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Inside this Issue:

- Case Report: Needling Techniques for Chronic Neck Pain
- Case Report: Machine Learning and Hemodynamic Instability
- In Brief: Comparing C-A-T® Gen 6 to Prototype Gen 7
- TCCC Guidelines: XStat™ Sponge for External Hemorrhage
- Comparison of Tactical Tourniquets
- Junctional Tourniquet Testing for Groin Hemorrhage
- SOF Testing of CRoC and JETT Tourniquets
- Triage Accuracy and Reliability During OEF
- Point-of-Care Ultrasound Update
- Editorials: SOLCUS After-Action Report, USASOC Division of Science & Technology, Traumatic Brain Injury, and Power to the People
- Letters to the Editor: Needle Decompression and The Hartford Consensus
- Ongoing Series: Clinical Corner, Human Performance Optimization, Infectious Diseases, Injury Prevention, Law Enforcement & Tactical Medicine, Operational Medicine in the Austere Environment, Picture This, Prolonged Field Care, Special Talk, World of Special Operations Medicine, TCCC Updates, TacMed Updates, *and more!*

Dedicated to the Indomitable Spirit and Sacrifices of the SOF Medic

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Management of External Hemorrhage in Tactical Combat Casualty Care: The Adjunctive Use of XStat™ Compressed Hemostatic Sponges

TCCC Guidelines: Change 15-03

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ABSTRACT

Exsanguination from wounds in the so-called junctional regions of the body (i.e., the neck, the axilla, and the groin) was responsible for 19% of the combat fatalities who died from potentially survivable wounds sustained in Afghanistan or Iraq during 2001 to 2011. The development of improved techniques and technology to manage junctional hemorrhage has been identified in the past as a high-priority item by the Committee on Tactical Combat Casualty Care (CoTCCC) and the Army Surgeon General's Dismounted Complex Blast Injury (DCBI) Task Force. Additionally, prehospital care providers have had limited options with which to manage hemorrhage resulting from deep, narrow-track, penetrating trauma. XStat™ is a new product recently approved by the US Food and Drug Administration as a hemostatic adjunct to aid in the control of bleeding from junctional wounds in the groin or axilla. XStat has now been recommended by the CoTCCC as another tool for the combat medical provider to use in the management of junctional hemorrhage. The evidence that supports adding XStat to the TCCC Guidelines for the treatment of external hemorrhage is summarized in this paper.

Keywords: *hemorrhage, junctional; hemorrhage, external; hemostatic; tourniquets; TCCC Guidelines; XStat™*

Proximate Cause for This Proposed Change

1. Exsanguination from junctional hemorrhage (i.e., the neck, the axilla, and the groin) was responsible for 19% of the combat fatalities who died from potentially survivable wounds sustained in the conflicts in Afghanistan and Iraq between 2001 and 2011.[1]

2. The Tactical Combat Casualty Care (TCCC) Guidelines dated 3 June 2015 recommend the Combat Application tourniquet (Composite Resources Inc.; http://combattourniquet.com) or SOF Tactical Tourniquet (Tactical Medical Solutions; https://www.tacmedsolutions.com) as the intervention of choice for initial control of life-threatening extremity hemorrhage if the bleeding site is amenable to limb tourniquet use.

3. For life-threatening external hemorrhage from wounds that are not amenable to tourniquet use, the hemostatic dressing Combat Gauze™ (Z-Medica; www.z-medica.com/healthcare), applied with 3 minutes of direct pressure, is recommended as the first option of choice for the initial control of bleeding, Celox Gauze (Medtrade Products Ltd.; http://www.celoxmedical.com) and ChitoGauze (HemCon Medical Technologies Inc.; http://www.hemcon.com) are recommended as alternates.[2–4]

4. If the junctional bleeding is from a site that is amenable to the use of a junctional tourniquet, the Combat Ready Clamp (CombatMedical; http://combatmedicalsystems.com), the Junctional Emergency Treatment Tool (North American Rescue; http://www.narescue.com), and the SAM Junctional Tourniquet (SAM Medical Products; http://www.sammedical.com) are the CoTCCC-recommended devices of choice. Combat Gauze or one of the other recommended hemostatic dressings should be applied with 3 minutes of direct pressure to gain control of the bleeding while a junctional tourniquet is being readied for use.[3,5]

5. The clearance of XStat by the US Food and Drug Administration (FDA) offers a new option for the control of external hemorrhage from junctional bleeding sites that are not adequately addressed by the aforementioned measures. The FDA clearance letter of 3 April 2014 states that XStat should be used:

> ". . . as a hemostatic device for the control of bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents. XStat™ is a temporary device for use up to four (4) hours until surgical care is acquired. XStat™ is intended for use in the battlefield. XStat™ is not indicated for use in: the thorax; the pleural cavity; the mediastinum; the abdomen; the retroperitoneal space; the sacral space above the inguinal ligament; or tissues above the clavicle."[6]

6. A study conducted at the Naval Medical Research Unit-San Antonio comparing XStat to Combat Gauze in a large-animal model of subclavian bleeding found that XStat was applied in less time than Combat Gauze (31 seconds versus 65 seconds) and resulted in less blood loss during the application time.[7]

Background

Control of External Hemorrhage

The majority of combat fatalities result from severe injuries that are inevitably fatal; some fatalities, however, result from wounds that are potentially survivable.[1,8] Eastridge et al. found that 87% of the combat fatalities resulting from wounds sustained during the Iraq or Afghanistan conflicts between 2001 and 2011 occurred in the prehospital phase of care.[1] Further, they found that 24.3% of these battlefield deaths resulted from wounds that were potentially survivable. Of those deaths that resulted from potentially survivable wounds, 90.9% were due to truncal, junctional, or extremity hemorrhage.[1] Despite the aversion to tourniquet use that prevailed in US trauma care in the past, since 1996, the TCCC Guidelines have recommended the use of limb tourniquets as the initial intervention of choice for life-threatening extremity hemorrhage on the battlefield.[10] Although most US Military units did not use limb tourniquets early in the conflicts in Afghanistan and Iraq, tourniquets began to be widely used in the military in the 2005–2006 time frame due to the combined efforts of the Committee on TCCC (CoTCCC), the US Army Institute of Surgical Research, the US Special Operations Command, and the US Central Command.[11–16] This resulted in a large reduction in preventable deaths from extremity hemorrhage and saved the lives of an estimated 1,000 to 2,000 US Military Servicemembers.[11,17,18]

With this remarkable reduction in mortality from extremity wounds, junctional hemorrhage (which, by definition, is not amenable to control with limb tourniquets) has become the leading cause of potentially preventable death from external hemorrhage.[1] Junctional hemorrhage was defined by the Army Surgeon General's Task Force on DCBI as ". . . hemorrhage that occurs at the junction of an extremity with the torso of the body at an anatomic location that precludes the effective use of an extremity tourniquet to control the bleeding. The definition also includes the base of the neck."[5,19] Wounds from dismounted improvised explosive device (dIEDs) became increasingly prevalent in Afghanistan at the end of 2010 and often include high unilateral or bilateral lower-extremity amputations.[19] The injury pattern that results from pressure-plate activated dIEDs often includes severe injuries to the urogenital, pelvic, and abdominal areas, as well as lower-extremity amputations.[3] External hemorrhage from both the proximal extremity amputations seen in DCBI and from other sites of external bleeding may be controllable with hemostatic dressings[4,20] or junctional tourniquets,[5] but the large variability of combat wound morphology requires that combat medical providers have a variety of options with which to address this prominent type of potentially preventable death. XStat is another important tool for the control of external hemorrhage that should be considered for addition to the Combat Medic aid bag.

XStat

To address the challenge of controlling external hemorrhage from sites where the bleeding vessel is deep in a wound with a narrow entrance track, researchers from Oregon Biomedical Engineering Institute have developed a unique, new hemostatic product called XStat. The XStat device consists of an applicator syringe filled with compressed minisponges that are coated with the hemostatic agent chitosan. XStat is injected into the wound cavity and the compressed hemostatic minisponges expand on contact with blood. The expanded sponges, now 12–15 times their original volume, exert pressure on the walls of the wound cavity from within, thereby eliminating the need for manual compression.

On 3 April 2014, the FDA granted de novo clearance of the XStat dressing under regulation number 21 CFR 878.4452, creating a new classification of medical device designated generically as follows:

> "**Non-absorbable, expandable, hemostatic sponge for temporary internal use:** A non-absorbable, expandable, hemostatic sponge for temporary internal use is a prescription device intended to be placed temporarily into junctional, noncompressible wounds, which are not amenable to tourniquet use, to control bleeding until surgical care is acquired. The sponges expand upon contact with blood to fill the wound cavity and provide a physical barrier and pressure that facilitates formation of a clot. The device consists of sterile, non-absorbable, radiopaque, compressed sponges

> and may include an applicator to facilitate delivery into a wound."[6]

Another important potential use of XStat is facilitating the conversion of extremity tourniquets to another method of bleeding control. The TCCC Guidelines recommend that limb tourniquets be converted to other methods of hemorrhage control, when feasible, if the tourniquet is still in place 2 hours after application.[21] This is not an FDA-approved indication for this product and there are currently no laboratory studies or clinical reports that document efficacy for this use of XStat, but this is an area that merits further consideration and research.

XStat Descriptive Information

XStat specifics include:

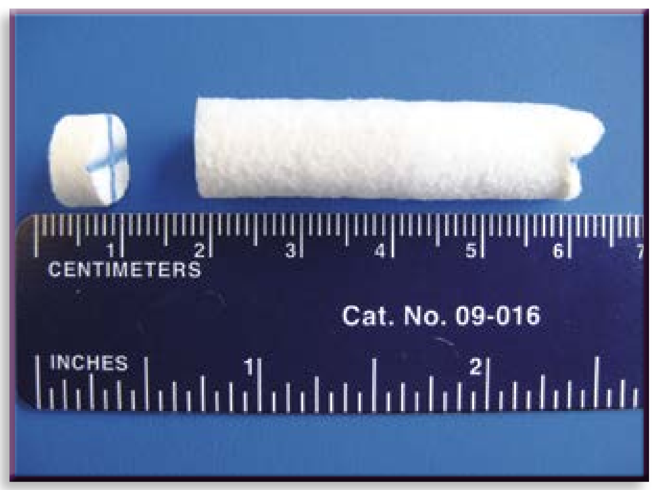
- The XStat system consists of approximately 92 flat, circular, compressed minisponges that are coated with chitosan and packaged in a 60mL syringe applicator (Figure 1). The unexpanded minisponges are 9 mm in diameter and 4.5 mm in height (Figure 2).[14]
- Each XStat minisponge has a radiopaque marker so the sponges can be located with radiography at the time of surgery.[22]
- The applicator has a small-diameter insertion device available for use in narrow wound tracts.[22]
- Approved XStat indications are as follows: "XStat™ is a hemostatic device for the control of bleeding from junctional wounds in the groin or axilla not amenable to tourniquet application in adults and adolescents. XStat™ is a temporary device for use up to four (4) hours until surgical care is acquired."[6] Although XStat was initially intended for use on the battlefield,[6] it has now been cleared for use in the civilian sector as well.[23]
- XStat is NOT approved for use in the thorax, the pleural cavity, the mediastinum, the abdomen, the retroperitoneal space, the sacral space above the inguinal ligament, or tissues above the clavicle.[6] Note that the latter restriction would preclude its use in maxillofacial or neck wounds.
- The compact XStat syringe applicator includes a telescoping handle and a sealed valve tip. The telescoping mechanism allows the handle to be stored in a shortened state to maximize compactness. The applicator tip is designed to prevent fluid ingress and to minimize the risk of premature sponge expansion.
- A National Stock Number (NSN) is necessary for an item to be included in standardized Department of Defense (DoD) equipment assemblages. The three-pack of XStat applicators is commercially available and NSN 6510-01-632-9440: APPLICATOR, HEMOSTATIC in DoD logistics systems. The single-pack XStat applicator is also now also commercially available and carries NSN 6510-01-644-7335: APPLICATOR, HEMOSTATIC SPONGES AND DISPENSER.
- The present cost to the US Government for a single-pack XStat applicator is approximately $350; the cost for the three-pack of XStat applicators is currently $1,050.
- The shelf life for XStat recommended by the manufacturer is presently 2 years.[24]
- The size of a three-pack of XStat applicators is 6 × 10 × 1.25 inches and the weight is 0.53 pounds. The size of a single-applicator pack of XStat is 2 × 10 × 1.5 inches and the weight is 0.17 pounds.

Following FDA clearance in 2014, the manufacturer of XStat, RevMedX, sent a shipment of XStat to Special Forces units for its initial fielding.[25]

Figure 1 *Photograph of one device, which consists of compressed sponges housed in a syringe-style applicator. One device consists of three applicators.*

(Photo courtesy of RevMedX)

Figure 2 *Photograph depicting side views of compressed and fully-expanded sponges. Radiopaque filaments are attached to one end of each sponge in an "x" pattern.*



(Photo courtesy of RevMedX)

Note that (1) it is anticipated that if XStat is being purchased in large quantity by the DoD, production costs and price to the government will drop in the future; the proposed target price for a single XStat applicator is $130[22]; and (2) more than one applicator of XStat may be required to fill a wound cavity and achieve the internal increase in pressure in the wound cavity needed to achieve hemostasis. Up to eight applicators of XStat were allowed in the Cestero et al. and Mueller et al. studies.[7,26] The median number of XStat applicators used in the Cestero et al. study was six.[7]

Discussion

The Need for XStat

For deep-tract or narrow-entrance wounds, visualization of the source of bleeding is difficult and packing the wound can be time consuming and possibly painful for the casualty. In addition, using one of the CoTCCC-recommended hemostatic dressings requires that manual compression be maintained on the wound for 3 minutes. This period of manual compression is not required with XStat.

XStat Efficacy Studies

The current recommendation for controlling junctional hemorrhage in TCCC is the immediate application of Combat Gauze and manual pressure followed by the use of one of the three junctional tourniquets as soon as one is available.[3,27]

XStat was specifically designed for the battlefield treatment of junctional bleeding from narrow-tract wounds. XStat is a hemostatic adjunct that applies internal pressure to bleeding sites in the depths of cavitary wounds, as opposed to hemostatic dressings, which are designed and labeled for external use and require manual pressure after application. This may be especially important when dealing with small wounds that do not allow for direct visualization of the bleeding vessel. The XStat system enables the required quantity of compressed sponges to be placed quickly into a narrow-tract wound. The subsequent expansion of the compressed minisponges provides internal pressure in the wound cavity and facilitates hemostatic interaction (adherence) of the chitosan coating with the bleeding tissues with little or no external pressure needed.

One point to note about the bleeding model used in the two studies discussed in the following paragraphs is that injuries to the subclavian vessels are associated with a high mortality rate, because of the large diameter of these vessels, the resultant high bleeding rate that injuries to them produce, and the difficulty in applying pressure to the bleeding site because of the overlying clavicle; 61% of patients with penetrating trauma to the subclavian vessels died before arriving at a hospital in one large case series.[28] Interestingly, isolated injuries to the subclavian vein have been reported to be associated with a higher mortality rate than isolated injuries to the subclavian artery.[28,29] Two possible reasons proposed for this observation have been offered: the first is that the vein is not able to contract as effectively as the artery after an injury; the second is that subclavian vein injuries may result in the introduction of air into the venous system and produce death by impeding pulmonary artery blood flow or causing cardiac or cerebral ischemia in individuals with a patent foramen ovale or other right-to-left shunts in the heart or lungs.[28] Bleeding that occurs from wounds in this area, as well as other wounds from deep, narrow wound tracts, may be difficult to control if the bleeding is at a location not amenable to junctional or extremity tourniquet use.

The initial study by Mueller et al.[26] of a chitosan-coated, compressed-sponge-based hemostatic system used a swine model of subclavian artery and vein bleeding created through a 4.5cm wound. This model was chosen because the bleeding subclavian vessels are difficult to compress, in contrast to the flatter geometry of wounds in the inguinal junctional area that allows for more effective pressure when applying Combat Gauze. There were eight animals in the minisponge study group and eight in a control Combat Gauze group. There was no external compression used in the minisponge group and up to eight applicators of the minisponges per animal were used to fill the wound cavity. The minisponges were applied within the 4-minute application time window. One Combat Gauze and one Kerlix gauze (MedTronic; http://www.medtronic.com) were used to pack the wound in the control group. These dressings were applied with 3 minutes of direct pressure, per the manufacturer's directions. At 60 minutes, survival was 100% (eight of eight) in the minisponge group and 37.5% (three of eight) in the Combat Gauze group.[26]

Cestero et al.[7] compared XStat with Combat Gauze (with and without compression) in a porcine model of subclavian artery and vein transection similar to that used in the Mueller et al. study.[26] (Note on the terminology: the wound that both groups of investigators created in their pigs was an axillary wound and the vessels that were transected were, in actuality, the axillary artery and vein. To access the subclavian artery in pigs, the surgeon must penetrate the pleural space, which was not done in either study. The only vessels that can be accessed at the upper-extremity junctional region in porcine models are axillary vessels. The terminology used in these studies is used in this article, with this caveat.) Access to the left subclavian artery and vein was made through a 4.5cm skin incision, approximately 4cm parallel to the sternum, directly over the left pectoralis major muscle. XStat was found to require significantly less time (31 seconds versus 65 seconds) to pack into the wound and to significantly reduce the amount of blood lost during application (1.3g/kg versus 5.1g/kg) without requiring manual compression by the provider after application into the wound. No significant differences were found with respect to either survival or post-treatment blood loss.[7] In contrast to the Mueller study, all animals in both the XStat and the Combat Gauze (with compression) arms of the study survived.[7]

A comparison of the Combat Gauze-treated animals in the two studies[7,26] revealed that they were similar with respect to skin incision size, vascular injury, pretreatment bleeding period, Combat Gauze application technique, observation time, and splenectomy procedure. One variation was in the fluid resuscitation procedure. Both studies infused a 500mL bolus of Hextend (BioTime; http://www.biotimeinc.com) followed by additional resuscitation with lactated Ringer's solution (LR) to achieve and maintain target mean arterial pressures (MAPs). In the Mueller et al. article,[26] LR was administered to maintain a target MAP between 60mmHg and 65mmHg; in the Cestero study, however, the target MAP was "above 65mmHg."[7] Sondeen and her colleagues found that the average MAP at which rebleeding occurred in an aortotomy bleeding model was 64mmHg.[30] This difference, therefore, might have been expected to result in increased bleeding and mortality in the animals in the Cestero study, which was not the observed outcome.[7] Another variation between the studies was that the Combat Gauze wound packing in the Mueller study was done by Combat Medics, whereas in the Cestero study, the packing was done by an experienced trauma surgeon.[7,26]

Kragh and Aden compared XStat to standard gauze (Kerlix) in a gel model of a simulated wound cavity and found that XStat was applied eight times faster (8 seconds versus 67 seconds) than packing the cavity with standard gauze. This study also found that XStat applied pressure more symmetrically throughout the wound cavity than did standard gauze.[14]

Additional Considerations

To date, there has only been one known use of XStat in a combat casualty and that was in a patient with intraoperative bleeding from a lower-extremity gunshot wound that shattered his femur. The bleeding had not been well controlled with Combat Gauze or cautery at first operation and required reoperation to evaluate. According to the surgeon, the XStat worked as intended and maintained hemorrhage control while the patient was being resuscitated. The wound was also packed with Combat Gauze on top of the XStat to achieve maximum compression. Both the Combat Gauze and the XStat were later removed without difficulty and the patient had no complications related to the XStat use (Elliot, personal communication). Note this was not an "approved" indication for XStat. It was placed intraoperatively and, therefore, by definition, does not meet the FDA definition of "until surgical care is acquired."[6]

Another clarification in terminology is needed. The Cestero paper refers to the axillary, neck, and groin areas as "noncompressible regions" with respect to hemorrhage control.[7] In fact, junctional hemorrhage in these areas is typically compressible. The 2012 Eastridge et al. paper notes, "Recent emphasis in battlefield trauma care has focused on reducing death from noncompressible hemorrhage through the use of tranexamic acid, controlling junctional hemorrhage with the Combat Ready Clamp, providing fluid resuscitation that minimizes dilutional coagulopathy and providing a battlefield analgesia option that does not cause respiratory depression or exacerbate hemorrhagic shock."[1] XStat will not help with the most common cause of preventable combat death, which is, indeed, noncompressible hemorrhage, but that which originates from internal sites within the abdominal or pleural cavities.

Given the cost differential, XStat must also be shown to be better than the currently approved TCCC interventions for junctional hemorrhage (i.e., hemostatic dressings and junctional tourniquets) in the most commonly encountered junctional wounding patterns, to represent a significant advance in prehospital trauma care. Comparative studies with Combat Gauze were discussed earlier in this article. There are, at present, no data showing that XStat works more effectively than the current CoTCCC-recommended junctional tourniquets for wounds in the inguinal or axillary junctional areas. Future clinical experience will determine the magnitude of the additional hemorrhage-control capability that combat medical providers will gain by adding XStat to their aid bags.

The FDA clearance letter notes, "The sponges expand upon contact with blood to fill the wound cavity and provide a physical barrier and pressure that facilitates formation of a clot."[6] It should be noted that a 4.5cm wound tract is somewhat larger than would be expected with the entrance tract from a gunshot wound. Both the Mueller and the Cestero papers used a subclavian vessel injury model that included a well-defined wound cavity.[7,26] The volumes of the wound cavities averaged 136mL and 131mL, respectively, in these two studies. If bleeding occurs from wounds with configurations that do not include a well-defined cavity, the minisponges may not be able to exert pressure on the site of the vascular injury in the same manner that occurs with expanding minisponges contained in a well-defined wound cavity. No published studies were found that address the efficacy of XStat relative to Combat Gauze in wounds that do not have a well-defined wound cavity.

Both the Mueller and the Cestero studies state that they allowed the use of up to eight applicators of XStat.[7,26] At a cost of $1,000 per three applicators, combat medical providers are unlikely to have eight applicators of XStat available for use. Actual casualties, however, may have wounds with smaller wound cavities than that created by the surgical dissection used in the Mueller and Cestero studies. In this event, one or two applicators of XStat would be more likely to suffice for hemorrhage control.

The current FDA clearance letter[6] specifically advises against the use of XStat on bleeding sites above the clavicle, which would preclude its use in life-threatening external hemorrhage from neck wounds. The reason for this exclusion is not addressed in the FDA clearance letter. Weppner reported 43 combat casualties with penetrating neck and/or maxillofacial trauma treated with tamponade of their bleeding vessels by inserting a Foley catheter through the skin wound and then inflating the balloon.[31] He demonstrated that mortality in this group was reduced (from 23% to 5%) in comparison with a similarly injured group of 35 casualties who were treated using direct pressure without the use of an inflated Foley catheter balloon.[31] This technique has also been used to control hemorrhage from injured subclavian vessels.[32] The compressed minisponges in XStat could theoretically be used in a similar manner to create internal pressure in a neck wound. One safety concern that would need to be addressed in considering this option is the potential for occlusion of the carotid or jugular vessels by one or more of the minisponges. No adverse outcomes resulting from vascular occlusions by the XStat minisponges were reported in the Mueller or Cestero studies.

The Armed Forces Medical Examiner's System (AFMES) conducts autopsies on all US Servicemembers who die of wounds sustained in combat. The subset of casualties who would in theory benefit the most from XStat would be those who have life-threatening hemorrhage originating in the depths of a wound with a narrow wound tract in a junctional location (other than the neck) that is not amenable to the application of a limb tourniquet and would not be well-addressed by the use of one of the three TCCC–recommended junctional tourniquets. Preventable deaths due primarily to this particular wounding pattern are uncommon (E. Mazuchowski, personal communication, November 2015).

XStat may also be beneficial by allowing for easier conversion from extremity or junctional tourniquets to an alternative means of hemorrhage control when needed to prevent ischemic damage from prolonged tourniquet use. XStat has not yet been studied for this potential mode of use.

The limited use of XStat to date is due to the recent introduction of this hemostatic adjunct into clinical use, the relatively high cost of first article production, the decreasing combat operational tempo for US Military forces at present, its limited availability, and the previous battlefield use restriction in the FDA clearance letter. The recent removal of the "battlefield only" restriction on XStat will allow for a much greater customer base by making XStat available for use in civilian trauma patients and potentially will lower the unit cost. Additionally, the relatively high pilot production costs of XStat may be mitigated significantly in the future through ongoing government-funded efforts to modify production techniques and to develop new device configurations to create a more economical product for military use.

Conclusions

XStat is a novel hemostatic adjunct composed of chitosan-coated compressed minisponges that expand when they come in contact with blood and absorb moisture. The expanding sponges, when confined within a cavitary wound, apply internal pressure to bleeding sites in the depths of the wound, as opposed to hemostatic dressings, which are designed and labeled for external use.

XStat has been designed and tested specifically in a highly lethal junctional bleeding model for penetrating injury that includes bleeding from both the subclavian artery and vein at the depth of a wound with a 4.5cm tract. The key properties that differentiate this hemostatic adjunct from other devices are as follows: (1) it is designed such that the wound would be, in effect, packed from the inside of the wound out, whereas hemostatic dressings are packed from the outside in; (2) the application time has been shown to be shorter than Combat Gauze; and (3) XStat does not require a 3-minute period of external manual pressure on the wound after application.

Based on the demonstrated ability of XStat to control severe bleeding from vascular injury sites located at the internal aspect of narrow-tract junctional wounds, this product offers an external hemorrhage control capability that may be more efficacious than Combat Gauze for these types of wounds. The Mueller[26] and the Cestero[7] studies have shown that XStat achieved 100% survival in subclavian vascular injuries, a wounding pattern that has been observed to be highly lethal in trauma patients. Furthermore, XStat may be a very valuable adjunct in treating axillary wounds, which is a junctional site that is relatively difficult to treat with the three current TCCC-approved junctional tourniquets.

XStat may also be a valuable adjunct in enabling conversion of both extremity and junctional tourniquets to other methods of hemorrhage control during casualty scenarios in which the casualty has not yet arrived at a military treatment facility with a surgical capability after 2 hours. This proposed use warrants further study.

PROPOSED CHANGE TO THE TCCC GUIDELINES

Current Wording

Tactical Field Care

4. Bleeding

b. For compressible hemorrhage not amenable to limb tourniquet use or as an adjunct to tourniquet removal, use Combat Gauze™ as the CoTCCC hemostatic dressing of choice. Celox Gauze and ChitoGauze may also be used if Combat Gauze™ is not available. Hemostatic dressings should be applied with at least 3 minutes of direct pressure. 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.

Tactical Evacuation Care

3. Bleeding

b. For compressible hemorrhage not amenable to limb tourniquet use or as an adjunct to tourniquet removal, use Combat Gauze™ as the CoTCCC hemostatic dressing of choice. Celox Gauze and ChitoGauze may also be used if Combat Gauze™ is not available. Hemostatic dressings should be applied with at least 3 minutes of direct pressure. 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.

Proposed Change

(New proposed material is in red text)

Tactical Field Care

4. Bleeding

b. For compressible 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.

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.

Tactical Evacuation Care

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b. For compressible 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:

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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.

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.

Vote

This proposed change to the TCCC Guidelines was approved by the required two-thirds or greater majority of the voting members of the CoTCCC.

Level of Evidence

The levels of evidence used by the American College of Cardiology and the American Heart Association were outlined by Tricoci in 2009[33]:

- 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 this taxonomy, the level of evidence for this change is Level C.

Recommendations for Further Research and Development

1. Evaluate XStat as a potential adjunct to allow for extremity and junctional tourniquet conversion. This would entail observation times of at least 6 hours and potentially as long as 72 hours if this product is intended to help medics meet the proposed prolonged field care goal of 72 hours of prehospital care.

2. Additional research should be conducted comparing XStat with both hemostatic dressings and junctional tourniquets in various large-animal bleeding models, including neck injury. This additional research should also include narrow-tract junctional wounds that approximate the width of the entrance tract from wounds from military assault rifles (both 5.56mm and 7.62mm) with severe bleeding in the depths of the wound tract.

3. If supported by the research findings, consideration should be given to approving XStat for use in neck wounds.

4. Some narrow-tract wounds may communicate with the thoracic or peritoneal spaces. What will happen if the XStat minisponges are inadvertently injected into these spaces? Research is needed to address this question.

5. A research project should be undertaken as a combined effort of the Joint Trauma System and the AFMES to identify all casualties, including those killed in action who are not entered in the DoD Trauma Registry, who sustained life-threatening hemorrhage from narrow-tract penetrating trauma. This effort should also note whether the wounds were amenable to treatment with limb tourniquets, hemostatic dressings, or junctional tourniquets, and whether these devices were used.

6. The Joint Trauma System Performance Improvement process should be used to identify all future casualties on whom XStat is used and how it performed. Additionally, the records of casualties who would have been good candidates for hemorrhage control with XStat (life-threatening hemorrhage from narrow-tract penetrating trauma not amenable to treatment with limb tourniquets, hemostatic dressings, or junctional tourniquets, or not responding to these treatment modalities), but for whom XStat was not used, should also be identified and reviewed for opportunities to improve.

7. Preliminary studies have shown that a chitosan-free version of XStat produces the same hemostatic efficacy with decreased cost. Follow-on research should include comparative studies using a chitosan-free XStat application.

8. A smaller-diameter applicator to facilitate XStat delivery to a narrower wound tract should also be evaluated. This also would potentially reduce the treatment cost and provide added capability to treat smaller entrance/wound tracts.

9. The Mueller and Cestero studies used only a 60-minute observation time. Further studies should include longer observation periods (4 hours and beyond) so that the utility of XStat for prolonged field-care scenarios may be evaluated.

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Disclaimer

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 Department of the Army or the Department of Defense. This recommendation is intended to be a guideline only and is not a substitute for clinical judgment.

Release

This document was reviewed by the Director of the Joint Trauma System and by the Public Affairs Office and the Operational Security Office at the US Army Institute of Surgical Research. It is approved for unlimited public release.

Disclosures

The authors have no disclosures.

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