Disclosure

Speaker name:
Dr Vanhulle Alain

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

I do not have any potential conflict of interest
GELITA-SPON® RAPID³ and GELITA TUFT-IT® in Different Open Vascular Procedures – First Experiences
Dr A. Vanhulle
AZ Sint Jan Campus Serruys Oostende Belgium

Vascular wounds must be safely and effectively closed

Bleeding has to be controlled to ensure the success of surgical procedures
Background:

Evaluate efficient blood management in open vascular procedures

The proper selection of hemostatic agents can greatly influence the patient’s clinical outcomes

Goal:

Analyze and report on the safety and performance of the innovative products
GELITA-SPON® RAPID3 and GELITA TUFT-IT®

Methods:

From May 2016 until September 2017 the products were used as a hemostatic agent in different open vascular procedures

Questionnaires were used with a five scale rating range from excellent to bad
GELITA-SPON® RAPID3

• Highly effective hemostat made of non chemically cross linked pharmaceutical-grade gelatine

• Unique microstructure with a high surface roughness in the nano range and a high porosity. Hemostatic performance might be linked to enhanced capillary effects in conjunction with the optimized anchoring of fibrinogen

• Very rapid absorption of human blood, 1 gr of sponge can absorb 40 gr of blood

• Dry use recommended for best performance

• Resorbes fully in 2 weeks, residue-free, lower risk of foreign body reaction
GELITA TUFT-IT®

- Special patented spinning technology product with a fibrous-fleece structure
- Non-woven gelatin fleece that can be tufted or peeled off in layers
- Can be applied just in the necessary amount leaving minimal material in situ
- Extremely flexible hemostat with very easy handling properties
- Ensures patient comfort without risk of encapsulation
Study design

Surgical vascular procedures:
- Femoral Popliteal Bypasses
- Carotid Endarterectomies
- Abdominal Aortic Aneurysms
- Femoral Endarterectomies

44 cases were rated on:
- Effectiveness to stop bleeding
- Blood absorption capacity
- Overall handling during surgery
- Ease of application to the bleeding site
GELITA-SPON® RAPID3
<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral Popliteal Bypass</td>
<td>10</td>
</tr>
<tr>
<td>Carotid Endarterectomy</td>
<td>3</td>
</tr>
<tr>
<td>Abdominal Aortic Aneurism</td>
<td>5</td>
</tr>
</tbody>
</table>

![Bar Chart](chart.png)

- **Effectiveness to stop the bleeding**
- **Blood absorption capacity**
- **Overall handling during surgery**
- **Ease of application to the bleeding site**
**GELITA TUFT-IT®**

<table>
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<tr>
<th>Type of surgery</th>
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<tbody>
<tr>
<td>Femoral Popliteal Bypass</td>
<td>7</td>
</tr>
<tr>
<td>Carotid Endarterectomy</td>
<td>9</td>
</tr>
<tr>
<td>Abdominal Aortic Aneurism</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
</tr>
</tbody>
</table>

**Effectiveness to stop the bleeding**

- Femoral Popliteal Bypass: 18
- Carotid Endarterectomy: 16
- Abdominal Aortic Aneurism: 14
- Other: 12

**Blood absorption capacity**

- Femoral Popliteal Bypass: 10
- Carotid Endarterectomy: 8
- Abdominal Aortic Aneurism: 6
- Other: 4

**Overall handling during surgery**

- Femoral Popliteal Bypass: 10
- Carotid Endarterectomy: 8
- Abdominal Aortic Aneurism: 6
- Other: 4

**Ease of application to the bleeding site**

- Femoral Popliteal Bypass: 6
- Carotid Endarterectomy: 4
- Abdominal Aortic Aneurism: 2
- Other: 2
GELITA TUFT-IT® - ease of application

Learning curve

Cases 1-8
- 88% satisfactory
- 12% poor

Cases 9-26
- 94% excellent
- 6% poor
Performance:
The rating for the effectiveness to stop the bleeding is reflected in the Time To Hemostasis (TTH).

<table>
<thead>
<tr>
<th>Product</th>
<th>TTH Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTH GELITA-SPON® RAPID³</td>
<td>less than 60 seconds: 28%, between 60 and 120 seconds: 72%</td>
</tr>
<tr>
<td>TTH GELITA TUFT-IT®</td>
<td>less than 60 seconds: 35%, between 60 and 120 seconds: 65%</td>
</tr>
</tbody>
</table>

Safety:
No device related adverse events occurred and no blood transfusions were needed.
Conclusion

**GELITA-SPON® RAPID3**
- Adaptability – adapts well to the bleeding site
- Keeps its consistency even when saturated
- Can be easily cut in to pieces
- Less easy to apply to 360° anastomoses
- Is used dry

**GELITA TUFT-IT®**
- Ultimately flexible and pliable
- Multi layered
- Can be used for difficult to reach bleeding sites
- Applying well to 360° anastomoses
- Is used dry

**REFERENCES**
Conclusion

Gelta Spon rapid and Tuft it are safe and powerfull hemostats each which its specific area of use.

It is comparable to oxydized regenerated cellulose products I used before but with the advantage of ease of application, faster and complete resorption, enormous absorption capacity.

The products have no antimicrobial properties due to pH neutral character, but they can be combined with drugs.

Economically ± 35 % cheaper than oxydized regenerated cellulose in Belgium.

Thank you for your attention