

Two-Year Results with Heparin-Bonded PTFE (Gore PROPATEN) Grafts for Femoropopliteal and Femorodistal Bypasses Are Encouraging

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Purpose

Several prosthetic materials have been used for femoropopliteal bypass grafting in patients with peripheral vascular disease in whom a venous bypass is not possible. Expanded polytetrafluoroethylene (ePTFE) is the most commonly employed, but patency results have not always equaled those achieved with vein, especially in below-knee (BK) reconstructions. This study assessed the performance of a new heparin-bonded ePTFE vascular graft that was designed to provide resistance to thrombosis and thereby decrease graft failures and possibly prolong patency.

Methods

From June 2002 to June 2003, 86 patients (62 men and 24 women; mean age, 70 years; 99 diseased limbs) were enrolled prospectively in a nonrandomized, multicenter study of the heparin-bonded ePTFE graft. Fifty-five above-knee (AK) and 45 below-knee (BK) (including 21 femorocrural) procedures were performed. Follow-up evaluations consisted of clinical examinations, ultrasonographic studies, and distal pulse assessment. Patency and limb salvage rates at 2 years were calculated by using Kaplan-Meier survival analysis.

Results

All grafts were patent immediately after implantation. There were no graft infections or episodes of prolonged anastomotic bleeding. The overall primary (Figure 1A) and secondary (Figure 1B) 2-year patency rates were 73.9% and 87.1%, respectively; the overall limb salvage rate was 94.8%. Two-year primary patency rates according to bypass type (Figure 1C) were 78.2%, 71.8%, and 65.3% for AK, BK femoropopliteal, and crural bypasses, respectively; the corresponding secondary patency rates (Figure 1D) were 92.1%, 81.3%, and 80.2%.

Conclusions

In this study, the heparin-bonded ePTFE graft provided promising 2-year patency and limb salvage results, with minimal complications, in patients with occlusive vascular disease. Longer-term and randomized studies are warranted to determine whether this graft provides results superior to those achieved with other prostheses, especially in cases at higher risk of early graft failure such as BK bypasses or patients with poor-run-off or advanced vascular disease.

Figure 1.

Kaplan Meier estimation of the primary (A and C) and -secondary (B and D) patency rate for the total population (A and B) and stratified for the distal anastomosis location (C and D), with the above-knee, below-knee, and crural anastomosis being the dashed, dotted, and full lines, respectively.