

CLINICAL CHALLENGE

Omniflow™ II

When a saphenous vein
is not available

Situation

- Patient has lower limb ischaemia
- A viable saphenous vein is not available

Challenge

- No synthetic prosthesis can match the performance or handling of vein
 - Lower long-term patency, particularly for below-knee revascularisation
 - More susceptible to infection
 - Susceptible to suture hole bleeding
 - Cuffs or jump grafts may be required

Solution

Omniflow II – the biosynthetic vascular prosthesis for lower limb revascularisation

- Superior patency to synthetic prostheses in below-knee settings
- Good long-term patency even with poor run-off
- Resistance to infection
- Handles like a saphenous vein
 - No need for cuffs or jump grafts at distal anastomosis
 - Minimal suture hole bleeding with standard vascular sutures

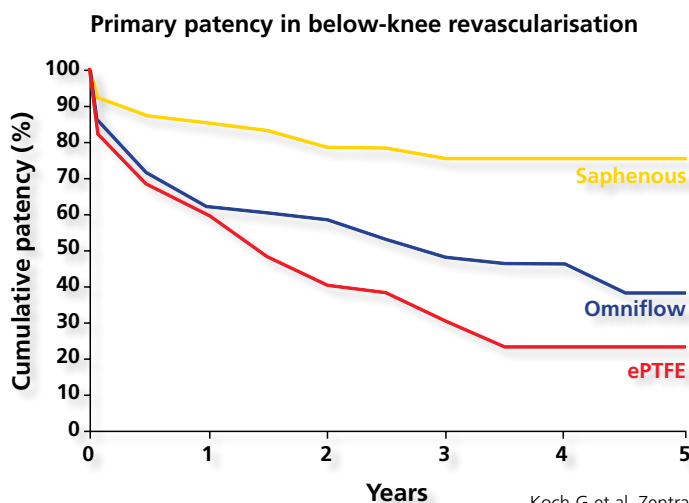


Patency rates with Omniflow in below-knee settings are statistically better than PTFE

In a study of 653 femoropopliteal reconstructions, performed over an 8 year period, patients requiring a below-knee graft but without an available saphenous vein were randomised to either Omniflow or PTFE.

Omniflow demonstrated superior performance to PTFE, with a three year primary cumulative patency of 50% for Omniflow and 30% for PTFE ($p < 0.05$).

At 18 months, randomisation to PTFE was abandoned based on the patency difference in favour of Omniflow.



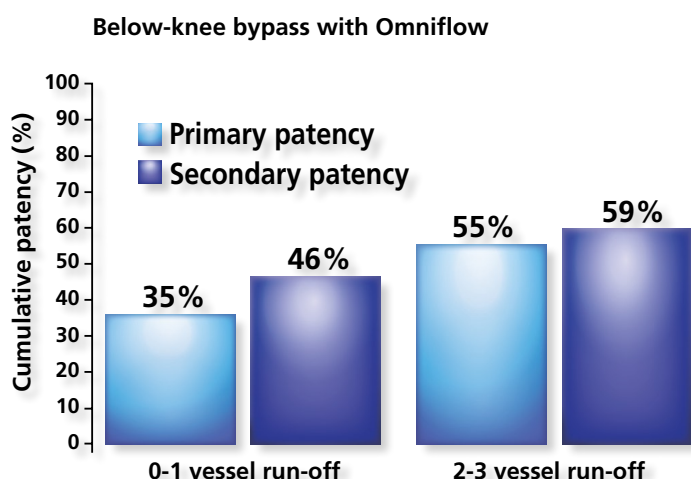
Koch G et al. Zentraibl Chir 1996; 121: 761-767.

Omniflow demonstrates good patency even with poor run-off

Over a period of 8 years, 274 Omniflow vascular prostheses were implanted in patients with critical lower limb ischaemia.

At 3 years, the patency was 55% for below-knee implants in patients with 2-3 vessel distal run-off ($n=44$): the secondary patency in the group was 59%.

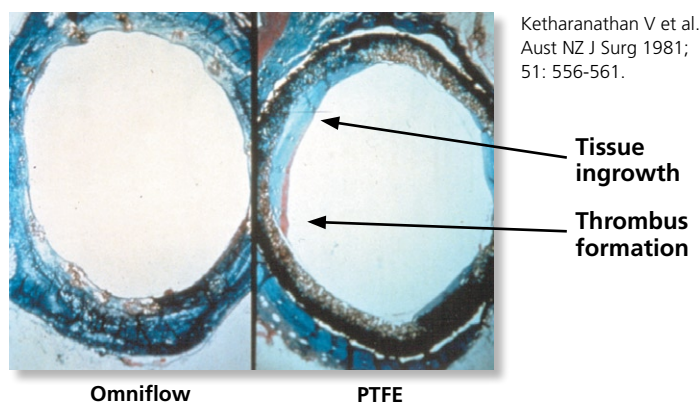
With 0-1 vessel run-off ($n=63$), the primary patency was 35%, and the secondary patency was 46%.



Koch G et al. Aust NZ J Surg. 1997; 67: 637-639.

Omniflow maintained lumen integrity whilst PTFE displayed tissue ingrowth and thrombus formation after thirteen months

Omniflow and PTFE were implanted in parallel in a canine model. The results clearly show that Omniflow maintains the integrity of its lumen whilst PTFE displays tissue ingrowth and thrombus formation, as demonstrated in these explants after 13 months. Omniflow is also well integrated into the host tissue, contributing to its resistance to infection.



Ketharanathan V et al. Aust NZ J Surg 1981; 51: 556-561.