PEPE II—a multicenter study with an end-point heparin-bonded expanded polytetrafluoroethylene vascular graft for above and below knee bypass surgery: determinants of patency.

AIM: The Propaten European Product Evaluation (PEPE II) study was a product evaluation intended to characterize the performance of the Gore Propaten vascular graft in above-knee (AK) and below-knee bypass (BK) surgery. METHODS: This prospective multicenter trial enrolled 142 patients with peripheral arterial disease. In 87 patients AK and in 52 patients BK bypasses (including 15 femorocrural) were implanted (67.6% males, 32.4% females). RESULTS: The one-year overall primary and secondary patency rates were 80% and 84.7%, respectively. Overall limb salvage rate at 12-months was 96.2%. The primary patency rate for AK bypasses was 82.7%, for BK femoro-popliteal bypasses 74.2% and for BK tibial-peroneal bypasses 79.4%. Secondary patency rates were 87.3%, 78.8% and 85.1%, respectively. Primary patency rates decreased depending on the number of patent run-off vessels (three 84.3%, two 80.8%, one 73.3%). Subgroup analysis showed that female patients had a significantly higher primary patency rate for BK bypasses (95.5% vs. 67.8%, P=0.037) compared to male patients. Subgroup analysis comparing patients younger and older than 70 years did not show a statistically significant difference in patency rates. Twenty-one patients
underwent 42 reinterventions after bypass surgery. CONCLUSIONS: Present data show that the end-point heparin-bonded polytetrafluoroethylene graft yields patency rates comparable to those obtained with other graft material in above-knee locations. The encouraging results for BK bypasses suggests that this graft is an excellent option for small diameter vascular reconstructions when autologous vein is unavailable.