A Keratin Biomaterial Gel Derived from Human Hair is Hemostatic in an Acute Liver Hemorrhage Model

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Statement of Purpose:
Rapid, voluminous hemorrhage instigates a cascade of events that are impossible to reverse in the absence of advanced medical care. Even trained first responders such as police officers and fire fighters often arrive at scenes of traumatic injury well beyond the point when the transfusion trigger has been reached, and are unable to implement life saving measures. On the battlefield, seventy percent of ballistic injuries result in death within the first hour. Currently, tourniquets and hemostatic agents can be used by those in the field, but these technologies have limitations that do not address many of the unique demands of administering aid at the scene. Ideally, a hemostatic dressing for first responders should be highly efficacious, easy to transport and store, and be able to be used by non-medical personnel including the victim themselves.

Methods:
In the present study, a total of 16 New Zealand rabbits were used. The animals received a standard-sized liver injury that consisted of transection of approximately one third of the left central lobe and were then randomized into one of four groups. Four animals served as negative controls and received no treatment, four animals received treatment with QuickClot®, four animals were treated with Hemcon® bandage, and four animals were treated with keratin gel. Vital stats and other data were recorded during surgery, blood samples were taken during and after surgery (surviving animals), and all surviving animals were sacrificed after 72 hours with liver biopsies taken for histological examination.

Results/Discussion:
24 hour survival rates were 0%, 62.5%, 62.5%, and 75% for the no treatment, QuickClot, Hemcon, and keratin groups, respectively (Figure 1). The keratin gel and QuickClot groups showed a statistically significant reduction in shed blood volume compared to the control (Figure 2). Moreover, the keratin gel group reached a hemostatic plateau more quickly. The keratin gel group also demonstrated greater maintenance of mean arterial pressure (data not shown), and the lowest shock index of all the materials tested (data not shown). The keratin gel adhered well to the bleeding surface of the liver and mediated a healing response after being left in place for three days.

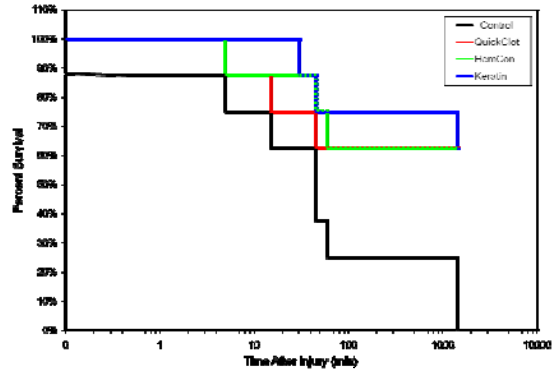

Figure 1. Kaplan-Mayer survival graph: Time is presented in minutes on a logarithmic scale. All animals in the control group died within 60 minutes. One animal form the keratin and one from the Hemcon group was sacrificed upon recommendation of the animal care stuff. Overall, keratin outperformed the other groups with only one death (sacrifice) compared with 2 deaths in the QuickClot and Hemcon (one sacrifice) groups.

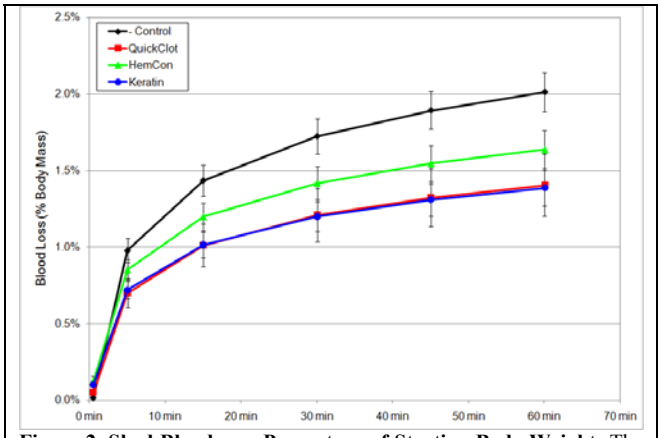

Figure 2. Shed Blood as a Percentage of Starting Body Weight: The Keratin and QuickClot groups lost significantly (*) less blood than the control and Hemcon group. Further, keratin and Hemcon made the transition to a hemostatic plateau phase sooner.

Conclusions:
We have recently discovered that certain keratin biomaterials are potent hemostatic agents. Keratin was efficacious in the present model of severe liver injury and lead to increased survival, more rapid hemostasis, decreased blood loss, stability of MAP, a lower shock index, and good tissue integration. Keratin gels are particularly amenable to use as a hemostat as they can be injected into locations where the source of bleeding cannot be visualized. The keratin gel is a powerful hemostatic dressing that could easily be used by first responders to treat hemorrhage at the scene of injury.