

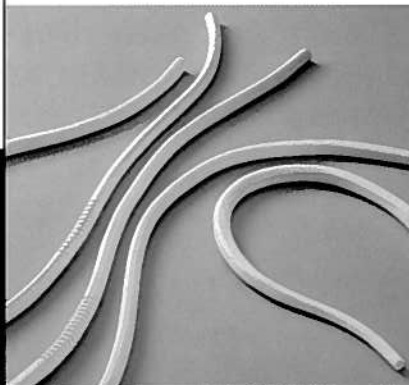


VASCULAR GRAFT



A Summary

CLINICAL
EXPERIENCE
FOR VASCULAR
ACCESS



STATISTICAL SUMMARIES

Cumulative Survival of 446 GORE-TEX® Stretch Vascular Grafts 1991-1997¹

Measure	1 Year	3 Years	5 Years
Primary Patency (Clot-free Survival)	85%	81%	79%
Secondary Patency (Graft Survival)	91%	87%	84%

Table 1

One-Year Primary Patency

Stretch ePTFE Grafts

Author	Number of Grafts	Primary Patency (N)	Primary Patency %
Davidson ²	420	315	75%
Derenoncourt ³	90	70	78%
Hakaim ⁴	79	56	71%
Tordoir ⁵⁻⁶	17	10	59%
Total/Mean	606	451	74%

Table 2

Non-Stretch ePTFE Grafts

Author	Number of Grafts	Primary Patency (N)	Primary Patency %
Mehta ⁷	1,064	649	61%
Derenoncourt	165	96	58%
Tordoir	20	6	30%
Total/Mean	1,249	751	60%

Table 3

Tables 2 & 3 show the stretch ePTFE graft data compared to the non-stretch ePTFE graft data. A consultant in clinical biostatistics* prepared these tables after reviewing the clinical reports. He concluded "...there is a highly significant difference between the groups, in favor of the stretch graft."

*This consultant was funded by W. L. Gore & Associates, Inc.

CLINICAL EXPERIENCE WITH GORE-TEX® STRETCH VASCULAR GRAFTS FOR VASCULAR ACCESS

- ▶ Six authors, 10 papers
- ▶ Over 650 patients
- ▶ One prospective, randomized study, published in a peer-reviewed journal
- ▶ One prospective, nonrandomized study, published in a peer-reviewed journal
- ▶ U.S. and European experience

Authors

Davidson (Dawidson)	Dallas, TX	1993, 1995, 1996, 1999
Simoni	Kalamazoo, MI	1993
Tordoir	Maastricht, Netherlands	1993, 1995
Colonna	Washington, D.C.	1995
Derenoncourt	National City, CA	1995
Hakaim	Jacksonville, FL	1997

IMPROVED INTRAOPERATIVE HANDLING

"... a modification of the ePTFE graft has been introduced with stretch properties leading to improved handling characteristics. . . . The conformability, increased resistance to kinking, and possibly ease of puncture and improved puncture hole healing of this graft might also result in better performance with fewer complications."⁵

"The GORE-TEX® Stretch Vascular Graft offers improved anastomotic conformability during implantation."⁸

"The graft ... maintains a small amount of longitudinal elastic recoil. Early experience with this graft in arterial reconstructive surgery showed a marked reduction in needle hole bleeding."⁹

"The conformability of the graft at the anastomotic sites was seen to be improved compared to standard ePTFE vascular grafts. Once moderately tensioned, the graft retracts slightly, making suturing easier. The longitudinal extensibility may also decrease the tendency for kinking at the antecubital fossa."⁸

"Increased resistance to kinking and better matching of the prosthesis to the bevel of the arteriotomy may lead to less early postoperative thrombosis due to technical failures."⁶

A technique for implanting the GORE-TEX® Stretch Vascular Graft for hemodialysis access has been illustrated in great detail by Davidson.²

CLINICAL OUTCOME: IMPROVED PATENCY

"The overall graft survival of 88% and 86% at two and three years equals or exceeds the best results reported in the literature with regular PTFE grafts. Most published reports indicate graft survival in the 50% - 60% range at two years."¹⁰

Cumulative Primary Patency Rates¹

Graft	3 mo	6 mo	9 mo	12 mo
Stretch	85%	80%	80%	59%
Standard	75%	50%	35%	29%

Analysis of the patency difference by the Lee-Desu method demonstrated a statistically significant difference ($p < 0.01$)

"Our preliminary report shows that the longitudinal stretch properties of the new PTFE prosthesis may result in better primary patency rates compared to standard ePTFE AV grafts."¹⁵

". . . a significantly greater number of occlusions occurred in the standard ePTFE grafts."¹⁵

"In a prospective study, we compared the complications and patency rates of stretch ePTFE prostheses with standard ePTFE grafts implanted for hemodialysis vascular access."¹⁶

"Primary patency rates were significantly better in the stretch ePTFE group. Thrombosis occurred more often in the standard ePTFE grafts . . ."¹⁶

"In an attempt to improve performance of the graft, the stretch PTFE replaced the standard PTFE two years ago, with gratifying results."³

". . . although the exact compliance characteristics of implanted stretch ePTFE grafts have not been fully elucidated, it appears that the longitudinal stretch properties that are unique to these grafts may contribute to the improved primary patency rates."⁴

Cumulative Primary Patency³

Graft	6 mo	12 mo	18 mo
Standard	67%	58%	48%
Stretch	93%	78%	78%

Analysis of the life table data for cumulative primary patency, using the log rank test, demonstrated a statistically significant difference ($p = 0.0004$)

Cumulative Secondary Patency³

Graft	6 mo	12 mo	18 mo
Standard	75%	68%	55%
Stretch	96%	86%	74%

Analysis of the life table data for cumulative primary patency, using the log rank test, demonstrated a statistically significant difference ($p = 0.0086$)

"Results presented in this retrospective study show that a statistically significant difference exists in primary patency and cumulative survival between non-stretch and stretch ePTFE grafts."³

Cumulative Survival of 446 GORE-TEX® Stretch Vascular Grafts 1991-1997¹

Measure	1 Year	3 Years	5 Years
Primary Patency (Clot-free Survival)	85%	81%	79%
Secondary Patency (Graft Survival)	91%	87%	84%

CLINICAL OUTCOME: REDUCED COMPLICATIONS

Complications¹

Complication	Stretch	Standard	p
Thrombosis	12%	40%	<0.001
Stenoses	10	24	N.S.
Mean # stenoses/graft	0.6	1.2	<0.01
Time to hemostasis	16 min.	24 min.	N.S.
Early use	71%	40%	<0.05

"... all surgical interventions for bleeding complications and aneurysm formation were done in patients with standard ePTFE grafts, this might reflect a better capability to close puncture holes in the wall of stretch ePTFE grafts."⁵

"We observed no episodes of bleeding or perigraft hematomas."¹¹

CLINICAL OUTCOME: REDUCED KINKING AND STENOSIS

"... duplex scanning showed a significantly greater number of stenoses in the standard ePTFE AV grafts compared to the stretch ePTFE grafts. This difference in the number of stenoses can explain the improved primary patencies of the stretch graft. Less kinking and an improvement in elastic properties around the venous anastomoses may account for this feature."⁵

"A tendency to kink was noted in the midregion of the standard ePTFE prostheses, initiating turbulent flow and subsequently, areas of low shear stress, with a greater chance of platelet deposition. Histologic examination in occluded standard ePTFE grafts showed midgraft intimal hyperplasia, while in none of the explanted stretch grafts was intimal hyperplasia found."⁵

"The conformability of the graft at the anastomotic sites was seen to be improved compared to standard ePTFE grafts. . . . The longitudinal extensibility may also decrease the tendency for kinking at the antecubital fossa."⁸

CLINICAL OUTCOMES: DIALYSIS UNIT EXPERIENCE

"Bleeding from the puncture sites was easily controlled by the dialysis staff after needle removal."⁹

"The unique characteristic of the stretch graft that makes early use possible seems to be the elastic recoil... This appears to result in less bleeding upon removal of the dialysis needles."¹¹

"The comments from the hemodialysis nurses have been uniformly positive. The graft feels softer and easier to cannulate. However the differences are very subtle."¹⁸

CLINICAL EXPERIENCE: WITH OTHER GORE PRODUCTS

Ring Graft

"...an extension graft across the elbow joint to the upper arm veins may be performed. In this case, the extension graft should be of the ringed reinforced type."²

GORE Tunneler

"The third type (of tunneler), which the authors currently use and prefer, is a sheath tunneler. . . . The use of the sheath tunneler essentially eliminates the risk of the graft twisting or kinking and produces a uniform and smooth subcutaneous tunnel. Also, the sheath eliminates the dragging of the graft through the tissues which may potentially damage the graft and cause kinking and rotation."²

Patch Angioplasty - GORE-TEX® Cardiovascular Patch

"Rounding off of the graft will have a similar effect on the anastomosis as a patch angioplasty . . ." (Doctor Dawidson's patch angioplasty technique is described on pp. 62-63.)²

GORE-TEX® Suture

"The authors prefer the GORE-TEX® CV-6 Suture on a TT-9 needle since the needle diameter is the same as that of its thread, thereby eliminating anastomotic bleeding from needle holes."²



W. L. Gore & Associates, Inc.
Medical Products Division
Flagstaff, Arizona 86004

Australia: +61 / 2-9453-0300
Benelux: +31 / 73-687-24-46
中国: +86 / 21-6485-4990
Deutschland: +49 / 89-46-12-0
España: +34 / 93-480-6900
France: +33 / 1-60-79-60-79
香港: +852 / 2622-9622
भारत: +91 / 22-8217166
Italia: +39 / 045-6209-333
日本: +81 / 3-3327-0011
한국: +82 / 2-393-3411
New Zealand: +64 / 9-415-8334
Österreich: +43 / 662-629-551
Singapore: +65 / 275-4673
Sverige: +46 / 31-706-78-00
臺灣: +886 / 2-87717799
United Kingdom: +44 / 1506-460123
United States: 800 / 437-8181
520 / 779-2771

GORE, GORE-TEX®, and designs
are trademarks of W. L. Gore & Associates.
© 1998, 1999, 2000 W. L. Gore & Associates, Inc.
AB0140-EN3 DECEMBER 2000

References

1. Davidson IJA, Ar'Rajab A, Balfe P, Dmochowski J, et al. Long-term outcome of PTFE arteriovenous grafts. In: Henry ML, eds. *Vascular access for hemodialysis—VI*. Chicago, W.L. Gore & Associates and Precept Press, 1999; 155-62.
2. Davidson IJA. PTFE bridge grafts. In: Davidson IJA, ed. *On call in...vascular access: surgical and radiologic procedures*. Austin, TX: RG Landes, 1996:37-76.
3. Derenoncourt FJ. PTFE for A-V access: six years of experience with 310 reinforced and stretch grafts. In: Henry ML, Ferguson RM, eds. *Vascular access for hemodialysis—IV*. Chicago: W. L. Gore & Associates and Precept Press, 1995:286-91.
4. Hakaim AG, Scott TE. Durability of early prosthetic dialysis graft cannulation: results of a prospective, nonrandomized clinical trial. *J Vasc Surg* 1997;25:1002-5.
5. Tordoir JHM, Hofstra L, Bergmans DCJJ, et al. Stretch versus standard expanded PTFE grafts for hemodialysis access. In: Henry ML, Ferguson RM, eds. *Vascular access for hemodialysis—IV*. Chicago: Precept Press, 1995:277-85.
6. Tordoir JHM, Hofstra L, Leunissen KML, Kitslaar PJEHM. Early experience with stretch polytetrafluoroethylene grafts for haemodialysis access surgery: results of a prospective randomised study. *Eur J Vasc Endovasc Surg* 1995;9:305-9.
7. Mehta S. Statistical summary of clinical results of vascular access procedures for hemodialysis. In: Sommer BG, Henry ML, eds. *Vascular Access for Hemodialysis—II*. Chicago: Precept Press, 1991:145-57.
8. Dawidson I, Melone D. Preliminary experience with a new PTFE graft for vascular access. In: Henry ML, Ferguson RM, eds. *Vascular access for hemodialysis—III*. Chicago: Precept Press, 1993:133-6.
9. Simoni EJ, Jain KM, Munn JS. Use of 6 mm stretch PTFE grafts for early use in hemodialysis. In: Henry ML, Ferguson RM, eds. *Vascular access for hemodialysis—III*. Chicago: W. L. Gore & Associates and Precept Press, 1993:142-5.
10. Dawidson IJA, Ar'Rajab A, Melone LD, et al. Early use of the GORE-TEX stretch graft. In: Henry ML, Ferguson RM, eds. *Vascular access for hemodialysis—IV*. Chicago: Precept Press, 1995:109-17.
11. Colonna JO II, Swanson SJ, Shaver TR. Successful early use of the stretch PTFE graft. In: Henry ML, Ferguson RM, eds. *Vascular access for hemodialysis—IV*. Chicago: Precept Press, 1995:273-6