



BUILDING
ENDOVASCULAR
SYNERGIES

Heparin bonded graft could challenge endovascular repair for TASC C-D lesions?



Raffaele Pulli



University of Florence - Italy

Disclosure

Speaker name:

.....

I have the following potential conflicts of interest to report:

- Travel grant from Gore Company
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)

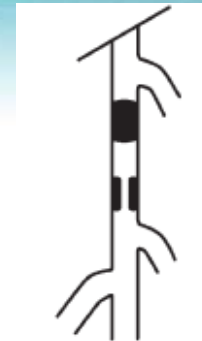
- I do not have any potential conflict of interest

TASC classification of femoro-popliteal disease

■ TASC C:

Multiple stenoses or occlusions totaling
≥ 15 cm with or without heavy calcification

Recurrent stenoses or occlusions that need
treatment after two endovascular
interventions



Recommendation 37

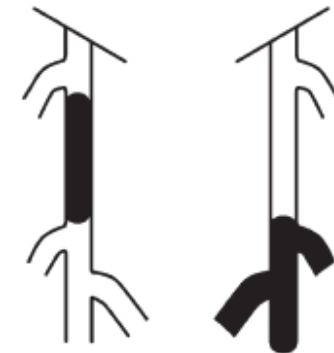
Preferred treatment : SURGICAL

(Comorbidities, patient preference and operator's long-term success rates)

■ TASC D:

Chronic total occlusions of CFA or SFA
(≥ 20 cm, involving the popliteal artery)

Chronic total occlusion of popliteal artery
and proximal trifurcation vessels

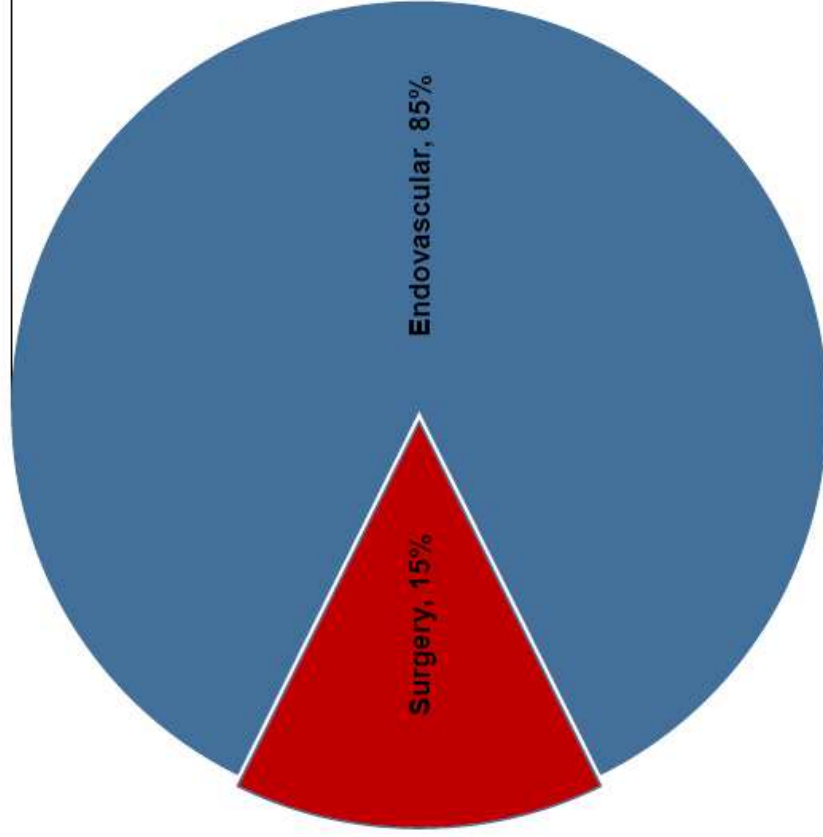


Recommendation 37

Treatment of choice: SURGICAL

European Vascular and Endovascular Monitor (EVEM)

Panel Report – 4th Quarter 2014



■ PTA only ■ PTA w/ BMS ■ PTA w/ DES ■ PTA w/ DEB ■ Stent Grafts/Covered Stents ■ Subintimal PTA

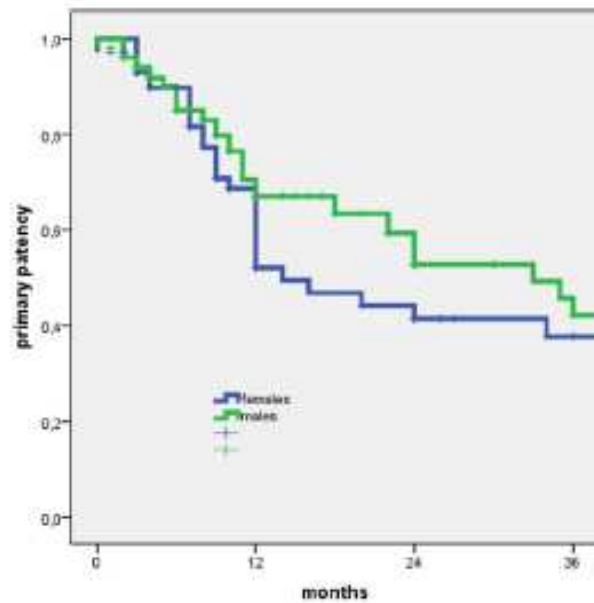
Gender-related outcomes in the endovascular treatment of infrainguinal arterial obstructive disease

Raffaele Pulli, MD,^a Walter Dorigo, MD,^a Giovanni Pratesi, MD,^b Aaron Fargion, MD,^a Domenico Angiletta, MD,^c and Carlo Pratesi, MD,^a *Florence, Rome, and Bari, Italy*

Journal of
Vascular Surgery

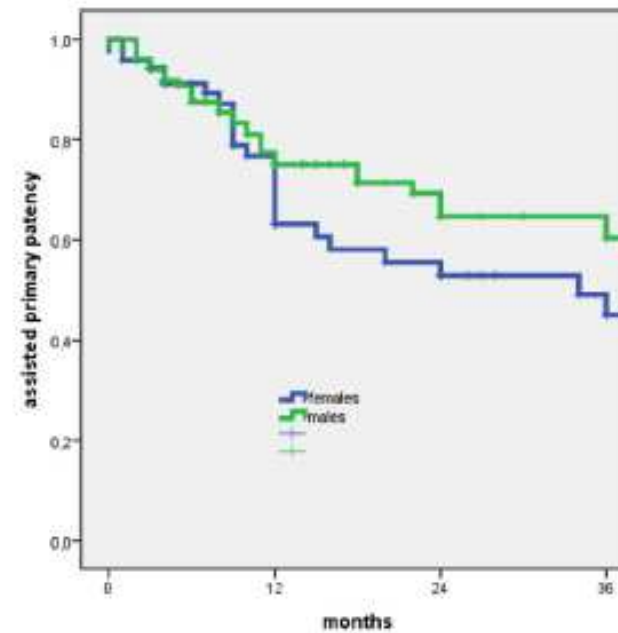
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J Vasc Surg, 2012



Months	0	12	24	36	S.E.
Group 1 – females (n. at risk)	73	28	15	8	7,7
Group 2 – males (n. at risk)	156	59	26	12	7,3

Fig 1. Kaplan-Meier curve for primary patency during follow-up with numbers of patients at risk and standard error (SE).



Months	0	12	24	36	S.E.
Group 1 – females (n. at risk)	73	33	19	11	8,2
Group 2 – males (n. at risk)	156	64	29	14	6,8

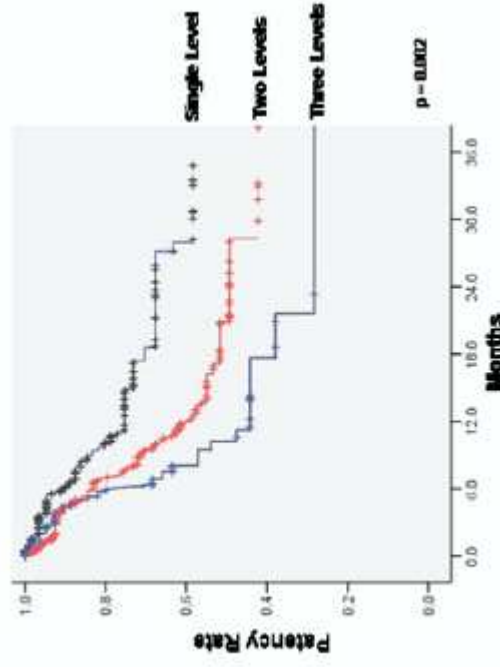
Fig 2. Kaplan-Meier curve for assisted primary patency during follow-up with numbers of patients at risk and standard error (SE).

Lesion severity and treatment complexity are associated with outcome after percutaneous infra-inguinal intervention

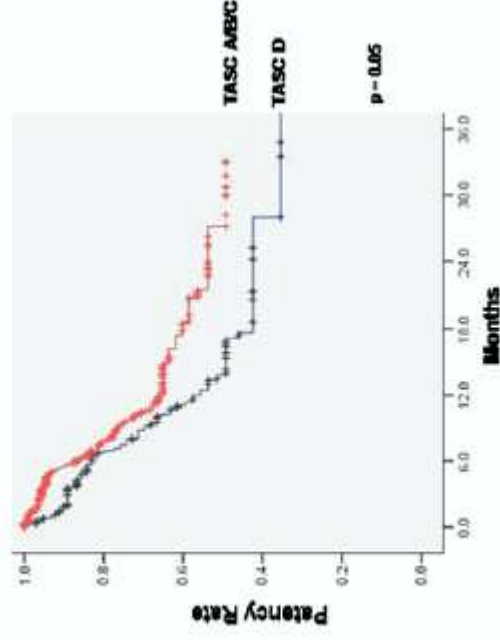
Brian G. DeRubertis, MD, Matthew Pierce, BS, Rabih A. Chaer, MD, Soo J. Rhee, MD, Rachid Benjeloun, MD, Evan J. Ryer, MD, Craig Kent, MD, and Peter L. Faries, MD, *New York, NY*

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Primary Patency Rate of Treated Limbs by Number of Levels of Disease Treated



Primary Patency Rate of Treated Limbs by TASC Classification



Journal of
Vascular Surgery®

Official Publication of the
Society for Vascular Surgery

JOURNAL OF VASCULAR SURGERY
October 2007

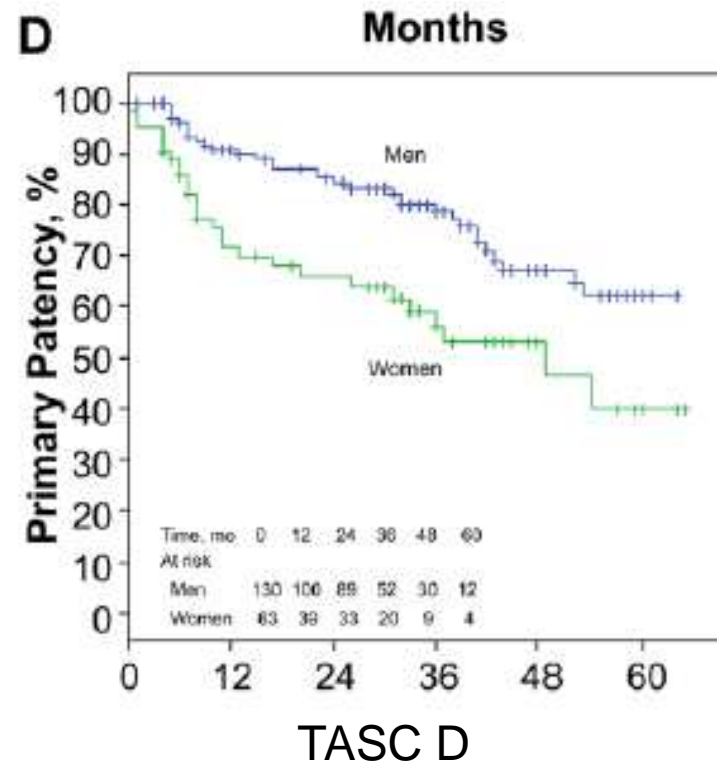
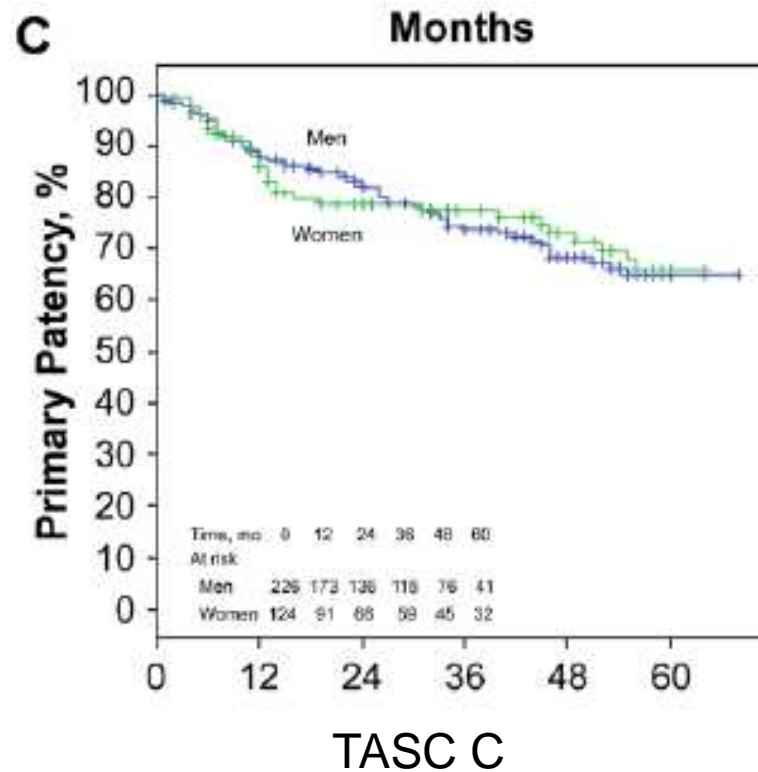
Gender-Related Long-term Outcome of Primary Femoropopliteal Stent Placement for Peripheral Artery Disease

Konstantinos Stavroulakis, MD¹, Konstantinos P. Donas, MD, PhD¹, Giovanni Torsello, MD¹, Nani Osada, PhD¹, and Eva Schönefeld, MD

JOURNAL OF
ENDOVASCULAR
THERAPY
INTERNATIONAL SOCIETY OF
MEDICAL AND INTERVENTIONAL
RADIOLOGY

Journal of Endovascular Therapy
2015, Vol. 22(1) 31-37

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Clinical Research

Primary Stenting of TASC C and D Femoropopliteal Lesions: Results of the STELLA Register at 30 Months

Jean-Michel Davaine^{1,2}, Julien Quéirat¹, Béatrice Guyomarch³, Alain Costargent¹, Philippe Chaillou¹, Philippe Patra^{1,4}, Yann Gouëffic^{1,2,4}  

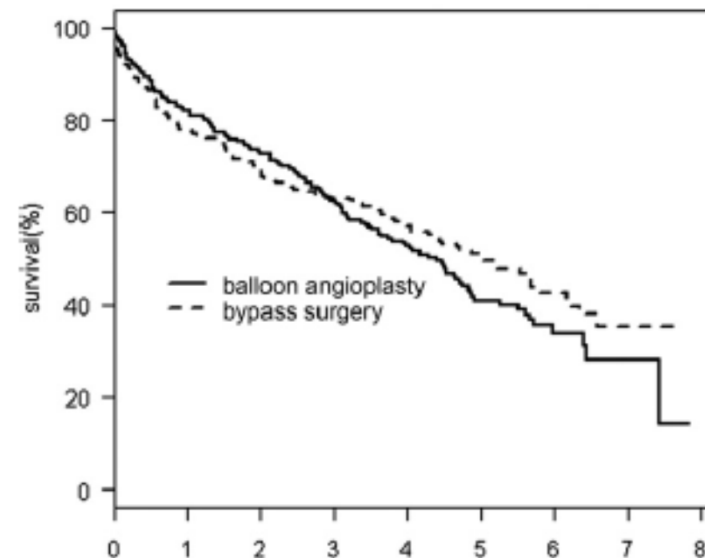
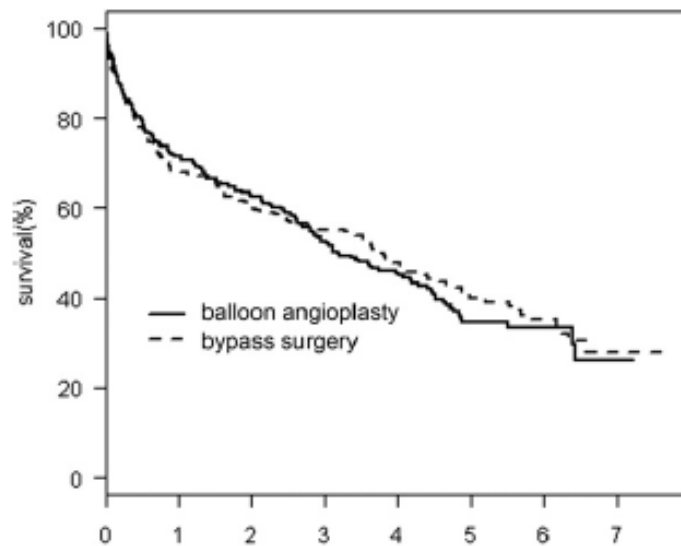
Results

Among the 58 patients (62 limbs) included, 40.3% presented an effort ischemia and 59.7% a critical ischemia (CI). The mean age was 71 ± 12 years. The lesions were classified as TASC D in 37.1% of the cases. The median length of the stenting was 26 ± 18 cm. The average follow-up was 26.1 months (1–30). At 30 months, a complete follow-up was obtained in 55 patients (58 limbs). The rate of survival was 79.6%. Nine of the 11 patients deceased presented initially with CI. Death was in connection with CI in 2 cases. At the date of latest news, 98.3% of the patients were under antiaggregating treatment, 20% received antitiamin K treatment, 75% received statins, and 75% received angiotensin-converting-enzyme inhibitors. The rates of maintenance of the primary and secondary clinical improvement were $68.6 \pm 6.0\%$ and $82.6 \pm 5.1\%$ at 12 months and $65.1 \pm 6.2\%$ and $78.4 \pm 5.6\%$ at 30 months, respectively. The mean Rutherford index was 4.1 ± 1.0 in preoperative, 0.7 ± 1.2 at 12 months, and 0.6 ± 1.1 at 30 months ($P < 0.001$). Two major amputations were carried out at 9 and 28 months for patients initially with CI. The mean systolic pressure index was 0.6 ± 0.1 in preoperative and 1.0 ± 0.2 at 1-year and 0.9 ± 0.3 at 30 months ($P < 0.001$). The rates of primary and secondary patency were $66 \pm 6.3\%$ and $80.9 \pm 9.5\%$ at 12 months and $62.2 \pm 6.6\%$ and $77.2 \pm 5.9\%$ at 30 months, respectively. Between 0 and 12 months, 12 (19.3%) intrastent restenosis (ISR) were noted. One ISR was observed after 12 months. At the same period, we observed 11 and 1 target lesion revascularization, respectively.

Conclusions

In the long run, the primary stenting of long FP lesions (≥ 15 -cm) is a safe and durable treatment. A strong clinical and ultrasound monitoring is indicated during the first year to maintain the clinical improvement.

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.

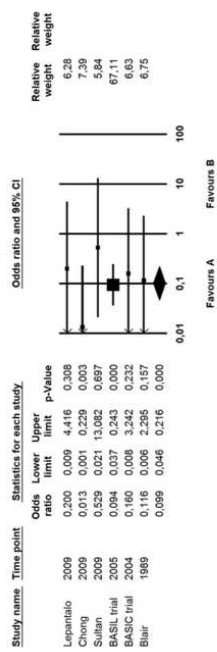
(Bradbury, J Vasc Surg 2010)

A meta-analysis of endovascular versus surgical reconstruction of femoropopliteal arterial disease

George A. Antoniou, MD, PhD,^a Nicholas Chalmers, FRCR,^a George S. Georgiadis, MD,^b Milto K. Lazarides, MD, EBSQVasc,^b Stavros A. Antoniou, MD,^c Ferdinand Serracino-Inglott, MD, MSc, FRCS,^a J. Vincent Smyth, ChM, FCRS,^a and David Murray, MD, FRCS,^a *Manchester, United Kingdom; Alexandroupolis, Greece; and Marburg, Germany*

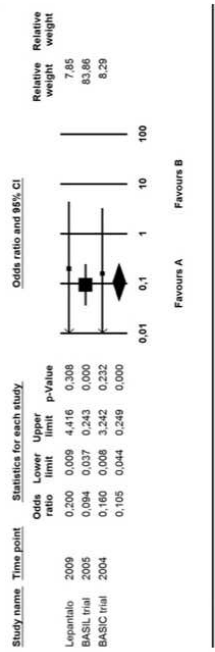
JOURNAL OF VASCULAR SURGERY
Volume 57, Number 1

Antoniou et al 249



Meta Analysis

a



Meta Analysis

b

CONCLUSIONS

There is insufficient evidence to demonstrate the superiority of one method over the other. Existing randomized trials and observational studies are limited by the variability in disease severity and methods of treatment. An endovascular-first approach may be advisable in patients with significant comorbidity, whereas for fit patients with a longer-term perspective, a bypass procedure may be offered as a first-line interventional treatment. Further randomized controlled trials evaluating the outcomes of surgical and endovascular treatment in carefully selected patients are required to delineate the efficacy of these methods for the treatment of femoropopliteal arterial disease.

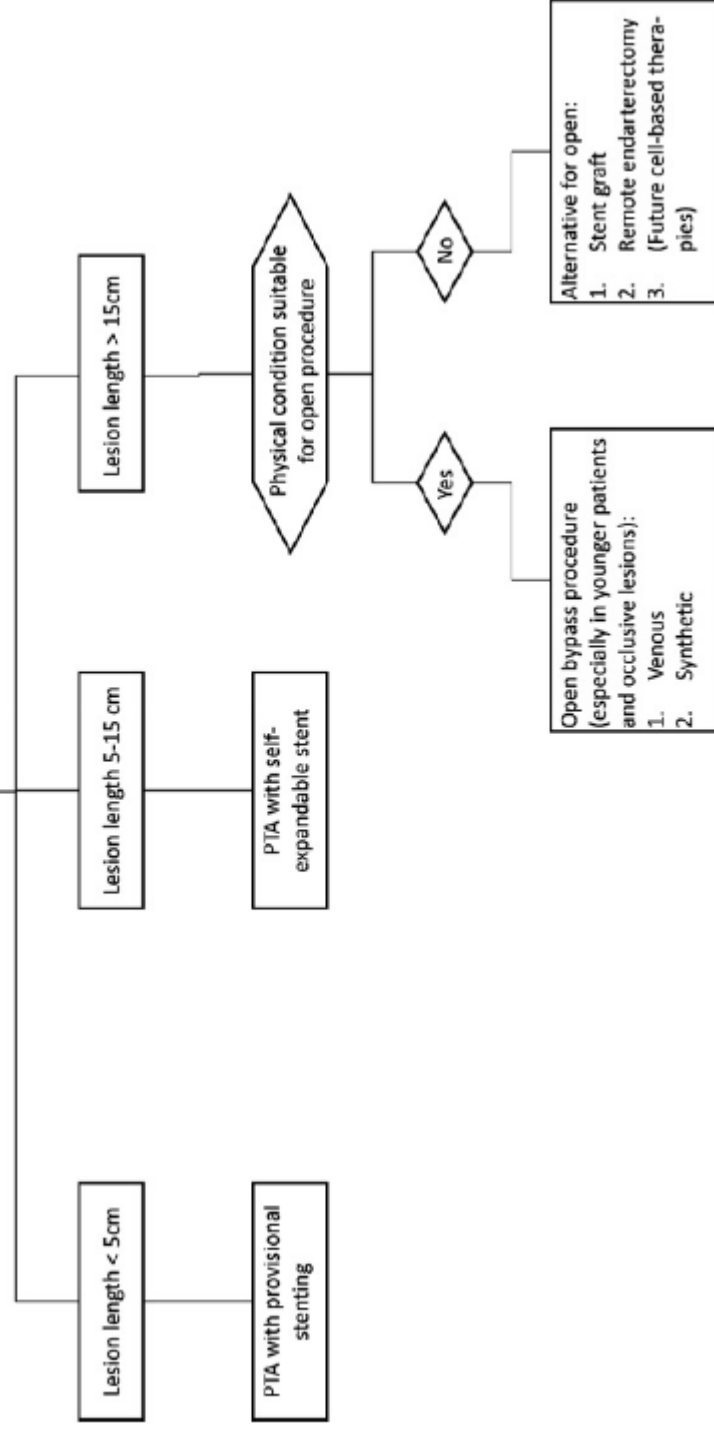
JOURNAL OF VASCULAR SURGERY
January 2013



Chapter IV: Treatment of Critical Limb Ischaemia

C. Setacci^{a,*}, G. de Donato^a, M. Teraa^{b,c}, F.L. Moll^c, J.-B. Ricco^d, F. Becker^e,
H. Robert-Ebadi^e, P. Cao^f, H.H. Eckstein^g, P. De Rango^h, N. Diehmⁱ,
J. Schmidli^j, F. Dick^j, A.H. Davies^k, M. Lepántalo^{l,m}, J. Apelqvist^{n,o}

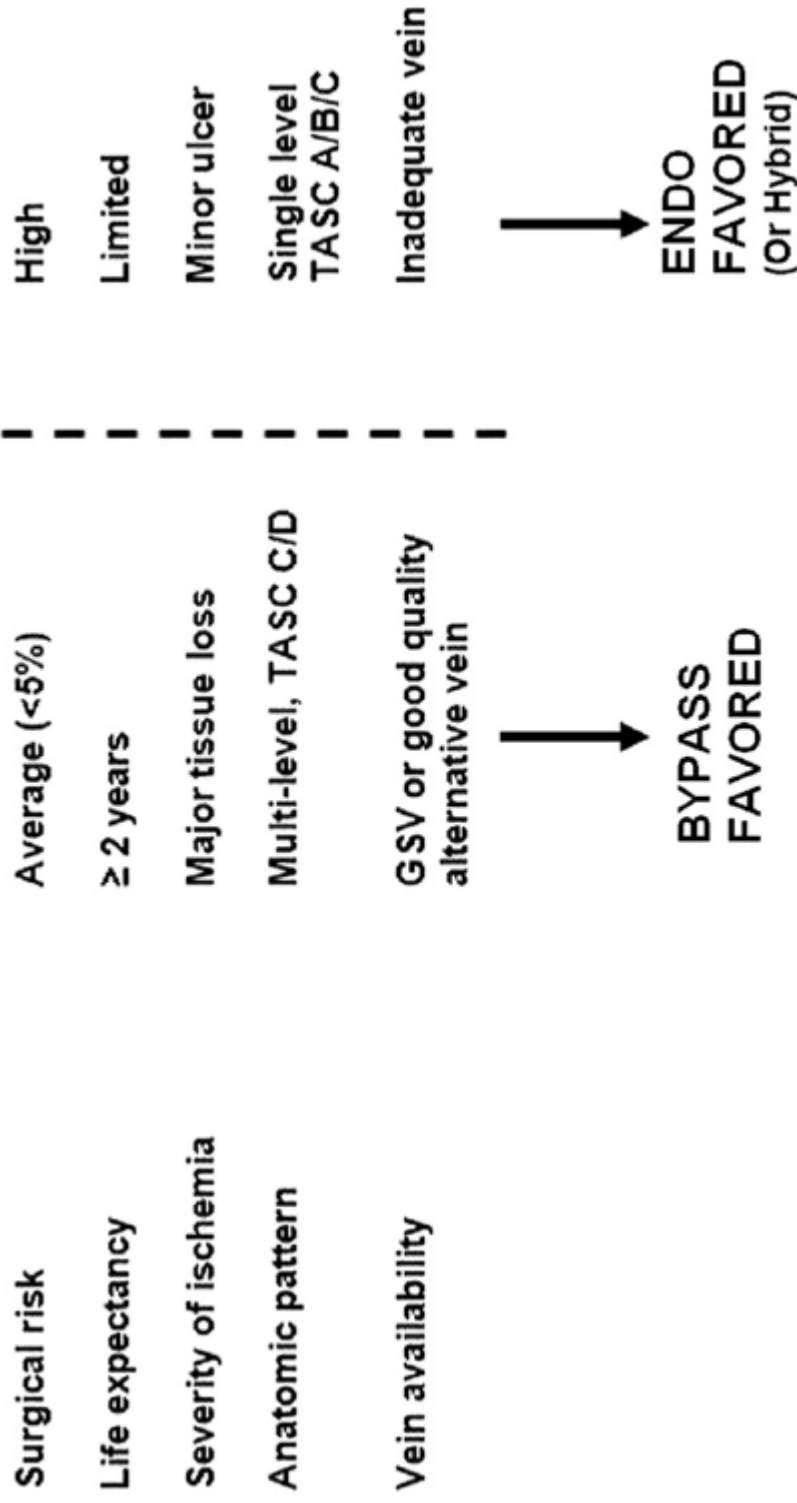
CLI (partially) based on SFA lesion



Critical appraisal of surgical revascularization for critical limb ischemia

Michael S. Conte, MD, *San Francisco, Calif*

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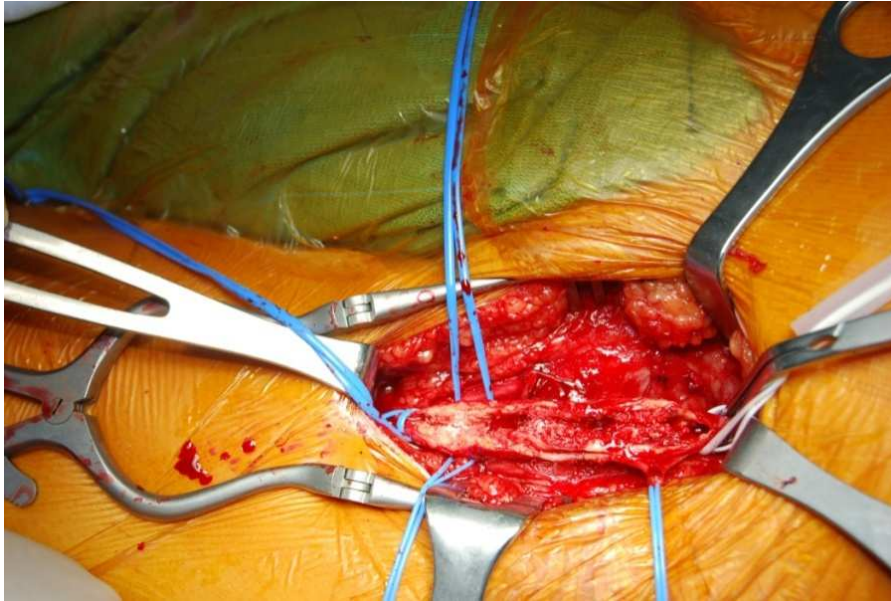


Are they fighting or loving ?



Hybrid procedures

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Vascular Surgery-University of Florence 2005-2014

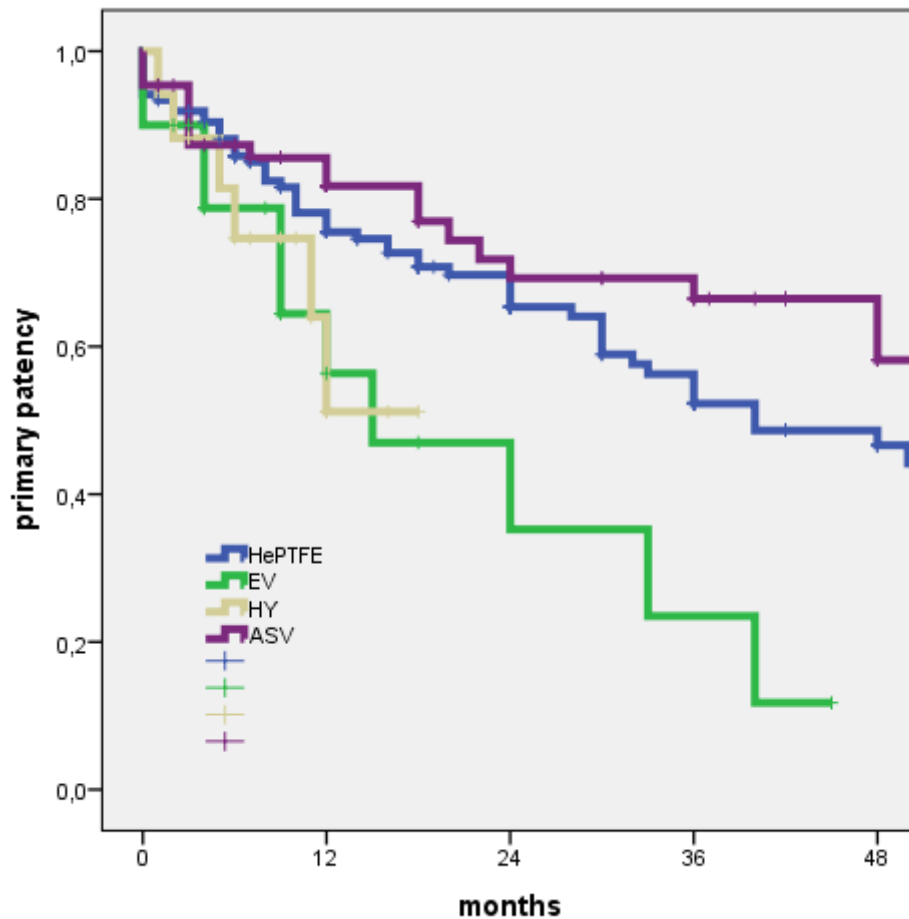
- **567 open and endovascular interventions for femoro-popliteal obstructive disease without tibial involvement**
- **411 interventions performed for TASC-II C and D lesions**
 - 194 HePTFE bypass**
 - 111 vein bypasses**
 - 58 endovascular procedures**
 - 51 hybrid procedures**

Vascular Surgery-University of Florence 2005-2014

	HePTFE (194)	ASV (111)	EV (58)	Hy (51)	p
Intermittent claudication	54 (28%)	43 (39%)	34 (58%)	34 (66%)	<0.001
Critical limb ischemia	140 (72%)	67 (61%)	24 (42%)	17 (34%)	<0.001
Above the knee	41 (21%)	2 (2%)	31 (53%)	37 (72%)	<0.001
Below the knee	153 (79%)	109 (98%)	27 (47%)	14 (28%)	<0.001

Vascular Surgery-University of Florence 2005-2014

RESULTS IN PATIENTS WITH CLI

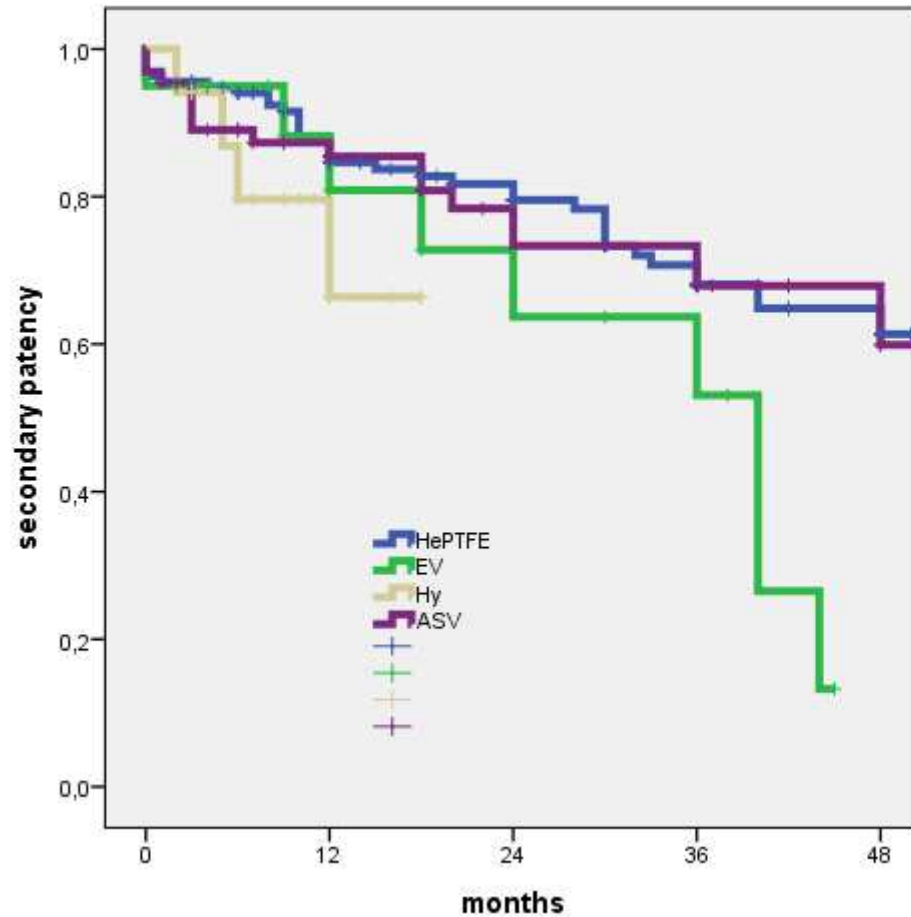


	Primary patency @ 4 years
HePTFE	46.5%
ASV	58.2%
EV	12%
HY	-

$p=0.009$, log rank 11.5

Vascular Surgery-University of Florence 2005-2014

RESULTS IN PATIENTS WITH CLI

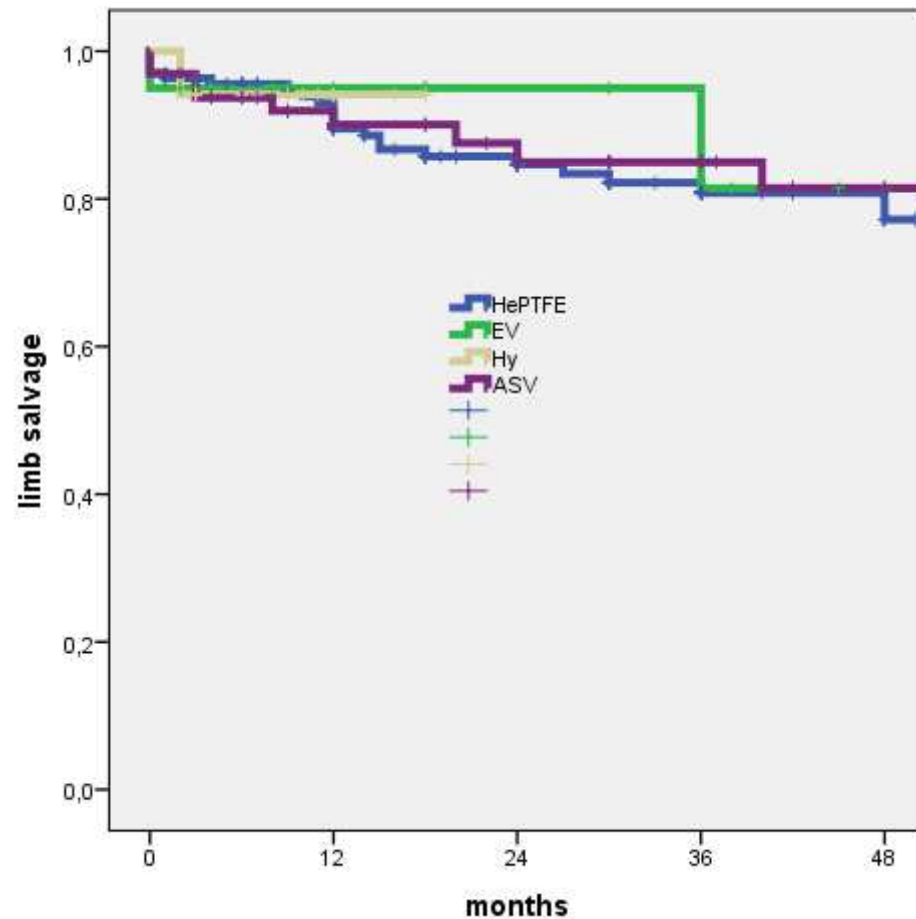


	Secondary patency @ 4 years
HePTFE	61%
ASV	67%
EV	14%
HY	-

$p=0.08$, log rank 6.7

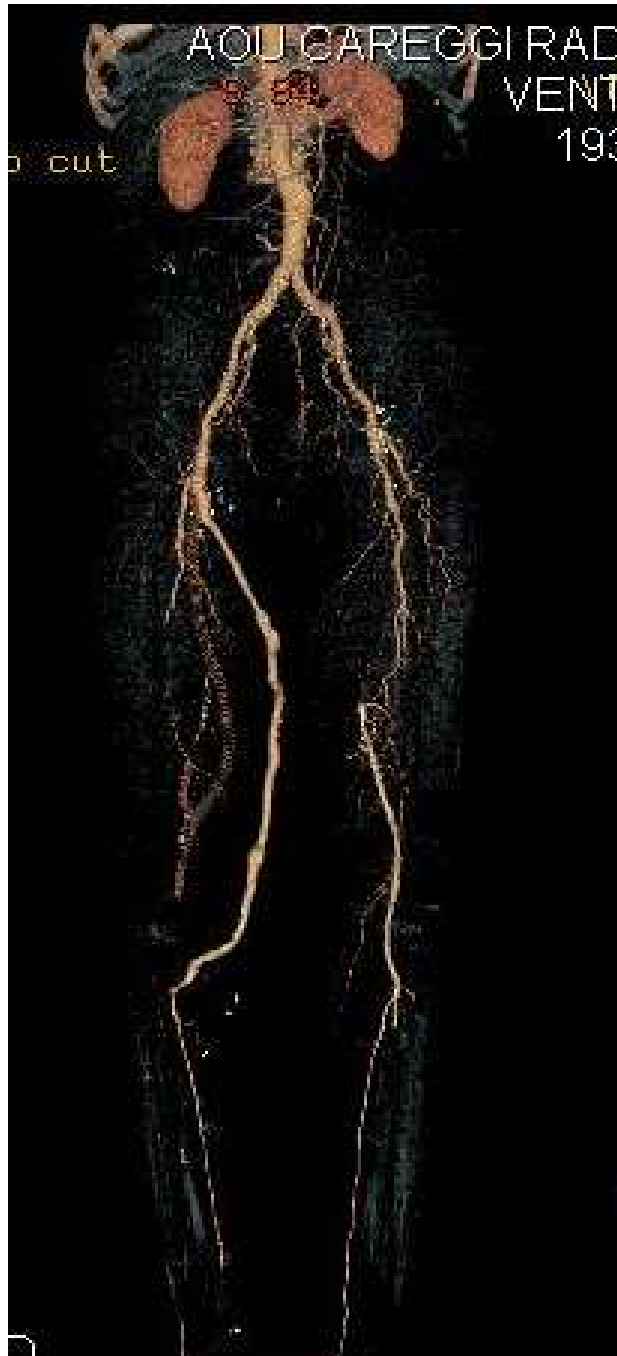
Vascular Surgery-University of Florence 2005-2014

RESULTS IN PATIENTS WITH CLI



	Limb salvage @ 4 years
HePTFE	77%
ASV	82%
EV	81%
HY	-

p=0.8, log rank 0.6



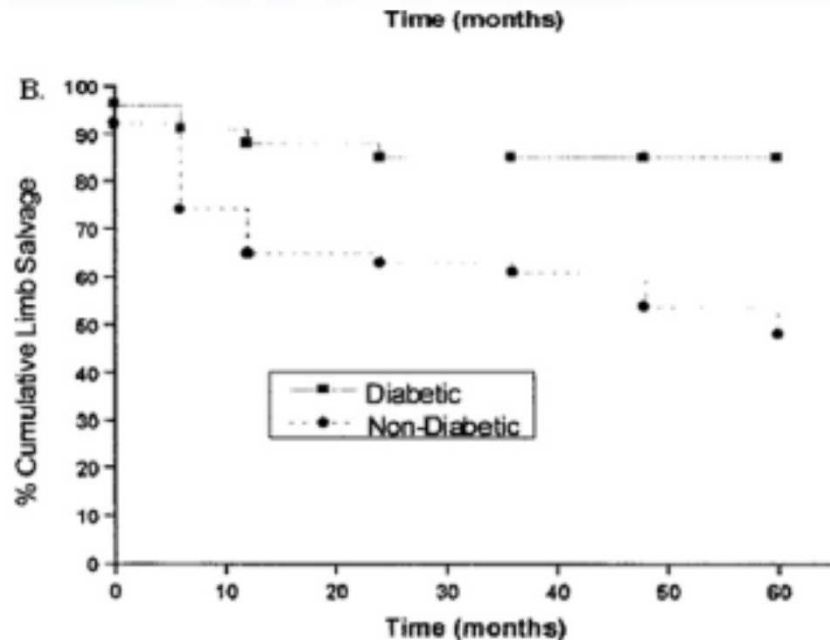
“The great saphenous vein performs better than polytetrafluoroethylene in femoropopliteal bypass grafting and should be used whenever possible.

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

Pereira et al., Meta-analysis of femoropopliteal bypass grafts for lower extremity arterial insufficiency

J Vasc Surg 2006;44:510-7.

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



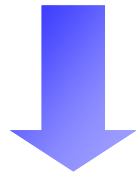
An adequate caliber, good quality great saphenous vein (GSV) is the optimal graft for distal bypass in the leg. The availability of such a conduit is a relevant limitation of lower extremity bypass surgery: **good ipsilateral greater saphenous vein may be lacking in up to 40% of the patients**, and the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

GRAFT MATERIAL

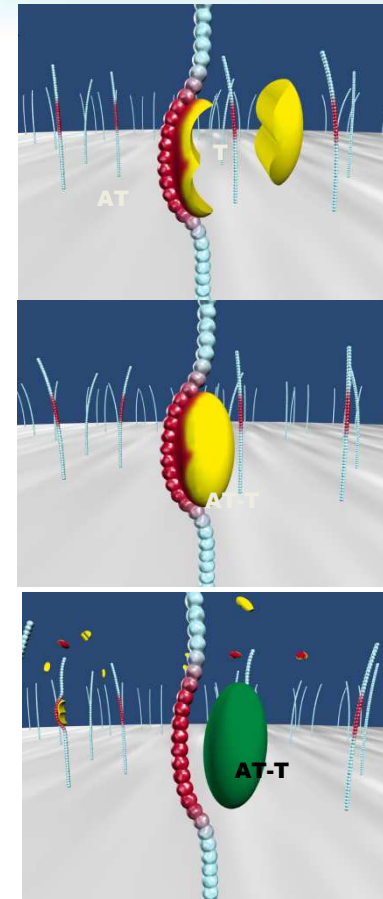
Chemical modifications

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PROPATEN (GORE-TEX®) is an ePTFE prosthetic graft with covalent end-point attachment of heparin to graft surface (CBAS), enabling maintenance of functional heparin bioactivity



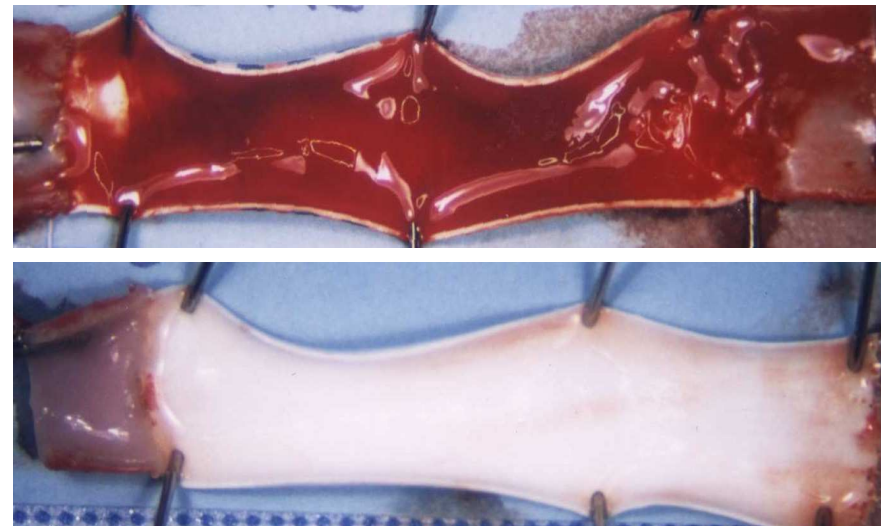
- **UNIFORM
HEPARINIZATION**
- **RETENTION OF HEPARIN
ON GRAFT SURFACE**



Experimental studies

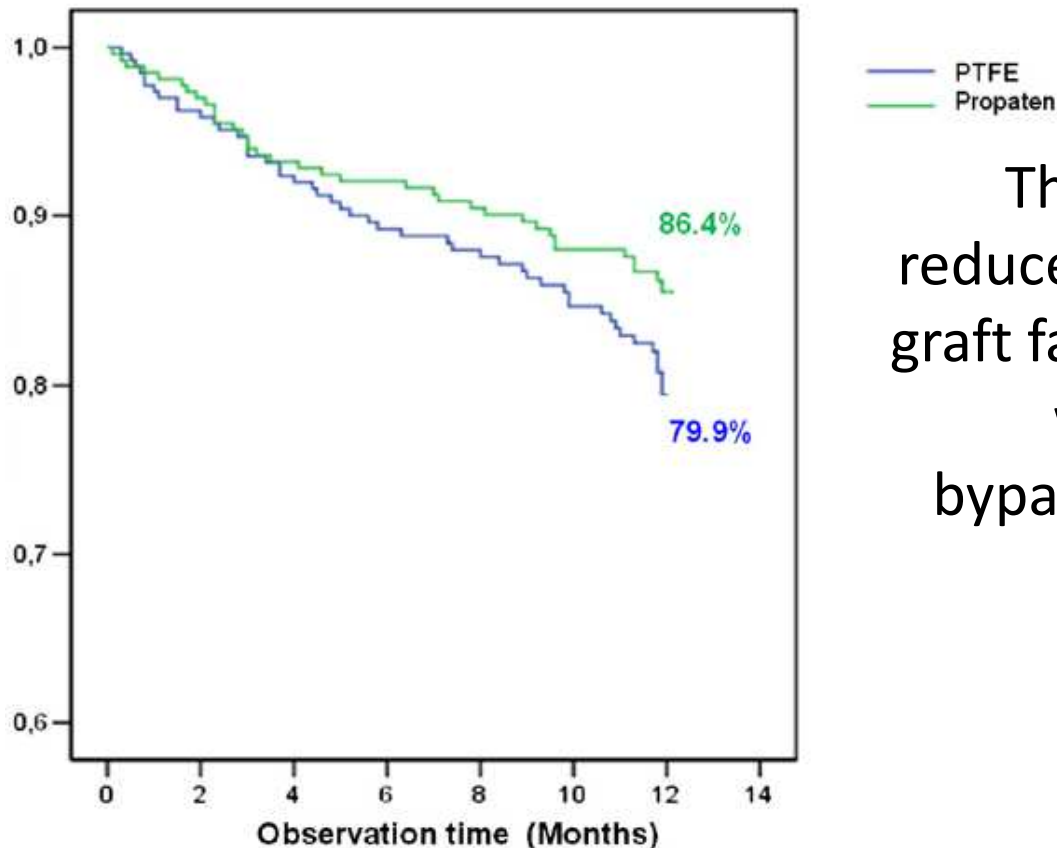
- Acute canine interposition experiments comparing CBAS-PTFE grafts to control ePTFE grafts showed significantly greater thrombus-free luminal surface
- In chronic canine interposition experiment, significantly improved patency was observed with CBAS-PTFE grafts
- Long term in vivo heparin bioactivity was demonstrated on CBAS-PTFE grafts explanted between 1 and 12 weeks

(Begovac, EJVES 2003)



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[☆]

J.S. Lindholt^{a,*}, B. Gottschalksen^b, N. Johannesen^c, D. Dueholm^d,
H. Ravn^e, E.D. Christensen^f, B. Viddal^g, T. Flørenes^h, G. Pedersenⁱ,
M. Rasmussen^j, M. Carstensen^k, N. Grøndal^a, H. Fasting^a



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 patients with critical ischaemia.

(Eur J Vasc Endovasc Surg 2011)

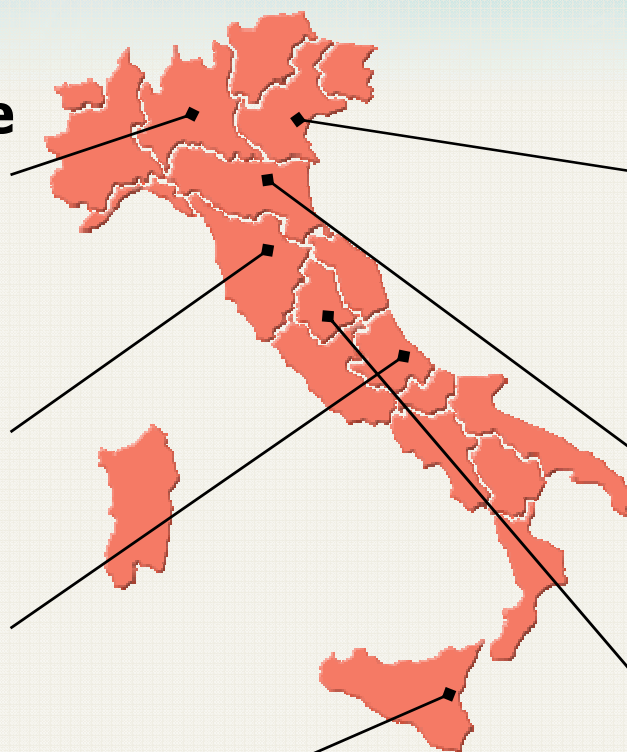
Italian Registry: participants centres

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

Università di Firenze
Carlo Pratesi

**Ospedale
di Avezzano**
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 REGISTRY

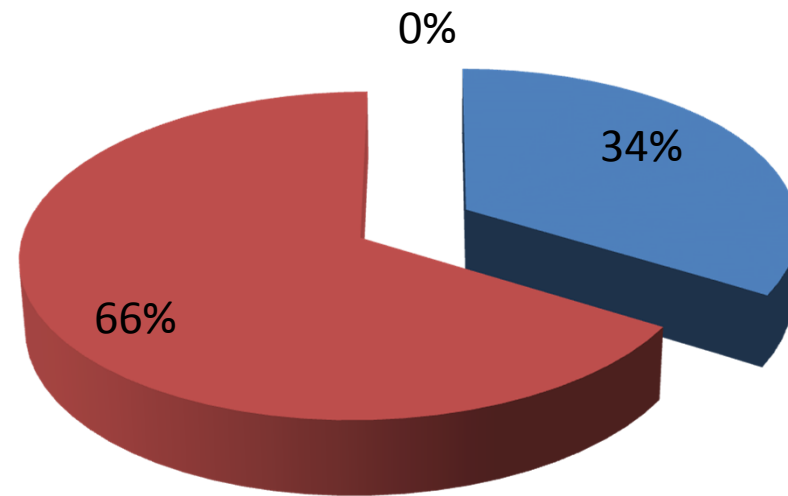
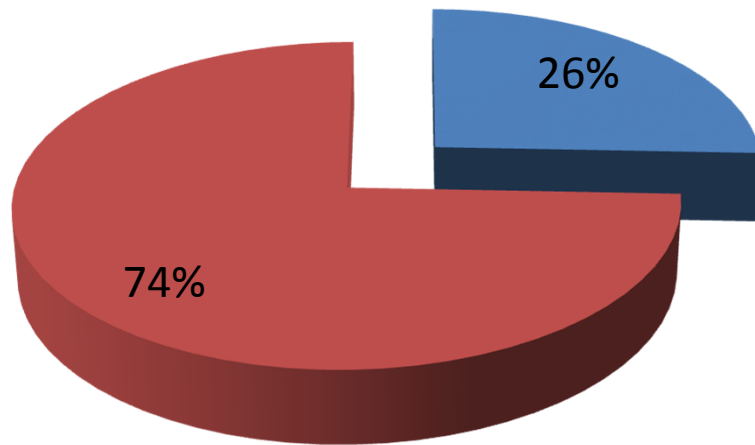
AVEZZANO, CATANIA, FIRENZE,
MESTRE, REGGIO EMILIA, TERNI, VARESE



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■ AK bypass 295 ■ BK bypass 857

■ Claudicants 388 ■ CLI 764 ■



1152 HePTFE bypasses



PROPATEN© ITALIAN REGISTRY GROUP
UPDATE in CLI patients

599 HePTFE

below-knee bypasses

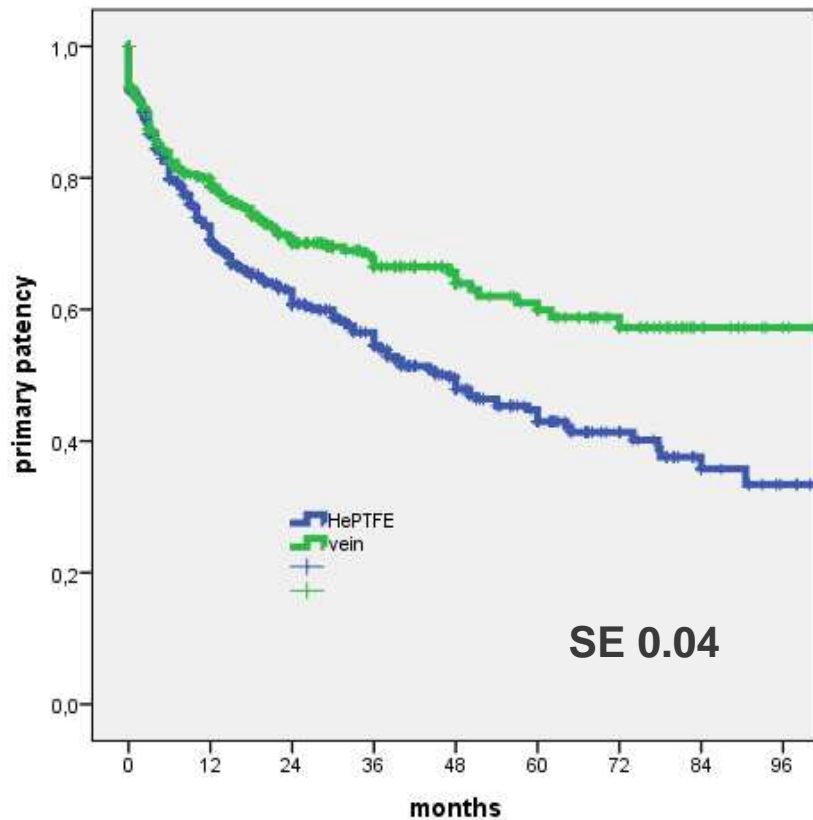
- 461 males (77%)
- 138 females (23%)

390 ASV

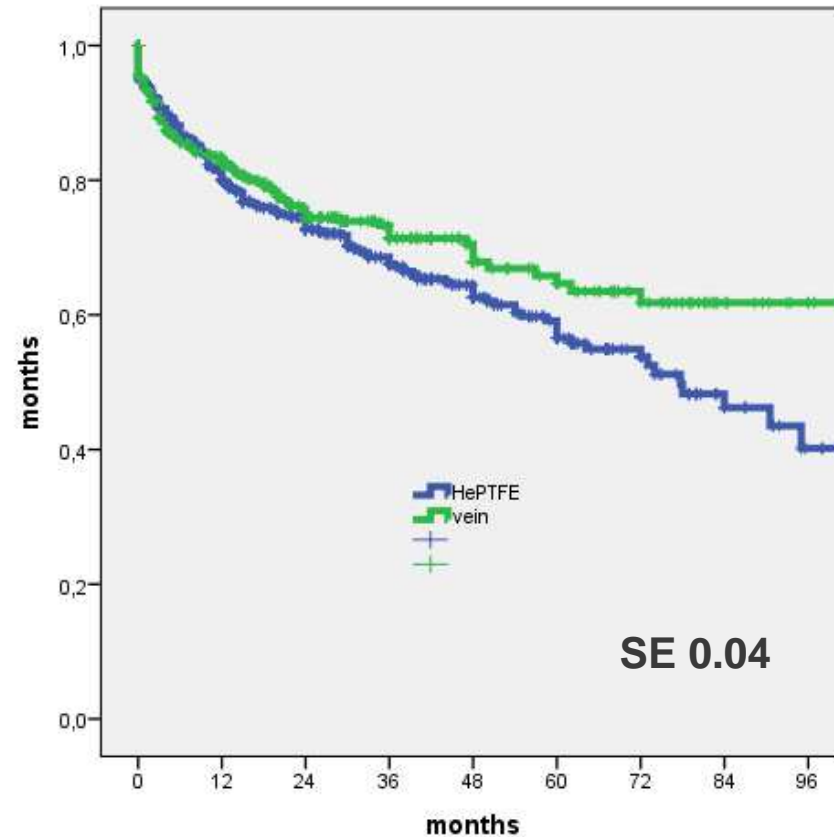
below-knee bypasses

- 292 males (75%)
- 98 females (25%)

Comparison with autologous saphenous vein bypass in CLI

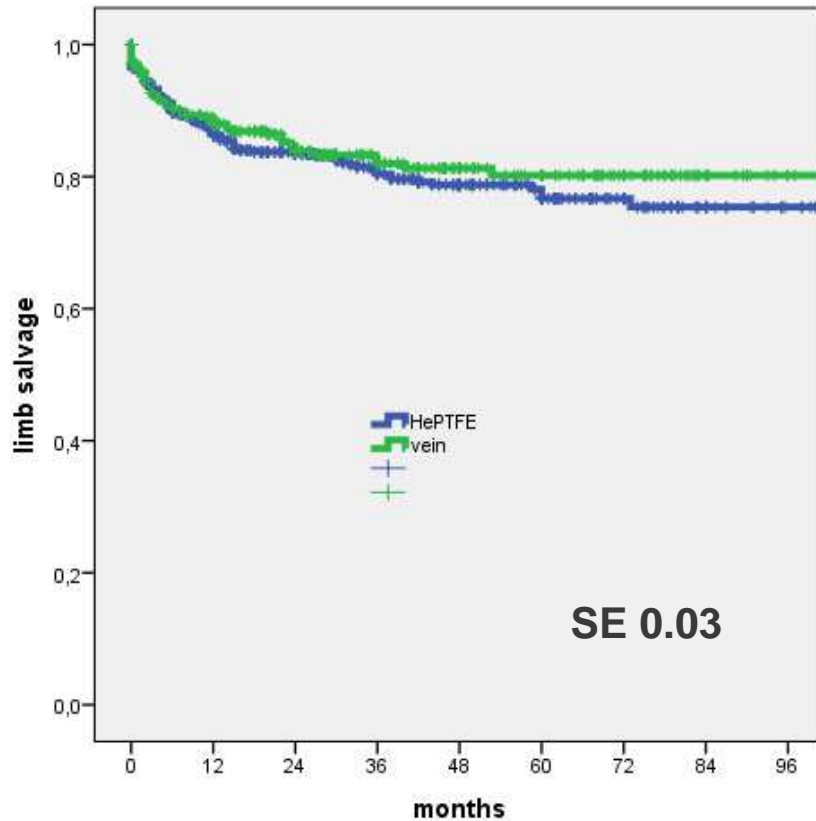


$p < 0.001$; log rank 13.3

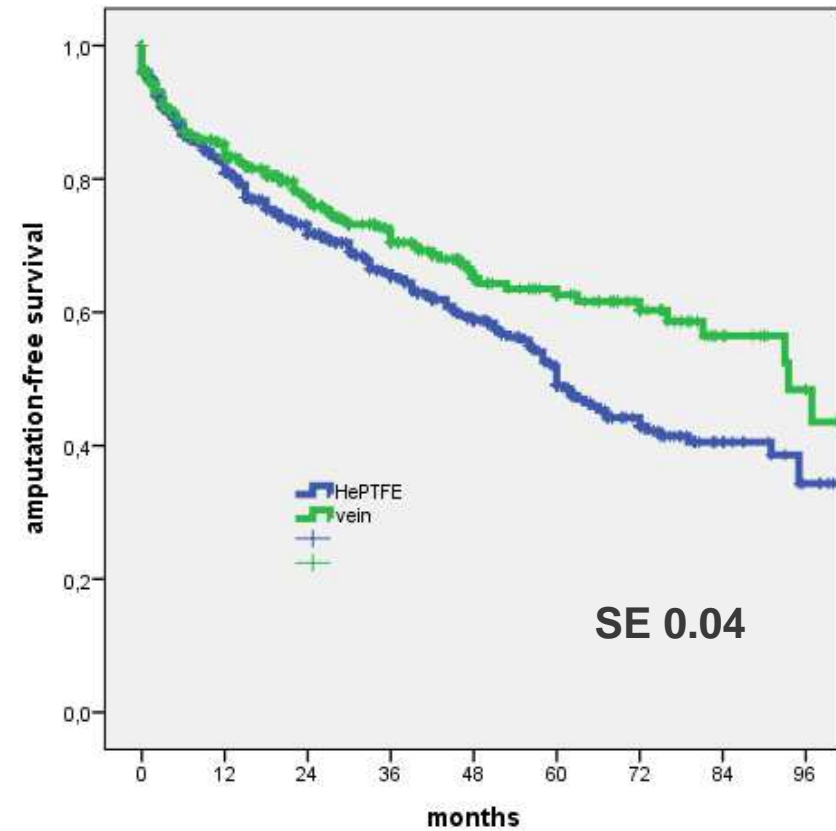


$p = 0.09$; log rank 2.7

Comparison with autologous saphenous vein bypass in CLI



p=0.4; log rank 0.6



p=0.08; log rank 4.2

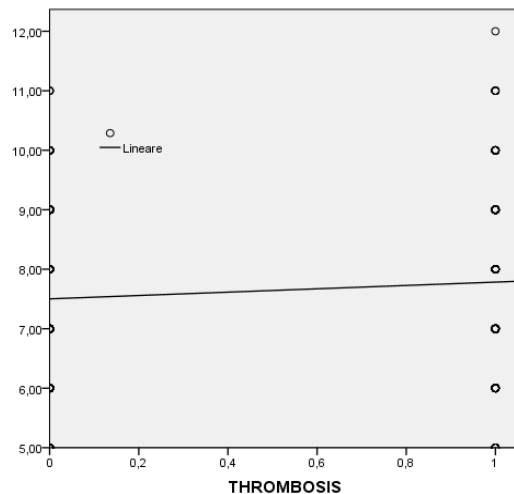
Uni- and multivariate analysis for primary patency in HePTFE group

	<i>Univariate analysis</i>				<i>Multivariate analysis</i>		
	Log-rank	<i>p</i>	95% <i>CI</i>	<i>OR</i>	95% <i>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

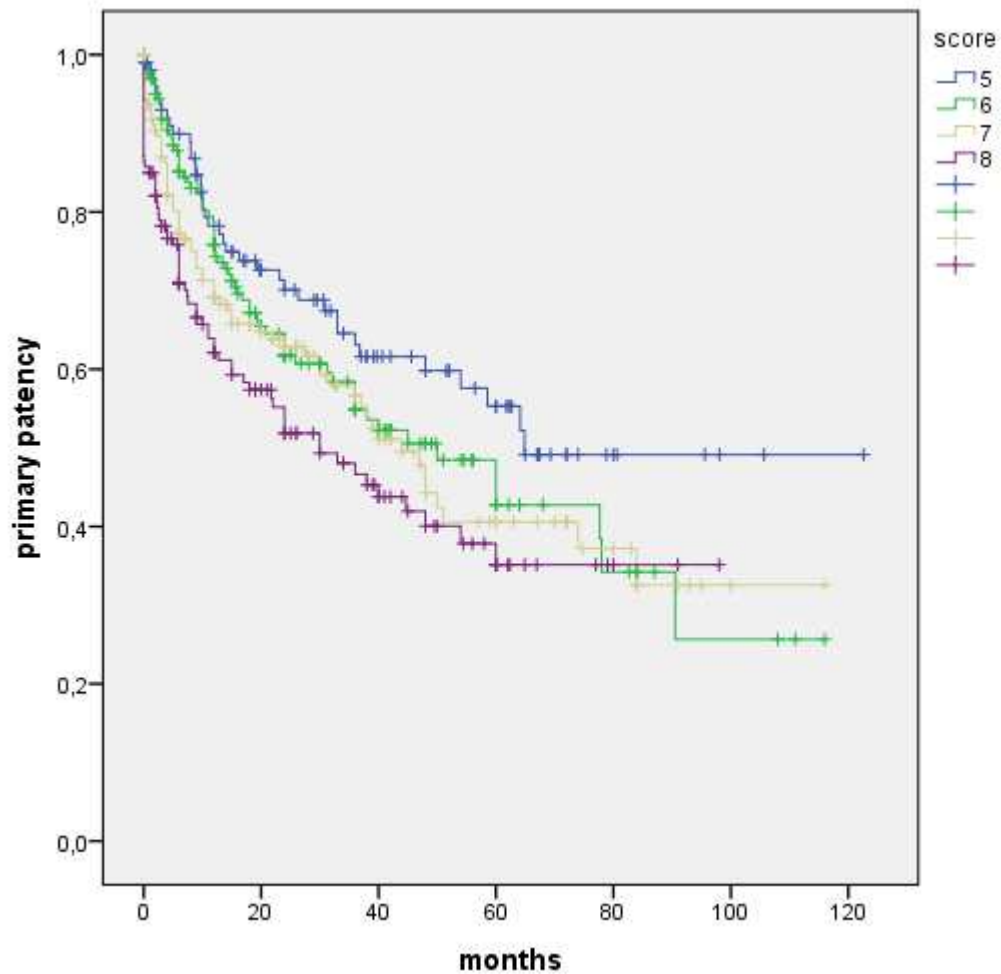
Gender	Male 1 point	Female 2 points	-
Reintervention	No 1 point	Yes 2 points	-
Tibial anastomosis	No 1 point	Yes 2 points	-
Run-off score	2 vessels 2 points	<2 vessels 3 points	
Rutherford class	Class 4 1 point	Class 5 2 points	Class 6 3 points



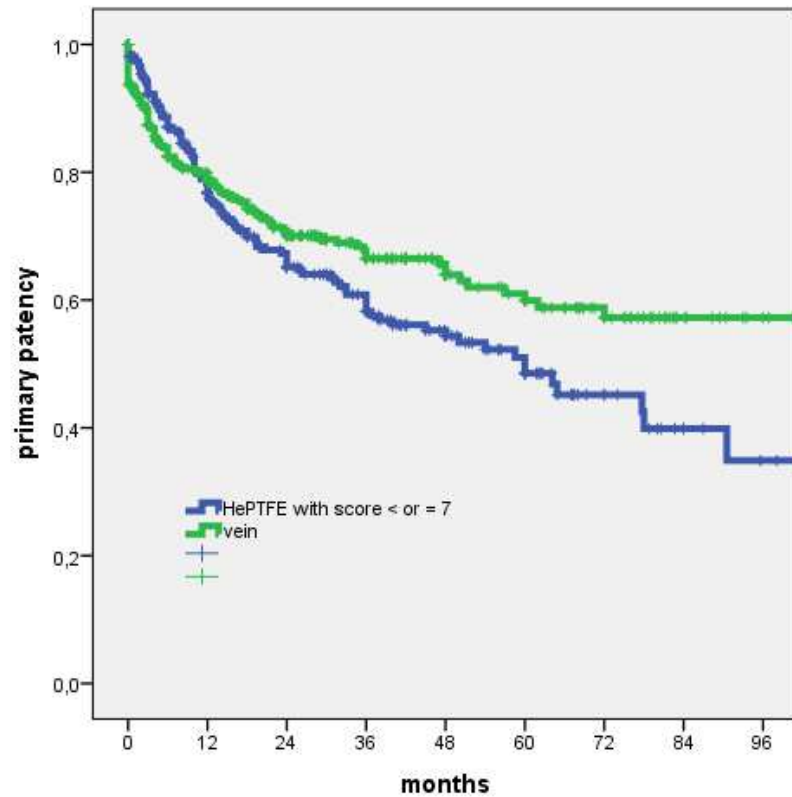
ANOVA test for thrombosis during follow-up found 7.502 as the cut-off score value ($p < 0.001$; $R = 0.09$).

Propaten© Score

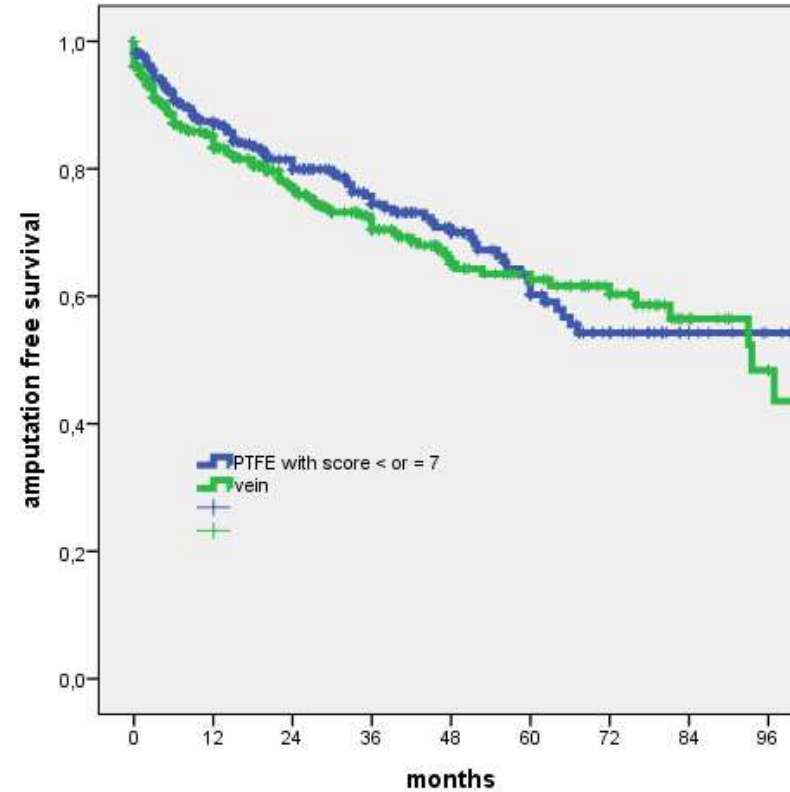
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Propaten© Score



p=0.08; log rank 3.1



p=0.5; log rank 0.3

Heparin bonded graft could challenge endovascular repair for TASC C-D lesions?

- Surgical bypass still offers better results in terms of primary and secondary patency
- The same rate of limb salvage in patients with CLI may suggest a first-line endovascular approach in patient at high surgical risk provided that we accept a lower primary patency rate and a higher reintervention rate

In case of surgical indication

HB PTFE graft:

- Good patency and limb salvage rates
- Vein remains the best choice; however, in case of unsuitable vein, heparin bonded PTFE graft is a good alternative with comparable limb salvage rate.

Can we change the paradigm on the basis of the suggested score ?

Factors				
Gender		Male		Female
Procedure		Primary		Redo
Severity of ischemia		Rest pain		Major tissue loss
Level of distal anastomosis		Popliteal		Tibial
Run-off status		=/> 2 vessels		< 2 vessels



He-bonded Graft



ASV

Can we change the paradigm on the basis of the suggested score ?

