



A REFLECTION OF PRE-HOSPITAL IMAGING ON TRAUMATIC INTRA-ABDOMINAL HAEMORRHAGE

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DECLARATION OF ORIGINALITY

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To my Wife and my Children, Eshaan and Ayla-Maryam - Thank you for your love
and support you are the delight of my eyes

Abstract

Torso haemorrhage remains one of the leading causes of preventable morbidity and mortality from trauma particularly in the prehospital setting. Early identification of the haemorrhage source is essential in order to improve outcomes and an effective imaging modality may help to establish the diagnosis. This thesis examines how to improve abdominal haemorrhage identification in the prehospital setting in order to achieve rapid haemorrhage control. The current literature is appraised and a national questionnaire distributed to frontline trauma care physicians. For haemorrhage identification research into ultrasound is recommended and for haemorrhage control novel procedures such as Resuscitative endovascular balloon occlusion of the Aorta (REBOA) are valued.

FAST (Focused abdominal sonography for trauma) is considered the most appropriate modality for haemorrhage identification in the prehospital setting⁽¹⁾ but it is associated with a steep learning curve^(2, 3). In order to improve training, a face, content and construct validation of a FAST simulator model is undertaken⁽⁴⁾. Furthermore to better understand an ideal performance, an ergonomic analysis of experts' workspace and force during a FAST scan is conducted. From this, an expert set of metrics is derived of the ideal ultrasound probe position and force for each FAST region. A learning curve study is implemented to assess two randomised groups of novices one trained with the expert metrics and the other trained using a standardised curriculum. The expert metrics group are faster and more accurate at

performing a FAST scan than the control. This is also the case in a prospective validity study.

REBOA is being investigated as a novel technique for prehospital haemorrhage control. Accurate inflation of the balloon catheter within the correct zone is critical to gain control of bleeding and prevent adverse effects, particularly in the prehospital setting. A feasibility study identifies that ultrasound guidance and balloon insufflation with contrast agent enhances catheter placement within Zone III. Subsequently, two groups of physicians are randomised to perform REBOA with and without ultrasound guidance. The former are faster and more precise than the latter group hence supporting the robustness of the ultrasound imaging technique.

Overall this thesis enhances prehospital abdominal haemorrhage identification by improving FAST training and augments haemorrhage control through accurate REBOA placement with the use of ultrasound and contrast agent.

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This thesis represents my original work. However, I could not have done this alone and the collaborations outlined below helped to achieve my research goals. I did also receive support from co-authors for manuscript review prior to peer-reviewed publication and they have been acknowledged in the relevant sections of the thesis.

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List of Acronyms

ASIS	Anterior Superior Iliac Spines
ATLS	Advanced Trauma Life Support
CAT	Combat Application Tourniquet
CEUS	Contrast Enhanced Ultrasound
CNS	Central Nervous System
CT	Computed Tomography
DOF	Degrees of Freedom
ED	Emergency Department
E-FAST	Enhanced Focused Assessment in Sonography for Trauma
FAST	Focused Assessment in Sonography for Trauma
HEMS	Helicopter Emergency Medical Services
HIFU	High Intensity Focussed Ultrasound
LUQ	Left Upper Quadrant
NIRS	Near Infra-Red Spectroscopy
RCT	Randomised Controlled Trial
REBOA	Resuscitative Endovascular Balloon Occlusion of the Aorta
RF	Radiofrequency
RUQ	Right Upper Quadrant
USS	Ultrasound
UK	United Kingdom

Chapter 1 Introduction

1.1 Background

1.1.1 Trauma care

Trauma is projected to become a leading cause of morbidity and mortality worldwide within the next decade⁽⁹⁻¹²⁾. Haemorrhage is considered the second most prominent cause of civilian trauma-related mortality accounting for up to 40%, with only central nervous system (CNS) injury being more lethal⁽¹³⁻¹⁸⁾. Almost all trauma mortality due to haemorrhage occurs within the first 24 hours of injury with the majority, up to 56% of civilian deaths⁽¹⁶⁾ and 87.3% of combat-related fatalities, occurring in the pre-hospital period⁽¹⁹⁾.

Of those casualties that survive to the hospital, haemorrhage is the major cause of mortality in the first hour of admission, as well as for over 80% of subsequent operating room deaths^(13, 16, 18, 20). The mortality of a patient suffering traumatic shock from intra-abdominal bleeding increases by approximately 1% for every 3 minutes that passes before definitive management⁽²¹⁾. If the trauma patient survives beyond 24 hours, then morbidity is high with any prior episode of haemorrhagic shock (systolic blood pressure less than 90mmHg) being associated with significant rates of organ failure (24%) or infection (39%)^(18, 22).

The young are disproportionately affected by trauma resulting in several potential effects for survivors including, on an individual level, disability and loss of earnings

for their family. It also has an impact on the economy as they are financially dependent on welfare support for the rest of their lives^(11, 12). In England alone, there are greater than 20,000 cases of major trauma resulting in approximately 5,400 deaths per year. The economic burden resulting from this is estimated to be £3.5 billion annually⁽²³⁾. These quoted figures are expected to rise in the future, hence, effective management of the trauma patient is essential to improve outcomes.

1.1.2 Mechanism of injury

In order to recognise and treat the patients' traumatic pathology, the mechanism of injury has to be clearly understood. This is established through a history from the patient, witness accounts and the evidence available at the scene; such as a "bullseye" sign on a car windscreen which may indicate a head injury.

The mechanism of injury inflicted can be broadly classified into blunt and penetrating trauma although the aetiology can be mixed such as in a blast or thermal injury. Additionally, an evaluation has to be made of the energy transfer that occurred, for example the speed of vehicles, calibre and size of the weapon. Traumatic injury is a result of the speed and amount of energy transmitted over a given surface area, as well as the elastic properties of the tissues to which the energy transfer is applied⁽²⁴⁾.

Blunt trauma in the civilian setting is normally due to road traffic incidents but other causes include falls, assault and blasts. Trauma from motor vehicle collisions includes the patient inside the vehicle, motorcycle crashes, cyclists and pedestrian impact. The possible scenarios for vehicle collisions include, frontal, lateral, rear,

rollover or a combination of them. Injuries resulting from this include fracture-dislocation of the lower extremities, spinal injuries as well as chest or abdominal trauma from compression injuries. Deceleration injury can cause avulsion of the stabilising portion of an organ from its mobile section. An unrestrained passenger, a vehicle rollover or ejection of the occupant can result in a much higher burden of injury⁽²⁴⁾.

Pedestrian injury from a vehicle impact results in several possible injury patterns. In an adult, a vehicle bumper impact results in lower extremity trauma but in a child it can cause chest and abdominal injuries. Head as well as torso injuries are more common with a vehicle windscreen and hood impact resulting in a bullseye sign as previously described. The subsequent impact with the ground results in head and spinal injuries as well as organ compression trauma.

Penetrating trauma and the resultant injury pattern can be determined by the amount of energy transferred. A low energy weapon may be a knife, a medium energy armament would be a handgun and a high energy firearm would include military rifles. The injury sustained also depends on the shape of the missile. This results in cavitation which has two components a permanent cavitation which is the creation of space left behind by the projectile consistent of damaged tissue. This includes some bullets which have a small cross-sectional area that will pass through tissue easily resulting in localised injury.

The second component is a temporary cavitation, where a high energy is transferred causing a pressure wave. This wave compresses the surrounding tissues creating a

temporary cavity which can be much larger in size than the missile itself resulting in injury to neighbouring organs. Examples of this are large cross-sectional front projectiles such as hollow point bullets which spread or mushroom on impact causing a greater energy transfer with more injury. The higher the energy transferred, the larger the pressure wave imparted and the greater the subsequent injuries⁽²⁴⁻²⁶⁾.

The mechanism of the injury sustained whether blunt or penetrating and the energy transferred, are key components of the history that the prehospital care team take into account when managing a trauma casualty.

1.1.3 Prehospital care

James Styner introduced a paradigm shift in trauma care. He was a United States Orthopaedic surgeon who suffered a tragic set of events on February 17th 1976. He was the pilot of a small aircraft, flying his family back home and unfortunately crashed in bad weather conditions. In the subsequent set of events, his wife passed away and three of his four children lay unconscious in freezing conditions. He managed to bring his family to a local hospital and was distraught by how poorly resourced they were to manage the injuries. Eventually, they were all transferred to the Lincoln General Hospital for definitive care^(27, 28). Following this he stated that:

“When I can provide better care in the field with limited resources than my children and I received at the primary facility, there is something wrong with the system and the system has to be changed^(27, 28)”.

Indeed, it was changed and Styner developed a systematic method for treating those suffering severe injuries named Advanced Trauma Life Support (ATLS), which is now taught globally as the gold standard in trauma management⁽²⁴⁾. This hallmark course has enabled medical personnel worldwide to be trained in and practice a common language of trauma care which has undoubtedly saved innumerable lives⁽²⁷⁻²⁹⁾.

Since the inception of ATLS, trauma care continues to improve but there are still many challenges to overcome. The so-called “golden hour”⁽³⁰⁻³³⁾ within which to stabilise a trauma patient from the point of injury remains elusive to many who have tried. This “golden hour” refers to the increased likelihood that patients would survive from the point of injury if they received medical care within this time period^(34, 35). Although there is no evidence behind this principle, the swift transport from prehospital to definitive care arises from this concept. To address this principle, there has been a focus on improving the management of trauma patients at the point of wounding with the introduction of prehospital emergency physicians and helicopter transport for faster evacuation⁽³⁶⁻⁴⁰⁾.

Prehospital care focuses on managing injured patients at the scene of an incident, whether that is in the urban or rural setting and transferring them to hospital. An emergency incident can elicit different categories of responses in the United Kingdom (UK). “Category A” calls are life-threatening situations and ambulance services have to reach 75% of these calls within eight minutes according to national standards. “Category B” are serious and not immediately life-threatening incidents and “Category C” are not serious and not life-threatening situations⁽⁴¹⁾.

The decision to activate a Category A call and to deploy prehospital care teams starts with the call to the emergency services. It is dependent upon the mechanism of injury as this can help identify injury patterns. If the incident is life-threatening, the response is appropriately escalated. Decisions made at this stage include the category of the response, the appropriate despatch of vehicle and crew as well as the need for any additional resources such as the helicopter emergency medical services (HEMS)⁽⁴²⁾.

The location of the incident is also important. If the incident is in an urban setting there are normally hospitals in close vicinity ranging from a district general hospital through to a Trauma centre. In this case, ground transportation with an ambulance or a rapid response emergency medical services car or motorbike may be appropriate and can usually respond swiftly to a Category A incident. However, if it is a major trauma incident in a rural location there are a number of issues to consider. Firstly, the delay in receiving prehospital care in the rural environment is one of the main factors contributing to traumatic injury mortality. Communication in rural settings is not reliable with delays before the patient is identified and the prehospital response alerted. Additionally, there are longer transport times for the emergency medical services to reach the patient and then transfer them to a trauma centre. In these cases, helicopter transport may be more appropriate for rural trauma, so that the emergency services can reach the patient quickly to stabilise them and transfer them to hospital^(43, 44).

Prehospital care teams consist of ambulance paramedics and emergency medical technicians who are normally the first responders to an incident. They have basic

and some advanced skills in trauma life support. If major trauma is identified additional resources can be summoned including a full HEMS crew. This consists of a prehospital physician, a nurse and a paramedic and they may be transported to the incident on ground or via a helicopter. They have additional skills such as airway support through intubation and ventilation as well as circulatory support and haemorrhage control.

The prehospital physician comes from a range of backgrounds including anaesthesia, emergency medicine and surgery. All of them have had formal training in prehospital medicine and anaesthesia for advanced airway skills. The HEMS nurse has undergone training in prehospital medicine and can assess, manage and transfer patients. The HEMS paramedic holds the role of the incident officer, co-ordinating resources at the scene as well as communicating with the control room. They also have additional clinical training and skills to support the team^(45, 46).

If the HEMS team is deployed, on arrival to an incident they conduct an assessment of the patient. This is in accordance with the ATLS protocol to protect and maintain the airway with cervical spine control, breathing and ventilation as well as establish circulatory support with haemorrhage control⁽²⁴⁾. They are also assessing for any neurological injury and immobilising the patient so that no further harm is caused to the patient during hospital transfer. This is called the primary survey. A secondary survey is also conducted where the patient is examined from head to toe and any additional injuries are managed. The HEMS team try to minimise the time spent at the scene of the incident, as they can stabilise a patient but cannot, for example, control torso bleeding which requires swift transportation to a trauma centre for

definitive care. This is in line with the principle of the golden hour previously described. They also pre-alert the receiving hospital so that the hospital response can be tailored to match the requirements of the trauma patient on arrival^(45, 46).

Packaging the patient for transport to hospital involves the HEMS team ensuring that the transfer is safe. This includes making sure that the primary survey is appropriately managed with any life-threatening injuries treated within their capabilities, for example the decompression of a tension pneumothorax. The patient is then adequately immobilised to minimise spinal movements, avoid clot disturbance which would cause repeated blood loss, as well as maintaining normothermia. If a pelvic fracture is suspected a pelvic splint is also applied. The cervical spine is immobilised with a cervical collar and head blocks to minimise movement. An orthopaedic scoop stretcher is used to lift the patient off the ground and onto a trolley bed. During hospital transfer, the HEMS team would monitor vital signs, provide continued cardiorespiratory system support and maintain communication with the receiving hospital⁽²⁴⁾.

The hospital response would include mobilising a trauma team, notifying the operating theatres or the interventional radiology team if an injury requiring their intervention is identified. Auxiliary departments are also alerted such as the CT department and blood bank. The trauma team consists of an ED or trauma consultant, trauma surgeon, general surgeon, radiologist, orthopaedic surgeon as well as ED nurses and a radiographer. Blood bank is alerted through a major haemorrhage or code red call and can issue emergency O-negative group blood if the patient is in extremis and requires it.

The concern with the hospital response is that there can be delays to definitive care. An example is a trauma patient with bleeding from the liver identified in the prehospital setting through FAST. On hospital arrival, if the patient is haemodynamically unstable, they would need to go straight to theatre rather than repeating the assessment again in the ED. This delay can increase the morbidity and likelihood of patient mortality ⁽¹⁹⁾. Hence, establishing a swift diagnosis is crucial to escalate the response and this will be covered in the next segment.

1.1.4 Prehospital Imaging

Imaging modalities available in the prehospital setting to diagnose haemorrhage include Near Infra-Red Spectroscopy (NIRS), Computed Tomography (CT) and Ultrasound. NIRS uses near infrared light between 650 to 950nm to assess the concentration of oxygenated haemoglobin in the brain, muscle and other tissue⁽⁴⁷⁾. Its main use is in neuroimaging where it complements functional magnetic resonance imaging. It has been investigated to diagnose intracerebral bleeding from a head injury in the prehospital setting ⁽⁴⁷⁻⁴⁹⁾. Its advantages are that it is portable and low-cost compared to magnetic resonance imaging. However, as it is limited by depth sensitivity, it has not been used to identify traumatic torso haemorrhage⁽⁴⁹⁾.

CT is the gold standard in trauma imaging. The detailed images obtained in a CT scanner and the speed of the imaging mean that the majority of trauma patients receive a CT prior to definitive treatment. This helps to establish a diagnosis as well as to identify other injuries the patient may have sustained which is a common occurrence in this cohort. The disadvantages of CT are that it is associated with

radiation exposure and is a relative contraindication in the pregnant patient and children. It is also contraindicated in those allergic to iodine.

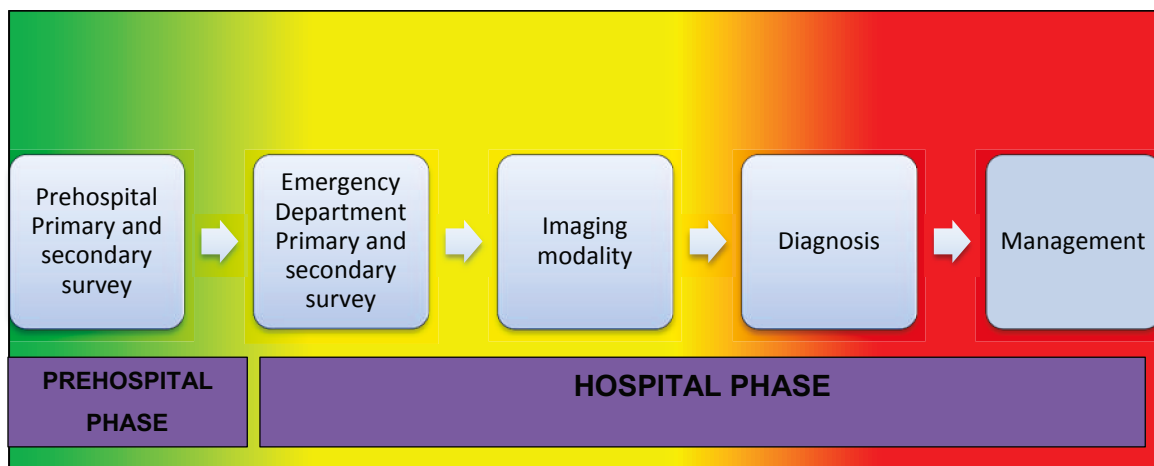
There are reports of mobile CT scanners being utilised in specialised ambulances with point of care labs and a telemedicine link to the radiologist. These are being trialled by two groups in Germany to accelerate the diagnosis of stroke in suspected patients so that thrombolysis can be expedited⁽⁵⁰⁻⁵²⁾. They have also been used for scanning patients' with head trauma, so that they can be referred to the appropriate hospital. This mobile CT scanner shows promise in triaging patients through a swifter diagnosis so that only those who are suitable are transferred onwards to a trauma centre⁽⁵³⁾.

Ultrasound offers the most appropriate modality for the prehospital diagnosis of torso haemorrhage. Focused Assessment in Sonography for Trauma (FAST) is portable, repeatable with no radiation exposure, swift in identifying haemorrhage and accurate in experienced hands. It is part of the ATLS protocol and is conducted after the primary survey⁽²⁴⁾. The drawback of FAST is that it has a wide sensitivity which is mainly due to operator skill and it has a steep learning curve⁽³⁾.

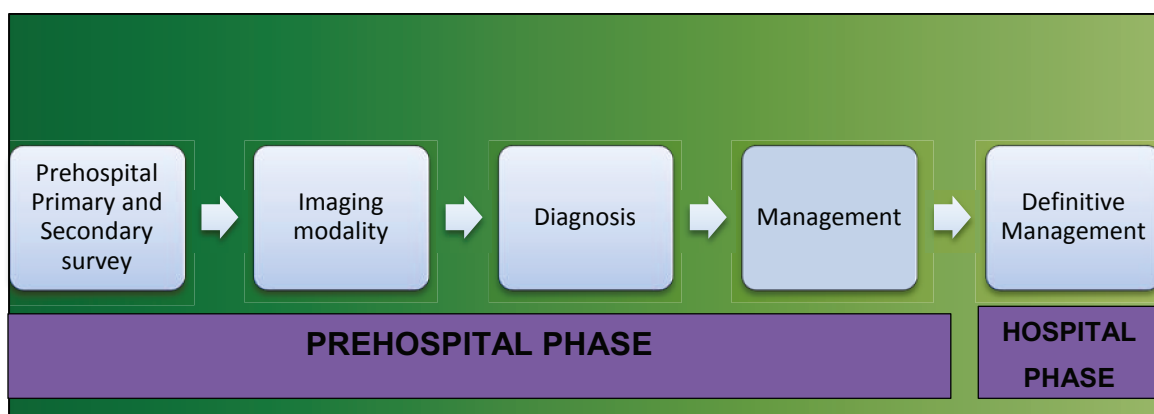
The purpose of a prehospital imaging modality such as FAST is that if it does identify intra-abdominal haemorrhage; then the response can be escalated with swifter transport, as well as communicating the findings to the receiving hospital. The hospital can mobilise their teams so that they are ready to receive the patient. This would ensure a smooth transition of the patient from the prehospital to the hospital phase of treatment for better integrated care. This pathway could expedite the

diagnosis and management of the trauma patient compared to the current system and may improve outcomes (*Figure 1.1*). An illustration of this point is Walcher et al⁽⁵⁴⁾ prospective multicentre study of 230 patients over a 12 month period. They performed prehospital FAST at a mean of 35 minutes before the ED. As a result of FAST, they changed their management in 30% of patients and altered the admitting hospital destination in 22% of cases. Therefore, prehospital imaging could fast-track the trauma workflow to definitive management.

CURRENT TRAUMA WORKFLOW



PROPOSED TRAUMA WORKFLOW



GOLDEN HOUR (Mins)

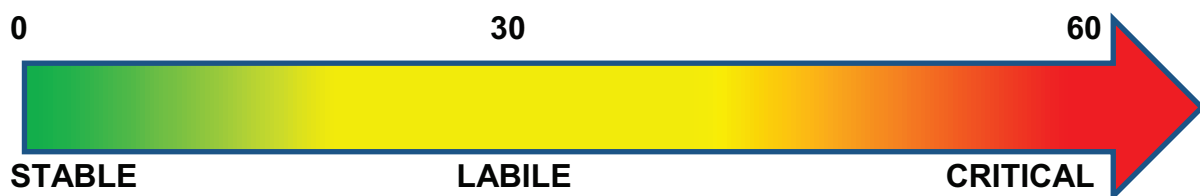


Figure 1.1 Depiction of current and proposed trauma workflow to highlight that early imaging could expedite diagnosis and management of the trauma patient. Casualty condition labelled by colour **STABLE = GREEN**, **LABILE=YELLOW**, **CRITICAL = RED**

1.1.5 Prehospital haemorrhage control

Once torso bleeding has been identified, haemorrhage control interventions need to be initiated. The challenge with intra-abdominal haemorrhage is that it is considered to be non-compressible bleeding and difficult to control in the prehospital setting. Therefore, the aim of prehospital care is for rapid transfer to hospital for definitive care. In the prehospital phase, measures that have demonstrated improvement include tranexamic acid, permissive hypotension, preventing haemodilution by limiting aggressive crystalloid administration, correction of acidosis and hypothermia^(18, 55-57). Although these are suitable for limiting haemorrhage, they may not be sufficient for patients with catastrophic uncontrolled intra-abdominal haemorrhage, who could benefit from further interventions^{(19) (58)}. This led to findings such as the prehospital haemorrhagic mortality being as high as 87.3% in combat casualties⁽¹⁹⁾.

Haemorrhage control has remained a major priority in trauma care since time immemorial, with the greatest focus occurring in times of war. One significant asset in trauma to control bleeding was the use of a tourniquet. In the 4th Century BC Alexander the Great's Army used tourniquets to stop blood loss of their wounded soldiers⁽⁵⁹⁾. Since then, the first major change to the design of the tourniquet was introduced in 1718 by a French Surgeon Jean Louis Petit. He proposed a screw device that you would "*tourner*", *to turn*, to occlude the blood flow hence the name tourniquet⁽⁶⁰⁾. Such a device is still applied today and has been used in the last decade of modern battlefields in Iraq and Afghanistan to control extremity haemorrhage^(61, 62) (*Figure 1.2*).



Figure 1.2 Photo of a Combat Application Tourniquet (CAT)

For injuries which cause cavities in junctional areas such as the groin where the iliac artery may be exposed there are numerous available haemorrhage control adjuncts on the market. Quickclot bandages are impregnated with Kaolin which promotes clotting by activating factor XII⁽⁶³⁾. The bandages can be tightly packed into cavities and the reaction activates the clotting cascade to promote clotting. Floseal can be injected into a cavity and then compressed with gauze⁽⁶⁴⁾. It consists of gelatine granules that swell to produce a tamponade effect. It also has high concentrations of thrombin which converts fibrinogen to fibrin accelerating clot formation. For intra-abdominal bleeding, there is no procedure which definitively controls bleeding in the prehospital phase although there are experimental studies which will be explored in this thesis.

1.1.6 Trauma Research

Given the scale of trauma globally, research in this field is still undeveloped and underfunded. This is because not enough academic institutions or funding bodies prioritise trauma research. Few centres try to establish a trauma research network although nascent links are developing such as the International Trauma network⁽⁶⁵⁾.

Undertaking trauma research is challenging due to several practical concerns, such as the fact that many of the patients are too physiologically unstable to tolerate research. There is also the ethical concern of conducting a randomised controlled trial, as all patients should be offered treatment rather than having a control group where treatment is withheld. Additionally, recruitment of enough trauma patients to satisfy the statistical power of a clinical study may be difficult^(65, 66).

Another challenge would be the issue of informed consent. Patients may have an impaired mental state due to their injury burden and opiate analgesia. They would not have the time or the mental capacity to weigh up the information to make a rational decision. A solution could be an ethics committee granting a retrospective or waiver of consent if the research topic is important enough to be in the public's best interest. This would of course involve discussion with the lay members of the ethics committee as well as public focus groups⁽⁶⁶⁾. Hence, research needs to be directed in an intelligent, systematic manner to address each facet of this vast topic to improve patient survival. In the same manner, in order to gain momentum in this field low hanging fruits should be targeted so that small gains lead to greater traction through more research funding which results in further advances in the future.

1.2 Aims of the Research

The aims of the thesis are:

- 1) To investigate the use of ultrasound as a diagnostic modality for traumatic abdominal haemorrhage identification.
- 2) Evaluate how to improve training in abdominal haemorrhage identification with ultrasound.
- 3) To assess how ultrasound could enhance haemorrhage control interventions in the prehospital setting.

1.3 Thesis Overview

Each chapter is based upon the following hypotheses:

- *Chapter 3. A FAST phantom can be validated and used for authenticated simulation training.*
- *Chapter 4. An Expert's FAST performance can be deconstructed to identify the objective metrics of an ideal scan.*
- *Chapter 5. Novices trained in probe manipulation ergonomics for FAST will learn faster with a higher degree of accuracy and maintain skill retention.*
- *Chapter 6. The accuracy of Zone III Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) placement can be enhanced with the use of ultrasound and microbubble contrast agents.*

Chapter 2 Traumatic Intra-abdominal haemorrhage identification and control

The opening chapter aims to gain a better understanding of prehospital traumatic abdominal haemorrhage identification and control. This is conducted in a systematic manner by first addressing this topic as a national questionnaire to trauma experts and frontline physicians. The challenges highlighted include a clear recommendation that more training, as well as research, is required for abdominal haemorrhage identification and control. For training, participants requested more exposure to simulators and cadavers. For research, ultrasound and novel haemorrhage control techniques such as REBOA were highlighted as requiring further investigation.

To augment the findings from the questionnaire, the literature is appraised to gain a clear understanding of the research undertaken on this topic to date as well as direct avenues for further research. A systematic literature review is performed to answer whether ultrasound is effective for prehospital traumatic abdominal haemorrhage identification. The literature was also evaluated for current haemorrhage control technology that could be used in the prehospital setting⁽⁶⁷⁾.

Chapter 3 Validating a FAST simulator

Of the priorities listed in the preceding chapter, ultrasound and simulation were stated as areas for further research. As there is no validated simulator a face, content and construct validation of a FAST simulator is conducted so that an authenticated phantom can be used for training⁽⁴⁾. A criticism associated with FAST

is the steep learning curve to gain proficiency ^(2, 3) and the aims of the following chapters of the thesis are to improve and accelerate training for novices.

Chapter 4 The Ergonomics of Ultrasound Probe manipulation

To better understand FAST, a study of the ergonomics of ultrasound probe manipulation is conducted. An expert performance is deconstructed into its basic blocks to unravel the critical steps, before it can be taught to others. Specifically, an experts hand motions and force are recorded to identify the ideal probe manipulation for each FAST region.

Chapter 5 FAST training through expertise

There is now a validated simulator for training novices as well as a set of expert metrics for each region of the FAST. Therefore a randomised study is conducted whereby one group of novices are trained to perform FAST based on expert metrics and are provided with the ideal probe position and force for each region whilst the control group are trained in accordance with the standard curriculum. A learning curve study is conducted and the group trained in the expert metrics prove to be faster and more accurate than the control group in conducting FAST. The expert metric group also have a faster rate of learning and plateau at a good level of performance much earlier than their control group. The conclusion of this chapter assesses both cohorts on a virtual patient in a prospective validity study. In this study, no aids are provided to the expert metrics group and they still prove to be faster and more accurate than their control group.

Chapter 6 Ultrasound enhanced Haemorrhage Control - REBOA

One of the priorities listed in the questionnaire by the expert consensus was for more research to be undertaken in novel haemorrhage control techniques. REBOA is one such procedure that is proving popular within the prehospital setting. Chapter 6 investigates how ultrasound could be used to augment this technique to enhance safety. A pilot study on a porcine model identifies that Zone III REBOA placement is improved with the use of ultrasound guidance and microbubbles insufflated into the balloon of the catheter to clearly visualise its placement. The benefits of ultrasound guided REBOA are demonstrated in a randomised study on human cadavers. Evidently, REBOA placement with the use of contrast enhanced ultrasound is faster and more accurate.

1.4 Original Contributions of this Thesis

- Capturing a consensus through a national questionnaire, that more training, as well as research, is required for abdominal haemorrhage identification and control. For training, more exposure to simulators and cadavers is necessary. For research ultrasound and novel haemorrhage control techniques should be explored.
- Validating a novel FAST phantom with a face, content and construct validity for authenticated simulation training.
- Developing a unique ultrasound accuracy scoring test for assessment in FAST training.
- Identifying the ergonomics of probe manipulation during a FAST scan.
- Addressing the steep learning curve associated with FAST by verifying an original training method for FAST scanning which accelerates aptitude.
- Demonstrating that contrast enhanced ultrasound improves Zone III REBOA placement in a pilot study.
- Validating that this enhanced technique is more effective for Zone III REBOA placement in a randomised controlled study.

1.5 Publications and Presentations from this Thesis

1.5.1 Publications arising from this thesis

1. **Chaudery M**, Clark J, Wilson M, Bew D, Yang G.Z, Darzi A. Traumatic intra-abdominal haemorrhage control: Has current technology tipped the balance towards a role for pre-hospital intervention? Journal of Trauma and Acute Care Surgery, 2015 January; 78(1):153-63. doi: 10.1097/TA.0000000000000472.
2. **Chaudery M**, Clark J, Dafydd D, Dunn J, Bew D, Wilson M, Darzi A. The Face, content and construct validity of a FAST simulator. Journal of Surgical Education, 2015 Sep-Oct; 72(5):1032-8. doi: 10.1016/j.jsurg.2015.04.003. Epub 2015 May 14.
3. **Chaudery M**, Clark J, Morrison J, Wilson M, Bew D, Darzi A. Can Contrast enhanced Ultrasonography improve Zone III REBOA placement for prehospital care? Journal of Trauma and Acute Care Surgery, 2016 January; 80(1):89-94. doi: 10.1097/TA.0000000000000863.

1.5.2 Presentations arising from this thesis

1. **Chaudery M**, Clark J, Sriskandarajah K, Bew D, Darzi. Improving Pre-hospital Haemorrhage identification and control - A National Trauma Questionnaire Poster presentation at the Association of Trauma & Military Surgery Conference. British Journal of Surgery, January 2015; 102(S1):128, DOI: 10.1002/bjs.9730

2. **Chaudery M**, Clark J, Apdifydd D, Dunn J, Yang GZ, Darzi A. The Face, content and construct validity of a FAST phantom. Oral Presentation and Poster at the International Hamlyn Symposium, July 2014.
3. **Chaudery M**, Clark J, Apdifydd D, Dunn J, Yang GZ, Darzi A. Radiological validity of a trauma FAST phantom. Poster Presentation at the European Congress of Radiology, Vienna, March 2015, 10.1594/ecr2015/C-1685

1.5.3 Presentations related to this thesis

1. Giataganas P, Mylonas G, **Chaudery M**, Vitiello V, Clark J, Darzi A, Yang GZ. A learning from demonstration framework for autonomous eFAST ultrasound scanning using a robotic manipulator. Hamlyn Symposium Oral Presentation, June 2013.
2. Mylonas G, Giataganas P, **Chaudery M**, Vitiello V, Darzi A, Yang GZ. Autonomous eFAST Ultrasound scanning by a robotic manipulator using learning from demonstrations. International Oral Presentation IROS Tokyo, November 2013.
3. **Chaudery M**, Clark J, Kunal, David Nott, Darzi. An intensive teaching session improves confidence in performing an e-FAST scan. International Poster Presentation at the Association of Surgeons of Great Britain and Ireland. British Journal of Surgery, January 2015; 102(S1):204, DOI: 10.1002/bjs.97

Chapter 2 Traumatic Intra-abdominal haemorrhage Identification and Control

2.1 Introduction

This opening chapter aims to address the topic of prehospital traumatic intra-abdominal haemorrhage identification and control in a systematic manner by first seeking direction from experts through a national questionnaire. This helps to highlight the current challenges in this field. The existing evidence on this theme is also evaluated through literature reviews. The first review explores whether ultrasound is effective for prehospital haemorrhage identification and the subsequent appraisal examines the current technology available for haemorrhage control. This thorough assessment of the subject is necessary to gain a good understanding of the topic and lay the foundation of the subsequent experimental chapters.

2.2 How can we improve prehospital abdominal haemorrhage identification and control? A national trauma questionnaire

2.2.1 Introduction

To date, there is no agreement amongst experts on the best management of abdominal haemorrhage in the prehospital setting. Many believe that rapid transport to the hospital is most effective⁽⁶⁸⁾. Indeed, this is likely to be the safest strategy for urban areas where transit times to hospital are short. However, in austere environments a patient with traumatic intra-abdominal bleeding can rapidly decompensate. Hence, FAST has been advocated as an effective means for detecting haemorrhage but it is not in widespread use amongst prehospital practitioners⁽¹⁾. For haemorrhage control of abdominal bleeding, there is no definitive procedure available for prehospital care but trials are underway for techniques such as REBOA⁽⁷⁾.

The objective of this national questionnaire was to gain a consensus of opinions from front line clinicians on how improvements in abdominal haemorrhage identification and its control in the pre-hospital setting could be achieved.

2.2.2 Methods

A qualitative questionnaire was formulated to address these objectives. Two independent trauma experts reviewed and validated the questionnaire to ensure it incorporated relevant questions to derive meaningful results. After multiple iterations, the approved questionnaire was dispatched to an online software platform (www.surveymonkey.com) and participants were invited to complete it by email. The format consisted of 13 questions with a free text box at the end for respondents to add any further ideas and comments (*Figure 2.1*). All participants' responses were anonymous and this study had ethical approval granted by the Imperial College Research Ethics Committee. The questionnaire was distributed to the following clinical stakeholders:

- The UK International Emergency Trauma Register who consist of ED physicians, anaesthetists, surgeons and nurses. They respond to large scale disasters overseas and have extensive expertise in providing prehospital care for trauma patients in remote environments.
- The HEMS Network, The London Major Trauma Network, Experts in Trauma and Pre-hospital Care. This group were invited to participate due to their expertise in prehospital care in urban and rural areas within the UK.
- Specialists in Austerity, Catastrophe and Conflict care. This cohort has managed trauma patients in challenging environments and their insight would enrich this questionnaire.

Questionnaire – How can we improve pre-hospital ABDOMINAL haemorrhage identification and control?

1. Background – Role
2. Background – Specialty
3. How many years of experience do you have in pre-hospital/austerity medicine?
4. Uncontrollable haemorrhage is the leading cause of trauma related mortality. How would you prioritise the following areas? (1 being the least important to 5 most important)
 - a. Reduce transfer times to hospital
 - b. Improve training in the use of imaging for abdominal haemorrhage **identification** in pre-hospital care.
 - c. Provide more training in abdominal haemorrhage **control** techniques for pre-hospital care.
 - d. Further research into abdominal haemorrhage **identification and control** in the pre-hospital setting
 - e. Other - Free text
5. How do you think training in abdominal haemorrhage **identification** for pre-hospital care should be delivered? (Can choose more than one option)
 - a. High fidelity ultrasound compatible simulator with integrated blood flow
 - b. Fresh frozen cadavers with integrated blood flow
 - c. Animal models with the use of ultrasound contrast agents
 - d. Other – Free text
6. How do you think training in abdominal haemorrhage **control** for pre-hospital care should be delivered? (Can choose more than one option)
 - a. High fidelity simulator
 - b. Cadaver
 - c. Animal model
 - d. Other – free text
7. What are your greatest challenges in pre-hospital/austerity care? (Can choose more than one option)
 - a. Airway management
 - b. Ventilator management
 - c. Haemorrhage **identification**
 - d. Haemorrhage **control**
 - e. Head injury management
 - f. Lack of resources
 - g. Speed of transfer to hospital
 - h. Lack of communication between the pre-hospital and hospital environment
 - i. Lack of documentation in pre-hospital care
 - j. Lack of training in pre-hospital care
 - k. Lack of regulation/critical incident reporting in pre-hospital care
 - l. Other - free text
8. Please order your top priorities to improve pre-hospital care? (with 1 being the LEAST important and 5 the MOST important)
 - a. Reduce transfer times to hospital
 - b. Improve communication and documentation between pre-hospital and hospital environments
 - c. Improve resources for pre-hospital care
 - d. More training in airway/ventilation management
 - e. More training in head injury management
 - f. More training in the use ultrasound for haemorrhage **identification**
 - g. More training in techniques for haemorrhage **control** from abdominal/junctional areas
 - h. Further research into abdominal haemorrhage **identification and control**
 - i. More governance in pre-hospital care for regulation and monitoring of critical incidents
 - j. Other – free text
9. Please order your top research priorities for abdominal haemorrhage **identification**? (with 1 being the LEAST important and 5 the MOST important)
 - a. Physiological signs
 - b. Use of ultrasound imaging
 - c. Use of ultrasound + contrast agents
 - d. Research into other modalities other than ultrasound for haemorrhage **identification**
 - e. Research into effective training of current haemorrhage **identification** techniques (e.g. eFAST scan)
 - f. Other – Free text
10. Please order your top research priorities for abdominal haemorrhage **control**? (with 1 being the LEAST important and 5 the MOST important)
 - a. C-clamp application for junctional areas e.g. iliac vessels
 - b. Endovascular control e.g. balloon occlusion of the aorta
 - c. Energy based device e.g. High intensity Focussed Ultrasound
 - d. Mechanical compression e.g. Gas/Foam insufflation
 - e. Other – Free text
11. What are your views regarding barriers to clinical trials taking place in the pre-hospital care setting for trauma patients? (Can choose more than one option)
 - a. Ethical approval
 - b. Gaining consent
 - c. Feasibility of conducting a randomised controlled trial
 - d. Research funding
 - e. Co-ordinated research network between paramedics and pre-hospital clinicians
 - f. All of the above
 - g. Other – Free text
12. Do you have any innovative ideas for haemorrhage **identification and control** from the abdominal region in the pre-hospital care setting?
 - a. Free text
13. Any further comments?

Figure 2.1 Questionnaire

2.2.3 Results

In total 54 participants responded with the majority being Consultants (43%) within Accident & Emergency and Pre-hospital Medicine as well as two Professors of Trauma and Surgery. The mean level of pre-hospital experience across the cohort was 13 years (SD=±8.0 Range=0-50). The specialities of respondents were Accident & Emergency (35%), Prehospital Medicine (33%) and Anaesthetics (13%) (*Figure 2.2*). Other backgrounds (19%) included General surgery, Orthopaedics, Plastics and Reconstructive surgery, Military Medicine, Trauma Surgery, Vascular surgery, Paediatric surgery, Paediatrics, Cardiothoracic surgery, Neurosurgery and Maxillofacial surgery.

Participants were asked to prioritise key areas in prehospital care; more than 26% stated that reducing transfer times was of the utmost importance. They also requested for more training in haemorrhage identification (22%) and control (25%) with further research (23%) required in this area. Respondents were questioned on how training in abdominal haemorrhage identification should be delivered. The majority (59%) stated a high fidelity ultrasound simulator. In the free text, 15% cited sound clinical judgement is also necessary. Specifically, emphasis should be placed on the history, the mechanism of injury sustained, as well as a thorough examination of the patient. For training in abdominal haemorrhage control, most (42%) were content with a high fidelity simulator, although a further 36% requested cadaveric teaching (*Figure 2.3*).

Question 7 aims to determine the greatest challenges in prehospital care. The joint top answer at 16% was haemorrhage control and lack of resources. This was followed by the speed of transfer to the hospital (13%), haemorrhage identification (11%) and lack of training in prehospital care (11%). The subsequent question probed the top priorities in improving prehospital care. The main answer at 13% was to reduce transfer times to hospital followed closely by improving resources in prehospital care (12%).

For research priorities into haemorrhage identification participants stated that physiological signs (23%) and ultrasound imaging should be explored (21%) (*Figure 2.4*). For research into haemorrhage control the majority were interested in mechanical compression (27%) and endovascular control, for example REBOA (25%) (*Figure 2.5*).

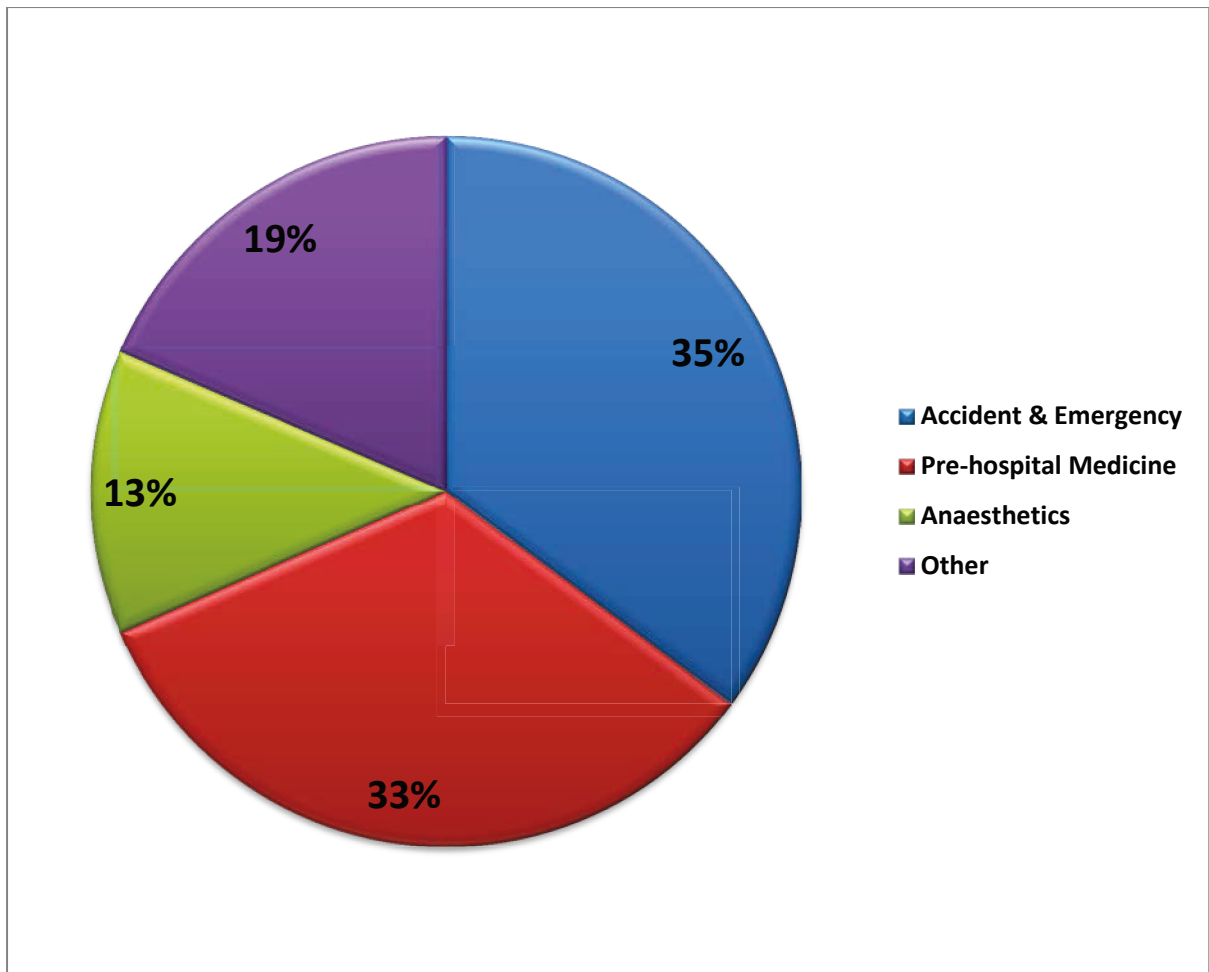


Figure 2.2 Background of respondents

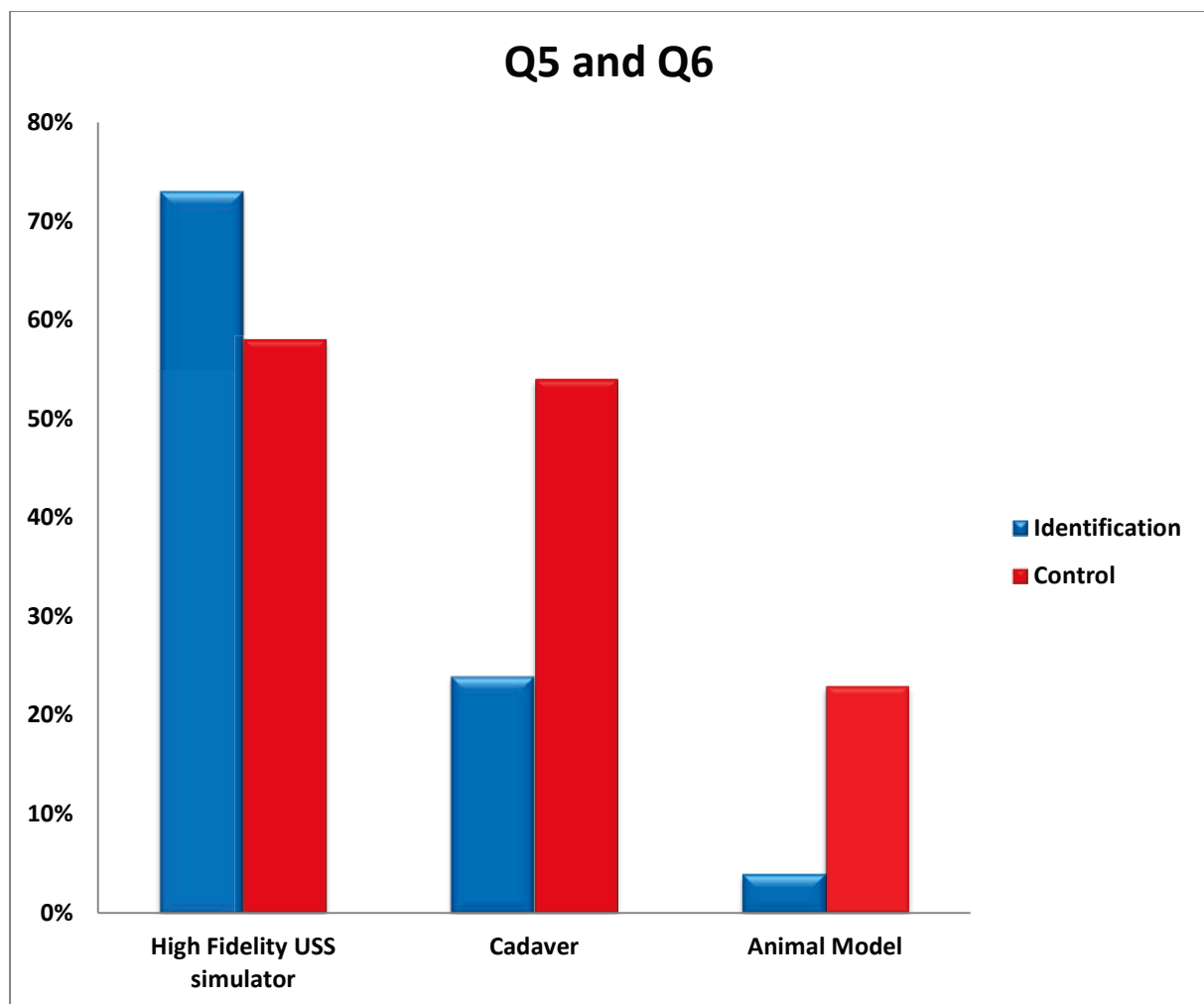


Figure 2.3 Question 5 and 6 how should training for abdominal haemorrhage identification and control be provided?

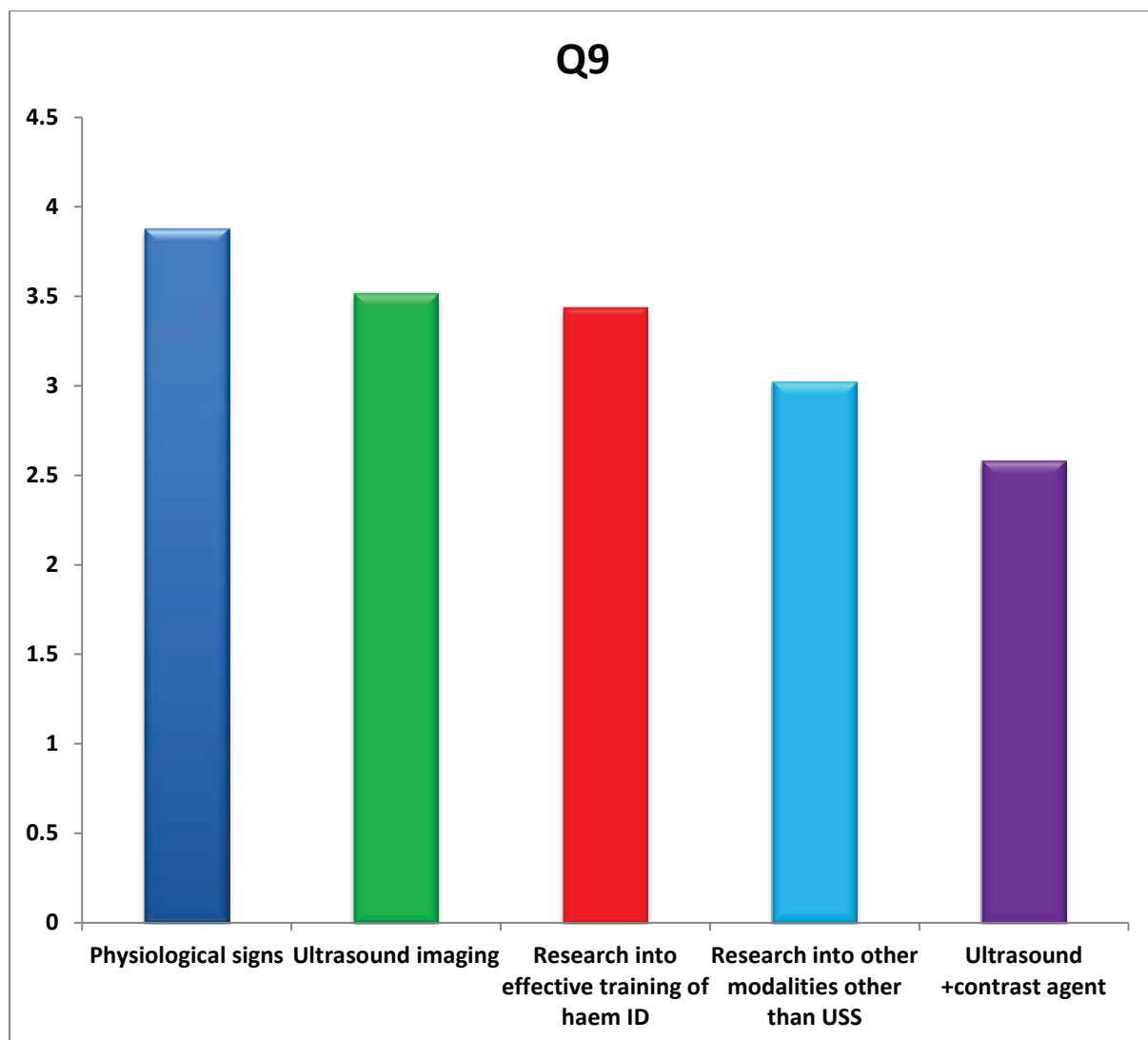
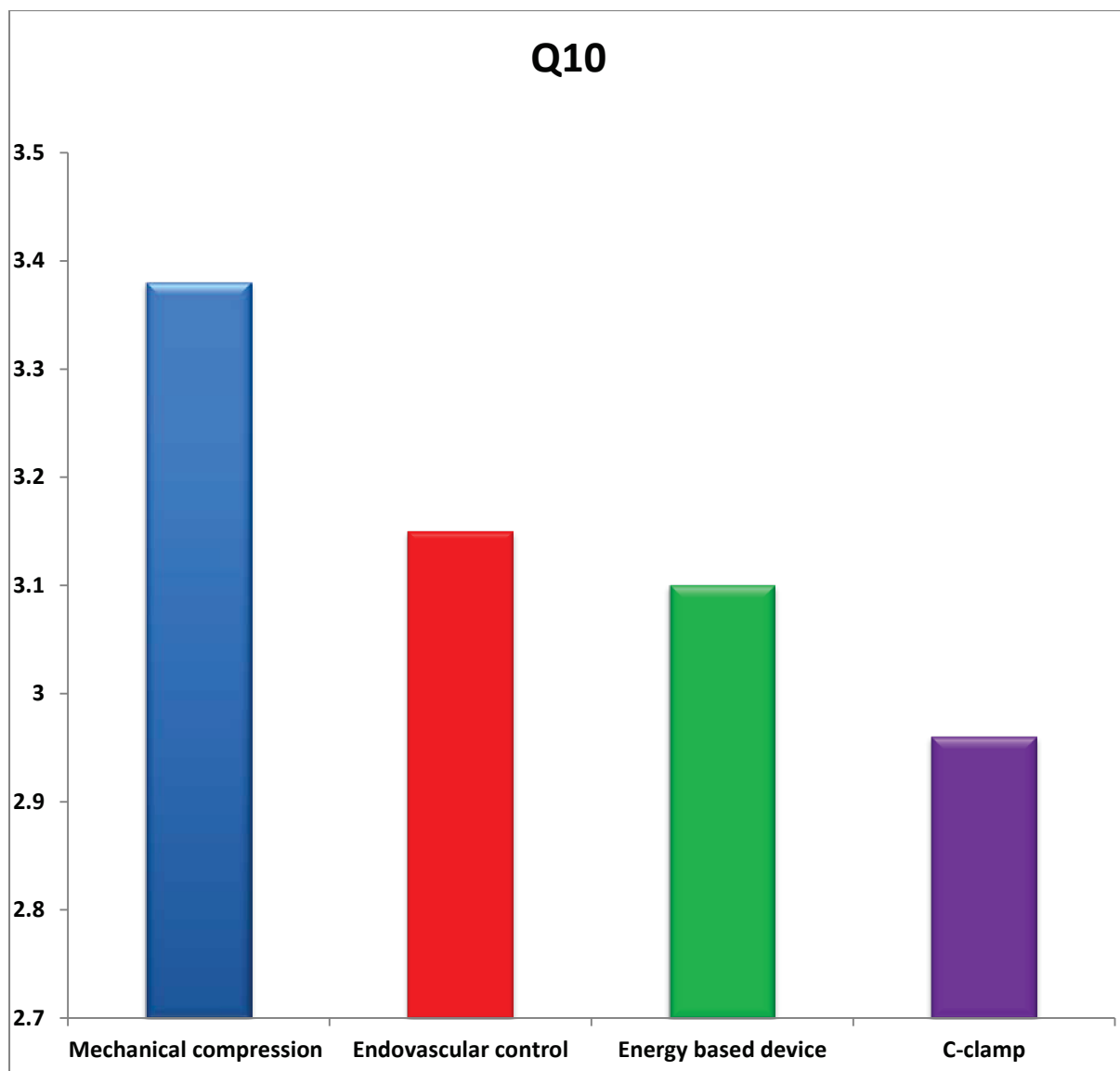


Figure 2.4 Which research areas should be priorities for haemorrhage identification? (Score out of 5 with 1 being the LEAST important and 5 the MOST important) (Haem=haemorrhage ID=Identification USS= Ultrasound)



**Figure 2.5 Which research areas should be priorities for haemorrhage control?
(Score out of 5 with 1 being the LEAST important and 5 the MOST important)**

Research is an integral part of clinical progression as identified by the respondents; they were requested to expand on the barriers to clinical trials taking place in the prehospital setting. Most specified gaining consent (19%); ethical approval (17%); the feasibility of conducting a randomised controlled trial (18%); research funding (14%) and co-ordinating a research network between paramedics and prehospital clinicians (14%). A further 17% stated that all the issues above were barriers.

For prehospital care to flourish there is a need to think laterally about innovative ideas, therefore, participants had a free text box to mention any such concepts. Responses included an abdominal tourniquet, FAST scan, more surgical training for prehospital physicians, junctional tourniquets, REBOA and prehospital extracorporeal membrane oxygenation. Other comments included:

Participant 1 *“Developing an effective strategy for resuscitation using blood products should be a research priority, especially in patients who require long transfers to a major trauma centre in whom we are currently over-reliant on permissive hypotension. Diagnosing haemorrhage in the prehospital phase is only of benefit if the hospital response can be escalated. We need to remove some of the barriers that delay the transition between phases of treatment. REBOA has the potential to salvage a small number of patients but if we were better at the basics we could have a bigger impact on mortality”*.

Participant 2 *“Training in the basics and knowledge of hard vascular signs. The appreciation that in closed abdominal trauma and a Rapid Sequence Induction at the*

scene, that an abdominal injury can be missed. Prehospital FAST and REBOA in appropriate cases.”

Participant 3 *“The Knowledge of hard vascular signs, as well as clinical examination, is poor and clinicians increasingly rely on CT. Identify it and put your finger on it. Minimise the time to definitive control!”*

2.2.4 Discussion

This questionnaire has highlighted that more training, as well as research into haemorrhage identification and control, is required. Respondents were keen to have greater exposure to high fidelity ultrasound simulators (59%) for haemorrhage identification training. For haemorrhage control, participants wished to hone their skill set on simulators (42%) or cadavers (36%). The main recommendations for research into haemorrhage identification were to investigate physiological signs and ultrasound. For haemorrhage control, respondents stated that research should focus on novel mechanical compression devices and endovascular control.

In the questionnaire, participants were informed that uncontrollable haemorrhage is a leading cause of mortality and asked which areas to prioritise for prehospital care. The top answer at 26% was for faster transit to the hospital. However, the military literature reports that the majority of deaths occurred in the prehospital setting despite rapid helicopter transport⁽¹⁹⁾. Hence, although swift hospital transfer is of great importance, this may not suffice in the haemodynamically unstable trauma patient. In such cases, prehospital intervention may be required to gain control of

haemorrhage, even if it is a temporary solution until definitive care can be achieved. An additional point noted was that if bleeding is identified in the prehospital setting then effective communication with the receiving trauma centre is necessary to remove the barriers between phases of treatment so that there is a seamless transition from the prehospital to the hospital phase.

Participants stated that one of the challenges of prehospital care was a lack of training. It is worth emphasising at this point, the importance of developing sound clinical judgement. This should be taught first so that the front line trauma clinician can piece together factors from the mechanism of injury, history and examination to better understand the injury burden of the trauma patient. With cumulative experience, this will help develop good clinical acumen. Following on from this, further training in assets such as FAST could be a valuable diagnostic tool to confirm a high index of clinical suspicion.

Participants stated that they wanted more haemorrhage identification research to be conducted into physiological signs. In today's era of wearable technology⁽⁶⁹⁾ there is a wealth of data that could be analysed, for example, to identify the stages of shock in real-time based on physiological signs. This data may help to identify patterns amongst certain age groups or cohorts of patients and allow the initiation of an early warning score⁽⁷⁰⁾ so that the emergency medical response can be escalated if the patient is deteriorating. Similarly a prehospital pathway could be formulated whereby if a combination of signs suggesting torso trauma and an early warning score threshold are met, it can automatically trigger a FAST scan.

Prehospital care needs to prioritise its training and research so that torso haemorrhage can be better controlled. It will require identifying the current challenges in prehospital care which this questionnaire has attempted to do and then addressing them in a systematic manner. Conducting research in prehospital care is challenging due to numerous issues such as ethical approval, research funding and co-ordinating research within a region. Nevertheless, prehospital care is ripe for innovation and now is the time to address this.

2.2.5 Conclusion

This national questionnaire established a consensus amongst front line trauma clinicians. The main recommendations from this survey were for more training as well as research in this challenging area. For training in haemorrhage identification and control, participants requested more exposure to high fidelity ultrasound simulators as well as cadavers. For research into haemorrhage identification, investigating physiological signs and ultrasound was recommended. Haemorrhage control research should focus on novel mechanical compression devices and endovascular control.

As one of the main results was for more research to be undertaken into haemorrhage identification with ultrasound, the subsequent review evaluates how effective ultrasound is for prehospital abdominal haemorrhage identification.

2.3 Is Ultrasound effective for prehospital traumatic abdominal haemorrhage identification?

2.3.1 Introduction

The FAST protocol has been strongly advocated by several international societies as an effective diagnostic modality both in the pre-hospital and hospital care setting for the rapid identification of bleeding⁽⁷¹⁻⁷⁴⁾. It was promoted in the 1970's in Europe and its uptake in the UK and North America was in the 1980s⁽⁷⁵⁾. It is now part of the ATLS protocol and is conducted after the primary survey⁽²⁴⁾. It is quick, portable, repeatable, inexpensive and effective in experienced hands with no radiation exposure to the patient⁽⁷⁶⁾ and therefore useful in paediatric and pregnant patients where a CT would be inappropriate. It can also be performed simultaneously with resuscitation which is not possible with CT. The FAST scan is a triage tool, particularly for prehospital care. It has an essential role in trauma patients who are in shock to quickly identify bleeding and guide the need for immediate operative or radiological intervention, where attempts to gain further imaging could adversely delay care. To this extent, FAST has been shown to reduce delays to theatre for the operative management of trauma patients⁽⁷⁷⁾.

FAST detects free fluid in the peritoneum or the pericardial space. It does this through the ultrasound machine which transmits high frequency sound pulses (1-5 Megahertz) through a probe. The probe is lined with quartz crystals which transmit and receive sound waves through the piezoelectric principle. This means that when an electric current is applied the crystals vibrate and in doing so transmit sound

waves. Additionally when the crystals receive sound waves they emit an electric current which can be registered by the ultrasound machine⁽⁷⁸⁾.

The sound waves travel through the body and when they hit tissue boundaries some of the waves are reflected back which are received by the probe. The ultrasound machine calculates the distance from the probe to the tissue boundary using the speed of sound (1,540m/s) and the time it took for the echo to return to the probe. The distance and intensity of the echoes is displayed as a two dimensional image. The strength of the echoes received is represented as brightness on the image. Tissues such as organs appear bright as they reflect back sound waves but fluid appears black as sound waves pass through it. This is how free fluid is detected in a FAST scan⁽⁷⁸⁾.

During a FAST scan there are four areas that are examined^(79, 80):

1. Hepatorenal space (Morison's pouch)

- The hepatorenal space is the most dependent position with the patient lying supine and hence is examined first for free fluid. The probe is usually placed midaxillary line between the 9th -11th ribs. Free fluid appears black between the bright capsule of the liver and the renal fascia (*Figure 2.6*).

2. Pericardial space

- The probe is placed under the xiphisternum and is angled upwards towards to the left shoulder. Free fluid appears between the fibrous pericardium and the heart

3. Splenorenal space

- The probe is placed at the posterior axillary line between the 7th and 9th ribs. Free fluid appears as a black stripe between the bright splenic capsule and the fatty renal fascia.

4. Pelvis – both longitudinal and sagittal views

- The probe is placed just above the symphysis pubis in the midline angled into the pelvis. Free fluid appears in the pouch of Douglas in females and rectovesical pouch in males. Two views are required so the probe is placed longitudinal above the symphysis pubis and then it is rotated 90 degrees to obtain the sagittal view.



Figure 2.6 Morison's pouch

Despite the stated benefits of FAST, it is not in common use amongst the prehospital community⁽²⁾. There are numerous reasons cited for this including a wide sensitivity for detecting a haemoperitoneum which is mainly due to varied operator skill⁽³⁾. Other causes include a steep learning curve to gain proficiency^(2, 3) hence the request from participants in the preceding questionnaire for more training on a high fidelity ultrasound simulator. Given the uncertainties about FAST that have just been stated, this review was undertaken to achieve a definitive answer on the value of ultrasound for detecting abdominal bleeding.

The aims of this review are to examine whether ultrasound is effective in identifying and localising traumatic abdominal bleeding.

2.3.2 Methods

A systematic search was undertaken of publications as per the PRISMA guidelines. Online databases utilised included PUBMED, MEDLINE, GOOGLE SCHOLAR, and EMBASE. The following mesh terms were searched for “Haemorrhage OR Bleeding” “identification/localisation/localization/detection AND Ultrasound AND Sonography AND Abdomen”. The most recent search date was 15th July 2015.

Inclusion criteria were defined as scholarly articles in English from the start of databases fulfilling the above mesh terms. Additionally abstracts and full text had to be available for further analysis. Exclusions included review articles and case reports but these were examined for further references.

2.3.3 Results

The results from the systematic search initially identified 416 papers. It was widened by not including “localisation” or “abdomen” in the criteria which identified 11,314 articles. This gave more breadth to the review and after exclusions there were 37 papers available for full-text analysis with a final 13 studies that met the conditions for this review (*Figure 2.7*)⁽⁸¹⁻⁹³⁾. Articles ranged in date from 2004 to 2015. There were 7 prospective and 6 retrospective studies (Table 2.1 Summary of papers). In our systematic search, there were no randomised and/or controlled trials identified. As the data was heterogeneous, no statistical analysis could be performed hence a narrative based review was performed. The results were split into the major methods by which ultrasound can identify and localise bleeding which are FAST, Contrast enhanced ultrasound (CEUS) and the 3D modality.

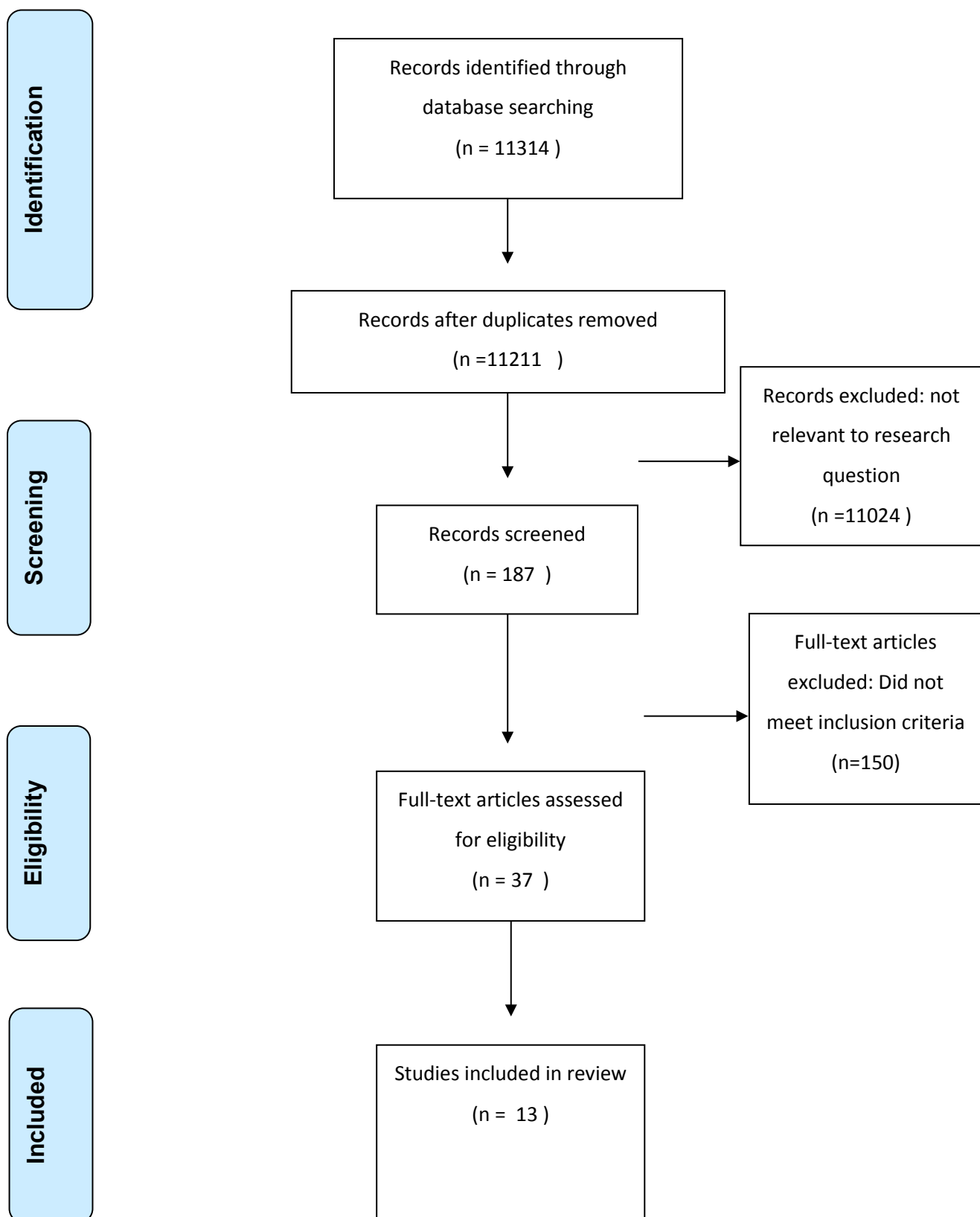


Figure 2.7 PRISMA Flow Diagram

Author, Year	Study Design	Study No.	FAST validated against	Sensitivity	Specificity	PPV, NPV	Accuracy
FAST							
Press, 2014	Prospective Prehospital HEMS in-flight	293	CT	64%	94%	50%, 96%	-
Kim, 2012	Prospective	240	CT	61%	96%	89%, 83%	-
Walcher, 2006	Prospective multicentre prehospital	230	Hospital US and CT	93%	99%	-	99%
Lapostolle, 2006	Prospective prehospital	169		-	-	-	90%
Soundappan 2005	Prospective, single blind	85	CT, US and Laparotomy	81%	100%	100%, 97%	97%
Hsu, 2007	Prospective	463	CT or Laparotomy	80%	100%	100%, 94%	93%
Holmes, 2004	Retrospective	447	CT or Laparotomy	79%	95%	86%, 93%	-
Richards, 2004	Retrospective	4320	CT, Diagnostic Peritoneal lavage, Laparotomy	68%	97.6%	-	-
Friese, 2007	Retrospective	126	CT and Laparotomy	26%	96%	85%, 63%	65%

CONTRAST ENHANCED ULTRASOUND							
Valentino, 2009	Prospective	133	CT	96.4%	98%	98.8%, 94.1%	-
Menichini, 2015	Retrospective	73	CT	100%	100%	100%, 100%	100%
Sessa, 2014	Retrospective	256	CT	96%	99%	98%, 98%	98%
Lv, 2011	Retrospective	392	CT	72%	-	-	-

Table 2.1 Summary of Papers

2.3.3.1 FAST

Studies identified in this review encompassing our mesh search terms that utilised FAST to identify haemorrhage include 6 prospective clinical studies, three of which were conducted in the prehospital setting and 3 retrospective studies. The FAST sensitivity (range 26% to 93%) varied widely between studies but the specificity (range 94% to 100%) was more accurate. The reason for the wide range of sensitivities may be because FAST is highly dependent upon operator skill. It is important to note that FAST does not exclude pathology and is not to be seen as a replacement for a CT scan. This is especially true in injuries involving hollow viscus structures and the retroperitoneum^(76, 77, 84).

The prehospital studies identified are of interest as they are relevant to not only the aims of this review but are also in line with objective of this thesis. Walcher et al⁽⁵⁴⁾ conducted a prospective multicentre study in 230 patients over a year. They performed prehospital FAST 35 minutes (mean time) before the hospital team. As a direct result of FAST, they changed their management in 30% of casualties and altered the destination in 22% of cases. Additionally, Lapostolle et al⁽⁹⁴⁾ prospective study performed 302 prehospital FAST studies and found that their diagnostic accuracy improved by 67% and by 90% when the initial diagnosis was in doubt. Evidently, prehospital FAST does have benefits in improving diagnostic accuracy, management and the appropriate hospital for trauma patients.

Richards et al⁽⁹¹⁾ conducted a retrospective review of 4,320 patients over a six-year period. The authors acknowledged that a haemoperitoneum was more commonly

identified in the right upper quadrant than in other areas, which is why this is one of the first areas examined during FAST. Additionally they stated that when there is isolated free fluid in the left upper quadrant, it is significantly associated with a splenic injury.

Soundappan et al⁽⁸¹⁾ performed a prospective, single-blind study examining the diagnostic accuracy of surgeon performed FAST in blunt paediatric abdominal trauma. They compared their FAST scan results with CT and laparotomy findings. The study incorporated 85 patients with an age range of 4months to 16 years and a mean injury severity score of 6 (range1-38). They identified free fluid within the peritoneal cavity with a sensitivity 81%, specificity 100%, negative predictive value 97%, positive predictive value 100% and an accuracy of 97%.

A similar study by Hsu et al⁽⁸²⁾ presented the FAST experience from an Australian trauma centre. They prospectively studied 463 blunt trauma patients with FAST and compared the results with a CT or laparotomy. Their results showed a respectable sensitivity 80%, specificity 100%, positive predictive value 100% and negative predictive value of 94%. On the other hand, Friese et al⁽⁸⁴⁾ performed a retrospective study of 126 FAST examinations in patients with a pelvic fracture and identified a specificity of 96% and a low sensitivity of 26%. The authors concluded that a negative FAST did not aid in the diagnosis of haemoperitoneum in patients with pelvic fractures and that these patients should undergo additional imaging.

2.3.3.2 Contrast enhanced ultrasound and 3D modality

Although FAST can identify a haemoperitoneum, rapid and accurate localisation of the site of bleeding is essential so that focused control measures can be implemented. Conventional ultrasound cannot always accurately identify the site of injury, characterise fluid as blood and determine the degree of bleeding. Contrast agents, namely microbubbles, can address these shortcomings. Microbubbles are less than a millimetre in size and consist of a lipid or protein shell containing a gas such as sulphur hexafluoride or perfluorocarbon⁽⁹⁵⁾. These bubbles oscillate when sonic energy is applied and have a high degree of echogenicity i.e. the ability to reflect back ultrasound waves. This makes them very easy to visualise under ultrasound as the blood vessels containing the microbubbles are enhanced from its surrounding environment⁽⁹⁶⁾.

CEUS is used to visualise organ perfusion, measure blood flow rate through organs and can help localise the site of bleeding. They are of significant benefit in reducing surgical exploration time and allow the clinician to focus on achieving targeted control of haemorrhage. CEUS is also useful post operatively to monitor the site of injury and confirm that the bleeding is controlled. CEUS has the advantage over MRI and CT for patients in renal failure or contrast allergy and is repeatable with no radiation exposure. The limitation of CEUS is that they have a short half-life and it can have side effects^(85, 96).

A commonly used contrast agent is Sonovue microbubbles approved for use in the European Union since 2001 (Bracco, Milan, Italy). This is a second generation

microbubble contrast that consists of an inert gas (sulphur hexafluoride, 8ul/ml of solution) covered in a phospholipid membrane. The contrast medium is reconstituted with 5mls of normal saline and can be administered immediately. It has a mean terminal half-life of 12 minutes (range 2-33 minutes). Common side effects (seen in between 1 and 10 patients in 1000) of microbubble contrast include hypersensitivity reaction, headache, paraesthesia, flushing, pain, dizziness, pruritus and raised blood sugar levels⁽⁹⁵⁾.

Liu et al⁽⁸⁷⁾ demonstrated that microbubbles enhanced the detection of bleeding in injured vessels and organs as well as in extravasated blood in a pre-clinical in vivo haemorrhage model. Within 6 seconds of contrast agent administration, active bleeding was detected. Delayed phase imaging performed 15 to 20 minutes after the injection of contrast allowed sufficient time for the agent to accumulate within the organ. This led to enhancement of the parenchyma as compared to the intra-hepatic or intra-splenic haematoma and the resulting difference helped to highlight the pathology.

The authors also conducted 3D CEUS and found that it improved the localisation of bleeding compared to 2D CEUS. The 3D multiplanar perspectives with volume rendering helped to provide a spatial relationship of the bleeding points, the haematoma and its orientation to surrounding vascular structures and the organ. Furthermore, the 3D ultrasound findings were considered to be accurate as corroborated by the final histology specimen⁽⁸⁷⁾.

Valentino et al⁽⁸⁵⁾ conducted a prospective clinical study in 133 patients with blunt abdominal trauma. They compared ultrasound with and without contrast and compared their findings to a CT scan as the gold standard. They found that CEUS versus conventional ultrasound had a higher sensitivity, specificity, positive and negative predictive value. The authors concluded that CEUS improves the diagnostic capability of ultrasound and is close to the sensitivity of a CT scan (*Figure 2.8*⁽⁸⁹⁾). They recommended its use to avoid radiation exposure especially in children as well as women of childbearing age and when a CT scan is not available ^(85, 89).

This is in concordance with the guidelines set by the European Federation of Societies for Ultrasound in Medicine and Biology; who recommend CEUS where CT is unavailable or contraindicated, such as an allergic reaction to iodinated contrast agents, inadequate quality of CT images due to artefacts, monitoring known traumatic pathology and in cases of minor blunt trauma specifically in children⁽⁹⁷⁾.

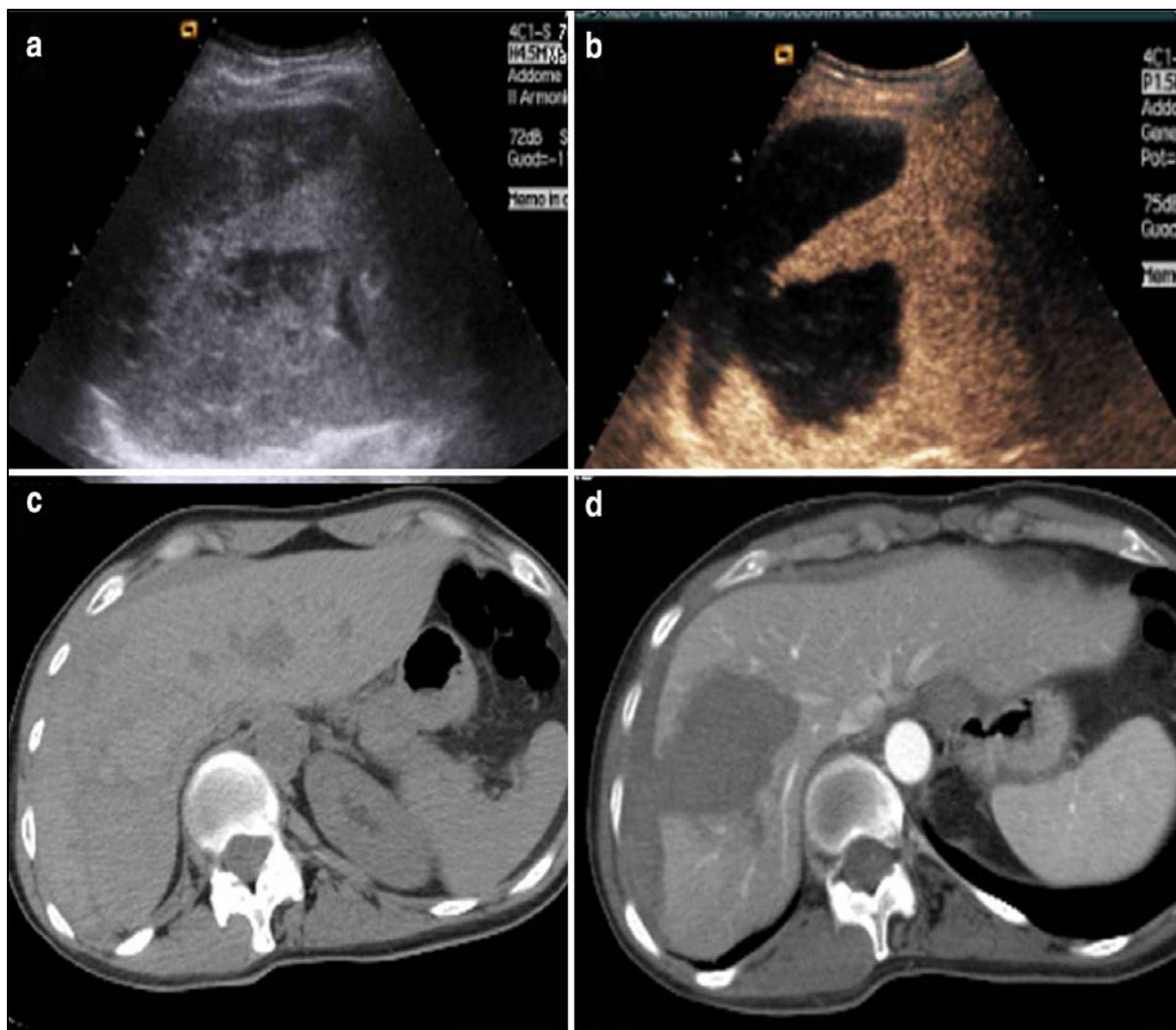


Figure 2.8 CEUS example: A patient presenting after sustaining blunt trauma
a) Ultrasound has identified that the liver has a hypoechoic area with a subcapsular haematoma;
b) A grade III laceration on segment VII with a parenchymal and subcapsular haematoma is identified with CEUS;
c) Multidetector computed tomography (MDCT) demonstrates the haematoma;
d) CE-MDCT scan displays matching outcomes to CEUS (Reproduced with permission from the Publisher)⁽⁸⁹⁾

Tang et al⁽⁸⁸⁾ performed an in-depth study of the performance of CEUS in a pre-clinical in vivo model by simulating blunt hepatic and splenic trauma. They graded the degree of organ injury with CEUS according to the American Association for the Surgery of Trauma scale. They compared the findings with the Becker CT scale for hepatic injury^(98, 99) and the Buntain scale for splenic injury⁽¹⁰⁰⁾. They identified a high degree of correlation between CEUS and CT at 93% for hepatic as well as splenic trauma. The authors also undertook a retrospective clinical study in 392 patients assessing the accuracy of CEUS imaging for active hepatic or splenic bleeding compared to CT. Their results stated that the detection of active bleeding using CEUS was not different to CT, as it could rapidly and safely identify active bleeding. The limitations of ultrasound that were noted included patient obesity, subcutaneous emphysema and the need for a skilled operator⁽⁸⁶⁾.

2.3.4 Discussion

As outlined in this review, FAST is effective in experienced hands to diagnose a haemoperitoneum⁽⁷⁶⁾. Additionally, contrast agents and 3D ultrasound modality can enhance the quality of images and guide the sonographer to the source of bleeding⁽⁸⁷⁾. For prehospital care, it is worth noting that although the above modalities may help to establish a diagnosis, this should not delay transfer to hospital and should ideally be performed in transit. This point was highlighted by Brun et al⁽¹⁰¹⁾ who performed a prospective study of 98 patients and compared the effectiveness of FAST on site and during transfer. The authors identified that it made no difference and advocated performing FAST during transit so as not to delay the journey and was even more reliable when repeated.

An important question hypothesised in a systematic review by Jorgensen et al⁽¹⁰²⁾ was whether prehospital ultrasound increased the survival of trauma patients. The authors stated that the data was too heterogeneous to answer its objectives. Of the 14 studies included, they noted that prehospital sonography was not only feasible but also highly reliable in detecting a haemoperitoneum. Furthermore, the diagnosis attained in the prehospital setting helped to prioritise the management, the most suitable receiving hospital and the mode of transportation.

Since Jorgensen et al⁽¹⁰²⁾ review, other scholars have found similar findings in their prehospital ultrasound experience. As it has proven to be effective, the focus has now shifted towards improving the technology through handheld devices and telemedicine. There are various handheld lightweight sonography devices currently on the market. Hoyer et al⁽¹⁰³⁾ examined four such devices in the prehospital setting and stated that they were all reliable. They did note issues with the handheld scanners that need addressing such as a short battery life as well as the small screen and inferior image quality compared to the machines used in the hospital.

Telemedicine has also been explored to relay live images remotely to the trauma centre. This enables the prehospital team to liaise with the receiving trauma clinician and experts so that a management plan can be implemented at the point of injury as well as during patient transit to hospital^(104, 105). Communication with the receiving team is important as it allows a smooth transition from the prehospital to the hospital phase of the patients management.

In this study there were a wide range of sensitivities and specificities. These could not be analysed in more detail to identify if participants were having difficulty in obtaining an image in one particular area of the FAST scan or the whole procedure and whether this was due to patient factors such as obesity or surgical emphysema⁽⁸⁴⁾. Nevertheless, ultrasound should be seen as a modality to rule in pathology due to its high specificity rather than to rule out pathology (wide-ranging sensitivity) and it is not currently a replacement for a CT scan⁽⁷⁷⁾.

2.3.5 Conclusion

This review confirms that FAST is effective in experienced hands. Contrast agents and the 3D modality enhance the quality of the ultrasound image and should be considered part of daily practice to aid the localisation of bleeding. Hence, further research could explore the routine administration of contrast agents to enhance the quality of FAST scans. Additionally, investigating the potential advantage that 3D ultrasound offers as an effective modality for enhancing the diagnosis of trauma related pathology specifically organ/vessel injury. Finally, assessing how these modalities could be applied in the prehospital setting to help establish an accurate diagnosis ideally with a handheld lightweight ultrasound device. Once a diagnosis of torso haemorrhage is established through FAST, an effective management plan can be initiated to gain control of bleeding. There are numerous technologies available that could be applied to control bleeding in the prehospital setting and this will be explored in the subsequent review.

2.4 What technology is available for prehospital traumatic intra-abdominal haemorrhage control?

2.4.1 Introduction

The current management of intra-abdominal haemorrhage control requires a multifactorial approach dependent not only on the severity of bleeding but also on the capabilities of the local trauma centre⁽¹⁰⁶⁾. It is evident from the literature stating a prehospital traumatic haemorrhage mortality of 56% for civilians and 87.5% for combat casualties that some patients require immediate haemorrhage control^(19, 107). With the implementation of pre-hospital clinicians, this may be possible to perform in order to minimise the overall impact of blood loss on outcomes. However, it should be noted that such interventions should not be overextended and ideally performed en-route so as not to delay transfer; as these are only stabilising manoeuvres until definitive control is achieved in hospital. The prehospital care of a trauma patient including haemorrhage identification and control have been described in Chapter 1.

This review aims to evaluate the current technologies that can be potentially deployed to control traumatic intra-abdominal haemorrhage and establishes the evidence behind their effectiveness. Although one can recognise that the correction of coagulopathy, acidosis, hypothermia, as well as permissive hypotension are important in haemorrhage control this review will focus only on local technological adjuncts that may aid in pre-hospital management.

2.4.2 Methods

A systematic search of publications was undertaken. The online databases utilised included PUBMED, MEDLINE, GOOGLE SCHOLAR and EMBASE. The following mesh terms were searched for “abdominal haemorrhage control”, “abdominal haemorrhage control AND trauma”, “prehospital”, “emergency medical services” with a focus on technological applications. The most recent search date was 26th August 2015. Inclusion criteria were defined as original studies in English, of abdominal haemorrhage control in animal or clinical trials, from the start of databases fulfilling the above mesh terms. Additionally abstracts and full text had to be available for further analysis. Exclusions included review articles and case reports but these were examined for further references. Two clinicians scrutinised the literature independently. The primary outcome assessed was mortality and secondary outcomes included blood loss and complications associated with each technique. Where appropriate, results were summarised as mean $\pm$ standard deviation, median $\pm$ interquartile range and clinical studies highlighted using the Oxford levels of clinical evidence. These are as follows:

- Ia: Systematic review or meta-analysis of randomized controlled trials
- Ib: Individual randomized controlled trials
- IIa: Systematic reviews of cohort studies
- IIb: Individual cohort study or low quality randomized controlled trials
- IIIa: Systematic review of case-control studies
- IIIb: Individual case-control study
- IV: Case series
- V: Opinion of an expert committee

As a guide, benefits of one technology over another were quantified using a mortality risk reduction, which included all studies whether pre-clinical or clinical. These risk reductions were not weighted. The mortality risk reduction was calculated by a formula of $CER - EER / CER$ [where CER (Control Event Rate) represented the control group mortality divided by total number of participants in control group and EER (Experimental Event Rate) represented the experimental group mortality divided by total number of participants in the experimental group].

2.4.3 Results

The results from the systematic search identified 1704 articles. After exclusions, there were 89 papers available for full-text analysis. This was refined to a final 37 studies that met the criteria for this review (*Figure 2.9*). Articles ranged in date from 1989 to 2015 with 15 Randomised Controlled Trials (RCT), 32 pre-clinical in vivo studies and 5 clinical studies. As the data was heterogeneous, no statistical analysis or meta-analysis could be performed apart from the mortality risk reduction in select cases. The results were subdivided into the following three technological categories:

- I. Mechanical compression (13 studies)
- II. Endovascular control (10 studies)
- III. Energy based haemostatic devices (14 studies)

The number of publications on this topic per year has exponentially increased demonstrating the wider interest in the need to address the shortfalls in trauma management (*Figure 2.10*).

The studies identified in this review were clinical or where stated pre-clinical meaning an animal model experiment. There are differences between pre-clinical and clinical studies that have to be taken into account. The challenges of conducting clinical trauma research have been highlighted in Chapter 1.1.6. Pre-clinical studies seem to be the only feasible means of assessing the efficacy of a novel haemorrhage control device or technique. The aim is that these studies may help us to understand what the likely outcome would be if it were to be performed in humans. There are a number of drawbacks of preclinical research that have to be taken into account such as the fact that the studies are conducted in controlled lab settings with specific trauma injuries that do not reflect the real-world scenario of a polytrauma patient with intra-abdominal haemorrhage⁽⁷⁾.

Additionally some of the animals undergo only 5 to 15 minutes of haemorrhage after which control manoeuvres are conducted. Such a short time period is not reflective of what is currently achieved in trauma patients. Numerous preclinical studies have heterogeneity of study design, methodology, randomisation and poor choice of comparison or control groups. Specifically in a trauma haemorrhage porcine model, it has the ability to auto-transfuse through its spleen. Hence any such study should have a splenectomy performed in advance which is not always the case^(7, 108).

Furthermore, the studies consist of small experimental numbers with inadequate statistical power; they have a positive publication bias, they fail to account for confounding variables and intention to treat methodology⁽¹⁰⁸⁾. Taking these drawbacks into account, pre-clinical research can highlight promising haemorrhage control techniques which after rigorous analysis can proceed to clinical studies.

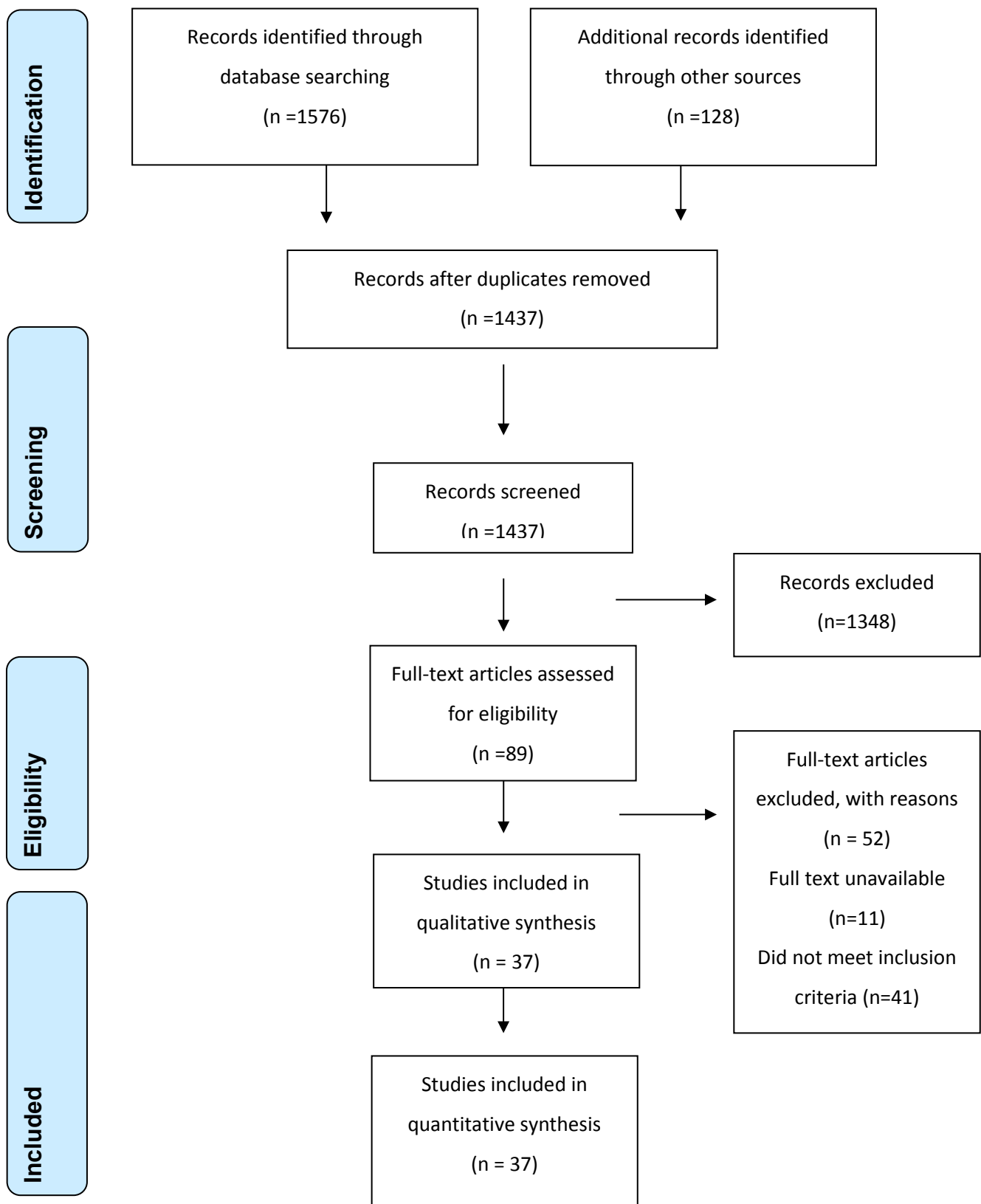


Figure 2.9 PRISMA Flow Diagram

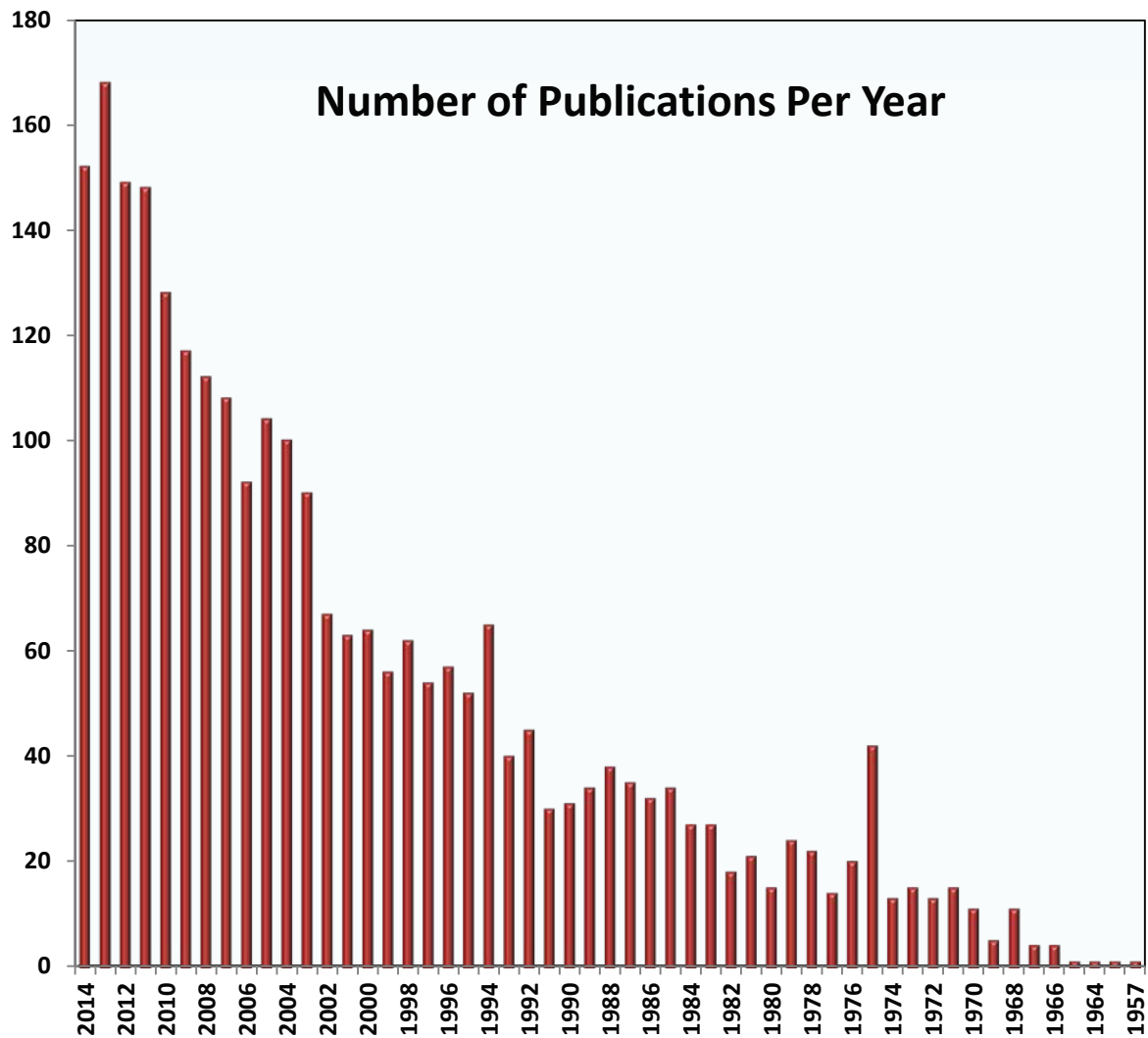


Figure 2.10 Number of publications per year on PubMed under the mesh search term “Abdominal Haemorrhage control”

2.4.3.1 Mechanical compression

Primary Outcome: The manual pressure and gas insufflation techniques had no mortality in the intervention group. Death in the intra-abdominal foam infiltration intervention group was 14/56 (25%)^(6, 109) which rendered a 63% mortality risk reduction (Table 2.2 Outcomes for mechanical compression)^(6, 109-120).

For intra-abdominal major vessel bleeding such as from the iliac arteries, a prospective study identified that up to 63Kg weight or 180mmHg (pneumatic tourniquet) on the distal aorta and 54kg on the proximal iliac artery could occlude flow which was confirmed with Doppler ultrasound^(116, 117).

Other treatment options identified for intra-abdominal bleeding with preliminary results include gas insufflation and intraperitoneal infiltration of foam. Although only trialled on organ related haemorrhage, CO₂ insufflation at a pressure of 20cm H₂O for 30minutes in splenic lacerations⁽¹¹¹⁾ and 20minutes for a grade V liver laceration demonstrated significant reductions in blood loss with better physiological parameters when compared to controls. In the case of the liver laceration, a 69% decline in blood loss using this technique over no intervention was demonstrated⁽¹¹⁰⁾.

Author, Year	Study Design/ Levels of Evidence	Number of participants	Site of injury	Method of compression	Blood loss	Mortality	Complications
CLINICAL STUDIES							
MANUAL PRESSURE							
Lyon 2012	Human Volunteers prospective study/ Level IV	9	n/a	External pneumatic abdominal aortic tourniquet	Occlusion of flow in 7 subjects at 180mmHg	None	Discomfort in 7 volunteers
Blaivas 2006	Human volunteers prospective study/ Level IV	9	n/a	Weight applied to distal aorta/iliac arteries	120 pounds required to occlude flow from proximal right iliac artery	None	None reported
ANIMAL STUDIES							
MANUAL PRESSURE							
Tiba 2015	Porcine Model	17	Iliac artery	Pelvic haemostasis belt(PHB) vs. military antishock trousers (MAST) vs. control	PHB blood loss less than MAST but similar to control	All PHB and 2 MAST survived 60 mins	None reported
GAS							
Ahmadi-noorbakhsh 2012	Rabbit model RCT	24	Grade V hepatic laceration	CO2 insufflation (GAS) versus dialysate solution(DIAL)	DIAL and GAS less blood loss than control	No mortality	None reported
Velmahos 2007	Porcine model RCT	19	Severe splenic injury	CO2 insufflation 20cm H2O pressure for 30 minutes	Blood loss lower in insufflation group	None	None reported
Jaskille 2005	Porcine model RCT	21	Grade V hepatic laceration	CO2 insufflation 20cm H2O pressure for 20 minutes	69% less blood loss in insufflation group	Control 30%	None reported
Sava 2003	Porcine model RCT	10	Inferior vena cava	CO2 insufflation 20cmH2O	Mean blood loss reduced by 61% with insufflation	None	None reported
Kasotakis 2013	Porcine model randomised	15	Severe splenic injury	CO2 insufflation at 20, 25, 30 mmHg pressure for 30 minutes	Blood loss less with 20mmHg	None	Worsening acidosis at higher pressures

FOAM							
Kheirabadi 2008	Rabbit model RCT	46	Severe Liver injury	Pressurised Fibrin sealant Foam (FSF) versus control and placebo	FSF had the least blood loss	Control 75%	None reported
Holcomb 2000	Rat model RCT	31	Severe Liver injury	Expanding fibrin sealant foam vs placebo foam	Less blood loss with fibrin foam	Equivalent mortality between groups	None reported
Duggan 2013	Porcine model with control	27	Hepato-portal injury grade V	Polyurethane foam	Less blood loss with foam	Control 92%, Foam 27%	Localised bowel wall necrosis with foam group
Rago 2014	Porcine model with control	29	Iliac artery severed	Polyurethane foam	Less blood loss with foam	3hr mortality Foam 100mls 50% 120mls 61%	Localised bowel wall necrosis with foam group
Rago 2014	Porcine model with control	20	Splenic injury	Polyurethane foam	Less blood loss with foam	0% with control, 100mls and 120mls foam at 28 days. No survivors in 150mls foam group	Localised bowel wall necrosis with foam group

Table 2.2 Outcomes for Mechanical Compression

Both studies had no mortality and a complication of abdominal compartment syndrome was noted at higher pressures⁽¹¹²⁾. Further research suggested that an optimum pressure of 20mmHg would mitigate these risks ⁽¹¹²⁾. A concern of gas insufflation is that a concomitant injury to the diaphragm could lead to a tension pneumothorax⁽¹¹⁰⁾. However, there are numerous reports of safe CO₂ insufflation in patients having a laparoscopic repair of a diaphragmatic injury ^(121, 122) although this is in a controlled environment as opposed to the unstable pre-hospital setting. There are also reservations about the practicalities of pre-hospital administration that Kasotakis et al⁽¹¹²⁾ have addressed by developing a portable gas insufflator (*Figure 2.11*). The authors stated that their research group are developing a smart sensorised needle that retracts upon entering the peritoneum.

Another proposed method of mechanical compression is through the intraperitoneal injection of foam. There have been various formulations of foam developed for this purpose including some impregnated with fibrin^(109, 115). The foam is injected into the abdomen percutaneously; it rapidly expands 29-fold by volume and tamponades bleeding (*Figure 2.12*)⁽⁶⁾. The foam is subsequently detached at laparotomy and any remaining fragments removed using irrigation and suction. Five studies have evaluated foam, with one grade V hepato-portal injury study in a porcine model which demonstrated reduced mean blood loss (0.47 ± 0.3 g/kg/min foam vs 3.0 ± 1.3 g/kg/min control) and improved median survival times (154 ± 48 minutes foam vs 43 ± 50 minutes control)⁽⁶⁾.



Figure 2.11 Prototype Portable CO2 Insufflator (Image reproduced with permission granted by publisher⁽⁵⁾)

As this is still in the experimental phase, indications for the use of foam could include major intra-abdominal trauma with refractory hypotension where there is a high suspicion of significant intra-abdominal bleeding⁽⁶⁾. Complications with foam similar to gas insufflation have been noted such as the potential for respiratory compromise in a large diaphragmatic injury; in addition to concern over pressure necrosis of the bowel wall⁽⁶⁾. Duggan and Rago et al^(6, 119, 120) noted that the areas of bowel necrosis were caused by pressure exerted by the polymer and would need repair for long term survival. However, they considered this to be an acceptable complication given the life-saving potential that foam offers for an otherwise high mortality event.

Where an assessment could be ascertained, gas insufflation had a mean blood loss of 582 ± 172 mls vs 1377 ± 342 mls control^(110, 111, 114) and foam had a blood loss of 21.2mls vs 44.6mls control⁽¹¹⁵⁾. To date, no clinical trials have been conducted to evaluate the use of gas or foam although, from preliminary studies, results suggest a 63% mortality risk reduction is achievable with foam. Evidently further research is necessary into both gas and foam treatments to assess its efficacy as well as safety before it enters clinical trials.

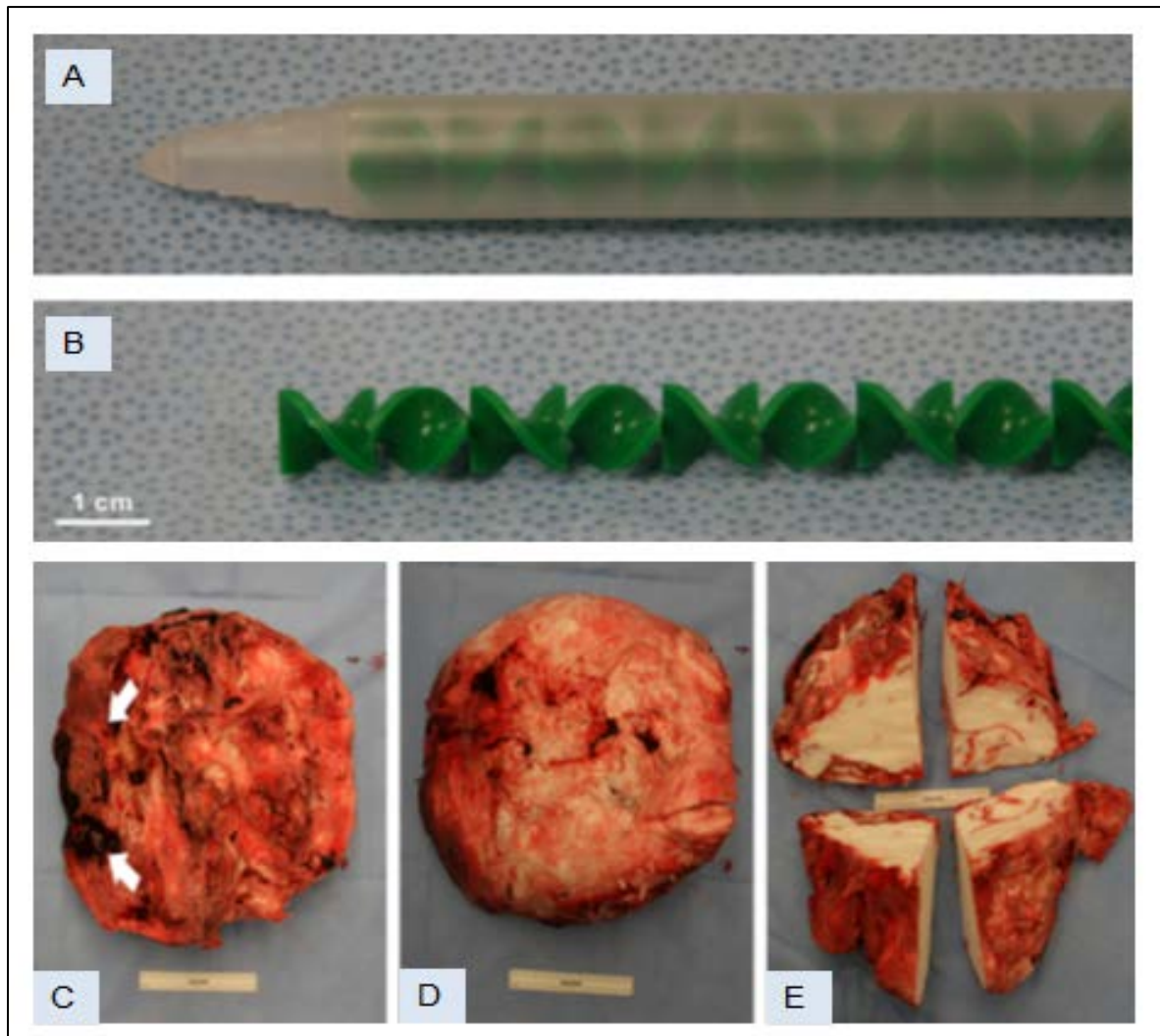


Figure 2.12 Foam injector and expansion characteristics of the foam a) Nozzle trocar is placed through umbilicus to inject foam b) Bespoke internal mixing element within the nozzle trocar for the isocyanate and polyol phase of the foam polymer formulation c) Polymer explanted as a single block demonstrating the 29-fold expansion characteristics of the foam from the 150 mls injected to the final volume of 4,339 mls. The ventral (c) and dorsal (d) surfaces of the material conformed to the internal abdominal viscera and site of injury (white arrows), scale bar of 15cm e) The blood absorption was limited to the polymer surface whilst the inner core was white (Image reproduced with permission granted by publisher⁽⁶⁾)

2.4.3.2 Endovascular control

Primary Outcome: Pre-clinical trials of REBOA demonstrated an overall mortality of 10/74 (13%) with a 74% mortality risk reduction. The three clinical REBOA studies were retrospective case series (*level IV evidence*) which identified 42/58 (72%) mortality ^(123, 124) (Table 2.3 Outcomes for Endovascular balloon occlusion of the aorta) ^(7, 108, 123, 125-131).

Vascular control is an essential requirement for traumatic intra-abdominal haemorrhage. The first surgical manoeuvre involves packing the abdomen with external compression of the aorta to reduce bleeding and increase central aortic pressure. An alternative approach that is commonly used in cardiothoracic and vascular surgery is endovascular aortic balloon occlusion. In the context of trauma this technique has been advocated by many authors and is termed REBOA. This technique involves inserting an endovascular balloon-catheter into the aorta to provide vascular control and afterload enhancement. This is accomplished via the femoral artery either through a percutaneous seldinger or cut down technique. The catheter is passed into the aorta over a guidewire and the balloon inflated in either Zone I (distal to left subclavian up to the coeliac axis) or Zone III (the infrarenal aorta) with Zone II being a no inflation region (*Figure 2.13*). REBOA acts as a temporising measure to arrest haemorrhage until definitive control can be established⁽⁷⁾.

Indications for Zone I REBOA include high grade injury to the liver, spleen, kidney and major abdominal vessels; for Zone III REBOA a severe pelvic fracture, pelvic

major vessel injury and traumatic amputation near the hip. Contraindications to its use include non-compressible haemorrhage from the axilla, neck, face and superior mediastinum⁽¹³²⁾. Morrison et al⁽¹³²⁾ conducted a retrospective gap analysis of injuries sustained by UK combat casualties and identified that one in five patients could have benefited from REBOA deployment. Specifically 60% of casualties required Zone I and 40% Zone III REBOA. Barnard et al⁽¹³³⁾ examined the England and Wales trauma registry over 12 months and identified that 0.5% of the civilian population may have been amenable to REBOA. Although this number is small, these patients had a high mortality at 32% and they may have been stabilised with this procedure.

Currently, REBOA has been promoted for hospital use whereby fluoroscopy, plain radiographs or ultrasonography are required to ensure correct placement⁽⁷⁾. In order to extend the use of REBOA to the pre-hospital setting, a method of ensuring accurate placement, while eliminating the need for fluoroscopy remains a formidable hurdle. For femoral access, ultrasound has been recommended⁽¹⁰⁸⁾ and this may be useful for the prehospital setting but it is still technically demanding, specifically in obese patients. Ensuring adequate placement in Zone I or III in the prehospital setting is challenging but recommendations include insertion distances based on external torso measurements^(134, 135) or the use of CEUS which will be evaluated in Chapter 6.

REBOA is prone to the same complications as any endovascular procedure namely vessel dissection/rupture, false aneurysm formation, inaccurate cannulation of the contralateral limb/visceral vessels^(7, 108). In Zone III REBOA, inadvertent occlusion proximal to the renal or visceral arteries may induce unnecessary organ ischaemia.

Equally, distal deployment will not adequately control aortic blood flow. If the REBOA balloon has been inflated for a prolonged period of time there will be an inevitable reperfusion injury which in the context of a trauma patient may be too much of a physiological insult to survive. Hence supporting the patient with adequate blood and fluid transfusions prior to balloon deflation, with intermittent inflation thereafter is necessary to allow the physiology to stabilise⁽¹³⁰⁾.

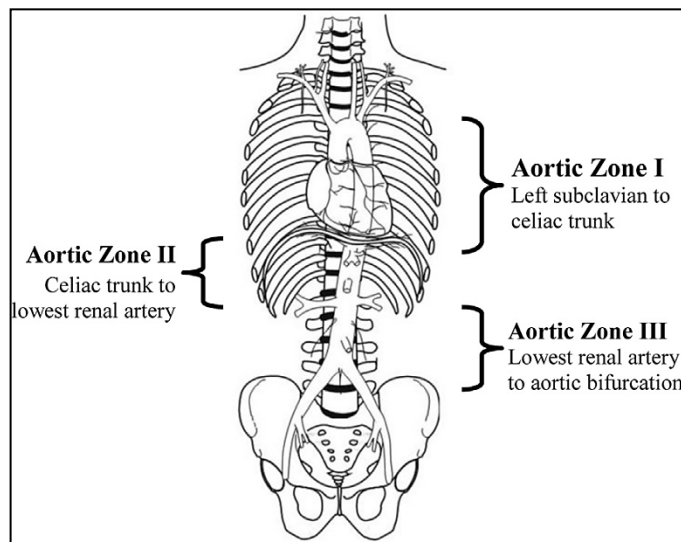


Figure 2.13 REBOA insertion Zones (Reproduced with permission from the Publisher⁽⁷⁾)

Author, Year	Study Design/ Levels of Evidence	Number of participants	Site of injury	Site of balloon inflation	Blood loss	Mortality	Complications
CLINICAL STUDIES							
Saito 2015	Clinical Study/ Level IV	24	Pelvic Fracture Blood in abdomen	Zone 1	Not reported	87.5%	9 cases of acute kidney injury and multiorgan failure, 3 lower limb amputations
Martinelli 2010	Clinical study/ Level IV	13	Pelvic fracture bleed	Zone 3	Not reported	54%	One thrombosis left common femoral artery
Gupta 1989	Clinical Study/ Level IV	21	Penetrating abdominal injury	Zone 1	Not reported	67%	Two cases where catheter exited through aortic injury. One case of ischaemic right lower extremity.
ANIMAL STUDIES							
Markov 2013	Porcine RCT	24	Iliac artery	Zone 1	ABO did not have less blood loss than control	Control 17%	90 minute ABO group had a greater renal dysfunction and liver necrosis than control
Morrison 2012	Porcine RCT	35	Iliac artery	Zone 3	ABO had less blood loss than control and combat gauze coagulopathy group	Control 100% Combat gauze coagulopathy 71%	None reported
White 2011	Porcine RCT	18	Iliac artery	Zone 1	Not reported	Control 17%	None reported
White 2011	Porcine RCT	24	Iliac artery	Zone 1	ABO had the least blood loss	Direct vascular control group 17%	None reported
Avaro 2011	Porcine RCT	25	Spleen trauma	Zone 1	Not reported	Control 100% Intervention group 56%	More cardiac ischaemia in the 60 minute than the 40 minute ABO group.
Figueiredo 1995	Canine RCT	28	Distal Aorta	Zone 3	No difference in blood loss between groups	Control 43%	None reported
Kralovich 1997	Porcine model RCT	10	Left external jugular vein	Zone 1	Not reported	Control 20% Intervention group 20%	Balloon deflation led to reduced coronary perfusion pressure and diminished left ventricular function

Table 2.3 Outcomes for Endovascular balloon occlusion of the Aorta (ABO= Aortic Balloon occlusion, Zone 1 = aorta from the commencement of the left subclavian artery to the coeliac artery, Zone 3 = from the infrarenal aorta to the bifurcation)

White et al⁽¹²⁵⁾ randomised porcine study compared REBOA to thoracotomy and aortic clamping. They demonstrated the physiological impact of haemorrhage with REBOA was less than with thoracotomy (pH 7.35 REBOA vs 7.24 thoracotomy; Lactate 4.27 REBOA vs 6.55 thoracotomy), with less fluid (667mls REBOA vs 2,166 mls thoracotomy) and norepinephrine support (0mcg REBOA vs 52.1mcg thoracotomy).

Avaro et al⁽¹²⁷⁾ performed REBOA at the supraceliac site for severe splenic trauma. They demonstrated that REBOA increased the proportion of 2-hour survivors significantly. However, it was noted that at 60 minutes of REBOA higher potassium levels and greater evidence of ischaemic cardiac lesions were noted with 9/16 mortalities. At 90 minutes of REBOA greater renal impairment, liver necrosis and higher fluid resuscitation requirements were found ⁽¹²⁸⁾. Hence, 40 minutes was deemed to be the safe threshold for REBOA after which the risks outweighed the benefits ⁽¹²⁷⁾.

This was also highlighted clinically where REBOA was deployed for cases of catastrophic pelvic haemorrhage with 7 mortalities documented from 13⁽¹²³⁾. The survivors had a shorter length of REBOA time (46minutes) than non-survivors (91minutes) and required less blood (17 units versus 20 units for non-survivors). However, the mean injury severity score of survivors was less than the non-survivors so the relation to the REBOA technique in isolation is difficult to determine accurately. Where a comparison could be inferred, the REBOA technique had reduced blood loss (11mls/min vs 822mls/min control)⁽¹²⁶⁾ although the complication

of lengthy inflation times and inappropriate placement could be potentially catastrophic.

The morbidity of REBOA was that longer occlusion times led to worse outcomes and hence forty minutes seemed to be the safe threshold ⁽¹²⁷⁾. Level IV evidence from three clinical retrospective studies of REBOA reported a 72% mortality ⁽¹²³⁾ and of these, two died of shock induced by balloon deflation. Kralovich et al⁽¹³⁰⁾ stated in a porcine RCT that REBOA deflation led to reduced coronary perfusion pressure, diminished left ventricular function and decreased systemic oxygen utilisation. This adverse effect was overcome by pre-loading with blood ten minutes before deflation⁽¹²⁸⁾ and after deflation performing intermittent inflation until cardiovascular stability returned⁽⁷⁾. Another recommendation to mitigate this risk was to locate an angiography suite close to the resuscitation room, in order to keep REBOA inflation time to a minimum⁽¹²³⁾. In relation to a concomitant head injury, it remains unclear as to whether the improved mean arterial pressure associated with the balloon occlusion enhances cerebral perfusion through improved cerebral oxygenation or whether the effects are deleterious through the potential rise in intracranial pressure⁽¹²⁸⁾.

2.4.3.3 Energy based haemostatic devices

Primary Outcome: The 14 studies identified were all pre-clinical studies. There was 1/11(9%) mortality in the High Intensity Focussed Ultrasound (HIFU) cohort ⁽¹³⁶⁾ and none with any of the other energy devices⁽¹³⁷⁻¹⁴⁰⁾.

There are several energy based devices under evaluation for surgical haemorrhage control. This review identified HIFU, radiofrequency (RF) ablation, microwave therapy and electrical pulse studies as potential technologies (Table 2.4 Outcomes for Energy based haemostatic devices) ⁽¹³⁶⁻¹⁴⁹⁾.

HIFU utilises multiple beams of ultrasound and via an acoustic lens converges them onto a single point. This helps to deliver high levels of focussed energy to a sub-millimetre area inducing a thermal and mechanical effect. It can be focussed to the target area with ultrasound or MRI and the temperature of the treated area can rise up to 85 degrees Celsius inducing coagulative necrosis⁽¹⁵⁰⁾ as well as cavitation, leading to the release of clotting factors and tissue emulsification which acts as a coagulum seal over the wound^(151, 152). In early HIFU research, the cavitation and its subsequent tissue damage was unreliable. To enhance safety, histotripsy was developed which are short high intensity bursts of ultrasound that help to control the cavitation. Additionally injecting microbubbles focuses HIFU even further hence limiting cavitation⁽¹⁵³⁾.

An advantage of HIFU over other modalities is that it can deliver energy at varying depths non-invasively, hence its approval for tumour ablation. HIFU has potential

advantages for prehospital haemorrhage control if it could be applied transcutaneously to specific bleeding points. The limitations are that distances greater than 10cm from the skin limits the likelihood of success⁽¹⁵⁴⁾ and at present it is still in the experimental phase and requires further research.

Numerous pre-clinical studies have highlighted its success at haemorrhage control of major vessels with later recanalisation⁽¹⁴²⁾; as well as for controlling hepatic haemorrhage with haemostasis achieved within a mean of 66 ± 18 seconds for 17 treatments with no subsequent blood loss⁽¹⁴³⁾. Zderic et al⁽¹⁴⁹⁾ noted that the use of microbubbles amplified the thermal and cavitation effects of HIFU which shortened the treatment time to haemostasis, (59 ± 23 seconds with microbubbles vs 70 ± 23 seconds without microbubbles) with an average 37% reduction in haemostasis time and 60% faster coagulum seal⁽¹⁴⁹⁾. Where comparisons could be inferred, HIFU reduced mean blood loss by 78% (3.9 ± 2.9 mls HIFU vs. 17.1 ± 6.9 mls control)^(142, 145).

Author, Year	Study Design	Number of participants	Site of injury	Blood loss	Mortality	Complications
ANIMAL STUDIES						
HIFU						
Noble 2002	Rabbit RCT	21	Spleen incisions	Not reported	None	1 splenic re-bleed
Zhao 2012	Rabbit model with control arm	20	Liver incisions	HIFU less than Control	None	None
Burgess 2007	Porcine model with control arm	5	Posterior liver wedge tissue extractions	HIFU less than Control	None	None reported
Zderic 2006	Rabbits with control arm	25	Femoral artery puncture	HIFU less than Control	None	4 occluded arteries
Vaezy 2004	Rabbit model with control arm	21	Liver incisions	Not reported	None	None
Vaezy 1997	Rabbit model with control arm	10	Liver incisions	Not reported	None	None
Zderic 2006	Rabbit model	10	Liver incisions	Not reported	None	None
Cornejo 2004	Porcine model	11	Blunt organ injury – liver and spleen	Mean 600+/-454mls	HIFU 9%	Occult vein bleed missed. HIFU ineffective veins > 6mm in size
Vaezy 1999	Porcine model	5	Spleen incisions	Not reported	None	None reported
Vaezy 1998	Porcine model	5	Major blood vessel punctures	Not reported	None	None reported
Other Energy based Haemostatic devices						
Yekuo 2009	RF Porcine model with control arm	10	Blunt liver trauma	RF less than control	Control 100%	None reported
Zacharoulis 2010	RF Porcine model	5	Multiple stab wounds liver and spleen	Not reported	20%	None reported
Takasu 2004	Microwave Porcine model RCT	13	Laceration to liver grade IV injury	Microwave less than control	None	Extensive adhesions to liver at 14 days from microwave therapy
Mandel 2013	Electrical Pulse Rat and Rabbit with control arm	28	Liver injury	Electrical pulse less than control	None	None

Table 2.4 Outcomes for Energy based haemostatic devices (HIFU = High Intensity Focussed Ultrasound, RF= Radiofrequency)

HIFU had a 9% mortality⁽¹³⁶⁾ and the morbidity of occluded arteries from its use⁽¹⁴²⁾. A shortcoming noted was that all studies applied HIFU either directly or near the injury and none have attempted the transcutaneous route. Furthermore, even when HIFU is applied directly, Cornejo et al⁽¹³⁶⁾ stated that it was ineffective at achieving haemostasis for veins larger than 6mm in size. Zhao et al⁽¹⁴⁵⁾ acknowledged these shortcomings as well as stating that artefacts such as reverberation, acoustic shadowing and refraction can limit its efficiency.

Other energy based haemostatic devices include RF ablation via percutaneous needle insertion. The RF energy delivery required to control bleeding can be adjusted to the respective injury. A low power setting is more effective in major vessel control as the coagulation zone is broader, although this does take much longer to achieve. The high power setting is effective for smaller vessels and is faster at attaining haemostasis. An example is Yekuo et al⁽¹³⁸⁾ who used contrast enhanced ultrasound to identify hepatic bleeding and guide RF needle electrodes to the site of injury with haemostasis achieved within a mean of 8.5 ± 4.5 minutes. There was a 60% reduction in blood loss in the intervention group (250mls RF ablation vs. 620 mls control) with no immediate complications.

Takasu et al⁽¹³⁷⁾ was the only microwave therapy study identified in this review. A grade IV liver laceration in a porcine RCT had microwave therapy applied through needle electrodes for one minute and had less mean blood loss than the control group (192 ± 58 grams microwave therapy vs. 448 ± 138 grams control). The authors noted at 14 days post treatment that their subjects had extensive adhesion formation around the liver but no other complications were reported. Mandel et al⁽¹⁴⁰⁾ utilised

electrical pulses, noting that short pulses of 25 microseconds at 1250V/cm were best at controlling haemorrhage from liver injury in rats and rabbits with a 60% reduction in blood loss compared to the control group. They postulated that the mechanism of coagulation was not thermal but likely to be endothelial cell injury resulting in vasoconstriction and thrombosis.

2.4.4 Discussion

The ideal pre-hospital treatment of traumatic intra-abdominal haemorrhage is controversial, particularly when mortality is high. There is no doubt that the shorter the time gap from the point of incident to definitive management, the greater the impact on outcomes both in terms of mortality and morbidity, hence the adoption of the “scoop and run” approach to initial management⁽¹⁵⁵⁾. Indeed, this may be the right course where transport times to a trauma centre are short. However, given that the majority of traumatic haemorrhage deaths occur in the pre-hospital setting⁽¹⁵⁶⁾ (16, 19) and in cases where there are long transit times, there is scope for more effective haemorrhage control at the scene with preference for the non-invasive method.

Prehospital care teams will need to make a judgement on when to intervene dependent upon factors such as the mechanism of injury, clinical parameters, transport time and available resources⁽¹⁵⁷⁾. As outlined both in the previous and this literature review, technology into diagnostic imaging, wireless communication with trauma centres and haemorrhage control modalities continues to evolve; this may result in tipping the balance in favour of the colloquially termed “stay and play” tactic.

The impact of this strategy will only be recognised once an effective method of intervention can be safely introduced.

With most studies undertaken within the pre-clinical setting only, REBOA is leading in translational evidence. Early REBOA has demonstrated encouraging results with the control of substantial haemorrhage from a major vessel being almost uniquely attributed to the technique. However, it is an invasive procedure and many questions remain as to its safe application within the pre-hospital setting. Specifically, minimising the risks related to both the site of balloon placement relative to the injury in question, as well as its use in patients with multiple concomitant injuries, particularly those with cerebral damage.

Of the energy based haemostatic devices, HIFU is clearly of interest to the research community. It seems to offer a promising solution but more research is needed to establish its efficacy through the transcutaneous route. Although the RF, microwave and electrical pulse devices have demonstrated proof of concept, there is scope for more research to establish a safe, reliable, rapid and preferably non-invasive energy based haemostatic device.

No singular solution for abdominal haemorrhage control that fits all is currently available. Indeed, more than one modality may be required, dependent upon and tailored to each trauma scenario. One aspect that is clear from this review and the preceding one is that the early identification of the site of haemorrhage is essential, ideally confirmed in the pre-hospital phase. This will enable the most suitable

intervention to be deployed promptly and prepare the local trauma centre for the most appropriate course of action.

Limitations of the review include the search criteria of haemorrhage control, which is a vast topic and as a research question could not be refined any further. Widening the inquiry beyond mortality to other outcomes was required to enable a more inclusive review. Despite the care to be comprehensive, some studies and technologies may have been missed. Additionally the data was heterogeneous with no uniform methodology or reporting of results and consequently the appropriate statistical analysis could not be undertaken. Another point to mention is that most studies report positive results and although a formal evaluation was not performed it does suggest a publication bias. A further limitation is that the majority of the studies in this review are pre-clinical, the true value of haemorrhage control technologies may not be realised until clinical trials are conducted. This will be a challenging area with careful consideration required given the risks involved against the potential benefits.

2.4.5 Conclusion

The management of traumatic intra-abdominal haemorrhage is a field gaining interest. Various technologies and approaches are emerging, each of which seem to demonstrate improvements in the mortality associated with catastrophic traumatic haemorrhage. Only five clinical trials were found as part of this review. These evaluated the effectiveness of mechanical compression and endovascular control (*Level IV*). Significant complications were evident that need to be weighed up against

the encouraging mortality risk reduction. This review documents a developing field whose outcome currently still supports the fast transit from the site of incident to the trauma centre as the most appropriate course of action given the lack of evidence to support definitive haemorrhage control at the scene.

2.5 Chapter Conclusion

This chapter has aimed to address the topic of prehospital traumatic intra-abdominal haemorrhage identification and control through a national questionnaire to experts in this field as well as literature reviews. As a result of the review, we know that FAST is effective in experienced hands to diagnose a haemoperitoneum. Additionally, one of the highlights from the questionnaire was that participants requested more training in haemorrhage identification through high fidelity ultrasound simulators. Hence, this will be investigated in the ensuing experimental chapters in order to validate a simulator and improve FAST training.

A further recommendation from the questionnaire was for more research into endovascular haemorrhage control. The literature review on this topic demonstrated that REBOA had encouraging results to control haemorrhage, although it is still in the experimental phase given the high rates of morbidity. As ultrasound with contrast agents can enhance the quality of the image obtained, the final experimental chapter will investigate if there is a role for prehospital imaging in improving REBOA placement.

Chapter 3 Validating a FAST simulator

Hypothesis: A FAST phantom can be validated and used for authenticated simulation training.

3.1 Introduction

Simulation involves the creation of an artificial environment which closely resembles reality. The aim is to immerse the learner in the simulated setting in order to perform deliberate practice⁽¹⁵⁸⁻¹⁶¹⁾. Clearly a complete novice practicing in the acute phase of a critically ill trauma patients is unacceptable and therefore, learning technical skills through simulation provides a realistic alternative for skill acquisition.

The advantages of simulation are that one is able to rehearse specific skills in a learner centred environment suited to the trainees needs. It also provides an ideal opportunity to analyse the learners actions, score their performance and provide constructive feedback within a safe environment. As trainees are further along the learning curve following their simulation training, this should ease the skill transfer to the clinical setting which is the main reason behind the drive for simulation⁽¹⁵⁸⁾. Moreover, the impact of simulation could be evaluated through Kirkpatrick's hierarchy^(162, 163). There is evidence that high-fidelity training does result in improved participant satisfaction, knowledge and performance (Kirkpatrick level 1 and 2). However, there is insufficient data on the translational value of simulators to the clinical environment (Kirkpatrick level 3 and 4)⁽¹⁶⁴⁾.

A high fidelity FAST simulator could bridge the training gap for prehospital and hospital clinicians to gain the necessary proficiency in this examination. This was also requested by the participants in the questionnaire from Chapter 2. According to consensus guidelines, such simulators should be validated prior to clinical teaching⁽¹⁶⁵⁾.

Aims

With no previous evidence available and as a guide for future training systems the aims of this study were:

- To perform a face, content and construct validity assessment of the FAST simulator.
- To establish a rigorous FAST assessment tool.

3.2 Methods

3.2.1 Face, Content and Construct validity assessment

Face validity assesses whether the simulator appears to be a realistic model for the purposes of simulation training. This is normally performed by experts in the field. If a simulator rates high in face validity, learners are more likely to engage in the simulation training and similarly if it rates low, they are less likely to find the simulation training useful. Content validity consists of a detailed evaluation of the simulator suitability for training purposes. Construct validity assesses the degree to which a simulator can differentiate participants of varying skill levels^(166, 167).

Clinicians of varying levels of experience were invited to participate in this study by open email invitation to the departments of emergency, radiology and surgery. In light of no prior research available to provide a categorical separation of FAST experience, expert opinion was gained from 8 radiologists working in the field at a level 1 trauma centre. To enable a broad differentiation of experience the categories chosen were: Novices who had no prior experience with ultrasound, Intermediates who had less than 6 months experience and had performed fewer than 50 FAST scans and Experts who had more than one year of experience with greater than 100 FAST scans performed. Electronic logbook data verified all participants ultrasound experiences and they all gave their informed consent as well as providing demographic information which is outlined in the results.

Topics taught were consistent with the UK College of Emergency Medicine Curriculum^(79, 80). Other countries have similar curricula such as the American and Australasian College of Emergency Medicine and the Canadian Emergency Ultrasound society⁽¹⁶⁸⁻¹⁷⁰⁾. All of them teach the same basic principles of a FAST scan. The teaching format varies from lectures, demonstrations, simulation, interactive web based learning and clinical sessions.

All participants received a standardised training presentation on FAST which is described in Chapter 2.3. These included the different ultrasound probes, the ultrasound machine settings, how to perform a FAST scan and the normal ultrasound torso anatomy in each of the regions of interest. Abnormal ultrasound images consistent with a positive FAST scan were not shown as this would prime the participants beforehand. At the end of the briefing, a clinical scenario was presented

stating that the simulator was a motorcyclist hit by a car who was haemodynamically unstable. The tasks requested were to perform a FAST scan and identify if there was any pathology present in each of the regions of interest. The participants had a reference torso diagram to help them recall in which order to perform the FAST scan (*Figure 3.1*). In each area, participants had to state if there was an abnormality present, attain the most accurate image of it and save the image for subsequent evaluation. At the end of the study, participants were given feedback on the images they obtained.

With no template available, a questionnaire for face and content validity of the FAST simulator was developed (*Figure 3.2*). This form was independently verified by radiology and trauma experts to ensure that the correct questions were being asked. Only the experts were requested to complete the survey at the end of the study.

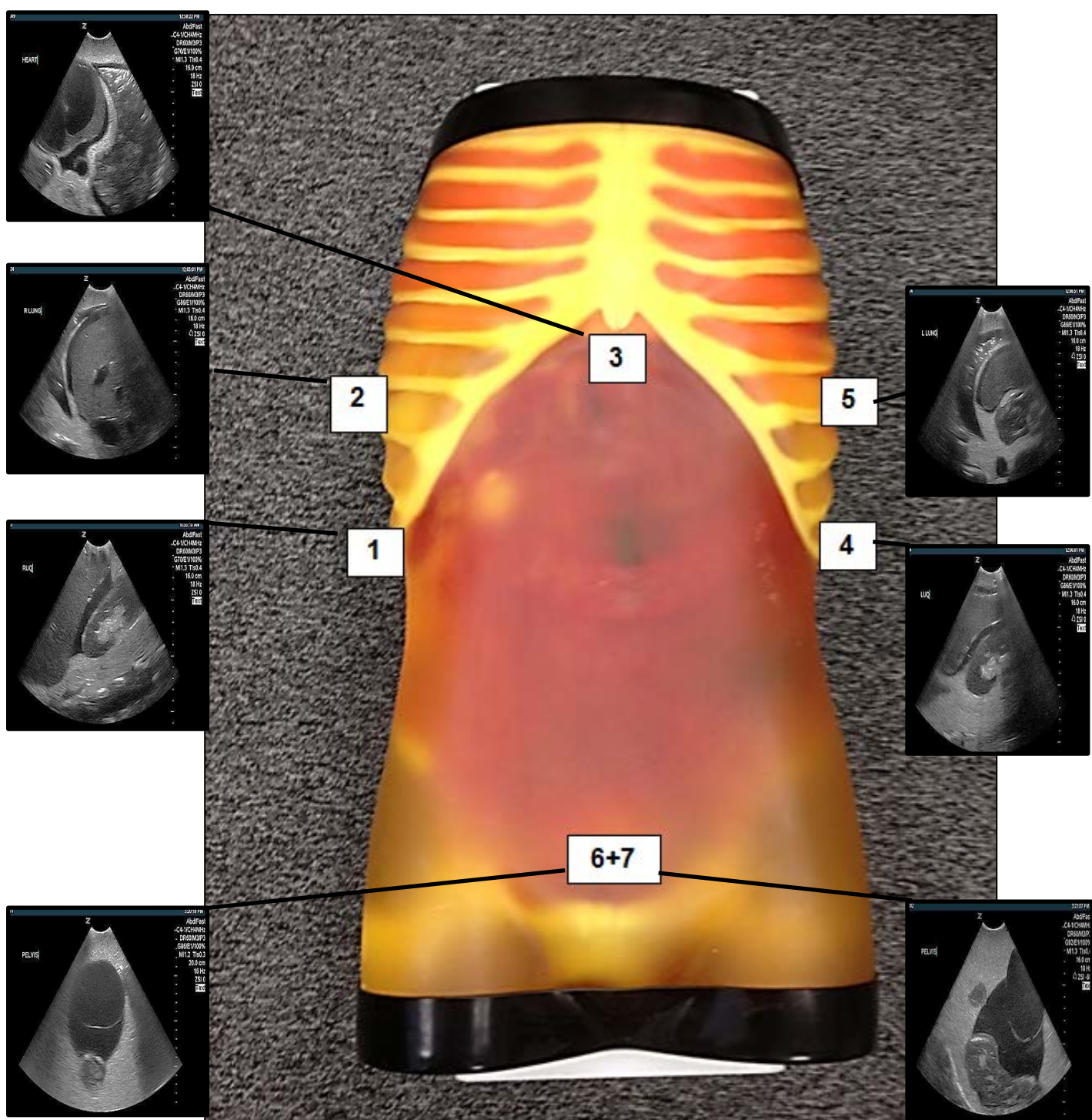


Figure 3.1 FAST scan sequence on the Kyoto Phantom with corresponding ultrasound images 1= Perihepatic view (Morison's pouch), 2= Right lung base view, 3= Pericardial subxiphoid view, 4= Perisplenic view, 5= Left lung base view, 6= Pelvis Transverse view, 7= Pelvis Sagittal view

1. The FAST phantom simulator was easy to use to perform a FAST scan

1	2	3	4	5
Strongly	Disagree	Neutral	Agree	Strongly Agree
Disagree				

2. Please rate degree of realism of the simulator anatomy under ultrasound

1	2	3	4	5
Very	Poor	Average	Realistic	Very Realistic
Poor				

3. The surface of the phantom felt realistic

1	2	3	4	5
Strongly	Disagree	Neutral	Agree	Strongly Agree
Disagree				

4. The pressure required to gain appropriate images was realistic

1	2	3	4	5
Strongly	Disagree	Neutral	Agree	Strongly Agree
Disagree				

5. The angle of the probe required to gain appropriate images was realistic

1	2	3	4	5
Strongly	Disagree	Neutral	Agree	Strongly Agree
Disagree				

6. The FAST simulator is useful as a training tool

1	2	3	4	5
Strongly	Disagree	Neutral	Agree	Strongly Agree
Disagree				

7. Please mark with a straight line on the Likert scale the degree of overall realism of the simulator to perform a FAST scan

0	5		10
Very	Average		Very
Poor			Realistic

8. Any Further Comments?

Figure 3.2 Face and Content Validity Questionnaire

3.2.2 The Kyoto phantom

FAST simulators can take various forms such as physical models, examples of this include the blue phantom mannequin (CAE healthcare, Sarasota, Florida, USA). This has adjustable fluid levels in each area of the FAST scan to tailor the pathology for the learner. On the other hand, the Kyoto phantom described below has fixed fluid levels at each region of interest. The advantages of physical models are that they provide a life-like simulator with anatomical landmarks that can assist in placing the probe in the correct location during the scan. The learners can also use their own departmental ultrasound machines to perform FAST scans and therefore, be accustomed to their instrument controls and settings. The limitations are that the mannequin image quality may be too good compared to real-life scans and hence not realistic. Furthermore, it cannot account for patients of different body habitus which requires different levels of force to be applied through the ultrasound probe.

There are also computer generated models such as the ScanTrainer (Medaphor, Cardiff, UK) which have virtual patients that the learner scans with haptic feedback. The advantage here is that real patient scans can be re-enacted; the disadvantage is that there is no mannequin and the learner cannot place the ultrasound probe according to anatomical landmarks. Additionally the learners cannot use their own departmental ultrasound machines for the scan.

Hybrid models such as Vimedix (CAE Healthcare, Sarasota, Florida, USA) and Simuwear (Simulab Corporation, Seattle, USA) consist of a mannequin with integrated software for self-directed learning. These provide the advantages of both

the physical and the computer generated models. The main drawback is that they cannot account for patients of different body habitus.

The “FAST/ER FAN” ultrasound simulator built by Kyotokagaku Ltd (Kyoto, Japan) was used in this study (*Figure 3.1*). It was the simulator of choice as it met the requirements for a high fidelity FAST study whilst accepting the aforementioned limitations. This phantom has pathology present in each quadrant which the participants were unaware of and they had to identify fluid in Morison’s pouch, spleno-renal angle, pelvis as well as a cardiac tamponade. The phantom also allowed users to assess for a bilateral haemothorax but not a pneumothorax which precluded a full Enhanced Focused Assessment in Sonography for Trauma (e-FAST) examination. Hence as an extension of the traditional FAST scan, a bilateral haemothorax was also included in the assessment process. The soft tissue and organs in this phantom are made of urethane based resin and the bones constructed of an epoxy based resin.

The study was conducted using the Zonare USS machine (Zonare Medical Systems, Inc. Mountain View California, USA) which is a standard hospital based ultrasound machine. This has a C4-1 Curved array transducer which has a bandwidth of 1-4MHz and provides an 80 degree viewing angle. The ultrasound exam mode was set to FAST scan at a depth of 16cm, in a standard 2D Abdominal B-mode.

There are other ultrasound machines available, particularly for the prehospital setting. The handheld scanners are the VScan (GE Healthcare, Chicago, USA), Philips Lumify (Amsterdam, Netherlands), Sonosite Sonoheart (Erlangen, Germany)

and Accuson P10 (Siemens, Munich, Germany). All of these provide point of care ultrasound and are lightweight. Limitations of them include a small screen with mediocre image quality as well as a short battery life compared to hospital machines⁽¹⁰³⁾.

3.2.3 To establish a rigorous FAST assessment tool

An assessment tool should be reliable, effective, objective, easy to deliver and repeatable by independent examiners⁽¹⁷¹⁾. Of the various FAST curricula available world-wide, there are different formats for assessing competency. These include a formal assessment through a clinical assessment or a simulator model, online review of normal and abnormal ultrasound images, workplace based assessments, auditing trainee error rates and reaching a predetermined number of performed scans.

The UK College of Emergency Medicine assessment form⁽⁸⁰⁾ asks the examiner, for each area of the FAST scan, if the image has been achieved by the trainee “yes/no” and to add any comments to be made about the scan performed. This was considered to be too subjective therefore a more robust objective format was developed. The outcomes that were being assessed included time to identify the pathology (Time 1), time to freeze the best image obtained (Time 2), total time taken to scan a region (Time 3), total time to complete FAST scan, number of errors made such as an inverse image, number of missed targets and image accuracy.

The accuracy of images obtained was verified by two independent expert radiologists who were blinded as to whether the subject was a

novice/intermediate/expert. Given that there is no validated scoring method available to verify the accuracy of ultrasound images, in conjunction with expert radiologists we devised a scoring tool that could be applied and then validated it. A mark of 0-4 was awarded based on whether the correct anatomy had been identified in that region and also for the quality of the image obtained as illustrated in *figure 3.3*.

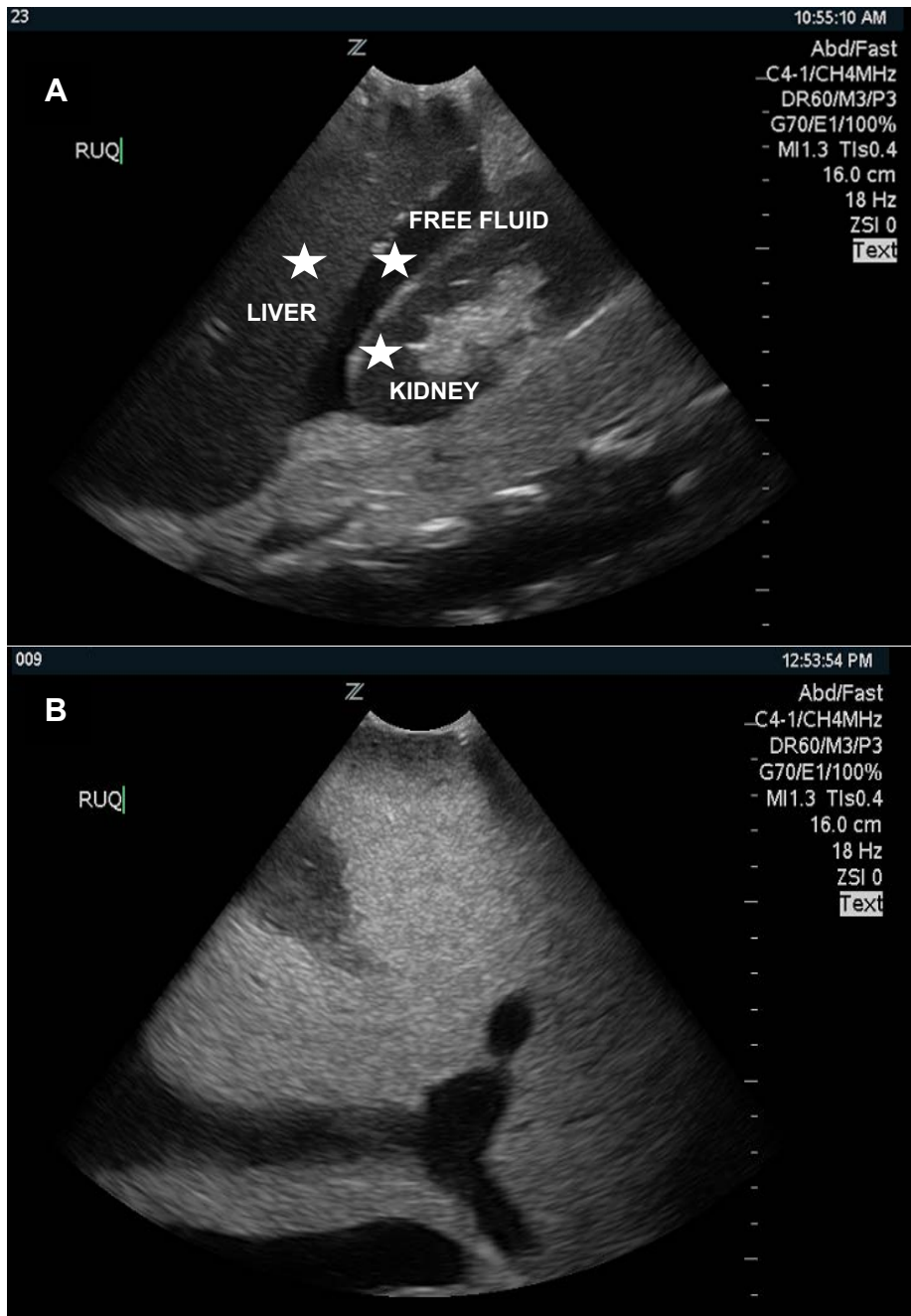


Figure 3.3 Ultrasound image of Morison's pouch with marks assigned. Participant A had full points awarded and Participant B had no marks assigned, the star represents a mark for the correct anatomy of Morison's pouch with a positive FAST scan result A) Liver=1, Kidney=1, Free fluid=1 and good image quality=1; Full 4 marks awarded B) Liver =0, Kidney=0, Free Fluid=0 and good image quality = 0; No points assigned.

3.2.4 Statistical analysis

Based on previous simulation studies a power calculation was performed on 10 subjects with a 2 tailed test, $\alpha=0.05$ and power $(1-\text{Beta}) = 0.8$ and a proposed 30% reduction in time taken to perform a FAST scan between experts and novices^(172, 173). This resulted in a minimum of 8 participants per group. The data is expressed as mean $\pm$ 1 standard deviation and median $\pm$ interquartile range. Construct validity was assessed using Mann-Whitney U test and Kruskal-Wallis test as appropriate and a $p<0.05$ was considered a significant result. The accuracy assessment was evaluated for inter-rater reliability using Kappa analysis. The statistical analysis was performed using IBM SPSS Statistics software (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). This study had ethical approval obtained from the Imperial College Research Ethics Committee.

3.3 Results

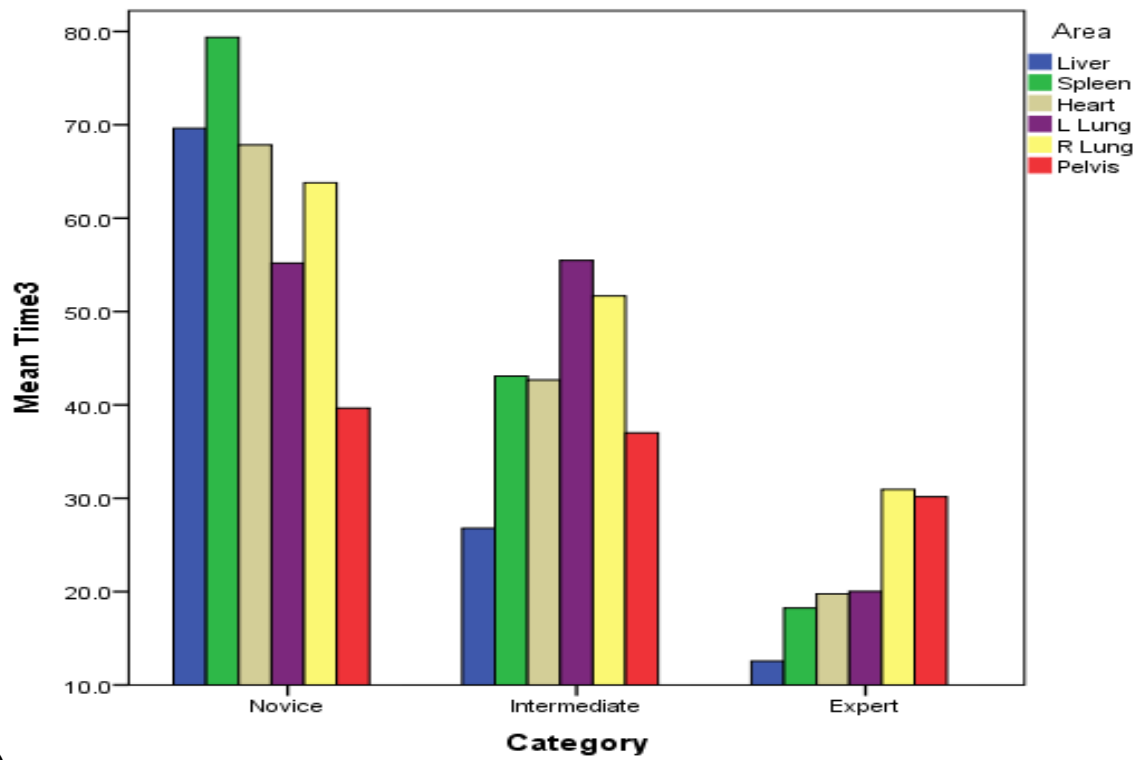
There were a total of 31 participants that consisted of 11 experts, 10 intermediates and 10 novices. The expert cohort had 4 Consultants from the Radiology, Emergency Department(ED) and Trauma specialities as well as 7 Senior Radiology Registrars. The experts had a mean of 5.68 ± 4.8 years of ultrasound experience. The intermediate group consisted of 6 ED registrars and 4 General Surgery Registrars. The Novice group were all Core Trainees in ED or General Surgery. The median number of ultrasound procedures previously performed by intermediates was 8 ± 23 with a range of 35 and experts 400 ± 670 with a range of 2900.

The Face and content validity questionnaire for the ultrasound phantom was completed by 11 experts. The marks (median score out of 5) were high across all categories, specifically the phantom was considered easy to use (5 ± 0.5), the anatomy (4 ± 0), feel (4 ± 1), pressure (4 ± 0.5), angle of the probe (4 ± 1.5) were considered lifelike and it was deemed as a useful training tool (5 ± 1); with an overall realism mark (median score out of 10) of 8 ± 1.5 on a Likert scale.

There was a significant difference in time taken to identify an abnormality (Time 1) and total time to perform a FAST scan across cohorts ($p<0.001$). There was no significant difference in time taken to freeze the image (Time 2) between groups ($p=0.646$). Inter-group analysis for Time 3 identified a significant difference between novice vs. experts ($p<0.001$) and intermediates vs. experts ($p<0.001$) but no significant difference between novice vs. intermediates ($p=0.174$). Further analysis of Time 3 identified that novices were taking much longer to scan the liver and spleen; Intermediates were taking the most time to scan the lung bases (*Figure 3.4, Table 3.1*).

There was a significant difference in missed targets and errors made across cohorts and in the inter-group analysis ($p<0.001$). Novices and intermediates missed and made the most errors when scanning the lung bases. Also, novices missed the spleen most often during their scan (*Figure 3.4b*). Experts did not miss any targets and made no errors when performing the FAST scan.

a)



b)

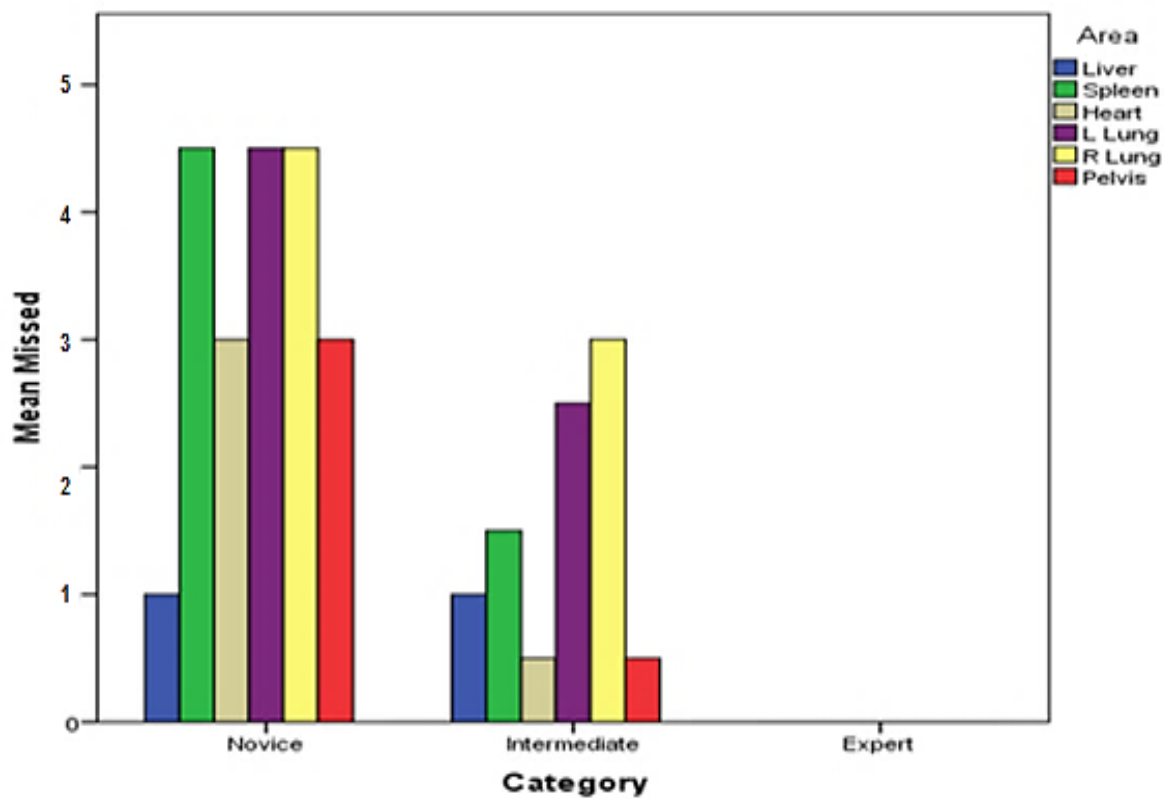
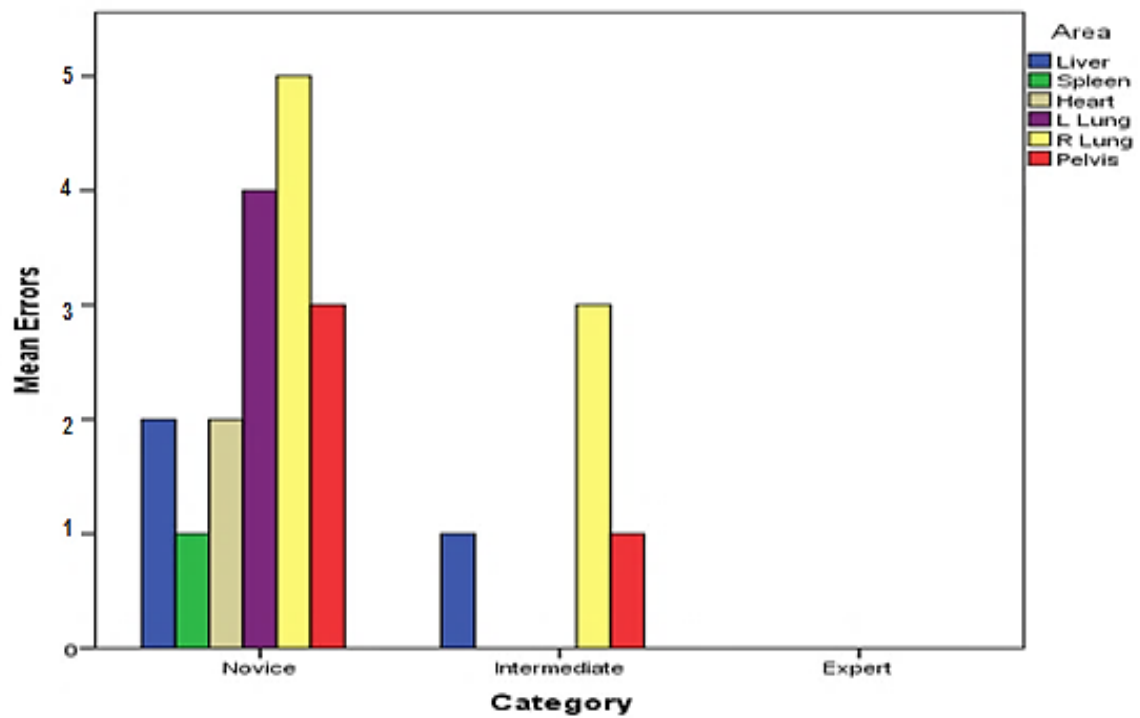


Figure 3.4 a) Mean of Time 3 (seconds) to scan each area per Category b) Mean Missed targets in each area per category

c)



d)

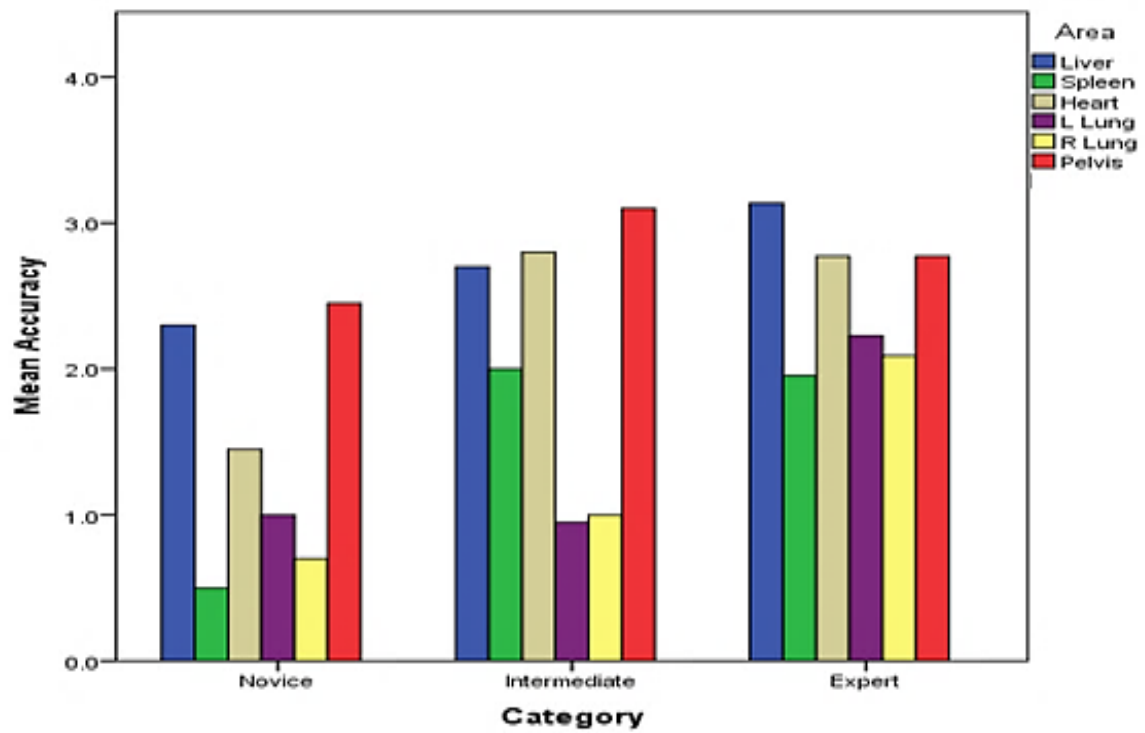


Figure 3.4 c) Mean Errors in each area per category d) Mean Accuracy score in each area per category

Mean Time3 (seconds)						
	Liver	Spleen	Heart	L Lung	R Lung	Pelvis
Novice	70	79	68	55	64	40
Intermediate	27	43	43	55	51	37
Expert	12	18	20	20	31	30
Mean Missed Targets						
	Liver	Spleen	Heart	L Lung	R Lung	Pelvis
Novice	1	4.5	3	4.5	4.5	3
Intermediate	1	1.5	0.5	2.5	3	0.5
Expert	0	0	0	0	0	0
Mean Errors						
	Liver	Spleen	Heart	L Lung	R Lung	Pelvis
Novice	2	1	2	4	5	3
Intermediate	1	0	0	0	3	1
Expert	0	0	0	0	0	0
Mean Accuracy						
	Liver	Spleen	Heart	L Lung	R Lung	Pelvis
Novice	2.3	0.4	1.5	1	0.7	2.5
Intermediate	2.7	2	2.8	0.9	1	3.1
Expert	3.2	2	2.8	2.2	2.1	2.8

Table 3.1 Summarised Table of Results: Mean of Time 3 (seconds) to scan each area per Category, Mean Missed targets in each area per category, Mean Errors in each area per category, Mean Accuracy score in each area per category

Two independent expert radiologists scored the images for accuracy. The Kappa analysis score of 0.72 ($P < 0.001$) specified a good level of agreement between the scores of the radiologists. There was a significant difference in the accuracy of images obtained across groups and in the inter-group analysis ($p < 0.001$). Specifically, novices, as well as intermediates, scored the lowest marks for images obtained at the lung bases and spleen (*Figure 3.4d*).

3.4 Discussion

Criticisms of FAST such as a steep learning curve to gain proficiency, as well as the lack of a standardised curriculum and assessment, have to be addressed^(2, 3). This study has established the validity of a FAST phantom that has the potential to accelerate novices up the learning curve and could provide benefit in establishing a diagnosis in the pre-hospital and hospital setting. The experts scored the phantom high in face and content validity across all categories and considered it to be a useful simulation tool. In terms of construct validity, the experts performed the FAST scan faster, with more accuracy and fewer errors than other groups. Hence time, accuracy, missed targets and errors are useful metrics for construct validity and can be used in future studies to aid differentiation of skill level.

There were common areas where intermediates and specifically novices were having difficulty. These were the lung bases and the spleen. Both the novices and intermediates were the slowest, least accurate and either missed or made the most errors in these regions. The main reason for the errors made by novices and intermediates seemed to be due to incorrect probe position with the image viewed

consisting of the wrong anatomy rather than not being able to recognise fluid that all participants managed to do with ease. This is useful to know as subsequent training could focus on these sections to ensure that future performance improves. This study has also demonstrated a method for assessing FAST performance on a simulator in an objective manner that has been validated by experts and can differentiate proficiency. This could be a more robust means of FAST assessment than current formats available^(80, 174).

Further areas of research include a more detailed analysis of expert performance which will be conducted in Chapter 4. Specifically where the expert places the probe on the phantom and the amount of force applied to gain the correct image. This knowledge of expert performance taught to novices may allow them to advance up the learning curve faster and will be examined in Chapter 5. A learning curve assessment of novices could also be performed to identify how many training sessions are required in order to gain benchmark competency. Predictive validity could ascertain how accurate the translation of the validated phantom is to the trauma patient.

There were limitations of this study namely the participants had been categorised based upon a broad differentiation of experience. The median ultrasound experience for intermediates was 8 ± 23 with a range of 35 and experts 400 ± 670 with a range of 2900. This wide disparity meant that the intermediates may have lacked enough experience as reflected in Time 3 where no significant difference was found between them and novices. Moreover based upon our expert cohort experience, the criteria for categorisation of more than 100 scans may have been too low. However, as no

standard method existed prior to the study, this was our best guide for FAST experience at that time. A further study could evaluate an intermediate group with more experience and raise the entry criteria for the expert category to ensure better differentiation of skill. Also assessing Time 2 which was the time to freeze the most accurate image of the area of interest may not have been a useful evaluation metric as no significant difference was found between groups.

With regards to FAST, a well-known limitation is the broad range of sensitivity (range 26% to 92%) as it is highly dependent upon operator skill⁽¹⁷⁵⁾, although the specificity (range 95% to 100%) is more accurate^(81, 82, 84, 176). It is also important to note that FAST does not exclude pathology and is not to be seen as a replacement for a CT scan⁽³⁾. This is especially true in injuries involving hollow viscus structures and the retroperitoneum^(76, 77, 84). Another shortcoming of FAST is that it is difficult to gain adequate images, even in experienced hands, in patients who are obese, those with subcutaneous emphysema^(177, 178) and its role in pelvic fracture remains unclear^(84, 179, 180).

3.5 Conclusion

Haemorrhage identification in trauma care remains a high priority^(18, 19). FAST offers a rapid, practical means of detecting bleeding within the torso and is particularly suited for prehospital care. This study has addressed some of the criticisms of FAST such as the lack of a standardised assessment^(2, 3). It has established the face, content and construct validity of a FAST phantom, which has the potential to accelerate training for novices in a safe, supportive environment. Additionally it has demonstrated a rigorous objective method for FAST assessment that has proven to be effective.

Chapter 4 The Ergonomics of Ultrasound Probe Manipulation

Hypothesis: An Expert's FAST performance can be deconstructed to identify the objective metrics of an ideal scan.

4.1 Introduction

Learning FAST, as with any new skill, requires extensive practice. Criticisms levelled against it include a steep learning curve to gain competency^(2, 3). This could be overcome by evaluating experts. An expert has focused observation skills with an extensive knowledge base and they use forward directed reasoning to solve problems. In the performance of a procedure, they have economy of movement, are able to self-regulate themselves and can anticipate and correct their own errors⁽¹⁸¹⁾.

Ergonomics is the study of an expert to better understand the efficiency of their movements. Areas where experts have been studied include laparoscopic surgery where common characteristics of proficiency have been identified. Hofstad et al⁽¹⁸²⁾ identified that expert surgeons performing minimally invasive surgery in a simulator had a shorter path length and were faster than novices in completing the task. Similarly, Shanmugan et al⁽¹⁸³⁾ identified in a LAP Mentor model that accuracy and path length were the most discriminatory markers between an expert and a novice.

Maslow⁽¹⁸⁴⁾ described four stages of learning from unconscious incompetence through to unconscious competence, which is the level where experts perform as

they have developed automaticity in their skill. Due to their unconscious competence, experts may have difficulty in teaching others how they can repeatedly perform at a high level. Hence to train novices, an expert performance has to be deconstructed into its basic blocks to unravel the critical steps. Once these have been identified they can then be taught to trainees to aid learning.

Aims

The aim of this study was to determine how the ergonomics of probe manipulation differ between experts and novices during a FAST performance.

4.2 Methods

4.2.1 Ultrasound probe

The ultrasound probe was mounted on an aluminium plate with a pair of sliding rails and a plastic outer casing (*Figure 4.1*). A metallic rod was sited on the casing to support a cubic rigid body that housed 12 infrared optical markers. These markers are processed by the Optotrak Certus system (NDI, Ontario, Canada) which records the dynamic position of the handheld probe in 3D space at a mean frequency of 40Hz in real-time with spatial accuracy of up to 0.1mm and resolution of 0.01mm. The data from the Optotrak was analysed in MATLAB (MATLAB and Statistical Toolbox Release 2012b, The MathWorks, Inc., Natick, Massachusetts, United States).

4.2.2 Registering of anatomical landmarks on the phantom and recording volume cone charts

In order to depict the volume covered by participants during a FAST scan, two sets of recordings were made. One was of the phantom itself and the other set was the hand motion of the participants during FAST. The data was logged from the 12 infrared optical markers housed on the cubic rigid body above the ultrasound probe (*Figure 4.1*) by the Optotrak Certus system.

Landmarks on the phantom were registered by fixing the probe at 90 degrees in the vertical plan to each relevant area. The optical markers were recorded at this point in 3D space by the Optotrak Certus system and logged in MATLAB. The anatomical landmarks recorded were the bilateral acromions, suprasternal notch, bilateral anterior superior iliac spines (ASIS), bilateral greater trochanters and symphysis pubis. This allowed fixed points to be mapped out which corresponded with the outline of the phantom as depicted in *Figure 4.2a*. During the participants FAST scan, hand motion was tracked by the Optotrak Certus System registering the 3D position of the 12 optical infrared markers (*Figure 4.2b*). The data was then processed through MATLAB to portray the 3D volume of hand motion during FAST, in relation to the fixed anatomical landmarks of the phantom and this is illustrated in *Figure 4.2c, d*. Once this registration process had been completed the Optotrak and phantom were fixed to the ground, to ensure no movement occurred. The experimental setup is demonstrated in *Figure 4.3*.



Figure 4.1 The ultrasound probe. The image on the left shows the ultrasound probe inside a plastic casing with a cubic rigid body that housed the 12 infrared optical markers. The force sensors are highlighted in the image on the right. ⁽⁸⁾.

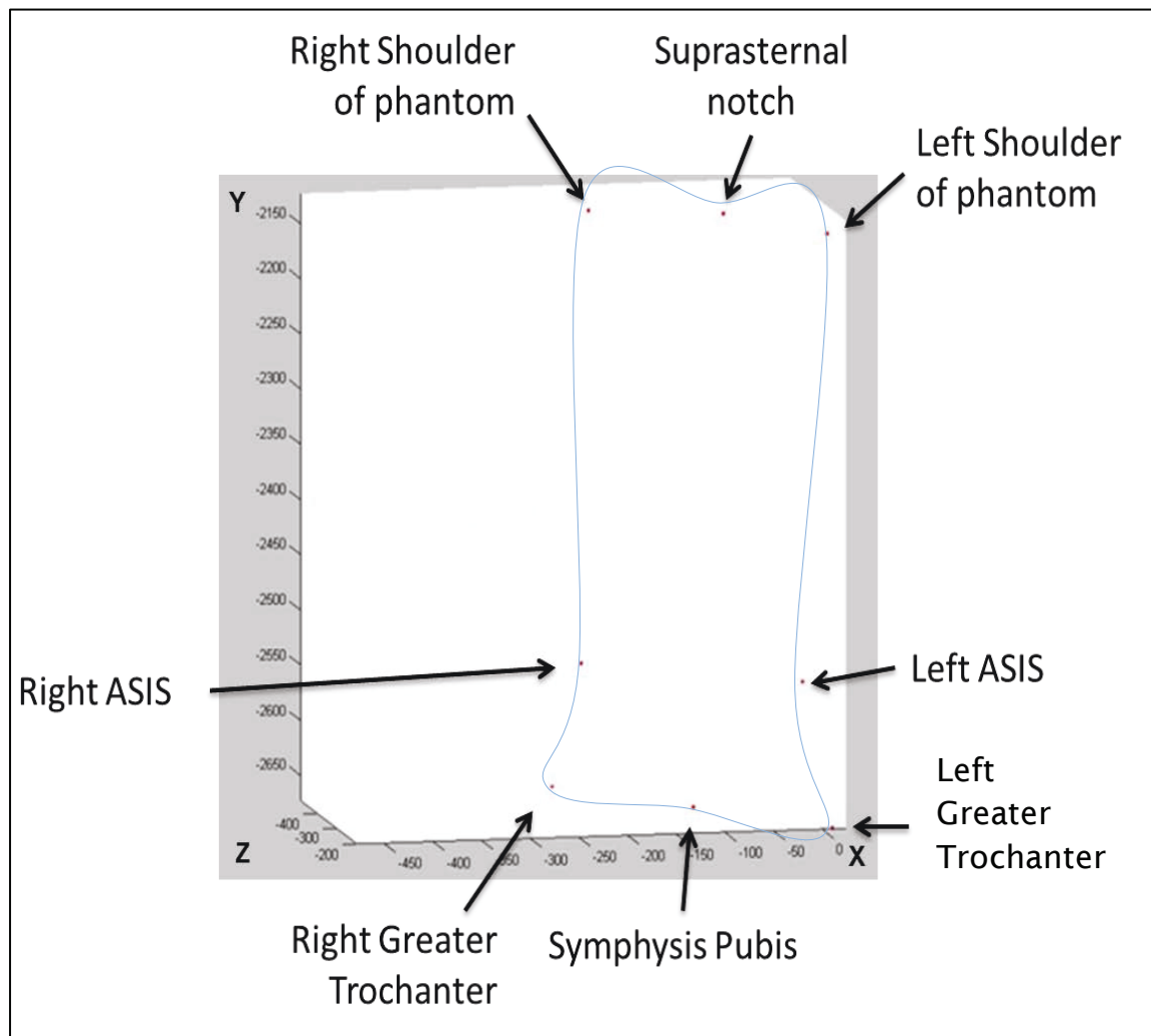


Figure 4.2a) Anatomical landmarks of the phantom marked with a red dot recorded with the infrared optical markers and the Optotrak captured in MATLAB. The 3D axis is labelled X, Y and Z respectively

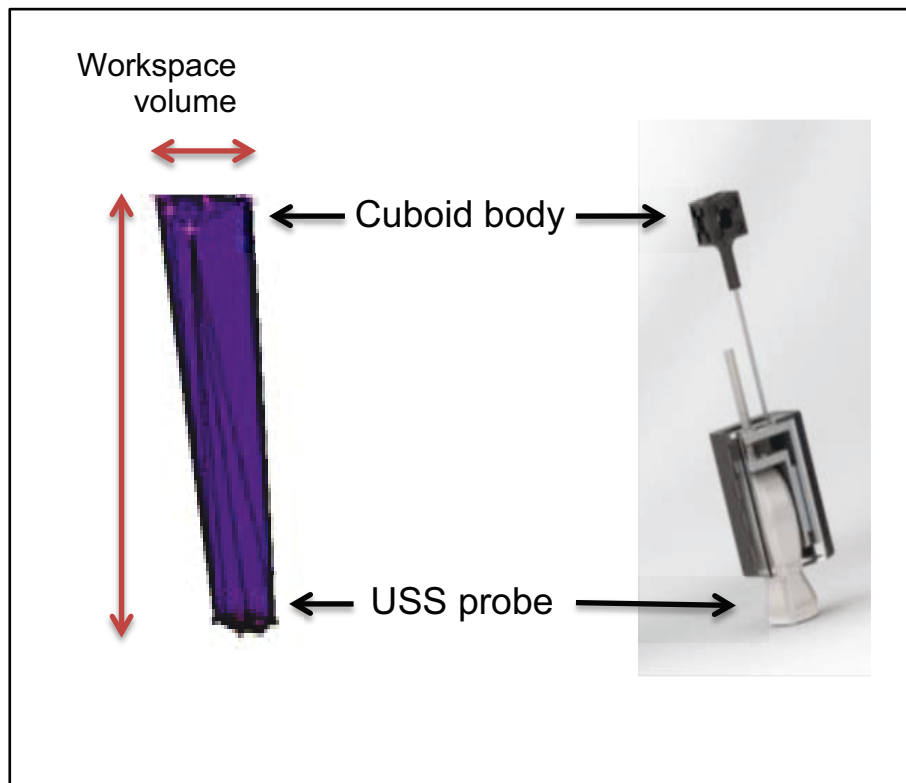


Figure 4.2b) Blown up image of a volume cone chart profile to depict its relation to the USS probe. The violet area marked with red arrows represents the workspace volume.

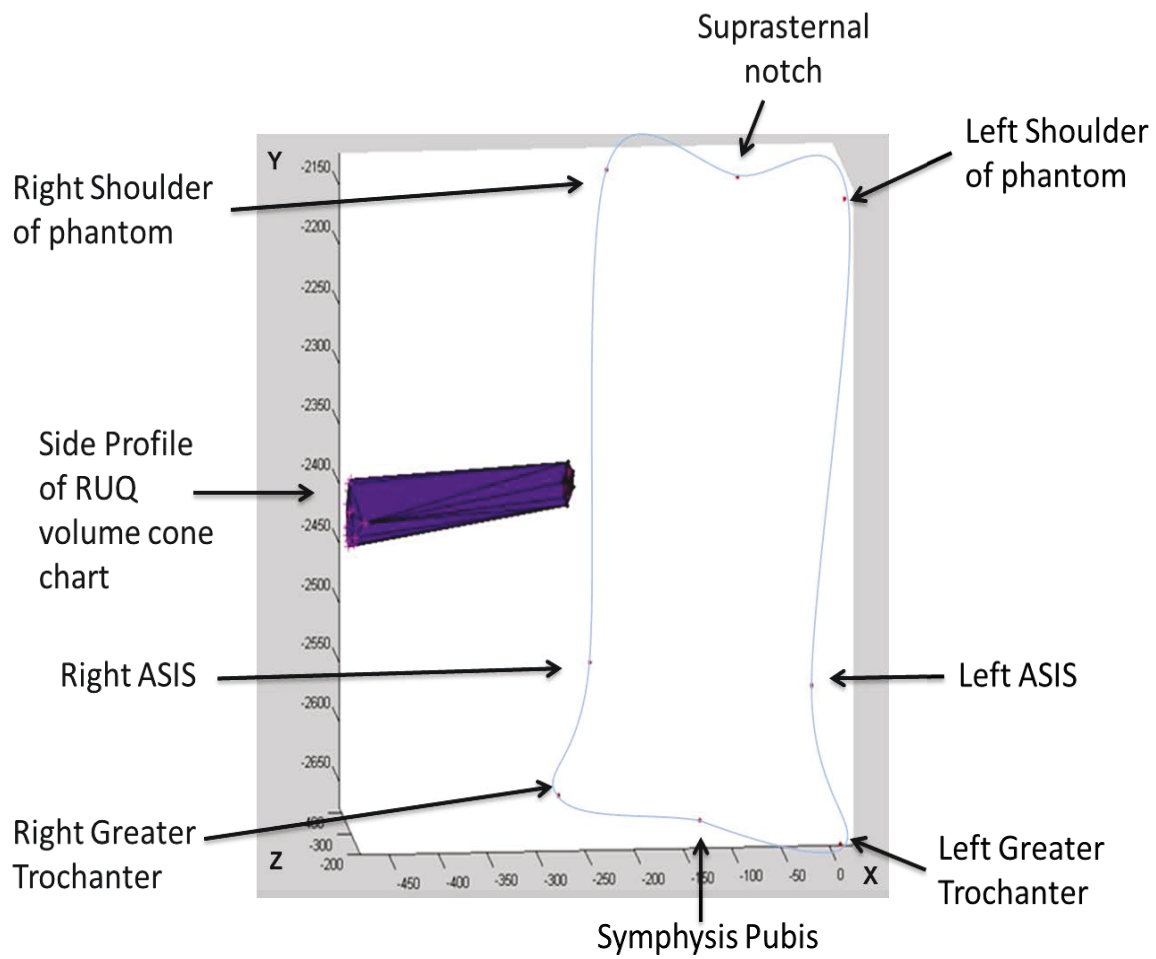


Figure 4.2c) Side profile of a volume cone chart in relation to the phantom's anatomical landmarks. The 3D axis is labelled X, Y and Z respectively.

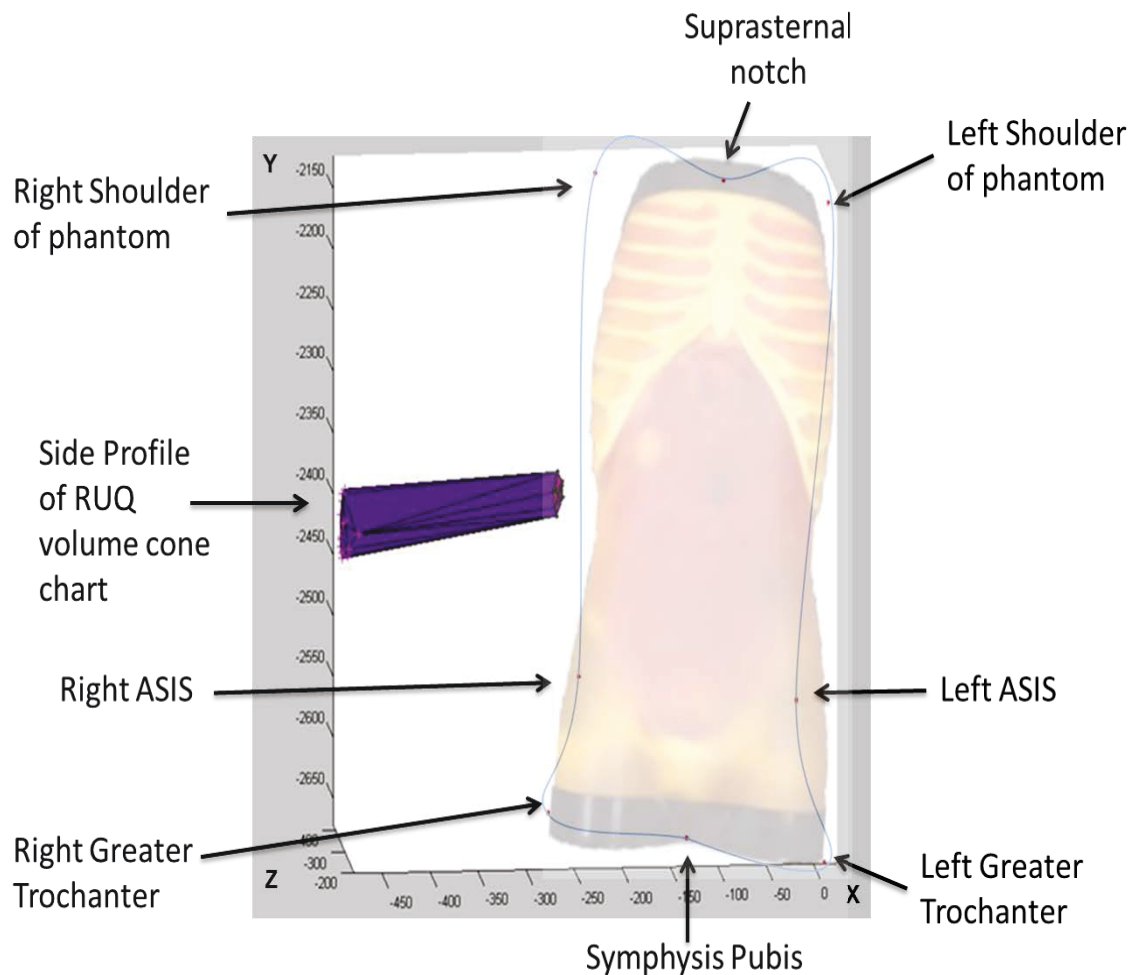


Figure 4.2d) Side profile of a Right Upper Quadrant (RUQ) volume cone chart in relation to the Kyoto phantom superimposed picture. The 3D axis is labelled X, Y and Z respectively.

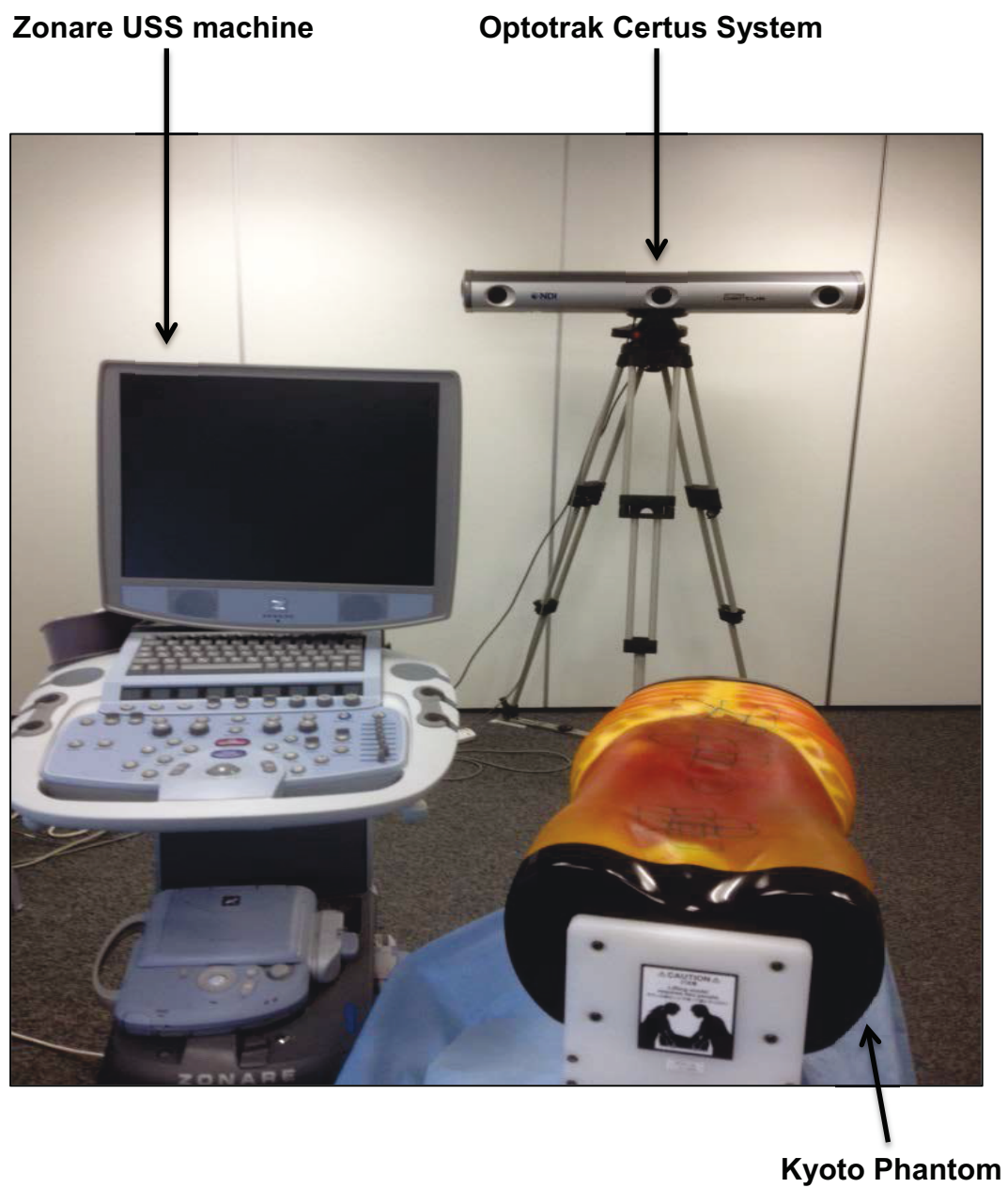


Figure 4.3 The experimental setup with the Kyoto phantom, Zonare ultrasound machine in the foreground and the Optotrak Certus System in the background

4.2.3 Validating the force sensor

In performing a FAST scan, variable amounts of force need to be applied in certain regions in order to gain the correct image. This is imperative in the pericardial view because a trauma patient identified to have a cardiac tamponade would need urgent management to release the blood in the pericardial sac. In order to recognise this critical pathology, adequate force needs to be applied in this area of the FAST scan to ascertain the correct view. Therefore, it is important to record this metric so that the ideal force for each FAST region can be quantified.

The force sensor is sited in the housing of the ultrasound probe as depicted in *figure 4.1*. When the probe makes contact with the phantom the rails allow the probe to engage with two force sensors (Honeywell FSG-15N1A) along the longitudinal axis of the transducer in 1 Degree of Freedom (DoF) . An Atmel based microcontroller was used to amplify and digitise the force sensor results which were analysed with Microsoft Excel (Microsoft. Microsoft Excel. Redmond, Washington: Microsoft, 2009. Computer Software)⁽⁸⁾. Validating the force sensor required applying weights to the tip of the probe from 0.1 to 5kg. The sensor results were calibrated to ensure that 0.1kg represented 1 Newton and this was continued incrementally until 5kg was reached. This validation process ensured the accuracy of the force sensors and was verified before the participants performed their procedure.

4.2.4 Participant recruitment and training

All participants gave their informed consent as well as providing demographic information. An experts performance was compared to novices for benchmarking purposes. The same criteria as previously described were used to select participants and train novices (Chapter 3.2). Participants were then tasked to perform FAST, capture an accurate image of the anatomy in each region and to state if pathology was present (*Figure 3.1*). All images were saved for further accuracy assessment. Within each region, the participants hand motions were tracked in 3D space using an Optotrak Certus System (NDI, Ontario, Canada) in addition to their force applications on the probe using a force sensing rig. All participants repeated the FAST scan three times to ensure reproducibility as well as attain a mean of their performance.

4.2.5 Assessment criteria

Every participant was evaluated by the following criteria in each region:

1. The volume covered by the probe in contact with surface of the phantom
2. The volume covered by the entire workspace
3. Force
4. Time and the validated accuracy scoring method was used in this study as previously described (Chapter 3.2.3)

The Zonare USS machine and simulator previously described ("FAST/ER FAN" Kyotokagaku Ltd) were used in this study (*Figure 3.1*).

4.2.6 Statistical analysis

The data is expressed as mean $\pm$ 1 standard deviation and median $\pm$ interquartile range. The results were assessed using Mann-Whitney U test, Chi-Square and Kruskal-Wallis test as appropriate and a $p < 0.05$ was considered a significant result. Kappa Analysis was used to assess inter-rater reliability accuracy scores. The statistical analysis was performed using IBM SPSS Statistics software (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). This study had ethical approval obtained from the Imperial College Research Ethics Committee.

4.3 Results

There were a total of 14 participants recruited, split equally between experts and novices. The expert cohort consisted of 4 consultants from radiology, emergency department and trauma as well as 3 senior radiology registrars. The mean ultrasound experience was 4.1 ± 3.1 years with a median of 500 ± 225 procedures performed. The novices had no prior experience with ultrasound.

4.3.1 Time

Experts were significantly faster than novices at identifying an abnormality (Time1), gaining the most accurate image (Time 2), time per area (Time 3) and total time for FAST scan ($P < 0.001$). For time per area, experts were similar in all areas whereas

novices showed a wide variation and took the longest in scanning the heart, lung bases and the Left Upper Quadrant (LUQ) (*Figure 4.4*).

4.3.2 Missed Areas, Errors and Accuracy

Experts did not miss any targets and made no errors ($P < 0.001$). Novices missed the bilateral haemothorax as well as the cardiac tamponade most often. They also made the most errors in these regions such as getting an inverse image of the pathology.

Two radiologists separately scored each image for accuracy with good inter-rater agreement ($\text{Kappa} = 0.6$, $P < 0.01$). Experts had a high degree of accuracy in all areas whereas novices scored significantly lower ($P < 0.001$) with the lowest marks at the lung bases and heart (*Figure 4.5*).

As stated in the previous chapter, time and the validated metrics differentiated the experts and the novices. To better understand why this is the case a more detailed analysis of workspace and force had to be conducted, the results of which are presented henceforth.

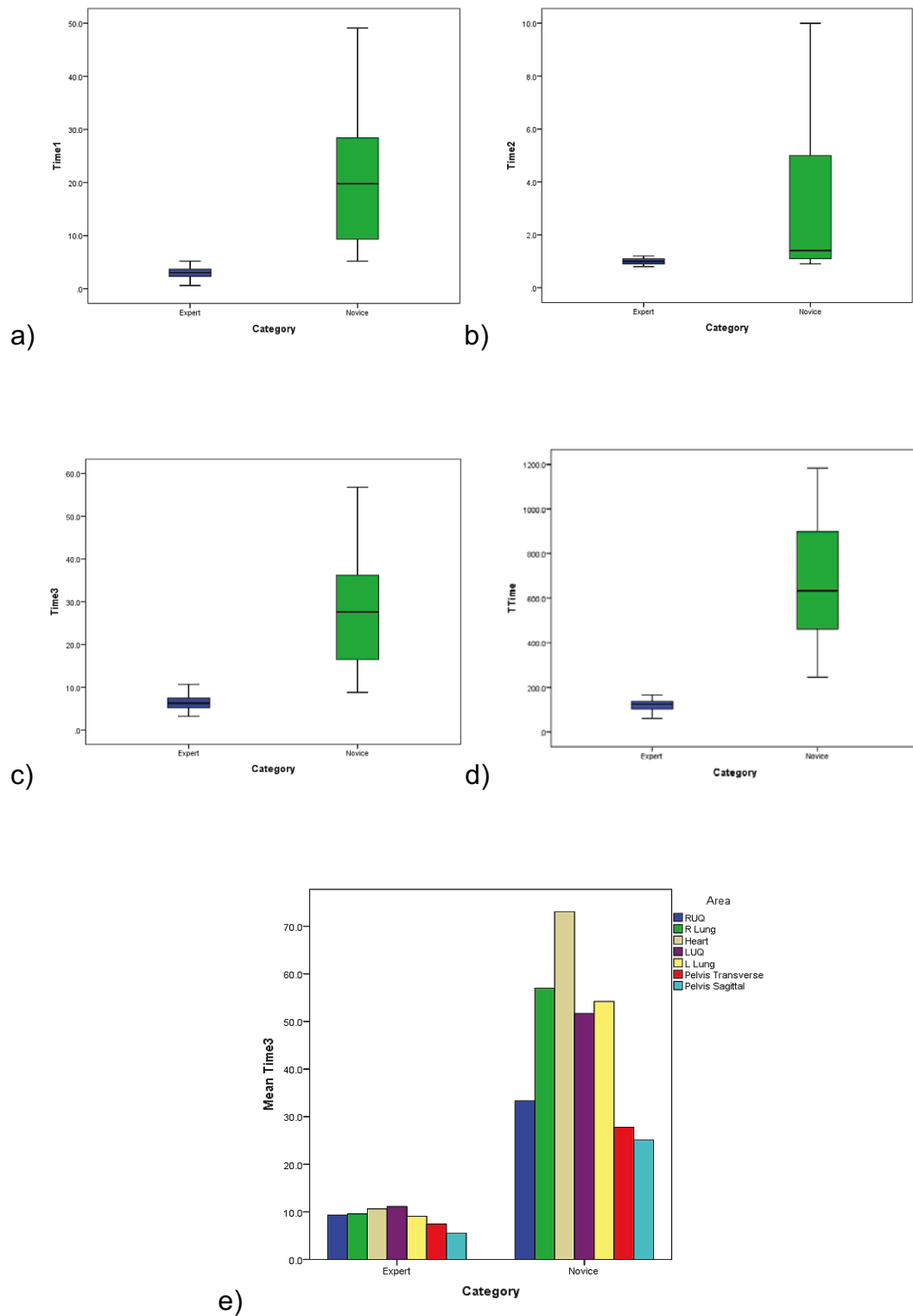


Figure 4.4 Expert vs. Novice Time (Secs) a) To identify an abnormality (Time1) b) To gain the most accurate image (Time 2) c) Per area (Time 3) d) Total Time to perform FAST e) Mean time per area

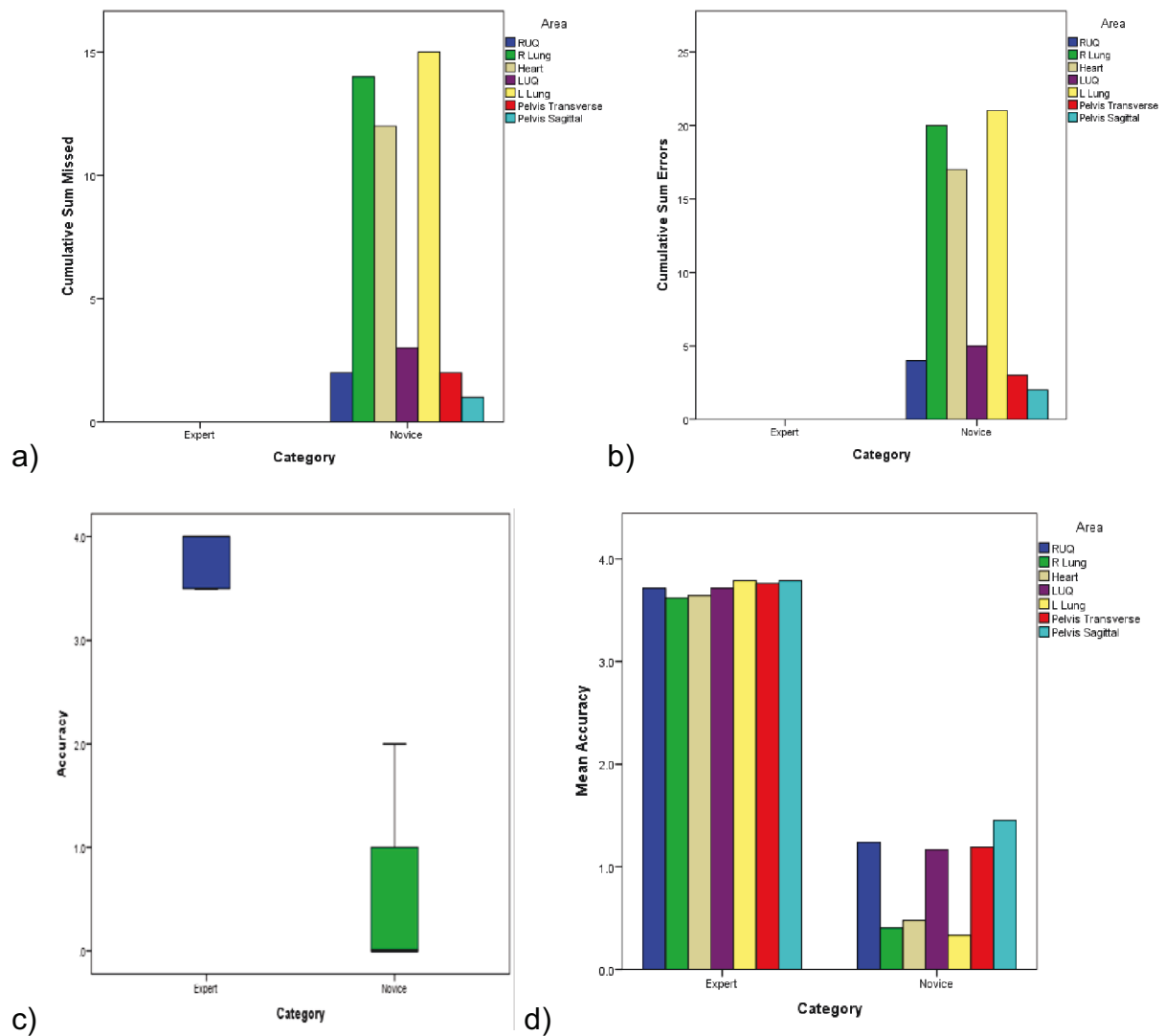
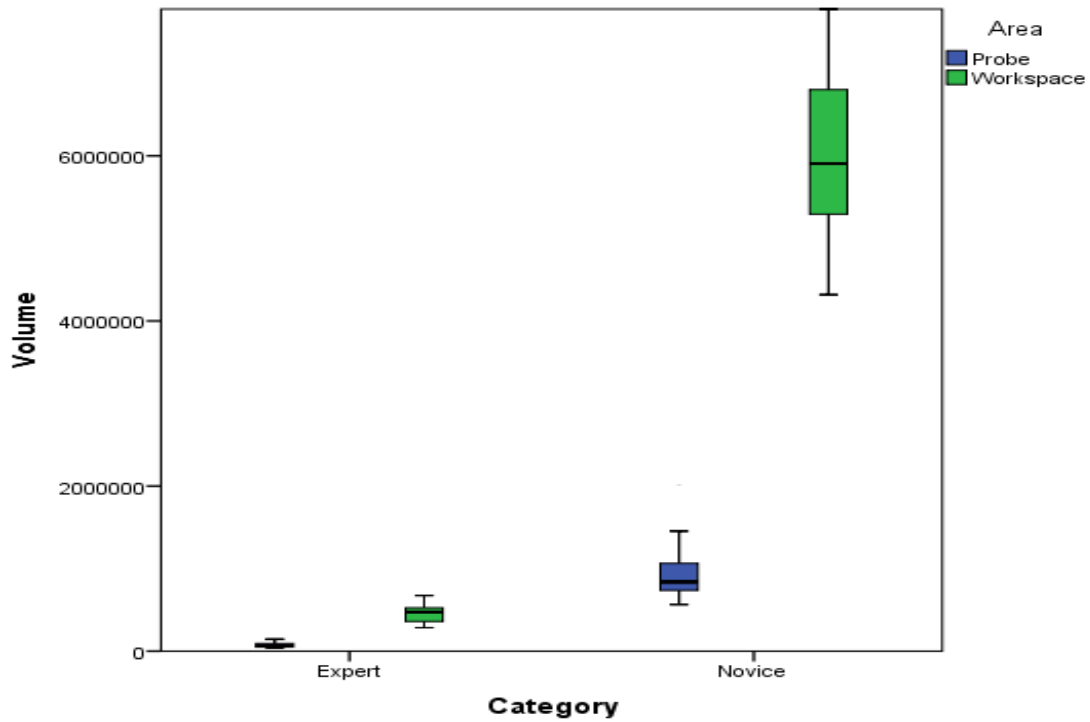


Figure 4.5 Expert vs. Novice Missed Targets, Errors and Accuracy a) Cumulative Sum Missed targets per area b) Cumulative Sum Errors per Area c) Mean Total Accuracy score d) Mean Accuracy score per Area

4.3.3 Workspace

Experts had a significantly smaller workspace than novices and this applied to the area covered by the probe as well as the total workspace volume (*Figure 4.6a*) ($P < 0.001$). When volume analysis was examined by region, experts were uniform in all areas whereas the novice performance varied per region with the largest workspaces associated with the heart, LUQ and lung bases (*Figure 4.6b*).

a)



b)

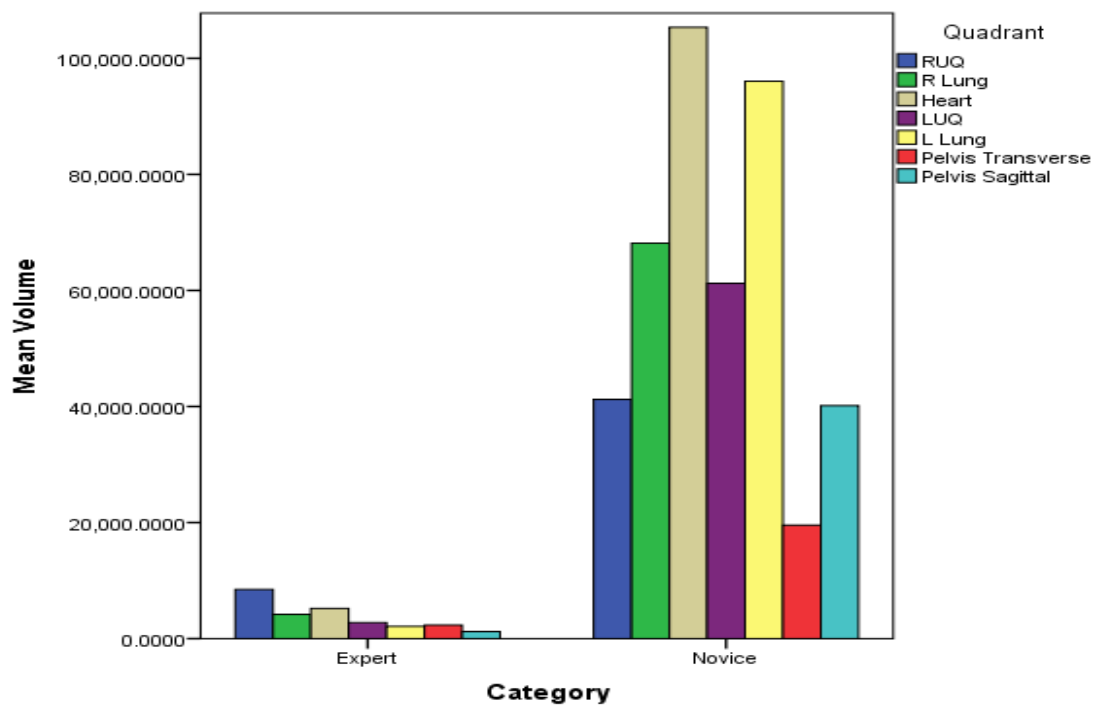


Figure 4.6 Workspace Volume (mm³) Expert vs. Novice a) Volume by probe and total workspace b) Volume per Region

4.3.4 Volume Cone charts

The 3D data recorded by the Optotrak Certus System was analysed through MATLAB to depict the volume covered by participants for each region of the FAST in relation to the fixed landmarks of the phantom. There is a clear difference between experts who have a very tight workspace centred precisely over the area of interest as compared to novices who have a much wider workspace and this disparity is illustrated in *figure 4.7*. It is also easier to visualise where the novices were having the most difficulty with larger workspaces associated with the heart, LUQ and lung bases.

a)

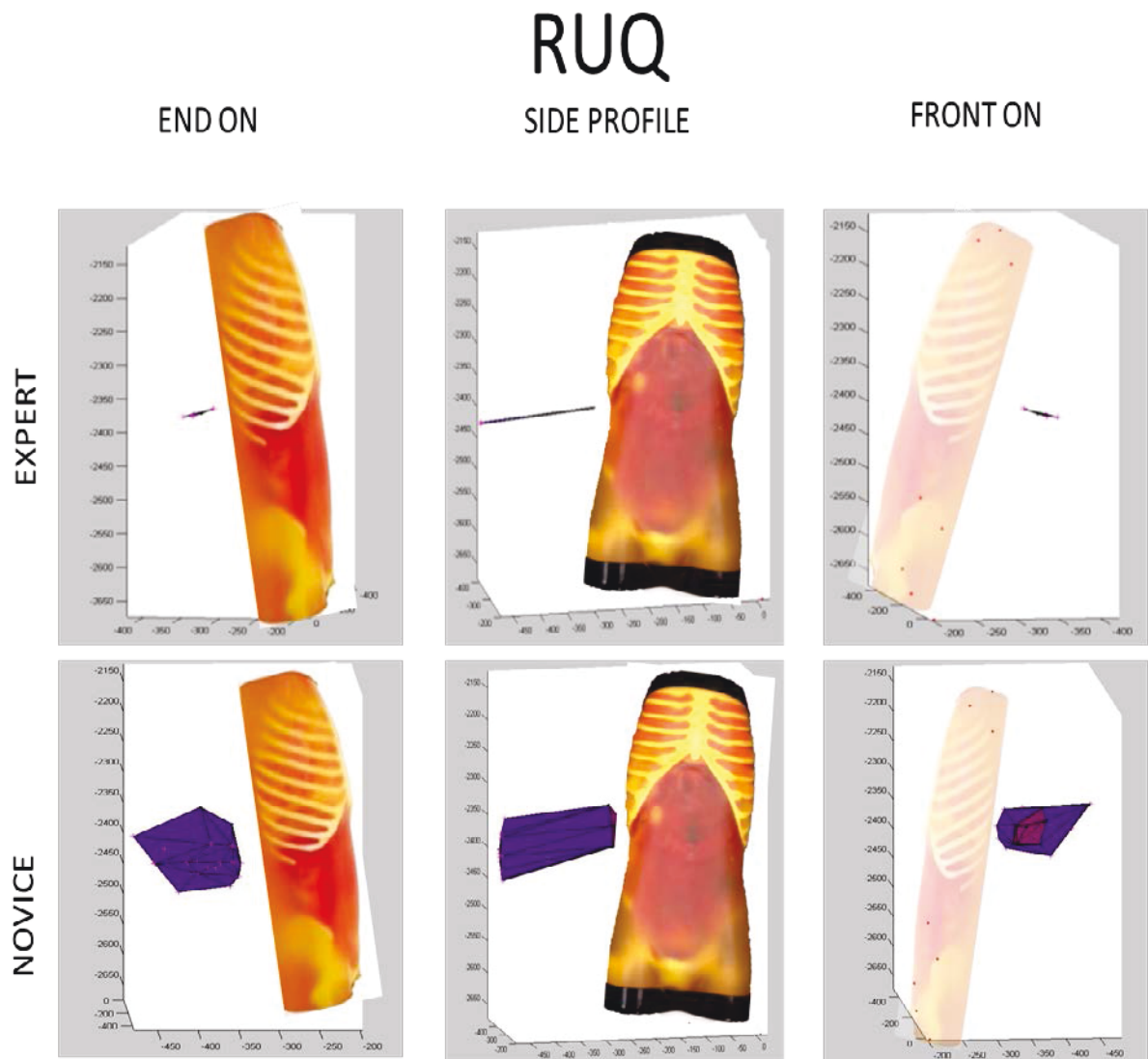


Figure 4.7 Volume Cone Charts for each region of the FAST scan. Expert volume cone charts are on the top row and Novice volume cone charts are on the bottom row. Each profile is a 90-degree turn of the last column. The end on profile is the user perspective and the front on profile is with the probe face towards the reader. The ultrasound probe face is magenta in colour on the cone chart. The workspace cone chart is coloured in violet a) Right Upper Quadrant b) Right Lung base c) Heart d) Left Upper Quadrant e) Left Lung base f) Pelvis Transverse g) Pelvis Sagittal

b)

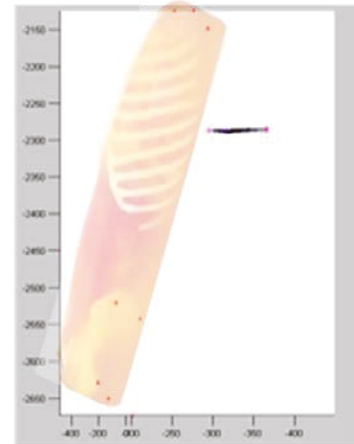
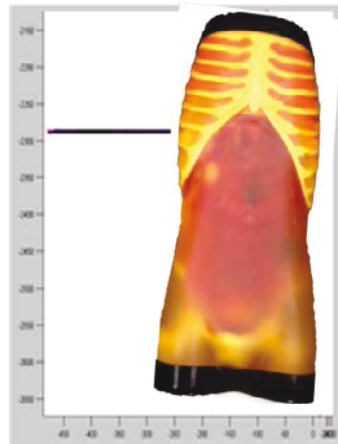
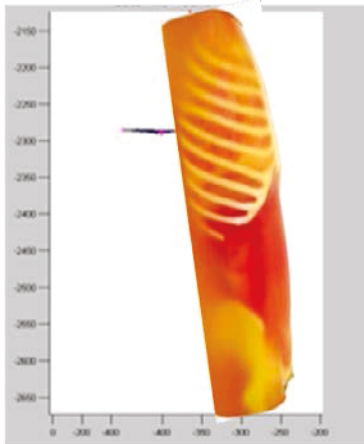
Right Lung

END ON

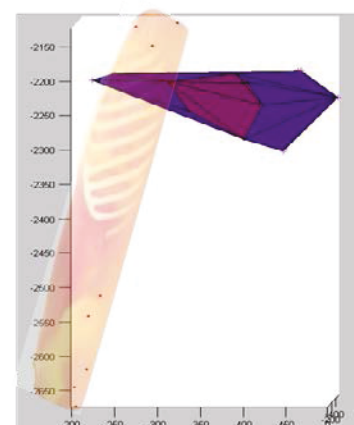
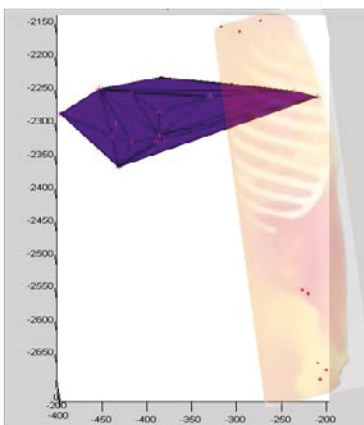
SIDE PROFILE

FRONT ON

EXPERT



NOVICE



c)

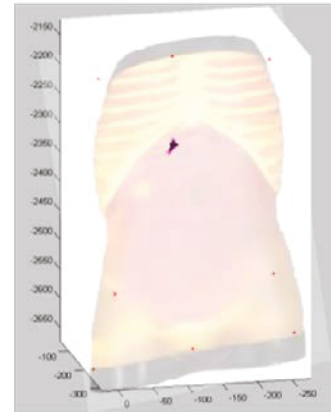
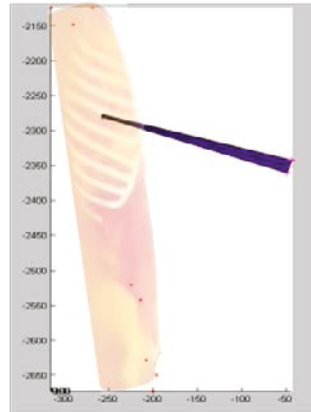
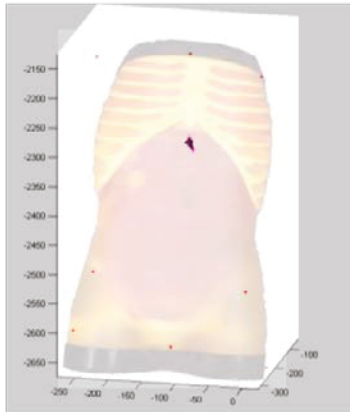
Heart

END ON

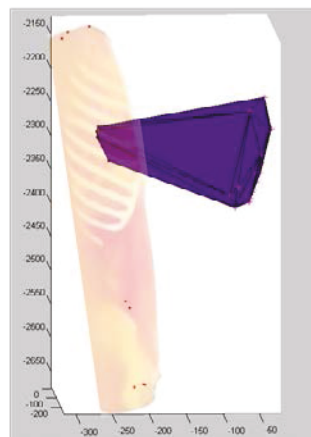
SIDE PROFILE

FRONT ON

EXPERT



NOVICE



d)

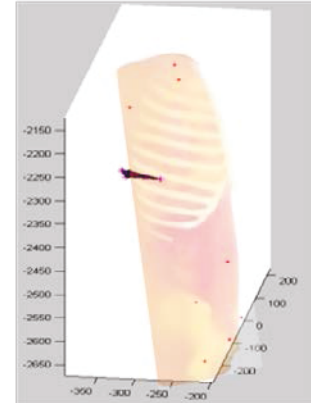
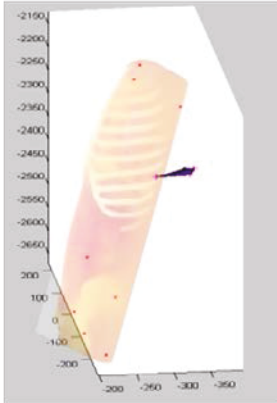
LUQ

END ON

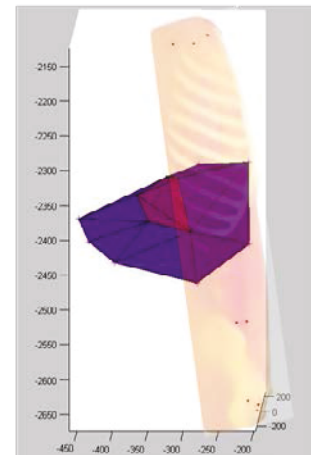
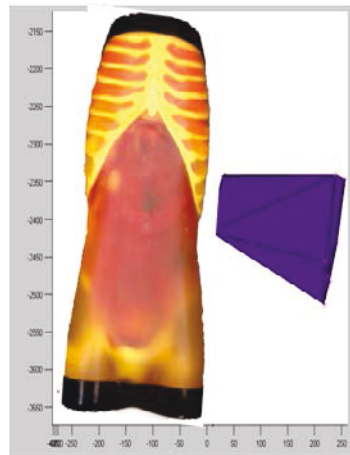
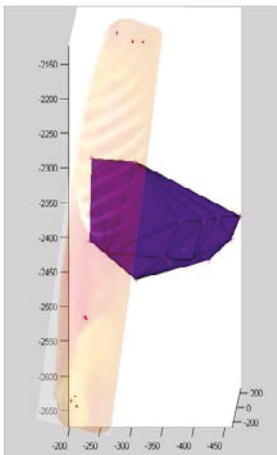
SIDE PROFILE

FRONT ON

EXPERT



NOVICE



e)

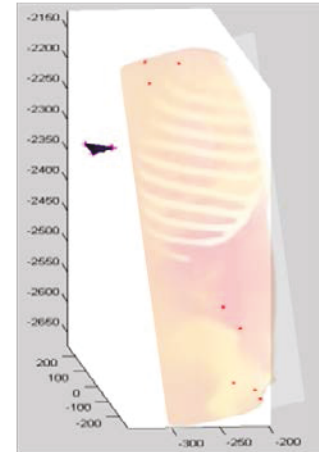
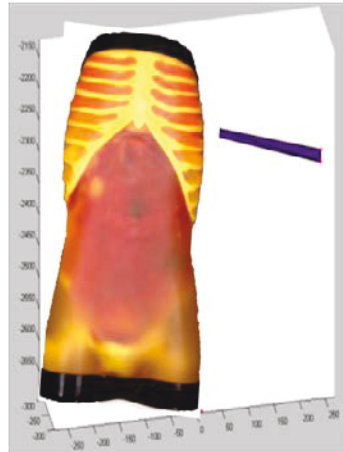
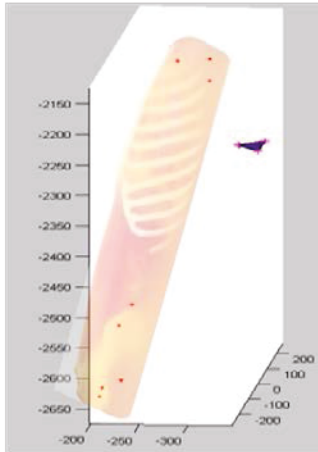
Left Lung

END ON

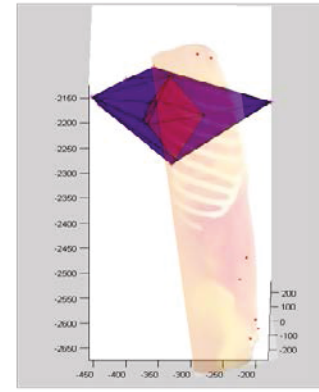
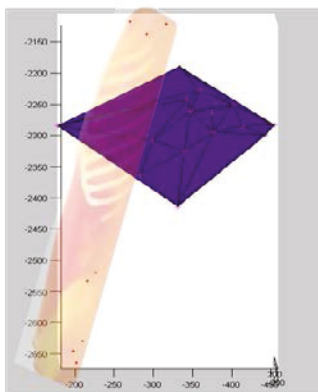
SIDE PROFILE

FRONT ON

EXPERT

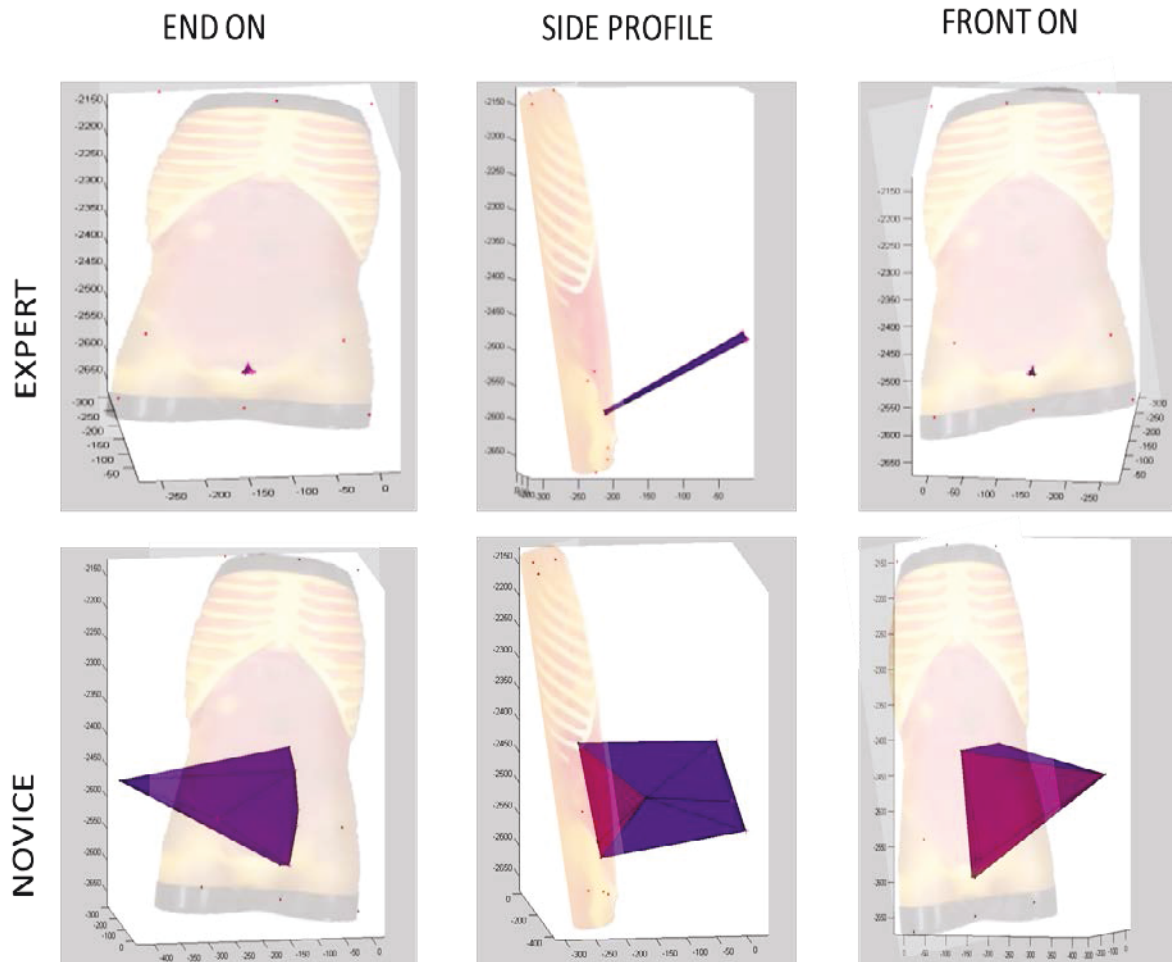


NOVICE



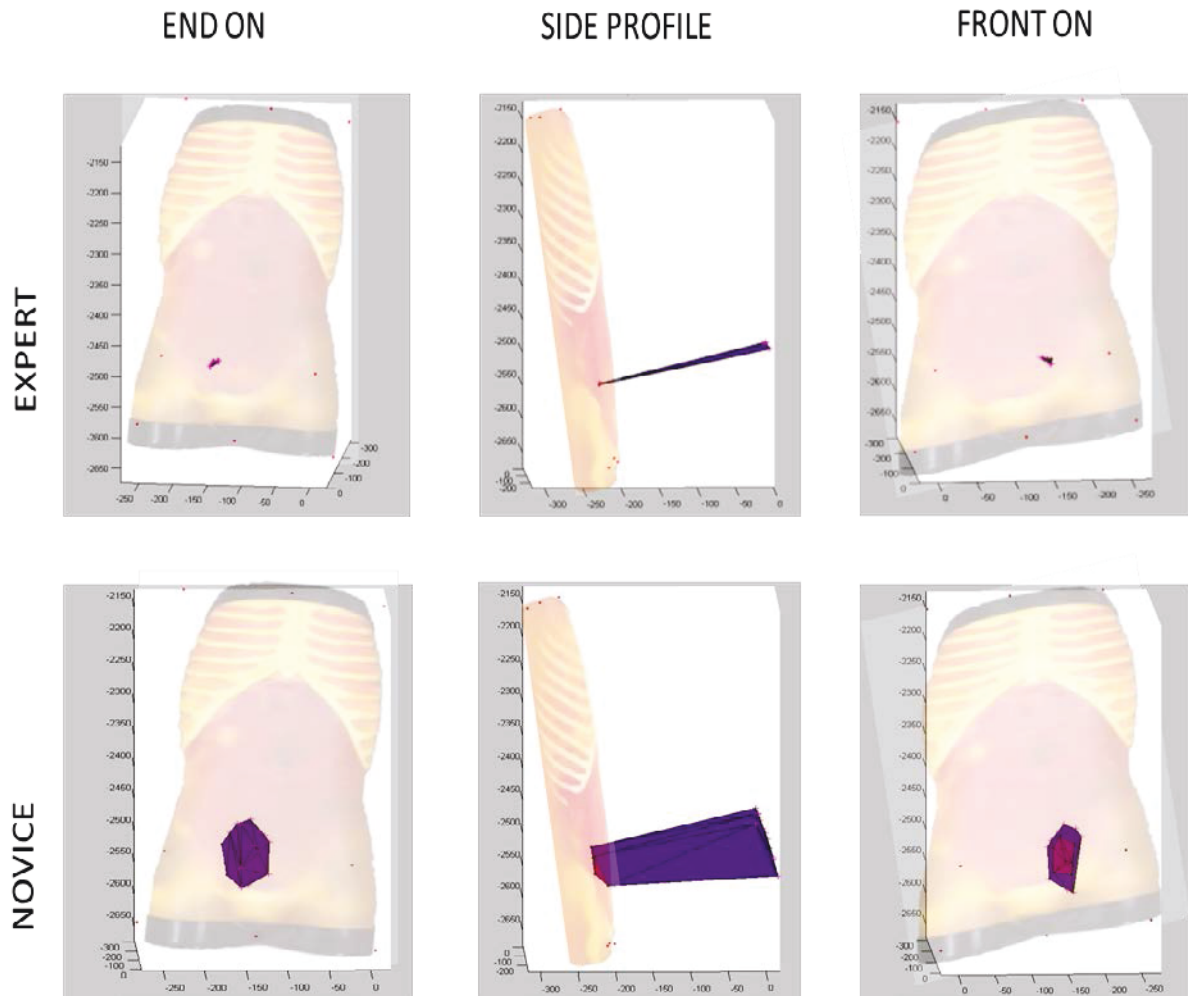
f)

Pelvis Transverse



g)

Pelvis Sagittal



4.3.5 Expert Probe Positions

From the workspace analysis, it was possible to plot all expert probe positions for each region of the FAST scan. As a result, a mean of all expert positions was derived to identify the ideal probe placement for each FAST region and this is illustrated in *figure 4.8*.

4.3.6 Force

Experts applied significantly more force than novices throughout the FAST scan (*Figure 4.9a*) ($P < 0.001$). As a result of studying experts the mean force required for each region of FAST can now be derived. Areas where the expert utilised more force included the heart, pelvis and lung bases which is depicted in *figure 4.9b*. A force timeline was made to visualise in real-time the pattern of force applied by an expert as compared to a novice. A clear pattern emerged whereby experts had peaks corresponding to areas where the probe is in contact with a FAST region and troughs where the probe is off the skin and moving to another area; whereas novices had less concordance as demonstrated in *figure 4.10*.

The charts in *figure 4.10* led to an analysis of the probe to skin contact time based on the real –time force readings. Experts had a higher time on the skin at 84% vs. 69% for novices and they had a much shorter time off the skin at 16% vs. 31% for novices, highlighting a more efficient scan method as outlined in *figure 4.11*. The skin contact time was significantly different between the two groups (Chi-Square $P < 0.001$). Correlation of force and workspace also highlighted that higher forces imparted through the probe tended to be performed in smaller workspaces. This finding applied only to experts ($P < 0.038$) and not novices ($P < 0.109$) (*Figure 4.12*).

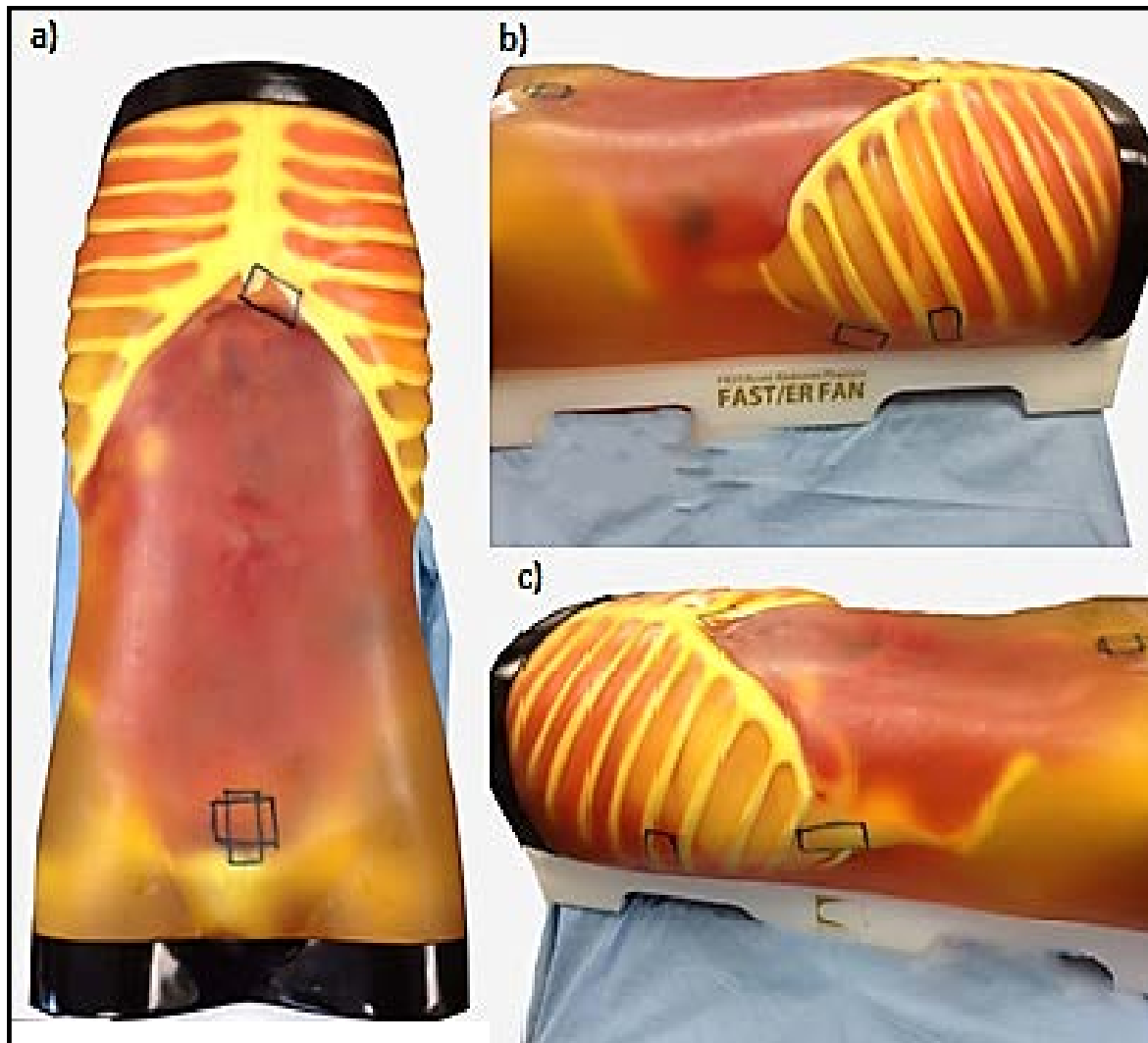
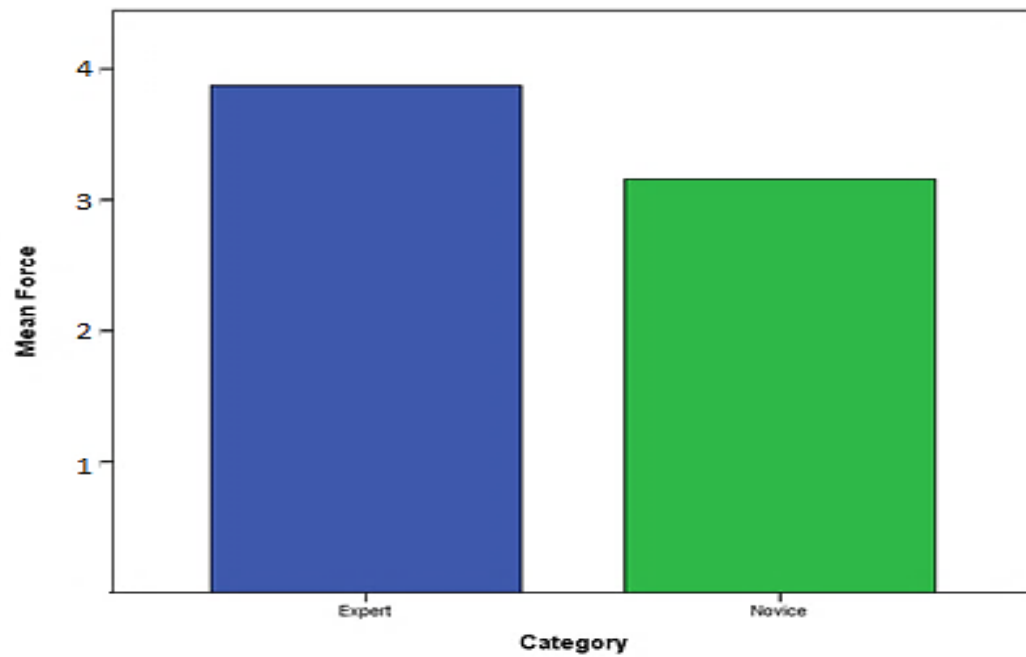


Figure 4.8 Kyoto FAST Phantom markings drawn as a blue box of the mean expert probe position in each area a) Front b) Left side c) Right side

a)



b)

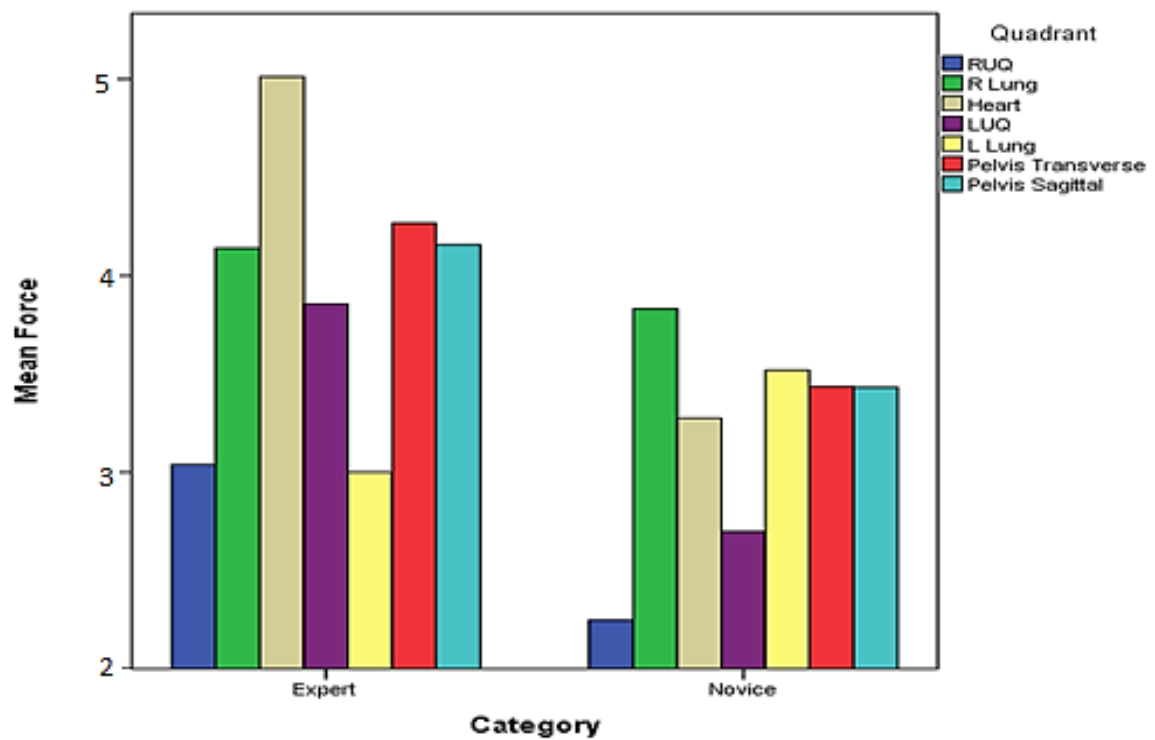
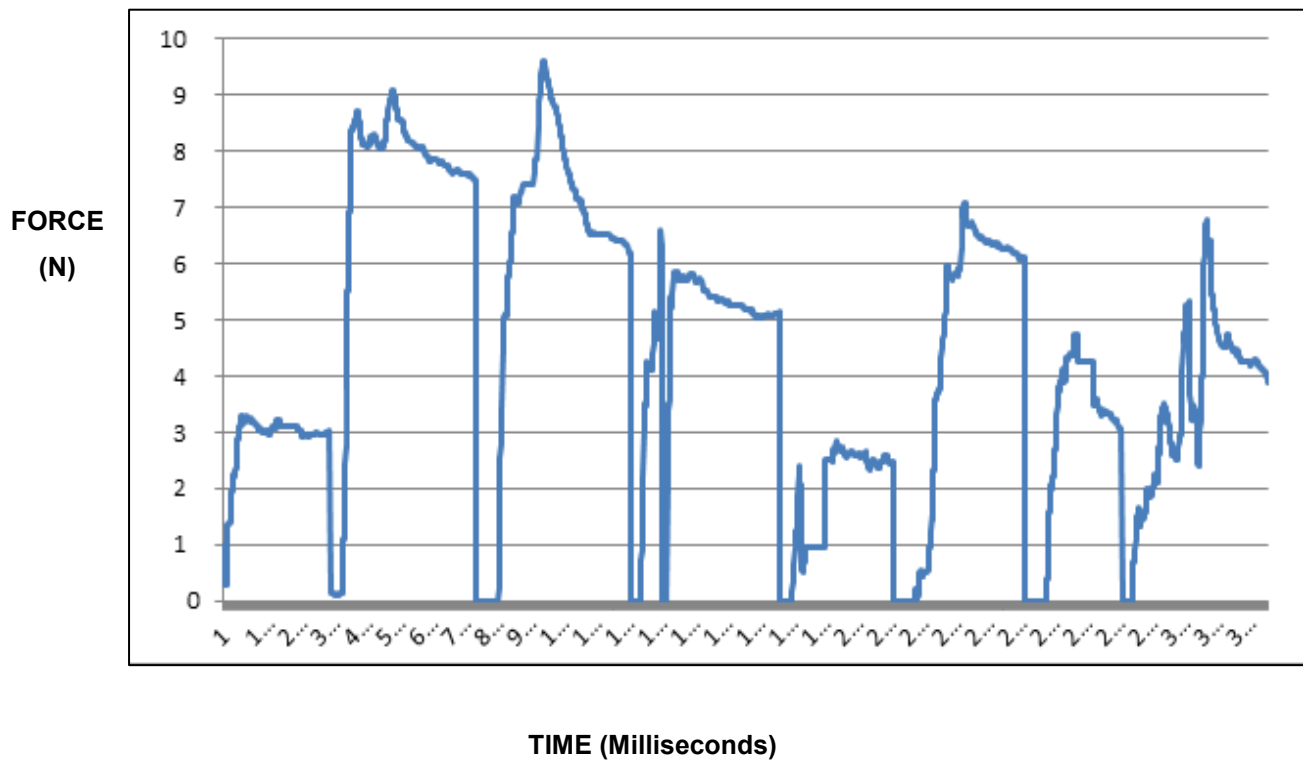


Figure 4.9 Total Mean Force (N) applied Expert vs. Novice a) Throughout FAST scan b) By region

a)



b)

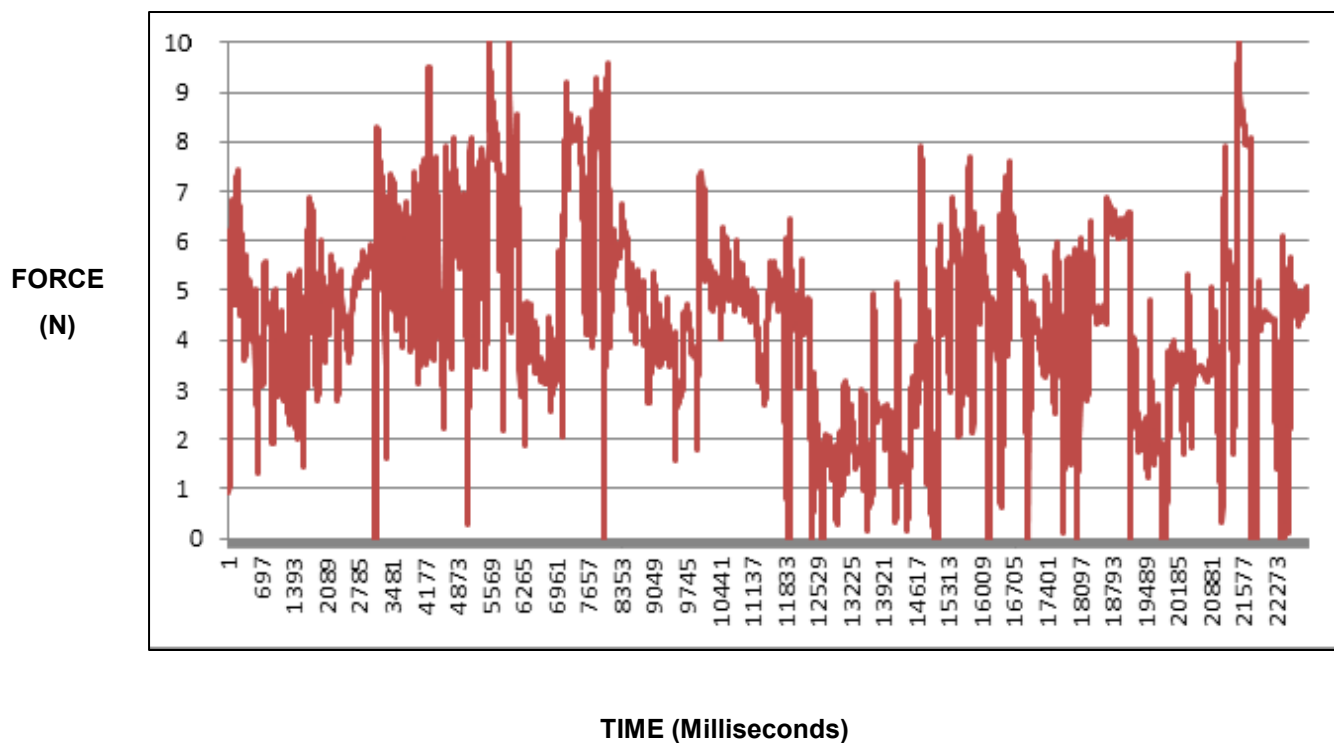


Figure 4.10 Force Timeline with Time on the X-axis and Force (N) on the Y-Axis. a) Expert Force represented by Blue line b) Novice Force represented by Red line

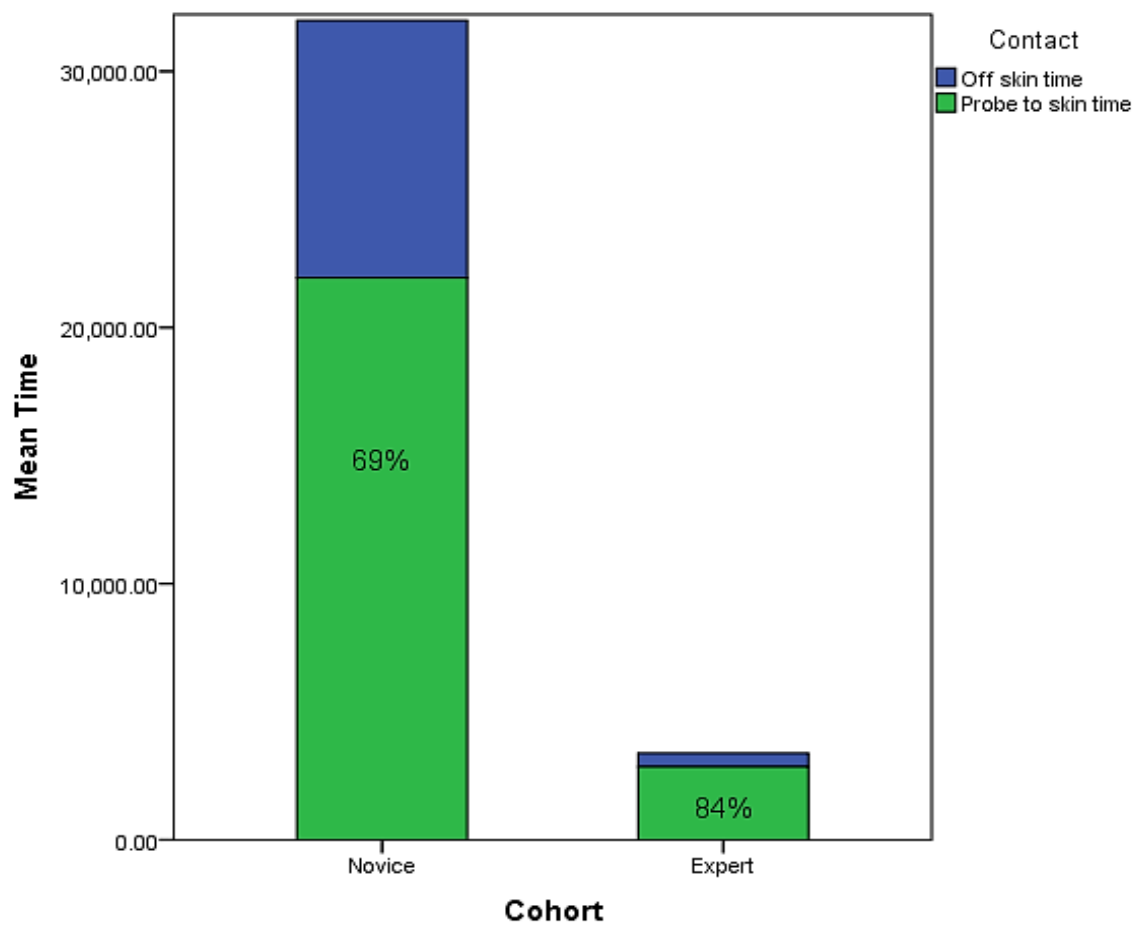


Figure 4.11 Novice vs. Expert Mean Probe to skin contact Time (milliseconds) expressed as percentages

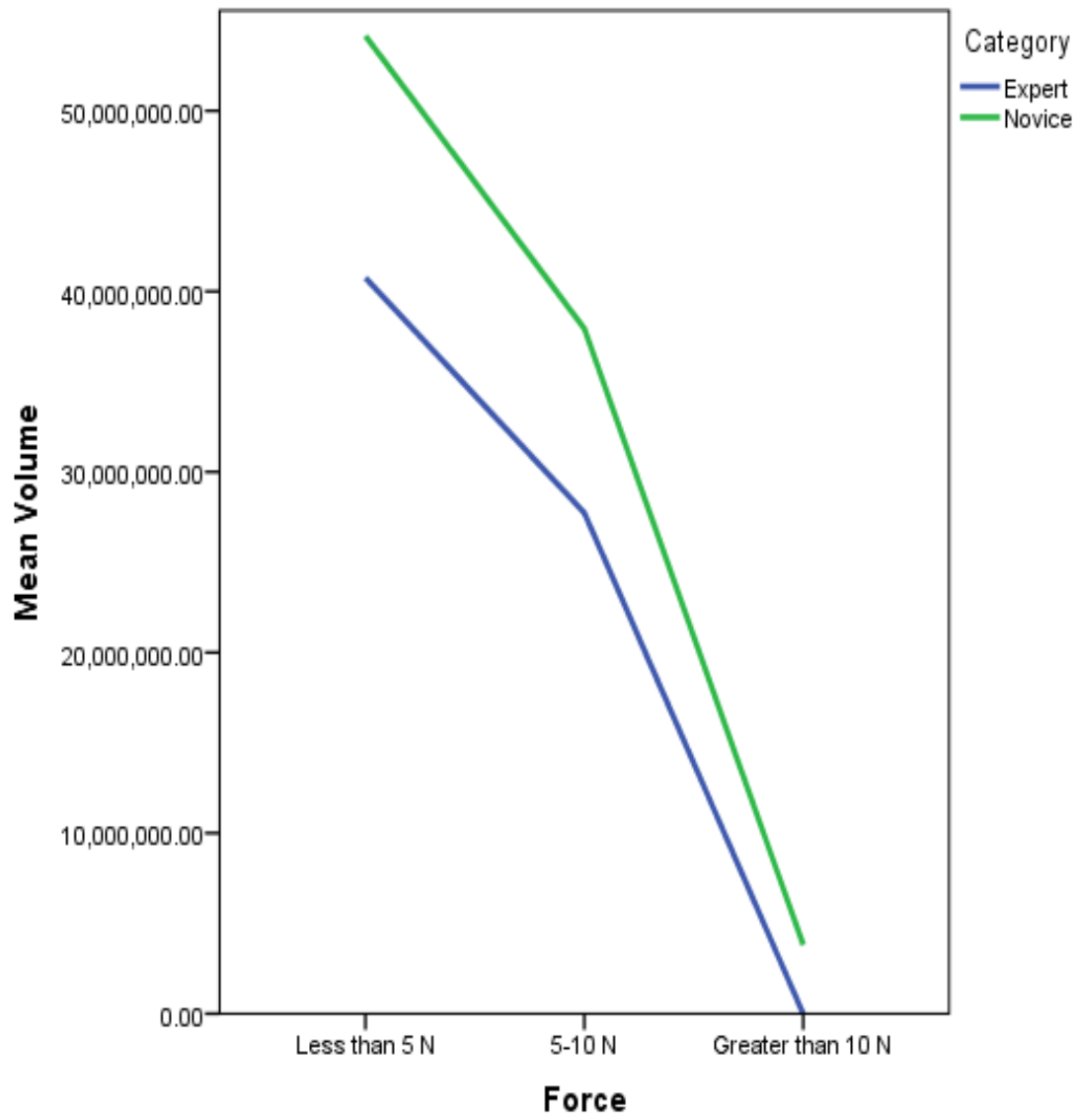


Figure 4.12 Mean Volume (mm³) per Force (N) Expert vs. Novice

4.4 Discussion

This study has demonstrated the ergonomics of expert probe manipulation in performing FAST. The results highlighted that experts although faster and more accurate than novices seemed to elicit trends of smaller probe workspaces and applied more force at anatomically relevant points. Novices showed a clear pattern of difficulty in finding pathology at the heart, lung bases and LUQ. As expected they were the slowest, made the most errors with missed targets and had lower levels of accuracy. They also had higher workspaces in these areas and this was depicted by volume analysis as well visually through the volume cone charts (*Figures 4.6, 4.7*). Their force charts over time were also discordant and erratic (*Figure 4.10*).

Possible reasons, why novices were having more difficulty at the heart, could be that when the probe is placed at the xiphisternum, a very shallow angle is required to gain an adequate image of the heart. This is difficult for the novice to attain and a common mistake in this region was gaining an image of the left lobe of the liver instead of the heart due to the incorrect angle of the probe. Additionally, because of the shallow angle much more force is required to gain an optimal image. Although it should be noted, that a trauma patient may not tolerate force being applied over the site of an injury. Experts used the most force when examining the heart whereas novices were not using enough force in this region and this is depicted in *figure 4.9*.

Hence, a combination of the correct angle and adequate force were required to attain the best image when examining the heart. At the spleen, as the organ is smaller than the liver, novices were struggling to identify it and commonly identified

the left kidney instead. For the lung bases, the left side seemed to be more difficult for novices to capture than the right for similar reasons. The above findings could aid trainers to focus more on these areas when teaching FAST scan to novices.

This study has also met its aim of identifying clear differentiators of expertise that could be used as further construct validity metrics. Some of these seem obvious such as time and accuracy whereas others have not been described before, such as probe to skin contact time and that high force can correlate with small workspaces as well as a cleaner pattern on the force timeline.

As a result of studying an expert's workspace, it was possible to plot the average probe position of all experts for each region. This resulted in placing position markers within each region of the phantom so that novices will know alongside anatomical landmarks where to fix the probe to gain an accurate image based on expert positions (*Figure 4.8*). Additionally based on the experts' results, this study has demonstrated the optimal force that needs to be applied in each area for an optimal image. Hence, a real-time force reading could be provided to novices so that adequate force is applied in each region. In doing so, we hypothesise that novices would be able to minimise their workspace requirements and optimise their probe to skin contact time. This should theoretically result in a higher degree of accuracy, reduced errors, fewer missed targets as well as shortening the time required to perform a FAST scan. The findings from this study could also be used to benchmark performances against expert standards. Therefore, this hypothesis will be examined in Chapter 5.

To our knowledge, this study on the ergonomics of expertise during a FAST scan has not been performed before. In other fields, academics identified certain traits in common with experts in laparoscopic surgery^(182, 183). These correspond with the findings in this study whereby experts had smaller workspaces and were significantly faster and more accurate.

4.5 Conclusion

This study has described the ergonomics of an expert FAST scan performance. As compared to novices, experts have smaller workspaces, apply more force and are faster with greater accuracy. It has also identified unique differentiators of expertise such as probe to skin contact time and that high force correlates with small workspaces. Furthermore, the ideal probe position and force for each region of the FAST has been derived from experts. A comprehensive FAST training curriculum could be developed from the findings to help accelerate training for novices.

Chapter 5 FAST training through expertise

Hypothesis: Novices trained in probe manipulation ergonomics for FAST will learn faster with a higher degree of accuracy and maintain skill retention.

5.1 Introduction

The aim of simulation training is to shorten the learning curve through deliberate practice with direct feedback and monitor progress until competency is achieved⁽¹⁵⁸⁻¹⁶¹⁾. There are numerous strategies to teach a novice a new skill. One common method described by Peyton involves a four stage approach⁽¹⁸⁵⁾:

1. The expert demonstrates the skill to the novice
2. The expert repeats the skill with an explanation of the technique
3. The expert performs the skill with the learner narrating the steps of the procedure
4. The learner performs the skill under supervision

After the four stages described, deliberate practice is required which involves repetitive performance to ensure an improvement in outcome. It is not only the quantity of time spent training that is important but the quality too. Characteristics of deliberate practice include undertaking a task at a suitable level of difficulty to adequately challenge the novice combined with immediate and constructive feedback. The same task is repeated numerous times and errors are corrected until mastery is achieved⁽¹⁵⁸⁾.

The current challenge of how FAST training could be delivered in an effective manner to the multitudes of first care providers, as well as criticisms about its steep learning curve need to be addressed. Chapter 2 highlighted that FAST is an effective diagnostic modality for detecting bleeding in experienced hands^(71, 76). The questionnaire in Chapter 2 also advocated for more training in FAST. Chapter 3 identified that simulation offers a realistic alternative for FAST training on a validated model⁽⁴⁾. One proposed method to address the concerns of FAST is to deconstruct an experts' performance, as has been conducted in the previous chapter and use these metrics as building blocks for training novices with a high fidelity simulator.

Aims

The aims of this study were:

1. To assess whether FAST teaching based on expert metrics plus a standard curriculum (Intervention Group A) could accelerate learning for novices as compared to those taught a standard curriculum alone (Control Group B).
2. To undertake a prospective validity assessment for which of the two training methodologies is more effective on a virtual patient.

5.2 Methods

5.2.1 Overview

In order to evaluate the two curriculums, the novices were randomly assigned a training methodology and were taught as well as assessed in the learning curve

phase. Once trained, their skills were assessed in the prospective validity phase which is outlined in *figure 5.1*, the study flow diagram.

The Zonare USS machine and simulator previously described ("FAST/ER FAN" Kyotokagaku Ltd) were used in this study (*Figure 3.1*). The ultrasound probe (*Figure 4.1*) and experimental set up from Chapter 4 was utilised in this study (*Figure 4.3*). The Optotrak Certus system (NDI, Ontario, Canada) was deployed to record the 3D probe position. The data from the Optotrak was analysed in MATLAB (MATLAB and Statistical Toolbox Release 2012b, The MathWorks, Inc., Natick, Massachusetts, United States). An Atmel based microcontroller amplified and digitised the force measurements. The force data was analysed with Microsoft Excel (Microsoft. Microsoft Excel. Redmond, Washington: Microsoft, 2009. Computer Software).

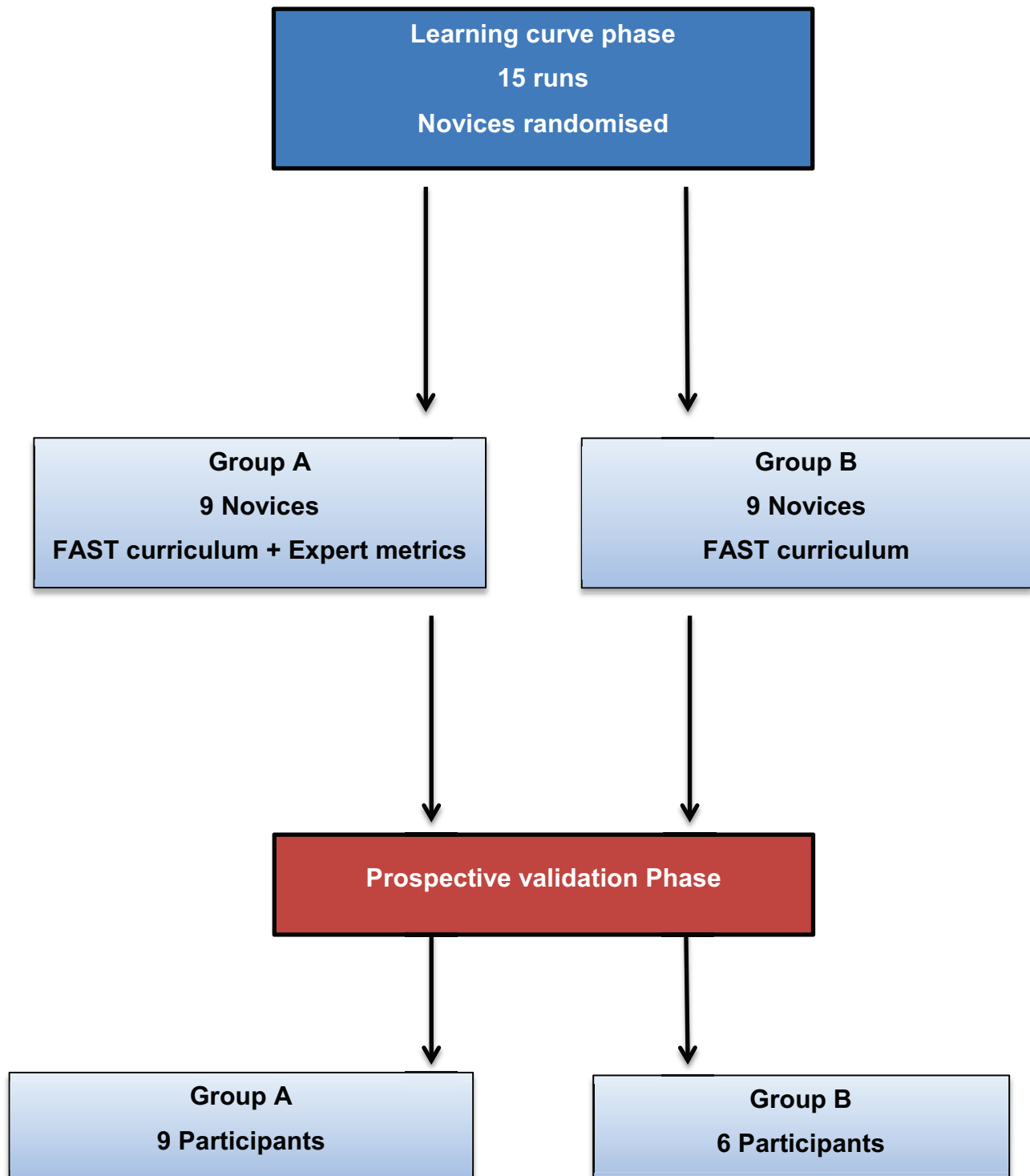


Figure 5.1 Study Flow Diagram

5.3 Learning curve phase

5.3.1 Learning curve phase methodology

A total of 18 novices were randomised by electronic number generation and 1:1 allocation ratio to split equally into two groups. All novices were medical students with an age range of 22-24 years old. Group A were all men and Group B had 5 males and 4 females.

The novices received a presentation on the fundamentals of sonography, how to perform FAST, followed by an expert demonstration in keeping with Peyton's methodology⁽¹⁸⁵⁾. They were electronically randomised into two groups. Group A (intervention group) were taught a standard curriculum based on the College of Emergency Medicine Level 1 Ultrasound guidelines⁽⁷⁹⁾ plus expert metrics. Group A had markings placed on the phantom of the experts ideal probe position in each region of interest. This had been derived from the seven experts in Chapter 4 and was calculated as a mean of all the experts probe positions for each FAST region (*Figure 4.8*). These markings alongside anatomical landmarks aided the novices in correct probe placement for each region. Group A also had a real-time force reading displayed to them and were prompted on how much force to apply based on the mean expert force recordings for each region. In contrast, Group B (the control group) were taught the standard curriculum alone⁽⁷⁹⁾.

In each area, subjects had to state if pathology was present, attain an accurate image and save it for accuracy assessment (*Figure 3.3*). Each subject performed 15

runs of FAST, split equally over three sessions. The participants would receive expert feedback at the end of every session. In line with distributed practice^(160, 161) each session was separated by a minimum of 48 hours. Competency had been achieved when performance plateaued.

5.3.2 Metrics tested

Every participant was evaluated in each region by the following metrics that had been previously validated:

1. The volume covered by the probe in contact with surface of phantom
2. The volume covered by the entire workspace
3. Force
4. Time and the validated accuracy scoring method was used in this study as previously described (Chapter 3.2.3)
5. Results compared to an expert and novice performance for benchmarking of prospective validity

5.3.3 Statistical analysis

From previous studies, eight was the minimum number of participants required per group. This was derived from a power calculation performed on ten subjects with a 2 tailed test, $\alpha=0.05$ and power $(1-\text{Beta}) = 0.8$ with a proposed 30% reduction in time taken to complete FAST between groups ^(172, 173). The data is expressed as mean $\pm$ 1 standard deviation and median $\pm$ interquartile range. The results have

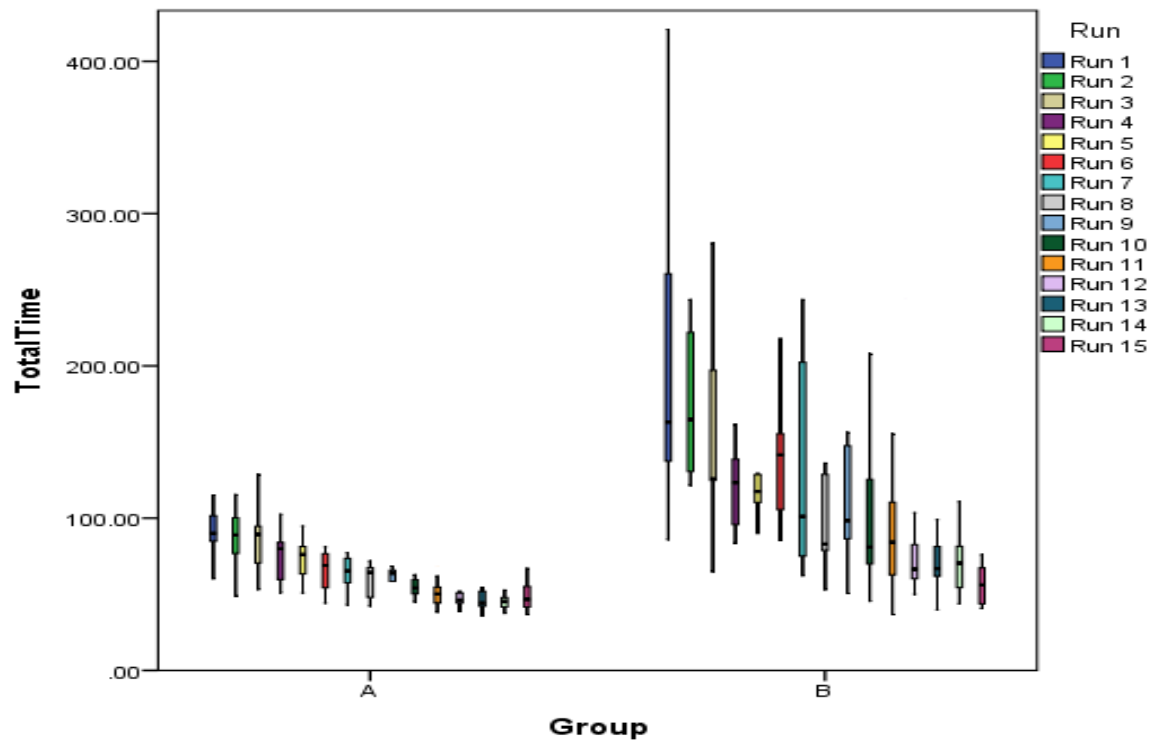
been analysed using Mann-Whitney U test, T-test, Kruskal-Wallis and Spearman's test as appropriate with a $p < 0.05$ considered a significant result. The statistical analysis was performed using IBM SPSS Statistics software (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). This study had ethical approval obtained from the Imperial College Research Ethics Committee.

5.3.4 Learning curve phase Results

5.3.4.1 Time

Group A were significantly faster in all times ($P < 0.001$) except Time 1 (Time to identify pathology). Group B showed a wide range of timings in the early sessions that improved by the last few runs. Contrastingly, Group A remained in a consistently tight range throughout their runs which improved with experience (*Figure 5.2a*, *Figure 5.2b*). For Time 3 (Time per Area), Group A were significantly faster than Group B in all areas and both groups took the longest to scan the LUQ (*Figure 5.2c*). Group B also took the most time to scan the heart and both lung bases which is a similar finding to the novices in the expert metrics analysis (Chapter 4). Group A did not take much longer in these areas which suggest that the aids available to them may have helped to overcome the difficulty faced by the control and novice group.

a)



b)

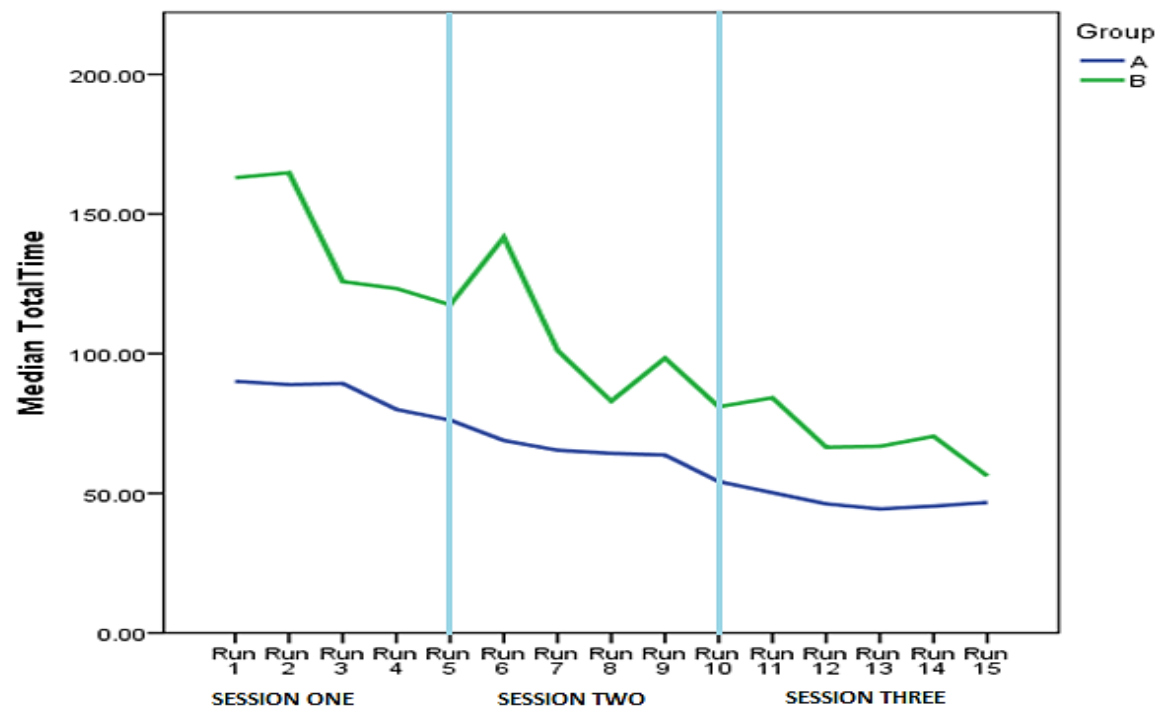


Figure 5.2 Time a) Total Time per Run (Secs) Group A vs. Group B b) Median Total Time (Secs) per Run Group A vs. Group B

c)

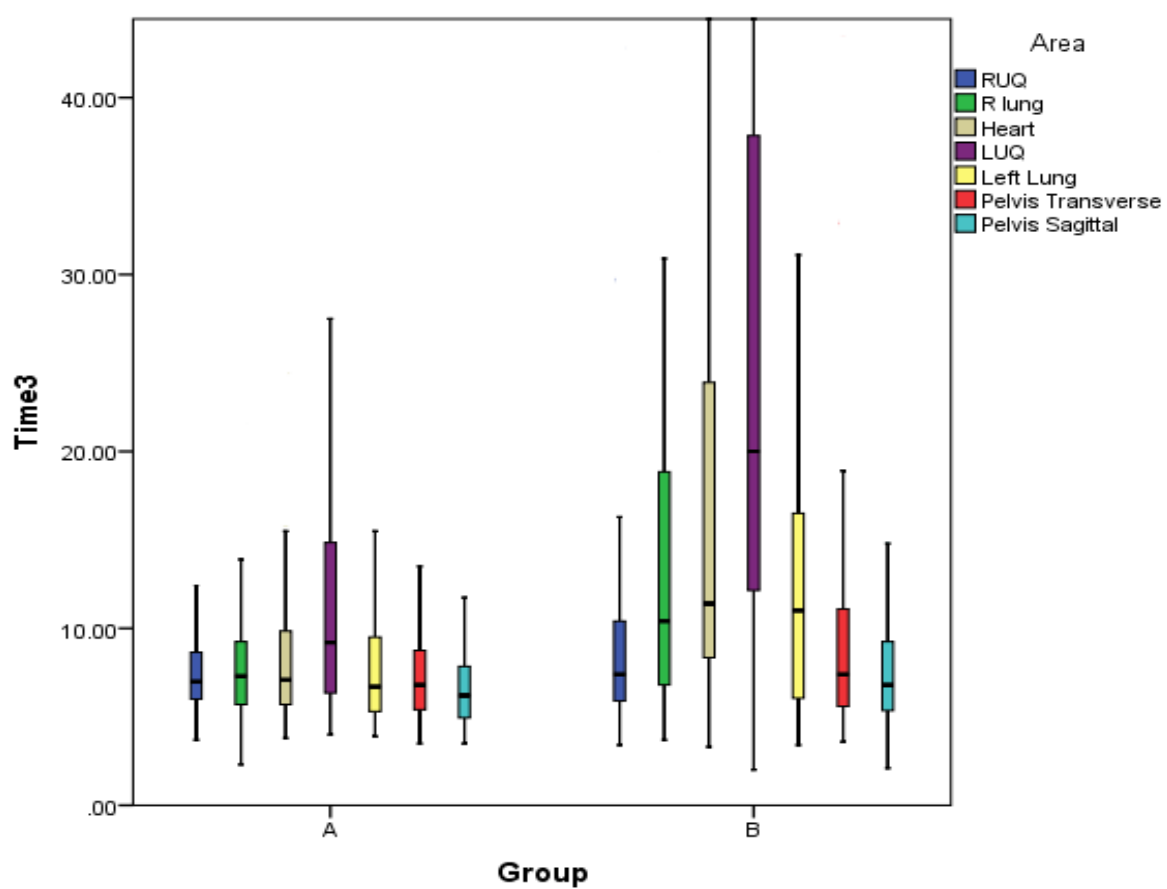


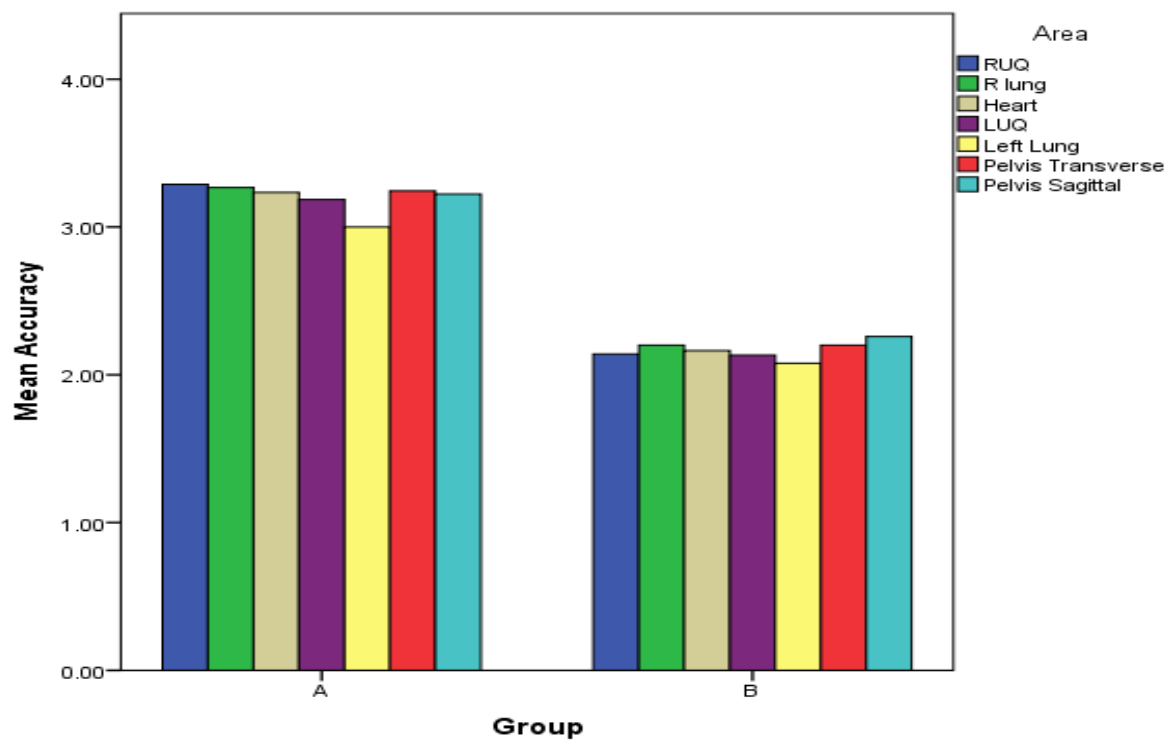
Figure 5.2 Time c) Time 3 per Area (Secs) Group A vs. Group B

5.3.4.2 Missed Areas, Errors and Accuracy

There was a significant difference between the groups in terms of missed targets and errors made ($P < 0.001$). Group B missed the left lung base and LUQ most often. Group A did not miss any pathology which may have been due to the position marker aids. Both groups made some errors such as an inverse image during their first few runs, with Group B making more errors; most often at the LUQ and left lung base.

For accuracy, there was a very good inter-rater agreement amongst the examiners ($\text{Kappa} = 0.8$ $P < 0.01$). Group A were significantly more accurate than Group B and both diminished marginally when scanning the left side of the phantom (*Figure 5.3a*) ($P < 0.001$). Accuracy improved in both groups through experience with Group A commencing their runs at a higher accuracy level than Group B and this is illustrated in *figure 5.3b*. On a scatterplot with locally weighted smoothing (*Figure 5.3c*), Group A's accuracy level plateaued at run 8 with smaller incremental improvements thereafter, indicating skill consolidation as well as a satisfactory performance level being achieved. Group B were lagging in accuracy in relation to Group A, but continued to show improvement with experience. By the time Group B had performed their 15th run, they had attained a mean accuracy score of 3 which Group A had reached by their 5th run.

a)



b)

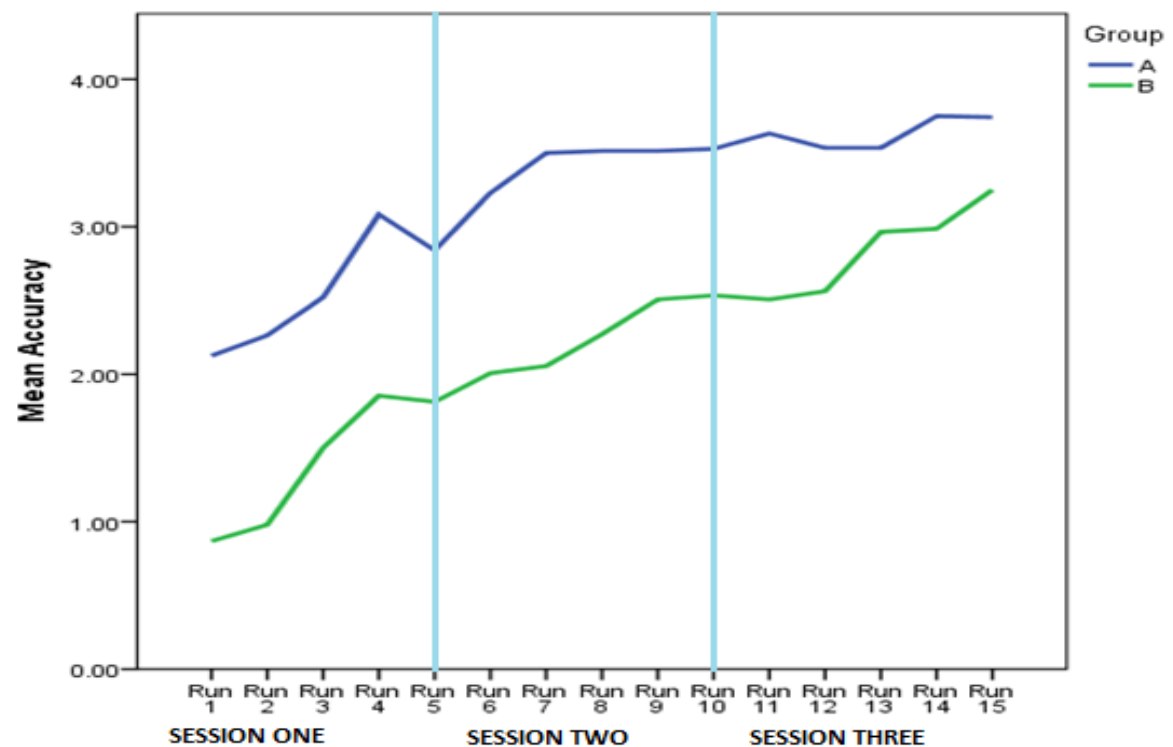


Figure 5.3 Accuracy a) Mean Accuracy score per Area Group A vs. Group B

b) Mean accuracy score per Run Group A vs. Group B

c)

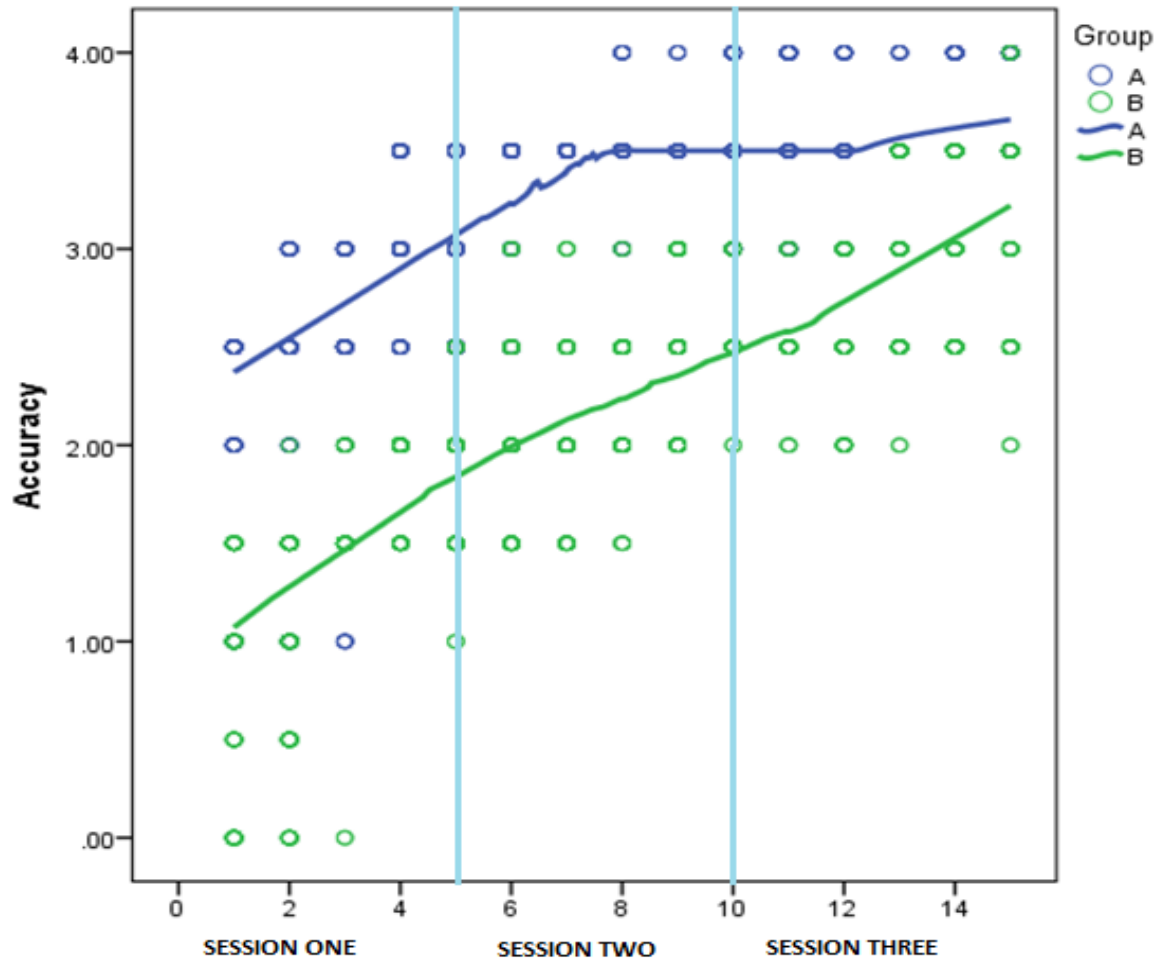


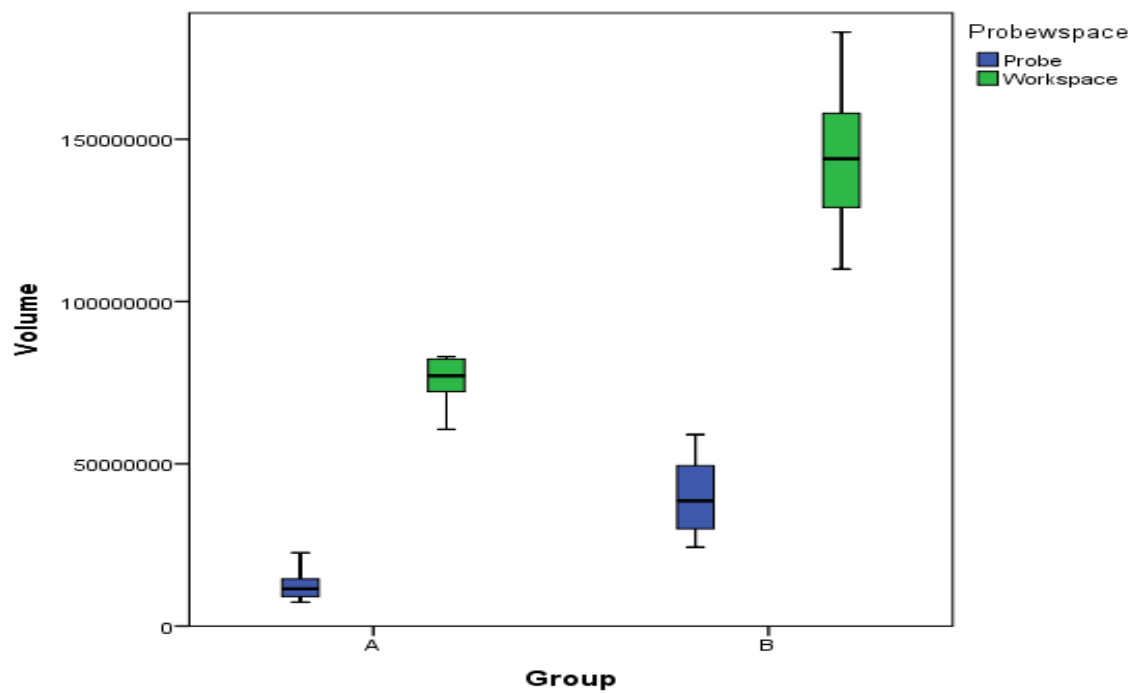
Figure 5.3 Accuracy c) Accuracy score scatterplot with locally weighted smoothing Group A vs. Group B

5.3.4.3 Workspace

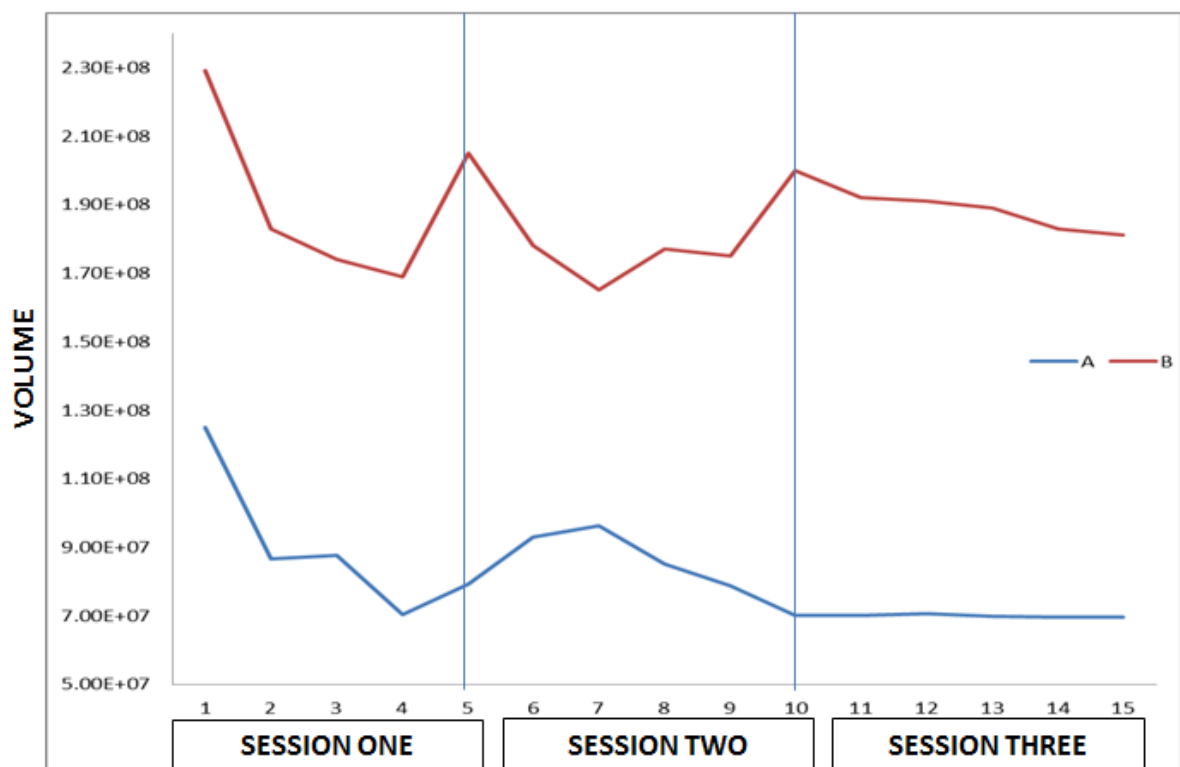
Group A had a significantly smaller probe and total workspace volume than Group B ($P < 0.001$) (*Figure 5.4a*). Further analysis was conducted to ascertain the rate of improvement per run and session. Group A began their first session with a much lower workspace volume than Group B and this may have been due to the position markers provided. Group A had plateaued by the 10th run at the end of the second session, which implied that the skill had been consolidated (*Figure 5.4b*). However, Group B had a higher workspace volume at the beginning of their third session compared to the end of their previous one implying that further practice was required. Their performance had plateaued by the end of the third session.

For workspace volume per region, both groups had higher volumes in their first few runs when scanning the left side - the most challenging area. By the last run, Group A's volume had significantly reduced on the left side whereas Group B's volume remained high at the LUQ.

a)



b)



**Figure 5.4 Workspace Volume a) Probe and Workspace volume mm³ of Group A and B
b) Total Workspace Volume mm³ per Run and Session Group A vs. Group B**

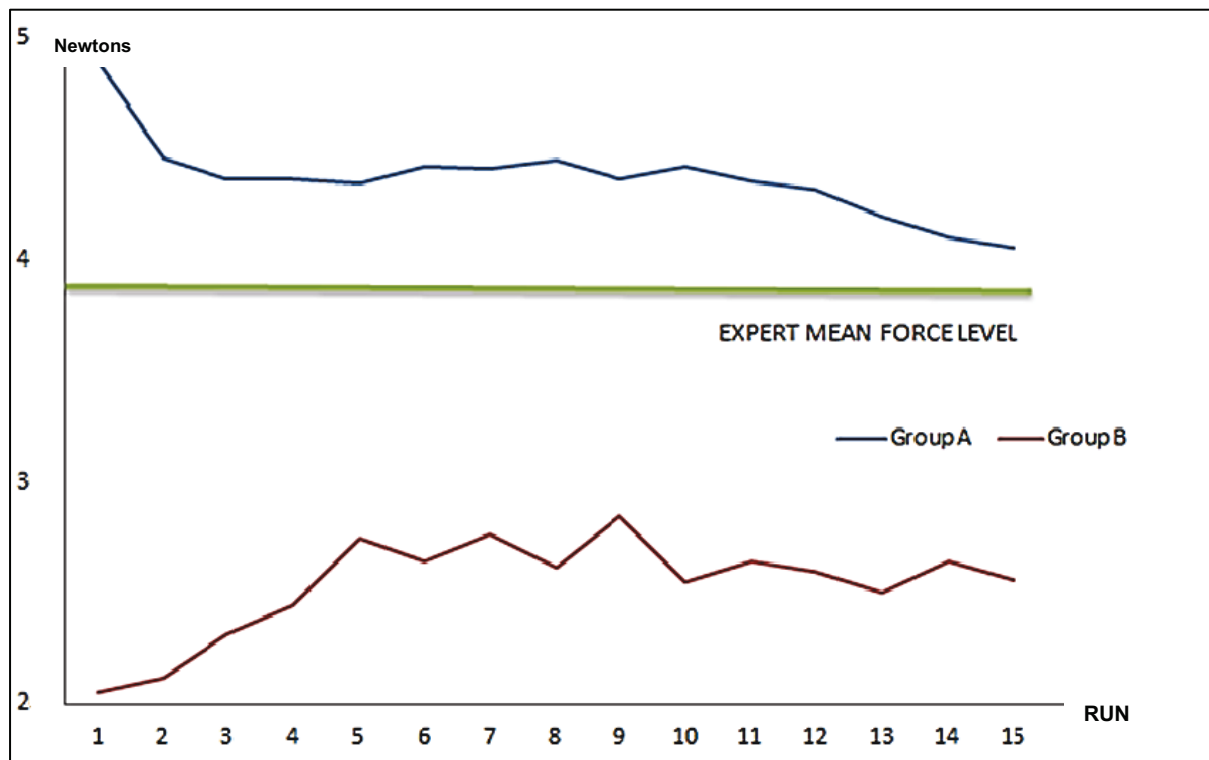
5.3.4.4 Force

Group A applied significantly more force than Group B during their performance ($P < 0.001$) and with practice approached the mean expert level. Although Group B's force improved over their runs, it was still significantly lower than an experts' (*Figure 5.5a*). From analysing experts, areas where more force was applied included the heart, LUQ and Left Lung. Group A's performance closely resembled an expert performance in these regions as well.

A force timeline was constructed to depict the pattern of force applied by both groups during their FAST performance. Based on this, analysis of the time that the probe was in contact with the skin could be conducted. The hypothesis was that the more time spent with the probe on the skin than off it would indicate an efficient performance. This finding had also been previously identified during the expert metrics analysis as a good differentiator from a novice. As outlined in *figure 5.5b*, Group A had a significantly higher probe to skin contact time compared to Group B highlighting the efficiency of Group A's performance (Chi Square $P = 0.0029$).

Another hypothesis examined was whether a high force correlated with a small workspace. The significance being that as the sonographer focuses on the target area; the force correspondingly increases to gain the best possible image. In this study, high force did significantly correlate with a small workspace for Group A ($P = 0.038$) but not for Group B ($P = 0.109$). Also noted in *figure 5.5c* was that the workspace of Group A commenced lower than Group B when less than 5 Newtons (N) of force was applied. The two groups do converge at more than 5N, but Group B's workspace volume remained higher.

a)



b)

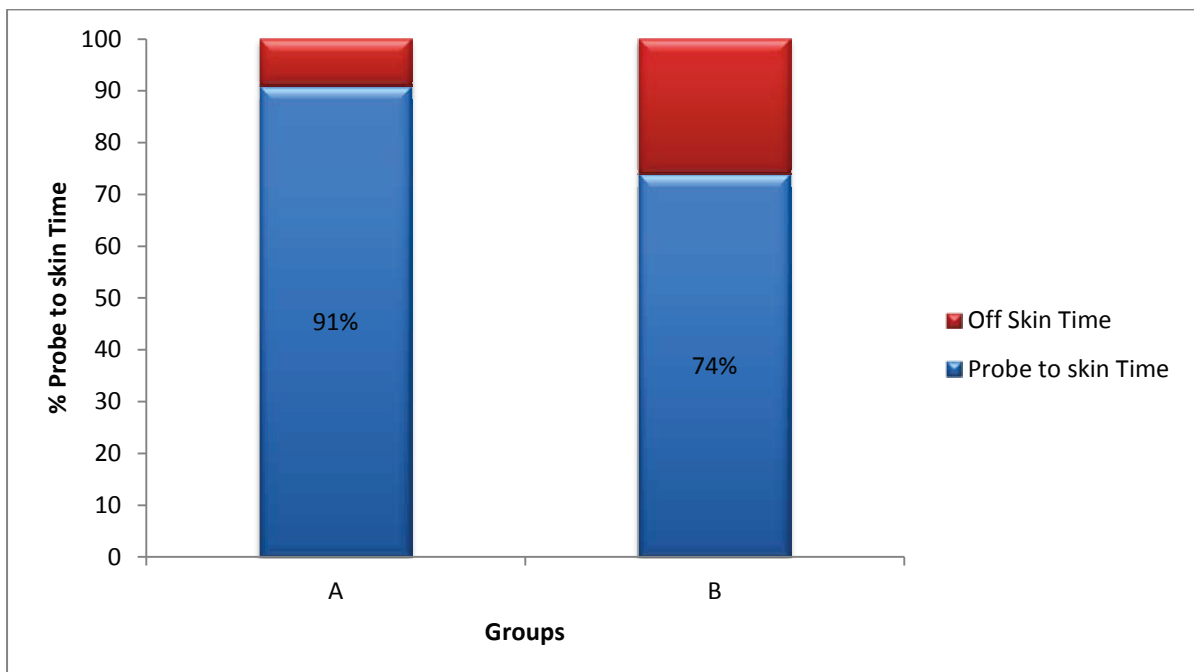


Figure 5.5 Force a) Mean Force (N) per Run Group A vs. Group B. The Green line represents the mean force level of an expert performance b) Probe to skin contact Time (%) Group A vs. Group B

c)

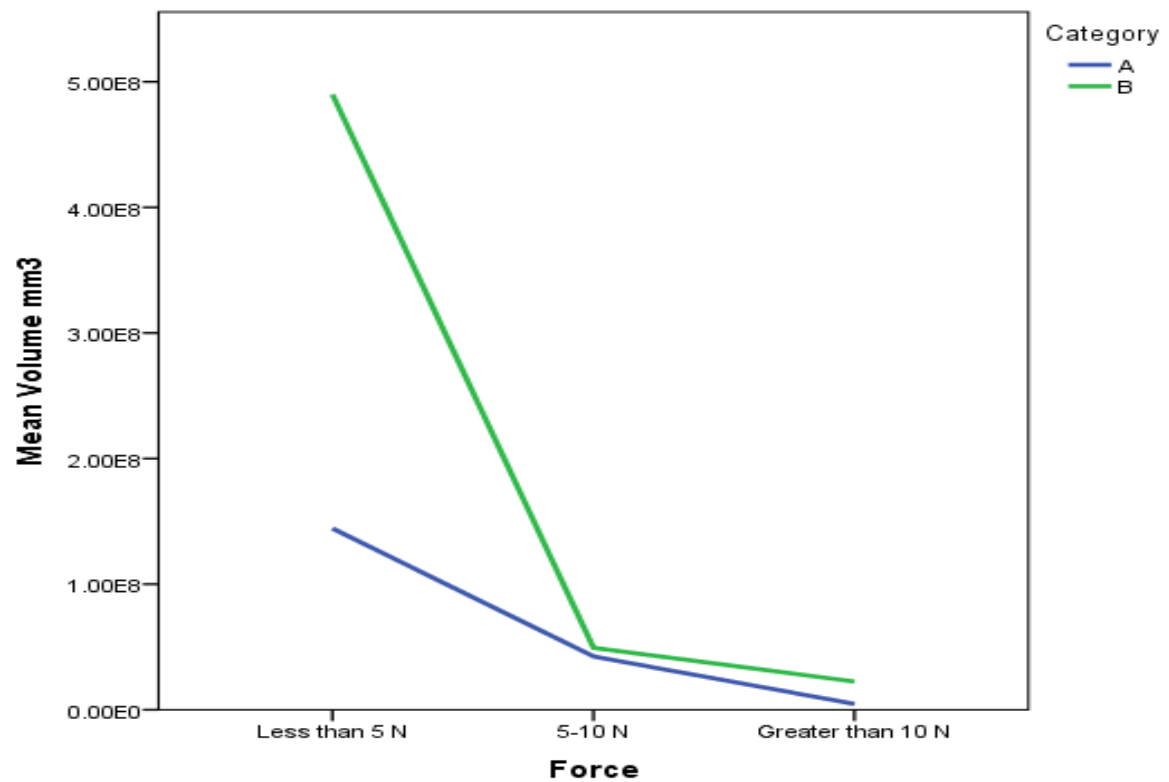


Figure 5.5 Force c) Mean Volume per Force (N) Group A vs. Group B

5.4 Prospective validation phase

5.4.1 Prospective validation phase methodology

This phase was performed one month after the learning curve study to determine which of the two training methodologies was more effective, whether there was skill retention and the translational value of the simulator. Participants were asked to perform a FAST scan on a healthy 75kg young male who acted as the virtual patient. They were requested to identify the correct ultrasound anatomy in each region.

On this occasion, Group A were not shown position markers and force readings that had been available in the previous phase. This was to nullify any potential bias of introducing aids in this prospective validity study. Both groups completed two complete runs of FAST with no assistance or feedback provided. The results were compared to expert and novice performances for benchmarking of prospective validity. The choice of a virtual rather than a real patient was for participants to demonstrate the identification of the correct anatomy in each region rather than pathology at this stage.

5.4.2 Prospective validity phase results

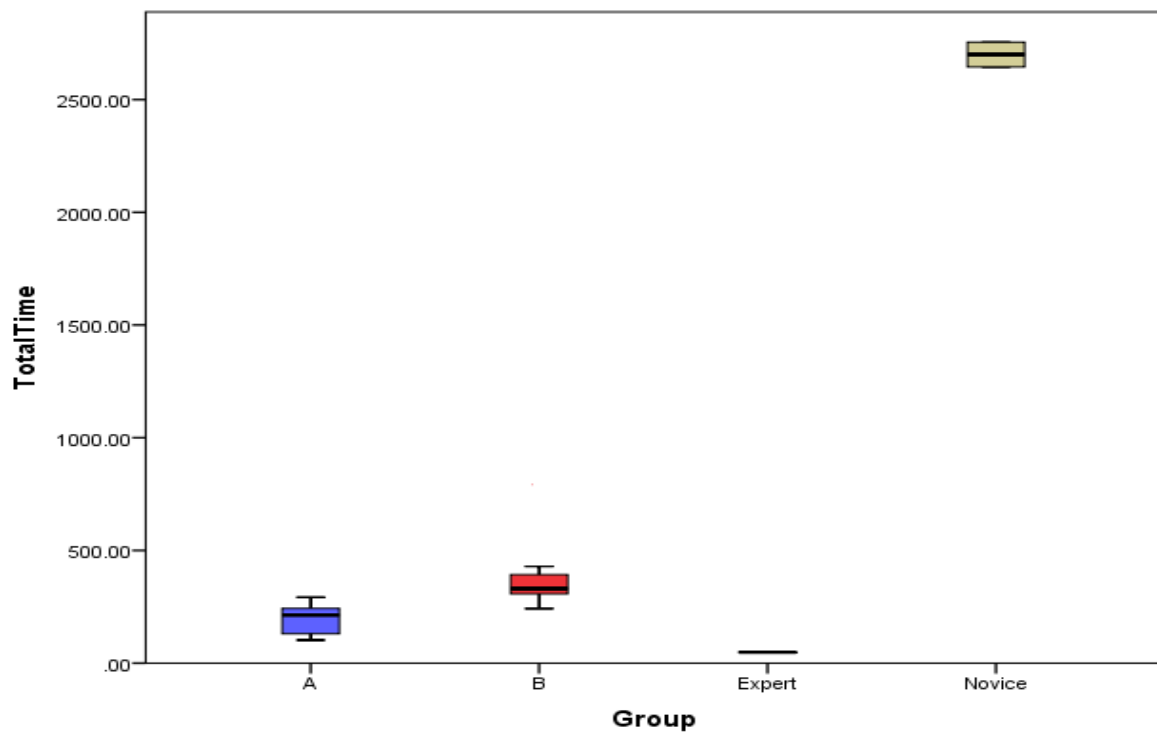
Group B had three participants that could not complete the study leaving 6 students in this cohort with an equal split of males and females. Group A had all 9 participants from the previous phase. The expert cohort consisted of 4 consultants from radiology, emergency department and trauma as well as 3 senior radiology registrars. The mean ultrasound experience was 4.1 ± 3.1 years with a median of

500±225 procedures performed. The 5 novices had no prior experience with ultrasound.

5.4.2.1 Time

Group A were significantly faster than Group B at all times ($P<0.05$) with the experts being the quickest ($P<0.05$). Both groups were significantly faster than a novice performance ($P<0.05$) and took the longest to examine the left side which corroborates the previous findings (*Figure 5.6a, b*).

a)



b)

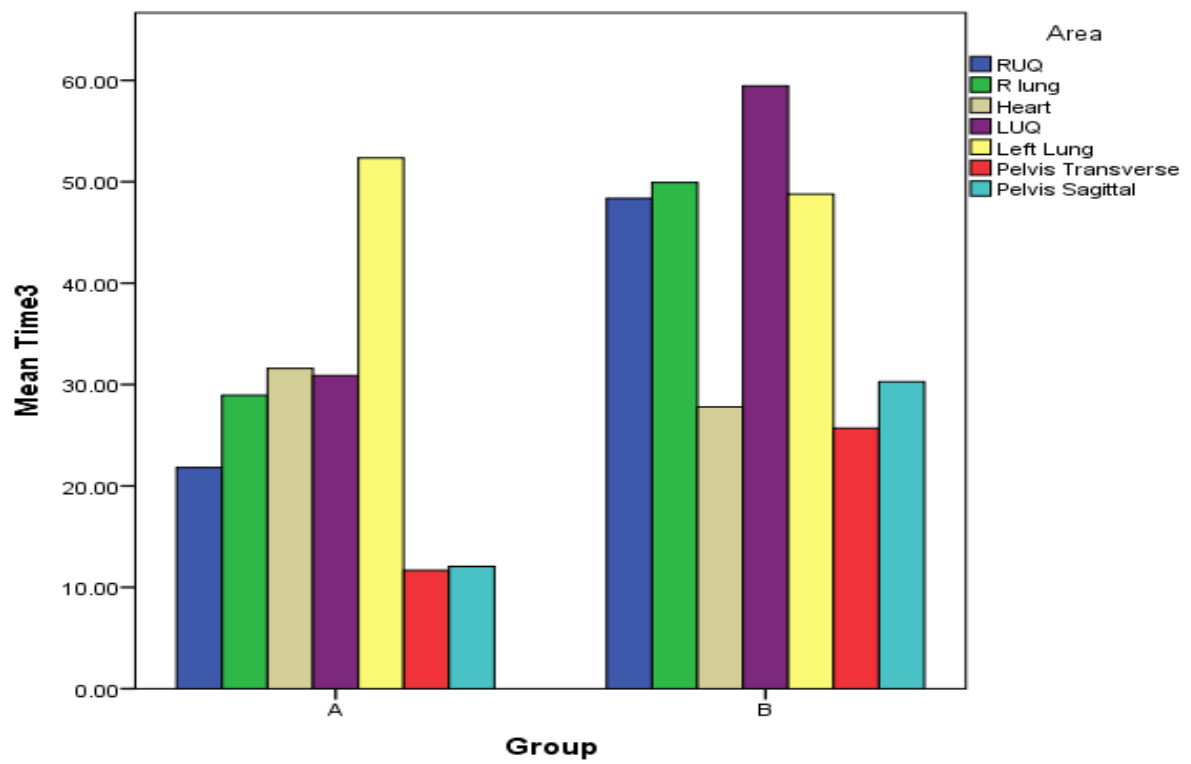


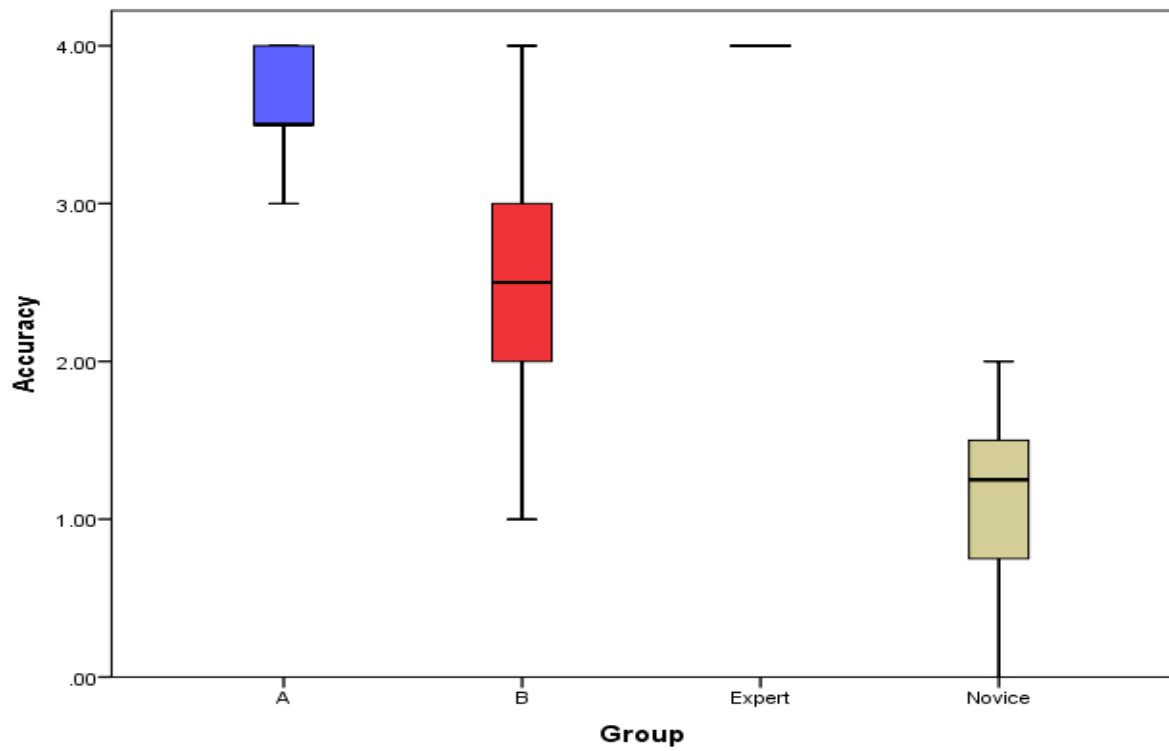
Figure 5.6 Time a) Total Time (Secs) per Group b) Mean Time (Secs) per Region Group A vs. Group B

5.4.2.2 Missed Areas, Errors and Accuracy

There was good inter-rater agreement for accuracy scores ($Kappa=0.62$). Group A had a significantly higher accuracy than Group B ($P<0.01$) with the experts being the most precise ($P<0.01$). Groups A and B had a significantly higher accuracy level than novices ($P<0.01$). Both groups' performance reduced when examining the left side, with Group B's diminishing more (*Figure 5.7a, b*).

Group A had significantly fewer errors than Group B ($P<0.01$) but both had less errors than a novice performance ($P<0.01$). Only the novices missed targets during their performance; all other groups did not miss any areas.

a)



b)

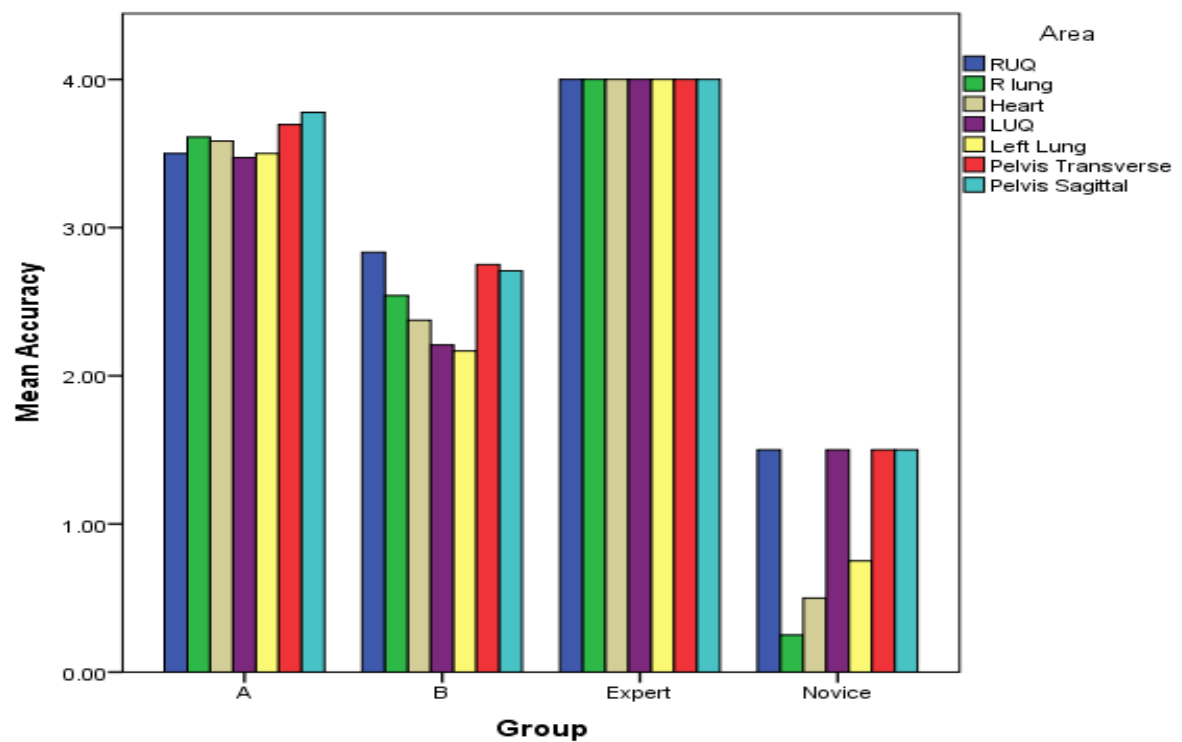
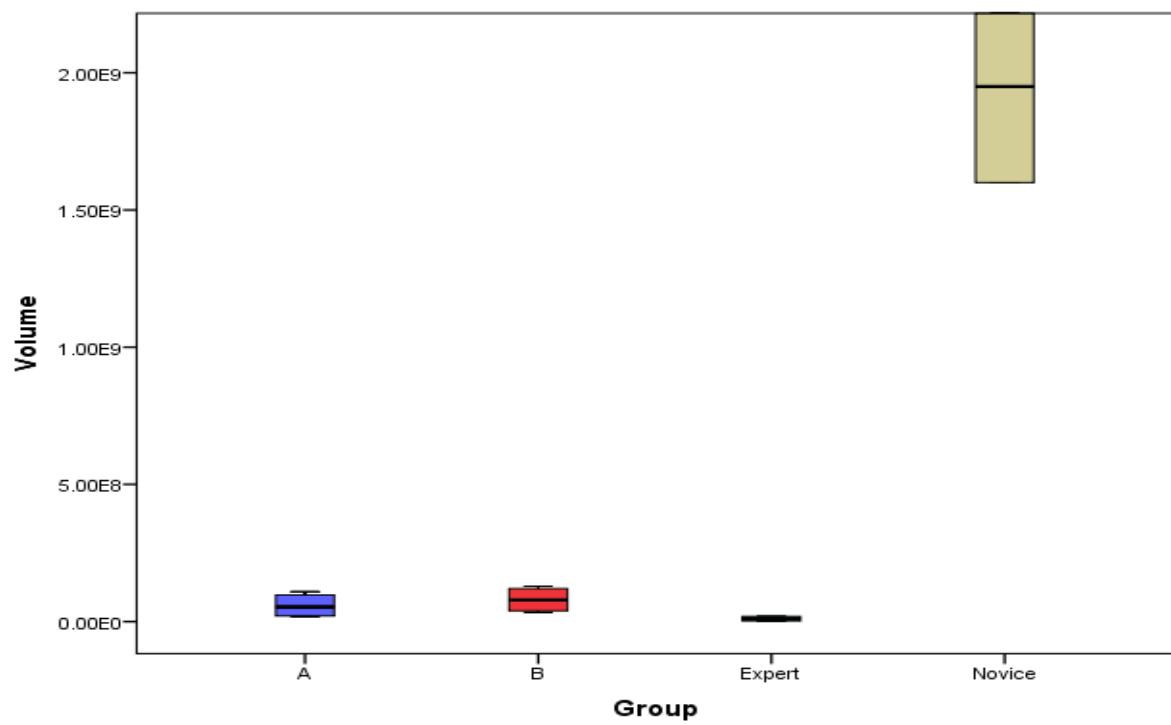


Figure 5.7 Accuracy a) Mean Accuracy score per group b) Mean accuracy score per Group per Region

5.4.2.3 Workspace

Group A had a significantly smaller workspace volume than Group B ($P < 0.05$). The Expert workspace volume was significantly less than Group B ($P < 0.05$) but not group A ($P = 0.08$). In comparison to a novice, all groups had a significantly smaller workspace volume ($P < 0.05$). Group B's volume remained high at the LUQ, an observation congruous with that seen in the learning curve phase (*Figure 5.8*).

a)



b)

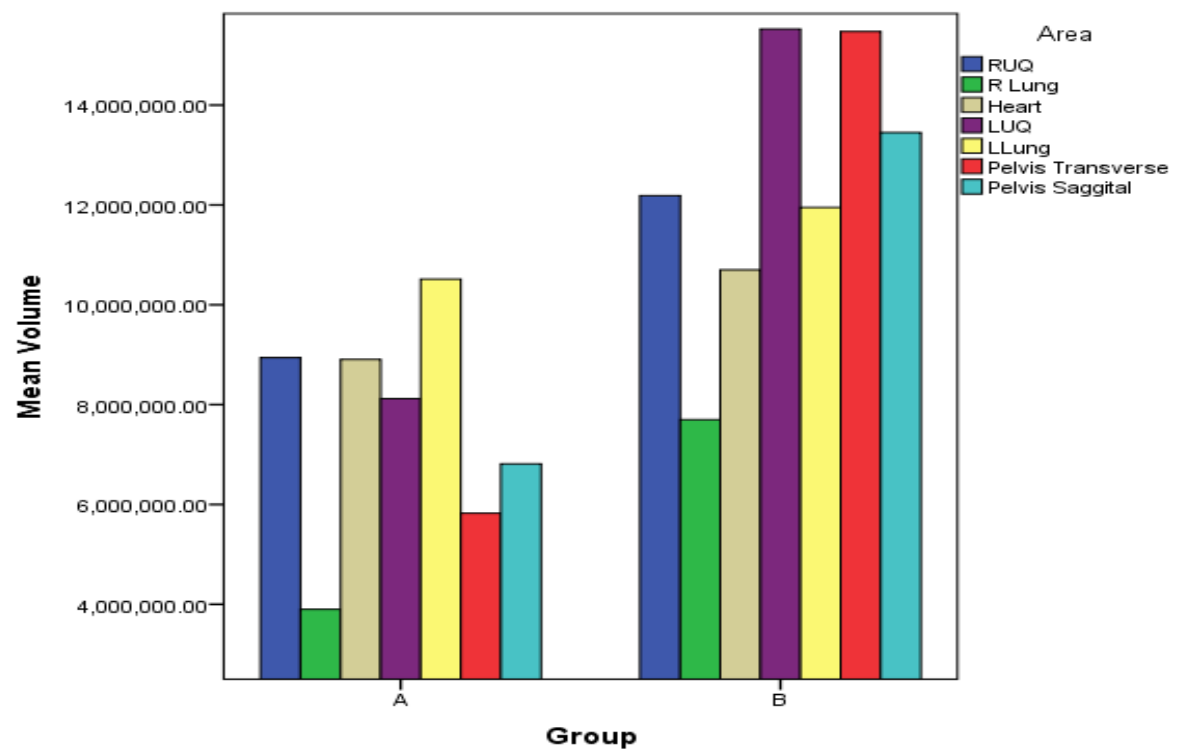


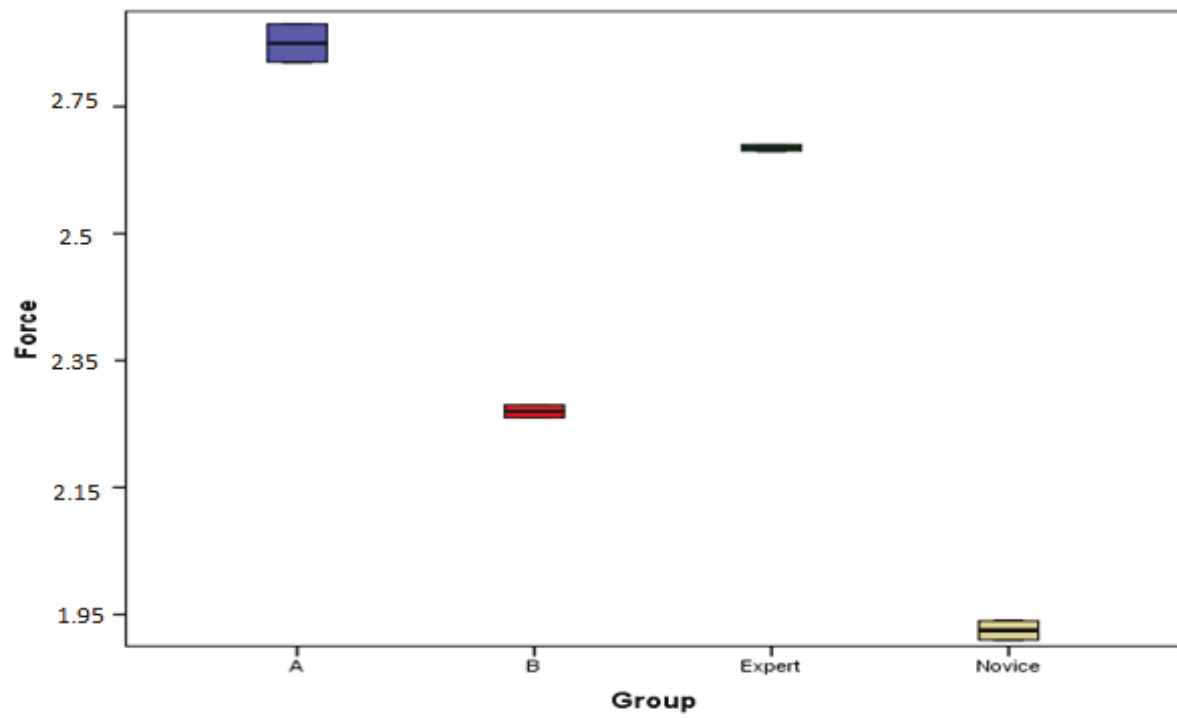
Figure 5.8 Workspace Volume a) Workspace Volume mm³ per Group b) Mean Volume mm³ per Region Group A vs. Group B

5.4.2.4 Force

Group A applied significantly more force than Group B ($P<0.05$). Group A's force was not significantly different to an expert ($P=0.1$) and Group B's force was significantly lower ($P<0.01$) which corresponded with the results from the previous phase (*Figure 5.9a*). Both groups' force was significantly higher than a novice's application of force ($P<0.01$). Group A had a significantly higher probe to skin time compared to Group B, which highlights their efficiency in performing a FAST scan ($P=0.04$) (*Figure 5.9b*).

In the previous phase, we emphasised that a high force correlated with a small workspace. As depicted in *figure 5.9c*, Group A's mean workspace volume commences at a much lower level than Group B and reduces with a higher force. Analysis of high force correlating with low workspace volume did not reach significance in this case with Group A ($P=0.338$) and Group B ($P=0.559$).

a)



b)

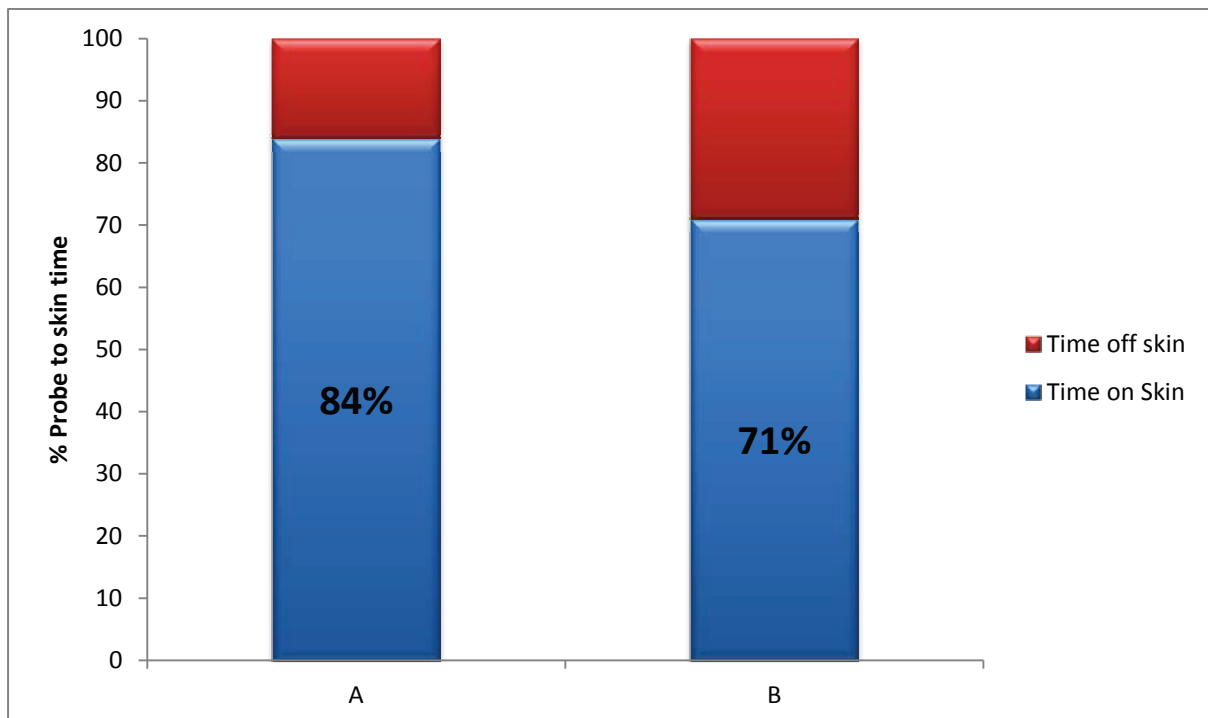


Figure 5.9 Force a) Force (N) per Group b) Probe to skin contact time (%) Group A vs. Group B

c)

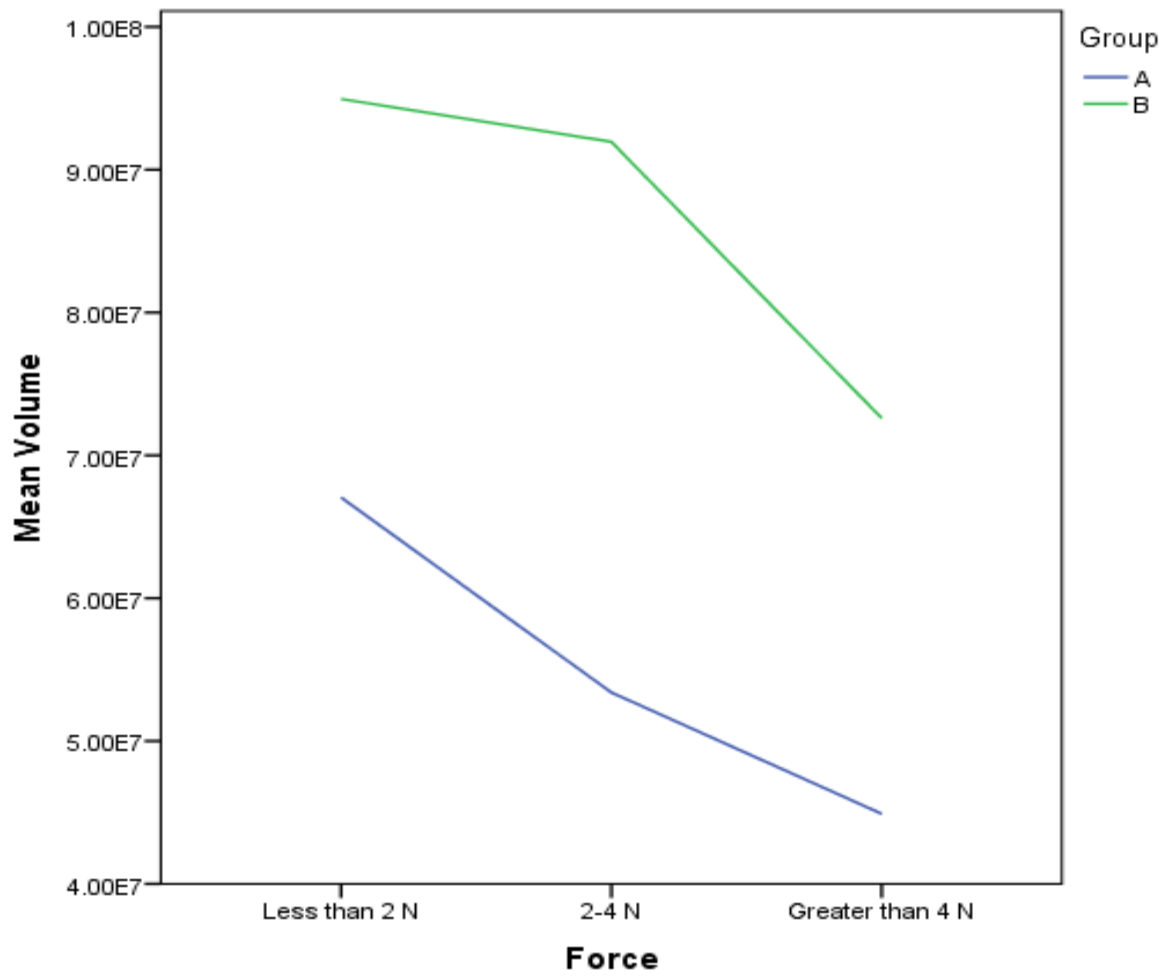


Figure 5.9 Force c) Mean volume per Force (N) Group A vs. Group B

5.5 Discussion

This randomised controlled study has met its hypothesis that teaching novices expert metrics through correct probe position and force application on a simulator will accelerate learning. Furthermore, it has demonstrated that these taught metrics directly translate into improved performance on a virtual patient as compared to those trained in the standard curriculum.

In the learning curve phase, Group A had significantly smaller workspace volumes than Group B and had achieved a plateau in their performance by run 10. This continued to improve into their third session after 48 hours of rest suggesting skill consolidation had been attained. Group B had another peak of workspace volume at the beginning of their third session signifying further practice was required, with a plateau in performance occurring closer to run 15.

Group A compared to Group B applied more force and performed an efficient scan resembling an expert performance. This was verified by a higher probe to skin contact time as well as applying greater force with associated smaller workspace volumes as they focused on the target area. Group A were significantly faster than Group B in completing the FAST scan with a narrow range of timings throughout their runs. They commenced their learning at a higher level of accuracy with fewer errors and no missed targets compared to Group B; findings likely to result from the availability of the position markers and force data to Group A. For accuracy, Group A plateaued at run 8 which is earlier than indicated by workspace performance plateau at run 10 (*Figures 5.3 and 5.4*). Furthermore, Groups A and B reached an accuracy

score of 3 by runs 5 and 15 respectively, which is clearly indicative of a more rapid rate of learning in Group A (*Figure 5.3*).

The methodology in the learning curve phase was aligned with the principles of distributed rather than massed practice^(160, 161). Motor skill learning advances at a fast phase during training and a slow period in between sessions⁽¹⁸⁶⁾ where memory consolidation occurs, hence the minimum 48-hour break. This rest period allows cognitive preparation and mental rehearsal that are essential for an adept enactment. A common feature of interval training is that the improved performance is not retained at the start of the next session, with novices commencing at a lower level⁽¹⁸⁶⁾. This phenomenon was observed in our study in between the first and second session in both groups. However, this was not the case from the second to the final session for Group A's workspace volume implying that that skill had been consolidated, whereas Group B required further training.

In the prospective validity phase, Group A compared to Group B had a significantly smaller workspace volume, applied more force, were faster, with fewer errors and more accurate. Both groups were better than novices across all outcomes which validates the simulator as a high fidelity model for FAST training. The experts were significantly better than Group B for workspace volume and force but not compared to Group A. As this study occurred one month later, we can deduce that Group A's teaching methodology was superior to Group B; as evidenced by the improved translational performance and long-term skill retention on the virtual patient.

A point worth noting is that current FAST training courses are one to two days in duration and adopt massed practice. After the course, a logbook is commenced but there is no guarantee that deliberate practice is being maintained. This study has highlighted that institutions offering FAST training should adopt distributed rather than massed practice into their curriculum to ensure skill consolidation before a logbook is instigated. Furthermore teaching correct probe position and force at each area as per Group A's training regime is superior to current teaching methods for FAST and is worth implementing into future training programmes.

Further research could include testing both groups on a patient with ascites until competency is achieved, following which clinical assessment could commence. Useful adjuncts to highlight correct probe position and force in the clinical setting should be explored. This would support trainees in accelerated skill acquisition and simplify FAST training for large scale use. Ultimately, this could streamline traumatic haemorrhage identification, leading to faster management in this time critical condition.

Limitations

The principles of deliberate practice require the participant to be constantly challenged to aid learning and development. Once performance had plateaued there was no option in our simulator to make the task harder, which if possible, could have provided more data as to which teaching methodology was better. Another limitation was that the simulation setting was not high fidelity. If it were to be repeated, immersing the learner in a more contextualised trauma environment may be more appropriate for training.

5.6 Conclusion

This randomised controlled study has identified that teaching novices expert metrics through correct probe position and force application accelerates learning compared to current teaching. Furthermore, this directly translated into improved performance on a virtual patient. Based on this study, a FAST curriculum could be developed to fast-track training for novices. Future studies could include innovative aids to highlight correct probe position and force application for trainees.

Chapter 6 Ultrasound enhanced haemorrhage control - REBOA

Hypothesis: The accuracy of Zone III REBOA placement can be enhanced with the use of ultrasound and microbubble contrast agents.

6.1 Introduction

When haemorrhage is identified in a trauma patient, early definitive control is critical to survival, with this taking the form of operative or angio-embolic manoeuvres. Unfortunately, a proportion of patients exsanguinate prior to attempts at arresting bleeding. This has prompted investigators to develop adjuncts that can bridge patients to definitive haemorrhage control. REBOA is such an adjunct that involves inserting an endovascular balloon-catheter into the aorta to provide control of bleeding and is described in Chapter 2.4.

Currently, REBOA is deployed in-hospital under image guidance namely fluoroscopy, X-ray or ultrasound guidance⁽⁷⁾. For the prehospital setting, performing an accurate deployment of Zone I or III REBOA without fluoroscopy is challenging but recommendations include inserting the catheter based on external torso measurements^(134, 135) or the use of CEUS. As highlighted in the questionnaire from Chapter 2 participants were keen that more research was undertaken in this area.

Aims

Our objective is to examine if the use of ultrasonography improves the accuracy of catheter placement within Zone III. To assess if the image obtained could be enhanced with the use of a contrast agent, namely microbubbles. To assess two groups of physicians trained with (Group A) and without (Group B) the enhanced technique.

6.2 Methods

6.2.1 Study Design and Setting

A “standard” and “enhanced” REBOA technique was developed using a porcine cadaver (Adult Landrace crossbreed female Swine 70kg). Following this, a mixed group of Consultant and Registrar level physicians were randomised into two groups and taught either the “enhanced” technique (Group A) or the “standard” technique (Group B) as part of a human cadaver trauma skills course which utilized fresh frozen cadavers (*Figure 6.1*). The particulars of performing trauma research (Chapter 1.1.6) and a pre-clinical study (Chapter 2.4) are discussed in earlier sections of this thesis.

The advantage of performing a cadaveric study is that the anatomical challenges of REBOA can be investigated in detail, such as femoral access, tortuous iliac arteries and the correct landing zone. The disadvantages in fresh frozen cadavers are that the vessels are not compliant and hence likely to rupture easily when the balloon is

inflated. Additionally, the major vessels contain ice which have to be completely thawed otherwise the access wires and the catheter will not pass through the vasculature easily. An alternative approach to perform this study would be the use of a REBOA simulator but at present this does not exist.

Permission for the animal component was obtained from the UK Home Office (No. 80/2297) using an accredited facility. The human study was undertaken at Guys hospital, licensed under the Tissue Human Authority Act (License No: 12123).

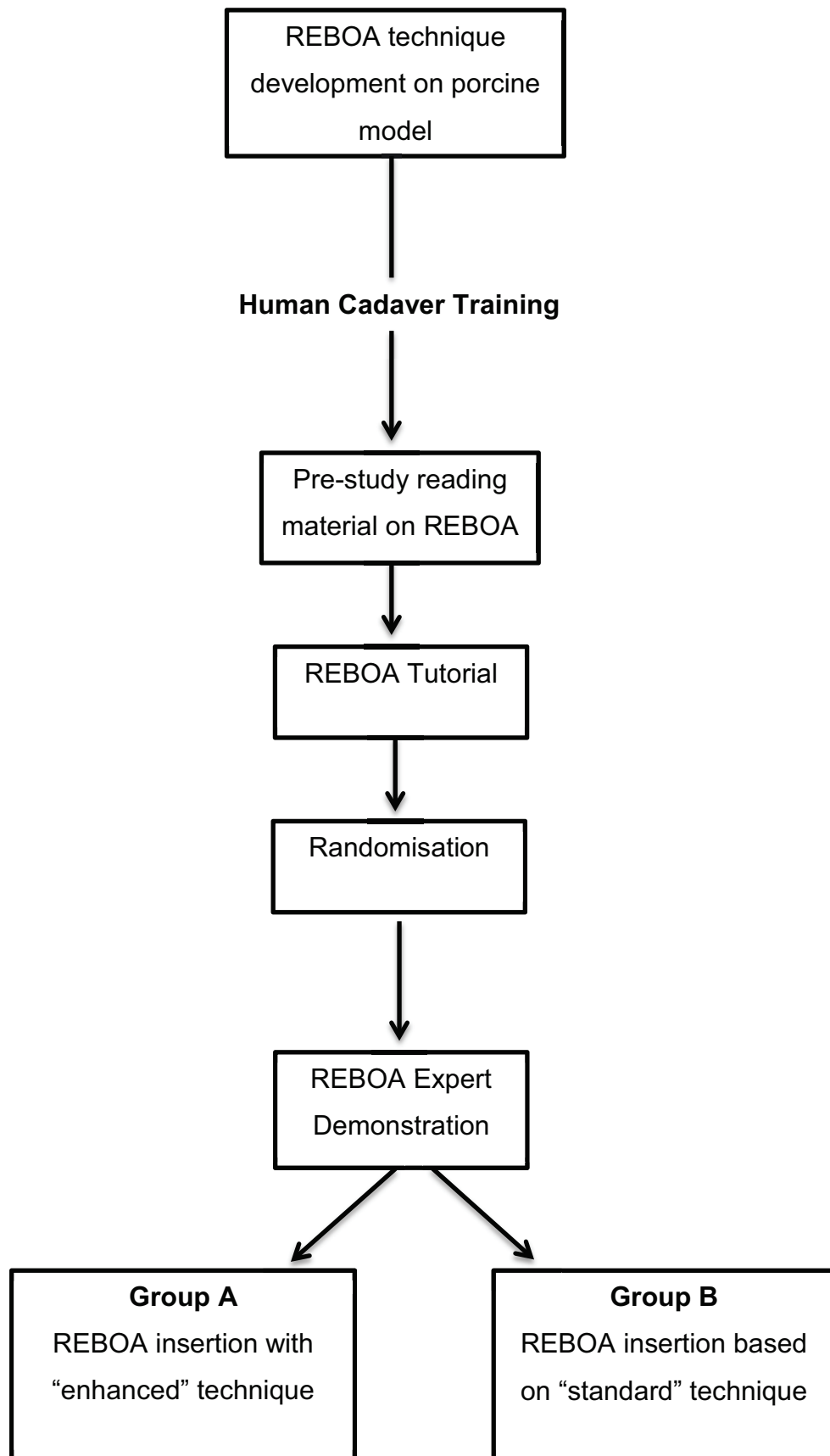


Figure 6.1 Flowchart of study design

6.2.2 Interventions: REBOA Technique Development

The equipment consisted of an Amplatz stiff wire 0.035-inch with an 8cm flexible tip, a Coda balloon catheter (14Fr, 120cm length, balloon maximum inflation diameter 40mm and maximum inflation volume 40mL, Cook Medical), introducer vascular sheath (18Fr, 30cm length, dilator length 42cm, Cook Medical). In the porcine cadaver, a cut-down technique was used to identify the femoral artery. The introducer sheath was inserted into the femoral artery and secured in place and the dilator was removed (*Figure 6.2*).

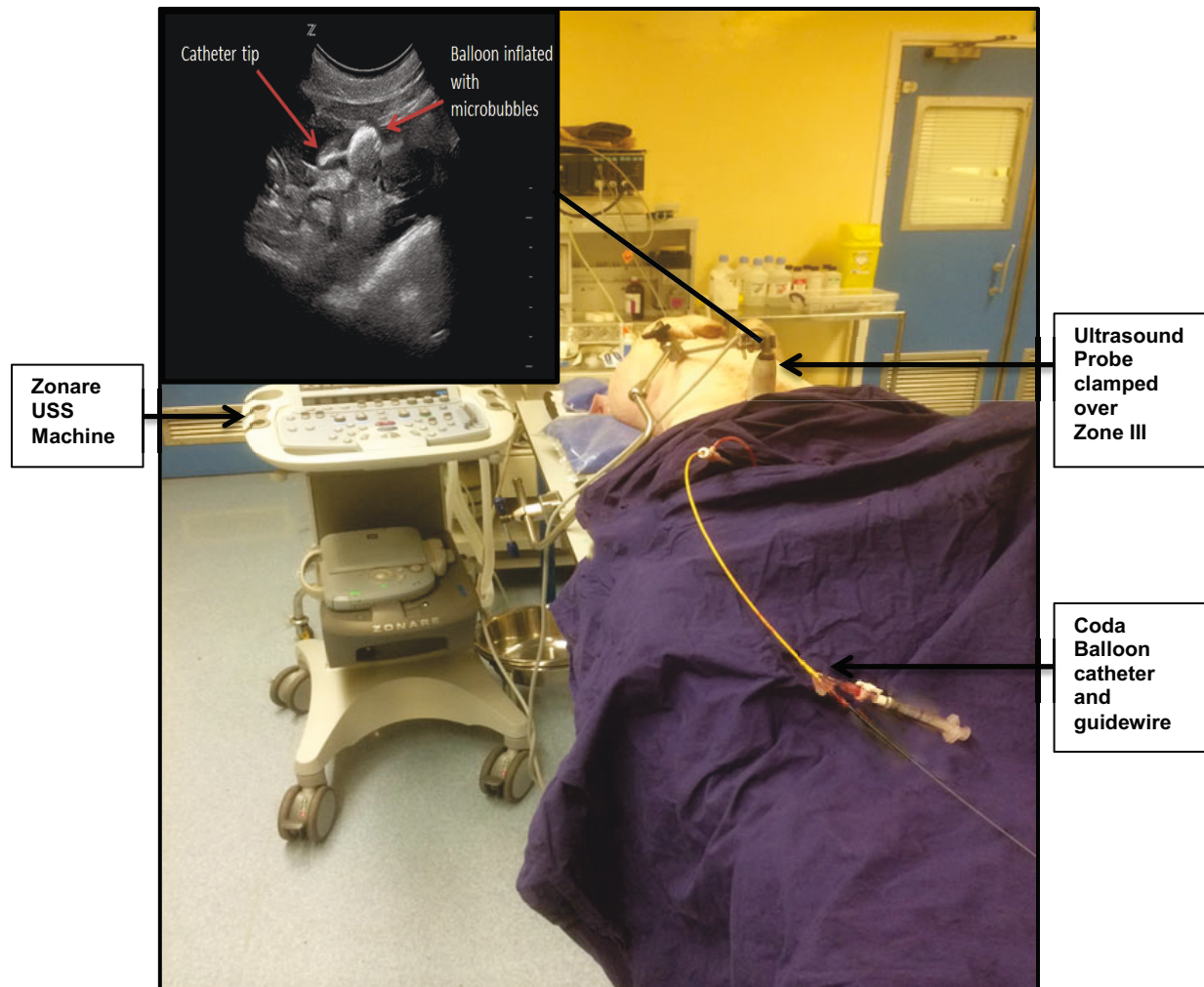


Figure 6.2 Porcine model experimental setup. The introducer sheath and coda balloon catheter over guidewire have been inserted into the right common femoral artery. Ultrasound probe clamped over Zone III of the aorta and ultrasound image of the catheter in the aorta with the balloon inflated to the left of the image.

6.2.3 The Standard Technique

The “standard” REBOA technique consisted of inserting the guidewire followed by the Coda balloon catheter. To ensure inflation in Zone III, the catheter had been measured from the point of insertion to just beyond the umbilicus. The catheter was advanced to Zone III where the balloon was inflated, concluding the manoeuvre.

Ultrasonography was not used to guide the technique but was employed to assess balloon position accuracy once the procedure was finished. The proximal Zone III landmark was where the left renal vein crossed the aorta and the inferior border was at the aortic bifurcation.

6.2.4 The Enhanced Technique

An “enhanced” REBOA technique consisted of the “standard” technique with the addition of ultrasonography guidance and a balloon contrast medium. The contrast agent used in this study which was previously described (Section 2.3.3.2) was Sonovue microbubbles approved for use in the European Union since 2001 (Bracco, Milan, Italy). The Zonare USS machine platform was used in this study (Zonare Medical Systems, Inc. Mountain View CA, USA). It has a C8-33D Curved array transducer with a bandwidth of 8-3MHz and provides a 79-degree viewing angle. The mode of ultrasonography examination was set to standard 2D Abdominal B-mode at a depth of 16cm.

6.2.5 Human Cadaver Training

6.2.5.1 Selection of Participants

A mixed class of Consultant and Registrar level physicians involved in trauma care were enrolled in a trauma skills course. They had no endovascular experience and did not have expertise in ultrasonography nor did they use it on a regular basis in their clinical work. The course consisted of a didactic component and practical sessions using fresh frozen cadavers (Science Care Tissue Labs, Phoenix, AZ). All candidates in the study consented to their participation following a verbal and written description of the study.

6.2.5.2 Methods and Measurements

Participants were given pre-study reading on REBOA that explained the background and the procedure, as well as the pertinent academic literature on the topic^(7, 19, 108, 123-125, 127, 128, 132, 134, 135, 187-191). On the day of the study, participants further consolidated their knowledge with a 30 minute tutorial on REBOA where the background, clinical indications, mechanistic principles and “standard” technique were discussed. The class was then randomised and divided into two groups by electronic number generation assignment. An endovascular expert demonstrated either the “standard” or “enhanced” technique on a cadaver to each respective group.

Before commencing the study, access had been established in both cadavers using a cut-down technique to insert the introducer sheath into the right common femoral artery. This was secured in place and the dilator was removed. Once both groups were ready to proceed, they were asked to perform REBOA independently with an assistant to hold the guidewire.

Participants in Group A individually used ultrasonography to define Zone III and then fixed the probe over the infra-renal aorta. They passed the guidewire followed by the catheter into Zone III under ultrasonography guidance through the introducer sheath. When satisfied that they had entered the correct Zone they inflated the balloon with microbubbles (*Figure 6.3*).

Group B used the “standard” technique to perform REBOA. They did not have ultrasonography guidance and inserted the catheter blindly based on performing a measurement from the point of insertion to just beyond the umbilicus. Once they had reached the correct length of insertion, the balloon was inflated with saline, concluding the procedure.

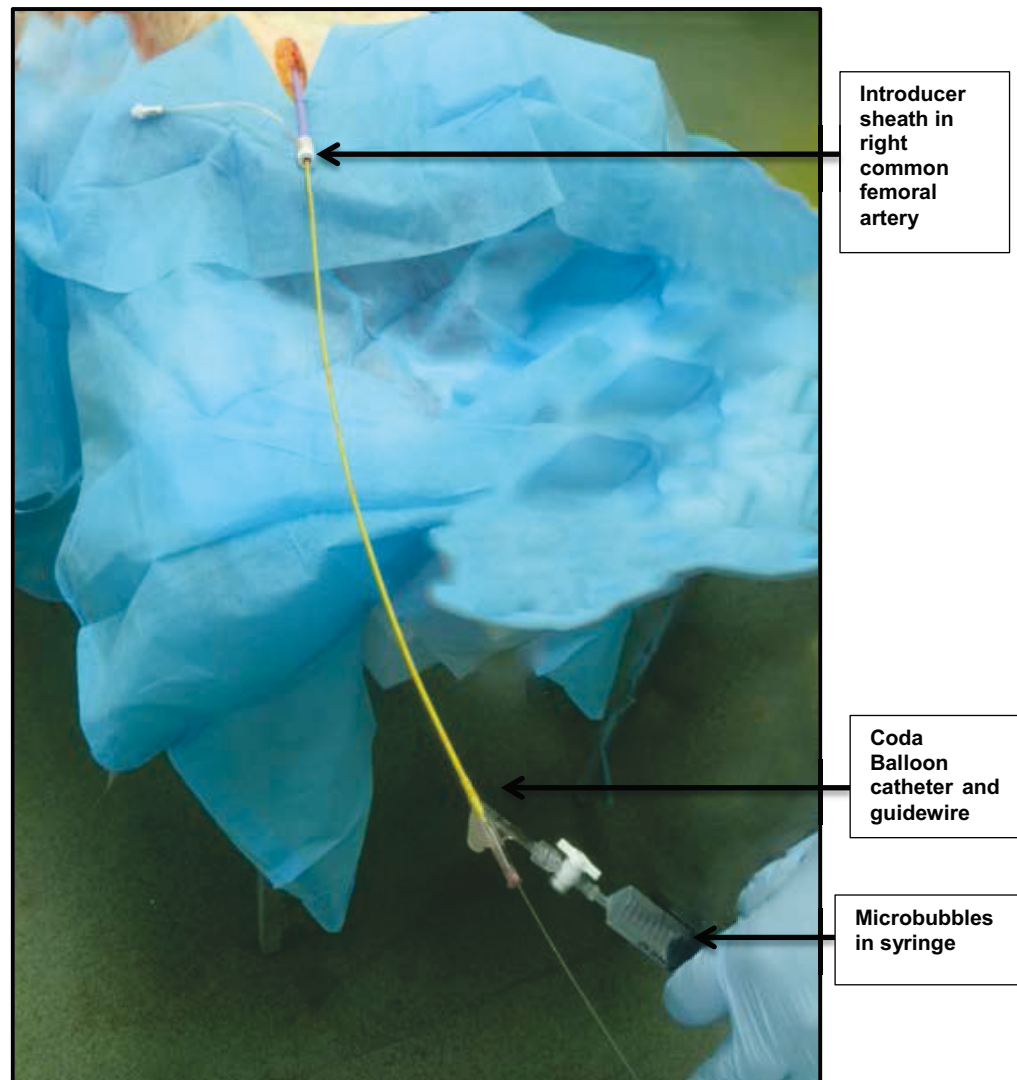


Figure 6.3 Human Cadaver Experimental setup. The introducer sheath and coda balloon catheter over guidewire have been inserted into the right common femoral artery. The microbubbles are ready to be injected into the balloon port of the coda balloon catheter.

6.2.5.3 Outcomes

The study outcomes related to the time of insertion, accuracy of placement and complications of REBOA insertion. Time of insertion (secs) was defined from when the guidewire was inserted into the introducer sheath and stopped when the Coda balloon catheter was fully inflated (stop cock on the balloon inflation port closed after injection). The accuracy of balloon placement within Zone III was confirmed with ultrasonography by an expert and a missed target was defined as placement in Zone I, II or in the contralateral limb. There was no blinding of the outcome assessments. Results were verified by three endovascular experts who performed REBOA for benchmarking purposes.

6.2.5.4 Analysis

Based on preceding literature, eight was the minimum number of participants required per group. This was derived from a power calculation performed on ten subjects with a 2 tailed test, $\alpha=0.05$ and power $(1-\text{Beta}) = 0.8$ with a proposed 30% reduction in time taken to complete REBOA between groups ^(172, 173). The data is expressed as Median and Interquartile Range (IQR). Where appropriate the Mann-Whitney U and Kruskal-Wallis test were used to analyse the data. The statistical analysis was performed using IBM SPSS Statistics software (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp).

6.3 Results

6.3.1 REBOA Technique Development

A single adult Landrace crossbreed female pig weighing 70kg was used to develop the REBOA technique. As the guidewire was inserted into Zone III, this was easily visualised as it was highly echogenic and was passed proximal to the Zone of interest (*Figure 6.4a*). The catheter was delivered over the guidewire and as it entered Zone III the tip could be identified and confirmed by moving the catheter back and forth. The balloon could not be seen during inflation with water or air under ultrasonography, although due to the expansion of surrounding tissue in the aorta, one could approximate that it was being inflated in this region. All these images were cross-checked with fluoroscopy and angiography to ensure that the correct area was being visualised.

The guidewire was left in place and the catheter re-inserted into Zone III. The balloon was inflated with 5mls of microbubbles and was immediately visible on ultrasonography with a snowstorm pattern discernible within the balloon and the presence of an acoustic shadow inferior to the balloon. The image of the balloon and its outline was bright due to the high echogenicity of the contrast (*Figure 6.4b, c*). The balloon was then aspirated and then reinflated with 5mls of air and microbubbles. In this case, the balloon was even easier to visualise as the contrast between the air and the microbubbles within the balloon helped to delineate it further (*Figure 6.4d*).

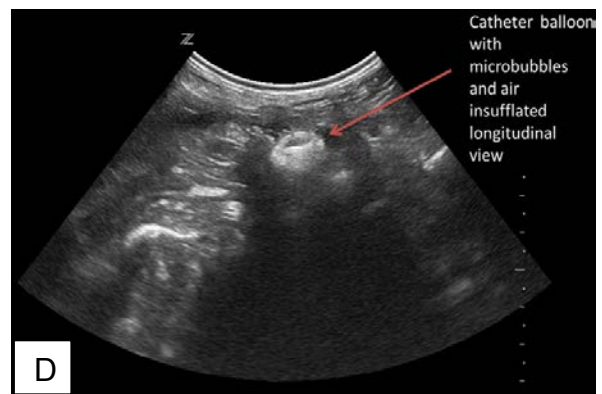
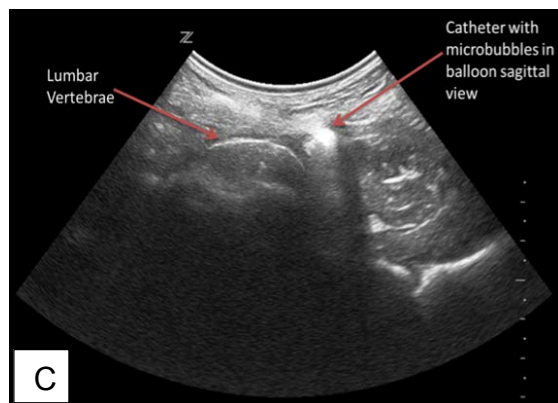
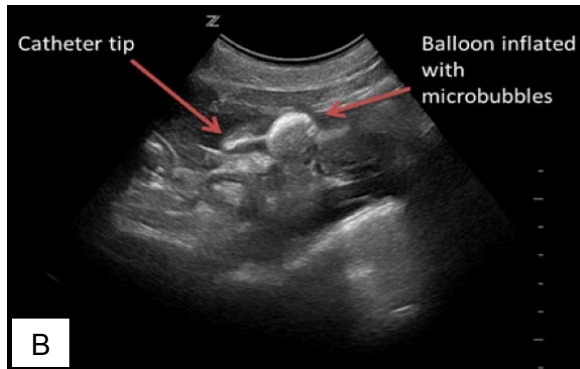
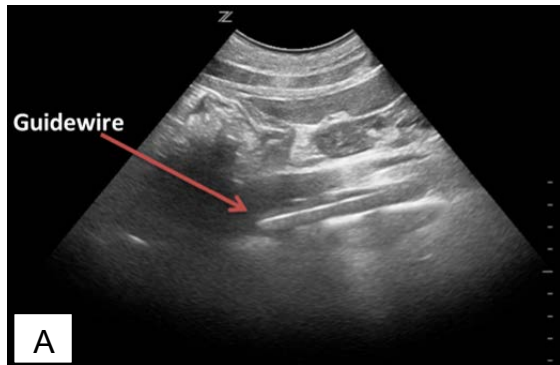


Figure 6.4 Ultrasonography images of guidewire and catheter (a-d):

- (a) Guidewire visualised under ultrasonography longitudinal view within Zone III of the aorta**
- (b) Longitudinal view of Coda catheter tip and balloon inflated with microbubbles within Zone III**
- (c) Sagittal view of Coda catheter tip and balloon inflated with microbubbles within Zone III**
- (d) Contrast enhanced ultrasonography longitudinal view of balloon inflated with microbubbles and air within the aorta**

6.4 Human Cadaver Training: Characteristics of the study subjects

There were 20 participants split equally between both groups. Group A consisted of 2 Consultant physicians as well as 4 registrars from the Emergency Department, one anaesthetic registrar and three helicopter emergency medical service physicians. Group B consisted of 2 Consultant physicians and 1 registrar from the General surgery department, 1 Consultant and 2 registrars from the Emergency Department, 2 anaesthetic and two helicopter emergency medical service physicians. The three Consultant experts who assessed the participants and performed REBOA for benchmarking purposes had over 25 years of endovascular and trauma experience between them.

6.4.1 Main Results

Group A were significantly faster than Group B in inserting and inflating the Coda balloon catheter at 51 seconds (40-67) vs. 90 seconds (80-129) [Median; (IQR)] ($p=0.003$) (*Figure 6.5*). The expert cohort (Median 18; IQR 17-19 secs) were significantly faster than both groups in performing REBOA ($p=0.001$). Group A were also significantly more accurate than Group B in inflating the balloon within Zone III with no missed targets ($p=0.023$). Group B had 5 missed targets the most common error being inflation within Zone II although in one case the catheter was inflated in Zone I (*Figure 6.6*). In this case the participant had failed to correctly measure the length of catheter insertion hence leading to the error of inflation within Zone I. There was also an instance where the participants stated that the guidewire was meeting resistance and examining this further with ultrasonography it had been pushed in too far and was abutting the thoracic aortic arch although no injury had been caused.

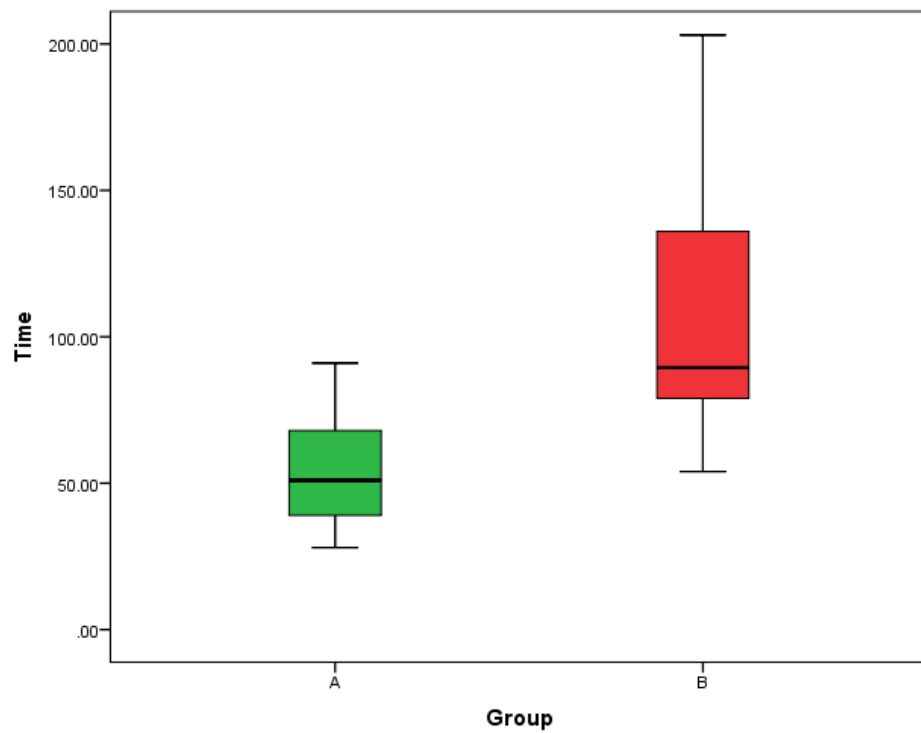


Figure 6.5 Time (Secs) to perform REBOA Group A vs. Group B

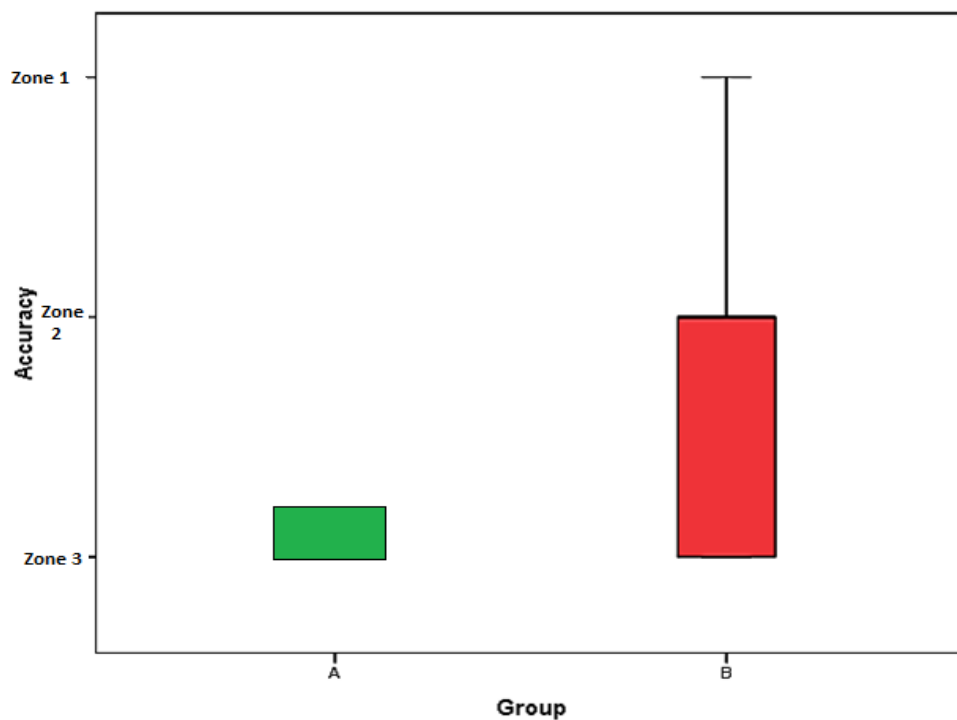


Figure 6.6 Accuracy of balloon placement within Zone III Group A vs. Group B

At the end of the study, the aorta was dissected out to assess for any injury as the last two participants stated that they felt resistance during insertion of the catheter. Examining the right common iliac artery it was noted that a subintimal flap had been created which extended into the distal aorta. It must have been caused by repeated insertions of the guidewire and catheter and explains why the participants were experiencing resistance (*Figure 6.7*).

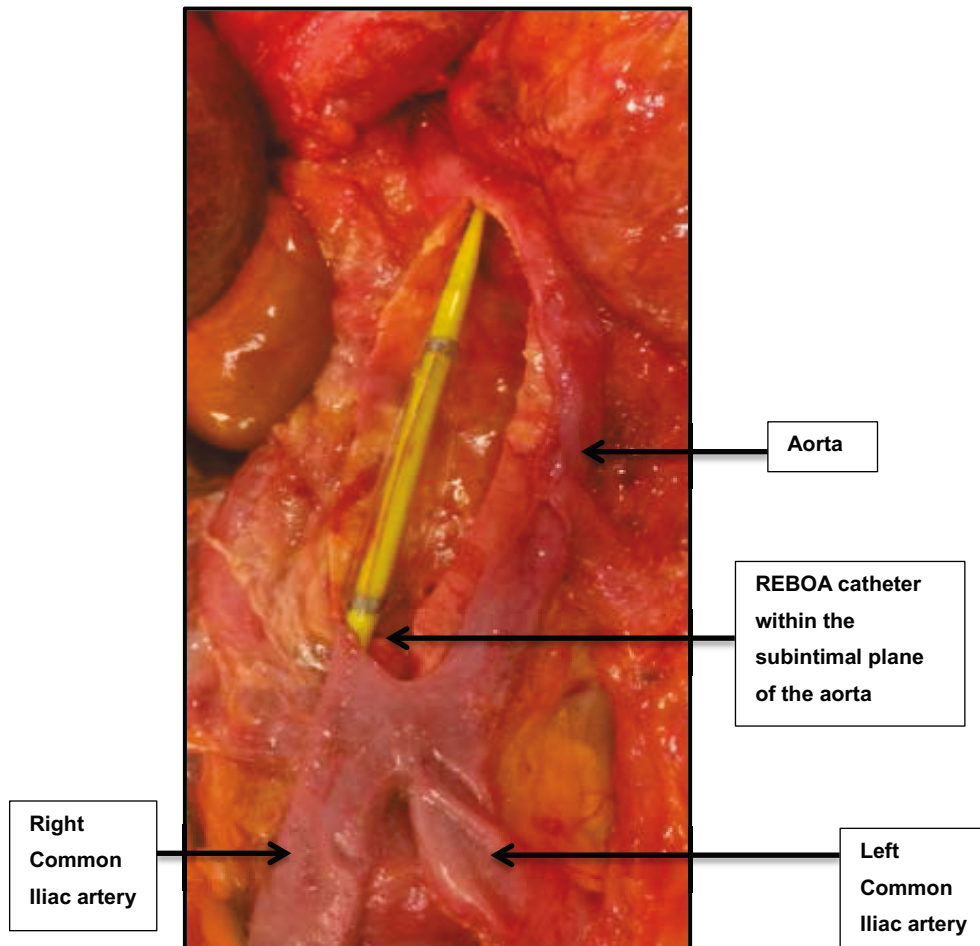


Figure 6.7 Dissection of the aorta exhibiting the REBOA Catheter within the subintimal plane of Zone III

6.5 Discussion

This study assessed the role of contrast enhanced ultrasonography for Zone III REBOA placement. The first two objectives were addressed by a porcine model, which demonstrated that the catheter could be identified with ultrasonography and balloon inflation visualised then enhanced with microbubbles injected through the balloon port.

Following the proof of concept, the technique was taught to participants on fresh frozen cadavers. This demonstrated that contrast enhanced ultrasonography helped to improve the accuracy of catheter placement within Zone III, but also accomplished this more rapidly than the standard technique. The participants found that it was much easier to visualise the balloon when inflating 5mls of air with the microbubbles due to the contrasting perspectives and this ensured a greater level of operator confidence. Whereas physicians using the blind “standard technique” were more apprehensive, with more time spent ensuring the correct length of catheter insertion and even had repeated attempts before balloon inflation.

For prehospital REBOA, there is a need for fluoroscopy free catheter placement methods and there are examples in the literature. Manning⁽¹⁹²⁾ described blind thoracic aortic catheter deployment for 22 medical cardiac arrest patients in the prehospital care setting. The length of catheter insertion to the thoracic aorta was measured from the sternal angle to umbilicus then to the inguinal crease and the position verified later with chest radiographs. All catheters were appropriately placed and femoral access was cited to be the greatest challenge which could be overcome

with the use of ultrasonography. Sovik et al⁽¹⁹³⁾ described blind aortic balloon occlusion catheter placement for post-partum haemorrhage in six patients. They did use ultrasonography for the guidewire placement to ensure correct insertion but did not use it for catheter insertion. Within this six patient series, one complication of aortic rupture following balloon inflation occurred, which required operative repair.

Within the trauma literature, Martinelli et al⁽¹²³⁾ report the largest series of Zone III occlusion for 13 hypotensive pelvic fractures. REBOA was performed in the emergency department using a blind technique. They inserted the catheter up to 50cm with partial balloon inflation and then withdrew the catheter until resistance was felt at the aortic bifurcation. The balloon-catheter was then advanced a further 5cm before fully inflating the balloon. In two cases, they inadvertently inflated within the iliac artery but were otherwise successful. Attempts have also been made to develop a mathematical solution to guide insertion distance based on CT morphometry data. Morrison et al⁽¹³⁴⁾ correlated torso height with aortic length using linear regression to develop insertion length equations.

This study demonstrates that ultrasonography has promise as a tool to guide REBOA placement. There are limitations of ultrasonography such as its broad sensitivity, which are mainly due to varied operator skill. If this study were to be repeated, recording and stratifying participants' outcomes by ultrasonography experience could help to derive a more meaningful dataset to analyse. Additionally if the model being examined is obese, has surgical emphysema or has much air within the bowel then the images are more difficult to acquire.

It is imperative that trauma personnel receive training in REBOA deployment. This study has outlined a model for REBOA training and assessment that could be integrated into a curriculum. It may be the case that ultrasonography, when available with a trained operator, is part of the REBOA insertion algorithm. Additionally contrast enhanced ultrasonography is well suited for austere REBOA deployment as it is a rapid, portable, effective, non-invasive diagnostic modality.

There are still a number of issues to address with REBOA use in prehospital care that are topics for further research. The hypothesis will need to be examined on cadavers with diverse body habitus as ultrasonography images are more difficult to acquire in obese individuals. It is also unclear whether contrast enhanced ultrasonography could be used for Zone I REBOA placement and this should be evaluated. The hypothesis should also be assessed in a perfused model to ascertain the true potential of ultrasonography⁽¹⁹⁴⁾; such as the use of Doppler and colour flow to confirm flow occlusion, as well as monitoring for balloon migration. Additionally for clinical use instead of air, Helium could be evaluated to inflate the balloon with the microbubbles, as it has the same properties and disperses quickly if the balloon inadvertently ruptures⁽¹⁹⁵⁾.

6.6 Conclusion

In summary, this is the first study to demonstrate that for prehospital Zone III REBOA catheter insertion, contrast enhanced ultrasonography is faster and more accurate than the standard technique. In a time-critical situation where the trauma patients physiology is in extremis, aids such as ultrasonography with a contrast agent could ensure safe catheter placement within the correct zone. This may be a viable option in trained personnel for prehospital use and should be investigated further.

Chapter 7 Conclusions and Future work

7.1 Achievements of this Thesis

This thesis examined how abdominal haemorrhage identification and control can be enhanced in the prehospital setting through the use of ultrasound. In Chapter 2 a national questionnaire tasked front line trauma clinicians to improve prehospital abdominal haemorrhage identification and its control. A UK consensus is achieved amongst the trauma community on how to tackle this challenging area. The majority of respondents were Consultants who stated a clear recommendation for more training as well as research into haemorrhage identification and control. For training, participants requested more exposure to simulators and cadavers. In terms of research, ultrasound, novel mechanical compression devices and endovascular control need to be explored further.

Chapter 2 consolidates the available evidence to affirm that FAST is effective for detecting abdominal bleeding in experienced hands. Furthermore, the localisation of bleeding can be augmented with the use of contrast agents and the 3D modality.

This chapter concludes with an extensive summation of available technology for prehospital abdominal haemorrhage control. Novel methods outlined include foam, gas insufflation, HIFU as well as manual compression⁽⁶⁷⁾. One of the most promising techniques highlighted is REBOA, which has a significant mortality risk reduction associated with it and is addressed in Chapter 6. The findings from the questionnaire and the literature review helped to gain a better understanding of the subject matter

as well as direct avenues for further research in the subsequent experimental chapters.

As stated in Chapter 2, more training is required in simulation as well as more research into ultrasound as an adjunct for prehospital management. Hence, the successive chapters examine FAST in more detail. Despite the benefits of FAST there has been a limited uptake in the prehospital setting because of a steep learning curve to gain proficiency as well as the lack of a standardised curriculum and assessment^(2, 3). In Chapter 3 the face, content and construct validation of a FAST phantom is achieved⁽⁴⁾. This fulfils the point raised from the questionnaire in Chapter 2 calling for authenticated simulation training. In addition, a more rigorous method of assessing FAST operator skill proves to be effective in differentiating proficiency.

Chapter 4 provides an original insight into the probe manipulation ergonomics of an expert FAST performance. Specifically, an experts hand motions and force are recorded to identify the ideal probe position and force application for each region of the FAST scan. This study of an expert FAST performance is critical to providing a model for training as well as guiding engineers for potential technology transfer within this area.

By deconstructing an expert performance into its building blocks, it can be assimilated to teach novices an enhanced method of learning FAST. This hypothesis is examined in Chapter 5. In a randomised learning curve study, one of the novice groups is trained in the expert metrics from the preceding chapter by having the ideal

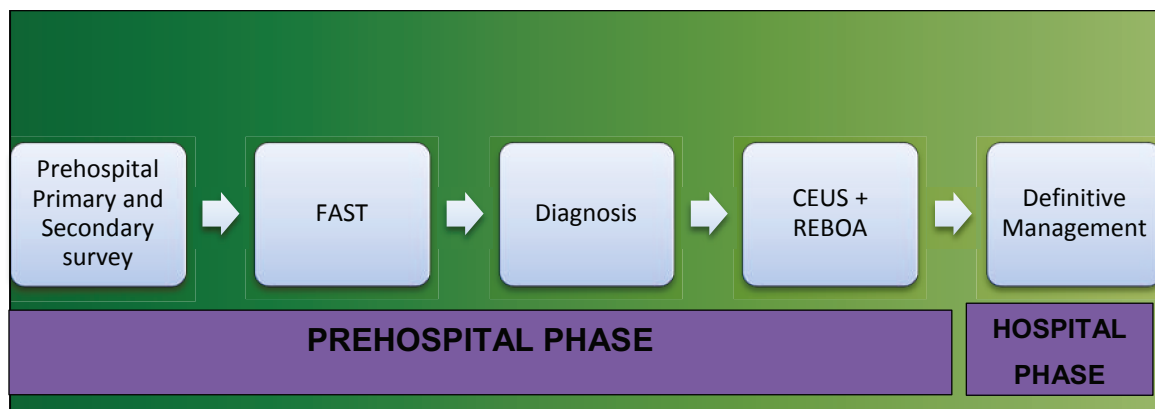
probe position and force for each region of the FAST provided to them; whilst the control group are trained in a standard curriculum. The findings establish that compared to the control cohort, the group trained in the expert metrics were faster and more accurate in conducting FAST, with a rapid rate of learning and an earlier plateau of competent performance. In order to test the robustness of the new teaching methodology both groups are examined again on a virtual patient in a prospective validity study. In this study, no aids are provided to the expert metrics group and they still prove to be faster and more accurate than their control group. Hence, Chapter 5 improves the steep learning curve associated with FAST^(2, 3) by verifying a faster and more effective method of training novices compared with the current curriculum in use.

One of the priorities listed in the questionnaire from Chapter 2 was for more research to be undertaken into novel haemorrhage control techniques such as REBOA. Therefore, Chapter 6 investigates how ultrasound and contrast agent could augment this technique. A pilot porcine model study identifies that the accuracy of Zone III REBOA placement is improved with an enhanced technique of ultrasound guidance and microbubbles insufflated into the balloon of the catheter. This methodology is then validated in a randomised study conducted on cadavers. A group of physicians perform Zone III REBOA using an enhanced technique and the control group insert the catheter based on a measurement from the point of insertion to Zone III with no sonographic guidance. The intervention group proved to be faster and more accurate than their control group, thereby augmenting a haemorrhage control intervention by verifying that ultrasound and microbubbles can improve Zone III REBOA accuracy.

In summary, this thesis has examined how abdominal haemorrhage identification can be improved in the prehospital setting. This has been achieved by validating a FAST simulator, identifying the ergonomics of probe manipulation during a FAST scan and outlining a training methodology which can accelerate learning for novices as well as having technological implications for an automated FAST platform. For advancing prehospital haemorrhage control, this thesis has demonstrated a method for improving REBOA placement with CEUS. It is envisaged that the findings from this thesis will have an impact on the prehospital trauma care pathway to ensure faster diagnosis and management of the trauma patient. In doing so, it will enable a seamless transition from the prehospital to the hospital phase as desired by a participant in the questionnaire from Chapter 2. As a result of the findings from this thesis, the original pathway described in *figure 1.1* can now be enhanced as illustrated in *figure 7.1*.

This figure illustrates an improvement of communication between the prehospital and hospital setting for an unstable trauma patient with intra-abdominal haemorrhage. In the prehospital setting, this occurs through recognition of life-threatening pathology with FAST, resulting in escalation of care with swift transport and reporting the findings to the receiving trauma centre. The hospital can then mobilise theatres or interventional radiology so that they are prepared for the patients' arrival. In the interim period, REBOA with CEUS is performed as a temporising bridge to surgery. On patient arrival in hospital, ED is bypassed and the patient is taken straight to definitive care. This is only possible due to enhanced communication between the prehospital and hospital setting enabling the integrated care of the patient. It is envisaged that this would improve outcomes.

PROPOSED TRAUMA WORKFLOW FOR INTRA-ABDOMINAL HAEMORRHAGE



GOLDEN HOUR (Mins)

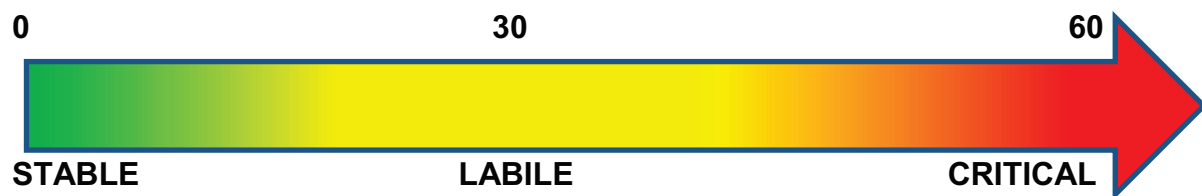


Figure 7.1 Depiction of proposed trauma workflow to highlight that FAST and CEUS with REBOA could expedite diagnosis and management of intra-abdominal haemorrhage. Casualty condition labelled by colour STABLE = GREEN, LABILE=YELLOW AND CRITICAL = RED

7.2 Future Work

It was clear from the outset of this thesis that considerable research is required to significantly impact on traumatic intra-abdominal haemorrhage control. There needs to be a focus on essential elements such as enhanced training in the current methods of early haemorrhage identification and control as well as encouraging innovation in developing new techniques. Further research in this area has a significant potential impact, not only locally but on a global scale. This thesis has aimed to address and review the current areas of haemorrhage identification and control with the objective of improving accuracy and safety in both areas. Within each preceding chapter directions for future work as well as limitations were discussed in detail. The two main themes along which future work could be focused on are outlined below.

7.2.1 Training

For high stake settings such as trauma care, continual practice is critical for a good performance. As stated in the questionnaire from Chapter 2, simulation has an important role in ensuring that high quality training is delivered so that skills are well honed prior to clinical application. Hence, there is a need for more research into simulation-based trauma education. This thesis has outlined the training and assessment for novices in both FAST and REBOA, which could be integrated into their respective curriculums. The domains for further work should be aligned with the pillars of simulation which include: matching simulation with the learners curriculum, providing authentic high fidelity clinical context, engaging in deliberate distributed

practice with constructive feedback and transferring these skills seamlessly to the clinical environment^(158, 159, 196, 197).

Additional studies could also explore team based training to allow constant rehearsal in the same manner as airline pilots⁽¹⁹⁸⁻²⁰⁰⁾ or Formula One pit teams perform⁽²⁰¹⁻²⁰³⁾. In conjunction with this, there is a need for ongoing team assessment to ensure there is no skill degradation and that optimal performance is maintained. In this manner, trauma practitioners will stay on the learning curve of the adaptive expert who is continually fine-tuning their skill armamentarium⁽²⁰⁴⁻²⁰⁶⁾.

7.2.2 Technological innovation

The most significant paradigm shift in trauma care will undoubtedly arise from technological innovation. This is a rapidly growing field with many exciting prospects on the horizon. In Chapter 5, it was recommended that developing a device to highlight the correct ultrasound probe position and force could accelerate training for novices. Taking such a tool into the field would need to take into account the different body habitus of the trauma patient. For this purpose, there may be a role for devices such as the Microsoft Kinect sensor⁽²⁰⁷⁾ to map out the body habitus of the patient in the back of an ambulance and then calibrate the findings with haptics to ensure correct probe position and force application. This could enable an automated and repeatable imaging system. In conjunction with telemedicine, this device may assist novices to perform the FAST scan under the guidance of an expert who can remotely evaluate the images at the point of injury, as conducted in a similar experiment by Boniface et al⁽¹⁰⁵⁾.

Telemedicine is possible due to enhanced satellite and wireless technology. This enables the hospital to come to the patient in the most remote areas of the world and even at the International Space station⁽²⁰⁸⁾. Real-time care can be provided by hospital-based experts to trauma patients at the scene of an incident alongside improved communication with prehospital staff. This can include an expert opinion on FAST scan images or to guide prehospital personnel through a procedure. This is possible due to increased connectivity, as well as cameras that can pan and tilt to allow the operator to have a wide field of view⁽²⁰⁹⁾.

An example is Song et al⁽¹⁰⁴⁾ who performed FAST in a moving ambulance on a FAST simulator model. The ultrasound machine was connected to a laptop which was linked to a 3G mobile phone network enabling real-time ultrasound image transfer to the hospital expert with an accuracy of 88%. Telemedicine can also allow experts to access autonomous robotic platforms that perform an automated FAST scan. This would be useful in areas such as remote/space medicine and the proof of concept was described by Mylonas et al (*Figure 7.2*⁽⁸⁾). The limitations of telemedicine are mainly related to connectivity. Rural areas may have inadequate internet coverage making telemedicine difficult to achieve. Limited bandwidth can also cause delays in communication and any interruptions can degrade images making clinical interpretation difficult^(104, 209).

For prehospital torso haemorrhage control, we are on the cusp of a major technological breakthrough. There are a number of promising innovations that have been comprehensively described in Chapter 2 such as foam insufflation, HIFU and REBOA⁽⁶⁷⁾. As stated in the review, HIFU can stop bleeding from a localised source

and its effect is enhanced in the presence of microbubbles^(136, 142, 149). If further technological enhancements are made which enable HIFU to be applied through the transcutaneous route, there could be a possibility of utilising it as a non-invasive means of arresting haemorrhage. A further advancement using the technique just described would be to use the microbubbles as a vehicle for drug delivery to the site of haemorrhage. This has already been used in a similar manner in the field of oncology for delivery of chemotherapy agents to the site of cancer⁽²¹⁰⁻²¹³⁾. In this case, it could be used to accelerate haemostasis by rupturing microbubbles containing pro-coagulant factors at the source of bleeding with the use of HIFU. These are plausible theories that require more research to assess their feasibility.

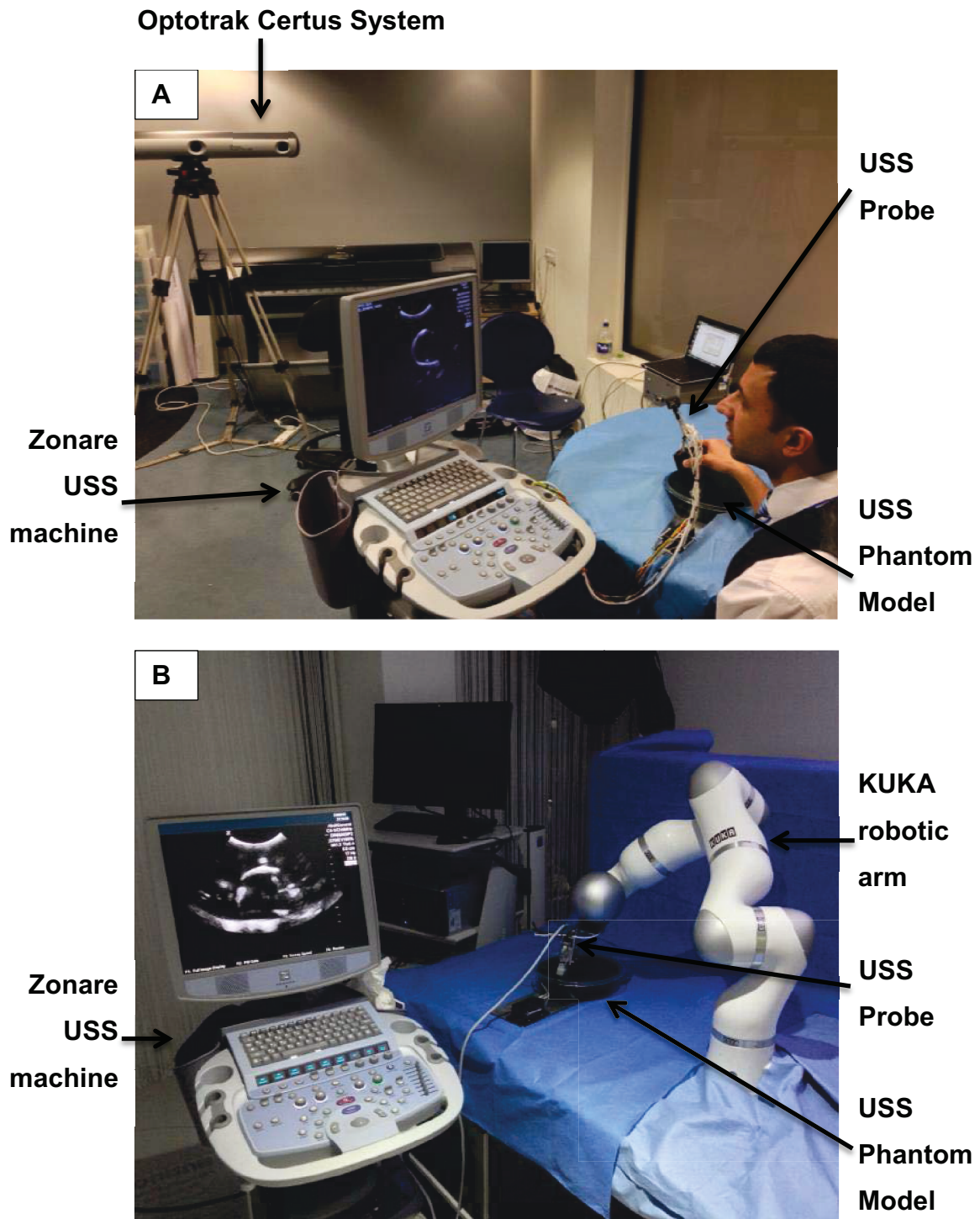


Figure 7.2 A) Experimental setup for data collection so that the robotic system can learn from demonstration how to perform an ultrasound scan of the phantom model. The components of the setup are the Zonare USS machine, Optotrak Certus system, USS phantom model, ultrasound probe with force sensing and 3D position markers. B) Experimental setup used for the execution of the autonomous ultrasound routines learned by demonstration. The key element is the robotically controlled ultrasound probe which replaces the human operator⁽⁸⁾.

In the case of REBOA, if the ultrasound probe can be fixed over Zone III as the patient is in transit to the trauma centre; this will enable the user to visualise balloon inflation as well as allow continuous monitoring to ensure that there is no balloon migration and to confirm distal flow occlusion. The establishment of a prehospital procedure such as REBOA or a similar device that definitively controls torso haemorrhage will significantly shift trauma care from the hospital to the point of injury. This could result in the patient arriving in the trauma centre already stabilised, with only ongoing surveillance necessary and ultimately reduce mortality.

There is also a need to explore next generation haemorrhage identification and control devices that could positively impact trauma care. There is a real prospect of embedding a multi-parameter biosensor at the point of injury which could provide a diagnosis, as well as rapid and accurate physiological information throughout the resuscitation phase, which will significantly aid goal-directed therapy⁽²¹⁴⁻²¹⁹⁾. The capacity to remotely monitor physiological markers and report immediate results, as well as trends to clinicians, will improve patient management. Biosensors could autonomously sense and act to release drugs on demand which will greatly aid patient care^(218, 219). Furthermore, these sensors can stay with the patient throughout their hospital care, as well as onwards to discharge and rehabilitation, with the ability to biodegrade when no longer required. These characteristics of biosensors make them particularly attractive to the pre-hospital setting, trauma care, austere environments and the military⁽²²⁰⁾.

7.3 Conclusion

Torso haemorrhage control remains a challenging area, particularly in the prehospital setting. This thesis has made progress towards tackling areas of this topic. The ultimate aim of this research is that the first prehospital responder is equipped with all the necessary tools to diagnose and achieve control of pathology at the scene, to the extent that no further management is necessary. Although this may seem far-fetched today, it is a real possibility that this could be achieved in the near future and undoubtedly it will require image enhancement at the scene.

For the trauma patient, we remain committed to delivering the finest care around the clock. This dedication and relentless pursuit of excellence are paramount to ensuring that we always deliver our best performance. Despite this, there are still patients that we cannot save and they remain imprinted on our minds. With every patient, there is a learning opportunity and in today's era of rapid communication any clinician worldwide can learn valuable lessons that may directly affect their own practice. It also means that we should remain perceptive to innovations in trauma care by being engaged with industry in the development of devices from the outset. This will allow swift dissemination of a validated innovation that could save countless lives. Trauma research has been an underfunded, under-researched area and is currently at the start of an exponential curve of innovation^(65, 221). There is no time better than the present for stakeholders to engage in this field in order to have a positive impact on trauma care.

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