SHORT REPORT

A Cautionary Case: The Synergraft Vascular Prosthesis

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To date no prosthetic vascular prosthesis performs as well as autologous conduits for small diameter arterial reconstruction. We report the outcome of our first case using a new vascular prosthesis marketed by Cryolife, the SynerGraft. This Xenograft prostheses is claimed to eliminate the problems of the previous generation of gluteraldehyde treated grafts. Two 50 cm SynnerGrafts were anastomosed end to end and used as a femoral-posterior tibial bypass graft in a 68-year-old man who presented with an acutely ischaemic left leg. Our patient represented at 8 weeks with aneurysmal degeneration along the course of the graft. We urge caution in the use of these grafts until convincing data in humans is presented.

Key Words: Blood vessel prosthesis; Adverse effects.

Introduction

To date no prosthetic vascular prosthesis performs as well as autologous conduits for small diameter arterial reconstruction. We report the outcome of our first case using a new vascular Xenograft prosthesis marketed by Cryolife, the SynerGraft. The SynerGraft is a new product produced by Cryolife. It is produced from Bovine ureter and comes as a 7 mm diameter conduit in lengths of between 30 and 75 cm stored in a buffer solution at room temperature for utilisation off the shelf. The manufacturing process is different from previously marketed Xenograft prostheses. The novel patented process involves denuding bovine ureters of cells by a sequence of hypotonic lysis and digestion with nucleases to leave just the underlying collagen matrix, thus epithelial cells, smooth muscle and fibroblasts are completely removed. When implanted in an animal dog model the grafts have been reported to be repopulated by host cells consisting of capillary in-growth, circumferentially oriented smooth muscle cells in the media and a luminal layer of cells resembling endothelium. The viability of the repopulated graft is claimed to eliminate the problems of the previous generation of gluteraldehyde treated grafts, known to be aneurysm formation, calcification of the conduit, neointimal hyperplasia, stenosis and occlusion.

Report

A 68-year-old man presented with an acutely ischaemic left leg. He had previously undergone extensive vascular surgery for aneurysmal disease, including an Aortic graft and a femoral-posterior tibial bypass graft. A duplex scan demonstrated that the femoral-posterior tibial graft in the left leg had occluded but the posterior tibial artery remained patent into the foot. There was no long saphenous vein available because both veins had been harvested for previous surgery. Arm vein was considered but was not utilisable due to recent repeated venepuncture. The foot had reduced sensation with no Doppler signals and urgent intervention was required. Thrombolysis was unlikely to achieve revascularisation soon enough. It was decided that revascularisation to the posterior tibial artery with a synthetic graft was the only option. Two 50 cm SynnerGrafts were anastomosed end-to-end and used as a femoral-posterior tibial bypass graft, achieving revascularisation of the foot with return of the posterior tibial pulse.

Our patient represented at 8 weeks with erythematous swellings along the course of the graft increasing in size since he first noticed the change 3 weeks prior to presentation.

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to representation. Otherwise, he was asymptomatic without pain, fever, malaise or change in his walking distance. On examination, the swellings were pulsatile and expansile measuring up to 2.6 cm in diameter. (Fig. 1) Vitals signs and blood tests were unremarkable and blood cultures showed no growth. It was decided to remove the SynerGraft due to the impending risk of rupture. (Fig. 2). There was difficulty removing the graft completely as some segments were densely adherent especially around the distal cuff and some sections of the graft were friable. Segments of the graft were sent for histology and microbiological culture. The graft tunnel was washed out with dilute aqueous iodine solution. Cephalic vein from both arms was harvested and joined end to end to achieve sufficient length to replace the SynerGraft and routed in the existing tunnel. He made an uneventful recovery from the surgery. He entered graft surveillance and this remained satisfactory at 6 months. The microbiology specimen demonstrated occasional pus cells on Gram smear but no organisms and subsequent culture was negative. Histology of the graft demonstrated the wall to consist of highly vascularised fibromuscular tissue, containing a dense transmural inflammatory cell infiltrate. This comprised numerous eosinophils, with scattered granulomata including multinucleated giant cells. The luminal surface was lined by thrombus that contained large numbers of neutrophils in areas (Fig. 3).

Discussion

The utilisation of bovine ureter as the source material for a vascular conduit is not new. Glutaraldehyde treated bovine ureter for use as vascular prosthesis has been reported since 1982.9 The manufacturer claims that the modification in production of its SynerGraft renders it unlikely to undergo aneurysmal degeneration and it has been used for dialysis a-v fistulae without apparent problems, but our experience demonstrates aneurysmal degeneration is possible.

The histological examination of the explanted SynerGraft did not suggest hyper-acute immune response to the Xenograft but simply an inflammatory response. An inflammatory response is expected and is promoted by the manufacturer as part of a revitalisation process and was still ongoing at 13 weeks in their dog experiment.3 Considering that prior to implantation bench testing has shown the grafts have similar burst strength to long saphenous vein,10 we hypothesise that it is the inflammatory response that is responsible for weakening of the wall. The absence of aneurysm formation in the six reported cases in the dog animal model studied beyond 6 weeks, taken at face value, may suggest the inflammatory response is different in humans or just that insufficient numbers have been studied.3

The company has suggested a future area of development for their graft, is to repopulate the graft in vitro prior to implantation. It may be that if this were accomplished successfully, it would ameliorate the inflammatory response on implantation which we are led to conclude was responsible for the failure of the graft wall integrity.

We urge caution in the use of these grafts until convincing data in humans is presented.
Fig. 3. Histology of the explanted graft: (a) inflammation throughout the wall, (b) numerous eosinophils, (c) granulomata and (d) the luminal surface lined by inflamed thrombus.

References


10 Personal communication. Cyolife Inc.

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