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EVALUATION OF A JUNCTIONAL TOURNIQUET DESIGNED FOR COMBAT, A HUMAN TISSUE STUDY

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KEY WORDS: hemorrhage, tourniquet, wounds and injuries, junctional hemorrhage, combat casualty care, femoral artery

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EVALUATION OF A JUNCTIONAL TOURNIQUET DESIGNED FOR COMBAT, A HUMAN TISSUE STUDY

Keith S. Gates, M.D., Lisa Baer, M.S., John B. Holcomb, M.D.

OBJECTIVE: Junctional bleeding in the groin area has become a leading cause of potentially preventable causes of death because of the lack of practical methods to control the bleeds outside of the surgical theater. Current techniques are not effective in controlling junctional bleeding effectively nor can they be maintained throughout evacuation. We have successfully developed a novel device called the Junctional Emergency Treatment Tool (JETT). The JETT is ideally suited to treat combined pelvic and lower extremity injuries sustained in high explosive, high-energy trauma on the battlefield and in the civilian environment. Our purpose was to assess the effectiveness of a novel junctional hemorrhage control device (JETT) in the control of life threatening hemorrhage from proximal injuries at the groin in a cadaver model.

METHODS: The Junctional tourniquet was compared to the standard issue combat tourniquet and a FDA approved junctional hemorrhage control clamp (CRoC). The device's ability to stop peristaltic fluid flow in a human cadaver model was assessed through proximal and distal dynamic measurements of arterial flow rates and pressures through the bilateral distal superficial femoral arteries.

RESULTS: In all subjects, when the device was applied there was an immediate cessation of fluid flow from the common femoral artery while the inlet flow pulsatile pressure was maintained.

CONCLUSIONS: The Junctional Tourniquet is a single device capable of effectively controlling bilateral lower extremity junctional hemorrhage at normal physiologic blood pressures where traditional tourniquets are ineffective or cannot be applied.

KEY WORDS: hemorrhage, tourniquet, wounds and injuries, junctional hemorrhage, combat casualty care, femoral artery

BACKGROUND/SIGNIFICANCE:

War has always spurred advances in trauma care and the present War on Terror has been no exception. Of the many advances, the most significant is the modern combat tourniquet.^{1,2} The widespread use of this device has proven that there is no more effective way to stop compressible extremity hemorrhage.^{3,4} As a result of its effectiveness, limb exsanguination is no longer the leading cause of preventable death on today's battlefield; hemorrhage amenable to truncal tourniquets now is. Evidence that the right device used in the right way at the right time for the right casualty can result in the best practical outcome.³⁻⁷

Delayed control of hemorrhage is the leading error in preventable traumatic deaths on the battlefield and in mature civilian trauma centers.^{8,9} Up to 91% percent of potentially survivable casualties on today's battlefield result in mortality due to uncontrolled hemorrhage.^{5,10} An analysis of 4,596 U.S. casualties who died in Iraq or Afghanistan between October 2001 and June 2011 revealed that the injury/physiologic focus of potentially survivable acute mortality was largely associated with hemorrhage (90.9%). The site of lethal hemorrhage was truncal (67.3%), followed by junctional (19.2%) and peripheral extremity (13.5%) hemorrhage. This study recognized that most casualties died of their injuries before ever reaching a surgeon.¹⁰ Junctional zone trauma is an injury occurring at the junction of anatomically distinct zones. These regions are traversed by major vascular structures in the region of the groin, proximal to the inguinal ligament, gluteal and pelvic areas, the perineum, axilla and shoulder girdle, and the base of the neck.^{5,11} Of these, groin hemorrhage is the most common type of junctional bleeding where regular tourniquets cannot work.^{10,12} Devices that control hemorrhage on the battlefield early in the continuum of care have been demonstrated to increase the survival of combat casualties.^{3,4,6,7} Adjunct devices that provide proximal control of bleeding through direct or indirect pressure can bridge patients to definitive surgical repair.^{7,13} These junctional hemorrhage deaths could be potentially mitigated by the deployment of an effective pre-hospital junctional hemorrhage control device.

Currently available techniques and devices do not address the unique anatomical characteristics and constraints of the junctional areas of the body, particularly in the commonly complex bilateral amputation injury pattern. Pressure point control is an ineffective technique that has been called a "euphemistic misnomer" by investigators because blood flow is restored momentarily in normal volunteers.¹⁴ Military anti-shock trousers are poorly effective and are not practical for use on the battlefield.¹⁵⁻¹⁹ Due to these conditions, the US Army Medical Research and Material Command and the multi-service Committee for Tactical Combat Casualty Care made the search for an effective truncal tourniquet a priority in 2009. The first FDA approved device was the Combat Ready Clamp (CRoC, www.combatmedicalsystems.com). The CRoC consists of an aluminum frame, nylon belting, and one hemispherical pressure disc on a T-handle. This FDA approved and deployed device controls unilateral hemorrhage from the common femoral artery.

The vision of the military's Joint Trauma System is that every soldier, sailor, marine, or airman injured on the battlefield or in the theater of operations has the optimal chance for survival and maximal potential for recovery. The US Army Medical Research and Material Command have posted a Request for Information (RFI) for 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
- 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 a long shelf-life, low cost, and low cube

We have successfully developed a novel device, in collaboration between the UT Health Science Center for Translational Injury Research and North American Rescue Products (www.narescue.com), called the Junctional Emergency Treatment Tool (JETT). This rugged, lightweight, tactical windlass device is ideally suited to treat combined pelvic and lower extremity injuries sustained in high explosive, high-energy trauma on the battlefield and in the civilian environment. It is a low cube, lightweight, durable device that is intuitive and easy to apply. It incorporates both a pelvic binder application and bilateral hemorrhage control devices designed to occlude unilateral or bilateral common femoral artery blood flow to the lower extremities. The device can be used instead of manual pressure, allowing the healthcare provider to attend to other casualties. The JETT consists of a belt assembly, with two trapezoidal pressure pads and threaded T-handles. This potentially lifesaving device addresses the gaps in battlefield hemorrhage control. It has the potential to control bilateral inguinal and extremity hemorrhage. (Figure 1)

PURPOSE: To assess the effectiveness of a novel junctional hemorrhage control device (JETT) in the control of life threatening hemorrhage from proximal injuries at the groin.

METHODS

STUDY DESIGN:

Our bleeding control model utilized fresh human cadavers to create an arterial flow hemorrhagic model. The cadavers were not embalmed and were not frozen but instead were refrigerated after death and maintained at a constant temperature above freezing at 45 degrees prior to use. All cadavers were placed at ambient temperature 24 hrs prior to use to allow them to come to room temperature. The human hemorrhagic arterial flow was created utilizing a peristaltic pump connected to a series of flow tubes and fluid pressure sensors in combination with an actual human cadaver arterial vessel system to recreate a proximal amputation model with uncontrolled hemorrhage at normal physiologic blood pressures. This is the CeTIR Human Hemorrhagic Cadaver Model. The Junctional tourniquet was first compared to the standard issue combat tourniquet currently issued to U.S. troops deployed in Helmand, Afghanistan. The combat tourniquet is considered by the Committee on Tactical Combat Casualty Care to be the “Gold-Standard” in extremity hemorrhage control. Following this the Junctional Tourniquet was then compared to a FDA approved junctional hemorrhage control clamp.

In detail; the proximal end of the inflow tubing was connected to a peristaltic pump (Harvard Apparatus, Ecoline Microprocessor Controlled pump, model VC-280). The pump was connected via aortic cannulation to recreate the physiological blood flow within the abdominal and pelvic arteries by providing pressurized pulsatile fluid flow into the distal arteries with a pump cycle rate of 270-330 pulses per minute.

A tube (4.7mm ID; 6.35mm OD; 0.8mm thickness) was placed in the bilateral distal femoral arteries to release fluid under constant pump pressure and for dynamic measurements of arterial flow rates through the bilateral distal superficial femoral arteries. Both arterial in-flow and left and right femoral artery out-flow were monitored and measured using fluid-filled pressure transducers connected to a data acquisition system. All pressure measuring instrumentation was independently calibrated. Arterial pressure was measured by placing a 16G IV catheter directly into the tubing line approximately 15cm from the inlet opening and 10cm from each of the outlet openings.

RESULTS

Experiment 1 established our bleeding cadaver model and tested the concept of the JETT device against the “Gold Standard” CAT tourniquet currently issued to combat troops. The entire procedure was repeated on two cadavers.

Control Phase: The distal system was opened to simulate bilateral wounds. A combat tourniquet was applied bilaterally to the active flow model and immediately stopped flow. The time of occlusion was held to 1 minute while the overall system pressure was maintained at approximately 90mmHg for each segment of the testing phase (bilateral, then unilateral each side).

Experimental phase: The system was again activated and the JETT device applied. Application of the JETT immediately occluded fluid flow through the major arteries of the leg. Flow through the common femoral artery was reduced and then stopped within 4 - 8 complete 360° turns of the device handle. Each time the device was applied, there was an immediate cessation in the simulated blood flow and reduction in the distal femoral artery pressure to zero. Femoral artery pressure dropped immediately with the application of the device and was zero pressure maintained throughout the application of the device each time it was applied. At the same time, physiologic blood pressures returned and were maintained above the level of the hemorrhage control device. The time of occlusion was held to 1 minute for each section while the overall system pressure was maintained at approximately 90mmHg (bilateral, unilateral each side). The system was closely assessed for leaks and changes. Hemostasis was held for the entire time the device was applied with no breaks or leaks in the system as the abdominal and thoracic blood pressures increased to normal levels. Once the device was released, the distal flow rates returned to their previous levels and pressures above the inguinal ligament dropped, indicating that the device did not significantly deform or occlude the vessels beyond the time of application. When properly applied, the JETT achieved hemostasis 100% of the time.

Experiment 2 was a comparative analysis between the JETT junctional tourniquet and a FDA approved device, the CRoC developed by Combat Medical Systems. The JETT device was tested with both small and large occlusion pads.

The JETT with small pads was applied and achieved bilateral flow control in 17 seconds (Figures 3, 4). When applied with large pads the JETT achieved bilateral flow control in 10 seconds. (Figures 5, 6) These times do not include device fitting time. Each time the device was applied, there was an immediate reduction in the fluid outlet flow while the inlet flow and femoral pressure was maintained (Figures 3 through 7). Flow through the common femoral artery was reduced and then occluded with ten complete 360° turns of the device. Femoral artery pressure 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 one minute the device was applied while the systemic pressure was maintained above 110mmhg. The application of the device did not permanently deform or obstruct the vessels as evidenced by the original baseline pressures returning after the device was released. The CRoC was applied

during the next phase of the experiment. The CRoC was applied first unilaterally to the right side (Figure 7) and then to the left (Figure 8), ultimately achieving bilateral hemorrhage control. The CRoC achieved unilateral flow control on the right in 30 seconds, on the left in 38 seconds for a cumulative time of 68 seconds to control flow bilaterally (Figures 7 and 8). Again, these times do not include device fitting time. The JETT and the CRoC both achieved hemostasis in a static cadaver 100% of the time.

DISCUSSION

Precise measurements confirmed the impression that a junctional tourniquet device, applied to the common femoral artery as it exits the pelvis under the inguinal ligament, would halt blood flow to the lower extremity. The modern Improvised Explosive Device (IED) has been expertly designed to produce the most lethal and devastating injuries in dismounted infantry. Complex lower limb injury caused by IEDs has become the signature wounding pattern of the conflict in Afghanistan.²⁰⁻²⁴ The IEDs currently encountered in Afghanistan are high in explosive content, often resulting in bilateral, proximal traumatic lower extremity amputations and associated pelvic injuries, all with increasing complexity.²⁵ Injury and death caused by mines/IEDs rose from 33% in 2006 to 72.7% in 2009 of all weapon effects causes.^{25, 26} The blast is directed in such a manner as to create very proximal double amputations involving bilateral lower extremities and triple amputations when the leading arm is also involved.²⁵ As observed in World War II; “The lethality of limb injuries is less than junctional areas as hemorrhage is less and slower and so the junctional hemorrhage control challenge is greater than in the limbs”.²⁷ Normal blood flow in vessels such as arteries is related to the fourth power of the radius, therefore larger, proximal vessels such as in the groin or axilla have greater arterial blood flow than distal limb arteries. Proximal arterial lesions are more lethal than distal ones, probably because greater vessel caliber at a higher pressure permits larger volume and more rapid blood loss.²⁷ Hemorrhage can be controlled by direct wound compression for a small, single wound or by compression of a proximal artery for multiple distal wounds.⁵ The common femoral artery (CFA) is the arterial supply to the lower extremity. The CFA exits from deep in the pelvis at the inguinal ligament and begins a superficial course immediately distal to the inguinal ligament. The inguinal ligament is easily located and has an overlying land mark in the inguinal fold that should be easily recognized by the field provider. The CFA is easily compressed, effectively cutting off the major blood supply to the lower extremity. The JETT’s trapezoidal compression pads are ideally suited to fit the inguinal fold and are wide enough to span the anterior thigh. In comparison to other available devices, the JETT is a low profile device that surrounds the pelvis with a binder/belt combination circumferentially binding the pelvis and the associated tissues securely in an inwardly compressive manner, thus further stabilizing the pelvis during transport. This feature may obviate the need to apply an additional pelvic binder in the event of an unstable pelvic fracture. By compressing the CFA and the associated tissues, the JETT rapidly controls catastrophic bleeding in bilateral lower extremity injury pattern commonly found on the modern battlefield. It is an intuitive, simple device of light weight and small cube that can be easily applied by first responders. Additionally, it does not interfere with splanchnic blood flow or respiratory effort.

We were able to demonstrate the effectiveness of junctional tourniquet devices at controlling very proximal hemorrhage in three separate human cadaver models. Experiment 1 compared the JETT to the gold standard CAT tourniquet. In two cadavers the JETT was as equally effective as the CAT at stopping flow at physiologic pressures. The JETT has the added advantage of being a single device that is capable of managing bilateral injuries at once. Experiment 2 demonstrated that the JETT, in 2 separate configurations, is equally effective at stopping hemorrhage when compared to the FDA approved device, the CRoC as seen in figures 3, 4, 5, and 6. In all three cases, pulsatile systolic blood pressure was established in the physiologic range of 120-130mmHg range. Upon injury simulation, the blood pressure remained above 110mmHg at all times with rapid pulsatile blood flow to the bilateral lower extremities. The JETT, with both large and small pads, applied first to the right side and then to bilateral common femoral arteries just below the inguinal ligament immediately stopped blood flow and maintained outflow pressures at zero throughout application in all test subjects.

The JETT addresses critical gaps in battlefield hemorrhage control and meets the Department of Defense Combat Casualty Care Research Program of the Medical Research and Materiel Command (USAMRMC) requirements for Junctional Tourniquets concerning the lower extremities. This device is capable of controlling difficult bleeding affecting the entire lower extremity. The JETT junctional tourniquet very rapidly and effectively occludes arterial bleeding from the common femoral arteries when applied below the level of the inguinal ligament. This device can be applied easily in a tactical environment, it does not slip during tightening or following application, it is capable of easy release and re-application. Additional characteristics which make it ideal for an austere field environment are that it is simple and easy to use with minimal training and does not require a medical provider for application. It is rugged, durable, reliable, persistently effective, and debris does not interfere with the actuating mechanism. Additionally, it is light weight, has a long shelf life, and is low cost and low cube. The JETT also has potential application in the civilian pre-hospital environment. It can be used to rapidly control major extremity hemorrhage in civilian trauma patients unilaterally or bilaterally. It would also be a simple effective and reliable device for comfortably maintaining hemostasis following percutaneous procedures in hospital settings.

LIMITATIONS

As in previous tourniquet research, it is important to note that we made no attempt to simulate field conditions. Potential interactions with combat equipment and field conditions were not the objectives of this study. The cadaver model is not a perfect example of a live tissue model and, although the subjects were of adequate size and stature, they may have had concomitant pathology that would likely not be prevalent in the age group found on the current battlefield. Additionally, we were unable to duplicate a circulating model of the entire vascular system. However, the purpose of this experiment was to demonstrate the anatomical considerations in the area of the pelvis and the effectiveness of the Junctional Emergency Tourniquet on the specific vascular anatomy in the inguinal region. For this purpose, the CeTIR Bleeding Cadaver Model was an excellent tool.

CONCLUSIONS

We conclude that the JETT is an effective device capable of controlling junctional hemorrhage where traditional tourniquets are ineffective or cannot be applied. This device specifically compresses the target tissues reliably and precisely. The JETT is capable of controlling blood flow at normal physiologic blood pressures in a human cadaver model. This device does not appear to interfere or damage any anatomic structures when applied properly. It doesn't appear to induce any more risk for vascular damage or neuropraxia than standard combat or pneumatic tourniquets commonly in use today. With further research and development, the principles of mechanical advantage and hemorrhage control could be applied to develop a device that would be able to occlude arterial bleeding from subclavian, axillary, and brachial arteries at compressible sites where standard tourniquets cannot be applied. Subsequent to FDA approval, we will compare these devices in healthy human volunteers to evaluate how they affect blood flow.

DISCLOSURE

Both Drs. Gates and Holcomb are co-inventors of the JETT Tourniquet and may receive royalties from the sale of the device in addition to royalties paid to the University of Texas Health Science Center at Houston. Grant funding for these studies provided by North American Rescue Products, LLC 35 Tedwall Court Greer, SC 29650-4791(NAR). This device will be marketed and sold by NAR. Both Drs. Gates and Holcomb have disclosed their relationship with NAR as a potential conflict of interest.

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	Device	Time to Bilateral Flow Control	Time to Unilateral Flow Control (Right/Left)
Cadaver 1:			
	CAT	26sec	13 sec Right 13 sec Left
	JETT	26sec	single application
Cadaver 2:			
	CAT	37.6sec	18.8 sec Right 18.8 sec Left
	JETT	17.5sec	single application
Cadaver 3:			
	JETT, small pads	17sec	single application
	JETT, large pads	10sec	single application
	CRoC	68sec	30sec Right 38 sec Left

Table 1: Application times by device. Comparison to the CAT is for efficacy and relative time differences. *The JETT is NOT meant to replace the CAT tourniquet and is indicated for different injury patterns.*



Figure 1. The Junctional Emergency Tourniquet (Generation 1)

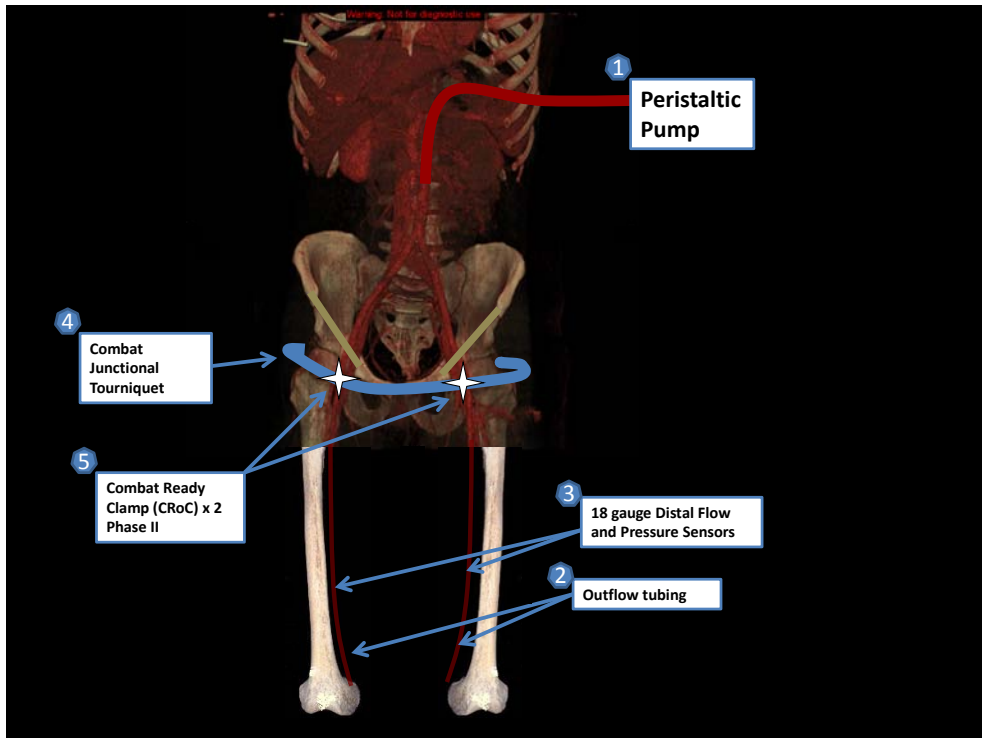


Figure 2. University of Texas CeTIR Bleeding Cadaver Model Experiment 2 Configuration

JUNCTIONAL EMERGENCY TOURNIQUET
Experiment #2 Small Pads
(1 second intervals)

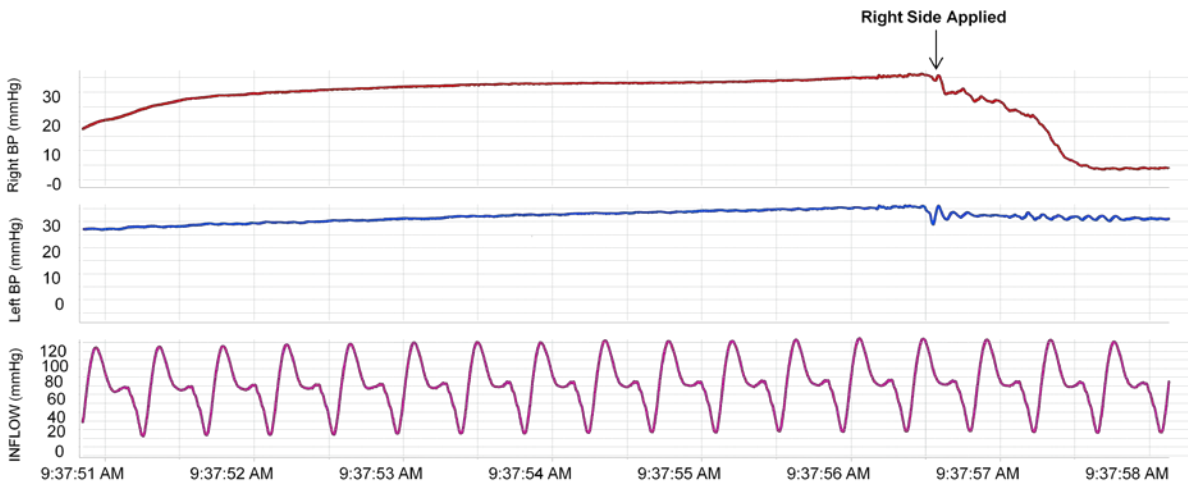


Figure 3
Unilateral Application, Right 7 second strip

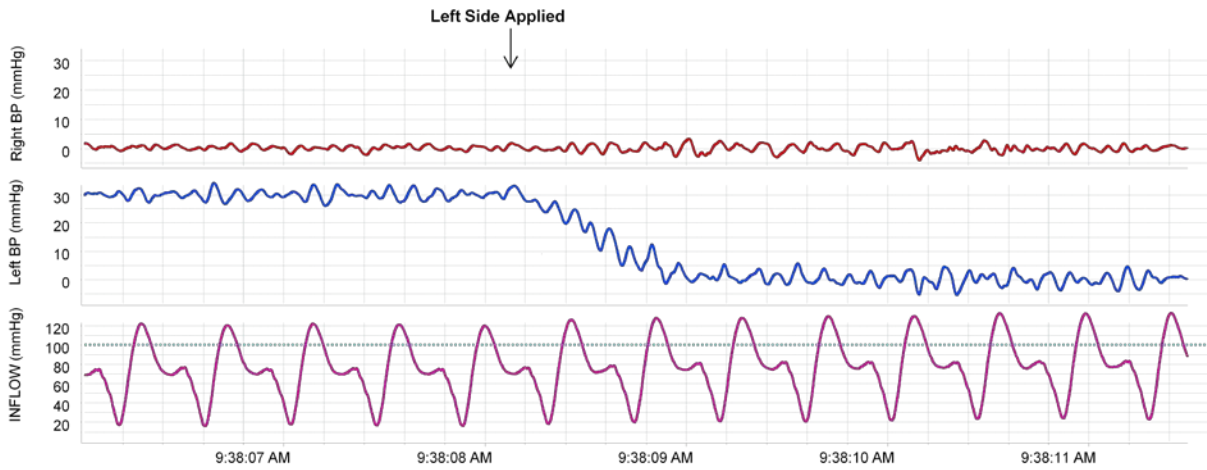


Figure 4
Bilateral Application 4 second strip

JUNCTIONAL EMERGENCY TOURNIQUET
Experiment #2 Large Pads
(1 second intervals)

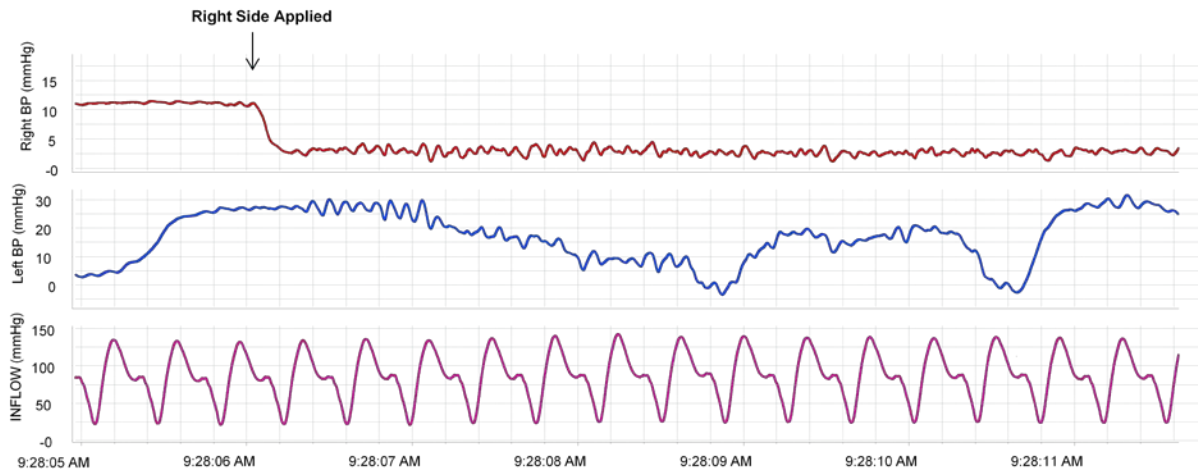


Figure 5
Unilateral Application, Right 7 second strip

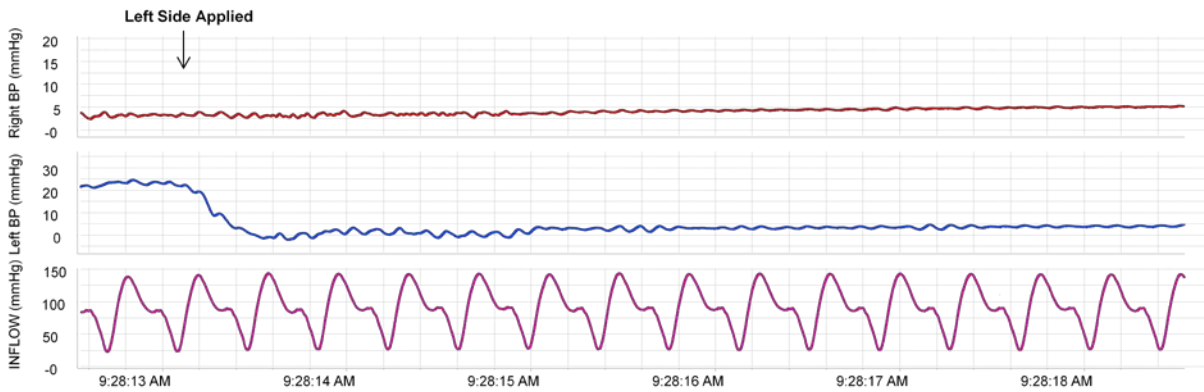


Figure 6
Bilateral Application 6 second strip

COMBAT READY CLAMP
Experiment #2
(1 second intervals)

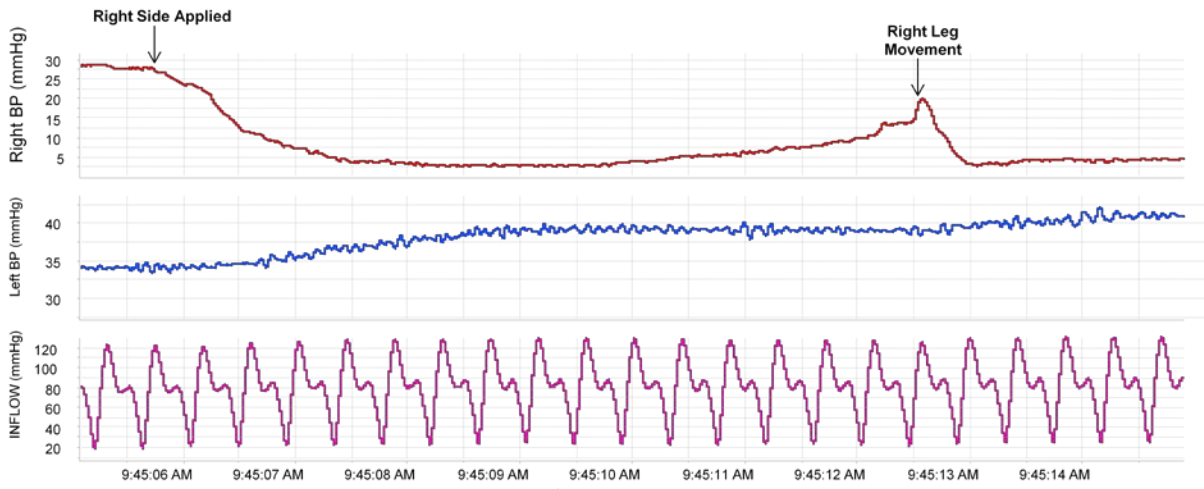


Figure 7
Unilateral Application, Right, 8 second strip

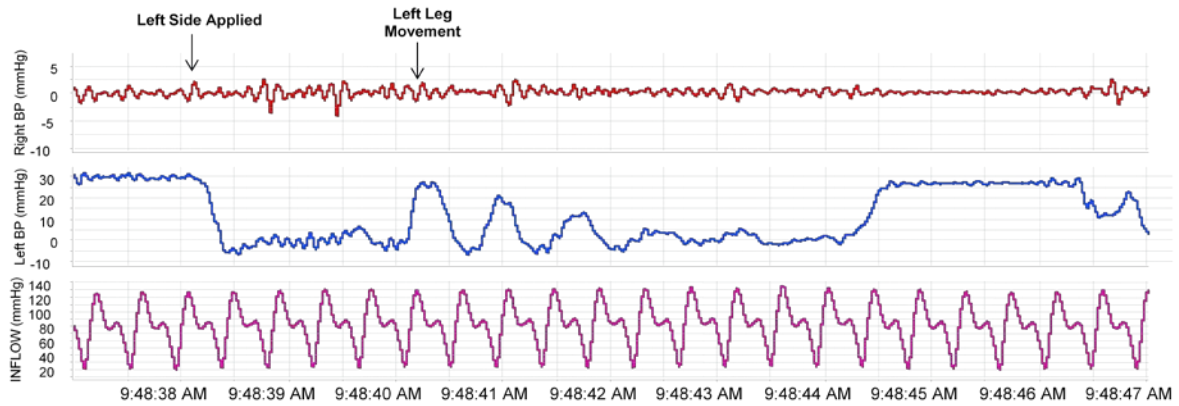


Figure 8
Bilateral Application, 9 second strip