CLINICAL CHALLENGE

Omniflow™ II

When an arteriovenous fistula cannot be constructed

Situation

- Patient requires AV access
- A viable AVF cannot be constructed

Challenge

- No synthetic prosthesis can match the performance of an AVF
  - Lower patency due to distal narrowing and intimal hyperplasia
  - Susceptible to graft infection
  - Susceptible to pseudo-aneurysm and seroma formation
  - More difficult to puncture
  - Revision leads to progressively more frequent interventions

Solution

Omniflow II – the biosynthetic vascular prosthesis for arteriovenous access

- Good long-term patency and long-term access
- Resistance to infection
- Resistance to aneurysm formation
- Ease of puncturing
- Rapid haemostasis with minimal pressure
- Responds well to revision

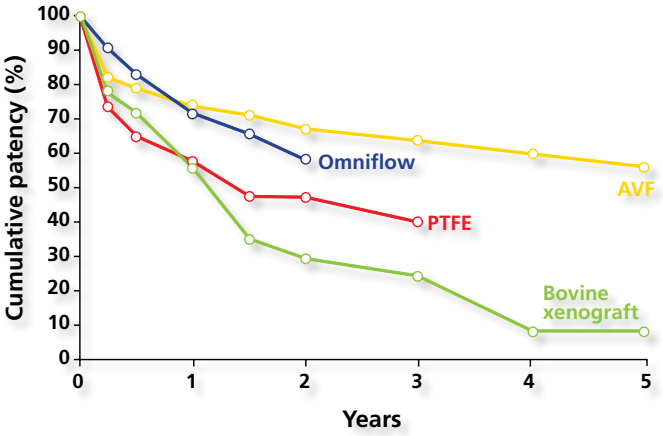
Omniflow demonstrates good patency in arteriovenous access

The patency rates of autologous AV fistulas (AVF), Omniflow, PTFE and bovine xenografts were compared in a retrospective study.

The primary and secondary patency rates at 2 years were 48% and 58% for Omniflow, 24% and 47% for PTFE, and 21% and 29% for bovine xenograft.

The patency rate for Omniflow was not statistically different from AVF.

Secondary patency of AV access grafts



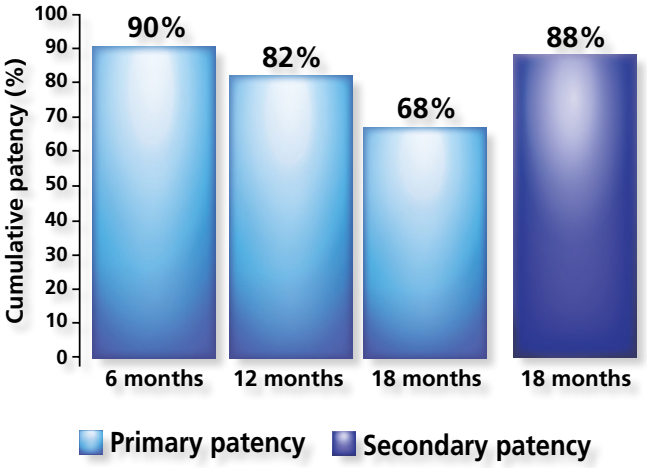
Enzler et al. Clin Transplant 1996; 10: 511-515.

Omniflow II – the biosynthetic prosthesis for vascular access in haemodialysis patients

In a study lasting 18 months, the safety and efficacy of Omniflow II was evaluated in patients who were not candidates for AVF.

The primary patency rates at 6, 12 and 18 months respectively were 90%, 82% and 68%. The secondary patency rate was 88%.

Patency rates for Omniflow II in AV access



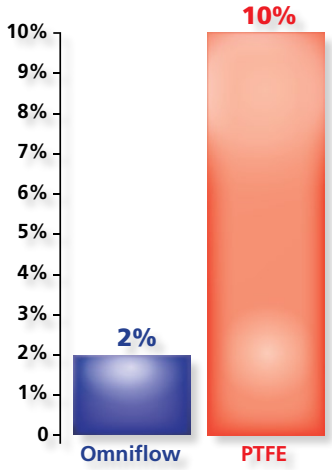
Palumbo et al. Abstract presented at the Renal week of the American Society of Nephrology, San Diego, CA 14-19/11/2006.

Omniflow demonstrates low complication rates in AV access

Enzler et al reported a 2% frequency of infections in Omniflow patients compared with 10% for PTFE.

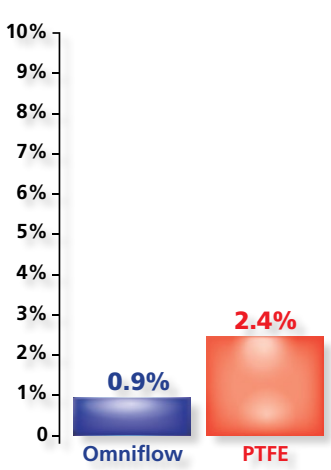
In another study (Wang and Chu), 591 operations in 482 patients were performed to create haemodialysis vascular access. The patients received haemodialysis ≥3 times per week. The aneurysm rate for Omniflow was 0.9% per patient year compared with 2.4% for PTFE.

Infection rate in AV access



Enzler et al. Clin Transplant 1996; 10: 511-515.

Aneurysm rate in AV access per patient year



Wang and Chu. Artif. Organs 1996; 20: 1278-1281.

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