Pre-Clinical Evidence for iTClamp(R)

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(R)

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.

Oostendorp S. E. van, Tan E. C. T. H., Geeraedts Jr. L. M. G. (2016). Prehospital control of life-threatening truncal and junctional haemorrhage is the ultimate challenge in optimizing trauma care; a review of treatment options and their applicability in the civilian trauma setting. *Scand J Trauma Resusc Emerg Med.* 2016; 24(1): 110

Achieving prehospital hemorrhage control is important to improving survival. The roles of wound clamps, injectable hemostatic sponges, pelvic circumferential stabilizers, resuscitative thoracotomy, REBOA, intra-abdominal gas insufflation, intra-abdominal self-expanding foam, and junctional tourniquets were all reviewed. The levels of evidence to support the adjuncts are low. The iTClamp was recommended for junctional hemorrhage when junctional tourniquets were not available, or would take too long to apply or when maintaining direct pressure was not an option. It was highlighted that it can be combined with wound packing and direct pressure. The key strengths are that it is easy to apply and can be placed on any compressible location.

Mckee J, Mckee I, Ball CG, Tan E, Moloff A, McBeth P, LaPorta A, Bennett B, Filips D, Teicher C, Kirkpatrick AW. Hemorrhage Control by Non-Medical First Responders: Effectiveness and Skill Retention Trial of iTClamp Use by a Group of Tactical Police in MHSRS. 2016. Orlando, FL.

We studied the ability of tactical police members, to control hemorrhage with the iTClamp using an anatomically-realistic model of massive upper extremity arterial haemorrhage. Study participants were asked to apply the iTClamp with both dry and wet gloves to simulate application in the presence and absence of blood. These skills were tested through three phases: Immediately following training (Acquisition), four months after training (Retention) and eight months after training, with version 2 of the iTClamp (Generalization). No additional training or access to the iTClamp was offered between phases. ACQUISTION: all tactical officers (n=23) were able to achieve hemostasis on the simulated hemorrhage. RETENTION: A total of 65% (n=15) of tactical officers completed both the acquisition and retention phases of the study and 14/15 officer's demonstrated proficiency using the iTClamp. GENERALIZATION: A total of 22% (n=5) of the tactical officers completed the final phase of the study. For all 5 officers a total of 223 days lapsed between initial training and the final application of the iTClamp. All officers were able to successfully apply the device in median 7.5 IQR 5.3 seconds. Only one needle stick was reported, one officer was stopped due to unsafe handling of the device, one could not remove the device and 4 dropped the device over the course of the study.

Bennett K, F.K., Holcomb J, Jenkins D, Conklin C, Reed J. Effectiveness and Usability of the iTClamp® for Managing Hemorrhage in Penetrating Trauma in MHSRS. 2016. Orlando, FL.

The literature search revealed 8 preclinical and 6 clinical peer reviewed publications. Eleven involving efficacy, 4 examining safety and 4 demonstrating usability. Pre-clinical animal tests demonstrated statistically significant improvements in survival, survival time and blood loss. Clinical publications support the pre-clinical findings: successful use on the neck, scalp and extremities was reported to be between 90%-100% with an average application time of 10 seconds. Military use was 100% effective following a high velocity GSW and a shrapnel injury to the thighs of non-US combatants. A randomized controlled trial comparing marksmanship, (using an AR-15) following iTClamp or tourniquet application to the upper extremity, demonstrated that the iTClamp impacts marksmanship significantly less than a tourniquet. Usability studies demonstrate that the device can be applied through 2 layers of uniform, while wearing wet gloves, or by novice or expert medical practitioners. The iTClamp has shown to be safe and effective with a unique mechanism of action that can be used alone or in conjunction with tourniquets and hemostatic dressings.

Mckee J, Mckee I, Ball CG, Tan E, Moloff A, McBeth P, LaPorta A, Bennett B, Filips D, Teicher C, Kirkpatrick AW. Case Reports Utilizing the iTClamp to Control Pre Hospital Craniomaxillofacial and Neck Injury in MHSRS. 2016. Orlando, FL.

Civilian cases of iTClamp use were reported to iTraumaCare. Of the 216 cases reported, 37% (n=80) were for control of Craniomaxillofacial (CMF) hemorrhage (94% scalp and 6% face) and 8% (n=16) were to control neck hemorrhage. Falls (n=24) and MVC (n=25) accounted for 61% of the CMF injuries while assault (n=6) accounted for 37.5% of penetrating neck trauma. Adequate hemorrhage control was reported in 85.5% and 81.5% of CMF and neck cases respectively. Direct pressure and packing was abandoned in favor of the iTClamp in 27.5% (n=22) of CMF cases and in 31% (n=5) of neck cases, including 1 case where the packing was seen disappearing down the trachea occluding the airway. This case series suggests the iTClamp may be considered as an alternative or adjunct to direct pressure for use in controlling exsanguination from both CMF and penetrating neck injuries in both the civilian and military setting.

Gary Shaw LT. A service evaluation of the iTClamp50 in pre-hospital external haemorrhage control. British Paramedic Journal. 2016;1(2):30-34.

The iTClamp was the subject of a service evaluation by the North East Ambulance Service NHS Foundation Trust. Experienced paramedics were asked to evaluate the device. After every application, the evaluating paramedic completed an evaluation. Paramedics who used the iTClamp found it enhanced their ability to quickly control external haemorrhage in difficult anatomical areas and could be used as part of a major haemorrhage control strategy. Overall, paramedics felt it was quick and easy to use following a short training session.

Reuter PG, T.S., Lesecq A, Freedman C, Agostinucci JM, Akodad H, Adnet F, Lapostolle F, High-Speed Handling of a Hemorrhage Control System by First-Aid Workers and Physicians; The CLICK-CLACK Study. Annals of Emergency Medicine, 2016. 68(4S): p. S144.

The aim of this study was to test a new hemorrhage control device, the iTClamp. Emergency physicians and first responders were first shown a short video demonstrating how to use the iTClamp. They were then asked to use the iTClamp to stop hemorrhage on a bleeding simulator. All the participants were able to stop the bleeding with a median time of 14 [IQR 11-18] seconds for physicians and 15 [12-18] seconds for first responders. This study further demonstrates the ease of use of the iTClamp in the emergency medicine environment.

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.

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