Limb salvage after successful pedal bypass grafting is associated with improved long-term survival

Manju Kalra, MBBS,[a] **Peter Gloviczki, MD,**[a] **Thomas C. Bower, MD,**[a] **Jean M. Panneton, MD,**[a] **William S. Harmsen, MS,**[b] **Greg D. Jenkins, BS,**[b] **Anthony W. Stanson, MD,**[c] **Barbara J. Toomey, RN,**[a] and **Linda G. Canton, RN, BSN,**[a] *Rochester, Minn*

Objectives: **Assessments of outcome after reconstruction for critical limb ischemia frequently ignore functional result and long-term morbidity and mortality. This study was undertaken to identify factors affecting long-term clinical outcome and survival after pedal bypass grafting.**
Methods: **The clinical data of 256 consecutive patients who underwent pedal bypass grafting for critical limb ischemia over a 12-year period were retrospectively analyzed.**
Results: **A total of 174 men and 82 women (median age, 70 years; range, 30-91 years) underwent 280 pedal bypass graft placements with autologous vein. Seventy-five percent of the patients were diabetic, and 20% had renal insufficiency (serum creatinine level > 2 mg/dL). The in-hospital mortality rate was 1.6% (4/256). The mean follow-up was 2.7 years (range, 0.1-10.1 years). Rates of primary and secondary patency, limb salvage, and survival at 5 years were 58%, 71%, 78%, 60%, respectively. A total of 160 limbs (57%) required additional interventions. Nineteen early graft thrombectomies/revisions and nine early amputations were performed. One hundred thirty-eight late interventions included 31 graft salvage procedures, 27 wound debridements, and 34 minor and 42 major amputations. At last follow-up or death, 219 (78%) limbs were being used for ambulation. End-stage renal disease (ESRD) and composite vein grafts predicted limb loss ($P < .001$, $P < .001$, respectively). Overall survival at 5 years was 60%. Survival after amputation was 79%, 53%, and 26% at 1, 3, and 5 years. Amputation and ESRD predicted higher mortality ($P = .014$, $P = .0001$, respectively).**
Conclusions: **Pedal bypass grafting resulted in good functional limb salvage, but at the expense of multiple interventions in more than half the cases. ESRD and composite vein graft were associated with poor long-term limb salvage. Amputation after bypass grafting was associated with significantly worse long-term survival. (J Vasc Surg 2001;33:6-16.)**

Major amputations for critical limb ischemia are still frequently performed in the United States, despite the increasing number of surgical reconstructions and endovascular procedures. In the past two decades, the amputation rate in the United States was 19 to 30 per 100,000 person-years and approached 140 per 100,000 person-years in patients older than 85 years.[1] Primary amputation carries a high mortality rate (13%-17%), and successful rehabilitation is limited to two thirds of survivors at best.[2-4] Infrainguinal revascularization can be performed, with a lower mortality rate (3%-4%) and successful limb salvage in more than three fourths of patients.[5,6]

Pedal bypass grafting has become an accepted form of treatment for patients with severe distal disease, limb-threatening ischemia, and tissue loss, regardless of age or diabetic status.[7,8] The safety and durability of these procedures with cumulative foot salvage rates of the order of 80% at 3 to 5 years have been demonstrated in several series over the past decade.[9-14] Increasing success with these procedures has extended their use to patients with extensive tissue loss, when bypass grafting is accompanied with free tissue transfer to achieve foot salvage.[15] Some authors, however, have expressed concern over the effectiveness of inframalleolar reconstruction in patients with end-stage renal disease (ESRD) and extensive heel gangrene.[16]

Traditionally, the success of distal bypass grafts has been judged in terms of graft patency and foot salvage. Assessments of outcome have frequently ignored long-term morbidity and mortality, functional result, and the need for repeat interventions. Prolonged rehabilitation and low rates of survival with a salvaged functional limb have been reported after successful infrainguinal reconstructions.[17] Factors affecting long-term survival after pedal bypass grafting are not well known. This study was undertaken to identify factors affecting long-term clinical outcome and survival after pedal bypass grafting.

PATIENTS AND METHODS

Clinical data of all patients undergoing pedal bypass grafts at the Mayo Clinic have been entered in an ongoing database. We retrospectively analyzed data from 256 consecutive patients who underwent 280 pedal bypass grafts for chronic critical limb ischemia over a 12-year period, from 1987 to 1998. Data collected included details of preoperative clinical status and evaluation, operation, early and late adjunctive procedures, and ambulatory and survival status during follow-up. Intraoperative angiograms of the first 100 patients were reviewed, and the runoff was

From the Division of Vascular Surgery,[a] the Section of Biostatistics,[b] and the Department of Diagnostic Radiology,[c] Mayo Clinic.
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Reprint requests: Peter Gloviczki MD, Mayo Clinic, 200 First Street SW, Rochester, MN 55905 (e-mail: gloviczki.peter@mayo.edu).

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Table I. Patient demographics

Risk factor	*No. of patients (%)*
Diabetes mellitus	191 (74.6)
Hypertension	172 (67.2)
Smoking	150 (58.6)
Coronary artery disease	132 (51.6)
Hyperlipidemia	105 (41.3)
Cerebrovascular disease	54 (21.1)
Renal insufficiency (serum creatinine level > 2 mg/dL)	50 (19.5)
ESRD*	19 (7.4)

*Dialysis (n = 15), renal transplant (n = 4).

Table II. Type of conduit

	No. (%)
Translocated saphenous vein	183 (65.4)
In situ saphenous vein	35 (12.5)
Reversed saphenous vein	17 (6.1)
Composite vein	45 (16.1)
Bilateral leg veins	18 (40.0)
Ipsilateral leg veins	15 (33.3)
Leg + arm veins	8 (17.8)
Arm veins alone	4 (8.9)

Table III. Sites of proximal anastomosis

	No. (%)
Long grafts	130 (46.4)
External iliac	1 (0.4)
Common femoral	51 (18.2)
Superficial femoral	78 (27.9)
Short grafts	150 (53.6)
Popliteal	139 (49.6)
Tibioperoneal trunk	1 (0.4)
Peroneal	2 (0.7)
Posterior tibial	3 (1.1)
Dorsalis pedis	1 (0.4)
Other artery	4 (1.4)

graded (1 = patent pedal arch, 2 = incomplete pedal arch, and 3 = little or no pedal arch).

Postoperative surveillance has been performed with duplex ultrasound scan since December 1989, and the protocol includes a return visit at 6 weeks to 3 months and every 6 months thereafter. For the purpose of this study, grafts were classified as patent on the basis of clinical examination of pulses by a physician or duplex scan examination by a registered vascular technologist. Details of functional ambulatory status were obtained during a clinic visit (213), from letters from patient/family member (6)/local physician (24), or by telephone conversation with the patient (33). Patients were classified as ambulatory if they were weight bearing on the index extremity and were using it for walking or transfer to a wheelchair.

Graft patency, limb salvage, and patient survival were assessed with the Kaplan-Meier survival method.[18] Estimates of patient survival at 1, 3, and 5 years subsequent to amputation are quoted with the date of amputation as time zero. Significance tests for long-term survival used the log-rank test for dichotomous and categoric risk factors.[19] Ordinal and continuous risk factors were evaluated for survival with a Cox proportional hazards model.[20] Analysis of amputation as a risk factor for patient survival also used a time-dependent Cox proportional hazards model.

Multivariate survival models of graft patency, limb salvage, and patient survival were constructed with a stepwise selection procedure. Candidate factors in the model were those identified univariately as being significantly associated with the survival end point. Again, the Cox proportional hazards model was used for evaluation, *P* values, odds ratios, and 95% CIs for the odds ratios reported. A *P* value less than .05 was considered to be statistically significant.

RESULTS

Patients

Between September 15, 1987, and December 21, 1998, 256 patients, 174 (68%) men and 82 (32%) women (median age, 70 years; range, 30-91 years), underwent 280 pedal bypass grafts. All limbs satisfied criteria for critical ischemia as proposed by the Reporting Committee of the Joint Council of the Vascular Societies.[21] Two hundred fifty-one (89.6%) limbs had ischemic ulcer or gangrene (Chronic Ischemia Category 5), and 29 (10.4%) limbs had rest pain alone (Category 4). Eighty limbs (28.6%) had evidence of foot infection or cellulitis.

Risk factors

One hundred ninety-one patients (74.6%) were diabetic, and nineteen patients (7.4%) had ESRD (dialysis [15] and renal transplant [4]). Cardiovascular risk factors are listed in Table I.

Preoperative evaluation

A total of 279 patients underwent digital subtraction arteriography; one patient underwent magnetic resonance angiography. Saphenous vein mapping was performed in 210 limbs. The ankle-brachial index was measured with a handheld Doppler probe in 243 limbs. In 93 limbs the vessels were noncompressible. In the remaining 150 limbs, the median ankle-brachial index was 0.44 (range, 0.11-1.29). Transcutaneous oxygen tension was measured in 247 limbs and was less than 20 mm Hg in 224.

Bypass graft procedure

All but one pedal bypass graft were performed electively by one of three staff surgeons and a vascular fellow or general surgery resident. Autogenous vein was used in all procedures. Nonreversed ipsilateral greater saphenous vein was the most frequent conduit used (Table II). There were

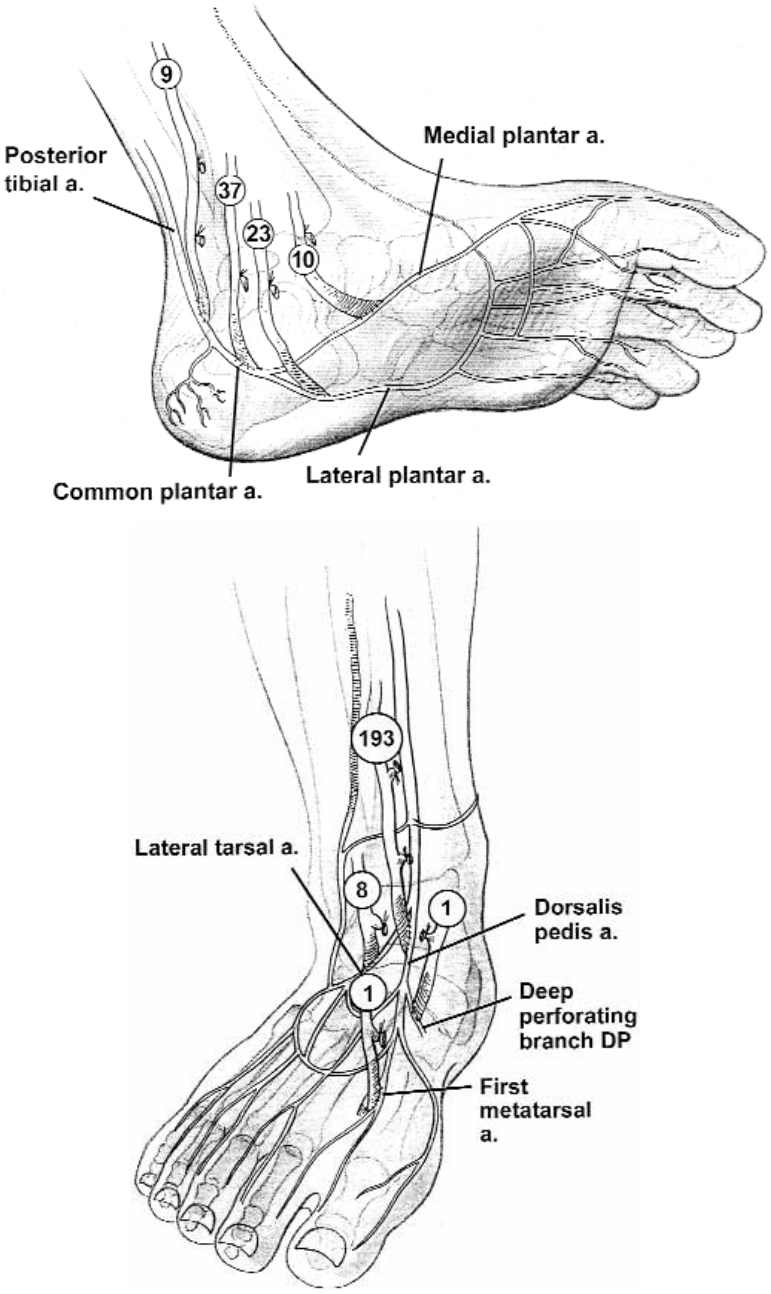

Fig 1. Sites of distal anastomosis in 280 pedal bypass grafts.

130 bypass grafts classified as "long" grafts and 150 as "short" grafts (Table III). The dorsalis pedis artery was the most frequent target vessel (Fig 1). An operating microscope was used to perform the distal anastomosis in more than half the cases. A bloodless field to perform the distal anastomosis was obtained with a thigh or calf tourniquet.

Grafts were assessed intraoperatively with completion angiography, (239) and blood flow measurement was assessed with an electromagnetic flow probe (270). The mean flow was 72.53 ± 39.53 mL/min (median, 65.0; range, 5-220). Patients with flows less than 50 mL/min received anticoagulation (heparin [180] and warfarin [114]) postoperatively.

Early results

Mortality. There were four early deaths (3 within 30 days) for an in-hospital mortality rate of 1.6% (30-day mortality rate, 1.2%). Causes of death included myocardial infarction, chronic obstructive pulmonary disease with respiratory failure, acute renal allograft dysfunction with

Table IV. Complications

	No. (%)
Early complications (within 30 d)	
Mortality*	4 (1.6)
Myocardial infarction	18 (6.4)
Renal insufficiency	6 (2.1)
Stroke	2 (0.7)
Deep venous thrombosis	2 (0.7)
Hematoma	18 (6.4)
Wound infection	17 (6.1)
Late complications	
Mortality*	76 (30.1)
Myocardial infarction	13 (4.7)
Wound infection	23 (8.4)
Graft infection	1 (0.4)
Graft occlusion	59 (21.5)
Graft stenosis	23 (8.4)

*Mortality was assessed in 256 patients and includes three deaths within 30 days and a fourth on day 40 during the same hospitalization.

Table V. Adjunctive procedures after 280 pedal bypass grafts

	No. of limbs (%)
Within 30 d	97 (34.6)
Wound debridement	49 (17.5)
Minor amputation	37 (13.2)
Graft thrombectomy	10 (3.6)
Graft revision	9 (3.2)
Hematoma evacuation	8 (2.9)
Myocutaneous flap	8 (2.9)
Skin grafting	7 (2.5)
Major amputation	9 (3.2)
Inflow procedure	3 (1.1)
During follow-up	97 (34.6)
Major amputation	42 (15.0)
Minor amputation	34 (12.4)
Wound debridement	27 (9.6)
Graft revision	23 (8.2)
Graft thrombectomy	8 (2.9)
Inflow procedure	1 (0.4)
New graft	1 (0.4)
Skin grafting	1 (0.4)
Sympathectomy	1 (0.4)

coagulopathy, and multisystem organ failure, in one patient each.

Complications. Early complications are listed in Table IV. They include four transmural and 14 subendocardial myocardial infarctions.

Graft patency. A total of 253 patients with 277 grafts were alive at 30 days. Nineteen grafts (6.8%) occluded early, requiring intervention (10 thrombectomy, 9 revision). Thirty-day primary and secondary patencies were 93.1% and 97.1%, respectively. At discharge, 269 grafts were patent, and eight were occluded.

Limb salvage. Thirty-day limb salvage was 96.7% with nine major amputations performed within 30 days: six after graft failure and three in presence of patent grafts.

Adjunctive procedures. A total of 140 adjunctive procedures were performed within 30 days in 97 limbs (Table V).

Late results

Mortality. The mean follow-up was 2.7 years (median, 2 years; range, 0.1-10.1 years). During follow-up, 76 patients (30.2%) died. The 1-, 3-, and 5-year cumulative survival rates were 87% (95% CI, 82.9-91.7), 76% (95% CI, 69.9-82.2), and 60% (95% CI, 52.5-68.8), respectively (Fig 2). One-, 3-, and 5-year survival rates in 50 patients subsequent to amputation after pedal bypass grafting were 79% (95% CI, 67.3-92.3), 53% (95% CI, 36.7-76.2), and 26% (95% CI, 9.3-75.2) (Fig 3).

Complications. There were 23 late wound infections (8.4%) and one graft infection (0.4%). There was an overall early and late wound complication rate of 14.9% (Table IV).

Graft patency. During follow-up, 59 (21.5%) grafts occluded and 23 (8.4%) developed stenoses. At last follow-up, 186 grafts were primarily patent, 32 secondarily patent, 62 were occluded (35 limbs amputated, 27 limbs salvaged). Of these 27 salvaged limbs, 22 had healed ulcers and relief of rest pain. Remaining five had minimal residual lesions, but were ambulatory. On life table analysis 1-, 3-, and 5-year cumulative primary patency rates were 66% (95% CI, 60.6-72.8), 59% (95% CI, 52.1-66.1), and 58% (95% CI, 50.9-65.0) and secondary patency rates were 78% (95% CI, 72.7-83.5), 72% (95% CI, 65.4-78.5), and 71% (95% CI, 64.1-77.7), respectively (Fig 2).

Limb salvage. There were 42 late amputations. Thirty-five limbs were lost after graft occlusion (12%), and 16 (6%) were lost despite patent grafts for an overall amputation rate of 18%. All 16 amputations with patent grafts were for ongoing foot infection and osteomyelitis; ESRD was a contributory factor in five patients. Cumulative limb salvage rates at 1, 3, and 5 years were 85% (95% CI, 80.3-89.5), 79% (95% CI, 73.9-85.1), and 78% (95% CI, 71.7-83.7), respectively (Fig 2).

Adjunctive procedures. A total of 138 adjunctive operative procedures were performed in 97 limbs during the follow-up period (Table V).

Outcome

At last follow-up or death, 65% (146) of ischemic ulcers/gangrenous wounds were healed, and another five healed and recurred, two of which were nearly healed again. A total of 219 (78%) of 280 operated limbs had a functional foot used for ambulation or transfer. Overall, 143 patients were alive with 161 salvaged feet at last follow-up. On life table analysis, 1-, 3-, and 5-year cumulative rates of patients alive with a salvaged limb were 75% (95% CI, 70.0-81.1), 61% (95% CI, 54.5-68.3), and 48% (95% CI, 40.5-56.4), respectively. At last follow-up, 150 patients were alive with a patent graft. Of these, 139 limbs were salvaged, and 135 were being used for ambulation. These results were achieved at the expense of adjunctive procedures in 160 limbs (57.1%); 85 limbs (30.4%) underwent two or more adjunctive procedures (Fig 4).

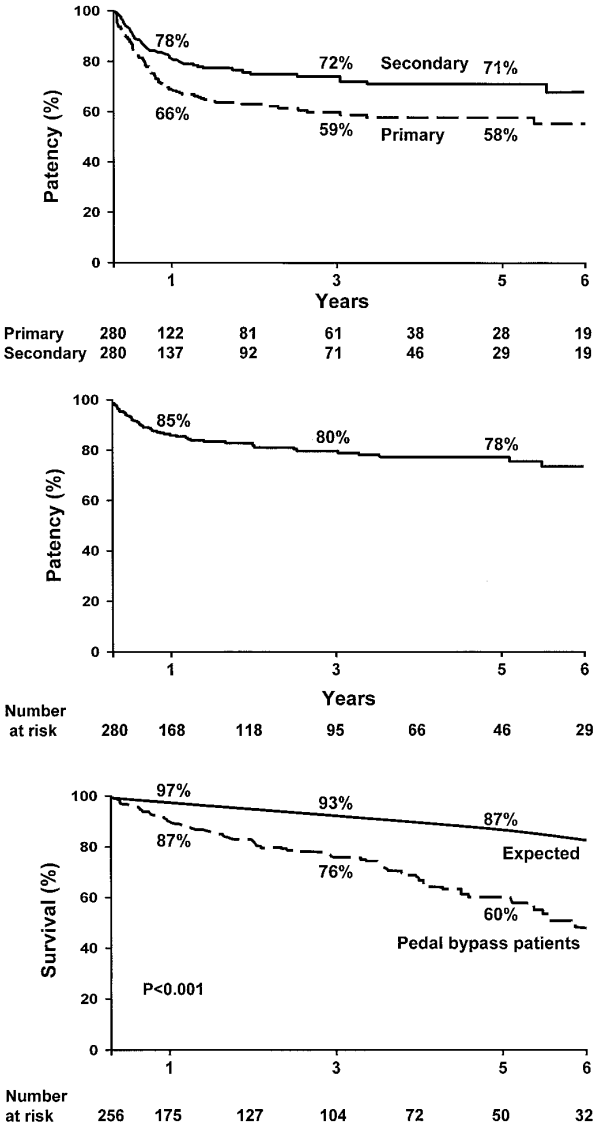

Fig 2. Cumulative graft patency, limb salvage, and patient survival after 280 pedal bypass grafts in 256 patients. SEM < 10% for all time points.

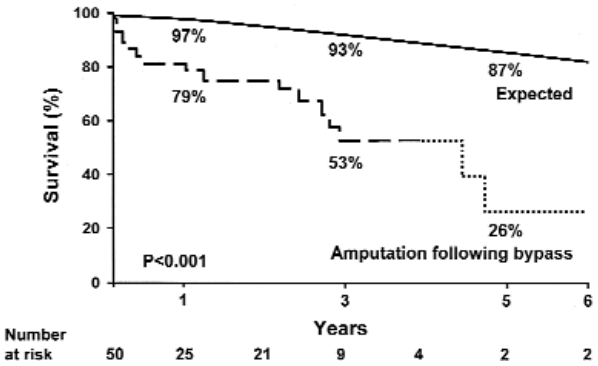

Fig 3. Cumulative survival rates in 50 patients subsequent to amputation after pedal bypass grafting compared with expected survival in an age- and sex-matched cohort. *Dotted line* represents SEM > 10%.

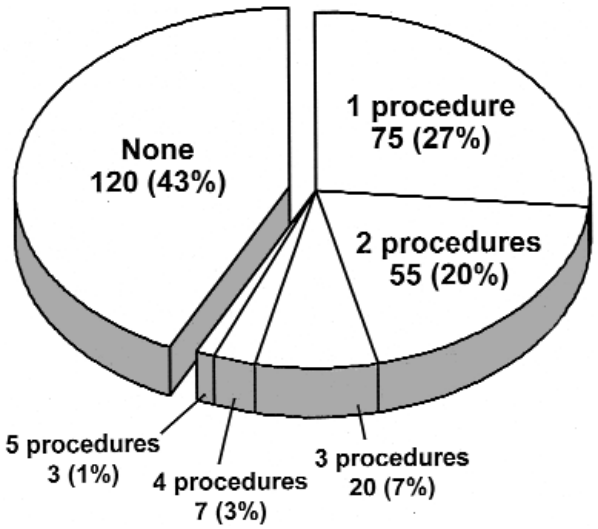

Fig 4. Incidence of adjunctive procedures in 280 limbs after pedal bypass grafting.

Risk factor analysis

Univariate analysis identified composite vein graft and secondary revascularization as factors associated with poor primary patency ($P < .001$, $P = .024$, respectively). Composite vein graft was associated with poor secondary patency ($P = .009$) and with limb loss ($P < .001$) (Table VI, Fig 5). Intraoperative graft blood flow of 50 mL/min or more and presence of diabetes were associated with improved primary ($P = .001$, $P = .024$, respectively) and secondary patency ($P = .003$, $P < .001$, respectively), but not limb salvage ($P = .075$, $P = .461$, respectively) (Table VI, Fig 6). Renal insufficiency was associated with worse limb salvage ($P = .048$). ESRD was associated with significantly worse limb salvage ($P < .001$) and patient survival ($P = .011$) (Table VI, Fig 7). A higher age at surgery correlated with worse long-term survival ($P = .0001$). With the dichotomization of age at 60 years, older age correlated with worse survival (5-year survival 56% vs 77%, $P = .015$). Factors significant on multivariate analysis are listed in Table VII.

DISCUSSION

Pedal bypass grafting with autologous vein is safe, effective, and durable as demonstrated by this and several previously published studies.[11,12] However, the decision between revascularization and primary amputation in elderly patients with multiple comorbidities and limited life expectancy is still a challenging and soul-searching exercise.

Table VI. Association of clinical variables with 5-year cumulative patency, limb salvage, and survival

		Primary patency		*Secondary patency*		*Limb*		*Survival*	
Risk factor	*No. of pts.*	*(%)*	P *value*	*(%)*	P *value*	*(%)*	P *value*	*(%)*	P *value*
Patient-related factors									
Sex									
Male	174	60	.177	72	.082	78	.796	56	.37
Female	82	53		66		76		67	
Age, > 80 y									
No	225	58	.823	70	.322	77	.356	65	< .001
Yes	31	56		78		85		24	
Diabetes									
No	65	54	.024	55	< .001	77	.461	50	.057
Yes	191	59		75		80		64	
Smoking									
No	106	55	.386	72	.987	77	.965	59	.889
Yes	150	60		69		78		61	
Renal insufficiency									
No	219	58	.425	72	.147	81	.048	64	.147
Yes	37	50		65		74		40	
ESRD									
No	237	58	.168	71	.223	80	< .001	62	.011
Yes	23	52		70		41		27	
Coronary disease									
No	124	56	.578	72	.579	80	.419	64	.177
Yes	132	59		69		75		55	
Cerebrovascular disease									
No	202	56	.515	69	.601	77	.855	65	.05
Yes	54	64		77		82		42	

		Primary patency		*Secondary patency*		*Limb salvage*		*Survival*	
Risk factor	*No. of limbs*	*(%)*	P *value*	*(%)*	P *value*	*(%)*	P *value*	*(%)*	P *value*
Limb-related factors									
Chronic ischemia									
Category 4	29	50	.655	51	.272	67	.75	63	.673
Category 5	251	59		73		79		60	
TcO_2									
> 20 mm Hg	27	79	.22	78	.582	84	.909	77	.179
< 20 mm Hg	224	54		69		75		58	
Secondary revascularization									
No	257	59	.024	72	.062	77	.956	57	.296
Yes	23	43		56		82		79	
Vein used									
Single-length	235	62	< .001	73	.009	81	< .001	60	.762
Composite	45	25		63		58		64	
Graft length									
Short graft	150	62	.323	70	.897	80	.592	63	.208
Long graft	130	53		71		75		58	
DP anastomosis									
No	87	58	.751	69	.652	76	.608	69	.065
Yes	193	50		72		78		56	
Flow rate									
≥ 50 mL/min	87	66	.001	78	.003	81	.075	58	.35
< 50 mL/min	193	39		53		68		68	
Runoff score*									
1	37	74		79		91		60	
2	40	50	.268	66	.636	67	.317	65	.315
3	22	60		64		76		73	

Renal insufficiency: serum creatinine level > 2 mg/dL.
*Runoff score available only in first 100 patients: 1 = patent pedal arch, 2 = incomplete pedal arch, 3 = little or no pedal arch.
DP, dorsalis pedis artery; *ESRD,* end-stage renal disease; *TcO_2,* transcutaneous oxygen tension.

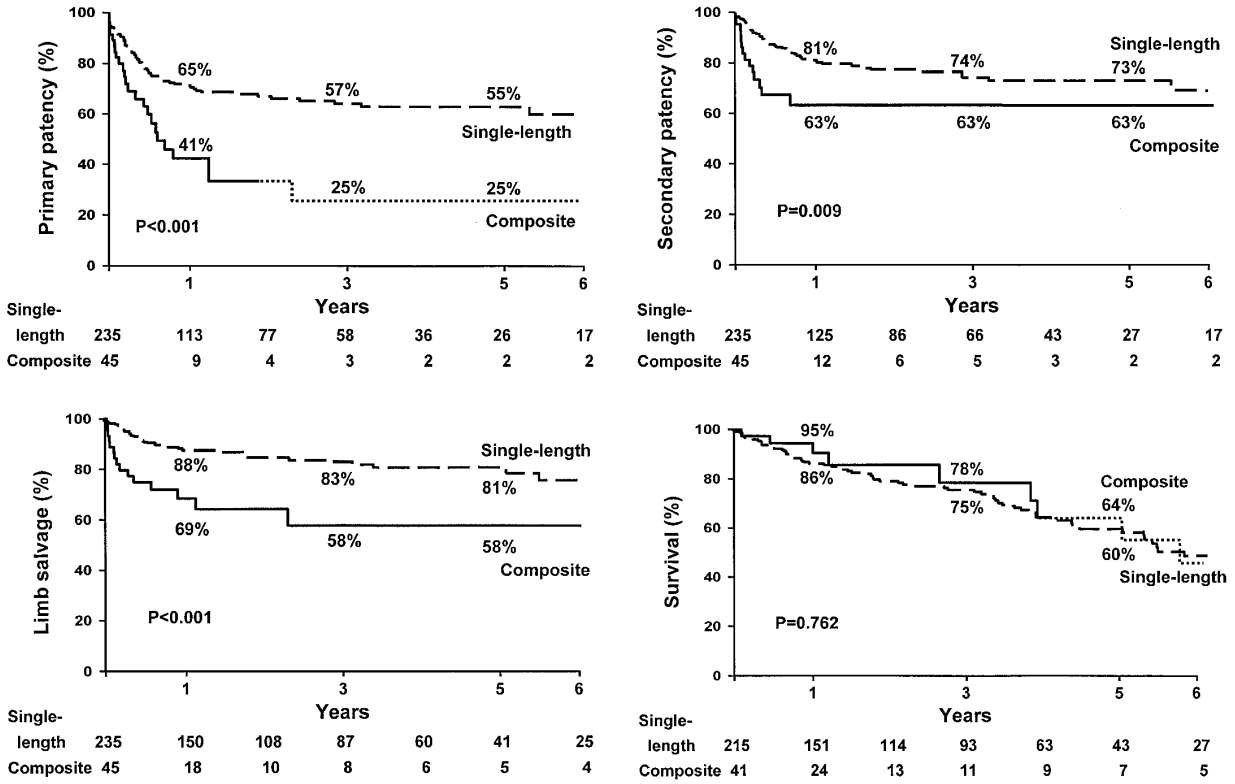

Fig 5. Cumulative graft patency, limb salvage, and patient survival after 45 pedal bypass grafts performed with composite vein in 41 patients compared with 235 bypass grafts performed with single-length vein in 215 patients. *Dotted line* represents SEM > 10%.

This retrospective analysis was undertaken to test our aggressive policy of attempting revascularization in all patients capable of ambulation or transfer, with the exception of patients with wet gangrene associated with sepsis. We previously reported our results in terms of graft patency and limb salvage, which compared favorably with other reported series.[13,22] Justification of aggressive revascularization requires assessment of other meaningful measures of outcome, such as long-term morbidity and mortality and functional status. An important consideration is the escalation in treatment costs in patients requiring multiple additional procedures for limb salvage and in those with failed reconstruction leading to amputation.[23,24]

The results of this series with a secondary patency rate of 71% and limb salvage rate of 78% at 5 years compare favorably with the reported literature (41%-84% and 54%-89%, respectively).[12,24-26] Diabetic patients fared significantly better in terms of primary and secondary graft patency although limb salvage was not significantly different from nondiabetic patients (80% vs 77%). The disease pattern in diabetic patients with atherosclerosis of the infrageniculate arteries and relative sparing of the pedal vessels[27] lends itself to successful pedal bypass grafting, with limb loss often occurring because of uncontrolled sepsis. The safety of distal bypass grafting in diabetic patients has been demonstrated by other authors, also.[7,12] Unlike other reports,[28,29] our series failed to confirm poorer long-term survival in diabetic patients with critical limb ischemia compared with nondiabetic patients. Akbari et al[7] also recently reported similar long-term survival in diabetic and nondiabetic patients after lower extremity revascularization.

On the other hand, patients with ESRD fared significantly worse in all respects, limb salvage and patient survival. Revascularization in these patients remains controversial with dismal results reported by several authors.[16,30,31] Patients with a renal transplant fared slightly better (limb loss, 1/4) than those undergoing dialysis (limb loss, 7/17), although the numbers are too small to make any firm conclusions. Our results would imply that patients with ESRD who require composite vein grafts may not merit an attempt at limb salvage; of six such patients, four limbs were lost by 7 months.

Octogenarians fared well in our hands with no difference in graft patency or limb salvage compared with their younger counterparts. Long-term patient survival was, however, worse in these elderly patients. Limb salvage rates in octogenarians were comparable to younger patients in other series as well, with satisfactory functional results at the cost of a modest increase in operative mortality (2.2 vs 6.7%).[8,32,33] However, the mortality rate after primary amputation is also higher in this age group

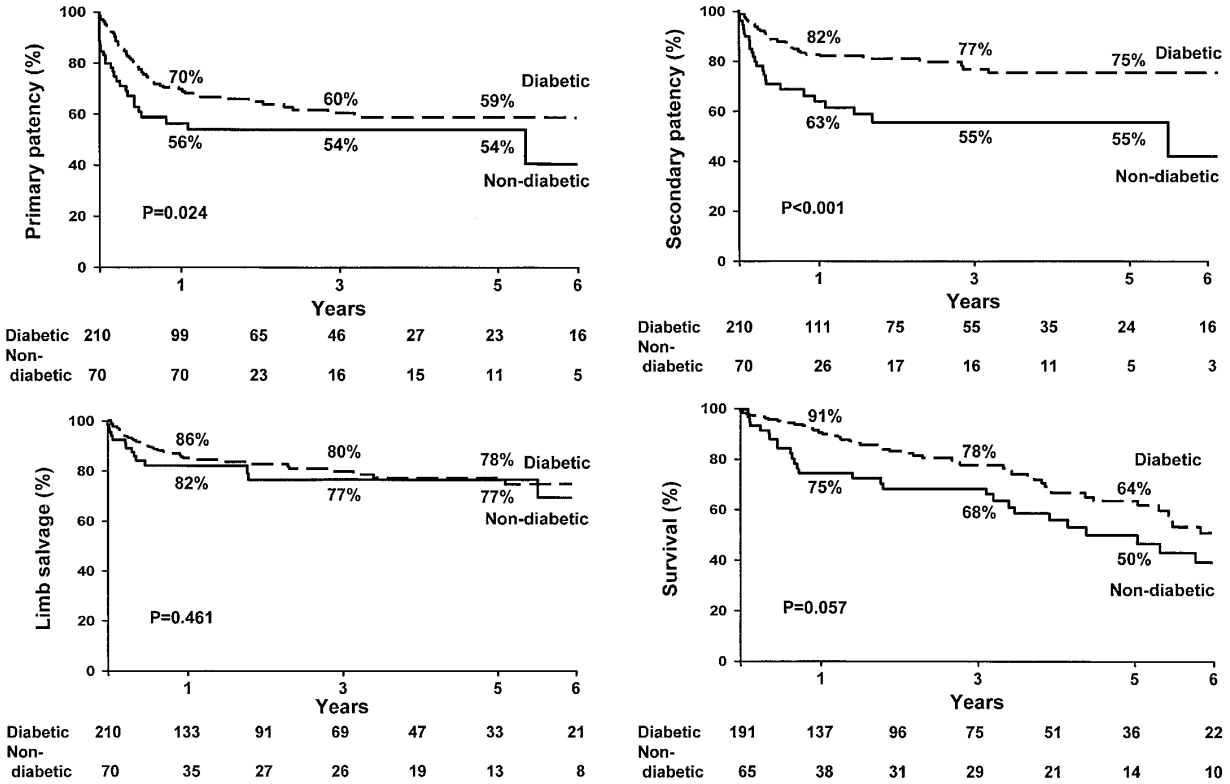

Fig 6. Cumulative graft patency, limb salvage, and patient survival after 210 pedal bypass grafts in 191 diabetic patients compared with 70 bypass grafts in 65 nondiabetic patients. SEM < 10% for all time points.

(9.8% vs 14.7%), with a considerably decreased chance of rehabilitation after amputation.[34-36]

Poor graft patency and limb salvage in limbs with composite vein grafts are disconcerting in our series and in others,[37,38] though not surprising. However, these results are still superior to those obtained with prosthetic grafts, and their use seems justified.[39]

Does failed revascularization result in a higher level of amputation? This question remains unanswered with several reports in the literature on either side of the argument.[40-42] In this study seven of 51 above-knee, 44 below-knee, and one Syme's amputations were performed. Presuming that all limbs would have been suitable for primary below-knee amputation before an attempt at revascularization preservation of the knee in 88% of secondary amputees is in concordance with the successful healing rate of primary below-knee amputations (85%-92%).[40,41] The cumulative probability at 5 years of having a below-knee amputation was not significantly different in diabetic patients compared with nondiabetic patients (21% vs 17%), nor was the probability of an above-knee amputation (2% vs 6%). Therefore, our data do not support the view that initial bypass grafting raises the level of amputation.

The most compelling finding of this study is that patients with failed revascularization and resultant amputation had worse long-term survival compared with the entire patient cohort. Amputation was a significant independent risk factor, predicting higher long-term mortality on multivariate analysis. Panayiotopoulos et al[42] reported better survival in 70 patients with successful femorocrural/pedal grafts compared with 82 amputees (62% vs 39% at 3 years), which included both primary and secondary amputations. Equivalent long-term survival rates have been reported in patients undergoing amputation after failed revascularization and in those undergoing primary amputation (37% and 30% at 3 years, respectively).[42] We did not do a similar comparative analysis because patients at our institution undergoing primary amputation are a different cohort with no scope for revascularization or ultimate ambulation. Five-year overall survival was significantly less than an age- and sex-matched cohort (60% vs 87%). Still, survival in our series was higher than in several other reports.[17,24,26,29]

Disappointing functional results have been observed after infrainguinal revascularization with only 45% of patients reporting feeling "back to normal" at 6 months and 54% requiring repeat operations.[43,44] Only 14% of patients undergoing infrainguinal revascularization achieved the ideal surgical results in one study, with no complications, long-term symptom relief, maintenance of functional status, and no repeat operations.[45] On assessment of residential and ambulatory status together at 1

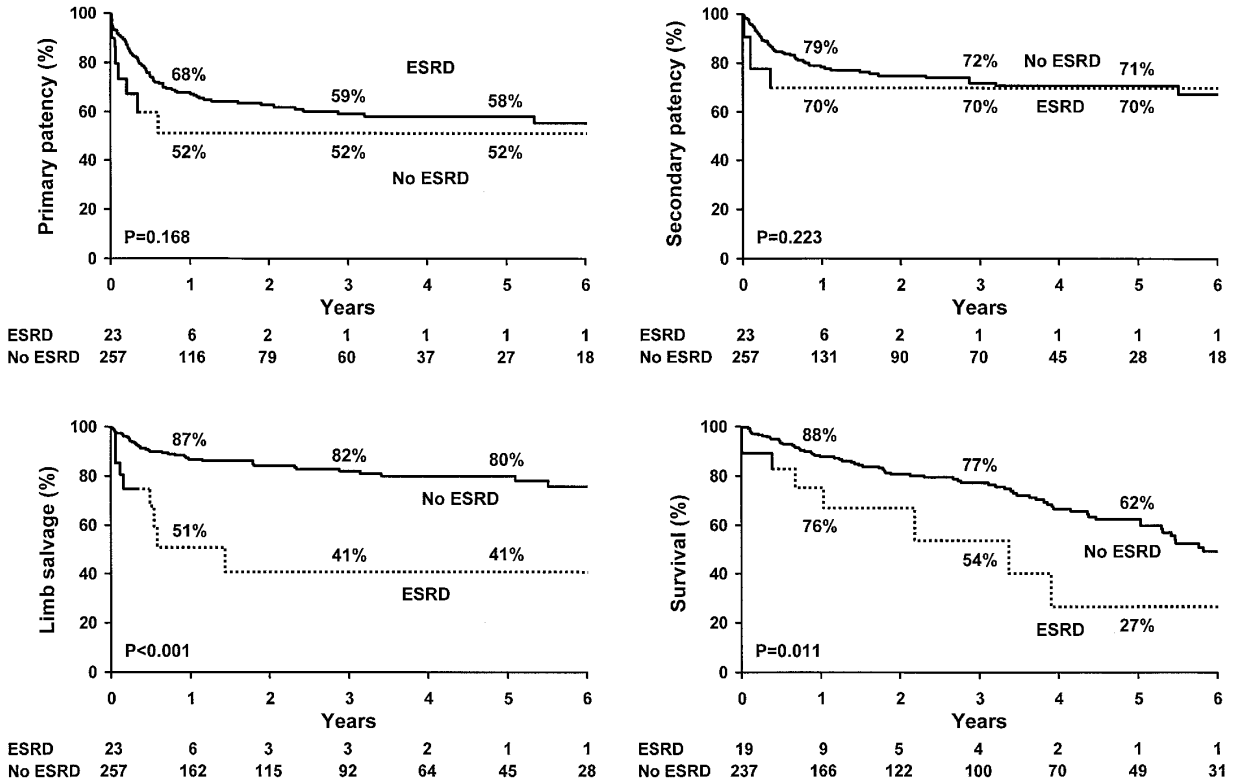

Fig 7. Cumulative graft patency, limb salvage, and patient survival after 23 pedal bypass grafts in 19 patients with ESRD compared with 257 bypass grafts in 237 patients without ESRD. *Dotted line* represents SEM > 10%.

Table VII. Multivariate analysis of risk factors affecting outcome

Variable	*Odds ratio*	*95% CI lower*	*95% CI upper*	P *value*
Primary patency				
Diabetes	0.59	0.378	0.919	.0196
Flow ≥ 50 mL/min	0.551	0.362	0.837	.0052
Composite vein	2.131	1.313	3.459	.0022
Secondary patency				
Diabetes	0.39	0.235	0.65	.0003
Flow ≥ 50 mL/min	0.504	0.302	0.842	.0089
Composite vein	1.908	1.034	3.521	.0389
Limb salvage				
ESRD	3.895	1.873	8.102	.0003
Composite vein	2.616	1.421	4.815	.002
Patient survival				
ESRD	5.78	2.408	13.874	.0001
Amputation	2.033	1.151	3.588	.0144
Age	1.068	1.041	1.096	.0001

year, Pomposelli et al[8] reported an improvement in 78% and maintenance in 88% of patients. They and other authors identified preoperative baseline functional status as a predictor of good functional outcome after revascularization.[43,46] In our series, 78% of limbs were used for ambulation at last follow-up or death.

Few studies have dealt with improvement in health-related quality of life after revascularization.[47,48] Successful outcome after pedal bypass grafting is often at the cost and morbidity of repeated interventions to salvage the graft and limb. Nearly one third of patients in our series had two or more adjunctive procedures. Late reinterventions are common after infrainguinal revascularizations.[45] Dawson and van Bockel[44] reported a cumulative reintervention rate of 25% at 1 year and 40% at 5 years. The costs of uncomplicated bypass graft surgery and primary amputation have been reported to be comparable when costs of the prosthesis and rehabilitation after amputation are included.[23,24] Raviola et al[23] reported escalation in cost of revascularization from $20,300 to $42,200 in patients requiring reinterventions, but also reported an equivalent increase in cost in the event of complications after primary amputation, from $20,400 to $40,600. Several reports have confirmed better functional results after revascularization.[8,35]

A drawback of our analysis is the lack of cost data to justify our policy of stretching the limits of limb revascularization to include every patient with hope of eventual ambulation. In view of improved survival after successful pedal bypass grafting demonstrated by this study, a prospective evaluation of cost per quality life-year added is warranted. It remains to be emphasized that ethical considerations far outweigh cost considerations in any indi-

vidual patient when deciding between revascularization and primary amputation.

We conclude that our results justify attempting distal bypass grafting to the foot vessels, even in high-risk patients. Revascularization with pedal bypass grafting results in good long-term limb salvage and functional ability for ambulation. Successful pedal bypass grafting is associated with improved long-term survival compared with survival in patients undergoing amputation. These results are, however, achieved at the cost of multiple interventions in more than half the patients, and the impact of this on health care costs needs to be assessed. Caution is recommended when offering distal reconstruction to patients with ESRD.

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DISCUSSION

Dr Frank W. LoGerfo (Boston, Mass). I want to compliment you on this excellent work, Dr Kalra. You have described your several target vessels, several inflow vessels, and several types of techniques in handling the conduit and bringing home the technical expertise that it takes to be successful in pedal bypass and how important it is in our training programs that we convey this information to our trainees. You may want to comment on how you accomplish this in your own program in terms of your trainees and your thoughts about their ability to carry on this work at the time of the completion of your program. It really can make a difference for patients.

Do you use angioscopy in preparation of the conduit? Can you comment on the mechanism of failure of the grafts that fail? What is the source of failure, and do you do graft surveillance?

Dr Manju Kalra. Thank you, Dr LoGerfo for your kind comments. Coming to your first question, all of these bypasses were performed by one of three consultant vascular surgeons together with a vascular fellow or general surgery chief resident. So trainees at our institution get an adequate exposure and opportunity to learn the techniques involved, and our vascular fellows are quite capable of carrying on this work in their future careers.

To answer your second question, we do not use angioscopy in preparation of the venous conduit. We have used a Mills valvulotome in most of our patients and cut the valves in the vein graft under direct vision.

As far as the mechanism of graft failure is concerned, the causes responsible for early graft failure were different from those seen in late failures. Early failure occurred in 19 grafts, and causes included technical problems, external compression of the graft by tense skin or tendon of the external hallucis longus muscle, and poor distal runoff. The most frequent cause of late failure was, of course, intimal hyperplasia in the vein graft and at the distal anastomosis.

Graft surveillance has been performed by duplex ultrasound at our institution since December 1989. The surveillance protocol has evolved during the study and now includes an examination before discharge from the hospital, a return visit at 6 weeks, and every 6 months thereafter.

Dr Frank B. Pomposelli (Boston, Mass). I, too, rise to compliment you on a truly excellent result with this operation. We've had a long-standing interest in this procedure as well.

I'm curious about your patients with end-stage renal disease and dialysis. We struggle with this group of patients as well. Did you have any patients in that group who had amputations with patent grafts? And are there any patients in that group or subset in whom you think an attempt at limb salvage is not appropriate?

Dr Kalra. Yes, the patients with end-stage renal disease do worry us, too, and that is why we presented them as a specific subgroup. In 19 such patients with 23 pedal grafts, nine amputations were performed. Six of these (66%) were done in the presence of patent grafts. The two risk factors that stood out on multivariate analysis for poor limb salvage were end-stage renal disease and composite vein graft. Of six patients who had both of these risk factors, we lost four limbs within 7 months. So, we agree with your group that we need to be realistic and cautious when we offer revascularization to this group of patients.

Dr James M. Seeger (Gainesville, Fla). Just a quick follow-up on that same thought process, in that you've identified a group of patients who clearly don't benefit, or benefit fairly poorly, and who, despite a successful graft, go on to amputation and then a high mortality. Are there any other factors, other than the fact they didn't have enough vein and had end-stage renal disease, that allowed you to identify those people preoperatively? Because in that group of patients, you're probably not benefiting them very well.

Dr Kalra. We looked at cardiovascular risk factors, the degree of ischemia, $TcPO_2$ levels in the foot, completeness of the pedal arch, and none of these factors were independent predictors of limb loss on multivariate analysis.