Sponsored by Cordis Corporation

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

One year of experience with the vascular stent system.

BY LUCA GARRIBOLI, MD, AND ANTONIO MARIA JANNELLO, MD

Every day, we encounter patients who ask us to help them get back to walking without pain. Most likely, they suffer from a lesion of the superficial femoral artery (SFA) that can be treated with an endovascular approach. At the same time, diabetic patients need revascularization of the femoropopliteal segment to improve their blood supply to the feet.

With the knowledge that the use of stents improves results in the SFA compared to percutaneous transluminal angioplasty (PTA),[1,2] the question is, which one on the market offers the best long-term results in terms of patency, target lesion revascularization (TLR), and fractures? Today, the acceptable patency rate at 1 year is almost 80%.[3,4] We have obtained very promising results with the S.M.A.R.T.® Flex vascular stent system (Cordis Corporation), which is designed to be more elastic, flexible, and durable.

CASE SERIES

From June 2014 to June 2015, we implanted 14 S.M.A.R.T.® Flex stents in patients with intermittent claudication or critical limb ischemia for chronic total occlusions or long diffused lesions of the femoropopliteal trunk, classified as TASC II C and D lesions.[5]

According to institutional standards, we placed a 6-F sheath under ultrasound guidance in the common femoral artery using the antegrade approach and passed the occlusion through the lumen with a 0.035-inch hydrophilic guidewire (Zipwire, Boston Scientific Corporation) supported by a 4-F straight catheter (Tempo, Cordis Corporation). All patients were administered an intra-arterial bolus of unfractionated heparin (70 U/kg). We initially inflated a 5/6-mm balloon (PowerFlex Pro, Cordis

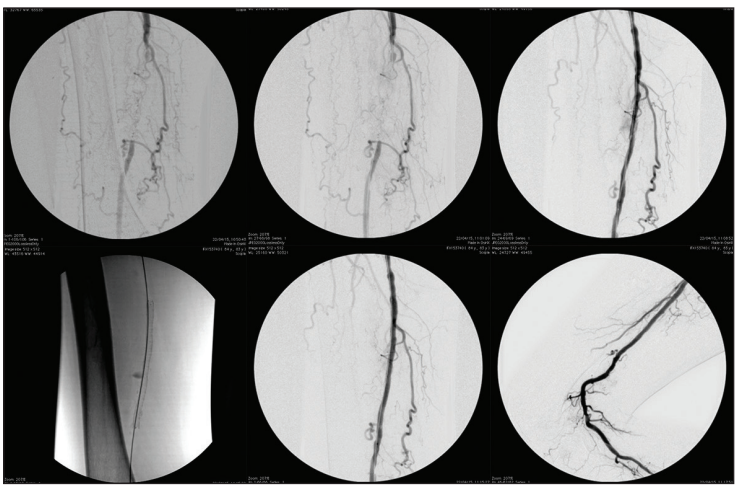

Figure 1. An example of the S.M.A.R.T.® Flex stent system in use. In these images, we can find the different phases of SFA stenting. Starting from the top left and following a clockwise pathway, we show the preliminary angiography, the passage of the 0.035-inch guidewire in the lumen, the results of the predilatation, the S.M.A.R.T.® Flex stent deployment, and in the last two images, the angiography control with and without the knee bent.

Sponsored by Cordis Corporation

TABLE 1. CLINICAL DATA

Age (y)	Disease	Length (cm)	Vessel	Stent Number	Stent Diameter (mm)	Stent Length (mm)	Follow-up (mo)	Antiplatelet Therapy	Second Procedure	Secondary Follow-up (mo)
70	Occlusion	8	SFA	1	6	100	15	Aspirin		
65	Steno-occlusive	12	SFA	1	6	150	14	Aspirin		
77	Steno-occlusive	4	SFA	1	6	60	12	Aspirin		
70	Steno-occlusive	8	SFA	1	6	100	12	Aspirin		
94	Occlusive	14	SFA	1	5	150	11	Aspirin	Redo angio-plasty	1
72	Steno-occlusive	12	SFA	1	6	150	6	Clopidogrel + aspirin	Redo angio-plasty with drug-eluting balloon	5
63	Occlusion	12	SFA	2	5 + 6	100 + 60	10	Clopidogrel + aspirin		
68	Steno-occlusive	18	SFA	1	6	200	9	Clopidogrel + aspirin		
68	Steno-occlusive	18	SFA	1	6	200	9	Clopidogrel + aspirin		
53	Occlusive	15	SFA	1	7	150	6	Ticlopidine		
77	Steno-occlusive	25	SFA	2 + 1	5 + 6 + 7	150 + 150 + 29	5	Aspirin		
83	Occlusive	10	SFA	1	6	100	5	Aspirin		
68	Occlusive	4	SFA	1	5	60	4	Clopidogrel		
76	Steno-occlusive	10	SFA	1	6	100	4	Aspirin		

Abbreviations: SFA, superficial femoral artery.

Corporation) for 3 minutes, obtaining a complete recanalization of the affected segment. We then stented all the segments according to our protocol (Figure 1).

The 14 patients ranged in age from 53 to 94 years (median, 72.5 years); nine patients were men, and five were women. Diabetes was present in six patients, 10 displayed hypertension and were previous smokers, dyslipidemia was present in eight patients, while four patients had cardiomyopathy, including atrial fibrillation, but without anticoagulation. The average follow-up was at 8 months (range, 4–14 months). As shown in Table 1, in six cases, we treated a complete occlusion of the SFA, whereas in the other eight patients, a long stenosis was encountered. The average length of the diseased segment was 12 cm (range, 4–25 cm).

In 12 patients, a single stent was sufficient to complete the procedure; in two patients, two stents were used. We generally prefer to use a single long stent rather than multiple stents to avoid areas of overlap, where the risk of stent fractures increases. The diameter implanted was 6 mm in nine patients, 5 mm in two patients, and 7 mm in one patient. If the size of the distal landing zone was smaller than

Sponsored by Cordis Corporation

the proximal one, we used a combination of different stent sizes, the smaller one distally (placed before the other one) and the larger one promimally. All of the patients underwent postoperative antiplatelet therapy: a single drug was administered in 10 patients (eight patients received aspirin 100 mg, one patient received clopidogrel 75 mg, one patient received ticlopidine 500 mg), while four patients received dual-antiplatelet therapy (aspirin 100 mg plus clopidogrel 75 mg). Antiplatelet therapy did not influence the stent patency or the appearance rate of TLR during follow-up.

Two patients underwent PTA for TLR during follow-up. The first patient underwent PTA with a balloon after 11 months, whereas in the second patient, who presented with severe in-stent restenosis after 6 months, a drug-eluting balloon was used. Both patients were free from TLR, the first patient at 1 month after the procedure and the second patient at 5 months after the procedure. We used a single 150-mm-long stent for both patients to treat a lesion of the mid-distal SFA—in the first patient for occlusion, and in the second patient for severe and multiple calcified stenoses. In our analysis, we acheived a primary patency rate of 86% (12 patients) at 6 months and a secondary patency rate of 100%.

CONCLUSION

The characteristics that make the S.M.A.R.T.® Flex stent suitable to treat the femoropopliteal region are its high resistance to kinking and bending due to the full interconnection of helical strut bands and flexible bridges and its high radial force, preventing recoil in very calcified lesions.[6] The 13 or 16 spiral connections (depending on stent diameter) reduce the cell area and offer optimal scaffolding to cover the plaque in an even and consistent way. Every day, the advent of new technologies raises the level of the difficulties we can manage. We are always ready to accept these challenges, but the results do not always meet our expectations.

Learning how to use devices to achieve the best outcomes for our patients is mandatory, although at the same time, it is important to know what the best tools are for different types of patients, lesions, and anatomical regions. In our analysis, we acheived an acceptable patency rate (86%) at 6 to 12 months, according to the literature,[1-4] and although our series is very limited in terms of the number of patients treated and the short follow-up, our preliminary results are promising, especially because we have treated very complex and long lesions where, in the past, the endovascular approach was not recommended. Although we are aware that further studies and more data are needed to confirm our success, this is a very good starting point. ■

1. Laird JR, Katzen BT, Scheinert D, et al. Nitinol stent implantation vs. balloon angioplasty for lesions in the superficial femoral and proximal popliteal arteries of patients with claudication: three-year follow-up from the RESILIENT randomized trial. J Endovasc Ther. 2012;19:1-9.
2. Geraghty PJ, Mewissen MW, Jaff MR, et al. Three-year results of the VIBRANT trial of VIABAHN endoprosthesis versus bare nitinol stent implantation for complex superficial femoral artery occlusive disease. J Vasc Surg. 2013;58 :386-395.e4.
3. Society for Vascular Surgery Lower Extremity Guidelines Writing Group, Conte MS, Pomposelli FB, et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. J Vasc Surg. 2015;61:2S-41S.
4. Zeller T. Current state of endovascular treatment of femoro-popliteal artery disease. Vasc Med. 2007;12:223-234.
5. Garriboli L, Jannello AM. S.M.A.R.T. flex vascular stent system: why should I choose this system to treat the SFA? Endovasc Today Eur. 2015;3:21-23.
6. Goverde P, Taeymans K, Lauwers K. Technical considerations and clinical results in treating extensive femoropopliteal occlusive disease. The S.M.A.R.T. flex vascular stent system solution. Endovasc Today Eur. 2014;2:24-27.

Luca Garriboli, MD
Department of Vascular Surgery
H. Sacro Cuore Don Calabria
Negrar (Verona), Italy
luca.garriboli@gmail.com
Disclosures: None.

Antonio Maria Jannello, MD
Department of Vascular Surgery
H. Sacro Cuore Don Calabria
Negrar (Verona), Italy
Disclosures: None.

EU872 5/16