Mid-term clinical outcome and predictors of vessel patency after femoropopliteal stenting with self-expandable nitinol stent

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Background: **Long-term clinical outcomes after femoropopliteal (FP) stenting with nitinol stents have not yet been clear. We investigated the mid-term efficacy of FP stenting with nitinol stents.**

Methods: **This study was a multicenter retrospective study. From April 2004 to December 2008, 511 consecutive patients (639 limbs; mean age 71 ± 7 years; 71% male) who underwent successful FP stenting with nitinol stents for de novo lesions were retrospectively selected and analyzed in this multicenter study. All patients had a minimum follow-up of 6 months. Restenosis was defined as >2.4 of peak systolic velocity ratio by duplex or >50% stenosis by angiogram. Primary patency was defined as treated vessels without restenosis and repeat revascularization. Secondary patency was defined as target vessels that become totally occluded and are reopened by repeat revascularization.**

Results: **Sixty-one percent of the patients had diabetes, 76% were claudicant, and 20% were on hemodialysis. Mean lesion length was 151 ± 75 mm. Mean follow-up period was 22 ± 11 months. Primary patency was 79.8%, 66.7%, and 63.1%, and secondary patency was 90.4%, 87.3%, and 86.2% at 1, 3, and 5 years, respectively. During the follow-up period, 53 patients (10%) died. Of them, cardiovascular death was 38% and stent fracture had occurred in 14%. On multivariate analysis by Cox proportional hazard ratio, cilostazol administration (hazard ratio [HR], 0.52;*$P < .0001$*), stent fracture (HR, 1.6;** $P = .03$**), hemodialysis (HR, 1.7;** $P = .01$**), and Trans Atlantic Inter-Society Consensus (TASC) II class C/D (HR, 2.4;** $P < .0001$**) were the independent predictors of primary patency after successful FP stenting.**

Conclusion: **Clinical efficacy of nitinol stent implantation for FP disease was favorable for up to 5 years. (J Vasc Surg 2010;52:608-15.)**

Endovascular therapy (EVT) for symptomatic lower extremity ischemia has become widespread due to technological advances, and the strategy of revascularization has shifted from surgical treatment toward EVT.[1-3] EVT for femoropopliteal (FP) lesions remains unsatisfactory in terms of vessel patency after the procedure,[4-7] but the 2-year vessel patency in the FP artery may be improved through use of a nitinol stent[8-10] in combination with pharmacotherapy,[11,12] compared to conventional endovascular treatment before the use of nitinol stents. EVT with a nitinol stent for FP lesions is widely performed, but long-term patency beyond 2 years is still to be achieved.[13] However, there are few reports on the predictors of primary patency in the era of the nitinol stent. Therefore, the purpose of this study was to examine the midterm efficacy of nitinol stent implantation for FP disease and to determine the factors associated with vessel patency after treatment.

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METHODS

Research design. Between January 2004 and December 2008, 1382 consecutive patients (1899 limbs) underwent successful EVT for FP artery disease (from the superficial femoral artery to the above-knee popliteal artery) at each hospital involved in the study. Of these cases, 871 patients (1260 limbs) were excluded because of treatment with angioplasty alone, restenotic lesions, use of a metallic stent, Rutherford class <2, history of lower extremities bypass surgery or EVT, or a follow-up interval <6 months. Therefore, 511 patients (639 limbs) who underwent successful EVT with a nitinol stent for de novo lesions were identified retrospectively and included in the analysis.

Baseline clinical characteristics and procedural data were collected from hospital medical records or databases. Clinical evaluation was performed at baseline and at least every 6 months thereafter. The mean follow-up period was 22 ± 11 months (range, 6-64 months). The clinical follow-up rate was 72% (n = 366) at 1 year, 31% (n = 160) at 2 years, 15% (n = 77) at 3 years, 6% (n = 33) at 4 years, and 1.4% (n = 7) at 5 years. The study protocol was approved by the hospital ethics committees, and the study was performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from every patient.

This study (Retrospective multicenter Analysis for Femoropopliteal stenting Registry) is registered with the University Hospital Medical Information Network-Clinical Trials Registry, as accepted by the International Committee of Medical Journal Editors (No. UMIN000002726).

Table I. Patient characteristics

Patient characteristics	
No. of patients	511
Age (y)	72.0 ± 7.3
Male gender (%)	361 (71)
Body mass index	22.3 ± 2.3
Hypertension (%)	451 (88)
Hyperlipidemia (%)	194 (38)
Diabetes (%)	313 (61)
Current smoker (%)	126 (47)
Hemodialysis (%)	100 (20)
CVD (%)	145 (28)
CAD (%)	284 (56)
IC/CLI (%)	388 (76)/123 (24)
Cilostazol (%)	319 (62)
Rutherford classification	
II/III/IV/V/VI	133/255/42/68/13

CAD, Coronary artery disease; *CLI,* critical limb ischemia; *CVD,* cerebrovascular disease; *IC,* intermittent claudication.

Table II. Lesion characteristics*

Lesion characteristics	
Number of limbs	639
Approach	
Antegrade (%)/retrograde (%)	486 (76)/153 (24)
Lesion length (mm)	150.5 ± 75.1
Reference vessel diameter (mm)	5.2 ± 0.5
Chronic total occlusion (%)	317 (50)
Calcified lesion (%)	217 (34)
Preprocedure ABI	0.57 ± 0.15
Postprocedure ABI	0.84 ± 0.15
Below-the-knee runoff	
0/1/2/3	45/163/217/214
Runoff scores	5.6 ± 2.3
IC/CLI	5.0 ± 2.1/7.6 ± 2.4
Type of nitinol stent	
Luminexx (%)	135 (21)
S.M.A.R.T. (%)	504 (79)
Number of stent	
Per lesion/per patients	1.8 ± 0.8/2.3 ± 1.1
Stent fracture (%)	88 (13.8)
TASC II classification	
A/B/C/D	206/143/139/151

ABI, Ankle brachial index; *CLI,* critical limb ischemia; *IC,* intermittent claudication.

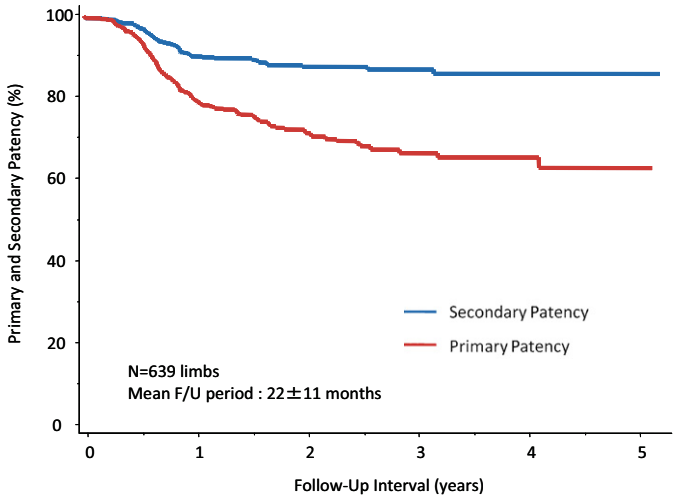
*Calcified lesion defined as obvious densities noted within the apparent vascular wall in the angiogram.

Procedures and follow-up. All patients were medicated with dual antiplatelet therapy (Aspirin 100 mg/day + clopidogrel 75 mg/day or ticlopidine 200 mg/day) from more than 2 days before the procedure. After insertion of a 6F or 7F sheath, an intra-arterial bolus of 3000 to 5000 IU of heparin was injected and supplemented as required to maintain an active clotting time of >200 seconds. A 0.035-inch, 0.018-inch, or 0.014-inch guidewire was used to cross the lesion. In treating all stenoses and occlusions of less than 10 cm in lesion length, the guidewire was advanced through the true lumen whenever possible. In occlusions of 10 cm or more, the guidewire was crossed subintimally. After passing the wire, balloon angioplasty was performed. All lesions were dilated with an optimally sized balloon. If a suboptimal result caused by flow-limiting dissection or residual stenosis of >50% was found after dilatation, a stent was implanted. For long total occlusion, the entire lesion was covered by the stent in all cases. Two types of nitinol stents were used: Luminexx (Bard, Murray Hill, NJ) and S.M.A.R.T. (Cordis J&J, Miami, Fla). The stent type was determined by the operators, and the stent size was chosen to be 1 to 2 mm larger than the reference vessel diameter. After the procedure, all patients were prescribed lifelong aspirin (100 mg/day) and prolonged (at least 1 month) clopidogrel 75 mg/day or ticlopidine 200 mg/day was recommended. Patients who had taken cilostazol (200 mg/day) before the procedure continued to receive cilostazol after the procedure. The resting ankle-brachial index (ABI), Rutherford class, stent fracture, and duplex ultrasound scan of the stented vessel were monitored within 30 days and every 6 months thereafter in concert with clinical examinations. Repeated revascularization was performed based on clinical symptoms and findings on duplex sonography or angiography scan.

Study outcome measures. The primary outcome measure was primary patency after treatment, and the secondary outcome measures were secondary patency, freedom from all-cause mortality, and incidence of stent fracture or leg amputation.

Definitions. Restenosis was defined as >2.4 of peak systolic velocity ratio by duplex scan[14] or >50% stenosis by angiography. Undetectable signal in stented segments by duplex scan was graded as complete occlusion. Primary patency was defined as a treated vessel without restenosis and any repeat revascularization. Secondary patency was defined as a target vessel that subsequently became totally occluded and was reopened by repeat revascularization. The total lesion length referred to was the portion that was treated with stenting. Stent fracture was defined as clear interruption of stent struts identified by x-ray film from more than 2 projections, with resulting kink or misalignment along the axial length of the stent. Leg amputation was defined as amputation above the ankle. Coronary artery disease (CAD) was defined as stable angina with documented CAD, history of percutaneous coronary intervention, history of coronary artery bypass graft surgery, or previous myocardial infarction. Cerebrovascular disease was defined as a hospital or neurologist report with the diagnosis of transient ischemic attack or ischemic stroke. Below-the-knee runoff was assessed by angiography before or after the procedure.

Statistical analysis. Values are reported as mean ± SD. Continuous variables were examined by use of the unpaired *t*-test. Categorical variables were compared by χ^2 test. Survival curves were estimated by the Kaplan-Meier method and compared with the log-rank test. Cox multivariate regression analysis was used to determine predictors for primary patency. Clinically prespecified predictors (age, male gender, diabetes, hypertension, hyperlipidemia, current smoker, stroke, CAD, hemodialysis, runoff score,[15] Trans Atlantic Inter-Society Consensus [TASC] II C/D,



years		0	1	2	3	4	5
at risk	Secondary patency	639	428	194	91	34	8
	Primary patency	639	381	160	68	27	5
%	Secondary patency	100	90.4	87.9	87.3	86.2	86.2
	Primary patency	100	79.8	71.8	66.9	65.8	63.2
SE	Secondary patency	.000	.012	.015	.016	.019	.019
	Primary patency	.000	.017	.021	.026	.028	.037

Fig 1. Overall primary and secondary patency in 639 limbs after femoropopliteal stenting with a self-expandable nitinol stent.

critical limb ischemia [CLI], preprocedual ABI, reference vessel diameter, calcified lesion, use of a Luminexx stent, cilostazol administration and stent fracture) with $P < .05$ on Cox univariate models were entered into the multivariable Cox regression model. A P value of $< .05$ was considered statistically significant.

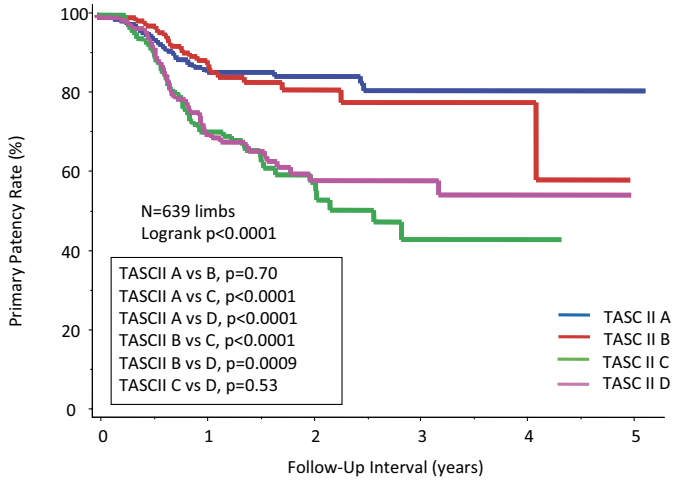
RESULTS

Patient and lesion characteristics. The age of the 511 patients (639 limbs) ranged from 40 to 94 years(mean, 72.0 ± 7.3 years). The characteristics of the patients and lesions are shown in Tables I and II. The percentages of patients with intermittent claudication (IC), resting pain, and ischemic tissue loss were 75.9%, 8.2%, and 15.9%, respectively. The mean lesion length was 150.5 ± 75.1 mm. In the TASC II classification, 206 patients (32.2%), 143 patients (22.4%), 139 patients (21.8%), and 151 patients (23.6%) were in classes A, B, C, and D, respectively. The mean runoff score in patients with IC was significantly lower than that of patients with CLI (5.0 ± 2.1 vs 7.6 ± 2.4; $P < .001$). The ABI values preprocedure and postprocedure were 0.57 ± 0.15 and 0.84 ± 0.15, respectively.

Outcome measures. In a treated limb-based analysis, the overall primary patencies were 79.8%, 66.7%, and 63.1%, and the secondary patencies were 90.4%, 87.3%, and 86.2% at 1, 3, and 5 years, respectively (Fig 1). In-stent restenosis was found in 152 of 639 treated limbs (23.8%) during the observation period. Of these limbs, 2 were treated with lower extremity bypass grafting, 11 with continued monitoring, and 139 with balloon angioplasty alone. After balloon angioplasty, re-restenosis occurred in 40.3% (56 of 139 limbs). Of the 56 re-restenotic lesions, 13 were treated with lower extremity bypass grafting, 5 with continued monitoring, and 38 with repeat balloon angioplasty.

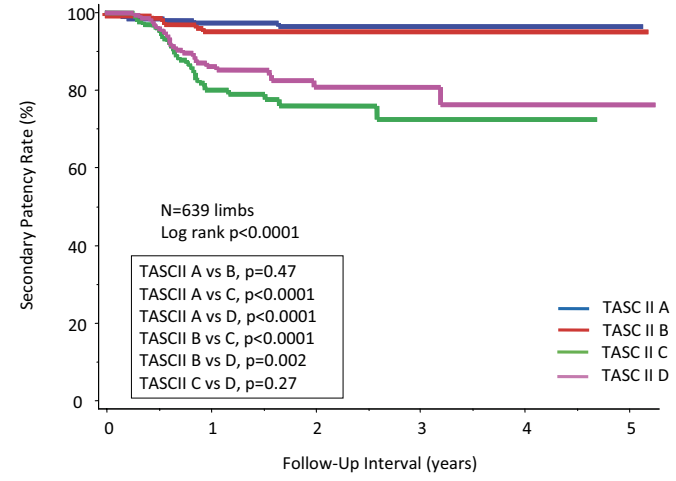
Significant differences in primary and secondary patencies were found among the TASC II classifications ($P < .0001$ by log-rank test), although primary patency did not differ between TASC II classes A and B or between classes C and D (Figs 2 and 3). However, the primary patency among TASC II classes A/B or C/D differed significantly in patients with IC or CLI ($P < .0001$ by log-rank test; Fig 4). Stent fracture occurred in 13.8% of limbs (88 of 639). Most of these fractures were single or multiple line fractures[16] (73.9%; 65 of 88). The changes of ABI and Rutherford class are shown in Fig 5. The improvements in ABI and Rutherford class were maintained up to 5 years. Leg amputation was performed in 15 limbs (2.9%; 2 limbs that originally presented with claudication and 13 limbs with CLI). The limb salvage rates were 98.7%, 96.7%, and 96.7% at 1, 3, and 5 years, respectively (Fig 6), and these rates at 2 years were significantly lower in patients with CLI than in those with IC (84.4% vs 99.5%; $P < .0001$ by log-rank test).

Multivariate analysis performed using a Cox hazards model showed that TASC II C/D (hazard ratio [HR], 2.39; 95% confidence interval [CI], 1.68-3.40; $P < .0001$), hemodialysis (HR, 1.65; 95% CI, 1.11-2.45; $P = .013$), stent fracture (HR, 1.57; 95% CI, 1.06-2.34; $P = .025$), and cilostazol administration (HR, 0.52; 95% CI, 0.37-0.71; $P < .0001$) were independent predictors of primary patency (Table III), and that TASC II C/D (HR, 5.76; 95% CI, 3.07-10.8; $P < .0001$) and cilostazol administration (HR, 0.38; 95% CI, 0.23-0.63; $P = .0001$) were



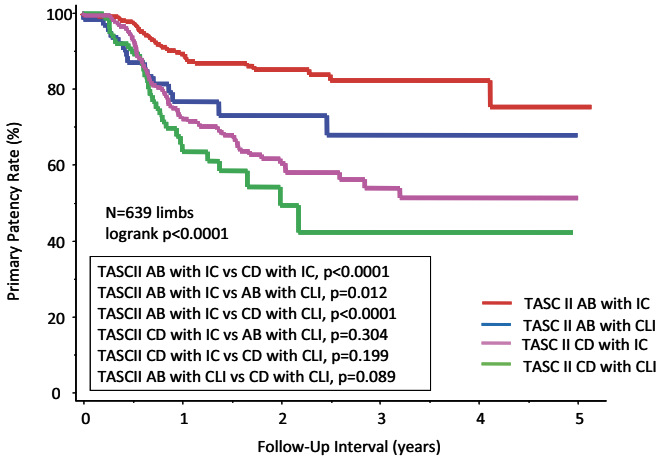
years		0	1	2	3	4	5
at risk	TASCII A	206	134	65	27	10	3
	TASCII B	143	90	33	15	4	1
	TASCII C	139	79	29	9	3	
	TASCII D	151	78	33	17	10	1
%	TASCII A	100	86.2	84.5	80.9	80.9	80.9
	TASCII B	100	88.5	82.2	78.9	78.9	59.2
	TASCII C	100	70.6	57.7	43.4	43.4	
	TASCII D	100	71.7	58.1	58.1	54.5	54.5
SE	TASCII A	.000	.025	.028	.036	.036	.036
	TASCII B	.000	.029	.039	.050	.050	.175
	TASCII C	.000	.040	.052	.071	.071	
	TASCII D	.000	.040	.050	.050	.059	.059

Fig 2. Primary patency among TASC II classifications.



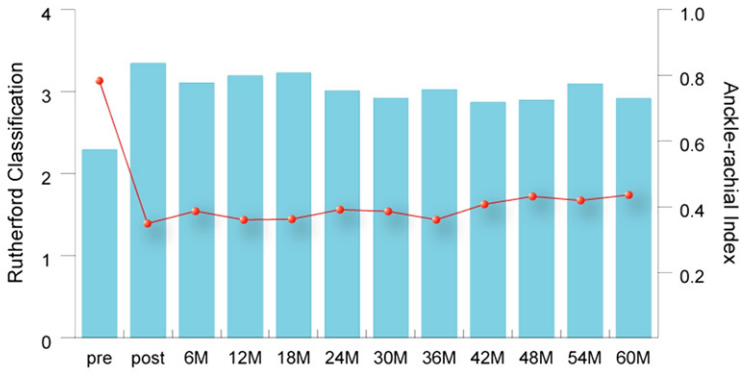
Years		0	1	2	3	4	5
at risk	TASCII A	206	150	73	36	13	3
	TASCII B	143	96	40	20	5	2
	TASCII C	139	89	36	15	5	
	TASCII D	151	93	45	20	11	3
%	TASCII A	100	97.4	96.5	96.5	96.5	96.5
	TASCII B	100	95.1	95.1	95.1	95.1	95.1
	TASCII C	100	80.2	76.1	72.6	72.6	
	TASCII D	100	86.2	80.8	80.8	76.3	76.3
SE	TASCII A	.000	.011	.015	.015	.015	.015
	TASCII B	.000	.020	.020	.020	.020	.020
	TASCII C	.000	.036	.041	.052	.052	
	TASCII D	.000	.030	.039	.039	.057	.057

Fig 3. Secondary patency among TASC II classifications.



years		0	1	2	3	4	5
at risk	TASCII AB with IC	282	195	81	32	13	3
	TASCII AB with CLI	67	29	17	10	1	1
	TASCII CD with IC	207	125	51	23	11	1
	TASCII CD with CLI	83	32	11	3	2	
%	TASCII AB with IC	100	89.4	85.8	82.8	82.8	75.9
	TASCII AB with CLI	100	76.9	73.2	68.0	68.0	68.0
	TASCII CD with IC	100	72.9	60.6	54.1	51.5	51.5
	TASCII CD with CLI	100	65.7	49.5	42.4	42.4	
SE	TASCII AB with IC	.000	.019	.024	.031	.031	.072
	TASCII AB with CLI	.000	.058	.065	.079	.079	.079
	TASCII CD with IC	.000	.032	.040	.048	.052	.052
	TASCII CD with CLI	.000	.061	.082	.096	.096	.

Fig 4. Primary patency among TASC II class A/B or C/D in patients with IC or CLI. *CLI*, Critical limb ischemia; *IC*, intermittent claudication.

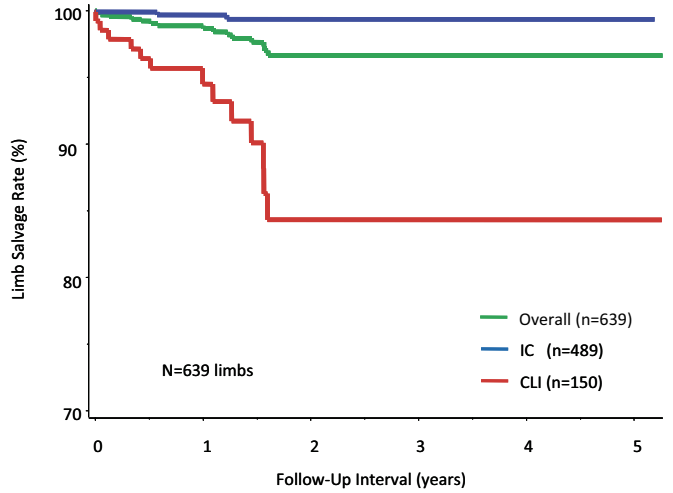


		pre	post	6M	12M	18M	24M	30M	36M	42M	48M	54M	60M
Ave.	ABI	0.57	0.84	0.78	0.80	0.81	0.75	0.73	0.76	0.72	0.73	0.77	0.73
	Ruth	3.16	1.40	1.55	1.44	1.45	1.57	1.55	1.44	1.63	1.73	1.68	1.75
SD	ABI	0.22	0.20	0.18	0.17	0.15	0.17	0.16	0.15	0.13	0.15	0.06	0.10
	Ruth	1.04	0.71	0.73	0.69	0.72	0.76	0.75	0.64	0.73	0.58	0.75	0.65

Fig 5. The changes of resting anckle-brachial index and Rutherford class. *CLI*, Critical limb ischemia; *IC*, intermittent claudication.

independent predictors of secondary patency in patients with a successful procedure. The reference vessel diameter (HR, 1.12; 95% CI, 0.86-1.47; $P = .40$) and runoff score (HR, 1.03; 95% CI, 0.97-1.10; $P = .30$) were not predictors of patency, and the type of stent used also had no influence on patency.

Freedom from all-cause mortality occurred in 94.8% of cases at 1 year, 83.2% at 3 years, and 77.3% at 5 years (Fig 7). During the observation period, 53 patients died. Cardiac death occurred in 14 patients (26.4%) and cardiovascular death (including cardiac death, stroke, and renal failure) accounted for 38% of the deaths (Table IV). Mortality in pa-



years		0	1	2	3	4	5
at risk	Overall	639	463	204	95	36	8
	IC	489	384	172	77	32	6
	CLI	150	79	32	18	4	2
%	Overall	100	98.7	96.7	96.7	96.7	96.7
	IC	100	99.8	99.5	99.5	99.5	99.5
	CLI	100	94.6	84.4	84.4	84.4	84.4
SE	Overall	.000	.005	.009	.009	.009	.009
	IC	.000	.002	.004	.004	.004	.004
	CLI	.000	.021	.044	.044	.044	.044

Fig 6. Limb salvage rate. *CLI*, Critical limb ischemia; *IC*, intermittent claudication.

Table III. Multivariate analysis of primary patency

Variables	*HR*	*95% CI*	P *value*
TASC II class C/D	2.39	1.68-3.40	<.0001
Hemodialysis	1.65	1.11-2.45	.013
Stent fracture	1.57	1.06-2.34	.025
Cilostazol administration	0.52	0.37-0.71	<.0001

CI, Confidence interval; *HR*, hazard ratio; *TASC*, Trans-Atlantic Inter-Society Concensus.

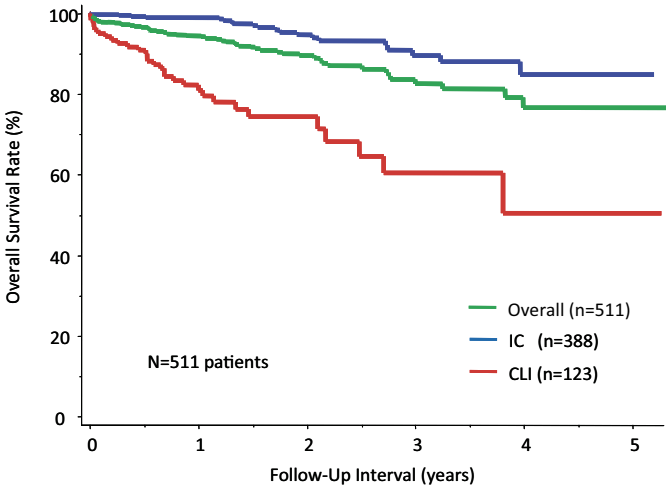
tients with CLI was significantly higher than in those with IC (26.0% vs 5.4%; $P < .0001$), and death caused by infectious disease, especially sepsis, was more frequent in patients with CLI (21.9% vs 0%; $P = .02$; Table IV).

DISCUSSION

In this study, provisional stenting was performed as a bailout measure in patients with a suboptimal outcome. Primary stenting for FP disease remains controversial,[17] but provisional stenting is acceptable due to its improvement of acute results. However, in-stent restenosis after the procedure is a major limitation. Of the 139 restenotic lesions in which balloon angioplasty was performed, re-restenosis occurred in 56 (40.3%) and this high incidence of re-restenosis is of concern. However, recent studies in a relatively limited number of cases have shown good outcomes using a paclitaxel-coated balloon[18,19] and the patency is likely to improve in future treatment of patients with restenosis.

The primary patency in patients with IC at 5 years after FP bypass grafting has been reported to be 77.2% for an above-knee vein graft and 57.4% for an above-knee polytetrafluoroethylene graft.[19] In this study, the primary patency of 5 years after FP stenting was 75.9% for patients with IC in the TASC II A/B group and 51.5% for those in the TASC II C/D group (Fig 4). The outcome in the TASC II A/B group but not that in the TASC II C/D group, was similar to that for above-knee FP bypass grafting with a vein graft. Similarly, the primary graft patency in patients with CLI 5 years after bypass grafting has been found to be 66% to 69% for an above-knee vein graft and 47% to 48% for an above-knee polytetrafluoroethylene graft.[20,21] In this study, the primary patency was 68.0% in the TASC II A/B group and 42.4% (at 4 years) in the TASC II C/D group (Fig 5). In patients with CLI caused by an FP lesion who were classified as TASC II A/B, the outcomes were good and close to those for above-knee FP bypass grafting with a vein graft. However, as for patients with IC, the outcomes for patients with CLI in the TASC II C/D group were not comparable to those for above-knee FP bypass grafting. However, despite the poorer outcome in the TASC II C/D patients, EVT may be an alternative to bypass surgery for patients with IC or CLI without a good vein graft.

The secondary patency was relatively good in all the TASC II groups (Fig 3). A lesion can be easily dilated by balloon angioplasty even if restenosis is advanced, provided that the lesion is not occluded. Noninvasive duplex sonography scan is effective for early detection,[22] which is also likely to contribute to maintenance of vessel patency. Patients with chronic lower extremity ischemia often have other atherosclerotic lesions, and the less invasive nature of



years		0	1	2	3	4	5
at risk	Overall	511	366	160	76	29	6
	IC	388	304	135	62	25	4
	CLI	123	62	25	14	4	2
%	Overall	100	94.4	89.8	82.1	76.2	76.2
	IC	100	99.0	94.7	88.5	83.9	83.9
	CLI	100	79.3	72.9	59.3	49.4	49.4
SE	Overall	.000	.011	.016	.028	.043	.043
	IC	.000	.005	.015	.029	.044	.044
	CLI	.000	.039	.048	.073	.109	.109

Fig 7. Freedom from all-cause mortality in 511 patients. *ABI*, Ankle-brachial index; *Ruth*, Rutherford class.

Table IV. Causes of death

Causes	*Total* *n = 53/511*	*IC* *n = 21/388*	*CLI* *n = 32/123*	P *value*
Cardiac death (%)	14 (26.4)	7 (33.3)	7 (21.9)	.35
Stroke (%)	4 (7.5)	1 (4.8)	3 (9.4)	.53
Renal failure (%)	2 (3.8)	1 (4.8)	1 (3.1)	.76
Malignancy (%)	8 (15.1)	7 (33.3)	1 (3.1)	.003
Sepsis (%)	7 (13.2)	0 (0)	7 (21.9)	.021
Pneumonia (%)	8 (15.1)	2 (9.5)	6 (18.8)	.36
Others (%)	8 (15.1)	3 (14.3)	5 (15.6)	.89
Unknown (%)	2 (3.8)	0 (0)	2 (6.3)	.24

CLI, Critical limb ischemia; *IC,* intermittent claudication.

EVT makes it applicable for some patients with TASC II C/D, based on the condition of regular follow-ups.

Diagnosis of CLI is associated with a poor prognosis of life and limb. In this study of 150 limbs in 123 patients with CLI, 13 limbs (11 patients) required amputation and 32 patients died in a mean follow-up period of 17 ± 10 months. The bypass vs angioplasty in severe ischemia of the leg (BASIL) study,[23] a landmark trial of first-line treatment for patients with CLI, showed that the rate of avoidance of limb amputation/death in patients treated with balloon angioplasty was similar to that in patients treated with surgery. In this study, we treated patients with CLI with a balloon-angioplasty–first strategy. In the BASIL trial, the amputation/death-free survival rates in the balloon-angioplasty–first group were 71% and 52% at 1 and 3 years after surgery, respectively, which are similar to our results of 77.7% and 58.1% at the same respective times. Therefore, our results confirm the poor prognosis of CLI and suggest no differences in response to treatment between Japanese and Western patients.

The efficacy of cilostazol after EVT for FP lesions has been shown previously.[11,12] In this study, the primary patency in the cilostazol-treated group (407 limbs) was significantly higher than that in the group that did not receive cilostazol (232 limbs; 76.4% vs 62.8% at 2 years; unadjusted $P = .0003$). There were some differences in baseline data between the two groups, with the cilostazol group including more patients with diabetes (67.2% vs 58.7%; $P = .03$), more smokers (30.7% vs 20.7%; $P = .03$), and more patients treated with a S.M.A.R.T. stent (83.3% vs 64.6%; $P = .049$). However, cilostazol was found to be an independent predictor of primary patency (Table III)

and cilostazol administration seems to be useful as adjuvant systemic therapy after EVT.

The efficacy of the nitinol stent has been shown, but outcomes within 2 years are evaluated in most studies. The lack of data for 2 years or more after FP stenting among TASC II classes makes it difficult to compare the patency with lower extremity bypass grafting. Therefore, it is important to evaluate the clinical efficacy of the self-expandable nitinol stent for FP lesions among TASC II classes up to 5 years after stenting.

Study limitations. There are several limitations that may have affected our clinical outcomes. First, this study was a retrospective, nonrandomized analysis, despite being a large-scale, multicenter study. Second, only two types of nitinol stents were implanted because these were the only available stents in Japan at the time. In addition, the low rate of patients with CLI (24%) and stent fracture (13.8% at a mean follow-up time of 22 months), and the high rate of cilostazol administration (62%) may have contributed to the overall patency. Therefore, further investigation of the new generation of nitinol stents is needed. Finally, clinical follow-up angiography or duplex ultrasound scans were not performed based on a strict protocol because of the retrospective enrollment of patients. Despite these limitations, the findings in this study indicate that good vessel patency is likely after FP stenting with a self-expandable nitinol stent.

CONCLUSION

The clinical efficacy of self-expandable nitinol stent implantation for FP disease was favorable for up to 5 years. A TASC II C/D status, hemodialysis, stent fracture, and cilostazol administration were independent predictors of primary patency after FP stenting.

AUTHOR CONTRIBUTIONS

Conception and design: YS, OI, KH
Analysis and interpretation: YS, OI, KH
Data collection: YS, OI, KH
Writing the article: YS
Critical revision of the article: YS
Final approval of the article: YS, OI, KH, HY, SN, MN
Statistical analysis: YS
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Overall responsibility: YS

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