Part X

Factors influencing results

Comparative Analysis Between Vein and Prosthetic Bypass Grafts for Surgical Management of Critical Leg Ischemia

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The quest for a suitable substitute for long saphenous vein has occupied vascular surgeons almost since the first use of vein grafts. In 1955, Linton (1) addressing the American Society for Vascular Surgery said "... it is generally believed that with the aid of modern chemistry the perfect prosthesis will be developed which will replace the natural vascular grafts. The advantage of having available all lengths and sizes of such replacements is almost an utopian dream". At present we can affirm that the research of this material still remains a dream. We have decided to introduce this book chapter and to comment the quest of Dr. Linton at our beginning because the comparison between prosthetic materials and autogenous veins is a match with an only winner: the autogenous vein wherever it is inserted. However, it is well known that autogenous vein is not always available because of a short length, a narrow diameter, the presence of thrombosis, fibrosis or varix formation or, in selected circumstances, its use should be reserved to cardiac revascularization procedures. From this point of view the analysis of the data from the literature have a great interest for vascular surgeons to aid a better selection of a vein substitute. During the past decades, several attempts to improve the suitability of prosthetic materials have been made. These researches will be part of our chapter.

Historically, Kunlin (2) pioneered, in 1948, the use of saphenous vein for femoro-popliteal above-knee bypass grafting procedures and experienced good results in terms of patency and limb salvage in a limited number of patients. One of these grafts remained patent for 27 years. In 1966, Garrett and DeBakey (3) first reported the use of autogenous vein for below-knee revascularization procedures. In 1976, Campbell et al. (4) reported the first North American experience with expanded polytetrafluoroethylene (ePTFE) vascular grafts. Six bypasses were above-knee and remained patent for 1 to 7 months. The clinical use of ePTFE material was based on the experimental evidences made by Matsumoto et al. (5), in 1973, on a canine model, showing its potential as a small-caliber alternative to autogenous veins. In the same years, other Authors experimented the use of externally supported knitted Dacron grafts, but few studies have been conducted on the use of Dacron grafts and few randomized prospective comparisons of ePTFE and knitted or woven Dacron grafts have been performed. At present it is well accepted in the world literature that the material of choice in the absence of autogenous veins should be the ePTFE. In 1976, Dardik and Dardik (6) reported their experience with glutaraldehyde-stabilized human umbilical cord vein bypass graft for femoro-popliteal above-knee reconstruction. The association between prosthetic materials and autogenous vein was first proposed in 1970 by DeLaurentis (7) and these reconstructions were called sequential bypass.

More recently, to improve the patency and limb salvage rates of infrainguinal prosthetic grafts some Authors (8,9) have proposed the interposition of a vein cuff at the distal anastomosis or the association of a peripheral arteriovenous fistula at distal anastomosis. Furthermore, alternative autogenous veins can be used in creating lower extremity bypass grafts including the cephalic and basilic arm veins, the lesser saphenous vein and remnants of the great saphenous vein. The first use of arm vein as an alternative conduit for lower extremity revascularization was reported in 1969 (10).

We are proposing to analyze the results of the different materials in relation with the location of the distal anastomosis: i.e. above or below-knee. This is because the level of distal anastomosis strongly influences patency and limb salvage rates. An important aspect that we would like to stress before the analysis of the results of vein and prosthetic reconstructions is the indication for surgery. Since we would anticipate that the results of peripheral bypass grafts are overall and especially for below-knee reconstruction frustrating and the patients risk to loose their limbs in a high percentage of the cases, a correct surgical indication should be posed. There is a general agreement that patients with rest pain, and minor or major tissue loss are the only candidates for arterial reconstruction. This clinical picture is called critical limb ischemia or limb threatening ischemia. To select patients for surgery we recommend the use of the classification proposed by Rutherford et al. (11) in 1997 and only a strict adherence to these parameters could permit the optimization of short- and long-term results. In Table I are reported the standards proposed by the Society for Vascular Surgery/North American Chapter.

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TABLE I
Clinical categories of chronic limb ischemia.*

Grade	Category	Clinical description
0	0	Asymptomatic – no hemodynamically significant occlusive disease.
	1	Mild claudication.
I	2	Moderate claudication.
	3	Severe claudication.
II	4	Ischemic rest pain.
III	5	Minor tissue loss – nonhealing ulcer, focal gangrene with diffuse pedal ischemia.
	6	Major tissue loss – extending above transmetatarsal level, functional foot no longer salvageable.

Legend: * Grades II and III, categories 4, 5 and 6, are embraced by the term chronic critical ischemia.
Modified by Rutherford et al.(11)

Above-knee bypass grafts

The femoropopliteal bypass grafts has become established as an effective mean of restoring arterial perfusion to the lower extremities threatened by occlusion of the superficial femoral artery. The patients with advanced occlusive lesions within the distal popliteal artery must rely on a patent deep femoral artery or a bypass graft to the infragenicular vessels for effective revascularization. A recent study conducted by Johnson et al. (12) has focused on the results of different materials for above-knee bypass grafts. Up-to-now the choice of a vascular prosthesis for femoro-popliteal above-knee arterial bypass graft was left to the surgeon's preference, because the available information on comparative evaluations were inconclusive.

The Department of Veterans Affairs Cooperative Study 141 tried to identify whether improved patency exists with different bypass graft materials for patients with femoro-popliteal above-knee bypass grafts. Seven hundred fifty-two patients were randomized to receive externally supported ePTFE (n=265), human umbilical vein (n=261) or saphenous vein (n=226). The indication for surgery was limb salvage in 67,5% of the cases. This well conducted and randomized study opens new horizons on the materials of choice for above-knee reconstruction. Although the literature has already indicated that saphenous vein should be preferred over the other material, since the large series of the Veterans Affairs, few prospective randomized studies that enrolled small number of patients were published. Bypass graft assisted patency rates were best for the saphenous vein, which was apparent after 12 months. The prosthetic bypass grafts had a similar performance for the first 24 to 30 months, but thereafter the human umbilical vein bypass graft performance was better than that of the ePTFE grafts. Bypass graft patency was slightly better in the claudication group than in those with critical ischemia. Cumulative 5-year patency rates were 73,3%, 38,6% and 53,2% respectively for saphenous vein, ePTFE and human umbilical vein bypass grafts. The failure rate of human umbilical vein bypass grafts during the immediate postoperative period (4,6%) and for the first 30-day (12,3%) was significantly higher than that of saphenous vein and ePTFE bypass grafts and may explain, in part, the reluctance of some surgeons to use the human umbilical vein. The human umbilical vein is also more difficult to handle in successfully performing a thrombectomy.

The very low failure rate (2,3%) and wound complication rate (6,1%) of ePTFE bypass grafts during the immediate postoperative period may also explain why the ePTFE graft choice is frequently made in patients who are candidate for femoro-popliteal above-knee revascularization. Patients can have a less invasive operative procedure with good early patency and a lower risk of wound complication, and the vein can be saved for further operations. In this study 11% of the patients had an unsatisfactory vein. Oral anticoagulation was administered during follow-up to improve long-term patency of ePTFE grafts. Cumulative 5-year amputation rates were 8,4%, 12,5% and 9,6%, respectively for saphenous vein, ePTFE and human umbilical vein bypass grafts. These data clearly indicate that saphenous vein permits an optimal outcome in terms of patency and limb salvage rates and support its use whenever is possible. The randomized study proposed by Veith et al. (13) in 1986, demonstrated that in patients affected with critical limb ischemia the use of saphenous

vein did not offer a significant advantage in terms of patency rates over ePTFE for above-knee bypass grafts. In a recently published prospective study in which a comparison between saphenous vein and ePTFE in claudicants undergoing bilateral above-knee femoro-popliteal bypass grafting was conducted, AbuRahma et al. (15) treated 43 patients with saphenous vein on one leg and PTFE on the other. All patients had 2-to-3 vessel runoff. In that series, the 72-month primary patency (saphenous vein 76% versus ePTFE 68%) and limb salvage (saphenous vein 98% versus ePTFE 98%) were comparable for the two groups. A meta-analysis performed by Michaels (15) at the end of the 80's demonstrated a clear superiority of vein grafts at 1 and 5 years (80% and 62%, respectively) over prosthetic materials (77% and 43%, respectively). The use of externally supported preclotted knitted Dacron grafts in femoro-popliteal bypass has been compared rarely in randomized prospective trials with ePTFE. It is clear from the data of the literature that the preference for ePTFE over Dacron is not evidence based. Due to the shortcomings of retrospective data (16), the results can be compared only with randomized trials. An early prospective trial which was partly randomized compared 36 ePTFE with 10 composite Dacron-vein below-knee bypasses, the Authors reached the conclusion that further use of Dacron-vein composites was not justified (17). A German trial randomized 250 patients with suprageniicular bypass. Unfortunately, since a preliminary report on the first 103 patients no further data of this trial have been published. Up to 18 months of follow-up no significant differences between ePTFE and Dacron were detected (18). A North American multicenter trial (19) has been recently published with a prolonged follow-up (20). In 240 above-knee grafts no differences in patency were detected between ePTFE and Dacron grafts. A randomized trial from Australia with a total of 108 patients (75 above-knee and 33 below-knee grafts) confirmed that there is no difference in primary and secondary patency between ePTFE and Dacron grafts in femoropopliteal position (21). The prospective randomized multicenter trial of Post et al. (22) randomized 203 patients and 194 were included in the final analysis (103 Dacron grafts and 91 ePTFE grafts). The distal anastomosis was above-knee in 141 and below-knee in 53 cases. Indication for surgery was critical limb ischemia in 43 (47%) patients of the ePTFE group and in 62 (60%) patients of the Dacron group. The primary 3-year patency of Dacron grafts was 64% and for ePTFE grafts was 61%. The corresponding 3-year secondary patency was 81% and 75%, respectively, the limb salvage rate 90% and 91%, respectively. From the data of the literature we can draw a conclusion that there is no difference in terms of patency and limb salvage rates between ePTFE and Dacron prosthetic graft materials. We are confident to suggest the use of both materials in the construction of femoro-popliteal grafts and in the absence of autogenous veins. An other aspect that should be stressed regarding the femoro-popliteal bypass is the use of the in situ or the reversed techniques to construct an autogenous vein graft. The theoretic advantages of the in situ technique include a better size match between the artery and the vein at the proximal and distal anastomosis. This technical aspect is particularly important for below-knee bypass. Since the discrepancy of calibre between the proximal and distal anastomosis in the above-knee anastomosis is not relevant as in below-knee reconstruction, in the literature is not present a demonstration that the in situ technique permits a clear advantage over the reversed technique. Up-to-now almost all prospective studies which have compared autogenous vein graft with prosthetic materials have invariably demonstrated, regardless the indication for surgery, a clear superiority of the autogenous veins over the synthetic materials in the above-knee reconstructions. However, there is still a debate in the literature regarding the proper material to use in these circumstances. We think that all doubts should be cancelled, whenever it is possible the autogenous vein should be preferred. In the rare cases in which the only alternative is a major amputation we suggest the use of synthetic grafts. Overall the differences in the outcome between autogenous and prosthetic materials in above-knee reconstructions is less evident than that below-knee. Since femoro-popliteal bypass may fail, the treatment of graft occlusion remains a challenge for the vascular surgeons. It appears that graft type has a significant influence on clinical outcome when femoro-popliteal bypass grafts occlude. There is a significantly higher risk of the development of limb threatening ischemia after occlusion of an ePTFE femoro-popliteal bypass graft than after occlusion of a saphenous vein graft (23). The study groups comprised 108 patients who underwent femoro-popliteal bypass graft using the saphenous vein and 81 in whom ePTFE was used and the patients were matched for age, sex and co-morbidities. Critical limb ischemia was the indication for surgery in 82% of the saphenous vein group and in 80% of the ePTFE group. Although the distal anastomosis was made below the knee in 60% of the saphenous vein group and in 16% of ePTFE group, limb threatening ischemia was more likely to occur after occlusion of ePTFE grafts (78%) than after occlusion of saphenous vein grafts (21%). Primary patency at 48-month was 58% for saphenous vein grafts and 32% for ePTFE grafts and limb salvage was achieved in 81% of saphenous vein grafts and in 56% of ePTFE grafts. The lesson learned from this study is that patients undergoing femoro-popliteal bypass grafting with ePTFE are at greater risk of ischemic complications from graft occlusion and more fre-

quently require emergency limb revascularization as a result of graft occlusion with respect to patients receiving saphenous vein grafts. These data support even more, if necessary, the use of autogenous vein whenever possible.

Below-knee bypass grafts

Over the past 20 years, surgeons have seen a remarkable evolution in the treatment of infra-inguinal occlusive disease. The expectations of surgeons and patients have been elevated as infra-inguinal bypass procedures and resultant limb salvage have become increasingly successful. This improvement has been achieved through a gradual accrual of surgical knowledge of the factors that significantly affect bypass function and longevity. An appreciation of the superiority of autogenous vein as a bypass conduit and the importance of vein quality and minimally traumatic preparation was documented. In particular, the long-term outcome of infra-inguinal arterial reconstructions is altered by changes in the anatomic and hemodynamic characteristics of the inflow artery, the outflow artery, and the bypass conduit. The two disease processes that primarily affect long-term patency are the progression of atherosclerosis and the development of fibrointimal hyperplasia. The progression of atherosclerosis in the inflow and outflow artery can result in diameter-reducing stenosis that threatens bypass patency. The occurrence and progression of fibrointimal hyperplasia to diameter-reducing lesions resulting in bypass failure are related to the injurious effects of modifying the poor quality venous conduit, correcting technical errors, handling the vein and performing anastomosis. The effect of operative technique on the development of lesions that threaten long-term bypass patency needs evaluation. Theoretically, the ideal conduit for infragenicular arterial reconstruction should consist of an antithrombogenic autogenous tube lined by normally functioning endothelium matched in size to the vessels it connects. Use of great saphenous vein, prepared atraumatically in situ, appears to be, for many Authors, the most reliable method of achieving this end. In its original incarnation, the in situ bypass as performed in the 1960s was an inferior technique to reversed vein bypass techniques (24-27). No form of distal bypass in the 1960s and 1970s delivered results comparable to those achievable today (28-32).

The inflow vessel was almost always the common femoral artery and bypass below the knee were considered to have an unlikely chance for success, especially if they involved the tibial arteries. The peroneal and pedal arteries were dismissed as viable outflow options. Vein were thought to be usable if they were at least 4 mm in diameter. The intactness of the distal pedal arch and bypass flows of more than 100 mL/minute were regarded as significant factors for bypass patency. Most importantly, countless limbs were amputated, simply because many surgeons did not have an expectation of success. Whether the vein should be reversed or left in situ is a matter of debate. The reversed method has become well established in the last 50 years as a procedure with good durable results. Many surgeons still considered this time-honoured technique the gold standard for infra-inguinal arterial reconstruction (33-36). The in situ technique is not a new concept, but has regained popularity during the past 15 years with the development of safe and reliable methods of valve disruption. Based on favourable comparisons with historic controls of the reversed bypass, and the theoretical (but not proven) advantages of improved preservation of endothelium, better hemodynamics and compliance characteristics, a number of Authors have concluded that the in situ vein grafting is superior to reversed vein grafting (37-41). However, several randomized studies have failed to show a significant difference between the two techniques (42-45).

A problem is that these studies were rather small and, hence, do not allow robust conclusions. In a recent large prospective study by Lawson et al. (46) comprising 193 patients with an in situ graft and 180 with a reversed graft was demonstrated that the assisted primary patency for infra-inguinal reconstructions at 2-year was 69% for the in situ technique and 70% for the reversed technique. The in situ technique is not the Holy Grail that some proponents would like us to believe. In about 30% of cases, in situ and reversed technique are not equally applicable, because the ispilateral greater saphenous vein is missing. If the ispilateral greater saphenous vein is available, neither technique gives significantly better assisted primary patency, secondary patency or limb salvage.

Concomitant advances in preoperative assessment and correction of cardiac disease, anesthetic management, and surgical technique have been combined to improve the safety and efficacy of vascular surgery procedures. As a result reconstructive surgical procedures for arterial occlusive disease are now being routinely performed on older patients, and bypass grafts to tibial or pedal vessels are commonly used with durable success. Little debate exists among surgeons concerning the appropriateness of intervention for patients with lower extremity ischemia of limb-threatening severity. In contrast, numerous reports have documented the benign natural history of intermittent claudication and have formed the basis for a conservative approach to this symptoms complex.

Therefore, the question is if, at present days, the construction of a peripheral bypass in claudicants has a role. The study of Conte et al. (47) analyzes this indica-

tion. The Authors performed 57 tibial reconstructions in 53 patients affected with claudication. All bypass were performed by using an autogenous vein and the distal anastomoses were always to the infra-popliteal vessels. Cumulative primary and secondary 5-year patency rates were 81% and 86%, respectively. No amputations were recorded during this interval.

This study demonstrates that bypass grafts to the tibial level with autogenous vein, when performed for claudication, have patency rates equivalent to those of femoro-popliteal bypass and significantly better than those obtained with tibial bypass for limb salvage. In most patients improved walking distance and relief from claudication is reliably achieved. We do not favour this indication, in our opinion, only patients affected with limb-threatening ischemia should be treated with peripheral reconstruction. Although in this report, the outcome in claudicants are optimal and the limb loss rate is null, there are numerous studies (48) that indicate as training exercise permits an amelioration of claudication symptoms thus reducing the need for surgery. The present policy in the performance of infra-inguinal reconstruction should be the delay of bypass construction until patients present major symptoms with limb threatening ischemia.

However, a significant proportion of patients who have critical lower-extremity ischemia do not possess an usable ipsilateral great saphenous vein. The incidence of absence of an adequate ipsilateral great saphenous vein has been reported to be as high as 40% to 45% (49-51). This poses a difficult clinical dilemma and has given rise to the question of which alternative conduit should be used for lower-extremity revascularization in the absence of an adequate ispilateral great saphenous vein. The alternatives include autogenous conduit such as the contralateral great saphenous vein, basilic and cephalic arm veins, lesser saphenous vein, remnant great sahenous vein, deep leg veins, inferior epigastic artery or prosthetic materials. A brief discussion merits the use of contralateral autogenous saphenous vein. Several factors detract from the appeal of contralateral great saphenous vein in certain patient populations. The need for revascularization of the contralateral limb is the leading reason. This need has been reported to be 20% to 23% (51,52). The relative risk of requiring contralateral lower-extremity revascularization is increased by the presence of diabetes mellitus, coronary artery disease, age older than 70 years, and an initial ankle-brachial index less than 0.53. The prosthetic grafts including ePTFE and Dacron with or without adjunctive measures such as vein cuffs, complementary distal arteriovenous fistula and more recently endothelial cell seeding into prosthetic grafts could represent an alternative to autogenous conduit. Other nonautogenous conduits that have been used include gluteraldehyde-stabilized umbilical vein, cryopreserved saphenous vein allografts and composite prosthetic-autogenous conduits. Since the first description of the arm veins for infrainguinal revascularization procedures, additional reports soon followed and demonstrated the feasibility of arm vein bypass grafts, but were limited by the small numbers of patients and short follow-up periods (54,55). Some early descriptions raised concern because of relatively poor long-term patency rates (56). However, definitive reports by Campbell, Andros and others confirmed the potential for achieving long-term patency and limb salvage using arm vein conduit (57,58). Despite these reports, concern regarding the use of arm vein for infrainguinal reconstructions has been expressed. Of particular concern are the fragility and difficulty of handling in arm vein preparation. In addition, arm vein harvest is time-consuming, and frequently, multiple segments of arm vein may be necessary to attain sufficient conduit length to perform long-length bypass graft procedures. More recent studies, published in the past 5-year, have demonstrated that the use of arm vein as the first alternative for lower-extremity revascularization permits to obtain long-term patency and limb-salvage rates that meets or exceeds those reported for other alternative conduits. Faries et al. (59) from Harvard Medical School (Boston, Massachusetts, USA) have analyzed 520 lower-extremity procedures performed between 1990 and 1998, followed prospectively with a computerized vascular registry. The arm veins were prepared by using intraoperative angioscopy for valve lysis and identification of luminal abnormalities. Seventy-two (13.8%) femoro below-knee popliteal artery, 174 (33.5%) femoro-tibial, 29 (5.6%) femoro-pedal, 101 (19.4%) popliteo-tibial/pedal, and 144 (27.7%) extension jump graft bypass procedures were performed for limb salvage (98.2%) or disabling claudication (1.8%). Eighty-five percent of the patients had diabetes and 77% of patients had a recent history of smoking. The grafts were composed of a single arm vein segment in 363 cases (69.8%) and of spliced composite vein with venovenostomy in 157 (30.2%) cases. The mean follow-up was 24.9 months. Overall primary patency rates for all graft types were 80.2%, 68.9% and 54.5%, respectively at 1, 3 and 5 years. The secondary patency rates were 80.7%, 70.3% and 57.5%, respectively at 1, 3 and 5 years. The limb salvage rates were 89.8%, 82.1% and 71.5% respectively at 1, 3 and 5 years. Breaking down these results with regard to the secondary patency and limb salvage rates, as it is easily understood, femoro-popliteal (69.8% and 80.7%) grafts had better results as compared with femoro-tibial (59.6% and 72.7%), femoro-pedal (54.9% and 56.8%) and popliteo-tibial/pedal grafts (39% and 47.6%). Furthermore, the patency of composite vein grafts was equal to that of single-vein conduits. The same Authors

(60) have compared alternative conduits for lower limb revascularization with prosthetic grafts. In this study autogenous arm vein grafts demonstrated increased patency and limb salvage, compared with prosthetic grafts. These increases achieved statistical significance in the femoro-below-knee-popliteal and femoro-tibial configurations.

On the basis of this study, an effort to use all-autogenous vein conduit is justified, however if no autogenous vein is available, prosthetic grafts provide a reasonable alternative to primary amputation. At the beginning of the experiences with prosthetic materials, and in particular with ePTFE, introduced in the clinical practice at the end of 1975, several retrospective studies demonstrated that mid- and long-term results with ePTFE were similar and sometimes even better than those achievable with autogenous materials. Some of the reasons for the widespread use of this prosthetic material were its easy handling with the avoidance of tedious vein dissection and preparation and its theoretic suitability in low flow and high resistance systems (61). Between the 70s and the 80s were published a wide number of papers showing the superiority of the prosthetic materials over the autogenous veins.

This is because of the lack of adequate comparative data that permitted a phase of over-utilization of ePTFE grafts, even in patients with potentially adequate saphenous vein. Despite the enthusiasm gained with ePTFE, an increasing debate raised in the literature soon after these experiences increased in number and the first randomized studies were published. The different results obtained at the beginning of the experience with prosthetic materials were biased by a different operative indication, most of the patients were in fact operated on for intermittent claudication, and the mixing up of the above-knee and below-knee outcomes. Once it was clear that prosthetic materials did not offer the same results of autogenous vein, several Authors proposed technical variants to improve the outcome. One of these technical variants is the use of vein cuffs or patches at the distal anastomosis that has attracted increasing interest in recent years (62-64).

The rationale for the addition of a vein cuff to the distal anastomosis is to prevent anastomotic narrowing caused by intimal hyperplasia by widening the anastomosis with autogenous tissue. In addition, vein cuff interposition between ePTFE and native artery has been shown to inhibit juxtaanastomotic neointimal hyperplasia in an animal model (65). Some clinical reports have also suggested that the addition of autologous tissue at the distal anastomosis might improve patency, Miller et al. (62) reported encouraging early results with the use of vein cuffs and more recently, Taylor et al. (64) used anastomotic vein patches at the tibio-peroneal level in 83 patients and reported patency rates at 1, 3 and 5 years of 74%, 58% and 54%, respectively. Parsons et al. (66) in 1996, compared the results of ePTFE grafts without cuffs or vein patches with the recommended adjuncts through a well done literature review. The Authors concluded the paper affirming that ePTFE bypass to an infra-popliteal artery remains a worthwhile option in patients without usable autologous vein. Other Authors proposed the construction of an arteriovenous fistula at or near the distal anastomosis to improve the patency in reconstructions to the infrageniculate level.

Improvement in the patency of these grafts with the addition of these fistulae is attributed to the theory that the fistula will reduce the resistance to flow and thereby increase the flow through the prosthetic graft. The increase in graft flow volume and velocity may overcome the thrombotic threshold velocity of the prosthetic material and thus increase its patency. In the recent study of Kreienberg et al. (67) the adjunct of an arteriovenous fistula at the distal anastomosis of ePTFE grafts permitted to obtain a primary patency rate of 48% at 2 years, a secondary patency rate of 48% at 3 years and a limb salvage rate of 76% at 3 years. Ascer et al. (68) reported their results with a unique type of arteriovenous fistula that combines the elements of distal arteriovenous fistula and a vein cuff.

The procedure is performed by anastomosing the cephalad portion of the ligated vena concomitant to the runoff artery and then piggybacking the graft on top of the vein. The Authors believe that the interposed vein acts not only as a fistula for venous decompression but also serves as a vein cuff for improved compliance and perhaps other mechanisms to improve graft patency. Cumulative patency reported for these grafts were 62% at 3 years, with limb salvage rates of 77%. In Table II-IV are reported the outcomes of various techniques and modalities for infra-popliteal revascularization procedures. These tables well express the wide differences in terms of patency and limb salvage rates between autogenous and prosthetic materials. Because of the dismal results of prosthetic grafts during the past decade several attempts have been made to create an endothelium on synthetic grafts surfaces able to resist the shear forces of the blood stream. The theoretical basis for synthetic graft endothelialization lies on the possibility that clot promoting functions can be suppressed and neointimal hyperplasia formation can be reduced thus decreasing the risk of graft thrombosis. Endothelial cells seeded into a synthetic material inhibit and reverse clotting and seems to diminish the neointimal hyperplasia formation in vitro, in animal and human studies. The world expert on endothelial cell graft seeding is Dr. Peter Zilla from South Africa. Zilla et al. (82) studied 17 patients with seeded ePTFE grafts by angiography and

TABLE II
Patency and limb salvage rates with ePTFE infra-popliteal bypass

Author Year	N°	1 Year (%)	3 Years (%)	5 Years (%)	
Veith (13)	1986	98			
Primary			48	33	-
Secondary			-	-	-
Limb salvage			76	61	-
Flinn (69)	1988	75			
Primary			45	-	-
Secondary			-	-	-
Limb salvage			-	-	-
Whittemore (70)	1989	21			
Primary			25	12	12
Secondary			-	-	-
Limb salvage			-	-	-
Quiñones-Baldrich (71)	1992	28			
Primary			44	22	22
Secondary			-	-	-
Limb salvage			-	-	-
Schweiger (72)	1993	211			
Primary			51	37	27
Secondary			63	45	34
Limb salvage			-	-	51
Fichelle (73)	1995	31			
Primary			61	43	31
Secondary			-	-	-
Limb salvage			-	-	-
Parsons (66)	1996	66			
Primary			71	39	28
Secondary			78	55	43
Limb salvage			84	71	66
Sayers (74)	1998	29			
Primary*			48	-	-
Secondary*			54	-	-
Limb salvage*			81	-	-

Legend: * Results not analyzed separately for ePTFE alone and with the adjunct of vein cuff and/or patch. No statistical differences are reported between these two different modalities

showed no evidence of obvious anastomotic narrowing. Deutsch et al. (83) have found thickness of the subintimal cell matrix along the course of a seeded graft 41 months after implantation. There were no areas of stenosing hyperplasia. However, several detrimental factors may limit the use of endothelial cell seeding i.e. the method for endothelial cell seeding is not easy applicable in all centers and some recent experimental findings questioned the real efficacy in reducing neointimal hyperplasia formation (84). In our opinion, endothelial cell seeding may represent, as soon as larger and randomized studies will be performed, the new horizon in the treatment of critical limb ischemia with synthetic materials. An other possibility for lower limb revascularization is represented by the use of arterial allografts. These were widely used in the 1950s (1) but were soon abandoned for prosthetic grafts because of low patency rates and frequent aneurysmal degeneration (85,86). Since then, tissue preservation technique have improved, with new preservation media and cryopreservation being now available. For these reasons, arterial allografts were recently reconsidered in two indications: prosthetic graft infection (87) and limb salvage. There are only few reports that analyse this technique of graft implantation (88-90). The first three have a limited number of patients and the follow-up is extremely short. The latter and more recent was conducted by Albertini et al. (91) in three France Centres. The Authors between 1991 and 1997 have performed 165 arterial allografts in 148 patients with a mean age of 70 years. The indication for surgery were rest pain in 54 cases and tissue loss in the remaining patients. In 123 (75%) cases, there was at least one previous revascularization on the same limb. The arterial allografts were retrieved from cadaveric donors. The distal anastomosis was placed to the below-knee popliteal artery in 34 cases, to a

TABLE III
Patency and limb salvage rates for ePTFE bypass performed with adjunctive vein cuffs to the infra-popliteal arteries

Author	Year	N°	1 Year (%)	3 Years (%)	5 Years (%)
Wolfe (63)	1991	55			
Primary			-	52	-
Secondary			-	-	-
Limb salvage			-	-	-
Taylor (64)	1992	256			
Primary			74	58	54
Secondary			-	-	-
Limb salvage			-	-	-
Morris (75)	1993	92			
Primary			51	29	-
Secondary			-	-	-
Limb salvage			74	64	-
Fichelle (73)	1995	65			
Primary			63	45	45
Secondary			-	-	-
Limb salvage			-	-	-
Karacagil (76)	1996	36			
Primary			50	38	-
Secondary			-	-	-
Limb salvage			-	-	-
Stonebridge (77)	1997	133			
Primary			80.3	-	-
Seondary			82.9	-	-
Limb salvage			86.3	-	-
Sayers (74)	1998	330			
Primary*			48	-	-
Secondary*			54	-	-
Limb salvage*			81	-	-
Kreienberg (67)	2000	59			
Primary			96.2	37.8	-
Secondary			98.1	47	-
Limb salvage			91.8	91.8	-

Legend: * Results not analyzed separately for ePTFE alone and with the adjunct of vein cuff and/or patch. No statistical differences are reported between these two different modalities

tibial artery in 114 and to a pedal artery in 17 cases. Primary patency rates at 1, 3 and 5 years were 48.7%, 34.9% and 16.1%, respectively. Secondary patency rates at 1, 3 and 5 years were 59.8%, 42.1% and 25.%, respectively and limb salvage rates at the same intervals were 83.8%, 76.4% and 74.2%, respectively. Causes of primary failure were the progression of the atherosclerotic disease in 15, myointimal hyperplasia in 16, graft degradation in 10 (four dilatations, three stenoses, two rupture and 1 dissection) and not described or unknown in 24 cases. The allograft degradation rate leading to primary failure in this study was 3%, this data is lower than reported earlier. The incidence of graft rupture was 1.2% which suggests that this condition is unusual and 1 of the 2 patients died of this complication. To our opinion this is a severe condition and if more of these should arise in the future, the technique should be certainly abandoned. Graft dilatation per se does not cause death but is responsible for redo procedures. This study shows that arterial allografts infrainguinal bypass grafts for critical ischemia lead to acceptable limb salvage but poor patency rates. A randomized trial would allow accurate comparison between this material and ePTFE grafts. In any case, we think that only better results at present would justify further clinical use of arterial allografts. It seems possible to decrease the incidence of degradations by improvement of harvesting and preservation techniques. Since the results of this technique are overall dismal, at present we discourage the use of arterial allografts in the treatment of critical limb ischemia. A possible use could be in the presence of graft infection or in the complete absence of veins with the contemporary presence of foot infection.

TABLE IV
Patency and limb salvage rates for arm vein bypass to the infra-popliteal arteries

Author	Year	N°	1 Year (%)	3 Years (%)	5 Years (%)
Sesto (78)	1992	35			
Primary			49	40	-
Secondary			68	44	-
Limb salvage			82	82	-
Harward (79)	1992	43			
Primary			67	49	-
Secondary			74	64	-
Limb salvage			73	63	-
Chalmers (80)	1993	42			
Primary			51	-	-
Secondary			85	-	-
Limb salvage			-	-	-
Londrey (81)	1994	169			
Single segment					
Primary			-	-	-
Secondary			78	60	52
Multisegment					
Primary			-	-	-
Secondary			56	39	29
Overall limb salvage		85	74		69
Hölzenbein (51)	1996	209			
Primary*			70.6	-	-
Secondary*			76.9	-	-
Limb salvage*			88.2	-	-
Faries (59)	2000	448			
Primary**			80	68.9	54.5
Secondary**			80.7	70.3	57.5
Limb salvage**			89.8	82.1	71.5

Legend: * The results are reported together with 41 femoropopliteal reconstructions.
**The results are reported together with 72 femoro-popliteal reconstructions.

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