

Original Article

Assessment of users to control simulated junctional hemorrhage with the combat ready clamp (CRoC™)

Elizabeth A Mann-Salinas, John F Kragh Jr, Michael A Dubick, David G Baer, Lorne H Blackbourne

US Army Institute of Surgical Research, San Antonio, TX

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Abstract: The Combat Ready Clamp (CRoC™) was designed to control hemorrhage from the groin region, on the battlefield. The purpose of this experiment was to determine whether CRoC™ user performance varied by the surface the casualty laid on (flat-hard, flat-soft, and curved-soft) and how quickly the device could be applied. The commercial manikin selected to assess user performance was designed to train soldiers in CRoC™ use. The manikin simulated severe hemorrhage from an inguinal wound, controllable by correct use of the CRoC™. Each individual (n = 6) performed 3 iterations on each of the 3 surfaces (54 iterations total). The CRoC™ achieved hemorrhage control 100% of the time (54/54). Patient surface affected time to stop bleeding. The flat-soft surface (padded, 55 ± 9.7 seconds) was significantly different from the curved-soft surface (litter, 65 ± 16.5 seconds) and had the lowest overall total time (p = 0.007); time for the hard-flat surface was 58 ± 9.5 seconds. Users were trained to use the Combat Ready Clamp effectively, and the surface the casualty was lying on made some difference to user performance. All six persons trained had success in all nine of their iterations of CRoC™ use – a 100% rate. These findings indicate that training was effective and that training of other users is plausible, feasible, and practical within the scope of the present evidence.

Keywords: Tourniquets, hemorrhage, human patient simulation

Introduction

The leading cause of potentially preventable death on the battlefield is hemorrhage [1]. Effective use of extremity tourniquets has increased survival in combat casualties, yet truncal bleeding remains a common cause of death [2]. Body areas too proximal for regular tourniquets, those areas at the junction of the trunk and appendages, are in need of junctional hemorrhage control [3]. Junctional tourniquets, such as the Combat Ready Clamp (CRoC™, Combat Medical Systems, Fayetteville, NC) have been designed to control junctional bleeding [2]. The Combat Ready Clamp has been used on the battlefield to save a life of a war casualty with a traumatic hindquarter amputation after an explosion [4].

The CRoC™ (**Figure 1**) was specifically designed to control difficult inguinal bleeding on the battlefield. By compressing the femoral artery in

the inguinal or groin area, the CRoC™ can control distal bleeding for high traumatic amputations as regular tourniquets cannot fit [2-4]. The CRoC™ has been studied in pigs and in human cadaver models to stop inguinal hemorrhage [5, 6]. A case report of human use has been published [4], yet assessment of multiple-user performance in realistic scenarios remains to be evaluated. The CRoC™ would be used mainly on three different surface types: hard and flat like a floor or the ground, soft and flat like a hospital bed or a gurney, and soft and curved like a litter in medical evacuation. Human patient simulation (HPS) permits standardized evaluation of device users in combat-like scenarios [7]. The purpose of this experiment was to determine whether CRoC™ user performance to stop simulated bleeding varied by casualty positioning surface; in addition, we assessed time to control bleeding and some indices of device safety.

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Assessment of combat ready clamp

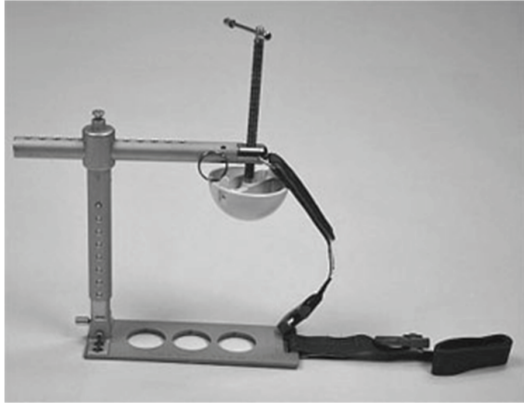


Figure 1. Combat Ready Clamp (CRoC™).



Figure 2. Supine manikin on hard surface with simulated bleeding during Combat Ready Clamp (CRoC™) assembly.

Methods

The experiment was conducted in the San Antonio Military Medical Center (SAMMC) Simulation Center. The study was conducted in accordance with a protocol approved by the US Army Medical Research and Materiel Command institutional review board.

The CRoC™ is a collapsible, lightweight, low cube device designed specifically to control difficult bleeding in the inguinal region via compression of large vessels. It is composed of lightweight metal with a rounded plastic disc to apply directed pressure over the femoral artery (**Figure 1**). A safety strap is attached to secure the device around the torso.

The CRoC™ users were six experienced medical researchers trained in CRoC™ use; five of

the six users were also healthcare providers. Each of the six users performed three iterations on each of the three surfaces mentioned below (54 iterations total). When not using the CRoC™, study personnel acted as timekeeper, observer, or manikin manager.

The manikin used was a custom-made physical simulator composed of viscoelastic artificial tissues, weighed approximately 150 pounds, and was developed specifically to simulate bleeding from the groin region to evaluate performance of the CRoC™ device (Operative Experience, Kennedyville, MD). The 5-liter bladder provided artificial blood loss from a simulated proximal right thigh through-and-through high-velocity gunshot wound to the right common femoral artery. The severe hemorrhage from the simulated wound was controllable by correct use of the CRoC™.

Manikin preparation included 1) infusion of simulated blood (4,000 ml of tap water, 60 ml of rubbing alcohol, 30 ml of simulated blood to tint the water) into the CRoC™'s bladder according to the manufacturer's recommendations; 2) re-infusion of 1,000 ml of simulated blood for every 1,000 ml of simulated blood loss during the experiment in order to maintain an adequate bladder pressure; 3) placement of a plastic drainage board under the manikin to collect blood from the thigh wounds into a bucket (**Figure 2**).

The CRoC™ device was placed adjacent to the manikin as stowed by combat medics, as follows: 1) The vertical arm was assembled from its two tubular parts, its horizontal arm receiver working end slid to shorten the arm maximally with pin engaged in last hole, and the vertical arm was folded down to the base plate. 2) The strap clip was extended to within 4 inches of the strap end. 3) All device components were bundled and over-wrapped by the strap. 4) The device was placed on the flat surface adjacent to the manikin and was in this configuration for every iteration of the experiment.

Three surfaces were used: 1) a hard, flat surface (metal table) on which the manikin lay with the drainage board underneath; 2) a soft, flat surface (mattress on a hospital gurney) with a plastic sheet under the manikin to collect blood loss; and 3) a soft, curved surface (standard NATO litter with a mesh fabric suspended

between the two side handle-rods. The litter was placed on the metal table so blood loss drained through mesh onto the drainage board and into the bucket).

The primary outcome of the experiment was effectiveness (simulated hemorrhage stops: Yes or No) of CRoC™ use on the three surfaces. There were three secondary outcomes. The first outcome was time to effectiveness (sum of individual steps: time to assemble the CRoC™, time to position and target, and time to stop hemorrhage, in seconds). The second outcome was estimated blood volume loss (in milliliters). The third outcome was related to safety, measured by (a) correct assembly (yes or no); (b) clip secure (yes or no); (c) slack in the strap (present or absent); (d) device breakage (yes or no); (e) distance of vertical arm offset from the torso (centimeters); (f) over-tightening (number of 180° turns upon device removal when bleeding recurred).

Time was measured with a stopwatch and three periods were calculated. Period 1 was CRoC™ assembly, the span from device pickup to completion of assembly. Period 2 was CRoC™ targeting, the span from completion of assembly to placement on the correct target point. Period 3 was bleeding stoppage, the span from targeting to bleeding stopped. The overall time was the span from device pickup to bleeding stopped, the sum of periods 1, 2, and 3. Vertical arm offset, the distance gap from the CRoC™'s vertical arm to the manikin torso, was measured in centimeters by using a ruler. Estimated blood loss (EBL) recovered from manikin drainage was measured in milliliters. Assessment of correct assembly required successful completion of all steps prior to CRoC™ positioning and targeting, or points were deducted for each step not performed (maximum of five points for assembly, one point for each of the five steps) described below.

The five assembly steps were as follows: 1) rotate (unfold) the vertical arm up from its base plate until the locking pin engages; 2) depress the locking side pin within the vertical arm's tube and extend the vertical arm out to engage the pin in either hole 1, 2, or 3 from the end of the arm; 3) lift the horizontal arm's locking pin and glide the horizontal arm into the vertical arm receiver and engage the pin into a hole; 4) insert the T-handle into the horizontal arm near

its tip, thread the T-handle through its receiver's grooves; and turn the T-handle clockwise until the threaded portion of the T-handle is exposed (3 to 5 threads out below the horizontal arm); and 5) snap the disc onto the T-handle's tip by pushing the tip into the disc's hole. The final assembly is as illustrated in **Figure 1**.

Targeting steps included the following: 1) placement of the fully assembled device with the base plate under the right buttock; 2) less than 2 cm of vertical arm offset; and 3) distance of disc center (pole) to target (midpoint of the pubic tubercle and anterior superior iliac spine) in centimeters. Assessment of targeting required (a) 100% on target for 2 points (disc center within 1 cm of target); (b) 50% on target for 1 point (center ≥ 1 cm but ≤ 2.5 cm from target); and (c) 0% on target for 0 points (center >2.5 cm from target).

The stop bleeding step was one of two options: (1) turn the T-handle clockwise until bleeding is stopped (visually) and welling of bleeding in the wound drops (recedes); or (2) reposition the CRoC™ by turning T-handle counterclockwise, repositioning the disc head atop the target and re-turning the T-handle to stop the bleeding. Bleeding stoppage was assessed as being successful if either stop bleeding criterion was met.

Safety criteria required that the strap be secured with the slip and that all slack be removed from the strap. Safety evaluation included (1) checking the number of T-handle turns to 'rebleed' (>10 drops per minute); one turn was a 180° arc; (2) ensuring that the strap clip was securely fastened; 3) checking that no slack was in the strap; 4) ensuring that no CRoC™ had breakage or damage; and (5) confirming that the vertical arm's offset was <2 cm.

Statistical analyses included descriptive statistics, Pearson correlation, analysis of variance, and mixed models. Data were expressed as mean \pm standard deviation unless otherwise noted; significance was at $p < 0.05$.

Results

All users successfully completed all iterations for all surfaces (six persons, three surfaces, and three iterations per surface for 54 iterations for the total experiment). CRoC™ users achieved hemorrhage control 100% of the time

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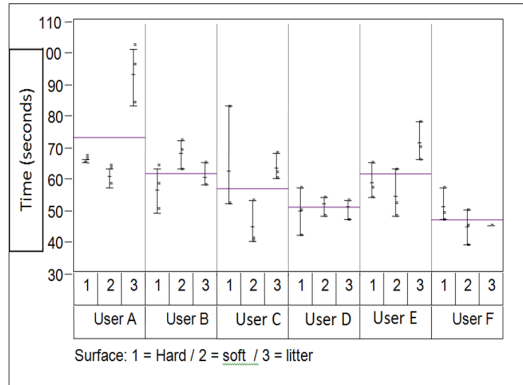


Figure 3. Time to achieve hemorrhage control by user, surface type, and iteration. The y-axis is time in seconds. The horizontal lines represent the median values for each user.

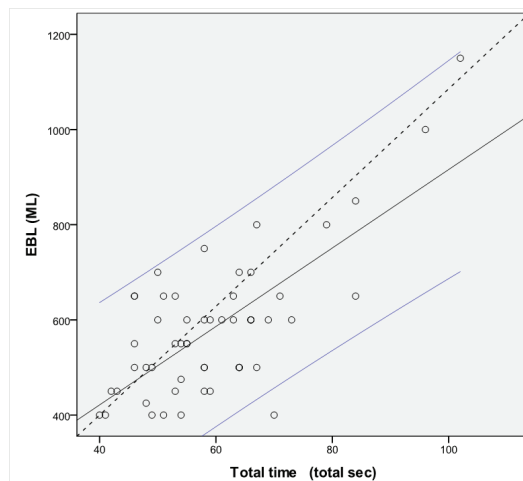


Figure 4. Correlation between estimated blood loss (EBL) volume and total time to stop bleeding for each user by each surface type (54 iterations in total). The dashed diagonal line represents the line of identity, the solid center line represents the fit line, and the outer lines represent 95% confidence limits.

(54/54). The surface on which the patient lay did affect time to achieve hemorrhage control. The iteration on the soft, flat surface (mean 55 ± 9.7 seconds) was significantly faster than on the litter (65 ± 16.5 seconds) and had the fastest overall total time ($p = 0.007$); the time for the hard, flat surface was 58 ± 9.5 seconds. Average time to control bleeding for all surfaces combined was 59 ± 12.9 seconds. Time to assemble the CRoC™ averaged 33 ± 7.4 seconds, time to position was 12 ± 4.8 seconds, and time to control bleeding was 15 ± 7.5 seconds. Although four of five users improved time to stop bleeding, there was no statistical differ-



Figure 5. Positioning the safety strap under the torso to attach the clip.

ence in overall iteration time ($p > 0.05$). There was a difference among individual user times to stop bleeding; user F was faster than the other users ($p < 0.0001$, **Figure 3**). Estimated blood loss averaged 581 ± 148 ml (range 400 to 1150 ml). Time to stop bleeding correlated positively with blood loss ($r = 0.72$; $p < 0.0001$; **Figure 4**).

Safety elements evaluated included the clip, which was secured 100% of the time (54/54); the strap, in which slack was absent 83% of the time (45/54); and the vertical arm, which was offset from the torso <0.5 cm 98% of the time (53/54) (**Figure 5**). The number of 180° turns to rebleed was 15 ± 4 (range 8 to 25); this first attempt to determine optimal number of turns was made in order to explore a threshold of over-tightening, which may over-compress adjacent nerves. Bleeding was stopped in 100% of cases, despite varied positioning over the targeted femoral artery; off-target distance averaged 2 ± 1.5 cm; range 0 to 6 cm) as 14 of 51 iterations had ≥ 3 cm (27%).

Discussion

Better control of battlefield hemorrhage has been associated with higher survival rates of combat casualties [2]. An immediate challenge remaining is control of junctional bleeding, including body areas at the junction of the trunk and its appendages. The CRoC™ was devel-

oped to fill the need to stop bleeding for difficult inguinal bleeding on the battlefield, and it has been successfully used in war [4] and in civilian care personal communication, John Kragh, Jr)). The CRoC™ has also successfully controlled bleeding from the groin in swine experiments and human cadavers in laboratory evaluations [5, 6]. The present study is the first report in evaluating different users on the surfaces on which casualties would likely be treated and transported.

We found that the CRoC™ achieved hemorrhage control in less than a minute and 100% of the time using a manikin specifically designed to train medics using the CRoC™. Even when the pressure disc's center was up to 6 cm off target (as opposed to being directly over the femoral artery), successful hemorrhage control was achieved. Surface type affected time but not the CRoC™ user's ability to stop bleeding; application of the CRoC™ on the soft, flat surface was fastest, followed by the hard, flat surface and then the curved, soft surface (NATO litter).

Several refinements to CRoC™ training materials and video may speed hemorrhage control. Suggestions include stowing the device in a configuration for fast assembly; indelibly marking the vertical arm at a target to guide rapid extension of arm to its optimal height (one of the last three holes for the adult-sized manikin); targeting when grasping and positioning the vertical arm as to center the pressure disc over the targeted artery; and stopping hemorrhage first before adjusting the safety strap. The evidence in the present study indicates that user performance affects device performance [8].

Human simulation was demonstrated in the present study as a useful method in training CRoC™ users and in evaluating user performance. Employing a standardized platform to conduct repeated evaluations of the CRoC™ with multiple users allowed for objective evaluation of the device. The customized manikin is a useful training device for medics to acquire skill and demonstrate competency. Simulators facilitate learning in four key areas: 1) gaining and retaining technical proficiency; 2) provide expert assistance in task-based learning; 3) learning within a professional context; and 4) support the learner-centered environment [7]. Specific features of medical simulations that

encourage the most effective learning include provision of feedback, repetitive practice, integration of curriculum, range of difficulty level, multiple learning strategies, capture of clinical variation, a controlled environment, individualized learning, defined outcomes and simulator validity [9].

Limitations of the present study are several. The experiment was our first with these methods and materials, and we chose a limited scope of hypothesis testing in order to concentrate on techniques. The participants in this study had prior experience with CRoC™ application and are not representative of novices. The end users of the device will ultimately be combat medics and first responders who may have limited opportunities to train with the CRoC™ tourniquet. The present study was of training efficacy under ideal circumstances, and further evaluation in simulated combat environments is warranted.

Future research efforts may evaluate the number of practice iterations required for competence for a novice CRoC™ user and assess for the optimal interval before refresher training is needed in order to maintain proficiency. The risk of over-tightening near the inguinal nerve requires further evaluation, and recommendations for pressure minimums and maximums so as to guide use are needed. Other future directions may include development of CRoC™ doctrine and formal training plans. Device design refinements, comparison of different devices or maneuvers (such as manual compression for hemorrhage control), best practice refinements, and differential performance by user groups (such as medics of varied experience) are all candidates for study, whether by researchers or trainers.

The primary findings of the present study were that people can be trained to effectively use the CRoC™ and that the surface the casualty lies on makes some difference. All six persons were trained well as users, and all nine of their iterations of CRoC™ use were effective (a 100% success rate). In addition, the CRoC™ users were able to control the simulated bleeding in less than a minute on average. These findings indicate that CRoC™ training can be effective; so such findings can be a plausible, feasible, and practical model for training other persons.

The minor findings of the present study were that trauma care simulation can be a practical method of evaluation and indicate refinements in medical device designs, manikin traits, and training methods [10].

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Conflict of interest statement

The authors have no conflicts of interest to report.

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Address correspondence to: Dr. LTC Elizabeth Mann-Salinas, US Army Institute of Surgical Research, 3650 Chambers Pass, Fort Sam Houston, TX 78234. Phone: 210-916-6379; Fax: 210-271-0830; E-mail: Elizabeth.Mann@us.army.mil

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