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# S.M.A.R.T.® Flex Vascular Stent System: Why Should I Choose This System to Treat the SFA?

A discussion of this device's enhanced technical features, with illustrative case reports.

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The use of stents to improve the results of balloon angioplasty in the superficial femoral artery (SFA) has been demonstrated in several trials.[1,2] Today, the focus is on what the most appropriate solution might be in order to offer the best long-term results in terms of patency, target lesion revascularization, and fractures, given the unique forces that are found in the femoropopliteal segment[3,4] such as elongation, compression, torsion, and flexion. Moreover, it is fundamental that the stent is able to provide a scaffold within the irregular intraluminal wall that results after balloon angioplasty damage or in case of wall thrombosis areas. Finally, the new generation of stents does not require oversizing, leading to less hyperplasia due to lower chronic outward force.[5]

Because of its shape-memory properties, nitinol is considered to be the most suitable material for use in the SFA, and hence, many nitinol stents have been launched on the market in the last 10 years. These devices differ among one another not only in regard to design and other characteristics, but also for the technological enhancements that these latest-generation products offer compared to older products.

In this article, we aim to underline the features of the S.M.A.R.T.® Flex Vascular Stent System (Cordis Corporation) while discussing a few in vivo cases.

## CASE 1: ELONGATION, COMPRESSION, AND TORSION

An 84-year-old man was admitted for severe claudication associated with lesions of his right foot (Figure 1). He had a 30-year history of diabetes and dyslipidemia. Angiography revealed an occlusion (10 cm) of the mid-distal SFA with patency of the popliteal segment and tibial vessels. As usually performed at our center, we placed a 6-F sheath under ultrasound guidance in the common femoral artery in antegrade flow 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). We initially inflated a 5-mm balloon (Powerflex Pro, Cordis Corporation) for 3 minutes and achieved complete recanalization of the affected segment, but with areas of dissection and irregular vessel walls.

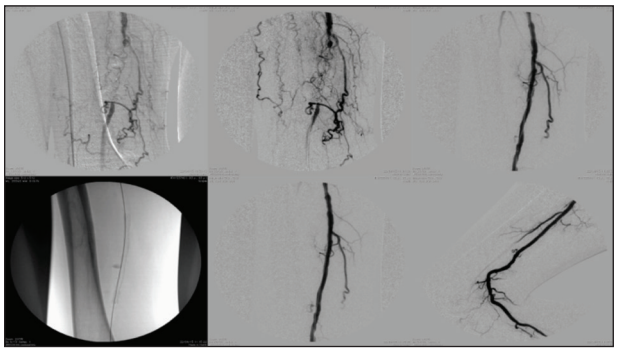

**Figure 1. In this picture, we show the different phases of SFA recanalization. After crossing the occlusion we predilate the SFA with a balloon and place a S.M.A.R.T.® Flex stent. The final pictures highlight the patency of SFA without compression after knee bending.**

In order to improve our result, and according to the more recent guidelines,[6] we decided to place a nitinol bare-metal stent to cover the treated arterial segment. We chose to use a 6- X 100-mm S.M.A.R.T.® Flex stent for the following reasons:

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1. The segment of SFA to be treated was the mid-distal, which is exposed to elongation and compression during hip flexion and knee bending. In fact, the SFA and popliteal arteries demonstrated axial compression that could vary its length up to 23%.[4] The S.M.A.R.T.® Flex helical strut bands are interconnected by flexible bridges, which enable axial compliance while offering a high level of longitudinal stability.
2. During SFA torsion, the flexible bridges reduce their distance without breaking, and at the end of the tension, they return to their original position.
3. The radial force offered by S.M.A.R.T.® Flex balances the muscular compression of the adductor channel.

## CASE 2: BENDING

A 63-year-old man underwent an ultrasound scan of his leg arteries for severe acute claudication and a walking distance of < 50 meters (Figure 2). He had a history of smoking without any other cardiovascular risk factors. Echo color Doppler revealed the occlusion of the proximal popliteal artery, which was 8 cm in length, as well as severe demodulation of the flow in the distal vessels. Angiography confirmed the ultrasound finding.

As usual, we used a 0.035-inch hydrophilic guidewire (Zipwire) to cross the occlusion, which was supported by a 4-F straight catheter (Tempo); we then dilated the occluded segment with a 5-mm balloon (Powerflex Pro). After the dilatation, a long dissection occurred along the popliteal artery, and thus, we completed the treatment by placing a nitinol bare stent.

Our choice was a 5- X 100-mm S.M.A.R.T.® Flex. The characteristics that make S.M.A.R.T.® Flex suitable to treat the proximal popliteal region are its (1) high flexibility and compression resistance due to the full interconnection of the helical strut bands and the flexible bridges, (2) high resistance to the kinking or bending that result in regular flow during daily activities, (3) high radial force that prevents recoil in very calcified lesions, and (4) low chronic outward force generated by correct sizing of the stent in the popliteal region.

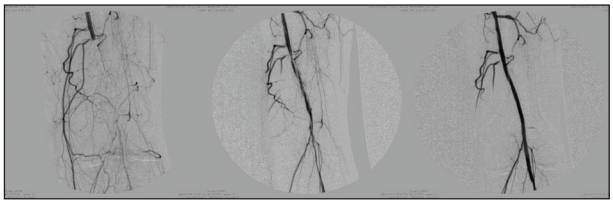

**Figure 2. The complete occlusion of the popliteal artery has been crossed, but the balloon angioplasty results in a severe dissection. The final images showed the optimal result after a S.M.A.R.T.® Flex stent placement.**

## CASE 3: SCAFFOLDING

A 53-year-old man presented with acute ischemia of the left leg due to a thrombosis in the SFA and popliteal artery (Figure 3). He was an active smoker with a history of dyslipidemia and 2 years of statin therapy. Angiography showed complete occlusion of the SFA from the middle-third and of the popliteal artery up to the knee joint.

We navigated within the thrombus with a 0.035-inch hydrophilic guidewire (Zipwire) supported by a 4-F straight catheter (Tempo) up to the patent distal popliteal artery. We then withdrew the catheter, injected 200,000 international units (IU) of urokinase (UK) to saturate the thrombus, and started a continuous infusion of UK (70,000 IU of UK per hour). To maintain an adequate level of anticoagulation, a bolus of 5,000 IU of heparin sulfate was administered to the patient, and 1000 IU/h was continued intravenously.

Angiography performed 6 hours later showed an incomplete lysis of the thrombus, whereas after 18 hours, the thrombus had almost completely disappeared, and angiography revealed multiple stenoses of the SFA. In order to address the stenotic disease of the SFA and avoid distal embolization of clots, we performed direct stenting with a single 7- X 150-mm S.M.A.R.T.® Flex and postdilated it with a 6-mm Powerflex Pro balloon.

In this particular case, we had to solve two main problems: the original multiple stenosis (cause of the acute thrombosis) and the residual wall thrombosis that could embolize distally. As previously mentioned, S.M.A.R.T.® Flex works very well in the mid-distal segment of the SFA. Moreover, the 13 or 16 spiral connections (depending on the stent diameter) reduce the cell area and offer an optimal scaffolding to cover the plaque in an even and consistent way.

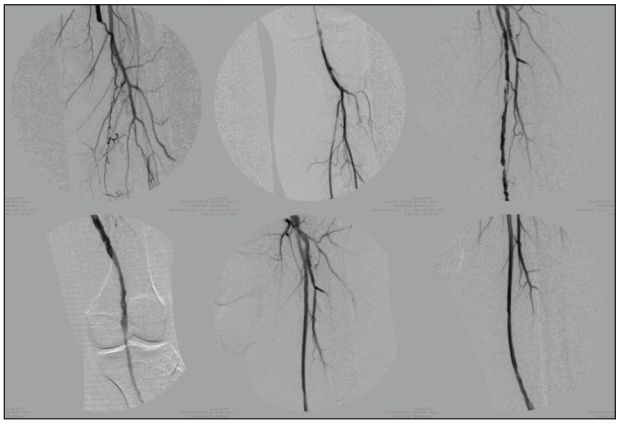

**Figure 3. The first two images show the initial occlusion of the SFA that also involves the popliteal artery. After thrombolysis, a stenosis of the femoropopliteal segment appears. To cure the stenotic disease associated with areas of wall thrombosis, we perform a direct stenting with postdilatation.**

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## CLINICAL EXPERIENCE

In our experience, we have treated more than 350 patients with different types of stents in the SFA and femoropopliteal segments with a patency rate of 82% in the first year. Since July 2014, we introduced the S.M.A.R.T.® Flex stent in our center and have used it in 20 patients in the femoropopliteal segment with a patency rate of 95% in the first 6 months of follow-up. Of these 20 patients, there has only been one case of acute occlusion (within 24 hours) of SFA stenting that required surgical treatment to restore distal flow. In 16 cases, we used a single stent; in three cases, two stents were placed; and only one case required three stents to cover nearly all of the femoropopliteal segment, which involved an acute thrombosis (this is the failed case).

## DISCUSSION

The stenting in the SFA has been proven to be the most effective endovascular treatment for occlusive disease, but until now, the stents available on the market have demonstrated limits due to the multiple critical factors involved in this particular area.[7] The acceptable patency rate at 1 year is nearly 80%, but obviously, we would all like this rate to be even higher.[8,9] For enhanced performance, a stent in the femoropopliteal segment requires specific features, including low chronic outward force, natural flexibility, high fracture resistance, optimal scaffolding, and improved laminar flow in order to decrease the risk of hyperplasia.

An ideal stent could certainly be invisible, minimally invasive, durable, etc. This might be a utopian ideal, but to obtain the best results, any stent has to be built aspiring to this goal. S.M.A.R.T.® Flex has yet to achieve this objective, but it works within the artery as well as possible today. One of the reasons is the low chronic outward force generated by the S.M.A.R.T.® Flex, which decreases the local inflammation and the risk of restenosis. Also, the S.M.A.R.T.® Flex is very easy to use and does not require an extensive learning curve in order to deploy it correctly, solving another critical issue in our daily activity.

In conclusion, the S.M.A.R.T.® Flex is a uniquely constructed, fully connected, self-expanding stent made from laser-cut superelastic nitinol tubes. The helical strut bands and the flexible bridges are interconnected, providing strength, flexibility, and durability. The fully connected structure facilitates a continuous but atraumatic synergy between stent and vessel wall and also enables axial compliance.[10] These features seem to be very promising to ensure best results. ■

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