

## ORIGINAL ARTICLE

# Treatment of failing vein grafts in patients who underwent lower extremity arterial bypass

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**Purpose:** We attempted to determine risk factors for the development of failing vein graft and optimal treatment in patients with infrainguinal vein grafts. **Methods:** We retrospectively reviewed a database of patients who underwent infrainguinal bypass using autogenous vein grafts due to chronic atherosclerotic arterial occlusive disease of lower extremity (LE) at a single institute between September 2003 and December 2011. After reviewing demographic, clinical, and angiographic features of the patients with failing grafts, we analyzed those variables to determine risk factors for the development of failing grafts. To determine an optimal treatment for the failing vein grafts, we compared results of open surgical repair (OSR), endovascular treatment (EVT) and conservative treatment. **Results:** Two hundred and fifty-eight LE arterial bypasses using autogenous vein grafts in 242 patients were included in this study. During the follow-up period of  $39 \pm 25$  months (range, 1 to 89 months), we found 166 (64%) patent grafts with no restenosis, 41 (15.9%) failing grafts, 39 (15.1%) graft occlusions, and 12 (4.7%) grafts lost in follow-up. In risk factor analysis for the development of a failing graft, no independent risk factors were identified. After 50 treatments of the 41 failing grafts (24 OSR, 18 EVT, 8 conservative management), graft occlusion was significantly more common in conservative treatment group and severe ( $>75\%$ ) restenosis was significantly more common following EVT than OSR ( $P = 0.001$ ). Reintervention-free graft patency was also superior in the OSR group to that of the EVT group (87% vs. 42%,  $P = 0.015$ ). **Conclusion:** OSR of failing grafts has better outcomes than EVT or conservative management in treating failing grafts.

**Key Words:** Lower extremity, Bypass, Failing graft, Stenosis, Graft occlusion

## INTRODUCTION

While the frequency of lower extremity (LE) bypass has recently declined due to widespread use of endovascular procedures, leg bypass with autogenous vein graft still remains the gold standard in treatment of long or multi-level, advanced atherosclerotic occlusive lesions of LE arte-

ries. After leg bypass using vein graft, vein graft patency is threatened by subsequent development of stenosis of the vein graft itself or at the anastomotic site in up to 20% of the cases, which is usually due to intimal hyperplasia or progression of native arterial disease [1-3].

The original use of the term "failing graft" was introduced by Veith et al. [4] in 1984. A failing graft is defined

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as a vein graft that is patent but hemodynamically failing due to stenosis and exposed to risk for graft occlusion. Underlying causes of failing grafts are stenotic or occlusive lesions in the inflow or outflow arteries, anastomotic sites, or within the vein graft itself. Among these, intrinsic vein graft lesions were known to be the most common cause (60 to 80%) of failing graft, which usually develop in the first 3 to 5 years following vein graft implantation [5]. The emergence of duplex ultrasonography (DUS) has allowed for vein graft surveillance following LE arterial bypass, increasing the likelihood of detecting failing grafts before occurrence of the graft occlusions.

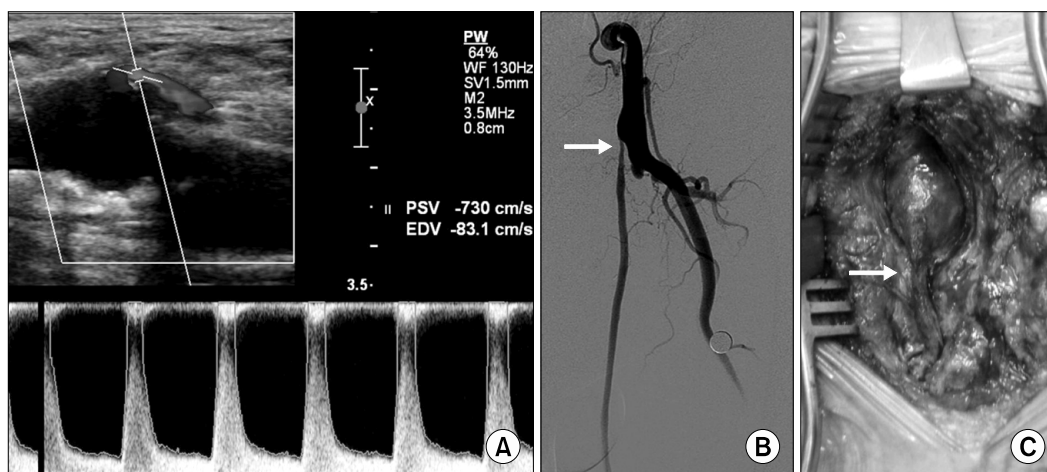
Previous studies have reported that 10 to 50% of failing grafts will occlude within 12 months if not properly treated [6,7]. Therefore, various endovascular or open surgical procedures have been utilized for the treatment of failing grafts, but, there is no consensus on which method is most effective to prolong the patency of the vein graft. In this study, we attempted to determine risk factors for the development of failing graft after infrainguinal vein grafts implantation and an optimal treatment of the failing graft by comparing the treatment outcomes of failing grafts between open surgical repair (OSR) versus endovascular treatment (EVT) versus conservative treatment.

## METHODS

We retrospectively reviewed a database of patients who underwent infrainguinal bypass of chronic LE arterial occlusive disease using autogenous vein grafts at a single institution between September 2003 and December 2011. LE bypasses performed on patients with nonatherosclerotic disease or vascular trauma were excluded from this study.

Postoperatively, all patients were prescribed an antiplatelet medication (aspirin,  $n = 42$  limbs; aspirin and clopidogrel,  $n = 216$  limbs) and a lipid-lowering medication (e.g., statin) for patients with hyperlipidemia unless contraindicated. Vein graft surveillance was performed using DUS (iU22, Philips, Amsterdam, The Netherlands) at 1 month after bypass surgery and every 6 months thereafter. On DUS, findings of increased peak systolic velocity (PSV  $> 300$  cm/sec), velocity ratio ( $\geq 4$ ) at the stenotic site, or diminished PSV ( $< 45$  cm/sec) distal to the stenotic lesion were used as diagnostic criteria for failing grafts regardless of whether there was symptomatic recurrence (Fig. 1A). Digital subtraction or computed tomography (CT) angiography was performed to confirm the location and severity of the stenotic lesion before treatment.

To determine risk factors for developing a failing graft after LE vein bypass, we conducted a multivariate analysis using demographic, clinical, and procedural variables.



**Fig. 1.** A failing vein graft near the proximal anastomosis of femoro-distal bypass. (A) Duplex ultrasonography showed high (730 cm/sec) peak systolic velocity at the stenotic lesion; (B) tight stenosis (arrow) on digital subtraction angiography; and (C) operative photo of stenotic segment of vein graft close to the proximal anastomosis.

Treatment modality of failing grafts was determined by the length of the stenotic lesion; short ( $\leq 2$  cm) stenotic lesions were treated with percutaneous transluminal angioplasty (PTA) (Fig. 2A, B) while longer ( $> 2$  cm) stenotic lesions were treated with vein patch angioplasty or graft extension using a new autogenous vein graft.

For vein patch angioplasty, we exposed the stenotic segment of the vein graft by meticulous dissection with No. 15 blade. To facilitate identification of the stenotic lesion by surgical dissection, vein graft and the stenotic lesion was marked on the overlying skin using DUS before the operation. After administration of intravenous heparin, the proximal and distal of the vein graft stenosis were controlled. Longitudinal incision was made along the anterior wall of the stenotic segment of the vein graft which sometimes crossed the anastomotic line. Patch closure of the stenotic segment was completed with 6-0 polypropylene continuous suture (Fig. 2C) of the autogenous vein patch. Proximal or distal extension of the vein graft was also performed using a new segment of great saphenous vein by bypassing the stenotic lesion (Fig. 2D).

Following the intervention, we continued to use antiplatelet agent and periodic vein graft surveillance using DUS. Patients who refused EVT or OSR were conservatively treated with prescribing antiplatelet and or lipid lowering agent and performed periodic follow-up

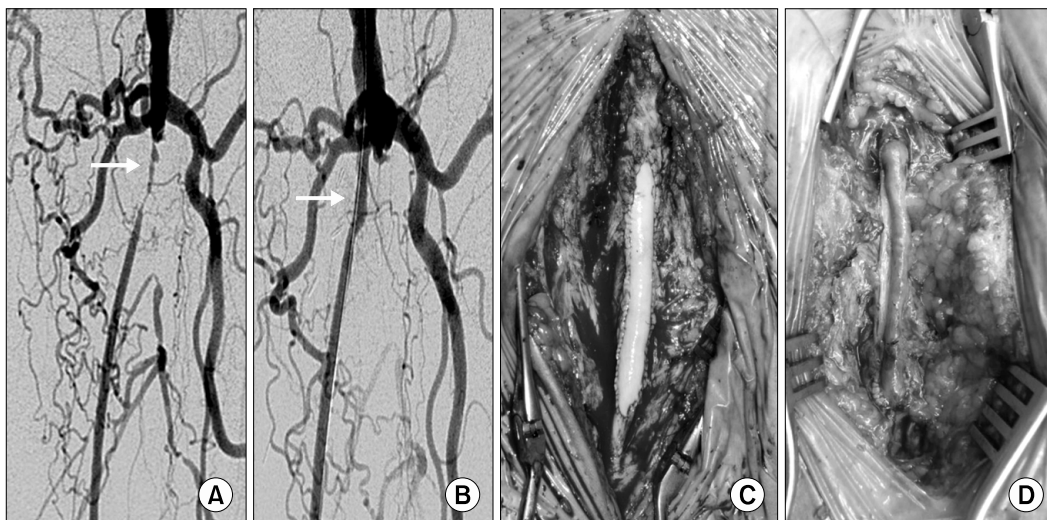
examinations of DUS.

We compared primary or primary assisted patency and reintervention-free patency of the original vein grafts among EVT, OSR, and conservative treatment groups. Graft patency rates were calculated using the Kaplan-Meier method, and compared them among groups using log rank tests. Reintervention-free patency was calculated from the time of vein graft revision. To determine factors related to treatment failure, multivariate analysis was conducted using logistic regression and the Cox proportional hazards model.

## RESULTS

Among 395 LE bypasses performed in 341 patients between September 2003 and December 2011, vein grafts were used in 274 limbs (69%) in 242 patients. In this study, we included 258 bypasses, excluding 16 bypasses (in 16 patients) performed for LE arterial occlusion due to non-atherosclerotic causes.

On postoperative follow-up examination of the vein grafts (mean,  $39 \pm 25$  months; range, 1 to 89 months) with DUS, we found 166 (64%) patent grafts with no restenosis, 41 (15.9%) failing grafts, 39 (15.1%) graft occlusions, 12 (4.7%) grafts lost to follow-up and 24 (9.5%) patients were



**Fig. 2.** Treatment of a failing graft. (A) Failing graft (arrow) close to the proximal anastomosis; (B) after balloon angioplasty (arrow) of the stenotic lesion; (C) vein patch angioplasty; and (D) proximal graft extension with a new vein graft.

dead.

Demographic and clinical features of the patients and characteristics of vein grafts were compared between groups with failing graft (n = 41 limbs in 37 patients) and patent graft with no restenosis (n = 166 limbs in 157 patients) (Table 1). There was no significant difference in demographic or clinical features of the patients and characteristics of the vein graft between the 2 groups.

The most common site of the stenotic lesions in the failing grafts was found near the proximal anastomosis (64%) as shown in Fig. 2B. Mean time to the detection of a failing graft was  $14.3 \pm 15.7$  months (range, 1 to 84 months) and

**Table 1.** Comparison of demographic, clinical features and vein graft characteristics between the groups of failing graft and patent graft with no restenosis

Characteristic	Failing graft (n = 41)	Patent graft with no restenosis (n = 166)	P-value
Age (yr)	67.7 ± 9.6 (42-82)	68.2 ± 11.5 (39-89)	NS
Male	36 (88)	146 (88)	0.539
Indications for leg bypass			0.598
Claudication	24 (58)	101 (61)	
Critical limb ischemia	17 (41)	55 (39)	
Type of vein graft			0.219
Reversed saphenous vein	39 (95)	164 (99)	
<i>In situ vein</i>	2 (5)	2 (1)	
Length of vein graft			0.178
Short vein graft <sup>a)</sup>	14 (34)	73 (44)	
Long vein graft <sup>b)</sup>	27 (66)	95 (57)	
Inflow procedure	10 (24)	31 (18)	0.356
Aorto-femoral bypass	4 (10)	3 (2)	
Femoro-femoral bypass	2 (4)	9 (5)	
Iliac stent or angioplasty	4 (10)	19 (11)	
Co-morbidity or risk factor			
Hypertension	32 (78)	120 (72)	0.281
Diabetes mellitus	21 (51)	80 (48)	0.438
Hyperlipidemia	11 (27)	48 (29)	0.367
Ischemic heart disease	17 (42)	59 (36)	0.456
Current smoking	26 (63)	97 (58)	0.377
Cerebral ischemic disease	8 (20)	34 (20)	0.588
Chronic renal failure	3 (7)	14 (9)	0.134

Values are presented as mean ± SD (range) or number (%).

NS, not significant.

<sup>a)</sup>Vein graft not crossing the knee joint such as femoro-above-knee popliteal bypass or below knee popliteal-distal bypass. <sup>b)</sup>Vein graft crossing the knee joint such as femoro-below-knee popliteal or below-knee popliteal or femoro-distal bypass.

most frequently detected later than 6 months after vein graft implantations. Failing grafts clinically presented with recurrent ischemic symptoms in 27 (66%) grafts while 14 (34%) were asymptomatic and detected by periodic surveillance using DUS. Two-thirds of stenotic lesions were found to be short ( $\leq 2$  cm) on angiography. Table 2 shows characteristics of the failing grafts.

On a risk factor analysis for the development of a failing graft, we were unable to find independent risk factors (Table 3).

In 50 treatments for 41 failing grafts, 24 were treated with OSR (13 graft extensions with new vein grafts; 11 vein patch angioplasties), 18 were treated with EVT (13 balloon angioplasties and 5 stentings), and 8 were managed conservatively. Among 24 OSR group, 5 patients were previously treated with EVT which resulted in an occurrence of restenosis.

During the mean follow-up period of  $12.4 \pm 16.0$  months

**Table 2.** Characteristics of failing grafts (n = 41)

Characteristic	Value
Location of the stenotic lesion	
Inflow artery	4 (10)
Vein graft close to the proximal anastomosis	27 (64)
Mid-graft	3 (7)
Vein graft close to the distal anastomosis	3 (7)
Outflow artery	1 (2)
Combined	3 (7)
Time to the detection of failing graft (mo)	$14.3 \pm 15.7$ (1-84)
< 6 mo after bypass surgery	11 (27)
$\geq 6$ mo after bypass surgery	30 (73)
Length of stenotic lesion on angiography (cm)	
$\leq 2$	27 (66)
$> 2$	14 (34)
Ankle brachial index	$0.83 \pm 0.02$
Clinical presentation	
No recurrent ischemic symptom	14 (34)
Claudication	24 (59)
Rest pain	1 (2)
Non-healing ulcer or gangrene	2 (5)
Duplex US findings	
Peak systolic velocity (cm/sec)	$466.19 \pm 198.6$
$> 300$	36 (88)
$< 45$	5 (12)
Velocity ratio	$6.71 \pm 2.81$

Values are presented as number (%), mean ± SD (range) or mean ± SD.

US, ultrasonography.



(range, 1 to 56 months) after treatment (n = 50) for 41 limbs with failing grafts, we have experienced 5 (10%) graft oc-

**Table 3.** Risk factor analysis<sup>a)</sup> for the development of a failing graft after lower extremity vein graft

Variable	HR (95% CI)	P-value
Male sex	0.778 (0.254-2.383)	0.660
Coexisting morbidity or risk		
Hypertension	1.079 (0.757-1.538)	0.673
Diabetes mellitus	1.087 (0.775-1.524)	0.628
Hyperlipidemia	1.156 (0.254-2.383)	0.751
Ischemic heart disease	0.988 (0.705-1.384)	0.942
Current smoker	0.825 (0.593-1.146)	0.251
Cerebral vascular disease	1.031 (0.681-1.561)	0.885
Chronic renal disease	0.827 (0.243-1.751)	0.113
Indications for bypass		
Critical limb ischemia	1.016 (0.506-2.041)	0.549
Length of vein graft		
Long vein graft	1.59 (0.757-3.130)	0.154
Vein graft		
Reversed vein	0.458 (0.421-2.982)	0.089

HR, hazard ratio; CI, confidence interval.

<sup>a)</sup>Cox's proportional hazard model.

clusion, 12 (24%) severe restenosis, and 1 (2%) major limb amputation. Graft occlusion developed in 4% in OSR group, 12% in EVT group and 25% in conservative treatment group. We have observed that graft occlusion was most common in conservative treatment group and occurrence of severe restenosis was significantly more common in EVT group than in OSR (56% vs. 8%,  $P = 0.001$ ) (Table 4). On a multivariate analysis using Cox's proportional hazard model to determine risk factors for treatment failure in patients with failing vein grafts, we found that EVT was an independent risk factor for the development of severe restenosis or graft occlusion ( $P = 0.004$ ; hazard ratio, 16.097) (Table 5).

Primary assisted patency rates in OSR and EVT group were not significantly different at 1, 3 and 5 years (Fig. 3A) but, 1 year reintervention-free patency rate was significantly higher in OSR group than in EVT group (87% vs. 42%,  $P = 0.015$ , log rank test) (Fig. 3B).

**Table 4.** Comparison of patient data and treatment results

Variable	Treatment			P-value
	Endovascular (n = 18)	Open surgical (n = 24)	Conservative (n = 8)	
Mean age (yr)	63.4	69.5	70.8	NS <sup>b)</sup>
Male sex	16 (88)	21 (87)	7 (88)	0.990 <sup>a)</sup>
Coexisting morbidity/ risk				
Hypertension	13 (72)	18 (75)	7 (88)	0.693 <sup>a)</sup>
Diabetes mellitus	10 (56)	13 (54)	4 (50)	0.966 <sup>a)</sup>
Hyperlipidemia	3 (23)	9 (38)	1 (13)	0.200 <sup>a)</sup>
Ischemic heart disease	8 (44)	9 (38)	5 (63)	0.467 <sup>a)</sup>
Current smoking	8 (44)	15 (63)	7 (88)	0.111 <sup>a)</sup>
Cerebral vascular disease	1 (6)	5 (21)	2 (25)	0.307 <sup>a)</sup>
Chronic renal disease	0 (0)	2 (4)	2 (25)	0.068 <sup>a)</sup>
Long vein graft	10 (56)	17 (70)	4 (50)	0.449 <sup>a)</sup>
Lesion location				
Close to prox. anastomosis	11 (61)	15 (63)	7 (88)	0.358 <sup>a)</sup>
Time to reintervention after vein graft implantation (mo)	17.1 ± 14.3	15.4 ± 18.9	8.4 ± 5.5	NS <sup>b)</sup>
Length of stenotic lesion (cm)	0.83 ± 0.51	1.24 ± 1.23	0.91 ± 0.25	NS <sup>b)</sup>
Mean duration of follow-up (mo)	9.5 ± 12.8	19.1 ± 17.7	4.9 ± 10.5	NS <sup>b)</sup>
Treatment results				0.001 <sup>a)</sup>
Graft occlusion	2 (12)	1 (4)	2 (25)	
Restenosis >75% or required intervention	10 (56)	2 (8)	-	

Values are presented as number (%) or mean ± SD.

Endovascular treatment included 13 balloon angioplasties and 5 stentings; open surgical repair included 13 graft extensions and 11 patch angioplasties using an autogenous vein; conservative treatment included antiplatelet medication with or without lipid lowering medication. NS, not significant.

<sup>a)</sup>Chi-square test. <sup>b)</sup>Student's t-test.

## DISCUSSION

In contrast to term “failed” graft, a “failing” graft denotes a patent autologous vein graft that is at risk of graft occlusion due to hemodynamically significant narrowing of the inflow artery, outflow artery, or the vein graft itself [4]. In current practice of vascular surgery, early detection of the failing grafts and optimal treatment of the target lesion has known to be important to prolong patency of the original vein grafts. As many as 80% of patients who present with recurrent limb ischemia after LE bypass have graft occlusions, and treatment option for the failed graft is usually limited to redo bypass or EVT which demands

**Table 5.** Multivariate analysis<sup>a)</sup> for treatment failure<sup>b)</sup> in patients with failing vein graft

Variable	HR (95% CI)	P-value
Age	0.942 (0.849-1.044)	0.942
Male sex	0.720 (0.063-8.235)	0.900
Indication for bypass		
Claudication	1	0.981
Critical limb ischemia	0.981 (0.187-5.135)	
Long vein graft	2.663 (0.300-23.611)	0.379
Age of stenotic lesion (mo)		
< 6	1	
6-12	0.897 (0.148-5.409)	0.904
> 12	0.236 (0.032-1.719)	0.154
Treatment modality		
Open surgical repair	1	0.004
Endovascular treatment	16.097 (2.385-108.6360)	

HR, hazard ratio; CI, confidence interval.

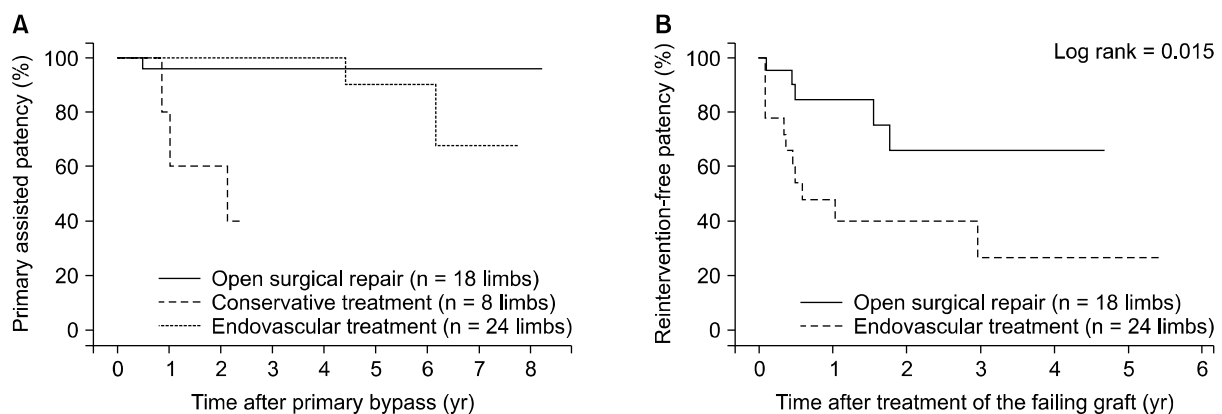
<sup>a)</sup>Cox's proportional hazard model. <sup>b)</sup>Treatment failure: graft occlusion, restenosis >75% or reintervention.

more challenging technique and usually results in poorer results than that of the primary bypass surgery [8,9]. Unlike the treatment of the failed graft, the graft patency (primary assisted patency) of the failing vein graft can be prolonged by a less invasive surgical or endovascular procedure.

Many patients with failing grafts are known to experience recurrent ischemic symptoms during the follow-up period, but 10 to 30% of the failing grafts are asymptomatic at the time of detection [7]. In the present study, two thirds of failing grafts presented with recurrent leg ischemic symptom while one-third of failing grafts were detected without recurrent ischemic symptoms. Like other previous reports [5,10], we also experienced an importance of the postoperative DUS surveillance of the vein grafts for early detection of failing grafts after LE bypass surgery with the vein graft.

Suggested DUS-based diagnostic criteria of failing grafts include high velocity criteria such as PSV > 300 cm/sec, PSV ratio > 3.5-4 at the stenotic segment, and low velocity criterion such as PSV < 45 cm/sec distal to the stenotic lesion [11,12]. The diagnostic criteria for failing grafts may differ from institution to institution. CT or conventional angiography is usually recommended to reconfirm the location and severity of the stenotic lesion before treatment. We also used digital subtraction or CT angiography after detection of failing graft with DUS.

Regarding the time interval between vein graft implantation and detection of a failing graft, many studies have reported that failing grafts are often detected be-



**Fig. 3.** Primary assisted (A) and reintervention-free patency rates (B) in surgical and endovascular treatment groups.

tween 3 months and 18 months after bypass surgery [10,13]. Schneider et al. [14] reported that 50% of failing grafts were detected within 1 year after bypass. Based on this observation, they recommended more frequent DUS examinations of the vein graft within the first 1 or 2 years after LE bypass grafting. In our study, 73% of the failing grafts were detected later than 6 months and 80% of failing grafts were detected within 2 years after bypass surgery.

The location of vein graft stenosis may be related to the type of vein graft (reversed vein graft vs. *in situ* vein), diameter of the vein graft, location of venous valves, or intraoperative vein graft injury by clamping or cannulation. Mills et al. [13] reported that the proximal and the distal anastomosis was similar in frequency of stenotic lesions. According to Berkowitz et al. [15] and Schneider et al. [14], 40% of stenotic lesions were located within 4 cm of the proximal anastomosis due to the location of venous valves or intraoperative vein graft injury from clamping or manipulation. However, Avino et al. [2] and Berceli et al. [10] reported that stenotic lesions were most commonly seen midgraft due to the diameter of the vein graft and the location of the vein valve. After performing LE bypasses with reversed vein grafts in majority of the patients, we observed that 64% of stenotic lesion was located near the proximal anastomosis which was followed by inflow artery, mid graft and vein graft close to the distal anastomosis.

A failing graft will typically progress to graft occlusion. Mofidi et al. [7] reported that 80% of failing grafts became occluded within 2 years when left untreated. It has been reported, however, that revision of the stenotic segment can significantly improve graft patency. According to previous reports, a successful revision of a failing graft can prolong the primary patency by 15% [11,16,17].

The optimal treatment for failing grafts has been a source of debate for decades. Though Mills et al. [11] recommended anticoagulation therapy for the treatment of failing grafts, many other authors recommended an earlier treatment of the target lesion with endovascular or surgical intervention [6,18]. Various procedures have been used to treat failing grafts including EVT (e.g., PTA, cutting balloon angioplasty, cryoplasty or stenting) and OSR (e.g., vein patch angioplasty, proximal or distal vein graft

extension). Avino et al. [2] recommended the use of PTA for patients with short (<2 cm) stenosis, vein graft diameter >3.5 mm, and age of the vein graft >3 months after implantation.

Several studies have reported higher failure rates of PTA compared to OSR [19-21]. Additionally, conflicting evidence has been reported regarding improved results in treatment of failing grafts with cutting balloon angioplasty [14,22]. Cutting balloon angioplasty was known to be associated with a higher technical success, low short-term patency and higher complication rates so that some authors do not recommend cutting balloon angioplasty for the treatment of the failing graft [23]. Recently, cryoplasty and drug-eluting stents (DES) were also introduced as a treatment for failing vein grafts. Vikram et al. [24] reported a 50% reintervention-free patency rate at 12 months following cryoplasty. As seen in coronary applications, experimental data for DES in infrainguinal failing grafts has recently begun to be released. [25]

On our retrospective study comparing outcomes of OSR, EVT, and conservative management for treatment of failing vein grafts, we found that significantly better reintervention-free patency rate after OSR compared to EVT. OSR is reported to provide long-term primary assisted patency in patients with a failing graft [1,14]. We report a 90% primary assisted patency rate at 5 years in OSR group. And we found higher rates of graft restenosis (>75%) or occlusion in EVT and conservative treatment groups than in OSR group. On a multivariate risk factor analysis for the treatment failure of the failing graft, EVT showed significantly higher risk of restenosis despite they were selectively performed for patients with a short stenotic lesion [5].

Surgical options in treatment of failing grafts depend on the location and length of the stenotic lesion as well as the availability of an available autogenous vein. Vein patch angioplasty or vein graft extension (proximal or distal) have been reported with excellent medium and long term patency rates [5]. Focal short stenotic lesions are often caused by intimal hyperplasia or sclerotic valve leaflets, which is a good candidate of vein patch angioplasty. Stenotic lesions near the anastomotic site or atherosclerotic lesions involving the distal runoff artery are suit-

able candidates for graft extension with a new vein graft [26].

The present study has several limitations including retrospective study design, different indication for each treatment group, use of balloon angioplasty in most cases for EVT and small number in each treatment group. This study was conducted during a period in which treatment protocols, techniques, and device availability was substantially changing.

To conclude our observation, we have experienced that infrainguinal failing vein can be detected in asymptomatic patients by postoperative DUS surveillance. Though there were above described limitations in this study, we found that successful OSR resulted in better outcomes than EVT in treating failing grafts.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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