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Novel Self-Expanding Interwoven Nitinol Stent for Treating Femoropopliteal Artery Disease: 12-Month Results of Single-Center First-in-Man Study

Shuofei Yang, MD, PhD[1], Qihong Ni, MD, PhD[1], Weilun Wang, MD, PhD[1], Jiaquan Chen, MD[1], Xiangjiang Guo, MD, PhD[1], Meng Ye, MD, PhD[1], Lan Zhang, MD, PhD[1], and Guanhua Xue, MD, PhD[1]

Abstract

Purpose: To evaluate the safety and efficacy of Innospring® stent, a novel self-expanding interwoven nitinol stent, in treating femoropopliteal atherosclerotic lesions. **Methods:** A prospective, single-center, single-arm, first-in-human study enrolled 15 patients (mean age 73.1 years; 13 men) to evaluate the safety and efficacy of the Innospring® stent monitored by core laboratories. The inclusion criteria were claudication or ischemic rest pain, de novo lesions or nonstented restenosis, >70% stenosis, lesion length <20 cm, and a reference vessel diameter of 4–7 mm. The primary safety endpoint was 30-day major adverse events. The primary efficacy end point was stent patency at 12 months. Follow-up evaluations were conducted at 30 days, 6 months, and 12 months. **Results:** The lesion length was 6.1 ± 3.5 mm. Fourteen (93.3%) patients had lesions of the superficial femoral artery and 3 (20.0%) patients had lesions of the popliteal artery. Nine (60.0%) patients had moderate-to-severe calcified lesion. Technical and procedural success was 100%. No patients experienced major adverse events in the first 30 days. The Rutherford category showed significant and sustained improvement at 6 and 12 months. The 12-month follow-up radiographs obtained in 13 patients confirmed the absence of stent fractures in 100% of examinations. The cumulative primary stent patency rate at 6 and 12 months were 93.3% and 84.6%, respectively. **Conclusion:** Stenting of the superficial femoral and popliteal arteries using the Innospring® stent is safe and effective. This competing interwoven nitinol stent may provide superior stent integrity and fracture-resistance as well as serve areas under extreme mechanical stress.

Clinical Impact

Endovascular recanalization is a widely accepted and recommended treatment for symptomatic peripheral artery diseases. The Innospring® stent is a novel self-expanding interwoven stent containing eight nitinol wires with additional radial force, fracture-resistance, and visibility under fluoroscopy. This first-in-human study using the Innospring® stent in patients with femoropopliteal occlusive disease reported that stenting of the superficial femoral and popliteal arteries using the Innospring® stent is safe and effective. This competing interwoven nitinol stent may provide an impressive stent integrity and fracture-resistance as well as serve areas under extreme mechanical stress.

Keywords

peripheral artery disease, endovascular therapy, self-expanding interwoven nitinol stent, femoropopliteal artery

Introduction

Endovascular recanalization is a standard, widely accepted, and recommended treatment for symptomatic peripheral artery diseases.[1] Long-term patency, however, remains a challenge when examining the full range of heterogenous lesion characteristics of the femoropopliteal artery (FPA). Despite the improved primary patency with deployment of laser-cut bare nitinol stents, the restenosis rates remain undesirable.[2] Moreover, stent fractures in the FPA are an adverse event caused by mechanical factors, such as external forces, vessel compression, torsion, and elongation.[3] Stent fractures were an independent risk factor for in-stent restenosis and the reocclusion of FPA stenting in the chronic phase.[4]

To minimize the re-stenosis rates via overcoming mechanical challenges, the Supera® stent (Abbott Vascular, Santa Clara, CA, USA), designed with interwoven braided nitinol wires, offers superior flexibility, radial strength, and kink resistance. Non-randomized trials have reported primary patency rates of up to 90%, 84%, and 82% at 1, 2, and 3 years, respectively.[5–7] For complex FPA lesions in the unselected patients, the primary patency rates were 83.3% and 72.8% after 12 months and 2 years, respectively.[8] Currently, the Supera® stent, providing a high radial force to resist elastic recoil and extrinsic compression from plaque, is the preferred choice for treating heavily calcified lesions.[9]

The Supera® stent contains 6 interwoven nitinol wires to confer additional radial strength and flexibility. However, the visibility of the Supera® stent under fluoroscopy requires improvement to facilitate accurate stent positioning by interventionalists. The Innospring® stent (Innomed, Suzhou, China) is a novel self-expanding interwoven stent containing 8 nitinol wires with additional radial force, fracture-resistance, and visibility under fluoroscopy. Herein, the first-in-human study using the Innospring® stent in patients with femoropopliteal occlusive disease is reported.

Methods

Study Design

This was a prospective, single-center, single-arm feasibility study evaluating the safety and efficacy of the Innospring® stent for treating obstructive lesions involving the femoropopliteal segment. The study was performed in Renji Hospital, School of Medicine, Shanghai Jiao Tong University. The study was approved by the institutional research board and ethics committee (No. 2017-216). All patients provided a written informed consent.

The inclusion criteria were as follows: (1) male or female >18 years old; (2) the subject or their legal representative was informed of the nature of the study and agrees to participate as well as comply with all follow-up visits, and had signed the consent form; (3) Rutherford category 2–5 and resting ankle-brachial index (ABI) ≤0.9; (4) lesions are located within the SFA and/or popliteal arteries; (5) target lesion stenosis >70% by visual assessment; (6) reference vessel diameter is between 4.0 and 7.0 mm; (7) one long or multiple serial lesions of up to 20 cm length that can be covered using a single balloon; (8) de novo or nonstented restenotic lesions; (9) at least one below-knee artery patent to the ankle; and (10) successful treatment of iliac inflow stenosis to the target limb. Stenosis can be treated during the same procedure using standard angioplasty and/or stenting. The inflow lesion(s) must be treated prior to treating the target lesion.

The exclusion criteria were follows: (1) evidence of aneurysm or acute thrombus in the target vessel; (2) previous bypass surgery of the target extremity; (3) allergy to a contrast medium that cannot be pretreated; (4) episode of acute limb ischemia in the past 30 days; (5) systemic infection with positive blood cultures/bacteremia within a week; (6) contraindication to antiplatelet, anticoagulant, or thrombolytic therapy; (7) myocardial infarction within 30 days prior to enrolment; (8) history of strokes or transient ischemic attacks within 90 days prior to enrolment; (9) acute or chronic renal diseases (creatinine > 2.5 mg/dL) and haemodialysis; (10) pregnant or breastfeeding; (11) participation in another research study that in the opinion of the investigator could affect the results of this study; and (12) history of unexplained neutropenia, coagulopathy, or thrombocytopenia.

Study Device

The novel, self-expanding Innospring® stent comprises 8 pairs of closed-ended interwoven nitinol wires braided in a closed cell configuration. The wire diameters vary with the stent diameters (0.0055 and 0.0065 inches for 4–6 and 6.5–8 mm diameter designs, respectively). The visibility of Innospring® under fluoroscopy was significantly improved, because one of the nitinol wires contains platinum in the inner layer (Figure 1A). For stents of the same size, the length of Innospring® stent assembled in the delivery system is shorter than that of the Supera® stent (Figure 1B). The cross-section shape of the Innospring® stent was octagonal and not hexagonal (Figure 1C). The Innospring® stent system includes an operating handle suitable for single-handed operation and a 6-F coaxial delivery system containing radiopaque markers to guide the deployment of the premounted stent across the target lesion (Figure 1D). Once positioned, the stent is deployed via a series of reciprocal actions that incrementally advance the stent distally out of the outer sheath. The stents used in this study were of 4–6 mm diameter and 40–150 mm length. In

[1]Department of Vascular Surgery, Renji Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai, China

Shuofei Yang and Qihong Ni contributed equally to the artile.

Corresponding Authors:
Lan Zhang, Department of Vascular Surgery, Renji Hospital, School of Medicine, Shanghai Jiao Tong University, Pujian Road 160, Shanghai 200127, China.
Email: zhanglanrjxg@gmail.com

Guanhua Xue, Department of Vascular Surgery, Renji Hospital, School of Medicine, Shanghai Jiao Tong University, Pujian Road 160, Shanghai 200127, China.
Email: xueguanhua2018@163.com

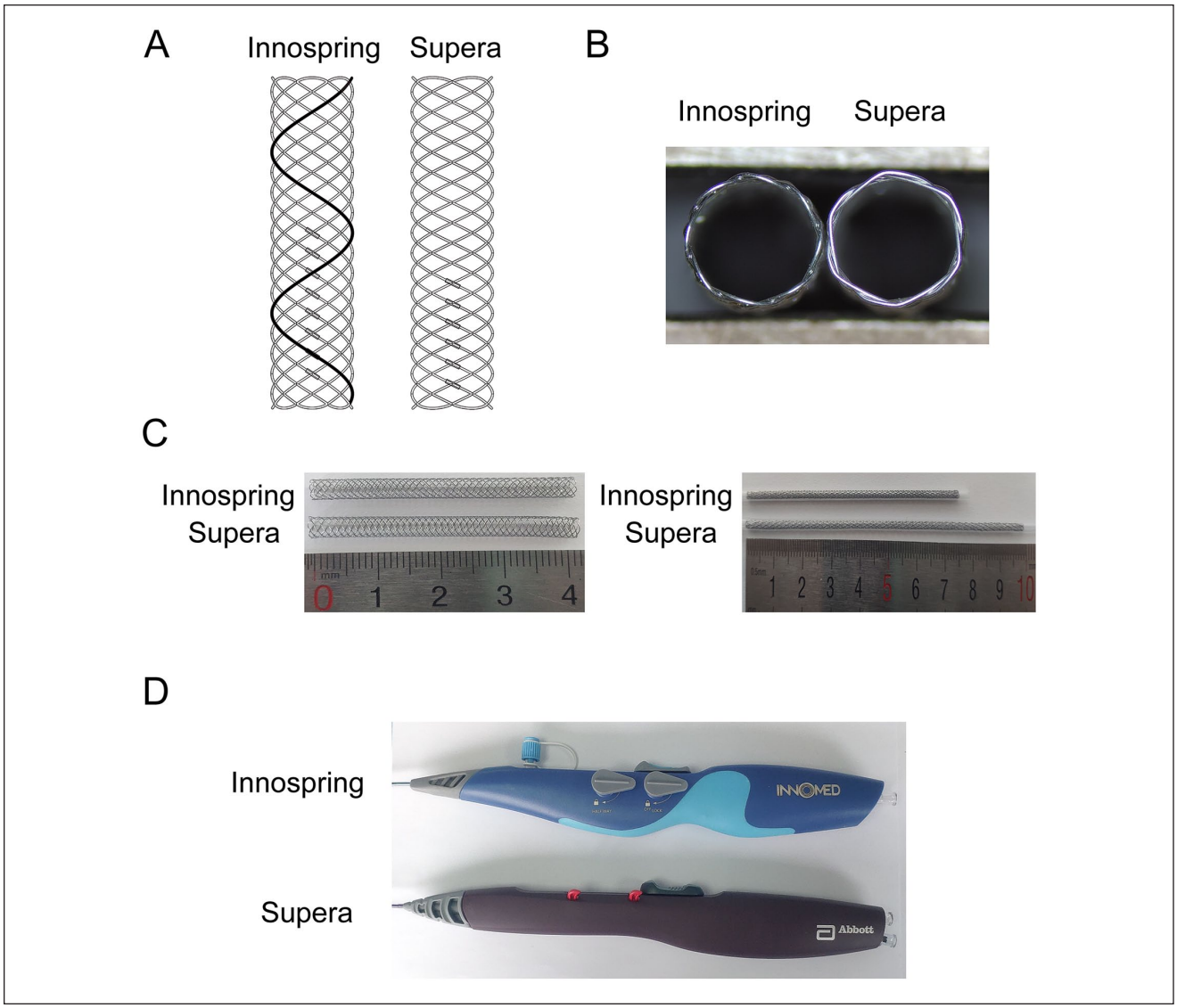

Figure 1. Several aspects of Supera® stent have been improved with new design of Innospring® stent. (A) Innospring® stent comprises 8 pairs of closed-ended interwoven nitinol wires braided in a closed cell configuration. One of the nitinol wires contains platinum in the inner layer. (B) The cross-section shape of the Innospring® stent was octagonal rather than hexagonal. (C) For identically sized stents, length of Innospring® stent assembled in the delivery system is shorter than that of Supera® stent. (D) Innospring® stent system includes an operating handle suitable for single-handed operation.

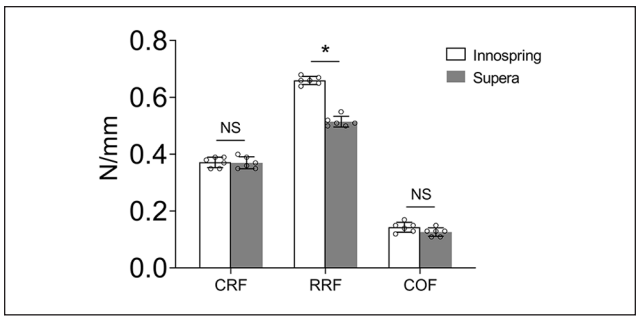

Figure 2. Comparison of CRF, RRF, and COF between Innopsring and Supera stent. CRF, compression resistive force; RRF, radial resistive force; COF, chronic outward force.

use, the Innospring® stent is advanced over a 0.018-inch guidewire to the target lesion through a previously placed 6-F introducer sheath or guide catheter.

This self-expanding stent is flexible, compliant, and resistant to fractures and kinks, as documented by independent testing (Medical Device Testing Services, Minnetonka, MN, USA), wherein the Innospring® stent withstood 10 million cycles of flexion/tension. The Innospring® stent resisted 10 million cycles of torsion fatigue and superposition dynamic bending fatigue testing (Suzhou Medical Implant Mechanics LLC, Suzhou, China) without fractures. In addition, the Innospring® stent produced a significantly higher radial resistive force than the Supera® stent during

Table 1. Demographic and Clinical Characteristics of Patients.

No.	Gender	Age	Medical history	Smoking	Amputation history	Rutherford category	ABI at rest
1	Male	53	HBP, DM, CAD	Current	Yes	4	0.31
2	Male	63	DM, CAD	Former	No	4	0.15
3	Female	79	DM	Nonsmoker	No	5	0.20
4	Male	57	HBP, DM, CAD	Current	No	3	0.41
5	Male	73	HBP	Nonsmoker	No	3	0.69
6	Male	77	HBP, DM, CAD, Stroke	Nonsmoker	No	3	0.63
7	Male	73	DM	Former	No	5	0.06
8	Male	67	HBP, DM, Stroke	Current	No	3	0.42
9	Male	75	HBP, CAD	Nonsmoker	No	4	0.78
10	Male	67	HBP	Current	No	3	0.39
11	Male	76	HBP, DVT	Nonsmoker	No	4	0.37
12	Male	82	HBP	Nonsmoker	No	4	0.40
13	Male	74	HBP, DM	Nonsmoker	No	4	0.01
14	Male	85	HBP, DM, CAD	Former	No	5	0.55
15	Female	69	HBP, DM	Nonsmoker	No	5	0.01

Abbreviations: HBP, high blood pressure; DM, diabetes mellitus; CAD, coronary artery disease; DVT, deep venous thrombosis; ABI, ankle-brachial index.

testing, whereas the compression resistive and chronic outward forces were similar (Figure 2).

Interventional Treatment and Medication Regimen

Although the treatment decisions were left to the discretion of the operator, the lesions were systematically predilated using a balloon catheter that matched the reference vessel diameter at a minimum. Similarly, the stent diameter was selected to match the reference vessel diameter at a 1:1 ratio to ensure deployment close to the nominal diameter of the stent, to optimize the mechanical properties. For lesions with severe calcification, vessel preparation with dilation before stent placement was performed using a balloon 0.5–1.0 mm larger than the reference vessel diameter. Systematic attempts, including 5 mm of lesion-free vessel proximal and distal to the stent, were performed to entirely cover the lesion. When >1 stent was required to cover the lesion, the stents overlapped by ≥ 1 cm. Postdilation was typically performed using identically sized balloons as those used for predilation.

The antithrombotic regimen was administered according to the standard institutional practices. Periprocedural anticoagulation with ≥ 5000 units of heparin was recommended. Dual antiplatelet therapy with aspirin (100 mg/d) and clopidogrel (75 mg/d) was prescribed for 8 weeks; then, aspirin or clopidogrel monotherapy was indefinitely prescribed.

Follow-Up and Study Endpoints

The primary efficacy end point was stent patency at 12 months, defined as freedom from restenosis (diameter stenosis $>50\%$, as identified by a peak systolic velocity ratio >2.4 measured using duplex ultrasonography) and freedom from target lesion revascularization (TLR). The primary safety endpoint was a composite of major adverse events and periprocedural death assessed at 30 days. Major adverse events included TLR or thrombosis and target limb major amputation. Secondary outcomes included technical and procedural success, ABI, and Rutherford category assessment at 6 and 12 months. Assessment of imaging studies were performed by the angiography and vascular ultrasound core laboratories at Renji Hospital. Follow-up evaluations were conducted at 30 days, 6, and 12 months.

Technical success was defined as successful stent implantation with a residual stenosis $< 30\%$. Procedural success was defined as technical success without cardiac and cerebral adverse events during the hospital stay period. The calcium scoring of the arterial segment (0–3) was based on the orthogonal fluoroscopic examination as follows: 0, no calcium on either side of an arterial segment; 1, calcium on 1 side of the artery, <5 cm in length; 2, calcium on both sides of an arterial segment, 5–10 cm in length; and 3, calcium on both sides of an arterial segment >10 cm in length, which also had intraluminal calcium.[10]

Statistical Analysis

Descriptive statistics were used to present mean values and standard deviation (SD) for continuous variables, median values (range), and counts and percentages for categorical variables. Cumulative patency rates and standard errors (SEs) were estimated using Kaplan–Meier analyses. Between-group comparisons were performed using the log-rank test. Continuous variables between 2 groups were

Table 2. Angiographic and Procedural Characteristics.

Variables	All patients (N=15)
Treated leg, N (%)	
L	7 (46.7)
R	8 (53.3)
Target lesion, N (%)	
Superficial femoral artery	14 (93.3)
Popliteal artery	3 (20.0)
P1	3 (20.0)
P2	1 (6.7)
P3	1 (6.7)
Chronic total occlusion, N (%)	7 (46.7)
Stenosis, N (%)	8 (53.3)
Calcifications, N (%)	
1	6 (40.4)
2	5 (33.3)
3	4 (26.7)
Vessel run-off, N (%)	
0–1	10 (66.7)
2–3	5 (33.3)
Lesion length, mean ± SD, cm	6.1 ± 3.5
Intervention Approach, N (%)	
Intraluminal crossing	12 (80.0)
Subintimal crossing	2 (13.3)
Undetermined	1 (6.7)
Using retrograde puncture technique	2 (13.3)
Stent length, mean ± SD, mm	9.7 ± 3.7
Pre-dilation, N (%)	15 (100.0)
Number of stents implanted per patient, N (%)	
1	14 (93.3)
2	1 (6.7)
Stent foreshortening, N (%)	0 (0)
Stent elongation, N (%)	
Nominal (0%–10%)	12 (80.0)
Minimal (10%–20%)	2 (13.3)
Moderate (20%–40%)	1 (6.7)
Severe (>40%)	0 (0)
Post-dilation, N (%)	13 (86.7)
Additional procedures, N (%)	
Inflow	
Iliac arteries (bare-metal stents)	1 (6.7)
Outflow	
Tibial arteries (plain old balloon angioplasty)	3 (20.0)
Post-procedure, N (%)	
Technical success	15 (100)
Procedural success	15 (100)

Abbreviations: L, left; R, right; SD, standard deviation.
Calcification score (orthogonal fluoroscopic examination of the arterial segment): 0 = no calcium on both sides of an arterial segment; 1=calcium on 1 side of the artery, <5 cm in length; 2=calcium on both sides of an arterial segment 5–10 cm in length; 3=calcium on both sides of an arterial segment >10 cm in length, which also had intraluminal calcium.

compared using Student's t-test for dependent samples. The categorical variables between 2 or more groups were compared using the chi-squared test. Statistical significance was set at $p<0.05$, and SPSS version 22.0 (SPSS, Chicago, Illinois) was used to analyze the data.

Results

Patient Population

This study enrolled 13 men (86.7%) and 2 women (13.3%) with a mean age of 73.1 ± 10.1 years. The baseline clinical characteristics of these 15 patients are listed in Table 1. Cardiovascular risk factors were highly prevalent, including hypertension in 12 (80.0%), coronary artery disease in 6 (40.0%), current or former smoking in 7 (46.7%), and diabetes in 9 (60.0%) patients. Furthermore, 33.3% of the patients presented with severe claudication (Rutherford category 3), and the remaining (66.7%) presented with critical limb ischemia (Rutherford category 4–5).

Angiographic and Procedural Characteristics

The angiographic and procedural characteristics are listed in Table 2. The lesion length was 6.1 ± 3.5 mm. Fourteen (93.3%) patients had lesions of the superficial femoral artery and 3 (20.0%) patients had lesions of the popliteal artery. Nine (60.0%) patients had moderate-to-severe calcified lesion. Twelve (80%) lesions were treated using intraluminal crossing and the retrograde puncture technique was used in 2 (13.3%) lesions. Notably, the iliac artery and infrapopliteal runoff vessel reconstruction was performed in 1 (6.7%) and 3 (20.0%) cases, respectively. The instructions for use mandated predilation of the lesion in a 1:1 fashion to the reference vessel to allow the most nominal deployment of the stent. If the lesion is not appropriately predilated, the stent may become elongated where the radial strength of the stent is reduced. In this study, no stent foreshortening or severe stent elongation (>40%) was observed. Nominal elongation (0%–10%) was found in 80% patients. The rate of stents deployed with minimal and moderate elongation was 13.3% and 6.7%. No procedure-related major complications, including puncture site hematoma or bleeding, distal embolization, thrombosis, and vascular perforation, occurred.

Clinical Outcomes and Adverse Events

Thirteen patients had complete 12-month follow-up data. No patients experienced major adverse events in the first 30 days. A patient (No. 7) died of acute myocardial infarction at 3 months, and another patient (No. 3) died of multiple organ dysfunction syndrome at 12 months (Table 3). The mean Rutherford category decreased from 3.9 before the

Table 3. 12-Month Follow-Up Outcomes.

No.	6-month primary patency	12-month primary patency	TLR	Stent fracture	All-cause death	Adverse events
1	Yes	Yes	No	No	No	Yes
2	No	No	No	No	No	No
3	Yes	/	No (at 6 months)	No (at 6 months)	Yes	Acute myocardial infarction
4	Yes	No	No	No	No	No
5	Yes	Yes	No	No	No	No
6	Yes	Yes	No	No	No	no
7	/	/	/	/	Yes	MODS (caused by severe pneumonia)
8	Yes	Yes	No	No	No	No
9	Yes	Yes	No	No	No	No
10	Yes	Yes	No	No	No	No
11	Yes	Yes	No	No	No	No
12	Yes	Yes	No	No	No	Duodenal ulcer bleeding
13	Yes	Yes	No	No	No	No
14	Yes	Yes	No	No	No	No
15	Yes	Yes	No	No	No	No

Abbreviations: MODS, multiple organ dysfunction syndrome; TLR, target lesion recanalization.

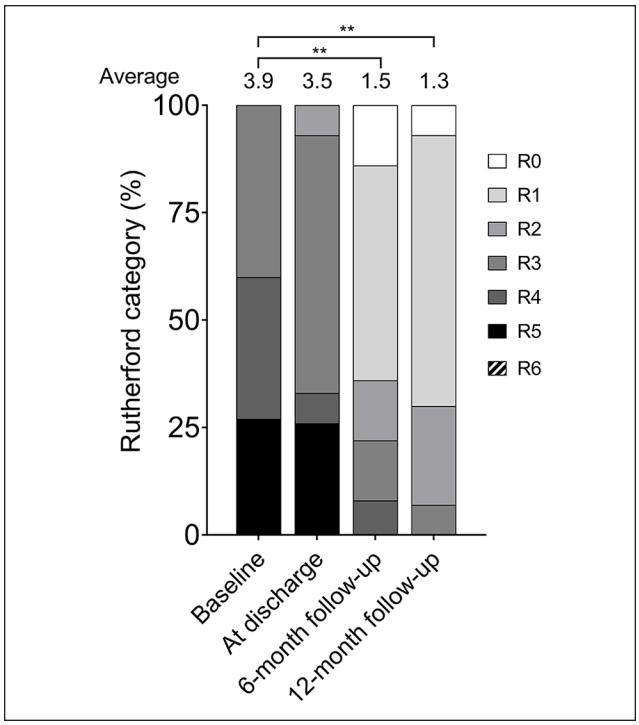

Figure 3. Comparison of Rutherford categories prior to intervention, at discharge and at 6-month or 12-month follow-up.

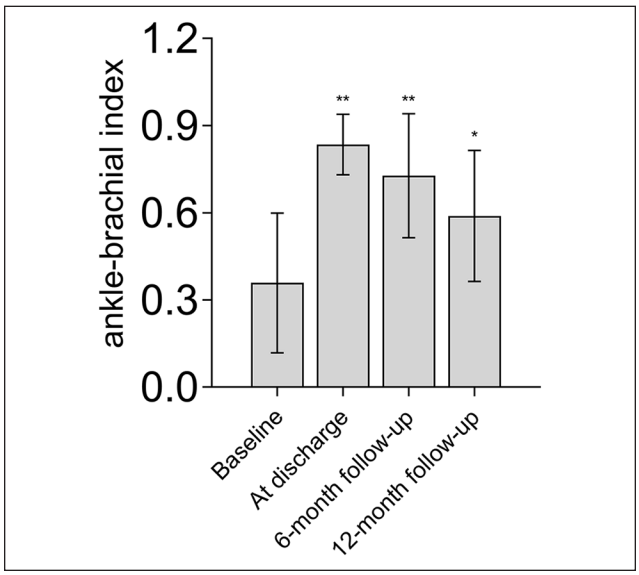

Figure 4. Comparison of ankle-brachial index prior to intervention, at discharge and at 6-month or 12-month follow-up.

index stent implantation procedure, to 1.5 and 1.3 at 6 and 12 months, respectively (Figure 3). The technical and procedural success rate were both 100% (Table 2). The ABI

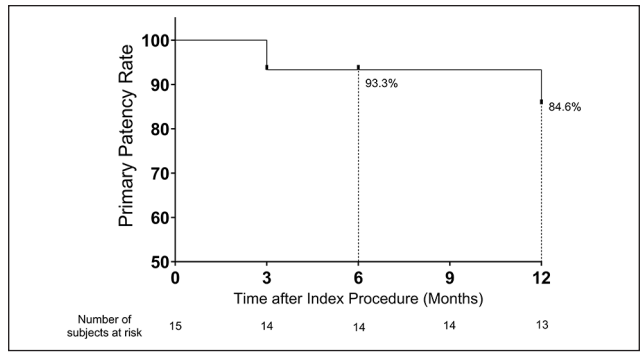

Figure 5. The cumulative primary patency rate of Innospring® stent at 6 and 12 months.

increased from 0.35 ± 0.25 before the stent implantation procedure, to 0.73 ± 0.21 and 0.62 ± 0.21 at 6 and 12 months, respectively (Figure 4). The 12-month follow-up radiographs obtained in 13 patients confirmed the absence of stent fractures in 100% of examinations. The cumulative primary stent patency rate at 6 and 12 months were 93.3% and 84.6%, respectively (Figure 5). The 12-month rate of freedom from TLR was 100% in this study (Table 3). A representative angiogram and radiographs of a patient treated with the Innospring® stent is shown in Figure 6.

Discussion

In the SUPERB Trial, the primary patency of Supera® at 12 months was 78.9%.[11] In Supera-SFA registry study, the 6-, 12-, and 24-month cumulative primary patency rates of Supera® for the treatment of complex femoropopliteal lesions in a "real world" medical practice were 93.1%, 84.7%, and 76.1%, respectively.[5] In this study, the primary patency rate of Innospring® at 12 months reached 84.6%. This excellent patency using the self-expanded wire-interwoven nitinol stents may be attributable to the favorable vessel preparation before stent deployment. Sufficient predilation maintains low chronic outward forces matching the adequate inner lumen size to the reference vessel size and outer stent diameter to the vessel size.[12] In this study, predilation corresponds to a deployed Innospring® stent outer diameter at a 1:1 ratio to match the reference vessel. Focal under-expanded stent segments and misaligned deployment can be improved via dilation following deployment.

Notably, 60.0% of the lesions in this study were moderate-to-severely calcified. Severe calcification can increase the technical difficulty and reduce the endovascular therapy durability in the femoropopliteal region.[13] Moreover, severe calcification can compromise the intraluminal passage of guidewires and balloon catheters, forcing them into a subintimal plane that may subsequently cause reentry failure. It may also serve as a physical impediment to stents and antirestenotic therapies, such as drug-coated balloons, as demonstrated

Figure 6. A representative angiogram (A) and radiographs (B) of patient treated with Innospring® stent.

by the unfavorable patency outcomes in this group.[14] The interwoven Supera® nitinol stent was considered to possess ideal qualities for calcified lesions, because it exhibited a significantly higher radial resistive force and crush resistance than the laser-cut stents.[15,16] In SUPERB trial, 325 patients were enrolled and only a single facture event of Supera® stent was reported during the 36-month follow-up period.[6] The Innospring® stent may possess an excellent patency rate for the calcified lesions with a further enhanced radial resistive force. However, the Innospring® stent also requires sufficient space created by aggressive predilation in the lumen to facilitate complete stent expansion and avoid elongation.

A stent fracture is an independent risk factor of in-stent restenosis and may adversely affect the outcomes of FPA stenting.[17] Kinking and fractures tend to occur at the repeated stress sites, and neointimal hyperplasia and restenosis may occur where the stent forces are the highest.[18,19] The stress is not effectively dissipated within the stent mesh network, because these forces are not uniformly distributed across the slotted-tube stent. Native arteries contain a reticular network of interconnected collagen and elastin fibers that dissipates radial, axial, and torsional forces as well as prevents the formation of focal areas of high wall stress. The Supera® stent is a biomimetic vascular stent that incorporates a wire-interwoven design to partially mimic the reticular structure of native collagen and elastin within vessels, emphasizing radial strength, flexibility, and kink resistance. The Innospring® stent is also a biomimetic vascular stent with a high radial resistive force. In this first-in-man study, no stent fractures were observed.

Although the Supera® stent can be precisely deployed at the distal segment, the proximal placement of the stent varies based on the ability to pack or stretch the deployment. The final length of the deployed stent may extend beyond

the intended stent length. However, the elongation of Supera® is a factor that reduces patency.[16] The Innospring® stent produced a significantly higher radial resistive force than the Supera® stent. For identically sized stents, the length of the Innospring® stent assembled in the delivery system is shorter than that of the Supera® stent. In addition, the Innospring® stent system facilitates single-handed operation with a newly designed operating handle.

This study has several limitations. The first-in-man evaluation of the Innospring® stent for treating FPA diseases was designed as a single arm study. No control group (eg, Supera® stent) was included, and the overall number of patients enrolled was small. This initial clinical experience with the Innospring® stent in patients with FPA disease require to be corroborated in larger multicenter studies that include adequate long-term clinical follow-ups and objective assessments of target lesion patency.

In conclusion, stenting of the superficial femoral and popliteal arteries using the Innospring® stent is safe and effective. This competing interwoven nitinol stent may provide an impressive stent integrity and fracture-resistance as well as serve areas under extreme mechanical stress. Additional studies are underway to assess the long-term efficacy of this promising novel interwoven nitinol stent.

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Declaration of Conflicting Interests

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ORCID iDs

Meng Ye https://orcid.org/0000-0002-8125-6854
Guanhua Xue https://orcid.org/0000-0003-0272-3109

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