

SUPERA Interwoven Nitinol Stent Outcomes in Above-Knee Interventions (SAKE) Study

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ABSTRACT

Purpose: To report experience with the novel interwoven-wire self-expanding nitinol SUPERA stent (IDEV Technologies, Inc./Abbott Laboratories, Inc, Webster, Texas) for the treatment of severely diseased superficial femoral and popliteal arteries.

Materials and Methods: Consecutive patients with severely diseased superficial femoral and popliteal arteries who received SUPERA stents ($n = 80$ patients [98 limbs]; mean age, 70.8 y; 80% male) were retrospectively identified. Patients were followed for an average of 14.3 months after intervention.

Results: Total occlusions were present in 39% of the lesions, 21% had tissue loss, and 61% demonstrated calcification on fluoroscopy. Patients were prescribed dual antiplatelet therapy (aspirin and clopidogrel) for at least 30 days unless contraindicated, followed by aspirin alone indefinitely. The mean ($\pm$ SD) lesion length was 143 mm ($\pm$ 98). Based on need for clinical intervention, primary patency was 96.9% at 6 months and 85.8% at 12 months (Kaplan-Meier estimates). Assisted primary patency and secondary patency rates at 12 months were 96.8% and 100%, respectively. Ankle-brachial index increased from 0.60 at baseline to 0.83 at last follow-up ($P < .001$). No stent fractures were found by fluoroscopy inspection in 19 limbs (16 patients) that required reintervention.

Conclusions: Based on experience with multiple operators at a single clinical center, the interwoven nitinol stent design provides a viable option for high-grade obstructive disease in the femoropopliteal artery.

ABBREVIATIONS

ABI = ankle-brachial index, PAD = peripheral arterial disease, SFA = superficial femoral artery

Percutaneous interventions for peripheral arterial disease (PAD) in the superficial femoral artery (SFA) and the femoropopliteal artery have been associated with high restenosis rates and poor long-term patency with balloon angioplasty alone (1). Treatment strategies in the SFA and femoropopliteal artery are potentially compromised by the high calcium content within the plaque and vessel wall, long length of lesions, and unique dynamic forces found within these arteries (2). Multiple clinical trials with laser-cut nitinol stents in primary stent placement have demonstrated improved patency rates compared

with either percutaneous transluminal angioplasty with provisional stent placement or a predefined percutaneous transluminal angioplasty performance goal (3–14). However, with 12-month patency rates in these trials ranging from 53%–83% after nitinol stent implantation, restenosis rates are still greater than desirable, especially in difficult lesion segments. Another potential risk factor for reocclusion stems from stent fractures, which range from 0.4%–8.1% at 12 months (7–9,11,14). Although minor fractures (type I and II) do not appear to lead to complications, multiple stent fractures are known to affect outcome (6,12,15).

Restenosis and stent fracture illustrate the need for continued improvement in stent technology (improved longitudinal flexibility, radial strength, and resistance to fracture) and vessel preparation procedures. Much of the current data available are based on well-controlled studies performed by stent manufacturers in the context of clinical trials aimed at device registration. By contrast, only a few limited “real-world” studies have been published (16–18) that would be more relevant to the operators. We have used the novel interwoven nitinol

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SUPERA stent (IDEV Technologies, Inc/Abbott Laboratories, Inc, Webster, Texas) based on the expectation that enhanced strength, flexibility, and fracture and kink resistance compared with traditional nitinol stents (19) would improve our clinical outcome. We report our single-center experience in patients with PAD who received interwoven nitinol stents in the femoropopliteal arteries.

MATERIALS AND METHODS

Study Design and Patient Population

All patients who received SUPERA interwoven nitinol stents in the femoropopliteal artery segment from March 2010–September 2011 at our hospital were retrospectively identified ($n = 80$ patients). Mean ($\pm$ SD) age was 70.8 years ($\pm$ 9.5) (range, 50–92 y); 64 (80%) patients were male. In 18 patients, bilateral treatment with SUPERA stents was performed, so that 98 limbs were included in the analysis. All patients had high-grade obstructive disease in the femoropopliteal artery segment (Rutherford class 3–5 symptoms). The patients' medical history included history of hypertension (95%), dyslipidemia (86%), diabetes mellitus (58%), smoking (79%), and coronary artery disease (70%) (Table 1).

The femoropopliteal artery segments were treated via endovascular approaches, including balloon angioplasty with or without adjunctive atherectomy (at the discretion of each operator), but concluded with stent placement using SUPERA stents (Fig 1). After the procedure, patients were instructed to remain on dual antiplatelet therapy for at least 30 days. Patients were scheduled for follow-up clinical evaluation according to the American College of Cardiology/American Heart Association PAD guidelines at 1 month, 6 months, and 12 months after intervention. All data presented here were collected by the authors through retrospective chart review.

Institutional Review Board Approval and Informed Consent

Institutional review board approval was not sought because the institutional review board at our institution does not require clearance for the type of retrospective chart review performed within this study. In accordance with institutional and local regulatory policies, all patients who underwent procedures within this study signed a written informed consent before the procedure that accounted for all endovascular treatment modalities offered to these patients.

Baseline and Follow-up Evaluations

In all patients, the diagnosis of PAD was determined by clinical evaluation and ankle-brachial index (ABI) measurements at baseline. In some cases in which the findings were equivocal, an exercise ABI was performed. Duplex ultrasound was performed on all patients at baseline to

Table 1. Patient Demographic and Clinical Characteristics

	All
No. patients	80
No. limbs	98
No. segments	98
Age (y), mean (SD) [range]	70.8 (9.5) [50–92]
Gender	
Male	64 (80%)
Female	16 (20%)
Concurrent conditions	
Arterial hypertension	76 (95%)
Dyslipidemia	69 (86%)
Diabetes mellitus	46 (58%)
Coronary artery disease	56 (70%)
History of myocardial infarction	10 (13%)
History of stroke	13 (16%)
Smoking	63 (79%)
Indication for stent placement (by limb)	
Claudication (Rutherford stage 3)*	67 (68%)
Ischemic rest pain (Rutherford stage 4)	10 (10%)
Tissue loss (Rutherford stage 5)	21 (21%)
Antiplatelet regimen prescribed for 30 days after procedure [†]	
Aspirin and clopidogrel	73 (91%)
Aspirin, clopidogrel, and warfarin	4 (5%)
Aspirin and ticlopidine	1 (1%)
Aspirin and clopidogrel, switched to prasugrel	1 (1%)
Clopidogrel alone	1 (1%)
Anticoagulant regimen after procedure	
Heparin	96 (98%)
Bivalirudin	2 (2%)

*Rutherford-Becker class 3 was defined based on presenting symptoms and was not based on a treadmill test.

[†]30-day compliance with antiplatelet regimen was not ascertained.

determine lesion length, calcification, stenosis, or occlusion. In patients who required reintervention (Fig 2), duplex ultrasound was also performed before reintervention to define the lesion location further. At the follow-up visits, patients underwent physical examinations and ABI measurements for the detection of restenosis.

Stent Procedure and Concurrent Therapy Regimen

The interwoven nitinol SUPERA stent is constructed from six pairs of nitinol wires woven together to create a helical pattern. The wires form closed loops at both ends of the stent. The stent is premounted and delivered via a 6-F or 7-F catheter–based delivery system over a 0.014-inch or 0.018-inch wire. All lesions were routinely dilated before stent placement using a balloon 0.5–1.0 mm larger than the reference vessel diameter to allow adequate

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