Superior Two-year Results of Externally Unsupported Polyester Compared to Supported Grafts in Above-knee Bypass Grafting: A Multicenter Randomised Trial

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Objectives: The aim of this study was to compare externally supported thin wall knitted polyester (P-EXS) and externally unsupported thin wall knitted polyester (P-non-EXS) for above-knee (AK) femoro-popliteal bypass grafting.

Design: A prospective multicenter randomised clinical trial.

Material and methods: Between 1999 and 2008, 265 AK femoro-popliteal bypass grafts (6 mm in diameter) were performed, including 136 P-EXS and 129 P-non-EXS. The selection of patients was based on the presence of disabling claudication or critical ischaemia. Follow-up took place at 3, 6, 12, 18, and 24 months and included clinical examination and duplex ultrasonography. The main end points of this study were primary patency rates at one and two years. Secondary end points were mortality, and primary assisted and secondary patency rates. Cumulative patency rates were calculated with life-table analysis and log-rank testing.

Results: The 1-year primary, primary assisted and secondary patency rates were 65%, 70% and 84%, respectively, for P-EXS and 76% ($p = 0.05$), 82% ($p = 0.03$) and 88% ($p = 0.35$), respectively, for P-non-EXS. Two-year primary, primary assisted and secondary patency rates were 45%, 57% and 70%, respectively, for P-EXS and 62% ($p = 0.003$), 75% ($p = 0.005$) and 84% ($p = 0.02$), respectively, for P-non-EXS. The overall mortality rate after two years was 11.3%.

Conclusion: In above-knee femoro-popliteal bypass grafting patency rates of externally supported knitted polyester grafts were inferior to their unsupported counterpart.

ISRCTN: At the time this study started this number was not the standard.

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INTRODUCTION

Above-knee (AK) femoro-popliteal bypass grafting is an effective treatment for either disabling claudication or critical ischaemia. Although autologous grafts are preferred, prosthetic material is still frequently used due to absence of these venous conduits.[1–3]

Literature on this topic shows many factors that could have an impact on graft patency.

In a previous study we showed that the outcome of polyester AK femoro-popliteal bypass grafting is nearly as good as venous conduit under the condition of an intact crural outflow.[4]

Another possible factor influencing the patency is the structure of the graft and its influence on kinking and compression in hip and knee flexion. Kinking is widely described in below-knee (BK) bypass grafts.[5,6] However, it is also reported in AK femoro-popliteal bypass grafts.[7] According to El-Massry et al., flexion of the knee could rotate the tibia extensively in posterior direction in relation to the femoral condyles. As a consequence, the AK popliteal artery may move upwards. The supported graft could possibly compensate the reduced distance by adopting a S-shaped configuration which is the only conformational change allowed by the support coil.[5] External support should enable use of a non-crimped graft without the danger of kinking in the femoro-popliteal position.[6,8] Obviously, kinking of the prosthesis influences the haemodynamic flow state of the vessel and therefore the patency. However, this hypothesis remains unconfirmed. The aim of this study was to compare the effects on patency of externally supported thin wall knitted polyester (P-EXS) and externally unsupported thin wall knitted polyester (P-non-EXS) for AK femoro-popliteal bypass grafting.

PATIENTS AND METHODS

In this multicenter randomised trial patients were included from September 1999 until August 2008. For this analysis all

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patients underwent a follow-up for at least 2 years. The protocol of this study followed the principles stated in the Declaration of Helsinki and the Consolidated Standards of Reporting Trials (CONSORT).[9] Furthermore, the Institutional Review Boards of all participating hospitals approved the study and informed consent was obtained from all patients.

All patients who required an AK femoro-popliteal bypass for disabling claudication, rest pain or tissue loss, and in the absence of suitable venous conduit, were eligible for this trial.

Criteria for exclusion were previous ipsilateral femoro-popliteal procedures, contra-indication for the use of acetyl salicylic acid or anticoagulants, patients receiving chemo- or radiotherapy, malignancy diagnosed or treated within 12 months, known allergy to iodine or contrast medium, and impaired renal function.

Demographic and risk factors were according to The Society for Vascular Surgery—International Society for Cardiovascular Surgery (SVS-ISCVS) risk score,[10] including patient history, physical examination and ankle—brachial index (ABI). Anatomical evaluation was performed with Digital Subtraction Angiography (DSA). The outflow was scored in the number of patent crural vessels. If the vessel was less than 50% stenosed, it was scored as a patent vessel.

Randomisation was done per centre with block size of 4. Patients were selected by means of a sealed envelope at the day of surgery in the operating theatre after inspection of the quality of the proximal and distal anastomotic sites.

Operations were performed by vascular surgeons under general or regional anaesthesia and all patients received antibiotic prophylaxis according to local guidelines. Intra-operatively, 5000 units of heparin were administered intravenously before clamping. The grafts applied were either a 6-mm externally supported thin wall fluoropolymer coated knitted polyester (P-EXS) or a 6-mm externally unsupported thin wall knitted polyester (P-non-EXS) (both Fluoropassiv™, Sulzer Vascutek, Inchinnan Renfrewshire, Scotland, United Kingdom). The prosthesis was placed in an anatomical or sub-sartorial position and in the P-EXS graft the supported coil was removed 5 mm to the anastomotic heal. The anastomoses were performed end-to-side with Prolene 6/0 (Johnson & Johnson, Ethicon, Norderstedt, Germany) proximal onto the common femoral artery and distal onto the AK popliteal artery.

In each participating centre, patients received thrombotic prophylaxis (Low Molecular Weight Heparin) and acetyl salicylic acid post-operatively, unless there was an indication for another form of anticoagulant therapy. Follow-up assessments were done at 3, 6, 12, 18, and 24 months. Graft patency was evaluated through palpation of pulses, ankle—brachial index measurements and duplex examination.

The main end points of this study were primary patency rates at one and two years. Secondary end points were mortality, primary assisted and secondary patency rates.

In accordance with the (SVS-ISCVS) guidelines, primary patency was defined as uninterrupted patency without any manipulation of the graft. Primary assisted patency was defined as uninterrupted graft patency, but maintained by prophylactic intervention such as angioplasty. Secondary patency was defined as restored patency after occlusion with or without revision of the graft.[10]

Table 1. Participating hospitals.

Hospital	P-EXS (*n*)	P-non-EXS (*n*)	Total (*n*)
Medisch Spectrum Twente Hospital, Enschede	73	69	142
Maastricht University Medical Centre, Maastricht	23	27	50
Twenteborg Hospital, Almelo	20	15	35
General Hospital Midden-Twente, Hengelo	10	10	20
Jeroen Bosch Hospital, Den Bosch	9	7	16
Deventer Hospital, Deventer	1	1	2

STATISTICS

The hypothesis tested was a 20% improvement in primary patency for the P-EXS cohort, from 60% to 80%. The study needed at least 108 patients in each group to obtain 90% statistical power with $\alpha = 0.05$. It was decided to include two groups of 135 patients each to compensate for loss to follow-up. Potential differences in categorical demographic and risk factors between the two groups were analysed by Pearson Chi Square test, or Fisher's Exact test, as appropriate. Calculation of patency rates was done with the life

Table 2. Pre-operative patient characteristics.

Parameter	P-EXS *n*(%)	P-non-EXS *n*(%)	*p*-value
Gender M/F	103/33	96/33	0.80
Age (y) mean (range)	65(39—84)	67(47—85)	0.14
Co-morbidity (%)			
DM	38(27.9)	33(25.6)	0.67
Hypertension	67(49.3)	67(51.9)	0.66
Hypercholesterolaemia	65(47.8)	68(52.7)	0.42
Cerebrovascular disease	15(11.0)	14(10.9)	0.96
Cardiac disease	51(37.5)	40(31.0)	0.27
Smoking			0.25
Never	31(22.8)	29(22.5)	
Quit	38(27.9)	40(31.0)	
<20/day	51(37.5)	36(27.9)	
>20/day	16(11.8)	24(18.6)	
Anticoagulant therapy			
Coumarin	21(15.4)	24(18.6)	0.49
Acetyl salicylic acid	94(69.1)	89(69.0)	0.98
Ischaemia category			0.10
Rutherford classification			
1 (Mild claudication)	8(5.9)	1(0.8)	
2 (Moderate claudication)	29(21.3)	31(24.0)	
3 (Severe claudication)	47(34.6)	54(41.9)	
4 (Rest pain)	22(16.2)	17(13.2)	
5 (Minor tissue loss)	30(22.1)	24(18.6)	
6 (Major tissue loss)	0(0.0)	2(1.6)	
No. patent crural vessels			0.71
0	8(5.9)	9(7.0)	
1	35(25.7)	37(28.7)	
2	45(33.1)	46(35.7)	
3	48(35.3)	37(28.7)	

table method, compared with a log-rank test and the results are displayed in Kaplan—Meier graphs. A p-value of <0.05 was considered to be significant.

RESULTS

Baseline characteristics

In total 266 patients were randomised for an AK femoro-popliteal bypass with P-EXS or P-non-EXS. One person did not receive the allocated intervention, leaving 265 patients (136 for P-EXS and 129 P-non-EXS) from six hospitals in the Netherlands for further analysis (Table 1). Fourteen patients have received a second procedure with one of the study prosthesis on the contralateral leg, however, these second procedures have been excluded from the analysis.

The group which was further analysed consisted of 199 (75%) male and 66 (25%) female patients. Patient demographic and risk factors were similar in both groups (Table 2).

Patients who participated were distributed between disabling claudication 64% (n = 170), rest pain 15% (n = 39), and tissue loss 21% (n = 56). Nineteen percent of the patients with critical ischaemia had inflow disease and 49% had outflow disease.

Operative details

Eighty-six bypass grafts (32%) were performed under general anaesthesia, the remaining bypasses under spinal or epidural anaesthesia. Intra-operatively 5000 units of heparin was administered during 259 procedures (98%). In 3 procedures, 3000 units of heparin was administered because of extensive bleeding, and in another three procedures a total of 7500 units was administered, because of a longer operation time.

Follow-up

Within 2 years of follow-up only 4 (1.5%) patients were lost. All other subjects had a follow-up of at least 2 years. Thirty days mortality rate was 0.8% (one patient with a P-EXS and one with a P-non-EXS bypass graft). Both patients died within the hospital. Within 2 years follow-up, 30 (11.3%) of

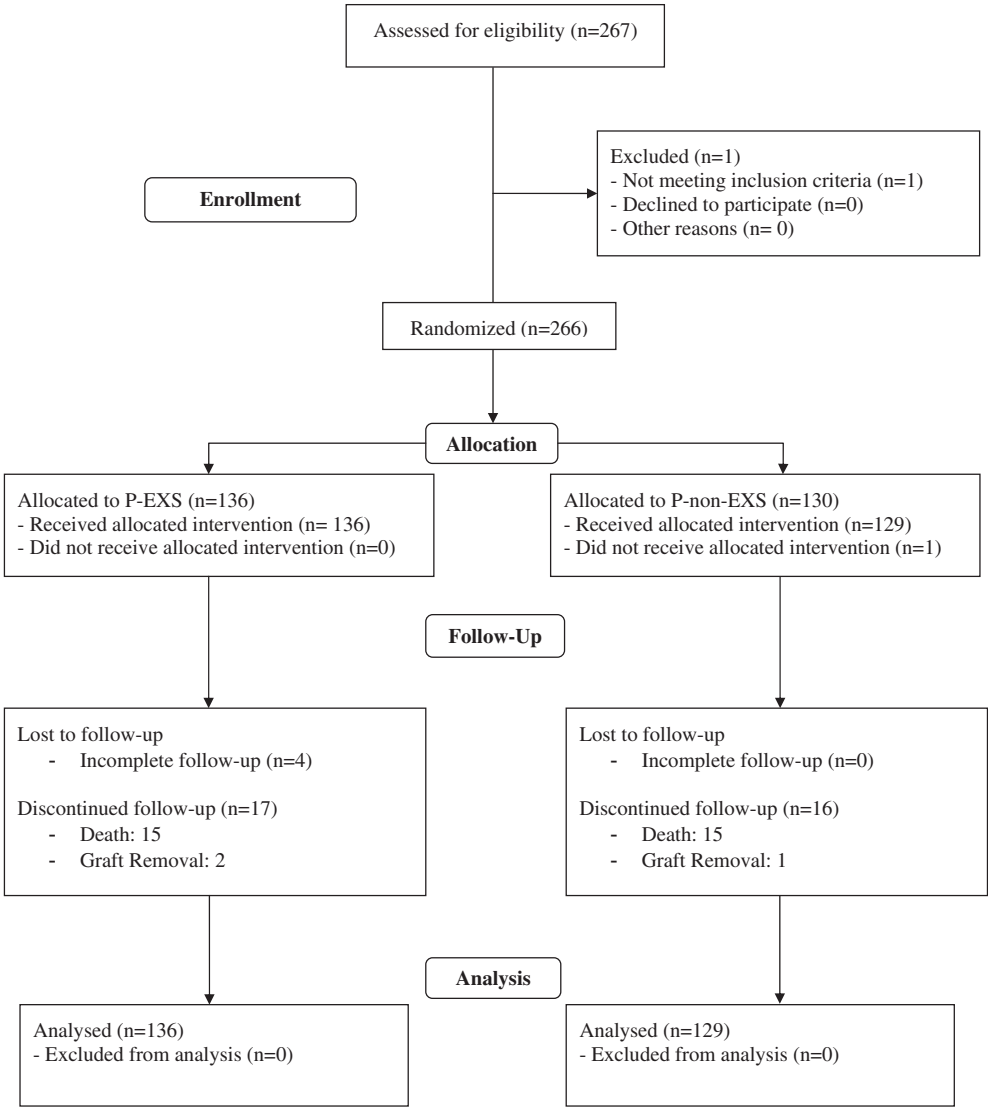

Figure 1. CONSORT-flowchart of participants in the study.

the initial 265 patients died; 15 in the P-EXS group and 15 in the P-non-EXS group (Fig. 1). At the time of death, 23 (77%) of these patients had a primary patent bypass, 3 had a primary assisted patent and 2 had a secondary patent bypass. Two patients had an occluded bypass.

Within 2 years follow-up, 54 grafts occluded, including 33 P-EXS (61%) and 21 P-non-EXS (39%). Additional procedures during follow-up were done in 66% of the patients with critical ischaemia (Rutherford 4–6). Sixteen patients received an amputation of which 3 major amputations. Seventeen patients received a thrombectomy, 3 patients thrombolysis treatment, and 12 patients needed a new bypass. In 10 patients the anastomosis had to be revised and 5 patients underwent angioplasty. Within the 2 years reporting period 3 (1.1%) grafts, 2 P-EXS and 1 P-non-EXS, had been removed because of an infection.

The 1-year primary, primary assisted and secondary patency rates were respectively 65%, 70% and 84% for P-EXS and 76% ($p = 0.05$), 82% ($p = 0.03$) and 88% ($p = 0.35$) for P-non-EXS.

The 2-year primary, primary assisted and secondary patency rates were respectively 45%, 57% and 70% for P-EXS and 62% ($p = 0.003$), 75% ($p = 0.005$) and 84% ($p = 0.02$) for P-non-EXS (Figs. 2–4).

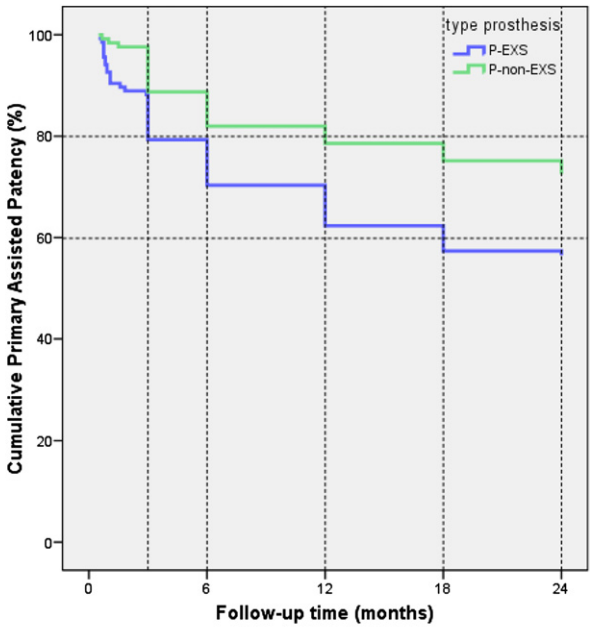

Figure 3. Kaplan–Meier curves of primary assisted patency rates for P-EXS (57%) and P-non-EXS (75%) ($p = 0.005$). The Standard error did not exceed 10% up to 24 months.

DISCUSSION

The present study has failed to show any beneficial effect of P-EXS for AK femoro-popliteal bypass grafts. Surprisingly, the results were in the opposite direction. Patency rates of P-EXS grafts at one and two year follow-up were lower than for P-non-EXS grafts. The concept of external support has primarily been proposed to avoid kinking in areas of high mobility such as in the knee area, and to avoid external compression in areas where the bypass is placed subcutaneously, such as for axillo-(bi)femoral bypass.[11–17] Although the use of an externally supported femoro-popliteal graft was first described in the 1980s, a randomised controlled

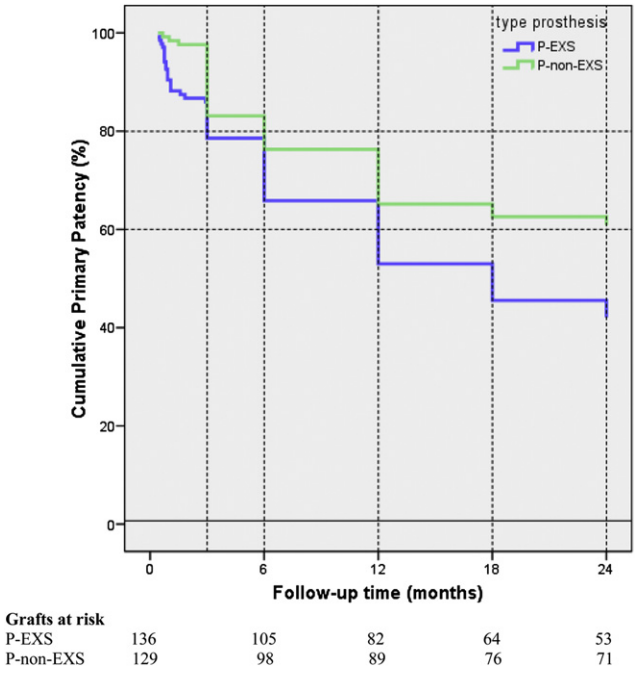

Figure 2. Kaplan–Meier curves of primary patency rates for P-EXS (45%) and P-non-EXS (62%) ($p = 0.003$). The Standard error did not exceed 10% up to 24 months.

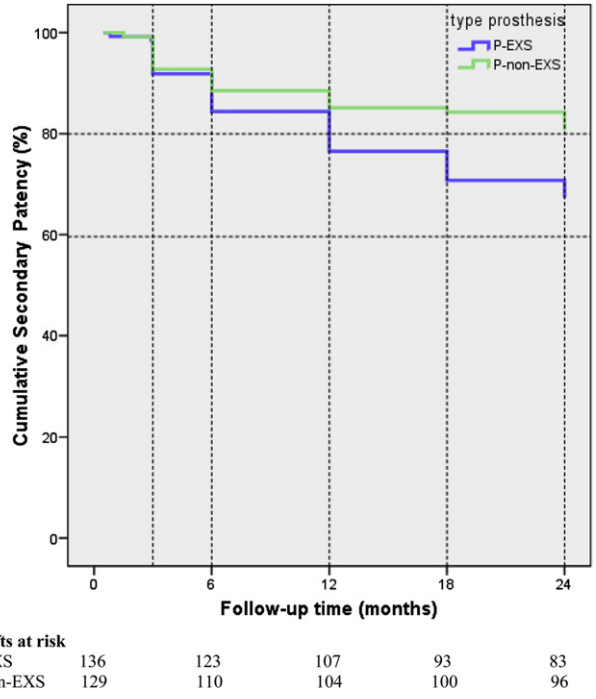

Figure 4. Kaplan–Meier curves of secondary patency rates for P-EXS (70%) and P-non-EXS (84%) ($p = 0.02$). The Standard error did not exceed 10% up to 24 months.

trial comparing externally supported with unsupported polyester for AK femoro-popliteal bypass grafting had never been conducted before.[6]

Several reports described patency results of externally supported prostheses for AK femoro-popliteal bypass grafts.[5,6,8,14–18] El-Massry et al. reported in a retrospective analysis of 200 externally supported polyester femoro-popliteal bypass grafts 3, 5 and 10-year primary patency rates of 76%, 71% and 50%, respectively.[5] The first trial comparing externally supported polyester with unsupported polyester for AK bypass grafting reported 4-year primary patency results of 78% and 56%, respectively.[8] A recent retrospective report showed after 8 years even significantly better results of the externally supported non-coated knitted polyester compared to gelatin-coated polyester.[15]

It is striking that our study with P-EXS showed such disappointing patency results compared to other trials with externally supported prostheses. However, all these studies used different types of supported prostheses. Moreover, 67% of subjects had only one or two patent crural vessels, accounting for a population with a rather poor outflow. Only one prospective non-randomised German trial used the same externally supported polyester prosthesis as we did. Although the results of the P-EXS exceeded our patency rates, it performed worse compared to externally supported PTFE.[16]

The patency results of our P-non-EXS cohort were also somewhat disappointing. Two other recent randomised controlled trials, implanting non-EXS polyester prostheses, showed 2-year primary patency results of 70%.[4,19] The only randomised controlled trial that also used the knitted polyester (Fluoropassiv™) prosthesis (P-non-EXS), noted 1-year primary and secondary patency rates of 36% and 49%. Two-year primary and secondary patency rates were 36% and 46%, respectively.[20] Compared to our trial these reported patency results were even lower (Tables 3–5).

We cannot fully explain why our patency rates of P-EXS were significantly worse compared to P-non-EXS. It is possible that the ringed prosthesis is less flexible. It can actually increase the tendency to kink at the junction between the ringed and non-ringed portion of the graft instead of its non-kinking property.[18] It is also possible that due to a difference in behaviour between the textile fixed to the external support and the textile free of the external support areas of high stress occur responsible for rupture of the textile and secondary disruption of the prosthesis.[21] Post-operative angiography showed that graft kinking and constriction still arise in coiled supported polyester thus external support of grafts with rings or other configurations does not necessarily prevent graft kinking, compression and reduced flow.[22]

In addition, the fixation of the external support on the textile could have been responsible of differences on tissue infiltration and healing between areas with and without support. It could also be responsible for differences of mechanical behaviour of the textile at the junction leading to tears of the luminal fibrin coverage of the prosthesis and promote thrombogenicity. This drawback could possibly counteract the advantages of the kink and compression resistance and explain our poorer results in areas that were not exposed to major kinks or compression.

Another explanation could be the post-operative dilatation of all polyester grafts once implanted, which seems to happen immediately post-operatively after clamp release. While 6 mm non-supported polyester grafts dilate to approximately 7.2 mm (+20%), externally supported grafts do not dilatate due to the external support. Several studies found better patency rates for larger grafts.[23,24] This effect may have influenced or biased this study as the non-supported grafts may have had an actual better flow, which can explain the better patency rates.

Fluoropassiv™ is a polyester graft with a surface covered with fluoropolymer molecules bonding with the polyester

Table 3. Life table primary patency.

Interval (mo)	No. at risk at beginning of interval	No. failed during interval	Withdrawn during interval	Cumulative patency rate (%)	Standard error (%)
P-EXS					
0–3	136	19	1	86	3
3–6	116	10	1	79	4
6–9	105	17	6	65	4
9–12	82	0	0	65	4
12–15	82	16	2	53	4
15–18	64	0	0	53	4
18–21	64	9	2	45	4
21–24	53	0	0	45	4
P-non-EXS					
0–3	129	3	5	98	1
3–6	121	18	5	83	3
6–9	98	8	0	76	4
9–12	90	0	1	76	4
12–15	89	13	0	65	4
15–18	76	0	0	65	4
18–21	76	3	2	62	4
21–24	71	0	0	62	4

Table 4. Life table primary assisted patency.

Interval (mo)	No. at risk at beginning of interval	No. failed during interval	Withdrawn during interval	Cumulative patency rate (%)	Standard error (%)
P-EXS					
0–3	136	16	1	88	3
3–6	119	12	1	79	3
6–9	106	12	6	70	4
9–12	88	0	0	70	4
12–15	88	10	3	62	4
15–18	75	0	0	62	4
18–21	75	6	2	57	4
21–24	67	0	0	57	4
P-non-EXS					
0–3	129	3	5	98	1
3–6	121	11	5	89	3
6–9	105	8	0	82	4
9–12	97	0	1	82	4
12–15	96	4	0	78	4
15–18	92	0	0	78	4
18–21	92	4	3	75	4
21–24	85	0	0	75	4

Table 5. Life table secondary patency.

Interval (mo)	No. at risk at beginning of interval	No. failed during interval	Withdrawn during interval	Cumulative patency rate (%)	Standard error (%)
P-EXS					
0–3	136	2	1	99	1
3–6	133	9	1	92	2
6–9	123	10	6	84	3
9–12	107	0	0	84	3
12–15	107	10	4	76	4
15–18	93	0	0	76	4
18–21	93	7	3	70	4
21–24	83	0	0	70	4
P-non-EXS					
0–3	129	1	5	99	1
3–6	123	8	5	93	2
6–9	110	5	0	88	3
9–12	105	0	1	88	3
12–15	104	4	0	85	3
15–18	100	0	0	85	3
18–21	100	1	3	84	3
21–24	96	0	0	84	3

giving an interpenetrating molecular network at the interface between the two polymers. The result is a new biomaterial with a supposed lower thrombogenicity. However, both P-EXS and P-non-EXS showed unsatisfactory patency results compared to other polyester prostheses. The reason for the early thrombosis in the knitted polyester prosthesis is unknown.

This study is the first randomised controlled trial in which externally supported knitted polyester for femoro-popliteal AK bypass grafting was compared to externally unsupported knitted polyester. The patency results of the P-EXS cohort were inferior to the P-non-EXS cohort.

Based on our results we see no benefit of external support in 6 mm polyester AK femoro-popliteal bypass grafts, and therefore unsupported grafts may be used as well.

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CONFLICT OF INTEREST

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