

# CLINICAL NOTE

## Summary of Key Publications

on the Omniflow II vascular prosthesis.

### PERIPHERAL RECONSTRUCTIONS

**Arterial femoropopliteal reconstruction: Vein, ePTFE or ovine collagen prosthesis** [*Zur Problematik des femoropoplitealen Gefäßersatzes: Vene, ePTFE oder ovines Kollagen*]. G. Koch, S. Gutschli, O. Pascher, J. Fruhwirth, H. Hauser (1996) *Zentralbl. Chir.* 121:761-767

The authors analyse 653 femoropopliteal and femorocrural bypasses performed over a 7-year period. 156 implants were saphenous vein, 270 Omniflow and 227 PTFE prostheses.

Patients receiving artificial prostheses had a higher frequency of increased anaesthesia risk, with 83% of both the Omniflow and PTFE groups in the ASA III-IV categories compared with 65% of the vein group. Risk factors for atherosclerosis (diabetes mellitus, hypertension, nicotine abuse etc.) were equally common in all groups.

Operating times were similar between the different graft materials for above-knee bypasses, however, for below-knee fem-pop reconstructions the operating time using artificial prostheses was reduced by 7-15 minutes (vein 96 min, PTFE 89 min, Omniflow 81 min) and for femorocrural bypasses by approx. 30 minutes (vein 127 min, PTFE 93 min, Omniflow 97 min).

In the absence of a saphenous vein patients were randomised to Omniflow or PTFE. This randomisation was, however, abandoned for below-knee fem-pop reconstructions due to the poor performance of the PTFE material.

3-year primary patency rates for above-knee bypasses were 90% in the vein group and 52-56% (N.S.) for PTFE and Omniflow, respectively. For below-knee fem-pop, 3-year primary patency rates were 76% in the vein group, approx. 50% for Omniflow and below 30% for PTFE.

Aneurysms developed in 1.1% (3 patients) of the Omniflow implants, however, not in any

vein or PTFE implant. Infection occurred in 1.8% (4 patients) of PTFE implants, however, not in any Omniflow or vein graft. Two of the infected PTFE prostheses had to be removed and both patients were amputated within one year.

**Analysis of 274 Omniflow Vascular Prostheses Implanted Over an Eight Year Period.** G. Koch, S. Gutschli, O. Pascher, H. Fruhwirth, H. Glanzer (1997) *Aust. N.Z. J. Surg.* 67:637-639

This paper is largely based on the same data set as the previous publication by the same group (above). This paper describes only the Omniflow implants and makes no comparison to vein or PTFE bypasses. The analysis focuses on comparing patency rates depending on the runoff situation.

For above-knee bypass 3-year secondary patency was 76.3% with 2-3 vessel runoff and 64.7% with 0-1 vessel runoff. Primary patency rates were 61.9% and 44% for 2-3 and 0-1 vessel runoff, respectively, and any reocclusions were treated with balloon catheter thrombectomy.

Below-knee fem-pop bypass had a 3-year secondary patency of 59.2% (primary patency 55.2%) with 2-3 vessel runoff and 46.1% (primary 35.3%) with 0-1 vessel runoff. Nearly all occlusions occurred between 0-6 months post implant.

Femorocrural bypasses had a 2-year secondary patency of 36.4% (primary 28.7%).

Limb salvage rates after 3 years were 81%, 71% and 60% for above- and below-knee fem-pop and femorocrural procedures, respectively.

Three aneurysms all appeared in the distal third of the implant and were attributed to mechanical damage to the prosthesis during implantation.

None of six wound infections affected the prosthesis and no prosthesis was removed.

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**Early Results of a Reinforced Biosynthetic Ovine Collagen Vascular Prosthesis for Small Arterial Reconstruction.** H. Yoshida, T. Sasajima, K. Goh, N. Otani, Y. Kubo (1996) *Surg. Today* [Jpn. J. Surg.] 26:262-266

The authors implanted 30 Omniflow prostheses in 29 patients. The dominant position was above-knee femoropopliteal bypass (28 grafts). The indication for surgery was intermittent claudication in 27 patients and limb salvage in 2 patients.

Six grafts failed 1, 1, 9, 17, 17 and 23 months post surgery due to external compression in two cases, infection in one, anastomotic intimal hyperplasia in one, and unknown causes in two cases. At three years overall primary patency for above-knee bypass was 83.7% and secondary patency 91.2%. No aneurysm was observed.

## ARTERIOVENOUS ACCESS

**Long-term Function of Vascular Access for Hemodialysis.** M.A. Enzler, T. Rajmon, M. Lachat, F. Largiadèr (1996) *Clin. Transplant.* 10:511-515.

The authors created 720 vascular accesses in 414 patients over a 12-year period, including 429 autologous fistulas (AVF) and 291 interposition grafts consisting of 150 bovine xenografts (Solcograft), 69 PTFE and 59 Omniflow prostheses and 10 autologous and one homologous vein grafts (in two cases the material was not specified). 414 accesses were primary and 306 were "redos".

The revision rate was 21% for AVF, 37% for bovine xenografts, 56% for Omniflow and 67% for PTFE prostheses. The low rate of revisions in bovine xenografts is outweighed by a higher rate of irreversible occlusions, which is not accounted for in this number but reflected in a lower patency rate. In particular the infection frequency in Omniflow is 2% vs.10% in PTFE prostheses.

Secondary patency rates for AVF were 74%, 67%, 64%, 56% and 36% at 1, 2, 3, 5, and 10 years, respectively. Corresponding rates for bovine xenografts were 56%, 29%

and 24% at 1, 2, and 3 years, for PTFE 58%, 47% and 40%, and for Omniflow 71%, 58% and 45%.

Primary and secondary patency rates for AVF were not significantly different from those of Omniflow, however, significantly higher than patency rates for PTFE and bovine xenografts.

Straight grafts fared slightly but not significantly better than loops. No difference was found between patency rates of second, third and fourth procedures. Primary and secondary patency rates were higher in men than in women, with secondary patency at 1, 3 and 5 years being 73%, 56% and 47%, respectively, in men and 65%, 47% and 35% in women.

**Clinical Use of Omniflow Vascular Graft as Arteriovenous Bridging Graft for Hemodialysis.** S.-S. Wang, S.-H. Chu (1996) *Artif. Organs* 20(12):1278-1281.

Over a 3½-year period the authors performed 109 AV accesses in 89 patients, randomised to 61 Omniflow prostheses in 47 patients and 48 GoreTex™ PTFE prostheses in 42 patients. The anatomic configurations were 50 forearm loop grafts, 19 forearm straight grafts and 40 thigh loop grafts. Haemodialysis was started 2 weeks after the operation and all patients received haemodialysis at least 3 times per week.

One- and four-year patency rates were 77.4% and 34.1%, respectively, in the Omniflow group and 69.0% and 25.9%, respectively, in the PTFE group. These differences were not statistically significant. In the Omniflow group the thigh and the loop forearm grafts had significantly better patency than the straight forearm grafts. In the PTFE group there were no significant differences between different sites.

One Omniflow patient (0.92% per patient per annum) and two PTFE patients (2.38% p.p. p.a.) required graft excision because of aneurysm formation. Two patients in each group (1.92% p.p. p.a. for Omniflow, 2.38% p.p. p.a. for PTFE) required graft removal because of antibiotic-resistant infection.