Composite sequential grafts for femorocrural bypass reconstruction: Experience with a modified technique

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Background: **To evaluate the efficacy of a modification of the composite sequential femorocrural bypass graft that we adopted in 1985, a retrospective case-note study was undertaken. The grafts combined a prosthetic femoropopliteal section with a popliteal to crural section with autologous vein, linked via a common intermediate anastomosis sited on the above-knee popliteal artery.**
Patients and methods: **Between 1985 and 2000, 68 grafts of this type were constructed in 65 patients with critical ischemia of the lower limb and insufficient autologous vein for construction of an all venous bypass. Reasons for insufficient long saphenous vein included previous lower limb bypass in 33 cases, phlebitis in 16 cases, venous hypoplasia in eight cases, and previous varicose vein surgery in seven cases. Distal anastomoses were carried out to the peroneal artery in 26 cases, the anterior tibial artery in 17 cases, the posterior tibial artery in 17 cases, and the pedal arteries in eight cases. Sources of vein included the long saphenous vein in 26 cases, the arm vein in 38 cases, and the short saphenous vein in two cases. In 22 limbs (32%), angiography had shown an occluded segment of above-knee popliteal artery, and in these cases, local popliteal disobliteration was performed to receive the composite anastomosis and to provide additional outflow.**
Results: **The 2-year cumulative primary patency, secondary patency, and limb salvage rates were 68%, 73%, and 75%, respectively. Localized popliteal disobliteration did not compromise graft patency (P = .07, with log-rank test).**
Conclusion: **In the absence of sufficient autologous vein, patients needing bypass to crural arteries can be offered reconstruction with composite sequential grafting with satisfactory results. Furthermore, an occluded above-knee popliteal segment is not a contraindication for composite sequential bypass reconstruction. (J Vasc Surg 2002;36:772-8.)**

Femorocrural bypass with an autologous vein graft is an effective treatment for critical lower limb ischemia resulting from extensive infrainguinal atherosclerotic occlusion. In observational studies, the best results have been achieved with the in situ long saphenous vein graft technique developed by Rostad, Hall, and Rostad[1] and popularized by Leather and Karmody.[2] Randomized studies, however, have shown that all configurations of autologous vein of at least 2.5-mm diameter are capable of yielding satisfactory results.[3] In comparison, although adjunctive measures, such as distal anastomotic cuffs or arteriovenous fistulae, have improved patency rates, results with prosthetic grafts are invariably inferior, especially when follow-up is extended beyond the first year.[4-6]

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Even after a determined effort to harvest sufficient autologous vein, a significant group of patients who lack sufficient vein to extend from the groin to the calf or foot remains. Reasons for this shortage of vein include previous harvest for coronary artery or leg bypass grafting, previous varicose vein surgery, or simple unsuitability because of phlebitis or hypoplasia. In such cases, consideration of supplementation of the available vein with a length of prosthetic graft is logical, and a variety of configurations of vein/prosthetic composites have been evaluated. Unfortunately, simple end-to-end composites have proved no better than prosthetic alone.[7,8] In theory, patency can be improved by increasing the flow through the prosthetic proximal portion of the graft, which is more vulnerable to low flow, and by using autologous material at the distal anastomosis, which is more vulnerable to neointimal hyperplasia. Thus, better results have been achieved with sequential graft configurations, incorporating an intermediate anastomosis onto the popliteal artery above or below the knee.

Most reports of this approach recommend anastomosis of the prosthetic graft to a patent popliteal segment, either above or below the knee, then addition of the vein graft as a "piggy-back" extension from the prosthetic. Two-year patency rates with these techniques have varied from 35% to 64%.[9-11] In an early report of composite sequential grafting, Bliss and Fonseka[12] in 1976 cited their intermediate anastomosis on an endarterectomized segment of upper popliteal artery and incorporated both vein and prosthesis into the popliteal arteriotomy, anastomosing them end to end as a "hitch-hike" configuration. No long-term results were presented, but 11 of 16 grafts remained patent at 2 to 14 months of follow-up. This configuration has not been widely adopted subsequently, but the technique we have used since 1985 is similar, differing only in the side-by-side relationship of the vein and prosthetic grafts on the popliteal arteriotomy (Fig 1).

PATIENTS AND METHODS

To evaluate the efficacy of this technique, the case records of patients who underwent composite sequential bypass grafting in our care between 1985 and 2000 were reviewed.

Preoperative assessment. Patients with critical lower limb ischemia in the presence of a normal femoral pulse underwent evaluation with duplex ultrasound scan or angiography and, if conditions were unsuitable for endovascular therapy, were considered for infrainguinal bypass. When ipsilateral long saphenous vein was unavailable or inadequate, other sources of vein for grafting were considered, including the opposite leg, both arms, and the short saphenous veins of both legs. Only when the sum total of available vein had been reviewed and judged inadequate was the option of composite sequential grafting considered. Initially in this series, we required evidence of a patent segment of proximal popliteal artery before proceeding, but latterly, we relaxed this requirement when we realized that disobliteration of occluded above-knee popliteal segments could restore the arterial lumen and reopen sufficient collateral outflow to permit the construction of a composite anastomosis. This was evident with the back bleed that invariably occurred on performance of the endarterectomy.

Selection of the appropriate crural artery to receive the distal graft anastomosis was made either on the basis of preoperative arteriography or more commonly through a combination of dependent Doppler assessment of the crural and pedal arteries supplemented with prebypass intraoperative arteriography.[13]

Surgical technique. The femoropopliteal component of the graft was performed with an 8-mm polytetrafluoroethylene prosthesis routed through a subsartorial tunnel. The composite anastomosis was made to the above-knee popliteal arteriotomy, after endarterectomy if necessary. In the presence of an occluded above-knee popliteal segment, disobliteration was carried out up to 6 cm proximally and distally with artery forceps. Endarterectomy was believed to be adequate when a significant back bleed was seen. The spatulated ends of the polytetrafluororethylene and vein grafts were aligned side by side along the arteriotomy and anastomosed with three longitudinal panels, namely polytetrafluororethylene to artery, vein to artery, and vein to polytetrafluororethylene (Fig 1). The vein segment was routed across the knee joint through a deep anatomic tunnel and in most cases was orientated in a nonreversed format, with a Hall-pattern valvulotome to secure antegrade flow. On the few occasions when an arm vein was used in reversed configuration, the distal anastomosis was performed before the popliteal. Distal anastomoses were performed in conventional end-to-side fashion with loupe magnification. In most cases, vein grafts in the calf were routed through deep tunnels, and in the case of bypass to the anterior tibial or dorsalis pedis, the grafts were introduced into the anterior tibial compartment in the proximal calf and threaded distally. Deep graft routing was preferred to minimize the possibility of graft exposure through wound breakdown in tissues compromised by chronic ischemia in patients with a high prevalence of nutritional, metabolic, and cardiorespiratory disorders. Patients were initiated on antiplatelet agent therapy perioperatively, unless they were already on anticoagulant therapy for other reasons.

Immediate postoperative assessment of graft patency was carried out with palpation of foot pulses supplemented with hand-held Doppler examination. In the vast majority of cases, duplex ultrasound scan was used for graft surveillance at regular intervals up to 18 months after surgery. In a small minority of cases (n = 2), graft patency was evaluated with measurement of ankle brachial pressure index earlier in the series, with a drop of more than 0.1 warranting angiography for confirmation of patency. Patients that were

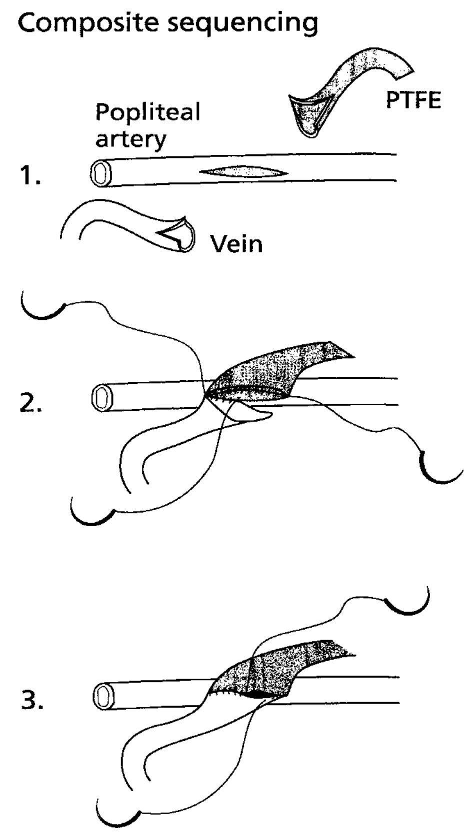

Fig 1. Side-by-side configuration of composite-sequential bypass.

Table I. Reason for insufficient saphenous vein and source of vein used for composite sequential bypass

Reason for insufficient vein	*No.*	*Vein used*	*No.*
Previous use		Ipsilateral long saphenous	23
		Arm vein	
Previous infrainguinal bypass	33	Cephalic	17
Coronary artery bypass	2	Cephalic-basilic loop	6
Other	2	Basilic	2
		Multiple sources	13
Phlebitic vein	16	Contralateral long saphenous	3
Hypoplasia	8	Short saphenous	2
Varicose vein surgery	7	Anterolateral thigh	1
		Previous graft	1
Total	68		68

still alive at the end of the study period had a duplex scan carried out prospectively for more up-to-date follow-up.

Statistical considerations. Cumulative graft patency, limb salvage, and mortality rates were calculated as recommended by the reporting standards committee of the Society for Vascular Surgery/North American chapter of the International Society for Cardiovascular Surgery with the Kaplan-Meier method.[14] Failure of either the proximal or the distal portions of the graft was scored as graft occlusion. Potential risk factors as predictors of graft failure were assessed with the log-rank test for univariate analysis. All factors evaluated with univariate analysis also underwent multivariate analysis with the Cox regression model.[15] A *P* value of less than .05 was deemed statistically significant (SPSS version 10 software, Chicago, Ill).

RESULTS

Patient details. A total of 1500 primary and 200 secondary infrainguinal bypass procedures were carried out between 1985 and 2000. Of these, a total of 68 consecutive composite sequential bypass graft operations were carried out on 65 patients with a median age of 73 years (interquartile range, 67 to 81 years). This group consisted of 38 men and 27 women. Thirty-three of these operations (49%) were done after the failure of a previous bypass graft. Most of these were carried out with general anesthesia (n = 61), with spinal (n = 5) and local (n = 2) anesthesia being reserved for patients at high risk. The indication for revascularization was tissue loss and rest pain in 33 and 35 cases, respectively. Almost half of the patients were actively smoking up to the time of surgery despite counseling. Twenty-two patients (32%) had diabetes, 24 (37%) were undergoing treatment for hypertension, 13 (20%) had angina, 13 (20%) had a history of myocardial infarct, and 11 (17%) had previously had a stroke.

Site of distal anastomosis. Distal anastomoses were carried out to proximal-third calf arteries in 14 cases, middle-third in 31 cases, distal-third in 15 cases, and pedal arteries in eight cases. The site of the distal anastomosis was the peroneal artery in 26 cases, the anterior tibial artery in 17 cases, the posterior tibial artery in 17 cases, and the pedal arteries in eight cases. This included one dual outflow graft that was anastomosed to the middle-third segments of both the peroneal and the posterior tibial arteries.

Source of vein. Table I illustrates the reasons for insufficiency of vein for bypass and the source of vein used. The most common reason was previous use in femorodistal or popliteal bypass reconstruction. Other causes included poor quality vein from phlebitis or venous hypoplasia. Arm vein was most frequently used (38 cases), with the cephalic vein being the most common, followed by arm vein from multiple sources and the cephalic-basilic loop. The available segment of ipsilateral long saphenous vein was used in 23 cases and the contralateral long saphenous vein in three cases, with the short saphenous and anterolateral thigh veins also used. In one case, a good quality segment of vein was harvested from a previously failed distal graft.

Popliteal segment patency. In 22 limbs (32%), angiography had shown an occluded segment of above-knee popliteal artery. In these cases, disobliteration was performed to restore a lumen to receive the composite anastomosis and to provide additional outflow via the geniculate arteries.

Outcome. The median follow-up period was 20 months (range, 0 to 120 months). Kaplan-Meier analysis calculated the 30-day cumulative primary and secondary patency rates as 81% and 88%, respectively. At 2 years, the cumulative primary patency rate was 68%, the cumulative secondary patency rate was 73%, and the limb salvage rate was 75% (Fig 2; Tables II, III, and IV, online only). The 30-day mortality rate for the whole series was calculated at 7.4% (5/68). The cause of death in all five cases was cardiac in origin. The 2-year cumulative survival rate was 65% (Table V, online only).

Of a total of eight early (less than 30 days) amputations, six were for graft thrombosis (thrombectomy unsuccessful), one for graft infection, and another after a graft had occluded after a distal bleed. In addition, two successful graft thrombectomies were carried out. Other early procedures included an adjunctive sympathectomy. Four early superficial wound dehiscences were seen.

Procedures carried out on grafts after the first 30 days included thrombolysis for two thrombosed grafts and jump grafts in two for stenoses. Failure of the venous segment alone warranted replacement of this portion in four cases. In addition, profundoplasty was carried out in one case and ligation of a bleeding graft from infection in another. A total of nine late amputations were performed. Other late

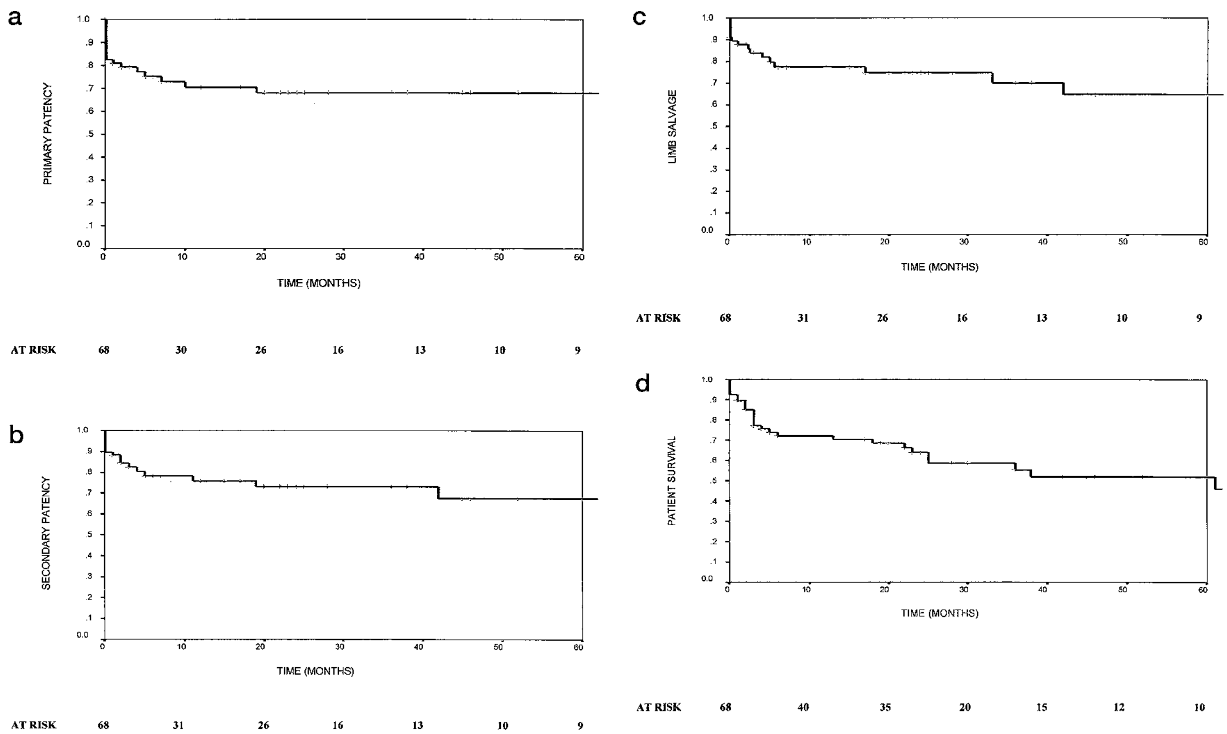

Fig 2. Kaplan-Meier curves show cumulative **(a)** primary graft patency, **(b)** secondary graft patency, **(c)** limb salvage, and **(d)** patient survival.

complications included a deep venous thrombosis in one patient.

While ischemic heart disease was a significant risk factor for graft failure (secondary patency) in multivariate analysis, hypertension, tissue loss, smoking, or diabetes did not reach statistical significance (Table VI). Importantly, neither the use of arm vein nor the performance of a popliteal endarterectomy of an occluded popliteal segment were significant factors for graft failure (Fig 3).

DISCUSSION

The aims of treatment of a critically ischemic leg are a good quality of life and limb salvage until death in a population that is afflicted by widespread atherosclerosis and shows reduced survival rates compared with matched control subjects. Amputation for peripheral vascular disease is associated with a high mortality rate, a poor quality of life, and a low likelihood of rehabilitation.[16] Therefore, an aggressive approach to the salvage of the critically ischemic leg is recommended for patients with a good chance of rehabilitation.[17]

The best long-term results are achieved with conduits constructed of vein rather than of prosthetic material.[18] In cases where a sufficient length of long saphenous vein is unavailable, arm vein may be sufficient or a single venous conduit may be constructed with splicing several segments of arm and leg veins. However, even with an aggressive policy of use of autologous vein only, a significant proportion of patients will not have sufficient good caliber vein in primary and secondary revascularizations, respectively.[19] Options available include the use of prosthetic material with a distal vein cuff or fistula, straight prosthetic-vein composites, composite sequential bypass, endarterectomy, and endovascular techniques. The advantage of sequential rather than straight prosthetic vein composites is prevention of graft kinking and avoidance of disparity in size between prosthesis and vein. To date, the results of all of these techniques have been variable. No randomized comparisons have been carried out. Subintimal angioplasty remains an alternative but, outside of a few centers, has not yielded long-term results equivalent to surgical reconstruction.[20] Endarterectomy of the superficial femoral artery with ring strippers is another option, thus providing the inflow for a short segment of vein to be used in constructing a graft from the popliteal artery to the crural vessels.[21] The obvious disadvantage with this technique is neointimal hyperplasia in the endarterectomized vessel.

The advantages of the composite sequential bypass over a prosthetic conduit with a venous cuff include the ability of vein to withstand distal low flow rates and compression on knee flexion. McCarthy et al[10] reported that those cases with an intermediate anastomosis at the above-knee popliteal artery had a better graft patency rate than those below the knee, although this was not

Table VI. Evaluation of risk factors for graft failure

Risk factor	*No.*	*24-month patency rate*	*Univariate analysis* P *value*	*Multivariate analysis* P *value*
Occluded popliteal				
Yes	22	78%	.07	.32
No	46	65%		
Arm vein				
Yes	38	80%	.08	.13
No	30	65%		
Diabetes				
Yes	22	65%	.24	.95
No	46	78%		
IHD				
Yes	26	64%	.19	.05
No	42	79%		
Smoking				
Yes	30	68%	–	.09
No	38	78%		
Tissue loss				
Yes	33	68%	–	.79
No	35	78%		
Hypertension				
Yes	24	71%	.31	.59
No	44	75%		

Table shows univariate (log rank test) and multivariate (Cox regression) analyses for risk factors. Degree of freedom is 1 in all cases. Missing values indicate intersection of lines, so that log-rank test cannot be used.
IHD, Ischemic heart disease.

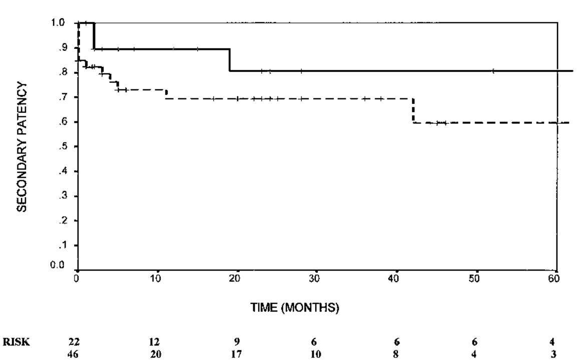

Fig 3. Effect of disobliteration (endarterectomy) of occluded popliteal segment on graft patency (*continous line* depicts those with occluded popliteal segment, and *dotted line* depicts those with patent isolated popliteal segment). Log-rank test results showed no statistically significant difference ($P = .07$).

statistically significant. Deep routing of grafts avoids wound-related contamination and may reduce torsion and kinking. The addition of an intermediate popliteal anastomosis improves distal flow and reduces outflow resistance. Furthermore, in the event of thrombosis of one segment, limb salvage may still be achieved via flow from the remaining segment of graft, although all four cases in our series with occlusion of the venous segment alone had recurrence of critical ischemia necessitating intervention. Replacement of the occluded segment without sacrifice of the whole graft may then be possible. The theoretical benefits of the side-by-side configuration include better compliance matching, reduced turbulence, and avoidance of a complete ring of thrombogenic material at the intermediate anastomosis. In addition, conjoining the prosthetic and venous anastomosis requires three rather than four lines of suturing and is simpler than the hitch-hike technique of Bliss and Fonseka.[12] Composite sequential bypass reconstruction may be more time consuming initially than use of an all prosthetic graft and requires expertise in distal reconstruction and endarterectomy. The theoretic disadvantage of competitive flow with steal from distal beds by the proximal anastomosis has not been encountered in our experience.[22]

It is widely believed that a patent isolated segment of popliteal artery is necessary for sequential bypass. However, with endarterectomy, perfusion of the geniculate collaterals is possible. This allows an intermediate anastomosis to be performed in all cases. No difference was seen in graft patency between our patients with an endarterectomy for an occluded popliteal artery and those with a patent isolated popliteal segment.

The results of this series are comparable with others with various configurations of composite sequential bypass. Of reported series with greater than 50 cases, Verta[23] reported a 2-year patency rate of 81% with the prosthetic-vein anastomosis carried out at the distal section of the prosthetic graft segment. McCarthy et al[10] anastomosed the venous segment to the hood of the prosthetic graft, yielding a 2-year patency rate of 64% in 67 patients, where 50% of the series was secondary procedures. Chang and Stein[11] reported a 2-year patency rate of 82% for composite sequential bypass, half of the group being redo procedures. Our experience, and those of others with direct end-to-end prosthetic to vein composite grafts, has been disappointing. Bastounis et al,[24] however, used an end-to-end prosthetic-vein composite graft with a kissing intermediate anastomosis of the vein onto the popliteal artery and obtained a 2-year secondary patency rate of 92% in a series of 96 composite grafts. This series included 60 distal procedures, of which only 21 were sequential, and unlike our series, all of these procedures were primary reconstructions. Approximately half of our series were secondary procedures, which traditionally produce lower patency rates.[25-27]

It is important to mention that despite previous lower limb revascularization and coronary artery bypass grafting, vein was available in the lower limb in more than 50% of cases. This is usually because of incomplete harvesting for bypass or incomplete stripping in varicose vein surgery. This further reinforces the need to make every effort to assess the suitability of remnant veins for bypass. Preoperative vein mapping with duplex Doppler scan has been advocated to assess venous suitability.[28] However, in our experience, direct exploration of the vein is necessary to ensure that no usable vein is missed.

Apart from Chang and Stein,[11] most large series have used only long or short saphenous veins. In our institution, we have used arm vein as well, which was first described by Bliss and Fonseka,[12] when good caliber saphenous vein was not available. In the absence of a sufficient length of quality cephalic or basilic vein, the cephalic-basilic loop can be used.[29,30] In our series, no difference was seen in patency between grafts that were constructed from arm veins and those that used leg vein.

Femoropopliteal bypass is an effective procedure in patients with rest pain alone and an isolated patent popliteal segment. In a randomized multicenter study, Darke et al[31] showed that there was no difference in graft patency and limb salvage when comparing distal and popliteal bypass in the presence of an isolated segment. Why we chose not to bypass to the popliteal artery in preference to longer distal grafts may be questioned because approximately 50% of the patients had rest pain only. First, this group consisted of a large number of patients with diabetes who are likely to show or develop further disease of the calf and foot vessels, which would compromise graft patency and future limb salvage. In addition, a patent isolated segment of popliteal artery was not present in almost one third of this study group. Finally, prediction of whether collateral vessels from the isolated segment will perfuse the calf vessels adequately is difficult.

In conclusion, the side-by-side configuration we describe for the intermediate anastomosis has theoretical and practical advantages and has yielded satisfactory results in our hands. Contrary to popular belief, disobliteration of an occluded popliteal segment allows the intermediate anastomosis to be carried out in all cases.

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Table II, online only. Kaplan-Meier table for primary patency

Time (mo)	*Status*	*Cumulative survival rate*	*Standard error*	*Cumulative events*	*No. remaining*
0.0	0			0	67
0.0	0			0	66
0.0	0			0	65
0.0	0			0	64
0.0	0			0	63
0.1	1			1	62
0.1	1			2	61
0.1	1			3	60
0.1	1			4	59
0.1	1			5	58
0.1	1			6	57
0.1	1			7	56
0.1	1			8	55
0.1	1			9	54
0.1	1			10	53
0.1	1	0.8254	0.0478	11	52
1.0	1	0.8095	0.0495	12	51
1.0	0			12	50
1.0	0			12	49
1.0	0			12	48
2.0	1	0.7927	0.0512	13	47
2.0	0			13	46
2.0	0			13	45
3.0	0			13	44
3.0	0			13	43
3.0	0			13	42
3.0	0			13	41
3.0	0			13	40
3.0	0			13	39
4.0	1	0.7723	0.0538	14	38
5.0	1	0.7520	0.0561	15	37
5.0	0			15	36
5.0	0			15	35
5.0	0			15	34
6.0	0			15	33
7.0	1	0.7292	0.0588	16	32
7.0	0			16	31
10.0	1	0.7057	0.0615	17	30
12.0	0			17	29
17.0	0			17	28
19.0	1	0.6805	0.0642	18	27
20.0	0			18	26
22.0	0			18	25
22.0	0			18	24
22.0	0			18	23
23.0	0			18	22
23.0	0			18	21
24.0	0			18	20
24.0	0			18	19
25.0	0			18	18
28.0	0			18	17
28.0	0			18	16
36.0	0			18	15
36.0	0			18	14
38.0	0			18	13
45.0	0			18	12
46.0	0			18	11
52.0	0			18	10
60.0	0			18	9

Table III, online only. Kaplan-Meier table for secondary patency

Time (mo)	*Status*	*Cumulative survival rate*	*Standard error*	*Cumulative events*	*No. remaining*
0	1			1	67
0	1			2	66
0	1			3	65
0	1			4	64
0	1			5	63
0	1			6	62
0	1	0.8971	0.0369	7	61
0	0			7	60
0	0			7	59
0	0			7	58
0	0			7	57
0	0			7	56
0	0			7	55
1	1	0.8807	0.0396	8	54
1	0			8	53
1	0			8	52
1	0			8	51
1	0			8	50
2	0			8	49
2	1			9	48
2	1	0.8448	0.0454	10	47
2	0			10	46
2	0			10	45
3	1	0.8260	0.0481	11	44
3	0			11	43
3	0			11	42
3	0			11	41
3	0			11	40
3	0			11	39
4	1	0.8048	0.0514	12	38
5	1	0.7837	0.0542	13	37
5	0			13	36
5	0			13	35
5	0			13	34
6	0			13	33
7	0			13	32
11	1	0.7592	0.0578	14	31
12	0			14	30
15	0			14	29
17	0			14	28
19	1	0.7321	0.0617	15	27
20	0			15	26
22	0			15	25
22	0			15	24
22	0			15	23
23	0			15	22
23	0			15	21
24	0			15	20
24	0			15	19
25	0			15	18
28	0			15	17
28	0			15	16
36	0			15	15
36	0			15	14
38	0			15	13
42	1	0.6758	0.0786	16	12
45	0			16	11
46	0			16	10
52	0			16	9
60	0			16	8

Table IV, online only. Kaplan-Meier table for limb salvage

Time (months)	*Status*	*Cumulative survival rate*	*Standard error*	*Cumulative events*	*No. remaining*
.00	1			1	67
.00	1			2	66
.00	1			3	65
.00	1			4	64
.00	1			5	63
.00	1	0.9118	0.0344	6	62
.00	0			6	61
.00	0			6	60
.00	0			6	59
.00	0			6	58
.00	0			6	57
.00	0			6	56
.25	1	0.8955	0.0374	7	55
1.00	1	0.8792	0.0401	8	54
1.00	0			8	53
1.00	0			8	52
1.00	0			8	51
1.00	0			8	50
1.00	0			8	49
2.00	0			8	48
2.00	0			8	47
2.00	0			8	46
2.25	1	0.8601	0.0436	9	45
2.50	1	0.8410	0.0466	10	44
3.00	0			10	43
3.00	0			10	42
3.00	0			10	41
3.00	0			10	40
3.00	0			10	39
4.00	1	0.8194	0.0502	11	38
5.00	1	0.7978	0.0533	12	37
5.00	0			12	36
5.00	0			12	35
5.00	0			12	34
5.50	1	0.7744	0.0566	13	33
6.00	0			13	32
7.00	0			13	31
12.00	0			13	30
15.00	0			13	29
17.00	1	0.7477	0.0607	14	28
17.00	0			14	27
20.00	0			14	26
22.00	0			14	25
22.00	0			14	24
22.00	0			14	23
23.00	0			14	22
23.00	0			14	21
23.00	0			14	20
24.00	0			14	19
25.00	0			14	18
28.00	0			14	17
28.00	0			14	16
33.00	1	0.7009	0.0727	15	15
36.00	0			15	14
38.00	0			15	13
42.00	1	0.6470	0.0848	16	12
45.00	0			16	11
46.00	0			16	10
60.00	0			16	9

Table V, online only. Kaplan-Meier table for patient survival

Time (months)	*Status*	*Cumulative survival rate*	*Standard error*	*Cumulative events*	*No. remaining*
0.00	1.00			1	67
0.00	1.00			2	66
0.00	1.00			3	65
0.00	1.00			4	64
0.00	1.00	0.9265	0.0317	5	63
1.00	1.00			6	62
1.00	1.00	0.8971	0.0369	7	61
1.00	0.00			7	60
1.00	0.00			7	59
2.00	1.00			8	58
2.00	1.00			9	57
2.00	1.00	0.8514	0.0434	10	56
2.00	0.00			10	55
2.00	0.00			10	54
3.00	1.00			11	53
3.00	1.00			12	52
3.00	1.00			13	51
3.00	1.00			14	50
3.00	1.00	0.7726	0.0517	15	49
3.00	0.00			15	48
3.00	0.00			15	47
4.00	1.00	0.7562	0.0532	16	46
4.00	0.00			16	45
5.00	1.00	0.7394	0.0546	17	44
5.00	0.00			17	43
5.00	0.00			17	42
6.00	1.00	0.7218	0.0561	18	41
6.00	0.00			18	40
13.00	1.00	0.7037	0.0575	19	39
17.00	0.00			19	38
18.00	1.00	0.6852	0.0589	20	37
19.00	0.00			20	36
20.00	0.00			20	35
20.00	0.00			20	34
20.00	0.00			20	33
20.00	0.00			20	32
22.00	1.00	0.6638	0.0608	21	31
22.00	0.00			21	30
22.00	0.00			21	29
23.00	1.00	0.6409	0.0629	22	28
23.00	0.00			22	27
24.00	0.00			22	26
24.00	0.00			22	25
24.00	0.00			22	24
25.00	1.00			23	23
25.00	1.00	0.5875	0.0680	24	22
28.00	0.00			24	21
30.00	0.00			24	20
30.00	0.00			24	19
30.00	0.00			24	18
36.00	1.00	0.5549	0.0717	25	17
36.00	0.00			25	16
38.00	1.00	0.5202	0.0751	26	15
42.00	0.00			26	14
45.00	0.00			26	13
46.00	0.00			26	12
52.00	0.00			26	11
60.00	0.00			26	10
60.00	0.00			26	9