Critical review of the reported stent fracture rates in the SFA and popliteal artery

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“A fracture is the separation of an object or material into two, or more, pieces under the action of stress.”

- 2002: iliac artery  
  (Sacks BA, J Vasc Interv Radiol, 1996)

- 2002: SFA  
  (Duda SH, Circulation, 2002)

- 2003: popliteal artery  
  (Babalik E, Circ J., 2003)
WHY?
Standardized evaluation of stent fractures in clinical trials.

WHERE?
Diagnostic X-ray room or a fixed unit angiography suite

HOW?
- Biplane x-rays: 2 different projections separated by at least 45°
- Exposure < 80kVp using a magnification of 1.5. ± additional views
- DICOM files

WHEN?
- Immediately after the procedure conventional x-ray imaging
- 12-month follow-up
Biplane x-rays
Classification
Incidence

2 - 65% (Rits J., Eur J Vasc Endovasc Surg. 2008)
Which bias?

Reproducibility of methods of diagnosis and classification

Independent laboratories expertise

Analysis of type 1 or type 2 fractures is challenging

Method of calculation

- in a stent-based analysis
- in a limb-based analysis

For example: 42 treated limbs - 90 stents - 15 stents fractures

- in a stent-based analysis: 17.2%
- in a limb-based analysis: 35.3%
### Incidence according the type of stent

#### Bare metal stents

<table>
<thead>
<tr>
<th>Stent</th>
<th>Fast Fracture rates</th>
<th>Vienna Fracture rates</th>
<th>Resilient Fracture rates</th>
<th>Durability I Fracture rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luminexx (Bard)</td>
<td>12%</td>
<td>2%</td>
<td>3.1%</td>
<td>8.1%</td>
</tr>
<tr>
<td>Absolute (Abbott)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifestent (Bard)</td>
<td></td>
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<tr>
<td>Everflex (Covidien)</td>
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</tbody>
</table>

#### Drug eluting stents

<table>
<thead>
<tr>
<th>Stent</th>
<th>Sirocco Fracture rates</th>
<th>Zilver-px registry Fracture rates</th>
<th>Zilver-px randomized trial Fracture rates</th>
<th>Strides Fracture rates</th>
</tr>
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<tbody>
<tr>
<td>Smart (Cordis)</td>
<td>18%</td>
<td>1.5%</td>
<td>0.9%</td>
<td>0%</td>
</tr>
<tr>
<td>Zilver –px (Cook)</td>
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*In a limb-based analysis*
Long lesions

**Luminexx®, SelX®, Smart®** (Scheinert, J Am Coll Cardiol. 2005)

- 13% for stented length < 8-cm
- 42.4% for stented length between 8 to 16-cm
- 52.0% for stented length > 16-cm

*(in a limb-based analysis)*

**Lifestent®** (Laird, Circ Cardiovasc Interv, 2010; Davaine, Eur J Vasc Endovasc Surg, 2012)

- 3.1% for mean lesion length of 61.8-mm
- 17.7% for mean lesions of 220-mm

*(in a stent-based analysis)*

**Everflex®** (Bosiers, J Endovasc Ther, 2009 and J Vasc Surg 2011)

- 8.1% for mean lesion length of 96.4-mm
- 6% for mean lesions length of 242-mm

*(in a limb-based analysis)*
Involvement of popliteal artery

Fracture rates

7%  27%  69%
3.1  6    17

Involvement of popliteal artery (RESILENT- DURABILY II – STELLA)
Clinical impact: controversies

Scheinert, J Am Coll Cardiol, 2005
Clinical impact: controverses

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<tr>
<th>Bare metal stents</th>
<th>Fast</th>
<th>Vienna</th>
<th>Resilient*</th>
<th>Durability I</th>
<th>Durability II</th>
<th>STELLA*</th>
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<td>6%</td>
<td>17.7%</td>
</tr>
<tr>
<td>ISR rates</td>
<td>32%</td>
<td>37%</td>
<td>19%</td>
<td>27.8%</td>
<td>10%</td>
<td>19.3%</td>
</tr>
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*in a stent-based analysis

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<tr>
<td>ISR rates</td>
<td>22.9%</td>
<td>13.8%</td>
<td>16.9%</td>
<td>32%</td>
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</table>
Stent fracture and in-stent thrombosis

Images 3, 4, and 5 show the progression of stent fracture and in-stent thrombosis.
Management of stent fractures: 
*stentosynthesis*

- No recommendations

- According to the clinical presentation
  
  - No symptoms: follow-up
  
  - Symptoms with restenosis or thrombosis
    - X rays to search stent fractures
    - type 1 or type 2 fractures: no specific treatment
    - types 3, 4 and 5: stentosynthesis
Stent fracture and in-stent restenosis
Stent fracture and in-stent thrombosis
Messages to take home

- Few data are available concerning the physiopathology and the risk factors of stent fractures in the femoropopliteal arterial segment.

- Controversies remain as to whether stent fractures are associated with restenosis, occlusion and clinical deterioration.

- Follow up and treatment strategies remain to be defined

- Use of drug eluting balloon or bioresorbable scaffolds could resolve definitely the problem of stent fractures.