# An Evidence-Based Review of the Use of a Combat Gauze (QuikClot) for Hemorrhage Control

***Brian T. Gegel, CRNA, DNAP***
***Paul N. Austin, CRNA, PhD***
***Arthur "Don" Johnson, RN, PhD, Col(ret), USAFR, NC***

*Trauma is a leading cause of morbidity and mortality. Uncontrolled hemorrhage related to the traumatic event is often the major cause of complications and death. The use of hemostatic agents may be one of the easiest and most effective methods of treating hemorrhage. The US military recommends a hemostatic combat gauze (QuikClot Combat Gauze) as the first-line hemostatic agent for use in treatment of severe hemorrhage. This review provides essential information for evidence-based use of this agent. The PICO (patient, intervention, comparison, outcome) question guiding this search for evidence was: Is QuikClot Combat Gauze, a hemostatic agent, effective and safe in controlling hemorrhage in trauma patients in the prehospital setting? The evidence appraised was a combination of lower-level human and animal research. It did not conclusively demonstrate that this combat gauze is an effective hemostatic agent for use in trauma patients, but the results are promising in supporting its use. The evidence does not describe serious side effects, exothermic reaction, and thromboemboli formation associated with other hemostatic agents. Further investigation to determine the effectiveness of hemostatic agents, specifically QuikClot Combat Gauze, in the management of trauma casualties in the prehospital setting is required. These should include large-scale, multicenter, prehospital randomized controlled trials.*

***Keywords:*** Combat gauze, hemorrhage control, hemostatic agent, trauma, QuikClot Combat Gauze.

Trauma represents a leading cause of morbidity and mortality. Uncontrolled hemorrhage related to the traumatic event is often the major cause of complications and death in these situations.[1-6] Substantial blood loss predisposes individuals to hypothermia, coagulopathy, acidosis, infection, and multiple organ failure.[1,2,7,8] These complications result in an increase in morbidity and mortality even after successful resuscitation.[1,2,7,8] Hypotension secondary to hemorrhage usually results, with deleterious consequences. Specifically, trauma patients with isolated systolic hypotension (< 90 mm Hg) have up to a 54% mortality rate.[8] Early control of hemorrhage and rapid hemostasis are essential not only for initial survival but also for optimal recovery.[9] It is of paramount importance for healthcare professionals to find and implement the most effective methods of managing hemorrhage.

The use of hemostatic agents may be one of the easiest and most effective methods of treating hemorrhage and preventing complications and death. Hemostatic agents were developed for first responders to control noncompressible hemorrhage in military and prehospital civilian settings. Certified Registered Nurse Anesthetists (CRNAs) are mission-essential anesthesia providers, who may be the most qualified healthcare professionals to control hemorrhage and initiate resuscitation in mass casualty situations. Although the role of the CRNA in military mass casualty situations is readily apparent, they may also play a key role in the civilian mass casualty setting. The CRNA must know the newest methods and agents used to control hemorrhage and also may direct the use of these agents as a part of the resuscitation effort.

## Background

Historically, 20% of combat casualties were killed in action. Ninety percent of those casualties never reached a field hospital. The major cause of death in this group was hemorrhage.[5] In Vietnam, almost 40% of soldiers who died of exsanguination had a source of hemorrhage that may have been controlled by hemostatic measures.[6] In the recent conflicts in Iraq and Afghanistan, uncontrolled hemorrhage accounts for almost 50% of the battlefield deaths before evacuation.[3] Hemorrhage remains the leading cause of death even when the individual survives long enough to be transported to a medical treatment facility.[10]

In 1996, the Committee on Tactical Combat Casualty Care (TCCC) was formed, setting the standard for management of combat casualties throughout the US military. According to the Committee on TCCC, the use of tourniquets is the standard of care for prehospital management of traumatic hemorrhage, whereas their use remains highly discouraged in the civilian trauma

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| Ability to rapidly stop large-vessel arterial and venous bleeding within 2 minutes through a pool of blood |
| No requirement for mixing or preapplication preparation |
| Simplicity of application by wounded victim, buddy, or medic |
| Lightweight and durable |
| Long shelf life: > 2 years in extreme environments |
| Safe to use with no risk of injury to tissues or transmission of infection |
| Inexpensive |

**Table 1.** Ideal Qualities of Prehospital Hemostatic Agents[13]

setting. Traumatic injuries may occur in anatomic locations where tourniquets cannot be used or employed effectively. Hemostatic agents have been developed to control hemorrhage in these areas. Also, the effectiveness of tourniquets may be improved, with reduced morbidity and mortality, if they are used in conjunction with these hemostatic agents.[11,12]

Pusateri et al[13] outlined the ideal qualities of hemostatic agents for civilian and military use (Table 1). The current hemostatic agents include zeolite, smectite, kaolin, chitosan, and plant-derived polysaccharides.[10,14-18] These hemostatic agents have been investigated in animal models. Investigations produced inconsistent and conflicting results regarding the effectiveness of hemostatic agents in controlling hemorrhage, which indicate the need for additional investigation.[10,13,17-23]

Two agents that were widely used by the US military, QuikClot (Z-Medica) and WoundStat (TraumaCure), have been removed from the inventory because of potential complications, specifically tissue injury to patient and provider and microemboli formation.[13,16,24] QuikClot is composed of zeolite and WoundStat is composed of smectite, and both are granular products.[13,16,24]

This review provides essential information for evidence-based use of a newer hemostatic agent, QuikClot Combat Gauze (Z-Medica). This agent is manufactured by the same company as QuikClot but contains a different hemostatic agent. QuikClot Combat Gauze is composed of a kaolin-impregnated rayon and polyester hemostatic dressing (Figure).[25]

## Materials and Methods

• ***The PICO Question.*** "PICO" is a common approach in evidence-based practice used to generate a well-built, clinically focused question from a specific patient scenario. It is a mnemonic describing the central components of focused question generation, with P indicating patient or problem being addressed; I, intervention or exposure being considered; C, comparison intervention or exposure when relevant; and O, clinical outcome.[26,27] The PICO question guiding this search for evidence was: Is the hemostatic agent QuikClot Combat Gauze effective and safe in controlling hemorrhage in trauma patients in the prehospital setting?


**Figure.** QuikClot Combat Gauze
(Permission obtained from manufacturer)

Hemostatic agents have evolved from first-generation granular or fine powders such as QuikClot, to second-generation wafers and sponges and to the newest generation of impregnated hemostatic dressings such as QuikClot Combat Gauze. The dressings are designed to simplify application and decrease complications. The Committee on TCCC recommends QuikClot Combat Gauze as the first-line hemostatic agent for treatment of severe hemorrhage.[11]

• ***Search Strategy.*** The search for evidence used the following approaches: online medical literature databases, ancestry approach, and informal networking. MEDLINE, PubMed, and The Cochrane Database of Systematic Reviews (2002 to December 2012) were searched for relevant evidence using the following search terms alone and in combination: *hemostatic agents, QuikClot, QuikClot Combat Gauze,* and *hemorrhage control*. Each reference list in located sources was examined for additional sources. Informal surveys of experts in prehospital care helped identify further resources. The strategy was revised in an ongoing fashion to optimize effectiveness and relevance.

The inclusion criteria were English-language evidence addressing the PICO question published in peer-reviewed journals in full text form, including evidence from both animal and human models. Evidence from lower-level case reports and case series was included because of the suspected lack of higher-level human evidence. Evidence using animal models was included because of the suspected small number of sources available involving humans related to the ethics involved in conducting human research with trauma patients in prehospital settings.

## Results

The search revealed 103 sources of evidence, with 11 meeting the inclusion criteria after review and removal of duplicates. All 8 randomized controlled trials

| Author | Subject No. | Model | Outcome | Comments and conclusion |
|---|---|---|---|---|
| Kheirabadi et al[28] (2009) | n = 38 | Femoral artery punch | **Survival**<br>SD: 20%, TS: 20% QCG: 80%[a]<br>**Blood loss**<br>SD: 75.5 mL/kg TS: 79.8 mL/kg QCG: 37.4 mL/kg | QCG was most effective hemostatic agent in this model.<br>It is recommended as the first line of treatment for life-threatening hemorrhage on the battlefield. |
| Kheirabadi et al[16] (2010) | n = 24 | Carotid artery and jugular vein transection | **Blood loss**<br>SD: 7.3 mL/kg QCG: 3.9 mL/kg[a] WS: 2.9 mL/kg[a]<br>**Vessel patency**<br>SD: 100% QCG: 100% WS: 12.5% carotid 25% jugular | Vessels treated with SD and QCG were patent and had no thrombus of any kind in the vessel lumen.<br>WS caused significant endothelial injury and transmural vessel damage. |
| Arnaud et al[29] (2011)[b] | n = 12 | Femoral artery and vein transection | **Survival**<br>TS: 100% QCG: 100%<br>**Blood loss**<br>TS: 1.3% EBV QCG: 0% EBV | QCG and TS effective in improving hemostasis. |
| | n = 16 | Femoral artery punch | **Survival**<br>TS: 50% QCG: 88%<br>**Blood loss**<br>TS: 31% EBV QCG: 19% EBV | |
| Schwartz et al[30] (2011) | n = 14 | Femoral artery punch | **Blood loss**<br>CG: 775 mL QCG: 1,225 mL<br>**Resuscitation fluid**<br>CG: colloid 786 mL, crystalloid 1,479 mL; QCG: colloid 807 mL, crystalloid 3,543 mL | Both CG and QCG effective in their hemostatic properties. |
| Watters et al[31] (2011) | n = 24 | Femoral artery punch | **Survival**<br>SD: 100% QCG: 100% XG: 100%<br>**Blood loss**<br>SD: 260 mL QCG: 374 mL XG: 204 mL<br>**Resuscitation fluid**<br>SD: 1,825 mL QCG: 2,000 mL XG: 1,170 mL | Advanced hemostatic dressings do not perform better than conventional in a care-under-fire scenario. |
| Mueller et al[32] (2012) | n = 16 | Subclavian artery and vein transection | **Survival**<br>MS: 100% QCG: 37.5%<br>**Blood loss**<br>MS: 118 mL[a] QCG: 1,242 mL<br>**Resuscitation fluid**<br>MS: 400 mL[a] QCG: 1,708 mL | MS provided statistically significant improvement in hemostasis and survival reducing blood loss and fluid resuscitation requirements compared to QCG. |
| Johnson et al[33] (2012) | n = 30 | Femoral artery and vein transection with 30% hemodilution | **Blood loss**<br>SD: 340 mL QCG: 36 mL[a] | QCG was clinically superior at controlling hemorrhage and produced a more robust clot that effectively tolerates hemodilution compared to control. |
| Johnson et al[34] (2012) | n = 22 | Femoral artery and vein transection with movement | **Blood loss**<br>SD: 351 mL QCG: 50 mL[a]<br>**Resuscitation fluid** (crystalloid)<br>SD: 209 mL QCG: 4,818 mL[a]<br>**Movement** (# of movements)<br>SD: 0.9 QCG: 36.6[a] | QCG is effective at hemorrhage control, provides greater latitude with fluid resuscitation, and produced a clot that can withstand movement without re-bleeding compared to control. |

**Table 2.** Summary of Animal (Porcine) Randomized Controlled Trials Examining QuikClot Combat Gauze (QCG)
Abbreviations: MS, Minisponge (Oregon Biomedical Engineering Institute); QCG, QuikClot Combat Gauze (Z-Medica); SD, standard dressing; TS, TraumaStat (Ore-Medix); WS, WoundStat (TraumaCure); XG, ChitoGauze (HemCon).
[a] Statistically significant ($P < .05$).
[b] Investigation used 2 methods of vascular injury.

(RCTs)[16,28-34] examining QuikClot Combat Gauze that met the inclusion criteria used an animal model. The remaining 3 sources found involved human subjects: 1 case series[35] and 2 case reports.[36,37] The evidence was appraised by the method proposed by Melynk and Fineout-Overholt[38] and is presented in Tables 2 and 3.

A systematic review was located comparing the relative efficacy and safety of available hemostatic agents relevant to prehospital emergency medical treatment but did not exclusively examine evidence investigating QuikClot

| Source | Evidence type and level[a] | No. of subjects | Outcome | Conclusion |
|---|---|---|---|---|
| Ran et al[35] 2010 | Case series Level 6 | 14 | Used during the Israel Defense Force operation in the Gaza Strip in 2009; success rate: 79% (11/14), with 93% (13/14) survival rate | QCG is effective, safe, and applicable for prehospital management of combat casualties. It should be issued to medics and advanced healthcare providers. |
| Patel et al[36] 2012 | Case report Level 6 | 1 | Successful hemostasis of vaginal venous hemorrhage after transobturator sling procedure | QCG may provide hemorrhage control and avoid the need for surgical intervention. |
| Fedor[37] 2012 | Case report Level 6 | 1 | Successful hemostasis of bleeding leech bite | QCG is a reasonable adjunct for treatment of bleeding leech bites. |

**Table 3.** Summary of Human Evidence Sources Examining QuikClot Combat Gauze (QCG)
[a]From Melynk and Fineout-Overholt[38] with levels of evidence ranging from level 1 (systematic reviews with or without a meta-analysis) to level 7 (opinion of authorities or reports of expert committees).

Combat Gauze.[39] It did not meet the inclusion criteria because it referenced only 1 RCT[28] investigating QuikClot Combat Gauze out of greater than 100 evidence sources. This RCT[28] was appraised separately in this review.

• ***Appraisal of RCTs Involving a Porcine Model.*** All the RCTs[16,28-34] examining QuikClot Combat Gauze used a porcine model (Table 2). There is evidence that swine provide an excellent model for investigating hemorrhagic shock and resuscitation because their cardiovascular anatomy and physiology are similar to humans.[40] The studies used different types of injury or hemorrhage models, and all varied in their methods, including splenectomy, unrestricted bleeding time, fluid resuscitation, endpoints, and outcomes. Common themes of these models were anatomic location, arterial, or arterial and venous hemorrhage. These included femoral artery punch,[28-31] femoral artery and vein transection,[29] femoral artery and vein transection with hemodilution,[33] femoral artery and vein transection with movement,[34] carotid artery and jugular vein transection,[16] and subclavian artery and vein transection.[32]

The RCT investigators examined multiple outcomes: survival,[28,29,31,32] blood loss,[16,28-34] resuscitation fluid amounts,[30-32,34] hemostasis with limb movement,[34] and vessel patency.[16] However, the outcomes were measured differently in individual studies. For example, survival was defined as up to 180 minutes in 2 studies[28,29] compared with 120 minutes[31] and 60 minutes[32] in other investigations. All investigators of the studies performed a power analysis to determine sample sizes and randomly assigned subjects to groups, but there was no blinding. Based on statistical analysis in the individual RCTs, the control and treatment groups were equivalent. In general, these studies were rigorously conducted, but comparison and/or meta-analysis would be difficult because of the heterogeneity in models and outcomes. Additionally, animal research generally provides low-level evidence, falling below editorials and expert opinion in the hierarchy of evidentiary relevance.[25]

• ***Appraisal of Case Series and Case Reports.*** A human case series[35] and 2 human case reports[36,37] investigating QuikClot Combat Gauze are described in Table 3. The case series[35] reported use of QuikClot Combat Gauzee during the Israel Defense Force experience in the Gaza Strip in 2009. Fourteen cases of QuikClot Combat Gauze use were reported and reviewed from 56 hemostatic interventions (42 tourniquets and 14 hemostatic dressings) in 35 human casualties. Data collection was accomplished by interviewing injured personnel and all associated medical providers. The authors acknowledged a possible recall bias and limited sample size. The case reports[36,37] detailed 2 uses of QuikClot Combat Gauze to control different types of hemorrhage.

Case reports and case series are prone to numerous types of bias, including recall and publication bias. The reported results in a given setting may not apply to other settings. The outcomes reported may not be fully related to interventions because of a lack of control of potential confounding factors. Lastly, professional journal publication favors positive outcomes and results.[26]

## Discussion

The evidence addressing the effectiveness of QuikClot Combat Gauze is a combination of human and animal research. Each evidence source contained limitations. The human research was low-level evidence with the potential for bias and lacked generalizability. The evidence using animal models investigating QuikClot Combat Gauze were all RCTs, but it falls lower than the human evidence in the evidence hierarchy.[25]

• ***Comparison of QuikClot Combat Gauze With Other Hemostatic Agents.*** All of the evidence from RCTs involved a swine model, multiple injury/hemorrhage models, investigated different outcomes, and produced mixed results (see Table 2).[16,28-34] QuikClot Combat Gauze was found to be an effective hemostatic agent, with 6 studies[16,28-30,33,34] reporting increased survival and/or decreased blood loss in different hemorrhage

models. Furthermore, QuikClot Combat Gauze allowed more effective fluid resuscitation and produced a stronger clot withstanding movement compared with control interventions.[34] However, an investigational hemostatic dressing composed of expanding minisponge technology from Oregon Biomedical Engineering Institute was statistically and clinically superior to QuikClot Combat Gauze. The expanding minisponge demonstrated improved hemostasis and survival, reducing blood loss and fluid resuscitation requirements.[32] Moreover, investigators reported that advanced hemostatic dressings including QuikClot Combat Gauze do not perform better than conventional wound management in care-under-fire scenarios.[31]

• ***Reports of Using QuikClot Combat Gauze in Humans.*** There are limited data and higher quality evidence demonstrating the effectiveness of QuikClot Combat Gauze in humans (Table 3). There are no systematic reviews with or without meta-analyses or RCTs examining hemostatic agent use or QuikClot Combat Gauze in the control of hemorrhage in humans. The only human studies investigating QuikClot Combat Gauze are a case series[35] and 2 case reports.[36,37] Ran et al[35] reported 14 uses of QuikClot Combat Gauze with a 79% (11/14) success rate and a 93% survival rate during the Israel Defense Force experience in the Gaza Strip in 2009. QuikClot Combat Gauze was applied to the head, neck, axilla, buttocks, abdomen, back, pelvis, and extremities, with 3 failures attributed to severe soft-tissue and vascular injuries. Injuries were caused by blast or penetrating (gunshot) mechanisms in 13 (93%) of 14 cases. The 2 case reports detailed successful hemostasis after QuikClot Combat Gauze was applied because of vaginal hemorrhage[36] or a bleeding leech bite.[37]

## Conclusion

The current evidence appraised for this review was a combination of findings from research using a porcine model[16,28-34] and from lower-level human research.[35-37] The evidence did not conclusively demonstrate that QuikClot Combat Gauze is an effective hemostatic agent for use in trauma patients, but the results were promising in supporting QuikClot Combat Gauze. In addition, the evidence did not describe serious side effects such as exothermic reactions with resulting tissue injury and thromboemboli formation associated with the earlier granular hemostatic agents (QuikClot containing zeolite and WoundStat containing smectite).[13,16,24]

Further investigation is required to determine the effectiveness of hemostatic agents, specifically QuikClot Combat Gauze, in the management of trauma casualties in the prehospital setting. These studies are particularly warranted because QuikClot Combat Gauze is recommended by the Committee on TCCC.[11] This research should include higher-level human studies such as large-scale, multicenter, prehospital RCTs. Such prehospital studies are difficult to conduct for ethical reasons, such as difficulty in obtaining informed consent. With proper safeguards and procedures, it is possible to conduct these important investigations.[41]

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## AUTHORS

Brian T. Gegel, CRNA, DNAP, is the owner of Veteran Anesthesia Services PLLC. At the time this article was written, he was a doctoral student at Texas Wesleyan University, Fort Worth, Texas, in the Doctorate of Nurse Anesthesia Practice Program and associate investigator with the Geneva Foundation. Email: bgegel@msn.com.

Paul N. Austin, CRNA, PhD, is a professor in the Doctorate of Nurse Anesthesia Practice Program at Texas Wesleyan University. Email: paustin@txwes.edu.

Arthur "Don" Johnson, RN, PhD, Col(ret), USAFR, NC, is a professor and director of research, US Army Graduate Program in Anesthesia Nursing, San Antonio, Texas, and Northeastern University, Boston, Massachusetts. Email: Arthur.don.johnson@amedd.army.mil.

## DISCLOSURE

The authors have no commercial associations that may pose a conflict of interest in connection with this work.

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The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the Army, Department of Defense, or the US Government.

## Author's Correction

An error appeared in the October 2013 *AANA Journal* article titled "A Review of the Evidence for Active Preoperative Warming of Adults Undergoing General Anesthesia." In the table on page 353 in the "Findings" column *post*operative forced air warming is mentioned repeatedly. Each mention should be of *pre*operative forced air warming. The online version of the article has been corrected.