

QuikClot[®] brand hemostatic agent: Reports from the Field

The following data was presented by Dr. Hasan Alam, MD, FACS, Director of Research, Trauma and Emergency Surgery, Massachusetts General Hospital/Harvard Medical School, Boston, Associate Professor of Surgery, The University of the Health Sciences, Bethesda, Maryland, at the August 2005 Advanced Technology Assessment for Combat Casualty Care (ATACCC) in St. Petersburg Beach, Florida meeting. The data was compiled and provided by Dr. Peter Rhee, MD, MPH, Captain, U.S. Navy.

It has been reported many times that exsanguination is the leading cause of death on the battlefield. QuikClot[®] brand hemostatic agent has now been used to treat severe, traumatic bleeding on the battlefields of Iraq and Afghanistan for over three years. Dramatic success has been reported many times. In the data compiled by Dr. Rhee, which included 68 cases, the product stopped bleeding in 63 patients who survived. Of the remaining five, the product stopped bleeding in two of the cases, but the patients died from other wounds. In the remaining three:

- ✚ One was a case of thoraco-abdominal gun shot wound on 11/26/04 (Army, OIF II) with damage to the spleen, colon, kidney, adrenal, spine, the patient was packed with thrombin, gel foam, Surgicel, QuikClot[®] and aFVIIx 2, but nothing stopped the bleeding and the patient died at level 2;
- ✚ Second was reported as an old person, civilian, hit by a train, pelvic disruption with large open wound, bleeding from pelvic fracture, hypothermic, acidotic, hemodiluted and was unable to get QC to the site of bleeding; and the third
- ✚ Gun shot wounds to neck and multiple other sites.

Alam reports that 75% of these cases were battlefield, while 25% were civilian use; 63% of users were physicians/trauma surgeons while 16% were medics, corpsman or EMTs. Of the reported civilian uses, 20% were pre-hospital versus 43% for the battlefield.

An array of weapons and modalities inflicted the injuries reported, including:

- ✚ Gun shot wounds, 17
- ✚ IED, 10
- ✚ Blunt trauma, 8
- ✚ RPG, 3

Wounds were reported to:

- ✚ Lower extremity, 24
- ✚ Chest, 10
- ✚ Upper extremity, 7
- ✚ Groin, 6
- ✚ Abdomen, 6
- ✚ Chest, 6
- ✚ Shoulder, 5
- ✚ Back, retroperitoneum, 4

56% of patients were reported as hypotensive, 15% not hypotensive and 20 were reported as unknown in this regard.

The time to control bleeding was reported as 1 minute median, average 4.4 minutes and a range of 1 to 12 minutes.

Burns were reported in two cases, on requiring a bilateral thoracotomy in a forward resuscitative surgical suite (FRSS). The report concludes that this patient would have died without the use of QuikClot[®]. Six patients reported pain on application.

60 (88%) of the users reported that they would use QuikClot[®] again, while the remaining eight did not report whether they would use the product again or not. None reported that they would not use QuikClot[®] again.

Alam concludes that QuikClot[®] stops bleeding, saves lives when applied properly and generates heat.

Other data has shown that there are multiple modalities that come into play when QuikClot[®] is applied to a wound that provide the basis for a very sound physiological explanation of the clot formed.

In addition to the risk of burning as a result of the exothermic reaction, two other opportunities for improvement have been reported to Z-Medica:

- ✚ Improve the ease of removal from the wound, and
- ✚ Provide a means to apply the product from any angle, even below.

The company has responded by introducing QuikClot ACS™ Accelerated Clotting Sponge. ACS is an improvement to the original QuikClot® which addresses the issue of material flowing away from the wound and improving the ability of the caregiver to get material to the wound. The company has listened to the voice of our customers and improved the delivery mechanism of the product by reconfiguring the granular material into a beaded format and placing 50 grams of the material into a porous surgical package. Two sponges are provided in every pack. The Army has just ordered 4,000 units of this improved product for use in Iraq.

The U.S. Air Force recently decided to include QuikClot® in the individual first aid kits of all personnel deployed to Iraq and Afghanistan. And there have been multiple reports on the success of the product in the media:

- ✚ CBS Evening News, February 24, 2005 in which Col. David Burris, Army surgeon, reported that QuikClot® has saved the lives of over 100 of our people in Iraq;
- ✚ a firsthand report on NPR's "Talk of the Nation" show in which a marine attributed QuikClot® with saving his life, as well continuing scientific publications demonstrating the products superb effectiveness in animal testing.

QuikClot® brand hemostatic agent is tested and found effective at stopping severe bleeding and saving lives when used as directed by Z-Medica.