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INtravaScular OptIcal Frequency Domain ImaGing EvaluaTion of the Femoropopliteal Lesion With JETSTREAM Atherectomy (INSIGHT JETSTREAM)

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ABSTRACT

Background: There have been no prior reports of detailed evaluations using intravascular imaging during Jetstream treatment.

Aims: This study, therefore, aimed to investigate the effects of calcification characteristics and wire bias on lumen gain in Jetstream atherectomy using optical frequency domain imaging (OFDI).

Methods: This study enrolled consecutive patients who underwent OFDI-guided Jetstream atherectomy with 1.85 mm, 2.4 mm blade down (BD), and 2.4 mm blade up (BU). Cross-sections were categorized into three groups based on OFDI findings before Jetstream atherectomy: fibrous plaques (FPs), calcified protrusions (CPs), and eruptive calcified nodules (ECNs).

Results: Twenty-seven patients (36 limbs) were enrolled, and 1502 cross-sections were serially analyzed. There were 186 FPs, 753 CPs, and 563 ECNs. The acquired lumen gain after all atherectomy steps was significantly larger in the ECNs group than in the CPs and FPs groups. ECNs had the strongest effect on the variability in the lumen gain. In the effect of wire bias on the degree of debulking, a significant correlation was observed between wire distance and lumen gain in 1.85- and 2.4-mm BD atherectomy procedures. However, in the 2.4-mm BU procedure, no significant correlation was recorded.

Conclusions: Jetstream atherectomy for ECNs can result in greater lumen gain. In the 1.85- and 2.4-mm BD atherectomy procedures, wire bias may be involved in lumen gain, whereas in the 2.4-mm BU procedure, lumen gain is obtained regardless of wire bias. In Jetstream atherectomy procedures, a detailed assessment using OFDI may contribute to predicting the degree of debulking.

Trial Registration: UMIN ID: UMIN000054588. https://center6.umin.ac.jp/cgi-bin/ctr/ctr_view_reg.cgi?recptno=R000061997.

1 | Introduction

Endovascular treatment (EVT) has recently been considered as a first-line therapy for lower extremity artery disease, especially femoropopliteal (FP) lesions [1]. In EVT procedures, percutaneous transluminal angioplasty has been widely practiced. Among these, drug-coated balloon (DCB) angioplasty has better patency than conventional balloon angioplasty; however, it is insufficient for calcified lesions, which have a higher risk of vessel recoil and restenosis [2–4]. Atherectomy improves clinical outcomes by debulking calcified plaques and modifying vessel compliance. The Jetstream atherectomy system (Boston Scientific, Marlborough, MA, USA) is a rotational atherectomy catheter system that demonstrates a low need for bailout stenting and good patency rates [5, 6]. However, few studies have investigated the effect of Jetstream atherectomy on target calcified lesions. Maehara et al. demonstrated that the Jetstream atherectomy system increased lumen dimensions in moderately or severely calcified FP lesions by removing superficial calcium using intravascular ultrasound (IVUS) assessment [7]. However, there have been no reports on the detailed assessment of differences in Jetstream catheter sizes, calcification characteristics, or the effect of wire bias on lumen gain. Optical frequency domain imaging (OFDI) devices offer high-resolution imaging enabling the more accurate assessments of intravascular findings than IVUS and can provide detailed evaluation of intravascular features in EVT procedures for FP lesions [8]. In the present study, we aimed to assess OFDI in detail during Jetstream atherectomy procedures.

2 | Methods

2.1 | Patient Population

The INtravaScular optIcal frequency domain imaGing evaluaTion of the femoropopliteal lesion with JETSTREAM atherectomy (INSIGHT JETSTREAM) was a retrospective, multicenter, observational study. Consecutive patients who underwent EVT with Jetstream atherectomy system at three institutions (Hyogo Prefectural Awaji Medical Center, Osaka Saiseikai Nakatsu Hospital, and Konan Medical Center) were enrolled. The following patients were included in this study: (1) patients who had undergone OFDI-guided EVT with the Jetstream atherectomy system from May 2023 to June 2024; (2) patients who underwent atherectomy in the order of 1.85-mm, 2.4-mm blade down (BD), and 2.4-mm blade up (BU) catheter sizes; and (3) patients who underwent OFDI at each stage of the Jetstream atherectomy. The following patients were excluded from this study: (1) patients who underwent Jetstream atherectomy in steps other than those described above, (2) patients who could not complete OFDI that should have been performed at each atherectomy step, and (3) patients with insufficient OFDI quality. The study protocol complied with the Declaration of Helsinki and was approved by the Ethics Committee of Hyogo Prefectural Awaji Medical Center. Informed consent was obtained in the form of an opt-out on the website of the Hyogo Prefectural Awaji Medical Center. This study was registered in the University Hospital Medical Information Network Clinical Trial Registry (UMIN ID: UMIN000054588).

2.2 | EVT Procedures

A 7 Fr sheath was inserted into the common femoral artery. After the infusion of 5000 units of unfractionated heparin, the activated clotting time was maintained at > 200 s. After a 0.014-inch guidewire was successfully crossed, OFDI was performed on the lesion. If the OFDI could not pass through the lesions, ballooning at 2.0 mm was performed, followed by an initial OFDI. The use of filters to decrease the risk of distal emboli was dependent on the operator's preference. Subsequently, rotational atherectomy was performed using the Jetstream atherectomy system. The catheter size of the Jetstream was increased from 1.85 to 2.4 mm BD to 2.4 mm BU, in that order. At each atherectomy step, the device was continuously advanced up to 1 mm/s. After all atherectomy steps were completed, DCB angioplasty was performed. Distal emboli was defined in cases

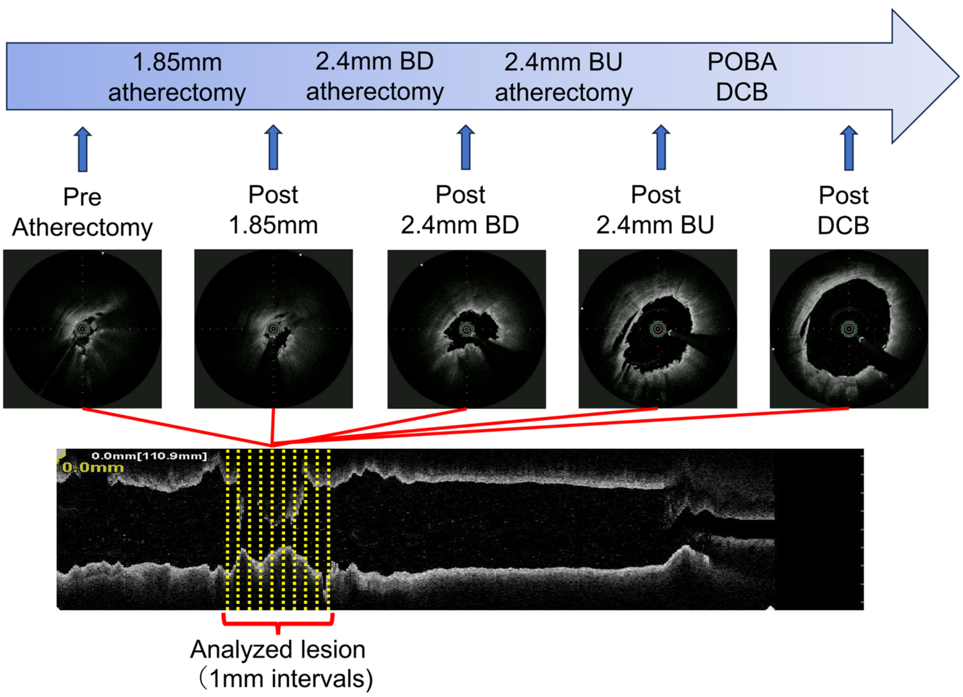

FIGURE 1 | Optical frequency domain imaging analysis. Lesions in which Jetstream atherectomy was performed were evaluated using optical frequency domain imaging. Quantitative and qualitative analyses were performed at 1.0-mm intervals. Serial analysis was performed in the same slice in five stages (pre, post 1.85 mm, post 2.4 mm blade down, post 2.4 mm blade up, and post-drug-coated balloon angioplasty). BD, blade up; BU, blade up; DCB, drug-coated balloon; POBA, plain old balloon angioplasty. [Color figure can be viewed at wileyonlinelibrary.com]

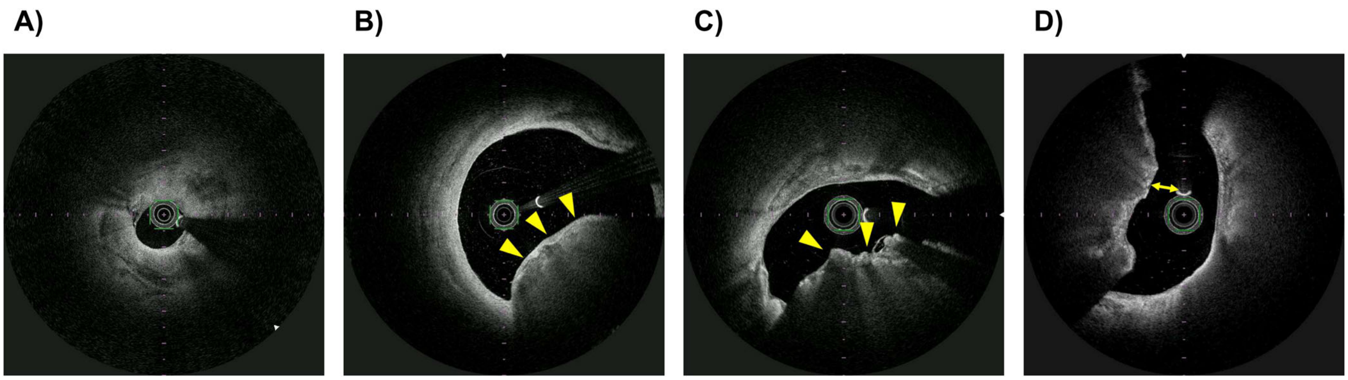

FIGURE 2 | Representative optical frequency domain imaging findings of plaque characteristics. (A) Fibrous plaques (FPs). (B) Calcified protrusion (CPs) characterized by a protruding calcific mass without small eruptive calcific nodules (arrowheads). (C) Eruptive calcified nodules (ECNs) characterized by the expulsion of a cluster of small calcified nodules into the lumen (arrowheads). (D) Wire distance was defined as the distance between the wire and the point of the plaque closest to the wire. [Color figure can be viewed at wileyonlinelibrary.com]

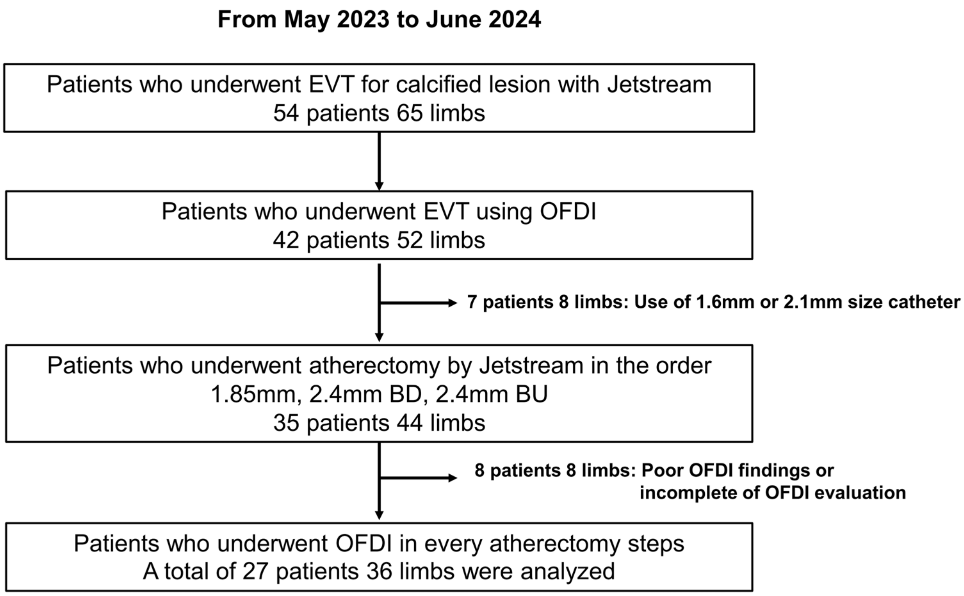

FIGURE 3 | Overview of the patient population.

that required additional treatment, such as aspiration or ballooning, and incidence rates were calculated accordingly.

2.3 | OFDI Image Analysis and Definitions

OFDI examinations were performed using an OFDI system (LUNAWAVE; Terumo Corporation, Tokyo, Japan). Following manual calibration, the OFDI catheter was advanced 5 mm distal to the target lesion over a 0.014-inch guidewire. Following catheter placement, saline solution was flushed through the guiding catheter using a 30- or 50-mL syringe with manual injection and manual compression of the femoral artery at the treatment side to remove blood flow. When a blood-free image was obtained, the OFDI catheter was retracted over a longitudinal distance of up to 150 mm at a rate of 40 mm/s using the standalone electronic control of the motor drive unit. OFDI was performed five times: before atherectomy, after 1.85 mm, after 2.4 mm BD, after 2.4 mm BU, and after DCB treatment. To analyze OFDI findings, offline OFDI analysis was performed using dedicated software (LUNAWAVE Offline Viewer; Terumo Corporation, Tokyo, Japan) by independent observers blinded to the clinical presentations and lesion characteristics of the patients. For qualitative and quantitative analyses, cross-sectional OFDI images were analyzed at 1-mm intervals in the lesion where Jetstream atherectomy was performed (Figure 1). Corresponding images obtained from the serial OFDI examinations were identified using the following landmarks: (1) side-branch location and (2) forms of calcification in the vessel. A general qualitative analysis was performed based on a previous consensus document [9]. For qualitative analysis of pre-EVT OFDI, we classified all cross-sections into three groups: fibrous plaques (FPs), calcified protrusions (CPs), and eruptive calcified nodules (ECNs) (Figure 2). FPs were defined as high backscattering and relatively homogeneous OFDI light signals; CPs were defined as protruding calcific masses with a smooth surface, and ECNs were defined as high-backscattering masses protruding into the lumen with an irregular surface [9, 10]. In the quantitative analysis, distal and proximal reference lumen areas, mean reference lumen areas, lumen areas, % lumen areas, minimum lumen diameters, maximum lumen diameters, mean lumen diameters, wire distance (Figure 2), and lumen

TABLE 1 | Patients characteristics.

Variables	*n* = 27
Age (years)	76.8 ± 9.2
BMI	20.1 ± 8.7
Male, *n* (%)	18 (66.7)
Diabetes, *n* (%)	19 (70.4)
Hypertension, *n* (%)	22 (81.5)
Dyslipidemia, *n* (%)	18 (66.7)
Past smoker, *n* (%)	10 (37.0)
Current smoker, *n* (%)	6 (22.2)
Hemodialysis, *n* (%)	8 (30.8)
CAD history, *n* (%)	19 (70.4)
CVD history, *n* (%)	5 (18.5)
Heart failure, *n* (%)	7 (25.9)
Medication	
Aspirin, *n* (%)	20 (74.1)
Clopidogrel, *n* (%)	15 (55.6)
Prasgurel, *n* (%)	7 (25.9)
Chilostazol, *n* (%)	11 (40.7)
Warfarin, *n* (%)	3 (11.1)
Statin, *n* (%)	18 (66.7)
Blood test	
Albumin (g/dL)	3.60 ± 0.60
Total-C (mg/dL)	149.7 ± 29.5
LDL-C (mg/dL)	82.1 ± 22.8
HDL-C (mg/dL)	54.8 ± 15.7
Triglyceride (mg/dL)	93.3 ± 41.2
HbA1C (%)	6.9 ± 1.2

Note: Values are presented as mean ± SD or absolute numbers (%).
Abbreviations: BMI, body mass index; CAD, coronary artery disease; CVD, cerebral vascular disease.

TABLE 2 | Lesion and procedure characteristics.

Variables	*n* = 36
SFA, *n* (%)	32 (88.9)
Pop A, *n* (%)	4 (11.1)
Approach	
Contralateral, *n* (%)	4 (11.1)
Ipsilateral, *n* (%)	32 (88.9)
Rutherford grade	
3, *n* (%)	19 (52.8)
4, *n* (%)	9 (25.0)
5, *n* (%)	7 (19.4)
6, *n* (%)	1 (2.8)
PACSS calcium score	
Grade 0, *n* (%)	0 (0.0)
Grade 1, *n* (%)	2 (5.6)
Grade 2, *n* (%)	1 (2.8)
Grade 3, *n* (%)	20 (55.6)
Grade 4, *n* (%)	13 (36.1)
Procedures	
Filter use, *n* (%)	20 (55.6)
DCB balloon diameter (mm)	5.6 ± 0.5
Complication	
Distal emboli	4 (11.1)
Unscheduled amputation	0 (0.0)
OFDI information	
Distal reference lumen area (mm^2)	19.51 ± 4.40
Proximal reference lumen area (mm^2)	22.63 ± 6.29
Mean reference lumen area (mm^2)	20.94 ± 4.82
Lesion length (mm)	42.1 ± 26.0

Note: Values are presented as mean ± SD or absolute numbers (%).
Abbreviations: DCB, drug-coated balloon; OFDI, optical frequency domain imaging; Pop A, popliteal artery; SFA, superficial femoral artery.

eccentricity index were manually measured in each cross-sectional OFDI image. The mean reference lumen area was defined as follows: distal reference lumen area+proximal reference area)/2% lumen area, which was defined as lumen area/mean reference area. The lumen eccentricity index was defined as follows: maximum lumen diameter/minimum lumen diameter. The total debulking area was defined as the sum of the acquired lumen gain after all atherectomy steps in the analyzed lesion.

2.4 | Statistical Analyses

All statistical analyses were performed using the SPSS software version 29 (IBM Corp., Armonk, NY, US). All data are presented as means ± standard deviations or proportions. Differences in continuous parameters between the three groups (FPs, CPs, and ECNs) were calculated using one-way analysis of variance. Categorical variables are presented as frequency counts. Linear mixed-effects models were used to explore the influence of different variables on lumen gain and to adjust for covariates. Univariate analysis was first performed, and all variables that satisfied $p < 0.1$ were included in the multivariate model.

3 | Results

3.1 | Patient and Lesion Characteristics

Of the 54 patients (65 limbs) who underwent EVT for calcified lesions with Jetstream from May 2023 to June 2024, 42 (52 limbs) underwent OFDI-guided EVT. Among them, seven patients (eight limbs) using a 1.6- or 2.1-mm-sized catheter and eight (eight limbs) with insufficient OFDI data quality were excluded. Finally, 27 patients (36 limbs) were enrolled in this study (Figure 3). The baseline patient characteristics are summarized in Table 1. All the patients received dual antiplatelet therapy. The lesions and procedural characteristics are shown in Table 2. Nineteen limbs exhibited intermittent claudication,

TABLE 3 | Cross-sectional based OFDI findings.

Variables	Pre	1.85 mm	2.4 mm BD	2.4 mm BU	Post
Characteristics of calcification					
FPs, *n* (%)	186 (12.4)				
CPs, *n* (%)	753 (50.1)				
ECNs, *n* (%)	563 (37.5)				
Lumen area (mm^2)	7.87 ± 5.24	8.77 ± 4.82	11.10 ± 4.70	14.16 ± 5.10	18.14 ± 5.02
% lumen area (%)	39.0 ± 23.4	43.9 ± 21.4	56.0 ± 21.2	71.4 ± 22.5	90.9 ± 18.9
Mean diameter (mm)	2.99 ± 1.16	3.22 ± 0.90	3.70 ± 1.12	4.19 ± 0.77	4.76 ± 0.66
Minimum diameter (mm)	2.24 ± 0.95	2.47 ± 0.83	2.95 ± 0.88	3.48 ± 0.68	4.16 ± 1.00
Maximum diameter (mm)	3.80 ± 1.26	4.05 ± 1.07	4.45 ± 0.96	4.90 ± 0.87	5.44 ± 0.78
Lumen eccentricity index	1.85 ± 0.69	1.75 ± 0.58	1.57 ± 0.40	1.43 ± 0.25	1.33 ± 0.18

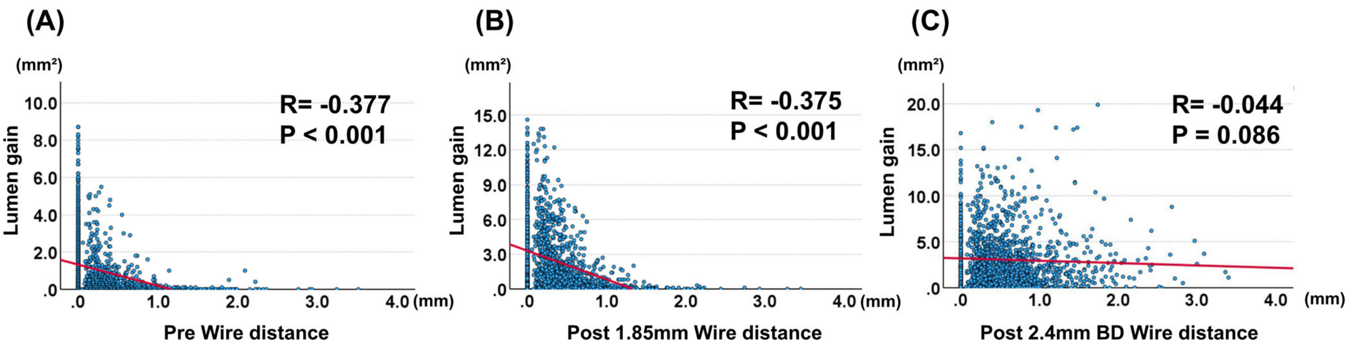

FIGURE 4 | Association between wire distance and lumen gain. (A) Association between pre-atherectomy wire distance and lumen gain after 1.85-mm atherectomy. (B) Association between post-1.85-mm wire distance and lumen gain after 2.4 mm blade down atherectomy. (C) Association between post-2.4-mm BD wire distance and lumen gain after 2.4 mm blade up atherectomy. [Color figure can be viewed at wileyonlinelibrary.com]

nine limbs exhibited rest pain, and eight limbs exhibited chronic limb-threatening ischemia. The mean lesion length was 42.1 ± 26.0 mm, and the mean reference lumen area was 20.94 ± 4.82 mm^2.

3.2 | Cross-Sectional Based OFDI Findings (Whole Over)

Among the 27 patients (36 limbs), 1502 cross-sections were serially analyzed. In the pre-OFDI findings, the numbers of cross-sections in which FPs, CPs, and ECNs were presented were 186, 753, and 563, respectively. For all groups combined, lumen gain became larger with increasing catheter size with Jetstream atherectomy (pre−post 1.85 mm: 0.89 ± 1.45 mm^2, post 1.85 mm−post 2.4 mm BD: 2.34 ± 2.83 mm^2, post 2.4 mm BD−post 2.4 mm BU: 3.05 ± 2.98 mm^2). However, the lumen eccentricity index became smaller with increasing catheter size (pre: 1.85 ± 0.69, post 1.85 mm: 1.75 ± 0.58, post 2.4 mm BD: 1.57 ± 0.40, post 2.4 mm BU: 1.43 ± 0.25) (Table 3). Figure 4 shows the correlation between wire distance and lumen gain in each atherectomy step. In both 1.85- and 2.4-mm BD atherectomy procedures, a significant correlation was found between wire distance and lumen gain ($R = -0.377$, $p < 0.001$; $R = -0.375$, $p < 0.001$, respectively). However, in the 2.4-mm BU procedure, no significant correlation was observed between them.

3.3 | Cross-Sectional-Based OFDI Findings (ECNs vs. CPs vs. FPs)

The ECNs group achieved significantly larger lumen gain compared to the CPs and FPs groups in every atherectomy step (pre−post 1.85 mm: 1.78 ± 1.83 vs. 0.40 ± 0.82 vs. 0.18 ± 0.04 mm^2, $p < 0.001$; post 1.85 mm−post 2.4 mm BD: 4.13 ± 3.11 vs. 1.42 ± 2.09 vs. 0.62 ± 1.27 mm^2, $p < 0.001$; post 2.4 mm BD−post 2.4 mm BU: 4.25 ± 3.41 vs. 2.41 ± 2.36 vs. 2.04 ± 2.68 mm^2, $p < 0.001$). The acquired lumen gain after all atherectomy steps was also significantly larger in the ECNs group compared with the CPs and FPs groups (10.17 ± 5.09 vs. 4.23 ± 3.62 vs. 2.84 ± 3.36 mm^2, $p < 0.001$) (Table 4, Figure 5). In multivariate linear analysis, ECNs had the strongest effect on variability in lumen gain after all atherectomy steps (coefficient β ± standard error = 3.733 ± 0.216, $p < 0.001$) (Table 5).

3.4 | Incidence of Distal Emboli

Distal emboli occurred in four procedures. In all of these cases, filters were not in place. The total lesion length and total debulking area were significantly larger in the procedures with distal emboli (38.7 ± 24.1 vs. 68.8 ± 29.0 mm, $p = 0.027$; 208.7 ± 89.6 vs. 689.7 ± 256.8 mm^2, $p = 0.032$, respectively) (Table 6).

TABLE 4 | Cross-sectional based OFDI findings (ECNs vs. CPs vs. FPs).

Variables	FPs ($n = 186$)	CPs ($n = 753$)	ECNs ($n = 563$)
Pre-atherectomy			
Mean reference lumen area (mm²)	19.86 ± 3.70	20.01 ± 3.67	20.33 ± 5.49
Pre-minimum lumen diameter (mm)	2.95 ± 0.81	2.51 ± 0.87#	2.24 ± 0.95*,†
Pre-maximum lumen diameter (mm)	4.00 ± 0.93	4.11 ± 1.14	3.31 ± 1.36*,†
Pre-lumen eccentricity index	1.41 ± 0.42	1.76 ± 0.63#	2.12 ± 0.73*,†
Pre-lumen area (mm²)	10.04 ± 4.65	9.16 ± 5.10	5.44 ± 4.69*,†
Pre % lumen area (%)	50.6 ± 20.45	45.2 ± 22.2#	26.9 ± 20.5*,†
Pre-wire distance (mm)	0.43 ± 0.56	0.49 ± 0.49	0.22 ± 0.37*,†
Post 1.85 mm			
Post 1.85 mm lumen area (mm²)	10.21 ± 4.64	9.56 ± 4.95	7.22 ± 4.27*,†
Post 1.85 mm % lumen area (%)	51.5 ± 20.3	47.3 ± 21.3#	36.9 ± 19.9*,†
Post 1.85 mm lumen eccentricity index	1.41 ± 0.33	1.74 ± 0.58#	1.88 ± 0.61*,†
1.85 mm wire distance (mm)	0.45 ± 0.55	0.44 ± 0.43	0.29 ± 0.35*,†
Post 2.4 mm BD			
Post 2.4 mm BD lumen area (mm²)	10.83 ± 4.37	10.99 ± 4.84	11.35 ± 4.60
Post 2.4 mm BD % lumen area (%)	55.0 ± 19.6	54.6 ± 20.1	58.2 ± 23.1†
Post 2.4 mm BD lumen eccentricity index	1.41 ± 0.39	1.59 ± 0.43#	1.59 ± 0.35*
Post 2.4 mm BD wire distance (mm)	0.44 ± 0.47	0.54 ± 0.50#	0.58 ± 0.55*
Post 2.4 mm BU			
2.4 mm BU lumen area (mm²)	12.87 ± 4.88	13.39 ± 4.75	15.61 ± 5.30*,†
Post 2.4 mm BU % lumen area (%)	66.1 ± 24.1	67.0 ± 19.1	79.1 ± 24.0*,†
Post 2.4 mm BU lumen eccentricity index	1.35 ± 0.24	1.43 ± 0.25#	1.45 ± 0.25*
Post-DCB			
Post-DCB lumen area (mm²)	19.07 ± 4.65	17.22 ± 4.69#	19.07 ± 5.34†
Post-DCB % lumen area (%)	97.1 ± 20.9	86.0 ± 16.4#	95.4 ± 19.7†
Post-DCB lumen eccentricity index	1.30 ± 0.16	1.33 ± 0.18	1.33 ± 0.18
Lumen gain			
Pre−post 1.85 mm (mm²)	0.18 ± 0.04	0.40 ± 0.82#	1.78 ± 1.83*,†
Post 1.85 mm−post 2.4 mm BD (mm²)	0.62 ± 1.27	1.42 ± 2.09#	4.13 ± 3.11*,†
Post 2.4 mm BD−post 2.4 mm BU (mm²)	2.04 ± 2.68	2.41 ± 2.36	4.25 ± 3.41*,†
Post 2.4 mm BU−post DCB (mm²)	6.19 ± 3.23	3.83 ± 3.04#	3.47 ± 3.30*
Pre−post 2.4 mm BU (mm²)	2.84 ± 3.36	4.23 ± 3.62#	10.17 ± 5.09*,†

Note: Values are presented as mean ± SD.
Abbreviations: BD, blade down; BU, blade up; DCB, drug-coated balloon.
#$p < 0.05$ versus FPs.
*$p < 0.05$ versus FPs.
†$p < 0.05$ versus CPs.

4 | Discussion

The primary findings of this study are as follows: (1) Jetstream atherectomy for ECNs could achieve a significantly larger lumen gain than that for CPs and FPs in every atherectomy step. (2) ECNs independently had the strongest effect on variability in lumen gain after all Jetstream atherectomy steps. (3) In both the 1.85- and 2.4-mm BD atherectomy procedures, there was a significant correlation between wire distance and lumen gain; however, no such correlation was observed in the 2.4-mm BU procedure.

Recently, the use of IVUS has had an effect on long-term outcomes, such as the patency rate in EVT procedures [11]. However, there have been a few reports suggesting the contribution of OFDI in EVT procedures. In coronary artery disease, Kobayashi et al. reported that optical coherence tomography-guided percutaneous coronary intervention with a rotational atherectomy device for calcified lesions obtained larger stent expansion compared with IVUS-guided percutaneous coronary intervention [12]. The resolution range of 10–20 µm, approximately 10 times higher than that of IVUS, allows detailed assessment of calcium characteristics. This

INSIGHT JETSTREAM with detailed OFDI evaluation revealed that the lumen gain obtained by Jetstream atherectomy depends not only on the pretreatment lumen diameter but also on calcium characteristics.

4.1 | Differential Effects of Jetstream Atherectomy in Calcified Characteristics

This study demonstrated that Jetstream atherectomy for ECNs could result in greater lumen gain than that for CPs. ECNs, rather than CPs, are independently associated with a higher major adverse cardiac event rate following percutaneous coronary intervention in patients with calcified plaques [13, 14]. However, the clinical significance of ECNs in FP lesions in patients with lower extremity artery disease remains unclear. Pathological studies have suggested that the eruption of calcified nodules disrupts the endothelium, leading to subsequent thrombus formation [15, 16]. Considering this, the ECNs observed in FP lesions may also contain a soft thrombus component and hard calcifications on the erupted surface, which may lead to a greater response to Jetstream atherectomy. The distinction between ECNs and CPs is possible in IVUS in some cases, although IVUS does not always accurately distinguish ECNs from CPs or clearly visualize the plaque surface due to its limited resolution [17]. OFDI is superior to IVUS in identifying thrombus and intimal destruction in these lesions and may be useful in atherectomy for calcified lesions in EVT.

The ability to predict how the degree of lumen gain is acquired after Jetstream atherectomy may be useful in predicting the effect of treatment and for anticipating distal emboli. In the J-SUPREME II trial with 31 Japanese participants, distal emboli was observed in three (9.4%) patients [18]. Moreover, in real-world reports of adverse events during Jetstream use from the FDA MAUDE database, the most common adverse event was distal emboli (4.4%) [19]. Distal emboli, which sometimes result in major amputation, are considered one of the most critical complications when using Jetstream. Unfortunately, there have been no systematic reports on the lesions and techniques more likely to cause distal emboli. However, when an atherectomy device is used, the risk of distal embolism is expected to increase with debulking. This study showed that Jetstream atherectomy for ECNs could result in a greater lumen gain than for CPs or FPs. Although this indicates that Jetstream is effective for ECNs, it also indicates that more debris is created when atherectomy is performed on ECNs. In fact, in the present study, we found that cases with distal emboli had a larger total debulking area than cases without distal emboli. Therefore, lesions predominantly composed of ECNs should be treated with greater attention to distal emboli, and the use of filters during Jetstream procedures should be considered.

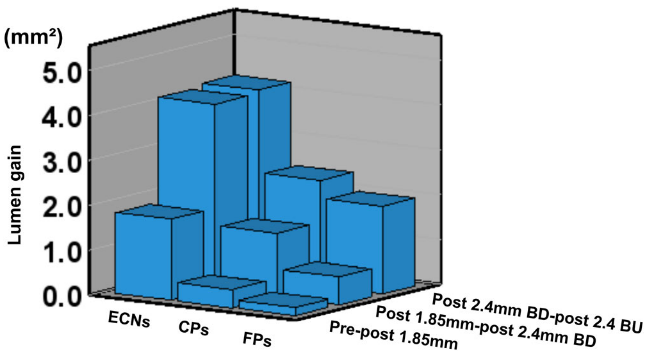

FIGURE 5 | Lumen gain in the three groups (eruptive calcified nodules, calcified protrusions, and fibrous plaques) in each atherectomy step. BD, blade down; BU, blade up; CPs, calcified protrusions; ECNs, eruptive calcified nodules; FPs, fibrous plaques. [Color figure can be viewed at wileyonlinelibrary.com]

4.2 | Effect of Wire Bias in Jetstream Atherectomy

The results of this study showed that wire bias had little effect on the degree of debulking only in the 2.4 mm BU procedure. This may be because BU debulking is different from BD debulking. The Jetstream atherectomy system uses a rotating tip to debulk calcification in the 1.85 and 2.4 mm BD procedures, whereas the 2.4 mm BU procedure uses a blade integrated behind the tip that rotates in the opposite direction. The blade built behind the tip rotates in the direction opposite to the normal rotation, causing the blade to rise, and the five plates protruding from the sides repel calcification. This means that while the BD results in circular cutting, the BU results in cutting by rotating pentagons

TABLE 5 | Linear multivariate analysis of factors related to lumen gain after Jetstream atherectomy (pre-2.4 mm BU).

	Univariate regression				Multivariate regression			
	Coefficients				Coefficients			
Variables	*B*	SE	*β*	*p* value	*B*	SE	*β*	*p* value
Pre-wire distance	−3.350	0.263	−0.313	< 0.001				
Pre-lumen area	−0.497	0.022	−0.512	< 0.001	−0.608	0.059	0.626	< 0.001
Pre % lumen area	−0.130	0.005	−0.598	< 0.001	−0.163	0.013	−0.749	< 0.001
Pre-minimum lumen diameter	−3.286	0.108	−0.617	< 0.001	−1.754	0.259	−0.329	< 0.001
Pre-lumen eccentricity index	2.617	0.178	0.335	< 0.001				
ECNs (0: CPs or FPs, 1: ECNs)	6.211	0.219	0.591	< 0.001	3.733	0.216	0.355	< 0.001

Abbreviations: CPs, calcified protrusions; ECNs, eruptive calcified nodules; FPs, fibrous plaques; SE, standard error.

TABLE 6 | Comparison between distal emboli and non-distal emboli cases.

Variables	Non-distal emboli ($n = 32$)	Distal emboli ($n = 4$)	p value
Lesion			1.00
SFA, n (%)	28 (87.5)	4 (50.0)	
Pop A, n (%)	4 (12.5)	0 (0.0)	
PACSS calcium score			0.31
Grade 1	2 (6.3)	0 (0.0)	
Grade 2	1 (3.1)	0 (0.0)	
Grade 3	16 (50.0)	4 (100.0)	
Grade 4	13 (40.6)	0 (0.0)	
Use of filters, n (%)	20 (62.5)	0 (0.0)	0.031
Mean reference lumen area (mm^2)	20.6 ± 4.8	23.8 ± 4.9	0.22
Lesion length (mm)	38.7 ± 24.1	68.8 ± 29.0	0.027
Total debulking area (mm^2)	208.7 ± 89.6	689.7 ± 256.8	0.032

Note: Values are presented as mean ± SD or absolute numbers (%).
Abbreviations: Pop A, popliteal artery; SFA, superficial femoral artery.

at high speed, and a high possibility exists that the blade will be bounced by calcification during driving, making unpredictable movements difficult. This may explain why the degree of cutting in the 2.4 mm BU procedure does not depend on the wire bias. A 2.4 mm BU may be described as a 3.4 mm size; however, this is not appropriate, and BU atherectomy should be recognized in a different category from BD atherectomy. Overall, it is necessary to understand the difference in the cutting mechanism and consider that it behaves differently from BD.

5 | Limitations

This study had several limitations. First, this was a retrospective study, indicating a potential selection bias. Second, the detailed mechanisms of calcium characteristics in FP lesions remain unclear owing to a lack of histological validation. Third, the Jetstream procedures using 1.6- or 2.1-mm systems were not included in this study because of the small sample size. These systems were excluded to accurately assess vascular characteristics at each atherectomy stage in a stepwise manner; however, additional studies are warranted to determine how vascularity is altered in these systems.

6 | Conclusions

Lumen gain increases with increasing catheter diameter during Jetstream atherectomy. Additionally, Jetstream atherectomy for ECNs can result in greater lumen gain. In both 1.85- and 2.4-mm BD atherectomy procedures, wire bias may be involved in lumen gain, while in the 2.4 mm BU procedure, lumen gain is obtained regardless of wire bias. In Jetstream atherectomy, a detailed assessment using OFDI may contribute to predicting the degree of debulking, considering the characteristics of calcification and wire bias.

Acknowledgments

The authors have nothing to report.

Ethics Statement

The study protocol complied with the Declaration of Helsinki and was approved by the Ethics Committee of Hyogo Prefectural Awaji Medical Center.

Consent

Informed consent was obtained in the form of an opt-out on the website of the Hyogo Prefectural Awaji Medical Center.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Due to the nature of this research, participants of this study did not agree for their data to be shared publicly, so supporting data is not available.

References

1. H. L. Gornik, H. D. Aronow, P. P. Goodney, et al., "2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines," *Circulation* 149 (2024): e1313–e1410.

2. G. Tepe, J. Laird, P. Schneider, et al., "Drug-Coated Balloon Versus Standard Percutaneous Transluminal Angioplasty for the Treatment of Superficial Femoral and Popliteal Peripheral Artery Disease: 12-Month Results From the IN.PACT SFA Randomized Trial," *Circulation* 131 (2015): 495–502.

3. O. Iida, Y. Soga, K. Urasawa, et al., "Drug-Coated Balloon vs Standard Percutaneous Transluminal Angioplasty for the Treatment of Atherosclerotic Lesions in the Superficial Femoral and Proximal Popliteal

Arteries: One-Year Results of the MDT-2113 SFA Japan Randomized Trial," *Journal of Endovascular Therapy* 25 (2018): 109–117.

4. F. Fanelli, A. Cannavale, M. Gazzetti, et al., "Calcium Burden Assessment and Impact on Drug-Eluting Balloons in Peripheral Arterial Disease," *Cardiovascular and Interventional Radiology* 37 (2014): 898–907.

5. G. T. Taneva, A. G. Pitoulias, K. Avranas, et al., "Midterm Outcomes of Rotational Atherectomy-Assisted Endovascular Treatment of Severe Peripheral Arterial Disease," *Journal of Vascular Surgery* 79 (2024): 887–892.

6. T. Zeller, H. Krankenberg, H. Steinkamp, et al., "One-Year Outcome of Percutaneous Rotational Atherectomy With Aspiration in Infrainguinal Peripheral Arterial Occlusive Disease: The Multicenter Pathway PVD Trial," *Journal of Endovascular Therapy* 16 (2009): 653–662.

7. A. Maehara, G. S. Mintz, T. M. Shimshak, et al., "Intravascular Ultrasound Evaluation of JETSTREAM Atherectomy Removal of Superficial Calcium in Peripheral Arteries," *EuroIntervention* 11 (2015): 96–103.

8. H. Otake, T. Kubo, H. Takahashi, et al., "Optical Frequency Domain Imaging Versus Intravascular Ultrasound in Percutaneous Coronary Intervention (OPINION Trial)," *JACC: Cardiovascular Imaging* 11 (2018): 111–123.

9. M. Fujihara, N. Kurata, Y. Yazu, et al., "Clinical Expert Consensus Document on Standards for Lower Extremity Artery Disease of Imaging Modality From the Japan Endovascular Treatment Conference," *Cardiovascular Intervention and Therapeutics* 37 (2022): 597–612.

10. Z. A. Ali, K. Karimi Galougahi, A. Maehara, et al., "Intracoronary Optical Coherence Tomography 2018," *JACC: Cardiovascular Interventions* 10 (2017): 2473–2487.

11. R. B. Allan, P. J. Puckridge, J. I. Spark, and C. L. Delaney, "The Impact of Intravascular Ultrasound on Femoropopliteal Artery Endovascular Interventions," *JACC: Cardiovascular Interventions* 15 (2022): 536–546.

12. N. Kobayashi, Y. Ito, M. Yamawaki, et al., "Optical Coherence Tomography-Guided Versus Intravascular Ultrasound-Guided Rotational Atherectomy in Patients With Calcified Coronary Lesions," *EuroIntervention* 16 (2020): e313–e321.

13. S. Iwai, M. Watanabe, A. Okamura, et al., "Prognostic Impact of Calcified Plaque Morphology After Drug Eluting Stent Implantation: An Optical Coherence Tomography Study," *Circulation Journal* 85 (2021): 2019–2028.

14. T. Hamana, H. Kawamori, T. Toba, et al., "Predictors of Target Lesion Revascularisation After Drug-Eluting Stent Implantation for Calcified Nodules: An Optical Coherence Tomography Study," *EuroIntervention* 19 (2023): e123–e133.

15. R. Virmani, A. P. Burke, A. Farb, and F. D. Kolodgie, "Pathology of the Vulnerable Plaque," *Journal of the American College of Cardiology* 47 (2006): C13–C18.

16. K. Yahagi, F. D. Kolodgie, F. Otsuka, et al., "Pathophysiology of Native Coronary, Vein Graft, and In-Stent Atherosclerosis," *Nature Reviews Cardiology* 13 (2016): 79–98.

17. T. Sugiyama, E. Yamamoto, F. Fracassi, et al., "Calcified Plaques in Patients With Acute Coronary Syndromes," *JACC: Cardiovascular Interventions* 12 (2019): 531–540.

18. O. Iida, K. Urasawa, Y. Shibata, et al., "Clinical Safety and Efficacy of Rotational Atherectomy in Japanese Patients With Peripheral Arterial Disease Presenting Femoropopliteal Lesions: The J-SUPREME and J-SUPREME II Trials," *Journal of Endovascular Therapy* 29 (2022): 240–247.

19. A. Min, F. Alkhalifa, A. Ahrari, et al., "Insights From the FDA's MAUDE Database Regarding the Real-World Safety of Jetstream Atherectomy for Peripheral Arterial Disease," *Journal of Endovascular Therapy* (2023): 15266028231202718, https://doi.org/10.1177/15266028231202718.