



CONTROVERSES
ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES
& UPDATES
IN VASCULAR SURGERY

JANUARY 17-19 2013

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

***Do the newest grafts
achieve comparable
results to saphenous
vein bypass?***

***THE HEPARIN-BONDED
ePTFE GRAFT***

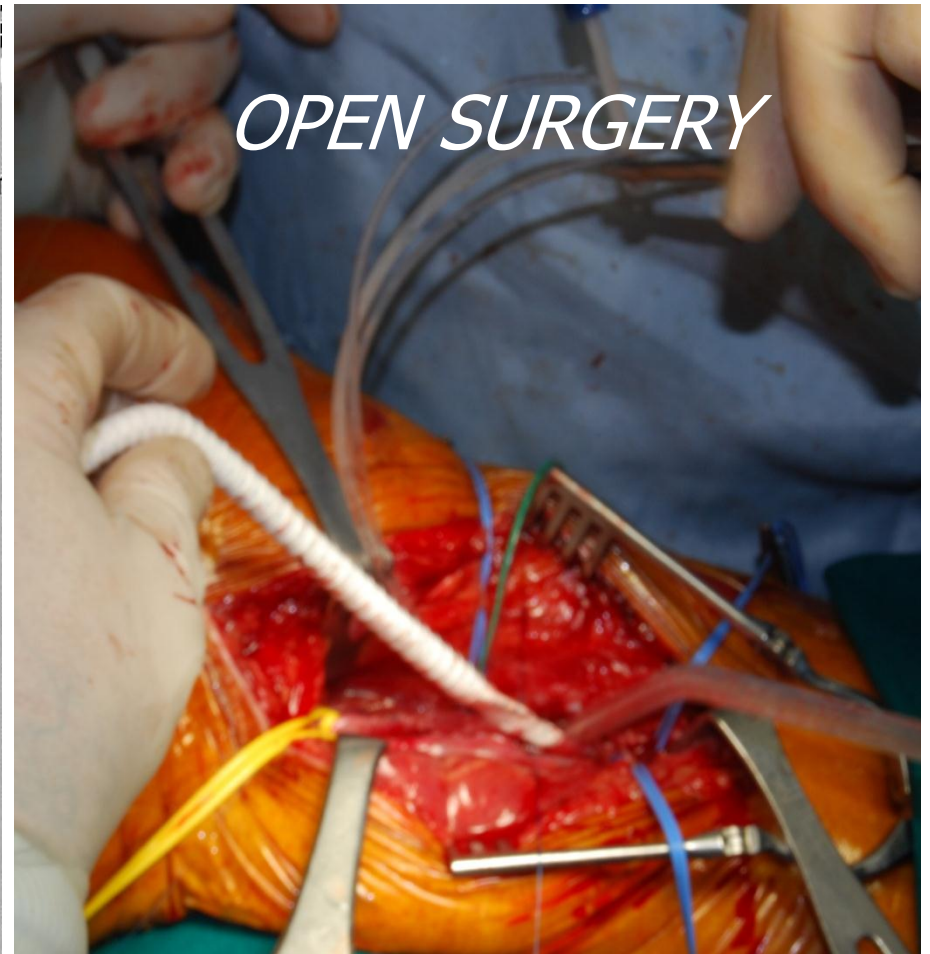
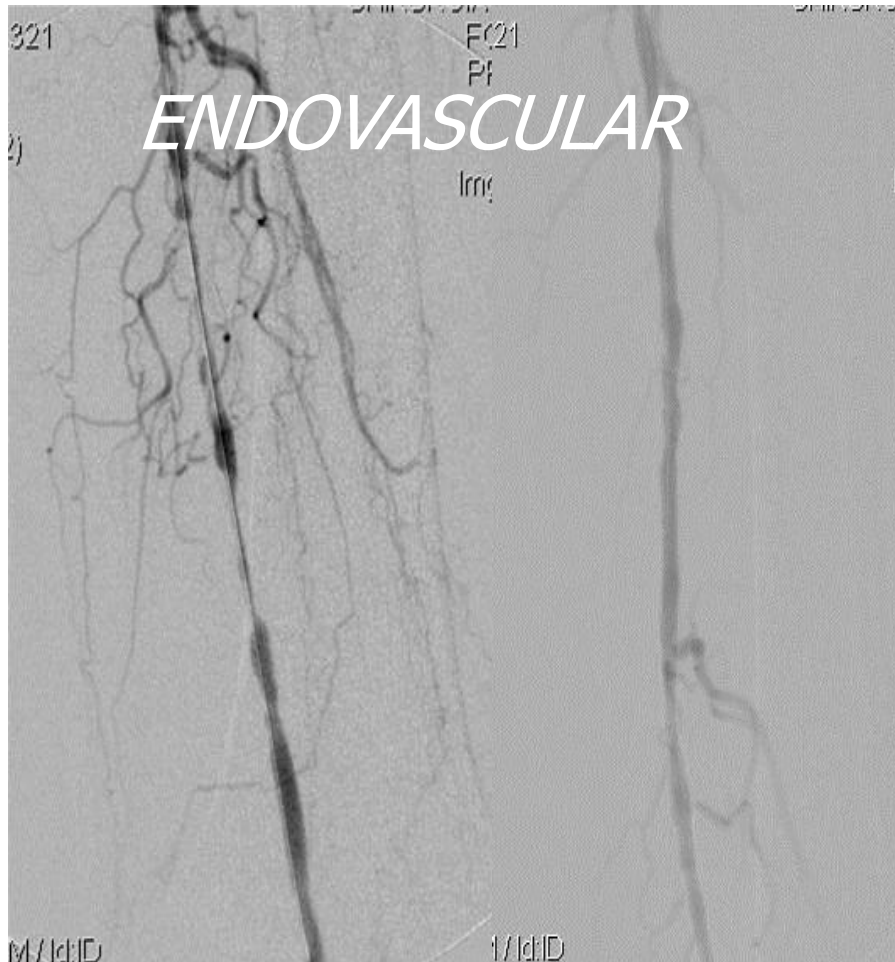
C. Pratesi

**Department of Vascular Surgery
University of Florence-Italy**

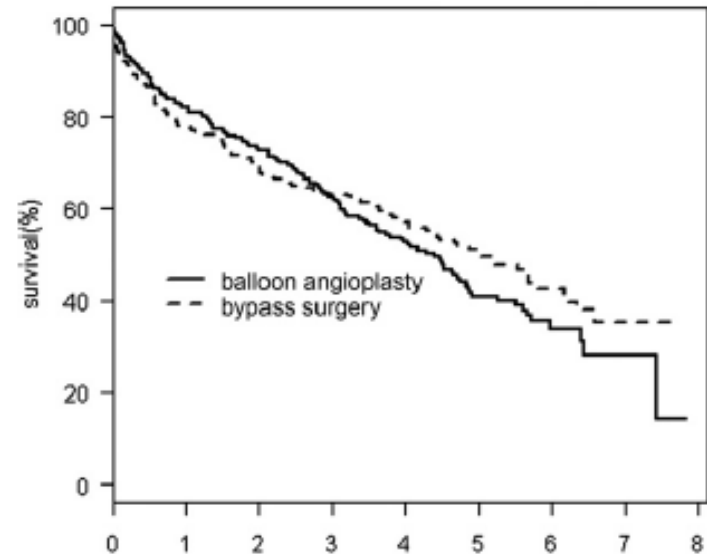
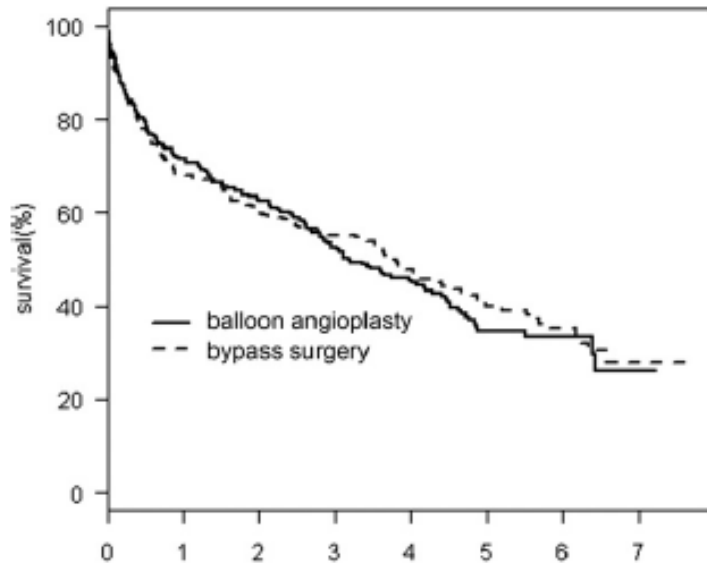
www.chirvasc-unifi.it



FEMORO-POPLITEAL DISEASE: treatment options



Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: An intention-to-treat analysis of amputation-free and overall survival in patients randomized to a bypass surgery-first or a balloon angioplasty-first revascularization strategy



Overall, there was no significant difference in AFS or OS between the two strategies. However, for those patients who survived for at least 2 years after randomization, a BSX-first revascularization strategy was associated with a significant increase in subsequent OS and a trend towards improved AFS.

Bradbury, J Vasc Surg 2010

FEMORAL-POPLITEAL BYPASS: factors affecting outcomes

- Clinical presentation
- Distal anastomosis
- **Graft material**
- Outflow vessels

TASC-2 Guidelines, J Vasc Surg 2007



Meta-analysis of femoropopliteal bypass grafts for lower extremity arterial insufficiency

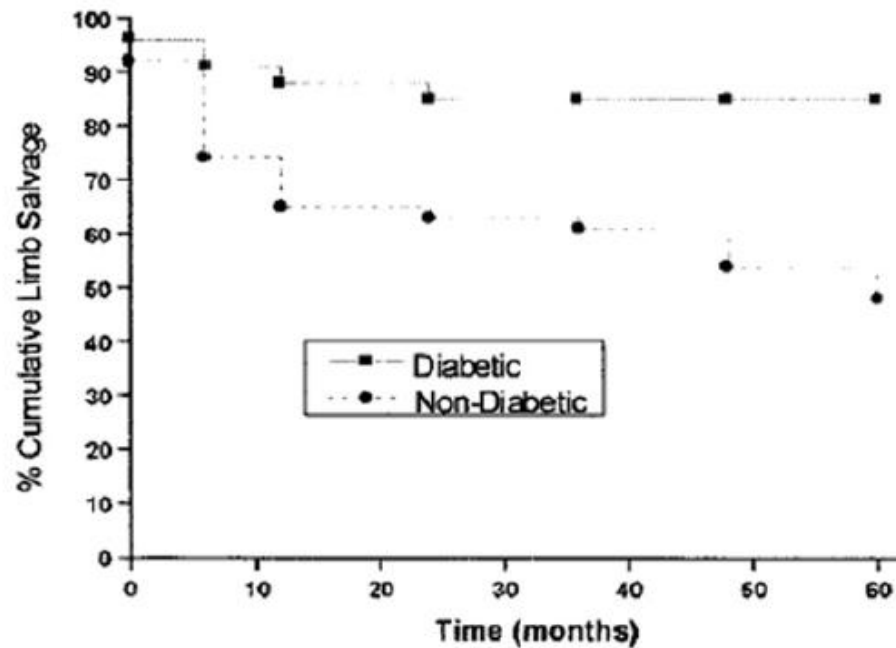


“The great saphenous vein performs better than polytetrafluoroethylene in femoropopliteal bypass grafting and should be used whenever possible.

However, the absence of a suitable saphenous remains an acceptable indication for a femoropopliteal bypass in PTFE.”

Pereira CE, J Vasc Surg 2006

Challenges of distal bypass surgery in patients with diabetes: Patient selection, techniques, and outcomes



An adequate caliber, good quality great saphenous vein (GSV) is the optimal graft for distal bypass in the leg. The availability of such a conduit is a relevant limitation of lower extremity bypass surgery: good ipsilateral greater saphenous vein may be lacking in up to 40% of the patients. The strong relationship between vein diameter and graft failure makes autologous saphenous vein unsuitable in some 25% of the patients with critical limb ischemia.

Conte MS, J Vasc Surg 2010

GRAFT MATERIAL:

How to improve ePTFE graft outcomes?

- Morphological modifications
(i.e. distal cuff)

- Biochemical modifications
(carbon impregnated or heparin bonded
grafts)

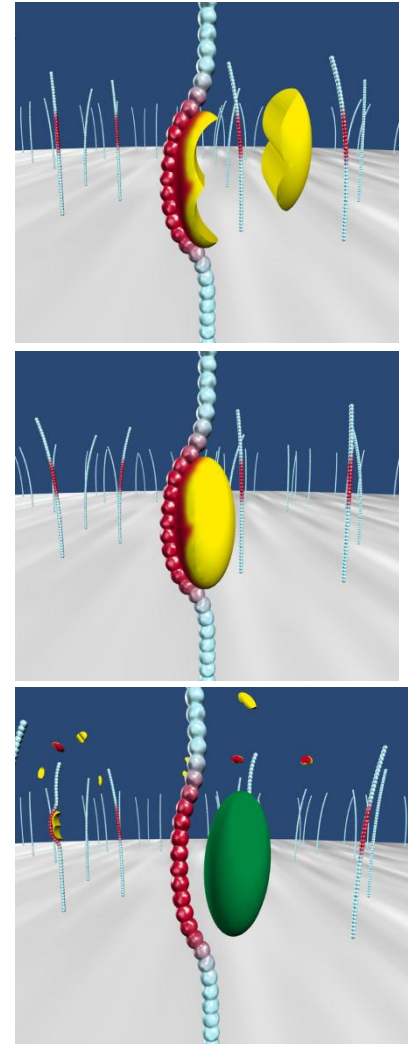
GRAFT MATERIALS

Heparin-bonded graft

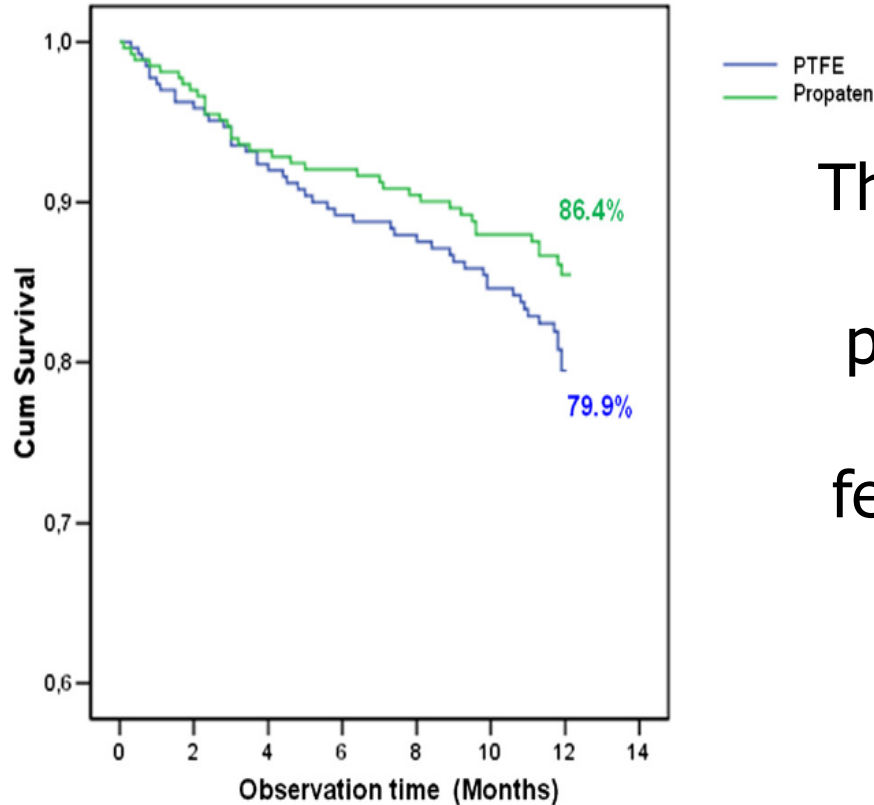
Recently an ePTFE prosthetic graft with covalent end-point attachment of heparin to graft surface (CBAS) has been introduced, enabling maintenance of functional heparin bioactivity

Supposed advantages

- **LOWERING THE RATES OF EARLY GRAFT THROMBOSIS**
- **REDUCTION OF EARLY REINTERVENTIONS**
- **IMPROVING LONG TERM PATENCY RATES**



The Scandinavian Propaten[®] Trial – 1-Year Patency of PTFE Vascular Prostheses with Heparin-Bonded Luminal Surfaces Compared to Ordinary Pure PTFE Vascular Prostheses – A Randomised Clinical Controlled Multi-centre Trial[☆]



The Hb-PTFE graft significantly reduced the overall risk of primary graft failure by 37%. Risk reduction was 50% in femoro-popliteal bypass cases and in cases with critical ischaemia.

(Eur J Vasc Endovasc Surg 2011)

Italian Propaten Registry

- To evaluate early and long term results of the use of a heparin-bonded ePTFE graft in patients undergoing surgical treatment for PAD.
- Choice of the graft at the surgeon's discretion and not only in the absence of a suitable vein.
- Endpoints:
 - early graft thromboses and amputations
 - primary, secondary patency and limb salvage rate during follow-up
 - analysis and comparison in subgroups



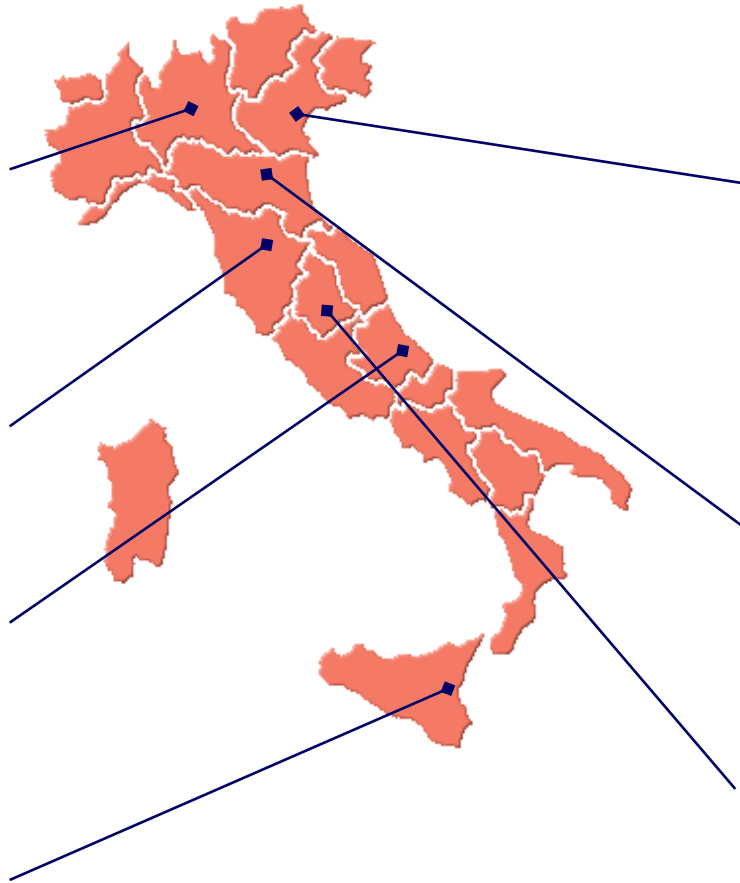
Centres Involved

**Università
dell' Insubria - Varese
*Patrizio Castelli***

**Università di Firenze
*Carlo Pratesi***

**Ospedale
di Avezzano (AQ)
*Giovanni De Blasis***

**Ospedale di Catania
*Vincenzo Monaca***



***Ospedale di Mestre
Vittorio Dorrucchi***

**Ospedale
di Reggio Emilia
*Enrico Vecchiati***

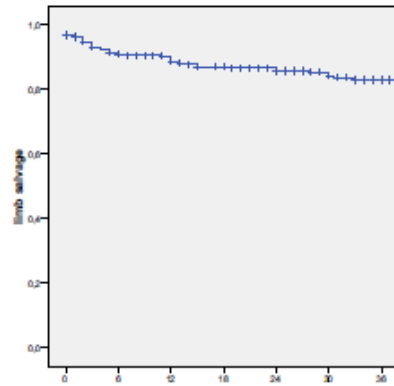
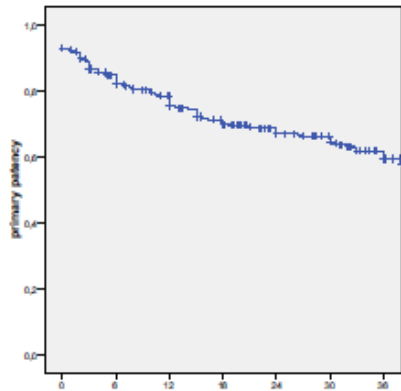
**Ospedale di Terni
*Fiore Ferilli***

Italian Propaten Registry

From the Society for Vascular Surgery

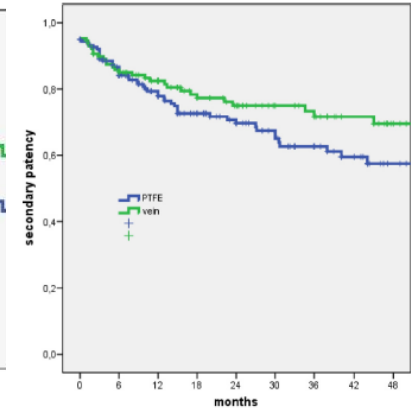
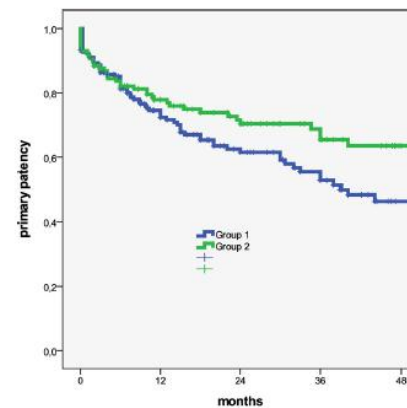
Midterm results from a multicenter registry on the treatment of infrainguinal critical limb ischemia using a heparin-bonded ePTFE graft

Raffaele Pulli, MD,^a Walter Dorigo, MD,^a Patrizio Castelli, MD,^b Vittorio Dorrucchi, MD,^c Fiore Ferilli, MD,^d Giovanni De Blasis, MD,^e Vincenzo Monaca, MD,^f Enrico Vecchiati, MD,^g Carlo Pratesi, MD,^a on behalf of the Propaten Italian Registry Group, *Florence, Varese, Venice-Mestre, Terni, Avezzano, Catania, and Reggio Emilia, Italy*



A multicenter comparison between autologous saphenous vein and heparin-bonded expanded polytetrafluoroethylene (ePTFE) graft in the treatment of critical limb ischemia in diabetics

Walter Dorigo, MD,^a Raffaele Pulli, MD,^a Patrizio Castelli, MD,^b Vittorio Dorrucchi, MD,^c Fiore Ferilli, MD,^d Giovanni De Blasis, MD,^e Vincenzo Monaca, MD,^f Enrico Vecchiati, MD,^g and Carlo Pratesi, MD^a on behalf of the Propaten Italian Registry Group, *Florence, Varese, Venice-Mestre, Terni, Avezzano, Catania, and Reggio Emilia, Italy*



2010



2011



External validation obtained



OVERVIEW ON PROPATEN DATABASE CONTROL PROCEDURES

The results of the control procedure to verify Propaten database (DB) validity and coherence are presented in this paper.

a) PREMISES

1. the total number of clinical cases (follow-up parameters included) collected in linear records was N=477;
2. data to be submitted to control has been "cleaned" by means of filters in order to confirm the coherence and completeness of the selected variables, previously analysed (in the details: months of follow-up / thrombosis / amputation / age - considered if >0)
3. after a random sorting on patients initials (anonymous during the whole procedure) a casual sample was extracted - Spss (Software Package for Statistical Sciences) SAMPLE function - which took out n = 50 subjects from the total available cases (this significant sample numerosity can be reasonably verified by re-examining diagnostic investigations and clinical files)

4. the error was estimated, in the errors concentration evaluation, as follows:

$$\text{err} = \text{sqr}((N / n - 1) / (N - 1)) = 0,013 \rightarrow +13\%$$

b) ELABORATION

Hereby tables report the elaborations carried out on sample check after medical examinations (descending order frequencies obtained using Spss)

Total errors, per patient, on all the 44 clinical variables considered

	Frequencies	Rates	Valid rates	Cumulative rates
Valid none	37	74,0	75,5	75,5
1 error / patient	9	18,0	18,4	93,9
2 error / patient	2	4,0	4,1	96,0
3 error / patient	1	2,0	2,0	100,0
Total	49	96,0	100,0	
Missing	1	2,0		
Total	50	100,0		

Overall errors, per patient, on the sample control variable: MONTHS OF FOLLOW UP

	Frequencies	Rates	Valid rates	Cumulative rates
Valid None	49	96,0	100,0	100,0
Missing	1	2,0		
Total	50	100,0		

Overall errors on the sample control variable: THROMBOSIS MONTHS

	Frequencies	Rates	Valid rates	Cumulative rates
Valid None	46	92,0	93,9	93,9
1 error	3	6,0	6,1	100,0
Total	49	96,0	100,0	
Missing 2	1	2,0		
Total	50	100,0		

Overall errors on the sample control variable: AMPUTATION MONTHS

	Frequencies	Rates	Valid rates	Cumulative rates
Valid None	49	96,0	100,0	100,0
Missing 2	1	2,0		
Total	50	100,0		

In conclusion, referring to the clinical variables reported and considering the numerical confirmation of the completeness of the others, the DB integrity can be reasonably validated and it can represent a fundamental basis for the scientific extrapolations already produced and for the elaborations in progress (with respect to the opportune significance estimations).





ITALIAN REGISTRY
Patients with Critical Limb Ischemia

476 HePTFE
below-knee bypasses

385 ASV
below-knee bypasses

Comparison with autologous saphenous vein bypass in CLI

Patient characteristics

	HePTFE (476 cases)	ASV (385 cases)	p
Female gender	108 (22.5%)	98 (25.5%)	0.3
Diabetes	227 (47.5%)	173 (45)%	0.4
Hypertension	426 (89%)	328 (85%)	0.07
Hyperlipemia	285 (60%)	194 (50%)	0.005
Renal failure	73 (15%)	53 (14%)	0.5
Coronary disease	227 (48%)	134 (35%)	< 0.001

Comparison with autologous saphenous vein bypass in CLI

Patient characteristics

	HePTFE (476 cases)	ASV (385 cases)	p
Rutherford' s 5-6	232 (49%)	181 (47%)	0.6
Redo surgery	138 (29%)	77 (20%)	0.002
Run-off status (<2 vessels)	219 (46%)	282 (73)%	< 0.001
Tibial anastomosis	73 (15%)	221 (57%)	<0.001



Comparison with autologous saphenous vein bypass

Adjunctive distal procedures

	HePTFE (476 cases)	ASV (385 cases)	p
No procedure	340 (71%)	357 (92.5%)	<0.001
Vein cuff or patching	142 (28%)*	23 (6%)	<0.001
Tibial PTA	4 (1%)	4 (1%)	-
Distal AVF	-	1 (0.5%)	-

**In 63% of patients with tibial anastomosis and in 23% of patients with popliteal anastomosis (p<0.001)*

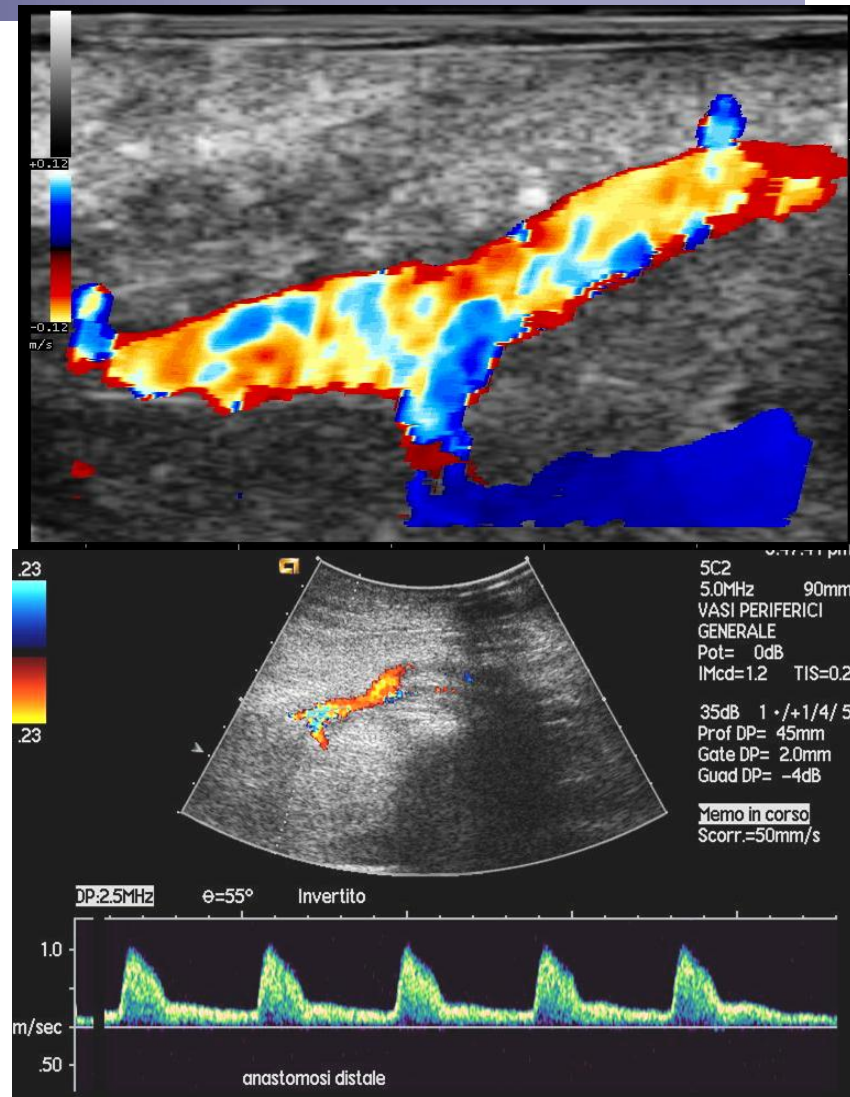
Comparison with autologous saphenous vein bypass in CLI

Thirty-day results

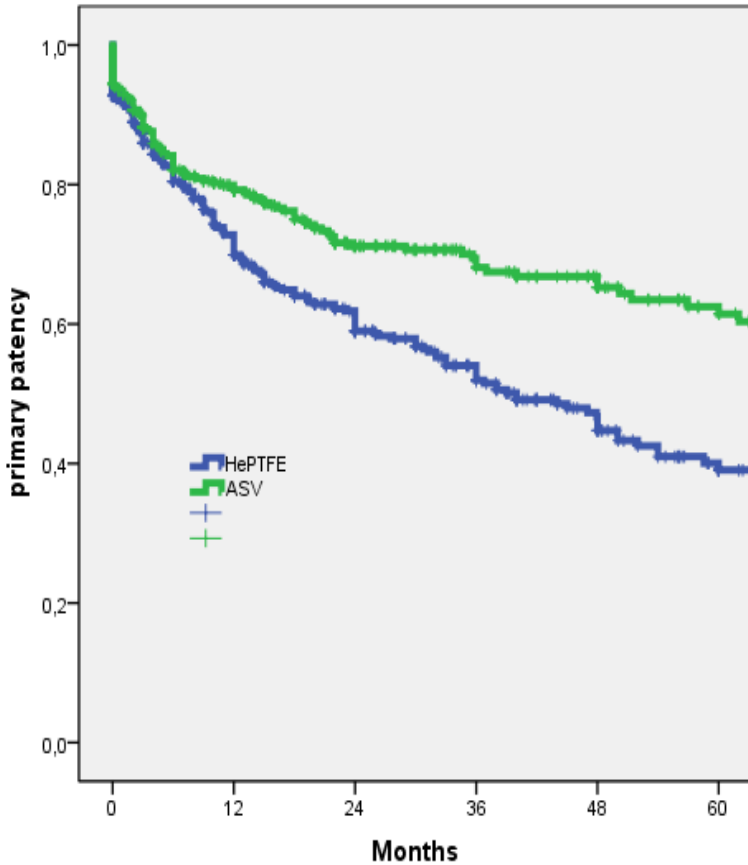
	HePTFE (476 cases)	ASV (385 cases)	p
Mortality	9 (1.8%)	3 (0.8%)	0.1
Thrombosis	36 (7.5%)	23 (6%)	0.3
Amputation	18 (3.7%)	8 (2%)	0.1

Follow-up

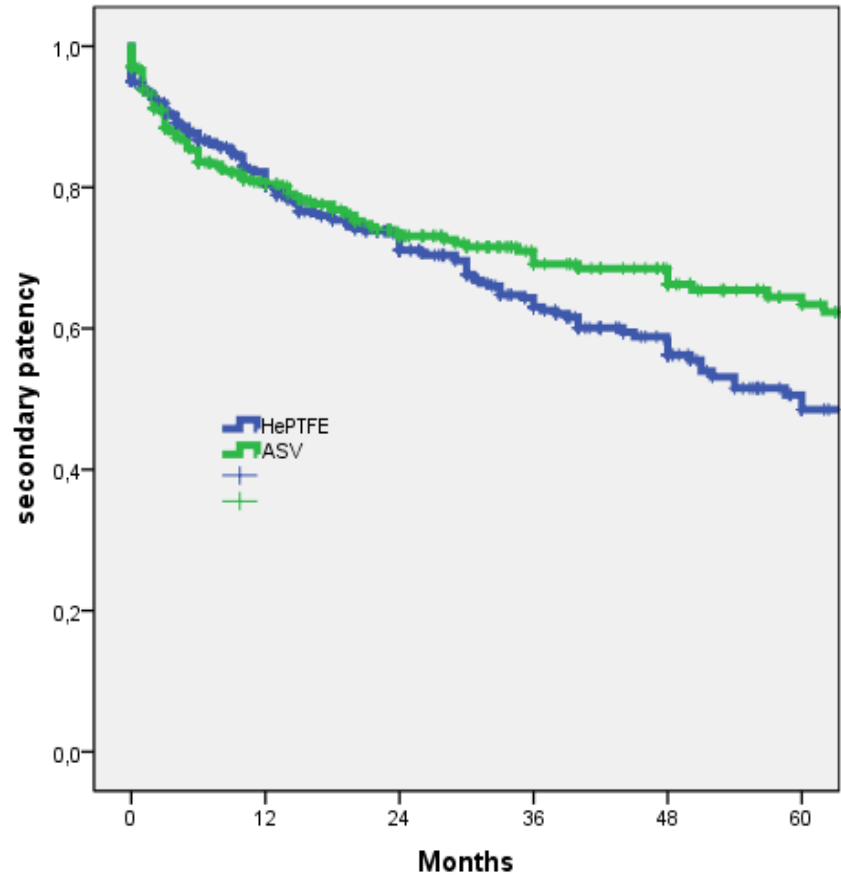
- Duplex-surveillance program consisted of DUS at 1-12 months and yearly thereafter
- Median duration of follow-up was 32 months (SD +/-26.4)
- 848 patients (98.5%) had an available postoperative follow-up



Primary and Secondary Patency of HePTFE graft vs autologous saphenous vein



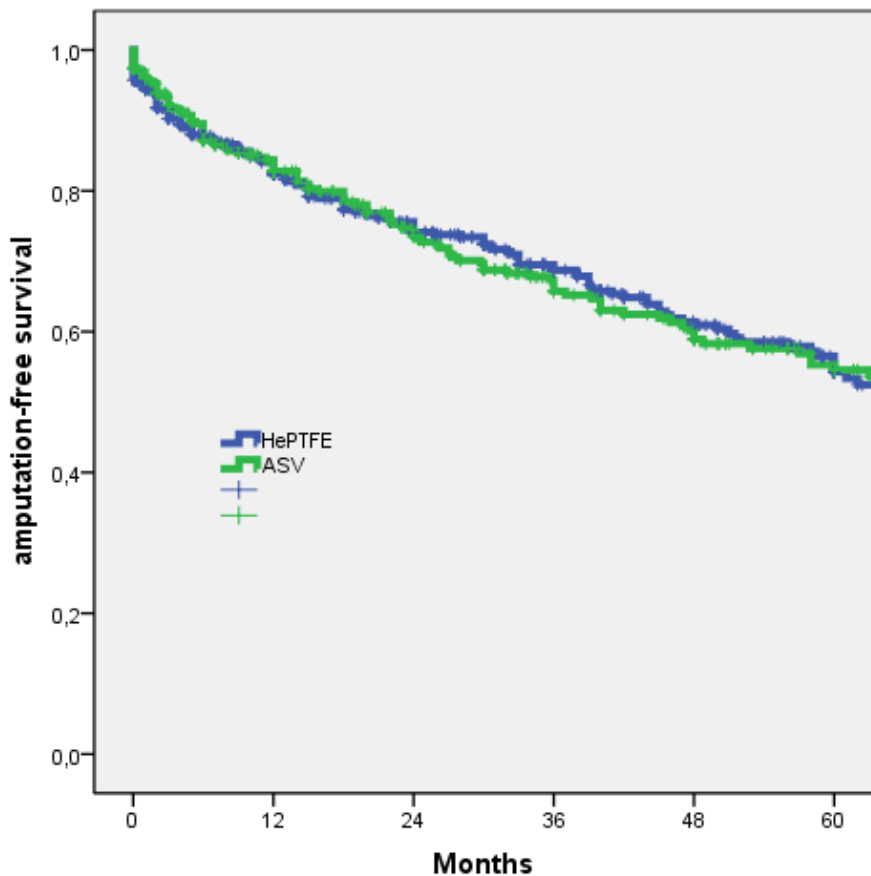
$p < 0.001$; log rank 20.1



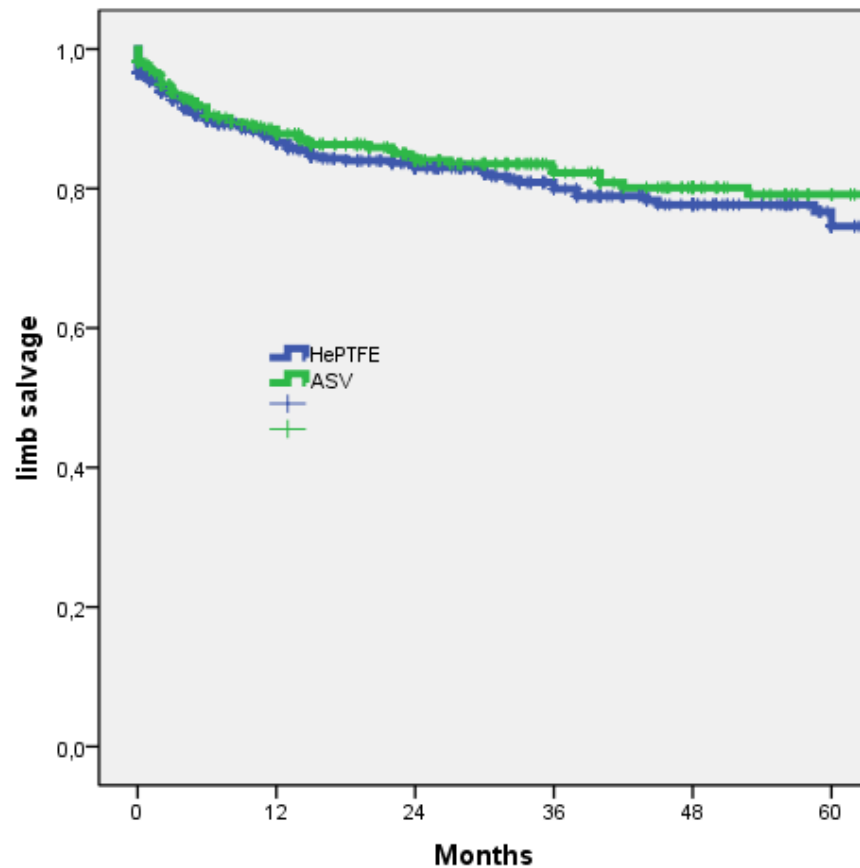
$p = 0.06$; log rank 3.8



Amputation-free survival and limb salvage of HePTFE graft vs autologous saphenous vein



$p=0.7$; log rank 0.1



$p=0.3$; log rank 0.9

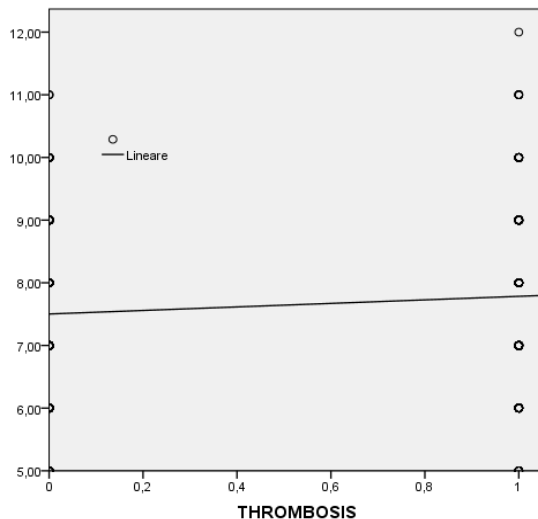
Uni- and multivariate analysis for primary patency in HePTFE group

	<i>Univariate analysis</i>				<i>Multivariate analysis</i>		
	Log-rank	<i>p</i>	<i>95% CI</i>	<i>OR</i>	<i>95% CI</i>	<i>OR</i>	<i>p</i>
Female gender*	6.2	0.002	1.1-2.2	1.6	1-1.9	1.5	0.02
Chronic renal failure	0.1	0.4	0.7-1.7	1.1			
Reintervention*	19.7	0.001	0.4-0.8	0.6	0.4-1	0.6	0.003
Diabetes	0.1	0.3	0.8-1.5	1.1			
Tibial anastomosis*	4.6	0.02	1-2	1.4	0.8-1.7	1.2	0.2
Distal procedures	1.7	0.08	0.9-1.7	1.2			
Run-off score <2*	6.4	0.003	1.1-1.9	1.5	0.9-1.6	1.2	0.2
Rutherford 5-6*	0.9	0.1	0.9-1.6	1.2			

**Factors affecting limb salvage at univariate analysis*

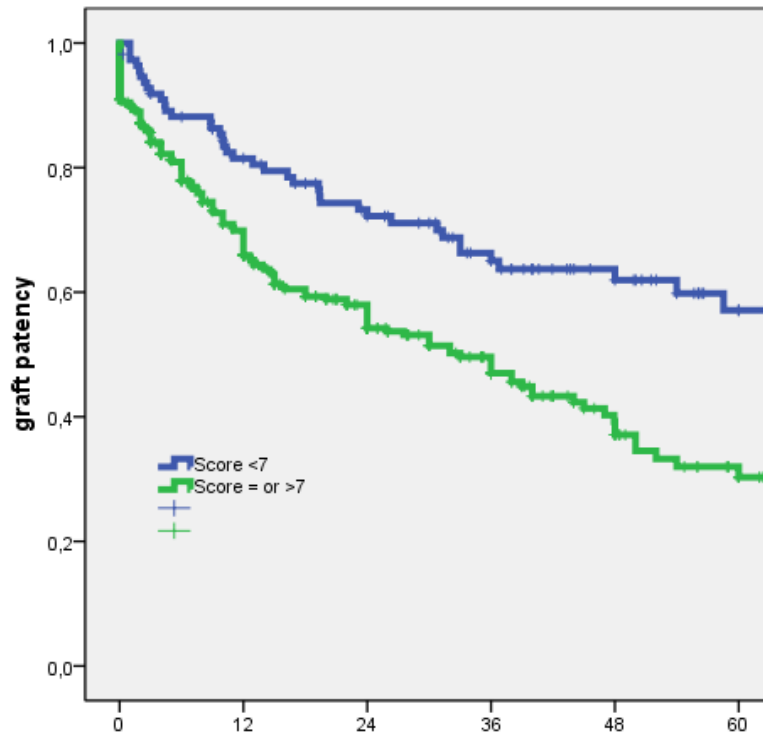
Propaten Score

	CONDITION	SCORE	CONDITION	SCORE	CONDITION	SCORE
Gender	Male	1	Female	2		-
Reintervention	No	1	Yes	2		-
Tibial anastomosis	No	1	Yes	2		-
Run-off score	3 vessel	1	2 vessels	2	1 vessels	3
Rutherford class	Class 4	1	Class 5	2	Class 6	3

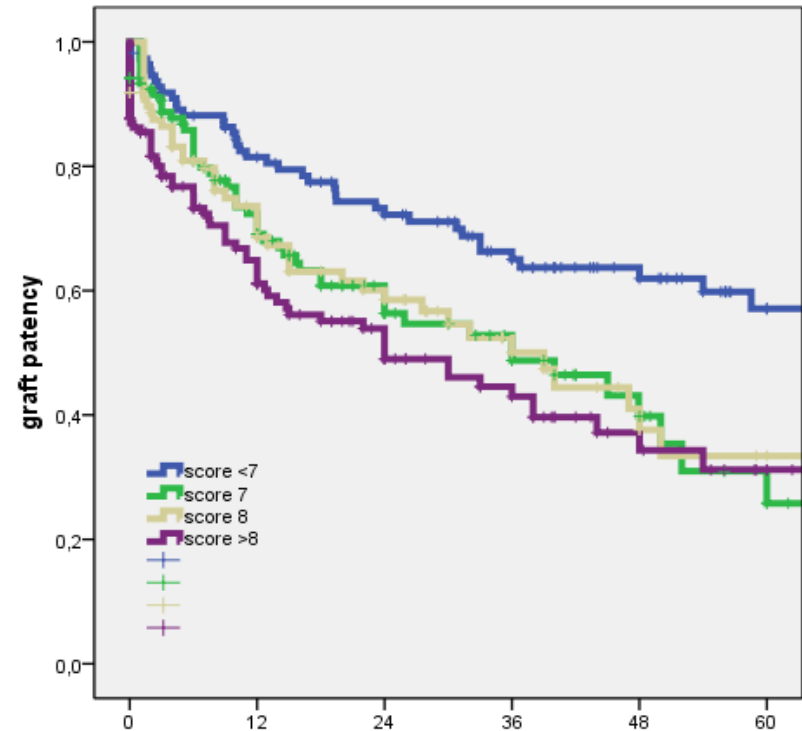


ANOVA test for thrombosis found 7.502 as the cut-off score value ($p < 0.001$; $R = 0.09$).

Propaten Score for Primary Patency

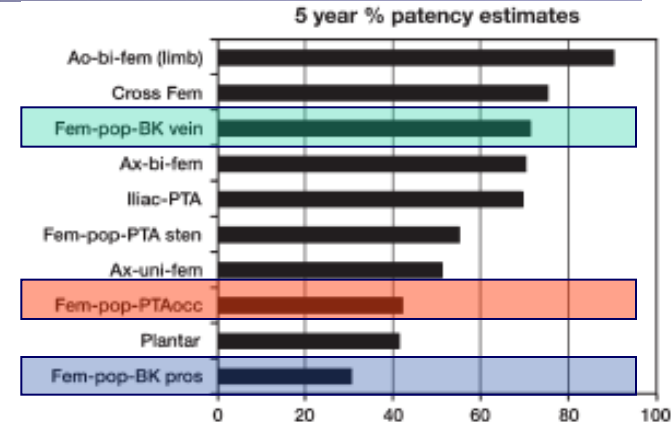
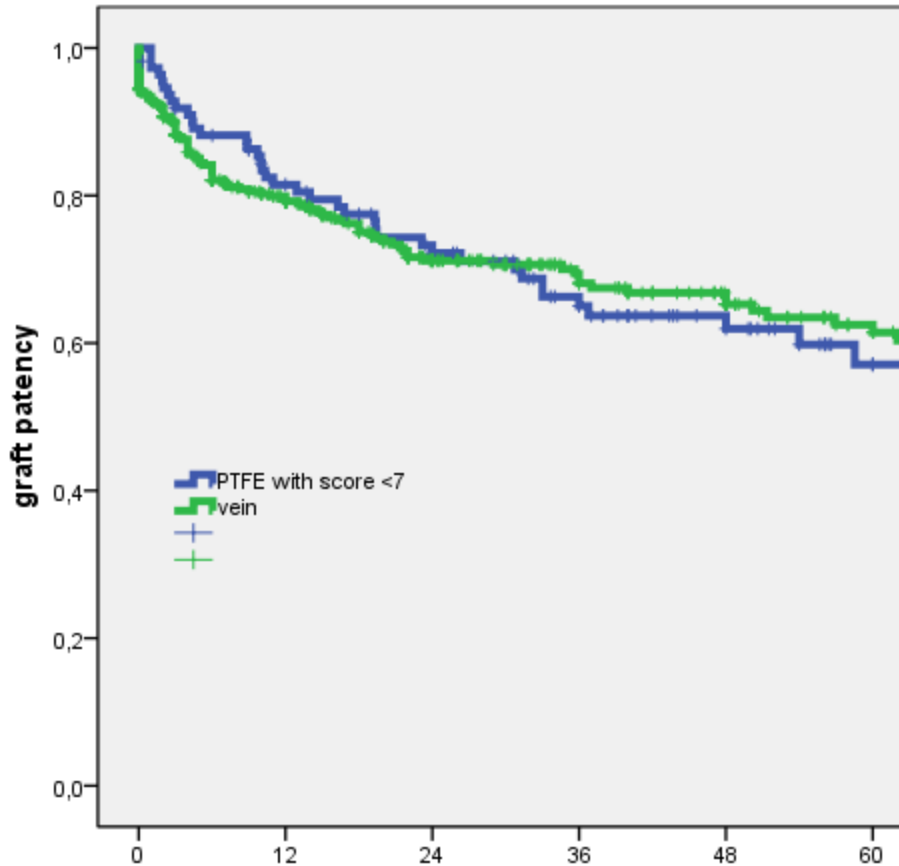


$p < 0.001$; log rank 14.7



$p = 0.001$; log rank 16.8

Propaten Patency with score < 7 vs Vein Patency



*TASC on management of PAD,
revision 2007*

p=0.6; log rank 0.2



Criticisms

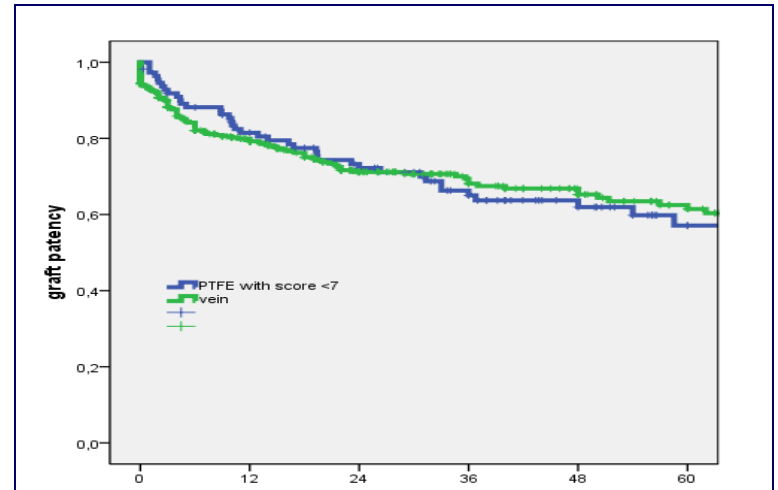
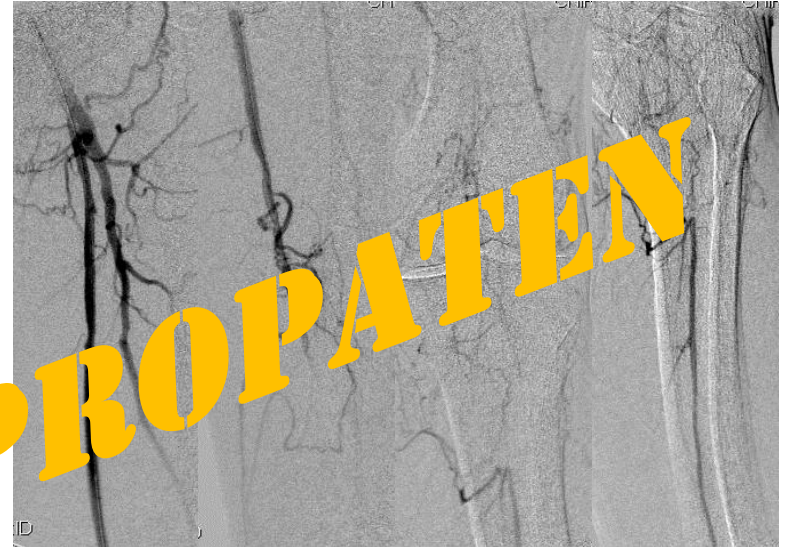
No randomization was planned and, as a consequence, the two groups differed in several aspects

**MULTICENTER RANDOMIZED TRIAL OF
PROPATEN VASCULAR GRAFT VERSUS
AUTOLOGOUS SAPHENOUS VEIN IN BELOW-
KNEE REVASCULARIZATION IN PATIENTS
WITH CRITICAL LIMB ISCHEMIA**

UNDER SCRUTINY OF THE ETHICAL COMMITTEE



Take home messages...





THANK YOU FOR THE KIND ATTENTION !