Advertorial

SFA stenting-problem resolved?

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The vascular territory that traditionally has been most difficult to deal with by endovascular means is the superficial femoral artery (SFA). Results of endovascular treatment of atherosclerotic stenotic and occlusive disease of the SFA using balloon angioplasty have been disappointing, with poor outcome in the mid- and long-term. Additional stenting of the lesions in the SFA did not increase patency rates, and several randomized trials using old stent technology (either balloon-expandable or self-expandable delivery systems) have proven that stenting, although yielding higher initial luminal gain and better angiographic success, does not have a positive effect in the long-term.
Recent developments in nitinol stent engineering have however dramatically changed the results of SFA-stenting. The first indication that the use of nitinol stents in the
SFA could improve outcome came from a randomized trial that compared drug-coated nitinol and bare-metal nitinol stents. The results of bare-metal stenting were unexpectedly positive, and no significant additional effect of adding drug-coating could be demonstrated. The same study also revealed a possible downside of placement of nitinol stents in the SFA, namely stent fracture, which has been associated with restenosis. The occurrence of stent fractures that are caused by the hostile environment of the SFA which exerts continuous forces of contraction/extension, torsion, compression and flexion, can be reduced by optimization of stent design and manufacturing while paying special attention to surface etching. With this in mind, recent publications demonstrate that the incidence of stent fractures can be below 2%. Below you can find an update on the data of the RESILIENT trial that further supports the evidence of improved results of SFA stenting. This is followed by a brief review of another application of this new stent technology, namely in patients with critical limb ischemia. The current developments will pave the way to a more endovascular approach of SFA disease (as most probably will be reflected in the new TASC-guidelines).

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The endovascular approach in critical limb ischemia

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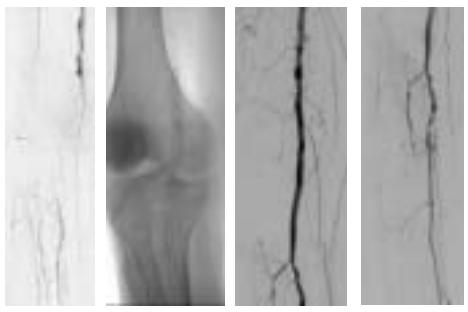
Critical limb ischemia is a condition characterized by the presence of rest pain and/or the presence of ulceration/gangrene of the lower limb. Most of the patients have multiple co-morbidities and a limited life-expectancy. In patients with critical limb ischemia the vascular territory involved can be either aorto-iliac, femoral, popliteal or crural, or a combination of the above. Aim of treatment is to reverse the vicious circle of inflammation, infection and/or tissue loss that leads to an increased oxygen demand, which can not be provided by the diseased vascular bed and therefore will lead to deterioration of disease. This can be accomplished by treating the complete vascular tree where needed. The majority of patients presents with atherosclerotic occlusive disease of the SFA/popliteal artery and/or crural arteries. The BASIL-trial, the only randomized trial in patients with critical limb ischemia published thus far, comparing endovascular therapy (using balloon angioplasty alone) with surgical bypass demonstrated equal outcome in both treatment arms at 2 years. The advantage of endovascular therapy lies mainly in shorter in-hospital stay and less mortality and morbidity in the early follow-up. The same problem of high restenosis rates that is seen with endovascular treatment of patients with intermittent claudication caused by occlusive disease of the SFA can occur in patients with critical limb ischemia. Therefore dedicated stents that can cope with the forces being exerted in the SFA and popliteal artery are needed in this category of patients as well. Results as obtained with new stent technology, using nitinol stents with mechanical properties specifically designed for the SFA territory indicate that higher patency rates as compared to balloon angioplasty alone and "old" stent technology can be achieved, and these results are likely to be applicable to the group of patients with CLI as well.

Case study
An 84-year old man presented to our institution with rest pain of the right lower limb, and severe trophical disturbances of the right foot. Duplex ultrasound revealed an occlusion of the popliteal artery and significant stenotic disease of the distal superficial femoral artery. The patient was scheduled for an endovascular procedure, and diagnostic angiography from an ipsilateral femoral approach confirmed the Duplex findings, and demonstrated single vessel run-off through a fibular artery (fig 1a). After successful recanalization of the occlusion a balloon angioplasty was performed using a 4x80 mm balloon. Control angiography (not shown) demonstrated suboptimal result, and subsequently 2 self-expandable nitinol stents (Lifestent NT, 8x80 mm and 4x80 mm) were placed from the distal SFA up to the popliteal bifurcation (fig 1b).

Post-dilation was performed using a 5x40 mm angioplasty balloon proximally and 4x40 mm distally. Control angiography demonstrated no residual stenosis, without signs of distal embolization (fig 1c-1d).
The clinical course was uneventful, with disappearance of rest pain, and increased ABI.



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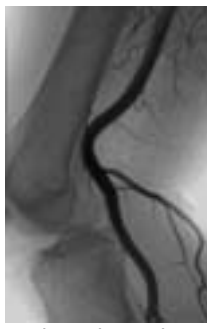
The Edwards LifeStent and the RESILIENT Trial: a new treatment option for the challenging SFA anatomy. Preliminary clinical results.

Prof. Maria Schoder, Dept. of Angiography and Interventional Radiology, Medical University of Vienna, Vienna, Austria, on behalf of RESILIENT investigators.

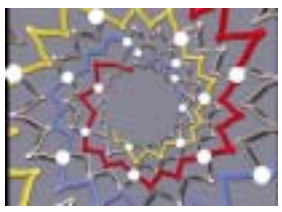


It is now well accepted to selectively use stents to improve patency rates after balloon angioplasty with flow-limiting dissections, residual stenosis or elastic recoil. Although nitinol is now considered as a credible alternative to stainless steel for SFA stenting, the fracture issue has been increasingly recognized. In the SIROCCO I study, systematic x-ray follow-up after long segment SFA stenting revealed a prevalence of 18.2% stent fractures with no related clinical impact (1). However, Scheinert and colleagues (2) demonstrated that depending on stent design, fractured stents could lead to a significant increase of restenosis and reocclusion rates, compared to non-fractured ones. In both study groups stent fractures were more frequent in long-stented SFA segments and when several overlapping stents were used.
High mechanical constraints in the SFA

The SFA is exposed to repetitive mechanical forces such as extension/contraction, torsion, compression and flexion that can generate important material fatigue. Not only the material and the surface finish seem to have an impact on stent fracture but also the design itself.

Traditional stent designs are based on laser cut, welded or interconnected zigzag rings. The Edwards LifeStent NT is a self-expanding Nitinol stent with a unique triple helical structure which behaves in a similar way to zigzag stents during radial deformation, like compression, but has a better ability to absorb axial deformations such as torsion, flexion, extension and contraction, while being adaptable to almost any type of shape, this with an excellent apposition to the arterial wall.
Edwards LifeStent shows less structural tensions vs. zigzag design

There are very few randomized studies comparing SFA stenting vs. PTA alone and data on long-term durability of stents in the SFA and in the proximal segment of the popliteal artery are lacking.
To evaluate the safety and efficacy of the LifeStent NT, the RESILIENT trial (Principal investigators Dr. John R. Laird, Cardiovascular Research Institute, Washington Hospital Center and Dr. Barry T. Katzen, Baptist Cardiac and Vascular Institute, Miami, Florida) a prospective, randomized, multicenter trial was initiated in 2004 (3). Inclusion criteria include a lifestyle-limiting claudication defined as Rutherford category 1 to 3. Target lesion(s) characteristics are de novo or restenotic (non-stented) stenosis or occlusions, with a less than 15cm single or tandem lesion length, located within the native SFA and/or proximal popliteal artery, 3cm above the knee joint and 1cm below the origin of the profunda femoris artery. At least one patent run-off vessel to the foot is required.



To evaluate the feasibility and the safety of a treatment using Lifestent in SFA and proximal popliteal artery lesions, 20 patients were enrolled in the initial non-randomized phase of the study. Baseline clinical and lesion characteristics of Phase I patients are shown in table 1. The 12-month follow-up data has shown promising results with a remarkable improvement of the target limb ankle-brachial index (ABI) and of the Rutherford category patient classification. The clinical patency rate was 90% and none of the stents presented a fracture (Table 2).
Furthermore, the Quality of Life measures, WIQ and SF-8 Scores improved significantly. Over 200 patients were randomized in the phase II (Pivotal) of the study in a 2:1 stent/PTA ratio, and data are expected to be presented next year.
Helical distribution of mechanical stress all over the Edwards Lifestent structure

Table 1: Baseline clinical and lesion characteristics

Characteristics	**Phase I**
Male, % (n)	75 (15)
Mean Age, Mean ± S.D.	70.5 ± 9.9
Hypercholesterolemia, % (n)	90 (18)
Hypertension, % (n)	85 (17)
Smoker, % (n)	80 (16)
Diabetes, % (n)	50 (10)
Rutherford Category	
Category 2, % (n)	70 (14)
Category 3, % (n)	30 (6)
Target limb ABI, Mean ± S.D. (n)	0.76 ± 0.26 (19)
Mean lesion length (mm), Mean ± S.D. (n)	83.7 ± 28.6 (20)
Calcified lesion, % (n)	66.7 (14)
Total occlusion, % (n)	23.8 (5)
Mean number of stents	1.8

Table 2: Baseline, 6- and 12-month follow-up data

Effectiveness Measures	**Baseline**	**6 Months**	**12 Months**
Target limb ABI (mmHg), Mean ± S.D., (n)	0.76 ± 0.26 (19)	0.93 ± 0.11 (18)	0.86 ± 0.13 (17)
Rutherford Category			
Category 0, % (n)	0.0% (20)	73.3% (15)	66.7% (18)
Category 1, % (n)	0.0% (20)	20.0% (15)	11.1% (18)
Category 2, % (n)	70.0% (20)	6.7% (15)	22.2% (18)
Category 3, % (n)	30.0% (20)	0.0% (15)	0.0% (18)
Clinical success, % (n)	N/A	100% (15)	94.4% (18)
TLR/TVR rate, % (n)	N/A	0.0% (20)	10.0% (20)
Stent fracture rate, % (n)	N/A	0.0% (17)	0.0% (17)

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