Heparin-Bonded Expanded PTFE Grafts For BTK Bypasses

What Is The Evidence That They Are Better And Are Propaten® (Gore) Grafts The Best For Extensive FemPop Disease ?

Based On An RCT And A Systemic Review And Meta-Analysis

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VEITH SYMPOSIUM Connecting The Vascular Community

Disclosures

Y. Gouëffic reports:

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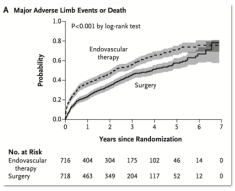
-**Personal fees and grants from** Abbott, BD, Biotronik, Boston Scientific, Cook, General Electric, Medtronic, Penumbra, WL Gore (medical advisory board, educational course, speaking)

Bypass surgery was associated with a lower incidence of major adverse limb events or death than initial endovascular intervention



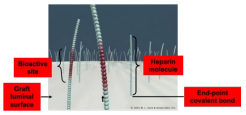
…In patients with CLTI who had an adequate single segment of great saphenous vein for conduit …

…A good quality vein of sufficient length and diameter for grafting is unavailable in about 30% of cases…

Farber, NEJM, 2023

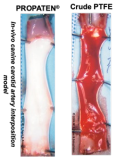
Propaten® Technology and Properties

CARMEDA® BioActive Surface (CBAS® Surface)

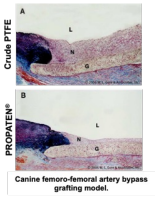


Heparin molecules are bound directly to the luminal surface of the graft.

Thromboresistance



Neointimal Hyperplasia Reduction



Canine femoro-femoral artery bypass grafting model.

Registries for BTK 2-year Primary Patency for Propaten® Grafts

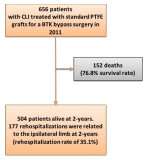
BTK 2-year primary patency for Propaten®: 75.6%

Studies	Date	Authors	Patients	2-year Primary Patency	Bypass localization
Lower limb revascularization with a new bioactive Prosthetic graft: Early and late results	2008	Dorigo et al. (1)	34	80,6%	BTK
Results with heparin-bonded polytetrafluoroethylene grafts for femorodistal bypasses	2006	Peeters et al.(3)	41	72,6%	FP3 + FC
Infrainguinal ePTFE vascular graft with bioactive surface heparin bonding	2005	Wallluscheck et al. (4)	17	81,0%	BTK
Heparin-bonded expanded polytetrafluoroethylene grafts for infragenicular bypass in patients with critical limb ischemia: 2-year results	2008	Dorrucci et al. (5)	20	85,0%	BTK
Heparin-bonded ePTFE grafts compared with vein grafts in femoropopliteal and femorocrural bypasses: 1- and 2-year results	2009	Daenens et al.(6)	57	83,0%	FP3 + FC

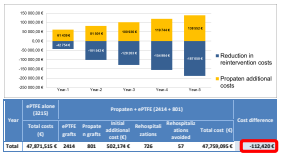
Dorigo W. Lower limb revascularization with a new bioactive prosthetic graft: early and late results. Ann Vasc Surg. 2008 Peeters P. Results with heparin bonded polytetrafluoroethylene grafts for femorodistal bypasses. J Cardiovasc Surg (Torino). 2006.Wallluscheck KP. Infrainguinal ePTFE vascular graft with bioactive surface heparin bonding. First clinical results. J Cardiovasc Surg (Torino). 2005. Dorrucci V. Heparin-bonded expanded polytetrafluoroethylene grafts for infragenicular bypass in patients with critical limb ischemia: 2-year results. J Cardiovasc Surg (Torino). 2008. Daenens K. Heparin-bonded ePTFE grafts compared with vein grafts in femoropopliteal and femorocrural bypasses: 1- and 2-year results. J Vasc Surg. 2009.

Budget impact comparison after 5 years


BMJ Open Budget impact analysis of heparin-bonded polytetrafluoroethylene grafts (Propaten) against standard polytetrafluoroethylene grafts for below-the-knee bypass in patients with critical limb ischaemia in France



After 5 years, the total difference between the observed crude PTFE and the simulated Propaten + crude PTFE groups was estimated at 112,420 €, in favor of Propaten grafts



Year	ePTFE alone (2211)	Propaten + ePTFE (2414 + 801)					Cost difference
	Total costs (€)	ePTFE grafts	Propaten grafts	Initial additional cost (€)	Rehospitalizations	Rehospitalizations avoided	Total cost (€)	
Total	47,871,515 €	2414	801	502,174 €	726	57	47,759,095 €	-112,420 €

Vergnaud S, Gouëffic, Y, BMJ Open 2018

The Scandinavian Propaten® Trial

The aim of this study was to compare the primary patency at 1 year of heparin-bound PTFE (Propaten) versus pure PTFE grafts femfem cross-over or fempop bypass above or below the knee with an artificial graft

Over the past fifteen years, several observational studies have investigated the clinical utility of hb-ePTFE in patients undergoing open surgical bypass below the knee. The present systematic review and meta-analysis aims to synthesize the available information from these studies.

Lindholt, Eur J Vasc endovasc surg, 2011

Lindholt, Br J Surg, 2016

Meta-Analysis Methodology

-MEDLINE and Embase databases, with no date restriction

-Proceedings and abstracts from relevant congresses were screened going back two years

-Searches were restricted to publications or abstracts in English.

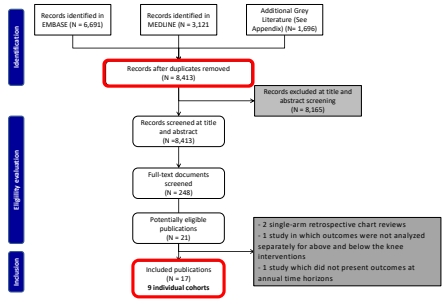
Inclusion Criteria and Outcomes

- Adult (> 18 years) patients with LLPAD undergoing **below-knee femoral bypass,**

-All included studies were in patients undergoing bypass with hb-ePTFE

-Clinically relevant outcomes included primary patency, secondary patency, limb salvage and amputation.

Literature search flow diagram (The PRISMA diagram)



Gouëffic, Ann Vasc Surg, 2024

Description of studies

-**9 retained studies and 17 publications**

-No prospective randomized comparative studies were identified for below-knee arterial bypass surgery

-**2,540 revascularization procedures**

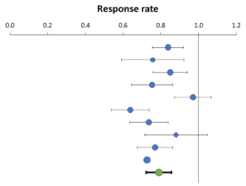
-**The majority of procedures (85.1%) were performed in of patients with CLTI**

-**The graft outflow was to the popliteal artery in 761 cases (54.2%),** to the tibiofibular trunk in 120 cases (9.6%), to the tibial artery in 358 cases (28.6%) and to the fibular artery in 55 cases (4.4%).

Gouëffic, Ann Vasc Surg, 2024

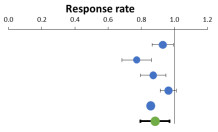
1-Year Primary Patency Ranged from 63.8% to 97.1%

Study	Response rate	CI-LL	CI-UL	Weight
Daenens 2009	0.838	0.755	0.921	11.06%
Hugl 2009	0.757	0.590	0.924	6.62%
Kaisar 2018	0.850	0.759	0.941	10.66%
Neville 2012	0.754	0.645	0.863	9.53%
Samson 2016	0.971	0.874	1.068	10.33%
Uhl 2015	0.638	0.537	0.739	9.98%
Uhl 2017	0.736	0.635	0.837	9.98%
Hirth-Voury 2020	0.880	0.715	1.045	7.07%
Peters 2008	0.769	0.675	0.863	10.42%
Pulli 2010	0.727	0.719	0.735	14.34%
Combined	**0.789**	**0.722**	**0.857**	**I²: 80.97%**



1-year limb salvage rate ranged from 77.2% to 96.4%

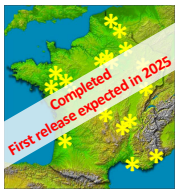
Study	Response rate	CI-LL	CI-UL	Weight
Kaisar 2018	0.930	0.865	0.995	19.32%
Uhl 2015	0.772	0.684	0.860	15.87%
Uhl 2017	0.872	0.795	0.949	17.52%
Hugl 2009	0.964	0.916	1.012	21.73%
Pulli 2010	0.857	0.851	0.863	25.55%
Combined	**0.883**	**0.796**	**0.971**	**I²: 85.88%**



REPLACE RCT

ClinicalTrials.gov Identifier: NCT03430076

Polytetrafluoroethylen (PTFE) vascular prostheses with heparin bonded luminal surfaces vs crude ePTFE in the treatment of critical limb ischemia lesions in the absence of a suitable autologous vein



PIs: Y. Gouëffic, E. Rosset, E. Steinmetz, J.P. Favre (on behalf of AURC)

Sponsor: Nantes university hospital

20 centers: CHU de Nantes, CHU de Dijon, CHU Ambroise Paré, CHU de Rennes, CHRU Lille, Hôpital de la Timone, CH Valenciennes,CHU Angers, CHU Besançon, CHU de Bordeaux, CHU Lyon, Hôpital Européen Georges Pompidou, Chu de Nice, Hôpital Bichat, CHU Poitiers, CHU Saint Etienne, CHU de Nancy, CHU Reims, CHU de Strasbourg, CHU de Clermont Ferrand.

REPLACE RCT Objectives

ClinicalTrials.gov Identifier: NCT03430076

Primary objective

To demonstrate the clinical superiority of Propaten® versus crude PTFE in the treatment of critical limb ischemia lesions (Rutherford 4-6) by below the knee bypass in patients without a suitable venous conduit.

228 patients to included (1:1)

REPLACE RCT Endpoints

ClinicalTrials.gov Identifier: NCT03430076

Primary endpoint: Primary patency at 1 year

It was defined as a patent graft without any intervention to open up or prevent a graft occlusion. Demonstrably patent graft should be by duplex ultrasound color-flow scan (independent core lab assessment)

Secondary endpoints

Technical success/Perioperative complications/Primary and secondary sustained clinical improvement/Secondary patency/MACE/MALE/Limb salvage/TVR/Secondary and assisted patency/Death (all cause)/Ankle brachial index/Quality of life / /Cost-utility analysis (CUA) and cost-effectiveness analysis (CEA)

REPLACE RCT Patients Selection

ClinicalTrials.gov Identifier: NCT03430076

Main inclusion criteria

- Rutherford classification: 4-6
- Adequate popliteal or tibial revascularization target
- Absence of an available autologous vein
- Indication of below the knee bypass with an artificial graft

Main exclusion criteria

- No atheromatous disease
- Planned above ankle amputation on ipsilateral limb within 4 weeks of index procedure
- Known allergy to heparin

Take Home Message

The meta-analysis demonstrates that Hb-PTFE has an acceptable clinical outcomes for BTK revascularization.

A budget impact analysis showed a positive impact on the national health insurance budget of the replacement of standard PTFE grafts by Propaten grafts for BTK bypass in patients with CLTI in France.

REPLACE RCT will be released in 2025. All 228 patients have been included and randomized. REPLACE RCT will be crucial for clinical decision-making and clinical guidelines.

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