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Original Article

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Safety and Performance of the MOZEC Sirolimus-Eluting Coronary Balloon in the Treatment of Stenotic Coronary Artery Lesions: A Real-World, Multicenter, Post-Marketing Surveillance Study

Rajendra Kumar Premchand Jain[a, j], Keyur Parikh[b], Selvamani Sethuraman[c], Kamal Sharma[d], Sanjeeb Roy[e], Suryaprakasa Rao Vithala[f], Kondal Rao Gollamandala[f], Gobu Packirisamy[g], Sai Sudhakar Mantravadi[h], Tomasz Roleder[i]

Abstract

Background: Drug-eluting balloons, surface-coated with antiproliferative agents such as sirolimus or paclitaxel, have emerged as an alternative therapeutic option for coronary stenosis. This study evaluated safety and effectiveness of the MOZEC sirolimus-eluting percutaneous transluminal coronary angioplasty (PTCA) balloon dilation catheter (Meril Life Sciences Pvt. Ltd., India) across diverse clinical scenarios in coronary artery stenosis treatment.

Methods: A prospective, single-arm, multicenter, real-world, post-marketing surveillance study evaluated the safety and performance of the MOZEC sirolimus-eluting balloon (SEB) in treating native coronary artery disease in daily clinical practice. Patients were followed for 24 months, with clinical visits or telephonic calls at 1, 6, 12, and 24 months after the index procedure. Safety endpoints included major adverse cardiac events (MACEs), and performance endpoints include change in late lumen loss, clinical success, and device success.

Results: A total of 141 patients were enrolled in the study. The MOZEC SEB was used in 127 (70.17%) *de novo* lesions, 40 (22.1%) in-stent restenosis lesions, and 14 (7.73%) bifurcations lesions. Over the 24-month follow-up period (n = 134), six cumulative MACEs (4.47%) were observed, comprising two cardiac deaths (1.49%), five myocardial infarctions (3.73%), and four target lesion revascularizations (2.99%). Late lumen loss analysis included 17 patients who underwent additional coronarography at the 6-month follow-up. In-segment and in-device late lumen loss at 6-month follow-up was 0.14 ± 0.37 mm.

Conclusions: The application of MOZEC SEB in various clinical scenarios demonstrated safety and efficacy over long-term follow-up. These findings align with the favorable vessel healing observed during the 6-month imaging follow-up.

Keywords: Coronary artery disease; Drug-eluting balloon; In-stent restenosis; Sirolimus-eluting balloon

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[a]Department of Cardiology, Krishna Institute of Medical Sciences, Secunderabad, Telangana, India
[b]Department of Cardiology, Care Institute of Medical Sciences, Ahmedabad, Gujarat, India
[c]Department of Cardiology, Meenakshi Mission Hospital and Research Centre, Madurai, Tamil Nadu, India
[d]Department of Cardiology, Sanjivani Superspeciality Hospitals Pvt. Ltd., Ahmedabad, Gujarat, India
[e]Department of Cardiology, Fortis Escorts Hospital, Jaipur, Rajasthan, India
[f]Department of Cardiology, Apollo Hospitals, Hyderabad, Telangana, India
[g]Department of Cardiology, Global Health City, Chennai, Tamil Nadu, India
[h]Department of Cardiology, Gleneagles Global Hospitals, Hyderabad, Telangana, India
[i]Department of Non-Surgical Clinical Sciences, Faculty of Medicine, Wroclaw University of Science and Technology (WUST), Wroclaw, Poland
[j]Corresponding Author: Rajendra Kumar Premchand Jain, Department of Cardiology, Krishna Institute of Medical Sciences, Secunderabad 500003, Telangana, India. Email: kumarpre@hotmail.com

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Introduction

Coronary artery disease places a significant economic burden in the whole world as it results in over 7 million deaths and 129 million disability-adjusted life years per year [1]. Percutaneous coronary interventions (PCIs) have become a cornerstone in the global treatment of coronary artery diseases. The gold standard involves the dilatation of coronary artery stenosis followed by the deployment of a metal stent to maintain vessel patency. While advancements in antimitotic drug-eluting stents (DESs) have significantly reduced the incidence of restenosis rates over the past decade; however long-term follow-up still presents questionable results because adverse cardiovascular events related to device failure were found similar in DES, as well as bare metal stents [2]. Despite these advancements, stent implantation encounters limitations, particularly in addressing in-stent restenosis (ISR), treating small vessels, and managing bifurcation lesions [3-5]. In light of these challenges, drug-eluting balloons (DEBs), surface-coated with antiproliferative agents such as sirolimus or paclitaxel, have emerged as an alternative thera-

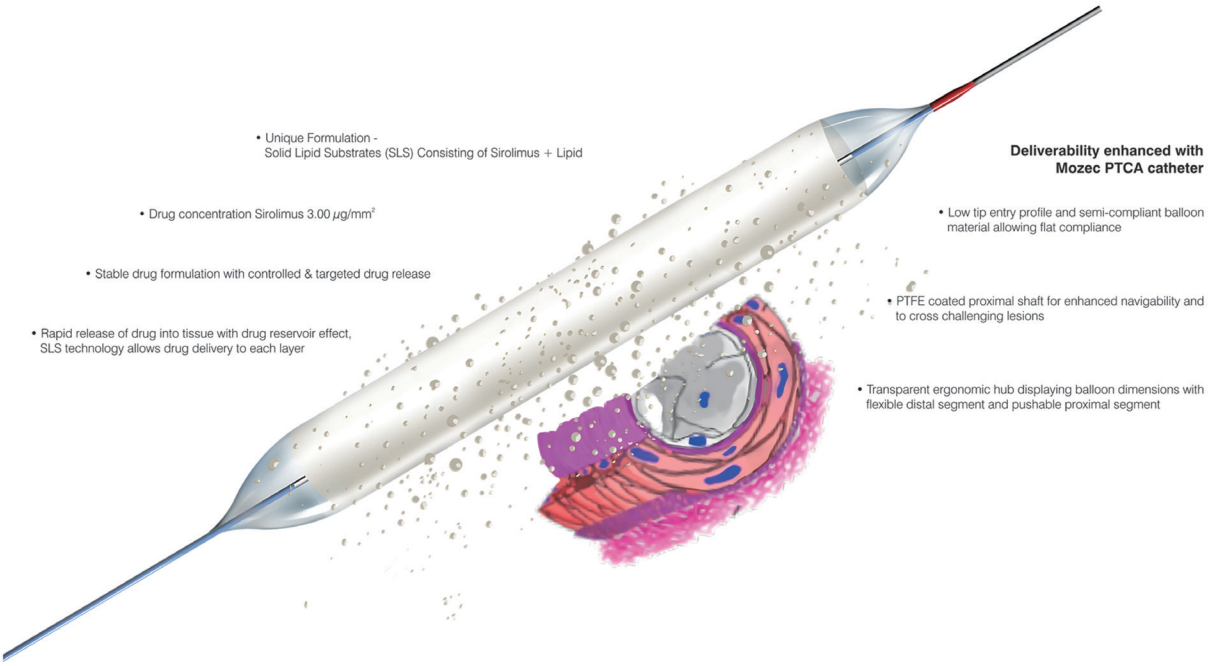

Figure 1. The MOZEC SEB showing its salient features and drug release mechanism. PTFE: polytetrafluoroethylene SEB: sirolimus-eluting balloon.

peutic option for coronary stenosis [6, 7]. Initially conceptualized for ISR management, DEBs facilitate homogeneous drug delivery across the vessel wall, effectively mitigating neointimal proliferation [8, 9]. The intravascular imaging has also showed favorable vessel healing after DEB application [10].

The introduction of DEB offers several advantages over DES, including reduced late-stage inflammatory responses, restenosis, and thrombosis rates [7]. Notably, DEBs lack a permanent metallic scaffold, and durable polymer matrix, preserving vascular anatomy, minimizing hemodynamic disruptions, and shortening the required duration of dual antiplatelet therapy (DAPT) [11-14]. These attributes make DEBs particularly advantageous for the treatment of native coronary artery stenosis [15]. Recent developments have introduced new sirolimus-eluting balloons (SEBs) specifically designed for the treatment of patients with native coronary artery, encompassing total occlusions and primary lesions in acute myocardial infarction (MI), as well as for post-dilatation of balloon-expandable stents [7, 16]. In this context, the present study aims to evaluate patient outcomes, assessing the safety and efficacy of the MOZEC sirolimus-eluting percutaneous transluminal coronary angioplasty (PTCA) balloon dilatation catheter (Meril Life Sciences Pvt. Ltd., India) across varied clinical scenarios in the treatment of coronary artery stenosis.

Materials and Methods

Study design

This prospective, single-arm, multicenter, real-world, post-marketing surveillance study evaluated the safety and effectiveness of the MOZEC sirolimus-eluting PTCA balloon dilatation catheter for the treatment of native coronary artery disease in daily clinical practice between June 2017, and August 2021. The study was registered with the Clinical Trials Registry of India (CTRI/2017/03/008002).

Study device

The CE-marked MOZEC SEB is based on drug delivery system featuring a unique formulation of solid lipid substrates (SLS) containing sirolimus (3.0 µg/mm^2). It has a stable drug formulation with controlled, targeted drug release and prolonged tissue residence time. The SLS have biodegradable lipid particles and excellent biocompatibility. The deliverability of the PTCA catheter (length: 142 cm) relies on a polytetrafluoroethylene-coated proximal shaft (diameter: 1.98 F) with a low-tip profile and a semi-compliant balloon to cross challenging lesions. The sizes (diameter) available are 2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, and 4.50 mm. The nominal pressure required to deflate the balloon is 7 atm for all diameters with rated burst pressure (RBP) 16 atm for diameter size 2.00 to 4.00 mm 14 atm for diameter size 4.50 mm. The features of the device are shown in Figure 1.

Patient population

The inclusion criteria included patients aged ≥ 18 years with target lesions in native coronary arteries, ranging in diameter from 2.00 mm to 4.50 mm, responsible for acute MI, total

coronary occlusions, and ISR. The enrolled lesions exhibited stenosis levels between ≥ 50% and ≤ 100% and lengths of ≤ 41 mm, as visually estimated. The treated lesion had to be covered by a single MOZEC SEB dilatation. Exclusion criteria included cardiogenic shock, unprotected left main disease, lesions requiring rotational atherectomy, coronary graft lesions, prior brachytherapy, life expectancy < 2 years, serum creatinine level > 2.0 mg/dL or 160 µmol/L, platelet count < 100,000 cells/mm^3 or > 700,000 cells/mm^3, patients on cytostatic or radiation therapy, allergy to anticoagulation/antiplatelet therapy, history of stroke within the prior 6 months, medical history of allergy to aspirin or sirolimus, active peptic ulcer or upper gastrointestinal bleeding within the past 6 months, and breastfeeding women.

Ethical statement

All patients signed the informed consent form prior to their enrollment in the trial. The independent ethics committees of each participating institution approved the trial protocol and supervised the ethical conduct of the trial at each clinical site. This study was conducted in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration.

Procedural details

The PCI technique was performed in accordance with the standard American College of Cardiology (ACC)/American Heart Association (AHA) guidelines. Vascular access via radial or femoral artery was chosen, as per physician's discretion. The procedure involved inserting a guidewire through the hemostatic valve connector under fluoroscopy, followed by crossing the lesion using the accepted PCI techniques. Predilatation was performed using a balloon catheter, with the radiopaque markers aiding in accurate positioning and placement. Stenotic lesions were dilated, and the MOZEC SEB was inflated at a nominal pressure of 7 atm for a minimum of 30 s to facilitate drug delivery. In cases of multiple inflations, the duration was extended up to 60 s. The standard antiplatelet/anticoagulation regimen was provided based on the ACC/AHA guidelines or at the investigator's discretion. Bailout stenting was advised as per the discretion of the treating interventional cardiologist in case of requirement.

Study flow

All patients were followed for 24 months through clinical visits or telephonic calls at 1, 6, 12 and 24 months after the index procedure. Details on follow-up schedule and assessments are summarized here (Supplementary Material 1, cr.elmerpub.com). As per the protocol, 30% (n = 37) of the target population was planned for late lumen loss (LLL) analysis; however, due to logistic/administrative constraints, a total of 17 patients underwent LLL analysis at 6-month follow-up.

Study endpoints

The primary safety endpoint was the analysis of major adverse cardiac events (MACEs) within a 24-month follow-up period after the application of MOZEC SEB. MACE was defined as a composite outcome comprising cardiac death, MI, and target lesion revascularization (TLR). TLR was described as any repeated PCI or bypass surgery of the target lesion due to complications.

Secondary study endpoints included the assessment of LLL, which was defined as the difference between the post-procedural minimum luminal diameter and the follow-up minimum luminal diameter at 6 months, as determined by quantitative coronary angiography (QCA). Clinical success was defined as procedural success without any complications (such as death, thrombosis of the TLR, or target vessel revascularization (TVR)) prior to discharge.

Device success was determined by successful delivery, balloon inflation, and deflation without bursting below the RBP. Additionally, a user rating on technical properties was recorded. User satisfaction was measured on a scale from 0 to 5, considering flexibility, trackability, pushability, crossability, inflation time, deflation time, radiopaque marker visibility, and ease of balloon removal. The scores were defined as follows: 0 = very poor, 1 = poor, 2 = below average, 3 = average, 4 = good, and 5 = excellent.

Statistical analysis

Data distribution was evaluated using the Kolmogorov-Smirnov test. Normally distributed data were expressed as mean ± standard deviation (SD), while non-normally distributed data were presented as median with interquartile ranges (IQR, 25th to 75th percentile). A paired t-test was used for analyzing the normally distributed data, and the Mann-Whitney U test was employed for non-normally distributed data. Categorical data were assessed using Fisher's exact test or the Chi-square test. A two-tailed P value of less than 0.05 was considered statistically significant. Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 22.0 (IBM, Armonk, New York, USA).

Results

Patient characteristics

A total of 141 patients were enrolled in the study. Figure 2 depicts the patient's disposition. The study cohort was predominantly male, comprising 77.30% of the participants. Most suffered from hypertension (66.67%) and diabetes mellitus (60.28%). The distribution of coronary artery disease was as follows: single-vessel disease in 39.72% (n = 56), double-vessel disease in 29.08% (n = 41), and multi-vessel disease (≥ triple vessel disease) in 31.20% (n = 44) of the patients. The baseline demographic characteristics and medical history of

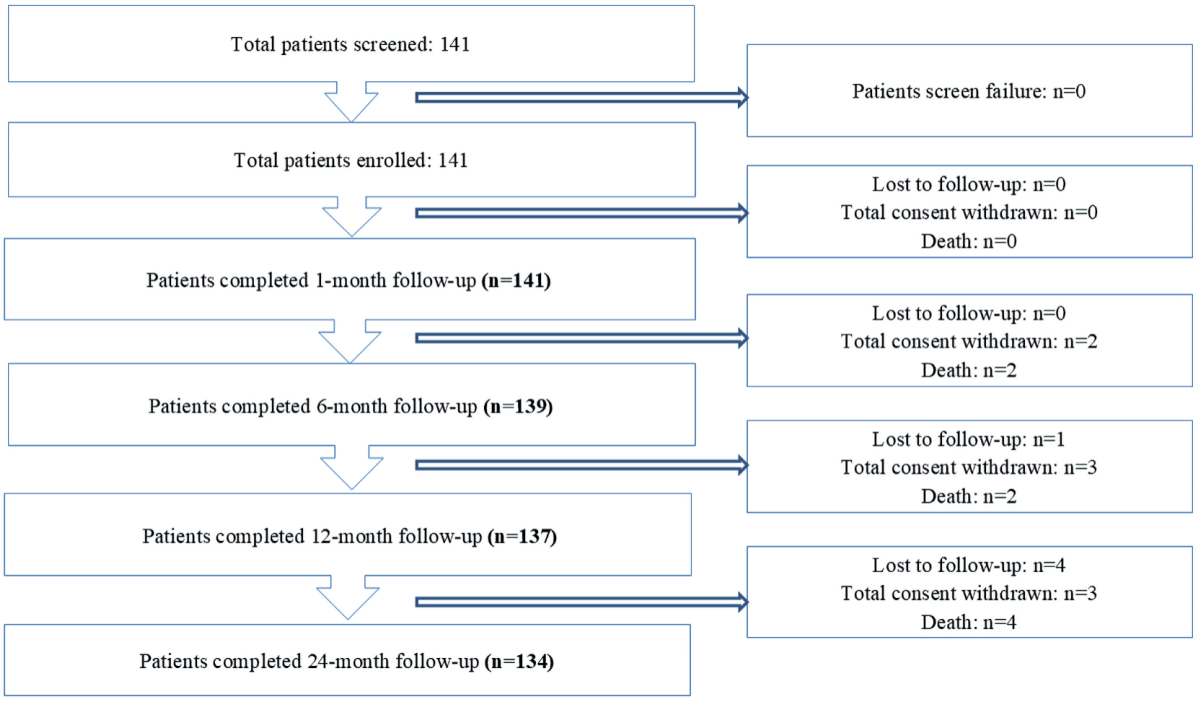

Figure 2. Disposition table.

the study patients are presented in Table 1.

Lesion characteristics

The MOZEC SEB balloon was used in 127 (70.17%) *de novo* lesions, 40 (22.10%) cases of ISR, and 14 (7.73%) bifurcations. Lesions were classified as type A1 in 42 cases (23.20%), type B1 in 31 cases (17.13%), type B2 in 35 cases (19.34%), and type C in 73 cases (40.33%). Mild calcifications were detected in 108 lesions (59.67%), moderate in nine lesions (4.97%), and severe in three lesions (1.66%). The location of the lesions is presented in Table 2.

Procedure details

Radial access was the most common vascular access, which was used in 111 cases (78.72%). The average diameter of the applied MOZEC SEB balloon was 2.54 ± 0.41 mm, with an average length of 20.68 ± 9.16 mm. Post-procedure Thrombolysis in Myocardial Infarction (TIMI) flow grades were TIMI 2 in one case (0.55%) and TIMI 3 in 180 cases (99.45%). Clinical features of the lesions are summarized in Table 2. Device success and clinical success were observed in 100% of cases. There were no instances of bailout stenting.

Clinical outcomes

During the 24-month follow-up, a total of six cumulative MACEs were observed (4.47%). Among these, four patients died (2.99%) with two of those deaths attributed to cardiac deaths (1.49%). Additionally, five patients experienced MI (3.73%), and four underwent TLR (2.99%) (Table 3). The Kaplan-Meier curve illustrating the overall survival rate at 24-month follow-up is presented in Figure 3. According to Figure 3, the survival probability was more in *de novo* group as compared to the ISR group at the end of 24 months (97.65% vs 93.10%) follow-up.

Late lumen loss

QCA analysis showed significant improvement in hemodynamic parameters at the 6-month follow-up. The analysis of LLL using QCA is detailed in Table 4 and visually represented in Figure 4.

User rating on technical properties

The device received good user rating scores across a range of critical parameters, as evaluated by operators. The flexibility rates received a score of 4.41 ± 0.68, showcasing its adaptability to various anatomical structures. Pushability and trackability scored 4.55 ± 0.57 and 4.55 ± 0.51, respectively, allowing smooth navigation through tortuous vessels. Crossability achieved a rating of 4.43 ± 0.66, efficiently crossing lesions with minimal resistance. Inflation and deflation times were swift, with ratings of 4.59 ± 0.52 and 4.55 ± 0.53, respectively, contributing to efficient positioning and retraction during procedures. Radiopaque marker visibility rated 4.62 ± 0.53,

Table 1. Baseline Patient Characteristics

	Patients (n = 141)
Characteristics	
Age (years), mean ± SD	59.00 ± 9.84
Male, n (%)	109 (77.30)
Body mass index, kg/m^2, mean ± SD	26.19 ± 3.73
Heart rate, beats/min, mean ± SD	77.93 ± 11.65
Systolic blood pressure, mm Hg, mean ± SD	127.43 ± 18.08
Diastolic blood pressure, mm Hg, mean ± SD	76.19 ± 10.25
Medical history, n (%)	
Diabetes mellitus	85 (60.28)
Dyslipidemia	6 (4.26)
Hypertension	94 (66.67)
Chronic renal insufficiency	1 (0.71)
Smokers	12 (8.51)
Alcoholics	6 (4.26)
Other illness[a]	17 (12.06)
Cardiac history, n (%)	
Previous MI	27 (19.15)
Previous PCI	40 (28.37)
Previous CABG	6 (4.26)
Family history of CAD	8 (5.67)
Diseased coronary arteries, n (%)	
Single vessel	56 (39.72)
Double vessels	41 (29.08)
Triple vessels	42 (29.79)
Four vessels	2 (1.42)

[a]Bronchial asthma, hyperplasia, hypothyroidism and fistula, epigastric hernia and asymptomatic cholelithiasis, non-obstructive hypertrophic cardiomyopathy, interstitial lung disease, obstructive sleep apnea, renal calculi, dyspnea, MI and HBsAg positive. MI: myocardial infraction; CABG: coronary artery bypass graft; CAD: coronary artery disease; HBsAg: hepatitis B surface antigen; PCI: percutaneous coronary intervention; SD: standard deviation.

ensuring accurate placement under fluoroscopy. The ease of removal scored 4.68 ± 0.51, facilitating streamlined retrieval post-procedure, thus enhancing overall procedural efficiency and patient comfort.

Discussion

This study investigated the safety and effectiveness of the MOZEC sirolimus-eluting PTCA balloon dilatation catheter for managing several coronary artery conditions in a wide range of clinical scenarios. This study presented noteworthy clinical and angiographic results. MACEs occurred at a rate of 4.47%, while all-cause mortality and TLR rates were 2.99%. Angiographic outcomes revealed significant improvement in the minimal lumen diameter (MLD) both in-device and in-segment. The in-device MLD at baseline was 0.49 ± 0.37 mm, which increased to 1.15 ± 0.47 mm at the 6-month follow-up (P = 0.0005). Similarly, the in-segment MLD improved from 0.49 ± 0.37 mm baseline to 1.15 ± 0.47 mm at 6 months (P = 0.0005). These findings indicated substantial improvements in luminal dimensions from baseline to 6 months and have demonstrated a favorable safety and efficacy profile of MOZEC SEB PTCA balloon.

The follow-up duration of the current investigation is notably longer than that of previously published studies, which typically reported outcomes at 1 year following the application of drug-coated balloon (DCB), such as the EASTBOURNE registry (an investigator-initiated study that enrolled real-world patients). The primary endpoint was TLR at 12 months, which was observed at a rate of 5.90%. Additional outcomes at 12 months included a MACE rate of 9.90%, an all-cause mortality rate of 2.50%, and a cardiac mortality rate of 1.50%. Comparing these findings to the current investigation, TLR rates were notably lower at the 24-month follow up, while MACE and all-cause mortality rates remained comparable [17]. The longer-term follow-up in the current study provided a comprehensive understanding of the sustained efficacy and safety of DCBs in clinical practice [18].

The Nanolute registry, a prospective study designed to evaluate the clinical performance of another sirolimus-coated balloon (SCB), focused on the treatment of *de novo* coronary lesions and ISR. At 24-month follow-up, the registry reported a MACE rate of 4.20%, MI rate of 0.20%, an all-cause mortality rate of 1.70%, a cardiac mortality rate of 0.7%, and TLR rate of 3.20% [19]. The current investigation has also reported outcomes comparable to those observed in the Nanolute registry, further supporting the clinical performance and effectiveness of SCBs in managing coronary artery disease. The incidence of MACE was relatively low (4.47%) and comparable to those observed in studies involving small vessels [12, 14].

Moreover, MOZEC SEB demonstrated clinical outcomes comparable to other SEBs with higher drug concentrations (4 µg/mm^2) and crystalline designs. Notably, the rate of MACEs observed in this study was lower than that seen in large clinical trials for SEB [12]. Previous studies have highlighted the favorable vessel response after DCB application in chronic total occlusions (CTOs) [16]. Building on this foundation, our study performed angiographic assessments of DCB application at mid-term follow-up, revealing favorable outcomes at 6 months, specifically regarding vessel remodeling. These findings align with data observed for other SEBs [20].

The treatment of ISR with sirolimus DEBs has shown varied outcomes regarding mortality and MACEs. While some studies indicate a favorable safety profile, others highlight significant occurrences of MACEs in patients treated with these devices [21-23]. ISR CTOs represented 15% of all CTOs in percutaneous interventions and were associated with higher long-term MACE rates compared to *de novo* CTOs, despite similar procedural success [24]. Similar to this, our study had more rate of mortality and MACEs in the ISR group.

Table 5 [14, 17, 19, 21, 25-29] shows the comparison of clinical outcomes of MOZEC SCB to other contemporary DCB (SeQuent Please, and MagicTouch) and DES (XIENCE,

Table 2. Location and Clinical Features of the Lesions

Total number of lesions treated	N = 181
Lesion's location, n (%)	N = 181
LAD	47 (25.96)
RCA	27 (14.91)
LCX	11 (6.07)
First diagonal	21 (11.60)
Second diagonal	1 (0.55)
First septal	1 (0.55)
Third obtuse marginal	2 (1.10)
R-PDA	7 (3.87)
Ramus	5 (2.76)
LMCA	1 (0.55)
Others	58 (32.04)
Total number of study devices used to treat the lesion, n	158
Clinical features of the lesions	
Reference vessel diameter (mm), pre-procedure, mean ± SD	2.53 ± 0.46
Minimum lumen diameter (mm), pre-procedure, mean ± SD	1.49 ± 0.94
Percentage diameter stenosis, mean ± SD	86.08 ± 11.02
Lesion length (mm), mean ± SD	18.40 ± 8.96
Reference vessel diameter (mm), post-procedure, mean ± SD	2.61 ± 0.46
Minimum lumen diameter (mm), post-procedure, mean ± SD	2.44 ± 0.51

LAD: left anterior descending artery; RCA: right coronary artery; LCX: left circumflex coronary artery; LMCA: left main coronary artery; R-PDA: right posterior descending artery; SD: standard deviation.

Resolute, Resolute Onyx, MiStent, Endeavor Sprint, Biolimus, and Orsiro). Notably, the MOZEC SEB demonstrates a favorable safety profile with relatively low incidences of MACEs (4.47%), cardiac death (1.49%), MI (3.73%) and TLR (2.99%) compared to other DES, which reported higher rates of adverse events. This comparison underscores the competitive efficacy of the MOZEC SEB in reducing MACEs and improving patient outcomes [25-29].

The results of this study, in conjunction with previously published outcomes of SEB application in *de novo* lesions, have significant implications for redefining the approach to coronary artery disease intervention. Given that DCB application has shown favorable clinical outcomes across different clinical scenarios, the choice between DESs and DEBs in specific clinical scenarios or lesion morphologies warrants careful consideration [30]. Furthermore, high-bleeding risk patients may benefit from DEB application due to shortened DAPT requirements [14].

Study limitations

The study has several limitations. Despite the inherent limitations of a single-arm study design, the observed outcomes

Table 3. Safety Outcomes

Events, n (%)	In-hospital (n = 141)	1-month (n = 141)	6-month (n = 139)	12-month (n = 137)	24-month (n = 134)
All-cause death	0	2 (1.42)	2 (1.44)	3 (2.19)	4 (2.99)
Cardiac death	0	1 (0.71)	1 (0.72)	2 (1.46)[b]	2 (1.49)
Non-cardiac death	0	1 (0.71)	1 (0.72)	1 (0.73)	2 (1.49)
MI	0	1 (0.71)	3 (2.16)[a]	5 (3.65)[b, c]	5 (3.73)
TLR	0	0	2 (1.44)[a]	4 (2.92)[c]	4 (2.99)
Cumulative MACEs	0	2 (1.42)	4 (2.88)	6 (4.38)	6 (4.47)

[a]Two patients suffered from MI and TLR. [b]One patient suffered from MI and cardiac death, [c]Two patients suffered from MI and TLR. MACEs: major adverse cardiac events; MI: myocardial infarction; TLR: target lesion revascularization.

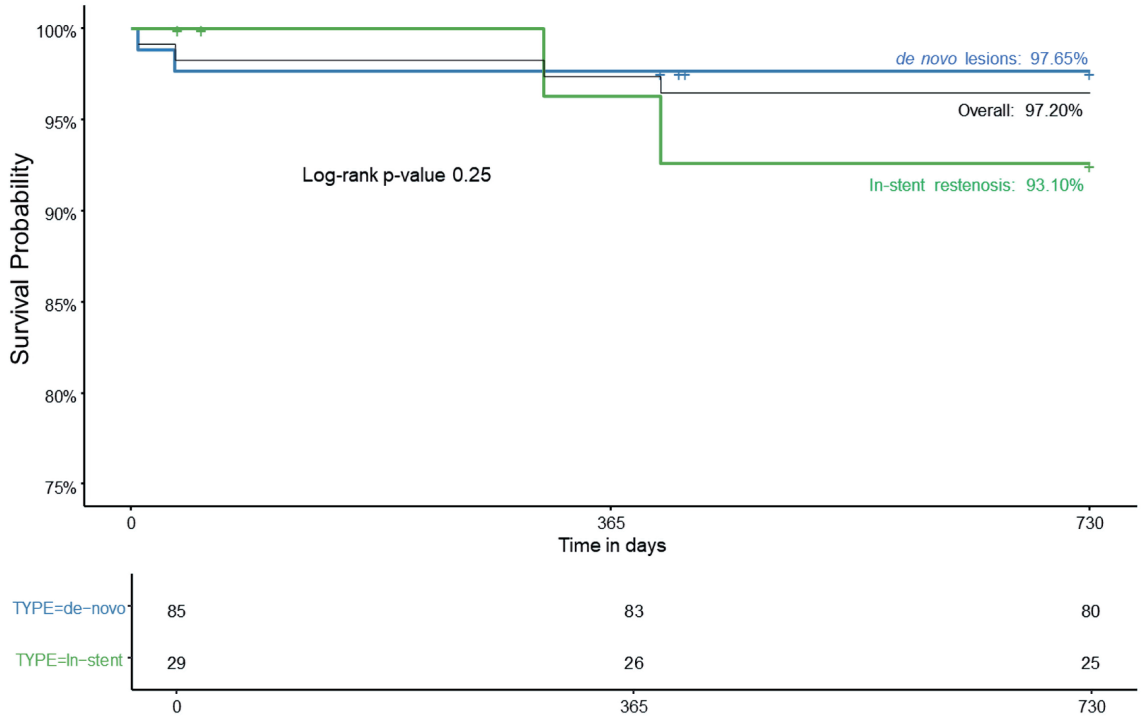

Figure 3. Kaplan-Meier curve for overall survival rate at 24-month follow-up.

provide a robust rationale for validation through future randomized controlled trials. Beyond the study design, there was no angiographic follow-up for every participant, although the low MACE rates suggest positive clinical outcomes. Additionally, the study population was heterogeneous, encompassing patients across a variety of clinical scenarios. However, previous large registries on SEB application in *de novo* lesions have indicated superior clinical outcomes compared to its application in ISR. Furthermore, the study represents a mid-term follow-up; thus, longer-term observations are necessary to fully ascertain the safety and efficacy of the MOZEC SEB application. Lastly, admission diagnoses, specifying whether conditions were acute coronary syndromes, stable, or others, were not recorded.

Conclusions

The application of MOZEC SEB in various clinical scenarios demonstrates safety and efficacy over the long-term 24-month follow-up. These findings align with the favorable vessel healing observed at the 6-month imaging follow-up.

Table 4. Quantitative Coronary Angiographic Analysis

Parameters	Pre-procedure (n = 17)	Post-procedure (n = 17)	6-month follow-up (n = 17)	P value
In-device				
Binary stenosis	0.93 ± 0.27	0.29 ± 0.47	0.31 ± 0.48	0.0078
MLD (mm)	0.49 ± 0.37	1.33 ± 0.28	1.15 ± 0.47	0.0005
In-segment				
Binary stenosis	0.93 ± 0.27	0.29 ± 0.47	0.31 ± 0.48	0.0078
MLD (mm)	0.49 ± 0.37	1.28 ± 0.25	1.15 ± 0.47	0.0005
Proximal edge				
MLD (mm)	2.04 ± 0.30	2.20 ± 0.53	2.22 ± 0.50	0.2368
Distal edge				
MLD (mm)	1.73 ± 0.31	1.70 ± 0.34	1.82 ± 0.47	0.6989

Values are given in mean ± SD. MLD: minimal lumen diameter; SD: standard deviation.

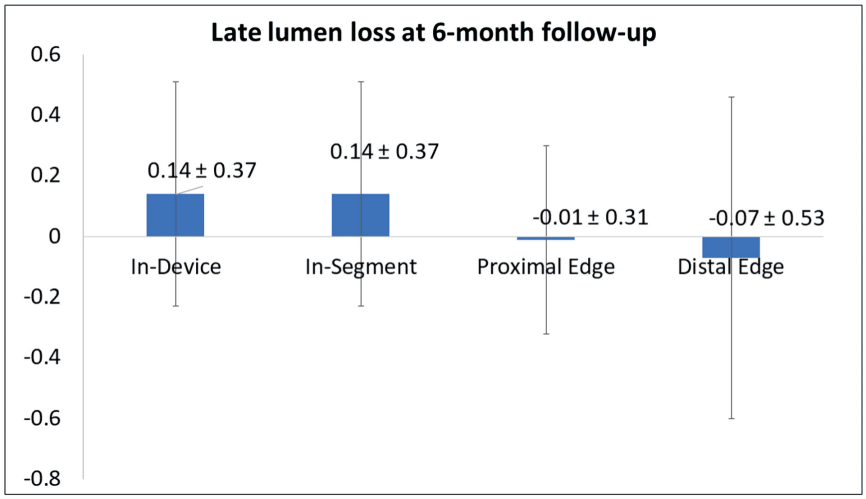

Figure 4. The late lumen loss at 6-month follow-up.

Table 5. Comparison of 2-Year Outcomes of MOZEC SEB With Contemporary DCB and DES

Study name	Study design	Device name	Sample size	Follow-up duration	Cardiac death	MI	TLR	MACE
MOZEC SEB	Real-world, multicenter, post-marketing surveillance study	MOZEC SEB	141	2 years	1.49%	3.73%	2.99%	4.47%
BASKET-SMALL 2 [14]	Multicenter, open-label, randomized noninferiority trial	Paclitaxel-coated balloon SeQuent Please®	382	1 year	3.1%	1.6%	-	7.5%
		Everolimus-eluting Xience® stent and paclitaxel-eluting TAXUS Element® stent	376	1 year	1.3%	3.5%	-	7.3%
EASTBOURNE prospective registry [17]	Prospective, multicenter, real-world study	Magic Touch sirolimus DCB	2,123	1 year	1.5%	2.4%	5.9%	9.9%
Nanolute registry final results [19]	Prospective registry	Magic Touch SCB	408	2 years	0.7%	0.2%	3.2%	4.2%
SELFIE registry [21]	Prospective, single-center registry	Magic Touch SCB	62	11 ± 7 months	1.6%	3.2%	3.2%	4.8%
BIONYX trial [25]	Prospective, patient- and assessor-blinded, randomized noninferiority trial	Orsiro SES	1,245	2 years	1.6%	3.2%	3.4%	8.6%
		Resolute Onyx SES	1,243	2 years	1.0%	3.3%	3.9%	8.3%
THRIVE study [26]	Prospective, multicenter, real-world, single-arm registry	XIENCE EES	365	2 years	0.8%	3.0%	2.1%	6.0%[a]
RESOLUTE clinical trial [27]	Prospective, multicenter, non-randomized, single-arm trial	Resolute ZES	139	2 years	0.7%	5.8%	1.4%	10.1%
DESSOLVE I and II trials [28]	DESSOLVE I: first-in-human, single-arm trial; and DESSOLVE II: randomized trial	MiStent SES	123	2 years	1.7%	2.5%	1.7%	6.7%[b]
		Endeavor Sprint ZES	61	2 years	1.7%	5.0%	1.7%	13.3%[b]
COMFORTABLE AMI RCT [29]	Prospective, randomized, single-blinded, controlled trial	Biolimus	575	1 year	2.9%	2.0%	1.6%	4.3%[c]

[a]MACEs (composite of cardiac death, MI, and TLR). [b]MACEs (death, MI, TVR). [c]MACEs (composite of cardiac death, target vessel-related reinfarction, and ischemia-driven target-lesion revascularization). MACE: major adverse cardiac event; MI: myocardial infarction; SEB: sirolimus-eluting balloon; TLR: target lesion revascularization; SCB: sirolimus-coated balloon; SES: sirolimus-eluting coronary stent system, EES: everolimus-eluting coronary stent system; ZES: zotarolimus-eluting coronary stent system; RCT: randomized controlled trial.

Supplementary Material

Suppl 1. Study schedule and assessments.

Acknowledgments

None to declare.

Financial Disclosure

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Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be constructed as a potential conflict of interest.

Informed Consent

All patients signed the informed consent.

Author Contributions

RKPJ and KS: conceptualization, and formal analysis. RKPJ and KP: methodology. All authors: investigation, resources, data curation, writing - original draft preparation; writing - review and editing, visualization, funding acquisition. RKPJ, KP and KS: supervision. All authors have read and agreed to the published version of the manuscript.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations

ACC: American College of Cardiology; ACS: acute coronary syndrome; AHA: American Heart Association; CAD: coronary artery disease; DAPT: dual antiplatelet therapy; DEBs: drug-eluting balloons; DESs: drug-eluting stents; LLL: late lumen loss; MACEs: major adverse cardiac events; MI: myocardial infarction; PCI: percutaneous coronary intervention; PMS: post-marketing surveillance; PTCA: percutaneous transluminal coronary angioplasty; QCA: quantitative coronary angiography; RBP: rated burst pressure; SEB: sirolimus-eluting balloon; SPSS: Statistical Package for the Social Sciences; TIMI: Thrombolysis in Myocardial Infarction; TLR: target lesion revascularization

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