

# Heparin-bonded PTFE claims superior patency above the knee

**F**rank Vermassen, Ghent University, Belgium, told delegates at the CX Symposium in April that the first randomised study of heparin-bonded expanded polytetrafluoroethylene (ePTFE) grafts showed a clear trend towards improved patency in femoropopliteal bypass.

Heparin-bonding, he said, could theoretically reduce thrombogenicity and diminish intimal hyperplasia.

“When you look at the clinical data available with heparin-bonded grafts, actually there is only one randomised study, and that is comparing heparin-bonded Dacron prosthesis with uncoated ePTFE grafts – so really comparing apples and pears.”

Vermassen said that he was asked by sales representatives of a manufacturer whether he would be willing to pay more for a heparin-bonded graft. “My answer was, ‘Well, no! Why? There’s no proof that this is indeed a better solution.’”

“Unfortunately, the big competitor on the ePTFE was not willing to participate in this project, but we found a small European company, JOTEC, that took

the challenge.”

So, in 2004, Vermassen and his colleagues launched a prospective, open label, randomised, multicentre study, comparing heparin-bonded ePTFE-grafts with the same ePTFE-grafts without heparin-bonding in femorodistal bypass.

A power analysis showed that 520 patients would be needed, with two years follow-up. The primary endpoint was primary patency.

The study enrolled 530 patients, of which 269 were randomised to heparin-bonded grafts and 261 to uncoated grafts. All grafts were 6mm ringed JOTEC ePTFE grafts – FlowLine Bipore and the FlowLine Bipore Heparin ePTFE grafts. Twenty three centres participated.

Inclusions criteria were:

symptomatic peripheral vascular disease, Fontaine IIB-IV (equivalent to Rutherford III-V); occlusion or significant stenosis of SFA and/or popliteal artery greater than 6cm;

adequate outflow artery; informed consent; follow-up possible.

Follow-up was undertaken at one, three, six, 12, and 24 months, with evaluation of patency by clinical examination and ankle brachial pressure index at each visit, and Duplex ultrasound at one, 12 and 24 months and when graft occlusion was suspected.

Amongst this cohort, 73% were above-knee bypasses, and 27% were below-the-knee, with coated and uncoated grafts divided equally between the groups.

“When we look at the whole group we can see that there’s a clear trend towards better patency with heparin bypasses vs. with non-heparin bonded bypasses,” said Vermassen.

**“When we look at the whole group we can see that there’s a clear trend towards better patency with heparin bypasses vs. with non-heparin bonded bypasses. However, when we look at above-the-knee bypasses alone, we see that there is a significant difference in this group, in favour of the heparin-bonded grafts.”**

But this difference, he pointed out, did not actually reach statistical significance.

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Frank Vermassen

significant difference in this group, in favour of the heparin-bonded grafts.” At two years the heparin-bonded group recorded a pri-

prising; many people would have thought the opposite.

“There are some interesting observations that we can make from this study. First of all, one would think that the effect of heparin would only work during the first weeks or months after implantation. But this is not seen to be the case.

“Another interesting observation, of course, is that the difference was only present in the above-knee bypasses. We think, in the below-the-knee group, that other factors, such as outflow, might be more important than the effect of heparin.”

mary patency rate of 80%, as compared to 63% for the uncoated prosthesis group.

In the below-the-knee bypasses, there was no difference between the two groups. “This might be sur-