

Pre-Clinical Evidence for iTClamp<sup>(R)</sup>

**Filips, D., Logsetty, S., Tan, J., Atkinson, I., & Mottet, K. (2013). The iTClamp Controls Junctional Bleeding in a Lethal Swine Exsanguination Model. *Prehospital Emergency Care*, 17(4), 526-532.**

Proof of concept study for iTClamp Hemorrhage Control Device. Lethal hemorrhagic injury to 20 swine found 100% of swine treated with iTClamp survived whether the clamp was placed immediately or placement was delayed. 60% treated with packing with standard gauze survived v. 0% survival if the wound was left untreated. The iTClamp was superior in terms of overall survival ( $p < 0.009$ ), total blood loss ( $p = 0.008$ ) and survival time ( $p = 0.003$ ) to standard gauze and the control. iTClamp is an effective temporary wound closure device.

**Mottet, K., Filips, D., Logsetty, S., & Atkinson, I. (2014). Evaluation of the iTClamp 50 in a human cadaver model of severe compressible bleeding. *J Trauma Acute Care Surg*, 76(3), 791-797.**

Laboratory cadaveric study testing effectiveness of iTClamp to control external fluid loss from injuries to compressible areas, maintain this control despite movement, as well as maintain distal perfusion. Wounds made to thigh, groin, neck, and arm and sterile water was pumped through the arteries. iTClamp was found to effectively stop fluid loss to all of these areas, the fluid used had no clotting factors, movement had no effect on the hematoma formation or maintenance and distal flow remained intact.

**Filips D, Mottet K, Lakshminarasimhan P, Atkinson I. (2014). The iTClamp@50, a Hemorrhage Control Solution for Care Under Fire. *International Review of the Armed Forces Medical Services*. 87(2):31-36.**

This article examined two aspects of usability. A bench top model was used to demonstrate that the iTClamp was effective to 180 mm Hg systolic pressure even through two layers of denim or 3 layers of military uniform. The second part of the study examined what level of medical background was required to operate the device without prior instruction. The data showed no differences based on medical background and that the device could be used by first aiders, police officers, EMT's, and doctors with equal proficiency.

**St John, A. E., Wang, X., Lim, E. B., Chien, D., Stern, S. A., & White, N. J. (2015). Effects of rapid wound sealing on survival and blood loss in a swine model of lethal junctional arterial hemorrhage. *J Trauma Acute Care Surg*, 79(2), 256-262.**

Laboratory study performed on 50 swine, 5-mm diameter femoral arteriotomy was performed and 1 of 7 interventions was randomized and applied after 30 seconds of free bleeding: control, iTClamp, standard gauze packing, iTClamp with standard gauze packing, compression, standard gauze packing with compression and hemostatic gauze packing with compression. At 3:30 minutes post arteriotomy all animals received one dose of Hextend (15mL/kg over 15 mins). Animals were monitored for 3 hours or until death. Survival rates were as follows: control and compression 0%, standard gauze packing 12.5%, iTClamp 62.5%, hemostatic gauze packing with compression 62.5%, standard gauze packing with compression 87.5% and iTClamp with standard gauze packing 100%. Proper wound packing was a key factor in this study and the iTClamp is seen as a viable option for junctional hemorrhage.

**Kirkpatrick, A.W., Mckee, J.L., Mckee, I., Panebianco, N., and Ball, C.G. (2015). Remote tele-mentored ultrasound directed compression to potentially accelerate hemostasis in exsanguinating junctional vascular injuries. *J Spec Oper Med*. (In Press).**

This was a tele-mentored ultrasound study performed in the laboratory on a swine model with a 5-mm diameter femoral arteriotomy. A firefighter applied the iTClamp to the wound after 3 minutes of free bleeding. The firefighter was then telementored to use ultrasound to visualize and stop the bleeding in the pseudo aneurism using direct ultrasound compression. While the iTClamp works without ultrasound guided pressure the pseudo aneurism created by the iTClamp allowed the surgeon to visualize the internal wound, something that is not possible when a wound is packed.

 Clinical Evidence for iTClamp<sup>(R)</sup>

**Barnung S., Steinmetz, J. (2014) A prehospital use of iTClamp for haemostatic control and fixation of a chest tube. *Acta Anaesthesiologica Scandinavica*, 58(2):251-253.**

Three case presentations of clinical use of iTClamp. iTClamp was used for quick and effective hemostatic control of a scalp laceration, a junctional wound and the third case reports an off-label use, to successfully affix a chest tube in an agitated patient.

**Thompson, L. (2014) Application of the iTClamp in the clinical management of haemorrhage: a case study. *Journal of Paramedic Practice*, Vol. 6, Iss. 5, pp 228 – 230.**

Case report of use on knife wound to posterior mandible. Paramedics report being initially skeptical of iTClamp's usefulness, but found it to be quick, easy, and painless with excellent control of bleeding in an otherwise awkward area to control bleeding.

**Hudson A, G. W. (2014). First UK use of the iTClamp™ haemorrhage control system: Case report. *Trauma*, 16(3), 214-216.**

Two case presentation of clinical use of the iTClamp to control bleeding in the neck. It both cases the bleeding was controlled and the patients were able to go for CT prior to being taken to the operating room.

**Kirkpatrick, A. W., & McKee, J. L. (2014). Tactical Hemorrhage Control Case Studies Using a Point-of-Care Mechanical Direct Pressure Device. *J Spec Oper Med*, 14(4), 7-10.**

Two case presentations of clinical use of the iTClamp in a military setting. In one case the iTClamp was used to control bleeding from a high velocity rifle wound and in the second from a shrapnel injury. In both cases the iTClamp was effective at controlling the bleeding.

**Edward C.T.H. Tan, J.H.P., Jessica L. Mckee, Michael J.R. Edwards, The iTClamp in the management of prehospital haemorrhage. *Injury*, In Press.**

Ten patients were treated with the iTClamp. Seven patients had a severe head injury due to various traumas, one patient had a neck injury from a disk cutter, one patient had an open chest wound and one patient had an open femur fracture. After applying the iTClamp, bleeding was controlled in 90% of these patients (n=9), with complete cessation reported in 60% (n=6), partial cessation with adequate control reported in 30% (n=3); in one patient, the bleeding could not be controlled with the iTClamp alone. It took an average of 10 seconds to apply the iTClamp, and the average usage satisfaction score was 7.7.

## Epidemiology, Pathophysiology of Bleeding in Trauma

**Hamilton, J. R., Sunter, J. P., Cooper, P. N. (2005). Fatal hemorrhage from simple lacerations of the scalp. *Forensic Science, Medicine & Pathology*, 1(4), 267-271.**

Post-mortem case review where hemorrhage from 'simple' scalp laceration was found to be the cause of death. Considerable amounts of blood can be lost from even simple scalp lacerations. Co-morbid factors, such as liver disease, can make this injury especially lethal.

**Kauvar, D., Lefering, R., & Wade, C. (2006). Impact of hemorrhage on trauma outcome: an overview of epidemiology, clinical presentations, and therapeutic considerations. *Journal Of Trauma*, 60(6), S3-11.**

Quantifies the impact of hemorrhage, identifies the primary clinical considerations related to hemorrhage in the trauma patient and focuses on hemorrhage preventions as a means to decrease the impact of bleeding in trauma. Minimizing blood loss in trauma will minimize the complications.

## Expert Consensus

**Jacobs LM, (2015) Joint Committee to Create a National Policy to Enhance Survivability from Intentional M-C, Active Shooter E. The Hartford Consensus III: Implementation of Bleeding Control: If you see something do something. *Bull Am Coll Surg*. 100:40-6.**

The most significant preventable cause of death in the prehospital environment is external hemorrhage. As demonstrated by guidelines enacted by the military, widespread bleeding control is critical to saving lives. Our nation has a history of learning hard lessons from wartime experiences; the case for hemorrhage control is no different. The Hartford Consensus directs that all responders have the education and necessary equipment for hemorrhage control and strongly endorses civilian bystanders to act as immediate responders. Immediate responders represent a foundational element of the ability of the U.S. to respond to these events and are a critical component of our ability to build national resilience. Immediate responders must be empowered to act, to intervene, and to assist.

## Other Hemorrhage Control Interventions

**Littlejohn, L. F., Devlin, J. J., Kircher, S. S., Lueken, R., Melia, M. R., & Johnson, A. S. (2011). Comparison of Celox-A, ChitoFlex, WoundStat, and Combat Gauze Hemostatic Agents Versus Standard Gauze Dressing in Control of Hemorrhage in a Swine Model of Penetrating Trauma. *Academic Emergency Medicine*, 18(4), 340-350.**

Laboratory study performed on 80 swine, femoral transection was performed and four hemostatic and one standard gauze dressings were randomized to the injured swine after 45 seconds of hemorrhage. All dressings were applied strictly per directions for use including 5 minutes of constant manual pressure. Subjects were monitored for initial hemostasis and rebleed rates. 85% achieved hemostasis no matter the hemostatic agent, 33% of those that achieved initial hemostasis rebled. Standard gauze was found to perform as well as or better than hemostatic agents. The most important factor in survival of these subjects was proper wound packing and proper and continuous pressure.