Outcomes of SUPERA™ Stent Used for the Treatment of *De novo* or Restenotic Superficial Femoral Artery or Complex Femoropopliteal Artery Lesions in Indian Patients

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Abstract

Objective: The study was conducted to evaluate the treatment outcomes of SUPERA™ stents in patients with *de novo* or restenotic lesions in the superficial femoral artery (SFA) or femoropopliteal artery (FPA). **Materials and Methods:** A real-world data collection registry across 20 centers in India enrolled patients (≥18 years) with SFA or FPA lesions treated with SUPERA™ stents. The registry was approved by the ethics committees of the respective sites and 284 subjects were enrolled prospectively after informed consent was obtained; data were collected specifically for this particular analysis. It evaluated baseline characteristics, procedural details, and quality of life, with primary outcome as 12-month freedom from target lesion revascularisation (TLR). Secondary outcomes included patency rate, stent fractures, all-cause death, clinical improvement on Rutherford–Becker classification, and health-related quality of life (HRQoL) using a 36-item Short Form Survey questionnaire. Comparisons were made between baseline and 12 months using Kaplan–Meier analysis, *t*-tests, and proportional comparisons. **Results:** At 12 months, 90.3% of patients were free from TLR, and 89.2% maintained primary patency with SUPERA™ stents; the all-cause death rate was 90.58%. Patients' HRQoL showed significant improvement and 92% of the patients showed clinical improvement as per the Rutherford–Becker classification. No stent fractures were reported. A total of 12.7%, 75%, and 12.3% of patients were prescribed mono antiplatelet therapy, dual antiplatelet therapy, or triple antiplatelet therapy. **Conclusion:** SUPERA™ stents show promise in the management of peripheral artery disease with appreciable freedom from TLR, good primary patency, and notable improvements in HRQoL at 12 months.

Keywords: Antiplatelet therapy, dual antiplatelet therapy, femoralpopliteal artery, Health-related quality of life, peripheral artery disease, SUPERA™, superficial femoral artery stent

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Introduction

Peripheral artery disease (PAD) is a major cause of atherosclerotic morbidity, affecting 230 million individuals globally.[1] The femoropopliteal artery (FPAs) are commonly affected in patients with PAD.[2] Atherosclerotic disease in

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FPAs can result in significant narrowing or blockages, causing intermittent claudication or rest pain with nonhealing ulcers, collectively termed chronic limb-threatening ischemia.[3] The European Society of Cardiology and the American College of Cardiology/American Heart Association recommend endovascular therapy for FPA lesion management.[4,5] However, the distinctive anatomy along with deformations during limb flexion pose challenges to long-term stent patency and durability. Shortening, compression, bending, and elongation can occur within the FPAs, potentially causing fractures and accelerating restenosis.[6]

Endovascular intervention is an effective alternative to surgery for complex PAD.[7] Self-expanding nitinol stents are preferred over balloon-expandable stents for treating FPA lesions due to their high radial strength, flexibility, resistance to deformation, and can be deployed without balloon dilation of the stent edge.[8] The SUPERA™ peripheral stent system is an interwoven self-expanding nitinol stent with high flexibility, radial resistive force, and resistance to kinking and fractures.[9-11] They exhibit superior conformity during knee flexion, with greater relative radii of curvature, lower nominal strain, and increased translocation distance.[12] Enhanced flexibility and resistance to deformation favor stent efficacy and durability.[13]

While various studies have explored the safety and efficacy of the SUPERA™ stent in addressing *de novo* or restenotic lesions in the superficial femoral artery (SFA) or complex FPA cases, none have specifically investigated the impact on health-related quality of life (HRQoL) among PAD patients.

This study aims to assess the effectiveness and safety of SUPERA™ stents in treating *de novo* or restenotic lesions in the SFA or complex FPA among Indian patients. The study also evaluated the HRQoL in patients.

Materials and Methods

Study design and population

A prospective, multicenter noninterventional, real world, data collection registry included patients (≥18 years) with *de novo* or restenotic lesions in the SFA or FPA, treated (<30% diameter stenosis with no procedural complications) with SUPERA™ stents and willing to sign the informed consent form. Patients older than 90 years and those with comorbidities limiting life expectancy to <1 year were excluded from the study. All the patients enrolled in the registry were implanted with SUPERA™ stents in routine procedures. Ethics committee approvals were obtained from participating institutions.

Data collection

The study assessed the patients' baseline characteristics (demographics, medical history); quality of life; lesion characteristics (lesion length and type [stenosis/occlusion], diameter stenosis); vessel information; wound, ischemia, and foot infection (WIFI) stage; red blood cell count; Type B Trans-Atlantic Inter-Society Consensus (TASC) lesions; calcification; vessel run-offs, indications; procedural specifics such as stent length, diameter, conformation after implantation, postprocedural complications, and medication prescribed.

At follow-up, data on patient well-being, status of wound, re-hospitalizations, if any, etc., were collected. For patients who visited the hospital at 12 months, X-rays were performed to check for stent fractures; for patients who were contacted via video consultations, the radiological investigations were performed at local hospitals/clinics near the patients' residences, and the data were shared with the consulting physician. All the data collected were entered in centralized electronic databases by the sites. The CRO team performed source data verification randomly on 20% of the patients at each site. Angiographic images were reviewed by an independent reviewer.

Follow-up

After discharge, patients were followed up at 12 months either through video consulting or at the clinic/hospital.

Study outcomes

The primary outcome was the rate of target lesion revascularisation (TLR) at 12 months after implantation with the SUPERA™ stent. Secondary outcomes at 12 months after SUPERA™ stent implantation included the following:

- Patency rate
- Incidence of stent fractures (detected through radiographic screening)
- Composite rate of freedom from all-cause death
- Clinical status of patients (according to Rutherford-Becker classification [RBC])
- Change in HRQoL using the 36-item Short Form Survey questionnaire (SF-36).

The study also examined the association of following various factors on the 12-month patency rate.

- Diabetes
- Critical limb ischemia, ischemic rest pain, claudication
- Lesion length (short [≤6 cm] medium [7–10 cm], and long [>10 cm])
- Lesion severity (Complex lesions were characterized as TASC C/D and/or RBC 5/6 and/or moderate/severe calcification and/or vessel run-off 0/1 and/or occlusion with ≥15 cm or ≥150 mm lesion length)
- Stent conformation (minimal compression [−11% to −20%], nominal deployment [±10%], minimal elongation [11% to 20%], moderate elongation [21% to 40%], and severe elongation [>40%])
- Stented arterial segment (SFA, Popliteal, and SFA + Popliteal).

Health-related Quality of Life analysis

Data related to quality of life were collected at baseline and 12 months follow-up. Printed copies of the scale in different vernacular languages were provided to the patients for their

responses. The queries of patients related to SF-36 were clarified by the site team. For patients who were followed up at 12 months through video consulting, the patients' responses to the questionnaire were recorded by the site team. The recording and averaging of items as per the entries made by the sites in the electronic case report forms for HRQoL were done centrally by the CRO. Overall changes in the HRQoL from baseline to 12 months were evaluated and compared between the following subgroups: Male versus female, diabetes versus nondiabetes, hypertension (HTN) versus non-HTN, coronary artery disease (CAD) versus non-CAD, smoking (reduced and previous) versus nonsmoking, and amputation versus no amputation.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) and categorical variables as count and per cent. The primary endpoint (TLR at 12 months), patency rate, and all-cause mortality were analyzed using the Kaplan–Meier method. The incidence of stent fractures and patient clinical status are presented as proportions. Changes in HRQoL (SF-36) from baseline to 12 months were assessed using paired *t*-tests. Data were analyzed using R software version 3.2.3 (Foundation for Statistical Computing, Vienna, Austria); $P < 0.05$ indicated statistical significance.

Results

Baseline characteristics

A total of 284 patients were enrolled from 20 centres across India. Eight patients were excluded due to various reasons; 276 patients were included in the final analysis [Figure 1]. Most patients were male (79.3%; $n = 219$). The mean age (± SD) and body mass index of the enrolled patients were 67.1 ± 9.6 years and 25 ± 3.8 kg/m^2, respectively [Table 1].

A history of diabetes mellitus, HTN, CAD, and previous myocardial infarction was reported in 84%, 63%, 30%, and 11% of the patients, respectively. Around 13% of the patients were current smokers, and 8% reported consuming alcohol regularly. Kidney disease was reported in 14% of the patients.

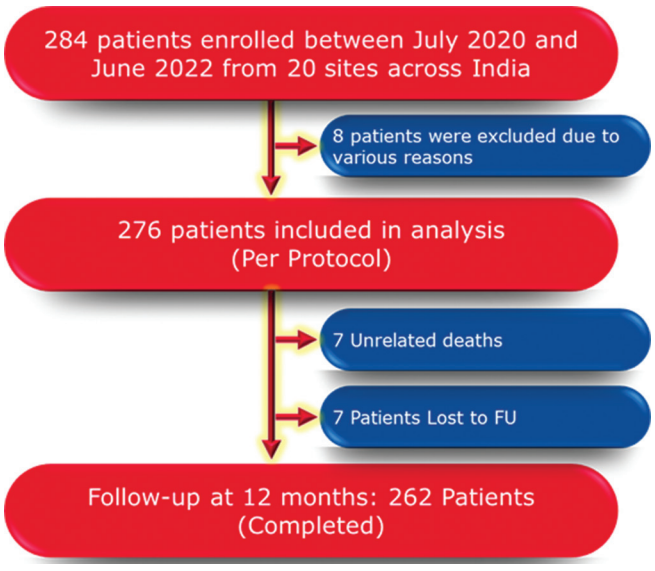

Figure 1: Study flow chart

Preprocedure assessment

The distal SFA and middle SFA were the most frequently affected vessels [Figure 2]. The mean diameter stenosis and lesion lengths were 91.7% ±19.7% and 105.4 ± 74.8 mm, respectively. About 45.3% of the lesions were >10 cm (n = 125), with occlusions present in 63.8% of the vessels.

Total occlusion was reported in 166 (60.1%) patients, severe calcification in 57 (20.7%), and 0 and 1 vessel runoffs in 8 (2.9%) and 78 (28.3%) patients, respectively [Table 2]. Most of the

Table 1: Baseline characteristics of patients

Characteristics	*N* (%) or Mean±SD
Male, *n* (%)	219 (79.3)
Female, *n* (%)	57 (20.7)
Age (years), mean±SD	67.1±9.6
BMI (kg/m^2), mean±SD	25.0±3.8
Medical history, *n* (%)	
Diabetes mellitus	233 (84)
Systemic hypertension	175 (63)
Dyslipidaemia	44 (16)
CAD	83 (30)
Kidney disease/dysfunction	39 (14)
Dialysis	9 (3)
Stroke	11 (4)
Previous myocardial infarction	29 (11)
Cerebral vascular disease	12 (4)
Heart failure	11 (4)
Chronic obstructive pulmonary disease	5 (2)
Bronchial asthma	3 (1)
Obesity, *n* (%)	
Obese	64 (23.2)
Overweight	112 (40.6)
Normal weight	100 (36.2)
Smoking status, *n* (%)	
Current	37 (13)
Former	81 (29)
Alcohol consumption, *n* (%)	21 (8)

SD: Standard deviation, BMI: Body mass index, CAD: Coronary artery disease

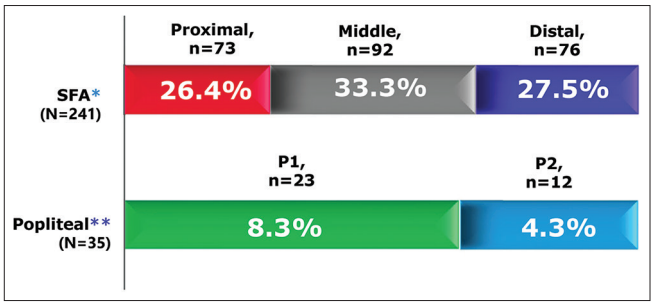

Figure 2: Vessels involved. *34 of 241 SFA lesions extended into popliteal artery, **15 of 35 Popliteal lesions extended into P3 segment. SFA: Superficial femoral artery

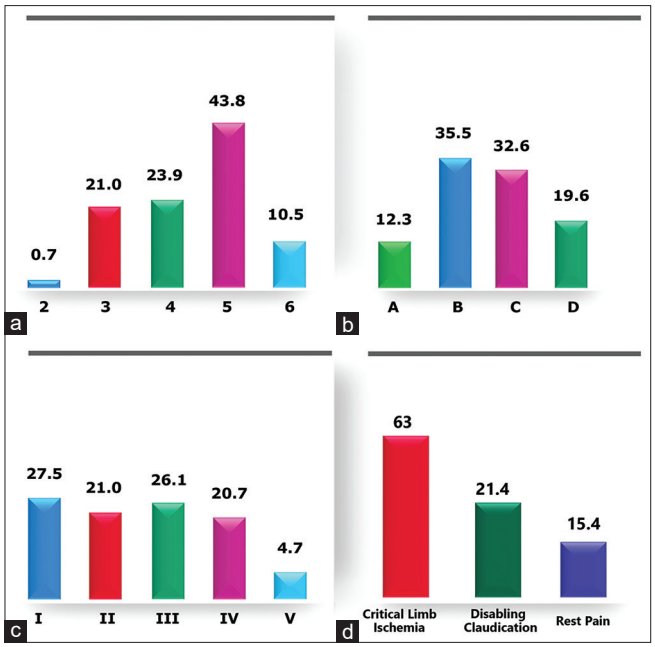

Figure 3: (a) Rutherford-Becker classification (RBC), (b) Trans-Atlantic Inter-Society Consensus Classification, (c) wound, ischemia, and foot infection (WIFI); and (d) indications for stenting

cases (n = 121, 43.8%) were classified as RBC 5 [Figure 3a]. Type B TASC II lesions were reported in in 98 (35.5%) patients [Figure 3b]. WIFI Stages I and III were reported in 76 (27.5%) and 72 (26.1%) patients, respectively [Figure 3c]. Critical limb ischemia was the predominant indication (n = 174; 63%) [Figure 3d].

Procedural details

A single stent was used in 235 (85%) patients [Table 3]. Balloon angioplasty, proximal or distal to SUPERA™ stents, was performed in 159 (57.6%) patients. Nominal deployment was noted in 152 (55.4%), compression in 5 (2.2%), and elongation in 119 (43.4%) patients [Figure 4].

Poststenting antiplatelet medications

Among the various antiplatelet regimens [Figure 5], triple antiplatelet therapy was used in 34 (12.3%) and dual antiplatelet therapy (DAPT) in 207 (75%) patients. Of those receiving DAPT, 84% followed the regimen for a year, whereas 6% of the patients on DAPT transitioned to mono antiplatelet therapy after 6 months.

Health-related Quality of Life

The HRQoL of patients improved significantly ($P < 0.00001$) at 12 months compared to baseline across nine parameters of the SF-36 questionnaire [Figure 6]. Improvements of >100% were noted in role functioning/physical, role functioning/emotional, and health change, and improvements of >50% were seen in physical functioning, social functioning, and pain.

Health-related Quality of Life subgroup analysis

While improvements in quality of life were observed across various subgroups, substantial improvements in role functioning and physical well-being were observed in all subgroups [Supplementary Figure 1].

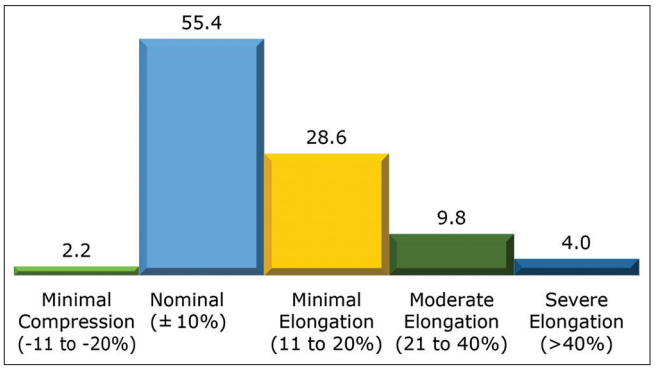

Figure 4: Stent conformation

Table 2: Clinical assessment

Characteristic	Mean±SD, *n* (%)
Hemodynamic characteristics	
ABI	0.5±0.3
TBI	0.5±0.3
TP	61.8±37.8
Other characteristics	
Distance covered before claudication (m)	118.9±214.9
Lesion characteristics	
Diameter stenosis (%)	91.7±19.7
Lesion length (mm)	105.4±74.8
Short (≤6 cm)	70 (25.4)
Intermediate (7–10 cm)	81 (29.3)
Long (>10 cm)	125 (45.3)
Lesion type	
Stenosis	100 (36.2)
Occlusion	166 (60.1)
Stenosis and occlusion	10 (3.6)
Reference vessel diameter (mm)	5.1±0.6
Minimal lumen diameter (mm)	1.0±1.6
Calcification	
None	16 (5.8)
Mild	104 (37.7)
Moderate	99 (35.9)
Severe	57 (20.7)
Vessel runoff	
0 vessel runoff	8 (2.9)
1 vessel runoff	78 (28.3)
2 vessel runoffs	114 (41.3)
3 vessel runoffs	76 (27.5)
Other lesion characteristics	
Total occlusion	166 (60.1)
Restenosis	19 (6.9)
In-stent restenosis	4 (1.4)

ABI: Ankle–brachial index, SD: Standard deviation, TBI: Toe–brachial index, TP: Toe pressure

Twelve months follow-up

No stent fractures were reported in the 262 patients who completed the 12-month follow-up.

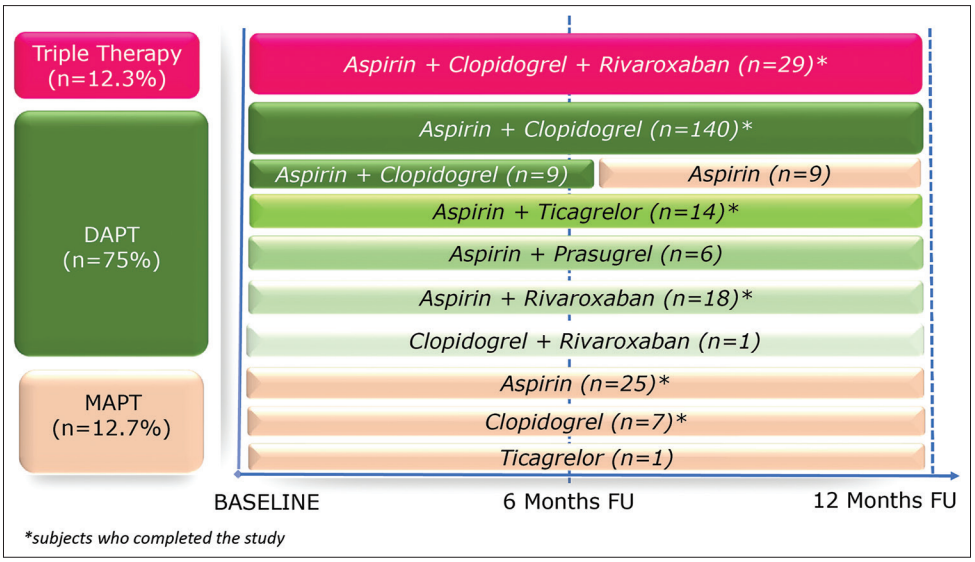

Figure 5: Different antiplatelet therapies administered to the patients after SUPERA™ stent implantation

Freedom from target lesion revascularisation, primary patency, and survival analysis

Freedom from TLR at 12 months was 90.3% [Figure 7a]. Primary patency was achieved in 89.2% of the patients [Figure 7b]. Overall, 26 deaths (cardiac, 10; natural, 10; neurological, 2; infection-related, 4) were reported. The survival rate at 12 months was 90.58% [Figure 7c].

Change in Rutherford-Becker classification

An improvement in the clinical status of ≥1 RBC category was noted in 92% of the patients at 12 months [Figure 8].

Primary patency rate across different subgroups

The primary patency rates were 87.6% and 97.6% in patients with and without diabetes, respectively [Supplementary Figure 2a]. Patients with disabling claudication had the highest patency rate (93.1%), followed by those with command-line interface (89.3%) and rest pain (83.3%) [Supplementary Figure 2b]. Similar assessments across lesion length, complexity of lesions, stent conformations, and stented arterial segments were performed [Supplementary Figure 2c-f].

Assessment by an independent reviewer

Independent reviewer analysis of angiographic images aligned closely with the investigator's assessments, suggesting a consistent and reliable evaluation was done [Supplementary Table 1].

Discussion

Treatment of obstructions in the FPA is challenging due to the dynamic forces impacting vessel walls.[13] Stenting has advantages over standard balloon angioplasty, but many stent types have yielded unsatisfactory outcomes.[14] The SUPERA™ peripheral stent, constructed from nitinol wire, offers improved radial resistive force and flexibility.[9,15,16]

This study analyzed real-world outcomes in 276 Indian patients with atherosclerotic FPA disease, who received SUPERA™ stents. The middle and distal SFA were the most affected vessels. Total occlusion was observed in 60.1% of the patients, and 20.7% exhibited severe calcification. Other studies also revealed similar patterns during preprocedure assessments. Garcia *et al*.[9] found that the middle SFA was most affected (54.3%; total occlusion, 26%; severe calcification, 44.7%), whereas Werner *et al*.[17] reported a high impact on the distal SFA (80%; total occlusion, 52.6%; severe calcification, 30.6%). These baseline characteristics highlight the severity of the FPA lesions in this study population.

In this study, the length of the lesions was 105.4 ± 74.8 mm. TASC type B was most common (35.5%), followed by type C (33%) and type D (20%) lesions. Similar studies on SUPERA™ stent in treating long FPA lesions (TASC C/D lesions; 234 ± 123 mm [220–252 mm]) have reported a primary patency rate of 77.9% and 86.9% freedom from TLR at 24 months, with no stent fractures.[18,19] Gostev *et al*.[19] reported primary patency rates (lesion length, 198 ± 82 mm) of 78.1% and 60% at 12 and 24 months of follow-up, respectively, along with 83.5% freedom from TLR at 12 months and 81.8% at 24 months.[19]

Approximately 85% of patients in this study received a single stent, whereas the reported range is 44.9%–92.9%.[9,16,20] In addition, 57.6% of the patients in this study also underwent additional endovascular procedures, such as balloon angioplasty. The stents exhibited various conformations, mostly with nominal deployment (−10% to 10% compression in 84.1% of cases).[20] Furthermore, the stent maximally expanded to its nominal diameter when deployed slowly with slight forward pressure on the delivery catheters.[15] These indicate the versatility and adaptability of the SUPERA™ stent in addressing the challenges posed by femoropopliteal obstructions.

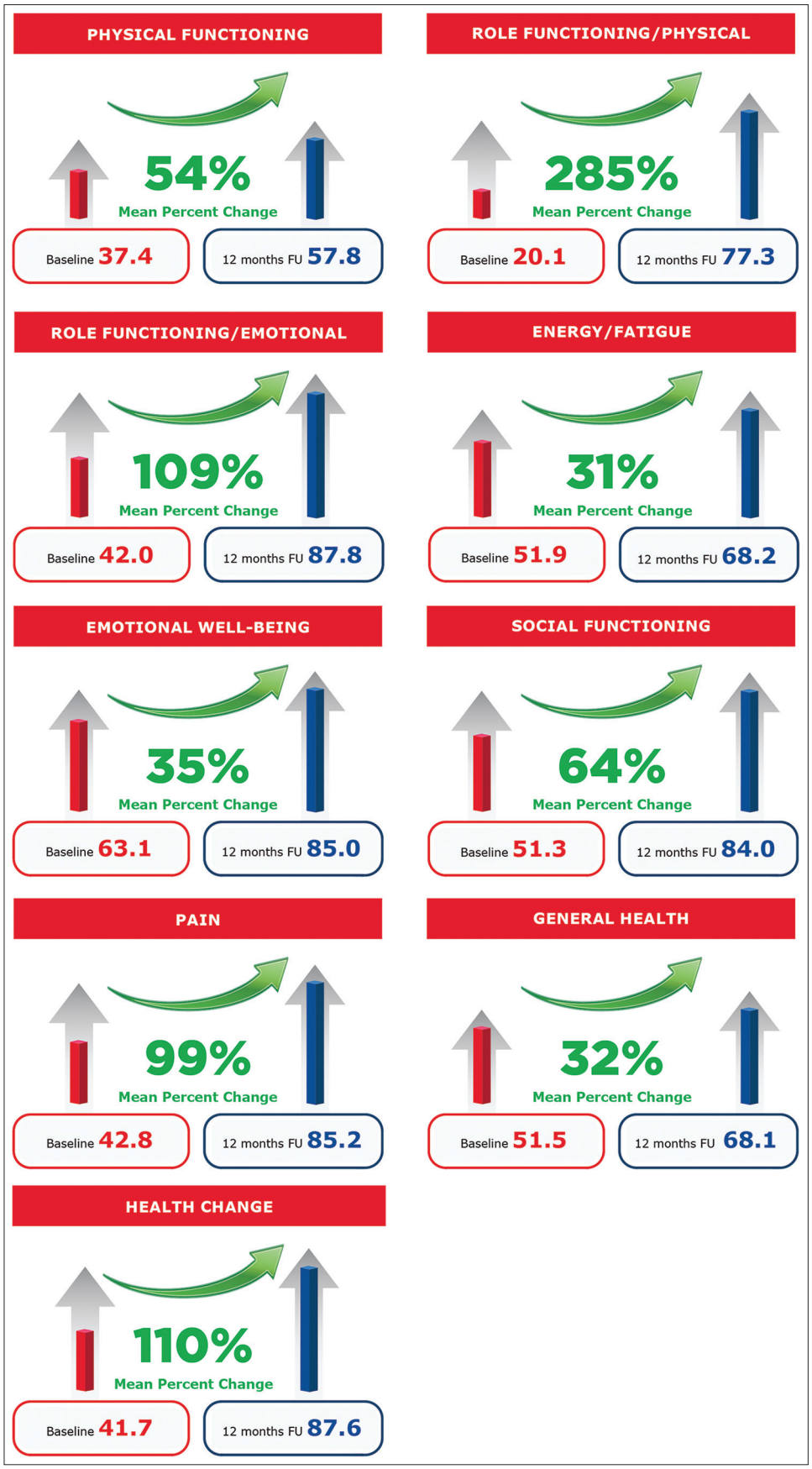

Figure 6: Improvement in quality of life at baseline versus 12-month follow-up on the basis of 36-item Short Form Survey Questionnaire (SF-36)

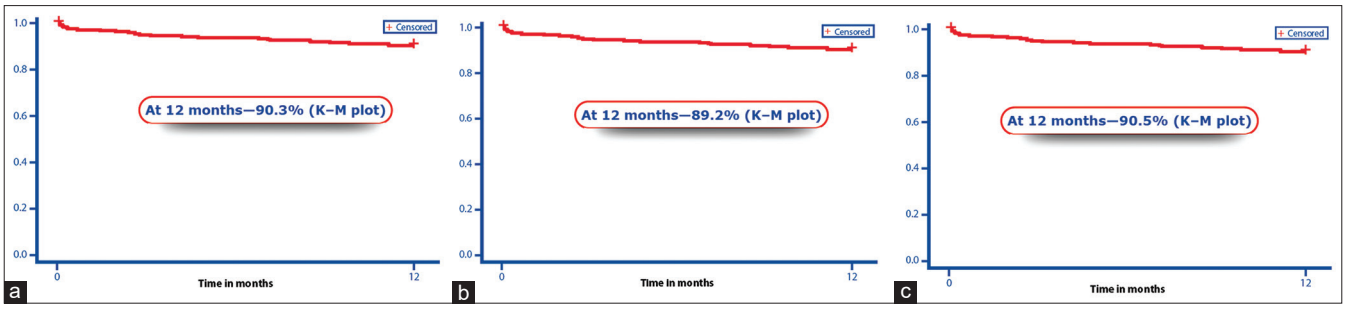

Figure 7: Kaplan–Meier analysis of: (a) freedom from target lesion revascularisation; (b) primary patency; and (c) overall survival

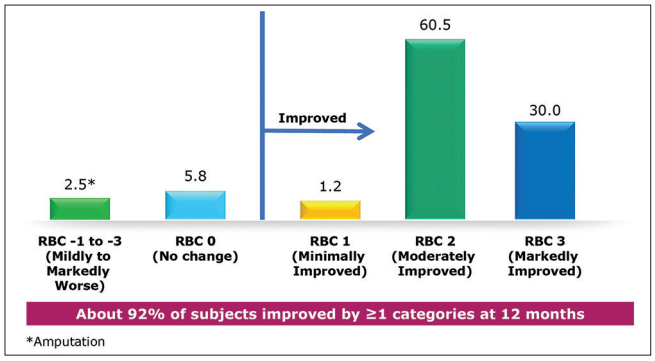

Figure 8: Clinical improvement in the Rutherford–Becker category

Preserving patency in intricate FPA lesions is a significant challenge in endovascular therapy.[17] At the 12-month follow-up, this study showed promising results with 90.3% of the patients achieving freedom from TLR. The primary patency rate was 89.2%, which surpassed rates reported in trials using other stents for FPA interventions, although no direct comparison was performed. Other trials using different stents have reported freedom from TLR values of 80%–90.5% and primary patency rates of 67%–88% at 12 months.[21-30] While no stent fractures were reported in the present study, stent fracture rates of 0.4%–12% have been previously reported. Registry-based studies have demonstrated 1-year primary patency rates of 64.7%–89.8%, with no stent fractures [Figure 9].[31]

Antiplatelet therapy in PAD is vital for preventing adverse events postintervention.[32] While poststenting DAPT is effective, guidelines suggest that this therapy be used cautiously due to bleeding risks.[33] Current guidelines advise aspirin or clopidogrel monotherapy for patients with symptomatic PAD, irrespective of the clinical setting.[34] In this study, 87.3% of the patients received DAPT, mainly aspirin plus clopidogrel and 12.3% of these patients also received rivaroxaban poststenting. DAPT was prescribed for up to 12 months. The high compliance to treatment with DAPT in the patients included in this study may be the reason for better patency and lower rates of TLR reported in our study. Further studies may be required to evaluate the relationship between the duration of DAPT and clinical outcomes such as TLR and patency. Other DAPT combinations included aspirin plus ticagrelor or aspirin plus rivaroxaban. DAPT has been administered for a minimum of 30 days in previous studies; however, these studies did not specify the exact DAPT durations [Table 4].

Table 3: Stent characteristics

Characteristic	*N* (%) or Mean±SD
Stent diameter	
Mean±SD (mm)	5.4±0.8
Range (mm)	4.5–6.5
4.5 mm, *n* (%)	55 (17)
5.5 mm, *n* (%)	245 (77)
6.5 mm, *n* (%)	17 (5)
Stent length	
Mean±SD (mm)	128.8±60.8
Range (mm)	40–200
Number of stents used	
One stent	236 (85.5)
Two stents	39 (14.1)
Three stents	1 (0.4)
Additional endovascular procedures before SUPERA™ stenting	
Atherectomy	3 (1.1)
Balloon angioplasty	275 (99.6)
Thrombolysis	3 (1.1)
Intra vascular lithotripsy	2 (0.7)
Embolectomy	2 (0.7)
Aspiration	2 (0.7)
Endarterectomy	1 (0.4)
Other stents implanted beside SUPERA™	
Downstream to SUPERA™	9 (3.3)
Upstream to SUPERA™	45 (16.3)
Balloon angioplasty (proximal or distal to the SUPERA™ stent)	159 (57.6)
Postprocedure amputation	
Major amputations	7 (2.5)
Minor amputations	1 (0.3)

SD: Standard deviation

The lower patency rates in patients with diabetes than in patients without diabetes in the present study indicate a potential negative impact of diabetes on stent outcomes in these arterial segments However, a retrospective study involving 1630 stable CAD patients who underwent various endovascular interventions including stenting showed no significant effect of diabetes on patency rates or major adverse cardiac and cerebrovascular events (MACCE).[37] Currently, there are no studies establishing

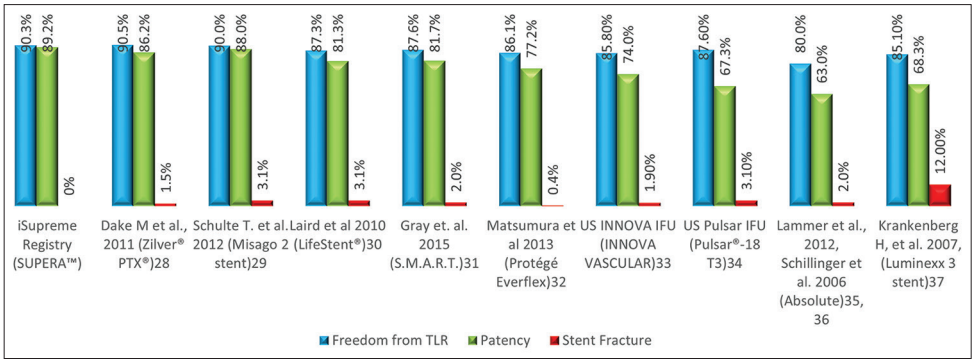

Figure 9: Comparison of freedom from target lesion revascularization, primary patency, and stent fracture rate of different non-SUPERA stents used for the treatment of femoropopliteal artery lesions

Table 4: Type and duration of antiplatelet therapies administered in different studies after SUPERA™ stent implantation for the treatment of superficial femoral artery or femoropopliteal artery lesions

Studies	Antiplatelet therapy administered and duration	Patency rate (12 months)
Salamaga *et al*., 2023[3]	DAPT* - 30 days	73.60
Guzzardi *et al*., 2022[14]	SAPT (aspirin 100 mg/ day) - indefinitely	83.10
Dalai *et al*., 2021[35]	DAPT** - till 6 months, aspirin (100 mg once a day) - lifelong	86.04
San Norberto *et al*., 2019[13]	DAPT* - at least 4 weeks, aspirin continued indefinitely later	89.60
Bhatt *et al*., 2018[7]	DAPT*- at least 30 days, with aspirin alone indefinitely	64.7–87.5^
Montero-Baker *et al*., 2016[16]	DAPT* - at least 30 days	89.80
Werner *et al*., 2014[17]	DAPT* - at least 4 weeks, with recommendation aspirin alone indefinitely	83.30
George *et al*., 2014[36]	DAPT* - at least 30 days, aspirin continued indefinitely	85.80

*DAPT: Aspirin + clopidogrel, **DAPT: Aspirin + clopidogrel/ticagrelor, ^At mean 15 months FU, depending on different stent conformations. DAPT: Dual antiplatelet therapy, FU: Follow-up, SAPT: Single antiplatelet therapy

a correlation between diabetes and stent outcomes in PAD patients. The observed difference in this study may be linked to lack of glycemic control control in diabetic PAD patients.[38]

In this study, simple lesions exhibited 100% patency, whereas complex lesions had a patency of 88.4%. Another investigation involving 99 patients with chronic obstructive arterial disease who underwent treatment with the SUPERA™ stent revealed an 83.1% patency rate for complex FPA lesions.[14] Considering these findings, the SUPERA™ stent is recommended as a viable option for primary stenting in anatomically complex FPA lesions.

The observed 100% patency for minimal compression stents emphasises the importance of maintaining nominal configurations for better outcomes. A retrospective study with 63 patients (77 limbs) treated for FPA lesions with SUPERA™ stent reported a patency rate of 81.8% for minimal compression conformation.[7]

Stent implantation in the popliteal artery is associated with certain limitations, including inadequate radial force to sustain vessel patency and the potential for device kinking or fracture.[35] The SUPERA™ stents demonstrated a 90.5% patency rate in the SFA and 85% in the SFA + popliteal region. A study involving 99 patients undergoing SUPERA™ stent implantation for FPA lesions reported a patency rate of 85.5% in the SFA and 86.4% in the SFA + popliteal region.[14]

Most patients (92%) showed an improvement of ≥1 RBC category at the 12-month follow-up. In a recent study assessing the efficacy of the SUPERA™ stent in treating long FPA lesions, a significant (P = 0.02) improvement in the RBC category was observed at 24 months,[18] reinforcing the positive impact of SUPERA™ stents on patients' functional capacity and limb perfusion.

The SF-36 questionnaire assessed HRQoL in patients who received the SUPERA™ stent and showed significant improvements across various subgroups, indicating that SUPERA™ stent not only contributes to the patient's physical improvement but also positively influences psychosocial aspects. The substantial improvement in role functioning and physical well-being highlights the potential for enhanced patient satisfaction and overall HRQoL. Patients with comorbidities showed better HRQoL than those without, possibly due to existing treatments, lifestyle modifications and improved adherence to their prescribed regimens poststenting. Current or former smokers received counseling aimed at smoking cessation or reduction after the procedure, and adherence to counseling could have contributed to better HRQoL in smokers than in nonsmokers. Moreover, patients who underwent amputation reported more intense pain, with notable relief poststenting and a higher degree of respite from pain than those who did not undergo amputation. Other studies have similarly reported notable improvements in physical scores and peripheral artery scores of the 12-item short form survey questionnaire at 6 and 12 months.

The strength of this study lies in the inclusion of a substantial and diverse patient population from multiple centres across India, enhancing the generalizability of the findings. The comprehensive evaluation encompassed various outcomes, including TLR, primary patency, clinical status, and HRQoL, thereby providing a thorough understanding of the impact of the SUPERA™ stent on different patient outcomes.

However, certain limitations of this study exist. First, the absence of a control group (single-arm study) limits the comparability of these results (outcomes of implantation with SUPERA™ stents) with those of other treatment modalities. Other limitations include potential selection bias (noninterventional design) and a relatively short follow-up (12 months).

Conclusion

The use of the SUPERA™ stent in treating FPA lesions achieved 90.3% freedom from TLR and 89.2% primary patency rate after 12 months in Indian patients. Better outcomes were noted in patients without diabetes, disabling claudication cases, long lesions (>10 cm), and nominal deployment. There was a significant improvement in clinical status, in terms of enhancement in the RBC category and a positive impact on HRQoL, particularly in the role functioning and physical well-being domains. Deployment of the SUPERA™ stent coupled with antiplatelet therapy (for 12 months) and rigorous poststenting inspection was found to improve patency rates and reduce TLR incidence even in patients with comorbidities. These findings provide robust real-world evidence supporting the effectiveness and safety of SUPERA™ stents to improve endovascular outcomes and HRQoL in PAD patients.

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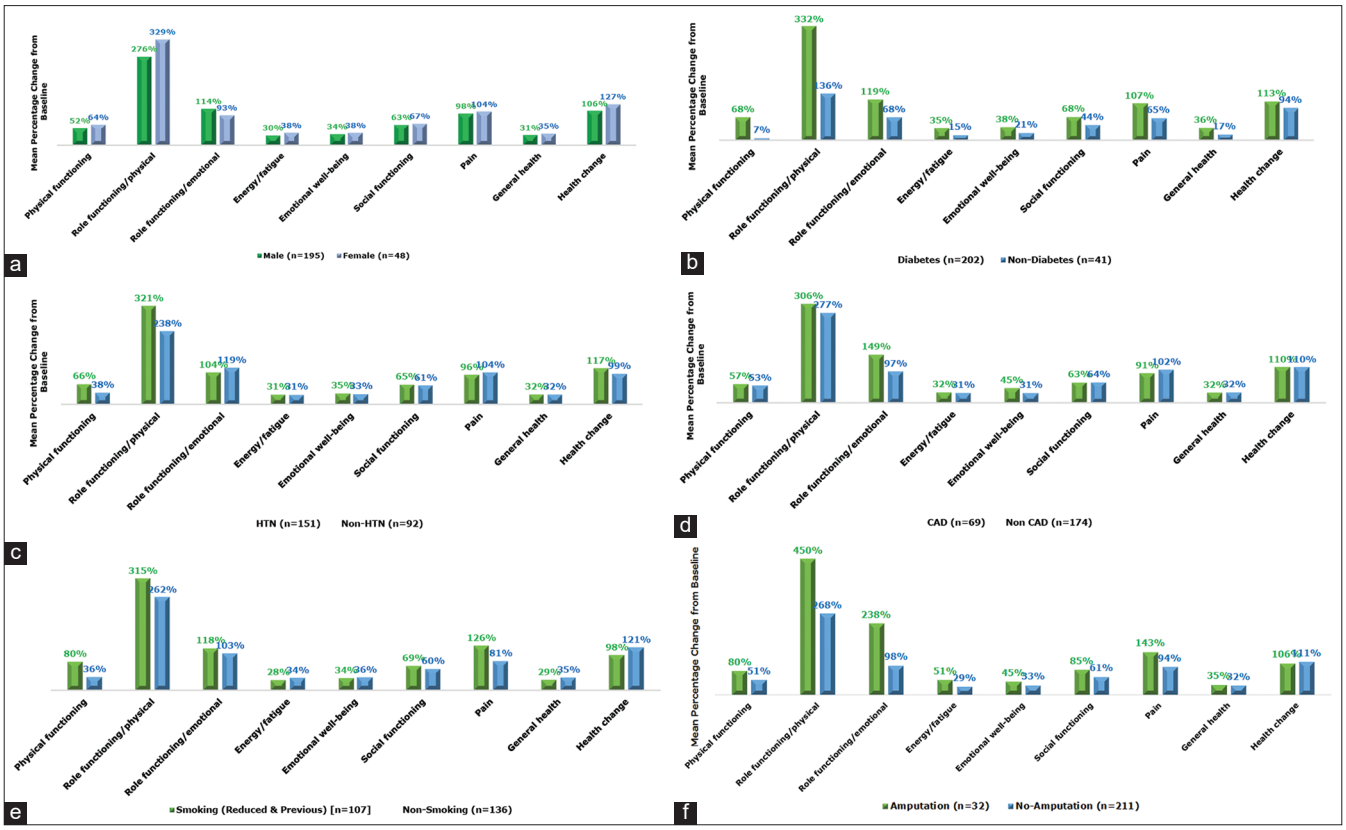
Conflicts of interest

There are no conflicts of interest.

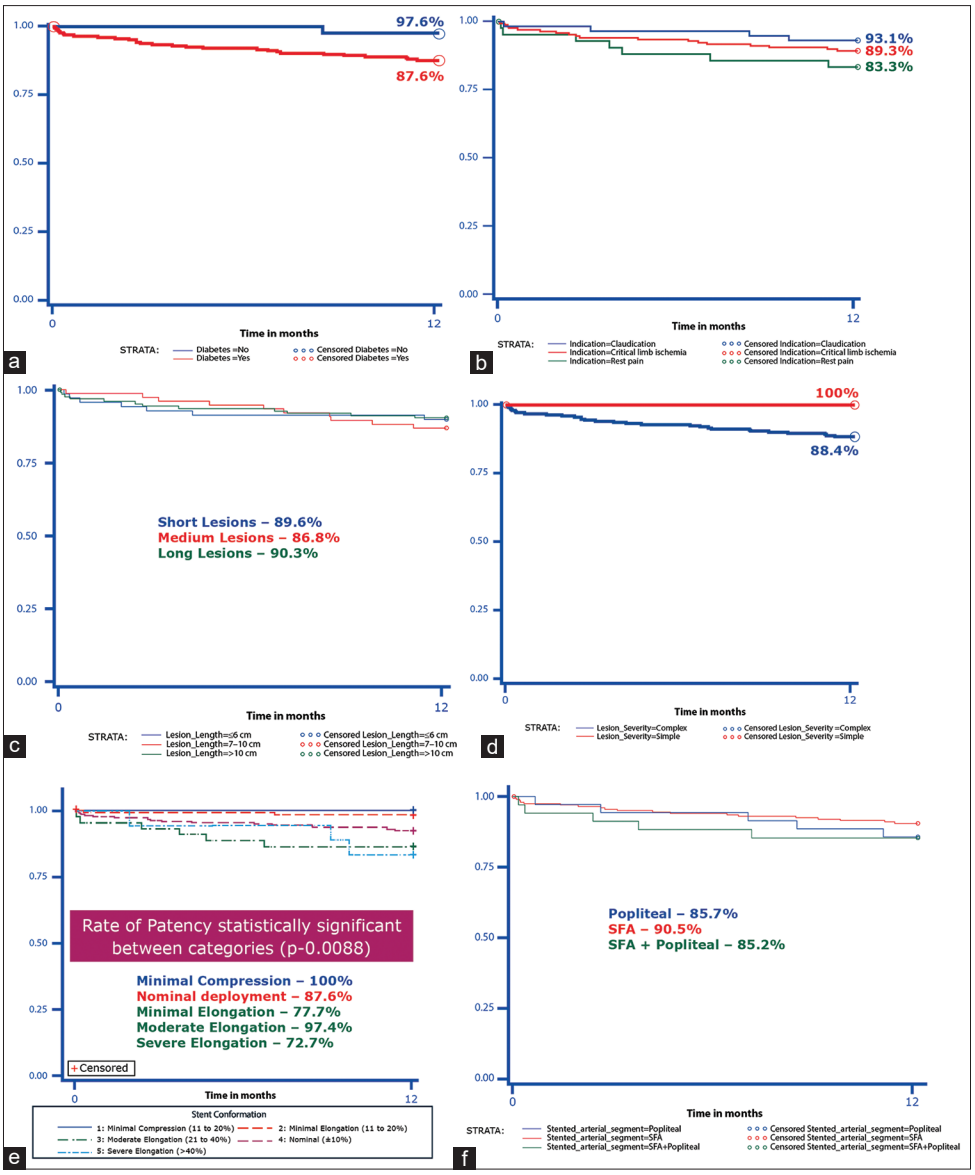
References

1. Polonsky TS, McDermott MM. Lower extremity peripheral artery disease without chronic limb-threatening ischemia: A review. JAMA 2021;325:2188-98.
2. Diamantopoulos A, Katsanos K. Treating femoropopliteal disease: Established and emerging technologies. Semin Intervent Radiol 2014;31:345-52.
3. Salamaga S, Stępak H, Żołyński M, Kaczmarek J, Błaszyk M, Stanišić MG, *et al.* Three-year real-world outcomes of interwoven nitinol supera stent implantation in long and complex femoropopliteal lesions. J Clin Med 2023;12:4869.
4. Aboyans V, Ricco JB, Bartelink ML, Björck M, Brodmann M, Cohner T, *et al.* 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European Society for Vascular Surgery (ESVS). Kardiol Pol 2017;75:1065-160.
5. AHA/ACC Guideline on the Management of Lower Extremity Peripheral Artery Disease. American College of Cardiology. Available from: https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2016/11/10/21/41/http%3a%2f%2fwww.acc.org%2flatest-in-cardiology%2ften-points-to-remember%2f2016%2f11%2f10%2f21%2f41%2fsunday-8am-2016-aha-acc-guideline-on -lepad-aha-2016. [Last accessed on 2023 Apr 03].
6. Desyatova A, Poulson W, Deegan P, Lomneth C, Seas A, Maleckis K, *et al.* Limb flexion-induced twist and associated intramural stresses in the human femoropopliteal artery. J R Soc Interface 2017;14:20170025.
7. Bhatt H, Kovach R, Janzer S, George JC. SUPERA stent outcomes in above-the-knee IntervEntions: Effects of COMPression and ELongation (SAKE-COMPEL) sub-study. Cardiovasc Revasc Med 2018;19:512-5.
8. Maleckis K, Anttila E, Aylward P, Poulson W, Desyatova A, MacTaggart J, *et al.* Nitinol stents in the femoropopliteal artery: A mechanical perspective on material, design, and performance. Ann Biomed Eng 2018;46:684-704.
9. Garcia L, Jaff MR, Metzger C, Sedillo G, Pershad A, Zidar F, *et al.* Wire-interwoven nitinol stent outcome in the superficial femoral and proximal popliteal arteries: Twelve-month results of the SUPERB trial. Circ Cardiovasc Interv 2015;8:e000937.
10. Bishu K, Armstrong EJ. Supera self-expanding stents for endovascular treatment of femoropopliteal disease: A review of the clinical evidence. Vasc Health Risk Manag 2015;11:387-95.
11. IDEV Technologies. Supera®Peripheral Stent System; 2014. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120020c.pdf. [Last accessed on 2023 Apr 04].
12. Shurtleff E, Vanderhyde M, Fitzwater F, Masoomi R, Maletsky L, Thomas P, *et al*. A novel unembalmed human cadaveric limb model for assessing conformational changes in self-expanding nitinol stents in the popliteal artery. Catheter Cardiovasc Interv 2019;93:113-9.
13. San Norberto EM, Fidalgo-Domingos LA, García-Saiz I, Taylor J, Vaquero C. Endovascular treatment of popliteal artery occlusion caused by a ruptured supera interwoven nitinol stent. Ann Vasc Surg 2019;59:308.e9-13.
14. Guzzardi G, Spinazzola A, Cangiano G, Natrella M, Paladini A, Porta C, *et al.* Endovascular treatment of femoro-popliteal disease with the Supera stent: Results of a multicenter study. J Public Health Res 2021;11:2360.
15. San Norberto EM, Flota CM, Fidalgo-Domingos L, Taylor JH, Vaquero C. Real-world results of supera stent implantation for popliteal artery atherosclerotic lesions: 3-year outcome. Ann Vasc Surg 2020;62:397-405.
16. Montero-Baker M, Ziomek GJ, Leon L, Gonzales A, Dieter RS, Gadd CL, *et al.* Analysis of endovascular therapy for femoropopliteal disease with the supera stent. J Vasc Surg 2016;64:1002-8.
17. Werner M, Paetzold A, Banning-Eichenseer U, Scheinert S, Piorkowski M, Ulrich M, *et al.* Treatment of complex atherosclerotic femoropopliteal artery disease with a self-expanding interwoven nitinol stent: Midterm results from the Leipzig SUPERA 500 registry. EuroIntervention 2014;10:861-8.
18. Nasr B, Gouailler F, Marret O, Guillou M, Chaillou P, Guyomarc'h B, *et al.* Treatment of long femoropopliteal lesions with self-expanding interwoven nitinol stent: 24 month outcomes of the STELLA-SUPERA trial. J Endovasc Ther 2023;30:98-105.
19. Gostev AA, Osipova OO, Cheban AV, Saaya SB, Rubtsun AA, Ignatenko PV, *et al.* Treatment of Long Femoropopliteal Occlusive Lesions With Self-expanding Interwoven Nitinol Stent: 24 Month Outcomes of the STELLA-SUPERA-SIBERIA Register Trial. J Endovasc Ther 2025;32:192-8.
20. Yang M, Shi B, Ma L, Yu C, Zhang X, Li T, *et al.* Treatment of atherosclerotic femoropopliteal artery disease with supera interwoven nitinol stent: A real-world study in China. Ann Vasc Surg 2022;85:183-9.
21. Dake MD, Scheinert D, Tepe G, Tessarek J, Fanelli F, Bosiers M, *et al.* Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: Twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. J Endovasc Ther 2011;18:613-23.

22. Schulte KL, Kralj I, Gissler HM, Bagnaschino LA, Buschmann I, Pernès JM, *et al.* MISAGO 2: One-year outcomes after implantation of the Misago self-expanding nitinol stent in the superficial femoral and popliteal arteries of 744 patients. J Endovasc Ther 2012;19:774-84.
23. Laird JR, Katzen BT, Scheinert D, Lammer J, Carpenter J, Buchbinder M, *et al.* Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: Twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc Interv 2010;3:267-76.
24. Gray WA, Feiring A, Cioppi M, Hibbard R, Gray B, Khatib Y, *et al.* S.M.A.R.T. Self-expanding nitinol stent for the treatment of atherosclerotic lesions in the superficial femoral artery (STROLL): 1-year outcomes. J Vasc Interv Radiol 2015;26:21-8.
25. Matsumura JS, Yamanouchi D, Goldstein JA, Pollock CW, Bosiers M, Schultz GA, *et al.* The United States StuDy for EvalUating EndovasculaR TreAtments of lesions in the superficial femoral artery and proximal popliteal by using the protégé EverfLex NitInol STent SYstem II (DURABILITY II). J Vasc Surg 2013;58:73-83.e1.
26. Innova™ Vascular. Self-Expanding Stent System. Available from: https://www.bostonscientific.com/content/dam/elabeling/pi/50723219-01A_Innova_eDFU_en-USA_s.pdf. [Last accessed on 2023 Dec 04].
27. Pulsar-18 Stent System. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160025B.pdf. [Last accessed on 2023 Dec 04].
28. Lammer J, Bosiers M, Zeller T, Schillinger M, Boone E, Zaugg MJ, *et al.* First clinical trial of nitinol self-expanding everolimus-eluting stent implantation for peripheral arterial occlusive disease. J Vasc Surg 2011;54:394-401.
29. Schillinger M, Sabeti S, Loewe C, Dick P, Amighi J, Mlekusch W, *et al.* Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med 2006;354:1879-88.
30. Krankenberg H, Schlüter M, Steinkamp HJ, Bürgelin K, Scheinert D, Schulte KL, *et al.* Nitinol stent implantation versus percutaneous transluminal angioplasty in superficial femoral artery lesions up to 10 cm in length: The femoral artery stenting trial (FAST). Circulation 2007;116:285-92.
31. Van Meirvenne E, Reyntjens P, Tielemans Y. Self-expanding interwoven nitinol stent in severe femoropopliteal arterial disease. Real life results of the supera peripheral stent system(®). Acta Chir Belg 2023;123:463-72.
32. Kronlage M, Wassmann M, Vogel B, Müller OJ, Blessing E, Katus H, *et al.* Short versus prolonged dual antiplatelet treatment upon endovascular stenting of peripheral arteries. Drug Des Devel Ther 2017;11:2937-45.
33. Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, *et al.* 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: Executive summary: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2017;135:e686-725.
34. Bonaca MP, Bauersachs RM, Anand SS, Debus ES, Nehler MR, Patel MR, *et al.* Rivaroxaban in peripheral artery disease after revascularization. N Engl J Med 2020;382:1994-2004.
35. Dalai S, Narayana RV, Pati R, Kadali M, Mazumdar A, Akkina N, *et al.* Supera stent for management of occlusive popliteal artery disease: An Indian experience. Indian J Surg 2021;83:487-94.
36. George JC, Rosen ES, Nachtigall J, VanHise A, Kovach R. SUPERA interwoven nitinol stent outcomes in above-knee IntErventions (SAKE) study. J Vasc Interv Radiol 2014;25:954-61.
37. Zibaeenezhad MJ, Sayadi M, Mohammadi SS, Khorshidi S, Hadiyan E, Rasouli N, *et al.* The impact of diabetes mellitus on clinical outcomes after percutaneous coronary intervention with different stent sizes. J Tehran Heart Cent 2022;17:207-14.
38. Singh S, Armstrong EJ, Sherif W, Alvandi B, Westin GG, Singh GD, *et al.* Association of elevated fasting glucose with lower patency and increased major adverse limb events among patients with diabetes undergoing infrapopliteal balloon angioplasty. Vasc Med 2014;19:307-14.



Supplementary Figure 1: Improvement in quality of life based on SF36 questionnaire conducted between different subgroups, (a) Male versus female, (b) Diabetes versus nondiabetes, (c) Hypertension (HTN) versus nonHTN, (d) Coronary artery disease (CAD) versus nonCAD, (e) smoking (reduced and previous) versus nonsmoking; and (f) amputation versus no amputation



Supplementary Figure 2: Kaplan–Meier analysis of patency across different subgroups, (a) Patency rate in diabetes versus nondiabetes, (b) Patency rate across different indications (critical limb ischemia, rest pain, and disabling claudication), (c) Patency rates across different lesion lengths (short lesions, medium lesions, and long lesions), (d) Patency rates between simple versus complex lesions, (e) Patency rates across different stent conformations (minimal compression, nominal, minimal elongation, moderate elongation, and severe elongation), (f) Patency rates across stented arterial segments (superficial femoral artery [SFA], SFA + popliteal, and popliteal)

Supplementary Table 1: Comparison of site versus independent reviewer assessment

Characteristics	Site assessment, *n* (%)	Independent reviewer assessment, *n* (%)
Calcification		
None	16 (5.8)	17 (6.2)
Mild	104 (37.7)	109 (39.5)
Moderate	99 (35.9)	98 (35.5)
Severe	57 (20.7)	52 (18.8)
TASC		
A	34 (12.3)	30 (10.9)
B	98 (35.5)	96 (34.8)
C	90 (32.6)	94 (34.1)
D	54 (19.6)	56 (20.3)
Vessel runoffs		
0	8 (2.9)	7 (2.5)
1	78 (28.3)	79 (28.6)
2	114 (41.3)	115 (41.7)
3	76 (27.5)	75 (27.2)
Occlusion	166 (60.1)	166 (60.1)
Stent conformation after deployment		
Nominal deployment	155 (55.4)	149 (53.9)
Compression	6 (2.2)	5 (1.8)
Elongation	117 (42.4)	122 (44.2)
Lesion length (mm), mean±SD	105.4±74.8	109.6±71.6
Diameter stenosis (%), mean±SD	91.7±19.7	91.8±16.2
Reference vessel diameter (mm), mean±SD	5.1±0.6	5.0±0.5
Minimal lumen diameter (mm), mean±SD	1.0±1.6	0.6±1.1

SD: Standard deviation, TASC: Trans-atlantic Inter-Society Consensus