Update On Fascia Suture Technique For Minimally Invasive Sheath Insertion: It Is Better Than PEVAR. Tips And Tricks For Doing It Right

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Disclosures

I have the following potential conflicts of interest to report:

Educational Program W.L Gore & Associates
Stockholder LeMaitre
Co-founder Meliora-Vision

The Fascia Suture


Fascia suture (FST) - History

1997  Described by Ted Dietrich
2006  First clinical evaluation by our group¹
   ➢ Technical success 88%
   ➢ Pseudoaneurysms 5%
2011-12  Further clinical studies²-⁴
   ➢ Technical success 87-93%
   ➢ Pseudoaneurysms 6-14%

¹ Larzon T et al. J Endovasc Ther 2006;13:152-57

• Access closure time
• Access related costs
• Complication rate
• Independent risk factors for failure
Patients scheduled for endovascular treatment fulfilling the inclusion criteria (n=122)
Randomized (n=100)
Eligible for analysis (n=99)
Fascia suture (n=48)
Prostar suture (n=51)
Excluded after conversion to AUI stentgraft and femoro-femoral bypass (n=1)
Excluded (n=22)
- Within exclusion criteria (n=6)
- Reassessed to no operative treatment (n=2)
- Reassessed to other operative treatment (n=2)
- Explored access (legality problems (n=3))
- Explored access (technical reasons) (n=1)

Outcome – Access closure time
Box-plot of access closure time by FST and Prostar (p<0.001)
Adjusted for experience:
Basic level (p=0.044), Proficiency level (p=0.014)

Complications
Kaplan-Meier plot of time to first access related complication (index site) in FST and Prostar, p=0.18 (log rank test)

Reinterventions
Kaplan-Meier plot of time to first reintervention in FST and Prostar, p=0.14 (log rank test)

Type of complications

<table>
<thead>
<tr>
<th>Type of complications</th>
<th>FST</th>
<th>Prostar</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>8%</td>
<td>18%</td>
<td></td>
</tr>
<tr>
<td>Thrombosis/stenoses</td>
<td>4%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Technical error (device)</td>
<td>0%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Neuralgia</td>
<td>2%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Total until discharge</td>
<td>15%</td>
<td>24%</td>
<td>~0.72</td>
</tr>
</tbody>
</table>

Adjusted for operators levels (proficiency/basic) by logistic regression

Technical failure rate

<table>
<thead>
<tr>
<th>Experience level</th>
<th>FST</th>
<th>Prostar</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proficiency level</td>
<td>4%</td>
<td>7%</td>
<td>~1.00</td>
</tr>
<tr>
<td>Basic level</td>
<td>27%</td>
<td>30%</td>
<td>~0.84</td>
</tr>
</tbody>
</table>

FST and Prostar failure rate

<table>
<thead>
<tr>
<th>Operator experience</th>
<th>Basic</th>
<th>Proficiency</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal demand</td>
<td>&gt;15 procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic level</td>
<td>&gt;15-49 procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proficiency level</td>
<td>&gt;60 procedures</td>
<td></td>
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</tbody>
</table>
### Access closure cost

<table>
<thead>
<tr>
<th>Per patient</th>
<th>FST</th>
<th>Prostar</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Euro (median)</td>
<td>349</td>
<td>1181</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### Lessons learned of the FST
- Proper puncture (not too high!!)
- Blunt dissection does not destroy the femoral fascia (fingers and retractors)
- Wide stitches in the fascia
- Monofilament suture and sliding knot

### Discussion
- Is 7 minutes a clinically relevant difference in access closure time?
- The FST, as a manual technique, might be harder to implement than a device
- New SMCD might be more easy to handle and cheaper

### Why is it better?
- It is cheaper and as good as SMCD
- Logistical advantages (no presuturing)
- Ruptured aortic aneurysms – an upside potential for FST

### Conclusions
- FST is a fast and cheap access closure technique
- The complication risk is low in experienced hands why a proper training program is necessary

### Thank you