HUMAN CADAVER ENDOVASCULAR TRAINING: THE ESTABLISHMENT AND VALIDATION OF A FRESH FROZEN PULSATILE HUMAN CADAVER ENDOVASCULAR TRAINING MODEL

A thesis submitted for the degree of Doctor of Medicine to the University of Newcastle upon Tyne, United Kingdom

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“Practice a whole bunch on a simulator and get good, then see a few, do a few, teach a few.”

Sacks D. Presidents address at the 2008 SIR annual members’ business meeting.
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I dedicate this thesis to my wife whose overwhelming patience and unrelenting support throughout the countless hours of hard-work, gave me the strength to complete it. An exceptional mother, wife and my best friend: with every ounce of my soul, thank you.

DECLARATION

I, Mr Craig Nesbitt, declare that:

None of the work associated with this thesis project has been submitted in support of an application for a higher degree or qualification at this or any other University, or other institute of learning. All of the work has been carried out by myself except where specifically indicated in the text if the thesis.

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CONFLICT OF INTEREST

I am grateful to Medtronic who provided financial support to help fund the purchase of the pulsatile pump, which was integral for the design of the pulsatile fresh frozen human cadaver endovascular training model.
Medtronic were not involved in the concept, design, running or analysis of any aspect of the trial. As investigators we hold full academic freedom over the results of the trial and subsequent presentation and publication.

ABSTRACT

AIMS:

The current study had the following aims:

1. Establish an effective pulsatile human cadaver pulsatile flow model (PHCM).
2. Explore the acceptability of PHCM
3. Assess the face and construct validity of PHCM.
4. Compare the effectiveness and transferability of endovascular skills taught on PHCM versus a virtual reality simulator (VRS).
5. Examine the role of video-enhanced feedback during technical skills training.

METHODS:

1. Cadaveric experiments were conducted at a licensed research facility: Newcastle Surgical Training Centre (NSTC).
2. Structured questionnaires were used to explore public and professional opinion.
3. Face and construct validity were assessed in a standard manner using practitioners of varying levels of experience.
4. Novice candidates were recruited and completed the same training regime on PHCM or VRS before crossing over onto the alternate model to compare the effectiveness of PMCH and transferability of endovascular skills. All performances were recorded and scored by two blinded experts using a validated clinical scoring tool.
5. Novice candidates were assessed performing a basic suturing exercise before and after varying forms of feedback (including video enhanced feedback).

RESULTS:

1. A PHCM was successfully created.
2. Patients and professionals support cadaveric endovascular training but expressed some reservations over its feasibility.
3. Expert practitioners confirmed the models face validity. PHCM has construct validity in differentiating between novice candidates and both intermediate

(p=0.000)* level and expert (p=0.000) practitioners (improved overall procedure score (OPS)).

4. PHCM training improved candidate's quantitative parameters (Time p=0.000, Fluoroscopy p=0.026, Contrast p=0.008) and clinical performance scores (p=0.000)*. Both PHCM and VRS demonstrated transferability of basic endovascular skills.

5. Video feedback is superior to a structured lecture (OPS) and individualized feedback was not superior to unsupervised video-enhanced feedback (p=1.000*).

CONCLUSION:

PHCM is a feasible, valid and effective model for training basic endovascular skills. The role of unsupervised video feedback could further enhance technical skills training and warrants further investigation.

* One Way ANOVA (Bonferroni)

ABBREVIATIONS

ACGME	Accreditation Council for Graduate Medical Education
BEME	Best Evidence in Medical Education
BS	Mean Blinded Score
CANMEDS	Canadian Medical Education Directions for Specialists
CAS	Carotid Artery Stenting
CST	Core surgical trainees
CVD	Cerebrovascular Disease
CT	Computer Tomographic
DO	Mean Direct Observation Score
EBSQ-VASC	European Board Of Surgery Qualification In Vascular Surgery
EVAR	Endovascular Aneurysm Repair
EWTD	European Working Time Directive
FDA	Food and Drug Administration
FYT	Foundation trainees
GRS	Global Rating Scale
HC	Human Cadaver
HTA	Human Tissue Authority
IHD	Ischaemic Heart Disease
IMPROVE	The Immediate Management of the Patient with Ruptured Aneurysm: Open Versus Endovascular repair
ISCP	Integrated Surgical Curriculum Project
MRS	Modified Reznick Scale
MS	Medical Students
NS	No Significant Difference
NSTC	Newcastle Surgical Training Centre
NUMS	Newcastle University Medical School
OPS	Overall Procedure Score
OSCE	Objective Structured Clinical Examination
PI	Principal Investigator
PG	Postgraduate

PHCM	Fresh Frozen Pulsatile Human Cadaver Model
PVD	Peripheral Vascular Disease
SD	Standard Deviation
SFA	Superficial Femoral Artery
SMA	Superior Mesenteric Artery
SMOTS	Scotia Medical Observation and Training System
TAVI	Transcatheter Aortic Valve Implantation
TEVAR	Thoracic Endovascular Aneurysm Repair
TSC	Task Specific Checklist
UTN	Unique Training Number
UK	United Kingdom
VEF	Video Enhanced Feedback
VITC	Vascular Interventions Training Course
VIST	Vascular Intervention Simulation Trainer
VR	Virtual Reality
VRS	Virtual Reality Simulation
WHO	World Health Organisation

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Introduction

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1.0 Introduction

1.1 Endovascular Surgery

Surgical practice is changing rapidly as technology continues to improve. The introduction of minimally invasive surgery has changed specialties such as gynaecology, urology and general surgery almost beyond recognition. This trend has also revolutionised vascular surgery with the introduction of endovascular techniques.

In 1953 Dr. Sven-Ivar Seldinger described using a catheter to replace a needle for diagnostic arteriography, thus beginning the practice of endovascular intervention (Seldinger 1953). Arterial dilatation was first described using a Teflon catheter in 1964 (Dotter 1964) and balloon angioplasty was then introduced in 1974 (Gruentzig et al, 1974). In the past 20 years endovascular interventions have increased exponentially; endovascular stents were introduced in 1985 and the world's first endovascular aortic aneurysm repair was performed in Russia by Nicholas Volodos in 1987 (Volodos et al, 1988).

Due to their minimally invasive nature, endovascular procedures are associated with reduced post-procedure discomfort, less blood loss, fewer overall complications and enhanced recovery. Endovascular treatment options offer both reduced morbidity and mortality when compared to their equivalent open procedure options (Van Herzeele (b) 2009**)**

Endovascular intervention now plays a crucial diagnostic and therapeutic role in almost all branches of surgery, none more so than vascular where endovascular techniques have transformed the specialty. An American survey found a 422% increase in endovascular procedures logged in the casebooks of vascular trainees

seeking board certification between 2001 and 2007 (Schanzer 2009). Prior to 2000 99% of elective aortic aneurysms were repaired via an open technique, by 2004 more than half were repaired by endovascular aneurysm repair (EVAR) (Schanzer et al 2009). Percutaneous lower limb treatment is now the first option of choice in patients with intermittent claudication who require intervention. The results of the IMPROVE trial (http://www.improvetrial.org/) may add further weight to a growing body of evidence in support of endovascular ruptured aneurysm repair.

1.2 Training in Endovascular Surgery

The explosion of therapeutic endovascular treatment options has also led to a need to tackle the issue of training in endovascular skills for the practitioners of the future. With the advent of laparoscopic surgery similar training issues were encountered, not least because endovascular surgery requires a different set of skills, not only technical but cognitive as well, when compared to open surgery (Neequaye et al, 2007). Indeed operating in a three dimensional field from a two dimensional view, altered haptics and emphasis on hand-fluro-eye co-ordination are all challenging skills to master. (Dessender et al 2011, Berger et al 2010).

Percutaneous coronary intervention completely transformed the treatment paradigm for cardio-thoracic disease. The impact on the cardiothoracic surgical specialty was profound due to a vastly reduced demand for open therapeutic surgery. Vascular surgeons are in a similar transitional phase as the modern specialty of vascular surgery continues to evolve. Vascular trainees must equip themselves with a skill set that will enable them to practice competently and confidently in both open and endovascular procedures. The endovascular surgeon is now a well-recognised and respected independent practitioner.

1.2.1 Training Challenges

Despite significant advances in various endovascular training techniques, surgical and interventional radiology trainees in England still rely on the somewhat outdated

apprenticeship model which was first introduced by William Halsted towards the end of the 19th century (Halsted 1904). The apprentice trainee learnt their trade from the consultant trainer, using real patients and with an emphasis on graded responsibility (Reznick et al 2006). The biggest challenge facing such a system is its subjective nature. Relying on trainers to select an appropriate case mix precludes any standardization and fails to meet any criteria to facilitate summative assessment (Ahmed et al, 2010).

Further challenges facing the current system of training in the UK include the medico-legal and ethical ramifications of training on patients, as well as issues of safety and cost. (Bridges et al, 1999).

The implementation of the European Working Time Directive (EWTD) has also hampered surgical training (Cairns et al. 2008). Trainees undergoing higher surgical training in the UK are now legally required to relinquish exposure to emergency and elective operating by a third in order to comply with the EWTD. Today's trainees would take nine years to achieve the same level of operative experience as their counterparts achieved in just six, practising before the EWTD (Lamont et al 2005). Yet despite a reduction in clinical exposure there are no plans to extend the number of years of training to reach consultancy. Current trainees will have less experience than consultants from an earlier generation by the end of their training (Pandey et al, 2006).

Endovascular training itself faces several unique challenges; diagnostic angiography was previously the main training procedure for honing basic catheter and wire handing skills for the novice trainee. However the introduction and popularity of less invasive imaging techniques, such as duplex ultrasonography and magnetic resonance angiography, have seen diagnostic catheter angiography and its training opportunities diminish.

As the scope for endovascular therapy increases, due to the rapid innovation, evolution and refinement of technology, so too do therapeutic options for patients. Those previously unsuitable for open complex vascular procedures are

increasingly brought to the endovascular specialists' table. A steadily ageing population present with ever more complex pathology. Such patients and their disease are less suitable for junior practitioners who require time and subsequently endovascular therapy tends to be a consultant led practice. Carotid Artery Stenting (CAS) is a prime example; a technically challenging procedure, performed by relatively few experts worldwide, with catastrophic consequences of technical error including disabling stroke and death (Van Herzeele (b) 2009). Subsequently training on patients is often inappropriate.

1.2.2 Endovascular Training Curricula

Over the past ten years UK general surgery has moved towards sub-specialisation. This shift has led to a climate where many generalists feel less competent to cover vascular emergencies. As early as 2004 the Vascular Society recommended centralising vascular services to higher volume centres and advocating specialist vascular surgeons to provide emergency cover for entire regions, or 'networks' of hospitals (Vascular Society 2004).

In response to the above challenges there has been a clear international trend towards independent certification in vascular surgery. Although many skills learnt in general surgical training are transferable, with ever increasing sub-specialisation these skills are less relevant to the modern day endovascular practitioner. Many of our European counterparts for example have formalised interventional radiology attachments and integrated simulator training courses within their professional curricula (Liapis 2009). Streamlined training programs and independent endovascular practice in high volume regional vascular centres is now widely agreed as the future for vascular and endovascular training.

The trend of limited training opportunities leads a 'compelling argument against training vascular surgeons in the finer intricacies of breast or gastrointestinal surgery' (Lamont et al, 2005). This is demonstrated by trainees in Denmark, who despite following a 40-45 hour working week, achieve, through targeted vascular

fellowships, trainee numbers of aortic aneurysm repair and infra-inguinal bypass, far in excess of those postulated to confer un-supervised compentency in the UK (Darke 2001).

It was widely accepted that the current training schedule of core general surgical training with latter vascular sub-specialisation was insufficient to meet the growing demands of endovascular surgeons. Endovascular fellowships either within the UK or abroad, served to fill in the gaps left during formal training. However, after years of campaigning the Vascular Society announced on March 16th 2012 that in the UK vascular surgery will also now stand alone with specialty status independent of general surgery. The first 'vascular trainees' began training in October 2013, the new curriculum contains endovascular competencies and it is hoped this new training programme will address the deficiencies seen in the old programme. Virtual reality simulation is utilized during a three day 'boot camp' prior to trainees commencing their posts, but has yet to be formally integrated thereafter. ~~The draft curriculum is awaiting final approval but contains an integrated and streamlined programme of open vascular and endovascular skills training (Vascular Society 2012). As yet, simulation is yet to be formally integrated, but the restructuring of the specialty is recognition of current deficiencies and a need to get to grips with this rapidly evolving specialty.~~

Despite these recent advancements, gaps continue to exist in modern endovascular training and this climate has also opened the door for more novel training adjuncts to address the imbalance, principally simulation. The Chief Medical Officer acknowledged in his 2008 annual report that simulation affords a crucial role in safer patient care, and went on to recommend simulation-based training to become fully integrated and funded within the training curricula of surgeons at all training stages (Gilbody et al 2011). In the Northern Deanery general surgical trainees from core training stage one through until specialty training level seven have dedicated simulation skills training integrated into their postgraduate curriculum. Technical skills appropriate to trainees grade, stage and specialty interest, are taught using animal, human cadaver and virtual reality simulators in a dedicated training facility. Work is ongoing to formally assess

trainees progression in an attempt to prove the benefit of this innovative approach. But it is already apparent that simulation will form a crucial part of medical postgraduate training.

1.3 Simulation

"Simulation is a person, device, or set of conditions which attempts to present education and evaluation problems authentically." (Issenberg et al 2005). It is already utilised for education and training in the aviation, space, military and nuclear power plant industries for training. The exact role of simulation in medical education is a rapidly evolving area.

Medical simulation has used a number of different methods, including actors simulating medical conditions, or even simulated virtual patients. Manikins which can be both static or interactive, computer virtual reality simulators, synthetic bench models, animals and human cadavers. Simulation can be offered on an individual basis, or directed towards teams. Ultimately medical simulation aims to enhance a trainee's learning experience and promote patient safety.

1.4 Simulators

A simulator is "apparatus that reproduces, to a greater or lesser degree of realism, a procedure that must be learned." (Desender et al, 2011)

1.4.1 History of Medical Simulators

'Harvey' is widely acknowledged to be one of the first developed medical simulators and was created as a cardiology simulator capable of task training using a computer-enhanced manikin model (Gordon 1974). Today medical simulators are utilized widely in all branches of surgery, especially for the training of minimally invasive techniques. Anaesthetic training, endoscopy and countless other specialties have adopted simulation into their training curricula.

Despite dramatic improvements in simulator technology, and an ever increasing popularity amongst trainees and trainers alike, conclusive evidence remains poor as to their exact benefit. A 2004 systematic review failed to demonstrate a firm advantage from expensive high-fidelity surgical simulators (Sutherland et al, 2006). It is widely accepted that simulation is merely an adjunct, and not a replacement for clinical experience (Kneebone et al, 2009), which remains the gold standard.

Yet few can dismiss the distinct advantages that simulators confer. For trainees, an opportunity to make mistakes in a safe environment, witness the consequences of these mistakes, and learn from them. For the trainers, a chance to examine the competence of trainees without putting patients at risk, allowing trainees to develop their technical skills away from the workplace and its European working time directive (EWTD) constraints (Lamont et al, 2005). Developing programmes that can be tailored to the individual trainees, who, it has been acknowledged, will develop and learn at different speeds (Desender et al, 2011).

1.4.2 Classification of Simulators

In general terms medical simulation methodologies can be categorised into six levels (Table 1), from level zero, which includes written scenarios to stimulate discussion, through to level six where interactive patient or computer controlled model driven patient simulators (Alinier 2007) provide a realistic multi-professional training experience Table 1a.

Table 1a. Classification of Simulation Tools and Training Approaches

Technological Simulation Level	**Description**
0	No specific equipment required
1	Three-dimentional models
2	Virtual reality and screen-based simulation

3	Real/standardized patients
4	Simplistic programmable mannequins
5	Sophisticated mannequins able to reproduce a patient's vital signs

In the context of endovascular simulation a more practical classification was suggested by Issenberg et al. Firstly according to the task they simulate. In this setting simulators can be procedure specific, part or whole task. Secondly on their fidelity, which refers to their exactness of duplication or realism (Issenberg et al, 2005). Finally on the technology they use, for example there are synthetic bench models, animal, cadaver, or computer virtual reality models. (Neequaye et al 2007).

1.4.2.1 Fidelity

The concept of realism is multi-faceted in the context of medical simulation. Tactile feedback, haptics, candidate interaction, and visual cues all play a role (Desender et al, 2011). Low fidelity simulators are made from materials that do not resemble the task they purport to simulate. An example is the simple suturing sponge used by novice surgeons to practice suturing and knot tying. High fidelity simulators use realistic materials and equipment to produce models that closely resemble authentic training conditions. Examples include animal, human cadaver and computer virtual reality models.

Contrary to popular belief that higher fidelity simulation offer superior training, evidence exists within the aviation industry, that in fact the opposite is true. Salas et al showed how with more novice trainers, the added stimuli of high fidelity models distracted trainers making the task more difficult (Salas et al 1998). This suggests that the fidelity of the simulator should be matched with trainee's level of experience.

Conflicting evidence exists within surgery, with one study of spermatic cord anastomosis in a rat model, showing no additional benefit with high fidelity simulation training compared with a low-fidelity silicone bench model (Grober et al, 2004). In contrast Sidhu et al demonstrated a clear benefit seen in both novice and intermediate trainees performing micro-anastomosis in live animals when trained on a high fidelity simulator compared with a low fidelity model (Sidhu et al, 2007). There are no publications to date that have compared the effect of simulator fidelity on acquisition of technical skills in endovascular surgery.

1.5 Simulation Models for Endovascular Training

Simulated models for endovascular training can be divided into four broad categories: synthetic, animal, human cadaver and virtual reality.

1.5.1 Synthetic:

Synthetic models are simple and cost effective means of training. Models range from basic low fidelity plastic models, to high fidelity systems that incorporate pulsatile flow and fluoroscopic imaging (Neequaye et al 2007). Generally synthetic models are simple to use and set up, do not require x-ray radiation, and tasks can be standardized. Furthermore, due to their transportability, these models can be used outside of the hospital/clinical environment which make these models more accessible.

Ahn et al (1993) created a lifelike flow-model of the lower limb with vinyl and latex vessels. More than 300 candidates used the model during a continuing medical education (CME) endovascular training course, performing a variety of therapeutic procedures. Greater than 80% reported a pertinent and valuable training experience (Ahn et al 1993). Wet-lab synthetic models have proven useful for teaching basic guidewire insertion and balloon inflation in percutaneous coronary intervention training. The Liverpool aneurysm glass flow model is a popular training

adjunct used at the Vascular Interventions Training Course (VIT C) course, held in Coventry, England (www.thevitc.com/testimonials.html). This model enables attending trainees to deploy endovascular stent grafts without the requirement of radiation. The model allows post procedure analysis of graft positioning, and stents can be easily removed to facilitate repeated performance. Similar models to facilitate both open and endovascular techniques are successfully utilised in the Vascular International courses held in Pontresina and Zurich, in association with both the Swiss, Austrian and European Vascular Societies (www.vascular-international.org).

One of the consistent down sides to synthetic models is the lack of realism of synthetic vessels. Silicone has a higher coefficient of friction compared to human vessel wall, thus creating the increased resistance experienced by candidates inserting wires and devices into silicone models. Silicone lubricants and even fish oils have been utilised to try and overcome this problem with limited success (Sugiu et al 2003). A study using a cerebral aneurysm silicone model for neuro endovascular intervention found frictional resistance and inability of devices to pass through curves in vessel walls (Suzuki et al, 2005).

Synthetic models fail to reproduce the dynamic behavior of the arterial system, and they are unable to provide realistic simulated tasks for advanced procedures such as carotid artery stenting. Despite literature supporting the efficacy of low-fidelity training in minimally invasive surgery (Rosser 1997), there is no such evidence to support the validity in an endovascular setting. Such models seem most useful as a tabletop demonstration for novice trainees (Palter et al 2010).

1.5.2 Animal:

Animal models offer superior face validity compared with synthetic models for endovascular training (Ahmed et al, 2009). A full spectrum of procedures in a fully functioning arterial tree can be performed, and realistic endovascular access using a percutaneous or surgical cut-down technique is feasible. Even the lack of natural

pathology has also been overcome with artificial induction of both occlusive and aneurysmal disease through iatrogenically injuring vessel endothelium (Ishii A et al, 2006) and suturing constricting prosthetic patches around surgically exposed vessels (Li et al, 2000). Anaesthetised porcine training courses are popular throughout Europe and the US. Evidence exists to support their use; The Porcine Transfer Study (Berry et al, 2007a), showed significantly improved performance parameters in novices undertaking an iliac stenting procedure after training on a porcine model.

Several European based vascular technical skills courses utilize animal models. The British home office have recently licensed the first such facility in the UK and it is proposed that the first UK based animal skills course will begin in early 2015 (Cook Medical™).

Despite enhanced fidelity and the proven validity of animal models, the anatomy of animals differs from that of human subjects and vessels are much smaller, thus limiting access and device insertion. Cows or large apes would overcome this size discrepancy but they are too expensive and rarely used (Garrett 2001).

Further limitations of animal models include the logistics of setting up the training facility, including trained staff, radiographers, anesthetist and an operating suite (Ahmed et al, 2009). Animals can only be used for a single training session, which add to the expense. In fact a detailed economic analysis revealed a difference of $1200 per candidate when training with a porcine model was compared to virtual reality simulation (Berry et al 2007b). Finally, it is contrary to UK law to operate on anaesthetised animals for medical training, which restricts this model for training, especially to UK trainees. It is difficult to justify the using of animal models when suitable alternate methods of training exist. An ongoing moral and ethical concern about their use further detracts from their involvement in training. (Martin et al, 1997)

1.5.3 Virtual Reality

Virtual reality is a communication interface based on interactive three-dimensional visualization allowing the trainee to interact and integrate different sensory inputs that simulate important aspects of real-world experience (Riva 2003). Endovascular virtual reality systems use these computer-generated images of the human vasculature to allow trainers the ability to interact with the model using an interface device (Satava 1993). A generic reusable instrument is inserted into the simulator model and the active tip is recognised by the machine, and displayed on the fluoroscopy screen in whatever form that has been pre-selected by the learner. In this manner, wires, catheters, stents, angioplasty balloons and coils can all be inserted in this simulated fashion.

Most high-fidelity models allow the trainer the option of adjusting the simulated C-arm, road mapping and cine-loop recording. Modules include iliac, aortic, renal, carotid, thoracic, coronary and neuro-intervention. Each contains graded scenarios from easy to difficult cases, introduced with a clinical monologue. Many simulators include real time cardiovascular monitoring, which is displayed along side the simulated fluoroscopy screen. Models are able to record performances, to enable trainers to assess candidates who can train at their convenience and receive feedback at the convenience of the trainer. Models can also provide post-procedure feedback on a number of different qualitative parameters. These include total procedure and fluoroscopy time, volume of contrast agent used, residual stenosis, accuracy of stent graft placement, and lesion coverage (Desender 2011).

Endovascular simulators were first introduced by industry. Companies developed the devices as a method of demonstrating their latest device. Their use as training adjuncts became most apparent when the Food and Drug Administration (FDA) published the recommendation that simulation training would be beneficial prior to granting a license for practitioners to perform carotid artery stenting (CAS) in their patients (Desender et al 2011). There are now a number of high fidelity endovascular simulators available, which are all catagorised as ‘part-task’, owing to their inability to simulate the arterial puncture element of interventional procedures. These models include the Simbionix Angio Mentor ^{TM}, CathLabVR, Simsuite® and the Procedius VIST.

There are disadvantages to VR models. Units cost in excess of £100,000 with added maintenance and recalibration costs, which can be considerable as these models are prone to technical failure. They also lack the tactile feedback found in real patient vessels and some find the computer-generated images unrealistic (see chapter 4). However, VR models are well placed to offer endovascular skills training, offering a perfect medium for simulating the two-dimensional fluoroscopic imagine. There are no ethical issues related to their use and procedures can be repeated indefinitely. They allow the more novice trainee an opportunity to hone their guidewire handling skills, and more expert practitioners a chance to rehearse new procedures in a safe environment prior to operating on patients. There is also great interest in the role of virtual reality as a model for objectively demonstrating procedural competence as part of a credentialing process (Neequaye et al, 2007).

The most recent advances include the option of down loading real patient images into the VR machine (simbionix Procedure rehearsal studio™). Models can then simulate that very case allowing practitioners an opportunity to rehearse challenging cases prior to the real performance. Some training facilities have simulated suites, capable of performing procedures with a full theatre team. The Orcamp (Orzone,) simulator suite in Gotherberg, Sweden is a full scale operating suite with operating table, C-arm, fluoroscopy screen and patient monitors. The results of a recent face validity study strongly support the use of such comprehensive simulation, demonstrating that once immersed in this authentic multi-disciplinary simulated environment, trainees learn operative technical, procedural and management skills (Lonn et al 2012).

1.5.4 Human Cadaver:

As an adjunct for medical training, human cadavers have played an integral role for many years. Yet current undergraduate trainees perform less cadaveric dissection in favour of fixed prosection specimens and synthetic models. Many would claim that any enhanced benefit from cadavers, is offset by the fact that few medical students will go into a surgical career. For this reason Reed et al concluded that

the anatomy lab is not an effective undergraduate educational environment (Reed et al, 2009).

However since the 2004 Human Tissue Act, doctors in the UK have been allowed to practise surgical procedures on cadavers for training and research purposes, this has led to a rising number of human cadaveric based workshops in higher surgical training. Cadavers offer the perfect training compromise, offsetting the added risks of operating on human subjects, the ethical and legal implications of animals and the improved fidelity of synthetic or simulated models.

Human cadavers have proved useful for training in both open and minimally invasive surgical techniques. Unembalmed cadaveric specimens allow every step of a laparoscopic procedure, from prepping and draping patients, to insufflation of pneumoperitoeum, and the eventual laparoscopic procedure. Training courses using such models are highly satisfactory for trainers and trainees alike (Supe et al 2005). The value of practicing on human tissue, using real surgical instruments, offers a unique environment that perfectly simulates the surgical anatomical understanding and visuo-spacial awareness required when operating on live cases. It is these advantages that have made cadaveric training courses so popular (www.nstcsurg.org/courses).

Gilbody et al (Gilbody et al 2011) undertook a systematic review of publications reporting cadaveric postgraduate courses in surgery. Eight courses in total were included, covering a range of surgical specialties including vascular, orthopaedic, neurosurgery, colorectal and general surgery. Despite the apparent increasing number of cadaveric courses, there is a surprising lack of evidence to support their effectiveness, and Gilbody et al called for further work to enhance the evidence base upon which to justify the added cost of cadaveric training.

The only published use of cadavers in vascular surgical training involves open surgical procedures (Reed et al 2009). The trial of American general surgical trainees, included skills training on infra-inguinal bypass, four quadrant fasciotomy

and carotid endarterectomy. There are no reported trials of human cadavers being used for endovascular training in the world literature.

In 2001 Garrett Junior in a short technical note (Garrett 2001) described a technique for the arterial perfusion of a fresh frozen human cadavers. The description included isolated human vascular circuits for the lower limbs, abdominal aorta and aortic arch. Through this technique it was reported that over two hundred cadavers have been prepared and used for both training and testing of endovascular graft devices. The reported advantages include a model with the highest fidelity, pulsatile antegrade flow, fluoroscopic vessel visualization, and the use of all types of sheaths, wires and catheters that would be used in the interventional suite. The only reported disadvantages included oedema due to third space loss of circulating fluid, and that once stents are released that section of the vasculature can no longer be utilized for further device deployment.

Following Garretts' report this technique of human cadaver perfusion has been adopted for stent graft development research: Fenestrated and branched endovascular stents, which are often used for short necked abdominal aortic aneurysms, are often complex, time consuming, and technically challenging to deploy. Linsen et al developed a new modular branched graft and deployed it successfully into six pulsatile human cadaver models. Advantages included a realistic model with lifelike conditions and bifurcated aorto-iliac anatomy. However the authors did comment on the lack of true pathology within their specimens, claiming that the non-aneurysmal cadavers resulted in decreased endograft manoeuvrability, once the stents sheath had been removed (Linsen et al, 2007).

Arbatli et al (Arbatli et al 2009) utilised a pulsatile human cadaver model for testing the feasibility and efficacy of stent graft implantation in the aortic arch and stenting of the supra-aortic branches. Using retrograde fenestration they created a totally endovascular technique for treatment of aortic arch pathologies. The authors were interested in achieving human physiological blood pressures and subsequently completely isolated the aorta from root to femorals via a median sterno-laparotomy. They also maintained the perfusing solution at $37^{o}C$ thus creating a pulsatile

human cadaver model that could mimic the human vascular environment for the deployment and testing of nitinol-based stent grafts whose radial expansive forces, and deployment diameters are affected by temperatures below 30^{o}C (Arbatli et al, 2009). They perfused two human cadavers commenting that the model is effective for testing memory-based equipment in the aortic arch and supra-aortic branches.

Jongkind et al (Jongkind et al, 2010) reported their experience of laparoscopic assisted descending thoracic aorta approach for branched endograft delivery to the aortic arch and pararenal aorta in a pulsatile cadaveric model. Three formalin prepared cadavers were used. A more invasive approach than that described by Garrett was used to create the pulsatile cadaver, with open removal of the left lung, and tying off of all unrequired branches from aortic root to femorals creating the closed circuit. An aneurysm was also induced into the aortic arch and pararenal. The authors reported that these experiments were successful, and concluded that the procedure is both a feasible and effective alternative to femoral access.

The down sides include that of cost and logistics. Dedicated training facilities with a Human Tissue Authority (HTA) license are costly to set up, run and maintain. Using cadavers for multiple specialties is one way of keep down costs, for example, the same cadaver can undergo an orthopaedic course for lower limb prosthesis, a colorectal course for laparoscopic bowel resection, and an Ear Nose and Throat (ENT) course for septo-rhinoplasty. However despite these cost saving strategies, the transport, storage and the eventual disposal of cadavers that have been donated as anatomical gifts, still make it a relatively expensive method for training.

1.5.4.1 Cadaver Fixation

Before refrigeration, alcohol and spices such as pepper were used for the preservation of human tissue. Ferdinand Blum was the German chemist who introduced formaldehyde fixation (Blum (b) 1893) which is still used to successfully preserve human tissue (Fox 1985). Gunter von Hagens introduced “plastination” which fixes human tissue with a highest degree of realism (Bohannon 2002).

Successful and suitable for prosection demonstration, these techniques provide a less realistic medium to simulate surgical dissection, due to the altered tissue following preservation.

Messmer et al suggested a technique of cadaveric exsanguinations facilitated by simulataneous infusion of anticoagulant. Methyl alcohol and conditioning fluid is then perfused into the empty vessels, before the body is frozen at -18^{o}C. This technique prolongs the life of the cadaver and preserves the integrity of its tissues for up to forty five days (Messmer et al 2010). There are no reports of its performance when utilized for surgical training courses.

Eisma et al recently reported the results of their trial comparing open thyroid dissection training using formalin and Theil preserved cadavers. Theil embalming is a soft fix technique, which preserves cadavers with life-like colours and flexibility (Theil 1992). It proved preferable to trainees in all aspects of the authors post trial questionnaire, suggesting soft fix techniques, although more expensive and challenging to achieve, are favoured with trainees (Eisma et al 2011).

The main drawback of fixed cadaveric specimens for surgical operating training is the poor specimen quality, and lack of realism when dissecting the tissues. Soft-fix cadavers seem to go some way to addressing this draw back, but fresh frozen human cadavers provide the greatest realism and tissue haptics. Reed et al used fresh frozen cadavers in their trial teaching open vascular procedures, including femoral, popliteal, abdominal aorta, carotid, axillary and subclavian artery exposure, and various anastomotic training exercises to surgical residents. All candidates found the cadaveric material optimal, leading the authors to conclude that fresh frozen cadavers offer a superior working environment over formalin fixed cadavers. Tissue planes are preserved and tissue handling is realistic. Formalin cadavers are stiff, discoloured and malodorous (Reed et al 2009)

The literature concerning cadaveric endovascular models is conflicting. Jongkind et al (Jongkind et al) created a satisfactory flow model, for stent graft deployment, using formalin fixed cadavers, and reported no draw backs, although such markers

of performance were not formally addressed in their methodology. Garrett jnr who described the first technique of cadaveric perfusion (Garrett 2001) used fresh frozen cadavers, but used a commercial solvent to flush the arterial system before use. Arbatli et al (Arbatli et al 2009) also utilised fresh frozen cadavers in their stent graft deployment experiment and flushed with saline alone.

The major drawbacks to fresh frozen cadavers are the expense of storage and disposal, and the logistics of setting up and maintaining the supporting facility. HIV and other diseases can be transmitted in cadaveric specimens unless properly screened.(Reed et al, 2009) However despite this there seems little argument that fresh frozen cadavers offer superior training experience.

1.6 Simulators as Methods of Training Endovascular Skills

Clinicians and trainers often refer to the "learning curve" of trainees acquiring technical skills. Referring to the time it takes or the number of attempts required before the learner achieves safe independent competence (Muir 2004). Theodore Wright first introduced this concept in 1936, when he published an article referring to the productivity of airline manufacture (Wright 1936). Unlike manufacturing production lines, surgeon's productivity and "learning curves" are highly specific to that individual. It is recognised that during the early part of that curve, most mistakes and errors will be made by the novice operator (Muir 2004). This understanding means training on patients at this stage could increase their risk of morbidity, and therefore seems intrinsically unethical.

Gallagher et al reviewed the surgical education, human-factor, and psychology literature in relation to the integration of virtual reality (VR) training into the training program for minimally invasive surgery. They concluded that simulation is efficacious in positively influencing the early part of the learning curve and this results in safer practice and more economic use of the operating theatre. However VR must be fully integrated into a well thought out education and training programme for it to successfully improve practitioners technical skills (Gallagher et

al 2005). Desender et al refer to the 'pre-trained' novice, whose early learning has taken place in the safety of simulated environment, prior to exposure on real patients (Desender et al 2011).

Endovascular practitioners exhibit this procedure related learning curve at both novice and expert standard, and hence their patients are at risk during this phase of learning. A study of two hundred consecutive CAS procedures demonstrated a clear procedure-related learning curve and improved performance with fewer errors by practitioners of greater experience (Lin et al 2005).

Acknowledging the patient related safety advantages of operator experience, there are a number of trials that demonstrate the improved performance of endovascular practitioners following simulator training. Concentrating on renal intervention, Aggarwal et al (Aggarwal et al (c) 2005) trained twenty novice endovascular practitioners to perform angioplasty and stenting of the left renal artery, on the VIST simulator. After only three repetitions all candidates demonstrated more efficient use of intravenous contrast and quicker procedure times (Aggarwal et al (c) 2005). Boyle et al (Boyle et al 2011) constructed their trial to assess the importance of feedback in endovascular technical skills acquisition. They demonstrated significant performance improvements and fewer errors in all of their candidates performing a renal artery angioplasty and stenting following six repetitions on the VIST simulator irrespective of their feedback. However greater improvements were seen in the feedback groups (Boyle et al 2011).

The efficacy of simulator training is also true for distal occlusive disease. Dawson et al (Dawson et al 2007) demonstrated improvements in time, fluoroscopy use, volume of injected contrast and management of complications in nine candidates performing iliac angioplasty and stenting following eight hours of training on the SimSuite high fidelity simulation model (Dawson et al 2007). Similarly following didactic endovascular skills training Chaer et al randomised ten of their twenty recruited candidates to receive additional simulator training. All candidates then performed iliofemoral angioplasty and stenting. Candidate's performances were videoed and scored by blinded, expert assessors, using a validated scoring tool.

Simulator trained candidates demonstrated improved measures of performance (Chaer et al 2006).

It is apparent that trials have demonstrated this clear improvement in technical ability over a range of measured outcome parameters following simulator training. Yet it is not necessarily appropriate for all practitioners. Dayal et al demonstrated that following simulator training for carotid artery stenting, experts (candidates who had performed more than three hundred endovascular procedures) showed no significant improvement in performance. It is therefore widely accepted the greatest training benefit from simulators is seen in inexperienced trainees who can develop and hone their basic guidewire and catheter skills at the beginning of the "learning curve", and these will become automated before they perform procedures in real patients (Gallagher et al)

Coates et al assessed fourteen novice interventional radiology operators before and after their training prgramme on a virtual reality simulator. All measured quantitative parameters and subjective assessments of performance from expert observers improved after simulated training (Coates et al 2010).

1.7 Transfer of Simulator Trained Endovascular Skills to Real Patients

The ultimate purpose of simulators is to positively impact on patient safety through practitioners' improved performance. Yet trials to prove this are technically and ethically challenging to set up and run. The earliest study to show a clinical skill benefit from medical simulation was conducted in cardiology trainees. Ewy et al utilized a cardiac simulation manikin model and showed improved technical ability in fourth year medical students trained on simulators, examining real patients, compared to their counterparts who had received traditional didactic teaching (Ewy et al, 1987). This was the first evidence that skills taught on simulators could be transferred into the real clinical world.

Seymour et al (Seymour et al, 2002) were the first to prove this transferability in a double-blind randomized control trial. Sixteen surgical residents were randomized to receive virtual reality (VR) training, or none, and then completed a laparoscopic cholecystectomy on a patient supervised by blinded assessors. VR trained candidates performed quicker with fewer errors and less non-target tissue damage (Seymour et al, 2002). There is now evidence of transfer of skills using a colonoscopy (Ahlberg et al 2005) and bronchoscopy simulator (Blum et al 2004).

Trials to test for simulation learnt skills 'transferability' into the operating room are ethically challenging to design. With the knowledge that novice learners benefit most from simulation, and that this may improve patient safety, it is hard to justify a trial where some novice operators will receive 'no-simulation' training before attempting a procedure on a patient. One solution from Berry et al was to use a surrogate patient in their trial using virtual reality and porcine simulators. Twelve vascular surgeons with novice endovascular experience were trained to perform an iliac artery stent using either virtual reality simulation, a porcine model, or a combination of both. Performances were scored using a validated tool for assessing technical skill. The authors demonstrated that virtual reality training improved performance scores on the cadaveric model. This is analogous to transfer into a real clinical setting (Berry et al (a) 2007).

Chaer et al (Chaer et al 2006) received institutional review board approval for their study which did involve a true clinical arm. Twenty endovascular novices were randomized to receive VR training or none, following introductory lectures. All candidates then performed two supervised procedures in the angio-suite, and performances were scored using the same validated scoring tool (see 1.10.5). An improvement in clinical ability was noted in those candidates who had received additional simulator training. Interestingly candidates did not improve their scores between performances on patients, suggesting simulator training may in fact be more efficacious at this stage than practice on real patients (Chaer et al 2006).

Despite this evidence that simulated training demonstrates transferability into the operating room, this trail was criticized in subsequent published discussions (Chaer

et al 2006); The additional expert feedback and training associated with simulation is absent from the group who receive no further training. This is a potential confounding bias, although the authors believe it unlikely to explain the whole story of candidate's apparent improvement. Further research is required to establish the transferability of technical endovascular skills learned on a VR model to real patients (Ahmed et al 2012).

Simulation should not be a one off training exercise, and advocates call for its complete integration into the postgraduate training curriculum for endovascular practitioners. Evidence that this supports a sustained improvement in catheter based skills would be the ideal.

1.8 Simulators as Methods of Assessment

The precise role for simulation in medical and surgical assessment remains unknown. The first use evolved in undergraduate training with the advent of the Objective Structured Clinical Examination (OSCE) (Harden 1979). Patients were used to simulate medical conditions and examiners could assess candidates demonstrating what they would do in a standardised and fair environment rather than what they might do in written essays or multiple choice answers (Aggarwal et al (b) 2010). These examinations are now widely integrated across the country, providing reliable and valid results of competency.

Simulators offer clear advantages as a standardized, highly realistic model, capable reproducing real-patient experiences and aspects of the real world in a fully interactive manner (Desender et al, 2011). However the exact role of simulation as a method of assessment remains unknown. The UK Integrated Surgical Curriculum Project (ISCP) hopes to integrate simulation into the curricular framework of higher surgical trainees, through a "systematic and competency-based progression, underpinned by robust assessment." (ISCP).

Aggarwal and colleagues attempted to define the exact role of simulators in surgical training and assessment with the clear objective of improving patient

safety, in a World Health Organisation (WHO) sponsored multi-centre, multi-national collaborative review. They used the CanMEDs framework that describes the skills of a good healthcare practitioner (CanMEDs 2005). CanMEDs sets out seven key competencies (Figure 1). Literature was reviewed in these seven domains by experts, facilitated by tele-conferencing. Finally when these experts met to confirm their findings, they produced a traffic light system with red indicating no use of simulation, orange potential, and green those areas where simulation has been shown to work. Simulation has been shown as an effective modality for promoting the competencies of 'medical expert', 'communicator' and 'collaborator' but further evidence is required with respect to the role of simulation as a mechanism for training and assessing 'scholarly skills, professionalism, management and health advocacy' (Aggarwal et al (b) 2011).

The Accreditation Council for Graduate Medical Education (ACGME) (ACGME 2003) listed six domains of clinical competence (Table 2a)

Table 2a: The six domains of clinical competence

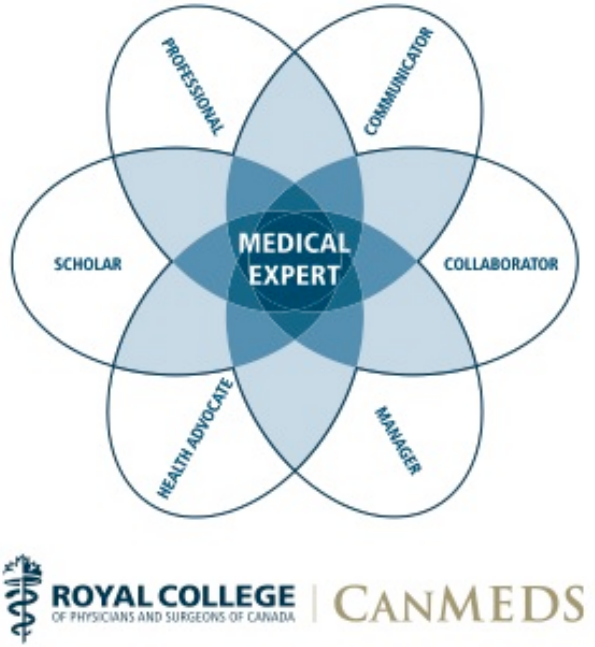
Domain	***Competence***
1	Patient care
2	Medical knowledge
3	Practice-based learning and improvement
4	Interpersonal and communication skills
5	Professionalism
6	System-based practice

For each domain Miller (Miller 1990) devised a framework upon which to assess learners. This included four levels, which were knowledge, competence, performance and action. Simulation is appropriately used to assess the first three levels (action refers to behavior in real practice), because it is able to provide

standardized experiences and provide outcome measures of reliable data (Issenberg et al 2005).

Simulation appears to have a role in all aspects of medical and surgical training and assessment, yet it is interesting, that despite these clearly defined criteria “at no stage are structured validated criteria used to objectively assess the technical competence of surgeons” in the UK (Pandey et al, 2006). Most surgical competency guidelines are centered on numbers of procedures, yet uncertainty exists as to what numbers constitute competency in endovascular therapy (Bech et al 2011). Furthermore, it is known that sheer volume does not guarantee proficiency and experts are seeking for effective assessment tools to assess procedural competence.

Figure 1. The CanMEDS Roles Framework:



1.8.1 Simulators as Methods of Assessment in Endovascular Surgery

Researchers in Holland have developed a high fidelity synthetic endovascular simulator, called the Simulator for Testing and Rating Endovascular SkillS (STRESS)-machine. The model has proven construct validity, and it is utilised in the European Board Of Surgery Qualification In Vascular Surgery (EBSQ-VASC) exam (Berger et al 2010).

Formal assessment of technical skills does not currently take place within vascular or endovascular training in the UK. Simulators may potentially play a role in the new vascular curriculum but this is yet to be confirmed (Vascular Society draft curriculum 5th September 2012). Martin et al believe the proposed benefits of such an approach include an opportunity to provide constructive feedback, assist trainees progression and identify deficiencies in order to tailor trainees future training to address them (Martin et al, 1997). Aggarwal et al agree but warn that to be efficacious these tools must 'convey a sense of realism and a degree of standardization to enable graded acquisition of technical skill' (Aggarwal et al, 2006).

1.9 Acquisition of a Technical Skill

Operator competence is usually measured in terms of technical proficiency. In an endovascular context this involves both technical and nontechnical skills. There are a number of theories in the literature that postulate how one learns a technical skill.

All models of skill acquisition acknowledge the importance of intense, deliberate repetitive practice when mastering a technical skill.

1.9.1 Fitt's and Posner's Theory:

This theory of motor skill acquisition follows three distinct stages. (Fitts 1967). The earliest *cognitive stage* is during which the trainee intellectualizes the task, getting to grips with the various steps and stages of the skill. In an endovascular setting this will involve familiarisation with the various wires and catheters and learning to work with fluoroscopy. Progression to the second *integrative stage* comes with practice, and performance is seen to flow with fewer interruptions, but the trainee will still be observed thinking about how to progress with the next procedural step. The final *autonomous stage* is demonstrated with fluid uninterrupted performance, the trainee is no longer concerned with thinking of the next step in the task, but refining the finer elements of the procedure.(Reznick et al, 2006)

1.9.2 Kopta's Theory:

Similar to Fitt's and Posner, Koptar believed in a three-phase progression towards skill acquisition. Improvement requires practice and feedback before the final *autonomous phase,* where the performer operates without cognitive input (Kopter 1971).

1.9.3 Schmidt's Schema Theory:

Schmidt's theory is based on how our motor skill acquisition develops. Every time a trainee performs a movement four pieces of information are gathered: the initial starting point information, aspects of the motor action itself, the success or failure of that action and finally the sensory consequences. In essence he believes that improvement requires practice in a wide variety of situations and encountering errors is equally important. Practice that lacks variety will not provide the learner

with sufficient information and the learner will not fully comprehend the relationship between the manoeuver outcome and their control of the movement parameters (Schmidt 1975).

1.9.4 Ericsson's Model:

Ericsson's model focused more on the concept of expert performance (Ericsson 1996). He defines surgical experts as those with consistently better outcomes than non-experts. Attaining such a status is the result of dedicated and deliberate practice. Ericsson believed mornings were the best time to practice, as this was when the ability to perform complex tasks was highest. Although emphasis today has moved away from just sheer volume as a marker of competence, literature does exist to support the theory that operative volume and clinical outcome are related. Ericsson used this to postulate that in fact many surgeons may not in fact reach true expertise in their career (Ericsson 1996).

1.10 Assessment of a Technical Skill

"No single assessment method can provide all the data required for judgment of anything so complex as the delivery of professional services by a successful physician" (Miller 1990). Indeed the objective measures of skill performance in endovascular intervention are poorly reported. A number of assessment tools are available. These include time-action analysis, motion analysis, VR simulator automated parameters, task specific checklists (TSC) and global rating scores (GRS).

1.10.1 Time-Action Analysis:

Time-action analysis involves breaking procedures down into segments and analysisng the time it takes the trainee to perform each step of a procedure. Although the technique has been adopted in minimally invasive training studies

(Bakker et al 2002) it is both time consuming and considered a poor measure of overall procdure quality.

1.10.2 Motion Analysis

Analysing economy of movement and purposeful motion is a more discriminatory way of assessing technique and the overall quality in technical skill performance. (Bann et al 2003) This particular method is in fact used to assess candidate's dexterity during open vascular skills assessment in the EBSQ-VASC using a motion-tracking device. The Imperial College Surgical Assessment Device is capable of measuring candidate's economy of movement by tracking hand-movement with a electromagnetic sensor. The model has been used to assess laparoscopic surgery (Smith et al 2002), but not, to date, used in assessment of endovascular skills performance.

1.10.3 VR Measurable Parametres

VR parameters have previously been described (see 1.5.3). They are automated scores derived from the VR models instantaneously following a candidates performance. A number of studies, looking a various endovascular interventions have shown construct validity based on VR measured parameters alone. Dayal et al looked at twenty-one trainees of varying levels of endovascular experience, performing CAS using the Procedicus VIST simulator. Analysis of their VR parameters demonstrated the models construct validity. (Dayal et al 2004). Following criticism aimed at studies including medical students (who lack the baseline knowledge of basic endovascular skills), Van Herzeele et al looked at qualified practitioners only and discovered a similar pattern. Experienced practitioners are quicker and use less fluoroscopy when completing a CAS procedure on the VIST simulator, compared to less experienced practitioners (Van Herzeele et al 2007).

It is widely accepted that increased speed does not necessarily translate to a performance that confers greater safety for patients (Patel et al 2006). Hislop et al highlighted this exact point explaining that innate endovascular aptitude, represented by time to complete a performance, can be improved with non-endovascular training such as video games (Hislop et al 2006).

1.10.5 Task Specific Check Lists and Global Rating Scales

Traditionally trainers made global rating assessments of trainees performance in the subjective assessment of their competency to perform a certain procedure. Such judgments are often unreliable measures of true performance (Streiner 1985). Research to identify a more reliable and standardized method of assessing technical skill led to the development of procedure specific checklists and global rating scales. Kopta developed one of the first checklists to assess orthopaedic trainees operative skills in 1971 (Kopta (b) 1971), and Schueneman et al used a rating scale which was able to differentiate trainees of various experience (Schueneman et al 1984).

Despite first being reported by Martin et al, the Objective Structured Assessment of Technical Skill (OSATS) model has become synonymous with the Canadian physician Richard Reznick (Martin et al 1997). It was developed to address the lack of standardisation seen in operations used for assessment, variations in examiners standards, and trainee performance. OSATS consists of two components: a task specific checklist (TSC), which breaks procedures down into a series of steps, and a global rating scale (GRS). The GRS is a quantitative assessment measure of technical skill based on seven aspects of performance, each scored on a Likert scale from 1 to 5. It includes parameters such as “respect for tissue”, “flow of operation”, and “instrument handling” (Martin et al 1996). The two components are necessary, as the TSC identifies where an error took place, and the GRS provides an objective score of overall performance.

OSATS was developed to assess the open surgical procedure performance, and has been shown to have construct validity in the assessment of open (Nielsen et al 2003) and laparoscopic (Eubanks et al 1999) technical procedures. It has also been adopted as the gold standard assessment tool for technical skills assessment in endovascular literature (Martin et al 1997, Chaer et al 2006, Hislop et al 2006, Berry et al 2007, Tedesco et al 2008, Van Herzeele et al 2009, Berger et al 2010, Riga et al 2010,). Hislop et al used a modified OSATS tool, calling it a modified Reznick scale (MRS) and showing it to have construct validity in their trial of practitioners performing carotid intervention (Hislop et al 2006). It was modified and formed the assessment tool of choice in Berry et al's porcine transfer study (Berry et al 2007). Chaer et al included nine items in their modified GRS, including parameters to measure "wire and catheter handling", "awareness of wire position", "maintenance of wire stability", "awareness of fluoroscopy usage" and "precision of wire/catheter technique" Chaer et al 2006).

Interestingly to date TSC and GRS have not been used for the assessment of endovascular performance in the interventional operating suite in real patients. Indeed Beard and colleagues (Beard J 2011) performed a prospective observational study of the methodology for assessment of surgical skills with the aim of comparing user satisfaction, acceptability as well as the reliability and validity of OSATS and Procedure Based Assessments (PBAs). They concluded that in fact PBAs have a higher utility for assessing technical skills observed in the operating theatre compared to OSATS. It is therefore acknowledged that although OSATS has been used in this thesis for technical skill assessment, the PBA may be a more appropriate method of assessment when operating on real patients.

1.10.6 Utility Index

The utility index is a concept of clinical performance assessment consisting of six components (Van Der Vleuten 2006): Educational x validity x reliability x cost x acceptability x feasibility. There is a growing appreciation that no single assessment tool (OSATS or PBAs) can adequately assess the clinical performance of a trainee. Indeed 'assessment planning should focus on assessment systems

with triangulation of data in order to build up a complete picture of a doctor's performance' (PMETB 2007)

1.11 The Role of Feedback:

There is no currently accepted consensus on the optimum way or indeed the need for providing feedback during technical skills training. Mahmoud and Darzi demonstrated a complete lack of learning curve in candidates training on a colonoscopy simulator when no feedback was provided (Mahmood 2004). However, to the contrary, O'Connor et al showed that the mere knowledge of results is as effective as expert feedback (O'Connor 2008) in their trial designed to teach suturing. A recent Best Evidence in Medical Education (BEME) review of simulation commented on the importance of trainee feedback to slow learner skill decay over time. (Issenberg et al 2005).

Boyle et al suggested expert and non-expert feedback was effective in reducing errors in candidates performing on an endovascular simulator. However candidates offered no feedback at all still showed significant improvement for all simulator metrics and video error scores (Boyle et al 2011).

1.12 The Ideal Endovascular Training Model:

The ideal model for endovascular training would have an arterial tree that closely resembles the human body, multiple appropriate branches, antegrade, pulsatile flow, at normal body temperature, multilayered vessels of normal human arterial caliber and the potential for dissection. It will allow trainees percutaneous needle access and the physical characteristics of limited elasticity found in human arteries, especially those of patients with peripheral artery disease. (Garrett 2001)

The ideal model will exhibit face validity; that it is both acceptable and realistic to use. It will also demonstrate construct validity, in measuring the trait that it purports

to measure. This is commonly interpreted as the model's ability to differentiate between practitioners of varying ability. (Aggarwal et al (a) 2006)

Finally it must be efficacious in its ability to improve a candidate's performance of endvascular skills when used for training.

Chapter 2

Endovascular Training – The Use of Human Cadavers and Virtual Reality Simulation: Questionnaires of Patient and Professional Opinion

Abstract

Aim

To establish the opinion of patients and clinicians on the use of virtual reality simulators and human cadavers for endovascular training

Methods

An anonymous, prospective, web-based, opinion questionnaire trial. Inclusion criteria were consultants and traubees involved in endovascular training or practice, including Vascular Surgeons, Cardiologists and Interventional Radiologists. **Experts in IC, IR and VS rated their agreement to statements regarding endovascular simulation (HC and VRS) through an online questionnaire. Patient's views on endovascular simulation were also sought via paper questionnaire.**

Results

100 professionals completed questionnaires. <25% were w=aware of endovascular HC training, none had first hand experience, five (5.6%) disagreed with its use. All candidates were aware of VRS, 80.9% had first hand experience. Many expressed interest in HC stating concerns regarding the realism of VRS. 107 patients responded. App patients agreed with HC training. Patients declared greater confidence in doctors training on HC versus VRS (p=0.000)

Conclusion

These are the first recorded opinions of professionals and patients regarding endovascular simulation training. Endovascular professionals question the suitability, appropriateness and feasibility of endovascular training, yet few are wholly satisfied with VRS.

Patients appreciate the need for adjunctive simulation training, but harbor mistrust in computer technology. Enhanced patient education is required to maintain confidence and trust.

Chapter 2

2.0 Endovascular Training – The Use of Human Cadavers and Virtual Reality Simulation: A Questionnaire of Patient and Professional Opinion

2.1 Introduction; Endovascular Training

As reviewed there are a number of training adjuncts to aid the endovascular trainee (Chapter 1). Currently the most popular, and with the largest body of evidence to credential their use, are virtual reality simulators (VRS) (1.5.3). Their role in training is expanding, and software is available enabling patient's computer tomographic (CT) images to be uploaded into the simulators to allow practitioners a chance to 'practice' cases of EVAR and CAS prior to conducting the procedure on patients themselves (Procedure Rehearsal™).

Evidence exists (Aggarwal et al 2006, Dawson et al 2007, Coates et al, 2010) that training on virtual reality simulators improves endovascular trainees' technique, and that this transfers into the operating room (Chaer et al, 2006) demonstrable by safer practice on patients.

The role of human cadavers, as previously reviewed, is less well reported (1.5.4) in endovascular training but, in almost all other branches of surgery fresh frozen cadaveric training is growing in popularity and is seemingly well accepted by trainees and trainers alike (Gilbody et al 2011).

2.2 Aims and Hypothesis

Practitioners and trainees in interventional cardiology, vascular surgery, and interventional radiology all undertake endovascular procedures. Many will have used VRS during their training. A pulsatile human cadaver model has formally been described (Garrett 2001) but it has not been assessed for its suitability or validity as a training model. It is unlikely that many will have had exposure to cadaveric endovascular training. We hypothesise that endovascular practitioners will question the suitability and feasibility of a PHCM, and favour VRS.

There is no mention in the literature reporting patients' opinions on endovascular specialists training and practicing on VRS or HC. We postulate that patients will be surprised to learn that modern endovascular doctors train on SVR and PHCM, but overall support this form of training.

The aims of this chapter:

1) To establish the opinion of endovascular experts on training in endovascular skills on both VRS and HC. We aim to explore issues of access, usability, realism and suitability. It was aimed to establish their feelings towards cadaveric training.

2) To determine patients' opinion on endovascular practitioners training on SVR and HC. It was aimed to determine their projected confidence in doctors trained on SVR and HC.

2.3 Endovascular Training on Virtual Reality Simulators and Human Cadavers. Questionnaire Based Study

In order to determine the opinion of both health care professionals and patients, two questionnaires were designed.

2.3.1 Methods - Endovascular Training on Virtual Reality Simulators and Human Cadavers: Professional Medical Opinion

An anonymous, prospective, web-based, opinion questionnaire trial was designed.

2.3.1.1 Inclusion Criteria

Consultants and trainees involved in endovascular training or practice were invited to take part in this questionnaire. This included:

- Vascular Surgeons: both trainees and consultants
- Cardiologists: both trainees and consultants
- Interventional Radiologists: both trainees and consultants

2.3.1.2 Exclusion Criteria

Consultants and trainees who declare no interest in endovascular practice or training.

2.3.1.3 Web-based Survey

A web-based approach to gathering responses was adopted. A questionnaire was transcribed into a web-based programme (surveymonkey™). This programme automatically generates a web link, which can be pasted into an email, giving the recipient access to the questionnaire online by clicking on the link. Responses are automatically collated through the web-based programme, and can be downloaded for further interrogation.

There is a function that prevents candidates from 'skipping' questions. However, we did not activate this function, due to concern that this would deter candidates from completing the full questionnaire.

2.3.1.4 The Medical Professional Opinion Questionnaire

The questionnaire can be found in Appendix 2. Each question will be covered in detail in the results section (2.5).

No personally identifiable data was recorded at any time. All questionnaire responses were completely anonymous. At certain points in the questionnaire, candidates were provided with a free text box to record their open worded opinions. It was agreed that any highly recognisable quotes (such as patients or doctors names), would be removed from further analysis to promote confidentiality.

2.3.2 Methods - Endovascular Training on Virtual Reality Simulators and Human Cadavers: Patient's Opinion

A prospectively collated patient questionnaire survey was designed.

2.3.2.1 Inclusion Criteria

- Any patients attending for an outpatient appointment at the Freeman Hospital who indicate that they wished to complete a questionnaire. At least half of respondents had to be non-vascular*
    - The aim was to determine the opinion of patients who would directly benefit from endovascular intervention, and those who would not (ie non-vascular out-patients).
- Age 16, - no upper limit
- Male and Female patients

* non-vascular patients are defined as patients who have no past medical history of vascular disease (peripheral vascular disease (PVD), ischaemic heart disease (IHD) or cerebrovascular disease (CVD)) and are not investigation for suspected vascular disease.

2.3.2.2 Exclusion Criteria

- Age <16 years
- Any patients who indicate that they do not want to complete a questionnaire

2.3.2.3 Patient's With Communication Difficulties

Every reasonable attempt was made to allow patients with communication problems to participate in this questionnaire study. Friends, relatives or translators of patients with communication difficulties were sensitively approached to ask if they could help facilitate completion of the questionnaire.
There were no instances during the trial where patients with communication difficulties were excluded from the trial.

2.3.2.4 Database

Patients data from questionnaires was held both on paper and electronically.
All data collected was completely anonymous. Craig Nesbitt (lead investigator) acted as custodian for the data generated. It was registered with the Newcastle Upon Tyne Hospital's Foundation Trust Caldicott Guardian and was held in compliance with the Data Protection Act 1998. All data will be destroyed within twelve months of completion of the study.

2.3.2.5 The Patient Opinion Questionnaire

The patient questionnaire can be found at Appendix 21. Full details of each question are discussed in the results section (2.5).
The questionnaire did not at any time record any personally identifiable information. All recorded data was anonymous. In certain areas, patients were provided with a text box for free text. It was decided that any highly recognisable quotes, such as the names of patients or doctors, would be removed from further analysis to ensure patient confidentiality.

2.3.2.5.1 The Patient Opinion Questionnaire – Patient Information Sheet

Prior to completing the patient questionnaire, each candidate was provided with a patient information sheet (Appendix 24). This information sheet explained the background to the questionnaire, a number of the concepts such as endovascular practice, and the nature of endovascular training. It took approximately five minutes to read the information sheet. It was important for potential candidates to have

sufficient time to read, comprehend and then reflect upon the proposed questionnaire before agreeing to complete it.

2.3.2.5.1 The Patient Opinion Questionnaire – Informed Consent

Candidates who indicated that they had read and understood the patient information sheet, and wished to complete a questionnaire received one. This was considered informed consent, and a box was ticked on the front of the questionnaire to indicate this process had taken place. Formal written consent was not sought.

2.3.2.5 Ethical Approval

The East Midlands – Leicester Research Ethics Committee approved the patient based questionnaire study on 14th June 2012. The Newcastle Upon Tyne Hospital s NHS trust approved the patient based questionnaire on 3rd July 2012.

2.4 Results

All data generated from both the patient and professional questionnaires was tabulated onto an excel spread sheet (Microsoft excel™). Mean, median, modal and standard deviation values were extracted in standard fashion. Statistical analysis was undertaken using the Statistical Package for the Social sciences version 19 (SPSS, Chicago). Advice was sought from a medical statistician at Newcastle University for the most appropriate statistical tests when analyzing the trial data. Mann Witney U test was used when comparing vascular and non-vascular patient responses to the same question. Wilcoxon matched pairs signs rank test was used when comparing responses to different questions within the same group. A p-value of <0.05 was considered to be significant.
The results from both questionnaires are displayed below.

2.4.1 Endovascular Training on Virtual Reality Simulators and Human Cadavers: A Questionnaire of Professional Medical Opinion

The questionnaire was emailed to the relevant specialties via the following websites. Their corresponding response rate is also shown:

Specialty	Website	Method of distribution	Response rate (%)
General Surgery (interest in vascular surgery) & Vascular Surgery	Rouleaux Club – Vascular Surgery Trainees Society	Questionnaire link emailed in monthly email to all members	26/257 (10.1)
Interventional	British Society of	Questionnaire link	72/500 (14.4)

radiology	Interventional Radiology	emailed directly to society members	
Interventional cardiology	British Cardiovascular Interventional Society	Questionnaire link emailed in monthly email to all members	2/950 (0.2)

2.4.1.1 Candidate Demographics

Endovascular practitioners (consultants and trainees) demographics are shown in Tables 1b and 1c

Table 1b. Specialty

Specialty	Response count	Percentage
General Surgery (interest in vascular surgery)	5	5.3
Vascular Surgery	15	16
Interventional radiology	72	76.6
Interventional cardiology	2	2.1
Total	94 (6 skipped question)	

Table 1c. Seniority

Year of Training	Response count	Percentage
ST3	5	5.4
ST4	6	6.5
ST5	3	3.3
ST6	3	3.3
ST7	3	3.3

Consultant	72	78.3
Total	92 (8 skipped question)	

2.4.1.2 Candidates Awareness of Cadaveric Endovascular Training

Consultants and trainees were asked to rate their awareness of HC endovascular simulation training (Table 2b):

"I am aware of human cadavers for training in endovascular intervention"

Table 2b. Awareness of Human Cadaver Endovascular Training

Response	Response count	Percentage
I am aware	22	24.4
I am not aware	68	75.6
Total	90 (10 skipped question)	

2.4.1.3 Candidates Interest in Cadaveric Endovascular Training

Consultants and trainees rated their declared interest at viewing a demonstration of a HC endovascular simulator (Table 3).

"Given the chance I would be interested in viewing a demonstration of the use of human cadavers as a training model for endovascular intervention; Basic guidewire handling skills, EVAR, TEVAR, peripheral angioplasty/stenting, TAVI, coronary, carotid etc."

Table 3. Candidate's Interest in Cadaveric Endovascular Training

Response	Response count	Percentage
Agree (interested) no concerns	38	43.2
Agree (interested) some concerns	14	15.9
Disagree, I would not be interested	36	40.9
Total	88 (12 skipped question)	

2.4.1.3.1 Candidates Concerns

Consultants and trainees were provided with a free text box to detail their apparent concerns at viewing a demonstration of the use of human cadavers as a training model for endovascular intervention. These concerns are details in Table 4

Table 4. Concerns Regarding Cadaveric Endovascular Intervention

N^{o}	Concern
1	*I am unsure if there would be any additional benefit over simulators.*
2	*How realistic? How will the vessels behave – will they be accessible?*
3	*Presumably these cadavers are prepared differently to those for dissection. Not sure how good the tissue characteristics would be.*
4	*Think that most of these are covered on simulators.*
5	*The real feeling when dealing with living vessels in which blood flowing must be so different than hard vascular wall in cadavers.*
6	*Not sure how transferrable the experience would be.*
7	*Would question value of this over current simulators. They are both limited by lack of patient feedback (e.g. pain as a sign o potential vessel rupture), physiology- e.g. blood pressure effects deploying TEVAR accurately.*
8	*How reproducible the training would be compared to in vivo.*
9	*Would need to simulate flow some how.*
10	*It is somewhat distasteful, although I'm not sure quite why!*
11	*I am not convinced that a cadaver is any closer to the real situation than simulators.*
12	*I feel the future of this will lie in computer simulated models.*

13,14	*No comment*

2.4.1.4 Previous Cadaveric Training Exposure

Consultants and trainees were asked to indicate if they had previoulsy attended a training course that utilised human cadavers (Table 5)

"I have attended a medical training course that has utilised human cadavers"

Table 5. Prior Exposure To Medical Cadaver Training

Response	Response count	Percentage
Yes	28	31.1
No	62	68.9
Total	90 (10 skipped question)	

2.4.1.4.1 Previous Cadaveric Courses

The specific cadaveric courses candidates had attended are listed below in Table 6.

Table 6. Cadaveric Courses

Course	N^{o} Attended
Vascular exposures master class	1
Amputations course Royal College of Surgeons	2
Society of Interventional Radiology EVAR course	1

Pain management course	1
Leiden vertebroplasty course, Holland	1
Medical School training/undergraduate training	8
Musculoskeletal interventions (mainly vertebroplasty)	1
Surgical skills course	1
Medical sciences Tripos at Cambridge university	1
Total	17
Did not indicate	11

2.4.1.5 Candidate's Agreement With Human Cadaver Training

Consultants and trainees were asked to indicate if they agreed with the use of HC for medical training. (Table 7):

"I agree with the use of human cadavers for training doctors"

Table 7. Agreement With Medical Cadaver Training

Response	Response count	Percentage
Yes, I agree	64	71.9
Yes, but I have some concerns	20	22.5
No, I do not agree	5	5.6
Total	89 (11 skipped question)	

2.4.1.5.1 Candidates Concerns

Conslтants and trainees were provided with a free text box to detail their concerns for the use of human cadavers for trainign doctors. These concerns are details in Table 8.

Table 8. Concerns Regarding the Use of Human Cadavers for Training Doctors.

N^{o}	Concern
1	*Ethical issues*
2	*No concerns as long as relevant laws are followed*
3	*Good for training doctors in anatomy. Little benefits for endovascular training.*
4	*For anatomical dissection and learning anatomy only.*
5	*Much of intervention uses 'feel' as well as vision. This would be quite different in a cadaver.*
6	*The legality of this needs to be proven.*
7	*Only if they really need to be used.*
8	*Assuming proper ethical/legal standards observed*
9	*Probably limited resource. Specifically for intervention, simulation a better option long term.*
10	*Unnecessary. Simulators should obviate the need.*
11	*The use of cadavers must be justified the advantage they confer over other options.*
12-20	*No comment*

2.4.1.6 Candidate's Awareness of Virtual Reality Endovascular Training

Consultants and trainees were asked to rate their awareness of virtual reality endovascular simulation training (Table 9):

"I am aware of the use of virtual reality simulators for training in endovascular intervention"

Table 9. Awareness of Virtual Reality Endovascular Training

Response	Response count	Percentage
Yes, I am aware	89	100
No, I am not aware	0	0
Total	89 (11 skipped question)	

2.4.1.7 Candidate's Prior Use of a Virtual Reality Endovascular Simulator

Consultants and trainees were asked if they had previously used a virtual reality endovascular simulator (Table 10)

"I have had an opportunity to use an endovascular virtual reality simulator"

Table 10. Prior Use of a Virtual Reality Endovascular Simulator.

Response	Response count	Percentage
Yes, I have	72	80.9
No, I have not	17	19.1
Total	89 (11 skipped question)	

2.4.1.8 Candidate's Preferred Training Simulator

Consultants and trainees were asked to indicate if they would prefer training on a VRS or a HC model (Table 11):

"Given the option, would you prefer to be trained endovascular skills on a virtual reality or human cadaver model?"

Table 11. Preferred Training Model

Response	Response count	Percentage
Virtual Reality	44	48.4
Human Cadaver	11	12.1
No preference	38	41.8
Total	93 (7 skipped question)	

2.4.1.8.1 Candidates Reasoning For Simulator Preference

Consultants and trainees were asked to indicate a reason for their preferred simulator. These reasons have been divided into those favouring VRS, those favouring a HC model, and those with no preference (Table 13a,b,c)

Table 12a. Reason for Preferring Virtual Reality Simulation

N^{o}	Concern
1	*Machine is not smelly, machine is re-usable.*
2	*I can see no benefit to using cadavers.*
3	*Modern units will soon allow us to model challenging cases.*
4	*Cleaner reproducible. Quantitative feedback on performance metrics.*
5	*A virtual reality simulator would suffice to learn techniques and am not sure what the additional benefits of cadavers would be.*
6	*Simulator due to its availability.*
8	*A virtual reality simulator has superior logistics, but they need to significantly improve on what is currently available.*
9	*Simulators: Less hassle, less smelly.*
10	*It depends on the level of sophistication of the VR.*
11	*My experience of VR has been very good.*
12	*When simulators are fully developed will be reproducible, validated, more readily available, less susceptible to ethical/personal objections.*
13-44	*No comment*

Table 12b. Reason for A Human Cadaver Model

N°	Concern
1	*Both systems have their drawbacks. Im not sure how pulsatile flow will be simulated in a cadaver. However, the cadaver does offer the benefit of realistic anatomy and tactile feedback.*
2	*A cadaver model because there are limited options for simulation with VR.*
3	*Cadaver in order to get the 'real' feel.*
4	*A cadaver model because the simulators that I have tried have not been adequate.*
5	*I think a cadaver model is probably (at least potentially) more life like and useful.*
6	*When VR is as good as HC, VR will be preferable. Until then the use of HC may be useful, but will still be artificial.*
7	*Cadaver, as currently VR are not yet sufficiently realistic.*
8	*If there is training that is only possible or much more realistic on human cadaver then yes – but animals also offer training opportunities.*
9-11	*No comment*

Table 12c. Reason for No Simulator Preference

N°	Concern
1	*The model should be optimised for the skill being taught*
2	*Both have advantages and disadvantages for different skills training. A combination of both would be best.*
3	*Any human analogue/model provides opportunity to learn procedural skills without risk to living patients.*
4	*Choice would depend on availability/cost and specific procedure attempted. I expect that some procedures/maneuvers would be better on one or other technique.*
5	*I think both have distinct advantages to offer.*
7	*A combination makes sense. Cadavers will be in short supply.*
8	*Whichever has the best combination of being realistic and available. I understand Europe also has live models for training.*
9	*The option of horses for courses is not included in the list.*
10	*Both are needed.*
11	*Limited experience of VR training so unable to judge.*
12	*Modern units will soon allow us to model challenging cases.*
13	*True to life in cadavers but can be a more controllable environment on a simulator.*
14	*I believe both would be helpful as a prelude to suitable experience on real patients under supervision.*
15	*I have never seen a simulator of any use. I would however prefer VR if it could be made better.*
16	*Vessels in simulators do not behave appropriately. Would cadaver provide a more realistic feel?*
17	*Both seem good options.*
18	*When VR is as good as HC, VR will be preferable. Until then the use of*

	HC may be useful, but will still be artificial.
19	*Both have advantages – e.g range of cases that can be simulated on VR simulators versus fidelity of cadavers.*
20	*The real thing (a live – hopefully – patient) is far and away the best way to learn how to carry out a whole procedure.*
21-38	*No comment*

2.4.2 Endovascular Training on Virtual Reality Simulators and Human Cadavers: A Questionnaire of Public Opinion

Questionnaires were distributed and subsequently collected during a single day of outpatient clinics on July 16th 2012. As described above (2.3.2.1) patients attending for an outpatient clinic appointment were approached. After a short formal introduction, candidates were offered a patient information sheet. Those patients who read, and understood the information sheet and indicated they were happy to complete a questionnaire were then given the questionnaire to complete.

One hundred and ten questionnaires were distributed. Three patients did not complete their questionnaires as they were subsequently called into their clinic appointment, and did not have sufficient time to wait and complete it following the appointment.

One hundred and seven patient questionnaire responses were received in total. Fifty-seven were received from patients who did not have any history of vascular disease, and were attending hospital for a non-vascular related complaint (non-vascular patients). Fifty responses were received from patients who had either under gone a surgical procedure for vascular disease or were under investigation for a vascular related illness (vascular patients). See 2.4.2.4 for further details.

2.4.2.1 Patients Age

Patients age (vascular and non-vascular patients), are displayed in Table 14

Table 14. Patient's Age- (Vascular and Non-Vascular Patients)

Age	Vascular (n=50)		Non-Vascular (n=57)		Test of between group difference*
	N°	Percentage	N°	Percentage	
< 20	0	0	0	0	NS†
21 – 30	2	4	3	5.3	NS
31 – 40	2	4	4	7	NS
41 – 50	7	14	7	12.3	NS
51 - 60	4	8	15	26.3	p=0.021
61 - 70	19	38	13	22.8	NS
71 – 80	8	16	8	14	NS
80+	8	16	7	12.3	NS
Total	50	100	57	100	

*Proportions test (Fishers Exact Test) †No significant difference

2.4.2.2 Patients Organ Donor Card Status

Patients were asked to indicate if they carried an organ donation card (Table 15)

"Do you carry an organ donor card?" Options included: *"Yes",* "*No (and I do not agree with organ donation)* and *"No (but I am in favour of organ donation)"*

Table 15. Patient's Organ Donor Status

Donor?	Vascular (n=50)		Non-Vascular (n=57)		Test of between group difference*
	N^{o}	Percentage	N^{o}	Percentage	
Yes	11	22	13	22.8	NS†
No (disagree)	9	18	9	15.8	NS
No (agree)	30	60	35	61.4	NS
Total	50	100	57	100	

*Proportions test (Fishers Exact Test) †No significant difference

2.4.2.3 Patients Status Regarding Donation of Their Bodies to Medical Research

Patients indicated if they had donated their bodeis to medical research, and if not, their opinion of donation (Table 16).

"Have you donated your body to medical research?" Options included: *"Yes" "No (and I do not agree with donating)", "No (but I am in favour of people donating to medical research)"* and *"No (but I may consider donating my body for medical research)"*

Table 16. Patients Status Regarding Body Donation

Status	Vascular (n=50)		Non-Vascular (n=57)		Test of between group difference*
	N^{o}	Percentage	N^{o}	Percentage	
Yes	3	6	2	3.5	NS†
No (disagree)	16	32	15	26.3	NS
No (agree)	19	38	23	40.4	NS
No (would consider)	12	24	17	29.8	NS
Total	50	100	57	100	

*Proportions test (Fishers Exact Test) †No significant difference

2.4.2.4 Dividing Patients into Vascular and Non-Vascular Categories

The opinion of vascular and non-vascular patients was sought. 'Non-vascular patients' were defined as patients who declared no personal history of vascular disease.

2.4.2.4.1 Current Vascular Complaints

Patients were asked to indicate if they currently suffered any vascular related medical conditions (Table 17)

"Please indicate with a tick if you have any of the following conditions:

- *Disease of the blood vessels - 'peripheral vascular disease' **(PVD)***
- *Heart problems, including angina, a previous heart attack, heart failure - 'ischaemic heart disease' **(IHD)***
- *History of stroke or mini-stroke – 'cerebrovascular disease **(CVD)**"*

Table 17. Patients Current Vascular Complaints

Group	Vascular (n=50)		Non-Vascular (n=57)		Test of between group difference*
	N^{o}	Percentage	N^{o}	Percentage	
PVD	20	40	0	0	p=0.00

IHD	22	44	0	0	p=0.00
CVD	11	22	0	0	p=0.00
Total	50	100	0	0	

*Proportions test (Fishers Exact Test)

2.4.2.4.2 Patients Currently Under Care of a Vascular Doctor

Patients were if they were currently under the care of a vascular doctor. The results are detailed in Table 18.

"Are you currently under the care of a vascular doctor (either investigating, treating or keeping an eye on a problem with your blood vessels) ?"

Table 18. Patients Currently Under Care of a Vascular Doctor

Vascular Doctor	Vascular (n=50)		Non-Vascular (n=57)		Test of between group difference*
	N°	Percentage	N°	Percentage	
Yes	50	100	0	0	p=0.00
No	0	0	57	100	p=0.00
Total	50	100	57	100	

*Proportions test (Fishers Exact Test)

2.4.2.5 Past Open Vascular Surgical History

Patients' declared their past (vascular) open surgical history (Table 19)

"Please indicate if you have ever undergone any of the following open vascular procedures:

- *Open surgery to bypass a blocked blood vessel*
- *Open surgery on your aorta*
- *Amputation"*

Table 19. Patients Open Vascular Surgical History

Open Vascular History?	Vascular (n=50)		Non-Vascular (n=57)		Test of between group difference*
	N°	Percentage	N°	Percentage	
Yes	18	36	0	0	p=0.00
No	31	64	57	100	p=0.00
Total	50	100	57	100	

*Proportions test (Fishers Exact Test)

2.4.2.5.1 Open Surgical Vascular Procedures

The open surgical procedures patients had undergone are detailed in Table 20.

Open vascular procedures were categorised into:

- *Open surgery to bypass a blocked blood vessel*
- *Open surgery on your aorta*
- *Amputation*
- *Other*

Table 20. Patients Open Vascular Procedures

Procedure	Vascular (n=18)		Non-Vascular (n=0)		Test of between group difference*
	N°	Percentage	N°	Percentage	
Bypass	11	61.1	0	0	p=0.00
Aorta	2	11.1	0	0	p=0.00
Amputation	1	5.6	0	0	p=0.00
Other	4	22.2	0	0	p=0.00
Total	18	100	0	0	p=0.00

*Proportions test (Fishers Exact Test)

2.4.2.6 Past Endovascular History

Patients' documented their past endovascular history (Table 21)

"Please indicate if you have ever undergone any of the following pinhole (endovascular) procedures:

- *Angiogram (dye test) to image the blood vessels in your legs*
- *Angioplasty (balloon stretch) of a narrowed blood vessel*
- *Stent insertion (stent to hold open a narrowed or blocked blood vessel)"*

Table 21. Patients Endovascular Surgical History

Endovascular History?	Vascular (n=50)		Non-Vascular (n=57)		Test of between group difference*
	N^o	Percentage	N^o	Percentage	
Yes	33	66	3	5.3	p=0.00
No	17	34	54	94.7	p=0.00
Total	50	100	57	100	

*Proportions test (Fishers Exact Test)

2.4.2.6.1 Endovascular Procedures

The endovascular procedures patients had undergone are detailed in Table 22.

Endovascular procedures were categorised into:

- *Angiogram (dye test) to image the blood vessels in your legs*
- *Angioplasty (balloon stretch) of a narrowed blood vessel*
- *Stent insertion (stent to hold open a narrowed or blocked blood vessel)*
- *Other*

Table 22. Patients Endovascular Procedures

Procedure	Vascular (n=33)		Non-Vascular (n=3)		Test of between group difference*
	N^{o}	Percentage	N^{o}	Percentage	
Angiogram	11	33.3	3	100	p=0.051
Angioplasty	2	6.1	0	0	NS
Stent	7	21.2	0	0	NS
Other	13	39.4	0	0	p=0.288
Total	33	100	3	100	NS

*Proportions Test (Fishers Exact Test)

2.4.2.7 Patients Family and Friends, Vascular-Related Medical History

Patients were asked to identify if they knew any friends or family who had vascular related conditions. These responses are detailed in Tables 23a and 23b

"Please indicate with a tick if you know anyone who has any of the following conditions:

- *Disease of the blood vessels - 'peripheral vascular disease' **(PVD)***
- *Heart problems, including angina, a previous heart attack, heart failure - 'ischaemic heart disease' **(IHD)***
- *History of stroke or mini-stroke – 'cerebrovascular disease **(CVD)**"*

nb. PVD, IHD and CVD are considered together in Table 23a for analysis as 'vascular disease'

Table 23a. Patients Family and Friends, Vascular-Related Medical History

Vascular Disease	Vascular (n=50)		Non-Vascular (n=57)		Test of between group difference*
	N^{o}	Percentage	N^{o}	Percentage	
Yes	33	66	47	82.5	NS†

No	17	34	10	17.5	NS
Total	50	100	57	100	

*Proportions Test (Fishers Exact Test) †No significant difference

Table 23b. Vascular-Related Medical History: Patients Family, Friend or both?

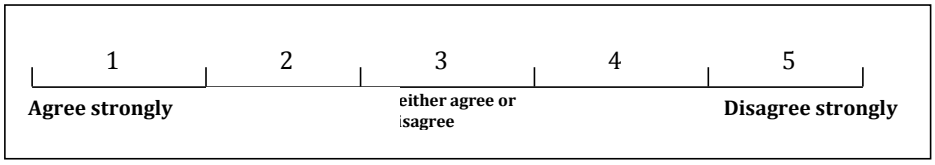
Vascular Disease	Vascular (n=33)		Non-Vascular (n=47)		Test of between group difference*
	N°	Percentage	N°	Percentage	
Family	12	36.4	22	46.8	NS†
Friend	2	6.1	5	10.6	NS
Both	1	2	2	4.3	NS
Did not specify	18	54.5	18	38.3	NS
Total	33	100	47	100	NS

*Proportions test (Fishers Exact Test) †No significant difference

2.4.2.8 Endovascular Simulation Training – Agreement With Statements

Patients rated their agreement with six statements regarding endovascular simulation training on a five-point Likert scale (Figure 2).

Figure 2. Likert Scale Used For Patient Statement Scoring



2.4.2.8.1 Training On Cadavers and Real Patients

Patients rated their agreement that doctors should be allowed to train on human cadavers and real patients (Table 24, Graph 24):

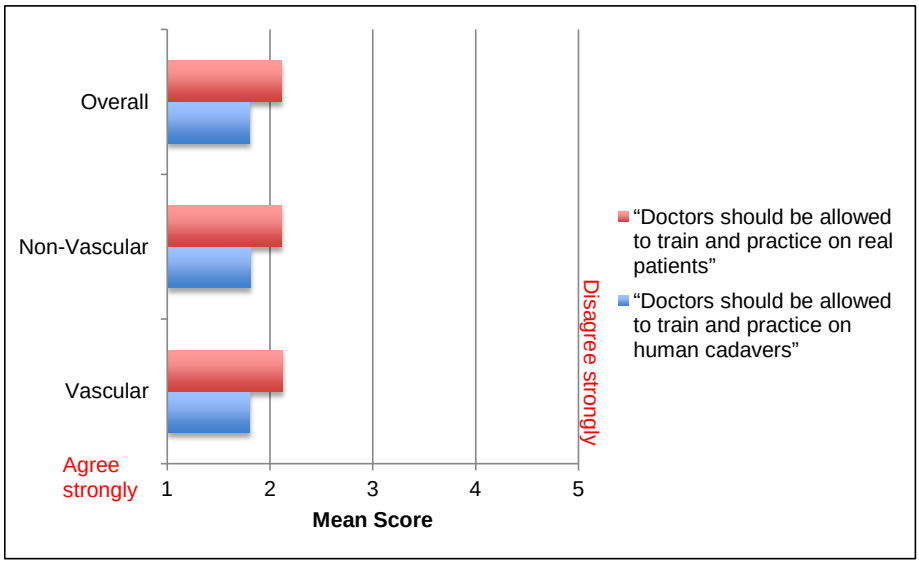
1. *"Doctors should be allowed to train and practice on human cadavers"*
2. *"Doctors should be allowed to train and practice on real patients"*

Table 24. Doctors Training On Cadavers and Real Patients

	1. "… practice on human cadavers"			*2 "…. practice on real patients"*		
	Mean	**SD***	**Mode**	**Mean**	**SD**	**Mode**
Overall (n=107)	1.8	0.89	1	2.11	0.97	2
Vascular Patients (n=50)	1.8	0.89	1	2.12	1.02	2
Non-Vascular Patients (n=57)	1.81	0.9	1	2.11	0.94	2

*Standard Deviation

Graph 24. Doctors Training On Cadavers and Real Patients



2.4.2.8.2 Training On Cadavers and Real Patients – Statistics

Table 25a. Comparing Vascular and Non-Vascular Patients

	1. "… practice on human cadavers"		*2 "…. practice on real patients"*	
	Mean (SD*)	**Mode**	**Mean (SD)**	**Mode**
Vascular Patients (n=50)	1.8 (0.89)	1	2.12 (1.02)	2
Non-Vascular Patients (n=57)	1.81 (0.9)	1	2.11 (0.94)	2
Significance test of between group difference[Ŧ]	NS		NS	

*Standard Deviation
[Ŧ]Mann Whitney U Test (Monte Carlo Sig 2-Tailed Test)

Table 25b. Comparing All Patients

	1. "… practice on human cadavers"		*2 "…. practice on real patients"*		**Significance test**[Ŧ]
	Mean (SD*)	**Mode**	**Mean (SD)**	**Mode**	
Overall (n=107)	1.8 (0.89)	1	2.11 (0.97)	2	**p=0.000**

*Standard Deviation
[Ŧ]Wilcoxon Matched Pairs Singed Ranks Test (Monte Carlo Sig 2 Tailed Test)

2.4.2.8.3 Training On Cadavers and Real Patients – Patient Comments

Patients were offered a free text box to justify their opinion. These comments are detailed in table 26

Table 26. Doctors Training On Cadavers and Real Patients: Patients Comments

	"Doctors should be allowed to train and practice on human cadavers"	
	Vascular Patients	**Non-Vascular Patients**
1	Only if human agrees prior to death	There aren't many other uses for dead bodies.
2	As a patient who has undergone CABG I fully understand the need to train doctors as highly and authentically as possible	How else can medical knowledge progress. All procedures' checks can be accountable so as to avoid a similar controversy as the Alder Hey ease
3	If it isn't done on the dead, how can students get it right for the living	After a post-mortem, could a surgeon not practice on the cadaver?
4	Everything possible Should be done to help the sick	I would have assumed this was already standard practice.
5		Depends on experience
6		Practicing on a real body is always better than computer simulation
7		Better than using computers!
8		Important to progress research into

		disease
9		Don't feel comfortable with this practice
	"Doctors should be allowed to train and practice on real patients"	
	Vascular Patients	**Non-Vascular Patients**
1	Depends on case	A necessary evil
2	Anything that helps doctors and patients in the long run	If the risks are low then doctors should be allowed to practice on real patients
3	Under suitable supervision	Very delicate procedures- there is maybe a risk with training new doctors for errors to occur
4		Depends what it is for
5		If patient knows the risk and is at risk of different type of surgery, and this is their wish and they give their consent, this procedure should be allowed.
6		Doctors have to train

2.4.2.8.4 Patients Confidence Of Cadaver and Virtual Reality Trained Doctors

Patients rated their confidence in doctors trained on human cadavers and virtual reality simulators (Table 27 and Graph 27):

1. *"I would feel confident undergoing a keyhole (endovascular) procedure by a doctor whose training included practice on a computer model."*

2. *"I would feel confident undergoing a keyhole (endovascular) procedure by a doctor whose training included practice on a human cadaver model"*

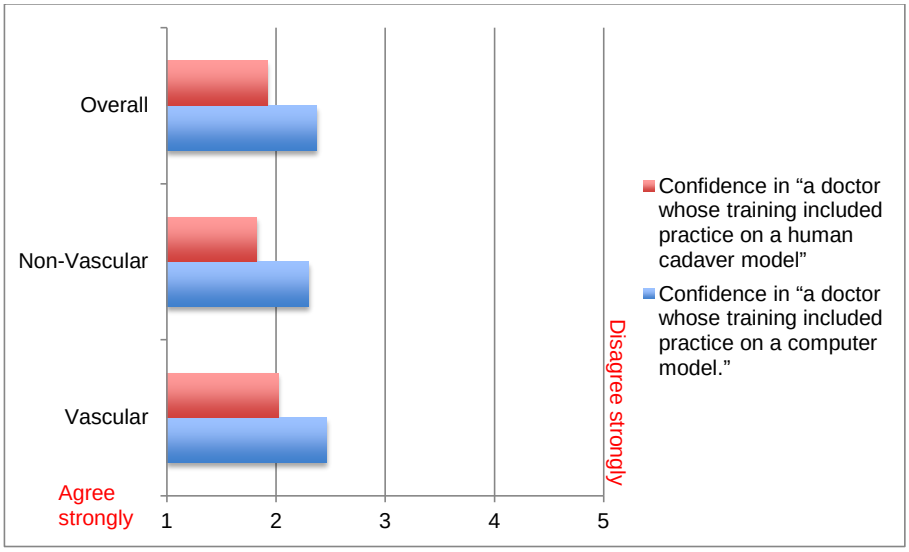
Table 27. Patients Confidence of Cadaver and Virtual Reality Trained Doctors

	1. Doctor trained on a computer model			*2. Doctor trained on a human cadaver model*		
	Mean	**SD***	**Mode**	**Mean**	**SD**	**Mode**
Overall (n=107)	2.37	1.02	2	2.02	0.8	2
Vascular Patients (n=50)	2.46	0.99	2	1.82	0.8	2
Non-Vascular	2.3	1.05	2	1.92	0.8	2

Patients (n=57)

*Standard Deviation

Graph 27. Patients Confidence of Cadaver and Virtual Reality Trained Doctors



2.4.2.8.5 Training On Cadavers and Real Patients - Statistics

Table 28a. Comparing Vascular and Non-Vascular Patients

	1. Doctor trained on a computer model **Mean (SD*)**	**Mode**	*2. Doctor trained on a human cadaver model* **Mean (SD)**	**Mode**
Vascular Patients (n=50)	2.46 (0.99)	2	1.82 (0.8)	2
Non-Vascular Patients (n=57)	2.3 (1.05)	2	1.92 (0.8)	2
Significance test of between group difference[Ŧ]	NS		NS	

*Standard Deviation
[Ŧ]Mann Whitney U Test (Monte Carlo Sig 2-Tailed Test)

Table 28b. Comparing All Patients

	1. Doctor trained on a computer model		*2. Doctor trained on a human cadaver model*		**Significance test**[Ŧ]
	Mean (SD*)	**Mode**	**Mean (SD)**	**Mode**	
Overall (n=107)	2.37 (1.02)	2	1.92 (0.8)	2	**p=0.000**

*Standard Deviation
[Ŧ]Wilcoxon Matched Pairs Singed Ranks Test (Monte Carlo Sig 2 Tailed Test)

2.4.2.8.6 Patients Confidence Of Cadaver and Virtual Reality Trained Doctors – Patient Comments

Patients were offered a free text box to justify their opinion. These opinions are detailed in table 29.

Table 29. Patients Confidence Of Cadaver and Virtual Reality Trained Doctors: Comments

"I would feel confident undergoing a keyhole (endovascular) procedure by a doctor whose training included practice on a computer model."		
	Vascular Patients	**Non-Vascular Patients**
1	As long as senior surgeon present	As long as procedure was monitored by fully qualified doctor
2		Computers are not fool proof
3		Would need to consider any disadvantages
4		Depends how realistic the model is

"I would feel confident undergoing a keyhole (endovascular) procedure by a doctor whose training included practice on a human cadaver model"		
	Vascular Patients	**Non-Vascular Patients**
1	As long as senior surgeon present	Beneficial for doctor, more confidence gained=better for patient
2		If asked, would have to think of benefits and disadvantages
3		Depends how it felt at the time
4		They would have had more experience

2.4.2.8.7 Patients Most Trusted Method of Training

Finally Candidates rated their agreement with two statements to gauge their opinion on the training model they felt gave them the most confidence in their doctor. These results are displayed in Table 30, Graph 30.

1. *"I would feel more confident undergoing a keyhole (endovascular) procedure by a doctor who had undergone training on a human cadaver model compared to a doctor who had undergone training on a computer model."*

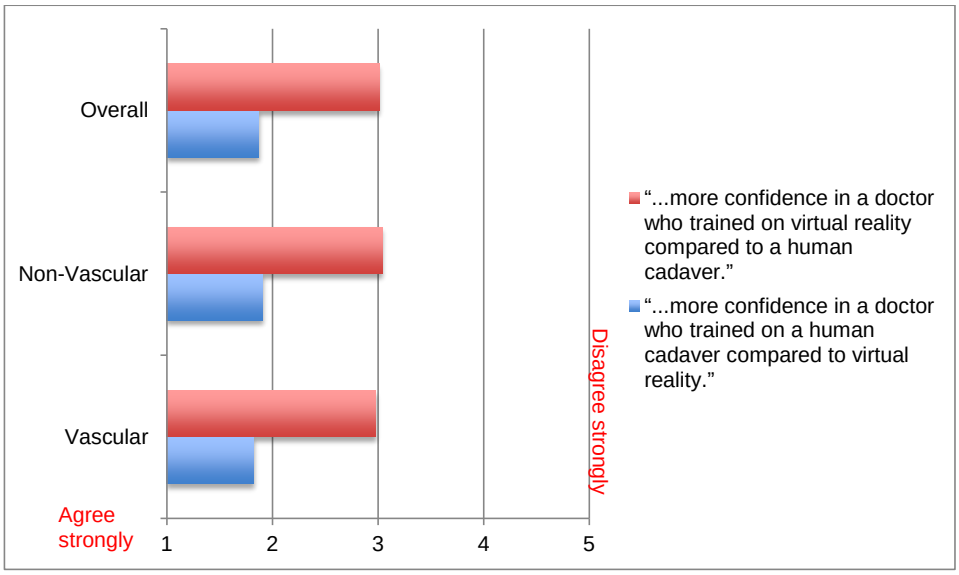
2. *"I would feel more confident undergoing a keyhole (endovascular) procedure by a doctor who had undergone training on a computer model compared to a doctor who had undergone training on a human cadaver model."*

Table 30. Patients Most Trusted Method of Training

	1. Human cadaver compared to computer model			*2. Computer model compared to human cadaver*		
	Mean	**SD***	**Mode**	**Mean**	**SD**	**Mode**
Overall (n=107)	1.87	0.8	2	3.01	0.94	3
Vascular Patients (n=50)	1.82	0.83	2	2.98	0.98	3
Non-Vascular Patients (n=57)	1.91	0.8	2	3.04	0.91	3

*Standard Deviation

Graph 30. Patients Most Trusted Method of Training



2.4.2.8.8 Patients Most Trusted Training Model - Statistics

Table 31a. Comparing Vascular and Non-Vascular Patients

	1. Human cadaver compared to computer model		*2. Computer model compared to human cadaver*	
	Mean (SD*)	**Mode**	**Mean (SD)**	**Mode**
Vascular Patients (n=50)	1.82 (0.83)	2	2.98 (0.98)	3
Non-Vascular Patients (n=57)	1.91 (0.8)	2	3.04 (0.91)	3
Significance test of between group difference[Ŧ]	NS		NS	

*Standard Deviation
ŦMann Whitney U Test (Monte Carlo Sig 2-Tailed Test)

Table 31b. Comparing All Patients

	1. Human cadaver compared to computer model		*2. Computer model compared to human cadaver*		**Significance test**Ŧ
	Mean (SD*)	**Mode**	**Mean (SD)**	**Mode**	
Overall (n=107)	1.87 (0.8)	2	3.01 (0.94)	3	**p=0.000**

*Standard Deviation
ŦWilcoxon Matched Pairs Singed Ranks Test (Monte Carlo Sig 2 Tailed Test)

2.4.2.8.9 Patients Most Trusted Training Model: Comments

Patients were offered a free text box to justify their opinion. These opinions are detailed in table 32.

Table 32. Patients Most Trusted Training Model: Comments

"I would feel more confident undergoing a keyhole (endovascular) procedure by a doctor who had undergone training on a human cadaver model compared to a doctor who had undergone training on a computer model."	
Vascular Patients	**Non-Vascular Patients**
1	Some experience, even on a dead person, is better than none
2	The more real training the better, a computer cannot simulate every eventuality
3	Depends on quality of computer simulation
"I would feel more confident undergoing a keyhole (endovascular) procedure by a doctor who had undergone training on a computer model compared to a doctor who had undergone training on a human cadaver model."	
Vascular Patients	**Non-Vascular Patients**
1 If the simulator model is clever it	With supervision.

	will be more powerful than a cadaver model	
2		I would generally feel confident in whatever was recommended by my consultant
3		Cant beat the real thing, although simulators are good

2.4.2.8.10 The Affect of Organ Donor Status & Agreement With Donation to Medical Research on Statement Scores

It was anticipated that patients who carried an organ donor card, or at least agree with organ donation, may have different opinions regarding doctors training methods, than those who don't. Also, those patients who agree with donating their body to medical science could likewise affect training opinions. To investigate this hypothesis, patients who carry a donor card and agree with organ donation, were compared to those who do not (Table 33a). Patients who agree with donating bodies to medical research were compared to those patients who do not (Table 33b)

Table 33a. The Affect of Patients Agreement with Organ Donation on Statement Scores

Organ Donor Opinion	**Agree (n=89)** Mean (SD*)	Mode	**Disagree (n=18)** Mean (SD)	Mode	***Test for between group difference*** ***ŦŦ***
"Doctors should be allowed to train and practice on human cadavers"	1.71 (0.89)	1	2.28 (0.75)	3	NS
"Doctors should be allowed to train and practice on real patients"	2.01 (0.91)	2	2.61 (1.09)	2	NS
Confidence in "a doctor whose training included practice on a computer model."	2.26 (0.95)	2	2.94 (1.21)	2	NS
Confidence in "a doctor whose training included practice on a human cadaver model"	1.81 (0.78)	2	2.44 (0.7)	2	NS
"...more confidence in a doctor who trained on a human cadaver compared to virtual reality."	1.83 (0.83)	1	2.06 (0.64)	2	NS

"...more confidence in a doctor who trained on virtual reality compared to a human cadaver."	2.98 (0.95)	3	3.17 (0.86)	3	NS

*Standard Deviation
ŦMann Whitney U Test (Monte Carlo Sig 2-tailed Test)

Table 33b. The Affect of Patients Agreement with Donating Their Body to Medical Research on Statement Scores

Donation to Medical Research Opinion	**Agree (n=76)** Mean (SD*)	Mode	**Disagree (n=31)** Mean (SD)	Mode	***Test for between group difference*** Ŧ
"Doctors should be allowed to train and practice on human cadavers"	1.7 (0.85)	1	2.06 (0.96)	2	**p=0.045**
"Doctors should be allowed to train and practice on real patients"	1.95 (0.83)	2	2.52 (1.18)	2	**p=0.024**
Confidence in "a doctor whose training included practice on a computer model."	2.3 (0.92)	2	2.55 (1.23)	2	NS
Confidence in "a doctor whose training included practice on a human cadaver model"	1.84 (0.78)	2	2.1 (0.83)	2	NS
"...more confidence in a doctor who trained on a human cadaver compared to virtual reality."	1.87 (0.84)	2	1.87 (0.72)	2	NS

"...more confidence in a doctor who trained on virtual reality compared to a human cadaver."	2.99 (0.99)	3	3.06 (0.81)	3	NS

*Standard Deviation
ŦMann Whitney U Test (Monte Carlo Sig 2-Tailed Test)

2.4.2.8.11 True Non-Vascular Patients

The criteria used to divide patients into 'vascular' and 'non-vascular' groups did not include patients known family or friends (2.4.2.7). This potential limitation is discussed in 2.5.3. Ten 'non-vascular patients' declared having no family or friends with vascular disease. These patients have no association with vascular disease whatsoever – so called 'true non-vascular patients'. They are compared to the remaining cohort below (Table 34).

Table 34. The Opinion of True Non-Vascular Patients

	True Non-Vascular (n=11) Mean (SD*)	Mode	**Remaining Cohort (n=96)** Mean (SD)	Mode	***Test for between group difference*Ŧ**
"Doctors should be allowed to train and practice on human cadavers"	1.9 (0.88)	2	1.79 (0.9)	1	NS
"Doctors should be allowed to train and practice on real patients"	2.5 (0.71)	2	2.07 (0.99)	2	NS
Confidence in "a doctor whose training included practice on a computer model."	2.2 (1.03)	2	2.39 (1.03)	2	NS
Confidence in "a doctor whose training included practice on a human cadaver model"	2.1 (0.74)	2	1.9 (0.81)	2	NS
"...more confidence in a doctor who trained on a human cadaver	2.2 (0.63)	2	1.84 (0.81)	2	NS

compared to virtual reality."					
"...more confidence in a doctor who trained on virtual reality compared to a human cadaver."	3 (0.82)	3	3.01 (0.95)	3	NS

*Standard Deviation
ŦMann Whitney U Test (Monte Carlo Sig 2-Tailed Test)

2.5 Discussion

One hundred medical professionals from endovascular specialties responded to the questionnaire. The large majority of responses came from interventional radiologists (76.6%) and it is acknowledged that the study subsequently did not represent the professional opinion of all endovascular specialties evenly. 78.3% of respondents were consultant grade. It is acknowledged that trainees are more likely to have contact with simulation during their training hence the predominance of consultant opinions must be noted when interpreting the results of the professional medical opinion questionnaire. A postal questionnaire, with pre-paid return envelopes is one strategy of potentially increasing response rate and targeting specific groups, but represents a costly and time-consuming method.

Five (5.6%) medical experts did not agree with human cadavers being used for training doctors. The vast majority (71.9%) had no reservations. Some were concerned about legal and ethical issues. The majority demonstrated their disbelief

as to the appropriateness of a cadaveric endovascular model. One commented that cadaver models have "*little benefits for endovascular training"* and another that the '*"feel"* of a patient "*would be quite different in a cadaver."*

Less than 25% of endovascular practitioners were aware that a cadaver could be used for endovascular skills training. None had ever used a cadaveric endovascular training model. This was reflected in the comments: *"I'm not sure how pulsatile flow will be simulated in a cadaver"* another stated, *"how will the vessels behave – will they be accessible?"* and "*I am unsure if there would be any additional benefit over simulators."*

Only 59.1% declared an interest to see an endovascular cadaver model (2.4.1.3) and just 12.1% a preference for HC versus VRS. This perhaps demonstrates consultants and trainees inexperience with fresh frozen human cadavers, which are quite different from fixed cadaveric specimens. Confirming this assumed misconception one respondent commented "*presumably these cadavers are prepared differently to those for dissection."* Another believed *"the real feeling when dealing with living vessels in which blood flowing must be so different than hard vascular wall in cadavers."* Cadavers are *"smelly",* and a virtual reality model *"cleaner"* and *"re-usable"* said another.

In contrast, all consultants and trainees were aware of the use of virtual reality endovascular simulation, and 80.9% had first hand experience. Despite their preference over HC a number of medical experts did declare their distaste for VRS*, "I have never seen a simulator of any use"*, *"vessels in simulators do not behave appropriately"*. One consultant drew a measured conclusion believing that *"both (models) have advantages and disadvantages for different skills training. A combination of both would be best."*

One hundred and seven patients completed the endovascular training questionnaire. Patients are in agreement with doctors training on HC and real patients, with stronger agreement in HC training (p=0.000). Patients appreciate the need for additional HC training, *"how else can medical knowledge progress?", "If it*

isn't done on the dead, how can students get it right for the living?" and the importance this training has on patient safety: *"everything should be done to help the sick".*

Patients appreciate the importance of simulation training, commenting that if it is *"beneficial for the doctor",* who gains *"more confidence"* then this is *"better for the patient".* Indeed patients agreed that they would have confidence undergoing an endovascular procedure by a doctor who had been trained on VRS or HC (2.4.2.8.4). However, there is some apprehension regarding VRS, one patient commented that *"computers are not fool proof",* another questioned their realism: *"depends on quality of computer simulation".*

Overall patients declared greater confidence undergoing an endovascular procedure by a doctor who has been trained on HC compared to VRS (p=0.000). This perhaps highlights a potential mistrust of computer technology in this relatively elderly cohort (Table 14), who have a more traditional view of medical training: *"you cant beat the real thing", "a computer cannot simulate every eventuality"*.
Fifty-seven patients (53%) were considered 'non-vascular' (2.4.2). The purpose of this distinction was to eliminate any associated bias of patients who may directly benefit from a vascular doctor's training. Yet no differences were observed when the responses from 'vascular' and 'non-vascular patients' were analysed (2.4.2.8.2, 2.4.2.8.5, 2.4.2.8.8).

It was noted that forty-seven (82.5%) 'non-vascular' responders had a friend or relative with vascular disease, leaving just eleven responses from 'true non-vascular' patients. When these responses were further scrutinized no differences were observed (2.4.2.8.11), although these numbers are small. To increase 'true non-vascular' responses the opinion of the general public could be sought, targeting people who declared no personal history of vascular disease, or have any friends or family with vascular disease. Although it may prove difficult to gain local research ethical approval.

It was postulated, that a patients agreement with organ donation and cadaveric research might affect their agreement with endovascular simulation training. Patients who agreed with organ donation (n=89) agreed more strongly that doctors should be allowed to practise on HC and they also felt comparatively “more confident” in doctors trained on a HC and VRS, when compared to those responders who did not agree with organ donation (n=18) (2.4.2.8.10). Patients who agreed with donation of humans for medical research (n=76) had a stronger acceptance and confidence in doctors trained in both HC and VRS (Graphs 27b). However no further significant differences in patient opinion were found when results were stratified according to patients’ organ donor agreement status (2.6.2.8.10).

2.9 Conclusion

This study is the first reported opinions of vascular professionals and patients regarding the rapidly expanding field of endovascular simulation training. They form an important insight into the minds of both the endovascular practitioners on the front line and their patients.

Endovascular professionals, both consultant and trainees, have great reservation as to the suitability, appropriateness and feasibility of a cadaveric endovascular training model. Indeed one medical expert felt the whole thing was simply “*distasteful”.* Most felt VRS offers a clean, reproducible, standardised method of skills training, and could *“see no benefit to using cadavers.”*

However, none of these medical expert respondents had ever practiced on a cadaver model, and in fact few had even heard of the concept. Some suggested dissatisfaction with virtual reality, and despite their scepticism, and ignorance, there were those who could see the potential benefit of the enhanced haptics, the superior anatomy, and the opportunity to train on a truly life like model.

It is clear that a cadaveric endovascular training model will have to overcome the doubters if it is to offer credible endovascular skills training to the practitioners of the future.

Concerning patients, there is overall trust and appreciation in the need for clinical simulation training. Patients demonstrate an understanding of the advantages and disadvantages of simulation, but seem to have relative mistrust in computer technology, when compared to a HC model. In a clinical climate of enhanced patient autonomy and apparent acceptance of doctors current training strategies, *"I thought this was already standard practice"*, it would seem appropriate to focus attention on greater public education in simulation training to ensure patient's confidence and trust is maintained.

Chapter 3

Design of a Pulsatile Human Cadaver Circulation Model

Chapter 3

3.0 Design of a pulsatile human cadaver circulation model

3.1 Pulsatile human cadavers

As previously reviewed (1.5.4) human cadavers are used extensively for training in a number of surgical and medical specialties. The suitability of fresh frozen cadavers for training open vascular surgical procedures has been recognised (Reed et al 2009). However their use for endovascular purposes has been less studied. Garrett (2001) described a technique for human cadaveric circulation (1.5.4) and how isolated pulsatile segments could be created including aorto-femoral, ilio-distal and carotid. Their use seems to have been more popular for stent graft development (Linsen et al 2007, Arbateli et al 2009, Jongkind et al 2010), rather than technical skills training. There is no literature to date on the suitability or feasibility of using pulsatile cadavers for training purposes.

The establishment of both a reliable and valid model for endovascular training requires flow through the vasculature of the vessels of a human cadaver, allowing clinicians access to these vessels in a realistic manner. Cadaveric preparation technique, infusate flow rate, pressure, viscosity and temperature are parameters that will potentially affect the realism of the model.

This chapter will describe how a suitable model for training was developed.

3.2 Fresh frozen human cadavers

3.2.1 The Newcastle Surgical Training Centre (NSTC)

Since the 2004 Human Tissue Act, a number of cadaveric training centres have been established in the UK running training courses for doctors.
The Newcastle Surgical Training Centre at the Freeman Hospital (NSTC) was the first hospital based anatomical examination training centre of its kind to hold a formal licence from the Human Tissue Authority (HTA) under the licence held by Newcastle University and offer advanced surgical training using cadaveric human tissue. The NSTC offers training in a host of surgical and medical disciplines including orthopaedics, gynaecology, anaesthetics, ear nose and throat, urology, breast surgery, trauma and general surgery.

3.2.2 Acquisition, storage and disposal NSTC Donors

Bequests of donor bodies after death to Newcastle University are used either for anatomical examination to teach anatomy to medical and dental students and other health care professionals at Newcastle University or for surgical training, education and/or research purposes at Newcastle Surgical Training Unit at Freeman Hospital.

Upon arrival at the NSTC the donors are body mapped to attain if any pre-mortem surgical procedures have been carried out. This will include any pre-existing vascular disease, or previous surgical or endovascular intervention. The donors are then allocated to potential appropriate courses and research projects. After the body map has taken place the donors are stored between -17°C & -20°C until the necessary body donation paperwork is complete. The HTA regulatory ruling is that donors can be kept for up to three years.

For surgical training courses the thawed and then stored at 3-5°C and monitored as to deterioration post thaw. From when the donor arrives with the Surgical Training Centre until the times arises to release them for cremation they are cared for by Senior Surgical & Mortuary technicians.

After all surgical training procedures have been carried out the process for body disposal and cremation is followed. All surgical wounds are sutured closed and any body parts that have been surgically removed are returned to the body.

3.3 The Flow Rig

Setting up a successful pulsatile human cadaver model requires a number of constituent parts to create the flowing circuit.

3.3.1 The Pulsatile Pump

In order to generate pulsatile flow within the vascular circuit a pulsatile syringe pump (Pulsatile Blood Pump 1405, Harvard Apparatus™) (figure 3) was used. This pump was used for all of the pulsatile cadaver experiments. The pump is capable of allowing adjustment of mean flow rate through altering both pump frequency (from 0 – 100 RPM), and stroke volume (15 – 100 cc/stroke), it can therefore reproduce normal human cardiac output.

Figure 3. The Pulsatile Blood Pump

3.3.2 The Tubing

Tubing in the circuit had to be large enough to carry a sufficient volume of fluid, and rigid enough not to kink under the suction pressure of the pulsatile pump. It was noted that reinforced tubing was radio-opaque, and therefore unsuitable for use when the tubing accessed or crossed the area of radiographic interest.

3.3.2.1 Experiment 1

In the preliminary experiment where tubing was brought into the cadaver (and therefore into the area of radiographic interest) inter-connections were used to non-reinforced (radio-lucent) tubing in sections that entered the radiographic field. Therefore a combination of 5/8" diameter unenforced and reinforced tubing was used to create the circuit.

3.3.2.2 All Subsequent Experiments

When the technique for perfusion was altered from experiment 1, reinforced 5/8" diameter tubing (Cory Bros Ltd) was used for both the inflow and outflow. This tubing was secured to the inflow and outflow pipe of the pump using metallic jubilee clips to prevent leakage at the tubing connections. Although leakage was not a problem at low flow rates, and low pressure, if higher flow was required, the jubilee clips prevented excessive leakage.

3.3.3 The Reservoir

The reservoir was adapted from a water storage vat, capable of holding 10 litres. (Figure 4)

Figure 4. The Pulsatile Pump & Reservoir

3.3.4 Cannula

Cannulas are required for both inflow and outflow in the model. Inflow cannulas needed to be large enough so as not to impede fluid inflow, and likewise, outflow cannulas needed to be large enough to allow thrombus and debris from the blood vessels to wash out during the initial flushing process.

3.3.4.1 Experiment 1

In this experiment inflow was taken directly into the root of the aorta and did not require a cannula (see 2.4.4.1). Outflow was taken from both left and right superficial femoral arteries, in straight 21Ch aortic perfusion cannula (manufactured by Tyco Healthcare™). Owing to high pressures, these cannulas were secured using standard plastic cable ties

3.3.4.2 All Subsequent Experiments

Both carotid and femoral vessels were assessed on a case-by-case basis and the largest feasible cannulas were inserted. Most commonly this involved a 21Ch inflow cannula in the right common carotid artery and two 18Ch outflow cannulas in the common femoral arteries. These cannulas were secured with 2-0 vicryl ties distal to the cannulas ridged end.

3.3.5 Perfusate

The viscosity of the fluid perfusing the pulsatile human cadaver model will affect flow rates, pressure, oedema and potentially the feel of endovascular equipment inside the vessels.

A fluid's viscosity can be calculated by considering laminar flow where two parallel layers of fluid slip against each other. (Pinnock et al 2003) This produces a 'shear stress' force between the layers of the fluid and a velocity gradient, which is at right angles to the direction of flow, the so-called 'shear rate'.

$$\textbf{Viscosity } (\eta) \textbf{ (Pa.s.)} = \frac{\text{Shear stress}}{\text{Shear rate}}$$

Viscosity is measured in pascals per second (Pa s) but is more commonly calculated in dyne second per square centimeter (dyne s/cm^2), or poise (P). Ten poise equal one pascal per second (Pa s) (Elert, 2011).

Blood was not used for our cadaver flow model because of the logistics of acquiring and storing out of date blood and the health, safety and ethical issues concerned with its use. A synthetic perfusate with the viscosity like blood was therefore required.

A Newtonian fluid is one in which the viscosity (η) remains constant despite changes in the velocity gradients during its flow, for example water. Blood is a non-Newtonian fluid because its viscosity falls as the shear rate between layers increases. At low flow rates weak bonds clump red blood cells together into aggregates known as rouleaux formations, thus increasing its viscosity. As shear rates increase these bonds are overcome and in addition red blood cells flatten in

shape, this reduces viscometric drag, thus reducing bloods viscosity. Viscometers are capable of determining bloods viscosity at varying shear rates (Pinnock et al 2003).
Blood viscosity also is influenced by protein concentration within the plasma, white cells and temperature.

At 37°C the viscosity of blood varies between 3 and 4 mPa.s (Elert, 2011). In the present study these values were achieved with a mixture of glycerol and saline. From the existing literature the changes in viscosity are known by percentage concentration of glycerol at varying temperatures (Table 35).

Table 35. Fluid viscosity at different temperatures for varying concentrations of glycerol, corrected to the value for water at 20°C of 1.002 mPa.s*

% wt glycerol	Viscosity (Pa.s)		
	20°C	**30°C**	**40°C**
100	1.408	0.610	0.283
99	1.146	0.498	0.234
98	0.936	0.408	0.195
97	0.763	0.339	0.165
96	0.622	0.280	0.142
95	0.521	0.236	0.121
80	0.0599	0.0338	0.0207
50	0.00598	0.00420	0.00309
20	0.00175	0.00135	0.00107

10	0.00131	0.00103	0.000823

*(Kaye, 1995)

Previous literature has demonstrated that, accepting 40^{o}C as the closest temperature to body's 37^{o}C, bloods viscosity (3-4mPA.s) is achieved at a 52.5% (by weight of glycerol) that equates to 51.4% by volume aqueous solution of glycerol and water (Bicknell et al 2004). For practical reasons a 50% glycerol: 50% saline solution warmed to 37°C was used in the pulsatile human cadaver model.

3.3.6 The Flow Circuit

Previous publications have described a closed loop flow-circuit (Garrett 2001, Arbatli et al 2009, Jongkind et al 2010) in which the perfusate is recycled and pumped continuously around the cadaveric model. The advantages are that there is no need to 'top-up' the fluid, and the model can run without further intervention. Most importantly, however, a closed system allows for higher pressures to be achieved within the circuit.

3.3.6.2 Measuring Pressure in the Flow Circuit

To measure the pressure within the cadaver, a standard pressure transducing circuit was set up;

A 500ml bag of saline was suspended from a drip and pressurised to 250mmHg. This was connected to the pressure transducer which in turn was connected to a 21 gauge cannula inserted proximal to the outflow cannula in the left groin. The circuit was purged of air. The pressure transducing circuit was zeroed at the level of the cadaveric right atrium whilst the pulsatile pump was running. The circuit was connected to a monitor through a pressure line, and a continuous arterial trace was generated.

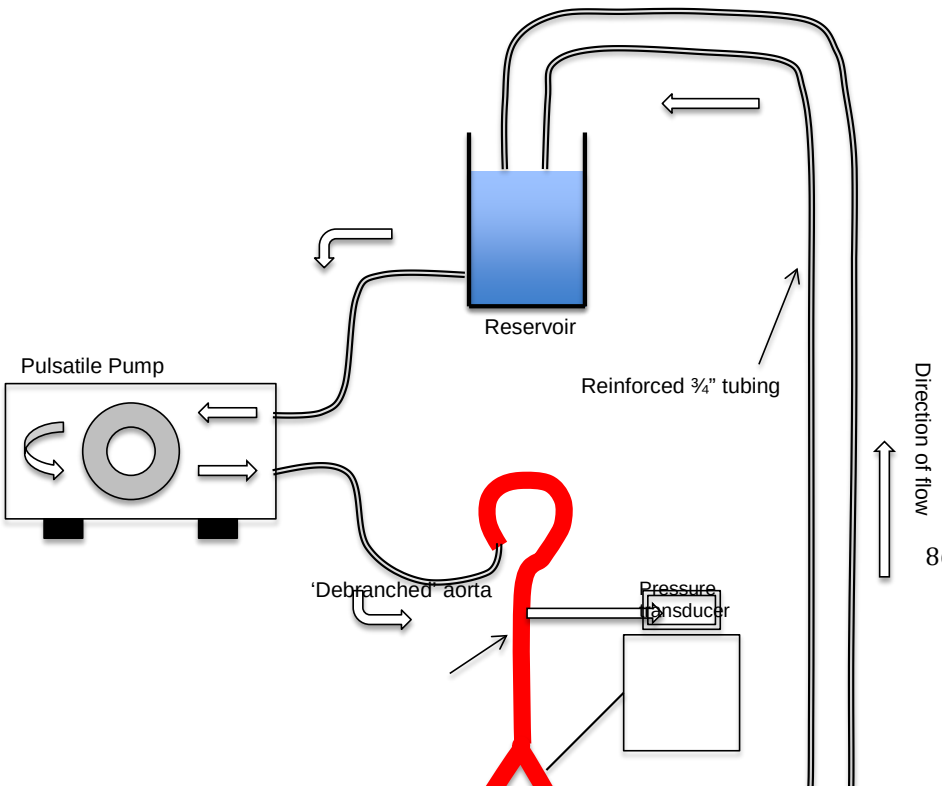
3.3.6.3 A 'Closed Circuit' Flow Loop (Experiment 1)

In this experiment, a closed circuit was created with the outflow tubing looping back into the reservoir which subsequently fed the pulsatile pump and re-entered the

cadaver through the inflow tubing. In order to reduce pressure loss through excessive tubing, the reservoir and pulsatile pump were positioned tight to the right lateral side of the operating table, connected together with the shortest length of tubing possible. Inflow tubing length was kept as short as possible. The outflow tubing was likewise kept as short as possible. The aim was to create an extra corporeal 'venous' return measuring the same distance as the corresponding distance from the cadaveric femoral vein – right atrium. It was accepted that the extra-corporeal circuit exceeded the distance of the corresponding cadaveric venous system but it was hypothesized that any loss of pressure would be more than compensated for, owing to the 'debranching' technique of the aortic surgical preparation technique.

Figure 5 shows a schematic representation of the closed loop flow circuit.

Figure 5. Schematic diagram of the closed loop flow circuit



3.3.6.4 An ‘Open Circuit” Flow In Subsequent Experiments

Despite a rigorous protocol of flushing the cadaveric vessels, residual or adherent thrombus would frequently dislodge and exit the outflow tubing, especially when endovascular procedures were being performed. Wires and catheters disturbed adherent post-mortem clot. This residual clot would subsequently enter the circuit and continue to flow around and through the model. Secondly, when training over extended periods of time (>6 hours, as was required in the validation experiments) intravenous contrast would begin to concentrate within the perfusate, until the fluid was almost completely radio-opaque. This affected the realism of the training experience. When attempts to induce physiological pressures into the system were subsequently abandoned, there was less emphasis on maintaining a ‘closed loop’. For these reasons it was agreed to establish an open circuit with a reservoir of clean perfusate preventing thrombus and contrast from re-circulating around the model (Figure 6). Tubing was run directly into outflow buckets, which were stored at the foot of the operating table (Figure 7) to prevent them impeding the radiographer.

Figure 6. Schematic diagram of the open loop flow circuit

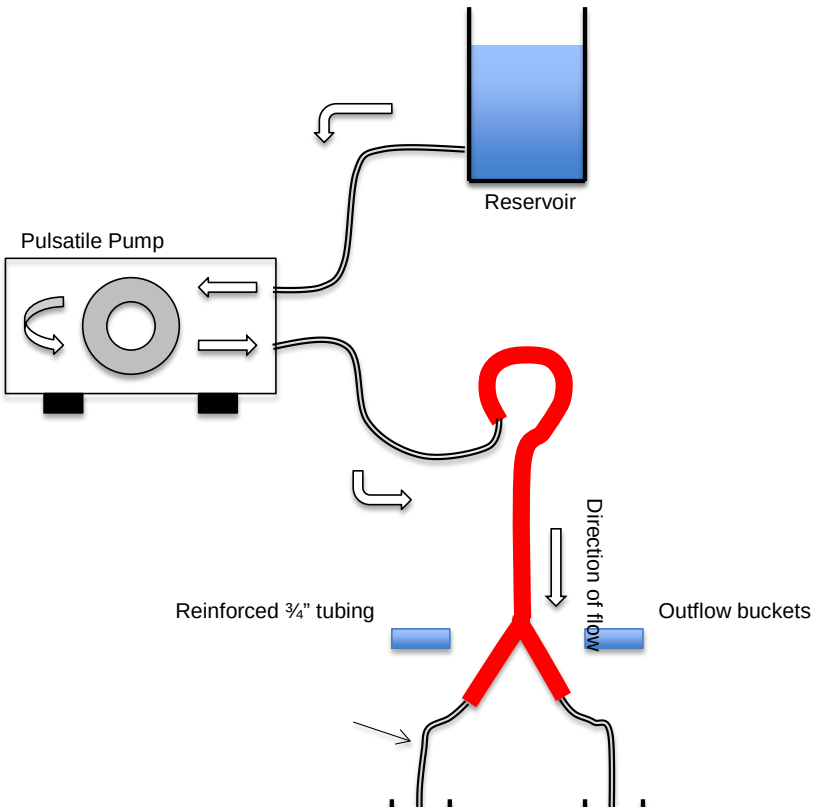


Figure 7. The outflow buckets in the 'open' flow circuit.

3.3.7 Flushing the Cadaver

Although the circulating perfusate was agreed as previously described (2.3.5). debate exists on the most appropriate fluid for initially flushing the cadaveric vessels. Garret (Garret, 2001) suggested permacol, “a commercially available solvent”, to remove post mortem clots. However, Arbatli et al (Arbatli et al, 2010) demonstrated that in fresh frozen cadavers post-mortem thrombus can be easily washed from the arterial vessels using saline alone.

Owing to the flammable nature of cleaning solvents, and their potential damage to the intima of the arterial vessels, it was decided to flush and perfuse the cadavers with saline alone.

3.4 The Initial Experiment: Experiment 1

Garrett’s report on cadaveric perfusion (Garrett 2001) did not address acquisition of physiological conditions such as normal human blood pressure. This generated concern that a minimally invasive approach to cadaveric perfusion would produce an inferior model for training. Subsequently Jongkind et al (Jongkind et al 2010) reported maintaining blood pressures of 120/80mmHg in three successive pulsatile cadaveric models, in their trial involving videoscopic approach to the thoracic aorta for aortic endograft delivery. After contacting the authors it was established that their technique for cadaveric perfusion was modified from Garrett’s original report (Garret, 2001). They also used formalin-prepared cadavers.

The present study centered around attempting to establish antegrade pulsatile flow through the cadaveric arterial vasculature with a normal human blood pressure using a similar method to Jongkind et al (Jongkind et al 2010). The principle area of interest was the abdominal aorta.

3.4.1 Cadaveric Preparation

The principle behind preparation was to create an isolated human vascular circuit within only the vessels of interest. This would reduce the loss of pressure from fluid entering unnecessary vessels/capillary beds. Advice was sought from the authors

of Jongkind et al (2010) who provided advice on an open technique of debranching the aorta in order to achieve normal human physiology, this was therefore adopted as the initial method of cadaveric preparation. In fact one of the team flew to Newcastle to oversee our initial experiment.

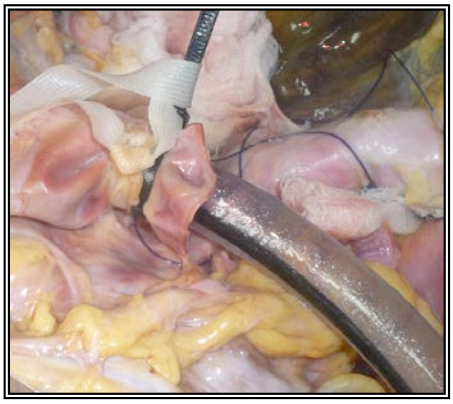
A fresh frozen human cadaver (female) was draped exposing groins, abdomen and chest. The thorax was opened through a midline sternotomy using an electric saw. This incision was extended down into a midline laparotomy wound. Vertical incisions were also made in both groins.

3.4.1.1 The Chest

The heart was removed transecting the aorta at the root, the inferior and superior vena cava close to the heart and dividing the pulmonary artery and vein close to their insertion and exit from the heart respectively. The left lung was also removed, dividing all vessels at the hilum to facilitate access to the thoracic aorta. The right and left subclavian arteries were isolated and transfixed using a 2-0 vicryl transfixion suture. The left common carotid was identified high in the carotid sheath and transfixed. The right common carotid was also isolated in the carotid sheath, divided and cannulated with a 21Ch straight aortic perfusion cannula, secured with a plastic cable tie. Every minor vessel arising from the aorta in the chest was systematically identified, isolated and tied using a combination of 3-0 vicryl hand ties and a ligaclips (Ethicon™), thus 'debranching' the aorta in the chest.

The reinforced tubing bringing the inflow was brought percutaneously through the right anterior chest wall and directly into the aortic root. Nylon ties and ribbon proved ineffective at securing the tubing in place owing to the high pressures when the model was flowing, and a standard plastic cable tie was adapted instead (Figure 8)

Figure 8. Reinforced ¾" tubing bringing inflow directly into the aortic root (Secured with nylon and cable ties)

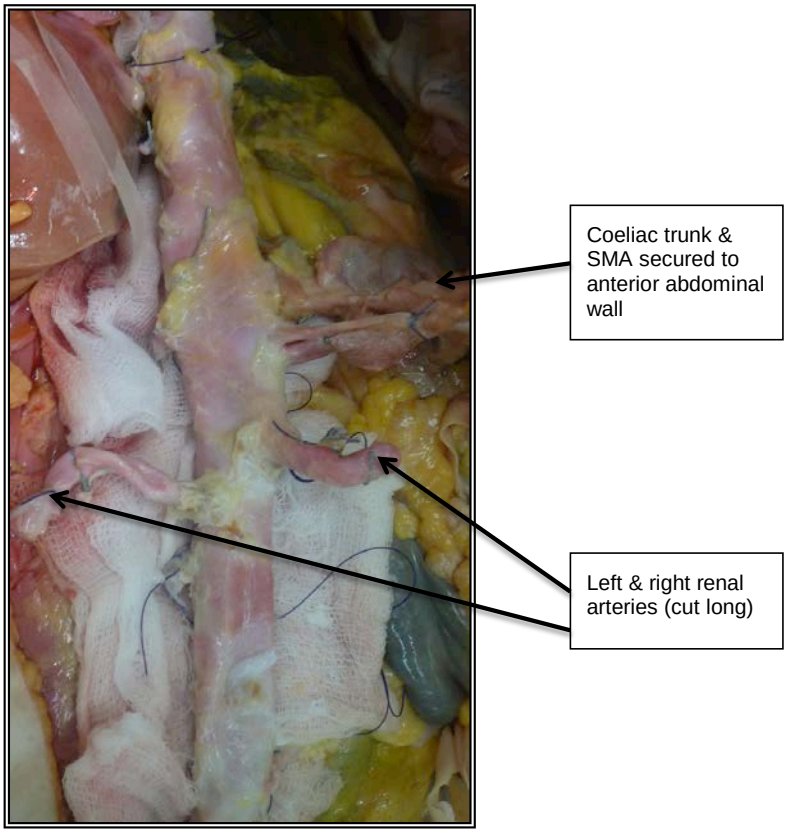


3.4.1.2 The Abdomen

The process of 'debranching' the aorta continued in the abdomen through careful dissection, identification and isolation of vessels arising from the abdominal aorta. Longer sections (>50mm) of the coeliac trunk, superior mesenteric artery (SMA) and inferior mesenteric artery (IMA) were isolated before being transfixed (Figure 9). Diaphragmatic, adrenal, gonadal and lumbar branches were all tied/clipped close to the aorta.

The left and right renal arteries were tied off just before their insertion into the renal parenchyma to preserve the longest possible segment of artery (Figure 9). Internal iliac arteries were identified and transfixed with 2-0 vicryl leaving the longest lengths feasible.

Figure 9. Debranched abdominal aorta



3.4.1.2.1 The Renal Arteries

To facilitate flow through the renal arteries, two standard Foley catheters were used. The balloon ends were cut and brought percutaneously through the lateral anterior abdominal wall. The open catheter ends were inserted, and secured (using 2-0 vicryl ties) into the renal arteries to create a passage for outflow (Figure 10). The catheters were secured to a standard catheter drainage bag, (with the bag cut from the end) and the tubing was allowed to drain directly into the outflow buckets positioned at the foot of the bed.

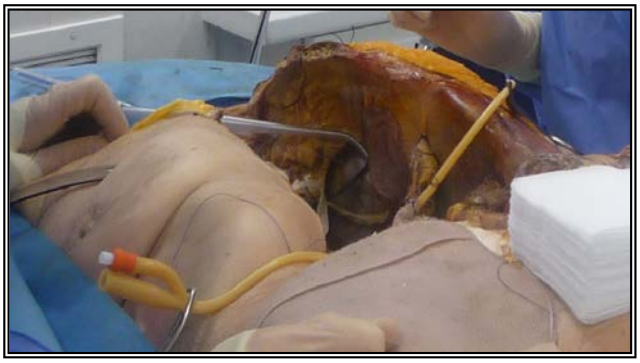


Figure 10. The Foleys catheters secured into the cut ends of the renal arteries. The inflow tubing can also be seen percutaneously entering the chest cavity.

3.4.1.3 The Groins

Through two standard vertical groin incisions, the femoral arteries were isolated from the inguinal ligament to the superficial femoral artery (SFA), with all branches either suture ligated or occluded with ligaclips. The profunda femoris was identified and tied off using 1-0 vicryl ties. The SFA were divided approximately 100mm distal to the profunda and divided. Two 21Ch straight aortic perfusion cannula were secured into the SFA's on both sides using both vicryl ties and reinforced later with plastic cable ties (Figure 11). ¾" non-reinforced tubing was used to carry the perfusate from the cadaver model. In the early experiments the outflow was diverted into the reservoir, creating a closed circuit (3.3.6.1).

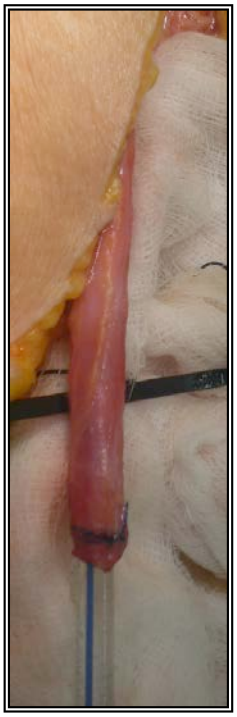


Figure 11. The outflow cannula secured in the transected left common femoral artery

3.4.1.4 Closure

The heart and the left lung were placed back into the thorax. The thoracic cavity was closed using interrupted silk ties. The left neck incision was closed using 2-0 un-dyed vicryl. The incision in the right side of the neck (containing the access cannula) was left open. In the abdomen, the coeliac trunk, SFA and IMA were ligated to the anterior abdominal wall to secure them into their correct orientation. The renal arteries were secured to the lateral side of the abdominal wall, again to restore them back to their correct anatomical orientation. The abdominal cavity was closed with a mass closure technique using loop 0-PDS. The groins were left open for the duration of the experiment.

3.4.2 Perfusing the Cadaver

A Robert's clamp was used to occlude the cannula in the right common carotid artery during the initial perfusion phase.

3.4.2.1 Flushing the Cadaver

Once the model was fully prepared the reservoir was filled with 10 litres of normal saline (as previously described in 3.3.7), the pulsatile pump was set to a stroke volume of 20cc per stroke, and a rate of 20RPM, and a %systole/%diastole output phase ratio of 35/65. Rates and volumes were kept low to begin with, to allow one to check all connections and observe for obvious leakage. After the first litre has passed through the cadaver the remaining 9 litres can be perfused at a higher rate and stroke volume (50cc/stroke, 50 RPM).

3.4.2.2 Subsequent Perfusion of the Working Model

As described above (2.3.5), a 50:50 mix of saline and glycerol was used as the final perfusate during experiments. After flushing, the reservoir was filled. The pulsatile pump settings were set to a stroke rate of 70cc per stroke, and a pump rate of 60 RPM. The %systole/%diastole output phase ratio of 35/65 was maintained throughout the experiment.

3.4.3 Investigator's Feedback From The Initial Experiment

Experiment 1 was the first attempt to establish a pulsatile human cadaveric endovascular training model. To our knowledge it is the first attempt to create such a model for training purposes outside of the US. Garret's (Garret, 2001) study remains the only report describing the use of pulsatile perfused cadavers for training. The report was brief, images and details at times limited and no objective or even subjective information was made describing the effectiveness of the model as an adjunct for training.

3.4.3.1 Atherosclerosis

Despite a rigorous screening process to exclude cadavers with severe atherosclerosis, the cadaver in experiment 1 had significant peripheral vascular disease. In particular the left common iliac was occluded impairing outflow. Open left common iliac endartarectomy was performed, the distal intima was tacked with interrupted 6-0 prolene, and the arteriotomy was closed with a continuous 5-0 prolene suture.

3.4.3.2 Leakage from the Model

Systematically isolating every branch from aortic root to superficial femoral artery was a time consuming task, taking a single operator almost 10 hours to complete. It proved challenging to identify every branch, especially posterior lumbar and thoracic vessels. Iatrogenic transection of even the smallest branches may initially go unnoticed, but in this attempt to generate human blood pressure, these vessels caused significant leakage from the system when the pulsatile pump perfused at high pressures. In addition the suture line along the endartarectomy arteriotomy wound leaked persistently, further hampering attempts to increase pressure within the closed circuit.

3.4.3.1.3 Control of Leakage.

During the early phase of the perfusion it became apparent that the aorta was leaking from multiple sites. The torso and abdominal cavities were re-opened, and whilst the pump was still running sites/vessels leaking were identified. Vessels with >5mm of length could either be controlled with a heamostat and 3-0 vicryl tie, or ligaclips. Vessels <5mm in length were over sewn with a 6-0 prolene suture, however, due to the non-coagulant nature of the perfusate, leakage continued around the suture. A combination of human tissue glue, and silicone-based sealants were adapted for persistent leaks, with varying grades of success. The tissue glue was noted to make the aortic wall rigid, which detracted from the advantages of a “fresh” aorta. The site of the attempted endartarectomy was a particular problem due to the long suture line. Again, glues and sealants were applied with limited success.

3.4.3.4 Blood Pressure in a Closed Circuit Pulsatile Cadaver

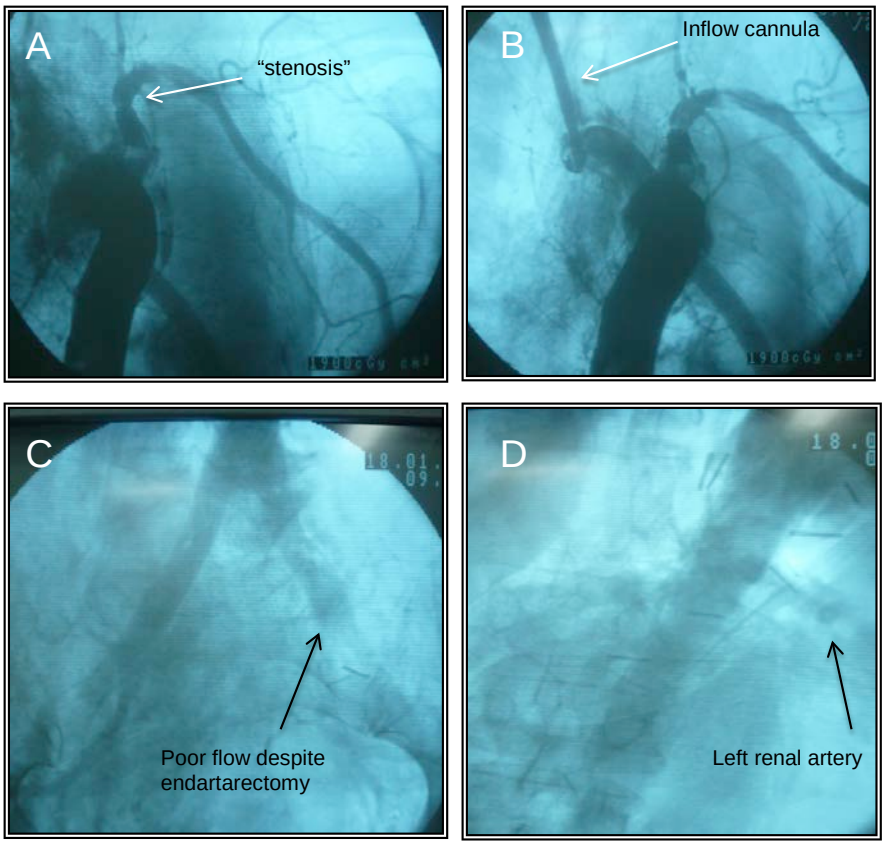
Due to persistent leakage from the model, the highest blood pressure achieved was 40mmHg systolic, but this was not sustainable. Further attempts to improve this pressure were abandoned due to worsening leakage when the pulsatile pump pressure was increased.

3.4.3.5 Early Angiographic Images

The cannula secured in the right common carotid artery was used for access and injection of radiopaque contrast. Images were achieved of the aortic arch demonstrating the aortic arch vessels, abdominal aorta and the iliac bifurcation (Figure 12).

The angiographic images in the abdomen, especially the renal arteries were disappointing. Interestingly, the flow that escaped beyond the hand tie in the left subclavian artery and its branches gave some indication of the finer anatomy that was demonstrable had a ‘debranching’ technique not been followed (this formed part of the reason behind changing the preparation technique (3.5) in subsequent experiments).

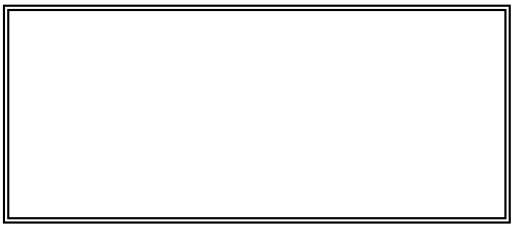
Figure 12 A: Aortic arch demonstrating flow beyond the hand tie, inducing stenosis in the cadaveric left subclavian artery. **B:** Aortic arch with contrast visible in the inflow cannula in the right common carotid. **C:** Cadaveric iliacs, poor flow is seen in the left common iliac artery (CIA) despite formal endartarectomy. **D:** Abdominal aorta with contrast seen in the left renal artery



3.4.3.6 Inclusion of Arterial Pathology – An Abdominal Aortic Aneurysm

In experiment 1 an attempt was made to introduce an abdominal aortic aneurysm into the model. The pulsatile pump was switched off. A longitudinal arteriotomy was made 20mm distal to the renal arteries, and extended to 20mm from the iliac bifurcation. An ellipse was created using Pott's scissors. Waterproof nylon material (from a standard umbrella!) was cut using a template (Figure 13 A.), which was deliberately larger than the arterial defect. Single 4-0 prolene sutures were placed at points 1, 2 and 3 (Figure 13 B.). This was to encourage the material to fill and form a saccular shape when the model was perfused. The nylon was sutured into the elliptical defect on the aorta using a continuous 4-0 prolene suture using a standard patch anigioplasty technique.

Figure 13: Template for aortic aneurysm.



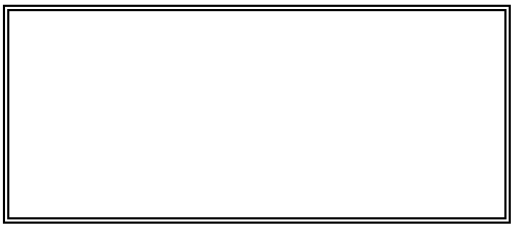
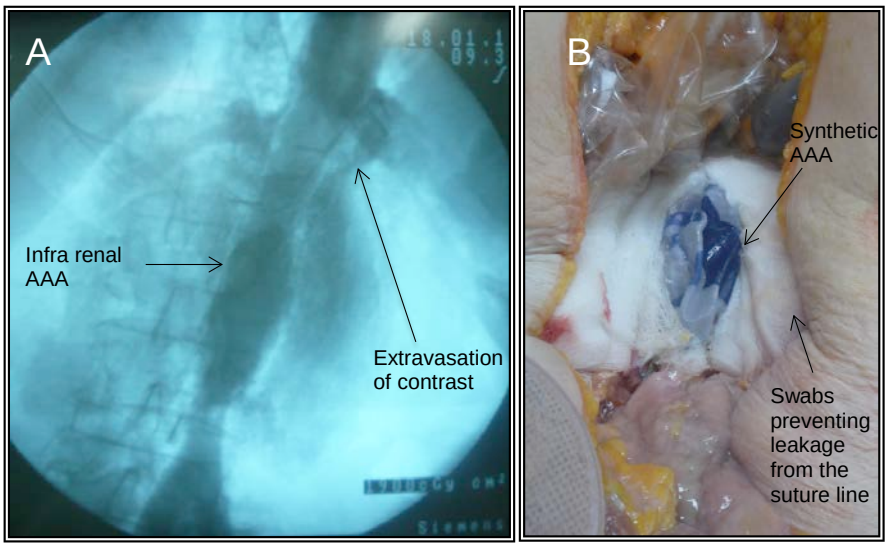


Figure 14 A: Angiographic image of the synthetic AAA in situ. **B:** Swabs surrounding the nylon aneurysm to prevent leakage from the suture line



Significant leakage was noted around the continuous suture line due to the non-coagulant properties of the perfusate. In an attempt to stem this leakage tissue glue and silicone based sealants were used with limited success. In the end swabs soaked in tissue glue were used to act as a barrier to the perfusate (Figure 14 B). This allowed angiographic images of the AAA in situ to be taken within the pulsatile cadaver flow model (Figure 14 A). However extravasation of contrast can be seen indicating further leakage from the model.

3.4.4 Investigators Conclusion's: Experiment 1

An open 'debranching' technique to create a model with physiological blood pressure proved time consuming, and fraught with complications. The invasive nature of the preparation technique, and disturbance of the natural anatomy caused persistent leakage of perfusate. Unlike patients, cadavers will continue to leak from even the smallest perforations (even those made from a 6-0 prolene suture), and this leakage proved undesirable.

A closed circuit allows contrast to concentrate in the perfuaste, and thrombus to circulate through the model. Due to leakage, it was not possible to demonstrate a significant advantage in terms of higher blood pressure.

Attempts to induce a AAA into the model were achieved with limited success but the main complication encountered was leakage. The amount of glues and sealants required rendered the aorta quite rigid, which detracts from the 'fresh frozen' nature of the model.

It was also noted that perfusate temperature has little impact upon the leakage from the model.

3.5 Subsequent Experiments: Perfection of the Fresh Frozen Human Cadaver Pulsatile Endovascular Training Model

Over the course of eight further experiments, the pulsatile human cadaver model was adjusted to produce a more suitable endovascular training adjunct.

3.5.1 A Minimal Approach to Cadaveric Preparation

One of the commonest complications noted in experiment 1 was the effect of iatrogenic injury on the effectiveness of the model. An extensive open preparation technique, in a cadaver where arterial branches are non-pulsatile, makes the process of 'debranching' difficult. Therefore a more minimally invasive approach was attempted. Ligaclips were avoided as they are radio-opaque and can impair the fluoroscopic image.

3.5.1.1 Inflow

Through careful neck dissection, the right common carotid artery was exposed in the carotid sheath. The anterior facial vein is ligated as in a standard carotid endartarectomy approach. A straight 5mm arteriotomy was made on the carotid artery and over a guidewire, a 21Ch straight aortic perfusion cannula was inserted. It was secured using a single vicryl suture placed distal to the cannulas ridged end. (Figure 15)

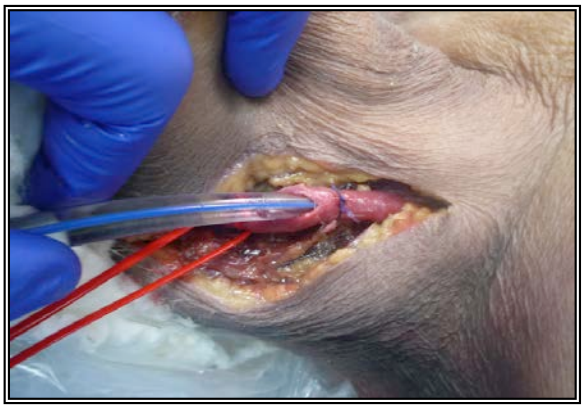


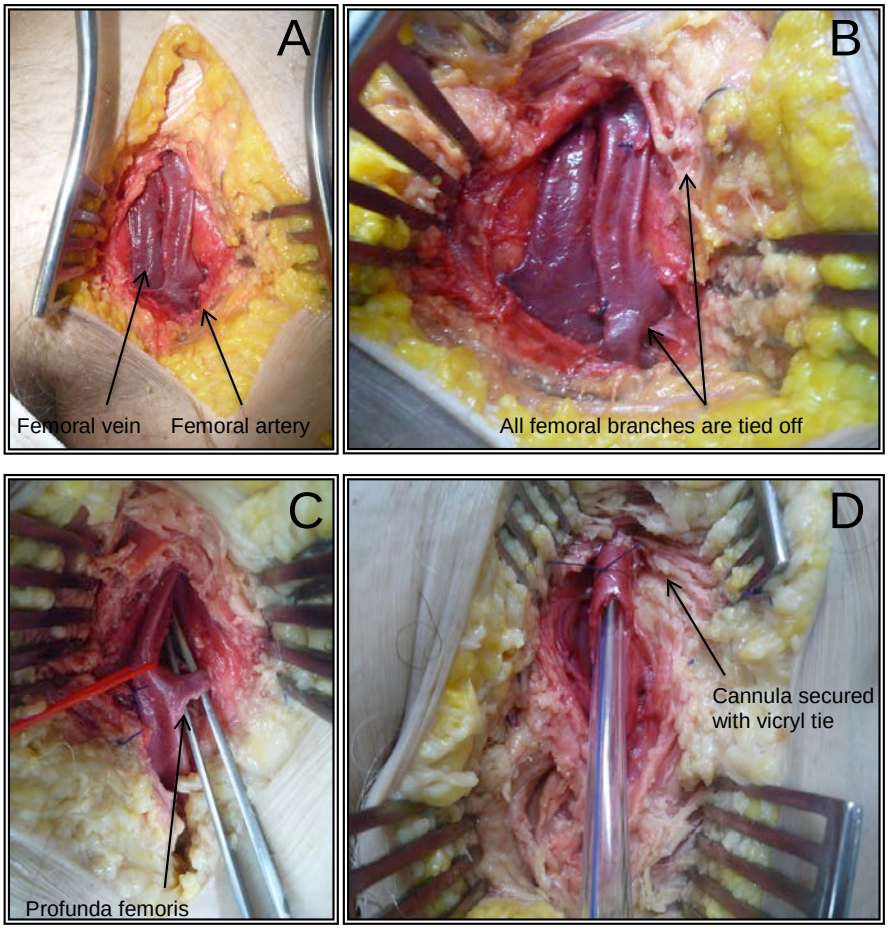
Figure 15. Inflow into the right common carotid artery

To prevent the cannula becoming dislodged during training on the model, which sometimes involved moving the cadaver to facilitate certain fluoroscopic images, the distal end was fed percutaneously through the cadaver's skin above the neck dissection wound, and it was secured to the skin (rather like a surgical drain) using a silk suture. The cannula was finally connected to the outflow of the pulsatile pump using reinforced ¾" tubing.

3.5.1.2 Outflow

Outflow was taken in two 18Ch (or 21Ch, if the arteries were large enough) placed in the groins. In the left groin, dissection was performed through a vertical incision exposing the femoral artery 20mm above and below the profunda femoris (Figure 16 A). All branches from the femoral in the groin were ligated to prevent traumatic transection when manipulating the cannula into the artery (Figure 16 B) The profunda was occluded with an 0-vicryl tie (Figure 16 C). A straight 5mm arteriotomy was made in the SFA, and the cannula was inserted and secured as described in 2.5.1.1 (Figure 16 D).

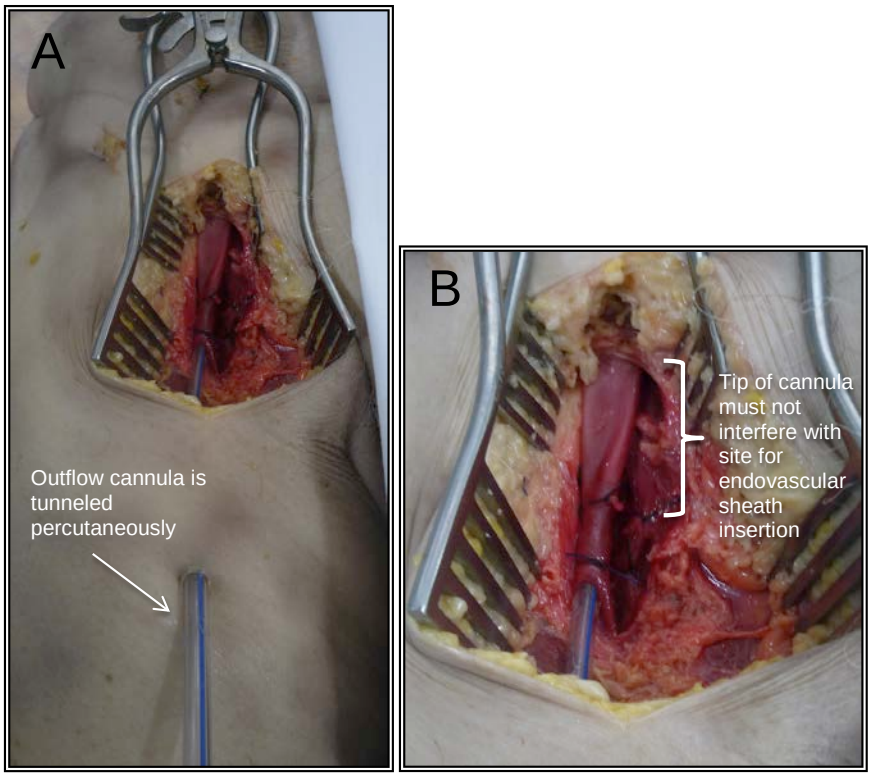
Figure 16 A-D: Preparation of the left groin



In the right groin, exposure was slightly more extensive exposing from inguinal ligament to the SFA. The profunda femoris was tied off, and the outflow cannula was secured in the SFA. It was necessary to insert the right groin outflow cannula more distal than the left, because an endovascular sheath also had to be inserted and must not be obstructed by the outflow cannula (Figure 17 A). As in 3.5.1.1 Cannulas were inserted over a guidewire, and then fed percutaneously through the skin distal to the groin dissection wound, before being suture secured with silk to prevent them becoming dislodged (Figure 17 B). The distal section of the right

groin wound was closed using 3-0 undyed vicryl, to hide the outflow cannula from sight. This was to facilitate a greater sense of realism when candidates were operating through the endovascular sheath, which was subsequently secured into the right groin (3.5.1.3).

Figure 17 A,B: Preparation of the right groin



Both outflow cannulas were attached to ¾" reinforced tubing and run into two collection buckets placed beneath the drapes at the foot of the bed (see Figure 7).

3.5.1.3 Endovascular Access

Endovascular access could be secured at any arterial site in the cadaver (femoral, radial, brachial, axillary etc). The main bulk of the training experiments involved the abdominal aorta, and therefore femoral access was opted for. Attempts to allow candidates the ability to access the femoral artery percutaneously were unsuccessful due to the lack of significant blood pressure achievable in the femoral artery. Therefore a 7Fr endovascular sheath was secured into common femoral artery in the right groin via an open 'cut-down' technique (Figure 18). Suturing the distal wound and draping meant candidates only saw the endovascular sheath visible in the right groin, in a very realistic recreation of real patients femoral access.

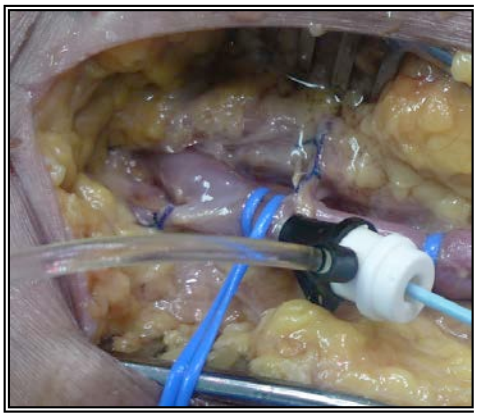


Figure 18. A 7Fr endovascular sheath in the right common femoral artery

3.5.1.4 Limited Isolation of the Pulsatile Cadaver

Areas that were not the focus of the cadavers training could be isolated using a minimally invasive technique. This both prevented oedema in the cadaver, and improved flow through the areas of interest, which improved the radiographic washout following cadaveric angiogram.

For the standard abdominal aorta endovascular training model:

(i) Cerebral Circulation

Flow was restricted into the cerebral circulation by isolating the left common carotid artery through careful neck dissection, accessing it within the carotid sheath. The left common carotid was occluded using a vessel loop pulled tight and secured to the drapes using a mosquito (Figure 19). To prevent any back flow past the right carotid inflow cannula, the right common carotid artery was ligated distal to the entry point of the inflow cannula.

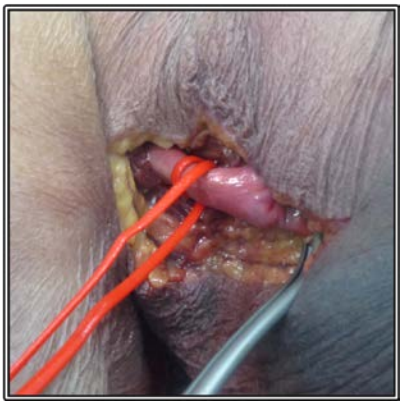
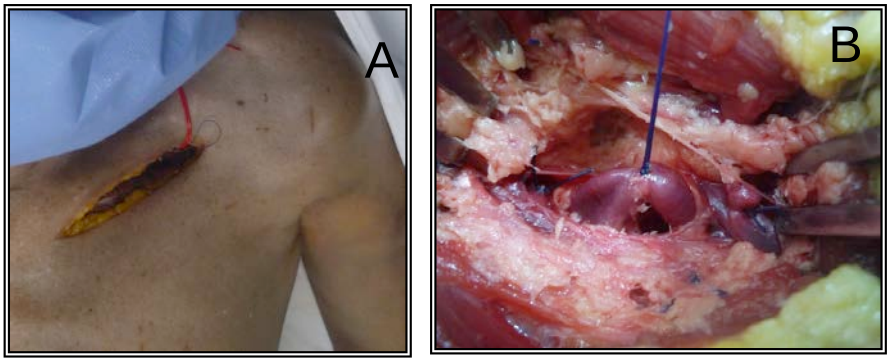


Figure 19. Left common carotid artery isolated (and later occluded) with a vessel loop

(ii) Upper limb Circulation

To prevent wasteful perfusion of the upper limbs both left and right subclavian artery were isolated through careful infra-clavicular dissection. Once isolated they were suture ligated using 2-0 vicryl ties. (Figure 20 A, B).

Figure 20 A: Subclavian artery accessed through a sub-clavicular approach
B: Left subclavian artery isolated and ligated with a 2-0 vicryl tie



(iii) Lower limb circulation

To prevent oedema in the lower limbs, right and left SFA were ligated distal to the outflow cannulas using vicryl ties.

3.5.1.5 Flushing the Cadaver

The cadaver was flushed as described in 3.4.2.1 In some cadavers, adherent/ post mortem thrombus that was evident angiographically (Figure 21), was carefully dislodged and removed using either a fogertys catheter, or for aortic thrombus, careful use of a standard aortic occlusion balloon.

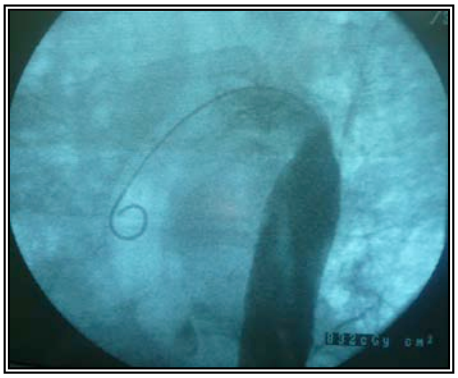


Figure 21.
Angiographic evidence of residual thrombus in the thoracic aorta

3.5.1.6 Perfusate

A 50:50 mix of glycerol and saline was used despite abandoning attempts to induce physiological pressures in the system. It was hypothesized that raising the osmotic potential of the perfusate reduced tissue oedema, especially when the model was being used for extensive periods of training (>6 hours). Anecdotally in one model perfused with saline alone extensive oedema and noted (most notably third space loss into the bowel). Although this does not detract from the training experience, it is never the less undesirable, and was less extensive with the glycerol mix perfusate.

3.5.1.7 Perfusate Temperature

The temperature of the perfusate was not controlled. It was agreed that it would have a minimal effect on the realism of the model, and may in fact precipitate cadaveric degradation. Perfusate was maintained at room temperature.

3.5.2 Perfusion

Through trial and error the study concluded that low flow, low pressure perfusion in an open circuit produced the most favourable training experience. The results from the face validity study confirmed this (Chapter 4). The relatively high flow rate and stroke volume used during the initial flushing is sufficient to 'open-up' the vasculature, and despite then switching to low flow and low pressure, it did not detract from the endovascular experience. Wires and catheters could be inserted and manipulated around the vessels despite the limited flow. Percentage systole/diastole output phase ratio was maintained at 35/65 throughout perfusion.
Table 36 details the protocol for cadaver perfusion during training.

Table 36. Cadaver Training Perfusion Protocol

Endovascular task	Pulsatile pump protocol	Pump settings	Additional comments
Intravascular guide wire and catheter manipulation	*Maintenance perfusion*	20cc/stroke. Pump rate 20 RPM	
Exchanging wires and catheters 'outside' of the body	*Oedema sparing perfusion*	20cc stroke volume. Pump rate 5 RPM	Especially in novice training, when this forms a lengthy part of the procedure
Performing an angiogram	*Angiography perfusion*	50cc per /stroke. Pump rate 50 RPM	Aim to increase 30 seconds before, and 30 seconds after contrast injection

3.5.3 Angiography

(i) Reduced Pressure Perfusion

Angiography was one area that the study identified a negative effect of the reduced pressure protocol. Following injection of contrast in a low flow system, it tended to linger producing an unrealistic lasting image (Figure 22).

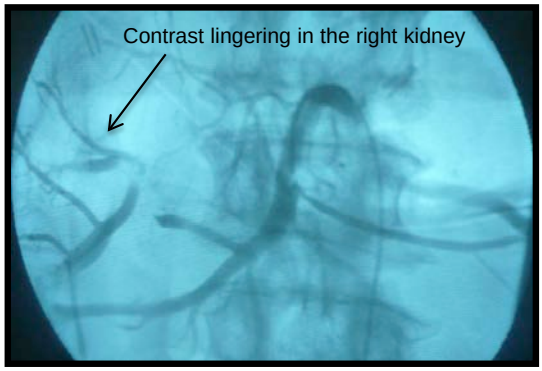


Figure 22. Selective catheterisation and angiography of the Superior mesenteric artery (SMA). Note contrast still lying within the right renal artery

To counter this complication, the flow rate was increased just before, during and for approximately 30 seconds after injection of contrast, and this produced a much more realistic angiographic image (Table 36: *angiography perfusion*)

(ii) Minimally Invasive Cadaver Preparation

Adopting a minimally invasive approach to cadaveric preparation meant that during visceral angiography, contrast would concentrate within the end viscera due to the apparent lack of end visceral outflow. The *angiogram perfusion* pump protocol (Table 36) however 'washed' the contrast from the viscera.

When the model was used for extended durations of training (> 6 hours) and the same viscera was subjected to angiography, (during the construct validity trial (Chapter 5), one cadaver was subjected to 50 left renal angiograms), there is no avoiding a degree of end visceral staining. This was felt to be an acceptable price to pay for a workable model that did not leak.

It was also felt that the protocol for the construct validity trial (with repetitive angiography of the left kidney) represented an unrealistic use of the model. A standard training day is unlikely to result in such a high number of repetitive angiograms of the same organ were it to be used for more standard training. Certainly, end organ staining was not a feature in the face validity study.

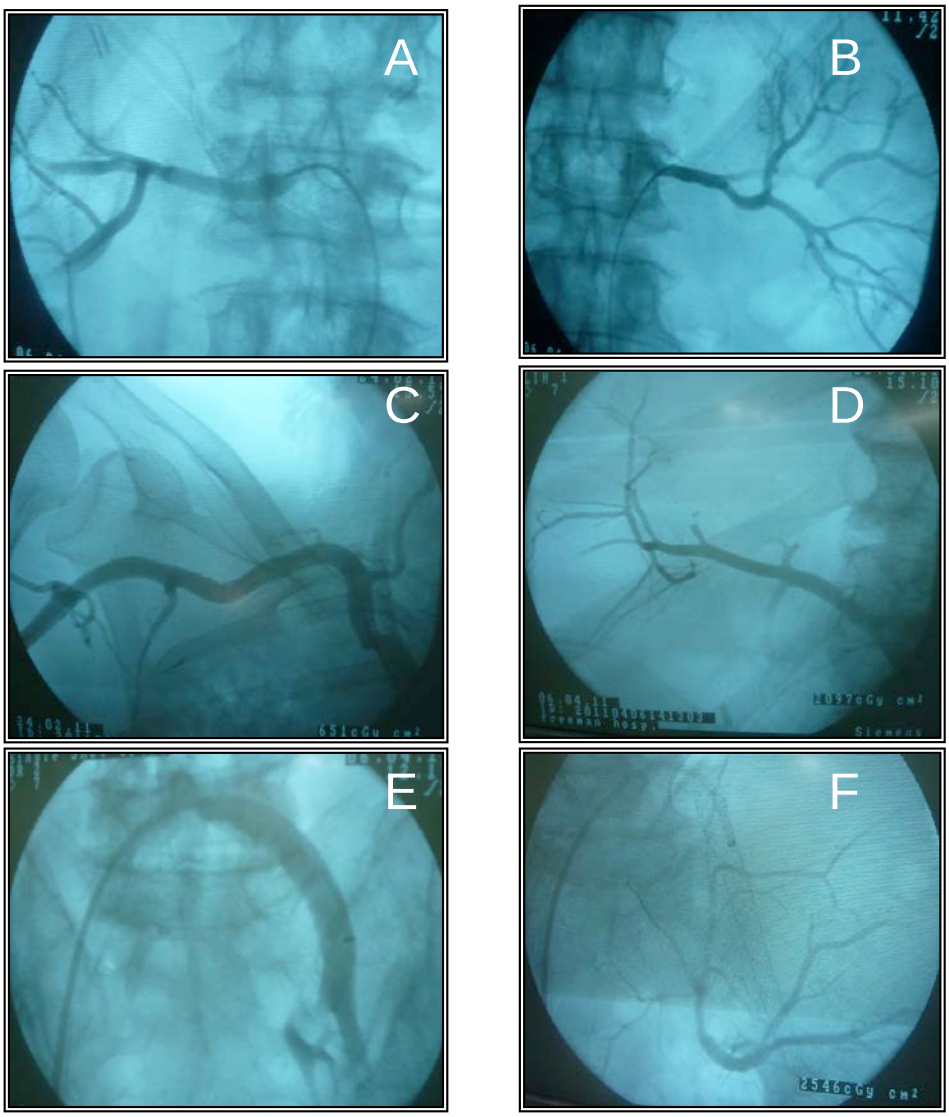
To reduce staining in the construct validity trials, contrast was diluted to 50:50 for direct renal artery injection. Also, following cannulation, and between candidate's

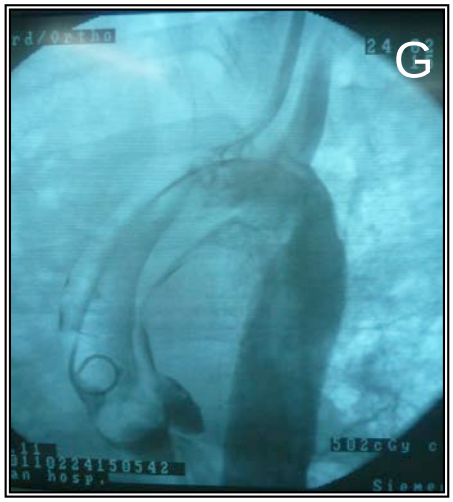
procedures, a bolus of 50ml saline was injected directly into the renal artery to further flush contrast from the kidney.

3.5.3.1 Angiographic Images

Despite these limitations, adopting a minimally invasive approach, and following a low pressure perfusion protocol produced superior angiographic images:
(Figure 23 A-H)

Figure 23 A: Right renal angiogram. **B:** Left renal angiogram. **C:** Right subclavian angiogram. **D:** Common hepatic angiogram. **E:** Left common iliac artery angiogram. **F:** Stenting of the left common iliac artery. **G:** Ascending and thoracic aortic angiogram showing the aortic valve. **H:** Angiogram of the aortic valve showing the left coronary artery.

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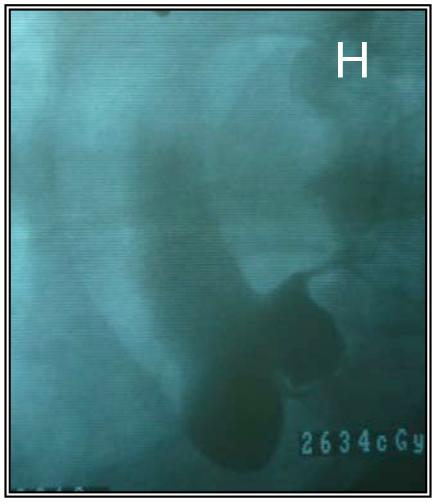
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2634cGy

3.5.5 Cost analysis

Human cadaver endovascular training is associated with several cost implications. Training on the PHCM at the NSTC for one day costs £ 4916.00

- Centre Hire (One day) £1950.00 (including instruments)
- Cost of one fresh frozen human cadaver £2500.00
- Disposables £16.00 (gloves/gowns)
- Cost of the pulsatile pump (Harvard apparatus™) £7,500
- Radiographer charges £450.00 per day

Nb The radiology C-arm was donated free of charge to the NSTC (actual cost £ £55,000)

VRS training is also associated with cost primarily in the purchase and set up of the model. To purchase and train on the VRS for one day would cost £100,650.00

- Unit cost (simbionix VRS) £100,000
- Cost of room hire at the NE Simulation Centre £650
- VRS also has ongoing service costs £10,000 per annum

The set up costs of VRS are considerably higher than PHCM training, yet it is acknowledged that the cost of subsequent and ongoing training on VRS would be cheaper (per day) than PHCM training. Also, if the costs of 'setting up' a human cadaver laboratory (like the NSTC) were considered they would be considerably higher than the purchase price of one VRS.

3.5.5 Discussion

In the cadaveric perfusion model a physiological arterial pressure would be desirable as it has implications in real life for distal embolization when positioning stents and performing angioplasty. However such pressures proved unachievable through a minimally invasive approach. Despite this, a number of distinct advantages were demonstrated through a minimally invasive preparation technique.

(i) Preparation Time

The preparation procedure was quicker. A model could be fuller prepared in just 4 hours by a single experienced operator.

(ii) Leakage

There is far less risk of iatrogenic injury, and subsequently leakage was not a significant feature following this technique.

(iii) Acceptability

The preparation procedure is far more dignified for cadaveric specimens. Our questionnaire (Chapter 2) feedback from both clinical experts and patients alike, comment on issues relating to the dignity of the use of gifted cadaveric tissue for training purposes. Avoiding direct opening of the abdominal and chest cavity, without removal of the heart or left lung, provided a far for acceptable method of preparation.

(iv) Improved angiographic images

Highly realistic angiographic detail was achieved in the minimally invasive cadavers (Figure 23). This represents a unique quality to the pulsatile human cadaver endovascular training model when compared to VRS.

(v) Cost Effectiveness

The NSTC re-use cadavers for courses in different specialties, providing specimens are of suitable quality. The minimally invasive approach meant cadavers could be utilised for several different courses following vascular

perfusion, thus allowing cadaveric costs to be shared, making the training a more feasible and cost effective option.

Conclusion

It was felt that a minimally invasive approach to cadaver preparation, and adopting a low pressure/perfusion protocol produced a highly satisfactory model capable of offering effective endovascular training. Guide wires, catheters, even peripheral stents, were trialed on these early models, all producing a highly realistic, highly satisfactory replication of real human practice.

Chapter 4

A Fresh Frozen Pulsatile Human Cadaver Model for Training Endovascular Practitioners. A Trial of Face Validity

Abstract

Aim

Determine the face validity of a pulsatile fresh frozen human cadaver model (PHCM) for training endovascular practitioners.

Methods

11 endovascular clinicians performed the same two procedures (catheterisation of the left renal artery and left subclavian artery) on PHCM, and Simbionix angiomentor virtual reality simulator (SVR). They were randomised to begin on either the PHCM or SVR. A pre-trail questionnaire determined participants' endovascular experience. After training participants rated statements relating to their experience on a numerical scale from 1 to 5, with 1 representing the strongest agreement with the statement.

Results

Compared to live patients PHCM scored significantly higher than SVR on statements regarding "realism of vascular access" (mean 2.27, (SD +/-0.75), p=0.002) "guide-wire manipulation" (1.36, (+/- 0.48), p=0.001) and "vessel catheterisation" (1.64 (+/-0.64), p=0.004). Candidates again favoured PHCM as "a valuable learning exercise" (p=0.016) and strongly favoured PHCM as a "useful training model" compared to SVR (p=0.004). No candidates "objected to training on human cadavers" (1.64 (+/-0.88)).

Conclusions

This is the first published trial in world literature to assess the validity of a PHCM for training endovascular practitioners. The PHCM demonstrates good face validity when compared to both real patients and the SVR model, and holds exciting potential.

Chapter 4

4.0 A Fresh Frozen Pulsatile Human Cadaver Model for Training Endovascular Practitioners. A Trial of Face Validity

4.1 Introduction

Following the optimization of a PHCM for training endovascular practitioners (Chapter 3), a study was designed to measure the model's face validity.

4.1.2 Face validity

The concept of face validity refers to a simple test of validity where researchers attempt to determine if the focus of the trial, whatever that may be, is achieving the designed target variable. In the context of the PHCM, the validity of the model was assessed to train endovascular practitioners effectively.

This methodology has been adopted in many trials of both laparoscopic and cadaveric training when trialists wished to gauge a simple measure of their models validity (Supe et al 2005, Reed et al 2009, Wadman et al 2010, Eisma et al 2010). The Best Evidence Medical Education (BEME) report (Issenberg et al 2005) on effective simulation training commented that face validity "provides context for understanding complex principles/tasks, increases visuo-spatial perceptual skills" and importantly, concluded that "learners prefer realism".

4.2 Aims and Hypothesis

Following the success of the early cadaver perfusion experiments (Chapter 3), it is hypothesized that the PHCM will function as a suitable and feasible model for training basic endovascular skills. Owing to its superior realism, it will be favoured by clinicians compared to SVR.

The aim of this trial was to establish if the PHCM demonstrated face validity comparing it to both real live patients, and SVR.

4.3 Methods

Practitioners who perform endovascular procedures (on live patients) on a daily basis were considered to be the best judges of the model's realism and suitability for training. In order to gain some perspective on the PHCM as a training model, a comparative training experience on a high fidelity virtual reality simulator (Simbionix ™ angiomentor), (SVR) was included in the trial's design.

4.3.1 Inclusion Criteria

- Vascular surgeons, radiology, cardiology and neurology interventionalists with any level of endovascular experience.

4.3.2 Exclusion Criteria

- Practitioners with no endovascular experience.

4.3.3 Process of Recruitment

A combination of email, and telephone invitation were made to all endovascular practitioners, both consultant, and trainees, within the Northern Deanery to attend the PHCM trial of face validity (see appendix 1). The venue was the Newcastle Surgical Training Centre (NSTC), and potential candidates were offered a drop-in system for attending between 9am and 6pm.

4.3.4 Introductory Lecture

On attending the NSTC all candidates were shown to the research office, where they were invited to read an introductory lecture on a lap-top in powerpoint™ format (Microsoft™ Powerpoint™ for Mac, 2011 Version 14.1), (Appendix 2). This standardised lecture was read by candidates in their own time. A trialist was available and candidates could ask questions at any stage.

4.3.5 Informed Consent

Candidates who indicated that they had sufficient time to participate in the trial were asked to sign a consent form (Appendix 3). Candidates consented to their performances being anonymously video recorded and analysed for training purposes both on the SVR simulator and the PHCM.

4.3.6 Randomisation

Candidates were then randomised using a closed envelope system, with numbers '1' and '2' "blocked'" in groups of ten.

4.3.6.1 Randomisation to Training Model

Candidates were randomised to begin training on either the VR simulator or PHCM first. This was to ensure no bias was encountered with candidates favouring the first or last model they used. Selecting number '1' randomised that candidate to begin their training on SVR, selecting number '2' randomised that candidate to begin their training on PHCM.

4.3.6.2 Randomisation to Procedure

Once assigned to a training model. Candidates were again randomised to begin on either the 'easy' or the 'intermediate' procedure first. A closed envelope system was used with options '1' and '2' "blocked" in groups of ten. Selecting number '1' randomised that candidate to begin on the easy procedure (cannulation of the left renal artery), selecting number '2' randomised that candidate to begin on the 'intermediate' procedure (cannulation of the right subclavian artery).

4.3.7 Candidates Unique Training Number

Candidates were each given a unique identifying number on a sticker that candidates would attach to their sterile gown. This number was used on all paper work related to candidates. This ensured questionnaire responses could be analysed anonymously.

4.3.8 Pre-Trial Questionnaire

Before candidates began training they completed a pre-trial questionnaire (Appendix 3) to determine certain candidate demographics. The questionnaire recorded their level of seniority, and previous exposure to both human cadaver and VR simulators. A series of questions recorded candidates' handedness, musical instrument experience, exposure to video games, use of correctional glasses for procedural work and ability to type. These factors have been used previously by researchers using groups of endovascular novices (Chaer et al 2006, Boyle et al 2011). It is suggested that these factors may be relevant to a candidate's ability to perform a technical skill.

Candidate's expertise was determined using a questionnaire dividing practitioners into low and high novice, intermediate and expert categories (Appendix 6). This system was adapted from previous similar studies (Hislop et al 2005, Berger et al 2010).

Finally candidates indicated their agreement with the statement *"I have no objections to working with/training on human cadavers",* using a five point Likert scale with one indicating the strongest agreement with the statement, and five, the strongest disagreement with the statement.

4.3.9 Index Training Procedures

Due to cadaver availability it was not possible to include an index case that involved deployment of a stent or angioplasty of stenosis. Once a stent has been deployed or a stenosis angioplastied this cannot be repeated in the cadaver model, and hence multiple cadavers would be required. Candidates were pre-warned that their training experience would involve vessel cannulation and subsequent angiograms alone, as this could be repeated by different practitioners in a standard format on a single cadaveric model.

Two index cases were selected:

4.3.9.1 Procedure 1: Cannulation of the Left Renal Artery and Angiogram

The procedure: *cannulation of the left renal artery and confirmatory angiogram from access in the right femoral artery*, was selected as this represented a 'simple' endovascular procedure. This procedure was also used as an index procedure in a number of trials (Coates et al 2010) including Berger et al's trial (Berger et al 2010) in which a simulator for testing and rating endovascular skills was validated. The so-called 'STRESS machine' has been subsequently included in the European Board of Surgery Qualifications in Vascular Surgery (EBSQ-VASC).

4.3.9.2 Procedure 2: Cannulation of the Right Subclavian Artery and Angiogram

The procedure: *cannulation of the right subclavian artery and confirmatory angiogram from access in the right femoral artery*, was selected as this is considered to be an endovascular procedure of 'intermediate' difficulty.

Renal and subclavian angiograms from the PHCM and SVR are shown in figure 24 and 25.

Figure 24. Cadaveric (A) and Virtual Reality (B) angiograms of the left renal artery

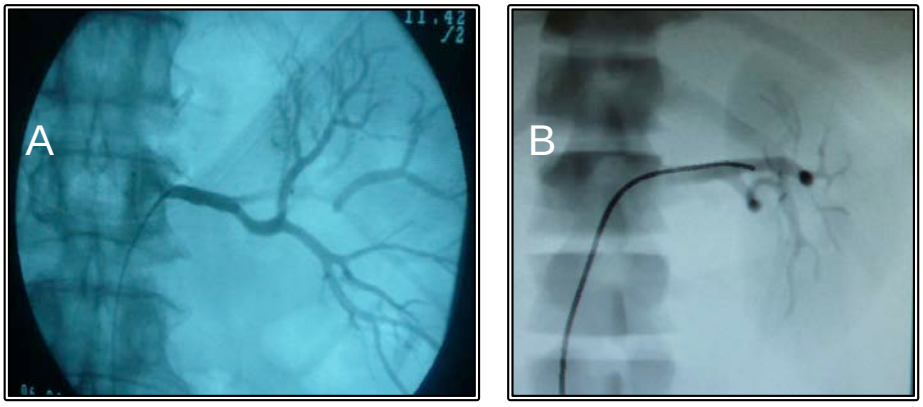
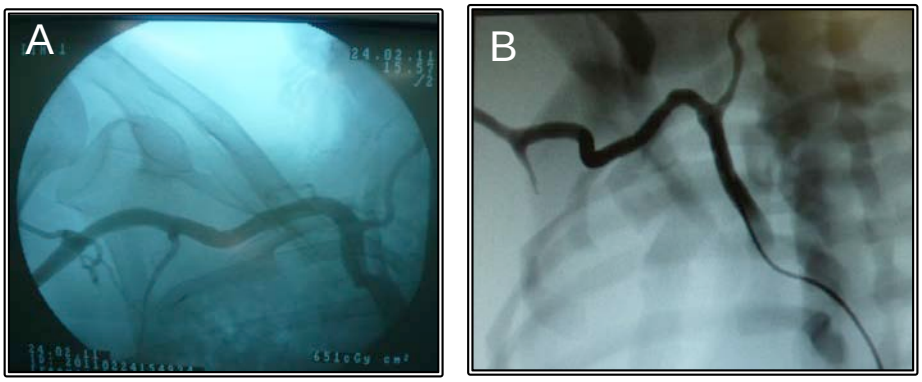


Figure 25. Cadaveric (A) and Virtual Reality (B) angiograms of the right subclavian artery



4.3.10 Training on the Pulsatile Human Cadaver Model (PHCM)

Candidates randomised to begin training on the PHCM were instructed to change into hospital scrubs and wear a standard lead gown for radiological protection, and a sterile gown and gloves, before entering the 'simulated' operating room (Figure 26a). Candidates were instructed on their randomised starting index procedure and given a brief explanation of their cadaver 'patient'. This explanation covered endovascular access which had already been secured in the right common femoral artery with a 7 French endovascular sheath (Figure 26b). A brief explanation of how the radiology C-arm works was also given as some practitioners may not have trained with this model.

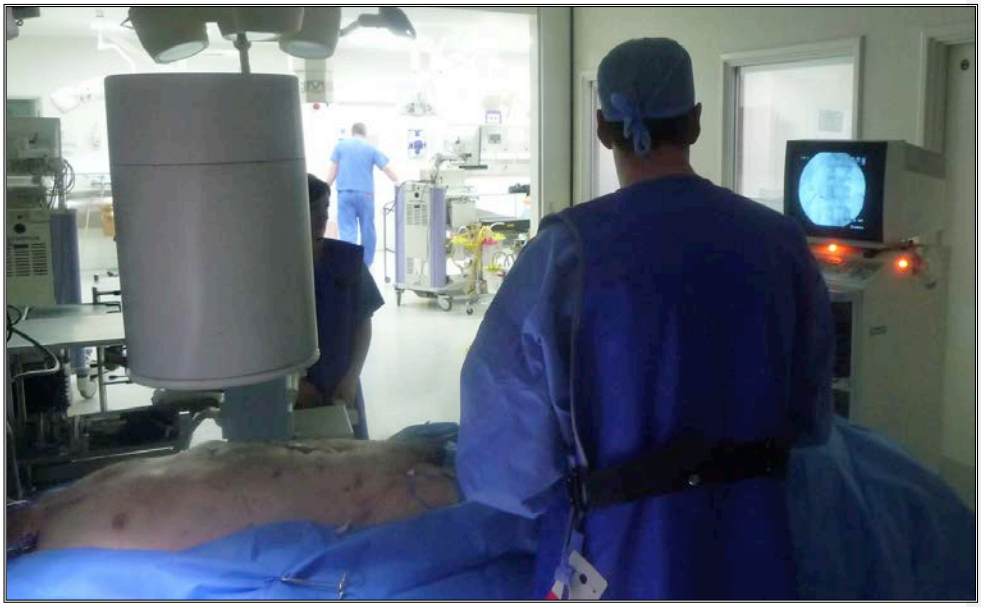
A ten-minute time limit was imposed on candidates performing each index task. As in an interventional theatre, candidates controlled the radiographer to facilitate image capture, and an experienced assistant was provided.

A Siemens™ (Sire mobil compact) C-arm was used for capturing radiographic images. This was capable of standard anterior-posterior and lateral image capture and single image store. There was no facility for angiographic cine runs, or

subtraction II fluoroscopy. Angiography was therefore simulated using hand injection of standard radiographic contrast (omnipaque Ltd™), which was diluted to a 70:30 mix with normal saline.

Standard endovascular equipment was made available for each index procedure (Table 37). Once familiar with their 'theatre' surroundings, candidates could start training in their own time. A procedure was deemed complete when angiographic evidence of left renal artery, or right subclavian artery was achieved respectively. Candidates would be prompted to remove all equipment on completing their first procedure, thus commencing their second procedure from the beginning. This was to make sure both procedures performed, in whatever random order, were completed from the same starting point, and therefore would be more equally comparable between both training model and between individual candidates.

Figure 26a. Candidates training on the PHCM



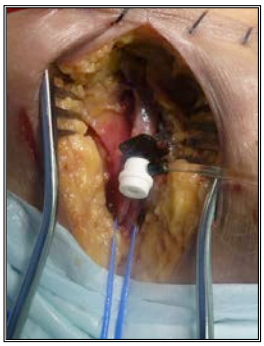


Figure 26b: Endovascular sheath secured in the right common femoral artery

Table 37. Equipment made available to candidates for their endovascular index procedures on both SVR and PHCM

	Guidewires	Diagnostic catheters
Procedure 1	▪ Standard J-tip wire (5mm tip) ▪ Angled glide/hydrophilic wire	▪ 4Fr Pigtail catheter ▪ 4Fr Cobra catheter
Procedure 2	▪ Standard J-tip wire ▪ Benston wire ▪ Angled glide/hydrophilic wire	▪ 4Fr Pigtail catheter ▪ 4Fr Cobra catheter ▪ 5Fr Head hunter ▪ 5Fr Berenstein ▪ 5Fr SIM 2 catheter

4.3.11 Training on the Simbionix Virtual Reality Simulator (SVR)

Candidates randomised to begin their training on the SVR were instructed to wear appropriate dress for angiographic theatre, as described above (4.3.10). On entering the simulated SVR theatre, candidates were familiarised with the SVR. A short (5 minute) explanation from a simulator expert was given, explaining how wires and guiding catheters are selected and inserted, how contrast injection was simulated and how the fluoroscopy is controlled. This was deemed necessary to

ensure candidates received a realistic SVR training experience, and were not restricted by the technology, which has its own learning curve.

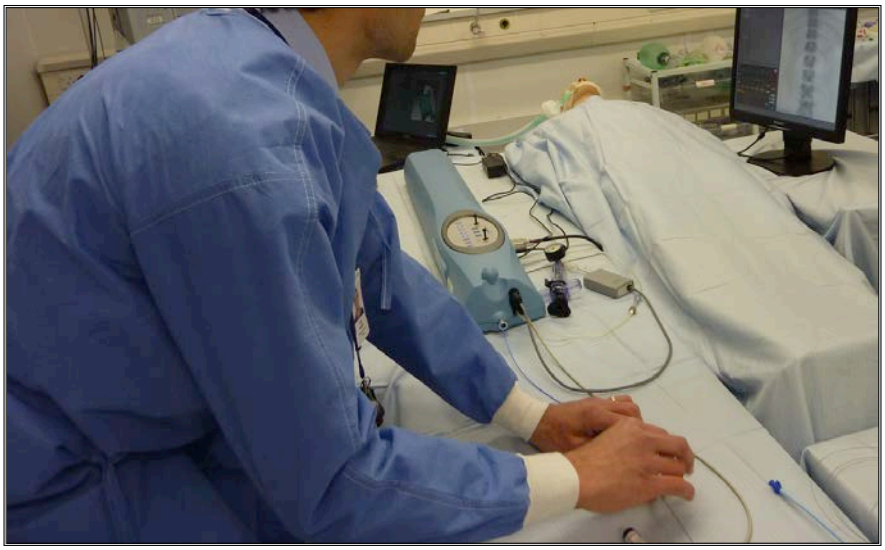
SVR is capable of high quality radiology image, including cine run, subtraction II and 3D reconstruction. Candidates were not prevented from using these additional radiology features if they felt they would assist them in their procedure.

As above (4.3.9) candidates were instructed on their first index procedure, and began training when they felt ready. A ten minute time limit was placed on candidates, for each procedure. Candidates demonstrated completion of the procedure with adequate angiographic evidence of the corresponding artery. Simulated theatre set-up was designed to be as realistic as possible, with the simulator covered in theatre drapes exposing only the simulated endovascular access port (Figure 27). As in the cadaver experiment, an assistant was available to select guidewires, and aid with catheter exchange.

4.3.11.1 Selecting Modules for the Index Cases

Simbionix angiomentor™ has a number of modules that are capable of simulating both index procedures. For both index cases, modules were selected that included no pathology in the target vessels. This was to create a realistic comparison to the PHCM which (it was presumed) would likewise contain no vascular disease in the target vessels. Simbionix is not capable of allowing both procedures to be performed in the same module as the radiographic image is limited to the case in question. For example, in a renal module, the radiographic image extends from distal thoracic aorta to iliac arteries. A renal module was used for index case 1, and a carotid module was used for index case 2.

Figure 27. Candidates training on the SVR



4.3.12 Post Trial Questionnaire

After completing both procedures on both models, candidates were shown from the simulated theatres, and completed a post trial questionnaire (Appendix 5). This questionnaire asked candidates to rate their agreement with a series of statements regarding their experience training on both the SVR and PHCM. Candidates agreement with these statements was recorded on a standard likert scale with '1' representing their greatest agreement and '5' their greatest disagreement with the statement. Questions were structured so that the same statement was made about each training model, to avoid any bias when answering. A final series of questions allowed candidates to rate their preferred model, the model they would recommend to others, and a 'free text' area allowed candidates to document any perceived advantages or disadvantages of each model encountered whilst training.

4.3.13 Subject Numbers

Based on previous literature assessing the face validity of novel simulation models for surgical training (Brehmer et al 2002, Eisma et al 2010, Willaert W et al 2010) the present study aimed to recruit a minimum of 12 candidates to the face validity trial.

4.3.14 Ethics Approval

Advice was sought from the Freeman Hospital Research Governance Manager, after assessing the trial protocol, it was decided that formal ethical approval was not required as it was deemed that the proposed trial represented 'technical development and training', not research.

4.3.15 Storage of Data

All data related to the trial (both paper and electronic) was stored on a password protected hospital trust computer, in a secure room within the NSTC, which is protected by both a card swipe system and locked out of hours.

4.4 Results

All data generated from the face validity trial was tabulated onto excel spread sheets (Microsoft excel™). Mean, median and modal values were extracted in standard fashion. Statistical analysis was undertaken using the Statistical Package for the Social sciences version 19 (SPSS, Chicago). Advice was sought from a medical statistician at Newcastle University for the most appropriate statistical tests when analyzing the trial data. Wilcoxon Matched Pairs Signed ranks test was used to compare questionnaire statements from the two simulators. A p-value of <0.05 was considered to be significant.

Figure 28 shows an algorithmic overview of the trial. Figure 29 shows the flow of candidates through the trial.

Figure 28. Algorithmic Overview of the Study

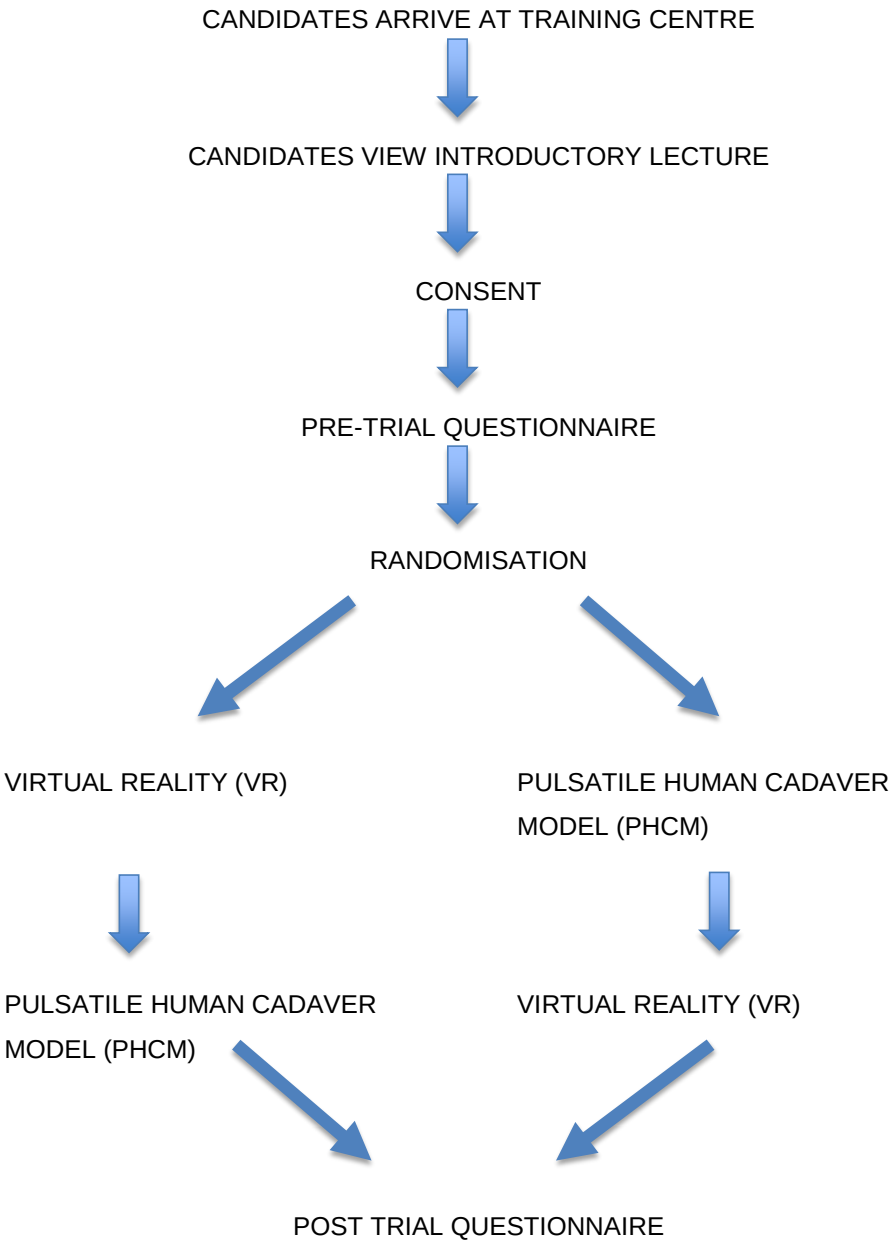
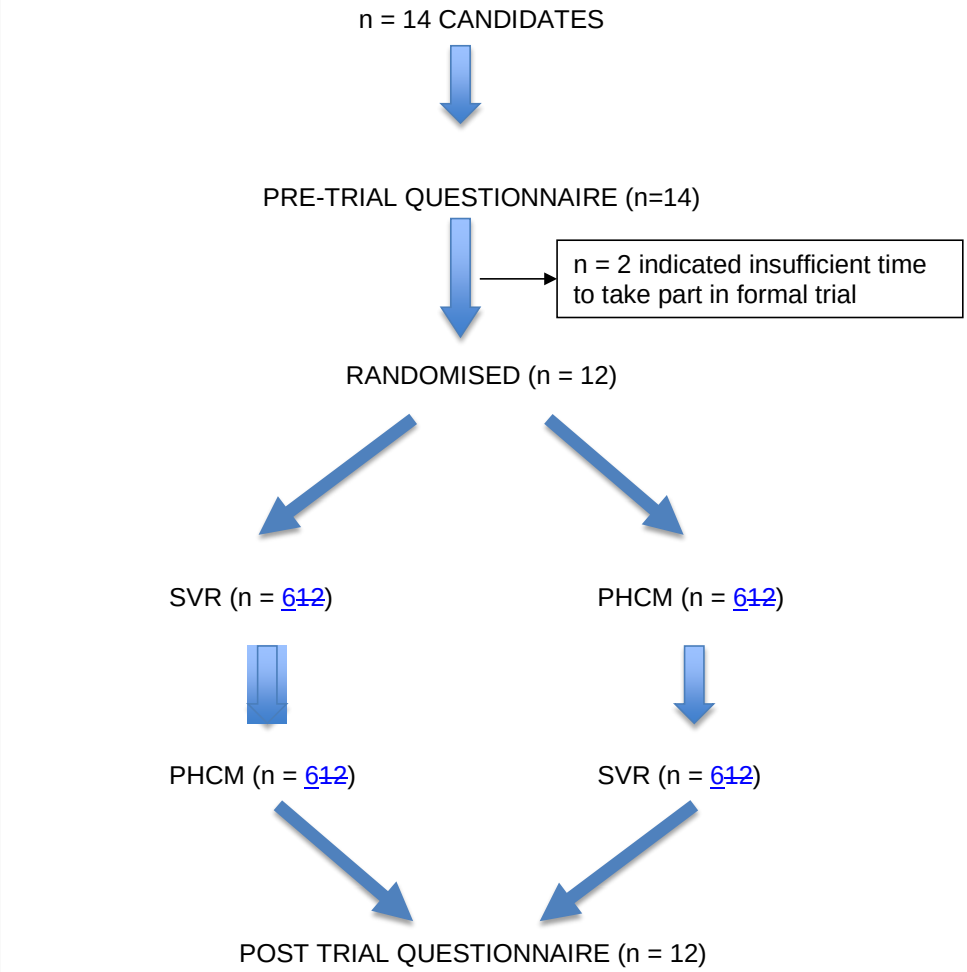


Figure 29 Trial Flow Chart



4.4.1 Candidate Demographics

14 candidates attended for the PHCM face validity trial. After reading the 'introductory lecture' (4.3.4) two candidates indicated that they had insufficient time to partake in the officlal trial.

The 12 candidates that completed the trial displayed the following demographics (Table 38). These demographics have all been shown to affect ones ability to acquire/perform a technical skill (Backstein 2003) and were recorded routinely before all clinical experiments in this thesis.

Table 38. Candidate Demographics

Deomgraphic	Candidate	
Seniority	5 consultant radiologists 3 consultant endovascular surgeons 4 senior trainees (2 vasc surgery, int radiology)	
Endovascular Experience*	Expert n = 8 Intermediate n = 4	
Wear glasses?	Yes n = 3 No n = 9	
Handedness	Left n = 0 Right n = 12	
Play musical instrument	Yes n = 4 No n = 8	n = 3 piano, n = 1 guitar
Play video games regularly	Yes n = 4 No n = 8	
Prev VR training	Yes n = 10 No n = 2	
Prev cadaver endovascular training	Yes n = 0 No n = 12	
Prev cadaver training (any)	Yes n = 10 No n = 2	n = 7 Undergraduate anatomy n= 1 Cadaver trauma course n = 1 PCNL course† n = 1 Advanced vascular skills course

*See Appendix 6

† Cadaveric Percutaneous Nephrolithotomy Course

4.4.2.1 Simbionix Virtual Reality (SVR)

All candidates completed both index procedures in the SVR (table 3). No procedural or technical complications were noted with the simbionix angiomentor™.

4.4.2.2 Pulsatile Human Cadaver Model (PHCM)

Not all candidates were able to complete both procedures on the PHCM (Table 39). This was partly due to candidates' level of experience, but also due to heavy atheromatous disease in the model.

Table 39. Index Procedures Attempted and Completed on SVR and PHCM

	SVR		PHCM	
	Index Procdure 1	**Index Procdure 2**	**Index Procdure 1**	**Index Procdure 2**
Procedure attempted (%)	n = 12 (100)	n = 12 (100)	n = 12 (100)	n = 12 (100)
Procedure completed (%)	n = 12 (100)	n = 12 (100)	n = 12 (100)	n = 8 (67)

4.4.2.2.1 Atheromatous Disease in the PHCM

The cadaver model used for the face validity study had extensive atheromatous disease in the aorta, in particular the aortic arch, making cannulation of the subclavian artery challenging even for the most experienced consultant operators. This highlights the unpredictable nature of the PHCM. The potential impact of this upon the study is discussed in 4.5.

4.4.3 Index Procedures Completed

Candidates took an average of 5.25 minutes (315.08 seconds) using an average of 18.17 ml of contrast to complete index procedure 1 on PHCM, and 4.10 minutes (245.75 seconds) to complete the same procedure on SVR, using an average of

15.58 ml of contrast. Candidates spent an average of 8.10 minutes (485.75 seconds) attempting index procedure 2, and 26.08ml of contrast on the PHCM, compared to just 4.14minutes (248.33 seconds), 19.17ml of contrast on SVR. Appendix 29 details all proceudural quantitative parameters. Table 40 provides a summary of the quantitative measure taken during the face validity study.

Table 40. Summary of Quantitative Measures Taken During Face Validity Trial

	PHCM		SVR	
	Index Procedure 1	**Index Procedure 2**	**Index Procedure 1**	**Index Procedure 2**
Total Procedure time (sec)*	315.08 (117.22)	485.75 (121.52)	245.75 (75.12)	248.33 (114.98)
Fluroscopy time (sec)*	283.17 (139.25)	415.92 (106.73)	218.25 (90.46)	204.00 (103.27)
Contrast used (ml)*	18.17 (6.85)	26.08 (6.11)	15.58 (7.04)	19.17 (8.76)

***Mean (standard deviation)

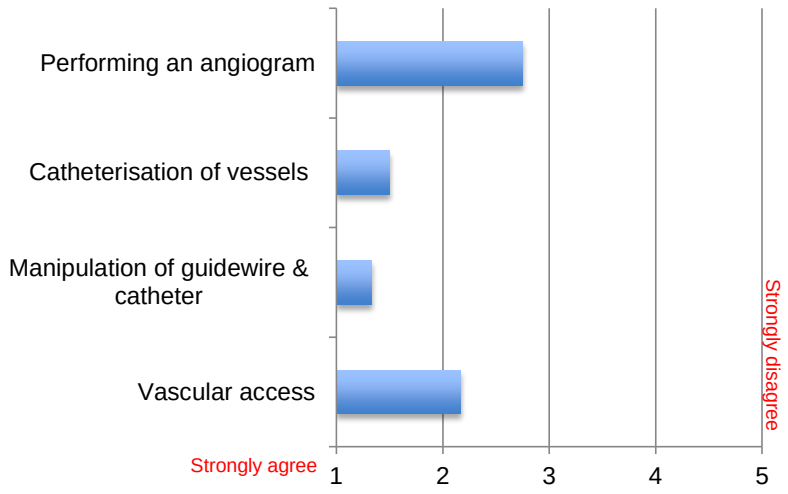
4.4.4 Post Trial Questionnaire Results

Graphs 4.4.4.1 – 4.4.4.4 represent the mean post trial questionnaire Likert scores for candidate's agreement with each question. These are analysed in further detail in section 4.5.

4.4.4.1 Mean Scores Comparing Simulators to Live Patients

Mean score for agreement with statements comparing PHCM to live patients

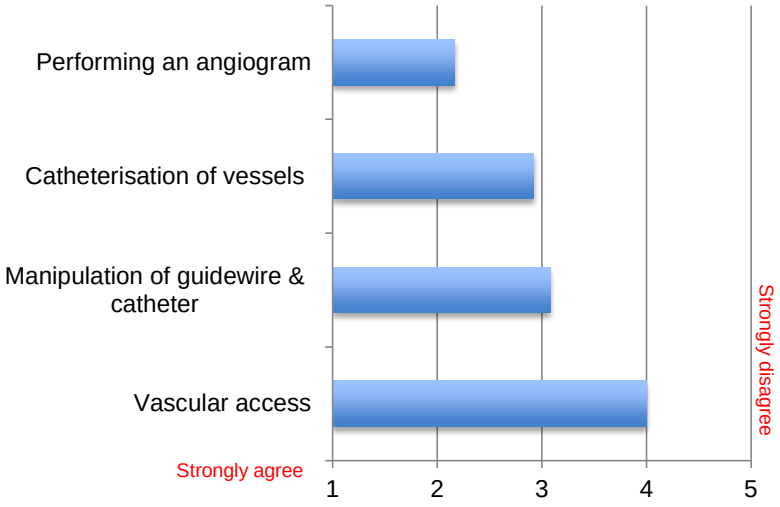
"……was realistic on PHCM compared to live patients"



	Performing an angiogram	Catheterisation of vessels	Manipulation of guidewire & catheter	Vascular access
Mean	2.75	1.50	1.33	2.17
SD	0.97	0.52	0.49	0.72

Mean score for agreement with statements comparing SVR to live patients

"……was realistic on SVR compared to live patients"

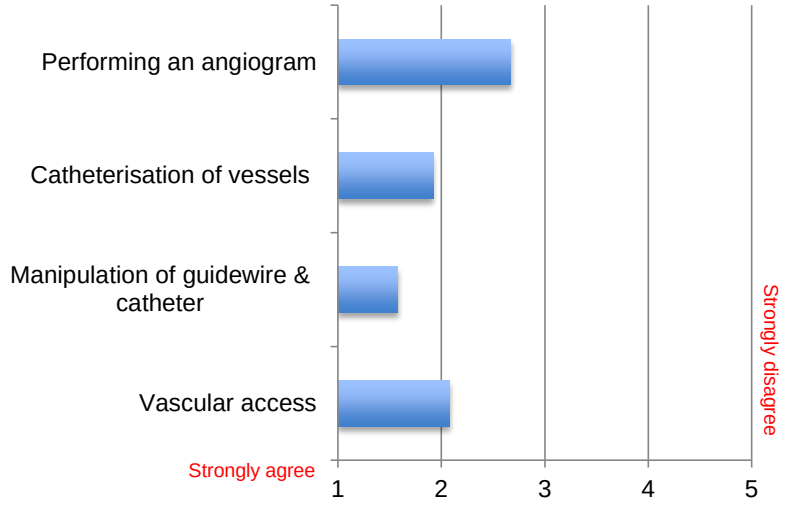


	Performing an angiogram	Catheterisation of vessels	Manipulation of guidewire & catheter	Vascular access
Mean	2.17	2.92	3.08	4.00
SD	0.58	0.90	0.90	1.04

4.4.4.2 Mean Scores Comparing the Two Simulators to One Another

Mean score for agreement with statements comparing PHCM to SVR

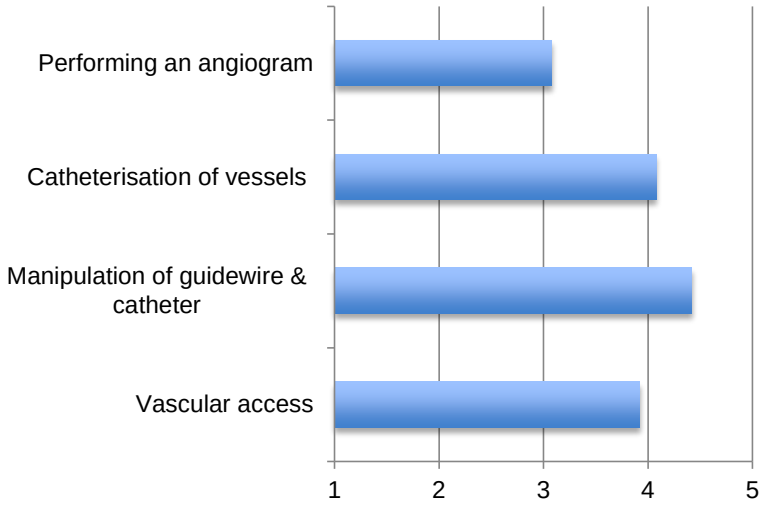
"……was more realistic on PHCM compared to SVR"



	Performing an angiogram	Catheterisation of vessels	Manipulation of guidewire & catheter	Vascular access
Mean	2.67	1.92	1.58	2.08
SD	1.23	0.79	0.67	0.67

Mean score for agreement with statements comparing SVR to PHCM

"……was more realistic on SVR compared to PHCM"

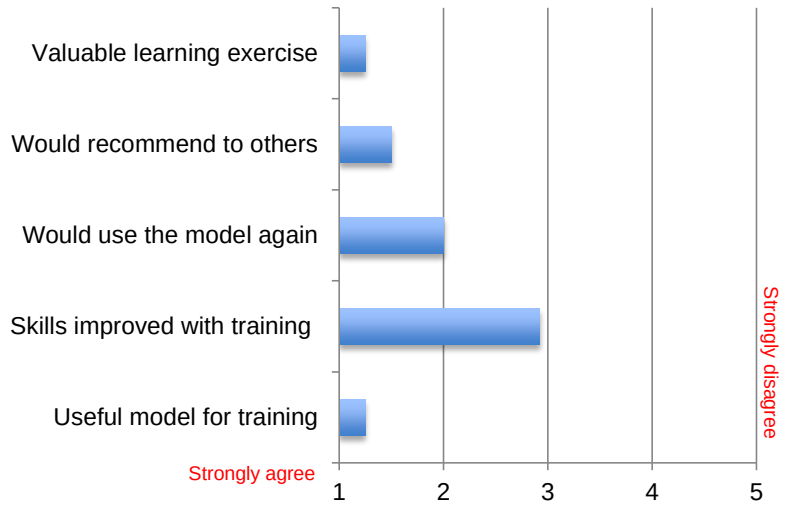


	Performing an angiogram	Catheterisation of vessels	Manipulation of guidewire & catheter	Vascular access
Mean	3.08	4.08	4.42	3.92
SD	1.08	0.79	0.67	0.67

4.4.4.3 Mean Scores For Additional Statements Regarding Both Simulators

Mean score for additional statements regarding PHCM

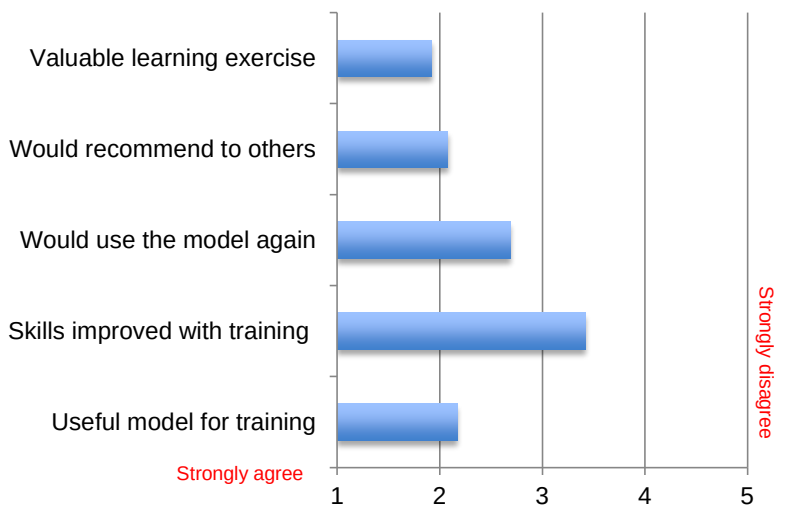
"Indicate your agreement with the following statements"



	Valuable exercise	Would recommend	Would use again	Skills improved	Useful model
Mean	1.25	1.50	2.00	2.92	1.25
SD	0.45	0.52	1.04	0.90	0.45

Mean score for additional statements regarding SVR

"Indicate your agreement with the following statements"

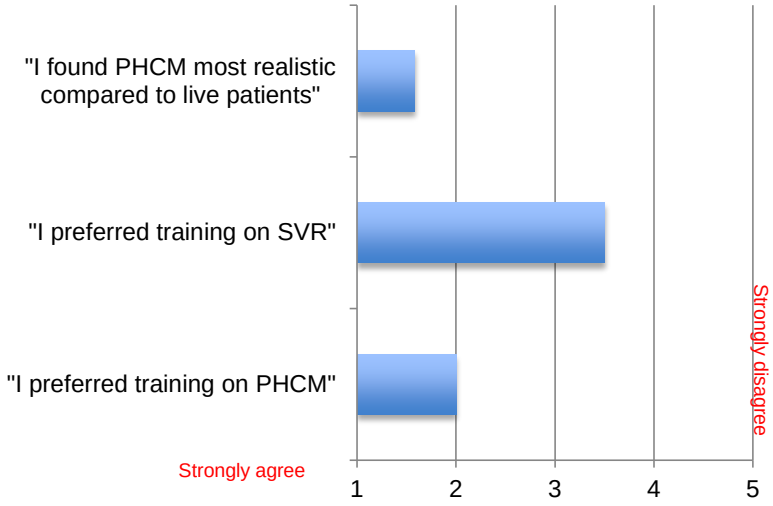


	Valuable exercise	Would recommend	Would use again	Skills improved	Useful model
Mean	1.92	2.08	2.83	3.42	2.17
SD	0.51	0.67	0.94	1.08	0.58

4.4.4.4 Mean Scores For Final Statements Regarding Training

Mean score for agreement with statement regarding Preferred Training Model

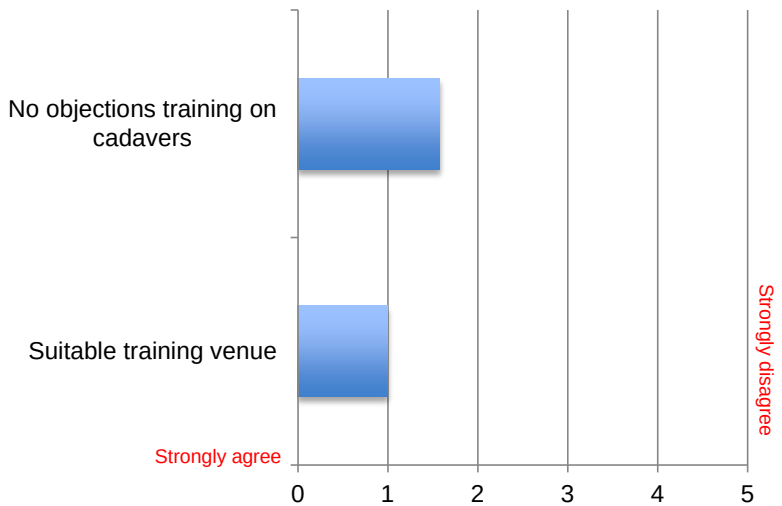
"Indicate your agreement with the following statement"



	PHCM most realistic	Preferred PHCM	Preferred SVR
Mean	1.58	2.00	3.50
SD	0.67	0.95	1.00

Mean score for agreement with final statements: Suitable Venue & Objection to Human Cadaver Training

"Indicate your agreement with the following statement"



	No objections training on cadavers	Suitable training venue
Mean	1.58	1.00
SD	0.92	0.65

4.4.5 Statistics

4.4.5.1. Significance Test of Likert Statement Score. SVR Versus PHCM and Additional Scores

Compared to live patients candidates showed a significant preference for PHCM concerning vascular access, manipulation of guidewires and catheterization of vessels. Candidates felt the PHCM was a more useful training model compared to SVR (p=0.004). For all other statements, no significant differences were demonstrated (Table 41).

Table 41. Significance Test of Likert Statement Score. SVR Versus PHCM

Statement	Candidates Preference	Significance Test*
Compared to live patients - vascular access was realistic on the ….	PHCM > SVR	p=0.002
Compared to live patients - manipulation of guidewire + catheter was realistic in the….	PHCM > SVR	p=0.001
Compared to live patients - catheterisation of vessels was realistic in the….	PHCM > SVR	p=0.004
Compared to live patients - performing an angiogram was realistic in the….	SVR > PHCM	p=0.096
Was a valuable learning exercise	PHCM > SVR	p=0.016
Would recommend….. to others	PHCM > SVR	p=0.062
Would use the model again	PHCM> SVR	p= 0.053
Training improved skills my skills	PHCM = SVR	p= 0.118
Was useful for training	PHCM > SVR	p= 0.004

***** *Wilcoxon Matched Pairs Signed Ranks test (Monte Carlo Sig. 2 tailed p=value)*

4.4.6 Candidates Comments

Candidates were invited to make comments on their perceived strengths and weaknesses of each model. These responses are detailed in table 6 and 7.

Table 42. Candidates perceived strengths and weaknesses of the PHCM model

Candidate	Strengths of PHCM	Weaknesses of PHCM
C1	*Good tactile feedback*	*Imaging and image manipulation* *Very atheromatous*
C2	*Absolutely realistic* *Scope for implanting stents/grafts*	*Scarce resource* *Preparation needed* *'Discomfort' some may feel using cadavers for training*
C3	*Realistic – the patient comes with all the flaws and difficulty of real life.* *Tactile feedback of proper wires/catheters etc* *Feels like a real patient that needs treating with respect*	*Very slow contrast washout mimics dissection* *Patients disease liable to become disrupted over time making it less realistic later in the day*
C4	*Life like diseased vessels*	*Contrast flow out not good enough* *Need subtraction/more usability of II*
C5	*Realism*	*Inflexible in terms of anatomy/pathology*
C6	*Realistic, wires/catheters are as in-vivo*	*No DSA*
C7	*Useful for cannulating*	*Very limited use without disease* *Difficult to find cadavers with real lesions* *Friction is not quite natural like in a real patient*
C8	*Realistic performance*	*Longevity* *Smell* *Aesthetics*
C9	*Allows for arterial catheter manipulation*	*Difficulty with angiograms (try with the pump off)*
C10	*Better haptic feedback*	*Durability*
C11	*No comment*	*No comment*
C12	*No comment*	*No comment*

Table 43. Candidates perceived strengths and weaknesses of the SVR model

Candidate	Strengths of SVR	Weaknesses SVR
C1	*Good imaging*	*No feedback* *Catherterisation not realistic*
C2	*Excellent introductory tool for beginners to learn basic guidewire/catheter skills*	*A little artificial*
C3	*Good to establish a sequence of events to complete a task in a beginner* *Stays fresh all day* *Predictable – although probably a weakness as patients aren't!*	*Unrealistic* *Entirely predictable responses. Poor tactile feedback. Artificial – favours a "probe and hope cos its only a machine" tendency, if not fully settled into the role play*
C4	*No ethical consideration* *Non threatening/stress free*	*Bit too easy*
C5	*Flexibility of programme*	*Poor feedback from wires/catheters*
C6	*No comment*	*No Comment*
C7	*Good tool to learn the steps of an intervention and provides good feedback eg wall contact, screening time etc*	*Haptic feedback is not very realistic and sire simulation only very limited*
C8	*Ease of set up*	*Cost* *Software glitches* *Less realistic* *Catheters/wires don't perform the same*
C9	*Clean system that does not require any set up time*	*Doesn't actually allow real catheters to be used*
C10	*Good for sequences and steps of procedures*	*Limited haptic feedback*
C11	*No comment*	*No comment*
C12	*No comment*	*No comment*

4.5 Discussion

As previously noted (1.5.3) high fidelity VRS has already been integrated into endovascular training across Europe and America. Although its official role in the UK vascular training curriculum remains uncertain, few would question the distinct advantages offered to trainees, especially in their formative years of endovascular training. HC on the other hand have been relatively ignored as credible endovascular training adjuncts (1.5.4). In the establishment of any new training model, a number of important parametres must be measured, to establish if the model is of genuine training benefit (Table 44). Issues of realism, acceptability and appropriateness can all be satisfactorliy measured with a well constructed trial of face validity.

Table 44. Features of the ideal training model

Model Parameter
➢ *Effective*
➢ *Appropriate*
➢ *Acceptable*
➢ *Realistic*
➢ *Re-usable*
➢ *Cost-effective*
➢ *Readily available*

In the present trial, PHCM was compared in a controlled environment under standard conditions, to both live patients and a VRS, through the opinion of endovascular experts.

Overall candidates were impressed with both the fidelity and haptics of the PHCM, (4.4.4.1). PHCM scored favourably (mean score <3) on all statements relating to training when compared to both live patients and SVR. The only feature of PHCM that scored less well when compared to live patients was that of “performing an angiogram” (mean score 2.8, SD 0.97), although this was not significant (p=0.096) (Table 41). This was in agreement with several comments made by the candidates on their post trial questionnaires (Table 42), indicating they did not find performing

an angiogram in the HC comparable to live patients, for example one candidate felt the washout of contrast was slow, and this mimicked dissection.

This observation was due to heavy atheromatous disease in the cadaver, which caused resistent residual thrombus that subsequently exacerbated the probem of residual contrast post angiogram. This remains a dissadvantage of the PHCM versus the more predictable training experience of SVR. In fact, the severity of disease in the HC resulted in difficulty in cannulating the right subclavian artery, indeed not all expert candidates were successful in completing this task in the alloted time (4.4.2.2.1). Despite aiming to create a fair comparative training experience, SVR is unable to simulate the degree of disease that was encountered in the HC, and therefore represented an easier task to complete.

It is almost impossible to predict the state of a cadaver's vessels prior to training, (unless there is a history of PVD or clinical evidence of arterial disease). Despite this apparent dissadvantage, it did not prevent candidates overall favouring their training experience on PHCM. When asked for their agreement with the statement that PHCM represented the most realistic training model when compared to live patients, the mean candidate score was 1.58 (SD 0.67) indicating strong agreement (4.4.4.4).

Candidates favoured the PHCM's degree of realism, and this was demonstrated in candidates' favourable questionnaire statement scores (4.4.4.1, 4.4.4.2) and their comments made in the free text boxes: "it felt like a patient that needed treating with respect", "wires/catheters are as i*n vivo*" and "absolutely realistic" (Table 42). In contrast candidates' commented that SVR was "a little artificial" with "entriely predictable responses, poor tactile feedback", and "limited haptic feedback" (Table 43). These comments did impact upon candidates' questionnaire statement scores comparing SVR to both live patients (4.4.4.1) and the PHCM (4.4.4.2). SVR did not score as highly as PHCM. In fact PHCM scored significantly higher on statements regarding realism, including vascular access (p=0.002), maniulation of the guidewire and catheter (p=0.001) and catheterisation of the vessels (p=0.004) (Table 41).

It is important to acknowledge the limited use of both models in the trial, as both were just used to simulate angiography. SVR is able to simulate unlimited numbers of angioplasty and stent implantation scenarios in a standard format. Angioplasty and stent deployment is possible in the PHCM, but not in a repeatable or standardized format. This remains a limitation of PHCM, and its affect on candidate's opinions in the present study is acknowledged.

Despite the limited use of the SVR, candidates recognised its benefts and commented on its ease of use and standardised nature. Overall it was felt to be an excellent model for introducing the basics to beginners (Table 43). However, the PHCM was favoured as a valuable learning tool (p=0.016), All candidates considered PHCM and SVR to represent a "useful training model" (mean 1.25, SD 0.45 versus mean 2.17, SD 0.58) but again favoured the PHCM (p=0.004) (4.4.4.4).

A number of candidates criticised the radiology equipment capabilities of the PHCM (Table 42). In contrast SVR is capable of subtraction II, 3D reconstruction and road mapping. However, with investment more sophisticated radiology equipment could easily be incorporated to enhance the PHCM training experience. The limitation of the equipment made available during this trial is acknowledged.

All candidates strongly agreed (mean 1.00, SD 0.65) that the training environment (NSTC) was "suitable" and none of the candidates "objected to training on a human cadaver" (mean 1.58, SD 0.92) (4.4.4.4), although it is acknowledged that this is the opinion of a self selecting group, and may mask opinions from other experts with more negative opinions. Not unsurprisingly, through this limted 'snap shop' of both models' training capabilities, candidates did not feel their endovascular skills had improved on either model (mean 2.92 (SD 0.90) PHCM, versus 3.42 (SD 1.08) SVR), (p=0.188) but no candidates indicated any adverse effects (4.4.4.3, Table 41).

Several limitations were encountered in the present trial, many of these due to the methodology of maintaining an equal training experience between the two

simulators, and it is acknowledged that this may have affected candidate's response. However, questionnaire statements were well tailored to the experience candidates received during the restricted use of the models, and the conclusions are tailored accordingly.

4.6 Conclusion

Overall it is concluded that PHCM demonstrated face validity. PHCM represents a feasible endovascular training model with a high degree of realism, and compares favourably to both live patients and high fidelity virtual reality simulation for a simple angiogram procedure. This present study is the first to report on the use of a PHCM for endovascular training. Further trials are necessary to establish its true efficacy as a successful training model for endovascular practitioners.

Chapter 5

A Fresh Frozen Pulsatile Human Cadaver Model for Training Endovascular Practitioners. A Trial of Construct Validity

Abstract

Aim

Determine the construct validity of a pulsatile fresh frozen human cadaver model (PHCM) for training endovascular practitioners.

Methods

PHCM is a novel adjunct for training basic endovascular skills. 23 candidates were recruited (7 Expert, 4 Intermediate, 12 Low Novice) to the trial. Each attempted catheterisation of the left renal artery (LRA) on PHCM under exam conditions. Performances were recorded (candidates hands and the fluoroscopy screen). Performances were then scored using a validated scoring tool by two independent endovascular experts, blinded to performer status, awarding each candidate an overall performance score (OPS). Total time taken, volume of contrast required, and total fluoroscopy time were also recorded.

Results

More intermediate (p=0.003) and expert (p=0.000) candidates were able to complete LRA compared to the novices.

Expert and intermediate candidates performed significantly quicker than the novices (p=0.000). No difference in total time was seen between intermediate and expert groups. No significant differences were demonstrated between the three groups comparing total fluoroscopy time and volume of contrast used.

OPS were superior (p=0.000) in the expert and intermediate groups when compared to the novices. No significant difference was observed between the intermediate and expert groups.

Conclusions

The PHCM demonstrates construct validity in differentiating between novice and both intermediate level and expert practitioners. No significant differences were seen between intermediate level trainees and expert practitioners. Further work is required to expand the functionality of the PHCM.

Chapter 5

5.0 A Fresh Frozen Pulsatile Human Cadaver Model for Training Endovascular Practitioners. A Trial of Construct Validity

5.1 Introduction

Following on from the success of the trial of face validity (Chapter 4), a further experiment was designed to establish if the PHCM demonstrated construct validity.

5.1.1 Construct Validity

Construct validity is 'extent to which a test measures the trait it purports to measure' (Bharathan 2012). This is often synonymous with the concept of a model's ability to discriminate between training individuals on the basis of their level of expertise.

The trial of construct validity was based on this concept namely the PHCMs ability to discriminate between candidates of varying expertise.

5.2 Aims and Hypothesis

It is hypothesized that the PHCM will demonstrate construct validity and differentiate between practitioners of varying levels of expertise.

The aim of this trial was to establish if the PHCM demonstrated construct validity.

5.3 Methods

The methods of the trial of construct validity are discussed below

5.3.1 Inclusion Criteria

- Practitioners with endovascular experience:
  - Ideally endovascular practitioners of moderate and expert level experience, but practitioners of any endovascular experience were invited to take part
- Endovascular novices:
  - The novice candidates would have no previous endovascular experience. This would be confirmed through a questionnaire which graded candidates experience (Appendix 6)

Nb. Candidates were different from those recruited into experiments conducted during Chapter 4

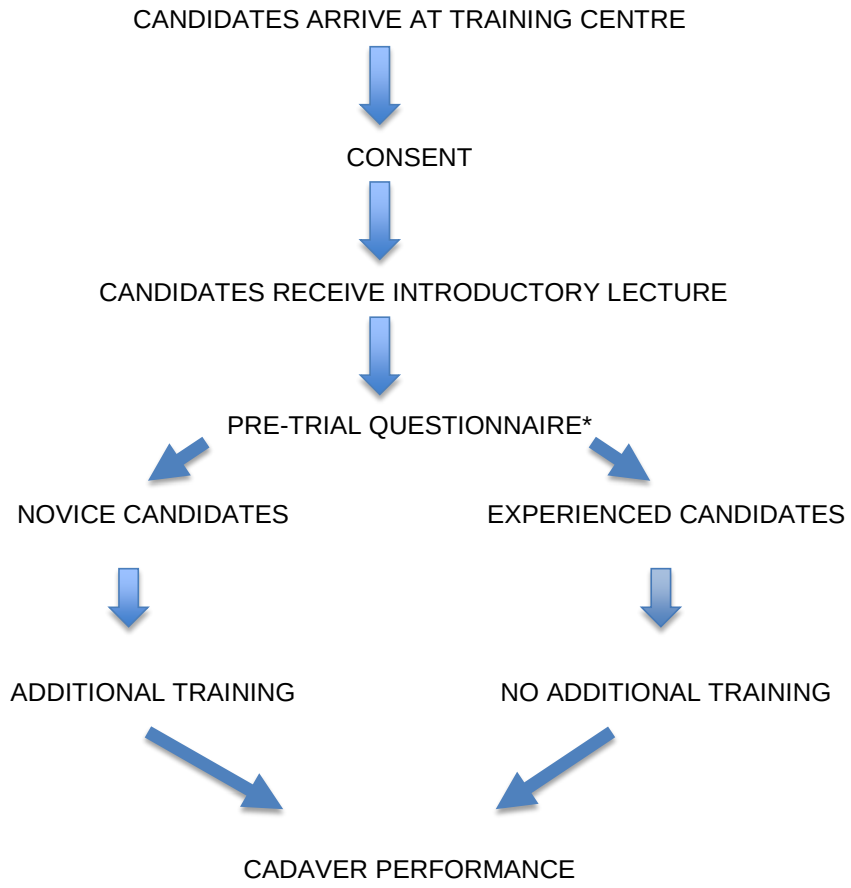
5.3.2 Exclusion Criteria

Non-medically trained candidates were not invited to take part.

5.3.3 Algorithmic Overview of the Construct Validity Trial

Figure 30 shows an algorithmic overview of the trial

Figure 30. Algorithmic Overview of the Construct Validity Trial



*Appendix 4

5.3.4 Introductory Lecture

All candidates (novices and experienced) received an introductory lecture; it was delivered using a standard PowerPoint™ format. This introduced candidates to the trial, and covered important issues regarding the PHCM. The lecture was generic, and delivered to all candidates regardless of their experience.

This introductory lecture was delivered by the principal investigator (PI), (Craig Nesbitt) and lasted approximately ten minutes.

The generic introductory lecture covered the following points:

- Brief mention of the background to the research project
- The basic concept of the PHCM
- The concept of a construct validity trial
- Details of the index procedure Including what equipment would be available
- Selective catheterisation and angiogram of the left renal artery from access in the right femoral artery
- The intention to video record their performances (hands only) for analysis
- The need for written consent

5.3.5 Pre-Trial Questionnaire

All candidates completed a pre-trial questionnaire (Appendix 3). This was the same questionnaire that was used in our trial of face validity (4.3.8).

5.3.6 Additional Novice Training

Many of the concepts and details in the introductory lecture (5.3.4) were new to the novice candidates, who were medical students. Therefore, they also received additional training prior to attempting their index cadaver procedure. Without this additional training the novice candidates were unable to proceed.

5.3.6.1 Additional Novice Lecture

An additional lecture was delivered by the PI that lasted approximately 10 minutes.

This additional novice lecture covered the following points:

- Basic endovascular concepts
- Seldinger access
- Wires & catheters
- Angiograms, stenting and angioplasty
- A step by step explanation of the index cadaver procedure

5.3.6.2 Additional Novice Video

Novices watched an edited expert performance of the index cadaver procedure being performed on the PHCM. The video contained expert commentary and lasted 5 minutes.

Novices also watched an edited expert performance of the index cadaver procedure being undertaken on VR. This performance was performed and commentated on by an endovascular expert. The reason for an additional VR video performance was because the quality of the images from the PHCM performance was less clear than VR. This was due to the radiography equipment available in our cadaver training facility (4.3.10). For training purposes it was decided that both videos would give novice candidates the optimum introduction to the index procedure. This video lasted 5 minutes.

Figure 31 shows still images of the various steps of the index procedure videos on both VR and PHCM.

Candidates were allowed to ask questions. Every care was taken to avoid providing any of the novice candidates additional training in addition to that outlined above. This was to ensure all novice candidates received the same pre-performance training.

5.3.7 Informed Consent

All candidates taking part in the PHCM trial of construct validity completed a written form of consent which allowed use of their videoed performances (hands only) for analysis. The form used was modified from the face validity trial (Chapter 4, Appendix 22)

5.3.8 Candidates Unique Training Number (UTN)

As in 4.3.7, candidates were identified with a unique candidate number/unique training number (UTN). This number was used on all paper work related to that candidate, and was used to identify performances when recorded in the cadaver simulated theatre. This ensured questionnaire responses and videoed performances could be analysed anonymously.

5.3.9 Index Cadaver Performance

Once candidates had undergone their pre-performance training, and signed a consent form they were shown into the cadaver lab. The PHCM was set up and prepared as described in detail in Chapter 3. The simulated theatre set up, and candidate attire was identical to that used in our face validity study. The equipment available to candidates was also the same as was used in 4.3.10 – Table 37.

Candidates performed a single index procedure on the PHCM (5.3.9.1). This performance was video recorded. Candidates were permitted to ask questions during their index performance, but encouraged to perform the procedure independently.

Candidates were given a maximum of ten minutes to complete the index procedure. After the ten minutes, candidates were asked to stop operating, and the cameras were switched off.

5.3.9.1 Index Cadaver Performance

The same procedure that was used in 4.3.9.1 was performed as the index cadaver performance in the trial of construct validity:
Cannulation of the left renal artery and confirmatory angiogram from access in the right femoral artery.

5.3.10 Recording Candidates Performances

Two static cameras (Sony™ handycam recorder) were set up on tri-pods. One camera was focused on the candidate's hands. The second camera recorded the fluoroscopy screen. The candidate's UTN was called out at the beginning of each recording, so footage could be identified for subsequent analysis.
Sound was recorded throughout the candidates' performances; this was to ensure questions asked could be noted by the blinded scorers, who would otherwise be unaware of any dialogue, as the video cameras were only recording candidates' hands, and the fluoroscopy screen.

5.3.11 Subject Numbers

The study aimed to recruit ten novice and ten experienced candidates to the trial of construct validity. These numbers are based on previous literature assessing the construct validity of novel simulation models for surgical training (Riga et al 2010, Bech et al 2011)

5.3.12 Ethics Approval

Advice was sought from the Freeman Hospital Research Governance Manager. After assessing the trial protocol, it was decided that formal ethical approval was

not required as the trial was considered ‘technical development and training’, not research.

5.3.13 Storage of Data

All data related to the trial (both paper and electronic) was stored on a password protected hospital trust computer, in a secure room within the Newcastle Surgical Training Centre (NSTC), which is protected by both a card swipe system (24hours) and locked out of hours.

5.3.14 Editing Video Performances

Candidates Video Performances were all down loaded into iMovie version 8.0.4 (Apple Mac™). Two videos existed per performance (one of the candidates hands, and the other of the fluoroscopy screen). Videos were edited to remove the beginning of the recording, when the candidates UTN was called out. A ‘video-in-video’ format was used, to make post-trial video scoring easier. The ‘hands’ shot was minimised into the ‘fluroscopy’ screen (Figure 32).

Figure 31. Individual Steps of the Index Training Procedure: Selective Catheterisation and Confirmatory Angiogram of the Left Renal Artery. VRS & PHCM.

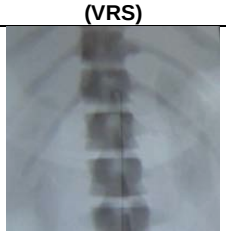
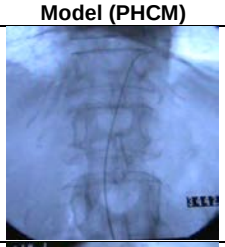
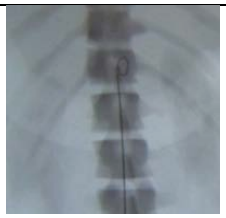
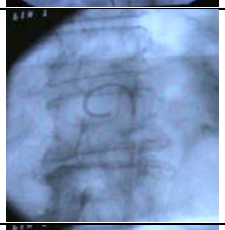
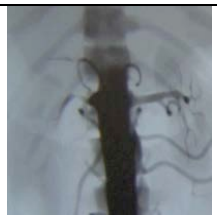
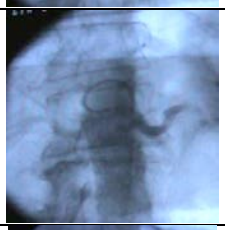
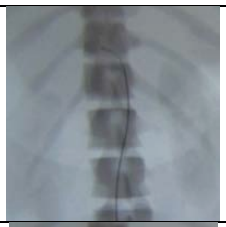
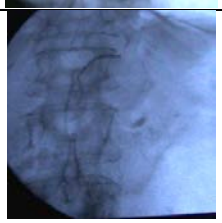
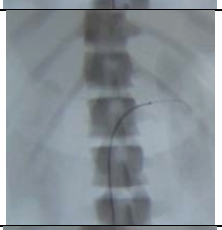
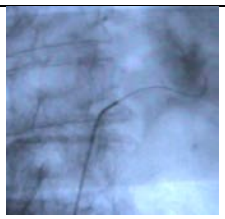
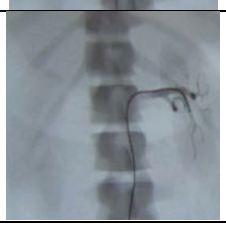
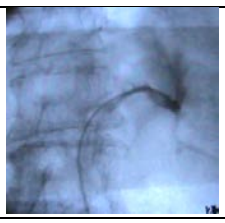
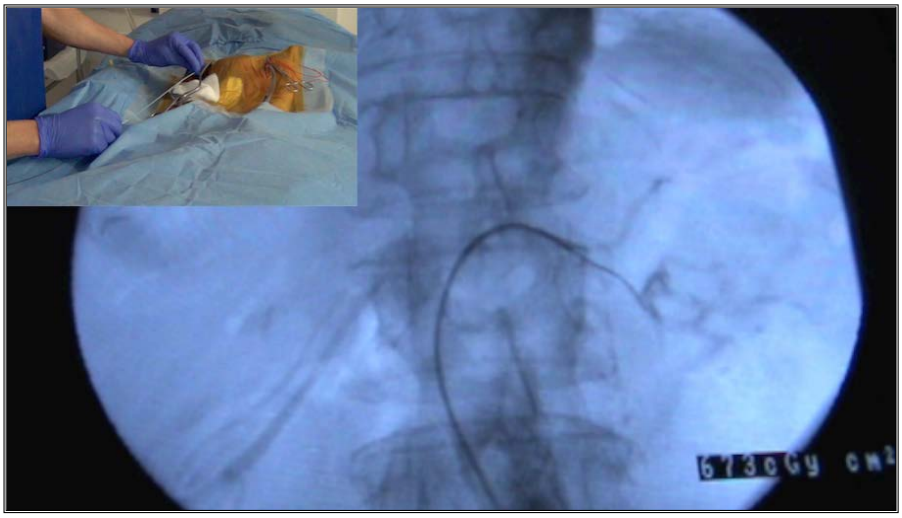
Virtual Reality Simulator (VRS)	Procedure Step	Pulsatile Human Cadaver Model (PHCM)
	**Step 1.** Candidate inserts a standard J wire	
	**Step 2.** Candidate inserts a 4Fr Pigtail catheter and positions it above the level of the renal arteries	
	**Step 3.** Candidate hand injects 10mls of IV contrast to achieve an aortic angiogram that adequately demonstrates the left renal artery	
	**Step 4.** Candidate exchanges the pigtail catheter for a 4 Fr Cobra catheter	
	**Step 5.** The cobra catheter is withdrawn until it engages in the left renal artery. Candidate injects a small amount of contrast to confirm position before advancing the hydrophilic wire	
	**Step 6.** Cobra catheter is advanced over the hydrophilic wire, and a confirmatory left renal angiogram is taken	

Figure 32. Screen shot of the edited video performances in the trail of construct validity. Note the 'hands' screen minimised at the top left corner of the fluoroscopy screen, as the candidate attempts to access the renal artery.



5.3.14.1 Randomisation of Videos

The videos were randomly ordered prior to analysis.

Each video was placed in order according to candidates UTN. Using a computer based programme (www.random.org) a random number sequence was generated from 1-23. Videos were re-ordered according to the random sequence.

In addition videos were edited of all footage, which might identify individuals before being scored.

5.3.15 Scoring Video Performances

Candidates' video performances were scored using a previously validated scoring tool for technical skills (Martin et al 1996). The present study modified the scoring tool in a similar fashion to previous authors, who have used the same 'modified' scoring tool for assessing endovascular procedures. This is discussed in section 1.10.5.

5.3.15.1 Quantitative Parametres.

Three quantitative measurements were recorded during each procedure:
Each candidate's performance was timed using a standard stopwatch. Candidates were permitted a maximum of ten minutes to attempt the index procedure. Candidates were not permitted to see the time during their procedure, this was to try and promote their 'standard practice', and discourage candidates from 'rushing against the clock'. An independent observer also recorded the volume of intravenous contrast used by each candidate (in milliliters). The duration of fluoroscopy was also recorded. This was recorded by an independent observer on a standard stopwatch.

5.3.15.1 A Modified Scoring Tool for Assessing A Basic Endovascular Procedure: Cannulation of the left renal artery and confirmatory angiogram from access in the right femoral artery.

The index procedure was broken down into sixteen procedural steps (Appendix 23) and candidates scored one point for each step that was completed successfully. Missed steps, or having to ask faculty a question, resulted in a zero score for that step, even if it was completed satisfactorily after asking the question.

The Global Rating Score (GRS) contained six items, similar to Hislop and co-workers (Hislop et al 2006). Their category entitled "Use of assistants" was removed from the present study because candidates were encouraged to perform the procedure independently. This was to avoid the chance of an assistant influencing the candidates performance in any way. This modified scoring tool has

been shown to demonstrate construct validity, and it has been adapted for use in competence testing in the EBSQ-VASC exam (Berger et al 2010). The GRS gave candidates a maximum score out of thirty (Appendix 23).
Finally, scorers had the opportunity to rate the overall performance, answering the following question:

Would you feel confident in allowing this trainee to perform this procedure, under supervision in the OR? Yes / No.

It was agreed that any disagreement between scorers would be considered a lack of agreement, and therefore a 'borderline' pass.
Each candidate performance resulted in three scores: The Task Specific Checklist (TSC), Global Rating Score (GRS) and the Overall Procedure Score (OPS).

5.3.15.2 Blinded Scorers

Two consultant interventional radiologists, who are endovascular experts (see Appendix 6) volunteered to score the video performances. Neither of these practitioners had been involved in this trial of construct validity at any stage.
They were blinded to the experience status of the operator.

5.3.15.2 Practice Scoring – Establishing Standards

To ensure both scorers understood the scoring procedure (Appendix 23), they were initially shown a compilation of clips from ten videos of edited performances of the index procedure being performed on the PHCM. These performance clips represented a mixture of abilities, from novice to expert. These clips also showed each individual step of the procedure being performed, again with varying abilities. The two blinded scorers openly discussed these videos, to establish joint standards of scoring that they were both in agreement with.

Following this practice scoring session, the blinded scorers scored the videos independently in their own time.

5.4 Results

All data generated from the construct validity trial was tabulated onto excel spread sheets (Microsoft excel™). Mean, median and modal values were extracted in standard fashion.

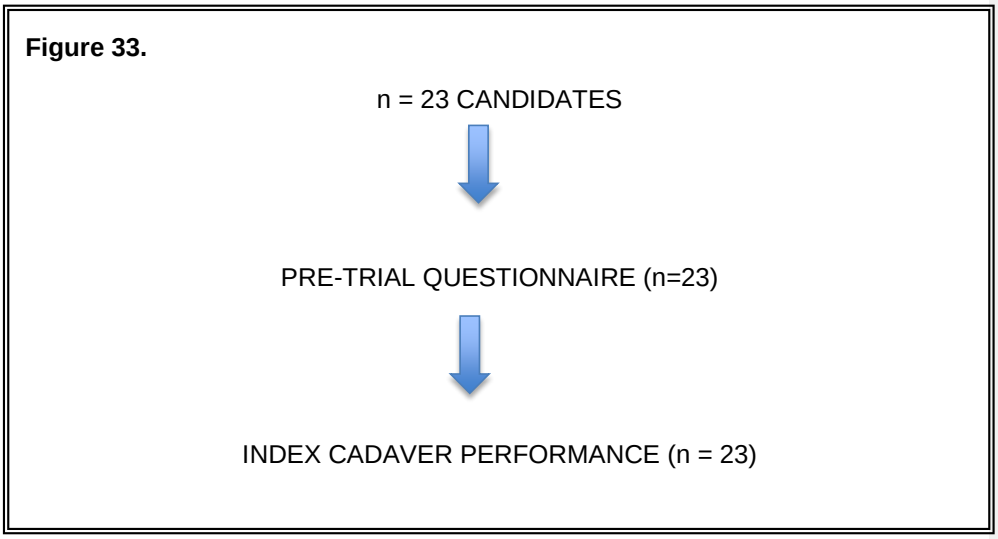
Statistical analysis was undertaken using the Statistical Package for the Social sciences version 19 (SPSS, Chicago). Cronbach's alpha was used as a measure of inter-rater variability.

Advice was sought from a medical statistician at Newcastle University for the most appropriate statistical tests when analyzing the trial data. Comparing both quantitative and clinical performance scores a 1-way ANOVA test was used, with Tukey and Bonferroni post-hoc tests. When comparing candidates satisfactory performances (6.5.4.3) a 2-proportions test of between group difference was used. For all comparisons a p-value of <0.05 was considered to be significant.

5.4.1 Trial Flow Chart

Figure 33 shows a flow chart of the Trial of Construct Validity.

Figure 33.



5.4.2 Candidate Demographics

Twenty three candidates attended for the PHCM construct validity trial. All recruited candidates completed their pre-trial questionnaire, and all candidates attempted the index cadaver performance.

These 23 candidates displayed the following demographics (Table 45, Table 46)

Table 45. The PHCM Trial of Construct Validity Candidate Demographics

Demoomgraphic	Candidate
Seniority	7 consultant interventional radiologists 4 senior trainees (3 vasc surgery, 1 radiology) 12 junior trainees (< FY2) †
Endovascular Experience*	Expert n = 7 Intermediate n = 4 Low Novice n = 12

† Foundation Training level 2
*See Appendix 6

Table 46. The PHCM Trial of Construct Validity Candidate Demographics

Demographic	Expert (E)	Intermediate (I)	Novice (N)	Proportions test of between group difference[Ψ] (P)
Number	7	4	12	
Wear glasses	Yes n = 0 No n = 7	Yes n = 0 No n = 4	Yes n = 1 No n = 11	E vs I ns*
				E vs N ns
				I vs N ns
Handedness	Left n = 1 Right n = 6	Left n = 0 Right n = 3	Left n = 0 Right n = 12	E vs I ns
				E vs N ns
				I vs N ns
Play musical instrument	Yes n = 4 No n = 3	Yes n = 2 No n = 2	Yes n = 6 No n = 6	E vs I ns
				E vs N ns
				I vs N ns
Ability to type	Yes n = 7 No n = 0	Yes n = 4 No n = 0	Yes n = 12 No n = 0	E vs I ns
				E vs N ns
				I vs N ns
Play video games regularly	Yes n = 1 No n = 6	Yes n = 1 No n = 3	Yes n = 7 No n = 5	E vs I ns
				E vs N ns
				I vs N ns
Prev VR endovascular training	Yes n = 4 No n = 3	Yes n = 3 No n = 1	Yes n = 0 No n = 12	E vs I ns
				E vs N p=0.009
				I vs N p=0.007
Prev cadaver endovascular training	Yes n = 0 No n = 7	Yes n = 0 No n = 4	Yes n = 0 No n = 12	E vs I ns
				E vs N ns
				I vs N ns
Prev cadaver training (any)	Yes n = 7 No n = 0	Yes n = 4 No n = 0	Yes n = 12 No n = 0	E vs I ns
				E vs N ns
				I vs N ns
	n = 7 Undergraduate anatomy n = 1 PCNL course[†]	n = 4 Undergraduate anatomy n= 1 Cadaver trauma course n = 1 Advanced vascular skills course	n = 12 Undergraduate prosection	

*Not statistically significant
[†] Cadaveric Percutaneous Nephrolithotomy Course
[Ψ] Fishers exact test

5.4.3 Procedures Completed

The index procedure was deemed completed when a candidate demonstrated angiographic evidence of target vessel cannulation (Figure 3, figure 4)

~~Only one candidate was not able to complete the index procedure~~ All expert and novice candidates completed the index procedure but only one novice was successful (Table 47).

Table 47. Completed Index Cadaver Performances

	Expert (E) (n=7)	Intermediate (I) (n=4)	Novice (N) (n=12)	Proportions test of between group difference (P) $^{\Psi}$
Procedure attempted (%)	n = 7 (100)	n = 4 (100)	n = 12 (100)	ns*
Procedure completed (%)	n = 7 (100)	n = 4 (100)	n = 1 (8)	E vs I ns
				E vs N p=0.000
				I vs N p=0.003

*Not statistically significant

$^{\Psi}$Fishers exact test

5.4.4 Quantitative Parameters

Three quantitative parameters were recorded during the candidates' index performances.

Expert level candidates took a mean of 6 minutes 7 (367 seconds) using a mean of 19.29 ml of contrast and 3 minutes 29 (209 seconds) of fluoroscopy to complete the index procedure.

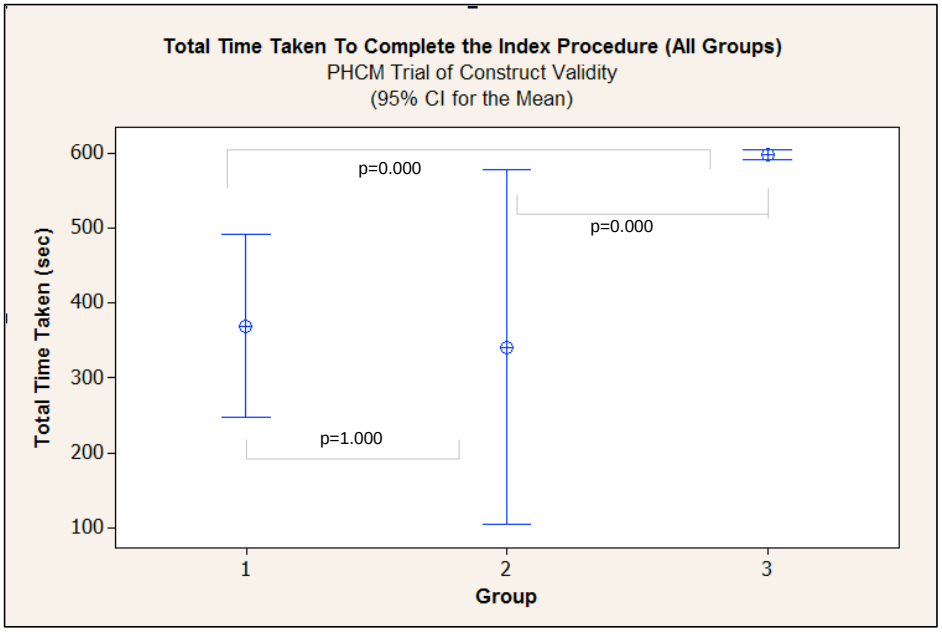
Intermediate level candidates took a mean of 3 minutes 41 (341 seconds) using a mean of 19 ml of contrast and 3 minutes 48 (228 seconds) of fluoroscopy. Finally, novice level candidates took a mean of 9 minutes 57 (597 seconds) using a mean of 23.17 ml of contrast and 4 minutes 35 (275 seconds) of fluoroscopy to complete the index procedure.

Details of all index procedure quantitative parameter scores are shown in Appendix 30. Figures 34, 35 and 36 display these values graphically. Table 48 provides a summary of these measures taken suring the PHCM construct validity study.

Only total time showed any significant difference between the three groups; expert candidates were quicker (p=0.000) than novices, as were the intermediate level trainees (p=0.000). However, there was no statistically significant variations in the total duation of fluoroscopy of volume of contrast required comparing all three groups (Table 48).

Key. 1 = Expert 2 = Intermediate 3 = Novice

Figure 34. Total Time Taken to Complete the Index Procedure



p value = One way ANOVA Bonferroni post hoc test

Figure 35. Average Total Fluroscopy Time Required Per Group

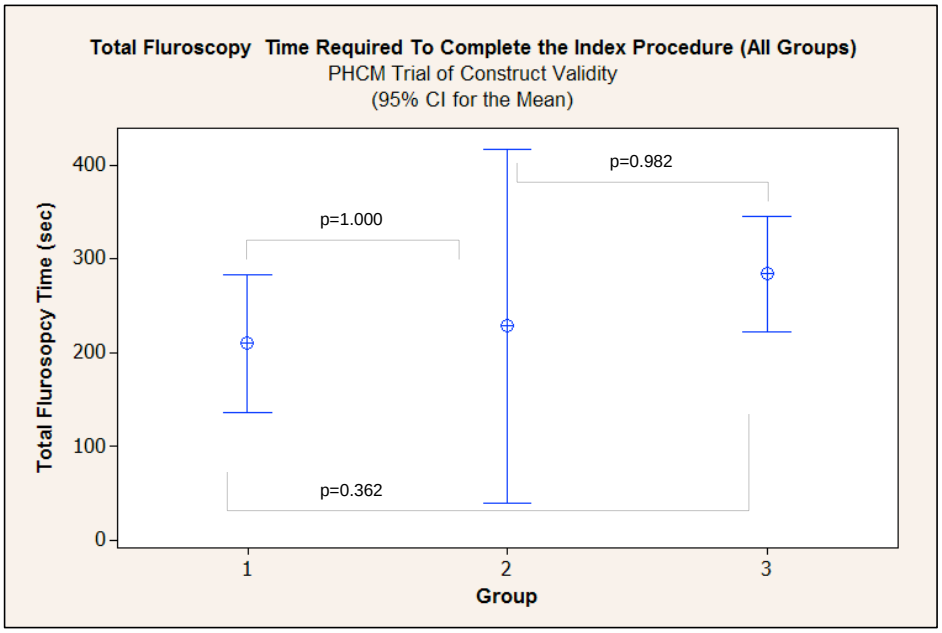
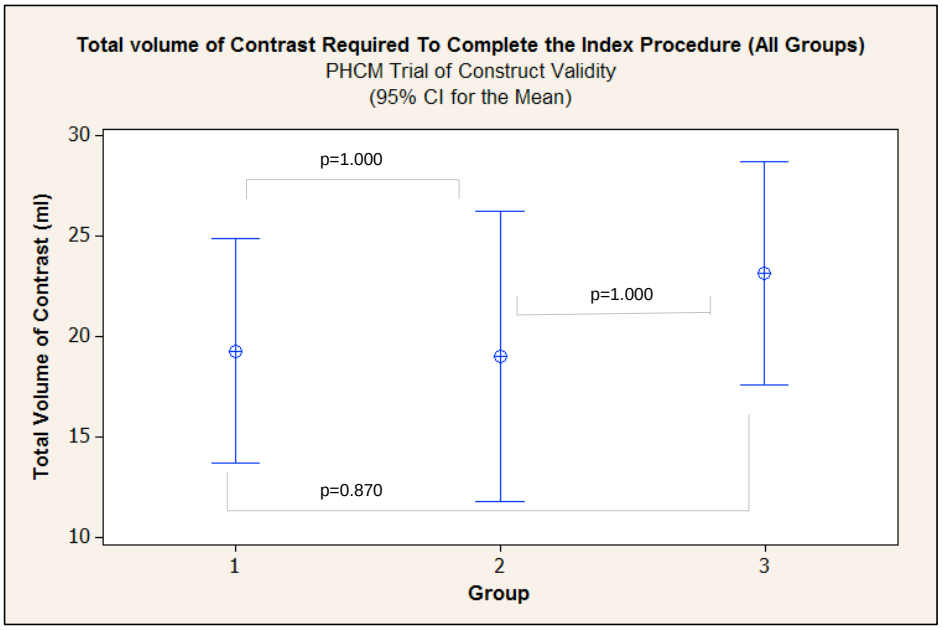


Figure 36. Total Volume of Contrast Required Per Group



p value = One way ANOVA Bonferroni post hoc test

Table 48. Summary of Quantitative Measures Taken During Construct Validity Trial

Quantitative parameterre	Expert (E)	Intermediate (I)	Novice (N)	One way ANOVA Bonferroni (Tukey)
Total Procedure time - sec*	368.29 (131.69)	340.50 (148.59)	596.92 (10.68)	E vs I p=1.000 (p=0.882) E vs N p=0.000 (p=0.000) I vs N p=0.000 (p=0.000)
Fluroscopy time - sec*	209.43 (79.76)	227.75 (118.46)	274.92 (98.42)	E vs I p=1.000 (p=0.950) E vs N p=0.362 (p=0.260) I vs N p=0.982 (p=0.583)
Contrast used - ml*	19.29 (6.07)	19.00 (4.55)	23.17 (8.76)	E vs I p=1.000 (p=0.998) E vs N p=0.870 (p=0.533) I vs N p=0.1.000 (p=0.609)

***Mean (standard deviation)
Statistically significant results

5.5.4 Clinical Performance Scores

Each attempt at the index procedure, was scored by two blinded expert scorers; this gave each candidate performance six individual scores (three from each expert scorer): a score for the TSC, GRS, and an OPS. These scores were combined to give average scores, which are used for all subsequent analysis.

5.5.4.1 PHCM Construct Validity Clinical Performance Scores - Table

All twenty-three candidates attempted the index procedure on the PHCM. Their clinical performance scores are displayed in table 49, alongside their satisfactory performance grade, which has been colour coded (discussed in further detail in 5.5.4.3). Measuring inter-rater variability, Cronbachs alpha was 0.966 indicating strong agreement between our two blinded scorers.

The average OPS for the expert candidates' was 43.00 (TSC 15.00, GRS 27.21). The average OPS for the intermediate candidates was 39.63 (TSC 15.00, GRS 24.63). The average OPS for the novice candidates was 19.88 (TSC 8.75, GRS 11.13). There is a significant difference between the OPS for the expert and novice candidates (p=0.000). Likewise a difference is also seen comparing intermediate level trainees to the novice candidates (p=0.000). However, there was no statistically significant difference seen between the expert and intermediate level candidates (Table 50).

The mean scores for expert, intermediate and novice candidate's performances are displayed graphically in section 5.5.4.2

Table 49. Mean Blinded Clinical Scores (TSC, GRS, OPS) and Procedure Satisfactory Score, for Candidates Performing the Index Training Procedure on PHCM – Construct Validity Trial.

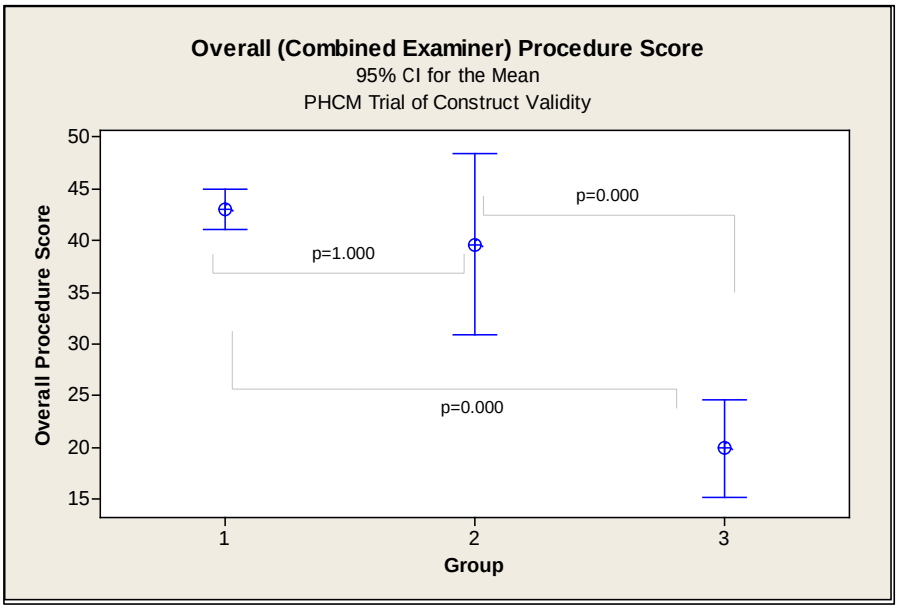
Seniority	Candidate	Task Specific Checklist (TSC)	Global Rating Score (GRS)	Overall Procedure Score (OPS)	Pass? Examiner 1	Pass? Examiner 2
Expert	Cand 1	15.50	28.50	44.00	Pass	Pass
	Cand 2	16.00	27.50	43.50	Pass	Pass
	Cand 3	15.00	24.00	39.00	Pass	Pass
	Cand 4	16.00	26.50	42.50	Pass	Pass
	Cand 5	16.00	29.50	45.50	Pass	Pass
	Cand 6	16.00	28.50	44.50	Pass	Pass
	Cand 7	16.00	26.00	42.00	Pass	Pass
Intermediate	Cand 8	15.50	29.00	44.50	Pass	Pass
	Cand 9	14.00	18.50	32.50	Pass	Pass
	Cand 10	15.00	23.00	38.00	Pass	Pass
	Cand 11	15.50	28.00	43.50	Pass	Pass
Novice	Cand 12	6.00	7.00	13.00	Fail	Fail
	Cand 13	4.50	6.50	11.00	Fail	Fail
	Cand 14	14.00	16.50	30.50	Pass	Pass
	Cand 15	14.00	18.00	32.00	Pass	Pass
	Cand 16	11.00	14.50	25.50	Pass	Fail
	Cand 17	9.50	12.50	22.00	Pass	Fail
	Cand 18	9.50	12.00	21.50	Fail	Pass
	Cand 19	5.50	6.00	11.50	Fail	Fail
	Cand 20	9.00	13.00	22.00	Fail	Pass
	Cand 21	9.50	13.50	23.00	Pass	Fail
	Cand 22	7.50	8.00	15.50	Pass	Fail
	Cand 23	5.00	6.00	11.00	Fail	Fail

Key Agreed Failure Agreed Pass Borderline pass

5.5.4.2 PHCM Construct Valiity Clinical Performance Scores – Graphs

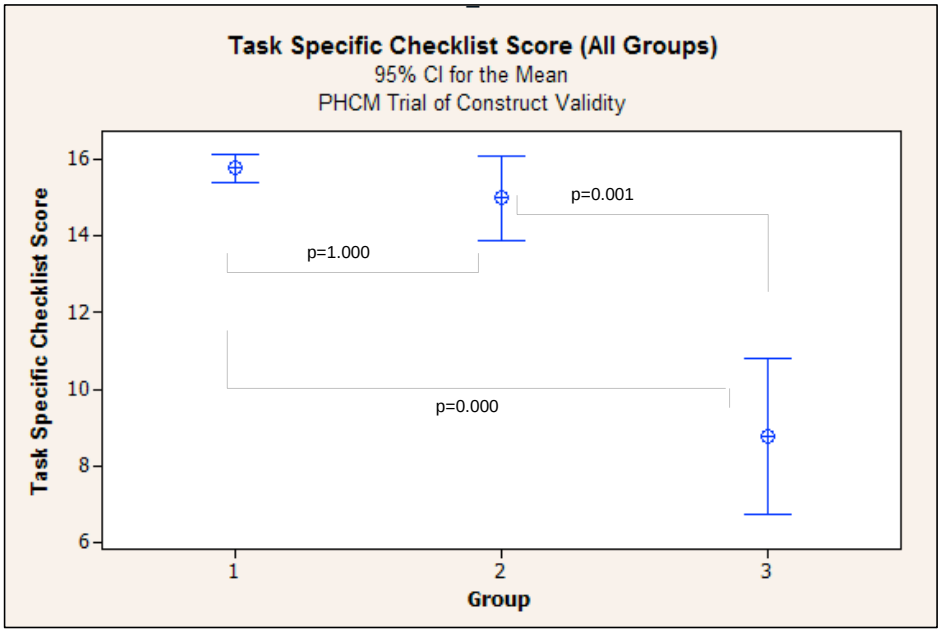
Key. 1 = Expert 2 = Intermediate 3 = Novice

(i) Overall (Combined Examiner) Procedure Score

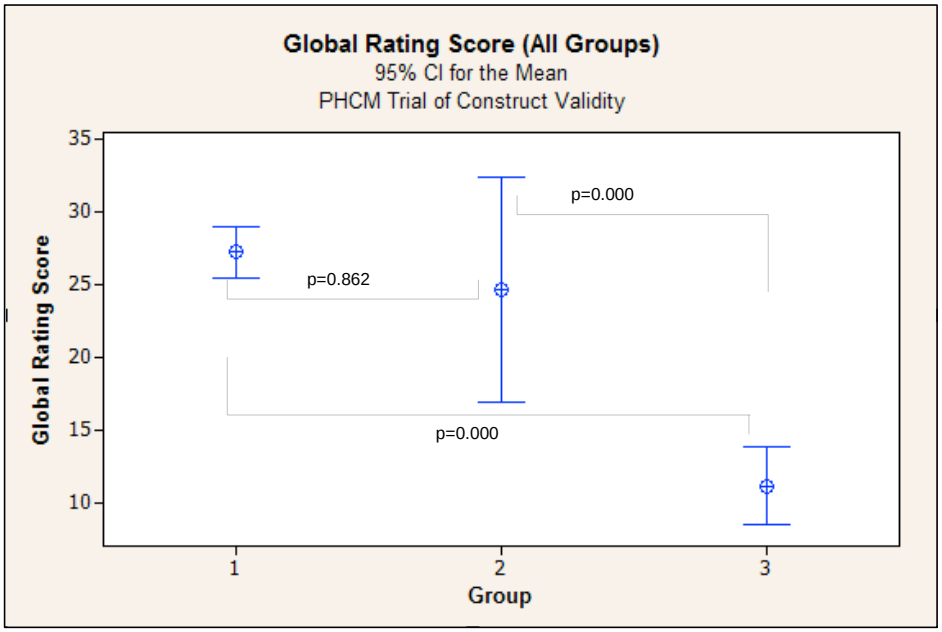


p value = One way ANOVA Bonferroni post hoc test

(ii) Combined Examiner Task Specific Checklist Score



(iii) Combined Examiner Global Rating Score



p value = One way ANOVA Bonferroni post hoc test

Table 50. Summary of Clinical Performance Scores (OPS, TSC, GRS), All Groups (Expert, Intermediate, Novice):Construct Validity Trial

Clinical Performance Score	Expert (E)	Intermediate (I)	Novice (N)	One Way ANOVA Bonferroni (Tukey)
Overall Procedure Score	43.00 (0.4)	39.63 (1.87)	19.88 (2.12)	E vs I p=1.000 (p=0.650) E vs N p=0.000 (p=0.000) I vs N p=0.000 (p=0.000)
Task Specific Checklist	15.79 (0.71)	15.00 (4.85)	8.75 (5.54)	E vs I p=1.000 (p=0.862) E vs N p=0.000 (p=0.000) I vs N p=0.001 (p=0.001)
Global Rating Score	27.21 (3.22)	24.63 (4.26)	11.13 (7.43)	E vs I p=0.877 (p=0.536) E vs N p=0.000 (p=0.000) I vs N p=0.000 (p=0.000)

*****Mean (standard deviation)

Statistically significant results

5.5.4.3 PHCM Construct Validity Trial: Satisfactory Performance

Both expert scorers rated each video performance to indicate if it represented a satisfactory performance that they would have been happy supervising in the operating room. These scores are displayed in a 'traffic light' colour system in Table 49, with green indicating a pass that both examiners agreed upon, red indicating an agreed failure, and orange, where no agreement was agreed, which is considered to represent a borderline pass. Visually it is seen that all of the expert and intermediate candidates were considered satisfactory (green), but only two novice candidates recorded similarly acceptable performances (p=0.000). Four novice candidates were agreed failures (p=0.014) and seven candidates recorded borderline scores (p=0.001)*

[*2 proportions test of between group difference.]

5.5 Discussion

There were no differences between the training groups in terms of their baseline demographics except for previous exposure to endovascular VRS training, where both the intermediate and expert groups had significantly more exposure (p=0.009 and p=0.007 respectively) (Table 46). All intermediate (p=0.003) and expert (p=0.000) candidates were able to complete the index procedure, but only one novice candidate was able to complete it (p>0.05) (Table 47)**.**

Of the quantitative parameters measured during each index performance, both expert and intermediate level candidates performed significantly quicker than the novices (p=0.000). No difference was seen between intermediate and expert groups. Fluoroscopy time and contrast volume used were not significantly different between any of the three groups (Table 48)

Quantitative measurements are poor indicators of performance quality. Candidates could rush a procedure to record a faster performance, fluoroscopy time can be saved through un-screened maneuvers and many novice candidates used low volumes of contrast, simple because they did not progress to the stage of the procedure where further contrast was required.
Caution must be used when drawing conclusions from analysis of qualitative parameters, especially when considered in isolation, as they can be misleading.

Using the modified Reznick scoring system, the two blinded expert video scorers showed strong agreement (Cronbachs Alpha 0.966). TSC, GRS and OPS were significantly superior in the expert and intermediate groups when compared to the novices. No significant difference was observed between the intermediate and expert groups (Table 50).

Finally, a significant difference was noted between those expert and intermediate candidates who recorded ‘satisfactory’ performances, when compared to the

novices. Again, no difference was seen between the intermediate and expert candidates (Table 49).

The failure to distinguish between intermediate level candidates and experts may be due to a number of reasons. Within the local Northern training deanery there are very few 'intermediate' level endovascular candidates. Numerous endovascular experts were invited to take part, but owing to their busy working schedules, only seven experts and four intermediate candidates were available to participate. The small number of candidates is acknowledged to be a study limitation that could be addressed by extending recruitment outside of the deanery in future studies. The index procedure upon which the trial of construct validity is based was a simple angiogram. Angiography is possibly less discriminatory of candidate's expertise as it requires less technical steps compared to a stenting or angioplasty procedure. However, it was not possible to reliably repeat either a stenting or angioplasty procedure in the PHCM, and hence angiography was used as the index procedure.

5.6 Conclusion

The present study has demonstrated that the PHCM has construct validity in differentiating between novice candidates and both intermediate level and expert practitioners. No significant differences were seen between intermediate level trainees and expert practitioners. However, further work is required to expand the functionality of the PHCM and through performance of a more complex procedure, such as angioplasty, intermediate level practitioners might be better discriminated from their expert counterparts.

Chapter 6

A Fresh Frozen Pulsatile Human Cadaver Model for Training Endovascular Practitioners. A Trial of Educational Impact

Abstract

Aim

To compare the effectiveness of high fidelity virtual reality simulation (SVR), a pulsatile fresh frozen human cadaver model (PHCM) and traditional lecture training (TLT) for training basic endovascular skills.

Methods

62 novices were recruited. Following an introductory lecture/demonstration Group 1 (n=12) attempted left renal artery angiogram (RAA) on PHCM, Group 2 (n=12) on SVR. Group 3 (n=24) received TLT (from an endovascular expert) on basic endovascular practice. Group 4 (n=24) received no additional training (NAT).

Candidates in group 1 and 2 repeated 8 attempts at RAA under exam conditions with 1 hour between attempts. Half of the TLT candidates were randomized to attempt RAA on SVR, the other half on PHCM. Half of the NAT group attempted RAA on SVR the other half on PHCM. All performances were recorded. Group 2 candidates 'crossed-over' and attempted RAA on PHCM and Group 1 trained candidates 'crossed over' onto SVR.

Videoed performances were randomized and scored by two blinded experts using a validated scoring tool.

Results

VRS trained candidates improved their overall performance score (OPS) (p=0.000), total procedure time (TPT)(p=0.000), fluoroscopy time (FT) (p=0.000) and volume of contrast used (VOC) (p=0.000) when performing RAA over the 8 attempts. PHCM candidates improved their OPS (p=0.000), TPT (p=0.000), FT (p=0.026), and VOC (p=0.008). VRS trained candidates demonstrated minimal improvement beyond their second attempt. PHCM improvement was slower with significant improvements observed out to performance 7. Both training regimes demonstrated transferability during cross-over performances on the alternate model. TLT shows a benefit over NAT for candidates attempting RAA on VRS:

9 TLT candidates completed RAA versus 2 NAT (p=0.012). No improvement was seen comparing TLT and NAT in those candidates attempting RAA on PHCM.
A trend towards enhanced overall procedure score (OPS) was seen in TLT candidates versus NAT on VRS (27.92 versus 20.54), (p=0.081). TLT conferred no benefit over NAT when candidates attempted RAA on PHCM (p=1.000)

Conclusion

A PHCM is a feasible model for training basic endovascular skills. It improved trainees efficiency and seems at least comparable to VRS. VRS training did lead to enhanced performance on PHCM (a 'pseudo-patient'), supporting the role of SVR training prior to real patient contact. TLT confered limited additional value in candidates performance on a PHCM, but did lead to improvements on VRS, supporting the role of lectures prior to novices beginning basic endovascular skills training on VRS.

Chapter 6

6.0 A Fresh Frozen Pulsatile Human Cadaver Model for Training Endovascular Practitioners. A Trial of Educational Impact~~fficacy~~

6.1 Introduction

Following on from the success of both the trial of face validity (Chapter 4), and construct validity (Chapter 5) further experiments were undertaken to establish the training potential of the PHCM.

6.2 Aims and Hypothesis

It is hypothesised that dedicated training on the PHCM will improve a candidate's technical ability. It is anticipated that this improvement will be comparable to training on a VRS. Furthermore it is postulated that an additional traditional didactic lecture will add little to a candidate's performance.

The aim of this trial was to establish the ~~efficacy~~ educational impact of the PHCM as a training model for teaching endovascular skills. The trial aimed to compare the effect of training on the PHCM compared to training on a VRS. Finally the efficacy of training on a PHCM and VRS was compared to a traditional didactic lecture.

The rationale for adding a didactic lecture arm was to establish what benefit is being achieved from expensive simulators and what benefit (if any) traditional didactic lectures can offer in teaching technical skills in endovascular intervention.

6.4 Methods

The methods of the trials of ~~efficacy~~ educational impact are discussed below

6.4.1 A Fresh Frozen Pulsatile Human Cadaver Model: A Trial of ~~Efficacy~~Educational Impact

This trial was designed to determine the efficacy of the PHCM as a model for training endovascular practitioners.

With the development of a novel training model (PHCM), the study wanted to establish if it was able to train endovascular techniques effectively when compared to both traditional didactic lectures and a VRS.

6.4.1.1. Efficacy

Efficacy is the "the ability of an intervention to produce the desired beneficial effect" (www.thefreedictionary.com). In the case of our PHCM, the desired beneficial effect was improved endovascular technique following dedicated practice.

6.4.2 Inclusion Criteria

- Practitioners with no endovascular experience – as in 5.3.2, endovascular novices (Appendix 6) were invited to take part.
- Medical students from Newcastle University from year groups one to five
- Foundation trainees and Core Trainees (medical and surgical) from the Northern Deanery.

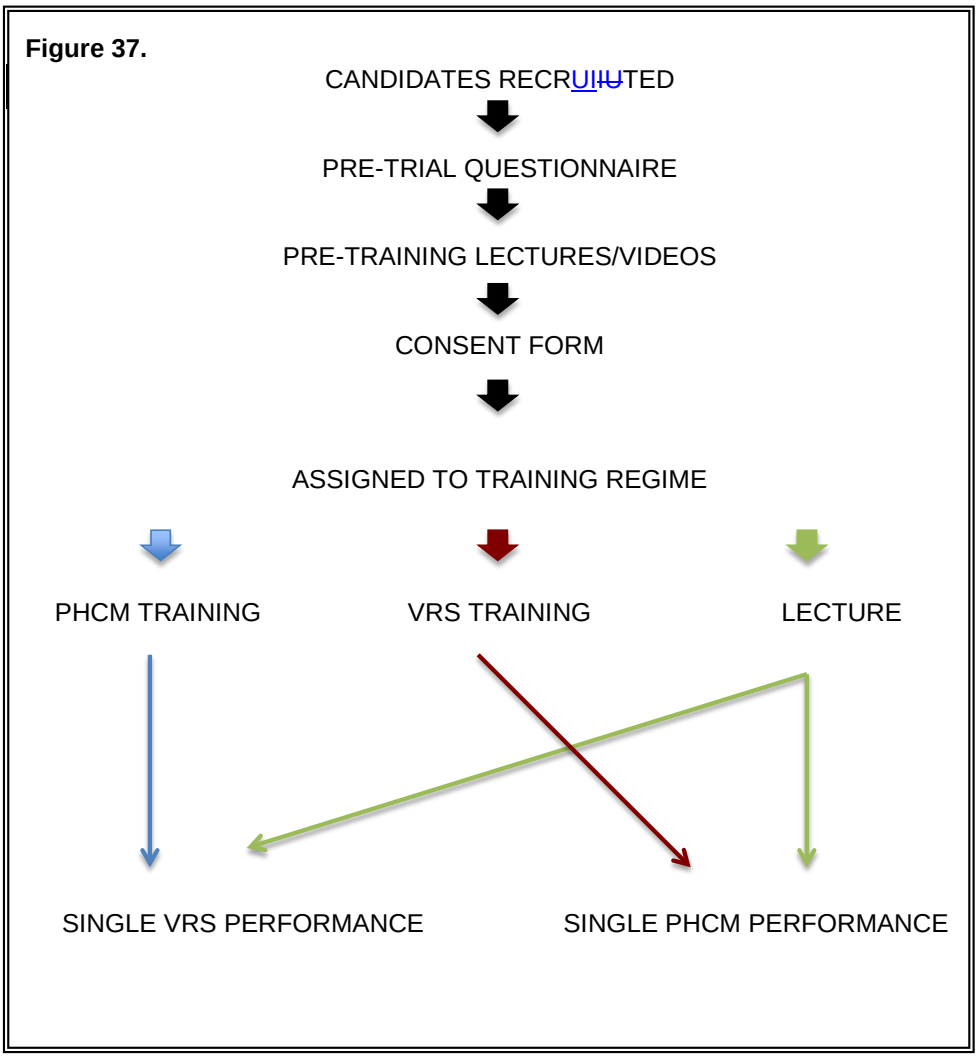
6.4.3 Exclusion Criteria

- Non-medically trained candidates were not invited to take part.
- Candidates more senior than CT2 grade were excluded from the trial owing to the potential of their prior exposure to endovascular practice

6.4.4 Algorithmic Overview of the PHCM Trial of Efficacy

Figure 37 shows an algorithmic overview of the PHCM trial of efficacy.

Figure 37.


CANDIDATES RECRUITED
PRE-TRIAL QUESTIONNAIRE
PRE-TRAINING LECTURES/VIDEOS
CONSENT FORM
ASSIGNED TO TRAINING REGIME
PHCM TRAINING
VRS TRAINING
LECTURE
SINGLE VRS PERFORMANCE
SINGLE PHCM PERFORMANCE

6.4.5 Candidate Recruitment

Candidates were recruited as volunteers to attend a training course experiment designed to introduce the candidate to the fundamentals of endovascular practice. Candidates were aware that the training course may involve human cadavers, a lecture based training programme or training on a high fidelity virtual reality simulator. Candidates were aware that the course was part of an experiment, but that it was primarily designed to give training in endovascular practice.

A generic email invitation to attend a training courses was made to medical students, foundation and core trainees. These candidates comprised a high percentage of endovascular novices and showed relative availability compared with more senior practicing clinicians.

Following permission form the Chair of the Board of Medical Studies, medical students were invited to attend these courses, as long as they were run outside of their undergraduate clinical commitments. Similarly, permission was successfully sought from both the Foundation and Core Trainee Heads of Department, but trainees had to ensure they had arranged official annual or study leave and covered all clinical commitments before attending.

Novice candidates were recruited to avoid prior exposure/experience having an effect on a candidates training. As novices, all candidates were starting from the same point, and measurable improvement could therefore be better attributed to the training model/technique, rather than prior confounding training/exposure.

6.4.6 Pre-Trial Questionnaire

All candidates completed a pre-trial questionnaire (Appendix 3). This was the same questionnaire that was used in the trial of face validity (4.3.8). Again it was important to establish certain candidate demographics, in order to establish if the selected training groups were equal.

6.4.7 Introductory Lectures

Despite this trial being run over several sessions, and candidates receiving different training regimes, all candidates received the exact same introductory lectures, to ensure pre-training preparation was the same. Lectures were delivered using a standard PowerPoint™ format. The lectures lasted, in total, twenty five minutes. These lectures were delivered by the PI (Craig Nesbitt). As in 5.3.6, these lectures were basic, to introduce candidates (often medical students) to the concept of endovascular intervention.

6.4.7.1 The Basics

This generic introductory lecture covered the following points:

- An explanation of what endovascular practice is
    - o Basic endovascular concepts:
    - Seldinger access
    - Wires & catheters
    - Angiograms, stenting and angioplasty
- Brief mention of the background to the research project
    - Challenges of training in endovascular practice
- Introduction to the different training methods for teaching endovascular practice
    - Including VRS, synthetic models, cadavers and traditional lectures
- The principle behind the trial of efficacy
    - A desire to compare different strategies

6.4.7.2 Details of the Training Models

This lecture covered important details relating to the training models. The following points were covered:

- An explanation of how the virtual reality endovascular simbionix angiomentor™ simulator works
    - Including images of the simulated endovascular sheath
- An explanation of how the PHCM works

- The principles behind traditional didactic lectures (Lecture trained candidates only)

6.4.7.3 Details of the Training Experiment

This lecture covered details of the training experiment itself. The following points were covered:

- Step by step explanation of the index training procedure (Figure 31)
    - Selective catheterisation and angiogram of the left renal artery from access in the right femoral artery
- The equipment that would be available when performing the index procedure (Figure 38, 39)
    - Candidates were shown these catheters and wires
- The desire to video record their performances (hands only) for analysis
- The need for written consent
    - Including candidates right to withdraw consent at any stage and for up to one week following the trial
- That performances were anonymised, and ability would in no way affect their clinical practice
- That question could be asked during a training performance but candidates were encouraged to perform as independently as possible.
- That feedback would not be offered between training procedures, but would be offered once the trial performances were complete

6.4.7.4 Videos of the Index Training Procedure

All candidates were shown an edited expert performance of the index procedure being performed on both the PHCM and VRS. The videos contained expert commentary. These were the same videos used in the trial of construct validity (5.3.6.2)

6.4.7.5 Pre-Training Candidate's Questions

Candidates were permitted to ask questions. But care was taken to avoid providing any additional training that might unbalance candidate's pre-performance training/preparation.

6.4.8 Informed Consent

As above (5.3.7) all candidates signed a written form of consent to allow use of their videoed performances (hands only) for analysis.

6.4.9 Candidate Assignment

Candidates were recruited prospectively for each individual trial separately. Recruitment was voluntary. Candidates were not formally randomised to training regimes. This is discussed in further detail in the discussion (6.6)

6.4.10 Candidates Unique Training Number (UTN)

As in 4.3.7, candidates were identified with a unique training number (UTN). This number was used on all paper work related to that candidate, and was used to identify performances when recorded in the simulated theatre. Thus ensuring questionnaire responses and videoed performances could be analysed anonymously (Table 51a).

Table 51a. Unique Training Numbers for Candidates Performing in the PHCM Trial of Efficacy

PHCM	VRS	Lecture
C1	V1	L1
C2	V2	L2
C3 etc…	V3 etc…	L3 etc…

6.4.11 Index Training Procedure

The same index training procedure was repeated during this trial of efficacy:
Cannulation of the left renal artery and confirmatory angiogram from access in the right femoral artery.
The individual steps of this procedure are shown previously in figure 31.

6.4.11.1 Recording Training Procedures

This has been previously detailed in 5.3.10

6.4.12 Training Regimes

Once candidates had completed their pre-trial questionnaire, undergone their pre-training lectures/videos, and signed a consent form they were assigned to a training programme.

6.4.12.1 PHCM

The PHCM was set up as described in Chapter 2. The simulated cadaver theatre set up, and candidate attire (including safety lead apron) was identical to that used in the face validity study. The equipment available to candidates was also the same as was used in Table 37 Procedure 1. The candidate's trolley was set up as shown in figure 38.

Upon entering the simulated cadaver theatre, candidates were all given a five-minute orientation. They were introduced to their radiographer, and shown how to work the C-arm. Candidates were shown the introducer sheath in the cadaveric right femoral artery, and familiarised themselves with the theatre trolley and equipment (figure 38). Candidates were shown the cameras that would be recording both their hands and the fluoroscopy screen, and encouraged to ignore these at all times. A trained independent facilitator acted as a theatre assistant. It was explained to candidates that this assistant would respond only to their instructions.

Following their orientation, candidates made their first video recorded attempt at the index procedure. As described later **(**6.4.13), they received no feedback during this attempt, and had ten-minutes to complete the procedure after which their attempt was brought to a stop and the video cameras switched off. Candidates were encouraged to perform independently without asking for help.
After completion of their first attempt, candidates were shown into an isolation room to prevent them observing other candidates' performances. They were permitted to undertake un-related academic work or watch a series of unrelated videos. After one hour, candidates were invited back into the cadaver simulated theatre to perform their second attempt. Conditions were identical to their first performance.

On each performance, a minimum of sixty minutes elapsed before the subsequent procedure was attempted. Candidates repeated this training regime until eight separate attempts at the index procedure had been video recorded.

6.4.12.1.1 Imaging

6.4.12.1.1 (i) The Siemens™ (Sire mobil compact) C-arm:
The same radiography equipment as used in Chapter 4 was available for this trial of efficacy. As described (4.3.10)

There were no provisions for subtraction images, or angiographic runs. Angiography was therefore simulated using hand injection of standard radiographic contrast (omnipaque Ltd™), which was diluted to a 70:30 mix with normal saline.

6.4.12.1.1 (ii) Manoeuvering the C-Arm:
Candidates were not expected (or scored) to manoeuvre the C-arm during their cadaver performances. The radiographer had been previously instructed to position the C-arm in an optimal location, and to respond instinctively only if a candidate was deemed to be potentially causing damage to the PHCM, such as struggling to negotiate a wire up the iliac artery without x-ray imaging. If a

candidate specifically requested the C-arm to move, then the radiographer would respond, but candidates were not assessed on positioning the C-arm.

This decision was made for two reasons. Firstly it was considered too complicated, on top of the performance, to expect novice candidates to position and adjust the C-arm. Secondly, it was an attempt to standardise the training regimes; in those candidates training on VRS, the image was always centered in an optimal location, and it was never necessary to alter the image. No marks were awarded for positioning the VR C-arm, thus ensuring equality between the two training models.

6.4.12.1.2 Deviation from the Standard Index Training Procedure

During the final day of the PHCM training experiment, the right common iliac artery became too challenging to safely negotiate the standard J-tip wire up into the aorta. The decision was made therefore to take this step from the procedure; an expert negotiated the J-wire into the aorta and candidates were instructed that their subsequent performances would begin with the J-wire already in-situ.
Candidates were permitted nine minutes and thirty seconds for these subsequent attempts.

To avoid scoring confusion, all candidates were awarded the point for inserting the Standard J-wire, so their maximum points available was the same as all other candidates. This is discussed in the limitations section (6.6.6)

Figure 38. PHCM Theatre Trolley

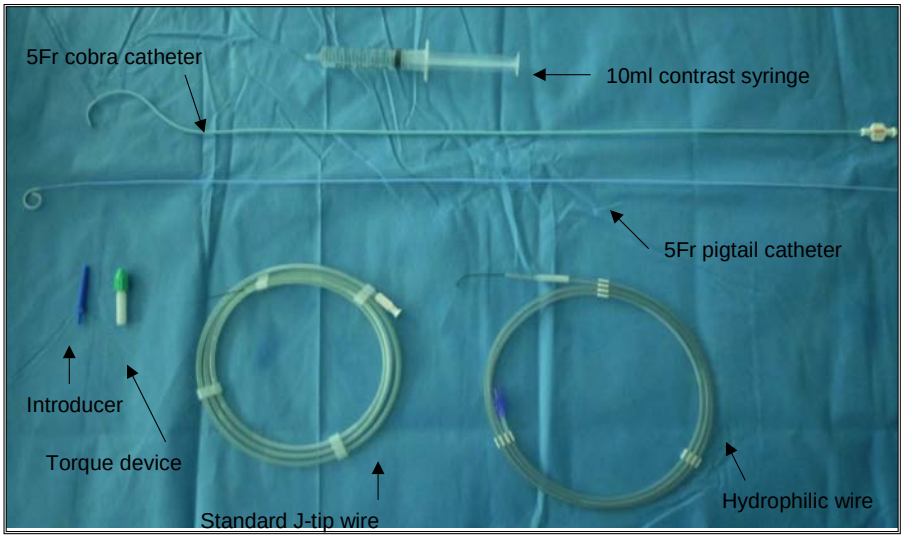
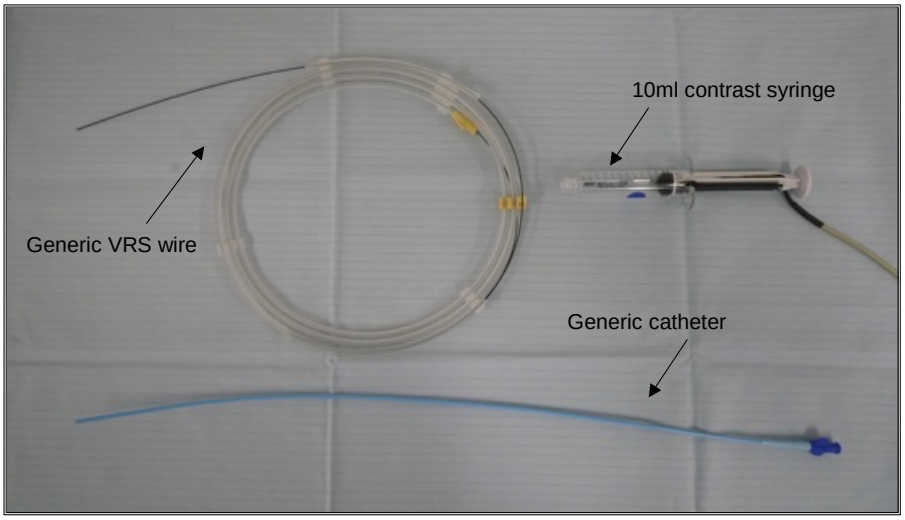


Figure 39. VRS Theatre Trolley



6.4.12.2 VRS

Candidates allocated to VRS training were taken to the simulated VR theatre. This was set up as described in Chapter 4 (4.3.11). Although the simbionix angiomentor is equiped with a wide range of catheters and wires, candidates were only permitted to select the same equipment that was offered to candidates who trainined on the PHCM (Table 37 Procedure 1) The VRS theatre trolley was set up as shown in figure 39.

As in 6.4.12.1 candidates received a five-minute orientation. They were shown how to record a real time fluoroscopy image, and allowed to take a closer look at the simulated endovascular sheath.

A demonstration was made to show candidates how, despite inserting apparently the same wire, it would appear on their fluoroscopy screen as the wire they had requested. The same was true for the catheter. This was especially important when candidates exchanged the pigtail for the cobra catheter, when the endovascular theatre assistant would simply hand the candidate back the exact same catheter.

As in the PHCM regime, candidates were shown and encouraged to ignore the recording cameras. The theatre assistant offered no constructive assistance unless prompted by the trainee.

The same conditions were followed for recording candidates index performance attempts with each candidate having ten minutes per attempt, and being isolated for sixty minutes between subsequent performances.

Candidates recorded eight attempts in total. No feedback was offered to candidates either during or between subsequent attempts.

6.4.12.2.1 Imaging

Candidates were only permitted to use the real time fluoroscopy setting, in keeping with the C-arm x-ray available in the PHCM regime. This is discussed in the discussion (6.6.7)

6.4.12.3 Lecture

Candidates allocated to the lecture training regime were shown into the NSTC lecture theatre. They received a traditional didactic lecture from an endovascular expert. No additional videos were shown.
The endovascular expert had observed the index procedure being performed in previous trials on both PHCM and VRS, but had not been involved in the trial design, training or subsequent video analysis.

The endovascular experts were given the following instruction to aid them in preparing their lecture

- All candidates would be low novice endovascular practitioners (predominantly medical students)
- The group size would be approximately twenty four
- The aim was to teach them to perform the index training procedure (6.4.11)
- Following this lecture candidates would be assessed performing the index training procedure on either the VRS or PHCM

The expert lecture was delivered in a standard powerpoint™ format. It covered the following points:

- Relevant anatomy, including x-ray images
- Key endovascular concepts were reaffirmed
    - Including the wires and catheters required for the index procedure*
- The index training performance was broken down into its constituent steps, and each was described in detail:
    1. Undertaking an adequate angiogram
    2. Cannulating the renal artery

3. Advancing the cobra catheter

- Hints and tips from real patient experience on how to complete each stage safely
- Common mistakes and how to avoid them

Candidates were encouraged to ask questions throughout the lecture.
During the lecture candidates were shown and allowed to handle the wires and catheters they would be using to perform the index training procedure.

6.4.12.3.1 Randomisation

Following the expert didactic lecture candidates were randomised to undertake their single simulated performance on PHCM or VRS. They were randomised using the same blocked technique previously described (4.3.6)

6.4.12.4 PHCM and VRS Cross-Over Performances

Those candidates who had completed a full training programme on both the PHCM and VRS were then invited to complete one further single performance of the index procedure.

Candidates who had trained on PHCM attempted the index procedure on the VRS. Candidates who had trained on VRS completed one attempt at the index procedure on the PHCM.

This was to determine if the training that the candidates had received on their respective simulators would transfer into the other model, as demonstrated by a superior performance on that simulator (PHCM or VRS), when compared to their novice counterparts at the beginning of their respective training regimes (on PHCM and VRS respectively).

Candidates were invited back to complete their cross over performance after 12 weeks. All crossover performances were completed following twelve weeks, and

within fourteen weeks of their respective training regimes. This selected period was due to the logistics of availability of the facilities in which the VRS and PHCM were housed.

6.4.12.4.1 Refreshing the Cross-Over Candidates

When candidates returned to complete their crossover performance they required a brief refresher on the index procedure. They also needed a short briefing on the new training model, which of course they had not previously encountered.

6.4.12.4.1.1 PHCM trained candidates performing on VRS

Using the same UTN, PHCM trained candidates returning to complete their crossover performance on VRS received a five-minute orientation, as previously described (in 6.4.12.2). Candidates familiarised themselves with the theatre trolley, and were shown a brief demonstration of how the wires and catheters were recognised on the VRS. They were also shown how to record a radiographic image. At no point were the exact steps of the index procedure re-discussed with the candidates. They were reminded that they should complete the procedure as independently as possible. Feedback during this procedure was prohibited.

Video conditions, and total time allotted were consistent. The same quantitative parameters were recorded as previously described (5.3.15). Upon completion, candidates were shown from the simulated theatre suite, and prohibited from talking with candidates who were waiting to perform their cross over procedure.

6.4.12.4.1.2 VRS trained candidates performing on PHCM

Using the same UTN, VRS trained candidates returning to complete their crossover performance on the PHCM were given a five minute orientation of the cadaver simulated theatre, as previously described (6.4.12.1). They familiarised themselves with the theatre trolley, and met their radiographer. A brief demonstration was given as to how they would capture a radiographic image. As above (6.4.12.4.1.1) care was taken not to re-discuss any of the individual steps of

the index procedure. Candidates performed independently, videoed and recorded. Again, upon completion they were shown from the cadaver theatre, and prohibited from talking to the other candidates. Feedback was not offered during their recorded performance.

6.4.13 Feedback

It was decided to remove feedback/performance-critique from the PHCM and VRS training regimes. This is discussed in greater detail in (6.6.2) Candidates undertook every attempt at the index procedure without any formal feedback, either during the performance or between subsequent performances.

6.4.13.1 Exceptions to the No Feedback Rule

Both the PI (Craig Nesbitt) and the observing endovascular experts were permitted to intervene under two conditions:

(i) Dangerous Practice

The PHCM is susceptible to all of the frailties of real human vessels. Therefore dangerous or improper practice could potentially rupture vessels or cause a dissection. In either of these scenarios, the PHCM would be potentially ruined, and the experiment would have to abandoned. This would simulate iatrogenic morbidity for the patient. It was therefore decided that feedback/intervention was permitted if it was to prevent a catastrophic complication that could ruin the model

(ii) Failure to Progress

The PI and observing experts could intervene if a candidate was failing to progress. This was defined as failure to progress after three successive performances, beyond the same step of the procedure e.g. inserting the standard J-tip wire. Minimal feedback only was permitted in these circumstances.

Of note, no candidate required such feedback during any of the training regimes.

6.4.14 Subject Numbers

The study aimed to recruit forty candidates into the trial of efficacy. A total of ten candidates for each training regime. These numbers are based on previous

literature assessing the construct validity and efficacy of novel simulation models for surgical training (Riga et al 2010, Bech et al 2011):

Based on a 2-tailed test, with an alpha (α) level of 0.05 and power (1 - β) 0.8. A predicted improvement in clinical performance score following training on a simulator of 30% gave us a minimum of ten subjects required in each arm. This is based on data from previous studies where novices were training using virtual reality simulator models (Seymour et al 2002, Aggarwal et al 2006a, Aggarwal et al 2006b)

6.4.15 Ethics Approval

Advice was sought from our Hospital Research Governance Manager. After assessing the trial protocol, it was decided that formal ethical approval was not required. The trial was considered 'technical development and training', not research.

6.4.16 Storage of Data

This has been previously detailed in 5.3.13

6.4.17 Editing Video Performances

Videos were edited as previously discussed in 5.3.14

6.4.17.1 Random Videos

Edited PHCM performances were randomized;, this included those performances from both the cadaver trained candidates, and those candidates randomised to cadaver following their expert lecture.

Video performances were placed in order of candidates performance, beginning with the PHCM trial and then the lecture regime. A random sequence of numbers

was then generated using a computer based programme (www.random.org), and this determined the new (random) order of the videos.

Edited VRS performances were randomised in the same manner.

- VRS edited and randomly ordered video performances were burned onto a DVD: "*VRS random performances"*
- PHCM edited and randomly ordered video performances were burned onto a second DVD: "*Cadaver random performances"*

6.4.18 Scoring Video Performances

This was carried out as described previously in 5.3.15

6.4.18.1 A Modified Scoring Tool for Assessing A Basic Endovascular Procedure: Cannulation of the left renal artery and confirmatory angiogram from access in the right femoral artery

The same scoring tool that was used in the trail of construct validity (5.3.15.1) was used in the trial of efficacy.

6.4.18.2 Blinded Scorers

The same two blinded expert endovascular practitioners scored the videos from the trial of efficacy. They were blinded to individual candidates, their attempt number as well as the training regime.
They were clearly able to differentiate between VRS and PHCM performances due to the easily recognizable computer graphics from the VRS fluoroscopy screen.

6.4.18.3 Practice Scoring – Establishing Standards

Expert scorers were experienced at marking PHCM performances, but required a period of practice before scoring the VRS performances. As per 5.3.12.2 both examiners were shown a collaboration of clips from ten videos of edited VRS performances. Our two blinded scorers openly discussed factors in these videos, to establish joint standards of scoring that they were both in agreement with, prior to

beginning the formal process of scoring. All subsequent scoring was performed independently.

6.4.19 Quantitative Parameters

Total procedure time, volume of contrast used and total fluoroscopy time were recorded as per 5.3.15.

6.4.20 PHCM and VRS Training Regime: Eight Repetitions

The choice of eight repetitions was based on previous literature indicating that novice performers learning curves plateau at between 2 and 5 repetitions of a technical skill (Seymour et al 2002, Aggarwal et al 2006a, Aggarwal et al 2006c). As the PHCM represents an entirely novel training model, eight repetitions would ensure any variation seen in a PHCM was not missed.

6.5 Results

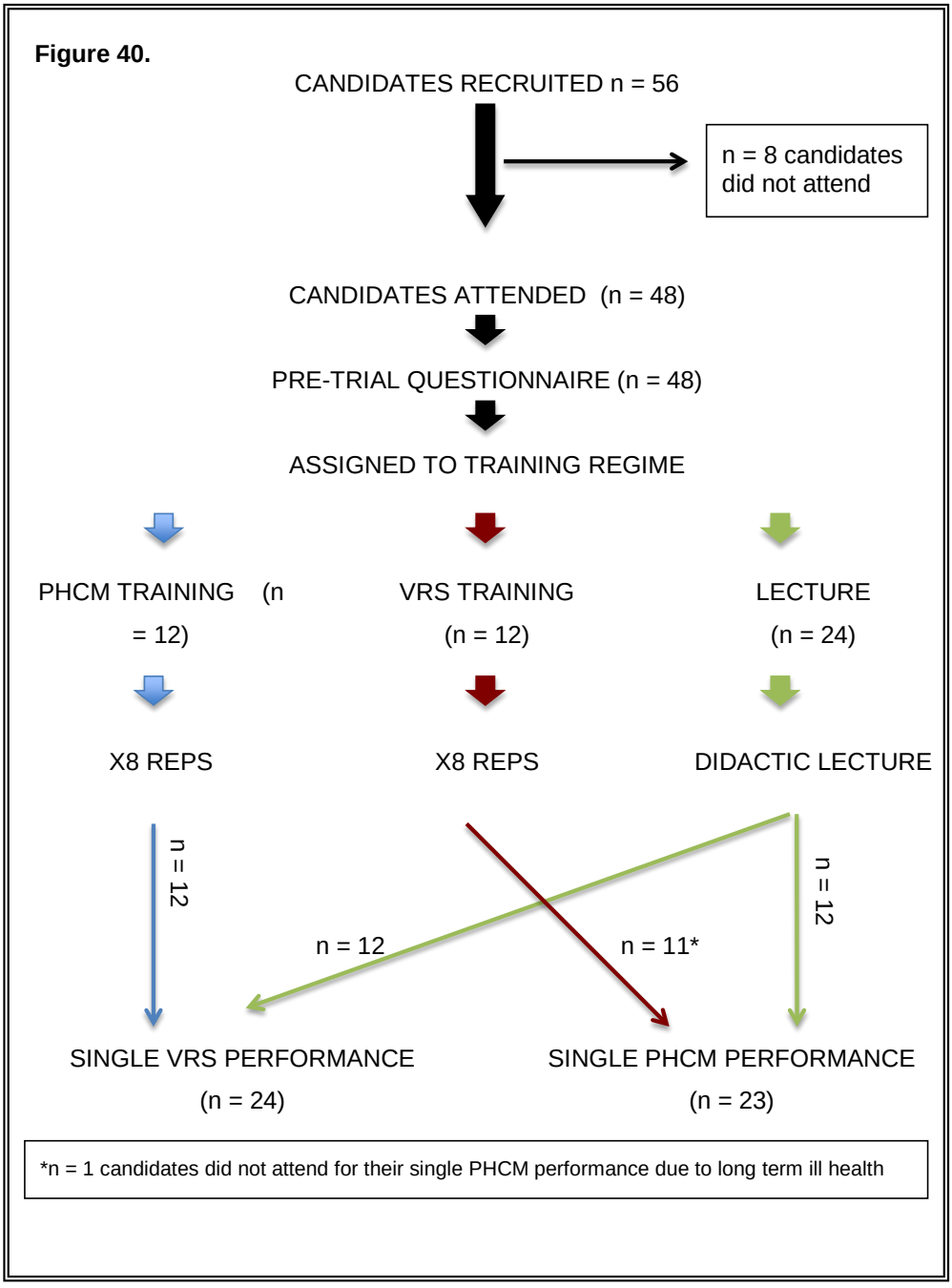
All generated data from the PHCM trial of efficacy was tabulated into excel spread sheets (Microsoft excel™). Mean, median and modal values were extracted in standard fashion.

Statistical analysis was undertaken using the Statistical Package for the Social sciences version 19 (SPSS, Chicago) and Minitab version16. Advice was sought from a medical statistician at Newcastle University for the most appropriate statistical tests when analyzing the trial data. Cronbach's alpha was used to test for expert scorer's inter-rater variability. A paired t-test was used to compare quantitative parameters, Fishers Exact test to compare demographic data and a 1-way ANOVA to compare clinical performance scores. A p-value of <0.05 was considered to be significant.

6.5.1 Algorithmic Overview of the PHCM Trial of Efficacy

Figure 40 displays an algorithmic overview of the PHCM trial of efficacy.

Figure 40.


CANDIDATES RECRUITED n = 56
n = 8 candidates did not attend
CANDIDATES ATTENDED (n = 48)
PRE-TRIAL QUESTIONNAIRE (n = 48)
ASSIGNED TO TRAINING REGIME
PHCM TRAINING (n = 12)
VRS TRAINING (n = 12)
LECTURE (n = 24)
X8 REPS
X8 REPS
DIDACTIC LECTURE
n = 12
n = 12
n = 11*
n = 12
SINGLE VRS PERFORMANCE (n = 24)
SINGLE PHCM PERFORMANCE (n = 23)
*n = 1 candidates did not attend for their single PHCM performance due to long term ill health

6.5.2 Candidate Demographics

In total, forty eight candidates were recruited to the PHCM trial of efficacy. Eight candidates did not attend for the trial; this was due to either sickness or unavoidable clinical work commitments. All candidates who attended completed their pre-trial and post trial questionnaires. Twelve candidates were assigned to training on the PHCM, 12 candidates were assigned to training on the VRS and twenty-four candidates were assigned to the expert lecture training regime. (6.5.1)

The 48 candidates did not vary in their baseline demographics. This is shown in Tables 51b, 52 and 53.

Table 51b. The PHCM Trial of Efficacy Candidate Demographics

Demographic	Candidate
Total	n = 48
Seniority	31 medical students (MS) 11 Foundation trainees (FYT) 6 Core surgical trainees (CST)
Endovascular Experience*	Low Novice n = 48

*See Appendix 6

Table 52. The PHCM Trial of Efficacy Candidate Demographics

Demographic	PHCM (i)	SVR (ii)	Lecture (iii)	Proportions test of between group difference (P)[Ψ]
Number	12	12	24 (total)[†]	
Seniority	n = 3 FYT n = 9 MS	n = 1 FYT n = 11 MS	n = 6 CST n = 7 FYT n = 11 MS	[⌘]
Wear glasses	Yes n = 1 No n = 11	Yes n = 3 No n = 9	Yes n = 5 No n = 19	i vs ii ns* i vs iii ns ii vs iii ns
Handedness	Left n = 0 Right n = 12	Left n = 1 Right n = 11	Left n = 2 Right n = 22	i vs ii ns i vs iii ns ii vs iii ns
Play musical instrument	Yes n = 6 No n = 6	Yes n = 9 No n = 3	Yes n = 11 No n = 13	i vs ii ns i vs iii ns ii vs iii ns
Ability to type	Yes n = 12 No n = 0	Yes n = 12 No n = 0	Yes n = 24 No n = 0	i vs ii ns i vs iii ns ii vs iii ns
Play video games regularly	Yes n = 7 No n = 5	Yes n = 6 No n = 6	Yes n = 9 No n = 15	i vs ii ns i vs iii ns ii vs iii ns
Prev VR endovascular training	Yes n = 0 No n = 12	Yes n = 0 No n = 12	Yes n = 0 No n = 24	i vs ii ns i vs iii ns ii vs iii ns
Prev cadaver endovascular training	Yes n = 0 No n = 12	Yes n = 0 No n = 12	Yes n = 0 No n = 24	i vs ii ns i vs iii ns ii vs iii ns
Prev cadaver training (any)	Yes n = 12 No n = 0	Yes n = 12 No n = 0	Yes n = 24 No n = 0	i vs ii ns i vs iii ns ii vs iii ns
	n = 12 Undergraduate prosection	n = 12 Undergraduate prosection	n = 12 Undergraduate prosection	

*Not statistically significant
[†] Lecture trained groups are considered together (2x n = 12)
[Ψ] Fishers exact test
[⌘] not statisticaly analysed

Table 53. The PHCM Trial of Efficacy - Lecture Training - Candidate Demographics

Demographic	Lecture - PHCM	Lecture - VRS	Proportions test of between group difference (P)[Ψ]
Number	12	12	
Seniority	n = 5 CST n = 4 FYT n = 3 MS	n = 1 CST n = 3 FYT n = 8 MS	na[⌘]
Wear glasses	Yes n = 2 No n = 10	Yes n = 3 No n = 9	ns*
Handedness	Left n = 0 Right n = 12	Left n = 2 Right n = 10	ns
Play musical instrument	Yes n = 5 No n = 7	Yes n = 6 No n = 6	ns
Ability to type	Yes n = 12 No n = 0	Yes n = 12 No n = 0	ns
Play video games regularly	Yes n = 6 No n = 6	Yes n = 3 No n = 9	ns
Prev VR endovascular training	Yes n = 0 No n = 12	Yes n = 0 No n = 12	ns
Prev cadaver endovascular training	Yes n = 0 No n = 12	Yes n = 0 No n = 12	ns
Prev cadaver training (any)	Yes n = 12 No n = 0	Yes n = 12 No n = 0	ns
	n = 12 Undergraduate prosection n = 5 Northern deanery 'Core surgical training programme'	n = 12 Undergraduate prosection n = 1 anatomy intercalated degree n = 1 Northern deanery 'Core surgical training programme'	

[⌘] not statisticaly analysed
*Not statistically significant
[Ψ]Fishers exact test

6.5.3 Quantitative Parameters – VRS & PHCM Trained Candidates, VRS & PHCM Trained Candidates Cross-Over Performances, and Lecture Trained Candidates.

Three quantitative measurements were recorded during each index performance: Total procedure time, total fluroscopy time and total volume of intravenous contrast used. There is a statistically significant difference in total procedure (p=0.014) and fluoroscopy time (p=0.044) between the VRS and PHCM trained candidates, but no difference in volume of contrast used (Table 54).
The 'cross-over' and lecture trained performances are discussed in section 6.5.3.5.

Table 54. Average Quantitative Measures Taken During The PHCM Trial of Efficacy – VRS and PHCM Trained Candidates

Quantitative parametre	VRS	PHCM	Test of between group difference[⌘]
Total Procedure time - sec*	264.71 (135.98)	439.50 (161.09)	p=0.014
Fluoroscopy time - sec*	167.69 (103.33)	250.05 (115.17)	p=0.044
Contrast used - ml*	15.51 (6.21)	18.69 (8.16)	p=0.2

***Mean (standard deviation)
[⌘]2 sample t-test

6.5.3.1 Virtual Reality Simulation (VRS) Training

All twelve candidates assigned to training on the VRS completed eight separate attempts of the index procedure. The measured quantitative parameters for each performance are found in Appendix 25.

Overall candidates took a mean of 8 minutes 43 (523 seconds) to complete the index procedure on their first attempt. They used a mean of 26 ml of contrast and required 5 minutes 39 (339 seconds) of fluroscopy.

Following training on the VRS, these same candidates required just 2 minutes 30 (150 seconds), (p=0.000), 12 ml of contrast (p=0.000) and 1min 40 (100 seconds) of fluroscopy (p=0.000). Table 55 displays significance tests of consecutive performance scores. Table 56 shows the initial and final performance quatitative parameters. This improvement in performance is shown graphically in section 6.5.3.1.1.

Table 55. Significance Test of Quantitative Scores; VRS Trained Candidates

Perform-ance / p value*	1 vs 2	2 vs 3	3 vs 4	4 vs 5	5 vs 6	6 vs 7	7 vs 8
Total Procedure Time (sec)	0.000	0.000	0.009	0.039	0.611	0.000	0.017
Fluroscopy Time (sec)	0.002	0.000	0.051	0.166	0.664	0.018	0.244
Contrast Volume (ml)	0.018	0.163	0.347	0.447	0.819	0.942	0.163

*paired t-test
*****Mean (standard deviation)
[⌘]Paired t-test

Table 56. Average Quantitative Measures. VRS Trained Candidates: First vs Final Performance

Quantitative parametre	VRS first attempt	VRS final attempt	Test of between group difference[⌘]
Total Procedure time - sec*	523.08 (99.94)	149.83 (35.06)	**p = 0.000**
Fluroscopy time - sec*	338.58 (138.36)	100.08 (11.75)	**p = 0.000**
Contrast used - ml*	26.25 (8.01)	11.75 (1.22)	**p = 0.000**

***Mean (standard deviation)
[⌘]2 sample t-test

6.5.3.1.1 VRS Training Parameters - Graphs

The quantitative parametres measured during the VRS training are displayed graphically in figures 41, 42 and 43.

Figure 41. Interval Plot of the Average Total Time Required by All VRS Candidates to Complete Each Procedure

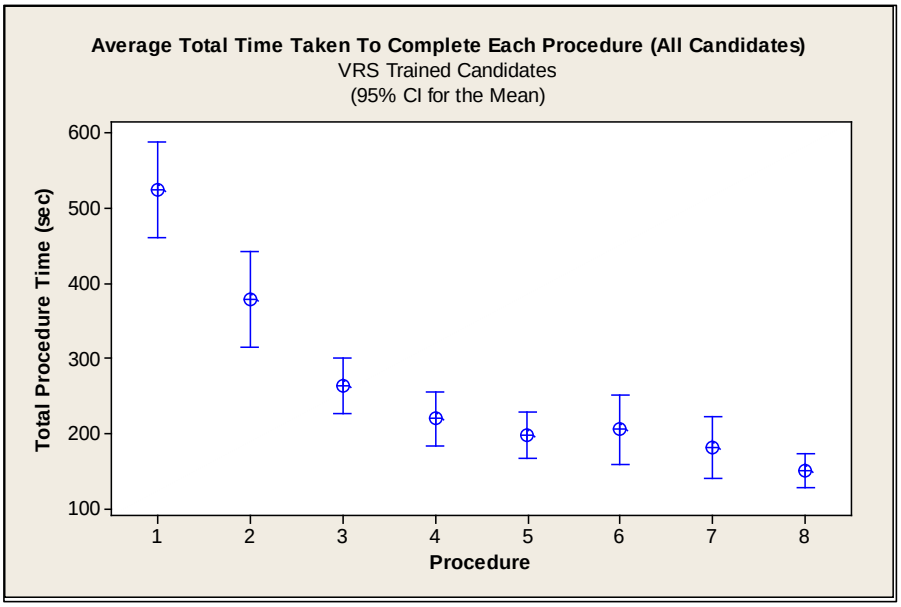


Figure 42. Interval Plots of the Average Total Fluoroscopy Time Required by All VRS Trained Candidates to Complete Each Procedure

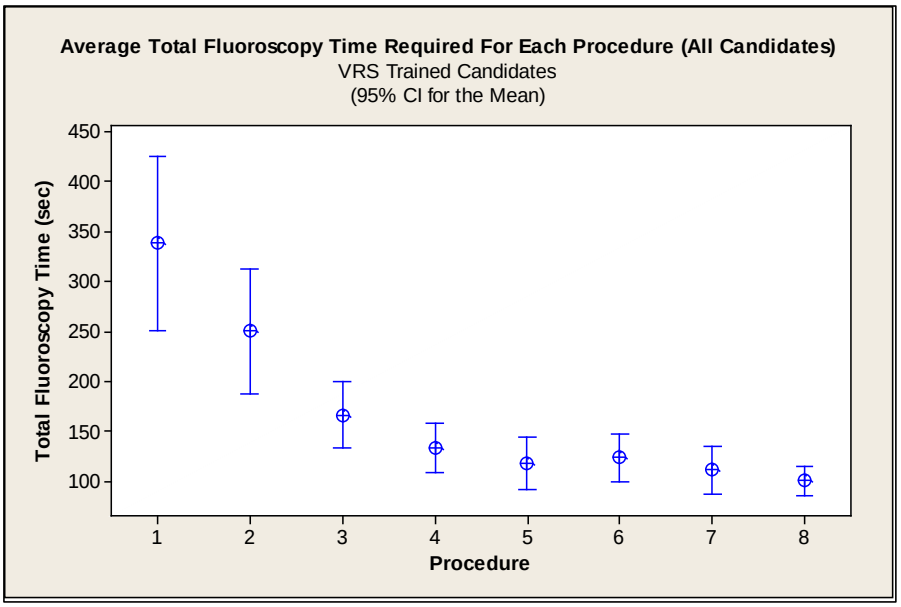
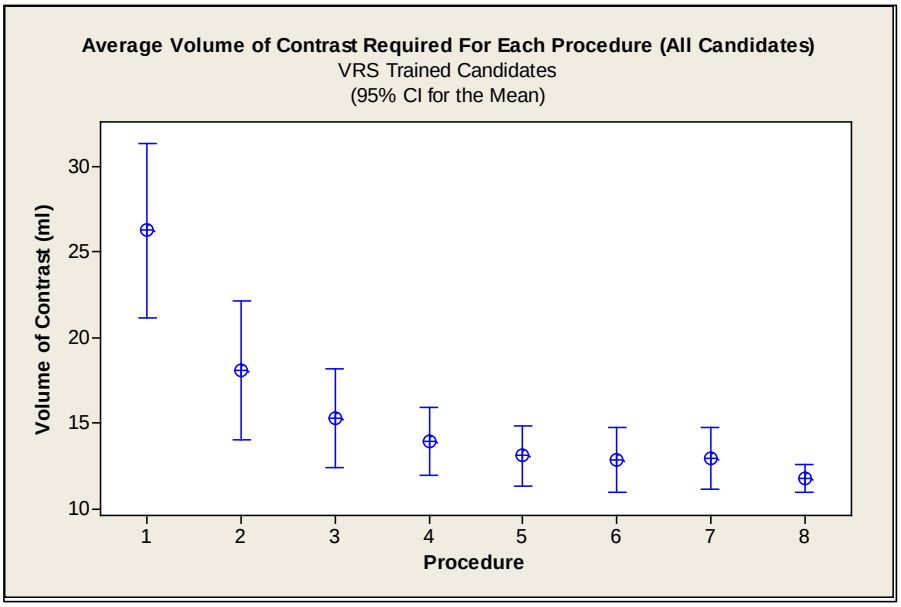


Figure 43. Interval Plots of the Average Total Volume of Contrast Required by All VRS Trained Candidates to Complete Each Procedure



6.5.3.2 Pulsatile Human Cadaver Model (PHCM) Training

All twelve candidates assigned to training on the PHCM completed eight separate attempts of the index procedure. The measured quantitative parameters for each performance are displayed in appendix 25.

Overall candidates took an mean of 9 minutes 57 (597 seconds) to complete the index procedure on their first attempt. They used an mean of 23 ml of contrast and required 4 minutes 46 (286 seconds) of fluroscopy.

Following training on the PHCM, these same candidates required just 4 minutes 54 (294 seconds) (p=0.00), 14 ml of contrast (p=0.008) and 2 minutes 52 (172 seconds) of fluroscopy (p=0.026) (Table 58).

Table 57 displays significance tests of consecutive performance scores. Table 58 shows the initial and final performance quatitative parameters. This improvement in performance is shown graphically in section 6.5.3.2.1.

Table 57. Significance Test of Quantitative Scores; VRS Trained Candidates

Perform-ance / p value*	1 vs 2	2 vs 3	3 vs 4	4 vs 5	5 vs 6	6 vs 7	7 vs 8
Total Procedure Time (sec)	0.248	0.119	0.019	0.427	0.245	0.020	0.729
Fluroscopy Time (sec)	0.670	1.000	0.159	0.682	0.085	0.293	0.727
Contrast Volume (ml)	0.423	0.255	0.345	0.298	0.156	0.129	1.000

*paired t-test

statistically significant

Table 58. Average Quantitative Measures. PHCM Trained Candidates: First vs Final Performance

Quantitative parametre	PHCM first attempt	PHCM final attempt	Test of between group difference[⌘]
Total Procedure time - sec*	596.92 (10.68)	293.92 (175.56)	**p = 0.000**
Fluroscopy time - sec*	285.75 (100.11)	172.08 (102.64)	**p = 0.026**
Contrast used - ml*	23.17 (8.76)	13.58 (4.12)	**p = 0.008**

***Mean (standard deviation)**
[⌘]paired t-test

6.5.3.2.1 PHCM Training Parameters - Graphs

The quantitative parameters measured during the PHCM training are displayed graphically in figures 44, 45 and 46.

Figure 44. Interval Plot of the Average Total Time Required by All PHCM Trained Candidates to Complete Each Procedure

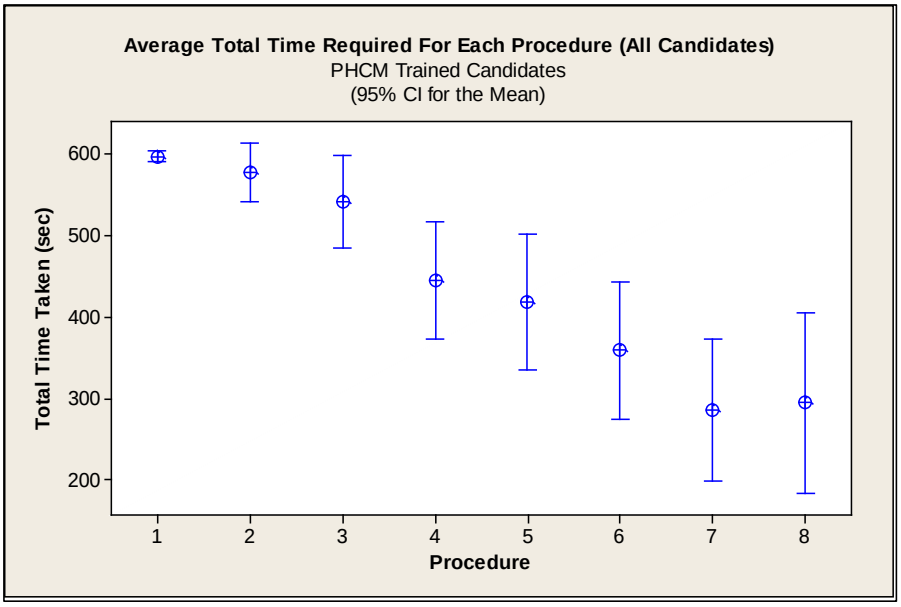


Figure 45. Interval Plots of the Average Total Fluoroscopy Time Required by All PHCM Trained Candidates to Complete Each Procedure

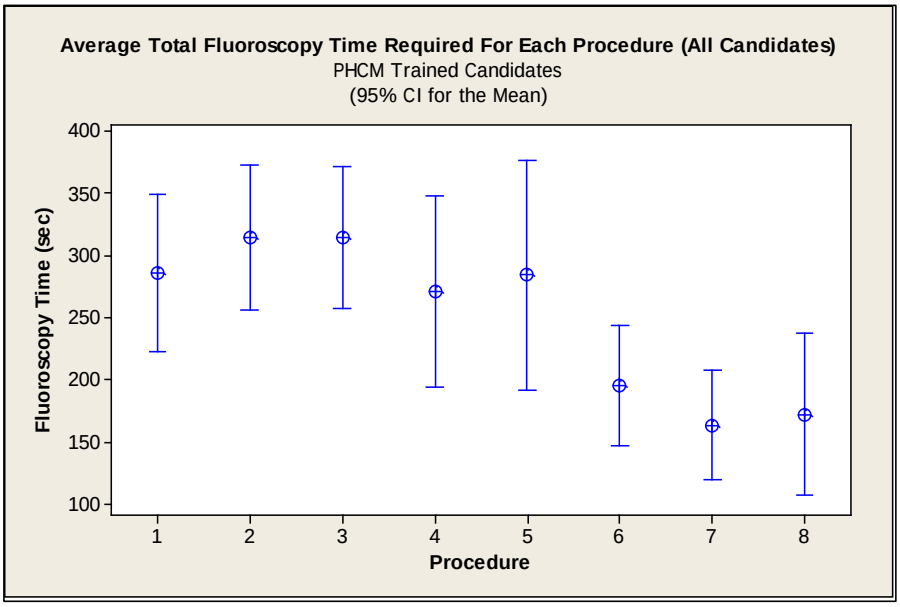
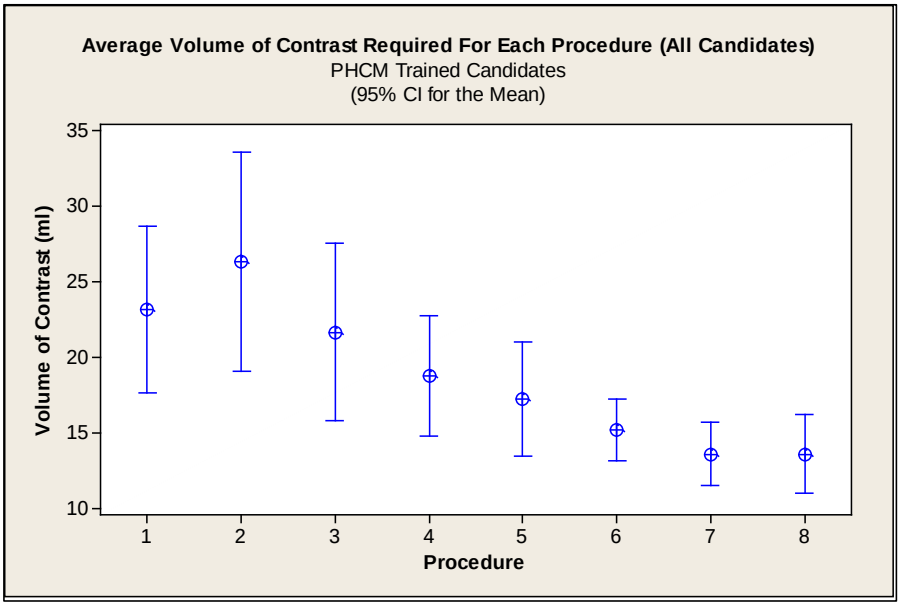


Figure 46. Interval Plots of the Average Total Volume of Contrast Required by All PHCM Trained Candidates to Complete Each Procedure



6.5.3.4 Expert Lecture Training

Follwing the expert lecture twelve candidates were randomised to perform on the PHCM and twelve on the VRS. Each candidate completed a single attempt of the index procedure. The measured quantitative parameters for both the PHCM and VRS performance are displayed in appendix 25.

Candidates randomised to perform on the PHCM took an average of 9 minutes 37 (577) seconds) to complete the index procedure, they used an average of 19 ml of contrast and required 3 minutes 55 (235 seconds) of fluoroscopy (Table 59).

In comparison the twelve candidates randomised to perform the index procedure on the VRS required an average 8 minutes 14 (494 seconds) (p=0.122), 24 ml of contrast (p=0.634) and 4 minutes 12 (252 seconds) of fluoroscopy (p=0.634) (Table 59).

Table 59. Average Quantitative Measures, Taken During The PHCM Trial of Efficacy – VRS and PHCM Cross-Over Performances, and Lecture Trial Performances (VRS and PHCM).

Quantitative parameter	PHCM trained VRS performance (A)	VRS trained PHCM performance (B)	Lecture - VRS (C)	Lecture - PHCM (D)	Test of between group difference[⌘]
Total Procedure time - sec*	352.08 (109.98)	511.45 (92.54)	494.42 (92.56)	577.17 (53.47)	**A** vs **B** p=0.001 (p=0.001)
					C vs **D** p=0.172 (0.122)
					A vs **C** p=0.002 (p=0.002)
					B vs **D** p=0.514 (p=0.307)
Fluoroscopy time - sec*	203.17 (117.44)	288.18 (77.58)	352.08 (124.81)	235.17 (104.58)	**A** vs **B** p=0.4 (0.251)
					C vs **D** p=0.068 (0.053)
					A vs **C** p=0.01 (p=0.008)
					B vs **D** p=1.00 (p=0.646)
Contrast used - ml*	20.75 (10.7)	15.18 (3.25)	23.58 (13.58)	18.67 (9.45)	**A** vs **B** p=1.00 (p=0.554)
					C vs **D** p=1.00 (p=0.634)
					A vs **C** p= 1.00 (p=0.901)
					B vs **D** p=1.00 (p=0.841)

***Mean (standard deviation)**

[⌘]One way ANOVA test: Bonferroni (Tukey)

6.5.3.4.1 Lecture Trial Procedure Completed

Not all candidates who were assigned to the expert lecture training were able to complete the index procedure, on VRS and PHCM (Table 60).

Table 60. Completed Index Cadaver Performances: Lecture Trained Candidates

	Lecture – PHCM (n=12)	Lecture – VRS (n=12)	Proportions test of between group difference (P)[Ŧ]
Procedure attempted (%)	n = 12/12 (100)	n = 12/12 (100)	ns*
Procedure completed (%)	n = 2/12 (17)	n = 9/12 (75)	p = 0.012

*Not statistically significant

[Ŧ] Fishers exact test

6.5.3.5 PHCM and VRS Cross-Over Performances

After completing their training programme on the PHCM and VRS respectively, all twenty four candidates were invited back to undertake a single attempt at the same index procedure on the alternate model to that which they had trained on.
The measured quantitative parameters for each of these 'cross-over' performances are shown in appendix 25.

The twelve candidates who had trained on PHCM required an average of 5.52 minutes (352 seconds), used 21 ml of contrast and required 3.23 minutes (203 seconds) of fluoroscopy when they performed on the VRS.

The twelve candidates who had completed their training on the VRS model, required an average 8.31 minutes (511 seconds), 15 ml of contrast and 4.48 minutes (288 seconds) of fluoroscopy to complete their 'cross-over' performance on the PHCM (Table 59). One candidate was unable to attend due to long term sickness.

Comparing these cross-over performances to the lecture trained candidates's performances, there was a statistically significant reduction in total procedure time (p=0.002), and fluroscopy time (p=0.008) between those candidates who had trained on the PHCM performing on the VRS and their lecture trained counterparts also performing on the VRS. All other direct comparisons were not statistically significant (Table 59).

6.5.3.5.1 PHCM and VRS Cross-Over Performances Completed

Not all candidates who performed the index procedure on the alternate model were able to complete the index procedure (Table 61).

Table 61. Completed Index Cadaver Performances: Lecture Trained Candidates

	VRS trained cross-over PHCM attempt (n=11)	PHCM trained cross-over VRS attempt (n=12)	Proportions test of between group difference (P) ₮
Procedure attempted (%)	n = 11 (100) †	n = 12 (100)	ns*
Procedure completed (%)	n = 7 (64) †	n = 11 (92)	ns

*Not statistically significant

† Of the 11 candidates who attended

₮ Fishers exact test

6.5.4 Clinical Performance Scores

As described (6.4.18), each attempt at the index procedure, was recorded, edited and scored by two blinded expert scorers. This gave each performance six individual scores (three from each expert scorer): A score for the TSC, GRS and OPS. These scores were combined to give average scores, which are used for all subsequent analysis.

6.5.4.1 Virtual Reality Simulation (VRS) Training

All twelve candidates assigned to training on the VRS completed eight separate attempts of the index procedure. The clinical performance scores are displayed in Appendix 26. Cronbach's alpha score for inter-rater variability between our two expert blinded scorers was 0.877 indicating good agreement between our scorers.

The average OPS for all twelve candidates' initial performance was 20.54. (TSC 10.29, GRS 10.25). The average OPS for their final attempt was 36.04 (TSC 14.21, GRS 21.88). This improvement is statistically significant (p=0.000) (Table 62)

The mean scores for all candidates' eight performances are displayed graphically in figures 47, 48 and 49.

Table 62. Significance Test of Combined Overall Procedure Score; VRS Trained Candidates

Procedure / p value*	1	2	3	4	5	6†	7	8
1	X	0.000	0.000	0.000	0.000	0.000	0.000	0.000
2	X	X	0.302	0.197	0.001	0.443	0.001	0.036
3	X	X	X	0.627	0.005	0.797	0.000	0.070
4	X	X	X	X	0.011	0.880	0.017	0.126
5	X	X	X	X	X	0.023	0.704	0.654
6	X	X	X	X	X	X	0.009	0.176
7	X	X	X	X	X	X	X	0.519
8	X	X	X	X	X	X	X	X

*Paired t-test

†Drop in performance score

Statistically significant

Figure 47. Average Combined Examiner Overall Procedure Score (OPS): VRS Trained Candidates.

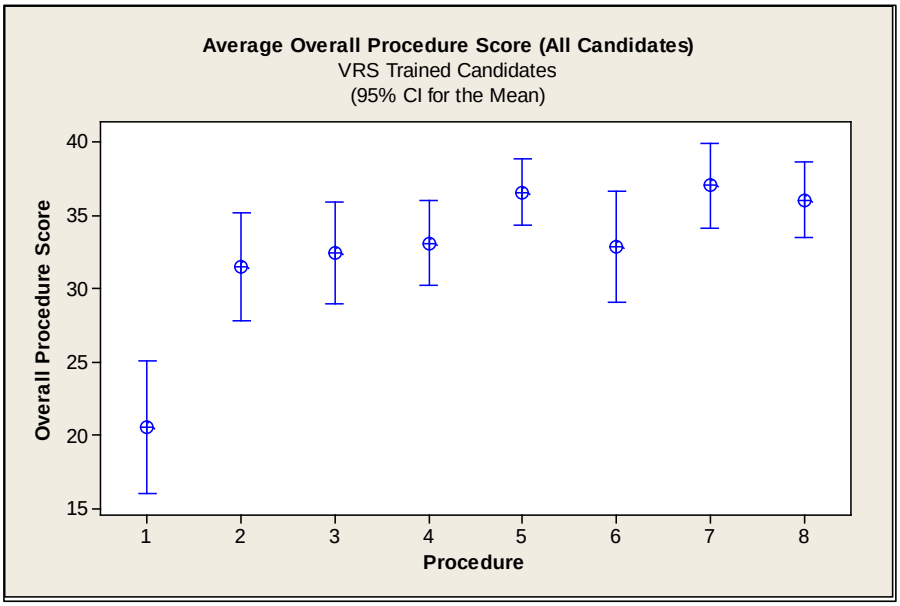


Figure 48. Average Combined Examiner Task Specific Checklist Score (TSC): VRS Trained Candidates.

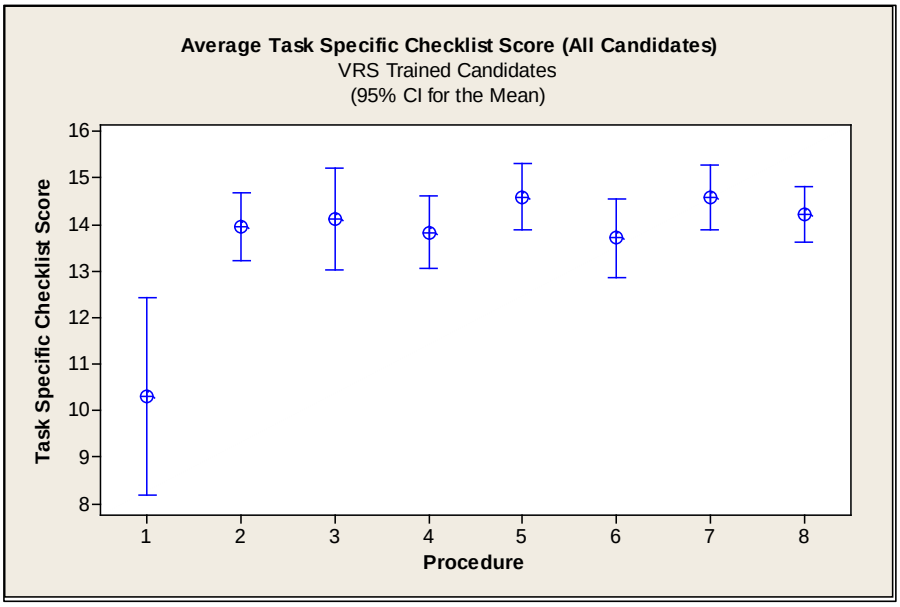
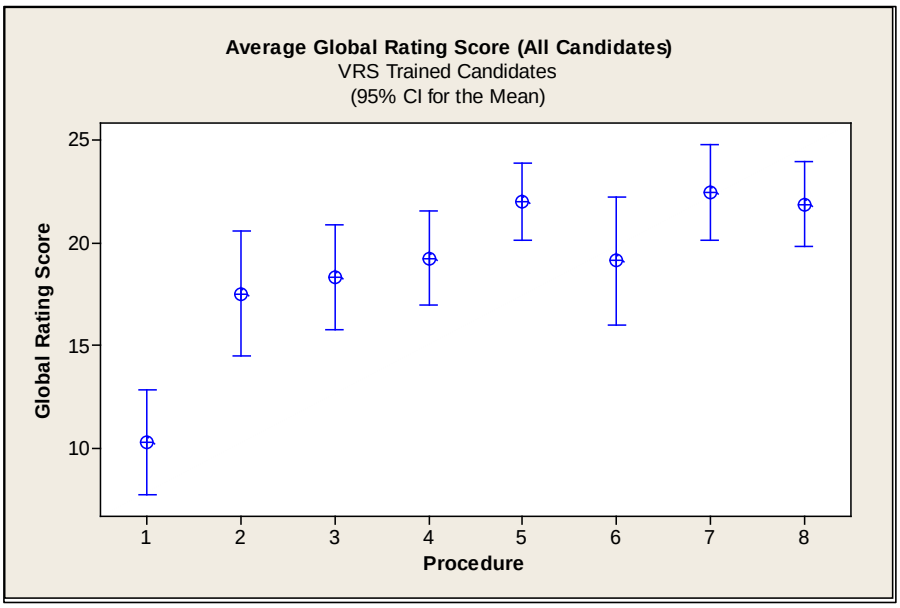


Figure 49. Average Combined Examiner Global Rating Score (GRS): VRS Trained Candidates.



6.5.4.1.1. VRS Trained Candidates: Satisfactory Performance

Three candidates were graded as satisfactory to perform the procedure (by both examiners), under supervision, in the operating room after their first attempt. After seven consecutive attempts this number was twelve. This improvement is statistically significant (Fishers exact p=0.000)

Of note the same statistically significant (p=0.014) improvement was seen after the fourth performance and no further improvement was seen beyond that (Table 63).

When a traffic light system is used to highlight satisfactory performance (Table 64), it is again clear that there is no vast improvement beyond performance three, with performance six having greater disagreement between the expert scorers.

Table 63. Significance Test of Examiners Agreement of Satisfactory Performance

Score / p value*	1 vs 8	1 vs 2	2 vs 3	3 vs 4	4 vs 5	5 vs 6	6 vs 7	7 vs 8
Pass?	0.000	ns†	ns†	ns†	ns†	ns†	ns†	ns†

*2 proportions test (Fishers exact)

†not statistically significant

Table 64. Candidates Trained on VRS: Pass/Fail

Key Agreed Failure Agreed Pass No Expert Agreement

Candidate	Procedure	Examiner 1 Pass?	Examiner 2 Pass?
1	1	Fail	Fail
	2	Pass	Fail
	3	Pass	Pass
	4	Fail	Fail
	5	Fail	Pass
	6	Pass	Pass
	7	Fail	Fail
	8	Fail	Fail
	9	Fail	Fail
	10	Pass	Fail
	11	Pass	Pass
	12	Fail	Fail
2	1	Pass	Fail
	2	Pass	Pass
	3	Fail	Fail
	4	Pass	Fail
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Fail
	8	Pass	Pass
	9	Fail	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Fail	Fail
3	1	Pass	Fail
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Fail
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Pass
	8	Pass	Pass
	9	Fail	Pass
	10	Pass	Fail
	11	Pass	Pass
	12	Fail	Fail
4	1	Pass	Fail
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Pass
	8	Pass	Fail
	9	Pass	Fail
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass

Candidate	Procedure	Examiner 1 Pass?	Examiner 2 Pass?
5	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Pass
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass
6	1	Pass	Fail
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Fail
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Pass
	8	Pass	Pass
	9	Pass	Fail
	10	Pass	Fail
	11	Pass	Pass
	12	Pass	Fail
7	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Pass
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Fail
8	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Pass
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass

6.5.4.2 Pulsatile Human Cadaver Model (PHCM) Training

All twelve candidates assigned to training on the PHCM completed eight separate attempts of the index procedure. The clinical performance scores are displayed in Appendix 26. Inter-rater variability score (Cronbach's Alpha) was 0.907 indicating good agreement between our scorers.

The average OPS for all twelve candidates' initial performance was 19.42 (TSC 8.58, GRS 10.83). The average OPS for their final attempt was 39.50 (TSC 15.00, GRS 24.5). This improvement is statistically significant (p=0.000).
The mean scores for all candidates' eight performances are displayed graphically in figures 50, 51 and 52

There was no statistically significant improvement seen beyond performance seven although there was still an upward trend to performance eight (Table 65)

Figure 50. Average Combined Examiner Overall Procedure Score (OPS): VRS Trained Candidates.

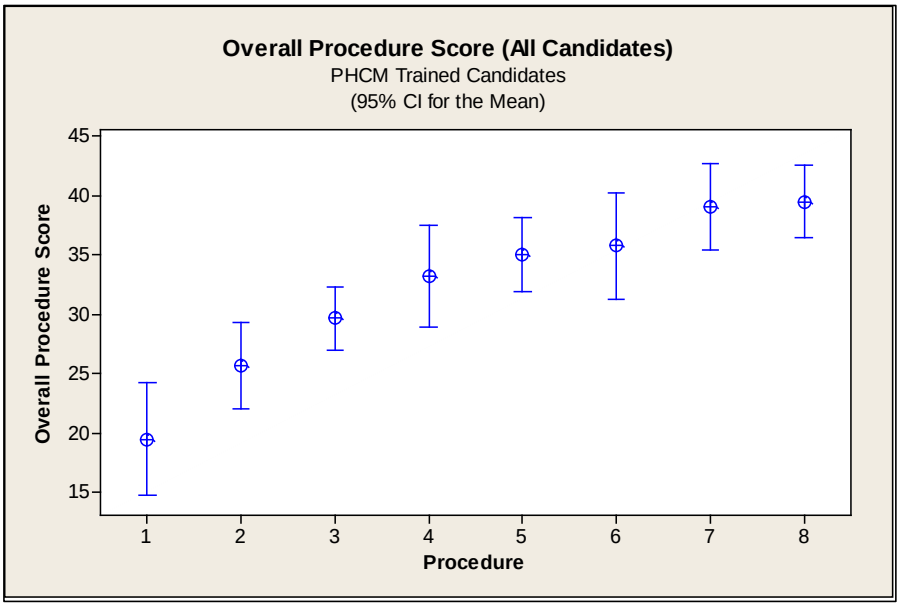


Figure 51. Average Combined Examiner Task Specific Checklist Score (TSC): PHCM Trained Candidates.

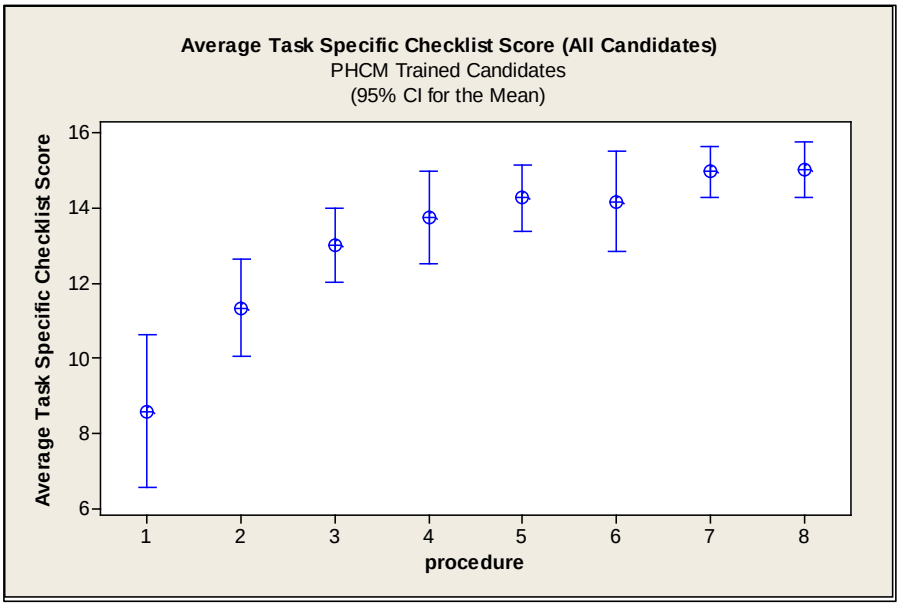


Figure 52. Average Combined Examiner Global Rating Score (GRS): PHCM Trained Candidates.

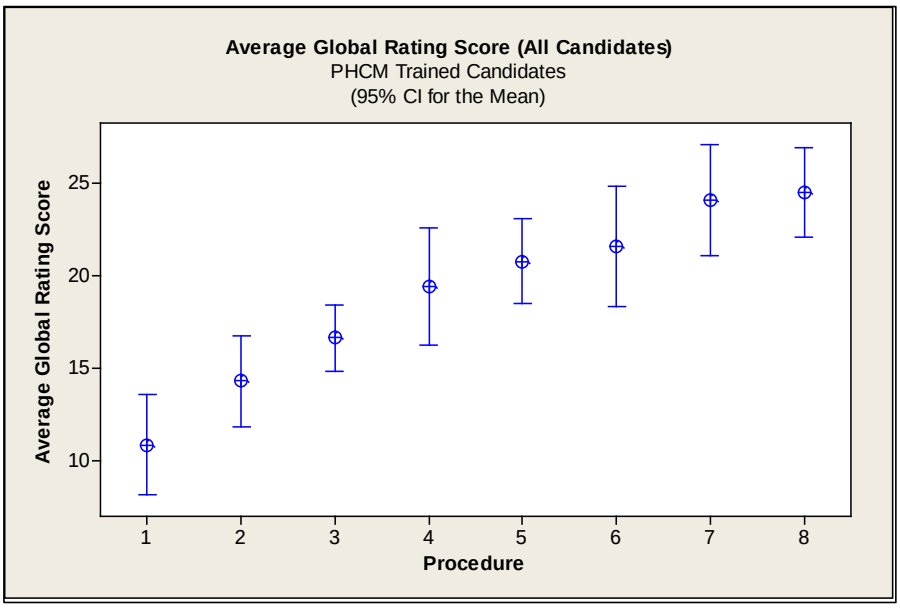


Table 65. Significance Test of Combined Overall Procedure Score; PHCM Trained Candidates

Procedure / p value*	1	2	3	4	5	6	7	8
1	X	0.008	0.000	0.000	0.000	0.000	0.000	0.000
2	X	X	0.026	0.001	0.000	0.000	0.000	0.000
3	X	X	X	0.066	0.002	0.017	0.000	0.000
4	X	X	X	X	0.216	0.167	0.003	0.001
5	X	X	X	X	X	0.729	0.014	0.008
6	X	X	X	X	X	X	0.071	0.022
7	X	X	X	X	X	X	X	0.658
8	X	X	X	X	X	X	X	X

*paired t-test

Statistically significant

6.5.4.2.1. PHCM Trained Candidates: Satisfactory Performance.

One candidate was initially graded as satisfactory to perform the procedure (by both examiners), under supervision, in the operating room. After seven consecutive attempts eleven candidates were deemed satisfactory. This improvement is statistically significant (Fishers exact p=0.000).

The clear and rapid improvement in performance is evident when colours are added to the table (Table 67). Of note, after just three attempts (Table 66), no further improvement in overall satisfactory performance was made.

Table 66. Improvement in Candidates Satisfactory Performance

Score / p value*	1 vs 8	1 vs 2	2 vs 3	3 vs 4	4 vs 5	5 vs 6	6 vs 7	7 vs 8
Pass?	0.000	ns†	0.009†	ns	ns	ns	ns	ns

*2 proportions test (Fishers exact)

†not statistically significant

Table 67. Candidates Trained on PHCM: Pass/Fail

Key Agreed Failure | Agreed Pass | No Expert Agreement

Candidate Procedure		Examiner 1 Pass?	Examiner 2 Pass?
1	1	Fail	Fail
	2	Fail	Fail
	3	Pass	Pass
	4	Pass	Fail
	5	Pass	Fail
	6	Fail	Fail
	7	Fail	Fail
	8	Fail	Pass
	9	Pass	Fail
	10	Pass	Fail
	11	Pass	Fail
	12	Fail	Fail
2	1	Pass	Pass
	2	Pass	Fail
	3	Pass	Pass
	4	Pass	Fail
	5	Pass	Pass
	6	Pass	Pass
	7	Fail	Fail
	8	Pass	Fail
	9	Pass	Fail
	10	Fail	Fail
	11	Fail	Fail
	12	Pass	Fail
3	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Fail
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass
4	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Fail
	5	Pass	Pass
	6	Fail	Pass
	7	Pass	Pass
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass

Candidate Procedure		Examiner 1 Pass?	Examiner 2 Pass?
5	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Fail
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass
6	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Fail
	7	Pass	Fail
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass
7	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Pass
	7	Pass	Fail
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass
8	1	Pass	Pass
	2	Pass	Pass
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Pass	Pass
	7	Fail	Pass
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass

6.5.4.4 Expert Lecture Training

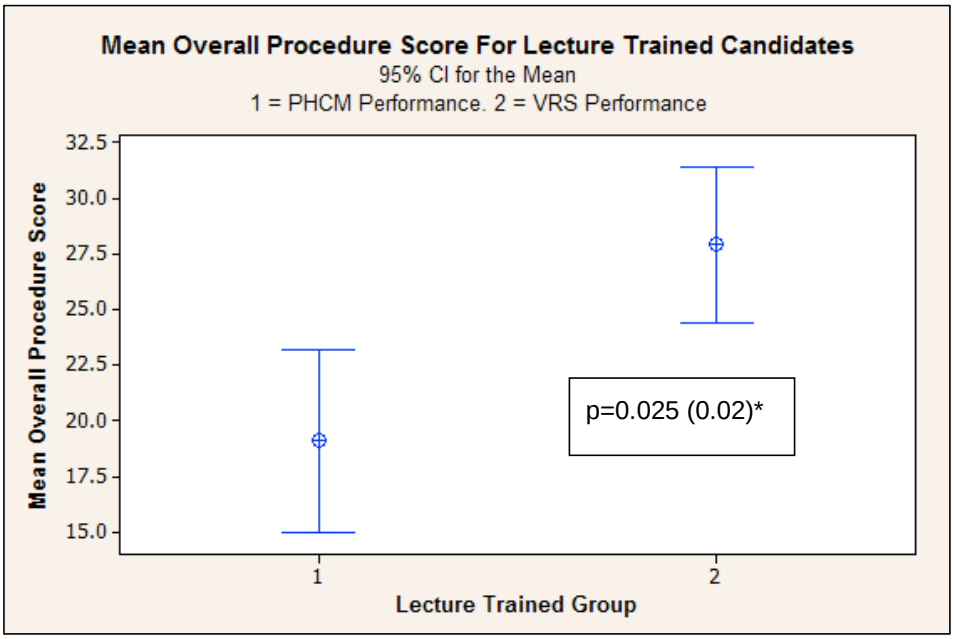
Following the expert lecture, all twelve candidates who were randomised to PHCM attempted the index procedure. Inter-rater variability score for the blinded examiners who scored the videoed performances was 0.862, indicating good agreement. The average OPS for these twelve candidates' performance was 19.08 (TSC 9.13, GRS 9.96).

All twelve candidates who were randomised to VRS attempted the index procedure. Cronbachs Alpha was 0.862. The average OPS for these twelve candidates' performance was 27.92 (TSC 13.25, GRS 14.67).

Individual clinical performance scores are displayed in Appendix 26. Mean scores are displayed graphically with their corresponding 95% confidence interval values in Figure 53. Candidates who performed on VRS scored significantly higher than those on PHCM (p=0.025).

Examiners rated each performance as 'satisfactory to perform under supervision in the operating room.' These scores are displayed in Table 68.

Figure 53. Mean Overall Procedure Scores (OPS) For the Lecture Trained Candidates: VRS and PHCM Performances.



*One way ANOVA test: Bonferroni (Tukey)

Table 68. Lecture Trial Candidates: VRS and PHCM Performance: Pass/Fail

Key Agreed Failure | Agreed Pass | No Expert Agreement

Procedure	Candidate	Examiner 1 Pass?	Examiner 2 Pass?
VRS Performance	1	Pass	Fail
	2	Pass	Pass
	3	Fail	Pass
	4	Pass	Pass
	5	Pass	Pass
	6	Fail	Fail
	7	Pass	Fail
	8	Pass	Pass
	9	Pass	Pass
	10	Fail	Fail
	11	Fail	Fail
	12	Pass	Pass
PHCM Performance	1	Pass	Fail
	2	Pass	Pass
	3	Pass	Fail
	4	Pass	Fail
	5	Pass	Pass
	6	Pass	Fail
	7	Fail	Fail
	8	Fail	Fail
	9	Fail	Fail
	10	Fail	Fail
	11	Fail	Fail
	12	Pass	Pass

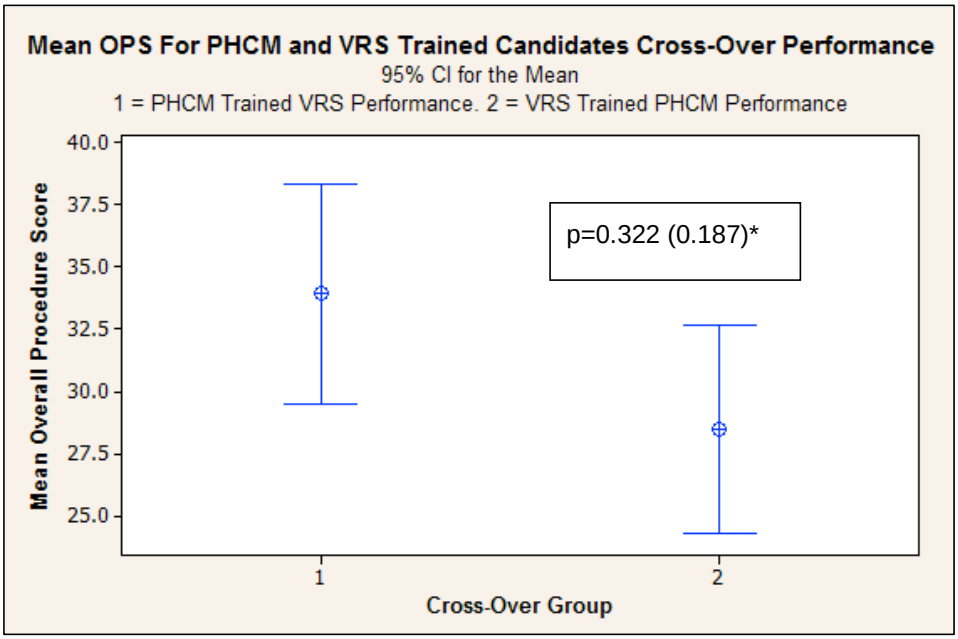
6.5.4.5 PHCM and VRS Cross-Over Performances

Following their training on the VRS, eleven of the twelve candidates returned to attempt the index procedure on the PHCM. All twelve candidates who were trained on the PHCM returned to attempt the index procedure on the VRS. Cronbach's Alpha score for inter-rater variability score was 0.947 indicating good agreement between our scorers.

Individual clinical performance scores are displayed in Appendix 26. The mean OPS for VRS trained candidates was 27.68 (TSC 12.32, GRS 15.36). Mean OPS for PHCM trained candidates was 34.17 (TSC 14.63, GRS 19.54). A trend towards improved score for PHCM trained candidates was seen, but this was not statistically significant (p=0.322). These mean scores are displayed graphically with their corresponding 95% confidence interval values in Figure 54.

Examiners satisfactory performance scores are displayed in Table 69.

Figure 54. Mean Overall Procedure Scores for the PHCM and VRS Trained 'Cross-Over' Performances



*One way ANOVA test: Bonferroni (Tukey)

Table 69. Cross-Over Performances: PHCM and VRS Trained Candidates Pass/Fail

Key Agreed Failure | Agreed Pass | No Expert Agreement

Procedure	Candidate	Examiner 1 Pass?	Examiner 2 Pass?
PHCM Trained VRS Performance	1	Pass	Pass
	2	Fail	Fail
	3	Pass	Pass
	4	Pass	Pass
	5	Pass	Fail
	6	Fail	Pass
	7	Pass	Pass
	8	Pass	Pass
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Pass	Pass
VRS Trained PHCM Performance	1	Fail	Fail
	2	Pass	Fail
	3	Pass	Pass
	4	Pass	Fail
	5	Pass	Fail
	6	Pass	Pass
	7	Fail	Fail
	8	Fail	Fail
	9	Pass	Pass
	10	Pass	Pass
	11	Pass	Pass
	12	Fail	Fail

6.5.4.6 Comparing Lecture Trained, VRS, PHCM Trained and 'Cross-Over' Performances

VRS and PHCM trained candidates initial performances is considerted as a pseudo-control group. These performances were made after minimal training (6.4.12.1, 6.4.12.2), and serve as a reasonable marker of novice baseline performance.

Candidates' 'cross-over' and lecture trained performance scores were compared to the VRS and PHCM trained candidates' initial performances. This is shown graphically in Figure 55. The corresponding significance tests are also shown on the graph, and tabulated in Table 70.

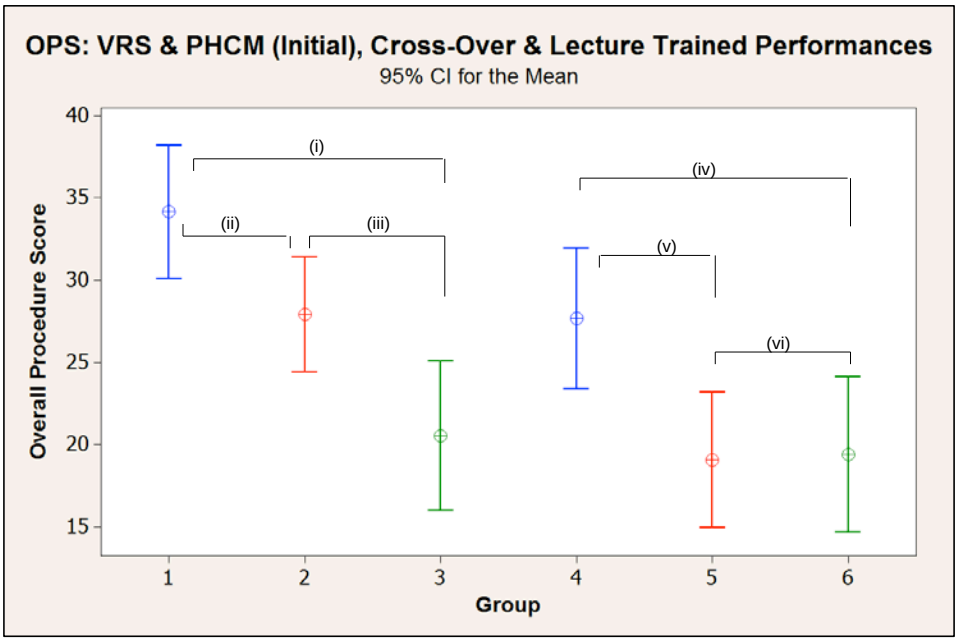
Training on PHCM conferred a significant benefit versus no training (p=0.000) when candidates performed on the VRS. Lecture training also resulted in a higher mean OPS, versus no lecture training (27.92 versus 20.54), but this did not reach statistical significance (p=0.119).

Training on VRS resulted in a higher mean OPS compared to no training when candidates performed on PHCM, although this reached borderline statistical significance (p=0.057 (p=0.030))*. Lecture training did not improve candidates OPS compared to no training.

Candidates' 'cross-over' and lecture trained satisfactory performance scores were compared to the VRS and PHCM trained candidates' initial performances. Candidates who trained on PHCM recorded more satisfactory performances on VRS versus no training (p=0.012). No other significant differences were seen between any of the other groups. This is shown in table 71.

*One way ANOVA test: Bonferroni (Tukey)

Figure 55. Comparing PHCM & VRS Initial and 'Cross-Over' Performances & Lecture Trained Candidates OPS



Key:
1. PHCM Trained VRS Cross-Over Performance
2. Lecture Trained VRS Performance
3. VRS Trained Candidates – Initial Performance
4. VRS Trained PHCM Cross-Over Performance
5. Lecture Trained PHCM Performance
6. PHCM Trained Candidates – Initial Performance

Significance Test of OPS*

(i) p=0.000 (0.000)

(ii) p=0.200 (0.300)

(iii) p=0.119 (0.081)

(iv) p=0.0.057 (0.028)

(v) p=0.040 (0.030)

(vi) p=1.000 (1.000)

* One way ANOVA test: Bonferroni (Tukey)

Table 70. Comparison of OPS Comparing PHCM & VRS Initial and 'Cross-Over' Performances & Lecture Trained Candidates – Significance Tests

Mean Clinical Performance Score	Task Specific Checklist	Global Rating Score	Overall Procedure Score
PHCM trained VRS 'cross-over' performance (1)	14.625*	19.54	34.17
Lecture - VRS (2)	13.25	14.667	27.92
VRS Trained: Initial Performance (3)	10.292	10.25	20.54
VRS trained PHCM 'cross-over' performance (4)	12.318	15.36	27.68
Lecture - PHCM (5)	9.125	9.96	19.08
PHCM Trained Initial Performance (6)	8.583	10.83	19.42
Test of between group difference[†]	**1** vs **2** p=1.000 (0.806) **1** vs **3** p=0.003 (0.002) **2** vs **3** p=0.130 (0.088) **4** vs **5** p=0.086 (0.061) **4** vs **6** p=0.021 (0.017) **5** vs **6** p=1.000 (0.996)	**1** vs **2** p=0.076 (0.054) **1** vs **3** p=0.000 (0.000) **2** vs **3** p=0.160 (0.105) **4** vs **5** p=0.037 (0.029) **4** vs **6** p=0.156 (0.103) **5** vs **6** p=1.000 (0.995)	**1** vs **2** p=0.200 (0.300) **1** vs **3** p=0.000 (0.000) **2** vs **3** p=0.119 (0.081) **4** vs **5** p=0.040 (0.030) **4** vs **6** p=0.057 (0.028) **5** vs **6** p=1.000 (1.000)

*****Mean

[†]One way ANOVA test: Bonferroni (Tukey)

Table 71. Cross-Over & Lecture Performances: Pass/Fail

Test of Between Group Difference

Satisfactory Performance	Pass	Test of Between Group Difference*
PHCM trained cross-over VRS performance (1)	9	**1** vs **2** p=0.400 **1** vs **3** p=0.012 **2** vs **3** p=0.193
Lecture – VRS (2)	6	
VRS Trained: Initial Performance (3)	2	
VRS trained cross-over PHCM performance (4)	5	**4** vs **5** p=0.667 **4** vs **6** p=0.193 **5** vs **6** p=1.000
Lecture – PHCM (5)	3	
PHCM Trained: Initial Performance	2	

***2** Proportions Test (Fishers Exact)

6.6 Discussion

Forty-eight candidates were recruited to the trial of ~~efficacy~~educational impact. They were allocated into one of the three training groups. Candidates in the Lecture group were of slightly higher clinical seniority (Table 51), however all groups consisted of endovascular novices. There were no significant differences in candidates' demographics between the three groups (Table 51, 52, 53).

Twelve candidates were allocated to training on VRS. After completeing their training regime (eight attempts) they performed the index procedure faster (p=0.000), used less fluoroscopy (p=0.000) and less contrast (p=0.000). It was observed that mean scores showed the largest improvement between the initial and third performance and then an apparent leveling off (Figure 41, 42, 43). Candidates were observed making significant improvements in their total procedure time out to their eigth procedure however beyond their second attempt candidates made no further (statistically significant) improvement in their fluoroscopy time and contrast volume used (Table 55).

Twelve candidates were allocated to PHCM. After completing their training regime they improved their total procedure time (p=0.000), fluoroscopy time (p=0.026) and volume of contrast used (p=0.008) (Table 58). Compared to the VRS candidates there is a steady improvement in total procedure time to attempt three, following which a statistically significant improvement is made (p=0.019) to procedure four, and a further jump in improvement (p=0.020) between attempts six and seven (Table 57). Average fluoroscopy time appears to remain constant until attempt five (Figure 45), there is also a wider variation in performance demonstrated by larger 95% confidence intervals about the mean (Figure 45). Volume of contrast also improved gradually, with an apparent plateau seen from attempt five (Figure 46).

Comparing training on VRS and PHCM candidates who trained on VRS performed quicker (p=0.014) and used less fluoroscopy (p=0.044), compared to their PHCM trained counterparts. There was no statistical difference between the volume of contrast used. A larger variation in performance was also also noted in PHCM

trainned candidates. This suggests that the VRS is an easier model for novice candidates to master, when compared to the PHCM.

Clinical performance scores (TSC, GRS and OPS) were recorded by two blinded examiners for each candidates performance, an average of these two scores was used for analysis. Candidates who trained on the VRS improved their TSC, GRS and OPS and this improvement was strongly significant (6.5.4.1). Looking between consecutive performances, there is both visually (Figures 47, 48, 49) and statistically (Table 62) a large improvement in scores between candidates' initial and second performance. There then follows a steady improvement in score, but no further significant improvement in maximum OPS demonstrated beyond performance five, with drops in performance on both the sixth and eighth procedure. This pattern correlates to previous literature which demonstrated that novice performers' learning curves plateau at between two and five repetitions of a technical skill (Seymour et al 2002, Aggarwal et al 2006a, Aggarwal et al 2006c).

It was observed that candidates became fatigued after their fifth performance, which affected their concentration. Some candidates were preoccupied with speed and performance quality was sacrificed. Some candidates failed to improve as they made the same uncorrected errors during each performance because formal feedback was prohibited (6.4.13)

There is a clear improvement in VRS candidate's satisfactory performance status (Table 64), with just three competent candidates at the initial attempt, and all twelve recording satisfactory attempts in the eighth and final attempt (p=0.000). However upon closer inspection, all of this improvement was made early, and in fact no statistically significant improvement was seen beyond their second attempt (Table 63).

Candidates who trained on the PHCM also improved their clincial performance score over the eight attempts, and this improvement was strongly significant (p=0.000). Unlike the VRS trained candidates, this improvement was more gradual (Figure 50), and a significant improvement was still seen up to performance seven

(Table 65). This observation again supports the conclusion that the PHCM is a more challenging model that requires longer to master.

Despite only one PHCM trained candidate recording a satisfactory performance on their initial attempt, after just two attempts, both examiners considered eleven candidates to be competent to perform the procedure under supervision in the interventional theatre (p=0.000) and no further improvement was noted beyond attempt three (Table 66, 67). This is a similar pattern to that seen in the VRS trained candidates (Table 63)

Expert feedback from the trial of face validity (Chapter 4) suggested that the PHCM represented a more “life-like” simulator. Subsequently it can be inferred that when training on real patients, novice candidates will continue making performance improvements after multiple attempts but require just two ‘practices’ before achieving a standard considered satisfactory by two expert practitioners, at least in terms of a simple guide-wire and catheter manipulation procedure.

Twenty four candidates were allocated to the didactic lecture training regime (6.4.12.3). Although the VRS seemingly represents an easier model, no difference in quantitative paremeters was demonstrated comparing the VRS and PHCM performances (Table 59). This can be explained by many of the PHCM candiates who failed to progress during their attempt. This meant (by default) they used less fluoroscopy and contrast. Yet the increased difficulty of PHCM was reflected in the number of candidates who successfully completed the procedure, with just two of the twelve on PHCM and nine on VRS; a statistically significant difference (p=0.012) (6.5.3.4.1). In addition, candidates who performed on VRS scored significantly higher clincial performance scores (p=0.025) than those who performed on the PHCM.

Concerning the PHCM and VRS trained candidates ‘cross-over’ performances, there was no statistically significant difference in either the recorded quantitative parameters or the clinical performance scores between these cross-over performances (Table 59, Figure 53).

As previously decribed in section 6.5.4.6, VRS and PHCM trained candidate's initial performance was considered as a pseudo-control. These 'control' performances were compared to both the lecture trained and 'cross-over' performances to establish if simulator training (PHCM and VRS) and a didactic lecture confer any performance benefits versus no training.

No differences in quantitative measurements were seen comparing VRS trained candidates and lecture trained candidates when they performed on PHCM (Table 59). In contrast PHCM training resulted in a faster (p=0.002) more radiographically efficient (p=0.01) VRS performance, versus a didactic lecture (Table 59). This observation is of less significance, as the PHCM represents a 'pseudo-patient', and transferring skills learnt on a "patient" into a simulator is less clincally relevant.

There is a statistically significant difference (p=0.04) in PHCM OPS (and GRS) in favour of those candidates who trained on the VRS versus candidates who received a traditional lecture. VRS trainng also resulted in superior perfromance scores versus no training, although this reached borderline significance (p=0.057, (p=0.028))*. There was no difference in OPS score between the lecture trained candidates and the control group (p=1.000) suggesting that a didactic lecture offers no benefit when candidates are learning to perform on a PHCM. [*One way ANOVA: Bonferoni (Tukey)].

There is a statistically significant difference (p=0.000) in VRS OPS (TSC and GRS) and the number of satisfactory performances (p=0.012) in favour of candidates trained on the PHCM (6.4.12.1) versus candidates who received no training. There is no difference seen between the lecture trained candidates (OPS or satisfactory performance) and those who underwent training on the PHCM (p=0.2), indicating that a didactic lecture is potentially as effective as a lengthy day spent training on the PHCM. Comparing lecture trained candidates and the control, a trend was seen in favour of the lecture trained cohort, but this did not reach statistical significance. This final observation suggests that there may be a role for didactic lectures prior to beginning training on VRS..

Several limitations were encountered during this trial. Unlike VRS the PHCM is not able to recreate (in a standardized fashion) a stenting or angioplasty procedure and hence the trial is based upon a simple angiographic task (6.4.11). The steps involved in its successful completion are perhaps not as discriminatory of a candidate's skill as compared to a more complex procedure. Further work is required to investigate the efficacy of the PHCM for training both angioplasty and stent deployment.

Feedback (during and after each procedure) was prohibited during the training regimes (6.4.13). It was not possible to ensure standard feedback to each candidate following each training attempt and this created concern that candidates may demonstrate improvement due to superior feedback rather than the model itself. The limitation of excluding feedback is acknowledged, although it did ensure each trainee performance was standardised and any observed improvement attributed more reliably to the training model.

It was only possible to train six candidates on the same PHCM, after which it became unsuitable due to tissue degeneration. To complete the PHCM training regime two PHCM had to be used. These cadavers had variant anatomy and different degrees of difficulty. Indeed the second model had particularly ectatic iliac vessels. Unfortunately novice candidates lacked the expertise to negotiate the guidewire through the diseased iliac artery. A deviation in the standard protocol was subsequently agreed: an endovascular expert negotiated the J-wire into the abdominal aorta and candidates began each procedure with the J-wire already in-situ (6.4.12.1.2). This reduced the risk of candidates dissecting the cadaveric vessels.

This created a bias because candidates who performed on the first PHCM model and all VRS trained candidates had to insert the J-wire as their first step. This could have been prevented by abandoning the second round of PHCM training when it became clear that the iliac artery were unsuitable. Subsequent studies could be conducted by experienced endovascular candidates. Alternatively, from

the outset every performance in every experiment could begin with a J-wire in situ as standard.

Of note no candidate failed to insert the standard J-tip wire during any attempt, suggesting that this first step is not a discriminatory step of candidate competence. The subsequent omission of this step from three of the candidates performances (6.4.12.1.2) is unlikely to have affected their performance scores, and hence this limitation has minimal impact on results and subsequent analysis.

The flaws of allocating, rather than randomizing candidates to training regimes is acknowledged (6.5.1). It was not logistically feasible to recruit all candidates on the same day and run concurrent training. Cadavers are a limited resource and access to the NSTC was limited. Training was undertaken in a linear fashion with candidates added sequentially according to availability of the models, training facilities and relevant personnel. Future studies would need to be more heavily supported, both financially, and in terms of personnel, in order to adhere to a more robust trial methodology.

The twelve-week lag time between crossover performances could have impaired candidate's ability to demonstrate transferability of their skills. It was not feasible to undertake crossover performances any sooner due to availability of the simulators and access to the training facilities. It was observed that candidates had forgotten skills learnt during their training initial regime that subsequently impaired their crossover performances. Despite this potential flaw a degree of consolidated learning has been demonstrated, as candidates did record superior performance scores versus the control despite a three-month lag time.

6.7 Conclusion

In a limited endovascular procedure, repetitive training on both a VRS and PHCM led to highly significant improvements in both quantitative parameters and clinical performance scores. VRS training led to quicker improvements, with most being observed after only two attempts, somewhat negating a lengthy training protocol. PHCM training has a longer learning curve, with more gradual improvement, reflecting the enhanced difficulty of a more realistic model.

VRS training did lead to enhanced performance on the PHCM, adding weight to the argument in favour of novice VRS training prior to real patient contact, if the PHCM can be considered a ‘pseudo-patient’. However, this trial did not examine the most efficacious way of delivering this VRS training, and further work is still required to answer this pertinent question.

The PHCM represents an efficacious training model, challenging, lifelike and susceptible to the frailties of the real human vasculature. Lectures add little to the candidates training experience, supporting a more hands-on approach when using the cadaver model. All candidates enjoyed the submersive experience of operating on a real patient, in a real theatre environment. Although this trial was not designed to answer the question of the transferability of PHCM training into real ‘live’ patients, one could postulate that the vastly enhanced realism will train candidates in a more sustainable, and clinically relevant manner. However, further work is requited to accurately answer this question.

Chapter 7

The Role of Feedback in Technical Skills Acquisition: Investigating the Efficacy of Video Assisted Feedback.

Abstract

Aim

The aim of our trial was to assess the role of video enhanced feedback, in particular the role of unsupervised, video enhanced feedback, in maximising candidate performance during undergraduate medical technical skills training.

Methodology

32 surgical suturing novices were recorded performing a simple suturing exercise in a Scotia Medical Observation Training System (SMOTS™) examination bay. Candidates were then randomised into three feedback groups: 1) standard lecture feedback (SLF), 2) viewed their initial performance on video – unsupervised (UVF). 3) Viewed their performance alongside an expert who provided additional feedback (EVF). All candidates were then recorded performing the same suturing skill. Pre and post feedback videos were edited, fully anonymised, randomly ordered and scored by two blinded suturing experts. Candidates completed post trial questionnaires of their satisfaction of the feedback they received.

Results

All trainees improved their performance scores following feedback (SLF p=0.007, UVF p=0.002, EVF p=0.001). Groups receiving UVF and EVF showed superior improvement over those receiving SLF (p=0.048, p=0.009). No difference was seen between UVF and IVF (p=0.593). Trainees preferred video enhanced feedback to SLF, favouring EVF. All were highly satisfied with UVF.

Conclusions

Video based feedback (UVF and EVF) demonstrated improved performance of suturing in the novices in our trial. Lecture based feedback is not favoured by students. EVF confers no superior benefit over UVF. Students unanimously agreed that they preferred video assisted feedback, to SLF.

Chapter 7

7.0 The Role of Feedback in Technical Skills Acquisition: Investigating the Efficacy of Video Assisted Feedback.

7.1 Introduction

Clinical feedback is defined as “specific information about the comparison between a trainee’s performance and a standard, given with the intent to improve the trainee’s performance” (Van De Ridder 2008).

The deliberate exclusion of feedback during the trial of efficacy has been acknowledged as a potential source of limitation (6.6.2). A study was therefore designed to look specifically at the role of feedback in technical skills acquisition to investigate this potential confounding variable. Chapter 7 will outline this trial

7.1.2 Feedback

As previously reviewed (1.11) the precise role of feedback in technical skills training remains unclear. Few would argue that feedback is not an important factor, but exactly how it is delivered, when and by whom remains a matter of debate.

For time, financial and logistical reasons it was not feasible to conduct a robust feedback study using the PHCM or SVR models. Training was therefore targeted at undergraduate technical clinical skills training.

7.1.2.1 Feedback At Undergraduate Level

The recent national student survey (National Student Survey 2011) revealed that across the country, and in all undergraduate curricula, students are unhappy with the amount of feedback they receive from their respective faculty. There was no

exception in medical students, who declared universal dissatisfaction with their university feedback.

Undergraduate medical school clinical skills training is an integral part of the undergraduate curriculum. At Newcastle University Medical School (NUMS) clinical skills are taught in Phase one of the course in a standardised format in dedicated training skills laboratories by qualified skills trainers. Large groups of medical students require training in a wide range of technical clinical skills including venepuncture, blood pressure measurement, and cardio-pulmonary resuscitation. Satisfactory ability to perform these skills are formally assessed in objective standardised clinical examinations (OSCE's). Successful completion of clinical skills training is progress within the course.

In order to enhance the medical students learning experience generally efforts should be made to improve feedback. Yet how much feedback, when it is delivered and by whom is still relatively uncertain.

7.2 Aims and Hypothesis

Successful clinical skills training requires appropriate feedback. It is hypothesized that medical students will favour individual feedback from trained experts and individualised feedback will result in superior performances, compared to generic feedback during technical skills training. Furthermore it is hypothesized that unsupervised video enhanced feedback will enrich students training experience and result in performance improvements comparable to individualised feedback.

The aim of this trial was to assess the role of video enhanced feedback (VEF), in particular to look at the potential role of unsupervised, video enhanced feedback, in maximising candidate performance during undergraduate medical clinical skills training.

7.3 Methods

In designing the trial to assess the role of a novel feedback technique it was important to identify the current way in which feedback is delivered to students during their clinical skills at Newcastle University.

7.3.1 Current Feedback Standards at Newcastle University Medical School

Through informal interviews with NUMS clinical skills tutors, it became clear that a standard approach for delivering feedback did not strictly exist. Feedback was often delivered in an ad-hoc fashion. Interestingly, staff commented that there simply was not the time or the staff to deliver individual feedback to all medical students. Staff felt that students who were experiencing difficulty during practical clinical skills sessions often received individual feedback but acknowledged that the majority of students received either generic lecture based feedback or no structured feedback at all.

Following further discussions with the clinical skills head of faculty, it was decided that 'generic lectures' would be considered as 'standard' feedback at NUMS in order to provide the study with a credible format for comparison.

7.3.2 Technical Skills

A technical skill is "any skill that is required to accomplish a specific task". (www.businessdictionary.com) It was imperative to select medical students with similar experience of the technical skill under investigation, in order to achieve non-biased intervention groups. The most obvious standpoint is to identify 'novices'. Even by the end of first year studies medical students have acquired a large skill set, making selection of a suitable technical skill challenging. Consensus was eventually reached by both clinical skills facilitators and trial supervisors that 'suturing' was a suitable technical skill as it is not formally taught or assessed in Phase 1 (pre-clinical) part of the MBBS course.

Skin suturing is a mandatory skill for all graduating doctors registering with the General Medical Council. (GMC tomorrows doctors). However, skin suturing is not

currently taught formally within the NUMS undergraduate clinical skills curriculum. This left a large potential cohort of Phase 1 novice experience suturing candidates for the proposed trial.

7.3.3 Feedback Groups

The suturing course/experiment centered around three different forms of technical skills training feedback, following a standard clinical skills session. Two intervention feedback groups were established, to compare with the 'standard' feedback group. In brief:

7.3.3.1 Group 1: Standard Lecture Feedback (SLF): 20 minutes

As above (7.3.1) candidates randomised to the standard feedback group received a generic lecture. This generic lecture took place in the clinical skills laboratory, and involved a twenty-minute power point presentation. The presentation covered the most common errors and difficulties, which had been observed in candidates who had performing during a pilot experiment of suturing teaching. The lecture was delivered in a didactic fashion, and although candidates were permitted to ask questions, care was taken to ensure no additional 'individualised' feedback was delivered.

7.3.3.2 Group 2: Unsupervised Video-Enhanced Feedback (UVF): 20 minutes

Candidates randomised to UVF were escorted to a remote private viewing room. Each candidate was given a lap top computer. The computer was installed with three videos which candidates were instructed to watch within a twenty-minute time frame. These videos included:

1) Seven minutes: A real time, unedited video of their own performance (without commentary).

2) Five minutes: An edited video of an expert performing the suturing exercise, with additional expert commentary

3) Five minutes: A video of an expert delivering 'hints and tips', which targeted the areas which had been previously identified as causing difficulties for candidates (7.3.12.1) performing this suturing exercise.

3 minutes was allowed for candidates to be able to stop, rewind and replay sections of videos they wished.

During their video viewing, a course supervisor was present to address any 'technical' problems candidates may have encountered whilst viewing their videos. They also ensured candidates stuck to time ensuring all three videos could be viewed during their twenty minutes allotted feedback time.
No individualised feedback was provided in this group at any stage.

7.3.3.3 Group 3: Individualised Video-Enhanced Feedback (IVF): 20 minutes

Candidates in the IVF group were again escorted to a private viewing room. A course facilitator/suturing expert accompanied each candidate. Together with their expert, candidates watched an unedited video of their suturing performance, and they were given real-time one to one technical skills feedback on their performance. Candidates and experts were permitted to pause, rewind and replay the video at any point, to ask questions, or deliver technical points of critique. IVF sessions were not permitted to last longer than twenty minutes to ensure uniformity in feedback time between the feedback groups.

7.3.4 Inclusion Criteria

- Medical students from Newcastle University who had 'low novice' experience at suturing (See appendix 6).
- Any age, any gender, and any seniority of student were permitted providing their suturing experience was 'low novice'.

7.3.5 Exclusion Criteria

- Any candidates who had greater than 'low novice' experience at suturing
- Non-medical undergraduate trainees

7.3.6 Process of Recruitment

Posters advertising a free voluntary beginners suturing course/experiment were placed in both the clinical skills laboratory and the medical students common room, at NUMS (Appendix 7). A generic invitation to all Phase 1 medical students was also made at the beginning of a compulsory lecture, and via the university intranet. The shout out, email and poster requested potential candidates to email the PI, expressing their interest and confirming their novice status. Potential volunteers had to confirm their availability for three potential dates; this was in order to facilitate randomisation (7.3.8). In anticipation of late dropouts, a total of thirty-six medical students were accepted onto the beginners suturing course/experiment.

7.3.7 Candidates Unique Training Number

Students who responded to the email and poster invitation (7.3.6) and indicated their availability for all three experiment days were assigned a unique identifying training number (UTN). This number was used in the process of randomisation (7.3.8) and it was used on all paper work and video performances related to that student. This ensured questionnaire responses and videoed performances could be analysed and linked anonymously.

7.3.8 Randomisation

Medical students were randomised using their UTN. All thirty-six students were randomised into the three feedback groups (7.3.3) using a closed envelope system with students UTN's blocked into groups of twelve. This created three numerically even training groups. Group 1 would meet on the first day of the trial, group 2 on the second and group 3 the third. Students were then emailed confirmation of their training group date and time.

7.3.9 Introductory Information Sheet

On attending the NUMS clinical skills training laboratory, all candidates were given a written information sheet (Appendix 8). Students were given five minutes to read this sheet, which detailed the aims and objectives of the course, and exactly how

the course/experiment would run. The need for informed consent was addressed, and students right to withdraw their consent at any stage was also highlighted.

7.3.10 Introductory Lecture

To affirm the aims and objectives of the course, students all received a short five minute introductory lecture, delivered using standard power point™. It was deemed necessary to reiterate that the course was entirely anonymous, performances would be videoed, consent could be revoked and scores would in no way affect their ongoing undergraduate studies (Appendix 9).
Students were given an opportunity to ask any questions that they wished.

7.3.11 Informed Consent

Following both their introductory information sheet and lecture, all students who indicated that they wished to remain a part of the voluntary training course, were administered with a written consent form (Appendix 10). It was made clear that this gave the course administrators permission to use their video performances for research purposes and that only their hands would be recorded, informed consent could be withdrawn at any time during the course, and for one week after completion of the course.

7.3.12 Teaching: A Basic Suturing Technique

All candidates were taught a basic suturing exercise using an approved Royal College of Surgeons of England technique (Intercollegiate BSS). The ‘instrument tied reef knot’ was taught as the method for securing sutures. In order to ensure uniformity in teaching technique between the three training groups, this teaching session was video recorded prior to the experiment, and candidates watched this video on the day of the trial. The teaching video was annotated with expert demonstrations of each step, and commentary, explaining the technique in detail. This ensured the teaching was entirely standardised. This teaching took fifteen minutes (Figure 56).

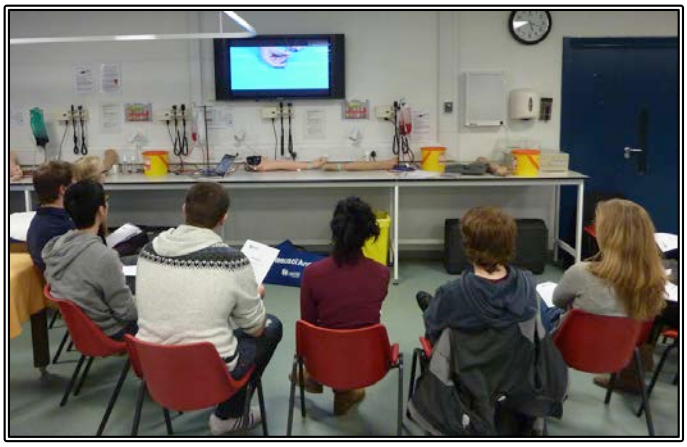


Figure 56: Candidates watching the suturing teaching video

Following this video teaching session, medical students were permitted to ask questions regarding any problems or concerns they may have, but course facilitators were careful not to offer any additional training that may bias the teaching offered to the three individual groups prior to their initial suturing assessment.

7.3.12.1 Teaching Video Pilot Studies

To ensure the teaching video was efficacious it was trialed in three small pilot teaching sessions involving senior medical students who were rotating through one of the regional teaching hospitals (The Freeman Hospital, Newcastle, UK). This included three separate sessions of groups varying in size from six to seventeen.

All students commented that the training offered in the video was both easily understandable and exhaustive for the task they were being asked to complete. No candidates in fact asked any additional questions.

Although this cohort included some students with moderate suturing experience, there were a large proportion of low novice candidates, who all agreed the video was suitable.

Although none of these students were assessed, the efficacy of the 'training video' for teaching the basic suturing technique was assessed. Common mistakes and difficulties encountered by candidates were observed and documented. These formed the basis of the 'generic lecture feedback', as described in section 7.3.3.1.

7.3.13 Pre-Trial Questionnaire

Before students began suturing training they completed a pre-trial questionnaire (Appendix 11) to determine student demographics. The questionnaire recorded their university year group and previous exposure to simulated suturing training. A series of questions recorded students' handedness, musical instrument experience, exposure to video games, use of correctional glasses for procedural work and ability to type. These factors have been previously cited (Chaer et al 2006, Boyle et al 2011) as having an effect on a candidate's ability to perform a technical skill. It was therefore desirable to ensure such factors were evenly distributed between the three randomised training groups. As in Chapter 4, candidate's expertise was determined to ensure volunteers were all of low-novice experience.

7.3.14 The Technical Skill Exercise

The teaching video (7.3.12) demonstrated how to insert three sutures into a synthetic model ('fake skin'), securing these sutures using an instrument tied reef knot. Following completion of the fifteen minute teaching video candidates were shown a powerpoint containing instructions for the training exercise they were required to complete (Appendix 12). This informed them that they would be required to insert three sutures using the technique shown, and then subsequently remove three sutures, again following a safe technique they had been shown on the video.

Each Scotia Medical Observation Training System (SMOTS – see 7.3.15) equipped examination bay contained all the equipment required to complete the suturing exercise, including a sharps bin for safe sharps disposal (figure 57). Students were informed that their performance would be recorded (only students

hands were recorded). In concordance with their NUMS OSCE, candidates were informed that they would be given seven minutes to complete this task, and they would be marked on their performance by an attending course facilitator. Unlike their NUMS OSCE, candidates were allowed to ask questions during their official recorded performance, but encouraged to complete the task as independently as possible in order to achieve a maximum performance score.

Figure 57: The equipment required for the suturing exercise, including scissors, forceps, needle holder, suture material and sharps bin. Note the suture pad is secured to the table; this was to ensure it remained constantly in view of the SMOTS recording cameras.

7.3.15 Scotia Medical Observation and Training System (SMOTS).

The Scotia Medical Observation and Training System™(SMOTS) is a purpose built video and audio enhanced training system, installed for training purposes in a variety of clinical and non-clinical environments worldwide. A series of fixed ceiling fully manoeuverable cameras (Figure 58) are capable of high definition video recording. Images are instantly stored and filed on a central computer for instant playback and assessment. Additionally audio equipment permit sound recording and the potential for two-way communication from the SMOTS control room, which is concealed behind a one-way glass mirror. (www.scotiauk.com/smots).

Figure 58: The fixed mounted, fully maneuverable high definition cameras installed in the SMOTS examining bays

7.3.15.1 SMOTS at Newcastle University

NUMS clinical skills laboratory has installed four SMOTS video and audio enhanced training stations. This allows clinical skills facilitators to record students training either individually or as groups. Two way audio permits remote viewing and interaction between candidates and examiners without a physical presence during the training scenario.

Each bay is separated allowing independent training to take place in each bay simultaneously. Performances are recorded onto the central SMOTS computer situated in the clinical skills office, separated from the training laboratory by one way glass to permit private viewing of the SMOTS training bays in a remote site.

Prior to recording for the feedback trial, cameras in all bays were focussed onto the synthetic skin pads. Two views of the students' hands were recorded to ensure every detail was captured for subsequent analysis. Care was taken to ensure cameras recorded only student's hands to ensure performances remained entirely anonymous.

7.3.15.2 Recording on SMOTS

Medical students performed their video performances (both before and after feedback) in one of the four SMOTS examining bays. As described above (7.3.15.1) SMOTS cameras were entirely focused on the synthetic suturing pads. In order to link students performances anonymously, prior to each performance a sheet identifying students by their UTN and highlighting if the performance was

'pre-feedback' or 'post-feedback' was temporarily displayed onto the camera. In a synchronised fashion, performances commenced and these identifying sheets were removed.

Performances took place four at a time until all pre-feedback performances had taken place (Figure 59). Before and after assessed performances, students were situated in a remote area of the training laboratory; they were supervised by a course facilitator and instructed not to discuss their performances with one another.

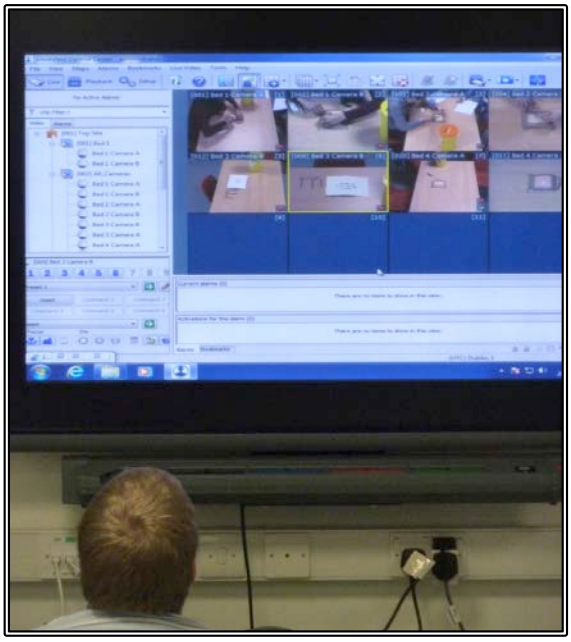


Figure 59: The central SMOTS viewing screen, shown here observed by a faculty member. 4 videos (2 views per SMOTS recording bay) record simultaneously

7.3.16 Pre-Feedback Performance

In groups of four, students were shown to their examining bays. Suturing was performed with candidates sitting; this was to ensure video capture of their entire performance (Figure 60). They were provided with the necessary equipment, including a sharps bin for safe disposal of their needle (Figure 57). Performances commenced simultaneously and were timed remotely. After their seven minutes students were stopped. Students received no feedback at any time during this performance.

Figure 60: Student performing the suturing task, observed and scored by a member of faculty*

* For reasons of candidate anonymity, the candidates shown in this picture are in fact members of the trial faculty (photographed with consent), simulating the suturing exercise

7.3.17 Validated Scoring Tool for Assessment of Technical Skill

Students' pre and post-feedback suturing performances were scored using a modified version of a previously validated clinical skills scoring tool (Appendix 13). As previously discussed (1.10.5), the Objective Structured Assessment of Technical Skill (OSATS) model consists of both a task specific check list and a global rating score, providing each performance with an overall score of technical performance. Finally, examiners would indicate if they felt a candidate should 'pass' or 'fail' that particular exercise based on their demonstrated suturing performance.

7.3.17.1 Ensuring Uniformity In Performance Scoring

All members of the faculty who were involved in scoring candidates on the day, met prior to the trial to discuss the scoring methodology. Ten edited video clips of a mock candidate (video was in fact the PI Craig Nesbitt), performing different parts of the suturing exercise, simulating varying degrees of skill, were shown to the faculty, who discussed their scoring technique with the group. The purpose of this session was to agree scoring and reduce the inter-rater variability.

7.3.18 Feedback

After completing their 'pre-feedback' performance, candidates received feedback in accordance with their randomised cohort (7.3.3). For logistical reasons, all candidates randomised to day 1 received the same feedback; this was repeated on day 2 and 3 respectively.

7.3.19 Post Feedback Performance

Following feedback, all students were again assessed performing the suturing exercise. Examining conditions were identical to their pre-feedback performance. Performances were scored using the same scoring tool (7.3.17), giving each candidate a score for their post feedback performance.

7.3.20 Post Trial Questionnaire

Following their post-trial performance students completed a post-trial questionnaire (Appendix 15). This asked students to rate their agreement with three statements regarding their feedback, on a 5-point Likert scale. Finally, free text boxes were provided, and students were encouraged to provide any additional comments relating to their chosen form of feedback.

7.3.21 Post Trial Debriefing Session

Following their post-trial performance students attended a short five-minute debriefing session. This summarised the training session, and again addressed the nature of their anonymised video performances and their right to revoke their informed consent for one further week. To enhance this important message each student received a debriefing document, which further highlighted these integral points (Appendix 14) and provided students with a point of contact should questions or concerns arise after the course had finished. During this session students were permitted to ask questions relating to their suturing teaching.

Following the debriefing session, students were awarded with a course certificate (Appendix 16).

7.3.22 Subject Numbers

A similar power study was used from Chapter 6 (6.4.14). This is because there is scant research upon which to base precedence when assessing different feedback techniques for training undergraduate medical technical skills. Trials using simulation intervention when teaching technical skills to novice operators was therefore adopted, (Aggarwal et al 2006a, Aggarwal et al 2006b, Seymour et al 2002) providing a predicted improvement in the present video-enhanced feedback intervention groups of 30%. This was then integrated into the power study:

Based on a 2-tailed test, with an alpha (α) level of 0.05 and power (1 - β) 0.8. A predicted improvement in overall procedure score by the present video-enhanced feedback intervention group of 30% gave a minimum of ten subjects required in each arm. This was the same estimated percentage improvement that was used by Seymour et al (Seymour et al 2002).

7.3.23 Ethics Approval

Ethics approval was a granted for the project by Newcastle University Ethics Research Council in June 2012 (Appendix 24)

7.3.24 Storage of Data

All recorded data was anonymous. No personal identifiable candidate details were kept. Anonymous questionnaire data (identified by students' anonymous UTN) were stored in a secure room within the Newcastle Surgical Training Centre (NSTC). Anonymous video performances were copied from the SMOTS hard drive and downloaded onto a secure computer housed permanently within the NSTC. This facility is protected by both a card swipe system and a standard alarm system out of hours.

Data is to be kept on a secure trust approved computer, housed within the NSTC. It will be held for a maximum of 12 months, after which it will be destroyed.

7.3.25 Blinded Video Analysis

Two suturing experts were selected to score all of the video performances for a second time. These experts were given full details of the methods of the suturing experiment and viewed the training video. They were also given instructions on how to score performances using the modified OSATS scoring tool. As previously described (7.3.12.1), a practice scoring session took place during which the expert scorers openly discussed their scoring justification on a series of edited video clips, and addressed any concerns that they may have had before going on to score all full edited versions of the videos. This was to reduce inter-rater variability.

One week following the trial (the period during which students could withdraw their consent), all students recorded video performances were arranged into a random order according to a sequence of randomly generated numbers created through an online programme. (www.random.org). Videos were then edited to remove any identifiable video footage, such as whether the video was pre or post feedback or any details of candidates UTN. These edited videos were then given to the experts to score. Experts were completely blinded to the status of the video. Scored video performances were then arranged back into correct order for analysis.

7.3.25.1 Expert Scorer

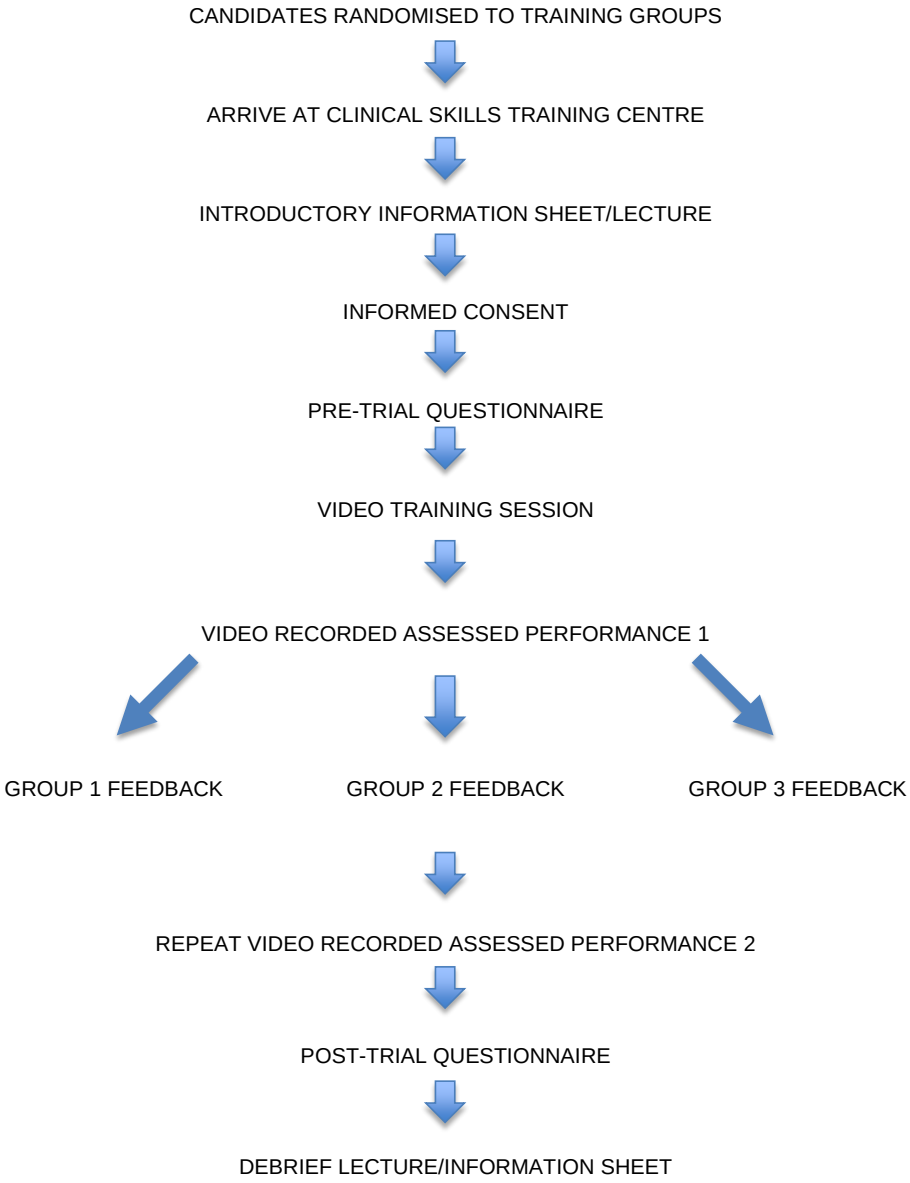
The expert scorers were both senior general surgical registrars (ST6). Both were competent to suture unsupervised and taught surgical suturing and knot tying on a regular basis during their own clinical practice.

7.3.25.2 Edited 'Anonymous' Videos

Although video performances only included students' hands and were edited to remove any identifiable information, it is accepted that some candidates' hands have recognisable features, such as nail varnish; this means that the blinded scorers may have been able to identify students performances.

Figure 61 shows an algorithmic overview of the trial.

Figure 61. Algorithmic Overview of the Study



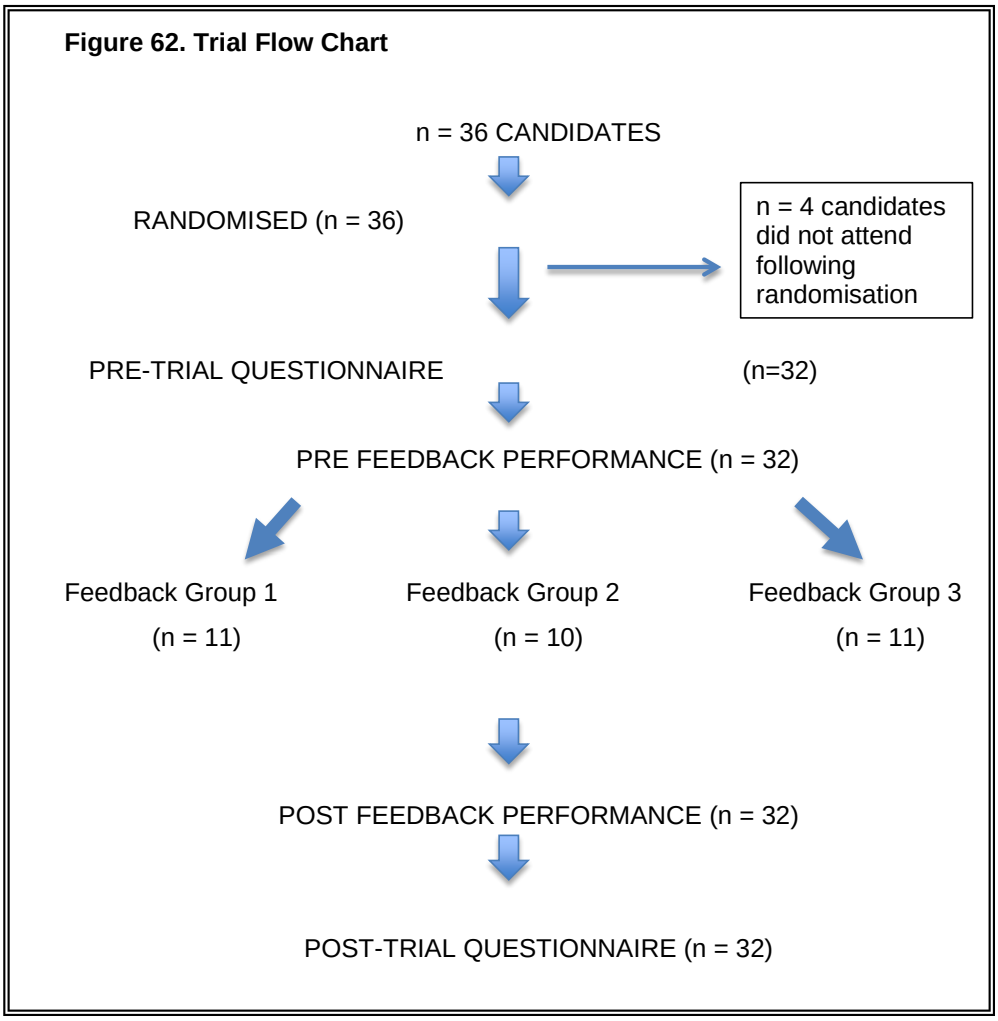
7.4 Results

As in Chapters 2, 3 and 4, all data generated from the video enhanced feedback was tabulated onto an excel spread sheet (Microsoft excel™). Mean, median, modal and standard deviation values were extracted in standard fashion. Statistical analysis was undertaken using the Statistical Package for the Social Sciences version 19 (SPSS, Chicago) and Minitab version16. Advice was sought from a medical statistician at Newcastle University for the most appropriate statistical tests when analyzing the trial data. Cronbach's alpha was used to test for expert scorer's inter-rater variability. Fishers Exact test was used to compare demographic data. Mann Witney U test was used when comparing groups' post trial questionnaire response scores and 1-way ANOVA to compare clinical performance scores. A p-value of <0.05 was considered to be significant.

7.4.1 Trial Flow Chart

Figure 62 shows a flow chart of the trial.

Figure 62. Trial Flow Chart



7.4.2 Medical Student Demographics

Thirty six students contacted and indicated they were interested in attending the introductory suturing teaching sessions. They were assigned a UTN and randomised as described (6.3.6) into three groups. One student did not attend on day one, two students did not attend on day two, and one student did not attend on day three.

The thirty two students who attended for the suturing experiment displayed the following demographics (Table 72), based on analysis of their pre-trial questionnaires.

Table 72. Candidate Demographics

Demographic	Group 1	Group 2	Group 3	Significance test of between group difference (P)
Number	11	10	11	
Age	19.5 (17-21)	20.2 (18-24)	20.2 (19-23)	ANOVA (NS)[¥]
Sex	6F, 5M	5F, 5M	7 M, 4 F	Proportions test[ŦF] (NS)
Seniority	7 yr 1 students 4 yr 2 students	7 yr 1 students 3 yr 2 students	6 yr 1 students 6 yr 2 students	Proportions test (NS)
Suturing experience*	Low novice	Low novice	Low novice	Proportions test (NS)
Wear glasses	5 Yes, 6 No	5 Yes, 5 No	7 Yes, 4 No	Proportions test (NS)
Handedness	1 left, 10 right	2 left, 8 right	2 left, 9 right	Proportions test (NS)
Play musical instrument	9 yes, 2 no	8 yes, 2 no	7 yes, 4 no	Proportions test (NS)
Play video games regularly	3 yes, 8 no	3 yes, 7 no	4 yes, 7 no	Proportions test (NS)
Ability to type	11 yes, 0 no	10 yes, 0 no	11 yes, 0 no	Proportions test (NS)
Previous suturing teaching	1 yes, 10 no	1 yes, 9 no	2 yes, 9 no	Proportions test (NS)

*See Appendix 7
[Ŧ]Fishers Exact Test
[¥]NS = Not significant

7.4.3 Training Completed

All students who attended for suturing training signed consent forms and completed all aspects of the training course (6.4.1).

7.4.4 Pre-Feedback Performance

All students completed their pre-feedback suturing performance. Their performances were recorded in a SMOTS examining bay. All students had seven minutes to complete the task.

7.4.4.1 Pre-Feedback Direct Observation Score (DO)

A member of the faculty directly observed and scored each performance using the modified OSATS scoring tool (5.3.11, Appendix 13). Scores derived from direct observation are referred to as 'DO' (Direct Observation score).

Table 73 shows the pre-feedback suturing performance scores for TSC, GRS and OPS for students marked via DO.

7.4.4.2 Pre-Feedback Blinded Scores (BS)

As described in section 6.3.17, each pre-feedback video was edited to remove identifiable information and then arranged in a random order. Two blinded expert scorers then scored each performance using the same scoring tool (6.3.11, Appendix 13). These scores were then combined (mean score) and put back into the correct order using the random sequence. Scores derived from blinded scorers are referred to as 'BS' (Mean Blinded Scores).

- Table 73 shows the BS pre-feedback suturing performance scores presented alongside the DO pre-feedback score, for TSC, GRS and OPS.
- The individual BS scores for each expert examiner (Examiner 1 and 2) are shown in Appendix 27.

- Cronbach's alpha was 0.859, indicating good agreement between the two blinded expert scorers.

7.4.4.3 Average Pre-Feedback Blinded Scores (BS) versus Direct Observation (DO)

Table 74 shows the average pre-feedback performance score for all candidates (TSC, GRS and OPS) in groups 1, 2 and 3 for both DO and BS, together with significance tests of between group differences (one way ANOVA test: Bonferroni).

7.4.4.4 Pre-Feedback Results: Summary

Analysing both BS and DO pre-feedback scores, there is no statistically significant difference between the three groups. There is also no significant difference comparing the DO and BS scores directly, indicating scores awarded on the day (DO) were similar to those awarded via BS. The statistical difference between DO and BS scores are shown in Table 74.

Table 73. Pre-feedback Suturing Performance Scores

		Group 1: *Generic Lecture Feedback*		**Group 2:** *Unsupervised Video Enhanced Feedback*		**Group 3:** *Individualised Video Enhanced Feedback*	
	Candidate	**DO***	**BS[ǂ]**	**DO**	**BS**	**DO**	**BS**
Task Specific Checklist (TSC)	1	24	14.5	26	28	6	4
	2	3	4	19	25.5	28	27.5
	3	9	7	23	25.5	12	17
	4	20	20.5	4	4	20	21.5
	5	8	10.5	18	22.5	18	26
	6	38	33.5	3	3.5	17	17
	7	12	16	22	22	28	19
	8	21	20	16	20	4	6.5
	9	7	9.5	18	22.5	14	9.5
	10	28	29	13	22	22	27
	11	37	37	DNA	DNA	17	12
Global Rating Score (GRS)	1	26	11	22	24	15	11.5
	2	12	12.5	17	26	16	20
	3	11	14.5	17	20	12	18
	4	27	23.5	11	11	20	16.5
	5	15	11	19	15.5	17	25
	6	31	25	8	9	17	15.5
	7	14	13.5	17	17.5	24	21.5
	8	22	17.5	19	14	7	11
	9	17	17	18	19	14	11.5
	10	25	23.5	19	21.5	18	19.5
	11	26	29	DNA	DNA	21	11
Overall Procedure Score (OPS)	1	50	25.5	48	52	21	15.5
	2	15	16.5	36	51.5	44	47.5
	3	20	21.5	40	45.5	24	35
	4	47	44	15	15	40	38
	5	23	21.5	37	38	35	51
	6	69	58.5	11	12.5	34	32.5
	7	26	29.5	39	39.5	52	40.5
	8	43	37.5	35	34	11	17.5
	9	24	26.5	36	41.5	28	21
	10	53	52.5	32	43.5	40	46.5
	11	63	66	DNA	DNA	38	23

*Direct Observation score
ǂMean Bllinded Score

Table 74. Average Pre-Feedback Clinical Performance Scores (TSC, GRS & OPS) Comparing DO and BS

	Task Specific Checklist (TSC)			Global Rating Score (GRS)	Overall Procedure Score (OPS)	
Direct Observation score (DO)ǂ						
Grp 1	18.82 (12.11)*	1 vs 2 p=1.000	20.55 (6.95)	1 vs 2 p=1.000 2 vs 3 p=1.000 1 vs 3 p=1.000	39.36 (18.60)	1 vs 2 p=1.000
Grp 2	16.20 (7.63)	2 vs 3 p=1.000	16.70 (4.14)		32.90 (11.34)	2 vs 3 p=1.000
Grp 3	16.91 (7.75)	1 vs 3 p=1.000	16.45 (4.59)		33.36 (11.59)	1 vs 3 p=1.000
Blinded Score (BS)ǂ						
Grp 1	20.68 (12.08)	1 vs 2 p=1.000	18.59 (4.08)	1 vs 2 p=1.000 2 vs 3 p=1.000 1 vs 3 p=1.000	39.27 (16.09)	1 vs 2 p=1.000
Grp 2	21.10 (10.89)	2 vs 3 p=1.000	18.30 (4.54)		38.40 (14.77)	2 vs 3 p=1.000
Grp 3	20.77 (8.36)	1 vs 3 p=1.000	18.36 (3.70)		38.55 (12.44)	1 vs 3 p=1.000

DO versus BSǂ	**TSC**	**GRS**	**OPS**
Group 1	p=1.000	p=1.000	p=1.000
Group 2	p=1.000	p=1.000	p=1.000
Group 3	p=1.000	p=1.000	p=1.000

*****Mean (standard deviation)

ǂOne way ANOVA test: Bonferroni

7.4.5 Post Feedback Performance

Following feedback students re-performed the same suturing excercise. These performances were again recorded in a SMOTS examining bay. As in their pre-feedback performance (6.4.5) candidates were scored by a member of the faculty via DO. Each video performance was edited, randomly ordered and scored by two blinded experts. Their combined (mean) scores were then calculated (BS).

7.4.5.1 Post-Feedback Direct Observation Score (DO)

A member of faculty directly observed and scored each performance using the modified OSATS scoring tool (6.3.11, Appendix13).

Table 75 shows the post-feedback suturing performance scores TSC, GRS and OPS for candidates marked via DO.

7.4.5.2 Post-Feedback Blinded Scores (BS)

Two blinded experts scored each performance using the same scoring tool (6.3.11, Appendix 13).

- Table 75 shows the mean post-feedback BS suturing performance scores presented alongside the DO score, for TSC, GRS and OPS for candidates marked by BS.
- The BS scores for each expert examiner (Examiner 1 and 2) are shown in Appendix 28 as well as the mean BS score.
- Cronbach's alpha was 0.862, indicating good agreement between the two blinded examiners. For all other figures, the mean value for BS is used.

7.4.5.3 Average Post-Feedback Blinded Scores (BS) versus Direct Observation (DO)

Table 76 shows the post-feedback performance scores (TC, GRS and OPS) for groups 1, 2 and 3 for both DO and BS, together with significance tests of between group differences (one way ANOVA test: Bonferroni).

7.4.5.4 Post-Feedback Results: Summary

Analysing both BS and DO post-feedback scores, there is no statistically significant difference between the three groups. There is also no significant difference comparing the DO and BS scores directly, indicating scores awarded on the day (DO) were similar to those awarded via BS. The statistical difference between DO and BS scores are shown in Table 76.

Table 75. Post-feedback Suturing Performance Scores

		Group 1: *Generic Lecture Feedback*		**Group 2:** *Unsupervised Video Enhanced Feedback*		**Group 3:** *Individualised Video Enhanced Feedback*	
	Candidate	**DO***	**BS[Ŧ]**	**DO**	**BS**	**DO**	**BS**
Task Specific Checklist (TSC)	1	37	33.5	41	38.5	20	17
	2	19	14.5	35	34	40	29
	3	19	18	36	30	34	32.5
	4	33	32.5	19	18	38	33.5
	5	20	15	40	34	40	36
	6	35	33.5	21	32.5	39	32.5
	7	29	28.5	40	36	40	31.5
	8	31	30.5	29	27	21	17.5
	9	22	18.5	37	32	37	31
	10	37	30	32	33	42	38.5
	11	39	32.5	DNA[⌘]	DNA	35	33.5
Global Rating Score (GRS)	1	34	25	34	31	23	20.5
	2	19	15.5	26	24.5	25	23.5
	3	15	13.5	27	22.5	21	24
	4	31	24.5	19	18	27	20.5
	5	21	15.5	29	26.5	32	27.5
	6	32	26.5	18	26	28	22
	7	23	20	34	28.5	35	24.5
	8	26	18.5	26	21	22	19
	9	24	20.5	24	24	28	24
	10	31	22	25	27.5	29	31.5
	11	25	26	DNA	DNA	29	23
Overall Procedure Score (OPS)	1	23	58.5	74	69.5	46	37.5
	2	25	30	61	58.5	65	52.5
	3	21	31.5	63	52.5	55	56.5
	4	27	57	38	36	65	54
	5	32	30.5	69	60.5	72	63.5
	6	28	60	39	58.5	67	54.5
	7	35	48.5	74	64.5	75	56
	8	22	49	55	48	43	36.5
	9	28	39	61	56	65	55
	10	29	52	57	60.5	71	70
	11	29	58.5	DNA	DNA	64	56.5

*Direct Observation score
[Ŧ]Mean Bllinded Score
[⌘]DNA: Did Not Attend

Table 76. Average Post-Feedback Clinical Performance Scores (TSC, GRS & OPS) Comparing DO and BS

	Task Specific Checklist (TSC)		Global Rating Score (GRS)		Overall Procedure Score (OPS)	
Direct Observation score (DO) ǂ						
Grp 1	29.18 (7.83)*	1 vs 2 p=1.000	25.55 (5.97)	1 vs 2 p=1.000	54.73 (13.23)	1 vs 2 p=1.000
Grp 2	33.00 (7.80)	2 vs 3 p=1.000	26.20 (5.33)	2 vs 3 p=1.000	59.10 (12.63)	2 vs 3 p=1.000
Grp 3	35.09 (7.58)	1 vs 3 p=0.954	27.18 (4.24)	1 vs 3 p=1.000	62.55 (10.34)	1 vs 3 p=1.000
Blinded Score (BS) ǂ						
Grp 1	31.23 (7.30)	1 vs 2 p=1.000	22.45 (3.35)	1 vs 2 p=1.000	53.68 (10.43)	1 vs 2 p=0.823
Grp 2	34.95 (5.01)	2 vs 3 p=1.000	23.10 (2.94)	2 vs 3 p=1.000	57.75 (7.84)	2 vs 3 p=1.000
Grp 3	34.86 (7.24)	1 vs 3 p=1.000	24.73 (2.90)	1 vs 3 p=1.000	59.68 (9.84)	1 vs 3 p=1.000

DO versus BS ǂ	**TSC**	**GRS**	**OPS**
Group 1	p=1.000	p=0.257	p=1.000
Group 2	p=1.000	p=1.000	p=1.000
Group 3	p=1.000	p=1.000	p=1.000

*****Mean (standard deviation)

ǂOne way ANOVA test: Bonferroni

7.4.6 Comparison of Pre and Post-Feedback Scores

Student's pre and post-feedback performance scores, (TSC, GRS, OPS) were compared to assess for any patterns of improvement.

Having shown no statistical difference between DO and BS scores, only BS scores are subsequently presented in the main thesis. All comparative DO scores are detailed in Appendix 30.

7.4.6.1 Comparison of Pre and Post-Feedback Clinical Performance Scores

Table 78 shows student's pre and post feedback clinical performance scores, (TSC, GRS and OPS). Table 77 details some descriptive statistics. All students have improved their OPS following feedback (mean and median), but the greatest improvements appear to have been made following video enhanced feedback (UVF and IVF).

Figure 63 graphically displays the mean pre and post feedback OPS between the three feedback groups (BS). This shows a strongly significant improvement in OPS following UVF (p=0.003), IVF (p=0.001) and SLF (p=0.007).

Table 77. Descriptive Statistics for the Pre and Post Feedback OPS

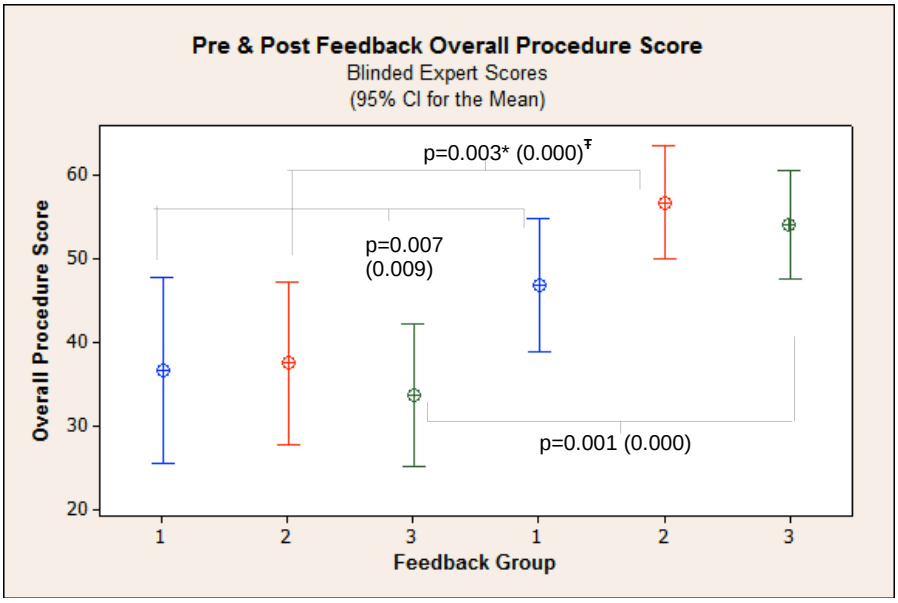
	Group 1: *Standard Lecture Feedback*		**Group 2:** *Unsupervised Video Enhanced Feedback*		**Group 3:** *Individualised Video Enhanced Feedback*	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**
Mean	36.32	46.77	37.30	56.45	33.45	53.86
Median	29.50	49.00	40.50	58.50	35.00	55.00
Mode	16.695	11.957	13.62	9.320	12.612	9.719

Table 78. Pre and Post-feedback Overall Procedure Scores (BS)

		Group 1: *Standard Lecture Feedback*		**Group 2:** *Unsupervised Video Enhanced Feedback*		**Group 3:** *Individualised Video Enhanced Feedback*	
	Candidate	**PRE**	**POST**	**PRE**	**POST**	**PRE**	**POST**
Task Specific Checklist (TSC)	1	15	34	28	39	4	17
	2	4	15	26	34	28	29
	3	7	18	26	30	17	33
	4	21	33	4	18	22	34
	5	11	15	23	34	26	36
	6	34	34	4	33	17	33
	7	16	29	22	36	19	32
	8	20	31	20	27	7	18
	9	10	19	23	32	10	31
	10	29	30	22	33	27	39
	11	37	33	DNA⌘	DNA	12	34
Global Rating Score (GRS)	1	11	25	24	31	12	21
	2	13	16	26	25	20	24
	3	15	14	20	23	18	24
	4	24	25	11	18	17	21
	5	11	16	16	27	25	28
	6	25	27	9	26	16	22
	7	14	20	18	29	22	25
	8	18	19	14	21	11	19
	9	17	21	19	24	12	24
	10	24	22	22	28	20	32
	11	29	26	DNA	DNA	11	23
Overall Procedure Score (OPS)	1	26	59	52	70	16	38
	2	17	30	52	59	48	53
	3	22	32	46	53	35	57
	4	44	57	15	36	38	54
	5	22	31	38	61	51	64
	6	59	60	13	59	33	55
	7	30	49	40	65	41	56
	8	38	49	34	48	18	37
	9	27	39	42	56	21	55
	10	53	52	44	61	47	70
	11	66	59	DNA	DNA	23	57

⌘Did Not Attend

Figure 63. Interval Plot of Student's Pre and Post-Feedback OPS with 95% Confidence Intervals and Significance Tests.



***Wilcoxon Matched Pairs Singed Ranks Test (Monte Carlo Sig 2 Tailed Test)**
ŦPaired T-test

Key

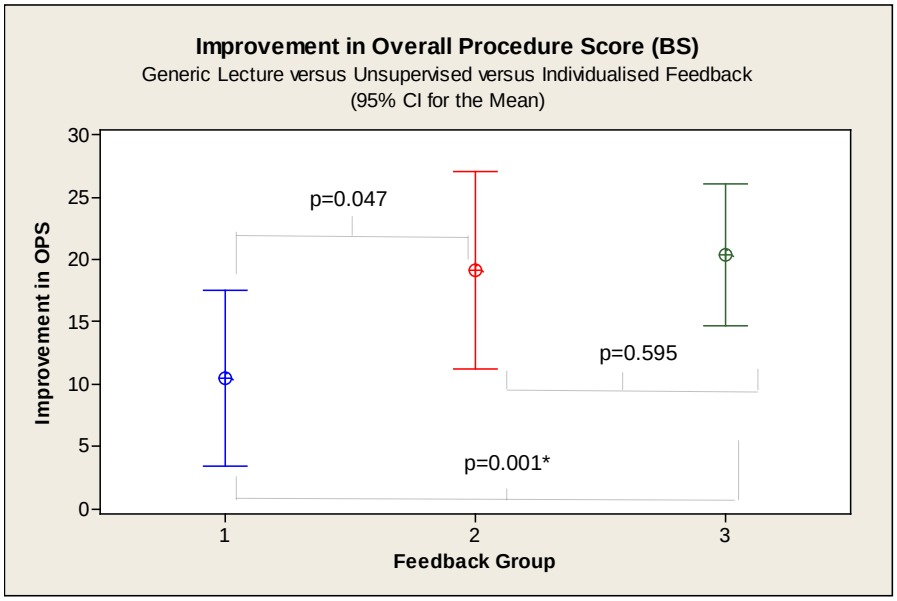
		Feedback Group
1		Standard Lecture Feedback
2		Unsupervised Video Feedback
3		Individualised Video Feedback

7.4.6.2 BS Comparison of Improvement in OPS: SLF versus UVF versus IVF

To further investigate the three feedback techniques the mean improvement in OPS was analysed and displayed graphically in Figure 64. There is no statistically significant difference between the two video groups (p=1.000) but significant improvement between SLF and UVF (p=0.047) and IVF (p=0.001). Indicating video enhance feedback is superior to a standard lecture.

Comparative DO scores are detailed in Appendix 30.

Figure 64. Interval Plot Comparing mean Improvement in OPS: SLF versus UVF versus IVF



***Mann Whitney U Test (Monte Carlo Sig 2-Tailed Test)**

Key

		Feedback Group
1		Standard Lecture Feedback (SLF)
2		Unsupervised Video Feedback (UVF)
3		Individualised Video Feedback (IVF)

7.4.7 Candidate Performance Success: Pass/Fail?

Each candidate's performance was marked using the scoring tool (Appendix 13), which included a score for whether or not the examiner felt that the candidate should 'pass'. A 'pass' represented a safe and satisfactory (but not necessarily perfect) suturing performance. Performances were graded both pre and post-feedback.

As detailed in 7.4.6 only BS scores are presented and comparative DO scores are detailed in Appendix 30.

Table 79 shows the pass/fail grade for students scored by the two blinded expert examiners pre and post-feedback. Because both blinded examiners delivered a pass/fail grade, where there was disagreement, this was considered as a borderline pass. A traffic light system was used to highlight the changes in pass/fail grade before and after feedback.

There is no statistical difference in pre-feedback pass rate comparing groups 1, 2 and 3. There is a statistically significant improvement in pass grade following both UVF ($p=0.020$) and IVF ($p=0.008$), but not following SLF ($p=0.198$).

A traffic light system is used to highlight the improvement following feedback.

Table 79. Pass/Fail Grade for Pre and Post Feedback Performances.

	Group 1: *Standard Lecture Feedback*				**Group 2:** *Unsupervised Video Enhanced Feedback*				**Group 3:** *Individualised Video Enhanced Feedback*			
Candidate	**Examiner 1**		**Examiner 2**		**Examiner 1**		**Examiner 2**		**Examiner 1**		**Examiner 2**	
	Pre	**Pre**	**Post**	**Post**	**Pre**	**Pre**	**Post**	**Post**	**Pre**	**Pre**	**Post**	**Post**
Cand 1	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Cand 2	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cand 3	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Cand 4	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes
Cand 5	No	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Cand 6	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	No
Cand 7	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Cand 8	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes
Cand 9	No	No	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes
Cand 10	No	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Cand 11	No	Yes	Yes	Yes	DNA	DNA	DNA	DNA	No	No	Yes	Yes
	Total		Total		Total		Total		Total		Total	
Pass	3		7		3		9		3		10	
Test of between Group Difference*	**p=0.198**				**p=0.020**				**p=0.008**			

***2 Proportions Test (Fishers Exact Test)**

7.4.8 Post Trial Questionnaire Statements

Students rated their agreement with three statements on the post-trial questionnaire on a 5-point Likert scale, with 5 representing their greatest agreement with the statement and 1 their greatest disagreement. The mean scores for each group are show graphically in Figure 65. These scores are compared statistically in Table 80.

1. *"The feedback I received was adequate"*
2. *"The feedback I received improved my subsequent performance"*
3. *"I would be highly satisfied with this form of feedback for future clinical skills training. For example – following venopuncture, basic life support training etc*

Figure 65. Mean score for agreement with statements regarding trial feedback

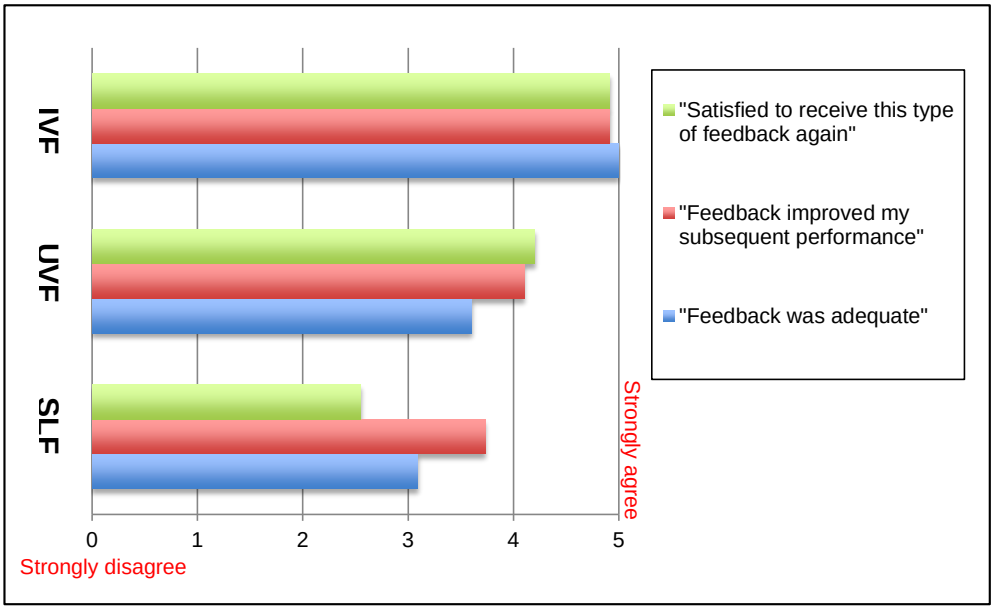


Table 80. Significance Test of Between Group Difference, Comparing Post Trial Questionnaire Likert Scores

Feedback Group / p-value	*"The feedback I received was adequate"*	*"The feedback improved my subsequent performance"*	*"I would be satisfied to receive this type of feedback again"*
1 vs 2	0.009	0.274	0.270
1 vs 3	0.000	0.001	0.000
2 vs 3	0.202	0.020	0.002

[†]Mann Whitney U Test (Monte Carlo Sig 2-Tailed Test)

Statistically significant

7.4.9 Candidates Post Trial Comments

Students were invited to make comments on their perceived advantages and disadvantages of the feedback they received. A selection of these comments are displayed in Tables 81, 82 and 83. A full list of all comments can be found in Appendix 17, 18, 19.

Table 81 Candidates perceived advantages and disadvantages of SLF

Advantages	**Disadvantages**
It did highlight some common mistakes	*It wasn't as helpful as personalised feedback*
highlighted important areas for improvement	*Didn't highlighted specifically what I was doing wrong& I feel that I could continue making the same mistakes*
Reminded me of errors I had made, provoking some internal reflection into my own performance	*It was too generalised*
Ensures that everyone receives some form of feedback	*It would have been much better if personalised*
Can be given to large groups	*Lecture format was dull meaning I occasionally stopped paying attention*

Table 82. Candidates perceived advantages and disadvantages of UVF

Advantages	Disadvantages
Allowed you to see if you had forgotten anything watching the expert one reminded you of anything you had forgotten	*No verbal feedback on performance given or written so you might not pick up on everything still*
You get to compare what you do to the 'pro' and you can pick up on the mistakes you make, very useful	*Watching my own video was of limited use as all I could see was that I clearly had no idea what I was doing.*
People are naturally self critical and so giving people the opportunity to observe themselves is both time efficient and beneficial	*Didn't know if I was doing anything wrong without noticing, direct feedback would help here*
I was able to identify the mistakes I made and hence correct these in subsequent attempt	*maybe linking the video with examiners feedback would make the quality of feedback even more helpful to students*
It was very useful being able to watch my performance, especially the fact that I could see my mistakes	*No personal feedback from the markers*

Table 83. Candidates perceived advantages and disadvantages of IVF

Advantages	Disadvantages
The video camera was very useful in showing where I went wrong. Questions posed by the examiner also helped my understanding	*Listening to other peoples questions/feedback may be useful in gaining extra information*
You can see exactly where and when to improve	*Took a bit of time*
Because feedback was individual I got a lot of information about my own performance/technique	*Time consuming*
Feedback was relevant to the individual task while watching the video, helped feedback be more specific	*I don't think the med school has the time/money to offer this sort of feedback!*
Tailored to specific weaknesses, chance to ask questions, ability to watch and see mistakes and then be told ways to improve	*You cant offer this in a large class, puts you under quite a lot of pressure*

7.4.10 Summary of Results

The three randomised groups contained no statistically significant demographic differences (Table 72). Students underwent identicle initial training using a video based teaching module (7.3.12). The pre-feedback clinical performance scores (TSC, GRS, OPS) scores (DO and BS) showed no statistical differences (Table 73).

7.4.10.1 Standard Lecture Based Feedback

Mean suturing performance scores imrpoved following SLF. This improvement was significant (Table 77, 78 and Figure 63).
SLF did not lead to a significant improvement in the number of candidates who recorded a satisfactory performance (Table 79).

7.4.10.2 Unsupervised Video Feedback

Students improved their clinical performance scores (TSC, GRS, OPS) following UVF. This difference is statistically significant (Table 77, 78 and Figure 63).
Following UVF significantly more students recorded a satisfactory performance, (Table 79)

7.4.10.3 Individualised Video Feedback

Students improved their performance scores (TSC, GRS, OPS) following IVF. This improvement is statistically significant (Table 77, 78 and Figure 63). Following IVF significantly more students recorded a satisfactory performance, (Table 79)

7.4.11 Comparison of Improvement

Although students in all three groups improved their performance scores following feedback, upon closer analysis (7.4.6.2) it was demonstrated that video feedback (UVF and IVF) was superior to SLF. No difference in improvement was demonstrated comparing UVF versus IVF.

7.5 Discussion

Feedback in any training domain is said to be either internal or external. Internal feedback is generated by the learner as they compare their performance to that of an expert. External feedback on the other hand is directed by the trainer who critiques the trainee, pointing out errors and strategies to improve their performance (Rogers 2000).

In sport, feedback is regarded as one of the most important elements when teaching motor skills (Lee et al 1994). Video feedback is used extensively in both team and solo sports such as athletics where it has been shown to improve technical performance through the refinement of technique following repeated video enhanced practice (Chrustina R et al 1990, Winfrey et al 1996).

The concept of self analysing video recorded peformances, and comparing these to recordings of an expert, has been shown to be an effective training strategy for improving musical performance (Caliendo 1999). Indeed a recent series of structured interviews with expert cellists confirmed they all placed great importance on their ability to self-critque, and believe video analysis is integral in this process (Winter 2012)

The combination of direct feedback and video-tape analysis is particularly effective in communication skills development. Watt (Watt 1995) demonstrated improved speaking performance when candidates were abe to view their speech combined with tutor feedback in his trial of communication skills. Similar findings have been shown in football where direct feedback combined with video performance analysis positively enhanced coaching staff's verbal behavior towards their players (More and Franks 1996).

Video taped assessment in surgical training was first introduced in the 1960's. Goldman et al published a series of papers decribing the success of video-taped analysis for identification of errors and their subsequent correction during open surgical procedures (Goldman et al 1969, 1970, 1972). In 1991 Stranc and co-

workers reported high levels of trainee satisfaction when they used a video-recorded feedback analysis programme to enhance the training of resident plastic surgeons; twenty basic procedures were recorded and the authors devised a mechanism to break these recorded performances down into five categories, similar to the GRS used in this trial (Appendix 13). Although no objective measure of perfromance was made, they demonstrated its feasibility widepread acceptance and concluded that video assessment enhanced the traditional observation style of training currently adopted at the time, allowing surgeons to “take a step back” and closely scrutinise and critique their own performance (Stranc et al 1991).

There are many theories of technical skill acquisition (1.9) in surgery but they share a common unifying characteristic namely that feedback is important in technical skill mastery. As previsouly discussed (1.9.1 and 1.9.2) one widely adopted theory of technical skills acquisition in surgery is the stages or phases theory. During the so-called *associative* phase the learner is practising and comparing their perfromance with that of an expert. It is during this phase that feedback is crucial (Kopta 1971). However despite this level of understanding the exact role of feedback during technical skils training in medicine and surgery remains an area of debate (1.11).

Several trials analysing the role of feedback in surgery have been conducted. Rogers et al (Rogers et al 1998) demonstrated superior performance in surgical novices’ performing a simple knot tying exercise following a traditional lecture and expert feedback technique, compared with a novel computer assisted training package. They concluded that expert feedback is essential to maximise candidate improvement.

Backstein and co-workers conducted a trial of orthopaedic trainees. Three orthopaedic skills were taught and assessed and trainees were randomised to receive either no feedback, video assisted expert feedback, or video and self-review (which included the trainee watching their own performance with no feedback at all). The authors showed no improvement in performance following either feedback group or in the no feedback control.

The results of the present trial demonstrate a significant improvement in novice suturing performance with both supervised and unsupervised video-assisted feedback (Figure 63). There are several possible reasons for this observation:

Rogers and co-workers concluded that the lack of external feedback when candidates use a computer assisted learning package caused their observed inferior improvement when compared to expert feedback. The results of the present trial suggest that a form of external feedback can be assimilated through the medium of expert video recordings. This could also explain the lack of significant difference in clinical performance score when comparing the UVF and IVF groups.

Backstein and co-workers assessed a high proportion of senior trainees in their trial, although they used a similar (modified OSATS) scoring tool to assess performance, it's possible that more subtle improvements seen in these senior trainees were missed or under reported with this generic performance scoring tool. In the present study only low-novice candidates were recruited, however this is also not without its limitations; one student commented that; *"watching my own video was of limited use as all I could see was that I clearly had no idea what I was doing"*. Poor pre-feedback performances were not common and even the candidate who criticised UVF feedback improved his OPS by more than 100% [pre-feedback OPS 17 – post-feedback OPS 41.5). Never the less, this remains a limitation of UVF.

Backstein et al also postulated that giving their trainees just one single opportunity (15 minutes) to view their videos was insufficient to achieve a response (Backstein et al 2003). Indeed in sporting paradigms, improvement is seen only after repeated video analysis. Backstein and co-workers tested this theory in a subsequent study, allowing candidates repeated video-assisted feedback plus expert feedback over a four week period, yet they still failed to show superior improvement when compared to just expert feedback alone (Backstein 2005). These results are similar to the observations made in the current trial which also failed to show superior improvement beween the unsupervised and individualised (expert assisted) video

feedback groups. However it is still surprising that in Backstein et al's initial trial they failed to observe any improvement in their video assisted feedback techniques over their control group who received no feedback at all.

In addition to watching their own performance, students in the present trial were also shown videos of narrated expert performances, which potentially assimilated external feedback, this is one explanation why despite a short time frame, (20 minutes) significant performance improvements were demonstrated following UVF.

In the current trial there was no statistically significant difference in students' clinical performance score recorded via DO or BS. Students in all feedback groups improved their performances following feedback (Figure 63) and this was statistically significant**.** Those who received video enhanced feedback (UVF, IVF) demonstrated superior imrpovemnt versus SLF (REF ???). However, no difference was demonstrated comparing the two video enhanced feedback groups (UVF versus IVF). This observation is also seen in the number of students recording a "satisfactory" performance (Table 79) there was no significant improvement seen following SLF but an equally significant improvement following UVF and IVF.

The analysis of students post questionnaire Likert scores indicated that statistically there is a significant difference in favour of video feedback (UVF and IVF) versus SLF when considering the statement that their feedback was "adequate". However further scrutiny shows that students prefer one to one, face to face feedback, and the IVF group rated all statements significantly higher compared to SLF, and higher than UVF in terms of "improving their subsequent performance" and "satisfaction to receive this type of feedback again" (Figure 65)

This is also reflected in students free text responses, (7.4.9) students perceive that individualised feedback yields the greatest benefit, claiming it is "*tailored to specific weaknesses"* offering a *"chance to ask questions, ability to watch and see mistakes and then be told ways to improve".* Intuitively one candidate acknowledged the feasibility of it during large group teaching sessions: "*I don't think the medical school has the time/money to offer this sort of feedback"*. Despite students

apparent preference for individualised feedback, they were also satisfied with UVF, and appreciated the opportunity to *"compare what you do to the 'pro' and you can pick up on the mistakes you make, very useful".* Students were dissatisfied with SLF, they felt it "*didn't highlight specifically what I was doing wrong & I feel that I could continue making the same mistakes" and "lecture format was dull meaning I occasionally stopped paying attention"* (Table 81).

Despite students apparent belief that individualised feedback is superior, the clinical performance scores do not support this assertion; as previously noted, IVF did not yeild any significant improvement vesus UVF, and those who receievd SLF also improved their scores significantly This observation is supported by the conclusions of O'Connor et al (O'connor 2008) who showed no significant improvement in laparoscopic suturing performance when candidates received additional expert performance feedback compared to simply the knowledge of their performance score.

The current trial has a relatively small sample size. It is acknowledged that there is little available data upon which to base a precedence for a truly accurate power calculation (7.3.22). Further research with larger groups is desirable to overcome this potential limitation. In addition, omiting a control group from the present trial is another drawback. An element of natural 'repetitive improvement' can be associated with repeat performance. However it was felt that omitting feedback would not be educationally beneficial and students may learn poor technique that would go uncorrected. Future studies could include a control group, but the students in this group could be offered formal feedback after the trial has concluded.

7.6 Conclusion

Video based feedback (unsupervised and individualised) has been shown to lead to superior benefit in performance of suturing in novices compared to generic lecture based feedback. Expert enhanced, individualised video assisted feedback demonstrates no superior benefit (in terms of clinical performance scores) over unsupervised video assisted feedback. Students unanimously agreed that they preferred video assisted feedback to a generic lecture.

The value of video enhanced feedback, in particular UVF has potential advantages for improving students clinical skills training without necessarily increasing the burden on individual trainers in the department. Further work is required to asses this potential

Chapter 8

Summary Discussion & Areas of Future Consideration

Chapter 8

8.0 Summary Discussion & Areas of Future Consideration

8.1 Summary Discussion

Virtual reality endovascular simulation (VRS) offers a safe, and effective adjunct to established gold-standard patient training (Van Herzeele 2009). Despite significant advancements made in the field of endovascular simulation, there is no recognized endovascular simulation-based curriculum for UK vascular trainees. Many trainees attain endovascular competencies through dedicated fellowships, often outside of the UK.

In almost all domains of surgery the role of human cadavers for training is increasing (Gilbody et al 2011). To date, evidence on the role of human cadavers in endovascular training is scant (Garrett 2001). We have highlighted endovascular professionals concerns around the use of VRS (Chapter 2). This thesis sought to establish a feasible fresh frozen pulsatile human cadaver endovascular model (PHCM) and validate its role in training endovascular skills.

Endovascular professional understanding and knowledge of cadaveric endovascular training is limited, and many questioned its suitability appropriateness and feasibility (Chapter 2). Despite these reservations, the feasibility of a PHCM was demonstrated (Chapter 3) and a subsequent trial of face validity concluded that *"PHCM represents a feasible endovascular training model with a high degree of realism, which compares favourably to both live patients and high fidelity virtual reality simulation for a simple angiogram procedure (4.6)".* Following on from this, a trial of construct validity showed that the *"PHCM has construct validity in differentiating between novice candidates and both intermediate level and expert practitioners." (5.6)*

In a cross over trial comparing SVR and PHCM it was shown that both models offer effective training in basic endovascular skills, although for beginners, cadaveric models pose a tougher challenge (6.5.4.2). Furthermore, dedicated SVR training enhanced subsequent cadaveric performance, adding further evidence to the transferability of SVR training (6.5.4.5). The role of traditional lectures adds little to the training experience on PHCM but seems to play a role in SVR (6.5.4.6), which overall appears an easier model to master and potentially more suitable for early years training.

Having deliberately excluded expert feedback during our trial of efficacy (Chapter 6), the role of feedback during technical skills training was explored further in Chapter 7. Inferior improvement was demonstrated through didactic lectures when compared to video enhanced feedback. The role of unsupervised video enhanced feedback demonstrates an exciting prospect for undergraduate clinical skills training, and places less burden on clinical skills tutors.

The current trials are the first to formerly investigate the role of a PHCM for training endovascular skills. It represents a valid alternative training adjunct and further investigative work is required to establish its exact role in training endovascular skills.

8.1 Future Considerations

The results from this thesis are planned for ongoing national and international presentation and publication in order to share the unique findings with the wider endovascular community. To date the findings have been enthusiastically and universally well received, many express their disbelief as to the validity of the PHCM and all have shown a genuine interest to learn more about its role in endovascular skills training.

Repeating the questionnaire of professional opinion following the presentation and publication of the results from the current trial may in fact yield a more positive opinion of the role of the PHCM for training endovascular skills. This represents a worthwhile study for the future.

The feasibility and effectiveness of the PHCM was based around simple (angiographic) procedures. Early, unpublished laboratory work has demonstrated the possibility of creating re-usable stenotic lesions in the PHCM, which are amenable to both angioplasty and subsequent stenting. Future work is required to ascertain the feasibility of this technique which would increase the usability and practicality of PHCM. It has been demonstrated (Chapter 6) that repetitive training yields improved performance, therefore If the PHCM is indeed capable of recreating pathological vascular lesions, its role in training endovascular skills would be greatly enhanced. This work is essential for the ongoing viability of the PHCM.

The potential for introducing aneurysmal disease was abandoned during the current study as training was focused on early stage, basic skills. However, further unpublished laboratory studies demonstrated effective arterial stenting in normal caliber vessels, which seemed to offer a highly realistic training experience especially during endovascular deployment of abdominal and thoracic aortic stents (EVAR, TEVAR).

SVR is equip with countless modules covering all aspects of the vasculature with varying difficulties of vascular pathology that can be practiced in an unlimited manner. Although technological setbacks are not uncommon and unit set-up costs are high, the ease and practicality of SVR may restrict trainer's enthusiasm in expanding the role of endovascular training on PHCM.

The PHCM is an expensive and time-consuming model to set up and use. It is limited to specialist cadaveic training facilities such as the NSTC. PHCM vessels are susceptible to puncture and dissection which can both render the model unusable. Yet these unique features can also be perceived as a significant advantage, as these features are comparable to live humans, who are often equally frail and fragile. Talks are currently ongoing with several stent graft companies interested in the potential of running a fresh frozen cadaveric endovascular training course.

Interventional cardiologists were enthusiastic about the potential role of the PHCM for training in percutaneous coronary intervention. Further unpublished experiments confirmed coronary vessels are easily accessible, thus offering a unique training experience. Future work is needed to expand the feasibility of cadaveric interventional cardiology training.

The human cadaver can also be used to create a highly realistic endovenous training model. The early results of experiments into a cadaveric endovenous training model were presented at the venous forum 2012 (Nesbitt 2012). Through selective lower limb venous perfusion, a highly realistic and functional training model can be created. The area of endovenous cadaveric training requires further investigation.

In addition to the use of human cadavers for training in endovascular and endovenous skills, there is an additional role of human cadavers for training in open vascular procedures. Future work could focus on creating a cost-effective cadaveric vascular training course, utilizing this unique training adjunct for a variety of open, endovascular and endovenous techniques. This hybrid approach to

training would exploit the unique nature of human cadavers for vascular surgical training.

The role of video-enhanced feedback also merits further study and a larger trial at NUMS has already been proposed. Unsupervised video feedback in particular carries great potential as a practical aide to standard skills training feedback. It is necessary to establish if such feedback is useful in training other clinical skills, and if unsupervised video feedback can be recreated on a wider scale.

A larger trial of UVF has been proposed and the ethical approval has been granted by Newcastle University. This trial will expand on the work carried out in Chapter 7 looking at the potential role of UVF but with larger groups and analysing three different clinical skills. It is hoped that if these results are positive Newcastle University will adopt UVF as a standard clinical adjunct for medical undergraduates.

Further work with the PHCM is also underway. WL Gore Ltd have expressed an interest in working with the PHCM. Further experiments are planned for later in 2014 with a view to establishing a cadaveric endovascular skills course. It is hoped that potential collaborative work can also be conducted with the Royal College of Surgeons of England at their cadaveric laboratory. Further work to increase the numbers of candidates in the trial of construct validity is one proposed area of future work.

The current study has gone a long way to investigating the feasibility, validity and practicality of a PHCM. In addition it has demonstrated the potential of a novel video enhanced feedback technique when training clinical skills. Several important areas for future investigation have been identified and further work will enhance this exciting area of endovascular skills training.

References

1. ACGME Outcomes Project (2000) Accreditation Council for Graduate Medical Education website: www.acgme.org (accessed 07/01/2012)

2. Ahlberg G, Hultcrantz R, Jaramillo E, Lindblom A, Arvidsson D. Virtual reality colonoscopy simulation: a compulsory practice for the future colonoscopist? Endoscopy. 2005;37 (12):1198-204.

3. Ahmed K, Keeling A, Fakhry M, Ashrafian H, Aggarwal R, Naughton P, Darzi A, Cheshire N, Athanasiou T, Hamady M. Role of Virtual Reality Simulation in Teaching and Assessing Technical Skills in Endovascular Intervention. Journal of Interventional Radiology 2010; 21:55-66.

4. (a)Aggarwal R, Grantcharov TP, Eriksen JR, Blirup D, Kristiansen VB, Funch-Jensen P, Darzi A. An Evidence-Based Virtual Reality Training Program for Novice Laparoscopic Surgeons. Annals of Surgery. 2006.244;2:310-314

5. (b)Aggarwal R, Mytton OT, Derbrew M, Hananel D, Heydenburg M, Issenberg B, MacAulay C, Mancini ME, Morimoto T, Soper N, Ziv A, Reznick R. Training and simulation for patient safety. Qual Saf Health Care 2010; 19(2): i34-i43.

6. (c)Aggarwal R, Black SA, Hance JR, Darzi A, Cheshire NJW. Virtual Reality Simulation can Improve Inexperienced Surgeons' Endovascular Skills. Journal of Vascular and Endovascular Surgery 2006; 31: 588-593.

7. (d) Aggarwal R, Grantcharov T, Moorthy K, et al. A competency-based virtual reality-training curriculum for the acquisition of laparoscopic psychomotor skill. Am J Surg. 2006;191(1):128–133.

8. Ahn SS, Moore WS, Kaiura TL, Shickman MD. The Ednovascular Training

Model for Continuing Medical Education Courses. The Journal of Continuing Education in the Health Professions 1993;13: 215-220.

9. Alinier G. A Typology of Educationally Focused Medical Simulation Tools. Medical Teacher 2007; 29:e243-e250.

10. Arbateli et al. Dynamic Human Cadaver Model for Testing the Feasibility of New Endovascular Techniques and Tools. Ann Vasc Surg 2010;24: 419-22

11. Backstein D, Agnidis Z, Regehr G, Reznick R. The effectiveness of video feedback in the acquisition of orthopedic technical skills. The American Journal of Surgery 2003;187:427-432

12. Backstein D, Agnidis Z, Sadhu R, MacRae H. Effectiveness of repeated video feedback in the acquisition of a surgical technical skill. Can J Surg. 2005; 48(3): 195–200.

13. Bakker NH, Tanase D, Reekers JA, Grimbergen CA. Evaluation of vascular and interventional procedures with time-action analysis: a pilot study. Journal of Vascular Interventional Radiology. 2002.; 13: 483-488.

14. Bann SD, Khan MS, Darzi AW. Mesurement of surgical dexterity using motion analysis of simple bench tasks. World Journal of Surgery. 2003; 27: 390-394.

15. Barathan R, Aggarwal R. Surgical Simulation, Skills Training and Assessment. Association of Surgeons in Training – The Pursuit of Excellence In Training. Conference Publication, Scientific Section. 2012.

~~15.~~16. Beard JD, Marriott J, Purdie H, Crossley J. Assessing the surgical skills of trainees in the operating theatre: a prospective observational study of the methodology. Health Technology Assessment 2011; 15(1)

~~16.~~17. Bech B, Lonn L, Falkenberg M, Bartholdy NJ, Rader SB, Schroeder TV, Ringsted C. Construct Validity and Reliability of Structured Assessment of endoVascular Expertise in a Simulated Setting. Eur J Vasc Endovasc Surg 2011; 42:539-548

~~17.~~18. (a)Berry M, Lystig T, Beard J, Klingestierna H, Reznick R, Lönn L. Porcine transfer study: virtual reality simulator training compared with porcine training in endovascular novices. Cardiovasc Intervent Radiol 2007 May-Jun;30(3):455-61.

~~18.~~19. (b)Berry M, Hellstrom M, Gothlin J, Reznick R, Lönn L. Endovascular training with animals versus virtual reality systems: an economic analysis. J Vasc Interv Radiol 2008;19(2 Pt 1):233-8.

~~19.~~20. Berger P, Willems MCM, Van Der Vliet JA, Schultze Kool LJ, Bergqvist D, Blankensteijn JD. Validation of the Simulator and Rating Endovascular SkillS (STRESS)-machine in a setting of competence testing. Journal of Cardiovascular Surgery. 2010; 51: 253-256.

~~20.~~21. Bicknell CD, Peck D, Lau NM, Alkhamesi NA, Cowling MG, Clark MW, Jenkins MP, Wolfe JH, Darzi AW, Cheshire NJ. The relationship between plasma MMP-1, -7, -8 and -13 levels and embolic potential during carotid endoluminal intervention. European Journal of Vascular and Endovascular Surgery 2004. 28(5):500-7.

~~21.~~22. Blackshear WM, Phillips D.J, and D.E. Strandness DE. Pulsed

doppler assessment of normal human femoral artery velocity pattern. Journal of Surgical Research. 1979. 27; (2): 73-83

~~22.~~23. (a)Blum MG, Powers TW, Sundaresan S. Bronchoscopy simulator effectively prepares junior residents to competently perform basic clinical bronchoscopy. Annals of Thoracic Surgery. 2004;78(1):287-91.

~~23.~~24. (b)Blum F. Der Formaldehyd als Hartungsmittel. Z Wiss Mikrosk. 1893; 10: 314-315.

~~24.~~25. Bohannon J. Gunther von Hagens. Plastination: putting a stopper in death. Science. 2003; 301: 1173.

~~25.~~26. Boyle E, O'Keefe DA, Naughton PA, Hill ADK, McDonnell CO, Moneley D. The importance of expert feedback during endovascular simulator training. Journal of Vascular Surgery. 2011;54: 240-248.

~~26.~~27. Bridges M, Diamond DL. The financial impact of teaching surgical residents in the operating room. American Journal of Surgery. 1999.177(1): 28-32.

~~27.~~28. The CanMEDSs. Better standards. Better physicians. Better care. Ottawa: Royal College of Physicians and Surgeons of Canada, 2005.

~~28.~~29. Caliendo E, Kopacz R. Improving student motivation and performance in music programs. Masters action research project. Saint Xavier University and IRI/Skylight, April 1999.

~~29.~~30. Cairns H, Hendry B, Leather A, Moxham J. Outcomes of the European Working Time Directive. British Medical Journal 2008. 337:a942

~~30.~~31. Chaer AR, DeRubertis BG, Lin SC, Bush HL, Karowski JK, Birk D, Morrisey NJ, Faries PL, McKinsey JF, Kent KC. Simulation Improves Resident Performance in Catheter-Based Intervention.Results of a Randomised, Controlled Trial. Annals of Surgery. 2006; 244: 343-352.

~~31.~~32. Christina R, Barresi J, Shaffner P. The development of response selection accuracy in a football linebacker using video training. Sports Psychology 1990;4: 11-17

~~32.~~33. Coates PJB, Zealley IA, Chakraverty S. Endovascular Simulator Is of Benefit in the Acquisition of Basic Skills by Novice Operators. Journal of Vascular Interventional Radiology. 2010; 21: 130-134.

~~33.~~34. Darke SG. Training in operative vascular surgery: gaining experience and competence. Annals of the Royal College of Surgeons of England. 2001. 83(supplement):258-260

~~34.~~35. Dawson DL, Meyer J, Eugene SL, Pevec WC. Training with simulation improves resident' endovascular procedure skills. Journal of Vascular Surgery. 2007; 45: 149-154.

~~1.~~36. Dayal R, Faries PL, Lin SC, Berheim J, Hollenbeck S, DeRubertis B, Trocciola S, Rhee J, McKinsey J, Morrissey NJ, Kent KC. Use of computer simulation as a component of catheter-based training. Journal of Vacsular Surgery. 2004; 40: 1112-1117.

~~35.~~37. Desender LM, Van Herzeele I, Aggarwal R, Vermassen FEG, Cheshire NJW. Traiongin with simulation versus operative room attendance. Journal of Cardiovascular Surgery. 2011; 52: 17-37

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

36.38. Dotter CT, Judkins MP. Transluminal Treatment of Arteriosclerotic Obstruction. Description of a New Technique and A Preliminary Report of Its Application. Circulation. 1964 30:654-670.

37.39. Eisma R, Mahendran S, Majumdar S, Smith D, Soames RW. A comparison of Theil and formalin embalmed cadavers for thyroid surgery training. The Surgeon. 2011; 9(3): 142-146.

38.40. Elert G. "Viscosity. The Physics Hypertextbook. by Glenn Elert". Hypertextbook.com. Retrieved 02-02-2011.

39.41. Ericsson KA. The acquisition of expert performance: an introduction to some of the issues. In Ericsson KA ed. The road to excellence: the acquisition of expert performance in the arts and sciences and sports, and games. Mahwah NJ: Lawrence Erlbaum Associates. 1996:1-50.

40.42. Eubanks TR, Clements RH, Pohl D, Willaims N, Schaad DC, Horgan S, Pellegrini C. An objective scoring system for laparoscopic cholecystectomy. J Am Coll Surg 1999;189:566-574.

41.43. Ewy GA, Felner JM, Juul D, Mayer JW, Salid AW, Waugh RA. Test of a cardiology patient simulator with students in fourth-year electives. Journal of Medical Education. 1987; 62: 738-743.

42.44. Fitts PM, Posner MI. Human Performance. Belmont CA: Brooks/Cole. 1967.

43.45. Fox CH, Johnson FB, Whiting J, Roller PP. Formaldehyde fixation. Journal of Histochemistry and Cytochemistry. 1985; 33: 845-853

44.46. Gallagher AG, Cates CU. Virtual Reality Training for the operating room and cardiac catheterization laboratory. Lancet. 2004;364:1538-1540

45.47. Gallagher AG, Ritter EM, Champion H, Higgins G, Fried MP, Moses G, Smith CD, Satava RM. Virtual reality simulation for the operating room: proficiency-based training as a paradigm shift in surgical skills training. Annals of Surgery. 2005; 241: 364-372.

46.48. Garrett HE Jr. A human cadaveric circulation model. Journal of Vascular Surgery 2001;33:1128-30.

47.49. General Medical Council: Tomorrow's Doctors. Duties of a doctor registered with the General Medical Council. Appendix 1: Therapeutic Procedures N^{o} 25.

48.50. Gilbody J, Prosthofer AW, Ho K, Costa ML. The use and effectiveness of cadaveric workshops in higher surgical training: a systematic review. Ann R Coll Surg Engl 2011; 93: 347-352.

49.51. Goldman LI, Maier WP, Rosemond GP, Saltzman SW, Cramer LM. Teaching surgical technique by the critical review of video-taped performance-the surgical instant replay. Surgery. 1969;66:237

50.52. Goldman LI, Maier WP, Saltzman SW, Rosemond GP. Patterns of inefficient operative technique identified by analysis of videotape performance. Current Topics in Surgical Research. 1970;2:545

51.53. Goldman LI, Saltzman SW, Rosemond GP. Television equipment and its application in the learning of surgical skills. Journal of Medical Education 1972;47:786

52.54. Gordon MS. Cardiology patient simulator. Development of an animated manikin to teach cardiovascular disease. American Journal of Cardiology. 1974; 34:350**e**5.

2.55. Grober ED, Hamstra SJ, Wanzel KR, Reznick RK, Matsumoto ED,

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

Sidhu RS, Jarvi KA. The educational impact of bench model fidelity on the acquisition of technical skill: the use of clinically relevant outcome measures. Annals of Surgery. 2004; 240:374-381.

~~3.~~56. Gruntzig A, Hopff H. Percutaneous Recanalization After Chronic Arterial Occlusion With A New Dilator-Catheter (modification of the Dotter technique). Dtsch Med Wochenschr. 1974. 99:2502-2510.

~~4.~~57. Halsted WS. The training of a surgeon. Bull Johns Hopkins Hospital. 10904;15:267-75.

~~5.~~58. Harden RM, Gleeson FA. Assessment of clinical competence using an objective structured clinical examination (OSCE). Medical Education. 1979; 13: 41-54.

~~6.~~59. Hislop SJ, Hsu JH, Narins CR, Gillespie BT, Jain RA, Schippert DW et al. Simulator assessment of innate endovascular aptitude versus empirically correct performance. Journal of Vascular Surgery 2006;43:47-55

~~7.~~60. Integrated Surgical Curriculum Project. www.iscp.ac.uk/Default.aspx. (accessed 7/1/2012).

~~8.~~61. Intercollegiate basic surgical skills course (participant handbook). The Royal College of Surgeons of England. Revised 4th Edition.

~~9.~~62. Issenberg SB, McGaghie WC, Petrusa ER, Gordon DL, Scalese RJ. Features and uses of high fidelity medical simulations that lead to effective learning: a BEME sysyematic review. Medical Teacher. 2005; 27(1): 10-28.

~~10.~~63. Ishii A, Viñuela F, Murayama Y, Yuki I, Nien YL, Yeh DT, Vinters HV. Swine model of carotid artery atherosclerosis: experimental induction by surgical partial ligation and dietary hypercholesterolaemia. AJNR Am J Neuroradiol. 2006 Oct;27(9):1893-9.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~11.~~64. Jongkind V, Yeung KK, Linsen MAM, Heidsieck D, Coveliers HME, Hoksbergen AWJ, Wisselink W. Direct Videoscopic Appraoch to the Thoracic Aorta for Aortic Endograft Deliver: Evaluation in a Human Cadaver Circulation Model. Journal of Endovascular Therapy 2010;12:12-18.

~~12.~~65. Kneebone R, Aggarwal R. Surgical training using simulation. BMJ 2009; 338: b1001

~~13.~~66. (a) Kopta JA. The development of motor skills in orthopaedic education. Clinical Orthopaedic Related Res. 1971;75: 80-85.

~~14.~~67. (b) Kopta JA. An approach to the evaluation of operative skills. Surgery. 1971; 70: 297-303.

~~15.~~68. Lamont PM, Scott DJA. The Impact of shortened traiuning times on ythej discipline of vascular surgery in the UK. The American Journal of Surgery 2005. 190; 269-272

~~16.~~69. Lee AM, Keh NC, Magill RA. Instructional effects of teacher feedback in physical education. J Teach Phys Ed. 1993;12:228-243

~~17.~~70. Liapis CD, Avgerinos ED, Sillesen H, Beneddetti-Valentini, Cairols M, Van Bockel JH, Bergqvist, Greenhalgh R. Vascular Training and Endovascular Practice in Europe. European Journal of Vascular and Endovascular Surgery. 200. 37, 109-115.

~~18.~~71. Lin PH, Chen C, Surowiec SM, Conklin B, Bush RL, Chaikof EL, Lumsden AB, Weiss V. A porcine model of carotid artery thrombosis for thrombolytic therapy and angioplasty: application of PTFE induced graft stenosis. J Endovasc Ther. 2000 Jun;7(3):227-35.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~19.~~72. Lin PH, Bush RL, Peden EK, Zhou W, Guerrero M, Henao EA, Carotid artery stenting and neuroprotection: assessing the learning curve and treatment outcome. American Journal of Surgery. 2005; 190: 850-857.

~~20.~~73. Linsen MAM, Vos AWF, Diks J, Rauwerda JA, Wisselink W. Modular Branched Endograft System for Aortic Aneurysm Repair: Evaluation in a Human Cadaver Circulation Model. Journal of Vascular and Endovascular Surgery 2007;41(2)126-29

~~21.~~74. Lonn L, Edmond J, Marco J, Kearney P, Gallagher A. Virtual Reality Simulation Training in a High-Fidelity Procedure Suite: Operator Appraisal. Journal of Vascular and Interventional Radiology 2012; 23 (10): 1361-1366.

~~22.~~75. Mahmood T, Darzi A. The Learining curve for a colonoscopy simulator in the absence of any feedback: no feedback, no learning. Surg Endosc 2004;8:1224-30

~~23.~~76. Martin JA, Regehr G, Reznick R, Macrae H et al. Objective structured assessment of technical skill (OSATS) for surgical residents. British Journal of Surgery 1997;84:273-278

~~24.~~77. Messmer C, Kellogg RT, Zhang Y, Baiak A, Leiweke C, Marcus JR, Levin LS, Zenn MR, Erdmann D. A Technique to Perfuse Cadavers That Extends the Useful Life of Fresh Tissues: The Duke Experience. Anat Sci Educ. 2010; 3: 191-194.

~~25.~~78. Miller GE. The assessment of clinical skills/competence/performance. Academic Medicine. 1990; 65(9): S63-S67.

~~26.~~79. More K, Franks I. Analysis and modification of verbal coahing behavior: the usefulness of a data-driven intervention strategy. Journal of Sports Science 1996;14: 523-43

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~27.~~80. Muir G. The “learning curve” in surgery: what is it, how do we measure it and can we influence it? BJUI. 2004; 93: 1173-1174.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~28.~~81. National Student Survey. Findings and trends 2006-2010. http://www.hefce.ac.uk/media/hefce/content/pubs/2011/201111/11_11.pdf. Accessed 24/05/2012

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~29.~~82. Neequaye SK, Aggarwal R, Van Herzeele I, Darzi A, Cheshire N. Endovascular Skills Training and Assessment. Journal of Vascular Surgery 2007;46:1055-64.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~30.~~83. Neequaye SK, Aggarwal R, Van Herzeele I, Darzi A, Cheshire NJ. Endovascular skills training and assessment. Journal of Vascular Surgery. 2007; 46: 1055-1064.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~31.~~84. Neilsen PE, Foglia LM, Mandel LS, Chow GE. Objective structured assessment of technical skill for episiotomy repair. Am J Obstet Gynecol 2003;189:1257-1260.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~53.~~85. O’Connor A, Schwaitzberg SD, Cao CG. How much feedback is necessary for learning to suture? Surg Endosc 2008;22:1614-9

~~54.~~86. Olabe J, Olabe J, Sancho V. Human Cadaver brain infusion model for neurosurgical training. Surgical Neurology 2009;72:700-702

~~55.~~87. Pandey, V, Wolfe JHN, Moorthy K, Munz Y, Jackson MJ, Darzi AW. Technical skills continue to improve beyond surgical training. Journal of Vascular Surgery. 2006;43:539-45

~~56.~~88. Patel AD, Gallagher AG, Nicholson WJ, Cates CU. Learning curves and reliability measures for virtual reality simulation in the performance assessment of carotid angiography. J Am Coll Cardiology. 2006; 47:1796-17802.

89. Pinnock C, Smith T, Lin T. Fundamentals of Anaesthesia 2nd Edition. 2003. Greenwich Medical Media Ltd.

~~57.~~90. Developing and maintaining an assessment system – a PMETB guide to good practice. PMETB January 2007.

~~58.~~91. Simbionix. Procedure Rehearsal Studio™. Simbionix USA Corp. 11000 Cedar Ave, Suite 210, Cleveland, Ohio 44106.

~~59.~~92. Reed AB, Crafton C, Giglia JS, Hutto JD. Back to basics: Use of fresh cadavers in vascular surgery training. Surgery 2009;146:757-63.

~~60.~~93. Reznick RA, MacRae H. Teaching Surgical Skills-Changes in the Wind. The New England Journal of Medicine. 2006; 355:2664-2669.

~~61.~~94. Riva G. Applications of virtual environments in medicine. Methods Inf Med. 2003; 42: 524-534.

~~32.~~95. Rogers DA, Regehr G, Howdieshell TR, Keh KA. The impact of external feedback on computer-assisted learning for surgical technical skill training. American Journal of Surgery 2000; 179:341-3

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~33.~~96. Rogers DA, Regehr G, Keh KA, Howdieshell TR. Computer-assisted learning versus a lecture and feedback seminar for teaching a basic surgical technical skill. American Journal of Surgery 1998; 175:508-510

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~34.~~97. Rosser JC, Rosser LE, Savalgi RS. Skill acquisition and assessment for laparoscopic surgery. Arch Surg 1997;132: 200-204

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~35.~~98. Salas E, Bowers CA, Rhodenizer L. It is not how much you have but how you use it: toward a rational use of simulation to support aviation training. International Journal of Aviation Psychology. 1998; 8: 197-208.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~36.~~99. Salmasi AM; Dorě C; Dancy M. Effects of age on aortic blood velocity at rest and during exercise in patients with coronary artery disease. Clin Auton Res. 1996; 6:99-106.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~37.~~100. Satava RM. Virtual reality surgical simulator – the first steps. Surg Endosc Ultrasound Intervent Tech. 1993; 7: 203-205.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~38.~~101. Schanzer A, Steppacher R, Eslami M, Arous E, Messina L, Belkin M. Vascular Surgery Training Trends From 2001-2007: A Substantial Increase in Total Procedure Volume is Driven By Escalating Endovascular Procedure Volume and Stable Open Procedure Volume. Journal of Vascular Surgery 2009; 49(5) 1339-1344.

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~39.~~102. Seldinger SI. Catheter Replaceent of the Needle in Percutaneous Arteriography: A New Technique. Acta Radiologica 1953. 39:368-376.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~40.~~103. Seymour NE, Gallagher AG, Roman SA, O'Brien MK, Bansal VK, Anderson DK, Satava RM. Virtual Reality Training Improves Operating Room Performance. Results of a Randomised, Double Blind Study. Annals of Surgery;236(4): 458-463

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~41.~~104. Schachner T, Boraros N, Ruttmann E, Hofer D, Nagiller J, Laufer G, Bonatti J. Training models for coronary surgery. Heart Surg Forum. 2007;10(4): 248-50.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~42.~~105. Schmidt RA. A schema theory of discrete motor skill learning. Psychol Rev. 1975;82: 225-260.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~43.~~106. Schueneman AL, Pickleman J, Hesslein R, Freeark RJ. Neuropsychologic predictors of operative skill among general surgery residents. Surgery 1984; 96: 288-295.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~44.~~107. Seymour NE, Gallagher AG, Roman SA, O'Brien MK, Bansal VK, Anderson DK, Satava RM. Virtual reality training improves operating room performance: results of a randomized, double-blinded study. Annals of Surgery. 2002; 236: 458-463.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~45.~~108. Sidhu RS, Park J, Brydges R, MacRae HM, Dubrowski A. Laboratory-based vascular anastomosis training: a randomized controlled trial evaluating the effects of bench model fidelity and level of training on skill acquisition. Journal of Vascular Surgery. 2007; 45: 343-349.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~46.~~109. Smith OG, Torkindgton J, Brown TF, Taffinder NJ, Darzi A. Motion analysis. Surgical Endoscopy. 2002; 16: 640-645.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~47.~~110. Society for Simulation in Healthcare. What is simulation? www.ssih.org/about simulation. Accesssed 07/01/2012

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~48.~~111. Stranc MF, McDiarmid JG, Stranc LC. Video assessment of surgical technique. British Journal of Plastic Surgery. 1991 44(1):65-8.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~49.~~112. Streiner DL. Global rating scales. In: Neufeld VR, Norman GR, eds. Assessing Clinical Competence. Series on Medical Education. New York: Springer. Springer Series on Medical Education. 1985; 7: 119-141.

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~50.~~113. Supe A, Dalvi A, Prabhu R, Kantharia C, Bhuiyan P. Cadaver as a model for laparoscopic training. Indian Journal of Gastroenterology. 2005; 24: 111-113

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~51.~~114. Sugiu K, Martin JB, Jean B, Gailloud P, Mandai S, Rufenacht DA. Artificial cerebral aneurysm model for medical testing, training and research. Nuerol Med Chir 2003;43: 69-73

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

~~52.~~115. Sutherland LM, Middleton PF, Anthony A, Hamdorf, J, Cregan P,

Formatted: Indent: Left: 0.63 cm, Hanging: 0.87 cm, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Indent at: 1.27 cm

Scott D, Maddern GJ. Surgical simulation: a systematic review. Annals of Surgery. 2006; 243: 291-300.

~~53.~~116. Suzuki Y, Fujitsuka M, Chaloupka JC. Simulation of Endovascular Neurointervention Using Silicone Models: Imaging and Manipulation. Neurol Med Chir (Tokyo) 2005; 45: 467-473.

~~54.~~117. The Provision of Vascular Services 2004. London UK: The Vascular Society of Great Britain and Ireland; 2004.

~~62.~~118. Theil W. Die Konservierung ganzer Leichen in naturlichen Farben. (The preservation of the whole corpse with natural colour). Ann Anat. 2992; 174: 185-195.

~~63.~~119. The Vascular Society: Joint Statement from the British Society of Interventional Radiology, The Vascular Society of Great Britain and Ireland and the Royal College of Radiologists. Vascular Surgery Training Update. June 21st 2012. www.vascularscoeity.org.uk/news-and-press/2012/.html (accessed 25/09/2012)

~~64.~~120. The Vascular Society of Great Britain and Ireland Provisional Vascular Surgery Curriculum. www.vascularscoeity.org.uk/news-and-press/2012/87-draft-vascular-surgery-curriculum.html (accessed 25/09/2012)

121. Van De Ridder JM, Stokking KM, Mcgaghie WC, Ten Cate OT. What is feedback in clinical education? Med Educ 2008;42:189-197

~~65.~~122. Van der Vleuten C. The assessment of professional competence: developments, research and practical implcations. Advances in Health Sciences Education. 1996; 1: 41-67

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~~66.~~123. (a) Van Herzeele I, Aggarwal R, Choong A, Brightwell R, Vermassen FE, Cheshire NJ. Virtual reality simulation objectively differentiates level of carotid stent experience in experienced interventionalists. Journal of Vascular Surgery. 2007; 46: 855-863

~~67.~~124. (b) Van Herzeele I. Virtul Reality Endovascular Simulation: Ready for Training. Nautilus Academic Books. 1st ed. 2009.

~~68.~~125. Palter VN, Grancharov TP. Simulation in Surgical Education. Canadian Medical Association Journal 2010; 182(11)1191-1196

~~69.~~126. Volodos' NL, Karpovich IP, Shekhanin VE, Troian VI, Iakovenko LF. A case of distant transfemoral endoprosthesis of the thoracic artery using a self-fixing synthetic prosthesis in traumatic aneurysm. [russian]. Grudn Khir 1988:84-86.

~~70.~~127. Wadman MC, Lomneth CS, Hoffman LH, Zeger WG, Lander L, Walker RA. Assessment of a New Model for Femoral Ultrasound-guded Central Venous Access Procedural Training: A Pilot Study. Academic Emergency Medicine 2010;17: 88-92

~~55.~~128. Wall W. Assess student learning outcomes in teaching business and professional speaking. Presented to the Speech Communication Association Convention, San Antonio, Texas, November 18-21, 1995.

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~~56.~~129. Willaert W, Aggarwal R, Nestel D, Gaines P, Vermassen F, Darzi A, Cheshire N. Patient-specific simulation for endovascular procdures: qualitative evaluation of the development process. The International Journal of Mdical Robotics and Computer Assisted Surgery 2010;6:202-210.

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~~57.~~130. Winfrey M, Weeks D. Effects of self-modelling on self efficacy and balance beam performance. Applied Res Coach Athletics Ann

1996;14:523-43

~~58.~~131. Winter H, Rees J. The analysis of video recordings as a method for enhancing self-assessment within surgery. Learning fro approaches used by expert musicians. Poster presentation at the Association of Surgeons in Training, Cardiff. 2012.

~~59.~~132. Wright TP. Factors Affecting the Cost of Airplanes. Journal of Aeronautical Sciences. 1936; 3(4): 122–128.

~~60.~~133. www.vascular-international.org (accessed 06/01/2012)

~~61.~~134. www.fda.gov/ohrms/dockets/ac/04/trasncripts/4033t1.htm US Food and Drug Administration Centre for Devices and Radiological Health Medical Devices Advisory Committee Circulatory System Devices Panel Meeting (accessed 11/1/12)

~~62.~~135. http://medical-dictionary.thefreedictionary.com/efficacy (accessed 11/06/2012)

~~63.~~136. http://www.random.org/sequences/ (accessed on multiple occasions January 2011 – July 2012)

~~64.~~137. http://www.businessdictionary.com/definition/technical-skills.html (accessed 12/05/2012)

~~65.~~138. http://www.scotiauk.com/smots/about/what/index.html (accessed 12/05/12)

~~66.~~139. www.thevitc.com/testimonials (accessed 16/05/2012)

~~67.~~140. www.nstcsurg.org (accessed on multiple occasions January 2011- July 2012)

~~68.~~141. http://www.improvetrial.org/ (accessed 12/05/2012)

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APPENDICES

APPENDIX 1~~A~~

ADVERT SENT TO ENDOVASCULAR PRACTITIONERS TO ATTEND THE PHCM TRIAL OF FACE VALIDITY.

Endovascular Human Cadaver Training Model

An open day for consultants and trainee's with endovascular experience

Date: Monday June 6th 2011
Time: Drop in anytime 9a.m. - 5p.m
Venue: The Newcastle Surgical Training Centre (ground floor, Freeman Hospital)

1) An opportunity to try a novel new model for training endovascular skills
2) Sessions are expected to take no longer than 30 minutes
3) A chance to compare this training experience with the angiomentor™ virtual reality simulator
4) Support ongoing local research into endovascular training

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Please contact us to confirm your interest, and indicate an approximate time of arrival:

Craig Nesbitt: Vascular Research Fellow
Email: craignesbitt@hotmail.co.uk
Direct line 07969223061
Lorraine Waugh: NSTC education manager
Email: Lorraine.waugh@nuth.nhs.uk
Direct line: 0191 2231264

APPENDIX 2~~B~~

INTRODUCTORY POWER POINT LECTURE FOR PARTICIPATING CANDIDATES

A Pulsatile Human Cadaver for Training Endovascular Surgeons

Introductory Lecture

Newcastle Surgery Training Centre
Freeman Hospital
June 6th

Thank you

- Thank you for attending todays "experts training day'
- It is designed to show case our human cadaver endovascular training model
- Please take time to read this short introductory presentation
- We are extremely grateful for your time, patience and feedback

Current challenges facing todays endovascular trainees

- Less time to practice
  - European Working Time Directive
- A unique skill set required
  - less people able to offer training
- Increasingly elderly patients
  - More complex disease
  - Sicker patients

  } Patients less suitable for training
- Newer diagnostic imaging (MRA/CTA/ Duplex)
  - Less diagnostic (*training)* angiograms

Novel Training Methodology

- In the climate of these training challenges several novel methods have emerged

1. Synthetic models (glass / plastic / latex)
   - e.g. The Liverpool Aneurysm Flow Model
2. Animal
   - Porcine
3. Virtual Reality
   - e.g. Simbionix angiomentor
4. Human Cadavers
   - Unknown entity

In Summary

- Endovascular training faces ongoing challenges
- Current models for training are limited
- There is a gap in the world literature when it comes to the feasibility and suitability of human cadavers for training endovascular practitioners

Newcastle Surgery Training Centre

- A specialist facility providing fresh cadaveric training in a wet lab environment
- Current courses include:
  - Orthopaedics, Urology, Gynaecology, ENT, Radiology, Cardiology, Upper GI, Colorectal and General Surgery
- **There are currently no courses being run in either vascular or endovascular surgery**

Hypothesis

- A fresh frozen cadaveric endovascular training model is possible
- The model will be both acceptable and realistic
- It will improve practitioners technique in performing endovascular procedures

Current Progress

- We have successfully perfused 4 human cadavers to date
- Endovascular procedures are feasible on the human cadaver model
- Your expert opinion will be invaluable to validate and perfect the model

Important Question

- Today we are trying to run a validation study with your help and co-operation
- We ideally want you to compare the cadaver training experience with our simbionix virtual reality model
- It will take 30-40 minutes to complete our proposed training exercise
- PLEASE INDICATE NOW to a member of our staff if you **do not** have the time to compare the training experience to virtual reality
- Otherwise continue reading this presentation

Randomisation

- Thank you for indicating that you have the time to undergo our training validation trial comparing our cadaver model to the simbionix VR simulator
- Please select a training envelope
- This has randomised you to start training on either the cadaver or VR simulator first

Trial Explanation

- Unfortunately we have restricted todays procedures to exclude stent deployment and angioplasty
- You are therefore only able to perform wire handling skills and angiograms
- This is because of our current limited availability of human cadavers, and the need to use them for future studies – sorry!

Validation Process

- After some initial orientation work we will ask you to perform 2 procedures:

1. **Catheterisation of left renal artery + angiogram**
2. **Catheterisation of left subclavian artery + angiogram**

Validation

- Would you object to us filming your procedures?
- One camera will film the fluoroscopy screen, the other will film your hands during the procedure
- These videos will form a crucial part of our proposed validation study
- These videos will be completely **anonymised**
- Before we can film your procedures you will be prompted to sign a consent form

Cadaver Training

- To enter the cadaver training lab you will be required to change into surgical scrubs and wear surgical shoes, hats and gloves as in theatre
  - One of our team will show you to the changing rooms where you can securely store your clothes and personal belongings
- A lead apron must be worn at all times
- An assistant will introduce you to the model
- Access has already been established with a sheath in the right common femoral artery

Virtual Reality

- The simbionix VR simulator is capable of many diagnostic and therapeutic procedures. For the purposes of today's validation trial we ask if you could limit yourself to the index cases:

1. **Catheterisation of left renal artery + angiogram**
2. **Catheterisation of left subclavian artery + angiogram**

Questionnaire

FINALLY

• Can we please ask you to complete a very short questionnaire before and after using the models

• One of our team will help guide you through the questionnaires

• If you are running out of time we can provide you with a questionnaire to take with you, as well as a self addressed envelope to return it to us here at the NSTC

We hope you enjoy your time here at the NSTC

- Again, thank you for your time, patience and feedback.
- Todays results could well prove crucial in the ongoing development of an exciting new training opportunity for endovascular trainees

APPENDIX 3~~C~~

CONSENT FORM TO PERMIT USE OF VIDEOED PERFORMANCES FOR THE FACE VALIDITY TRIAL

Candidate Number

Consent Form

- I give my consent to allow my performance on the human cadaver endovascular training model to be anonymously videoed for training and research purposes

Signed:_____ Date:_____

Print name: _____

- I give my consent to allow my performance on the simbionix endovascular training model to be anonymously videoed for training and research purposes

Signed:_____ Date:_____

Print name: _____

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APPENDIX 4~~D~~

FACE VALIDITY PRE-TRIAL QUESTIONNAIRE & CONSTRUCT VALIDITY PRE-TRIAL QUESTIONNAIRE

Candidate Number

PRE- TRIAL QUESTIONNAIRE

1. Please indicate your seniority (with a cross X)

ST3	ST4	ST5	ST6	ST7	ST8	Consultant radiologist	Consultant vascular surgeon	Other (please indicate)

2. Please estimate how many endovascular procedures have you been involved in in the last 12 months - assisted and performed

   (please indicate with a cross X)

Number	Assisted	Performed
0		
1-10		
11-25		
26-50		
>50		

3. Do you wear glasses? Yes / No
4. Are you right or left handed? Right / Left
5. Do you play a musical instrument? Yes / No
   If yes please state instrument: ______________________________
6. Are you able to type? Yes / No
7. Do you play video-games on a regular basis? Yes / No
8. Have you ever used a virtual reality simulator for practicing endovascular procedures? Yes / No
9. Have you ever used a human cadaver for practicing endovascular procedures? Yes / No
10. Have you ever used human cadavers for ANY medical training? Yes / No
    If yes, please indicate where:______________________________

Finally, please indicate your agreement with the following statement:

"I have no objections to working with/training on human cadavers"

1	2	3	4	5
Strongly agree		Neither agree nor disagree		Strongly disagree

APPENDIX 5E

POST-TRIAL QUESTIONNAIRE: FACE VALIDITY STUDY

POST TRIAL QUESTIONNAIRE

Candidate Number

Section 1: Comparison to Live Patients

Vascular access was realistic on the Human Cadaver model compared to live patients

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Vascular access was realistic on the Simbionix VR model compared to live patients

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

Manipulation of the guide-wire and catheter was realistic in the Human Cadaver model compared to live patients

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Manipulation of the guide-wire and catheter was realistic in the Simbionix VR model compared to live patients

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

Catheterization of the vessels was realistic on the Human Cadaver model compared to live patients

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Catheterization of the vessels was realistic on the Simbionix VR model compared to live patients

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

Performing an angiogram was realistic on the Human Cadaver model compared to live patients

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Performing an angiogram was realistic on the VR simbionix model compared to live patients

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

Section 2: Comparison to Virtual Reality

Manipulation of the guide-wire and catheter was more realistic in the Human Cadaver model compared to the Simbionix VR model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Manipulation of the guide-wire and catheter was more realistic in the Simbionix VR model compared to the Human Cadaver model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

Vascular access was more realistic on the Human Cadaver model compared to the Simbionix VR model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Vascular access was more realistic on the Simbionix VR model compared to the Human Cadaver model

1 2 3 4 5

Agree strongly — Neither agree or disagree

Catheterization of the vessels was more realistic on the Human Cadaver model compared to Simbionix VR model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Catheterization of the vessels was more realistic on the Simbionix VR model compared to the Human Cadaver model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

Performing an angiogram was more realistic on the Human Cadaver model compared to the Simbionix VR model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Performing an angiogram was more realistic on the Simbionix VR model compared to the Human Cadaver model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

I believe the Human Cadaver training model is a useful tool for training endovascular guidewire handling skills

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

I believe the Simbionix VR model is a useful tool for training endovascular guidewire handling skills

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

I feel that my catheter and guidewire handling skills improved after training on the Human Cadaver model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

I feel that my catheter and guidewire handling skills improved after training on the Simbionix VR model

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

Given the opportunity I would like to use the Human Cadaver model again for training/practicing endovascular guidewire skills

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Given the opportunity I would like to use the Simbionix VR model again for training/practicing endovascular guidewire skills

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

I would recommend the Human Cadaver model as a tool for training endovascular techniques to colleagues/other trainee's.

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

I would recommend the Simbionix VR model as a tool for training endovascular techniques to colleagues/other trainee's.

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

---

Training on a Human Cadaver is a valuable learning exercise

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

Training on a Simbionix VR model is a valuable learning exercise

1 2 3 4 5

Agree strongly — Neither agree or disagree — Disagree strongly

I preferred training on the Human Cadaver model

1	2	3	4	5
Agree strongly		Neither agree or disagree		Disagree strongly

I preferred training on the Simbionix VR model

1	2	3	4	5
Agree strongly		Neither agree or disagree		Disagree strongly

Section 3: Final Questions

Please indicate any weaknesses you feel the Human Cadaver model has as a tool for training endovascular techniques:

_____
_____
_____
_____
_____

Please indicate any weaknesses you feel the Simbionix VR model has as a tool for training endovascular techniques:

_____
_____
_____
_____
_____

Please indicate any strengths you feel the Human Cadaver model has as a tool for training endovascular skills:

_____
_____
_____
_____
_____

Please indicate any strengths you feel the Simbionix VR model has as a tool for training endovascular skills:

_____
_____
_____
_____
_____

I found the venue (Newcastle Surgery Training Centre) a suitable place to train

1	2	3	4	5
Agree strongly		Neither agree or disagree		Disagree strongly

I have no objections to working/training on human cadavers

1	2	3	4	5
Agree strongly		Neither agree or disagree		Disagree strongly

Overall I found the Human Cadaver model the most realistic when compared to live patients

1	2	3	4	5
Agree strongly		Neither agree or disagree		Disagree strongly

Please return your questionnaire to:

Craig Nesbitt
Newcastle Surgical Training Centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
NE7 7DN

Thank you for your patience

APPENDIX 6~~F~~

QUESTIONNAIRE OF ENDOVASCULAR EXPERIENCE

How many procedures have you been involved in in the last 12 months? assisted and performed

(please indicate with a cross X)

Number	Assisted	Performed
0		
1-10		
11-25		
26-50		
>50		

KEY:

	Assisted	Performed
Novice low	0	0
	1-10	0
	11-25	0
	26-50	0
	0	1-10
	1-10	1-10
Novice high	0	11-25
	>50	0
Intermediate	>11-25	1-10
	>1-10	11-25
		25-50
Expert		>50

APPENDIX 7~~G~~

POSTER ADVERTISING THE FEEDBACK FOLLOWING SUTURING TEACHING EXPERIMENT

DO YOU WANT TO LEARN TO SUTURE?

A FREE one day, hands-on course for medical students

Date: February 1st, 2nd or 3rd.
Time: 17:00 hrs – 19:00 hrs
Venue: Newcastle University Clinical Skills Department

A research team from Newcastle University, including surgeons from Newcastle Freeman Hospital, want to teach you how to suture. They are investigating the importance of feedback, and need volunteers.

Are you interested in learning a new and essential clinical skill?
Gain hands-on training from an expert faculty.
Support a local research group.

Please contact us to confirm your interest, and indicate which day you can attend

Craig Nesbitt: Vascular Research Fellow
Email: craignesbitt@hotmail.co.uk
Direct line 07969223061

APPENDIX 8~~H~~

PARTICIPANT INFORMATION SHEET: SMOTS TRIAL

A Basic Introduction to Suturing: Course explanation

The following course has been designed to provide you with a basic introduction to suturing. It is a GMC recommendation that all undergraduate medical students be taught to suture. This is an important skill that you will require when you graduate and start practicing as a doctor.

As a university we are constantly looking for ways of improving the teaching we deliver. In total we are running three suturing courses this week. During this course you will receive feedback from the faculty. This feedback is designed to enhance your performance. Feedback is being delivered in different ways over the three courses. We are hoping to assess which form of feedback is the best.

An outline of the course:

1) We will ask you to complete a questionnaire: This will not ask any personal information, but elements that have been previously shown to affect how candidates learn to stitch.
2) We will then teach you how to stitch using an approved technique from the Royal College of Surgeons of England: This will be in a video format
3) After your teaching we will ask you to insert three stitches using the technique you have been taught: **This is not an exam**, but we will mark your performance, however it is **completely anonymous**.
4) We require your consent: We wish to video your performance. This will be **completely anonymous**. The video will ONLY FILM YOUR HANDS. Your performance will have no influence on your medical training.
5) You will be given a period of feedback: This has been designed to enhance your learning.
6) After your feedback session you will be asked again to insert three stitches: Your performance is **anonymous**.
7) After this you will be asked to give us your feedback on how you found your training, in particular the feedback you received: Again, this will be **anonymous**, so you can be brutally honest!

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IMPORTANT INFORMATION:

- This is a voluntary course.
- Questionnaire responses and video performances are completely anonymous.
- All data will be stored securely within the Newcastle Surgical Training Centre
- No personal details will be recorded at any time
- You can withdraw your consent AT ANY TIME (for up to one week after completing the course)
- You can withdraw and leave this course at any time.

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If you have any concerns or questions please approach ANY of the course faculty who will be happy to help in any way. Alternatively use any of the contacts below.

Many thanks, I hope you enjoy the course

Craig Nesbitt | Laparoscopic Research Fellow in Surgical Education

Newcastle Surgical Training Centre

Freeman Hospital | Freeman Road | Newcastle upon Tyne | NE7 7DN
Direct line: 0191 21 38589 | Fax: 24 37248 | mobile: 07969 223061 **Error! Hyperlink reference not valid.**

APPENDIX 9ɨ

SMOTS INTRODUCTION LECTURE

Technical skills training and the role of feedback

Craig Nesbitt
Laparoscopic research fellow in surgical education
Newcastle Surgical Training Centre

Undergraduate Training

- Lab/skills centre based
- Standardised
- Formal assessments of competence

FEEDBACK

Feedback

- Mahmoud et al 2004
  - complete lack of learning curve without feedback
- O'Connor et al 2008
  - knowledge of results = expert feedback
- Boyle et al 2011
  - Improvement without feedback
  - Expert = non-expert feedback in reducing errors

SMOTS

What's its role? Does it work?

SMOTS

- Scotia Medical Observation and Training System
- Fixed ceiling cameras
  - Recorded, store and file for instant playback / assessment
- Built in audio equipment
  - Two-way communication

Your Feedback

- All candidates will receive feedback on their performance
- You will be randomised into one of three groups to receive different forms of feedback

Today's Exercise

- Before you begin we will ask you to complete a pre-trial questionnaire
- All candidates will be taught a basic suturing technique (no practice offered)
- All candidates will be formally assessed performing the basic suturing skill
  - Assessments will be anonymously videoed
  - We require your consent to use these anonymous video performances
- You CAN ask for help during your assessment

Before you go

- Following your second performance you will complete a post-trial questionnaire
- Please offer as much feedback as you can
  - You could shape the future of clinical skills training at Newcastle!
- You will all receive a certificate of attendance
- Thank you again for your assistance

Repeat Assessment

- Following your feedback, you will repeat the same suturing exercise
- Performances will again be filmed anonymously

APPENDIX 10~~J~~

SMOTS CONSENT FORM

Candidate Number

Consent Form

I give my consent to allow my suturing performance to be anonymously videoed for training and research purposes

Signed:_____ Date:_____

Print name: _____

APPENDIX 11~~K~~

SMOTS PRE-TRIAL QUESTIONNAIRE

Candidate Number

PRE- TRIAL QUESTIONNAIRE

i)1. Age:

ii)2. Sex: Male ☐ Female ☐

iii)3. Please indicate your seniority (with a cross X)

Medical Student Year 1	Medical Student Year 2	Medical Student Year 3	Medical Student Year 4	Medical Student Year 5	Other (please indicate)

iv)4. Please indicate your area of specialist interest (with a cross X)

General Practice	Surgery (inc obsterics/ gyanaecology & orthopaedics)	Medicine	Anaesthetics	Other (please indicate)

v)5. Please estimate how many times you have sutured in the last 12 months - assisted and performed

(please indicate with a cross X)

Number	Assisted	Performed
0		
1-10		
11-25		
26-50		
>50		

vi)6. Do you wear glasses? Yes / No

vii)7. Are you right or left handed? Right / Left

viii)8. Do you play a musical instrument? Yes / No

If yes please state instrument: ___________________________

ix)9. Are you able to type? Yes / No

x)10. Do you play video-games on a regular basis? Yes / No

xi)11. Have you ever been taught to suture before using simulated 'fake' skin? Yes / No

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APPENDIX 12

PRE-TRIAL EXPERIMENT INSTRUCTIONS: SMOTS TRIAL

- You will now be asked to place **3 interrupted sutures** into a wound. Then **remove them** with the scissors provided
- Please secure your sutures with an **instrument tied reef knot.**
- You can assume that you are sterile – you do not need to wear gloves for this exercise.
- You do not need to wash your hands or introduce yourself to the 'patient'.
- You are **only** being assessed on your ability to insert then remove sutures.
- You will have 7 minutes to complete this exercise after which you will be asked to stop by the examiner.
- **You can ask for help**, but we encourage you to complete the exercise independently if possible.

APPENDIX 13~~M~~

SMOTS SCORING TOOL

Candidate Number

Task-Specific Check List: Suturing Exercise

	Not done or incorrect			Done correctly			Instruction required		
Suture	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**
1. Selects appropriate equipment: - needle holder, toothed forceps, scissors & suture	0			1			0		
2. Needle loaded correctly: - 2/3rds along needle, 2mm from tip of needle holder	0	0	0	1	1	1	0	0	0
3. Begins suturing from one end of the wound: - not from the middle	0			1			0		
4. Individual sutures: - equal bites made equidistant from wound edge - same as depth of the wound	0	0	0	1	1	1	0	0	0
5. Needle enters skin at 90^{o}	0	0	0	1	1	1	0	0	0
6. Smooth passage of needle through skin	0	0	0	1	1	1	0	0	0
7. Removes needle safely: - never handles needle tip - aware of needle tip when drawing through the suture	0	0	0	1	1	1	0	0	0
8. Suture drawn through to create “short end” - no excessive wastage of suture	0	0	0	1	1	1	0	0	0
9. Suture secured with an Instrument tied reef knot: - 3 throws in correct direction to lock the knot	0	0	0	1	1	1	0	0	0
10. Appropriate force used to “snug” the knot down	0	0	0	1	1	1	0	0	0
11. Secures suture ends in needle holder and passes these to an assistant	0	0	0	1	1	1	0	0	0
12. Cuts suture ends using scissors supported on left index finger	0	0	0	1	1	1	0	0	0
13. Appropriate length of suture left (approx 5mm)	0	0	0	1	1	1	0	0	0
14. Places subsequent sutures twice the width of the wound depth apart	0			1			0		
15. 3 sutures placed in total	0			1			0		
16. Knots drawn off centre of the wound	0			1			0		
17. Sutures removed with scissors - correct two-handed technique	0	0	0	1	1	1	0	0	0
18. Disposes of sharps in sharps bin provided	0			1			0		

Candidate Number

Respect for Tissue				
1 Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments	2	3 Careful handling of tissue but occasionally caused inadvertent damage	4	5 Consistently handled tissues appropriately with minimal damage
Time and Motion				
1 Many unnecessary moves	2	3 Efficient time/motion but some unnecessary moves	4	5 Economy of movement and maximum efficiency
Instrument Handling				
1 Repeatedly makes tentative or awkward moves with instruments	2	3 Competent use of instruments although occasionally appeared stiff or awkward	4	5 Fluid moves with instruments with no awkwardness
Knowledge of Instruments				
1 Frequently asks for wrong instrument or used inappropriate instrument	2	3 Knows names of most instruments and used appropriate instrument for the task	4	5 Obviously familiar with the instruments required and their names
Use of Assistants				
1 Consistently placed assistants poorly or failed to use assistant	2	3 Good use of assistants most of the time	4	5 Strategically used assistant to the best advantage at all times
Flow of Operation				
1 Frequently stopped operating or needed to discuss next move	2	3 Demonstrated ability for forward planning with steady progression of procedure	4	5 Obviously planned course of operation with effortless flow from one move to the next
Knowledge of Specific Procedure				
1 Deficient knowledge. Needed specific instruction at most operative steps	2	3 Knew all important aspects of the operation	4	5 Demonstrated familiarity with all aspects of the operation
Overall, on this task, should this candidate		**Pass ☐**	**Fail ☐?**	

APPENDIX 14~~N~~

PARTICIPANT DEBRIEFING DOCUMENT: SMOTS TRIAL

Participant Debriefing Document

We hope you have enjoyed your suturing course. We are very grateful for your time, patience and feedback.

Please remember that if you have any questions or concerns you can approach any of the course faculty now, or alternatively contact me at a later date (see contacts below).

You can withdraw your consent for us to use your anonymised videos for our research project for up to 1 week after this date.

Please be assured that all of your comments and feedback are completely anonymous.

The results of your performances are completely anonymous.

We will keep your both your questionnaires and video performances locked securely within the Newcastle Surgical Training Centre.

Many thanks

Craig Nesbitt | Laparoscopic Research Fellow in Surgical Education

Newcastle Surgical Training Centre

Freeman Hospital | Freeman Road | Newcastle upon Tyne | NE7 7DN
Direct line: 0191 21 38589 | Fax: 24 37248 | mobile: 07969 223061 **Error! Hyperlink reference not valid.**

APPENDIX 15~~O~~

SMOTS POST-TRIAL QUESTIONNAIRE

Candidate Number

POST- TRIAL QUESTIONNAIRE

Please indicate your agreement with the following statements

"The feedback I received was adequate"

1 2 3 4 5

Strongly disagree — Neither agree nor disagree — Strongly agree

"The feedback I received improved my subsequent performance"

1 2 3 4 5

Strongly disagree — Neither agree nor disagree — Strongly agree

"I would be highly satisfied with this form of feedback for future clinical skills training. For example – following venopuncture, basic life support training etc

1 2 3 4 5

Strongly disagree — Neither agree nor disagree — Strongly agree

Please indicate ANY advantages you feel your form of feedback gave you during this training exercise:

Please indicate ANY disadvantages you feel your form of feedback gave you during this training exercise:

APPENDIX 16~~P~~

SMOTS STUDY CERTIFICATE OF ATTENDANCE

The Newcastle upon Tyne Hospitals NHS
NHS Trust

BASIC SUTURING COURSE

- (as part of the Newcastle University Medical School Clinical Teaching Feedback Experiment)

At the Newcastle University Clinical Skills Laboratory

Newcastle University,

On the

20th February 2012

Mr Craig Nesbitt
Laparoscopic Research Fellow in Surgical Education
Newcastle Upon Tyne Hospitals NHS Trust

APPENDIX 17~~Q~~

GROUP 1. POST-TRIAL QUESTIONNAIRE FEEDBACK. SMOTS TRIAL

Advantages

Candidate UTN	Comment
1.1	*It did highlight some common mistakes, some of which I'd made and I found that useful. It was also useful to have the general principles gone through again. It was as it was immediate*
1.2	*It was general and so highlighted things for improvement without highlighting anything I personally did poorly but it didn't decrease my confidence*
1.3	*Repeated the key points of the process which reminded me of the steps, in particular using the left hand when cutting the suture*
1.4	*Reminding me of the correct order of procedure and highlighting important areas for improvement*
1.5	*Allowed to review any gaps in my knowledge (anything I had forgotten); included common areas for improvement*
1.6	*Step by step was helpful, especially numbering it all*
1.7	*Reminded me of errors I had made, provoking some internal reflection into my own performance*
1.8	*Ensures that everyone receives some form of feedback, very easy to compare to other methods of feedback does not depend upon the person giving the feedback if multiple people give it.*
1.9	*Can be given to large groups*
1.10	*It reminded me of what to do and was good as I remembered making some mistakes mentioned*
1.11	*Remembered to tighten suture and put knots on the same side*

Disadvantages

Candidate UTN	Comment
1.1	*It wasn't as helpful as personalized feedback would have been, preferably with the chance for me to improve: "you did this wrong, try that specific bit again and I'll show you how to do it better"*
1.2	*Doesn't aid specific difficulties*
1.3	*Didn't highlighted specifically what I was doing wrong& I feel that I could continue making the same mistakes which aren't covered in the feedback. Also didn't say how to change the performance to improve, or any areas that were particularly good/bad*
1.4	*Didn't allow me to ask specific questions on how to improve. It was too generalized*
1.5	*Not personal; not hands-on (just involved watching a video)*
1.6	*Could have added to feedback by showing on the video again*
1.7	*Parts of it weren't applicable, would have been more helpful beforehand. I only had to guess at my performance via a criterion of 'common errors'. Lecture format was dull meaning I occasionally stopped paying attention*
1.8	*There were sections within the feedback that I already knew therefore wasting time that could have been spent on feedback that could aid me*
1.9	*Not personailsed, information about mistakes commonly made by others may not be relevant to me*
1.10	*It would have been much better if personalized – what was good? What was bad? Also I may have just improved through practice and not this generic feedback*
1.11	*Should have shown videos of correct techniques for vital steps*

APPENDIX 18~~R~~

GROUP 2. POST-TRIAL QUESTIONNAIRE FEEDBACK. SMOTS TRIAL

Advantages

Candidate UTN	Comment
2.2	*Allowed you to see if you had forgotten anything watching the expert one reminded you of anything you had forgotten*
2.3	*It made it clear how much time I wasted positioning the needle and setting up, it also showed me where I went wrong in my needle angle/equal bite distances*
2.4	*You get to compare what you do to the 'pro' and you can pick up on the mistakes you make, very useful*
2.5	*It was useful being able to see my previous performance and where I wasted time*
2.6	*The majority of time you know exactly what to do, you just get nervous or forget small things. People are naturally self critical and so giving people the opportunity to observe themselves is both time efficient and beneficial*
2.7	*It helped to jog my memory because when I went in the first time I really couldn't remember the video. It helped to go through it in my head multiple times with the video*
2.8	*I was able to identify the mistakes I made and hence correct these in subsequent attempt*
2.9	*Allowed me to compare my own method with that of an expert*
2.10	*It was very useful being able to watch my performance, especially the fact that I could see my mistakes*
2.11	*Being able to see my performance the first time around helped me see what I thought I did wrong and helped me think about the procedures before going again*

Disadvantages

Candidate UTN	Comment
2.2	*No verbal feedback on performance given or written so you might not pick up on everything still. The expert video and tip and tricks videos were quite long*
2.3	*nil*
2.4	*It would be good to get additional verbal or written feedback telling you how to improve/where you went wrong as im sure I missed some of my mistakes in the video*
2.5	*I had very little experience going into the task and as a result I spent most of my first attempt trying to work out what to do, this meant I knew what I had missed from the first video. However watching my own video was of limited use as all I could see was that I clearly had no idea what I was doing. It might have been useful to see my video before the expert video so I could have been more aware what to look for.*
2.6	*If you genuinely didn't know what you were doing I guess it wouldn't help really.*
2.7	*None – it was really good and helped me think about what I was doing with the equipment*
2.8	*none*
2.9	*Didn't know if I was doing anything wrong without noticing, direct feedback would help here*
2.10	*No disadvantages, but maybe linking the video with examiners feedback would make the quality of feedback even more helpful to students*
2.11	*No personal feedback from the markers, not sure which part I did wrong exactly*

APPENDIX 19~~S~~

GROUP 1. POST-TRIAL QUESTIONNAIRE FEEDBACK. SMOTS TRIAL

Advantages

Candidate UTN	Comment
3.1	*Helped me to understand what I was doing. The video camera was very useful in showing where I went wrong. Questions posed by the examiner also helped my understanding*
3.2	*You can see exactly where and when to improve and how to do it next time differently. Tailored to what I personally did well/less well. Could ask questions to clarify when unsure*
3.3	*Allowed me to see exactly where I was going wrong, gave some good hints and tips to help improve*
3.4	*Because feedback was individual I got a lot of information about my own performance/technique specifically. Being able to see the videos also helped me to identify where/what I had improved to remember it*
3.5	*DNA*
3.6	*Technique and confidence. Was able to see what I did well and observe what I was actually doing, rather than what I thought I was doing*
3.7	*It was good to evaluate what I did right or wrong and actually see it.*
3.8	*Feedback was relevant to the individual task while watching the video, helped feedback be more specific*
3.9	*Tailored to specific weaknesses, chance to ask questions, ability to watch and see mistakes and then be told ways to improve as they present themselves*
3.10	*It was a lot more useful to see a video of myself carrying out the procedure as it allowed me to realize at what exact moments I made a mistake*
3.11	*1 to 1 tuition, persoanlised feedback is very useful. Getting to practice again following feedback*
3.12	*It was great, mainly due to its 1 to 1 nature.*

Disadvantages

Candidate UTN	Comment
3.1	*nil*
3.2	*none*
3.3	*none*
3.4	*Listening to other peoples questions/feedback may be useful in gaining extra information*
3.5	*DNA*
3.6	*Took a bit of time*
3.7	*Could be time consuming we had to wait for videos to be shown*
3.8	*none*
3.9	*none*
3.10	*none*
3.11	*I don't think the med school has the time/money to offer this sort of feedback!*
3.12	*You cant offer this in a large class, puts you under quite a lot of pressure*

APPENDIX 20~~T~~

EXPERT OPINION CADAVER TRAINING QUESTIONNAIRE

Interventional radiology	
Interventional cardiology	
Transplant surgery	

Question 2:
Please indicate your year of training:

Year	Please tick ☐
ST3	
ST4	
ST5	
ST6	
ST7	
Consultant	
Other, please specify	

Question 3:
I am aware of human cadavers for training in endovascular intervention:

Response	Please tick ☐
I am aware	
I am not aware	

Question 5:
I have attended a medical training course that has utilized human cadavers

Response	**Please tick ☐**
Yes	
No	
Please specify name of course:	

Question 6:
"I agree with the use of human cadavers for training doctors"

Response	**Please tick ☐**
Yes, I agree	
Yes, but I have some concerns	
No, I do not agree	
Please indicate concerns or reason for disagreement:	

Question 7:
I am aware of the use of virtual reality simulators for training in endovascular intervention

Response	**Please tick ☐**
Yes, I am aware	
No, I am not aware	

Response	Please tick ☐
Virtual Reality	
Human Cadaver	
No preference	
Please indicate a reason for your choice:	

APPENDIX 21~~U~~

PATIENT CADAVER TRAINING QUESTIONNAIRE

For Office Use Only:
Informed Consent Yes ☐

The Newcastle upon Tyne Hospitals NHS
NHS Trust

No (and I do not agree with donating) ☐

No (but I am in favour of people donating to medical research) ☐

No (but I may consider donating my body for medical research) ☐

Question 3:
Please indicate with a tick if you have any of the following conditions:

~~(a)~~i) Disease of the blood vessels (so called 'peripheral vascular disease') ☐

~~(b)~~ii) Heart problems (including angina, a previous heart attack, heart failure) ☐

~~(c)~~iii) History of stroke or mini-stroke ☐

Question 4:
Please indicate with a tick if you know anyone who has any of the following conditions:

i) Disease of the blood vessels (so called peripheral vascular disease) ☐

ii) Heart problems (including angina, a previous heart attack, heart failure) ☐

iii) History of stroke or mini-stroke ☐

Please indicate who has this condition (eg friend, aunty, grandfather etc – (do not include names please)

Question 5:
Are you currently under the care of a vascular doctor (either investigating, treating or keeping an eye on a problem with your blood vessels) ? Yes ☐ No ☐

Question 6:
Please indicate if you have ever undergone any of the following open vascular procedures:

i) Open surgery to bypass a blocked blood vessel ☐

ii) Open surgery on your aorta ☐

iii) Amputation ☐

iv) Other, please explain ________________________________

Question 8:
Please indicate if you have ever undergone any of the following pinhole (endovascular) procedures:

i) Angiogram (dye test) to image the blood vessels in your legs ☐

ii) Angioplasty (balloon stretch) of a narrowed blood vessel ☐

iii) Stent insertion (stent to hold open a narrowed or blocked blood vessel) ☐

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iv) Other, please explain _____

Please indicate your agreement with the following statements by circling the number which best fits your opinion:

(a) Doctors should be allowed to train and practice on human cadavers

1	2	3	4	5
Agree strongly		ther agree or agree	Mostly disagree	Disagree strongly

Please use this box if you would like to explain your answer:

(b) Doctors should be allowed to train and practice on real patients

1	2	3	4	5
Agree strongly	Mostly agree	Neither agree or disagree	Mostly disagree	Disagree strongly

Please use this box if you would like to explain your answer:

(c) I would feel confident undergoing a keyhole (endovascular) procedure by a doctor whose training included practice on a computer model.

1	2	3	4	5
Agree strongly	Mostly agree	Neither agree or disagree	Mostly disagree	Disagree strongly

Please use this box if you would like to explain your answer:

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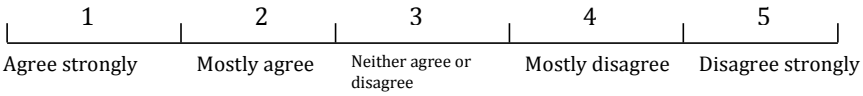
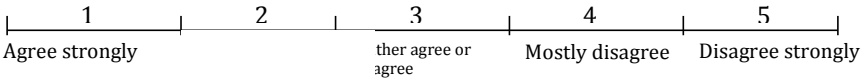
(d) I would feel confident undergoing a keyhole (endovascular) procedure by a doctor whose training included practice on a human cadaver model



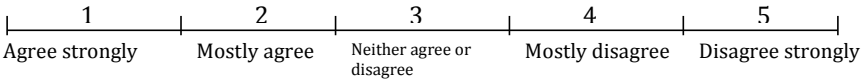
Please use this box if you would like to explain your answer:

(e) I would feel more confident undergoing a keyhole (endovascular) procedure by a doctor who had undergone training on a human cadaver model compared to a doctor who had undergone training on a computer model.



Please use this box if you would like to explain your answer:

(f) I would feel more confident undergoing a keyhole (endovascular) procedure by a doctor who had undergone training on a computer model compared to a doctor who had undergone training on a human cadaver model.



Please use this box if you would like to explain your answer:

APPENDIX 22~~V~~

CONSENT FORM FOR CONSTRUCT VALIDITY TRIAL

Candidate Number

Consent Form

- I give my consent to allow my performance on the human cadaver endovascular training model to be anonymously videoed for training and research purposes

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Signed:_____ Date:_____

Print name: _____

APPENDIX 23~~W~~

CADAVER VIDEO SCORING TOOL

Task-Specific Check List: Left Renal Artery Catheterisation

	Not done or incorrect	Done correctly	Instruction required
1. Selects Standard J-Tip Wire	0	1	0
2. Inserts J-tip wire safely	0	1	0
3. Selects Pigtail catheter	0	1	0
4. Inserts Pig-tail catheter safely	0	1	0
5. Removes J-tip wire safely	0	1	0
6. Performs adequate aortic angiogram	0	1	0
7. Re-inserts J-tip wire safely	0	1	0
8. Removes Pigtail catheter safely	0	1	0
9. Selects Cobra catheter	0	1	0
10. Inserts cobra catheter safely	0	1	0
11. Cannulates left renal artery safely	0	1	0
12. Selects hydrophilic wire	0	1	0
13. Inserts hydrophilic wire safely	0	1	0
14. Advances cobra catheter safely	0	1	0
15. Removes hydrophilic wire safely	0	1	0
16. Angiographic confirmation of left renal artery catheterisation	0	1	1

Respect for Tissue				
1 Frequently used unnecessary force on tissue and/or lesion, potential for tissue damage	2	3 Careful handling of tissues and/or lesion, but occasional potential for inadvertent tissue damage	4	5 Consistently handled tissues and/or lesion appropriately with minimal tissue damage
Time and Motion				
1 Make unnecessary moves and/or excessive time	2	3 Efficient time and moves but some unnecessary moves and/or excessive time	4	5 Clear economy of moves and time with maximum efficiency
Instrument Handling				
1 Repeated tentative, awkward, and/or inappropriate moves with instruments	2	3 Competent use of instruments, but occasionally appeared stiff or awkward	4	5 Fluid movements with instruments and no stiffness or awkwardness
Flow of Operation				
1 Frequently stopped operating and seemed unsure of next move; demonstrated imprecise and/or wrong operative technique	2	3 Demonstrated some forward planning with reasonable progression of procedure; careful operative technique with occasional errors	4	5 Planned course of operation with effortless flow throughout; fluent, secure, and correct operative technique in all stages of procedure
Overall Performance				
1 Very poor	2	3 Competent	4	5 Clearly superior
Final Product				
1 Unacceptable quality	2	3 Average quality	4	5 Superior quality
Would you feel confident in allowing this trainee to perform this procedure, under supervision in the OR? Yes / No				

APPENDIX 24~~X~~

PATIENT INFORMATION SHEET

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear.

vessels doctors can diagnose and treat vascular disease without the need for big incisions. Procedures are usually quicker and most can be performed under a local anaesthetic. This technique has revolutionised the treatment options now available for patients with vascular disease.

We are constantly trying to find new ways of training doctors to help reduce risk to patients.

A lot of surgeons' training involves computers that mimic reality; however they are not truly 'life-like'. In 2006 a new law (Human Tissue Act) allowed doctors to practice surgical procedures on human bodies. This only comes from patients who have donated their bodies to medical research. Dedicated cadaveric (dead body) training offers doctors a life-like way of training, and learning new techniques. Facilities now exist throughout the United Kingdom, running hundreds of training courses in a variety of specialties including vascular surgery.

There is a research project taking place in Newcastle, developing the use of human cadavers for training in endovascular surgery. Early results indicate these models are preferred by the doctors to using computers.

We would like to ask you a few questions about doctors training on computers and cadavers in vascular surgery. This will take no more than 5 minutes of your time.

or doctors), will be removed from our analysis to further protect your confidentiality.

- All costs associated with this questionnaire study have been covered by the Northern Vascular Centre research department.
- We may present these opinions to other doctors at medical meetings, or publish the opinions in a medical journal.

If you would like to complete a questionnaire, please indicate this to a member of the team who will confirm you have read and understood this information sheet before providing you with your questionnaire.

Your help and co-operation is hugely appreciated

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APPENDIX 25~~Y~~

QUANTITATIVE SCORES FOR VRS, PHCM, CROSS-OVER AND LECTURE TRAINED CANDIDATES

Quantitative Parametres for Each Performance – VRS Trained Candidates

Candidate / attempt		Total Procedure Time – min (sec)	Fluroscopy Time – min (sec)	Contrast - ml	Candidate / attempt		Total Procedure Time – min (sec)	Fluroscopy Time – min (sec)	Contrast - ml
1	1	10:00 (600)	06:45 (405)	30	**4**	1	10:00 (600)	02:34 (154)	30
	2	08:44 (524)	05:47 (347)	20		2	06:58 (418)	02:27 (147)	15
	3	05:11 (311)	03:29 (209)	15		3	05:02 (302)	02:02 (122)	12
	4	04:38 (278)	01:34 (94)	15		4	04:49 (289)	02:02 (122)	12
	5	04:11 (251)	01:20 (80)	12		5	04:13 (253)	02:11 (131)	12
	6	04:32 (272)	01:43 (103)	8		6	04:47 (287)	02:41 (161)	15
	7	04:11 (251)	01:25 (85)	12		7	04:09 (249)	02:13 (133)	11
	8	03:23 (203)	01:10 (70)	9		8	03:14 (194)	01:55 (115)	12
2	1	08:05 (485)	06:20 (380)	35	**5**	1	08:56 (536)	03:13 (193)	25
	2	06:14 (374)	04:40 (280)	15		2	05:02 (302)	03:00 (180)	12
	3	03:54 (234)	02:31 (151)	9		3	03:32 (212)	01:48 (108)	12
	4	03:15 (195)	01:53 (113)	12		4	03:46 (226)	02:18 (138)	15
	5	03:23 (203)	02:17 (137)	15		5	02:59 (179)	01:31 (91)	12
	6	03:10 (190)	01:56 (116)	15		6	02:29 (149)	01:19 (79)	12
	7	02:35 (155)	01:31 (91)	12		7	02:02 (122)	01:00 (60)	12
	8	02:21 (141)	01:40 (100)	12		8	01:48 (108)	01:23 (83)	12
3	1	10:00 (600)	06:27 (387)	30	**6**	1	05:41 (341)	03:16 (196)	25
	2	07:41 (461)	04:56 (296)	15		2	04:13 (253)	03:23 (203)	15
	3	05:39 (339)	03:27 (207)	25		3	03:02 (182)	02:03 (123)	10
	4	04:58 (298)	02:27 (147)	15		4	02:43 (163)	01:49 (109)	12
	5	04:39 (279)	02:04 (124)	15		5	02:12 (132)	01:24 (84)	10
	6	04:22 (262)	01:42 (102)	12		6	02:09 (129)	01:22 (82)	12
	7	04:04 (244)	01:59 (119)	14		7	01:50 (110)	01:15 (75)	10
	8	03:00 (180)	01:26 (86)	14		8	01:43 (103)	01:11 (71)	12
7	1	10:00 (600)	08:46 (526)	10	**10**	1	05:29 (329)	02:23 (143)	20
	2	06:46 (406)	05:37 (337)	15		2	03:27 (207)	01:35 (95)	15
	3	05:20 (300)	03:17 (197)	20		3	03:34 (214)	01:46 (106)	15
	4	04:19 (259)	02:53 (173)	15		4	02:25 (145)	00:52 (52)	10
	5	03:07 (187)	02:13 (133)	15		5	02:05 (125)	00:53 (53)	10
	6	02:27 (147)	01:46 (106)	15		6	03:04 (184)	01:37 (97)	8
	7	02:18 (138)	01:40 (100)	15		7	02:22 (142)	01:17 (77)	12
	8	02:35 (155)	02:07 (127)	12		8	02:28 (148)	01:24 (84)	10
8	1	08:21 (501)	08:00 (480)	40	**11**	1	08:05 (485)	06:48 (408)	20
	2	04:43 (283)	03:49 (229)	15		2	06:00 (360)	04:32 (272)	20
	3	03:52 (232)	03:14 (194)	15		3	03:19 (199)	02:39 (159)	15
	4	03:40 (220)	03:18 (198)	22		4	02:24 (144)	02:28 (148)	12
	5	02:55 (175)	02:20 (140)	12		5	02:30 (150)	01:57 (117)	12
	6	02:51 (171)	02:37 (157)	12		6	02:32 (152)	02:15 (135)	15
	7	02:15 (135)	02:11 (131)	12		7	02:30 (150)	01:56 (116)	20
	8	02:00 (120)	01:56 (116)	12		8	01:51 (111)	01:43 (103)	12
9	1	10:00 (600)	04:51 (291)	30	**12**	1	10:00 (600)	08:20 (500)	20
	2	08:03 (483)	02:55 (175)	35		2	07:52 (472)	07:26 (446)	25
	3	04:51 (291)	02:18 (138)	20		3	05:48 (348)	04:43 (283)	15
	4	04:11 (251)	02:44 (164)	15		4	02:48 (168)	02:27 (147)	12
	5	03:24 (204)	01:42 (102)	20		5	03:45 (225)	03:38 (218)	12
	6	06:02 (362)	03:25 (205)	12		6	02:42 (162)	02:17 (137)	18
	7	05:08 (308)	03:15 (195)	15		7	02:40 (160)	02:33 (153)	10
	8	03:07 (187)	01:41 (101)	12		8	02:28 (148)	02:25 (145)	12

Quantitative Parametres for Each Performance – PHCM Trained Candidates

Candidate / attempt		Total Procedure Time – min (sec)	Fluroscopy Time – min (sec)	Contrast - ml		Candidate / attempt		Total Procedure Time – min (sec)	Fluroscopy Time	Contrast - ml
1	1	10:00 (600)	03:43 (223)	30		**4**	1	09:23 (563)	02:47 (167)	10
	2	10:00 (600)	06:23 (383)	20			2	08:40 (520)	02:42 (162)	12
	3	10:00 (600)	05:53 (353)	18			3	07:42 (462)	02:19 (139)	15
	4	06:54 (414)	04:25 (265)	30			4	05:35 (335)	02:01 (121)	12
	5	05:39 (339)	04:11 (251)	25			5	04:30 (270)	01:37 (97)	15
	6	05:18 (318)	03:09 (189)	20			6	03:55 (235)	01:39 (99)	20
	7	03:31 (211)	02:10 (130)	17			7	02:25 (145)	01:07 (67)	10
	8	03:01 (181)	02:12 (132)	20			8	02:40 (160)	01:17 (77)	10
2	1	10:00 (600)	00:54 (54)	10		**5**	1	10:00 (600)	06:10 (370)	30
	2	10:00 (600)	04:40 (280)	35			2	10:00 (600)	05:09 (309)	15
	3	10:00 (600)	05:11 (311)	30			3	06:00 (360)	03:44 (224)	20
	4	08:28 (508)	05:32 (332)	30			4	07:07 (427)	03:34 (214)	20
	5	06:24 (384)	03:33 (213)	30			5	04:31 (271)	02:03 (123)	12
	6	05:00 (300)	02:47 (167)	18			6	06:03 (363)	03:40 (220)	12
	7	04:43 (283)	03:14 (194)	20			7	04:27 (267)	02:45 (165)	12
	8	03:46 (226)	02:30 (150)	22			8	03:20 (200)	02:07 (127)	12
3	1	10:00 (600)	04:33 (273)	28		**6**	1	10:00 (600)	06:09 (369)	10
	2	06:51 (411)	04:08 (248)	20			2	10:00 (600)	05:34 (334)	10
	3	06:53 (413)	04:07 (247)	20			3	07:57 (477)	04:46 (286)	15
	4	05:31 (331)	03:08 (188)	20			4	08:22 (502)	05:41 (341)	20
	5	04:50 (290)	02:59 (179)	20			5	07:20 (440)	05:27 (327)	15
	6	03:46 (226)	01:57 (117)	15			6	06:29 (389)	05:08 (308)	17
	7	03:22 (202)	02:10 (130)	15			7	03:42 (222)	02:29 (149)	13
	8	02:18 (138)	01:08 (68)	15			8	04:02 (242)	02:21 (141)	14
7	1	10:00 (600)	04.30 (270)	20		**10**	1	10:00 (600)	05.12 (912)	20
	2	10:00 (600)	04.12 (252)	50			2	10:00 (600)	07.30 (450)	30
	3	10:00 (600)	05.33 (333)	15			3	10:00 (600)	07.26 (446)	45
	4	05:34 (334)	02.04 (124)	12			4	10:00 (600)	07.51 (471)	15
	5	05:12 (312)	02.19 (139)	22			5	10:00 (600)	08.28 (508)	12
	6	10:00 (600)	05.50 (350)	14			6	04:58 (298)	03.53 (233)	12
	7	05:05 (305)	01.53 (113)	16			7	03:04 (184)	02.16 (136)	12
	8	08:57 (537)	05.32 (332)	12			8	03:51 (231)	02.48 (168)	10
8	1	10:00 (600)	05.08 (308)	30		**11**	1	10:00 (600)	05.55 (355)	30
	2	10:00 (600)	03.07 (187)	30			2	10:00 (600)	05.42 (342)	30
	3	09:44 (584)	04.13 (253)	28			3	10:00 (600)	05.43 (343)	24
	4	10:00 (600)	05.41 (341)	20			4	05:40 (340)	02.48 (168)	14
	5	08:30 (510)	04.33 (273)	18			5	06:43 (403)	05.34 (334)	14
	6	10:00 (600)	03.26 (206)	16			6	03:39 (219)	01.45 (105)	12
	7	10:00 (600)	05.30 (330)	16			7	03:07 (187)	01.44 (104)	12
	8	10:00 (600)	05.11 (311)	16			8	02:54 (174)	01.08 (68)	12
9	1	10:00 (600)	06.58 (418)	30		**12**	1	10:00 (600)	05.10 (310)	30
	2	10:00 (600)	07.25 (445)	30			2	10:00 (600)	06.22 (382)	34
	3	10:00 (600)	07.18 (438)	20			3	10:00 (600)	06.41 (401)	10
	4	10:00 (600)	07.50 (470)	20			4	05:37 (337)	03.35 (215)	12
	5	10:00 (600)	07.48 (468)	14			5	10:00 (600)	08.20 (500)	10
	6	07:40 (460)	02.31 (151)	16			6	04:58 (298)	03.16 (196)	10
	7	08:34 (514)	03.50 (230)	12			7	05:02 (302)	03.32 (212)	8
	8	10:00 (600)	05.56 (356)	12			8	03:58 (238)	02.15 (135)	8

Quantitative Parametres for Each Performance – Lecture Trained Candidates: PHCM & VRS Attempt

Model	Candidate	Total Procedure Time – min (sec)	Fluroscopy Time – min (sec)	Contrast - ml
PHCM	1	10.00 (600)	0.49 (49)	15
	2	7.34 (454)	4.55 (295)	10
	3	10.00 (600)	1.43 (103)	12
	4	10.00 (600)	4.37 (277)	9
	5	10.00 (600)	4.59 (299)	30
	6	10.00 (600)	4.46 (286)	10
	7	10.00 (600)	5.20 (320)	37
	8	10.00 (600)	5.26 (326)	30
	9	10.00 (600)	1.37 (97)	22
	10	10.00 (600)	3.50 (230)	20
	11	7.52 (472)	2.52 (172)	19
	12	10.00 (600)	6.08 (368)	10
VRS	1	09.31 (571)	06.34 (394)	30
	2	06.44 (404)	04.36 (276)	11
	3	08.54 (534)	03.40 (220)	15
	4	08.50 (530)	06.34 (394)	20
	5	06.10 (370)	05.20 (320)	30
	6	10.00 (600)	05.00 (300)	20
	7	10.00 (600)	10.00 (600)	18
	8	06.24 (384)	05.56 (356)	15
	9	06.33 (393)	05.38 (338)	44
	10	10.00 (600)	07.34 (454)	10
	11	08.44 (524)	07.40 (460)	54
	12	08.43 (423)	01.53 (113)	16

Quantitative Parametres for Each Performance – VRS and PHCM Cross-Over Performances

Training regime	Candidate	Total Procedure Time – min (sec)	Fluroscopy Time – min (sec)	Contrast - ml
PHCM trained candidates - VRS Attempt	1	06.33 (393)	02.12 (132)	35
	2	04.53 (293)	02.18 (138)	15
	3	05.22 (322)	03.01 (181)	18
	4	04.34 (274)	02.02 (122)	16
	5	04.01 (241)	01.41 (101)	22
	6	04.44 (284)	03.34 (214)	15
	7	10.00 (600)	06.22 (382)	28
	8	08.22 (502)	06.24 (384)	46
	9	04.33 (273)	02.27 (147)	8
	10	07.22 (442)	03.46 (406)	12
	11	04.48 (288)	01.41 (101)	17
	12	05.13 (313)	02.10 (130)	17
VRS trained candidates - PHCM attempt	1	07.17 (437)	04.44 (284)	12
	2	07.51 (471)	03.19 (199)	14
	3	06.24 (384)	03.10 (190)	20
	4	08.33 (513)	04.22 (262)	16
	5	05.46 (346)	03.11 (191)	14
	6	DNA	DNA	DNA*
	7	08.25 (505)	04.30 (270)	16
	8	10.00 (600)	06.43 (403)	22
	9	09.30 (570)	06.48 (408)	15
	10	10.00 (600)	05.26 (326)	14
	11	10.00 (600)	05.44 (344)	12
	12	10.00 (600)	04.53 (293)	12

*Candidate unable to attend due to long-term sickness.

APPENDIX 26~~Z~~

CLINICAL PERFORMANCE SCORES FOR VRS, PHCM, CROSS-OVER AND LECTURE TRAINED CANDIDATES

Mean Blinded Clinical Scores (TSC, GRS, OPS) for Candidates Trained on VRS.

Candidate	Procedure	TSC	GRS	OPS
1	1	7.00	6.50	13.50
	2	12.50	12.50	25.00
	3	13.50	14.00	27.50
	4	14.00	16.50	30.50
	5	13.00	18.00	31.00
	6	13.00	13.00	26.00
	7	13.50	19.00	32.50
	8	14.50	23.50	37.50
2	1	13.00	12.00	25.00
	2	14.50	19.00	33.50
	3	15.00	22.00	37.00
	4	13.00	18.50	31.50
	5	15.00	20.50	35.50
	6	13.50	17.00	30.50
	7	15.50	25.00	40.50
	8	13.50	16.50	30.00
3	1	9.50	7.00	16.50
	2	13.50	15.50	29.00
	3	15.50	17.50	33.00
	4	15.50	21.00	36.50
	5	16.00	21.50	37.50
	6	16.00	25.00	41.00
	7	15.50	22.50	38.00
	8	14.50	20.50	35.00
4	1	8.00	7.00	15.00
	2	13.50	16.00	29.50
	3	14.50	16.00	30.50
	4	15.00	18.00	33.00
	5	15.50	19.50	35.00
	6	12.50	14.00	26.50
	7	14.00	23.00	37.00
	8	16.00	25.00	41.00
5	1	13.00	13.00	26.00
	2	15.50	21.50	37.00
	3	15.50	23.50	39.00
	4	13.50	19.00	32.50
	5	15.00	24.00	39.00
	6	15.00	23.50	38.50
	7	15.50	27.50	43.00
	8	13.50	23.00	36.50
6	1	14.50	19.00	33.50
	2	15.50	26.00	41.50
	3	16.00	23.00	39.00
	4	15.50	27.00	42.50
	5	15.00	26.50	41.50
	6	15.00	27.00	42.00
	7	15.50	28.00	43.50
	8	14.00	23.00	37.00

Candidate	Procedure	TSC	GRS	OPS
7	1	8.00	8.00	16.00
	2	12.50	15.00	27.50
	3	14.50	17.00	31.50
	4	14.00	17.50	31.50
	5	15.00	21.50	36.50
	6	14.50	25.00	39.50
	7	15.00	22.50	37.50
	8	13.00	19.50	32.50
8	1	10.00	9.50	19.50
	2	13.50	19.50	33.00
	3	14.50	18.00	32.50
	4	11.50	16.00	27.50
	5	15.50	25.00	40.50
	6	15.00	19.00	34.00
	7	14.50	23.00	37.50
	8	15.00	27.50	42.50
9	1	8.00	7.00	15.00
	2	12.50	11.00	23.50
	3	12.50	15.00	27.50
	4	13.00	16.00	29.00
	5	14.50	21.50	36.00
	6	13.00	13.00	26.00
	7	15.00	18.50	33.50
	8	15.00	24.00	39.00
10	1	13.00	14.00	27.00
	2	14.50	20.00	34.50
	3	12.50	17.00	29.50
	4	14.00	23.50	37.50
	5	14.00	26.00	40.00
	6	12.50	16.50	29.00
	7	12.50	17.50	30.00
	8	13.50	19.50	33.00
11	1	15.00	13.50	28.50
	2	15.50	23.00	38.50
	3	15.50	24.50	40.00
	4	14.50	23.00	37.50
	5	14.50	22.50	37.00
	6	12.50	19.00	31.50
	7	15.50	25.50	41.00
	8	15.00	23.50	38.50
12	1	4.50	6.50	11.00
	2	14.00	11.00	25.00
	3	10.00	12.00	22.00
	4	12.50	15.00	27.50
	5	12.00	17.50	29.50
	6	12.00	17.50	29.50
	7	13.00	17.50	30.50
	8	13.00	17.00	30.00

Mean Blinded Clinical Scores (TSC, GRS, OPS) for Candidates Trained on PHCM.

Candidate	Procedure	TSC	GRS	OPS
1	1	6.00	7.00	13.00
	2	15.00	17.50	32.50
	3	13.00	15.50	28.50
	4	15.00	22.00	37.00
	5	15.50	24.50	40.00
	6	15.50	23.50	39.00
	7	16.00	30.00	46.00
	8	15.00	25.00	40.00
2	1	4.50	6.50	11.00
	2	11.00	14.50	25.50
	3	12.50	15.50	28.00
	4	15.00	20.00	35.00
	5	15.50	24.50	40.00
	6	15.50	25.00	40.50
	7	15.50	26.00	41.50
	8	16.00	27.00	43.00
3	1	14.00	16.50	30.50
	2	13.00	22.00	35.00
	3	15.00	18.50	33.50
	4	16.00	27.50	43.50
	5	15.00	24.50	39.50
	6	16.00	30.00	46.00
	7	14.50	25.00	39.50
	8	16.00	29.00	45.00
4	1	14.00	17.50	31.50
	2	13.50	18.50	32.00
	3	14.50	21.00	35.50
	4	15.00	26.50	41.50
	5	15.50	24.50	40.00
	6	14.50	23.00	37.50
	7	15.50	29.50	45.00
	8	15.00	26.50	41.50
5	1	11.00	14.50	25.50
	2	11.00	12.00	23.00
	3	14.50	19.00	33.50
	4	13.00	15.50	28.50
	5	14.00	24.00	38.00
	6	14.50	20.50	35.00
	7	15.50	26.00	41.50
	8	16.00	26.50	42.50
6	1	9.50	12.50	22.00
	2	12.00	15.00	27.00
	3	15.00	22.00	37.00
	4	14.00	19.50	33.50
	5	14.50	19.00	33.50
	6	13.50	16.50	30.00
	7	15.50	26.00	41.50
	8	15.50	28.00	43.50

Candidate	Procedure	TSC	GRS	OPS
7	1	7.50	10.00	17.50
	2	10.50	15.50	26.00
	3	11.00	15.00	26.00
	4	14.00	18.00	32.00
	5	15.50	21.50	37.00
	6	9.50	12.50	22.00
	7	14.00	20.00	34.00
	8	14.50	19.00	33.50
8	1	5.50	5.00	10.50
	2	8.00	9.00	17.00
	3	13.00	13.50	26.50
	4	10.00	11.00	21.00
	5	12.50	15.50	28.00
	6	10.50	14.50	25.00
	7	12.00	12.50	24.50
	8	12.00	16.00	28.00
9	1	9.00	13.00	22.00
	2	12.00	13.50	25.50
	3	10.00	13.50	23.50
	4	11.00	15.50	26.50
	5	12.50	16.50	29.00
	6	14.50	20.50	35.00
	7	15.00	20.00	35.00
	8	14.00	22.50	36.50
10	1	9.50	13.50	23.00
	2	11.50	12.50	24.00
	3	12.00	15.50	27.50
	4	11.50	13.50	25.00
	5	12.00	17.00	29.00
	6	15.00	21.50	36.50
	7	15.50	25.50	41.00
	8	15.00	23.50	38.50
11	1	7.50	8.00	15.50
	2	8.00	8.00	16.00
	3	13.00	15.00	28.00
	4	15.00	21.50	36.50
	5	15.50	21.50	37.00
	6	16.00	27.50	43.50
	7	15.00	25.00	40.00
	8	15.00	25.00	40.00
12	1	5.00	6.00	11.00
	2	10.50	13.50	24.00
	3	12.50	15.50	28.00
	4	15.50	22.50	38.00
	5	13.00	16.50	29.50
	6	15.00	24.00	39.00
	7	15.50	24.00	39.50
	8	16.00	26.00	42.00

Mean Blinded Clinical Scores (TSC, GRS, OPS) for Lecture Trial Candidates: VRS and PHCM Performances.

Procedure	Candidate	TSC	GRS	OPS
VRS	1	13.00	13.50	26.50
	2	14.50	15.00	29.50
	3	13.50	17.50	31.00
	4	15.00	17.00	32.00
	5	14.50	16.50	31.00
	6	8.50	8.00	16.50
	7	13.00	13.00	26.00
	8	15.50	17.50	33.00
	9	14.50	16.00	30.50
	10	8.50	10.00	18.50
	11	13.50	13.00	26.50
	12	15.00	19.00	34.00
PHCM	1	9.50	12.50	22.00
	2	13.00	15.50	28.50
	3	8.50	8.50	17.00
	4	11.00	11.00	22.00
	5	8.50	13.00	21.50
	6	8.00	10.00	18.00
	7	7.00	6.00	13.00
	8	8.00	6.00	14.00
	9	6.00	6.00	12.00
	10	6.50	6.00	12.50
	11	8.00	8.00	16.00
	12	15.50	17.00	32.50

Mean Blinded Clinical Scores (TSC, GRS, OPS) for VRS and PHCM Trained Cross-Over Performances

Procedure	Candidate	TSC	GRS	OPS
PHCM Trained VRS Performance	1	15.00	20.50	35.50
	2	9.00	9.00	18.00
	3	14.50	19.00	33.50
	4	15.50	23.00	38.50
	5	14.00	17.00	31.00
	6	14.00	14.00	28.00
	7	16.00	22.00	38.00
	8	14.50	17.50	32.00
	9	16.00	24.00	40.00
	10	15.50	23.00	38.50
	11	16.00	24.00	40.00
	12	15.50	21.50	37.00
VRS Trained PHCM Performance	1	8.50	8.00	16.50
	2	14.50	17.00	31.50
	3	15.50	18.50	34.00
	4	11.50	12.00	23.50
	5	12.50	15.00	27.50
	6	DNA	DNA	DNA
	7	14.50	23.50	38.00
	8	10.50	10.50	21.00
	9	11.50	11.50	23.00
	10	12.00	18.00	30.00
	11	13.50	19.50	33.00
	12	11.00	15.50	26.50

APPENDIX 27~~Aa~~

PRE-FEEDBACK CLINICAL PERFORMANCE SCORES:
EXAMINER 1 AND 2 AND MEAN PERFORMANCE SCORES (BS)

Pre-feedback Blinded Examiner Scores

		Group 1: *Generic Lecture Feedback*			**Group 2:** *Unsupervised Video Enhanced Feedback*			**Group 3:** *Individualised Video Enhanced Feedback*		
	Candidate	**1***	**2ǂ**	**Mean**	**1***	**2ǂ**	**Mean**	**1***	**2ǂ**	**Mean**
Task Specific Checklist (TSC)	Cand 1	19	10	14.5	35	43	28	5	3	4
	Cand 2	3	5	4	25	54	25.5	36	19	27.5
	Cand 3	4	10	7	34	32	25.5	23	11	17
	Cand 4	17	24	20.5	5	12	4	28	15	21.5
	Cand 5	13	8	10.5	30	27	22.5	24	28	26
	Cand 6	37	30	33.5	5	10	3.5	21	13	17
	Cand 7	21	11	16	29	30	22	23	15	19
	Cand 8	24	16	20	26	25	20	7	6	6.5
	Cand 9	11	8	9.5	31	30	22.5	14	5	9.5
	Cand 10	34	24	29	31	31	22	36	18	27
	Cand 11	40	34	37	DNA	DNA	DNA	16	8	12
Global Rating Score (GRS)	Cand 1	12	10	11	26	37	24	14	9	11.5
	Cand 2	12	13	12.5	24	30	26	22	18	20
	Cand 3	11	18	14.5	25	24	20	21	15	18
	Cand 4	22	25	23.5	13	20	11	20	13	16.5
	Cand 5	12	10	11	19	29	15.5	22	28	25
	Cand 6	25	25	25	10	27	9	19	12	15.5
	Cand 7	16	11	13.5	20	33	17.5	18	15	21.5
	Cand 8	18	17	17.5	17	23	14	12	10	11
	Cand 9	18	16	17	22	28	19	13	10	11.5
	Cand 10	27	20	23.5	25	33	21.5	22	17	19.5
	Cand 11	31	27	29	DNA	DNA	DNA	12	10	11
Overall Procedure Score (OPS)	Cand 1	31	20	25.5	61	31	52	19	12	15.5
	Cand 2	15	18	16.5	49	20	51.5	58	37	47.5
	Cand 3	15	28	21.5	59	20	45.5	44	26	35
	Cand 4	39	49	44	18	19	15	48	28	38
	Cand 5	25	18	21.5	49	23	38	46	56	51
	Cand 6	62	55	58.5	15	24	12.5	40	25	32.5
	Cand 7	37	22	29.5	49	27	39.5	41	30	40.5
	Cand 8	42	33	37.5	43	21	34	19	16	17.5
	Cand 9	29	24	26.5	53	19	41.5	27	15	21
	Cand 10	61	44	52.5	56	29	43.5	58	35	46.5
	Cand 11	71	61	66	DNA	DNA	DNA	28	18	23

*Blinded examiner 1
ǂBlinded Examiner 2

APPENDIX 28~~Bb~~

POST-FEEDBACK CLINICAL PERFORMANCE SCORES:
EXAMINER 1 AND 2 AND MEAN PERFORMANCE SCORES (BS)

Post-feedback Blinded Examiner Scores

		Group 1: *Generic Lecture Feedback*			**Group 2:** *Unsupervised Video Enhanced Feedback*			**Group 3:** *Individualised Video Enhanced Feedback*		
	Candidate	**1***	**2ǂ**	**Mean**	**1***	**2ǂ**	**Mean**	**1***	**2ǂ**	**Mean**
Task Specific Checklist (TSC)	Cand 1	37	40	38.5	39	41	40.0	19	21	20
	Cand 2	26	22	24	37	38	37.5	41	37	39
	Cand 3	26	25	25.5	39	35	37.0	37	35	36
	Cand 4	34	31	32.5	27	22	24.5	39	35	37
	Cand 5	18	20	19	42	32	37.0	42	38	40
	Cand 6	39	41	40	39	26	32.5	39	36	37.5
	Cand 7	34	30	32	42	41	41.5	37	38	37.5
	Cand 8	38	30	34	30	30	30.0	23	21	22
	Cand 9	23	23	23	35	37	36.0	32	34	33
	Cand 10	35	35	35	35	32	33.5	42	41	41.5
	Cand 11	40	40	40	DNA	DNA	DNA	42	38	40
Global Rating Score (GRS)	Cand 1	26	28	27	27	27	27.0	22	18	20
	Cand 2	21	17	19	24	23	23.5	28	26	27
	Cand 3	20	18	19	22	21	21.5	25	27	26
	Cand 4	27	19	23	18	16	17.0	29	19	24
	Cand 5	19	19	19	29	22	25.5	28	26	27
	Cand 6	27	25	26	28	20	24.0	28	20	24
	Cand 7	20	19	19.5	29	22	25.5	27	22	24.5
	Cand 8	23	23	23	19	21	20.0	22	21	21.5
	Cand 9	22	18	20	27	21	24.0	25	20	22.5
	Cand 10	27	21	24	26	20	23.0	29	32	30.5
	Cand 11	29	26	27.5	DNA	DNA	DNA	26	24	25
Overall Procedure Score (OPS)	Cand 1	63	68	65.5	66	68	67.0	41	39	40
	Cand 2	47	39	43	61	61	61.0	69	63	66
	Cand 3	46	43	44.5	61	56	58.5	62	62	62
	Cand 4	61	50	55.5	45	38	41.5	68	54	61
	Cand 5	37	39	38	71	54	62.5	70	64	67
	Cand 6	66	66	66	67	46	53.5	67	56	61.5
	Cand 7	54	49	51.5	71	63	67.0	64	60	62
	Cand 8	61	53	57	49	51	50.0	45	42	43.5
	Cand 9	45	41	43	62	58	60.0	57	54	55.5
	Cand 10	62	56	59	61	52	56.5	71	73	72
	Cand 11	69	66	67.5	DNA	DNA	DNA	68	62	66

*Blinded examiner 1
ǂBlinded Examiner 2

APPENDIX 29

APPENDIX 29 (a) Quantitative Measures Taken During the Face Validity Trial – Candidates 1-6

APPENDIX 29 (b) Quantitative Measures Taken During the Face Validity Trial – Candidates 7-12

Appendix 29~~C~~ (a): Quantitative Measures Taken During the Face Validity Trial – Candidates 1-6

Candidate	1				2				3				4				5				6			
Model	PHCM		SVR		PHCM		SVR		PHCM		SVR		PHCM		SVR		PHCM		SVR		PHCM		SVR	
Index Procedure	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2
Total Procedure time*	4.36 (276)	10.0 (600)	4.22 (262)	1.32 (92)	2.46 (166)	6.07 (367)	2.10 (130)	4.04 (244)	5.03 (303)	5.43 (343)	3.45 (225)	2.08 (128)	6.36 (396)	10.0 (600)	4.30 (270)	5.12 (312)	5.31 (331)	7.18 (438)	3.18 (198)	3.26 (206)	2.38 (158)	4.50 (290)	2.03 (123)	2.17 (137)
Fluroscopy time*	3.52 (232)	8.34 (514)	2.26 (146)	0.35 (35)	2.03 (123)	4.58 (298)	1.33 (93)	2.49 (169)	2.53 (173)	4.39 (279)	2.50 (170)	1.42 (102)	6.00 (360)	8.21 (501)	3.57 (237)	4.34 (274)	4.20 (260)	6.48 (408)	3.00 (180)	3.05 (185)	2.17 (137)	4.22 (262)	1.51 (171)	2.05 (125)
Contrast used (ml)	15	25	5	5	12	23	18	14	10	30	5	5	15	20	25	25	20	28	20	20	18	26	10	18

*minutes (seconds)

Appendix 29~~C~~ (b): Quantitative Measures Taken During the Face Validity Trial – Candidates 7-12

Candidate	**7**				**8**				**9**				**10**				**11**				**12**			
Model	**PHCM**		**SVR**		**PHCM**		**SVR**		**PHCM**		**SVR**		**PHCM**		**SVR**		**PHCM**		**SVR**		**PHCM**		**SVR**	
Index Procedure	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
Total Procedure time*	5.46 (346)	10.0 (600)	4.02 (242)	3.03 (183)	5.51 (351)	10.0 (600)	4.01 (241)	3.54 (234)	1.56 (116)	5.39 (339)	3.46 (226)	4.39 (279)	6.47 (407)	9.08 (548)	5.54 (354)	6.01 (361)	7.36 (456)	8.50 (530)	5.23 (323)	4.55 (295)	7.55 (475)	9.34 (574)	7.35 (455)	8.29 (509)
Fluroscopy time*	3.55 (335)	7.56 (476)	3.20 (200)	2.12 (132)	4.23 (563)	8.50 (530)	2.57 (177)	3.21 (201)	1.36 (96)	4.32 (272)	3.05 (185)	4.17 (257)	5.18 (318)	8.26 (506)	6.45 (405)	5.29 (329)	6.53 (413)	8.02 (482)	5.07 (307)	3.52 (232)	6.28 (388)	7.43 (463)	5.48 (348)	6.47 (407)
Contrast used (ml)	12	22	14	24	16	18	12	20	15	28	12	15	25	35	20	30	28	38	20	20	32	20	26	34

*minutes (seconds)

APPENDIX 30~~Dd~~

APPENDIX 30~~Dd~~ (a) INDEX PROCEDURE QUANTITATIVE PARAMETER SCORES FROM THE TRIAL OF CONSTRUCT VALIDITY: EXPERT CANDIDATES

APPENDIX 30~~Dd~~ (b) INDEX PROCEDURE QUANTITATIVE PARAMETER SCORES FROM THE TRIAL OF CONSTRUCT VALIDITY: INTERMEDIATE CANDIDATES

APPENDIX 30~~Dd~~ (c) INDEX PROCEDURE QUANTITATIVE PARAMETER SCORES FROM THE TRIAL OF CONSTRUCT VALIDITY: NOVICE CANDIDATES

Appendix 30~~Dd~~ (a): Quantitative Measures Taken During the Construct Validity Trial – Expert

Expert Candidate	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Procedure complete	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Total Procedure time*	4.11 (251)	9.34 (574)	7.02 (422)	5.13 (313)	7.57 (477)	3.16 (196)	5.45 (345)
Fluroscopy time*	2.26 (146)	5.50 (350)	4.00 (240)	2.33 (153)	4.11 (251)	1.57 (117)	3.29 (209)
Contrast used (ml)	16	32	18	20	20	14	15

Appendix 30~~Dd~~ (b): Quantitative Measures Taken During the Construct Validity Trial – Intermediate

Expert Candidate	**1**	**2**	**3**	**4**
Procedure complete	Yes	Yes	Yes	Yes
Total Procedure time*	1.59 (119)	7.07 (427)	7:05 (425)	6.31 (391)
Fluroscopy time*	0.52 (52)	4.22 (262)	5.02 (302)	4.55 (295)
Contrast used (ml)	15	25	20	16

*minutes (seconds)

Appendix 30~~Dd~~ (c): Quantitative Measures Taken During the Construct Validity Trial – Novice

Expert Candidate	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Procedure complete	No	No	No	Yes	No	No	No	No	No	No	No	No
Total Procedure time*	10:00 (600)	10:00 (600)	10:00 (600)	9:23 (563)	10:00 (600)	10:00 (600)	10:00 (600)	10:00 (600)	10:00 (600)	10:00 (600)	10:00 (600)	10:00 (600)
Fluroscopy time*	3.43 (223)	0.54 (54)	4.33 (273)	2.47 (167)	6.10 (370)	6.09 (369)	4.30 (270)	5.08 (308)	6.58 (388)	5.12 (312)	5.55 (355)	5.10 (310)
Contrast used (ml)	30	10	28	10	30	10	20	30	30	20	30	30

*minutes (seconds)

APPENDIX 31~~E~~e

PUBLICATIONS AND PRESENTATIONS

Oral Presentations.

1. Training Basic Endovascular Skills: A Comparison of High Fidelity Virtual Reality Simulation and A Fresh Frozen Pulsatile Human Cadaver. NESBITT C, McCaslin J, Macdonald S, Williams R, Nice C, Searle R, Ashour A, Stansby G. British Society of Interventional Radiology Annual Meeting. Manchester November 2013.

2. The Role of Feedback in Technical Skills Acquisition: Investigating the the Efficacy of Video Assisted Feedback. C NESBITT, D Sakutombo, A Gungadeen, I Pooleman, H Jones, J Chambers, G Stansby, R Searle. Association for the Study of Medical Education. Edinburgh. July 2013.

3. Training Basic Endovascular Skills: A Comparison of High Fidelity Virtual Virtual Reality Simulation and A Fresh Frozen Pulsatile Human Cadaver. NESBITT C, McCaslin J, Macdonald S, Williams R, Nice C, Searle R, Ashour A, Stansby G. British Society of Endovascular Therapy. Warwickshire June 2013.

4. Training Basic Endovascular Skills: A Comparison of High Fidelity Virtual Virtual Reality Simulation and A Fresh Frozen Pulsatile Human Cadaver. NESBITT C, McCaslin J, Macdonald S, Williams R, Nice C, Searle R, Ashour A, Stansby G. The North East Surgical Society and Royal College of Surgeons. Freeman Hospital, April 2013.

5. The Role of Feedback in Technical Skills Acquisition: Investigating the Efficacy of Video Assisted Feedback. C NESBITT, D Sakutombo, A Gungadeen, I Pooleman, H Jones, J Chambers, G Stansby, R Searle. Association of Surgeons in Training, March 2013.

6. The Fresh Frozen Pulsatile Human Cadaver Model A Novel Technique for Training Endovascular Practitioners – A Trial of Face Validity. NESBITT C, McCaslin J, Williams R, Macdonald S, Ashour H, Searle R, Stansby G. The British Society of Endovascular Therapy. Warwickshire, June 2012.

7. A Pulsatile Human Cadaver Model for Training Endovascular Skills – A Novel Technique for Training Endovascular Practitioners. NESBITT C, McCaslin J, Williams R, Macdonald S, Ashour H, Searle R, Stansby G. International Surgical Congress of the Association of Surgeons of Great Britain and Ireland. Liverpool May 2012.

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Poster Presentations.

8. The Role of A Traditional Lecture in Teaching Basic Endovascular Skills: Skills: Comparing High Fidelity Virtual Reality Simulation and A Fresh Frozen Pulsatile Human Cadaver. NESBITT C, Alison R, McCaslin J, Nice C, Searle R, Macdonald S, Stansby G. British Society of Interventional Radiology Annual Meeting. Manchester November 2013.

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9. The Role of A Traditional Lecture in Teaching Basic Endovascular Skills: Skills: Comparing High Fidelity Virtual Reality Simulation and A Fresh Frozen Pulsatile Human Cadaver. NESBITT C, Alison R, McCaslin J, Nice C, Searle R, Macdonald S, Stansby G. British Society of Endovascular Therapy. Warwickshire June 2013.

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10. Endovascular Simulation Training. A Questionnaire of Patient and Professional Opinion. Maitland S, NESBITT C, Macdonald S, Searle R, Stansby G. British Society of Endovascular Therapy. Warwickshire June 2013.

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11. The Roll of Video Assisted Feedback in Technical Skills Acquisition. NESBITT C, Searle R, Stansby G. The 5th International Conference of Clinical Skills. Prato (Italy) May 2013.

12. Endovascular Simulation Training. A Questionnaire of Patient and Professional Opinion. Maitland S, NESBITT C, Macdonald S, Searle R, Stansby G. Association of Surgeons in Training. March 2013.

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13. The Establishment of a Fresh Frozen Human Cadaveric Flow Model for Endovenous Training. NESBITT, C Oates, S Macdonald, H Ashour, G Stansby. The Venous Forum. Royal College of Physicians, London. April 2012

14. The Pulsatile Human Cadaver Model - A Novel technique for Training Training Endovascular Practitioners. NESBITT C, McCaslin J, Williams R, Macdonald S, Ashour H, Searle R, Stansby G. Association of Surgeons in Training. March 2012

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15. A Fresh Frozen Pulsatile Human Cadaver Model for Training Endovascular Practitioners. A Trial of Face Validity. NESBITT C, McCaslin J, Williams R, Macdonald S, Ashour H, Searle R, Stansby G. The International Symposium on Endovascular Therapy. Miami, USA. Jan 15th-19th 2012.

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16. A Fresh Frozen Pulsatile Human Cadaver Model for Training Endovascular Practitioners. A Trial of Face Validity. C NESBITT, J McCaslin, R Williams, S Macdonald, H Ashour, R Searle, G Stansby. Vascular Society's Annual Scientific Meeting. Edinburgh 23rd-25th November 2011.

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Local (oral) Presentations

1. Training Basic Endovascular Skills: A Comparison of High Fidelity Virtual Reality Simulation and A Fresh Frozen Pulsatile Human Cadaver. NESBITT C, McCaslin J, Searle R, Nice C, Williams R, Macdonald S, Stansby G. The Northern Vascular Group Meeting. April 2013. **Awarded Trainee Prize for Best Presentation**

2. Endovascular Simulation Training. A Questionnaire of Patient and Professional Opinion. Maitland S, NESBITT C, Macdonald S, Searle R, Stansby G. The Northern Vascular Group Meeting. April 2013.

3. Introducing The Pulsatile Fresh Frozen Human Cadaver Endovascular Training Model. The Northern Vascular Group Meeting. NESBITT C, McCaslin J, Searle R, Macdonald S, Stansby G. October 7th 2011

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