Journal of Cardiovascular Disease Research

ISSN: 0975-3583,0976-2833 VOL 16, ISSUE 9, 2025

Oneyear outcomes of a Stenoflex Sirolim useluting, biodegradable polymer coated coronary stent system in real world coronary artery disease patients

Dr Devang desai ,Dr jasmin vahora
Institute:unicare hospital surat

Objectives

The aim of our study was to determine the safety and performance of the Stenoflex SirolimusEluting Coronary Stent System (SES) in all-comer patients with coronary artery disease (CAD) in one-year clinical follow-up period.

Methods

A single centre, observational, post-marketing study conducted in 92 patients with CAD who were implanted with Stenoflex SES at a tertiary cardiac center in South Gujarat, India. The primary endpoint was major adverse cardiac event (MACE) at one year defined as the composite of cardiac death, myocardial infarction (MI) and target lesion revascularization (TLR). Clinical follow-up was performed at 1, 6, and 12 months. Major adverse cardiac event occurred at 30 days and subsequently at 6 months and at long-term follow-up of 1 year was analyzed.

Results

MACE observed at 1 and 6 months follow-up was 1(0.01%) and 1 (0.01%) respectively. Cumulative 1 year MACE was 1(0.01%) with 1 (0.01%) all cause death.There was no any event of MI,TLR or ST during the study period. One MACE observed at one month was due to ventricular arrhythmia leading to sudden cardiac death.

Conclusions

The present study suggests that the Stenoflex SES is safe and effective in a “real-world”, allcomers CAD patients, indicating low rates of MACE.

Keywords

Biodegradable polymer

Cobalt–chromium
Ultrathin struts
Sirolimus-eluting stent

1. Introduction

Coronary artery disease (CAD) is the leading cause of mortality across the globe.[1] For the last few years, the drug eluting stents (DES) have become the standard of care for the vast majority of patients undergoing percutaneous coronary intervention (PCI).[2] The DES have been used in various clinical and anatomical profiles as there is significant reduction in restenosis rates and the need for repeat revascularisation.3, 4 As the first-generation DES were associated with an increased risk of late events including stent thrombosis (ST) and late restenosis, efforts to prevent these risks have included prolongation of antiplatelet therapy, and improvement in stent platforms, polymer carriers, and drug selection .[3] Hypersensitivity reaction to the non degradable polymer is one of the possible explanation for the complex mechanism of stent thrombosis. [4] The DES coated with nondegradable polymer have residual polymers which are accused of instigating inflammatory reaction with delayed healing and re-endothelialization of the DES.5, 6, 7, 8, 9, 10

Due to its degradable nature biodegradable polymer has the advantage of reducing the sustained inflammatory responses of the arterial wall which facilitate re-endothelialization and minimize the risk of thrombus formation and late restenosis.[3] The DES such as Stenoflex SirolimusEluting Coronary Stent System (Kamal Medtech Pvt. Ltd., Delhi-NCR, India) has been developed with an aim to reduce neointimal hyperplasia and fast remodeling of arteries. The Stenoflex Sirolimus-Eluting Coronary Stent System (SES) has a CE approved biodegradable polymer comprised of Poly-β-hydroxybutyrate-co-β-hydroxyyvalerate(PHBV). The Stenoflex SES is built on NexGen, an ultra-thin (65 μm) cobalt–chromium L605 platform with longitudinal 'S'connectors with spatial cell design arrangement which ensures radial strength, side branch access , zero foreshortening and reduced intra-arterial injury.

The sirolimus formulated with the biodegradable polymer has proven drug release kinetics with initial brust of sirolimus followed by sustained release up to 30 days. Biodegradable polymers completely degrades by hydrolysis and enzymatic degradation which is excreted from the body in form of CO2 and H2O.Consequently, the purpose of the present study was to determine the safety and performance of the Stenoflex SES in all-comer patients with CAD at one-year clinical follow-up.

2. Objective

The aim of this study was to determine the safety and performance of the Stenoflex SES in allcomer patients with CAD.

3. Material and methods

3.1. Device description

The Stenoflex SES (Kamal Pvt. Ltd.,Delhi NCR, India) is built on NexGen, an ultra-thin (65 μm) cobalt–chromium platform with optimum cell size and spatial arrangement of cells with longitudinal 'S'connectors. The SES is coated with 1.25 μg sirolimus/mm^2 of stent surface area. The biodegradable polymer, which acts as a drug carrier, is a Poly-β-hydroxybutyrate-co-βhydroxyyvalerate(PHBV). The Stenoflex SES was available in sizes of 8, 13, 16, 20, 24, 28, 32, 36, 40, 43, 47 mm lengths and diameters of 2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50 mm.

3.2. Study design and population

This single center study was conducted at tertiary cardiac care centre in India; with a total of 92 patients were included in this study. This was a post-marketing study of all-comer patients who underwent stenting for the management of CAD using Stenoflex SES. The study was performed with the approval of the local ethics committee. Informed, written consent was obtained from all study participants. The PCI procedures were performed according to current standard guidelines.[13] Clinical and angiographic data from all the patients who were treated with Stenoflex SES were observed in this study. The clinical/telephonic follow-up was performed at the following time points: 30 days, 6 months, and 12 months after discharge. All the serious adverse events were evaluated by Adjudication committee.

All patients received dual antiplatelet therapy (DAPT) including a loading dose of aspirin as per investigator's discretion. Aspirin was coupled with clopidogrelor ticagrelor. The procedural anticoagulation was achieved with heparin . The intra-procedural administration of glycoprotein IIb/IIIa inhibitor was at the investigator's discretion. All patients were recommended the DAPT (aspirin; 75–150 mg daily indefinitely and clopidogrel; 75 mg daily or

prasugrel; 10 mg daily or ticagrelor; 90 mg twice daily for at least 12 months) after the procedure.

3.3. Definitions and end points

Major adverse cardiac event (MACE) was defined as the composite of cardiac death, MI, target lesion revascularization (TLR). All cause of death were considered cardiac unless a non-cardiac cause could be established clearly, either by clinical assessment or by pathological study. The ST was classified according to the definitions of the Academic Research Consortium.[14] Procedural success was defined as successful stent placement at the desired position with <30% residual stenosis.[15] At follow-up, data were collected relating to current clinical status, any prior hospitalization and occurrence of any MACE. The primary endpoint was MACE at 1-month and 6-month follow-up and secondary endpoints were MACE at 1-year follow-up.

3.4. Statistical analysis

Categorical data were presented as counts and percentages. All clinical and angiographic continuous variables were presented as a mean ± standard deviation. The time-to-event curve was presented as per the Kaplan–Meier method. All data were processed using the Statistical Package for Social Sciences, version 15 (SPSS, Chicago, IL, USA).

4. Results

4.1. Baseline demographics characteristics

The analysis consists of baseline clinical data and consecutive follow-up data collected at 1 month, 6 months, and 12 months. Of 92 patients enrolled in the study, 66 (71.7%) were male, and mean age was 56.4 ± 10.3 years. The baseline demographics of the patients are outlined in Table 1. There was a history of diabetes in 42 (45.6%) patients, hypertension in 65 (70.6 %), hyperlipidemia in 32 (34.8 %), and family history of CAD in 21 (22.8 %) patients. Of 92 patients, 41.3% (38) patients were included and treated with a diagnosis of unstable angina. Among 92, 43 (46.7 %) patients were Smoker and 18 (19.5%) patients had previous MI.

Baseline lesion characteristics are mentioned in Table 2.

Table 1. Demographic and baseline characteristics.

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

Table 2. Lesion and procedural characteristics.

Characteristics	**Patients = 92/lesions = 119**
Target vessel location	
Left anterior descending, *n* (%)	63(68.5%)
Right coronary artery, *n* (%)	53 (57.6%)
Left circumflex, *n* (%)	33 (35.9%)
Others, *n* (%)	11 (12.0%)
Total number of patient treated lesions, n	92
Treated with 1 lesion, *n* (%)	29(31.5%)
Treated with 2 lesions, *n* (%)	39 (42.4%)
Treated with 3 lesions, *n* (%)	23 (25.0%)
Treated with 4 lesions, *n* (%)	1 (0.1%)
Average number of lesions per patient	1.2 ± 0.8
Reference vessel diameter (mean ± SD, mm)	3 ± 0.3
Lesion length (mean ± SD, mm)	19.5 ± 9.1
Diameter stenosis (mean ± SD, %)	88.7 ± 7.5
Type of stenosis	
***De novo*, *n* (%)**	116(97.5%)
In-Stent, *n* (%)	2(1.7%)
Bifurcation, *n* (%)	1 (0.8%)
Type of lesion	
Long, *n* (%)	18 (15.1%)
Diffused, *n* (%)	72(60.5%)
Thrombus, *n* (%)	8(6.7%)
CTO, *n* (%)	9 (7.5%)
Calcified, *n* (%)	1 (0.8%)
Pre-procedural TIMI flow grade	
0, *n* (%)	13(14.1%)

Characteristics	Patients = 92/lesions = 119
I, *n* (%)	31(33.7%)
II, *n* (%)	44 (47.8%)
III, *n* (%)	4 (4.3%)
Pre-dilatation, *n* (%)	72 (78.2%)
Access site location, n	92
Femoral, *n* (%)	54(58.7%)
Radial, *n* (%)	38(41.3%)
Average number of stents per patient	1.2 ± 0.1
Average number of stents per lesion	1.2 ± 0.1
Average stent length (mean ± SD, mm)	24.1 ± 7.4
Average stent diameter (mean ± SD, mm)	3.0 ± 0.3

CTO – chronic total occlusion, TIMI – thrombolysis in myocardial infarction.

4.2. 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.

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

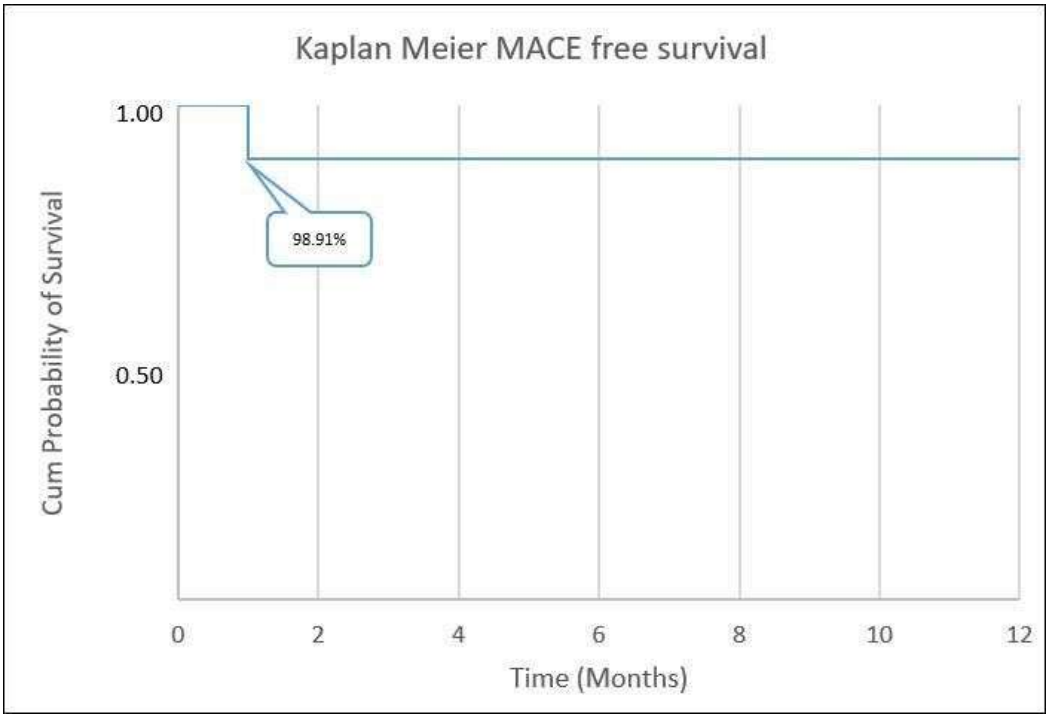

Fig. 1. Time-to-event curve at up to 1-year follow-up by Kaplan–Meier method.

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 ± 7.4 mm and average stent diameter was 3.0 ± 0.3. 119 Stenoflex stents were implanted (ratio of 1.29 stents/patient, which is a reflection of real-world population).

5. Discussion

In this retrospective study, the Stenoflex SES has demonstrated excellent performance in CAD patients including high procedural success and clinical performance. The patient population had high rates of diabetes (45.6 %) and hypertension (70.6 %). In this study, we observed the Stenoflex SES, which is based on an ultra-thin cobalt–chromium platform with innovative cell design with an aim of optimizing performance of Stenoflex SES. The thin struts allow the production of stents with an extremely low profile nearly 1.00 mm that helps in device

deliverability and flexibility. First-generation DES was linked with late ST[16, 17] and was created on bulky stent platforms with questionable deliverability and polymer biocompatibility.[18] The ultra thin novel Stenoflex SES stent design with longitudinal 'S' connectors reduce the stresses during expansion and thereby prevent 'Edge Flaring' & knife edge focal injury during expansion. Further the stent and balloon match precisely to minimize Dog-Boning effect.We observed no ST .Therefore, the Stenoflex SES demonstrated complete wall apposition and thus led to rapid endothelialisation. Stenoflex SES was designed keeping in mind that the DES should facilitate re-endothelialisation. The resultant DES has the ability to be arterially biocompatible and thus offers predictable safety and performance profile.

The drug used is sirolimus, which is an ideal choice considering that it acts on the common final pathway of cell division cycle without an exceptional risk of necrosis induction. It is a macrolide with cytostatic rather than cytotoxic properties that impedes advancement from G1 to S in the cell cycle and inhibits the vascular smooth muscle cell migration and proliferation.[19]

The biomimicry characteristic of the BioMime SES is maintained due to its biodegradable polymer coating of Poly-β-hydroxybutyrate-co-β-hydroxyyvalerate(PHBV). The biodegradable polymer is non-inflammatory and has excellent drug-release kinetics; it is also a right polymer choice because of its ability to avoid cracking, webbing, lumping or sticking to the balloon surface.

The ongoing concerns related to ST in implanted stents prompted us to analyze the thrombosis rates with scrutiny in the present study. Stent thrombosis incidences observed with Stenoflex SES at 1-year follow-up (0.00%) were low and comparable with current industry standards like sirolimus-eluting Orsiro stent (0.4%) and biolimus-eluting Nobori stent (1.2%) at 1-year follow-up.[20]

This study has some limitations. One of the chief limitations is the nature of the study—a retrospective analysis of a post-marketing study. In addition, a 12-month follow-up period might not be long enough for the safety and performance of the Stenoflex SES. Consequently, further studies with longer follow-up periods, are necessary.

The present study supports conducting randomized clinical studies to evaluate the Stenoflex SES among the other drug-eluting stents on longer term.

6. Conclusions

The Stenoflex SES with biodegradable polymer is safe and effective in a real-world, all-comers CAD patients including those with high-risk and very complex lesions, indicating low rates of MACE over 1-year follow-up period.

Conflicts of interest

The authors have none to declare.

BIBILIOGRAPHY

1. Epidemiology and the magnitude of coronary artery disease and acute coronary syndrome: a narrative review
U Ralapanawa, R Sivakanesan ,Journal of epidemiology and global health 11 (2), 169-17
2. Martin, D., Boyle, F.: 'Drug-eluting stents for coronary artery disease: a review, Medical Engineering &Physics (2011) Volume: 33, Issue: 2, Pages: 148-163. PubMed 21075668. doi:
10.1016/j.medengphy.2010.10.009
3. M. Hamon, R. Niculescu, D. Deleanu, *et al.*
Clinical and angiographic experience with a third-generation drug-eluting Orsiro stent in the treatment of single de novo coronary artery lesions (BIOFLOW-I): a prospective, first-in-man study ,EuroIntervention, 8 (9) (2013), pp. 1006-1011
4. Safety and efficacy of ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer drug-eluting stents: a meta-analysis of randomized trials
Ping Zhu 1 , Xin Zhou 1 , Chenliang Zhang 1 , Huakang Li 1 , Zhihui Zhang 2 , Zhiyuan Song 3
5. S. Cook, E. Ladich, G. Nakazawa, et al.
Correlation of intravascular ultrasound findings with histopathological analysis of thrombus aspirates in patients with very late drug-eluting stent thrombosis Circulation,
120 (5) (2009), pp. 391-399
6. N.G. Kounis, G. Hahalis, T.C. Theoharides
Coronary stents, hypersensitivity reactions, and the Kounis syndrome J
Interv Cardiol, 20 (5) (2007), pp. 314-323
7. M. Joner, A.V. Finn, A. Farb, *et al.*
Pathology of drug-eluting stents in humans: delayed healing and late thrombotic risk J Am Coll Cardiol, 48 (1) (2006), pp. 193-202
8. D.A. Siqueira, A.A. Abizaid, J. de Ribamar Costa, et al.
Late incomplete apposition after drug-eluting stent implantation: incidence and potential for adverse clinical outcomes . Eur Heart J, 28 (2007), pp. 1304-1309
9. G. Nakazawa, A.V. Finn, E. Ladich, et al.
Drug-eluting stent safety: findings from preclinical studies

Expert Rev Cardiovasc Ther, 6 (10) (2008), pp. 1379-1391

10. O.F. Bertrand, R. Sipehia, R. Mongrain, et al.
Biocompatibility aspects of new stent technology
J Am Coll Cardiol, 32 (3) (1998), pp. 562-571
11. Biodegradable-polymer-based, sirolimus-eluting Supralimus® stent: 6-month angiographic and 30-month clinical follow-up results from the Series I prospective study
Sameer Dani1,2*, MB DM; Neville Kukreja3, MA, MRCP; Prakashvir Parikh1, MB DM; Hasit Joshi1,2, MB DM; Jayesh Prajapati1,2, MB DM; Sharad Jain1,2, MB DM; Sunil Thanvi1,2, MB DM; Bhupesh Shah4, MB DM; Jyoti-Prakash Dutta5, BSC 2008 May;4(1):59-63. doi: 10.4244/eijv4i1a11
12. A first-in-man study of sirolimus-eluting, biodegradable polymer coated cobalt chromium stent in real life patients
Ashok Seth a, Praveen Chandra b,⁎, Nagendra S Chouhan b, Ashok S Thakkar c . 2012 Nov;64(6):547–552. doi: 10.1016/j.ihj.2012.07.011 PMCID: PMC3861257 PMID: 23253405
13. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines Writing Committee Members; Lawton JS, Tamis-Holland JE, Bangalore S, Bates ER, Beckie TM, Bischoff JM, Bittl JA, Cohen MG, DiMaio JM, Don CW, Fremes SE, Gaudino MF, Goldberger ZD, Grant MC, Jaswal JB, Kurlansky PA, Mehran R, Metkus TS Jr, Nnacheta LC, Rao SV, Sellke FW, Sharma G, Yong CM, Zwischenberger BA. J Am Coll Cardiol. 2022 Jan 18;79(2):197-215. doi: 10.1016/j.jacc.2021.09.005. Epub 2021 Dec 9. PMID: 34895951
14. HM Garcia-Garcia , Standardized End Point Definitions for Coronary Intervention Trials: The Academic Research Consortium-2 .
Consensus Document (ARC-2, 2018). Eur Heart J. 2018 Jun 14;39(23):2192-2207 https://pubmed.ncbi.nlm.nih.gov/29897428/
15. Hiroki Watanabe, MD, Takeshi Morimoto, MD, Hiroki Shiomi, MD, Masahiro Natsuaki, MD, Kazuya Kawai, MD, Ken Kozuma, MD, Keiichi Igarashi, MD,Impact of Angiographic Residual Stenosis on Clinical Outcomes After New-Generation Drug-Eluting Stents Implantation: Insights From a Pooled Analysis of the RESET and NEXT Trials . Journal of the American Heart Association,Volume 7, Number13,https://doi.org/10.1161/JAHA.118.008718.
16. G. Nakazawa, A.V. Finn, M. Joner, Delayed arterial healing and increased late stent thrombosis at culprit sites after drug-eluting stent placement for acute myocardial infarction patients: an autopsy study
Circulation, 118 (11) (2008), pp. 1138-1145
17. S. Cook, P. Wenaweser, M. Togni, et al.
Incomplete stent apposition and very late stent thrombosis after drug-eluting stent implantation.
18. Circulation, 115 (18) (2007), pp. 2426-2434
Alexandre Abizaid ,Sirolimus-eluting coronary stents: a review ,Vascular Health and Risk Management 2007:3(2) 191–201
19. T.F. Luscher, J. Steffel, F.R. Eberli, et al.

ISSN: 0975-3583,0976-2833 VOL 16, ISSUE 9, 2025
Drug-eluting stent and coronary thrombosis: biological mechanisms and clinical implications .Circulation, 115 (8) (2007), pp. 1051-1058

20. L.O. Jensen, P. Thayssen, M. Maeng, et al.
Randomized comparison of a biodegradable polymer ultrathin strut sirolimus-eluting stent with a biodegradable polymer biolimus-eluting stent in patients treated with percutaneous coronary intervention .doi: 10.1016/j.ahj.2015.05.009 2015 Aug;170(2):210-5.. Epub 2015 May 22.