iTClamp-Mediated Wound Closure Speeds Control of Arterial Hemorrhage With or Without Additional Hemostatic Agents

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ABSTRACT

Background: Exsanguination is the leading cause of preventable posttraumatic death, especially in the prehospital arena. Traditional hemorrhage control methods involve packing the wound with hemostatic agents, providing manual pressure, and then applying a pressure dressing to stabilize the treatment. This is a lengthy process that frequently destabilizes upon patient transport. Conversely, the iTClamp, a compact wound closure device, is designed to rapidly seal wound edges mechanically, expediting clot formation at the site of injury. **Objectives:** To determine the efficacy of the iTClamp with and without wound packing in the control of a lethal junction hemorrhage. **Methods:** Given the limited available information regarding the efficacy of the iTClamp in conjunction with traditional hemostatic agents, this study used a swine model of severe junctional hemorrhage. The goal was to compare a multiagent strategy using the iTClamp in conjunction with XSTAT to the traditional method of Combat Gauze packing with pressure dressing application. Readouts include application time, blood loss, and rebleed occurrence. **Results:** Mean application times of the iTClamp treatment alone or in conjunction with other hemostatic agents were at least 75% faster than the application time of Combat Gauze with pressure dressing. Percent blood loss was not significantly different between groups but trended the highest for Combat Gauze treated swine, followed by iTClamp plus XSTAT, iTClamp alone and finally iTClamp plus Combat Gauze. **Conclusion:** The results from this study demonstrate that the iTClamp can be effectively utilized in conjunction with hemostatic packing to control junctional hemorrhages.

KEYWORDS: *iTClamp; hemorrhage; trauma; junctional wounds; hemostatic agent*

Introduction

Exsanguination is the leading cause of preventable posttraumatic death and is responsible for over 35% of deaths in the prehospital setting alone.[1–3] While the effective application of tourniquets leads to decreased mortality from extremity hemorrhage, junctional injuries not amenable to traditional tourniquets continue to pose significant complications in prehospital medicine. Because junctional areas contain major vascular groups, associated injuries can rapidly lead to death by exsanguination. Rapid, in-field control of junctional bleeding can therefore be a lifesaving intervention. However, current treatment options are limited.

The current standard of care involves packing the wound, often with hemostatic agents, followed by direct, manual pressure.[4] However, this method is often ineffective in achieving and maintaining hemostasis during patient movement and transportation.[5] Importantly, it is a time-consuming approach, requiring several minutes of manual pressure from a provider, time which could be used to both reduce blood loss and allow providers to address other associated trauma complications.[6]

One alternative to treating junctional wounds with manual direct pressure is application of a junctional tourniquet. These function in the control of junctional hemorrhage by applying direct pressure over the femoral artery. However, junctional tourniquet application requires the manipulation of the injured patient, resulting in variable application times and application success.[7] Junctional tourniquets have also shown poor stability during simulated patient transport. Finally, junctional tourniquets are typically bulky devices making them logistically challenging for prehospital care.

The iTClamp Hemorrhage Control System (iTraumaCare, https://www.innovativetraumacare.com/itclamp) is a second generation wound closure device that has received US Food and Drug Administration (FDA) approval for the control of severe bleeding in the extremities, axilla and inguinal areas.[8] This device may address the limitations of standard packing or junctional tourniquet application by mechanically sealing the wound and allowing for formation of a stable clot.[9] At 31.2 g and a size of approximately 6 cm × 4.5 cm × 3.5 cm, the iTClamp is compact and portable. The simple clamp design allows for rapid application, and a self-locking mechanism prevents unintentional opening.

There are limited studies evaluating the potential benefit of an off-label use of applying iTClamp in conjunction with hemostatic agents. Previously, we developed a swine model to assess the feasibility of such application in junctional injuries of the groin, axilla, and neck.[7] Building on that study, we sought to evaluate the hemostatic efficacy of the iTClamp in conjunction with two hemostatic wound treatments, Combat Gauze (QuikClot, https://quikclot.com/QuikClotProducts/QuikClot

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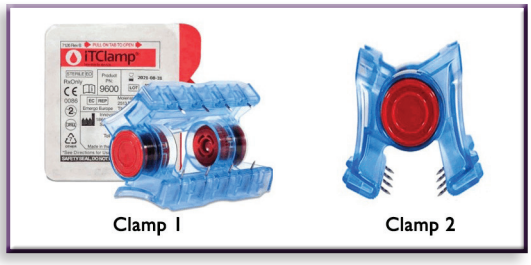
-Combat-Gauze.htm) and XSTAT (RevMedx, https://www.revmedx.com/xstat/). We hypothesized that in a swine model of severe junctional hemorrhage, a multiagent strategy using the iTClamp in conjunction with XSTAT or Combat Gauze would be faster to apply and as effective in hemorrhage control as compared to the traditional method of Combat Gauze packing with pressure dressing application.

Materials and Methods

Materials

iTClamp is a 6 cm × 4.5 cm × 3.5 cm hinged, plastic self-locking wound closure device with two rows of stainless-steel teeth of suture needle construction designed to grab and pull together then lock into place opposing tissue edges of a wound (Figure 1).

FIGURE 1 *iTClamp.*



XSTAT 30 (US Patent 8,828,050 B2) is a syringe containing ninety-three 1-mm tablet-size chitosan-coated sponges designed to rapidly expand to create a tamponade effect when injected deep into a wound.

Combat Gauze is a 7.6 cm × 3.7 m z-folded nonwoven gauze coated in kaolin, a naturally occurring inorganic mineral that promotes clotting by activating factor XII of the coagulation cascade.[10]

The Emergency Trauma Dressing (North American Rescue, https://www.narescue.com/emergency-trauma-dressing-etd.html) is a 6-in elastic wrap equipped with a sterile nonadherent pad intended to absorb blood and apply direct pressure to a wound.

Swine Model of Extremity Arterial Hemorrhage

To evaluate the efficacy of the hemostatic agents, we used a swine arterial injury model (6-mm arteriotomy), modified to accommodate the different anatomic sites and devices.[6,11] This study was approved by the Institutional Animal Care and Use Committee and was conducted in compliance with the Animal Welfare Act and Regulations and per the principles of the "Guide for the Care and Use of Laboratory Animals" (Institute of Laboratory Animals Resources, National Research Council, National Academies Press, 1996). Animals were maintained in a facility accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). International. Subjects were 32 female Yorkshire cross-bred swine weighing a mean (SD) of 41.2 kg (4.9), purchased from Smithfield Farms (Turlock, VA).

Presurgical Preparation

Swine were fasted for 12 hours with water provided ad libitum before surgery. Animals were premedicated with ketamine (0.025mg/kg intramuscularly [IM]) for analgesia. Then, injection of tiletaminezolazepam (Telazol 4mg/kg IM) was used for induction and 5% isoflurane in oxygen via facemask used for initial anesthesia. The swine were intubated and ventilated with 100% oxygen. The tidal volume and ventilation rate were adjusted to maintain an end-tidal partial pressure of carbon dioxide ($EtCO_2$) of 40 ± 2mmHg. Anesthesia was maintained with 2% isoflurane added to 100% oxygen gas via respirator. Lactated Ringer's (LR) was administered at 5mL/kg/h through an ear vein. Blood pressure (systolic and diastolic), mean arterial pressure (MAP), heart rate (HR), and respiratory rate (RR) were monitored. Baseline vitals were assessed every 5 minutes for 15 minutes, then averaged for statistical analysis.

Surgical Procedure

After anesthetizing subjects, a 4-cm incision was made through the skin of the medial thigh. The femoral artery was then surgically isolated. Hemorrhage was induced with a 6-mm vascular punch to create an arteriotomy. Following unrestricted bleeding for 45 seconds, the site was treated with a randomly assigned hemostatic treatment regimen, described in Table 1. All treatments were applied by a single physician trained in the use of all study materials.

TABLE 1 *Treatment Groups and Descriptions*

Abbreviation	n	Treatment Description
CG	7	Combat Gauze (CG) packed into the wound and manual pressure applied for 3 min, following by application of a pressure dressing
IT	9	The wound was sealed with the iTClamp (IT) alone, per manufacturer's recommendations
IT+CG	8	Combat Gauze packed into the wound, then the wound was immediately closed with an iTClamp
IT+XS	8	XSTAT injected into the wound, then the wound was immediately closed with an iTClamp

Animal Monitoring and Assessment

After treatment application, the injury was observed for 30 seconds and assessed for initial hemostasis. If continued bleeding was noted, indicating a failure to seal, the investigator removed and reapplied the iTClamp. This was followed by another 30 seconds assessment for hemostasis, repeating if necessary. A bolus of Hextend (500mL) was administered 5 minutes after injury to simulate standard battlefield treatment practices. Heart rate, blood pressure, and respiratory rate were recorded every 5 minutes beginning after the completion of femoral artery isolation. External blood loss during the free bleed and treatment application process was collected via a suction device and preweighted gauze and recorded.

Subjects were monitored up to 1 hour postinjury or until early endpoint criteria were met, defined as by the loss of the normal sinus electrocardiographic waveform and/or $EtCO_2$ of 0mmHg for longer than 10 minutes. No additional resuscitative measures were taken. After 1 hour, the injured leg of the surviving subjects was flexed and stretched five times, mimicking patient movement to test the stability of the hemostasis. At necropsy, any hemostatic agents, free blood or clot within the wounds were evacuated and measured.

Design and Data Analysis

In this between-subjects design, continuous variables (baseline values and time to application) were assessed using analysis

of variance (ANOVA) with post hoc localizing pairwise comparisons and correction for multiple comparisons. Binomial outcomes (survival, hemostasis, rebleed) were assessed using χ^2 tests. Application attempts, which could not be assumed to be from a Gaussian distribution, were assessed with the Kruskal-Wallis test. Repeated-measures (HR, RR) between-group differences over time were assessed using repeated-measures ANOVA. Statistical tests were performed using Prism 8 (GraphPad Software, https://www.graphpad.com/scientific-software/prism/); sample size calculations were performed using G*Power.[12] All differences were considered statistically significant at the $p < .05$ threshold.

Results

Swine in each treatment group were statistically similar in body weight, and at baseline HR and RR; mean and standard deviations for each measurement are shown in Table 2.

TABLE 2 *Baseline Values*

Baseline Values	IT+XS	IT+CG	IT	CG
Weight (kg)	40.62 (4.34)	43.91 (5.44)	39.33 (5.52)	41.03 (3.07)
Heart rate (bpm)	80.5 (12.31)	96.13 (20.77)	93.44 (17.59)	93.57 (9.43)
Respiratory rate (breaths/min)	29.13 (6.18)	24.13 (5.11)	29.56 (10.94)	26.00 (7.14)

Weights were recorded prior to instrumentation on the day of surgery. Heart rate and respiratory rate baselines were recorded after anesthesia and instrumentation and prior to injury. Values are mean (standard deviation).

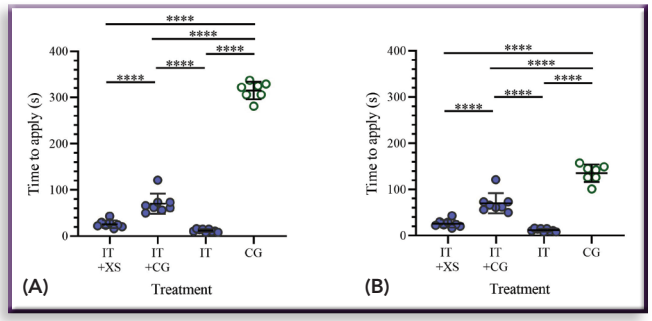
Application Time

After a 45-second free bleed, each treatment strategy was applied. Application time was measured from the time the selected hemostatic agent was picked up until the iTClamp was locked or the pressure dressing was fully wrapped. Mean time to apply was significantly slower for CG [mean (SD) = 315 sec (18.9)], compared to IT+CG, [mean (SD) = 70.3 sec (22.0); $p < .0001$], IT+XS (mean (SD) = 26 sec (8); $p < .0001$], and IT [mean (SD) = 12 sec (3); $p < .0001$] (Figure 2A). IT+CG was significantly slower than IT+XS ($p < .0001$) and IT ($p < .0001$). IT+XS and IT were not significantly different ($p = .51$). Even if the 3-minute (180 sec) pressure application time was excluded from the CG treatment time, CG was still significantly slower [mean (SD) = 135.1 sec (18.9)] than IT or IT+XS and IT+CG (each $p < .0001$) (Figure 2B). These findings support our hypothesis that addition of a mechanical closure mechanism speeds the time of application.

Hemostasis and Application Attempts

Ultimately, hemostasis was obtained in all the subjects. However, there were differences in the rate of initial hemostasis achieved on the first attempt. We defined initial hemostasis as the cessation of blood loss outside of the wound during the 30-second interval immediately following completion of hemostatic application. CG was able to reliably achieve this in 100% of cases. Conversely, all the iTClamp treatments had some failed attempts, with success on the first attempt 88% for IT applications, 75% for IT+CG applications, and 63% for IT+XS applications. Chi square revealed no statistically significant differences between groups in initial hemostasis, χ^2 (degrees of freedom [*df*] = 3) = 3.77, $p = .29$ (Table 2). Because

FIGURE 2 *Time to application.*



Time to application for iTClamp with XSTAT (IT+XS), iTClamp with Combat Gauze (IT+CG), iTClamp alone (IT), and Combat Gauze with pressure dressing (CG) including 3 min of pressure held for CG **(A)** and excluding 3 min of pressure held for CG **(B)** Symbols reflect individual data points; horizontal midpoint line represents the mean and error bars indicate standard deviation. (Horizontal lines represent pairwise comparisons, $p < .0001$).

the iTClamp does not cover a wound but is intended to seal it, any bleeding from the wound was considered a failure and was a binary outcome.

Failure to achieve initial hemostasis as defined above triggered the removal of the iTClamp or pressure dressing and reapplication. This process was repeated until hemostasis was achieved. CG required one application attempt for each animal, while IT required a second attempt for one animal. IT+CG required a second attempt for two animals and IT+XS required a second attempt for two animals and a third attempt for one animal.

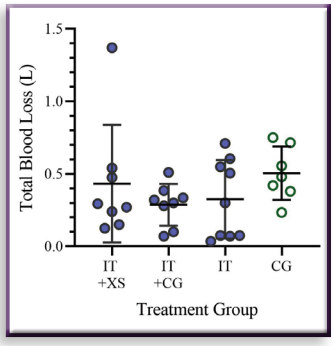
Rebleed

Any evidence of external blood loss after the initial hemostatic period was considered a rebleed episode. Occurrence of rebleed was statistically similar across groups, χ^2 ($df = 3$) = 0.64, $p = .88$. IT+XS had two rebleeds, while other groups had one rebleed each (Table 2).

Blood Loss

Percent blood loss trended the highest for CG treated swine [mean (SD) = 18.4% (8)], followed by IT+XS [mean (SD) = 16.1% (14.6)] and IT [mean (SD) = 13.4% (10.2)] (Figure 3). IT+CG had the lowest average blood loss [mean (SD) = 9.5% (4.5)], which trended lower than CG ($p = .09$).

FIGURE 3 *Total blood loss.*
Symbols reflect individual data points, horizontal midpoint line represents the mean, and error bars indicate standard deviation.



Heart Rate

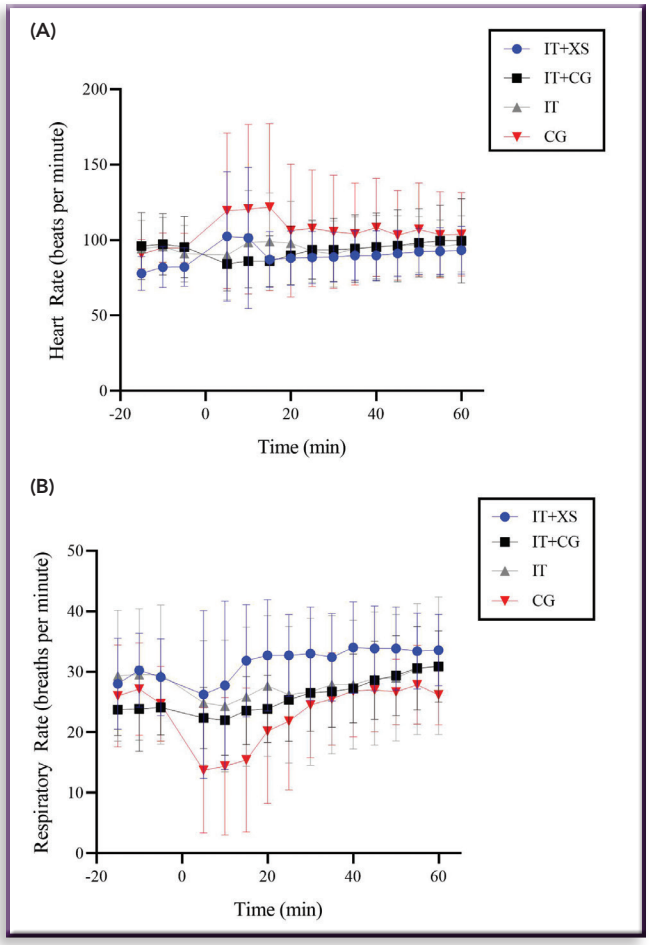
Subjects' vital signs were monitored as a measure of physiologic response to hemorrhage to assist in determination of the significance of blood loss. Figure 4A shows that treatment groups were not significantly different in the average of three baseline heart rate (HR) measures ($p = .19$), though IT+XS trended lowest. Treatment groups did not significantly differ

overall between treatment groups at each time point or within treatment groups compared to their respective baselines.

Respiration Rate

The average of the three, baseline RR measures was not significantly different between treatment groups ($p = .53$). Within CG-treated swine, RR was significantly lower compared to their own baseline (5 minutes to 15 minutes) following CG application ($p < .05$) (Figure 4B). There were no other significant differences in RR between treatment groups at each time point or within treatment groups compared to their respective baselines.

FIGURE 4 *Vital signs during experiment.*



(A) Heart rate over time for iTClamp with XSTAT (IT+XS), iTClamp with Combat Gauze (IT+CG), iTClamp alone (IT), and Combat Gauze with pressure dressing (CG). **(B)** Respiration rate over time for iTClamp with XSTAT (IT+XS), iTClamp with Combat Gauze (IT+CG), iTClamp alone (IT), and Combat Gauze with pressure dressing (CG). Symbols represent the average; error bars represent standard deviation.

Survival

Overall, 94% (29 of 31) of swine survived during the observation period. One death occurred in each of the IT+XS and CG treatment groups. No statistically significant differences between groups in survival were revealed: χ^2 ($df = 3$) = 2.30, $p = .52$ (Table 3).

Discussion

Lethal hemorrhage is a time critical disease requiring rapid and effective control to prevent mortality. Junctional hemorrhages are challenging to manage due to their noncompressible nature and the limited and variable efficiencies of existing devices.[7,13] Controlling a junctional hemorrhage with direct pressure is an effective, and sometimes the only available, method. Here, we show that in small, linear wounds pressure may also be provided by a mechanical wound closure device. The use of the iTClamp, both in isolation and in conjunction with hemostatic packing, resulted in faster application times without compromising hemostatic efficacy compared to manual pressure with CG.

TABLE 3 *Outcome Measures*

Outcome	IT+XS	IT+CG	IT	CG
Initial hemostasis	5/8 (63%)	6/8 (75%)	8/9 (88%)	7/7 (100%)
Rebleed	2/8 (25%)	1/8 (13%)	1/9 (11%)	1/7 (14%)
Survival	7/8 (88%)	8/8 (100%)	9/9 (100%)	6/7 (86%)

Initial hemostasis, rebleed, and survival are tabulated as fraction of total swine experiencing each outcome measure.
IT = iTClamp, CG = Combat Gauze, IT+XS = iTClamp with XSTAT, IT+CG = iTClamp with Combat Gauze.

Our findings support prior studies demonstrating the ability of the iTClamp to effectively stop hemorrhage.[6,9,14] Additionally, we demonstrated that hemostatic agent packing can be successfully combined with iTClamp treatment. A study by St. John et al. previously noted that the use of the iTClamp in conjunction with standard gauze resulted in less blood loss and greater survival than packing with standard gauze alone. However, these benefits appeared to be lost if pressure was held on the wound for 3 minutes after packing.[14] This suggests that the use of the iTClamp is functionally equivalent to 3 minutes of manual pressure, with our data showing similar blood loss between treatment groups supports.

The iTClamp functions by direct wound closure. The wound edges are everted, and the inguinal cavity is compressed to a greater extent than in its preinjury state. Additionally, this exerts a greater pressure on the bleeding site creating a tamponade effect aiding in coagulation. Of course, as this mechanism relies on creating a smaller compartment to control hemorrhage, complex wounds involving multiple anatomic compartments may see reduced or limited efficiency. This was observed during two of the IT treated swine in which a superficial hematoma formed and subsequently appeared to spontaneously resorb. Evaluation of the wound at necropsy revealed that the pressure of the hematoma had caused a separation of fascial planes and bleeding into adjacent compartments. While this would lead to some increased blood loss verses intact facial planes, the overall volumes would be comparatively small and total blood loss was not significantly greater across treatments.

Direct comparison of hemostasis between pressure dressing and iTClamp treatment groups was difficult to interpret due to the differences in their mechanisms. As the iTClamp does not cover a wound but is intended to seal it, any bleeding from the wound was considered a failure in initial hemostasis. On the other hand, the assessment of hemostasis failure was limited in the CG treatments. The CG covers the wound, and in addition to the packed combat gauze, the pressure dressing could absorb a significant amount of blood before showing signs of blood loss. However, this limitation would only bias the results against the effectiveness of the iTClamp, and yet the iTClamp was found to be similarly effective as CG alone.

While hemostasis was achieved on the first attempt for all CG treatments, use of the iTClamp resulted in failure to achieve hemostasis on the first attempt in 6 of 25 attempts. We anticipated that failed hemostasis and the need for reapplication would result in slower application times and larger blood losses. However, this was not the case due to the ability of the iTClamp to be rapidly disengaged and repositioned. Observationally, failures in the IT+CG and IT+XS treatment applications appeared to occur secondary to extrusion of the packing material, precluding an effective seal between wound edges. This was remedied by removing excess packing materials.

Previous studies suggested that XSTAT expands more evenly and with a balanced pressure distribution compared to gauze packing, increasing hemostasis and decreasing blood loss.[15–17] Mueller et al. used up to eight syringes of XSTAT to achieve this result, which was not compatible with use of the iTClamp. In our study these attributes did not appear to confer an additional advantage over standard of care. Upon necropsy, CG, with or without IT, was more commonly clotted around the arteriotomy site than IT+XS.

While hemostatic efficacy is paramount in the evaluation of hemostatic agents, an agent's application time can be critical in the actively hemorrhaging patient. Faster application of hemorrhage control devices should result in less blood loss, and once hemorrhage is more quickly controlled, the provider can address other trauma-associated complications. In prehospital settings, faster hemorrhage control also allows for more rapid transport of patients to definitive care.[6] Faster device and agent application can be reasonably anticipated to improve patient outcomes. Additionally, lengthy application times can be prohibitive and even hazardous to both patient and providers in settings such as the battlefield, austere locations, or other tenuous environments. As most domestic and foreign terrorism-based incidents continue to involve explosives or firearms, rapid and effective hemorrhage control devices can be a force multiplier in mass casualty situations by allowing a provider to quickly contain hemorrhages from multiple sources or patients.[18]

Our findings supporting the rapid deployment of the iTClamp are consistent with previous reports.[6,9,14] In all three iTClamp treatment groups, application times were significantly faster than traditional packing/wrapping techniques. Furthermore, investigator time spent with each subject was even longer during CG application when the additional 3 minutes of direct pressure that must be held after application per manufacturer's recommendations is considered. Additionally, while they cannot be directly compared across studies, all three iTClamp treatments were faster than reported applications of current junctional tourniquet devices (84–124 seconds).[7]

Unsurprisingly, the application time of the iTClamp alone was faster than when used in conjunction with either CG or XSTAT. The use of CG with the iTClamp required significantly more time to apply then with the XSTAT (70 seconds and 20 seconds, respectively). These data are consistent with prior studies which identified XSTAT as a much faster mode of wound packing than gauze.[15,17,19] CG comes in a 12-foot roll that must be manually packed, while XSTAT is applied via a rapidly deployable single syringe mechanism.

There were important observations concerning the use of the iTClamp. While all agents have a potential to fail to obtain hemostasis, our data suggest this may be higher with the iTClamp than with traditional methods, likely owing to its more technical nature. Additionally, this failure rate tends to increase when it is used in conjunction with packing agents. We feel this highlights a valuable observation that should be addressed during training on iTClamp use. Specifically, that Operators who choose to seal packed wounds with an iTClamp should ensure that all gauze is packed tightly into the wound with care to avoid overpacking and that any excess gauze extruding from the wound is removed prior to application of the iTClamp.

Limitations

Our study sought to evaluate the immediate utility of mechanical wound closure for hemorrhage control, and therefore cannot directly comment on the potential long-term sequelae or eventual patient outcomes between techniques. However, it seems reasonable that quicker control should result in improved outcomes and decrease resource utilization. Likewise, to reduce confounders, we elected not to administer tranexamic acid, provide blood products, or take any other resuscitative measures that may impact the efficacy of hemorrhage control in trauma patients. Finally, for feasibility purposes we utilized a single, linear wound type and our results may therefore not be applicable to all wound types.

Conclusion

The iTClamp was quicker to apply and as effective in hemostasis compared to the standard packing and pressure dressing method. Our findings demonstrate that the iTClamp may be effectively used in conjunction with hemostatic packing when care is taken not to overpack the wound to control junctional hemorrhages of limited complexity and size. Given its efficacy, speed and compact size, the iTClamp may be well-suited for fielding with the proper training as an adjunct to standard hemorrhage control methods, particularly in the prehospital setting.

Acknowledgments

We thank Greg J. Zarow, PhD, for his study design advice.

Disclosure

The authors have indicated they have no financial relationships relevant to this article to disclose.

Funding

This research was supported by funding from a Deputy Surgeon General Clinical Investigation Award.

Author Contributions

MB contributed to drafting the article or revisiting it critically for important intellectual content and final approval of the version to be published. JM and AW contributed to acquisition of data. EF contributed to analysis and interpretation of data, drafting the article or revisiting it critically for important intellectual content, and final approval of the version to be published. SS contributed to all of the above.

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Winter 2022
Volume 22, Edition 4

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