



## **USAISR INSTITUTIONAL REPORT**

### **Evaluations of the Combat Ready Clamp to Control Bleeding in Human Cadavers, Manikins, Swine Femoral Artery Hemorrhage Model and Swine Carcasses**

**Edited by Michael A Dubick, PhD and John F Kragh, Jr, MD**

**June 2012**



**UNITED STATES ARMY INSTITUTE OF SURGICAL RESEARCH    FORT SAM HOUSTON    TEXAS**

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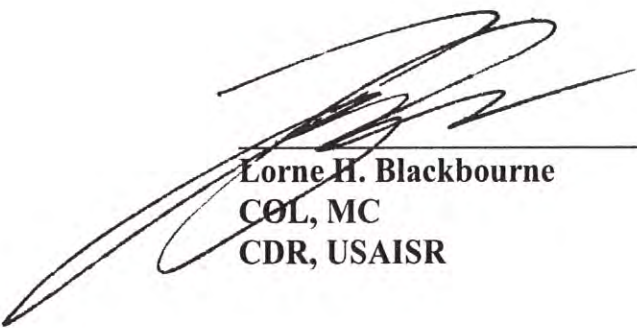
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**Lorne H. Blackbourne  
COL, MC  
CDR, USAISR**

*14 June 2012*  
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Running title: Combat Ready Clamp in cadavers and swine

## Preface

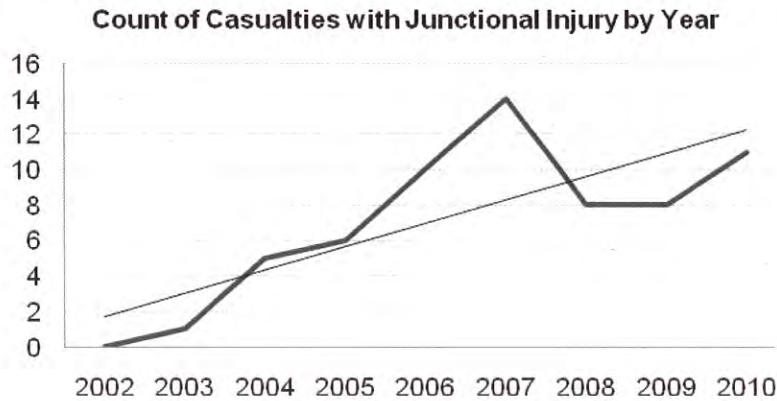
Hemorrhage remains the major cause of death on the battlefield. While deaths from extremity hemorrhage have been reduced dramatically by the application of tourniquets, deaths from high extremity wounds, such as in the groin region where tourniquets cannot be placed or are less effective, have seen an increase over the course of recent combat operations. In August 2010, the Combat Ready Clamp (Combat Medical Systems, Fayetteville, NC) received FDA 510(k) clearance for prehospital hemorrhage control of pelvic, groin or buttock bleeding in warfare. Although 500 units have been sold and 125-200 deployed, there is but one anecdotal report of its effectiveness in treating a casualty. This document is a compilation of 4 studies to gather data on the efficacy and initial safety of the Combat Ready Clamp. The studies include initial efficacy testing in a bleeding human cadaver model, an evaluation of efficacy and initial safety in a bleeding human manikin model, live animal testing in a swine groin injury model and evaluation in a swine carcass model of bleeding. The goals of this document are to provide the Combat Developer and other decision makers with sufficient data to support continued fielding of the Combat Ready Clamp as the initial fill for a capability gap in theater.

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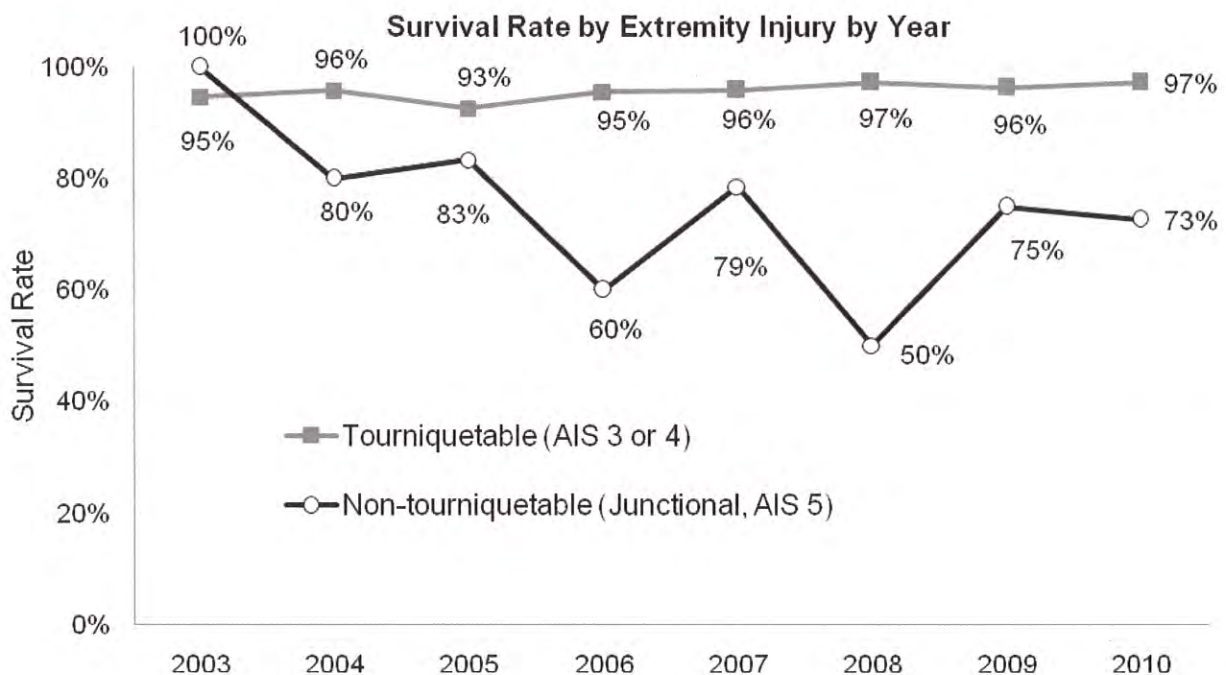
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A Decade of Tourniquets in War (H-11-033) was a trauma registry count of junctional injury in its severest form.

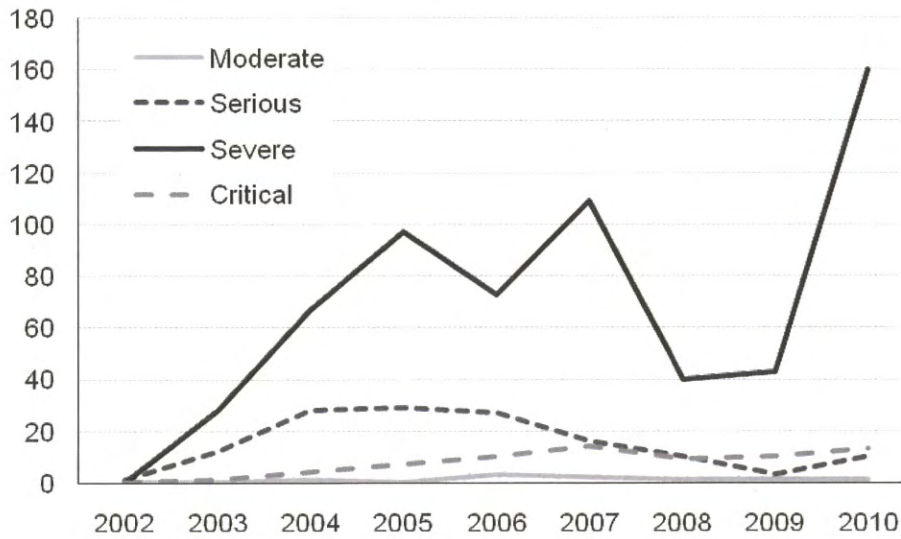
- **Junctional injuries were countable, were counted (63), and became more frequent.**



- **Tourniquet-able (serious and severe) injuries became more survivable over time while junctional injuries (critical) became more lethal.**
- **Junctional injuries can be survivable, e.g., 100% survival in 2003.**
- **Junctional injuries became more lethal despite doctrine, e.g., Combat Gauze.**
- **Junctional injuries became more lethal, e.g., 27% death rate in 2010.**

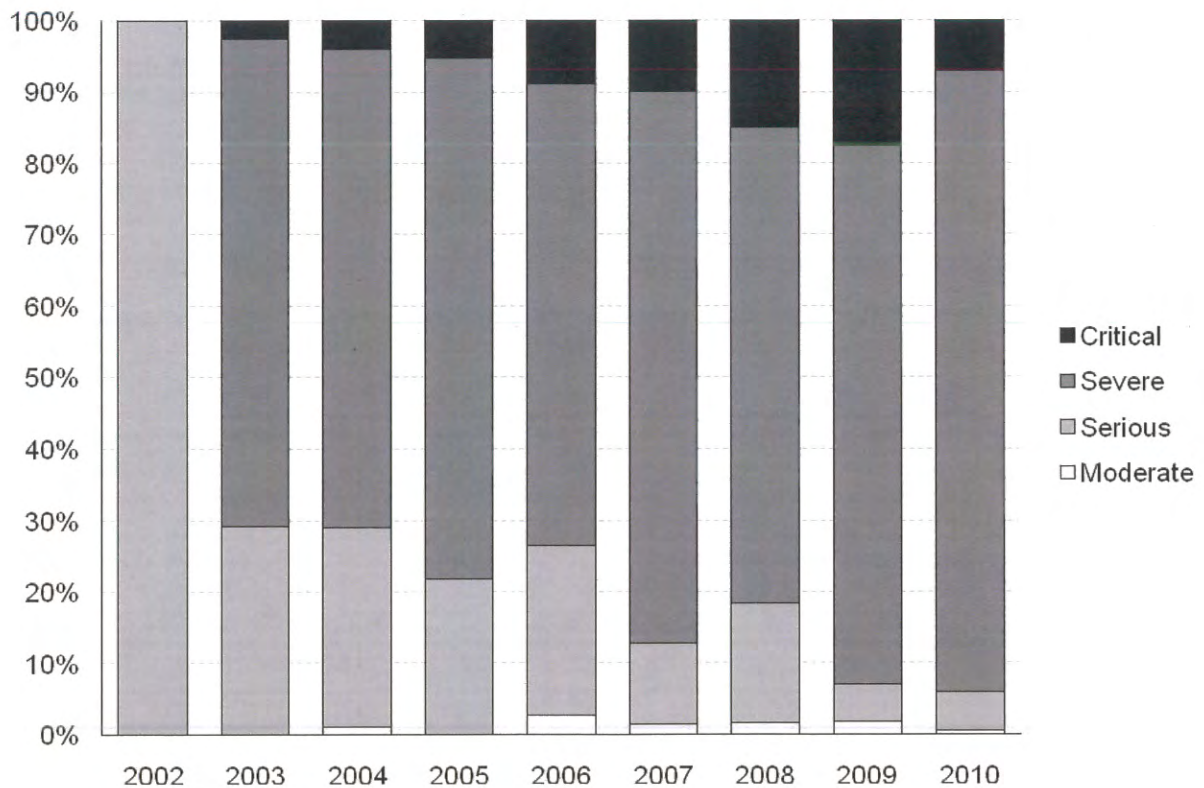


A Decade of Junctional Bleeding in War (H-12-003) was a trauma registry count of junctional injury in its common form.



- Junctional extremity injury casualties were counted (830) and became more frequent.
- Junctional injuries were predominantly severe.

### Junctional Extremity Injury Severity Rate



Combat Ready Clamp as a Prehospital Hemorrhage Control Device to Stop Bleeding and Save  
Lives: Efficacy Data from Human Bodies

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Running title: Combat Ready Clamp for hemorrhage control

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## **Abstract**

INTRODUCTION: Approximately 80 percent of potentially survivable casualties on today's battlefield nevertheless result in mortality due to uncontrolled hemorrhage. Devices that control hemorrhage on the battlefield early in the continuum of care may likely increase the survivability of combat casualties. The object of this study is to test the feasibility of the Combat Ready Clamp (CRC), a device developed by Combat Medical Systems for controlling abdominal or pelvic hemorrhage.

METHODS: The Wake Forest University human cadaver hemostasis model was used to test the efficacy of the CRC. This testing platform uses a pulsatile peristaltic pump to produce realistic constant blood flow within the arteries of a fresh unembalmed human cadaver. Testing hemostatic devices and procedures using intact fresh human tissue has some advantages over alternative live tissue models when a mechanical device is employed to reduce arterial flow rates. Authentic human anatomy is an important requirement for validating the efficacy of hemorrhage control devices when an external control clamp device is applied to control flow in the external iliac artery at or above the inguinal ligament where peripheral limb tourniquet application cannot be used. In this feasibility study, peristaltic tubing was inserted and sealed within the thoracic aorta in 2 different unembalmed fresh human cadavers. An external peristaltic pump was used to deliver fluid through arteries in the descending abdomen, pelvis and limbs of the cadaver with a constant peristaltic speed and constant arterial flow rate consistent with physiological levels. The right popliteal artery was cut in order to measure dynamic changes in downstream arterial flow rates from fluid pumped through the thigh before, during and after the application of hemorrhage control devices with constant peristaltic pumping. In addition, a pressure transducer was inserted into the right femoral artery to accurately measure dynamic

changes in limb arterial pressure before, during and after the application of the hemorrhage control devices against the constant pressure from the peristaltic pump. A Combat Application Tourniquet (CAT) was used first in control trials to demonstrate the validity of this testing system. The CAT was applied to the thigh to validate measurements of hemorrhage control from the popliteal artery. The CAT was removed and the CRC was then applied to the external iliac artery above the inguinal ligament. Experimental endpoints included the measurement of changes in arterial flow rates and alterations in arterial pressure measure before, during and after the application of the CRC to the external iliac artery.

RESULTS: The human hemostatic testing model developed at the Wake Forest University School of Medicine was used to demonstrate the capacity of the CRC to stop arterial flow when applied to the external iliac artery. The CRC completely stopped blood flow and arterial pressure with only 4 to 9 turns of the device when the clamp is applied to the surface of the cadaver abdomen above the inguinal ligament. The CRC controlled arterial flow through the external iliac in three trials in both cadavers.

CONCLUSION: The Combat Ready Clamp is a device that can be effective at controlling hemorrhage of the external iliac artery when properly applied at or above the inguinal region.

KEY WORDS: tourniquet; junctional hemorrhage; cadavers; hemorrhage control devices; tourniquets

**Task:** To test the feasibility of using compression clamp device to treat abdominal or pelvic bleeds using the Wake Forest University hemostasis model in unembalmed human cadavers with vascular pressure.

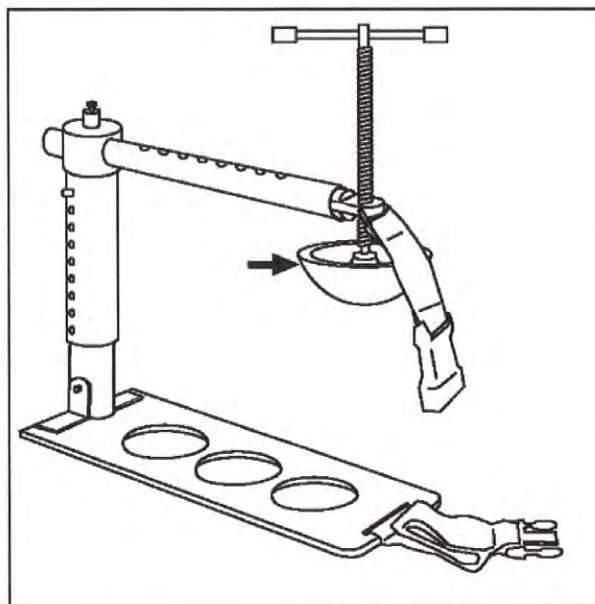
### **Background**

The effective use of tourniquets to control traumatic bleeding from limbs with either the Combat Applications Tourniquet (CAT) or the Special Operations Forces Tourniquet (SOFT-T) has proven to greatly reduce the numbers of combat deaths due to extremity hemorrhage.<sup>1</sup> Even with these important advances in trauma management on the battlefield, 80 percent of potentially survivable deaths are the result of uncontrolled hemorrhage. Of those, 25-30 percent occurs in the regions of the body where traditional tourniquets such as the CAT are not applicable or effective including the lower abdomen and pelvis.<sup>2,3</sup> This indicates a vital need for the development of additional hemorrhage control devices to effectively control traumatic hemorrhages in casualties with injuries to these regions during the critical period of pre-hospital care and transport from the battlefield.

The US Army Medical Research and Material Command have posted a Request for Information (RFI) on devices that could potentially stop bleeding at compressible sites where standard tourniquets cannot be applied. This device should:

- 1) Control difficult hemorrhage;
- 2) Can be applied easily in a tactical environment with a minimum level of familiarization;
- 3) Must not slip during tightening or following application;
- 4) Be capable of easy release and re-application;
- 5) Be of light weight;
- 6) Have long shelf life, low cost and low cube.

In a cooperative research agreement between the US Army Institute of Surgical Research, the Wake Forest University School of Medicine Center for Applied Learning and Combat Medical Systems, a device to control pelvic hemorrhage has been developed. The Combat Ready Clamp (CRC) is a device designed and developed by CMS with mechanical clamping properties and surface application technology to reduce or block blood flow from internal bleeding injuries in adults that current devices cannot address. It received FDA 510(k) clearance in August 2010 for use in the battlefield to control difficult bleeds in the inguinal area. The aluminum device weighs about 1.6 lb and comes partially assembled for folding flat in the medic's aid bag. For use, the medic attaches the horizontal arm, the pressure handle and the pressure disk (Fig 1). The vertical and horizontal arms can be adjusted for exact placement on the wound and the pressure handle is tightened to pressurize the wound with the pressure disk. The medic then uses the strap to go around the casualty to prevent the CRC from slipping.



*Fig 1. Drawing of Combat Ready Clamp (CRC) focusing on the adjustable horizontal arm, the threaded pressure handle, the pressure disk that contacts the wound, and the strap for securing the clamp.*

The following experiment was designed to test the feasibility of the CRC in controlling hemorrhage to the external iliac artery at or above the inguinal ligament.

#### **Inclusion/Exclusion Criteria**

Two Human Cadavers were used in this experiment with a weight range 130lbs-200lbs. The cadavers had no grafts and no vascular surgeries in the abdominal aorta, iliac or femoral vessels. The cadavers were not embalmed and were not frozen but instead they were refrigerated after death and maintained at a constant temperature above freezing which ranged from 2.2 to 3.3 °C prior to use. Both cadavers were used within one week of death. The cadavers were placed at ambient temperature 4 hours prior to testing.

## **Methods**

While live tissue animal models (i.e. porcine studies) are perhaps ideal for studying the hemostatic properties of blood clotting chemicals and agents, externally applied clamping devices that rely upon mechanical occlusion of blood vessels to reduce and stop blood flow require authentic human anatomy for optimal testing. Cadaver I was approximately 60 year old male with a total body mass of 175 lbs. Cadaver II was approximately 70 year old female with a total body mass of 110lbs. Cadavers were inspected for presence of surgeries in the areas to be tested and placed in a supine position on a surgical table. A schematic illustration of the human hemostasis model is found in figure 2 below.

A left thoracotomy was performed at the T5-T6 to create a 5cm x 5cm window wall for tube placement into the thoracic aorta above the diaphragm. The thoracic aorta was dissected from the posterior mediastinal parietal pleura and endothoracic fascia and a traverse aortotomy was performed to insert peristaltic tubing within the descending thoracic aorta. A 6mm surgical tubing was placed approximately 7cm into the descending aorta. The connection of the tube was sealed and held in place using two 3" long plastic zip tie. Care was taken not to compress the aorta when tightening the zip ties. A clamp was then placed on the left subclavian artery to prevent back flow. The proximal end of the surgical tube was connected to a peristaltic pump (Cole Parmer Masterflex 75553-30). The pump was used to recreate physiological blood flow within abdominal and pelvic arteries by providing pressurized pulsatile fluid flow into the distal arteries with a pump cycle rate of 100-120 pulses per minute. The popliteal artery was opened to release fluid under constant pump pressure and for dynamic measurements of both arterial flow rates through the right extremity and arterial pressure in the distal femoral artery. A 4 cm incision was made through the vastus medialis to expose the popliteal artery as it emerges through the adductor hiatus at the distal end of the canal of Hunter. The popliteal artery was

released and a transverse arterotomy was made to place a 4mm surgical tube 3cm into the proximal end of the artery. The tube was held in place and a seal was created using a 4" flex tie. Care was taken not to compress the artery when placing the flex tie. The distal end of the surgical tube was placed in a 5 gallon pail to collect fluid. A reservoir 5 gallon bucket was filled with neutral water containing 4% neutral red dye as blood simulant. The collection hose of the pump was placed in the bucket. Clots or plaque were removed to allow constant flow and prevent flow impedance. The pump was primed with 30 ml of fluid and the vessels rinsed and flushed with three liters of fluid prior to calibration for constant flow rate. The peristaltic pump was calibrated and adjusted to achieve a constant flow rate of 100-120 cycles per minute. This resulted in the measurement of a resulting popliteal artery flow rate of between 250 -300 ml/min. The average flow rate for this experiment was 287ml/min. (equal to a hemorrhagic rate of approximately one unit of blood loss every 94 seconds).

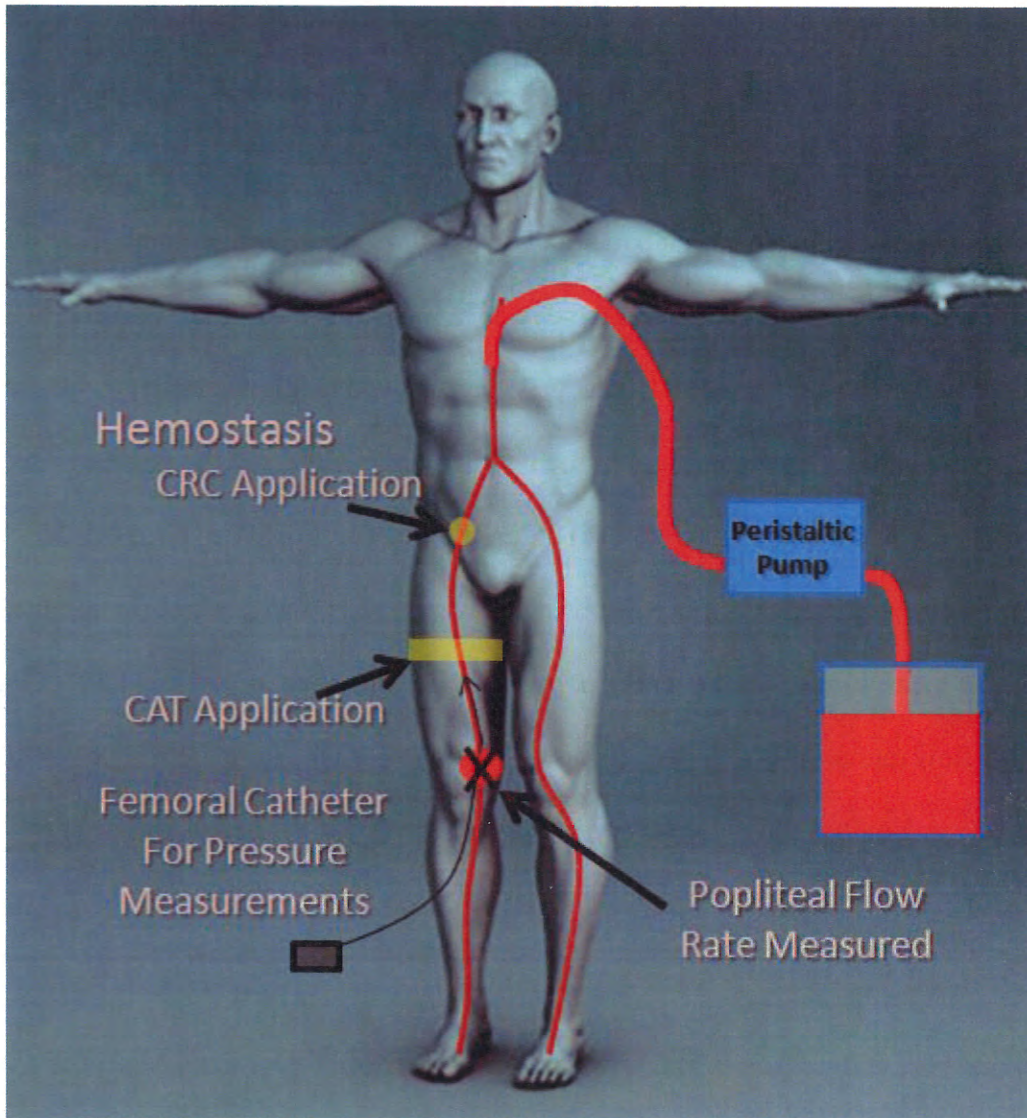


Figure 2. The human hemostasis testing model used in this experiment. Testing was completed using fresh (unembalmed and not previously frozen) cadavers. A peristaltic pump is used to pump a blood simulant into the cadaver through a thoracotomy providing access to the thoracic aorta. A constant flow rate of fluid through the abdominal aorta, iliac and femoral arteries is achieved by a surgical hemorrhage placed in the right popliteal artery. The dynamic flow rate is monitored at the popliteal artery and dynamic changes in pressure measurements are measured with a catheter pressure transducer placed in the femoral artery.

Arterial pressure was monitored using fluid filled pressure transducers (model 156PC15GWL, Microswitch) placed into the femoral artery and powered by a TS430 bridge amplifier (Transonic Systems Inc., Ithaca, NY).

Data was recorded using GLP compliant IOX2 software (EMKA Technologies. Falls Church, VA) using the blood pressure module. A photograph of the human hemostasis model is provided in figure 3. Measurements of arterial pressure ranged from 36mm Hg to 48 mm Hg consistent with the pressure levels anticipated in a living femoral artery that is drained by a rapidly bleeding popliteal artery opened by traumatic injury to release blood flow and pressure.

#### Positive Control

A CAT tourniquet was used as a positive control hemostasis device to validate this system. The CAT is the current extremity tourniquet of choice for Tactical Combat Casualty Care and extremity hemostasis in the military.<sup>4</sup> It has been shown that 3 turns of the CAT windlass is enough to create a tourniquet effect in the extremities when properly applied and cinched to the thigh. With a constant flow rate equivalent to one unit blood loss per 94 seconds, the CAT was applied to the thigh across the middle of the femoral triangle as shown in figure 4 below. As predicted, this application of the CAT completely blocked popliteal blood flow with approximately 3 to 4 complete turns of the CAT windlass replicating the well established physiological conditions and interventional practices required for lower limb hemostasis in living patients. Constant blood flow immediately resumed with the release of the CAT under constant pump pressure.



*Figure 3. Human hemostasis model. Note left thoracotomy, right lower extremity incisions, and right groin with compression device applied to the surface of the abdomen where CAT application is not possible.*



*Figure 4. Photograph of CAT tourniquet applied as a positive control. Note that flow into the collection bucket has been stopped with the application of the CAT.*

#### CRC Device Application

Experiments were then conducted using the CRC applied to the surface of the inguinal region in order to block flow in the external iliac artery in an “edge of body armour” region where a combat tourniquet cannot be applied to control traumatic hemorrhage. The CRC was placed in accordance with the manufacturer’s instructions. The location of the ball of the device was made

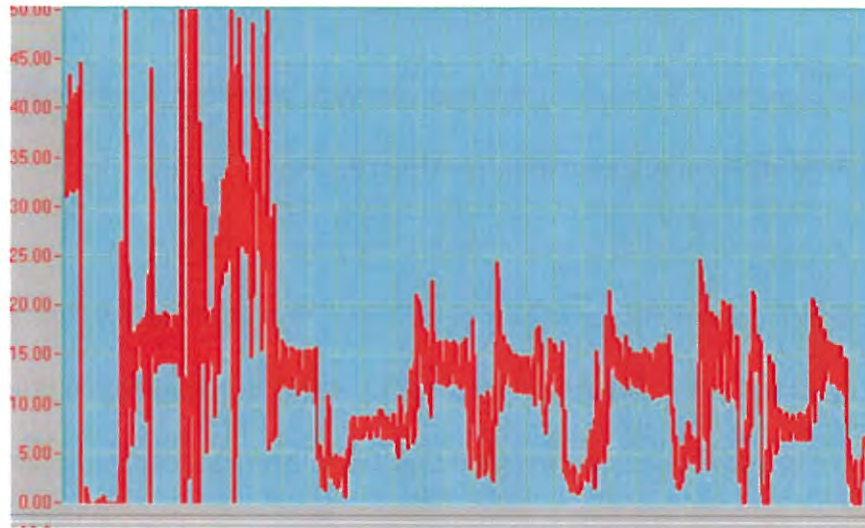
at a spot approximately 50% between the anterior superior iliac spine and the pubic tubercle immediately superior to the inguinal ligament as shown in figures 2 and 3. The CRC was positioned in place so that the surface of the device ball was tangent to the plane of the skin but not tightened to depress the skin prior to the onset of device application. A constant flow rate was measured and maintained prior to the application of the CRC device. The constant flow rate was monitored by the fluid flow rate through the external iliac and femoral arteries with output measurements at the popliteal artery. Constant pressure was monitored in the femoral artery prior to the application of the clamp. Dynamic changes were monitored in fluid flow rates and femoral artery pressure before, during and after the release of the CRC device. The pump was left running for several minutes to check for collateral flow under constant pressure and then the CRC device was released to monitor the rate of return of constant flow and pressure.

### **Results: Combat Ready Clamp application**

Three trials were completed for each of the two cadavers with representative measurements of femoral arterial pressure from multiple trials provided below.

#### **Cadaver I**

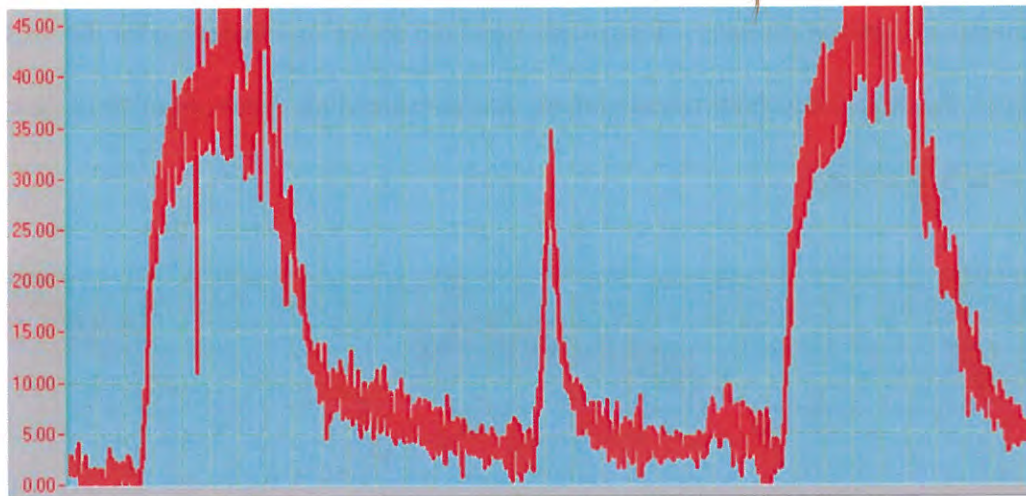
Constant blood flow (approximately one unit blood loss / 94 seconds) and a constant flow rate were achieved. Pressures in the femoral artery (36-48 mmHg) were monitored prior to the application of the CRC device over the external iliac in the inguinal region. Accurate positioning and placement of the CRC device over the external iliac artery as described in the methods was critical to the observed alterations in blood flow and pressure (see Figure 5 below). The application of the CRC immediately depressed flow but this result was variable when the ball of the device was not positioned accurately directly over the external iliac artery. This result is consistent with a mechanical occlusion of the artery derived from pressure at the periphery of the device ball rather than the center of the ball. The occlusion was greatest during the turn of the device but then released between turns. Adjustment of the center of the ball more accurately over the external iliac resulted in the immediate and sustained reduction in blood flow and measurements in fluid pressure.



*Figure 5. Femoral artery pressures recorded with the onset of the initial application of the CRC device in Cadaver I. Each segment line on the abscissa represents 10 seconds of time and each segment on the ordinate represents 5 mm Hg of pressure. Note the variable changes in femoral arterial pressure as measured in mmHg when the position of the CRC ball is adjusted in the inguinal region of the abdomen over the external iliac artery.*

Accurate placement of the device on the surface of the abdomen over the external iliac artery improved with practice. Observe in figure 6 below results from the application of the clamp for three minutes followed by the release of the clamp for one minute and then finally the reapplication of the device. Each time the device was applied there was an immediate reduction in the fluid flow and femoral pressure. Flow through the external iliac was reduced with only 4 complete 360° turns of the device handle reducing fluid flow out the popliteal from an initial flow rate equivalent to one unit of blood lost every 94 seconds to the rapid and complete cessation of bleeding. Femoral arterial pressure precipitously dropped immediately with the application of the device and was sustained by the device each time it was applied. Hemostasis was held for the entire three minutes of the device except for one interruption (peak in the middle

of figure 5) when the device position was altered demonstrating pump pressure during the period of hemostasis is constant. Note that the release of pressure resulted in an immediate and complete recovery of pressure in figure 6. These results indicate that the application of the device did not permanently deform or obstruct the vessel but instead the release of the clamp immediately restored the pressure in the femoral artery to constant levels.



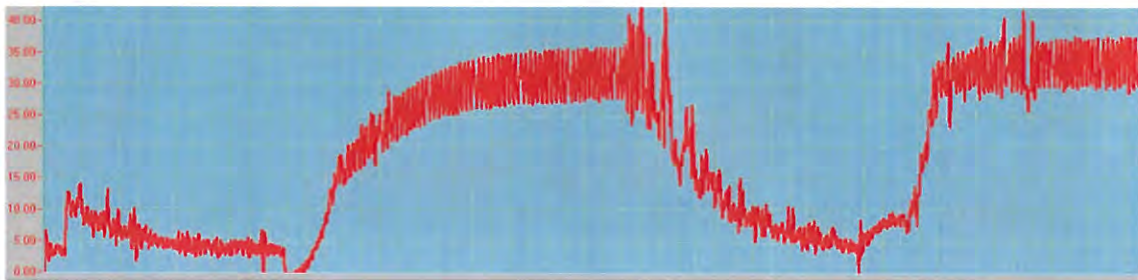
*Figure 6. Femoral artery pressures recorded with the onset of the peristaltic pump to achieve a constant flow rate and pressure for 30 seconds followed by the application of the CRC device for three minutes in Cadaver I. Note the application of the CRC device reduces femoral pressure and stops flow within 10 seconds. Hemostasis is held for the entire three minutes except for one interruption (peak in the middle) when the device position is altered demonstrating pump pressure is constant. When the device is later released after 3 minutes there is an immediate recovery of pressure within 10 seconds of release. The pressure returns to the original prior level. Reapplication of the device for a second time again immediately blocks blood flow and eliminates femoral pressure when the external iliac is blocked. Each segment line on the abscissa represents 10 seconds of time and each segment on the ordinate represents 5 mm Hg of pressure.*

## Cadaver II

In cadaver II the results were remarkably similar with cadaver I over multiple trials.

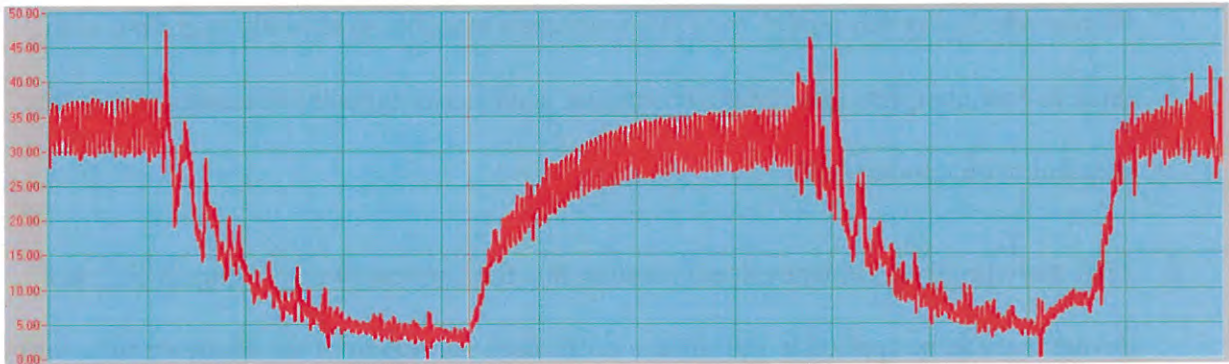
Representative recordings of femoral pressure are provided below (Fig 7). In this cadaver approximately nine turns of the device handle were required to achieve complete hemostasis.

Note the application of the CRC device quickly reduced flow through the external iliac to reduce measurements of femoral pressure. Hemostasis was held stable by the device for the 90 seconds so that when the device was later released there was an immediate recovery of fluid flow and femoral arterial pressure.



*Figure 7. Femoral artery pressures recorded prior, during and then after the CRC device application to the surface of the inguinal region of the abdomen to block the external iliac artery at or above the inguinal ligament. Note that when the pump is turned on 2 minutes into this recording pressure rapidly builds in the femoral artery. This constant pressure is maintained for 90 seconds prior to the initial application of the CRC device in Cadaver II. Note the application of the CRC device quickly reduces flow through the external iliac to rapidly reduce measurements of femoral pressure. Hemostasis is held for the 90 seconds so that when the device is later released there is an immediate recovery of fluid flow and femoral arterial pressure. Note that the pressure returns to the original prior level. Each segment line on the abscissa represents 10 seconds of time and each segment on the ordinate represents 5 mm Hg of pressure.*

Finally, in Cadaver II multiple applications of the device were recorded with intervals of constant fluid flow and constant pressure. Note in figure 8 below that each application of the CRC device resulted in a rapid cessation in fluid lost from the popliteal and an immediate drop in femoral pressure (in less than five seconds).



*Figure 8. Femoral artery pressures recorded prior, during and then after the repeated application of the CRC device to the surface of the inguinal region in Cadaver II. Note the application of the CRC device quickly reduces flow through the external iliac to rapidly reduce measurements of femoral pressure. Hemostasis is held so that when the device is later released there is an immediate recovery of blood flow and femoral arterial pressure. Note that the pressure returns to the original prior level. Reapplication of the device again immediately blocks flow and release of pressure a second time again restores constant flow and pressure. Each segment line on the abscissa represents 5 seconds of time and each segment on the ordinate represents 5 mm Hg of pressure.*

## **Conclusions**

1. The human hemostasis model is a useful model for testing mechanical tourniquets and clamps that control bleeding. The flow rate of the peristaltic pump was adjusted to achieve physiological levels of fluid loss from the popliteal artery equivalent to one unit / 94 seconds. Using this model, the CAT tourniquet was able to abruptly stop flow with three to four complete turns of the tourniquet windlass as expected in cases of extremity bleeding with a living limb.
2. This study provides evidence demonstrating that the Combat Ready Clamp (CRC) is a device that can be applied to the surface of the inguinal region of the abdomen for control of hemorrhage by arresting blood flow in regions of the external iliac that are not otherwise accessible to hemostatic occlusion with a CAT. The CRC device provides an opportunity for practitioners to intervene in at least some “edge of armour injuries” not currently treatable with a tourniquet. It may be applied to arrest bleeding during that critical period when battlefield combat casualties may be spared death from hemorrhagic shock during the earliest stages of care and transportation for hospital treatment.
3. The accurate position of the CRC device is required for hemostasis. An adjustment in the position of the center of the device ball resulted in a sustained reduction in flow rates and femoral pressure. This result indicates that the accurate positioning and when necessary, repositioning of the device on the surface of the patient abdomen is important so that the clamp is positioned directly over the external iliac artery.
4. The release of the clamp rapidly restores blood flow completely with a restoration of down-stream arterial pressure indicating that the device does not deform or permanently block arterial flow.

### **Acknowledgments**

The opinions or assertions expressed herein are the private views of the authors and are not to be construed as official or as reflecting the views of the US Department of the Army or the US Department of Defense.

One of the authors (CM) is an employee of Combat Medical Systems LLC (CMS), the developer and distributor of the Combat Ready Clamp. The work described was performed as part of the company's efforts for obtaining 510(k) clearance from the US FDA as a vascular clamp, regulatory Class II. None of the other authors had any affiliation with CMS or any potential conflicts of interest to declare.

Dr Johnson and Chris Murphy prepared the work for the FDA application 510(k) with some assistance from Drs Kragh, Dubick, and Blackbourne.

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**Figure 1.** Combat Ready Clamp (CRoC)

The CRoC is mainly used on 3 different surface types: hard and flat like the ground or a floor; on a hospital bed or gurney if applied in a hospital; and on a NATO litter when used during evacuation. The purpose of this experiment was to determine if CRoC user performance varied by casualty positioning surface (flat and hard, flat and soft [padded], or curved and soft [NATO litter]).

## **Methods**

All phases of the experiment were conducted in the San Antonio Military Medical Center (SAMMC) Simulation Center. The manikin used was a custom-made physical simulator, composed of viscoelastic artificial tissues, weighing approximately 150 pounds, and developed specifically 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 with right femoral artery injury. The model replicated severe hemorrhage from the simulated wound, controllable by correct use of the CRoC.

### Primary outcome:

Effectiveness (simulated hemorrhage stops: Yes or No) of CRoC on three patient surfaces: flat and hard (table), flat and soft [padded patient transport gurney], or curved and soft [NATO litter].

### Secondary outcomes:

1. Time to effectiveness (sum of individual steps, to include: time to assemble CRoC, time to position and target, and time to stop hemorrhage, in seconds).
2. Estimated blood loss (EBL) in milliliters.

### 3. Safety measures:

- a) correct assembly (yes or no);
- b) clip secure (yes or no) and slack in strap (present or absent);
- c) device breakage (yes or no, and description of component involved);
- d) distance of vertical arm offset from torso (centimeters);
- e) overtighten (number of 180 degree turns until re-bleed occurs).

Manikin preparation included: 1) infusion of simulated blood (4,000 ml tap water, 60 ml rubbing alcohol, 30 ml simulated blood to tint fluid) into CRoC manikin according to manufacturer's recommendations; 2) for every 1,000 ml of simulated blood out during the experiment, 1,000 ml of simulated blood was re-infused to maintain a relatively constant internal bladder pressure; 3) a plastic drainage board under the manikin directed simulated bleeding from both anterior and posterior proximal thigh wounds into a bucket. (Figure 2)



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

Device preparation: The CRoC device was placed adjacent to the manikin as stowed by combat medics:

1) Vertical arm assembled from its two tubular parts with its horizontal arm receiver working end slid to shorten the arm maximally, with pin engaged in last hole, fold vertical arm down to base plate; 2) Strap clip extended to within 4 inches of strap end; 3) all device components bundled and over-wrapped by strap; and 4) device placed on flat surface adjacent to manikin. The device was in this configuration for each iteration of the experiment.

Scenarios: The three experimental surfaces consisted of:

- 1) Hard, flat surface: metal table that accommodated the manikin and a drainage board to direct simulated bleeding into the bucket;
- 2) Soft flat surface: hospital gurney with mattress with plastic placed under manikin to direct simulated bleeding into the bucket;
- 3) Soft, curved surface: mesh NATO litter, placed on metal table with simulated bleeding allowed to drain through mesh surface onto drainage board and into bucket.

Participants: The users comprised six expert users of the device who were trained and certified in correct use of the CRoC prior to the experiment. In the present study, each individual (n=6) performed 3 iterations on each of the 3 surfaces (3 iterations, 3 surfaces, 6 users = 54 total).

Data collection:

- 1) Time was measured with a stopwatch; periods were calculated  
Period 1: device pickup to assembly complete; Period 2: assembly complete to targeting to groin region of manikin complete; Period 3: targeting complete to bleeding stopped; and Overall time: from device pickup to bleeding stopped; sum of Periods 1 to 3.
- 2) Vertical arm offset distance from vertical arm to torso was measured in cm using a ruler.
- 3) Estimated blood loss (EBL) recovered from manikin drainage was measured in milliliters.

Assessment of assembly: all steps must have been successfully accomplished prior to positioning or points were deducted for each step not performed (maximum of 5 points for assembly, 1 point for each of 5 steps):

Assembly steps:

- 1) Rotate (unfold) vertical arm up from base plate until locking pin engages;
- 2) Depress locking side pin within the vertical arm's tube, and extend vertical arm out to length to engage pin in hole at end (hole 1, 2 or 3);
- 3) Lift the horizontal arm locking pin and glide the horizontal arm into the vertical arm receiver and engage pin into a hole;
- 4) Insert T-handle into horizontal arm near its tip, thread through the T-handle receiver's grooves; turn T-handle clockwise until threaded portion of T-handle is exposed (3-5 threads out below horizontal arm);
- 5) Put disc head on T-handle tip and click the tip into the disc's hole.

Targeting steps: 1) Placement of fully assembled device with baseplate under right buttock; 2) Less than 2 cm distance of vertical arm offset from torso; 3) Not less than 1 cm distance of pressure disc center (pole) from groin; 4) Distance of disc head center (pole) to target (midpoint of pubic tubercle and anterior superior iliac spine) in cm.

Assessment of Targeting:

- a) 100% on target = 2 points (center within 1 cm of target)
- b) 50% on target = 1 points (center  $\geq 1$  cm but  $\leq 2.5$  cm of target)
- c) 0% on target = 0 points (center  $> 2.5$  cm of target)

Stop bleeding steps: 1) Turn T-handle clockwise until flow of simulated bleeding is stopped (visually) or welling of bleeding in wound drops (recedes); or 2) Repositioning CRoC may be done by turning T-handle counterclockwise, repositioning the disc head atop the target and re-turning T-handle to stop bleeding

Assessment of stopping bleeding: Success was determined if either stop bleeding steps were completed.

Safety steps: 1) Secure strap with clip, and 2) Pull strap to remove slack

Safety evaluation: 1) Number of turns of T-handle to 'rebleed' seen ( $>10$  drops per minute); one turn is an 180-degree arc; 2) Clip securely fastened; 3) No strap slack; 4) No CRoC breakage or damage; 5) Distance of vertical arm from torso less than 2 cm

Statistical analysis was performed using descriptive techniques, analysis of variance, and mixed models. Data are expressed as mean  $\pm$  SD or where indicated, as median. Significance was accepted for  $p < 0.05$ .

## **Results**

All six individuals successfully completed 3 iterations on each of the three experimental surfaces ( $n = 54$ ). The CRoC effectively achieved hemorrhage control 100% of the time (54/54). Patient surface did affect time to achieve hemorrhage control. The soft surface ( $55 \pm 9.7$  seconds) was significantly different from the litter ( $65 \pm 16.5$  seconds) and had the lowest overall total time ( $p = 0.007$ ); time for the hard surface was  $58 \pm 9.5$  seconds. Mean time to control hemorrhage for all surfaces combined was  $59 \pm 12.9$  seconds. Mean time to assemble CRoC was  $33 \pm 7.4$  seconds; time to position was  $12 \pm 4.8$  seconds; and time to control bleeding was  $15 \pm 7.5$  seconds.

Although 4 of 6 users improved time to achieve hemorrhage control over the three iterations, there was no statistical difference in overall iteration time ( $p > 0.05$ ). There was a difference in individual user time to achieve hemorrhage control; User F was different from the others ( $p < 0.0001$ )(Figure 3).

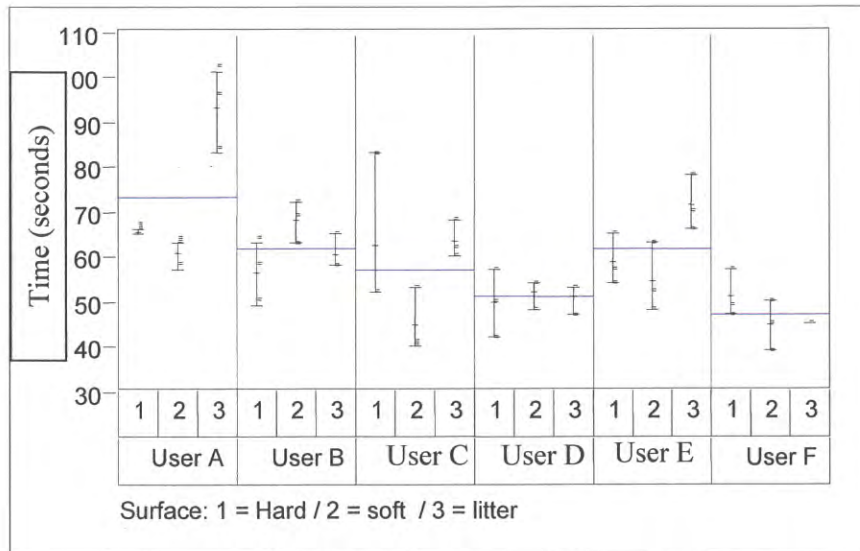


Figure 3: Time to achieve hemorrhage control, by user, surface type, and iteration. The y-axis is time in seconds. Horizontal lines represent median values for each user.

Estimated blood loss (EBL) averaged  $581 \pm 148$  ml (range 400 to 1150 ml). Time to hemorrhage control correlated positively with EBL ( $r = .72$ ;  $p < 0.0001$ ). (Figure 4)

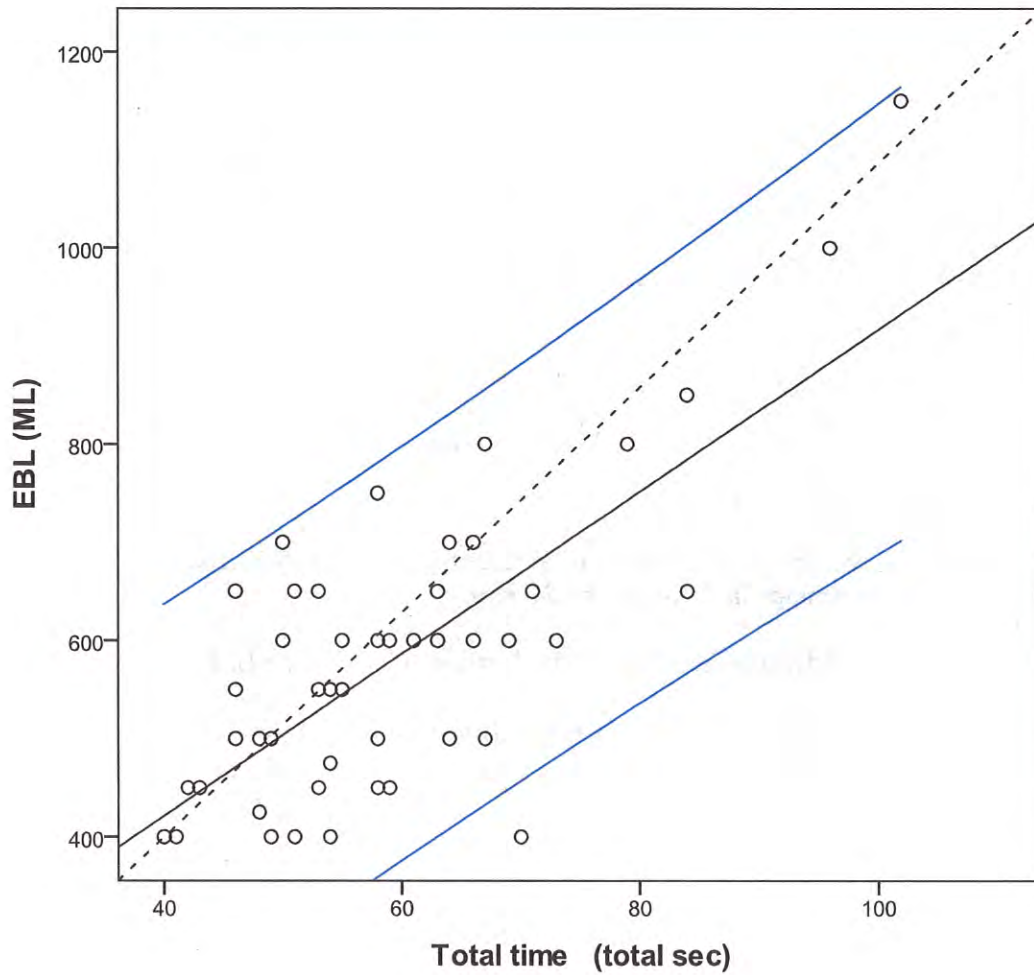


Figure 4: Correlation between EBL volume and total time to hemorrhage control for each user for each surface type (n = 54). Dashed diagonal line represents line of identity, solid black line represents fit line, blue lines represent 95% confidence intervals.

Safety elements evaluated included: clip secured 100% of the time (54/54); absence of slack in the strap 83.3% of the time (45/54); and vertical arm offset from torso < 0.5 cm 98.1% of the time (53/54) (Figure 5). The number of 180 degree turns to rebleed was  $15 \pm 4$  (range 8 to 25); this is the first attempt to determine optimal number of handle turns to avoid overtightening, which could damage surrounding anatomical structures such as the inguinal ligament. Control of hemorrhage was achieved in 100% of cases, despite variability in positioning over femoral artery target; number of centimeters from target ranged from 0 to 6 cm ( $2.14 \pm 1.5$ ) with 14/51 cases  $\geq 3$  cm from target (27%).



**Figure 5.** Process of securing strap across torso to stabilize CRoC for transport.

### **Conclusions**

1. The CRoC achieved hemorrhage control 100% of the time using a manikin specifically designed to test the device. Positioning of device can be up to 6 cm from target (directly over femoral artery) with successful hemorrhage control.
2. Patient surface type affected CRoC ability of user to achieve hemorrhage control; the soft padded surface was associated with the most rapid control of bleeding, followed by the hard surface and then the NATO litter.
3. Human simulation is a practical and useful method for training and evaluation of CRoC user performance.
4. Several refinements to the CRoC training materials and video are recommended to decrease time to achieve hemorrhage control, to include: storage of device in a manner that speeds assembly in the field; mark vertical arm with a target to guide rapid extension of arm to optimal position (approximately the last three holes); positioning the horizontal arm to target inguinal area; and necessity to achieve control of bleeding prior to adjusting or positioning the safety strap.

User performance affects device performance.<sup>3</sup> Future research efforts will evaluate the number of practice iterations will be required for a novice CROc user, and to determine frequency of refresher training to maintain proficiency.

### **Acknowledgements**

Thank you to the participants in the simulation experiments: Ralph Sweet, RN; Dominique Greydanus; John Ward, PhD; Bijan Kheirabadi, PhD; Sayed Husaini. Simulation Center Director Robert Coffman, RN provided technical and logistic support for this project.

The opinions or assertions contained herein are the private views of the author and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

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# **Title: *In Vivo* Assessment of Combat Ready Clamp (CRoC) to Control a Junctional Hemorrhage in Swine**

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**Contributors: Irasema B. Terrazas, MS, John F. Kragh, MD, Michael A. Dubick, PhD, Lorne H. Blackburne, MD**

**Introduction:** With the success of regular tourniquets (TQ) and hemostatic dressings in the current war, isolated limb exsanguination is no longer the most common cause of preventable death on the battlefield. The hemorrhage from junctional wound, however, has become more lethal and pertinent in the current conflicts due to improvised explosive device (IED) explosions. The most common type of junctional bleeding occurs in groin wound where regular TQ cannot be placed effectively. A collaborative effort of several organizations has led to development of a mechanical device, known as the Combat Ready Clamp (CRoC), to address junctional bleeding. The CRoC was designed to exert mechanical pressure directly over the wound or indirectly over skin and deeper tissues to occlude underlying blood vessels and stop external or internal bleedings. However, the instrument has not been tested in live subjects with uncontrolled hemorrhage.

**Objective:** To examine the feasibility and effectiveness of CRoC to control arterial hemorrhage in our standard groin injury model in swine with a pre-existing coagulopathy.

**Methods:** Six Yorkshire pigs ( $40.1 \pm 2.4$  kg) were anesthetized, mechanically ventilated and subjected to midline laparotomy. Splenectomy was then performed, fluid replacement administered (3X lactated Ringers), and the abdominal incision closed with suturing. Next, the femoral artery was dissected and prepared for injury. To induce coagulopathy, each animal was subjected to 50% isovolemic blood exchange with Hextend and 4°C hypothermia (core temperature= 34.5° C).

Prior to injury, the CRoC was partially assembled and placed beneath and next to the pig. The CRoC's pressure disk was also aligned with the artery to ensure that the pressure is directly exerted on the injury site when the device is applied. Next, vascular injury (6 mm hole) was made on the femoral artery and free bleeding was allowed for 15 seconds for measuring pre-treatment blood loss. The groin wound was then packed with 10 layers of 4"x4" surgical gauze, covered with a folded laparotomy sponge and compressed manually for 2 minutes. Afterwards, the wound was observed for 2 minutes and once rebleeding became evident (no hemostasis), the remaining parts of the CRoC (horizontal arm, pressure screw and disc) were assembled and the disc was rapidly screwed down to exert enough pressure to stop the hemorrhage.

The CRoC was left in place for 1 hr and any blood loss during this period and during the application procedure was collected and measured. At 1 hr, the animal was scanned by CT methods and images of blood circulation through its lower body blood vessels were obtained. The hind legs were then flexed and stretched five times to mimic walking motions and to determine the stability of the CRoC to maintain hemostasis. Next, the clamp was removed and the wound was observed for another hour or less until the animal exsanguinated. Blood loss during this period was also measured for comparison with the period that the clamp was applied (i.e., control). Limited fluid resuscitation (maximum of 3 liters Hextend at 50 ml/min) was administered as needed to maintain MAP at or above 65 mmHg.

**Results:** The arterial injury caused profuse bleeding with an average blood loss of 126 ml in 15 seconds before treatment. Application of the CRoC (final assembly and tightening the screw) took an average of 90 seconds which stopped the hemorrhage and prevented rebleeding during the 1 hr observation in all animals (n=6). This was accomplished by setting up the CRoC at its lowest height and screwing down the pressure disk almost entirely to generate sufficient pressure to secure hemostasis. This pressure was 800-900 mmHg as measured with a digital barometer and pneumatic cuff that was placed beneath the pressurizing disk.

Almost all blood loss during the first hr of observation (~90 ml) occurred during the application of the CRoC with minimal oozing afterwards. Blood pressure (MAP) remained at or above 65 mm Hg (Fig. 1)

and a minimal volume of fluid was administered during this period. Walking simulation also did not cause slippage of the clamp or rebleeding. Removal of clamp at 1 hr, however, promptly led to rebleeding in 5 out of 6 experiments and animals exsanguinated during the second hour of observation despite receiving resuscitation fluid. Rebleeding did not occur in one experiment after removal of the clamp possibly due to tight packing of the gauze in the wound when the CRoC was applied. The overall hemostatic results are shown in table 1. Blood test results are summarized in table 2. The data collectively show the effectiveness of the CRoC in preventing hemorrhagic shock and maintaining homeostasis in pigs with a lethal vascular injury.

CT scans and Doppler tests of hind legs showed no evidence of blood flow in the distal tissues when the clamp was applied on the groin wound. Moreover, the CT images of the arteries revealed complete occlusion of external and internal iliac arteries above (proximal) the CRoC-applied area and no collateral circulation in proximal and distal tissues. The images of a representative experiment before application (baseline) and after application of the CRoC are shown in Fig. 2. Histological examination of tissues (local muscle, femoral artery, vein and nerve) showed no apparent damage associated with acute application of the CRoC. Only focal inflammatory cell (PMNs) infiltration was seen on the endothelium layer of femoral veins and in perineural tissues of femoral nerve. These insignificant findings were expected given the short duration of CRoC application and the absence of blood reflow and functional tests of the compressed tissues.

It was intended to use one CRoC repeatedly for performing the entire study; however, after five usages the pressure screw was damaged and could not be turned to release/operate the clamp in normal way. A second clamp was then used for the last two experiments which also developed the same problem after three applications.

**Summary:** Application of CRoC over gauze in the pig groin wound consistently stopped a lethal arterial bleeding that could not be managed with dressing alone. These results indicate that the CRoC is a powerful hemostatic adjunct and can potentially be useful for treating some junctional bleedings. In the present study, the CRoC applied pressure was substantially higher (~ 10 X) at the injury site than the animals' systolic pressure in order to control hemorrhage. Such high pressure effectively occluded major extremity arteries (external and internal iliac vessels) and prevented collateral circulation in the affected leg. Applying the clamp with such high pressure also caused metal damages (screw thread) and made the instrument inoperable after a few tests. Histological examination of tissues showed no significant acute damages in blood vessels and nerves after a 1 hour compression with the CRoC. The long-term effects of CRoC application and total ischemia induced by this device on limb function remains unknown and warrant further investigation.

#### **Conclusions:**

- 1. Application of CRoC on a pig groin wound consistently and securely (no slippage) stopped a lethal arterial hemorrhage.**
- 2. In order to stop the junctional hemorrhage, the CRoC had to be applied at significantly higher pressure (~10X ) than systolic pressure.**
- 3. CRoC application prevented blood flow in major arteries and blocked all collateral circulation in the affected leg.**
- 4. Histological examination showed no significant acute damages to compressed blood vessels and nerves (minor inflammation only).**
- 5. The long-term effects of CRoC's application and the consequences of ischemia and reperfusion injury of the treated limb remain unknown.**

**Table 1: Hemostatic outcomes of CRoC application and release in pigs groin hemorrhage model**

| Values (MEAN $\pm$ STDEV)         | 1st 60 MIN<br>w/CRoC<br>n=6 | 2nd 60 MIN<br>w/o CRoC<br>n=6 |
|-----------------------------------|-----------------------------|-------------------------------|
| Hemostasis Achieved/Maintained    | 6/6                         | 1/6                           |
| Time to Hemostasis (min)          | 4.6 $\pm$ 4.3               | Not measurable                |
| Pre-Treatment Blood Loss (mL/kg)  | 3.2 $\pm$ 0.4               | N/A                           |
| Post-Treatment Blood Loss (mL/kg) | 2.2 $\pm$ 1.3               | 61.6 $\pm$ 32.3               |
| Hextend Resuscitation (mL/kg)     | 0.7 $\pm$ 1.1               | 34.8 $\pm$ 21.7               |
| Survival Time (min)               | 60 $\pm$ 0                  | 38.2 $\pm$ 16.1               |
| Survival                          | 6/6                         | 1/6                           |

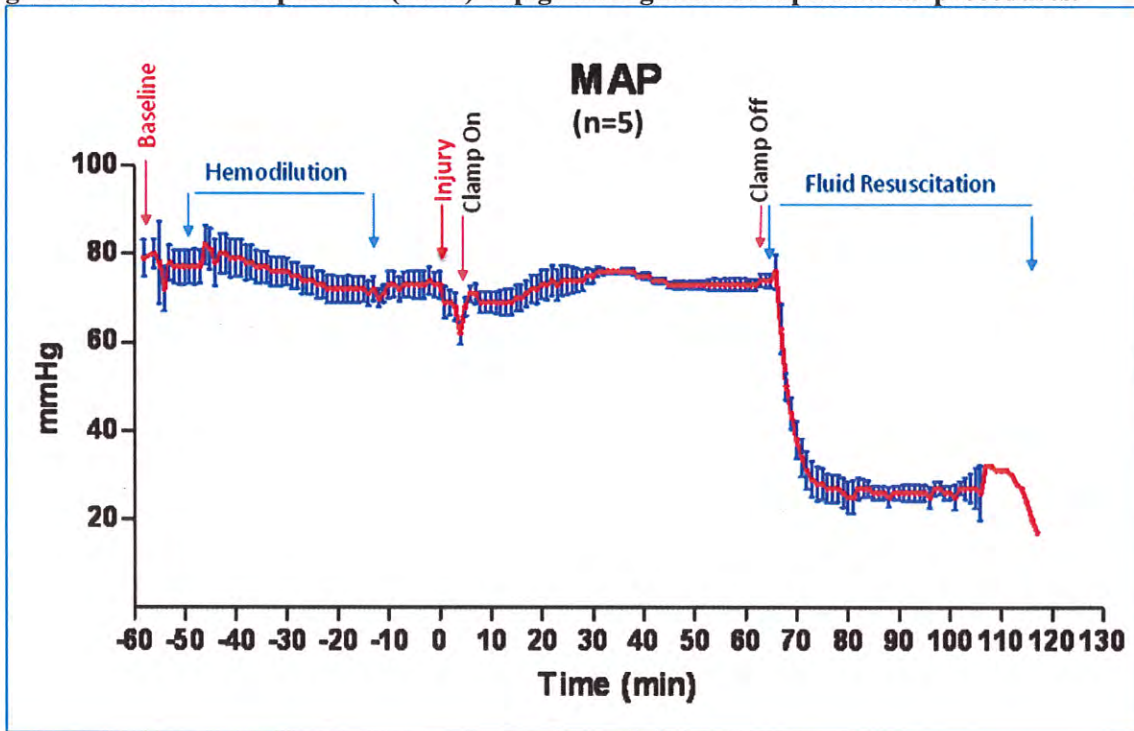
Data expressed as mean  $\pm$  SEM.

**Table 2: Blood pressure and hematological measurements of pigs at different time points of experiments**

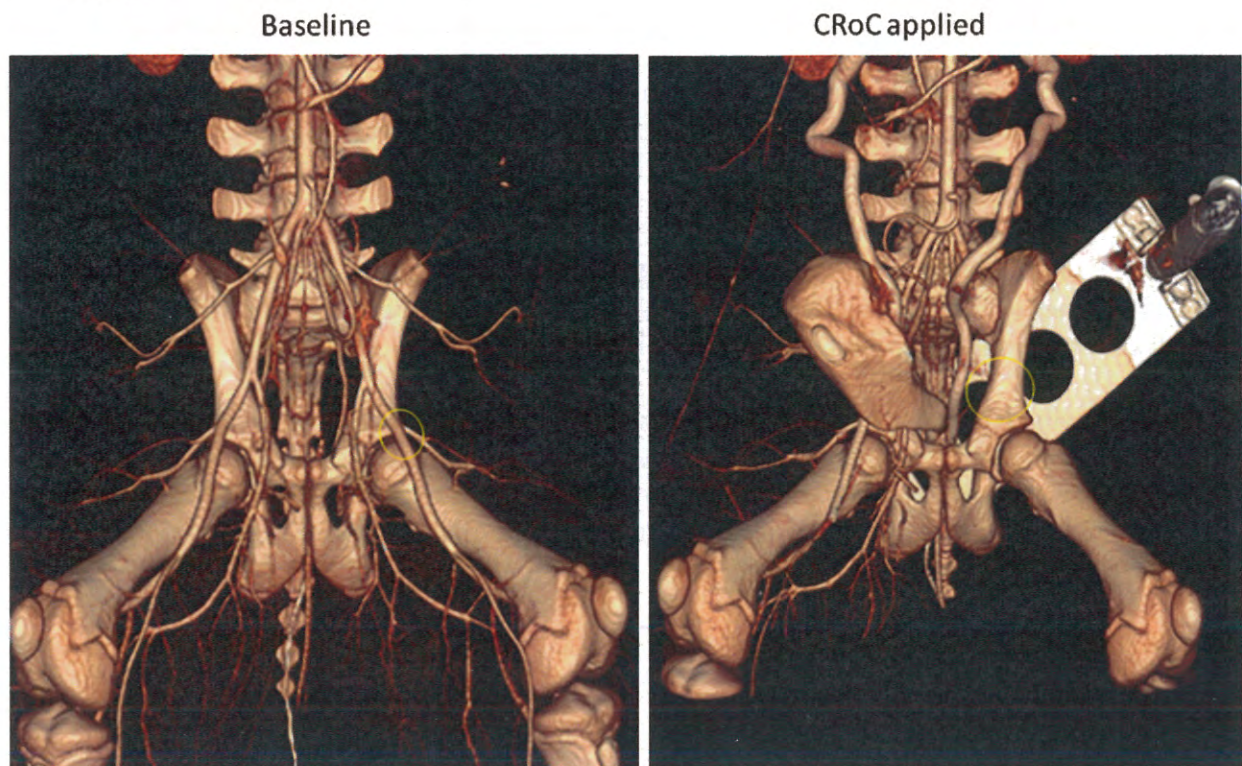
| Values<br>(MEAN $\pm$ STDEV) | BASELINE<br>n=6    | Post-<br>hemodilution<br>n=6 | 1ST 60 min<br>w/CRoC<br>n=6 | 2nd 60 min<br>w/o CRoC*<br>N=6 |
|------------------------------|--------------------|------------------------------|-----------------------------|--------------------------------|
| MAP (mmHg)                   | 77.3 $\pm$ 7.03    | 70.3 $\pm$ 6.02              | 72.5 $\pm$ 5.75             | 23.2 $\pm$ 18.26               |
| HGB (g/dL)                   | 9.6 $\pm$ 0.92     | 4.3 $\pm$ 0.42               | 4.3 $\pm$ 0.53              | 1.4 $\pm$ 1.44                 |
| HCT (%)                      | 29.1 $\pm$ 2.79    | 13.4 $\pm$ 1.41              | 12.9 $\pm$ 1.77             | 8.8 $\pm$ 5.38                 |
| PLT (1000/ $\mu$ L)          | 401 $\pm$ 42.58    | 91.5 $\pm$ 18.82             | 178.6 $\pm$ 24.76           | 48 $\pm$ 62.41                 |
| PT (sec)                     | 11.3 $\pm$ 0.41    | 12.3 $\pm$ 0.47              | 12.3 $\pm$ 0.56             | 22.4 $\pm$ 8.34                |
| aPTT (sec)                   | 16.5 $\pm$ 0.8     | 20.2 $\pm$ 2.1               | 20.5 $\pm$ 1.99             | 36 $\pm$ 13.08                 |
| Fibrinogen (mg/dL)           | 304.9 $\pm$ 135.12 | 185.6 $\pm$ 94.8             | 191.4 $\pm$ 83.17           | 86.5 $\pm$ 11.18               |
| pHt                          | 7.4 $\pm$ 0.02     | 7.4 $\pm$ 0.02               | 7.5 $\pm$ 0.03              | 7.5 $\pm$ 0.05                 |
| Lac (mM)                     | 1.6 $\pm$ 0.43     | 2.4 $\pm$ 0.11               | 1.7 $\pm$ 0.48              | 8.9 $\pm$ 3.49                 |
| BE (mM)                      | 4.3 $\pm$ 0.91     | 5.1 $\pm$ 1.64               | 7.3 $\pm$ 0.82              | 0 $\pm$ 4.23                   |
| Temp. ( $^{\circ}$ C)        | 37.5 $\pm$ 0.45    | 34.7 $\pm$ 0.19              | 34.7 $\pm$ 0.08             | 34.1 $\pm$ 0.44                |

Data expressed as mean  $\pm$  SEM. \* The intended observation period but most measurements were done at early time prior to exsanguination.

Figure 1. Mean arterial pressure (MAP) of pigs throughout the experimental procedures.



**Figure 2. CT images of arterial blood circulation before and after CRoC application. The yellow circles show the arterial injury site (baseline) and approximate spot where CRoC was applied. Note that the images of CRoC horizontal arm and pressure screw were edited out to reveal underlying**



Pig 480

## **The effectiveness of the Combat Ready Clamp (CRoC) for controlling junctional hemorrhage in a perfused swine carcass model**

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**Purpose:** The purpose of this study is to test the effectiveness of the Combat Ready Clamp (CRoC) for controlling truncal hemorrhage in a perfused swine carcass model

### **Methods:**

Five female Yorkshire swine carcasses weighing approximately 40 kilograms were studied. Immediately following death, they were exsanguinated, eviscerated, and perfused to remove all blood. Branches of the aorta that were cut during organ removal were ligated or clamped. They were then refrigerated overnight.

On the following day, a Statham dome was connected to the left femoral artery for recording arterial pressure. A transit time flow probe was placed on the right external iliac artery for recording flow. A pulsatile blood pump for large animals was connected to the aorta. Pressure and flow measurements were made during simulated hemorrhage. Flow rate was varied as shown in Table 1.



**Figure 1. Simulated hemorrhage after a stab wound on the groin.**

The pump was turned on and simulated bleeding from a deep incision in the groin area was created (Figure 1).

### **Results:**

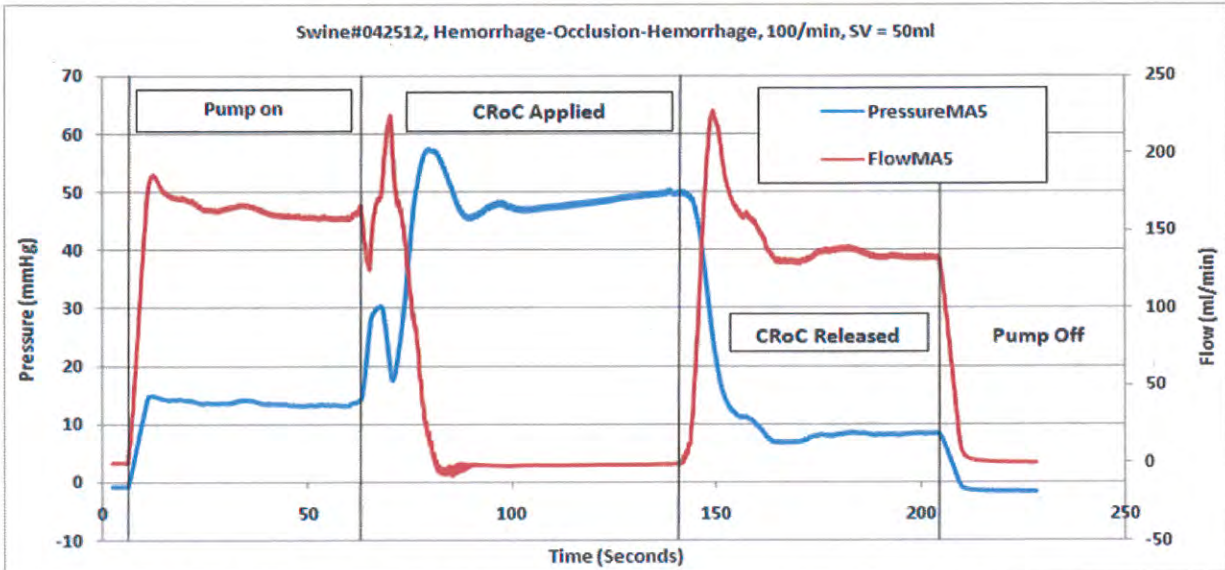
Hydrostatic pressure (blue) was recorded from the left femoral artery and flow (red) was recorded from the right external iliac artery (Figure 2). Pump stroke rate and volume were varied to achieve different pressures and flows as shown in Table 1.

When the pump was turned on after creating the injury, the pressure increased and caused high flow bleeding in the wound (Figure 2, Pump on).

When the CRoC was applied, intravascular pressure increased and outflow (bleeding) dropped to zero ml/min. (Figure 2, CRoC applied).

When the CRoC was removed, rebleeding started and as a result pressure dropped (Figure 2, CRoC released).

The flat segment on the RED line showed that flow (bleeding) reduced to ZERO when the CRoC was fully applied (Figure 2).



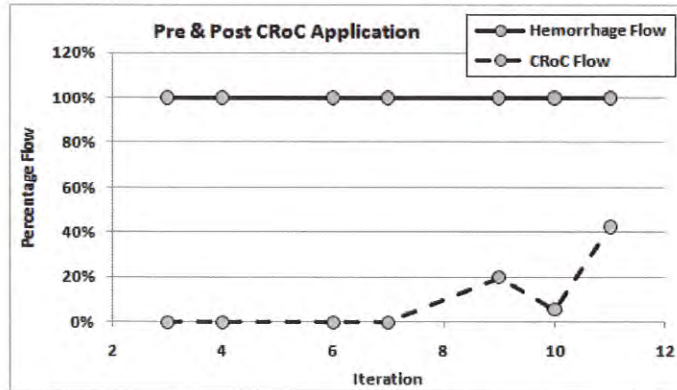
**Figure 2. Arterial pressure and external iliac artery flow during simulated hemorrhage, CRoC application and CRoC release.**

Similar results were seen during continuous pressure and flow measurements in thirteen applications of the CRoC on five swine carcasses at mean arterial pressures (MAP) ranging from 10 to 88 mmHg (Table 1).

| Pump On      |                | CRoC Applied          |                |
|--------------|----------------|-----------------------|----------------|
| Hemorrhage   |                | Hemorrhage Controlled |                |
| MAP<br>mm Hg | Flow<br>ml/min | MAP<br>mmHg           | Flow<br>ml/min |
| 10           | 160            | 45                    | 0              |
| 14           | 158            | 48                    | 0              |
| 20           | 275            | 50                    | 0              |
| 30           | 449            | 13                    | 191            |
| 38           | 513            | 73                    | 103            |
| 38           | 513            | 78                    | 29             |
| 44           | 500            | 63                    | 0              |
| 49           | 500            | 80                    | 0              |
| 51           | 500            | 88                    | 0              |
| 57           | 348            | 51                    | 0              |
| 79           | 500            | 107                   | 0              |
| 81           | 388            | 101                   | 0              |
| 88           | 410            | 81                    | 0              |

**Table 1. The results of thirteen applications of the CRoC to junctional hemorrhages in five swine carcasses at pressures ranging from 10 to 88 mmHg.** Pressures and flows are listed in order by Pump on hemorrhage pressure. They are not listed chronologically.

The CRoC failed on the eleventh application in the perfused swine carcass model when the device's t-arm (T-handle) became bound (Figure 3).



**Figure 3. Post CRoC application flow as a percentage of initial hemorrhage flow. Number of applications of the CRoC before failure.** Pressure and flow were not recorded for all applications. Simulated flow measurements are shown in chronological order for one CRoC device in this figure.

Application of more force damaged the threads on the T-arm and produced metal shavings.

#### **Conclusion:**

The CRoC is effective in controlling junctional hemorrhage in a perfused swine carcass model. The CRoC is designed for one-time use. Repetitive use of the device in the perfused swine carcass model resulted in instrument failure. Communication with investigators using the CRoC in other models revealed that similar failure of the CRoC occurred in the live swine model, but was not seen in a human manikin model. Further study is needed to estimate failure rate.