Comparison of outcomes of GORE® PROPATEN® Vascular Grafts with heparin end-point covalent bond and alternative autologous vein for below-knee surgical bypass procedures in critical limb ischemia patients

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OBJECTIVES

Critical limb ischemia is an advanced stage of peripheral arterial disease. The great saphenous vein (GSV) is the conduit recommended as the gold standard for lower-limb bypass procedures. However, in many cases the GSV may not be available. Other conduits such as alternative autologous saphenous veins (AAV), utilizing other veins such as the arm and the small saphenous vein, and synthetic vascular grafts are options when GSV is unavailable.

This study compares clinical outcomes and health care resource use reported from literature reviews for AAV and a synthetic graft, the GORE® PROPATEN® Vascular Graft with heparin end-point covalent bond (PROPATEN® Device).

METHODS

Four literature reviews were conducted pooling data from published studies on the PROPATEN® Device and AAV, the methods and results have been published elsewhere. One literature review pooled data on AAV clinical outcomes, O.R. time and hospital stay.[1] Three separate literature reviews on the PROPATEN® Device pooled data on:

- Patency rates[‡];
- Graft infections rates[§];
- O.R. time and hospital stay.[2]

These reviews were used to indirectly compare the outcomes of hospital stay, operating room (O.R.) time, clinical patency and wound infection rate.

RESULTS

No studies compared the PROPATEN® Device and AAV only. In comparative studies the comparator was GSV or other synthetic and cryopreserved grafts. Literature reviews pooled data for the respective arms, an indirect method of comparison is a limitation of this study.

CONCLUSIONS

The data reported indicate that treatment with the PROPATEN® Device

- Shortens the hospital stay and O.R. time;
- May offer better clinical outcomes with improved patency rates;
- Results in lower rates of wound infection.

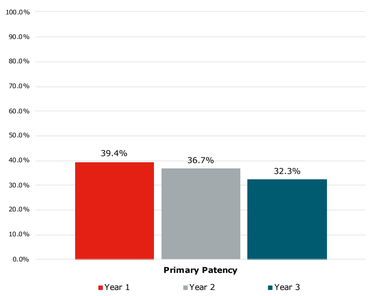
The lack of comparative studies is a limitation. More comparative studies are therefore recommended.

[‡] Data on file 2023; W. L. Gore & Associates, Inc; Flagstaff, AZ.
[§] Data on file 2022; W. L. Gore & Associates, Inc; Flagstaff, AZ

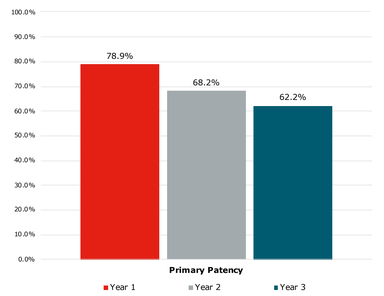
Primary patency at year 1, 2 and 3 was higher with the PROPATEN® Device (78.9% versus 39.4%, 68.2% versus 36.7%, 62.2% versus 32.3%) *(Figure 1)*.

Figure 1 – Primary patency (%)

Primary patency year 1 to 3 — Alternative autologous vein[1]



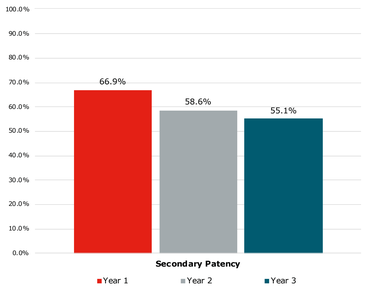
Primary patency year 1 to 3 — PROPATEN® Device[1]



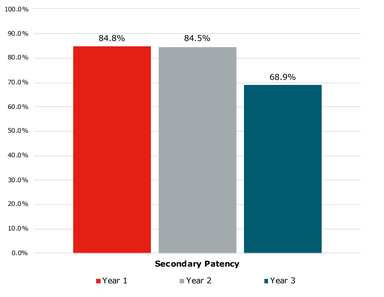
Secondary patency at year 1, 2 and 3 was higher with the PROPATEN® Device (84.8% versus 66.9%, 84.5% versus 58.6%, 68.9% versus 55.1%) *(Figure 2)*.

Figure 2 – Secondary patency (%)

Secondary patency year 1 to 3 — Alternative autologous vein[1]



Secondary patency year 1 to 3 — PROPATEN® Device[1]

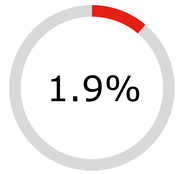


The wound infection rate was lower with the PROPATEN® Device at 1.9% compared to 15.9% for AAV *(Figure 3)*.

Figure 3 — Wound infection rate (%)

Wound infection rate — Alternative autologous vein[1]

Wound infection rate — PROPATEN® Device[5]



Hospital stay was reported to be 3.1 days shorter with the PROPATEN® Device compared to AAV (6.6 days versus 9.7 days) *(Figure 4)*.

Figure 4 — Hospital stay (days)

Hospital stay — Alternative autologous vein[1]

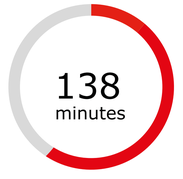
Hospital stay — PROPATEN® Device[2]

O.R. time was 124 minutes shorter with the PROPATEN® Device compared to AAV (138 minutes versus 262 minutes) *(Figure 5)*.

Figure 5 — O.R. time (minutes)

Operating room time — Alternative autologous vein[1]

Operating room time — PROPATEN® Device[2]



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2. Iqbal K, Pons M. EE4 Hospital resource use in below-knee surgical bypass procedures with eptfe vascular grafts with heparin end-point covalent bond in critical limb ischemia peripheral arterial disease (PAD) patients. Presented at ISPOR 2023: Impacting Innovation, Value, and Healthcare Decision Making ; May 7-10, 2023; Boston, MA. *Value in Health* 2023;26(6)Supplement:S60.

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