CLINICAL CHALLENGE

Omniflow™ II

When there is concomitant diabetes

Situation

- Patient has diabetes and requires peripheral revascularisation or AV access
- A viable saphenous vein is not available or an AV fistula cannot be constructed

Challenge

- Patients with diabetes are
  - at high risk for lower limb amputation
  - often young and require long-term solutions to vascular and renal ailments
  - susceptible to infection
- No synthetic prosthesis can match the performance of a vein for peripheral revascularisation or an AVF for AV access
  - Lower long-term patency
  - Susceptible to infection

Solution

Omniflow II – the biosynthetic vascular prosthesis when there is concomitant diabetes

- Good long-term patency, even with poor run-off
- High limb-salvage rate
- Resistance to infection

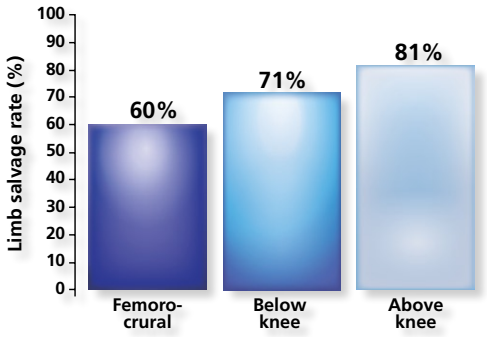
Omniflow demonstrates high limb salvage rates

Over a period of 8 years, 274 Omniflow vascular prostheses were implanted.

All of the patients had either pain at rest or gangrene of the foot or toe, and ankle pressure <50 mmHg.

After 3 years, limb salvage rates of 81%, 71% and 60% were reported in above-knee, below-knee and femorocrural bypass, respectively.

Limb salvage with Omniflow after 3 years



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

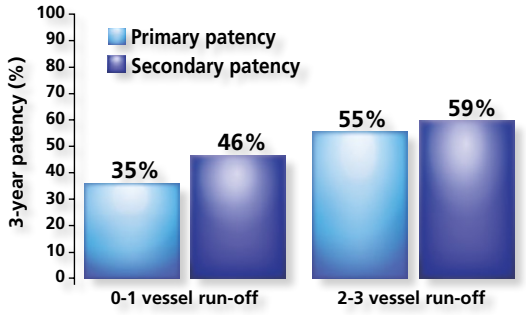
Omniflow demonstrates good patency even with poor run-off

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%.

Below-knee bypass with Omniflow



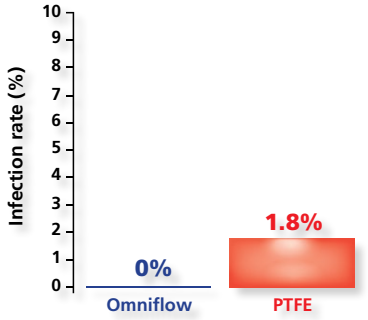
Koch G et al. Aust NZ J Surg. 1997; 67: 637-639.

Omniflow demonstrates a lower infection rate than PTFE

A study was undertaken of 653 arterial femoropopliteal reconstructions (inclusive of above-knee, below-knee and femorocrural bypass), performed over an 8-year period.

There were no infections in 270 Omniflow prosthesis compared with the rate for PTFE of 1.8%.

Femoropopliteal bypass operations



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

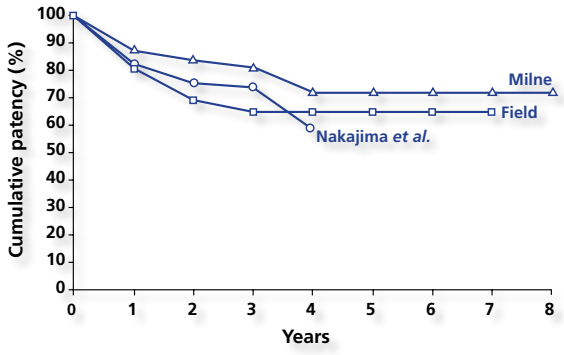
Omniflow II demonstrates long-term patency

Long term follow-up of patients with either above- or below-knee grafts demonstrated long-term patency with Omniflow II.

In a study by Nakajima et al, the patency was 82.0% after one year, 75.7% after two years, 73.8% after three years and 59.0% after 4 years.

Similarly, patency rates of 60-70% were demonstrated by Field and Milne.

Secondary patency rates for Omniflow II



Nakajima et al. Jpn J Vasc Surg 1996; 5: 801-807.
Milne P. Personal communication.
Field P. Data on file, Bio Nova International.

bio nova

Bio Nova International Pty Ltd, North Melbourne, Victoria 3051, AUSTRALIA
Website: www.bionova.com.au Telephone: +61 3 9326 6955 Facsimile: +61 3 9329 8071 BN 9-8.3(0)-1 24308