In recent years, implantation of nitinol stents into the superficial femoral artery (SFA) has become a widely used technique resulting in improved clinical outcome of percutaneous procedures. However, with the frequent use of nitinol stents, several concerns have been raised: It is known, that metallic stents are thrombogenic and induce intima hyperplasia, resulting in the occurrence of acute stent thrombosis or in-stent restenosis. The latter is of major concern, since restenosis rates are in the range of 20% - 40% after one year (1,2), so the clinical benefit of the procedure is jeopardized at an early stage. A disadvantage of metallic stents is the possibility of stent fractures, which are frequently found especially in long stented segments and are associated with a higher restenosis rate (3). Another concern is that stents remaining in the SFA may be an obstacle to additional future treatment. Since the risk of vessel occlusion or restenosis is the highest within the first 3 to 6 months, the need for vessel scaffolding is limited after that time. This is why the concept of biodegradable stents is a promising alternative.

The biodegradable Remedy™ Peripheral Stent (Fig. 1) has received CE certification in 2007 and is available on the European market since 2009. It is the only biodegradable stent that is approved for the treatment of SFA lesions in Europe. It is composed of polylactic acid (PLLA), a polymer that is slowly hydrolyzed into water and CO2. PLLA has been widely used in the human body and has proven to be non-toxic. Within the first 6 months it retains its radial strength and flexibility to prevent restenosis, thereafter the stent is bioabsorbed. First studies have already confirmed the safety and feasibility of the Remedy™ Peripheral Stent in SFA lesions. Recently, it has been re-designed to increase its strength and performance. Delivery is performed with a balloon-expandable system, which is compatible with a 7 French sheath. Two gold markers provide excellent visibility of the stent (Fig. 2). It is available in diameters of 5 to 8 mm and in a length of 36 and 78 mm (Fig. 3).

**Stent Information**

<table>
<thead>
<tr>
<th>Material</th>
<th>PLLA (poly-L-lactic acid) medical grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent design</td>
<td>Zig zag helical coil</td>
</tr>
<tr>
<td>Strut thickness</td>
<td>0.009 inch (0.24 mm)</td>
</tr>
<tr>
<td>Radio-opaque marker</td>
<td>2 gold markers</td>
</tr>
<tr>
<td>Stent diameter</td>
<td>5.0 / 6.0 / 7.0 / 8.0 mm</td>
</tr>
<tr>
<td>Stent length</td>
<td>36 mm and 78 mm</td>
</tr>
<tr>
<td>Stent expansion</td>
<td>5.0 and 6.0 mm stent ; 7.0 mm 7.0 and 8.0 mm stent ; 9.0 mm</td>
</tr>
</tbody>
</table>
Case presentation

The following patient was treated with the Remedy™ Peripheral Stent in 2009. He suffered severe claudication (Rutherford 3). Angiography revealed a high grade stenosis of the left SFA (Fig. 4a). After balloon angioplasty, severe dissection and recoil were evident (Fig. 4b). In this situation the decision was made to implant the Remedy™ Peripheral Stent (Fig. 4c), with good primary result. The symptoms resolved, after two years the patient was still symptom-free and the vessel was still patent, whereas the stent had dissolved (Fig. 4d).

An advantage of the concept of bioabsorbable stents is the possibility to combine it with other treatment modalities, e.g. with atherectomy or drug coated balloons (DCB). First results of DCB angioplasty have shown promising results. However, flow limiting dissections and vessel recoil limit the efficacy of this treatment. Therefore the concept of stabilizing the vessel without leaving a permanent metallic foreign body is very appealing. The concomitant treatment of SFA lesions with DCB and the Remedy™ Peripheral Stent is currently under investigation in the Center of Vascular Medicine, Parkhospital, Leipzig. 20 patients are treated first with a paclitaxel eluting balloon, subsequently with the Remedy™ Peripheral Stent. First results of this study are expected in 2012.

Bioabsorbable stents are a valuable treatment alternative for SFA lesions. Its application is safe and the clinical results are promising. Even more appealing is the perspective to combine the advantages of bioabsorbable stents with local drug-eluting technology: this approach can better address the overall patient clinical outcome because temporary mechanical treatment may optimize the results obtained with bare balloon angioplasty or local drug therapy.


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