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Original Article

Long-Term Results of Femorotibial Polytetrafluoroethylene Bypass with a Distal Vein Cuff for Critical Limb Ischemia

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Objective: Although autologous veins are the first-choice conduit for femorotibial artery bypass, if there are no appropriate autologous veins, we perform femorotibial artery bypass using polytetrafluoroethylene (PTFE) with a distal vein cuff for patients with critical limb ischemia (CLI). This study examined the long-term outcomes of femorotibial artery bypass using PTFE with a Miller's cuff.

Materials and Methods: Using prospectively collected data for 444 distal bypasses, a retrospective analysis was conducted for 32 femorotibial PTFE bypasses with a Miller's cuff (PTFE-Miller's cuff) performed for patients with CLI from April 1994 to December 2016.

Results: Primary and secondary patency rates of PTFE-Miller's cuff at 3 years were 35.8% and 51.2%, respectively. Limb salvage rate of PTFE-Miller's cuff at 3 years was 71.0%.

Conclusion: Although the patency rate was low and failed to yield satisfactory results, the limb salvage rate remained relatively high. Femorotibial PTFE bypass with a Miller's cuff was a useful technique of limb salvage for patients with CLI in whom an appropriate autologous vein could not be used.

Keywords: tibial bypass, distal vein cuff, critical limb ischemia, Miller's cuff

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Introduction

Critical limb ischemia (CLI) can result in lower limb loss if revascularization is not immediately performed. The Trans-Atlantic Inter-Society Consensus (TASC) recommends autologous veins as the first-choice conduit for femorotibial artery bypass.[1,2] However, there are some patients who lack appropriate autologous veins for femorotibial artery bypass at a rate of 15% to 30%.[3–5]

As several studies have shown, tibial artery endovascular therapy (EVT) is a safe and effective procedure for the treatment of CLI. However, low patency and high restenosis rates after EVT have been reported, and frequent reintervention is required to achieve limb salvage.[6,7] In such clinical settings, it is difficult to determine the optimum procedure for revascularization of the tibial artery region.

Although femorotibial artery bypass may be performed using a prosthetic graft in the absence of appropriate autologous veins, graft patency and limb salvage rate in this case are not satisfactory.[8] Since the outcome of femorotibial artery bypass with polytetrafluoroethylene (PTFE) alone is poor, some interposition procedures involving the placement of a vein cuff at the distal anastomosis have been developed to improve the patency rate.[9,10] Among these procedures, the Miller's cuff technique was developed in 1984 by Miller and has shown good results to date.[11–15]

In recent studies, distal bypass performed with heparin-bonded expanded PTFE vascular graft (GORE PROPATEN Vascular Graft, W. L. Gore & Associates, Flagstaff, AZ, USA) shows satisfactory short-term results in patients undergoing surgical treatment for CLI. However, those results contained the below-knee bypass, and some additional techniques, such as distal vein patch, were performed on the tibial artery in those cases.[16]

We therefore investigated whether acceptable limb salvage rates of femorotibial PTFE bypass could be achieved with a Miller's cuff for CLI, even where the patient's background evidenced unfavorable conditions.

Methods

Patients

We performed 444 distal bypasses for CLI from April 1994 to December 2016 (104 bypasses, April 1994–March 2007 at the Steel Memorial Yawata Hospital; 168 bypasses, April 2007–March 2011 at the Kokura Memorial Hospital; 129 bypasses, April 2011–March 2015 at the Steel Memorial Yawata Hospital; 43 bypasses, April 2015–December 2016 at the Saiseikai Yahata General Hospital, Kitakyushu). All patients suffered from threat of limb loss, rest pain and tissue loss (Fontaine classification 3, 4). Of these patients, 32 patients underwent femorotibial PTFE bypass with a Miller's cuff (PTFE-Miller's cuff).

Approval for this project was obtained from the hospitals (Steel Memorial Yawata Hospital, Kokura Memorial Hospital, and Saiseikai Yahata General Hospital)' institutional review boards.

Clinical endpoints

The primary endpoint was freedom from major amputation, and the secondary endpoints were graft patency, amputation-free survival, overall survival, and postoperative complications. Clinical records of prospective patients were collected in a database and retrospectively analyzed. The graft patency was analyzed per graft, freedom from major amputation and amputation-free survival were analyzed per limb, and overall survival was analyzed per patient. In the PTFE-Miller's cuff, the graft patency rate was estimated for 32 bypass grafts. The survival rate and limb salvage rate were calculated for 31 patients, as one patient underwent bypass twice on the ipsilateral limb.

Strategy for CLI

In cases of contracted limb or severe systemic conditions for general anesthesia, there was no possibility for limb salvage. For these cases, we recommended primary major amputation. Our strategy for CLI caused by occlusive disease in the crural artery region was to first perform femorotibial artery bypass using autologous veins; however, when the lesions are within a short range, EVT is performed. EVT had never been performed by us prior to March 2007; EVT was adopted after April 2007 for patients lacking appropriate autologous veins and performed only for TASC A or B lesions until March 2015, and its indication expanded gradually to TASC C and D lesions in April 2015.

Therefore, we performed femorotibial PTFE bypass with a Miller's cuff as the first choice for cases without appropriate autologous veins until March 2007. After April 2015, we performed EVT as the first choice for such cases or for those who were in a poor systemic condition for bypass surgery, leaving femorotibial PTFE bypass with a Miller's cuff as the second option for cases of EVT failure.

We did not use the Miller's cuff as a distal vein cuff for below-the-ankle bypass due to the height of the cuff, which made it difficult to close the skin. In such cases, we performed below-the-ankle bypass using a composite graft when the appropriate autologous veins were absent. Direct bypass to the tibial artery using a prosthetic graft was not performed.

Assessment of autologous veins

Decisions on the availability of autologous veins for femorotibial artery bypass were made according to several criteria. First, by duplex ultrasonography or computed tomography, we assessed whether the diameter of the following veins (in order): the ipsilateral great saphenous vein, the contralateral great saphenous vein, and the lesser saphenous vein was ≥ 2 mm preoperatively. The final decision on vein availability was made intraoperatively based on whether the harvested vein diameter was ≥ 3 mm for femorotibial artery bypass. Where necessary, a deep vein or arm vein was also used. However, based on the strategy of the chief vascular surgeon, the autologous vein was not actively used if any suspicious findings concerning the venous diameter (visually < 3.0 mm) were noted during surgery, and the deep vein or arm vein was not used until March 2007.

Procedures

The harvested saphenous vein of about 4 cm was incised longitudinally; both ends of the incised vein were anastomosed, and a vein cuff was made so that the height was approximately 1 cm and the length was 2 cm. The vein cuff was anastomosed to the tibial artery, and a PTFE graft, the end of which was shaped like a cobra head, was anastomosed to the upper edge of the vein cuff. The PTFE was guided to the groin through a subcutaneous route and anastomosed to the femoral artery. Finally, angiography was performed to check the shape of the anastomosis and to ensure a good peripheral blood flow (**Fig. 1A**).[9]

Medications and follow-up

Heparin was infused postoperatively for a period ranging from 48 h to 7 days, and vitamin K antagonist was administered to patients who underwent femorotibial PTFE bypass with a Miller's cuff from the day after surgery with a target prothrombin time international normalized ratio of between 2.0 and 2.5 and then permanently if it was not contraindicated. Antiplatelet drugs were also administered

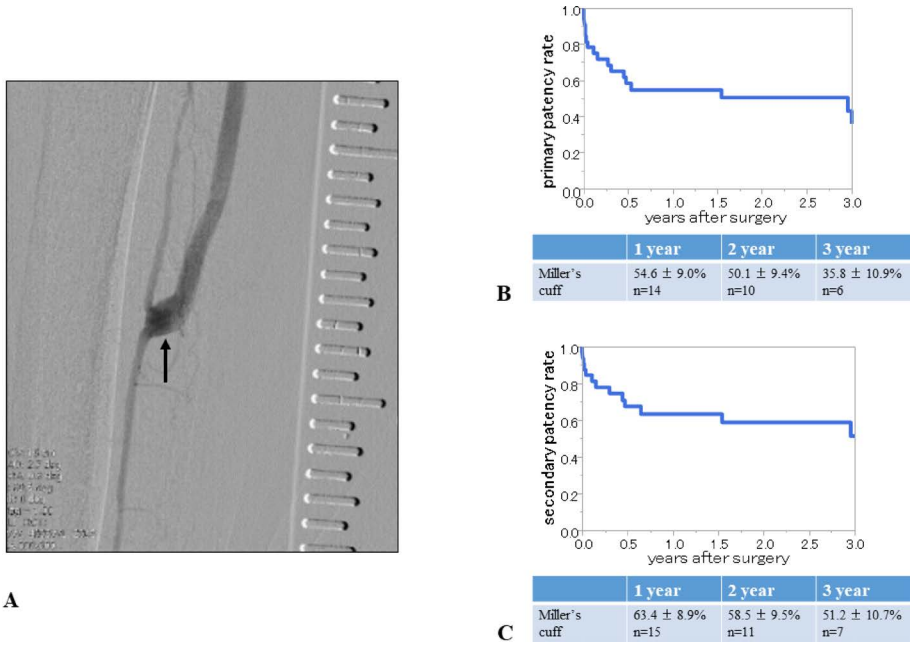


Fig. 1 Arteriography 1 year postoperatively revealed that the femoro-anterior tibial PTFE bypass with a Miller's cuff (arrow) was patent (**A**). Primary patency rate (**B**), secondary patency rate (**C**)±standard error of PTFE-Miller's cuff.

to every patient.

The patients were followed regularly as outpatients every 1–3 months for the first 2 years and for 3–6 months thereafter. Routine surveillance included pulsation of the arteries in the lower leg, assessment of the ankle brachial index, and duplex ultrasonography. When a reduced blood flow to the graft was suspected, arteriography was performed to evaluate the stenosis, and percutaneous transluminal angioplasty with a cutting balloon was considered as the first strategy for revision. Resurgery was performed when severe ischemic symptoms recurred after graft failure and revascularization was necessary. Patients who were unable to visit the institution were interviewed over the phone, at least annually, to confirm their condition.

Definitions

We defined diabetes mellitus (DM) as fasting blood glucose >105 mg/dl or as taking hypoglycemic drugs or as self-injected insulin. Coronary artery disease (CAD) was defined as a history of angina pectoris, myocardial infarction, percutaneous coronary intervention, or coronary artery bypass grafting. Cerebrovascular disease (CVD) was defined as a history of transient ischemic attack, cerebral infarction or cerebral hemorrhaging, and/or any revascularization of the carotid arteries. End-stage renal disease (ESRD) was defined as hemodialysis or peritoneal dialysis.

Early graft occlusion was defined as a loss of primary patency within 30 days of bypass surgery. Major adverse limb events were defined as major amputation or major reintervention, including a new bypass grafting, jump grafting, interposition graft revision or thrombectomy, and thrombolysis related to the target lesion. We defined operative death as mortality within 30 days of bypass surgery.

Statistical analyses

Survival curves were calculated by Kaplan–Meier method. All statistical analyses were performed using the JMP Pro version 13.0.0 software program (SAS Institute, Cary, NC, USA).

Results

Baseline characteristics

Patient characteristics of the study are shown in **Table 1**. The mean age was at 77.6 years (range, 60–92 years). The patients frequently had a history of DM (45.2%), CAD (64.5%), CVD (41.9%), and ESRD (35.5%).

Details of surgical procedures

The details of the surgical procedures are summarized in **Table 2**. All patients were symptomatic with threatened limb loss, including nine limbs for rest pain and 23 limbs for tissue loss (Fontaine classification 3 and 4; 28.1% and 71.9%). Twenty-one (65.6%) bypasses were performed as de novo revascularization and 11 (34.4%) as resurgery. The distal anastomoses were to the anterior tibial artery in 16 (50.0%) limbs, the posterior tibial artery in eight limbs (25.0%), and the peroneal artery in eight (25.0%) limbs.

Table 1 Patient characteristics

Factors	PTFE-Miller's cuff (n=32)
Age, mean (range)	77.6 (60–92) years
Sex, female	25.8%
Diabetes mellitus	45.2%
Coronary artery disease	64.5%
Cerebrovascular disease	41.9%
End-stage renal disease	35.5%

Table 2 Details of the surgical procedures

Factor	PTFE-Miller's cuff (n=32)
Lower limb status	
Fontaine 3	9 (28.1%)
Fontaine 4	23 (71.9%)
Operation	
De novo revascularization	21 (65.6%)
Resurgery	11 (34.4%)
Distal anastomosis	
Anterior tibial artery	16 (50.0%)
Posterior tibial artery	8 (25.0%)
Peroneal artery	8 (25.0%)

Table 3 30-day mortality and morbidity

Factors	PTFE-Miller's cuff (n=32)
Graft infection	2 (6.3%)
Surgical site infection	1 (3.1%)
Haematoma	2 (6.3%)
Major adverse limb events	6 (18.8%)
Major amputation	3 (9.4%)
Gastro-intestinal bleeding or infarction	1 (3.1%)
Cerebral infarction	1 (3.1%)
Pneumonia	1 (3.1%)
Sepsis	1 (3.1%)
Operative death	1 (3.1%)

30-day mortality and morbidity

Table 3 summarizes the 30-day mortality and morbidity rates. The two (6.3%) limbs developed graft infection, one of which required graft removal. In addition, early graft stenosis or occlusion was observed in five limbs; three of which followed graft revision, thrombectomy, patch angioplasty, or interposition to maintain graft patency. As a result, one limb that required graft removal due to infection and two limbs that suffered graft occlusion and which could not be successfully repaired resulted in major amputation in the early postoperative period (9.4%). Finally, one (3.1%) patient died due to purulent cholangitis within 30 days of surgery.

Long-term outcomes

The mean follow-up duration was 2.4 years (range, 2 days–8 years). The primary patency of the PTFE-Miller's cuff was 54.6%, 50.1%, and 35.8% at 1, 2, and 3 years, respectively (**Fig. 1B**). The secondary patency of the PTFE-Miller's cuff was 63.4%, 58.5%, and 51.2% at 1, 2, and 3 years, respectively (**Fig. 1C**).

The limb salvage rate was 93.4% at 3 months, 78.9% at 6 months, and 71.0% at 1 year and remained stable at 3 years (**Fig. 2A**).

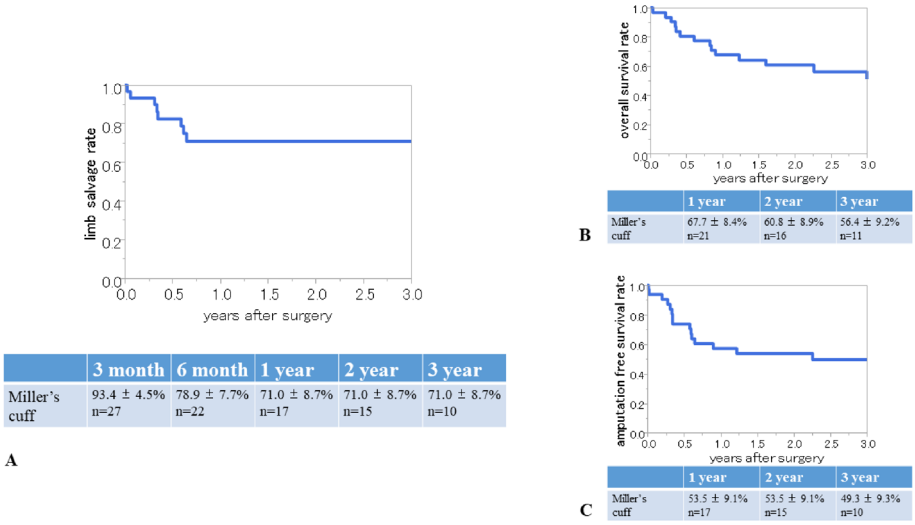
However, the prognosis was poor; the overall survival rate of the PTFE-Miller's cuff was 67.7%, 60.8%, and 56.4% at 1, 2, and 3 years, respectively (**Fig. 2B**). The amputation-free survival rate was 53.5%, 53.5%, and 49.3% at 1, 2, and 3 years, respectively (**Fig. 2C**).

Discussion

The 2017 European Society of Cardiology (ESC) Guidelines for the diagnosis and treatment of peripheral arterial diseases recommends that patients with chronic limb-threatening ischemia due to long occlusions of crural arteries undergo bypass surgery with an autologous vein for superior long-term patency and leg survival, and for this, the great saphenous vein is indicated as the first-choice conduit for revascularization of the infra-popliteal arteries (Class of recommendation I, Level of evidence A). If the patient has an increased risk of surgery or does not have an autologous vein, EVT can be attempted (Class of recommendation IIa, Level of evidence B).[17]

A low patency rate and high restenosis rate have been reported after tibial artery EVT. However, if strict hemodynamic surveillance and timely re-interventions are performed until the wound heals, a relatively satisfactory limb salvage rate is possible, even for patients with tissue loss.[6,7] Tibial artery EVT is an option for patients with a poor systemic condition. Indeed, our strategy for CLI has changed in concert with the guidelines, and since April 2015, we have been actively incorporating catheter treatment in the absence of appropriate autologous veins, or in cases of a poor systemic condition, for bypass surgery.

Autologous veins, especially the ipsilateral single-segment great saphenous vein, remain the optimum conduit for femorotibial artery bypass; however, it has been reported in a previous study that the percentage of unusable ipsilateral greater saphenous vein for infrainguinal revascularization was approximately 15%–30%.[3–5] In such cases, the contralateral great saphenous vein, lesser saphenous vein, the deep vein or arm vein can also be used as an appropriate conduit. However, the proportion of these veins used for femorotibial artery bypass has not been reported in detail. In our study, spliced vein bypass had a good limb salvage rate and better results than the



A

	3 month	6 month	1 year	2 year	3 year
Miller's cuff	93.4 ± 4.5% n=27	78.9 ± 7.7% n=22	71.0 ± 8.7% n=17	71.0 ± 8.7% n=15	71.0 ± 8.7% n=10

B

	1 year	2 year	3 year
Miller's cuff	67.7 ± 8.4% n=21	60.8 ± 8.9% n=16	56.4 ± 9.2% n=11

C

	1 year	2 year	3 year
Miller's cuff	53.5 ± 9.1% n=17	53.5 ± 9.1% n=15	49.3 ± 9.3% n=10

Fig. 2 Limb salvage rate (**A**), overall survival rate (**B**), and amputation-free survival rate (**C**)±standard error of PTFE-Miller's cuff.

PTFE graft with a Miller's cuff, as described in the previous literature.[18,19] In contrast, a previous comparison of spliced vein bypass and a PTFE graft with a distal vein cuff revealed no significant differences in the limb salvage rate, although the patency rate is inferior for limb-threatening ischemia.[5,20,21]

Although there is no clear description in the 2017 ESC Guidelines regarding tibial bypass using a prosthetic graft, our findings suggest again that femorotibial PTFE bypass with a Miller's cuff is an important salvage surgery procedure for CLI, even in cases without adequate autologous veins or where catheter treatment was unsuccessful.

Graft infection is a point of concern when using a prosthetic graft, especially for CLI with foot infection. In our cases of PTFE-Miller's cuff, graft infections occurred in two limbs (6.3%) within 30 days of bypass surgery. Once graft infection has occurred, the situation may become serious, leading to major limb amputation. Accordingly, when using a prosthetic graft for CLI with tissue loss, we had to closely monitor the patient for infection. Regarding the type of graft, externally supported expanded PTFE vascular grafts (W. L. Gore & Associates, Flagstaff, AZ, USA) were mainly used, however, in the last two cases, we used a heparin-bonded expanded PTFE vascular graft (GORE PROPATEN Vascular Graft, W. L. Gore & Associates, Flagstaff, AZ, USA), which has been commercially available for clinical use in Japan since 2014.

In recent studies, the use of heparin-bonded grafts has been reported to show satisfactory early and midterm results in patients undergoing surgical treatment of CLI. However, it is impossible to perform a direct comparison of these studies with our results because these studies included several cases of below-knee bypasses, and additional treatments such as the distal vein patch technique were used. Furthermore, the results of bypass surgery in a small proportion (12.9% or 18%) of dialysis-dependent patients were considered to be poor.[16,22] As Azuma et al. pointed out, one of the main characteristics of Japanese patient populations is that many dialysis-dependent patients are included.[23] Indeed, 35.5% of our patients were dialysis-dependent. Therefore, we expect that the use of heparin-bonded grafts with a Miller's cuff may provide good results for patients in the absence of appropriate autologous veins, even under such adverse conditions.

Given that the limb salvage rate with the femorotibial PTFE bypass with a Miller's cuff remained relatively high despite the insufficient patency rate, we speculate that a large volume of direct blood flow to the ischemic tissue may have resulted in wound healing, possibly keeping the limb salvation rate high. Although we did not evaluate the blood flow dynamics or wound healing in this study, we hope to investigate this matter in a larger number of cases of femorotibial PTFE bypass with a Miller's cuff in the future.

Study limitations

This study was a retrospective analysis, the study duration was long, and the strategy of treatment was operator-dependent and changed in the middle of the study. Although it may be difficult to collect a large number of cases of PTFE bypass with a Miller's cuff due to the special disease conditions, a larger prospective study is needed.

Conclusion

Although the patency rate of femorotibial PTFE bypass with a Miller's cuff was low and satisfactory results were never achieved, the limb salvage rate with this approach

remained relatively high, at 71.0% after 3 years, and stable tissue blood flow early in the postoperative period seemed to be effective in ensuring wound healing. Femorotibial PTFE bypass with a Miller's cuff is an important technique of limb salvage for a severely ischemic limb in which an appropriate autologous vein cannot be used, or in cases in which bypass or EVT fails.

Disclosure Statement

Atsushi Guntani and other co-authors have no conflicts of interest to declare.

Author Contributions

Study conception and analysis: AG, SM
Data collection: AG, SM, SK
Writing: AG
Critical review and revision: all authors
Final approval of the article: all authors

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