HaemoCer™, a hemostatic agent,
for bleeding control of the sternum

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SHORT-TITLE: Hemostatic agents for sternal bleeding control

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Abstract

Profuse bleeding from the sternal marrow after sternotomy is routinely controlled with bone wax. Unfortunately, bone wax should be avoided in patients being at high risk for nonunion of the sternum and infections. We present an alternative technique to control bleeding from the sternal bone marrow using a plant based polysaccharide hemostat (HaemoCer™). Having effective bleeding control, we did not observe any adverse events.

Key words: HaemoCer™, bleeding control, sternum, surgery, hemostat, polysaccharide,
**Introduction:**

Profuse bleeding from the sternal marrow after sternotomy is routinely controlled with bone wax because it is effective, cheap and therefore favorable. Unfortunately, bone wax inhibits osseous fusion and promotes infections [1-4]. With today’s increasing number of patients at high risk for sternal instability and wound healing complications following cardiac surgery, improved techniques for sternal bleeding control without the use of bone wax are available.

We present an alternative technique to control bleeding from the sternal bone marrow using HaemoCer™ (BioCer-GmbH, Bayreuth; Germany), a new absorbable, plant based surgical hemostat.

**Technique:**

HaemoCer™ is a powder-like hemostat made from bio-inert polysaccharide material, consisting of irregular formed particles with a high surface (Fig. 1) for fast water absorbans. The powder does not contain any components of animal or human origin. HaemoCer™ adsorbs water in the range of 18 times of its own weight. Its mode of action is, therefore, to dehydrate quickly (seconds) extra vasating blood, thus achieving a high concentration of platelets, erythrocytes and the factors of the coagulation cascade. This process supports the immediate clotting of e.g. the bleeding bone surface after sternotomy.

After this initial phase, HaemoCer™ forms a gel-like, adhesive mass which serves as a preliminary mechanical barrier against further bleeding. This “instant gelling” is followed by the formation of a fibrin mesh. HaemoCer™ particles are chemically dissolved,
completely absorbed and metabolized within 2 days. 1 unit of HaemoCer™ contains 5 g powder.

**Case report:**

A 75-year-old male with coronary heart disease (main stem 80% stenosis, various stenosis of the LAD and 75% proximal stenosis of the RCA) was referred to our department for coronary arterial bypass graft (CABG) revascularization. In addition, the patient suffered from insulin dependent diabetes, kidney insufficiency (Creatinine on admission 2.1 mg/dl) and pulmonary hypertension. Other comorbidity was general arterial vascular disease with occluded carotid arteries on both sides (brain perfusion via vertebral artery) and multiple vascular operations of the femoral arteries. The body mass index was 32.6. The patient was due to severe main stem stenosis on Clopidogrel 7 m/day and ASA 100 mg/day.

After median sternotomy, mild osteoporosis was visible. To control bleeding from this fragile sternum, electrocautery to the periostium was sparingly used. HaemoCer™ as topical hemostat was applied on each side of the sternal spongiosa (Fig 2a) as much as bleeding from bone marrow stopped (Fig 2b). In addition, towels were wrapped immediately around the absorbable hemostatic powder before the retractor opened the thorax. After external pacing control (AAI 80/min) full heparinization (Active Clotting Time > 300 sec) was initiated to perform off-pump coronary bypass (OPCAB) with three grafts: LITA to LAD and veins to the circumflex artery and right coronary artery using off-pump stabilizer. After surgery, protamin was administered to antagonize heparin. Extant HaemoCer™ was applied for bleeding control on the areas of anastomosis and to the sternum. Finally, the sternum was closed routinely with wires, followed by skin closure with intracutan suture.
The postoperative course of the patient was uneventful: On ICU extubation was performed 6 hours postoperatively. The delivery volume of the chest drains was 540 ml after 24 hours. The chest drains were removed on the second postoperative day. The patient returned to the ward with standard care on the first postoperative day and was discharged from the hospital on the 7th postoperative day. The postoperative results of clinical chemistry were in postoperative normal range. CK max. was 540 U/l and CK-MB max. was 43 U/l. Both values returned on 4th postoperative day in normal range. Haemoglobin min. was 8.5 g/dl. One unit of red blood cells were given. No enhanced bleeding, infection or sternal wound healing complications occurred postoperatively. At 3 months follow up, the patient was in good physical condition. Echocardiography revealed good cardiac function. The sternum was stabil. The patient had no wound infections or any adverse events.

**Results:**

In total, 19 patients undergoing coronary surgery had sternal bleeding control with HaemoCer™. Satisfactory control of bleeding was observed in 17 cases. In one patient we added additional a patch of oxidized regenerated cellulose (Nu-Knit; Ethicon, Johnson & Johnson, Somerville, NJ). In another patient, having emergency-CABG and Clopidogrel + ASA loading, continuous mild bleeding was noted and accepted throughout the operation after using a second unit of HaemoCer™. No adverse events, e.g. allergic reaction, unstable sternum, deep wound infection, general infection, graft alteration or any severe organ dysfunction, were observed. There was no in-hospital morbidity or mortality during three months follow up. No rethoracotomy because of graft alteration, bleeding or unstable sternum was necessary. No irritation of bypass grafts was noted.
Discussion:

Surgeons normally recommend avoiding bone wax as much as possible for sternal bleeding control and strongly recommend avoiding its use in high-risk patients for infection or nonunion altogether [5]. In particular, use of bonewax in elderly patients and those with osteoporosis is often ineffective. The spongiosa scaffold of the sternum will be destroyed during setting of bone wax and the marrow cavity may absorb large quantities of bone wax while enhanced bleeding continues. In summary, bone wax has three adverse effects: 1) inhibition of bone healing, 2) increased infection rates and 3) inflammatory reaction [3]. Despite these negative effects, bone wax is still in widespread use, presumably due to the perceived lack of suitable alternatives. However, since the majority of cardiac surgical procedures are now routinely performed with low mortality, a substantial effort to minimize morbidity associated with sternal instability or infections is appropriate. Accordingly, new methods to control sternal bleeding without bone wax were published [3;6-8]. Other agents like microfibrillar collagen may also have an acceptable hemostatic effect, but its use may have other potential adverse effects. The small diameter of its needle-shaped structure might pass through the filters of blood saving devices and enter the patient's circulatory system. This may result in organ damage, e.g. lung or brain [9].

As shown in our cases, the HaemoCer™ surgical hemostat is a simple, safe and effective method for bleeding control in high-risk patients. In our experience, we had effective, or at least satisfactory, intraoperative bleeding control. In conclusion, to avoid sternal bleeding complications with associated wound healing problems and mediastinitis, HaemoCer™ can be temporarily administered safely and effectively.
References


9. Robicsek F, Duncan GD, Born GVR, Wilkinson HA, Masters, TN, McClure M.

Tables:

Table 1:

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<td>OPCAB (n)</td>
<td>19</td>
</tr>
<tr>
<td>age (years)</td>
<td>68±14</td>
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<tr>
<td>RITA/LITA (n)</td>
<td>11</td>
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<tr>
<td>COPD (n)</td>
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<td>Severe Osteoporosis (n)</td>
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<tr>
<td>B.M.I. &gt; 30 (n)</td>
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Table 2:

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<tr>
<td>Satisfactory bleeding control (n)</td>
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<td>Hemoglobin</td>
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<tr>
<td>preop. (g/dl)</td>
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<tr>
<td>postop. (g/dl)</td>
<td>9.4±1.6</td>
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<td>Drainage 24 h (ml)</td>
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<tr>
<td>Cell saver (ml)</td>
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<tr>
<td>Blood units (U)</td>
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Figures:

Figure 1:
Figure 2a:

![Image of surgical procedure with HaemoCer applied]

Figure 2b:

![Image of surgical procedure with HaemoCer applied]
**Legends:**

**Table 1:** Demographic data

**Table 2:** Intra- and postoperative results

**Figure 1:** Scanning Electron Microscopy HaemoCer™-particles

**Figure 2a+b:** HaemoCer™ was applied on both sides of the sternotomy