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ORIGINAL ARTICLE

PERIPHERAL ARTERIAL DISEASE

Ad-interim 6- and 12-month results from a prospective multicenter investigation on Renzan Stent in the treatment of patients with femoro-popliteal disease in Tuscany (CURRENT Registry)

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ABSTRACT

Background: The CURRENT registry is a prospective, multicenter, real-world investigation designed to evaluate the safety and effectiveness of the Renzan™ stent (Terumo MicroVention Inc., Aliso Viejo, CA, USA) in patients with femoro-popliteal peripheral artery disease (PAD), including complex lesions and chronic limb-threatening ischemia (CLTI). This study reports the interim outcomes at 6 and 12 months.

Methods: A total of 89 patients with symptomatic PAD (Rutherford category IV-V 64.1%) were enrolled across three centers in Tuscany, Italy. All patients underwent endovascular treatment with the Renzan™ dual-layer interwoven nitinol stent. Baseline and follow-up assessments included clinical evaluation and duplex ultrasound imaging. The primary safety endpoint was the composite rate of all-cause death, target lesion revascularization (TLR), and major amputation at 30 days. The primary efficacy endpoint was primary patency at 6 months. Estimated patency and reintervention rates were reported at 12 months using Kaplan-Meier analysis.

Results: Technical and procedural success was achieved in 100% of cases. At 30 days, no deaths, TLRs, or

major amputations occurred. At 6 months, the composite safety endpoint was met in 94.3% of patients. Primary patency was 100% at 1 and 3 months, 92.0% at 6 months, and declined to 78.7% (95% CI: 55.3-88.1%) at 12 months. Freedom from TLR was 97.2% at 6 months and 78.5% (95% CI: 63.7-88.7%) at 12 months. Exploratory multivariable analysis identified diabetes mellitus, previous peripheral endovascular intervention, and below-the-knee involvement as independent predictors of loss of patency, whereas dual antiplatelet therapy beyond 1 months was associated with a reduced risk of patency loss.

Conclusions: The Renzan™ stent demonstrated excellent early safety and efficacy outcomes in a challenging PAD population, with sustained mid-term patency despite a high proportion of complex lesions. These preliminary results support the use of this new mimetic stent design in real-world clinical settings and warrant further confirmation with longer-term follow-up.

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Key words: Peripheral arterial disease; Stents; Chronic limb-threatening ischemia; Endovascular procedures.

Introduction

Peripheral artery disease (PAD) involving the femoro-popliteal segment is a common cause of morbidity, especially in elderly patients with cardiovascular risk factors. Endovascular treatment has emerged as the first-line approach for most cases of femoro-popliteal disease, including chronic limb-threatening ischemia (CLTI).[1, 2] However, restenosis and stent failure remain a significant challenge due to biomechanical stress, anatomical curvature, and calcification that characterize this vascular segment despite optimal medical management.[3, 4]

Over the past decade, the development of drug-eluting technologies[5] has improved patency rates, but up to 30% of complex lesions often require adjunctive stenting due to suboptimal outcomes with drug-coated balloons alone.[5] In this setting, interwoven nitinol stents have been proposed to offer enhanced mechanical resistance, fracture durability, and flexibility.[6] Among them, the Renzan™ stent (Terumo MicroVention Inc., Aliso Viejo, CA, USA) is a novel peripheral platform composed of two layers of tubular braided nitinol wire mesh, designed specifically for femoro-popliteal anatomy.

The CURRENT registry (A ProspeCtive mUlticenteR investigation on RENzan stent safety and efficacy in the treatment of patients with femoro-popliteal disease in Tuscany, Clinicaltrials.gov ID: NCT05701293) was designed to collect real-world data on the use of the Renzan™ stent in patients with symptomatic PAD, with very few exclusion criteria. The present study reports the first clinical outcomes at 6 months and the estimated outcomes at 1 year, including safety and efficacy endpoints, from the CURRENT registry.

Materials and methods

Study design and population

The CURRENT registry is a prospective, single-arm, post-market, multicenter observational cohort study conducted in Tuscany, Italy, with a predefined protocol and structured clinical and imaging follow-up schedule designed to systematically evaluate the safety and effectiveness of the Renzan™ Peripheral Stent System (Terumo MicroVention Inc., Aliso Viejo, CA, USA) in real-world clinical practice for the treatment of patients with femoro-popliteal artery disease.

Eligible patients were adults with Rutherford-Becker category 2 to 5 PAD undergoing endovascular treatment with the Renzan™ stent. Patients with unstable clinical conditions or those unable to adhere to follow-up protocols were excluded.

Anatomical inclusion criteria for the CURRENT registry were designed to reflect real-world clinical practice while ensuring appropriate conditions for Renzan™ stent deployment. Eligible lesions were located in the common femoral, superficial femoral, and/or popliteal arteries, with angiographic evidence of ≥50% stenosis or total occlusion. There were no predefined lesion length limits, and both de novo and restenotic lesions, including cases of

in-stent restenosis, were eligible for treatment, provided that the reference vessel diameter ranged between 4.0 mm and 8.0 mm based on visual assessment. Multiple Renzan stents could be used, when necessary, with a mandatory overlap between stents of 0.5 to 1 cm.

A patent inflow artery was required, with no significant stenosis (defined as <50%) at the iliac level. In cases where ipsilateral iliac lesions were present, inclusion was permitted only if successful endovascular treatment of the inflow was achieved, defined as residual stenosis ≤30% after percutaneous transluminal angioplasty (PTA) or stenting. Target lesions had to be crossable with a guidewire and dilatable up to a 1:1 ratio with the planned stent diameter, based on the operator's judgment.

Adequate distal runoff was also mandatory: at least one native tibial artery (anterior tibial, posterior tibial, or peroneal) had to be patent and free from significant stenosis (≥50%) on angiographic evaluation, without prior revascularization. Additional revascularization of the remaining tibial arteries during the same procedure was permitted, if clinically indicated.

Each patient was examined regarding their anamnestic features, medications, and procedural details. The most common comorbidities included: coronary artery disease (a history of coronary artery-related events, with or without surgical or endovascular interventions), hypertension (blood pressure exceeding the guideline cutoff or use of antihypertensive medication), diabetes mellitus (defined by an occasional plasma glucose value of 200 mg/dL [11.1 mmol/L], fasting plasma glucose of 126 mg/dL [7.0 mmol/L] [fasting 8 to 12 hours], or a 2-hour oral glucose tolerance test value in venous plasma of 200 mg/dL [11.1 mmol/L], or through use of insulin or antidiabetic drugs), chronic obstructive pulmonary disease (diagnosed as chronic bronchitis, emphysema, classical asthma, or a combination of these), chronic kidney disease (defined as chronic renal insufficiency with serum creatinine >1.2 mg/dL), smoking history (any current or past regular tobacco use), congestive heart failure, history of cerebrovascular events (stroke and/or transient ischemic attacks), history of malignancy (any current or past diagnosis), dyslipidemia, and atrial fibrillation.

Lesion morphology and calcification was assessed angiographically during the index procedure using native fluoroscopy and contrast angiography. Calcification severity was graded according to the Peripheral Arterial Calcium Scoring System (PACSS). For the purposes of this analysis, lesions with PACSS grades 1-4 were considered calcified, while PACSS grade 0 lesions were classified as non-calcified.

Device description

The device under investigation is the Renzan™ Peripheral Stent System from Terumo MicroVention Inc. (35 Enterprise, Aliso Viejo, California 92656, USA).

The System consists of a self-expanding nitinol stent pre-mounted on the distal portion of a rapid exchange delivery catheter. The stent is made of a nickel-titanium alloy with radiopaque markers on each end of the stent. The nitinol stent is constructed from 2 layers of tubular braided nitinol wire mesh. The outer layer consists of nitinol wire braided into a closed cell structure with flared ends. The inner layer consists of nitinol wire braided into a closed cell structure with micro-sized pores (300-400 μm).

The delivery catheter has a rapid exchange port designed to allow coaxial passage of a 0.46 mm (0.018") or smaller guide wire in diameter. The stent is capable of being recaptured when a minimum of 20mm of stent length remains inside the catheter. Figure 1 shows a case of Renzan stent implantation at the level of a popliteal occlusion.

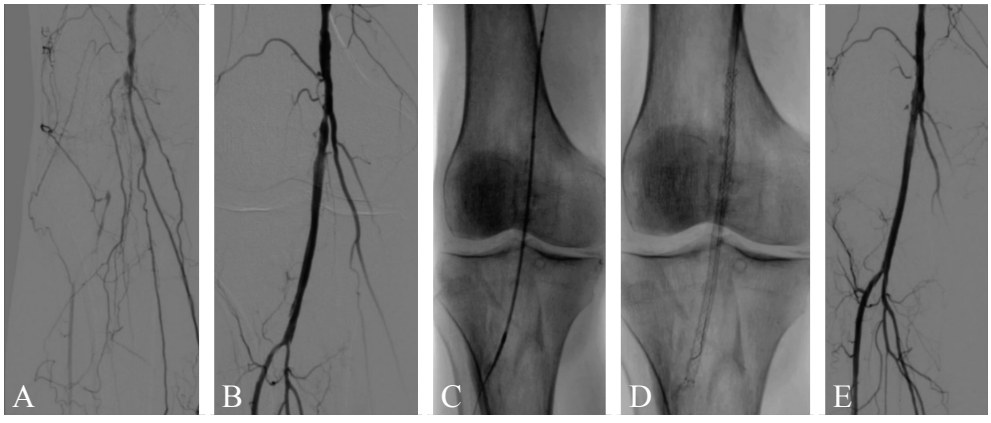

Figure 1.—Case of Renzan implantantion in occluded popliteal artery. A) Initial angiography highlighting long complete occlusion of popliteal artery; B) angiography after recanalization and adequate vessel preparation; C) advancement of Renzan stent; D) Renzan stent deployment; E) final angiography revealing the patency of the stent implanted and below-the-knee arteries.

Data collection and follow-up

Clinical data will be collected at patient enrollment, procedure, discharge, planned follow-up (1, 6, 12, 24, 36 months post-procedure), unplanned or interim follow-ups, and patient death.

Moreover, operator feedback was systematically collected using a standardized evaluation form completed by the treating physician immediately after each procedure. The assessment included key device performance characteristics such as pushability, trackability, deployment ease, fluoroscopic visibility, and placement accuracy, using predefined qualitative rating categories.

Patients should adhere to a follow-up visit time restriction of±14 days for the 1-month follow-up; ±45 days for the 6, and 12-month follow-up visits, and±60 days for the 24- and 36-month follow-up visits.

Duplex scanning will be performed during clinical visit with particular attention to the registration of the Peak Systolic Velocities (PSV) recorded at 3 locations: 1 cm proximal to the treated area, within the treated area at the level of the highest PSV and at 1 cm distal to the treated area. The grading of the stenosis is based on the ratio between the proximal most normal PSV waveform (PSV prox) and the PSV in the stenosis (PSV intrastenotic) and is defined as the proximal peak velocity ratio (PSVR). In case of more than one Renzan stent implanted, a further record of PSV value has to be registered at the level of every overlapping zone.

The present analysis includes the entire cohort enrolled and treated during the study period. All patients completed the scheduled follow-up with no losses to follow-up and withdrawals. Time-to-event analyses beyond 6 months reflect censoring related to ongoing follow-up rather than incomplete data. Patency and restenosis were evaluated using PSVR, with a threshold of ≥2.4 considered indicative of ≥50% restenosis.[7] Clinical events, including death, target lesion revascularization (TLR), and major amputation, were recorded.

Study endpoints

The primary safety endpoint of the study was defined as a composite of all-cause mortality, TLR, and major amputation above the ankle, all occurring within 30 days of the index procedure. The primary efficacy endpoint was the rate of primary patency at 6 months, which was defined as the absence of restenosis, indicated by a peak systolic velocity ratio of less than 2.4, and the absence of clinically driven TLR.

Target limb revascularization (non-lesion related) was defined as any repeat endovascular or surgical revascularization performed in the target limb but outside the originally treated arterial segment, and therefore not meeting the criteria for TLR. In addition to these, secondary endpoints included device success, technical success, and procedural success, as well as clinical improvement reflected by a change in Rutherford category. Other key secondary outcomes were freedom from major adverse events (MAEs) and the absence of stent fracture or migration during follow-up.

Since the CURRENT Registry was designed as a prospective, observational study conducted in the context of routine clinical practice using a CE-marked device, formal approval from the local ethics committees was not required. However, in accordance with national regulations and good clinical practice, all participating centers notified their respective ethics committees of the ongoing data collection for research purposes. The study was conducted in full compliance with the principles of the Declaration of Helsinki, and all patients provided written informed consent prior to enrolment.

Statistical analysis

Continuous data were shown as mean values±standard deviation. Categorical variables were expressed as fractions. Analysis of variance was used for independent tests to compare groups on continuous variables after demonstrating a normal distribution of the data. The Kaplan-Meier method was used to create survival curves to evaluate primary patency, freedom from TLR and freedom from any reintervention.

An exploratory multivariable Cox proportional hazards regression analysis was performed to evaluate potential predictors of loss of primary patency. Clinically relevant baseline and lesion-related variables were entered into the model, and results were expressed as hazard ratios (HR) with corresponding 95% confidence intervals (CI). Given the limited number of events and the interim nature of the analysis, this model was considered hypothesis-generating.

All statistical analyses were performed with GraphPad Prism 10.1.1 (GraphPad Software Inc,

San Diego, CA, USA) and Jamovi 2.3.18.0 (Sydney, Australia).

Results

A total of 89 patients were enrolled and treated in the CURRENT registry during the study period, and all completed the 6-month follow-up, with no losses to follow-up

or early withdrawals. The mean age was 73.7±12 years, and the majority were male (N.=59, 66.3%).

Most patients had a high burden of cardiovascular comorbidities. Hypertension was present in 85.4%, dyslipidemia in 84.3%, and diabetes mellitus in 52.8%. Notably, chronic kidney disease was reported in 28.1% of patients, and atrial fibrillation in 18%. Obesity was identified in 14.6%. In terms of smoking status, 29.2% were current smokers, while 47.2% were former smokers. Regarding previous vascular history, 27% had undergone prior peripheral artery interventions, and 27% had undergone coronary revascularization. Prior cerebrovascular intervention was reported in 9%. The full details of baseline population characteristics are listed in Table I.

At presentation, the distribution of Rutherford classification was as follows: category III (36%), IV (18.0%), and V (46.1%), indicating a population with predominantly advanced symptomatic PAD.

At baseline, single antiplatelet therapy was prescribed in 52 patients (58.4%), dual antiplatelet therapy in 21 (23.6%), and direct oral anticoagulants in 17 (19.1%). Statin therapy was used in 66 patients (74.2%), and cilostazol in 9 patients (10.1%).

Table I.—*Baseline characteristics of study population.*

Variables	Total population (N.=89)
Age (years) (mean±SD)	73.7±12
Male (N., %)	59 (66.3%)
Smoking habit (N., %)	
Active	26 (29.2%)
Former	42 (47.2%)
Hypertension (N., %)	76 (85.4%)
Diabetes mellitus (N., %)	47 (52.8%)
Chronic kidney disease (N., %)	25 (28.1%)
Obesity (N., %)	13 (14.6%)
Dislypidemia (N., %)	75 (85.4%)
Atrial fibrillation (N., %)	16 (17.9%)
Previous peripheral artery endovascular intervention (N., %)	24 (26.9%)
Previous coronary intervention (N., %)	24 (26.9%)
Previous cerebrovascular intervention (N., %)	8 (9.0%)
Drugs at admission (N., %)	
SAPT	52 (58.4%)
DAPT	21 (23.6%)
LWMH	5 (5.6%)
DOAC	17 (19.1%)
Statin	66 (74.1%)
Cilostazol	9 (10.1%)
Rutherford's grade at admission (N., %)	
III	32 (36%)
IV	16 (17.9%)
V	41 (46.1%)

SD: standard deviation; SAPT: singke antiplatelet therapy; DAPT: double antiplatelet therapy; LWMH: low molecular weight heparin; DOAC: direct anticoagulant.

Lesion and procedural characteristics

Endovascular procedures were performed via percutaneous access in 92.1% of cases (N.=82), while contralateral access (cross-over technique) was required in 39.3% (N.=35). Inflow lesions were noted in 5 patients (5.6%). Below-the-knee (BTK) involvement was observed in 55% of patients (N.=49), often necessitating multilevel revascularization.

Most treated lesions were de novo (78.7%), with a mean lesion length of 123.9±78.0 mm. The proximal reference vessel diameter averaged 5.7±0.5 mm. Chronic total occlusions (CTOs) were frequent, observed in 69.7% of cases, with a mean occlusion length of 106.8±81.5 mm. Lesions were calcified in 67.4% of patients.

Lesions were most frequently multilevel: proximal Superficial femoral Artery (SFA) was involved in 24.7%, mid SFA (57.3%), and distal SFA in 61.8%. The popliteal artery was also frequently involved: P1 in 37.1%, P2 in 22.5%, and P3 in 9.0%.

Calcification severity, assessed using the PACSS, showed that 32.6% of lesions were grade 0, while grade 1 was observed in 18.0%, grade 2 in 20.2%, grade 3 in 17.0%, and grade 4 in 12.2% of lesions, indicating a substantial prevalence of moderate-to-severe calcified disease within the study population.

Predilatation was performed in 100% of cases, including the use of a non-compliant high-pressure balloon in 70% and intravascular lithotripsy (IVL) in 13.5%.

In detail, IVL was used in case of patients presenting with moderate-to-severe angiographically calcified lesions (PACSS 3-4). IVL was performed as a vessel preparation strategy to modify vessel compliance and facilitate optimal stent expansion and apposition in heavily calcified segments. In these cases, stent implantation was performed as part of the planned revascularization strategy following IVL.

A successful RENZAN deployment was achieved in 89/89 (100%) of procedures.

A single Renzan™ stent was implanted in 73% of patients, while 19.1% received two stents (17 cases) and 7.9% required three (7 cases). Post-dilatation was performed in 89.8% of cases. Only one patient (1.1%) had a residual stenosis >30% after the index procedure. BTK revascularization during the index procedure was performed in 30 patients (33.7%).

Intraoperative complications occurred in 2 cases (2.5%), neither of which was stent-related. Specifically, one case involved femoral access bleeding, controlled with manual compression, and another experienced distal embolization

Table II.—*Procedural features.*

Variables	Total Population (N.=89)
Contralateral vascular access (cross-over procedure) (N., %)	35 (39.3%)
Percutaneous access (N., %)	82 (92.1%9
Inflow lesion (N., %)	5 (5.6%)
Lesion localization (N., %)	
CFA	3 (3.4%)
SFA proximal	22 (24.7%)
SFA medium	51 (57.3%)
SFA distal	55 (61.8%)
Popliteal artery P1	33 (37.1%)
Popliteal Artery P2	20 (22.5%)
Popliteal Artery P3	8 (9.0%)
BTK involvement (N., %)	49 (55.1%)
De novo lesion (N., %)	70 (78.6%)
Lesion length (mm) (mean±SD)	123.9±78
Proximal reference vessel diameter (mm) (mean±SD)	5.7±0.5
Chronic total occlusion (N., %)	62 (69.7%)
Lenght of the occlusion (mm) (mean±SD)	106.8±81.5
Calcified lesion (N., %)	60 (67.4%)
PACSS 1-2	34 (38.2%)
PACSS 3-4	26 (29.2%)
Predilatation with standard PTA (N., %)	89 (100%)
Intra-vascular lithotripsy	12 (13.5%)
Non-compliant balloon	62 (70%)
Stent positioned (N., %)	
Single	65 (73.0%)
Double	17 (19.1%)
Triple	7 (7.8%)
Post-dilatation needed (N., %)	52 (58.4%)
Residual stenosi >30%	1 (1.1%)
BTK revascularization during the index procedure (N., %)	30 (33.7%)
Additional retrograde approach	6 (6.7%)
Procedure duration (minutes) mean±SD)	98.1±61.4
Scopy time (minutes) (mean±SD)	27.2±20.6
contrast medium (ml) (mean±SD)	73.2 ±43.8

SD: standard deviation; CFA: common femoral artery; SFA: superficial femoral artery; BTK: below-the-knee.

Table III.—*Operator's feedback of the device performance.*

Variables	Total population (N.=89)
Pushability/Trackability (N., %)	
High	84 (94.4%)
Medium	5 (5.6%)
Deployment maneuver (N., %)	
Easy	77 (86.5%)
Some difficulties	12 (13.5%)
Visibility (N., %)	
High	84 (94.4%)
Medium	5 (5.6%)
Precision during deployment (N., %)	
High precision	81 (91.0%)
Medium precision	8 (9.0%

Table IV.—*Postoperative variables.*

Variables	Total population (N.=89)
Hospitalization (days) (mean±SD)	3.8±3.5
Vascular access complications (N., %)	3 (3.4%)
Drugs at discharge	
SAPT	4 (4.5%)
DAPT	77 (86.5%)
ASA+low-dose rixaroban	4 (4.5%)
Cilostazol	4 (4.5%)

SD: standard deviation; SAPT: singke antiplatelet therapy; DAPT: double antiplatelet therapy; ASA: acetylsalicylic acid.

during recanalization maneuvers, which was managed with mechanical thromboaspiration, with no reported need for further bailout surgery. The mean procedural time was 98.1±61.4 minutes, fluoroscopy time averaged 27.2±20.6 minutes, and the mean volume of contrast medium was 73.2±43.8 mL (Table II).

Operator feedback on device performance

Operator experience with the Renzan™ stent was consistently positive across most technical aspects of the procedure. Pushability and trackability were rated as high in most cases, with 84 out of 89 procedures (94.4%) receiving top ratings. Only five operators' experiences were described a medium-level in this regard. The deployment maneuver was generally described as smooth and intuitive, with 77 operators (86.5%) reporting it as easy to perform, while a minority (13.5%) experienced some degree of difficulty during deployment. Of note, no cases of excessive force applied during intraoperative deployment were recorded. Visibility of the device under fluoroscopy was also rated highly, reflecting the effective positioning of radiopaque markers at both ends of the stent. High visibility was reported in 94.4% of the procedures. Precision during stent placement was another favourable feature, with 81 operators (91%) indicating high confidence in deployment accuracy (Table III).

Postoperative course and discharge therapy

The postoperative course was generally uneventful. The average length of hospital stay following the procedure was 3.8±3.5 days. Vascular access site complications were reported in three cases (3.4%), with no major systemic or bleeding events requiring escalation of care. At discharge, many patients, 77 out of 89 (86.5%), were discharged on dual antiplatelet therapy. Single antiplatelet therapy was prescribed in four patients (4.5%), typically in cases with higher bleeding risk or contraindications to the double. Another four patients (4.5%) were treated with the combi-

nation of aspirin and low-dose rivaroxaban (2.5 mg BID), a strategy increasingly adopted in PAD patients at high ischemic risk. Cilostazol was prescribed in four patients (4.5%) as an adjunctive agent (Table IV).

Safety outcomes and major adverse events

The Renzan™ stent demonstrated an excellent short- and mid-term safety profile in the CURRENT registry population. At 30-day follow-up, none of the patients experienced the composite primary safety endpoint, which included all-cause death, TLR, or major amputation of the index limb. Consequently, the primary safety endpoint at 30 days was 100% (89 out of 89). Within the first 30 days, five patients (5.6%) experienced a MAE. These included two cases of stent thrombosis (one managed with clinically driven reintervention at 2 months and one treated conservatively), one target limb revascularization unrelated to the index lesion, and two major bleeding events requiring blood transfusion. No deaths or major amputations were observed.

At 6 months, the composite primary safety endpoint remained favorable, with 84 out of 89 patients (94.3%) free from death, TLR, or major amputation. However, a modest increase in adverse events was observed over time: a total of 16 patients (18%) experienced at least one MAE within 6 months. During this period, three clinically driven target lesion revascularizations were recorded at 2, 2, and 4 months, while two deaths occurred at 2 and 3 months. No major amputations of the index limb were documented.

Freedom from major adverse events at 6 months was achieved in 73 of 89 patients (82%). A total of eight stent thromboses (8.9%) were reported between 1 and 6 months; three were managed with repeat endovascular reintervention and five were treated conservatively. Additionally, six target limb revascularizations unrelated to the treated segment (6.7%) and two major bleeding events requiring transfusion (2.2%) were observed.

Medium term outcomes

Primary patency at 1 and 3 months was 100% and 94.4% respectively. At 6 months, patency remained high at 92.0%. At 12 months, the Kaplan-Meier estimated primary patency declined to 78.7% (Figure 1).

The analysis of PSV values at overlapping areas did not reveal any significant increase either in the patent stents or in the case of restenosis. In particular, in the case of stent restenosis in patients who received more than one stent (N.=3), the significant increase of PSVR was at the proximal edge in one case, at the distal edge in 1 case, and along the entire stent's length, including the overlapping segment, in the remaining one.

Freedom from TLR was very high in the early phases, reaching 100% at 1 month and 98.7% at 3 months. At 6 months, the Kaplan-Meier estimate remained favorable at 97.2%. A further decline was observed thereafter, with freedom from TLR estimates of 78.5% at 12 months with a Standard Error (SE) <10% (Figure 2).

The rate of freedom from any reintervention mirrored the TLR results. At 1 and 3 months, freedom from reintervention was 100% and 96.2%, respectively. At 6 months, the estimate remained 93.2%, while at 12 months the estimate decreased to 72.2% (SE <10%) (Figure 3).

Exploratory predictors of loss of primary patency

An exploratory multivariable Cox proportional hazards regression analysis was performed to evaluate potential predictors of loss of primary patency. In the model, diabetes mellitus (HR 2.42; 95% CI 1.34-7.53; P=0.04), previous peripheral endovascular intervention (HR 2.59; 95% CI 1.65-5.21; P=0.04), and BTK involvement (HR 3.78;

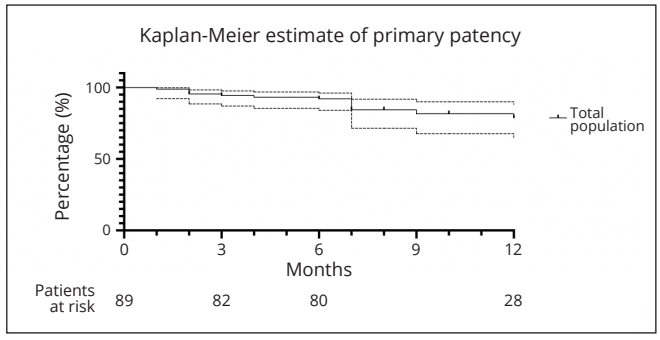

Figure 2.—Kaplan-Meier estimates curves highlighting primary patency.

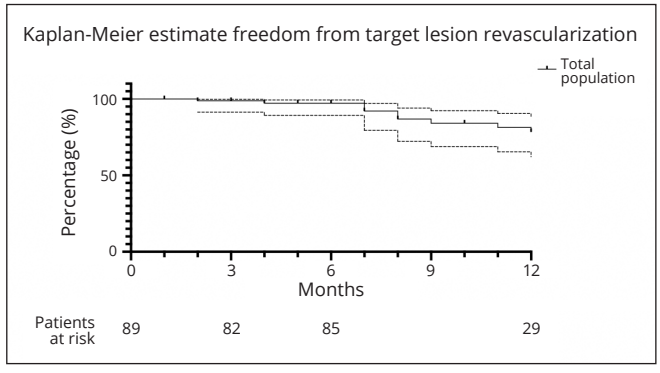

Figure 3.—Kaplan-Meier estimates curves highlighting freedom from target lesion revascularization.

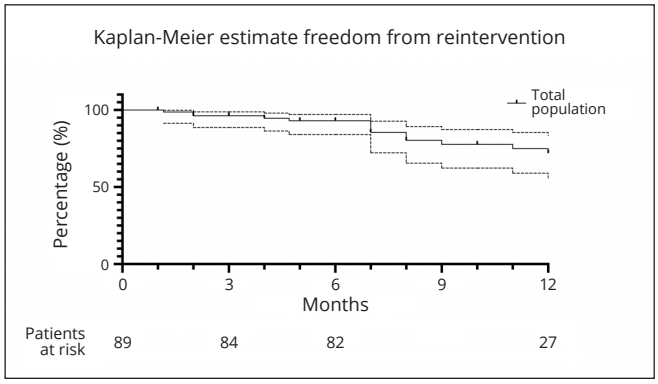

Figure 4.—Kaplan-Meier estimates curves highlighting freedom from any reintervention.

95% CI 1.23-6.61; P=0.04) were independently associated with loss of patency, whereas dual antiplatelet therapy beyond 1 month was associated with a reduced risk of loss of patency (HR 0.85; 95% CI 0.65-0.95; P=0.04). Other variables, including lesion length >150 mm, severe calcification (PACSS 3-4), and chronic total occlusion, showed non-significant trends toward higher risk (Table V).

Discussion

The present CURRENT prospective registry provides innovative and significant clinical data on the effectiveness of the Renzan stent for the endovascular treatment of patients with femoro-popliteal lesions.

Endovascular treatment for complex femoro-popliteal lesions has significantly advanced over the past few decades. Over time, stents have proven to be an essential aid in improving outcomes of less-than-ideal angioplasty procedures, despite various setbacks and their intrinsic limitations. However, most stents, regardless of their coatings, encounter considerable challenges. Although advancements in alloy composition and drug-eluting coatings have led to better clinical results, the constant mechanical stresses endured by stents in the femoro-popliteal segment led to complications such as stent compression and fracture, resulting in a persistently high risk of patency loss. The traditional design of self-expanding laser-cut nitinol stent for the femoro-popliteal area has been made by the crown of the stent with various strut alignments, including peak-to-peak or peak-to-valley connection, evolved to helical linking bridges or full helical stent designs.[8]

A different design has been offered by stents constructed from multiple nitinol wires braided or interwoven together, which creates a flexible and strong structure. Till the launch of the Renzan stent in 2024, the Supera™ Peripheral Stent System (Abbott Vascular, Santa Clara, CA, USA) has been the only interwoven nitinol stent on the market. The Supera was launched in Europe in 2010, and it has been without competitors, proving to be not only quite

Table V.—*Multivariable analysis for loss of patency.*

Variables	HR	95% CI	P value
Age	1.45	0.67-5.16	0.1
Male	1.31	0.45-3.28	0.2
Smoking habit before index procedure	1.56	0.56-6.90	0.6
Hypertension	0.96	0.34-1.67	0.8
Diabetes mellitus	2.42	1.34-7.53	0.04
Chronic kidney disease	2.89	0.56-9.45	0.2
Obesity	0.95	0.56-4.95	0.6
Dislypidemia	1.59	0.82-3.71	0.15
Atrial fibrillation	0.76	0.41-1.97	0.4
Previous peripheral artery endovascular intervention	2.59	1.65-5.21	0.04
Previous coronary intervention	1.45	0.78-2.49	0.2
Previous cerebrovascular intervention	2.67	0.34-6.41	0.7
Rutherford's grade at admission IV-V	2.93	0.77-7.12	0.1
Inflow lesion	1.34	0.56-2.45	0.6
BTK involvement	3.78	1.23-6.61	0.04
De novo lesion	0.67	0.34-1.89	0.4
Lesion length >150 mm	2.37	0.86-4.11	0.1
Chronic total occlusion	1.56	0.45-3.59	0.2
PACCS 3-4	1.74	0.67-4.28	0.1
Two or more stents implanted	1.90	0.49-4.21	0.3
Dual antiplatelet therapy beyond >1 months	0.85	0.65-0.95	0.04

HR: hazard ratio; CI: confidence interval; BTK: below-the-knee; PACSS: peripheral arterial calcium scoring system.

flexible and conformable to the artery's natural curves and movements, but also quite resistant to external compression better than some traditional stent designs. This property has been particularly remarkable in the case of calcified lesions or in subintimal recanalization. The novel design and the design characteristics, consistent with expectations, have contributed to improved clinical outcomes, as reported in the literature.

In 2022, a systematic review was published,[9] including data from 2011 up to 2021 regarding seventeen studies assessing the safety and efficacy of the Supera interwoven nitinol stent, for a total of 2015 patients (mean lesion length of 137.2 mm were included, 44.9% femoropopliteal artery and 37.4% popliteal artery involvement, chronic total occlusions 49%). Pooled primary patency and freedom from TLR rates at 1 year are 83.5% and 90.3% respectively. The smoothed hazard ratio estimate indicated that the risk of losing primary patency reached its peak between 4 and 5 months, whereas the risk of TLR was highest between 7 and 8 months following the intervention.

More recently, the SUPERSUB II study, a multicenter prospective observational study, evaluated the early and long-term effectiveness of the Supera stent after subintimal recanalization of femoro-popliteal artery occlusion.[10] In 92 patients, a technical and procedural success of 100% and 98% was reported. At 12 and 24 months, the freedom from clinically driven TLR and the primary patency resulted in 94, 93% and 90, 87%, respectively. These favorable outcomes were further corroborated by some recent studies[11, 12] which reported very promising primary patency rates at 1 and 6 months with a slight decrease observed during longer follow-up.

More recently, a multicenter study conducted across 20 centers[13] demonstrated a 89.2% of maintained primary patency at 12 months among 284 patients, while the STELLA-SUPERA-SIBERIA Study,[14] building upon and providing a more in-depth analysis of the previous study,[15] reported primary patency rates of 78.1% and 60% at 12 and 24 months, respectively.

The Renzan stent was launched in the European market in March 2024. It is essentially modelled after Terumo's successful Roadsaver™ carotid stent, but with modifications to the flared ends, lengths, and delivery platform. The outer layer uses an interwoven stent design, while the inner layer consists of a nitinol micromesh, also interwoven. This combination offers the advantage of flexibility, low chronic outward forces, good radial resistance force, and crush resistance combined with strong protection against distal embolization.

To date, no studies on the Renzan device have been published, and its clinical performance remains under investigation. The PRIZER trial, a prospective, multicenter post-marketing study designed to evaluate the Renzan stent in femoropopliteal lesions, planned to enroll approximately 135 patients and is currently ongoing.[16] Its results are expected to provide valuable evidence on the performance of the Renzan stent. Some 6- and 12-month preliminary data have been presented as an oral presentation at an international meeting, revealing promising results, although still unpublished.

In the present CURRENT registry, the Renzan™ stent showed outstanding early and mid-term patency and safety, comparable to the Supera device. Stent deployment was successful, with 100% and no intraprocedural complications occurred, including the absence of distal embolization. Notably, the nearly complete early patency (92.0% at 6 months) and high freedom from TLR align with the best-in-class performance seen in contemporary interwoven nitinol devices. The 12-month decline to 78.7% reflects the known challenge of long-term durability in highly calcified, tortuous, or chronic total occlusion-laden lesions. Indeed, most reinterventions occurred in patients with adverse anatomical features, such as long occlusions that prevented the identification of truly healthy landing zones.. Importantly, the CURRENT cohort included patients with advanced Rutherford categories (IV-V classes in 64.1%), CTO (69.7%), calcified occlusions 67.4%, and multilevel disease (BTK involvement in 55%), which are factors known to affect long-term outcomes adversely. One out of three patients in the series required concomitant BTK revascularization as an index of the high anatomical complexity of the cases included in the registry, influencing the estimated 12-month outcomes. Notably, none of the seventeen studies included by Bontinis *et al.* in the systematic review assessing the safety and efficacy of the Supera stent reported such a complex cohort of PAD. Still the drop of patency rate at 1 year (74.6%) in the CURRENT registry is not considerably different from that reported by Bontinis (83.5%).[8]

Some more interesting and innovative data from the Registry came from the analysis of overlapping stent segments in the patient who received two or more Renzan stents. We believed that the not non-significant increase of PSV noted in the overlapping area was strictly related to the meticulous registry protocol, which required a stent overlapping of 5 mm. The ideal scenario of overlapping only the flared portion of the stent with a nice contact of the edge of the inner micromesh layers was reached in nearly

all cases, and this may have influenced the good patency of this area over time. The feeling is that an imbrication of 1 or more centimeters, by creating an overlapping region of four layers, may work as a trigger for intimal hyperplasia and consequently in-stent restenosis.

Further data from the CURRENT registry are expected at 1- and 2-year follow-up and may further confirm the performance of the Renzan stent as well as the clinical outcomes of this cohort of patients with severe CLTI.

Limitations of the study

This study has several limitations. First, the absence of a control group and comparative design limits the ability to directly compare the performance of the Renzan™ stent with alternative treatment strategies, including drug-eluting stents or drug-coated balloons. In addition, the single-arm, non-randomized design of the registry may introduce selection bias, as treatment decisions were made at the discretion of the treating physicians in a real-world clinical setting.

Second, duplex ultrasound assessments were performed locally at each participating center without core laboratory adjudication, which may introduce interobserver variability. However, all participating centers are experienced vascular units using standardized duplex ultrasound protocols as part of routine clinical practice.

Third, although stent integrity was routinely evaluated during duplex ultrasound follow-up when technically feasible and systematically assessed during angiographic reinterventions, no dedicated imaging protocol with radiographic or fluoroscopic screening was implemented for systematic stent fracture detection. Therefore, asymptomatic or subclinical stent fractures may have been underdiagnosed.

Furthermore, as the Renzan™ stent was newly introduced at all participating centers, a learning curve effect cannot be excluded and may have influenced procedural optimization and outcomes. Similarly, the multicenter design, while enhancing the generalizability of the findings, may have introduced variability in procedural techniques and perioperative management.

Finally, the relatively modest sample size (N.=89) and the interim nature of this analysis, with follow-up currently limited to 12 months, may limit the robustness of long-term conclusions. Longer-term follow-up and larger patient cohorts will be essential to confirm the durability and safety of this device over time.

Conclusions

A new interwoven nitinol stent for the femoro-popliteal disease is now available. The dual-layer micro-mesh Renzan stent design of interwoven nitinol wires offers a good combination of flexibility, crush resistance and radial force and seems quite promising for complex femoropopliteal lesions.

The ad-interim 6-month results of the CURRENT registry show excellent early safety and efficacy outcomes. The estimated 12-month patency rate declined accordingly to the high complexity of the CLTI population included in the registry, mainly due to the contemporary BTK vessel disease involvement. These preliminary results should be further validated by longer follow-up data.

References

1. Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, *et al.*; GVG Writing Group for the Joint Guidelines of the Society for Vascular Surgery (SVS), European Society for Vascular Surgery (ESVS), and World Federation of Vascular Societies (WFVS). Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia. Eur J Vasc Endovasc Surg 2019;58(1S):S1, 109.e33.

2. Abdelghany M, Diaz-Sandoval LJ, Patrone L, Pasqui E, Nakama T, Ansaarie I, *et al.* Definitions and historical development of treatment of chronic limb-threatening ischemia. J Crit Limb Ischemia 2024;4:6–12.

3. Silveira FT, Razuk Á, Saad PF, Saad KR, Telles GJ, Ravizzini PI, *et al.* Stent fractures in the superficial femoral artery: predisposing factors and their implications. J Vasc Bras 2022;21:e20200014.

4. Ipema J, Roozendaal NC, Bax WA, de Borst GJ, de Vries JP, Ünlü Ç. Medical adjunctive therapy for patients with chronic limb-threatening ischemia: a systematic review. J Cardiovasc Surg (Torino) 2019;60:642–51.

5. Marques L, Hopf-Jensen S, Preiss M, Mueller-Huelsbeck S. An Update on Drug-eluting Technology in Peripheral Arteries to Treat Peripheral Arterial Disease. Heart Int 2021;15:73–8.

6. 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.

7. Schlager O, Francesconi M, Haumer M, Dick P, Sabeti S, Amighi J, *et al.* Duplex sonography versus angiography for assessment of femoropopliteal arterial disease in a "real-world" setting. J Endovasc Ther 2007;14:452–9.

8. Henry M, Klonaris C, Amor M, Henry I, Tzvetanov K. State of the art: which stent for which lesion in peripheral interventions? Tex Heart Inst J 2000;27:119–26.

9. Bontinis V, Antonopoulos CN, Bontinis A, Koutsoumpelis A, Giannopoulos A, Ktenidis K. A systematic review and meta-analysis of Supera interwoven nitinol stents for the treatment of infrainguinal peripheral arterial disease. J Cardiovasc Surg (Torino) 2022;63:137–45.

10. Palena LM, Isernia G, Parlani G, Veroux P, Ficarelli I, Frascheri A, *et al.* A multicenter prospective observational study appraising the effectiveness of the Supera stent after subintimal recanalization of femoro-popliteal artery occlusion: the SUPERSUB II study. Catheter Cardiovasc Interv 2024;103:963–71.

11. Tang X, Ma H, Zhou G, Shu X, Li Y, Guo M. Efficacy of Supera Stent in the Treatment of Complex Femoropopliteal Artery Lesions: A Short-Term Result Analysis of Real-World Evidence. Ann Vasc Surg 2024;109:101–10.

12. Lukic B, Miletic M, Milosevic S, Dragas M, Saponjski J, Koncar I, *et al.* Endovascular Treatment of Femoro-Popliteal Disease with the Supera Stent: A Single Center Experience. J Clin Med 2025;14:1704.

13. Parakh R, Venkatesh VR, Ravi KR, Chand G, Varinder Singh B, Kumar B, *et al.* Outcomes of SUPERA™ Stent Used for the Treatment of

De novo or Restenotic Superficial Femoral Artery or Complex Femoropopliteal Artery Lesions in Indian Patients. Indian Journal of Vascular and Endovascular Surgery 2025;12:4–13.

14. 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.

15. 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.

16. ClinicalTrials.gov. Prospective Multicenter Study to Confirm the Performance of the Renzan Stent in Treatment of SFA/POP Artery Disease (PRIZER). Identifier: NCT04546477 [Internet]. Available from: https://clinicaltrials.gov/study/NCT04546477 [cited 2026, Mar 17].

Conflicts of interest
The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Ethical approval
All procedures performed have been conducted in accordance with the 1964 Helsinki Declaration and its later amendments. Since the CURRENT registry was designed as a prospective, observational study conducted in the context of routine clinical practice using a CE-marked device, formal approval from the local ethics committees was not required. However, in accordance with national regulations and good clinical practice, all participating centers notified their respective ethics committees of the ongoing data collection for research purposes. The authors confirm that this article does not report any studies involving embryos, gametes and human embryonic stem cells conducted by the authors. The authors confirm that this article does not report any studies involving animals conducted by the authors.

Informed consent
Written informed consent was obtained from all participants prior to inclusion in the study and for publication of their data

Authors' contributions
Conceptualization: Gianmarco de Donato; Raffaele Pulli; Raffaella Berchiolli; Edoardo Pasqui; methodology: Gianmarco de Donato; Raffaella Berchiolli; Edoardo Pasqui; Nicola Troisi; validation: all Autors; investigation: Gianmarco de Donato; Edoardo Pasqui; Raffaella Berchiolli; Nicola Troisi; Giuseppe Galzerano; Sara Speziali; Raffaele Pulli; data curation; writing—original draft preparation and visualization: Gianmarco de Donato; Edoardo Pasqui; writing—review and editing: All Authos; Gianmarco de Donato; Edoardo Pasqui; su-pervision: Gianmarco de Donato, Raffaele Pulli; Raffaella Berchiolli. All authors read and approved the final version of the manuscript.

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History
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