Non-Compression Applications for Arterial Hemorrhage Control with WoundClot Hemostatic Gauze

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May, 2014

Though hemostatic products have developed constantly during the last decade, hemorrhage is still the primary cause of mortality in the battlefield. According to the ISR department in the US army, 84% of potentially survivable injuries, ended in death due to lacking ability to control hemorrhage. 67% of these injuries were non-compressionaional or non-tourniquetable. (Pusateri, 2012). The need for more efficient hemostatic products for severe trauma is obvious, especially for non-compressionaional injuries or non-accessible bleeding source scenarios. In 2012, the ISR department in the US military stated that non-compressionaional hemostatic devices for severe arterial and venous bleeding are in high priority. (kheirabadi, 2012)

In 2013, Core Scientific Creations Ltd, has finished the development of a new hemostatic medical device, designed to stop severe arterial and venous hemorrhage, with out the need to compress directly onto the wound, by engineering a hemo-daynamic polymer, which upon activation uses strong physical forces to attach itself onto the blood vessels and exposed tissue, forming a unique level of adherence. WoundClo™, is made from non-oxidized cellulose with a molecular structure designed to entrap platelets and coagulants in a modified physical molecular matrix, specifically designed to create this hemo-daynamic polymer membrane, with high adherence and resilience, able to withhold massive blood pressure and restrict blood flow almost immediately.

At the same time, specifically designed molecular functional groups transform to enhance and promote the natural coagulation process. The efficacy of WoundClo was tested extensively in different application methods, using well-accepted protocols for hemostatic devices in severe trauma applications, in groin arterial and venous injuries.

Efficacy studies for Non-Compression Hemorrhage control in swine for a hemostatic device

All of the studies were approved by the national ethics committee of the state of Israel.

For non-compression efficacy studies on Femoral arterial and venous injuries three models of groin injuries were used with an increased degree of severity. The degree of severity is indicated by the type of trauma simulated: the amount and type of blood vessels injured, the type of injury (partial or full transection) and the accessibility to the wound area.

Landrace crossed large swines were used in these studies, with a body weight of 35-45 Kg each. The animals were injured under general anesthesia. At least 15 seconds of free bleeding was allowed before applying the tested device.
All animals were monitored with no further intervention outside fluid infusion.

**The most moderate** injury was done by a 3.5 cm lateral incision on the femoral artery. After 15 seconds of free bleeding, two pieces of 5x5 cm WoundClot Trauma gauze were gently placed onto the wound site. The gauzes were held in the blood flow for a few seconds to allow the product to absorb blood for activation, and then placed on to the injured blood vessel.

The applicator then removed his hands from the wound, allowing the activated gauze to adhere itself to the injured blood vessel.

The first indication observed was the ability of the gauze to adhere to the femoral artery despite the blood pressure erupting from the wound. The gauze stayed in place with no external intervention.

After 2 minutes a significant reduction in blood flow from the wound was indicated which reduced steadily until complete stop after 4 min.

After 10 minutes of observation with no additional blood flow, the experiment was declared a success.

A full transection of both the femoral artery and vessel was done, after exposing the groin area. Free bleeding was allowed for 25 seconds and then two 10x10 cm pieces of WoundClot Trauma gauze were gently placed one after the other onto the wound site. The gauzes were held in the blood flow for a few seconds to allow the product to absorb blood for activation, and then placed on to the injured blood vessel.

The applicator then removed his hands from the wound, allowing the activated gauze to physically adhere itself to the injured blood vessel.

A sponge towel was gently placed on top of the wound to absorb excess bleeding, with light placement pressure only and excess blood was suctioned externally.

The first indication sighted was a significant increase in the swine’s blood pressure followed by a gradual decrease in blood flow, reaching complete stop after 11 minutes.

**The highest degree of severity** was designed to simulate a non-medicated trauma injury in the groin.

The left thigh and groin of the swine was grossly stabbed by a scalpel, transecting the tissue, blood vessels and nerves across the groin.

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<table>
<thead>
<tr>
<th>Severity</th>
<th>Injury</th>
<th>Blood Vessel</th>
<th>WoundClot Dimensions</th>
<th>Time to Hemostasis</th>
<th>Applied Pressure</th>
<th>Hemostasis upon removal</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>3.5 cm linear incision</td>
<td>Femoral Artery</td>
<td>2 of 5 x 5 cm</td>
<td>4 minutes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>++</td>
<td>Perpendicular transection</td>
<td>Femoral Artery &amp; Venous</td>
<td>2 of 10 x 10 cm</td>
<td>11 minutes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>+++</td>
<td>Stabbing Thigh</td>
<td>Femoral Artery &amp; Venous (invisible bleeding source)</td>
<td>8 x 100 cm</td>
<td>17 minutes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
A massive arterial and venous blood flow was indicated recognizing the difference in the blood color between the two vessels. A nervous trauma was indicated by the twitch in the left leg.

Free bleeding was allowed shortly and a Z-fold, 8x100 cm. WoundClot trauma gauze was packed into the wound, using a soak, placement non-pressure method.

Each fold was inserted into the wound, allowed to soak for a second and then placed gently inside the wound cavity. This process was repeated until the gauze was totally placed in the wound without applying pressure.

The applicator then removed his hands from the wound, allowing the activated gauze to physically adhere itself to the injured blood vessel.

Immediate reduction in bleeding volume was indicated which decreased gradually until complete stop after 17 minutes from application time.

**Hemostasis Stability**

Real life scenarios and second phase treatment in a professional medical facility have to be taken into consideration and evaluated. Therefore, in order to deeply understand the bleeding control effects of the products, we examined the injured site’s condition after taking out the WoundClot device at the end of the monitoring period. The results show that when WoundClot was removed, in 100 % of the cases, large clot formations could be seen at the injured site and complete hemostasis preserved.

Furthermore, the animal's leg was moved and stretched vigorously to simulate walking in order to examine the bleeding control results after gauze removal. A steady state was observed without renewed bleeding indicating the formation of natural clotting at the injured site.

**Conclusions:**

WoundClot demonstrate unique and remarkable capabilities in non-compression hemorrhage control of severest traumatic injuries, including non-tourniquetable cases. Moreover, the hemostasis achieved with the use of much less of hemostatic product unlike other available products in the market, which required the use of force for hemostasis.

**References:**


- Kheirabadi B.S., “Survey of Currently Available (FDA approved) and Future Hemostatic Dressings/Agents” IPR meeting, Chantilly, VA, 2012.