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The S.M.A.R.T.® Flex Vascular Stent System Solution

Technical considerations and clinical results in treating extensive femoropopliteal occlusive disease.

BY PETER GOVERDE, MD; KIM TAEYMANS, MD; AND KATRIEN LAUWERS, MD

In the treatment of peripheral arterial disease, endovascular interventions have increased exponentially over the last few decades.[1] Around 40% of those procedures are done in the femoropopliteal arterial segment,[2] and yet its treatment remains a challenge to the interventionist. Balloon angioplasty is still the first therapeutic option to choose, with a high rate of acute procedural success, but target lesion revascularization and target vessel revascularization remain elevated.[3]

Percutaneous transluminal angioplasty (PTA) sometimes induces a subtotal rupture of the vessel wall going through the plaque, intima, and media down to the level of the adventitia. Uncontrolled vessel wall expansions may result in dissections and can cause irregular intraluminal defects or torn tissue flaps hanging into the flow channel. Subsequently, this can create

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hemodynamic disturbances triggering thrombus formation, leading to restenosis or even occlusion.

For scaffolding the damaged wall, self-expanding nickel-titanium (nitinol) stents are frequently used to restore the luminal integrity. Nitinol stents demonstrate elastic and thermal memory properties very suitable for the infrainguinal arterial bed. They also conform better to the unique biomechanical environment of the femoropopliteal artery as a result of their resistance to torsion, flexion, extension, contraction, and compression.[4]

Endovascular treatment of the superficial femoral artery (SFA) presents significant challenges in achieving durable results due to the unique forces to which the SFA is subjected. The continuity with both the popliteal and common femoral arteries exposes the SFA to elongation. Also, its superficial course and interaction with surrounding musculature subject the SFA to compressive and torsional forces (Figure 1).[5] These mechanical forces imparted on the vessel can result in metal fatigue and stent fracture, which has been associated with restenosis.[6] In addition, stent implantation in the SFA will trigger a more potent inflammatory
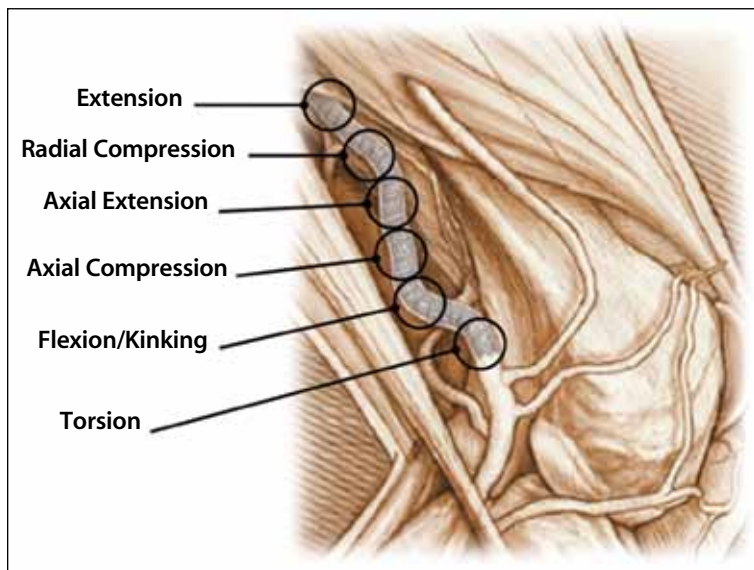

Figure 1. Arterial motion is dynamic and varies continuously, causing local biomechanical forces that pose a significant challenge to a future implant.

(Labels on figure: Extension, Radial Compression, Axial Extension, Axial Compression, Flexion/Kinking, Torsion)
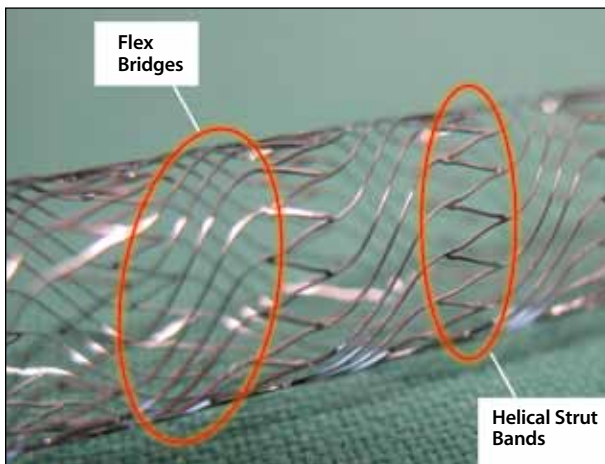
Figure 2. The S.M.A.R.T.® Flex Vascular Stent System is a fully connected, laser-cut nitinol self-expanding stent with high flexibility and compression resistance due to the full interconnection of the helical strut bands by the flex bridges.

response than balloon angioplasty alone.[7,8] In part, this is related to micromovements of the stent alongside the vessel wall, leading to activation of the endothelium and inflammation. Using multiple overlapping stents in the treatment of long SFA lesions can create hinge points, which may potentiate stent fracture. Additionally, the potential for significant multivessel disease and popliteal and tibial outflow lesions, as well as complex long and calcific lesions often encountered in SFA stenosis, can complicate lasting success after endovascular interventions.

Thus, the current limitation of SFA and popliteal stenting is restenosis. This can be initiated by stent fractures due to compression, torsion, or bending forces; by vessel wall injury due to radial expansion or chronic outward force; and by wall shear stress due to altered hemodynamics.

TECHNICAL CONSIDERATIONS

In vitro results showed that physiological loads that act on the femoropopliteal artery, in combination with stenting, can lead to a change in global deformation characteristics of the vessel.[9] Increased stress and strain values and altered deformation characteristics were observed in stented portions of the SFA, possibly leading to alterations in stent material.[10] Thus, the fatigue resistance of nitinol stents implanted into femoropopliteal arteries is a critical issue for the particular biomechanical environment of this region. Hip and knee joint movements due to daily activity expose the SFA—and therefore the implanted stents—to quite large and cyclic deformations, influencing stent fatigue resistance.[11,12]

Fracture susceptibility and resistance is largely a function of stent design, and previous studies[13] have already demonstrated that for both performance and durability, not all laser-cut self-expanding stents are alike. 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 interconnection of the helical strut bands and the flex bridges provides strength, flexibility, and durability (Figure 2). The fully connected structure is meant to facilitate a continuous but atraumatic synergy between stent and vessel wall, and this also enables axial compliance. Unlike other femoropopliteal stent designs, the fully connected structure provides enhanced durability and redundancy with 13 or 16 connections (depending on
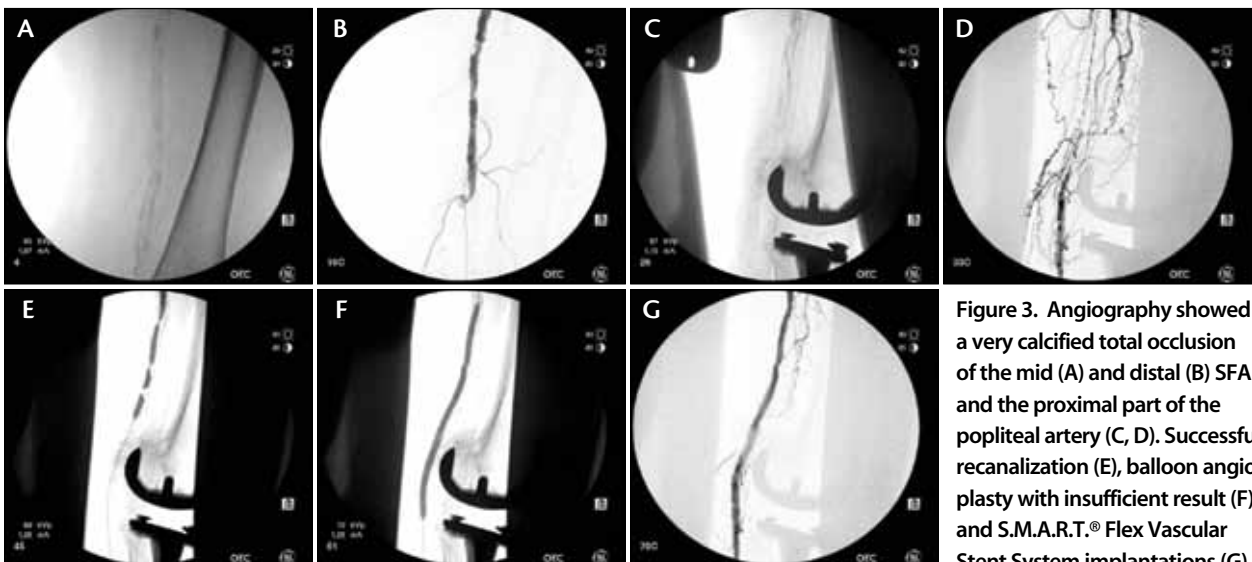

Figure 3. Angiography showed a very calcified total occlusion of the mid (A) and distal (B) SFA and the proximal part of the popliteal artery (C, D). Successful recanalization (E), balloon angioplasty with insufficient result (F), and S.M.A.R.T.® Flex Vascular Stent System implantations (G).
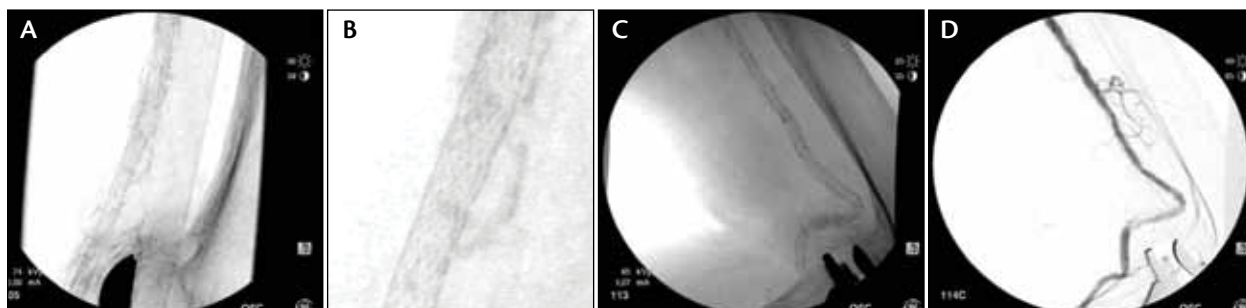
Figure 4. Complete deployment of the S.M.A.R.T.® Flex Vascular Stent System, despite the heavy calcium load (A, B). Even in 90° flexion, the arterial flow was not compromised by the calcifications and stent bending (without kinking) (C, D).

the stent diameter) around the circumference compared to that of three or four connections in most competitive stents. Numerous and vigorous comparative fatigue tests demonstrated that the S.M.A.R.T.® Flex Vascular Stent System had a greater fracture resistance and a greater ability to resist compression and maximize luminal diameter, enabling increased blood flow.

The design of this stent takes into account that durability is not simply reflected in high-cycle fatigue resistance but also in the system's ability to deliver the stent in a uniform way and as intended. With a biased axial compliant delivery system, the S.M.A.R.T.® Flex Vascular Stent System does not significantly elongate when deployed. A quick and accurate placement from the 6-F–compatible, over-the-wire (0.035-inch) system is provided by the unique marking mechanism, the uniform and fully connected stent design, and the simple push-and-pull mechanism. During and after deployment, the stent is intended to conform to the vessel wall in the configuration designed for optimum performance.[14]

CASE EXAMPLE

A 77-year-old woman had rest pain in the left leg, Rutherford-Becker category 4. She had a history of diabetes, arterial hypertension, cardiomyopathy, percutaneous transluminal coronary angioplasty, coronary artery bypass grafting, and a knee prosthesis. Angiography revealed a heavily calcified occlusion (± 250 mm) of the distal part of the mid-SFA, distal SFA, and proximal popliteal artery. With an antegrade access, we succeeded in a recanalization (with successful re-entry) of the occluded segment. First, the lesion was treated with a POWERFLEX® Pro (Cordis Corporation) 5- X 150-mm balloon (three inflations), resulting in a narrow channel due to extensive recoil and two flow-limiting dissections (Figure 3). Two S.M.A.R.T.® Flex Vascular Stent Systems (distal, 5 X 200 mm; more proximal, 5 X 100 mm) were

then deployed, with a balloon touch-up afterward. Postprocedure angiogram showed a nice expansion of the whole stent, and 90° flexion images demonstrated that arterial flow was not jeopardized by stent kinking or bending (Figure 4).

CLINICAL EXPERIENCE

We have started a prospective, consecutive follow-up study of our implanted S.M.A.R.T.® Flex Vascular Stent Systems at the femoral and proximal popliteal area. We have treated 43 patients, of whom 31 had a TASC II C or D lesion. More than half of the population had moderate to severe calcium burden, and the mean stenosis severity was 87.9%. The regions of stent placement were as follows: proximal SFA, three patients; mid-SFA, 18 patients; distal SFA and proximal popliteal artery, 22 patients (of whom, 10 received stents in only the proximal popliteal area). The average lesion length was 149.6 mm (4–375 mm), and the mean stent length was 171.2 mm (6–390 mm). The technical success rate was 100%. After every device implantation in the mid and distal SFA and the proximal popliteal region, a flexion angiogram was obtained to see if there was kinking or compression of the stent(s). Either in 90° or in full flexion, the arterial circulation was not compromised by stent kinking or bending. The 30-day results showed 100% freedom from major adverse events and 100% primary patency with subsequent 100% freedom from target lesion revascularization. No fractures were observed during this period; in a subgroup of 21 patients, there were no fractures at 3 and 6 months.

CONCLUSION

The SFA poses a unique combination of anatomic, histological, hemodynamic, and biomechanical challenges to which an implant should respond. An ideal mechanical implant mimics, rather than resists, the vessel's motion. The S.M.A.R.T.® Flex Vascular Stent System, with a fully connected yet highly flexible design,

provides exceptional stability that can help reduce stent stretching during deployment, thereby increasing placement accuracy and achieving the intended radial force and scaffolding. This allows arteries to maintain as much natural behavior and function as possible while addressing atherosclerotic issues. Early clinical results pointed out that the use of the S.M.A.R.T.® Flex Vascular Stent System in treating femoral and proximal popliteal lesions is safe and feasible, with excellent primary patency rates and no fractures at 30 days. ■

Peter Goverde, MD, is a vascular surgeon at Vascular Clinic ZNA, ZNA Stuivenberg Hospital, in Antwerp, Belgium. He has disclosed that he has no financial interests related to this article. Dr. Goverde may be reached at +32 3 217 74 81; peter.goverde@zna.be.

Kim Taeymans, MD, is with Vascular Clinic ZNA, ZNA Stuivenberg Hospital, in Antwerp, Belgium. She has disclosed that she has no financial interests related to this article.

Katrien Lauwers, MD, is with Vascular Clinic ZNA, ZNA Stuivenberg Hospital, in Antwerp, Belgium. She has disclosed that she has no financial interests related to this article.

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