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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Short-term outcomes of Solaris self-expanding covered stent in iliac artery occlusive disease: a single-center retrospective cohort

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PURPOSE

Endovascular therapy is the preferred treatment for most iliac artery lesions; however, outcomes in complex TransAtlantic Inter-Society Consensus II (TASC) C–D anatomy remain less consistent than in simpler disease. This study evaluated the short-term clinical and patency outcomes of the Solaris self-expanding covered stent in a real-world cohort of patients with iliac artery disease.

METHODS

This single-center retrospective study included 99 consecutive patients (140 iliac arteries) treated with the Solaris self-expanding covered stent between October 2023 and December 2025. Demographic, lesion, procedural, and follow-up data were analyzed. Primary patency was estimated using the Kaplan–Meier method, and TASC A–B and TASC C–D lesions were compared using the log-rank test.

RESULTS

The mean age was 63.4 ± 9.8 years, 82.8% of patients were men, and TASC C–D lesions accounted for 55.7% of treated arteries. A total of 184 covered stents were implanted, and technical success was 100%. Median follow-up was 278 days (range, 32–576 days). Estimated Kaplan–Meier primary patency was 100% at 6 months and 97.6% at 12 months, with no significant difference between TASC A–B and TASC C–D lesions (log-rank $P = 0.206$). Complete clinical improvement (Rutherford category 0) was achieved in 80.8% of patients, and 96.0% improved by at least one Rutherford category. Procedure-related complications were infrequent, and no procedure-related deaths occurred.

CONCLUSION

In a real-world cohort with a high proportion of complex iliac lesions, the Solaris self-expanding covered stent demonstrated excellent technical success, durable short-term patency, and favorable clinical outcomes.

CLINICAL SIGNIFICANCE

The Solaris self-expanding covered stent demonstrated high technical success, excellent 12-month patency, and meaningful symptom improvement in patients with iliac artery occlusive disease, including a substantial proportion of complex TASC C–D lesions. These real-world findings suggest that this device may provide a durable endovascular solution for challenging iliac anatomy while maintaining a favorable safety profile.

KEYWORDS

Iliac artery disease, peripheral artery disease, endovascular treatment, covered stent, primary patency

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Lower extremity peripheral arterial disease (PAD) affects more than 200 million individuals and contributes substantially to cardiovascular morbidity and mortality.[1] PAD may affect multiple vascular territories, among which iliac artery involvement is a common indication for endovascular treatment, most commonly using bare-metal or covered stents, whereas surgical reconstruction is generally reserved for selected anatomies or after failed endovascular treatment.[2] Long-term patency in the external iliac artery can typically be achieved with balloon angioplasty followed by stenting, whereas primary stent implantation has emerged as the preferred technique for the common iliac artery.[2]

Covered stents have demonstrated favorable safety, efficacy, and high primary patency rates in aortoiliac occlusive disease.[3] Contemporary covered stents have achieved primary patency rates exceeding 90% at midterm follow-up, even in complex aortoiliac lesions.[4] In addition, the randomized Covered Versus Balloon Expandable Stent Trial (COBEST) demonstrated significantly better short- and long-term patency with covered stents than with bare-metal stents.[5] By separating luminal blood flow from the diseased arterial wall, covered stents may reduce restenotic tissue proliferation compared with bare-metal platforms. Balloon-expandable covered stents are particularly useful when accurate ostial deployment and radial support are required, whereas self-expanding systems may better adapt to long or tortuous arterial segments. Self-expanding covered stents have therefore been increasingly used in calcified lesions and chronic total occlusions.[6] Previous studies have demonstrated favorable midterm outcomes with self-expanding covered stents in complex iliac artery disease.[7,8]

Despite this growing experience, evidence specifically addressing self-expanding covered stents in the iliac segment remains limited. In particular, published clinical data on the Solaris covered stent for iliac artery disease remain scarce. Therefore, the purpose of this study was to evaluate the procedural, clinical, and patency outcomes of the Solaris covered stent in a real-world cohort undergoing endovascular treatment for iliac artery disease, including a substantial proportion of complex lesions.

Main points

- Solaris self-expanding covered stents achieved 100% technical success in a real-world cohort of patients with iliac artery disease.
- Kaplan–Meier primary patency was 97.6% at 12 months despite 55.7% of treated iliac arteries being classified as TransAtlantic Inter-Society Consensus II C–D.
- Marked clinical improvement was observed, with complete symptom resolution achieved in 80.8% of patients and low procedure-related complication rates.

Methods

Study design and patient population

This study was approved by Ankara Bilkent City Hospital Institutional Review Board (approval number: E2-24-6194; approval date: 07.02.2024). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and its subsequent amendments. Due to the retrospective nature of the study and the use of anonymized data, the requirement for informed consent was waived by the Ethics Committee.

All consecutive patients treated with the Solaris self-expanding covered stent (Scitech Medical, Goiania, Brazil) between October 2023 and December 2025 were identified from the institutional database. Patients in whom the device was implanted at non-iliac sites, including the superficial femoral artery (n = 15), common femoral artery (n = 1), popliteal artery (n = 1), and axillary artery (n = 2), were excluded. The remaining 99 patients undergoing iliac artery intervention constituted the study population (Figure 1). All interventions were performed by a single interventional radiologist (MC) (> 20 years of experience in PAD interventions).

Lesion characteristics and procedural details were recorded on a per-lesion basis. Clinical outcomes, including Rutherford category improvement, complications, and mortality, were analyzed on a per-patient basis. In patients with bilateral interventions, each treated iliac artery was documented separately for lesion-specific analyses. Reinterventions performed after primary patency loss were recorded, and secondary patency was assessed thereafter.

Endovascular procedure

The Solaris device is a self-expanding endograft consisting of a nitinol scaffold encapsulated in a thin polytetrafluoroethylene membrane. The Solaris covered stent is compatible with a 0.035-inch guidewire and was delivered through 8F or 9F introducer sheaths according to the selected stent dimensions. Vascular access was obtained through the common femoral artery in 92 patients and through the brachial artery in 7 patients, depending on lesion anatomy and the anticipated crossing strategy. After vascular access was secured, systemic anticoagulation was achieved with intravenous unfractionated heparin. Hemodynamically significant stenosis or occlusion was confirmed using digital subtraction angiography, and lesions were crossed with a 0.035-inch guidewire and standard diagnostic or support catheters. Stent dimensions were selected according to angiographic vessel measurements and lesion morphology. Predilation was performed in severely stenotic or occluded lesions to facilitate device delivery. Postdilation was performed when residual stenosis or incomplete stent expansion was observed on completion angiography. Technical success required successful stent implantation with residual stenosis below 30% on completion angiography. Unless contraindicated, all patients received clopidogrel 75 mg daily for 6 months and lifelong acetylsalicylic acid 100 mg daily.

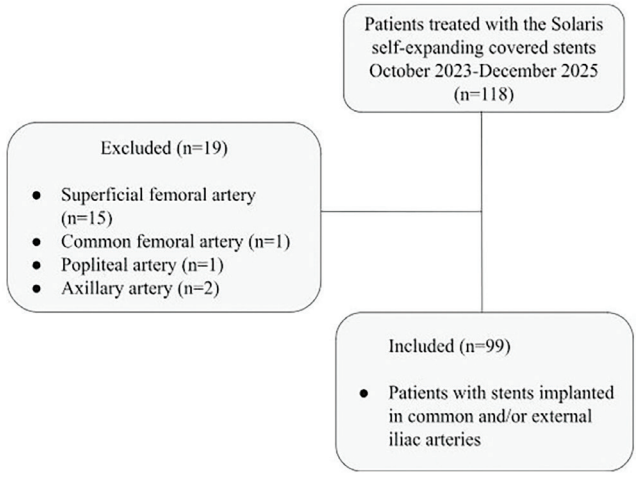

Figure 1. Patient selection flowchart.

Alternative antithrombotic regimens were used in selected patients according to individual clinical circumstances, including contraindications to dual antiplatelet therapy or preexisting indications for anticoagulation.

Definitions and follow-up

Lesion complexity was graded according to the TransAtlantic Inter-Society Consensus (TASC) II classification. Preprocedural lesion assessment was routinely performed using computed tomography angiography in conjunction with digital subtraction angiography findings obtained during the intervention. Clinical status was evaluated using the Rutherford Classification. Primary patency was defined as patency of the treated segment without reintervention, whereas secondary patency was defined as restored patency following additional endovascular intervention after primary patency loss. Follow-up evaluations were performed using clinical examination and Doppler ultrasound at approximately 6 and 12 months after the procedure. Hemodynamically significant restenosis was defined as > 50% luminal narrowing or a peak systolic velocity ratio > 2.5 on duplex ultrasonography. Computed tomography angiography was performed selectively in patients with recurrent symptoms or suspected restenosis on Doppler ultrasound. Clinical outcomes were assessed at the last available follow-up. Clinical improvement was assessed on a per-patient basis using the last available postprocedural Rutherford assessment. Procedural complications, including access-site complications, distal embolization, and contrast-induced acute kidney injury, were recorded.

Statistical analysis

Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation or median (range), whereas categorical variables were reported as frequencies and percentages. Primary patency was estimated using the Kaplan–Meier method, and patency between TASC groups was compared using the log-rank test. Kaplan–Meier estimates of primary patency were reported at 6 and 12 months. A P value < 0.05 was considered statistically significant.

Results

Baseline characteristics

Between October 2023 and December 2025, 99 consecutive patients underwent iliac artery treatment with the Solaris covered stent and were included in the analysis. The mean age was 63.4 ± 9.8 years, and 82.8% of the patients were men. Patients exhibited a high prevalence of cardiovascular risk factors (Table 1).

Lesion and procedural characteristics

A total of 140 iliac arteries were treated. Isolated common iliac artery stenting was performed in 41.4% of treated arteries, isolated external iliac artery stenting in 29.3%, and combined common and external iliac artery stenting on the same side in 29.3%. A majority (55.7%) of treated lesions were classified as complex TASC C–D lesions. Median lesion stenosis was 90% (range, 50%–100%), and median lesion length was 46.5 mm (range, 15–160 mm). A total of 184 covered stents were implanted, with a median stent diameter of 9 mm (range, 6–9 mm) and median stent length of 80 mm (range, 40–100 mm). Additional ipsilateral endovascular interventions were commonly performed because of concomitant multilevel PAD. Detailed procedural and lesion characteristics are summarized in Table 2.

Clinical and patency outcomes

Technical success was 100%. The median Rutherford category improved from 3 (range, 2–6) at baseline to 0 (range, 0–5) at the last available follow-up. Complete symptom resolution (Rutherford category 0) was achieved in 80 of 99 patients (80.8%), and 95 of 99 patients (96.0%) improved by at least one Rutherford category.

The median follow-up duration was 278 days (range, 32–576 days). Three lesions (2.1%) experienced primary patency loss at 187, 311, and 420 days after the index procedure and underwent successful repeat endovascular intervention. Secondary patency was maintained in all three lesions, which remained patent for an additional 300, 34, and 73 days, respectively, until the last follow-up. No secondary patency loss occurred during follow-up. Kaplan–Meier analysis demonstrated an estimated 12-month primary patency of 97.6% [95% confidence interval (CI), 94.5%–100.0%]. Primary patency at 12 months was 100.0% (95% CI, 95.4%–100.0%) in TASC A–B lesions and 96.2% (95% CI, 91.0%–100.0%) in TASC C–D lesions, with no significant difference between the groups (log-rank P = 0.206) (Figure 2).

Complications and mortality

Procedure-related complications were infrequent. One patient developed an access-site groin hematoma that was managed conservatively. Distal arterial embolization occurred in one patient and was successfully treated by aspiration thrombectomy during the same session. Acute kidney injury developed in two patients within the first week after the procedure, and both recovered without requiring dialysis. No procedure-related deaths occurred. During follow-up, 10 deaths were recorded, all occurring more than 30

Table 1. Baseline characteristics of the study cohort (n = 99)

Characteristic	Value
Age, years (mean ± SD)	63.4 ± 9.8
Male	82 (82.8)
Hypertension	71 (71.7)
Diabetes mellitus	56 (56.6)
Coronary artery disease	57 (57.6)
Dyslipidemia	67 (67.7)
Prior cerebrovascular event (stroke/TIA)	6 (6.1)
Hemodialysis dependent	3 (3.0)
History of lower-extremity amputation	5 (5.1)
Current smoker	66 (66.7)
Pack-years, median (range)	45 (0–125)
Baseline Rutherford category, median (range)	3 (2–6)
Post-procedural antithrombotic therapy	
ASA alone	23 (23.2)
Dual antiplatelet therapy (ASA + clopidogrel)	70 (70.7)
Anticoagulant therapy (including NOACs)	6 (6.1)

Values are presented as n (%). ASA, acetylsalicylic acid; NOAC, non-vitamin K antagonist oral anticoagulant; SD, standard deviation; TIA, transient ischemic attack.

Table 2. Patient, lesion and procedural characteristics.

Variable	Value
Patient- and procedure- level characteristics (n=99)	
Covered stents deployed, n	184
Procedure duration, min (median, range)	48 (15–168)
Femoral vascular access	92 (92.9)
Brachial vascular access	7 (7.1)
Technical success	99 (100.0)
Median follow-up, days (range)	278 (32–576)
Treatment laterality	
Left	33 (33.3)
Right	29 (29.3)
Bilateral	37 (37.4)
Lesion-level characteristics (n=140 treated iliac arteries)	
Lesion stenosis, % (median, range)	90 (50–100)
Lesion length, mm (median, range)	46.5 (15–160)
Treated segments	
Common iliac artery only	58 (41.4)
External iliac artery only	41 (29.3)
Common + external iliac (same side)	41 (29.3)
TASC II classification	
TASC A	19 (13.6)
TASC B	43 (30.7)
TASC C	33 (23.6)
TASC D	45 (32.1)
Concomitant ipsilateral procedures	
SFA balloon angioplasty, n	18
SFA stenting, n	8
Below-the-knee angioplasty, n	4
CERAB technique, n	3
Combined SFA + below-the-knee angioplasty, n	17

Categorical variables are presented as n (%) unless otherwise specified; variables explicitly labeled as "n" are presented as counts only. Continuous variables are presented as median (range). Percentages were calculated using the denominator corresponding to the respective level of analysis (99 patients or 140 treated iliac arteries).
Abbreviations: CERAB, covered endovascular reconstruction of the aortic bifurcation; SFA, superficial femoral artery; TASC, TransAtlantic Inter-Society Consensus.

days after the procedure. Causes of death included coronary events (n = 7), sepsis (n = 2), and pulmonary embolism (n = 1), and all were considered unrelated to the procedure.

Discussion

In this single-center retrospective cohort of 99 consecutive patients (140 iliac arteries) treated with the Solaris self-expanding covered stent, primary patency was 100% at 6 months and 97.6% at 12 months. Complete clinical improvement (Rutherford 0) was achieved in 80.8% of patients, and 96.0% improved by at least one Rutherford category. More than half of the treated lesions were TASC C or D, yet no statistically significant difference in primary patency was observed between TASC A–B and TASC C–D lesions (log-rank $P = 0.206$). However, this comparison was limited by the small number of primary patency loss events. Only three lesions (2.1%) required reintervention, all of which maintained secondary patency. Procedure-related complications were uncommon, and there were no procedure-related deaths.

The randomized COBEST trial of 77 patients with aortoiliac occlusive disease demonstrated that covered stents conferred superior short- and long-term patency compared with bare-metal stents, while still achieving acceptable patency rates in more advanced lesions.[5] In a propensity-matched analysis of 128 chronic iliac occlusions, midterm patency was overall comparable between bare-metal and self-expanding covered stents, but the covered group performed significantly better in long, calcified TASC D lesions.[7] The randomized Dutch Iliac Stent trial, which compared balloon-expandable covered stents with bare-metal stents in advanced common iliac disease, found broadly similar midterm outcomes between the two strategies.[9] A subsequent meta-analysis of 10 studies involving 1,695 lower extremities also reported similar 2-year limb salvage and patency rates between covered and bare-metal stents, but a significantly greater freedom from target-lesion revascularization with covered stents.[10] In the context of these previous studies, our 12-month primary patency of 97.6%, with no patency events in TASC A–B lesions and an estimated 96.2% primary patency in TASC C–D lesions, is consistent with favorable outcomes reported in contemporary covered stent series. As anticipated from the literature, the self-expanding covered platform showed numerically lower short-term primary patency in TASC C–D lesions than in TASC A–B lesions. However, only three primary patency loss events occurred during follow-up, substantially limiting the statistical power of the log-rank comparison. Therefore, the absence of a statistically significant difference should not be interpreted as evidence of equivalent performance between TASC strata.

Covered stents are frequently preferred in calcified and complex iliac artery disease because they provide a barrier between the atherosclerotic plaque and the lumen, thereby reducing neointimal hyperplasia and restenosis compared with bare-metal stents. Self-expanding covered stents differ from balloon-expandable platforms by offering greater flexibility and conformability, features that may be particularly advantageous in tortuous anatomy and long occlusions.[6] Despite a substantial proportion of complex lesions, including TASC D lesions accounting for 32.1% of treated iliac arteries and a median lesion length of 46.5 mm, technical success was achieved in all cases, and durable short-term patency was maintained. Similarly, a dedicated multicenter series evaluating self-expanding covered stents in external iliac artery disease demonstrated approximately 90% midterm primary patency even in the presence of marked calcification and vessel tortuosity.[8] Collectively, these observations support the role of self-expanding covered stents as a versatile treatment option across a broad spectrum of iliac artery anatomy.

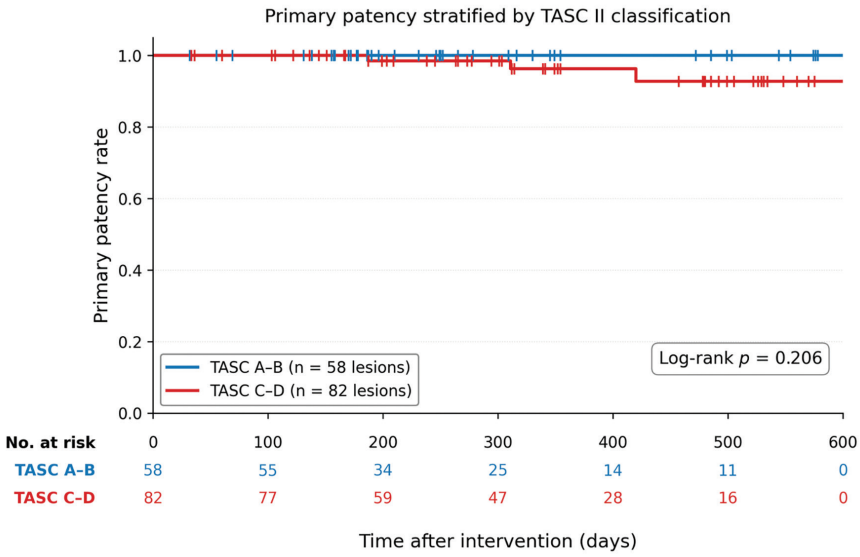

Figure 2. Kaplan–Meier estimates of primary patency stratified by TASC II lesion complexity (TASC A–B vs. TASC C–**D**). No statistically significant difference was observed between strata (log-rank $P = 0.206$). TASC, TransAtlantic Inter-Society Consensus.

Beyond patency, the degree of clinical improvement observed in this cohort is noteworthy. The median Rutherford category improved from 3 at baseline to 0 at the last follow-up, with complete symptom resolution (Rutherford 0) achieved in 80.8% of patients and improvement by at least one Rutherford category in 96.0%. These findings appear broadly consistent with the preliminary results of the European multicenter SOLARIS Peripheral Post-Market Clinical Follow-Up study, which are currently available only as a conference abstract.[11] However, the present study evaluated a larger real-world cohort with a substantially greater burden of complex anatomy, with TASC C–D lesions representing 55.7% of treated iliac arteries and TASC D lesions alone accounting for nearly one-third of all treated lesions. This distribution may more closely reflect the lesion complexity encountered in contemporary tertiary referral practice.

Another important aspect of the present study is that iliac interventions were frequently performed as part of a multilevel revascularization strategy rather than as isolated procedures. Concomitant superficial femoral artery and below-the-knee interventions were commonly required, and the Covered Endovascular Reconstruction of the Aortic Bifurcation technique was performed in selected patients.[12] This reflects the diffuse and multilevel nature of PAD routinely encountered in clinical practice, where isolated iliac disease is relatively uncommon. Despite this complexity, high technical success and favorable short-term patency outcomes were maintained, supporting the feasibility of self-expanding covered stents in complex endovascular workflows.

Procedural safety outcomes in the present cohort were acceptable and consistent with contemporary iliac intervention series. A single access-site hematoma, one distal embolization managed by aspiration thrombectomy, and two cases of contrast-associated acute kidney injury that resolved without dialysis represent a complication rate comparable to or lower than that reported in large iliac stenting cohorts.[13] No procedure-related deaths occurred despite a high cardiovascular comorbidity burden (57.6% with coronary artery disease, 71.7% with hypertension, 66.7% current smokers), and the deaths recorded during follow-up all occurred beyond 30 days and were unrelated to the procedure. These findings further suggest that self-expanding covered stents can be used safely in complex iliac artery lesions.

Several limitations should be acknowledged. First, the retrospective single-center design introduces the possibility of selection bias and residual confounding. Second, the absence of a comparator arm precludes direct comparison with bare-metal or balloon-expandable covered stents. Third, follow-up imaging was primarily based on Doppler ultrasound rather than systematic computed tomography angiography, which may have underestimated subclinical in-stent restenosis. Furthermore, the relatively small number of primary patency loss events limited the statistical power of subgroup analyses, including the log-rank comparison between TASC strata. In addition, follow-up duration was heterogeneous across the cohort because of the retrospective inclusion period, limiting the evaluation of long-term outcomes beyond 1 year. Moreover, all procedures were performed by a single experienced operator, ensuring procedural consistency; however, this may limit the generalizability of the findings to centers with different levels of operator experience. Finally, concomitant endovascular procedures performed in a substantial proportion of patients may have contributed to the observed improvement in Rutherford category, limiting the ability to attribute this finding solely to iliac revascularization. Conversely, the strengths of the study include a relatively large real-world cohort for a device-specific iliac series, single-operator standardization, lesion-level analysis with clear handling of bilateral disease, and complete capture of concomitant endovascular procedures. Larger prospective multicenter studies with longer follow-up and comparative designs are warranted to further validate the results of this study.

In this single-center retrospective cohort with a high proportion of complex iliac artery lesions, the Solaris covered stent demonstrated excellent technical and clinical outcomes, achieving 100% technical success and durable short-term primary patency of 97.6% at 12 months. Patency outcomes were favorable despite the high proportion of TASC C–D lesions, with low reintervention and complication rates and no procedure-related deaths. In addition, substantial clinical improvement was observed, with a marked reduction in Rutherford category across the cohort. These findings suggest that the Solaris covered stent may represent a feasible and durable option for complex iliac artery interventions.

Footnotes

Conflict of interest disclosure

The authors declared no conflicts of interest.

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