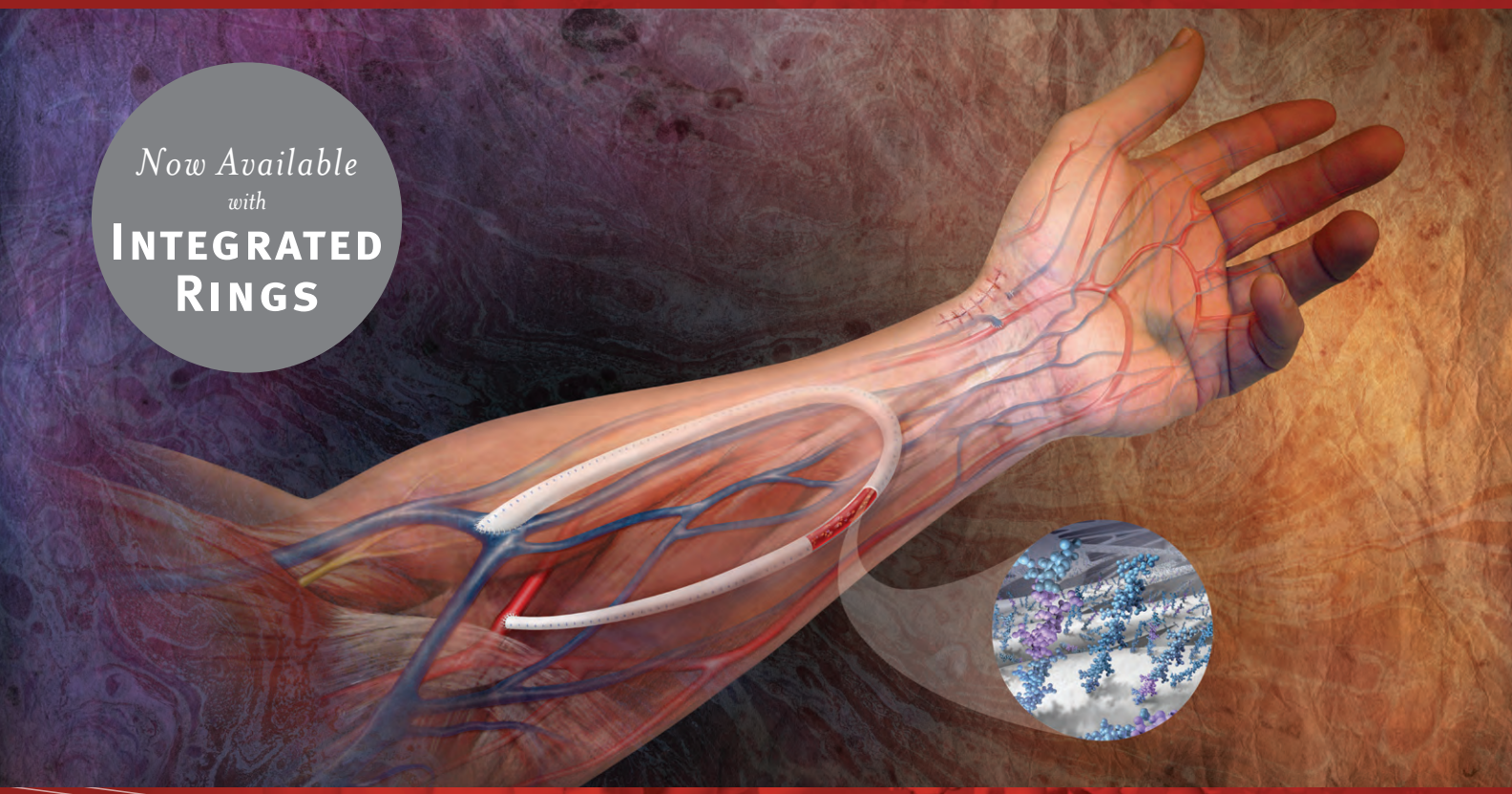
Transcending Mechanical Solutions

for Dialysis Access



PERFORMANCE through innovation

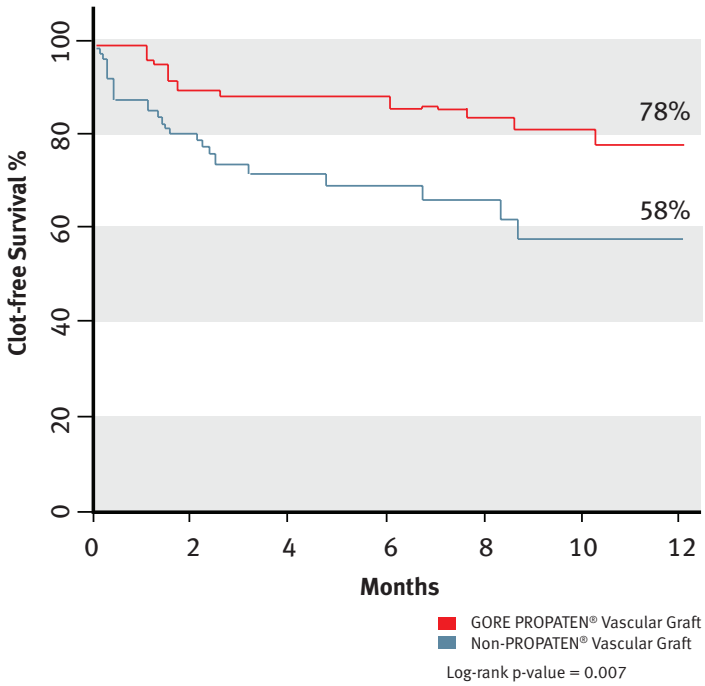
GORE PROPATEN® VASCULAR GRAFT

Clinical Experience

GORE PROPATEN® Vascular Graft (n = 83), Standard ePTFE (n = 67)*

— Ingemar Davidson, MD [1]
UT Southwestern
Dallas, Texas

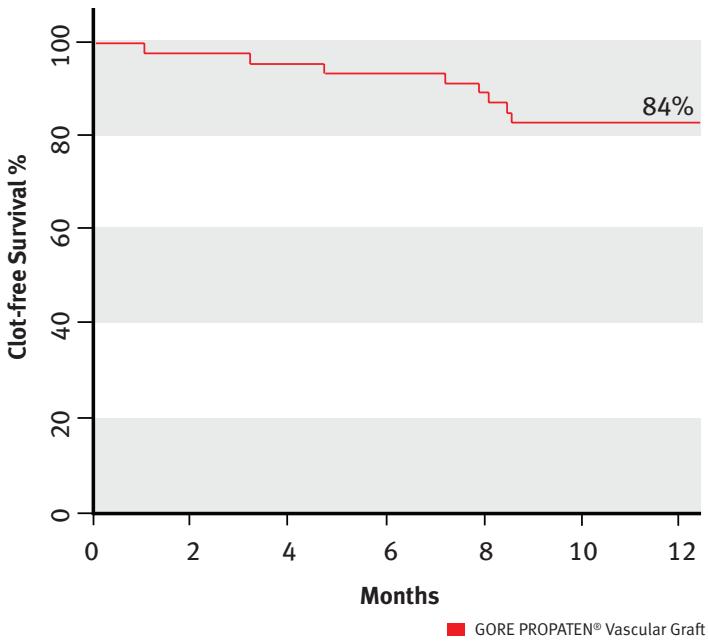
Significant 20% improvement in clot-free survival as compared to the control group.



GORE PROPATEN® Vascular Graft (n = 49)*

— John Ross, MD
Bamberg Community Hospital
Bamberg, South Carolina

In the presence of stenosis prevention or delay of thrombosis provides the opportunity to treat a failing graft rather than a failed graft. This may mean a simpler intervention that can be a scheduled elective event rather than an emergent treatment.



* Clot-free survival is defined as grafts without thrombosis

GORE PROPATEN® Vascular Graft (n = 24), Standard ePTFE (n = 29)

— David Shemesh, MD [2]
Shaare Zedek Medical Center
Jerusalem, Israel

[GORE] Propaten [Vascular] graft may have a better primary and secondary patency rate and lower thrombosis rate compared with standard ePTFE.

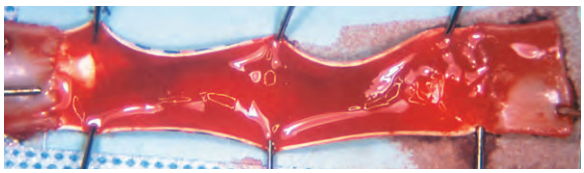
Study Results

	Standard ePTFE	GORE PROPATEN® Vascular Graft
n	29	24
Thrombosis n	11 (38%)	5 (21%)
Interventions n	19	8
Interventions per Patient Year	2.6	0.8

Addressing Vascular Graft Failure Modes

Thrombosis — Begovac, *et al.* [3]

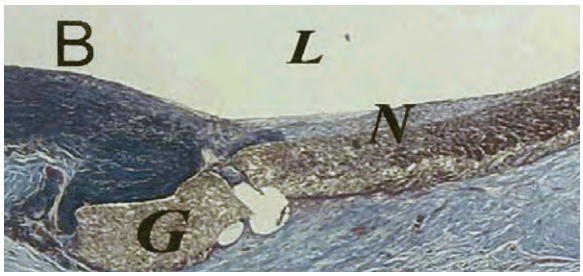
GORE PROPATEN® Vascular Graft



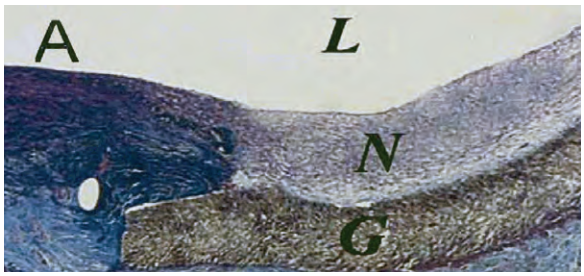
Control ePTFE Graft

The bioactive luminal surface of a 3 mm diameter GORE PROPATEN® Vascular Graft remains free of thrombus, while the non-bioactive surface of a control graft (3 mm diameter) is covered with thrombus. Grafts were explanted after two hours in a challenging carotid shunt canine model.

Intimal Hyperplasia — Lin, *et al.* [4]



GORE PROPATEN® Vascular Graft

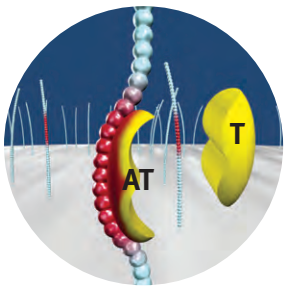


Control ePTFE Graft

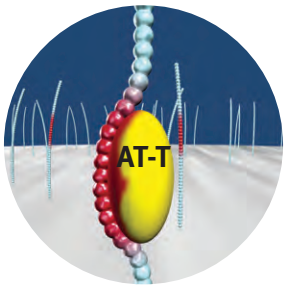
Neointimal hyperplasia at the distal anastomoses of an aortoiliac bypass graft model in baboons. Statistically significant reduction in neointimal hyperplasia at the distal anastomosis was observed for the GORE PROPATEN® Vascular Graft as compared to untreated control ePTFE.

A) Distal anastomosis of untreated control ePTFE graft
B) Distal anastomosis of the GORE PROPATEN® Vascular Graft.
L: Lumen; N: Neointima; G: ePTFE Graft. Collagens are blue, elastin is black, others are red.
(Verhoeff-Masson stain; original magnification X40) Images reproduced with permission from Elsevier.

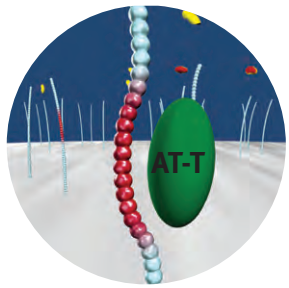
Proprietary End-point Covalent Bonding



- *Heparin molecules are bonded to the graft's luminal surface*
- *Bioactive site of the heparin molecule binds to antithrombin (AT)*



- *Antithrombin binds to thrombin (T) – a neutral AT-T complex is formed*
- *Thrombin loses its ability to catalyze the conversion of fibrinogen to fibrin*



- *Neutral AT-T complex detaches from the heparin molecule*
- *Heparin bioactive site becomes available to again bind antithrombin*

Selected Literature

[1] Davidson I, Hackerman C, Kapadia A, Minhajuddib A. Heparin bonded hemodialysis e-PTFE grafts result in 20% clot free survival benefit. *Journal of Vascular Access* 2009;10(3):153-156.

[2] Shemesh D, Goldin I, Zaghal I, Berelowitz D, Verstandig A, Olsha O. Heparin-bonded graft (PROPATEN®) versus standard graft in prosthetic arteriovenous access. Abstract presented at the 6th International Congress of the Vascular Access Society (VAS); April 20-22, 2009; Rome, Italy. *Journal of Vascular Access* 2009;10(2):100-101.

[3] Begovac PC, Thomson RC, Fisher JL, Hughson A, Gällhagen A. Improvements in GORE-TEX® Vascular Graft performance by Carmeda® bioactive surface heparin immobilization. *European Journal of Vascular & Endovascular Surgery* 2003;25(5):432-437.

[4] Lin PH, Chen C, Bush RL, Yao Q, Lumsden AB, Hanson SR. Small-caliber heparin-coated ePTFE grafts reduce platelet deposition and neointimal hyperplasia in a baboon model. *Journal of Vascular Surgery* 2004;39(6):1322-1328.

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Consult Instructions for Use