

NICE has also issued guidance on percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease.

NICE is aware of the following CE marked devices that appear to fulfil a similar function to the Spiral Flow PV graft:

- Gore Propaten heparin-bonded vascular graft
- Gore INTERING vascular graft.

Costs and use of the technology

The list prices of the different sized (diameter by length respectively) Spiral Flow PV grafts, excluding VAT, are:

- Spiral Flow PV graft 6 mm×50 cm: £952
- Spiral Flow PV graft 6 mm×60 cm: £1032
- Spiral Flow PV graft 6 mm×70 cm: £1320
- Spiral Flow PV graft 6 mm×80 cm: £1520
- Spiral Flow PV graft 8 mm×50 cm: £952
- Spiral Flow PV graft 8 mm×60 cm: £1032
- Spiral Flow PV graft 8 mm×70 cm: £1320

- Spiral Flow PV graft 8 mm×80 cm: £1520.

The lifespan of the technology is dependent on functionality of the graft. Grafts with higher patency rates are less likely to need repeated interventional procedures and will therefore reduce overall cost to the NHS.

In 2013–14, 4285 bypass procedures of the femoral artery were performed, including 330 emergency procedures. Of these 2542 used autologous vein grafts, while 810 used prosthetic grafts (HSCIC 2015).

The payment by results tariff for 2013–14 (Department of Health 2013) has been provided for information. The NHS tariffs for outpatient attendance relating to consultant-led vascular surgery services (service code 107) are:

- first attendance: £156 (WF01B/WF02B)
- follow-up attendance: £93 (WF01A/WF02A).

The NHS costs for combined day case or ordinary elective spells (Payment by Results 2013–14) are:

- bypasses to tibial arteries: £8266 (HRG code, QZ03Z)
- amputations without complications and co-morbidities: £7625 (HRG code, QZ11B)
- amputations with complications and co-morbidities: £14,724 (HRG code, QZ11A).

The costing report for the NICE guideline on lower limb peripheral arterial disease suggests that amputation may be offered when revascularisation options such as bypass cannot control critical limb ischaemia. It estimates that in addition to the procedure itself, the cost of care to the NHS is approximately £20,000 per patient in the year following an amputation.

Likely place in therapy

The Spiral Flow PV graft could be used for patients with peripheral arterial disease needing a synthetic bypass graft. Use of the device is not expected to change the current clinical pathway.

Specialist commentator comments

Two specialist commentators stated that the Spiral Flow peripheral vascular (PV) graft is more expensive than standard expanded polytetrafluoroethylene grafts and there is not enough evidence to make a conclusion about whether it is better. One commentator noted that randomised controlled trials and cost-effectiveness analyses would be needed in order to make a confident conclusion about the effectiveness of the Spiral Flow PV graft. Another commented that although the available studies use patency as an outcome measure, studies that measured amputation rates or wound healing would be more clinically relevant.

Two specialist commentators noted that the quality of evidence for the Spiral Flow PV graft is very limited, and suggested that the results should be treated with caution.

One specialist commentator noted that while the evidence for this device is limited, with some evidence prone to methodological problems and bias, this is an interesting concept that is backed by basic science.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women, and
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Peripheral arterial disease (PAD) is more common in people over the age of 60 years and affects more men than women. People with diabetes have an increased risk of developing PAD, and diabetes is recognised as a long-term health condition that may cause disability. Age, sex and disability are protected characteristics under the Equality Act 2010.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency (MHRA) website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this equipment.No reports of adverse events were identified from searches of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

Forty-eight studies of potential relevance to the Spiral Flow PV graft were identified, of which 41 were excluded from further assessment because they did not meet the inclusion criteria. A further 2 studies were excluded because they covered the same patients as a more recent publication. The remaining 5 studies are summarised in this briefing. The 5 remaining studies, 2 fully published (Stonebridge et al. 2012; Bechara 2014) and 3 available only as abstracts (Shaper 2014; Marusiak et al. 2014; Çetingök 2011) are summarised in this briefing (tables 1–5).

Study outcome definitions and results

Several of the studies describe outcomes in terms of patency. Patency describes whether a graft remains open and functional over time. Primary patency refers to grafts or vessels that remain patent over time, or that have limited restenosis that has not needed further intervention. Primary assisted patency refers to grafts or vessels that remain patent over time, but which have needed some further intervention to maintain patency. Secondary patency describes grafts or vessels that are currently patent, including those which have previously occluded and have had an intervention to restore patency.

The study by Bechara (2014) compared the primary and secondary patency rates of the Spiral Flow PV graft, to those of a non-spiral flow inducing Propaten graft (WL Gore) that has a thromboresistant surface. This retrospective study compared the primary and secondary patency rates in 20 Spiral Flow PV grafts and 39 Propaten grafts. The full results are presented in table 1. The authors concluded that the concept of mimicking natural flow was interesting but did not translate into a clinical benefit for the Spiral Flow PV graft because primary and secondary patency rates were either similar or worse in the Spiral Flow PV graft. No statistical analysis was included in this study.

The study by Stonebridge et al. (2012) was a prospective, multicentre, non-consecutive, non-comparative study to assess the safety and medium-term patency performance of the Spiral Flow PV graft. The results showed primary patency rates of 81% (above the knee) and 57% (below the knee) and secondary patency rates of 81% and 64% (above and below the knee respectively) at both 24 months and 30 months follow-up, and also showed that the Spiral Flow PV grafts can remain patent for 30 months (table 2). There were no amputations in the 30-month study period.

The case series reported by Cetingok (2011) was only available as an abstract and is presented in table 3. In total, 73 Spiral Flow PV grafts were implanted in 47 people from June 2009 to August 2011. The primary and secondary patency rates at 14-month follow-up were 93% and 98% respectively. This study did not have a comparator group. The authors reported 1 death that was unrelated to the graft, and that 5 grafts became thrombosed. These were successfully thrombolysed to restore graft patency. There is no information on the cause of occlusions in this study.

The case series presented by Marusiak et al. (2014) was also only available as an abstract and did not have a comparator group. In this study, 75 devices were implanted in 72 people with an observed primary patency rate of 85% and a secondary patency rate of 96% (table 4). The authors attributed the deaths of 2 of the study participants to critical limb ischaemia in people presenting with serious comorbidities. The authors also reported some adverse events, namely occlusion of 11 grafts. Patency was successfully restored in 8 out of 11 of the occluded grafts through thrombolysis, transluminal angioplasty or open surgical intervention. The cause of the occlusions was not given.

Shaper (2014) carried out a single-centre prospective study with a retrospective control group, and this study was also only available as an abstract. The authors carried out a comparison of 54 Spiral Flow PV grafts and 124 conventional polytetrafluoroethylene (PTFE) grafts at 1-year follow-up. The manufacturer of the PTFE graft was not stated by the authors. The overall primary and secondary patency rates for the conventional graft were 48% and 55% respectively, and the primary and secondary patency rates were 76% and 87% for the Spiral Flow PV graft. No statistical analysis has been reported. Adverse events were reported for the conventional PTFE graft and the Spiral Flow PV graft. The amputation rate for the conventional PTFE graft was 10%, and it was 2% for the Spiral Flow PV graft. Full results are presented in table 5.

Table 1 Summary of the Bechara (2014) retrospective comparative study

Study component	Description

Objectives/ hypotheses	The primary and secondary patency rates of the Spiral Flow peripheral vascular graft were compared with the Propaten graft.
Study design	Retrospective, single centre, comparative study.
Intervention	Spiral Flow graft (SFG) manufactured by Vascular Flow Technologies. Comparator: Propaten graft (PG) manufactured by WL Gore.
Setting	A hospital in the USA. Patients treated between January 2010 and January 2012.
Inclusion/ exclusion criteria	Not stated.
Primary outcomes	Primary and secondary patency rates.
Methods	Data were retrospectively reviewed for patients having below-the-groin (infrainguinal) bypass using prosthetic grafts. Kaplan–Meier analyses were done to estimate primary and secondary patency rates. Short-term and mid-term data between these 2 grafts was examined.
Participants	59 adults. 20 people were treated with the SFG and 39 using a PG. The number of grafts used is not reported. 14/20 Spiral Flow grafts (70%) were femoral to popliteal artery bypass (above and below the knee), and 6/20 cases (30%) were femoral to tibial artery bypass. Similar percentages were seen in the Propaten graft group.

Results	The author states that statistically, the 6-, 12-, 18-, and 24-month primary and secondary patency rates for both grafts were the same, regardless of the distal target artery. However there is no statistical analysis to support this and results for the PGs were better in most groups. For the popliteal artery (above and below knee) target group the primary patency rates were as follows: • at 6 months: PG=94%; SFG=79% • at 12 months: PG=61%; SFG=50% • at 18 months: PG=61%; SFG=50% • at 24 months: PG=54%; SFG=50%. For the popliteal artery (above and below knee) target group the secondary patency rates were: • at 6 months: PG=94%; SFG=86% • at 12 months: PG=66%; SFG=57% • at 18 months: PG=66%; SFG=57% • at 24 months: PG=66%; SFG= 57%. For the tibial artery bypass groups the primary patency rates were: • at 6 months: PG=51%; SFG=50% • at 12 months: PG=36%; SFG=33% • at 18 months: PG=37%; SFG=17%. For the tibial artery bypass groups the secondary patency rates were: • at 6 months: PG=54%; SFG=60% • at 12 months: PG=34%; SFG=40% • at 18 months: PG=34%; SFG=20%.
Adverse events	None reported.

Conclusions	The authors concluded that the design of the Spiral Flow PV graft to mimic physiologic flow at the distal anastomosis is an interesting concept but has not translated into clinical benefit compared with another ePTFE graft. There should be different graft configurations for tibial targets and popliteal artery targets.
Abbreviations: ePTFE, expanded polytetrafluoroethylene; PG, Propaten graft; SFG, Spiral Flow graft.	

Table 2 Summary of the Stonebridge et al. (2012) case series

Study component	Description
Objectives/ hypotheses	To assess safety and medium-term patency performance of the Spiral Flow peripheral vascular (PV) graft.
Study design	Prospective, multicentre, non-consecutive, non-comparative study.
Intervention	Spiral Flow PV graft.
Setting	10 hospitals in the Netherlands and Belgium. Enrolment took place between February 2006 and November 2007.

Inclusion/ exclusion criteria	Inclusion criteria: • Aged 40–75 years. • Must need above-the-knee or below-the-knee outflow unilateral infrainguinal bypass graft for PAD of superficial femoral artery. • Use of a perioperative/postoperative antiplatelet agent. • Must provide written, informed consent. Exclusion criteria: • Known hypersensitivity to graft constituents. • Sensitivity, allergy, or contraindication to antithrombotics and antiplatelet medication. • Severe comorbid condition. • Significantly disordered hepatic function. • A recognised form of thrombophilia, a history of deep vein thrombosis, or early pregnancy loss. • Presence of a significant medical condition. • Vascular operative reconstruction in the same leg. • Poorly controlled diabetes mellitus (haemoglobin A1C >7.5%).
Primary outcomes	Primary and secondary patency rates.

Methods	Procedures were done in accordance with local preference, with no special requirement, except securing the distal anastomosis first. No adjuvant surgical technique was used. A completion angiography was done in all cases. Patients were followed up at 6 weeks and at 3, 6, 9, 12, 18, 24 and 30 months. Follow-up assessment included clinical assessment and colour Doppler assessment. 10 patients had additional examination at 3 and 6 months to assess whether the graft actually produced and maintained spiral laminar flow. Kaplan–Meier analyses were used to calculate primary and secondary patency rates.
Participants	39 people with PAD leading to pain at rest or lifestyle-inhibiting or severe claudication needing an above-the-knee or a below-the-knee bypass graft. The study was limited to a patient group needing only a unilateral bypass graft to optimise patient survival and add a degree of group homogeneity. The number of grafts used is not reported. Treated patient demographics: • mean age 70.3 (range 38–83) years • sex (male:female) 3:1 • side (right/left) 23/16 • recorded diabetes (yes/no) 8/31 • previous vascular surgery 19 • above-the-knee 23/below-the-knee 16.

Results	The 12, 18, 24 and 30-month assessment respective primary patency rates were: • 86%, 81%, 81% and 81% for above-the-knee bypasses • 73%, 73%, 57% and 57% for below-the-knee bypasses. In the case of secondary patency rates, respective numbers at 12, 18, 24 and 30 months were: • 86%, 81%, 81% and 81% for above-the-knee bypasses • 86%, 79%, 64% and 64% for below-the-knee bypasses.
Adverse events	2 withdrawals (a graft dehiscence after trauma at 14 days, and a graft infection at 45 days); both cases needed graft excision. 1 death due to cancer. 3 early occlusions in the above-the-knee group; all from the same centre (at 49, 51 and 72 days). None of these had either thrombolysis or re-exploration, so no information is available as to the underlying cause. 2 people in the below-the-knee group had thrombolysis on occlusion (247 days and 276 days); the former occluded due to an iliac stenosis and the latter due to a distal outflow artery stenosis, not identified by preoperative angiography. There were no amputations in the study group.
Conclusions	The graft's performance was equal to, or better than, some of the recently published results for other enhanced grafts. No amputations were done on people in this study and this suggests a different mode of prosthetic graft failure that may not be predominantly distal anastomotic neointimal hyperplasia. A bigger spiral flow-inducing advantage may be possible where blood flow rates are higher. The flow inducer may need to be tailored differently for low flow or more distal environments. This study shows potential for the idea of spiral flow-enhanced prosthetic grafts.
Abbreviations: DVT, deep vein thrombosis; PAD, peripheral arterial disease.	

Table 3 Summary of Cetingok (2011) case series

Study component	Description
Objectives/ hypotheses	Not stated.
Study design	Not stated.
Intervention	Spiral Flow peripheral vascular graft.
Setting	People treated from June 2009 to August 2011, country unknown.
Inclusion/ exclusion criteria	Not stated.
Primary outcomes	Not stated.
Methods	47 patients with a mean follow-up period of 14 months. A total of 73 implantations were carried out (a number of patients had more than one graft): • 45% above-the-knee bypass • 55% below-the-knee bypass.
Participants	94% male 6% female Mean age at operation was 67 (41–89). 77% were stage IIb Fontaine Classification 23% were stage III Fontaine Classification.
Results	At 14 months mean follow-up: • primary patency=93% • secondary patency=98%.
Adverse events	5 grafts (7%) thrombosed and were successfully thrombolysed to fully restore patency. There was 1 patient death unrelated to the graft.

Conclusions	Not stated.

Table 4 Summary of Marusiak et al. (2014) case series

Study component	Description
Objectives/ hypotheses	Not stated.
Study design	Retrospective multicentre study carried out between February 2010 and February 2013.
Intervention	Spiral Flow PV graft.
Setting	Not stated.
Inclusion/ exclusion criteria	Inclusion – severe claudication, critical limb ischaemia, ulcer or rest pain. Exclusion – none specified.
Primary outcomes	Not stated.
Methods	72 patients suitable for surgical revascularisation were enrolled: • 68% above-the-knee femoral to popliteal bypass • 32% below-the-knee femoral to popliteal bypass. Median follow-up was 11 months (2–36 months). Low molecular weight heparin was given postoperatively for 12 weeks. Risk factors involved and scored included smoking, diabetes, hypertension and being overweight. Risk factors for vascular disease and indications for surgery were similarly distributed in above-knee and below-knee bypasses. Patients had duplex sonography at 3 months to verify spiral flow.

Participants	75 devices implanted. Demographics: • 61 male and 11 female • Mean age not stated.
Results	Technical success was achieved in 100% of cases. Primary patency rate: 85% Secondary patency rate: 96%
Adverse events	11 grafts became occluded; 8 were successfully reopened through thrombolysis, percutaneous transluminal angioplasty or open surgical intervention. There were 3 permanent occlusions. 2 deaths were reported; these were linked to serious comorbidities. There was no bleeding or infections.
Conclusions	This new concept of vascular graft focuses on the preservation of a spiral outflow from the graft. The existence of spiral flow is well documented in healthy arteries and it may prevent atherosclerotic disease.
Abbreviations: PV, peripheral vascular.	

Table 5 Summary of Shaper (2014) case series

Study component	Description
Objectives/ hypotheses	Not stated.
Study design	Single-centre prospective study with retrospective control group.
Intervention	Spiral Flow peripheral vascular (PV) graft. Comparator: Conventional PTFE grafts.
Setting	Single centre, country unknown.
Inclusion/ exclusion criteria	Not stated.

Primary outcomes	Primary and secondary patency rates at 1 year.
Methods	Data available for 68 Spiral Flow PV grafts from February 2011 to October 2014. 136 conventional PTFE grafts from same unit from Jan 2003 to Dec 2008. Retrospective analysis. Comparison based on 1 year data available on 124 conventional and 54 Spiral Flow PV grafts.
Participants	Number of patients not stated. Standard grafts: Age 70.3 (45–93) years, 48% male, 55% critical limb ischemia, AK 13%, BK 87% BK/TV/C. Spiral Flow PV grafts: Age 69.6 (47–92) years, 78% male, 53% critical limb ischemia, AK 48%, BK/TV/C 52%.
Results	Standard grafts: Overall primary patency was 48%: 50% AK, 48% BK/TV/C Overall secondary patency was 55%: 71% AK, 53% BK/TV/C. Spiral Flow PV grafts: Overall primary patency was 76%: AK 77%, BK/TV/C 61% Overall secondary patency was 87%: AK 88%, BK/TV/C 79%.
Adverse events	Standard graft amputation rate=10%. Spiral flow PV graft amputation rate=2%.
Conclusions	The authors' conclusions were that: • Benchmarked against conventional grafts, the Spiral Flow PV grafts achieved 30% actuarial improvement in primary and secondary patency. • Results up to 3 years, particularly of more complex grafts, would appear to indicate a sustained patency advantage over conventional grafts. • Initial results were sufficiently encouraging to warrant continued usage and further long-term data acquisition.
Abbreviations: AK, above knee; BK, below knee; C, complex; PTFE, polytetrafluoroethylene; TV, tibial vein.	

Recent and ongoing studies

The manufacturer has stated that there is an ongoing open enrolment, post market observational registry for the use of the Spiral Flow PV graft in peripheral vascular disease and peripheral bypass. This registry involves more than 20 sites in the UK, Europe and the USA. It aims to enrol 50 patients and to record follow-up data at up to 12 months. The data from this registry are intended to be published at the end of 2016.

Costs and resource consequences

No published evidence on resource consequences was identified.

The Spiral Flow PV graft can be used as an alternative to standard expanded polytetrafluoroethylene grafts and no additional resources would be used before or during the bypass procedure. The manufacturer states that the Spiral Flow PV graft is currently used in approximately 22 hospital trusts in the UK.

The techniques for using the device are the same as for current methods, and no additional training would be needed.

Strengths and limitations of the evidence

The currently available evidence for the clinical effectiveness of the Spiral Flow PV graft was limited in both quantity and quality, and comprised 1 fully-published comparative study, 1 fully-published non-comparative study and 3 case series available as abstracts for conference presentations. It is unclear whether any of the studies were carried out in the UK, therefore results may not be generalisable to current NHS practice.

All of the included studies involved small numbers of patients, with a maximum of 72 people being treated with the Spiral Flow PV graft in each study. It is unclear whether patients in these studies were enrolled consecutively and this raises concerns about selection and attrition bias. Additionally, the Stonebridge et al. (2012) multicentre study treated 39 patients in 10 sites; this indicates that the number of patients treated at each centre was very low with a risk of significant selection bias. The paper does not report how many patients were lost to follow-up.

Only 1 paper (Stonebridge et al. 2012) clearly reports the inclusion and exclusion criteria. However, the inclusion age of this study was stated as 40–75 years but the reported age range of people

enrolled was 38–83 years. Primary outcomes were not reported by Cetingok (2011) or Marusiak et al. (2014), while Bechara (2014) did not report any adverse events.

Two studies (Bechara 2014; Shaper 2014) reported comparative data. The Bechara study collected all data retrospectively and the study by Shaper (2014) collected prospective data on Spiral Flow PV grafts, but gathered control group data retrospectively. There is a possibility of changes in clinical practice confounding the results because the test and control group were collected at different time points. Additionally there was an imbalance in patient enrolment in the Shaper (2014) study, and the prospective group treated with Spiral Flow PV grafts was small compared with the retrospective control group (54 compared to 124 respectively at 1 year). This, together with the retrospective data collection in both the Shaper and Bechara studies raises the possibility of selection bias.

The Bechara (2014) study, reporting on 20 patients, did not make any distinction between above- and below-knee popliteal grafts, which have very different results (Vermassen 2010). This makes it difficult to draw meaningful conclusions from the data.

Three of the included studies (Cetinkgok 2011, Marusiak et al. 2014, and Shaper 2014) were not reported in full, and are available only as abstracts that have not been peer reviewed. The lack of available detail on these studies means that these results should be treated with caution.

Dr Shaper is a consultant to Vascular Flow Technologies, the manufacturer of the Spiral Flow PV graft and this could be a source of potential bias. Similarly, 3 of the authors of the Stonebridge et al. (2012) study are founder members of TFT, a company developed to commercialise spiral flow applications in vascular devices.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- Cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate for the treatment of intermittent claudication in people with peripheral arterial disease (2011) NICE technology appraisal guidance 223
- Endovascular stent-grafting of popliteal aneurysms (2011) NICE interventional procedure guidance 390
- Lower limb peripheral arterial disease: diagnosis and management (2012) NICE guideline CG147

- Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices (2011) NICE interventional procedure guidance 380
- Percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease (2012) NICE interventional procedure guidance 433

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Search strategy and evidence selection

Search strategy

The following search strategy was used to search Ovid MEDLINE (R) 1946 to February week 3 2015:

("spiral flow PV graft" or "spiral laminar flow" or "spiral flow graft" or "vascular flow technologies").tw.

Similar search strategies were adapted for Medline in Process, Embase, PsycInfo, Cochrane Library (all components), Pubmed, HEED, NHS Evidence and Web of Science. The searches returned a total of 46 references after duplicate removal.

Evidence selection

Retrieved results were independently sifted by 2 researchers using the selection criteria below, and disagreements discussed and resolved.

- Population: Patients with peripheral arterial disease needing an above-the-knee or below-the-knee bypass graft.
- Intervention: Spiral Flow PV graft
- Comparator: Autogenous lower extremity bypass

Standard PV graft

- Outcomes:

  After the first sift 39 records were removed based on the following criteria:

  - non-English language studies
  - not relevant to selection criteria
  - review articles and protocols.

  Full articles were retrieved for the remaining 9 studies. Due to the paucity of data, all studies meeting the selection criteria were considered for inclusion. Additional studies were provided by the manufacturer. Ultimately 5 references met the criteria and were included in this briefing.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Cedar. The interim process & methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

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