Evaluation of Skin Damage from Accidental Removal of a Hemostatic Wound Clamp (The iTClamp)

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Conflicts of interest/funding/disclaimer: Jessica Mckee is the Clinical Director of Innovative Trauma Care (Edmonton, Alberta, Canada), the company that funded this study and manufactures and distributes the iTClamp, one of the devices tested in this study. Jessica Mckee has had her travel covered by Innovative Trauma Care as part of her position with the company and is entitled to stock options. Prasanna Lakshminarasimhan was the technical engineer of Innovative Trauma Care. Ian Atkinson is the Chief Technical Officer of Innovative Trauma Care. Ian Atkinson also sits on the board for Innovative Trauma Care, is entitled to stock options, and is on several patents with the company. Innovative Trauma Care has also covered Ian Atkinson's travel when it is related to his employment with the company. Major Andrew W. Kirkpatrick has been paid a consulting fee and travel compensation from Innovative Trauma Care. Andrew Kirkpatrick has also consulted for Acelity (San Antonio, Texas USA) and Cook Medical (Bloomington, Indiana USA); Cook Medical has also paid for his travel on other projects. Dr. Anthony LaPorta declares that he has no conflict of interest. This study was funded by Innovative Trauma Care. There is no grant or funding number. The opinions expressed are solely the opinions of the authors and do not represent any official positions or policies of any agencies or departments of the Governments of Canada or the United States of America.

Abstract

Background: Controlling bleeding early in the prehospital and military setting is an extremely important and life-saving skill. Wound clamping is a newly introduced technique that may augment both the effectiveness and logistics of wound packing with any gauze product. As these devices may be inadvertently removed, the potential consequences of such were examined in a simulated, extreme, inadvertent disengagement.

Methods: The wound clamp used was an iTClamp (Innovative Trauma Care; Edmonton, Alberta, Canada) that was applied and forcefully removed (skin-pull) from the skin of both a human cadaver and swine. Sixty skin-pull tests were sequentially performed to measure the pull weight required to remove the device, any potential skin and device damage, how the device failed, and if the device could be re-applied.

Results: Observations of the skin revealed that other than the expected eight small needle holes from device application, no other damage to the skin was sustained in 98.3% of cases. Conversely, of the 60 devices pulled, 93.3% of the devices sustained no damage and all could be re-applied. Four (6.7%) of the devices remained in place despite a maximum pull weight >22lb_F (pound-force). The mean pull weights for pin bar pull were (lb_F): vertical 9.2 (SD = 5.0); perpendicular 2.5 (SD = 1.7); and parallel 5.3 (SD = 3.1). For the encompassed pull position group, mean pull weights were (lb_F): vertical 5.7 (SD = 2.3); perpendicular 3.0 (SD = 2.5); and parallel 14.5 (SD = 3.5). The overall mean for all groups was 6.7 (SD = 5.2). The two main reasons that the iTClamp was pulled off were because the friction lock let go or the needles slipped out of one side of the skin due to the angle of the pull.

Conclusion: Inadvertent, forcible removal of the iTClamp created essentially no skin damage seen when the wound clamp was forcibly removed from either cadaver or swine models in a variety of positions and directions. Thus, the risks of deployment in operational environments do not seem to be increased.

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Introduction

With bleeding still being the leading cause of preventable death worldwide,[1,2] and more than 12 million traumatic wounds treated in the United States every year,[3] finding a way to treat bleeding is understandably a primary concern for both military and civilian care providers. New hemorrhage control devices, such as junctional tourniquets, hemostatic agents, hemostatic dressings, extremity tourniquets, and wound clamps, are appearing more frequently in the

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literature, as is an evaluation of these products. These evaluations generally include application time, effectiveness, preference, and safety.[4-6] Several other factors such as regulatory approval, cost, weight, pain, shelf life, and durability have also been suggested as a means to study these products and inform decision on hemorrhage control protocols.[7,8] However, whether initiating medical aid during care under fire, civilian prehospital, during transport, or in hospital, understanding the impact of the agitated patient or agitated environment should also be considered important. An aggressive patient or environment may render a device less-effective than what is demonstrated during less-traumatic encounters. A seemingly easy to apply device may become impossible to utilize, or simply ineffective, in the wake of a patient or situation that is combative. The iTClamp (Innovative Trauma Care; Edmonton, Alberta, Canada) is a simple, mechanical, skin sealing device applied for hemorrhage control which has demonstrated efficacy in exsanguinating hemorrhage.[9-13] Although there have been no clinical reports of an iTClamp being inadvertently pulled from the skin's surface, there is a risk of any hemorrhage-control device being removed by an agitated patient or adverse environment. Since the iTClamp has eight needles on it that anchor it to the skin, a trial was conducted to determine if the iTClamp would create additional skin damage if forcefully removed in the closed position.

Methods

The iTClamp is a self-locking, hemostatic clamp with eight needles that penetrate the skin to evert the skin edges between pressure bars. Pressure is evenly distributed across the bars, which seal the skin over the wound. This action stops the bleeding by creating a temporary contained hematoma until surgical repair. In order to ascertain potential skin damage that could be caused by inadvertent, traumatic disengagement of the iTClamp, with needles still engaged in the skin, human cadaveric and swine skin were tested. A 1.75-inch linear wound was used, as this is the maximum length of a wound that can be sealed prior to using two iTClamps. This was done to ensure that all the needles were engaged in the incision during the testing. The study protocol, both the cadaver and animal portions, was approved by and conducted at the Medical Education and Research Institute (MERI) in Memphis, Tennessee USA. The iTClamps that were used as part of this study were donated by Innovative Trauma Care for this project.

Cadaver Model

The cadaver was thawed for 72 hours at room temperature. Wounds were made on the back of both thighs, the back of both calves, and on the buttock. Wounds were linear and 1.75 inches in length, each wound was labeled, and a new wound was created for each device pull. A total of 30 device pulls were performed on the cadaver.

Swine Model

Male, Yorkshire swine between 18-24 kg were used for this study. The swine used were freshly euthanized just prior to the study being performed. Linear, 1.75-inch wounds were made on the swine's abdomen and a new wound was made for each device pull. The swine's abdomen was chosen as it is the most similar to human skin. A total of 30 device pulls were performed on the swine.

Vectors of Disengaging Force

To test varying vectors and mechanisms of inadvertent disengagement, two pull positions were tested in each of three pull directions. The two pull configurations were designated the encompassed device pull and the pin bar pull. Encompassed device pull (Figure 1) meant that wire was wrapped around the base of the iTClamp prior to the pull test, and pin bar pull (Figure 2) meant that wire was attached to the pin bar prior to the pull test. A force gauge (Wagner FDIX Digital Tension and Compression Force Gauge; 50lb/25Kg/250 Newton Capacity; Wagner Instruments; Greenwich, Connecticut USA) was then attached to the end of the wire and pulled forcefully in one of the three directions: vertical, parallel, and perpendicular. For both of the positions, vertical pull meant to pull straight up vertically on the device (Figure 3 and Figure 4) and directly away from the skin. Parallel pull meant to pull on the device horizontally in the direction that the pressure bars are parallel to each other (Figure 5 and Figure 6), being a pull across the skin in the direction of the long axis of the clamp. Perpendicular pull meant to pull on the device horizontally, perpendicular to the pressure bars (Figure 7 and Figure 8), thus along the skin on the broad front of the device.

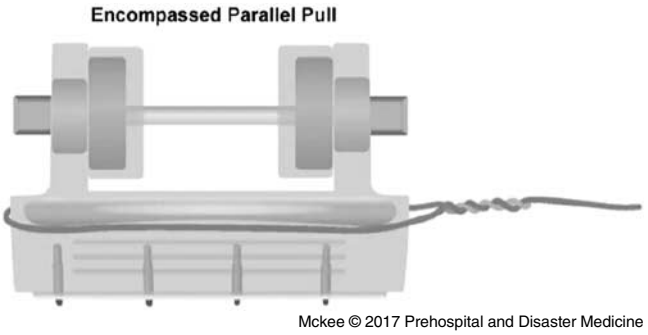

Figure 1. Encompassed Device Pull.

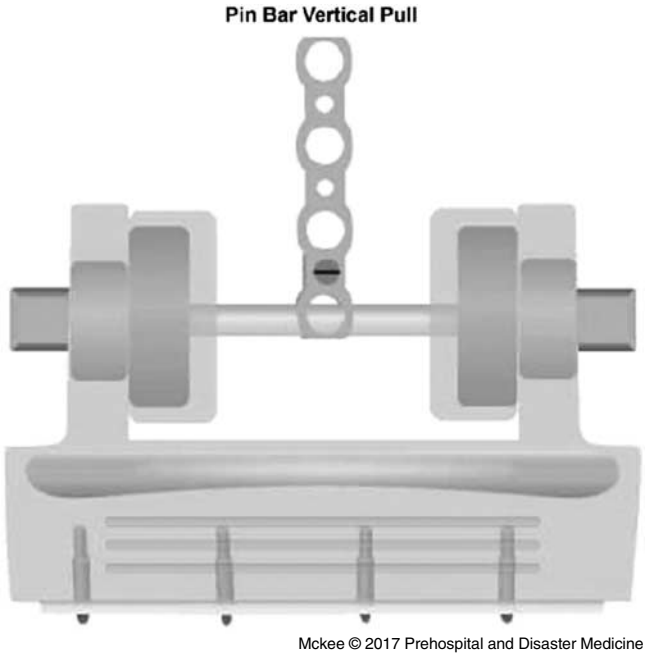

Figure 2. Pin Bar Pull.

Four outcomes were considered: pull force (measured in pound force: lb_F), skin effects, device failure, and re-application rates. These outcomes were defined as follows: *force* - the force required to remove the device from the skin (recorded in lbs); *skin effects* - once the device was pulled from the skin's surface, the skin was

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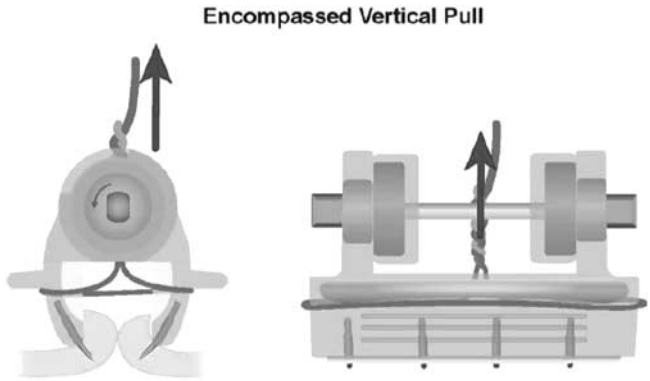

Figure 3. Encompassed Device Vertical Pull.

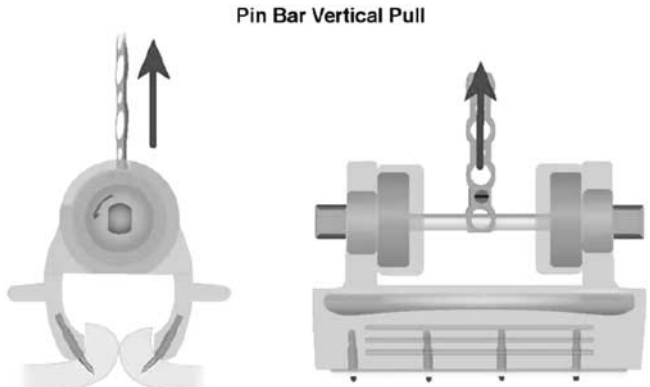

Figure 4. Pin Bar Vertical Pull.

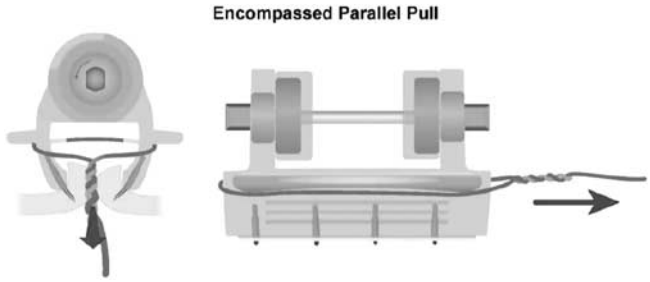

Figure 5. Encompassed Device Parallel Pull.

examined and any tearing, ripping, or deformity was recorded (each wound was also digitally recorded with high-quality images); mechanism of *device failure* - it was noted if the iTClamp was simply pulled from the skin due to force, if the device remained intact on the skin's surface, or if the device mechanically failed (any physical damage to clamps was recorded); and *re-application* - denoted the ability of the clamp to be successfully re-applied to the skin after it had been previously pulled from the skin's surface. For this determination, each clamp was re-applied to the same wound it was pulled from. Each of these outcomes was decided by two study staff to ensure inter-rater reliability.

Study Procedure

A standardized, 1.75-inch linear incision was made in the skin on the designated study model. The iTClamp was applied to the wound in either the encompassed device pull or pin bar pull

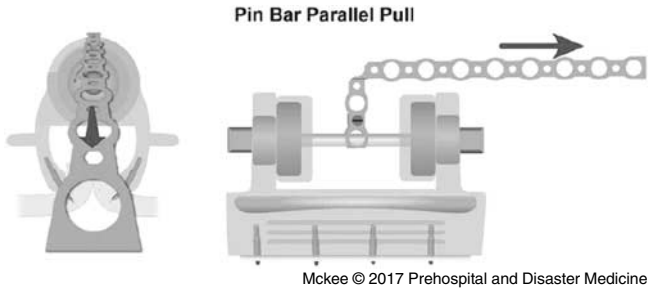

Figure 6. Pin Bar Parallel Pull.

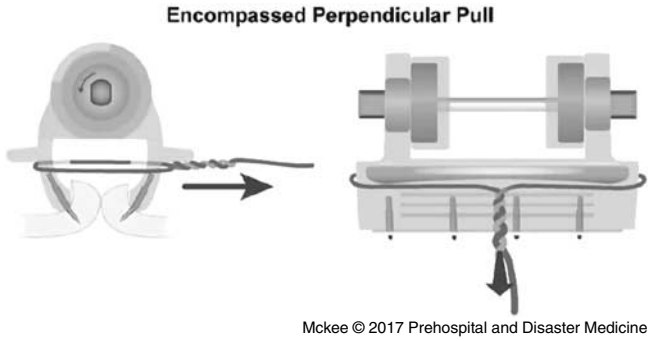

Figure 7. Encompassed Device Perpendicular Pull.

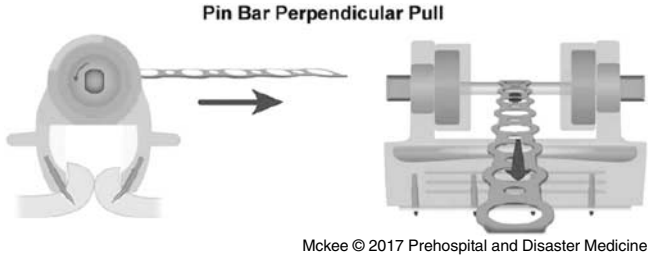

Figure 8. Pin Bar Perpendicular Pull.

position. The force gauge was attached to the wire that was on the iTClamp. Study staff then attempted to pull the iTClamp off of the model in one swift motion in one of the three vector directions: vertical, parallel, or perpendicular. A total of 30 skin pulls were thus completed on each of the cadaver model and swine model (five encompassed/vertical, five encompassed/parallel, five encompassed/perpendicular, five pin bar/vertical, five pin bar/parallel, and five pin bar/perpendicular per model). A new iTClamp was used each time.

Statistical Analysis

Statistical analysis was performed using SPSS (version 21; IBM Corp.; Armonk, New York USA). Descriptive stats were used to examine the data. As the data were not normally distributed, Mann-Whitney U tests were used to compare the data. Mann-Whitney U tests were used to compare pull force between the models as well as when the pull force information from the models was combined to compare between the pull positions and pull directions.

Results

Detailed skin observation revealed that other than the expected eight needle punctures from the device application, there was no other damage to the skin regardless of specimen, position, or

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Pull Test			N	Mean (SD) (lbs)	Minimum (lbs)	Maximum (lbs)
Encompassed Device Pull						
	Swine and Cadaver Combined					
		Vertical	10	5.67 (SD = 2.34)	2.86	10.56
		Perpendicular	10	2.97 (SD = 2.55)	0.80	8.82
		Parallel	10	14.55 (SD = 3.52)	11.10	22.06
	Swine					
		Vertical	5	5.58 (SD = 2.24)	2.86	8.86
		Perpendicular	5	3.26 (SD = 3.28)	0.86	8.82
		Parallel	5	16.9 (SD = 3.57)	13.06	22.06
	Cadaver					
		Vertical	5	5.76 (SD = 2.69)	4.24	10.56
		Perpendicular	5	2.67 (SD = 1.88)	0.80	4.92
		Parallel	5	12.19 (SD = 1.09)	11.10	14.02
Pin Bar Pull						
	Swine and Cadaver Combined					
		Vertical	10	9.18 (SD = 4.99)	2.48	17.90
		Perpendicular	10	2.48 (SD = 1.68)	0.62	6.50
		Parallel	10	5.32 (SD = 3.07)	1.72	9.20
	Swine					
		Vertical	5	11.23 (SD = 5.47)	5.05	17.90
		Perpendicular	5	2.44 (SD = 0.99)	1.25	3.45
		Parallel	5	7.20 (SD = 3.11)	1.72	9.20
	Cadaver					
		Vertical	5	7.13 (SD = 3.34)	2.48	13.20
		Perpendicular	5	2.51 (SD = 2.32)	0.62	6.50
		Parallel	5	3.44 (SD = 1.62)	1.90	5.67

Table 1. Descriptive Statistics for Swine and Cadaver Pull Tests

direction of the pull in 98.3% (n = 59) of the tests. One (1.3%) of the encompassed device parallel pulls in the swine model revealed minor skin surface tearing following a 14.98 lb_F lateral pull (Figure 9), during which the device simply pulled off the skin. Of the 60 devices pulled, 93.3% (n = 56) of the devices sustained no damage and four (6.7%) showed minimal damage (slight needle bend); however, all of the devices could be re-applied. The overall mean pull force for all groups was 6.70 (SD = 5.20) lb_F. The pull force for each group is located in Table 1. During the test, over one-half of cases (n = 32; 53.3%) ended when the iTClamp simply pulled off the skin; also, the needles slipped out of one side of the skin due to the angle of the pull (n = 15; 25.0%), the friction lock disengaged (n = 6; 10.0%), or the device stayed attached to the skin (n = 7; 11.7%). Of the seven devices that stayed attached to the skin, four (6.7%) of the devices remained in place despite a pull weight >22 lb_F. When comparing the models (swine and cadaver), there was no significant difference in the force required to remove the iTClamp (P = .19). Overall, the swine model demonstrated a mean pull force of 7.76 (SD = 5.90) lb_F with a minimum pull force of 0.86 lb_F and a maximum pull force of 22.06 lb_F. The mean

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Comparing Swine to Cadaver for Pull Direction		P Value
	Pin Bar Vertical	.42
	Pin Bar Perpendicular	.69
	Pin Bar Parallel	.15
	Encompassed Vertical	1.000
	Encompassed Perpendicular	1.000
	Encompassed Parallel	.02
Combined Swine and Cadaver Comparing Position (Pin Bar vs Encompassed)		
	Vertical	.05
	Perpendicular	1.000
	Parallel	1.000
Combined Swine and Cadaver Comparing Direction (Pin Bar and Encompassed Combined)		
	Vertical vs Perpendicular	.000
	Vertical vs Parallel	.19
	Perpendicular vs Parallel	.000

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Table 2. Mann-Whitney U test to Compare Groups

overall pull force for the cadaver model was 5.61 (SD = 4.08) lb_F with a minimum pull force of 0.62 lb_F and a maximum pull force of 14.02 lb_F. When examining the models (swine vs cadaver), comparing position and direction (Table 2), the encompassed device parallel pull demonstrated a significant difference (P = .02), with the swine model requiring slightly more force to remove the iTClamp. When comparing pin bar versus encompassed device, vertical pull showed a significant difference (P = .05), with the pin bar pull requiring more force to dislodge the iTClamp. When all models (swine, cadaver, pin bar, and encompassed) were combined, the parallel pull had the highest overall pull force at 9.93 (SD = 5.71) lb_F, the vertical pull was second at 7.42 (SD = 4.19) lb_F, followed by the perpendicular pull at 2.72 (SD = 2.11) lb_F. There was a significant difference seen between the vertical pull and perpendicular pull (P = .000) and the parallel pull and perpendicular pull (P = .000), but no difference between vertical pull and parallel pull (P = .19).

Discussion

Hemorrhage control has been identified as the single most effective intervention after traumatic injury that may save lives on a global basis. Frequently, timeliness and logistical simplicity are the most

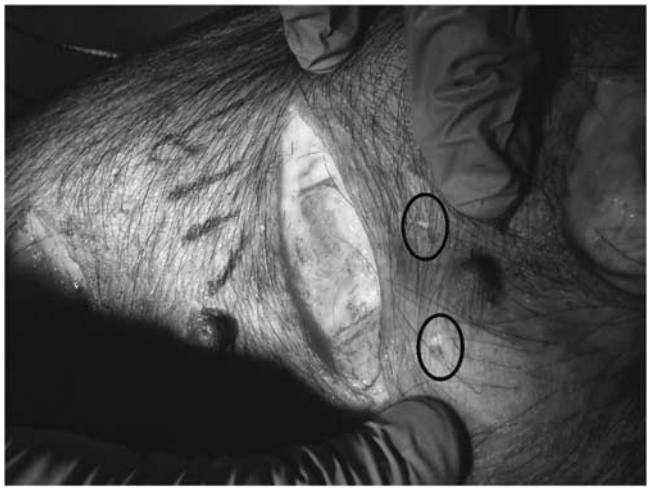

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Figure 9. Minor Skin Tear Seen on the Encompassed Device Parallel Pull from Swine Model.

critical factors in saving lives as rapid application makes the difference between exsanguination and prevention of death. In the last 20 years, there have been remarkable innovations in topical hemorrhage control with an array of advanced devices and bandages to arrest external hemorrhage. Although to date, no one bandage has been proven superior,[4,8,14,15] the combination of a wound clamp applied to secure-packed hemostatic bandages has proved superior in animal models over bandage alone.[13] This suggests great potential for the iTClamp to fill a critical role in prehospital and tactical hemorrhage control. However, the wound clamp involves a minimally invasive procedure with eight needles that physically engage the skin. As for any invasive device, safe utilization needs to be confirmed before wide-spread clinical adoption.

Numerous published case reports have demonstrated the benefits of the iTClamp to control hemorrhage.[9–13,16] However, the potential consequences of inadvertent, unplanned removal have not been well-studied. In operational settings, it is typical that a victim will require transport to definitive care, which may be a significant challenge in itself with risks of inadvertent dislodgment while being carried, littered, or loaded on and off road and aircraft-type ambulances. Akin to Beckett's work looking at the potential complications of transport of thoracic needles used for decompression in tactical settings with transport,[17] it will be important for all potential hemorrhage-control modalities to consider potential transportation failures. Further, when dealing with agitated patients, the patient themselves needs to be considered, regardless of the environmental hazards. Physical assaults have been reported in up to 92% of Emergency Medical Service providers in the prehospital environment.[18–20] The emergency department is documented as the most common workplace location for physical assault;[21] in a military setting, care providers not only have to be concerned with combative patients and providing good patient care, but also with protecting themselves and casualties in an agitated environment from contact with enemy forces and incoming hostile fire.[7] Having a full understanding of how any hemorrhage-control device will perform in these situations is essential.

The iTClamp has shown promising results for use in both the civilian and military population; it has demonstrated efficacy in exsanguinating injuries[9–13] without further damaging the skin,

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even when abruptly removed. Given the necessity to attend to other urgent needs of the acutely aggravated patient, including physical or chemical restraint or verbal de-escalation,[22,23] rapid, hands-free hemorrhage control has its merits, especially in care under fire situations.[24] Further, interventions that address preventable death until the tactical situation allows more comprehensive care, and do not cause more damage to tissue if forcibly removed, have value to helping obtain the Tactical Combat Casualty Care/TCCC guiding objectives: "(1) treat the casualty, (2) prevent additional casualties, and (3) complete the mission."[7] Therefore, the fact the iTClamp allows care providers to be hands-free to either deal more comprehensively with a multi-trauma or with the special circumstances of aggressive environments, but does not damage the skin when forcibly removed, appears to be a definite asset.

Limitations

Unavoidable limitations in this study included the need to use the models of thawed cadaver and freshly euthanized swine as an approximation for live human skin, including the frail nature of cadaver skin. These wounds were also not actively perfused, so the ability to control hemorrhage, both from the inciting wound and after being forcibly removed, could not be assessed.

Conclusion

Inadvertent, forcible removal of the iTClamp created essentially no skin damage seen when the wound clamp was forcibly removed from either cadaver or swine models in a variety of positions and directions. Thus, the risks of deployment in operational environments do not seem to be increased.

References

1. Champion HR. Epidemiological basis for future improvements in trauma care. *Seminars in Hematology*. 2004;41(Suppl 1):173.
2. Eastridge BJ, Mabry RL, Seguin P, et al. Death on the battlefield (2001-2011): implications for the future of combat casualty care. *J Trauma Acute Care Surg*. 2012; 73(6 Suppl 5):S431-S437.
3. Stussman BJ. National Hospital Ambulatory Medical Care Survey: 1994 emergency department summary. *Adv Data*. 1996;275:1-20.
4. Grissom TE, Fang R. Topical hemostatic agents and dressings in the prehospital setting. *Curr Opin Anaesthesiol*. 2015;28(2):210-216.
5. Kragh JF, Lunati MP, Kharod CU, et al. Assessment of groin application of junctional tourniquets in a manikin model. *Prehosp Disaster Med*. 2016;31(4):358-363.
6. Bulger EM, Snyder D, Schoelles K, et al. An evidence-based prehospital guideline for external hemorrhage control: American College of Surgeons Committee on Trauma. *Prehosp Emerg Care*. 2014;18(2):163-173.
7. Butler FK Jr., Holcomb JB, Giebner SD, McSwain NE, Bagian J. Tactical combat casualty care 2007: evolving concepts and battlefield experience. *Mil Med*. 2007; 172(11 Suppl):1-19.
8. Kheirabadi B. Evaluation of topical hemostatic agents for combat wound treatment. *US Army Med Dep J*. 2011: 25-37.
9. Filips D, Logsetty S, Tan J, Atkinson I, Mottet K. The iTClamp controls junctional bleeding in a lethal swine exsanguination model. *Prehosp Emerg Care*. 2013;17(4):526-532.
10. Mottet K, Filips D, Logsetty S, Atkinson I. Evaluation of the iTClamp 50 in a human cadaver model of severe compressible bleeding. *J Trauma Acute Care Surg*. 2014; 76(3):791-797.
11. Thompson L. Application of the iTClamp in the management of hemorrhage: a case study. *Journal of Paramedic Practice*. 2014;6(5):180-181.
12. Hudson A GW. First UK use of the iTClamp hemorrhage control system: case report. *Trauma*. 2014;16(3):214-216.
13. St John AE, Wang X, Lim EB, Chien D, Stern SA, White NJ. Effects of rapid wound sealing on survival and blood loss in a swine model of lethal junctional arterial hemorrhage. *J Trauma Acute Care Surg*. 2015;79(2):256-262.
14. Bennett BL, Littlejohn L. Review of new topical hemostatic dressings for combat casualty care. *Mil Med*. 2014;179(5):497-514.
15. Littlejohn LF, Devlin JJ, Kircher SS, Lueken R, Melia MR, Johnson AS. Comparison of Celox-A, ChitoFlex, WoundStat, and combat gauze hemostatic agents versus standard gauze dressing in control of hemorrhage in a swine model of penetrating trauma. *Acad Emerg Med*. 2011;18(4):340-350.
16. Barnung S, Steinmetz J. A prehospital use of ITClamp for hemostatic control and fixation of a chest tube. *Acta Anaesthesiol Scand*. 2014;58(2):251-253.
17. Beckett A, Savage E, Pannell D, Acharya S, Kirkpatrick A, Tien HC. Needle decompression for tension pneumothorax in Tactical Combat Casualty Care: do catheters placed in the midaxillary line kink more often than those in the midclavicular line? *J Trauma*. 2011;71(5 Suppl 1):S408-S412.
18. Grange JT, Corbett SW. Violence against emergency medical services personnel. *Prehosp Emerg Care*. 2002;6(2):186-190.
19. Corbett SW, Grange JT, Thomas TL. Exposure of prehospital care providers to violence. *Prehosp Emerg Care*. 1998;2(2):127-131.
20. Pozzi C. Exposure of prehospital providers to violence and abuse. *J Emerg Nurs*. 1998;24(4):320-323.
21. Currier GW. Atypical antipsychotic medications in the psychiatric emergency service. *J Clin Psychiatry*. 2000;61(Suppl 14):21-26.
22. Baker SN. Management of acute agitation in the emergency department. *Adv Emerg Nurs J*. 2012;34(4):306-318; quiz 319-320.
23. Weiss S, Peterson K, Cheney P, Froman P, Ernst A, Campbell M. The use of chemical restraints reduces agitation in patients transported by emergency medical services. *J Emerg Med*. 2012;43(5):820-828.
24. LaPorta A KA, Mckee J, Roberts D, et al. Randomized control trial comparing marksmanship following application of a tourniquet or hemostatic clamp in healthy volunteers. *Royal Army Medical Corps*. In Press.