Factors Affecting Reduction in SFA Stent Fracture Rates

From first-generation to new stents, examining how design has an impact on fracture rates in the SFA.

BY MARTIN WERNER, MD

The superficial femoral artery (SFA) is highly exposed to biomechanical forces occurring during leg movement. The superficial course of the artery, with crossing of flexion points as well as interaction with the surrounding musculature, exposes the artery to external forces, including compression, torsion, and elongation. The implantation of metallic stents is standard for the treatment of SFA atherosclerotic disease; however, concerns exist about the potential for nitinol stents to fracture and the clinical implications of these stent fractures. Some reports suggest that stent fractures are associated with a higher incidence of in-stent restenosis, thrombosis, or embolism. Others do not report a significant association between stent fracture and clinical deterioration.

Within the last few years, new stent designs have been developed to meet the demands in the SFA. This article reviews the factors leading to the reduction of SFA stent fracture rates in newer stent designs.

EVILOUTION OF FEMOROPOPLITEAL STENTS

First-generation balloon-expandable stainless steel stents did not perform well against the biomechanical stresses in the SFA due to their limited flexibility and susceptibility to permanent deformation from extrinsic pressure. The failure of this approach led to the development of self-expanding shape-memory alloy stents. These alloys, usually nitinol, were more flexible and provided better stability and resistance to repeated stress. Based on the results of several randomized trials, nitinol stents are now the mainstay in the treatment of femoropopliteal artery disease. However, nitinol stent fractures were observed in up to 20% of cases (Table 1).

For that reason, new stent designs were developed with the objective to reduce the incidence of stent fractures in the SFA.
From a technical standpoint, the flexibility and adaptability of a stent is determined by the number and arrangement of the interconnectors between the stent struts, strut length, and strut cross-sectional shape, strut angles, stent material, and surface. New-generation nitinol stents, such as the EverFlex stent (Covidien), have gained better flexibility by a reduction of cell interconnections and spiral orientation of interconnections.

The SMART Vascular Stent (Cordis Corporation), for example, has a unique 36-strut, six-bridge construction with an offset peak-to-valley design providing smooth lumen and stent contourability without strut overlapping or fish scaling. The fracture rate in an unpublished trial was only 2% after 2-year follow-up (STROLL trial, data on file, Cordis Corporation).

Another new-generation stent is the Zilver stent (Cook Medical), which is also available as a drug-eluting stent (Zilver PTX). Here, the manufacturers have paid special attention to improve the stent surface, thereby eliminating the imperfections that can lead to stent fractures (Table 1).

The EPIC stent (Boston Scientific Corporation) has radial tandem architecture combined struts of varying lengths, which allowed a reduction of connectors. Enhanced surface finishing processes might have additionally added to improved stent integrity, durability, and the 0% fracture rate after 1 year.19

Fracture rates are related to lesion length. In the FESTO registry,22 the incidence of stent fractures increased with lesion length, and major stent fractures were associated with restenosis. This was also observed for the Everflex stent in the DURABILITY I study.14 The Lifestent (Bard Peripheral Vascular, Inc.), for example, received FDA approval based on the results of the RESILIENT trial,12 with a low 3.1% fracture rate (Table 1). The mean lesion length in this study was 7.1 cm. Another prospective trial, the STELLA study for long TASC C and D lesions,5 investigated the same device in femoropopliteal lesions with a mean lesion length of 22 cm and reported a nearly 18% fracture rate. This clearly illustrates the direct correlation of lesion length and stent fracture rate.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Stent</th>
<th>No. of Patients</th>
<th>Lesion Length (cm)</th>
<th>12-Month Primary Patency (%)</th>
<th>Fracture Rate (%)</th>
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<tbody>
<tr>
<td>SIROCCO8</td>
<td>2006</td>
<td>SMART</td>
<td>46</td>
<td>8.1</td>
<td>68.1 (2 y)</td>
<td>20</td>
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<td>FAST11</td>
<td>2007</td>
<td>Luminexx 3</td>
<td>101</td>
<td>4.5</td>
<td>68.3</td>
<td>12</td>
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<td>DURABILITY I14</td>
<td>2009</td>
<td>Everflex</td>
<td>151</td>
<td>9.6</td>
<td>72.2</td>
<td>8.1</td>
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<tr>
<td>RESILIENT12</td>
<td>2010</td>
<td>Life Stent</td>
<td>134</td>
<td>7.1</td>
<td>81.3</td>
<td>3.1</td>
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<td>ZILVER-PTX13</td>
<td>2011</td>
<td>Zilver PTX</td>
<td>241</td>
<td>6.6</td>
<td>83.1</td>
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<td>MISAGO 215</td>
<td>2012</td>
<td>Misago</td>
<td>744</td>
<td>6.4</td>
<td>87.6</td>
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<td>STELLA5</td>
<td>2012</td>
<td>LifeStent</td>
<td>58</td>
<td>22</td>
<td>66</td>
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<td>DURABILITY 20016</td>
<td>2011</td>
<td>Everflex</td>
<td>100</td>
<td>24.2</td>
<td>64.8</td>
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<td>SUPERB17</td>
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<td>7.8</td>
<td>86.3</td>
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<td>SUMMIT19</td>
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<td>Epic</td>
<td>100</td>
<td>7</td>
<td>85.1</td>
<td>0</td>
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<tr>
<td>VIBRANT20</td>
<td>2013</td>
<td>Viabahn</td>
<td>72</td>
<td>18</td>
<td>53</td>
<td>2.6</td>
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<tr>
<td>COMPLETE SE21</td>
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<td>Complete SE</td>
<td>196</td>
<td>6.1</td>
<td>72.6</td>
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</table>
CONCEPTS FOR IMPROVED BIOMECHANICAL COMPATIBILITY

The Supera Stent

The Supera stent (Abbott Vascular) (Figure 1) also offers a new stent design. This stent has been proven to be fracture resistant in several registries, and its US IDE trial. The stent is not made from a laser-cut nitinol tube but rather consists of six pairs of nitinol interwoven wires formed in a helical pattern to provide improved radial and longitudinal characteristics, answering the need for a fracture-resistant stent with high flexibility and compression resistance. The longest follow-up was in the SUPERB IDE trial. At 1 year, in 264 patients there were no fractures. At 2 years, a fracture was detected; however, it is important to note that this patient had undergone directional atherectomy three times in the same vessel. Additional trial follow-up was obtained in the SUPERA-500 registry. Follow-up radiographs of 304 stents, obtained in 229 patients at a mean follow-up of 16.6 months, confirmed the absence of stent fractures in 100% of examinations.

The Tigris Stent

Another novel approach in optimizing the stent architecture in the femoropopliteal segment is the dual-component design of the Tigris vascular stent (Gore & Associates) (Figure 2). This device consists of a helical spiral frame formed by a single nitinol wire. The helical segments of the frame are interconnected by fluoropolymers with heparin coating. The ePTFE bridges allow the segmental structures to be shifted against each other. This results in high flexibility, low straightening force, resistance to stent elongation, and the ability to absorb longitudinal forces.

OTHER FACTORS

There is some evidence that occurrence of stent fractures is not only determined by the stent architecture and stent length but also by technique of implantation. In a post-hoc analysis of the DURABILITY I study, stent elongation occurred during implantation in 90% of all fractured stents. The investigators argued that elongated stent placement increases the amount of continuous strain exerted on the stent struts, resulting in more fractures.

Furthermore, the implantation of multiple overlapping stents increases the axial stiffness of the stented segment. It is unclear if avoidance of stent overlap by using a single long stent instead of two shorter stents would result in a reduction of stent fractures.

SUMMARY

In general, the fracture rate reported in recent SFA trials has declined within the last few years (Table 1). Besides completely new stent designs, as described, manufacturers have also improved stent characteristics of slotted tube stents by reducing cell interconnections and spiral orientation of interconnections, as well as improved surface finishing processes. Avoidance of stent elongation during deployment may have also contributed to a decrease in stent fractures. However, although stent fracture rates in the SFA are declining to very low levels, restenosis remains an issue, and hampers the long-term success of stent-based treatment of the SFA.

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