Publishing license number: 19/GP-BVHTTDL issued by the Ministry of Culture, Sports and Tourism on April 17, 2025.

ENDOVASCULAR DRUG-ELUTING STENT PLACEMENT FOR SUPERFICIAL FEMORAL ARTERY OCCLUSIVE DISEASE: MIDTERM OUTCOMES AT A SINGLE CENTRE

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ABSTRACT

Background: The Eluvia drug-eluting stent (DES; Boston Scientific), a paclitaxel-eluting nitinol stent with a sustained-release fluoropolymer coating, has demonstrated superior restenosis inhibition compared with bare-metal stents for superficial femoral artery (SFA) disease. Systematic data on midterm outcomes in the Vietnamese clinical setting remain limited.

Objective: To describe the clinical characteristics, lesion morphology, procedural parameters, and midterm outcomes (12- and 24-month Kaplan-Meier estimates) of Eluvia DES implantation for SFA occlusive disease at University Medical Center Ho Chi Minh City (UMC HCMC).

Patients and methods: Retrospective single-arm descriptive study analysing 71 consecutive patients who underwent Eluvia stent implantation between January 2021 and January 2024. Patency and survival rates were estimated using the Kaplan-Meier method.

Results: Mean age was 72.1 ± 9.4 years; 73.2% were male; mean BMI was 21.3 ± 2.9 kg/m². Comorbidities included diabetes mellitus (63.4%), hypertension (73.2%), and smoking (97.2%); 39.4% had chronic limb-threatening ischaemia (CLTI). Chronic total occlusion (CTO) accounted for 47.9% of lesions; mean DSA lesion length was 177 ± 98 mm; mean total stent length was 202.4 ± 46.7 mm (2.1 ± 0.8 stents/patient). Rutherford IV predominated (54.9%). Technical success was 100% by SVS criteria. Kaplan-Meier estimates at 12 and 24 months were: primary patency 90.1% and 73.2%; overall survival 94.3% and 84.5%; and freedom from clinically driven target lesion revascularisation (CD-TLR) 91.5% and 78.8%, respectively. ABI improved from 0.43 ± 0.18 to 0.83 ± 0.14 ($p<0.001$).

Conclusion: Eluvia DES implantation for SFA occlusive disease is feasible with encouraging initial results at a Vietnamese tertiary cardiovascular centre. The single-arm retrospective design precludes comparative conclusions; prospective controlled studies are warranted.

Keywords: *Paclitaxel-eluting stent; superficial femoral artery; peripheral artery disease; chronic limb-threatening ischaemia; endovascular intervention.*

1. INTRODUCTION

Peripheral artery disease (PAD) affecting the superficial femoral artery (SFA) is a leading cause of claudication and chronic limb-threatening ischaemia (CLTI) in adults. The SFA is particularly vulnerable to restenosis given its length, repeated flexion-extension stress during ambulation, and propensity for long-segment occlusion in chronic disease.

Balloon angioplasty (PTA) alone yields 12-month patency rates of only 40–60% [1]. Bare-metal nitinol stents improve short-term results (12-month patency ~70–75%) but carry substantial restenosis rates at two to three years [2,3]. The ZILVER PTX trial [4,5] demonstrated that DES was superior to both PTA and bare-metal stents, with 5-year primary patency of 66.4%. The Eluvia stent, designed with a sustained-release fluoropolymer matrix for controlled paclitaxel delivery, has shown non-inferior or superior outcomes compared with Zilver PTX in the IMPERIAL trial [6,7,8]. However, systematic data on Eluvia DES outcomes in the Vietnamese clinical context have not been published. Real-world practice in Vietnam differs substantially from Western registries in several important respects: patients typically present at more advanced disease stages, body habitus differs markedly (mean BMI approximately 21 kg/m² versus 26–28 kg/m² in European cohorts), cardiovascular risk factor profiles are distinct, and access to endovascular technology has expanded rapidly over the past decade. Reporting local outcomes is therefore not merely a geographic exercise but addresses a genuine evidence gap, providing Vietnamese clinicians with context-specific data to inform patient selection and device utilisation. This study aims to describe the clinical characteristics, procedural parameters, and midterm outcomes of Eluvia DES implantation for SFA occlusive disease at UMC HCMC, establishing a foundational local reference for this technology.

2. PATIENTS AND METHODS

2.1. Study design

Retrospective single-arm descriptive study of a consecutive case series at the Department of Thoracic and Vascular Surgery, University Medical Center Ho Chi Minh City, from January 2021 to January 2024. Given the single-arm design without a control group, results cannot support conclusions regarding the comparative superiority of Eluvia DES over bare-metal stents or PTA. The study was approved by the Institutional Review Board of UMC HCMC (113/HĐĐĐ-ĐHYD, 25/01/2022); individual informed consent was waived due to the retrospective design.

2.2. Eligibility criteria

Inclusion criteria: Age ≥ 18 years; SFA stenosis ≥ 50% or complete occlusion confirmed on DSA; Rutherford classification ≥ III or haemodynamically significant lesion; Eluvia stent implantation performed during the study period at UMC HCMC.

Exclusion criteria: Open surgical bypass alone; below-the-knee intervention without SFA intervention; insufficient medical records.

TASC II classification for femoro-popliteal lesions was not systematically collected during the retrospective period, as this variable was not routinely coded in DSA records.

2.3. Procedural technique

All procedures were performed in a dedicated DSA suite via antegrade common femoral artery

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***Received:** 27/05/2026 **Revised:** 16/06/2026*
***Accepted:** 25/06/2026*
***DOI:** 10.47972/vjcts.v56i.1791*

access using the Seldinger technique (100%). All 71 patients (100%) underwent pre-dilation before stenting; 45 patients (63.4%) underwent post-dilation at the operator's discretion. A mean of 2.1 ± 0.8 stents per patient were deployed over a total stent length of 202.4 ± 46.7 mm, with full lesion coverage and ≥ 5 mm margins. Technical success was defined per SVS criteria: residual stenosis < 30%, no flow-limiting dissection, and antegrade flow confirmed on completion DSA. Dual anti-platelet therapy (aspirin 100 mg + clopidogrel 75 mg) was prescribed for a minimum of 6 months.

2.4. Variable definitions and outcome measures

Lesion length: measured on pre-intervention DSA (mm). CLTI: tissue loss/ischaemic ulceration/foot infection per GVG 2019 [6]. ISR: ≥ 50% diameter stenosis within the stent lumen. CD-TLR: re-intervention at the stent site when (1) ≥ 50% stenosis detected by Doppler ultrasound (PSV ratio > 2.4) or angiography, and (2) clinical worsening (Rutherford class increase ≥ 1 or ABI decrease ≥0.15). Primary patency: freedom from CD-TLR and complete stent occlusion on follow-up Doppler. Secondary patency: maintained flow after any re-intervention.

2.5. Follow-up

Patients were assessed at 1, 6, and 12 months, with additional assessment at 24 months where follow-up duration permitted. Each visit included Rutherford classification, ABI measurement, and Doppler ultrasound. Given the retrospective design and variable follow-up duration, not all patients had completed the full observation window at the time of analysis. Of the 71 enrolled patients, 59 had evaluable follow-up data at 12 months and 38 at 24 months; the remainder were censored at their last known follow-up date. Follow-up completeness at 12 months was 83.1%. Patency and survival rates were therefore estimated using the Kaplan-Meier method to account for censored observations and variable follow-up lengths.

2.6. Statistical analysis

Normally distributed continuous variables are expressed as mean ± SD; non-normal variables as median (IQR); categorical variables as frequency and percentage. Patency and survival rates were estimated by Kaplan-Meier analysis. Statistical significance was set at $p < 0.05$ (two-tailed). STATA 14.0 was used for all analyses.

3. RESULTS

3.1. Baseline characteristics

A total of 71 patients underwent Eluvia stent implantation over 52 months. Mean age was 72.1 ± 9.4 years (range 52–96); 73.2% were male. Mean BMI was 21.3 ± 2.9 kg/m²; 14.1% were underweight (BMI < 18.5). Comorbidity burden was substantial: diabetes mellitus 63.4%, hypertension 73.2%, chronic kidney disease 31.0%, and smoking 97.2%, reflecting the high cardiovascular risk profile typical of a tertiary PAD referral population. CLTI with tissue loss or infection was present in 28 patients (39.4%) (Table 1).

Table 1. Baseline patient characteristics

Characteristic		UMC (n = 71)
Age (years), mean ± SD		72.1 ± 9.4
Range (years)		52–96
Male, n (%)		52 (73.2%)
BMI (kg/m²), mean ± SD		21.3 ± 2.9
Underweight (BMI < 18.5), n (%)		10 (14.1%)
Normal (18.5–22.9), n (%)		39 (54.9%)
Overweight/Obese (≥ 23), n (%)		19 (26.8%)
Comorbidities	Diabetes mellitus, n (%)	45 (63.4%)
	Hypertension, n (%)	52 (73.2%)
	Chronic kidney disease, n (%)	22 (31.0%)
	Smoking (current/former), n (%)	69 (97.2%)
	CLTI (necrosis/infection), n (%)	28 (39.4%)

Characteristic		UMC (n = 71)
Procedure setting	Elective, n (%)	62 (87.3%)
	Same-day/Urgent, n (%)	9 (12.7%)
	Re-intervention (same limb), n (%)	6 (8.5%)

SD: standard deviation; BMI: body mass index; CLTI: chronic limb-threatening ischaemia.

3.2. Lesion characteristics

Chronic total occlusion (CTO) was the most common lesion type (34 cases; 47.9%), followed by combined stenosis and occlusion (27 cases; 38.0%), pure stenosis (6 cases; 8.5%), and ISR (3 cases; 4.2%). Mean DSA lesion length was 177 ± 98 mm. Rutherford classification was complete for all 71 patients: Rutherford IV predominated (39 cases; 54.9%), followed by Rutherford III (21 cases; 29.6%) and Rutherford V (11 cases; 15.5%), confirming a substantial ischaemic burden (Table 2).

Table 2. Lesion characteristics, technical approach, and access details

Characteristic		UMC (n = 71)
Lesion type	Chronic total occlusion (CTO), n (%)	34 (47.9%)
	Combined stenosis and occlusion, n (%)	27 (38.0%)
	Stenosis only, n (%)	6 (8.5%)
	In-stent restenosis (ISR), n (%)	3 (4.2%)
	Other, n (%)	1 (1.4%)
Lesion characteristics	DSA lesion length (mm), mean ± SD	177 ± 98
	Reference vessel diameter (mm), mean ± SD	5.1 ± 0.7
Side of intervention	Right limb, n (%)	36 (50.7%)
	Left limb, n (%)	29 (40.8%)
	Bilateral (staged), n (%)	2 (2.8%)
Rutherford classification (n = 71)*	Rutherford III, n (%)	21 (29.6%)
	Rutherford IV, n (%)	39 (54.9%)
	Rutherford V, n (%)	11 (15.5%)
Technical approach	Pre-dilation, n (%)	71 (100%)
	Post-dilation, n (%)	45 (63.4%)
	Antegrade access, n (%)	71 (100%)

SD: standard deviation; CTO: chronic total occlusion; ISR: in-stent restenosis; DSA: digital subtraction angiography.

** No Rutherford VI patients were identified; cases with extensive necrosis requiring major amputation were typically referred directly to open surgery.*

3.3. Procedural parameters

Median procedure time was 78 minutes (IQR 52–125; mean 90.8 ± 52.0 minutes). Mean total stent length was 202.4 ± 46.7 mm with 2.1 ± 0.8 stents per patient, reflecting the predominantly long, multi-segment lesion profile of this cohort. The wide range of procedure times reflects lesion complexity, from short focal stenoses to long-segment CTOs (Table 3).

Table 3. Procedural parameters and operative time

Parameter		UMC (n = 71)
Procedure time (minutes)	Mean ± SD	90.8 ± 52.0
	Median (IQR)	78 (52–125)
	Min – Max (minutes)	15–268

Parameter		UMC (n = 71)
Total operating room time (minutes)	Mean ± SD	106.8 ± 50.6
	Pre-procedure preparation time (min), mean ± SD	15.5 ± 12.3
Procedure time distribution	< 60 minutes, n (%)	22 (31.0%)
	60–120 minutes, n (%)	31 (43.7%)
	> 120 minutes, n (%)	18 (25.4%)
Stent characteristics	Number of stents per patient, mean ± SD	2.1 ± 0.8
	Total stent length deployed (mm), mean ± SD	202.4 ± 46.7
	Operators, n	9
	Cases by primary operator, n (%)	38 (53.5%)

SD: standard deviation; IQR: interquartile range.

3.4. In-hospital outcomes

Technical success by SVS criteria was 100%. No intraoperative deaths or emergency open conversions occurred. Major cardiovascular events within 30 days occurred in 3 patients (4.2%), higher than K-ELUVIA 2024 (1.9%), possibly reflecting the greater comorbidity burden in this cohort. Thirty-day mortality was 2.8% (n = 2). Minor in-hospital amputation was required in 12 patients (16.9%), predominantly among CLTI patients with pre-existing tissue loss. Full in-hospital outcomes are presented in Table 4.

Table 4. In-hospital outcomes and post-procedural complications

Outcome	UMC (n = 71)	K-ELUVIA (n = 104)
Technical success, n (%)	71 (100%)	103 (99.0%)
Intraoperative death, n (%)	0 (0%)	0 (0%)
Emergency open conversion, n (%)	0 (0%)	—
Access site haematoma requiring treatment, n (%)	3 (4.2%)	4 (3.8%)
Acute in-stent thrombosis ≤ 24 h, n (%)	1 (1.4%)	1 (1.0%)
Acute limb ischaemia requiring re-intervention, n (%)	0 (0%)	—
Contrast-induced nephropathy, n (%)	2 (2.8%)	—
Major cardiovascular events (MI/stroke) ≤ 30 days, n (%)	3 (4.2%)	2 (1.9%)
Minor amputation during hospitalisation, n (%)	12 (16.9%)	—
30-day mortality, n (%)	2 (2.8%)	1 (1.0%)
Postoperative hospital stay (days), mean ± SD	3.2 ± 1.7	—

MI: myocardial infarction; SD: standard deviation.

3.5. Midterm follow-up outcomes

Kaplan-Meier estimates at 12 months: primary patency 90.1%; freedom from CD-TLR

91.5%; secondary patency 94.3%; overall survival 94.3%. ABI improved from 0.43 ± 0.18 pre-intervention to 0.83 ± 0.14 at 12 months ($p<0.001$). Kaplan-Meier estimates at 24 months: primary patency 73.2%; freedom from CD-TLR 78.8%; overall survival 84.5%. Kaplan-Meier curves are presented in Figure 1. Comparative data with reference registries are shown in Tables 5a and 5b.

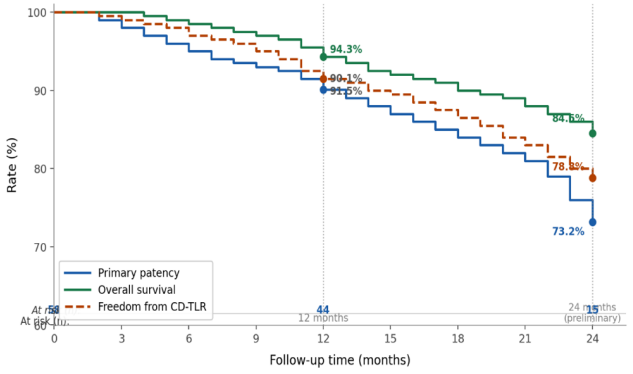

Figure 1. Kaplan-Meier curves for primary patency, overall survival, and freedom from CD-TLR

Table 5a. Comparison of baseline characteristics with reference Eluvia registries

Characteristic		
UMC (n=71)	**K-ELUVIA (n=104)**	**Stavroulakis (n=130)**
Age (years), mean ± SD		
72.1 ± 9.4	68.2 ± 10.4	71 ± 8
Male, n (%)		
52 (73.2%)	86 (82.7%)	82 (63.0%)
Diabetes mellitus, n (%)		
45 (63.4%)	70 (67.3%)	46 (35.0%)
CLTI, n (%)		
28 (39.4%)	31 (30.1%)	40 (31.0%)
CTO, n (%)		
34 (47.9%)	60 (57.7%)	101 (74.0%)
DSA lesion length (mm)		
177 ± 98	168 ± 118	194 ± 108
Total stent length (mm)		
202.4 ± 46.7	—	—
Stents per patient, mean ± SD		
2.1 ± 0.8	—	—

Table 5b. Comparison of midterm follow-up outcomes

Outcome	UMC (n=71)	K-ELUVIA (n=104)	Stav-roulakis (n=130)
12-month outcomes			
Primary patency, % (KM)	90.1%	84.4%	90.0%
Freedom from CD-TLR, %	91.5%	89.1%	94.0%
Secondary patency, %	94.3%	—	95.0%
Overall survival, %	94.3%	—	95.0%
ABI post-intervention, mean ± SD	0.83 ± 0.14	—	—
24-month outcomes			
Primary patency, % (KM)	73.2%	76.3%	71.0%
Freedom from CD-TLR, %	78.8%	79.1%	80.0%
Secondary patency, %	78.8%	—	80.0%
Overall survival, %	84.5%	—	85.0%

KM: Kaplan-Meier; CD-TLR: clinically driven target lesion revascularisation; ABI: ankle-brachial index.

4. DISCUSSION

This study presents the first systematic Vietnamese experience with Eluvia DES implantation for SFA occlusive disease in 71 consecutive patients. Given the single-arm retrospective design, these results do not support conclusions regarding the comparative advantage of Eluvia DES over bare-metal stents or PTA; their primary value lies in establishing feasibility and safety data within the Vietnamese clinical context.

The study population represented a severe, real-world PAD referral cohort: 47.9% CTO, 39.4% CLTI, mean lesion length 177 ± 98 mm. Diabetes prevalence (63.4%) and hypertension (73.2%) were comparable to K-ELUVIA 2024 (67.3%), reflecting the high cardiovascular risk profile typical of a tertiary referral centre. The smoking rate of 97.2% was exceptionally high and represents the foremost cardiovascular risk factor requiring integration into a comprehensive treatment strategy [8].

Notably, the cohort was not exclusively CLTI: Rutherford IV (rest pain) predominated at 54.9%, underscoring the broad clinical spectrum managed with Eluvia DES at this centre.

The 12-month Kaplan-Meier primary patency estimate of 90.1% is numerically comparable to Stavroulakis 2021 (90.0%) and higher than K-ELUVIA 2024 (84.4%) [8,9]. The 24-month estimate of 73.2% falls within the range reported by these two registries (71–76.3%). These comparisons, however, are strictly indirect and should be interpreted with considerable caution. The three cohorts differ meaningfully in baseline characteristics (CLTI prevalence 39.4% vs 30.1–31.0%, CTO rate 47.9% vs 57.7–74.0%), lesion complexity metrics, follow-up completeness, and healthcare system context. No head-to-head comparison was conducted, and the observed numerical differences may reflect patient selection, referral patterns, or reporting differences rather than true outcome heterogeneity. These data should therefore be regarded as contextual benchmarks rather than evidence of comparative efficacy.

Several limitations warrant acknowledgement: (1) The single-arm retrospective design limits causal inference; (2) Post-dilation data and some detailed procedural variables were not fully captured; (3) The absence of a control arm precludes comparative analysis; (4) TASC II classification was not systematically collected, although mean DSA lesion length (177± 98 mm) and CTO rate (47.9%) indirectly reflect lesion complexity, the absence of TASC II data limits comparability with international studies; (5) Arterial wall calcification was not systematically quantified, severe calcification is a known adverse prognostic factor for DES outcomes and may affect paclitaxel delivery efficacy; prospective collection of this variable is recommended.

5. CONCLUSION

Eluvia drug-eluting stent implantation for SFA occlusive disease is technically feasible and safe in a Vietnamese tertiary referral population characterised by advanced age, high comorbidity burden, and predominantly long-segment lesions. A 12-month Kaplan-Meier primary patency of 90.1% and 24-month primary patency of 73.2% are consistent with results from international Eluvia registries, despite a more comorbid patient profile. These findings establish a local evidence base to guide practice in Vietnam. Prospective controlled studies are warranted to confirm comparative effectiveness against bare-metal stents and balloon angioplasty in this population.

DECLARATIONS

Conflicts of interest: The authors declare no conflicts of interest related to this study.

Funding: This research received no external funding.

Ethics approval: Approved by the

Institutional Review Board of University Medical Center Ho Chi Minh City. Individual informed consent waived due to the retrospective design.

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