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Combat Vascular Trauma: From Characterization to Innovation

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ABSTRACT

The way that soldiers are injured in modern conflicts has changed. Bullet and ballistic weapons are causing fewer casualties, and more commonly Improvised Explosive Devices (IED) are injuring them. The purpose of this thesis is to characterize the injury pattern of the antipersonnel IED (AP-IED) in victims from the Afghanistan conflict, to retrospectively examine the incidence and type of vascular trauma in a Canadian level 1 trauma center and to develop and novel device for control of junctional vascular injuries.

The injury pattern of 100 consecutive AP-IED victims was recorded. Multiple amputations occurred in 70% of IED victims: 5 quadruple amputations, 27 triple amputations, and 38 double amputations. Pelvic fractures occurred in 21 victims and severe perineal, gluteal or genital injuries were present in 46 patients. The casualty fatality rate was 19%.

All adult trauma patients who presented to a Canadian Level I trauma centre with injuries to named arterial or venous vessels from 1 January 2011- 31 December 2015 were reviewed. The majority of patients were male (70.1%) with an injury severity score of 15 or greater in 63.3%. Blunt mechanism accounted for 61.4%. Vessel injuries to the neck (20.4%), thorax (20.4%), abdomen/pelvis (19.7%), upper extremity (24.5%) and lower extremity (15.0%) were identified. Prehospital tourniquet use for arterial injuries occurred in 12.2%. Non-operative management was used in 39 patients (28.3%) and open and endovascular repair were undertaken on 59 (42.8%) and 17

(12.3%) respectively. No temporary intravascular shunts or balloon aortic occlusion devices were used. Thirteen different subspecialty disciplines managed vascular trauma at this centre.

A novel device for the control of pelvic and junctional hemorrhage was developed and tested in porcine and human cadavers. Placement of a catheter into the femoral vessel was followed by expression of the balloon with inflation by CO2 in a proximal direction. Thus it can navigate and treat damaged pelvic vasculature, occluding the distal aorta, and is technically simple to use. This CO2 balloon system was tested on model aortas with inline fluid flow and pressure monitoring to determine the maximum pressure the balloons could occlude. The device was tested on both intact and injured cadaveric porcine aortas for its ability to occlude fluid flow and to test the devices safety for use in arteries. The device was tested on a dye-perfused human cadaveric model. The results of the study indicate the device can occlude fluid flow to supra-physiologic pressures and will rupture before injuring the vessel in the event of over inflation. It has the advantage of being able to navigate and treat injured pelvic vessels and is easy to use. This device may provide a tool to community hospitals and forward medical care providers in managing non-compressible pelvic hemorrhage.

Key words: *blast, trauma, vascular injury, improvised explosive device, military*.

THE CO-AUTHORSHIP

While each of the co-authors listed below made important contributions to this work, I am the principle author who analyzed the data, composed the manuscript, and designed, built, and tested the device.

Dr. Vivian McAlister, M.B., CCFP(C), FRCSC, FRCS(I), FACS as my supervisor provided me direction and guidance on study design, data analysis and manuscript revisions. He was the treating surgeon in Afghanistan for the AP-IED data collection. He was instrumental in the review and publication of each chapter.

Dr. Adam Power, MD, MBE, and FRCRC as my supervisor provided me direction and guidance on study and device design. He was invaluable in his encouragement and critical appraisal of the prototype construction and testing. He was instrumental in the review and publication of each chapter.

Dr. Kelly Vogt, MD, MSc, FRCSC was instrumental to the design and analysis of the retrospective vascular trauma study. She provided critical review of Chapter 3.

Dr Joseph Taddeo, MD, FACS was a trauma surgeon in Afghanistan and was involved in data collection.

Melissa Devine, RN is a critical care nurse who was involved in data collection in Afghanistan.

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Dedication

Major Phil Casswell and Major Larry Sandford taught me how to be a soldier and an officer. They instilled in me a sense of duty toward accomplishing the mission and caring for my fellow soldiers. Their teachings are the foundation upon which my career and this work have been built, and to them both I am forever thankful.

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AAA, abdominal aortic aneurism

AAST, American Association for the Surgery of Trauma

AKA, above knee amputation

AORTA, Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery

APM, antipersonnel mine

AP-IED, antipersonnel improvised explosive device

AV-IED, anti-vehicle improvised explosive device

BKA, below knee amputation

CO_2, carbon dioxide

CA-IED, crowd attack improvised explosive device

CFA, common femoral artery

CTA, Computed tomography angiography

Fr, French, 1 Fr = 1/3 mm

ICRC, International Committee of the Red Cross

ICD-10, International Statistical Classification of Diseases and Related Health Problems 10th revision

IED, improvised explosive device

ISS, Injury Severity Score

LHSC, London Health Services Centre

KAF, Kandahar air field

PPE, personal protective equipment

PROOVIT, Prospective Observational Vascular Injury Treatment Registry

R3-MMU, role 3 multinational medical unit

REB, research ethics board

REBOA, resuscitative endovascular balloon occlusion of the aorta

REDCap, Research Electronic Data Capture

SPSS, Statistical Package for the Social Sciences

TAA, through ankle amputation

TCCC, Tactical Combat Casualty Care

TKA, through knee amputation

UEA, upper extremity amputation

CHAPTER 1

INTRODUCTION

CHAPTER 1: INTRODUCTION

1.1 Introduction

Between January 2002 and until March 2014 Canadian soldiers were in Afghanistan, first in a combat role fighting the Taliban and al-Qaeda, then in a training role preparing the Afghan National Army. More than 40,000 Canadian soldiers would serve in Afghanistan during this conflict and Canada would suffer its first combat casualties since the Korean War. 158 Canadian Armed Forces soldiers died including Captain Nichola Goddard, the first female Canadian soldier to ever die in combat.[1]

This war presented a change in the way Canadian soldiers were injured. The majority of the people injured in this war were not harmed by bullets and conventional fighting but by Improvised Explosive Devices (IEDs).[2,3] IEDs are explosives, either taken from conventional weapons and repurposed, or created *de novo*. They then are detonated either by remote control, a pressure plate, or a trip wire to explode and injure or kill their target. These custom-made bombs may be used to attack vehicles, large crowds, or a dismounted soldier walking on patrol.[4] This change in the way our solders are attacked has changed the type of injuries treated by our combat hospitals.[5-7]

In treating these IED casualties combat surgeons needed to become adept at vascular damage control surgery. Canadian surgeons treating trauma patients in Kandahar, Afghanistan reported over 100 vascular repairs between 2005 and

2010.[8] The use of tourniquets, temporary intravascular shunts and aggressive vascular ligation became commonplace. The Afghanistan war changed the way military surgeons treat vascular trauma patients.[9]

Most of the changes in vascular trauma care were made out of necessity and adaptations to the casualties the surgeons were receiving. In order to prospectively monitor outcomes the *Joint Theatre Trauma Registry* was developed. As these deployed surgeons returned home they brought with them their experiences managing vascular trauma from combat. The American Association for the Surgery of Trauma (AAST) sponsored the Prospective Observational Vascular Injury Treatment Registry (PROOVIT) in order to document changes in treatment of American vascular trauma and monitor outcomes. [10]

Although much has been published about the medical experience in the Afghanistan war there remains several unanswered problems. What is the medical description of the injury pattern of the IED? Do combat damage control vascular techniques apply to a Canadian trauma population? Is there any novel way we can gain hemorrhagic control of the vascular trauma injured patient that is fast, safe and easy to use? It is the purpose of this thesis to address these three questions.

In order to be able to prepare for combat we must understand the way we are being attacked. In order to be prepared to treat our casualties we must know the nature of the injuries they will incur. Although many case series have been published of IED

injured patients,[5,6,11] there is no prospectively collected definitive description of what the injury pattern of the IED casualty is. The International Committee of the Red Cross (ICRC) has established the injury pattern of the conventional antipersonnel landmine.[12] That work helped with the medical justification for the eventual banning of land mines by 162 countries with the Ottawa Treaty in 1999.[13] In order to ensure that physicians and surgeons are adequately prepared to treat IED victims, this injury pattern must be described. In order that protective equipment for our soldiers can be appropriately developed this injury pattern must be described. Moreover, as a society in order to judge how we view the use of these weapons, this injury pattern must be described. To provide a definitive description of the injury pattern of the antipersonnel IED 100 consecutive casualties of this weapon had their injuries recorded and described.

In order to implement the lessons learned from treating vascular trauma in Afghanistan, as well as to know how to apply the data obtained from American prospective registries we must understand the Canadian incidence and description of vascular trauma as well as what our current practice patterns are. Who treats vascular trauma in Canada? What injuries do they encounter and how do they treat them? The differences in the mechanism of injury, as well as the trauma system receiving the patient, may be important in determining what changes in practice Canadian trauma systems should adopt. Given that Canadian trauma patients are less likely to be injured by an IED or an assault rifle, how should we use the information gained from wartime experiences? How does Canadian vascular

trauma differ from that found in Afghanistan or the United States? To answer this question, we conducted a retrospective cohort study evaluating all patients with traumatic vascular injuries over a five year period at London Health Sciences Center (LHSC), a Canadian level 1 trauma center.

With the advent of Tactical Combat Casualty Care (TCCC) and personal protective equipment (PPE) more soldiers are being treated for, and surviving, potentially preventable causes of death on the battlefield.[14] However, IEDs can cause junctional vascular injury and non-compressible torso hemorrhage not amenable to tourniquet application of TCCC techniques.[15] This has caused an interest in Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) with the publication of a Joint Trauma System Clinical Practice Guideline for the use of REBOA[16] . However many REBOA techniques require two meter endovascular wires and 12 French (Fr) sheathes that preclude this technique from being adopted in a forward medical environment. Where REBOA portends great theoretical advantage is in the evacuation of combat casualties from the point of injury to surgical care. Morrison *et al*.'s analysis of the UK joint trauma registry over a ten-year period identified 174 deaths that had indications for REBOA. One hundred forty-five of these patients died before reaching hospital (83%), with a mean time to death of 75 minutes. The authors suggested that REBOA could act as en route hemorrhage control to get these casualties to a surgeon; as many as 18% of modern combat casualties may benefit from REBOA treatment [17]. We have designed a novel device that does not require

long endovascular wires and would be more amenable to insertion into injured junctional vessels.

In this thesis, the injury patter of the antipersonnel IED (AP-IED) has been described. A Canadian Level I trauma centre cohort of vascular trauma patients has been described to help guide implementation of the lessons learned from treating combat vascular trauma patients and American registries. Finally, a novel device to treating the junctional and non-compressible vascular injures has been developed and tested. Given the change in the way solders are injured in combat and the significance this has on the type of injury being treated, the first aim of this study is to determine the combat injury pattern caused by IED versus previous bullet or APM casualties. Secondly, if the type of injury has changed, then both the training to deal with this trauma needs to be characterized and suitability of interventional devices needs to be explored. The latter aim will be addressed by defining how Canadian Level I trauma centres deal with vascular injuries and proposing a novel device to treat non-compressible vascular injuries in combat situations or local communities. This current body of work further characterizes combat vascular trauma and proposes an innovative treatment option. In this thesis, combat vascular trauma has been taken from characterization to innovation.

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CHAPTER 2

INJURY PROFILE SUFFERED BY TARGETS OF THE ANTIPERSONNEL IMPROVISED EXPLOSIVE DEVICE

CHAPTER 2: INJURY PROFILE SUFFERED BY TARGETS OF THE ANTIPERSONNEL IMPROVISED EXPLOSIVE DEVICE

2.1 INTRODUCTION

Antipersonnel mines (APM) came into widespread use in the Second World War. Originally they were used to protect anti-tank mines, but then went on to become a weapon system in and of themselves. They were designed to injure but not kill, in order to remove a target from combat and to increase the logistical burden of caring for the casualty. These weapons are typically buried and left for the target to trigger. The weapon is indiscriminate because non-combatants such as children and civilians may detonate them. They are also frequently left buried and active after fighting in that region, or the conflict itself, has ended. Following a public relations campaign that highlighted the indiscriminate injuries caused by APMs, 162 countries signed the 1999 Ottawa treaty ceasing their production and use.[1] An important basis of that campaign was the clinical description of APM related injuries by Robin Coupland and Adriaan Korver for the International Committee of the Red Cross (ICRC).[2] Three patterns of injury were found among 754 victims treated at two ICRC hospitals following wounding by blast or fragmentation mines. In pattern 1 injuries, the victim triggers a blast mine by stepping on it and suffers the full effect of the explosion. In pattern 2 injuries, victims are farther away from the centre of the explosion, whether it is a blast or fragmentation mine, and suffer wounds from fragments. Pattern 3 injuries are caused by handling the mine (blast or fragmentation), resulting in severe injuries to the hands and possibly the face and chest. Pattern 1 victims suffer one or more traumatic amputations of the lower limb,

whereas pattern 2 victims have fragment wounds scattered over the body. Pattern 2 victims may have fragment injuries of the lower limbs but the damage is not severe enough to cause traumatic amputation.

This distinguishing feature of a traumatic amputation between pattern 1 and pattern 2 injuries was confirmed in a later report of 4616 APM victims which presented further evidence of the severity of injury particularly to the limbs.[3] Of 1077 (23%) pattern 1 victims, 606 (56%) had below knee amputation (BKA), 26 (2%) bilateral BKA, 349 (32%) unilateral above the knee amputations (AKA), 57 (5%) bilateral AKA, and 39 (4%) a combination of AKA and BKA.[3] Their description of the typical pattern 1 injury profile caused by an APM, which has been confirmed by other studies, is of a traumatic amputation of the foot or leg with scattered penetrating injuries elsewhere. [2-5]

The improvised explosive device (IED) is increasingly used in modern conflicts including Afghanistan.[6,7] The majority of these weapons have been directed against pedestrian individuals in a similar fashion to APM.[8,9] As with APM, injuries suffered by victims of the anti-personnel IED (AP-IED) depend on whether they were the target of the explosive device or at some distance from the centre of the explosion. It does not depend on the manufacture of the explosive device, industrial as in APM versus improvised as in AP-IED. Indeed elements of conventional explosives may be used to construct an AP-IED. The blast injury depends on the energy transferred by the explosion to the victim. However it was our impression that pattern 1 injuries

caused by AP-IED were significantly worse than those reported for APM.[2] The purpose of this paper is to describe the profile of pattern 1 injury suffered by the target of the AP-IED compared to the target of APM.

2.2 METHODS

The cohort of patients under study was defined as those pedestrian victims of an AP-IED who suffered a traumatic amputation. In order to be included in the study, casualties were required to have been reported by the first responder as being the dismounted (pedestrian) victim of an IED explosion and to have suffered a traumatic amputation. Casualties that were non-pedestrian (i.e. in a vehicle) or whose situation was unknown were excluded. The study was designed to describe the injuries suffered by 100 consecutive targets of AP-IED attacks who presented to the North Atlantic Treaty Organization Role 3 Multinational Medical Unit (R3-MMU) in Kandahar Air Field (KAF). The hospital received casualties from the point of injury or via a forward treatment centre.[10] A R3-MMU is the highest level of in-theatre medical care and would be equivalent to a civilian level-II trauma centre, as defined by the American College of Surgeons Committee On Trauma. A specifically designated trauma nurse (M.D.), and attending surgeons (J.T., V.M.) prospectively collected data for each patient. Data was collected between January 2010 and July 2011, or until data from 100 victims had been obtained. Data collected included: nationality, age, gender, mortality status, specific injuries, and imaging results. The level of traumatic amputation, the level of soft tissue injury, the fracture pattern (including pelvic fractures) as well as perineal and gluteal injuries were specifically recorded. Generally, coalition patients were transferred after damage control surgery, whereas local patients also received definitive care at the R3-MMU. Data were collected until the time of first discharge from the hospital. In order to minimize bias, patients were included sequentially as a consecutive series with a

predefined definition of AP-IED target. The R3-MMU was the only surgical facility in the region and would receive all AP-IED victims for care. Patient level data is reported identifying the injuries of each of the 100 victims. The paediatric victims are also presented separately. The data collection was complete with injury data captured for all 100 victims. Categorical data was analysed using the chi-square test. AP-IED data was compared to previously published APM data[2]. This study was approved by the commander of the R3-MMU KAF and by the Research Ethics Board of the University of Western Ontario (REB # 104124).

2.3 RESULTS

One hundred consecutive casualties with amputations from AP-IEDs were identified and their injuries were described. All of the patients were male. The mean, and median, age of the victims was 25 years. The age range was from ages 6 to 44 years. There were 9 patients under the age of 18 (Figure 2.1). Twenty-seven patients were Afghan local nationals and 61 were coalition soldiers (USA, Canada, UK); there were 12 victims whose nationality was not captured (Table 2.1). Eleven patients were dead upon arrival and another 8 died of their wounds in the hospital, giving a 19% casualty fatality rate. Gender, injury pattern, and age or approximate age, was recorded for all victims.

Figure 2.1 Victim ages

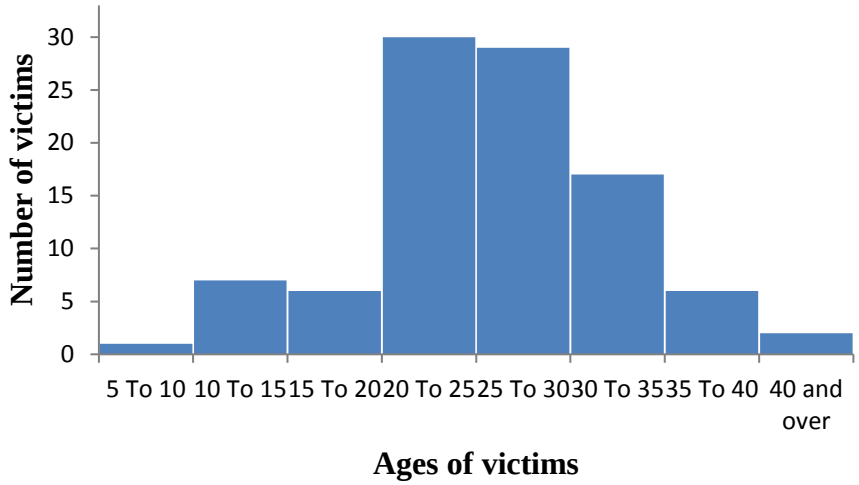


Table 2.1 Victim characteristics

Characteristic	
Number of patients	100
Age, mean (SD)	25 (6.8) yrs
Median	25 yrs
Range	6 – 44 yrs
Male	100
Female	0
Nationality	
Afghan	27
Coalition	61
American	49
Canadian	8
UK	4
Not specified	12
Mortality	19
Killed in Action	11
Died of wounds	8

SD = standard deviation

AP-IED victims were more likely than a similar cohort of APM victims to suffer multiple amputations (70.0% vs. 10.4%; p<0.001) or genital injury (26.0% vs. 13.4%; p=0.007). Seventy victims (70%) sustained multiple amputations: 5 patients suffered quadruple amputations, 27 had triple amputations, and 38 victims had double amputations (Figure 2.2). Two victims had hip disarticulations, 41 had at least one AKA, and 56 had at least one BKA (including through knee and through ankle amputations). Sixty-five victims had bilateral lower extremity amputations and 37 had at least one upper extremity amputation (at the level of the hand or higher) (Table 2.2). Pelvic fractures were present in 21 victims, all but one of whom had multiple amputations. Forty-six patients had perineal and gluteal injuries; these included 8 anorectal injuries, 8 penile injuries, and 26 scrotal injuries including 10 orchiectomies. There were 13 facial injuries, 9 skull fractures and 3 traumatic brain injuries. Eye injuries were found in 11 patients, none of whom were wearing eye protection. Of the 9 paediatric patients, 3 had triple amputations and 5 had double amputations. There was one pelvic fracture and two perineal injuries among the paediatric victims (Table 2.3). Pelvic fracture was more likely if the victim had multiple amputations (28.6% vs. 3.3%; p=0.005) or had a perineal or gluteal injury (32.6% vs. 11.1%; p=0.009). Those victims with multiple amputations also had more perineal and gluteal injuries (52.9% vs. 30%; p=0.036) and a higher mortality (24.3% vs. 6.7%; p=0.039).

Figure 2.2: Number of amputations per victim

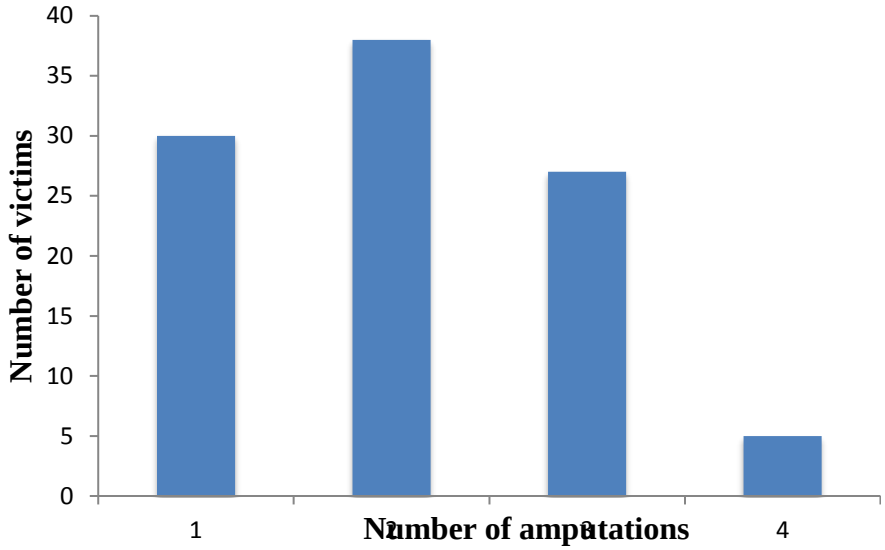
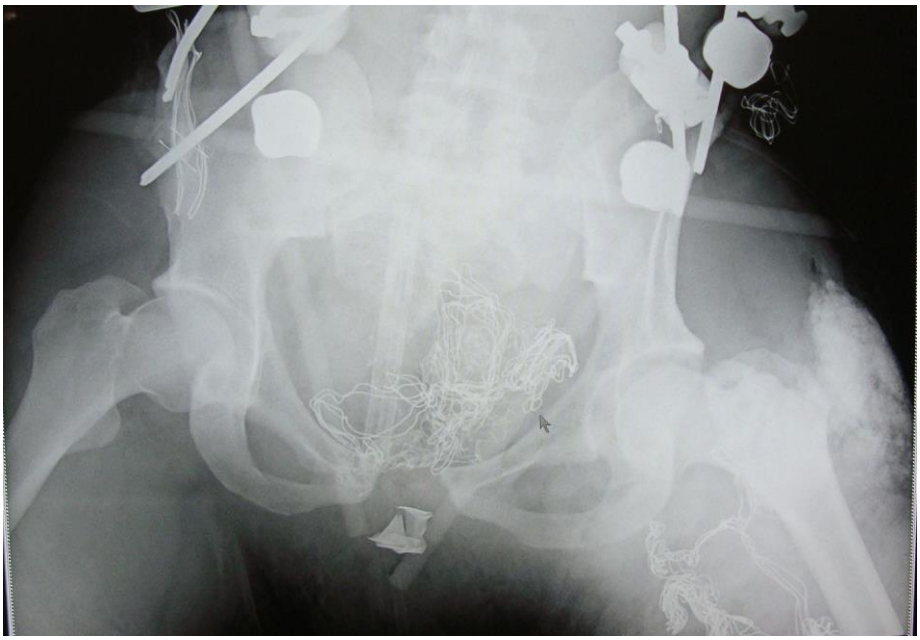


Figure 2.3



X-ray taken for placement of a pelvic external fixator showing: disruption of pelvic ring by the force of an anti-personnel improvised explosive device; combat gauze packing a severe perineal injury; silica laden soil injection by the explosion.

Table 2.2 Distribution of amputations

Amputation Type	Overall	Pelvic Fracture	Perineal, Gluteal, Genital Injury	Killed in Action	Died of Wounds	Casualt Fatality Rate
HipDis/TKA/UEA	1	0	0	0	1	1/1
HipDis/-	1	0	0	0	1	1/1
AKA/AKA/UEA/UEA	4	0	3	0	0	0/4
AKA/AKA/UEA	7	3	6	0	0	0/7
AKA/AKA	8	2	4	2	1	3/8
AKA/BKA/UEA	2	1	0	1	1	2/2
AKA/TKA/UEA	1	1	0	0	1	1/1
AKA/BKA	7	1	5	0	0	0/7
AKA/TKA	7	4	6	0	0	0/7
AKA/UEA/UEA	1	0	0	0	0	0/1
AKA/UEA	1	0	0	0	0	0/1
AKA/TAA	1	0	0	0	0	0/1
AKA/-	2	0	0	0	0	0/2
BKA/BKA/UEA/UEA	1	0	0	0	1	1/1
BKA/BKA/UEA	13	4	6	4	2	6/13
BKA/TKA/UEA	1	0	1	0	0	0/1
BKA/BKA	9	3	5	2	0	2/9
BKA/UEA	2	0	0	0	0	0/2
BKA/TKA	1	0	0	1	0	1/1
BKA/-	22	1	9	1	0	1/22
TKA/TKA/UEA	1	1	1	0	0	0/1
TKA/TKA	1	0	0	0	0	0/1
TKA/-	1	0	0	0	0	0/1
TAA/UEA	1	0	0	0	0	0/1
TAA/-	3	0	0	0	0	0/3
UEA/-	1	0	0	0	0	0/1

HipDis, hip disarticulation; AKA, above knee amputation; BKA, below knee amputation; TKA, though knee amputation, TAA, though ankle amputation; UEA, upper extremity amputation, which includes above elbow, below elbow and hand amputations.

Table 2.3 Distribution of paediatric amputations

Age (Years)	Amputation Type	Pelvic Fracture	Perineal, Gluteal, Genital Injury	Disposition
16	AKA/BKA	No	No	Survived
14	AKA/AKA	No	Yes	DOW
14	AKA/UEA/UEA	No	No	Survived
11	UEA/TKA/AKA	Yes	No	DOW
10	BKA/BKA/UEA	No	No	KIA
10	UEA/TAA	No	No	Survived
10	BKA/AKA	No	Yes	Survived
10	BKA/BKA	No	No	KIA
6	UEA	No	No	Survived

Therefore, the typical injury profile suffered by targeted victims of AP-IEDs included: bilateral lower extremity amputations (often above the knee); mangling or amputation of an upper extremity; extensive soft tissue injury with deep contamination by soil, extending into gluteal and perineal regions; pelvic ring disruption and genital mutilation.

2.4 DISCUSSION

The mechanism of injury is the same for all anti-personnel explosive devices. The severity of injury depends upon the energy transferred by the explosion to the victim. There is nothing inherently different between the APM and the AP-IED. Indeed the AP-IED might be considered a subset of APM. However, the comparison in this study is between the conventional blast APM, industrially manufactured for national armies and the AP-IED, that were manufactured locally from available

materials and used in the recent conflict in Afghanistan. Coupland and Korver believed they were dealing with the former device.[2,3,4] In a textbook reflecting on the Russian experience in Afghanistan, Bruysov and colleagues illustrated the mechanism of injury from the conventional blast APM in a series of experiments using rapid sequence photography which confirmed Coupland and Korver's description of a foot amputation with scattered penetrating injuries elsewhere.[11]

The AP-IED, sometimes portrayed as a primitive or crude weapon crafted from locally available resources because of a lack of access to conventional weapons, has evolved with use in different conflicts. From rudimentary devices of nails in wooden boxes used in Cambodia and Columbia, AP-IEDs used in recent conflicts are better directed and more destructive. The injury profile from the modern AP-IED is far worse than originally described for conventional blast APMs. Whereas the blast APM typically results in a unilateral lower limb amputation, the modern AP-IED causes bilateral high amputation of the lower extremities. Triple amputations were not seen with APM but occurred in 27% of victims of AP-IEDs. Severe perineal and gluteal injury with soft tissue contamination with soil was commonly present in the victims of the AP-IED but is not seen among the ICRC experience with APM injured patients. [2] The energy transfer endured by targeted victims of AP-IEDs must be far greater than that caused by APMs. A measure of the force is the fact that it is sufficiently powerful to disrupt the pelvic ring in one fifth of the patients (Figure 2.3).

It is not the purpose of this paper to undermine the abhorrence of injuries caused by

conventional APMs, which are often devastating and ruin lives. Both the APM and AP-IED injure indiscriminately. In this series, almost one in ten victims of AP-IEDs was a child, a tragic feature in common with APMs. Even more disconcerting is the frequency with which children suffer the severest injuries from the powerful explosive force of the AP-IED: 89% suffered multiple amputations and 33% lost three limbs.

The AP-IED victims wore different types of personal protective equipment (PPE) or none at all. Coalition soldiers wore PPE including helmets, body armour, and anti-ballistic eyewear. Each nation issued its own style and brand of PPE. Local Afghan soldiers often used helmets but their use of body armour was more inconsistent and they almost never used ballistic eyewear. Civilian casualties were not wearing any PPE. This heterogeneity of PPE use in our sample may have affected the pattern of injury characterized in this study but the sample size was insufficient to determine accurately the injury preventative role of PPE. We felt there was a lower than expected rate of abdominal, thoracic and eye injuries in victims wearing PPE. We also felt that the design purpose of PPE, to prevent fragment injury, was confirmed in patients with pattern 2 injuries who are not included in this study.

It is possible that we have magnified the severity of the injury pattern by concentrating our focus upon patients that met our definition of being targeted by the AP-IED, that is having sustained at least one limb amputation. It is also possible that if a casualty was injured by an unexploded ordinance or classical land mine but reported by first responders to have been injured by an AP-IED they may have been

erroneously included. However our findings are in keeping with other descriptions of IED injuries in the literature. Jacobs *et al*. classified the limb injury pattern of 103 consecutive casualties of IEDs treated at a UK Role 3 facility in Helmand Province, Afghanistan.[12] They included victims who did not have amputation of a limb. They found 76 victims suffered significant bilateral lower limb injuries, with 50 who required bilateral lower limb amputation. Thirty-three victims suffered genital or perineal injury, 9 sustained pelvic ring disruption, and 40 sustained significant upper limb injury. They found that all pelvic fractures and 80% of genital injuries were sustained among casualties with bilateral lower limb amputations. A retrospective review of the UK Joint Theatre Trauma Registry examined UK services personnel who were casualties of IEDs in Afghanistan, who sustained lower extremity amputations between January 2007 and December 2010.[13] This registry includes post-mortem reports of soldiers who were killed and never received hospital care. The registry is restricted to UK service members and contains no local nationals or civilian injuries. They examined 656 IED victims with 138 killed in action (21%) and 31 who died of their wounds (4.7%) resulting in a 25.9% casualty fatality rate. Of the 169 victims who sustained a traumatic lower extremity amputation, 69 were killed in action (40.8%) and 31 died of their wounds (18.3%). They found that the level of amputation was inversely correlated with survival with only two survivors from hindquarter amputation out of 39 patients with this level of injury. Another retrospective review of the UK Military Trauma Registry focused on soldiers from Afghanistan with bilateral leg amputation.[8] They examined 43 casualties with at least two amputations; 80% of these were from AP-IEDs with the

other 20% being from anti-vehicle-IEDs. The most common bilateral amputation was a bilateral AKA (58%), and 20% of victims suffered triple amputation. 14% of victims sustained open pelvic fractures and 44% suffered perineal or genital injury. No victims survived the loss of all four limbs.

The soft tissue injury is a particularly difficult problem encountered by those caring for victims of AP-IEDs. The directed explosion forces soil up along soft tissue planes far above the point of entry. This may worsen the level of eventual amputation and it condemns the victim to multiple operations to remove the contamination. Even still, it may leave the victim at the mercy of unusual antibiotic resistant soil organisms such as *Acinetobacter baumannii.*[14]

Knowing the pattern of injury helps responders tailor care. As Jacobs and colleagues have suggested, first responders should apply tourniquets bilaterally even if the victim is not bleeding, as haemorrhage is likely to start once resuscitation restores intravascular volume.[12] While current protocols require medics to apply a neck collar to all victims of IEDs, spinal injury is rare in AP-IED victims despite the magnitude of the force.[9] On the other hand, we recommend that all AP-IED victims with perineal injuries or multiple amputations have pelvic binders placed by the first responders, as both are associated with pelvic fracture. This may reduce the large amount of blood that may be lost silently with pelvic disruption. Multiple surgical teams have to work simultaneously to rescue these patients. Surgeons have to be adept at dealing with pelvic and gluteal bleeding, sometimes by pre-peritoneal packing and by ligating the internal iliac artery. Rehabilitation requires mobilization

on temporary lower limb prostheses despite injured upper limbs. Finally, victims of this severe injury pattern need life-long support because disabilities may become more pronounced as the capacity to compensate fades with age.

In collecting information on 100 consecutive patients, we hope to have described a generalizable result. Due to the nature of the conflict and the local culture, all of the patients examined were male. While we would expect the severity of the injury pattern to be generalizable to females, we cannot explicitly determine the effect of the modern AP-IED on the female pelvis and perineum.

The use of conventional APM has decreased in the last 20 years since the campaign to prohibit their use. Pattern 1 injuries seen in recent conflicts are far more often from AP-IEDs than conventional APMs. ICRC includes AP-IEDs in its definition of APM if the victim triggers the weapon. The injury profile described in this report is illustrated in the recent edition of its textbook on war surgery.[15] Despite the huge force endured by the targeted victim of the AP-IED, the casualty fatality rate that we observed was 19%. This rate is an underestimate, as some casualties who were killed at the site of the AP-IED may not have been brought to our facility and others may have died as a result of injuries after transfer or discharge. Reports regarding APM are also affected by this problem. The observed mortality rate with AP-IED is of the same order as that elsewhere.[15] The injury pattern suffered by the target of the AP-IED is markedly worse than that of conventional APM. Pelvic binders and tourniquets should be applied at the point of injury to patients with multiple amputations or perineal injuries. The AP-IED causes more severe injury than APM. It

is a weapon which of its nature causes superfluous injury and unnecessary suffering. Just as the reports by Coupland and Korver provided the medical evidence upon which the prohibition of conventional APM was based, it is hoped that reports regarding the pattern of injury caused by the modern AP-IED will result in an abhorrence of this weapon and those who use it.

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CHAPTER 3

INCIDENCE AND MANAGEMENT OF VASCULAR TRAUMA: A CANADIAN EXPERIENCE

CHAPTER 3: INCIDENCE AND MANAGEMENT OF VASCULAR TRAUMA: A CANADIAN EXPERIENCE

3.1 Introduction

In the past decade there has been a shift in the therapies and philosophies associated with treating vascular trauma. Damage control resuscitation and the use of vascular shunting and tourniquets have become more emphasized [1-4]. Much of this evolution has been as a result of findings captured in trauma registries in Iraq and Afghanistan [5-7]. Novel technologies have been introduced to temporize the exsanguinating vascular trauma patient, including the resuscitative endovascular balloon occlusion of the aorta for hemorrhage control (REBOA)[8].

In order to describe the state of vascular trauma therapy in the United States, as well as to be able to capture long-term outcomes from vascular trauma intervention, the American Association for the Surgery of Trauma (AAST) developed a Prospective Observational Vascular Injury Treatment Registry (PROOVIT) [9]. This registry, which is comprised of 14 Level I and Level II trauma centers, has published their first year's findings. An American retrospective evaluation of vascular trauma, and in particular intravascular shunt use, has also recently been published [10]. This paper described shunt usage, rates of limb salvage and mortality, shunt thrombosis, length of time shunts were in place, and the operation at definitive repair.

The epidemiology of trauma is very different in Canada than in the United States. Since penetrating trauma is much less prevalent in Canada, it would stand to reason

that the epidemiology of traumatic vascular injuries would likewise have a different distribution. Moreover, vascular trauma may be more likely to be managed by a vascular surgeon in Canada than a trauma surgeon as compared to the United States, where many trauma centre have in-house trauma surgeons 24 hours a day.

The aim of this study was to conduct a retrospective review of vascular trauma at London Health Sciences Center (LHSC), a Canadian level I trauma center, over a five-year period. Any named vessel injury of the extremities, torso, or neck was captured, allowing for a description of the epidemiology of vascular trauma at this Canadian centre and an understanding of the present usage of damage control vascular surgery, specifically the use of shunts, tourniquets and aortic blockers. This retrospective study will provide a Canadian context through which the American prospective data of the PROOVIT registry can be interpreted. It will allow for an understanding of the present Canadian incidence of named vessel injury as well as our adoption of damage control techniques. This will help guide efforts in trauma system management, surgical education, and research and innovation.

3.2 Methods

The medical records and trauma registry of London Health Sciences Centre (LHSC) were searched for all patients with the International Statistical Classification of Diseases and Related Health Problems 10th revision (ICD -10) codes for vascular injury. All adult trauma patients (18 years of age or older) with injuries to named arterial or venous vessels in the legs, arms and torso, and neck from 1 January 2011-31 December 2015 were included. Data was collected using the Research Electronic

Data Capture (REDCap) secure data platform. Vessel injuries in the head were not included because of significant difference in the treatment and outcomes of these types of injuries. This five-year period was selected because it is sufficiently long to capture a representative sample of vascular trauma, and it is sufficiently modern to capture the new changes in vascular trauma practice, which may have occurred since the lessons learned from the conflicts in Afghanistan and Iraq.

The primary outcome of this study is the description of the incidence of injury to named vessels in the London trauma patient population. Further descriptive data such as demographics, baseline co-morbidities, injury type, injury mechanism, injury severity on presentation, modality used to characterize and identify the injury, type of injury encountered, and technique of repair, whether a tourniquet, intravascular shunt or occlusion device was used, was also be captured. Further information, such as if the patient presented to a trauma centre or was transferred from a peripheral hospital, if the surgeon was a trauma or vascular surgeon, if a temporary versus definitive repair was done, type of definitive repair, length of time the shunt was in place if used, occurrence of shunt thrombosis, fasciotomy rate, occurrence of compartment syndrome limb salvage and requirement for amputation, and mortality during hospital stay, was also collected. This information was obtained from the trauma registries, initial operative report, and electronic medical record.

Continuous parameters are expressed as means with standard deviations and medians with interquartile ranges, as appropriate. Categorical data are expressed as proportions. SPSS Version 23 (IBM Inc., 2011) was used for data analysis. The Research Ethics Board of the University Western Ontario approved this study (REB # 107912).

3.3 RESULTS

From 1 January 2011 to 31 December 2015, 127 patients presented with named vessel injuries as a result of trauma. 89 patients were male (70.1%) and the mean age was 40.8 years. Blunt mechanism accounted for 61.4% of injuries and the most common mechanism of injury was motor vehicle crash (33.1%). The most common penetrating mechanism was stabbing which accounted for 18.1%. The mean Injury Severity Score (ISS) score was 21.8 with 63.3% of patients having an ISS of 15 or greater. Hypotension was present in 11.3% of patients on admission. The modality most commonly used to identify injury was Computed Tomography Angiogram (CTA) (58.3%) with operative exploration being the second most common (35.4%) (Table 3.1).

A wide range of vascular injuries was identified, with the most common being the descending thoracic aorta (14.3%) (Table 3.2). Non-operative management was most common (28.3%) followed by open surgery (48.8%) and endovascular repair (12.3%). Among those trauma vascular patients who received interventions, open surgery was the most common (77.9%). Endovascular techniques were commonly

used for aortic injuries (58.3%) (Table 3.4). Only one case used a damage control approach with the vast majority of practitioners opting for initial definitive repair. There was no temporary intravascular shunt use. The most common repair was with autologous vein (16.7%) and primary repair and ligation were each used 15.9% of the time. Fasciotomies were performed 12 times, 9 of which were prophylactic. 12 patients died in hospital with three dying before attempted vascular management. Overall mortality was 9.4%. There were 3 amputations, 4 surgical site infections and 4 strokes (Table 3.3).

Table 3.1 Epidemiology of vascular trauma patients

	London	PROOVIT
Total number of patients with named vessel injury	127	542
Demographics		
Male, n (%)	89 (70.1)	382 (70.5)
Age, mean (SD), years	40.8 (18.3)	37.7 (17.4)
BMI, mean (SD)	26.5 (5.6)	
Transferred from outside hospital, n (%)	64 (50.4)	
Comorbidities, n (%)		
Coronary artery disease	2 (1.6)	
Diabetes mellitus	4 (3.1)	11 (2.0)
Fully anticoagulated	1 (0.8)	2 (0.4)
Antiplatelet use	3 (2.4)	9 (1.7)
Bleeding disorder	1 (0.8)	
Dialysis	0 (0)	
Cirrhosis	1 (0.8)	
Injury type, n (%)		
Blunt	78 (61.4)	255 (47.0)
Penetrating	47 (37)	198 (36.5)
Mixed	2 (1.6)	5 (0.9)
Mechanism, n (%)		
Motor vehicle crash	42 (33.1)	152 (28.0)
Other or unknown	35 (27.6)	134 (24.7)
Stabbing	23 (18.1)	39 (7.2)
Fall	9 (7.1)	39 (7.2)
Industrial accident	8 (6.3)	17 (3.1)
Gunshot	5 (3.9)	129 (23.8)
Pedestrian vs auto	2 (1.6)	30 (5.5)
Athletic injury	3 (2.4)	2 (0.4)
Presentation		
ISS, mean (SD)	21.8 (13.8)	20.7 (14.7)
ISS ≥15, n (%)	81 (63.3)	174 (32.1)
Head AIS score ≥3, n (%)	23 (18.1)	65 (12.0)
Abdominal AIS score ≥3, n (%)	36 (28.3)	78 (14.4)
Chest AIS score ≥3, n (%)	49 (38.2)	66 (12.2)
Extremity AIS score ≥3, n (%)	62 (48.8)	154 (28.4)
Admission SBP, mean (SD)	125.5 (29.3)	120 (34)
Hypotension (SBP ≤90) on arrival, n (%)	12 (11.3)	64 (11.8)
GCS score ≤8 in arrival, n (%)	15 (14.2)	97 (17.9)
Admission hemoglobin, mean (SD)	126 (20.0)	12.3 (2.2)
Admission pH, mean (SD)	7.27 (0.11)	7.26 (0.15)
Admission lactate, mean (SD)	3.5 (2.7)	4.4 (4.2)
Platelets, mean (SD)	214.9 (71.7)	227 (77)
Modality used to identify/characterize injury, n (%)		
Operative exploration	45 (35.4)	161 (29.7)
CTA	74 (58.3)	215 (39.6)
Duplex ultrasound	0 (0)	17 (3.1)
Traditional Angiography	5 (3.9)	62 (11.4)
MRA	2 (1.6)	
Transesophageal echo	1 (0.8)	
Type of injury identified, n (%)		
Transected	65 (51.2)	136 (25.1)
Occlusion	13 (10.2)	96 (17.7)
Partial transection or flow limiting defect	45 (35.4)	138 (25.5)
Pseudoaneurysm	11 (8.7)	49 (9.0)

Table 3.2 Distribution of vascular injuries

Named Vessel injured	Total injuries (n = 147)
Neck, n(%)	**30 (20.4)**
Common carotid	1 (0.7)
Internal carotid	6 (4.1)
External carotid	0 (0)
Vertebral artery	17 (11.6)
Superior thyroid artery	1 (0.7)
Facial artery	1 (0.7)
Internal jugular vein	2 (1.4)
External jugular vein	2 (1.4)
Thorax, n (%)	**30 (20.4)**
Aortic arch	3 (2.0)
Descending thoracic aorta	21 (14.3)
Innominate artery	1 (0.7)
Subclavian artery	1 (0.7)
Coronary artery	1 (0.7)
Internal mammary artery	1 (0.7)
Intercostal artery	1 (0.7)
Inferior vena cava	1 (0.7)
Innominate vein	0 (0)
Subclavian vein	0 (0)
Abdomen/Pelvis, n (%)	**29 (19.7)**
Abdominal aorta	3 (2.0)
Common iliac	1 (0.7)
External iliac	2 (1.4)
Internal iliac	1 (0.7)
Celiac Artery	1 (0.7)
Common hepatic artery	0 (0)
Superior mesenteric artery	0 (0)
Renal artery	3 (2.0)
Splenic artery	0 (0)
Left gastric artery	1 (0.7)
Middle colic artery	1 (0.7)
Internal pudendal artery	4 (2.7)
Superior gluteal artery	2 (1.4)
Inferior gluteal artery	1 (0.7)
Obterator artery	2 (1.4)
Lateral femoral circumflex artery	1 (0.7)
Retro Hepatic IVC	0 (0)
Infra-renal IVC	3 (2.0)
Iliac vein	0 (0)
Portal vein	0 (0)
Renal vein	2 (1.4)
Splenic vein	0 (0)
Gonadal vein	2 (1.4)
Upper extremity, n (%)	**36 (24.5)**
Axillary artery	3 (2.0)
Brachial artery	13 (8.8)
Radial artery	7 (4.8)
Ulnar artery	7 (4.8)
Posterior circumflex humeral artery	1 (0.7)
Princeps pollicis	1 (0.7)
Axillary vein	0 (0)
Basilic vein	2 (1.4)
Brachial vein	2 (1.4)
Lower extremity, n (%)	**22 (15.0)**
Common femoral artery	0 (0)
Superficial femoral artery	3 (2.0)
Deep femoral artery	0 (0)
Popliteal artery	7 (4.8)
Anterior tibial artery	4 (2.7)
Posterior tibial artery	3 (2.0)
Peroneal artery	0 (0)
Common femoral vein	0 (0)
Superficial femoral vein	2 (1.4)
Deep femoral vein	0 (0)
Popliteal vein	2 (1.4)
Great saphenous vein	0 (0)
Posterior tibial vein	1 (0.7)

3.3 Management and complications of vascular injuries

Management n(%)	London	PROOVIT
Non-operative management	39 (28.3)	276 (50.9)
Endovascular repair	17 (12.3)	40 (7.4)
Initial non-definitive open surgery	1 (0.7)	165 (37.8)
Definitive open surgery	59 (42.8)	126 (23.2)
Damage control technique	1 (0.7)	57 (10.5)
Fasciotomy	12 (8.7)	
Shunt used	0 (0)	14 (2.6)
Ligation	22 (15.9)	31 (5.7)
Primary repair	22 (15.9)	37 (6.8)
Autologous repair	23 (16.7)	61 (11.3)
Synthetic graft	3 (2.2)	7 (1.3)
Died before vascular management	3 (2.2)	
Embolization	9 (6.5)	
Complications		
In hospital mortality	12 (9.4)	48/376 (12.7)
Amputation	3 (2.4)	18 (3.3)
Compartment syndrome	3 (2.4)	
Shunt thrombosis	0	16 (3.0)
Dislodged shunt	0	
Surgical site infection	4 (3.1)	6 (1.1)
Stroke	4 (3.1)	12 (2.2)

3.4 Management of specific arterial injuries

	Nonoperative management	Endovascular repair	Open Surgery	Died before repair
Neck, n (%)				
Common carotid	1/1 (100)	0/1	0/1	0/1
Internal carotid	6/6 (100)	0/1	0/1	0/1
External carotid	0	0	0	0
Vertebral artery	17/17 (100)	0/17	0/17	0/17
Thorax, n (%)				
Aortic arch	1/3 (33.3)	1/3 (33.3)	1/3 (33.3)	0/1
Descending thoracic aorta	7/21 (33.3)	13/21 (61.9)	1/21 (4.8)	0/1
Innominate artery	1/1 (100)	0/1	0/1	0/1
Subclavian artery	0/1	1/1 (100)	0/1	0/1
Abdominal/Pelvis, n (%)				
Abdominal aorta	2/3 (66.6)	0	1/3 (33.3)	0/1
Common, external, or internal iliac arteries	0/4	0/4	1/4 (25)	3/4 (75)
Celiac artery	1/1 (100)	0/1	0/1	0/1
Renal artery	2/3 (66.6)	0/3	1/3 (33.3)	0/3
Upper extremity, n (%)				
Axillary artery	1/3 (33.3)	1/3 (33.3)	1/3 (33.3)	0/3
Brachial artery	0/13	0/13	13/13 (100)	0/13
Radial artery	0/7	0/7	7/7 (100)	0/7
Ulnar artery	0/7	0/7	7/7 (100)	0/7
Lower extremity, n (%)				
Common, superficial or deep femoral artery	0/3	2/3 (66.6)	1/3 (33.3)	0/3
Popliteal artery	0/7	0/7	7/7 (100)	0/7
Anterior tibial artery	1/4 (25)	0/4	3/4 (75)	0/4
Posterior tibial artery	0/3	0/3	3/3 (100)	0/3
Peroneal artery	0	0	0	0

There were 49 peripheral arterial injuries. Prehospital tourniquets were used on 6 occasions (12.2%) with only one having a tourniquet time recorded (4.5 hours). Tourniquets were applied in the trauma bay 4 times. Resuscitative thoracotomies were performed three times, on two occasions by a general surgeon and once by a trauma surgeon. No REBOA was used (Table 3.5).

Vascular surgeons managed the majority of the vascular injuries (n = 77), with plastic surgeons (n = 11), interventional radiologists (n = 11), and general surgeons being the next most common (n = 9) (Table 3.6). All vascular injuries managed by plastic surgery were in the upper extremity. Interventional radiology deployed endovascular stents to the subclavian artery and the axillary artery. All other interventional radiology interventions were embolizations to the internal pudendal, superior and inferior gluteal, obturator, and posterior circumflex of the humeral arteries. Neurology managed two vertebral artery injuries.

3.5 Tourniquets, fasciotomies, and resuscitative techniques (n)

	London n (%)	**PROOVIT n (%)**
Peripheral artery injuries	49	233
Prehospital tourniquet use	6/49 (12.2)	47/233 (20.2)
Trauma bay tourniquet use	4/49 (8.2)	
Fasciotomy, prophylactic	9/49(18.4)	33/233 (14.2)
Fasciotomy therapeutic	3/49 (6.1)	19/233 (8.2)
REBOA use	0	
Resuscitative thoracotomy	3	
Temporary intravascular shunt use	0	

3.6 Discipline of physician who managed the vascular injury

Discipline managed vascular injury	Total patients (n=127)
General surgeon	9
Trauma surgeon	3
Vascular surgeon	77
Orthopedic surgeon	2
Thoracic surgery	3
Cardiac surgery	2
Plastic surgery	11
Otolaryngology	3
Urology	1
Gynecology	1
Neurosurgery	2
Interventional radiology	11
Neurology	2

3.4 DISCUSSION

In order to improve linkage of management of vascular traumatic injuries to short and long-term outcomes, the American Prospective Observational Vascular Injury Treatment (PROOVIT) registry was initiated [9]. This registry was inspired by the success of military vascular trauma registries in Iraq and Afghanistan [5-7]. Their view was to document the evolution of vascular care from the prehospital environment to definitive management. Concepts such as tourniquet use, temporary intravascular shunts and damage control principles have been used extensively in the military setting with good success and are now being incorporated into civilian institutions practice [1,2,11,12].

The PROOVIT registry may be very important in monitoring the effectiveness of these damage control techniques as well as the expanding field of endovascular

intervention for trauma. This registry captures patients from 13 American level I Trauma Centres and one level II trauma Centre. However, the type of trauma experienced, as well as the resources available, and training of the practitioners providing the care and therapy may be different than what exists in Canada. While establishing a Canadian prospective vascular trauma database is an ambitious way to examine the Canadian experience, a faster and less costly approach is to retrospectively examine Canadian vascular trauma and use that data as a lens through which the American experience can be interpreted. By knowing the ways in which the Canadian and American vascular trauma population are similar, and the ways that they differ, the findings from the PROOVIT registry that are applicable to Canadian practice can be identified.

The Canadian patients were of similar age (40.8 vs. 37.7) (hereafter, LHSC results are given before those from PROOVIT) and were also predominantly male (70.1% vs. 70.5%). The mean injury severity score between the two groups was similar (ISS 21.8 vs. ISS 20.7) with this study having a larger proportion of patients with ISS scores above 15 (63.3% vs. 32.1%). Both groups had very similar rates of hypotension on admission (11.3% vs. 11.8%). Canadian patients were more likely to have suffered from a blunt mechanism of injury (61.4% vs. 47%). The most common mechanism of blunt injury was motor vehicle crash for both populations (33.1% vs. 28.0%); however, whereas the most common penetrating mechanism in the PROOVIT registry was gunshot (23.8%) at LHSC the most common penetrating mechanism was stabbing (18.1%).

The most common non-operative method of identifying vascular injury was CTA but this modality was more common in the Canadian experience (58.3% vs. 39.6%) with the PROOVIT patients receiving duplex ultrasound (0% vs. 3.1%) and traditional angiography more often (3.9% vs. 11.4%). The Canadian patients were more likely to receive operative exploration (35.4% vs. 29.7%). The most common vessel injuries in this study was the descending thoracic aorta (14.3%) followed by the vertebral artery (11.6%) whereas the most commonly injured vessel in the PROOVIT registry was the internal carotid artery (11.4%). This difference may be reflective of the greater proportion of blunt trauma in the Canadian trauma population.

Both studies found non-operative intervention was the most common but it was more frequent in the PROOVIT registry (28.3% vs. 50.9%). Endovascular intervention was more popular in Canada (12.3% vs. 7.4%). This difference may be due to the prevalence of blunt aortic injury in the Canadian group.

No patient received a temporary intravascular shunt in this study whereas 2.6% did in PROOVIT. This study found that 12.2% of extremity arterial injuries received prehospital tourniquets whereas 20.2% did in the PROOVIT registry. Unfortunately the time of tourniquet application was poorly documented with only one tourniquet time available and that being a long application of 4.5 hours. In PROOVIT 25%

lacked documentation of tourniquet time and 40.4% of tourniquets were on for less than one hour.

The Canadian vascular trauma population is sufficiently similar to the population of the PROOVIT registry for the results that are accrued from the PROOVIT registry to be of great interest. In particular endovascular techniques for trauma are being expanded to junctional areas such as subclavian or axillary arteries[13] as well as more peripheral arteries [14]. There were Canadian trauma patients receiving these therapies, and knowing the outcomes of these interventions will be very important. That outcomes information can be obtained from the PROOVIT registry and will likely be applicable to the Canadian trauma population.

One way in which the Canadian and American populations likely differ is in who repairs the vascular injury. In our study, vascular surgeons repair the majority of vascular trauma, with only three injuries in five years being repaired by a trauma fellowship trained surgeon. Multiple subspecialty surgeons were involved in managing vascular injuries. This diffusion of who is responsible for vascular trauma is likely very different from an American centre who may have an in-house trauma surgeon managing the majority of vascular injuries. This is an important Canadian characteristic to recognize and appreciate as findings and outcomes of vascular trauma research are attempted to be disseminated and Canadian trauma systems evolve and implement new techniques.

Tourniquet use is much less frequent in Canada. Not all peripheral arteries need a tourniquet. A distal radial transection will likely go into spasm and can safely be controlled with direct pressure. However, military experience has shown that tourniquet use can be safe and effective[11,16]. If a tourniquet is being used, documenting when it is applied and removed is important both for an understanding of the patient's recovery and ischemic injury, but also to be able to study the effect of this tool in a civilian environment. Military patients are usually air-lifted quickly to a surgical facility meaning that tourniquets are on for only a short time[15]. If civilian application times are consistently longer then the algorithm for their use will likely differ from our military counterparts.

Commercial intravascular temporary shunts are available at LHSC and could have been used during the study period. There have been civilian studies showing their safe and effective use for both damage control and staged orthopedic vascular injuries [10]. The PROOVIT registry will collect further data with respect to the safety and optimal use of this tool. This may prove to be an example of a vascular trauma tool worthy of adoption into the Canadian armamentarium.

The vascular trauma patient in this study had similar age and injury severity to those in the PROOVIT registry; however, was more likely to have suffered a blunt injury and was likely treated by a vascular surgeon. No temporary intravascular shunts were used and prehospital tourniquet use was less frequent and, when applied, their time of occlusion was poorly captured. The PROOVIT registry may be

of particular use to Canadian patients in tracking the outcomes of endovascular trauma interventions as endovascular therapies were used for aortic injuries, junctional injuries and extremity vascular injuries at this Canadian trauma center. Hopefully with the present data the PROOVIT experience can be optimally interpreted and lessons learned applied to a Canadian context.

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CHAPTER 4

NOVEL JUNCTIONAL VASCULAR INJURY OCCLUSION DEVICE

CHAPTER 4: NOVEL JUNCTIONAL VASCULAR INJURY OCCLUSION DEVICE

4.1 Introduction

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an emerging technique used to support blood pressure and decrease hemorrhage in trauma. As it continues to be studied and experience increases, new applications of this technology are being proposed. The most enthusiastic supporters have suggested REBOA as a potential pre-hospital intervention to enable the exsanguinating trauma patient to survive until surgical intervention[1]. Given the injury pattern of modern combat casualties, ultrasound-guided placement of a REBOA device in the distal aorta may help more patients survive evacuation to surgical management. In order for this to be feasible, a novel device needs to be developed that is not encumbered by a long wire, is easy to use, and can manage damaged iliac and femoral vessels.

Modern conflicts have seen a shift in the type of weapons used against coalition soldiers. In the recent Afghan war, fewer soldiers were injured with rifles and conventional ballistic weapons than were injured by improvised explosive devices (IED)[2,3]. Medically, it is most appropriate to classify these weapons by their target: crowd attack IED (CA-IED), anti-vehicle IED (AV-IED), and the antipersonnel IED (AP-IED)[4]. CA-IEDs cause injury by projectile fragments and their effect may be magnified by enclosed spaces, AV-IED have very large explosions and cause injuries similar to high-energy motor vehicle collisions, and AP-IEDs cause multiple

amputations and significant pelvic and perineal injury[4,5]. These victims can present the challenge of non-compressible torso hemorrhage[6,7].

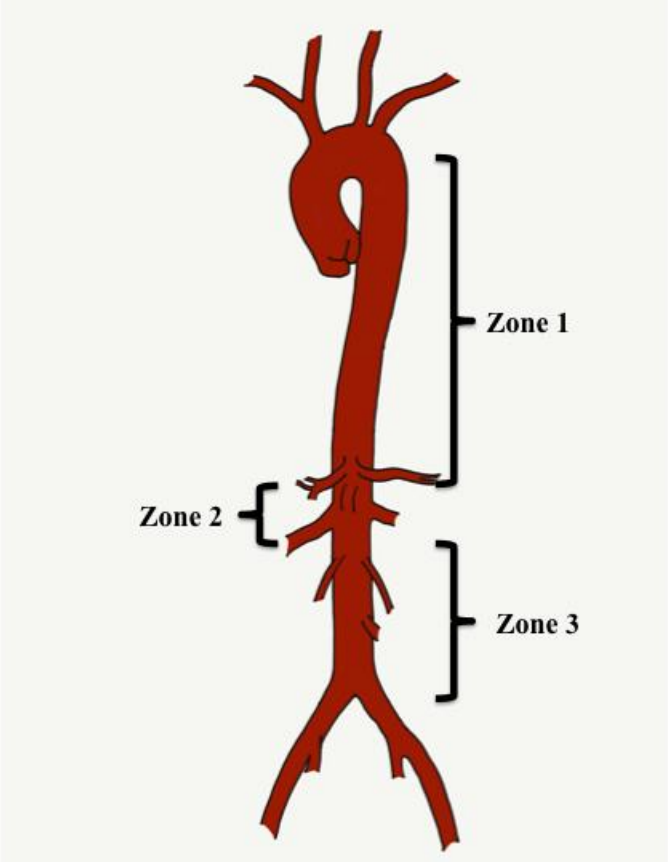
Combat pre-hospital medical care has simultaneously made great advancements. With Tactical Combat Casualty Care (TCCC) and personal protective equipment (PPE), more soldiers are being treated for, and surviving, potentially preventable causes of death on the battlefield [8]. However, there is very little a forward military physician can offer a patient with non-compressible torso hemorrhage other than rapid evacuation to a surgical facility. Could REBOA temporize the bleeding IED victim for transportation to the operating room? If the correct device was available pre-hospital combat use of the REBOA could save soldiers lives.

4.1.1 Standard REBOA technique

In 2011, Stannard *et al*. described the modern five-step technique of REBOA insertion via femoral artery cannulation and defined three zones of balloon deployment. The five steps for the REBOA procedure are: 1) arterial access and sheath insertion, 2) balloon positioning, 3) balloon inflation, 4) balloon deflation, and 5) sheath removal. They defined Zone I as the thoracic aorta extending from the subclavian artery to the celiac artery, Zone II as the non-occlusion zone between the celiac artery and renal arteries and Zone III as the infrarenal aorta to the iliac bifurcation (Figure 4.1). Deployment of REBOA in zone I is analogous to the hemostatic control of a resuscitative thoracotomy with cross clamping of the thoracic aorta, which controls hemorrhage from the abdomen and pelvis and

increases cerebral and coronary blood flow. REBOA in Zone III provides occlusion to help control pelvic or junctional hemorrhage without causing visceral ischemia [9].

Figure 4.1 Zones of REBOA deployment



Aortic zones related to REBOA. Zone I extends from the origin of the left subclavian artery to the celiac artery and is a potential zone of occlusion. Zone II extends from the celiac artery to the lowest renal artery and is a a no-occlusion zone. Zone III exists from the lowest renal artery to the aortic bifurcation. REBOA in this zone may provide particular utility for instances of pelvic and junctional femoral hemorrhage.

4.1.2 REBOA in the Military

The origins of REBOA are in military medicine. Lieutenant-Colonel Carl Hughes of the United States Army Medical Corps, used balloon aortic occlusion in two patients in the Korean Conflict and although both died he speculated that this technique could save lives in the future [10]. Although originating in the treatment of combat casualties, aortic balloon occlusion for hemorrhage control was first adopted in the civilian context for the management of abdominal aortic aneurysms, [11] and it is only in the past decade that REBOA for trauma patients has transitioned from an experimental technique to a tool for clinical study and use [12].

Interest in REBOA re-emerged within the military context during the Afghanistan and Iraq conflicts and military surgeons have been actively involved in its research and development [12]. The American military has published the Joint Trauma System Clinical Practice Guideline for REBOA, identifying its use as an alternative approach to thoracotomy in some cases, and described a role for preemptive placement in high-risk unstable patients [13]. This guideline is designed to apply in a location with surgical capability. A REBOA data tool is used to capture the technique's use for study. A retrospective analysis indicated that as many as 18% of modern combat casualties could benefit from REBOA treatment [14]. This technique is less morbid than a resuscitative thoracotomy and may have a role in the hypotensive pre-arrest patient by increasing their blood pressure and decreasing hemorrhage before progression to arrest and the need for resuscitative thoracotomy[15]. A recent

systematic review showed that REBOA increased systolic blood pressure by a mean of 53 mmHg (95% confidence interval 41-61 mmHg), but it did not demonstrate a clear reduction in hemorrhage-related mortality [16]. The studies comprising this review were case series, case reports and cohort studies; as registries accrue, prospective studies may illuminate additional circumstances showing an advantage of the REBOA technique in treating trauma patients with difficult to control hemorrhage.

Where REBOA portends great theoretical advantage is in facilitating the evacuation of combat casualties from the field to definitive surgical management. Morrison *et al*.'s analysis of the UK joint trauma registry over a ten-year period identified 174 deaths that met indications for REBOA. One hundred forty-five of these patients died before reaching hospital (83%), with a mean time to death of 75 minutes. The authors suggested that REBOA could act as en route hemorrhage control to get these casualties to a surgeon[14]. This application requires that REBOA be used in a pre-surgical environment. Before REBOA can be implemented in battlefield operations in a forward environment, medical leadership must make decisions regarding what method should be used to gain arterial access, which patients this therapy would apply to, the zone of REBOA deployment, and what training would be required for medical officers using this therapy.

4.1.3 Arterial Access

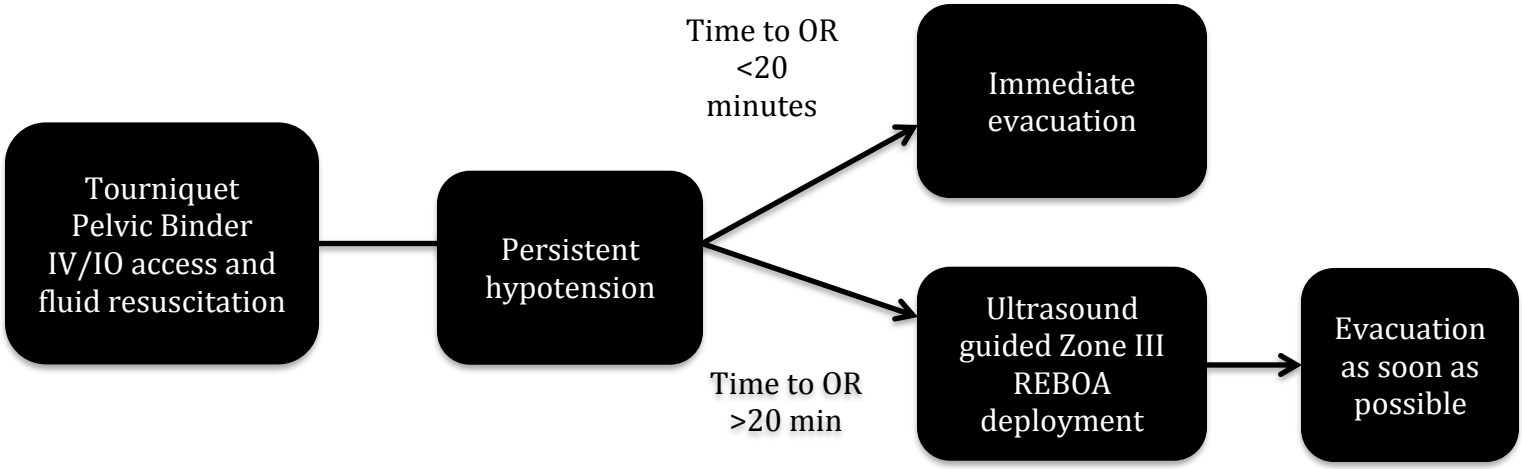
Arterial access is the first step in deployment of REBOA and providers currently have the option of a formal vascular cut-down, external anatomical landmarking with percutaneous access, or ultrasound-guided percutaneous access [9]. Vascular cut-down yields direct visualization of the target vessel, facilitating reliable cannulation of the common femoral artery (CFA) in a pulseless or profoundly hypotensive patient; however, it can be time consuming and requires surgical training. Landmark percutaneous access carries increased risk of venous cannulation, increased risk of vascular injury, and overall lower success rates [17]. Additionally, the probability of successful placement is compromised in the extremely hypotensive or pulseless patient [16]. Ultrasound-guided femoral artery access has the advantage of making catheter placement possible in the patient with severe hypotension without requiring a cut-down. It may increase the speed of percutaneous access, and the ultrasound can also be used to confirm the positioning of the balloon once it is deployed [1]. In the civilian context, all three techniques are used, with 50% gaining access by cut down, 28% by land marks and 11% by ultrasound guidance[18]. For the combat casualty in a non-surgical environment, ultrasound-guided percutaneous vascular access is the most attractive option; it alleviates the training requirement for performing a cut-down, may still be performed in the context of extreme hypotension, and ultrasound use is a skill already familiar to most military physicians. An environment that could facilitate

forward REBOA placement could be equipped with portable ultrasound, making this approach both feasible and efficacious.

4.1.4 REBOA and evacuation

Exsanguination is the number one cause of death on the battlefield and thus hemorrhage control must be the top priority of the provider treating the injured soldier [19,20]. REBOA has the potential to help combat casualties survive to surgery in situations where they would otherwise die without aortic occlusion [14]; however, delaying transport of a combat casualty while attempting to perform interventions could also be problematic and deadly. In the hands of experts, REBOA can be deployed in six minutes[18,21]. We believe this represents a reasonable benchmark by which military REBOA programs should self-evaluate. If a combat REBOA program were implemented, a potential algorithm could be as follows: if an IED victim has hypotension after tourniquet application, pelvic binder application, and fluid resuscitation; and, if evacuation to the operating room will be greater than 20 minutes, then REBOA should be considered (Figure 4.2). Rapid evacuation to a surgical facility should not be delayed for REBOA insertion. Given that the mean time to death of patients that would have potentially benefited from REBOA was 75 minutes [14], a patient who could be imminently evacuated would likely derive greater benefit from rapid access to higher-level surgical care than from delayed evacuation and REBOA placement.

Figure 4.2 Potential algorithm for forward medical center REBOA use



4.1.5 Zone of deployment

The most common REBOA zone of deployment in the civilian setting is Zone 1 (78.6%)[18]. Deployment in the thoracic aorta will control all hemorrhage below the level of the diaphragm, much like an aortic cross-clamp in a resuscitative thoracotomy. The major disadvantage of deployment at this zone is the associated spinal cord and intestinal ischemia[15,22]. In the swine model, 30 minutes of occlusion is well tolerated but by 90 minutes there is evidence of liver necrosis and renal dysfunction [23]. Zone 3 deployment does not offer control of intra-abdominal hemorrhage; however, it provides excellent control of pelvic and junctional bleeding without the risk of visceral ischemia[9,15]. Zone 3 poses fewer technical challenges for placement, can use shorter wires than with Zone I deployment, and may be an easier skill to teach and maintain for non-surgeon medical officers. Zone 3 REBOA will likely be less cumbersome in a more forward environment, and it does not run the risk of life-threatening visceral ischemia in the context of delayed evacuation. While personal protective equipment provides some thoraco-abdominal protection, the injury pattern of the AP-IED is associated with significant pelvic injury that may be amenable to this technique[5]. These characteristics make anatomical Zone 3 deployment the most practical location for the pre-hospital combat physician.

4.1.6 Training

REBOA is a new technique to military medicine, with the majority of data on REBOA coming from trauma and vascular surgeons with considerable endovascular

experience, working in a civilian setting [18]. Many of the pioneers of this technique espouse caution with its rapid adoption [24]. Japan has one of the largest experiences with REBOA in civilian trauma. In their system, emergency physicians can be credentialed after performing REBOA three times during residency training [25]. REBOA patients may have their device placed by an emergentologist, and definitive treatment provided by interventional radiology without direct surgeon involvement [26]. Prospective data from the Japan Trauma Data Bank was used to match REBOA patients to propensity score-adjusted non-REBOA patients, demonstrating a decrease in survival in the REBOA patients by an odds ratio of 0.30 (95% confidence interval, 0.23-0.4) [25]. A 24 patient Japanese series demonstrated that REBOA did increase mean systolic blood pressure, but they encountered complications such as the balloons not deflating, vascular injury while trying to obtain access, and a 12.5 % requirement for amputation, one of which arose from an iatrogenic vascular injury [27]. The American experience as captured in the Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry has only reported three endovascular specific complications, including distal embolism and pseudo-aneurysm; no patients required amputations in the 46 REBOA patients captured by the registry [18]. Early American clinical series did not demonstrate any procedure-related deaths or major complications [21]. Some authors have cautioned against the widespread adoption of REBOA, fearing that use by less qualified practitioners may generate poorer outcomes before this technique has been adequately studied and its indications for use and required provider training have been defined [24]. Most contributors to the American REBOA registries are trauma and vascular surgeons

who have taken, or are instructors on, REBOA training courses [18,28,29]. It is important that medical officers placing REBOA in combat environments be adequately trained and their skillset maintained.

A pre-hospital military physician may be a trained surgeon, but more likely will be a general duty medical officer with experience in central line placement and ultrasound use, but not in endovascular techniques. Training curricula would need to be developed with cadaveric and animal models to ensure that these forward physicians could safely place the device and know which patients may potentially benefit from the intervention. As mentioned above, an ultrasound-guided percutaneous technique would likely be the most appropriate. With the development of smaller caliber devices (7 Fr)[12], the possibility of training a medical officer to safely insert a Zone III REBOA to facilitate transportation of an IED casualty to a surgical facility is likely an achievable future reality, but we must move towards this goal with prudence and careful planning supported by robust research. A strong training curriculum focused on both skillset acquisition and maintenance is crucial to a successful combat REBOA program.

4.1.7 Future of combat REBOA

Both military and civilian trauma surgical centers are using REBOA for the treatment of hemorrhaging trauma patients [13,30]. Responsibly, these therapies are being utilized within a framework of active clinical registries and ongoing research to clarify the use, safety, and indications of this new technique. REBOA as it is

presently designed is not yet ready for the pre-hospital or combat pre-surgical environments and should only be used in well-trained hands in an environment with ready surgical capabilities. However, REBOA does have promise as a forward medical tool if a new device could be designed to meet the needs of this very different medical environment. Lives would be saved if a physician at a forward medical center, with appropriate training and skill set maintenance, was able to insert a balloon under ultrasound-guidance to occlude the distal aorta of an unstable casualty to allow them to survive to surgery where they otherwise would have died. Recent experience in Iraq and Afghanistan demonstrated a 98% survival rate for those injured soldiers that could be evacuated to a facility with surgical capability [31]. For this reason it is important to develop tools that have the potential to increase the proportion of battlefield injured that make it to surgical care. If an appropriate internal tourniquet were designed it would likely be able to save soldiers' lives, enabling evacuation to a surgeon's life-saving care.

4.1.8 Requirements for a combat REBOA device

The REBOA equipment presently available requires insertion wires that are over a meter long and it needs a large sterile area to control and insert this equipment [9]. That setup is not conducive to a forward combat medical environment. Once inserted the presently cumbersome setup would not be easily transported in a medevac helicopter or armored ambulance. Also the person inserting this device will likely be a physician but not necessarily a surgeon. With the current REBOA implementations the guide wire must be manipulated up to the aortic zone of

deployment. If the iliacs have been damaged by an IED blast this could become a difficult or impossible task. Another pitfall would be if the wire advanced down the contralateral iliac rather than up the aorta. Inflating a fluid filled balloon in the iliac or femoral arteries could be a devastating complication. For a combat occlusion device to be feasible it would have to: be easy to use, have a short wire, be able to be transported with the patient, be able to manage blast injured pelvic vessels, be able to tolerate contralateral iliac intubation. We have designed a novel device to meet these requirements.

4.2 CREATION OF OCCLUSION DEVICE

4.2.1 Methods

A novel device was designed to cause Zone 3 aortic occlusion (Figure 4.3). Rather than using a Seldinger technique, guiding the apparatus over a wire, a latex balloon expands up the vessel as it inflates. The device is self-guided. This 16 mm x 22 cm balloon inflates up the vessel. As the balloon expands it carries a wire that is attached inside the balloon with it. This allows for a measurement of length of deployment as well as the application of gentle pressure to facilitate deployment. The balloon is inflated from a pressurized carbon dioxide (CO_2) canister.

Figure 4.3 Novel iliac and aortic occlusion device

Device construction

A 16 g CO_2 canister was used to inflate the balloon. This was attached with a variable valve allowing for control of inflation and a pressure gauge to monitor balloon internal pressure (Figure 4.4). A ¼ inch ball valve was used as a pressure release to allow for deflation of the balloon and retraction of the device (Figure 4.5). A 1.1 mm diameter braided wire enters the device through a rubber seal of near identical diameter. When the balloon device is deployed a plastic bead is pulled into the rubber seal. The more inflated the balloon becomes, the greater of the force of the bead into the seal preventing air leak. The balloon is 22 cm in length and 1.6 cm in diameter. It begins invaginated in the device and then inflates and deploys

longitudinally with CO_2 inflation (Figure 4.4). Once maximum length is achieved the balloon will further distend laterally.

The balloons were fabricated by rolling sheets of 0.05 mm latex onto a dowel and applying liquid latex along the seam (Figure 4.5). The cylindrical latex tube was then rolled off the dowel (Figure 4.6) and then attached with epoxy to the braided wire (Figure 4.7) and invaginated into the device.

Figure 4.4 CO_2 inflation devices

Figure 4.5 Rolling of the latex on the dowel

Figure 4.6 Rolling the balloon off of the dowel

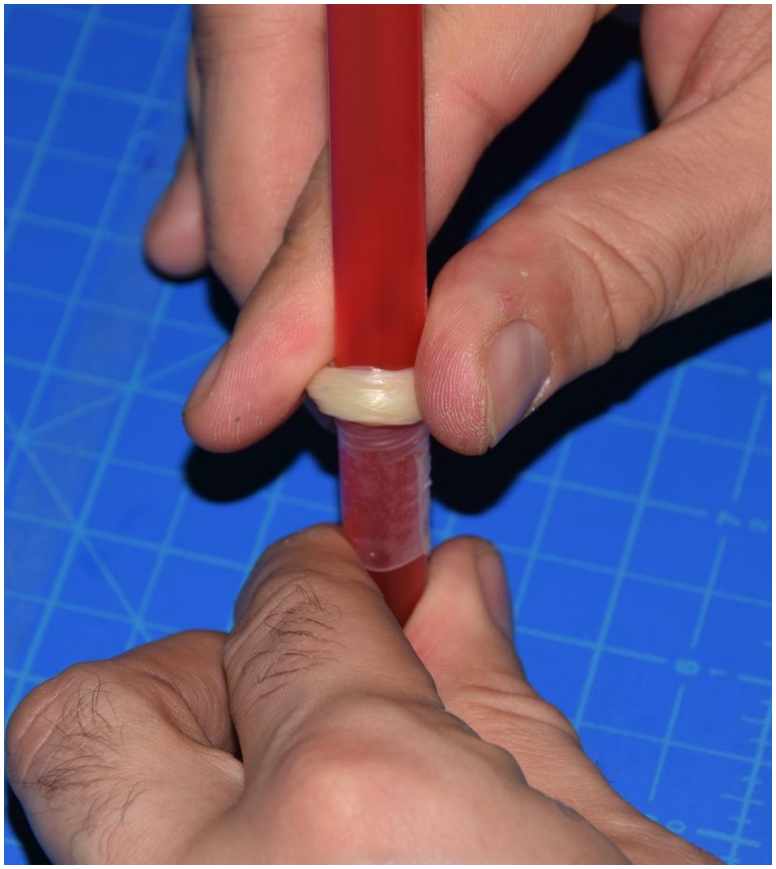
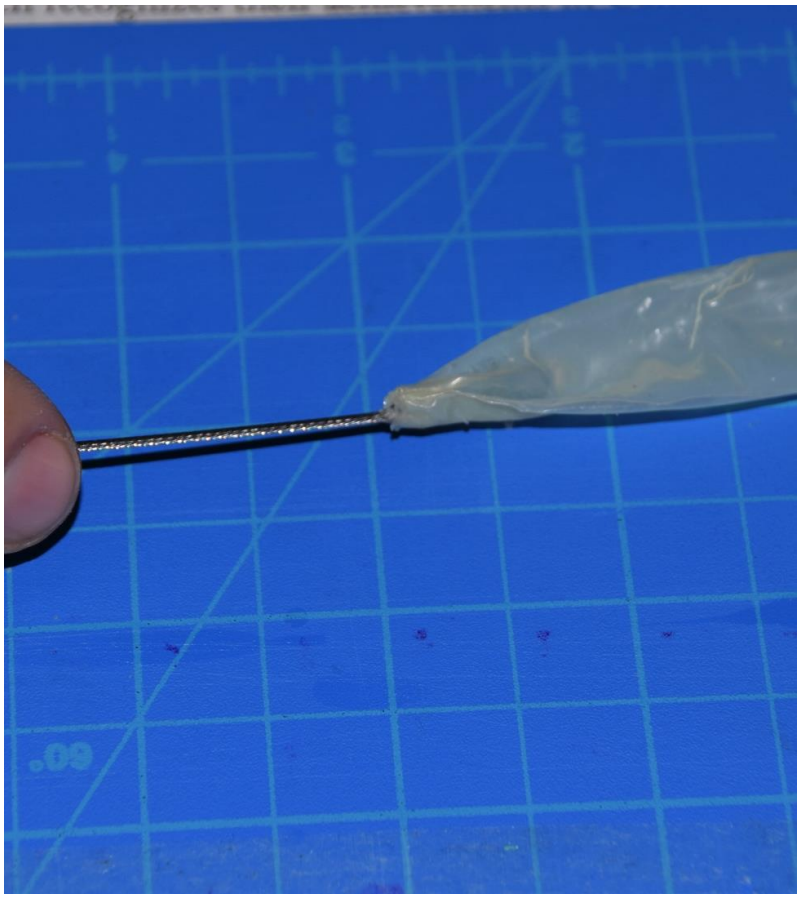


Figure 4.7 Balloon attached to the braided wire



Occlusion pressure testing

In order to determine against what pressure the device could obtain and maintain occlusion, a testing model was created (Figure 4.8). This aortic model consisted of a 2 cm diameter vinyl model aorta with 2 cm diameter vinyl iliac limbs that had water pumped through it at variable pressures (Figure 9). A PSI gauge was placed in continuity with the water flow to measure how high the water pressure could be raised maintaining balloon occlusion before rupture. During each experiment the testing apparatus and the PSI gauge were video taped so that an accurate PSI

rupture pressure could be recorded and occlusion of flow was confirmed (Figure 4.10). A variable speed pump was used to increase the water pressure until rupture was obtained and PSI recorded.

Figure 4.8 Aortic occlusion testing apparatus

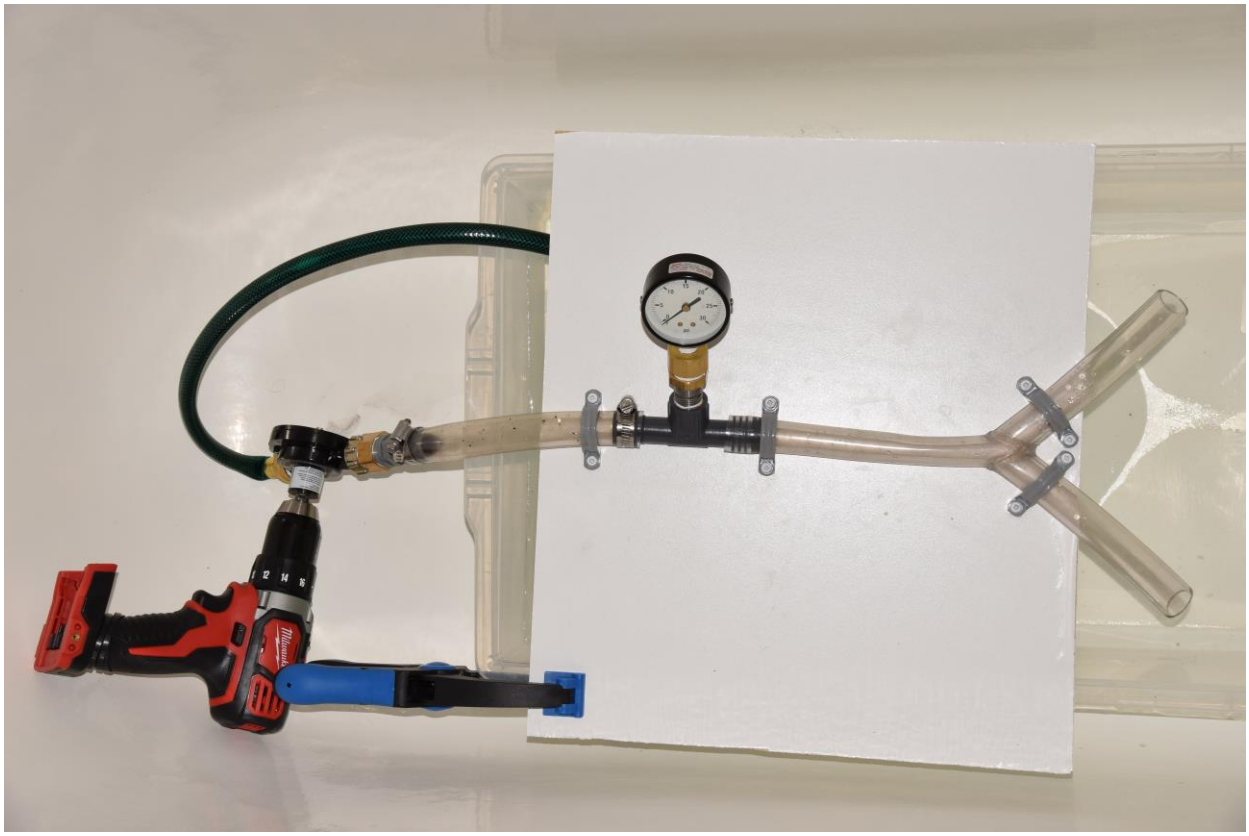


Figure 4.9 Un-occluded flow through testing apparatus

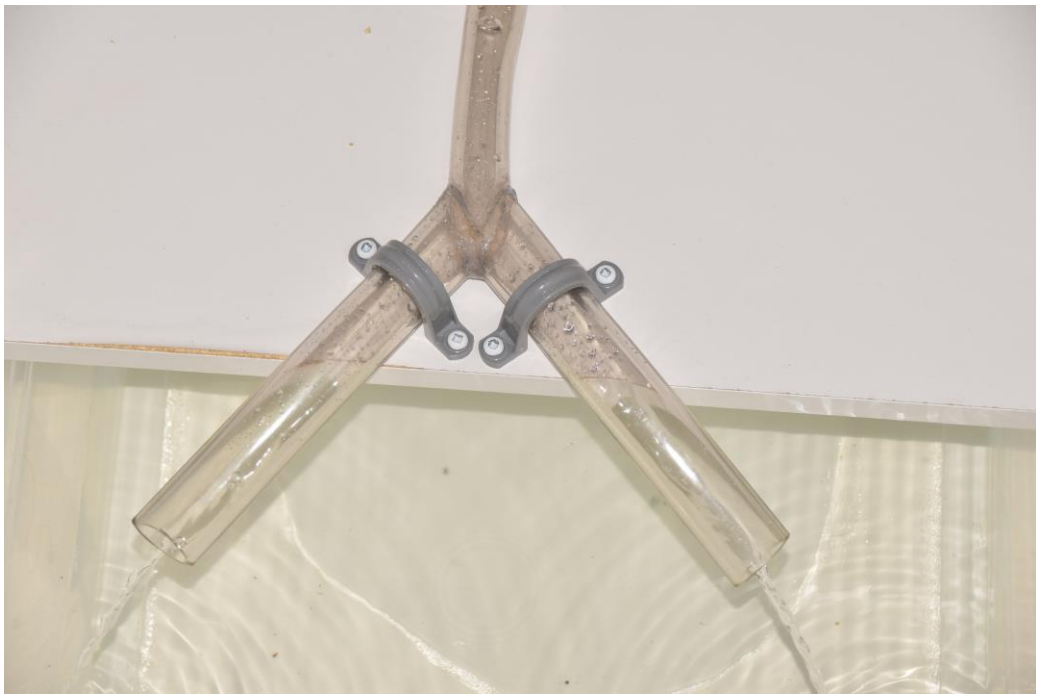
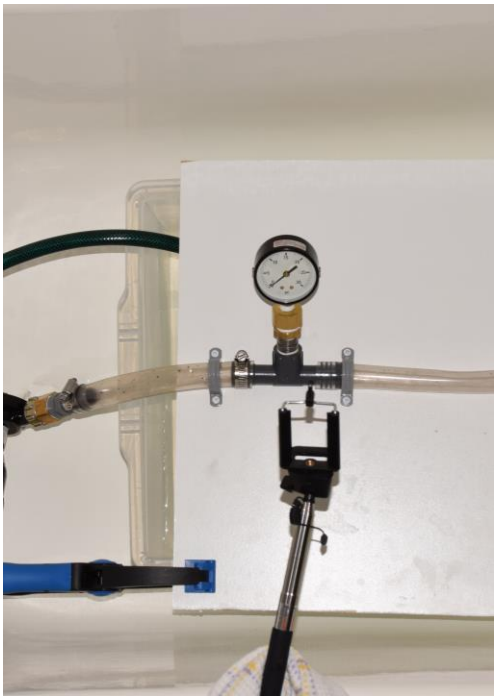


Figure 4.10 PSI gauge and camera mount



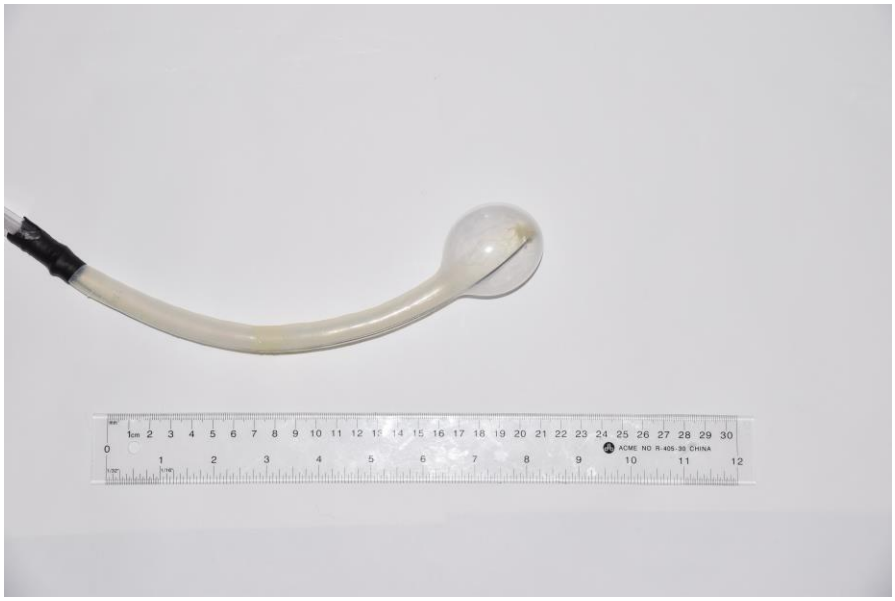
In order to determine the internal balloon pressure that would cause rupture, a pressure gauge was put in series with the device and the balloon was gradually inflated until the balloon ruptured. The gauge was video taped during the experiments to ensure accurate pressure recording.

4.2.2 Results

The invaginated balloon of the device would expand out of the tip of the catheter until it reached its full length (Figure 4.11) and then would further stretch to up to 5.5 cm in diameter (Figure 4.12).

Figure 4.11 Deployed balloon

Figure 4.12 Further inflation of deployed balloon



The device was deployed into the occlusion pressure testing apparatus (Figure 4.13). Once occlusion had been obtained the upstream water pressure was gradually increased until the balloon ruptured. The mean rupture pressure was 561 mmHg (SD 124) with the minimum rupture pressure of 362 mmHg, well above any physiologic human blood pressure (Figure 4.14). The balloon internal pressures were also measured and as one would expect were equal to upstream pressures at the time of rupture.

Once the device had been shown to be able to deploy and occlude flow above physiologic pressures, the deployment apparatus was miniaturized. The final deployment catheter had an external diameter of 6.35 mm and an internal diameter of 2.76 mm (Figure 4.15). This device could be deployed in a human sized model with a 2 cm aorta and 1 cm iliac vessels (Figure 4.16).

Figure 4.13 Balloon occluding pressure-testing apparatus

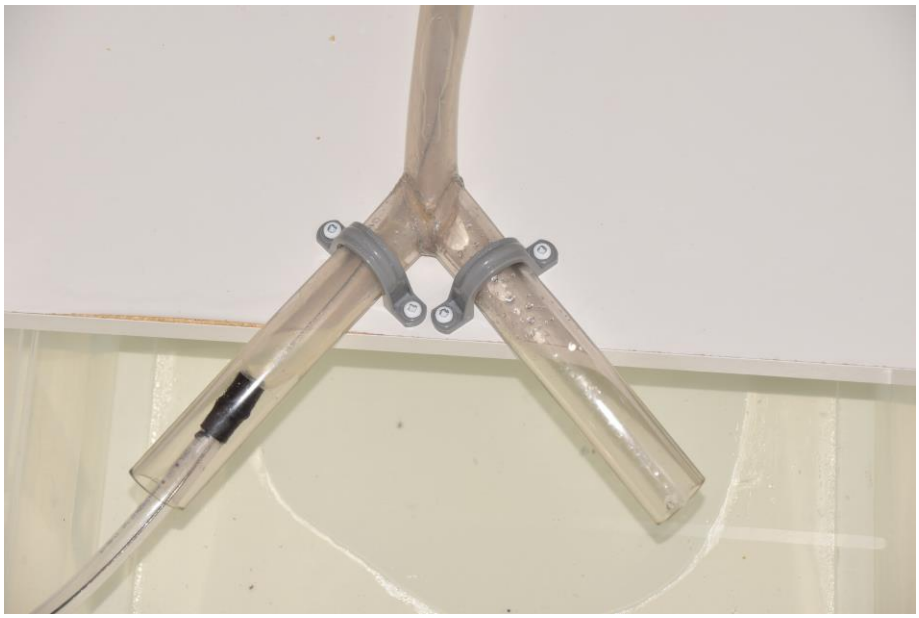
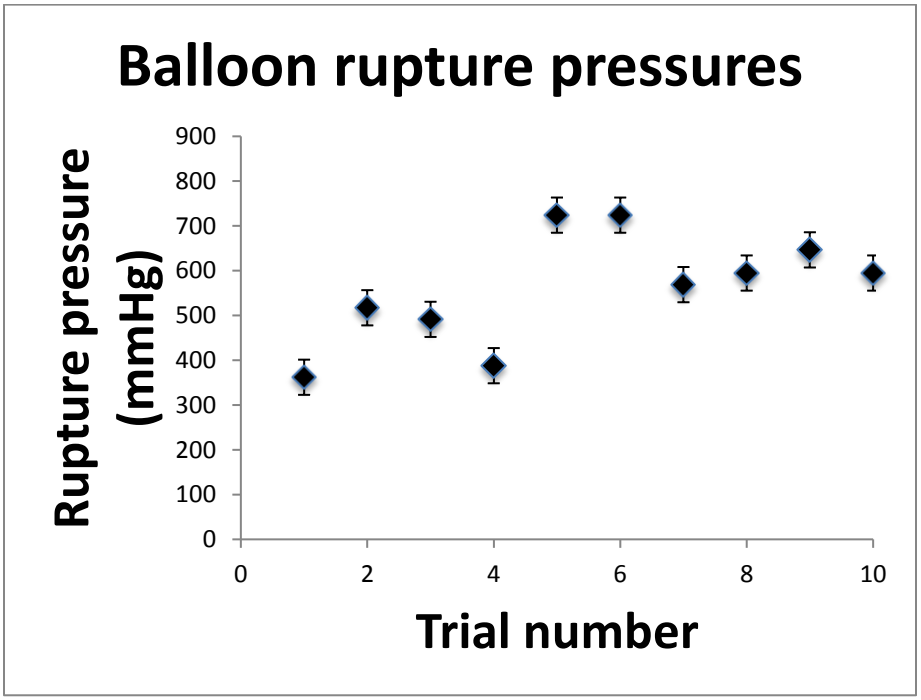
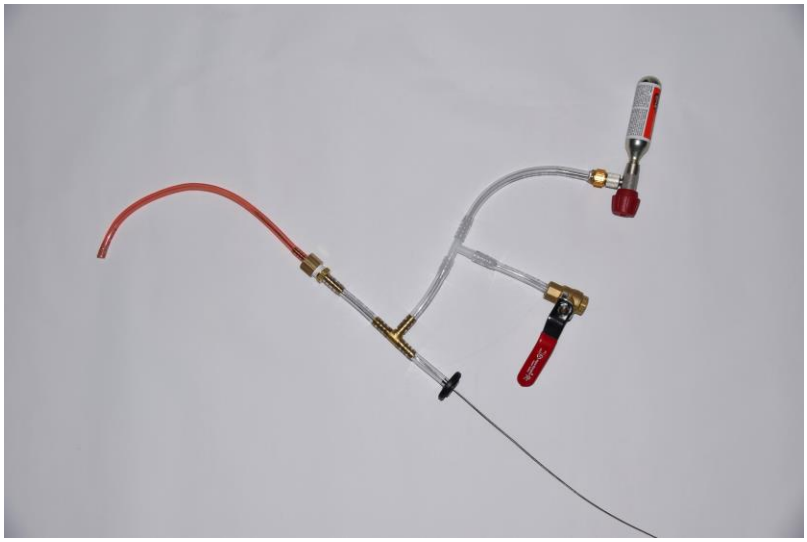


Figure 4.14 Balloon rupture pressures



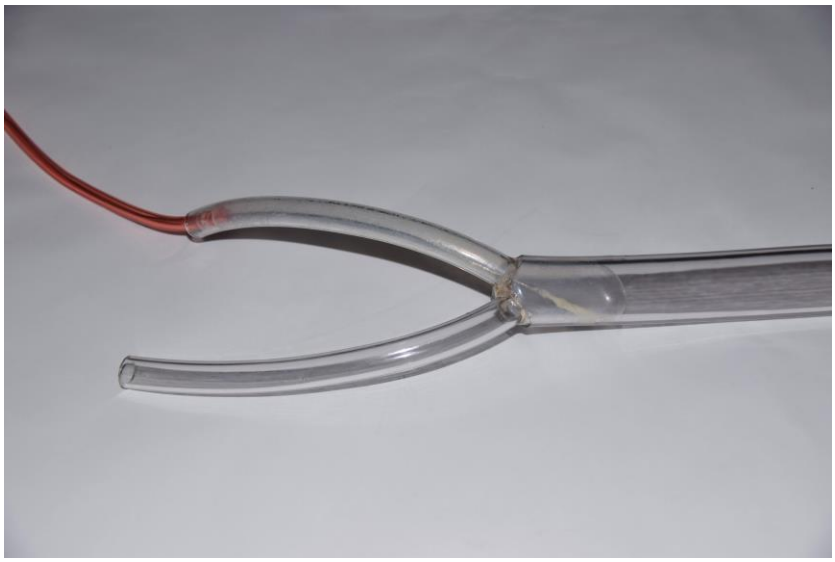
The graph displays the rupture pressures for 10 balloons. The error bars represent standard error measurement.

Figure 4.15 Smaller deployment device



The smaller device was then tested on aortic models of human anatomical scale with 2 cm diameter aortic tubing and 1 cm diameter iliac tubing. The device was successful in occluding flow in this model.

Figure 4.16 Deployment of the balloon in a human sized aortic model



4.2.3 Discussion

We have created a device that can be inflated in a human scaled model and cause occlusion of fluid flow to above human physiologic pressures. It is easy to use requiring only arterial access and turning on the CO_2. The device self inflated and self guided up the model aorta to cause effective occlusion. The internal wire allows the measurement of the length of deployment as well as extraction of the device. The next step was to test the device's ability to occlude flow in animal tissue and in damaged iliac models.

4.3 PORCINE MODEL TESTING

4.3.1 Methods

Occlusion of cadaveric porcine aorta

A cadaveric porcine aorta was placed into the testing apparatus, replacing the artificial tubing. Small arterial branching vessels were suture ligated. The device was then used to cause flow occlusion and this was video taped. Normal saline was infused through the testing apparatus during cadaveric porcine experiments. The porcine aortas were obtained from a local abattoir on the day of slaughter. The experiments were conducted on the day of slaughter (Figure 4.18).

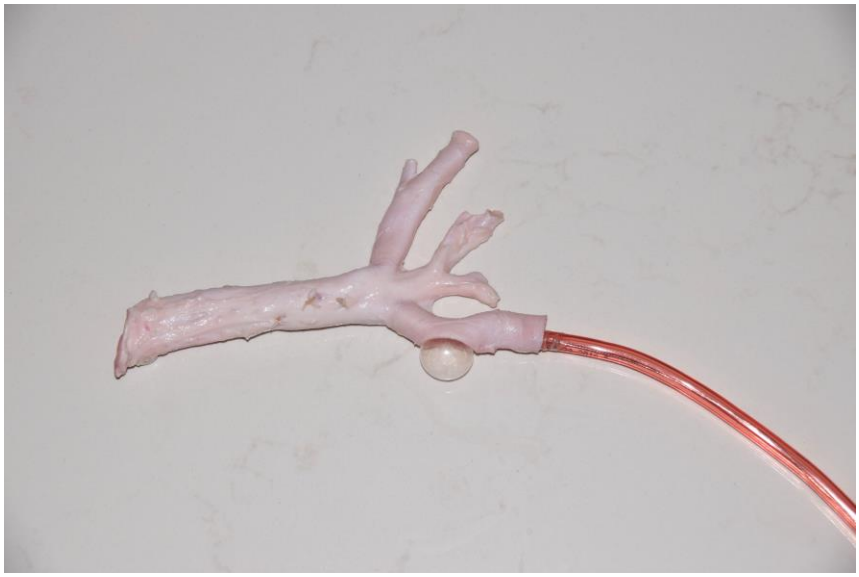
Modeling damaged iliac vessels

In order to model the balloon progression and occlusion of flow that would occur in a damaged iliac, a 1 cm diameter defect was cut in the iliac vessel of the porcine model. The device was then used to inflate up the damaged limb while the

experiment was video taped. This was done on three different porcine aortas. Three different balloons were used on each model for a total of nine balloons being tested (Figure 4.18)

Figure 4.17 Porcine aorta model

Figure 4.18 Porcine aorta with 1 cm diameter iliac defect with device deployed



4.3.2 Results

The porcine aorta was attached to the perfusion apparatus. The device was deployed up the porcine iliac and aorta and occluded fluid flow. The balloon device was successful in occluding flow of water in a porcine aorta model with a perfusion pressure of 120 mmHg. All nine balloons that were tested were able to provide effective occlusion.

When a 1 cm defect was cut in the iliac to simulate a traumatically damaged vessel, the balloon was able to fill the defect and continue on its proximal course to cause occlusion.

Figure 4.19 Porcine aorta occluded at a perfusion pressure of 120 mmHg

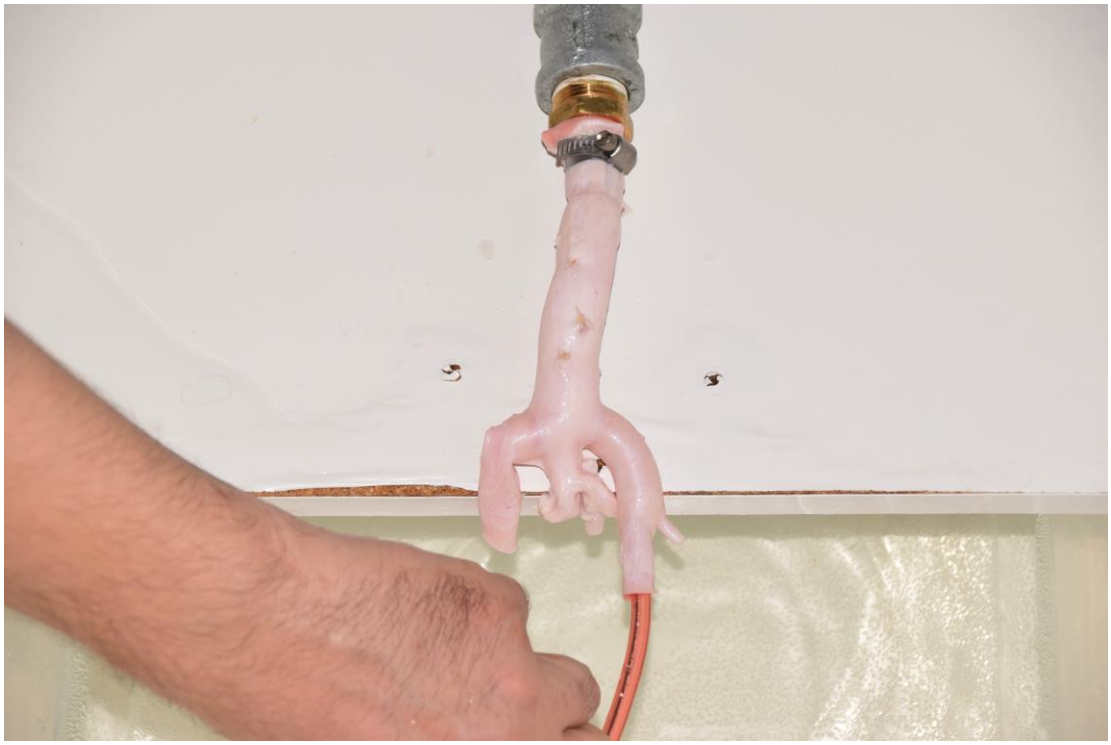
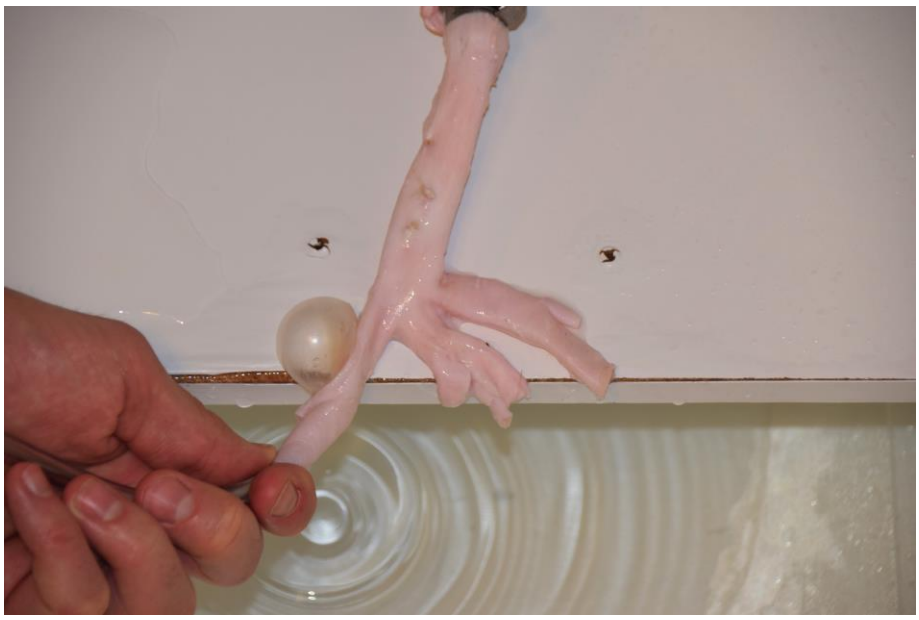


Figure 4.20 Porcine aorta with iliac defect occlusion testing



4.3.3 Discussion

The device was shown to be able to occlude the flow of fluid through porcine blood vessels at a fluid pressure of 120 mmHg. Furthermore, when a 1 cm defect was cut into the iliac the balloon would fill that defect and continue its course up the vessel to cause more proximal occlusion. This device has shown it can be used on a tissue model and can navigate a model of iliac injury. By inflating to fill the defect in the blood vessel it will occlude flow out of that defect. The technique of inserting a Foley catheter into a junctional injury has already been used in trauma. This device accomplishes a similar effect at the site of vessel injury with the added advantage of being able to continue more proximally to provide aortic occlusion. The next step is to show it can be deployed in human anatomy.

4.4 PERFUSED HUMAN CADAVERIC TESTING

4.4.1 Methods

Human cadaver had a catheter inserted in their subclavian artery and was perfused with a water and red dye solution. The cadaver was provided through the bequeathal program, Department of Anatomy & Cell Biology, Western University, London, Ontario, Canada, in accordance with the Anatomy Act of Ontario. These cadavers were never treated with formalin and were preserved by freezing until they were thawed for the experiments. The femoral arteries were dissected bilaterally. The device was deployed in the right common femoral artery (Figure 4.21) and flow through the left femoral arteriotomy was observed for occlusion of flow. The cadavers were perfused to a pressure of 120 mmHg (Figure 4.22).

4.4.2 Results

The device was deployed in the right femoral artery. When it was deployed, flow through the arteriotomy in the left femoral artery stopped.

Figure 4.21 Device inserted into a human cadaver

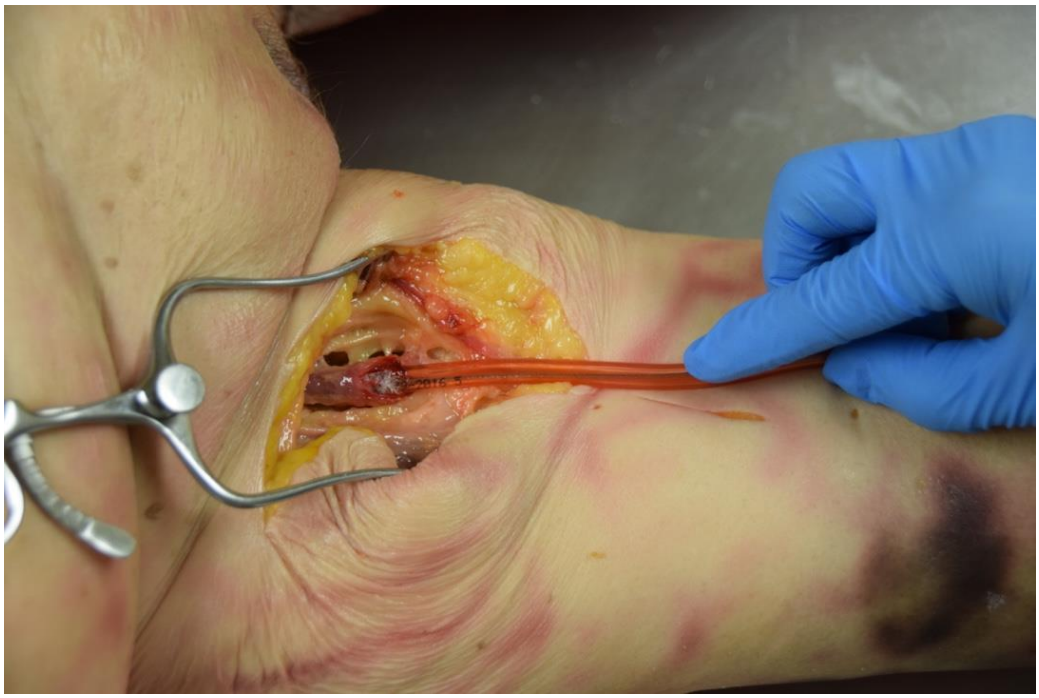
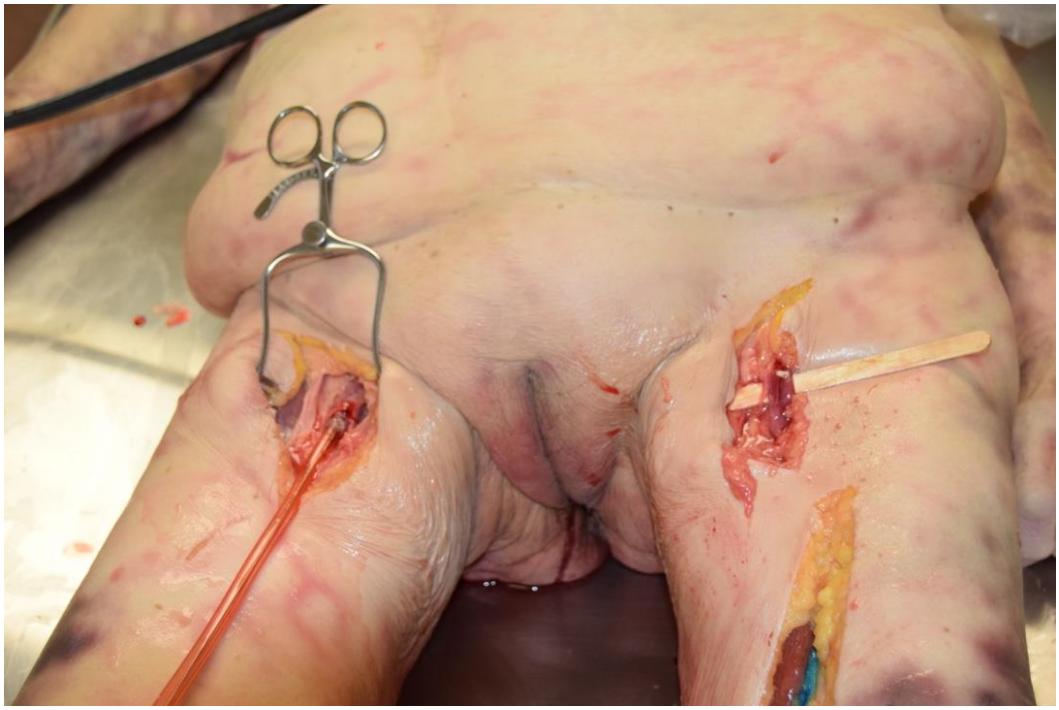


Figure 4.22 Occlusion of flow in a perfused human cadaver



4.4.3 Discussion

This device has been tested on a perfused human cadaver model. It has shown that it can occlude flow of fluid in human blood vessels at a pressure of 120 mmHg. It was deployed through a cut down and arteriotomy. It has not shown feasibility in a synthetic aorta, in porcine tissue vessels as well as perfused human vasculature.

4.5 GENERAL DISCUSSION

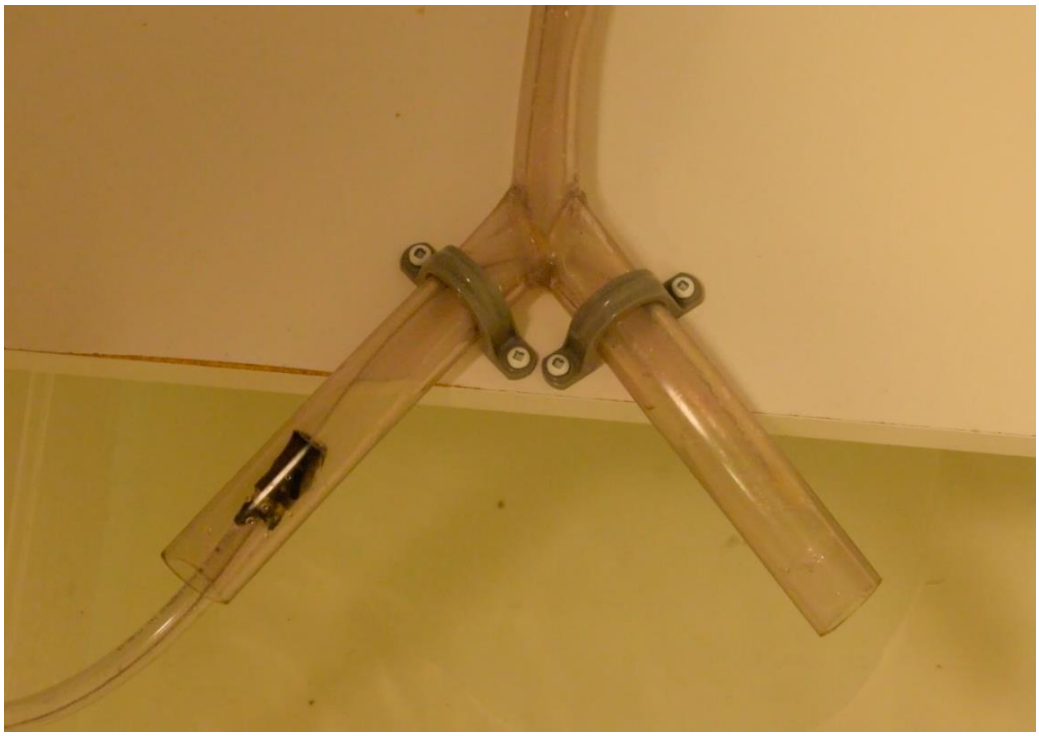
For a combat occlusion device to be feasible it would have to: be easy to use, have a short wire, be able to be transported with the patient, be able to manage blast injured pelvic vessels, and be able to tolerate contralateral iliac intubation. We have designed a novel device to meet these requirements.

By having the wire internal to the balloon the problem of the guide-wire becoming extraluminal is alleviated. When advancing a wire through a damaged vessel it could exit the lumen and create a false passage. With this novel device the operator does not need to be a skilled endovascular surgeon navigating the wire to the perfect position before the device can be inserted; instead the balloon leads the way. If the iliac vessel is injured preventing proximal navigation the balloon will inflate at that site of injury causing tamponade. This is similar to the previously established technique of inflating a Foley catheter into a junctional injury for tamponade. If the device could not be advanced because of iliac injury a second device could be

inserted into the contralateral side. If again it could not be advanced both can be left in place causing bilateral iliac tamponade and aiding in hemorrhage control. This is superior to the tradition REBOA where if the wire cannot be safely advanced the technique must be aborted.

One of the dangers of standard REBOA application is that the guide wire may descend down the contralateral iliac artery rather than advance into the aorta. If the REBOA balloon was then inserted and inflated in the contralateral iliac or femoral artery, rather than achieving aortic occlusion the procedure would cause further vascular trauma. In the hands of skilled endovascular surgeons this complication may be reliably avoided however it is a real concern for forward application of this tool in combat medicine. The advantage of this device is that if the balloon and its internal wire do go down the contralateral iliac, bilateral iliac occlusion is safely obtained as the balloon inflates up one limb and down the other (Figure 4.17). This feature makes this novel device more suitable for a combat application. The internal wire inside the balloon can help in gentle navigation and advancement and also be used to measure depth of balloon expansion without the challenges of classical Seldinger endovascular technique. Since it is the balloon that gently leads the way the device will occlude as far as it travels rather than having to perfectly position a REBOA for deployment.

Figure 4.23 Balloon with contralateral limb intubation and bilateral occlusion



Traditional REBOA balloons are inflated with saline, not CO_2. Although a variant of this novel device can be produced with hydro-inflation, CO_2 inflation has some advantages. The $C0_2$ cartridges are small and light and easily managed. The main advantage of water inflation is that it is essentially non-compressible. Once the balloon is inflated and occlusion is achieved the balloon will not be compressed as blood pressure is restored. With the CO_2 inflated balloon as blood pressure increases the balloon will be compressed and it is possible that more CO_2 will need to be put into the balloon. However, this compressibility is advantageous when inflating the balloon in a damaged iliac. Rather than ripping apart the vessel with uncompressible expanding water balloon a gentler and softer compressible balloon fills the space of the defect while minimizing further destruction of the vessel.

Having a self-expanding water balloon advance down the iliac to the aorta would have a higher risk or vessel rupture. The compressibility of CO_2 makes it perfect for this application. As has been demonstrated in our experiments occlusion of flow to supra-physiologic levels can still be achieved. CO_2 is also a good choice in the event of balloon rupture. This gas is rapidly absorbed and expelled though the lungs. This is the same reason for its use in laparoscopic surgery. Any gas embolism formed would be in the distal circulation and unlikely to cause cardiac or brain gas embolism. CO_2 with its small sized containers, ease of use, compressibility and physiologic absorption make it an ideal choice for this device.

This novel device has a wire that is only 30 cm in length which is much more easily handled than the 260 cm wires used in standard REBOA[9]. With the present design this device requires a short sheath to be inserted into the femoral artery. This is the same as with REBOA placement. During patient transport of the casualty, care must be taken not to disturb this sheath. Although this novel device and REBOA share this challenge, the compact nature of the novel device and the short wire would make transporting the casualty simpler.

This novel aortic occlusion device has the advantage of having a shorter wire, being easier to transport with the patient, being able to provide occlusion to damaged iliac vessels, and can be inserted bilaterally. With further development and live animal testing this device may be able to be implemented in a forward environment to help combat casualties survive to the surgical care.

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CHAPTER 5

GENERAL DISCUSSION

CHAPTER 5: GENERAL DISCUSSION

5.1 VASCULAR TRAUMA AND THE AP-IED

Combat vascular trauma is the next area where military medical research can save lives. Vascular procedures were the fourth most common performed in the Afghanistan and Iraq wars; however, they were the area in which there was the biggest change in practice over the course of the conflicts and greatest need for increased training and innovation.[1,2]

The IED was the most common weapon to kill and injure Canadian soldiers in the Afghanistan war. [3] Through prospectively examining 100 consecutive IED victims we have provided a characterization and medical description of this weapons injury pattern. The IED causes multiple amputation as well as pelvic fractures and significant perennial and gluteal injuries. Although tourniquets and pelvic binder have been very effective in saving the lives of the combat injured [4] if we are going to save even more soldiers lives we must develop strategies to control the non-compressible hemorrhage caused by these weapons.

5.2 PHYSICIANS AND LAND MINES

War physicians played an integral role in the determination that the use of land mines is unethical. Land mines are indiscriminate weapons. Unlike a rifle or rocket that is pointed at its target, a land mine is buried with the hopes that the enemy will detonate it. But the enemy may not be the first person to step on it. It may be a 12-year-old child or other

civilian. When a conflict is over, the soldiers pointing their rifles and rockets leave; however, the land mine remains buried and remains equally as dangerous. Once the war is over and all the soldiers have left, that 12-year-old child remains in danger from these weapons.

The lack of discrimination and horrible wounds of land mines prompted the emergence of public campaigns for them to be banned. The work of advocates like Jody Williams, Bobby Muller, Princess Diana, and Lloyd Axworthy helped bring together 162 countries to sign *The Convention on the Prohibition of the Use, Stockpiling, Production and Transfer of Anti-Personnel Mines and on their Destruction* (the Ottawa Treaty) [5] in Ottawa, Canada in 1997. This was viewed as an international and Canadian success story. The International Campaign to Ban Landmines and Jody Williams were jointly awarded the Nobel Peace prize in 1997.

What is less well-known are the contributions of Dr Robin Coupland and Dr Adriaan Korver to the anti-land mine effort. Prior to the publication of their work, surprisingly little attention had been paid to land mines in the medical literature. Coupland and Korver described the injury patterns of antipersonnel land mines by reporting and analyzing the experience with land mines of 13 International Committee of the Red Cross Hospitals in Asia and Africa. They were able to develop a classification system for the pattern of land mine injuries and describe what land mines did to their victims [6-8]. Their work provided the medical foundation for the ethical debates surrounding the creation of the Ottawa Treaty, which would eventually lead to the banning of land mines by 162 countries. They played a vital role in providing medically accurate and experiential

knowledge of the land mine's impact on its victims and who the victims were. Only a physician could have the requisite knowledge and experience to play that role. The contributions made by Coupland and Korver allowed Canada and the global community to make an informed decision.

5.3 ETHICAL WAR AND THE LAW OF ARMED CONFLICT

Although horrible suffering occurs during war, the global community has acknowledged that military necessity cannot be used to justify all violence. Customary Law based on global practices and principles had long existed; however, these laws of custom began to be codified as can be seen in the St Petersburg declaration in 1868 and the multiple Geneva and Hague Conventions. These were attempts to publicly declare what acts during war would be considered illegal. War is not a lawless state of violence in which all actions are excused. People fighting wars are not exempt from ethics and the judgment of right and wrong. The global community has accepted the concept of war crimes, and people engaging in wars cannot escape ethical and legal accountability.

A prohibition of superfluous injury or unnecessary suffering is a cardinal principle of the International Court of Justice [9]. The St Petersburg declaration, which was concerned with what weapons would be acceptable in combat, forbade "the employment of arms which uselessly aggravate the suffering of disabled men.[10]" This was reaffirmed in the Hague Conventions, which were some of the first attempts to codify what constituted a war crime. The Hague Conventions specified that it was "prohibited to employ weapons, projectiles and material and methods of warfare of a nature to cause superfluous injury or unnecessary suffering.[11]" Whereas the St Petersburg Declaration and Hague Conventions

were defining what ammunition could be used and how wars were to be fought, the Geneva Conventions defined the humanitarian treatment of war. Here again it was affirmed that "it is prohibited to employ weapons, projectiles and material and methods of warfare of a nature to cause superfluous injury or unnecessary suffering.[12]" Be it in treaties defining how wars should be fought, or in treaties outlining humanitarian treatment during war, it has been agreed upon time and again that superfluous injury or unnecessary suffering is illegal. This prohibition is a part of customary law and applicable to all parties of any armed conflict [9]. Although it may be required in war to take a life, to intentionally make someone suffer beyond what is necessary to render him or her *hors de combat* is wrong. It is a crime.

The horrible consequences of AP-IEDs were ubiquitous in the Afghanistan war. Anyone who buried one of these weapons would know the violence and injury they were inflicting on their victims. This knowledge speaks directly to the mental element, or *mens rea*, of their crime. The users of these weapons knowingly mutilated their victim causing injuries far worse than would be required to incapacitate them. The users of this weapon knew that it was indiscriminate and that civilians or children may be the victims.

The application of unnecessary harm is not universalizable principle. Neither side would want themselves to be tortured by their enemy. Inflicting more injury than required for military victory shows no respect for the humanity of your enemy. This is why the infliction of unnecessary suffering has been universally rejected in the global community. It fails both a utilitarian calculus and universal application of a deontological rule. There can be no reasonable ethic that would make it moral to inflict unnecessary suffering.

5.4 THE ILLEGALITY OF THE AP-IED

It could be argued that the enemy in Afghanistan had no access to conventional weapons and, given the power and organization of the coalition soldiers, had to revert to using AP-IEDs. However, even if the objections of the indiscriminate nature of this weapon and the fact that it will persist beyond the conflict are overlooked, the fact that it has been designed to cause maximum harm is inexcusable. They could have created a weapon similar to a land mine that caused foot or limb amputation and each of the soldiers injured in this way would be incapacitated and removed from the fight. Instead they developed a weapon that would cause as much injury as possible. In making these weapons they chose to optimize the harm and damage they could produce.

Whereas antipersonnel land mines cause amputation of the foot or leg resulting in the incapacitation of the victim, an AP-IED causes multiple amputations, perineal and genital mutilation, pelvic fractures and extensive soft tissue injury, and significant life long disability. The doctors who cared for casualties in Afghanistan routinely saw the destruction and devastation cause by these weapons, and like Coupland and Korver, they have captured and described the medical details of these patients. [13-16] The next step is to express moral outrage and protest against the use of these weapons in kind with Jody Williams, Bobby Muller, Princess Diana and Lloyd Axworthy. Not only do AP-IEDs have the same indiscriminate harm of land mines, they cause superfluous injury and unnecessary suffering. Improvised explosive devices are unethical weapons; their users have committed a war crime.

5.5 A NOVEL DEVICE

IEDs cause multiple amputations and massive pelvic injury. REBOA has been proposed as a technique that can treat the non-compressible hemorrhage of the combat injured. A gap analysis identified that as many as 18.5% of combat casualties might benefit from aortic occlusion. [17] Given that 98% of the coalition soldiers injured in Afghanistan survived if they could reach surgical care any device that could control hemorrhage until a patient can be evacuated to higher care would be of great help and likely save lives.[18]

The REBOA technique has been used in combat and the patients did survive to be evacuated to a surgical facility.[19] However, this was accomplished by having surgeons and emergentologists with extra endovascular training in a forward Special Forces environment. This is not a feasible model for a broad military application. If endovascular balloon occlusion of the aorta is going to save soldiers' lives in wars like we just experienced in Afghanistan, General Duty Medical Officers with family residency training or Physicians Assistants will have to perform the procedures. If a practitioner is capable of placing a central line they can use this novel device. It has been designed expressly for combat application and it will make REBOA more accessible to forward military operations. The novel device presented here does not require wire guidance, or x-ray confirmation of placement. The balloon led technique can manage damaged iliac vessels and rapidly and easily provide aortic occlusion, stopping pelvic hemorrhage.

This device may also be useful in a civilian environment. With centralization of vascular surgeons and clinicians in peripheral hospitals managing and treating fewer elective vascular surgeries, there has been a loss of skillset in the periphery. Patients with significant vascular injuries are often rapidly evacuated to a tertiary center for definitive repair. This novel device with its easy use and promise for navigating injured and perhaps calcified and aged vessels may have applications stopping hemorrhage for transport to definitive care. This new technology has the potential to save both military and civilian lives.

5.6 VASCULAR INJURIES AT A CANADIAN CENTRE

In order to better understand what vascular injuries are encountered in a civilian Canadian environment a retrospective five-year study was conducted. This demonstrated that vascular surgeons managed the majority of vascular injuries; however, surprisingly 13 different specialties managed vascular injuries. If there is to be change in the way that vascular surgery is managed, there must engagement with all of the multidisciplinary partners who manage these patients.

There are potential areas for improvement in how vascular trauma was managed. A damage control approach was taken in only one patient out of the 127 examined. The use of damage control techniques like aggressive ligation and temporary intravascular shunts may allow sick trauma patients to be able to get to the intensive care unit faster for correction of their physiologic derangements and then return later for definitive vascular repair.

There may be a population that would have benefited from the novel device. There were 29 patients with abdominal and pelvic vascular injuries. Some of these patients may have been able to have their bleeding controlled in the periphery or in the emergency room, decreasing their blood loss and physiologic derangement before getting to the operating room. As this new technology is further developed and its indications refined, the vascular trauma data collected here will be useful in identifying civilian populations worth considering for its application.

5.7 FUTURE DIRECTIONS

The three projects which comprise this work each have next steps to be taken. Next generation prototypes of the new device tested here need to be developed that can be inserted through a 7 or 8 Fr sheath. This is feasible given that it has been shown to function in a catheter with an 8 Fr internal diameter. This size is important since its removal will not require repair of an arteriotomy and can be controlled with direct pressure. This prototype should be tested on animal models demonstrating its physiologic effects and safety profile as the next step before eventual human application.

The Canadian vascular trauma research registry is going to be applied to multiple centers. At present four other Canadian level 1 trauma centers are in the progress of collecting the same retrospective data over the same time period. This will allow for a more robust description of the Canadian vascular trauma experience that can be compared to American registries.[20] It will also allow for intra-Canadian comparison to be done and for the establishment of a Canadian vascular trauma research network. If this work proves to be fruitful, a prospective Canadian vascular trauma registry could be established.

There is now a medical description of the injury pattern of the AP-IED and it is much more serious and devastating than that of the APM. In this instance the next steps are less of a scientific and more of an ethical and societal nature. Armed with the medical knowledge of what and AP-IED can do, the medical community and society at large should oppose the use of these weapons much as they did in opposition to the use of landmines.

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