CLINICAL NOTE

Omniflow™ II

Selecting the right diameter of the Omniflow II prosthesis

Vascular prostheses of PTFE suffer from narrowing of the lumen eventually affecting their patency. In contrast, due to its tissue impervious wall, the lumen of the Omniflow II is retained over the long term and smaller diameter Omniflow II may be used where a wider diameter PTFE prosthesis would be chosen. In most peripheral bypass and AV access applications the preferred diameter of Omniflow II is 6 mm.

Background

Selecting the correct diameter of a vascular bypass prosthesis is an exercise in balancing the anatomical requirements with rheological factors, in order to obtain a conduit that will remain patent, with or without assistance, for as long as possible. According to Poiseuille's law the flow is proportional to the fourth power of the vessel diameter; therefore it may be tempting to always select the widest prosthesis to obtain a higher flow, particularly centrally in the vessel. This equation assumes, however, that there is no outflow resistance but in reality, for a bypass with sufficient inflow, the flow rate will always be limited by the outflow resistance. At a constant flow rate, the velocity being inversely proportional to the square of the diameter, a larger diameter will give a *lower* velocity with a higher risk of thrombus formation in blood vessel prostheses.

In light of this, the challenge for the vascular surgeon is to select a conduit that is:

(a) wide enough to deliver sufficient blood flow to the distal anastomosis;
(b) narrow enough to avoid unnecessary loss of blood velocity; and
(c) has a diameter that is well matched to the receiving artery.

The difference between Omniflow II and PTFE

Based on experience, many surgeons would choose a 7-8 mm PTFE (polytetrafluoroethylene, Teflon™) prosthesis for a femoropopliteal bypass. Although challenged[1], studies on PTFE prostheses have demonstrated that PTFE prostheses with 7-8 mm diameter give higher patency than 5-6 mm prostheses[1]. The most likely reason for this is the gradual narrowing of the lumen that occurs in PTFE prostheses, thereby over time reducing the diameter to ~6 mm distally in a 7-8 mm graft.

In contrast, the most commonly used diameter for Omniflow II in femoropopliteal bypass is 6 mm. It is the experience of many Omniflow II users that Omniflow II prostheses with 6 mm diameter generally give the best clinical results both in femoropopliteal and femorodistal bypass reconstructions, when diameter matching requirements do not limit the options[2]. Studies with PTFE and Omniflow prostheses implanted side by side in experimental animals support this view, as there is clear tissue ingrowth into the PTFE prosthesis already after one year[3] [Exhibit 1].

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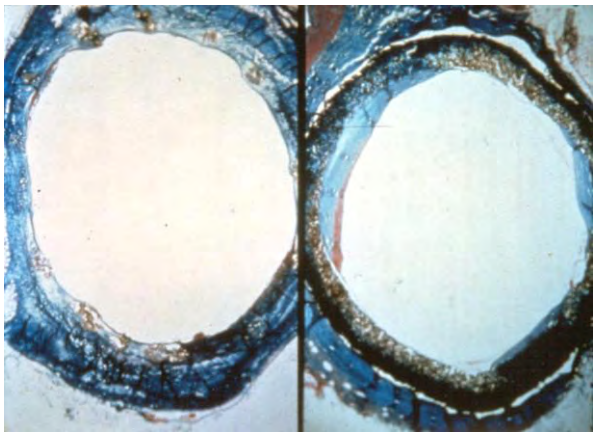

Exhibit 1. *Omniflow (left) and ingrowth into PTFE prosthesis (right) after 13 months side by side in the same experimental dog[3].*

In contrast, Omniflow II's biosynthetic wall is designed to be impervious to tissue ingrowth and Omniflow II retains its original inner diameter for long periods.

Even after seven years implanted in a patient[4], Omniflow retains a well-preserved flow surface [Exhibit 2]. This feature allows selecting the diameter of the Omniflow II according to other criteria, in order to optimise the graft's clinical performance.

Exhibit 2. *Flow surface of an Omniflow prosthesis explanted after 7 years as a femoropopliteal bypass graft[4].*

Arteriovenous access

When designing an arteriovenous access conduit, it is important to select a prosthesis diameter that gives sufficient flow and is conducive to easy puncturing by dialysis staff and, increasingly often, by the unassisted home dialysis patient.

In an arteriovenous shunting situation, flow is generally not directly limited by outflow and controlling the graft diameter is therefore important to avoid steal symptoms.

Also in arteriovenous access cases the 6 mm Omniflow II is the most commonly used option. Occasionally 8 mm diameter may be preferred for e.g. a thigh loop access, however, it is recommended that 8 mm be reserved for special cases where a 6 mm prosthesis is considered unsuitable.

Practical considerations

Due to tissue ingrowth into PTFE prostheses, a 6 mm Omniflow II prosthesis may be selected instead of a 7-8 mm PTFE prosthesis, whose lumen is narrowed over time.

Whilst very small internal diameters (<3 mm) have proven disadvantageous in distal saphenous vein bypass procedures[5], utilising 6 mm Omniflow II prostheses appears to be optimal in femoropopliteal bypasses.

For arteriovenous access, 6 mm Omniflow II seems to give the best combination of high flow rate and easy puncturing whilst still avoiding steal syndrome and allowing easy anastomosis.

Acknowledgements

This paper is based on valuable contributions from a number of Omniflow II users in several countries. Bio Nova would like to thank them for their input and discussion.

Disclaimer

This document is a discussion paper on the use of the Bio Nova Omniflow II vascular prosthesis. This paper is not an extension to the Instructions For Use document supplied with each prosthesis. The suitability of any therapy suggested in this paper has to be evaluated based on the individual circumstances for each patient.

References

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[5] Ishii Y *et al.* (2004), **Vascular** 12:225-32