



## **TWELVE-MONTH SAFETY AND EFFECTIVENESS OF A NOVEL BIODEGRADABLE POLYMER SIROLIMUS-ELUTING CORONARY STENT IN CLINICAL PRACTICE**

**DR. SURESH. M.K**  
**DR. VIKASH. M**

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**1.PROFESSOR AND HOD, DEPARTMENT OF GENERAL MEDICINE, SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES, KULASEKHARAM, TAMILNADU, INDIA.**

**2.JUNIOR RESIDENT, DEPARTMENT OF GENERAL MEDICINE, SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES, KULASEKHARAM, TAMILNADU, INDIA.**

**CORRESPONDING AUTHOR**  
**DR. VIKASH. M**

**JUNIOR RESIDENT, DEPARTMENT OF GENERAL MEDICINE, SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES, KULASEKHARAM, TAMILNADU, INDIA.**

### **ABSTRACT:**

#### Introduction:

Coronary artery disease (CAD) remains the top cause of death worldwide.<sup>1</sup> In recent years, drug-eluting stents (DES) have become the preferred treatment for most patients undergoing percutaneous coronary intervention (PCI).<sup>2</sup> These stents are utilized in various clinical and anatomical scenarios due to their significant reduction in restenosis rates and the decreased necessity for repeat revascularization.

**Objectives:** The objective of this study was to evaluate the safety and efficacy of the Stenoflex Sirolimus-Eluting Coronary Stent System (SES) in a cohort of all-comer patients with coronary artery disease (CAD) over a one-year clinical follow-up period.

**Methods:** This investigation was a single-center, observational, post-marketing study involving 92 patients with CAD who received the Stenoflex SES at a tertiary cardiac center in Southern Tamil Nadu, India. The primary endpoint was the incidence of major adverse cardiac events (MACE) at one year, defined as a composite of cardiac death, myocardial infarction (MI), and target lesion revascularization (TLR). Clinical follow-up assessments were conducted at 1, 6, and 12 months. The occurrence of MACE at 30 days, 6 months, and at the one-year follow-up was analyzed.

**Results:** The incidence of MACE at 1 and 6 months was 1 (0.01%) and 1 (0.01%), respectively. The cumulative one-year MACE rate was 1 (0.01%), with 1 (0.01%) all-cause mortality. There were no instances of MI, TLR, or stent thrombosis (ST) during the study period. The MACE observed at one month was attributed to ventricular arrhythmia resulting in sudden cardiac death.

**Conclusions:** The findings of this study suggest that the Stenoflex SES is safe and effective in a "real-world" population of all-comer CAD patients, demonstrating low rates of MACE. **Keywords:** Biodegradable polymer



## **Introduction:**

Coronary artery disease (CAD) remains the top cause of death worldwide.<sup>1</sup> In recent years, drug-eluting stents (DES) have become the preferred treatment for most patients undergoing percutaneous coronary intervention (PCI).<sup>2</sup> These stents are utilized in various clinical and anatomical scenarios due to their significant reduction in restenosis rates and the decreased necessity for repeat revascularization.<sup>3, 4</sup> The first-generation DES were linked to a higher risk of late complications, such as stent thrombosis (ST) and late restenosis, prompting measures to extend antiplatelet therapy and enhance stent platforms, polymer carriers, and drug choices.<sup>3</sup> A hypersensitivity reaction to the non-degradable polymer is one potential explanation for the complex mechanism behind stent thrombosis.<sup>4</sup> DES with non-degradable polymer coatings have residual polymers that can trigger inflammatory reactions, delaying healing and re-endothelialization.<sup>5, 6, 7, 8, 9, 10</sup> Biodegradable polymers, due to their degradable nature, offer the advantage of reducing prolonged inflammatory responses in the arterial wall, facilitating re-endothelialization, and minimizing the risk of thrombus formation and late restenosis.<sup>3</sup> DES, like the Stenoflex Sirolimus-Eluting Coronary Stent System (Kamal Medtech Pvt. Ltd., Delhi-NCR, India), have been developed to decrease neointimal hyperplasia and promote rapid arterial remodeling. The Stenoflex Sirolimus-Eluting Coronary Stent System (SES) features a CE-approved biodegradable polymer made of poly  $\beta$ -hydroxybutyrate-co- $\beta$ -hydroxyvalerate (PHBV). The Stenoflex SES is constructed on the NexGen platform, which is ultra-thin (65  $\mu$ m) and made of cobalt-chromium L605, with longitudinal S' connectors and a spatial cell design that ensures radial strength, side branch access, zero foreshortening, and reduced intra-arterial injury. Sirolimus, formulated with a biodegradable polymer, exhibits proven drug release kinetics, starting with an initial burst followed by a sustained release for up to 30 days. Biodegradable polymers completely degrade through hydrolysis and enzymatic processes, eventually being excreted from the body as CO<sub>2</sub> and H<sub>2</sub>O. Consequently, the aim of the current study was to assess the safety and performance of the Stenoflex SES in all-comer patients with CAD over a one-year clinical follow-up.

This study investigates the one-year clinical outcomes associated with the Stenoflex stent in a real-world cohort of patients undergoing PCI for CAD. By evaluating procedural success, safety endpoints such as stent thrombosis and myocardial infarction, and efficacy measures including target lesion revascularization and restenosis rates, the study aims to provide comprehensive insights into the stent's performance in routine clinical practice. These findings will contribute to the growing body of evidence guiding interventional strategies and device selection in contemporary cardiology.

## **AIM AND OBJECTIVE OF THE STUDY**

### **Aim:**

The aim of this study is to evaluate the one-year clinical outcomes of the Stenoflex sirolimus-eluting biodegradable polymer-coated coronary stent system in a real-world population of patients with coronary artery disease (CAD).

### **Objectives:**

The objectives of the study are to assess the procedural success rates of Stenoflex stent implantation in routine clinical practice, to evaluate safety endpoints such as the incidence of stent thrombosis and



myocardial infarction within one year post-implantation, and to measure efficacy outcomes, including rates of target lesion revascularization and restenosis at one year.

## MATERIALS AND METHODS

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Data was collected from patients attending the Department of General Medicine and Cardiology at Sree Mookambika Institute of Medical Sciences, Kanyakumari, Tamil Nadu, between March 2024 and September 2025. This single-center post-marketing study included a total of 92 patients who underwent stenting for the management of CAD using Stenoflex SES. The study was conducted with the approval of the local ethics committee, and informed written consent was obtained from all participants. Percutaneous coronary interventions were performed according to current standard guidelines. Clinical and angiographic data from all patients treated with Stenoflex SES were collected and analyzed. Follow-up assessments were conducted at 30 days, 6 months, and 12 months after discharge using both clinical visits and telephonic contact. All serious adverse events were reviewed by an adjudication committee.

All patients received dual antiplatelet therapy, including a loading dose of aspirin, in combination with either clopidogrel or ticagrelor as per the investigator's discretion. Procedural anticoagulation was achieved with heparin, and the intra-procedural administration of glycoprotein IIb/IIIa inhibitors was also left to the investigator's discretion. Patients were recommended to continue dual antiplatelet therapy with aspirin (75–150 mg daily indefinitely) and clopidogrel (75 mg daily) or an equivalent ticagrelor regimen.

## STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS). Quantitative data were expressed as mean  $\pm$  standard deviation, while categorical variables were expressed as frequencies and percentages. Independent t-tests were used to compare continuous variables after verifying normal distribution. Chi-square tests were applied to analyze differences between categorical variables. Logistic regression models were used to adjust for age and estimate the independent effects of hypertension, ischemic heart disease, and diabetes mellitus. A p-value of less than 0.05 was considered statistically significant.

### **Results:**

#### **1.1. *Baseline demographics characteristics***

The analysis includes initial clinical data and subsequent follow-up information gathered at intervals of 1 month, 6 months, and 12 months. Out of the 92 participants in the study, 66 (71.7%) were male, with an average age of  $56.4 \pm 10.3$  years. Table 1 provides a summary of the patients' baseline demographics. Among the patients, 42 (45.6%) had a history of diabetes, 65 (70.6%) had hypertension, 32 (34.8%) had hyperlipidemia, and 21 (22.8%) had a family history of CAD. Of the



92 patients, 38 (41.3%) were diagnosed and treated for unstable angina. Additionally, 43 (46.7%) were smokers, and 18 (19.5%) had experienced a previous MI.

Baseline lesion characteristics are mentioned in Table 2.

Table 1. Demographic and baseline characteristics.

<b>Characteristics</b>	<b>Stenoflex Sirolimus Eluting Coronary Stent <i>n</i> = 92 patients</b>
<i>Patient demographics</i>	
<b>Age (mean ± SD, yrs)</b>	56.4 ± 10.3
<b>Male, <i>n</i> (%)</b>	66 (71.7%)
<i>Baseline medical history</i>	
<b>History of diabetes mellitus, <i>n</i> (%)</b>	42(45.6%)
<b>History of hypertension, <i>n</i> (%)</b>	65 (70.6%)
<b>History of hyperlipidemia, <i>n</i> (%)</b>	32 (34.8%)
<b>Smoker, <i>n</i> (%)</b>	43(46.7%)
<b>Family history of coronary artery disease, <i>n</i> (%)</b>	21(22.8%)
<i>Cardiac history</i>	
<b>Previous MI, <i>n</i> (%)</b>	18 (19.5%)
<b>Previous PCI, <i>n</i> (%)</b>	20 (21.7%)
<b>Previous CABG, <i>n</i> (%)</b>	12 (13.0%)
<i>Cardiac status before index procedure</i>	
Anginal status	
<b>Asymptomatic, <i>n</i> (%)</b>	4 (4.3%)
<b>MI, <i>n</i> (%)</b>	39 (42.4%)
<b>Stable angina, <i>n</i> (%)</b>	11(11.9%)
<b>Unstable angina, <i>n</i> (%)</b>	38 (41.3%)
Type of PCI	



**PAMI, n (%)** 29(31.5%)

**Facilitated, n (%)** 63(68.5%)

CABG – coronary artery bypass grafting, MI – myocardial infarction, PCI – percutaneous coronary intervention, PAMI – primary angioplasty in myocardial infarction.

**1.2. Clinical and angiographic outcomes**

The composite of MACE rates at 30-day, 6-month, and 12-month follow-up was 0.01%, 0.01% and 0.01%, respectively. The summary of MACE during 1-year study period is presented in Table 3. Total 1 (0.01%) patients experienced MACE during 1 year. Of which, 1(0.01%) was all cause death, no MI ,no TLR. Furthermore, no patient had target vessel revascularization (TVR) or any incidence of ST. The time-to-event analysis performed by Kaplan–Meier method was found to be 98.91 % (Fig. 1).

Table 3. Major adverse cardiac events at in-hospital stay, 1-month, 6-month and 1-year follow-up.

<b>Events</b>	<b>In Hospital n = 92</b>	<b>1 month n = 91</b>	<b>6 month n = 91</b>	<b>12 month n = 91</b>
<b>All cause of death, n (%)</b>	0	1(0.01%)	1(0.01%)	1(0.01%)
<b>MI, n (%)</b>	0	0	0	0
<b>TLR, n (%)</b>	0	0	0	0
<b>TVR, n (%)</b>	0	0	0	0
<b>Stent thrombosis, n (%)</b>	0	0	0	0
<b>Total MACE, n (%)</b>	0	1(0.01%)	1(0.01%)	1(0.01%)

MI – myocardial infarction, TLR – target lesion revascularization, TVR – target vessel revascularization, MACE – major adverse cardiac events.

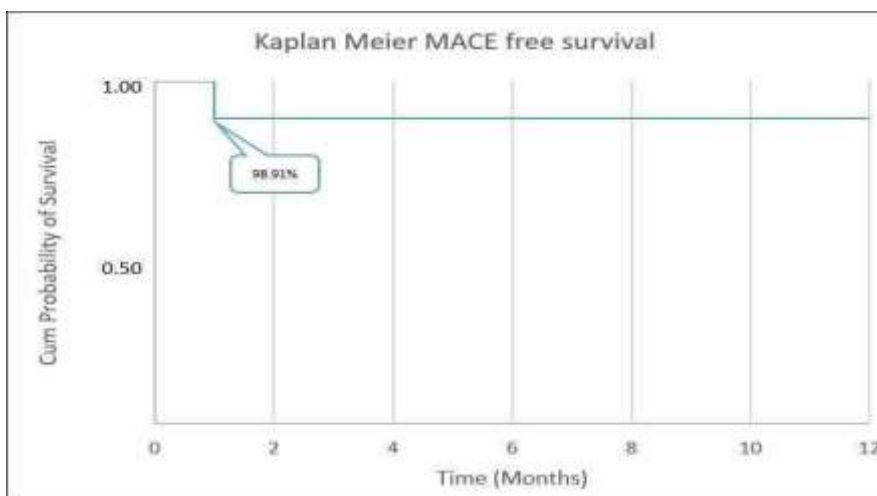


Fig. 1. Time-to-event curve at up to 1-year follow-up by Kaplan–Meier method.



Baseline lesion characteristics are mentioned in Table 2. An analysis of baseline angiography revealed that 31.5% of patients had single lesions who were treated with Stenoflex stent. The mean lesion length was 20.5 mm and mean pre-procedural diameter stenosis was 88.9%. The most prevalent target vessel was left anterior descending (LAD) artery (68.5%) and 60.5% of lesions were diffused. The average number of lesions was 1.29 per patient. The average stent length was  $24.1 \pm 7.4$  mm and average stent diameter was  $3.0 \pm 0.3$ . 119 Stenoflex stents were implanted (ratio of 1.29 stents/patient, which is a reflection of real-world population).

### Discussion:

In this retrospective post-marketing study, the Stenoflex sirolimus-eluting stent (SES) demonstrated excellent procedural success and favorable clinical performance in patients with coronary artery disease (CAD). The study population was characterized by a high prevalence of cardiovascular risk factors, with diabetes mellitus present in 45.6% of patients and hypertension observed in 70.6%, highlighting the inclusion of a high-risk cohort. Despite this elevated risk profile, the outcomes observed with the Stenoflex SES were encouraging, suggesting its suitability for use in complex CAD populations.

The Stenoflex SES is engineered using an ultra-thin cobalt–chromium platform with an innovative cell architecture specifically designed to optimize mechanical performance and clinical outcomes. The presence of ultra-thin struts allows the stent to achieve an exceptionally low crossing profile of approximately 1.00 mm, which significantly improves deliverability and flexibility, particularly in tortuous, calcified, or long coronary lesions. These design characteristics facilitate easier navigation through complex coronary anatomy while maintaining adequate radial strength after deployment.

Earlier generations of drug-eluting stents (DES) were associated with increased rates of late stent thrombosis and were constructed on comparatively bulky stent platforms, which posed challenges related to deliverability, conformability, and polymer biocompatibility.<sup>16–18</sup> In contrast, the Stenoflex SES incorporates longitudinal “S”-shaped connectors that distribute mechanical stress more evenly during stent expansion. This design minimizes localized stress concentrations, thereby reducing the risk of edge flaring and knife-edge focal vascular injury at the stent margins. Furthermore, precise matching between the stent and the delivery balloon ensures uniform expansion and effectively minimizes the dog-boning effect. Notably, no instances of stent thrombosis were observed in the present study, underscoring the safety of the stent design.

Optimal stent-to-vessel wall apposition achieved with the Stenoflex SES promotes rapid endothelialization, a critical factor in reducing thrombotic risk. The stent was deliberately designed to facilitate early re-endothelialization, thereby restoring vascular healing and improving long-term outcomes. As a result, the Stenoflex SES demonstrates excellent arterial biocompatibility and offers a predictable safety and performance profile in clinical practice.

Sirolimus was selected as the antiproliferative agent due to its well-established efficacy and favorable safety profile. Sirolimus acts on the common final pathway of the cell division cycle without inducing excessive cellular necrosis. As a macrolide compound with cytostatic rather than cytotoxic effects, sirolimus inhibits progression from the G1 to the S phase of the cell cycle, thereby suppressing vascular smooth muscle cell proliferation and migration, which are key mechanisms underlying neointimal hyperplasia and in-stent restenosis.<sup>19</sup> This pharmacological action contributes to sustained vessel patency while preserving vascular integrity.



The biomimetic properties of the BioMime SES are further enhanced by the use of a biodegradable polymer coating composed of poly- $\beta$ -hydroxybutyrate-co- $\beta$ -hydroxyvalerate (PHBV). This polymer is non-inflammatory and demonstrates excellent drug-release kinetics, allowing controlled elution of sirolimus over time. Importantly, the PHBV polymer was selected for its mechanical stability and resistance to cracking, webbing, lumping, or adherence to the balloon surface during deployment, thereby ensuring consistent stent performance and uniform drug delivery.

Given the persistent concerns regarding stent thrombosis following DES implantation, thrombosis rates were carefully evaluated in the present study. At the 1-year follow-up, the incidence of stent thrombosis with the Stenoflex SES was 0.00%, which compares favorably with established industry benchmarks, including the sirolimus-eluting Orsiro stent (0.4%) and the biolimus-eluting Nobori stent (1.2%) at similar follow-up durations.<sup>20</sup> These findings further support the thromboresistant profile of the Stenoflex SES.

Despite these positive findings, certain limitations of the study must be acknowledged. The retrospective design and post-marketing nature of the analysis introduce potential selection and reporting biases. Additionally, a follow-up duration of 12 months may be insufficient to fully assess the long-term safety, durability, and performance of the Stenoflex SES, particularly with respect to very late stent thrombosis and restenosis.

In conclusion, the results of the present study provide strong support for the safety and effectiveness of the Stenoflex SES in patients with CAD. However, these findings also underscore the need for well-designed, randomized controlled trials with larger patient populations and extended follow-up periods to further evaluate and compare the long-term outcomes of the Stenoflex SES against other contemporary drug-eluting stents.

### **Conclusion:**

The present retrospective post-marketing study demonstrates that the Stenoflex sirolimus-eluting stent (SES) is a safe and effective therapeutic option for patients with coronary artery disease, including those with a high prevalence of comorbid conditions such as diabetes mellitus and hypertension. Despite the inclusion of a high-risk patient population, the Stenoflex SES showed excellent procedural success and favorable short-term clinical outcomes.

The ultra-thin cobalt–chromium platform, innovative cell architecture, and longitudinal “S” connector design of the Stenoflex SES contribute to superior deliverability, flexibility, and optimal stent expansion while minimizing procedural complications such as edge flaring and dog-boning. These design advantages facilitate complete vessel wall apposition and promote rapid endothelialization, thereby reducing the risk of stent thrombosis. The absence of stent thrombosis at one-year follow-up further supports the thromboresistant and biocompatible profile of the stent.

The use of sirolimus as the antiproliferative agent, combined with a biodegradable PHBV polymer coating, ensures effective inhibition of neointimal hyperplasia while maintaining vascular healing. The controlled drug-release kinetics and non-inflammatory nature of the polymer enhance arterial compatibility and contribute to predictable safety and performance outcomes.

Although the findings are encouraging, the retrospective nature of the study and the limited follow-up duration represent important limitations. Therefore, larger, prospective, randomized clinical trials with extended follow-up periods are warranted to validate these results and to compare the long-term safety and efficacy of the Stenoflex SES with other contemporary drug-eluting stents.



Overall, the results of this study support the Stenoflex SES as a promising and reliable option for the management of coronary artery disease in routine clinical practice.

### Conflict of interest statement:

There is no conflict of interest among the authors.

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