Mid-term Results of Distal Bypass using Polytetrafluoroethylene Grafts and A Distal Vein Patch (DVP), A Retrospective Study

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ABSTRACT

Background: *Tibial artery bypass for limb salvage may be required in patients without adequate autogenous vein. The interposition of venous tissue at the distal anastomosis has been advocated to improve the results of prosthetic grafts to tibial arteries.* ***Purpose of the Study:*** *To study technical feasibility and results of Tibial by-pass using polytetrafluoroethylene (PTFE) with a distal vein patch (DVP), we record the results of this technique over 2-year were performed follow-up.* ***Materials & Methods:*** *From January 2012 to December 2015, 30 bypass grafts in 30 patients were performed with PTFE/DVP as the conduit. The technique was used for patients suffered critical limb ischemia with no available adequate vein as a conduit. Follow-up ranged from 1 to 24 months. Results are reported as primary patency or limb salvage (amputation rate).* ***Results:*** *Bypass grafts originated from the common femoral artery (8 [27%]), the superficial femoral artery (21 [70%]), and the external iliac artery (1 [3%]). Recipient arteries included anterior tibial (17 [57%]), posterior tibial (12 [40%]), and peroneal (1 [3%]). We recorded limb salvage rate of 70% in 24 months. We had 4 mortalities (13.33%) during the same follow-up period. Immediate techniqual success was 83.3% (25/30 procedure). The total incidence of major amputation was 9 cases (30%) at the 2 years follow up. Primary graft patency was 93.1 % at 1 month, 92.5% at 6 months, 88.4% at 12 months, and 63.33% at 24 months.* ***Conclusion:*** *The DVP technique allows PTFE bypass grafts to distal arteries with acceptable mid-term patency and limb salvage. This technique can be considered a safe & effective method for limb salvage in patients has no available vein conduit for bypass.*

Key Words: *Distal bypass, Vein patch, PTFE Grafts*

INTRODUCTION

There is little question that the great saphenous vein is the conduit of choice for tibial bypass grafting. However, there seems to be an increasing number of patients in need of tibial bypass graft for limb salvage who do not have adequate saphenous vein available, [1, 2]

Several alternative conduits have been proposed, including lesser saphenous vein, arm vein, composite veins, composite vein with polytetrafluoroethylene (PTFE), and PTFE with or without a distal arteriovenous fistula. Unfortunately, these alternative conduits have not resulted in equivalent results to the great saphenous when used for distal bypass graft to tibial arteries, [3,4]. This has led some to advocate primary amputation with no attempt at limb salvage in certain patient subgroups. [5]

Conversely, several authors have reported on the use of venous tissue at the distal anastomosis in the form of cuffs, collars, and boots to improve the results of prosthetic grafts to tibial arteries,[6, 7]. These techniques have been proposed as an option for revascularization in patients without adequate saphenous vein in an attempt to obtain limb salvage [8].

MATERIALS & METHODS

30 bypass grafts performed in 30 patients with PTFE/DVP as the graft conduit were constructed from March 2012 to June 2014. All patients were evaluated preoperatively with contrast arteriography to plan the appropriate revascularization. An attempt was made to assess the saphenous vein (ipsilateral or contralateral) through careful physical examination supplemented with duplex ultrasound evaluation.

When the vein was of questionable quality, it was evaluated under direct vision at operation. In each patient who received a PTFE/DVP bypass graft, the ipsilateral and the contralateral greater saphenous vein either was unavailable, having been used for previous revascularization procedures, or were unsuitable because of inadequate length or quality. The data of this study is analyzed as regard the primary patency rate within 2 years post-operatively and the complications rate including the amputation & infection.

Technique:

The bypass grafts were performed with patients under epidural anesthesia in most cases. The artery chosen as the inflow site was exposed in standard fashion. A retroperitoneal approach to the external iliac artery was used in one case because of multiple previous groin procedures with subsequent scar formation. Distal exposure varied according to the tibial artery chosen for bypass graft. After proximal and distal arterial exposure, a 2- to 3-cm segment of vein was harvested from any available location. Vein for the patch included saphenous remnants or arm vein which is harvested under local anesthesia. This vein segment was gently irrigated with prepared vein solution and opened longitudinally. The vein solution was composed of buffered saline solution, heparin (5000 units), calcium chloride (10%, 100 mg), and papaverine (120 mg). Any valves were excised, and the vein segment was briefly stored in the vein solution. An externally reinforced, 6-mm, thin-walled PTFE graft (Gore, USA) was then tunneled between the proximal and distal arterial exposures. The tunnel was routed medially; however, when a bypass graft to the anterior tibial artery was planned, the tunnel was made laterally. In addition, if a distal peroneal artery was targeted via a lateral approach with segmental fibulectomy, a lateral tunnel was also used. Heparin was given, and an end-to-side proximal anastomosis was performed between the PTFE graft and the inflow artery with a standard continuous suturing technique. A 2- to 3-cm arteriotomy was then performed in the artery chosen for distal anastomosis. The venous segment was cut to the appropriate length and width in preparation for the patch. In most cases, the width was left unaltered to allow for a generous patch to permit bulging of the patch under arterial flow somewhat like a cuff. Rarely, the vein width was trimmed to allow for a better size match with a small tibial artery. The vein patch was sutured to the artery with 6-0 Proline suture by means of standard parachute techniques. The PTFE/DVP anastomosis was then performed again using 6-0 Proline as shown in Fig 3. A longitudinal venotomy was then made in the proximal two thirds of the patch. The venotomy was positioned to begin the heel of the PTFE/vein anastomosis just beyond the artery/vein patch suture line. The PTFE graft was cut to the appropriate length in a sigmoidal fashion to allow the sides to flare in a "cobra-head" configuration. The PTFE graft was then sutured to the vein patch with 6-0 Proline suture in a continuous fashion allowing a rim of venous tissue interposed between the PTFE graft and the arterial wall. More venous tissue was left interposed at the toe of the anastomosis than the heel.

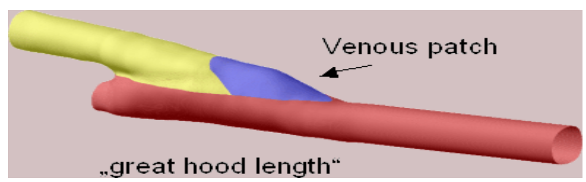


Figure 1: Venous patch

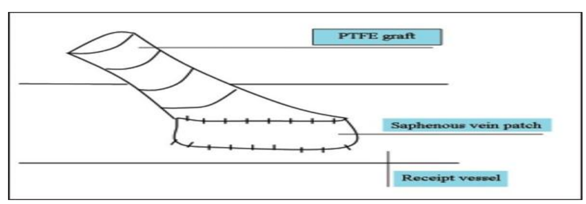


Fig. 2: Miller cuff

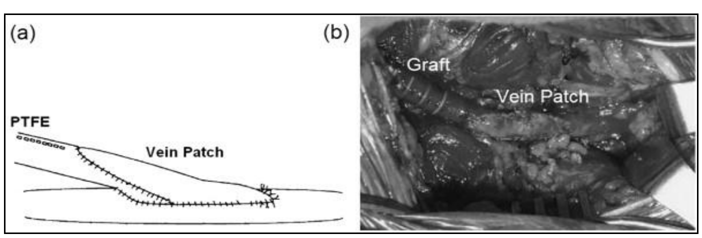


Fig. 3: Venous Patch

Patients were transferred to the intensive care or step-down unit on the basis of their medical condition. A heparin infusion was started 4 to 6 hours postoperatively with Coumadin administered on the first postoperative day. Long-term anticoagulation with Coumadin was continued with an international normalized ratio of 2.0 as the goal. Patients were seen in the office 7 to 10 days after discharge from the hospital. The follow-up protocol included physical examination of the limb with pulse status, ankle pressures, and waveforms and graft duplex evaluation at 3 months, at 6 months, and then annually.

RESULTS

Thirty PTFE/DVP grafts were performed in 30 patients with follow-up ranging from 30 days to 2 years. Patient demographics included 21 men and 9 women (mean age, 67 years). Risk factors of the patients are showed in the table 1.

Demographic features & risk factors	*Number of patients (%)*
Gender (Male)	
Diabetes mellitus	22/30 (73.3%)
Hypertension	11/30 (36.7%)
IHD	9/30 (30%)
Renal impairment	4/30 (13.3%)
Obesity	5/30 (16.6%)

All patients presented with limb threatening condition. Table 2 showed the presenting symptoms

Presenting symptoms	*Number of limbs (%)*
Rest pain	3/30 (10%)
Unhealed ulcerations	16/30 (53.3%)
Progressive gangrene	11/30 (36.7%)

The take-off artery for the bypass is shown in table 3

Take-off artery	*Number (%)*
External iliac	1 (3.3 %)
Common femoral artery	8 (26.6%)
Superficial femoral artery	21 (70%)

Recipient arteries are addressed in table 4

Recipient arteries	*Number (%)*
Anterior tibial	17 (56.6 %)
Posterior tibial	13 (43.3%)
Peroneal	1 (3.3%)

Two of the posterior tibial bypass grafts went in the inframalleolar plantar branches.

There was one perioperative death due to myocardial infarction (3.3%) with a 13.3% (4/30) total mortality rate during the 24-month follow-up period. The perioperative complications including wound infections, skin necrosis, severe bleeding that required blood transfusion, significant hematoma & systemic inflammatory response (SIRS) following revascularization are reported in this study.

Table 5 showed the incidence of these reported complications.

Complications	*Number (%)*
Wound infections	3/30 (10%)
Skin necrosis	2/30 (6.6%)
Severe bleeding	2/30 (6.6%)
Significant hematoma	6/30 (20%)
SIRS	1/30 (3.3%)

Immediate techniqual success was 83.3% (25/30 procedure). Five grafts failed in the early perioperative period (48 hours), leading to three amputations. Four of the patients with failed grafts had an operative thrombectomy with no technical problem noted at the time of reoperation and one patient went directly to amputation without an attempt to reestablish graft patency due to bad general condition of the patient.

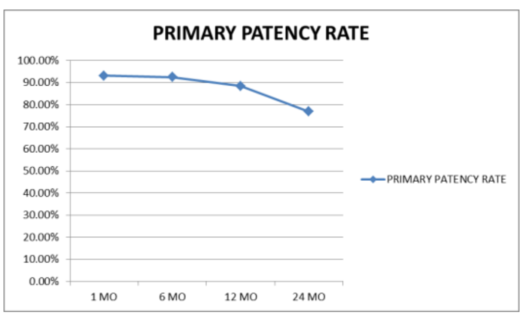
Two of the thromboectomies were successful, and these grafts were patent at 12 and 24 months. Two thromboectomies were unsuccessful, resulting in amputation. The total numbers of limbs that continued for follow up was 27. Another 9 grafts occluded in the follow-up period of 24 months, leading to another 6 amputations. Two of these failed grafts were opened by means of lytic therapy with angioplasty of underlying stenotic lesions, and one remains patent 12 months later. Four failed grafts required open (surgical) thrombectomy, and three required revision. These three grafts were revised with a short distal extension by the use of a new segment of PTFE and new vein patch to bypass progressive distal arterial disease. Two of these grafts remain patent at 6 and 12 months. The total incidence of major amputation was 9 cases (30%) at the 2 years follow up.

Table 6: showed the patency rate & mortality

Follow up period (months)	*Number of patients*	*Primary patency rate (%)*	*Notes*
1	29	27/29 (93.1%)	One perioperative mortality
6	27	25/27 (92.5%)	Another two patient died
12	26	23/26 (88.4%)	Another one patients died
24	26	20/26 (76.9%)	

Graft patency and limb salvage rates were determined at follow-up intervals ranging from 1 to 24 months. Primary graft patency was 93.1 % at 1 month, 92.5% at 6 months, 88.4% at 12 months, and 63.3% at 24 months.

Figure 4 showed the primary patency rate



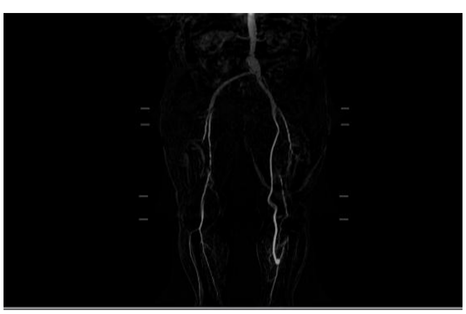


Fig. 4: Showed a case of bypass from SFA to PTA

DISCUSSION

Autogenous saphenous vein is the conduit of choice for tibial revascularization. Despite the use of duplex ultrasound techniques to improve the ability to locate acceptable saphenous vein, there is a seemingly growing subset of patients in whom the choice of conduit remains problematic because of a lack of suitable saphenous vein. This group has been estimated at almost 30% of those needing distal reconstruction with an increase to near 50% for those undergoing a repeat or secondary procedure.[9, 10]

PTFE bypass grafts with direct anastomosis to the distal arteries have been used with generally poor results. Clinical series report 1-year patency rates between 20% and 50% with 3-year patency rates from 12% to 40%.[11, 12, 13] these bypass grafts are technically demanding, requiring an anastomosis between a small, diseased tibial artery and a fairly noncompliant prosthetic material. The major cause of these grafts failures involving PTFE bypass grafts to infrainguinal arteries appears to be myo-intimal hyperplasia at the outflow anastomosis. Smooth muscle cell migration and proliferation result in hyperplasia distal to the toe and at the heel of the anastomosis causing a reduction in lumen area and subsequent graft failure.14 Thrombogenicity may also play a role at the interface between the high resistance outflow artery and larger prosthetic graft.[15]

There have been many attempts to improve the results of PTFE bypass grafts to infra-popliteal arteries through the interposition of venous tissue between the PTFE and recipient artery. Although Siegman[16] first advocated the use of a venous cuff in 1979 to facilitate the technical performance of anastomoses to calcified arteries, Miller et al6 first described a vein cuff in an attempt to improve the patency of PTFE bypass grafts to distal arteries. Miller et al reported a benefit for the vein cuff for PTFE bypass grafts to the below-knee popliteal artery (57% patency vs 29% patency at 36 months) without an advantage at the above-knee position.[6] No tibial artery bypass grafts were reported in this series. Taylor et al8 reported a technique with a vein patch at the distal portion of the anastomosis with patency rates of 74% and 58% at 12 and 36 months, respectively. Stonebridge et al[17] have reported a prospective, randomized trial for PTFE grafts with a vein cuff. They did report a benefit for the vein cuff technique in tibial bypass grafts (52% vs 29% at 24 months); however, the report randomized 246 popliteal bypass grafts and only 15 tibial grafts. Hobson et al recently reported a benefit for tibial bypass graft with the Miller cuff. In 30 grafts they noted 54% patency for the cuffed grafts versus 12% patency for the non-cuffed grafts at 24 months.[18] Several authors have reported on the use of arteriovenous fistulas to improve PTFE patency to infrainguinal arteries. Dardik et al[19] use human umbilical vein graft with a concomitant anastomotic arteriovenous fistula, reporting 61% patency at 36 months. Ascer et al[20] have also reported on an arteriovenous fistula technique using the corresponding tibial vein with a PTFE bypass graft to the vein as a type of vein cuff. This technique has resulted in 62% patency at 36 months. The Albany group has recently reported a retrospective series comparing PTFE grafts with the Tyrrell/Wolfe vein boot technique with grafts performed with an arteriovenous fistula distal to the actual anastomosis.[21] This St Mary's boot technique has been advocated as taking advantage of the best features of the prior techniques with promising early clinical results. The Albany series involved predominantly tibial bypass grafts, but did include a number of popliteal grafts. They noted similar graft patency between the two techniques at 12 and 36 months (96% vs 86% and 38% vs 48%, respectively). These authors indicated that they prefer the St Mary's boot technique because of technical ease and advantages in terms of graft salvage and secondary patency.

The addition of a Miller cuff, Taylor patch, or St Mary's boot to PTFE bypass grafts has led to a seeming improvement in patency versus PTFE alone; however, these adjunctive techniques have some theoretical and practical disadvantages. Miller[6] reported several early graft thromboses possibly related to increased turbulence caused by excessive bulging of the venous tissue at the distal anastomosis. The Taylor patch involves the direct suturing of PTFE to the artery at the heel of the anastomosis where hyperplasia is known to develop and requires the dissection of a long segment of tibial artery to accommodate the anastomosis. Our technique involved a standard patch angioplasty already familiar to vascular surgeons, with subsequent implantation of a PTFE graft into the vein patch. The length of vein segment required for this technique is minimized (2-4 cm). The vein is minimally trimmed to allow a pseudo-cuff to form without excessive bulging. The PTFE graft must be anastomosed to the proximal two thirds of the vein patch. This leaves a rim of venous tissue at the heel of the anastomosis and allows a vein pseudo-cuff to develop at the distal portion of the anastomosis. Ideally, the distal portion of the vein patch expands in a cuff-like configuration under arterial flow without ballooning into a protuberant bulge. Completion arteriography is mandatory in these cases because even a minor error can lead to graft failure.

The advantages bestowed by venous tissue at the distal anastomosis derive from both biologic and mechanical factors. A biologic “buffer zone” between the tibial artery and prosthetic graft has appealing theoretical possibilities. Although the causes of myo-intimal hyperplasia have not been completely delineated, the addition of venous tissue to PTFE grafts at the distal anastomosis may lead to a favorable biologic situation and decrease the development of hyperplasia as has been demonstrated in an animal model.[22] Venous endothelium may also confer a beneficial effect through fibrinolytic and antiplatelet activity, although these effects remain unproved. The mechanical factors of shear stress and compliance mismatch have also been implicated in prosthetic graft failure. Theoretically, vein interposed between a stiff prosthetic graft and a more pliable artery would minimize the expansibility mismatch created with pulsatile flow and thus decrease mechanical injury at the anastomosis. However, an animal study addressing these mechanical properties did not prove them important in the reduction of observed hyperplasia.23 Anastomotic turbulence and outflow resistance have also been suggested as mechanisms of graft failure. Anastomotic geometry may be altered by the presence of vein at the distal anastomosis, thereby effecting turbulence and shear forces that play a role in the hyperplastic process.[15, 24] finally, it is possible that venous tissue simply enlarges the distal anastomosis so that the formation of hyperplasia must encroach on a wider lumen before becoming clinically significant. The venous tissue is also technically easier to suture to small, calcified tibial arteries as originally observed by Seigman.[16] The secondary suture line between the PTFE graft and vein also becomes more technically appealing.

This study involves only tibial artery bypass graft for patients in a limb-threatening situation. The patient group was typically high risk with comorbidities of diabetes, renal failure, and coronary artery disease. Careful perioperative medical care and excellent anesthetic techniques are crucial for acceptable results. We noted a relatively high proportion of men and diabetes in this series, possibly given the tertiary nature of the referral patterns. Using cobra fashion for the venous patch at the site of the anastomosis gives a good primary techniqual success and also improves the primary patency rate of the PTFE grafts, reaching to 88% at the first year follow up. This matches with Miller's study but again the wide cuff increases the turbulence of blood flow and this leads to early grafts thrombosis. We also noted that graft failures could be lysed or thrombectomized often without any underlying anatomic defect found as the cause of graft failure. This was also noted by the Albany group in their failed grafts. Therefore, we think that an attempt at lytic therapy or thrombectomy through a limited distal incision is warranted in the event of graft failure. Intraoperative arteriography can then be used to determine the need for anastomotic revision or extension with a new vein cuff.

In conclusion, we think that patients in danger of limb loss without adequate saphenous vein can be considered for tibial bypass graft with PTFE/DVP as the conduit. This series shows that acceptable long-term patency and limb salvage can be achieved in these challenging patients. As the population ages and policies toward limb salvage become more aggressive, vascular surgeons will require alternative conduits to autogenous saphenous vein in a certain subset of patients. Although this was not a randomized trial, these early results indicate that a PTFE graft with a DVP may prove an acceptable alternative in the absence of saphenous vein. In our practice PTFE/DVP is preferred to PTFE bypass graft alone or composite grafts constructed with PTFE and longer segments of saphenous vein. A multicenter prospective randomized trial may be of benefit to address the question of the best alternative for the patient without suitable autogenous saphenous vein for limb salvage.

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