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Proficiency-based simulation training in open and endovascular surgery.

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Proficiency-based simulation training in open and endovascular surgery

By

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I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree (Doctor of Medicine) is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

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Abstract

The traditional form of surgical skills training and recent changes in health care have created challenges in keeping up the standards in skills training of future surgeons. The structured development of simulation training might help tackle these challenges. The main aim of this thesis was to explore whether basic surgical skills acquired using proficiency-based simulation training in superficial femoral artery (SFA) angioplasty and saphenofemoral junction (SFJ) dissection translate to real-world performance.

Four studies were performed. In the first study, a procedure-specific checklist for SFA angioplasty was developed and validated using the Vascular Intervention Simulation Trainer (VIST) simulator. In the second study, the impact of an assistant on the technical skills of the primary operator performing SFA angioplasties on the VIST simulator was assessed. The first and the second studies were essential to study the transfer of endovascular skills after proficiency-based simulation training in SFA angioplasty to the interventional suite (third study). The fourth study describes the transfer of open vascular surgical skills after proficiency-based bench model simulation training in SFJ dissection to the operating room (OR).

Simulation-trained trainees scored higher than the controls on the procedural checklist developed (86.80 ± 5.36 vs. 67.60 ± 6.02 $P = 0.001$) and a global rating scale (37.20 ± 4.09 vs. 24.40 ± 5.32 $P = 0.003$) when performing SFA angioplasty on patients. Similarly, bench model simulation-trained trainees scored higher than the controls on procedural (30.33 ± 2.07 vs. 18 ± 2.19 $P <$

0.001) and global (28.33 ± 1.86 vs. 18.50 ± 4.04 $P < 0.001$) rating scales when performing SFJ dissection on patients.

Basic surgical skills acquired using proficiency-based simulation training in SFA angioplasty and SFJ dissection do translate to real world performance. Structured proficiency-based simulation training in SFA angioplasty and SFJ dissection should be incorporated into surgical training programs.

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Glossary

ICEPS	Imperial College Evaluation of Procedure-Specific Skill
OR	Operating Room
OSATS	Objective Structured Assessment of Technical Skills
RCSI	Royal College of Surgeons in Ireland
SFA	Superficial Femoral Artery
SFJ	Saphenofemoral Junction
TASC	TransAtlantic interSociety Consensus
TER	Transfer Effectiveness Ratio
VIST	Vascular Intervention Simulation Trainer

Chapter One: Introduction

1.1 Recent changes in the health care system

Recent changes in the health care system have brought new challenges for the training of future surgeons. The Caiman reforms, increasing medico-legal issues, a growing awareness of costs and budgetary accountability, the shift towards a consultant-based service and more recently the reduction in working hours are all posing new threats to the already compromised current training programs (Varghese *et al.*, 1999). The avoidable death of a patient, Libby Zion, caused by overworked junior doctors led New York State to adopt the Bell Commission's recommendations according to which residents could not work more than 80 hours a week or more than 24 consecutive hours. From August 2004, the European Working Time Directive was enacted into law for junior doctors in Ireland like in the rest of Europe. There is a widespread view amongst surgeons that some proposed models of implementation of the 48-hour week would be incompatible with the quality of surgical training (Morris-Stiff *et al.,* 2005; Roche-Nagle, 2004). It has been estimated that the "new European working time" for junior doctors and the introduction of specialist training have reduced surgical training time by around two thirds (Chikwe *et al.,* 2004; Somaseker *et al.,* 2003). In addition, young doctors are less willing to sacrifice family and leisure time for onerous hours in the hospital. Moreover, with increased patients' expectations and long waiting lists, ethical and legal concerns for patients' safety have increased the challenge to train surgical trainees.

All these changes have not only created challenges in keeping up the standards in skills training of future surgeons, but have also forced surgical educators to search for new methods of teaching surgical skills that will

optimize learning and resulting surgical expertise while minimizing associated costs. It is difficult to elucidate and address which components of the current training system contribute most to quality of training. However, a well designed strategy of increased use of structured training combined with educational courses and skills training programs may help to tackle all of these issues simultaneously.

1.2 Current surgical education system

The traditional form of surgical skills training is carried out in the operating theatre, where hands-on tutoring is given by a senior surgeon assisting the trainee in performing part or all of an operative procedure. It is considered increasingly unethical for junior surgical trainees to develop their technical skills on live patients because the margin of error is greater for inexperienced surgeons. The 1999 US report 'To Err is Human' estimated that as many as 98 000 deaths per year could be attributed to medical error. It was determined that adverse events occurred in 4% of the hospitalisations in New York State and that 28% of these adverse events were due to negligence with 14% leading to death (Brennan *et al.*, 2004). Furthermore, in the era of cost containment and health care crises, the current form of operative room training has been claimed to be expensive, time-consuming and inefficient in the provision of surgical care (Bridges and Diamond, 1999; Richards *et al.*, 2000). It has been estimated in the US that procedures performed by surgeons-in-training took almost 13 minutes longer than those performed by expert surgeons. As there are over 1000 trainees in the US, the total cost associated with increased operative time was estimated at $53 million per year (Bridges and Diamond, 1999). In another study, it was

estimated that the total number of operations available for training in a single health board was 38% less than the number recommended by surgical training bodies (Crofts *et al.*, 1997). In the study, the authors calculated that to increase the proportion of operations undertaken by trainees from the current 30% to 70% would require an extra 270 theatre days (or £1.3m) annually. In addition, the current training paradigm lacks objective feedback on trainee performance.

Minimally invasive surgery, which involves the use of instruments and a camera or fluoroscopy, has been adopted in many surgical fields such as in colectomy, hysterectomy, cholecystectomy and endovascular surgery. Compared to conventional surgery, minimal invasive surgery is associated with reduced pain, less tissue damage, smaller surgical scars and reduced recovery time. Minimally invasive surgery is technically challenging, especially for the novice surgeons, and requires more facilities than conventional surgery (Cuschieri, 1995). The surgeon's technical ability is often hampered by constraints such as limited degree of freedom of the surgical tools, loss of depth perception as the 3D surgical field is converted into a 2D screen and increased operative time. It was found that 90% of common bile duct injuries occurred within the first 30 operation performed by trainee surgeons and that the probability of such an injury dropped from 1.7% to 0.17% by the 50^{th} case (Moore and Bennett, 1995). This emphasises the importance of the learning curve in surgical training and adds more challenges to the current training system for junior surgeons.

The traditional approach of "see one, do one, teach one" is rapidly being replaced with the more progressive concept of "learn the procedure before

the operating room." The internet, didactic teaching, three dimensional imaging and recently simulation training have allowed surgical trainees to become familiar with the surgical procedure before entering the operating theatre.

1.3 Alternatives for surgical skills training

There are several options available to learn surgical skills outside the operating theatre with each option having its own advantages and limitations. These options are: the use of cadaveric materials, animal models, synthetic bench models and virtual reality simulators.

1.3.1 Cadaveric material

A human cadaveric model has been described that offers realistic conditions for surgical skills training. In this model, antegrade arterial flow is established by pumping fluid into an inflow cannula placed in the descending aorta via the axillary artery and an outflow cannula in the superficial femoral artery, thus providing antegrade pulsatile flow. The cadaveric model allows full procedures to be performed including arterial puncture and closure, though preserved cadaveric tissue differs in feel and deformation from living tissue. Limited availability and high costs related to preservation and appropriate storage limit the potential use of human cadavers in different surgical fields such as endovascular intervention (McLachlan *et al.*, 2004).

1.3.2 Animal model

Animal models also offer a high degree of realism. However, the use of animal models is limited by expense, requirement for specialist facilities,

legal and ethical issues, as well as anatomical and size differences between animals and humans. Furthermore, the animals can only be used for one session. Despite these limitations, large animal models offer a highly realistic training option for different surgical training courses.

1.3.3 Synthetic bench model

Synthetic models range from low-fidelity solid plastic models to high-fidelity systems with pulsatile flow and fluoroscopy (Berry *et al.*, 2002; Chong *et al.*, 1998; Lermusiaux *et al.*, 2001). These models are relatively inexpensive and benefit from being portable and simple to set up. Low-fidelity simulation is an effective method of minimally invasive skills training (Rosser *et al.*, 1997) Bench model simulators cannot, however, fully replicate the dynamic behaviour of the human tissue. Advanced models such as carotid territory simulation are also limited by the effect of friction during passage of devices through curves (Suzuki *et al.*, 2005). These tabletop demonstrations are an essential early step in training, but for advanced skills training higher fidelity options such as animal models and virtual reality simulation may be needed.

1.3.4 Virtual reality simulator

Innovations in technology are influencing the whole spectrum of medicine. In surgical training, technological advancement for the development and refinement of surgical skills has come to the forefront in recent years (Gallagher *et al.*, 2005; Lake, 2005). Virtual environments and computer-based simulators are well established training tools in many fields such as aviation and the military (Ressler *et al.*, 1999; Rolfe and Staples, 1986). In the field of surgical skills training, simulation technology offers an opportunity

both to trainees and trainers to learn and teach surgical skills outside the operating room in a non-patient, stressless, pseudorealistic environment, with potential benefits for patient safety (Gould *et al.*, 2006).

Virtual reality training can replace the early part of the learning curve, which would otherwise be achieved in the clinical situation by practicing on live patients. Moreover, trainees can make mistakes without exposing the patients to any risk. Evidence suggests that enhanced surgical simulators have the potential to reduce the time and cost involved in training junior surgeons. Virtual reality training also appears to improve trainees' performances (Knoll *et al.*, 2005; Scott *et al.*, 2000; Testoni *et al.*, 2004). Furthermore, simulators offer their users sophisticated task-training exercises and they record errors, therefore simulation provides a way of measuring operative efficiency and performance. As such, it functions both as an educational tool and skills validation instrument (Stylopoulos *et al.*, 2004). For these reasons, simulation technology has been used in many medical fields such as in laparoscopy (Kothar *et al.*, 2002), endoscopy (Bloom *et al.*, 2003), trauma (Lee *et al.*, 2003) and endovascular surgery (Dayal *et al.*, 2004). The transfer of technical skills acquired by simulation-based training to the operative setting has also been described in the literature for laparoscopic cholecystectomy and colonoscopy/sigmoidoscopy (Sturm *et al.*, 2008).

There are disadvantages to virtual reality simulation. These devices represent a significant capital cost. Endovascular simulators for example cost approximately $200,000, with additional maintenance costs. The devices are still prone to technical failure and require regular calibration and

maintenance. Simulation-based training should be robust, structured and validated as a training tool for specific surgical procedures.

1.4 The concept of proficiency-based simulation training

The use of simulator-based training should be aimed at acquiring proficiency. It should not be restricted in duration or indeed to a fixed number of sessions (Darzi *et al.*, 1999). Trainees can practice a standardised procedure until they reach a certain benchmark level. This level is based on experts' procedure performance outcome and is defined as proficiency level. Proficiency level should be determined objectively using validated assessment instruments. Trainees should attain this level regardless of the amount of practice needed and time required before they are allowed to perform any procedure on a patient in an operative theatre or angiography suite.

The surgeons consulted to set the proficiency standards do not need to be the most gifted operators; rather they should form a representative sample of the proficient population. If the proficiency level is set too high, trainees will never reach it and if set too low, inferior skill sets will be produced (Gallagher *et al.*, 2005). Ideally, proficiency level would be set nationally or internationally.

Proficiency-based progression training enhances motivation and learning, thus maximizing skill acquisition and retention. Skill retention has been documented following proficiency-based progression training, with as high as 93% to 99% retention at 5 months for basic laparoscopic skills and 90% to 95% retention at 6 months for laparoscopic suturing (Stefanidis *et al.*, 2006a;

Stefanidis *et al.*, 2006b). Proficiency-based progression training also optimises the surgeons' learning experience and more importantly, it exposes patients to less risk during the trainees' learning curve. For these reasons, proficiency-based training is currently being embraced as the preferred method of training.

1.5 Assessment instruments for simulation training

In the past, the number of procedures performed by a surgical trainee and the duration of training have been used as crude measures of proficiency. The number of procedures performed does not reflect proficiency however, as someone might perform a procedure badly and repeatedly. Therefore, objective, continuous and validated assessment instruments should be used to set proficiency level and to assess trainees at the end of simulation and/or traditional training to ensure proficiency level has been reached. Furthermore, the use of such robust assessment instruments is essential when comparing between groups of trainees trained differently, such as when comparing simulation-trained trainees and no-simulation-trained trainees (controls) performing a certain surgical procedure on a patient. Moreover, validated assessment instruments can be used to assess surgical trainees at the end of a surgical skills training course to ensure that essential surgical technical skills have been acquired. Previous simulation-based studies have used global rating scales, procedural-specific checklists and objective machine output (such as total procedure time, fluoroscopy time and amount of contrast material used in endovascular simulators) as assessment tools (Chaer *et al.*, 2006; Dawson *et al.*, 2007; Van Herzeele *et al.*, 2008).

Other assessment instruments such as time-action analysis, error analysis and motion analysis have also been described in the literature.

1.5.1 Global rating scale

The surgical education group at the University of Toronto led by Richard Reznick (1993) was the first research group to attempt to assess technical skills in an objective and reproducible fashion. They developed the Objective Structured Assessment of Technical Skills (OSATS) global rating scale to assess performances on synthetic bench models (Reznick, 1993). The OSATS global rating scale is a quantitative assessment tool based on appraisal of seven aspects of quality in operative performance such as respect for tissue, knowledge of instruments and their handling, time and motion and the use of assistants (Reznick *et al.*, 1997). These seven items are common to all surgical procedures. Each of the seven items is scored using a Likert scale from 0 to 5. The OSATS has been widely used to assess surgical skills in different surgical procedures. Furthermore, a modified global scale has been shown to differentiate endovascular experience and training using a virtual reality simulator (Hislop *et al.*, 2006).

1.5.2 Procedure-specific checklist

Procedure-specific checklists used in conjunction with global rating scales have been shown to be effective and reliable tools in measuring surgical dexterity. These have been applied to synthetic and cadaveric models as well as in the live operating scenario (Anastakis *et al.*, 1999; Vassiliou *et al.*, 2005). A task-specific checklist delineates whether a trainees has or has not

performed an element of a specific procedure. A procedural checklist is unique to a specific procedure.

1.5.3 Virtual reality simulator

A major advantage of virtual reality simulation is the ability to automatically and instantly provide an objective performance report based on quantitative and qualitative assessment parameters. Used in a standardized setting, it is possible to distinguish between subjects of different levels of experience (Dayal *et al.*, 2004). Assessment of nontechnical skills such as appropriate drug administration and physiological monitoring is also possible with most of the current generation of simulators. For example SimSuite (Medical Simulation Corp) requires appropriate case selection and Angiomentor (Symbionix, Cleveland, OH) has advanced patient physiology reporting with the ability to administer a range of drugs including heparin, atropine, and glycerine trinitrate.

1.5.4 Other assessment instruments

Other forms of assessment instruments described are time-action analysis, error analysis and motion analysis. Time-action analysis has been used as a method of objective assessment of performance in open and minimally invasive surgery (Den Boer *et al.*, 1999; Minekus *et al.*, 2003; Ruurda *et al.*, 2004). The method can be applied to real life or simulator performance and involves breaking down the procedure into a series of steps with performance analyzed by how long an individual takes to complete each step (Bakker *et al.*, 2002; Den Boer *et al.*, 2001). This procedure is, however,

labour-intensive in terms of setup and video analysis time. In addition, the amount of time taken to complete an individual procedural step does not offer any measure of quality of performance.

Error analysis has been proposed to discriminate between levels of technical skills. It is possible to differentiate technical skill by examining both the frequency and type of errors committed during laparoscopic cholecystectomy (Sarker *et al.*, 2005; Tang *et al.*, 2004b) and pyloromyotomy (Tang *et al.*, 2004a). Patel *et al.* (2006) reported a reduction in the composite catheter-handling error scores of interventional cardiologists performing a virtual reality carotid angiogram following simulator training.

Motion analysis may offer a less time consuming option. Efficient and purposeful hand movements are a discriminator of technical skill in surgery (Bann *et al.*, 2003). The Imperial College Surgical Assessment device (ICSAD) has been used to track hand movement in three dimensions using electromagnetic sensors. It produces a composite score based on economy of movement and qualitative analysis (Datta *et al.*, 2001).

Whatever assessment instrument is used, its value or effectiveness must be assessed. Table 1.1 lists the qualities of the ideal assessment instrument (Aggarwal *et al.*, 2007a). The achievement of a robust and validated training assessment tool in the development of any simulator-based training is an essential component of the training process.

Table 1.1 Qualities of the ideal surgical assessment tool (Aggarwal *et al.*, 2007a)

Feasibility	is a measure of whether something is capable of being done or carried out
Validity	
Face validity	is the extent to which the examination resembles real life situations
Content validity	is the extent to which the domain that is being measured is measured by the assessment tool—for example, while trying to assess technical skills we may actually be testing knowledge
Construct validity	is the extent to which a test measures the trait that it purports to measure. One inference of construct validity is the extent to which a test discriminates between various levels of expertise
Concurrent validity	is the extent to which the results of the assessment tool correlate with the gold standard for that domain
Predictive validity	is the ability of the examination to predict future performance
Reliability	
Test-retest	is a measure of a test to generate similar results when applied at two different points
Inter-rater	is a measure of the extent of agreement between two or more observers when rating the performance of an individual

1.6 Simulation training for endovascular intervention

Catheter-based interventions have brought huge changes to the management of peripheral vascular disease. Compared to open surgery, the endovascular treatment of vascular disease is associated with reduced pain, smaller scars, faster recovery and reduced mortality (Greenhalgh *et al.*, 2005). This has led to increased interest in endovascular training for vascular surgeons (Messina *et al.*, 2002). However, the introduction of catheter-based interventions poses technical challenges to inexperienced trainees and trainers. Interventionalists need to know how to manipulate an endovascular instrument (guidewire or angiographic catheter) within a three dimensional field while viewing it on a two dimensional screen (Aggarwal *et al.*, 2006). This basic concept also applies to laparoscopic and endoscopic interventions (Aggarwal *et al.*, 2004). In addition, interventionalists need to deal with reduced tactile feedback and the increased need for hand–eye coordination (Patel *et al.*, 2006). Furthermore, they need to predict guidewire-lesion interaction, understand the behaviour of the guidewire and catheter combination and learn the limits of each technique. There are relatively few experts worldwide for newer techniques such as carotid artery stenting (CAS), which leads to difficulties in developing structured training programmes. As a result of the expansion of diagnostic and therapeutic endovascular intervention, there is a need to address the specific issue of endovascular skills training and to establish an endovascular training curriculum to reach proficiency level.

Endovascular simulation has been available for approximately a decade and the technology is evolving rapidly. Several endovascular virtual reality

simulators are commercially available including SimSuite (Medical Simulation Corporation, Denver, Colorado), Procedius Vascular Intervention System Training (VIST) simulator (Mentice AB, Göteborg, Sweden) and the ANGIO Mentor (Simbionix, Cleveland, Ohio). These are all classified as high-fidelity simulators as they include haptic, aural and visual interfaces and provide a realistic representation of the procedure. They provide a variety of training modules including angioplasty and stenting of renal, coronary, iliac and femoral vessels.

Endovascular simulation provides a surgical environment similar to that in an operative theatre or angiography suite. A trainee can practice performing a procedure with the simulator and his/her performance can be recorded. Thereafter, the device software provides results and feedback regarding trainee performance efficiency, procedure outcome and timing. Furthermore, trainee performance can be observed by an expert who can provide direct feedback to the trainee. Video recordings of his/her performance can be used by the trainee as teaching feedback. Endovascular simulation enables novices to learn basic guidewire and angiographic catheter handling skills and enables experts to rehearse new procedures in the skills laboratory prior to intervention on a patient.

Many studies have demonstrated that virtual reality training in endovascular interventions using the VIST (Vascular Intervention Simulation Trainer) simulator is valid, feasible and acceptable (Aggarwal *et al.*, 2006; Dawson *et al.*, 2007; Dayal *et al.*, 2004; Hsu *et al.*, 2004; Van Herzeele *et al.*, 2008). Dayal *et al.* (2004) demonstrated improved simulated performance of a Carotid artery stenting (CAS) procedure by novice subjects in terms of

procedure time, fluoroscopy time, and supervisor assessment of catheter handling following a minimum of 2 hours of supervised training on the VIST simulator. Expert subjects (>300 endovascular procedures) did not show any statistically significant improvement following training. Hsu *et al.* (2004) performed a randomized study in which both novice and expert subjects (>50 endovascular procedures) were randomized to receive supervised simulator-based CAS training or no training. Significant improvement in procedure completion time was reported in the simulator trained group, in both novice and expert subjects. Aggarwal *et al.* (2006) analyzed the learning curves of experienced open vascular surgeons and demonstrated improved performance (procedure time and contrast fluid used) following virtual reality simulator training using a renal artery stenting model. Since the use of simulators in the training of endovascular intervention, only one randomized study had a clinical application. Chaer *et al.* (2006) conducted the first randomized study examining the transfer of simulation-based endovascular skills training to the clinical environment. In the study, twenty surgical residents with similar demographic background and visiospatial scores were randomized into 2 groups. One group received simulation-based training and the other group received no simulation training. All trainees had no past experience in endovascular intervention. Thereafter, each trainee performed two consultant-supervised, clinical cases of lower limb occlusive disease angioplasty within 2 weeks of training. Trainees where assessed using a procedure-specific checklist and a previously validated global scale (Reznick *et al.*, 1997). The author found that simulation-trained candidates scored higher than the control group in both clinical cases. In the study, simulation

training was not allowed to exceed 2 hours, lesions treated were different among trainees as they included a variety of iliac, femoral and popliteal stenoses or occlusions and the procedure checklist used was not validated. All simulation-based endovascular studies performed to date restricted their candidates' simulator training in either time or number of sessions.

1.7 Simulation training for open vascular surgery

To date, several studies have demonstrated the effectiveness of different bench model vascular surgery simulators as assessment tools by distinguishing between surgeons of differing levels of experience either in a laboratory (Black *et al.*, 2007; Datta *et al.*, 2006; Datta *et al.*, 2004; Munz *et al.*, 2004; Pandey *et al.*, 2006; Wilasrusmee *et al.*, 2007) or in a simulated operative theatre (Black *et al.*, 2010; Moorthy *et al.*, 2005; Moorthy *et al.*, 2006). Little has been described in the literature with regard to the use of bench model simulators in the training of basic vascular surgery technical skills (Bath *et al.*, 2011; Sidhu *et al.*, 2007). All bench model simulation-based training studies restricted their simulation training in either number of sessions or duration.

Another important question in bench model simulation training is whether this type of training impacts the acquisition of technical skills by surgical trainees. Surgical performance as measured on a bench model of surgery has been shown to correlate with actual technical ability in the operating theatre -- so-called predictive validity (Datta *et al.*, 2004; Wilasrusmee *et al.*, 2007). Furthermore, performance on a bench model has been shown to transfer to both human cadaveric and live animal operating models (Anastakis *et al.*,

1999). However, the ultimate test of simulation is to demonstrate that performance after simulation training improves in the operative theatre.

1.8 Summary

The traditional form of surgical skills training and recent changes in health care have created challenges in keeping up the standards in skills training of future surgeons. Structured simulation training to proficiency level might help tackle these challenges.

This thesis will explore the design of proficiency-based vascular surgery simulation training in both endovascular intervention (superficial femoral artery angioplasty) and open vascular surgery (saphenofemoral junction dissection). It will study the transfer of basic endovascular and open vascular surgery technical skills after proficiency-based simulation training to the interventional suite and operating room respectively. The incorporation of simulators into vascular surgery skills training programs will be discussed and we will suggest further avenues of exploration.

Chapter Two: Materials and Methods

2.1 Objectives

To design a proficiency-based vascular surgery simulation training curriculum in endovascular intervention (superficial femoral artery angioplasty) and open vascular surgery (saphenofemoral junction dissection), four studies were performed.

In the first study, a procedure-specific checklist for superficial femoral artery angioplasty (SFA) was developed and validated. In the second study, the impact of an assistant on the technical skills of the primary operator performing SFA angioplasties was assessed. The first and the second studies were essential to design a proficiency-based simulation training curriculum for SFA angioplasty and to study the transfer of endovascular technical skills after proficiency-based simulation training to the interventional suite (third study). The fourth study describes the transfer of basic open vascular surgery technical skills after proficiency-based simulation training in saphenofemoral junction (SFJ) dissection to the operating theatre. This chapter will describe the materials and methods used in each of the four studies.

2.2 Development and assessment of a procedure-specific checklist for superficial femoral artery angioplasty using an endovascular simulator

2.2.1 Development of a preliminary procedure-specific checklist for superficial femoral artery angioplasty

In early 2010, two consultants in interventional radiology and one consultant in vascular surgery established the essential steps to perform an antegrade SFA angioplasty, excluding the steps required to gain arterial access. This list of essential steps was based on 20 years' collective experience in performing SFA angioplasty. This resulted in a preliminary 28-item procedure-specific checklist. Table 2.1 lists the items in the preliminary checklist.

Table 2.1. List of the items in the preliminary procedure-specific checklist for SFA angioplasty

Task description
1. Check patient history with regard to anticoagulation, claudication, duration of symptoms etc.
2. Check pre-procedure imaging (ex: MRA, CTA, Duplex).
3. Choose appropriate initial guidewire.
4. Prepare initial guidewire (ex: wet guidewire with heparine-saline solution).
5. Insert guidewire to appropriate level with appropriate care for obstruction/vessel trauma.
6. Choose appropriate working catheter.
7. Prepare working catheter (ex: flush catheter with heparanised saline).
8. Feed working catheter over guidewire to appropriate level: catheter does not pass beyond tip of wire.
9. Withdraw initial guidewire leaving working catheter in place.
10. Inject contrast material to outline lesion (roadmap should be taken at this time) and define the extent of the lesion using roadmap.
11. Choose appropriate guidewire to cross lesion.
12. Prepare guidewire for use.
13. Insert guidewire through working catheter. Use roadmap to help cross the lesion and avoid subintimal disection. Cross lesion.
14. Manipulate working catheter to be positioned distal to lesion.
15. Exchange crossing guidewire with working guidewire.

16. Make sure guidewire does not travel into crural arteries or side branches of popliteal.
17. Give 50 to 75 units/kg of Heparin.
18. Withdraw working catheter leaving guidewire in place.
19. Choose appropriate balloon size for angioplasty.
20. Prepare balloon catheter.
21. Insert balloon catheter across lesion making sure guidewire does not travel distally.
22. Inflate balloon by mechanical inflation device.
23. Use fluroscopy guidance while performing balloon angioplasty.
24. Decompress balloon fully with 20cc syringe.
25. Remove balloon over guidewire leaving guidewire in place.
26. Inject contrast material to check lesion post angioplasty.
27. Check run-off post angioplasty.
28. Remove instruments under fluroscopy guidance.

2.2.2 Content validity of the developed checklist: A modified Delphi process

A modified Delphi method was then used to validate the contents of the checklist. This method is designed to achieve consensus among experts on critical decisions (Clayton, 1997). In brief, a principal investigator runs the study by administering repeated survey rounds to a panel of experts who are blinded to each other's identity. This enhances group decision-making by eliminating individual influence (RAND Science and Technology Policy Institute, 2001). In the first round, experts are asked to answer specific questions and give feedback. The experts' input is then analysed and the checklist modified accordingly by the principal investigator who conducts a second round for further comments and feedback. Several rounds are conducted until a consensus is reached among the panel.

In this study, five consultants in interventional radiology based in Europe were approached by e-mail. An invitation letter was sent to each expert individually. An expert was defined as a radiology/vascular surgeon consultant who has performed a minimum of two hundred SFA angioplasties in the past five years. After obtaining the experts' agreement for their participation in the study, the preliminary 28-item checklist was sent to each individual from the panel. The experts did not know each other's identity.

Experts were asked to score each item based on a 1 to 9 Likert-like score as follows:

- Score 1-3 if you think the item is not important and should be eliminated from the checklist.

- Score 4-6 if you think the item is important and should be part of the checklist.
- Score 7-9 if you think the item is critically important and should be part of the checklist.

Experts were also invited to change the text freely and give feedback. Consensus among the panel of experts was reached after the second round of the survey.

After the first round of the modified Delphi study, the mean score of each item was calculated. Items with a mean score equal to or less than 3 were eliminated, text revisions were made and feedback was analysed. The revised checklist was sent again to the panel and consensus was reached after the second round. The internal consistency coefficient (Cronbach alpha) of the items and the experts was also calculated after each round of the survey. Cronbach's alpha will generally increase as the intercorrelations among test items increase, and is thus known as an internal consistency estimate of reliability of test scores. Cronbach's alpha is widely believed to indirectly indicate the degree to which a set of items measures the same construct. A reliability of 0.7 or higher is considered as statistical significance.

2.2.3 Construct validity of the developed checklist: A comparison between experts' and medical students' technical performance on the Vascular Intervention Simulation Trainer (VIST) simulator

2.2.3.1 Simulation device

The VIST was specifically designed as a virtual reality simulator for training in endovascular interventional procedures. The VIST device simulates the procedure exactly as it is performed on a live patient with the full vascular anatomy created from patient-specific digital data. A procedure performed on the VIST simulator can therefore be assessed and measured accurately and reliably. The VIST simulator has been used in the assessment and training of surgical trainees in previous studies (Chaer *et al.*, 2006; Van Herzeele *et al.*, 2008). In addition, face and construct validity of this machine has been described in the literature (Dayal *et al.*, 2004).

The Procedicus VIST simulator is based on a dual processor (2 x 2.8 GHz processor), Pentium IV computer running Windows Microsoft XP Professional with 1 GB RAM, a 40-GB hard disk drive, a GeForce FX5200 128MB graphics card, and two 17-inch flat-panel monitors (Fig. 2.1). The interface and the actual devices used in the real procedure (catheters, wires, stents, and so on) are linked to the virtual reality simulator through a proprietary full physics software package that then generates the fluoroscopic display. The simulation interface device is designed to sense the simultaneous translation and rotation of three co-axial tools (clinical tools), the flow of air from a syringe that shows as a contrast injection on the display, pressure by fluid compressed with an indeflator, and operation of a foot switch for fluoroscopy and cine-angiography. Output of the device to the user is the application of force and torque on each of the tools on the basis of the calculations of the simulator for the full physics vascular anatomy simulated.

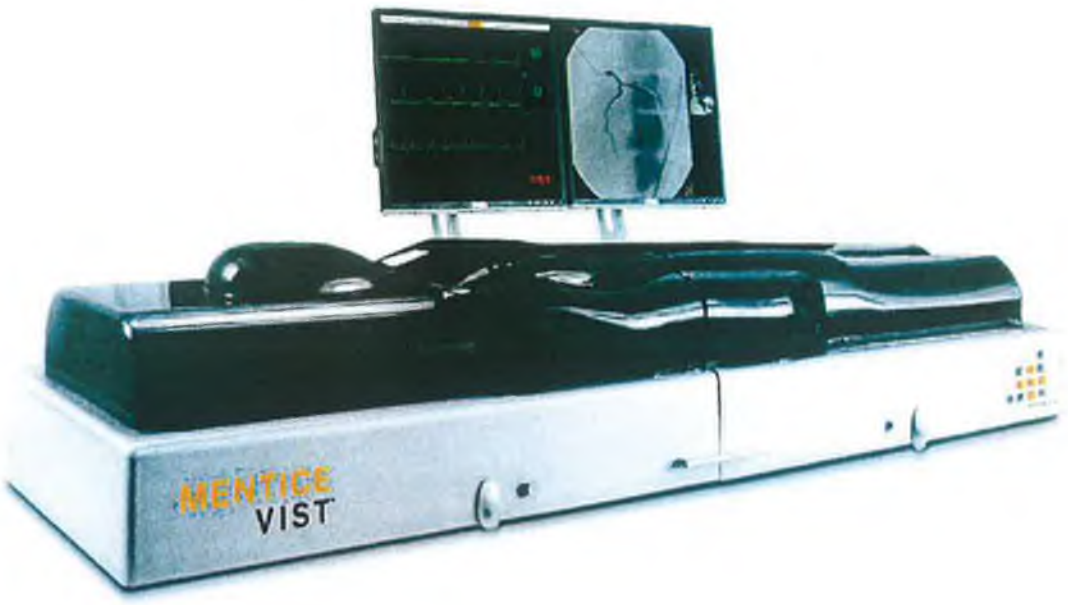

Figure 2.1 The Procedicus Vascular Interventional System Trainer virtual reality simulator (Mentice AB, Gothenburg, Sweden).

The forces applied to the clinical tools are sensed by strain gauge sensors, fitted between a cart base and a suspended mechanism that is locked on the tool. The resolution of the force measurement system is 0.025 N. The calibration of the sensor is performed dynamically (in real time), and the offset error is lower than 0.025 N. The span of the force measurement is ±2.5 N. Within this range, the forces in the force feedback loop are controlled in a closed loop. The force feedback range is (theoretically) ±30 N, and after 2.5 N, the forces are controlled in an open loop.

The translational position is measured with an optical encoder that, in combination with the transmission system, gives a resolution of 0.11 mm. The rotational angle is measured with an optical encoder that, in combination with the gear ratio to the locking device, gives a resolution of 7.9 to 31.4 milliradians (depending on the cart). The tool diameters are measured with

an infrared optical sensor that gives a resolution of 0.02 mm and has a precision of about ±15%. The algorithms that calculate the diameter calibrate the parameter settings in real time, to avoid drifting. The measurement span is between 0.1 and 3.0 mm.

All testing described below was performed in a quiet room with a table height of approximately 100 cm and the monitor position at eye level, simulating the catheterization laboratory environment.

2.2.3.2 Study design

To test the checklist, four experts in endovascular intervention and 11 final-year medical students were invited to the simulation laboratory in the Royal College of Surgeons in Ireland (RCSI) individually. After reading the subject information leaflet and signing a consent form, each expert/student was asked to perform two antegrade SFA angioplasties on the VIST simulator (trial 1 and trial 2). Performing an arterial access was not part of the procedure. Students had one demonstration on how to perform the procedure before they were asked to do the angioplasty. The steps to perform the procedure were attached in front of the operator and an assistant was available. Two video cameras were used to record each procedure. One video camera recorded the screen and the other recorded the hands of the operator. To hide the identity of the operator, video cameras were muted and each operator was asked to wear surgical gloves. It was not possible to identify the operators from the video recording. The video recordings from trial 1 and trial 2 were assessed by another expert who was blinded to the operators' identity, using the developed checklist and a global rating scale

adapted from a previously validated scoring system (Table 2.2) (Chaer *et al.*, 2006; Reznick *et al.*, 1997).

Table 2.2 Global rating scale of endovascular performance.

Name: Date:

Attending: Procedure:

0	1	2	3	4
1. Time and motion				
Many unnecessary moves		Efficient time/motion; some unnecessary moves		Clear economy of motion; maximum efficiency
2. Wire and catheter handling				
Repeatedly makes awkward, tentative moves; inappropriate use		Competent use; occasionally stiff or awkward		Fluid moves; no awkwardness
3. Awareness of wire position				
Seldom aware of wire position		Mostly aware; occasionally unaware of position		Always aware of wire position
4. Maintenance of wire stability				
Rarely maintaines wire stability; loses wire access		Wire usually stable; occasionally forward/backward motion		Wire always stable; no loss of wire access

5. Awareness of fluoroscopy usage		
Excessive use of fluoro	Appropriate use; some unnecessary use	Economy of fluoro; maximum efficiency
6. Precision of wire/catheter technique		
Imprecise technique; frequent overshooting	precise technique; occasional overshooting	Perfect precise technique
7. Flow of operation		
Frequently stopped; seemed unaware of next move	Some forward planning; reasonable progression of procedure	Obviously planned course; effortless flow
8. Knowledge of procedure		
Deficient Knowledge	Knew all important steps of procedure	Familiar of all aspects of procedure
9. Quality of final product		
Very poor	Acceptable	Clearly superior
10. Ability to complete the case		
Not able to complete case	Able to complete case with assistance	Able to complete case independently

11. Need for verbal prompts Repeatedly needed prompts	Needed prompts sometimes	Able to complete the case without prompts
12. Attending takeover Occurred at every stage	Occurred during some portions of the procedure	Able to complete the case without attending takeover

Each item was rated between 0 and 4 when using the procedure-specific checklist (Scale: 0=Fail; 1=Success, not very good; 2=Success, good; 3=Success, very good; 4=Success, excellent). Rating was based on the ability to perform the individual steps efficiently from a technical and a result aspect. The maximum score that could be given using the checklist was 96. The global rating scale had a similar scoring system for 12 items with a maximum score of 48.

2.2.3.3 Statistical Methods

The results generated from both assessment tools (the procedure-specific checklist and the global rating scale) were entered into a database and subsequently analysed using the SPSS 15 software supplier. Considering the nature of the data (the results showed a parametric distribution), independent sample t test was performed to test for statistically significant changes. All values were represented as mean ± SD and mean differences were considered significant for a *P* value of less than 0.05. A Pearson correlation analysis was used to measure the correlation between the procedure-specific checklist and the global rating scale. Cronbach's alpha was used to assess the reliability of the procedure-specific checklist.

The RCSI Ethics Committee approved the study protocol in advance.

2.3 Impact of an assistant on the technical skills of the primary operator in superficial femoral artery angioplasty

2.3.1 Study design

Eight experts in peripheral endovascular intervention were invited to the simulation laboratory in the RCSI individually. For this study, an expert was defined as an interventional radiologist or a vascular surgeon who has performed at least 200 SFA angioplasties in the past 5 years. After reading the subject information sheet and signing a consent form, each expert was assigned randomly to performing two antegrade SFA angioplasties (procedure 1 and procedure 2) with an assistant (assistant group) (n=4) or no assistant (control group) (n = 4) on the VIST simulator. The same assistant (a research fellow in endovascular intervention) was available to all four experts in the assistant group. Experts in the control group had no assistant available.

In the first study described earlier, twenty eight steps to perform antegrade SFA angioplasty were identified (Table 2.1, page 22). Performing an arterial access was not part of the procedure. Procedural steps were attached in front of each operator and experts were asked to adhere to the steps strictly.

Each expert was asked to wear surgical gloves. Two video cameras recorded the performance of each expert. One camera recorded the fluoroscopy screen and the other camera recorded the operator's hands. To hide the identity of the operators, video cameras were muted. One expert from the assistant group assessed the video recording from procedure 1 and procedure 2 of the controls, and one expert from the control group assessed

the video recording from procedure 1 and procedure 2 of the experts in the assistant group. Assessing experts were blinded to each other's identity and to the identity of the experts in the video recording. The assessors rated the performance of the experts using a previously validated procedure-specific checklist for SFA angioplasty (Table 2.3) (methods to establish content and construct validity are described earlier under section 2.2, page 21 and results and discussion of the validating studies are described in chapter 3 page 54) and a validated global rating scale adapted from a previously validated scoring system (Table 2.2, page 30) (Chaer *et al.*, 2006; Reznick *et al.*, 1997). In addition, objective parameters from the VIST simulator were compared in the two groups. These parameters were total procedure time, fluoroscopy time, amount of contrast material used and accuracy of balloon angioplasty (the distance difference between the midpoint of the balloon used and the midpoint of the lesion to be treated).

Table 2.3. Procedure-specific checklist for SFA angioplasty

Examiner Checklist for Superficial Femoral Artery Angioplasty

Candidate Name: Date:

Examiner Name: Session:

Scale: 0=Fail 1=Success, not very good 2=Success, good 3=Success, very good 4=Success, excellent

Task description	Scale
1. Check patient history with regard to anticoagulation, claudication, duration of symptoms etc.	0 1 2 3 4
2. Check pre-procedure imaging (ex: MRA, CTA, Duplex).	0 1 2 3 4
3. Choose appropriate initial guidewire.	0 1 2 3 4
4. Insert guidewire to appropriate level with appropriate care for obstruction / vessel trauma.	0 1 2 3 4
5. Choose appropriate working catheter.	0 1 2 3 4
6. Prepare working catheter (ex: flush catheter with heparanised saline).	0 1 2 3 4
7. Feed working catheter over guidewire to appropriate level: catheter does not pass beyond tip of wire.	0 1 2 3 4
8. Inject contrast material to outline lesion (roadmap should be taken at this time) and define the extent of the lesion using roadmap.	0 1 2 3 4
9. Choose appropriate guidewire to cross lesion.	0 1 2 3 4

10. Prepare guidewire for use.	0 1 2 3 4
11. Insert guidewire through working catheter. Use roadmap to help cross the lesion and avoid subintimal disection. Cross lesion.	0 1 2 3 4
12. Manipulate working catheter to be positioned distal to lesion.	0 1 2 3 4
13. Exchange crossing guidewire with working guidewire.	0 1 2 3 4
14. Make sure guidewire does not travel into crural arteries or side branches of popliteal.	0 1 2 3 4
15. Give 50 to 75 units/kg of Heparin.	0 1 2 3 4
16. Withdraw working catheter leaving guidewire in place.	0 1 2 3 4
17. Choose appropriate balloon size for angioplasty.	0 1 2 3 4
18. Insert balloon catheter across lesion making sure guidewire does not travel distally.	0 1 2 3 4
19. Inflate balloon by mechanical inflation device.	0 1 2 3 4
20. Use fluroscopy guidance while performing balloon angioplasty.	0 1 2 3 4
21. Decompress balloon fully with 20cc syringe.	0 1 2 3 4
22. Remove balloon over guidewire leaving guidewire in place.	0 1 2 3 4
23. Inject contrast material to check lesion post angioplasty.	0 1 2 3 4
24. Check run-off post angioplasty.	0 1 2 3 4

Each item in the procedure-specific checklist was rated between 0 and 4 (Scale: 0=Fail; 1=Success, not very good; 2=Success, good; 3=Success, very good; 4=Success, excellent). Rating was based on the ability to perform the individual steps efficiently from a technical and a result aspect. The maximum score that could be given using the checklist was 96. The global rating scale had a similar scoring system for 12 items with a maximum score of 48.

2.3.2 Statistical Methods

The results generated from both assessment tools (the procedure-specific checklist and the global rating scale) were entered into a database and subsequently analysed using the SPSS 15 software supplier. Considering the nature of the data (the results showed a parametric distribution), an independent sample t test was performed to test for statistically significant changes. All values were represented as mean ± SD and mean differences were considered significant for a *P* value of less than 0.05. A Pearson correlation analysis was used to measure the correlation between the procedure-specific checklist and the global rating scale.

The RCSI Ethics Committee approved the study protocol in advance.

2.4 Skills transfer after proficiency-based simulation training in superficial femoral artery angioplasty

2.4.1 Study design

Ten first-year general surgical registrars with no prior exposure to endovascular intervention were invited to the simulation laboratory in the RCSI individually. After reading a subject information leaflet and signing a consent form, each registrar received didactic teaching in the basic endovascular skills required to perform TransAtlantic interSociety Consensus (TASC) A (short stenosis, <3cm) antegrade SFA angioplasty. In the first study described earlier, twenty eight steps to perform antegrade SFA angioplasty were identified (Table 2.1, page 22). Performing and closing an arterial access were not part of the procedure. Didactic teaching involved a PowerPoint presentation and videos on the 28 steps to perform antegrade SFA angioplasty. Videos consisted of recordings of the fluoroscopy screen and the hands of an interventional radiologist consultant performing antegrade SFA angioplasty on the VIST simulator and a real patient. Each trainee received specific information on choosing, preparing and manipulating different guidewires and catheters and on the use of contrast material and fluoroscopy. Didactic teaching was delivered by the same research fellow in endovascular simulation training on a one-to-one basis for the duration of one hour.

After didactic training, each trainee was blindly randomised using a sealed envelope to either receiving additional training on the VIST endovascular

simulator on a TASC A antegrade SFA angioplasty model to proficiency (simulation group) (n=5) or no additional training (control group) (n=5).

Proficiency level was determined from the first study described earlier. In that study, eleven novices (final-year medical students) and four experts (radiology/vascular surgeon consultant who has performed a minimum of 200 SFA angioplasties in the past five years) performed two antegrade SFA angioplasties each on the VIST simulator (Trial 1 and Trial 2) to validate the construct of a procedural checklist for SFA angioplasty (section 2.2.3.2, page 28). As there were improvement in the total time and fluoroscopy usage between the first and the second trial for the experts and the novices which represented time to become familiar with the simulator device (chapter 3, page 70), we considered the average score in the procedural checklist, global rating scale and objective simulator parameters (total procedure time, fluoroscopy time, amount of contrast material used, accuracy of balloon angioplasty and percentage of lesion covered) of the 4 experts in the second trial to represent proficiency level (Table 2.4). The endpoint of simulation training for the 5 trainees was acquiring proficiency in two consecutive TASC A antegrade SFA angioplasties on the VIST simulator. Proficiency-based simulation training was not restricted to time or number of sessions. The same research fellow trained each of the surgical registrars on the VIST simulator on a one-to-one basis. The 28 steps to perform the procedure were attached in front of the operator and an assistant was available. All 5 simulation-based trained trainees acquired proficiency eventually.

Table 2.4. Proficiency level for SFA angioplasty on the VIST simulator

Parameters	Proficiency level
1. Total procedure time	504 s
2. Fluoroscopy time	203.25 s
3. Amount of contrast material used	7.65 cc
4. Accuracy of balloon angioplasty[a]	3.25 mm
5. Percentage of lesion covered	100 %
6. Global rating scale	47.75
7. Procedure-specific checklist	95.25

a. The distance difference between the midpoint of the balloon used and the midpoint of the lesion to be treated

All ten trainees then performed one SFA angioplasty in an interventional suite within five days of didactic only/didactic and simulation training. All clinical cases were TASC A antegrade SFA angioplasties comparable to procedures viewed during didactic/simulation training. Before their procedures, each patient was provided with an information leaflet and signed a consent form. The 28 steps to perform the procedure were attached in front of the operator and an assistant was available. Performing and closing an arterial access were not part of the study and were performed by a consultant in interventional radiology.

One consultant in interventional radiology supervised each trainee performing the procedure. The same consultant supervised the ten trainees and was blinded to the training status of the surgical registrars. After the end of the procedure, the supervising consultant scored each trainee using a procedure-specific checklist for SFA angioplasty (table 2.3, page 36) (methods to establish content and construct validity were described earlier under section 2.2, page 21 and results and discussion of the validating studies are described in chapter 3 page 54) and a validated global rating scale adapted from a previously validated scoring system (Table 2.2, page 30). The procedural checklist reflects the steps required to perform the procedure excluding the arterial access. The global rating scale used reflects the overall endovascular skills performance and is not specific to the procedure performed. It has been adapted from a previously validated scoring system (Chaer *et al.*, 2006; Reznick *et al.*, 1997).

Each item was rated between 0 and 4 when using the procedure-specific checklist (Scale: 0=Fail; 1=Success, not very good; 2=Success, good;

3=Success, very good; 4=Success, excellent). Rating was based on the ability to perform the individual steps efficiently from a technical and a result aspect. The maximum score that could be given using the checklist was 96. The global rating scale had a similar scoring system for 12 items with a maximum score of 48. Performance of the two groups of trainees was studied and compared.

2.4.2 Statistical Methods

The results generated from both assessment tools (the procedure-specific checklist and the global rating scale) were entered into a database and subsequently analysed using the SPSS 18 software supplier. Considering the nature of the data (the results showed a parametric distribution), an independent sample t test was performed to test for statistically significant changes. All values were represented as mean ± SD and mean differences were considered significant for a *P* value of less than 0.05. A Pearson correlation analysis was used to measure the correlation between the procedure-specific checklist and the global rating scale.

The RCSI Ethics Committee and the Beaumont Hospital Ethics Committee approved the study protocol in advance.

2.5 Skills transfer after proficiency-based bench model simulation training in saphenofemoral junction dissection

2.5.1 Simulation model

To study skills transfer after bench-model simulation training, saphenofemoral junction (SFJ) ligation was selected, as it is an operation that is regularly performed by most surgeons at all levels of experience in general and vascular surgery. The model was a newly developed synthetic model (Limbs & Things, Bristol, UK) (Fig. 2.2) depicting the human SFJ and its tributaries. This model allows incision of the skin and dissection through the superficial fatty and deeper fascial layers. Once beyond the fascial layer, the surgeon has to identify the fluid-filled long saphenous vein with its four groin tributaries, divide the tributaries, and then perform a saphenofemoral disconnection. Use of a synthetic model allows for standardization of the tasks. This bench model simulator has been described and used in the assessment and training of surgical trainees in previous studies (Datta *et al.*, 2006; Datta *et al.*, 2004; Moorthy *et al.*, 2005; Moorthy *et al.*, 2006; Pandey *et al.*, 2006). In addition, face, construct and concurrent validity of this model has been described in the literature (Datta *et al.*, 2004).

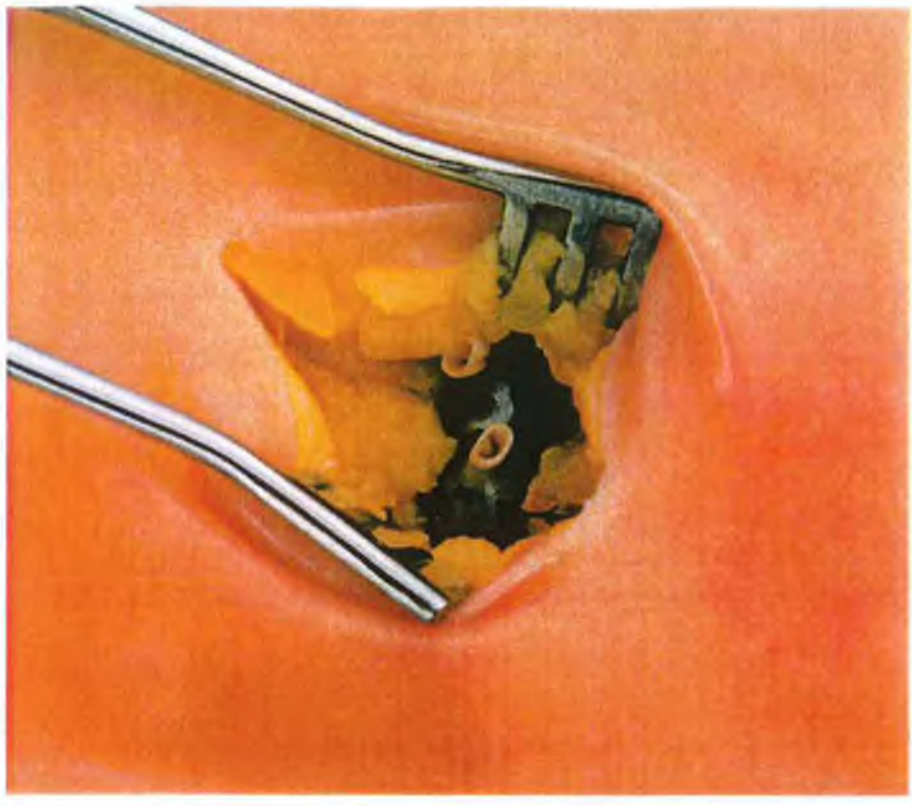

Figure 2.2. Saphenofemoral junction groin model (Limbs & Things, Bristol,UK). Tissue consists of silicone with latex fluid-filled vessels.

2.5.2 Study design

Twelve basic surgical trainees (equivalent to PGY 1 and 2) with no prior exposure to varicose vein surgery were invited to the simulation laboratory in the RCSI individually. After reading a subject information leaflet and signing a consent form, each trainee received didactic teaching in the basic surgical skills required to perform SFJ dissection. A previous study identified seven operative components for SFJ dissection (Table 2.5) (Pandey *et al.*, 2006). In this study we used the same seven domains with a slight modification in two domains: the use of Ligaclips instead of knot tying when dividing the tributaries, and transfixion of the SFJ in place of flush ligation.

Table 2.5. Operative components for saphenofemoral junction dissection (Pandey *et al.*, 2006)

Operative component	Proficiency
1. Incision	Use surface landmarks to make an appropriately located and sized incision. Handled scalpel expertly.
2. Dissection	Superior and atraumatic dissection into the correct anatomical plane. Confident handling of instruments whilst dissection.
3. Retraction	Excellent use of retractors. Allowed good visualization of all necessary structures. Atraumatic.
4. Tributaries	Identified all known tributaries. Sought other possible tributaries.
5. Haemostasis	Superior ligaclip. Atraumatic. No clip slipping.
6. SFJ Clearance	Identified the SFJ. Expert dissection of tissues off the vessels. Atraumatic. Cleared well proximally and distally.
7. SFJ Transfixion	Excellent safe and secure transfixion of the SFJ.

Didactic teaching involved a PowerPoint presentation and videos on the essential steps to perform SFJ dissection. Videos consisted of recordings of the hands of a vascular surgeon consultant performing SFJ dissection on the plastic bench model simulator and on a real patient. Each trainee was instructed on choosing and manipulating different instruments and the use of diathermy and suture material. Didactic teaching was delivered by a research fellow in surgical simulation training on a one-to-one basis for a duration of one hour.

After didactic teaching, each trainee was blindly randomised using a sealed envelope to either receiving additional training on the plastic bench model simulator on SFJ dissection to proficiency level (simulation group) (n=6) or no additional training (control group) (n=6). Proficiency level was defined as the independent completion of the procedure by the trainee with efficiency in all steps. Table 2.5 (page 46) describes proficiency in each of the 7 surgical domains of SFJ dissection. The endpoint of simulation training for the 6 trainees was acquiring proficiency in 2 consecutive SFJ dissections on the bench model simulator. Proficiency-based simulation training was not restricted in duration or number of sessions. The same research fellow trained each of the surgical trainees on the plastic simulator on a one-to-one basis. All 6 simulation-based trainees acquired proficiency eventually.

All twelve trainees then performed one SFJ dissection in an operative theatre within five days of didactic only/didactic and simulation training. To attempt to standardize the live operating assessment conditions for each of the trainees, only patients undergoing day surgery were considered for the study. Moreover, all clinical cases concerned primary varicose veins with no

complications such as phlebitis, lipodermatosclerosis, or ulceration. Before undergoing the procedure, each patient was provided with an information leaflet and signed a consent form. A vascular surgeon consultant supervised and assisted each trainee performing the procedure. The same consultant supervised the twelve trainees and was blinded to the training status of the surgical trainees. After the end of the procedure, the supervising consultant scored each trainee using the Imperial College Evaluation of Procedure-Specific Skill (ICEPS) procedure-specific rating scale (Table 2.6) (Moorthy *et al.*, 2005; Pandey *et al.*, 2006) and the Objective Structured Assessment of Technical Skill (OSATS) global rating scale (Table 2.7) (Martin *et al.*, 1997; Reznick *et al.*, 1997). Both rating scales have been previously validated. The ICEPS consists of the 7 domains specific for SFJ dissection. The OSATS consists of 7 items which reflect the overall basic surgical skills performance and is not specific to the procedure performed. Performance of the 2 groups of trainees was studied and compared.

Table 2.6. Imperial College Evaluation of Procedure-Specific Skill (ICEPS) rating scale for saphenofemoral junction ligation. Descriptive comments at anchoring points aid marking.

Candidate Name: Date:

Examiner Name: Session:

1	2	3	4	5
1. Incision				
Does not use surface landmarks. Inappropriate placement of incision. Poor handling of scalpel		Appropriate incision in terms of location and size. Looked at ease with scalpel		Handled scalpel expertly
2. Dissection				
Appeared unsure and excessively hesitant while dissecting. Caused trauma to tissues. Did not dissect anatomic plane		Controlled and safe dissection into the correct anatomic plane. Caused minimal trauma of tissues.		Superior and atraumatic dissection into the correct anatomic plane.
3. Retraction				
Clumsy use of retractors. Did not allow visualization of important structures		Good use of retractors allowing visualization of important structures.		Excellent use of retractors. Allowed good visualization of all structures.

4. Tributaries		
Could not or did not try to identify any tributaries	Identified all known tributaries. Did not seek other possible tributaries	Identified all known tributaries. Sought other possible tributaries
5. Haemostasis		
Poor quality of vessel clipping. Clips frequently slipped	Competent vessel clipping	Superior ligaclip. Atraumatic. No clip slipping.
6. SFJ Clearance		
Did not identify the SFJ or excessively traumatic dissection around that vessel	Identified the SFJ. Safely dissected tissue away from vessel. Reasonable clearance of vessel. Minimal trauma	Identified the SFJ. Expert dissection of tissues off the vessels. Atraumatic.
7. SFJ Transfixion		
Did not transfix the SFJ or poor transfixion of SFJ	Good transfixion of SFJ	Excellent safe and secure SFJ transfixion

Table 2.7. Objective Structured Assessment of Technical Skill (OSATS) global rating scale

Candidate Name: Date:

Examiner Name: Procedure:

	1	2	3	4	5
1. Respect for tissue	Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled tissues appropriately with minimal damage
2. Time and motion	Many unnecessary moves		Efficient time/motion but some unnecessary moves		Economy of movement and maximum efficiency
3. Instrument handling	Repeatedly makes tentative or awkward moves with instruments		Competent use of instruments although occasionally appeared stiff or awkward		Fluid moves with instruments and no awkwardness
4. Knowledge of instruments	Frequently used		Knew the name of most		Obviously familiar with

inappropriate instrument	instruments and used appropriate one for the task	the instruments required and their names
5. Use of assistants Consistently placed assistants poorly or failed to use assistants	Good use of assistants most of the time	Strategically used assistant to the best advantage at all times
6. Flow of operation Frequently stopped operating or needed to discuss next move	Demonstrated ability for forward planning with steady progression of operative procedure	Obviously planned course of operation with effortless flow from one move to the next
7. Knowledge of Specific procedure Deficient knowledge. Needed specific instruction at most operative steps	Knew all important aspects of the operation	Demonstrated familiarity with all aspects of the operation

Each item was rated between 1 and 5 using the ICEPS and the OSATS rating scales, with 1 representing a poor performance, 3 (an average score) representing a competent performance, and 5 representing an excellent performance. Rating was based on the ability to perform the individual steps efficiently from a technical and a result aspect. The minimum score that could be given using the ICEPS scale or the OSATS scale was 5 and the maximum was 35.

2.5.3 Statistical Methods

The results generated from both assessment tools (ICEPS and OSATS) were entered into a database and subsequently analysed using the SPSS 18 software supplier. Considering the nature of the data (the results showed a parametric distribution), an independent sample t test was performed to test for statistically significant differences. All values were represented as mean ± SD and mean differences were considered significant for a *P* value of less than 0.05. A Pearson correlation analysis was used to measure the correlation between the procedure-specific and the global rating scales.

The Royal College of Surgeons in Ireland Ethics Committee and the Adelaide and Meath Hospital Ethics Committees approved the study protocol in advance.

Chapter Three: Development and Assessment of a Procedure-Specific Checklist for Superficial Femoral Artery Angioplasty Using an Endovascular Simulator

3.1 Introduction

Catheter-based interventions have brought huge changes to the management of peripheral vascular disease. Compared to open surgery, the endovascular treatment of vascular disease is associated with reduced pain, smaller scars, faster recovery and reduced mortality (Greenhalgh *et al.*, 2005). This has led to increased interest in endovascular training for vascular surgeons (Messina *et al.*, 2002). Virtual reality simulators have been used for training and assessment outside the operating theatre, with potential benefits for patient safety (Gould *et al.*, 2006).

Simulation technologies are well established training tools in complex technical fields such as aviation and the military (Ressler *et al.*, 1999; Rolfe and Staples, 1986). In the medical field, simulation has been widely used in laparoscopy (Kothar *et al.*, 2002), endoscopy (Bloom *et al.*, 2003), trauma (Lee *et al.*, 2003) and endovascular surgery (Dayal *et al.*, 2004). The transfer of technical skills acquired by simulation-based training to interventional suites has also been described in the literature on endovascular management of peripheral vascular disease (Chaer *et al.*, 2006). The use of simulator-based training should be aimed at acquiring proficiency. It should not be restricted in duration or indeed to a fixed number of sessions (Darzi *et al.*, 1999). It should be robust, structured and validated as a training tool for specific surgical procedures. Inherent to this methodology in training surgeons of the future is the use of validated assessment tools in the appraisal and determination of proficiency.

Previous simulation-based peripheral endovascular studies have used global rating scales, procedural-specific checklists and objective machine output such as total procedure time, fluoroscopy time and amount of contrast material used (Chaer *et al.*, 2006; Dawson *et al.*, 2007; Van Herzeele *et al.*, 2008). The global rating scale is a quantitative assessment tool based on appraisal of seven aspects of quality in operative performance (Reznick *et al.*, 1997). A modified global scale has been shown to differentiate endovascular experience and training using a virtual reality simulator (Hislop *et al.*, 2006). Procedure-specific checklists used in conjunction with global rating scales have been shown to be an effective and reliable tool in measuring surgical dexterity. This has been applied to synthetic and cadaveric models as well as in the live operating scenario (Anastakis *et al.*, 1999; Vassiliou *et al.*, 2005). To date, a validated procedure-specific checklist in superficial femoral artery (SFA) angioplasty does not exist in the literature.

3.2 Objectives

As catheter-based endovascular intervention is the preferred initial treatment in the treatment of many patients with SFA disease, it is essential to develop standardised tests to assess trainees' skills in performing SFA angioplasty. The purpose of this study was to develop and validate a consensus-driven checklist to assess trainees' skills in performing SFA angioplasty using the Vascular Intervention Simulation Trainer (VIST) simulator.

A modified Delphi method was used to reach experts' consensus on a checklist of procedural steps. Thereafter, the checklist was tested by comparing the score of experts and final-year medical students. The

procedure-specific checklist scores were also correlated to a previously validated global rating scale.

3.3 Materials and Methods

In early 2010, five international experts were invited to evaluate a preliminary 28-item checklist for SFA angioplasty using two rounds of a modified Delphi method. Thereafter, four experts and 11 final-year medical students performed two SFA angioplasties each (trial 1 and trial 2) on the VIST simulator. Their performance was recorded and blindly assessed by one expert using the developed checklist and a previously validated global rating scale.

Please refer to chapter 2, section 2.2, page 21 for detailed description of the materials and methods used in this study.

3.4 Results

3.4.1 The modified Delphi process

The mean value of the 28 tasks on a 1 to 9 Likert-like scale ranged from 2.2 to 8.8 in the 1st round of the Delphi study. Four items were eliminated after the 1st round of the study as their mean Likert score was equal to or less than 3. The resulting 24-item checklist was confirmed by the experts in the 2nd round. The mean Likert score ranged from 4.2 to 8.4 in the 2nd round of the study. Table 3.1 shows the mean Likert score of each item in the first and the second round of the Delphi study.

Table 3.1. Mean Likert score of each item in the first (D1) and the second (D2) round of the Delphi study

Task description	D1	Result	D2
1. Check patient history with regard to anticoagulation, claudication, duration of symptoms etc.	8.6		8.4
2. Check pre-procedure imaging (ex: MRA, CTA, Duplex).	8.8		8.2
3. Choose appropriate initial guidewire.	5.8		5.4
4. Prepare initial guidewire (ex: wet guidewire with heparine-saline solution).	2.8	Item removed	
5. Insert guidewire to appropriate level with appropriate care for obstruction/vessel trauma.	5.6	Text revised	6.8
6. Choose appropriate working catheter.	4.8		4.8
7. Prepare working catheter (ex: flush catheter with heparanised saline).	4.0	Text revised	4.8
8. Feed working catheter over guidewire to appropriate level: catheter does not pass beyond tip of wire.	6.2	Text revised	6.6
9. Withdraw initial guidewire leaving working catheter in place.	3.0	Item removed	
10. Inject contrast material to outline lesion (roadmap should be taken at this time) and define the extent of the lesion using roadmap.	7.4		7.8

11. Choose appropriate guidewire to cross lesion.	6.8		6.4
12. Prepare guidewire for use.	3.8		4.2
13. Insert guidewire through working catheter. Use roadmap to help cross the lesion and avoid subintimal disection. Cross lesion.	7.6		8.0
14. Manipulate working catheter to be positioned distal to lesion.	4.8		4.2
15. Exchange crossing guidewire with working guidewire.	5.0		4.8
16. Make sure guidewire does not travel into crural arteries or side branches of popliteal.	7.2		6.8
17. Give 50 to 75 units/kg of Heparin.	6.4		6.4
18. Withdraw working catheter leaving guidewire in place.	4.8		5.2
19. Choose appropriate balloon size for angioplasty.	6.4		6.6
20. Prepare balloon catheter.	3.0	Item removed	
21. Insert balloon catheter across lesion making sure guidewire does not travel distally.	6.2		5.0
22. Inflate balloon by mechanical inflation device.	6.2	Text revised	5.0
23. Use fluroscopy guidance while performing balloon angioplasty.	6.2		5.8
24. Decompress balloon fully with 20cc syringe.	6.0		6.2
25. Remove balloon over guidewire leaving	7.6		7.6

guidewire in place.		
26. Inject contrast material to check lesion post angioplasty.	8.2	7.6
27. Check run-off post angioplasty.	8.4	8.4
28. Remove instruments under fluroscopy guidance.	2.2	Item removed

The internal consistency (Cronbach's alpha) of the five international experts and the 28 items in the 1st round was 0.890 and 0.452 respectively. The internal consistency of the five experts and the 24 items in the 2nd round was 0.856 and 0.802 respectively. Figure 3.1 demonstrates the difference in Cronbach's alpha values of the experts and the checklists' items in the first round of the Delphi study. Figure 3.2 demonstrates the difference in Cronbach's alpha values of the experts and the checklists' items in the second round of the Delphi study.

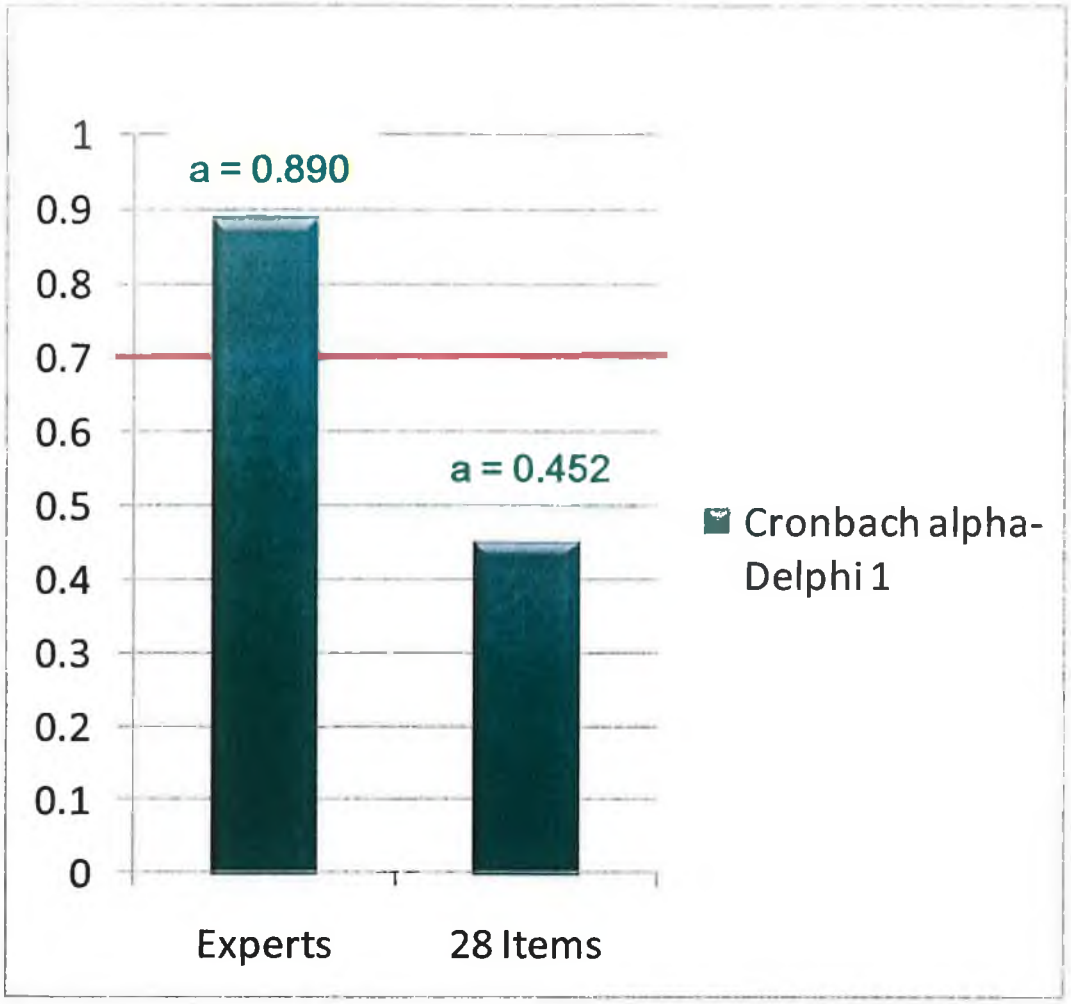

Figure 3.1. The difference in Cronbach's alpha values of the experts and the checklists' items in the first round of the Delphi study

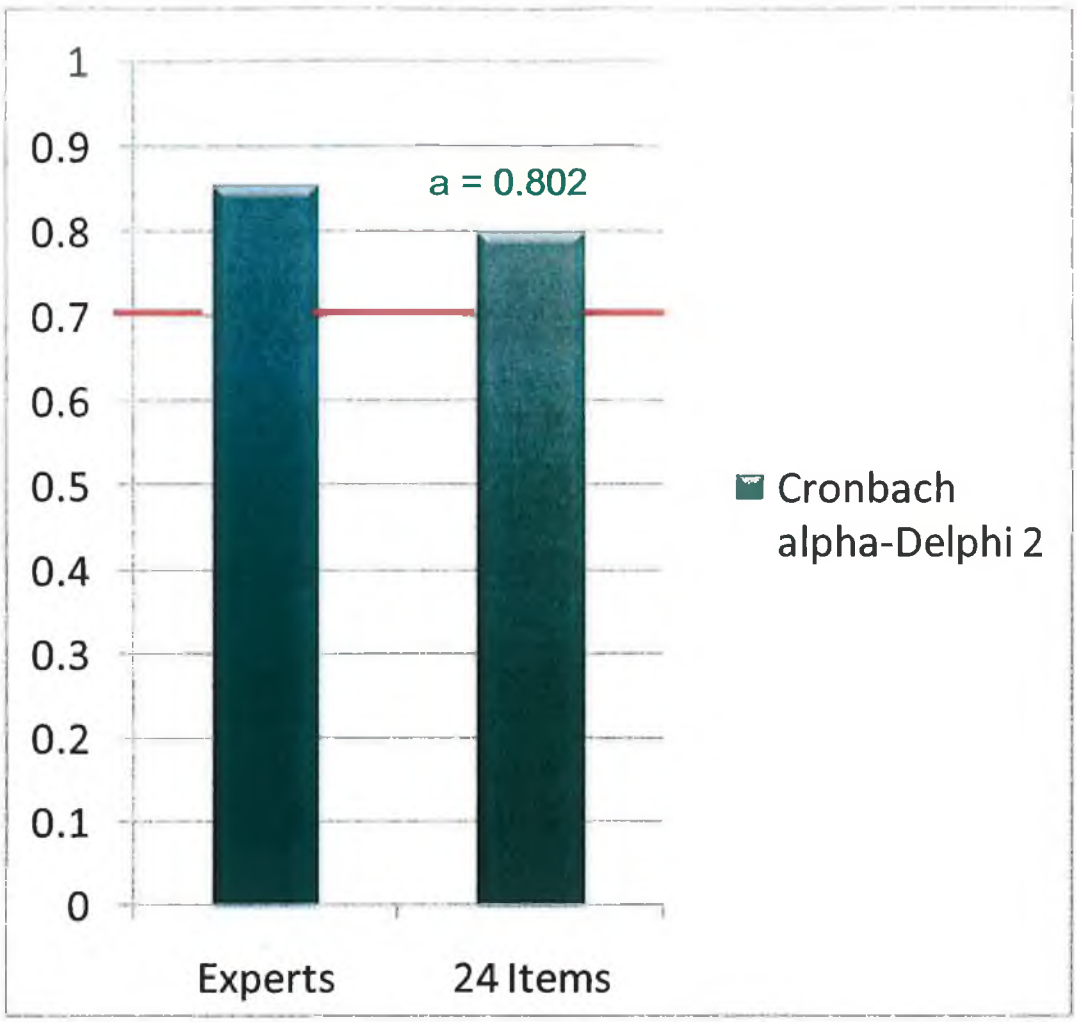

Figure 3.2. The difference in Cronbach's alpha values of the experts and the checklists' items in the second round of the Delphi study

3.4.2 Comparison between experts' and students' technical performance on the VIST simulator

There were significant differences in the checklist score between experts and students in the first (94.25 ± 2.22 vs. 74.91 ± 8.79 $P = 0.001$) (Figure 3.3) and the second simulator trial (95.25 ± 0.50 vs. 76.82 ± 9.44 $P < 0.001$) (Figure 3.4). Table 3.2 shows the mean value of experts' and students' scores for each item in the checklist for trial 1 and 2. Significant differences were also noted between experts' and students' scores in the global rating scale in the first (47.75 ± 0.50 vs. 9.64 ± 9.34 $P < 0.01$) and the second trial (47.75 ± 0.50 vs. 14.64 ± 13.94 $P < 0.01$). The correlation between the developed checklist and the global rating scale was significant in the first ($r = 0.869$) and the second trial ($r = 0.871$).

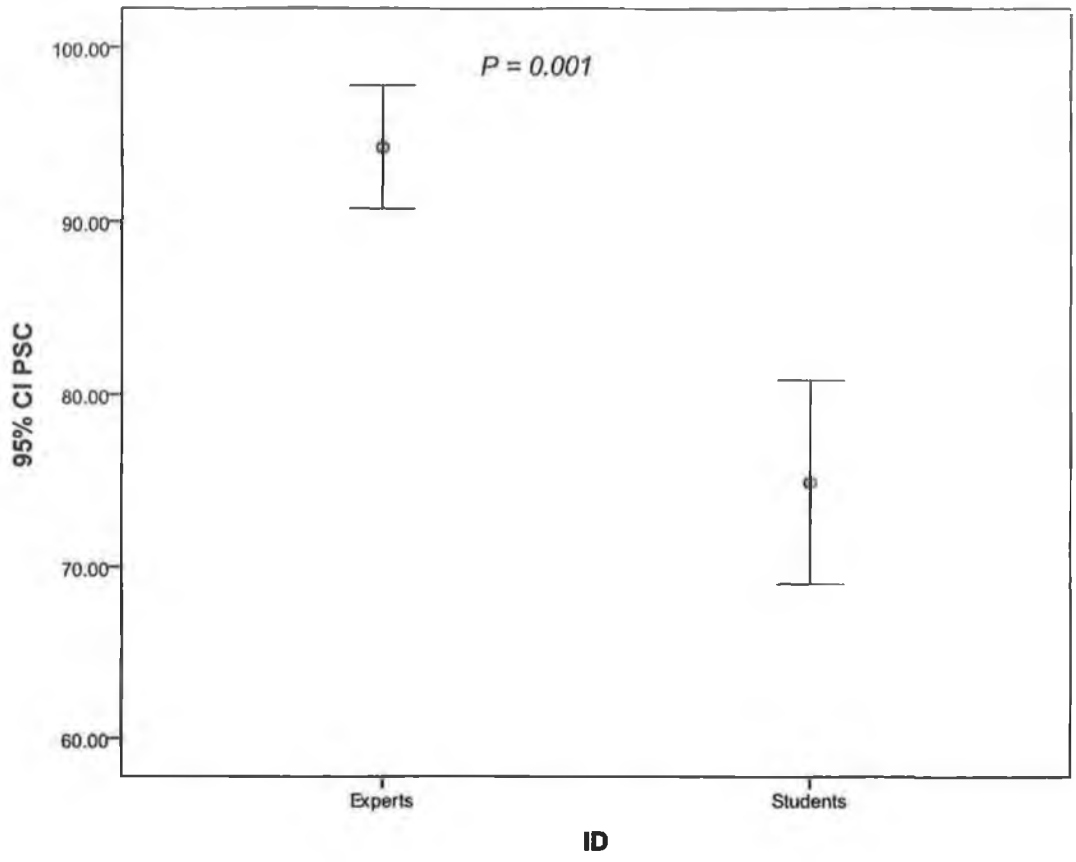

Figure 3.3. Error bar graph. The mean difference in the checklist score between experts and students in the first trial on the VIST simulator is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. PSC, procedure-specific checklist. ID, group identity.

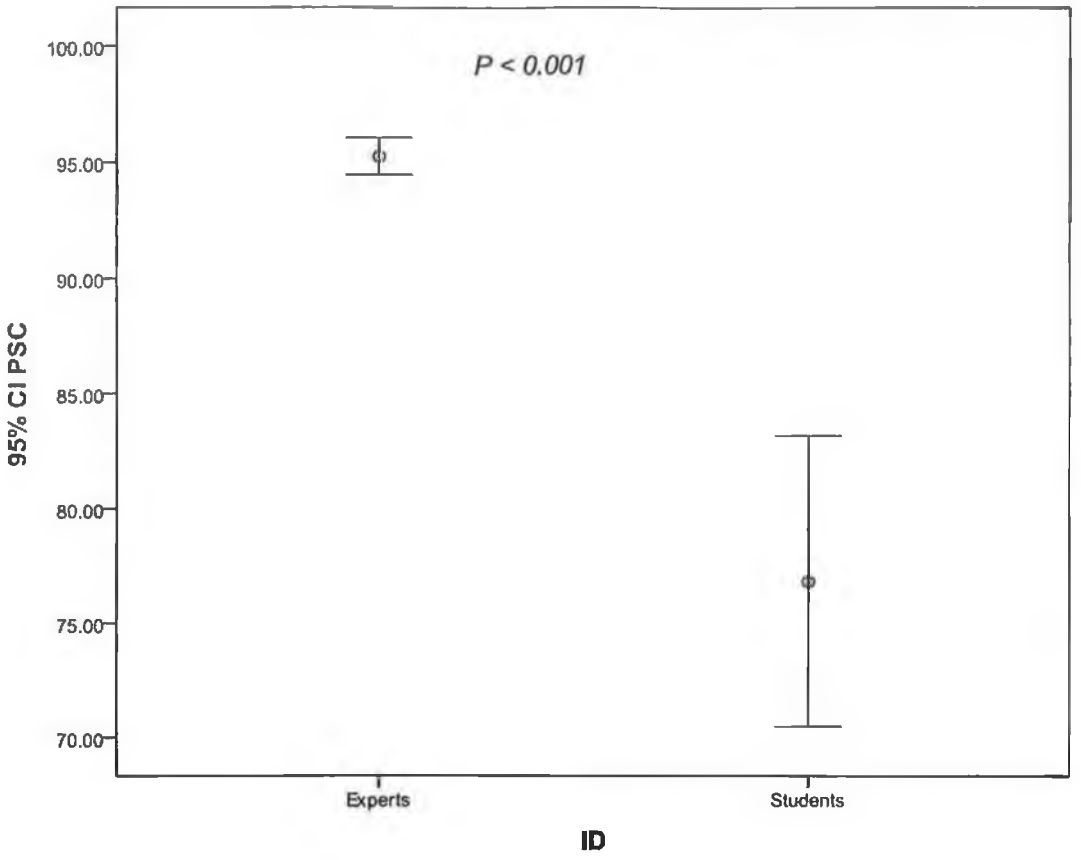

Figure 3.4. Error bar graph. The mean difference in the checklist score between experts and students in the second trial on the VIST simulator is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. PSC, procedure-specific checklist. ID, group identity.

Table 3.2. Mean value of experts' (Ex) and students' (St) scores for each item in the checklist for trial 1 and 2 on the VIST simulator

Task description	Trial 1			Trial 2		
	Ex	St	*P*	Ex	St	*P*
1. Check patient history with regard to anticoagulation, claudication, duration of symptoms etc.	4.0	4.0	N/A[a]	4.0	4.0	N/A
2. Check pre-procedure imaging (ex: MRA, CTA, Duplex).	4.0	4.0	N/A	4.0	4.0	N/A
3. Choose appropriate initial guidewire.	4.0	4.0	N/A	4.0	4.0	N/A
4. Insert guidewire to appropriate level with appropriate care for obstruction/vessel trauma.	4.0	2.3	0.002	4.0	2.7	0.002
5. Choose appropriate working catheter.	4.0	4.0	N/A	4.0	4.0	N/A
6. Prepare working catheter (ex: flush catheter with heparanised saline).	4.0	4.0	N/A	4.0	4.0	N/A
7. Feed working catheter over guidewire to appropriate level:	4.0	1.7	0.0001	4.0	2.3	0.002

catheter does not pass beyond tip of wire.						
8. Inject contrast material to outline lesion (roadmap should be taken at this time) and define the extent of the lesion using roadmap.	4.0	4.0	N/A	4.0	4.0	N/A
9. Choose appropriate guidewire to cross lesion.	4.0	4.0	N/A	4.0	4.0	N/A
10. Prepare guidewire for use.	4.0	4.0	N/A	4.0	4.0	N/A
11. Insert guidewire through working catheter. Use roadmap to help cross the lesion and avoid subintimal disection. Cross lesion.	3.8	1.4	0.0001	3.5	2.0	0.02
12. Manipulate working catheter to be positioned distal to lesion.	3.8	1.6	0.002	4.0	2.1	0.002
13. Exchange crossing guidewire with working guidewire.	4.0	1.3	0.0001	4.0	1.6	0.0003
14. Make sure guidewire does not travel into crural arteries or side branches of popliteal.	4.0	2.2	0.002	4.0	2.6	0.03
15. Give 50 to 75 units/kg of	4.0	4.0	N/A	4.0	4.0	N/A

Heparin.						
16. Withdraw working catheter leaving guidewire in place.	3.0	1.0	0.02	4.0	1.4	0.0001
17. Choose appropriate balloon size for angioplasty.	4.0	4.0	N/A	4.0	4.0	N/A
18. Insert balloon catheter across lesion making sure guidewire does not travel distally.	4.0	2.0	0.006	4.0	1.5	0.0001
19. Inflate balloon by mechanical inflation device.	4.0	4.0	N/A	4.0	4.0	N/A
20. Use fluroscopy guidance while performing balloon angioplasty.	4.0	4.0	N/A	4.0	3.6	NS[b]
21. Decompress balloon fully with 20cc syringe.	4.0	4.0	N/A	4.0	4.0	N/A
22. Remove balloon over guidewire leaving guidewire in place.	3.8	1.5	0.0004	3.8	1.3	0.001
23. Inject contrast material to check lesion post angioplasty.	4.0	4.0	N/A	4.0	3.6	NS
24. Check run-off post angioplasty.	4.0	4.0	N/A	4.0	4.0	N/A

a. N/A, cannot be computed because the standard deviations of both groups are zero. *b*. NS, not significant.

The Cronbach's alpha value of the 24-item checklist for the 15 operators (four experts and 11 students) was also calculated in the first and the second trial to evaluate the reliability of the checklist. Whereas a value of 0.7 or more is known to be of statistical significance, Cronbach's alpha was equal to 0.948 in the first and 0.93 in the second trial.

3.4.3 Objective measurements obtained from the VIST simulator

The difference between experts and students in the total time required to perform the 24 steps was significant in the first (715.50 s ± 119.62 vs. 983.73 s ± 196.25 $P = 0.04$) and the second trial (504.00 s ± 46.32 vs. 723.45 s ± 136.73 $P = 0.009$). The difference in fluoroscopy time between the 2 groups was significant in the first (256.00 s ± 44.47 vs. 714.00 s ± 180.40 $P < 0.001$) and the second trial (203.25 s ± 20.40 vs. 562.45 s ± 173.05 $P = 0.001$). There was no significant difference in the amount of contrast used or the accuracy of balloon angioplasty (the distance between the midpoint of the balloon used and the midpoint of the lesion to be treated) between the 2 groups in both trials.

3.5 Discussion

The use of endovascular simulation in training and assessing junior doctors to manage peripheral vascular diseases has been well described in the literature (Chaer *et al.*, 2006; Dawson *et al.*, 2007; Van Herzeele *et al.*, 2008). Previous studies have used global rating scales, parameters recorded by the simulators (such as procedure and fluoroscopy time) and procedure-specific checklists for assessment purposes. As there is no known validated assessment instrument specific to the endovascular management of

peripheral vascular disease, a checklist to assess trainees' competency in performing SFA angioplasty on the VIST simulator was created and validated. Antegrade SFA angioplasty was chosen as a test procedure. This was due to the fact that it is less complicated than other peripheral vascular diseases angioplasties, yet it involves the basic guidewire/catheter skills in endovascular intervention needed to assess the technical skills of junior surgical and radiology trainees. Performing an arterial access was not part of the checklist as the VIST simulator cannot simulate arterial access. The content of the checklist was validated using two rounds of a modified Delphi study. Thereafter, the checklist was tested by comparing the performance of four experts and 11 final-year medical students performing two SFA angioplasties each on the VIST simulator.

The Delphi method is designed to achieve consensus among experts on critical decisions. This type of approach has been used in numerous examples in the context of endovascular surgery. In the management of peripheral vascular disease, a Delphi study was used to examine the level of agreement among vascular surgeons and interventional radiologists regarding their preference for the surgical or endovascular management of severe limb ischaemia (Bradbury *et al.*, 2002). A Delphi study was used to analyse the consistency and variance in endovascular abdominal aortic aneurysm repair (EVAR) suitability assessment between clinicians (Rödel *et al.*, 2006). A Delphi study was also used to create and validate different checklists, such as the pre-induction checklist in anaesthesia (Thomassen *et al.*, 2010), the laparoscopic Nissen fundoplication assessment instrument (Peyre *et al.*, 2009) and the central venous catheter insertion assessment

tool (Huang *et al.*, 2009). In this study, feedback from five international experts was used to create a checklist for proficiency in SFA angioplasty. Although some steps to perform SFA angioplasty may differ between experts (as some experts perform the initial angiogram through the access sheet, other experts give heparin earlier in the procedure and one expert introduces both angiogram catheter and working guide wire together at the same time), a consensus in the essential steps to perform SFA angioplasty was reached. The resulting checklist can be used by faculty to train and assess trainees on the VIST simulator.

As there was only one assessor available to score the video performance of the 15 operators (11 students and 4 experts), it was not possible to test the inter-observer variability (variability between different observers reporting on the same material) in the experimental design. Instead intra-observer variability (variability between observations when reporting more than once on the same material) was recorded. Intra-observer variability was limited, as demonstrated when the differences in the developed checklist scores between the experts and the students remained significant in the second trial. Furthermore, the internal consistency or reliability (Cronbach's alpha) of the checklist for the 15 operators was significant in trial 1 and trial 2. In addition, the correlation between the developed checklist and a previously validated global rating scale was significant in both trials. When studying the checklist's individual items, only 9 items from the 24 item-checklist showed significant differences between experts and students in the first and second trial. These 9 items represent the specific technical steps for which the machine is able to simulate. Other steps, although critically important to

perform the procedure, were performed equally well by all candidates. Missing a step was not an option as steps were attached in front of each operator. Although this was the case when using the simulator, non-technical steps might show a difference between both groups in real life even when the steps are attached in front of the operator. This is because poor technical performance might increase the operators' stress level in real life and affect non-technical performance. Further studies need to be done in this field.

For the 2 groups (experts and students), objective measurements obtained from the VIST simulator (total procedure time, fluoroscopy time, amount of contrast material used and accuracy of balloon angioplasty) were also compared. The aim was to determine proficiency level for these objective parameters. Novices need to reach experts level (for the objective parameters as well as the procedural checklist) to acquire proficiency. Interestingly, after only one demonstration on how to perform a simple SFA angioplasty, novices used the same amount of contrast and positioned the balloon angioplasty similarly to experts. On the other hand the total procedure time and fluoroscopy time remained significantly different between experts and novices. Another interesting finding is the large decrease in the total procedure time and fluoroscopy time for experts between trial 1 and trial 2. This drop represents time to become familiar with the simulation device, as this drop was also noted for the novice group.

This study demonstrates that the use of the developed checklist shows a clear difference between the performance of experts and novices. This adds construct validity to the face validity of the endovascular simulator for SFA angioplasty. The achievement of a robust and validated training assessment

tool in the development of any simulator-based training is an essential component of the training process. This novel approach is the first to demonstrate these important facets for this procedure-specific task.

This study has several limitations; first of all, the checklist can only assess simple SFA angioplasties. In daily endovascular practice, possible complications such as the occurrence of a dissection during recanalisation of a SFA occlusion, or the occurrence of distal thrombo-emboli can occur. The developed checklist is not capable of assessing these complications. This is because the VIST machine cannot simulate such important scenarios and therefore validating a checklist which represents such complications would have been impossible. Secondly, the developed checklist demonstrates significant differences between novices and experts. Skills differences between trainees of different seniority and experts with different seniority were not determined. It would be interesting to evaluate the accuracy of the validated checklist with trainees of differing seniority. This may further enhance the strength of this task-specific assessment model.

3.6 Conclusion

Using input from a panel of five international experts, a consensus-driven procedural checklist that can be used to assess trainees' competence as they perform SFA angioplasty was developed and validated. The model employed and the application of these results demonstrated construct validity of the developed checklist. This robust assessment tool can now be incorporated into training programmes for endovascular surgeons of the future.

Chapter Four: Impact of an Assistant on the Technical Skills of the Primary Operator in Superficial Femoral Artery Angioplasty

4.1 Introduction

Endovascular intervention is the preferred initial treatment in the treatment of many patients with peripheral vascular diseases. In addition to the technical skills of the primary operator, other factors may influence the overall outcome of the endovascular procedure. The impact of an assistant on the operator's technical skills in performing endovascular interventions has not been assessed to date.

The role of an assistant has been described in the literature in different surgical fields, such as laparoscopic surgery (Chiu *et al.*, 2008; Sur *et al.*, 2008). In the field of anaesthesia, trained assistants reduced errors and improved safety (Weller *et al.*, 2009). The literature on endovascular intervention is replete with training and assessment of the primary operator (Dayal *et al.*, 2004; Tedesco *et al.*, 2008), but deficient with regard to the impact of an assistant on the technical skills of the operator.

Virtual reality simulators have been used for training and assessment outside the operating theatre, with potential benefits for patient safety (Gould *et al.*, 2006). Having their roots in aviation and military (Ressler *et al.*, 1999; Rolfe and Staples, 1986), virtual reality simulators have been widely used in laparoscopy (Kothar *et al.*, 2002), endoscopy (Bloom *et al.*, 2003), trauma (Lee *et al.*, 2003) and endovascular surgery (Chaer *et al.*, 2006; Dawson *et al.*, 2007; Van Herzeele *et al.*, 2008). The use of endovascular simulators has been confined to either training or assessment of the primary operator.

4.2 Objectives

Whether the presence of an assistant in endovascular interventions can affect the procedure time or the procedure outcome has not yet been described in the literature. The purpose of this study was to assess the impact of an assistant on the technical skills of the primary operator performing superficial femoral artery (SFA) angioplasties on the Vascular Intervention Simulation Trainer (VIST) simulator.

4.3 Materials and Methods

Eight experts in endovascular intervention performed two SFA angioplasties each (procedure 1 and procedure 2) on the VIST simulator. Four experts had an assistant available (assistant group) and four experts had no assistant (control group). Their performances were video-recorded. The experts' performances in the assistant group were blindly assessed by one expert from the control group and the experts' performances in the control group were blindly assessed by one expert from the assistant group. In addition to objective simulator parameters (total procedure time, fluoroscopy time, amount of contrast material used and accuracy of balloon angioplasty), a validated global rating scale and procedural checklist were used for assessment.

Please refer to chapter 2, section 2.3, page 34 for a detailed description of the materials and methods used in this study.

4.4 Results

4.4.1 Procedure-specific checklist

Experts who performed SFA angioplasties on the VIST simulator with the aid of an assistant scored higher than the controls on the 24-item procedure-specific checklist in the first procedure (assistant/control) (94.25 ± 2.22 vs. 89 ± 2.45 $P = 0.019$) (Figure 4.1). The difference between the 2 groups persisted in the second procedure (95.25 ± 0.50 vs. 89.50 ± 2.38 $P = 0.015$) (Figure 4.2). Table 4.1 shows the mean value of experts' scores in the two groups (assistant group and control group) for each item in the procedural checklist for procedure 1 and 2.

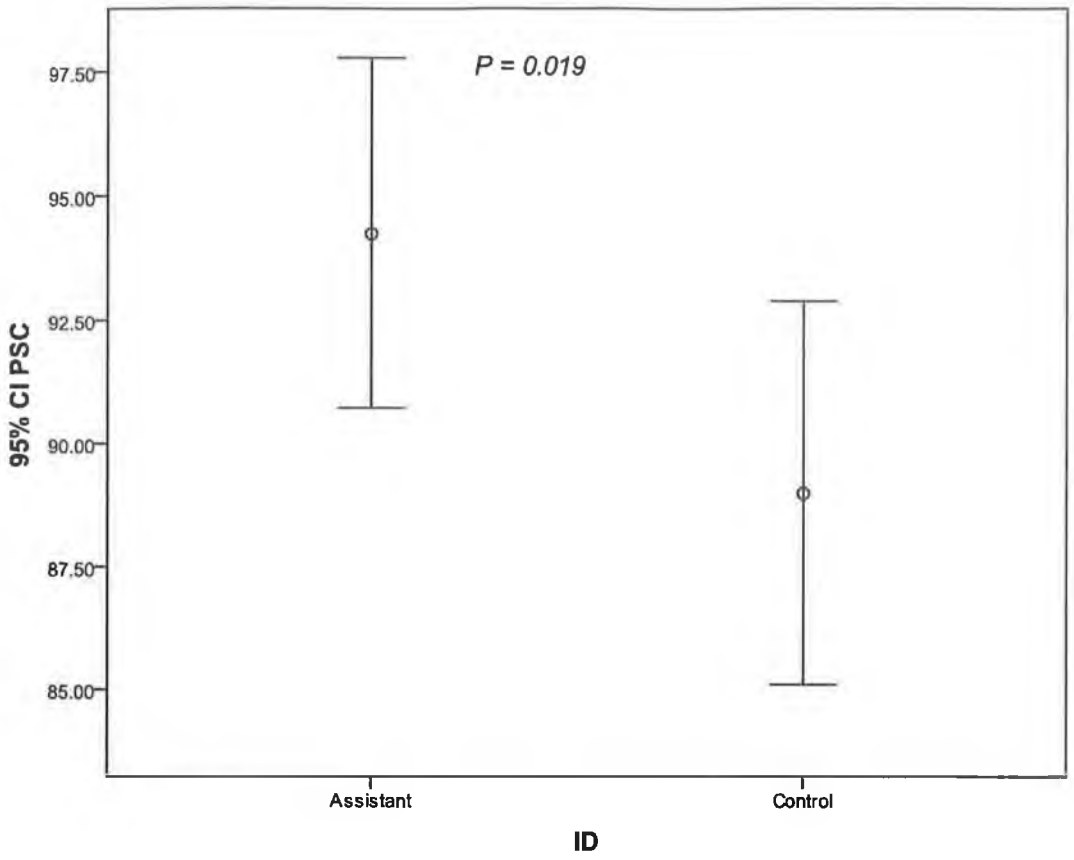

Figure 4.1. Error bar graph. The mean difference in the 24-item procedure-specific checklist score between experts in the assistant group and experts in the control group in the first procedure on the VIST simulator is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. PSC, procedure-specific checklist. ID, group identity.

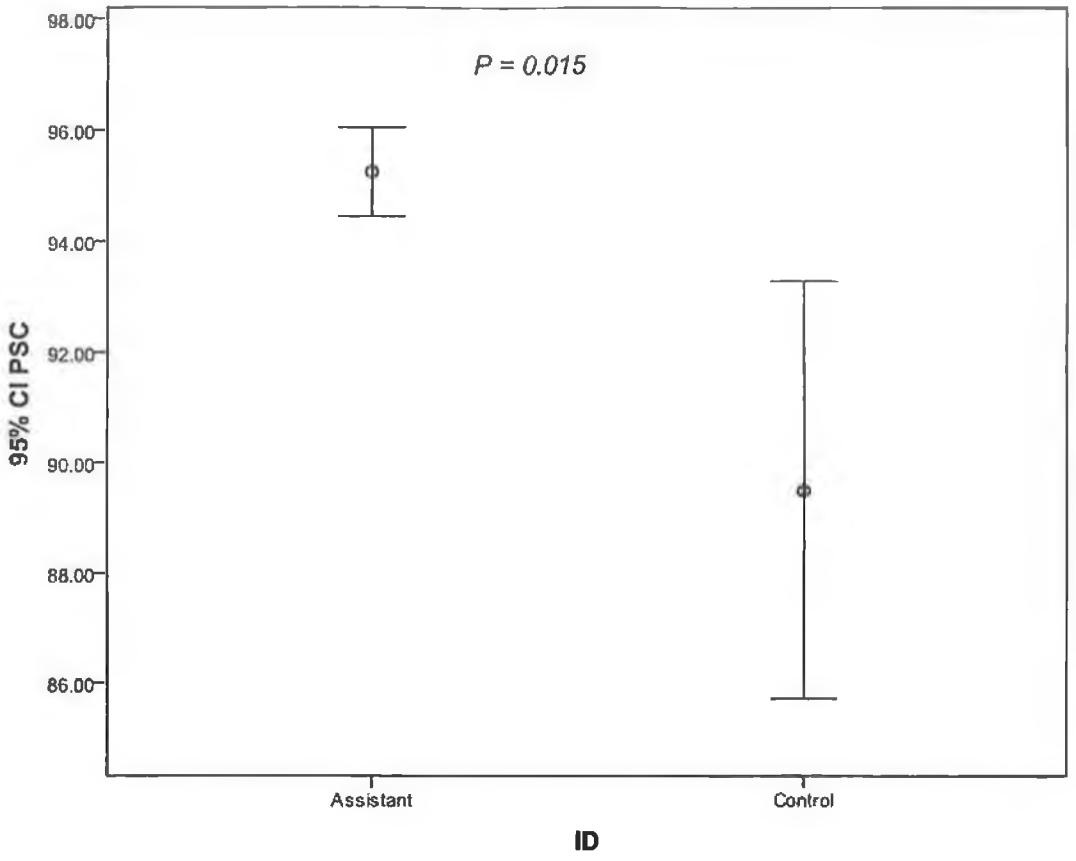

Figure 4.2. Error bar graph. The mean difference in the 24-item procedure-specific checklist score between experts in the assistant group and experts in the control group in the second procedure on the VIST simulator is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. PSC, procedure-specific checklist. ID, group identity.

Table 4.1. Mean value of experts' scores in the assistant (A) and the control (C) group for each item in the procedural checklist for procedure 1 and 2

Task description	Procedure 1			Procedure 2		
	A	C	*P*	A	C	*P*
1. Check patient history with regard to anticoagulation, claudication, duration of symptoms etc.	4.0	4.0	N/A[a]	4.0	4.0	N/A
2. Check pre-procedure imaging (ex: MRA, CTA, Duplex).	4.0	4.0	N/A	4.0	4.0	N/A
3. Choose appropriate initial guidewire.	4.0	4.0	N/A	4.0	4.0	N/A
4. Insert guidewire to appropriate level with appropriate care for obstruction/vessel trauma.	4.0	2.5	0.182	4.0	2.25	0.188
5. Choose appropriate working catheter.	4.0	4.0	N/A	4.0	4.0	N/A
6. Prepare working catheter (ex: flush catheter with heparanised saline).	4.0	4.0	N/A	4.0	4.0	N/A
7. Feed working catheter over guidewire to appropriate level: catheter does not pass beyond tip of wire.	4.0	3.75	0.391	4.0	4.0	N/A

8. Inject contrast material to outline lesion (roadmap should be taken at this time) and define the extent of the lesion using roadmap.	4.0	4.0	N/A	4.0	4.0	N/A
9. Choose appropriate guidewire to cross lesion.	4.0	4.0	N/A	4.0	4.0	N/A
10. Prepare guidewire for use.	4.0	4.0	N/A	4.0	4.0	N/A
11. Insert guidewire through working catheter. Use roadmap to help cross the lesion and avoid subintimal disection. Cross lesion.	4.0	3.75	0.391	4.0	3.5	0.182
12. Manipulate working catheter to be positioned distal to lesion.	4.0	3.75	0.391	4.0	2.0	0.116
13. Exchange crossing guidewire with working guidewire.	4.0	3.0	0.207	4.0	4.0	N/A
14. Make sure guidewire does not travel into crural arteries or side branches of popliteal.	4.0	4.0	N/A	4.0	4.0	N/A
15. Give 50 to 75 units/kg of Heparin.	4.0	4.0	N/A	4.0	4.0	N/A
16. Withdraw working catheter leaving guidewire in place.	3.0	2.75	0.848	4.0	2.5	0.182
17. Choose appropriate balloon	4.0	4.0	N/A	4.0	4.0	N/A

size for angioplasty.						
18. Insert balloon catheter across lesion making sure guidewire does not travel distally.	4.0	3.0	0.207	4.0	4.0	N/A
19. Inflate balloon by mechanical inflation device.	4.0	4.0	N/A	4.0	4.0	N/A
20. Use fluroscopy guidance while performing balloon angioplasty.	4.0	4.0	N/A	4.0	4.0	N/A
21. Decompress balloon fully with 20cc syringe.	4.0	4.0	N/A	4.0	4.0	N/A
22. Remove balloon over guidewire leaving guidewire in place.	3.75	2.0	0.228	3.75	2.75	0.346
23. Inject contrast material to check lesion post angioplasty.	4.0	4.0	N/A	4.0	4.0	N/A
24. Check run-off post angioplasty.	4.0	4.0	N/A	4.0	4.0	N/A

b. N/A, cannot be computed because the standard deviations of both groups are zero.

4.4.2 Global rating scale

Experts who performed SFA angioplasties on the VIST simulator with the aid of an assistant scored higher than the controls on the 12-item global rating scale in the first procedure (assistant/control) (47.75 ± 0.50 vs. 33.50 ± 5.07 $P = 0.011$) (Figure 4.3). The difference between the two groups persisted in the second procedure (47.75 ± 0.50 vs. 38 ± 6.98 $P = 0.032$) (Figure 4.4). Table 4.2 shows the mean value of experts' scores in the two groups (assistant group and control group) for each item in the global rating scale for procedure 1 and 2.

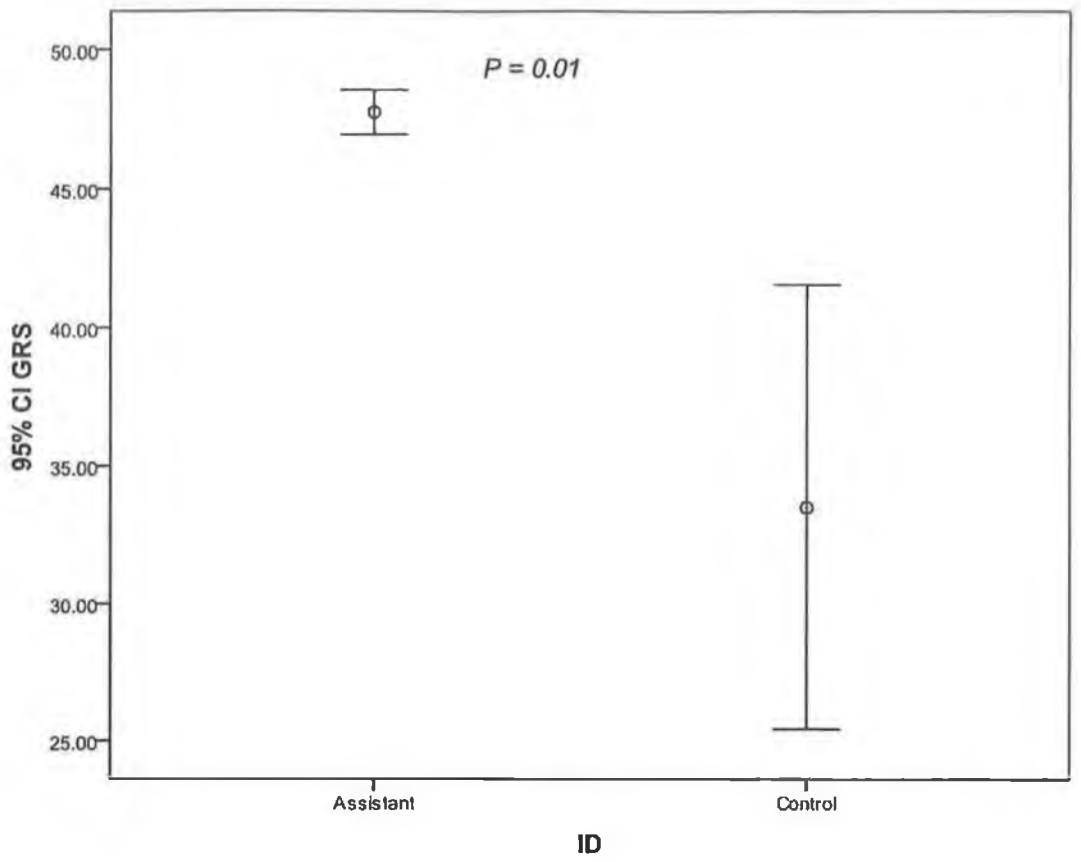

Figure 4.3. Error bar graph. The mean difference in the 12-item global rating scale score between experts in the assistant group and experts in the control group in the first procedure on the VIST simulator is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. GRS, global rating scale. ID, group identity.

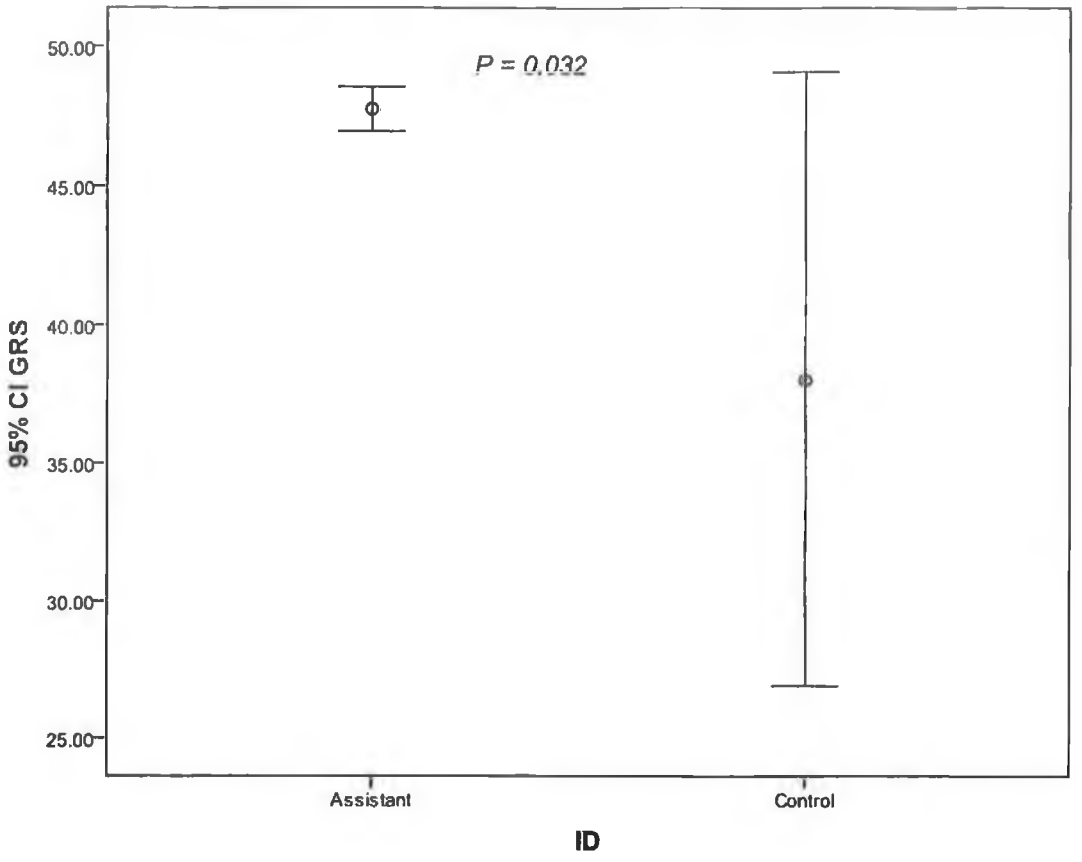

Figure 4.4. Error bar graph. The mean difference in the 12-item global rating scale score between experts in the assistant group and experts in the control group in the second procedure on the VIST simulator is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. GRS, global rating scale. ID, group identity.

Table 4.2. Mean value of experts' scores in the assistant (A) and the control (C) group for each item in the global rating scale for procedure 1 and 2

Task description	Procedure 1			Procedure 2		
	A	C	*P*	A	C	*P*
1. Time and motion	4.00	1.75	0.058	4.00	2.75	0.094
2. Wire and catheter handling	4.0	2.0	0.003	4.0	2.5	0.1
3. Awareness of wire position	4.0	3.25	0.215	4.0	3.25	0.058
4. Maintenance of wire stability	3.75	2.5	0.067	3.75	3.0	0.168
5. Awareness of fluoroscopy usage	4.0	2.75	0.015	4.0	3.0	0.05
6. Precision of wire/catheter technique	4.0	2.75	0.015	4.0	2.25	0.006
7. Flow of operation	4.0	2.25	0.006	4.0	3.5	0.182
8. Knowledge of procedure	4.0	2.25	0.1	4.0	3.0	0.207
9. Quality of final product	4.0	2.0	0.003	4.0	2.75	0.08
10. Ability to complete the case	4.0	4.0	N/A[a]	4.0	4.0	N/A
11. Need for verbal prompts	4.0	4.0	N/A	4.0	4.0	N/A
12. Attending takeover	4.0	4.0	N/A	4.0	4.0	N/A

a. N/A, cannot be computed because the standard deviations of both groups are zero.

4.4.3 Correlation between the procedural checklist and the global rating scale

The correlation between the procedure-specific checklist and the global rating scale was significant in the first (r = 0.727) and the second procedure (r = 0.877).

4.4.4 Objective simulation parameters

There were no significant differences between the two groups (assistant group and control group) with regard to objective simulation parameters in the first procedure: total procedure time (assistant/control) (765.50 s ± 119.62 vs. 776.25 s ± 17.75 *P* = 0.87); fluoroscopy time (256 s ± 44.47 vs. 301.75 s ± 129.88 *P* = 0.53); amount of contrast material used (9.40 cc ± 4.08 vs. 10.05 cc ± 3.36 *P* = 0.81); accuracy of balloon angioplasty (1.45 mm ± 0.83 vs. 3.43 mm ± 2.35 *P* = 0.19). The difference between the two groups remained insignificant in the second procedure: total procedure time (assistant/control) (504 s ± 46.32 vs. 558.75 s ± 32.84 *P* = 0.1); fluoroscopy time (203.25 s ± 20.40 vs. 218.75 s ± 38.24 *P* = 0.5); amount of contrast material used (7.65 cc ± 1.28 vs. 8.33 cc ± 2.33 *P* = 0.63); accuracy of balloon angioplasty (3.25 mm ± 1.25 vs. 3.30 mm ± 2.42 *P* = 0.97).

4.5 Discussion

The literature on simulation-based endovascular intervention is replete with training and assessment of the primary operator (Chaer *et al.*, 2006; Dawson *et al.*, 2007; Van Herzeele *et al.*, 2008), but deficient with regard to the influence of an assistant on the procedure outcome. It was hypothesized that

an assistant helps perform an endovascular intervention faster, but it was not known to date whether an assistant in endovascular intervention has an impact on the primary operator's technical skills and hence the overall procedure outcome. In this study, the technical skills of two groups of experts (one group had an assistant available and the other group had no assistant available) performing SFA angioplasties on the VIST simulator were compared.

Antegrade SFA angioplasty was chosen as a test procedure. This procedure was selected as it is less complicated than angioplasties performed in the context of other peripheral vascular diseases, yet it involves basic guide wire/catheter skills in endovascular intervention. Performing an arterial access was not part of the checklist as the VIST simulator cannot simulate arterial access. Experts in endovascular intervention were chosen as study subjects to ensure that all individuals had the same level of technical skills. As the aim of the study was to evaluate the technical skills of the operator and not to assess knowledge, the steps to perform the procedure were attached in front of each expert and all experts were asked to adhere to the steps. To hide the identity of the experts, video cameras were set on mute and experts were asked to wear surgical gloves. Experts from each group were evaluated by one expert from the other group. Evaluating experts were blinded to each other's identity and to the identity of the experts in the video recording. Objective simulation parameters and two validated scoring systems (a global rating scale and a procedural checklist) were used for the assessment.

There were no significant differences between the two groups of experts in the scores of the individual items of the procedural checklist in procedure 1 and procedure 2, but significant differences were noted in the overall score between the two groups in the two procedures. Regarding the global rating scale, although five items in the first procedure and only one item in the second procedure showed significant differences between the two groups of experts, the overall score was significant in both procedures. The reason behind this might be the small number of subjects in the study. On the other hand, the total time to perform the procedure was not significant between the two groups of experts in the two procedures. Whether this was because the overall time to perform the 28 steps is not long enough to show significant differences between the two groups or because an assistant has no impact on how fast the primary operator performs the procedure is not known.

As there was only one assessor available from each group to score the video performance of the 4 experts in the other group, it was not possible to test the inter-observer variability (variability between different observers reporting on the same material) in the experimental design. Instead the intra-observer variability (variability between observations when reporting more than once on the same material) was recorded. Intra-observer variability was limited, as demonstrated when the differences in the overall scores for the procedural checklist and the global rating scale between the two groups of experts remained significant in the second procedure.

In this study, the same assistant was available to the four experts in the assistant group. The assistant's role was to prepare the guide wires and catheters for use (simulating wetting guide wires and flushing catheters with

heparinised saline solution), engaging catheters over guide wires for use by the primary operator, holding and stabilizing guide wires in place and injecting contrast material and heparin. Defining the role of the assistant is critically important. In a previous study, standardization of the laparoscopy-assisted distal gastrectomy procedure for assistants led to a shorter operation time and reduced complications (Hiki *et al.*, 2008).

A research fellow in simulation-based endovascular training was the assistant available in this study. It is not known yet whether the skill of the assistant would affect the technical skills of the primary operator in this study design. In a previous study, the outcome of abdominal aortic aneurysm surgery was not influenced by whether a board-certified surgeon or an experienced registered nurse was the first assistant (Archie, 1992). Similarly, in coronary revascularization surgery, surgical nurses were used effectively in low-risk cases without compromising postoperative results (Alex *et al.*, 2004). In the last decade, robots have been used as assistants in different surgical procedures such as in aorto-femoral bypass grafting, having the ability to combine conventional laparoscopic surgery with stereoscopic 3D magnification and ultra-precise suturing techniques (Desgranges *et al.*, 2004). In addition, when robot-assisted laparoscopic cholecystectomy has shown no significant advantages over human-assisted laparoscopic cholecystectomy (Gurusamy *et al.*, 2009), in renal surgery robots have given the console surgeon greater independence from the assistant (Rogers *et al.*, 2009).

4.6 Conclusion

In a randomised control experiment involving eight experts in endovascular intervention performing SFA angioplasties on a simulator, the presence of an assistant had a positive influence on the technical skills of the primary operator. Further studies are needed to assess and identify the role of the assistant in more complex endovascular interventions.

Chapter Five: Skills Transfer After Proficiency-Based Simulation Training in Superficial Femoral Artery Angioplasty

5.1 Introduction

The expansion of diagnostic and therapeutic endovascular intervention has led to increased interest in endovascular training for vascular surgeons (Messina *et al.*, 2002). However, the introduction of catheter-based interventions poses technical challenges to inexperienced trainees and trainers. Interventionalists need to know how to manipulate a guidewire/catheter within a three dimensional field while viewing it on a two dimensional screen (Aggarwal *et al.*, 2006). Interventionalists also need to deal with reduced tactile feedback and the increased need for hand-eye coordination (Patel *et al.*, 2006). As a result of the expansion of diagnostic and therapeutic endovascular intervention, there is a need to address the specific issue of skills training in endovascular intervention.

Recent changes in health care have created new challenges in the training of future surgeons. The Caiman reforms, increasing medico-legal issues, a growing awareness of costs and budgetary accountability, the shift towards a consultant-based service and more recently the reduction in working hours are all posing new threats to the already compromised current training programs (Varghese *et al.*, 1999). All these changes have created challenges in keeping up the standards in skills training of future surgeons.

The traditional form of surgical skills training is carried out in the operating theatre, where hands-on tutoring is given by a senior surgeon assisting the trainee in performing part or all of an operative procedure. In the era of cost containment and health care crises, the current form of operative room training has been claimed to be expensive, time-consuming and inefficient in

the provision of surgical care (Bridges and Diamond, 1999; Richards *et al.*, 2000). Simulation-based surgical training offers an opportunity both to trainees and trainers to learn and teach surgical skills outside the operating room in a pseudorealistic environment with potential benefits for patient safety (Gould *et al.*, 2006).

Simulation technologies have been well established in complex technical fields such as aviation and the military (Ressler *et al.*, 1999; Rolfe and Staples, 1986). In the medical field, simulation has been widely used in laparoscopy (Kothar *et al.*, 2002), endoscopy (Bloom *et al.*, 2003), trauma (Lee *et al.*, 2003) and endovascular surgery (Dayal *et al.*, 2004). The transfer of technical skills acquired by simulation-based training to the operative setting has also been described in the literature for laparoscopic cholecystectomy and colonoscopy/sigmoidoscopy (Sturm *et al.*, 2008). The use of simulator-based training should be aimed at acquiring proficiency. It should not be restricted in duration or indeed to a fixed number of sessions (Darzi *et al.*, 1999). Simulator-based training should be robust, structured and validated as a training tool for specific surgical procedures.

Simulation technology has been used in endovascular skills training and assessment for approximately 10 years. Many studies have demonstrated that virtual reality training in peripheral endovascular interventions is valid, feasible and acceptable (Chaer *et al.*, 2006; Dawson *et al.*, 2007; Van Herzeele *et al.*, 2008). The transfer of technical skills acquired by simulation-based training to interventional suites has also been described in the literature on the endovascular management of peripheral vascular disease (Chaer *et al.*, 2006). In the last study mentioned, simulation training was not

allowed to exceed two hours, lesions treated were different among trainees as they included a variety of iliac, femoral and popliteal stenoses or occlusions and the procedure checklist used was not validated.

5.2 Objectives

Endovascular simulators have been available and in use for physician training and assessment for approximately a decade and the technology is evolving rapidly. The purpose of this randomised, controlled, prospective study was to explore whether endovascular skills acquired by proficiency-based simulation training in TransAtlantic interSociety Consensus (TASC) A (short stenosis, <3cm) antegrade superficial femoral artery (SFA) angioplasty transfer to interventional suites.

5.3 Materials and Methods

Ten general surgical trainees with no past experience in endovascular intervention received didactic training in the technique of TASC A antegrade SFA angioplasty. Thereafter, trainees were randomised with five receiving further training on the Vascular Intervention Simulation Trainer (VIST) simulator up to a predetermined level of proficiency. Simulation training was not restricted in duration or number of sessions. All ten trainees then performed one TASC A antegrade SFA angioplasty in an interventional suite within five days of didactic only/didactic and simulation training. Trainees' performance was assessed by one supervising consultant in interventional radiology blinded to the trainees' training status, using a previously validated procedural checklist and global rating scale. The same consultant assessed all ten trainees.

Please refer to chapter 2, section 2.4, page 39 for a detailed description of the materials and methods used in this study.

5.4 Results

5.4.1 Trainees' background information

Ten general surgical trainees were enrolled in the study. Five were male and five were female. Trainees' age ranged between 29 and 31. All trainees had completed a one year internship and two years of basic surgical training. The latter introduces trainees to the principles of surgery and involves rotating through hospitals at six-month intervals. All trainees had no prior exposure to endovascular intervention.

5.4.2 Acquiring proficiency level

After one hour of didactic training, five trainees received further training on the VIST simulator up to a predetermined level of proficiency (Table 2.4, chapter 2, page 41). Proficiency-based simulation training was not restricted to time or number of sessions. All simulation-trained trainees reached predetermined proficiency targets at a median of 2.4 hours (ranging from 2 to 3 hours) and a median of 5.8 procedures (ranging from 5 to 7 procedures). Training was delivered by the same trainer (a research fellow in endovascular simulation training).

5.4.3 Procedural specific checklist

Overall, trainees who received proficiency-based simulation training scored higher than the controls on the 24-item procedure-specific checklist (simulation/control) (86.80 ± 5.36 vs. 67.60 ± 6.02 $P = 0.001$) (Table 5.1).

Moreover, simulation training led to improvement in five individual measures of the procedure-specific checklist. Table 5.1 shows the mean value of trainees' scores in the two groups (simulation group and control group) for each item in the procedural checklist.

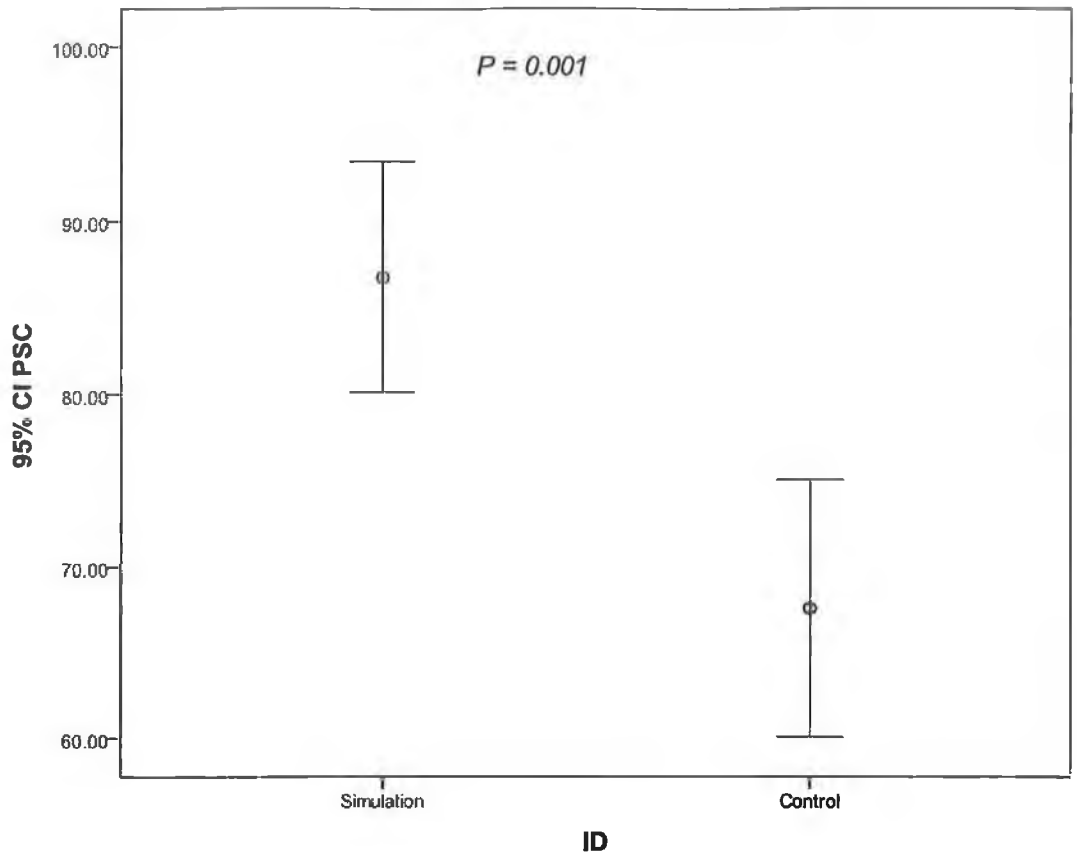

Figure 5.1. Error bar graph. The mean difference in the 24-item procedure-specific checklist score between simulation-trained trainees and controls is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. PSC, procedure-specific checklist. ID, group identity.

Table 5.1. Mean value of trainees' scores in the simulation-trained (S) and the control (C) group for each item in the procedure-specific checklist

Task description	S	C	*P*
1. Check patient history with regard to anticoagulation, claudication, duration of symptoms	4.0	4.0	N/A[a]
2. Check pre-procedure imaging (ex: MRA, CTA, Duplex)	4.0	4.0	N/A
3. Choose appropriate initial guidewire	4.0	4.0	N/A
4. Insert guidewire to appropriate level with appropriate care for obstruction/vessel trauma	3.6	2.6	N/S[b]
5. Choose appropriate working catheter	4.0	3.2	N/S
6. Prepare working catheter (ex: flush catheter with heparanised saline)	4.0	4.0	N/A
7. Feed working catheter over guidewire to appropriate level: catheter does not pass beyond tip of wire	3.2	2.4	N/S
8. Inject contrast material to outline lesion (roadmap should be taken at this time) and define the extent of the lesion using roadmap	3.8	3.2	N/S
9. Choose appropriate guidewire to cross lesion	4.0	3.8	N/S
10. Prepare guidewire for use	4.0	4.0	N/A
11. Insert guidewire through working catheter. Use roadmap to help cross the lesion and avoid	2.8	2.4	N/S

subintimal disection. Cross lesion			
12. Manipulate working catheter to be positioned distal to lesion	3.4	2.0	0.025
13. Exchange crossing guidewire with working guidewire	3.0	1.4	0.014
14. Make sure guidewire does not travel into crural arteries or side branches of popliteal	2.8	1.6	N/S
15. Give 50 to 75 units/kg of Heparin	3.8	2.4	N/S
16. Withdraw working catheter leaving guidewire in place	2.8	0.6	0.004
17. Choose appropriate balloon size for angioplasty	3.4	3.2	N/S
18. Insert balloon catheter across lesion making sure guidewire does not travel distally	3.2	1.4	0.034
19. Inflate balloon by mechanical inflation device	4.0	3.8	N/S
20. Use fluroscopy guidance while performing balloon angioplasty	4.0	3.4	N/S
21. Decompress balloon fully with 20cc syringe	3.6	3.0	N/S
22. Remove balloon over guidewire leaving guidewire in place	3.4	2.2	N/S
23. Inject contrast material to check lesion post angioplasty	4.0	3.6	N/S
24. Check run-off post angioplasty	4.0	1.2	< 0.001

c. N/A, cannot be computed because the standard deviations of both groups are zero.

d. N/S, not significant

5.4.4 Global rating scale

Overall, trainees who received proficiency-based simulation training scored higher than the controls on the 12-item global rating scale (simulation/control) (37.20 ± 4.09 vs. 24.40 ± 5.32 $P = 0.003$) (Table 5.2). Moreover, simulation training led to improvement in almost all of the individual measures (10 out of 12 items) of the global rating scale. Table 5.2 shows the mean value of trainees' scores in the two groups (simulation group and control group) for each item in the global rating scale.

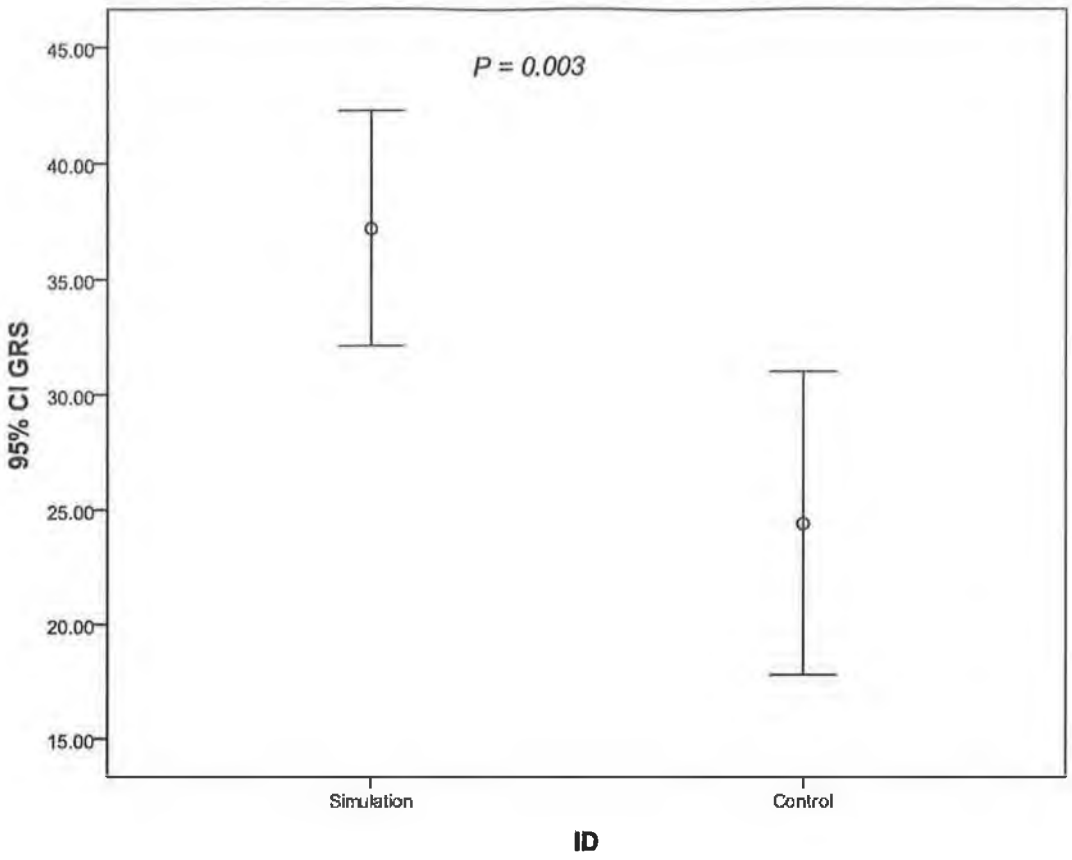

Figure 5.2. Error bar graph. The mean difference in the 12-item global rating scale score between simulation trained trainees and controls is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. GRC, global rating scale. ID, group identity.

Table 5.2. Mean value of trainees' scores in the simulation trained (S) and the control (C) group for each item in the global rating scale

Task description	S	C	*P*
1. Time and motion	3.0	2.2	N/S[a]
2. Wire and catheter handling	3.0	2.0	0.013
3. Awareness of wire position	3.0	1.4	0.014
4. Maintenance of wire stability	3.0	2.0	0.013
5. Awareness of fluoroscopy usage	2.8	1.6	0.028
6. Precision of wire/catheter technique	3.2	2.4	0.035
7. Flow of operation	3.4	2.4	N/S
8. Knowledge of procedure	3.4	2.0	0.025
9. Quality of final product	3.4	2.6	0.05
10. Ability to complete the case	2.8	1.8	0.008
11. Need for verbal prompts	2.8	1.6	0.005
12. Attending takeover	3.4	2.4	0.02

a. N/S, not significant

5.4.5 Correlation between the procedure-specific checklist and the global rating scale

The correlation between the procedure-specific checklist and the global rating scale was significant ($r = 0.951$, $P < 0.001$).

5.5 Discussion

As catheter-based intervention is the preferred treatment in many cases of patients with peripheral vascular diseases, endovascular skills training for vascular surgery trainees has become essential. The traditional form of surgical skills training, recent changes in health care and the introduction of new technologies such as laparoscopic, endoscopic and endovascular interventions have all created challenges in keeping up the standards in skills training of future surgeons. Structured simulation training to proficiency might help tackle these challenges. Although endovascular simulation technology has been used in the training and assessment of surgical doctors for approximately a decade, training in these cases has been restricted to either duration or fixed number of sessions. In this study, we have shown that proficiency-based simulation training in SFA angioplasty translates to real world performance.

Ten general surgical trainees were involved in this study. All trainees had similar background clinical experience and were novices with regard to endovascular intervention. TASC A antegrade SFA angioplasty was chosen as a test procedure. This was due to the fact that it is less complicated than other peripheral vascular diseases angioplasties, yet it involves the basic guidewire/catheter skills in endovascular intervention needed to train and

assess the technical skills of junior surgical trainees. Steps required to perform and close an arterial access were not part of the study as the VIST simulator cannot simulate these steps. The 28 procedural steps were attached in front of each of the 5 operators when training on the VIST machine and in front of all 10 operators when performing the clinical cases as the aim was to assess technical skills of the trainees and not knowledge. The same trainer delivered didactic teaching to all trainees and trained the five trainees on the VIST simulator. The same consultant in radiology intervention, who was blinded to the training status of the operators, supervised all trainees during the clinical application and assessed each trainee using validated procedural and global checklists.

The differences in the overall score between simulation-trained trainees and controls in the two assessment instruments (procedural checklist and global rating scale) demonstrates that proficiency-based simulation training in endovascular skills might be transferable to clinical practice. When studying individual items from the assessment instruments, 10 out of 12 items in the global rating scale and 5 out of 24 items in the procedural checklist showed significant differences between the two groups. In a previous study involving a comparison between consultants and medical students performing antegrade SFA angioplasty on the VIST simulator (chapter 3), only 9 of the 24-item procedural checklist showed significant differences between experts and novices. These 9 items represented the technical steps the VIST was capable to simulate. In this study, significant differences were noticed in 5 out of those 9 items. Simulation training did not lead to improvement in the non-technical steps (as in the steps which involve choosing instruments or

giving heparin). This might be explained by the fact that in these non-technical steps simulation training presents no advantage over didactic training. Missing a step was not possible as steps were attached in front of each operator.

A number of issues in this study deserve consideration. First, simulation training was aimed at acquiring proficiency regardless of duration or number of sessions. Although the number of simulation-trained individuals was small, it was obvious that trainees had different abilities in acquiring endovascular skills. This difference was also noted in a previous study when 10 surgical residents with similar aptitude test scores were trained on the VIST simulator to perform peripheral endovascular angioplasties for a duration not exceeding two hours (Chaer *et al.*, 2006). It is not known yet whether this difference in ability is innate or acquired or a mixture of both. Furthermore, it is not known to date which psychomotor tests correlate best with endovascular skills. As trainees acquired proficiency with different duration and number of sessions, simulation training should be aimed at acquiring proficiency without limitation in duration or session number. Another important argument is whether score differences between the two groups of trainees might be related to simulation-trained trainees spending more time with the trainer, notwithstanding the use of the simulation device. However, we do not believe that time alone is likely to have had as such impact as the fact that this was spent with the simulation device.

This study has a few limitations. First of all the number of trainees involved in the study was small. This might partly explain the insignificant differences in the scores of some of the items in the procedural checklist and the global

rating scale. Furthermore, the small number of subjects restricted the ability to study the differences in the clinical skills performances among simulation-trained individuals when performing the procedure on patients to see whether the variation in the capability to learn/perform technical skills persisted after proficiency-based simulation training. Secondly, we had only one expert available to assess the 10 trainees performing the procedures on patients. As a result, we could not determine inter-observer variability. Finally, each candidate performed only one clinical case. It would be interesting to evaluate skills retention for the five trained individuals in our study. In a previous study, Chaer *et al.* (2006) demonstrated significant differences in the global and procedural checklists scores between simulation-based trained surgical residents and controls in two consecutive clinical cases of lower limb angioplasty, although simulation training was not allowed to exceed two hours.

Simulation-based surgical training offers an opportunity both to trainees and trainers to learn and teach surgical skills outside the operating room in a non-patient, stressless, safe environment. Virtual reality training can replace the early part of the learning curve, which would otherwise be achieved in the clinical situation by practicing on live patients. Simulators offer their users sophisticated task-training exercises and they record errors, therefore providing a way of measuring operative efficiency and performance. However there are limitations to this form of medical simulation learning technology. Simulation education is expensive. The average cost of currently available endovascular simulators is in the range of $200,000 to $400,000.

Furthermore simulation education requires dedicated facilities, personnel and constant technological support.

5.6 Conclusion

The results generated from this preliminary study show that basic endovascular skills acquired by proficiency-based simulation training in TASC A antegrade SFA angioplasty seem to be transferable to interventional suites. Simulation training should be aimed at acquiring proficiency without limitation in duration or number of sessions. Structured proficiency-based endovascular simulation training should be incorporated into surgical training programs. Future studies should aim at developing structured and validated simulation training curriculums for different surgical procedures and should look at skills retention.

Chapter Six: Skills Transfer After Proficiency-Based Bench Model Simulation Training in Saphenofemoral Junction Dissection

6.1 Introduction

The traditional form of surgical skills training and recent changes in health care have created challenges in keeping up the standards in skills training of future surgeons (Bridges and Diamond, 1999; Richards *et al.*, 2000; Varghese *et al.*, 1999). These challenges have forced surgical educators to search for new methods of teaching surgical skills to optimize learning and resulting surgical expertise while minimizing associated costs. Structured simulation training to proficiency level might help tackle these challenges.

To date, several studies have demonstrated the effectiveness of different bench model vascular surgery simulators as assessment tools by distinguishing between surgeons of differing levels of expertise either in a laboratory (Black *et al.*, 2007; Datta *et al.*, 2006; Datta *et al.*, 2004; Munz *et al.*, 2004; Pandey *et al.*, 2006; Wilasrusmee *et al.*, 2007) or in a simulated operative theatre (Black *et al.*, 2010; Moorthy *et al.*, 2005; Moorthy *et al.*, 2006). Little has been described in the literature with regard to the use of bench model simulators in the training of basic vascular surgery technical skills (Bath *et al.*, 2011; Sidhu *et al.*, 2007). Reported bench model simulation-based training studies were restricted in either number of sessions or duration. The use of simulator-based training should be aimed at acquiring proficiency. It should not be restricted in duration or indeed to a fixed number of sessions (Darzi *et al.*, 1999). Simulator-based training should be robust, structured and validated as a training tool for specific surgical procedures.

Another important aspect in bench model simulation training is to explore whether this type of training impacts the acquisition of technical skills by surgical trainees. It has been shown that surgical performance as measured on a bench model of surgery correlates with actual technical ability in the OR - so-called predictive validity (Datta *et al.*, 2004; Wilasrusmee *et al.*, 2007). Furthermore, it has been shown that performance on a bench model does transfer to both human cadaveric and live animal operating models (Anastakis *et al.*, 1999). However, the ultimate test of simulation is to demonstrate that performance after simulation training improves in the OR.

6.2 Objectives

Bench model simulation training has been used to improve the technical skills of surgical residents. As the ultimate test of simulation is the improvement of performance in an OR situation, the purpose of this randomised, controlled, prospective study was to explore whether basic surgical skills acquired by proficiency-based bench model simulation training in saphenofemoral junction (SFJ) dissection transfer to the OR. This is the first study that evaluates the transfer of surgical skills training acquired on a bench model vascular surgery simulator to the OR.

6.3 Materials and Methods

Twelve junior surgical trainees with no past experience in varicose vein surgery received didactic training in the technique of SFJ dissection. Thereafter, trainees were randomised with six receiving further training on a synthetic bench model simulator up to proficiency level. Simulation training was not restricted in duration or number of sessions. All twelve trainees then

performed one SFJ dissection in an OR within five days of didactic only/didactic and simulation training. The trainees' performance was assessed by one supervising consultant blinded to the trainees' training status, using a previously validated Imperial College Evaluation of Procedure-Specific Skill (ICEPS) procedure-specific rating scale and the Objective Structured Assessment of Technical Skill (OSATS) global rating scale. The same consultant assessed all twelve trainees.

Please refer to chapter 2, section 2.5, page 44 for a detailed description of the materials and methods used in this study.

6.4 Results

6.4.1 Trainees' background information

Twelve trainees were enrolled in the study. Eight were male and four were female. Trainees' age ranged between 26 and 29. All trainees had completed a one year internship and are surgeons in training in the basic surgical training program. This program introduces trainees to the principles of surgery and involves rotating through hospitals at six-monthly intervals for a duration of two years. All trainees had no previous experience of varicose vein surgery.

6.4.2 Acquiring proficiency level

After didactic training, six trainees received further training on the bench model simulator up to proficiency level. Proficiency-based simulation training was not restricted in duration or number of sessions. All simulation-trained trainees reached predetermined proficiency targets at a median of 6.3 hours

(ranging from 5 to 7 hours) and a median of 5.2 procedures (ranging from 4 to 6 procedures). Training was delivered by the same trainer (research fellow in vascular surgery simulation-based training).

6.4.3 ICEPS Procedure-specific rating scale

Overall, trainees who received proficiency-based bench model simulation training scored higher than the controls on the 7-item ICEPS procedure-specific rating scale (simulation/control) (30.33 ± 2.07 vs. 18 ± 2.19 $P < 0.001$) (Figure 6.1). Moreover, bench model simulation training led to improvement in all of the 7 individual measures of the ICEPS rating scale. Table 6.1 shows the mean value of trainees' scores in the two groups (simulation group and control group) for each item in the ICEPS procedure-specific rating scale.

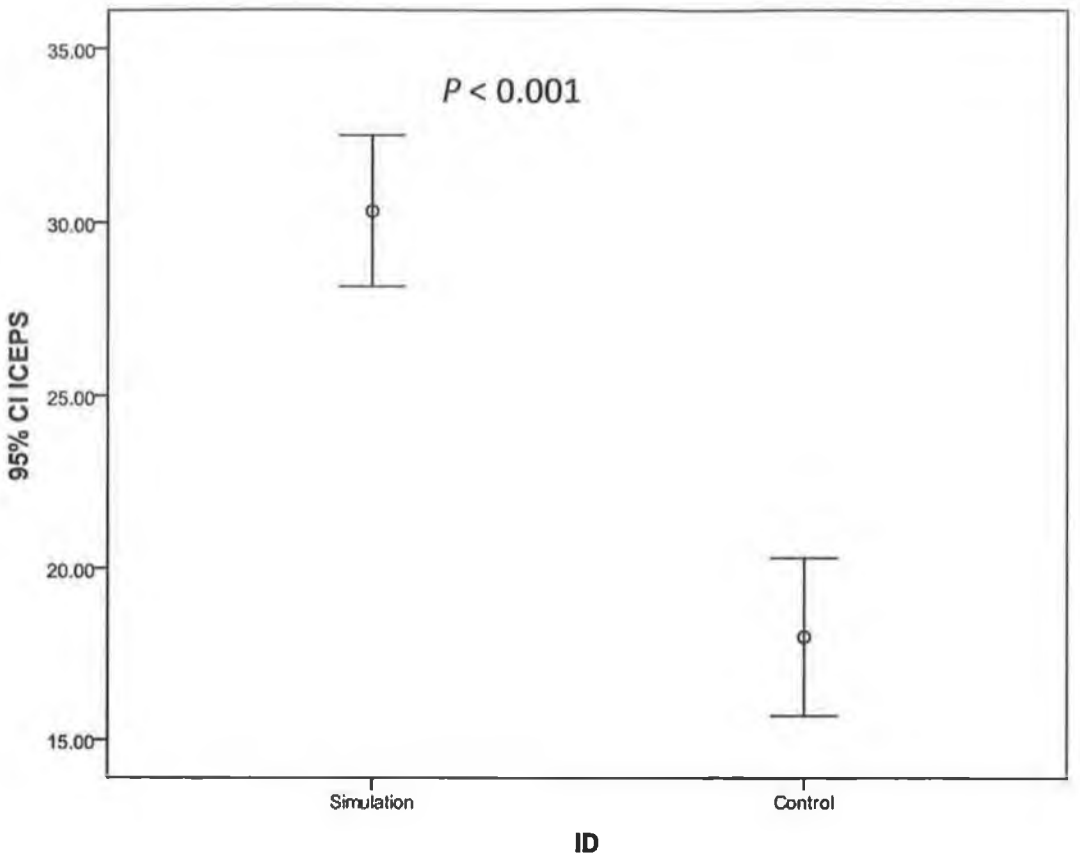

Figure 6.1. Error bar graph. The mean difference in the 7-item ICEPS procedure-specific rating scale score between simulation-trained trainees and controls is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. ICEPS, Imperial College Evaluation of Procedure-Specific Skill. ID, group identity.

Table 6.1. Mean value of trainees' scores in the simulation group and the control group for each item in the ICEPS procedure-specific rating scale

Task description	Simulation group	Control group	*P* value
1. Incision	4.50	2.67	0.001
2. Dissection	3.83	2.83	0.017
3. Retraction	4.00	2.50	0.001
4. Tributaries	4.33	2.67	0.002
5. Haemostasis	4.83	2.50	0.002
6. SFJ Clearance	4.12	2.33	< 0.001
7. SFJ Transfixion	4.67	2.50	< 0.001

6.4.4 OSATS Global rating scale

Overall, trainees who received proficiency-based bench model simulation training scored higher than the controls on the 7-item global rating scale (simulation/control) (28.33 ± 1.86 vs. 18.50 ± 4.04 $P < 0.001$) (Table 6.2). Moreover, bench model simulation training led to enhancement in 6 of the 7 individual measures of the OSATS rating scale. Table 6.2 shows the mean value of trainees' scores in the two groups (simulation group and control group) for each item in the global rating scale.

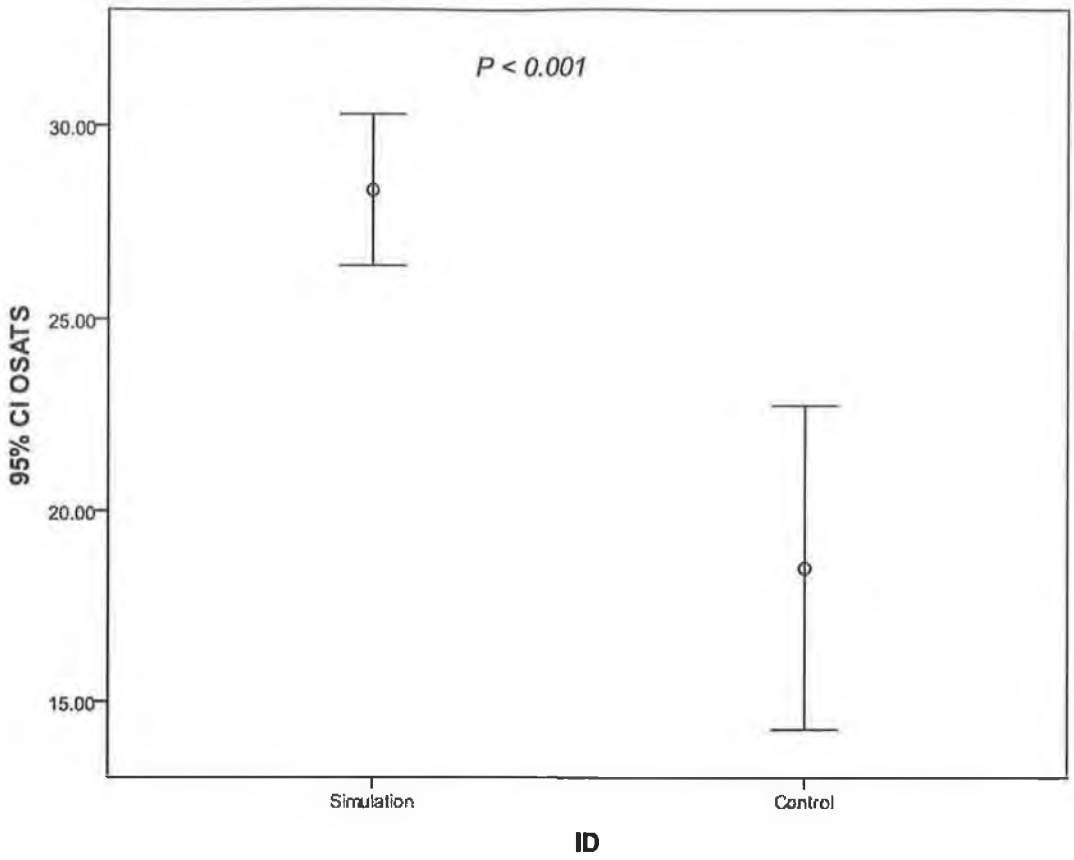

Figure 6.2. Error bar graph. The mean difference in the 7-item OSATS global rating scale score between simulation trained trainees and controls is represented by a circle. The extended lines represent the confidence intervals. CI, 95% confidence intervals. OSATS, Objective Structured Assessment of Technical Skill. ID, group identity.

Table 6.2. Mean value of trainees' scores in the simulation group and the control group for each item in the OSATS global rating scale

Task description	Simulation group	Control group	*P* value
1. Respect for tissue	4.00	3.33	NS[a]
2. Time and motion	4.00	2.33	0.003
3. Instrument handling	4.33	2.83	0.002
4. Knowledge of instruments	4.00	3.00	0.049
5. Use of assistants	3.83	2.17	0.001
6. Flow of operation	4.17	1.83	< 0.001
7. Knowledge of specific procedure	4.00	3.00	0.021

a. NS, not significant

6.4.5 Correlation between the ICEPS and the OSATS rating scales

There was a positive correlation between the ICEPS procedure-specific rating scale and the OSATS global rating scale ($r = 0.92$, $P < 0.001$).

6.5 Discussion

The traditional form of surgical skills training and recent changes in health care have created challenges in keeping up the standards in skills training of future surgeons. Structured simulation training to proficiency level might help tackle these challenges. Although bench model simulators have been used in the training and assessment of surgical doctors for more than a decade, these studies restricted either the duration or the number of sessions. In this study, we have shown that proficiency-based simulation training in SFJ dissection translates to real world performance.

Twelve general surgical trainees took part in this study. All trainees had similar background clinical experience and were novices with regard to varicose vein surgery. We chose varicose vein surgery as a test procedure as it is routinely performed by most surgeons at all levels of expertise in general and vascular surgery. In addition it involves the basic surgical skills needed to train and assess junior surgical trainees. To standardize the study, all clinical cases involved in the study concerned primary uncomplicated varicose veins. The same trainer delivered the same didactic teaching to all trainees and trained the 6 trainees on the bench model simulator to proficiency level. The same vascular surgeon consultant, who was blinded to the training status of the trainees, supervised all 12 trainees during the clinical procedures and assessed each trainee using validated procedural

and global rating scales. The differences in the overall score between simulation-trained trainees and controls in the two assessment instruments (ICESPS and OSATS) demonstrates that proficiency-based bench model simulation training in basic surgical skills might be transferable to clinical practice. Moreover, the differences between the technical scores of the two groups was significant in all 7 individual domains of the ICEPS rating scale and in 6 of the 7 items of the OSATS rating scale.

A small number of issues in this study deserve consideration. First, bench model simulation training was aimed at acquiring proficiency regardless of duration or number of sessions. Although the number of simulation-trained individuals was small, it was obvious that trainees had different abilities in acquiring basic surgical skills. This difference was also noted in a previous study when 10 surgical residents with similar aptitude test scores and background technical skills were trained on an endovascular simulator to perform peripheral endovascular angioplasties, although training was not allowed to exceed two hours (Chaer *et al.*, 2006). It is not known yet whether this difference in ability is innate or acquired or a mixture of both. Furthermore, it is not known to date which psychomotor tests correlate best with different surgical skills. As duration and number of sessions to acquire proficiency varied between trainees, simulation training should be aimed at acquiring proficiency without limitation in duration or number of sessions. Another question is whether score differences between the two groups of trainees might be related to model-trained trainees spending more time with the trainer, notwithstanding the use of the plastic model. However, we do not

believe that time alone is likely to have had as such impact as the fact that this was spent with the simulation model.

This study has a few limitations. First of all the number of trainees involved in the study was small. Although this was sufficient to demonstrate differences in the rating scales' scores between the two groups of trainees, the small number of subjects restricted the ability to study the differences in the technical skills performances among bench model simulation-trained individuals when performing the procedure on patients, to evaluate whether the variation in the capability to learn/perform technical skills persisted after proficiency-based simulation training. Secondly, there was only one expert available to assess the 12 trainees performing the procedures on patients. As a result, inter-observer variability could not be determined. Finally, each candidate performed only one clinical case. It would be interesting to evaluate skills retention for the 6 simulation-trained individuals in this study. Skill retention has been documented following proficiency-based progression training, with as high as 93% to 99% retention at 5 months for basic laparoscopic skills and 90% to 95% retention at 6 months for laparoscopic suturing (Stefanidis *et al.*, 2006a; Stefanidis *et al.*, 2006b).

Simulation-based surgical training offers an opportunity both to trainees and trainers to learn and teach surgical skills outside the operating room in a non-patient, stressless, safe environment. Moreover, simulation training can replace the early part of the learning curve, which would otherwise be achieved in the clinical situation by practicing on live patients. Furthermore, some simulators offer their users sophisticated task-training exercises and they record errors, therefore simulation provides a way of measuring

operative efficiency and performance. However there are limitations to this form of medical simulation learning technology. Simulation education is expensive. When the cost of each bench model simulator used in this study was $460, the average cost of available endovascular simulators, as an example, is in the range of $200,000 to $400,000. Furthermore, simulation education requires dedicated facilities and some simulators require constant technological support.

6.6 Conclusion

The results generated from this preliminary study show that basic surgical skills acquired by proficiency-based bench model simulation training in SFJ dissection seem to be transferable to the OR. Simulation training should be aimed at acquiring proficiency without limitation in duration or number of sessions. Structured proficiency-based simulation training in SFJ dissection should be incorporated into surgical training programs. Future studies should aim at developing structured and validated simulation training curriculums for different surgical procedures and look at skills retention.

Chapter Seven: Discussion

7.1 The structure of simulation training

The traditional form of surgical skills training and recent changes in health care have created challenges in keeping up the standards in skills training of future surgeons. In addition, the introduction of new technology may potentially increase the number of adverse events that occur, such as the rate of common bile duct injuries during laparoscopic cholecystectomy (Adamsen *et al.*, 1997; Windsor and Pong, 1998), therefore increasing the need for adequate surgical skills training. Moreover, the traditional apprentice model in surgical training will likely not be applicable for procedures that are extremely technical and single-operator-dependent, such as carotid angioplasty and stenting. Challenges in skills training such as these have prompted the United States Food and Drug Administration to accept the use of virtual reality simulation as part of a training approach for carotid stenting (Gallagher and Cates, 2004a; Gallagher and Cates, 2004b). Haluck *et al.* (2001) reported that 92% of US surgery programme directors felt there is a need for teaching surgical motor skills outside the operating room. Simulation technology offers an opportunity both to trainees and trainers to learn and teach surgical skills outside the operating room in a non-patient, stressless, pseudorealistic environment, with potential benefits for patient safety (Gould *et al.*, 2006). As the ultimate test of simulation is the improvement of performance in an OR situation, in this thesis, we have explored whether basic endovascular and surgical technical skills acquired using proficiency-based simulation training in SFA angioplasty and SFJ dissection respectively, translate to real world performance.

Although skills transfer after simulation training has been described for colonoscopy/sigmoidoscopy (Sturm *et al.*, 2008) and laparoscopic cholecystectomy (Ahlberg *et al.*, 2007; Grantcharov *et al.*, 2004; Scott *et al.*, 2000; Seymour *et al.*, 2002), most studies restricted either the number of sessions or the duration rather than using proficiency in the simulated environment as their end point of training. Skills transfer has been also documented in the endovascular management of peripheral vascular disease (Chaer *et al.*, 2006). However in the study, endovascular simulation training was not allowed to exceed two hours, lesions treated were different among trainees as they included a variety of iliac, femoral and popliteal stenoses or occlusions and the procedure checklist used was not validated. No studies have explored the transfer of simulation-acquired skills in open vascular surgery.

To use a specific simulator for surgical skills training, reliability, feasibility and validity of the devise should be demonstrated (Table 1.1, page 13). In addition, reliability and validity of the assessment tools should be evaluated. Thereafter, proficiency level should be set. As outlined earlier, training should not be limited to time or number of sessions. Finally, the transfer of skills acquired by proficiency-based training should be evaluated.

The first step was to develop and assess a consensus-driven checklist for SFA angioplasty using the VIST simulator. This is described in **chapter three**. The development and validation of such a procedure-specific checklist was necessary before we could assess proficiency-based simulation-trained trainees and controls when performing SFA angioplasty on patients (described in chapter five). We then evaluated the impact of an assistant on

the technical skills of the operator performing SFA angioplasty on the VIST simulator. This is described in **chapter four**. We felt this was important in the establishment of a proficiency-based simulation training curriculum in SFA angioplasty. As the ultimate test of simulation is the improvement of performance in an operating room situation, in **chapter five** we explored whether basic endovascular skills acquired by proficiency-based simulation training in SFA angioplasty transfer to the interventional suite. The VIST simulator was chosen as it has been described in the assessment and training of surgical trainees in previous studies (Chaer *et al.*, 2006; Van Herzeele *et al.*, 2008). In addition, face and construct validity of this machine has been described in the literature (Dayal *et al.*, 2004). Finally, as no studies have explored the transfer of simulation-acquired skills in open vascular surgery, in **chapter six** we explored whether basic surgical skills acquired using proficiency-based bench model simulation training in open SFJ dissection translate to real world performance. Varicose vein surgery was chosen as it is routinely performed by most surgeons at all levels of expertise in general and vascular surgery. In addition, it contains the basic surgical skills needed to train and assess junior surgical trainees. The SFJ model (Limbs & Things, Bristol, UK) used has been described in the assessment and training of surgical trainees in previous studies (Datta *et al.*, 2006; Datta *et al.*, 2004; Moorthy *et al.*, 2005; Moorthy *et al.*, 2006; Pandey *et al.*, 2006). In addition, face, construct and concurrent validity of this model has been described in the literature (Datta *et al.*, 2004).

From our results, structured proficiency-based virtual reality and bench model simulation training in SFA angioplasty and SFJ dissection should be

incorporated into surgical training programs. Future studies should aim at developing structured and validated simulation training curriculums for different surgical procedures, studying the transferability between procedures and looking at skills retention.

7.2 Simulation technology in airline industry

The first known flight simulation device consisted of a seat mounted in a half-barrel and two wheels. The use of digital computers for flight simulation began in the 1960s and became universal by the 1980s. Flight simulation is used for a variety of reasons, including flight training (mainly of pilots) in both civil and military aircrafts, for the design and development of the aircraft itself and for research into aircraft characteristics, control handling qualities and so forth.

In many professional flight schools, initial training is conducted partially in the aircraft and partially in relatively low cost training devices. As the student becomes familiar with basic aircraft handling and flight skills, more emphasis is placed on instrument flying and advanced aircraft systems, and the portion of flight training conducted in these devices increases significantly. Finally, for more advanced aircraft-specific training, Full Flight Simulators (FFS) are used.

Simulation based training allows for the training of maneuvers or situations that may be impractical (or even dangerous) to perform in the aircraft, while keeping the pilot and instructor in a relatively low-risk environment on the ground. For example, electrical system failures, instrument failures, hydraulic system failures, environmental system failures and even flight control failures

can be simulated without risk to the pilots or an aircraft. Flight simulation also provides an economic advantage over training in an actual aircraft once fuel, maintenance and insurance costs are taken into account.

7.3 The cost effectiveness of simulation training

Simulation-based surgical training offers an opportunity both to trainees and trainers to learn and teach surgical skills outside the operating room in a low risk, stressless, safe environment. Moreover, simulation training shortens the learning curve in the clinical situation thereby reducing risks to patients. However, there are limitations to this form of medical simulation learning technology. Simulation education is expensive. The average cost of currently available endovascular simulators is in the range of $200,000 to $400,000. The cost of each bench model simulator for SFJ dissection training described earlier in chapters two and six was $460. In addition, simulation education requires dedicated facilities. On the other hand, the health system costs related to the use of the operating room for resident teaching in the US have been estimated to be approximately $50,000 per surgical resident over a training period of 4 years (due to increased operative time and decreased efficiency when operating with a trainee) (Bridges and Diamond, 1999). Although it is difficult to calculate the cost benefit of simulation technology in surgical skills training, we believe that any improvement in the operator surgical skills and procedure outcome after simulation training will have significant cost implication. While the cost associated with the use of simulation in surgical training can be calculated precisely, the cost of training inadequately can be hidden initially, but becomes evident later.

An important assessment of a simulator device is the evaluation of the ratio of time spent training on the simulator to the time saved training on a patient, the so-called Transfer Effectiveness Ratio (TER). This concept was first developed in the aviation industry and is considered essential for the scientific analysis of aviation simulator training (Povenmire and Roscoe, 1971). The TER in the airline industry was proposed to be 0.5, i.e., every hour spent on a multimillion dollars flight simulator reduces time to achieve proficiency in the air by 30 minutes (Roscoe, 1971). Orlansky and String (1977) investigated 33 TERs from transfer of effectiveness studies from military, organisational and academic institutions and found a median TER of 0.45. Despite its widespread use in aviation and industry, it was not until 2007 that Aggarwal *et al.* (2007b) first applied the concept of TER to surgical training. This group used the LapSim simulator as part of a proficiency-based curriculum and as a final assessment, measured performance of laparoscopic cholecystectomies using a cadaveric porcine gallbladder and liver specimen in a box trainer. The authors were able to quantify the benefits of virtual reality training in terms of the TER, and determined that every minute spent on the virtual reality simulator was equivalent to 2.28 minutes on the porcine model. Even if the TER is small, it is still likely to be cost effective as time on a simulator is not only cheaper than time in the operating room, but also safer.

7.4 The pros and cons of simulation technologies in surgical training

Simulation-based training can be a safe, cost-effective, and easily accessible tool for gaining experience in surgery. One of the most important advantages of computer simulators for surgical training is the opportunity they afford for

independent learning. Unlike the anatomy lab or operating room, the student may practice at his/her convenience, regardless of the availability of cadavers or patients. However, if the simulator does not provide useful instructional feedback to the user, this advantage is significantly blunted by the need for an instructor to supervise and tutor the trainee while using the simulator.

Virtual reality training can replace the early part of the learning curve, which would otherwise be achieved in the clinical situation by practicing on live patients. Trainees can make mistakes without exposing the patients to any risk. Evidence suggests that enhanced surgical simulators have the potential to reduce the time and cost involved in training junior surgeons. Virtual reality training also appears to improve trainees' performances (Knoll *et al.*, 2005; Scott *et al.*, 2000; Testoni *et al.*, 2004).

A major advantage of virtual reality simulation is the ability to automatically and instantly provide an objective performance report based on quantitative and qualitative assessment parameters. As such, it functions both as an educational tool and skills validation instrument (Stylopoulos *et al.*, 2004). Used in a standardized setting, it is possible to distinguish between subjects of different levels of experience (Dayal *et al.*, 2004). Assessment of nontechnical skills such as appropriate drug administration and physiological monitoring is also possible with most of the current generation of simulators. For example SimSuite (Medical Simulation Corp) requires appropriate case selection and Angiomentor (Symbionix, Cleveland, OH) has advanced patient physiology reporting with the ability to administer a range of drugs

including heparin, atropine, and glycerine trinitrate. For these reasons, simulation technology has been used in many medical fields such as in laparoscopy (Kothar *et al.*, 2002), endoscopy (Bloom *et al.*, 2003), trauma (Lee *et al.*, 2003) and endovascular surgery (Dayal *et al.*, 2004).

However, there are limitations to this form of medical simulation learning technology. Simulation education is expensive. The average cost of currently available endovascular simulators is in the range of $200,000 to $400,000. In addition, simulation education requires dedicated facilities. A number of issues will become increasingly important for defining the role of simulation technologies in surgical training and practice. These include the refinement of simulation technology, identification of the appropriate context for their use, reduction of costs to increase availability, identification of appropriate metrics, and scientific validation of the techniques for both teaching and competency assessment.

7.5 Conclusion

There are various components of the educational process upon which a surgical simulator would have an impact. The device is simply the tool; it is the content of the educational experience that requires careful crafting to ensure that added value is provided (Satava, 1996). Surgical education requires a focus in quality as well as quantity (Sinha *et al.*, 2008).

Proficiency-based progression simulation training is unlikely to replace real life experience but is an adjunct for training to allow us to send a pre-trained surgeon into the operating theatre. Instead of starting from first principle, he/she can then polish or perfect his/her newly learned skills in real life

situations. This optimises the surgeons' learning experience but more importantly, it exposes patients to less risk during the latter part of the trainees' learning curve. It also focuses training effort on those surgeons who require the most training, as those trainees who already perform well will take less effort to reach proficiency level. In summary, proficiency-based simulation training programmes recognise and address the differences in learning styles and abilities among surgical trainees.

We have successfully demonstrated that basic endovascular and open vascular surgery technical skills acquired using proficiency-based simulation training in SFA angioplasty and SFJ dissection respectively do translate to real world performance. The use of simulation wherever feasible conveys a critical educational and ethical message to all: patients are to be protected whenever possible and they are not commodities to be used as conveniences of training (Ziv *et al.*, 2003). In the future, it is likely that national and international-level resident assessments composed of a wide array of standardised skills will provide reliable proficiency criteria, which can be used to guide development of universal proficiency-based training programmes.

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