

S.M.A.R.T.® Flex Vascular Stent System: Experience and Outcomes in Two Italian Centers of Excellence

A new-generation stent for the treatment of TASC II C and D lesions of the SFA.

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Despite advancements in technology and continually improving results, the management of peripheral artery disease (PAD) in the lower extremities remains a significant challenge, from focal occlusions to multilevel critical limb ischemia. To many, the current gold standard treatment for patients with critical limb ischemia, defined as chronic ischemic rest pain, ulcers, or tissue loss, remains infrainguinal bypass.¹⁻⁴ Surgical revascularization is the treatment of choice for TASC II C and D lesions, and vein bypass remains the treatment against which any infrainguinal arterial reconstruction technique for superficial femoral artery (SFA) occlusion should be compared.

Considerable progress has been made in percutaneous endovascular SFA treatment, including the development of subintimal techniques and reentry devices for crossing chronic total occlusions and longer, more flexible nitinol stents. Although vein bypass is the gold standard treatment for TASC II C and D lesions, it is not feasible in all patients because of comorbidities or general contraindications to surgery. As a result, more than 90% of TASC II C and D lesions are treated with an endovascular approach.⁴⁻⁶ Subsequent surgical revascularization of aortoiliac and femoropopliteal chronic total occlusions is often feasible regardless of whether endovascular revascularization is successful.⁵

SFA STENT PLACEMENT

In the superficial femoral and popliteal segments, the role of primary stent placement remains a topic of research and discussion. The use of self-expanding bare-metal stents has been shown to improve the durability of percutaneous transluminal angioplasty (PTA) performed on the superficial femoral and popliteal segments in properly selected patients.⁷

Stents can be placed after unsuccessful PTA and/or treating infrainguinal occlusive disease due to early elastic recoil, residual stenosis, or flow-limiting dissection after PTA.^{8,9} However, different forces, such as longitudinal stretching, external compression, torsion, and flexion, act on the superficial femoropopliteal artery and may lead to stent fractures and eventually restenosis.

Older trials evaluating the role of stenting in the peripheral arterial circulation were disappointing. One-year primary patency rates were 22% with the PALMAZ® Stent (Cordis Corporation) and 30% with the Wallstent® (Boston Scientific Corporation).¹⁰

Today, nitinol self-expanding stents are the most commonly placed stents in patients with femoropopliteal disease. Stent length has been shown to be a major determining factor for long-term primary patency, which explains the high variability of primary patency rates (45.9%–92%).¹¹

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S.M.A.R.T.® FLEX VASCULAR STENT SYSTEM

In stented portions of the SFA, increased stress and major deformity have been found, which may lead to alterations (ie, rupture, kinking) in stent material.¹² Thus, biomechanics as it relates to fatigue resistance of nitinol stents implanted in the femoropopliteal arteries is an important concern. The daily activity of the hip and knee joint exposes the SFA — and therefore the implanted stents — to cyclic deformations that could influence stent fatigue resistance.^{13,14} The most important characteristic of a bare-metal stent is fracture resistance.¹⁵

The S.M.A.R.T.® Flex Vascular Stent System (Cordis Corporation) is a uniquely constructed, fully connected, self-expanding stent made from laser-cut superelastic nitinol tubes. The helical strut bands and the flex bridges are interconnected, which provides strength, flexibility, and durability. The fully connected structure facilitates a continuous but atraumatic synergy between the stent and vessel wall, which also enables axial compliance.

Most femoropopliteal stents have three or four connections around the circumference, whereas the S.M.A.R.T.® Flex Vascular Stent System has 13 or 16 connections (depending on the stent diameter) in addition to a fully connected structure, which enhances durability and structural redundancy.

In several vigorous comparative fatigue tests, the S.M.A.R.T.® Flex Vascular Stent System demonstrated greater fracture resistance and greater ability to resist compression and maximize luminal diameter, enabling increased blood flow.

Not only is the durability of the stent reflected in its high-cycle fatigue resistance, the stent system design also ensures that the stent is uniformly delivered as intended. During placement, the S.M.A.R.T.® Flex Vascular Stent System does not significantly elongate because of a biased axial compliant delivery system. The stent conforms perfectly to the vessel wall, which determines an optimum performance.¹⁵⁻¹⁷

CLINICAL EXPERIENCE

Our dual-center experience is a nonconsecutive prospective evaluation of patients who received the S.M.A.R.T.® Flex Vascular Stent Systems at the femoral and popliteal arteries, with a particular focus on cases that involved the “articular” tract of the popliteal artery.

We have treated 50 patients who had a reduced qual-

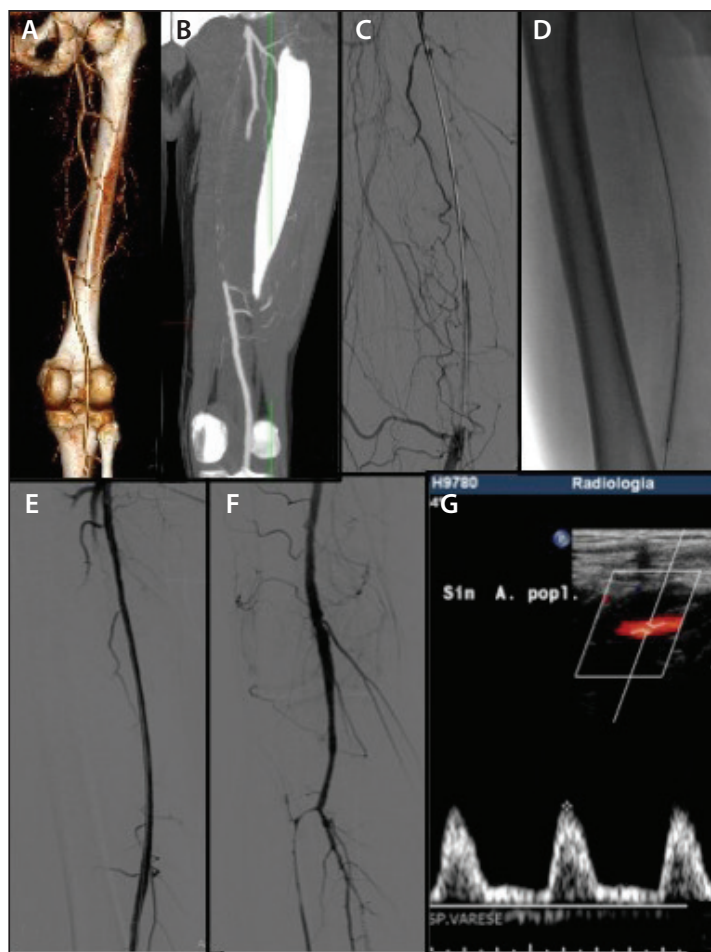


Figure 1. CT angiography with a three-dimensional volume rendering showing a complete occlusion of starting at the middle third of the SFA (A, B). Intraprocedural SDA showing occlusion of the left SFA to the distal third artery and a normal lumen near the articular tract of the popliteal artery (C). Single-shot DSA showing correct stent positioning (D). Postprocedural DSA showing correct positioning of the S.M.A.R.T.® Flex Vascular Stent System (E); arterial blood flow to the limb was secured, and artery caliber was restored (F). Postprocedural CDUS showing patency of the popliteal artery in the treated limb (G).

ity of life, as determined by PAD symptoms such as pain during movement, pain at rest, decreased quality and duration of sleep, inability to perform activities of daily living, and loss of independence.

Pretreatment workup imaging demonstrated that 35 patients had chronic total occlusions of the femoropopliteal and trifurcation vessels, classified as TASC II C and D lesions; three patients had associated popliteal artery aneurysms. The regions of stent placement were the proximal SFA, mid-SFA, distal SFA, proximal popliteal artery, and distal popliteal artery with articular involvement.

The technical success rate was 100%. After each device was implanted into the mid-SFA, distal SFA, and

the proximal popliteal region, a flexion angiogram was obtained to evaluate whether the stent(s) exhibited kinking or compression. In all patients, the arterial circulation was not compromised by stent kinking or bending either at 90° or in full flexion.

No minor or major intraprocedural complications were observed, no obstructions were observed on day 1 postimplantation, and primary patency was 100% at 1 month postimplantation, as assessed by color Doppler ultrasonography (CDUS). A stent occlusion was observed in one patient at 2 months postimplantation, likely due to inadequate therapy compliance by the patient. No stent fractures were observed during this period.

CASE EXAMPLE

A 76-year-old woman had a long smoking history and a history of cardiomyopathy and percutaneous transluminal coronary angioplasty. She had leg pain with claudication in the left leg with a walking distance of 50 meters.

Pretreatment workup was performed, including CT angiography with a three-dimensional volume rendering, which showed a complete occlusion starting at the middle third of the SFA and extending approximately 15 cm (Figure 1A and 1B). The same results were seen on multiplanar reconstructed paracoronary CT.

Intraprocedural SDA showed occlusion of the left SFA to the distal third artery, where a normal lumen could be appreciated near the articular tract of the popliteal artery (Figure 1C). Because of the vascular fibrocalcification, we decided to perform direct stenting in order to avoid distal embolization. Intrastent angioplasty was later performed to bring the vessel close to its initial diameter. Single-shot DSA showed correct stent positioning (Figure 1D). Postprocedural DSA showed correct positioning of the S.M.A.R.T.® Flex Vascular Stent System (Figure 1E), which secured arterial blood flow to the limb and restored the correct artery caliber (Figure 1F). Postprocedural CDUS was performed to assure the patency of the popliteal artery in the treated limb (Figure 1G).

CONCLUSION

PAD is an important clinical problem worldwide. Vein bypass remains the gold standard treatment, but because of individual patient characteristics and comorbidities, there is no single best way to manage PAD. The continuous technologic development of new devices is increasing indications for percutaneous treatment. The S.M.A.R.T.® Flex Vascular Stent System can be used to treat patients with extensive disease at the distal periarticular tract and has shown promising results. Further studies involving a larger series of patients are needed to confirm the current results. ■

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