



# Outcomes of Isolated Endarterectomy and Patch Angioplasty of the Common Femoral Artery According to Current Inclusion Criteria for Endovascular Treatment

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**Purpose:** This study aimed to evaluate the outcomes of isolated common femoral endarterectomy with patch angioplasty (IFEA) in the endovascular era.

**Materials and Methods:** In 2012-2022, 189 limbs underwent femoral endarterectomy with patch angioplasty. Of them, 45 IFEAs were included. We evaluated safety based on early complications; efficacy with primary patency (PP) and reintervention, above-ankle amputation, or stenosis (RAS)-free survival. We also evaluated lesion characteristics and outcomes according to the inclusion criteria (IC) of vascular mimetic implant-common femoral artery (VMI-CFA) stenting trial.

**Results:** Forty-one patients were male, and 30 IFEAs were required for claudication. No cases of early mortality occurred. Ten limbs (22%) developed local/non-vascular complications (hematoma, 3; lymphocele, 5; wound infection, 2), of which 8 resolved spontaneously. The overall PP and secondary patency rates were 100% at 1 year and 87% and 97% at 3 years, respectively. Twenty-one lesions (47%) did not meet the IC. The PP within the IC was 100% at 1 and 3 years, and the PP outside the IC was 100% at 1 year and 73% at 3 years ( $P=0.068$ ). The overall RAS-free survival rates were 91% at 1 year and 81% at 3 years. All cases of RAS occurred in lesions outside the IC. The multivariate analysis showed that dialysis was associated with poor RAS-free survival (adjusted odds ratio, 8.56; 95% confidence interval, 1.9-35.5;  $P=0.005$ ).

**Conclusion:** The recent VMI-CFA trial results should be interpreted with caution. IFEA is a low-risk and durable procedure; however, careful follow-up is warranted in patients undergoing dialysis.

**Key Words:** Endarterectomy, Common femoral artery, Stents, Treatment outcome

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## INTRODUCTION

In parallel with international trends, the number of endovascular treatments for peripheral arterial occlusive dis-

ease in Korea has been increasing, making it the preferred treatment method (80%-95% of all procedures) [1]. Atherosclerosis obliterans of the common femoral artery (CFA) is a disease characterized by bulky atheroma, eccentric plaque,

and heavy calcification (similar to that in coral reefs) and frequently involves femoral bifurcation. It has been considered a no-stent zone as future surgical or endovascular treatment, including access options, might become limited, and stent fracture could result from joint-related flexion and kinking after stent placement. Therefore, CFA occlusive disease has been traditionally treated by open surgical endarterectomy with or without patch angioplasty for long-term patency [2-4]

Recent advancements in endovascular equipment and technical skills have increased the number of percutaneous CFA procedures. The endovascular treatment of such lesions involves pharmacologic antiproliferative therapies in conjunction with atherectomy or provisional stenting as well as primary stenting with interwoven nitinol stents, which are less susceptible to fracture and have higher crush resistance than other self-expanding stents [5,6]. Furthermore, the effectiveness of endovascular treatment, which has acceptable patency and limb salvage rates, may be equivalent to or better than open surgical endarterectomy, which has higher morbidity and mortality rates. Few randomized controlled trials have compared these approaches for CFA lesions; however, their findings are inconsistent and divergent [7,8]. Furthermore, the inclusion criteria (IC) regarding lesion severity and morphology were incomparable with real-world data [5,8]. Consequently, consensus is lacking regarding the optimal endovascular technique for CFA.

The present study evaluated the surgical complications, outcomes, and patency of isolated common femoral endarterectomy with patch angioplasty (IFEA) in the endovascular era according to the IC of a recent endovascular stenting study [5].

## MATERIALS AND METHODS

### 1) Data source and variables

This study was approved by the local Institutional Review Board of Kyungpook National University Hospital (no. KNUCH 2022-04-013), which waived the requirement for informed consent due to the retrospective nature of the study. Between January 2012 and January 2022, 189 limbs (181 patients) underwent CFA endarterectomy with patch angioplasty with or without additional endovascular or surgical procedures for chronic limb ischemia. Among them, limbs that underwent additional endovascular treatment (n=99), surgical treatment (n=23), and both endovascular and surgical treatment (n=22) were excluded; thus, 45 IFEA procedures were analyzed. During the study period, we also excluded limbs treated with IFEA for acute limb ischemia (n=4) and cases of femoral endarterectomies without patch

angioplasty (n=2) based on our hospital's policy to implement patch angioplasty. Patient characteristics, imaging findings, surgical details, and follow-up results were collected after a medical chart review and review of pre- and postoperative images. Patient demographics included age, sex, and the presence of other comorbidities. Lesion characteristics were evaluated based on the presence of CFA occlusion and combined femoropopliteal occlusion. CFA lesion characteristics were also classified according to Azema classification and evaluated whether the CFA lesion satisfied the IC of the endovascular stenting trial with an interwoven stent (vascular mimetic implant [VMI]-CFA trial) [5,9,10]. Each lesion was classified according to the Peripheral Academic Research Consortium (PARC) calcium classification system and graded as focal, mild, moderate, or severe [11].

Perioperative complications were classified as local/nonvascular, local/vascular, or systemic/remote and graded according to the recommended standards for reports managing lower-extremity ischemia [12]. During the follow-up period, we recorded any reinterventions of the index limb, amputations above the ankle, and restenosis of the target lesion irrespective of reintervention (RAS), and analyzed primary patency (PP) and secondary patency.

### 2) Operative details and follow-up protocol

The IFEA was performed according to standard techniques. After anesthesia, a longitudinal incision was made in the groin of the affected limb and the CFA was dissected. If the lesion extended proximally to the external iliac artery (EIA) or distally to the superficial (SFA) and deep femoral artery (DFA) beyond the CFA, the dissection was extended to EIA at the retroperitoneal space or SFA or DFA up to where the lesion was not severe. Intravenous heparin sodium (50-100 IU/kg) was administered after the arterial dissection, followed by a longitudinal arteriotomy according to the lesion extent. Subsequently, an endarterectomy was performed of the occluded plaque using an adequate cleavage plane. Extraction endarterectomy without inspection was not performed in the distal EIA and SFA. Tacking sutures were placed of the endarterectomized artery were placed at the distal end of the endarterectomy site to avoid plaque lifting and dissection. Proximal tacking sutures were not routinely placed. After the endarterectomy, the luminal surface was carefully inspected for debris-free surface area, and a patch angioplasty was routinely performed. The most commonly used patch was the bovine pericardial patch (Vascu-Guard; Synovis Surgical Innovations, St. Paul, MN, USA) (n=41 limbs). For the remaining 4 limbs, a polytetrafluoroethylene patch (W.L. Gore & Associates, Flagstaff, AZ, USA) was used.

In patients with proximal DFA disease, a profundaplasty was performed according to the surgeon's decision. In patients with concomitant femoropopliteal occlusive disease, especially long-segment proximal SFA occlusion, who did not require revascularization in this area, an arteriotomy and patch angioplasty were performed toward the DFA after the endarterectomy.

The usual postoperative follow-up protocol was as follows: 1) follow-up ankle-brachial index (ABI) before discharge; 2) duplex ultrasonography (DUS) and ABI at 1 month; 3) clinical follow-up at 3 months; 4) ABI follow-up at 6 months; 5) DUS and ABI at 1 year; and 6) annual DUS and ABI. In each follow-up period, a physical examination was performed and the presence of sustained symptom improvement was checked; if symptoms worsened or ABI value decreased by more than 0.15, additional DUS or computed tomography was performed. The same evaluation protocol was applied to patients who returned to the hospital with symptoms before the scheduled follow-up, with additional procedures for correction if needed. Typical postoperative medications were aspirin (100 mg/day) and statins. In the case of existing dual antiplatelet therapy or anticoagulants for another reason, those medications were maintained.

### 3) Outcomes of interest and definitions

Primary efficacy outcome was IFEA patency. An additional analysis of the PP of the IFEA site was performed based on the IC of the VMI-CFA trial. Primary safety outcome was 30-day morbidity and mortality rates. Morbidity was classified as grade 1, 2, or 3 according to the recommended standards for lower-extremity ischemia. The secondary outcome was RAS-free survival and the risk factors were analyzed.

PP was defined as uninterrupted patency of the IFEA site without occlusion, a peak systolic velocity ratio  $>2.5$ , and any reintervention, including both surgical and endovascular procedures. Secondary patency was defined as IFEA patency after occlusion following a successful endovascular or surgical procedure. The IC for the VMI-CFA trial were as follows: 1) Azema type 2 or 3 class lesions except type 1 lesion extending to the distal EIA; 2) a lesion localized between the origin of the circumflex iliac artery and the proximal (1 cm) SFA; 3) patent SFA and popliteal arteries; and 4) a patent DFA. Reintervention was defined as surgical and endovascular reinterventions of the index limb. Amputation was defined as amputation above the ankle. Stenosis was defined as restenosis or occlusion of the target lesion irrespective of reintervention; the criteria for restenosis were the same as the velocity criteria for patency.

### 4) Statistical analysis

Student t-test or the Mann-Whitney U-test was performed after the normality test, while the chi-squared test (for adequate-sized samples) or Fisher exact test (for smaller samples) was performed of categorical variables. Kaplan-Meier plots were used to assess the PP and RAS-free survival rates, while the log-rank test was used to determine the statistical significance of the differences between the survival curves. A Cox regression analysis was performed to identify independent risk factors for RAS-free survival. All statistical results were analyzed using IBM SPSS statistics (v. 20.0; IBM Corp., Armonk, NY, USA), and significance was assumed at values of  $P < 0.05$ .

## RESULTS

### 1) Patient and lesion characteristics

During the study period, 45 IFEA procedures were performed in 43 patients (mean age, 70 years; male, 91%). Treatment was indicated by disabling claudication in 30 (67%) limbs and chronic limb-threatening ischemia (CLTI) in 15 limbs (rest pain in 8 limbs, minor tissue loss [toe ulcer in 5; toe gangrene in 1] in 6 limbs, and ulceration of stump after transmetatarsal amputation in 1 limb). Patient characteristics according to operative indications are summarized in Table 1. Among comorbidities, the frequency of renal insufficiency (glomerular filtration rate  $<60$  mL/min/1.73 m<sup>2</sup>) and requirement for dialysis was higher among patients with CLTI than in claudicants.

The lesion characteristics are summarized in Table 2. Among the CFA lesions, total occlusion was noted in 27 limbs (60%) and combined femoropopliteal occlusion in 6 limbs (13%). Azema class 3 lesions (located at the CFA and its bifurcation) occurred in 31 limbs (69%) versus Azema class 2 lesions (limited to the CFA) in 10 limbs (22%). Among the lesion calcification grades according to the PARC calcium classification, severe calcification was the most frequent (40% of the total limbs) in the claudication and CLTI groups.

A total of 21 CFA lesions (47%) did not meet the IC of the VMI-CFA trial, a significantly higher proportion of the CLTI group than the claudication group (93% vs. 23%,  $P < 0.001$ ). Among the 21 limbs that did not meet the IC, lesions extending to more than 1 cm of the proximal SFA were the most common reason in 14 limbs (67%), followed by combined femoropopliteal occlusion in 6 limbs (29%), lesion extending to the distal EIA over the CIA in 4 limbs (19%), and occlusion of the DFA in 1 limb. Four limbs had multiple lesions that did not meet the IC.

**Table 1.** Patient characteristics

	Total (n=45)	Claudication (n=30)	CLTI (n=15)	P-value
Sex, male	41 (91)	27 (90)	14 (93)	>0.999
Age (y)	69.9±8.8	70.1±9.4	69.5±7.6	0.823
Previous ipsilateral revascularization	4 (9)	2 (7)	2 (13)	0.591
Hypertension	35 (78)	22 (73)	13 (87)	0.456
Diabetes mellitus	20 (44)	14 (47)	6 (40)	0.671
Coronary artery disease	20 (44)	13 (43)	7 (47)	0.832
Congestive heart failure	3 (7)	1 (3)	2 (13)	0.254
Arrhythmia	8 (18)	6 (20)	2 (13)	0.699
Cerebrovascular disease	15 (33)	10 (33)	5 (33)	>0.999
Chronic obstructive lung disease	7 (16)	5 (17)	2 (13)	>0.999
Renal insufficiency <sup>a</sup>	13 (29)	5 (17)	8 (53)	0.016*
Dialysis	4 (9)	0 (0)	4 (27)	0.009*
eGFR	74.0±31.4	81.2±23.6	59.6±40.1	0.056
Dyslipidemia	23 (51)	17 (57)	6 (40)	0.292

Data are presented as mean±standard deviation or number (%).

CLTI, chronic limb-threatening ischemia; eGFR, estimated glomerular filtration rate.

<sup>a</sup>eGFR<60 mL/min/1.73 m<sup>2</sup>.

\*Statistically significant P<0.05.

**Table 2.** Lesion characteristics

	Total (n=45)	Claudication (n=30)	CLTI (n=15)	P-value
CFA occlusion	27 (60)	17 (57)	10 (67)	0.519
Femoropopliteal occlusion	6 (13)	2 (7)	4 (27)	0.157
Azema classification				0.187
1	4 (9)	2 (7)	2 (13)	
2	10 (22)	9 (30)	1 (7)	
3	31 (69)	19 (63)	12 (80)	
4	0	0	0	
VMI-CFA inclusion	24 (53)	23 (77)	1 (7)	<0.001*
PARC calcium classification				0.475
Focal	9 (20)	4 (13)	5 (33)	
Mild	7 (16)	5 (17)	2 (13)	
Moderate	11 (24)	8 (27)	3 (20)	
Severe	18 (40)	13 (43)	5 (33)	

Data are presented as number (%).

CLTI, chronic limb-threatening ischemia; CFA, common femoral artery; VMI, vascular mimetic implant; PARC, Peripheral Academic Research Consortium.

\*Statistically significant P<0.05.

## 2) Perioperative complications

The perioperative complications are summarized in Table 3. There were no cases of in-hospital or early mortality. Local/nonvascular wound complications occurred in 10 (22%) limbs (hematoma in 3, lymphocele in 5, and wound infection in 2). Among them, 8 were grade 1 and resolved spontaneously with conservative treatment. One patient

required 3 sessions of aspiration due to lymphocele and another patient underwent drainage of the femoral wound due to infection and delayed closure after wound dressing. These 2 complications were grade 2 local/nonvascular complications.

No local/vascular complications occurred in the perioperative period. Regarding systemic complications, 3 systemic complications occurred; all were myocardial infarctions. In

2 patients, there was no hemodynamic consequence, which resolved with conservative treatment; 1 patient underwent percutaneous coronary intervention with stent insertion at 6 days after the index operation.

**Table 3.** Early complications after isolated endarterectomy and patch angioplasty of common femoral artery

	No. of limbs (n=45)
Local/nonvascular	10 (22)
Hematoma	3
Grade 1	3
Grade 2	0
Lymphocele	5
Grade 1	4
Grade 2	1
Wound infection	2
Grade 1	1
Grade 2	1
Local/vascular	0 (0)
Systemic/remote	3 (7)
Cardiac (myocardial infarction)	3
Grade 1	2
Grade 2	1

Data are presented as number (%) or number only.

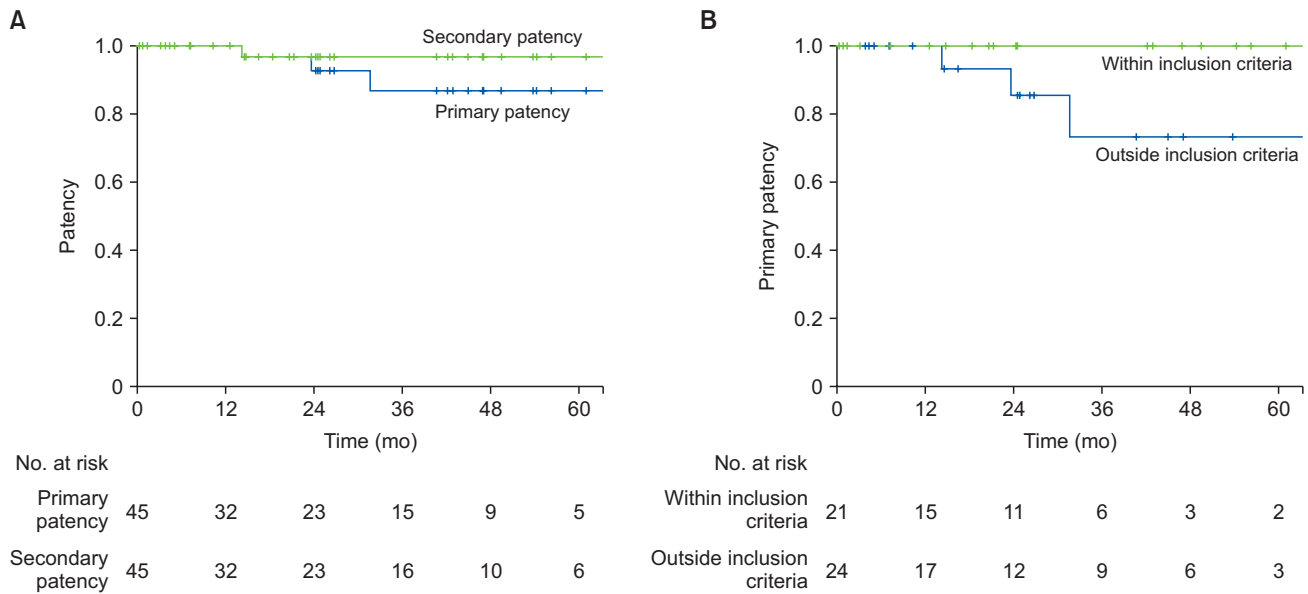
3) Patency rate

The mean radiological follow-up duration was 27.9 months. During the follow-up period, 2 balloon angioplasties of the IFEA site due to stenosis and 1 occlusion of the IFEA without further treatment were occurred. The overall primary and secondary patency rates were 100% and 100% at 1 year and 87% and 97% at 3 years, respectively (Fig. 1A).

An additional analysis according to the VMI-CFA IC demonstrated that the PP of lesions meeting the criteria was 100% at 1 and 3 years, while the patency of lesions that did not meet the criteria was 100% at 1 year and 73% at 3 years (P=0.068; Fig. 1B). All 3 PP loss events occurred in lesions that did not meet the IC of the VMI-CFA trial. There were no statistically significant differences in PP according to Azema classification (Azema classification 1/2 vs. 3, P=0.734), lesion calcification (PARC classification 1/2 vs. 3/4, P=0.396), or CFA occlusion (stenosis vs. occlusion, P=0.184).

4) RAS-free survival and RAS risk factors

The mean clinical follow-up duration was 37.6 months. During the follow-up period, 5 reinterventions, 2 amputations, and 1 IFEA occlusion without further treatment were noted in 7 patients. The detailed RAS events during follow-up are summarized in Table 4. The overall RAS-free survival rates were 91%, 85%, and 81% at 1, 2, and 3 years,



**Fig. 1.** Patency after isolated endarterectomy and patch angioplasty of the common femoral artery (CFA). (A) Overall primary and secondary patency. (B) Primary patency according to the inclusion criteria of the vascular mimetic implant-CFA trial.

respectively (Fig. 2A).

The risk factors for RAS-free survival after the univariate and multivariate analyses are summarized in Table 5. On univariate analysis, CLTI ( $P=0.034$ ), renal insufficiency ( $P=0.014$ ), and dialysis ( $P=0.001$ ) were clinical factors associated with poor RAS-free survival. Among the anatomic factors, lesions that did not meet the VMI-CFA IC showed poor RAS-free survival ( $P=0.004$ ), and all RAS events occurred in lesions that did not meet the criteria. The multivariable analysis showed that statistical significance was present only in patients undergoing dialysis (adjusted odds ratio, 8.56; 95% confidence interval, 1.9-35.5;  $P=0.005$ ; Table 5, Fig. 2B).

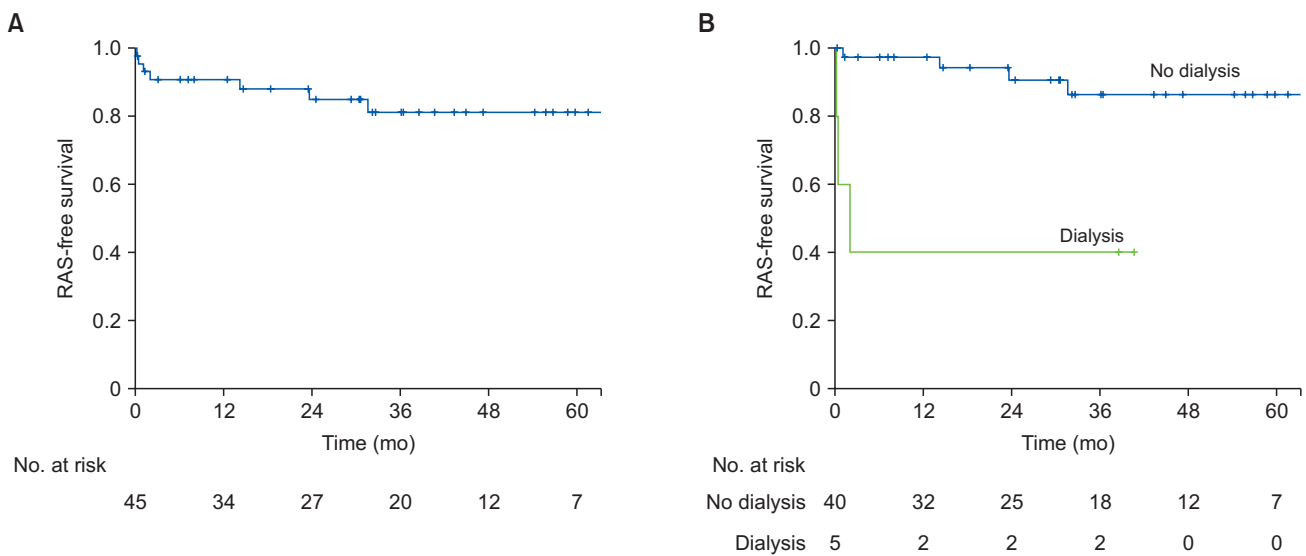
## DISCUSSION

The current study of the real-world presentation of CFA disease showed that nearly half of the lesions in this study did not meet the IC for the recent VMI-CFA trial [10]. In addition, the follow-up results of PP demonstrated a different tendency depending on whether the lesion met the IC. IFEA for lesions within the IC demonstrated highly effective and durable results with 100% PP at 1 and 3 years. None of the patency loss events that occurred in lesions met the IC, and all RAS events showed the same results. Therefore, interpretations of the results of recent VMI-CFA trials for atherosclerotic CFA disease should be made cautiously and not generalized to the real-world presentation of such lesions.

**Table 4.** Reintervention and amputation of index limb, and stenosis during follow-up

Patient	Category	Cause	Interval (mo)	Method	Procedure
1	Reintervention	Patch stenosis FP occlusion	31	Endo	Balloon angioplasty (patch) Atherectomy with DCB (FP)
2	Reintervention	Sustained symptom	1	Open	Femoropopliteal bypass
3	Amputation		2		BK amputation
4	Reintervention	BTK occlusion	1	Endo	Balloon angioplasty (BTK)
	Amputation		3		BK amputation
5	Reintervention	BTK occlusion	1	Endo	Balloon angioplasty (BTK)
6	Reintervention	Patch stenosis Iliac and FP stenosis	23	Endo	Iliac stent Balloon angioplasty (patch, FP)
7	Stenosis	Patch occlusion	14	No Tx	Conservative

DCB, drug-coated balloon; FP, femoropopliteal; BK, below-knee; BTK, below the knee; Tx, treatment.



**Fig. 2.** Any reintervention of the index limb, amputation above the ankle, or stenosis (RAS)-free survival after isolated endarterectomy and patch angioplasty of common femoral artery. (A) Overall RAS-free survival. (B) RAS-free survival according to dialysis status.



**Table 5.** Risk factors for RAS-free survival after univariable and multivariable analysis

	With RAS (n=7)	Without RAS (n=38)	Univariable analysis P-value <sup>a</sup>	Multivariable analysis	
				aOR (95% CI)	P-value
Sex, male	7 (100)	34 (89)	0.406		
Age (y)	70.1±4.5	69.8±9.4	0.877		
CLTI	5 (71)	10 (26)	0.034*	2.14 (0.3-15.9)	0.319
Previous ipsilateral revascularization	1 (14)	3 (8)	0.665		
Hypertension	6 (86)	29 (76)	0.469		
Diabetes mellitus	4 (57)	16 (42)	0.556		
Coronary artery disease	4 (57)	16 (42)	0.569		
Congestive heart failure	0 (0)	3 (8)	0.411		
Cerebrovascular disease	4 (57)	11 (29)	0.206		
COPD	1 (14)	6 (16)	0.986		
Renal insufficiency	5 (71)	8 (21)	0.014*	2.90 (0.4-21.1)	0.198
Dialysis	3 (43)	2 (5)	0.001*	8.56 (1.9-35.5)	0.005*
Dyslipidemia	2 (29)	21 (55)	0.234		
CFA occlusion	3 (43)	24 (63)	0.302		
Femoropopliteal occlusion	2 (29)	4 (11)	0.267		
Azema class 3	5 (71)	26 (68)	0.948		
PARC severe calcification	2 (29)	16 (42)	0.688		
Profundaplasty	1 (14)	9 (24)	0.551		
VMI-CFA exclusion	7 (100)	14 (37)	0.004*	3.94 (0.3-49.3)	0.152

Data are presented as number (%) or mean±standard deviation.

RAS, reintervention of the index limb, amputation above the ankle, or stenosis; aOR, adjusted odds ratio; CI, confidence interval; CLTI, chronic limb-threatening ischemia; COPD, chronic obstructive lung disease; CFA, common femoral artery; PARC, Peripheral Academic Research Consortium; VMI, vascular mimetic implant.

<sup>a</sup>Log-Rank test for RAS-free survival.

\*Statistically significant P<0.05.

With recent advancements in endovascular devices and techniques, some advocates for the endovascular treatment of atherosclerotic CFA disease have reported acceptable outcomes, including PP, and no longer consider CFA disease a no-endovascular or no-stent zone [5,8,9]. However, to delineate the concerns about long-term durability after endovascular treatment of CFA lesions, randomized controlled trials with similar lesion characteristics are indispensable. To date, only 2 randomized controlled trials have compared the effectiveness and complications of endovascular and surgical treatments for CFA occlusive lesions; however, their results are inconsistent and divergent. The TECCO trial [8] compared endovascular stenting with the last generation of self-expandable stents versus surgical endarterectomy for 117 CFA lesions. The results demonstrated lower perioperative morbidity and mortality rates in the endovascular stenting group as well as no intergroup differences in sustained clinical improvement, PP, and target lesion and extremity revascularization rates at 24 months. Therefore, the investigators in this study concluded that the endovascular treatment of CFA is an alternative to surgery, while further

endovascular options should be assessed for CFA atherosclerotic lesions.

Another study compared bioabsorbable stents with surgical endarterectomy in 80 CFA lesions [7]. The clinical and hemodynamic results, including ABI change, limb salvage, and overall survival rates, were comparable between groups. However, unlike previous studies, this study demonstrated that an increased rate of repeat procedures in the endovascular stenting group outweighed the lower surgical site infection rate versus the surgical endarterectomy group. In addition, short-term patency rates were significantly worse among patients who underwent stenting than among those who underwent endarterectomy. Hence, a clear consensus is lacking regarding the optimal treatment for CFA disease, such as surgical or endovascular methods, and it remains unclear and controversial.

To date, conventional balloon angioplasty and previously described bioabsorbable stents have failed to show promising results in CFA lesions [7,13]. Bonvini et al. [13] reported on the medium-term outcomes of 360 consecutive procedures for CFA disease in which balloon angioplasty

was performed as the primary intervention, and the bail-out stenting rate was significant at 36.9%. At the 1-year follow-up, the restenosis rate >50% by duplex scanning and target lesion revascularization was observed in 27.6% and 19.9% of patients, respectively. Regarding the results of endovascular stenting in CFA disease, Baumann et al. [14] reported that the primary sustained clinical improvement rate was significantly better among patients in whom stents had been implanted subsequent to CFA angioplasty than in those who underwent angioplasty alone. The recent TECCO trial [8] previously demonstrated comparable results after endovascular stenting for CFA disease compared with surgical endarterectomy and criticized the weak radial force of bioabsorbable stents that failed to show promising results.

Based on these results, and with the introduction of new interwoven nitinol biomimetic stents Supera (Abbott Cardiovascular, Santa Clara, CA, USA) characterized by higher radial force and flexibility compared with previous laser-cut nitinol stents, it has been studied and used for the treatment of CFA occlusive disease with the expectation of comparable results to those of surgical endarterectomy. Moreover, since wound complication rates of endovascular treatment are inevitably lower than those of surgical endarterectomy due to the nature of endovascular treatment, endovascular treatment may be a better treatment method if the long-term patency rate is similar between endovascular and surgical treatments. The reported outcomes after Supera interwoven stent placement in VMI-CFA trial were surprising, with PP rates of 95.2% at 1 year and 92.8% at 2 years [15].

However, the study included native CFA lesions localized between the origin of the circumflex iliac artery and the proximal (1 cm) SFA with a patent DFA and good SFA runoff. In addition, patients with tissue loss and lesions in occluded DFA or SFA were excluded from this study. Therefore, those with severe lesions or symptoms were excluded. In fact, 47% of lesions in this study did not meet the IC for the VMI-CFA trial, and the most common cause (67%) was extension into more than 1 cm of the proximal SFA. In addition, as described earlier, the patency of lesions within the IC for the VMI-CFA trial was extremely high with no PP loss during follow-up. Therefore, the VMI-CFA trial should not be considered representative of the real-world setting, and its results should not be interpreted as applicable to patients with commonly encountered CFA disease. Based on the good outcomes of the VMI-CFA trial, the SUPERSURG-RCT trial comparing surgical endarterectomy with endovascular Supera stent placement is ongoing, and its investigators have expanded the IC to lesions localized between 1 cm proximal to the origin of the circumflex iliac artery and the proximal (2 cm) SFA and DFA versus the VMI-CFA trial.

Thus, this head-to-head comparison can clarify the role of the interwoven stent in CFA lesions and allow us to develop complementary strategies with surgery and minimally invasive Supera peripheral stent implantation.

The proponents of endovascular treatment in CFA disease have argued that CFA endarterectomy is not as “benign” a procedure considering its postoperative mortality and morbidity rates including wound-related complications. Nguyen et al. [16] reported a 3.4% mortality rate and 8% wound-related complications rate after CFA endarterectomy in 1,843 patients using the American College of Surgeons National Surgical Quality Improvement Program. However, a recent meta-analysis comparing endovascular and open repair for CFA atherosclerotic disease suggested that perioperative mortality is not in favor of endovascular repair [3]. Although perioperative morbidity showed an advantage for endovascular repair, the long-term PP rate was much higher after open repair [3]. In the present study, no perioperative mortality was reported, and most wound complications were resolved without treatment. In addition, the PP of IFEA did not differ according to the presence of CFA occlusion, Azema classification, or calcification grade, which influences PP after endovascular treatment. Another factor to consider in the VMI-CFA trial's IC is that the guidewire must cross the target lesion prior to enrollment; therefore, the actual intent-to-treat outcomes in this study may differ. Therefore, we believe that IFEA is a safe and durable method for patients with CFA disease and may be particularly useful in cases of the above-mentioned severe lesions.

This retrospective study has some limitations. First, our results were based on a single-center experience with a relatively short follow-up time and small number of patients. Second, this study did not include a nonsurgical control group. To determine the effectiveness of IFEA, the results of endovascular treatments, such as stenting, should also be assessed. However, according to our hospital's policy, endarterectomy should be performed on patients with CFA disease; therefore, the endovascular treatment of CFA lesions is rarely performed. Further prospective studies enrolling a larger number of patients and control groups, such as stenting, are needed to confirm our study findings.

## CONCLUSION

A significant proportion of CFA diseases did not meet the IC for the recent VMI-CFA trial. In addition, the PP of lesions within the IC tended to indicate good patency. Therefore, interpretations of the results of recent VMI-CFA trials for atherosclerotic CFA disease should be made cautiously and cannot be generalized to real-world presentations of such lesions. IFEA is a low-risk durable procedure;



however, dialysis negatively affected RAS-free survival after IFEA, warranting careful follow-up.

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## CONFLICTS OF INTEREST

The authors have nothing to disclose.

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Conception and design: HKK, SH. Analysis and interpretation: SP, DH, WSY, HKK. Data collection: SP, TK, DH, HKK. Writing the article: SP, TK, HKK. Critical revision of the article: WSY, HKK, SH. Final approval of the article: all authors. Statistical analysis: SP, DH, HKK. Overall responsibility: HKK.

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