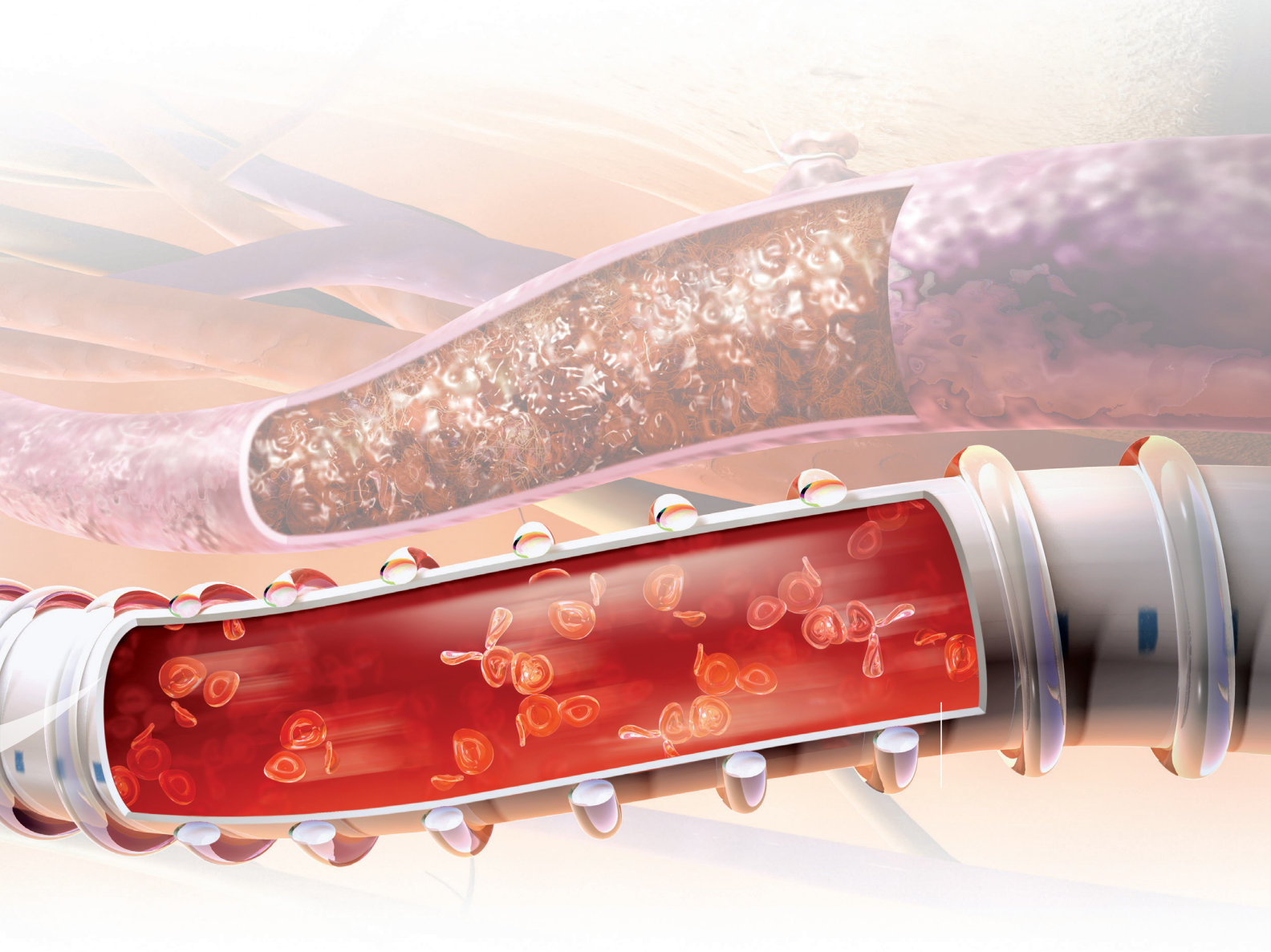


GORE® PROPATEN® Vascular Graft

Proven patency. Measurable value.

LITERATURE SUMMARY

GORE
Creative Technologies Worldwide

Table of contents

Glossary of terms

AK	Above-knee bypass
BK	Below-knee bypass
CBAS	A trademark of Carmeda AB, a wholly owned subsidiary of W. L. Gore & Associates, Inc., referring to the proven heparin bonding technology on GORE® PROPATEN® Vascular Graft
CLI	Critical limb ischemia
ePTFE	Expanded polytetrafluoroethylene
ESRD	End-stage renal disease
HePTFE	Heparin-bonded expanded polytetrafluoroethylene
SFA	Superficial femoral artery
TP trunk	Tibioperoneal trunk

Legend


Retrospective


Prospective

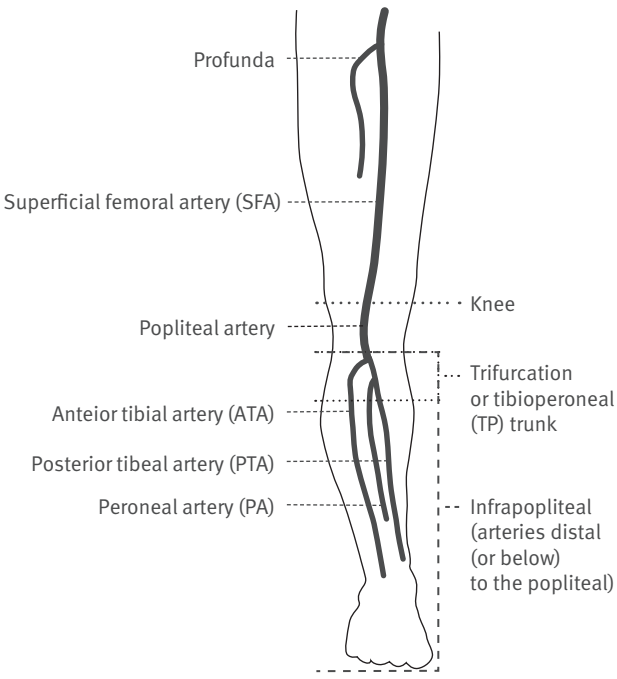

Randomized


Non-randomized


Multicenter

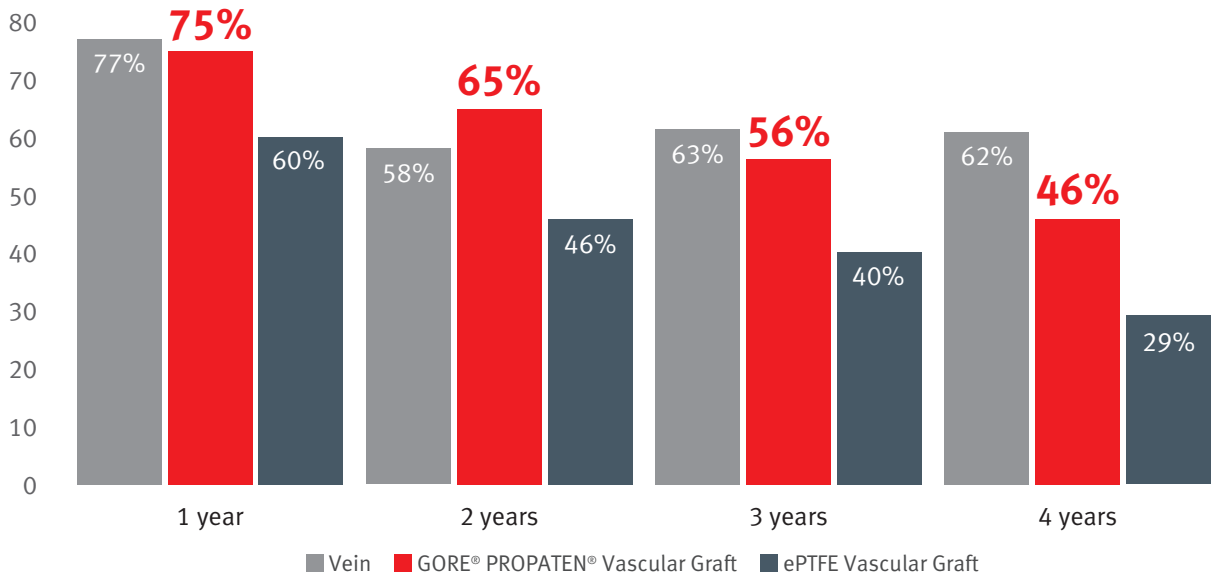

Single-center

Lower limb anatomy



Overall weighted average* primary patency in below-knee bypasses

	1 year	2 years	3 years	4 years
Vein	77%† N = 2,936	58%†,‡ N = 1,272	63%† N = 675	62%†,‡ N = 615
GORE® PROPATEN® Vascular Graft	75%§ N = 971	65%§ N = 782	56%§ N = 703	46%§ N = 693
ePTFE Vascular Graft	60%† N = 2,549	46%† N = 2,249	40%† N = 1,941	29%† N = 599



* Weighted Average $= \dfrac{(N_1 \times \text{Primary Patency}_1) + (N_2 \times PP_2) + \ldots + (N_n \times PP_n)}{N_1 + N_2 + \ldots + N_n}$

† Data based on an analysis of current literature: several MEDLINE® Database searches were performed to identify publications pertaining to ePTFE synthetic vascular graft and vein infragenicular bypasses. Search criteria included (1) articles published from January 2000 to January 2012, (2) key words used were below knee, polytetrafluoroethylene, prosthetic, bypass, patency, (3) articles in English language, (4) N equal or greater than 30 bypasses, (5) clinical publications, (6) reviews, case reports or meta-analysis articles were excluded, (7) articles containing the key word AV access (including synonyms) were excluded. Articles that did not meet the above criteria were deemed ineligible for this analysis. (data on file 2019; W. L. Gore & Associates, Inc; Flagstaff, AZ.)

‡ In studies where 1-year and 3-year patency data were reported, but 2-year patency data were not reported, the 2-year patency rate used in this analysis was interpolated as the average of the 1-year and 3-year patency rates.

§ Below-knee (BK) inclusion criteria for GORE® PROPATEN® Vascular Graft literature used in this analysis were (1) articles in English language, (2) clinical journal articles or book chapters, (3) non-overlapping patient populations, (4) BK bypass primary patency reported for at least 12 months of follow-up and (5) N = 50 or more BK bypasses. Additional exclusion criteria were (1) reviews, case reports or meta-analysis articles and (2) articles containing the key word AV access (including synonyms). (data on file 2019; W. L. Gore & Associates, Inc; Flagstaff, AZ.)

Comparison of propaten heparin-bonded vascular graft with distal anastomotic patch versus autogenous saphenous vein graft in tibial artery bypass[1]

Kaisar et al. 2018
Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston, TX, USA

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years	3 years	4 years
Infrapopliteal N = 62	85%	71%	64%	57%

Patient characteristics*

Rutherford classification

	N	%
2	1	2
3	20	32
4	15	24
5	18	29
6	8	13

Bypass indication

	N	%
Claudication	10	16
Rest pain	23	37
Tissue loss	29	47

Hypertension	Diabetes	Renal failure
74%	52%	15%
N = 46	N = 32	N = 9

Distal anastomotic vessel

	N	%
TP trunk	9	15
Anterior tibial	14	23
Posterior tibial	22	36
Peroneal	17	27

Study details

- Retrospective, non-randomized, single-center analysis of prospectively collected data
- All GORE® PROPATEN® Vascular Graft bypasses utilized a distal patch using either autologous vein (58%) or bovine pericardium (42%)
- All grafts were 6 mm diameter
- Wound care techniques included aggressive wound debridement, negative-pressure wound closure and intravenous antibiotics
- Compared to autologous vein, patients receiving a GORE® PROPATEN® Vascular Graft experienced a shorter operative time and length of hospital stay, although the difference did not reach a statistical significance
- No statistically significant difference in primary patency, secondary patency, or limb salvage between patients receiving autologous vein and GORE® PROPATEN® Vascular Graft at 4 years

* GORE® PROPATEN® Vascular Graft group.

"Propaten grafts [GORE® PROPATEN® Vascular Graft] with distal anastomotic patch have similar clinical outcomes compared to the saphenous vein graft in tibial artery bypass. Our data support the use of Propaten graft [GORE® PROPATEN® Vascular Graft] with distal anastomotic patch as a viable conduit of choice in patients undergoing tibial artery bypass." *— J. Kaisar*

Comparison of venous and HePTFE tibial and peroneal bypasses in critical limb ischemia patients unsuitable for endovascular revascularization[2]

Uhl et al. 2015
Department of Vascular Surgery, Krankenhaus Barmherzige Brüder, Regensburg, Germany

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years	3 years
Infrapopliteal N = 89	64%	43%	34%

Patient characteristics

Rutherford classification

	N	%
4	23	26
5	66	74
6	7	8

CLI **100%** N = 89

Hypertension **90%** N = 80

Diabetes **46%** N = 41

Renal insufficiency **46%** N = 41

Prior operation **48%** N = 43

Distal anastomotic vessel

	N	%
TP trunk	4	5
Anterior tibial	52	67
Posterior tibial	12	15
Peroneal	10	13

Study details

- Retrospective, non-randomized, single-center analysis of prospectively collected data
- GORE® PROPATEN® Vascular Graft was utilized in patients lacking an adequate autologous vein (diameter less than 3 mm or more than two vein segments required to achieve needed length)
- 30-day mortality and major amputation rates were both 7%
- Survival rates at 1 year and 3 years were 77% and 47%, respectively

"The results of our study show that autologous vein grafts are still first choice for tibial and peroneal bypasses in patients with critical limb ischemia. If no adequate vein is available, heparin-bonded expanded polytetrafluoroethylene bypasses are an acceptable alternative to an otherwise impending major amputation." *— C. Uhl*

Heparin-bonded ePTFE (Propaten): is it as good as autologous vein for tibial bypass?[3]

Neville et al. 2014
Division of Vascular Surgery, George Washington University, Washington, DC, USA

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year
Infrapopliteal N = 62	75%

Patient characteristics*

Rutherford classification

	N	%
3	5	8
4	17	27
5	30	48
6	10	16

Hypertension **73%** N = 45

Diabetes **47%** N = 29

ESRD **13%** N = 8

Prior bypass **44%** N = 27

Distal anastomosis

	N	%
Anterior tibial	15	24
Posterior tibial	22	35
Peroneal	21	34
Dorsalis pedis	4	6

* GORE® PROPATEN® Vascular Graft group.

Study details

- Retrospective, non-randomized, single-center study
- Comparing GORE® PROPATEN® Vascular Graft to great saphenous vein
- Distal vein patch was used at all distal anastomoses
- There was no statistically significant difference in primary patency or limb salvage between GORE® PROPATEN® Vascular Graft and single-segment great saphenous vein

"This experience with heparin-bonded ePTFE grafts for solely tibial artery bypass yielded patency and limb salvage rates that are comparable to intact great saphenous vein." — *R. Neville*

"We believe that a quality saphenous vein remains the ideal conduit for tibial bypass, although HePTFE should be considered when intact ipsilateral or contralateral vein is not available. In our practice, HePTFE has emerged as the choice over arm vein, especially in the ESRD patient who needs upper extremity vein for dialysis access. We would also choose HePTFE over composite short saphenous vein given the increased dissection required and length of conduit." — *R. Neville*

Subpopliteal revascularization. Criteria analysis for the use of E-PTFE (Propaten®) as first choice conduit[4]

Monaca et al. 2013
Vittorio Emanuele Policlinic University Hospital, Presidio Ospedaliero “Ferrarotto”, Catania, Italy

Primary patency of GORE® PROPATEN® Vascular Graft

	5 years	9 years
Infrapopliteal N = 212	52%	41%

Patient characteristics

Rutherford classification

	N	%
3	87	41
4	91	43
5	34	16

Hypertension	Diabetes	Renal failure
88%	41%	18%
N = 187	N = 87	N = 38

Proximal anastomosis

	N	%
Common femoral artery	212	100

Distal anastomosis

	N	%
BK popliteal	154	73
TP trunk	58	27

Study details

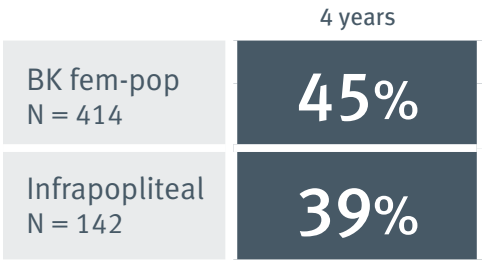
- Retrospective, non-randomized, multicenter analysis
- Patients were considered at a low risk for thrombosis: Exclusion criteria included re-do operations, poor plantar and perimalleolar circulation, severe tissue loss and single-vessel runoff
- Secondary patency at 5 and 9 years was 58% and limb salvage at 5 and 9 years was 93%

“...in low thrombotic risk patients mid-and long-term patency of vein and Propaten® graft [GORE® PROPATEN® Vascular Graft] is comparable. In case of PTFE use, we reported shorter surgery time, reduced hospital stay and wound complications. These observations led us to primarily choose the prosthetic graft in that subset of cases, saving the VSG [great saphenous vein] for distal revascularization in case of occlusive disease progression.” — *V. Monaca*

Results from an Italian multicentric registry comparing heparin-bonded ePTFE graft and autologous saphenous vein in below-knee femoro-popliteal bypasses[5]

Dorigo et al. 2012
Department of Vascular Surgery, University of Florence, Florence, Italy

Primary patency of GORE® PROPATEN® Vascular Graft



Patient characteristics

Arterial hypertension
87%
N = 482

Diabetes
46%
N = 253

Chronic renal failure
15%
N = 82

History of smoking
72%
N = 403

	N	%
Hyperlipemia	330	59
Coronary artery disease	251	45
BK fem-pop	414	75
Infrapopliteal	142	26
TP trunk	69	13
Anterior tibial	27	5
Posterior tibial	35	6
Peroneal	11	2

Study details

- Retrospective, non-randomized, multicenter analysis
- Comparing GORE® PROPATEN® Vascular Graft and autologous saphenous vein
- There was no statistically significant difference in secondary patency or limb salvage between GORE® PROPATEN® Vascular Graft and autologous saphenous vein

"...we had a 13% increase in secondary patency rates in ePTFE group, whereas the corresponding figure was only 6% in patients with occluded vein, thus confirming both the possibility of effectively treating occluded heparin-bonded grafts and the difficulty of dealing with occluded vein bypasses." — *W. Dorigo*

"In patients with critical limb ischemia, the rates both of amputations at 4 years and of amputation-free survival were not different between autologous vein and heparin-bonded ePTFE... and this is an encouraging result, considering that limb salvage probably represents the main outcome in all these critical patients." — *W. Dorigo*

Midterm results from a multicenter registry on the treatment of infrainguinal critical limb ischemia using a heparin-bonded ePTFE graft[6]

Pulli et al. 2010
Department of Vascular Surgery, University of Florence, Italy

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years	3 years
BK fem-pop N = 238	75%	67%	61%
Infrapopliteal N = 86	66%	57%	52%

Patient characteristics*

Rutherford classification

	N	%
4	230	54
5	143	34
6	52	12

Vessel runoff

	N	%
0 – 1	186	44
2 – 3	239	56

	N	%
Arterial hypertension	367	86
History of smoking	326	77
Diabetes	192	45
Chronic renal failure	72	17
Out-flow procedures		
Vein cuff	45	11
Patching	23	5
Tibial angioplasty	5	1
Other procedures	12	3

* Total N = 425.

Study details

- Retrospective, non-randomized, multicenter study
- All patients had CLI
- Combined fem-pop and infrapopliteal limb salvage rate at 3 years was 81% in these CLI patients

"...the good results at 3 years in primary interventions in patients with more than one distal vessel and with rest pain could suggest a significant role of the heparin-bonded graft in these subgroups of patients." — *R. Pulli*

"Primary and secondary patency rates make this graft an excellent alternative to autologous saphenous vein when it is absent, unsuitable, or of poor quality." — *R. Pulli*

Heparin-bonded ePTFE grafts compared with vein grafts in femoropopliteal and femorocrural bypasses: 1- and 2-year results[7]

Daenens et al. 2009
University Hospital Gasthuisberg, Belgium

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years
BK fem-pop N = 57	92%	83%
Infrapopliteal N = 97	79%	69%

Patient characteristics

Rutherford classification

	N	%
3	63	26
4	60	25
5	84	35
6	17	7

Smokers

62%

N = 149

	N	%
BK fem-pop	57	37
Infrapopliteal	97	63
TP trunk	10	10
Anterior tibial	37	38
Posterior tibial	29	30
Peroneal	21	22

Study details

- Retrospective, non-randomized, single-center study
- Compared results from GORE® PROPATEN® Vascular Graft to autologous vein bypasses
- Adjunctive techniques:
  - Below-knee fem-pop: 2 Miller cuff, 2 Taylor patch, 2 Linton patch
  - Below-knee fem-distal: 11 Miller cuff, 3 Taylor patch, 7 Linton patch, 15 AV fistula
- The 2-year limb salvage rates for below-knee fem-pop and fem-distal bypasses were 98% and 87%, respectively
- 2-year autologous vein patency rates for below-knee fem-pop and fem-distal were 72% and 64%, respectively

"In this large retrospective study, heparin-bonded ePTFE grafts had 1- and 2-year primary patency results that were not significantly different from those for ASV grafts. Results in BK FP and FC applications were especially promising." — *K. Daenens*

"Overall, our results...provide solid additional evidence that heparin-bonded ePTFE grafts represent an important new option in the treatment of peripheral arterial disease."
— *K. Daenens*

PEPE II — A multicenter study with an end-point heparin-bonded expanded polytetrafluoroethylene vascular graft for above and below knee bypass surgery: determinants of patency[8]

Hugl et al. 2009
Department of Vascular Surgery, Medical University, Innsbruck, Austria

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year
BK fem-pop N = 37	74%
Infrapopliteal N = 15	79%

Patient characteristics*

Fontaine classification stage

	N	%
Stage 1	1	< 1
Stage II	62	45
Stage III	26	19
Stage IV	50	36

Vessel runoff

	N	%
1	40	29
2	50	36
3	47	34

Hypertension	Diabetes	Current tobacco use
71%	42%	42%
N = 98	N = 59	N = 58

* Total N = 139, which includes 87 patients with above knee bypasses.

Study details

- Prospective, non-randomized, multicenter study
- Patients without suitable autologous vein
- The 1-year secondary patency rates for below-knee fem-pop and infrapopliteal bypasses were 79% and 85%, respectively
- Overall 1-year patency and limb salvage rates were 80% and 96%, respectively*

"...present data show that using the endpoint heparin bonded ePTFE graft for lower limb revascularization produces excellent results for AK bypasses and encouraging results for BK bypasses, when compared with data obtained from studies which used other prosthetic material. These encouraging results for BK bypasses were even seen in the subgroup of patients that generally have worse revascularization results due to the presence of risk factors." — *B. Hugl*

"...our data suggests that the use of this graft is an excellent option when no autologous vein is available." — *B. Hugl*

Heparin-bonded expanded polytetrafluoroethylene graft for infragenicular bypass: five-year results[9]

Lösel-Sadée & Alefelder. 2009
Department of Vascular Surgery, Sana Kliniken Dusseldorf, Dusseldorf, Germany

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years	3 years	4 years	5 years
BK fem-pop N = 30	77%	71%	71%	71%	71%
Infrapopliteal N = 45	64%	57%	50%	50%	50%

Patient characteristics*

Rutherford classification

	N	%
3	6	8
4	43	57
5	25	33
6	1	< 1

Vessel runoff

	N	%
1	41	55
2	18	24
3	16	21

Hypertension	Diabetes	Renal insufficiency
96%	49%	31%
N = 72	N = 37	N = 23

	N	%
BK fem-pop*	30	40
Infrapopliteal	45	60
TP trunk	12	27
Anterior tibial	14	31
Posterior tibial	9	2
Peroneal	9	2
Dosalis pedis	1	< 1

* Distal of the knee articulation.

Study details

- Retrospective, non-randomized, single-center study
- Vein cuffs were created at the distal anastomosis in 5 patients; no patches were used
- The 3- and 4-year secondary patency rates for below-knee fem-pop and infrapopliteal bypasses were 83% and 72%, respectively
- The 5-year limb salvage rate was 84%

"The primary patency results are especially encouraging in light of the fact that the patients were seriously ill, as indicated by the high rates of Rutherford category 4 to 6 disease, renal insufficiency, and previous treatment for PAD and the low rate of multiple-vessel runoff in the series."

— H. Lösel-Sadée

Will heparin-bonded PTFE replace autologous venous conduits in infrapopliteal bypass?[10]

Peeters et al. 2008
Department of Cardiovascular and Thoracic Surgery, Imelda Hospital, Bonheiden, Belgium

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years	3 years
BK fem-pop N = 41	86%	79%	75%
Infrapopliteal N = 37	71%	60%	60%

Patient characteristics*

Rutherford classification

	N	%
3	85	56
4	29	19
5	39	26

Vessel runoff

	N	%
0	7	5
1	76	50
2	43	28
3	27	18

Hypertension	Diabetes	Renal insufficiency
64%	27%	9%
N = 88	N = 37	N = 12

	N	%
BK fem-pop	41	53
Infrapopliteal	37	47
TP trunk	11	30
Anterior tibial	10	27
Posterior tibial	10	27
Peroneal	6	16

* Limb salvage rates are for both above knee and below-knee bypasses.

Study details

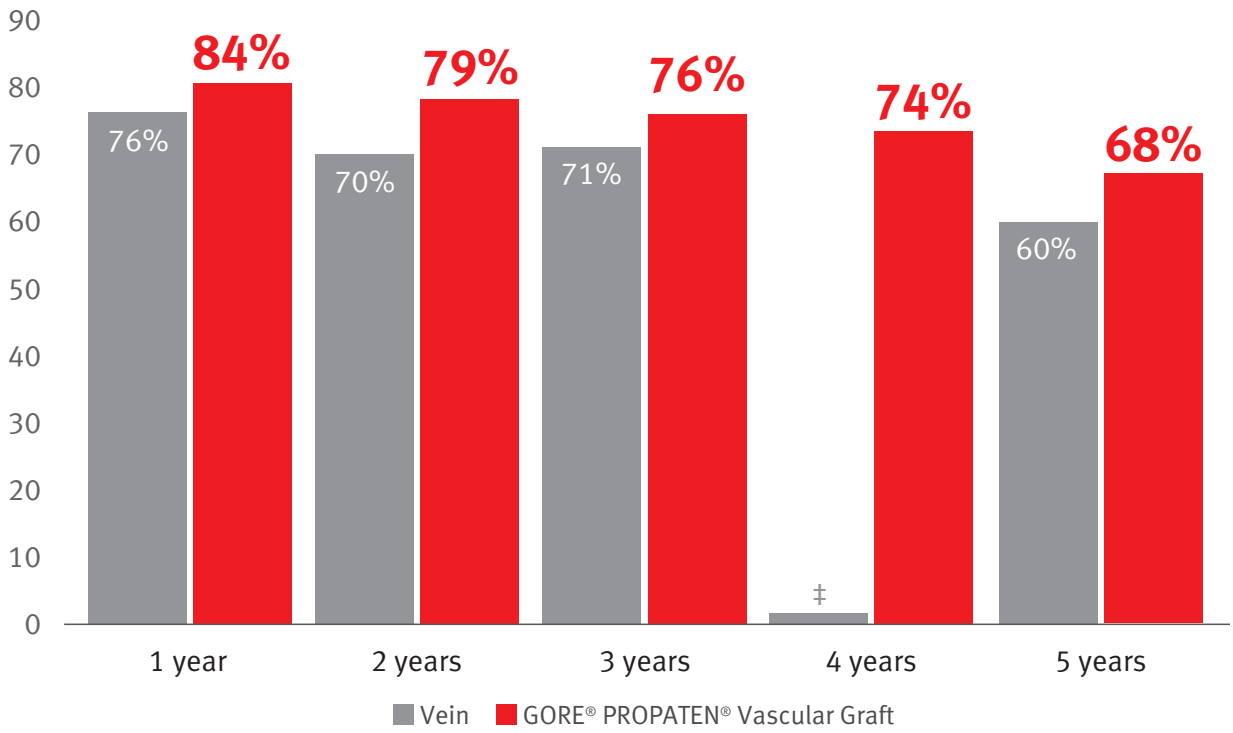
- Prospective, non-randomized, multicenter study
- No adjunctive techniques (patches or cuffs) were used in the study
- The 3-year secondary patency rate for below-knee fem-pop and infrapopliteal bypasses were 80% and 62%, respectively
- The 3-year limb salvage rate for all CLI patients was 86%*

"Propaten® Vascular Graft [GORE® PROPATEN® Vascular Graft] may succeed in bridging the gap between venous and regular PTFE bypass...especially for infrapopliteal bypasses."

— P. Peeters

Overall weighted average* primary patency in above-knee bypasses†

	1 year	2 years	3 years	4 years	5 years
Vein	**76%** N = 242	**70%** N = 236	**71%** N = 109	‡	**60%** N =95
GORE® PROPATEN® Vascular Graft	**84%** N = 860	**79%** N = 606	**76%** N = 520	**74%** N = 445	**68%** N = 445



$$\text{* Weighted Average} = \frac{(N_1 \times \text{Primary Patency}_1) + (N_2 \times PP_2) + \ldots + (N_n \times PP_n)}{N_1 + N_2 + \ldots + N_n}$$

† Above-knee (AK) inclusion criteria for GORE® PROPATEN® Vascular Graft literature used in this analysis were (1) articles in English language, (2) clinical journal articles or book chapters, (3) non-overlapping patient populations and (4) AK bypass primary patency reported for at least 12 months of follow-up. Additional exclusion criteria were (1) reviews, case reports or meta-analysis articles and (2) articles containing the key word AV access (including synonyms). (data on file 2019; W. L. Gore & Associates, Inc; Flagstaff, AZ.)

‡ No data available.

Results from a multicenter registry of heparin-bonded expanded polytetrafluoroethylene graft for above-the-knee femoropopliteal bypass?[11]

Piffaretti et al. 2018
Università degli studi dell'Insubria, Varese, Italy

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years	3 years	4 years	5 years
AK fem-pop N = 360	82%	78%	74%	71%	64%

Patient characteristics

Rutherford classification

	N	%
3	200	55
4	86	24
5	68	18
6	10	3

Hypertension
81%
N = 294

Diabetes
39%
N = 141

History of smoking
59%
N = 216

Study details

- Retrospective, non-randomized, multicenter analysis
- At the time of publication, the GORE® PROPATEN® Vascular Graft Italian registry had tracked 1,401 interventions performed for peripheral arterial obstructive disease using GORE® PROPATEN® Vascular Graft in a "real-world" setting
- Estimated survival at 5 years was 75%
- Estimated amputation-free survival at 5 years was 74%
- Estimated assisted primary patency, secondary patency and limb salvage at 5 years were 65%, 75% and 95%, respectively
- Postoperative medical treatment with warfarin alone was found to be an independent risk factor for loss of primary patency compared to dual antiplatelet therapy

"[Above-the-knee femoropopliteal bypass] with the use of HB-ePTFE remains an effective option, with low rate of perioperative complications and satisfactory long-term results."
— G. Piffaretti

"...in our opinion, "[Above-the-knee femoropopliteal bypass] is a valid and viable first-line alternative to endovascular surgery in long or complex lesions of the SFA." *— G. Piffaretti*

Heparin-bonded expanded polytetrafluoroethylene femoropopliteal bypass grafts outperform expanded polytetrafluoroethylene grafts without heparin in a long-term comparison[12]

Samson et al. 2016
Sarasota Vascular Specialists in Sarasota, Florida, USA

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years	3 years	4 years	5 years
AK fem-pop N = 87	92%	85%	85%	85%	85%

Patient characteristics*

	N	%
Gangrene	27	20
Ulceration	39	30
Rest pain	40	30
Claudication	43	33

Runoff vessels*

	N	%
0	2	2
1	44	37
2	49	41
3	24	20

Hypertension	Diabetes	Smoking
84%	45%	32%
N = 110	N = 59	N = 42

* GORE® PROPATEN® Vascular Graft group.

Study details

- Retrospective, non-randomized, single-center review of prospectively collected data
- No adjunctive technique (patches or cuffs) were used
- Most grafts were 6 mm ring reinforced
- PLAVIX® Clopidogrel Bisulfate usage had a significant benefit on overall primary patency
- Loss of patency was found to be related to younger age, absence of claudication, isolated popliteal artery and lower post-operative ABI
- As early as 3 months, a significant difference in patency favoring GORE® PROPATEN® Vascular Graft was seen and was maintained at 5 years (75% versus 56%) and in both AK (85% versus 59%) and BK (60% versus 0%/undeterminable) locations

"These data show that the Propaten HePTFE graft [GORE® PROPATEN® Vascular Graft] offered significantly better long-term patency over the SePTFE graft, suggesting Propaten [GORE® PROPATEN® Vascular Graft] as the prosthetic graft of choice for bypasses to the femoropopliteal artery when autologous vein is unavailable or inappropriate." — *R. Samson*

"Propaten HePTFE grafts [GORE® PROPATEN® Vascular Grafts] seem to be as effective as vein for AK femoropopliteal artery bypass. Because of the excellent results observed in this series, we now use the Propaten graft [GORE® PROPATEN® Vascular Graft] preferentially over great saphenous vein for AK bypass except in younger patients with available appropriate autologous conduit." — *R. Samson*

The Scandinavian Propaten® Trial — 1-year patency of PTFE vascular prostheses with heparin-bonded luminal surfaces compared to ordinary pure PTFE vascular prostheses — a randomized clinical controlled multi-centre trial[13]

Lindholt et al. 2011
Vascular Research Unit, Department of Vascular Surgery, Viborg Hospital, Denmark

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year
AK fem-pop N = 112	81%

Patient characteristics*

Smokers
53%
N = 144

Diabetes
15%
N = 39

Critical limb ischemia (CLI)
36%
N = 100

* GORE® PROPATEN® Vascular Graft group, N = 272, which includes 160 patients with fem-fem bypass.

Study details

- Prospective, randomized, multicenter (11 centers) study comparing GORE® PROPATEN® Vascular Graft versus standard ePTFE
- Fem-pop (majority above-knee) and fem-fem bypasses
- Statistically significant improvement in primary and secondary patency with GORE® PROPATEN® Vascular Graft versus standard ePTFE for all bypasses
- In fem-pop patients with CLI, GORE® PROPATEN® Vascular Graft primary patency was 80% while standard ePTFE patency was 58% ($P < 0.05$)
- GORE® PROPATEN® Vascular Graft reduced the risk of graft occlusion by 40% overall and by 50% in patients with CLI

"We have seen that the GORE® PROPATEN® Vascular Graft keeps its promise as shown in previously conducted prospective and retrospective studies."

— J. Lindholt

Heparin-bonded ePTFE grafts compared with vein grafts in femoropopliteal and femorocrural bypasses: 1- and 2-year results[7]

Daenens et al. 2009
University Hospital Gasthuisberg, Belgium

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years
AK fem-pop N = 86	92%	83%

Patient characteristics*

Rutherford classification

	N	%
3	63	26
4	60	25
5	84	35
6	17	7

Smokers
62%
N = 149

Redo bypass
36%
N = 86

Study details

- Retrospective, non-randomized, single-center study
- Study compared results from GORE® PROPATEN® Vascular Graft to autologous vein bypasses
- The 1- and 2-year primary patency rates for above-knee fem-pop bypasses using autologous vein were 91% and 80%, respectively

* GORE® PROPATEN® Vascular Graft group, N = 240.

"Overall, our results...provide solid additional evidence that heparin-bonded ePTFE grafts represent an important new option in the treatment of peripheral arterial disease."

— K. Daenens

Will heparin-bonded PTFE replace autologous venous conduits in infrapopliteal bypass?[10]

Peeters et al. 2008
Department of Cardiovascular and Thoracic Surgery, Imelda Hospital, Bonheiden, Belgium

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year	2 years	3 years
AK fem-pop N = 75	81%	78%	75%

Patient characteristics*

Rutherford classification*

	N	%
3	85	56
4	29	19
5	39	25

Runoff vessels*

	N	%
0	7	5
1	76	50
2	43	28
3	27	18

Diabetes*
27%
N = 37

Hypertension†
64%
N = 88

Coronary artery disease
30%
N = 42

Nicotine use†
48%
N = 66

Study details

- Prospective, non-randomized, multicenter study
- No adjunctive techniques (patches or cuffs) were used in the study
- 73% of patients had been previously treated for peripheral vascular disease (PVD)
- The 3-year limb salvage rate for all CLI patients was 86%‡

* Total N = 153 limbs.
† Total N = 138, which includes 97 patients that underwent below-knee bypasses.
‡ Limb salvage rates are for both above and below-knee bypasses.

"...it is our opinion that the Propaten Vascular Graft [GORE® PROPATEN® Vascular Graft] may succeed in bridging the gap between venous conduits and regular ePTFE grafts."

— P. Peeters

Heparin-bonded expanded polytetrafluoroethylene vascular graft for femoropopliteal and femorocrural bypass grafting: 1-year results[14]

Bosiers et al. 2006
Dendermonde, Bonheiden, and Genk, Belgium

Primary patency of GORE® PROPATEN® Vascular Graft

	1 year
AK fem-pop N = 55	84%

Patient characteristics*

Rutherford classification*

	N	%
3	58	58
4	16	16
5	26	26

Runoff vessels*

	N	%
0	7	7
1	51	51
2	21	21
3	21	21

Hypertension†	Diabetes†	Renal insufficiency†
72%	28%	9%
N = 62	N = 24	N = 8

Study details

- Prospective, non-randomized, multicenter study
- All grafts were thin-wall, ringed, 6 mm diameter configurations
- Angiography performed immediately after graft implantation to detect technical failures
- Postoperatively, patients received PLAVIX® Clopidogrel Bisulfate usage (75 mg/day) for the first month after surgery, low-molecular-weight heparin (0.6 mL/day) for the first three weeks and ASPIRIN Acetylsalicylic Acid (100 mg/day) indefinitely
- 96% secondary patency at one-year for above-knee fem-pop bypass

* N = 100 limbs.

† N = 86 patients.

"In the light of these in vivo results, we speculate that a decrease in platelet and thrombus deposition on the CBAS ePTFE graft surface may have contributed to the promising 1-year patency rates in our clinical series. Although amelioration of intimal hyperplasia is not the primary target of heparinization technology, it is intriguing to consider the possibility that the CBAS graft surface might simultaneously address two sources of graft failure: thrombosis and intimal hyperplasia." — *M. Bosiers*

"Our findings… indicate that use of this graft is an excellent option for infrainguinal bypass grafting in patients with peripheral vascular disease when autologous vein is not available." — *M. Bosiers*

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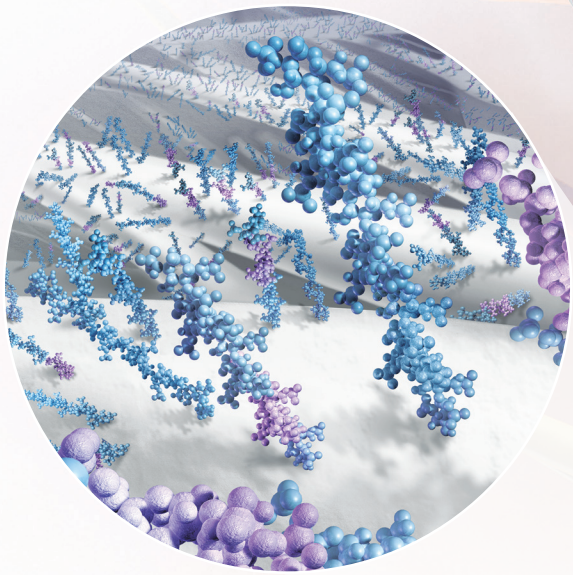
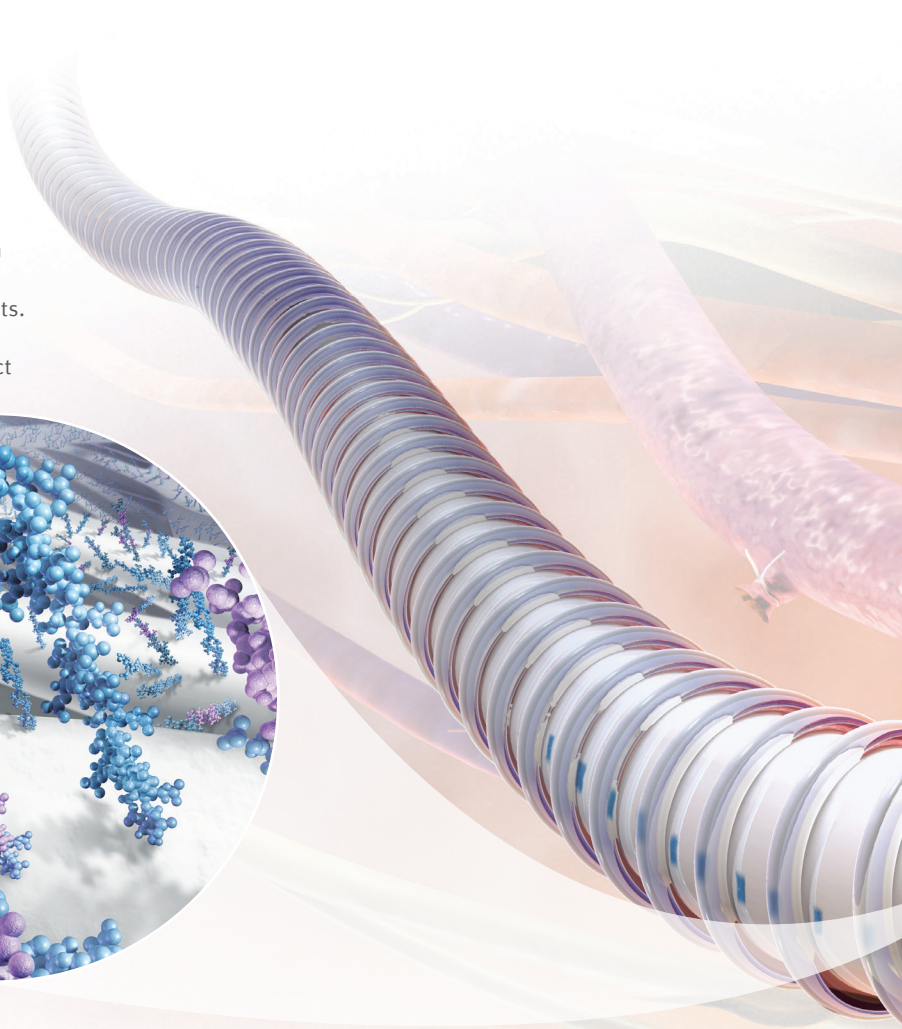
Features Gore's CBAS Heparin Surface, the proven heparin bonding technology for lasting thromboresistance, used in many of Gore's interventional and vascular surgery products. End-point covalent bonding keeps heparin anchored to the graft surface, while the bioactive site remains free to interact with the blood to help prevent clotting.[15]





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Consult Instructions for Use
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INDICATIONS FOR USE: GORE® PROPATEN® Vascular Grafts are intended for use as vascular prostheses for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures. **CONTRAINDICATIONS:** A. DO NOT use the GORE® PROPATEN® Vascular Graft in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. B. DO NOT use any configuration of GORE® PROPATEN® Vascular Grafts with Removable Rings, Non-Removable Rings or Integrated Rings for coronary artery bypass or cerebral reconstruction procedures. C. DO NOT use GORE® PROPATEN® Vascular Grafts as a patch. If cut and used as a patch, GORE® PROPATEN® Vascular Grafts may lack adequate transverse strength. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

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