Comparing Short and Midterm Infrainguinal Bypass Patency Rates Between Two ePTFE Prosthetic Grafts: Spiral Laminar Flow and Propaten

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ABSTRACT: Objective: The ideal prosthetic graft to use for lower extremity bypass in patients with no vein conduit is yet to become available. Spiral laminar flow graft (SLFG) was designed to reduce turbulent flow at the distal anastomosis, hence reducing neointimal hyperplasia to improve graft patency. We examined our data for this type of graft and compared it to the Propaten graft by W.L. Gore (PG), which is another polytetrafluoroethylene (ePTFE) graft. Method: Single-center data were retrospectively reviewed for patients undergoing infrainguinal bypass using prosthetic grafts between January 2010 and January 2012. Kaplan-Meier analyses were performed to estimate primary and secondary patency rates for patients undergoing femoral to popliteal artery bypass (above and below the knee) as well as femoral to tibial artery bypass. The same was done for patients undergoing infrainguinal bypass using PG during the same time period. Results: 20 infrainguinal bypasses were performed using SLFG and 39 using PG were identified. A majority of the SLFG cases (14, 70%) were femoral to popliteal bypass (above and below the knee) and 6 cases (30%) were femoral to tibial artery bypass. Similar percentages were seen in the PG group. Statistically, the 6-, 12-, 18-, and 24-month primary and secondary patency rates for both grafts were the same regardless of the distal target artery. The primary patency for the popliteal artery (above and below knee) target group were 94%, 61%, 61%, and 54% for the PG group, and 79%, 50%, 50%, and 50% for the SLFG group, respectively. The secondary patency rates were 94%, 66%, 66%, and 66% for the PG group and 86%, 57%, 57%, and 57% for the SLFG group, respectively. The 6-, 12-, and 18-month primary patency rates for the tibial artery bypass groups were 51%, 36%, and 37% for the PG group and 50%, 33%, and 17% for the SLFG group, respectively. The secondary patency rates were 54%, 34%, and 34% for the PG group and 60%, 40%, and 20% for the SLFG group, respectively. Conclusion: The design of the SLFG to mimic physiologic flow at the distal anastomosis is an interesting concept, but it has not translated into clinical benefit in comparison to another ePTFE graft in our series. Further research and modifications are needed to achieve the ideal graft for infrainguinal arterial bypass.

Key words: peripheral vascular disease, patency
Peripheral arterial disease (PAD) affects more than 5 million people in the United States. Most patients with PAD of the lower extremity either are asymptomatic or have claudication or pain with walking. Most patients with claudication can be managed medically and with lifestyle modification. Approximately 25% of PAD patients will progress to critical limb ischemia (CLI). The CLI group consists of patients with rest pain, tissue loss, and gangrene. If left untreated, most patients with CLI will require an amputation. People with diabetes are at high risk for developing PAD. Vascular surgeons and interventionalists are heavily involved with limb salvage and improving quality of life by increasing walking distance and relieving pain. Patients with occlusive lower extremity disease resulting in PAD are best treated with open revascularization using an autogenous vein such as the greater saphenous vein. Patients who need a bypass and who do not have adequate vein quality require the use of other alternative conduits such as biological or synthetic grafts. In addition, there are multiple adjuncts that can be performed to improve bypass patency, such as the use of a vein cuff at the distal anastomosis and heparin-bonded grafts. Intimal hyperplasia at the distal anastomosis site is a common cause of graft failure. This results from alteration in flow hemodynamics and wall shear stress. As a result, grafts have been developed to mimic normal physiologic blood pattern or spiral laminar flow.

This manuscript will discuss the data for autogenous lower-extremity bypass in comparison to prosthetic grafts and will also address our experience with the relatively new spiral flow graft.

**AUTOGENOUS VEIN**

The great saphenous vein (GSV) is currently the best conduit for lower-extremity revascularization. The length and location of the GSV allow its harvest and use for bypass with minimal consequences to the patient. The 4-year patency for GSV in lower extremity reconstruction is more than 70%. The importance of having a good GSV caliber to improve bypass patency was highlighted in the PREVENT III study. The study showed that grafts with a diameter between 3.0 mm and 3.5 mm had a 1.5-fold risk for primary failure, and grafts with a diameter of less than 3 mm had a 2.4-fold risk. This was performed in comparison to veins with diameter greater than 3.5 mm. In addition, composite veins had a 1.5-fold increase in primary failure and arm veins had a 1.6-fold risk when compared to single-segment GSV. This highlights the importance of a single-segment GSV of good caliber for lower-extremity bypass so that patency is not reduced. This single long-segment GSV requirement is absent in up to 20% of the patients undergoing lower extremity bypass. Vascular surgeons turned to other conduit alternatives for lower extremity revascularization.

**PROSTHETIC CONDUITS**

Both polyester fabric grafts as well as expanded polytetrafluoroethylene (ePTFE) have been used in lower-extremity bypass. The polyester is less commonly used, but a randomized study comparing the two conduits in femoropopliteal bypasses showed no difference between the two grafts at 5 years. Multiple randomized studies have shown similar patency between prosthetic grafts and vein bypasses to the above-knee popliteal artery. However, for distal tar-
gets (below the knee), prosthetic grafts had much worse patency rates compared to vein bypass.\textsuperscript{10} In an attempt to improve prosthetic patency for distal bypasses, some surgeons perform vein patches in a variety of forms.

In our practice, we prefer the use of vein grafts for distal bypasses. If there is no adequate vein graft we will use a prosthetic graft; occasionally we perform a distal vein patch and place the prosthetic graft on top of it. Some authors have reported 82\% and 62\% primary patency at 1 year and 4 years respectively when using this adjunctive technique.\textsuperscript{11}

**SPIRAL GRAFT**

Neointimal hyperplasia (NIH) at the distal anastomosis is one of the causes of late graft failure. The burden of NIH is more pronounced in prosthetic grafts compared to vein. Changes in flow hemodynamics as well as compliance mismatch between the prosthetic graft and target vessels are several causes of NIH. As such, many different graft designs have been created to address these issues. One of these grafts is called the Spiral Laminar Flow (SLF) graft (Vascular Flow Technologies). This graft is engineered to produce hemodynamics similar to a physiologic spiral laminar flow.

The first-in-man study from Europe showed 12-, 24-, and 30-month primary patency rates of 86\%, 81\% and 81\% for the above-the-knee bypasses and 73\%, 57\%, and 57\% for the below the knee bypasses.\textsuperscript{12} These are encouraging results but the study is a nonrandomized study and has no other experimental group for comparison. It included 40 patients, the majority receiving above-the-knee popliteal bypass.

Our group was one of the earlier users of this graft in the United States. The concept of minimizing turbulent flow and reducing NIH is very intriguing and we implanted the first graft in 2010 to treat a patient with rest pain and no appropriate vein conduit. We examined our single center data for patients undergoing infrainguinal bypass using an SLF graft vs a Pro-paten ePTFE graft. Propaten (W.L. Gore) is another example of graft modification to improve patency. It is pharmacologically modified by the bonding of heparin to it. We examined our short-term and midterm data between these 2 grafts. We found similar primary and secondary patency between the 2 groups. Twenty infrainguinal bypasses were performed using SLFG and 39 using PG were identified. The majority of the SLFG cases (14, 70\%) were femoral to popliteal bypass (above and below the knee), and 6 cases (30\%) were femoral to tibial artery bypass. Similar percentages were seen in the PG group. Statistically, the 6-, 12-, 18-, and 24-month primary and secondary patency rates for both grafts were the same regardless of the distal target artery. The primary patency for the popliteal artery (above and below knee) target group were 94\%, 61\%, 61\%, and 54\% for the PG group and 79\%, 50\%, 50\%, and 50\% for the SLFG group, respectively. The secondary patency rates were 94\%, 66\%, 66\%, and 66\% for the PG group and 86\%, 57\%, 57\%, and 57\% for the SLFG group, respectively. The 6-, 12-, and 18-month primary patency rates for the tibial artery bypass groups were 51\%, 36\%, and 37\% for the PG group and 50\%, 33\%, and 17\% for the SLFG group, respectively. The secondary patency rates were 54\%, 34\%, and 34\% for the PG group and 60\%, 40\%, and 20\% for the SLFG group, respectively.
Limitations to this study include its retrospective nature as well as the small sample size.

**THE SPINAL GRAFT**

One of the major limitations of the graft is its stiffness compared to other ePTFE grafts. Also the distal graft configuration results in a huge mismatch when performing a distal bypass to the tibial vessels (Figure 1). In our practice at first we cut only the toe of the graft but not the heel in an effort to match the distal tibial target and at the same time maintain the laminar flow through the graft (Figure 1; red arrow). It became clear after this that the laminar flow is mainly dependent on the spiral inducer segment placed around the graft (Figure 1; blue arrows) and not the cuff configuration. Since then, we have been cutting the distal graft to match the target vessel.

One very noticeable difference between the spiral graft and other grafts performed for lower-extremity bypass is the flow pattern seen through the graft during completion angiogram. It seems the flow “swirls” as it goes through the spiral graft (Figure 2) because of its configuration. This might be related to the less turbulent flow seen in this graft.

**CONCLUSION**

The design of the SLFG to mimic physiologic flow at the distal anastomosis is an interesting concept but has not translated into clinical benefit in comparison to another ePTFE graft in our series. Further research and modifications are needed to create the ideal graft for infrainguinal arterial bypass.

**FUTURE CONSIDERATIONS**

The spiral graft design to mimic physiologic flow is very interesting. Moving forward, the graft need to be less stiff to make it more user friendly when performing distal bypasses. The distal cuff is long and wide and

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**Figure 1.** Spiral Flow Graft (Vascular Flow Technologies) distal end. The blue arrow points to the customized beveled cuff. The red arrows point to the Spiral inducer segment responsible for the nonturbulent flow through the distal anastomosis.
needs modification. In my professional opinion, instead of one graft for all bypasses, there should be different graft configurations for tibial targets and popliteal artery targets.

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