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Infrapopliteal Composite Bypass with Autologous Vein and Second Generation Glutaraldehyde Stabilized Human Umbilical Vein (HUV) for Critical Lower Limb Ischaemia

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Objective. *To audit a single center consecutive series of infrapopliteal composite bypasses with second generation glutaraldehyde stabilized human umbilical vein.*
Design. *Retrospective study.*
Patients. *From January 1996 to July 2006 89 femoro-distal bypasses were constructed in 85 patients with HUV and residual vein segments as composite grafts in the absence of sufficient length of autologous vein.*
Methods. *All patients with infrainguinal bypass operations were registered prospectively. Bypasses to infrapopliteal arteries performed with HUV-composite grafts were reviewed for graft patency, limb salvage, patient survival and possible biodegeneration of the HUV.*
Results. *Early graft thrombosis was noted in 21.3%, necessitating revision surgery. Primary, primary assisted and secondary patency rates were 35%, 40% and 42% respectively, with a limb salvage rate of 87% after 5 years. Graft infection occurred in 7 limbs. Aneurysmal HUV graft degeneration was not detected by duplex scanning.*
Conclusion. *HUV-composite bypasses provide acceptable patency and favorable limb salvage rates. Patency was similar to previous series using PTFE-composite bypasses but was significantly inferior to vein bypass. Possible biodegradation of the HUV grafts seems to be of minor clinical relevance.*

Keywords: Limb salvage; Blood vessel prosthesis; Bioprosthesis; Human; Umbilical veins; Vascular patency.

Introduction

In 1976 Dardik reported the successful clinical use of glutaraldehyde stabilized human umbilical veins (HUV) reinforced with a loose external Polyester mesh as a new small calibre biologic vascular graft in femoro-distal bypass.[1] Despite promising patency rates in above and below knee femoro-popliteal bypass, results in the femoro-distal position were less favorable.[2–7] First generation HUV grafts soon exhibited a disappointing tendency for early postoperative thrombosis and formation of graft aneurysms due to biodegeneration.[8] This resulted in a widespread reluctance to use any kind of biological vascular prostheses in infrainguinal bypass surgery.

After modification of the tanning process and reinforcement of the external Dacron mesh the second generation of glutaraldehyde stabilized HUV has been available for infrainguinal arterial reconstruction for almost two decades. A single centre consecutive series of femoro-distal bypasses with this modified HUV-graft, employing the composite technique, has been assessed for long term graft function, secondary procedures to maintain or restore patency and limb salvage.

Patients and Methods

From a total of 2196 infrainguinal bypass operations performed between January 1996 and July 2006 and prospectively documented in a computerized database all femoro-distal bypasses to a single outflow infrapopliteal vessel with HUV as part of a composite graft were identified. Patient characteristics,

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perioperative and follow-up data were retrieved retrospectively from patient charts.

The HUV was only chosen if, after intraoperative exploration and assessment by the operating surgeon, sufficient autologous vein was not available. Whenever possible the anastomosis to a crural or pedal artery was performed with autologous vein and the composite technique was preferred when a prosthesis was used. Composite grafts were used when a segment of suitable autologous vein was available but the length of harvested vein was assessed as insufficient for a complete autogenous reconstruction by the operating surgeon. To ensure that as much autologous vein as possible was used in some instances spliced vein was combined with the HUV.

HUV grafts were rinsed prior to implantation according to the manufacturers' rinsing procedure protocol. Distal anastomoses were constructed under systemic heparinisation with polypropylene suture in the conventional end-to-side manner. The composite anastomosis was performed with vein and HUV beveled at 45° including the external Dacron mesh into the suture line. For the proximal anastomosis the common femoral or the proximal superficial femoral artery were chosen and additional endarterectomy or profundaplasty performed if necessary. Bypasses were placed preferentially in a subfascial position using a hollow plastic sheath tunneler. Subcutaneous extra-anatomic placement was only used in the presence of extensive scarification in the popliteal fossa, due to previous bypass procedures.

Graft patency was confirmed by intraoperative flow measurement (Cardio-Med Medi-Stim, Oslo, Norway; Transonic Systems, Ithaca, NY, USA) after completion of the anastomosis. Prior to discharge another early postoperative duplex scan or angiography were performed.

Except for contraindications, oral anticoagulation with phenprocumon (Marcumar®) was started postoperatively after continuous intravenous administration of heparin and additional temporary administration of combined antiplatelet therapy (Aspirin® and Tyklid® or Aspirin® and Plavix®). This combined antiplatelet therapy was discontinued when the intended INR level (2.0 to 2.5) was reached and administration of phenprocumon (Marcumar®) was continued indefinitely. Only in the presence of contraindications for oral anticoagulation was antiplatelet therapy administered as the only long term medication.

Follow up examinations were performed after 3, 6, 12, 18 and 24 months with annual surveillance thereafter. Follow up included clinical examination of the operated limb, ABI measurement, duplex-scan of the graft and angiography in cases of ipsi- or contralateral ischaemia. A bypass was assessed as patent according to the recommended standards for reports dealing with lower extremity ischaemia.[9] Amputation with a patent graft or infection of a patent graft with subsequent replacement was considered as graft failure. All follow-up data were prospectively entered in a computerized data base (ACCESS 2000 for windows) and analysed (SPSS for Windows, version 11.0; Chicago, Ill, USA) with Kaplan-Meier and log-rank test (p-value < 0.05 significant) according to the regulations for clinical studies of the ethics committee of the state of Rhineland-Palatinate, Germany.

Results

89 femoro-distal bypasses were performed in 46 men and 39 women (85 patients) with a mean age of 74 ± 8.9 years. Three patients underwent bilateral surgery, one subsequently (staged) and two simultaneously. In one patient the same leg was reoperated with the same technique. Some bypasses (35%) were placed in a subcutaneous position. Preoperative ABI of the operated limb was 0.32 ± 0.27. Patient characteristics, risk factors, indications for surgery and previous ipsilateral vascular operations or interventions and inflow procedures are listed in Tables 1 and 2. Operative details are listed in Table 3.

Early results

In hospital mortality was 4.6%, with four patients experiencing fatal cardiac events, in one instance after simultaneous bilateral operations. 25 systemic complications were noted in 22 patients leading to a combined mortality and morbidity of 25.3%. Early

Table 1. Patient demographics

	No. of patients $n = 85$*	%
Mean age	74.8 ± 8.9y (49.6–95.8y)	
Female	39	45.9
Male	46	54.1
Risk factors		
Hypertension	81	95.3
Hyperlipidemia	54	63.5
Diabetes	55	64.7
Smoking	28	33.0
CAD	60	70.6
CVA	16	18.8
ESRD	5	6.5

CAD: coronary artery disease; CVA: cerebrovascular accident; ESRD: end stage renal disease.

* Three patients with bilateral operation, one patient with subsequent reoperation of the same leg.

Table 2. Indications for bypass surgery, previous ipsilateral operations or interventions and inflow procedures

	No. of operations $n = 89$	%
Rest pain	21	23.6
Necrosis/ulceration	65	73.0
Acute deterioration of chronic ischaemia	3	3.4
Previous ipsilateral operation	34	38.2
Bypass	29	24.3
Profundaplasty	2	5.1
Thrombectomy	3	2.6
Ipsilateral vein partially harvested previously	39	43.8
Previous ipsilateral intervention	10	11.2
PTA (stent)	9	10.1
Thrombolysis	1	1.1
Inflow procedure (operation)	13	14.6
Aortofemoral bypass	8	9.0
Iliofemoral bypass	1	1.1
Crossover bypass	4	4.5
Inflow procedure (intervention)	5	5.6
PTA (stent) common iliac artery	4 (3)	4.5 (3.4)
PTA external iliac artery	1	1.1

Table 3. Operative details of 89 HUV-composite bypasses

Operative details	Number of operations: 89	%
Proximal anastomosis		
Common femoral	70	78.7
Proximal superficial femoral	5	5.6
Profunda femoris	3	3.4
Aortofemoral bypass	6	6.7
Crossover bypass	4	4.5
Infrainguinal bypass	1	1.1
Distal anastomosis proximal and middle calf	69	77
Tibioperoneal trunc	3	3.4
Posterior tibial	13	14.6
Peroneal	36	40.4
Anterior tibial	17	19.1
Distal anastomosis at ankle and foot	20	23
Posterior tibial	3	3.4
Peroneal	3	3.4
Anterior tibial	7	7.9
Dorsalis pedis	7	7.9
Proximal part HUV		
HUV 6 mm diameter	40	44.9
HUV 5 mm diameter	49	55.1
Distal part		
Greater saphenous vein ipsilateral*	60	67.4
Greater saphenous vein contralateral**	14	15.7
Lesser saphenous ispi- or contralateral	4	4.5
Arm vein***	9	10.1
Superficial femoral vein	2	2.2
Extraanatomic bypass course	31	34.8
Anatomic bypass course	58	65.2

* Spliced with additional saphenous or alternative vein in 6 cases.
** Spliced with additional saphenous or alternative vein in 2 cases.
*** Spliced with additional saphenous or alternative vein in 2 cases.

postoperative failure was noted in 19 bypasses (21.3%) after a mean of 5.8 days. Revision was initiated in 15 cases and patency could be restored in 12 bypasses by means of simple graft thrombectomy (11) and partial replacement of the venous component in one case. New bypasses were constructed in two patients. Subsequently four of the revised bypasses developed infection and were replaced with spliced superficial femoral vein (2) and other alternative venous segments or a silver impregnated Dacron graft (1) or in the fourth case resulted in amputation despite patency. Graft revision was not successful in two cases, in three cases revision of the thrombosed graft was not intended and major amputation within 30 days was necessary in two of these patients. In one patient bleeding from a varicose segment of the venous bypass component necessitated subtotal replacement with new HUV. Additional early local complications are listed in Table 4.

Late results

Median (mean) follow-up was 26 (37) months (1−116 months) and one patient was lost to follow-up after 48 months. 41 patients died during follow up from cardiovascular events or tumor leading to a 5-year survival of 50%.

Bypass occlusion during follow-up was noted in 30 legs necessitating secondary intervention by thrombectomy, distal graft extension or partial replacement and redo bypass in 16 cases. Eight patients could be managed conservatively with preservation of a viable limb. Six legs were amputated without further attempts at revascularisation and one leg was amputated after unsuccessful revision. Thrombectomy was never successful in restoring further undisturbed patency: either patiency could not be restored or the bypass reoccluded at a later point. 14 new bypasses were constructed, in five cases after various attempts to restore or maintain patency of the composite graft, in two cases with spliced arm veins. In four of these redo bypasses the venous part of the failed composite bypass was anastomosed with a new HUV. (details see also Table 5) Within the first four postoperative months three further infections of subcutaneously placed HUVs were noted, each of them after postoperative haematoma or lymph fistula. Successful partial (2) or total (1) replacement of the infected prosthesis with superficial femoral vein was

Table 4. Early postoperative (30 days) complications

	No. of operations 87*; no of patients 85	%
Mortality (MI, cardiac failure)	4	4.6
MI, cardiac failure; arrhythmia	14	16.1
Stroke	0	0
Respiratory failure	2	2.3
Sepsis	1	1.1
Delirium	5	5.7
Others	3	3.4
Combined mortality and morbidity**	22	25.3
Graft occlusion	19	21.3
Operative revision performed	15	
Patency restored	12	
New bypass	3	
Major amputation	2	2.2
Graft infection	3	3.4
Hematoma (surgical revision)	2	2.2
Wound infection, lymph fistula, delayed wound healing	12	13.5

MI: myocardial infarction.
* Two patients operated simultaneously bilateral.
** 25 systemic vascular and nonvascular complications in 22 patients.

Table 5. Late postoperative (>30 days) complications

Median (mean) follow-up 26 (37) months (1.0–116 months)	No. of operations $n = 89$	%
Death (cardiovascular, tumor)	41	48.2
Graft occlusion	30	33.7
No revision	14	15.7
Amputation	6	
Conservative management	8	
Operative revision performed	16	18.0
Thrombectomy	5	
Successful	0	
New bypass after revision*	5	5.6
HUV or Omniflow**	5	
New bypass without revision	9	10.1
Arm vein	2	
HUV or Omniflow***	7	
Major amputation		
With patent graft (infection, 2 mo)	1	1.1
Occluded graft (after revision 2)	8	9.0
Graft infection (successful replacement)****	4 (3)	4.5
Aneurysmal degeneration	0	0

* Previous thrombectomy or patch angioplasty; PTA or partial graft replacement to restore or maintain patency.
** Anastomosis to the venous part of composite graft in one case.
*** Anastomosis to the venous part of composite graft in three cases.
**** Infection rate together with three early infections 7.9%.

performed in these cases. Aneurysmal degeneration or other signs of biodegradation were not detected by means of duplex ultrasonography. Primary, primary assisted and secondary patency rates were 35%, 40% and 42% respectively after 5 years, with a limb salvage rate of 87% (see also Fig. 1). Results were in the direction of improved patency for anatomically placed grafts (Fig. 2) and a better outcome for grafts to the proximal and middle calf in regards of patency (Fig. 3) and limb salvage.

Discussion

The use of suitable vein segments combined with synthetic grafts was introduced soon after peripheral bypass became a more widely used operation.[10] As this technique did not exhibit a significant advantage for primary popliteal bypass it has not been recommended for routine use.[11] For infrapopliteal bypass, the best long term results are achieved with saphenous vein grafts, which provide satisfactory long term patency and limb salvage. Many authors emphasize the role of the *in situ* technique with favorable long term results[12,13] and excellent results for ankle and pedal bypasses with autologous vein have been reported.[14] Others recommend the use of alternative sources of vein before prosthetic material is considered

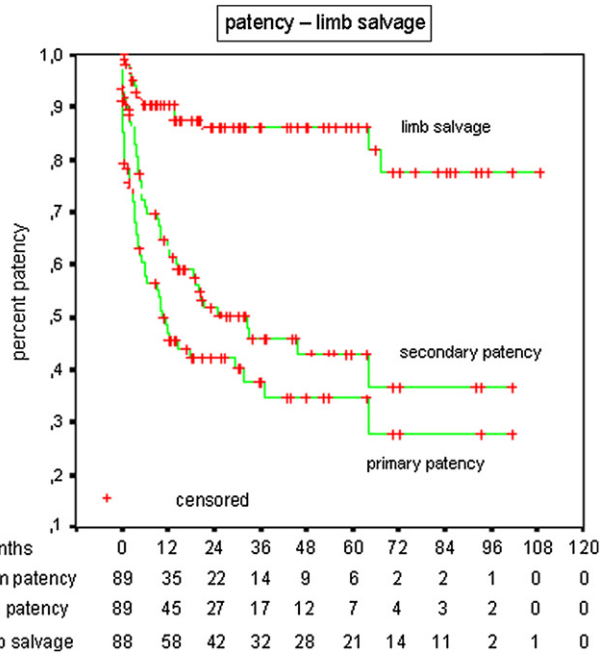

Fig. 1. Primary patency, secondary patency and limb salvage in 89 HUV-composite bypasses to infrapopliteal arteries.

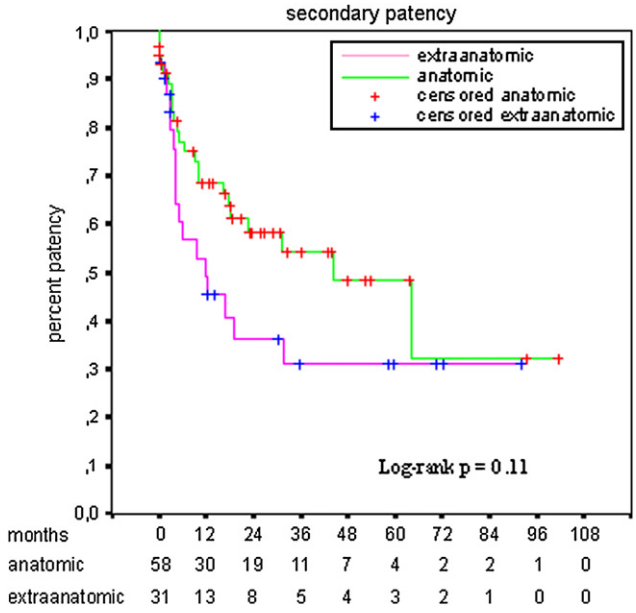

Fig. 2. Secondary patency and graft course of 89 HUV-composite bypasses to infrapopliteal arteries.

and reported superior patency compared to synthetic grafts.[15]

In cases of insufficient vein, prosthetic material must be considered. As the results with synthetic bypasses and direct anastomoses to small vessels are generally not regarded as satisfactory, modified anastomoses with vein cuffs in combination with PTFE have been used and shown to improve patency.[16,17] Historically there has been no clear advantage for the combination of suitable vein segments with a PTFE prosthesis compared to a complete prosthetic bypass with a poor 5-year patency of 28%.[18] However, a modern series has reported a favorable outcome for PTFE-composite grafts with a long term patency for single outflow PTFE-composite grafts with a late patency of 56% and a limb salvage rate of 53%.[19] Karacagil showed similar results for composite or cuffed PTFE bypasses, with a 3 year patency rate of 25% and a limb salvage rate of 55%.[20] Bastounis reported promising results in 96 PTFE saphenous vein composite grafts for popliteal and infrapopliteal bypass with a 5-year secondary patency of 75% and a limb salvage rate of 80%.[21] Whereas the results of these series clearly support the combined use of synthetic and autologous material, Faries demonstrated a clear advantage for spliced arm veins over PTFE composite grafts with a 5-year patency and limb salvage of 57% and 76% for arm veins versus 0% for PTFE composite grafts.[15] Therefore every effort should be made to use autologous reconstruction before the composite technique is considered.

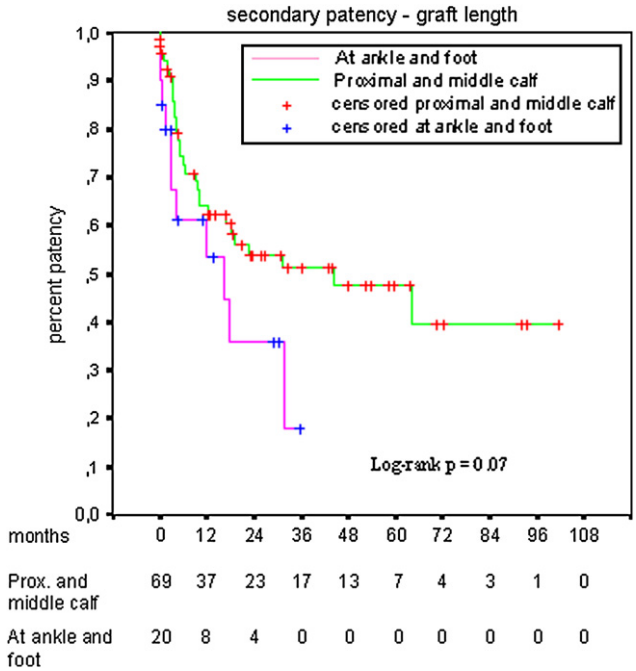

Fig. 3. Secondary patency and bypass length of 89 HUV-composite bypasses to infrapopliteal arteries.

Two randomized studies comparing the performance of HUV and PTFE in femoropopliteal position have shown significantly better results for HUV[22,23] and therefore its use was introduced in crural and pedal bypass. Encouraging results with this graft in sequential distal bypass for limb salvage have been reported previously, with a high limb salvage rate.[24] This significantly better outcome might be explained by the different angiographic pattern with preservation of a patent popliteal or proximal crural segment in many cases. Our series of single outflow crural and pedal HUV-composite bypasses had a disappointing rate of early graft failure, necessitating further interventions with a high rate of graft infections (7.8%, four after early revision) in the first 6 months with the need for further complicated interventions, although patency and limb salvage could be preserved in five of seven cases. Also the later use of arm veins indicates that the possibility of using these at the initial procedure had been underestimated, since there were two redo procedures (for graft occlusion) using arm vein grafts. It is noteable that late occlusion could not be successfully treated by means of simple thrombectomy and that most service interventions to avoid bypass failure were not successful. However, in many cases the anastomosed peripheral artery remained patent after bypass failure and successful reoperation either with a new biological graft or arm veins was possible. This might be explained by the presence of

a venous segment with viable endothelium that could tolerate low arterial flow in the anastomotic region in cases of proximal bypass thrombosis. In addition a considerable number of legs remained viable despite no further intervention. This is reflected by the high limb salvage rate of over 80% after 5 years, higher than the reported lower rates for PTFE with vein cuffs or vein patches.[25–27] The only recent favorable results for crural bypasses with PTFE and a distal vein patch were published by Neville.[28]

An advantage of the composite technique might be that the venous part of the bypass may be preserved in case of prosthetic occlusion and can be used as recipient site for a new bypass. In our series this was possible in four cases. There exist very few recent data about HUV-composites. Feinberg found a disappointing patency and limb salvage rate in 21 HUV-composite bypasses, due to a very high rate of early thrombosis and anastomotic disruption. Therefore, these authors abandoned the use of HUV in composite grafts.[29] The only available modern series of crural bypass with HUV using the adjunctive common ostium AV fistula reported by Dardik showed a 6 year patency of 47% with a limb salvage rate of 61%.[30] Our reported series of 89 operations compares favorable with the published patency rates for PTFE-composite and enabled a promising limb salvage rate, but at the price of a high rate of secondary interventions.

The historically reported tendency for aneurysm formation seems to be of minor clinical relevance in this subgroup of patients with critical ischaemia. A recent analysis by Strobel found an incidence of 16% in their series of 108 HUV bypasses with a low late intervention rate.[31]

Conclusion

HUV-composite bypasses provide success with respect to late patency and but carry a significant risk of early infection and a need for secondary interventions. Limb salvage seems to be favourable.

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