Multi Centre Study to Assess the Feasibility of a New Covered Stent and Delivery System in Combination with Remote Superficial Femoral Artery Endarterectomy (RSFAE)

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Objectives. To evaluate the feasibility and efficacy of an innovative new covered stent and adjustable deployment system (aSpire™ Covered Stent, Vascular Architects Inc., San Jose, CA, USA) in combination with remote superficial femoral artery endarterectomy (RSFAE) for the treatment of long segment femoropopliteal occlusive disease.

Design. Prospective multi-centre trial.

Materials and methods. Sixty-two limbs in 61 patients (41 men; median age 69 years, range 40–88) with severe disabling claudication (n = 56) or critical limb ischaemia (n = 6) were treated in five European centres with aSpire stenting after RSFAE for long segment occlusions (mean length 25 cm). Follow-up was by duplex scanning at 1-, 6-, 12- and 18-months. Primary, primary-assisted and secondary patency rates were analysed.

Results. The median follow-up was 17 (range 2–34) months. A mean of 1.3 stents (range 1–3) were deployed with a median stent diameter of 7 mm (range 6–9). There were one early and 24 late failures. At 18-months the cumulative primary, primary-assisted and secondary patency rates were 60, 70 and 72%, respectively. There were no device related adverse events, such as kinking or fracturing and no stent migrations.

Conclusions. The aSpire stent and the delivery system are both safe and feasible in combination with RSFAE. The mid term follow-up appears favourable in view of the long segment occlusions treated. Further follow-up is required to compare the mid- and long-term outcomes with current stents and conventional femoropopliteal bypass.

Keywords: Stents; Endarterectomy; Minimal invasive surgical procedure; Femoral artery; Atherosclerosis; Peripheral vascular disease; Intermittent claudication.

Introduction

The prevalence of intermittent claudication (IC) in the general population aged 55–74 years is about 5% and is caused by superficial femoral artery (SFA) occlusive disease in 50% of patients.1–3 Progression of atherosclerotic disease occurs in half of patients after an average follow-up of two-and-a-half years.4 Arterial reconstruction is required for symptomatic progression in 9–21% of patients per year.5,6 The management of femoropopliteal occlusive disease remains a challenge. Treatment options include conservative measures, endovascular intervention, endarterectomy or surgical bypass. Percutaneous transluminal angioplasty (PTA) and (selective) stent placement is well established in occlusive iliac disease with 5-year patency rates of 80%.9 However, in femoropopliteal occlusive disease the use of stent-grafts is still of uncertain clinical benefit and autologous venous bypass surgery still offers the best long term patency.10 Due to the invasive nature of this last technique less invasive alternatives are desirable. The ongoing development of stent-grafts with improved patency rates is promising, since they combine the advantages of minimal invasiveness endovascular treatment with the creation of an anatomical endoprosthetic smooth conduit. Currently, high initial technical success is obtained with femoropopliteal stenting, but the radial expansion force of unsupported graft material is too low to resist external compression. Conversely, the presence of a dense metal skeleton promotes luminal thrombosis or extensive intimal hyperplasia in response to injury of the vessel wall. Furthermore,
covering collaterals with stent grafts can put the viability of the limb at risk, particularly if acute occlusion occurs.

A new stent was developed to overcome all of the aforementioned problems. It is made from nickel titanium (nitinol), manufactured in a double spiral configuration and covered with a thin sleeve of expanded polytetrafluoroethylene (ePTFE). Advantages of this stent are high radial force, flexibility and crush and kink resistance. The delivery system ensures accurate placement, whilst the open spiral design maintains compliance, promotes laminar flow and allows collaterals to be preserved.

The purpose of this feasibility study was to examine the efficacy of this new stent and its delivery system (aSpire™, Vascular Architects Inc., San Jose, CA, USA) in combination with remote superficial femoral artery endarterectomy (RSFAE) for the treatment of long segment occlusive disease of the femoropopliteal artery in a prospective European multi-centre trial.

Methods

This study was a prospective non-randomised evaluation of the aSpire stent and delivery system with patients not being evaluated on an intention to treat basis. Thus, patients were only included once the RSFAE procedure was successful and the guidewire positioned beyond the distal transition zone. Between May 2001 and September 2002, 62 limbs in 61 patients (41 men, median age 69, range 40–88 years) were treated in five European centres: St Antonius, Nieuwegein, The Netherlands; Catharina, Eindhoven, The Netherlands; Imelda, Bonheiden, Belgium; Policlinico S. Metteo, Pavia, Italy and Southampton General Hospital, Southampton, UK. Local ethics committee approval for each institution and written informed consent for each patient was obtained prior to enrolment into the study. Indication for treatment was long segment occlusive disease of the femoropopliteal artery, or further stents can be placed to line the entire vessel lumen and ensure complete expansion. Either a single stent is placed in the distal endarterectomized artery, or further stents can be placed to line the entire

The aSpire covered stent

The aSpire covered stent (Fig. 1) combines the components of a vascular stent and a surgical graft. The stent is made from nitinol, manufactured in the shape of a double spiral and fully encapsulated with a thin layer of ePTFE, such that there is no tissue to metal, or metal to blood contact. The crush resistant nitinol frame provides radial strength whilst allowing conformability to the vessel lumen. It is also flexible enabling it to withstand the torsional stresses typically found in the femoropopliteal segment. The aSpire stent is deployed via a delivery catheter that consists of two independent shafts, one within the other. These shafts are rotated in opposite directions to coil and uncoil the stent. The stent can be released from either end independently and shortening of the stent does not occur on release. After stent expansion, if placement is not optimal, it can be re-coiled, repositioned and re-expanded. Using these controls the stent can be deployed precisely in the desired location. This, together with the open design, allows the distal intimal flap to be tackled down, but the collaterals or side branches to be preserved, which should theoretically improve durability and patency. The stent-graft is available in lengths of 25, 50, 100 and 150 mm with a range of diameters from 6 to 12 mm.

Procedure

RSFAE is a modification of the semiclosed endarterectomy and has been previously described by Ho et al. Under general anaesthesia a vertical incision in the groin is made to gain access and control of the common, deep and superficial femoral arteries. After anticoagulation with 5000 IU of intravenous heparin, the common femoral artery is opened via a longitudinal arteriotomy extending to the origin of the SFA, and an endarterectomy is performed with a ring stripper (Vollmar Dissector, Aesculap®, South San Francisco, CA, USA). Under fluoroscopic guidance the ring strip cutter (MollRing Cutter™; Vascular Architects Inc., San Jose, CA, USA) is advanced and a remote endarterectomy is performed with removal of the diseased segment. A guide wire is then passed across this lesion, onto which is rail roaded, the stent delivery catheter. Deployment of the aSpire stent is performed under further fluoroscopic guidance ensuring a 2 cm overlap of the distal intimal flap. It is almost always necessary to post-dilate the aSpire to model it to the vessel lumen and ensure complete expansion. Either a single stent is placed in the distal endarterectomized artery, or further stents can be placed to line the entire

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artery, ensuring major side branches and collaterals remain patent and are not occluded by the stents.

Outcome definitions and statistical analysis

Stenosis was diagnosed when the peak systolic flow velocity ratio was greater than two-and-a-half. The absence of colour flow indicated an occlusion and was followed by angiography. Primary patency was defined as uninterrupted patency of the treated femoropopliteal segment with no additional reintervention performed. If surgical or radiological intervention was necessary for restenosis, the artery was designated assisted primary patent. When a successful reintervention was undertaken following a re-occlusion of the treated artery, the artery was classified as secondary patent. Patient survival was calculated by Life-table analysis and cumulative primary, primary assisted and secondary patency rates were calculated by Kaplan–Meier plots according to the Reporting standards of the SVS/ISCVS.12,13 Statistical analysis was performed with the Software Package for the Social Sciences (version 10.0 for Windows, SPSS, Inc., Chicago, III). Significance was determined at a $P$ level less than .05.

Results

Procedure

All included patients underwent successful aSpire stent placement. The mean length of occlusion treated was 25 cm (range 10–35), with a mean of 1.3 (range 1–3) stents used per procedure. A total of, respectively, 65 and 16 stents with a length of 100 and 50 mm were deployed with a median stent diameter of 7 mm (range 6–9). All stents were patent on discharge with no problems such as stent fracture or migration. The median follow-up is 16.5 (range 2–34) months.

There were no in-hospital deaths. There was one in-hospital myocardial event and one further patient suffered a cardiac event at 1 month. One patient developed an early stent failure (within 1 month), which was thought to be due to an intimal flap and was successfully treated with thrombolysis; the stent later occluded at 7 months. Two further patients developed a false aneurysm—of which one was located around the stent—as a complication of the remote endarterectomy: one patient required a PTFE bypass performed at day 9; the other patient required no further intervention. Minor wound complications included three superficial infections, two haematomas and two seromas, without the need for surgical intervention.

Follow-up

There were 25 failures within 18 months: 15 occlusions (six in-stent, two proximal, one distal and six unrecorded) and ten stenoses (five in-stent native SFA, two immediately proximal, two distal and one at both ends of the stent). The fate of these patients is detailed in Fig. 2. There were no limb amputations. There were in addition, two non-procedure related deaths at 7 and 11 months.

The cumulative primary, primary-assisted and secondary patency rates were 83.9, 95.2 and 98.4% at 6-months, 65.4, 81.6 and 83.2% at 12-months and 59.8, 69.9 and 71.5% at 18-months, respectively, (Tables 2 and 3, and Fig. 3).

Discussion

Despite the high initial technical success rate of percutaneous transluminal angioplasty (PTA) in femoral disease, the long-term results are disappointing, particularly for long occlusions.14,15 The PTA causes an extensive intimal dissection with consequential elastic recoil and intimal hyperplasia leading to acute re-occlusion or restenosis. Stent placement has not resulted in improved patency.16,17 Rather, the stent is indicated as a secondary measure to preserve the PTA-result, should complications such as a dissection
occur. Sub-intimal angioplasty (SIA) is feasible and can be effective in some patients with a high comorbidity with lower extremity arterial occlusions and threatened limbs but has also poor patency results.\textsuperscript{18,19} The use of an endograft—after debulking or not—to line the treated segment completely has not improved the patency and its indication remains limited to aneurysmal disease, pseudoaneurysms, arterio-venous fistulas or arterial rupture, (with 2-year primary and secondary patency rates ranging from 14–74 to 49–83\%, respectively\textsuperscript{20–23}).

RSFAE is a minimal invasive endovascular procedure that enables the treatment of long segment (>10 cm) occlusive femoropopliteal disease. It has been extensively described by various institutions with 5-year primary assisted patency rates similar to prosthetic above knee bypass surgery\textsuperscript{24–28}. A stent is placed at the remote endarterectomy endpoint to

![Fig. 1. The aSpire covered stent and the delivery system.](image)

![Fig. 2. Outcome of restenoses and occlusions after RSFAE and aSpire stenting.](image)

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create a smooth distal transition zone back to normal intima. Previous studies have shown that the stented area following RSFAE is unlikely to be the cause, or site of restenosis. This does not, however, imply that improvements in stent design are unnecessary. The distal transition zone and the stent are located in Hunter’s canal, an area prone to movement and excessive forces, where high radial force and kink resistance are required in order to prevent stent fracture and migration. Thus, only a short stent or a flexible longer stent can be used. Current stents suffer from technical difficulties with non-adjustable placement techniques leading to sub-optimal results and loss of collaterals.

Endovascular femoropopliteal procedures continue to evolve with the development of new stents and delivery systems. The goal is to achieve long-term (i.e. 5 year) patency rates of 75%, similar to the gold standard treatment of conventional autologous vein bypass grafting. Stenting after RSFAE offers many important advantages. It is a minimally invasive procedure that may confer haemodynamic advantages with reduced neointimal hyperplasia formation, whilst allowing conventional surgery to be performed if a re-oclusion with recurrence of symptoms occurs. Stent-graft failure may be categorised into early failures reflecting technical difficulties with initial graft deployment, and late failures as a result of disease progression.

This study reports on the use of the aSpire covered
stent, an innovative new stent that has been specifically developed for the femoropopliteal segment. The unique design of the stent and delivery catheter has several important advantages over other currently available systems. Firstly, the vascular stent consists of a nitinol spiral frame that is encapsulated in a thin layer of ePTFE. The ePTFE covering provides enhanced luminal coverage in comparison to other nitinol stents, and yet does not occlude important collaterals or side branches. In addition, the aSpire covered stent exhibits longitudinal flexibility, reducing the incidence of stent fracture and migration in an area prone to excessive movement. The crush resistant nitinol frame also provides radial strength whilst allowing conformability to the vessel lumen. Finally, the spiral design also confers haemodynamic advantages over conventional endovascular stents. As a result of the spared collaterals, flow can still be maintained if restenosis or occlusion occurs. In four of our patients which an occlusion occurred no secondary intervention was performed because there was no recurrence of symptoms (Fig. 4 shows the vessel occluded but the aSpire maintaining distal flow through the preservation of a collateral).

Despite the technical success rate of 100%, this study reports on the very first aSpire cases in Europe and the follow-up results may be influenced by the learning curve. In addition, the majority of the stent delivery systems used were the original version, which, being a 9 French system, were less user friendly than the latest 7 French compatible versions. The new system has much-improved delivery to simplify the wrap down and expansion process.

Our 18-month primary and secondary patency rates compare favourably with other recently published studies. Jahnke et al. and Bray et al. describe percutaneous Hemobahn placement over the entire length of the femoropopliteal segment, following angioplasty and without prior vessel debulking. Only Jahnke et al. have reported slightly better patency results (74% at 18 months) but they included patients with a wide range of symptoms (13% with Rutherford categories 1 and 2) and a mean occlusion length of only
11 cm compared to 25 cm in this study. Occlusion length is an important predictor of patency.\textsuperscript{4,35}

Two studies have described complete endografting of the artery with the enduring, following remote endarterectomy in the majority of cases, with a primary patency of 42–50\% at 18 months.\textsuperscript{36,37} These disappointing results were in part due to a high early re-occlusion rate and restenosis at the proximal and distal anastomosis, which contributed to its subsequent withdrawal from clinical use. There is as yet no clear evidence based advantage for disease debulking with remote endarterectomy or percutaneous balloon dilatation. Recanalisation, however, is extremely difficult in long occlusive lesions. This study reports on patients who are most likely to benefit from debulking: the mean occlusion length is long at 25 cm with 56\% moderate/severe vessel calcification.

Our overall cumulative primary, primary-assisted and secondary patency rates of, respectively, 60, 70 and 72\% at 18-months are comparable to the results of Rosenthal \textit{et al.} who described a primary patency of 69\% and primary assisted patency of 89\% at 18 months in 40 patients treated with RSFAE and aSpire stenting.\textsuperscript{38} The development of drug eluting stents, such as the nitric oxide eluting aSpire stent, may further improve these results and might make complete endolining of the endarterectomised segment with multiple aSpire stents of additional value.

In summary, the aSpire stent system allows accurate, fine-tuneable stent placement with a good technical success rate. Patency results of the aSpire stent combined with RSFAE are still early but appear favourable in view of the long segment occlusions treated. Further follow-up is required to compare the mid- and long-term outcomes with other currently available stents.

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