

QuikClot Use in Trauma for Hemorrhage Control: Case Series of 103 Documented Uses

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Background: Local hemostatics have recently been introduced for field use to control external hemorrhage. The objective of this report is to describe the initial clinical experience with QuikClot, a zeolite that works by absorbing water and concentrating coagulation factors to stop bleeding in a series of patients.

Methods: Documented cases using a self-reporting survey sheet submitted by the users and first-hand detailed interviews with the users when possible.

Results: There were 103 documented cases of QuikClot use: 69 by the US military in Iraq, 20 by civilian trauma sur-

geons and 14 by civilian first responders. There were 83 cases involving application to external wounds and 20 cases of intracorporeal use by military and civilian surgeons. All field applications by first responders were successful in controlling hemorrhage. The overall efficacy rate was 92% with eight cases of ineffectiveness noted by physicians in morbid patients with massive injuries when the QuikClot was used as a last resort. These reported failures were thought to be a result of the coagulopathic state of the patient from massive resuscitation or the inability to get the product directly to the source of

hemorrhage. When the QuikClot was applied on responsive patients, the heat generated by the exothermic reaction caused mild to severe pain and discomfort. There were three cases of burns caused by the heat generated by the QuikClot application with one case requiring skin grafting. There was one major complication from intracorporeal use caused by scar formation from a foreign body reaction.

Conclusions: QuikClot has been effectively used by a wide range of providers in the field and hospital to control hemorrhage.

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Whether in the field and or the hospital, expedient hemorrhage control is of paramount importance in management of trauma. The US military has recently developed and tested a number of local hemostatic agents designed to facilitate rapid hemorrhage control.^{1,2} One of these products, approved by the Food and Drug Administration (FDA) for external use and distributed for use in the battlefield the US military is a manufactured granular mineral zeolite called QuikClot.^{3,4} This inert mineral product composed of oxides of silicon, aluminum, sodium, and magnesium and small amounts of quartz. It acts as molecular sieve

and rapidly adsorbs water in a nonchemical, physical reaction. Although this process generates heat, the primary mechanism effecting hemostasis is caused by the absorption of water and the rapid concentration of platelets and clotting factors⁵ that promotes rapid clot formation. Although this product is being sold and distributed, its clinical use and efficacy has not yet been reported in a case series. This report describes the first 103 documented clinical use of this local hemostat.

METHODS

The data for this report were generated by summarizing case reports (Fig. 1) that were submitted by the users of QuikClot or by direct interviews with users. The survey forms were distributed to individuals that reported use to the manufacturer and through “word of mouth”. Personal interviews were conducted by the reporting author (P.R.) with the users who filled out the survey sheets to obtain details of its use when possible. Approximately 75% of the users who filled out the surveys were contacted to discuss the cases. Approximately 30 other known case reports were available at the time of this report, but they were neither confirmable nor documented and thus not used for this report. The uses of QuikClot were not under any study or study protocol. There were cases collected from Los Angeles County Medical Center and the summation of the data from this hospital was with the approval by the institutional review board.

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QuikClot[®] Brand Hemostatic Agent Evaluation Sheet

Evaluator Information
 Name & Rank: On File
 Company/Organization:
 City, State, Zip, Country: 10th Mountain Div.
 Phone: DSN 318-231-2411 Email: 1 Date of Use: 18Mar06

Description of Injury
 Location on Body: R. lower leg and R. inner thigh
 Size and Shape: R. Lower Leg = severed limb, and inner thigh = laceration 6 inches
 Arterial, Venous, Capillary, Unknown: R. Lower was Arterial and venous and Inner thigh was Arterial
 Source/ Cause of Wound: Mine Blast

Treatment Prior to the Use of QuikClot[®] Hemostat
 Length of time between injury and initial treatment: unk.
 Treatment attempted before QuikClot[®] hemostat: Tourniquete and pressure dressing
 Result of treatment: Used quick clot asap on inner thigh wound due to amount of bleeding. And used QC on stump for further action in assuring bleeding stopped.

Additional Information / Comments:
 I have seen the video of the pig and was blown away at the quick possitive results of the instant halt of bleeding. Just awsome.

Application of QuikClot[®] Hemostat
 Estimate blood pressure at time of application: 90/26
 Describe application of QuikClot[®] Hemostat: Wiped wound clear to I.D. blood source and used approx. 1/3 - 1/2 of the bag to staop the bleeding.
 Wipe away blood first? Yes
 Amount used: 1/3 - 1/2
 Action immediately after application: dropped my jaw in complete amazment and then applied an two 4x4's and then an Isreali pressure dressing
 Degree to which QuikClot[®] hemostat controlled bleeding:
 Time to control: 3-5 seconds. And viewed no blood through the top layer of QC applied to the wound.
 Estimated blood pressure after application: Keep in mind I also admin. I.M. 4 mg of Morphine. And yes I know that I should have done a slow push through the I.V.

Fluid Resuscitation
 Previous to or Following QuikClot[®] Hemostat Application: 500 ml of Hetastarch 6% followed by 2,000 ml of Ringers.
 Effect, if any: yes eleviated B/P to approx 100/40

Follow Up
 Follow up done: None
 Complications: Unknown
 Benefits: Hopefully a man gets home to his kids soon because of QC

Overall Evaluation
 Did QuikClot[®] Hemostat improve outcome? Most definetly
 Would you use QuikClot[®] Hemostat again? Yes very much so
 Additional Information/ Comments: It would be a shame to EVER see this item fall to the wayside do to negative press or some arrogant surgeons oppinion that it cause to much additional work on there behalf to repair the injury in a whole. Sorry for the negetivity I just really believe in the possotive effects of this product and will continue to be more than passionate about my feelings for this product. It has given me more confidence in what tools I have available to me and that I can honestly look a wounded soldier in his eyes and say don't worry brother I wont let you down. You will make it home alive. Please do everything in your powers to keep this in our militarys inventory. Again thank you for enabling me to provide a human the basic right to live and to someday be able to function in life once again. US Army Combat Medic and Ranger

Fig. 1. Self-reporting survey sheet. Typical report that was submitted.

Table 1 User Data

Type of Provider	No. Times Used	Reported Efficacy for Hemorrhage Control
Civilian	34	
Non medical layperson	1	1/1
Police	8	8/8
Civilian EMT/Fire fighter	5	5/5
Trauma surgeons	20	16/20
Military—Operation Iraqi Freedom	69	
Casualty self use	2	2/2
Medic/corpsman	36	36/36
Medical officer	31	27/31
Total	103	95/103

RESULTS

The documented users of the QuikClot as a local hemostatic agent included US military and civilian personnel. US military users were first responders (US Army medics and US Navy corpsman), as well as medical officers who used QuikClot during the war in Iraq (Operation Iraqi Freedom). Civilian users were police officers, paramedics, laypersons, and trauma surgeons. The users and their frequency of QuikClot use are shown in Table 1.

The location of QuikClot application was both external and intracorporeal as shown on Table 2. Many had multiple applications and these instances occurred in Iraq by military first responders. The locations of the QuikClot application were quite varied. Most of the locations were on external extremity wounds. The majority of its use in the extremity was after ineffectiveness of direct pressure or tourniquet use.

QuikClot was also applied to areas that tourniquets could not be applied to such as the chest wall, back, abdominal wall, groin, buttocks, and shoulder. An example of this scenario was an injury to the proximal upper arm. On arrival to a surgical facility, the casualty was hypotensive and was taken to the operating room. The casualty had a subclavian artery and vein injury, but there were other multiple bleeding sites including the pectoralis, deltoid, and upper arm muscles (Fig. 2). QuikClot was applied to control the bleeding from the various sites to allow the surgeons to quickly obtain surgical control of the subclavian artery that was repaired. Reports of use in the head and neck region included use for severe scalp lacerations as well as neck and face. One case of use in the face included a sailor who was struck by a rotor blade from a helicopter causing multiple injuries (Fig. 3). An



Fig. 2. Casualty with injury to the right shoulder region.



Fig. 3. QuikClot use on the face of a sailor who sustained lacerations to face and extremities from a helicopter rotor.

independent duty Navy corpsman applied QuikClot to the face and extremity injuries and transported the patient to a casualty receiving and treatment ship where a surgeon was available. The treating surgeon stated that he thought the QuikClot was effective in controlling the bleeding and was lifesaving. Civilian examples include the use of QuikClot by a fireman to treat the bleeding site of a hemodialysis catheter that was accidentally pulled out and a police officer who applied it to the neck of a self-inflicted slash wound.

Blunt civilian trauma was the mechanism on eight cases and five of these patient uses were for severe scalp lacerations. The remaining three injuries from blunt trauma were the avulsion site of a left diaphragm from the chest wall, blunt liver laceration, and a major laceration of the groin with femoral neck and pelvic fracture after being stuck by a train. The mechanism of injury and effectiveness of QuikClot are shown in Table 3. There were 22 cases of blast injury from artillery or improvised explosive devices. The remaining 73 indications were from penetrating trauma. The penetrating trauma cases were mostly military-related injuries including high-velocity gunshot wounds and penetrating fragmentation injury. Five of the penetrating injuries were from lacerations caused by knife wounds.

Table 2 Locations of Use

	No. Times Used
Head/scalp/neck	12
Upper or lower extremity	61
Chest/Upper back	16
Abdomen/back/buttocks/pelvis/groin	18
Intra corporeal (chest, abdomen, pelvis)	20

Some patients had multiple uses.

Table 3 Effectiveness by Mechanism

Mechanism	Reported Efficacy for Hemorrhage Control
Blunt trauma	6/8
Blast (artillery, rockets, improvised explosive devices)	21/22
Penetrating	
Stab wound	3/5
Gunshot wounds	65/68

In the military field setting, pressure dressings were attempted first, and when they failed, tourniquet use was attempted on extremities when possible. The current instruction for use in the combat battlefield is for external source of hemorrhage that is life threatening and uncontrolled by all other means. After ineffectiveness of these measures, QuikClot was to be used. When QuikClot was initially distributed widely to marines and corpsmen, the instructions for use were on the package. The users included Army medics and Navy corpsman as well as medical officers. The medical officers were either emergency medicine physicians attached to a forward echelon I facility or general surgeons at a forward resuscitation surgical facility. The experience from the field medic or corpsman was different from medical officers. The field medic or corpsman experience was universally positive, and they all described 100% efficacy. Approximately 25% of this type of use reported concomitant mild to severe pain and discomfort associated with the exothermic reaction from QuikClot if the casualty was responsive. None of the medics or corpsmen thought that QuikClot caused additional injury. They also universally thought that QuikClot was helpful and that if they were to deploy again, they would definitely use it again.

The reports from the medical officers and trauma surgeons were different from those of the medics and corpsman as ineffectiveness to control hemorrhage was noted (Table 4). The reasons for ineffectiveness of hemorrhage control were universally thought to be a result of coagulopathy from hemorrhage and resuscitation or because QuikClot was not adequately delivered directly to the source of hemorrhage such as acetabular or pelvic fractures. Six of the eight patients in

Table 4 Ineffectiveness of QuikClot to Control Hemorrhage

Location of Hemorrhage	Mechanism
Clavicular wound	High-velocity firearm
Acetabular/femoral fracture*	High-velocity firearm
Thoracoabdominal	High-velocity firearm
Groin wound	High-velocity firearm
Sternum	Stab wound
Chest wall	Stab wound
Proximal shoulder	Blast injury
Acetabular and pelvic fracture	Struck by train

* QuikClot Advanced Clotting Sponge.

Table 5 Intracorporeal Use

Location	Reported Efficacy for Hemorrhage Control
Thoracic	9/11
Chest wall	7/8
Thoracic spine	2/2
Sternum	0/1
Abdominal	8/9
Liver	0/1
Flank/psoas muscle	5/5
Pelvis	3/3

which QuikClot failed to control bleeding were in a moribund state and died.

Information regarding hypotension from bleeding was available on 80% of the reports and in these patients 85% were "hypotensive" indicating possible life-threatening hemorrhage. Intracorporeal uses numbered 20 (Table 5) and included the thorax, abdomen, and pelvis. The intracorporeal uses were all by trauma surgeons (Los Angeles County Medical Center/Massachusetts General Hospital), and in four cases, it was used in Iraq at a forward resuscitation surgical site. Intra-abdominal uses were for abdominal wall or retroperitoneal bleeding and pelvic bleeding, but in one instance, it was for severe liver bleeding in a moribund coagulopathic patient who died.

There were four documented complications in these series. There were three burn cases and one of these cases required further wound care that included split thickness skin grafting. The other two cases were mild partial thickness burns that did not require any further wound management and healed spontaneously (Fig. 4). In one instance, QuikClot was placed into the retroperitoneum after a civilian gunshot wound to the back. This patient returned several months later with ureteral obstruction caused by scar formation that may have been caused by the foreign body reaction from Quik-



Fig. 4. QuikClot application to a wound in the sacral region with partial thickness burn to the anal region. This wound only required skin care.

Clot. This patient required resection of the ureter and a psoas hitch procure.

DISCUSSION

This is the first reported series of (QuikClot) use in humans to control bleeding. The field use by first responders, whether it was in the civilian setting or in the combat setting, was 100% effective. The military field experience was from either US Army medics or US Navy corpsman supporting the efforts in the Iraq War. Most uses were in extremities in hypotensive casualties, and all thought that QuikClot was used in life-threatening injuries. Overall, the efficacy was 92% but was caused by the ineffectiveness noted by Medical Officers in the field and by trauma surgeons. These ineffective cases were in coagulopathic moribund patients who had application of QuikClot as a last resort. The main reason for the ineffectiveness seemed to have occurred when QuikClot could not be applied to the main source of hemorrhage.

The US military is continually searching for the ideal local hemostatic agent that will control bleeding in the field. Continued research is ongoing to further enhance the currently available products as well as testing many other products. Although many products have been tested, to date there are only two FDA-approved devices at the time of this report that are distributed for use in the battlefield. These products are a chitosan-based dressing (Hemcon) and QuikClot. The US Army currently distributes Hemcon and the US Navy and Marines distribute QuikClot. Each service has a separate process for choosing and distributing local hemostatics. The current recommendation for using QuikClot by the US Navy is for life-threatening external hemorrhage that is not controllable by routine means.⁶ The Committee for Tactical Combat Casualty Care comprising the four services (US Army, Navy, Air force, Coast Guard) currently recommends the use of a pressure dressing, and if this does not control the bleeding, it recommends to escalate to using Hemcon or QuikClot. This guideline can be found in the military module section of the prehospital trauma life-support course.

QuikClot was tested by the US Navy in a porcine model of severe hemorrhage, which uses a large soft tissue injury to the groin of a swine, resulting in bleeding from the femoral artery and vein. In this model, QuikClot was found to be the most highly effective method for controlling bleeding and resulted in reduced mortality. This and several other studies have demonstrated its benefits and potential problems. Although seemingly effective in animal models, the main problem is the exothermic reaction that is caused by the QuikClot and this is a potential for tissue injury. There are other negative attributes of this product that include the fact that the reported version of QuikClot is granular and is similar to pouring a coarse sandy material in the wounds. Although this product is sterile, it can be problematic as it is difficult to extract all of the QuikClot out of the wounds and it will cause a foreign body reaction. QuikClot is now available in a bag format so the granules do not freely distribute in the wound



Fig. 5. Pelvic roentgenogram of high-velocity gunshot wound to the femoral head. Bagged QuikClot was applied but failed because of bony bleeding from the fractures.

(QuikClot Advanced Clotting Sponge). One of the cases in this series includes the use of this product, but it failed to control hemorrhage. The reason for its ineffectiveness to control hemorrhage was a result of the inability to get the Advanced Clotting Sponge directly to the source of hemorrhage that was from the acetabular and femoral neck fracture caused by a high-velocity firearm (Fig. 5). QuikClot 1st Response is also a bagged zeolite that has been reengineered to remain effective while reducing the exothermic reaction and in vivo experiments have shown the maximal temperature to be only 105°F.⁷

The use of improvised explosive devices in the military setting results in massive tissue loss and contamination (Fig. 6). In most circumstances, and the additional contamination caused by QuikClot was thought to be a minor overall factor. These injuries are usually irrigated and debrided multiple times and the wounds are usually left open, so the inability to completely remove all of the residual QuikClot has not yet been reported to be a major problem. The negative aspects of this product are real, but if exsanguination is the alternative, it may be the lesser of the two evils.

The civilian field experience was reported by various providers including law enforcement, Emergency Medical Technicians or Paramedics, and firemen. Examples of their use include application for lacerations from knives, barbed wire fence, glass windows, gunshot wounds to the neck and a hemodialysis catheter dislodgment. In all of these cases, QuikClot was thought to be completely effective in hemorrhage control. The training and medical experience of this group is unknown but it is probably limited in regards to hemorrhage control. From the description of these uses it was not possible to exactly quantify the amount of hemorrhage, but all the reports stated that the bleeding was massive and

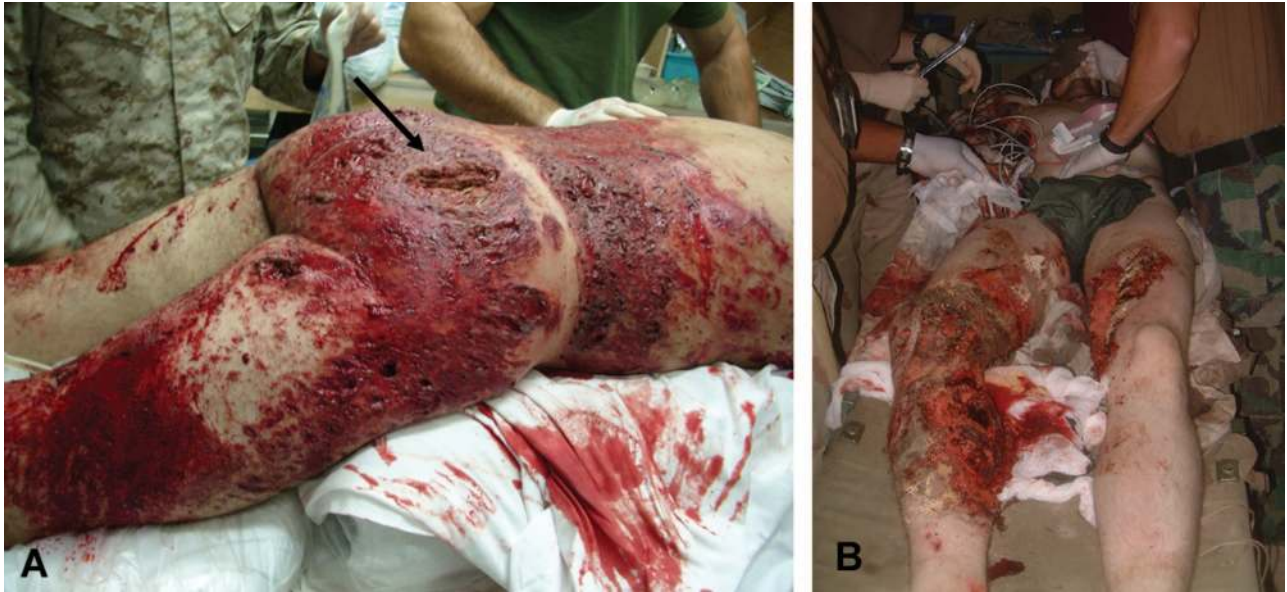


Fig. 6. Type of severe wounds caused by improvised explosive devices with massive contamination. A, arrow points to the deep wound that had QuikClot application. B, type of wound that QuikClot was used in.

the hemorrhage control was “lifesaving”. It is easily arguable that not all these cases needed QuikClot for hemorrhage control such as in the case of the hemodialysis catheter dislodgment.

Although QuikClot is only approved for external use by the FDA and is only recommended for external use by the manufacturer, there were 20 cases of intracorporeal use of QuikClot. The majority of intracorporeal uses were at Los Angeles County Medical Center by various trauma surgeons. These cases included use in the chest, abdomen, and pelvis. These uses were “off label” and not used in a study protocol. One of the intrathoracic uses has been previously reported in literature.⁸ Intrathoracic use in this series includes similar applications by Navy surgeons in forward surgical system where uncontrolled bleeding was from a thoracic spine and chest wall injury that was refractory to all other surgical means. This casualty was paralyzed from the initial wounding but survived and did well without complications from the intracorporeal use of QuikClot. An example of its use in civilian blunt trauma was an intrathoracic application for persistent chest wall bleeding from a large avulsion of the right diaphragm with liver herniation. Despite all conventional means to control diffuse bleeding, the area of avulsion had persistent bleeding. On the third operation within the first 24 hours of admission for persistent bleeding, the bleeding was finally stopped only with the QuikClot application. Another example of intrathoracic use was the successful application of QuikClot to the uncontrollable chest wall or sternal bleeding from a gunshot wound. Interestingly, this patient also had persistent bleeding from a distal coronary laceration. Hemcon, a local hemostatic that is not exothermic was applied to the coronary arterial bleeding. This case illustrates

appropriate uses of different local hemostatics in different situations.

Abdominal uses were for gunshot wounds that resulted in uncontrollable gunshot tract bleeding in the retroperitoneal region or pelvis. In three cases, patients bled after an exploratory celiotomy and persistent rebleeding from the gunshot wound tract in the psoas muscle. These wounds were effectively treated with QuikClot. In these cases. After all other conventional measures such as (electrocautery, gelfoam with thrombin, lap sponge packing) failed, QuikClot stopped the bleeding during the second operation. None of these patients developed infectious complications even when there was hollow viscous contamination.

There were eight reported ineffective uses of QuikClot to control bleeding. In each scenario, the patients were hemodiluted, coagulopathic, and moribund. Because the mechanism of action relies on concentration of innate coagulation factors in blood, it is not surprising that QuikClot was not effective in these circumstances. It is also important to note that in the cases when QuikClot was ineffective, it was because the wounds were of a nature such that it was difficult getting product directly on the source of bleeding. This is not necessarily an ineffectiveness of the product, as it cannot be expected to work unless the product is properly delivered to the source of hemorrhage.

The long-term complications are not fully known from this type of report. There is one known casualty that required split thickness skin grafting. Two other superficial burns have been recorded, but they did not require any other therapy. In these types of injuries, the application of a sterile granular substance would probably be inconsequential given the fact that there is severe contamination. In approximately four

cases where QuikClot was used for avulsion type lacerations in the scalp, these wounds were irrigated out and suture repaired. Although the bleeding was completely controlled, upon irrigation and removal of the QuikClot granules, the scalp lacerations began to bleed. This suggests that QuikClot did not cause third-degree burns. These wounds did have long-term follow-up and no complications attributable to QuikClot were noted.

There is one known case of a serious complication from QuikClot use. It was used in the pelvis for uncontrollable hemorrhage from the sacroiliac joint resulting from a gunshot wound. After ligation of the iliac vein the gunshot wound tract had persistent bleeding despite all other conventional means to stop bleeding. The application of QuikClot immediately stopped the bleeding. Long-term follow-up on this patient demonstrated ureteral obstruction 2 months after the initial treatment, and on subsequent surgery, it was found that the intense foreign body reaction caused scar formation obstructing the ureter. A psoas hitch to the bladder was performed to remedy this complication.

It is important to note that this case series is an accumulation of reports submitted by users and thus is not probably representative of its true use, efficacy, or complications. It has to be assumed that as with most new products introduced, most users are willing to provide success stories and it will take time for the reports of ineffectiveness and complications to be accumulated. This report may generate those reports of ineffectiveness. The difference in the ineffectiveness between first responders and physicians is caused by either a “threshold effect” as the corpsman and medics were probably more eager to use in less severe injuries and may also be a result of physicians waiting too long before its use. Because the product is approved by the FDA and readily available for commercial use, it is exceedingly difficult to obtain reports of each use whether it is in the civilian sector or the military setting. Currently, there are no means to completely collect all experiences of this new device.

In summary, this report is the first series of the clinical experience using QuikClot in humans. The overall efficacy

was 92% but the field experience by various providers was 100%. The QuikClot is approved for use on uncontrolled external hemorrhage but there have been 20 cases of intracorporeal use for uncontrollable life-threatening hemorrhage that was not amendable to conventional therapy. Ineffectiveness of QuikClot has been reported in coagulopathic patients where it was thought that QuikClot could not be applied directly to the bleeding source. Although some complications have been reported, its ultimate complication rate is not yet fully known. As with any tool available for medical use, there are appropriate circumstances where it is useful and circumstances where it is not. Obtaining training before use would be preferred whenever possible.

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