Safety and Effectiveness Evidence of SAM® Junctional Tourniquet to Control Inguinal Hemorrhage in a Perfused Cadaver Model

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ABSTRACT

B : Hemorrhage from the trunk–appendage junctions is a common, preventable cause of death on the battlefield. The recently U.S. Food and Drug Administration (FDA)-cleared SAM® Junctional Tourniquet (SJT) was designed to control out-of-hospital inguinal and axillary hemorrhage. The purpose of the present study was to provide safety and effectiveness data associated with use of the SJT. Such data provided support for regulatory clearance. M : The SJT was tested in a perfused cadaver experiment simulating inguinal or axillary wound hemorrhage. R : No safety problems or tissue damage occurred, and flow normalized promptly after tourniquet removal. During SJT use, an average of 107mmHg occluded the distal external iliac artery in an average of 7 seconds of inflation time; manual pressure as a control averaged 139mmHg. In SJT use, an average of 739mmHg occluded the axillary artery in an average of 5 seconds of inflation time; manual pressure as a control averaged 1237mmHg. The control was a referent that achieved results that were similar in one body area but different in the other; both findings indicate the device is as safe as, if not safer than, manual compression. C : The SJT was shown to be safe and effective in hemorrhage control in a cadaver model for both the axillary and inguinal areas. The SJT's Target Compression Devices required pressures approximately equal to or lower than manual pressure to achieve hemostasis in these junctional regions.

KEYWORDS: *hemorrhage, trauma, groin, injuries and wounds, first aid, damage control emergency medical services, resuscitation, tourniquet*

Introduction

More than 90% of potentially survivable battlefield deaths today are caused by controllable hemorrhage, and in nearly 20% of such cases, the bleeding is junctional.[1] Moreover, increased rates of occurrence of explosion-related injuries have correlated with increased junctional hemorrhage. Unfortunately, trunk–appendage junctions are sites where regular tourniquets cannot fit, yet these sites are susceptible to injury as they are routinely beyond the edge of body armor. Junctional areas can be compressed to control hemorrhage, but manual compression is often difficult or ineffective in the field. Several junctional tourniquets have been developed in order to provide reliable compression.[2]

A high proportion of these explosion-related casualties also sustain a pelvic fracture due to the high-energy mechanism of injury.[3,4] For example, patients with a bilateral above-knee amputation treated at Camp Bastion Hospital, Afghanistan, had a 39% incidence of associated pelvic fracture.[5] This high rate of pelvic fractures led one military service to mandate prehospital application of a pelvic binder for all explosion-related victims.[6] Civilian pelvic fractures also have a high mortality rate, and early fracture immobilization is important for best care.[7,8]

The SAM® Junctional Tourniquet (SJT, SAM Medical Products, Wilsonville, OR; http://www.sammedical.com/) is indicated to control junctional hemorrhage of the inguinal and axillary areas, as well as to immobilize and reduce pelvic fractures. It consists of a pelvic belt to which pneumatic point pressure devices (Target Compression Devices [TCDs]) are attached. The SJT was cleared initially by the U.S. Food and Drug Administration (FDA) on March 18, 2013, and the information used to evidence the FDA clearance included testing in a perfused cadaver model. Junctional tourniquets have been fielded to U.S. forces in limited numbers; for example, the United States Army Medical Materiel Agency sent 460 SJTs to theater in October 2013. The purpose of the present study is to provide data to assess in the use of the SJT for the control of simulated junctional hemorrhage.

Methods

Initial Development of the SJT From a Preexisting Device Indicated for Pelvic Fracture Stabilization

The SJT (National Stock Number 6515-01-618-7475) was developed using the SAM® Pelvic Sling as a

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platform. The SAM® Pelvic Sling previously had been developed in collaboration with Legacy Health Systems under military funding (Office of Naval Research Grant N00014-01-1-0132) and is a pelvic binder indicated for the reduction of displaced, open-book–type pelvic fractures. Cadaveric and human clinical studies have demonstrated that there is a specific range of force that is most effective in reducing pubic symphysis diastasis in patients with pelvic fractures while maintaining patient safety.[9,10] For this safety reason, the SAM® Pelvic Sling (and now also the SJT) incorporates a mechanism that limits the applied circumferential tension to the threshold amount.

This control mechanism is relevant to tourniquet use. Operators under various conditions (fatigue, stress, training level, etc.) may not remove all slack when tightening a traditional belt. Slack leads to variation in the amount of force exerted into tissue and thus variation in effectiveness.[11] The controlled force mechanism of the SJT provides a safe and effective force for reduction of pelvic fractures while also limiting operator variability and slack before TCD inflation. The cost of the SJT currently is USD $292.50 (Defense Logistics Agency, Federal Logistics Information System; http://www.logisticsinformationservice.dla.mil/webflis/pub/pub_search.aspx).

Inguinal and Axillary Junctional Hemorrhage Indication—Cadaver Model

The device was tested at Wake Forest University using adult human cadavers that were fresh, whole, and unembalmed.[12,13] Three cadavers in total were used. For the inguinal area, there were two cadavers—one application on one and five applications on the other. For the axilla, all trials were performed on a third cadaver. Tubing connected a peristaltic pump to the thoracic aorta. Simulated blood (colored water) was pumped through the arterial system to achieve an average arterial flow rate of 330mL/min, which approximates normal flow through the axillary and external iliac arteries. The brachial artery was opened to allow bleeding and to monitor blood flow continuously through the axillary artery. Similarly, the popliteal artery was opened to bleeding and to monitor blood flow continuously through the external iliac and femoral arteries.

There were two target points for the application of pressure. The first was the skin of the infraclavicular fossa medial to the coracoid process; this target was over the axillary artery. The second was the skin at the midpoint of the inguinal ligament; this target was over the external iliac artery. A compression sensor was placed at the target point between the skin and the TCD to record changes in surface pressure during arterial compression. The pressure was recorded at the time of hemorrhage control. Hemorrhage control was defined as a minimum of 45 seconds of continuous blood flow cessation.

The experimental control was manual pressure alone at the target point to occlude the artery. The pressure was recorded at the time of hemorrhage control.

The SJT was applied with the TCD centered atop the target point according to the directions for use (Figures 1 and 2). Time to achieve hemorrhage control was recorded from the start of TCD inflation. The SJT had a total of 12 trials—six were inguinal and six were axillary. Between trials, the TCD was deflated, the SJT was unbuckled, and its belt was loosened. Two individuals conducted both the manual and SJT tests.

Figure 1 *SJT instructions for use in the inguinal area.*

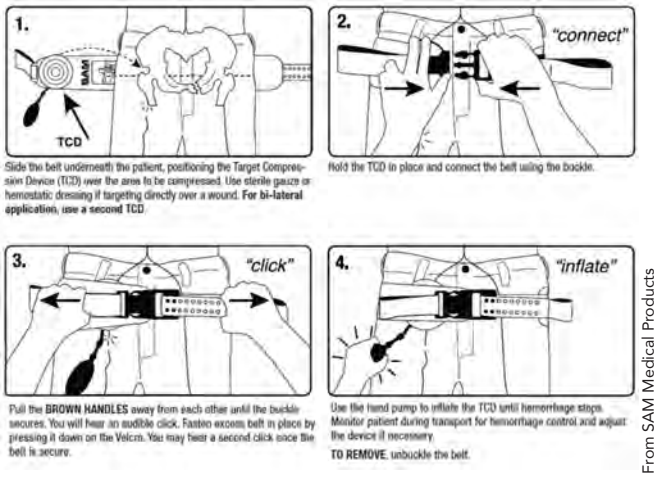

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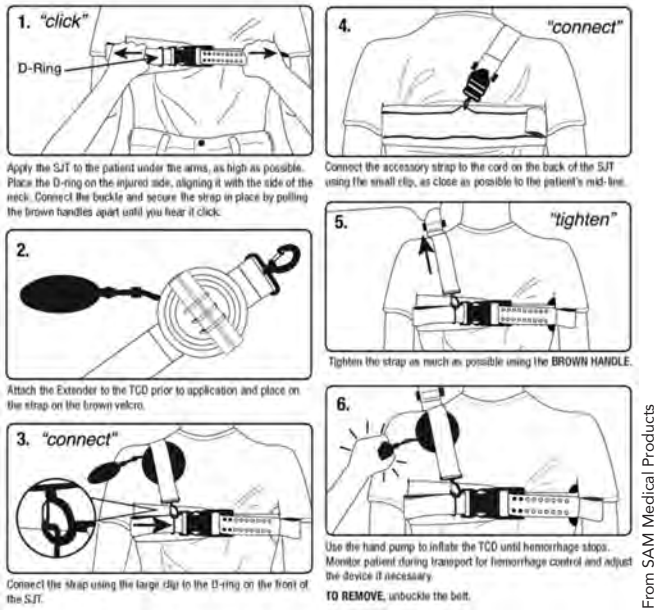
Figure 2 *SJT instructions for use in the axilla area.*



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Results

In the experimental control, an average of 139mmHg of pressure in manual compression at the inguinal ligament stopped blood flow in the distal external iliac artery (Table 1).

Table 1 *Experimental Control Data of Manual Pressure at Occlusion in Inguinal Use*

C	M P O (H)
1	115
1	140
2	160
2	125
2	155
Average ± SD	139 ± 19.1

In SJT use, an average of 107mmHg occluded the distal external iliac artery at the inguinal ligament in an average of 7 seconds of inflation time (Table 2).

In the experimental control, an average of 1237mmHg of pressure in manual compression stopped blood flow in the axillary artery (Table 3). In SJT use, an average of 739mmHg in TCD use occluded the axillary artery at the target point in an average of 5 seconds of inflation time (Table 4). In one inguinal trial, bleeding stopped as soon as the buckle was secured and no inflation was necessary—the point pressure from the uninflated TCD (76mmHg) was adequate. In this trial, the time to occlude the vessel and control hemorrhage was thus 0 seconds. On the inguinal trials, the number of hand pumps required to inflate the TCD and achieve hemorrhage control was four, none, six, two, five, and six, respectively.

No repositioning of the SJT or its TCD was necessary to achieve hemorrhage control, and pressure was sustained throughout the duration of compression (Figures 3 and 4). Release of pressure from either manual compression or TCD use on the target point immediately restored blood flow. Prompt restoration indicated that the arteries were not torn or damaged by the compression or the release of pressure.

Table 3 *Experimental Control Data of Manual Pressure to Occlusion in Axillary Use*

C	M P O (H)
3	1228
3	1152
3	1331
Average ± SD	1237 ± 89.8

Discussion

The main finding of the present study is that the SJT was shown to be a safe and effective hemorrhage control device in a perfused cadaver model in both the axillary and inguinal areas. The SJT's TCDs require pressures approximately equal to or lower than manual pressure to achieve hemostasis in the junctional regions. The TCDs, which are pneumatic point pressure devices of the SJT, achieve hemorrhage control quickly and consistently in a human cadaveric model.

On the modern battlefield, foot Soldiers and, in particular, medics are challenged in prioritizing decisions about the loads they carry and available packing space for items like a potentially life-saving medical device such as the SJT. Many items are considered, but only a few can be carried and packed. The SJT, however, is a device with multiple indications. A multiple-use device may be more likely to be useful and therefore fielded and carried. With greater availability, such devices are therefore more likely to be used in care and thus more likely to save more lives.

Table 2 *SJT Trial Data in Inguinal Use*

T	C	T H C ( )	≥45 S H ?	M P U D (H)	R A R ?
1	1	2	Yes	150	Yes
2	2	0	Yes	76	Yes
3	2	3	Yes	85	Yes
4	2	2	Yes	70	Yes
5	2	25	Yes	94	Yes
6	2	10	Yes	164	Yes
Average ± SD		7 ± 9.5		106 ± 40.2	

Table 4 *SJT Data in Axillary Use*

T	C	T H C ( )	≥45 S H ?	M P U D (H)	R A R ?
1	3	4	Yes	702	Yes
2	3	4	Yes	755	Yes
3	3	4	Yes	837	Yes
4	3	6	Yes	776	Yes
5	3	6	Yes	705	Yes
6	3	5	Yes	661	Yes
Average ± SD		5 ± 0.8		739 ± 62.9	

Figure 3 *Representative surface pressure tracing of SJT use in the inguinal area measured via use of a compression sensor placed between the skin and the pressure source.*

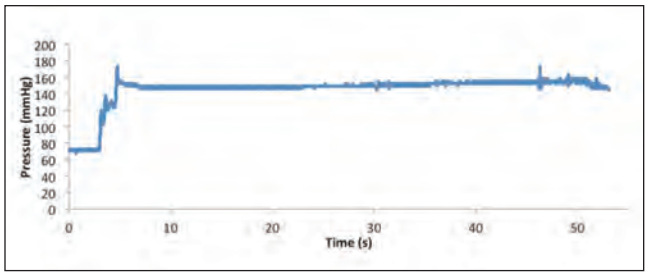
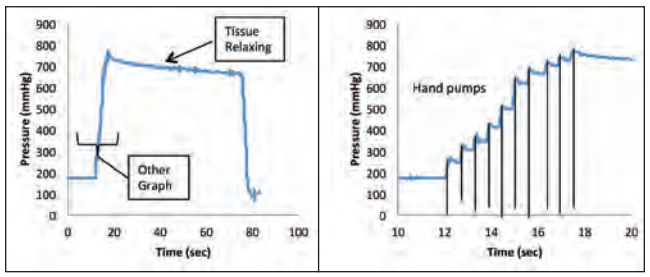


Figure 4 *Representative surface pressure tracings of SJT use in the axillary area measured via use of a compression sensor placed between the skin and the pressure source.*



Traditionally, the most lethal types of injury on the battlefield are seldom encountered in the civilian setting. Nonetheless, recent events have encouraged some adoption of military care techniques in the civilian sector.[14] Improvisation may be effective in some cases for extremity hemorrhage, as demonstrated by the reported use of improvised tourniquets by emergency medical services responders and bystanders in the Boston Marathon bombing.[15] However, junctional hemorrhage is a more complex injury and improvisation may be ineffective.[16] Junctional wounds are more anatomically complex and larger, involve larger blood vessels that bleed faster and are in need of faster hemorrhage control, and are more often associated with other wounds that may indicate other lifesaving interventions. Improvisation may be ineffective since junctional hemorrhages are so challenging early in care. Preparedness in the form of an available, effective junctional tourniquet with its corresponding training for possible users may save civilian lives as well.

With the methods used, we observed variability in the number of pumps of the bulb needed during TCD use. This variability resulted from loosening the belt and repositioning the TCD between each trial such that the TCD's location changed a bit and affected how well it targeted the artery. Furthermore, the variation in TCD positioning appeared to cause variation in how much pressure was needed for hemorrhage control. Although these observations were not hypothesis-driven, they make sense according to the understanding of mechanical hemorrhage control, and they may need further study.

The present experiment had several limitations. The experiment was designed to provide sufficient evidence for the regulatory clearance of the medical device and not to simulate battlefield care. Cadaver tissue is not live tissue. Cadavers have no coagulation and they may have less collateral flow than normal humans. The experiment was conducted under ideal circumstances such that the results represent efficacy under those specific conditions; they do not necessarily reflect clinical effectiveness. A controlled laboratory setting is not a chaotic battlefield environment. The short application times may not be indicative of those occurring with the normal first-time users since the users were both trained and experienced. Moreover, presented times of application do not include the time taken to unwrap the device, place it around the patient, and secure it.

Also, the user on the inguinal area was the developer of the SJT and another person who helped in development of the SJT was the user on the axilla area; neither of these users probably represents the average intended user. Future directions for research include normal human subject testing, testing by medics on manikins and

on human subjects that are of the age of casualties, and assessments of the quality of training needed for users.

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Disclaimers

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the Department of Defense or United States Government. The authors are employees of the U.S. government. This work was prepared as part of their official duties and, as such, there is no copyright to be transferred.

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