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BYPASS SURGERY IN LIMB SALVAGE: POLYTETRAFLUOROETHYLENE PROSTHETIC BYPASS

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Abstract

Polytetrafluoroethylene (PTFE) grafts have proven to be an adequate alternative conduit for peripheral bypass operations. Whether or not one uses PTFE depends on several factors: surgeon preference, individual patient circumstances, or when autologous greater saphenous vein is not available or adequate. These conventional grafts have evolved and undergone modification. The intraluminal surface has been coated with carbon or bonded with heparin. The structure of grafts has been modified with the creation of a hood or cuff, with the incorporation of a stent-graft segment for a sutureless anastomosis, or the fusion of PTFE with an outer polyester layer to minimize suture hole bleeding. This evolution intends to limit graft thrombogenicity, ameliorate the formation of intimal hyperplasia, decrease complications, and improve overall graft patency.

Introduction

Limb salvage in patients with peripheral vascular disease, especially those who suffer from critical limb ischemia (CLI), requires more than just adequate revascularization. Aggressive wound care, debridement, and the appropriate use of antibiotics may also be necessary as part of a comprehensive treatment. Autologous greater saphenous vein (AGSV) is the conduit of choice for peripheral revascularizations. However, there are some patients in whom autologous vein is not available or adequate. Other patients may have severe comorbid conditions and would benefit from an expeditious operation that avoids the time and trauma of vein harvesting. Lastly, surgeon preference or judgment may be another consideration in the use of a conduit other than vein. For these patients, PTFE grafts are a reliable and commonly used prosthetic material for peripheral bypass that have evolved and been modified to improve their overall performance (Figure 1).

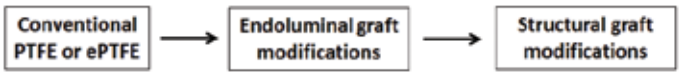

Figure 1. Evolution of PTFE grafts.

Conventional Polytetrafluoroethylene Grafts

Multiple reports and clinical studies have shown PTFE grafts to be an adequate alternative conduit for peripheral bypass operations. In a randomized study by Johnson and Lee, 265 patients underwent a femoral to above-the-knee popliteal artery bypass using a supported PTFE graft.[1] The cumulative assisted primary patency rates at 2 and 5 years were 69% and 39%, respectively. Eagleton and associates performed 74 femoral to infrapopliteal artery bypass operations for limb salvage using with expanded PTFE (ePTFE).[2] The primary patency, assisted primary patency, and secondary patency rates at 24 months were 40 ± 10%, 48 ± 11%, and 52 ± 11%, respectively. Limb salvage was successful in 62 ± 10%. Forty-six percent of bypasses were performed with a distal arteriovenous fistula, 35% with an end-to-side distal anastomosis, and 19% with a vein patch distal anastomosis.

The patency of ePTFE as a femoropopliteal bypass alternative was evaluated in a prospective randomized trial that compared it to AGSV. The study enrolled 49 patients with occlusion of the superficial femoral artery and limb threatening ischemia. At 54-month follow-up, the patency rate for the ePTFE group was 37% as compared to 70% for the patients who had AGSV. The study concluded that AGSV is far superior to PTFE.[3] In a study by Bergan and colleagues, 446 femoral distal reconstructions were performed.[4] Patients were divided into groups depending on whether the distal insertion site was the popliteal or infrapopliteal artery, and patients received a randomized vein or PTFE graft or an obligatory PTFE graft. The 30-month patency for randomized AGSV bypass to infrapopliteal arteries was significantly better than the patency of randomized or obligatory PTFE graft to the same level. In contrast, another study used PTFE only when AGSV was unsuitable or not available. The cumulative patency rates at 30 months were similar at 54% for AGSV and 45% for PTFE. The authors concluded that PTFE is a suitable alternative when AGSV is unavailable.[5]

The creation of a distal arteriovenous fistula is an attempt to improve graft patency results of prosthetic bypasses to infrapopliteal arteries. Ascer and colleagues performed this technique with an adjunct vein interposition graft at the distal anastomosis to improve compliance mismatch.[6] Their cumulative 3-year assisted primary patency was between 62% and 78%. The 3-year limb salvage rate was 78%. However, others have shown that creating an arteriovenous fistula at the distal anastomotic site of a tibial bypass augments flow only in the postoperative period without added effectiveness or graft patency.[7]

The interposition of a venous segment at the distal anastomosis has been advocated to improve the results of prosthetic grafts to tibial arteries. Neville and associates treated 79 patients using PTFE bypass grafts with a distal vein interposition patch.[8] Half of the patients had tissue loss, the other half had rest pain, and 53% had diabetes. The peroneal artery was the most common distal

target. The 4-year primary patency and limb salvage rates were 63 ± 10.6% and 79 ± 8.5%, respectively. The authors concluded that the technique of interposition vein patch at the distal anastomosis to the tibial arteries has an acceptable long-term patency and limb salvage rate. In a multicenter randomized study designed to examine the effect of a Miller vein cuff at the distal anastomosis of femoral to above- or below-knee popliteal artery PTFE bypass, 120 patients received a Miller cuff and 115 did not. The cumulative 5-year patency for above-knee bypass with or without a Miller cuff was similar. However, the cumulative 3-year patency rate for below-knee bypass with a Miller cuff was significantly better compared to a non-cuffed bypass.[9]

Modification of the PTFE intraluminal surface

The results with PTFE prostheses have varied, especially when the distal anastomosis is below the knee. Foreign surfaces have an effect on blood that leads to activation of the coagulation cascade and platelet aggregation. In the case of these vascular grafts, the PTFE is the foreign surface. This surface, which is in contact with the blood, has been targeted with graft modifications that intend to improve patency. Hapfer and associates performed a prospective, randomized, multicenter trial to determine if carbon-impregnated ePTFE vascular grafts have better long-term patency or limb salvage rates than nonimpregnated or standard ePTFE grafts in patients with chronic CLI undergoing crural revascularization.[10] In this trial, 130 patients received a carbon-coated ePTFE graft and 135 patients received the uncoated ePTFE graft. More than 90% of the patients had rest pain or gangrene. Primary patency, secondary patency, and limb salvage rates after 36 months were 33%, 43%, and 67% in the carbon-coated group and 30%, 38%, and 58% in the uncoated ePTFE group, respectively. This study showed no statistically significant advantage of the carbon-coated ePTFE vascular graft in terms of patency or limb salvage over the uncoated ePTFE vascular graft at 36 months.

The concept of covalently bonding a small amount of heparin to the inner surface of the graft, with the intention of decreasing its thrombogenicity, makes intuitive sense. There is increasing evidence that PTFE grafts to which heparin has been bound may provide better patency results. In a review that compared 240 patients who underwent a lower-limb bypass procedure with a heparin-bonded (hb) ePTFE graft to 110 patients with AGSV, the 1- and 2-year primary patency results were not significantly different.[11] The primary patency rates at 1 and 2 years for the hb-ePTFE grafts were 92% and 83% for above-knee femoral-popliteal bypass, 92% and 83% for below-knee femoropopliteal bypass, and 79% and 69% for femoral-tibial bypass, respectively. In the AGSV group, the primary patency rates at 1 and 2 years were 91% and 80% for above-knee femoropopliteal bypass, 72% and 72% for below-knee femoropopliteal bypass, and 69% and 64% for femoral-tibial bypass, respectively. Two-year limb salvage rates in the hb-ePTFE graft group and AGSV were 92% and 100%, 98% and 91%, and 87% and 96% for each corresponding bypass, respectively.

Dorigo and associates reported their experience with below-knee bypass using an hb-ePTFE graft in diabetic patients with CLI in a multicenter retrospective registry. Their results were compared to patients operated on with AGSV in the same centers during an 8-year period.[12] There were 180 patients who underwent below-the-knee revascularization with an hb prosthetic graft, while 133 patients had below-knee bypass with ipsilateral AGSV. The estimated 48-month survival rates were similar in both groups. Primary patency rate, assisted primary patency, secondary patency, limb salvage, and amputation-free survival for those undergoing bypass with the hb-ePTFE were 46.3%, 47.3%, 57.5%, 75.4%, and 59.9%, respectively. Primary patency rate, assisted primary patency, secondary patency, limb salvage, and amputation free-survival for those undergoing bypass with AGSV were 63.5%, 69%, 69.6%, 82.4%, and 64.4%, respectively. Of interest, approximately half the patients were either on single antiplatelet therapy or oral anticoagulation postoperatively in each group. This data confirmed that the hb-ePTFE graft provides satisfactory early and midterm results in diabetic patients undergoing surgical treatment for CLI. While autologous saphenous vein maintains its superiority in terms of primary patency, secondary patency rates and limb salvage rates were comparable.

In a blinded, multicenter, controlled trial, 569 patients scheduled to undergo a femoral-femoral or femoral-popliteal artery bypass were randomized 1:1 to receiving either an hb-PTFE or ordinary PTFE graft.[13] Overall, primary patency after 1 year was 86.4% for hb-PTFE grafts and 79.9% for PTFE grafts. Secondary patency was 88% in the hb-PTFE graft group and 81% in the other. The authors observed that hb-PTFE grafts significantly reduced the overall risk of primary graft failure by 37%. Subgroup analysis showed a 50% risk reduction in femoral-popliteal bypass operations in cases presenting with CLI.

In an in vivo human study, the systemic effects of the endoluminal bonded heparin were examined in 20 patients undergoing femoral-popliteal bypass grafting with either standard PTFE or hb-ePTFE.[14] Blood samples were drawn before and directly after the operation and at days 1, 3, 5, and week 6 after surgery. No statistical differences were observed in the measurement of prothrombin fragment 1+2, fibrinopeptide A, soluble glycoprotein V, thrombin-antithrombin complexes, and D-dimers. Moreover, no antibodies against antiplatelet factor 4/heparin could be demonstrated for up to 6 weeks after implantation. However, Thakur and colleagues reported the first case of heparin-induced thrombocytopenia (HIT) developing from a heparin-bonded graft.[15] The HIT responded promptly to graft explantation. Heparin-bonded grafts have been shown to leach heparin into plasma and induce platelet aggregation in the presence of heparin-associated antiplatelet antibodies.[16] Heparin-induced thrombocytopenia causes a prothrombotic state that counteracts the potential advantages of heparin bonding.[17] The possibility of sensitizing patients to heparin leaching from a heparin-bonded graft with the activation of platelets and secondary thrombosis suggests that these grafts should be used with caution in at-risk patients with existing heparin-associated antiplatelet antibodies.

Figure 2. Dynaflo® bypass graft (BARD Peripheral Vascular, Tempe, AZ) designed for above-knee peripheral bypass. Bracket indicates the precuffed or hooded configuration. A smaller cuff configuration exists for below-the-knee bypass.

Structural Graft Modifications

The development of intimal hyperplasia is one of the culprits for bypass or graft failure. As a result, scientists have introduced structural modifications of the conduit that alter the flow hemodynamics at the distal anastomosis. The concept hinges on creating laminar flow at the distal anastomosis, which in turn can influence and decrease the occurrence of intimal hyperplasia. Precuffed or hooded grafts (Figure 2) have been considered a good alternative conduit for below-knee popliteal and tibial lower extremity reconstructions in the absence of an autologous vein. Gulkarov and associates reviewed their experience in 57 patients who underwent 60 lower extremity bypass operations over a 3-year period.[18] In this report, 24 revascularizations were constructed to tibial outflow sites, 28 were placed to the below-knee sites, and 8 were placed to the above-knee popliteal artery. At 1 year, primary, assisted primary, and secondary patencies and limb salvage rates for below-knee popliteal bypass were 83.5%, 89.5%, 94.7%, and 94.4%, respectively. Primary, assisted primary, and secondary patencies and limb salvage rates for tibial bypass were 44.4%, 44.4%, 63.2%, and 74.9%, respectively. Donker and colleagues performed 110 lower extremity bypass operations using precuffed ePTFE grafts.[19] The cumulative 3-year patency rates for supragenicular, infragenicular and femorocrural ePTFE grafts were 45%, 24%, and 24%, respectively. The cumulative 3-year patency rates using AGSV for supragenicular, infragenicular, and femorocrural bypass were 94%, 74%, and 52%, respectively. Limb salvage after 3 years was 59% in the ePTFE group compared to 78% in the AGSV group. The authors concluded that precuffed or hooded grafts offer acceptable and promising early patency and limb salvage rates when used for peripheral bypass.

Ferreto and colleagues described a consecutive series of 5 patients who underwent a femoral to above-the-knee popliteal artery bypass with a modified graft.[20] The distal segment of a PTFE graft was sutured to the proximal portion of a partially deployed Viabahn® stent graft (W.L. Gore, Flagstaff, AZ). The distal portion of the Viabahn® graft was then deployed 2.5 cm into the popliteal artery and ballooned to ensure optimal apposition. The proximal end of the PTFE graft was sutured to the common femoral artery. Symptoms resolved in all cases, with complete ulcer healing occurring in five patients within 3 weeks. Short-term follow-up (<6 months) demonstrated patent grafts with no loss of device integrity in all cases. This case series illustrates an alternative for bypass creation, particularly in cases where challenging arterial anastomoses are required. This technique can now be performed with a new commercially available Gore® Hybrid graft (W.L. Gore, Flagstaff, AZ) that integrates this configuration (Figure 3).

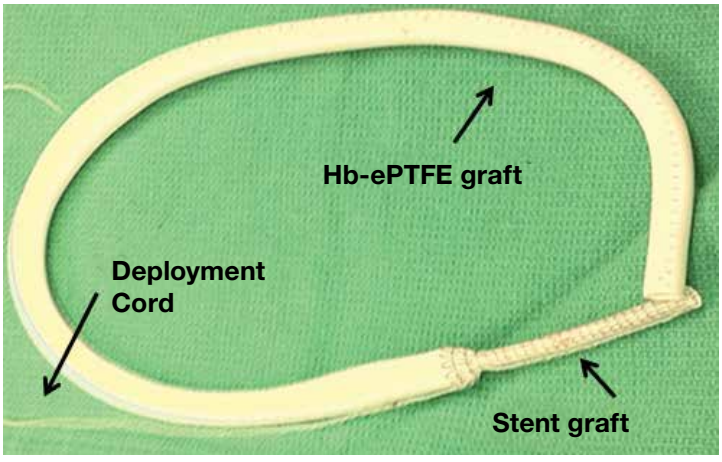

Figure 3. Configuration of the hybrid vascular graft.

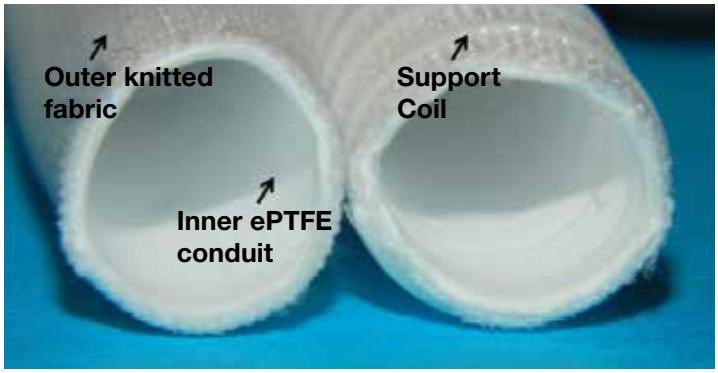

Figure 4. Fusion vascular graft with and without an external support coil.

A common problem with ePTFE grafts is intraoperative bleeding at the sutured anastomosis at the time of implantation. In a new concept, a thin ePTFE conduit has been fused with an outer layer of knitted polyester fabric (Figure 4). The Fusion™ graft (Maquet, Wayne, NJ) design intends to minimize needle hole suture line bleeding. Currently, there are two ongoing clinical trials. The FINEST trial is designed to compare the safety and primary patency between the heparin-bonded Fusion™ graft and the thin wall ePTFE graft. The endpoints for this trial include primary and secondary patency at 6 months and suture hole bleeding at the time of implantation. In addition, the PERFECTION trial intends to prospectively evaluate the Fusion™ vascular graft for femoral above-the-knee bypass and determine its primary patency at 30 days, 6 months, and 12 months and primary assisted and secondary patency at 12 months. The results of these trials are not currently available.

Conclusion

Polytetrafluoroethylene grafts are the most commonly used synthetic conduits for peripheral arterial bypass procedures although their long-term patency has not been as favorable as AGSV. Alternative surgical implantation techniques have been employed to improve the patency and decrease failure at the distal anastomosis. To decrease graft thrombogenicity, the inner luminal surface has been modified with carbon coating or heparin bonding. Structural graft changes have been developed with the intent of improving graft patency, decreasing intimal hyperplasia, and reducing suture hole bleeding.

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Keywords: critical limb ischemia; peripheral arterial bypass graft; polytetrafluoroethylene (PTFE) graft; autologous greater saphenous vein (AGSV); heparin-bonded PTFE; graft patency

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