Eur J Vasc Endovasc Surg (2021) 61, 121–127

Long Term Outcomes of Endovascular Therapy for Failing Distal Bypass Vein Grafts

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WHAT THIS PAPER ADDS

This observational study included clinical data regarding patency, would healing rate, and amputation free survival of patients undergoing endovascular therapy (EVT) for failing distal bypass vein grafts between 2009 and 2019 at a single institution in Japan. This study adds to the limited knowledge regarding the benefit of EVT for failing distal bypass vein grafts demonstrating acceptable patency, wound healing, and major amputation free survival.

Objective: Although distal bypass using vein has been established with acceptable outcomes for chronic limb threatening ischaemia (CLTI), the major issue affecting long term outcomes is vein graft disease. This study aimed to analyse the peri-procedural results and long term outcomes of endovascular therapy (EVT) for failing vein grafts after distal bypass.

Methods: A retrospective analysis of 113 failing vein grafts (94 patients, 113 limbs) after distal bypass between 2009 and 2019 at the study hospital.

Results: The mean age was 74 ± 9 years and 72% of the patients were men. Of the 113 grafts, 54 grafts (48%) were detected in asymptomatic patients, 41 grafts (36%) in patients with recurrent ulcer or gangrene, and 18 grafts (16%) in patients with rest pain. The failing grafts were treated by low pressure long inflation balloon angioplasty with a mean balloon size of 3.0 ± 0.8 mm. The mean procedural time was 60 ± 29 min and procedural success was 98% (111 grafts). During the mean follow up period of 34 months, EVT was performed a median frequency of two times (range 1–11 times). The primary and assisted primary patency of the EVT revised grafts were 41% and 80% at one year, 34% and 68% at three years, 31% and 58% at five years, respectively. Of 41 limbs with recurrent ulcer or gangrene, the wound healed in 34 limbs (85%). The complete healing rate was 71% at three months and 84% at 12 months. Eight patients required major amputation, and the freedom from major amputation rate was 96% at one year and 80% at five years.

Conclusion: Long term outcomes including patency, wound healing rate, and amputation free survival after EVT for failing vein grafts were acceptable. EVT could be a viable alternative to surgical revascularisation in patients with a failing distal bypass graft for CLTI.

Keywords: Chronic limb threatening ischaemia, Endovascular therapy, Failing graft, Revascularisation
Article history: Received 4 June 2020, Accepted 22 September 2020, Available online 13 October 2020

INTRODUCTION

For patients with chronic limb threatening ischaemia (CLTI) and infrapopliteal occlusive disease, distal bypass using autologous vein graft has been recommended because of its durable revascularisation.[1,2] However, some vein grafts develop clinical stenoses because of intimal hyperplasia. The distal bypass secondary patency rate has been reported to be 70% at five years.[3–5]

In the management of the failing grafts (stenosed and non-thrombosed grafts), surgical revascularisation remains the standard procedure.[6] However, the techniques require additional autologous veins and carry the risk of complications associated with re-operation. Endovascular therapy (EVT, balloon angioplasty) has frequently been performed for infrainguinal vein grafts because of its minimally invasive nature. However, there are few reports regarding the long term results of EVT for failing infrapopliteal distal bypass vein grafts.[7–9]

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1078-5884/
https://doi.org/10.1016/j.ejvs.2020.09.021

The aim of this study was to analyse the peri-procedural results and long term outcomes of EVT as a primary intervention in patients with failing distal bypass vein grafts.

MATERIAL AND METHODS

Between January 2009 and December 2019, the authors performed 356 distal bypasses (281 patients) for *de novo* infrapopliteal lesions. Distal bypass was defined as any bypass with a distal anastomosis onto the posterior tibial, anterior tibial, dorsalis pedis, plantar, or peroneal arteries. Of 356 distal bypasses (281 patients), 316 distal bypasses (241 patients) were enrolled in the outpatient surveillance programme, excluding 15 hospital deaths (5%) and 25 early graft occlusions during hospitalisation (7%). Of these, retrospective analysis was made of 94 patients (113 grafts, 113 limbs) who underwent EVT (balloon angioplasty) for failing distal bypass vein grafts as primary intervention. A failing graft was defined as a vein graft that remained patent but had duplex evidence of a significant stenosis that threatened patency if untreated. Exclusion criteria were as follows: EVT for a thrombosed graft (failed graft); for an ipsilateral native artery; or for a failing graft in a patient with an unhealed wound after distal bypass. Primary patency, assisted primary patency, freedom from major amputation, survival rate, and amputation free survival (AFS) after EVT were evaluated. Graft patency was calculated from the time of the first angioplasty procedure. Primary patency was defined as freedom from all cause graft failure, including stenosis or occlusion, without the need for additional intervention. Assisted primary patency was defined as freedom from graft occlusion, regardless of the need for additional intervention.[10] Wound healing rate was evaluated for patients with recurrent ulcers. The factors affecting primary and assisted primary patency of the EVT revised graft were analysed using the following valuables: age, sex, diabetes, hypertension, haemodialysis, hypercholesterolaemia, smoking history, coronary artery disease, cerebrovascular disease, non-ambulatory status, distal bypass operation time, proximal anastomotic site, distal anastomotic site, use of a spliced vein graft, use of the great saphenous vein, method of bypass surgery, vein graft diameter, intra-operative bypass flow, CLTI recurrence, long graft stenosis, multiple graft stenoses, balloon size, use of a cutting balloon, and the time interval between distal bypass and initial EVT.

Bypass method

An autologous vein was harvested if the diameter was >2.5 mm by duplex ultrasound. The first choice was the great saphenous vein and the second choice was the small saphenous vein. Most bypasses were performed in a non-reversed or *in situ* fashion using the valvulotome (LeMaitre Vascular, Inc., MA, USA). Short bypass (graft length $\leq$ 10 cm) was performed in a reversed fashion. Proximal and distal anastomoses were performed using 6-0 and 7-0 polypropylene, respectively. Intra-operative completion angiography was performed routinely to assess graft stenosis, anastomotic configuration, and distal runoff. Absence of significant graft and anastomotic stenosis were conditions for completion of the operation. If angiography revealed significant stenosis, revision was performed. Graft flow was also measured using a transit time flowmeter just before wound closure.

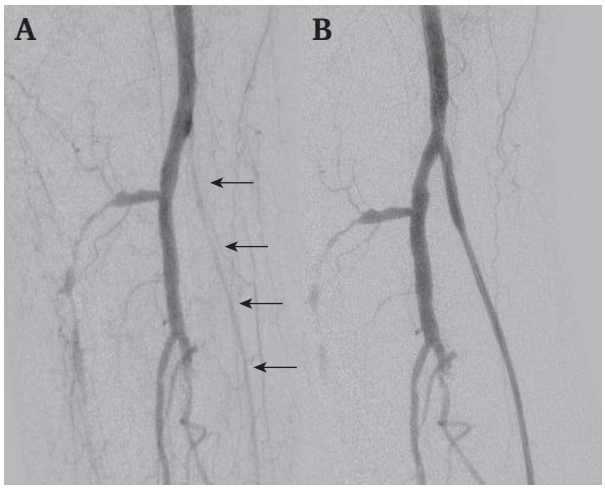

Figure 1. (A) Diagnostic angiogram of a non-reversed saphenous vein graft with high grade long stenosis (black arrows) in a patient with below knee popliteal to dorsalis pedis artery bypass. (B) Completion angiogram showing the stenotic lesion resolved by balloon angioplasty.

Medication

Patients who had already taken antiplatelet agents, including cilostazol, continued to take the same medicines. For patients not on antiplatelet agents, aspirin (100 mg daily) or clopidogrel (75 mg daily) was started at least one week before EVT and continued lifelong. The patients with diabetes were treated with oral hypoglycaemic agents or insulin injection, with target haemoglobin A1C level (HgbA1C) of <7%. All the patients with hypercholesterolaemia were treated with statins.

Graft surveillance

All patients undergoing distal bypass or EVT were enrolled in a graft surveillance programme, which involved duplex ultrasound (DUS) and measurement of ankle brachial pressure index at one, two, three, four, and six months after the procedures and every three months thereafter. The DUS criteria for further investigation by angiography were a graft stenosis with increased peak systolic velocity >300 cm/s or evidence of decreased graft flow <45 cm/s. If rest pain or ulcer recurred, angiography was performed regardless of the DUS findings.

Endovascular therapy procedure

All patients underwent vein graft EVT in hospital. Ipsilateral femoral access was often preferred. In a case of proximal anastomosis to the common femoral artery, a retrograde or

Table 1. Demographics of 94 patients treated by endovascular therapy (EVT) for failing infrapopliteal bypass vein graft for chronic limb threatening ischaemia

Variable	Patients (n = 94)
Age − years	74 ± 9
Male sex	68 (72)
Diabetes	75 (80)
Hypertension	85 (90)
Hypercholesterolaemia	55 (59)
Smoking	63 (67)
Coronary artery disease	48 (51)
Cerebrovascular disease	21 (22)
Haemodialysis	49 (52)
Ambulatory status of EVT	
Ambulatory	70 (74)
Ambulatory with assistance	16 (17)
Non-ambulatory	8 (9)
Clinical presentation at EVT	
Asymptomatic	54 (48)
Rest pain	18 (16)
Ulcer	41 (36)

Data are presented as n (%) or mean ± standard deviation. EVT = endovascular therapy.

Table 2. Surgical reconstruction details of 113 distal vein bypasses in 94 patients with chronic limb threatening ischaemia treated by endovascular therapy for a failing graft

Variable	Distal bypass (n = 113)
Inflow artery	
Femoral artery	46 (41)
Popliteal artery	67 (60)
Outflow artery	
Posterior tibial artery	52 (46)
Anterior tibial artery	11 (10)
Peroneal artery	14 (12)
Dorsalis pedis artery	27 (24)
Plantar artery	9 (8)
Type of bypass graft	
Single vein	91 (81)
Spliced vein	22 (19)
Type of vein	
Great saphenous vein	94 (80)
Other veins	24 (20)
Type of bypass fashion	
Non-reversed	95 (84)
Reversed	11 (10)
In situ	7 (6)

Data are presented as n (%).

a contralateral femoral approach was selected. Before placing a 5 or 6 French sheath, heparin sodium was administered intravenously at 3 000 units (additional 1 000 units every 1 h thereafter). After pre-intervention angiography, all the stenotic lesions were treated. The stenosis was crossed with a 0.014 inch guidewire (Jupiter FC, Boston Scientific, MA, USA; Gladius, Asahi Intecc, Tokyo, Japan) and a standard percutaneous transluminal angioplasty balloon (Coyote, Boston Scientific; MASTULY, Lifeline, Tokyo, Japan) was advanced. The balloon size was selected based on the diameter of the adjacent vessel (2.5—4.0 mm). The failing graft was dilated with low pressure (3—6 atm) and long inflation time (2 min) (Fig. 1). If the stenosis could not be completely resolved, a cutting balloon (Peripheral cutting balloon, Boston Scientific) was applied. Procedural success was defined as remaining stenosis <30% without any signs of graft rupture on completion angiography.

Ethical consideration

This study was approved by the ethics committee of JA Hiroshima General Hospital (approval number 20—7).

Statistical analysis

Continuous variables are expressed as mean values ± standard deviation. Categorical variables are presented as absolute values and percentages. According to the recommended standards for reports published by the Society for Vascular Surgery, primary patency, primary assisted patency, freedom from major amputation, survival, and amputation free survival (AFS) rates were calculated using Kaplan—Meier analysis with log rank test.[10] Univariate Kaplan—Meier analysis was used to select potential risk factors for primary and assisted primary patency of the EVT revised vein grafts. Variables with $p < .05$ in univariable analysis were considered to be potential risk factors for primary and assisted primary patency of the EVT revised vein grafts and they were selected for multivariable Cox proportional hazard analysis. A p value $< .05$ was considered significant. The statistical analyses were performed with EZR (Saitama Medical Centre, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).[11]

RESULTS

Ninety-four patients (113 limbs) who underwent EVT for failing grafts after distal bypass were included. Patients' demographics and cardiovascular risk factors are summarised in Table 1. The mean age of the patients was 74 ± 9 years and 72% were men. Diabetes (80%) and renal failure with haemodialysis (52%) were frequent. Operative details of the prior distal bypass are listed in Table 2. The most common inflow artery was the below knee popliteal artery (60%), and the most common outflow artery was the posterior tibial artery (46%). Single segment vein was commonly used (81%) and non-reversed bypass fashion was applied in most cases (84%).

Of 113 failing grafts, 54 (48%) were asymptomatic and detected by regular graft surveillance and the remaining 59 grafts (52%) were diagnosed in patients with rest pain (18 limbs) or recurrent ulcer (41 limbs) (Table 1). In the 41 limbs with recurrent ulcer, 31 limbs (76%) had small and shallow ulcers without gangrene, and 10 (24%) had deep ulcers and gangrene.

The mean time interval between prior distal bypass and initial EVT was 7.3 ± 7.0 months. Procedural success was 98% (111 grafts). Two grafts (2%) were damaged by high pressure dilation and required surgical intervention. Details

Table 3. Details of 113 failing distal vein grafts and their lesions in 94 patients with chronic limb threatening ischaemia

Variable	Graft (n = 113)
Lesion	
Single	99
Long (>2 cm)	42 (37)
Focal	57 (50)
Multiple	14
Focal+Focal	13 (12)
Focal+Focal+Focal	1 (1)
Graft age	
≤3 months	26 (23)
>3 months	87 (77)

Data are presented as n (%).

of the failing grafts are summarised in Table 3. The EVT sites were single segment in 99 grafts (88%) and multiple segments in 14 grafts (12%). Of the 99 failing grafts with single segment lesion, a long stenosis (>2 cm) was detected in 42 grafts (37%). The mean balloon size was 3.0 ± 0.8 mm. Cutting balloons were used in 27 grafts (24%). The mean procedural time was 60 ± 29 min. There were no major cardiovascular events. Puncture site haematoma occurred in two limbs (1.8%), neither of which required surgical intervention.

The follow up rate was 100% and the mean follow up period was 34 ± 28 months. EVT was performed a median two times (range 1—11 times: 2 times, 27 grafts; 3 times, 7 grafts; 4 times, 6 grafts; 5—11 times, 10 grafts). A single EVT was performed for 63 grafts (56%) and multiple EVT for 50 grafts (44%). Multiple EVT was performed on the same lesions in 33 grafts (66%), both the same and new lesions in 14 grafts (28%), and new lesions alone in three grafts (6%). Diabetes was well controlled after the first EVT with HbA1c of 6.3 ± 0.8% (4.7—7.9%).

Primary patency of the EVT revised grafts was 41% at one year, 34% at three years, and 31% at five years. Assisted primary patency was 80% at one year, 68% at three years, and 58% at five years (Fig. 2).

Major amputation was required in eight patients (asymptomatic in one, rest pain in three, ulcer in four). The freedom from major amputation rate was 96% at one year, 94% at three years, and 80% at five years. The survival rate after EVT was 86% at one year, 57% at three years, and 50% at five years. Overall AFS was 83% at one year, 55% at three years, and 49% at five years. AFS of the patients undergoing single EVT and multiple EVT was 82% and 84% at one year, 64% and 40% at three years, 55% and 40% at five years, respectively. There were no significant differences between these (p = .27) (Table 4).

Of the 41 limbs with recurrent ulcer, the wound had healed in 34 limbs (85%). The mean wound healing time after EVT was 3.6 ± 4.8 months. The median frequency of EVT required for wound healing was once (range one to four times). The complete healing rate was 71% at three months and 84% at 12 months (Table 5). The recurrent ulcer healing

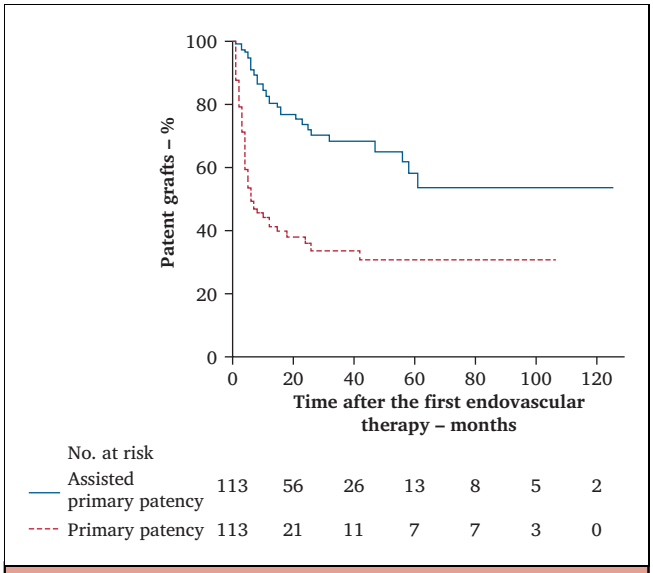

Figure 2. Cumulative Kaplan—Meier estimate of primary graft patency (red line) and assisted primary patency (blue line) after endovascular salvage therapy of 113 failing distal bypass vein grafts in 94 patients with chronic limb threatening ischaemia and infrapopliteal lesions. The standard error of the patency rate estimate does not exceed 10% for any curve.

rate was higher than that of gangrene (93.5% *vs.* 50.0% at 12 months, p = .011) (Table 5).

Multivariable analysis showed the risk factors influencing primary patency were haemodialysis (HR 2.0; 95% CI 1.2—3.5; p = .009), long stenosis (>2 cm) (HR 2.2; 95% CI 1.3—3.8; p = .003), multiple stenosis (HR 2.2; 95% CI 1.2—4.3; p = .016), and graft age less than or equal to three months (HR 2.0; 95% CI 1.2—3.5; p = .014) (Table 6). The risk factors influencing assisted primary patency were long stenosis (>2 cm) (HR 5.3; 95% CI 2.5—11.2; p < .001) and graft age less than or equal to three months (HR 3.6; 95% CI 1.7—7.8; p = .001) (Table 6).

DISCUSSION

The main results of this study were: first, primary and assisted primary patency of the EVT revised distal bypass graft were 41% and 80% at one year and 31% and 58% at

Table 4. Amputation free survival in patients treated by endovascular therapy (EVT) for failing venous distal bypass graft originally reconstructed for chronic limb threatening ischaemia

Treatment	Patients	Amputation rate after EVT for failing graft − %				p value
		1 y	2 y	3 y	5 y	
All	94 (100)	82.5	68.3	54.5	48.6	
Single EVT	57 (60.1)	81.8	69.5	64.4	54.7	.27*
Multiple EVT	27 (28.7)	83.6	66.8	39.5	39.5	

Data are presented as n (%) unless stated otherwise. EVT = endovascular therapy; y = year.
* Difference of amputation free survival rate between patients undergoing single EVT and those undergoing multiple EVT.

Table 5. Wound healing rate in patients treated by endovascular therapy (EVT) for failing venous distal bypass graft originally reconstructed for chronic limb threatening ischaemia

Wound	Limbs	Wound healing rate after EVT for failing graft − %				p value
		1 mo	3 mo	6 mo	12 mo	
All	41 (100)	41.5	70.7	84.0	84.0	
Ulcer	31 (75.6)	48.4	77.4	93.5	93.5	.011*
Gangrene	10 (24.4)	20.0	50.0	50.0	50.0	

Data are presented as *n* (%) unless stated otherwise. EVT = endovascular therapy; mo = month.
* Difference of wound healing rate between the patients with ulcer and those with gangrene.

five years, respectively. Second, EVT for focal stenosis (≤2 cm), single stenosis, or late stenosis (graft age less than three months) resulted in better graft patency. Third, monthly graft surveillance contributed to the early detection of a failing graft and to a favourable freedom from major amputation rate (94% at three years). Fourth, in patients with recurrent ulcer, early EVT facilitated wound healing of 84% at 12 months.

In this study, primary and assisted primary patency of the EVT revised distal bypass grafts were 41% and 80% at one year, 34% and 68% at three years, and 31% and 58% at five years, respectively. Similar results have been reported by others.[7,9] To maintain patency of the failing grafts, multiple EVTs are required frequently. In this study, EVT was performed a median of two times and maximum of 11 times. Furthermore, AFS of patients undergoing multiple EVTs was comparable with that of patients undergoing single EVT ($p = .27$). Considering that the assisted primary patency is favourable and multiple interventions can be performed safely, EVT is a feasible strategy for a failing graft after distal bypass.

The mean interval from distal bypass to initial EVT was 7.3 ± 7.0 months in this study. Similarly, Patel *et al.* reported a median interval of five months (range 1–46 months).[9] Westin *et al.* reported that their first EVT was performed a median of 12 months after infrapopliteal bypass (range 4–45 months).[7] Such an early intervention indicates that some vein grafts fail early after distal bypass, and that early detection of the failing grafts leads to early EVT.

In this study, the patency of the EVT revised grafts was significantly better in patients with favourable grafts including focal (≤2 cm) and single lesion, and graft age less than three months. In contrast, some reports have recommended that unfavourable grafts including long or multiple lesions as well as young graft age less than three months, should be repaired surgically.[7,12–14] The unfavourable grafts are caused by multiple intra-operative factors such as low vein quality (small diameter or poor dilation), residual venous valve, technical injury, and size mismatch. Thus, in case of a favourable graft

Table 6. Univariable and multivariable analysis of factors associated with primary and assisted primary patency of the 113 failing distal vein grafts in 94 patients salvaged by endovascular therapy

Variables	Primary patency			Assisted primary patency		
	Univariable*	Multivariable†	HR (95% CI)	Univariable*	Multivariable†	HR (95% CI)
Female sex	.51			.03	.69	1.3 (0.4–4.9)
Age ≥70 years	.10			.12		
Rutherford class 6	.22			.59		
Insulin (ID)	.52			.24		
Hypertension	.64			.27		
Hypercholesterolaemia	.46			.33		
Smoking	.26			.01	.51	0.6 (0.6–2.4)
CAD	.96			.43		
CVD	.86			.74		
Haemodialysis	<.001	.009	2.0 (1.2–3.5)	.88		
Non-ambulatory	.49			.83		
OT ≥180 min	.55			.66		
BK inflow	.41			.76		
Ankle	.60			.68		
Spliced vein graft	.93			.85		
In situ	.12			.25		
SVG <3 mm	.07			.36		
GF <20 mL/min	.19			.22		
Cutting balloon	.16			.67		
Balloon size <3 mm	.26			.85		
Symptomatic	.06			.34		
Multiple lesion	.02	.016	2.2 (1.2–4.3)	.06		
Long stenosis	<.001	.003	2.2 (1.3–3.8)	<.001	<.001	5.3 (2.5–11.2)
Graft age ≤3 months	.01	.014	2.0 (1.2–3.5)	.006	.001	3.6 (1.7–7.8)

ID = insulin dependent; CAD = coronary artery disease; CVD = cerebrovascular disease; OT = operation time; BK = below knee; SVG = saphenous vein graft; GF = graft flow; HR = hazard ratio; CI = confidence interval.
* *p* value of univariable Kaplan–Meier analysis.
† *p* value of multivariable Cox proportional hazard analysis.

without any intra-operative factors, EVT should be selected as the first line therapy.

The freedom from major amputation rate was 94% at three years in the present study. This acceptable result was partly because of early detection of the failing graft by strict graft surveillance. In addition, 48% of the patients were asymptomatic when the failing grafts were observed. Westin *et al.* conducted frequent graft surveillance and achieved an excellent freedom from major amputation rate of 96% at two years.[7] Simosa *et al.* reported that 48% of their patients with failing grafts were asymptomatic and the freedom from major amputation rate was 90% at two years under careful graft surveillance.[13] Although graft surveillance is not necessarily effective for detecting a failing graft,[15] vigilant surveillance after distal bypass and efforts to identify the failing grafts yield better graft patency and limb salvage.

There have been no reports on symptom oriented outcomes such as wound healing rate after EVT for failing grafts in distal bypass. In this study, graft EVT for patients with recurrent ulcer provided good wound healing. The wound healing rate was 42% at one month, 71% at three months, and 84% at 12 months. Although aggressive EVT to the diseased infrapopliteal arteries has been reported to yield acceptable wound healing of 34–70% at 12 months,[16–19] failing graft EVT after distal bypass showed better and faster wound healing. There are two reasons for this improved wound healing: first, wound ulcers were detected at an early stage (in the present study, 76% of the recurrent ulcers were small and shallow). In a series of revascularisation for CLTI (surgery 48%, EVT 52%), Leithead *et al.* showed that AFS was lower in patients with advanced ulcers regardless of ischaemic grade;[20] second, blood flow through the revised vein graft was superior to that through the diseased or revised infrapopliteal native artery. Spillerova *et al.* reported that a higher wound healing rate after bypass surgery was associated with more blood supply to the ischaemic ulcer through the vein graft compared with that after EVT in patients with infrapopliteal occlusive disease.[21] To achieve early wound healing, graft EVT rather than native artery EVT should be prioritised.

Limitations

This study was a retrospective analysis at a single institution, with a relatively short follow up period. Several types of standard balloons were used for different lesions, and the patency rate of each balloon was not evaluated because of small sample size. Drug coated balloons were not used in this study because graft EVT using this balloon has not been approved in Japan.[22] Also, the quality of the autologous vein grafts was not evaluated. Despite these limitations, the present authors believe that the results will provide new insight into EVT for failing grafts after distal bypass.

Conclusions

Long term outcomes including patency rate, amputation free survival, and wound healing rate after EVT for a failing vein graft were acceptable in this study, suggesting that EVT could be a viable alternative to surgical revascularisation for failing grafts after distal bypass for CLTI. EVT should be the first priority for favourable failing grafts such as single and focal stenosis ($\leq$2 cm) and graft age less than three months because of better primary and assisted primary patency rates.

CONFLICTS OF INTEREST

None.

FUNDING

None.

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Eur J Vasc Endovasc Surg (2021) 61, 127

COUP D'OEIL

COVID-19 and Brachial Artery Shotgun Injury

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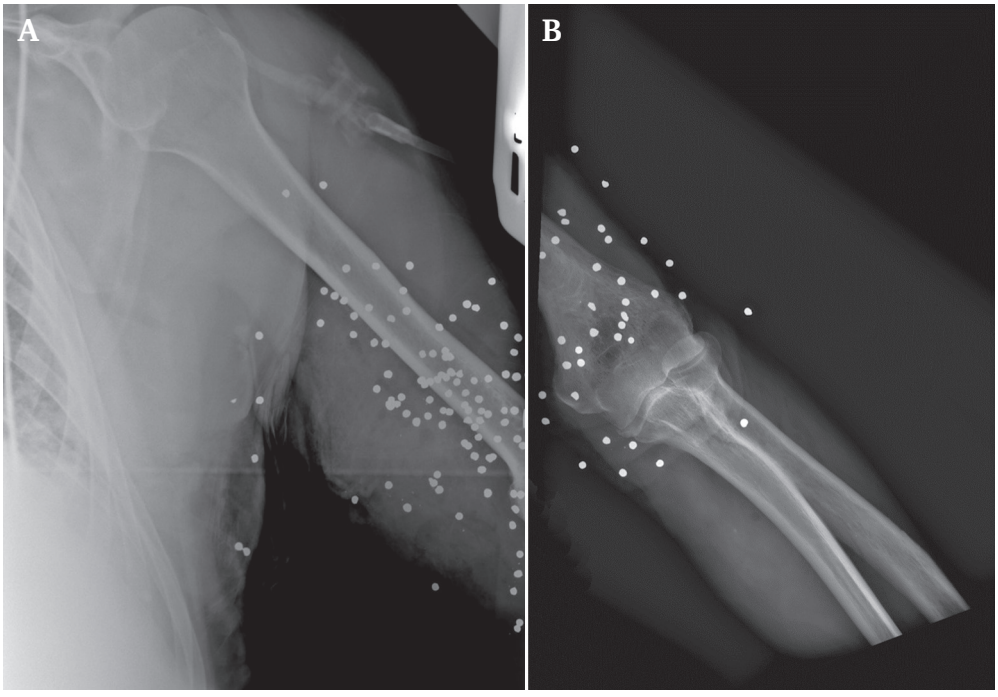

A 77 year old man quarantined with his COVID-19 positive family developed respiratory symptoms and attempted suicide. Trauma computed tomography showed multiple shot pellets in the chest and left arm (A, B); angiography was inconclusive because of metal artefact. Diminished radial and missing ulnar pulses were noted. Emergency surgery in a dedicated COVID-19 operation room showed a single penetration injury of the proximal brachial artery with thrombosis. Soft tissue exploration, Fogarty catheter thrombectomy, sutured arterial repair, and fasciotomy were performed. After COVID-19 confirmation, follow up imaging was omitted (palpable peripheral pulses and preserved upper limb function). The patient is stable, with intermittent nasal oxygen at the COVID-19 care unit.

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https://doi.org/10.1016/j.ejvs.2020.08.017