

FEATURE ARTICLES

Management of Hemorrhage From Craniomaxillofacial Injuries and Penetrating Neck Injury in Tactical Combat Casualty Care

iTClamp Mechanical Wound Closure Device

TCCC Guidelines Proposed Change 19-04

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ABSTRACT

The 2012 study *Death on the battlefield (2001–2011)* by Eastridge et al.¹ demonstrated that 7.5% of the prehospital deaths caused by potentially survivable injuries were due to external hemorrhage from the cervical region. The increasing use of Tactical Combat-Casualty Care (TCCC) and other medical interventions have dramatically reduced the overall rate of combat-related mortality in US forces; however, uncontrolled hemorrhage remains the number one cause of potentially survivable combat trauma. Additionally, the use of personal protective equipment and adaptations in the weapons used against US forces has caused changes in the wound distribution patterns seen in combat trauma. There has been a significant proportional increase in head and neck wounds, which may result in difficult to control hemorrhage. More than 50% of combat wounded personnel will receive a head or neck wound. The iTClamp (Innovative Trauma Care Inc., Edmonton, Alberta, Canada) is the first and only hemorrhage control device that uses the hydrostatic pressure of a hematoma to tamponade bleeding from an injured vessel within a wound. The iTClamp is US Food and Drug Administration (FDA) approved for use on multiple sites and works in all compressible areas, including on large and irregular lacerations. The iTClamp's unique design makes it ideal for controlling external hemorrhage in the head and neck region. The iTClamp has been demonstrated effective in over 245 field applications. The device is small and lightweight, easy to apply, can be used

by any level of first responder with minimal training, and facilitates excellent skills retention. The iTClamp reapproximates wound edges with four pairs of opposing needles. This mechanism of action has demonstrated safe application for both the patient and the provider, causes minimal pain, and does not result in tissue necrosis, even if the device is left in place for extended periods. The Committee on TCCC recommends the use of the iTClamp as a primary treatment modality, along with a CoTCCC-recommended hemostatic dressing and direct manual pressure (DMP), for hemorrhage control in craniomaxillofacial injuries and penetrating neck injuries with external hemorrhage.

KEYWORDS: *craniomaxillofacial injury; penetrating neck injury; junctional hemorrhage; compressible hemorrhage; hemorrhage control; iTClamp; TCCC; Tactical Combat Casualty Care*

Proximate Cause for This Change

The physical proximity and relatively exposed location of major vascular, neural, and airway structures in the head and neck make wounds in this region a challenge to treat, especially for the Role 1 provider.² These regions are not amenable to tourniquet use, and the anatomy of the scalp makes compression challenging. Direct pressure of the neck can lead to airway and

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vascular compromise. Finally, the large blood vessels of the neck can produce rapid exsanguination when they are injured.

Several recent publications³⁻⁹ have documented the efficacy of the iTClamp as a hemostatic intervention for controlling external hemorrhage secondary to craniomaxillofacial injury (CMFI) and penetrating neck injury (PNI), highlighting the need for this device to be considered as an addition to the hemostatic adjuncts currently recommended in TCCC.

Case Report*

A 44-year-old woman presented to the emergency department with 25 stab wounds to the chest and neck. Two close Zone 1 stab wounds at the base of the neck just above the clavicle resulted in uncontrolled external hemorrhage. The patient was unresponsive and her systolic blood pressure was 70mmHg. The wound was packed with Combat Gauze by physicians, but then it became saturated with blood. The physicians removed the saturated Combat Gauze and placed a single iTClamp over both stab wounds. Because there was leaking observed from the wound, the physicians removed the iTClamp, repacked the wound cavity with Combat Gauze, and then used the iTClamp to seal the wound (Figure 1). The physicians noted that wound packing with Combat Gauze combined with iTClamp application “allowed them to decrease the wound cavity and close the skin which resulted in hemostasis.”⁵ The patient was subsequently stabilized. She received 4 units of packed red blood cells and 6 units of fresh-frozen plasma and had a computed tomography (CT) scan performed for further assessment before undergoing operative treatment (Figures 2 and 3).

The surgeons explored her neck wounds and ligated the injured first branch of the subclavian vein. The ability to perform advanced imaging before surgery allowed the surgeon

FIGURE 1 Chovanes J, Schneider DJ, Mckee JL, Wang JL. Bridging the Gap: A novel method for hemorrhage control. *J Health Educ Res Dev.* 2017;5(1). Used with permission under the terms of the Creative Commons Attribution 3.0 License (<http://creativecommons.org/licenses/by/3.0/>).



FIGURE 2 Chovanes J, Schneider DJ, Mckee JL, Wang JL. Bridging the Gap: A novel method for hemorrhage control. *J Health Educ Res Dev.* 2017;5(1). Used with permission under the terms of the Creative Commons Attribution 3.0 License (<http://creativecommons.org/licenses/by/3.0/>).

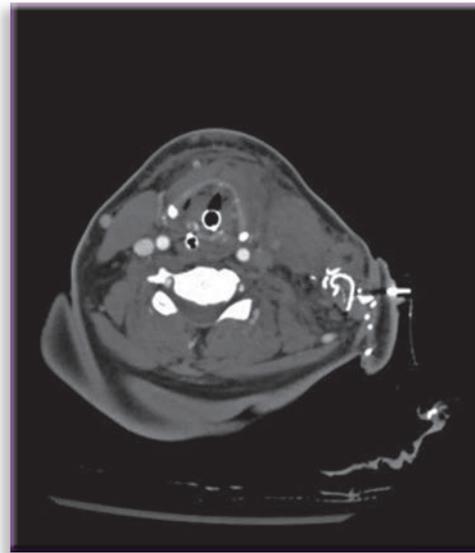
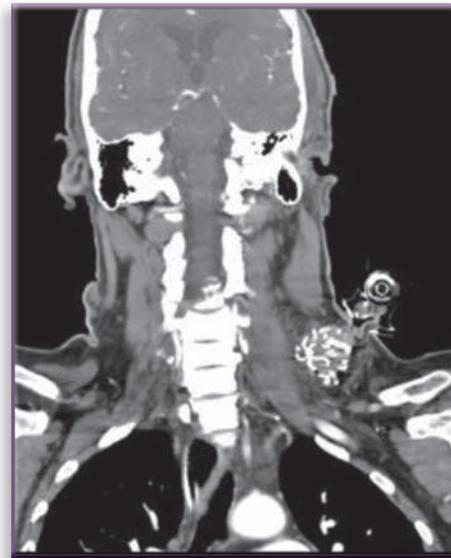


FIGURE 3 Chovanes J, Schneider DJ, Mckee JL, Wang JL. Bridging the Gap: A novel method for hemorrhage control. *J Health Educ Res Dev.* 2017;5(1). Used with permission under the terms of the Creative Commons Attribution 3.0 License (<http://creativecommons.org/licenses/by/3.0/>).



to assess other potential bleeding sites and to decide where to begin surgical exploration of the multiple stab wounds. The ability to rapidly stabilize this patient for further diagnostic studies demonstrates the effectiveness of the device and the reliability of its effect. This creates greater flexibility during triage and provides the surgical team with more time for pre-operative planning. Although this intervention occurred in the emergency department, it could easily have been accomplished in the prehospital setting, including the Role 1 environment, to provide early hemorrhage control and prevent a patient from developing shock.

*This case report is from Chovanes J, Schneider DJ, Mckee JL, Wang JL. Bridging the Gap: A novel method for hemorrhage control. *J Health Educ Res Dev.* 2017;5(1). All the information in this section is from that reference.

Background

Uncontrolled hemorrhage remains the number one cause of mortality from potentially survivable combat trauma.¹ Along with tension pneumothorax and compromised airway, uncontrolled hemorrhage has been the primary focus of TCCC since its inception. The reintroduction and use of limb tourniquets in the modern US military for the prehospital treatment of life-threatening extremity hemorrhage was first controversially recommended in the original 1996 report describing TCCC in Special Operations Forces.¹⁰ The hemostatic dressings Combat Gauze (2008),¹¹ Celox Gauze (2014), and ChitoGauze (2014)¹² were subsequently recommended by the Committee on Tactical Combat Casualty Care (CoTCCC) to help address external hemorrhage at locations not anatomically amenable to tourniquet use or as an adjunct to tourniquet conversion. XStat (hemostatic compressed foam sponges) was the most recent hemostatic adjunct recommended in 2016.¹³ Junctional tourniquets (the Combat Ready Clamp, the Junctional Emergency Treatment Tool, and the SAM Junctional Tourniquet) were added to the TCCC Guidelines in 2013¹⁴ as another option for use when the bleeding occurs at those locations.

With the near-ubiquitous use of body armor among US forces¹⁵ and the increased use of TCCC, particularly the first-line use of tourniquets at the point of injury, the overall rates of combat-related death have decreased remarkably over the past 18 years of combat.^{16–19} Coincidentally, the use of body armor along with changes in wounding patterns from improvised explosive devices (IEDs) has shifted the anatomical distribution of injuries.^{15,20} Since the Vietnam Conflict, there has been a significant reduction in the percentage of chest injuries, from 13.4% to 5.9%, along with a near doubling in the relative incidence of CMFI and PNI from 16% to 30.0% in the first 4 years of conflict in Afghanistan and Iraq.^{20,21}

Combat trauma patients often sustain wounds to more than one zone of the neck, and wounds are no longer well defined as previously seen with gunshot wounds¹⁵ (Figure 4). The emerging wounding pattern is scattered with multiple small fragments penetrating to various depths and from varying angles.¹⁵ Injuries to the major vascular structures of the head and neck region can lead to uncontrolled bleeding, hypotension, shock, and death.^{22–26} Even seemingly innocuous injuries can lead to higher than anticipated blood loss^{24,25} and can be lethal.^{23,27,28}

As previously noted, anatomic and physiological complexities of the head and neck make wounds in this region a challenge to treat, especially for the Role 1 provider.² These regions are not amenable to tourniquet use or circumferential pressure dressings. The anatomy of the scalp makes compression challenging, and packing with hemostatic dressing is not possible. Compression of the neck can lead to airway compromise and harmful disruption in cerebral perfusion. Finally, the large blood vessels found in the head and neck can produce rapid exsanguination when they are injured. Currently, the TCCC guidelines recommend Combat Gauze or XStat as options for hemorrhage control in these areas.

It is important to note the many lessons in hemorrhage control that have been learned in the last decade and a half of conflict. The US military's focused efforts to prevent exsanguination from extremity wounds have been remarkably effective in

FIGURE 4 Image provided by Innovative Trauma Care. Available at <https://www.innovativetraumacare.com/>. Used with permission.



reducing potentially survivable injuries from this cause. Frequent emergency tourniquet application has reduced death rates by 85%, from 23.3 deaths per year to 3.5 deaths per year.^{1,29,30} Tourniquets, however, cannot be applied in the head and neck region.

Eastridge et al. provide a detailed analysis of all battlefield deaths from 2001 to 2011.^{1,29,30} This study found that 87.3% of battlefield death occurs prehospital, with 35.2% occurring instantaneously and 52.1% occurring acutely, meaning death occurs from minutes to hours post injury and prior to reaching an MTF. The analysis also described 24.3% of these as potentially survivable injuries. Of the potentially survivable injuries, 90.9% were related to hemorrhage (Figure 5), of which 19.2% were junctional injuries. Junctional injuries were further classified as 60.8% located in the axilla or groin and 39.2% located in the cervical region. This means that 7.5% of the total potentially survivable injuries were noted to be in the neck (Figure 6).

The current recommendation in TCCC for the treatment of CMFI and PNI is hemostatic dressings applied with at least 3 minutes of sustained direct pressure.³¹ Hemorrhage in the head

FIGURE 5 Adapted from Eastridge BJ, Mabry RL, Seguin P, et al. Death on the battlefield (2001–2011): implications for the future of combat casualty care. *J Trauma Acute Care Surg.* 2012;73 (6 suppl 5):S431–S437.

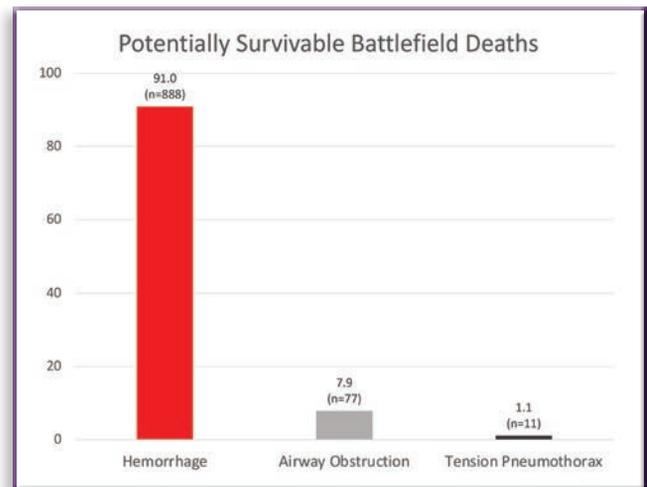
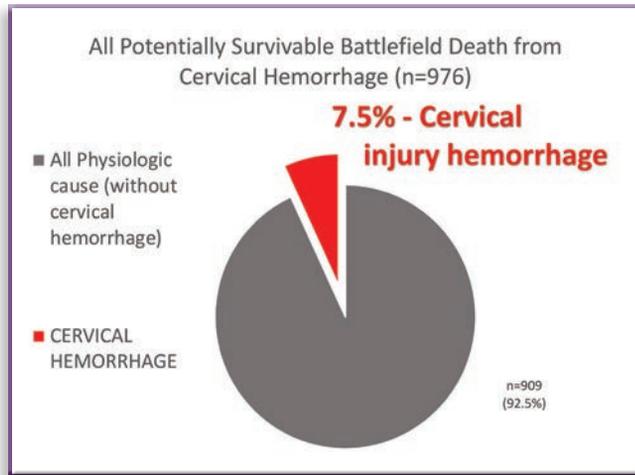


FIGURE 6 Adapted from Eastridge BJ, Mabry RL, Seguin P, et al. *Death on the battlefield (2001–2011): implications for the future of combat casualty care.* J Trauma Acute Care Surg. 2012;73 (6 suppl 5):S431–S437.



and neck region, however, can be difficult to control: tourniquets are not applicable; CMFI and PNI can be hard to access; treatment techniques are technically challenging; and dressings are difficult to apply and prone to displacement.^{21,22,32–34} Consistent direct pressure is demanding to maintain and has been associated with a low success rate due to rebleeding and exsanguination prior to reaching definitive care, particularly in the face of a mass casualty or multiple injuries.^{32,35} Rapid hemorrhage control for CMFI and PNI remains a challenge on the battlefield with the existing tools. While the head, face, and neck are only 12% of the body’s surface area exposed during combat,^{15,36} as many as 50% of injured military personnel will have a CMFI or PNI as one of their wounds.^{15,36}

This prevalence rate is concerning as it is associated with a 10% to 50% mortality rate due to exsanguination.^{28,37,38} Despite the prevalence of CMFI and PNI reported, and their association with uncontrolled hemorrhage, there is still a tendency to ignore or minimize these injuries.²⁸ This highlights the notion that care providers continue to underestimate blood loss from the scalp, which, left untreated, can lead to anemia, shock, and even death.^{22,28}

During a mass casualty event or when managing a polytrauma patient, a decrease in the quality of trauma care can be experienced,³⁹ and missed injuries are common.⁴⁰ As many as 8% of polytrauma patients are found to have missed clinically significant injuries, 37% of which are head and neck injuries.⁴⁰ Polytrauma patients are up to 2.61 times more likely to have missed head and neck injuries. In this situation, discounting CMFI or PNI hemorrhage can be particularly prominent and dangerous.⁴⁰

Prevention of these injuries would be preferable, but despite many depictions of full-facemask, pilot-type helmets

for ground combat forces, the preference and recent trend in the US military are for lighter and smaller headgear, with more visibility and mobility—in part because of the necessary movement required of the neck and because obstructions can limit senses that are vital in hostile environments.²¹ This leads to these regions experiencing disproportionately more fatal injuries.³⁶

In September 2018, CoTCCC reviewed the current literature on the clinical and experimental use of the iTClamp. The following were addressed during this review:

1. What is the mechanism of action of the iTClamp?
2. How does the iTClamp compare with other methods of hemorrhage control in the head and neck region?
3. What is the evidence for the effectiveness of the device?
4. What are the indications, contraindications, and warnings for the device?
5. What are the training requirements and knowledge retention for the use of this device?
6. How safe is the iTClamp to the patient and provider?

A literature search was conducted to identify clinically relevant literature to evaluate the use, safety, and efficacy of the iTClamp. PubMed, Google Scholar, and EMBASE were searched for English-language articles published in the past 10 years using the search terms: “direct mechanical pressure,” “iTClamp,” “hemorrhage control clamp,” “acute skin closure and hemorrhage,” and “wound seal.” As appropriate, the searches were repeated with the word “haemorrhage.” The Naval Medical Center Portsmouth Combat Trauma Research Program provided additional information from currently unpublished data that were presented at national and international conferences.

Discussion

In September 2018, McKee et al. reported 245 cases of iTClamp use for hemorrhage control in the *Journal of Special Operations Medicine*⁸ (Figures 7 and 8). These cases were self-reported by users as part of the manufacturer’s postmarketing surveillance effort during the period April 2013 to October 2016.* Of the 245 cases of iTClamp use, 81% (n = 198) were reported to result in adequate hemorrhage control. Analysis of use by anatomical location showed 115 applications to the head and neck with 87.0% reporting adequate hemorrhage control. The iTClamp demonstrated effective hemorrhage control across all anatomical regions, a variety of wound sizes and shapes, and multiple mechanisms of injury.

The iTClamp is small and lightweight (approximately 1 oz) with FDA-approved indications for use on multiple sites. It works in all compressible areas, including large and irregular lacerations, and on the scalp.

Numerous case reports^{4–7,41–43} and animal^{44–46} and cadaver^{47,48} studies demonstrate iTClamp effectiveness and ease of use for

*“Medical device manufacturers as well as other firms involved in the distribution of devices must follow certain requirements and regulations once devices are on the market. These include such things as tracking systems, reporting of device malfunctions, serious injuries or deaths, and registering the establishments where devices are produced or distributed. Postmarket requirements also include postmarket surveillance studies required under section 522 of the [Federal Food, Drug, and Cosmetic] Act as well as post-approval studies required at the time of approval of a premarket approval, humanitarian device exemption, or product development protocol application.” (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/default.htm>)

FIGURE 7 Adapted from McKee JL, Kirkpatrick AW, Bennett BL, et al. Worldwide case reports using the iTClamp for external hemorrhage control. *J Spec Oper Med.* 2018;18(3):39–44.

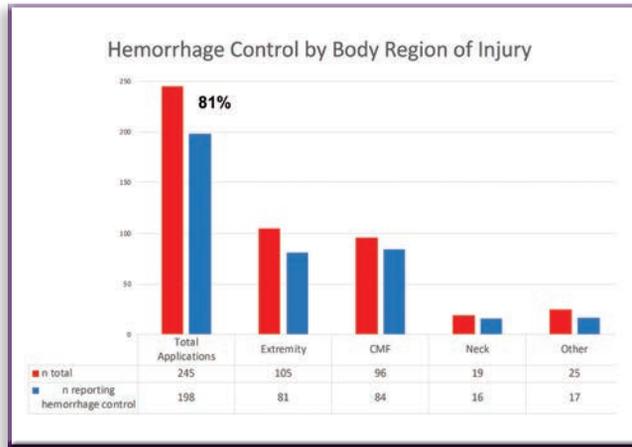
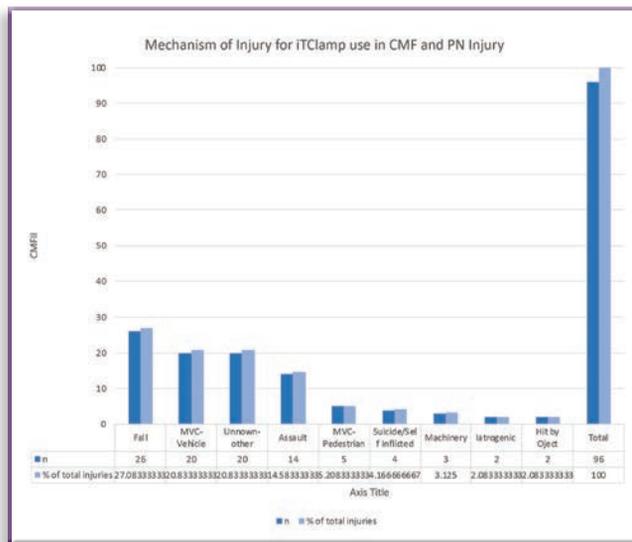


FIGURE 8 Adapted from McKee JL, Kirkpatrick AW, Bennett BL, et al. Worldwide case reports using the iTClamp for external hemorrhage control. *J Spec Oper Med.* 2018;18(3):39–44.

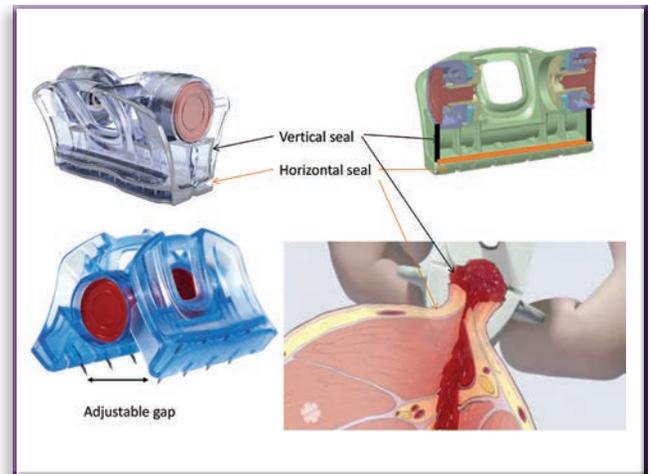


a variety of laceration applications. An animal study,⁴⁵ case reports,^{4,6,7,41–43} and usability studies^{49,50} demonstrate iTClamp safety including the absence of tissue damage even after forcible removal of the device from the patient after application.⁵¹ Studies across all skill levels of medical providers and nonmedical first responders validate the ability of all users to control bleeding rapidly with the iTClamp.^{43,49,52}

1. What is the mechanism of action of the iTClamp?

The iTClamp is the first in a new class of hemorrhage control devices that uses the hydrostatic backpressure of a hematoma inside a wound cavity to generate pressure and produce a hemostatic effect on the injured vessel. The device establishes a fixed fluid-tight seal through wound edge approximation. This seal creates a hematoma that tamponades injured vessels via hydrostatic pressure to replace direct pressure on the injured vessel (Figure 9) (<https://www.youtube.com/watch?v=iVO-QRTGM7U>). Once the hydrostatic pressure in the wound cavity equalizes with the internal pressure of the injured vessel, it creates a hemostatic environment independent of coagulation factors.

FIGURE 9 Provided by Innovative Trauma Care. Available at <https://www.innovativetraumacare.com>. Used with permission.



The mechanism is easily visualized on the CT-angiography images in a study reported in the *Journal of Trauma* in which cadavers were reperfused with water.⁴⁷ Because there were no coagulation factors present, the study demonstrated that the mechanical forces involved were exclusively responsible for hemorrhage control. The iTClamp's unique design makes it ideal for application to the head and neck (<https://www.youtube.com/watch?v=6AzCtPAOBTY>).

Although the iTClamp is available in only one size, the device can be used in series for wounds longer than 5 cm. Placing multiple iTClamps end to end can create the appropriate seal on longer wounds (Figure 10) (<https://www.youtube.com/watch?v=8b8E2JQTMhc>).

FIGURE 10 Provided by Innovative Trauma Care. Available at <https://www.innovativetraumacare.com>. Used with permission.



Additionally, larger wounds should be packed with a CoTCCC-recommended hemostatic dressing prior to use to decrease cavity volume and reduce hemorrhage. For wounds where the skin is tighter, such as the scalp, the device closure can be adjusted by the user so that less skin is required to seal the wound. The unique mechanism of action of the iTClamp can replace direct pressure and compliments existing hemostatic adjuncts recommended by CoTCCC. It is not intended to replace but rather to augment all current TCCC approved hemorrhage control devices.

2. How does the iTClamp compare with other methods of hemorrhage control in the head and neck region?

There are no similar devices to which direct comparisons can be made. Comparisons with other classes of hemostatic devices need to be interpreted with the understanding that

mechanisms of action are different and complementary. When considering the clinical endpoints of mortality and total blood loss, the iTClamp is an effective device. Table 1 compares the weight, volume, and cost of different hemorrhage control devices and adjuncts.

TABLE 1 Product Comparisons Across Different Classes of Hemorrhage Control Devices

Product	Cost, US\$	Volume (packaged), in ³	Weight, oz
C-A-T	32	23	2.7
Kerlix	2	36	2.2
Combat Gauze	40	15	0.8
XStat 30	235	92	3.5
iTClamp	35	6	1.3

To compare topical hemostatic dressings, a DoD consensus group accepted a standardized lethal swine model for evaluation, referred to as the USAISR hemorrhage model.^{53,54} This allows appropriate comparisons between gauze-based dressings, such as Combat Gauze, Celox Gauze, and ChitoGauze, which have similar application procedures.¹² The iTClamp has consistently been shown to be effective in controlling hemorrhage, either alone or in combination with packed gauze and hemostatic agents in multiple independent studies,^{6,7,41,42,44-47,49,50,55,56} using the standard USAISR hemorrhage control model.

St. John et al.⁴⁶ evaluated the iTClamp versus hemostatic dressing, plain gauze, and direct pressure in various combinations. In comparison with Combat Gauze and direct pressure, the application of the iTClamp was significantly faster and did not require 3 minutes of direct pressure as mandated in TCCC guidelines for hemostatic dressings (hemostatic dressing + seal (125.8 [56.2] seconds), hemostatic dressing + compression (223.0 [6.8] seconds)). The iTClamp significantly improved both survival and blood loss in both packed and unpacked wounds versus controls. Survival was similar between gauze + compression (87.5%), hemostatic dressing + compression (62.5%), and gauze + seal (100%) ($p > .05$). Combining the iTClamp and wound packing demonstrated improved survival and considerably reduced treatment times.

The authors did not evaluate the iTClamp with a hemostatic dressing because the dressing manufacturer's instructions state that the hemostatic dressing is to be compressed for at least three minutes after application and the iTClamp does not require compression. The authors did not want to add "off-label" use of the hemostatic dressing. It is important to note

that plain gauze is NOT a recommended treatment option per TCCC guidelines.

The iTClamp has also demonstrated effectiveness in cases where patients were known to be coagulopathic prior to trauma.^{9,43} Given the shorter application time, the ability to combine with existing hemostatic agents, and comparable survival to hemostatic dressings, the iTClamp can be seen as an alternative to prolonged manual compression for wounds where the skin edges can be approximated.

3. What is the evidence for the effectiveness of the iTClamp?

Animal and Cadaver Studies

The first published controlled trial of iTClamp use involving 20 animals with a lethal femoral junctional injury model was published in 2013.⁴⁵ Although the authors did not use the standard USAISR model, it was a 100% lethal model in which 5 cm of femoral artery and vein were excised just below the inguinal ligament and overlying muscles were excised. There were five animals in each of the four study arms: control (no treatment); iTClamp placement after 10 seconds of bleeding (high pressure bleed); delayed iTClamp placement after 3 minutes of bleeding (low pressure, animal in shock); and standard gauze packing after 3 minutes of bleeding (an additional 3 minutes of direct pressure were also added to this arm). There was no hemostatic dressing arm in this study. The study period was 180 minutes. Early and late applications of the iTClamp resulted in significantly higher survival rates ($p = .003$) (Table 2). Blood loss was decreased in the early iTClamp (120mL) and late iTClamp (480mL) groups compared to standard gauze packing (680mL) and control (1060mL) ($p < .002$). Researchers did not observe breakthrough bleeding in the iTClamp groups after initial application.

A 2014 study⁴⁷ involved three fresh thawed cadavers that were declotted and reperfused with water using a peristaltic pump to replicate human blood flow. A complex elliptical wound was excised over compressible bleeding areas in the neck, arm, groin, and leg of two cadavers. A 6mm arteriotomy was made in the common carotid, common femoral, and superficial femoral arteries. The brachial artery was completely transected. In the third cadaver, simple 4.4cm scalp incisions were made through all tissue layers to the bone over the left frontal, left temporal, right frontal, and midline frontal areas. Ten measurements of fluid loss from each compressible region were made in both static (cadaver not moving) and dynamic conditions (body regions were flexed and extended over the area of injury to replicate patient movement). There were

TABLE 2 Comparison of Survival for Different Methods of Hemorrhage Control

Mean (SD)	Negative Control (n = 5)	Seal (n = 8)	Packing (n = 8)	Packing + Seal (n = 8)	Compression (n = 5)	Packing + Compression (n = 8)	HS-Packing + Compression (n = 8)
Weight, kg	29.6 (2.3)	30.2 (2.8)	28.8 (2.3)	28.6 (2.0)	27.6 (1.2)	29.3 (4.6)	29.8 (1.3)
Baseline MAP, mmHg	73.0 (7.9)	79.6 (5.8)	76.6 (5.7)	78.6 (11.2)	74.7 (5.0)	78.3 (8.5)	74.1 (5.2)
MAP at 1 min of free bleeding, mmHg	41.0 (7.5)	52.7 (12.5)	48.5 (14.1)	54.3 (16.1)	58.0 (4.3)	56.5 (8.5)	56.3 (10.6)
Survival time,† min	36 (30-53)	180 (171-180)	152 (92.5-169.5)	180 (180-180)	42 (37-43)	180 (180-180)	180 (61-180)
Survival, %*	0	62.5	12.5	100	0	87.5	62.5

*Significantly heterogeneous variable across intervention groups by Pearson χ^2 test ($p < .05$).

†Survival time reported as median (interquartile range).

Adapted from St John AE, et al. Effects of rapid wound sealing on survival and blood loss in a swine model of lethal junctional arterial hemorrhage. *J Trauma Acute Care Surg.* 2015;79(2):256-262.

statistically significant reductions in fluid loss between control and treatment groups in all compressible regions tested ($p < .05$) but no differences between treatment groups with and without patient movement ($p < .02$). Furthermore, contrast-enhanced angiography performed after iTClamp placement demonstrated persistent distal flow in the injured artery after hemostasis was obtained. This study demonstrates the ability of the iTClamp to control external hemorrhage at multiple different anatomic sites as well as during patient movement. This study also demonstrates that the mechanism of action for the observed hemostasis is increased extravascular hydrostatic pressure and is not dependent on the innate clotting ability of blood. Finally, this study demonstrates that because the iTClamp equalizes pressure with the artery and does not occlude the artery, distal flow may be maintained in the injured vessel.

The results of a large animal study of the iTClamp was reported in 2016.⁴⁶ The bleeding model used was a version of the standard USAISR model that was slightly modified with a shorter surgical incision to accommodate the size of the iTClamp. Severe junctional hemorrhage was induced in anesthetized swine using a 5mm femoral arteriotomy. After 30 seconds of free bleeding, animals were randomized to one of seven arms: a control group and six therapeutic arms (direct pressure, plain gauze packing, the iTClamp alone, plain gauze with the iTClamp, plain gauze with direct pressure, and Combat Gauze with direct pressure). At 3:30 minutes, all animals received one 15mL/kg bolus of Hextend infused over 15 minutes. This was followed by lactated Ringer's solution for hypotension up to 100mL/kg (infused at 3mL/kg per minute as needed to maintain a goal MAP of 60mmHg). Animals were monitored for 3 hours. Survival with the iTClamp alone (62.5%) was improved compared to control (0%) ($p < .001$), and with plain gauze and iTClamp (100%) compared to plain gauze alone (12.5%) ($p < .001$). Survival was similar between the iTClamp, plain gauze with compression (87.5%), Combat Gauze with compression (62.5%), and plain gauze with iTClamp (100%) ($p \geq .05$) groups. Blood loss and lactate were similarly improved between the groups. The iTClamp statistically improved survival and decreased bleeding in both packed ($p < .001$) and unpacked wounds ($p < .001$). Application times were shortest in the groups using the iTClamp ($p < .001$). The study concluded that the time to achieve hemorrhage control was significantly reduced with the iTClamp without impacting survival or blood loss, making it a viable alternative to prolonged wound compression in junctional wounds.

A study by McKee in 2019 examined the efficacy of the iTClamp in a model of simulated bleeding in the neck.⁴⁸ Two fresh thawed cadavers were declotted and reperfused with water using a peristaltic pump to simulate human blood flow. A 6mm arteriotomy was made in the common carotid artery and fluid loss was compared across four groups: control (no treatment); direct pressure; Foley balloon catheter inflation; and the iTClamp. Direct pressure, Foley balloon, and iTClamp were equally effective compared with control. Patient movement did not reduce the effectiveness of the iTClamp in this model. The application of the iTClamp was significantly faster than Foley balloon catheter inflation.

The Combat Trauma Research Group (CTRG) from Naval Medical Center Portsmouth (NMCP) studied 31 swine using the USAISR standard hemorrhage model.⁵⁷ They compared

Combat Gauze with pressure dressing, iTClamp, iTClamp with Combat Gauze, and iTClamp with XStat. The researchers evaluated blood loss (Figure 11), survival, hemostasis, re-bleeding, and time to application (Figure 12). The iTClamp (either alone or in combination with XStat or Combat Gauze) was found to be significantly faster than Combat Gauze with pressure dressing and with similar outcomes. In another study, CTRG developed a swine model for controlling junctional hemorrhage using the iTClamp in conjunction with hemostatic agents.⁵⁸ They evaluated application time and blood loss comparing iTClamp and Combat Gauze to iTClamp and XStat in neck, axilla, and groin wounds of different lengths. Although the arterial wound was a standard 6mm arteriotomy,^{53,54} the skin incisions were either 5cm or 10cm to allow application of one or two devices. Application of the iTClamp with XStat was faster than iTClamp with Combat Gauze ([27 sec, 95% CI: 22–32 sec] versus [41 sec, 95% CI: 35–47 sec], $p < .02$), but there was no significant difference in blood loss.

Clinical Evidence

There is an increasing body of clinical evidence in the medical literature that describes the success of the iTClamp in controlling external hemorrhage. The 2018 JSOM case series by McKee et al. is the largest case series of the device's field use⁸ (Figure 13). A case series by Tan⁷ reported 10 uses of

FIGURE 11 Adapted from Stuart SM. *The Efficacy of iTClamp Combined with Hemostatic Agents in a Swine Model of Arterial Hemorrhage.* 23rd Annual American Academy of Emergency Medicine Scientific Assembly, Orlando, FL, March 2017. Lecture.

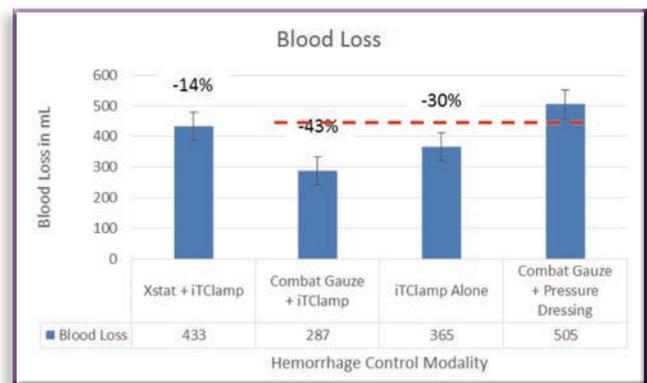


FIGURE 12 Adapted from Stuart SM. *The Efficacy of iTClamp Combined with Hemostatic Agents in a Swine Model of Arterial Hemorrhage.* 23rd Annual American Academy of Emergency Medicine Scientific Assembly, Orlando, FL, March 2017. Lecture.

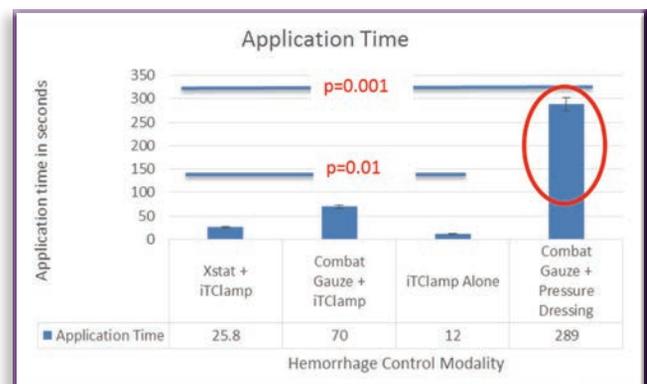
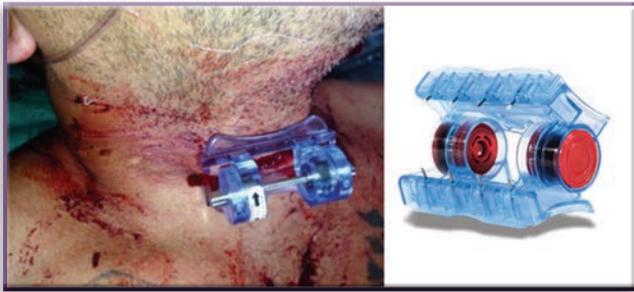


FIGURE 13 McKee JL, et al. *The iTClamp in the treatment of prehospital cranio-maxillofacial injury: a case series study.* J Inj Violence Res. 2019;11(1):29–34. Used with permission under the terms of the Creative Commons Attribution 3.0 License (<http://creativecommons.org/licenses/by/3.0/>)



the iTClamp where eight of the cases involved CMFI or PNI. Hemorrhage was described as adequately controlled in nine of the cases. Another case series of 24 patients, including 14 with head and neck injuries, was reported by the Northeast Ambulance Service in the United Kingdom, where paramedics also carried tourniquets and hemostatic dressings.³ Paramedics described the iTClamp as effective, quick, and easy to apply; as causing minimal pain; as being easy to learn; and as having high user satisfaction. Overall, paramedics in the field found that the iTClamp “enhanced their ability to quickly control external hemorrhage in difficult anatomical areas and could be used as part of a major hemorrhage control strategy.”³

Clinical use of the iTClamp specifically for scalp and face lacerations was reported in the Journal of Injury and Violence Research in 2019.⁹ Of 216 cases reviewed, 37% (n = 80) were for control of hemorrhage from CMFI (94% scalp and 6% face). Adequate hemorrhage control was reported in 87.5% (n = 70) of cases. Direct pressure with packing was abandoned in favor of the iTClamp in 27.5% (n = 22) of cases.

Effective use of the iTClamp has been reported in several other published cases, including successful control of PNI^{4,5} and CMFI⁴¹ hemorrhage with arterial involvement.^{4,6} In one case, a paramedic used the iTClamp to treat a knife wound to the posterior mandible and found it quick, easy, painless, and effective in an otherwise awkward area to treat.⁶ In a case report describing a hypotensive patient (no palpable radial pulse) with a left shoulder stab wound not amenable to tourniquet application, the bleeding was successfully controlled with the iTClamp.⁵⁹ Initial attempts at hemorrhage control with direct pressure or pressure dressing were unsuccessful due to patient agitation and noncompliance. An iTClamp was quickly applied without patient complaint and provided immediate hemorrhage control. Bleeding from the circumflex scapular artery was subsequently found on CT scan (performed with the iTClamp in place) and was controlled with embolization by interventional radiology. No operative repair of the injured vessel was required, and the patient made an uneventful recovery.

There have been several case reports of the iTClamp use in tactical scenarios. In one case, police officers used a combination of tourniquets and the iTClamp to control a life-threatening femoral artery injury from a 7.62mm (AK-47) gunshot wound in an unconscious patient.⁶⁰ An entrance wound was observed on the medial left thigh, just proximal to the knee. The first police officer was a combat veteran with prior training on tourniquet use and applied a SOF-T tourniquet above the wound.

After the tourniquet was applied, continued hemorrhage was noted. Further examination showed an exit wound near the groin with a likely femoral fracture. As the first officer and his partner readied to apply another, more proximal tourniquet, a third police officer arrived with an iTClamp that he had recently been trained to use. The third officer instructed the second officer on how to apply the iTClamp to the exit wound. iTClamp application achieved rapid hemorrhage control prior to the successful application of the second tourniquet, and the patient regained consciousness. The patient was found to have injuries to both the femoral artery and vein and survived surgical repair.

Two additional case reports of iTClamp use were reported in JSOM.⁴² In the first, a 26-year-old man suffered a 7.62mm (AK-47) gunshot wound to the right medial thigh. Hematoma formation in the wound tract and noticeable tissue deformation without external hemorrhage was observed, although no hemorrhage control intervention was in place. After examination and patient movement, arterial bleeding was observed from the wound. The medic chose to use the iTClamp as the initial intervention. After application, the bleeding stopped, there was no further hematoma expansion, there was no complaint of discomfort, and surgical repair was described as greatly eased. In the second case, a 28-year-old man suffered a fragmentation wound to the lower left medial thigh. Combined arterial and venous bleeding was described. Before the iTClamp application, the patient was applying self-aid with ineffective intermittent manual pressure. Hemorrhage was controlled after iTClamp application, and there was no complaint of pain during or after application. It is important to note that these two cases describe treatment that is not in accordance with current TCCC guideline recommendations. Limb tourniquet application is the primary method to control life-threatening external hemorrhage that is anatomically amenable to tourniquet use.

4. What are the indications, contraindications, and warnings for the iTClamp?

We recommend the iTClamp as a primary treatment modality for external hemorrhage from wounds in the head and neck region. The iTClamp should be combined with XStat or a CoTCCC-recommended hemostatic dressing to facilitate hemostasis and reduce total blood loss in large penetrating neck wounds with external hemorrhage. If the wound is longer than 5cm (2 inches), additional iTClamps should be placed end to end in series. Although it is advisable to hold direct pressure at the bleeding site until the iTClamp is applied, there is no need for additional direct pressure once the iTClamp has been placed.

The manufacturer’s contraindication for iTClamp are included with the product’s “Directions for Use”:

Do not use where wound edge approximation cannot be obtained (for example, large skin defects under high tension).

Additionally, the manufacturer provides these relevant warnings and precautions:

1. Do not use where delicate structures are near the skin surface, within 10mm of the application site, such as the orbits of the eye;
2. This device is intended for temporary use only; use beyond 6 hours has not been studied;

3. The device will not control hemorrhage in noncompressible sites, such as the abdominal and chest cavities;
4. When used to control hemorrhage in the neck, consider the need for appropriate airway management as per local protocols under medical direction; and
5. The device is not compatible with magnetic resonance imaging (MRI) procedures.

Although there have been no case reports of airway compromise in neck injuries treated with the iTClamp, when using the device to treat a PNI, the airway should always be frequently monitored to ensure that hematoma formation does not cause airway compromise. This is not an additional requirement for the person providing care since airway monitoring should be the standard of care in the management of any neck injury; however, there should be a reinforcement of the need for airway monitoring when the iTClamp is used.

The iTClamp is designed to provide temporary control of hemorrhage in wounds that will eventually require definitive surgical care. iTClamp placement and effectiveness should be monitored during treatment and transport to ensure that hemostasis is maintained and the device is secure. The device has FDA approval for up to 24 hours of application time. Although there have been no reports of harm from prolonged placement of the device, its use has not been studied past 6 hours.

5. What are the training requirements and knowledge retention for the use of the iTClamp?

A 2014 article from the *International Review of the Armed Forces Medical Services*⁵⁰ looked at what level of medical background was required and how intuitive was it to operate the device without prior instruction. The data showed no differences based on medical background and the device could be used by first aid responders, police officers, EMTs, and physicians (15 volunteers in total) with equal proficiency and with no prior training. Average time to the first application without training was 13.1 seconds. A second application was repeated with wet gloves and averaged 6.8 seconds.

A study evaluating the ability of tactical police to control hemorrhage with the iTClamp was published in the *Canadian Journal of Surgery* in 2015.⁴⁹ Using a model of massive upper extremity arterial hemorrhage, study participants applied the iTClamp with both dry and wet gloves to simulate application in the presence and absence of blood. The primary outcomes were the ability to achieve hemostasis and time to achieving hemostasis during both wet and dry applications. All participants were able to achieve hemostasis in both dry and wet applications. There was no significant difference in time to application between dry and wet applications (median, 5.5 versus 6.2 sec; $p = .654$). During 46 applications and removals, there were no needle stick injuries sustained from the eight needles contained in the iTClamp device. All participants rated the iTClamp easy to use and were confident in their ability to apply the device.

The 2015 CLICK-CLACK study from France evaluated the level of difficulty entailed in training personnel to use the iTClamp.⁵² Thirty-three emergency physicians and 35 first-aid workers were shown a 47-second video on applying the iTClamp and then asked to apply the clamp on a validated arterial bleeding arm simulator. The median time to stop

simulated blood flow was 14 seconds for physicians and 15 seconds for first aid workers. Comparable rapid, effective performance was achieved in both groups with ultra-short, video-only training. This not only demonstrates the easy acquisition of the necessary skills for effective use of the device but also suggests that that purely digital learning without hands-on training may be an effective training method.

Retention of training in nonmedical personnel was described in a 2016 report with favorable results.⁶¹ Tactical police officers were trained in the use of the iTClamp. Their training was tested by the completion of a written examination, and then the monitored proper application of the iTClamp to a bleeding simulator; 100% of the participants passed both the written test and the skills assessment—no one needed to be stopped due to improper or unsafe application. Four months later, the same group of officers was retested. They had no exposure to the iTClamp in the intervening time. Of the 15 officers, 14 were able to safely and correctly apply the device to the bleeding simulator. One officer was unable to complete the task and was stopped for unsafe handling of the device. This study demonstrates that nonmedical personnel can be trained to use the iTClamp effectively and that they maintain excellent knowledge retention.

The results of these training studies should also be compared to the current standard treatment modalities for external hemorrhage. Wound packing with a hemostatic dressing, for example, may seem like a straightforward process but evidence suggests otherwise. A study was done with 33 experienced Israeli Defense Force (IDF) medics using Combat Gauze and a wound packing simulator.⁶² The model was validated by a physician instructor to verify that it was not too difficult for medic use. Half the medics were randomized to being mentored and half were not. Only 5/33 (15%) medics were able to adequately pack the wound and pass, four of whom were mentored. Of the 85% of medics that did not pass, 70% of them thought that they had passed and most thought that the scenario was not difficult (ranked 4.5/10). This illustrates that wound packing may not be as effective as expected in first responders and that there may be a significant training requirement to maintain proper skill for application of hemostatic dressings.

6. How safe is the iTClamp to the patient and provider?

Considering that the mechanism of action of the iTClamp requires four pairs of needles to penetrate the patient's skin and compress the wound edges in order to achieve a seal, it is necessary to evaluate the safety of the device and its potential for causing pain.

Investigators used a cadaver model to look at the depth of needle penetration and conducted CT angiograms to look at the nature of the simulated hematoma formation and how it affected distal arterial flow.⁴⁷ The needles penetrated an average 4.2mm into the skin with a 10mm maximum depth of penetration. The CT angiograms found the hematomas to be contained in the muscle and subcutaneous tissues and distal flow was preserved in a partially injured artery.

Our review has found no reports or evidence of tissue injury from iTClamp application. In an animal study, investigators applied the iTClamp for 180 minutes to surgically created wounds.⁴⁵ Skin tissue samples were harvested at necropsy for histologic examination. Histopathology found no observable

changes in the epidermal or dermal layers surrounding the wounds that had an iTClamp applied. An additional study was performed with an extended application time and similar results.⁵⁰ After 6 hours, the device was removed and skin proximal to the wound was excised. A control skin sample from the same animal was excised for comparison. A veterinary pathologist examined the samples, blinded to wound versus control samples. The histopathology demonstrated that the observed changes were consistent with an acute inflammatory process, such as would be expected following injury, but there was no obvious necrosis or tissue destruction as a result of device application.⁵⁰ These findings indicate that tissue necrosis or injury does not occur even after extended use and that the device appears safe for application up to 6 hours.

To assess what happens when an iTClamp is inadvertently dislodged from the skin during patient transport, a study was performed using both fresh thawed cadaver skin and abdominal pig skin.⁵¹ The iTClamp was forcibly torn from the two types of skin at three different angles: horizontally along the long axis of the device; horizontally along the short axis of the device; and vertically upward from the wound. The force required to remove the device was measured. In all 60 attempts to remove the device, there was no tearing or additional damage seen on the skin aside from the presence of eight small holes (the equivalent of a 21-gauge needle) (Figure 14). An average of 10 pounds of force was required to remove the device, and 7% of the devices remained in place after the maximum pulling weight of 22 pounds was applied. This study helps to establish the iTClamp's safety for use in the combat environment where casualties often have to be moved and there is a significant possibility of traumatic dislocation.

The iTClamp has been shown to be well tolerated by patients, especially compared with tourniquets. A study was performed in 2015 using 13 trained police marksmen to determine whether the application of the iTClamp impairs marksmanship.⁶³ Pain was a secondary outcome measure. Application of the iTClamp to healthy volunteers was compared to a similar group on whom Combat Application Tourniquets (C-A-T) were applied. Marksmanship was tested at 5, 10, 15, 30, and 60 minutes postapplication. Six subjects were randomized to the C-A-T group and seven to the iTClamp group. Subject participation in the study ended if the range safety officer thought that the subject could no longer handle their weapon safely, if the subject reported a pain level ≥ 8 on a 0-to-10 Likert scale, or if the subject voluntarily withdrew. Of the six C-A-T subjects, one subject was unable to complete the 5-minute shoot, five subjects completed the 5-minute shoot but not the 10-minute shoot, and one subject completed the 10-minute shoot. None of the C-A-T group completed the 15-minute shoot. Four of the C-A-T group were stopped for unsafe weapons handling or inability to fire their weapons and two withdrew due to pain. All seven subjects in the iTClamp group maintained precision to 60 minutes.

Initial pain scores between the two groups were not significantly different ($p = .09$) but the 5- and 10-minute tourniquet pain scores were significantly higher than the iTClamp pain scores (6.6 ± 1.5 versus 1.0 ± 0.58 , -5.6 [95% CI -7.0 to -4.3], $p < .001$, and 8.5 ± 0.6 versus 1.0 ± 0.6 , -7.5 [95% CI -8.3 to -6.7], $p < .001$, respectively).⁶³ The iTClamp subjects experienced a decrease in pain between the initial application and the 5-minute pain scores (3.0 ± 1.0 versus 1.0 ± 0.6 , -2.0

[95% CI 1.3 to 2.8], $p = .001$).⁶³ This reduction in pain was sustained throughout the study period.

Conclusion

The iTClamp is an effective mechanical hemorrhage control device for use in the head and neck to treat CMFI and PNI with external hemorrhage. This device can be rapidly applied, does not cause tissue damage even with extended use of up to 6 hours, and causes minimal pain. The iTClamp can be used either alone or in combination with a CoTCCC-recommended hemostatic dressing or XStat. Using the iTClamp eliminates the need for the 3 minutes of direct pressure that is required when using a hemostatic dressing. Each iTClamp seals 5cm of wound opening and multiple devices can be used in series to close longer wounds; however, it may not be effective in wounds where skin edges cannot be easily approximated. Use of the iTClamp over delicate structures such as the eye or within 10mm of the orbit is contraindicated. Usability and safety studies demonstrate that medical personnel of all experience levels can safely and effectively use the iTClamp with easy skill acquisition and knowledge retention. Its low cost, light weight, small profile, and durable design are all highly desirable features for use in the combat environment.

PROPOSED CHANGE TO THE TCCC GUIDELINES

Current wording

Tactical Field Care

3. Massive Hemorrhage

- a. Assess for unrecognized hemorrhage and control all sources of bleeding. If not already done, use a CoTCCC-recommended limb tourniquet to control life-threatening external hemorrhage that is anatomically amenable to tourniquet use or for any traumatic amputation. Apply directly to the skin 2 to 3 inches above the bleeding site. If bleeding is not controlled with the first tourniquet, apply a second tourniquet side-by-side with the first.
- b. For compressible (external) hemorrhage not amenable to limb tourniquet use or as an adjunct to tourniquet removal, use Combat Gauze as the CoTCCC hemostatic dressing of choice.
 - Alternative hemostatic adjuncts:
 - Celox Gauze or
 - ChitoGauze or
 - XStat (best for deep, narrow-tract junctional wounds)
 - Hemostatic dressings should be applied with at least 3 minutes of direct pressure (optional for XStat). Each dressing works differently, so if one fails to control bleeding, it may be removed and a fresh dressing of the same type or a different type applied. (Note: XStat is not to be removed in the field, but additional XStat, other hemostatic adjuncts, or trauma dressings may be applied over it.)
 - If the bleeding site is amenable to use of a junctional tourniquet, immediately apply a CoTCCC-

recommended junctional tourniquet. Do not delay in the application of the junctional tourniquet once it is ready for use. Apply hemostatic dressings with direct pressure if a junctional tourniquet is not available or while the junctional tourniquet is being readied for use.

- Celox Gauze or
- ChitoGauze or
- XStat (best for deep, narrow-tract junctional wounds)
- iTClamp (may be used alone or in conjunction with hemostatic dressing or XStat)

Tactical Evacuation Care

2. Massive Hemorrhage

- a. Assess for unrecognized hemorrhage and control all sources of bleeding. If not already done, use a CoTCCC-recommended limb tourniquet to control life-threatening external hemorrhage that is anatomically amenable to tourniquet use or for any traumatic amputation. Apply directly to the skin 2 to 3 inches above the bleeding site. If bleeding is not controlled with the first tourniquet, apply a second tourniquet side-by-side with the first.
- b. For compressible (external) hemorrhage not amenable to limb tourniquet use or as an adjunct to tourniquet removal, use Combat Gauze as the CoTCCC hemostatic dressing of choice.
 - Alternative hemostatic adjuncts:
 - Celox Gauze or
 - ChitoGauze or
 - XStat (best for deep, narrow-tract junctional wounds)
 - Hemostatic dressings should be applied with at least 3 minutes of direct pressure (optional for XStat). Each dressing works differently, so if one fails to control bleeding, it may be removed and a fresh dressing of the same type or a different type applied. (Note: XStat is not to be removed in the field, but additional XStat, other hemostatic adjuncts, or trauma dressings may be applied over it.)
 - If the bleeding site is amenable to use of a junctional tourniquet, immediately apply a CoTCCC-recommended junctional tourniquet. Do not delay in the application of the junctional tourniquet once it is ready for use. Apply hemostatic dressings with direct pressure if a junctional tourniquet is not available or while the junctional tourniquet is being readied for use.

- Hemostatic dressings should be applied with at least 3 minutes of direct pressure (optional for XStat). Each dressing works differently, so if one fails to control bleeding, it may be removed and a fresh dressing of the same type or a different type applied. (Note: XStat is not to be removed in the field, but additional XStat, other hemostatic adjuncts, or trauma dressings may be applied over it.)
 - If the bleeding site is amenable to use of a junctional tourniquet, immediately apply a CoTCCC-recommended junctional tourniquet. Do not delay in the application of the junctional tourniquet once it is ready for use. Apply hemostatic dressings with direct pressure if a junctional tourniquet is not available or while the junctional tourniquet is being readied for use.
- c. For external hemorrhage of the head and neck where the wound edges can be easily re-approximated, the iTClamp may be used as a primary option for hemorrhage control. Wounds should be packed with a hemostatic dressing or XStat, if appropriate, prior to iTClamp application.
 - The iTClamp does not require additional direct pressure, either when used alone or in combination with other hemostatic adjuncts.
 - If the iTClamp is applied to the neck, perform frequent airway monitoring and evaluate for an expanding hematoma that may compromise the airway. Consider placing a definitive airway if there is evidence of an expanding hematoma.
 - DO NOT APPLY on or near the eye or eyelid (within 1cm of the orbit).

Proposed Change

(New proposed material is in red text.)

Tactical Field Care

3. Massive Hemorrhage

- a. Assess for unrecognized hemorrhage and control all sources of bleeding. If not already done, use a CoTCCC-recommended limb tourniquet to control life-threatening external hemorrhage that is anatomically amenable to tourniquet use or for any traumatic amputation. Apply directly to the skin 2–3 inches above the bleeding site. If bleeding is not controlled with the first tourniquet, apply a second tourniquet side-by-side with the first.
- b. For compressible (external) hemorrhage not amenable to limb tourniquet use or as an adjunct to tourniquet removal, use Combat Gauze as the CoTCCC hemostatic dressing of choice.
 - Alternative hemostatic adjuncts:

Tactical Evacuation Care

2. Massive Hemorrhage

- a. Assess for unrecognized hemorrhage and control all sources of bleeding. If not already done, use a CoTCCC-recommended limb tourniquet to control life-threatening external hemorrhage that is anatomically amenable to tourniquet use or for any traumatic amputation. Apply directly to the skin 2 to 3 inches above the bleeding site. If bleeding is not controlled with the first tourniquet, apply a second tourniquet side-by-side with the first.
- b. For compressible (external) hemorrhage not amenable to limb tourniquet use or as an adjunct to tourniquet removal, use Combat Gauze as the CoTCCC hemostatic dressing of choice.
 - Alternative hemostatic adjuncts:
 - Celox Gauze or
 - ChitoGauze or
 - XStat (best for deep, narrow-tract junctional wounds)
 - iTClamp (may be used alone or in conjunction with a hemostatic dressing or XStat)
 - Hemostatic dressings should be applied with at least 3 minutes of direct pressure (optional for XStat). Each dressing works differently, so if one fails to

control bleeding, it may be removed and a fresh dressing of the same type or a different type applied. (Note: XStat is not to be removed in the field, but additional XStat, other hemostatic adjuncts, or trauma dressings may be applied over it.)

- If the bleeding site is amenable to use of a junctional tourniquet, immediately apply a CoTCCC-recommended junctional tourniquet. Do not delay in the application of the junctional tourniquet once it is ready for use. Apply hemostatic dressings with direct pressure if a junctional tourniquet is not available or while the junctional tourniquet is being readied for use.
- c. For external hemorrhage of the head and neck where the wound edges can be easily re-approximated, the iTClamp may be used as a primary option for hemorrhage control. Wounds should be packed with a hemostatic dressing or XStat, if appropriate, prior to iTClamp application.
- The iTClamp does not require additional direct pressure, either when used alone or in combination with other hemostatic adjuncts.
 - If the iTClamp is applied to the neck, perform frequent airway monitoring and evaluate for an expanding hematoma that may compromise the airway. Consider placing a definitive airway if there is evidence of an expanding hematoma.
 - DO NOT APPLY on or near the eye or eyelid (within 1cm of the orbit).

Levels of Evidence for the Above Recommendations

The levels of evidence used by the American College of Cardiology and the American Heart Association were outlined by Tricoci in 2009⁶⁴:

Level A: Evidence from multiple randomized trials or meta-analyses.

Level B: Evidence from a single randomized trial or nonrandomized studies.

Level C: Expert opinion, case studies, or standards of care.

Using the taxonomy above, the levels of evidence for the recommendations in this change are shown below.

1. The iTClamp is effective at controlling external hemorrhage in selected cases of external hemorrhage. Level C
2. The iTClamp is safe to use for the control external hemorrhage. Level C

Recommendations for Further Research

1. The Joint Trauma System performance improvement process should be used to identify all future casualties on whom the iTClamp are used and how the device performed. Consider casualties with CMFI and PNI as well as other injuries for which the iTClamp was used.
2. Clinical study to evaluate outcomes of prehospital iTClamp use, in both military and civilian trauma settings.
3. Evaluate the use of the iTClamp as a hemostatic adjunct for tourniquet conversion in casualties with extremity hemorrhage.

Disclaimers

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Defense Health Agency, the Department of Defense, nor the US Government. This recommendation is intended to be a guideline only and is not a substitute for clinical judgment.

Disclosures

Ms Mckee has been employed as a contractor for Innovative Trauma Care, the company that manufactures and distributes the iTClamp. She has had her travel covered by Innovative Trauma Care as part of her position with the company and is entitled to stock options. The other authors have no disclosures to report.

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