



**SELECTED COMMENTS FROM THE REPORT OF
THE ARMY INSTITUTE FOR SURGICAL RESEARCH (ISR)
HEMOSTATIC EVALUATION STUDY**

Release Date: March 5, 2008

Introduction: Hemorrhage remains the greatest threat to survival in the first 24 hours after traumatic injury, accounting for nearly 50% of the deaths on the battlefield and 39% of civilian deaths from trauma.

Stated ISR Objective: To determine the efficacy of four new hemostatic products to stop a severe extremity hemorrhage that cannot be controlled by currently available agents in swine (in a research model used for evaluating ballistic injury wound treatments.)

Methodology: ISR tested 10 animals for each product using a femoral artery injury to mimic severe ballistic injury, which calls for product insertion after only 45 seconds of free bleeding. Pressure was held for two minutes, with up to two applications of product possible if it was warranted. Each animal was then observed for 180 minutes to check for re-bleeding.

WoundStat Comparative Information:

- WoundStat (WS) received FDA clearance on August 2007 as a safe hemostatic agent with an indication for emergency treatment of external wounds with moderate to severe bleeding.
- The superior effectiveness of WS over QuikClot products, chitosan {HemCom}, and the Army field bandage was demonstrated in a large animal study using the ISR hemorrhage model {*Journal of Trauma*, August 2007}.

Study Results and Observations:

- WoundStat was the most effective treatment; it was significantly more effective than HemCon, QuikClot ASC+, and Celox based upon measures of survival, blood loss, and duration of hemostasis. It was also more effective than Super QR, the only other product tested.
- WoundStat was the only product that resulted in 100% survival of study animals for 180 minutes, the maximum time called for in the study. All 10 WS animals survived and the next best case was only six out of 10 animals.
- Animals treated with WS lost the least amount of blood post-treatment. The next closest treatment resulted in almost four times the blood loss as experienced in animals treated with WS.
- WS demonstrated no exothermic reaction, unlike two other products.
- Treatment and coverage of a complex wound with multiple bleeding sites are easier with granular agents such as WS.
- The results of this study clearly demonstrated that recent improvements made in the HemCon and QuikClot ACS+ products were inadequate to overcome severe arterial hemorrhage. The latter product failed to produce hemostasis in six consecutive animals despite two applications in each. Therefore, further testing of this material was discontinued.
- HemCon produced hemostasis in only six out of 10 pigs, but only one survived.
- Super QR, when in contact with blood, produced significant heat, with persistent high temperatures causing damage to underlying tissue including nerve structures.
- The hemostatic potency of Celox seems to be all or none; three of the animals tested out of 10 never achieved hemostasis and a fourth only stopped bleeding in six and a half minutes. The reason for this inconsistency could not be determined.

Conclusions: WoundStat was the only hemostatic agent that resulted in eventual 100% hemostasis and survival of all test animals. Among the agents tested, WoundStat appears to be the most efficacious agent in treating arterial bleeding.