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French Single-Center Experiences With S.M.A.R.T.® Flex

The safety and efficacy of the S.M.A.R.T.® Flex stent in the management of PAD.

BY NIZAM EDRISS, MD; THIERRY COPPIN, MD; AND ISABELLE PATTE, PharmD

Peripheral artery disease (PAD) affects approximately 1% of the population older than 40 years.[1] Symptoms include reduction of arterial blood flow, causing excessive pain, walking impairment, delayed wound healing (with the threat of tissue loss), and the potential for major amputation.

Endovascular therapy has become, in many cases, the first therapeutic option to treat PAD, especially in patients with significant medical conditions often associated with several comorbidities. Percutaneous transluminal angioplasty (PTA) remains the primary treatment for the management of patients with PAD.[2] Stent placement is typically only necessary in cases of suboptimal or failed results.[3] This situation is frequently observed with long and complex lesions, notably in superficial femoral artery (SFA) occlusions.

A self-expandable stent made of nitinol is commonly used in PAD interventional procedures, particularly in SFA lesions. However, the SFA is subject to various mechanical forces, such as longitudinal compression and elongation, as well as flexion and torsion.[4,5] Choosing the appropriate stent depends on several stent characteristics such as precision of deployment, delivery system, stent design, and also expectations for better patency improving the clinical outcomes.

DATA REVIEW

This registry study of patients at our institution aims to assess the safety and efficacy of the S.M.A.R.T.® Flex stent (Cordis Corporation) and to estimate a possible clinical benefit.

From July 2013 to May 2015, we treated 92 patients who received, on a selective stenting basis in case of suboptimal or failed results from balloon dilatation, one or more S.M.A.R.T.® Flex stents. Fifty-nine patients were male, and 33 were female, with a mean age of 70 years. The patients had the usual cardiovascular risk factors of arterial hypertension (61%), diabetes mellitus (34%), current and former smokers (43%), hyperlipidemia (45%), and renal insufficiency treated by iterated hemodialysis (3%).

Clinical status was dominated by intermittent claudication (59%), critical limb ischemia (CLI), and Rutherford

TABLE 1. BASELINE CLINICAL DATA

Characteristics	Baseline Data
Number of patients	92
Mean age, y	70
Male gender	59 (64%)
Cardiovascular risk factors	
- Diabetes mellitus	31 (34%)
- Arterial hypertension	56 (61%)
- Hypercholesterolemia	41 (45%)
- Smoker	40 (43%)
- Hemodialysis	3 (3%)
Rutherford class 3	54 (59%)
Rutherford class 4	8 (9%)
Rutherford class 5	22 (24%)
Rutherford class 6	8 (9%)

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TABLE 2. MAJOR CLINICAL ADVERSE EVENTS

Event	Frequency
Death	9 (9.8%)
Major amputation	6 (6.5%)
Bypass surgery	4 (4.3%)
Target lesion revascularization	8 (8.6%)

TABLE 3. ULTRASOUND FOLLOW-UP DATA

Characteristics	Frequency
Surviving patients	83 (90.2%)
Follow-up available	83 (90.2%)
Follow-up time	14 ± 13 months
Stent occlusion	13 (14.1%)
Restenosis > 50%	7 (7.6%)
Primary patency	68 (81.9%)
Secondary patency	76 (91.6%)

class 4 and 5 (33%). Some patients in Rutherford class 6 were indicated for limb salvage because their situations were critical, which explains some of the perioperative cardiovascular death.

The angiographic findings in the 92 patients revealed 118 lesions, most of which were in the SFA (94 [74.6%]; mean length, 11.5 cm) and the iliac artery (24 [20.2%]; mean length, 5 cm). In 14 (14.8%) cases, there was a simultaneous iliac and femoral revascularization. In addition to the long lesion lengths, the patients also had other challenging characteristics, with 68.6% having total occlusion and 34% being heavily calcified and having diabetes (Table 1). By intention-to-treat analysis, the technical success was 98% without major procedural complications.

Cardiovascular-related deaths at 30 days were 3.4%, which shows the severity of cardiovascular disease and the high rates of associated comorbidities, such as stroke, diabetes mellitus, and renal failure.

Clinical follow-up was conducted for all patients and included a clinical visit and Doppler ultrasound at 6 weeks after the operative procedure, and at every 6 months thereafter. During the clinical follow-up, there were nine (9.8%) deaths, including three that occurred in the 30-day postoperative period due to severe cardiovascular disease. No deaths were found to be directly attributed to the intervention. Four (4.3%) patients required bypass surgery, and eight (8.6%) required target lesion revascularization (TLR). Six (6.5%) patients underwent major amputations due to reocclusion, without any possibility of revascularization (Tables 2 and 3).

At mean follow-up of 16 months (range, 5–28 months), the primary and secondary patency rates remained high, at 81.9% and 91.6%, respectively. The patency was best in the iliac disease subgroup and matches the highest benchmark found in the field.[6] In our study, the iliac primary and secondary patency rates were 93.3% and 95.7%, respectively.[7] Moreover, there were no issues attributed to stent implantation.

DISCUSSION

The new generation of stents, such as the S.M.A.R.T.® Flex stent, broadens the endovascular therapeutic options for patients with PAD, including not only patients with intermittent claudication but also patients in bailout situations of limb salvage. The clinical benefits of improvement of walking distance and limitation of tissue loss are clearly related to the patency rate.

Despite the recent improvements in endovascular therapy, it remains difficult to choose between primary stenting versus selective (after failure of PTA) stenting. In our institution, we often opt for secondary stenting after

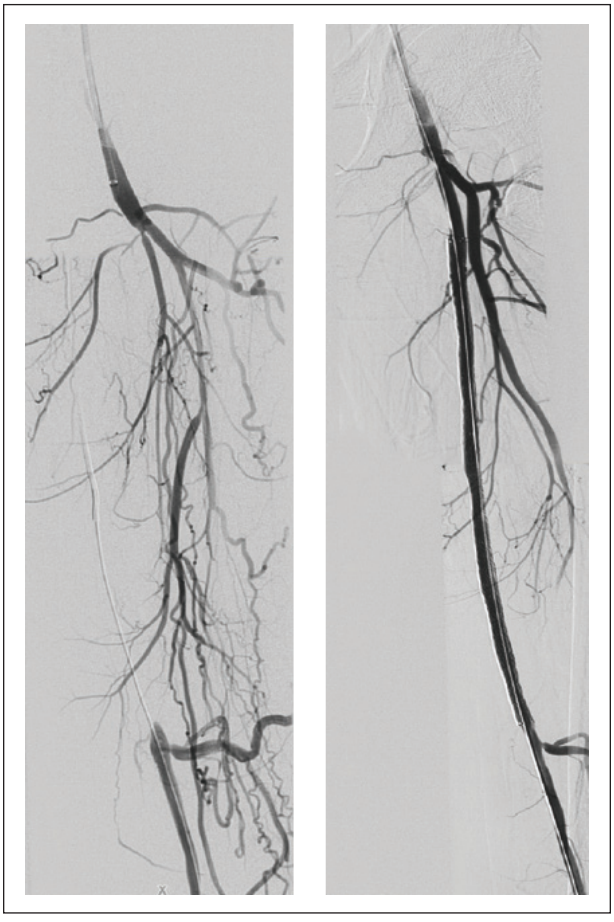

Figure 1. Before and after stenting the SFA with the S.M.A.R.T.® Flex stent.

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suboptimal PTA results; however, primary stenting may be preferred for recanalization of long occlusions and complex lesions, avoiding many perioperative complications (ie, embolization, dissection, flaps, recoil) (Figure 1).

CONCLUSION

Our registry demonstrates the safety and efficacy of the S.M.A.R.T.® Flex stent in the management of PAD. Excellent results can be achieved in daily practice with this device, leading to a clear tendency toward better clinical results, although a wider randomized study and longer-term follow-up data are needed to confirm the clinical benefits.[8,9] ■

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One-year results of heavily calcified femoropopliteal artery stenting.

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Current recommendations for treating lower limb peripheral artery disease (PAD) are suggested by the TASC II consensus.[1] Peripheral artery stents are commonly used as an alternative to invasive treatment for peripheral occlusive disease,[2] and technical success can be achieved in most cases with a low risk of complications. Newer techniques and technologies are effective in the most complex lesions of the iliac arteries, superficial femoral artery (SFA), and popliteal artery; however, late clinical failure is caused essentially by restenosis and risk of stent fracture and distortion. In preventing elastic recoil, treating angioplasty balloon dissections, and stabilizing the arterial wall, stents are becoming essential in most procedures. The ideal stent has to have a high resistance to deformation and a balance between chronic outward force and radial resistive force; a low chronic outward force and a high radial resistive force are required to obtain the best performance.[3-8]

We review our consecutive retrospective study results of the S.M.A.R.T.® Flex stent (Cordis Corporation) in the areas of patients free from target lesion revascularization (TLR), patency rates (assisted and secondary), and fracture rate.

METHODS

Between June 2014 and June 2015, we reviewed all patients in whom we had used S.M.A.R.T.® Flex stents for the treatment of PAD. All patients had clinically severe intermittent claudication or critical limb ischemia (stages 3–6 of the Rutherford classification). One or two S.M.A.R.T.® Flex stents (minimum 5-mm overlap) were utilized as necessary in each procedure.

Sizing was based on arteriography during the procedure, and the diameter of the stent used was equal to the artery's diameter. Intraoperative flexion angiograms were obtained when stents were deployed at the end of the SFA and proximal popliteal artery (Figure 1).

The main judgment criterion was the patency rate at 1-year follow-up and the number of patients free from TLR.

RESULTS

Forty-one patients (41 lower limbs) were treated with S.M.A.R.T.® Flex stents with a mean follow-up of 8 months (range, 3–15 months). Five patients had two stents with a 5-mm overlap, with a total of 46 stents deployed. We included 21 patients who were TASC II stage B, one patient who was TASC A, 16 patients who were TASC C, and three patients who were TASC D (Figure 2). All of our PAD patients were either

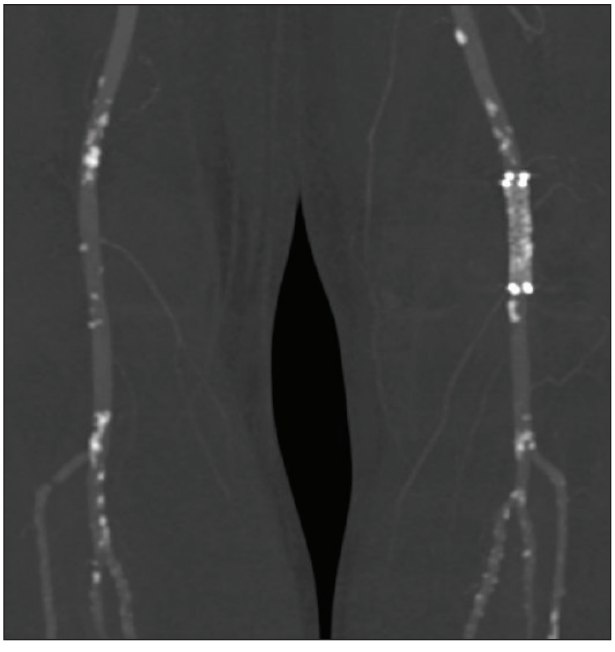

Figure 1. Popliteal artery stenting.

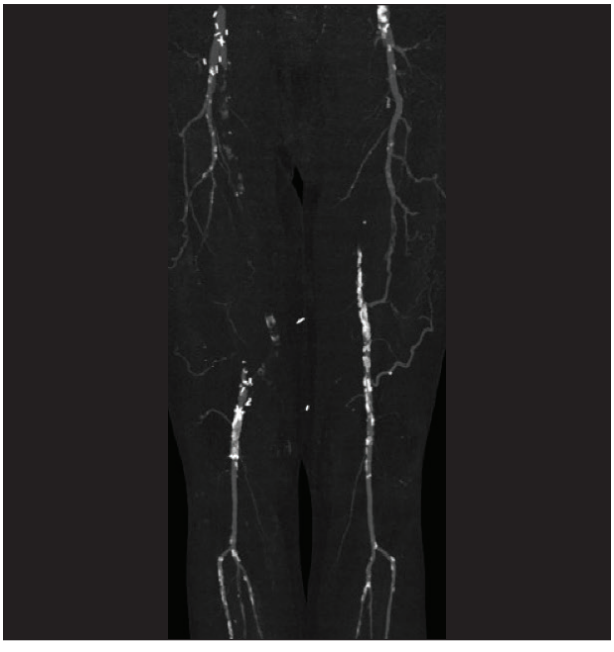

Figure 2. TASC D lesions with calcified arteries.

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TABLE 1. POPULATION CHARACTERISTICS

Characteristics	n	%
Age < 60 y	31	76
Body mass index > 28 kg/m²	6	15
ASA score > 2	15	36
Diabetes	14	34
High blood pressure	35	85
Coronary insufficiency	16	39
Heart failure	10	24
Oral anticoagulant chronic treatment	3	7
Tobacco smokers	25	61
Alcoholics	2	5
Hypercholesterolemia	18	45
TASC A	1	2
TASC B	21	51
TASC C	16	39
TASC D	3	7
Rutherford 3	31	76
Rutherford 4	8	20
Rutherford 5	2	5
Number of stents > 1	5	12
Postoperative antiplatelet drugs = 2	38	92

Abbreviations: ASA, The American Society of Anesthesiologists; TASC, Trans-Atlantic Inter-Society Consensus.

Rutherford stage 3 (31 patients), Rutherford stage 4 (eight patients), or Rutherford stage 5 (two patients) (Table 1).

All patients had severe calcium burden, and their mean stenosis severity was 94%. Thirty-four percent of the patients were diabetic, 61% of them were tobacco smokers, and 76% were younger than 60 years. For three patients, the stents were placed in the proximal popliteal artery; two concerned the SFA and the first two segments of the proximal popliteal artery, and one was the proximal popliteal artery alone. The mean stent length was 125 mm (range, 40–345 mm).

The technical success rate was 100% at 30-day follow-up, all free from major adverse events. The rate of freedom from TLR at 1 year was 62%, and the assisted primary patency and secondary patency rates were 92% and 97%, respectively. Three patients had complete stent occlusion: one patient was TASC II C, and two patients were TASC D (Figure 3).

Twelve patients presented with severe stenosis (> 70%) in the first year of follow-up, corrected by a new angioplasty; the 1-year limb salvage rate was 97%. There was a major amputation at 11 months of follow-up after TLR failure (TASC D patient). This patient was the only one who had a type 4 stent fracture and subsequent total stent occlusion. We made a venous below-the-knee bypass, which was ineffective (also occluded afterward). One type 1 stent fracture was found in the follow-up period, near the proximal popliteal artery articular segment; however, this fracture has not led to any clinical consequences.

DISCUSSION

This article is a single vascular unit review of the S.M.A.R.T.® Flex stent performances at 1 year. Our results are encouraging and are comparable to those mentioned in the literature.[9-11]

We found two stent fractures at 1 year (all in extremely calcified arteries); one type 1 without any clinical relevance and one type 4. This last patient received two stents for the distal SFA and the proximal popliteal artery, and the overlapping of the stents was in the second popliteal segment. We think this was the reason for this type 4 fracture and subsequent total stent occlusion. The patient had a bypass occluded thereafter and a major amputation at 11-month follow-up. All stent fractures occurred inside or close to the first popliteal articu-

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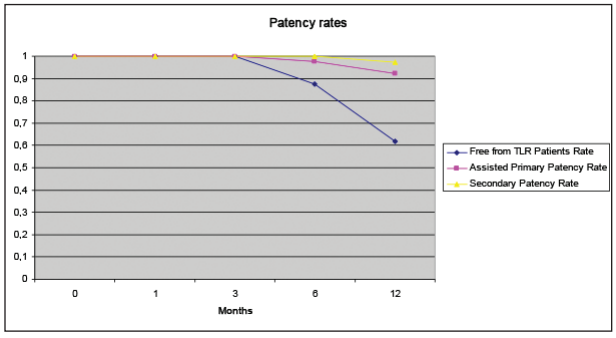

Figure 3. Patency rates and freedom from TLR rates.

lar segment. This is a known risk factor, but symptomatic fractures remain rare.[12-15] Twelve patients underwent repeat angioplasty due to in-stent restenosis at the first year (29% of in-stent restenosis), which is comparable with results reported in the literature; extremely calcified arteries produce more inflammatory response and subsequently more hyperplasia.[16]

CONCLUSION

The S.M.A.R.T.® Flex stent is easy to use with a greater longitudinal stability and a good resistance to fracture. The S.M.A.R.T.® Flex stent, with a fully connected design that minimizes restenosis with reduced chronic outward force, had 1-year results that were very promising, and we are confident in the future of this product, especially in the complex lesions of the SFA and proximal popliteal arteries. ■

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