Title: The use of oxidized regenerated cellulose (ChitoCell®) in open surgeries

Soheila S. Kordestani
Affiliation: Medical Engineering Department, Amirkabir University of Technology, Tehran, Iran, Post Code: 15875-4413
ChitoTech Company, Unit 9&11, East Wing, No. 83, Khaghani Building, Somayeh Avenue, Tehran, Iran, Post Code: 1571838318.
Email: sskordestani@aut.ac.ir

Aref Rezaimanesh
Affiliation: Medical Center of Ayatollah Kashani, Shahrekord University of Medical Sciences, Shahrekord, Iran
Email: rezai3108@gmail.com

Farzaneh NayebHabib
Affiliation: ChitoTech Company, Unit 9&11, East Wing, No. 83, Khaghani Building, Somayeh Avenue, Tehran, Iran, Post Code: 1571838318.
Email: fnayebh@chitotech.com

Abstract
The objective of this study was to evaluate the hemostatic properties of ChitoCell® (an oxidized regenerated pad) and measuring relating times to stop bleeding in open surgeries. Internal bleeding and post oozing was controlled in all 10 patients by the application of Chitocell on the bleeding points. The flexible physical properties, along with hemostatic, and bactericidal characteristics of Chitocell makes it a professional tool for hemostatic and controlling capillary, venous, and small arterial hemorrhage during all types of surgery.

Keywords: Oxidized regenerated cellulose; ChitoCell®, Hemostasis
**Introduction**

Oxidized regenerated cellulose has been used as an effective material to control bleeding in all kinds of surgeries and has been approved in advanced countries since 1960 (Levy ML, 1997). Many companies start to produce commercial products from this material to be used in surgeries as a hemostasis agent instead of ligation or conventional methods to control bleeding for capillary, venous, and small arterial hemorrhage (Gabay M, 2006).

ChitoCell® (hemostatic pad manufactured by ChitoTech Inc.) is frequently left behind on the surgical bed for controlling capillary, venous, or suture line bleeding postoperatively. As it absorbs blood and gets saturated, it gently swells into a brownish black gelatinous mass which aids in the formation of clot. ChitoCell® exerts its effect through the intrinsic coagulation pathway. ChitoCell® also fulfills the first principle of hemostasis i.e. pressure. As this kind of product absorbs fluid, it swells and exerts pressure on the surrounding tissue contributing to hemostasis (Bouras AF, 2010; Schulman C, 2006; Schonauer C, 2003).

**Materials and Methods:**

*Hemostatic Activity of Oxidized Regenerated Cellulose*

**A. Number of selected patients**

10 patients with different types of surgical procedures were treated using ChitoCell®.

**B. Type of surgeries**

<table>
<thead>
<tr>
<th>Vast bleeding in epidural</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volvulus Surgery</td>
</tr>
<tr>
<td>Axillary lymphoma</td>
</tr>
<tr>
<td>Hernia inguinal</td>
</tr>
<tr>
<td>Splenectomy</td>
</tr>
<tr>
<td>Intracranial hemorrhage</td>
</tr>
<tr>
<td>Cholecystectomy</td>
</tr>
<tr>
<td>Cholecystectomy</td>
</tr>
<tr>
<td>Colostomy</td>
</tr>
</tbody>
</table>

During year 2011, 10 patients presented for the mentioned surgeries in Medical Center of Ayatollah Kashani. Cauterization was not attempted at the oozing or bleeding surface. Decision of ChitoCell® application on the bleeding points was taken. ChitoCell® was placed on the oozing or bleeding points on the affected area (Figures 1-8). Further observation for 10 minutes was done to note any active bleeding. Vitals were monitored in the postoperative period. Patients were discharged in stable condition after 7-10 hours of surgery.

*Bactericidal Activity of Oxidized Regenerated Cellulose*

Three bacterial suspensions (cell density 106, 107 and 108 CFU/mL) were prepared and their turbidity was adjusted to McFarland 0.5 Standard. Then the ChitoCell® Pads were cut into 2x6 cm pieces, using a sterile scissor and then were added to the each bacterial suspension. Immediately after adding ChitoCell® pad’s pieces to the bacterial suspensions, the stopwatch was started and 0, 1, 6 and 24 hours later a loop full of each bacterial suspension was inoculated on the Nutrient Agar medium. The media were incubated at 37°C under atmosphere conditions of 5% CO₂. The suspensions without adding ChitoCell® pad’s pieces were used as Blank. The results of the test suspensions were compared to the Blanks and reported.
Results:
Table 1 summarizes time of hemostasis after application of ChitoCell®

<table>
<thead>
<tr>
<th>Raw</th>
<th>Type of surgeries</th>
<th>Time of hemostasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vast bleeding in epidural</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>Volvulus Surgery</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>Axillary lymphoma</td>
<td>6</td>
</tr>
<tr>
<td>4</td>
<td>Hernia inguinal</td>
<td>7</td>
</tr>
<tr>
<td>5</td>
<td>Splenectomy</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>Intracranial hemorrhage</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>Cholecystectomy</td>
<td>9</td>
</tr>
<tr>
<td>8</td>
<td>Cholecystectomy</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>Colostomy</td>
<td>5</td>
</tr>
</tbody>
</table>

Figure 1. Vast bleeding in epidural

Figure 2. Splenectomy
Figure 3. Vast bleeding in epidural

Figure 4. Axillary lymphoma

Figure 5. Hernia inguinal

Figure 6. Volvulus Surgery
Bactericidal Activity of Oxidized Regenerated Cellulose

ChitoCell® demonstrated broad spectrum bactericidal activity that may reduce the incidence of infection. Antimicrobial activity of ChitoCell® against Pseudomonas aeruginosa, Staphylococcus aureus, MRSA, MRSE and VRE has been suppressed immediately after contact.

Discussion:
ChitoCell® provides an absorbable physical matrix for clotting initiation, is saturated on contact with blood 7-10 times its own weight; however, the rate at which the body absorbs it depends on the amount used, the extent of blood saturation, and the tissue bed (McCarthy, 2009; Schreiber MA, 2011; and Hoogerwerf BJ, 2009). It achieves hemostasis by mechanical pressure. This is thought to be relatively bacteriostatic when compared with other hemostatic agents, due to a low pH. They are used to control capillary, venous, and small arterial bleedings. It must be used dry without addition of saline or thrombin. Loescher and Robinson (Loescher AR, 1998) reported that this material can cause temporary sensory disturbances. Absorption of ORC will occur in approximately 4-8 weeks.

Conclusion:
ChitoCell® as a hemostatic pad would facilitate rapid hemostasis in open surgeries and have extended bactericidal activity on Pseudomonas aeruginosa, Staphylococcus aureus, MRSA, MRSE and VRE. All patients included in the study were monitored with precision and related risks minimized with appropriate use. ChitoCell® is effective in controlling bleeding during all surgeries done in this clinical trial without any postoperative adverse reports.
References

Schreiber MA, Neveleff DJ. (2011). Achieving hemostasis with topical hemostats: Making clinically and