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**Purpose of Study:** Examine the efficacy of BallistiClot™ hemostatic agent after inducement of a lethal groin injury by shotgun ammunition.

**Methods:** A trail examination of a (non-approved FDA) hemostatic agent entitled, BallistiClot™ (Emergency Medical Devices, LLC) was applied following a complex groin injury to the femoral vessels in an animal model that simulates combat injury. This trail examination adhered to the policies and principles as stated in the Guide for the Care and Use of Laboratory Animals (Institute of Laboratory Animals Resources, National Research Council, National Academy Press, 1996) and the methods used in this trial were approved by an independent Intuitional Animal Care and Use Committee (IACUC), 2007.

One Yorkshire swine (~82 kg) was anesthetized with an intramuscular Telazol (ketamine and valium 30mg/kg). An endotracheal tube was inserted in addition to an IV line placed in a left external jugular vein using a surgical cut down technique. Patency of the IV line was maintained with an initial saline bolus flush. The IV saline was frequently flushed following IV drug administration. The veterinary staff monitored the animal to maintain sedation along with pain management throughout the 180 minutes.

Once positioned on an authorized weapons range the right proximal medial thigh was manually exposed and a black marker pen was used to place an X on the skin at the desired point of injury. A lethal injury was induced by a 12-gauge shotgun slug fired 6-8 inches from the black X mark. This traditional shotgun slug (1500-1700 fps) induced femoral artery and vein disruption causing uncontrolled hemorrhage inside the wound cavity with evidence of an entry and exit wound. Severe bleeding was observed by the investigators immediately after slug penetration. Time was recorded at point of injury. A gloved hand technician applied manual compression equal to ~150 mmHg; (Arnuad et al 2007) over the entry wound. Within 20-30 seconds, manual pressure was released and the wound cavity was filled with gauze and manual pressure was reapplied for one minute in effort to gain hemorrhage control before the hemostatic agent was applied. Without good hemorrhage control prior to hemostatic agents is administered, a high percentage of agent failure is observed after 5 minute of manual pressure (J. Hagmann personal communication). At the end of this period, manual pressure was released, gauze was completely removed and a single BallistiClot™ 60 cc syringe containing inorganic hectorite clay within a suspension solution was injected into the wound cavity in less than 5 seconds. This was followed by gauze wound packing placed on top of the BallistiClot™ to ensure equal distribution of this agent down to the disrupted femoral vessels. Manual pressure (~150 mmHg) was then immediately applied directly over the wound site for a total of five minutes without interruption. Immediately of this period



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manual pressure was released slowly and the wound was observed for bleeding. Since no obvious bleeding occurred after 2 minutes, the top layers the gauze was removed down to the BallistiClot™ material and we continued to observed for bleeding. No partial or massive bleeding occurred over the next 10 minutes. Within 10 minutes, it was decided to repeat this injury on the left proximal medial thigh. Two 12-gauge shotgun slugs were fired into the femoral vessel region within seconds since the first slug did not cause immediate massive hemorrhage. The same methods listed above were followed. At no time was there any bleeding from this second wound cavity or even from the first wound cavity.

The swine was lifted back on an army litter and carried 200 yards down a slight uneven grade back to the training area without rebleeding and placed under a tent where the animal was covered with an impermeable plastic wrap to prevent heat loss and was monitored for approximately additional 120 minutes. Vital signs (HR, RR, SpO2, rectal temp) were continuously recorded every thirty minutes from point of injury along with all drug administered by the veterinary staff. At no time in this prolonged care phase did either wound site continue to bleed.

**Summary:** After 180 minutes from the point of injury, BallistiClot™ application into these two wound cavities followed by manual pressure arrested lethal arterial and venous hemorrhage within 5 minutes. It is most evident that BallistiClot has unique hemostatic characteristics that have been successfully demonstrated to be efficacious to arrest arterial hemorrhage induced by a 12-gauge slug mechanism of injury. The method to deliver this agent, as a solution applied from a single or multiple 60cc syringes, is very unique and has potentially great application of treating specific combat injuries creating a wound track. It is recommended that an efficacy study be conducted with a greater number of trials and compare this agent to other proven hemostatic agents.

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