SealFoam™, a New Topical Hemostat for Bleeding Control in Surgery

H. Mair, A. Schütz
Department of Cardiac Surgery, BHZ Vogtareuth, Germany

Background:
Bleeding from or near graft anastomosis in coronary bypass surgery is a well known problem. There are many different strategies in bleeding control ranging from additional suturing to improvement of blood coagulation, depending on the severity of the bleeding. Another approach is the use of topical hemostats with efficacious and safe use [1]. We describe here the use of a new topical hemostatic sponge, SealFoam™ (Starch Medical Inc., San Jose, CA, USA).

Patients and Methods:
In 4 patients (age: mean 70.5 years; 3 males) OPCAB (3) or CABG (1) was performed in routine fashion. Bleeding from graft anastomoses (2 veins-aorta, 1 vein-Cx and 1 LIMA-LAD) were observed after Protamin was given. Seal Foam was trimmed, positioned on the bypass anastomosis and gently and temporarily pressed for approximately 1.5 minutes.

Device Description
SealFoam™ is a new absorbable polysaccharide hemostat, a plant based hemostatic foam, lyophilized and pliable. It is a wafer-like pad which may be trimmed to suit the surgical procedure. SealFoam™ utilizes the same absorbale modified polymer particles as PercloT™ and is indicated for a diverse range of press-and-release applications and unique wound contours. It does not contain any components of animal or human origin. The rapid hemostatic effect (30-60 sec) of the pad is produced by the dehydration and subsequent hemoconcentration of blood in contact with the particles of the sponge. The concentration of serum proteins and cells creates a viscous gel. It is fully absorbed in approximately 48 hours.

Results:
Satisfactory hemostasis was achieved by temporary pressing SealFoam on the bleeding site in all patients. Flow measurements revealed patent grafts. The postoperative course was uneventful in all patients. There was no reoperation necessary. In 6 weeks follow-up there was no graft failure or death.

Table: Results of intra- and postoperative outcome

<table>
<thead>
<tr>
<th></th>
<th>preop. (mg/dl)</th>
<th>postop. (mg/dl)</th>
<th>Drainage (ml)</th>
<th>Blood units (U)</th>
<th>Allergic reaction (n)</th>
<th>Wound infection (n)</th>
<th>Reop. failure or bleeding (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>12.9 ± 1.6</td>
<td>9.9 ± 1.6</td>
<td>570-850</td>
<td>5/3 pts</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Conclusion:
In our patients, SealFoam™ proved to be a safe agent in clinical practice for haemostyptic purposes with good immediate results. In addition it supports an universal range of surgical bleeding applications.