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SHORT REPORT

A Helical PTFE Arteriovenous Access Graft to Swirl Flow Across the Distal Anastomosis: Results of a Preliminary Clinical Study

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Intimal hyperplasia develops preferentially in regions where the blood flow is stagnant and wall shear stress low. The small amplitude helical geometry of the SwirlGraft™ was designed to ensure physiological-type swirling flow, and thus suppress the triggers. We report the first conceptual testing of the SwirlGraft™. Primary, assisted primary and secondary patency rates at 6 months in 20 patients were 57.9 ± 11.4%, 84.4 ± 8.3% and 100 ± 0.0%. There was angiographic evidence of reduction of helical geometry in a proportion of the grafts.

The helical graft is associated with high assisted primary and secondary patency. Elaboration of the surgical implantation techniques and an improved SwirlGraft™ design can be expected to exploit the advantages of the helical concept.

Keywords: Vascular access; Helical geometry; PTFE; Hemodialysis; Patency; Swirl.

Introduction

Failure of ePTFE vascular access grafts is predominantly caused by progressive intimal hyperplasia at the graft/vein anastomosis. Intimal hyperplasia (IH) develops preferentially in regions where flow is stagnant and wall shear stress is low,[1–4] causing endothelial gene regulatory responses.[5]

Native arterial geometry is three-dimensional, causing blood swirling and the expectation of relatively uniform wall shear stress and inhibition of flow stagnation.[4,6] However, arterial bypass grafts are essentially two-dimensional,[7] and hence associated with adverse fluid dynamics.

The Small Amplitude Helical Technology (SMAHT) prosthesis, SwirlGraft™, was developed to achieve physiological-type swirling in and downstream of vascular access grafts. We report the first test in patients.

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Report

Between December 2004 and November 2005, eleven men and 9 women (median age 72, range 24–86 yrs.) requiring PTFE vascular access grafts were recruited in 6 centers (Table 1). Patients were treated according NKF-K/DOQI guidelines,[8] with institutional review board approval. Graft patency rates were calculated by life table method using SPSS 12.0 (Chicago, USA) for statistical analysis. Antibiotic, anticoagulation and anesthetic regimes were as per unit protocol.

The 20 Swirlgraft™ implantations were uneventful. Mean suture line blood loss duration was 2.9 minutes (0 to 10 min), procedure duration was 78 minutes (45 to 105 min), and technical success rate at 1 month was 90%.

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Table 1. Demographics & co-morbidities

	$N = 20$
Male gender	55%
Age [yr]	72 (24–86)
BMI [kg/m^2]	25.3 ± 4.5
Prior VA surgery	65%
Smoking	25%
Diabetes	30%
Hypertension	50%
Ischemic heart disease	20%
Peripheral vascular disease	15%
Diagnosis renal failure	
glomerulonephritis	10%
interstitial nephritis	5%
cystic kidney disease	5%
congenital disease	5%
renal vascular disease	25%
diabetes	10%
other (multisystemic) diseases	15%
unknown aetiology	25%

BMI = Body Mass Index; VA = Vascular Access; median (range); mean ± SD.

On 1 June 2006, the mean follow-up was 9.5 months (range 1.6–15.6), and the total follow up time 15.9 patient-years (py). One patient was transplanted and 3 patients died of non graft related causes (2 stopped dialysis treatment, 1 myocardial infarction).

The 6-month primary patency rate was 57.9% ± 11.4 (SE) (Fig. 1). Nine patients developed 18 stenoses. Six (33%) were identified in the outflow vein and 4 (22%) at the graft/vein anastomosis. Seven stenoses were located in the graft and at the proximal anastomosis. One patient had an unrelated stenosis of the brachiocephalic vein for which he was observed.

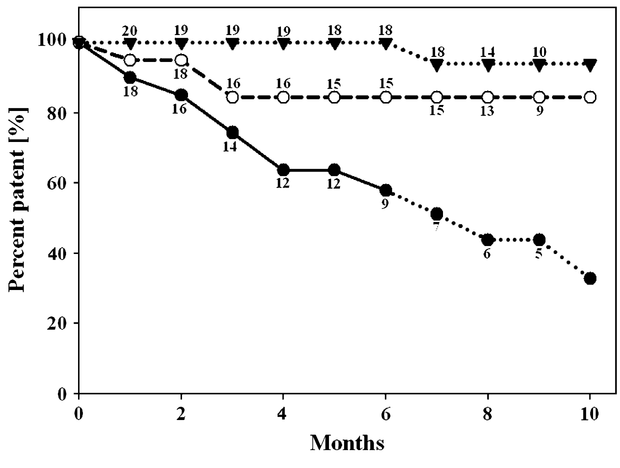

Fig. 1. Patency rates of the SwirlGraft™ with number of patients at risk. Solid line = primary patency; Dashed line = assisted primary patency; dotted line = secondary patency.

The thrombosis-incidence was 0.69/py. Ten out of the 11 thromboses occurred in 2 patients.

Twenty interventions were required for graft salvage: 11 PTA procedures (0.69/py), 7 surgical revisions (0.44/py) and in 2 cases mechanical thrombolysis (0.13/py). The 6-month assisted primary and secondary patency were 84.4% ± 8.3 and 100% ± 0.0 respectively.

Angiograms performed when access flow measurement or duplex suggested a flow problem, revealed reduction of helical geometry in at least 3 of 9 angiograms at a mean of 5.1 months.

Discussion

Review of currently available literature suggests that one year primary and secondary patency rates of standard ePTFE hemodialysis grafts are approximately 40% and 65%, respectively.[9] As most failures occur secondary to intimal hyperplasia at the graft/vein anastomosis, inhibition of this process could have a major impact on morbidity and healthcare costs of end-stage renal disease patients. In this prospective, first in-man study, technical success (90% <1 month) is in line with DOQI standards.[8] The 6-month primary patency at 58% is similar to that of standard ePTFE AV-grafts but the assisted primary (84%) and

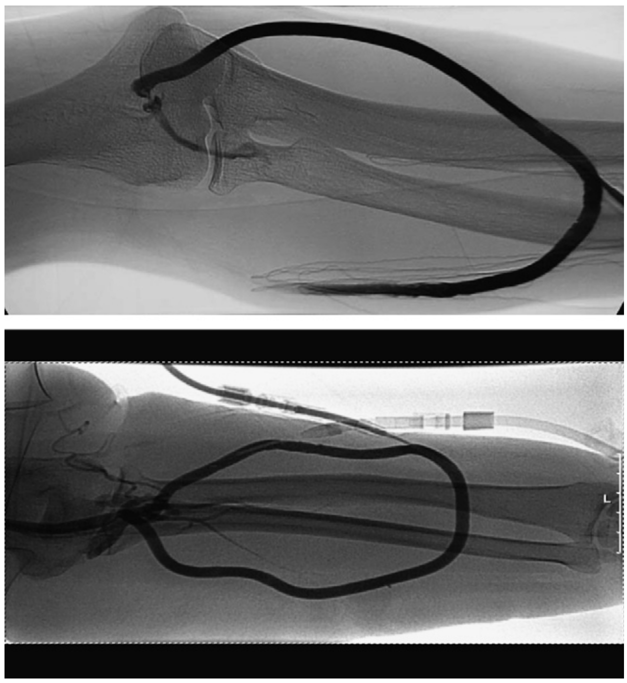

Fig. 2. Upper angiogram: possible loss of graft helical geometry. Lower angiogram: intact graft helical geometry.

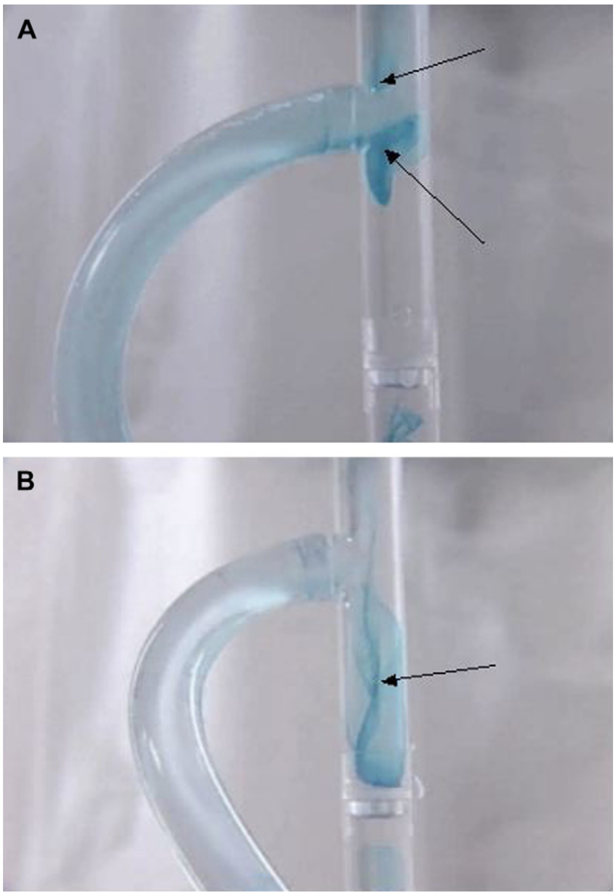

Fig. 3. Ink flow studies of the distal anastomosis of simulated bypass grafts. In standard, planar anastomoses (3A, top), tracer remains in stagnant areas around the heel and toe of the anastomosis (arrowed) after the centre of the graft and host vessels has cleared. With non-planar helical-type geometry (3B, bottom), the heel and toe are clear of ink a similar time after tracer injection seen in 3A. Helical flow patterns can be seen in the occluded proximal (lowermost) limb of the model (arrowed). From: Caro *et al.*[4]

secondary patency (100%) rates are at the highest end of reported series and suggest possible benefit. Angiographic examination in a limited number of grafts suggests that there was reduction of helical geometry at or after implantation, implying function like that of conventional ePTFE prostheses (Fig. 2). This may have been due to overstretching during implantation, or by elongation under arterial pressure; these problems have been addressed in subsequent iterations of the graft.

The helical geometry of the SwirlGraft™ produces swirling and mixing of blood flow, in a manner like that believed to be present in native human arteries. Flow model experiments and computational fluid dynamic studies show that such conditions powerfully affect the flow across end-to-side anastomoses. Low wall shear is minimized and stagnation eliminated (Fig. 3), reducing the likelihood of IH development.[1,4]

In a small porcine carotid artery − to − jugular vein study, there was markedly less intimal hyperplasia and thrombosis in SwirlGrafts™ than conventional ePTFE grafts.[10] In contrast to the present clinical study, the grafts were implanted during open surgical exposure, allowing attention to preservation of helical geometry.

Another potentially important finding of this study is the site of stenosis development; Kanterman *et al*. found that almost 60% of angiographic AV-graft stenoses were located at the distal anastomosis.[11] In our study however, only 22% of the stenoses were confined to this region and 33% were detected in the outflow vein. The explanation remains unclear.

Our thrombosis incidence (0.69 per py) exceeds DOQI standards,[8] but only 2 grafts in this relatively small patient group caused 91% of the thromboses. So, salvaging has led to increased longevity at the expense of a higher thrombosis rate.

In conclusion, with the right modifications to implantation techniques and Swirlgraft™ design we believe a randomized controlled trial with this device is justified.

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