A Novel Highly Porous Silica and Chitosan-Based Hemostatic Dressing Is Superior to HemCon and Gauze Sponges

Michael S. Englehart, MD, S. David Cho, MD, Brandon H. Tieu, MD, Melanie S. Morris, MD, Samantha J. Underwood, MS, Ayhan Karahan, MD, Patrick J. Muller, BS, Jerome A. Differding, MPH, David H. Farrell, PhD, and Martin A. Schreiber, MD

Background: Hemostatic dressings have become increasingly popular as the optimal initial treatment for severe hemorrhage. The purpose of this study was to compare the hemostatic properties of a novel highly porous silica and chitosan-based dressing (TraumaStat) to HemCon, and gauze dressing in a severe groin injury model in swine.

Methods: Thirty swine were blindly randomized to receive TraumaStat, HemCon, or standard gauze dressing for hemostatic control. A complex groin injury involving complete transaction of the femoral artery and vein was made. After 30 seconds of uncontrolled hemorrhage, the randomized dressing was applied and pressure was held for 5 minutes. Fluid resuscitation was initiated to achieve and maintain the baseline mean arterial pressure and the wound was inspected for bleeding. Failure of hemostasis was defined as pooling of blood outside of the wound. Animals were then monitored for 120 minutes and surviving animals were euthanized.

Results: Blood loss before treatment was similar between groups ($p > 0.1$). TraumaStat had one failure, compared with five for gauze, and eight for HemCon ($p = 0.005$, TraumaStat vs. HemCon). TraumaStat significantly reduced median blood loss when compared with both HemCon and gauze (117 vs. 774 and 268 mL respectively, $p < 0.05$). At study conclusion, TraumaStat animals had a greater median hematocrit than both HemCon (24 vs. 19, $p = 0.033$), and gauze (24 vs. 19, $p = 0.049$) animals. Median volume of fluid resuscitation and mortality were not different between groups ($p > 0.1$).

Conclusions: TraumaStat was superior to HemCon and gauze dressings in controlling bleeding from a severe groin injury. TraumaStat may be a better hemostatic dressing for control of active hemorrhage than current standards of care.

Key Words: Trauma, Hemostatic dressing, HemCon, Gauze, Hemorrhagic shock.

Hemorrhagic shock is the leading cause of death after combat, and the second leading cause in civilian trauma centers.\(^1\)\(^\text{-3}\) Traditional treatment strategies for hemorrhagic shock include resuscitation with crystalloid and blood to restore and maintain blood pressure.\(^4\)\(^\text{-5}\) The mainstay of treatment for severe hemorrhage from extremity wounds has also included topical compression followed by surgical control where appropriate. Rapid control of hemorrhage has important clinical applications for improved survival and a reduction in delayed causes of death from resultant coagulopathy, infection, and multisystem organ failure.\(^6\)

Recent technical advancements have led to a proliferation of available topical hemostatic agents that have proven equivalent or superior to gauze dressings in temporary control of hemorrhage.\(^7\)\(^-\)\(^12\) As described recently by Pusateri et al.,\(^13\) the ideal hemostatic bandage should be: safe to use, stable at room temperature and extreme conditions, ready and easy to use with minimal training, lightweight and durable, able to stop large vessel arterial and venous bleeding within minutes of application, and inexpensive. Currently, the approved hemostatic dressings in use by the United States military include the chitosan dressing HemCon (HemCon, Portland, OR), standard gauze such as the army battlefield dressing, and zeolite products such as QuikClot (Z-Medica, Newington, CT).\(^13\) Gauze dressing has been used for centuries, and is still considered the standard of care in many military and civilian trauma centers. Although HemCon has gained popularity for its effectiveness with limited side effects, QuikClot produces significant thermal tissue injury leading some to recommend its use only as a last resort in life-threatening situations.\(^13\)

Recently, a novel hemostatic dressing, TraumaStat, (OreMedix, Lebanon, OR) has been developed that combines chitosan with silica and polyethylene to produce a product that is conformable like gauze, but has over a 100-fold greater surface area than HemCon or gauze (Fig. 1, A and B). In theory, this would allow for a more robust interaction with blood and coagulation factors to increase the rapidity and strength of the resultant clot. Preliminary in vitro testing has suggested improved hemostatic performance over HemCon and gauze. These dressing have not been tested in a clinical
The purpose of this study was to compare the hemostatic properties of TraumaStat to HemCon and gauze dressing in a lethal groin injury model of severe uncontrolled hemorrhage in swine. We hypothesized that TraumaStat would provide better hemostasis and improved survival.

**METHODS**

**In Vitro Coagulation Analysis**

Dressings were assayed for their procoagulant activity using a spectrophotometric clotting assay. Samples (1 cm × 1 cm) of each dressing were placed in the bottom of a spectrophotometer cuvette and incubated with 1.5 mL normal human citrated plasma (FACT, George King Biomedical, Overland Park, KS) for 1 minute at 37°C. Clotting was initiated by the addition of 136 μL of 0.2 mol/L CaCl$_2$, and the absorbance at 405 nm was measured for 20 minutes at 37°C. The dressing that generated the most vigorous clotting response was selected as the initial study dressing.

**Swine Hemorrhage Model**

This was a randomized controlled trial using 30 Yorkshire crossbred swine. The animals were fasted for 16 hours before surgery, except for water ad libitum. We preanesthetized the swine with an intramuscular injection of 8 mg/kg Telazol (Fort Dodge Animal Health, Fort Dodge, IA), followed by induction with 2% isoflurane. Animals were orotracheally intubated and placed on mechanical ventilation that was adjusted to keep $P_{CO_2}$ values between 40 mm Hg and 45 mm Hg. An esophageal thermometer was placed, and the animal temperature was maintained at 38.0°C ± 1.5°C using external warming devices. A left ventral cervical cut down was performed and 8F polyethylene catheters were inserted into the common carotid artery and external jugular vein for continuous blood pressure analysis and fluid infusion, respectively. Mean arterial pressure (MAP) and heart rate were continuously recorded and averaged every 10 seconds using a digital data collection system with a blood pressure analyzer (DigiMed, Louisville, KY). The animals underwent a midline celiotomy, and suprapubic Foley catheter placement. The abdomen was then closed with towel clamps. A standardized 10 cm incision was made in the right groin to expose the femoral artery and vein.

After a 15-minute stabilization period, the baseline MAP was recorded and a complex groin laceration was made to include complete transection of the femoral artery and vein, with semitranssection of the adductor muscles. This was followed by 30 seconds of uncontrolled hemorrhage which was collected and recorded in preweighed suction canisters. Blood from the injury that spilled out of the wound cavity that was not collected by suction was collected by preweighed laparotomy pads that were placed under the animals. Animals were prerandomized to receive one of three topical hemostatic dressings: HemCon, gauze, or TraumaStat. After uncontrolled hemorrhage, the randomized dressing was applied through a pool of blood into the wound and pressure was held for 5 minutes. The team member applying the dressing was not blinded to the product applied, but the individual applying pressure was blinded to ensure consistency between groups. This was achieved by covering each dressing with a laparotomy sponge. All dressings and sponges were preweighed to determine the volume of blood loss in addition to blood suctioned into preweighed canisters.

At 30 seconds, fluid resuscitation was initiated with lactated Ringer’s at 165 mL/min to achieve and maintain the baseline MAP throughout the duration of the study. After 5 minutes, pressure was released and the wound inspected for bleeding. Failure of hemostasis was defined as blood pooling outside of the wound. Blood loss after dressing application included blood that pooled outside of the wound plus accumulated blood within the respective dressing at study conclusion. Animals were monitored for 120 minutes and surviving animals were killed. Postmortem, all wounds were inspected to ensure a similar injury pattern and proper dressing application. Labs (ABG, Hematocrit, chemistry panel, and lactate) were obtained at baseline, 30 minutes, 60 minutes, and 120 minutes after injury. Representative samples from each hemostatic dressing were taken, and analyzed with a Scanning Electron Micrograph (SEM). The primary outcome was blood loss.

**Fig. 1.** TraumaStat. The conformable nature of TraumaStat is seen in (A), and the SEM of an unused dressing in (B) shows the high absorptive surface area.
This protocol was approved by the Institutional Animal Care and Use Committee, at Oregon Health & Science University. This facility adheres to the National Institutes of Health guidelines for the use of laboratory animals. This study was funded in its entirety by an institutional grant from OreMedix. All members of OreMedix were blinded to the topical dressing applied and the study in its entirety. Company affiliates were only made aware of the results after the study was completely finished and the data fully analyzed. No member of the study team has any financial or vested interest in OreMedix or its parent company ENTEK and there are no conflicts of interest.

**Statistical Analysis**

Categorical variables were analyzed with a Chi-squared test unless the value of any cell was less than 5 and then Fisher’s exact test was used. A Student’s t test was used to compare the means of continuous variables between all three groups using a post hoc analysis of variance. These data are presented as means ± Standard error of the mean. Any data that did not follow a normal distribution was analyzed with a nonparametric analysis (Mann-Whitney U test). These are presented as medians with the 25th–75th interquartile ranges. Statistical significance was defined as a p value <0.05. SPSS version 13.0 (SPSS, Chicago, IL) was used to perform the statistical analyses. Graphs were produced using Microsoft Excel 2003 (Microsoft, Redmond, WA), and Origin 6.0 (Microcal Software, Northampton, MA).

**RESULTS**

Ten animals were randomized to each study group. As seen in Table 1, each group had a similar blood loss after 30 seconds of uncontrolled hemorrhage, and the preinjury MAP was not different between groups. Figure 2 demonstrates the mean MAPs compared between dressing types. There was one death each in the TraumaStat and gauze groups, and three in the HemCon group (p > 0.1). TraumaStat dressings had fewer failures than HemCon (p = 0.005, Table 1), and a significantly reduced median post-treatment blood loss compared with both HemCon and gauze (p < 0.05, Table 1 and Fig. 3). The volume of resuscitation fluid utilized was equivalent (p > 0.1) (Table 1). Postmortem analysis of the injury demonstrated a consistent injury pattern in every animal in every group: complete transection of the femoral artery and vein, with semitransection of the adductor muscles (p = 1.0). All dressings were appropriately applied to the wound with the exception of one animal in the HemCon group (p > 0.1).

Each group had a similar hematocrit at baseline but throughout the study the TraumaStat group had a progressively higher hematocrit than either of the other two groups which became significant at 120 minutes (p < 0.05) (Fig. 4). Lactate values were similar between groups throughout the study (p > 0.1) (Fig. 5).

Representative SEM images from each of the three dressings are shown in Figure 6. These images show a greater formation of clot and adherence of red blood cells to TraumaStat than gauze dressing and HemCon.

---

**Table 1 Comparison of Group Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>TraumaStat (n = 10)</th>
<th>HemCon (n = 10)</th>
<th>Gauze (n = 10)</th>
<th>TraumaStat vs. HemCon</th>
<th>TraumaStat vs. Gauze</th>
<th>HemCon vs. Gauze</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>36.8</td>
<td>34.7</td>
<td>33.1</td>
<td>0.289</td>
<td>0.031</td>
<td>0.705</td>
</tr>
<tr>
<td>Preinjury MAP (mm Hg)</td>
<td>73.1</td>
<td>71.7</td>
<td>81.4</td>
<td>0.791</td>
<td>0.140</td>
<td>0.112</td>
</tr>
<tr>
<td>Mean 30 s Blood loss (mL)</td>
<td>412 ± 52</td>
<td>479 ± 36</td>
<td>373 ± 49</td>
<td>0.406</td>
<td>0.496</td>
<td>0.131</td>
</tr>
<tr>
<td>Deaths</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0.582</td>
<td>1.0</td>
<td>0.582</td>
</tr>
<tr>
<td>Dressing failures</td>
<td>1</td>
<td>8</td>
<td>5</td>
<td>0.005</td>
<td>0.141</td>
<td>0.350</td>
</tr>
<tr>
<td>Median blood loss after treatment (mL)</td>
<td>116.8</td>
<td>774.3</td>
<td>267.9</td>
<td>0.013</td>
<td>0.049</td>
<td>0.174</td>
</tr>
<tr>
<td>Median fluid resuscitation (mL/kg/min)</td>
<td>0.025</td>
<td>0.210</td>
<td>0.066</td>
<td>0.013</td>
<td>0.028</td>
<td>0.151</td>
</tr>
<tr>
<td>Median fluid resuscitation (mL/kg/min)</td>
<td>3,120.0</td>
<td>4,730.0</td>
<td>4,440.0</td>
<td>0.257</td>
<td>0.257</td>
<td>0.940</td>
</tr>
</tbody>
</table>

**Fig. 2.** Mean arterial blood (MAP) compared between groups over the course of the study.
Fig. 3. Scatter plot of blood loss for each animal after dressing application (*p < 0.05).

Fig. 4. Hematocrit. TraumaStat animals had a greater Hematocrit at study conclusion than either HemCon or gauze sponges (*p < 0.05). Data presented as means ± SEM.
DISCUSSION

This study evaluated the effectiveness of a novel hemostatic dressing compared with two other FDA approved dressings, HemCon and gauze. TraumaStat has recently received FDA approval. TraumaStat reduced blood loss resulting in a greater hematocrit than either of the other groups, and had fewer failures when compared with HemCon. The improved hemostatic efficacy shown in this study is likely to be due to the structure and chemical composition of the dressings. SEMs of the three dressings are shown in Figure 6. TraumaStat is primarily composed of silica fibers arranged to produce an extremely high surface area (110 m²/g) and a porous structure which is maintained by the polyethylene component. The fibers are partially treated with chitosan derivatives. Silica is a potent activator of the intrinsic clotting pathway and the very high

Fig. 5. Lactate. No differences were observed between any group at any time point throughout the study (p > 0.1). Data presented as means ± SEM.

Fig. 6. (A) Gauze, (B) HemCon, and (C) TraumaStat. Representative sample SEMs of post-treatment dressings utilized in the study. Because of a greater surface area, TraumaStat has a much greater interaction with the blood and clotting factors resulting a greater degree of clot formation.
surface area permits diffuse activation of clotting in the wound. Chitosan has mucocative properties that contribute to the dressing’s ability to adhere to the wound increasing the interaction of silica with blood at the wound-dressing interface. The porous structure of the dressing permits blood to enter the dressing further increasing the surface area of this interaction by not limiting it to the surface of the dressing. During this study, we commonly observed some degree of saturation of the dressing with blood as part of the process of hemostasis.

The SEMs of the three dressings are indicative of their qualities. Gauze is a translucent fiber with a loose open weave made of cotton. These fibers have a mild affinity for red blood cells as shown in Figure 6, A. The surface area of gauze is approximately 1 m²/g. The HemCon dressing is relatively smooth with a surface area of 1.2 m²/g and adherence of red blood cells is not noted in Figure 6, B. The intense affinity of the TraumaStat dressing for red blood cells is shown in Figure 6, C.

Although numerous studies have proven the effectiveness of HemCon over traditional hemostatic dressings, a recent study of a novel hemostatic dressing proved HemCon to be nearly ineffective in a similar animal model as our own.12 During our study, we found that this may be in part due to the relative nonconformable nature of HemCon, and accounted for the one dressing misapplication and likely the overall reduced effectiveness seen with HemCon. This is of vital importance as most actively bleeding external wounds are of irregular depth and geometry frequently requiring a more conformable dressing to produce effective hemostasis. Interestingly, gauze dressing outperformed HemCon in our study. We think that this is due in part to its ability to be easily and tightly packed within the wound to stop hemorrhage. TraumaStat combines excellent hemostatic properties with the conformable nature of gauze dressing to rapidly and effectively stop significant arterial and venous bleeding.

There were no differences in mortality between groups. This may be in part due to the fact that animals were continually resuscitated with fluid to achieve and maintain the baseline MAP. Continuous fluid infusion may have artificially sustained animals for the short duration of the study. Although there was no difference in the median volume of fluid infused, this may be due to the wide variance observed within each group. The degree of resuscitation has a profound effect on outcome in this model. We chose to resuscitate and maintain animals at their baseline blood pressure. Resuscitation to a normal blood pressure is most consistent with current civilian practices.

TraumaStat compares favorably with HemCon as far as cost. The cost of a quantity of TraumaStat used in a single application (1 animal) in this study was $80 US, whereas one roll of HemCon, also one application, was $100 US. Laparotomy sponges carried the least cost, at $1.25 per application.

There are several limitations to this study. First, TraumaStat was tested against only two approved hemostatic dressings. Although QuikClot remains an effective hemostatic agent still in use by military and civilian trauma centers, its use as a primary agent has declined because of concerns of extreme temperatures causing significant tissue injury. For this reason it was not included in this preliminary study. We sought to compare TraumaStat to gauze which is the current standard of care in every trauma center and HemCon which is widely used by the military. New forms of both HemCon and QuikClot have become available. HemCon now produces chitosflex which is a more conformable form of the dressing with a similar chemical makeup. QuikClot Advanced Clotting Sponge has been developed by Z-Medica. This formulation is contained in a porous surgical fabric and it produces a less exothermic reaction. Further studies will need to be conducted to compare Trauma Stat’s hemostatic properties to these formulations and other dressings such as the Modified Rapid Hemostatic Dressing, dry fibrin sealant, and numerous other novel dressings currently being investigated. Additional procoagulant compounds could also be substituted for the chitosan in TraumaStat to provide even better hemostasis. This may additionally help us to determine whether the hemostatic properties of TraumaStat are a result of the unique chemical composition, physical properties, or both. Future studies investigating this are ongoing.

Second, complete transection of the femoral vessels could have caused retraction of the artery with resultant vasospasm that artificially contributed to improved hemostasis. Removal of a portion of the anterior arterial wall, as reported by Sondeen et al.,8 would eliminate the effect of arterial retraction. Numerous studies of hemorrhagic shock in swine have used various traumatic lacerations to arterial vessels. To date there have been no studies in the literature comparing these two techniques. Each technique appears to be used with near equal frequency in the literature, with no clear favored technique that has proven more reproducible or clinically relevant. The potential for arterial retraction should have occurred equally in each group, and therefore should not have significantly altered the differences seen between groups. Finally, patients with penetrating injuries to large vessels more commonly have complete transection of vascular structures and not “glancing” injuries that blow out only one side of the vessel wall. These injuries very frequently involve both artery and vein, an effect which is not duplicated with a single hole in the front wall of the artery.

As another example, Ward et al.12 tested HemCon against several different novel hemostatic dressings. In this report, the study animals performed much more poorly than in our study; 80% of the HemCon animals died, while never regaining adequate blood pressure (defined as 65 mm Hg) and requiring large volume resuscitation. There are several different reasons why the animals in this study may have had worse outcomes. In the HemCon group, our initial mean pretreatment blood loss was greater after 30 seconds (479
mL) than after 45 seconds in the Ward study (291 mL). This suggests that our injury model is at least as severe, if not more severe, as the model used by Ward et al. However, our post-treatment blood loss averaged 774.3 mL in 120 minutes (6.5 mL/min), where the post-treatment blood loss in the Ward study was 3,149 mL over 180 minutes (17.5 mL/min). One possible explanation is that these authors standardized their application of the dressing by using a blood pressure cuff to exert 200 mm Hg of pressure over a 6 cm × 8 cm surface. This is equivalent to 3.9 pounds per square inch. Although we did not discretely measure the pressure exerted on the dressing in our model, the force generated manually is likely to be far in excess of 3.9 pounds per square inch. We chose not to create a standardized device for applying pressure to more closely simulate a clinically relevant circumstance, namely that of an injured patient being tended to in the field by a provider applying manual pressure. In our study, a single individual applied pressure for each of the applications and they were blinded to the dressing therapy used. Further, Ward et al. allowed for a second application of the dressing if the first treatment failed, including removal of the first product and application of a second. This could easily have dislodged any clot that was present and contributed to increased blood loss. These factors could contribute to the much greater post-treatment blood loss.

Third, we did not test coagulation parameters in each animal. Our laboratory has extensive experience in coagulation studies of hemorrhagic shock in swine, and there have never been any significant variations in baseline coagulation parameters in any of these studies. Although coagulopathy could have developed throughout the study, this would likely be the result of a dilutional coagulopathy from fluid resuscitation which occurred due to a dressing failure. Fourth, TraumaStat has only been tested in animal models, long-term adverse sequelae such as infection, and bleeding after prolonged use are unknown. Additional studies are required to test the effectiveness of TraumaStat in a variety of conditions and injuries such as intra-abdominal solid organ injuries and injuries in a coagulopathic setting.

CONCLUSION

TraumaStat is a novel hemostatic dressing comprised of chitosan, silica, and polyethylene that has proven to have improved hemostatic properties when compared with HemCon and gauze sponges. TraumaStat’s significantly increased surface area and more conformable texture allows for greater interaction with blood and coagulation factors to produce a stronger, more hemostatic clot. Our study demonstrated that TraumaStat resulted in significantly better hemostasis than either HemCon or gauze with fewer failures, a reduced blood loss, and greater hematocrit at study conclusion. TraumaStat may be a better hemostatic agent than the current standards of care being used in both the civilian and military setting.

REFERENCES


DISCUSSION

Dr. Evan Renz (San Antonio, Texas): Good morning, Dr. Nagy and colleagues. Thank you very much for the opportunity to review this paper. I think we could probably all agree that the development and employment of the hemostatic dressings to treat both military and civilian trauma casualties is clearly worth our best research efforts and Dr. Schreiber’s lab continues to produce valuable information.

Copyright © Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.
regarding hemostasis related to trauma within military and civilian communities.

I appreciate very much Dr. Englehart and his colleagues for contributing to this body and knowledge and for providing their well-crafted manuscript for review and discussion weeks in advance.

I now invite Dr. Englehart to address several questions to help us further appreciate his work. First, a question regarding the model used to create the traumatic insult. Since severing both the artery and vein may allow retraction and constriction of the artery, thereby potentially decreasing hemorrhage, did you debate using a model which penetrates only the front wall or a side of the vessel such as created by a grazing gunshot wound or a stab wound, and if so, please comment on your choice of the model.

Second, the authors indicate that preliminary in vitro testing suggested improved hemostatic performance over gauze and Chitosan bandages. I would be interested to know more about the type of testing performed in these in vitro studies, where they were performed, and to have the citations for these studies.

Third, the authors make note that the Trauma Stat product apparently increased conformability. Their observations of the new dressing’s ability to better stem the tide of the hemorrhage may be significant, but I would like more description as to why this may be so. Is it possible that the construct of the dressing containing the Chitosan silica and polyethylene simply plugged the hole through the mechanical means more than biologically?

Despite the inclusion of the sample scanning electron micrographs within the text, it is not clear to me exactly how the addition of the silica to the product affects the end result and I would certainly be interested to hear from the authors additional description in this regard.

Fourth and last, most surgeons and anesthesiologists would agree that the estimation of the interoperative blood loss is difficult to predict. The authors report on the volume of blood lost following application of the dressing and emphasized the significant difference noted between the products in this regard.

Since this is a key point in the discussion, I would be interested to know in greater detail the technique utilized by your team to accurately quantify the blood that pooled outside the wound, plus that which accumulated in the dressing itself.

Was the suction or quantified rinsing technique utilized? Were the dressings weighed? Was another technique used to estimate the blood loss? I would encourage the authors to describe this technique in your final manuscript.

The authors listed several areas of possible weakness in their study and I applaud their objective willingness to compare Trauma Stat material with newer versions of both the Hemcon and the Quick Clot products, as well as other new products on the horizon, to test their conclusions.

The authors should, again, be commended for their diligence and the scientific inquiry which may well contribute to saving many lives on the battlefield, or even in our own backyards.

**Dr. Michael Englehart** (Portland, Oregon): Thank you, Dr. Renz, for your insightful comments and questions. Regarding the choice of the model, in the literature, hemorrhagic shock studies utilizing some form of groin injury have utilized both a complete transection, or a slash model, and a semi-transection, or a punch model, something similar to that.

It seems to be more dependent upon research or preference and there have been no formal study comparing one method versus the other to determine which is better or more appropriate.

We believe that the complete transection is a little bit more clinically relevant, as patients suffering from injury, particularly those on the battlefield, more commonly have complete injury to an artery or vascular structure, rather than just a grazing bullet wound. We believe this represents a little bit more of a clinically relevant model than just a semi-transection.

The in vitro testing, this was done as a preliminary step in testing the product. This was performed in collaboration between the company as well as Oregon Health Sciences University and was a collaboration between academics and industry and it was a performed at a PhD pathology lab at our institution.

Numerous changes were made to both the physical and chemical composition of the dressing to improve its performance and optimize its hemostasis. We picked the best product that they had developed over subsequent testings. There’s actually been no formal study on data reported in the literature on this as yet. We’re continuing to develop the product to improve its performance and to optimize its use.

Regarding whether the effect of this dressing is purely just out of the pressure phenomenon and not necessarily related to any of its chemical makeup, part of that reason is why we did utilize the gauze dressing, because it has limited, if any, chemical influence on the hemodynamic properties and its hemostasis.

In comparison, you would think that if it was purely a pressure-related effect that it would perform similar to gauze dressing. We know that silica is a potent activator of the coagulation cascade and as I’ve been told by the manufacturer of this product, it helps greatly increase the surface area.

That, combined with the procoagulant properties of Chitosan, make this a very powerful hemostatic dressing that we believe is superior in its ability to control hemorrhage and not just plugging a hole.

Finally, in terms of measuring blood loss, we did–As you saw in the video, we suctioned the blood with pre-readied canister and all dressings and all sponges utilized in this study were all pre-weighed, so we could get a very accurate measurement of blood that pooled outside of the wound and blood that accumulated within the dressing to better quantify the amount of blood loss.

**Dr. John T. Malecynski** (Lancaster, Pennsylvania): I enjoyed your paper and I agree that I think the Chitosan based...
coagulants do show a lot of promise. I have one question, though. It seemed that you had deaths in every group, one to three, from what I can remember, and then you had up to eight wound failure or packing failures.

Your observation period was two hours. Can you explain how you can have a packing or wound or coagulation failure, but not have the animal exsanguinate during that period of time?

**Dr. Michael Englehart:** I’ll attribute that to several factors. The first is not all failures were the same. Some tended to ooze a fair bit of blood and some tended to fail immediately and regain the pulsatile hemorrhage.

We were actively resuscitating these animals to try and maintain their blood pressure and I think that artificially tended to keep some animals alive. If we had given them a fixed volume of fluid and let them be, I think we would have seen a much larger difference in the mortality and it probably would have been a superior advantage from our dressing versus the other ones.

**Dr. Heena Santry** (Chicago, Illinois): I would have expected a product that reduced blood loss to also improve lactic acidosis and you didn’t find that in your study. Do you have any theories that might explain that?

**Dr. Michael Englehart:** We had similar thoughts to that. Again, I think part of it would have to do with the resuscitation perhaps washing out a little bit of the lactate. I would agree with that, that I was a little surprised to see that the lactate was similar and was not elevated. Again, I think it is a little bit of an artificial representation, given that we were continually keeping these animals alive.

If we had given them, again, a fixed volume of fluid and just let them be, we would have almost certainly seen a difference in the lactate values.