

FlowLine Bipore Heparin as femoro-popliteal bypass

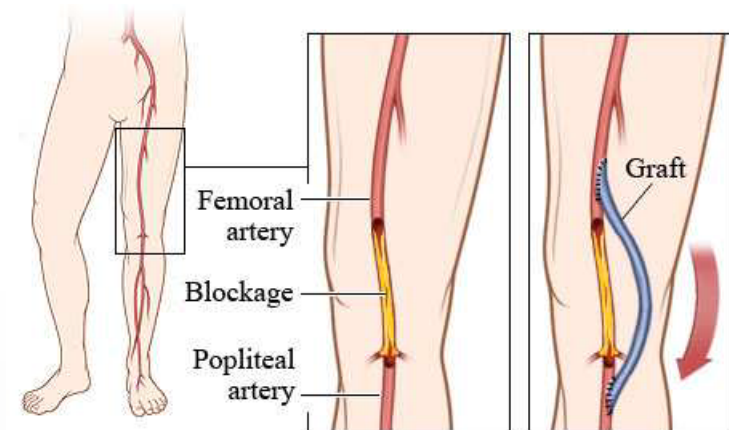
Late breaking RCT results

presented at CX Symposium 2009

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Background

- Occlusion of SFA and/or popliteal artery
 - fem-pop or fem-tib bypass



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- Synthetic bypass grafts – polyester or ePTFE – are frequently used when autologous vein is not available
- Results of synthetic bypass grafts are less good than with autologous vein

Background

- Reduction of the thrombogenic character of the graft by binding heparin
- Creation of blood friendly surface
- Already used in extracorporeal circuits and a reduction of thrombus formation has already been shown

Related publications

- 1 randomized study in polyester grafts (209 patients):
significant improvement in results could be shown comparing heparin-bonded dacron prosthesis and uncoated PTFE
- Observational studies in PTFE grafts
 - Fraedrich (J Cardiovasc Surg – in press)
 - Dorucci (J Cardiovasc Surg 2008)
 - Dorigo (Ann Vasc Surg 2008)
 - Peeters (J Cardiovasc Surg 2006)
 - Battaglia (J Cardiovasc Surg 2006)
 - Bosiers (J Vasc Surg 2006)

Study Design

- Prospective, open label, randomized, multicentric study comparing **FlowLine Bipore Heparin** vs **FlowLine Bipore ePTFE** grafts (L=80 cm, D=6 mm, TW, reinforced)
- Randomization on a 1/1 basis with 2 years FU period
- Primary / secondary endpoints: primary / secondary patency, limb salvage and mortality
- Study started in May 2004 (B) and November 2004 (D), respectively

Inclusion Criteria

- Symptomatic peripheral vascular disease (Fontaine IIB-IV)
- Occlusion or significant stenosis of SFA and/or popliteal artery > 6 cms
- Adequate outflow artery
- Informed consent
- Follow-up possible

Exclusion Criteria

- Acute limb ischemia
- Patient planned for amputation
- Ipsilateral, not corrected > 70% inflow stenosis
- Age < 18 years
- Patient possibly pregnant
- Age expectancy < 1 year
- Recent AMI (< 1 month)
- Allergy for contrast or heparin
- Important bleeding or coagulation disorder

Follow up

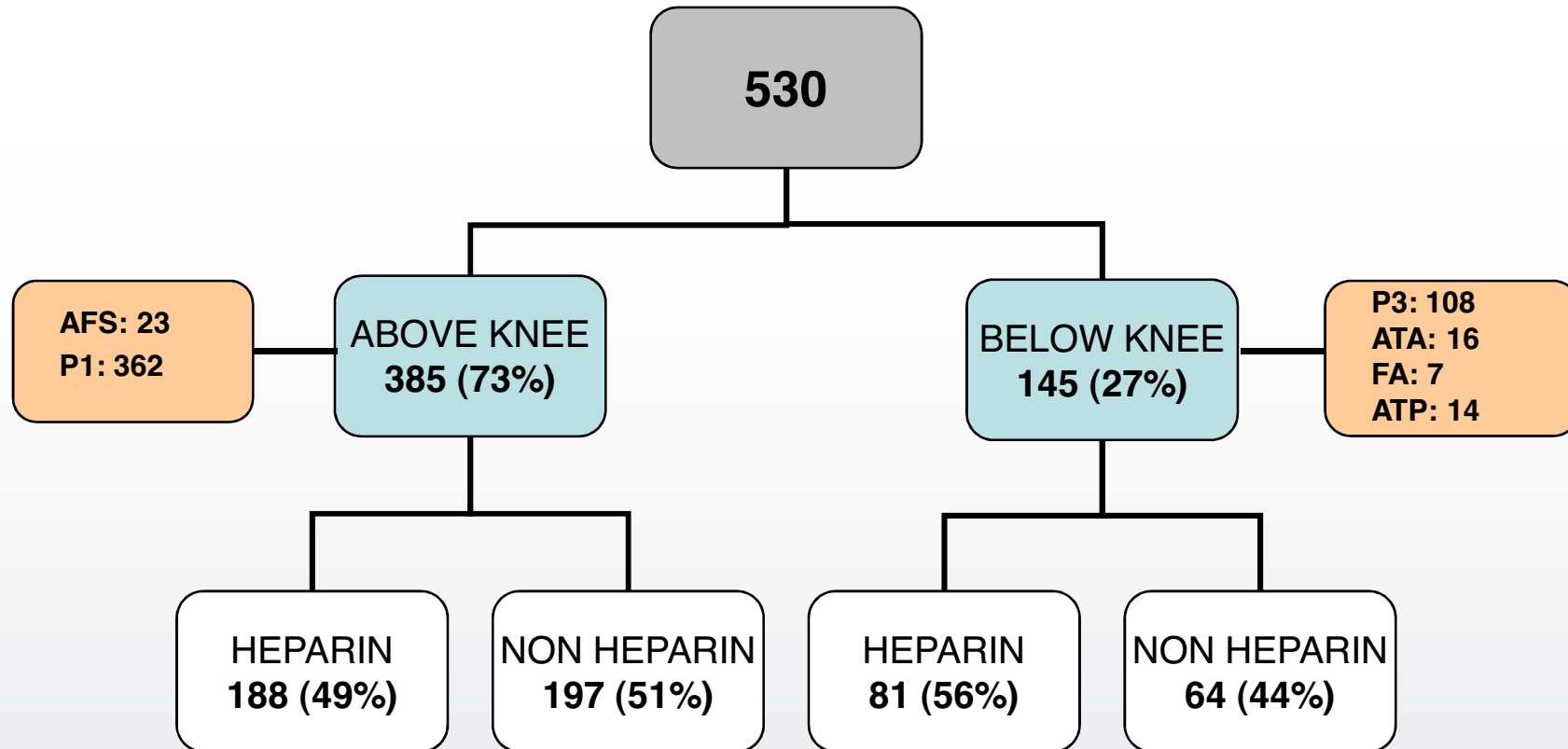
- Follow-up visits at 1, 3, 6, 12, 24 months
- Evaluation of patency by clinical examination and ABI at each visit
- Duplex at 1, 12 and 24 months and when graft occlusion is suspected

Enrollment

- Inclusion period 05/2004-12/2007:
 - 537 patients enrolled in 23 centres
 - 530 evaluable

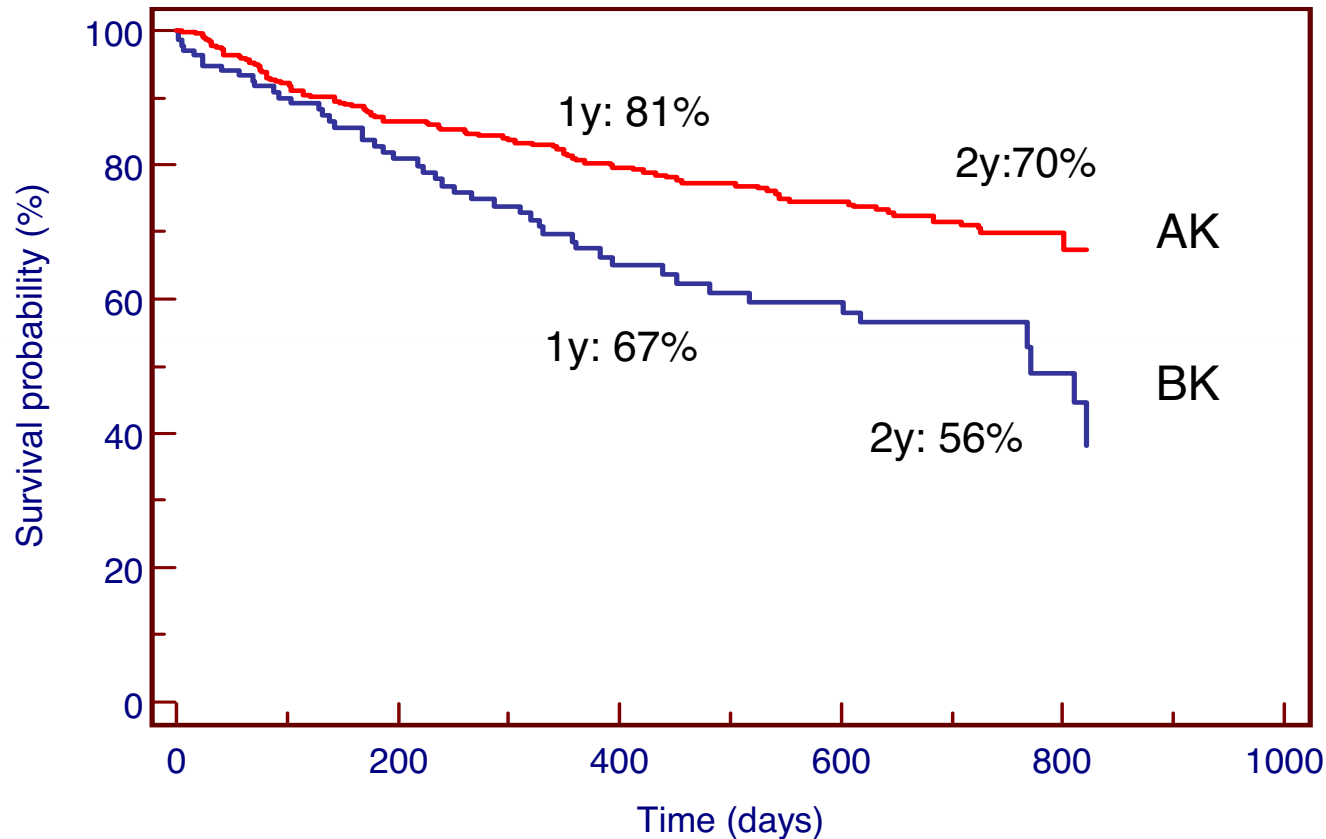
- 269 FlowLine Bipore Heparin vs 261 FlowLine Bipore
- 6mm, reinforced ePTFE grafts

Study course

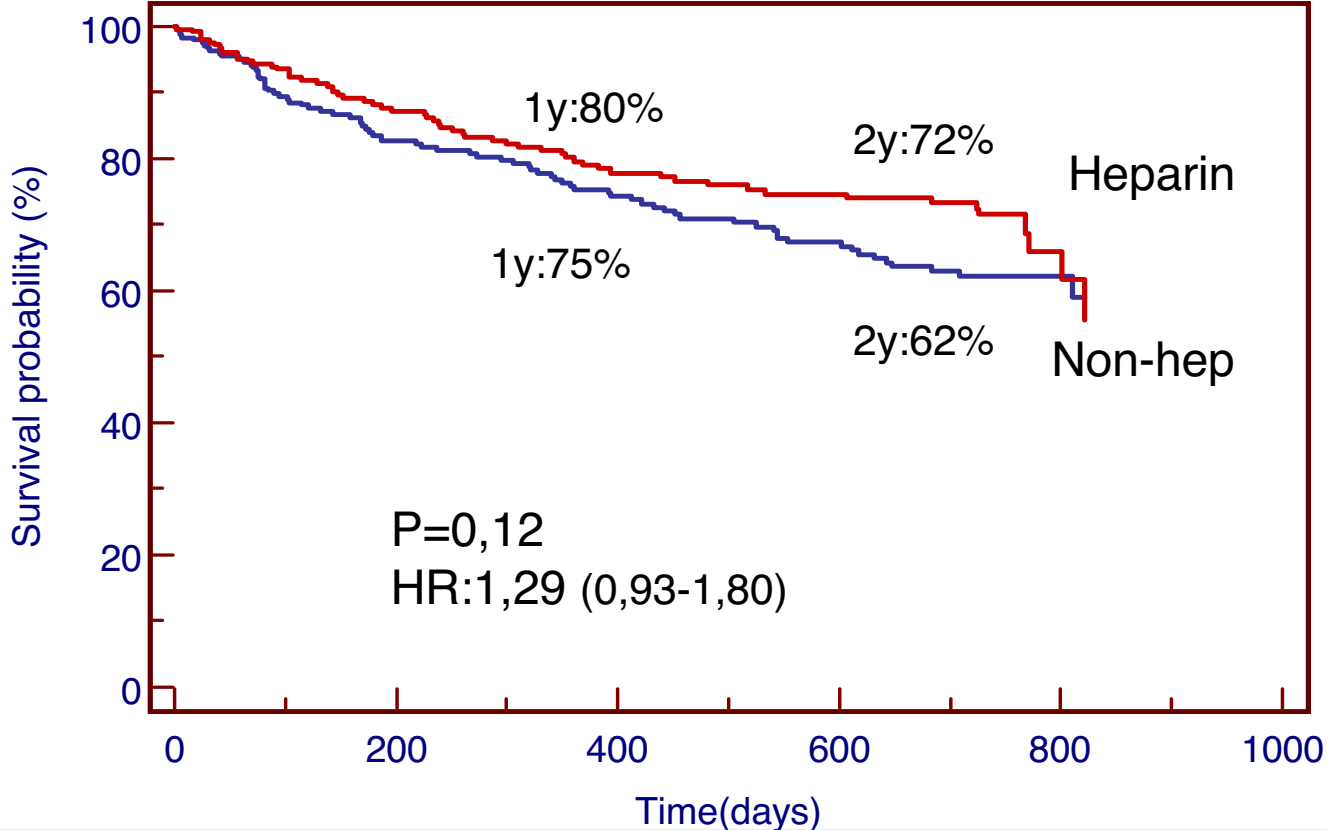


AK vs BK Bypasses

Primary patency

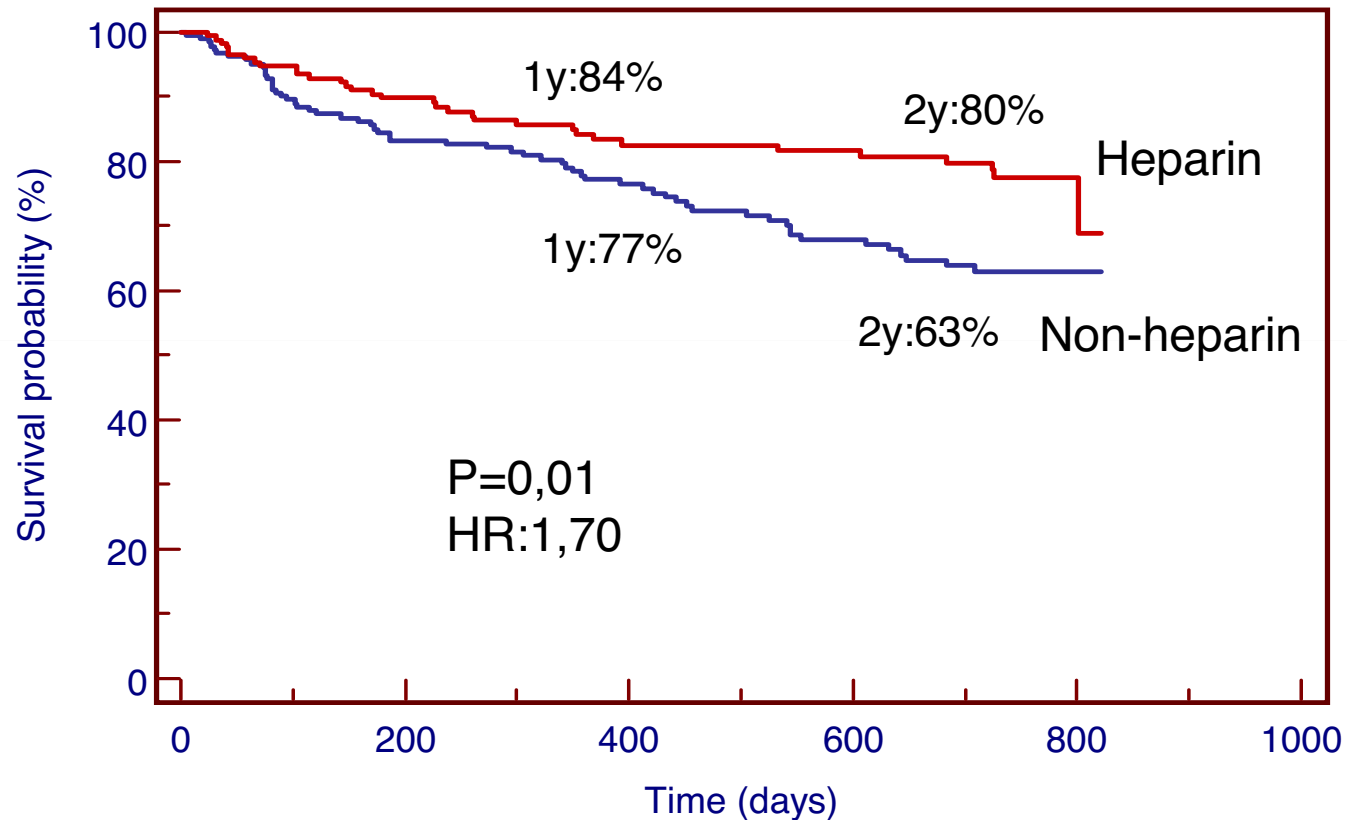


FLB vs FLB Heparin Primary patency



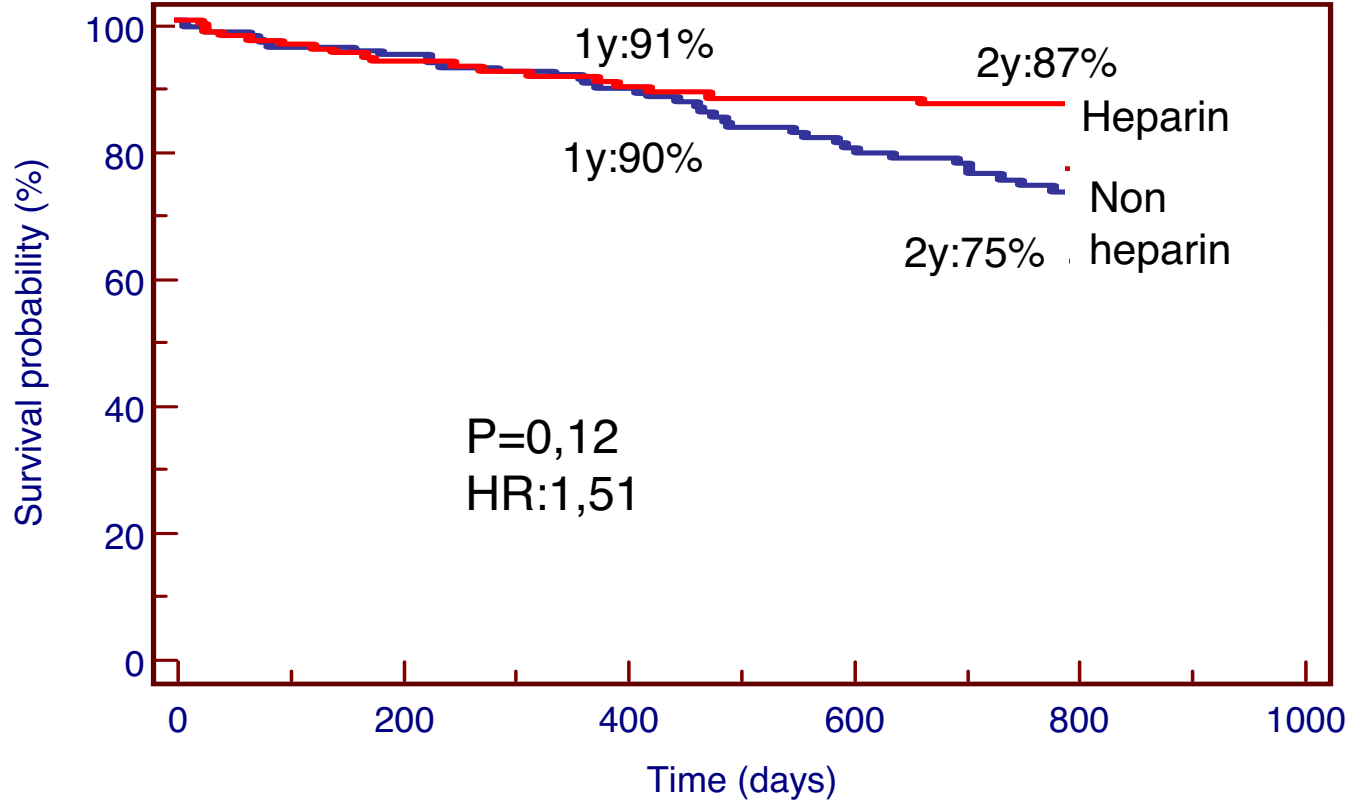
FLB vs FLB Heparin

Primary patency in AK bypasses



FLB vs FLB Heparin

Secondary patency in AK bypasses



Observations

Curves continue to dissociate up to 2 years

- Less thrombogenicity in the early phase leads to less intimal hyperplasia and less thrombosis in a later phase

Conclusions

- First randomized study on the value of heparin-bonding in ePTFE grafts
- One of the largest prospective randomized studies on femoro-popliteal bypass
- Clear trend towards improved patency in the whole group
- Significant difference in favor of heparin-bonded grafts in AK bypasses